the facility Risk Management and should be considered for continuous quality improvement efforts. Such events help TRA and Radiology Administration learn about how to prevent recurrence and better avoid MR safety related issues in the future.

FDA MedWatch

TRA strongly recommends that any MR-related accident be reported to the FDA via MedWatch, the FDA Safety Information and Adverse Event Reporting Program (https://www.fda.gov/Safety/MedWatch/default.htm).

PRIMARY MR HAZARDS

Magnetic resonance (MR) utilizes three variants of magnetic fields to generate images:

- a strong static magnetic field (B_o),
- radiofrequency (RF) magnetic fields (B_1), and
- time varying magnetic field gradients (dB/dt).

Each of these components presents its own set of unique safety hazards – hence the MR safety program is designed to mitigate the risks of each. MR personnel are tasked with preventing or limiting the mechanical effects, heating effects, and electromagnetic effects that are inherent to the MR environment that may harm patients, visitors, ancillary team members, and equipment.

Static Magnetic Field (B_o)

Safety issues related to the strong static magnetic field include potential biological effects and various mechanical effects resulting from various forces that may ultimately cause patient discomfort or injury or may damage medical devices. Table 1 specifies the static magnetic field strengths above which the FDA considers "significant risk."

Biological Effects

When an electrical conducting fluid (such as blood) flows in an applied magnetic field, a transverse electromotive force (EMF) is developed that is proportional to the flow velocity and the field strength. This EMF induces small currents in tissues that in turn leads to small electric voltages on the body surface that can be detected by the use of metal electrodes on the skin. It actually produces a large signal during the T-wave phase of the cardiac cycle – hence this magneto-hemodynamic effect contributes to the difficulty in obtaining acceptable ECGs during MR procedures.

Bulk physical movement (like rapid head turning or rapid movement into or out of the magnet) also induces electrical currents throughout tissue – and these weak currents activate highly sensitive sensory tissues. For example, individuals who move their eyes rapidly while in the magnetic field in a darkened room may experience sensations of brief flashing lights called "magnetophosphenes."

Individuals moving in close proximity of the MR scanner may experience sensations of nausea and vertigo. [According to Schenck (2000), these are likely the result of "extraneous excitation of motion sensations by weak magnetohydrodynamic forces in the semicircular canals of the inner ear and the resulting conflict between the position sensing apparatus of the vestibular and visual systems."]

Such sensory effects are temporary and are not harmful. However, even mild levels of extraneous sensory effects can be disconcerting to a patient. Therefore, to enhance their comfort, **patients should always be moved *slowly* in and out of the magnet and should be instructed to minimize their motion while they are within the magnet bore.**

Table 1. "Significant risk" static magnetic field strengths (FDA 2014).

Population	Main Static Magnetic Field
Adults, children, and infants aged > 1 month	> 8 T
Neonates (infants aged 1 month or less)	> 4 T

Mechanical Effects

The main mechanical hazards associated with the static field are translational forces (i.e., "missile effect") and rotational forces (i.e., torque) experienced by ferromagnetic objects within the magnetic field. Translational forces may cause unsecured ferrous objects to accelerate uncontrollably towards the bore of the magnet. Additionally, either type of force may also cause movement or malfunction of implanted medical devices and metal debris within a person's body.

A ferromagnetic material is one having a high susceptibility to magnetization. The strength of the magnetization depends upon the strength of the applied magnetic field. In addition, the magnetization may remain after the removal of the applied field.

Once the ferromagnetic material is magnetized, it creates its own magnetic fields.

The best method to counter these risks is comprehensive screening of all patients and staff members for ferromagnetic objects within or on their bodies prior to their entry into the magnet room. Furthermore, to keep the MR area free of unsecured ferromagnetic items that might become dangerous projectiles, the MR technologist must be constantly aware of who and what enters the control area and magnet room.

Not all stainless steel is ferromagnetic.

Stainless steel is an alloy made of the metallic elements iron, chromium, nickel, manganese, and copper and the non-metal element carbon. The combination of these various components determines its ferromagnetic properties.

There are five classifications of stainless steel (and each class has multiple grades):

1. Ferritic stainless steels consist of chromium and iron and contain very little carbon. As the name suggests, these types of stainless are the most ferromagnetic.
2. Austenitic stainless steels, the most common types, consist of chromium (16-26%), nickel (6-12%), and iron. They are generally described as non-magnetic. However, they may become magnetic when machined or worked.
3. Martensitic stainless steels consist of carbon (0.2-1.0%), chromium (10.5-18%) and iron. They are ferromagnetic.
4. Duplex stainless steels consist of chromium (18-26%) nickel (4-7%), molybdenum (0-4%), copper, and iron. These stainless steels consist of approximately 50% austenite and 50% ferrite, hence they are ferromagnetic – but not as much as the ferritic, martensitic, and PH types of steels.
5. Precipitation hardening (PH) steels have very high strengths due to the addition of copper, niobium, and aluminum. Although ferromagnetic, the do not magnetize and demagnetize as easily as ferritic or duplex steels.

Fringe Fields

Every magnet has fringe fields and the extent and steepness of the fringe field gradient depends upon the magnetic field strength, the design of the magnet (open versus tunnel bore), and shielding (active, passive, cladding, or whole room shielding). Although the magnet manufacturer provides calculated fringe field or gauss line plots (Figure 1), each installation actually differs due to the unique surrounding structures at each location (such as large metal objects like support beams or nearby medical equipment). Nonetheless, MR personnel should have a thorough understanding of the fringe fields of each scanner at each facility.

MR technologists who work with a variety of MR scanners at different facilities should be aware of the differences between the various scanner fringe fields and exercise care accordingly.

FDA guidelines refer to a magnetic field of 0.5 mT (5 G) as the upper limit where the field strength is of no potential concern for the general public, including persons with implanted electronic devices (Tsai 2015). At each facility, independent measurements of the 0.5 mT (5 G) isocontour may be required to confirm that it does not extend beyond the magnet control area or potentially occupied spaces adjacent to the magnet room (such as the building roof or patient care areas on the next floor).

1. The plot of fringe field or gauss lines from the manufacturer should be readily available for each magnet and kept in the MR control area.
2. Measurement of the 0.5 mT (5 G) field line should be completed to confirm its location for each magnet.
3. The floor should be marked to show the 0.5 mT (5 G) line.

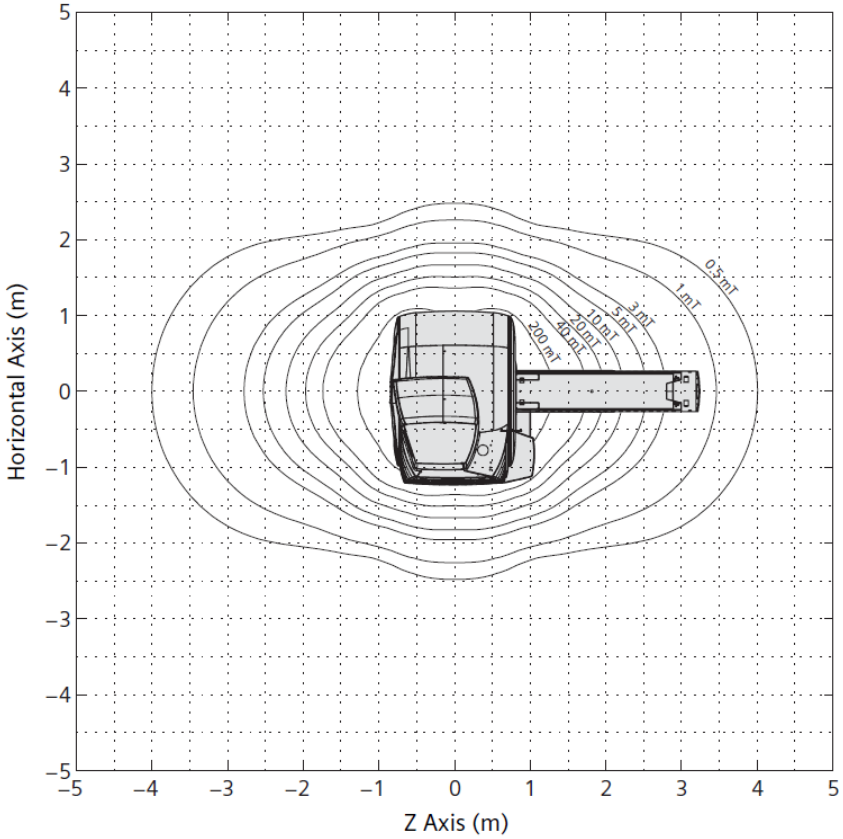

Figure 1. Calculated fringe fields for 1.5T Siemens Avanto. View from top of magnet (Siemens 2004).

Translational Forces (Missile Effect)

Ferromagnetic materials experience an attractive force when placed in a magnetic field gradient. This force is proportional to the magnetic field strength, B_o, and the magnetic field gradient, dB/dx. It is greatest just inside the magnet bore (Figure 2), where the gradient is near its maximum and the magnetic field is increasing. (The location of the maximum spatial gradient as defined by the MR manufacturer is often not clinically relevant as the location

is not accessible by the patient.) It then falls off towards the imaging volume where the gradient falls to zero at the bore isocenter.

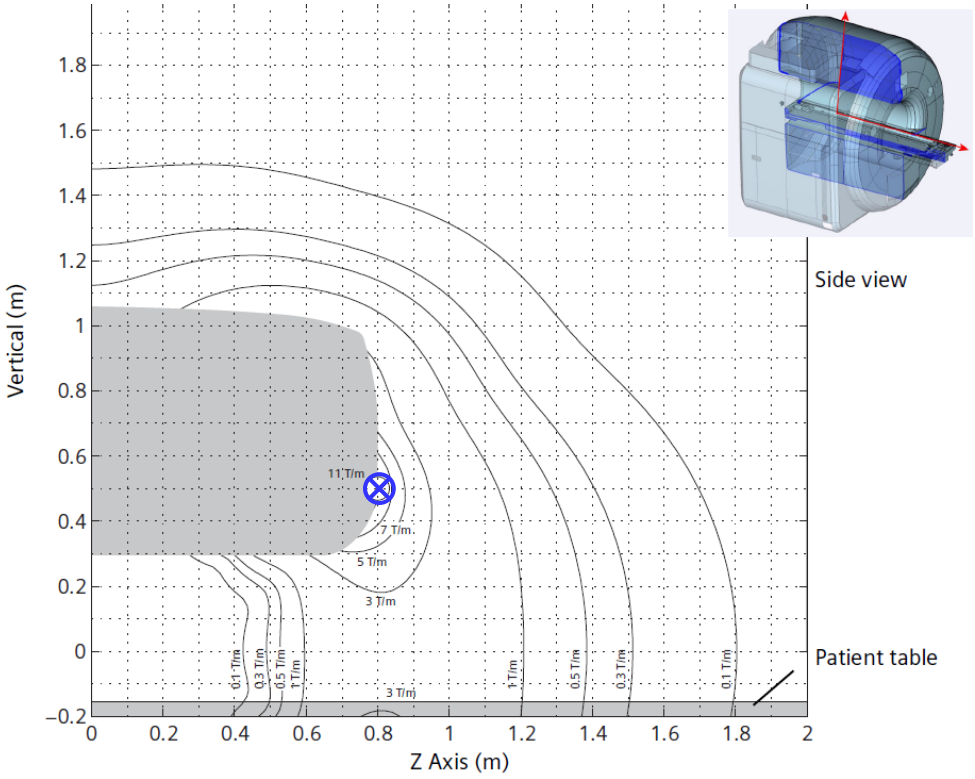

Figure 2. Spatial gradient (dB/dx) of static magnetic field B_o for 1.5T Siemens Avanto. Side view. Force on magnetically saturated ferromagnetic object greatest at location ⊗ (Siemens 2004).

The manufacturer's plot of spatial gradients should be readily available for each magnet and kept in the MR control area.

Rotational Forces (Torque)

In addition to an attractive force, ferromagnetic objects also experience torque or rotational forces as they tend to align along the magnet's field lines. Torque depends upon the shape of the object, with elongated objects (such as a pen, long cylinder, or intracranial aneurysm clip) demonstrating the most. Torque force increases with field strength and is greatest at the isocenter of the magnet bore.

Lenz's Forces

Also associated with the static magnetic field are Lenz's forces. Rapid motion of a large metallic object – even one that is not grossly ferromagnetic – perpendicular to the static magnetic field can result in forces on the object that oppose its motion. If a patient has a large implanted metallic device such as a metallic nonferrous infusion pump, the patient might complain of experiencing a tugging or pulling force on the pump. To minimize the induction of Lenz's forces, the technologist should move the patient *slowly* into or out of the magnet bore.

Implant Interactions

The strong static magnetic field can affect implantable medical devices in patients and in team members working in proximity to the magnet. Any ferromagnetic component within such a device may experience both the translational force (i.e., the device may try to move to the center of the magnet bore) and/or torque (i.e., the device may try to align with the magnetic field lines). Both of these effects can cause tissue damage and/or damage to the device.

Interaction with Other Equipment

If the equipment has significant ferromagnetic components, it may experience translational forces and become a projectile hazard. Furthermore, the functionality of monitoring equipment with ferromagnetic components can be affected. For example, if the equipment is moved within the field, induced currents may result from the movement and affect the equipment.

Radiofrequency (RF) Electromagnetic Fields (B_1)

The pulses of RF energy used to generate signal for MR image formation consist of oscillating electromagnetic fields. These RF fields have both a magnetic component and an electrical component and can be characterized by wavelength and frequency. Biological effects caused by RF radiation can be classified into non-thermal and thermal effects.

Non-Thermal Effects

Biological Effects

Although RF radiation may cause changes in biological systems without an increase in temperature, the non-thermal effects are not well understood and have not been studied with the use of MR systems (Shellock 2000). However, this subject has been addressed by Adey (1981) and Beers (1989).

Implant Interactions

RF radiation can interact with the operation of electronic medical devices, causing them to malfunction. For example, RF fields could interfere with the electronics of a pacemaker causing asynchronous or rapid pacing. Furthermore, currents may be induced within implanted control wires, even if the device itself has been removed. To mitigate the risk, thorough screening is essential to exclude those individuals with implanted devices that are not safe in the MR environment such as cochlear implants, infusion pumps, neurostimulators, and certain pacemakers.

Thermal Effects

Because patient tissues can conduct electrical current, exposure of tissue to RF radiation results in electrical currents that produce heat due to resistive losses. Hence the primary safety concerns associated with the applied RF fields are diffuse (whole-body) heating and focal (localized) heating. Diffuse heating causes heat stress and is concerning because the elevation of core body temperature to sufficiently high levels may be life threatening. Focal heating causes burns.

To counter the whole-body heating risks associated with the RF field, the technologist must be cognizant of the causes of heat stress and how it may be mitigated. To lessen the risk of focal burns, comprehensive screening must be completed to exclude from the MR scanner room any patient with metal objects – either external (such as jewelry) or internal (such as implanted metal devices). In addition, while positioning the patient for the exam, the MR technologist must make sure that no conductive materials (such as wire leads that might act as an RF antenna) come in contact with the patient's skin.

The heating associated with RF electromagnetic radiation is a potential hazard only to the volume of tissue being exposed to the transmitted RF. Furthermore, the drop off of the RF energies falls relatively quickly as function of distance from this volume (Figure 3). That means, even if electrically conductive material must remain with the bore during imaging, thermal risk would not be an issue if a focal transmit RF coil is used to restrict the RF to a volume that does not include the conductor.

Diffuse Heating

The actual increase in tissue temperature caused by exposure to RF radiation is dependent on multiple factors associated with the thermoregulatory system of the individual and the surrounding MR environment. With regard to the thermoregulatory system, when subjected to a thermal challenge, the human body loses heat by means of convection, conduction, radiation, and evaporation. Each of these mechanisms is responsible to a varying degree for heat dissipation as the body attempts to maintain thermal equilibrium. When the thermoregulatory effectors are not capable of totally dissipating the heat

load, there is an accumulation or storage of heat along with an elevation in local and/or overall tissue temperatures.

Various underlying health issues may affect an individual's ability to tolerate a thermal challenge. These include hypertension, diabetes, cardiovascular disease, fever, old age, and obesity. Likewise, various medications such as diuretics, beta-blockers, calcium channel blockers, amphetamines, vasodilators, vasoconstrictors, tranquilizers, sedatives, and muscle relaxers can alter or seriously impair thermoregulatory responses to a heat load (Shellock 2000).

The human body utilizes four methods to remove heat:

1. Convection is the loss of body surface heat to cooler air currents.
2. Conduction is heat loss via direct body surface contact with a colder surface.
3. Radiation is the transfer of body surface heat to cooler surfaces and objects not in direct contact with the body.
4. Evaporation is heat loss due to a damp or wet surface exposed to cooler air.

With regard to the surrounding MR system, environmental factors also affect the amount of tissue heating and its associated tolerable RF exposure. These include the ambient temperature, relative humidity, and air flow. A temperature of 67°F and low humidity are recommended for the MR scanner room.

Unlike other imaging modalities where patients are more comfortable when covered with warm blankets, MR patients (particularly those with a fever) should not be covered during procedures.

Specific Absorption Rate (SAR)

The thermoregulatory and other physiological changes that a human displays in response to exposure to RF radiation are dependent on the amount of energy that is absorbed. The dosimetric term used to describe the absorption of RF radiation is the Specific Absorption Rate (SAR). It is defined as the RF power absorbed per unit mass of an object and is measured in units of watts per kilogram (W/kg). MR scanners limit core temperature rise by limiting SAR.

The SAR that is produced during an MR procedure is a complex function of numerous variables including the RF frequency (determined by the static magnetic field strength, with resonant frequencies producing the greatest effect), the transmitted RF excitation flip angle (e.g., 90° versus 180° pulse), the repetition time, the type of RF coil used, the volume of tissue contained within the coil, the configuration of the anatomical region exposed, the orientation of the body to the field vectors, and other factors.

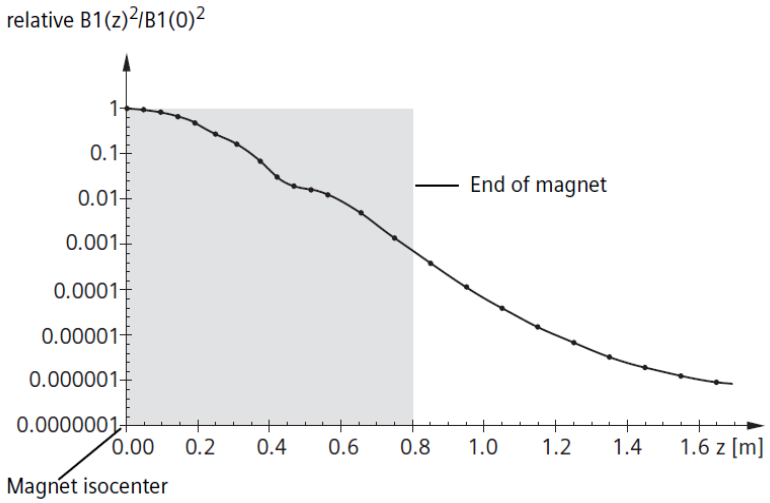

Figure 3. RF power distribution along patient axis for Siemens Avanto. Area shaded in gray indicates length of magnet. Ratio $B_1(z)^2/B_1(0)^2$ provides worst-case estimate of SAR contribution to person positioned at distance z from isocenter. SAR contribution relative to SAR applied to person in center of bore. For example, person standing in front of system aperture absorbs maximum of 0.2% of RF power applied to patient scanned in center of bore (Siemens 2004).

SAR limits have been established by the International Electrotechnical Commission (IEC) (Table 2). "Normal" operating mode means none of the outputs have a value that my cause physiological stress to patients. In "First Level Controlled" operating mode, one or more outputs reach a value that may cause the patient physiological stress that must be controlled by medical supervision. Although a current accurate patient weight and height must be entered for the scanner to calculate an accurate SAR, each MR manufacturer differs as to how SAR is estimated. Hence the value reported by the scanner should not be taken as a solid "limit" on safety – it should be taken as a quantitative estimate with some degree of inaccuracy (Allison 2015).