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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 is excluded.

2. Terminology

2.1 Definitions

2.1.1 *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.

2.1.2 *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.

2.1.3 *magnetic resonance (MR) environment*, *n*—refers to the electromagnetic environment present in the vicinity of an MR system within the 5-G line.

2.1.4 *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.

2.1.5 *MR-safe*, *adj*—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 term MR safe since a device which is safe under one set of conditions may not be found to be so under more extreme MR conditions.

2.1.6 *MR-compatible*, *adj*—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 term MR-compatible since a device which is compatible under one set of conditions may not be found to be so under more extreme MR conditions.

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

3. Summary of Test Method

3.1 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.

4. Significance and Use

4.1 This test method may be used to evaluate degree of MR compatibility for passive implants by providing a quantified measure of the image artifact produced under a standard set of scanning conditions.

4.2 This test method applies only to passive implants that have been established to be MR-safe.

5. Apparatus

5.1 An MR imaging system with a static field strength of 1.5 T is recommended. Alternatively, a different static field strength may be used and the measurements may be extrapolated to what would occur in a 1.5 T system, if a valid extrapolation method is known. The MRI system must have the ability to swap readout and phase-encode directions.

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

6. Test Specimen

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

6.2 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.

6.3 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.

[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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