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Designation: F2182 – 19

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

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

1. Scope

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

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

1.8 *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.*

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

[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.

[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.

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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:*[6]

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

14971 Medical devices – Application of risk management to medical devices

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

2.5 *Other Standard:*[7]

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

3. Terminology

3.1 *Definitions:*

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

3.1.2 *implant—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, no volume averaging is applied).

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

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

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

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*—The E-field probe needs to be calibrated in medium 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)**

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

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

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

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

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

3.1.12 ΔT—RF-induced temperature rise.

4. Summary of Test Method

4.1 The implant to be tested is placed completely within a phantom material with RF physical properties (that is, electrical conductivity, electrical permittivity, thermal conductivity, thermal capacity, mass density) similar to the averaged properties of the human body. The implant is placed at a location with well characterized 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. The phantom is placed in an MR RF test system and subject to a

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

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

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

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

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well-controlled RF exposure of sufficient magnitude and duration to demonstrate a local background RF exposure in the testing location that shall be measured with adequate signal-to-noise ratio.

4.2 The test procedure is divided into two steps: *(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 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 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.

5.2 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.

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.

6.2 *Temperature Sensor*—A suitable temperature-measuring device (for example, fiber optic 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 temperature probe shall have a precision of no worse 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.

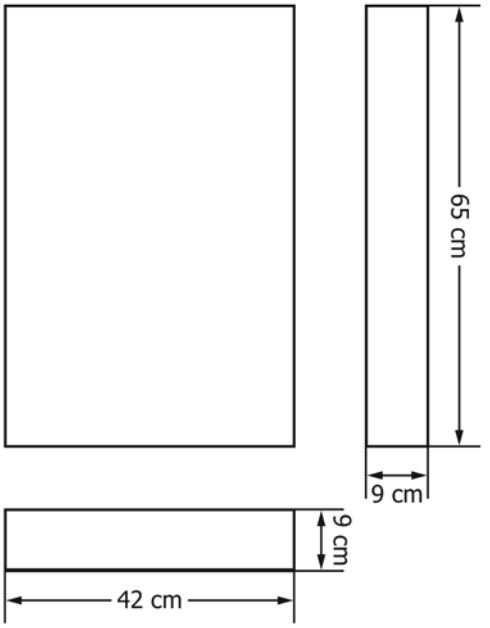
6.3 *Electric Field Sensor*—A suitable device for measuring the electric field of at least one axis at the RF exposure level that is used for temperature measurement with an implant in place.

7. Test Specimens

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

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

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



NOTE 1—Other dimensions can also be used.

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

FIG. 1 Example of Dimensions of Phantom Gelled-saline Medium Used for Testing

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 to any phantom surface **(3)**. This is to minimize RF coupling with phantom surface and heat transfer into the environment. An example of a phantom dimensions which may be used and which has a volume of approximately 24.6 L is shown in Fig. 1.

8.2 *Phantom Material*—Phantom materials for the RF-induced heating test 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 - 128 MHz. The conductivity of the phantom material in the range 64 MHz - 128 MHz can be measured at lower frequencies. (See Stuchly et al. **(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 constant, or relative electric permittivity (ε_r) shall be 80 ± 20 at the appropriate test frequency (64 MHz or 128 MHz).

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8.2.3 *Viscosity*—The viscosity shall be great enough so that the phantom material does not allow bulk transport or convection currents. Generally, this is achieved by inclusion of a gelling agent.

8.3 *Phantom Formulation*—A suitable gelled saline that has the properties described in 8.2 can be made with 1.32 g/L NaCl and 10 g/L partial sodium salt of polyacrylic acid (PAA) in distilled or deionized water. Another formulation can be made with NaCl and hydroxyethyl cellulose (HEC) in distilled or deionized water.

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, 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 (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.

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 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 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, 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, 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.

8.5 *Implant Placement and Orientation*—Choose a location for the implant where the local background SAR and incident E-field are known and of sufficient magnitude to heat the implant-free region at least 10 times the precision of the temperature sensor (for example, 1°C for sensors with 0.1°C precision) by the completion of the run without the implant in place, if temperature measurement is used for evaluation of the local background SAR (8.10). Additionally, choose a volume in which the implant is placed so that the incident E-field does not vary substantially over this volume. When the primary dimension of the implant cannot be identified (that is, the implant does not have an elongated structure), several orientations of the implant with respect to the incident field shall be analyzed to evaluate induced heating (**6**). Finally, to minimize RF coupling with phantom surface and heat transfer into the environment, position the implant so that it is at least 2 cm from the gel surface, bottom, and walls of the container. See X1.5.

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

[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.

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 may be placed at the desired test location with probes affixed to the device itself. Control studies for such tests should be conducted such that the probes are held at the test position via being affixed to a suitable non-conductive holder dimensionally similar to the device under test. Medical grade paper tape, of a composition that saturates with the slurry material, has been found useful for securing the temperature probes to devices and holders. As an example, 3M Micropore 1530-0 surgical tape is a product that has been found appropriate. It is noted that exploiting neutral buoyancy to test a device without a separate holder, when appropriate, may offer advantages in reproducibility and accuracy, as this technique eliminates any contribution to, or inhibition of, heating from an implant holder. Further, direct coupling of the temperature probe to the device under test as described ensures that all actual heating is captured.

NOTE 12—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**) provides information on how to determine the E-fields and gives E-field distribution in the phantom in a 1.5 T RF birdcage coil.

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

8.7 *Phantom Measurement Setup*

8.7.1 Secure at least three temperature probes on or near those locations with a repeatable probe placement precision of ±1 mm between the probe and the implant. Within this suggested tolerance, the probe can be in contact with the device. The sensing portion of the temperature probe varies for different probes. The location of the sensing portion of the probe needs to be precisely determined for each individual temperature probe (**8**).

8.7.2 Take photographs showing the position of the implant in the phantom and the relative locations of the temperature probes and the implant. Also take a photograph of the implant showing a dimensional scale.

8.7.3 Fill the phantom with the gelled saline (8.3). Stir the phantom gelled saline to ensure that it is thoroughly mixed. Be sure that there are no air bubbles at the temperature probes. Visually examine the location of the temperature probes relative to the implant immediately before and after the heating assessment because significant variations in measured ΔT can occur with slight variations in temperature probe positions relative to the implant.

8.7.4 If the testing is performed in an MR scanner room, the patient comfort fan inside the MR system bore should be turned off or the air flow blocked or directed away from the phantom so that there is no movement of air inside the MR system bore while performing the temperature measurements. If the patient comfort fan cannot be turned off, the phantom should be covered after the implant is in place in order to minimize the effect of air flow on the temperature measurements.

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

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

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

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

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

8.7.6 To provide a measure of the run-to-run repeatability of the applied RF power and local E-field place a 10 cm titanium-alloy rod in a position of high E-field sufficiently distant from the implant, place a temperature probe at the tip of the rod and measure the temperature during the testing. An optimal position for the reference titanium-alloy rod and temperature probe may be on the contra-lateral side of the phantom from the implant using the longitudinal axis passing through the geometric center of the phantom as the reflection axis. (See Fig. 2.) The heating results of titanium rod may be used to scale the implant heating to compensate for run-to-run variations, as long as magnetic field polarization is unchanged.

8.8 *Thermal Equilibrium of Phantom Material with Surroundings*—Record temperatures using a minimum of four temperature probes, when feasible, for a sufficient time to show thermal equilibrium (for example, 2 min) prior to the application of the RF energy to allow evaluation of whether or not the temperature is at steady state prior to the 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. Record the temperature from each temperature probe at least once every 2 s. After the RF exposure is turned off, monitor and record the temperature for at least two additional minutes, to ensure that RF-exposure – rather than other sources – is indeed the cause of the observed temperature rise. The temperature within the room should be stable to ±2.0°C per hour, unless otherwise specified.

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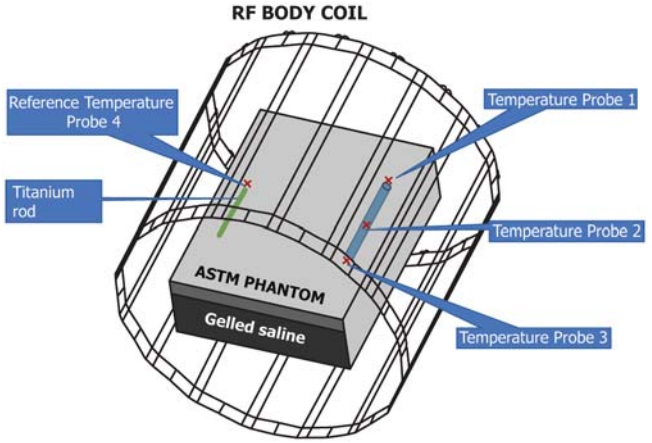

NOTE 1—Temperature probes 1, 2, and 3 are in the locations of greatest heating on or near the implant. Temperature probe 4 is the Temperature Reference Probe.

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

NOTE 3—Heating in the phantom may be asymmetric (**9**, **10**, **11**, **12**, **13**); therefore considerable experimentation or computation may be required to determine the temperature probe placement for which sufficiently high heating can be measured (**14**, **15**, **16**, **17**). For instance, for an elongated implant, the greatest heating will likely occur near the ends of the implant. Implant heating may also be maximal at sharp points or edges. Fig. 2 shows examples (not normative) of probe location: one probe could be at the end (probe 1), another (probe 2) positioned at the middle of the implant, and a third at the other end of the implant (probe 3). Optionally locate the reference titanium-alloy rod and temperature probe (probe 4) in the position of high E-field as described in 8.7.

FIG. 2 Example Diagram of Apparatus for Testing of RF Heating Near an Implant During MR Imaging

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

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 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 a similar spatial position as during the implant testing. Care should be taken to ensure minimal bubble or air entrapment in the gel with removal of the implant to help avoid inadvertent hot spot formation.

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

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

8.11 *Implant With Multiple Components*

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

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

9. Guidelines on Determination of Labeling Based on Implant Testing

9.1 The implant manufacturer is responsible for establishing the relationship between ΔT in phantom and the ΔT that is expected in the patient population under the specified exposure conditions specified in the MR labeling. The complexity of this evaluation depends on the ΔT obtained in the phantom, the patient population, the location of the implant inside the patient, and the exposure conditions. A scientifically based rationale rather than correlation data may be sufficient to establish this relationship.

10. Report

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

10.1.1 A description of the implant product, including images with scale.

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

10.1.3 Description of the materials of construction (ASTM designation or other).

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

10.1.5 A complete description of the phantom used in testing, including a photograph or diagram of the phantom, dimensions and weight of the phantom, filling material of the phantom and container, and a description of implant holder(s). If the PAA gelled saline described in 8.3 is not used, include results of measurements of the physical parameters specified in 8.1 and provide a rationale for using an alternative test medium.

10.1.6 A complete description of the temperature probes used in testing, including manufacturer, model number, and relevant technical information. A photograph or diagram showing placement of the implant and temperature probes and

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