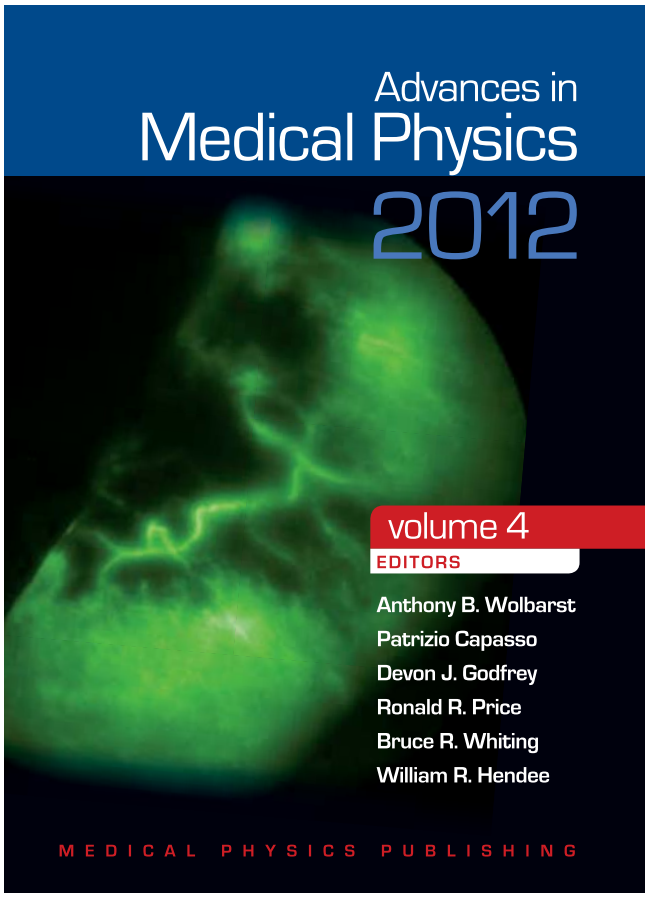


Here is a sample chapter from this book.

CHAPTER 11

Current Issues in MRI Safety

Michael C. Steckner, Ph.D., M.B.A.
Senior Manager, MR Research
Toshiba Medical Research Institute USA, Inc.
Cleveland, Ohio

"I ought to say," explained Pooh as they walked down to the shore of the island, "that it isn't just an ordinary sort of boat. Sometimes it's a Boat, and sometimes it's more of an Accident. It all depends."

"Depends on what?"

"On whether I'm on the top of it or underneath it."

—A.A. Milne

11.1 Introduction

Since its commercial inception in the 1980s, Magnetic Resonance Imaging (MRI) has proven itself to be a remarkably powerful and statistically safe diagnostic modality. Half a decade ago, a British Government assessment suggested that there were then over 20,000 MR units in the world (IOP 2005). At the time of this writing, it is estimated that some 30,000 are in operation and, despite the current global economic downturn, this number will doubtless continue to increase. An MRI system can typically scan dozens of patients a day, which means that tens of millions are being examined each year; so well over 100 million patients having been studied to date, with relatively few injuries or deaths.

Still, MRI machines are not perfectly safe. People have suffered minor or severe injuries or died from ferrous objects flying toward the main magnet; aneurism clips wrenched out of place; adverse behavior of implanted devices; asphyxiation following the unplanned release of magnet cryogens; untoward contrast agent reactions; and other causes (FDA 2011).

This chapter focuses on the challenges of protecting patients from the effects of strong MRI attractive forces on implantable devices such as pacemakers; it will discuss how proper testing and the appropriate labeling of such devices is a key action that leads to safer scanning. The chapter also addresses what the MR industry is doing to support the ongoing efforts of the active implant industry to produce devices that work in and around MR scanners.

11.2 Displacement (or Attractive) Forces Safety

Historically, MRI manufacturers have contraindicated the scanning of patients with implanted devices (IEC 2002) for multiple reasons, such as concern that displacement of the object would injure the patient, or that the device may distort the radiofrequency (RF) magnetic fields and cause unsafe levels of local internal heating. There have been many reports of injuries or significant pain caused by interactions of implant devices with MRI machines (FDA 2011).

A number of implant manufacturers have tested their devices with standard methods and received MR Conditional labeling approval from regulatory agencies (ASTM 2002, 2006a, 2006b, 2007). With such approved labeling, it would be technically possible for the users of a specific MR scanner to compare the limitations noted in the device labeling with the characteristics of the MR scanner to be used and determine if the patient could be safely scanned per device manufacturer guidelines. The published data for MR scanners, however, was originally intended for applications other than implanted device conditional labeling (IEC 2010). Thus the available information may be applied improperly during the testing of the device, or interpreted incorrectly when determining if it is safe to scan the patient.

This section first defines MR Conditional labeling, then clarifies the attractive forces situation as understood from the MR manufacturers' perspective. The process regarding the medical decision to scan the patient is beyond the scope of this chapter.

11.2.1 MR Conditional Labeling

Currently, there are three terms that define how an object or device is to be considered with regard to MRI safety: MR Safe, MR Unsafe, and MR Conditional. The intent of these three categories is to define any object as always safe around any MR scanner, as always unsafe around any MR scanner, or those objects that under certain specific conditions do not cause any known hazards. These terms are defined in an American Society for Testing and Materials International (ASTM) standard (ASTM 2006c) as follows:

- **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 specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), RF fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.
- **MR Safe:** An item that poses no known hazards in all MR environments. MR Safe items include nonconducting, nonmagnetic items such as plastic Petri dishes. Someone can demonstrate an object to be MR Safe by providing a scientifically based rationale rather than test data.
- **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.

Figure 11–1 shows the three symbols for MR Safe, MR Conditional, and MR Unsafe. The black and white versions are permitted variants.

Most implanted devices are in the MR Conditional category. It is a challenge to define test conditions and simple criteria by which a pass/fail or critical threshold value can be used to determine MR Conditionality. Ideally, the definition of the limiting condition is sufficiently simple that relatively simple device labeling and MR system specifications can be unambiguously interpreted.

11.2.2 The Attractive (or Displacement) Forces Around an MRI

Given that the reader has likely experienced the attractive forces created by magnetic fields on ferrous objects, it is unnecessary to explain the mechanism in any detail. However, it is important to understand how the displacement

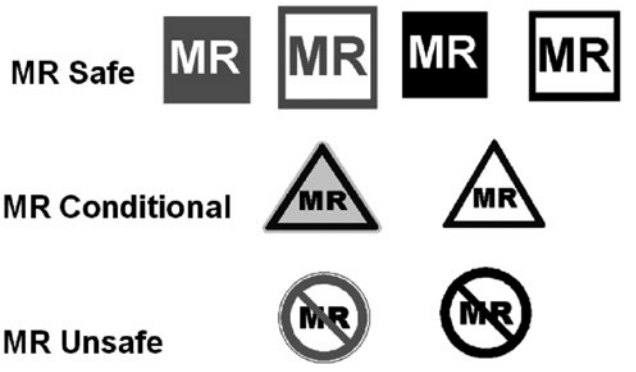


Figure 11–1. The three symbol sets for MR Safe, MR Conditional, and MR Unsafe. (Courtesy of Dr. Terry Woods, FDA.) See COLOR PLATE 40.

forces vary around an MR scanner, as they can change rapidly from powerful to negligible in a short distance.

The advertised field strength (e.g., 1.5 tesla (T), 3T, etc.) of an MR scanner occurs at the center of the imaging volume. Outside of that volume, the field strength generally drops off to negligible levels not too far from the magnet. Modern magnets are designed to cause a rapid field roll-off, called the "Spatial Field Gradient" (SFG), so that they can be situated in the smallest possible space, for economic reasons. Such magnets are called *self-shielded*, and they actually consist of two co-linear magnets coexisting closely within the same container. The "inner" magnet creates the desired imaging field, whereas the "outer" one is designed to null it everywhere else. The inner and outer magnets are designed to work together to achieve the target magnetic field distribution simultaneously in the imaging volume and the space external to the magnet.

The SFG is to be distinguished from the gradients that are applied intentionally for spatial encoding during an MRI scan. These two differently created gradients share the same units of *magnetic field/distance*. It is the spatial encoding gradients that are responsible for the loud knocking sound heard during a scan. It is important that users carefully check which system specification they are consulting when analyzing the MR Conditional labeling of the device in question.

The magnetic field is created with discrete wire bundles—typically 10 bundles in a conventional cylindrical (i.e., superconducting) magnet. Each of these produces a magnetic field "hotspot" in the immediate vicinity, but they sum at a distance to provide a highly homogeneous field in the imaging volume and rapid field roll-off outside the magnet.

There is only a small distance between external surfaces of the container that holds the magnet windings and the actual magnet windings themselves. For both conventional cylindrical magnets and vertical-field magnets, the strongest fields are found around the edges of the patient entry aperture or at the back end (service) aperture. For a cylindrical magnet, there are two relatively large wire bundles of different radii in close proximity at both the patient and the service aperture. The highest local maxima in the patient-accessible space (with magnet covers on) can exceed the nominal field strength of the magnet, especially with vertical-field magnets. The local maxima might even be higher under the covers when even closer to the wire bundles. For precise details of any specific magnet, consult the system manual or contact the vendor.

The reader might intuitively assume that the strength of the magnetic field is the only determinant of displacement forces. In fact, the rate at which the magnetic field drops off is also a determinant of displacement forces. Furthermore, the displacement forces on an object are also a function of the material type (ferromagnetic, diamagnetic, or paramagnetic), and whether or not the material is magnetically saturated. Displacement forces vary as a function of the SFG, which, for a conventional cylindrical magnet, varies greatly around the maxima. Thus, in one position the attractive forces may be acceptable (e.g., one can easily hold on to the item) but in a slightly different position, the forces may tear the item from your grasp no matter how tightly you hold it. If you need a little more convincing about the attractive forces of an MRI magnet, check out the article by Sobel et al. (1992), which shows how a heavy-duty block and tackle were not able to pry a floor polisher from a magnet. The rapid change of attractive forces may have also been a factor in the death of a young boy hit by a flying oxygen tank (YouTube 2011). Please do not underestimate the attractive forces of an MRI magnet, or how greatly the forces can vary with small changes in position.

By the international MR safety standard that is about to come into force (IEC 2010), and the current edition (IEC 2002), MRI manufacturers are obligated to provide certain technical details about the system, listed in the "Compatibility Technical Specification Sheet" (CTSS). With regards to displacement forces, the standard states that the CTSS "shall be provided with sufficient information to enable testing the proper operation of peripheral equipment" where "peripheral equipment" are power injectors, anesthesia equipment, etc. It is noteworthy that there is no discussion of implants. The original intent of the standard was to assist peripheral device equipment manufacturers; unfortunately, as will be discussed later, the information required by the CTSS is sufficient for those peripheral device purposes but not ideally suited for implanted device testing purposes. In part, the CTSS requires:

> The position where the spatial gradient of the main magnetic field is a maximum, and the values of B_0 and the spatial gradient of B_0 at that location. At this location the force on a saturated ferromagnetic object resulting from the spatial gradient of the main magnetic field is maximum.
>
> The position where the product of the magnitude of the magnetic field B_0 and the spatial gradient of B_0 is a maximum and the value of B_0 and the spatial gradient of B_0 at

> that location. At this location, the force on a diamagnetic or paramagnetic object, or a ferromagnetic material below its magnetic saturation point, is a maximum.[1]

The standard does not explicitly specify which scientific units to use, which has resulted in more end user confusion, as will be discussed later. By convention, these international standards use SI units (International System of Units). The newest magnet designs are generating SFG values of in excess of 18 tesla per meter (T/m) for conventional cylindrical magnets and in excess of 25 T/m for vertical field systems.

11.2.3 Testing and Scanning the Device

The testing of devices for displacement forces is defined in ASTM standard F2052 (ASTM 2006a). The intent is to compare the displacement or magnetic force (F_d or F_m) with that of gravity (F_g). The standard does not explicitly state that the forces must be perpendicular, but their diagram, shown here as Figure 11–2a, indicates it clearly. If the forces were not perpendicular, a mathematical correction could be applied. Ideally, the test would be conducted where the displacement force is strongest but, at that point, gravity and displacement forces are not perpendicular. Note that as described above, the CTSS requires the maximum displacement force location, not the location where the displacement force and gravity are perpendicular. For a conventional cylindrical MR system, the displacement force and gravity are perpendicular on a line that passes through magnet isocenter (the middle point of the patient imaging space) coaxial with the long axis of the patient bore space, as shown in Figure 11–2b. The current edition of the ASTM standard does not provide testing guidance for vertical-field units.

The point of strongest displacement force for an MRI system is close to the edge of the aperture, and it is not horizontal. Some device testing may be performed at this point of maximum displacement force, as shown in Figure 11–3, but it is not known if the results were corrected for actual force angles (Shellock et al. 2009). Per reference, the test results might then result in a device label that states "Spatial gradient field of 720 gauss/cm or less," which happens to be one commonly reported test value (Shellock et al. 2009). We assume that the 720 gauss per centimeter (G/cm) value represents the SFG at the position of testing, which is considerably smaller than the 18 to 25 T/m SFGs noted above for the newest magnet designs. Note the different units between 720 G/cm and 18 T/m, which are explained below. Also, note that the SFG values given in the previous section per CTSS requirements are system maxima, not the value where the force of gravity and magnetic attraction (ASTM test position) are perpendicular.

If the deflection angle is 45 degrees, assuming the test situation of Figure 11–2a, the forces of displacement and gravity are equal ($F_d = F_g$) and the total force acting on the device is 1.4* F_g. If the deflection angle is <45 degrees, as shown in Figure 11–3, then ($F_d < F_g$) and if the deflection angle is >45 degrees, then ($F_d > F_g$). By convention, the device is deemed safe from a displacement force perspective if the deflection angle <45 degrees. However, if the deflection angle is >45 degrees, further investigation may be needed to determine conditions at which it may become unsafe.

[1] IEC 60601-2-33 ed. 3.0. Copyright © 2010 IEC Geneva, Switzerland. www.iec.ch.

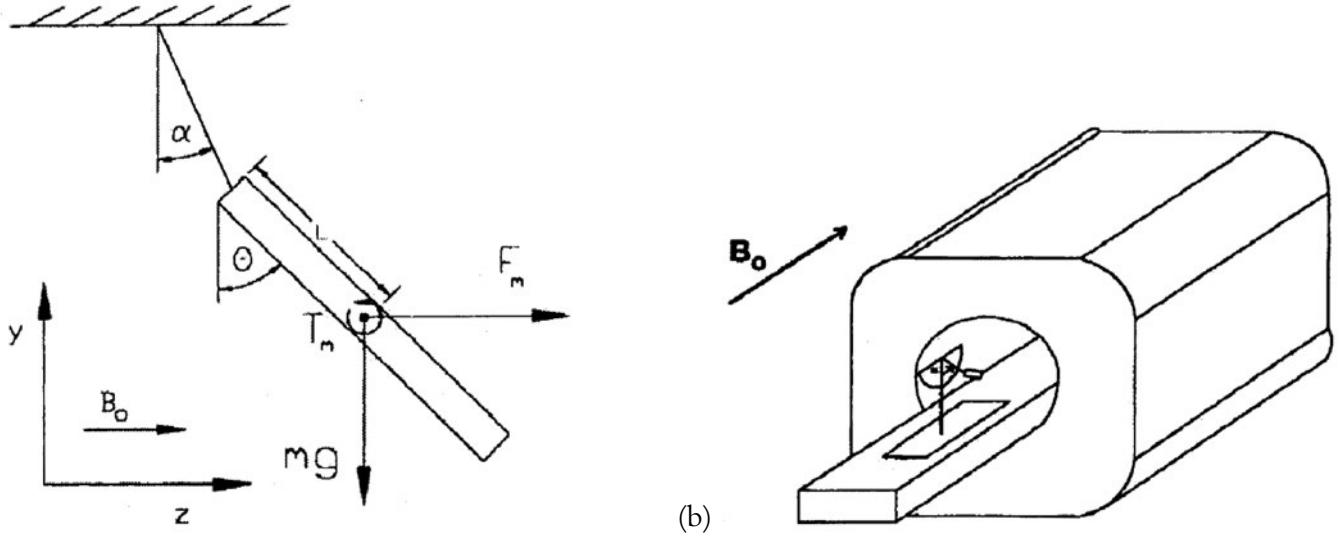


Figure 11–2. Two diagrams showing a device testing configuration for the determination of magnetically induced displacement forces (F_m). (a) shows the testing configuration where gravity is orthogonal to the magnetically induced displacement force. (b) shows approximately where to position the test fixture to achieve the configuration shown in (a). (Reprinted, with permission, from *ASTM F2052 05(2009)e1, Standard Specification and Test Methods for Bioabsorbable Plates and Screws for Internal Fixation Implants,* copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. A copy of the complete standard may be obtained from ASTM, www.astm.org.)

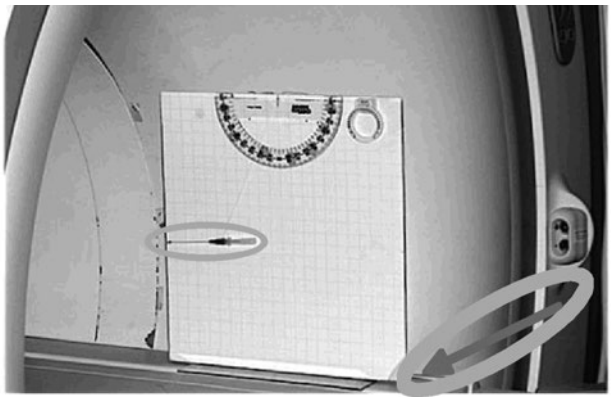
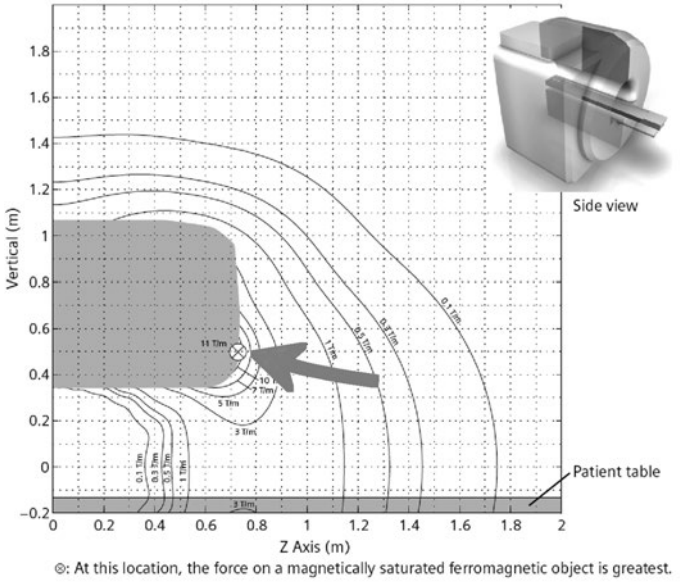


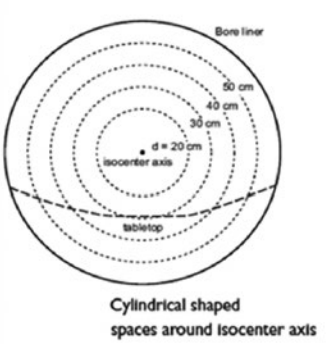
Figure 11–3. A device undergoing magnetically induced displacement force testing. The device in the small gray oval is attached to a just visible fine thread mounted to the center of the test fixture protractor. Note the test fixture mounted at the edge of the patient couch near the magnet cover, as shown by the arrow within the large gray oval. (Reprinted from *Radiology,* vol 253, issue 1, "MR labeling information for implants and devices: explanation of terminology," F. G. Shellock, T. O. Woods, and J. V. Crues 3rd, pp. 26–30, © 2009, with permission from the author and Radiological Society of North America (RSNA), Oak Brook, IL.)

Given that the critical decision angle is 45 degrees, it would be ideal to not limit the MR Conditional labeling to the SFG test value as assumed above, especially if the testing conditions are lower than the system's published SFG value. One possible solution is computing the critical SFG value that would increase (or decrease) the measured deflection angle to the 45-degree critical decision angle. Of course, the scaling SFG numbers must be accompanied by appropriate error analysis, especially for those devices that have very low deflection angles and thus higher critical SFG values. By such analysis, those devices with low deflection angles could be scanned in systems with higher SFG values. For example, the critical SFG for the device in Figure 11–3 could be perhaps twice as large as the SFG at the testing location. Correction for actual relative force angles is assumed here. In the case of Figure 11–3, it is not known if the magnetic displacement force is pointing up and artificially increasing the deflection angle (conservative), or pointing down and artificially decreasing the deflection angle (not conservative). Typically, device labeling does not indicate whether the limiting SFG is corrected or uncorrected, exposed field or scaled result. Scaling the measurements with appropriate error analysis is straightforward, but does nothing for devices already in use, unless they were all relabeled with regulatory approval. It would also be possible to use maps showing the SFG values at multiple locations around the magnet and to seek a spatial trajectory that keeps the MR Conditional labeled device within limits, with risks as described below.

Some MR vendors have started to voluntarily release SFG maps at the request of users, with some of the examples shown in Figures 11–4. Figure 11–4a shows one cut plane through a magnet, with lower left corner positioned at isocenter. In



(a)



	[T/m]	[Gauss/cm]
On the patient axis	2.5	250
Cylindrical shape of 20 cm diameter	2.6	260
Cylindrical shape of 30 cm diameter	2.8	280
Cylindrical shape of 40 cm diameter	3.1	310
Cylindrical shape of 50 cm diameter	3.6	360

(b)

Figure 11–4. Two SFG maps from different conventional cylindrical magnet MRI systems. (a) A sagittal cut through the magnet (as visualized in the insert). The contour plot shows only slightly more than one quadrant in the sagittal plane where patient isocenter is near the bottom left of the contour plot. The contour lines show points of equal SFG (T/m). Given magnet symmetry, the same SFG map applies to the other quadrants, with appropriate mirroring. The green arrow points to the location of highest SFG, where the attractive force on a magnetically saturated ferromagnetic object is greatest. (b) The maximum SFG as a function of radial distance from isocenter; the location on the cylindrical shell is not identified. The diagram is from the perspective of looking into the bore of a cylindrical magnet system. (Reprinted from Steckner et al. (2011).)

Figure 11–4b, another map indicates the maximum as a function of radial distance from isocenter. If SFG maps are used to determine a patient trajectory, it is essential to control all patient movements. If, for example, a patient with a device in the head quickly sat up while on the MR scanner couch, there is the potential that the patient could transition through the highest SFG region known to be near the magnet aperture and potentially exceed the device SFG value. It is essential to correctly interpret the SFG maps and associated issues if using this approach.

Based on the testing results, typical MR Conditional labeling for a device would indicate something like "Spatial gradient magnetic field of 720-gauss/cm or less" as an acceptable scan condition (Shellock 2008). That, incidentally, does not match the SFG values described in the previous section. Results specified in G/cm are 100 times larger than T/m results. To reduce confusion some MR manufacturers have started to quote SFG figures in both units, a good idea. Optimally, test houses will provide their results in both units, and device manufacturers will label their devices in both units.

11.3 Active Implant Safety and Other Changes to the MR Safety Standard to Support Implants

Patients with active, electrically powered implants may have medical needs that might benefit from MR images. It is claimed by the active implant device community that presently 1.5 million Americans have pacemakers, of whom approximately 200,000 opt out of MRI scans every year (DOTmed® 2011).

Historically, both active and passive implants have been considered an MRI contraindication because of concerns about potential attractive forces on implants, potential concentration of RF magnetic fields causing intense and unsafe levels of local heating, and permanent damage to the implant (if active).

Few active implants have MR Conditional labeling, but there have been recent changes to the MR safety standard that support MR Conditional active implants (IEC 2010). Likewise, recent standards activity may help guide the future development of active implants, and other ongoing discussions are being carried out on how to enable the MR scanning of patients with appropriately labeled active implants.

11.3.1 Recent Changes to the MR Safety Standard

Until recently, active implants have been contraindicated by the MR safety standard. There have been off-label uses of these devices with varying degrees of success, and there are ongoing efforts to design new active implants that function in an MR device, with certain scanning limitations. Consequently, the MR safety standard now notes the significant risk associated with scanning patients having either active or passive implants, and it directs the operator to study the device labeling for further instructions. Note that patients should still be screened for devices that are contraindicated. MR vendors may continue to contraindicate devices, but are in the process of releasing more technical information regarding the scanner and sequences at the console, and also in the scanner technical documentation, specifically tailored to the needs of implanted devices. This information would then enable the implant vendors to specify the necessary conditions in their labeling under which their implants could enter the MR scanner and provide the MRI operator the necessary information to confirm the performance characteristics of the particular scanner being used.

11.3.2 The Compatibility Technical Specification Sheet

The original intent of the Compatibility Technical Specification Sheet (CTSS) is to provide sufficient information "to enable testing the proper operation of peripheral equipment" (IEC 2010). Peripheral equipment relates to power injectors, in-room anesthesia equipment, etc. In addition, recent European regulatory activity related to worker safety has resulted in additional information being required in the CTSS. The list of information now required includes: a description of the magnet (type, field strength, bore dimension, spatial distribution of surrounding field, position of maximum spatial change of field distribution, etc.), the gradients (type, amplitude, slew, etc.), RF system (types of coils, amplifier power levels. etc.). Also, the CTSS also suggests each MR vendor provide "compatibility protocols" that can be routinely run on the scanner that would enable the peripheral equipment manufacturer to test the functionality of its equipment, particularly in more extreme regions of the MR scanner performance envelope. Such tests do not guarantee that the peripheral equipment will function properly nor do the tests analyze the impact the peripheral equipment will have on image quality.

It is anticipated that future editions of the safety standard will call for additional information as broad agreement is found on what is necessary and appropriate, and is suitably coordinated with other standards to minimize end-user confusion and to enhance patient safety.

11.3.3 Other Changes to the MR Safety Standard

The most recent edition of the MR safety standard released in early 2010, and to be fully adopted by around 2013, has introduced an "About" function similar in concept to what is found with many software packages and will be located on the operator's console. It will provide hardware and software specification information, or where to find the information in the system documentation, some information already discussed in the CTSS, and other details such as the nominal frequency range of operation per nuclei, and the maximum gradient output in specific regions (IEC 2010). The intent is

to make information quickly and easily available to the MR operator.

There have also been changes to the standard to provide more accurate information for existing needs. Some implanted devices have been labeled with Specific Absorption Rate (SAR) limitations. The purpose of SAR is to ensure that a patient is not excessively heated by the RF magnetic fields used to create the MR signal. One aspect of SAR control involves ensuring that the heating of a patient will not overwhelm his or her thermoregulatory system (the so-called "first-level controlled mode"). An intermediate limit (the so-called "normal mode") is also available for those patients who are suspected of having a compromised thermoregulatory system (e.g., age, significantly overweight, or taking certain medications) and cannot tolerate higher heat levels. The intent of the standard is to ensure that it is known in which of the two modes the patient is scanned. The actual SAR value is not required by the MR safety standard, but most MR vendors display the value.

It is difficult to calculate SAR accurately and the MR vendors have developed various proprietary models to satisfy the needs of their respective systems. There are three challenges associated with providing an SAR value. First, there are relatively large errors associated in measuring where RF power is distributed during normal operations. Second, an MR operator may be provided with the incorrect information on weight, or accidentally enter it incorrectly. Last, the Normal and First Level Controlled Operating Modes specify "not to exceed" SAR values; thus MR vendors introduce conservative factors to ensure that the system is operating in the specified mode.

Given that SAR was the only system indication related to RF power deposition, it was adopted by various device vendors for their MR Conditional labeling. SAR is a poor indicator for device heating (Nitz et al. 2005). The interaction between devices and the RF magnetic fields can be more precisely understood by quantifying the magnitude of the RF magnetic fields. The newest edition of the safety standard will now require the display of the maximum "B1+ rms" averaged over the worst 10-second period of the scan, where B1+ is the technical label for the RF magnetic fields required for MRI. A root-mean-square (rms) description of the RF magnetic field is a slightly better measure for device purposes. Unfortunately, "B1+ rms" is still of limited use because it can only be calculated for the ideal case, assuming the MR system is perfectly calibrated on an ideal signal source. Each patient uniquely distorts the B1 field spatially, and the consequences for implanted devices are complex. It will be necessary for the device vendors to understand these complexities and to determine appropriate safety margins for the MR Conditional labeling.

Some of the recent changes to the MR safety standard have been driven by European worker regulatory activities, but may also be of potential interest to the implant vendors. There is a concern about worker exposure to the encoding gradients and the RF magnetic fields. The latest edition of the safety standard requires MR vendors to publish information describing the fields caused by both system components outside of the normal patient imaging space. For spatial-encoding gradients, an imaginary cylinder describing the imaging volume is extended outside of the magnet and values are specified on the surface of the virtual cylinder. For the RF magnetic fields, a conical surface is defined with the point at imaging isocenter and angle defined by the patient aperture size.

Additionally, three new symbols have been introduced (Figure 11–5). Their intent is to provide a universally recognizable symbol for the different types of RF coils used in MR systems. Those that also include a transmitting function are of particular interest to implant vendors. Use of the symbols is not mandatory, but provision of a recognized set of symbols will hopefully minimize confusion.

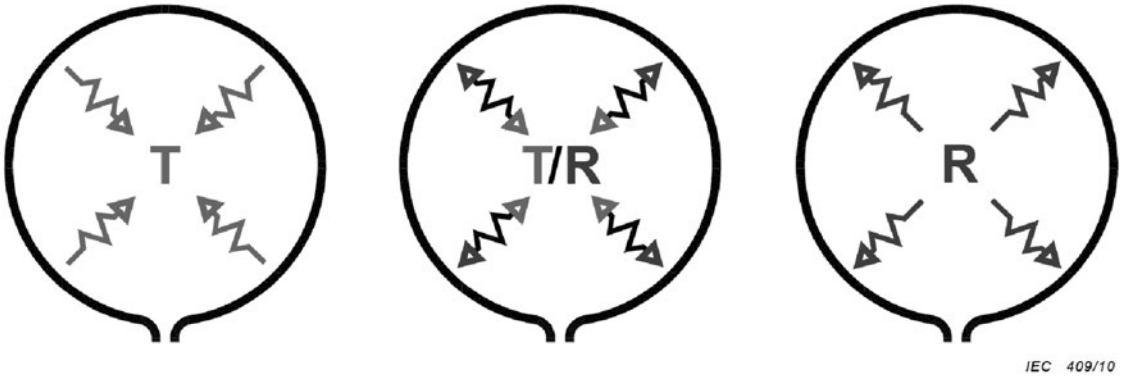


Figure 11–5. IEC-defined symbols for RF coils. T denotes RF coils with transmit capability (active "hot" red color) and R denotes coils with receive capability (a passive "cold" blue color). Note that a coil marked with transmit capability may be used just as a receive coil or just as a transmit coil. IEC 60601-2-33 ed. 3.0. Copyright © 2010 IEC Geneva, Switzerland. www.iec.ch. See COLOR PLATE 41.

11.3.4 Possible Future Changes to the MR Safety Standard

Work on the next edition of the MR safety standard has just begun. Ongoing discussions will provide for more information to support implants and new control features, and will describe advances in patient heating safety. New research tools have expanded knowledge about patient heating and advances in MR RF technology have created new possibilities that have spawned extensive safety control discussions. While it is too early to predict what will eventually be put into the next edition of the safety standard, it is useful to briefly describe some of the activities and possible future directions.

To support the development of active devices needing MR Conditional labeling, The International Organization for Standardization (ISO) is in the process of publishing the first edition of a "Technical Specification" (ISO 2012). This document was prepared by members of various ISO committees responsible for active implant devices and by members of the International Electrotechnical Commission (IEC) committee responsible for the MR safety standard. Since there is not much experience on the development of MR Conditional active devices, there is insufficient information to develop a full standard at this time. The Technical Specification is a first attempt to build the necessary understanding of all relevant issues by presenting a series of device/MRI interaction hazards and a series of test methodologies for evaluating device operation against these hazards. Specific compliance criteria and the determination of risk resulting from device behavioral response are not specified, so it is the responsibility of the user to determine what appropriate actions are required based on test results.

In some cases a tiered approach has been created to potentially simplify testing. For example, a relatively simple test may conclusively determine that the requirements could be exceeded with significant margin for error. Tighter error margins may require more sophisticated tests. Some of the tests are not fully defined as some have not been fully reduced to specific implementations. By publishing a framework, it is hoped that the relevant technical community of users can provide feedback to the standards committee on the suitability of the various tests. The intent is to iterate the Technical Specification and release a full Standard once experience of its use in practice has occurred. Given recognized and accepted tests, device manufacturers can make claims based on these tests for regulatory agency evaluation. This new Technical Specification should complement by other device standards that provide more specific guidance appropriate to certain types.

Once all of these device-device and device-patient interactions are understood and engineering solutions rigorously tested, it will be necessary to produce an implant with simple labeling that clearly indicates the safe MR operating limits. These "MR Conditional" labeling statements will likely include the static magnetic field strength, maximum spatial encoding gradient field strength and slew rate, and maximum permissible RF field amplitude. Thus MR scanners will require a new layer of control that matches the MR Conditional labeling of the device. These new limits will impact sequence performance in a different way. It will also be necessary to provide the MR operator the information required so that device-by-device scanning decisions can be made. Presently, there is typically no direct link between such MR Conditional labeling claims, MR scanner operational control, or MR scanner technical information.

Current MR/implant industry discussions are focusing on which electromagnetic field specifications are important and the appropriate threshold values. There is also discussion within the MR vendor community on how to actually represent these new proposed limits to the user as it represents a significantly different way to constrain sequence operation. Currently there are two modes of MR operation: normal and first-level controlled operating mode. First-level mode is entered, if the MR operator approves, if the sequence has the remote possibility of causing peripheral nerve stimulation in the patient as a result of gradient amplitudes and switching rates. First-level mode can also be entered, if the MR operator approves, if the sequence has the potential to moderately warm the patient. Warming is of concern if the patient's thermoregulatory system is compromised and might not be able to tolerate the additional heat burden. It is the responsibility of the MR operator to determine if the patient is physiologically capable of being scanned in the first-level mode. If any new non-physiologic–based MR scanner limits are introduced, the active implant device labeling and instructions would have to be fully understood by the MR operator and strictly followed as the consequences of incorrect scanner operation could be quite serious.

Because of these issues and the long MR history of contraindicating active implants, the IEC MR safety committee responsible for IEC 60601-2-33 (IEC 2010) are currently discussing one additional optional mode of operation with a special effort to make the associated user interface as nearly identical as possible across all MR scanners to minimize confusion in the MR user community. In simple terms, the electromagnetic field limits being currently discussed would approximate normal mode limits and could be described as limiting MRI to circa 1990s-equivalent imaging.

Based on the data collected, future higher performance levels and/or additional levels could be envisioned as active implant device immunity increases. There have also been discussions about future lower performance levels to enable existing devices to be scanned with appropriate control. This is all subject to standards passing expert vote and regulatory

agency approval. In the future we can hope that all implants can be designed to performance levels in excess of any MR operations, thereby eliminating the need for any special intermediate control levels. Until then, additional controls and caution will be necessary. It is important that all involved with the scanning of MR Conditional devices stay informed of all necessary information.

11.4 Acknowledgments

The author thanks the International Electrotechnical Commission (IEC) for permission to reproduce information from its International Standard IEC 60601-2-33 ed. 3.0 (2010).

11.5 References

ASTM (2002). American Society for Testing and Materials International. Designation: ASTM F2182-02a. Standard Test Method for Measurement of Radio Frequency Induced Heating near Passive Implants during Magnetic Resonance Imaging. West Conshohocken, PA: American Society for Testing and Materials International, 2002.

ASTM (2006a). American Society for Testing and Materials International. Designation: ASTM F2052-06e1, standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment. West Conshohocken, PA: American Society for Testing and Materials International.

ASTM (2006b). American Society for Testing and Materials International. Designation: ASTM F2213-06. Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment. West Conshohocken, PA: American Society for Testing and Materials International, 2006.

ASTM (2006c). American Society for Testing and Materials International. Designation: ASTM F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. West Conshohocken, PA: American Society for Testing and Materials International, 2006.

ASTM (2007). American Society for Testing and Materials International. Designation: ASTM F2119-07. Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants. West Conshohocken, PA: American Society for Testing and Materials International, 2007.

DOTmed® (2011). "FDA approves first MRI-compatible pacemaker." February 9, 2011. http://www.dotmed.com/news/story/15333?utm_campaign=campaign&utm_source=2011-02-10&utm_medium=email. Accessed February 2, 2012.

FDA (2011). Food and Drug Administration. MAUDE – Manufacturer and User Facility Device Experience. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

IEC (2002). International Electrotechnical Commission. IEC 60601-2-33, Second edition 2002-05, Medical Electrical Equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. Geneva, Switzerland. http://www.iec.ch/.

IEC (2010). International Electrotechnical Commission. IEC 60601-2-33, Third edition 2010-03, Medical Electrical Equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis. Geneva, Switzerland. http://www.iec.ch/.

ISO (2012). International Organization for Standardization, ISO/TS 10974 ED1, Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device. Geneva, Switzerland. http://www.iso.org. Under development (Target date: June 14, 2012).

IOP (2005). Institute of Physics. Curiosity-Driven Research: MRI (2005). http://webarchive.nationalarchives.gov.uk/+/http://www.berr.gov.uk/files/file28050.pdf.

Nitz, W. R., G. Brinker, D. Diehl, and G. Frese. (2005). "Specific absorption rate as a poor indicator of magnetic resonance-related implant heating." *Invest Radiol* 40(12):773–776.

Shellock, F. G. (2008). *Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2008 Edition*. 1st edition. Los Angeles, CA: Biomedical Research Publishing Group, 2008.

Shellock, F. G., T. O. Woods, J. V. Crues 3rd. (2009). "MR labeling information for implants and devices: Explanation of terminology." *Radiology* 253(1):26–30.

Sobel, D. F., M. Larsen, J. Zyroff, S. Seat, C. Deblois, P. Garver, T. Gonzalez, J. Guy, S. Kleiman, H. Knowles et al. (1992). "Buffing up MR images." *AJNR Am J Neuroradiol* 13(1): 301–302.

Steckner, M. C., G. Frese, J. van den Brink, and D. J. Schaefer. (2011). "Interpreting 'Spatial Field Gradient' MR Conditional Device Labeling and IEC 60601-2-33 3rd edition Fringe-Field Compatibility Technical Specification Sheet Requirements" in Proc. 19th Annual Meeting of the International Society for Magnetic Resonance in Medicine (ISMRM), Montreal, Canada, Abstract 4658, 2011.

Woods, Terry. Private communication, FDA. Chair of the ASTM committee.

YouTube, 2011. Colombini MRI Case: Root Cause Analysis – Tobias Gilk & Reliability Center. http://www.youtube.com/watch?v=0nA-UceHMqc.