



Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging¹

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1. Scope

1.1 This test method covers measurement of radio frequency (RF) induced heating on or near a passive medical implant and its surroundings during magnetic resonance imaging (MRI).

1.2 This test method is one required to determine if the presence of a passive implant may cause injury to the patient with the implant during an MR procedure. Other safety issues that should be addressed include magnetically induced displacement force and torque, as well as proper device function while in various configurations in the MR environment.

1.3 The amount of RF-induced temperature rise for a given specific absorption rate (SAR) will depend on the RF frequency, which is dependent on the static magnetic field strength of the MR system. While the focus in this test method is on 1.5 Tesla (T) or 3 Tesla cylindrical bore MR systems, the RF-induced temperature rise for an implant in MR systems of other static magnetic field strengths or magnet designs can be evaluated by suitable modification of the method described herein.

1.4 This test method assumes that testing is done on devices that will be entirely inside the body. For other implantation conditions (for example, external fixation devices, percutaneous needles, catheters or tethered devices such as ablation probes), modifications of this test method are necessary.

1.5 This test method applies to whole body magnetic resonance equipment, as defined in section 2.2.103 of the IEC Standard 60601-2-33, Ed. 2.0, with a whole body RF transmit coil as defined in section 2.2.100. The RF coil is assumed to have quadrature excitation.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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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1.7 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

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

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 IEC Standard:³

60601-2-33, Ed. 2.0 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis, 2002

2.3 NEMA Standard:⁴

NEMA MS 8—2008 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems

3. Terminology

3.1 Definitions:

3.1.1 *gelled saline*—phantom medium consisting of sodium chloride and polyacrylic acid or sodium chloride and hydroxyethylcellulose in water as specified in this test method.

3.1.2 *implant, n—in medicine*, an object, structure, or device intended to reside within the body for diagnostic, prosthetic, or other therapeutic purposes.

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.

⁴ Available from National Electrical Manufacturers Association (NEMA), 1300 N. 17th St., Suite 1752, Rosslyn, VA 22209, <http://www.nema.org>.