Designation: F2182 – 19ε2

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.

ε[1] NOTE—Editorially revised throughout in January 2020.
ε[2] NOTE—Corrected editorially in April 2020.

1. Scope

1.1 This test method covers measurement of radio frequency (RF)-induced heating on or near a passive medical implant 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 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 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 (T) or 3 T MR systems, the ΔT 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. Testing for devices with other implantation conditions (e.g., external fixation devices, percutaneous needles, catheters or tethered devices such as ablation probes) is beyond the scope of this standard; for such devices, modifications of this test method 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 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.

1.7 A device with deployed dimensions of less than 2 cm in all directions may 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 h of exposure at 1.5 T/64-MHz or 3 T/128-MHz frequencies (**1**, **2**)[2] and ANSI/AAMI/ISO 14708-3:2017). This condition is not valid when multiple replicas of the device (e.g., 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.

1.8 *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, health, and 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.*

[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.

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 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis

2.3 *NEMA Standard:*[5]

MS 8 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems

2.4 *ISO Technical Specificaton:*[6]

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

3.1.3 *local background RF exposure*—the electric field tangential to the primary axis of the implant at a single position within the phantom (i.e., 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 (i.e., no volume averaging is applied).

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

$$SAR = \lim_{t \to 0} c \frac{\Delta T}{\Delta t} \quad (1)$$

Where: c = 4150 J/(kg°C) is the specific heat of the gel, ΔT is the change in temperature of the gel (°C), and Δt is the change in time (s).

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

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

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*—This test method describes two equivalent approaches for determination of radiofrequency induced heating: an approach using background heating and one reliant upon characterization of electric field (E-field). Either of these approaches is sufficient to characterize radiofrequency heating under the intent of this test method. All guidance pertinent to the approach not utilized when testing in accordance with this test method is understood to be optional. Specifically, procedural steps pertinent to the measurement or characterization of E-field are not required when the background temperature measurement methodology is chosen.

3.1.4.2 *Discussion*—The E-field probe needs to be calibrated in gelled-saline for the given RF exposure.

3.1.5 *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)**

3.1.6 *magnetic resonance imaging (MRI)*—imaging technique that uses a static magnetic field, time-varying gradient magnetic fields, and radio frequency fields to provide images of tissue by magnetic resonance of nuclei.

3.1.7 *MR RF test system*—an apparatus that produces the RF field of the MR system.

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

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

3.1.10 *Specific Absorption Rate (SAR)*—RF power absorbed per unit of mass (W/kg). **(IEC 60601-2-33)**

3.1.11 ΔT—RF-induced temperature rise.

[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, www.nema.org.

[6] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, 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.

4. Summary of Test Method

4.1 The passive implant to be tested is placed completely within a phantom filled with an appropriate medium with RF physical properties (i.e., 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 known local background RF exposure. The phantom material is a gelled-saline consisting of a saline solution and a gelling agent. Temperature probes shall be placed at locations where the maximum local ΔT is expected. Pilot experiments may be needed to determine such locations and, thus, the proper placement of the temperature probes for the heating assessment of the implant. The phantom is placed in an MR system or an RF test system and subjected to a well controlled RF exposure of sufficient magnitude and duration to demonstrate a local background RF exposure in the testing location for the implant that shall be measured with an adequate signal-to-noise ratio.

4.2 The test procedure is divided into two steps: *(1)* the ΔT on or near the implant at several locations is measured using fiber-optic thermometry probes (or equivalent technology). ΔT is also measured at a reference location remote (i.e., of a distance of at least 30 cm) from the implant. *(2)* the implant is removed and temperature measurements (with temperature probe) or electric field measurements (with E-field probe) are repeated at the same 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 ΔT associated with RF power deposition during an MR procedure, involving a specific frequency of RF irradiation of a passive implant. The method allows characterization of the heating propensity of an implant rather than the prediction of heating during a specific MR procedure in a patient. The results may be used as an input to a computational model for estimating ΔT 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 examination.

6. Apparatus

6.1 *Test Apparatus*—The test apparatus consists of a suitable phantom and an MR RF test system, with characterized uncertainty.

6.2 *Temperature Sensor*—A suitable temperature-measuring device (e.g., fiberoptic or fluoroptic thermometry probe), which meets accuracy requirements in the electromagnetic (EM) exposure environment is used to measure temperature versus time during the RF exposure with and without the implant in an appropriate position within a gelled-saline filled phantom . The temperature probe shall have a precision of no less than 0.1°C, an accuracy of ±0.5°C, a sensitive element not larger than 1 mm in any direction, and with temporal resolution of at least 2s.

6.3 *Electric Field Sensor*—A suitable device for measuring the electric field on at least one axis at the RF exposure level that is used for the temperature measurement with an implant in an appropriate position within a gelled-saline filled phantom.

7. Test Specimens

7.1 While this test method may be used on prototype or predicate devices, for purposes of implant qualification and to ensure patient safety relative to the use of MRI technology, the implant evaluated according to this test method should be representative of a finished device according to its intended use or in-situ condition. For example, a balloon-expandable stent, the stent should be expanded and deployed to its proper dimensions (i.e., length and diameter).

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

7.2 Other than described as in 7.1, for purposes of device qualification, the implant shall not be altered in any manner prior to testing other than positioning or otherwise configuring the implant in the orientation that generates the greatest heating for that MR system's frequency. A justification for such orientation shall be provided.

8. Procedure

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

8.2 *Phantom Material*—Phantom material for the RF-induced heating testing of an implant shall meet the following criteria:

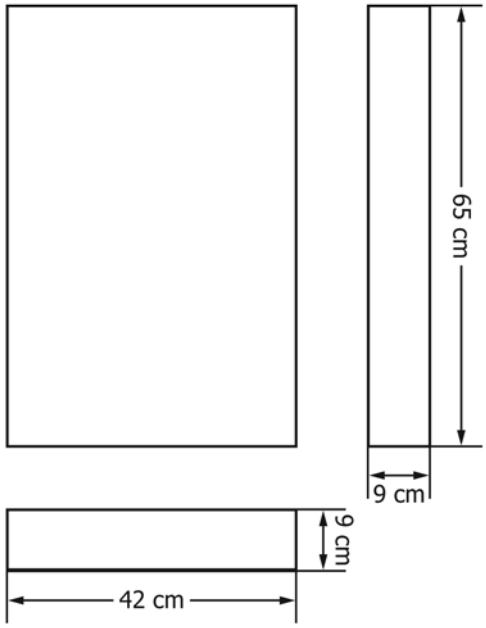
8.2.1 *Electrical Conductivity*—Electrical conductivity of the phantom material at the test temperature shall be 0.47 ± 10 % S/m.

NOTE 4—The conductivity at the test temperature was originally selected to be similar to the average conductivity of human body tissue at body temperature for frequencies in the range 64 MHz to 128 MHz (corresponding to 1.5 and 3 T, respectively). However, as an option, the conductivity of the phantom material in the range 64 MHz to 128 MHz can be measured at lower frequencies. (See Stuchly et al. **(4)** for data on tissue electrical properties and Athey et al. **(5, 6)** for procedures for measurement of electrical properties.)

8.2.2 *Dielectric Constant*—The dielectric constant, or relative electric permittivity (ε_r) shall be 80 ± 20 at the appropriate test frequency (64 MHz or 128 MHz).

NOTE 5—Based on the recipe provided, the phantom material will have diffusivity thermal properties of about 1.3×10^{-7} m^2/s and heat capacity of 4150 J/(kg·°C) and a relative permittivity in the range of 80 ± 20, as specified above.

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.



NOTE 1—Other dimensions can also be used.

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

FIG. 1 Example of dimensions of the gelled-saline medium used for testing that would fill the phantom.

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 distilled or deionized water. A second suitable formulation using NaCl and hydroxy ethyl cellulose (HEC) in distilled or deionized water can be found in X1.3.

NOTE 6—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 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 (e.g., for PAA, the specific heat of the gel is 4150 J/(kg°C) at 21°C and there is a linear rise of 2.35 J/(kg°C) in the specific heat from 20 to 40°C). The gelled-saline could have a shelf life of two 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 stored in 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 ± 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 lower than 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.

Use NaCl >99 % pure.

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

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

8.3.1.2 Preparation of PAA gelled-saline:

(1) Add NaCl to distilled or deionized water and stir to dissolve completely.

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 slowly to avoid lumps, stir to suspend completely.

(3) After one hour, blend the suspension into a slurry. A slow blender has been found to be 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, with a minimal amount of bubbles, and free of lumps.

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

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

8.4 *Implant Holder*—To facilitate proper placement of the implant inside the gelled-saline filled phantom, an implant holder 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 bottom of the phantom **(7, 8, 9)** 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 electromagnetic field, if an implant holder is used it must be made of appropriate materials (i.e., 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. 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] The sole source of supply of the apparatus known to the committee at this time is 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.

8.5 *Implant Placement and Orientation*—The implant must be positioned within the gelled-saline filled phantom where the local background RF exposure is known and of sufficient magnitude to heat the implant-free region at least 10 times the precision of the temperature sensor (e.g., 1°C for sensors with 0.1°C precision) by the completion of the run without the implant in place, if temperature measurement is used for evaluation of the local background SAR (8.10). Additionally, a volume in the phantom should be selected in which the implant is placed so that the incident E-field does not vary substantially over that volume. When the primary dimension of the implant cannot be identified (i.e., the implant does not have an elongated structure), induced heating for several orientations of the implant with respect to the incident field shall be evaluated in order to determine the worst-case for implant heating (**6**). Finally, to minimize RF coupling with the phantom surface and heat transfer into the environment, position the implant so that it is at least 2 cm from the gelled-saline surface, bottom, and walls of the container. See X1.5. 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 to 15 cm from the sidewall of the phantom and 10 to 15 cm from the supero-inferior midline of the phantom where results will be substantially equivalent (Note 11). The actual position of the implant before the test shall be documented (e.g., using digital photographs) and the position immediately upon completion of the test shall be verified as consistent.

NOTE 11—An implant holder may not be required if the device exhibits neutral buoyancy in the slurry. Such an implant may be placed at the desired test location with probes affixed to the implant itself. Control studies for such a test should be conducted such that the probes are held at the test position via a suitable non-conductive holder dimensionally similar to the implant under evaluation. Medical grade paper tape, of a composition that saturates and is permeable to the gelled-saline has been found useful for securing the temperature probes to devices and holders. As an example, 3M Micropore 1530-0 surgical tape (3M Company) is a product that has been determined to be appropriate. Notably, direct coupling of the temperature probe to the implant undergoing testing as described herein ensures that all actual heating related to RF energy deposition is captured.

NOTE 12—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 65 cm or longer.

NOTE 13—Amjad et. al (**10**) provides information on how to determine the E-fields and gives E-field distribution in the phantom in a 64-MHz transmit RF body coil.

8.6 *RF Exposure*—Use an MRI pulse sequence 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 an implant in the ASTM International phantom, it is important to ensure that the incident electric field is sufficiently homogeneous (i.e., ±1 dB variability) in amplitude and phase (see ISO TS 10974). Such distribution will depend on implant dimensions, implant orientation within the phantom, and transmit RF coil geometry. In situations where it is not possible to ensure a homogeneous electric field across the entire implant surface, additional analysis will be needed by means of modified phantoms and/or computational models.

8.7 *Implant and Control Measurement Setup*

8.7.1 Secure a sufficient number of temperature probes on or near those locations with a repeatable probe placement precision of ±1 mm between the sensing portion of the temperature probe and the implant. The number of probes should be enough to characterize the device heating, noting that multiple runs may be necessary. Within this suggested tolerance, the temperature probe can be in contact with the implant. Because 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 (**11**).

8.7.2 Take a photograph of the implant showing a dimensional scale. Additionally, take photographs showing the position of the implant in the phantom and the relative locations of the temperature probes with respect to the implant.

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 the measured ΔT may occur with slight variations in temperature probe positions relative to the implant.

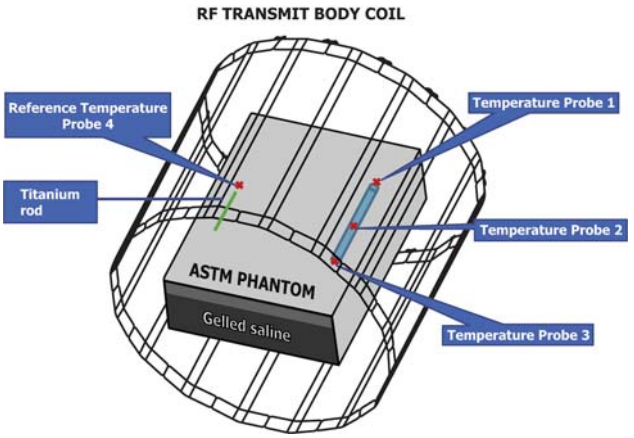
NOTE 14—The order of actions described in 8.7.2 and 8.7.3 can be reversed (i.e., the assessment of the position of the implant can be done after filling the phantom. The overarching requirement is that the position of the device within the phantom and of the probes is established to the degree necessary to ensure reproducibility of the study.

8.7.4 If the testing is performed in an MR system room, the patient comfort fan inside the bore of the MR system 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 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.

NOTE 15—Covering the phantom is advisable and covering the phantom will mitigate effects of circulating airflow in the event that the patient comfort fan cannot be turned off.

8.7.5 Begin RF esposure. Record the ΔT for 15 min with a temporal resolution of at least 2 s. Include in the report plots of measured (i.e., unscaled) ΔT versus time. Recording times other than 15 min can also be accepted, as long as properly justified. Calculate maximum ΔT scaled to local background RF exposure (i.e., 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. Report the value at the end of the heating run of ΔT per unit local background RF exposure and per unit time (i.e., °C/((W/kg) * minute) or °C/((V^2/m^2) * minutes).

NOTE 16—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 (i.e., less than 15 min) as long as temperature measurements of sufficient magnitude to establish a meaningful result occur.



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—Heating in the phantom may be asymmetric (**7**, **8**, **9**, **12**, **13**). Therefore, considerable experimentation or computation may be required to determine the temperature probe placement for which sufficiently high or worst-case 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 temperature probe locations for an elongated implant, as follows: one probe positioned at the end of the implant (probe 1), another positioned at the middle of the implant (probe 2), and a third at the other end of the implant (probe 3). Other probe locations may be more appropriate depending on the implant geometry. Optionally, a reference titanium-alloy rod and an additional temperature probe (probe 4) may be located in the position of high E-field as described in 8.7.

NOTE 3—This standard does not specify a procedure to assess whole-body SAR. Assessment of whole-body SAR can only be done reliably using the NEMA MS 8 standard. Global SAR values or reference values are not representative of vendor supplied SAR values on the software console.

FIG. 2 Example apparatus used for testing of RF-induced heating near an implant during MRI.

8.7.6 To provide a measurement of the run-to-run repeatability of the applied RF power and local E-field, as an optional step, you may place a 10 cm titanium-alloy rod in a position of high E-field sufficiently distant from the implant, place a temperature probe in the holes of the rod (see X1.7), 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.

8.8 *Thermal Equilibrium of Phantom Material with Surroundings*—Record temperatures for a sufficient time to show thermal equilibrium (e.g., 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 RF exposure. The thermal equilibrium between the gelled-saline and surroundings needs to be ensured by the user before the testing. The temperature of the room should also be measured at the beginning of the experiment. The temperature within the room should be stable to ±2.0°C/h, unless otherwise specified. Record the temperature from each temperature probe at least once every 2s. 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.

NOTE 17—Stirring of the gelled-saline in between experiments is recommended to establish a homogeneous background temperature distribution of the medium.

8.9 *Measurements Without the Implant in Place (Local Background RF Exposure)*—For the same RF exposure applied in 8.7, the local ΔT at the same 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 a similar spatial position as during the implant testing. Record the ΔT 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 similar spatial positions as during the implant testing. Care should be taken to ensure minimal bubble or air entrapment in the gelled-saline with removal of the implant to help avoid inadvertent hot spot formation.

NOTE 18—Measurements of ΔT with and without the implant present can be obtained in any order as long as the implant and probe locations are controlled.

8.10 *Determination of Local Background SAR (Measurement of Local Power Density in the Phantom Without the Implant Present)*—Use Eq 1 to calculate local background SAR at each of the four temperature probe locations. Calculate the *dT/dt* using a linear fit over a time where the signal-to-noise is sufficient (e.g., around 5-10 min). Report the ΔT per unit local background RF exposure and per unit time (i.e., °C/((W/kg)·s) or °C/((V²/m²) s).

NOTE 19—An alternative method for determining local background SAR using a reference implant is given in X1.8.

8.11 *Implant With Multiple Components*—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 20—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') in this bench test. The following parameters are typically included in 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 (i.e., 64MHz or 128 MHz), and device orientations (absolute and relative bending, and so forth). If it is not possible to identify the single worst-case configuration (e.g., 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. An FDA-issued guidance document provides an example of a possible 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.

NOTE 21—Notably, the measurements of RF-induced heating of an implant in the phantom may not be fully predictive of the heating of the