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.

Designation: 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: issues of magnetically induced torque, radiofrequency (RF) heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the 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 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, health, and environmental practices and determine the applicability of regulatory 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

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 Ed. 3.2 Medical Electronic Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis

GHTF/SG1/N071:2012 definition 5.1, Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'

[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.

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

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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), n*—strength of the applied magnetic field, H, expressed in amperes per meter (A/m).

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

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

[from IEC 60601-2-33]

3.1.11 *medical device, n*—any instrument, apparatus, implement, machine, appliance, implant, reagent for *in-vitro* 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;

(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. **[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 of the bore and on the z-axis of the bore. The test location is chosen so that the spatial field gradient (that is, spatial gradient of the static magnetic field) is within 20 % of the maximum spatial field gradient on the axis of the bore. The angular deflection from the vertical of the string holding the test sample is measured. 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—The spatial field gradient within 20 % of the 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 or in the MR environment. Other safety issues which should be addressed include, but