Designation: F2182 – 02a

Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging[1]

This standard is issued under the fixed designation F2182; 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 measurement of Radio Frequency (RF) induced heating near a passive medical implant and its surroundings during Magnetic Resonance Imaging (MRI).

1.2 This test method is one of those required to determine if the presence of a passive implant may cause injury to the person with the implant during an MRI procedure. Other safety issues that should be addressed include magnetically induced displacement force and torque.

1.3 The amount of RF-induced temperature rise for a given specific absorption rate (SAR) will depend on the RF frequency, which is proportional to the static magnetic field strength. Because of possible additional heating, particularly when device dimensions exceed a quarter wavelength, conclusions from measurements made at one frequency may not apply to other frequencies. While the focus in this test method is on 1.5 T cylindrical bore imagers, the RF-induced temperature rise in the open MRI systems can be evaluated by suitable modification of the methods described here.

1.4 This test method assumes that testing is done on devices that will be entirely inside the body.

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 *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]

A340 Terminology of Symbols and Definitions Relating to Magnetic Testing [3]

F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment [3]

F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

2.2 *IEC Standard:*[4]

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

3. Terminology

3.1 *Definitions*—For the purposes of this test method, the definitions in 3.1.1-3.1.10 shall apply.

3.1.1 *isocenter*—geometric center of the gradient coil system, which generally is the geometric center of a scanner with a cylindrical bore.

3.1.2 *magnetic resonance imaging (MRI)*—diagnostic imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei.

3.1.3 *magnetic resonance (MR) environment*—area within the 5 G line of an MR system.

3.1.4 *magnetic resonance system (MR System)*—ensemble of MR equipment, accessories including means for display, control, energy supplies, and the MR environment.

3.1.5 *medical implant*—a structure or device that is placed within the body of the patient for medical diagnostic or therapeutic purposes.

3.1.6 *MR safe*—the device, when used in the MR environment, has been demonstrated to present no additional risk to

[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 Nov. 10, 2002. Published December 2002. Originally approved in 2002. Last previous edition approved in 2002 as F2182 – 02. DOI: 10.1520/F2182-02A.

[2] *Annual Book of ASTM Standards*, Vol 03.04.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

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

the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

3.1.7 *MR compatible*—the device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

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

3.1.9 *radio frequency (RF) magnetic field*—the magnetic field in MRI that is used to flip the magnetic moments. The frequency of the RF field is γB_0 where γ is the gyromagnetic constant, 42.56 MHz/T for protons, and B_0 is the static magnetic field in Tesla.

3.1.10 *specific absorption rate (SAR)*—the mass normalized rate at which RF energy is deposited in biological tissue. SAR is typically indicated in W/kg.

4. Summary of Test Method

4.1 The implant to be tested is placed in a phantom material that simulates the electrical and thermal properties of the human body. The phantom material will include saline solution and a gelling agent. Fiber optic temperature probes are placed at locations where the induced heating is expected to be greatest. The phantom is placed in an MR system with a cylindrical bore or an apparatus that reproduces the RF field of this type of system. An RF field with SAR of at least 1 W/kg averaged over the volume of the phantom is applied. The temperature rise at the sensors is measured during the approximately 15 min of RF application, or other appropriate period, depending on the mass and thermal conductivity of critical parts of the device. Temperature measurements at one or more locations away from the device serve as the control.

5. Significance and Use

5.1 This test method describes a test procedure for evaluating the RF-induced temperature rise in MRI in the vicinity of an implanted medical device. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. The conditions and results of the testing should be included in the device labeling so that the attending physician can make the decision of whether to allow the patient with the implant to undergo an MRI procedure.

6. Apparatus

6.1 *Test Apparatus*—The test apparatus consists of a suitable phantom and an MR imager for production of the RF field. The phantom, implant and MR imager are to simulate the electrical and physical environment that the patient and device experience during an MRI procedure.

6.2 *Temperature Sensor*—A suitable temperature measuring device, usually a fiber optic probe, is used to measure temperature versus time of RF exposure in the vicinity of the implant. The temperature sensor will have a resolution of 0.1°C and a sensitive volume not to exceed 1 mm in radius. Fluoroptic temperature probes have been found to be satisfactory for this purpose.[5]

7. Test Specimens

7.1 For purposes of device qualification, the implant or device evaluated according to this test method shall be representative of a finished sterilized device. For the purposes of device qualification, the device evaluated according to this test method should be a finished sterilized device.

NOTE 1—The device does not have to be sterile at the time of testing. However, it should have been subjected to all processing, packaging, and sterilization steps before testing because any of these steps may affect the magnetic properties of the device.

7.2 For purposes of device qualification, implant devices shall not be altered in any manner prior to testing.

7.3 This test method may be used on prototype devices during product development.

8. Procedure

8.1 *Phantom Morphology*—Use a phantom geometry that reflects how the implant is placed in the body. The phantom container needs to be large enough to allow the device to be placed in a position representative of where it would be in the body. The container and all its parts should be made of material that is an electrical insulator and is non-magnetic. A whole body phantom should simulate the RF loading that would occur with a patient. The phantom should have the general shape of a patient (Fig. 1) but a rectangular phantom (Fig. 2) is also acceptable.[6] For application of RF by the body coil, the phantom should contain at least 30 kg of phantom material. For an implant inserted entirely in the head, a spherical phantom with dimensions similar to those of the human head may be appropriate. Generally, a homogeneous phantom will suffice, but in certain cases it may be appropriate to incorporate materials of different conductivity within the phantom.

8.2 *Phantom Material*—Phantom materials simulating tissue for the RF heating test during MRI shall meet the following criteria.

8.2.1 *Conductivity*—Conductivity shall be 0.4 to 0.8 S/m at 64 MHz, depending on the tissue to be modeled. (See Stuchly et al. (**1**)[7] for data on tissue electrical properties and Athey et al. (**2**) for procedures for measurement of electrical properties.) Electrical conductivity at low frequency will be less than at 64 MHz. The phantom conductivity should be 0.2 to 0.4 S/m for measurements made at a frequency of 1 kHz. (Stuchly and Stuchly (**3**)).

[5] Particularly suitable are the Luxtron (Luxtron Corporation, Santa Clara, CA, USA) Models 790, 3000, and 3100 Fluoroptic Thermometer Systems and the 0.6 mm diameter SFF-10 probe.

[6] The phantom in Fig. 2 may be purchased from Fab Lab Inc., Suite 1501325 Armstrong Rd., Northfield, MN 55057, cbenson@fablab.net.

[7] The boldface numbers in parentheses refer to the list of references at the end of this standard.

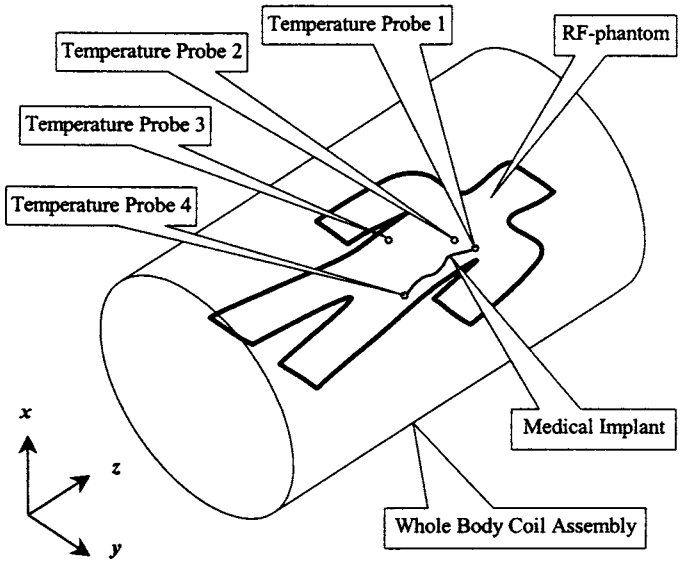
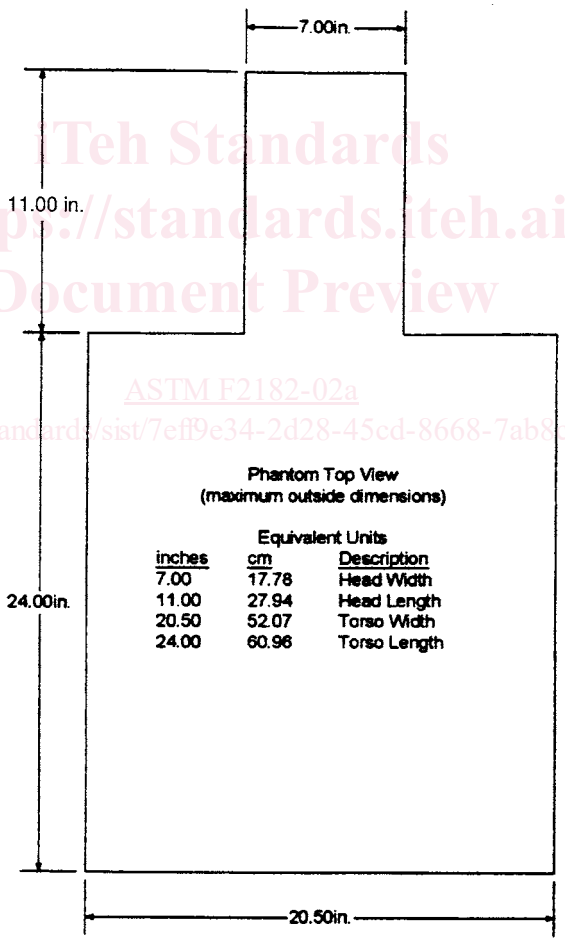


FIG. 1 Diagram of Apparatus for Testing of RF Heating Near an Implant During MR Imaging



NOTE—The depth is 26.5 cm and 30 L of phantom material fills the phantom to a depth of 9 cm.

FIG. 2 Sample Rectangular Phantom to Model the Human Trunk and Head for Use in a Cylindrical Bore Imager

8.2.2 *Dielectric Constant*—Dielectric constant shall be 60 to 100 at 64 MHz.

8.2.3 *Thermal Parameters*—The phantom material shall have thermal properties similar to those of the body which has

diffusivity of about 1.3 × 10^{-7} m^2/s and heat capacity close to that of water, 4184 J/kg °C.

8.2.4 *Viscosity*—The viscosity shall be sufficient so that the phantom material does not allow bulk transport or convection currents. Generally, this is achieved by inclusion of a gelling agent.

8.3 *Phantom Formulation*—A suitable gelled phantom (Rezai (**4**)) can be made with 0.8 g/L NaCl and 5.85 g/L Polyacrylic acid[8] into distilled water. This formulation has a room temperature conductivity of about 0.25 S/m and a viscosity sufficient to prevent convective heat transport. A number of other phantom formulations may be appropriate and some are described in the rationale.

NOTE 2—Note that the amount of aqueous solution absorbed decreases with increasing salt concentrations.

8.4 *Device Placement*—A representative experimental apparatus is depicted in Fig. 1. First, stir the phantom material to homogenize it. Place the device in the phantom in the location where it would be in a patient. If the device has long conducting wires, give consideration to possible resonant effects. Arrange wires in the worst case situation that would be experienced clinically. For example, long wires should be placed near the edge of the phantom in order to maximize reception of the induced electric field. Coil the leads according to the usual clinical technique. More than one run may need to be done to cover the clinically relevant situations. Cover the phantom with a cover or plastic sheet after the device is in place in order to minimize effects of air flow on the temperature measurements.

8.5 *Temperature Probe Placement*—Place at least three temperature probes on and near device parts that are expected to generate the greatest heating. Some experimentation may be required to determine the best probe placement. For example, for an elongated implant the greatest heating will likely occur near the end. One probe could be at the end (probe 1 in Fig. 1), another (probe 2) 5 mm from the end, a third at the other end of the implant (probe 4). Be sure there are no air bubbles at the probe tips. To provide confirmation of the whole body averaged SAR, place a probe (probe 3) at the side of the phantom where the heating is expected to be greatest.

8.6 *RF Field Application*—Use an imaging protocol producing an intensive RF field. The whole-body averaged SAR should be at least 1 W/kg for a 50 kg patient and 2 W/kg is desirable. A sample protocol for a 1.5 T (64 MHz) scanner is provided in Table 1. Note that the key parameter for a high SAR is to maximize the number of 180° RF pulses per second. The protocol in Table 1 generates 48 180° pulses per second and a whole body averaged SAR of 1.14 W/kg for a 50-kg patient. Use a protocol duration of at least 15 min in order to achieve adequate signal to noise in evaluation of the rate of temperature rise.

8.7 *RF Field Monitoring*—Record the applied whole body averaged SAR reported by the MR system software. Check that the temperature rise at the reference location is consistent with the reported SAR. Record the flip angle and bandwidth of the RF pulses, as well as the number of RF pulses applied per unit time. If the scanner software provides it, record the RMS average applied B_1 field and the total average power deposited in the patient.

TABLE 1 Sample RF-Intensive Imaging Protocol

Scan Type	Spin Echo, Axial
Slice Thickness	10 mm
RF Coil Type	Body or Head Coil
Number of Echos	4
TE	15 ms
TR	83.3 ms
NEX	112
# ACQ (slices)	1
Field of View FOV	large
Scan time	19:58
Bandwidth	1250 Hz

TABLE 2 Formulations (Percentages by Weight) and Properties of RF Phantom Materials (Chou et al. (5))

	Brain	Muscle
Water	93 %	91.48 %
TX-151 Gelling Agent (Oil Center Research, Lafayette, LA, USA)	7 %	8.4 %
NaCl	0	0.12 %
Conductivity (S/m)	0.52	0.8
Relative Dielectric Constant	78.1	79.8

8.8 *Thermal Equilibrium of Phantom with Surroundings*—Monitor temperature in the phantom for at least 10 min prior to the application of the RF. There must be sufficient thermal equilibrium between the phantom and surroundings that the temperature of the phantom does not change by more than 0.2°C during the observation time. The temperature within the scan room should be 23 ± 3°C and should be stable to ±1°C per h.

8.9 *Recording of Temperature versus Time*—Record the temperature at least 5 times per min. Begin recording at least 2 min prior to the start of the scan. This will allow evaluation of whether or not the temperature reaches steady state during the scan. After the RF is turned off, monitor and record the temperature for at least 2 additional min. The fan inside the bore is to be turned off while performing the temperature measurements.

8.10 *Control Measurements (optional)*—Take the implant out, and with temperature probes in the same locations as for the test, repeat the temperature measurements to determine the background temperature rise.

9. Report

9.1 *Report Contents*—Include the following in the report for each specimen tested:

9.1.1 Device product description.

9.1.2 Device product number.

9.1.3 Materials of construction. (ASTM designation or other.)

9.1.4 Photograph or drawing of device geometry showing key morphological features and dimensions.

9.1.5 Photograph or diagram of phantom, which includes the dimensions of the phantom.

[8] Catalog 43,636-4, Aldrich Chemical Company, Inc., Milwaukee, WI, USA. http://www.sigmaaldrich.com.