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Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants[1]

This standard is issued under the fixed designation F2119; 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 characterizes the distortion and signal loss artifacts produced in a magnetic resonance (MR) image by a passive implant (implant that functions without the supply of electrical or external power). Anything not established to be MR-Safe or MR-Conditional is excluded.

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

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

F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

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

3. Terminology

3.1 *Definitions:*

3.1.1 *artifact width, n*—the maximum distance (mm) from the edge of the implant to the fringe of the resulting image artifact found in the entire set of images acquired using this test method.

3.1.2 *image artifact, n*—a pixel in an image is considered to be part of an image artifact if the intensity is changed by at least 30 % when the device is present compared to a reference image in which the device is absent.

3.1.3 *magnetic resonance (MR) environment, n*—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.

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

3.1.5 *MR-Conditional, adj*—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.

3.1.6 *MR-Safe, adj*—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.

3.1.7 *MR-Unsafe, adj*—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.

3.1.8 *tesla (T), n*—the SI unit of magnetic induction equal to 10^4 G.

4. Summary of Test Method

4.1 Pairs of spin echo images are generated both with and without the implant in the field of view. Image artifacts are assessed by computing differences outside the region corresponding to the implant between reference and implant images. Once the worst case conditions using the spin echo pulse sequence are ascertained, a pair of gradient echo images are acquired under the same conditions.

5. Significance and Use

5.1 This test method provides a quantified measure of the image artifact produced under a standard set of scanning conditions.

[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.

5.2 This test method applies only to passive implants that have been established to be MR-Safe or MR-Conditional.

6. Apparatus

6.1 An MR imaging system with a static field strength of 1.5 T or 3.0 T is recommended. The MRI system must have the ability to swap readout and phase-encode directions.

6.2 A reference object made from a nondistorting medium, such as 0.5-in. diameter nylon rod.

7. Test Specimen

7.1 The implant for which image artifact is to be measured shall serve as the test specimen.

7.2 For the purposes of device qualification, the device evaluated according to this test method should be a finished sterilized device.

NOTE 3—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.

7.3 This test method may be used on prototype devices at any stage of production during product development. A justification for using a prototype instead of the finished device must be provided.

8. Procedure

8.1 *MR Imaging Parameters for Testing Artifacts:*

8.1.1 The recommended MR imaging test environment for evaluation of artifacts are given as follows. An alternative may be used if an adequate case can be made for relevance to the specific device. Field of view, slice thickness, and matrix size shall be adjusted to achieve pixel dimensions to accurately measure the artifact. Two example situations are described, one for small implants, such as a coronary stent, and one for larger implants such as an artificial hip joint.

Static field strength:	1.5T (see 6.1)
Bandwidth:	32 kHz (required)
Field of view:	sufficient to encompass the entire implant and the artifact
Small implant (for example, coronary stent):	
Matrix size:	256 × 256
Slice thickness:	3 mm
Large implant (for example, hip implant):	
Matrix size:	256 × 128
Slice thickness:	5 mm
Two different pulse sequences will be used:	
Pulse sequence:	spin echo
TR:	500 ms
TE:	20 ms
Pulse sequence:	gradient echo
TR:	100 – 500 ms
TE:	15 ms
Flip angle:	30°

8.1.2 The device should be immersed in a solution. For example, a copper sulfate ($CuSO_4$) solution (1–2 g/L) may be used to reduce T_1 and keep TR at a reasonable level. The device may be suspended in nylon netting. If a copper sulfate solution is inappropriate for a particular device, a substitute may be used but a justification must be provided. Nickel chloride ($NiCl_2$) and manganese chloride ($MnCl_2$) are possible substitutes. To achieve adequate field homogeneity, there should be at least 4 cm of clearance between the device and each side of the container holding the solution and the implant.

8.1.3 Each image must contain a reference object, (made of nylon or some other material, which does not cause distortion), so that the position of the device may be accurately assessed. For example, a section of 0.5-in. diameter nylon rod positioned so that it appears as a circle in the image could serve as the reference object. Each image must also contain a physical size scale, generally displayed on MR images, so that distances may be measured.

8.2 *Set of Images To Be Acquired:*

8.2.1 A complete set of spin echo image pairs, as described in 8.2.2-8.2.4, shall be acquired.

8.2.2 An individual test image pair shall consist of an image of the reference object only, and an image containing both the reference object and the device being tested. The device must be tested in three mutually orthogonal orientations relative to the static field. Orientations for which the implant will not fit in the bore may be omitted. Cylindrically symmetric devices may be tested parallel to the static field and in just one direction perpendicular to the static field. Sagittal, relative to static field direction, images should be acquired in all cases.

8.2.3 For images containing both the device being tested and the reference object, for each orientation two sets of images must be acquired using both possibilities for designation of readout and phase-encode directions. For images containing the reference object only, one image is acquired using either possibility for designation of readout and phase-encode direction. The reference object is oriented along the right-left axis so that it extends beyond the length of the device being tested so that the reference object will appear in each image containing the tested device.

8.2.4 For each image pair and each orientation and each readout/phase-encode direction designation, a sufficient number of contiguous slices to span the entire device must be acquired. So, for example, a device that is completely contained within one slice will require three orientations times two readout/phase-encode designations = six images containing the device being tested + three images containing the reference object only.

8.2.5 For the worst case (largest artifact size) set of conditions (orientation, readout/phase-encode designation, and slice number) from the set of spin echo images, an image pair (see 8.2.2) using the gradient echo pulse sequence must be acquired. It is probably most time efficient to acquire these images while the object is in position for acquiring the spin echo images.

8.3 *Measurement of Artifact Size:*

8.3.1 The distance (in mm) from the device boundary to the fringe of the artifact (±30 % zone, see 3.1.2) should be measured. To compute the distance in mm, take the distance in pixels and multiply by the ratio of the field of view (FOV) expressed in mm to the matrix dimension (m) also measured in mm. Distance (mm) = Distance (pixels) × FOV/m. This distance may be evaluated quantitatively at the system console

using software, commonly included with MRI scanners, to plot intensity profiles. Alternatively, if necessary, the distance may be evaluated visually at the console or on film but in this case a conservative definition of the artifact fringe location should be adopted to ensure that artifact size is not underestimated. For each image, the artifact must be characterized by the worst case (maximum) distance as the boundary of the device is completely circumscribed. The worst case (maximum) distance found in the entire set of images acquired (as prescribed above) must be used to characterize the artifact.

8.3.2 Difficulty may arise if the MRI image consists of a void corresponding to the implant surrounded by a void corresponding to the artifact. The boundary of the implant may not be visible. In this case, the border of the implant, measured without MRI, for example, using a ruler or calipers, may be superimposed in the center of the void so that distances from implant boundary to the artifact fringe can be measured. The superimposed implant border should be scaled to match the MRI image distance scale.

9. Report

9.1 The report shall include the following for each specimen tested:

9.1.1 Device product description.

9.1.2 Device product number and lot number.

9.1.3 Device size (physical dimensions).

9.1.4 The gradient echo image pair and a representative set of spin echo images, including those that exhibit the worst artifacts.

9.1.5 MRI system make, model, and static field strength.

9.1.6 MRI parameters including TR, TE, bandwidth, receiver, field of view, matrix size, and coil used.

9.1.7 The method used for measuring artifact.

9.1.8 Spin echo artifact width and gradient echo artifact width, (see 3.1.1).

9.1.9 Solution (and solution concentration) used to immerse the device. If a $CuSO_4$ solution is not used, include a justification for the solution used.

10. Precision and Bias

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

11. Keywords

11.1 image artifact; implant; metals for surgical implants; MRI (magnetic resonance imaging); MR compatibility; MR safety

APPENDIX

(Nonmandatory Information)

X1. RATIONALE FOR DEVELOPMENT OF THE TEST METHOD

X1.1 This test method characterizes the artifact produced by a passive implant, which has been determined to be MR-Safe or MR-Conditional. Test Methods F2052 and F2213 can be used to determine magnetically induced displacement force and torque, respectively, on a medical device in the MR environment, and Test Method F2182 can be used to measure radio frequency induced heating during MRI. Although a commercial 1.5 T MR system currently produces the conditions that are most commonly encountered, 3 T MR systems have been cleared for market and are becoming more common in clinical situations.

X1.2 The size of an artifact induced by a passive implant in a given MR environment has a complex relationship to implant size, shape, and composition. Acceptability of an artifact will depend on implant type and location in addition to which part of the body is being imaged. The protocol described in this test method provides an objective basis for quantifying the extent of an artifact associated with an implant. This information may be used to compare potential artifact sizes for many implants and may be useful for health care professionals in selecting implants for various applications.

X1.3 For most applications, image artifacts are smaller for fast spin echo pulse sequences than conventional spin echo and gradient echo pulse sequences; however, the combined use of spin echo and gradient echo pulse sequences in the test method provides a valid method for ranking implants with regard to tendency to produce artifacts under controlled conditions.

X1.4 This test method was revised in 2007 to reference the MR safety terminology in Practice F2503 and the MR Test Methods F2182, F2213, and F2052. The historical definitions for MR safe and MR compatible were removed and the definitions of MR-Safe, MR-Conditional, and MR-Unsafe were inserted. The definition for MR environment was revised to be in agreement with the definitions in Practice F2503.

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