Designation: F 2052 – 00

Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment[1]

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 magnetic field on passive implants (implants that function without the supply of electrical power) and the comparison of that force to the weight of the implant.

1.2 This method does not address the issues of magnetically induced torque or RF heating.

1.3 This 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 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 method is applicable only to magnet systems in which the direction of the magnetic field (and the direction of the magnetically induced deflection force) is horizontal.

2. Referenced Documents

2.1 *ASTM Standards:*

A 340 Standard Terminology of Symbols and Definitions Relating to Magnetic Testing

F 1542 Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips

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_o is the static field in an MR scanner.

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

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

3.1.7 *magnetic resonance imaging* (MRI)—imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei.

3.1.8 *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.

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

4. Summary of Test Method

4.1 An implant 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 deflects less than 45°, then the magnetically induced deflection force is less than the force on the implant due to gravity (its weight).

5. Significance and Use

5.1 This test is one of those required to determine if the presence of a passive implant may cause injury to the person with the implant during an MRI scan and in the vicinity of the MRI scanner. Other safety issues which should be addressed

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include magnetically induced torque and RF heating.

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

5.4 This test alone is not sufficient for determining if an implant is safe in the MR environment.

6. Apparatus

6.1 The test fixture consists of a sturdy 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 be less than 1% of the weight of the device. The string should be long enough so that the device may be suspended from the test fixture and hang freely in space. Motion of the string should 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 devices that are in the finished sterilized condition.

7.2 For purposes of device qualification, implant 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. 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. 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° (Fig. 2).

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

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

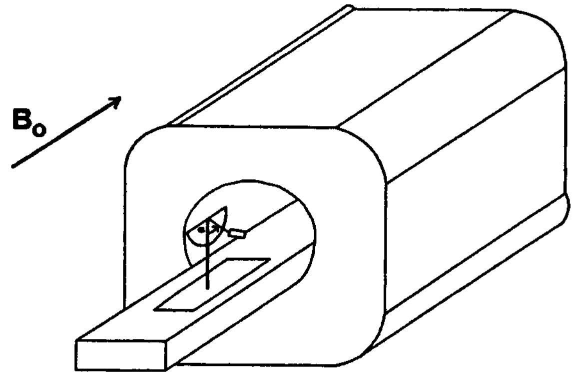

FIG. 1 Test Fixture Mounted on the Patient Table of an MRI Scanner

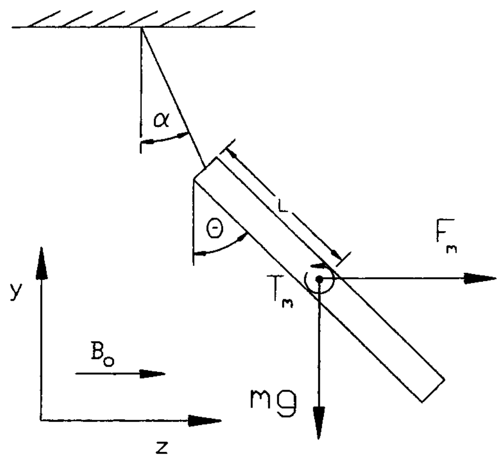

FIG. 2 Test Device in Magnetic Field

9. Calculations

9.1 Calculate the mean deflection angle using the absolute values of the 3 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 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.

10.1.2 Device product number.

10.1.3 Materials of construction (ASTM designation or other).

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

10.1.5 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, orient the coordinate system so that the y-axis is vertical and the z-axis is parallel to the patient table.

10.1.6 Values of |B|, the magnitude of the magnetic field and |∇B|, the magnitude of the spatial gradient of the magnetic field, at the test location.

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

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

10.1.9 Weight of the implant.

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

10.1.11 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; metals (for surgical implants); 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 that may be subjected to magnetic resonance imaging. Note that this standard only addresses the magnetically induced deflection force and that the results of this test alone are not sufficient to determine whether a particular implant is safe in the MR environment. The deflection force is produced by the spatial gradients in the static magnetic field. The static field also produces a torque on an implant 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 would be subjected if it were not in a large magnetic field, e.g. 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 to be safe in the MR environment, it must be shown to produce negligible levels of RF induced heating and gradient induced voltages. The terms MR safe and MR compatible are defined below.

*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.

*MR compatible** —The device, when used in the MR environment, is MR 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 and gradient induced voltages may be designated MR Safe for the MR environment in which it was tested.

Currently, a commercial 1.5 T MRI scanner produces the conditions that would most commonly be encountered by an implant.

X2. DERIVATION OF FORCE RELATION

X2.1

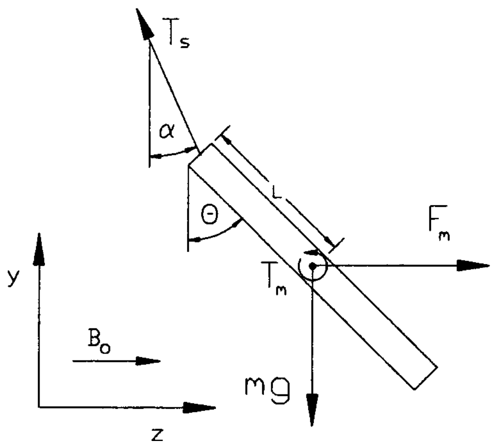

FIG. X2.1 Free Body Diagram of Implant in Magnetic Field

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:

$$\Sigma F_z = 0 = F_m - T_s sin\alpha \quad \text{(X2.1)}$$

$$\Sigma F_y = 0 = T_s cos\alpha - mg \quad \text{(X2.2)}$$

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 composed of more than one material.

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