MRI-Ready Monitor Systems Manual

MRI Procedure Information for the St. Jude Medical™ Confirm Rx™ Insertable Cardiac Monitor
Model DM3500

ST. JUDE MEDICAL™

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

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

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Pat. http://www.abbott.com/patents

Contents

Introduction

This manual explains the procedures and precautions that must be followed when scanning a patient who is implanted with a St. Jude Medical™ MR Conditional 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 a Confirm Rx ICM. Contact Technical Support if you have any questions (page 5).

Testing has demonstrated that the Confirm Rx ICM is conditionally safe for use in the MRI environment when used according to the instructions in this manual.

Refer to the Confirm Rx ICM user's manual for a complete listing of device specific indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Symbols

Table 1. MR Conditional symbols

Symbol	Description
	Device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.

MR Conditional Models

Table 2. Approved models and implant locations

Item name	Model	Location of implanted device
Confirm Rx™ ICM	DM3500	Device implanted completely within the region from the right parasternal line to the left midclavicular line, between the 1st rib to the 6th rib

MRI Safety Information

A patient with the Confirm Rx™ ICM may be safely scanned under the conditions given in this manual.

Scanning under different conditions may result in severe patient injury or device malfunction.

3T MRI Scan Parameters for St. Jude Medical™ MR Conditional Confirm Rx™ ICM

When performing a 3T MRI scan on a patient with a Confirm Rx ICM, the following scan parameters must be followed.

Table 3. 3T MRI scan parameters

Parameter	Setting
Item Name/Identification	Confirm Rx™ Model DM3500 Refer to the MR Conditional Models table (page 1)
Static Magnetic Field Strength [T] and Type of Nuclei	3 Tesla/128 MHz excitation frequency (hydrogen atom only)
Magnet Type and Static Magnetic Field Orientation	Cylindrical-bore magnet, horizontal field orientation
Maximum Spatial Field Gradient [T/m] and [Gauss/cm]	24 T/m (2400 Gauss/cm)
Maximum Gradient Slew Rate per axis [T/m/s]	200 T/m/s
RF Transmit Conditions	First Level Controlled Operating Mode or Normal Operating Mode Integrated Whole Body RF Transmit coil with RF excitation: ▪ Circularly polarized (CP), or ▪ Multichannel-2 (MC-2)
RF Receive Coil Type	Any receive coil may be used
Scan Duration and Wait Time between scans	No limitations on scan duration or wait time between scans
Scan Region / Patient Landmarking Criteria	Full body scans allowed / Any landmark is acceptable
Patient Characteristics	Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 4) ▪ Instructions for Radiologists and MRI Technologists (page 5)
Patient Position in Scanner	Supine or prone; patient's arms must be at his or her sides
Device Configuration	Location of implanted device: Device implanted completely within the region from the right parasternal line to the left midclavicular line, between the 1st rib to the 6th rib
Instructions to be followed before and after the MRI exam	Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 4) ▪ Instructions for Radiologists and MRI Technologists (page 5)
MR Image Artifact	The presence of this device may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact.

1.5T MRI Scan Parameters for St. Jude Medical™ MR Conditional Confirm Rx™ ICM

When performing a 1.5T MRI scan on a patient with a Confirm Rx ICM, the following scan parameters must be followed.

Table 4. 1.5T MRI scan parameters

Parameter	Setting
Item Name/Identification	Confirm Rx™ Model DM3500 Refer to the MR Conditional Models table (page 1)
Static Magnetic Field Strength [T] and Type of Nuclei	1.5 Tesla/64 MHz excitation frequency (hydrogen atom only)
Magnet Type and Static Magnetic Field Orientation	Cylindrical-bore magnet, horizontal field orientation
Maximum Spatial Field Gradient [T/m] and [Gauss/cm]	24 T/m (2400 Gauss/cm)
Maximum Gradient Slew Rate per axis [T/m/s]	200 T/m/s
RF Transmit Conditions	Normal Operating Mode Integrated Whole Body RF Transmit coil -or- Detachable RF Transmit-Receive coils (Head, Lower Extremity, or Upper Extremity) with RF excitation: ▪ Circularly polarized (CP)
RF Receive Coil Type	Any receive coil may be used
Scan Duration and Wait Time between scans	No limitations on scan duration or wait time between scans
Scan Region / Patient Landmarking Criteria	Full body scans allowed / Any landmark is acceptable
Patient Characteristics	Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 4) ▪ Instructions for Radiologists and MRI Technologists (page 5)
Patient Position in Scanner	Supine; patient's arms must be at his or her sides
Device Configuration	Location of implanted device: Device implanted completely within the region from the right parasternal line to the left midclavicular line, between the 1st rib to the 6th rib
Instructions to be followed before and after the MRI exam	Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 4) ▪ Instructions for Radiologists and MRI Technologists (page 5)
MR Image Artifact	The presence of this device may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact.

Instructions for Cardiac Physicians and Clinicians

The role of cardiac physicians and clinicians in preparing a patient for an MRI scan is to:

- Confirm that no adverse conditions to MRI scanning are present (page 4).
- Review the potential interactions (page 4).
- Confirm that the patient has an MR Conditional Confirm Rx™ ICM.
- Provide the radiologists and MRI technologists with all pertinent information about the Confirm Rx ICM. That includes the model name, model number, and implant location that was recorded in the patient record during the insertion procedure. Patient records must be complete and accurate because radiology uses the records to verify that the patient has an MR Conditional Confirm Rx ICM.
- Interrogate the Confirm Rx ICM and save the data to media because the MRI scan may corrupt the data stored in the Confirm Rx ICM. To save the data to media prior to the MRI, any of the following methods may be used:
  - Interrogate the Confirm Rx ICM using the Merlin™ PCS programmer.
  - Transmit Confirm Rx ICM data to Merlin.net™ Patient Care Network (PCN) using a patient-initiated Record Symptoms transmission.
  - Transmit Confirm Rx ICM data to Merlin.net PCN using a clinic-scheduled transmission.

  CAUTION: Do not bring any external control devices, such as the Merlin™ Patient Care System (PCS) Model 3650 or a mobile device, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.
- Inform patients to bring their patient ID card with them on the day of their MRI procedure.

After the MRI procedure is complete:

- Clear the data that was collected during the MRI scan because the MRI scan may have temporarily affected event detection and device recording.
- Check the programmed parameters of the Confirm Rx ICM using the Merlin PCS programmer or Merlin.net PCN. Ensure that monitoring is enabled.

Confirm that No Adverse Conditions to MRI Scanning are Present

If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- A device implanted in sites other than the approved locations specified by the MRI labeling (see MR Conditional Models table (page 1)). Implant location can be confirmed by referring to the patient records.
- Patients who have any portion of their Confirm Rx™ ICM exposed due to skin erosion. The MRI scan may cause heating of the Confirm Rx ICM, which could result in serious patient injury.
- Other non-MR Conditional implants, for example abandoned leads.

  NOTE: Scanning patients who have other MR Conditional implants is acceptable provided all MR Conditional requirements for each implanted device are met.

Review the Potential Interactions

The Confirm Rx™ ICM has been designed to minimize the potential adverse events that may cause patient harm.

Potential interactions between the MRI scanner and the MR Conditional device include:

- The static magnetic and gradient magnetic fields produced by an MRI scanner may exert force, vibration, and torque effects on the Confirm Rx ICM. Patients may feel a mild tugging or vibration sensation at the insertion site while in or near the MRI scanner.
- The gradient magnetic and RF fields generated by an MRI scanner could potentially interact with the device resulting in tissue heating, nerve stimulation, and device damage.
- The gradient magnetic and RF fields generated by an MRI scanner could potentially interact with the device, which may affect sensing and event detection, and could cause the Confirm Rx ICM to record inappropriate data.

Instructions for Radiologists and MRI Technologists

The role of radiologists and MRI technologists is to:

- Confirm that no adverse conditions to MRI scanning are present (page 5).
- Review the potential interactions (page 5).
- Confirm that the implanted ICM is MR Conditional. If you have questions about whether an MRI scan should be performed on a patient, contact St. Jude Medical Technical Support (page 5).
- Select the correct scan parameters. Refer to the MRI scan parameters table (3T MRI table (page 2) or 1.5T MRI table (page 3)) for the applicable scan parameter settings.
- Perform the scan and monitor the patient.

Confirm that No Adverse Conditions to MRI Scanning are Present

If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- A device implanted in sites other than the approved locations specified by the MRI labeling (see MR Conditional Models table (page 1)). Implant location can be confirmed by referring to the patient records.
- Patients who have any portion of their Confirm Rx™ ICM exposed due to skin erosion. The MRI scan may cause heating of the Confirm Rx ICM, which could result in serious patient injury.
- Other non-MR Conditional implants, for example abandoned leads.

  NOTE: Scanning patients who have other MR Conditional implants is acceptable provided all MR Conditional requirements for each implanted device are met.

Review the Potential Interactions

Potential interactions between the MRI scanner and the MR Conditional Confirm Rx ICM include:

- The static magnetic and gradient magnetic fields produced by an MRI scanner may exert force, vibration, and torque effects on the Confirm Rx™ ICM. Patients may feel a mild tugging or vibration sensation at the insertion site while in or near the MRI scanner.
- The gradient magnetic and RF fields may induce currents and voltage in the device, which could lead to tissue heating, nerve stimulation, and device damage.
- The gradient magnetic and RF fields may induce voltages in the sensing circuitry, which may affect sensing and event detection, and could cause the Confirm Rx ICM to record inappropriate data.

Perform the Scan and Monitor the Patient

During the MRI scan, visually and audibly monitor the patient.

CAUTION: **Do not bring any external control devices, such as the Merlin™ Patient Care System (PCS) Model 3650 or a mobile device, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.**

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)
- + 61 2 9936 1200 (Australia)
- manuals.sjm.com

For additional assistance, call your local St. Jude Medical representative.

Appendix A: ICM Patient Eligibility Form for MRI Scans

Complete this form to determine the eligibility of a patient with an implanted St. Jude Medical Confirm Rx™ Insertable Cardiac Monitor (ICM) 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 for help.

Scanning patients who have other MR Conditional devices is acceptable provided all MR Conditional requirements for each implanted device are met.

> NOTE: Before conducting an MRI scan, always ensure that you are using the most recent version of the MRI-Ready Monitor Systems manual. You can obtain the most recent version of the manual online at manuals.sjm.com, or you can contact Technical Support.

Patient's name	
Cardiac Physician name and contact information (office name, address, phone number)	
Confirm Rx ICM Model Number	
Confirm Rx ICM Implant Location	

Eligibility Factor		**Yes**	**No**	**Unsure**
1.	Does the patient have an MR Conditional Confirm Rx ICM implanted in the approved location? See the Patient ID card for Confirm Rx ICM model number.			
2.	Have you confirmed that no adverse conditions to MRI scanning are present?			
3.	Does the intended scan meet the MRI scan parameters listed in the MRI scan parameters tables in the MRI-Ready Monitor Systems manual?			
4.	Are all medical devices implanted in the patient MR Conditional?			
5.	Has the Confirm Rx ICM data been saved or uploaded via the Merlin™ PCS Programmer or Merlin.net™ Patient Care Network?			

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For additional assistance, call your local St. Jude Medical representative.

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