Designation: F2182 – 09

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 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 of those 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.

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. Because of possible additional heating, particularly when implant dimensions approaches or exceeds onequarter of the wavelength of the RF field inside the phantom, conclusions from measurements made at one 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 MR systems, the RF-induced temperature rise for an implant in open MR systems 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.

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

[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. 15, 2009. Published January 2010. Originally approved in 2002. Last previous edition approved in 2002 as F2182 – 02a. DOI: 10.1520/F2182-09.

[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.

3.1.3 *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 (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 *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 *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 *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.

3.1.13 *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.

3.1.14 *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

4.1 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

5.1 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 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 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.

NOTE 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

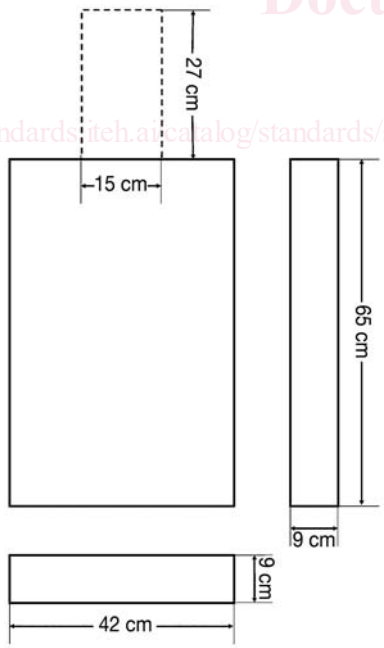
8.1 *Phantom Morphology*—The phantom container and all its parts should be made of material that is an electrical insulator and is non-magnetic and non-metallic. The phantom container should be constructed so that the phantom gelled-saline material is of the dimensions shown in Fig. 1.

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

8.2.1 *Conductivity*—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] The boldface numbers in parentheses refer to a list of references at the end of this standard.



NOTE 1—The phantom container should be constructed so that the phantom material is of the dimensions shown in the figure. Dotted portion of the phantom is optional.

NOTE 2—The diagram shows the dimensions of the gelled saline phantom material, *not* the dimensions of the container.

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

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, 4160 J/kg°C.

8.2.4 *Viscosity*—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 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 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.

[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,[1] which you may attend.

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

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 *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.

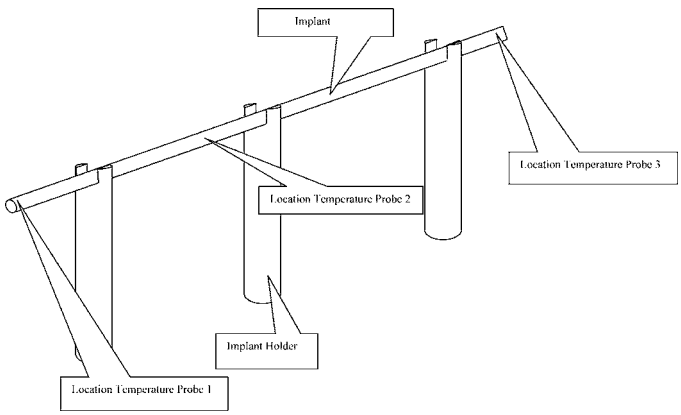
NOTE 9—For the standard rectangular phantom geometry, with the phantom centered in the bore, and the lateral side of the implant placed 2 cm from the phantom wall, this location provides a high uniform tangential electric field.

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 *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 enough, appropriately oriented, and far enough away from the temperature measurement locations so as not to disturb the local field distribution close to these locations. Fig. 2 shows an example of an appropriate implant holder—small cylinders with less than 5 mm diameter. These may be placed in whatever orientation is required as long as they will not significantly alter the local electrical or thermal environment being measured. The implant holder shall be mounted perpendicular to the major field components of the induced electric field inside the phantom. Adequate mounting of this example implant holder would be perpendicular to the bottom or side wall of the phantom. Because implant holders with material differences from the phantom fluid will cause local field disturbances, temperature or SAR probes should be located at least two implant holder-diameters away from the implant holder to minimize this effect on the 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.

8.7 *Phantom Temperature Measurement Setup*—Secure at least three temperature probes on or near the portions of the implant that are expected to generate the greatest heating with a repeatable probe placement precision of ±0.5 mm between the probe and the implant. Determine the position(s) of maximum heating near the implant by theoretical means and/or by pilot experiments for the specific device and device configuration under test. To provide a measure of the run to run repeatability of the applied RF power and local E-field, without



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

disturbing the fields near the implant, locate a reference temperature probe in a position of high E-field sufficiently distant from the implant. An optimal position for the reference probe may be on the contra-lateral side of the phantom from the implant using the longitudinal axis passing through the geometric center of the phantom as the reflection axis. (See Fig. 3.) This location should be at least 15 cm from the implant where E-fields tend to have similar field strength as those present at the implant **(3)**. This gives a position with the same radial distance from the longitudinal axis of gelled saline. An optimal position for the reference probe may be on the contralateral side of the phantom using the longitudinal axis passing through the geometric center of the phantom as the reflection axis.

NOTE 11—The sensing portion of the temperature probe varies for different probes. The location of the sensing portion of the probe needs to be precisely determined for each individual temperature probe **(5)**.

NOTE 12—Heating in the phantom may be asymmetric (**17, 18**), therefore onsiderable experimentation or computation may be required to determine the temperature probe placement for which maximum heating can be measured (**16, 19, 20**). For instance, for an elongated implant, the greatest heating will likely occur near the ends of the implant. Implant heating may also be maximal at sharp points or edges. As shown in Fig. 3, one probe could be at the end (probe 1), another (probe 2) positioned at the middle of the implant, and a third at the other end of the implant (probe 3). Locate the reference temperature probe (probe 4) in the position of high E-field as described in 8.7.

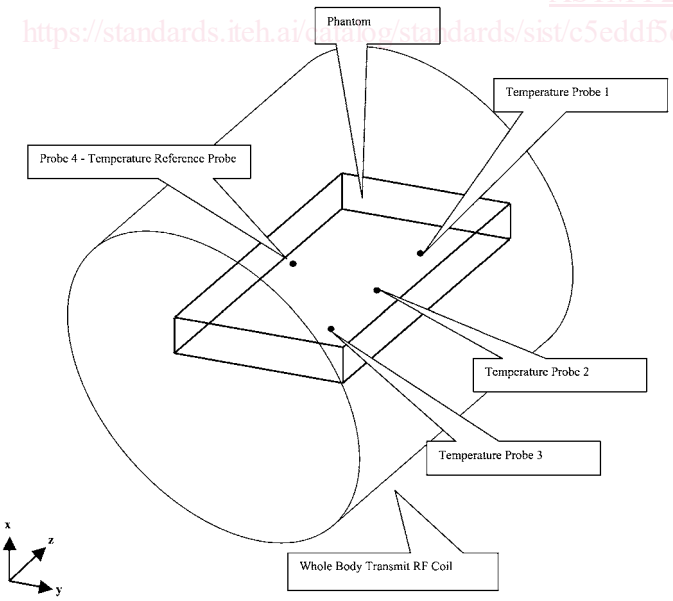
8.8 *Implant Temperature Measurements*:

8.8.1 Take photographs showing the position of the implant in the phantom and the relative locations of the temperature probes and the implant. Also take a photograph of the implant showing a dimensional scale.

8.8.2 Fill the phantom with the gelled saline (8.3). Stir the phantom gelled saline to ensure that it is thoroughly mixed. Be sure that there are no air bubbles at the temperature probes. Visually examine the location of the temperature probes relative to the implant immediately before and after the heating assessment because significant variations in measured temperature rises can occur with slight variations in temperature probe positions relative to the implant. The patient comfort fan inside the MR system bore should be turned off or the air flow must be blocked or directed away from the phantom so that there is no movement of air inside the MR system bore while performing the temperature measurements. If the patient comfort fan cannot be turned off, the phantom should be covered after the implant is in place in order to minimize effects of air flow on the temperature measurements.

8.9 *RF Field Application*—Use a protocol producing a relatively high level of RF power to achieve the required temperature rise as indicated in 8.4 and a whole body averaged SAR of approximately 2 W/kg. SAR levels of greater than 2 W/kg may also be used.

NOTE 13—If using an MR system to apply RF power to the phantom, the sequences in Tables 1-3 have been found to be satisfactory for RF heating testing. These are a limited set of representative sequences, presented as they might be prescribed on some common MR systems. MR systems and pulse sequences from other manufacturers can certainly be used to apply adequate RF for this test method.



NOTE—Temperature probes 1, 2, and 3 are in the locations of greatest heating on or near the implant. Temperature probe 4 is the Temperature Reference Probe.

FIG. 3 Diagram of Apparatus for Testing of RF Heating Near an Implant During MR Imaging

TABLE 1 Sequence for a 1.5-Tesla Phillips Achieva, Phillips Medical System, Best, The Netherlands, Active-shielded, Short Bore, Horizontal Field Scanner

NOTE—The body radiofrequency (RF) coil was used to transmit and receive RF energy that has been found to be satisfactory.

MRI Parameters	
Sequence	Turbo Spin Echo
TR	260 ms
TE	6 ms
Echo train laength	16
Plane	Coronal
Flip angle	90°
Bandwidth	69 kHz
Field of view	45 cm
Matrix	264 × 256
Section thick	10 mm
Total slices	4
WB-SAR	4 W/kg
NSA	27
Dynamics	4
Scan time	15:11

TABLE 2 Sequence for a 1.5-Tesla/64-MHz, Magnetom, Siemens Medical Solutions, Malvern, PA, Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, Horizontal Field Scanner

MRI Parameters	
Sequence	True Fisp
TR	30 ms
TE	1.3 ms
Flip angle	66°
Bandwidth	977 Hz/px
Field of view	40 cm
Matrix	128 × 128
Sections	10 mm
Skip	10 %
Total slices	43
Scan time	15:00

TABLE 3 Sequence for a 3-Tesla Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI; Active-shielded, Horizontal Field Scanner

NOTE—The body radiofrequency (RF) coil was used to transmit and receive RF energy that has been found to be satisfactory.

MRI Parameters	
Sequence	Fast spin echo
TR	425 ms
TE	14 ms
Echo train length	4
Plane	Axial
Flip angle	90°
Bandwidth	16 kHz
Field of view	40 cm
Matrix	256 × 256
Section thick	10 mm
Total slices	40
Transmitter gain	80
Scan time	15:00

8.10 *Thermal Equilibrium of Phantom Material with Surroundings*— Record temperatures using a minimum of four temperature probes for at least 2 min prior to the application of the RF energy to allow evaluation of whether or not the temperature is at steady state prior to the scan. There must be sufficient thermal equilibrium between the gelled saline and surroundings that the RMS temperature of the gelled saline for the first 10 s and the RMS temperature of the gelled saline for the last 10 s of the 2 min observation time does not change by more than 0.2°C. The temperature within the scan room should be 21 ± 4°C and should be stable to ±1.0°C per h.

8.11 *MR System or RF Coil Field Records*—If available, record the MR system's estimated whole body averaged SAR, local SAR, peak SAR, partial body SAR, flip angle(s), the number of RF pulses applied per unit time, the bandwidth of the RF pulses, the RMS average applied B1 field, total time/duration over which the field was intermittently applied, and the total average power deposited in the phantom material.

8.12 *Recording of Temperature versus Time*—Record the temperature from each temperature probe at least once every 4 s. Begin recording temperature at least 2 min prior to the start of the scan. After the RF energy is turned off, monitor and record the temperature for at least two additional minutes. Record the temperature in the scan room within 15 min prior to application of RF and within 15 min after completing the test.

NOTE 14—Depending on the particular gelled saline formulation used, it may be possible to stir the gelled saline and measure the average temperature of the gelled saline well enough to calculate the whole body averaged SAR. At time of publication of this standard, equivalence between whole body averaged SAR determined by stirring the gel and by the method given in Section 9 has not been demonstrated.

8.13 *Repeat*—If the measurement is to be repeated, the implant should be tested in exactly the same location and with the temperature probes in exactly the same locations. Repeat 8.4 through 8.12.

8.14 *Local SAR and Measurements Without the Implant in Place*—For the same RF fields applied in 8.9, the local temperature rises at the secured temperature probe locations should be determined without the implant present by measuring the local temperature changes. As described in 8.7, the temperature probes should be placed at the same spatial positions as during the implant testing. Care should be taken to ensure minimal bubble or air entrapment in the gel with removal of the implant to help avoid inadvertent hot spot formation.

8.14.1 *Determination of Local SAR*—The local SAR at each of the four temperature probe locations *without* the implant in the gelled-saline filled phantom shall be calculated based on local temperature measurements according to the following equation:

$$SAR = c\frac{\Delta T}{\Delta t} \quad (1)$$

where:

c = 4160 J/kg/°C, the specific heat capacity of the phantom material,
T = the temperature in °C, and
Δt = time in seconds.

Record the temperature increase over 15 min and calculate the *dT/dt* using a linear fit over the 15 min.

NOTE 15—An alternative method for determining local SAR using a reference implant is given is X1.8.

9. Determination of Whole Body (Phantom) Averaged SAR using Calorimetry in Saline-filled Phantom

9.1 This section describes the calorimetric method to measure the whole body (phantom) averaged SAR (WB-SAR).

NOTE 16—The measurement of the phantom WB-SAR is needed because the WB-SAR is an essential value for the MR Conditional labeling. The labeling must guarantee that in a patient scanned in the normal operating mode or the first level control mode the implant does not produce dangerously high heating. The implant heating measured in the phantom at a certain phantom WB-SAR and at a certain local SAR in the phantom must then be related to the possible *in-vivo* heating in the normal or first level control mode. This maximum *in-vivo* heating for the normal and first level control mode stated in the labeling can be used by the MR scanner user as a criterion if a certain patient can undergo a particular MRI scan.

NOTE 17—NEMA MS 8—2008 describes calorimetric and pulse energy methods for whole-body SAR measurements.

9.2 This procedure needs to be performed once for each physical location of the phantom within the MR test system. If the MR test system is an MR scanner, both the implant measurement described above and the calorimetry measurement in this section need to be done with the same MR test sequences and the same version of the MR scanner software to ensure that the same RF power deposition occurs. The phantom is filled with a saline solution with a conductivity of 0.47 S/m (2.5 g/L NaCl dissolved in deionized water). The calorimetry for the phantom is performed as follows:

9.2.1 Ensure that the saline solution is within ±0.5°C of the scan room temperature.

9.2.2 Place the phantom on the patient table and stir the saline.

9.2.3 Measure the saline temperature in the central portion of the phantom container with a high precision thermometers or temperature probe (with accuracy ≥0.05°C).

9.2.4 Cover the phantom with a lid to avoid evaporation and cooling of the saline which can produce considerable error. Leave the insulation at the top of the phantom in place.