Boston Scientific

MRI TECHNICAL GUIDE

⚠MR IMAGEREADY™ MR Conditional ICM System

REF M301 M302 M312

ABOUT THIS MANUAL

This manual is intended for use by physicians and other health care professionals (HCPs) involved in managing patients with an Insertable Cardiac Monitor (ICM) ("the device"), and radiologists and other HCPs involved in performing magnetic resonance imaging (MRI) scans on such patients.

NOTE: *For the purposes of this Technical Guide, MRI is used as a general term and encompasses all MR-based clinical imaging activities.*

Read this manual in its entirety before scanning patients who are implanted with the device.

This manual contains instructions for carrying out an MRI scan on patients implanted with the device.

Refer to the patient's records to locate model numbers for all components of the patient's implanted system.

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INTRODUCTION

CHAPTER 1

This chapter contains the following topics:

SYSTEM DESCRIPTION

The ICM device is an MR Conditional device and is designed to allow patients to be safely scanned by a magnetic resonance imaging (MRI) machine. Testing has demonstrated that the device is safe for use in the MRI environment when used according to the MRI conditions for use. It is important that the radiology staff involved in the procedure read and understand the instructions in this manual before performing an MRI scan. For non-MRI related instructions, refer to the clinician's User Manual for the device.

For additional information, see the Boston Scientific Website at *http://www.bostonscientific.com/imageready*.

For additional reference information, go to *www.IFU-BSCI.com*.

MRI CONDITIONS OF USE

The following Conditions of Use must be met in order for a patient with a LUX-Dx, LUX-Dx II, or LUX-Dx II+ device to undergo an MRI scan. Adherence to the Conditions of Use must be verified prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MR Conditional scan.

MRI Conditional Models

Patient has a LUX-Dx, LUX-Dx II, or LUX-Dx II+ ICM model number M301, M302, or M312 inserted.

WARNING: Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it.

MRI Scanning System

A patient with a device can be safely scanned in an MR system that meets the following conditions:

1. Horizontal, ^{1}H proton, closed bore scanners only
2. MRI magnet strength of 1.5 T (approximately 64 MHz) or 3 T (approximately 128 MHz)
3. Spatial gradient no greater than 30 T/m (3,000 G/cm)
4. Specific Absorption Rate (SAR) limits:

   SAR limits up to First Level Controlled Operating Mode[1] may be applied for the entire active scan session as follows:

   - Whole body averaged, ≤ 4.0 W/kg
   - Head, ≤ 3.2 W/kg
5. Gradient Field limits: Maximum specified gradient slew rate ≤ 200 T/m/s per axis
6. There are no restrictions for positioning the device within the integrated body coil of the MRI scanner. The use of receive-only coils is not restricted. Local transmit-only coils or local transmit/receive coils may be used, but should not be placed directly over the device.
7. Patient in supine or prone position only

The system response to conditions other than those listed above for the radiology conditions has not been evaluated.

1. As defined in IEC 60601-2-33, 201.3.224, 3rd Edition.

WARNINGS

General

- **MR conditional requirements.** Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result.

- **Scanning with other devices.** Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it.

MRI Site Zone III Exclusion

- **Mobile devices and magnet are MR Unsafe.** The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[2]. Under no circumstances should the mobile device or magnet be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

PRECAUTIONS

- **False event detection.** The sensing circuitry of the device may detect electromagnetic signals during an MRI, which may cause inappropriate sensing and recording of inappropriate data.

- **MRI artifacts.** The presence of the device may cause MRI image artifacts and distortion. Image artifacts and distortion may extend beyond the boundaries of the device and must be considered when planning an MRI scan as well as in interpreting MRI images in proximity to the device. In non-clinical 1.5 T and 3 T testing, the maximum image artifact associated with the device extended approximately 4.5 cm radially from the device when testing with spin-echo sequencing in a 3 T MRI system.

  NOTE: *All normal risks associated with an MRI procedure apply to MRI scans with the ImageReady MR Conditional ICM System. Consult MRI scanner documentation for a complete list of risks associated with MRI scanning.*

POTENTIAL ADVERSE EVENTS

Potential adverse events differ depending on whether the MRI Conditions of Use are met ("MRI Conditions of Use" on page 1-2). For a complete list of potential adverse events, refer to the clinician User's Manual.

MRI scanning of patients when the Conditions of Use are met could result in the following potential adverse events:

- Patient discomfort due to slight movement or heating of the device

MRI scanning of patients when the Conditions of Use are **NOT** met could result in the following potential adverse events:

- Damage to the device

- Patient discomfort due to slight movement or heating of the device

Before proceeding with an MRI scan, verify that the patient and the MRI scanner meet the MRI Conditions of Use ("MRI Conditions of Use" on page 1-2). This verification must be performed prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MR Conditional scan.

2. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007.

PATIENT FLOW

CHAPTER 2

This chapter contains the following topics:

PATIENT FLOW

A sample patient flow sequence for a patient inserted with a device who needs an MRI scan is described below.

1. MRI recommended to patient by a physician.

2. Patient or physician or radiologist contacts the health care provider who manages the patient's MR Conditional device.

3. Radiology determines patient eligibility for scan per the information in this Technical Guide.

4. The model name, mode number, and serial number of the device is identified, and this information is communicated to the HCPs involved in performing the MRI scan. The physician should ensure the patient has no other devices that are known to pose a hazard in an MR environment.

   WARNING: Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it.

5. The radiology staff confirms the MRI equipment meets all requirements specified in Radiology Conditions of Use. If the radiology staff has questions about whether the patient should receive an MRI scan, the staff should contact the patient's cardiologist. The cardiologist may need to contact Boston Scientific for guidance

6. The patient undergoes scan according to the conditions of use described in this Technical Guide.

   CAUTION: The sensing circuitry of the device may detect electromagnetic signals during an MRI, which may cause inappropriate sensing and recording of inappropriate data.

RADIOLOGY CHECKLIST FOR SCANNING

APPENDIX A

This appendix is provided for convenience. Refer to the remainder of this Technical Guide for the full list of Warnings and Precautions and complete instructions for using the device.

Conditions of Use – Radiology

The following Conditions of Use must be met in order for a patient with a device to undergo an MRI scan.

☐ Horizontal, ^{1}H proton, closed bore scanners only

☐ MRI magnet strength of 1.5 T (approximately 64 MHz) or 3 T (approximately 128 MHz)

☐ Spatial gradient no greater than 30 T/m (3,000 G/cm)

☐ Specific Absorption Rate (SAR) limits:

SAR limits up to First Level Controlled Operating Mode[1] may be applied for the entire active scan session as follows:

- Whole body averaged, ≤ 4.0 W/kg
- Head, ≤ 3.2 W/kg

☐ Gradient Field limits: Maximum specified gradient slew rate ≤ 200 T/m/s per axis

☐There are no restrictions for positioning the device within the integrated body coil of the MRI scanner. The use of receive-only coils is not restricted. Local transmit-only coils or local transmit/ receive coils may be used, but should not be placed directly over the device.

☐ Patient in supine or prone position only

Scanning Procedure

Pre-scan

1. Ensure Radiology has cleared the patient for scanning eligibility based on the MRI Conditions of Use and has provided the model number of the inserted device.

2. Ensure patient meets all Radiology Conditions of Use for MRI scanning (see left column).

1. As defined in IEC 60601-2-33, 201.3.224, 3rd Edition.

SYMBOLS ON PACKAGING

APPENDIX B

SYMBOLS ON PACKAGING

Commonly used medical device symbols that appear on the labeling are defined at *www.bostonscientific.com/SymbolsGlossary*.

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