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F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants (Withdrawn 2022)[3]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

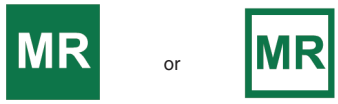
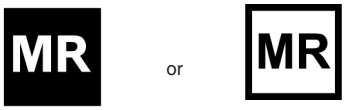
Icon Geometric Shape and Appearance	Meaning
A square 	MR Safe
An equilateral triangle with radiused outer corners 	MR Conditional
A circle with a diagonal bar 	MR Unsafe

TABLE 2 Requirements for Black and White 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

6.3.2.3 For all items external to the body of a person for which it is technically feasible, labeling for MR Conditional items shall appear on the item and include conditions for safety in the MR environment from Section 5.

NOTE 3—Adding that information on the item allows immediate access to the MR conditions.

NOTE 4—This supplementary marking of information for safe usage may be particularly useful for inclusion on non-implanted items that are anticipated to enter the MR environment, such as anesthesia equipment, power injectors, medication pumps, patient transport equipment, physiological monitoring equipment, monitors, interventional equipment, step stools, IV poles, carts, room furnishings, item packaging and labeling, etc.

NOTE 5—This marking may also be used if one portion of a kit or item with accessories is MR Conditional. For example, indicate "stent only" for a system that consists of stent plus delivery catheter.

6.3.3 The MR Unsafe marking consists of the letters "MR" surrounded by a red circle with a diagonal red bar across the letters extending from the upper left quadrant to the lower right quadrant of the circle and oriented at 45° from the horizontal (Table 1 and Fig. 8). When color reproduction is not practical, the icon may be printed in black and white (Table 2 and Fig. 9). The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.

6.4 The icons shall comply with the layout requirements given below. The colors are given in Table 3. Note that the colors represented in an electronic or paper copy of this practice may not match the colors as defined in Table 3.

6.4.1 *MR Safe Icon, Color Option 1 (Fig. 1):*

FIG. 1 Color Option 1

6.4.1.1 The colors of the MR Safe icon shall be as follows for option 1:

(1) Background color: green.

(2) Letters 'MR': white.

(3) The letters 'MR' shall be capitalized, in Arial font and centered in the square. The letters shall be sized as large as possible to be contained within the green square, but not touching the border of the square.

6.4.2 *MR Safe Icon, Color Option 2 (Fig. 2):*

FIG. 2 Color Option 2

6.4.2.1 The colors of the MR Safe icon shall be as follows for option 2:

(1) Background color: white.

(2) Letters 'MR': green.

(3) Frame: green. The width of the frame shall be approximately 10 % of the length of a side of the square.

(4) The letters 'MR' shall be capitalized, in Arial font and centered in the square. The letters shall be sized as large as possible, but not touching the border of the frame.

6.4.3 *MR Safe Icon, Black and White Option 1 (Fig. 3):*

6.4.3.1 For option 1 of the black and white version of the MR Safe icon, the colors shall be as follows:

(1) Background color: black.

(2) Letters 'MR': white.

TABLE 3 Examples from Color Order Systems for the Icon Colors (DIN, RAL, Munsell, AFNOR, and NCS examples from ISO 3864-1:2)[A]

Color	DIN 5381 DIN 6164	RAL	Munsell	AFNOR NF X08-002 and X08-010	NCS	Pantone
Red	7,5 : 8,5 :3	RAL 3001	7,5R 4/14	N°2805	S 2080-R	Pantone 1807 C
Yellow	2,5 : 6,5 : 1	RAL 1003	10YR 7/14	N°1330	S 1070-Y10R	Pantone 1235 C
Green	21,7 : 6,5 : 4	RAL 6032	5G 4/9	N°2455	S 3060-G	Pantone 3415 C
White	N : 0 : 0,5	RAL 9003	N 9,5	N°3665	S 0500-N	Pantone White
Black	N : 0 :9	RAL 9004	N 1	N°2603	S 9000-N	Pantone 6 C

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FIG. 3 Black and White Option 1

(3) The letters 'MR' shall be capitalized, in Arial font and centered in the square. The letters shall be sized as large as possible, but not touching the border of the square.

6.4.4 *MR Safe Icon, Black and White Option 2 (*Fig. 4*):*

FIG. 4 Black and White Option 2

6.4.4.1 For option 2 of the black and white version of the MR Safe icon, the colors shall be as follows:

(1) Background color: white.

(2) Letters 'MR': black.

(3) Frame: black. The width of the border shall be approximately 10 % of the side length of the square.

(4) The letters 'MR' shall be capitalized, in Arial font and centered in the square. The letters shall be sized as large as possible, but not touching the frame.

6.4.5 *MR Conditional Icon, Color Option (*Fig. 5*):*

FIG. 5 MR Conditional Icon Geometry, Color Option

6.4.5.1 The colors of the MR Conditional icon shall be as follows:

(1) Background color: yellow.

(2) Triangular frame: black.

(3) Letters 'MR': black.

(4) The letters 'MR' shall be capitalized, in Arial font and sized as large as possible within the black frame, but not touching the frame.

6.4.6 *MR Conditional Icon, Black and White Option (*Fig. 6*):*

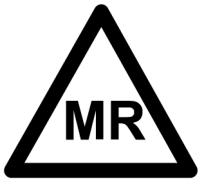

FIG. 6 MR Conditional Icon Geometry, Black and White Option

6.4.6.1 For the black and white version of the MR Conditional icon, the colors of the icon shall be as follows:

(1) Background color: white.

(2) Triangular frame: black.

(3) Letters 'MR': black.

(4) The letters 'MR' shall be capitalized, in Arial font and sized as large as possible within the black frame, but not touching the frame.

6.4.7 *Supplementary Marking for MR Conditional Items, Color Option (*Fig. 7*):*

FIG. 7 Supplementary Marking for MR Conditional Items, Color Option

6.4.7.1 For the color option of the MR Conditional Supplementary marking, colors shall be as follows:

(1) Background color: yellow.

(2) Rectangular Frame: black.

(3) Text: black.

(4) The safety color yellow shall cover at least 50 % of the total area of the icon.

(5) The text shall be in Arial font.

6.4.8 *Supplementary Marking for MR Conditional Items, Black and White Option (*Fig. 8*):*

FIG. 8 Supplementary Marking for MR Conditional Items, Black and White Option

6.4.8.1 For the black and white option of the MR Conditional Supplementary marking, the colors shall be as follows:

(1) Background color: white.

(2) Rectangular Frame: black.

(3) Text: black.

(4) The text shall be in Arial font.

6.4.9 *MR Unsafe Icon, Color Option (*Fig. 9*):*

FIG. 9 MR Unsafe, Color Option

6.4.9.1 The colors of the MR Unsafe icon shall be as follows:

(1) Background color: white.

(2) Circular frame and diagonal bar: red.

(3) Letters 'MR': black.

(4) The letters 'MR' shall be capitalized, in Arial font, and sized as large as possible within the circular frame, but not touching the frame.

6.4.10 *MR Unsafe Icon, Black and White Option (*Fig. 10*):*

6.4.10.1 For the black and white version of the MR Unsafe icon, the colors of the icon shall be as follows:

FIG. 10 MR Unsafe, Black and White Option

(1) Background color: white.

(2) Circular frame and diagonal bar: black.

(3) Letters 'MR': black.

(4) The letters 'MR' shall be capitalized, in Arial font and sized as large as possible within the circular frame, but not touching the frame.

7. Keywords

7.1 magnet; magnetic; medical devices; metals (for surgical implants); MRI (magnetic resonance imaging); MR safety

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The intent of this practice is to provide needed information about the safety of items in and near MR scanners using a compact and easily recognized set of icons and terms. The terms MR safe and MR compatible as first defined in 1997 in the FDA draft guidance document, "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems," were used to describe the safety of devices in and near MR equipment and accessories. The obsolete historical definitions are:

MR safe (obsolete definition)	The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device that is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.
MR compatible (obsolete definition)	The device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device that is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

There was a great deal of confusion surrounding this terminology and incorrect assumptions were often made. Users often *incorrectly* assumed that items labeled MR safe or MR compatible were safe or compatible for any MR environment. MR environments vary in terms of magnetic field strength and RF conditions. Therefore, an item tested under one set of conditions may be affected differently by the conditions in another MR environment. In addition, some devices labeled MR safe and MR compatible using the historical definitions in X1.1 have gauss line restrictions or RF pulse sequence limitations that must be adhered to in order to safely have the item in the MR environment. In short, when using the historical definitions it was impossible to definitively establish an item as MR safe or MR compatible without also specifying the conditions under which the item was tested. The current terms in this practice (MR Safe, MR Unsafe, and MR Conditional, Section 3) assist in clearing up this confusion.

NOTE X1.1—This revised terminology has not yet been applied to all items tested before the approval of Practice F2503. Therefore, there are items that still contain the prior terminology (that is, use the old terms MR safe and MR compatible) in their labeling.

NOTE X1.2—IEC 60601-2-33 requires that every MR system come with a compatibility technical specification sheet (CTSS) containing parameters that describe the MR equipment. The specification sheet is part of the MR equipment user manual and can be used to assess MR Conditional requirements.

X1.2 It is important to note that an item marked MR Conditional is safe at the listed conditions only.

X1.3 Although commercial 1.5 T and 3 T MR systems currently produce the conditions that are most commonly encountered, higher and lower strength MR systems are becoming more common in clinical situations. Testing an item at one B_0 field strength may not be adequate to claim safety at other field strengths.

X1.4 A brief list of potential risks and hazards that have been observed include:

X1.4.1 Magnetically induced displacement force and torque can depend on:

(1) The strength of the static magnetic field,

(2) The SFG of the static magnetic field,

(3) The magnetic saturation of the item's material,

(4) The magnetic susceptibility of the item's material, and

(5) Item geometry and mass.

X1.4.2 Radiofrequency (RF) induced heating of an item from the transmit RF coil.

(1) RF induced heating can occur with any electrically conductive item.

(2) RF induced heating can depend on:

(a) The electrical conductivity and permittivity of the item (impedance of electronic item parts),

(b) The geometric dimension of the item and configuration,

(c) The surrounding tissue conductivity and permittivity,