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Standard Test Method for Measurement of Radio Frequency Induced Heating On or 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 Frequencyradio frequency (RF) induced heating on or near a passive medical implant and its surroundings during Magnetic Resonance Imagingmagnetic 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 personpatient with the implant during an MRIMR 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 todependent on the static magnetic field strength of the MR system. Because of possible additional heating, particularly when deviceimplant dimensions approaches or exceed as onequarter of the wavelength of the RF field inside the phantom, conclusions from measurements made at one frequency may static magnetic field strength do not apply to other field strengths and frequencies. While the focus in this test method is on 1.5 T or 3 Tesla cylindrical bore imagers, MR systems, the RF-induced temperature rise in the for an implant in open MRIMR systems can be evaluated by suitable modification of the methodsmethod 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.

1.7 *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]

A340Terminology of Symbols and Definitions Relating to Magnetic Testing

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 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]

[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] 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*, Vol 03.04.volume information, refer to the standard's Document Summary page on the ASTM website.

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

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

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

~~3.1.1~~*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 *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.~~ local SAR—specific absorption rate (SAR) averaged over any 10 g of tissue of the patient body and over a specified time. **60601-2-33, Ed. 2.0**

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

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

3.1.6 ~~*MR safe*—the device, when used in the MR environment, has been demonstrated to present no additional risk to 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.~~ magnetic resonance system (MR system)—ensemble of MR equipment, accessories including means for display, control, energy supplies, and the MR environment. **60601-2-33, Ed. 2.0**

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

3.1.8 *MR Conditional*—an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, *dB/dt* (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

3.1.9 *MR Safe*—an item that poses no known hazards in all MR environments.

NOTE 1—MR Safe items include nonconducting, nonmagnetic items such as a plastic petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data.

3.1.10 *MR test system*—MR system or an apparatus that reproduces the RF field of this type of system.

3.1.11 *MR Unsafe*—an item that is known to pose hazards in all MR environments.

NOTE 2—MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

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

~~3.1.9~~

3.1.13 *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~~

3.1.14 *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

~~4.1The 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~~

~~[4] 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.

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.

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 implant is placed at a location with well characterized exposure conditions. The local SAR is assessed to characterize the exposure conditions at that location. The phantom material is a gelled saline consisting of a saline solution and a gelling agent. Fiberoptic temperature probes are placed at locations where the induced implant heating is expected to be the greatest (this may require pilot experiments to determine the proper placement of the temperature probes). The phantom is placed in an MR system or an apparatus that reproduces the RF field of such an MR system. An RF field producing a whole body averaged SAR of about 2 W/kg averaged over the volume of the phantom is applied for approximately 15 min, or other time sufficient to characterize the temperature rise and the local SAR.

4.2 The measurement is divided into two parts: In Step 1, the implant heating is measured and the RF energy is assessed by measuring the local SAR at a temperature reference probe. The temperature rise on or near the implant at several locations is measured using fiber-optic thermometry probes during approximately 15 min of RF application. In Step 2, the implant is removed and the local SAR is assessed at the same positions where the implant heating was measured in Step 1 and at the location of the temperature reference probe. All measurements shall be done with the implant holders in place. The local SAR value at the temperature reference probe is calculated and is used to verify that the same RF exposure conditions are applied during Steps 1 and 2.

5. Significance and Use

5.1This 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.

5.1 This test method describes a test procedure for evaluating the RF-induced temperature rise associated with an MR procedure involving a specific frequency of RF irradiation of an implant. The heating measurements are made twice, once with the implant and then repeated at the same location without the implant. These two measurements estimate the local SAR and the local additional temperature rise with the implant.

5.2 If there is a significant temperature rise associated with the implant, the results may be used as an input to a computational model for estimating temperature rise in a patient. The combination of the test results and the computational model results may then be provided to regulatory bodies and physicians to assess the safety of a patient with the implant during an MR scan.

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. —The test apparatus consists of a suitable phantom and an MR test system for production of the RF field. The phantom, implant, and MR test system are utilized to approximate the electrical and physical environment that the patient and device experience during an MR procedure. The phantom, implant, and MR test system are utilized to establish the heating behavior of a device in a known RF field in a standardized phantom.

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.

7.Test Specimens

7.1For 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. —A suitable temperature measuring device, usually a fiberoptic thermometry probe, is used to measure temperature versus time of RF exposure on or in the vicinity of the implant. The temperature sensor will have a resolution of no worse than 0.1°C and a spatial resolution not to exceed 1 mm in any direction.

NOTE1—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.

7.2For purposes of device qualification, implant devices shall not be altered in any manner prior to testing. 3—Fluoroptic temperature probes have been found to be satisfactory for this purpose.

7. Test Specimens

7.1 For purposes of device qualification, the implant evaluated according to this test method shall be representative of a finished device in the as-implanted condition; for example, balloon expandable stents should be balloon expanded.

7.2 For purposes of device qualification, implants shall not be altered in any manner prior to testing other than positioning/coiling of the implant in order to orient it in the anticipated worst case scenario for that device/scanner frequency.

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 (—The phantom container and all its parts should be made of material that is an electrical insulator and is non-magnetic and non-metallic. The phantom container should be constructed so that the phantom gelled-saline material is of the dimensions shown in Fig. 1) but a rectangular phantom (Fig. 2) is also acceptable. 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**) 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**)). —Conductivity of the gelled saline at test temperature shall be 0.47 ± 10 % S/m at 64 MHz and 128 MHz.

NOTE 4—The conductivity at the test temperature was selected to match the average conductivity of the human body at body temperature. Electrical conductivity in the MHz range is greater than conductivity measured in the kHz range. The conductivity at 64 MHz and 128 MHz is valid using measurements at the lower frequencies specified in 8.3.1. (See Stuchly et al. **(1)** [5] for data on tissue electrical properties and Athey et al. **(2)** for procedures for measurement of electrical properties.)

[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.

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

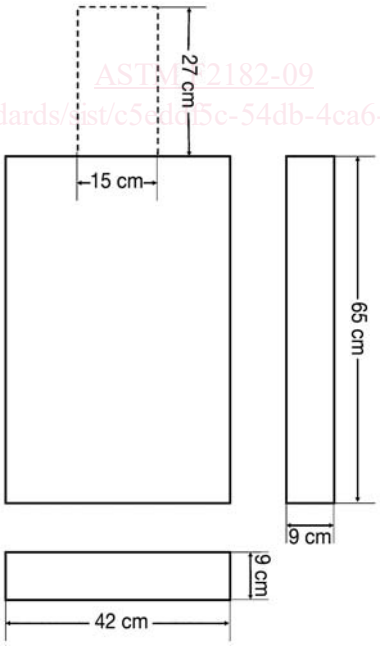

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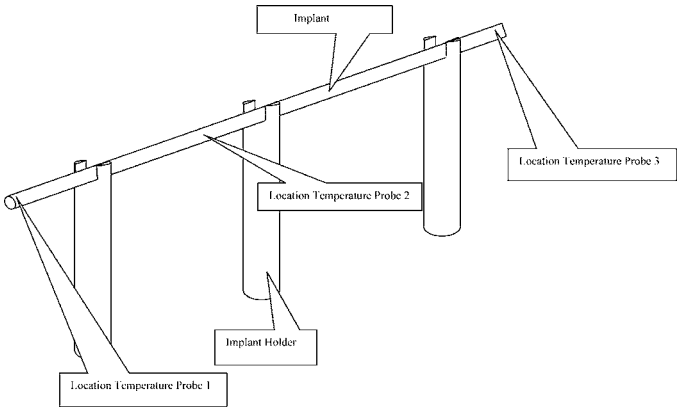
FIG. 1 Dimensions of Phantom Material (Gelled Saline) in a Rectangular Phantom



NOTE—Because implant holders with material differences from the phantom fluid will cause local field disturbances, temperature probes should be located at least 2 implant holder-diameters away from the implant holder to minimize the effect on the temperature measurements. For example, if an implant holder is 5 mm wide, the temperature probe should be placed at least 10 mm away from the implant holder.

FIG. 2 Example of Appropriate Implant Holder

8.2.2 *Dielectric Constant*—Dielectric constant shall be 60 to 100 at 64 MHz and 128 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.~~ 4160 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.~~ —The viscosity shall be great enough so that the phantom material does not allow bulk transport or convection currents. Generally, this is achieved by inclusion of a gelling agent.

NOTE 5—The amount of aqueous solution absorbed decreases with increasing salt concentrations.

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 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.~~ —A suitable gelled saline that has the properties described in 8.2 can be made with 1.32 g/L NaCl and 10 g/L polyacrylic acid (PAA) in water. For this formulation, room temperature conductivity is approximately 0.47 S/m and viscosity is sufficient to prevent convective heat transport.

NOTE~~2—Note that the amount of aqueous solution absorbed decreases with increasing salt concentrations.~~ 6—Another formulation can be made with NaCl and hydroxyethyl cellulose (HEC) in water. See X1.4. Comparative testing between PAA and HEC gels has not been performed prior to publication of this test method.

8.3.1 It is essential to strictly follow the mixing protocol and use the given ingredients in order to achieve reliable and repeatable results. The following protocol needs to be followed precisely. The resulting gel (PAA) should have conductivity of 0.40 to 0.60 S/m at temperatures between 20 and 25°C measured at frequencies lower than 15 kHz. The specific heat of the gel is 4160 J/(kg k) at 21°C and there is a linear rise of 2.35 J/(kg K) per degree kelvin in the specific heat from 20 to 40°C. The gelled saline should have a shelf life of two months. However, a new batch of gelled saline is needed when there is a change in any property, such as volume, conductivity, color, or viscosity. The phantom should be sealed in an airtight container whenever possible to prevent evaporation and/or contamination. Evaporation will alter the gelled saline properties.

NOTE 7—The objective is to have a resulting gel with a conductivity of 0.47 S/m at frequencies of 64 and 128 MHz, however, the ability to make a precise formulation of the material exceeds the ability to precisely measure its complex permittivity at these frequencies using readily available methods. As such, care must be taken in following the instructions, and it is suggested to measure the conductivity with a simple device at low frequencies (between approximately 1 and 15 kHz) in order to check that the recipe was made without large errors or deviations.

8.3.1.1 Ingredients of PAA gelled saline:

Water—deionized or distilled water, conductivity less than 1 mS/m.

NaCl—reagent grade, >99 % pure.

Polyacrylic acid—Aldrich product number 436364, 'Polyacrylic acid partial sodium salt', CAS no. 76774-25-9.[6] See Note 8.

NOTE 8—Different products have different gelling properties. The product listed above has been found to produce a gelled saline with the required properties.

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

8.3.1.2 Preparation of PAA gelled saline:

(1) Add NaCl to water and stir to dissolve completely. Verify that the conductivity is 0.26 ± 10 % at 25°C measured at frequencies lower than 15 kHz.

(2) Add PAA, stir to suspend completely.

(3) After one hour, blend the suspension into a slurry. A kitchen grade immersion blender with a blade has been found to be satisfactory. The blender is turned on intermittently for at least 20 min in order to remove all lumps of any discernable size.

(4) The slurry is ready to use after 24 h. Stir occasionally. The appearance of the slurry should be semi-transparent, free of bubbles, and free of lumps of any discernable size.

(5) Verify that the conductivity is between 0.40 to 0.60 S/m at 25°C measured at frequencies lower than 15 kHz.

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.~~ Implant Placement and Orientation in Known E-field —For the chosen phantom geometry (8.1), computationally or experimentally determine the applied radiofrequency E-fields throughout the phantom geometry for the MR test system or with the transmit RF coil used in the test in the absence of the implant. Amjad et. al **(3)** provides information on how to determine the E-fields. Choose a location for the implant where the E field is known and of sufficient magnitude to heat the implant-free region at least 10 times the precision of the temperature sensor (for example, 1°C for sensors with 0.1°C precision) by the completion of the run without the implant in place (8.14). Additionally, as possible, choose a volume in which the implant is placed so the undisturbed E-field does not vary significantly over this volume. Orient the longest linear dimension of the implant aligned with the E-field in this volume so that there is a high uniform electric field tangent to the implant. For a complicated multi-component implant, testing may need to be done with the implant in multiple orientations in the phantom at the same location. In order to minimize heat transfer into the environment, orient the implant so that it is at least 2 cm from the gel surface, bottom, and walls of the container. See X1.5.

NOTE 9—For the standard rectangular phantom geometry, with the phantom centered in the bore, and the lateral side of the implant placed 2 cm from the phantom wall, this location provides a high uniform tangential electric field.

8.5 *Implant Configuration*—For multi-component implants that include flexible components that are not clinically used in a straight configuration (for example, catheters or guidewires), the flexible components should be assembled and attached to the rigid implant in a clinically relevant worst case configuration. Demonstrate the worst case implant configuration and provide evidence that you have tested in the worst implant configuration **(4)**. Testing in more than one implant configuration will be required if the worst case clinically relevant configuration of the implant is unknown.

NOTE 10—For example, a trochanteric reattachment device consists of a trochanter plate and three flexible cables that are crimped into three separate loops and threaded through three proximal slots in the plate. The plate with flexible cable assembly should be tested in the clinically relevant worst case orientation inside the phantom.

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.~~ Implant Holder—To facilitate proper placement of the implant inside the gelled-saline filled phantom, an implant holder is needed. Because any such holder may have an effect on the local field environment, the implant holder must be made of appropriate materials (for example, nonmetallic, nonconducting), be small

[6] The sole source of supply of the apparatus known to the committee at this time is Aldrich Chemical Company, Inc., Milwaukee, WI, USA. http://www.sigmaaldrich.com. If you are aware of alternative suppliers, please provide this information to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend.