Designation: F2503 – 20

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 international standard applies to the practice of marking of items that might be used in the magnetic resonance (MR) environment.

1.2 The purpose of this practice is to mark items that might be brought into the MR environment and to recommend information that should be included in the marking.

1.3 The standard specifies the permanent marking of items, which are used in an MR environment, by means of terms and icons.

1.4 MR image artifacts are not considered to be a performance issue and so are not addressed in this international standard practice (see X1.5).

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *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.*

1.7 *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 document. 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

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:*

IEC 60601-2-33 Medical Electrical Equipment—Part 2-33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis[3]

ISO 14971 Medical Devices—Application of Risk Management to Medical Devices[4]

ISO/IEC Guide 51 Safety Aspects—Guidelines for their Inclusion in Standards[4]

ISO TS 10974 Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *harmful interaction*—unintended direct or indirect interaction of items with MR equipment, especially with the static magnetic field, the gradient fields and the RF fields of the MR equipment, that can pose hazards to patients or other persons.

3.1.1.1 *Discussion*—In this context, the affected image quality or image artifacts are not considered to be a harmful interaction.

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

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

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

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

3.1.4 *magnetically induced displacement force*—force produced when a magnetic object is exposed to the spatial gradient of a static magnetic field. This force will tend to cause the object to translate in the spatial gradient of the static magnetic field.

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

3.1.6 *magnetic induction or magnetic flux density (B in T)*—that magnetic vector quantity which at any point in a magnetic field is measured either by the mechanical force experienced by an element of electric current at the point, or by the electromotive force induced in an elementary loop during any change in flux linkages with the loop at the point. The magnetic induction is frequently referred to as the magnetic field. B_0 is the static field in an MR equipment and accessories. Plain type indicates a scalar (for example, *B*) and bold type indicates a vector (for example, ***B***).

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, definition 201.3.217**

3.1.8 *magnetic resonance (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.

3.1.8.1 *Discussion*—The MR equipment is a programmable electrical medical system (PEMS). **IEC 60601-2-33, definition 201.3.218**

3.1.9 *magnetic resonance (MR) examination*—process of acquiring data by magnetic resonance from a patient. **IEC 60601-2-33, definition 201.3.219**

3.1.10 *magnetic resonance (MR) environment*—the three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). 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.

3.1.11 *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.

3.1.11.1 *Discussion*—Additional conditions, including specific configurations of the item, may be required. Demonstrated safety can be achieved by scientific rationale in certain circumstances.

3.1.12 *Supplementary Marking*—additional information that, in association with a marking as "MR Conditional," states via additional language the conditions in which an item can be used safely within the MR environment.

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 *medical device*—any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, 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 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 which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means. **ISO 13485**

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.

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

3.1.19 *tesla, (T)*—the SI unit of magnetic induction equal to 10^4 gauss (G).

4. Significance and Use

4.1 Interactions of medical devices and other items with the MR environment has resulted in serious injuries and death of patients and other individuals. Additionally, hazards stemming

from equipment malfunction are of concern. Section 4.2 lists possible direct and indirect causes of hazards in the MR environment.

4.2 Potential direct and indirect causes of hazards:

4.2.1 Direct causes:

4.2.1.1 mechanical causes, including magnetically induced displacement force, torque, and vibration

4.2.1.2 electromagnetic causes, including induction (heating, stimulation) and discharge (spark gap)

4.2.1.3 acoustic causes

4.2.2 Indirect causes:

4.2.2.1 malfunction of items, for example of vital components such as valves, monitors and pumps

4.3 This practice provides a uniform system for marking to indicate the conditions for which it has been determined that a medical device or other item may be safely placed and used in the MR environment. It provides simple visual icons and terms which are intended to reduce injuries and other mishaps that occur when items that pose hazards in the MR environment are brought into the MR environment.

5. Requirements for Assessment of Potential Hazards Caused by Interactions of an Item and the MR Environment

5.1 Perform testing sufficient to characterize the behavior of the item in the MR environment.

5.1.1 In particular, testing for items that may be placed in the MR environment should address magnetically induced displacement force (Test Method F2052), magnetically induced torque (Test Method F2213), and RF heating (Test Method F2182 for passive implants and ISO TS 10974 for active implants). Additionally, electronic components shall be evaluated for malfunction.

5.1.2 Other possible safety issues to consider for the hazard assessment include, but are not limited to, thermal injury, induced currents/voltages, interaction with the switched gradient field (dB/dt) for all items that may go inside the magnet bore, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, and the malfunction of the item and the malfunction of the MR equipment and accessories. See Table X1.1 for some hazards and associated test methods. Also see section X1.2.1.4.

5.2 List any parameter that affects the safety of the item. Describe any condition that is known to produce an unsafe condition.

NOTE 1—These remarks do not claim to be complete. Therefore it is recommended that the user of this standard consider specific questions and topics that may be applicable to the specific item being evaluated. Some potential hazards to patients and others in the MR environment are given in X1.2.1 and Table X1.1.

6. Methods of 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. 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 the conditions for safety in the MR environment.

7. Information Included in MR Marking

7.1 Medical devices and other items vary widely in size, and the amount of information that practically can be included in marking varies accordingly. For implants, the MR marking shall be included in the labeling (including the instructions for use, package inserts, patient and physician manuals) and on the patient information card. Non-implanted items, where feasible, shall have MR marking on the item as well as in the labeling. Some items (for example, small or very thin ones) do not provide any surfaces which can be marked practically. For items for which direct marking is not practical, the MR marking shall be included in the labeling. For both implants and non-implanted items, the MR marking may be placed on the product packaging label (e.g. on the box), however the package label should clearly indicate the item(s) inside the packaging to which the MR marking applies (e.g., implant only or implant and delivery system).

7.2 The marking method shall not compromise performance or function of the marked item and should remain readable over the anticipated service life of the item.

7.3 *Minimum Information*—As a result of the testing 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.

7.3.1 The MR Safe icon consists of the letters "MR" surrounded by a green square (Table 1 and Figures 1 and 2). Two options are given. When color reproduction is not practical, the icon may be printed in black and white (Table 2 and Figures 3 and 4). The use of the colored icon is strongly encouraged for the added visibility and information provided

TABLE 1 Requirements for Colored MR Icons

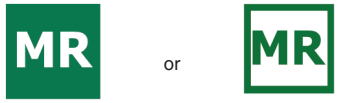
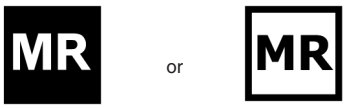
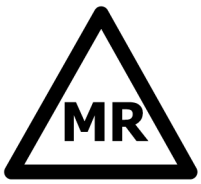
Icon Geometric Shape and Appearance	Meaning
A square 	MR Safe
An equilateral triangle with radiused outer corners 	MR Conditional
A circle with a diagonal bar 	MR Unsafe

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

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.

7.3.2 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 Figure 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 Figure 6). The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.

7.3.2.1 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.

(1) The MR Conditional icon may be supplemented by supplementary marking which includes 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 (Figure 7).

7.3.2.2 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 2—This marking may be particularly useful for inclusion on nonimplanted items that are used in the MR environment, for instance on electronic equipment, room furnishings, or item packaging and labeling.

NOTE 3—This marking may also be used if one portion of a kit or device with accessories is MR Conditional. For example, indicate "stent only" for a system that consists of stent plus delivery catheter.

7.3.3 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 Figure 8). When color reproduction is not practical, the icon may be printed in black and white (Table 2 and Figure 9). The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.

7.4 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 document may not match the colors as defined in Table 3.

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

FIG. 1 Color Option 1

7.4.1.1 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.

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

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

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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