Medtronic

REVEAL LINQ™ LNQ11

⚠️ Insertable Cardiac Monitor
MRI procedural information

MRI Technical Manual

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Medtronic, MyCareLink, Reveal, Reveal LINQ
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1 Introduction

The Medtronic Reveal LINQ Model LNQ11 Insertable Cardiac Monitor (ICM) is an MR Conditional device and, as such, is designed to allow patients to be safely scanned by a magnetic resonance imaging (MRI) machine. Preclinical testing has demonstrated that the Reveal LINQ device is safe for use in the MRI environment when used according to the MRI conditions for use. Before performing an MRI scan on a patient that has an implanted Reveal LINQ device, the radiology and cardiology staff involved in the procedure should understand the requirements and instructions in this manual. For non-MRI related instructions for use for a Reveal LINQ device, such as the implant procedure and programming instructions, cardiologists should refer to the Reveal LINQ ICM Clinician Manual.

2 MRI conditions for use

The Reveal LINQ device is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to specified MRI conditions for use. The MR Conditional symbol shown below is used to indicate the conditional safety of devices and components in the MR environment.

A patient with a Reveal LINQ device can be safely scanned in an MR system that meets the following conditions. Failure to follow these conditions for use may result in a hazard to the patient during an MRI scan:

- Horizontal cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5 Tesla (T) or 3.0 T must be used.
- Hydrogen proton MRI equipment must be used.
- Maximum spatial gradient of the static magnetic field specification must be ≤25 T/m (2500 gauss/cm).
- Whole body gradient systems with gradient slew rate specification must be ≤200 T/m/s per axis.
- The Whole Body Specific Absorption Rate (WB-SAR) as reported by the MRI equipment must be ≤4.0 W/kg; the head SAR as reported by the MRI equipment must be ≤3.2 W/kg.
- Do not use local transmit coils on the chest, trunk, or shoulder region.
- There are no restrictions on the placement of receive-only coils, and there are no restrictions on the use of local transmit or receive coils for imaging of the head or extremities.

3 Potential adverse events

There are no known potential adverse events for MRI scans performed on Reveal LINQ patients when the conditions in Chapter 2 are followed.

4 Cardiology responsibilities before and after the MRI scan

Before a radiologist performs an MRI scan on a Reveal LINQ device patient, the cardiology staff should ensure the patient record is up to date with all pertinent information about the implanted Reveal LINQ device, such as model name, model number, and serial number. The patient records must be complete and accurate because the radiology staff uses the records to verify that the patient has a Reveal LINQ device and that the patient has no other devices, leads, or implanted items that are known to pose a hazard in an MR environment.
After a radiologist performs the MRI scan, Medtronic recommends that a clinician review the patient's data for inappropriately collected episodes that may have occurred during the MRI scan. The data can be collected at the clinician's convenience through a programmer interrogation or by the patient through manual interrogation with the patient's home monitor (for example, the MyCareLink patient monitor).

5 Radiology requirements

Before the patient receives an MRI scan, the radiology staff should confirm that the following requirements are met:

- The MRI equipment meets all requirements specified in Chapter 2, “MRI conditions for use”, page 4.
- The pre-scan cardiology responsibilities have been performed (for more information, see Chapter 4, “Cardiology responsibilities before and after the MRI scan”, page 4).

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 Medtronic for guidance.

An X-ray image of the Reveal LINQ device, such as shown in Figure 1, can be used to identify that a patient has a Reveal LINQ device (typically implanted in the left chest area).

Figure 1. Front and side view X-ray images of an implanted Reveal LINQ device

6 Potential effects during an MRI scan

The Reveal LINQ device design and the MRI conditions for use (described in Chapter 2) limit potential effects during an MRI scan to the following. Such effects will not harm the patient or damage the device.

MRI interactions – Due to the static magnetic field and gradient magnetic fields produced by MRI equipment, the magnetic material of an implanted device may exert force, vibration, and torque effects that the patient may or may not feel. The MRI scan may induce currents and voltages in the device, which could lead to tissue heating, nerve stimulation, and electrical stress on device components.

Image artifact and distortion – Image artifact and distortion can result from the presence of the Reveal LINQ device within the field of view. Image artifact and distortion resulting from the presence of the device within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

False Detection and Data Corruption – The MRI scan may impact the sensing circuitry of the Reveal LINQ device which may corrupt the recorded data in the device or could cause false event detection and recording of inappropriate data.
7 Following the MRI scan

The radiology and cardiology staff should ensure that the post-scan cardiology responsibilities described previously in this manual are performed.