



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 F 2213; 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 *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.*

2. Referenced Documents

2.1 ASTM Standards:²

A 340 Terminology of Symbols and Definitions Relating to Magnetic Testing

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

F 2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

F 2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

F 2182 Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging

2.2 IEC Standard:

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

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 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

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.

Current edition approved Jan. 1, 2004. Published February 2004. Originally approved in 2002. Last previous edition approved in 2002 as F 2213 – 02.

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 the International Electrotechnical Commission (IEC), 3 rue de Varembe, Case postale 131, CH-1211, Geneva 20, Switzerland.

