



Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment¹

This standard is issued under the fixed designation F2052; 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 test method covers the measurement of the magnetically induced displacement force produced by static magnetic field gradients on medical devices and the comparison of that force to the weight of the medical device.

1.2 This test method does not address other possible safety issues which include but are not limited to issues of magnetically induced torque, RF heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the MR system.

1.3 This test method is intended for devices that can be suspended from a string. Devices which cannot be suspended from a string are not covered by this test method. The weight of the string from which the device is suspended during the test must be less than 1 % of the weight of the tested device.

1.4 This test method shall be carried out in a horizontal bore MR system with a static magnetic field oriented horizontally and parallel to the MR system bore.

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 and health practices and determine the applicability of regulatory requirements prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

¹ This test method 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 Sept. 15, 2015. Published September 2015. Originally approved in 2000. Last previous edition approved in 2014 as F2052 – 14. DOI: 10.1520/F2052-15.

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.

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

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2.2 Other Standards:³

IEC 60601–2–33 Ed. 2.0 Medical Electronic Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis

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

ISO 14971 Medical devices - Application of risk management to medical devices

3. Terminology

3.1 Definitions:

3.1.1 *diamagnetic material*, n —a material whose relative permeability is less than unity.

3.1.2 *ferromagnetic material*, n —a material whose magnetic moments are ordered and parallel producing magnetization in one direction.

3.1.3 *magnetic field strength* (H in A/m), n —strength of the applied magnetic field.

3.1.4 *magnetic induction or magnetic flux density* (B in T), n —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

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.