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

Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging[1]

This standard is issued under the fixed designation F2182; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method covers measurement of radio frequency (RF) induced heating on or near a passive medical implant and its surroundings during magnetic resonance imaging (MRI).

1.2 This test method is one ~~of those~~ required to determine if the presence of a passive implant may cause injury to the patient with the implant during an MR procedure. Other safety issues that should be addressed include magnetically induced displacement force and torque, as well as proper device function while in various configurations in the MR environment.

1.3 The amount of RF-induced temperature rise for a given specific absorption rate (SAR) will depend on the RF frequency, which is dependent on the static magnetic field strength of the MR system. ~~Because of possible additional heating, particularly when implant dimensions approaches or exceeds one quarter of the wavelength of the RF field inside the phantom, conclusions from measurements made at one static magnetic field strength do not apply to other field strengths and frequencies.~~ While the focus in this test method is on 1.5 Tesla (T) or 3 Tesla cylindrical bore MR systems, the RF-induced temperature rise for an implant in ~~open~~ MR systems of other static magnetic field strengths or magnet designs can be evaluated by suitable modification of the method described herein.

1.4 This test method assumes that testing is done on devices that will be entirely inside the body. For other implantation conditions (for example, external fixation devices, percutaneous needles, catheters or tethered devices such as ablation probes), modifications of this test method are necessary.

1.5 This test method applies to whole body magnetic resonance equipment, as defined in section 2.2.103 of the IEC Standard 60601-2-33, Ed. 2.0, with a whole body RF transmit coil as defined in section 2.2.100. The RF coil is assumed to have quadrature excitation.

1.6 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

2.2 *IEC Standard:*[3]

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

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[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

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

2.3 *NEMA Standard:*[4]

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

3. Terminology

3.1 *Definitions:*

3.1.1 *gelled saline*—phantom medium consisting of sodium chloride and polyacrylic acid or sodium chloride and hydroxyethylcellulose in water as specified in this test method.

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

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

3.1.4 *local SAR*—specific absorption rate (SAR) averaged over any 10 g of tissue of the patient body and over a specified time.

60601-2-33, Ed. 2.0

3.1.5 *magnetic resonance (MR) environment*—volume within the 0.50 mT (5 gauss (G)) line of an MR system, which includes the entire three dimensional volume of space surrounding the MR scanner. For cases where the 0.50 mT line is contained within the Faraday shielded volume, the entire room shall be considered the MR environment.

3.1.6 *magnetic resonance imaging (MRI)*—imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei.

3.1.7 *magnetic resonance system (MR system)*—ensemble of MR equipment, accessories including means for display, control, energy supplies, and the MR environment.

60601-2-33, Ed. 2.0

3.1.8 *MR Conditional*—an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, *dB/dt* (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

3.1.9 *MR Safe*—an item that poses no known hazards in all MR environments.

NOTE 1—MR Safe items include nonconducting, nonmagnetic items such as a plastic petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data.

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

3.1.11 *MR Unsafe*—an item that is known to pose hazards in all MR environments.

NOTE 2—MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

3.1.12 *passive implant*—an implant that serves its function without supply of electrical power.

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

3.1.14 *specific absorption rate (SAR)*—the mass normalized rate at which RF energy is deposited in biological tissue. SAR is typically indicated in W/kg.

4. Summary of Test Method

4.1 The implant to be tested is placed in a phantom material that simulates the electrical and thermal properties of the human body. The implant is placed at a location with well characterized exposure conditions. The local SAR is assessed to characterize the exposure conditions at that location. The phantom material is a gelled saline consisting of a saline solution and a gelling agent. ~~Fiberoptic temperature~~ Temperature probes are placed at locations where the induced implant heating is expected to be the greatest (this may require pilot experiments to determine the proper placement of the temperature probes). The phantom is placed in an MR system or an apparatus that reproduces the RF field of such an MR system. An RF field producing a sufficient whole body averaged SAR of about 2 W/kg averaged over the volume of the phantom is applied for approximately 15 min, or other time sufficient to characterize the temperature rise and the local SAR.

4.2 The ~~measurement~~ test procedure is divided into two ~~parts:~~steps. In Step 1, the ~~implant heating is measured and the RF energy is assessed by measuring the local SAR at a~~ temperature ~~reference probe. The temperature~~ rise on or near the implant at several locations is measured using fiber-optic thermometry probes (or equivalent technology) during approximately 15 min of RF application. Temperature rise is also measured at a reference location during Step 1. In Step 2, the implant is removed and the ~~local SAR~~ same RF application is ~~assessed at~~repeated while the ~~same positions where the implant heating was measured in Step 1 and~~ temperature measurements are obtained at the ~~location of the temperature reference probe.~~ same probe locations as in Step 1. All measurements shall be done with the implant holders in place. The local SAR ~~value at~~ is calculated from the temperature ~~reference~~ measurements for each probe ~~is calculated and~~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.

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

5. Significance and Use

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

~~5.2If there is a significant temperature rise associated with the implant, the~~ 5.2 The results may be used as an input to a computational model for estimating temperature rise due to the presence of that implant in a patient. The combination of the test results and the computational model results may then be ~~provided~~used to ~~regulatory bodies and physicians to~~help assess the safety of a patient with the implant during an MR scan.

6. Apparatus

6.1 *Test Apparatus*—The test apparatus consists of a suitable phantom and an MR system or MR test system for production of the RF field. The phantom, implant, and MR test system are utilized to approximate the electrical and physical environment that the patient and device experience during an MR procedure. The phantom, implant, and MR test system are utilized to establish the heating behavior of a device in a known RF field in a standardized phantom.

6.2 *Temperature Sensor*—~~A suitable temperature measuring device, usually a fiberoptic thermometry probe, is used to measure temperature versus time of RF exposure on or in the vicinity of the implant. The temperature sensor will have a resolution of no worse than 0.1°C and a spatial resolution not to exceed 1 mm in any direction.~~ —A suitable temperature measuring device, usually a fiberoptic or fluoroptic thermometry probe, is used to measure temperature versus time during the RF exposure on or in the vicinity of the implant. The temperature sensor will have a resolution of no worse than 0.1°C, a temperature probe spatial resolution not to exceed 1 mm along the specific axis of measurement in any direction, and a temporal resolution of at least 4 s.

NOTE ~~3—Fluoroptic temperature probes have been found to be satisfactory for this purpose.~~ 3—It may be necessary to perform multiple measurements near the position of interest to ensure that the temperature probe is in the location of greatest temperature rise.

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

7. Test Specimens

~~7.1For purposes of device qualification, the implant evaluated according to this test method shall be representative of a finished device in the as-implanted condition; for example, balloon expandable stents should be balloon expanded.~~

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

~~7.3This test method may be used on prototype devices during product development.~~

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

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

8. Procedure

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

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

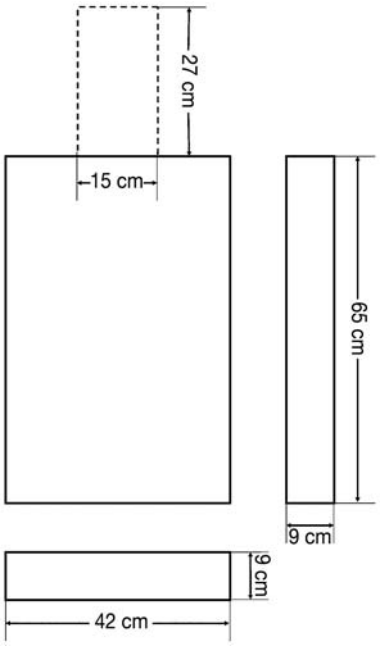
8.2.1 *Conductivity*—~~Conductivity of the gelled saline at test temperature shall be 0.47 ± 10% S/m at 64 MHz and 128 MHz.~~ —Conductivity of the gelled saline at test temperature shall be 0.47 ± 10 % S/m.

NOTE ~~4—The~~ 5—The conductivity at the test temperature was selected to match the average conductivity of the human body at body temperature. Electrical conductivity in the MHz range is greater than conductivity measured in the kHz range. The conductivity at 64 MHz and 128 MHz is valid using measurements made at ~~the~~ lower ~~frequencies specified in 8.3.1.~~frequencies. (See Stuchly et al. **(1)**[5] for data on tissue electrical properties and Athey et al. **(2)** for procedures for measurement of electrical properties.)

8.2.2 *Dielectric Constant*—~~Dielectric constant shall be 60 to 100 at 64 MHz and 128 MHz.~~ —Dielectric constant, or relative electric permittivity (ε_r) shall be 80 ± 20 at the appropriate test frequency (64 MHz or 128 MHz).

8.2.3 *Thermal Parameters*—The phantom material shall have thermal properties similar to those of the body which has diffusivity of about 1.3×10^{-7} m ^{2}~~/s and heat capacity close to that of water, 4160 J/kg°C.~~ /s and heat capacity 4150 J/kg°C. This is close to the heat capacity of water.

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



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

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

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

8.2.4 *Viscosity*—The viscosity shall be great enough so that the phantom material does not allow bulk transport or convection currents. Generally, this is achieved by inclusion of a gelling agent. ~~Note5—The amount of aqueous solution absorbed decreases with increasing salt concentrations.~~

8.3 *Phantom Formulation*—A suitable gelled saline that has the properties described in 8.2 can be made with 1.32 g/L NaCl and 10 g/L polyacrylic acid (PAA) in water. For this formulation, room temperature conductivity is approximately 0.47 S/m and viscosity is sufficient to prevent convective heat transport.

NOTE~~6—Another formulation can be made with NaCl and hydroxyethyl cellulose (HEC) in water. See~~ 6—The amount of aqueous solution absorbed decreases with increasing salt concentrations.

NOTE 7—Another formulation can be made with NaCl and hydroxyethyl cellulose (HEC) in water. See X1.4. Comparative testing between PAA and HEC gels has not been performed prior to publication of this test method.

~~8.3.1It~~8.3.1 It is essential to strictly follow the mixing protocol and use the given ingredients in order to achieve reliable and repeatable results. The following protocol needs to be followed precisely. The resulting gel (PAA) should have conductivity of ~~0.40 to 0.60~~0.47 ± 10 % S/m at temperatures between 20 and 25°C. The conductivity does not need to be measured at ~~frequencies lower than 15 kHz.~~64 MHz or 128 MHz. The specific heat of the gel is ~~4160~~4150 J/(kg ~~k)~~K) at 21°C and there is a linear rise of 2.35 J/(kg K) per degree kelvin in the specific heat from 20 to 40°C. The gelled saline should have a shelf life of two months. However, a new batch of gelled saline is needed when there is a change in any property, such as volume, conductivity, color, or viscosity. The phantom should be sealed in an airtight container whenever possible to prevent evaporation and/or contamination. Evaporation will alter the gelled saline properties.

NOTE~~7—The~~ 8—The objective is to have a resulting gel with a conductivity of 0.47 S/m at frequencies of 64 and 128 MHz, however, the ability to make a precise formulation of the material exceeds the ability to precisely measure its complex permittivity at these frequencies using readily available methods. As such, care must be taken in following the instructions, and it is suggested to measure the conductivity with a simple device at low frequencies (between approximately 1 and 15 kHz) in order to check that the recipe was made without large errors or deviations.

8.3.1.1 Ingredients of PAA gelled saline:

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

NaCl—reagent grade, >99 % pure.

Polyacrylic acid—Aldrich product number 436364, 'Polyacrylic acid partial sodium salt', CAS no. 76774-25-9.[6] See ~~Note 8~~Note 9.

NOTE ~~8~~9—Different products have different gelling properties. The product listed above has been found to produce a gelled saline with the required properties.

8.3.1.2 Preparation of PAA gelled saline:

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

(2) Add PAA, stir to suspend completely.

(3) After one hour, blend the suspension into a slurry. A kitchen grade immersion blender with a blade has been found to be satisfactory. The blender is turned on intermittently for at least 20 min in order to remove all lumps of any discernable size.

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

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

~~8.4*Implant Placement and Orientation in Known E-field*—For the chosen phantom geometry (8.1), computationally or experimentally determine the applied radiofrequency E-fields throughout the phantom geometry for the MR test system or with the transmit RF coil used in the test in the absence of the implant. Amjad et. al (3~~**Verify that the conductivity is 0.47 ± 10 % S/m at 20 to 25°C measured at frequencies lower than 15 kHz.**

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

8.4.1 Demonstrate the worst case implant configuration and provide the evidence used to determine the configuration used for testing ~~(4)provides information on how to determine the E-fields. Choose a location for the implant where the E field is known and of sufficient magnitude to heat the implant-free region at least 10 times the precision of the temperature sensor (for example, 1°C for sensors with 0.1°C precision) by the completion of the run without the implant in place (8.14). Additionally, as possible, choose a volume in which the implant is placed so the undisturbed E-field does not vary significantly over this volume. Orient the longest linear dimension of the implant aligned with the E-field in this volume so that there is a high uniform electric field tangent to the implant. For a complicated multi-component implant, testing may need to be done with the implant in multiple orientations in the phantom at the same location. In order to minimize heat transfer into the environment, orient the implant so that it is at least 2 cm from the gel surface, bottom, and walls of the container. See X1.5.~~. Testing in more than one implant configuration will be required if the worst case clinically relevant configuration of the implant is unknown.

~~NOTE9—For the standard rectangular phantom geometry, with the phantom centered in the bore, and the lateral side of the implant placed 2 cm from the phantom wall, this location provides a high uniform tangential electric field.~~

~~8.5*Implant Configuration*—For multi-component implants that include flexible components that are not clinically used in a straight configuration (for example, catheters or guidewires), the flexible components should be assembled and attached to the rigid implant in a clinically relevant worst case configuration. Demonstrate the worst case implant configuration and provide evidence that you have tested in the worst implant configuration (~~**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 **(4)**. ~~Testing in more than one implant configuration will be required if the worst case clinically relevant configuration of the implant is unknown.~~

[6] The sole source of supply of the apparatus known to the committee at this time is Aldrich Chemical Company, Inc., Milwaukee, WI, USA. http://www.sigmaaldrich.com. If you are aware of alternative suppliers, please provide this information to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend.

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NOTE ~~10—For example, a trochanteric reattachment device consists of a trochanter plate and three flexible cables that are crimped into three separate loops and threaded through three proximal slots in the plate. The plate with flexible cable assembly should be tested in the clinically relevant worst case orientation inside the phantom.~~

~~8.6~~ *12—For example, a trochanteric reattachment device consists of a trochanter plate and three flexible cables that are crimped into three separate loops and threaded through three proximal slots in the plate. The plate with flexible cable assembly gives an endless number of possible configurations to consider.*

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

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

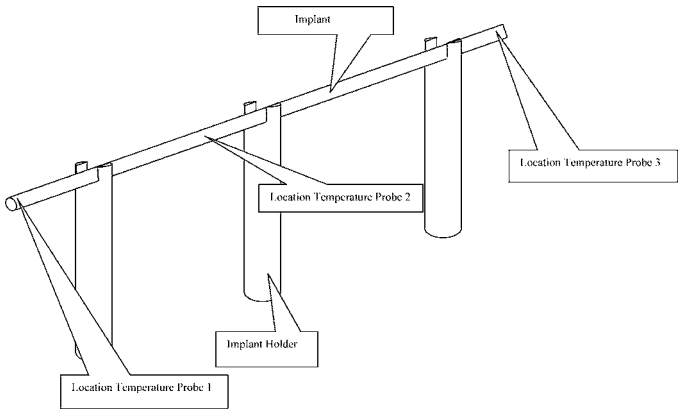
8.4.3 The location of the maximum heating can be assessed experimentally using multiple temperature probe locations evaluating all possible locations of high heating for all relevant device configurations. Alternatively, or in combination, the location of maximum heating can be predicted computationally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

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

NOTE 15—If large diameter loops can be formed by conductive components, that configuration may represent the worst case for heating. High heating may also occur in long, thin devices with a large length to diameter ratio, or at sharp edges, points, the ends of devices, and at corners (Ref **22-24**).

8.5 *Implant Holder*—To facilitate proper placement of the implant inside the gelled-saline filled phantom, an implant holder is needed. Because any such holder may have an effect on the local field environment, the implant holder must be made of appropriate materials (for example, nonmetallic, nonconducting), be small enough, appropriately oriented, and far enough away from the temperature measurement locations so as not to disturb the local field distribution close to these locations. Fig. 2 shows an example of an appropriate implant holder—small cylinders with less than 5 mm diameter. These may be placed in whatever orientation is required as long as they will not significantly alter the local electrical or thermal environment being measured. The implant holder shall be mounted perpendicular to the major field components of the induced electric field inside the phantom. Adequate mounting of this example implant holder would be perpendicular to the bottom or side wall of the phantom. Because implant holders with material differences from the phantom fluid will cause local field disturbances, temperature or SAR probes should be located at least two implant holder-diameters away from the implant holder to minimize this effect on the measurements. For example, if an implant holder is 5 mm wide, the temperature probe should be placed at least 10 mm away from the implant holder.

8.6 *Implant Placement and Orientation in Known E-field —*Choose a location for the implant where the local background SAR and E-field are known and of sufficient magnitude to heat the implant-free region at least 10 times the precision of the temperature



NOTE—Because implant holders with material differences from the phantom fluid will cause local field disturbances, temperature probes should be located at least 2 implant holder-diameters away from the implant holder to minimize the effect on the temperature measurements. For example, if an implant holder is 5 mm wide, the temperature probe should be placed at least 10 mm away from the implant holder.

FIG. 2 Example of Appropriate Implant Holder