



# Guide to Optimize Scan Sequences for Clinical Diagnostic Evaluation of Metal-on-Metal Hip Arthroplasty Devices using Magnetic Resonance Imaging<sup>1</sup>

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## 1. Scope

1.1 This guide describes the recommended protocol for magnetic resonance imaging (MRI) studies of patients implanted with metal-on-metal (MOM) devices to determine if the periprosthetic tissues are likely to be associated with an adverse local tissue reaction (ALTR). Before scanning a patient with a specific implant, the MR practitioner shall confirm that the device is MR Conditional and that the scan protocol to be used satisfies the conditions for safe scanning for the specific implant. This guide assumes that the MRI protocol will be applied to MOM devices while they are implanted inside the body. It is also expected that standardized MRI safety measures will be followed during the performance of this scan protocol.

1.2 This guide covers the clinical evaluation of the tissues surrounding MOM hip replacement devices in patients using MRI. This guide is applicable to both total and resurfacing MOM hip systems.

1.3 The protocol contained in this guide applies to whole body magnetic resonance equipment, as defined in section 2.2.103 of IEC 60601-2-33, Ed. 3.0, with a whole body radiofrequency (RF) transmit coil as defined in section 2.2.100. The RF coil should have quadrature excitation.

1.4 The values stated in SI units are to be regarded as standard.

1.5 *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. The user may consider all precautions and warnings provided in the MR system and hip implant labeling prior to determining the applicability of these protocols.*

## 2. Referenced Documents

2.1 *ASTM Standards*:<sup>2</sup>

A340 [Terminology of Symbols and Definitions Relating to Magnetic Testing](#)

F2503 [Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment](#)

2.2 *IEC Standard*:<sup>3</sup>

IEC 60601-2-33, Ed. 3.0 [Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis, 2010](#)

## 3. Terminology

3.1 *Definitions*—For the purposes of this standard the following definitions shall apply:

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

3.1.2 *MR - Conditional*—an item that has been demonstrated to pose no known hazards in a specific 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), radiofrequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required (Practice F2503).

3.1.3 *Metal-on-Metal (MOM) hip replacement*—a hip arthroplasty device in which the articulating surfaces of the femoral head and the acetabular cup are fabricated from metal.

## 4. Summary of Protocol

4.1 Surface coil fast spin echo (FSE) sequences of the affected hip in three planes and a larger field-of-view (FOV) short tau inversion recovery (STIR) sequence to include both

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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

<sup>3</sup> Available from International Electrotechnical Commission (IEC), 3, rue de Varembe, P.O. Box 131, CH-1211 Geneva 20, Switzerland, <http://www.iec.ch>.