



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

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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>.