Designation: ~~F2182 – 11a~~ F2182 – 19

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~~ (RF)-induced heating on or near a passive medical implant ~~and its surroundings~~within a phantom during magnetic resonance imaging (MRI). The test method does not specify levels of heating considered to be safe to the patient and relies on users to define their own acceptance criteria.

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.~~does not address other possible safety issues which include but are not limited to issues of magnetically induced-displacement, magnetically-induced torque, image artifact, acoustic noise, tissue heating, interaction among devices, and the functionality of the device and the MR system.

1.3 The amount of RF-induced temperature rise (ΔT) for a given ~~specific absorption rate (SAR)~~ incident electric field 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~~tesla (T) or 3 ~~Tesla cylindrical bore~~ T MR systems, the ~~*RF-induced*~~ΔT ~~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~~ Testing for devices with other implantation conditions (for example, external fixation devices, percutaneous needles, catheters or tethered devices such as ablation ~~probes),~~ probes) is beyond the scope of this standard; for such devices, modifications of this test method ~~are~~ may be necessary.

NOTE 1—RF-heating induced by any electrically conductive implanted device may be impacted by the presence of other metallic or otherwise electrically conductive devices present nearby.

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.~~is written for several possible RF exposure systems, including Volume RF transmit coils. The exposure system needs to be properly characterized, within the stated uncertainties, in term of local background RF exposure for the implants which are tested.

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 A device with deployed dimensions of less than 2 cm in all directions does not need to be tested with respect to RF-induced heating, as it is expected to generate ΔT of less than 2°C over 1 hour of exposure at 1.5 T and 3 T frequencies (**1**, **2**[2] and ANSI/AAMI/ISO 14708-3:2017). This condition is not valid when multiple replicas of the device (for example, multiple anchors) are implanted within 3 cm of the device.

NOTE 2—The above values were derived from existing data and literature. The 3 cm distance is recommended to avoid any RF coupling with other neighboring devices.

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

1.8 *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~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

B348 Specification for Titanium and Titanium Alloy Bars and Billets

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:*[4]

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

2.3 *NEMA Standard:*[5]

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

2.4 *ISO Standards:*[6]

13485 Medical devices – Quality management systems – Requirements for regulatory purposes

14971 Medical devices – Application of risk management to medical devices

TS 10974 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device

2.5 *Other Standard:*[7]

ANSI/AAMI/ISO 14708-3:2017 Implants for surgery - Active implantable medical devices — Part 3: Implantable neurostimulators

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

3.1.3 *~~isocenter—~~local background RF exposure—~~geometric center of the gradient coil system, which generally is the geometric center of a scanner with a cylindrical bore.~~*the electric field tangential to the primary axis of the implant at a single position within the phantom (that is, no volume averaging is applied).

3.1.4 *local background SAR*—the SAR determined from (thermal or electrical) measurements at a single position within the phantom (that is, no volume averaging is applied).

The local background SAR can be derived from the temperature with the following equation:

$$SAR = \lim_{t \to 0} c \frac{\Delta T}{\Delta t} \tag{1}$$

~~specific~~Where: ~~*absorption*~~*c* ~~rate (SAR) averaged over any 10 g of tissue~~ = 4150 J/(kg°C) is the specific heat of the gel, ΔT is the change in temperature of the ~~patient body~~gel (°C), and ~~*over*~~Δt ~~a specified time.~~is the change in time (s). **~~60601-2-33, Ed. 2.0~~**

Local background SAR can alternatively be derived from incident electric field (through direct measurements of incident electric field):

[3] 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.

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

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

[6] ~~The boldface numbers in parentheses refer to a list of references at the end of this standard.~~Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

[7] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

$$SAR = \frac{\sigma \|E\|^2}{2\rho} \quad (2)$$

Where: σ is the electrical conductivity of the gel (S/m), ||*E*|| is the magnitude of the peak electric field (V/m), and ρ is the density of the gel (kg/m^3).

The local background SAR (in W/kg) is calculated from the temperature measurements or the E-field measurements for each probe location, including the reference location. The local background SAR at the reference probe is used to verify that the same RF exposure conditions are applied during various exposure steps.

3.1.4.1 *Discussion—*

The E-field probe needs to be calibrated in medium for the given RF exposure.

3.1.5 *magnetic resonance (MR) environment—equipment—*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.medical electrical equipment which is intended for in vivo magnetic resonance examination of a patient, comprising all parts in hardware and software from the supply mains to the display monitor. **(IEC 60601-2-33)**

3.1.6 *magnetic resonance (MR) system*—ensemble of MR EQUIPMENT, ACCESSORIES including means for display, control, energy supplies, and the CONTROLLED ACCESS AREA, where provided. **(IEC 60601-2-33)**

3.1.7 *magnetic resonance imaging (MRI)*—imaging technique that uses static and time varying 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.

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

3.1.9 *passive implant*—an implant that serves all of its functionfunctions without supply of electrical power.

3.1.10 *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.tesla.

3.1.11 *specific absorption rateSpecific Absorption Rate (SAR)*—the mass normalized rate at which RF energy is deposited in biological tissue. SAR is typically indicated in W/kg.RF power absorbed per unit of mass (W/kg). **(IEC 60601-2-33)**

3.1.12 Δ*T*—RF-induced temperature rise.

4. Summary of Test Method

4.1 The implant to be tested is placed in completely within a phantom material that simulates the electrical and thermal with RF physical properties (that is, electrical conductivity, electrical permittivity, thermal conductivity, thermal capacity, mass density) similar to the averaged 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. local background RF exposure. The phantom material is a gelled saline consisting of a saline solution and a gelling agent. Temperature probes are shall be placed at locations where the induced implantmaximum local *heating*Δ*T* is expected to be the greatest (this may require pilot experiments to determineexpected. Pilot experiments may be needed to determine such locations and thus the proper placement of the temperature probes).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.RF test system and subject to a well-controlled RF exposure of sufficient magnitude and duration to demonstrate a local background RF exposure in the testing location that shall be measured with adequate signal-to-noise ratio.

4.2 The test procedure is divided into two ~~steps.~~steps: ~~*In(1)* Step~~The ~~*1,*~~ΔT ~~the temperature rise~~ on or near the implant at several locations is measured using fiber-optic thermometry probes (or equivalent ~~technology)~~technology). ~~*during*~~ΔT ~~approximately 15 min of RF application. Temperature rise~~ is also measured at a reference location ~~during Step 1. In~~remote from the implant. ~~*Step(2)* 2, the~~ 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.~~temperature measurements (with temperature probe) or electric field measurements (with E-field probe) are repeated at the locations used in Step 1, under the same local background RF exposure of Step 1.

5. Significance and Use

5.1 This test method describes a test procedure for evaluating the ~~*RF-induced*~~ΔT ~~temperature rise~~ associated with ~~an MR procedure~~RF emitted during MR procedures, 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.~~method allows characterization of the heating propensity of the implant rather than the prediction of heating during a specific MR procedure in patients.

5.2 The results may be used as an input to a computational model for estimating ~~*temperature*~~ΔT ~~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.~~RF exposure system. The MR RF system uncertainty should be characterized.

6.2 *Temperature Sensor*—A suitable ~~temperature measuring device, usually a fiberoptic~~temperature-measuring device (for example, fiber optic or fluoroptic thermometry ~~probe,~~ probe), which meets accuracy requirements in the electromagnetic (EM) exposure environment 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~~with and without implant in place. The temperature probe shall have a precision of no worse than 0.1°C, ~~a temperature probe spatial resolution not to exceed 1 mm along the specific axis of measurement~~ an accuracy of ±0.5°C, a size of the sensitive element not larger than 1 mm in any direction, and ~~a~~with temporal resolution of at least ~~4~~2 s.

~~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.~~

6.3 *Electric Field Sensor*—A suitable device for measuring the electric field of at least one axis at the RF exposure level that is used for temperature measurement with an implant in place.

7. Test Specimens

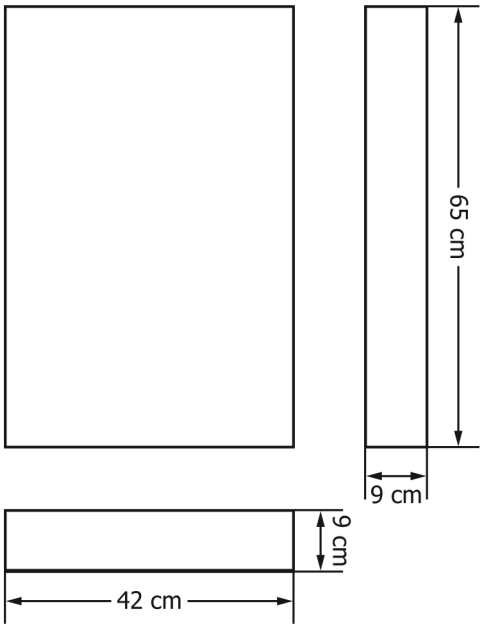
7.1 While this test method may be used on prototype or predicate devices, for purposes of device qualification, the implant evaluated according to this test method shall be representative of a finished device in the as-implanted or ~~in situ~~ in-situ condition; for example, ~~balloon expandable~~ balloon-expandable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

NOTE 3—Sterilization is not needed unless expected to affect the dimensions, electrical, or thermal properties of the device.

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~~positioning or otherwise configuring the implant in ~~order to orient it in the anticipated worst case scenario~~ the orientation that generates the highest heating for that device/scanner frequency. A justification for such orientation shall be provided.

8. Procedure

8.1 *Phantom Morphology*—The phantom container and all its parts ~~should~~shall be made of materials that are electrical insulators and non-magnetic and non-metallic. The dimensions of the phantom container should ~~be constructed so that the phantom gelled-saline material is of the dimensions shown in~~ensure a 2 cm minimum distance from any point of the device to any ~~Fig. 1. The~~phantom surface ~~**phantom(3).** material shown in~~This is to ~~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~~minimize RF coupling with phantom surface and heat transfer into the environment. An example of a phantom dimensions which may be used and which has a volume of approximately 24.6 L is shown in Fig. 1~~of the gel material.~~ .



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.~~Other dimensions can also be used.

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

FIG. 1 Example of Dimensions of Phantom ~~Material (Gelled Saline) in a Rectangular Phantom~~Gelled-saline Medium Used for Testing

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

8.2.1 *Electrical Conductivity*—~~Conductivity~~ Electrical conductivity of the ~~gelled saline~~phantom material at the test temperature shall be 0.47 ± 10 % S/m.

NOTE 4—The conductivity at the test temperature was originally selected to ~~match~~ be similar to the average conductivity of ~~the~~ human body tissue at body ~~temperature. Electrical conductivity~~temperature for frequencies 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~~ range 64 MHz - 128 MHz. The conductivity of the phantom material in the range 64 MHz - 128 MHz can be measured at lower frequencies. (See Stuchly et al. (~~14~~) for data on tissue electrical properties and Athey et al. (~~25~~, 6) for procedures for measurement of electrical properties.)

NOTE 5—Based on the recipe provided, the phantom material will have thermal properties of diffusivity of about 1.3×10^{-7} m^2/s and heat capacity 4150 J/(kg·°C).

8.2.2 *Dielectric Constant*—Dielectric constant, or relative electric permittivity (~~ε~~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.~~

8.2.3 *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 partial sodium salt of 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.~~distilled or deionized water. Another formulation can be made with NaCl and hydroxyethyl cellulose (HEC) in distilled or deionized water.

~~NOTE 6—The amount of aqueous solution absorbed decreases with increasing salt concentrations.~~

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. Also please note that the potassium salt will not provide an equivalent gel.

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~~ conductivity should be measured and the temperature at which the measurement is done should be reported. The linear rise of the specific heat per degree kelvin is negligible (for example, for PAA, the specific heat of the gel is 4150 ~~J/(kg K)~~ J/(kg°C) at 21°C and there is a linear rise of 2.35 ~~J/(kg K) per degree kelvin~~ J/(kg°C) in the specific heat from 20 to ~~40°C.~~40°C). The gelled saline ~~should~~could have a shelf life of two ~~months.~~ months or more. 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~~stored in ~~an airtight~~a sealed 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,~~± 10 % S/m in the frequency range of 64 to 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,~~Use NaCl >99 % pure.

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

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 distilled or deionized water and stir to dissolve completely. ~~Verify that the conductivity is 0.26 ± 10 % at 25°C measured at frequencies lower than 15 kHz.~~

NOTE 9—It is expected that the electrical conductivity at this stage be 0.26 ± 10 % at 25°C measured at frequencies lower than 15 kHz.

(2) Add ~~PAA,~~ PAA slowly to avoid lumps, stir to suspend completely.

(3) After one hour, blend the suspension into a slurry. A ~~kitchen grade immersion blender with a blade~~ slow blender 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.~~satisfactory to minimize bubbles.

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

(5) Verify that the conductivity is 0.47 ± 10 % ~~S/m at 20 to 25°C~~ S/m, measured at frequencies lower than 15 ~~kHz.~~kHz (see Note 7). The temperature at which the measurement is done should be reported.

NOTE 10—When testing unsealed hollow devices, ensure that the spaces are all filled with the gel.

~~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.~~

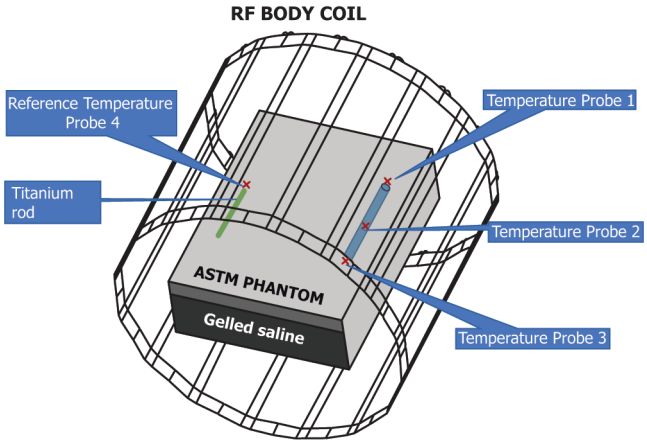
~~NOTE 11—An MR critical medical device is a medical device that may experience high heating during MRI exposure. MR critical medical devices include active implantable medical devices (AIMDs), implants that are powered from outside of the body, and elongated metallic structures that are in the range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

[8] The sole source of supply of the apparatus known to the committee at this time is ~~Aldrich Chemical Company,~~ Millipore-Sigma, 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~~

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.

NOTE 2—If the device is too small for three probes, then it is acceptable to use fewer probes.

NOTE 3—Heating in the phantom may be asymmetric (**9**, **10**, **11**, **12**, **13**); therefore considerable experimentation or computation may be required to determine the temperature probe placement for which sufficiently high heating can be measured (**14**, **15**, **16**, **17**). 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. Fig. 2 shows examples (not normative) of probe location: 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). Optionally locate the reference titanium-alloy rod and temperature probe (probe 4) in the position of high E-field as described in 8.7.

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

~~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).~~

8.4 *Implant Holder*—To facilitate proper placement of the implant inside the gelled-saline filled phantom, an implant holder ~~is needed. Because any such~~ may be required to fix the position of the device within the conductive slurry. The holder may be a standalone apparatus securely attached to the phantom, or it may be a system of support based upon, for example, a thread network affixed to the lid of the phantom. Other approaches are possible and must meet the intent of any implant holder, that is, to provide reproducible positioning of the implant while not interfering with implant heating within the test. Because any physical implant holder may have an effect on the local ~~field environment, the~~ electromagnetic field, if an implant holder is used it must be made of appropriate materials ~~(for example, nonmetallic, nonconducting),~~ (that is, electrically nonconductive, nonmetallic, and nonmagnetic), must 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.~~Whether or not an implant holder is used, a control study to measure background heating at the probe locations, or alternatively, electromagnetic field at those locations, should be performed without the implant in place. When a holder is used, appropriate verification should be obtained to provide confidence that the implant holder itself will not contribute to or inhibit local heating.

8.5 *Implant Placement and ~~Orientation in Known E-field~~ Orientation*—Choose a location for the implant where the local background SAR and incident 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~~ place, if temperature measurement is used for evaluation of the local background SAR (~~8.14~~8.10). Additionally, ~~as possible,~~ choose a volume in which the implant is placed so that the ~~undisturbed~~incident E-field does not vary ~~significantly~~substantially over this volume. ~~Finally, in order~~ When the primary dimension of the implant cannot be identified (that is, the implant does not have an elongated structure), several orientations of the implant with respect to the incident field shall be analyzed to evaluate induced heating (**6**). Finally, to minimize RF coupling with phantom surface and heat transfer into the environment, ~~orient~~position 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.~~

8.5.1 The positioning of the implant under test shall be established and maintained with sufficient precision and accuracy such that the test is reproducible. For typical implant geometries and dimensions, experience has shown that positioning as described above establishes a volume for testing that spans 10-15 cm from the sidewall of the phantom and 10-15 cm from the supero-inferior midline of the phantom where results will be substantially equivalent (Note 11). The actual position of the device before the test shall be documented, for example photographically, and the position upon completion of the test shall be verified as consistent. Positioning of the device may be achieved with the use of an implant holder.

~~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 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 11—~~If the device is too small for three probes, then it is acceptable to use fewer probes.~~An implant holder may not be required if the device exhibits neutral buoyancy in the slurry. Such devices may be placed at the desired test location with probes affixed to the device itself. Control studies for such tests should be conducted such that the probes are held at the test position via being affixed to a suitable non-conductive holder dimensionally similar to the device under test. Medical grade paper tape, of a composition that saturates with the slurry material, has been found useful for securing the temperature probes to devices and holders. As an example, 3M Micropore 1530-0 surgical tape is a product that has been found appropriate. It is noted that exploiting neutral buoyancy to test a device without a separate holder, when appropriate, may offer advantages in reproducibility and accuracy, as this technique eliminates any contribution to, or inhibition of, heating from an implant holder. Further, direct coupling of the temperature probe to the device under test as described ensures that all actual heating is captured.

NOTE 12—~~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~~For the standard rectangular phantom geometry, with the phantom centered in the bore of the volume coil, 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 at 64 MHz for RF coil length of ~~(658)~~. cm or longer.

NOTE 13—~~Heating in the phantom may be asymmetric (~~Amjad et. al ~~**9, 10**~~**), therefore considerable experimentation or computation may be required to determine the temperature probe placement for which maximum heating can be measured** (~~**11**~~7,)~~**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~~ provides information on how to determine the E-fields ~~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~~and gives E-field distribution in the phantom in a 1.5 T RF birdcage ~~8.7.~~coil.

8.6 *RF Exposure*—Use an MRI scan protocol or select a transmit power generating a level of RF power sufficient to achieve the required ΔT, as indicated in 8.7. When evaluating RF-induced heating of devices in the ASTM phantom it is important to ensure that the incident electric field is sufficiently homogeneous (that is, ±1 dB variability) in amplitude and phase (see ISO TS 10974). Such distribution will depend on device dimensions, device orientation within the phantom, and RF coil geometry. In situations where it is not possible to ensure homogeneous electric field across the entire device surface, additional analysis will be needed by means of modified phantoms or computational models.

8.7 ~~*Implant Temperature Measurements:*~~*Phantom Measurement Setup*

8.7.1 Secure at least three temperature probes on or near those locations with a repeatable probe placement precision of ±1 mm between the probe and the implant. Within this suggested tolerance, the probe can be in contact with the device. 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**).

8.7.2 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.

8.7.3 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*~~ΔT ~~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.~~

8.7.4 If the testing is performed in an MR scanner room, the patient comfort fan inside the MR system bore should be turned off or the air flow 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 the effect of air flow on the temperature measurements.

8.7.5 Record the ΔT for 15 min with a temporal resolution of at least 2 s. Include in the report plots of measured (that is, unscaled) ΔT vs. time. Recording times other than 15 min can also be accepted, as long as properly justified.

8.7.5.1 Calculate maximum ΔT scaled to local background RF exposure (that is, SAR = 1 W/kg or $\|\mathbf{E}\|^2 = 1$ $(V/m)^2$) and include this value and the time of RF application in the report.

8.7.5.2 Compare scaled ΔT for the implant to the background temperature rise with no implant of (0.0145 (°C/min)/(W/kg))(time).

8.7.5.3 Report the value at the end of the heating run of ΔT per unit local background RF exposure and per unit time (that is, °C/((W/kg)*minute) or °C/((V^2/m^2)*minutes).

NOTE 14—Fifteen minutes is a time increment that has been historically used for RF exposure duration for testing of RF-induced heating of passive implants in MRI. In the interest of improving test efficiency while ensuring measurement integrity, the standard allows the test duration to be reduced (that is, less than 15 min) as long as temperature measurements of sufficient magnitude to establish a meaningful result occur.

8.7.6 To provide a measure of the run-to-run repeatability of the applied RF power and local E-field place a 10 cm titanium-alloy rod in a position of high E-field sufficiently distant from the implant, place a temperature probe at the tip of the rod and measure the temperature during the testing. An optimal position for the reference titanium-alloy rod and temperature 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. 2.) The heating results of titanium rod may be used to scale the implant heating to compensate for run-to-run variations, as long as magnetic field polarization is unchanged.

~~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.~~

8.8 *Thermal Equilibrium of Phantom Material with Surroundings*—Record temperatures using a minimum of four temperature ~~probes for at least 2 min~~probes, when feasible, for a sufficient time to show thermal equilibrium (for example, 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~~ RF exposure. The thermal equilibrium between the gelled saline and surroundings ~~that the RMS~~ needs to be ensured by the user before the testing. The 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.~~ room should also be measured at the beginning of the experiment. Record the temperature from each temperature probe at least once every 2 s. After the RF exposure is turned off, monitor and record the temperature for at least two additional minutes, to ensure that RF-exposure – rather than other sources – is indeed the cause of the observed temperature rise. The temperature within the ~~scan~~ room should be stable to ~~±1.0°C per hour.~~±2.0°C per hour, unless otherwise specified.

~~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.~~

NOTE 15—Stirring of the gel in between experiments is recommended to establish homogeneous background temperature distribution of the gel.

~~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.

8.9 *Local SAR and Measurements Without the Implant in Place*—*Place (local background RF exposure)*—For the same RF fieldsexposure applied in 8.98.7, the local *temperature*ΔT 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 a similar spatial position as during the implant testing. Record the ΔTspatial positions with a temporal resolution of at least 2 s. Alternatively, the local background RF exposure without the implant present should be determined by measuring the local electric field. The electric field probe should be placed at a similar spatial position 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:

$$SAR = c\frac{\Delta T}{\Delta t} \tag{1}$$

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.

8.10 *Determination of Local Background SAR*—(measurement of local power density in the phantom without the implant present)—The local background 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 Eq 1. Calculate the *dT/dt* using a linear fit over a time where signal-to-noise is sufficient (for example, around 5-10 min). Report the ΔT per unit local background RF exposure and per unit time (that is, °C/((W/kg)·s) or °C/((V^2/m^2) s).

NOTE 16—An alternative method for determining local background SAR using a reference implant is given in X1.8.

8.11 *Implant With Multiple Components*

8.11.1 RF heating for devices with multiple components needs to be assessed for all relevant device configurations and possible orientations relative to the incident electric field.

NOTE 17—Preliminary testing and/or computational modeling can be used to identify the device orientation and/or configuration with the highest level of RF-induced heating (called the 'worst-case configuration'). The following should be considered in the worst-case assessment: 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, RF frequency (that is, 64 MHz or 128 MHz), device orientations (absolute and relative bending, paths, and so forth), and the patient habitus. This assessment is necessary because the RF heating of the device in the phantom is not predictive of the heating of the device in a patient. If it is not possible to identify the single worst-case configuration (for example, two or more configurations that generate similar results), RF engineering principles and pilot studies can be used to reduce the total number of possible cases that need to be physically tested to a manageable amount. RF heating assessment should be conducted using the worst-case configuration(s). An FDA-issued guidance document provides an approach to reduce the number of possible device configurations or combinations to a manageable number for the testing of RF-induced heating in the MR environment (**18**). Other approaches to identify the worst case are also acceptable.

9. Determination of Whole Body (Phantom) Averaged SAR using Calorimetry in Saline-filled PhantomGuidelines on Determination of Labeling Based on Implant Testing

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.

9.1 This procedure needs to be performed once for each physical location ofThe implant manufacturer is responsible for establishing the relationship between *the*ΔT phantom within the MRin phantom and the *test*ΔT system. If the MR test system is an MR scanner, both the implant measurement described above and the calorimetry measurement in this section need tothat is expected in the patient population under the specified exposure conditions specified in the MR labeling. The complexity of this