Designation: F2503 – 23

Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment[1]

This standard is issued under the fixed designation F2503; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice applies to medical devices and other items that are anticipated to enter the magnetic resonance (MR) environment.

NOTE 1—"Medical devices and other items" will be referred to as "items" for the remainder of this practice.

1.2 The practice specifies the marking of items anticipated to enter the MR environment by means of terms and icons, and recommends information that should be included in the labeling.

1.3 MR image artifacts are not in the scope of the mandatory portions of this practice because they do not present a direct safety issue resulting from specific characteristics of the MR examination (see X1.12).

1.4 The values stated in SI units are to be regarded as standard.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 The following referenced documents are indispensable for the application of this practice. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.2 *ASTM Standards:*[2]

F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants (Withdrawn 2022)[3]

F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

2.3 *Other Standards and Documents:*

IEC 60601-2-33 Medical Electrical Equipment—Part 2-33: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis[4]

ISO 14971 Medical Devices—Application of Risk Management to Medical Devices[5]

ISO/IEC Guide 51 Safety Aspects—Guidelines for their Inclusion in Standards[5]

ISO TS 10974 Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device[5]

3. Terminology

3.1 *Definitions:*

3.1.1 *active item*—an item that serves its functions with the supply of electrical power (definition modified from Test Method F2213, *passive implant*).

3.1.2 *cylindrical MR system*—MR system with a substantially cylindrical patient aperture, and a static magnetic field (B_0) aligned with the long axis of the cylinder. **IEC 60601-2-33**

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from International Electrotechnical Commission (IEC), 3, rue de Varembé, P.O. Box 131, CH-1211 Geneva 20, Switzerland, http://www.iec.ch.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

3.1.2.1 *Discussion*—This is inclusive of elliptical patient aperture systems.

3.1.3 *hazard*—potential source of harm. **ISO/IEC Guide 51**

3.1.4 *item*—object that might be brought into the MR environment.

3.1.5 *magnetically induced displacement force*—force produced when an item is exposed to the spatial field gradient. This force may cause the item to translate.

3.1.6 *magnetically induced torque*—torque produced when an item is exposed to a magnetic field. This torque may tend to cause the item to align itself along the magnetic field in an equilibrium direction that induces no torque.

3.1.7 *magnetic resonance (MR)*—resonant absorption of electromagnetic energy by an ensemble of atomic nuclei situated in a magnetic field. **IEC 60601-2-33**

3.1.8 *medical device*—any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of:

(1) Diagnosis, prevention, monitoring, treatment, or alleviation of disease;

(2) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(3) Investigation, replacement, modification, or support of the anatomy or of a physiological process;

(4) Supporting or sustaining life;

(5) Control of conception;

(6) Disinfection of medical devices;

(7) Providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

3.1.8.1 *Discussion*—Products which may be considered to be medical devices in some jurisdictions but not in others include:

(1) Disinfection substances;

(2) Aids for persons with disabilities;

(3) Devices incorporating animal and/or human tissues;

(4) Devices for *in vitro* fertilization or assisted reproduction technologies. **ISO 13485**

3.1.9 *MR Conditional*—an item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields.

3.1.9.1 *Discussion*—Additional conditions, including specific configurations of the item, may be required.

3.1.10 *MR environment*—three-dimensional volume surrounding the MR magnet that contains both the Special Environment (Faraday shielded volume) and the B_0 Hazard Area (space around the MR equipment where the static magnetic field can cause harm). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories, and for which access control is part of the risk mitigation. **Adapted from IEC 60601-2-33**

3.1.11 *MR equipment*—medical electrical equipment which is intended for *in vivo* magnetic resonance examination of a patient comprising all parts in hardware and software from the supply mains to the display monitor. **Adapted from IEC 60601-2-33**

3.1.12 *MR examination*—process of acquiring data by magnetic resonance from a patient. **IEC 60601-2-33**

3.1.13 *MR Safe*—an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.

3.1.13.1 *Discussion*—An item composed entirely of electrically nonconductive, nonmetallic, and nonmagnetic materials may be determined to be MR Safe by providing a scientifically based rationale rather than test data. Examples of MR Safe items are a cotton blanket or a silicone catheter.

3.1.14 *MR Unsafe*—an item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

3.1.14.1 *Discussion*—ISO 14971 Medical devices–Application of risk management to medical devices, includes a process for evaluating risks, including identifying unacceptable risks. MR Unsafe items include items such as a pair of ferromagnetic scissors.

3.1.15 *passive item*—an item that serves its functions without the supply of electrical power (definition modified from Test Method F2213, *passive implant*).

3.1.16 *radio frequency (RF) magnetic field*—the magnetic field in MRI that is used to flip the magnetic moments. The frequency of the RF field is γB_0 where γ is the gyromagnetic constant, 42.56 MHz/T for protons, and B_0 is the static magnetic field in Tesla.

3.1.17 *safety*—freedom from unacceptable risk. **ISO 14971**

3.1.18 *spatial field gradient (SFG)*—spatial rate of change of the main magnetic field $|\nabla|\vec{B}||$. **IEC 60601-2-33**

3.1.18.1 *Discussion*—Attractive magnetic forces on magnetizable or saturated ferromagnetic objects scale linearly with SFG.

3.1.19 *specific absorption rate (SAR)*—radio frequency power absorbed per unit of mass (W/kg). **IEC 60601-2-33**

4. Significance and Use

4.1 Interactions of items with the MR environment have resulted in serious injuries and death of patients and other individuals. This practice lists hazards that may be present in the MR environment. It specifies marking of items anticipated to enter the MR environment and recommends information that should be included in the associated labeling.

4.2 This practice provides a uniform system of visual icons and terms for marking items for use in the MR environment.

5. Hazards Pertaining to Items Entering the MR Environment

5.1 For items entering the MR environment that could interact with the static magnetic field associated with an MR scanner, assess static magnetic field interactions.

5.1.1 Static magnetic field interactions can include, as applicable, force, torque, and malfunction.

5.2 For items entering the MR environment that could interact with the time varying gradient field (dB/dt), assess time varying gradient magnetic field (dB/dt) interactions.

5.2.1 Switched gradient magnetic field (dB/dt) interactions can include, as applicable, gradient-induced heating, vibration, electrical extrinsic potential (induced voltages), and malfunction.

5.3 For items entering the MR environment that could interact with the RF field, assess RF field interactions.

5.3.1 RF-induced interactions can include, as applicable, RF-induced heating, RF rectification, and RF-induced malfunction.

5.4 Other possible considerations for assessment can include, but are not limited to, interaction between different items. Also see X1.4.

NOTE 2—MR image artifacts, while not considered a direct safety issue (see 1.3), should be considered. The accompanying documentation should contain a statement concerning item-induced MR image artifacts.

5.5 An assessment may include testing. See Table X1.1 for a list of some of the potential hazards and associated test methods.

5.6 An assessment may include computational simulations (for example, RF-induced heating).

5.7 An assessment may include leveraging previous results with appropriate justification and/or scientific rationale.

6. MR Marking

6.1 The marking method shall not compromise performance or function of the marked item and should provide legibility over the anticipated service life of the item.

6.2 Items that are anticipated to enter the MR environment vary widely in size, and the amount of information that can practically be included in marking varies accordingly. For implanted items, the MR marking shall be included in the labeling (including the instructions for use, package inserts, patient and physician manuals, patient information card) and may be included on the item. Non-implanted items, where feasible, shall be marked with the appropriate MR icons. If a non-implanted item is MR Conditional, where feasible, include the conditions for safety in the MR environment on the item as well as in the labeling. Some items (for example, small or very thin ones) do not provide adequate surfaces that can be marked practically. For items for which direct marking is not practical, the MR marking shall be included in the labeling. For both implanted and non-implanted items, the MR marking may be placed on the product packaging label (for example, on the box), however the package label should clearly indicate the item(s) inside the packaging to which the MR marking applies (for example, implant only or implant and delivery system).

6.3 *Minimum Information*—As a result of the assessment described in Section 5, mark the item as MR Safe, MR Conditional, or MR Unsafe using the icons as shown in Tables 1 and 2.

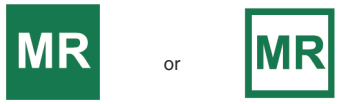
6.3.1 The MR Safe icon consists of the letters “MR” surrounded by a green square (Table 1 and Figs. 1 and 2). Two options are given. When color reproduction is not practical, the icon may be printed in black and white (Table 2, Figs. 3 and 4). The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. For both color and black and white options in Tables 1 and 2, the option that is most visible for the individual application should be chosen.

6.3.2 The MR Conditional icon consists of the letters “MR” within a yellow equilateral triangle with a thick black band around the perimeter (Table 1 and Fig. 5). The triangle is oriented with its horizontal side below the letters “MR.” When color reproduction is not practical, the icon may be printed in black and white (Table 2 and Fig. 6). The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.

6.3.2.1 For MR Conditional items, the item labeling (instructions for use, package inserts, operator manual, patient information card, patient and physician information pamphlets, as appropriate) shall include appropriate information from Section 5.

6.3.2.2 The MR Conditional icon on non-implanted items may include a supplementary marking. This marking should include the appropriate information from Section 5 and describes the conditions for which the item has been demonstrated to be MR Conditional. The supplementary marking consists of text surrounded by a rectangular frame (Figs. 7 and 8).

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