CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL and the nine-squares symbol are trademarks and service marks of St. Jude Medical, LLC and its related companies.


© 2017 St. Jude Medical, LLC. All Rights Reserved.
# Contents

Introduction ............................................................................................................................................................. 1  
Symbols................................................................................................................................................................... 1  
MR Conditional Models and Implant Locations.......................................................................................................... 1  
St. Jude Medical MR Conditional Device ................................................................................................................... 1  
  MRI Scanning and Equipment Requirements ........................................................................................................... 2  
  Warnings ........................................................................................................................................................................ 2  
  Precautions ................................................................................................................................................................. 2  
  Potential Adverse Events ........................................................................................................................................... 2  
Instructions for Physicians and Clinicians ................................................................................................................ 3  
Instructions for Radiologists and Radiology Professionals ........................................................................................ 3  
  Performing the Scan and Monitoring the Patient .................................................................................................... 3  
Technical Support .................................................................................................................................................. 3  
Appendix A: Patient Eligibility Form for MRI Scans .............................................................................................. 4
Introduction

This manual explains the procedures and precautions that must be followed when scanning a patient who is implanted with a St. Jude Medical™ Confirm Rx™ Insertable Cardiac Monitor (ICM).

It is important to read the information in this manual before conducting an MRI scan on a patient with an ICM. This manual contains information about the components that comprise the MR Conditional system, applicable warnings and precautions related to the MR Conditional system, and the requirements that you must follow in order for the ICM to be conditionally safe for MRI scans.

Preclinical testing has demonstrated that the Confirm Rx ICM, model DM3500, is safe for use in the MRI environment when used according to the MRI conditions for use.

NOTE: Before conducting an MRI scan, always ensure that you are using the most recent version of these MRI procedures. Contact Technical Support (page 3) or get the most recent version online at manuals.sjm.com. For more information about MR Conditional products, visit the St. Jude Medical product information page at sjm.com/MRIReady.

NOTE: For non-MRI related instructions for use of the ICM, such as the insertion procedure and programming instructions, refer to the Confirm Rx ICM user’s manual or Merlin™ PCS on-screen help. Contact Technical Support (page 3) if you have any questions.

Symbols

Table 1. MR Conditional symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🚨</td>
<td>Magnetic Resonance (MR) Conditional, an item with demonstrated safety in the MR environment within defined conditions.</td>
</tr>
</tbody>
</table>

MR Conditional Models and Implant Locations

Table 2. Approved models and implant locations

<table>
<thead>
<tr>
<th>Component</th>
<th>Model</th>
<th>Location of implanted component</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICM</td>
<td>DM3500</td>
<td>From the right parasternal line to the left midclavicular line, between the 1st rib to the 6th rib</td>
</tr>
</tbody>
</table>

St. Jude Medical MR Conditional Device

Personnel planning or performing an MRI scan of a patient with an ICM must follow the procedures and restrictions outlined in this manual.

Failure to follow the procedures outlined here may result in serious harm to the device and the patient.
MRI Scanning and Equipment Requirements

When performing an MRI scan on a patient with an ICM, the following scan parameters must be followed.

NOTE: For information about the MRI equipment that will be used to scan the patient, including important safety information, equipment features, and instructions for use, refer to the manual for the MRI equipment.

Table 3. MRI scanning and equipment requirements

<table>
<thead>
<tr>
<th>Scan parameters</th>
<th>Setting</th>
<th>Notes and Warnings</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI system type</td>
<td>1.5-T Cylindrical-bore magnet, horizontal</td>
<td>WARNING: Only use a 1.5-T cylindrical-bore magnet for hydrogen based imaging. Other MRI systems, such as 1.0-T or vertical field orientation machines, have not been tested and could damage the ICM.</td>
</tr>
<tr>
<td></td>
<td>field orientation</td>
<td>WARNING: The use of local transmit coils placed directly over the device is untested.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>NOTE: There are no restrictions on the placement of receive-only coils. There are no restrictions on the use of local transmit-receive coils (quadrature, birdcage design only) for imaging of the head or extremities.</td>
</tr>
<tr>
<td>RF Power (SAR)</td>
<td>Normal Operating Mode (Whole body SAR ≤ 2 W/kg)</td>
<td>NOTE: The specific absorption rate (SAR) requirements will be met if the scanner is in the specified operating mode.</td>
</tr>
<tr>
<td>Gradient slew rate</td>
<td>≤ 200 T/m/s per axis</td>
<td>WARNING: Do not use gradient slew rates greater than 200 T/m/s because they have not been tested and could increase the risk of induced stimulation or damage the ICM.</td>
</tr>
<tr>
<td>Spatial field gradient</td>
<td>≤ 24 T/m (2400 G/cm)</td>
<td></td>
</tr>
<tr>
<td>Patient position</td>
<td>Supine, patient’s arms must be at his or her sides</td>
<td>WARNING: Any prone patient positions, or positions where the patient’s arm is raised above his or her head, are excluded and have not been tested.</td>
</tr>
</tbody>
</table>

Warnings

- **Location of implant.** To meet the MR Conditional requirements, the ICM must be implanted according to the approved locations specified by the MRI labeling. Implant location can be confirmed with X-ray imaging or by referring to the patient records.
- **Skin erosion.** Do not perform an MRI scan on patients who have any portion of their ICM exposed due to skin erosion. The MRI scan may cause heating of the ICM, which could result in serious patient injury.
- **Other implanted medical devices.** Scanning patients who have other MR Conditional devices is acceptable as long 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, such as an abandoned lead. If you are unclear what implants are present, perform an X-ray to determine the implant type and location.

Precautions

- **External devices.** Do not allow external control devices into the scanner magnet room, such as a programmer or controller. Because these devices contain ferromagnetic material, they can be affected by the MRI magnet, may present a projectile hazard, and are considered MR Unsafe.

Potential Adverse Events

There are no known potential adverse events for MRI scans performed on the patient when the conditions of use are followed.
Instructions for Physicians and Clinicians

Before radiology performs an MRI scan on a patient with an ICM, the cardiology staff should perform the following tasks:

1. Provide the radiology professional with all pertinent information about the ICM, such as model name, model number, and implant location that was recorded in the patient record during the insertion procedure. The patient records must be complete and accurate because radiology uses the records to verify that the patient has an MR Conditional system.

2. Use the programmer or Merlin.net™ Patient Care Network (PCN) to interrogate the data stored in the ICM and save the data to media. The MRI scan may corrupt the recorded data in the ICM.

3. Inform patients to bring their patient ID card with them on the day of their MRI procedure.

After the MRI procedure is complete (preferably within a week of MRI scan):

1. It is recommended that the cardiologist clears the data that was collected during the MRI scan because the MRI scan may have temporarily affected event detection and device recording.

2. Check the programmed parameters of the ICM using the programmer or Merlin.net PCN. Ensure that monitoring is enabled.

Instructions for Radiologists and Radiology Professionals

Before conducting an MRI scan on a patient with an ICM, you must perform the following steps:

1. Confirm that the inserted system contains only MR Conditional components.
   NOTE: If you have questions about whether an MRI scan should be performed on a particular patient, contact St. Jude Medical Technical Support (page 3).

2. Confirm that no adverse conditions to MR scanning are present.
   NOTE: Refer to the patient eligibility form (page 4) to assist in confirming that there are no adverse conditions to MR scanning.

3. Select the MRI parameters according to the scanning requirements in the MRI Scanning and Equipment Requirements section (page 2).

4. Perform the MRI scan.

Performing the Scan and Monitoring the Patient

While performing the scan, follow these guidelines:

- Ensure any external control devices, such as a programmer, are left outside of the scanner magnet room (Zone IV) as they are considered MR Unsafe.
- During the MRI scan, visually and audibly monitor the patient, including verbal communication.

The following potential effects during the scan should be considered:

- When selecting the field of view and imaging parameters, consider that image distortion may occur around the ICM. Consider these factors also when interpreting the MRI images.
- The magnetic material of an ICM may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. Patients may feel a mild tugging or vibration sensation at the insertion site while in or near the MRI scanner.
- The gradient magnetic field and modulated RF field may induce currents and voltages in the device, which could lead to tissue heating, nerve stimulation, and electrical stress on device components.
- The gradient magnetic field and modulated RF field may induce voltages in the sensing circuitry, which may affect sensing and event detection and thus could lead to inappropriate data recorded by the ICM.

Technical Support

St. Jude Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)

For additional assistance, call your local St. Jude Medical representative.
Appendix A: Patient Eligibility Form for MRI Scans

Complete this form to help you determine the eligibility of a patient with an implanted Confirm Rx™ Insertable Cardiac Monitor (ICM) device for an MRI scan.

If the answers to all of the following questions are “Yes,” consult the MRI Ready Monitor Systems Manual for complete information on conducting an MRI scan. If the answer to any of the questions is “No,” do not perform the scan. If “Unsure,” contact the patient’s physician or St. Jude Medical Technical Support (page 3) for help.

WARNING: Scanning patients who have other MR Conditional devices is acceptable as long as 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. If you are unclear what implants are present, perform an X-ray to determine the implant type and location.

NOTE: Before conducting an MRI scan, always ensure that you are using the most recent version of these MRI procedures. Contact Technical Support (page 3) or get the most recent version online at manuals.sjm.com. For more information about MR Conditional products, visit the St. Jude Medical product information page at sjm.com/MRIReady.

<table>
<thead>
<tr>
<th>Patient’s name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician’s name and contact information (office name, address, phone number)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Confirm Rx ICM Model Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirm Rx ICM Implant Location</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Eligibility Factor</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does the patient have a MR Conditional Confirm Rx ICM device implanted in the approved location? (See the patient’s ID card for ICM device model number)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Does the intended scan meet the MRI scan parameters listed in the MRI Scanning and Equipment Requirements section (page 2) of the MRI Ready Monitor Systems Manual?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Are all of the medical devices implanted in the patient MR Conditional?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Has the Confirm Rx ICM device data been saved or uploaded via the Merlin Programmer or Merlin.net PCN?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>