



Designation: F2503 – 23^{ε1}

Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment¹

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.

^{ε1} NOTE—References in 6.3.3 were editorially corrected in October 2023.

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

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 April 1, 2023. Published May 2023. Originally approved in 2005. Last previous edition approved in 2020 as F2503 – 20. DOI: 10.1520/F2503-23E01.

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 Diagnosis⁴

ISO 14971 Medical Devices—Application of Risk Management to Medical Devices⁵

ISO/IEC Guide 51 Safety Aspects—Guidelines for their Inclusion in Standards⁵

ISO TS 10974 Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device⁵

3. Terminology

3.1 Definitions:

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 Varembe, 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>.

3.1.1 *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**

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 $|\nabla|B||$. **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