



Designation: F 2052 – 002

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

This standard is issued under the fixed designation F 2052; 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 standard~~ test method covers the measurement of the magnetically induced displacement force produced by ~~the spatial gradients of a static magnetic field gradients on passive implants (implants that function without the supply of electrical power) medical devices~~ and the comparison of that force to the weight of the ~~implant 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 or, 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 thin string. Devices which cannot be suspended from a thin string are not covered by this test method.

1.4 The method. The weight of the thin string from which the device is suspended during the test must be less than 1 % of the weight of the tested device.

1.5 This test method is applicable only to magnet systems shall be carried out in a system in which the direction of the magnetic field (and 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:*

A-340 ~~Standard Terminology~~ 340 Terminology of Symbols and Definitions Relating to Magnetic Testing²

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical & Surgical Materials & Devices and is the direct responsibility of Subcommittee F04.15 on Materials Test Methods.

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~~F-1542 Standard Specification 1542 Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips³~~
~~F 2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants³~~
~~F 2182 Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging³~~

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 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, \mathbf{B}).

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

3.1.6 *magnetic resonance (MR) environment*—refers to the electromagnetic environment present in the vicinity of an MR scanner—area within the 5 gauss (G) line of an MR system.

3.1.7 *magnetic resonance imaging equipment (MR equipment) (MRI)*—imaging technique that uses static and time varying—medical electrical equipment which is intended for in-vivo magnetic fields to provide images of tissue by the 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.

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*—an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component, part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or is intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

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.

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

3.1.10 *passive implant*—an implant that serves its function without the supply of electrical power.

3.1.11—

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

4. Summary of Test Method

4.1 An implant

4.1 A medical device is suspended by a ~~fine~~ 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 ~~implant device~~ deflects less than 45° , then the magnetically induced deflection force is less than the force on the ~~implant 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 ~~passive implant~~ medical device may cause injury to the ~~person with the implant individuals~~ during an ~~MRI scan~~ MR examination and in the vicinity of the ~~MRI scanner~~ MR environment. Other safety issues which should be addressed include but may not be limited to magnetically induced ~~torque and torque~~, RF heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the MR system.

² Annual Book of ASTM Standards, Vol 03.04.

³ Annual Book of ASTM Standards, Vol 13.01.

5.2 If the ~~implant device~~ deflects less than 45° , then the magnetically induced deflection force is less than the force on the ~~implant 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 ~~sptatic magnetic field gradient~~ in one ~~MRI scanner MR system~~ does not preclude a deflection exceeding 45° in a ~~scanner system~~ with a higher field strength or larger ~~spatial~~ static field gradients.

5.4 This test ~~method~~ alone is not sufficient for determining if ~~an implant 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 ~~should shall~~ be less than 1 % of the weight of the device. The string ~~should shall~~ be long enough so that the device may be suspended from the test fixture and hang freely in space. Motion of the string ~~should 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 ~~standard~~ test method should be representative of manufactured ~~implant medical devices that are in the have been processed to a finished-sterilized-condition-condition~~ (for example, sterilized).

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

7.3 ~~This standard test method may be used on prototype devices during product development.~~

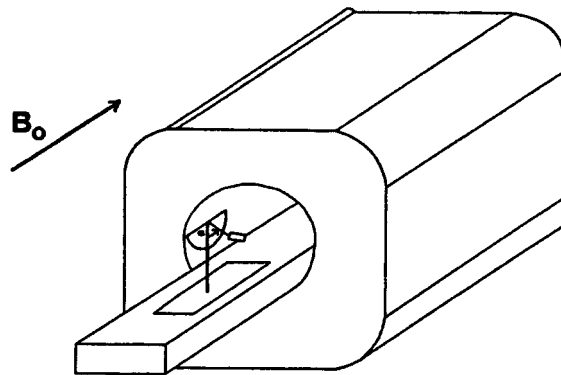
8. Procedure

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 scanner system~~. The test device is suspended from a ~~thin~~ 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 ~~0.5~~¹ $^\circ$ (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—The test fixture may need to be offset to locate the position of maximum deflection of an MRI Scanner.

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

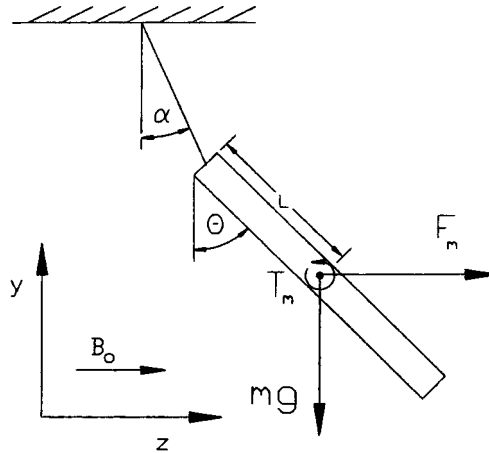


FIG. 2 Test Device in Magnetic Field

NOTE 1—For a paramagnetic, diamagnetic or ferromagnetic device below saturation, the location of maximum deflection is at the point where $|\mathbf{B}| |\nabla \mathbf{B}|$ is a maximum. For a ferromagnetic device above the magnetic saturation point, the maximum deflection will occur at the location where $\nabla \mathbf{B}$ is a maximum. If it is not known whether the device is paramagnetic, diamagnetic or ferromagnetic, perform the test at both locations.

9. Calculations

9.1 Calculate the mean deflection angle using the absolute values of the α 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 implant 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 number.

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

10.1.4 Materials of construction (ASTM designation or other).

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

10.1.5.6 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 MRI scanner, MR system, orient the coordinate system so that the y -axis is vertical and the z -axis is parallel to the patient table.

10.1.6.7 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.

10.1.7.8 Measured deflection angle, α , at the test location for each repetition of the test.

10.1.8.9 Mean deflection angle calculated using the absolute value of the measured values for deflection angle, α .

10.1.9.10 Weight of the implant.

10.1.10 Weight tested device.

10.1.11 Weight of the string used to suspend the implant device from the test fixture.

10.1.12 Weight of material used to constrain the device during the test.

10.1.13 Mean magnetically induced displacement force, F_m , calculated from measured test data for each device tested.

11. Precision and Bias

11.1 The precision and bias of this test method has not been established.

12. Keywords

12.1 implant;

12.1 medical device; metals (for surgical implants and medical devices); MRI (magnetic resonance imaging); MR safety

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE FOR DEVELOPMENT OF THE TEST METHOD

X1.1 The primary reason for this ~~standard~~ test method is to determine the magnetically induced deflection force on ~~passive implants~~ medical devices that may be subjected to magnetic resonance imaging. Note that this ~~standard test method~~ only addresses the magnetically induced deflection force and that the results of this test alone are not sufficient to determine whether a particular ~~implant device~~ is safe in the MR environment. The deflection force is produced by the ~~spatial gradients in the~~ static magnetic field gradients. The static field also produces a torque on ~~an implant~~ a device that acts to align the object with the magnetic field (like a compass needle aligns itself with the Earth's magnetic field). For a device to be safe in the MR environment, the magnetically induced deflection force and torque should be less than forces and torques to which the ~~implant device~~ would be subjected if it were not in a large magnetic field, ~~e.g. for example,~~ a force less than the weight of the device and a torque less than that produced by normal daily activities (which might include rapidly accelerating vehicles or amusement park rides). ~~In addition, for a device~~ Other possible safety issues include but are not limited to be safe in the MR environment, it must be shown to produce negligible levels of RF heating, induced heating, acoustic noise, interaction among devices, and gradient induced voltages.

The terms the functionality of the device and the MR system.

The terms *MR safe* and *MR compatible* are defined below as follows:

*MR safe**—The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

*MR compatible**—The device, when used in the MR environment, is MR-S safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device.* The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

A device which produces a deflection of less than 45° using this standard test method, passes a torque test, and demonstrates negligible levels of RF heating (see Test Method F 2182) and gradient induced voltages may be designated MR-S safe for the MR environment in which it was tested.

Currently,

Although a commercial 1.5 T MRI scanner MR system currently produces the conditions that would most commonly be encountered by a medical device, 3 T MR systems have been cleared for market and are becoming more common in clinical situations. It is important to note that a medical device that is safe or compatible in a 1.5 T scanner may not be so in a 3 T system. Also, there can be major differences in the characteristics of open and cylindrical MR systems. For instance, the static field spatial gradients may be significantly higher in open systems.

X2. DERIVATION OF FORCE RELATION GIVEN IN 8.4

X2.1

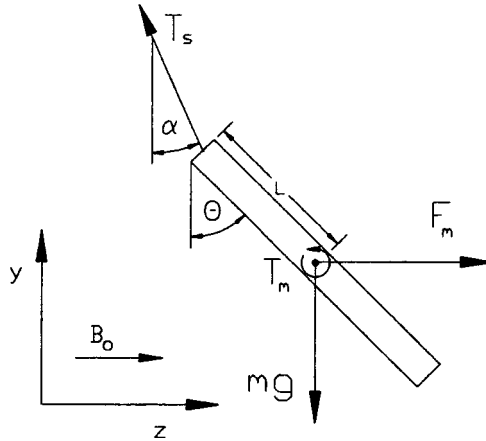


FIG. X2.1 Free Body Diagram of Implant Device in Magnetic Field

Definitions of symbols:

- T_s = tension in string
- T_m = torque due to magnetic field
- F_m = magnetically induced deflection force due to magnetic field spatial gradient
- L = distance from string attachment to center of mass of device
- m = mass of device
- α = angular deflection of string measured with protractor
- θ = angular rotation of device
- g = acceleration due to gravity

Assumptions:

1. Magnetism is a body force like gravity.
2. The center of magnetic force is not required to coincide with the center of mass, though the two locations are shown to be coincident in Fig. X2.1. The force equations written below are independent of the point of application of the magnetically induced force and torque.
3. The device is oriented in the magnetic field so that F_m and T_m are the only components of magnetically induced force and torque.

Summing forces in the free body diagram in Fig. X2.1:

$$\Sigma F_z = 0 = F_m - T_s \sin \alpha \tag{X2.1}$$

$$\Sigma F_y = 0 = T_s \cos \alpha - mg \tag{X2.2}$$

Solving the two equations gives $F_m = mg \tan \alpha$.

Note that the solution is independent of the point of attachment of the string. Also note that because the derivation of the relation for F_m uses only the force equilibrium equations, the relation for F_m also holds if the center of magnetic force does not coincide with the center of mass, as might be the case for an implant a device composed of more than one material.

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