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

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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.

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.

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

[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.

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