Designation: ~~F2052 – 15~~ F2052 – 21

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

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 (spatial field gradient) 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~~to: issues of magnetically induced torque, ~~RF~~ radiofrequency (RF) heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the ~~MR~~ magnetic resonance (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 ~~filed~~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~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory ~~requirements~~limitations prior to use.*

1.7 *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 *ASTM Standards:*[2]

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

[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.

F136 Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)
F1537 Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
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~~IEC 60601-2-33 Ed. ~~2.0~~3.2 Medical Electronic Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis
~~ISO 13485:2003(E)~~GHTF/SG1/N071:2012 ~~Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes, definition 3.7~~definition 5.1, Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'
~~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),~~H in A/m),~~ n*—strength of the applied magnetic ~~field.~~field, H, expressed in amperes per meter (A/m).

3.1.4 *magnetic induction or magnetic flux density ~~(B in T),~~ (B), 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.~~ point and expressed in tesla (T). The magnetic induction is frequently referred to as the magnetic field. B_o is the static field in ~~a~~an MR system. Plain type ~~indicates a scalar~~ (for example, *B*) indicates a scalar and bold type ~~indicates a vector~~ (for example, ***B***~~).~~) indicates a vector.

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

3.1.6 *magnetic resonance diagnostic device, n*—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.

3.1.7 *magnetic resonance (MR) environment, n*—volume within the 0.50 mT (5 gauss (G)) line of an MR system, which includes the entire ~~three-dimensional~~ 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.

3.1.8 *magnetic resonance equipment (MR equipment), n*—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).

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

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

3.1.10 *magnetic resonance system (MR system), n*—ensemble of MR equipment, accessories, including means for display, control, energy supplies, and the ~~MR environment.~~controlled access area, where provided.

[from IEC ~~60601–2–33~~60601-2-33]

~~3.1.9 *magnetic resonance examination (MR examination), n*—process of acquiring data by magnetic resonance from a patient.~~

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

3.1.11 *medical device, n*—any instrument, apparatus, implement, machine, appliance, implant, ~~in vitro~~reagent for *in-vitro* ~~reagent or calibrator,~~ 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, 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.~~

(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 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.

3.1.11.1 *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~~[from GHTF/SG1/N071:2012, 5.1]**

3.1.12 *magnetically induced displacement force, n*—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, n*—a material having a relative permeability which is slightly greater than unity, and which is practically independent of the magnetizing force.

3.1.14 *spatial field gradient (SFG), n*—the spatial rate of change of the main magnetic field, $\|\nabla|\vec{B}_0\|\|$, expressed in tesla per meter (T/m). **[from IEC 60601-2-33]**

3.1.15 *tesla, (T), n*—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 in an MR system at a location near the entrance ~~to~~of the bore and on the ~~axis~~z-axis of the bore. ~~In order to increase the measurement sensitivity, this location shall be~~ The test location is chosen so that the spatial

~~gradient of the field strength, ∇~~field gradient (that is, spatial gradient of the static magnetic field)~~B = dB/dz,~~ is within 20 ~~percent~~% of the maximum ~~value of the spatial~~ spatial field gradient on the axis of the bore. The angular deflection from the vertical of the string ~~from~~holding the ~~vertical~~ test sample is measured. ~~If the device deflects less than 45°, then the deflection force induced by the MR system's magnetic field is less than the force on the device due to gravity (its weight).~~An analysis using the measured deflection angle, static magnetic field strength, and spatial field gradient at the test location is then performed to determine the allowable static magnetic field strength and spatial field gradient under specified conditions, for example, clinical 1.5 T, 3.0 T, and/or 7.0 T MR systems.

NOTE 1—~~It is important to choose a test location on the bore axis with as large a value of ∇~~The spatial field gradient within 20 % of ~~B as practical in order to increase the measurement sensitivity. This is particularly important if the test result is used in an analysis like that in~~ the ~~Appendix X3 to determine a maximum allowable spatial gradient to which the device may safely be exposed.~~maximum spatial field gradient value is specified to provide adequate measurement sensitivity.

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~~or in the MR environment. Other safety issues which should be addressed include, but may not be limited ~~to~~to: magnetically induced torque (see Test Method F2213) and ~~RF~~ radiofrequency (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~~ maximum magnetically induced displacement force for the specified magnetic field conditions (see Appendix X3) is less than the force on the device due to gravity (its ~~weight). For this condition,~~ weight), 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~~Earth's gravitational field. This statement does not constitute an acceptance ~~criterion, however~~ criterion; it is provided ~~for~~as a conservative reference point. It is possible that a greater magnetically induced ~~deflection~~displacement force can be acceptable and would not harm a ~~patient. For forces greater than gravity the location of the implant and means of fixation must be considered. Magnetically induced deflection forces greater than the force of gravity may be acceptable when they can be justified for the~~ patient or other individual in a specific case.

NOTE 2—For instance, in the case of an implanted device that is or could be subjected to a magnetic displacement force greater than the force due to gravity, the location of the implant, surrounding tissue properties, and means of fixation within the body may be considered. For a non-implanted device with a magnetically induced force greater than the gravitational force, consideration should be given to mitigate the projectile risk which may include fixing or tethering the device or excluding it from the MR environment so that it does not become a projectile.

5.3 ~~A deflection of less than 45° at the location of the maximum spatial gradient of the~~ The maximum static magnetic field ~~in one MR system does~~strength and spatial field gradient vary for different MR systems. Appendix X3 ~~not preclude a deflection exceeding 45° in a system with a higher field strength or larger static field spatial gradients.~~provides guidance for calculating the allowable static magnetic field strength and spatial field gradient.

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.

NOTE 3—For devices with low mass, it may be appropriate to test multiple devices simultaneously in order to increase the mass of the test object.

NOTE 4—Should the device weight be small to the degree that a support weighing less than 1 % of its weight is impracticable, a scientific rationale shall be applied to the test results in order to determine whether or not the observed deflection of the device reflects a ~~deflection~~displacement force in excess of the gravitational force.

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 The test shall be conducted in a horizontal bore MR system with a static magnetic field oriented horizontally and parallel to the bore. Fig. 1 shows the test fixture mounted on the patient table of an MR 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 test location. The test location is at the entrance of the MR system bore and on the axis of the bore. At the test location, the magnetically induced force, F_m, is horizontal and both ~~B and ∇B_0~~ and $|\nabla|\vec{B}_0\|$ act in the ~~z direction.~~ z-direction. In order to increase the measurement sensitivity, this location shall be chosen so that the spatial ~~gradient of the field strength,~~field gradient, $|\nabla|\vec{B}_0\|$~~∇~~ = dB_0 ~~= dB/dz,~~ /dz, is within 20 ~~percent~~% of the maximum value of the spatial field gradient on the axis of the bore. Record the Cartesian coordinates (*x, y, z*) of the test location. Also determine and record the values of the field strength, ~~*B,*~~B_0, and the spatial ~~gradient of the field strength,~~field gradient, $|\nabla|\vec{B}_0\|$~~∇~~ = dB_0 ~~= dB/dz~~ /dz, at the test location. 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 held so that the bulk of the device is at the test location (see Appendix X2). If anything (for example, tape) is used to hold the device during the test, demonstrate that the added mass does not significantly affect the measurement. When possible, the combined weight of material used to hold the device during the test shall be less than 1 % of the weight of the device. If the weight of the holding material exceeds 1 % of the weight of the device, report the weight of the holding material.

NOTE 5—In particular, ~~nonrigid,~~nonrigid or multi-component devices (for example, a pacemaker lead) need to be held (for example, bundled) so that the bulk of the device is at the test location.

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).~~activated.)

NOTE 6—At the test ~~location, the~~ location (which is on the z-axis), the magnetically induced force, F_m, is horizontal and both B_0 and $|\nabla|\vec{B}_0\|$~~∇B~~ act only in the ~~z direction.~~z-direction.

NOTE 7—For paramagnetic materials (for example, implant quality 316L stainless steel, nitinol, CoCrMo alloys, and titanium and its ~~alloys, 316L stainless steel)~~ alloys) and for unsaturated ferromagnetic material, the magnetically induced ~~deflection~~displacement force is proportional to the product of the static magnetic field and the spatial ~~gradient of the static magnetic field.~~ field gradient (also referred to as the force product). For devices composed of these materials, the location of maximum deflection is at the point where ~~|~~$|\vec{B}_0\|\nabla|\vec{B}_0\|$~~B|~~ ~~∇B|~~ is a maximum. For saturated ferromagnetic ~~materials,~~ materials (for example, cold-worked austenitic stainless steels or ferromagnetic components of batteries), the maximum deflection will occur at the location where $|\nabla|\vec{B}_0\|$~~∇B~~ is a maximum.

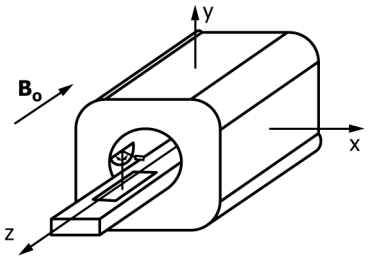

FIG. 1 Test Fixture Mounted on the Patient Table of a~~a~~n MRI System

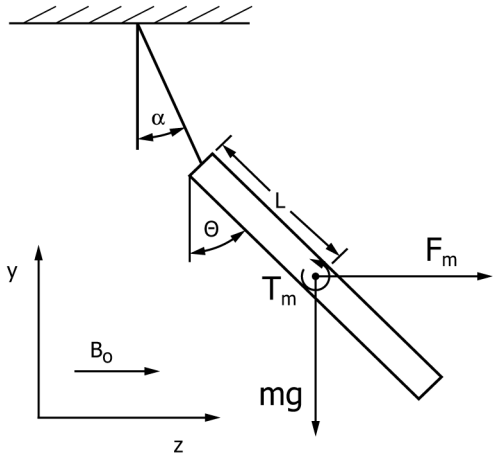

FIG. 2 Test Device in Magnetic Field

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~~displacement force for the device using the mean value for the deflection ~~angle α~~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).~~

NOTE 8—If the mean value for α is less than 45°, F_m, the magnetically induced displacement force, is less than the force on the device due to gravity (its weight) at the test location. However, because the test location is not the location of the maximum spatial field gradient or the location of maximum force product $|\vec{B}_0\|\nabla|\vec{B}_0\|$, F_m may be greater than the device weight at other locations in the test MR system or in other MR systems.

~~NOTE 7—This standard does not address what the maximum acceptable magnetic induced force should be for any device. See Appendix X1 for elaboration.~~

9.3 For paramagnetic test devices, use Eq X3.9 with α_C (for example $\alpha_C = 45°$), the measured mean deflection angle α_L, and the magnetic field strength and spatial field gradient at the test location to determine an allowable spatial field gradient for a specified magnetic field strength.

9.4 For devices containing saturated ferromagnetic material, use Eq X3.11 with the measured mean deflection angle α_L, α_C (for example, $\alpha_C = 45°$), and spatial field gradient at the test location to determine an allowable spatial field gradient for a specified magnetic field strength.

9.5 If for a specified magnetic field strength and spatial field gradient (that is, for condition "C" in the equations in Appendix X3), the magnetically induced displacement force is greater than the force induced by gravity and the device is intended to be used in those field conditions, a rationale supporting safe use under those conditions shall be developed. For an implant or other device in contact with a patient, the rationale might include consideration of the tissue adjacent to the implant and the means of fixation of the device.

NOTE 9—This standard does not address what the maximum acceptable magnetically induced force should be for any device. See Appendix X1 for elaboration.

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 test device during the test using a ~~right-handed~~ right-handed coordinate system with origin (0,0,0) at the isocenter of the MR system as shown in Fig. 1. Include a diagram showing the MR system and the coordinate axes.

NOTE 10—For devices that deflect during the test, this location is the device position after it is released and allowed to deflect.

10.1.7 Values of $|\vec{B}_0|$, ~~B|~~, the magnitude of the static magnetic field strength and $|\nabla|\vec{B}_0||$ ~~∇₂B|~~, the magnitude of the spatial ~~gradient of the magnetic field,~~ field gradient, at the test location.

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

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

10.1.10 Weight of the tested device.

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

10.1.12 Weight of the holding material if it exceeds 1 % of the device weight (see 8.3).

10.1.13 For devices with a ~~deflection angle, α greater than 45°, mean~~ displacement force greater than the force due to gravity ($\alpha_C > 45°$), the values of all variables used in Eq X3.9 or Eq X3.11 and the magnetically induced displacement force, F_m, calculated ~~from measured test data for each device tested.~~for field conditions, C.

10.1.14 For paramagnetic test objects with displacement forces less than gravity, the values of allowable static magnetic field strength and spatial field gradient from 9.3 and the values used for all other variables in Eq X3.9.

10.1.15 For ferromagnetic test objects with displacement forces less than gravity, the values of allowable static magnetic field strength and spatial field gradient from 9.4 and the values used for all other variables in Eq X3.11.

10.1.16 ~~If determined, value of the maximum allowable spatial gradient of the magnetic field and all details of the analysis used to determine the maximum allowable spatial gradient of the magnetic field (see~~ For test objects with both paramagnetic and ferromagnetic materials with displacement forces less than gravity, the values of allowable static magnetic field strength and spatial field gradient from ~~Appendix X3~~9.3~~).~~ and the values used for all other variables in Eq X3.9 or Eq X3.11.

11. Precision and Bias

11.1 The precision ~~and bias~~ of this test method ~~has not been established.~~is based on an interlaboratory study of ASTM F2052, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, conducted in 2017. Seven laboratories tested six test samples. Every "test result" represents an individual determination. Each laboratory was asked to submit three replicate test results, from a single test run, for each material. The details of this study are provided in ASTM Research Report No. RR:F04-2001.[4] The results are summarized in Tables 1 and 2, which provide the repeatability and reproducibility statistics for the maximum allowable spatial field gradient at 1.5 T and 3.0 T. Practice E691 was followed for the design and analysis of the data.

11.1.1 *Repeatability Limit (r)*—Two test results obtained within one laboratory shall be judged not equivalent if they differ by more

[4] Supporting data have been filed at ASTM International Headquarters and may be obtained by requesting Research Report RR:F04-2001. Contact ASTM Customer Service at service@astm.org.