~~Designation:F2503–05~~ Designation: F 2503 – 08

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 F 2503; 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 covers the marking of medical devices and other items to indicate their safety in the magnetic resonance (MR) environment.

1.2 The purpose of this practice is to *(1)* recommend that items that may be brought into the MR environment be permanently marked to indicate the MR environment to which a specific item may safely be exposed, and *(2)* recommend information that should be included in the marking. It is recognized that direct marking on the item is not practical for implants and certain other medical devices. Where direct marking is not practical, this practice recommends that the marking be included in the labeling and on patient information cards (see 7.1).

1.3 Image artifact is not considered to be a safety issue and so is not addressed in this practice (see X1.5).

~~1.4~~

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F 2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

F 2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

F 2182 Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

F 2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

2.2 *Other Standards:*

ISO 3864-1:2002(E) Graphical Symbols—Safety Colours and Safety Signs—Part 1: Design Principles for Safety Signs in Workplaces and Public Areas[3]

ISO 13485:2003(E) Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes, definition 3.7[3]

ISO/IEC Guide 51:1999, definition 3.5[4]

IEC 60601-2-33, Ed. 2.0 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis[4]

3. Terminology

3.1 *Definitions:*

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

3.1.2 *item*—medical device or other object that may be brought into the MR environment.

3.1.3 *magnetically induced displacement force*— force produced when a magnetic object is exposed to the spatial gradient of

---

[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.

~~Current edition approved Aug. 1, 2005. Published August 2005.~~

Current edition approved Oct. 1, 2008. Published November 2008. Originally approved in 2005. Last previous edition approved in 2005 as F 2503 – 05.

[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 American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[4] Available from International Electrotechnical Commission (IEC), 3 rue de Varembé, Case postale 131, CH-1211, Geneva 20, Switzerland.

a static magnetic field. This force will tend to cause the object to translate in the spatial gradient of the static magnetic field.

3.1.4 *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.

3.1.5 *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 system. Plain type indicates a scalar (for example, B) and bold type indicates a vector (for example, $\boldsymbol{B}$).

3.1.6 *magnetic resonance (MR)*—resonant absorption of electromagnetic energy by an ensemble of atomic particle situated in a magnetic field.

3.1.7 *magnetic resonance (MR) environment*—volume within the 0.50 mT (5 gauss (G)) line of an MR system, which includes the entire three dimensional volume of space surrounding the MR scanner. For cases where the 0.50 mT line is contained within the Faraday shielded volume, the entire room shall be considered the MR environment.

3.1.8 *magnetic resonance system (MR system)*— ensemble of MR equipment, accessories, including means for display, control, energy supplies, and the MR environment. **IEC 60601-2-33**

3.1.9 *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), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

3.1.10 *MR Safe*—an item that poses no known hazards in all MR environments.

NOTE 1—MR 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.

3.1.11 *MR Unsafe*—an item that is known to pose hazards in all MR environments.

NOTE 2—MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

3.1.12 *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**

3.1.13 *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.

3.1.14 *safety*—freedom from unacceptable risk in the MR environment.

3.1.15 *specific absorption rate (SAR)*—the mass normalized rate at which RF energy is deposited in biological tissue. SAR is typically indicated in W/kg.

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

4. Significance and Use

4.1 Medical devices and other items have caused serious injuries and death for patients and other individuals in the MR environment.

4.2 This practice provides a uniform system for marking to indicate the MR conditions that have been determined to be acceptable for a medical device or other item. 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. Methods of Marking

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

6. Required Information

6.1 Perform 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 (Test Method F 2052), magnetically induced torque (Test Method F 2213), and RF heating (Test Method F 2182).

NOTE 3—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.

6.2 Any parameter that affects the safety of the item should be listed. Any condition that is known to produce an unsafe condition must be described.

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 should be included in the package labeling (including the instructions for use and package inserts) and on the patient information card. For nonimplanted items intended to be used in the MR environment, the MR marking should be positioned in a prominent location on the item as well as in the item labeling. Some items (for example, small or very thin items) do not provide any surfaces which can be marked practically. For items for which direct marking is not practical, the MR marking should be included in the labeling.

7.2 *Minimum Information*—As a result of the testing described in Section 6, mark the item as MR Safe, MR Conditional, or MR Unsafe using the icons as shown in Tables 1 and 2.

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

7.2.2 The MR Conditional icon consists of the letters "MR" within a yellow equilateral triangle with a thick black band around the perimeter (Table 1). 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). The use of the colored icon is strongly encouraged for the added visibility and information provided by the presence of the color.

7.2.2.1 For MR Conditional items, the item labeling (instructions for use, package inserts, operator manual, patient information card, as appropriate) will include ~~the~~appropriate information ~~required in~~from 3.1.9 and Section 6.

(1) The MR Conditional icon may be supplemented by a supplementary sign which includes the appropriate information from 3.1.9 and Section 6 and describes the conditions for which the item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. The supplementary sign consists of text surrounded by a rectangular frame.

NOTE 4—This sign 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.

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

TABLE 1 Requirements for Colored MR Icons

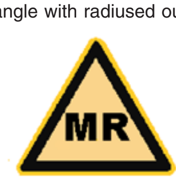
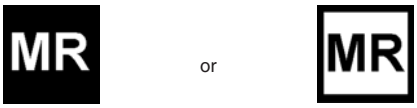
Icon Geometric Shape and Appearance	Meaning
A square  or 	MR Safe
An equilateral triangle with radiused outer corners 	MR Conditional
A circle with a diagonal bar 	MR Unsafe

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

7.3 The icons shall comply with the layout requirements given below (see ISO 3864-1 7.2, 7.3, and 7.5). 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.

7.3.1 *Color Option 1*:

FIG. 1 Color Option 1

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

(1) Background color: green

(2) Letters 'MR': white

(3) Border: white

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

(5) The letters 'MR' shall be capitalized, in Arial font and oriented in the center of the square. The letters shall be sized as large as possible to be contained within the green square, but not touching an edge of the green square.

7.3.2 *Color 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

[A]