Designation: ~~F2182 – 19~~ F2182 – 19$^{\varepsilon 1}$

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.

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~~to: issues of ~~magnetically induced-displacement,~~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 ~~(for example,~~ (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 ~~does~~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 ~~hour~~h of exposure at 1.5 ~~T and~~T/64-MHz or 3 ~~T~~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 ~~(for example,~~ (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]

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

2.4 *ISO ~~Standards:~~Technical Specificaton:*[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—~~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 ~~(that is,~~ (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 ~~(that is,~~ (i.e., no volume averaging is applied).

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

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

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):

$$SAR = \frac{\sigma \|E\|^2}{2\rho} \tag{2}$$

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] 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.~~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, ~~http://www.iso.org.~~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.

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 ~~medium~~gelled-saline for the given RF exposure.

~~3.1.5 *magnetic resonance (MR) equipment*—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)**~~

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

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

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

3.1.7 *MR RF test system*—an apparatus that produces the RF field of the MR system.*passive implant*—an implant that serves all of its functions without supply of electrical power.

3.1.8 *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.

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

3.1.10 ΔT—RF-induced temperature rise.

4. Summary of Test Method

4.1 The passive implant to be tested is placed completely within a phantom ~~material with~~ filled with an appropriate medium with RF physical properties ~~(that is,~~ (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 ~~well characterized~~ known local background RF exposure. The phantom material is a ~~gelled saline~~ 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~~and, thus, the proper placement of the temperature ~~probes.~~ probes for the heating assessment of the implant. The phantom is placed in an MR system or an RF test system and ~~subject~~subjected to a ~~well-controlled~~ 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~~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~~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.

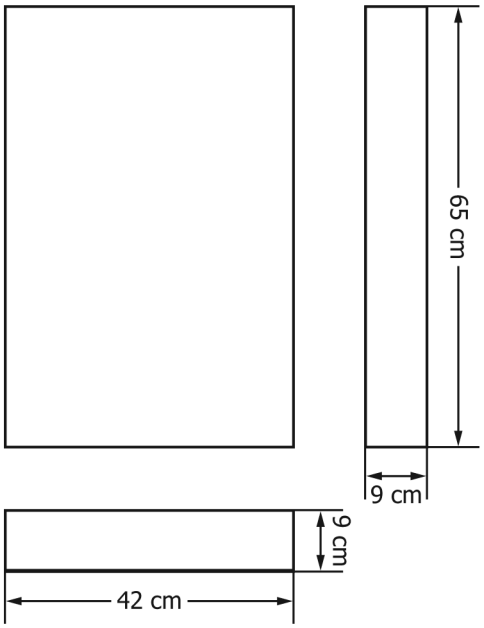
5. Significance and Use

~~5.1 This test method describes a test procedure for evaluating the ΔT associated with RF emitted during MR procedures, involving a specific frequency of RF irradiation of an implant. The method allows characterization of the heating propensity of the implant rather than the prediction of heating during a specific MR procedure in patients.~~

5.1 This test method describes a test procedure for evaluating the ΔT~~The~~ 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 ~~scan.~~examination.

6. Apparatus

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



NOTE 1—Other dimensions can also be used.

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

FIG. 1 Example of ~~Dimensions of Phantom Gelled-saline Medium Used for Testing~~dimensions of the gelled-saline medium used for testing that would fill the phantom.

6.2 *Temperature Sensor*—A suitable temperature-measuring device ~~(for example, fiber optic~~ (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 ~~implant in place.~~ the implant in an appropriate position within a gelled-saline filled phantom . The temperature probe shall have a precision of no ~~worse~~less than 0.1°C, an accuracy of ±0.5°C, a ~~size of the~~ sensitive element not larger than 1 mm in any direction, and with temporal resolution of at least ~~2 s.~~ 2s.

6.3 *Electric Field Sensor*—A suitable device for measuring the electric field ~~of~~on at least one axis at the RF exposure level that is used for the temperature measurement with an implant in ~~place.~~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 ~~device qualification, the~~ implant qualification and to ensure patient safety relative to the use of MRI technology, the implant evaluated according to this test method ~~shall~~should be representative of a finished device ~~in the as-implanted~~ according to its intended use or in-situ ~~condition; for~~condition. For example, ~~balloon-expandable stents should have the balloon expanded to the proper diameter.~~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 ~~device.~~implant.

7.2 Other than described as in 7.1, for purposes of device qualification, ~~implants~~ 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 ~~highest~~greatest heating for that ~~device/scanner~~ 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 ~~device~~ 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 ~~a phantom dimensions~~ dimensions of the gelled-saline volume inside the phantom which may be used ~~and which has~~is shown in Fig. 1~~a volume of approximately 24.6 L is shown in~~. The volume in this example is approximately 24.6 ~~Fig. 1.~~L.

8.2 *Phantom Material*—Phantom ~~materials~~material for the RF-induced heating ~~test~~ testing of an implant shall meet the following ~~criteria.~~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 ~~- 128 MHz. The~~ 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.)

~~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~~ 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.

8.3 *Phantom Formulation*—A suitable ~~gelled saline~~ 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. ~~Another formulation can be made with NaCl and hydroxyethyl~~ A second suitable formulation using NaCl and hydroxy ethyl cellulose (HEC) in distilled or deionized ~~water.~~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. ~~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 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,~~ (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~~ gelled-saline could have a shelf life of two months or more. However, a new batch of ~~gelled saline~~ 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~~ 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 ~~(between approximately 1 and 15 kHz)~~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:~~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~~ gelled-saline with the required properties.

8.3.1.2 Preparation of PAA ~~gelled saline:~~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 ~~all~~ 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 ~~phantom,~~ 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 ~~(that is,~~ (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

[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.

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.

8.5 *Implant Placement and Orientation*—~~Choose a location for the implant~~ The implant must be positioned within the gelled-saline filled phantom where the local background ~~SAR and incident E-field are~~ RF exposure is known and of sufficient magnitude to heat the implant-free region at least 10 times the precision of the temperature sensor ~~(for example,~~ (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, ~~choose~~ 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 ~~this~~that volume. When the primary dimension of the implant cannot be identified ~~(that is,~~ (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 ~~analyzed to evaluate induced~~ 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 ~~gel~~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.

~~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 11—An implant holder may not be required if the device exhibits neutral buoyancy in the slurry. Such ~~devices~~ an implant may be placed at the desired test location with probes affixed to the ~~device~~implant itself. Control studies for such ~~tests~~ a test 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~~implant under ~~test.~~evaluation. Medical grade paper tape, of a composition that saturates ~~with the slurry material,~~ 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 ~~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,~~ determined to be appropriate. Notably, direct coupling of the temperature probe to the ~~device under test~~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 (~~7~~10) provides information on how to determine the E-fields and gives E-field distribution in the phantom in a ~~1.5 T~~64-MHz transmit RF ~~birdcage~~body coil.

8.6 *RF Exposure*—Use an MRI ~~scan protocol~~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 ~~devices~~ an implant in the ASTM ~~phantom~~ International phantom, it is important to ensure that the incident electric field is sufficiently homogeneous ~~(that is,~~ (i.e., ±1 dB variability) in amplitude and phase (see ISO TS 10974). Such distribution will depend on ~~device~~implant dimensions, ~~device~~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 ~~device~~implant surface, additional analysis will be needed by means of modified phantoms ~~or~~and/or computational models.

8.7 ~~*Phantom*~~ *Implant and Control Measurement Setup*

8.7.1 Secure ~~at least three~~ 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 ~~device. The~~ implant. Because the sensing portion of the temperature probe varies for different ~~probes. The~~probes, the location of the sensing portion of the probe needs to be precisely determined for each individual temperature probe (**811**).

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 ~~and the implant. Also take a photograph of the implant showing a dimensional scale.~~ with respect to the implant.

8.7.3 Fill the phantom with the ~~gelled saline~~ gelled-saline (8.3). Stir the phantom ~~gelled saline~~ 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