MRI Anatomy and Positioning Series

Module 9: MRI Safety

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Introduction

Welcome to the Hitachi Medical Systems America, Inc. MRI Anatomy and Positioning Series. In this ninth module, we will be examining MR Safety. In the ever-evolving world of MRI, it is imperative that we constantly seek education and training in order to continually keep our patients safe in the MR environment. We will be reviewing site access restrictions for the static magnetic field, personnel and patient access restrictions, device and object screening, bioeffects, and various implants and devices.

“The greatest safety feature in any MRI department is a well-trained, well-educated diligent MRI professional with solid communication skills. As MRI professionals, we must always remember that our first allegiance is to our patients. We have to ensure that the tools are present for safe patient care.” This quote is from Wendy Stirnkorb, MRI imaging center manager and safety officer at University of Chicago Medicine. She has taken on the position of MR safety officer, a position not found at many sites, as few technologists feel comfortable or competent to take on this title, despite the fact that the ACR has been advocating for the creation of MRI safety officer positions since 2002. In their most recently published guidance paper, the ACR encourages facilities to train and designate someone as a medical director for MRI safety. As part of ACR’s accreditation process, the supervising physician would design and implement an MRI safety program, and select an MR safety officer or director. Imaging equipment is becoming more sophisticated, and facilities are recognizing the importance of safety issues for all imaging areas, not just MRI.

The number of adverse MRI events continues to be a serious issue for imaging centers and radiology departments. There has been a dramatic increase in adverse MRI events in recent years, from 40 reported adverse events in 2004 to 164 reported events in 2012. These numbers are from a review of the Food and Drug Administration’s (FDA) Manufacturer and User Facility Device Experience (MAUDE) database. There were fluctuations in the numbers of reported adverse MRI events from 2009 to 2012, as indicated below:

- 2009 – 194 adverse events reported
- 2010 – 169 adverse events reported
- 2011 – 186 adverse events reported
- 2012 – 164 adverse events reported

The number of new MRI scanner installations doubled between 2004 and 2009, but the increase in adverse events almost quintupled for that time period (from 40 to 194 events). MRI safety advocates Dr. Emanuel Kanal and Tobias Gilk have discounted the idea that the significant rise in adverse events was due to more fastidious reporting by imaging facilities. They believe that probably less than 10% of the events that are occurring are reported, meaning that the number of actual events could be anywhere from 10 to 100 times greater than the number of events that have been reported. Another disturbing fact is that, upon review of the MRI accidents in the FDA's MAUDE database for 2008 and 2009, 92% of the reported accidents fell into three categories, and the majority of these accidents were avoidable! The three categories included:

1. Radiofrequency (RF) thermal injuries or burns during an MRI scan
2. Projectile effects from ferromagnetic objects inadvertently brought into MR imaging environments
3. Hearing loss among patients who were not adequately protected
Kanal has stated that adverse events can be prevented by establishing and maintaining consistent MRI safety education among healthcare practitioners, so they are aware of the potential risks that could occur throughout the MR imaging process. In addition, he has stated that there should be adequate MRI site access restriction and supervision by MRI healthcare professionals over patients and other non-MR personnel. Training for nonmedical personnel, such as maintenance staff, housekeeping staff, and security officers on how to conduct themselves in the MRI setting is just as important as it is for MRI technologists and radiologists. Nonmedical employees may not realize that an MRI scanner is always “on,” and have been responsible for projectile and other accidents at some facilities. Anyone who works in and around the MRI setting should receive education and training programs on a regular basis.

The FDA has held numerous public workshops on MRI safety over the years, and ACR introduced its MRI safe practice guidelines to improve MRI safety approximately 14 years ago. Dr. Kanal has stated that the radiological community and industry should universally and voluntarily adopt these easily implemented recommendations, guidelines, and practices in order to continue to maintain and improve our MRI safety record throughout our industry. Tobias Gilk questions how we have been so ineffective in managing the risks and reducing the rates of accidents in this time of increased MRI safety awareness. We know so much about what causes these accidents and how to prevent them, but we have failed profoundly in implementing protection.

In January, 2015, MRI safety advocates launched the American Board of Magnetic Resonance Safety (ABMRS). ABMRS leadership includes Dr. Kanal as chair, and Tobias Gilk as secretary/treasurer. The ABMRS will create and standardize testing and certification for MR safety competence for individuals responsible for ensuring the safety of MR clinical and research environments. Certification categories will include the positions and titles of MR medical director/physician (MRMD), MR safety officer (MRSO), and MR safety expert (MRSE). The MRMD title includes physicians such as radiologists, who are responsible for safe MR exam administration. Only licensed physicians can sit for this certification. The MRSO title includes professionals such as technologists, especially those who may have a supervisory MRI safety role at the point of care. The MRSE title includes professionals such as MR medical physicists in an expert, technical consulting role, who may help determine the safety of complex situations. There are no prerequisites for these formal written examinations, and an examination content syllabus is available from the ABMRS. These certifications are valid for a 10 year period, after which recertification is required. The first set of exams for MRMD and MRSO were given in June, 2015, to over 100 candidates. The first MRSE testing was in October, 2015. These examinations test candidates on their knowledge of underlying MR safety concepts, as well as their ability to apply this knowledge to maximize the accessibility of MR examinations to real-world clinical and research situations. Areas examined include static magnetic fields, gradient magnetic fields, radiofrequency energies, contrast agents, clinical safety considerations, bioeffects, and medicolegal implications.

There must be a concerted effort on the part of all of us working in healthcare and MRI to maintain a safe MRI environment for our patients, as well as any other non-MR personnel. Regular education and training, as well as the addition of certified safety officers at various levels, should provide improved guidelines for better safety regulation in our MRI profession.

These materials are provided for general informational and educational purposes only and should not be construed as advice or opinion on any specific facts or circumstances. You are urged to confer with an MRI safety consultant concerning any specific safety questions you may have. MR safety is ultimately the responsibility of each MR facility.
Site Access Restriction–Static Magnetic Field

In addition to the people-oriented safety strategies that are brought to the forefront through training and policy placement, organizations need to adopt strategies of safety oriented architectural and interior design. Architectural enhancements and design elements can support the other safety strategies, which is an approach termed “defense in depth.” The design of the many functional areas of an MR suite can be used to encourage safety and best practices. Many MR equipment manufacturers provide design templates intended to meet the minimal siting requirements for their specific equipment. However, these templates typically depict only the control, equipment, and magnet rooms. The 2013 ACR Guidance Document on MR Safe Practices addressed many additional safety issues that are often left to be resolved by facility owners and design professionals. These issues include placement of patient/family waiting areas, interview areas, physical screening/changing areas, crash carts, infection control provisions, etc., which all directly impact safety within the MR suite. Suggestions from the ACR document are incorporated in the zone explanations below.

Zones

In theory, the MR site is divided into four zones. Each zone has specifications as to whom or what is permitted in that particular area (Figure 1).
Zone I

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

Zone II

This region is the interface between the uncontrolled and publicly accessible Zone I, and the strictly controlled Zones III and IV. Patients are greeted in Zone II, and are then under the supervision of MR personnel. “Clinical screening” is performed in this region, which involves the patient providing personal and confidential information in response to insurance questions, medical history, and the initial review of the safety screening form. An area that offers auditory and visual privacy for the patient should be provided for clinical screening purposes. It is recommended that facilities prospectively plan for electronic patient medical records, which are useful in the clinical screening process. Hospital-based MR facilities may complete the clinical screening of inpatients in their patient rooms, but all screenings are to be double-checked and verified by the appropriately trained MR personnel before the MR examination.

Before entering Zone III, all persons and objects should be physically screened for the presence of ferromagnetic materials. Physical screening should consist of removal of all jewelry, any metallic/ferromagnetic objects, and any prostheses (as indicated by manufacturer’s conditional use requirements and physician instructions). Patients should either change into facility provided gowns/scrubs, or have their street clothes thoroughly screened, which includes identifying pocket contents and identifying the composition of metallic fibers, fasteners, and reinforcing. A location should be provided in Zone II where patients can change out of street clothes and into the facility-provided gowns or scrubs. If the facility does not provide a changing space, or does not require that patients change, they must provide alternative means of identifying and removing items which the patient may have brought with them that could pose a threat in the MR environment. Having all patients change into a gown or scrubs is helpful, but it does not preclude a patient from entering Zone III with ferromagnetic material on them.

Patients will arrive with wheelchairs, walkers, portable oxygen and other appliances that may be unsafe in the MR environment. An area should be provided in Zone II where patients can transfer from unsafe appliances to facility provided MR safe or MR conditional appliances (Figure 2). Unsafe appliances should be secured in a “ferrous quarantine” storage area that, ideally, is locked out of sight. These appliances should be returned to the patient at their time of discharge from the MR suite.

A readily accessible crash cart and emergency resuscitation equipment can be stored in Zone II or Zone III. Provisions for the stabilization and resuscitation of patients are necessary, due to the risks associated with contrast agents, sedation, anesthesia, as well as the overall fragile health state of some MR patients. A supply of emergency medications used to treat adverse reactions to contrast agents should be maintained. Emergency resuscitation equipment should be tested, verified, and labeled as safe for usage in the MR environment. MR facilities that provide care to patients who require “clinical support” during their MR exam should have the appropriate emergency response equipment available, as well as emergency response personnel that are trained in MR safety issues. The emergency response personnel should be trained and readily available for response to any adverse patient events in the MR area.
Ferromagnetic Detection Systems

A high-strength hand-held magnet can be used to evaluate the gross magnetic characteristics of objects of unknown composition. However, it may not demonstrate attraction for ferromagnetic components that are not superficially located, or that cannot be brought into close proximity of the hand-held magnet. A ferromagnetic detection system is more effective as a quality assurance tool, as it can verify the successful screening, as well as identify ferromagnetic objects which were not discovered by conventional screening methods. It should be installed in Zone II, in a location which facilitates use and throughput. Ferromagnetic detection devices may currently be found within Zone III, even as close to Zone IV as the door to the magnet room. However, recommended use of ferromagnetic detection is to verify the screening of patients before they pass through the controlled point of access into Zone III. Ferromagnetic detection systems are recommended by organizations concerned with MRI safety, including the American College of Radiology and the Joint Commission.

Ferromagnetic detection systems (FMDS) are available as portal systems, pillar devices, or handheld versions. These devices are specifically designed to only detect ferromagnetic objects, as these are the only objects that pose a missile-related hazard. Other materials, such as aluminum and copper, are nonferromagnetic and, therefore, are not detected by an FMDS. Ferromagnetic detection systems detect threats, and work by monitoring the ambient, or surrounding magnetic field, using magnetic
sensors. The ambient field is a combination of the fringe field of the magnet, the Earth’s magnetic field, and the contribution from architectural steel and any other stationary steel objects in the vicinity. A ferromagnetic object will distort the ambient field in its vicinity. If it is brought close to an FMDS, the distortion is detected as a changing magnetic field, and an alert is triggered. A ferromagnetic detection system ignores static magnetic fields, which do not change with time. The FMDS is only sensitive to changing magnetic fields, or moving ferromagnetic objects. It is insensitive to a stationary ferromagnetic object. If an object is placed near the FMDS, it will be detected as it is put in place, but thereafter ignored, until it is moved again. Ambient magnetic fields are very large compared with the magnetic perturbations caused by ferromagnetic objects, so it is difficult to measure tiny changes on a large background field. Therefore, the large static background is removed by the FMDS by filtering it out. This includes the static magnetic field (the magnet of the MR system), as well as the Earth’s magnetic field.

When using a handheld FMDS, the ferromagnetic object may be stationary, but the FMDS is moving. It is this relative motion that is important when using a handheld device. The manufacturer’s instructions should be reviewed and closely followed for proper use of a handheld FMDS. A handheld device can be used for a patient on an MR Conditional gurney or in an MR Conditional wheelchair, rather than only ferrous-free transportation equipment. An MR Conditional item is defined as an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. In order to get full coverage of the patient on a gurney, the patient should turn over from one side to the other side. It is difficult to get full coverage of a patient in a wheelchair, unless they can stand for a short time. Because this is a manual process, the quality and reliability of the screening depends on the person performing the scan using the handheld FMDS.

When using a stationary FMDS, only moving ferromagnetic objects are detected. Use of a stationary FMDS can enhance the safety level of an MRI facility, as it can be used to constantly control access to the MR system room. The stationary FMDS will provide a warning alarm in cases when the scan room door may be unsupervised, and someone is trying to enter the scan room. It is believed that most missile-related accidents are caused by non-MRI workers entering the MR system room. The FMDS alarm can also serve as a reminder for technologists to stop and do a final check of all patients and equipment that are entering the scan room. It may become “routine” for an MR Conditional gurney to set off the alarm, but the technologist must be sure to stop and investigate each individual situation. There may be MR Unsafe equipment under the gurney (such as an oxygen cylinder), or there may be a ferromagnetic object under the sheets. When using a wall-mounted FMDS, cooperative ambulatory patients receive a fast and easy head-to-toe whole-body screening. Nonambulatory patients should ideally be placed on or in a ferrous-free gurney or wheelchair, and pushed in two directions (a “drive-by”) parallel to the FMDS by a ferrous-free MR technologist. A wall-mounted FMDS does not offer the close range required for detection of the smallest objects, but it is useful for the detection of larger personal items.

Frank Shellock, PhD, was the lead author of a study performed in 2013 that tested a vertically mounted pillar-type ferromagnetic detection system. This design allows head-to-toe scanning of a patient. Testing involved various implants and other items made from materials with relatively low magnetic value (i.e. orthopedic implants made from titanium or cobalt-chromium), as well as items known to be contraindicated for MRI examinations, such as cardiac pacemaker pulse generators and a ferromagnetic armor-piercing bullet. A single object was attached to a volunteer in a location that approximated its position during an MRI scan. The device performed quite well, and was able to identify 91% of the pulse generators used for electronically activated devices. A positive alarm from a FMDS indicates that the patient needs additional attention to determine whether or not the alarm is associated with an MR
conditional device. This system also alarmed for two armor-piercing bullets, which indicates its ability to
detect small objects that could result in injuries to patients. Although these findings are highly specific to
this particular FMDS and the investigation protocol, they indicate that ferromagnetic detection systems
may be useful tools for screening MRI patients, especially those with implanted or embedded items.

Screening a patient using an FMD is an additional step in the screening process, and is the last step
before the MRI examination. It is not a replacement for any aspect of the screening process, but rather
an addendum that adds a final objective check prior to the MRI scan. Screening questionnaires should
include an area where results of the FMD screening can be recorded, as well as any actions or
observations that result from the FMD screening. If an alarm occurs, the patient should be investigated
for the presence of a ferromagnetic object, and it should be removed, if possible. The patient should
then be rescreened using the FMD. If a ferrous object is not found, the FMD screening should be
repeated in case the original result was a false alarm. If a genuine alarm cannot be resolved, the MRI
technologist must suspect the possibility that the ferromagnetic object is internal, either an implant or a
foreign body. The patient’s history must then be thoroughly checked before proceeding with an MRI
exam. Initial results of early research into the use of a patient-screening FMD indicate that the FMD is
capable of detecting many in vivo ferromagnetic objects, which has important implications for patient
safety in the MRI environment.

Zone III

All access to Zone III is to be highly restricted, as serious injury or death can result from interactions
between unscreened non-MR personnel or ferromagnetic objects or equipment and the MR scanner’s
environment in this area. These interactions can include both the MR scanner’s static and time-varying
magnetic fields. Access to regions within Zone III (which includes Zone IV, or the magnet room itself)
should be controlled by, and entirely under the supervision of, MR personnel. Specifically identified MR
personnel must ensure that this safe practice guideline is strictly adhered to for the safety of the
patients and other non-MR personnel, additional health care personnel, and the equipment itself.

Zone III regions should be physically restricted from general public access by key locks, passkey locking
systems, or any other reliable, physically restricting method that can differentiate between MR and non-
MR personnel. Only MR personnel should be provided the access keys or passkeys to Zone III. Hospital
or site administration, physicians, security, and other non-MR personnel should not be considered as
exceptions to this guideline.

Zone III, or at least any area within it where the static magnetic field’s strength exceeds 5 gauss, should
be demarcated and clearly marked as being potentially hazardous. Since magnetic fields are three-
dimensional volumes, Zone III controlled access areas may project through floors and ceilings of the MR
suite, thus imposing magnetic field hazards on persons on floors other than that of the MR scanner.
Areas of magnetic field hazards should be clearly delineated, even in areas that are typically not
occupied, such as rooftops and storage rooms. These Zone III regions should be similarly restricted from
non-MR personnel. Analysis of magnetic field strength plots should be performed in both the horizontal
and vertical directions to accurately identify areas above, below, and on the same level as the MR
system where persons may be at risk of interactions with the magnetic field.

Hazards from the fringe magnetic field are also included under Zone III. Potential hazards may be
superimposed on spaces outside the MR suite due to magnetic fringe fields, which project beyond the
confines of the magnet room. Fringe field issues could potentially include levels above or below the MR
site, and even outside the building. All occupiable areas that are exposed to potentially hazardous magnetic fringe field strengths must be identified and access to these areas must be restricted.

In order to further control access to the MR environment of Zone III, signs should be prominently displayed that make individuals and patients aware of the risks associated with the MR system. Use of the word “DANGER!” with the additional phrases “Restricted Access,” “Strong Magnetic Field,” and “This Magnet is Always On!” strongly convey the fact that the reader is in a controlled access area (Figure 3). Warnings concerning the presence of magnetic fields, their force and torque on magnetic materials, and the exclusion of loose ferrous objects should also be included on the signs. Due to the fact that some metallic implants are acceptable for patients undergoing MRI procedures while others are not, further information on the sign should clarify that patients and other individuals entering this area should consult the appropriate MRI personnel with any questions, as seen below:

“Persons with certain metallic, electronic, magnetic, or mechanically-activated implants, devices, or objects may not enter this area. Serious injury may result. Do not enter this area if you have any questions regarding an implant, device, or object. Consult the MRI Technologist or Radiologist.”

“Objects made from ferrous materials must not be taken into this area. Serious injury or property damage may result. Electronic objects such as hearing aids, cell phones, and beepers may also be damaged.”

Smaller signs or decals that reinforce the potentially hazardous nature of the MR environment are also recommended, using the phrase “DANGER! This magnet is always on!” Investigations of accidents involving large ferromagnetic objects such as oxygen cylinders, wheelchairs, etc. revealed that the offending personnel thought the powerful magnetic field was only active during the MR procedure.
Signs should be strategically placed in and around the MR environment to ensure that all patients and individuals see them before entering Zone III, as well as before they enter the actual scan room. A sign should be placed on the door or entrance to the MR system room, as well as near or on the door frame, in case the door is open.

Ideally, facilities should be designed to include a holding area in Zone III for post-screened MR patients. This holding area should be equipped to prevent patient exit and subsequent re-entry after being screened, which would help prevent the inadvertent, or intentional, introduction of unscreened objects and personnel. Shared patient holding areas in radiology facilities with different modalities can present safety challenges, and are discouraged by safety experts. A patient waiting for a CT scan in a co-mingled waiting area will not be screened for MR contraindications, and could potentially enter a restricted access MR area with a contraindicated implant or ferrous object. A post-screened holding area within Zone III would be physically secured, and access would be limited to only MR personnel and successfully MR prescreened non-MR personnel accompanied by MR personnel.

Trained MR personnel are considered the greatest safety resource of MR facilities. They must be afforded visual control over all persons entering or exiting Zones III or IV. When seated at the MR operator console, the technologist should be able to view the patient, as well as the approach and entrance into Zone IV. Suites should also be designed to provide a view from the MR operator’s console to the patient holding area. If this cannot be achieved, remote video viewing devices are an acceptable substitute. If applicable, the technologist should also be able to view the recovery area from the operator console.

**Zone IV**

This zone is synonymous with the MR scanner magnet room itself. Zone IV will always be located within Zone III, as it’s the MR magnet and its associated magnetic field that are the reasons Zone III exists. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. A red light and lighted sign stating “The Magnet is On” should be illuminated at all times. Ideally, signage should also inform the public that the magnetic field is active even when power to the facility is deactivated. The sign should have a battery backup energy source, in order to remain illuminated in the event of a loss of power to the site.

As mentioned above, trained MR personnel should have direct visual observation to access pathways into Zone IV. When stationed at the operator console in the scan control room, MR technologists should be able to directly observe and control the entrances or access corridors to Zone IV. Observation of these areas can be through line of site or by means of video monitors.

In case of cardiac arrest, respiratory arrest, or other medical emergencies within Zone IV that require urgent medical intervention or resuscitation, appropriately trained and certified MR personnel should immediately initiate basic life support or CPR as required. At the same time, the patient should be emergently removed from Zone IV to a predetermined magnetically safe location. Priorities should be focused on stabilizing the patient first, then evacuating the patient as quickly and safely as possible. Removal from the magnetic environment is crucial, so that safe resuscitative efforts are not restricted. The site access restrictions for Zones III and IV must be maintained during emergency situations for the safety of all involved.
Cryogen safety in the magnet room is included in Zone IV. The most commonly used cryogens in MR environments are liquid helium and liquid nitrogen. Their physical properties present significant potential safety hazards. If exposed to room air, these cryogenic liquids will rapidly boil off and expand into a gaseous state, producing several potential safety concerns, including:

- **Asphyxiation potential** – Cryogenic gases replace oxygenated air
- **Frostbite considerations** – Cryogenic liquids are at exceedingly low temperatures
- **Fire hazards** – May exist in the unlikely event of a quench; condensed air contains a higher oxygen content, which increases the risk of combustion
- **Pressure considerations** – May exist in the unlikely event of a quench if some of the cryogenic gases escape into the magnet room

Cryogen refills are infrequently required by contemporary superconducting magnets, but bringing hundreds of liters of liquid cryogen to the magnet brings with it risks to persons near the magnet. This operation should only be performed by appropriately trained personnel. Unnecessary personnel should not be in attendance, meaning MR personnel staff and patients should not be in Zone IV during a cryogen transfill. Appropriate precautions should be in place to prevent situations of pressure entrapment and asphyxiation during transfills. Dewars containing cryogenic liquids should never be stored inside an MRI facility, or in any enclosed facility, unless the facility is specifically designed to obviate the associated pressure, temperature, and asphyxiation risks.

With most MR systems, if the magnet quenches, the escaping cryogenic gases are ducted outside the building to an unoccupied discharge area (Figure 4). However, cryogen vent/quench pipe assemblies have been known to fail, which leads to considerable quantities of cryogenic gases being inadvertently discharged into the magnet room/Zone IV. Cryogen vent systems are part of the room design, and therefore are the customer’s responsibility to maintain. Facilities are advised to evaluate the design and inspect the construction of their cryogen vent systems to help identify and correct potential weaknesses that could fail in a quench, and to inspect their cryogen vent systems annually.

Thermal expansion of cryogens can positively pressurize the magnet room and entrap persons inside until the pressure is equalized. Recommendations for MRI suite design and construction to reduce risks to patients and staff in case of a cryogen leak in Zone IV include use of an emergency exhaust pathway. The emergency exhaust grille should be located in the ceiling opposite the entrance to the magnet room door, in order to draw the vaporous cloud of cryogenic gas away from the door exiting from the magnet room. Many MR manufacturers are requiring that rooms for superconducting magnets be equipped with an additional form of passive pressure relief/pressure equalization to minimize the risks of positive-pressure entrapment. An outward swinging door to the scan room is not, in and of itself, an appropriate means of pressure relief, as it could burst open with tremendous pressure in a severe positive pressure situation. In addition, breaking a control room window should not be advocated as a primary means of relieving/equalizing Zone IV pressure in a quench situation. Many RF shielded observation windows are constructed in such a manner that breaking them is quite difficult, and not a timely means of pressure relief.
All persons must be protected from possible cryogen exposure at the point of discharge. A quench safety exclusion zone with a minimum clear radius of 25 feet should be established and clearly marked with surface warnings and signage. This area should not contain any serviceable equipment, air intakes, operable windows, or unsecured doors that either require servicing, or offer a pathway for cryogenic gasses to re-enter the building. Persons who must enter this quench safety exclusion zone should be permitted to do so only after receiving specific instruction on quench risks and response.

Medical equipment, including peripheral and/or accessory devices, that has an MR Conditional rating may still be disrupted by exposure to conditions within Zone IV that exceed the equipment’s conditional rating threshold. MR facilities should identify the allowable conditional rating for each MR Conditional piece of equipment which may be brought into Zones III and IV. Equipment may be conditionally safe for one specific field strength, but unsafe at higher or lower field strengths. It is recommended that facilities identify the location of critical isogauss line(s) for MR Conditional equipment and accessory devices used within the MR suite (Figure 5). Additionally, the isogauss lines should be delineated on the floor and walls of the magnet room to aid in the positioning and safe and effective operation of said equipment. Facilities should evaluate all MR Conditional patient monitoring devices, ventilators, medication pumps, anesthesia machines, biopsy and other devices and equipment which may be brought into the magnet room for magnetic field tolerances. One should never proceed with scanning if any object, regardless of its size, accidentally becomes attached to the magnet in the MR suite.
Figure 5 Example of Oasis fringe fields with 5 gauss line measurements highlighted; gauss line positions are affected by room shielding designs

Housekeeping and cleaning personnel are often restricted from Zones III and IV due to safety concerns within these regions. For infection control purposes, the magnet room finishes and construction details should be designed to facilitate cleaning by appropriately trained staff with nonmotorized equipment. With the increasing numbers of MRI-guided procedures and interventional applications, basic infection control protocols should be considered. These may include seamless floors, scrub-able surfaces, and hand washing stations.

In addition to the recommendations for general safety design issues addressed above, there are a host of “site-specific” and “magnet-specific” operational and technical design considerations relevant to MR facility design. These design issues include items such as staff access, conflicts with other imaging modalities, vibration sensitivity, throughput/efficiency, HIPAA considerations, magnet shim tolerances, shielding design, etc. It is highly recommended that facilities seek expert assistance in the planning and design of their MRI suites, in addition to incorporating the guidance found in the 2013 ACR Guidance Document on MR Safe Practices.

**MR Facility Emergency Preparedness Guidelines**

It is the obligation of healthcare facilities to minimize the disruption from quenches or natural disasters, and accelerate their ability to restore critical patient care services when interrupted. Not only the staff and structure must be protected, but also the equipment, which may be very sensitive to environmental changes, including vibration, power supply, and water damage. Facilities may have to contend with hurricanes, earthquakes, tornadoes, fires, ice storms, snowstorms, and/or blackouts. We must be sure that our facilities, equipment, and infrastructure are adequately protected, so we can provide care when it is most widely and desperately needed.
Quench

A quench refers to the sudden loss of magnet superconductivity when the liquid cryogens that normally cool the magnet coil windings boil off rapidly. In the superconducting state, cryogens (usually liquid helium) keep the magnet coil windings very cold. The resistance of the magnet coil windings is zero, and hence, no energy is required to maintain current flow. If the temperature of the coil windings rises above the superconductivity threshold, the windings suddenly develop a finite resistance. The circulating current passing through this elevated coil resistance creates heat, which causes a sudden explosive boil-off of the liquid helium. Generally, a quench is accompanied by a loud bang, thundering sound, hissing, or rushing sound with this gas expulsion. (The mention of “resistance” within the superconductive magnet should not be confused with another type of MR magnet, which is called a resistive magnet. Resistive magnets do not require cryogens, but need a constant power supply to maintain a homogeneous magnetic field, and therefore can be quite expensive to maintain. Resistive magnets typically operate at field strengths of 0.6T and lower).

Quenching may occur spontaneously, caused by a fault in the magnet, or manually, by activation of the magnet emergency STOP button (Figure 6). The magnet emergency STOP button should only be used when a shutdown of the static field is necessary, as in the event of the magnetic field causing injury to a patient or other personnel (i.e. to free someone pinned to the magnet, or to remove a large ferromagnetic object captured in the field when human injury is imminent).

Figure 6 Oasis ERDU (Emergency Rundown Unit) found in scan room; press STOP button to quench magnet

In the event of a system quench, regardless of whether it is spontaneous or manual, all personnel and patients must be evacuated from the MR scan room as quickly and as safely as possible. Site access must be immediately restricted until the arrival of MR equipment service personnel. Restricted access is especially important if cryogenic gases are observed to have vented partially or completely into the scan room, evidenced by the sudden appearance of white “clouds” or “fog” around or above the MR scanner. Condensation on the vent pipe may also appear as a “fog,” even when the cryogens are venting properly. Police and fire response personnel should be restricted from entering the MR scan room with their equipment until it can be confirmed that the magnetic field has been successfully dissipated.
A manually initiated preemptive quench may be recommended as a response to an impending disaster (hurricane, tornado, etc.), but should be started only after careful consideration and preparation. A quench subjects a magnet to a change of 500°F thermal shock within a few dozen seconds, which can cause major physical damage. It is also possible for the venting cryogenic gases to breach the quench tube and cause significant damage to the magnet room, as well as jeopardizing the safety of those in the vicinity. Before initiating a preemptive quench, the facility should verify the function of the emergency exhaust system, verify or provide a means of pressure relief, and perform a visual inspection of the cryogen vent pipe to check for signs of condensation, leaking water, or ice inside the pipe. The MRI manufacturer should be contacted for their specific instructions and recommendations, which may be to perform a controlled static magnetic field ramp-down, as opposed to a manual quench.

**Fire/Police Responders**

Response from fire, police, and/or security personnel may be required in the event of an emergency in the MR suite. Representatives from these departments should be prospectively invited to the facility for tours and presentations on MR safety. They must be made aware of the potential hazards involved with responding to emergencies in the MR suite, especially as it pertains to their normal equipment (axes, air tanks, guns, etc.) (Figure 7). In the presence of an actual fire in Zones III or IV, the magnetic fields may still be present and fully operational. Therefore, firefighters or other non-MR personnel responding with firefighting equipment cannot be given free access to Zones III and IV. MR Conditional or MR Safe fire extinguishing equipment should be stored in Zone III or IV, and must be clearly marked and readily accessible.

![Figure 7 Firefighter with equipment](image)

The helium or nitrogen gases in superconducting magnets are not flammable, and do not pose a direct fire hazard. However, liquid oxygen that can result from the supercooled air in the vicinity of these released gases might increase the fire hazard in the magnet area. It is not a requirement that the magnet be quenched during a response to a fire or emergency, as long as there are trained MR personnel available to ensure that emergency responders are kept out of the MR scanner room and behind the 5 gauss line. If the fire is in a location in Zone III or IV that necessitates the presence of firefighting or emergency responders and their equipment, the decision to quench a superconducting magnet must be seriously considered, in order to protect the health and lives of the emergency personnel. In a quench situation, appropriately trained and designated MR personnel must ensure that all non-MR personnel are restricted from Zones III and IV until the designated MR personnel has
personally verified that the static field is either no longer detectable, or at least sufficiently attenuated as to no longer present a potential hazard to someone moving by it with large ferromagnetic objects (i.e. firefighting equipment).

When dealing with resistive magnets in emergency situations, the magnetic field should be shut down as completely as is possible, and verified as such, before emergency personnel have access to Zone IV. For permanent, resistive, or hybrid systems whose magnetic fields cannot be completely shut down, MR personnel should be available to warn emergency responders that a powerful magnetic field is still operational in the magnet room.

**Water Damage**

Every facility has the potential for water damage, whether it’s from roof failure, burst pipes, or a storm surge (Figure 8). An MRI scanner can be incapacitated or destroyed by a small quantity of water. If water damage is an anticipated possibility, the gantry and equipment should be covered with sturdy plastic that is taped in place. Electronics that can be lifted up off the ground should be moved to a higher area. If not designed to protect against water damage, some items in certain situations may need to be replaced (i.e. the RF shield floor assembly in a flood). Many facilities have emergency generators in basements or low-lying areas that may flood easily. Individual sites should evaluate their possible risks from water damage, as well as make preparations in case the building enclosure fails or is flooded.

![Figure 8 Example of flooding](image)

**Structural Damage**

Though less likely with current magnet systems, vibrations from seismic events have the potential to initiate a quench of the magnet system. Structural damage or motion may also damage the RF shield enclosure, which would potentially degrade image quality until repairs are made.

**Power Outage**

Cryogens will begin to boil off at an accelerated rate if they are not kept liquefied within the superconducting magnet. This is what occurs when there is no electrical power to the vacuum pump/coldhead. This additional cryogenic gas discharge may cause any accumulated water in the cryogen vent to freeze, occluding the pipe and increasing the possibility for a cryogen vent breach in the event of a quench. If power to the vacuum pump is not restored, within a few days to a week, the magnet will spontaneously quench and discharge most or all of its remaining cryogenic gasses (Figure 9). This poses a safety risk to anyone near the discharge point. If power is restored to the vacuum
pump/coldhead, and cryogen levels are restored before a quench, there should be no long-term consequences to the magnet’s operation from a power interruption.

![Figure 9 Cryogen discharge](image)

Temporary electrical power may be provided either through on-site or portable generators. Some hospitals have been drawn to the concept of co-generation, where they generate their own electricity all the time. It is economically feasible for larger facilities, and is beneficial for them in emergencies.

**Code Response**

It is imperative that personnel responding to a call for emergency medical attention in the MR suite be aware of, and compliant with, MR safety protocols. As with fire and police responders, code teams should receive specialized training, in order to minimize risks to patients, staff and equipment. Appropriately trained and designated MR personnel should be given authority for screening, access restrictions and quench decisions.

Once basic CPR is initiated, the coding patient should be immediately moved out of Zone IV to a prospectively designated location where the code can be run and/or where the patient can remain until the arrival of emergency personnel (Figure 10). Full resuscitation of patients within Zone IV is complicated by the inability to accurately interpret electrocardiographic data. In addition, all personnel within Zone IV are put at risk of injury from ferromagnetic objects that may be brought into Zone IV by emergency response personnel that are answering the code.

![Figure 10 Practicing CPR](image)
It is advised that all MR facilities perform regular drills to rehearse and refine emergency response protocols to protect patients, MR staff, and responders.

**Prevention**

All healthcare facilities should have emergency preparedness plans, with MRI facilities being sure to address the unique aspects of MRI equipment. Facilities can prospectively anticipate the types of emergency incidents they may encounter based on geographic location (i.e. earthquakes, tornadoes, massive snow or ice storms), as well as the assumption that all facilities have the potential for power interruptions and fluctuations, flooding, fire, and code situations (Figure 11). State and federal offices of emergency preparedness can be an excellent resource as far as risks and strategies for preparation. Constant preventive maintenance for MR systems can help keep sites “prepared” all year round. In addition, many vendors offer remote monitoring to keep tabs on the system’s status. MRI facilities and MRI departments in hospitals must assess the immediate needs of the community once disaster has struck, and restore critical patient care services first.

*Figure 11 Emergency incident may be caused by tornado*
Personnel and Patient Access Restriction – Static Magnetic Field

Personnel Definitions

MR Medical Director

Each site should name an MR Medical Director who will be responsible for ensuring that MR safe practice guidelines are established and maintained as current and appropriate for the site (Figure 12). The MR Medical Director should have the necessary education and experience in MR safety to qualify as Level 2 personnel. This director is responsible for identifying those individuals who qualify as Level 2 personnel, as well as designating the necessary training for them. The MR Medical Director maintains final authority for all medical decisions concerning MRI, including clearance of any patients with safety screening issues (e.g., an MR conditional implant, pregnant patient, etc.).

![Figure 12 MR Medical Director/Radiologist](image)

The MRI Safety Director (Officer) coordinates closely with the MRI Medical Director (with whom resides final authority for all medical decisions concerning MRI), who may not regularly work within the MRI suite.

The site’s administration is responsible for ensuring that the policies and procedures that result from the MR safe practice guidelines are implemented and adhered to at all time by all of the site’s personnel.

MR Personnel

Individuals working within at least Zone III of the MR Environment should be documented as having successfully completed at least one of the MR safety live lectures or prerecorded presentations approved by the MR medical director. Attendance should be repeated annually, and documentation should be provided to confirm these ongoing educational efforts. These individuals are then referred to as MR Personnel, either level 1 or level 2.

MR personnel should undergo MR-screening as part of their employment interview process to ensure their safety in the MR environment. As employees, they should also report to the MR medical director any trauma, procedure, or surgery they experience or undergo where a ferromagnetic object or device may be introduced within or on them. Appropriate screening can then be conducted to determine the safety of permitting the employee in Zone III, as even nonferromagnetic objects can cause problems for employees. An incident involving employee safety occurred in Vienna, Austria, in 2013. One month prior to the incident, a nurse from the anesthesia department had a prosthetic stapes implanted, which was
listed as nonferromagnetic, and considered safe (for patients) in field strengths up to 3 tesla. During the incident, the anesthesia nurse had rushed toward the MRI scanner, and placed her head inside the bore to help her patient. At that time, the nurse experienced severe pain in the ear that contained the otologic prosthesis. Because the nurse and the “device” entered the bore of the magnet quickly, the nonferromagnetic device was subject to Lenz’s law. This states that any metallic object that experiences a difference in magnetic flux is subjected to an opposing force, which was the pull and pain that the nurse experienced on her otologic prosthetic. Patients are typically moving into the bore slowly, but healthcare personnel may be responding to a patient very quickly, with vertical or rotational movement of their heads. The medical physicist that investigated this case, Dr. Nadia Oberhofer, suggested that manufacturers provide a risk assessment for healthcare workers, as well as patients, regarding nonferromagnetic implants. Scanning of patients with some devices may be permissible, while personnel might not be permitted to be in or near the gantry with the same device. Personnel often do not operate under the same circumstances as patients, so the MR medical director needs to be informed of the status of new devices on or in MR personnel.

As a safety consideration in emergency situations, sites or facilities should consider assigning appropriately trained security personnel, who have also been trained and designated as MR personnel, to respond to the MR department. This person should be on site before the arrival of firefighters or emergency responders to ensure that they do not have free access to Zones III or IV.

**Level 1 MR Personnel**

Level 1 MR personnel includes those individuals who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III. This category would include employees such as MRI department office staff and patient aides. They are permitted unaccompanied access throughout Zones III and IV, and are permitted to be responsible for accompanying non-MR personnel into and throughout Zone III. They are *NOT* permitted to directly admit, or be designated responsible for, non-MR personnel in Zone IV.

**Level 2 MR Personnel**

Level 2 MR personnel includes those who have been more extensively trained and educated in the broader aspects of MR safety issues, including the potential for thermal loading or thermal burns, and direct neuromuscular excitation from rapidly changing gradients. This category would include employees such as the MRI technologists, radiologists, and radiology department nurses. One specifically identified level 2 MR person should accompany or supervise (with visual or verbal contact) non-MR personnel for as long as they are in Zones III or IV. In cases of shift change, meal breaks, etc., the supervision of non-MR personnel must be transferred to another level 2 MR person.

As level 2 MR personnel, MR technologists should be in compliance with technologist qualifications of the accrediting body, if their site is accredited (Figure 13). There should be a minimum of 2 MR technologists, or one MR technologist and one other individual with MR personnel designation in the immediate Zone II through Zone IV MR environment. In emergency coverage situations, the MR technologist can scan with no other individuals in their Zone II through Zone IV environment, as long as there is in-house ready emergency coverage by designated department of radiology MR personnel.
Non-MR Personnel

Patients, visitors, or facility staff members that do not meet the criteria of level 1 or level 2 MR personnel are referred to as non-MR personnel. This category includes any individuals or groups that have not, in the previous 12 months, undergone the designated formal training in MR safety issues that has been defined by the MR safety director of that site.

Patient and Non-MR Personnel Safety

ALL non-MR personnel that wish to enter Zone III must first pass an MR safety screening process. Only MR personnel are authorized to perform an MR safety screening before permitting non-MR personnel into Zone III. The screening process and screening form for patients, non-MR personnel, and MR personnel should be essentially identical. One should operate under the assumption that screened non-MR personnel, health care practitioners, or MR personnel might enter the bore of the MR scanner during the MR imaging process. A parent accompanying a child for an MR exam, or a health care practitioner tending to a patient in the MR scanner may lean into the bore of the magnet at some point during the MR scan.

Written MR Safety Screening

Conscious non-emergent patients and non-MR personnel should complete written MR safety screening questionnaires before their introduction to Zone III (Figure 14). They should be MR safety screened on site by a minimum of two separate individuals, with at least one of those individuals being level 2 MR personnel, and at least one of these screenings being verbal or interactive. Family or guardians of non-responsive patients, or of patients who cannot reliably provide their own medical histories, should also complete the written MR safety screening questionnaire before they or the patient moves into Zone III. An oral review of the screening questionnaire should be performed with the family member or guardian before accessing Zone III. Emergent patients and their accompanying non-MR personnel may be screened only once, as long as the screening is performed by level 2 MR personnel. The non-emergent patient, the emergent patient or the guardian and the screening MR staff member must sign the completed screening form. This form should become part of the patient’s medical record. Each question must be answered with a “yes” or “no” response, or further information must be provided as requested.
Physical Safety Screening

Any individual undergoing an MR procedure must remove all readily removable metallic personal belongings and devices on or in them, including, but not limited to, watches, jewelry, pagers, cell phones, body piercings (if removable), contraceptive diaphragms, metallic drug delivery patches, cosmetics containing metallic particles, and clothing items which may contain metallic fasteners, hooks, zippers, loose metallic components or metallic threads. It is recommended that patients be required to wear a site-supplied gown (or scrubs) without metal fasteners, if feasible.

Body Piercings, Tattoos, and Permanent Cosmetics

Body piercing jewelry can be made of ferromagnetic and non-ferromagnetic metals, as well as nonmetallic materials. The presence of body piercing jewelry that is made from ferromagnetic or conductive material of a certain shape may present problems for MR patients and those in the MR environment. Risks include uncomfortable sensations from movement or displacement of the jewelry, depending on the site of the body piercing, and the ferromagnetic qualities of the jewelry. Additionally, if the jewelry is made from electrically conducting material, there is a possibility of MRI-related heating that could cause excessive temperature increases and burns. If it is not possible to remove a patient’s metallic body piercing jewelry, the patient should be informed of the potential risks. If the jewelry is made from ferromagnetic material, some means of stabilization (application of adhesive tape or bandage) should be used to prevent movement or displacement of the item. To avoid potential heating of body piercing jewelry made from conductive materials, it is recommended that gauze, tape, or similar material be wrapped around the jewelry to insulate it, preventing contact with the underlying skin. The patient should be instructed to immediately inform the MR operator if heating or unusual sensation occurs in association with the body piercing jewelry.

It is known that tattoos and permanent cosmetics (eyeliner, eyebrows, etc.) may cause artifacts and may be associated with relatively minor, short-term cutaneous reactions. However, the exact frequency and
severity of soft tissue reactions or other problems related to MR imaging, while unknown, is considered to be quite low. The FDA considers the inks used in intradermal tattoos, including permanent makeup, to be cosmetics, and considers the pigments used in the inks to be color additives requiring premarket approval under the federal Food, Drug, and Cosmetic Act. The FDA has not exercised its authority over tattoo inks or pigments. Ferromagnetic metallic compounds have been found in tattoo pigments, especially iron oxide. These pigments can cause an electromagnetic reaction that has the potential to distort the local magnetic field. The ferromagnetic compounds also have the potential to induce an electric current that increases the local skin temperature, enough to cause a cutaneous burn. The worst offenders are tattoos with black pigment or any other pigments containing iron oxide, as well as those tattoos with designs displaying loops, large circular objects, or multiple adjacent points (Figure 15). Simple loops of this conductive material can conceivably carry a level of voltage significant enough to cause a burn. Guidelines and recommendations for management of patients with permanent cosmetics and tattoos, per Frank G. Shellock, PhD., include:

- Questions on the screening form to identify the presence of permanent cosmetics or decorative tattoos
- Ask the patient about applications of any permanent coloring techniques (tattoos), including cosmetic applications, such as eyeliner
- Inform the patient of the risks associated with the site of the tattoo
- Advise the patient to immediately inform the MRI technologist regarding any unusual sensation felt at the tattoo site in association with the MR procedure
- Closely monitor the patient through both visual and auditory means
- Treat the patient prophylactically or symptomatically with a cold compress (wet washcloth) or ice pack applied to the tattoo site during the MR procedure

Additionally, patients must be made aware that tattoos placed within 48 hours before a pending MR examination have the potential for smearing or smudging of the edges of the new tattoo. Additional caution should be taken with “homemade” tattoos, as the ingredients used to make their pigments may be unknown.
Metallic Foreign Bodies

All patients and non-MR personnel with a history of potential ferromagnetic foreign object penetration or implant must undergo further investigation before being permitted entrance to Zone III. Additional screening methods include patient history, plain x-ray films, prior CT or MR studies of the anatomic area in question, or access to written documentation as to the type of implant or foreign object that might be present (Figure 16). After positive identification of the type of implant or foreign body, best effort assessments should be made to identify the MR compatibility or MR safety of the implant or foreign object. The preferred identification would be written records of the results of formal testing of the implant before implantation. Product labeling regarding the implant or object, or peer-reviewed publications regarding MR compatibility and MR safety testing of the specific make, model, and type of object can also be incorporated. Patients with a history of orbit trauma by a potential ferromagnetic foreign body for which they sought medical attention should have their orbits cleared by plain x-ray orbit films, or by a radiologist’s review and assessment of prior contiguous cut CT or MR images, obtained since the suspected traumatic event.

![Figure 16 Examples of x-rays of metallic foreign bodies near eye](image)

In cases where an MR examination is deemed clinically necessary, but the patient is unconscious or unresponsive, cannot provide reliable history, and for whom history cannot be reliably obtained from others, level 2 MR personnel should physically examine the patient. Any scars or deformities anatomically indicative of an implant, and whose origins are unknown, and may have been caused by ferromagnetic foreign bodies, implants, etc., should be subject to plain-film radiography (if recent films or CT or MR studies of those areas are not available). In addition, plain film imaging of the skull or orbits and chest to exclude metallic foreign objects should be performed, if not obtained recently. These steps must be taken to ensure that these types of patients have no potentially harmful embedded or implanted metallic foreign objects or devices.

Conventional metal detectors that do not differentiate between ferrous and non-ferromagnetic materials are not recommended for screening purposes. They should not be necessary for the detection of large metallic objects, such as oxygen tanks that are placed on the patient’s gurney. These objects should be detected, and fully excluded, during the routine patient screening process. As previously discussed, ferromagnetic detection systems (FMDS) are recommended for use as an adjunct to thorough and conscientious screening of persons and devices. Although many FMDS are currently found in Zone III, even at the door to the magnet room, it is recommended that this screening be performed in Zone II, before patients or non-MR personnel reach the point of controlled access in Zone III.
Transdermal Medication Patches

Transdermal patches allow continuous and prolonged drug delivery that may be more effective and safer than oral medication. They also offer the potential to deliver medications that would otherwise require injections. However, some drug delivery patches contain metallic foil or other metallic components that may cause excessive heating or a burn if left on the patient during an MRI procedure (Figure 17). The patient’s prescribing physician should be consulted before a transdermal patch is removed and/or repositioned, as these actions can lead to an alteration of the patient’s dose of medication. The patient’s physician should also determine if a new patch should be applied after the MRI examination, or if the original patch can simply be replaced. If the patch is to be removed then replaced, a specific staff member should be given responsibility to ensure that it is replaced and repositioned correctly after the MR examination. An alternative to removing the patch is to place an ice pack directly on the patch for the duration of the MR examination. However, the rate of delivery or absorption of the medication to the patient may still be substantially altered. A radiologist, as well as the prescribing physician, may need to be consulted before proceeding with any actions that may alter the medication patch.

![Figure 17 Examples of transdermal medication patches](image)

The FDA was made aware of the risk of burns during MRI scans due to metallic backings on transdermal drug patches. Most, but not all, of the patches that contained metal in their backings provided a warning in their labeling about the risk of burns to patients who wear the patches during an MRI scan. As of March, 2009, the FDA had evaluated the composition of available patches to determine which of them contained metal components. The FDA was working with some manufacturers to update their labeling to include adequate warnings to patients about the risk of burns to the skin if the transdermal patch is worn during an MRI scan.

Not all transdermal medication patches contain a metallic component, so they would not have to be removed for an MRI examination. In addition, if the body part where the patch is located is not within the transmit RF coil, there is no risk to the patient. Careful review of labeling for the specific patch and consultation with the radiologist and prescribing physician are necessary for patient safety.
Pregnancy Issues

Pregnant Health Care Practitioners

Pregnant technologists and other health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy, as there do not appear to be deleterious effects from exposure to the static magnetic field of the MR system. A policy is recommended that permits pregnant technologists to engage in activities such as positioning patients, scanning, archiving, injecting contrast, and entering the MR scan room in response to an emergency. Regardless of their trimester, pregnant health care practitioners are permitted to enter the MR system room and attend to the patient. Although they are permitted to work in and around the MR environment, pregnant technologists and health care practitioners should not remain within the MR scanner bore or Zone IV during actual data acquisition or scanning. This is important in cases where technologists or health care practitioners might remain in the scan room to assist with interventional procedures, and would be exposed to the MR system’s electromagnetic fields at levels similar to those used for patients. The recommendation that pregnant health care practitioners not remain in the scan room during scanning is not based on indications of adverse effects, but rather the impression that insufficient data pertaining to the effects of the other electromagnetic fields of the MR system precludes supporting or allowing unnecessary exposures.

Pregnant Patients

MRI has long been used to evaluate obstetrical, placental, and fetal abnormalities in pregnant patients. It is recognized as a beneficial diagnostic tool, and is utilized to assess a wide range of diseases and conditions affecting both the pregnant patient and the fetus. Few studies have been directed toward determining the relative safety of using MR procedures in pregnant patients. Safety issues include possible bioeffects of the static magnetic field of the MR system, risks associated with exposure to the gradient magnetic fields, the potential adverse effects of radiofrequency (RF) energy, and possible adverse effects related to the combination of these three electromagnetic fields. Risks associated with the MR environment are difficult to assess for pregnant patients due to the number of possible combinations of the various factors in the MR setting, including field strength differences, pulse sequences, exposure times, etc. This is further complicated by the on-going updates and improvements in hardware and software.

Present data has not conclusively documented any deleterious effects of MR imaging exposure on the developing fetus. No special consideration is recommended for the first, versus any other, trimester of pregnancy. However, as with all interventions during pregnancy, females of reproductive age should be screened for pregnancy before permitting them access to MR imaging environments (Figure 18). If pregnancy is established, the potential risks versus benefits of the pending MR study should be reassessed in determining whether or not the requested MR examination could safely wait until the pregnancy is over to be performed. As stated in the Policies, Guidelines, and Recommendations for MR Imaging Safety and Patient Management issued by the Safety committee of the Society for Magnetic Resonance Imaging in 1991, “MR imaging may be used in pregnant women if other nonionizing forms of diagnostic imaging are inadequate or if the examination provides important information that would otherwise require exposure to ionizing radiation (e.g. fluoroscopy, CT, etc.). Pregnant patients should be informed that, to date, there has been no indication that the use of clinical MR imaging during pregnancy has produced deleterious effects.” This policy has been adopted by the American College of
Radiology and is considered to be the “standard of care” with respect to the use of MR procedures in pregnant patients. This information applies to MR systems operating up to and including 3 tesla.

Figure 18 Symbol for pregnant patient

MR scans can be performed at any stage of pregnancy if the risk-benefit ratio to the patient warrants that the study be performed. The risk-benefit ratio should be determined by a level 2 MR personnel-designated attending radiologist, who should confer with the referring physician. The radiology report or the patient’s medical record should document the following:

- The information requested from the MR study cannot be acquired by nonionizing means (e.g. ultrasonography)
- The data is needed to potentially affect the care of the patient or fetus during the pregnancy
- The referring physician believes that it is not prudent to wait until the patient is no longer pregnant to obtain this data

It is reported that MR procedures in pregnant patients should NOT be withheld in the following situations:

- Patients with active brain or spine signs and symptoms requiring imaging
- Patients with cancer that require imaging
- Patients with chest, abdomen, and pelvic signs and symptoms of active disease when sonography is non-diagnostic
- In specific cases of suspected fetal anomaly or complex fetal disorder

Studies of gadolinium-based MRI contrast media being used during pregnancy have been limited, and the effects on the human embryo or fetus are incompletely understood. Studies have demonstrated that at least some of the gadolinium-based MR contrast agents readily pass through the placental barrier and enter the fetal circulation. They are then filtered in the fetal kidneys and excreted into the amniotic fluid. Here, the gadolinium-chelate molecules are in a relatively protected space, and may remain in this amniotic fluid for an indeterminate amount of time before finally being reabsorbed and eliminated. The longer the chelated molecule remains in this space, the greater the potential for dissociation of the potentially toxic gadolinium ion from its ligand. The impact of free gadolinium ions being released in any quantity in the amniotic fluid is unclear, but their deposition in the developing fetus raises concerns of possible secondary adverse effects. The risk to the fetus from gadolinium-based MR contrast agent administration remains unknown, and may be harmful. For all these reasons, MR contrast agents should not be routinely provided to pregnant patients.
The decision to administer a gadolinium-based MR contrast agent to a pregnant patient must be made on a case-by-case basis by the level 2 MR personnel-designated attending radiologist, in conjunction with the referring physician and the patient. This decision should be accompanied by a well-documented and thoughtful risk-benefit analysis. The analysis should be able to defend the decision to administer contrast based on overwhelming potential benefit to the patient or fetus outweighing the theoretical, but potentially real, risks of long-term exposure of the developing fetus to free gadolinium ions. The radiology report or the patient’s record should document the following:

- The information requested from the MR study cannot be acquired without the use of IV contrast or by using other imaging modalities
- The information needed affects the care of the patient and fetus during the pregnancy
- The referring physician is of the opinion that it is not prudent to wait to obtain this information until after the patient is no longer pregnant

The pregnant patient that is undergoing the MR examination with contrast should also provide informed consent to document that she understands the risks and benefits of the MR procedure, as well as alternative diagnostic options available (if any), and that she wishes to proceed with the contrasted MR examination.

**Claustrophobia, Anxiety, and Emotional Distress Issues**

Patient distress and anxiety can contribute to adverse outcomes for the MR procedure, including unintentional exacerbation of the patient’s distress, as well as a compromise in the quality of the exam, which affects the diagnostic aspects of the imaging study. The efficiency of the MRI department or facility also decreases due to delayed, prematurely terminated, or cancelled studies. Investigations have reported that anywhere from 0.7% to 20% of patients attempting to undergo MR procedures have incomplete or failed exams due to serious distress, such as claustrophobia. Patient compliance during the MR procedure is of paramount importance in achieving a diagnostically acceptable examination. The earlier that patient distress and anxiety are detected by the referring physician, the radiologist, or the MRI technologist, the earlier appropriate interventions can be put in place. This leads to improvements in patient comfort, the quality of imaging, and overall efficiency of the facility.

The most commonly cited factors that cause distress for MR patients are the physical environment of the MR system, and the anxiety associated with the underlying medical problem that necessitates the MR examination. The confining dimensions of the MR system can bring on apprehension, claustrophobia, anxiety, fear, and panic attacks (Figure 19). A patient’s limited line of sight from inside the scanner can prompt feelings of uncontrolled confinement and detachment. These feelings may be reduced by the technologist’s assurance of both visual and verbal monitoring of the patient during their exam, as well as the patient’s control of the alert bulb. Additional distressing sensations include the prolonged duration of the exam, the acoustic noise, the temperature inside the scanner, and the stress related to restricted movement. The architecture of vertical field magnets is presumed to reduce the frequency of distress associated with MR procedures. Hitachi’s Oasis 1.2T vertical field open magnet can offer patients an obstructed view of 270°, depending on the patient positioning and coil needed for the MR examination. Newer generations of high field strength (1.5T-3T) magnets have shorter and wider bore configurations, which should also ease feelings of being confined or enclosed.
Referring clinicians should take the time to explain to patients the reasons for ordering an MR procedure (as opposed to another imaging modality), and what they expect to learn from the results with respect to implications for treatment and prognosis. Patients are typically more cooperative if they are educated about the MR examination, especially those aspects that may be difficult or challenging. The ordering physician and/or the MR technologist should discuss, in everyday terms, the internal dimensions of the MR system, the reasons for the acoustic noise, the level of noise to expect, and the estimated amount of time the examination might take. Studies have documented a decrease in the incidence of premature termination of MR examinations when patients were provided with detailed information about their procedures. In addition, a brochure or video presentation can be offered to the patient, with access to MR-trained healthcare professionals who can answer questions before the examination. Making the patient as comfortable as possible, within the limits of the positioning necessary for their MR exam, can also minimize stress. Pads and sponges can be used to help the patient achieve and maintain the proper positioning for scanning, as well as to maintain their safety in the MR coil and in the bore of the magnet. Ear protection should always be provided to decrease acoustic noise from the scanner. Patients should always be given the patient alert bulb, and be made aware of the two-way intercom system. They should also be given the reassurance that the MR staff is monitoring them through both visual and verbal means, and can quickly respond to them in the scan room, if needed.

Additional interventions might be necessary for patients who continue to experience mild to moderate distress after the aforementioned steps have been taken. Often times, allowing an appropriately screened relative or friend to remain with the patient in the scan room is all that is needed to successfully complete an MR examination. If the patient does not have someone that can accompany them during the scan, the MR tech or another staff member can increase their verbal contact with the patient during their exam. Depending on the type of MR scan requested for the patient, and their underlying medical conditions, prone positioning might alleviate the “closed-in” feelings associated with being supine in the scanner. It might also be helpful to position the patient so they enter the scanner feet-first, rather than head-first. Again, this situation will be dependent on the type of scan ordered, and the table travel limits of the system. Some MR coils are outfitted with mirrors which can be positioned to allow the patient to see outside the scanner, thus minimizing some distress. Anxious patients may also benefit from having their eyes covered (by a washcloth or blindfold) so they are less aware of the close proximity of their surroundings. Changes can also be made to the MR environment to help with patient anxiety. Some people feel less anxious with higher lighting levels, which can be accommodated by adjusting the lights in the scan room, as well as the lights on or in the scanner itself (Figure 20). If a fan is available inside the scanner, an increase in airflow may also help reduce the sensation of confinement. Music or audio communication systems that transmit through headphones have been
developed specifically for use with MR systems, and reports indicate that they help reduce some symptoms of anxiety. Patients may even be encouraged to bring their own music, as long as they can remain still in the scanner while it is playing. Monitors and special goggles have also been developed for use in the MR scan room, as visual stimuli can distract patients and reduce distress.

Figure 20 Positioning of lights around Hitachi’s Oasis scanner

Analgesia, Anesthesia, and Patient Monitoring

Analgesia

Patients who are severely distressed, anxious, or claustrophobic may benefit from a short-acting sedative or anxiety-reducing medication. Typically, the patient should request such medication from the physician ordering the MRI, after discussing their personal situation with that doctor. The prescribing physician should also instruct the patient as to time(s) of dosing of their medication to achieve maximum effect from the medication while the patient is in the MR scanner. Patients receiving these types of medications should be accompanied to and from the MRI department or facility. MR personnel should refer to their department or site’s policies and procedures for proper handling of these cases, as a thorough review of this subject is beyond the scope of this seminar.

Sedation/Anesthesia

It is imperative that physiologic monitoring be performed to ensure patient safety whenever sedatives are used, including in the MR environment. Anesthesia consultation may be needed for proper patient management. MR facilities should establish policies and guidelines for patient preparation, monitoring, sedation, and management of post-sedation recovery. These policies and guidelines should be based on the standards established by the American Society of Anesthesiologists (ASA), the American College of Radiology (ACR), the American Academy of Pediatrics Committee on Drugs (AAP-COD), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Practice Guidelines for Sedation and Anesthesia from the ASA indicate that a person must be present that is responsible for monitoring the patient if sedative or anesthetic medications are used.
Patient Monitoring

Conventional monitoring equipment and accessories were not designed to operate in the MR environment, as the electromagnetic fields can adversely affect or alter the operation of these devices. Various monitors and support devices have been developed or specially modified to perform properly during MRI procedures. Monitoring during an MRI examination is indicated whenever a patient requires observations of vital physiologic parameters due to an underlying health problem, or is unable to respond or alert the MRI technologist or other healthcare worker regarding pain, respiratory problems, cardiac distress, or other difficulties that might arise during the examination. In addition, a patient should be monitored if there is a greater potential for a change in physiologic status during the MRI procedure. High-risk patients may also require various support devices and accessories to ensure their safety. Patients that may require monitoring include:

- Physically or mentally unstable patients
- Patients with compromised physiologic functions
- Patients who are unable to communicate
- Neonatal and pediatric patients
- Sedated or anesthetized patients
- Patients undergoing MR-guided interventional procedures
- Patients who may have a reaction to an MRI contrast agent
- Critically ill or high-risk patients

It is also prudent to have appropriate monitoring equipment and accessories readily available for the proper management and support of patients who may experience adverse effects or idiosyncratic reactions to MRI contrast agents. Contrast reactions can be serious, and/or life-threatening.

The Safety Committee of the Society for Magnetic Resonance Imaging published guidelines and recommendations concerning the monitoring of patients during MRI procedures in 1992. Their directives stated that all patients undergoing MRI procedures should, at the very least, be visually (e.g. using a camera system) and/or verbally (e.g. intercom system) monitored, and that patients who are sedated, anesthetized, or are unable to communicate should be physiologically monitored and supported by the appropriate means. Guidelines issued by the Joint Commission on Accreditation of Healthcare organizations (JCAHO) indicate that patients receiving sedatives or anesthetics require monitoring during both the administration of and recovery from these medications. The American Society of Anesthesiologists also recommends that certain patients need to be monitored using proper equipment and techniques.

It is crucial for patient safety that the specific physiologic parameters to be monitored during the MRI procedure are properly selected. Various factors must be considered, including the patient’s medical history, present condition, medications and their side effects, and the type of MR procedure to be performed. A patient receiving a sedative might need monitoring of their respiratory rate, apnea, and/or oxygen saturation, while a patient requiring general anesthesia would need monitoring of multiple physiologic parameters. Appropriate physiologic monitoring and management of the patient by trained personnel must continue after the MRI procedure is performed, especially if a sedative or general anesthesia has been used. Policies and procedures for the management of the patient in the MRI
environment should be comparable to those used in the operating room or critical care setting, especially with respect to monitoring and support requirements.

Healthcare professionals that are permitted to monitor patients during MRI procedures must have appropriate training and experience. Operation of the monitoring equipment and accessories used in the MRI environment may require additional training, as the healthcare professional must be able to recognize equipment malfunctions, device problems, and recording artifacts. They must also be able to identify and manage adverse events using appropriate equipment and procedures in the MRI environment. Emergency plans should be in place, and practiced regularly, for medical emergencies in the MR environment. Patients may need to be removed from the MR system room for treatment, as the equipment necessary to treat them may not be safe in the MR environment.

The types of equipment to be used for patient monitoring and support must be carefully considered and properly implemented to ensure the safety of both patients and healthcare professionals in the MR system room. Necessary or critical physiologic monitoring devices that have ferromagnetic components should be permanently fixed to the floor or tethered to the wall and properly labeled with warning information to prevent them from being moved too close to the MR system. All personnel involved with MRI procedures should be aware of the importance of the placement and use of the equipment, and the hazards of moving portable equipment too close to the MR system.

Electromagnetic fields associated with the MR system can significantly affect the operation of monitoring equipment. The monitoring equipment itself may emit spurious noise that, in turn, produces distortion or artifacts on the MR images. Physiologic monitors may also leak RF, which produces electromagnetic interference that can substantially alter MR images. RF-shielded cables, RF filters, special outer RF-shielded enclosures, or fiber-optic techniques can be used to prevent image-related or other RF-related interactions in the MRI environment.

While the MR system is operating, electrical currents may be generated in the conductive materials of monitoring equipment that are used as part of the interface to the patient. These currents can be of sufficient magnitude to cause excessive heating and thermal injury to the patient. First, second, and third degree burns have occurred in association with MRI procedures that were directly attributed to the use of monitoring devices. These injuries have been associated with electrocardiographic lead wires, gating systems, pulse oximeters, and other types of monitoring equipment and accessories comprised of wires, cables, or similar components made from conductive materials.

ECG monitoring in the MR environment is challenging, due to the inherent distortion of the ECG waveform that occurs using higher field strength MR systems. This effect is observed when blood, which is a conductive fluid, flows through the large vascular structures in the presence of the static magnetic field. The result is typically an increase in the amplitude of the T-wave, or other non-specific waveform-changes. Altered T-waves or ST segments may be associated with cardiac disorders, so it may be necessary to obtain a baseline ECG recording prior to and immediately after the MRI procedure to determine a patient’s cardiac status. Additional artifacts caused by the static, gradient, and RF electromagnetic fields of the MR system can severely distort the ECG, making observation of morphologic changes and detection of arrhythmias difficult (Figure 21). ECG artifacts in the MR environment may be decreased by:

- Using ECG electrodes that have minimal metal
• Using ECG electrodes recommended by the MR manufacturer, and following instructions for use issued by the electrode manufacturer
• Selecting electrodes and cables that contain nonferromagnetic metals

Monitoring equipment has been modified to record the ECG while ensuring patient safety in the MR environment. ECG electrodes have been specially developed for use during MRI procedures to protect the patient from potentially hazardous conditions, as well as to reduce MRI-related artifacts. Standard ECG leads and cables may cause excessive heating that could burn the patient, due to the electrical current that is generated in the leads and cables during the operation of the MR system. Leads should be kept from touching the patients during the scan. In addition, patients that require ECG monitoring who are unconscious, sedated, or anesthetized should be examined after each imaging sequence with the intention of repositioning of the ECG leads and any other electrically conductive material with which the patient is in contact. Cold compresses or ice packs can also be placed on all necessary electrically conductive material that touches the patient during scanning. Fiber-optic ECG recording techniques eliminate the potential for burns by removing the conductive patient cable and its antenna effect that are typically responsible for excessive heating.

An MRI compatible pulse oximeter, and/or a noninvasive heart rate and blood pressure monitor can also be used to obtain intermittent or semi-continuous recordings of heart rate during the MR procedure.

Manual sphygmomanometers can be adapted for use during MRI procedures. An automated noninvasive blood pressure monitor is not highly recommended for use, as the intermittent inflation of the cuff may disturb lightly sedated patients, causing them to move and disrupt the MR scan.

The respiratory bellows can be used to monitor respiratory rate, with the caution that it can only record body movements associated with respiratory efforts (Figure 22). The bellows cannot detect apneic episodes related to upper airway obstruction, and may not provide sufficient sensitivity for assessing patients during an MR procedure. The use of more appropriate monitoring devices for respiratory rate is recommended.
Oxygen saturation is an important variable to measure in sedated and anesthetized patients. Fiber-optic technology is now used for pulse oximeters, as it is not affected by interference from the electromagnetic fields during the MR procedure, and has no conductive pathways formed by metallic materials that could cause burns.

Skin and/or body temperature should be monitored during MR procedures for several reasons, including:

- Neonates have inherent problems retaining body heat; this tendency is increased during sedation
- Patients may be exposed to high levels of RF power during MR procedures, and with some MR sequences
- Patients may have underlying conditions that impair their ability to dissipate heat

Monitoring skin temperature alone is not sufficient to ensure patient safety, as it would not provide proper information relative to deep body temperature. The use of hard-wire or thermistor techniques to record temperatures in the MR environment may cause artifacts or erroneous measurements due to direct heating of the temperature probes. A fluoroptic thermometry system with fiber optic probes is recommended for use in the MR environment.

In cases where several different physiologic parameters must be monitored simultaneously while patients are undergoing MR procedures, there are multi-parameter patient monitoring systems available that are acceptable for use in the MR environment.

Ventilators typically contain mechanical switches, microprocessors, and ferromagnetic components that may be adversely affected by the electromagnetic fields used by MR systems. Some ventilators are approved for use at a safe distance from the MR system, and are labeled “MR Conditional.” Their conditions for use must be followed carefully, including the recommendation of permanently fixing these ventilators to the floor or tethering them to prevent missile-related accidents. Healthcare workers should be trained regarding the specific MR conditional aspects of these ventilators.

There are a variety of devices and accessories that may be necessary for the support and management of high-risk or sedated patients that have been manufactured to be acceptable for use in the MR environment.
Device and Object Screening

Labeling Information for Implants and Devices

The MR environment may pose risks or problems to patients with certain implants and other medical devices, primarily due to factors that include electromagnetic field interactions, MR imaging-related heating, and the creation of artifacts. In addition, for electrically activated implants and some medical devices, there are concerns that the MR system may affect the operation of the medical device and/or induce currents in the device. As the use of MR imaging grew in the 1990s, the FDA recognized the need for standardized tests to address MR safety issues for implants and other medical devices. Testing methods have been developed over the years, by various organizations, including the American Society for Testing and Materials (ASTM) International (formerly the American Society for Testing and Materials), with an ongoing commitment to ensure patient safety in the MR environment.

The FDA is responsible for reviewing the MR terminology and labeling that manufacturers provide for their devices. The MR terminology has continued to evolve to keep pace with advances in MR technology; however, members of the MR community frequently do not understand the terms that are used, and are often confused by the conditions that are specified in “MR conditional” labeling. This lack of understanding may result in patients with implants being exposed to potentially hazardous MR imaging conditions, or in inappropriately preventing patients from undergoing needed MR examinations. There is now new labeling terminology, which is associated with expanded labeling information.

Labeling Terminology

In 1997, the FDA Center for Devices and Radiological Health first proposed terms to be used to label MR information for medical devices. The terms were defined as follows:

- **MR Safe** – The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient, but may affect the quality of the diagnostic information.
- **MR Compatible** – The device, when used in the MR environment, is MR safe, and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device.

In addition, the FDA’s document stated “The use of the terms, ‘MR compatible’ and ‘MR safe’ without specification of the MR environment in which the device was tested should be avoided since interpretation of these claims may vary and are difficult to substantiate rigorously. Statements such as ‘intended for use in the MR environment’ or similar claims along with appropriate qualifying information are preferred (i.e. test conditions should be specifically stated).” The term “MR environment” encompasses the static, gradient (time-varying), and radiofrequency (RF) electromagnetic fields that may affect an implant or device. Testing of an implant or device for “MR safety” involved in vitro assessments of static magnetic field interactions, MR-related heating, and, in some cases, induced electrical currents (from gradient magnetic fields), while “MR compatibility” testing required all of these assessments, as well as characterization of artifacts. It may have also been necessary to evaluate the effect of various MR imaging conditions on the functional or operational aspects of an implant or device.
It became apparent that the terms “MR safe” and “MR compatible” were confusing and were often used interchangeably or incorrectly. Sometimes, the terms were used without including the list of conditions for which the device had been demonstrated to be safe, which can inappropriately give the impression that the device is safe or compatible in all MR environments. Because the misuse of these terms could result in serious accidents for patients and others in the MR environment, the ASTM released new terms in August, 2005. The new terminology is:

- **MR Safe** – An item that poses no known hazards in all MR imaging environments. MR safe items are nonconductive, nonmetallic, and nonmagnetic. An item may be determined to be MR safe by providing a scientifically based rationale rather than test data. The MR safe designation means that the object would be safe under any allowable MRI conditions. (One must use caution when medical or mass media tout an item as being “MRI Safe,” which occurred with the Medtronic Revo MRI SureScan Pacing System. This pacemaker system was designed to permit MR examinations, but it has important limitations, or *conditions, for its safe use in MRI*. The Medtronic Revo MRI SureScan Pacing System was the first MR Conditional pacemaker, not MR Safe pacemaker.)

- **MR Conditional** – An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the MR environment include static magnetic field strength, spatial gradient, time rate of change of the magnetic field (dB/dt), RF fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g. the routing of leads used for a neurostimulation system), may be required. For MR conditional items, the item labeling includes results of testing sufficient to characterize the behavior of the item in the MR environment. Testing for items should address magnetically induced displacement force and torque, RF heating, as well as other safety issues such as thermal injury, induced currents/voltages, electromagnetic compatibility, neurostimulation, acoustic noise, the safe functioning of the item, and the safe operation of the MR system. Any parameter that affects the safety of the item should be listed, and any condition that is known to produce an unsafe condition must be described.

- **MR Unsafe** – An item that is known to pose hazards in all MR environments. MR unsafe items include magnetic items such as a pair of ferromagnetic scissors.

In addition to the terms “MR safe,” “MR conditional,” and “MR unsafe,” the ASTM introduced corresponding icons, consistent with international standards for colors and shapes of safety signs (Figure 23). The icons are intended for use on items that may be brought into or near the MR environment, as well as in product labeling for implants and other medical devices. They may be reproduced in color or in black and white; however, the use of color is encouraged for increased visibility.
The updated terminology has not been applied retrospectively to the many implants and devices that previously received FDA-approved labeling using the terms “MR safe” or “MR compatible”—in other words, those items tested and appropriately labeled prior to the release of the new terminology in August, 2005. Moving forward from 2005, as manufacturers make submissions to the FDA for existing devices, the FDA has requested that they update their labeling to use the new MR terminology. Products that are new on the market after the August, 2005, terminology change should be labeled using the new terminology.

**Explanation of MR Conditional Label Information**

The actual content of conditional labels is often misunderstood with respect to the conditions indicated for a given implant. Below is an example of MR conditional labeling for an implant called “Example Implant,” with an explanation of the content provided for each aspect of the label (Figure 24).

- **MRI Information**
  - Non-clinical testing has demonstrated the Example Implant is MR Conditional. It can be scanned safely under the following conditions:
  - Static magnetic field of 3-Tesla.
  - Spatial gradient field of 720-Gauss/cm or less.
  - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15-minutes of scanning.
  - In non-clinical testing, the Example Implant produced a temperature rise of less than 2.0°C at a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of MR scanning in a (static magnetic field strength _________) (model ________) (MR system manufacturer ________) (software version _________) MR scanner.

- **Image Artifact**
  - MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

**Figure 24 Example of MR Conditional label**

- **MRI Information** – Non-clinical testing has demonstrated the Example Implant is MR Conditional. It can be scanned safely under the following conditions:
- **Static magnetic field of 3 tesla** – This is the static magnetic field for which the implant had acceptable test results, generally the highest static magnetic field used for testing the implant.
In some cases, labeling may state, “static magnetic field of 3 tesla or less” or “static magnetic field of 3 tesla, only” or “static magnetic field of 1.5 tesla or 3 tesla.” Careful reading and implementation of this portion of the labeling information is advised in order to avoid possible patient injuries. One should never assume MR compatibility or safety information about a device if it is not clearly documented in writing.

- **Spatial gradient field of 720 gauss/cm or less** – This parameter is often misinterpreted, as the user sees the term “gradient field” and presumes that it refers to the time-varying or gradient fields used during MR imaging. The term “spatial gradient field” for medical device labeling relates to the rate at which the static magnetic field strength changes over space per unit length (720 gauss/cm in this example). The point of the highest spatial magnetic gradient is the position where translational attraction is typically assessed for an implant or device. MR system manufacturers can provide spatial gradient magnetic field information for their particular MR systems.

- **Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning** – The term “scanning” applies to each particular pulse sequence that is used, with multiple sequences used when performing an MR imaging examination. To safeguard the patient, the whole-body averaged SAR for each scan sequence must be maintained at or below 2 W/kg for each scan sequence.

- **In nonclinical testing, the “Example Implant” produced a temperature rise of less than 2.0°C at a maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of MR scanning in a (static magnetic field strength_____) (model______) (MR system manufacturer_______) (software version_______) MR scanner** – This additional information is in regards to the temperature rise that is associated with certain MR parameters, which is based on the findings obtained in the MR-related heating test. As seen in this example, the expected “worst case” temperature rise is 2.0°C or less during MR imaging performed at a whole-body averaged SAR of 2 W/kg for 15 minutes, using a particular MR system type (i.e. with the make, model, and software of the imager indicated). The whole-body averaged SAR of 2 W/kg is the level commonly reported in device labeling, but higher or lower SAR levels may be indicated. This labeling section may also include information regarding a particular type of coil that should be used with the particular implant or medical device (e.g., a transmit body coil or transmit head RF coil).

- **Image Artifact** – MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant. Information is typically provided in the label that characterizes the size and shape of the artifacts associated with certain pulse sequences (e.g. T1-weighted spin echo, gradient echo). The size of the artifact from an implant or device may affect the decision as to whether or not MRI should be used as a diagnostic tool. For devices with a lumen, such as stents, the labeling may indicate whether the lumen is obscured by the size of the artifact. The FDA recommends that the patient register the conditions under which their MR conditional implant can be imaged safely with the MedicAlert Foundation, or another equivalent organization.
Operating Modes

In some cases, device or implant labeling may indicate that, for safety purposes, the MRI system must remain in the Normal Operation mode during all scanning of the patient with that specific device or implant. Operating modes for MR equipment were developed by the International Electrotechnical Commission (IEC) and published as IEC-60601-2-33, *Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis*. These safety requirements provide protection for the patient, the operator, ancillary personnel, and the general public. Operating modes for the MR equipment are based upon certain action levels of time-varying magnetic fields (dB/dt), radio frequency magnetic fields, specific absorption rate (SAR), and acoustic noise.

The IEC 60601-2-33 standard specifies three operating modes: Normal Level Controlled, First Level Controlled, and Second Level Controlled. These operating parameters define the permissible limit values for dB/dt, SAR, and acoustic noise. The action levels for these limits are based on current scientific literature related to patient safety.

- **Normal Level Controlled Operation Mode** – In the Normal Operating Mode, all operating parameters of the MRI system are below the level that may cause physiological stress to patients (Figure 25). Only routine monitoring (visual and auditory contact and communication with the patients, as appropriate) is required, and no specific indications or measures need to be displayed.

![Figure 25](image)

*Figure 25 Normal Level Controlled Operation Mode as seen on Hitachi scanner*
• **First Level Controlled Operation Mode** – If the system is operating in the First Level Controlled Operation Mode, physiological stress may occur. In addition to monitoring, medical supervision is required to assess the risk versus benefit of the particular scan (Figure 26).

![Warning](image)

Figure 26 First Level Controlled Operation Mode as seen on Hitachi scanner

The example warning window provides the following options:

**YES** – Confirms the user would like to proceed with the scan

**NO** – Cancels the scan start. The user must adjust the scan parameters to reduce the SAR or dB/dt and restart the scan task.

• **Second Level Controlled Operation Mode** – Operating in the Second Level Controlled Operation Mode, where the dB/dt value exceeds the limit value of First Level Controlled Operation Mode, may produce significant risk to patients; it is not permitted for normal clinical use. This mode is used for approved human studies only. Security measures (software password) prevent unauthorized operation in this mode.
New Metric for RF-Induced Heating

Device manufacturers have begun to have labeling approved with a given B1+rms value that is not to be exceeded (Figure 27). This is a more precise RF exposure metric compared to SAR. When following B1+rms as a condition of use, the SAR value is irrelevant, unless a particular operating mode is specified.

![Figure 27 B1+rms value for Advisa DR MRI and Advisa SR MRI](image)

Specific Absorption Rate (SAR) is a measure of the rate at which RF energy is deposited in tissues, and it is specific to the body part. No universal standard is in place for estimating SAR—it is estimated for each sequence by the MRI system software. The method, calculations, and resultant value reported will vary with the MR equipment manufacturer. The same patient with a given MR conditional implant or device will have different SAR values on different MR systems, even if the acquisition parameters are identical.

The FDA and a Joint Working Group of engineers and scientists from MR equipment and device manufacturers have recommended that B1+rms be used as a metric for device heating as opposed to SAR. This measurement is the average effective RF magnetic field generated by the RF transmit coil for a given pulse sequence. It is calibrated by the MR system software during the prescan phase. B1+rms is patient independent, and is determined by basic MRI requirements. It is used in every MR system manufacturer’s SAR calculations.

B1+ (or simply B1) refers to the positively rotating component of the B-field, or magnetic field, which is used to excite the protons. Root mean square (rms) is also known as the quadratic mean, and is a statistical measure of the magnitude of a varying quantity. Combining these two terms results in B1+rms, a measure of the magnitude of the positively rotating component of the B-field. It is expressed in units of microtesla (µT). One very important characteristic of B1+rms is that it is not an estimated value, but a known value, based on the pulse sequence and the associated parameters. It is not patient dependent, nor is it calculated differently based on the MR system manufacturer. A given B1+rms value on system A is the same on system B. Another advantage of B1+rms is that once a particular sequence is adjusted to a desired B1+rms value, the sequence can be saved in the protocol library. The sequence will remain at that value for the next patient, unless you alter the scan parameters.
In 2013, the IEC mandated that all MR systems manufactured going forward must display the B1+rms (Figure 28). However, it was not mandated to update older systems.

**Spatial Gradient Magnetic Fields**

As seen on medical device labeling, this term relates to the rate at which the static magnetic field strength changes over space or distance per unit length. This measurement is important because the intensity of the static magnetic field around an MR system varies with respect to the distance from the scanner. The spatial gradient magnetic field is measured in units of tesla/meter or gauss/centimeter (to convert T/m to G/cm, multiply by 100). This term and measurement should not be confused with the time-varying gradient magnetic fields (dB/dt) produced by the gradient coils, which are used for spatial encoding of the MR signals.

The spatial gradient (SG) of the magnetic field produces an attractive displacement (or translational) force on ferromagnetic objects that are placed into the static magnetic field of the MR system. Assessment of this displacement force, or translational attraction, is one aspect of implant testing that is performed when evaluating a medical device. The MR-specific labeling for medical implants and devices typically provides information for the “highest spatial gradient magnetic field” at which the device was tested, and that the device is allowed to be exposed to, in order to ensure the safety of the patient relative to the device’s translational attraction.

The FDA usually accepts the determination of translational attraction for a medical device that is conducted according to the procedure described by the American Society for Testing and Materials (ASTM).

Spatial gradient magnetic field values have caused much confusion over the years, as they can be calculated from different locations. For clinical purposes, the device used to measure the deflection angle should be placed at the point of the highest spatial magnetic gradient field within the patient-accessible volume. This value has relevance for patients with medical devices insofar as they may pass through this area when entering the MR system. The FDA now mandates that MRI manufacturers publish the value and location of the peak spatial gradient magnetic field that is accessible to the patient. In addition, in order to comply with IEC standards, manufacturers must report both the peak values within the patient-accessible volume, and the peak values with the MR system covers removed.

The spatial gradient fields increase in intensity as one gets closer to the surface of the magnet. Patients must pass through varying spatial gradient fields as the anatomy of interest is moved to isocenter. Since the spatial gradient fields are not uniform, each part of the patient’s anatomy could be exposed to different spatial gradient levels. However, the anatomy of interest and/or the anatomy that contains the implant or device in question may not be exposed to the highest spatial gradient levels (Figure 29). MR professionals must directly compare the MR Conditional device or implant label with the specifications of the MR system in which the patient will be scanned. Spatial gradient specifications are often listed with different units of measure, so these values should be converted to the same units. In addition, one must be aware of the location of the area of maximum spatial gradient, and whether or not the implant or device will actually be exposed to that maximum value, or to lower values that may still be above the
spatial gradient limit for that particular device. Labels may also include terminology such as “either/or,” “less than or equal to,” and may include limitations as to magnet field direction, use of specific types of coils, SAR readings associated only with normal operating mode, etc.

<table>
<thead>
<tr>
<th>Spatial Gradient (G/cm) @ r800 mm</th>
<th>Vertical Distance from Covers (cm)</th>
<th>Zone Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥500</td>
<td>22-11.5</td>
<td>Green</td>
</tr>
<tr>
<td>≥720</td>
<td>11.5-7.5</td>
<td>Tan</td>
</tr>
<tr>
<td>≥1000</td>
<td>7.5-0.0</td>
<td>Red</td>
</tr>
</tbody>
</table>

![Spatial gradient boundaries at various distances from gantry covers of Oasis MR system](image)

**Figure 29 Spatial gradient boundaries at various distances from gantry covers of Oasis MR system**

### Lenz’s Forces

Faraday’s Law states that a moving or changing magnetic field will induce a voltage in a perpendicularly oriented electrical conductor. Lenz’s Law builds on this, and states that the induced voltage will generate its own magnetic field, whose orientation and magnitude will oppose that of the initial time-varying magnetic field that created it in the first place. As an example, move an electrical conductor perpendicularly toward the magnetic field B0 of an MR scanner. Even if this conductor is not grossly ferromagnetic, the motion itself will result in the generation of voltages within the conductor. The magnitude of the generated voltage is directly proportional to the rate of motion, as well as the spatial gradient of the magnetic field B0 through which it is being moved. Conducting objects that are turning in the static field will also experience a torque due to the induced eddy currents. Therefore, moving a large metallic, but nonferromagnetic, electrical conductor toward the magnet bore will result in the induction of a voltage and associated magnetic field. This magnetic field will orient in a manner and at a strength as to oppose the motion of the metallic object into the bore of the MR scanner. If, for example, one tries to move a nonferrous oxygen tank into the bore of an MR scanner, Lenz’s forces will be sufficiently strong to virtually stop forward progress of the tank as the scanner bore is approached. In addition, the faster one moves the tank into the bore, the greater the opposing force that is created to stop this motion.

Lenz’s forces have potential consequences for large implanted metallic devices, such as certain metallic nonferrous infusion pumps. These items may not pose a projectile hazard, but rapid motion of the patient/implant perpendicular to the magnetic field of the MR scanner can be expected to result in
forces on the implant that oppose this motion, and these forces may be detected by the patient. If the patient complains to health care personnel about tugging or pulling forces on their implant, it may be erroneously concluded that their device does have ferrous components, and the examination may be cancelled. Lenz’s forces can be decreased by slow movement of any large metallic nonferrous devices into and out of the magnet bore. Decreasing Lenz’s forces should result in a decrease in misunderstandings between patients and MR professionals, resulting in a decrease in exam cancellations.

## Static Magnetic Field

### Translational Forces (Missile Effect)

The “missile effect” refers to the capability of the fringe field component of the static magnetic field of an MR system to attract a ferromagnetic object, drawing it rapidly into the scanner by considerable force. The force with which projectiles are pulled toward a magnetic field is proportional to the strength of the magnetic field, the mass of the object (and its material), and the distance from the magnet. Close to the magnet, the magnetic field increases in strength rapidly over a short distance. The translational force is greatest where the difference in field strength across the object is greatest (i.e. where the difference in field strength from point A to point B is maximized, which is near the bore) (Figure 30). Objects can be transformed into projectiles, becoming airborne as they accelerate toward the center of the magnetic field at speeds of up to 40 miles per hour (e.g. paper clips can travel at a velocity of 40 mph at 3T). Larger objects travel at higher velocities and can be fatal. Obviously, this missile or projectile effect can pose a significant risk to the patient inside the MR system, as well as to staff or other persons in the path of the projectile. Considerable damage to the MR system may also result due to the impact of the ferromagnetic object.

![Figure 30 Translational force is greatest where the difference in field strength across an object (from point A to point B) is maximized.](image)

Items that might typically be found in uniform pockets, or that are “tools of the trade” for assorted personnel can quickly become dangerous projectiles if they are too close to the static magnetic field (Figure 31). Amongst various personnel, these possible projectiles include:

- **Medical personnel** – Scissors, hairclips and bobby pins, paperclips and staples, clipboards and pens
- **Maintenance and janitorial personnel** – Dustpans, mops and buckets, floor buffers, vacuum cleaners, tools and tool kits
- **Law enforcement personnel** – Guns, knives, handcuffs, clipboards, flashlights
- **Fire department personnel** – Axes, hose couplings, nozzles, pike poles, fire extinguishers, oxygen tanks
Figure 31 Examples of ferromagnetic items that could become projectiles in the MR environment

The use of trained MR personnel that restrict access to Zone IV should decrease any incidences of possible projectiles entering the scan room.

**Rotational Forces (Torque)**

Rotational forces relate to the North-South orientation of the scanner’s magnetic field. Ferrous objects will attempt to align their long axes with this orientation. Rotational forces will rotate objects until they are aligned with the magnetic field. Translational and rotational forces occur at the same time, making objects into dangerous projectiles. Rotational forces are greatest at the center of the field, while the translational force is greatest where the difference in magnetic field across the object is greatest.

Strongly ferromagnetic implants have shown considerable rotation, or torque, when in the presence of a magnetic field. Torque exerted on both small and large ferromagnetic implants can cause serious effects, as unanchored implants can potentially move unpredictably within the body. For implants that demonstrate weak ferromagnetic forces, a wait time of several weeks prior to scanning allows fibrous scarring to set in, which may help anchor the implant in position. The risk of motion for implants that have been demonstrated to be nonferrous is reduced to the risks resulting from Lenz’s forces alone.

An unanticipated ferromagnetic implant or foreign body may be discovered during the course of an MRI examination, typically detected by the sizable field-distorting artifact it creates. The medical director, safety officer, and/or physician in charge should be notified immediately to assess the situation. It is important to note that the forces on the implant will change, and may even increase, during attempts to remove the patient from the scanner bore. The greater the rate of motion of the patient/device through the magnetic fields of the scanner bore, the greater the forces acting upon that device will likely be. If at all possible, the device should be immobilized during the patient’s extraction from the bore, and the extraction should be performed at a slow, cautious, deliberate rate. The patient should be extracted along a straight line course parallel to the center of the magnet, and should remain immobilized until they are as far as possible from the MR scanner itself before patient/object motions in other directions are attempted or permitted. Allowing the patient to sit up as soon as they are out of the magnet bore exposes the ferrous object to significant torque- and translation-related forces, despite being outside the scanner bore.
Bioeffects

As yet, virtually no long-term adverse biological effects of extended exposure to MRI have been described. However, when reviewing the separate components of the MR imaging process, several reversible effects from the various fields can be observed. Bioeffects may occur from the three different types of electromagnetic fields that are utilized to create MR images, including:

- **Static magnetic field** – Aligns the proton spins and generates a net magnetization vector in the human body
- **Gradient magnetic field** – Produces different resonant frequencies for aligned protons, depending on their spatial positions on the gradient axes
- **Radio frequency field** – Centered at the proton resonant frequency; rotates the vector out of the direction of the static magnetic field; vector’s return to equilibrium is different for each tissue, resulting in two main imaging parameters of T1 and T2, which relate to image contrast

Static Magnetic Fields

With the introduction of MRI as a clinical imaging modality in the early 1980s, human exposure to strong static, or unchanging, magnetic fields substantially increased. Since 2003, the FDA limit for static magnetic field strength for clinical imaging has been 4.0T for neonates and infants up to one month, and 8.0T for children older than one month up to adults. Use of static magnetic fields up to 8.0T is considered a “non-significant risk” for adults. Higher field strengths are permitted for research purposes. Currently, the most powerful MR system used for human subjects operates at 9.4T, with plans to develop higher field strength scanners. Short-term exposures to 9.4T by patients and volunteers resulted in no readily identifiable health risks. However, a study conducted to evaluate sensory symptoms and vestibular function in workers exposed to 9.4T revealed that all participants noted sensory symptoms related to the exposure. It is not clear whether long-term vestibular damage or other changes occur.

In regards to the effects of long-term exposure to more typical static magnetic fields (0.2T-3T), several physical mechanisms of interaction between tissues and static magnetic fields exist that could theoretically lead to pathological changes in human subjects. However, quantitative analysis of these mechanisms indicates that they are below the threshold of significance with respect to long-term adverse bioeffects. No permanent hazardous effects of a static magnetic field exposure on human beings have yet been demonstrated.

There is extensive information regarding the effects of static magnetic fields on biological tissues with respect to short-term exposures. Studies have been performed concerning alterations in cell growth and morphology, cell reproduction, DNA structure and gene expression, nerve activity, etc. The majority of these studies concluded that exposures to static magnetic fields produce no substantial or harmful bioeffects. The documented serious injuries and few fatalities that have occurred with MR system magnets were in association with the inadvertent introduction or presence of ferromagnetic objects into the MR environment.
Currently, the peer-reviewed literature does not contain carefully controlled studies that support the absolute safety of chronic exposure to powerful magnetic fields. Although there is no evidence for a cumulative effect of magnetic field exposure on health, further studies of the exposed populations (MR healthcare professionals, patients that undergo repeat studies, interventional MR users, etc.) will help establish guidelines for occupational and patient exposures to powerful static magnetic fields.

The magnet’s fringe field, which is the stray magnetic field outside the bore, is considered to be a secondary concern. Hazards of fringe fields are associated with the siting of MR systems, as the static magnetic field has no respect for the confines of conventional walls, floors or ceilings. It is recommended that the general public, which includes those who have not been properly screened for the effects of magnetic fields, should be limited in their exposure to magnetic field strengths of 5 gauss (G) and below. Many MR facilities are sited so that public areas are below 5G, and areas above 5G are inaccessible or clearly marked.

Although no permanent biological effects have been observed in human subjects at field strengths below 2T, reversible effects have been noted on ECGs due to the magnetohemodynamic effect. Movement of a conductive fluid, such as blood, across a magnetic field induces a voltage across the artery. This induced voltage distorts the patient’s ECG signal, appearing as an increase in the amplitude of the T-wave proportional to the strength of the magnetic field (Figure 32). This hemodynamic effect is considered reversible, as the patient’s ECG tracing should return to normal once the patient is removed from the magnet. Cardiac gating problems may exist at higher field strengths due to this magnetohemodynamic effect. The MR system may trigger from the higher amplitude T wave, rather than the R wave, resulting in insufficient cardiac gating.

![Figure 32 Magnetohemodynamic effect may cause higher amplitude of T wave; upper graph is with patient outside the magnet bore; lower graph is with patient inside the magnet bore showing elevated T wave](image)

An additional effect of moving fluid (blood) in a strong static magnetic field is the magnetohydrodynamic effect. This effect involves an additional electrical charge generated by ions in blood that are moving perpendicular to the magnetic field. There are no significant changes expected at field strengths of 1.5T. However, at 6.0T, a 10% blood pressure change is expected, and a blood pressure increase is predicted theoretically for a 10.0T field. Interactions of induced electrical potentials and currents within a solution (e.g. blood) and an electrical volume force cause a slowing in the direction opposite to the fluid flow. This decrease in blood flow velocity must be compensated for by an elevation in pressure.

Additional reversible biological effects have been observed on human subjects exposed to static magnetic fields of 2.0T and above. These effects have included fatigue, headaches, hypotension and irritability. Statistically significant sensory effects from magnetic fields of 1.5T and 4.0T included sensations of nausea, vertigo, and metallic tastes. However, no statistical significance was found for effects such as headache, hiccups, tinnitus, vomiting, and numbness at those field strengths. A higher
incidence of positive reports originated from those subjects exposed to the 4.0T field, but there was no evidence that these effects were at all harmful.

**Time Varying Gradient Magnetic Fields**

Gradient coils are resistive wire windings used in MR systems to provide position-dependent variation in the magnetic field strength. They are pulsed on and off during and between RF excitation pulses to encode spatial information contained in the emitted RF signal. Gradient fields are switched on and off during image acquisition. In doing so, they create a time-varying magnetic field. Health concerns are not related to the strength of the gradient field, but rather to changes in the magnetic field that cause induced currents. There is concern in MRI with nerves, blood vessels, and muscles that act as conductors in the body. Faraday’s law of induction states that changing magnetic fields induce electrical currents in any conducting medium, with the induced currents being proportional to the material’s conductivity and the rate of change of the magnetic field. In MR, this effect is determined by factors such as pulse duration, wave shape, repetition pattern, and the distribution of the current in the body. The induced current is greater in peripheral tissues as the amplitude of the gradient is higher away from isocenter of the magnet. The rate of change of a magnetic field is termed dB/dt, and is defined as the ratio between the amount of change in the amplitude of a magnetic field (dB), and the time required to make that change (dt), with the letter “d” symbolizing delta, or change. The units used to measure this magnetic field change are tesla/second (T/s).

**Induced Currents**

Biological effects that vary with current amplitude from the changing magnetic fields include reversible alterations in vision, irreversible effects of cardiac fibrillation, and alterations in the biochemistry of cells. Visual alterations occur due to the induction of electric currents that stimulate the retina or visual cortex. Patients report the sensation or illusion of flashes of light, or magnetophosphenes (Figure 33). At extremely high amplitudes of gradient change, cardiac stimulation or even ventricular fibrillation are possible. However, the induction of cardiac stimulation would require gradient fields at much higher orders of magnitude than those currently available on commercial MRI systems.

![Figure 33 Example of how magnetophosphenes may appear](image)

The FDA limits the time rate of change of gradient fields (dB/dt) to levels which do not result in severe discomfort or painful peripheral nerve stimulation. Mild cutaneous sensations and involuntary muscle contractions have been reported, especially when faster sequences such as echo planar imaging are used. Extra caution must be exercised when using faster sequences on patients with implanted or retained wires in anatomically or functionally sensitive areas (e.g. myocardium or epicardium, implanted electrodes in the brain), as induced currents in these areas could be quite dangerous for the patient. The induced current in the patient is proportional not only to the rate of change of the magnetic field, but also to the cross-sectional area of the body that is exposed to the changing field. The sensory threshold
(level of strength a stimulus must reach to be detected) is higher for gradients that switch along the sagittal axis than for those that switch along the coronal axis, as the cross sectional area of the typical supine patient is larger in the coronal plane as compared to the sagittal plane. In addition, the maximum dB/dt occurs at the ends of the imaging coil, where the magnetic fields are at their maximum. Studies have indicated that the anatomical sites of peripheral nerve stimulation vary depending on the activation of a specific gradient (x, y, or z gradient). Involved calculations and testing are performed to determine safety standards for peripheral nerve stimulation, resulting in the operating zones or modes reported on MR systems. Normal operating mode and first level controlled operating mode limits should be observed during routine scanning. Second controlled operating mode should only be entered for research purposes, with security measures in place to prevent unauthorized entry into this mode (Figure 34). The best means to address the discomfort of peripheral nerve stimulation is to instruct patients not to clasp their hands together, or cross their legs during scanning. Both actions cause a conductive loop that may lead to dB/dt effects. Patients should be instructed to report any tingling, muscle twitching, or painful sensations that might occur during scanning, with the scanner operator remaining in constant contact with the patient to ensure that the patient does not feel any discomfort. Special considerations should be given regarding children, pregnant women, epileptics, patients with metallic implants, cardiac arrhythmia, peripheral neuropathy, comatose patients, or patients who are unable to communicate. All large metallic prostheses should be individually evaluated for excessive heating due to gradient induced currents within the metal, as most metallic prostheses are excellent conductors.

![Figure 34 Operating mode dB/dt limitations](image)

**Auditory Considerations**

As current is passed through the gradient coils during an MRI scan, a significant amount of acoustic noise is created. The rapid variations of currents within the gradient coils in the presence of the static magnetic field create strong forces that cause the gradients to vibrate against their mounting, creating loud noises. The acoustic noise level is influenced by many factors, including:

- **Gradient strength and slew rate** – Strength of the gradient magnetic field is not as significant as the rate of change of the field generated when the gradient magnetic field is switched on or off; gradient strength is expressed in units of G/cm or mT/m, where 1 G/cm=10mT/m,
meaning the magnetic field changes by 1 gauss over each centimeter, or 10 milli-tesla over each meter; slew rate is the rate of change of gradient amplitude, and is quoted in evaluating gradient performance and potential physiological effects; slew rate is calculated by dividing gradient strength used by the rise time, which is the time taken to reach that strength

- Decreases in section thickness, field of view, repetition time (TR), and echo time (TE) enhance noise
- Sequence type – EPI and other fast imaging sequences are louder

Noise levels on most commercial MR systems are considered to be within recommended safety guidelines if hearing protection is provided. Noise can cause both reversible and irreversible effects. These effects include communication interference, patient annoyance, transient hearing loss, as well as permanent hearing loss, especially in patients who are susceptible to hearing impairment. Current documents from the FDA state that instructions from manufacturers of MR equipment should state that hearing protection is required for all patients studied on MR imaging systems capable of producing sound pressures that exceed 99dB (A). The hearing protection must be sufficient to reduce the A-weighted r.m.s. (root mean square) sound pressure level to below 99dB (A), which is the average noise limit for noise measured over a period of time (~20 seconds).

All patients should be provided with hearing protection in the form of earplugs and/or headphones to reduce the probability of temporary, as well as permanent acoustic damage (Figure 35). In addition, anyone remaining in the magnet room with the patient during scanning should also be furnished with earplugs. Most MR manufacturers recommend earplugs with a Noise Reduction Rating (NRR) of 29-33 decibels (dB). Earplugs must be properly inserted in the ears, as improper placement can reduce the effectiveness of earplugs by 7-10 dB. Many manufacturers are now offering “quiet” gradient systems, which have a significant reduction in gradient noise during image acquisition.

![Figure 35 Example of earplug](image)

### Time Varying Radiofrequency Magnetic Fields

Non-ionizing radiation is electromagnetic radiation that does not “ionize” an atom, meaning it does not remove an electron from the atom. The radiofrequency (RF) fields in MRI are non-ionizing, and do not pose the same risks as x-rays do. However, the RF fields do cause tissue heating. The excess energy may penetrate the surface of the body and become absorbed by the tissues, which then dissipate this excess energy in the form of heat. If not regulated, the RF pulses could cause extensive heating and possible tissue damage, with this heating found to be greatest at the skin surface or periphery. One source stated that RF power deposition represents the greatest risk for patient safety in MRI exams.
Specific Absorption Rate (SAR) is the measure of absorption of the electromagnetic energy in the body. It is typically measured in Watts of power per kilogram of patient’s body weight. SAR levels corresponding to the three IEC 60601-2-33 operating modes are listed in the table below (Figure 36). These values are based on environmental conditions of a magnet scan room temperature below 24°C and a relative humidity below 60%. The values are reduced for elevated temperature and humidity, as these environmental conditions impact the body’s thermoregulatory system, and could change the operating mode for a given value of SAR.

![Figure 36 SAR levels corresponding to the three IEC 60601-2-33 operating modes](image)

SAR can be difficult to determine, as it depends on many factors, including:

- Frequency – The higher the frequency, the more energy will be deposited as heat
- RF power and duty cycle
- Transmitter coil type and size – The larger the volume of the transmitter coil, the higher the SAR
- Number and type of RF pulses used within the pulse sequence
- Patient positioning – Patients positioned near isocenter within the coil will have lower SAR values, due to less reflected RF energy during transmission
- Flip angle – Higher flip angles require more RF energy
- Number of slices per TR – The more slices per TR, the higher the SAR
- Number of RF pulses per slice – The more RF pulses per slice, the higher the SAR (FSE>Spin Echo>Gradient Echo)
- Magnetic field strength – Lower magnetic field strengths have lower SAR, as less energy is required by each RF pulse to accomplish the desired flip angle
- Physiology and weight of the patient (weight must be entered correctly)
One method by which a scanner may estimate SAR is:

1. Scanner runs a calibration routine
2. Determines energy needed to get a 90° and 180° flip angle
3. Adds up energy of all RF pulses in a sequence and divides by pulse repetition (TR) to get power
4. Divides by patient weight to get whole body SAR
5. Peak local SAR can be much higher than whole body SAR. It is estimated that peak local SAR is minimally 2.5 times higher than whole body SAR on most scanners.
6. System may adjust scan parameters if estimate exceeds predetermined levels, or notify system operator that parameter adjustments must be made

Studies show that patient exposure up to ten times the recommended levels produces no serious adverse effects, despite elevations in skin and body temperatures. As body temperature increases, blood pressure and heart rate also increase slightly. Patients with compromised thermoregulatory systems are unable to dissipate heat quickly, causing a rise in the temperature of their “irradiated” tissue. If the tissue’s temperature rises above 42-43°C for several minutes, tissue damage will occur. The effect is stronger (more damage in a shorter time) as the temperature increase gets larger. Various health conditions may affect a patient’s thermoregulatory system, including cardiovascular disease, hypertension, diabetes, fever, advanced age, and obesity. Medications including diuretics, beta-blockers, calcium blockers, amphetamines, and sedatives can also alter thermoregulatory responses to additional body heating. Areas of the body that are unable to dissipate heat (orbits and testicles) have shown no significant increase in temperature with standard pulse sequences. However, these areas may need to be re-evaluated with the development of ever-faster sequences with increased RF deposition to the patient. Studies are actually reporting a poor correlation between body temperature and skin temperature changes versus whole-body-averaged SARs associated with clinical MR procedures. These findings are not surprising, in light of the range of thermophysiologic responses that are possible in human subjects relative to a given SAR level.

Electrical voltages and currents can be induced within electrically conductive materials that are within the bore of the MR scanner during the MR imaging process. This may result in the heating of this conductive material, of a caliber sufficient to cause injury to human tissue. The larger the diameter of the conductive loops, the greater the potential induced voltages or currents, and the greater the potential for resultant thermal injury to adjacent patient tissue. When electrically conductive materials (wires, leads, implants, metal devices, etc.) are required to remain within the bore of the MR scanner with the patient, care must be taken to ensure that no large-caliber electrically conducting loops are formed within the MR scanner. When electrically conductive materials that are external to the patient are required to be within the bore of the MR scanner with the patient during imaging, thermal insulation should be placed between the patient and the electrically conductive material. Efforts should be made to keep any electrical conductors from directly contacting the patient during imaging, even to the point of placing cold compresses or ice packs on electrically conductive leads. Monitors and sensors used in the MR scan room may also have the potential for thermal burns. Systems using electrically nonconducting paths (e.g., fiberoptic cable and plastic tubing) or high-resistance paths (e.g., carbon ECG leads) are preferred, providing they meet monitoring needs. All unused sensors, cables, and surface coils should be removed from the MR system before imaging begins. At no time should a label of MR Conditional for thermal issues at a given field strength be applied to any field strength, higher or lower, other than the specific one at which safety was demonstrated.
Resonant circuitry can be established during MRI between the RF energies being transmitted and specific lengths of long electrically conductive wires or leads, which can then act as efficient antennae. The tips of these leads or wires can heat to temperatures in excess of 90°C in a few seconds. Patients with long electrically conductive leads (such as Swan-Ganz catheters) or electrically active implants containing leads (such as pacemakers) should be considered at risk for MR studies if the body coil is to be used for RF transmission over the region of the electrically conductive lead. Virtually any lead lengths can produce substantial heating. Of all electrically conductive implants, it is specifically wires, or leads, that pose the greatest potential hazard for establishing substantial power deposition/heating considerations.

To help safeguard against thermal injuries or burns, the patient’s tissues should not directly contact the inner bore of the scanner during the MRI process (Figure 37). Pads and other insulating devices should be provided for this purpose. In addition, the patient’s tissues should not form a large conductive loop, which is created if their arms or legs are crossed while in the MR scanner. Thermal injuries from skin-to-skin contact have been reported, meaning this contact should be minimized or eliminated in regions that will receive RF energy.

Tattoos can be an area of concern for burning sensations, if they contain metallic pigments. Cool compresses or ice packs can be placed over tattoos to counteract MRI-induced heating. There have been reports of thermal injuries/burns associated with clothing that contained electrically conductive materials, such as metallic threads, electrically conductive designs, and silver impregnated clothing. Consideration should be given to having all patients remove their own clothing and change into provided gowns or scrubs before undergoing MR imaging (Figure 38).
Implants and Devices

MR procedures may be contraindicated for patients primarily because of risks associated with movement or dislodgment of a ferromagnetic biomedical implant, material, or device. Hazards and problems related to the presence of a metallic object include induction of currents, excessive heating, changes in the operational aspects of the device, and difficulty in interpretation or misinterpretation of an imaging artifact as an abnormality.

Active Implants

Active implants are those with powered electronic components. This category includes:

- **Cardiac stimulators** – Pacemakers, ICDs
- **Neurostimulators** – Spinal cord stimulators, deep brain stimulators, cochlear implants, vagus nerve stimulators
- **Drug pumps** – Insulin pumps, pain pumps
- **Sensors** – Loop monitor/ recorder

Pacemakers and ICDs

Currently, most cardiac pacemakers and implantable cardioverter defibrillators (ICDs) are still considered a relative contraindication for patients referred for MR procedures. In addition, individuals with these implants should be prevented from entering the MR environment because of potential risks. Various mechanisms exist that could present potential problems to patients with these devices, including:

- Movement and/or vibration of the pulse generator or lead(s)
- Temporary or permanent modification of the function of the device (i.e., damage to the device)
- Inappropriate sensing, triggering, or activation of the device
- Excessive heating of the leads
- Induced currents in the leads
- Electromagnetic interference

The effects of the MR environment and MR procedures on the functional and operational aspects of cardiac pacemakers and ICDs vary, depending on several factors, including the type of device, how the device is programmed, the static magnetic field strength of the MR system, and the imaging conditions used for the procedure.
“Modern-day” pacemakers, with decreased ferromagnetic components and more sophisticated circuitry, are allowing certain patients to undergo MR examinations by following specific guidelines to minimize or prevent risks. In February, 2011, the FDA cleared the first pacemaker for conditional use in an MRI environment, which was the Medtronic Revo MRI SureScan Pacing System (Figure 39). Guidelines for use of this pacemaker include, but are not limited to, the following:

- Patient cannot have previously implanted active or abandoned medical devices or leads
- SureScan pacer must be implanted in left or right pectoral region for minimum of 6 weeks
- Scanning can only be performed on 1.5T systems
- Isocenter for scanning cannot be between C1-T12
- Health professionals with cardiology and radiology training must be present during MR scanning
- Device must be checked to confirm pre-exam functioning after MR scans

Since the FDA’s approval of Medtronic’s pacemaker for conditional use in MRI in 2011, multiple companies have worked to achieve approval for various implanted cardiac devices. Biotronik has received approval for a single and dual chamber pacemaker system, as well as for a cardiac resynchronization defibrillator. Boston Scientific also has an FDA-approved MR-conditional pacing system, along with a mini-ICD device. The FDA approved the first implantable cardioverter defibrillator (ICD) designed to be used safely in patients undergoing MRI in September, 2015, which was an ICD manufactured by Medtronic.

Radiologists and cardiovascular specialists must be familiar with restrictions for each cardiac implantable electronic device, recognizing that because each MR conditional device is unique, there are no “universal” labeling guidelines that are applicable for all. The entire system (pulse generator and leads) must be labeled MR conditional for a system to be considered MR conditionally safe. Each patient could possibly have a “system” that includes active and inactive (abandoned) hardware. The presence of abandoned leads, or a combination of MR conditional labeled and non-labeled hardware, renders the system as a whole MR Unsafe, or at best “MR unknown.” It is recommended that radiology and cardiology personnel and a fully stocked crash cart be readily available for MRI examinations for any patient with an implanted pacemaker or ICD. A programmer that can be used to adjust the device should be readily available. The goal of pre-MRI programming should be to mitigate the risk to the patient and the device while undergoing MRI. All such patients should be actively monitored throughout.
the examination. At the conclusion of the examination, the device should be interrogated to confirm that the function is consistent with the pre-examination state. If a patient with a pacemaker or ICD inadvertently enters the magnet area and/or has an MRI examination, the patient’s cardiologist should be contacted before the patient is discharged from the MRI suite. Exposure to the static magnetic field alone may adversely affect the function of the device, or alter its programming.

MR healthcare professionals are encouraged to contact the respective manufacturer of any cardiac pacemaker or ICD to obtain the latest safety information to ensure patient safety.

Stimulation Systems

Neurostimulators

The incidence of patients receiving implanted neurostimulation or neuromodulation systems for treatment of neurological disorders and other conditions is increasing. The electromagnetic fields used for MR procedures may produce a variety of problems because of the inherent design and intended function of neurostimulation systems, including those used for deep brain stimulation (DBS), spinal cord stimulation (SCS), vagus nerve stimulation (VNS), and other similar devices (Figure 40). Altered function of a neurostimulation system that results from exposure to the electromagnetic fields of an MR system may cause discomfort, pain, or serious injury to the patient.

The greatest reported concern for various devices used for neuromodulation is MRI-related heating. Variables that impact heating include:

- The specific type of neuromodulation
- Electrical characteristics of the specific neuromodulation system
- Field strength and RF wavelength of the MR system
- Type of transmit RF coil or source of RF energy
- Amount of RF energy delivered
- Specific absorption rate (SAR)
- Technique used by the system to calculate or estimate SAR
- Patient’s anatomy undergoing MR imaging
- Orientation and configuration of implantable pulse generator, extension (cable that connects pulse generator to implanted lead), and lead relative to source of RF energy
The exact criteria for the particular neurostimulation system with regard to the implantable pulse generator, leads, electrodes, and operational aspects of the device and the MR system conditions must be defined by comprehensive testing and carefully followed to ensure patient safety.

MRI/neurostimulation system interactions are various, and risk to the patient can range from minimal to severe. The following interactions were related to a specific deep brain neurostimulator; however, the same or similar effects may be found with other neurostimulator systems. Interactions may include:

- **Heating** – The MRI RF field induces voltages onto the lead system that can produce significant heating effects at the lead electrode-tissue interface or at the location of any breaks in the neurostimulator lead system; component heating from the MRI RF field is the most serious risk from MRI exposure, as it can result in thermal lesions, possibly resulting in coma, paralysis, or death

- **Magnetic Field Interactions** – Force and torque effects are produced by the static magnetic field, and this field attracts any magnetic material; force and torque effects may produce movement of the neurostimulator that can be uncomfortable to the patient, open a recent incision, or both; some manufacturers are designing components with minimal magnetic materials

- **Induced Stimulation** – Gradient magnetic fields may induce voltages onto the lead system that may cause unintended stimulation; voltage of the induced stimulation pulses is proportional to the time rate of change (dB/dt) of the gradient pulses, the effective loop area created by the
neurostimulator lead system, and the location of the lead system with respect to the gradient coils of the MRI

- **Effects on Neurostimulator Function** – The static, gradient, and RF fields of the MRI may affect the operation and programming of the neurostimulator; the static magnetic field may cause the neurostimulator to turn ON or OFF if it uses a magnetically controlled switch that allows the patient to control stimulation by the application of a handheld magnet; the static, gradient and RF fields may temporarily affect or disable other functions, such as telemetry or stimulation pulses; parameters will need to be reprogrammed if the MRI causes a Power On Reset of the neurostimulator

- **Image Artifacts and Distortion** – The neurostimulation system components, particularly the neurostimulator, can cause significant imaging artifacts and/or distortion of the MRI image, especially if the neurostimulator components contain magnetic material; the neurostimulator can cause signal loss or signal void in the MR image, or severely distort the image if it is within several inches of the neurostimulator

The various types of neurostimulator systems may have additional restrictions, such as the types of MR coils that can or cannot be used, field strength and field direction requirements for the MR system, or specific examination parameters that cannot be exceeded. MR healthcare professionals are encouraged to contact the respective manufacturer of any neurostimulation system to obtain the latest safety information to ensure patient safety.

**Bone Fusion/Spinal Fusion Stimulators**

These electronic implants are placed beneath the skin and muscle near the vertebral column to provide a faster consolidation of bone grafts. Use of these stimulators leads to higher fusion rates and improved surgical outcomes, with a reduced need for orthopedic instrumentation. Studies performed under specific experimental conditions for the lumbar/torso area (i.e., 1.5T MR system, excessive exposures to RF fields, excessive exposures to gradient magnetic fields, etc.) demonstrated that the implantable spinal fusion stimulator will not present a hazard to a patient undergoing MR imaging with respect to movement, heating, or induced electrical fields during the use of conventional MR techniques associated with 1.5T/64-MHz. There was no evidence of malfunction of the implantable spinal fusion stimulator based on in vitro and in vivo experimental findings with conventional pulse sequences and parameters. MR examinations have been performed on many patients with implantable spinal fusion stimulators, involving a wide-variety of imaging parameters and conditions, with no reports of substantial adverse events. There have been no reports of neuromuscular stimulation in association with the presence of implantable spinal fusion stimulators in patients that underwent MR procedures. RF energy-induced heating during MR imaging does not appear to present a major problem for patients with these stimulators, as long as there is not a broken lead. Lead integrity should be assessed using a radiograph prior to the MR procedure. MR healthcare professionals are encouraged to contact the respective manufacturer of any fusion stimulator system to obtain the latest safety information to ensure patient safety.
Pumps and Infusion Systems

There are a variety of pumps and infusion systems that serve different purposes. They may be implanted in the body, or used externally. Because of these variations, MR healthcare professionals are encouraged to contact the respective manufacturer of any pump and/or infusion system to obtain the latest safety information to ensure patient safety.

One type of implantable pump is a device that stores and dispenses medication to a specific site at a constant factory-set flow rate. Testing on one such pump and its corresponding intraspinal catheter for drug delivery (from Advanced Neuromodulation Systems) revealed no measurable interactions with a 1.5T static magnetic field. There was no additional risk to the patient from heating during MRI, and no peripheral nerve stimulation (PNS).

Ambulatory infusion systems are designed to help healthcare providers administer medications accurately, monitor patient’s response to therapy, stimulate early clinical assessment, and facilitate patient recovery. For some pumps (Smiths Medical), the operator’s manual states that magnetic fields produced by MRI may adversely affect the operation of the pump. The ambulatory infusion pump should be removed from the patient during an MRI exam, and it should be kept at a safe distance from magnetic energy.

Medtronic’s external epidural pump is used to infuse medication and/or fluids into patients primarily for pain management. Routes of delivery are generally intravenous, epidural and/or regional. The warning that accompanies this pump is that external radio frequency interference or electromagnetic radiation may be associated with safety hazards such as under infusion of medication.

Insulin pumps can simplify the management of diabetes through their continuous infusion of rapid-acting insulin. They can be used as external devices, or they can be implanted internally (Figure 41). For some external pumps, it is advised to remove the pump before an MRI, and keep the pump outside the MR scan room. Insulin delivery is regulated by the pump’s motor, which can be damaged by strong magnetic fields. Some implantable pumps should be removed before an MR exam, while some infusion sets can remain attached to the patient during an MR procedure.

Figure 41 Example of an insulin pump

The performance of an implantable constant-flow pump (IsoMed by Medtronic) was not impacted at 1.5T, but a limited effect on the quality of diagnostic information was noted. Presence of the pump can
cause a twofold increase of the local temperature rise in nearby tissues during an MRI. This problem was not seen in testing, but can be corrected by adjusting parameters to reduce the SAR. The measured induced electric field near the pump was below the threshold necessary to cause peripheral nerve stimulation. The magnetic force and torque from the static magnetic field were less than the force and torque due to gravity. As far as image distortion, some image dropout was noted in the region near the pump. This problem was more severe with gradient echo sequences, and can be minimized through parameter adjustments.

MR healthcare professionals are encouraged to contact the respective manufacturer of any pumps and infusion systems to obtain the latest safety information to ensure patient safety.

**Passive Implants**

The main issues affecting the safety and compatibility of passive implants in the MR environment concern magnetically induced displacement force and torque, radio frequency (RF) heating, and image artifacts. The MR static field induces displacement forces and torques on magnetic materials. Patients have been killed by the projectile effect on devices, and by the rotations produced by magnetically induced force and torque. RF heating in the body is created by currents induced by the RF excitation pulses applied during MR scanning, which can result in severe patient burns. The presence of an implant may produce an image artifact that may appear as a void region, or as a geometric distortion of the true image. If the artifact is near the area of interest, the artifact may make the MR scan uninformative or lead to an inaccurate clinical diagnosis, potentially resulting in inappropriate medical action.

**Wires and Sutures**

Advances in interventional MR procedures have resulted in the need for guidewires that are acceptable for endovascular therapy, drainage procedures, and other similar applications. Conventional guidewires are made from stainless steel or Nitinol, materials known to be conductive. The radiofrequency fields used for MR procedures may induce substantial currents in guidewires, leading to excessive temperature increases and potential injuries.

A study of the aspects of the RF heating resonance phenomenon used a Nitinol-based guidewire inserted into a vessel phantom, which was then imaged using 1.5T and 0.2T MR systems. Continuous temperature monitoring was employed at the guidewire tip. Temperature increases of up to 17°C were measured while imaging the guidewire at an off-center position in the 1.5T MR system. No temperature rise was measured during MRI performed using the 0.2T MR system. These results increase the potential for use of low-field, open MR systems for MR-guided endovascular interventions, in light of the heating hazards seen at higher static magnetic field strengths.

Another investigation on heating of a Nitinol-based guidewire was performed with the guidewire partly immersed in an oblong saline bath, to simulate an endovascular intervention. The tip of the guidewire started at a baseline level temperature of 26°C, and reached temperatures up to 74°C after 30 seconds of scanning using a 1.5T MR system. Touching the guidewire produced a skin burn.

The guidewire under investigation acted as a linear conductor. The resonating RF waves accounted for the excessive heating of the guidewire in higher field strength MR systems. Recent advances in guidewire designs have yielded guidewires that appear to be more acceptable for interventional MRI procedures with respect to both safety and visualization aspects.
Patients with skin staples or superficial metallic sutures (SMS) may undergo an MR examination if the skin staples or SMS are nonferromagnetic, and are not in or near the anatomic volume of RF power deposition for the study to be performed (Figure 42). If the nonferromagnetic skin staples or SMS are within the volume to be RF irradiated, the patient should be made aware that they may experience warmth or even burning along the distribution of the skin staples or SMS, and that these sensations should be reported immediately. A cold compress or ice pack can be placed along the skin staples or SMS to serve as a heat sink for any focal power deposition, thereby decreasing the likelihood of a clinically significant thermal injury or burn to adjacent tissue.

In Shellock’s testing of thirteen different sutures (metallic and nonmetallic) with the needles removed, all were acceptable for patients when evaluated at 1.5T. Two of those thirteen sutures showed minor deflection angles and torque at 3T. However, the *in situ* application of these materials provides counter-forces to prevent movement or dislodgement. All of the sutures tested at 3T (with their needles removed) are considered acceptable for MR purposes.

**Coils, Stents, Filters, and Grafts**

Coils, stents, filters, and vascular grafts have been evaluated relative to the use of MR systems (Figure 43). Several of these demonstrated magnetic field interactions. However, the devices that exhibited positive magnetic field interactions typically became incorporated securely in tissue within six weeks after implantation due to ingrowth and other mechanisms. For most coils, filters, stents, and grafts that have been tested, it is unlikely that these implants would become moved or dislodged as a result of exposure to MR systems operating at 1.5T or less. In addition, many of these items have been evaluated at 3T. There may be concern for MR-related heating with certain configurations or shapes of coils, stents, filters, and vascular grafts.

Many of these types of implants are made of nonferromagnetic materials, and are acceptable for patients undergoing MR procedures relative to the use of the particular field strength utilized in the *ex vivo* testing. It is not necessary to wait after surgery to perform an MR procedure in a patient with a “passive” metallic implant that is made from a nonmagnetic material. Reports in peer-reviewed literature describe placement of vascular stents or other similar devices using MR-guidance at both 1.5T and 3T.

Patients with the specific coils, stents, filters and vascular grafts indicated in “The List” in Shellock’s Reference Manual for Magnetic Resonance Safety, Implants, and Devices have had procedures using MR systems operating at static magnetic field strengths of 3T or less without reported injuries or other problems. MR facilities should never have a “general” policy to scan patients with coils, stents, filters and grafts if the acceptable MRI conditions are unknown, or if there is no specific MR labeling available. New coils, stents, filters, and vascular grafts are developed on an ongoing basis, but not all of the newer devices have undergone comprehensive MR testing, including with respect to the 3T MR environment.
One investigation was performed to evaluate potential problems for four different types of stents – one of titanium alloy, one of Nitinol, and two of stainless steel. An “appreciable attraction torque and force” was found for the two stainless steel stents, with the report that “it is uncertain whether this is a potential risk for dislodgment.” In consideration of these results, the investigators advised that specific information on the type of stent is necessary before an MRI examination is planned. In addition, the MR information may change, as was the case for a specific endovascular graft. It was labeled as a contraindicated implant, but was revised to MR conditional.

Various coils, stents, filters, and vascular grafts have been evaluated at 3T field strength. Of the tested implants, two exceeded the American Society for Testing and Materials (ASTM) guideline for safety with deflection angles greater than 45 degrees. However, similar to other comparable implants, tissue ingrowth and other mechanisms are sufficient to prevent them from posing a substantial risk to a patient or individual in the 3T MR environment. These issues warrant further consideration. In addition, assessments have been performed on bare metal and drug eluting coronary artery stents for magnetic field interactions and MR-related heating at 3T or less. These types of stents are often placed in an effort to prevent the restenosis that occurs with as many as 50% of patients that have coronary artery disease and are initially treated by percutaneous transluminal coronary angioplasty (PTCA). For most bare metal and drug eluting coronary stents, patients may undergo MRI procedures immediately after placement. Labeling for each coil, stent, or filter should always be consulted for MR safety guidelines.

Valves

Heart Valves

Many heart valve prostheses and annuloplasty rings have been evaluated for MR issues, including the presence of magnetic field interactions associated with exposure to MR systems at field strengths as high as 4.7T. The majority displayed measurable yet relatively minor magnetic field interactions, as the attractive forces exerted on the heart valve prostheses and annuloplasty rings were minimal compared to the force exerted by the beating heart. An MR procedure is not considered to be hazardous for a patient that has any heart valve prosthesis or annuloplasty ring tested relative to the field strength of the magnet used for the evaluation. There have been no reports of a patient incident or injury related to the presence of a heart valve prosthesis or annuloplasty ring. However, not all heart valve prostheses have been evaluated, and at least one prototype exists that has magnetic components (Figure 44).

Research has been performed to examine the effects of aging on cardiac tissue strength and its ability to withstand forces associated with a 4.7T magnet. The goal was to determine the forces required to cause partial or total detachment of heart valve prostheses in patients with age-related degenerative diseases that were exposed to MRI. The study concluded that specific age-related degenerative cardiac diseases
stiffen and strengthen tissue, resulting in significant forces required to pull a suture through valve annulus tissue. These forces are substantially greater than those magnetically-induced at 4.7T. Therefore, patients with degenerative valvular diseases are unlikely to be at risk during exposure to static magnetic fields less than or equal to 4.7T.

The theoretical possibility exists for electromagnetic interaction with heart valves that contain metallic disks or leaflets. Any metal moving through a magnetic field will develop another magnetic field that opposes the primary magnetic field, a phenomenon referred to as the “Lenz effect.” In theory, “resistive pressure” may develop with the potential to inhibit both the opening and closing aspects of the mechanical heart valve prosthesis. The Lenz effect is proportional to the strength of the static magnetic field, indicating that problems could exist for patients with heart valves with metal leaflets if they undergo procedures in MR systems greater than 1.5T. However, this phenomenon has not been observed in association with MR examinations.

As with any device or implant that may be entering the MR environment, MR healthcare professionals are encouraged to contact the respective manufacturer of any heart valves to obtain the latest safety information to ensure patient safety.

### Cerebrospinal Fluid (CSF) Shunt Valves

Cerebrospinal fluid (CSF) shunts are used for the treatment of hydrocephalus, which is an accumulation of cerebrospinal fluid in the brain from increased production, pathway obstruction, or decreased absorption of the fluid. The shunt is positioned to enable the CSF to be drained from the cerebral ventricles or sub-arachnoid spaces into another absorption site through a system of small catheters (Figure 45). A regulatory device, such as a valve, may be inserted into the pathway of the catheters to moderate the pressure or flow rate, and keeps the CSF flowing away from the brain. Some valves are fixed pressure or monopressure valves, while others have adjustable or programmable settings. Shunt valves may utilize magnetic components, in which case highly specific safety guidelines must be followed in order to safely perform MRI procedures. In May of 2016, Medtronic’s StrataMR line of valves and shunts received FDA clearance for conditional use in MR environments. Their valves have a magnet inside the valve mechanism that allows the neurosurgeon to adjust the performance level setting as needed in his or her office. The StrataMR system is intended to maintain its performance level setting...
during MRI exposure when scanned in accordance with labeling, but still recommends that the neurosurgeon check performance levels after the valve has been exposed to MRI.

![Diagram of a typical shunt](image)

**Figure 45 Diagram of a typical shunt**

Information published after testing a variety of CSF valves reveals that many are safe for use with a static magnetic field of 3T or less, but confirmation of valve settings and/or pressure settings is recommended before and after an MRI procedure. Other conditions, such as spatial gradient magnetic field limit, MR operating mode, MR-related heating, artifacts, SAR levels, etc., vary amongst the different valve manufacturers. MR healthcare professionals are encouraged to contact the respective manufacturer of any CSF shunt valve to obtain the latest safety information to ensure patient safety.

**Intracranial Aneurysm Clips**

The presence of an aneurysm clip in a patient referred for an MR procedure represents a situation that requires the utmost consideration because of the associated risks. Certain types of intracranial aneurysm clips (e.g. those made from martensitic stainless steels) are a contraindication to the use of MR procedures because excessive, magnetically induced forces can displace these implants and cause serious injury or death. By comparison, aneurysm clips classified as “nonferromagnetic” or “weakly ferromagnetic” (e.g., those made from Phynox, Elgiloy, austenitic stainless steels, titanium alloy, or commercially pure titanium) are acceptable for patients undergoing MR examinations (Figure 46).

If a patient is identified as having an intracranial aneurysm clip in place, an MR examination should not be performed until it can be documented that the specific manufacturer, model, and type of aneurysm clip is MR Safe or MR Conditional. According to the ACR Guidance Document on MR Safe Practices: 2013, all intracranial aneurysm clips manufactured in 1995 or later for which the manufacturer’s product labeling continues to claim MR Conditional labeling may be accepted for MR scanning without further testing. Clips manufactured before 1995 require either pretesting before implantation, or individual review of previous MRI of the clip or brain for that particular case. A level 2 MR attending radiologist should assess the size of the artifact associated with the clip relative to the static field strength on which it was studied, the sequence type, and the MR parameters selected in order to issue an opinion as to whether the clip demonstrates significant ferromagnetic properties or not. Access to the MR scanner would then be based on that opinion. Even though a patient with an aneurysm clip has safely undergone a prior MR examination at any static magnetic field strength, that fact is not sufficient evidence of the implant’s MR safety. Variations in static magnetic field strength, static magnetic field spatial gradient,
orientation of the aneurysm clip to the static magnetic field or static field gradient, rate of motion through the spatial static field gradient, etc. are variables that are virtually impossible to control or reproduce. These variables may not have resulted in an adverse event in one circumstance, but may result in significant injury or death on a subsequent exposure.

Figure 46 Example of an intracranial aneurysm clip; image obtained intraoperatively

Various studies performed on patients with nonferromagnetic aneurysm clips that underwent MR imaging using a 1.5T system resulted in no adverse outcomes. This is important for aneurysm patients, as MR imaging has been found to be superior to CT with regard to showing small zones of ischemia postoperatively. There have been no reports of injuries to patients or individuals in the MR environment related to the presence of an aneurysm clip made from a nonmagnetic or “weakly” magnetic material.

Patients with ferromagnetic aneurysm clips (based on the extent of the artifact seen during MR imaging or other information) have undergone MR procedures without sustaining injuries. In these cases, the aneurysm clips were exposed to magnetic-induced translational attraction and torque associated with MR systems operating at 1.5T or less. Although these cases do not prove safety, they do demonstrate the difficulty of predicting the outcome for patients with ferromagnetic aneurysm clips that undergo MR procedures. Variables to consider include the size, shape, mass, and material of the aneurysm clip. There is controversy regarding the amount of ferromagnetism that needs to be present in an aneurysm clip to constitute a hazard for a patient in the MR environment. This issue has created problems for both MR healthcare professionals and the manufacturers of aneurysm clips. Testing techniques that utilize the deflection angle test and an evaluation of torque are the most appropriate means of determining which specific aneurysm clip may present a hazard to a patient or individual in the MR environment. To date, only one ferromagnetic aneurysm clip-related fatality has been reported in the peer-reviewed literature. The patient became symptomatic at a distance of approximately 1.2 meters from the bore of the MR system, suggesting that translational attraction of the aneurysm clip was likely responsible for the dislodgment of this implant. The incident was the result of erroneous information pertaining to the type of aneurysm clip that was present in the patient. The clip was thought to be a nonmagnetic type, but turned out to be magnetic.
The following guidelines are recommended with regard to performing an MR procedure on a patient or before allowing an individual with an aneurysm clip into the MR environment:

1. Specific information (i.e., manufacturer, type or model, material, lot and serial numbers) about the aneurysm clip must be known, especially with respect to the material used to make the aneurysm clip, so that only patients or individuals with nonferromagnetic or weakly ferromagnetic clips are allowed into the MR environment. This information is provided by the manufacturer in the labeling of the aneurysm clip. The implanting surgeon is responsible for properly recording and communicating this information in the patient’s or individual’s records.

2. An aneurysm clip that is in its original package and made from Phynox, Elgiloy, MP35N, titanium alloy, commercially pure titanium or other material known to be nonferromagnetic or weakly ferromagnetic does not need to be evaluated for ferromagnetism. The manufacturers ensure the pertinent MR safety or conditional aspects of these clips and, therefore, are responsible for the accuracy of the labeling.

3. If the aneurysm clip is not in its original package and/or properly labeled, it should undergo testing for magnetic field interactions following appropriate testing procedures to determine if it is safe.

4. The radiologist and implanting surgeon are responsible for evaluating the information pertaining to the aneurysm clip, verifying its accuracy, obtaining written documentation, and deciding to perform the MR procedure after considering the risk vs. benefit aspects for a given patient.

5. Consideration must be given to the static magnetic field strength that is to be used for the MRI procedure and the strength of the static magnetic field used to test magnetic field interactions for the aneurysm clip in question.

A concern emerged that a potential alteration in the magnetic properties of pre-or post-implanted aneurysm clips may occur due to long-term or multiple exposures to strong magnetic fields. Kanal and Shellock conducted an *in vitro* investigation, with findings that indicated a lack of response to the magnetic field exposure conditions that were used. Their conclusion was that long-term or multiple exposures to 1.5T MR systems should not result in significant changes in the magnetic properties of various nonferromagnetic or weakly magnetic aneurysm clips.
An additional problem related to aneurysm clips is that artifacts produced by these metallic implants may substantially detract from the diagnostic aspects of MR procedures. MR imaging, MR angiography and functional MRI are frequently used to evaluate the brain or cerebral vasculature of patients with aneurysm clips. The extent of the artifact produced by an aneurysm clip will have a direct effect on the diagnostic aspects of the MR procedure. An investigation was conducted to characterize artifacts associated with aneurysm clips made from nonferromagnetic or weakly ferromagnetic materials. Five different aneurysm clips made from five different materials were evaluated. The artifact testing revealed that the size of the signal voids were directly related to the type of material (i.e., the magnetic susceptibility) used to make the particular clip. The materials responsible for the artifacts, in decreasing order of artifact size, included:

1. Elgiloy
2. Cobalt alloy
3. Phynox
4. Titanium alloy
5. Commercially pure titanium

These results have implications when one considers the various critical factors that are responsible for the decision to use a particular type of aneurysm clip (e.g., size, shape, closing force, biocompatibility, corrosion resistance, material-related effects on diagnostic imaging, etc.). An aneurysm clip that causes a large artifact can impact the diagnostic capabilities of the MR procedure, especially if the area of interest is in the immediate location of where the aneurysm clip was implanted. Aneurysm clips made from titanium alloy and commercially pure titanium create minimal artifacts. The use of titanium aneurysm clips reduced MR artifacts by approximately 60% compared to stainless steel aneurysm clips. MR imaging artifacts may be further reduced by using spin echo pulse sequences with high bandwidths, or, if necessary, gradient echo pulse sequences with low echo times.

As with all devices and implants, MR healthcare professionals are encouraged to contact the respective manufacturer of any intracranial aneurysm clip to obtain the latest safety information to ensure patient safety.

**Foreign Bodies: Bullets, Pellets, and Shrapnel**

The majority of bullets and pellets tested in the MR environment were found to be composed of nonferromagnetic materials. However, these items are often “contaminated” by ferromagnetic metals, which necessitates careful consideration of the risk vs. benefit of an MR procedure for a patient with retained bullets, pellets, and/or shrapnel. Additional consideration must be given to whether the metallic object is located near or in a vital anatomic structure, with the assumption that the object is likely to be ferromagnetic and can potentially move. Ammunition that proved to be ferromagnetic tended to be manufactured in foreign countries and/or used for military applications. Shrapnel typically contains steel and, therefore, presents a potential hazard to patients undergoing MR procedures.

The federal government requires the use of steel shotgun pellets, as opposed to lead, in many of the eastern United States. This initiative was meant to reduce lead poisoning in “puddling” type ducks. However, the presence of steel shotgun pellets presents a potential hazard to patients undergoing MR procedures, and causes substantial imaging artifacts at the immediate position of these metallic objects.
A study performed at the University of California, San Francisco (UCSF) set out to examine the safety of retained bullets in MRI scanners. Earlier research suggested that bullets lodged in patients were generally safe in 1.5T scanners, but their safety in 3T and 7T scanners was unknown. Retained bullets are considered to be “metal implants,” which can pose risks to soft tissue and to vascular and neural structures due to movement and heating effects in the MR environment. The group’s hypothesis was that commonly available bullets do not cause clinically relevant heat, movement, or artifact during MRI at stronger field strengths. They scanned 32 commercially available bullets, and seven shotgun pellets, which are typically composed of a lead core with copper coatings or jackets. One bullet in the sample was an armor-piercing bullet with a hardened steel core, a copper-coated jacket, and a lead tip (Figure 47). Two of the shotgun pellets also contained steel. The bullets were embedded in phantoms, and scanned in three different field strengths – 1.5T, 3T, and 7T. The bullets were tested for the following parameters:

- **Ex vivo translational force** – Calculated using a deflection angle technique for bullets attached to a string and placed in a 1.5T scanner at the point of greatest magnetic field
- **Rotational force** – Describing the force and speed with which each sample aligned with its long axis within the static magnetic field; each bullet was placed on a grid device and allowed to freely rotate after being placed in the center of the MRI bore
- **Radiofrequency-induced heating** – Measured in five representative bullets using a custom temperature probe and fast spin-echo T2-weighted sequences; designed to test the worst-case-scenario exposure to the FDA-approved limit of RF-induced excitation at 3T for 15 minutes, reporting the highest temperature achieved
- **Artifact** – Measured by placing the bullets in a gel-filled head phantom dosed with gadolinium; gradient echo sequences were chosen to approximate a worst-case scenario

According to the results, non-steel containing items showed no magnetic field effect, meaning they did not move. All items containing steel deflected to an angle of 90°, with the armor-piercing bullet displaying the greatest amount of movement. This bullet’s translational force exceeded safe levels at all three field strengths. MRI-induced heating was not significant, regardless of bullet composition. All of the bullets created some artifact, but the armor-piercing bullet was the worst. It generated 100 times greater signal loss than the bullets that did not contain steel. The authors concluded that regular commercially available bullets manufactured in the U.S. are safe in scanners up to 7T. The armor-piercing bullets with steel cores, and stainless steel shotgun pellets should be considered unsafe due to movement. MRI should be avoided when bullets known to contain steel are located very near critical anatomic structures, which emphasizes the importance of obtaining forensic information on retained projectiles wherever possible.
A retrospective investigation in 2010 examined the potential hazards for patients undergoing MRI at 1.5T with retained metal fragments from combat and terrorist attacks. One patient reported a superficial migration of a 10mm fragment after MRI, but no other adverse reactions were reported. The authors concluded that 1.5T MRI examinations are safe in patients with retained metal fragments from combat and terrorist attacks that are not in the vicinity of vital organs. However, caution is advised, as well as an assessment of risk vs. benefit for the patient. Unless you know exactly what is inside the patient, you cannot say with 100% confidence that it is safe.

**Orthopedic Implants, Materials, and Devices**

Most of the orthopedic implants, materials, and devices evaluated for MRI issues (i.e., magnetic field interactions, heating, and artifacts) are made from nonferromagnetic materials and, therefore, are safe or “MR conditional” according to specific conditions for patients undergoing MR procedures. Patients with many of the orthopedic implants, materials, and devices indicated in “The List” portion of Shellock’s Reference Manual for Magnetic Resonance Safety, Implants, and Devices as being “MR safe” or “MR conditional” have undergone MR procedures using systems operating at 3T or less without incident.

One type of screw that is used for anterior cruciate ligament reconstruction has been found to be highly ferromagnetic. However, this screw is firmly imbedded in bone for its specific application, and is held in place with sufficient retentive force to prevent movement or dislodgment. Patients with this screw have safely undergone MR procedures using systems operating at 1.5T.

In certain instances, due to the length or formation of a conductive loop, MRI-related heating may be a problem for some orthopedic implants, especially cervical fixation devices or external fixation systems. External fixation systems comprise specially designed frames, clamps, rods, rod-to-rod couplings, pins posts, fasteners, wire fixations, fixation bolts, washers, nuts, hinges, sockets, connecting bars, screws and other components used in orthopedic and reconstructive surgery (Figure 48). Indications for external fixation systems are varied, and include the following treatment applications:

- Open and closed fracture fixation
- Pseudoarthroses of long bones (both congenital and acquired)
- Limb lengthening by metaphyseal or epiphyseal distraction
- Correction of bony or soft tissue defects
- Correction of bony or soft tissue deformities

As one can imagine, the assessment of MRI issues for external fixation systems is particularly challenging due to the myriad of possible components, many of which are made from conductive materials, as well as the myriad of configurations used for these devices. The primary concern is MRI-related heating, which is dependent on particular aspects (e.g., lengths of the component parts) of the external fixation system. The safety aspects of scanning patients with external fixation systems are dependent on the specific MR system, with regards to the strength of the static magnetic field, the RF field, the RF transmit coil or transmitter, the pulse sequences to be used, the body part to be imaged, the position of the fixation device relative to the transmit RF coil or transmitter, etc.
To ensure patient safety, guidelines are typically applied on a case by case basis and, therefore, MR professionals are referred to product labeling approved by the FDA for a given external fixation system. The acceptable MRI conditions typically apply to the specific configurations used in the evaluation of a given fixation device, only. Other configurations may be unsafe.

It has been reported that torque acting on metallic implants or instruments due to eddy-current induction in association with MR imaging can be considerable. Larger implants, such as fixation devices, made from well-conducting materials, are especially affected. Significant vibrations at off-center positions of the metal parts may explain why some patients with metallic implants sometimes report feeling heating sensations during MR examinations.

Many orthopedic implants have been evaluated for magnetic field interactions at 3T in “The List” portion of Shellock’s Reference Manual for Magnetic Resonance Safety, Implants, and Devices. Most are considered to be acceptable for patients based on findings for deflection angels, torque, and their intended in vivo uses. MRI-related heating was evaluated, and can be a concern for certain devices, especially external fixation systems and cervical fixation devices.

**Magnetically-Activated Implants and Devices**

Various types of implants incorporate magnets for a variety of reasons. A magnet may be used to retain the implant in place, to guide a ferromagnetic object into a specific position, to permit the functional aspects of the implant, to change the operation of the implant, or to program the device. MR procedures typically should not be performed in patients with these implants or devices, as there is a high likelihood of demagnetizing, displacing, or perturbing the function of these implants. However, in some cases, patients with magnetically-activated implants and devices may undergo MR procedures, as long as certain precautions are followed.

Magnetically-activated implants and devices may necessitate surgery to replace or reposition them if they are damaged by exposure to MR systems. This situation might include dental implants, magnetic sphincters, magnetic stoma plugs, magnetic ocular implants, otologic implants, and other prosthetic devices. Whenever possible, and without risk to the patient, magnetically-activated implants or devices should be removed prior to MR procedures in order for these exams to be performed safely. Knowledge of the specific aspects of the magnetically-activated implant or device is essential to recognize potential problems, and to guarantee that an MR examination may be performed without risk.
Cochlear Implants

Cochlear implants are electronic devices used to treat severe to profound hearing loss. They deliver useful auditory signals from the environment to the patient by electronically bypassing nonfunctional parts of the ear, and directly stimulating the auditory nerve. Cochlear implants consist of internal and external portions (Figure 49). The external parts include a microphone, speech/sound processor, and a transmitter. Manufacturers recommend that any removable external components should be removed before entering the MRI scan room. The internal parts include a receiver-stimulator and an electrode. The transmitter and the internal portions are kept in correct alignment by using magnets present in both the internal and external parts of the device. MR procedures may be contraindicated for patients with cochlear implants due to the possibility of injuring the patient and/or altering or damaging the function of the device.

Studies conducted to determine cochlear implant safety for MR procedures have resulted in highly specific guidelines. Some cochlear implants require the use of 0.2T or 0.3T MR systems only, while other cochlear implants can be scanned at field strengths of 1.5T and 3.0T. The magnet associated with the cochlear implant may require surgical removal prior to the MRI examination, and surgical replacement following the scan. One manufacturer does not require the surgical removal of the internal magnet, but does require the use of a 0.2T MRI system only. If it is anticipated that a patient will need repeated MRIs, one manufacturer recommends that their magnet be removed and replaced with a non-magnetic titanium plug, which prevents the growth of fibrous tissue into the recess left when the magnet is removed. Another manufacturer has the internal magnet replaced with a Magnet Insert Dummy.

Additional MRI concerns are the substantial artifacts that may still exist, even when the internal magnet of the cochlear implant has been removed. Any additional metal in the implant can affect the quality of the MRI, but does not damage the implant. “Image shadowing” may result in a loss of diagnostic information in the vicinity of the implant. One manufacturer mentions that the MRI static field may exert a small force on the implant, even without the internal magnet. The maximum force is less than the normal weight of the implant, so the force may be perceptible during the MRI procedure, but it is not harmful.
Recently, some cochlear implants have received approval designating them as “MR Conditional.” One manufacturer has produced a cochlear implant that is approved for use in a 3.0T magnet, and has a self-aligning implant magnet that can remain in place, with no magnetic pulling on the implant during an MRI scan. As these implants are constantly improving and evolving, MR healthcare professionals are advised to contact the respective manufacturer in order to obtain the latest safety information for a given cochlear implant to ensure patient safety relative to an MR procedure.

Ocular Implants, Lens Implants, and Devices

Many lens implants pose no hazard to the patient during an MRI procedure since they do not contain metallic materials. Of the many different ocular implants, lens implants, and devices tested in the MR environment and reported in Shellock’s Reference Manual for Magnetic Resonance Safety, Implants, and Devices, very few demonstrated positive magnetic field interactions in association with exposure to 1.5T MRI systems. These included an eyelid spring, a retinal tack made from martensitic (i.e., ferromagnetic) stainless steel, a magnetic ocular implant, and a round wire eyelid spring.

A patient with an eyelid spring or round wire eyelid spring may experience discomfort, but would probably not be injured as a result of exposure to an MR system. Patients have undergone MR procedures with eyelid wires after having a protective plastic covering placed around the globe, along with a firmly applied eye patch as a precaution.

Although no cases of injury have been reported, the retinal tack made from martensitic stainless steel, and the magnetic ocular implant may cause injury to a patient.

A study from 2013 reported that certain color contact lenses may contain iron oxide or other metals, meaning that their presence during MRI may be problematic due to the associated imaging artifacts.

MR healthcare professionals are advised to contact the respective manufacturer in order to obtain the latest safety information for a given ocular implant, lens implant, or other ocular device to ensure patient safety relative to an MR procedure.

Breast Tissue Expanders and Implants

Adjustable breast tissue expanders and mammary implants are utilized for breast reconstruction following mastectomy, for the correction of breast and chest-wall deformities and underdevelopment, for tissue defect procedures, and for cosmetic augmentation. These devices are typically equipped with either an integral injection site or a remote injection dome that is utilized to accept a needle for placement of saline for expansion of the prosthesis intra-operatively and/or postoperatively (Figure 50).

There are many different types of breast tissue expanders, with many different safety guidelines for use in MRI. One expander provides a choice of injection domes- standard or micro-injection. Another type is indicated for temporary implantation only, as its injection port contains stainless steel to guard against piercing the injection port with the needle that is used to fill the implant. Many breast expanders have magnetic ports to allow for a more accurate detection of the injection site. These devices are substantially attracted to the static magnetic fields of MR systems and, therefore, may be uncomfortable, injurious, or contraindicated for patients undergoing MR procedures. Expanders with magnetic ports produce relatively large artifacts on MR images and, as such, assessment of the breast using MR imaging is problematic. The metallic artifact could obscure the precise location of an
abnormality. A patient with a breast tissue expander that has a metallic component should be identified prior to MRI so that the radiologist is aware of the potential problems related to the generation of artifacts as well as a possible injury.

One particular type of breast tissue expander from McGhan Medical has been deemed unsafe for MR procedures. The MAGNA-SITE expander is intended for temporary subcutaneous implantation to develop surgical flaps and additional tissue coverage. This expander involves the MAGNA-SITE integrated injection site, and the MAGNA-FINDER external locating device, both of which contain rare-earth permanent magnets. When the MAGNA-FINDER is passed over the surface of the tissue being expanded, its rare-earth permanent magnet indicates the location of the MAGNA-SITE injection site. MAGNA-SITE expanders cannot be placed in patients who already have implanted devices that would be affected by a magnetic field (e.g., pacemakers, drug infusion devices, etc.). Diagnostic testing with MRI is contraindicated in patients with MAGNA-SITE expanders in place. The static magnetic field of the MRI system could cause movement of the MAGNA-SITE expander, resulting in not only patient discomfort, but also expander displacement, which would require revision surgery. The MAGNA-SITE magnet could also interfere with MRI detection capabilities.
One report of a case of bilateral tissue expander infusion port dislodgement occurred in a woman with the MAGNA-SITE components implanted after bilateral mastectomy. Several weeks postoperatively, she underwent MR imaging of her spine. Subsequently, the infusion ports could not be located with the MAGNA-FINDER. A chest radiograph demonstrated bilateral dislodgment of the infusion ports. Surgical removal and replacement of the tissue expanders was required.

In another incident involving a tissue expander, a woman developed a burning sensation at the site of the expander during an MR procedure. The sensation resolved rapidly once the scan was discontinued. This case emphasizes the importance of alerting patients with tissue expanders to the possibility of localized symptoms in the region of the implant during MR scanning.

MR healthcare professionals are advised to contact the respective manufacturer in order to obtain the latest safety information for any given breast tissue expander and implant to ensure patient safety relative to an MR procedure.
Conclusion

Safety is the responsibility of all those who work in the MR environment, but especially the MR technologist and MR radiologist. As MR professionals, we must advance our safety education and training to stay abreast of this ever-changing aspect of our imaging world. The certification of both MR Safety Officers (from the ranks of technologists) and MR Medical Officers (radiologists) offer a means to continue our efforts to ensure the safety of MR clinical and research environments.

As previously mentioned, you are urged to confer with an MRI safety consultant concerning any specific safety questions you may have. MR safety is ultimately the responsibility of each MR facility.

This concludes the Safety module of the Hitachi Medical Systems America’s MRI Anatomy and Positioning Series. You must complete the post-test for this activity with a score of 75% or better in order to receive Continuing Education credits.
Appendix A: References for Safety Seminar

- Barnes, Eric. (9February2012). Most, but not all, bullets are safe to scan with MRI. Retrieved from http://www.auntminnie.com/index.aspx?sec=prtf&sub=def&pag=dis&itemId=98244
Appendix B: References for Pictures

- Figure 1 – Hitachi Medical Systems America, Inc.
- Figure 2 – http://rad-planning.com/RADblog/2012/03/01/4-zone-primer/
- Figure 3, sign on left – http://www.safetysign.com/products/p19475/danger-restricted-access-label
- Figure 3, sign on right – http://www.mriequip.com/store/pc/viewprd.asp?idproduct=335
- Figure 4 – http://www.shieldingsystems.com/cryogen_quench_systems.php
- Figure 5 – Hitachi Medical Systems America, Inc.
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