Review Article

Standards for Medical Devices in MRI: Present and Future

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The purpose of this review is to define the current standards addressing safety of medical devices in MRI and to describe ongoing standards development efforts. The American Society for Testing and Materials (ASTM International) began developing standard test methods for determining the MR safety of medical devices in MRI in 1997. To date, five ASTM standards addressing testing and marking medical devices and other items for use in the MR environment have been published. International Standards Organization (ISO) 14630, the general requirements standard for nonactive surgical implants, is currently being revised to include information about MR safety of passive implants and to reference the ASTM standards. To address the unique safety issues of active implants, and in particular, active implants with leads, like pacemakers and neurostimulators, a joint working group between ISO TC150/SC6 on active implants and International Electrotechnical Commission (IEC) SC 62B MT40 on magnetic resonance equipment for medical diagnosis is working to develop a technical specification for active implantable medical devices (AIMDs) in MRI. While much progress has been made, work still needs to continue to develop a complete body of test methods to allow the evaluation of the safety of medical devices in the MR environment.

Key Words: MRI safety; medical devices; implants; MR environment; standards; standard test methods
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AS THE USE OF MRI spread rapidly in the 1990s, the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) recognized the need for standards to address the safety of implants and other medical devices in the MR environment. In 1997, CDRH requested that ASTM (American Society for Testing and Materials, now ASTM International) develop suitable test methods and guidance to address safety and effectiveness issues for medical devices in the MR environment. The request led to the formation of ASTM task group F04.15.11 on the safety and compatibility of implant materials and medical devices in the magnetic resonance (MR) environment. The group first met in 1998 and decided to develop test methods for evaluating magnetically-induced displacement force and torque, radio frequency (RF) heating, and image artifact. To date, they have written and published five ASTM standards addressing testing and marking medical devices and other items for use in the MR environment. International Standards Organization (ISO) 14630, the general requirements standard for nonactive surgical implants, is currently being revised to include information about MR safety of passive implants and to reference the ASTM standards (1). Concern about the safety of active implantable medical devices (AIMDs) in the MR environment led to the formation of a joint working group between ISO TC150/SC6 on Active Implants and International Electrotechnical Commission (IEC) SC 62B MT40 on magnetic resonance equipment for medical diagnosis, which held its first ad hoc meeting in early 2007.

The first ASTM MR test method was published in 2000, F2052-00, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment. Since that time, it has been revised to make it appropriate for all medical devices and to include current MR safety terminology, with the latest revision published as ASTM F2052-06e1 (2). Four more MR standards have been published: F2119-01 (3) on evaluation of MR image artifacts, F2182-02a (4) on measurement of RF-induced heating, F2213-06 (5) on measurement of induced torque, and F2503-05 (6) on marking. To proceed as rapidly as possible, the group decided to initially limit the scopes of the test methods to passive implants. Since the initial publication, the force and torque test methods were expanded to include all medical devices. Work is continuing to amend the other test methods to make them applicable for all medical devices, including both passive and electrically active devices as well as implants and devices that are not implanted. In all of the standards development efforts in ASTM, ISO, and IEC, great care is being taken to avoid duplication of effort and to develop a body of standards that will address MRI safety and compatibil-

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ity for the entire spectrum of medical devices and equipment that may be introduced into the MR environment. This effort to develop a complete set of standards without duplication is facilitated by frequent communication between the three standards development organizations, which is made possible by the fact that many of the MR safety experts participate in the ongoing standards development efforts in all three groups.

CURRENT ASTM MR STANDARDS

Terminology

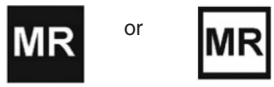
CDRH first proposed definitions for MR safe and MR compatible in "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems," which was released for comment in February 1997 (7). Manufacturers began using the terms to label medical devices for the MR environment. However, in time it became clear that the terms were confusing and were often used incorrectly. To clear up the confusion and because the misuse of the terms could result in accidents that would harm patients or others in the MR environment, the ASTM MR task group developed a new set of terms with associated icons. The new terminology was published in ASTM F2503-05 in August 2005.

The new terms, MR Safe, MR Conditional, and MR Unsafe are defined as follows:

- MR Safe—an item that poses no known hazards in all MR environments. Note: Safe items include nonconducting, nonmagnetic items such as a plastic Petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data (6).
- 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 (6).
- MR Unsafe—an item that is known to pose hazards in all MR environments. Note: MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors (6).

In addition to the terms, the standard introduces corresponding icons, consistent with international standards for colors and shapes of safety signs. The icons, shown in Table 1, are intended to be used on items that may be brought into or near the MR environment as well as in product labeling. The icons may be reproduced in color or in black and white; however, the use of color is encouraged because of the added visibility. The MR Safe icon consists of the letters "MR" in green in a white square with a green border, or the letters "MR" in white within a green square. The MR Conditional icon consists of the letters "MR" in black inside a yellow triangle with a black border. The MR Unsafe icon consists of the letters "MR" in black on a white field inside a red circle with a diagonal red band.

Table 1
Requirements for Colored MR Icons*

Icon geometric shape and appearance	Meaning
A square 	MR safe
An equilateral triangle with radiused outer corners 	MR conditional
A circle with a diagonal bar 	MR unsafe

*Reprinted, with permission, from ASTM F2503-05 (6).

For MR Conditional items, the item labeling will include results of testing sufficient to characterize the behavior of the item in the MR environment. In particular, testing for items that may be placed in the MR environment should address magnetically induced displacement force and torque, and RF heating. Other possible safety issues include, but are not limited to, thermal injury, induced currents/voltages, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, and 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 (6).

Displacement Force

The spatial gradient of a magnetic field produces a displacement force on magnetic objects placed into the magnetic field. This displacement force is responsible for the projectile effect that continues to cause accidents in the MR environment. ASTM F2052-06e1 describes a method for determining the displacement force (2).

The device of interest is suspended by a thin string and moved to the position in the field that produces the greatest displacement (Fig. 1). The angular deflection of the device from the vertical is measured and the deflection force is calculated. If the angular deflection is less than 45°, and the magnetic force is in the horizontal direction, the deflection force is less than the device's weight and it is assumed that any risk imposed by the application of the magnetically-induced deflection force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field (2).

Torque

An MR scanner's static magnetic field produces a torque on an object that acts to align the long-axis of the

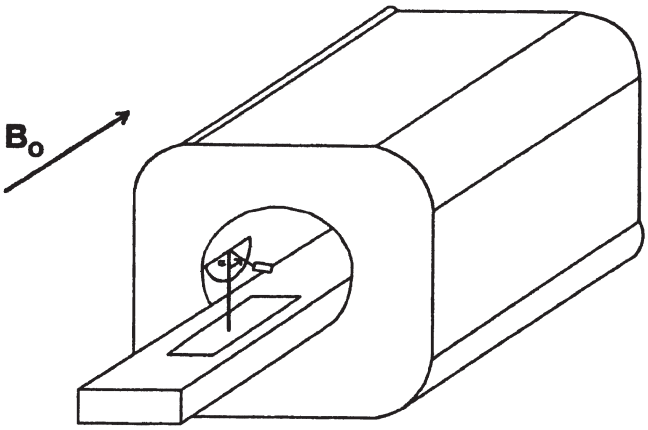


Figure 1. Deflection force test fixture. Fixture may be offset to place test device in location of maximum deflection. Reprinted, with permission, from ASTM F2052 (2).

object with the magnetic field, just as a compass needle aligns itself with the earth's magnetic field. ASTM F2213-06 provides a method for measuring the torque (5). The rationale in F2213-06 describes how the magnetically-induced force and torque are related. If the force is minimal, the torque is expected to also be minimal.

The device, with one principal axis aligned in the vertical direction, is placed on a holder suspended on a torsional spring. The test fixture is then placed in the center of the MR scanner where the static magnetic field is a maximum (Fig. 2). The angular deflection of the holder from its equilibrium position is recorded and the torque is calculated. The frame supporting the spring and holder is rotated through 360°, and the torque as a function of the angle of the device is determined. The measurements are repeated for the other two principal axes of the device to determine the maximum torque. If the maximum torque is less than the product of the longest dimension of the implant and its weight, then the magnetically induced torque is less than the worst case torque on the implant due to gravity. For this condition, it is assumed that any risk imposed by the application of the magnetically induced torque is no greater than any risk imposed by normal daily activity in the Earth's gravitational field (5).

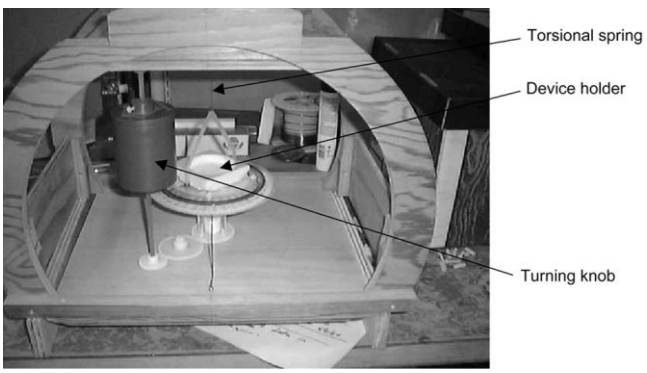


Figure 2. Torque measurement apparatus. The turning knob rotates the torsional spring and device holder. Reprinted, with permission, from ASTM F2213 (5).

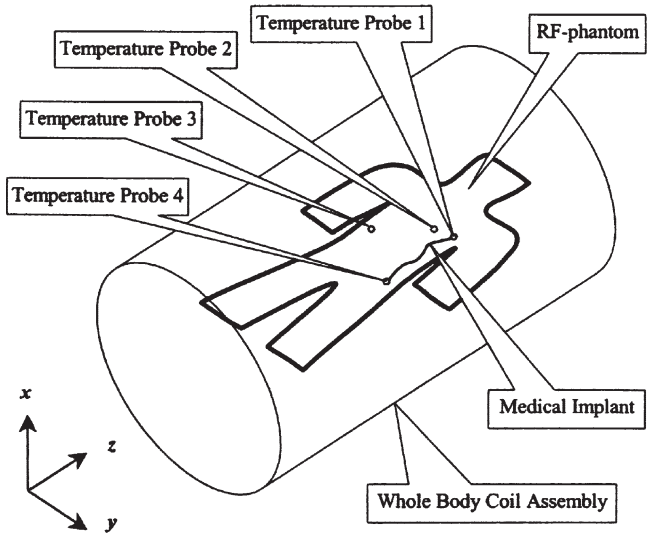


Figure 3. Implant and temperature probe placement in the phantom for testing of RF heating near an implant during MRI. Reprinted, with permission, from ASTM F2182-02a (4).

RF Heating

The RF excitation pulses applied during an MR scan induce currents in the body which heat the body. The SAR, measured in watts per kilogram (W/kg), is defined as the rate at which RF energy is deposited in tissue. The SAR is a function of the frequency, type, and number of the RF pulses, the duration and repetition rate of pulses, and the type of transmission coil and it increases approximately as the square of the frequency (8). ASTM F2182, the test method for measuring RF-induced heating of passive implants was published in 2002 (4). In addition, the joint IEC ISO working group has issued a new work item proposal for a technical specification that will define requirements for the safety and compatibility of MRI for patients with an active implantable medical device. Probably the most critical component of the technical specification is the section addressing RF heating of AIMDs.

To perform F2182, the implant is placed in a gelled saline phantom that simulates the electrical and thermal properties of the body. The phantom is placed in an MR scanner and subjected to an RF field with a SAR of at least 1 W/kg averaged over the volume of the phantom. The temperature rise at worst case locations on or near the implant is measured during at least a 15-minute scan. Some experimentation is required to determine the worst case locations, both for the device within the phantom and for the temperature probes on or near the implant (Fig. 3). The potential for heating is maximized for devices with a length in the range of an odd number of half wavelengths of the MR RF field. For 1.5 T and 3.0 T scanners (with Larmour frequencies approximately 63.8 MHz and 127.7 MHz, respectively), critical lengths can occur for lengths greater than approximately 6 cm. The critical length for a specific de-

vice during a particular MR scan can not be calculated precisely, so it is necessary to evaluate a range of lengths and conditions to determine the worst case conditions for RF induced heating.

A recent work questions the practice of using SAR to guide MRI safety recommendations regarding heating since SAR calculations may differ for different MR scanners (9). To further investigate the issue, the FDA worked with the ASTM MR task group to design and implement an interlaboratory comparison of SAR for different MR systems to better assess the magnitude of the problem. The results of the study show that for an insulated 20-cm-long wire with bare ends, the heating can be up to 48°C above the ambient temperature (ΔT) in the normal operating mode of a 1.5 T MR system (Kainz W., FDA/CDRH, unpublished results). Testing done as part of the interlaboratory comparison has also shown that anatomical placement of the implant inside the phantom does not model worst case heating in the patient (Kainz, W., unpublished results). The results are being used to guide the ongoing effort to revise F2182. It has been proposed that a worst-case local electrical field distribution for an implant in a patient be determined computationally. The implant can then be placed in a position in the ASTM phantom that duplicates those field conditions and heating measurements can be performed to determine heating of the implant. The SAR values displayed on MR scanner consoles are intended to give an upper bound on the amount of energy deposited into a patient and were not intended to be used as a precise value for calculating heating during phantom measurements of implant heating. To avoid errors in using the SAR displayed on the MR scanner console when performing phantom testing for implants, the IEC is considering a proposal to display on the scanner console the root mean square of the RF magnetic field, $B1_{rms}$. The use of $B1_{rms}$ is expected to be a useful metric of the potential for implant heating since the SAR and other heating parameters are proportional to the square of $B1_{rms}$. Device manufacturers might then specify an allowable upper value for $B1_{rms}$ when scanning their implants.

Image Artifact

Image artifact does not generally affect the safety of a device in the MR environment; however, physicians need information about the size and location of image artifacts with respect to the location of the portion of the body that is to be imaged. In addition, many interventional MR procedures require needles or other devices that are visible on the MR image, but which produce small enough artifacts to allow the visualization of the site of the intervention. ASTM F2119-01 identifies a protocol for determining image artifact using standardized pulse sequences (3).

DISCUSSION

In conclusion, over the past seven years, the ASTM task force on MR has evolved into a broad-based international group with members from academia, industry, the medical community, government agencies from the U.S. and other countries, and individuals from countries including the U.S., the U.K., Germany, the Netherlands, and Japan. Many of these members and additional experts in the area of active medical devices are also participating in the joint ISO IEC joint working group to address the safety of AIMDs. ASTM has published five standards addressing the safety of medical devices and other items in the MR environment, and ISO 14630 is being revised to include requirements to address MR safety for passive implants. While the development of these standards has made a significant impact on the evaluation of the safety of devices in the MR environment, the documents will continue to evolve to produce a body of standards that can be used to determine the safety of any device in the MR environment.

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