Designation: F2182 – 11a

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 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.

1.7 *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.

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

3.1.4 *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**

3.1.5 *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.

3.1.6 *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.

3.1.7 *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**

3.1.8 *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. 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 sufficient 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 test procedure is divided into two steps. In Step 1, the temperature rise on or near the implant at several locations is measured using fiber-optic thermometry probes (or equivalent technology) during approximately 15 min of RF application. Temperature rise is also measured at a reference location during Step 1. In Step 2, the implant is removed and the same RF application is repeated while the temperature measurements are obtained at the same probe locations as in Step 1. All measurements shall be done with the implant holders in place. The local SAR is calculated from the temperature measurements for each probe location, including the reference location. The local SAR value at the temperature reference probe is used to verify that the same RF exposure conditions are applied during Steps 1 and 2.

5. Significance and Use

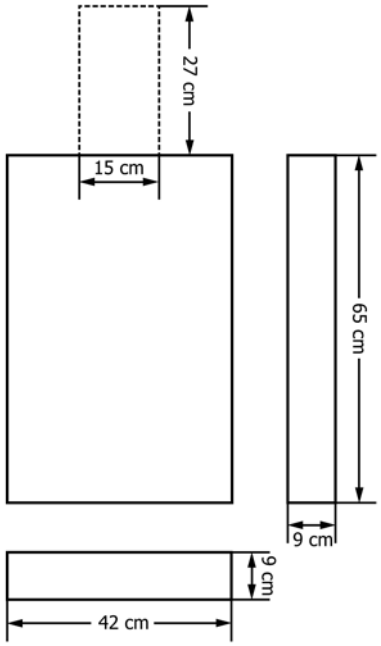
5.1 This test method describes a test procedure for evaluating the RF-induced temperature rise associated with an MR procedure involving a specific frequency of RF irradiation of an implant. The heating measurements are made twice, once with the implant and then repeated at the same location without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

5.2 The results may be used as an input to a computational model for estimating temperature rise due to the presence of that implant in a patient. The combination of the test results and the computational model results may then be used to help 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 system or 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 or fluoroptic thermometry probe, is used to measure temperature versus time during the RF exposure on or in the vicinity of the implant. The temperature sensor will have a resolution of no worse than 0.1°C, a temperature probe spatial resolution not to exceed 1 mm along the specific axis of measurement in any direction, and a temporal resolution of at least 4 s.



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

NOTE 3—It may be necessary to perform multiple measurements near the position of interest to ensure that the temperature probe is in the location of greatest temperature rise.

NOTE 4—The temperature probe should be transparent to the applied RF field and must not disturb the local E-field (electric fields) significantly. It is assumed that probes that are not electrically conductive are acceptable.

7. Test Specimens

7.1 While this test method may be used on prototype or predicate devices, for purposes of device qualification, the implant evaluated according to this test method shall be representative of a finished device in the as-implanted or in situ condition; for example, balloon expandable stents should be balloon expanded to the proper diameter.

7.2 Other than described as in 7.1, for purposes of device qualification, implants shall not be altered in any manner prior to testing other than positioning/coiling or otherwise configuring the implant in order to orient it in the anticipated worst case scenario for that device/scanner frequency.

8. Procedure

8.1 *Phantom Morphology*—The phantom container and all its parts should be made of materials that are electrical insulators and 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. The phantom material shown in Fig. 1 has a volume of approximately 24.6 L. The phantom material including the optional portion has a volume of approximately 28.2 L. To test larger devices, it may be necessary to increase the depth of the gel material.

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.

NOTE 5—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 made at lower frequencies. (See Stuchly et al. **(1)**[5] for data on tissue electrical properties and Athey et al. **(2)** for procedures for measurement of electrical properties.)

8.2.2 *Dielectric Constant*—Dielectric constant, or relative electric permittivity (ε_r) shall be 80 ± 20 at the appropriate test frequency (64 MHz or 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 4150 J/kg°C. This is close to the heat capacity of water.

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.

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

NOTE 7—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 0.47 ± 10 % S/m at temperatures between 20 and 25°C. The conductivity does not need to be measured at 64 MHz or 128 MHz. The specific heat of the gel is 4150 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 8—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

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

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 9.

NOTE 9—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 0.47 ± 10 % S/m at 20 to 25°C measured at frequencies lower than 15 kHz.

8.4 *Implant Configuration and Worst-case Configuration*—All implants need to be tested in a worst case configuration and orientation that would produce the greatest heating in the phantom. For example, complex implants or implants with nonlinear components can be difficult to assess for worst case using basic radio frequency engineering knowledge. Parameters like the electrical and magnetic implant material properties (single and multilayer, coatings, and so forth), the surrounding material (conductivity, permittivity, permeability), number of implant components, types and dimensions, number of intended MR environments (frequencies: 8.5 MHz (0.2 T) to at least 298 MHz (7 T), and orientations (absolute and relative bending, paths, and so forth) have to be considered for worst case.

8.4.1 Demonstrate the worst case implant configuration and provide the evidence used to determine the configuration used for testing (**3**). Testing in more than one implant configuration will be required if the worst case clinically relevant configuration of the implant is unknown.

NOTE 10—The RF heating of a device in a specific location in the phantom is not predictive of the heating of the device in a geometrically similar location in a patient for the local RF intensities and orientations are very different.

8.4.2 All multiple component and flexible medical devices and implants fall under the category of MR critical medical devices. As such, these devices need sound and thorough MR heating assessments. To assess the safety of MR critical medical devices in the MR environment all relevant device configurations and several different orientations relative to the incident electrical field need to be considered. It is possible to limit the number of required test configurations for which there can be a large or even infinite number.

NOTE 11—An MR critical medical device is a medical device that may experience high heating during MRI exposure. MR critical medical devices include active implantable medical devices (AIMDs), implants that are powered from outside of the body, and elongated metallic structures that are in the range of the critical length for which the device becomes resonant in an MR system (**3**).

NOTE 12—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 gives an endless number of possible configurations to consider.

NOTE 13—As another example, the following parameters are given for an orthopedic hip prostheses system which consists of three different types of caps, five different inlays, three different balls, four different hip stems and each component may have three different materials and ten different system sizes as well as two different types of implantation (with and without cement). It is also assumed that the implant system can be oriented in two different orientations related to B0. These give, in theory, a number of 583 200 different cases for only one magnetic field strength.

While it may not be possible to identify the single worst case configuration for such an implant system, basic radio frequency engineering principles and pilot studies can be used to reduce the total number of possible cases to a manageable amount. For example, it might be demonstrated that, for the three different caps in the previous hip example, one of the caps has significantly higher heating in a subset of configurations. Such evidence could justify testing primarily with that cap as a 'worst case.' Alternatively, if the caps have identical design but use different coatings that have extremely similar RF characteristics (for example, dielectric constant), it might be possible to demonstrate this equivalence with a small number of tests.

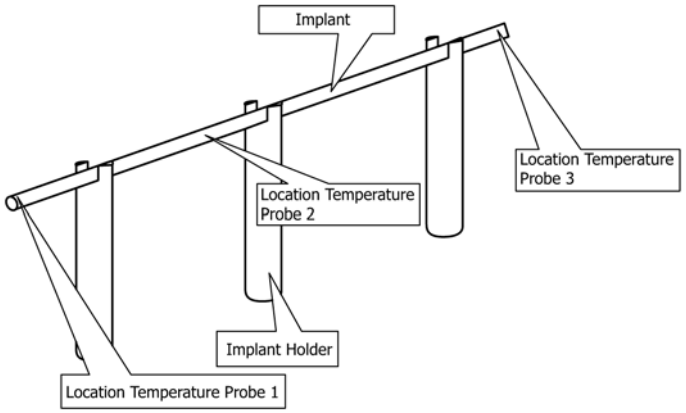
8.4.3 The location of the maximum heating can be assessed experimentally using multiple temperature probe locations evaluating all possible locations of high heating for all relevant device configurations. Alternatively, or in combination, the location of maximum heating can be predicted computationally using electromagnetic and thermal simulation tools to calculate the E-field, B-field, SAR and/or temperature distribution on the surface of the device. Such supporting computational analyses must include sound experimental validation data.

NOTE 14—Make sure you have performed sufficient testing or computational analysis so that you know what configuration produces the greatest heating.

NOTE 15—If large diameter loops can be formed by conductive components, that configuration may represent the worst case for heating. High heating may also occur in long, thin devices with a large length to diameter ratio, or at sharp edges, points, the ends of devices, and at corners (Ref **4-6**).

8.5 *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,

[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 1—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.

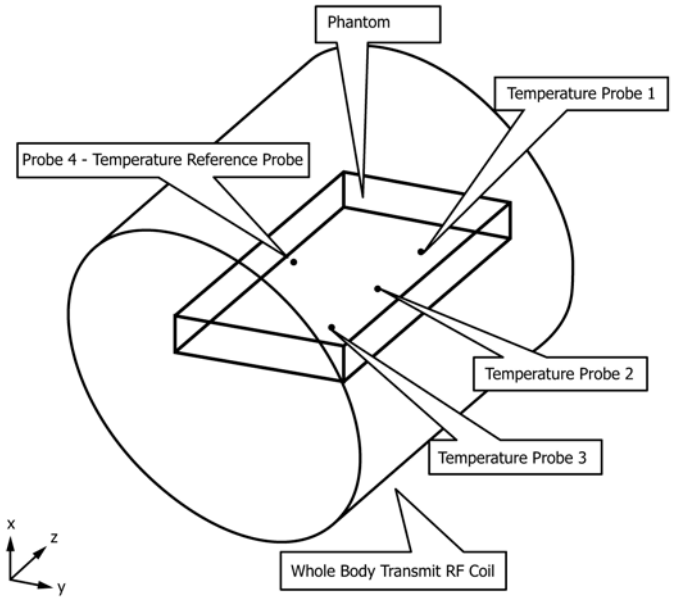
FIG. 2 Example of Appropriate Implant Holder

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.

8.6 *Implant Placement and Orientation in Known E-field*—Choose a location for the implant where the local background SAR and E-field are 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. Finally, 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 16—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 over a length of approximately 15 cm.

NOTE 17—Amjad et. al (7) provides information on how to determine the E-fields and gives E-field distribution in the phantom in a 1.5 T RF birdcage.



NOTE 1—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

NOTE 18—In order to determine the worst case, a variety of sample sizes and configurations may need to be tested.

NOTE 19—If the implant is large relative to the size of the high uniform E-field, it is possible for the entire implant not to be contained in this region. Additionally, the implant might have a specific feature or configuration that generates higher heating than other parts or configurations of the implant. Thus for large implants, to ensure the feature that is more likely to heat up is within the high |E| field, the change in temperature with the implant with respect to the background change in temperature without the implant [$\Delta T/(\Delta T_{\text{background without implant}})$, where T = temperature] for each implant temperature measurement probe should be compared. If the $\Delta T/\ \Delta T_{\text{background without implant}}$ is significantly higher for a portion of the implant not in the high E-field, then further testing (for example, alternative implant positioning within the phantom or use of a different phantom) or analysis is necessary.

8.7 *Phantom Temperature Measurement Setup*—Determine the implant's maximum heating locations. This may be done by theoretical means and/or by pilot experiments for the specific device and device configuration under test. Secure at least three temperature probes on or near those locations with a repeatable probe placement precision of ±0.5 mm between the probe and the implant. To provide a measure of the run to run repeatability of the applied RF power and local E-field, without 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 (7). This gives a position with the same radial distance from the longitudinal axis of gelled saline.

NOTE 20—If the device is too small for three probes, then it is acceptable to use fewer probes.

NOTE 21—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 (**8**).

NOTE 22—Heating in the phantom may be asymmetric (**9, 10**), therefore considerable experimentation or computation may be required to determine the temperature probe placement for which maximum heating can be measured (**11, 12, 13**). 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 8.6 and a whole body averaged SAR of approximately 2 W/kg. SAR levels of greater than 2 W/kg may also be used.

NOTE 23—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.

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

NOTE 1—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 1—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 stable to ±1.0°C per hour.

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 5 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 24—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 8.6 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 Background SAR*—(measurement of local power density in the phantom without the implant present)—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 = 4150 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 25—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 26—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 a patient with an implanted device. who is scanned in the normal operating mode or the first level control mode, will not be exposed to dangerously high RF 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 27—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 ±0.5ºC 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 thermometer or temperature probe (with accuracy ≥0.05ºC).

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. Through a narrow slot in the insulation (which is on the phantom during RF exposure), insert a handle for a stirring mechanism that is moved back and forth to mix the saline being careful to not move or disturb the temperature probe. To minimize cooling from evaporation, a second piece of foam insulation, with a corresponding slot, should be placed inside the top of the phantom and left to float on the saline.

9.2.5 Place the phantom in the same physical location in the MR test system that the phantom occupied during the test with the implant in place, and run the sequence. Flip angle calibration (pre-scan) is done with the phantom in place within the bore. It is critical that the phantom be in precisely the same physical location and orientation within the MR test system to have the same RF energy deposition.

9.2.6 Quickly take the phantom out of the MR test system and stir the saline without opening the lid.

9.2.7 Measure the saline temperature with a high precision thermometer or temperature probe (with accuracy ≥0.05ºC).

9.2.8 Calculate the whole body (phantom) averaged SAR using the equation in 8.14.1 with c = 4150 J/(kgºC).

9.3 The phantom should be thermally insulated with thermal insulation material on all sides. The conductance of the thermal insulation shall be less than 0.029 W/m·K (greater than an R-value of 5.0 ft^2·h·°F/Btu). This value can be reached with a 25 mm or thicker sheet of extruded polystyrene. Fill the phantom with approximately 25 L of saline, which corresponds to a fill height of about 9 cm or 3.5 in.

9.4 *Recommended MR Test System Parameters and Conditions:*

9.4.1 Phantom—72 kg, 166 cm tall, 40 years old.

9.4.2 Use transmit RF body coil only.

9.5 Use a protocol to produce a relatively high level of RF power deposition as described in 8.9. If using an MR system to apply RF power to the phantom, the sequences described Tables 1-3 in may be used.

10. Report

10.1 *Report Contents*—Include the following in the report for each device tested:

10.1.1 Implant product description, including photograph with scale provided in the image.

10.1.2 Implant product number and/or other identifying numbers (for example, serial number, lot number, and so forth).

10.1.3 Materials of construction (ASTM designation or other).

10.1.4 Photograph or drawing of implant geometry showing key morphological features and dimensions.

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

10.1.6 Photograph or diagram showing placement of the implant and temperature probes and location of phantom in the MR test system with respect to the isocenter. For probes that do not contact the implant, document the distance from the sensing portion of the probe to the implant. For probes that are in contact with the implant, document the location of the sensing portion of the probe on the implant. MR images may be provided as supplementary information.

10.1.7 If the MR test system is an MR scanner, provide manufacturer, model number, software version, type of RF transmit coil, and the static magnetic field strength and frequency of the MR system.

10.1.8 Manufacturer, model number, and relevant technical information on temperature probes, phantom material, implant holder, and phantom container and any other components in the experimental apparatus. If the PAA gelled saline described in 8.3 is not used, include results of measurements of the physical parameters specified in 8.1 and provide a rationale for using an alternative test medium.

10.1.9 Analysis used to determine electrical field distribution in the phantom at the test location.

10.1.10 Description of RF protocol used and the local SAR at the location of the implant. If available, report the flip angle and bandwidth of the RF pulses, as well as the number of RF pulses applied per unit time. If provided, report the RMS B1 field in units of micro Tesla and the average power deposition in the phantom in Watts. Report the entered patient weight for the tests and the RF output power, which may be expressed in terms of transmit gain on some scanners. Report the weight of the gelled saline in the phantom. Report the whole body, local, and peak SAR if provided on the MR scanner console.

10.1.11 For each temperature probe, provide graphs and tables of temperature versus time for (*1*) the test case with the implant in the phantom and, (*2*) the control case with no implant. Include temperature measurements before, during, and after application of the RF magnetic field according to 8.12, Recording of Temperature versus Time. Include any information you have about the uncertainty of your temperature measurements in the report (**14**).

10.1.12 Report the ΔT= Maximum temperature – initial temperature before RF power application starts for each temperature probe over the entire measurement period.

10.1.13 Report the calculated background local SAR at each temperature probe.

10.1.13.1 Report the *dT/dT* (change in temperature measured with the implant in place/change in temperature without the implant in place) at each time point for each temperature measurement probe.

10.1.14 Provide a theoretical or empirical rationale justifying the placement of the probes.

10.1.15 Report the temperature in the scan room within 15 min prior to application of RF and within 15 min after completing the test.

10.1.16 Report the calorimetric assessed whole body averaged SAR (averaged over the phantom material) and if measurements were performed in an MR system, the console displayed whole body averaged SAR for the phantom.

10.1.17 Report and justify any modifications to the test method.

11. Precision and Bias

11.1 The precision and bias of this method has not been established.

NOTE 28—Round robin testing of the method will be conducted.

NOTE 29—The temperature data in these measurements can be subject to a high degree of experimental error without sufficient care and control of the many variables. Uncertainty related to the measurements should be reported.

12. Keywords

12.1 implant; MRI (magnetic resonance imaging); MR safety; RF (radio frequency) heating

APPENDIX

(Nonmandatory Information)

X1. RATIONALE FOR DEVELOPMENT OF THE TEST METHOD

X1.1 Overview and General Information

X1.1.1 This document specifies a test method to evaluate the RF-induced temperature rise that would be produced on or near an implant in a phantom. Hazards other than RF-induced heating need to be considered to determine whether a patient with an implant can safely undergo an MRI procedure (**15**). In particular, magnetically induced displacement force and torque must be evaluated before an implant can be determined to be MR Safe or MR Conditional as defined in Practice F2503. Test Method F2052 provides a test method for determining magnetically induced displacement force and Test Method F2213 provides a method for determining magnetically induced torque. The amount of image artifact should also be determined, although this is not a direct safety issue. In order

to provide additional information to clinicians to help them to make a decision about the appropriateness of a given MR examination for a patient with an implant, a statement about image artifact produced by the implant using a gradient echo technique with at least a 10 ms TE value at the field strength tested should be included in the product labeling and on the patient implant card. Test Method F2119 provides a method for evaluating image artifact for passive medical implants. A maximum *dB/dt* of 20 T/sec is specified in IEC 60601-2-33, Ed. 2.0 as a known value which will not cause peripheral nerve stimulation in patients. IEC 60601-2-33, Ed. 2.0 contains patient threshold curves derived from experimental observation.

X1.1.2 It can be shown that for a given pulse shape and flip angle, the deposited RF energy is proportional to the square of the magnetic field strength. Consequently, the static magnetic field strength of the MR system has a dramatic effect on RF heating. Recently, MR systems have been introduced into clinical use with field strengths as high as 9.4 T (**16**). Such an MR system may be expected to deposit much higher levels of RF energy than a 1.5 T MR system for a similar pulse sequence. It is important to note that implant heating can be different in MR systems with different field strengths and frequencies. For instance, an implant that demonstrates a low level of heating at 1.5 T/64-MHz may heat substantially more in an MR system with either a higher or lower field strength and frequency (**17**).

X1.1.3 Physics and safety issues associated with RF power deposition in MRI have been described by Schaefer (**18**). Very briefly, the time-varying RF field induces currents in the body by Faraday's law of induction. The intensity of the induced RF currents tends to be greatest near the surface of the body.

X1.1.4 The mechanism for additional RF heating can be understood as follows (Smith (**19**)). An electrically conductive, elongated implant will concentrate the RF currents induced in the body, resulting in an increased current density and increased SAR in the vicinity of the implant. For an elongated implant, the greatest heating will occur near the ends. Also, there are geometric functions to consider given the reduced wavelength with increasing field strength (dielectric resonance).

X1.1.5 Neglecting the conductivity, wavelength λ_m in a material is given by:

$$\lambda_m = \frac{\lambda_0}{\sqrt{\varepsilon_{rel}}} \quad \text{(X1.1)}$$

where:

$\lambda_0 = c/f$ = wavelength in air,
c = 3×10^8 m/s,
f = radian frequency, and
ε_{rel} = relative dielectric constant.

For example, at a frequency of 64 MHz and $\varepsilon_{rel} = 81$ (a representative value for tissue), $\lambda_0 = 4.7$ m and $\lambda_m = 0.52$ m. Including the effects of conductivity would decrease the wavelength. Conductive coatings covering a metallic implant will also affect the wavelength. Objects that combine different types of materials may require a different treatment.

X1.1.6 When implant dimensions approximate one-half of a wavelength, antenna resonance effects may result in very large temperature rise. (Konings et al. (**20**)). Geometry and implant construction (for instance thickness of an insulating coating) affects the effective wavelength and greatest heating may also occur at other lengths (both longer and shorter). There are a number of published reports in which guidewires and other elongated implants exhibit significant RF-induced heating near the ends(**21-9**). Simple metallic structures less than 2 cm in dimension are not expected to exhibit clinically significant RF-induced temperature rise.

X1.1.7 SAR values reported by the MR system software are intended to ensure the safety of the patient and may be conservative, overestimating the SAR level. They were not designed to be used with phantom measurements and thus the standard calls for determining the whole body averaged SAR and the local SAR at the implant in the phantom by calorimetry.

X1.1.8 For a given configuration, the SAR is expected to be predicted by knowledge of the pulse sequence. Thus, the standard calls for a detailed recording of the type of RF pulses that are applied. The RF power deposition is expected to be proportional to transmitted RF bandwidth and to the square of the flip angle.

X1.2 Section 5—Significance and Use

X1.2.1 Temperature measurements are performed with the implant and without the implant in the phantom. After correcting for thermal dissipation, the ratio of the temperature rises in these two cases determines the amplification in temperature rise due to the presence of the implant. By computational models which estimate the local electric fields in anatomically appropriate location in a patient, this measured amplification can be scaled to provide an estimate of the temperature rise due to the implant device at those locations in a patient. It is generally not accurate or appropriate to estimate the MR-related temperature rise associated with an implant in a human by equating the temperature rise in an anatomically similar location in the phantom due to the variation in electrical properties inside the body (for example, the air in the lungs has a significant effect on the electric fields near the heart). The electric field distribution inside the phantom is not the same as the electrical field distribution inside the human body.

X1.2.1.1 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 due to the presence of that implant in a patient. The combination of the test results and the computational model results may then be used to help assess the safety of a patient with the implant during an MR scan.

X1.2.2 The following terms from IEC 60601-2-33, Ed. 2.0 describe the operating characteristics of MR systems. They are provided to give MR healthcare professionals information about maximum RF power levels. For this test method, these terms provide comparative values of RF power levels and times for safe exposure levels to be applied to patients during MR procedures.

X1.2.2.1 *Whole Body SAR*—SAR averaged over the total mass of the PATIENTS body and over a specified time.

X1.2.2.2 *Partial Body SAR*—SAR averaged over the mass of the PATIENTS body that is exposed by the VOLUME RF TRANSMIT COIL and over a specified time.

X1.2.2.3 *Normal Operating Mode*—Mode of operation of the MR EQUIPMENT in which none of the outputs have a value that may cause physiological stress to PATIENTS.

NOTE X1.1—The international safety standard for MR systems, IEC 60601-2-33, Ed. 2.0, currently limits whole body averaged SAR to 2 W/kg for a 6-min averaging time in the normal operating mode. The partial body SAR limit ranges from 2 to 10 W/kg, in the Normal Operating Mode, depending on the part of the patient that is exposed to the RF field.

X1.2.2.4 *First Level Controlled Operating Mode*—Mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that may cause physiological stress to PATIENTS which needs to be controlled by MEDICAL SUPERVISION.

NOTE X1.2—The First Level Controlled Operating Mode limits the whole body averaged SAR to 4 W/kg for a 6-min averaging time. The partial body SAR limit for the First Level Controlled Operating Mode ranges from 4 to 10 W/kg, depending on the part of the patient that is exposed to the RF field.

X1.2.2.5 *Second Level Controlled Operating Mode*—Mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that may produce significant risk for PATIENTS, for which explicit ethical approval is required (that is, a human studies protocol approved to local requirements).

NOTE X1.3—For the Second Level Controlled Operating Mode, no limits for RF energy are given. However, values used in the Second Level Controlled Operating Mode are considered to be the responsibility of the local institutional review board (IRB) that has authorized settings for RF energy used during MRI procedures above the First Level Controlled Operating Mode values.

X1.2.2.6 *Short Term SAR*—For any operating mode, the short term SAR level shall not exceed three times the stated values over any 10 s period.

X1.2.2.7 *SPECIFIC ABSORPTION RATE (SAR)*—Radio frequency power absorbed per unit of mass of an object (W/kg).

X1.2.2.8 *HEAD SAR*—SAR averaged over the mass of the head and over a specified time.

X1.2.2.9 *LOCAL SAR*—SAR averaged over any 10 g of tissue of the body and over a specified time.

X1.2.3 The rate of temperature rise, assuming no convection or perfusion, is related to the local SAR by the equation:

$$\frac{\partial T}{\partial t} = \frac{SAR}{C} + \alpha \nabla^2 T \qquad \text{(X1.2)}$$

where:

C = heat capacity in J/(kg K), and
α = thermal diffusivity in m^2/s.

If the thermal diffusivity is zero or the SAR is uniform, then a medium (for example, gelled saline) with the heat capacity of water, C = 4150 J/(kg K), and an SAR level of 1 W/kg will have a ΔT = (1 W/kg · 900 s)/(4150 J/(kg K)) = 0.22°C temperature rise in 15 min. With thermal diffusivity greater than zero, if the temperature is initially uniform and the SAR is uniform in the region of the probe, then in the limit as t → zero, $dT/dt = SAR/c$. Also, with thermal diffusivity greater than zero if the highest SAR is concentrated in a small region, then the associated temperature rise will approximately be within a boundary layer of thickness δ of that region, where $\delta^2 = 4\ \alpha t$ (22); for $\alpha = 130 \cdot 10^{-9}$ m^2/s and t=900 s, δ = 0.022 m (2.2 cm).

X1.2.4 Blood perfusion of tissues will generally result in a temperature rise near the implant (that is, if the implant is contained within the tissue or organ receiving the RF energy) that is less than what would be recorded in the phantom measurement. Additionally natural convection in wet tissue and forced convection and conduction in blood vessels will also reduce the temperature rise when these conditions are present at or near the implant location. Thus, the measurement of the temperature rise in the phantom is likely to overestimate the actual temperature rise for an implant, in situ.

X1.2.5 Blood perfusion and the local field distribution in a patient can create less temperature rise for specific implants, tissue types, and exposure conditions when compared to a phantom measurement. Thus, the temperature rise for a particular implant in the phantom could overestimate the actual temperature rise for an implant inside a specific patient. Substantial numerical evaluations using anatomical models representing the whole patient population might be required to determine the phantom overestimation.

X1.2.6 Such an approach is outside the scope of this test method. The complexity of this evaluation depends on the obtained phantom temperature rise, the patient population, the location of the implant inside the patient, and the exposure conditions. The implant manufacturer is responsible for establishing the relationship between "worst case" phantom temperature increase and the temperature rise that is expected in the patient population. A scientifically based rationale rather than correlation data may be sufficient to establish this relationship.

X1.3 Section 8.2—Phantom Material

X1.3.1 A gelled saline should be used to fill the phantom. A gelled material is specified to prevent measurement of unrepresentatively low temperature rises due to convective flow of heat. Smith et al. (19, 23) reported that the temperature rise near a heat source is significantly less in saline than in gelled saline. (Upon heating, the density of the saline solution changes, resulting in fluid transport.) If the phantom material is not gelled, the measured temperature rise may underestimate that which would occur *in-vivo*.

X1.4 Section 8.3—Phantom Formulation

X1.4.1 An alternative phantom formulation consisting of 1.55 g/L NaCl and 31 g/L hydroxyethylcellulose (HEC) in water has been used. Both PAA and HEC formulations have a room temperature conductivity of about 0.47 S/m and a viscosity sufficient to prevent convective heat transport. Comparative testing for PAA and HEC gels has not been performed.

X1.4.1.1 As with the PAA gelled saline, the chemicals used and mixing protocol must be followed precisely to achieve reliable and repeatable results. The resulting gel 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 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.

X1.4.1.2 Ingredients of HEC gelled saline:

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

NaCl—reagent grade, >99 % pure.

Hydroxy Ethyl Cellulose—Sigma Aldrich, product number 09368 (Fluka), CAS no. 9004-62-0.[6] See Note X1.4.

NOTE X1.4—Different products have different gelling properties. The product listed above has been found to produce a gelled saline with the required properties.

X1.4.1.3 Preparation of HEC gelled saline:

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

2. Stir in the HEC powder slowly. If powder is added too quickly, lumps will form.

3. Stir as required to keep the suspension homogeneous while it thickens. Take care to prevent the formation of a more viscous layer at the bottom of the container. Stir continuously for at least 3 h until a uniform gelled saline is formed. It is recommended that an electric stirrer be used.

4. The slurry is ready to use after 24 h. The appearance of the slurry is transparent and free of bubbles.

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

X1.5 Section 8.6—Implant Placement and Orientation in Known E-Field

X1.5.1 For a typical MR system with the static magnetic field along the long axis of the bore, the RF magnetic field is circularly polarized and perpendicular to the axis of the bore. To a reasonable approximation, Faraday's law of induction can be used to estimate the eddy current loops that will be formed. An important feature is that the induced eddy currents will be greatest near the surface of the body.

X1.5.2 The measurement should be done with a high local E-field applied to the implant for accurate temperature measurements. It is also important that the applied E-field be as uniform as possible so that results can more easily be incorporated into and/or compared with computational models.

X1.5.3 *SAR in the Phantom*—Fig. X1.1 shows the SAR distribution for the rectangular phantom in the coronal (left) and axial (right) mid-planes in circularly polarized birdcage coils. The rotation sense is CW. Top plots are for 64 MHz and lower plots are for 128 MHz. Medium conductivity is 0.47 S/m. B1 is average across the slice at z=0. Phantom average SAR is 0.32 W/kg at 64 MHz and 0.63 W/kg at 128 MHz. The arrows in the coronal plots indicate the direction and relative magnitude of the electric field. The calculation is for a depth of 9 cm. Note that this calculation is a model and the results for an actual scanner may vary.

X1.5.4 Consideration should be given to the size of the implant and the depth of the gel. As the gel depth increases, the E-field distribution changes, tending to become more homogeneous. As the phantom is moved outside the center of the bore, the inhomogenieties in the E-field increase.

X1.6 Section 8.7—Phantom Temperature Measurement Setup

X1.6.1 Heating is expected to be mainly due to concentration of eddy currents in the phantom material by geometrical features of the implant. For elongated, insulated wires, the MR-related heating is localized to the tips or ends especially if uninsulated. Heating may also be high at a central uninsulated area in an elongated insulated wire. Possible "failed" or broken conditions of the implant may also be considered. For example, Chou et al. (**24**) reported considerable heating near the broken lead wire of a spinal fusion stimulator.

X1.7 Section 8.9—RF Field Application

X1.7.1 In order to achieve an adequate RF application the following may provide guidance. To adjust the RF power, first increase the optimum echo train length (number of 180° pulses) if a fast/turbo spin echo pulse sequence is used and increase the flip angle if necessary and feasible. Balance this step iterating with the selection of TR and number of slices and number of averages to result in a high SAR and the appropriate scan duration.

X1.8 Section 8.14.1—Determination of Local SAR

X1.8.1 *Determination of Local SAR Using a Reference Implant:*

X1.8.1.1 The local SAR may also be determined with a reference implant. The reference implant is a ⅛-in. diameter × 10 cm long rod made from Grade 5 high strength titanium. One-mm diameter holes are drilled through the rod transverse to the axis and these two holes are centered 1 mm from each end of the rod. Temperature probes are placed in the holes and temperature versus time is recorded. The local background SAR along the length of the rod is determined by fitting the measured temperature rise to the calculated rise.

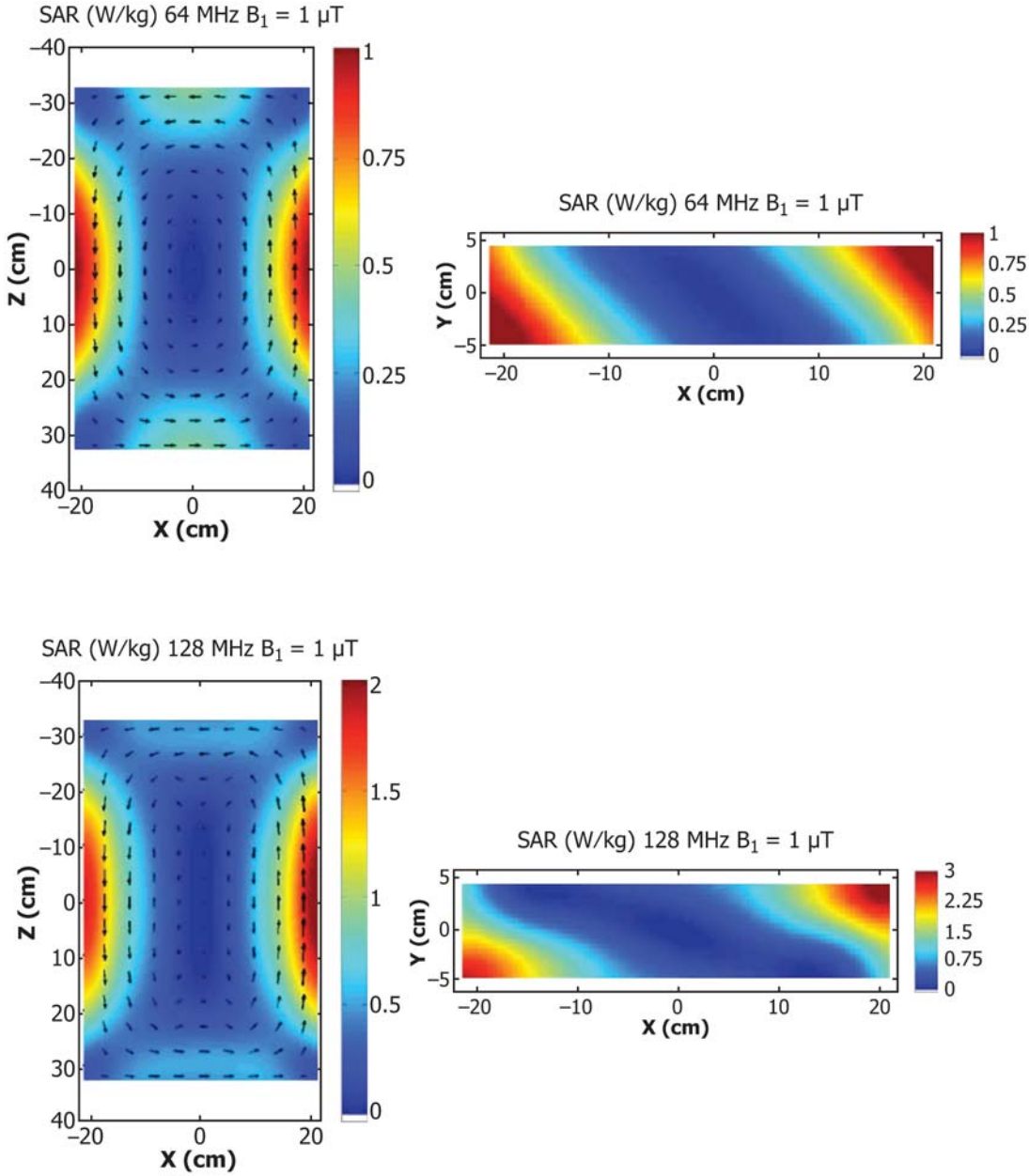
X1.8.1.2 Fig. X1.2 illustrates the set-up. The implant is removed and the rod is placed in the same region of the phantom as was the implant. (The depth of the rod in the phantom and distance from the wall are the same as for the implant.) The sensitive portions of the temperature probe are inside the holes in the rod. The same phantom material that was used for measurements of temperature rise with implant is used for the measurements with the rod. The reference probe is retained for this measurement.

X1.8.1.3 To determine the local SAR, do the following:

(1) With the rod in the phantom, apply the same RF sequence that was used with the implant. The RF application time will be at least 6 min and cool-down down will be at least 30 s.

(2) Plot the temperature versus time for the two probes at the ends and verify that these curves have a shape similar to the calculated rises in Fig. X1.3.

(3) Record ΔT_{360}, the temperature rise in °C after 6 min of RF application.



NOTE 1—In these plots, the E-field is directly proportional to SAR^0.5.

FIG. X1.1 SAR Distribution in the Phantom

(4) For a phantom conductivity of 0.46 S/m, the average local SAR along the length of the rod in W/kg is $\Delta T_{360}/1.30$ at 64 MHz and $\Delta T_{360}/1.45$ at 128 MHz.

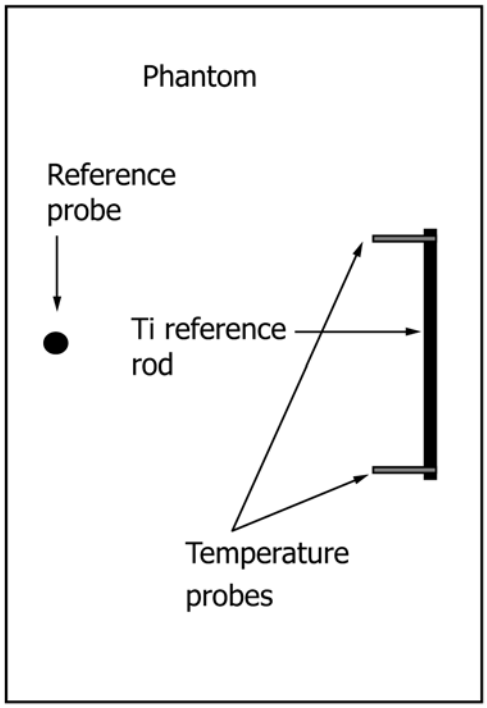
(5) With the rod longitudinally centered in the torso of the phantom, so that the tangential electric field is symmetrical about the center, the temperature rises will be the same for the two probes at the ends.

X1.9 Duration of Testing

X1.9.1 Fifteen minutes is a reasonable maximum time increment for a single clinical scan duration for one pulse sequence or "series," so this standard recommends a 15 min minimum exposure duration. In the interest of improving test efficiency while ensuring measurement integrity, the standard allows the test duration to be truncated when temperature measurements of sufficient magnitude to establish a meaningful result occur.

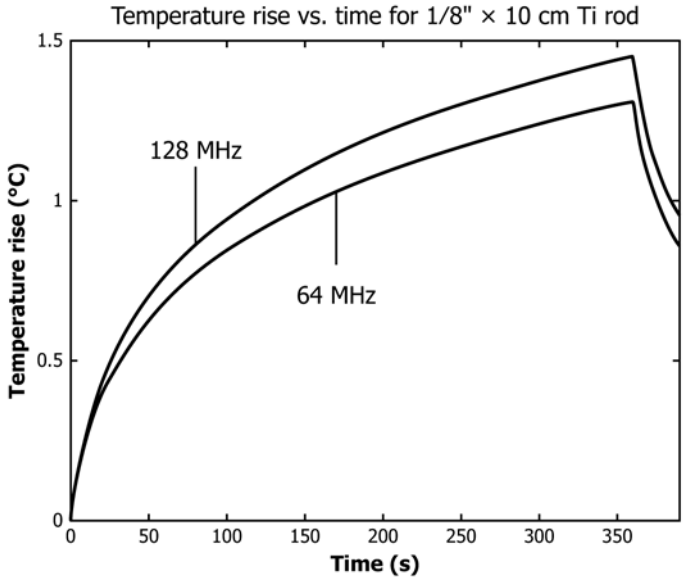
X1.10 Summary of Changes

X1.10.1 In 2009 the standard was revised to include new knowledge about RF induced implant heating associated with MR imaging. Numerous changes were made in the test method, including adding an optional HEC formulation for the phantom material, a simplification of phantom geometry to allow a rectangular phantom. and changing the implant location in the phantom to a location of maximum heating rather than a physiological location of the implant within the phantom.



NOTE 1—The reference implant is a ⅛-in. diameter × 10 cm long rod made from Grade 5 high strength titanium. Temperature probes are placed in 1-mm diameter holes that are centered 1 mm from the ends.

FIG. X1.2 Titanium Reference Implant in the Phantom



NOTE 1—Calculated temperature rise at probes in Fig. X1.2 versus time for the ⅛-in. × 10 cm titanium rod with a uniform tangential background electric field that produces a local SAR of 1 W/kg in a medium of conductivity 0.46 S/m. The RF is turned on at 0 s and off at 360 s. After 6 min of RF application, the rise is 1.30°C at 64 MHz and 1.45°C at 128 MHz.

FIG. X1.3 Calculated Temperature Rise at Probes

X1.10.2 In 2011, the standard was amended clarify some of the steps in the test procedure and add notes that provide assistance in determining worst case configurations.

X1.11 Interpretation of Results

X1.11.1 Worst case maximum temperature rise may be interpreted on the basis of a number of factors such as anatomical location of the implant, MR scanning duration, implant geometry, thermal injury effect, pain threshold, neurological response, and thermal excursions cited in the literature for various surgical procedures.

X1.11.2 References (**25-29**) may be useful in the interpretation of RF heating results.

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RELATED MATERIAL

ASTM Terminology A340 of Symbols and Definitions Relating to Magnetic Testing[2]

Neufeld, E., Kuhn, S., Szekely, G., Kuster, N., "Measurement, simulation and uncertainty assessment of implant heating during MRI," *Phys. Med. Biol*, Vol 54, 2009, pp. 4151–4169.