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

1. Scope

1.1 This test method covers measurement of Radio Frequency (RF) induced heating 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 person with the implant during an MRI procedure. Other safety issues that should be addressed include magnetically induced displacement force and torque.

1.3 The amount of RF-induced temperature rise for a given specific absorption rate (SAR) will depend on the RF frequency, which is proportional to the static magnetic field strength. Because of possible additional heating, particularly when device dimensions exceed a quarter wavelength, conclusions from measurements made at one frequency may not apply to other frequencies.

1.4 This test method assumes that testing is done on devices that will be entirely inside the body.

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 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 *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:*
A 340 Terminology of Symbols and Definitions Relating to Magnetic Testing[2]
F 2052 Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment[3]
F 2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants[3]
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, 2001

3. Terminology

3.1 *Definitions*—For the purposes of this test method, the definitions in 3.1.1-3.1.8 shall apply.

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

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

3.1.3 *medical implant*—a structure or device that is placed within the body of the patient for medical diagnostic or therapeutic purposes.

3.1.4 *MR safe*—the device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

3.1.5 *MR compatible*—the device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device which is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

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

3.1.7 *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.

3.1.8 *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 phantom material will include saline solution and a gelling agent. Fiber optic temperature probes are placed at locations where the induced heating is expected to be greatest. The phantom is placed in an MR system with a cylindrical bore or an apparatus that reproduces the RF field of this type of system. An RF field with SAR of at least 1 W/kg averaged over the volume of the phantom is applied. The temperature rise at the sensors is measured during the approximately 15 min of RF application, or other appropriate period, depending on the mass and thermal conductivity of critical parts of the device. Temperature measurements at one or more locations away from the device serve as the control.

5. Significance and Use

5.1 This test method describes a test procedure for evaluating the RF-induced temperature rise in MRI in the vicinity of an implanted medical device. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. The conditions and results of the testing should be included in the device labeling so that the attending physician can make the decision of whether to allow the patient with the implant to undergo an MRI procedure.

6. Apparatus

6.1 *Test Apparatus*—The test apparatus consists of a suitable phantom and an MR imager for production of the RF field. The phantom, implant and MR imager are to simulate the electrical and physical environment that the patient and device experience during an MRI procedure.

6.2 *Temperature Sensor*—A suitable temperature measuring device, usually a fiber optic probe, is used to measure temperature versus time of RF exposure in the vicinity of the implant. The temperature sensor will have a resolution of 0.1°C and a sensitive volume not to exceed 1 mm in radius. Fluoroptic temperature probes have been found to be satisfactory for this purpose.[5]

7. Test Specimens

7.1 For purposes of device qualification, the implant or device evaluated according to this test method shall be representative of a finished sterilized device. For the purposes of device qualification, the device evaluated according to this test method should be a finished sterilized device.

NOTE 1—The device does not have to be sterile at the time of testing. However, it should have been subjected to all processing, packaging, and sterilization steps before testing because any of these steps may affect the magnetic properties of the device.

7.2 For purposes of device qualification, implant devices shall not be altered in any manner prior to testing.

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

8. Procedure

8.1 *Phantom Morphology*—Use a phantom geometry that reflects how the implant is placed in the body. The phantom container needs to be large enough to allow the device to be placed in a position representative of where it would be in the body. The container and all its parts should be made of material that is an electrical insulator and is non-magnetic. A whole body phantom should simulate the RF loading that would occur with a patient. The phantom should have the general shape of a patient (Fig. 1) but a rectangular phantom (Fig. 2) is also acceptable.[6] For application of RF by the body coil, the phantom should contain at least 30 kg of phantom material. For an implant inserted entirely in the head, a spherical phantom with dimensions similar to those of the human head may be appropriate. Generally, a homogeneous phantom will suffice, but in certain cases it may be appropriate to incorporate materials of different conductivity within the phantom.

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

8.2.1 *Conductivity*—Conductivity shall be 0.4 to 0.8 S/m at 64 MHz, depending on the tissue to be modeled. (See Stuchly et al. (**1**)[7] for data on tissue electrical properties and Athey et al. (**2**) for procedures for measurement of electrical properties.) Electrical conductivity at low frequency will be less than at 64 MHz. The phantom conductivity should be 0.2 to 0.4 S/m for measurements made at a frequency of 1 kHz. (Stuchly and Stuchly (**3**)).

8.2.2 *Dielectric Constant*—Dielectric constant shall be 60 to 100 at 64 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} m²/s and heat capacity close to that of water, 4184 J/kg °C.

8.2.4 *Viscosity*—The viscosity shall be sufficient 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 phantom (Rezai (**4**)) can be made with 0.8 g/L NaCl and 5.85 g/L Polyacrylic acid[8] into distilled water. This formulation has a room temperature conductivity of about 0.25 S/m and a viscosity sufficient to prevent convective heat transport. A number of other phantom formulations may be appropriate and some are described in the rationale.

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[5] Particularly suitable are the Luxtron (Luxtron Corporation, Santa Clara, CA, USA) Models 790, 3000, and 3100 Fluoroptic Thermometer Systems and the 0.6 mm diameter SFF-10 probe.

[6] The phantom in Fig. 2 may be purchased from Fab Lab Inc., Suite 1501325 Armstrong Rd., Northfield, MN 55057, tel. +1-507-645-2815, cbenson@fablab.net.

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

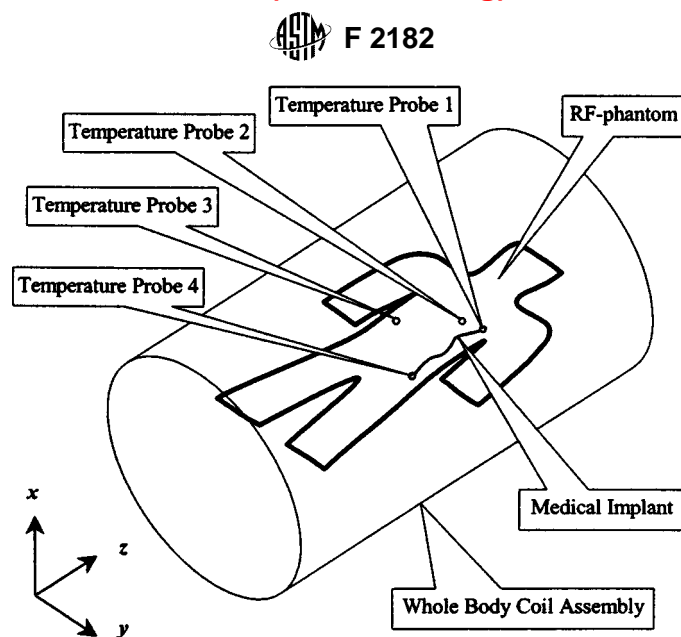[8] Catalog 43,636-4, Aldrich Chemical Company, Inc., Milwaukee, WI, USA.

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FIG. 1 Diagram of Apparatus for Testing of RF Heating Near an Implant During MR Imaging

8.4 *Device Placement*—A representative experimental apparatus is depicted in Fig. 1. First, stir the phantom material to homogenize it. Place the device in the phantom in the location where it would be in a patient. If the device has long conducting wires, give consideration to possible resonant effects. Arrange wires in the worst case situation that would be experienced clinically. For example, long wires should be placed near the edge of the phantom in order to maximize reception of the induced electric field. Coil the leads according to the usual clinical technique. More than one run may need to be done to cover the clinically relevant situations. Cover the phantom with a cover or plastic sheet after the device is in place in order to minimize effects of air flow on the temperature measurements.

8.5 *Temperature Probe Placement*—Place at least three temperature probes on and near device parts that are expected to generate the greatest heating. Some experimentation may be required to determine the best probe placement. For example, for an elongated implant the greatest heating will likely occur near the end. One probe could be at the end (probe 1 in Fig. 1), another (probe 2) 5 mm from the end, a third at the other end of the implant (probe 4). Be sure there are no air bubbles at the probe tips. To provide confirmation of the whole body averaged SAR, place a probe (probe 3) at the side of the phantom where the heating is expected to be greatest.

8.6 *RF Field Application*—Use an imaging protocol producing an intensive RF field. The whole-body averaged SAR should be at least 1 W/kg for a 50 kg patient and 2 W/kg is desirable. A sample protocol for a 1.5 T (64 MHz) scanner is provided in Table 1. Note that the key parameter for a high SAR is to maximize the number of 180° RF pulses per second. The protocol in Table 1 generates 48 180° pulses per second and a whole body averaged SAR of 1.14 W/kg for a 50-kg patient. Use a protocol duration of at least 15 min in order to achieve adequate signal to noise in evaluation of the rate of temperature rise.

8.7 *RF Field Monitoring*—Record the applied whole body averaged SAR reported by the MR system software. Check that the temperature rise at the reference location is consistent with the reported SAR. Record the flip angle and bandwidth of the RF pulses, as well as the number of RF pulses applied per unit time. If the scanner software provides it, record the RMS average applied B_1 field and the total average power deposited in the patient.

8.8 *Thermal Equilibrium of Phantom with Surroundings*—Monitor temperature in the phantom for at least 10 min prior to the application of the RF. There must be sufficient thermal equilibrium between the phantom and surroundings that the temperature of the phantom does not change by more than 0.2°C during the observation time. The temperature within the scan room should be 23 ± 3°C and should be stable to ±1°C per h.

8.9 *Recording of Temperature versus Time*—Record the temperature at least 5 times per min. Begin recording at least 2 min prior to the start of the scan. This will allow evaluation of whether or not the temperature reaches steady state during the scan. After the RF is turned off, monitor and record the temperature for at least 2 additional min. The fan inside the bore is to be turned off while performing the temperature measurements.

8.10 *Control Measurements (optional)*—Take the implant out, and with temperature probes in the same locations as for the test, repeat the temperature measurements to determine the background temperature rise.

9. Report

9.1 *Report Contents*—Include the following in the report for each specimen tested:

9.1.1 Device product description.

9.1.2 Device product number.

9.1.3 Materials of construction. (ASTM designation or other.)

9.1.4 Photograph or drawing of device geometry showing key morphological features and dimensions.

9.1.5 Photograph or diagram of phantom, which includes the dimensions of the phantom.

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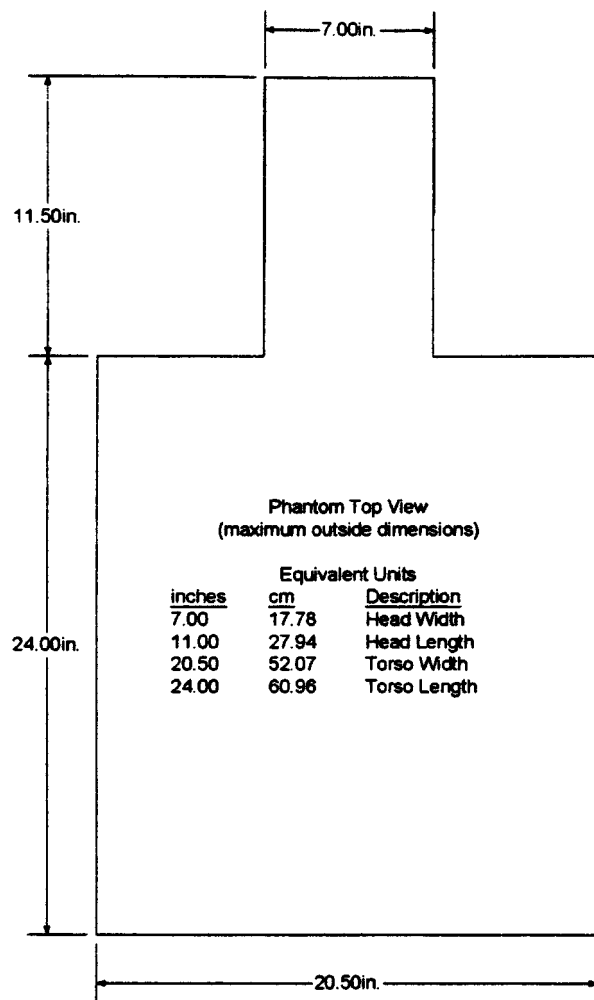
NOTE—The depth is 26.5 cm and 30 L of phantom material fills the phantom to a depth of 9 cm.

FIG. 2 Sample Rectangular Phantom to Model the Human Trunk and Head for Use in a Cylindrical Bore Imager

TABLE 1 Sample RF-Intensive Imaging Protocol

Scan Type	Spin Echo, Axial
Slice Thickness	10 mm
RF Coil Type	Body or Head Coil
Number of Echos	4
TE	15 ms
TR	83.3 ms
NEX	112
# ACQ (slices)	1
Field of View FOV	large
Scan time	19:58
Bandwidth	1250 Hz

TABLE 2 Formulations (Percentages by Weight) and Properties of RF Phantom Materials (Chou et al. (5))

	Brain	Muscle
Water	93 %	91.48 %
TX-150 Gelling Agent (Oil Center Research, Lafayette, LA, USA)	7 %	8.4 %
NaCl	0	0.12 %
Conductivity (S/m)	0.52	0.8
Relative Dielectric Constant	78.1	79.8

9.1.6 Photograph or diagram showing placement of device and temperature probes and location of phantom in the imager with respect to isocenter. Document the distance from the probe tips to the device.

9.1.7 Manufacturer, model number, software version, type of RF coil, and the static magnetic field strength of the MR system.

9.1.8 Manufacturer, model number and technical information on temperature probes, phantom material and other elements of the experimental apparatus. If the phantom material described in 8.3 is not used, include results of measurements of

the physical parameters specified in 8.2.

9.1.9 Description of RF protocol used and the whole body averaged SAR. The SAR may be the value reported by the scanner software. Report the flip angle and bandwidth of the RF pulses, as well as the number of RF pulses applied per unit time. If available, report the RMS B_1 field in units of Gauss and the average power deposition in the patient in watts. Report the entered patient weight for the tests and the RF output power, which may be expressed in terms of transmit gain on some scanners.

9.1.10 Graphs or tables of temperature versus time for (*1*) the test case with the device in the phantom and, if available,

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(2) the control case with no device. Include temperature measurements before, during and after application of the RF magnetic field.

9.1.11 Report the maximal temperature rise extrapolated to a whole body SAR of 2 W/kg. For example, if the applied SAR is 1.5 W/kg results in a temperature rise of 3°C, the temperature rise extrapolated to 2 W/kg is 4°C.

9.1.12 A theoretical or empirical rationale justifying the placement of the probes.

9.1.13 A record of the temperature in the phantom for at least 5 min prior to application of RF, recorded at 1 min intervals.

9.1.14 A record of the temperature in the scan room for at least 15 min prior to application of RF and throughout the test, recorded at 5 min intervals.

10. Precision and Bias

10.1 The precision and bias of this method has not been established.

11. Keywords

11.1 implant; MRI (magnetic resonance imaging); MR safety; RF (Radio Frequency) heating

APPENDIX

(Nonmandatory Information)

X1. RATIONALE FOR DEVELOPMENT OF THE TEST METHOD

X1.1 Overview and General Information

X1.1.1 This document specifies a test method to predict the RF-induced temperature rise that would be produced in the vicinity of a medical implant in a patient undergoing an MRI procedure. Hazards other than RF-induced heating need to be considered to determine whether a patient with an implant can safely undergo an MRI procedure. In particular, magnetically induced displacement force and torque must be evaluated before an implant can be determined to be MR safe. Test Method F 2052 provides a test method for determining magnetically induced displacement force. Additional issues, such as the determination of image artifact (See Test Method F 2119) must be considered to determine whether an implant is MR compatible.

X1.1.2 It can be shown that for a given pulse shape and flip angle, the deposited energy is proportional to the square of the magnetic field strength. Consequently, field strength has a dramatic effect on RF heating. Recently, MR systems have been introduced into clinical use with field strengths as high as 8 T. Such an MR system may be expected to deposit much higher levels of RF energy compared to a 1.5 T system for a similar pulse sequence. Medical practitioners should be advised in the product labeling of the consequences of exposing the patient with an implant to MR systems operating with static magnetic field strengths higher than 1.5 T.

X1.1.3 Physics and safety issues associated with RF power deposition in MRI have have described by Schaefer (**6**). Very briefly, the time varying RF field induces currents in the body by Faraday's law of induction. The intensity of the induced RF currents tends to be greatest near the surface of the body.

X1.1.4 The mechanism for additional RF heating can be understood as follows (Smith (**7**)). An electrically conductive, elongated implant will concentrate the RF currents induced in the body, resulting in an increased current density and increased SAR in the vicinity of the implant. For an elongated implant, the greatest heating will occur near the ends. Also, there are geometric functions to consider given the reduced

wavelength with increasing field strength (dielectric resonance).

X1.1.5 Neglecting the conductivity, wavelength λ_m in a material is given by:

$$\lambda_m = \frac{\lambda_0}{\sqrt{\epsilon_{rel}}}$$

where:
$\lambda_0 = c/f$ = wavelength in air,
c = 3×10^8 m/s,
f = radian frequency, and
ϵ_{rel} = relative dielectric constant.

For example, at a frequency of 64 MHz and $\epsilon_{rel} = 81$ (a representative value for tissue), $\lambda_0 = 4.7$ m and $\lambda_m = 0.52$ m. Including the effects of conductivity would decrease the wavelength.

X1.1.6 When implant dimensions approximate one-half of a wavelength, antenna resonance effects may result in very large temperature rise. (Konings et al. (**8**)).

X1.1.7 SAR values reported by the MR system software may be conservative and thus the standard calls for monitoring the temperature rise at a reference location near the periphery of the phantom, where the background SAR is expected to be about 2.5 times the average.

X1.1.8 For a given configuration, the SAR is expected to be predicted by knowledge of the pulse sequence. Thus the standard calls for a detailed recording of the type of RF pulses that are applied. The power deposition is expected to be proportional to bandwidth and to the square of the flip angle.

X1.2 Section 5—Significance and Use

X1.2.1 The international safety standard for MR systems, IEC 60601-2-33, currently limits whole body average SAR to 2 W/kg for a 6-min exposure. The whole body SAR is defined as the total power deposition in the patient divided by the mass. The partial body SAR is the power deposition divided by exposed patient within the effective volume of the RF transmit coil. This effective volume of the RF transmit coil is that volume in which no more than 95 % of the total absorbed RF

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power is deposited inside a homogeneous material which fills the volume normally accessible by the patient. The partial body SAR limit ranges from 2 to 10 W/kg, depending on how much of the patient is exposed to the RF field.

X1.2.2 The rate of temperature rise in the absence of thermal diffusion is related to the SAR by the equation:

$$\frac{dT}{dt} = \frac{SAR}{C}$$

where:
C = heat capacity in J/(kg-°C).

For water, $C = 4180$ J/(kg-°C); therefore, an SAR of 1 W/kg results in a temperature rise of 0.86°C in 1 h.

X1.2.3 Blood perfusion will generally result in a temperature rise near the implant less than what is obtained in the phantom measurement. Thus the measurement of the rate of temperature rise in the phantom is likely to overestimate the actual temperature rise.

X1.2.4 The temperature rise will depend on a variety of factors beyond the SAR and time of RF application. Given the complexity of the measurements and their interpretation, the maximum measured temperature rise and the test conditions should be stated in the product labeling. The medical practitioner can then use the information from the test to better assess the potential risks.

X1.2.5 There are a number of literature reports in which guidewires and other elongated implants exhibit significant RF-induced heating near the ends. Metallic structures less than 2 cm in dimension are not expected to exhibit clinically significant RF-induced temperature rise. Electrically insulating materials are also not expected to exhibit significant temperature rise.

X1.3 Section 8.1—Phantom Morphology

X1.3.1 It is desirable that the phantom material and phantom container have the following characteristics:

X1.3.1.1 Appropriately model the electrical characteristics of the human body.

X1.3.1.2 Appropriately model the thermal characteristics of the human body.

X1.3.1.3 Appropriately model the geometrical characteristics the human body, especially the characteristics of the region where the implant is placed.

X1.3.2 Ideally the phantom should model the size and shape of the entire body and contain materials that simulate the electrical properties of the different tissues of the body. The different electrical properties of human tissue result in a complicated current flow pattern that may not be adequately reproduced in a phantom containing just one type of conducting material. A reduced sized phantom may not exhibit whole body spatial resonances that might occur in a patient. These issues may be particularly relevant for static field strength in excess of 1.5 T. However, a simplified phantom is less costly and easier to construct, and in many cases will provide adequate prediction of the potential for RF heating near the implant.

X1.3.3 The tissue is primarily resistive at 64 MHz, so the exact value of dielectric constant is not crucial. The required thermal properties will be met if the phantom is primarily made from aqueous solution.

X1.4 Section 8.2—Phantom Material

X1.4.1 A gelled or semi-solid phantom is specified to prevent measurement of unrepresentatively low temperature rises due to convective flow of heat. Smith (**9**) found that the temperature rise near a heat source is significantly less in ungelled saline than in gelled saline. (Upon heating, the density of the saline solution changes, resulting in fluid transport.) If the phantom material is not gelled, the measured temperature rise may underestimate that which would occur in-vivo.

X1.4.2 In addition to the formulation described in 8.3, additional phantom formulations may be appropriate. Formulations developed by Chou et al. (**5**) and summarized in Table 1 have been found suitable for RF MRI testing at 64 MHz.

X1.4.3 Hydroxyethylcellulose (HEC; BP Chemicals) in a 3 % by weight concentration increases the viscosity of saline solution, but the enhancement does not appear to be as effective as can be achieved with Polyacrylic acid. (Smith (**9**))

X1.5 Section 8.4—Device Placement

X1.5.1 For a typical MR system with the static magnetic field along the axis of the bore, the RF magnetic field is circularly polarized and perpendicular to the axis of the bore. To a reasonable approximation, Faraday's law of induction can be used to estimate the eddy current loops that will be formed. An important feature is that the induced eddy currents will be greatest near the surface of the body

X1.6 Section 8.5—Temperature Probe Placement

X1.6.1 Heating is expected to be mainly due to concentration of eddy currents in the phantom material by geometrical features of the implant. For elongated wires the heating is very localized. In addition to placement of a probe at the site of greatest heating, placement of a probe 5 mm from that site can be used to estimate the power of the heat source. (Smith (**9**)) Possible failed conditions of the device should be considered. For example, Chou et al. (**10**) reported considerable heating near the broken lead wire of a spinal fusion stimulator.

X1.7 Section 8.9—Recording of Temperature versus Time

X1.7.1 The rate at which temperature returns to equilibrium can be used to estimate the localization of the heating (Smith (**9**)). Therefore, the standard calls for recording temperature at least 5 times per minute and for two minutes after cessation of the RF field.

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