



Designation: F2213 – 06 (Reapproved 2011)

Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment¹

This standard is issued under the fixed designation F2213; 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 torque produced by the static magnetic field in the magnetic resonance environment on medical devices and the comparison of that torque to the equivalent torque applied by the gravitational force to the implant.

1.2 This test method does not address other possible safety issues which include but are not limited to issues of magnetically induced force due to spatial gradients in the static magnetic field, RF heating, induced heating, acoustic noise, interaction among devices, and the functionality of the device and the MR system.

1.3 The torque considered here is the magneto-static torque due to the interaction of the MRI static magnetic field with the magnetization in the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method. Currents in lead wires may induce a torque as well.

1.4 The sensitivity of the torque measurement apparatus must be greater than $1/10$ the “gravity torque,” the product of the device’s maximum linear dimension and its weight.

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 and health practices and determine the applicability of regulatory limitations prior to use.*

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. Referenced Documents

2.1 ASTM Standards:²

F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

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

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2.2 Other Standards:

IEC 60601-2-33 Ed. 2.0 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis, 2002³

ISO 13485:2003(E) Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes, definition 3.7³

3. Terminology

3.1 *Definitions*—For the purposes of this test method, the definitions in 3.1.1 – 3.1.18 shall apply:

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 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

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>.

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}).

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

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

3.1.6 *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.

3.1.7 *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.

3.1.8 *magnetic resonance 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).

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

3.1.10 *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.

3.1.11 *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

3.1.12 *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 *magnetically induced torque*—torque produced when a magnetic object is exposed to a magnetic field. This torque will tend to cause the object to align itself along the magnetic field in an equilibrium direction that induces no torque.

3.1.14 *magnetization (M in T)*—magnetic moment per unit volume.

3.1.15 *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

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

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

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

4. Summary of Test Method

4.1 The static field in a magnetic resonance system produces a torque on a device that acts to align the long axis of the object with the magnetic field. The torque is evaluated using a torsional pendulum method. A device is placed on a holder suspended by a torsional spring. The apparatus is placed in the center of the magnetic resonance equipment magnet where the magnetic field is uniform. The torque is determined from the measurement of the deflection angle of the holder from its equilibrium position. The frame holding the spring and holder assembly is rotated and the torque as a function of angle of the implant is determined. The maximal magnetic torque is compared to the worst case gravity torque, defined as the product of the maximum linear dimension of the device and the device 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 during a magnetic resonance examination and in the magnetic resonance environment. Other safety issues which should be addressed include but may not be limited to magnetically induced force (see Test Method F2052) 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 maximal torque is less than the product of the longest dimension of the medical device and its weight, then the magnetically induced deflection torque is less than the worst case torque on the device due to gravity. For this condition, it is assumed that any risk imposed by the application of the magnetically induced torque is no greater than any risk imposed by normal daily activity in the Earth's gravitational field. This is conservative; it is possible that greater torques would not pose a hazard to the patient.

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

5.4 The sensitivity of the torque measurement apparatus must be greater than $\frac{1}{10}$ the “gravity torque,” the product of device weight and the largest linear dimension.

5.5 The torque considered here is the magneto-static torque due to the interaction of the MRI static magnetic field with the magnetization in the implant. The dynamic torque due to interaction of the static field with eddy currents induced in a rotating device is not addressed in this test method. Currents in lead wires may induce a torque as well.

6. Apparatus

6.1 The test fixture is depicted in Fig. 1. It consists of a sturdy structure supporting a holding platform supported by a torsional spring. Materials should be non-ferromagnetic. The device may be taped or otherwise attached to the holding platform. The supporting structure will have fixed to it a protractor with 1° graduated markings and the holding platform will have a marker so that the angle between the basket and the support structure can be measured. The supporting structure is rotated with the turning knob. The equilibrium angle between the supporting structure and the holding platform outside the magnetic field represents the zero torque angle. The torque inside the magnet is equal to the product of the deflection angle and spring constant. The torsional spring diameter should be chosen so that the maximal deflection angle is less than 25° . A photograph of a torque apparatus is shown in Fig. 2.

7. Test Specimens

7.1 For purposes of device qualification, the device evaluated according to this test method should be representative of

manufactured devices that have been processed to a finished condition (for example, sterilized).

7.2 For purposes of device qualification, any alteration from the finished condition should be reported. For instance, if sections are cut from the device for testing, this should be reported.

8. Procedure

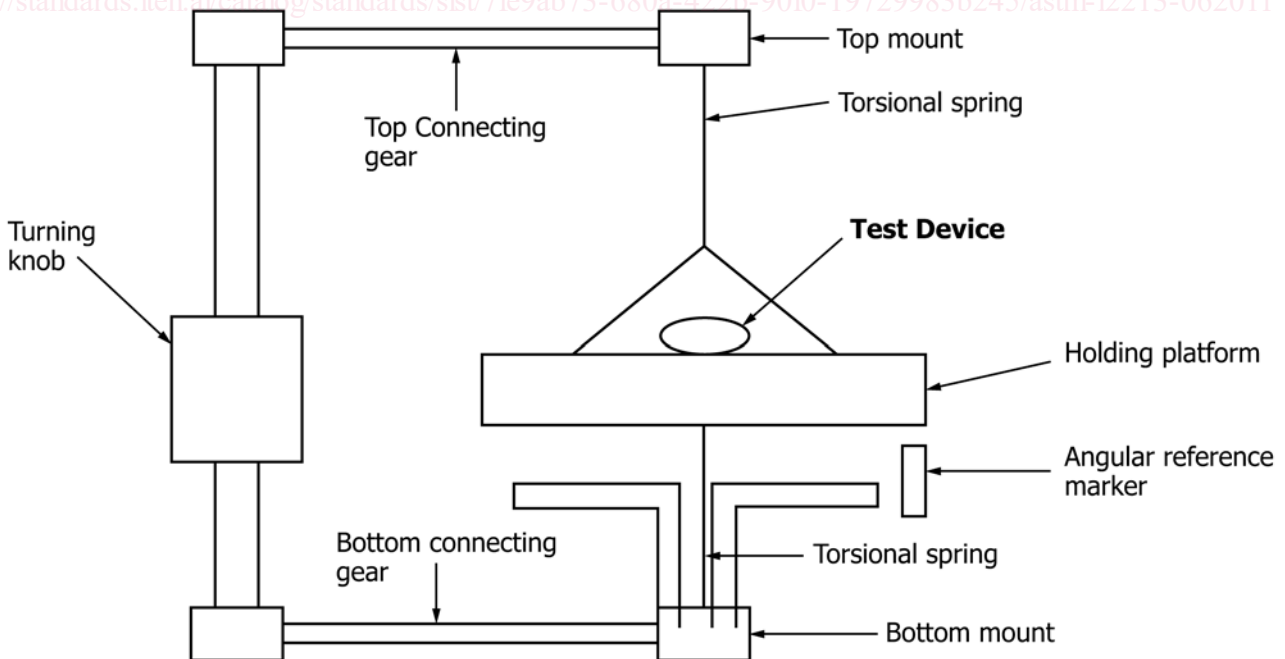
8.1 Fig. 1 depicts the test fixture, which is placed in the middle of the magnet where the magnetic field is uniform. The test device is placed on the holding platform with one of its principal axes in the vertical direction. The entire apparatus is placed in the center of the magnet in the region of uniform magnetic field. Rotate the fixed base and measure the deflection of the device with respect to the base at 10° increments for angles between 0° and 360° . Note that at angular values where the angular derivative of the torque changes sign, there will be an abrupt change in deflection angle as the device swings to the next equilibrium position. Try to measure the deflection angle as close as possible to this swing so that the maximal torque will be determined.

8.2 Repeat the process in 8.1 twice, once for each of the other two principal axes of the device in the vertical direction.

8.3 Lead wires should be arranged in a manner that is representative of the *in vivo* configuration. If feasible, the wires should carry the currents that are applied *in vivo*.

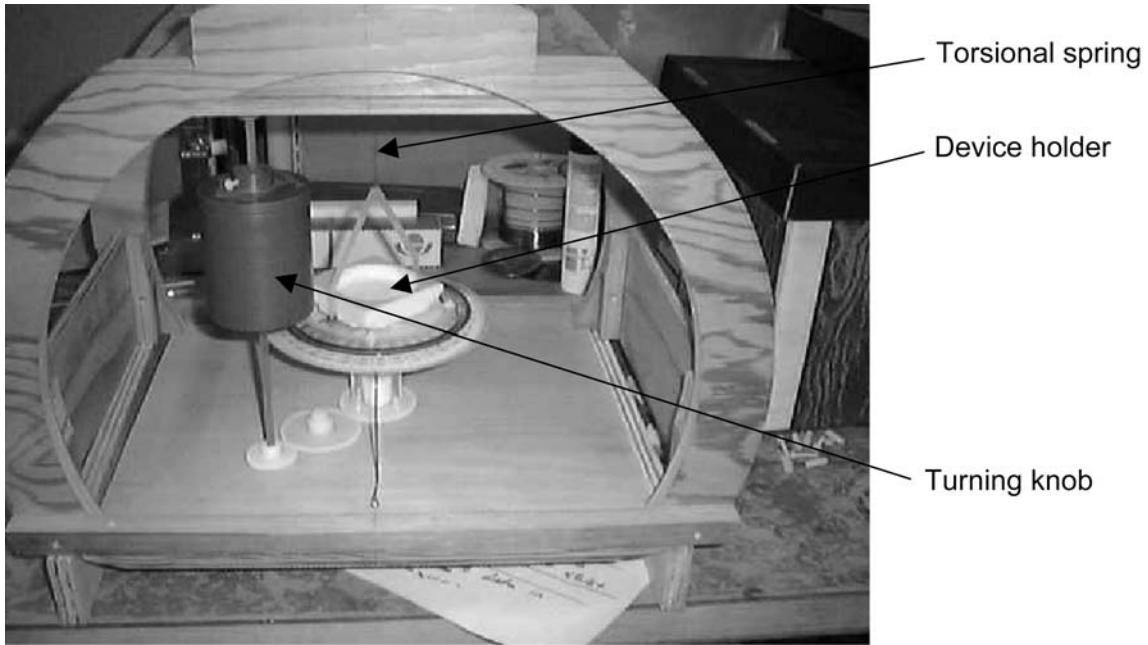
9. Calculation

9.1 The torque is $\tau = k\Delta\theta$ where $\Delta\theta$ is the deflection angle of the basket from its equilibrium position relative to the fixed base outside the magnet and k is the spring constant.



NOTE 1—The angular reference marker is used to locate the angular marks on protractors connected to the bottom mount and the holding platform.

FIG. 1 Diagram of the Torque Apparatus



NOTE 1—The turning knob is used to rotate the mounts supporting the torsional pendulum.

FIG. 2 Photograph of an Apparatus for Measurement of Magnetic Torque

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 a photograph with dimensional scale.

10.1.2 A diagram or photograph showing the three configurations 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 Weight of the device.

10.1.7 Dimensioned diagram or photograph describing the device.

10.1.8 Description of the type of magnet and the value of the static field B_0 .

10.1.9 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 isocenter of the magnet. Include a diagram showing the MR system and the coordinate axes.

10.1.10 Diagram or photograph of the test apparatus, including the value of the spring constant.

10.1.11 Plots of torque in units of N-m versus angular position of a device axis with respect to the direction of the static field. There will be three plots in total, one for each principal axis of the device oriented in the vertical direction.

10.1.12 Calculations of torque that would be exerted on current loops in the device (see Appendix X4).

10.1.13 Include a description and photograph of alterations that were done to the device.

11. Precision and Bias

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

12. Keywords

12.1 force, magnetic; implant; metals (for surgical implants); MRI (magnetic resonance imaging); MR safety; torque, magnetic