



Designation: F2052 – 06^{ε1}

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.

^{ε1} NOTE—Paragraph X1.3 was added editorially in May 2006.

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 system in which the direction of the magnetically induced deflection force is horizontal.

1.5 The values stated in SI units are to be regarded as standard. Values in parentheses are for information only.

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.

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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.

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

3. Terminology

3.1 Definitions:

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

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

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

3.1.4 *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

³ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

field. B_o is the static field in an MR system. Plain type indicates a scalar (for example, B) and bold type indicates a vector (for example, \mathbf{B}).

3.1.5 *magnetic resonance diagnostic device*—a device intended for general diagnostic use to present images which reflect the spatial distribution or magnetic resonance spectra, or both, which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images or spectra, or both, may also be produced.

3.1.6 *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.

3.1.7 *magnetic resonance equipment (MR equipment)*—medical electrical equipment which is intended for *in-vivo* magnetic resonance examination of a patient. The MR equipment comprises all parts in hardware and software from the supply mains to the display monitor. The MR equipment is a Programmable Electrical Medical System (PEMS).

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 *magnetic resonance examination (MR examination)*—process of acquiring data by magnetic resonance from a patient.

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

3.1.11 *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, and
- (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

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

3.1.13 *paramagnetic material*—a material having a relative permeability which is slightly greater than unity, and which is practically independent of the magnetizing force.

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

4. Summary of Test Method

4.1 A medical device is suspended by a string at the point in a magnetic field that will produce the greatest magnetically induced deflection. The angular deflection of the string from the vertical is measured. If the device deflects less than 45° , then the magnetically induced deflection force is less than the force on the device due to gravity (its weight).

5. Significance and Use

5.1 This test method is one of those required to determine if the presence of a medical device may cause injury to individuals during an MR examination and in the MR environment. Other safety issues which should be addressed include but may not be limited to magnetically induced torque (see Test Method F2213) and RF heating (see Test Method F2182). The terms and icons in Practice F2503 should be used to mark the device for safety in the magnetic resonance environment.

5.2 If the device deflects less than 45° , then the magnetically induced deflection force is less than the force on the device due to gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field.

5.3 A deflection of less than 45° at the location of the maximum static magnetic field gradient in one MR system does not preclude a deflection exceeding 45° in a system with a higher field strength or larger static field gradients.

5.4 This test method alone is not sufficient for determining if a device is safe in the MR environment.

6. Apparatus

6.1 The test fixture consists of a sturdy nonmagnetic structure capable of holding the test device in the proper position without deflection of the test fixture and containing a protractor with 1° graduated markings, rigidly mounted to the structure. The 0° indicator on the protractor is oriented vertically. The test device is suspended from a thin string that is attached to the 0° indicator on the protractor. In order for the weight of the string to be considered negligible when compared to the weight of the device, the weight of the string shall be less than 1 % of the weight of the device. The string shall be long enough so that the device may be suspended from the test fixture and hang freely in space. Motion of the string shall not be constrained by the support structure or the protractor. The string may be attached to the device at any convenient location.

7. Test Specimens

7.1 For purposes of device qualification, the device evaluated according to this test method should be representative of manufactured medical devices that have been processed to a finished condition (for example, sterilized).

7.2 For purposes of device qualification, the devices should not be altered in any manner prior to testing.

8. Procedure

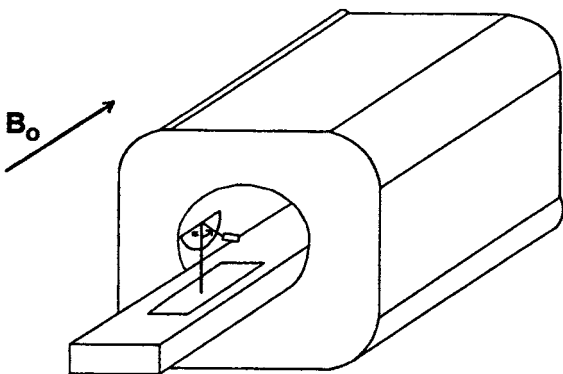
8.1 Any magnet with a horizontal magnetic field that produces a large spatial gradient may be used for the test. Fig. 1 shows the test fixture mounted on the patient table of an MRI system. The test device is suspended from a string attached to the 0° indicator on the test fixture protractor. Position the test fixture so that the center of mass of the device is at the location where the deflection is a maximum (see Note 1). Mark the location of the maximum deflection so all test repetitions will be conducted at the same location. Hold the device so that the string is vertical and then release it. Record α , the deflection of the device from the vertical direction to the nearest 1° (see Fig. 2).

8.2 Repeat the process in 8.1 a minimum of three times for each device tested.

8.3 The device should be constrained so that the bulk of the device is at the point of maximum deflection (see Appendix X2). If anything (for example, tape) is used to constrain the device during the test, demonstrate that the added mass does not significantly affect the measurement. The combined weight of material used to constrain the device during the test shall be less than 1 % of the weight of the device.

8.4 If the device contains an electrical cord or some type of tether, arrange the device so the cord or tether has a minimal effect on the measurement. For such devices, it may be necessary to perform a series of tests to characterize the operating conditions that will produce the maximum deflection. (For instance, for an electrically powered device, tests in a number of states may be necessary to determine the operating condition that produces the maximum deflection. Possible test configurations include but are not limited to: electrical cord only, device only, device with cord attached and device turned off, device with cord attached and device activated).

NOTE 1—For devices below saturation, the location of maximum deflection is at the point where $|\mathbf{B}| |\nabla \mathbf{B}|$ is a maximum. Above the magnetic saturation point, the maximum deflection will occur at the location where $\nabla \mathbf{B}$ is a maximum.



NOTE 1—The fixture may need to be offset to locate the position of maximum deflection.

FIG. 1 Test Fixture Mounted on the Patient Table of an MRI System

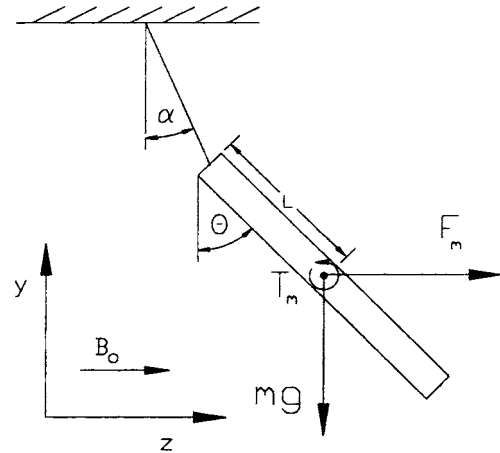


FIG. 2 Test Device in Magnetic Field

9. Calculations

9.1 Calculate the mean deflection angle using the absolute values of the values for deflection angle, α , measured in Section 8. (It is possible that instead of being attracted to the magnet, the device might be repelled by the magnet. Therefore, the absolute value of the deflection angle should be used when calculating the mean deflection angle.)

9.2 Calculate the mean magnetically induced deflection force for the device using the mean value for the deflection angle α determined in 9.1 and the following relation (derived in Appendix X2): $F_m = mg \tan \alpha$, where m is the mass of the device and g is the acceleration due to gravity. If the mean value for α is less than 45°, F_m , the magnetically induced deflection force, is less than the force on the device due to gravity (its weight).

10. Report

10.1 The report shall include the following for each specimen tested:

10.1.1 Device product description, including dimensioned drawing(s) or photograph(s) with dimensional scale.

10.1.2 A diagram or photograph showing the configuration of the device during the test.

10.1.3 Device product identification (for example, batch, lot number, type number, revision, serial number, date of manufacture).

10.1.4 Materials of construction (ASTM designation or other).

10.1.5 Number of specimens tested with explanation for the sample size used.

10.1.6 Cartesian coordinate (x, y, z) location of the center of mass of the device during the test using a right handed coordinate system with origin at the isocenter of the magnet. Include a diagram showing the magnet and the coordinate axes. If the test magnet is an MR system, orient the coordinate system so that the y -axis is vertical and the z -axis is parallel to the patient table.

10.1.7 Values of $|\mathbf{B}|$, the magnitude of the magnetic field and $|\nabla \mathbf{B}|$, the magnitude of the spatial gradient of the magnetic field, at the test location.