

ACR Guidance Document on MR Safe Practices: Updates and Critical Information 2019

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The need for a guidance document on MR safe practices arose from a growing awareness of the MR environment's potential risks and adverse event reports involving patients, equipment, and personnel. Initially published in 2002, the American College of Radiology White Paper on MR Safety established de facto industry standards for safe and responsible practices in clinical and research MR environments. The most recent version addresses new sources of risk of adverse events, increases awareness of dynamic MR environments, and recommends that those responsible for MR medical director safety undergo annual MR safety training. With regular updates to these guidelines, the latest MR safety concerns can be accounted for to ensure a safer MR environment where dangers are minimized.

Level of Evidence: 1

Technical Efficacy Stage: 5

J. MAGN. RESON. IMAGING 2020;51:331–338.

RISKS IN THE MAGNETIC RESONANCE (MR) environment continue to evolve with the more common use of higher field strength magnets, higher radiofrequency (RF) frequencies, and more complex equipment. Since the publication of the foundational American College of Radiology White Paper on MR Safety in 2002, there have been several revisions adding critical knowledge to the growing understanding of risks posed in the MR environment.^{1–4} This document provides two types of updates. First, it offers a set of

refinements to sections of the previously published ACR Guidance Documents on MR Safe Practice.^{1–4} These updates emerged from a deeper understanding of patient safety in areas such as pre-MR exam screening, patient attire requirements to prevent possible burn injuries, and adverse event response procedures. Second, it addresses new areas of MR safety concern. For the current version of the complete ACR Guidance Document on MR Safe Practice, please visit <https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety>.

View this article online at wileyonlinelibrary.com. DOI: 10.1002/jmri.26880

Received Jun 19, 2019, Accepted for publication Jul 11, 2019.

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Refinements to Previously Published ACR Guidance on MR Safe Practice

Patient and Non-MR Personnel Screening

As previous guidance has indicated, the use of radiographs of the orbits is recommended for all patients who have sought medical attention for orbit trauma by a metallic foreign body.⁵ However, there are no current data indicating the safety benefit of two views. Therefore, one or two radiographic views of the orbits are now recommended in cases involving an injury to the eye. Furthermore, it must be noted that a successful MR examination after orbital trauma involving a metallic foreign body is not considered sufficient proof of safety for a subsequent MR examination (although an evaluation of a prior study's susceptibility artifact of the region of the orbits may provide an experienced reader with important information on the ferromagnetic nature of a foreign body).

Guidance on the management of prisoners with restraints undergoing MR examinations has also been previously detailed.¹⁻⁴ However, guidance on prison or security personnel weapons (ie, firearms) has not been previously mentioned. Ferromagnetic firearm weapons should not be permitted into Zone III unless deemed absolutely essential for maintenance of security due to the design of the facility. Furthermore, ferromagnetic firearms that are loaded pose a serious threat in Zone IV (the MR system room) due to the possibility of inadvertent discharge.⁶

Some materials used in clothing have been increasingly associated with thermal injury and/or burns in patient's undergoing MRI. Additionally, recent trends in the manufacturing of clothing and other related products have incorporated ferromagnetic and/or conductive materials (eg, antimicrobial silver and copper) that are not reliably disclosed in labeling.⁷ Such clothing products include, but are not limited to, sportswear (including underwear), brassieres, orthotic-related items (eg, stump covers or stump shrinkers), and blankets.⁸ Reliance on clothing labeling is not sufficient, as the Federal Trade Commission (FTC) "guidelines" allow clothing to contain as much as 5% impurities, which could be significant for a patient undergoing an MRI examination.⁹ For areas in or around the volume of transmitted RF power, we recommend patients wear only MR-Safe gowns or scrubs supplied by the imaging facility.

While in general thermal risks associated with individual small dermal implants and/or piercings are atypical, dermal adornments that are in close proximity or directly contact one another may increase the risk of thermal injury if the items are in the volume associated with RF energy power deposition. In addition, conductive loops may be created by skin adornments such as tattoos, especially with dark colors of ink (black, brown, and blue) and curved patterns.¹⁰⁻¹⁵ Thus, with regard to MR safety and the risk of thermal injury, continued vigilance is recommended when screening patients for skin adornments (temporary or permanent).

Patient Safety

Patient safety is substantially affected by policies and practices in Zone III and Zone IV, especially as it pertains to movement, timeouts for information confirmation, and response to adverse events.

ZONE IV. The entry door to Zone IV (MR system room) should be closed except when it must be 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 or plastic chains secured across the scanner room doorway.

FULL-STOP AND FINAL CHECK. In instances where the patient is sedated or anesthetized, an inpatient, or an emergent case, a "full-stop and final check" performed by the MRI technologist along with support staff is recommended to confirm the completion of MR safety screening for the patient, support equipment, and personnel MR screening immediately prior to crossing from Zone III to Zone IV. "Full-stop and final check" may also be useful for nonsedated outpatients and inpatients prior to movement from Zone III to Zone IV. The purpose of this final check is to confirm patient name, ensure that all screening has been appropriately performed, and that there has been no change in patient and/or equipment status while in Zone III.

BURN PREVENTION. To help safeguard against thermal injuries or burns, insulating pads should be placed between the patient's skin and any transmit RF coil located behind the walls and ceiling of the bore of the magnet system, especially the area of the transmit RF body coil, to ensure spacing between the bore wall and the patient's skin. A single-layer bed sheet is insufficient insulation or spacing. It is also important to recognize that large conducting loops may be created within the patient's own tissues by points of skin-to-skin contact, such as thigh-to-thigh contact. Thus, providing insulation in such areas may also be required to prevent burns. To prevent excessive heating and possible burns in patients in association with MR procedures, the previously published guidelines are recommended.¹⁶

NON-MR CONDITIONAL CARDIAC DEVICES. Guidance regarding performing MRI examinations in patients with non-MR Conditional cardiac devices including implanted pacemakers, implantable cardioverter defibrillators, cardiac resynchronization therapy pacemakers, and cardiac resynchronization therapy defibrillators is deferred to current recommendations from the Heart Rhythm Society recommendations.¹⁷

Emerging Areas of MR Safety Concern

Specific Absorption Rate and Specific Energy Dose—Are They Useful?

There are two commonly used metrics that characterize the amount of RF energy that is absorbed by the human body; specific absorption rate (SAR) and specific energy dose (SED).

The dosimetric term used to estimate the rate of absorption of RF energy is the SAR, which is the mass normalized rate at which RF power is coupled to biological tissue and is presented in units of watts per kilogram (W/kg) on the MR system.¹⁸ The most commonly used SAR metric presented on the scanner is the whole-body-averaged value.^{19–21} SAR is a measurement estimating the rate of energy absorption by the patient, not a total dose of energy.

SED is also referred to as the specific absorbed energy (SAE). "Specific" refers to a given body part or tissue, "energy" represents the imparted RF energy, and "dose" denotes the estimated energy absorbed by the body of a human subject. SED is commonly reported in units of joules per kilogram (J/kg) or kilojoules per kilogram (kJ/kg). By definition, SED is a measurement of the total dose of energy calculated to have been absorbed by the patient, not a rate of energy deposition, and is computed from the SAR multiplied by the duration of exposure to this RF power.

Recently, certain manufacturers have implemented SED limits on their MR scanners. The use of an SED limit is intended to prevent the excessive temperature rises in patients that may be associated with long-duration and/or high-SAR pulse sequences conducted at high rates of RF power absorption. The primary rationale for using SED limits is to protect a patient from experiencing physiologic stress or discomfort related to an inordinately high thermal load (eg, total spine or body exams).²²

While discomfort related to whole-body heating during MRI may be experienced by the patient, an actual burn does not occur if the load is sufficiently dissipated over time (although, notably, burns have occurred in patients even when MRI systems were operating within guidelines for RF power deposition).^{19,23–25} It should be noted that the thermal load associated with an MRI examination is a separate phenomenon from focal RF-related thermal injury (ie, burns).²⁰ Limiting the SED of an MRI exam does not necessarily reduce the risks of a thermal injury. Thus, separate precautions for burn prevention need to be implemented routinely for MRI.¹⁶

Various health conditions may reduce an individual's ability to manage a thermal challenge during MRI, including cardiovascular disease, hypertension, diabetes, fever, old age, and obesity. Medications, including diuretics, beta-blockers, calcium blockers, amphetamines, and sedatives, can alter the patient's thermoregulatory responses to a heat load.²⁶ Importantly, certain medications may have a synergistic effect with RF radiation with respect to tissue heating.²⁰

The International Electrotechnical Commission (IEC) permits each MR system manufacturer to conduct its own risk

assessment and structure criteria for MR system operator alerts, warnings, and/or "lock outs" (ie, stopping the MR exam) as it deems appropriate.^{22,27} Therefore, depending on the software operating on the MR system, the scanner may not present SED information (eg, for older software versions), it may provide SED warnings at predetermined intervals with or without a "lock out," or it may provide warnings and prevent additional scanning on a given patient for up to 24 hours if the MR system manufacturer-defined threshold is reached. MR healthcare professionals should be aware of the SED procedure that a given MR system utilizes and understand the context of alerts and possible scanning restrictions. If restrictions exist, it may be necessary to make modifications to the scanning protocol (ie, reducing the total scan time, decreasing the number and duration of sequences with high whole body averaged SAR values, etc.) in order to complete the examination.

If an MR exam is sufficiently prolonged by adequate rest and cooling-off periods between sequences, it should be possible to safely scan the patient even with high SED values.

Spatial Field Gradient (SFG)

WHAT IS THE SFG? The SFG characterizes the temporally fixed spatial gradient magnetic field surrounding the MR system. The SFG is the rate of change in the magnetic field as a function of position around the MR system. The SFG decreases with increasing distance from the ends of a typical cylindrical, horizontal-field magnet. MR Conditional labeling of implants and devices provides two numbers: the maximum static field (B_0) and the maximum spatial magnetic field gradient (dB/dx) to which a given implant or device has been tested and considered to be safe when implanted in a patient undergoing an MRI examination.^{28,29} The magnet manufacturer supplies an SFG map or chart, which demonstrates the strength of the SFG at specific locations. These can be used by the MR system operator to evaluate whether the maximum SFG to which the implant will be subjected exceeds the "MR Conditional" labeled value.^{29,30}

HOW TO USE SFG. MR scanner vendors usually provide maximum SFG values for model-specific systems. However, applying those SFG values to day-to-day decisions can be confusing. The maximum SFG values quoted by the manufacturer for a given MR system is often located under the shroud or cover of the scanner, in a region not directly accessible by the patient. Since an implant or device within a patient may not be exposed in this region (ie, depending on its implantation site), the model-specific maximum SFG values are unlikely to be relevant to clinical decision-making when performing an MRI exam in a patient with an MR Conditional implant or device.³⁰

MR scanner vendors may also provide a plot or map of SFG levels as a function of position. Some manufacturer-

provided SFG maps depict the spatial field gradient in an axial plane with equidistant, concentric circles around the scanner's isocenter (Fig. 1). Each circle represents the cross-section of a cylindrical volume within the MR system's bore, and the maximum SFG value within this volume is listed for each circle. Limitations of such axial SFG maps include the difficulty in referencing an implant or device to the MR system's central Z-axis (ie, for a horizontal field magnet, the bore wall would be more appropriate), and the ambiguity of the exact location of the maximum SFG value along the cylindrical volume associated with each circle since axial "cylinder" maps typically provide only the greatest SFG value within the cylinder for the entire length of the bore. Another common representation of spatially-varying SFG values are maps that depict either sagittal or coronal planes passing through the center of the MR system's bore, with contours defining regions of constant SFG values (ie, isogradient contours). Some systems provide only a one-quarter view, although the SFG values are typically symmetrical both horizontally (about both the central Y- and central X-axes) and radially (about the central Z-axis). Thus, one-quarter SFG maps may be mirrored to yield a map that covers the entire MR system.

A spatial map of the SFG is necessary to estimate translational forces on ferromagnetic objects in the vicinity of the MR system.³⁰ It is essential that the physician responsible for MR safety, and/or the physician's designee(s) (eg, MR physicist), be able to apply the manufacturer-provided SFG values and maps to a scanning scenario with a known MR Conditional implant or device, taking into consideration the

anatomy scanned and where the implant or device is located, with respect to its course as the patient moves into and out of the MR system.³⁰

Intraoperative and Other Nonstandard MR Environments

MR systems are increasingly being installed in environments outside of conventional diagnostic MR facilities. Examples of such facilities include intraoperative/interventional MR, positron emission tomography (PET) MR, and MR-guided radiation therapy.³¹⁻³³ Each of these facilities present unique challenges to implementing MR safety policies and standard operating procedures, particularly with regard to personnel, screening, site contamination and infection control, and adverse event management.

The type and number of personnel who work in these new and complex MR settings are often more varied and numerous than in conventional diagnostic MR facilities. For example, in the intraoperative/interventional setting, such personnel commonly include interventional radiologists, surgeons, anesthesiologists, nurses, physician assistants, and others.³⁴ Nuclear medicine personnel are necessary employees in the PET/MR facility. Many of these personnel may not have undergone MR safety training as a part of their conventional clinical training to work in those unique environments.

The physician responsible for MR safety, known as the magnetic resonance medical director (MRMD), is required to ensure continued appropriate evaluation and screening of patients, implants or devices, and equipment (eg, patient

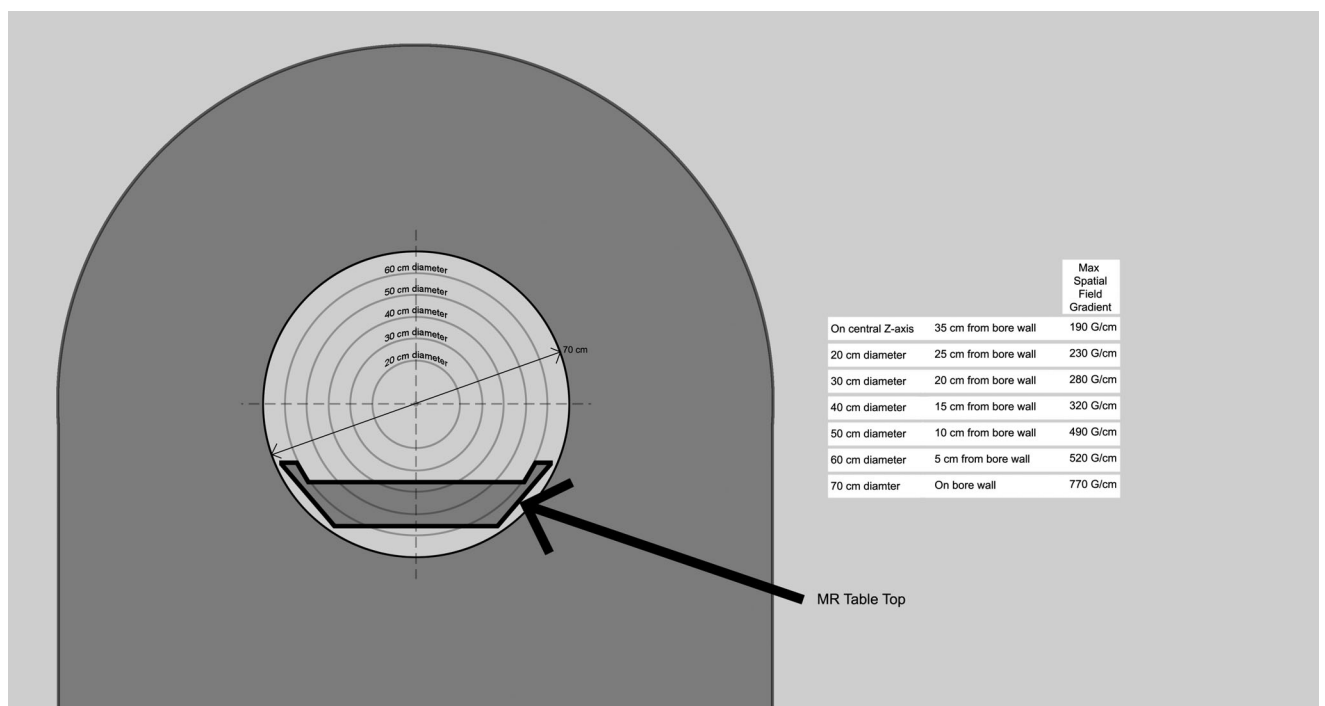


FIGURE 1: Axial view SFG map of an MR system indicating maximum SFG values that may be encountered within each of the nested cylindrical volumes within the diameter of the bore. Illustration courtesy of Tobias Gilk.

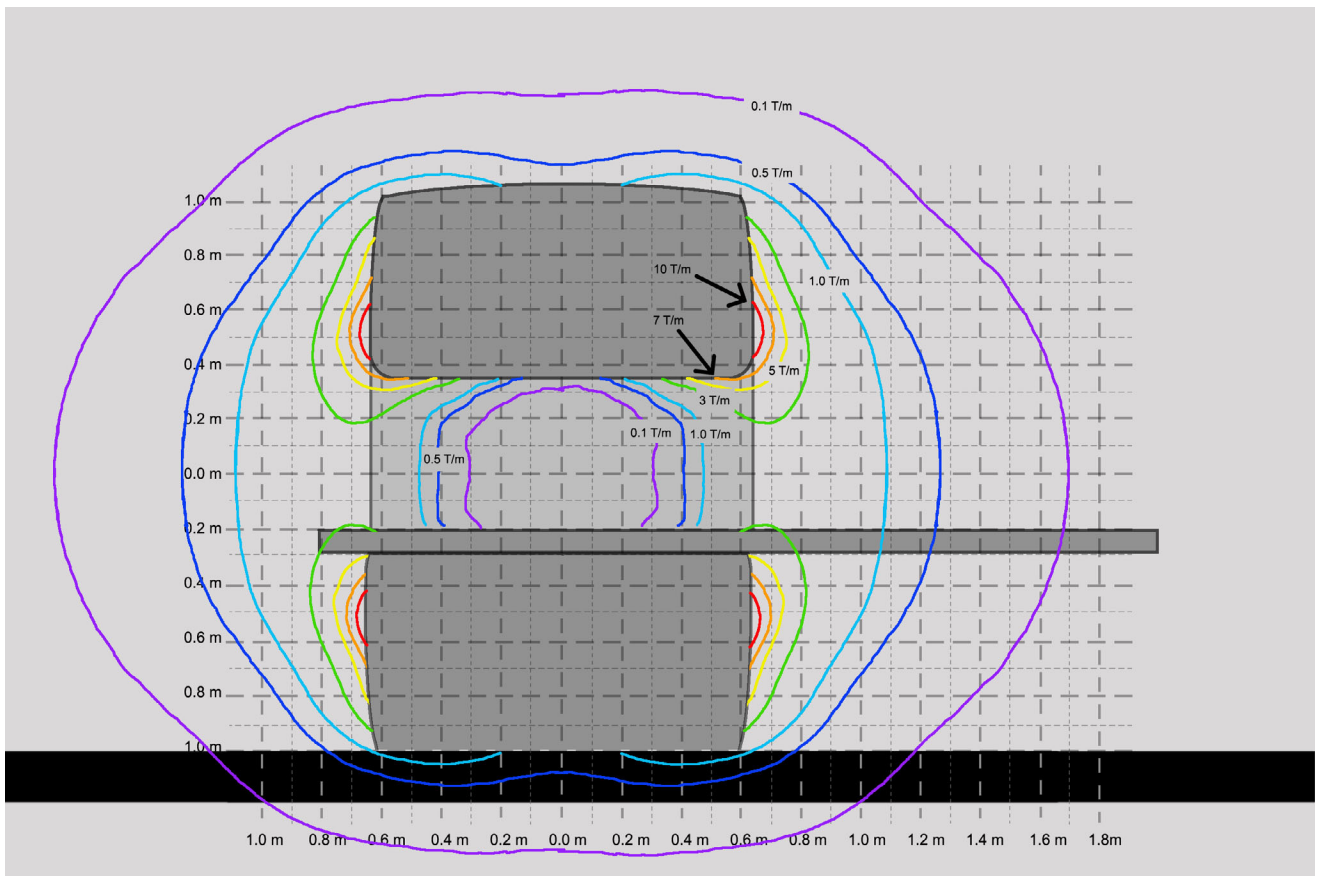


FIGURE 2: Sagittal view spatial field gradient (SFG) map of an MR system. Note the weakening isograd lines as one moves the length of the patient table away from the bore. Each dotted line represents spatial increments of 10 cm. Illustration courtesy of Tobias Gilk.

support equipment and surgical, radiation, and anesthesia devices) that are brought into the MR environment. All devices must undergo standardized evaluations and labeling to determine their status as being MR Safe, MR Conditional, or MR Unsafe before being brought into Zone IV.⁴

Standard operating procedures for cleaning the facility with respect to infection control and handling of radioactive materials and potential radioactivity contamination (eg, in the case of a PET/MR facility) must be established and implemented. All such safety procedures must be overseen by Level 2 MR Personnel under the direction of the MRMD.

The physical environment for intraoperative/interventional MR also presents substantial challenges. Multiple Zone IV (MR system room) entrances (eg, operative room [OR] patient entry, control room entry) each require appropriate controlled access. Transient changes in MR Zones can occur in dynamic MR environments; that is, a space that may be Zone IV in one instance and convert to Zone III at another time. Thus, multiple points of entry and variable room configurations place a substantial burden on the effective planning and design of these facilities with regard to MR safety.

Attempts to "retrofit" safe practices into intraoperative/interventional MR environments that have already been constructed can be challenging and, thus, may lead to unintended

consequences. Careful planning of the facility prior to construction is highly recommended.

Finally, policies and procedures for emergent situations must be developed by the MRMD and reviewed by personnel expected to execute the defined procedures. These environments present unique circumstances that require site-specific coordination in order to manage time-sensitive emergent responses. In the development of these procedures, the role(s) of the responsible persons must be clearly identified and documented. For each MR examination and/or procedure performed in these complex MR environments, we recommend specifying a role fulfilled by a single person at a given time to lead emergent or adverse event management under the guidelines established by the MRMD.

Although challenges to each 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 screening before and fulfilling patient and staff member safety during their time in the MR suite. We recommend that all Level 1 and Level 2 MR personnel, including the MRMD, undergo annual MR safety training in line with recent accreditation requirements from The Joint Commission (TJC).³⁵

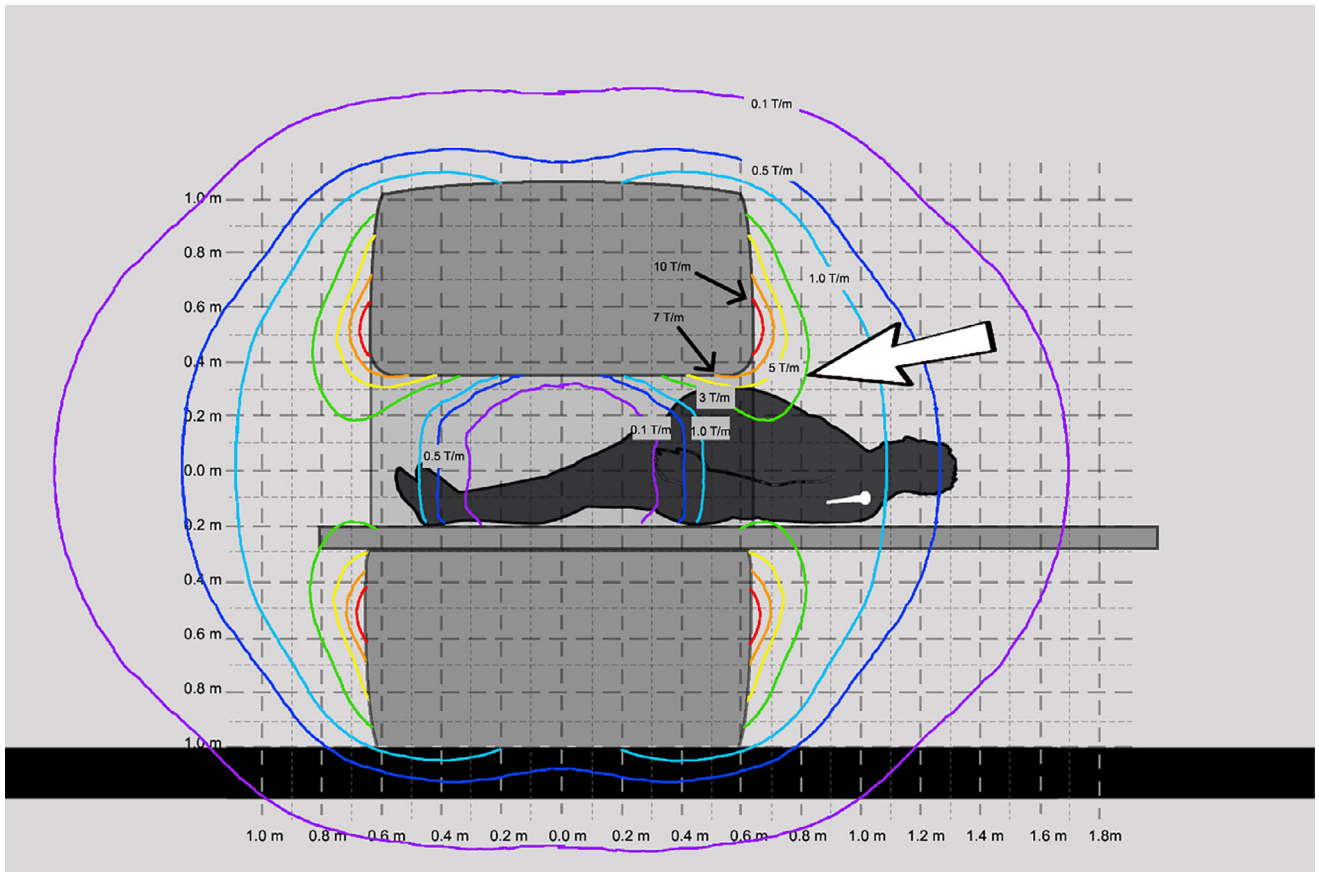


FIGURE 3: Same view as Fig. 2, but showing a patient positioned for a knee study. Even though this diagram shows an MR system with maximum SFG in excess of 10 T/m (1000 G/cm), an orthopedic implant in the patient's shoulder would not even enter the maximum field region of 3 T/m (300 G/cm), indicated by the white arrow. This diagram highlights that the importance of understanding the safety of device is impacted by its movement in/out of the scanner and location relative the area being imaged with respect to the magnet isocenter. Illustration courtesy of Tobias Gilk.

Clinical 7T MR Systems

The recent Food and Drug Administration (FDA) clearance for clinical utilization of 7T MR necessitates the development of specific guidelines for 7T scanners.^{36,37} Compared with lower field strength MR environments, implants, devices, and foreign bodies are typically exposed to higher frequencies of transmitted RF energy, which may increase resonant circuit heating potentials in electrically conductive materials that were too small to experience significant heating at 3.0T and below. There are also significantly higher translational, rotational, and Lenz's forces associated with 7T environments.³⁸ Certain implants, such as active implants or devices (eg, neuromodulation devices, cochlear implants, etc.) that retain functionality at lower field strengths may potentially malfunction or suffer interference, altered settings, or permanent damage at 7T.³⁹ Perhaps most important, in human tissue resonant circuitry conditions for linear metallic implants can manifest for objects with conductive lengths of as little as 5–7 cm within human tissue.^{40–42} While there are relatively few linear implants used in human subjects presently that are ~25–30 cm in length required to satisfy resonant circuitry conditions at 1.5T (64 MHz), there are many more indwelling metallic implants that approach

5–7 cm in length.⁴³ Thus, rapid resonant-related heating leading to dangerous temperature elevations of shorter electrically conductive objects is theoretically more likely at 7T (298 MHz) than at 1.5 T (64 MHz) or even 3T (128 MHz).

Furthermore, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) noted that temporary effects, such as vertigo, tinnitus, and hearing loss, could be a concern,⁴⁴ although it was determined that there was otherwise a lack of serious permanent health effects due to an individual's exposure to the 7T MR environment. Other potential bioeffects that are a greater concern at 7T include nystagmus, nausea, motion disturbances, dizziness, magnetophosphenes (perceived visual flashes of light from induced voltages in the retina and/or optic nerve), and the electro-gustatory effect (eg, metallic taste in the mouth).

A major concern for implants and devices in the 7T environment or in patients undergoing MRI is that relatively few objects have undergone standardized testing to determine their level of safety. Because 7T MRI exposes implants and devices to higher static magnetic field strength and RF frequency, each item must be evaluated at 7T, even if the object

had been previously deemed safe for a patient undergoing an MRI examination at 1.5T or 3T.

As with other complex MR environments, guiding MR safety principles must drive practice decisions in the 7T setting. While a specific implant or device may not yet be tested for MR issues (eg, magnetic field interactions, heating, and artifacts), the guiding principles of medicine suggest that we use risk vs. benefit assessment with the most current information available, as in all medical decision-making, to determine if a certain patient diagnostic question, possibly with particular implant or device considerations, warrants undergoing MRI at 7T.

Conclusion

Driven by changing technologies and clinical practices, MR safety continues to evolve. Updates to prior guidance documents addressing MR safety include revised recommendations for patient screening and safety.

Patient screening updates include the reinforcement that prior uneventful MRI examinations do not ensure subsequent uneventful procedures, particularly in patients with prior orbital trauma. A screening radiograph study (1 or 2 view) may be required after questionnaire. New clothing trends warrants that all patients remove all clothing items, particularly if items are located in the area of the transmitted RF energy. Patients are to use clothing known to be MR-safe and such clothing may be provided by the facility as needed.

Patient safety updates include the recommendations of a Zone IV caution barrier during scanning and "full-stop and final checks" for sedated or anesthetized patients, emergent patients, or inpatients preparing to enter Zone IV.

Furthermore, we stress that near-field/proximity tissue-burn adverse events are best addressed with adequate insulation pads that provide distance between the patient and the transmit RF coil. Safe distances are manufacturer-specific. Similarly, potential conductive loops created by the patient and/or patient position are best addressed by preventing points of skin-to-skin contact that may be within or near the volume of the transmitting RF coil.

The rationale for SAR/SED limits is based on the concept that all patients exposed to MR environments are subject to whole-body heating, and those patients at particular risk of adverse consequences from heating are those limited in their ability to thermoregulate. If scan times are sufficiently prolonged, by including adequate rest and cooling-off periods between sequences, it is possible to safely scan even with high SED values.

In addition, SFG maps provided by manufacturers vary considerably in their ease of application to determine the safety of implants or devices in a specific patient and specific type of scan. A thorough understanding of the manufacturer's SFG map as it applies to implants and devices is essential for patient safety.

Increasingly complex MR environments are utilized to maximize patient care in diagnostics and treatment. The need for continued diligence in these particularly complex environments underscores the mandate that all personnel are trained appropriately for their role in these environments. Annual MR safety-specific training is recommended for physicians ultimately responsible for MR safety (ie, the MRMD). For each MR scan, it is recommended that a single role for a single person is designated to oversee the execution of a safe scan. This recommendation applies to the traditional hospital and outpatient facilities, but is especially pertinent to the increasingly complex MR environments. Finally, as 7T scanners become increasingly available for clinical use, heightened awareness of and vigilance related to safety concerns that apply to 7T are urgently needed.

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