MRI Ready Systems Manual

MRI Procedure Information for
the St. Jude Medical™ MR Conditional Pacing System

ST. JUDE MEDICAL

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 system.

It is important to read the information in this manual before conducting an MRI scan on a patient with an implanted St. Jude Medical™ MR Conditional pacing system. Contact Technical Support (page 8) if you have any questions.

Refer to the Merlin™ Patient Care System (PCS) on-screen help or to the appropriate pulse generator or lead user's manual for non-MRI related information.

The St. Jude Medical MR Conditional pacing system includes a St. Jude Medical MR Conditional pulse generator connected to one or more St. Jude Medical MR Conditional leads. For a list of the lead/pulse generator combinations that have been tested, see the St. Jude Medical MR Conditional Pacing Systems (Table 2) at the beginning of this manual.

Testing has demonstrated that the St. Jude Medical™ MR Conditional pacing system is conditionally safe for use in the MRI environment when used according to the instructions in this manual.

Enable the MRI Settings to turn on a mode of operation that allows a patient with an MR Conditional pacing system to be safely scanned by an MRI scanner when used according to the instructions in this manual.

Symbols

Table 1. MR Conditional symbols

Symbol	Description
	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
	MR environment and conditions specified for pulse generator/lead combinations listed as "Scan Set A." See MR Scan Parameter Sets (page 2).
	MR environment and conditions specified for pulse generator/lead compbinations listed as "Scan Set B." See MR Scan Parameter Sets (page 2).

St. Jude Medical MR Conditional Pacing Systems

The following pacemaker/lead combinations discussed in this manual have been tested and determined to be MR Conditional Pacing Systems. Patients with these pacing systems may undergo MR scanning only with the set of scan parameters listed in Table 3. The pulse generators in Table 2 are MR conditional when paired with the Tendril MRI Model LPA1200M lead only.

Table 2. St. Jude Medical MR Conditional Pacing Systems Pulse Generator/Lead Combinations and MRI Scan Parameter Sets

	Leads
Pulse Generators	**Tendril MRI Model LPA1200M (all lead lengths)**
Accent MRI	Scan Set A
PM1124	
PM1224	
PM2124	
PM2224	
Assurity MRI	Scan Set A
PM1272	
PM2272	
Endurity MRI	Scan Set A
PM1172	
PM2172	
Endurity	Scan Set B
PM1162	
PM2162	

MR Scan Parameter Sets

Table 3. MRI scan parameter sets

Scan Parameters	Set A	Set B
Scanner Type	Horizontal Closed Bore	Horizontal Closed Bore
Imaging System	1.5 Tesla/64 MHz excitation frequency (hydrogen atom)	1.5 Tesla/64 MHz excitation frequency (hydrogen atom)
Whole Body SAR (Specific Absorption Rate)	≤4 W/kg	≤2 W/kg
Head SAR	≤3.2 W/kg	≤3.2 W/kg
Gradient Slew Rate	≤200 T/m/s	≤200 T/m/s
Scan Regions	Full Body	Superior: Isocenter 10 cm superior to C1 vertebra Inferior: Isocenter at or inferior to L4 vertebra
Symbol		

CAUTION
If the pacing system comprises a combination of leads that have differing scan regions, use the scan set with the most restrictive scan region.
For pacing systems using Set B scan parameters, the accumulated imaging time per MRI procedure (as displayed by the MRI scanner) should not exceed 30 minutes. Do not start another MRI procedure until 30 minutes after the end of the initial procedure.
Use of local transmit-only coils or local transmit/receive coils has not been studied. Receive-only coils can be safely used.

St. Jude Medical MR Conditional Product Models

Pulse Generators

Table 4. St. Jude Medical MR Conditional pulse generators with SJM MRI Activator™ handheld device functionality and presence of radiopaque MR Conditional marker

Model Name and Number	Operates with the SJM MRI Activator™ handheld device Model EX4000	Radiopaque MR Conditional X-ray marker
Accent MRI PM1124 PM1224 PM2124 PM2224	Yes	Yes
Assurity MRI PM1272 PM2272	Yes	Yes
Endurity MRI PM1172 PM2172	Yes	Yes
Endurity PM1162 PM2162	No	Yes

Lead Models

Table 5. St. Jude Medical MR Conditional leads

Model Name and Number	Radiopaque MR Conditional X-ray marker
Tendril MRI LPA1200M (all lead lengths)	Yes

Instructions for Cardiologists

The role of cardiologists in preparing a patient for an MR scan is to:

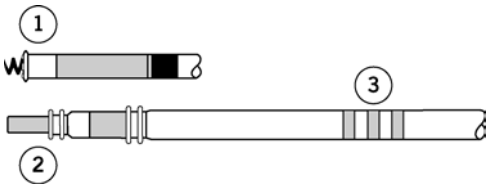
- Confirm that the patient has an MR Conditional pacing system (page 3)
- Confirm that no conditions adverse to MR scanning are present (page 3)
- Review the potential adverse events (page 4)
- Generate a report of the patient's permanently programmed parameters (page 4)
- Select and Save MRI Settings (page 5)
- Review the MRI Checklist (page 5)
- Disable the MRI Settings (page 6)

I. Confirm that the Patient has an MR Conditional Pacing System

1. Review the patient's ID card and Parameter report (generated by the Merlin PCS) to obtain the model numbers for both the implanted lead(s) and pulse generator.
2. Check the model numbers against the table of appropriate pulse generator/lead combinations at the beginning of this manual.
3. Certain MR Conditional leads and pulse generators are equipped with a unique radiopaque marker that is identified as a MR Conditional x-ray marker. These markers are illustrated in the figures below. Tables 4 and 5 above provide information on which products contain the MR Conditional radiopaque marker.

Figure 1. Radiopaque MR Conditional marker in pacemaker models

Figure 2. Radiopaque MR Conditional marker in Tendril MRI lead models



1. Distal tip
2. Proximal connector
3. MR Conditional marker, 3 platinum rings

NOTE

Patients can be considered safe for an MRI scan only if the implanted system consists of a St. Jude Medical MR Conditional pulse generator connected to the appropriate St. Jude Medical MR Conditional leads.

II. Confirm that No Adverse Conditions to MRI Scanning are Present

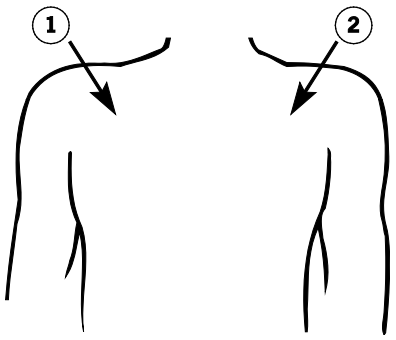
1. If any conditions exist that could make MR scanning unsafe, do not scan the patient. Such conditions include:
   - Fever (for patients with pacing systems using the Set B scan parameters)
   - A combination of lead(s) and pulse generator that is not listed as MR Conditional, as outlined in Table 2
   - Broken or intermittently functioning St. Jude Medical MR Conditional leads
   - Lead impedance measurements not within the programmed lead impedance limits
   - Abandoned cardiac hardware, including leads, lead extenders, or lead adaptors
   - St. Jude Medical MR Conditional pacing system implanted in sites other than the left and right pectoral region (see figure below)
   - Unstable capture thresholds or capture threshold values of > 2.5 V at a pulse width of 0.5 ms

- Complaints of diaphragmatic stimulation at a pacing output of 5.0 V or 7.5 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI Settings are enabled
- Positioning patients on their side (lateral recumbent) within the MRI bore

NOTE

Lead fractures or other damage to the leads may cause changes in the electrical properties of the St. Jude Medical MR Conditional pacing system that makes the system unsafe for an MRI scan. Patients with damaged leads may be harmed if an MRI scan is performed.

Figure 3. Correct locations for pulse generator implant



1. Right-pectoral region
2. Left-pectoral region

III. Review the Potential Adverse Events

The St. Jude Medical™ MR Conditional pacing system has been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MRI environment:

- Lead electrode heating and tissue damage resulting in loss of sensing or capture or both
- Device heating resulting in tissue damage in the implant pocket or patient discomfort or both
- Induced currents on leads resulting in continuous capture, VT/VF, hemodynamic collapse, or all three
- Damage to the device or leads causing the system to fail to detect or treat irregular heartbeats or causing the system to treat the patient's condition incorrectly
- Damage to the functionality or mechanical integrity of the device resulting in the inability to communicate with the device
- Movement or vibration of the device or leads
- Lead dislodgement
- Syncope due to loss of pacing if no pacing support is programmed with MRI settings
- Competitive pacing and potential for VT/VF induction due to asynchronous pacing when MRI Settings are enabled

Potential interactions between the MR scanner and the pacing system include:

- The magnetic material of an implanted system may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. These effects have been shown to be minimal in St. Jude Medical™ MR Conditional pacing systems. Patients may feel a mild tugging or vibration sensation at the site of the device implant while in or near the MRI scanner.
- The gradient magnetic and RF fields produced by an MRI scanner could potentially interact with the pacing system and cause unintended stimulation of the heart. When all conditions outlined in this manual are met, the voltages and pulse widths induced on the leads of the St Jude Medical MR Conditional Pacing System are limited so that the potential for capturing the heart is minimized.
- The RF fields generated by an MRI scanner could induce voltages onto an implanted lead system that may cause heating at the lead electrodes. This heating could damage the tissue surrounding the electrodes and compromise pacing and sensing thresholds at that site. When all conditions outlined in this manual are met, St. Jude Medical MR Conditional leads have been tested and shown to limit heating at the electrodes and to minimize thermal damage of the surrounding cardiac tissue.

IV. Generate a Report of the Patient's Permanently Programmed Parameters

CAUTION

Do not bring the Merlin™ Patient Care System (PCS) Model 3650 or the SJM MRI Activator™ handheld device Model EX4000 into Zone IV (MRI scanner magnet room), as defined by the American College of Radiology. Each device is MR Unsafe.

1. Interrogate the device with the Merlin PCS.
2. If needed, perform capture, sense, and lead impedance tests.
3. From the FastPath™ screen, select the Print button to print the Diagnostics and any other relevant reports.

   The Merlin PCS will print to the default printer (internal printer, external printer or PDF).
4. Make the report available to the radiologist or MR technician who will perform the scan.

NOTE

Diagnostic data collection is suspended when MRI Settings are enabled.

It is recommended that the clinician perform a complete follow-up prior to the MRI procedure to save all diagnostic and test data.

V. Select and Save MRI Settings

NOTE

The Merlin PCS must be operating with software version 19.2 or greater to interrogate an MR Conditional device.

The MRI parameter settings are selected at the physician's discretion.

The default MRI parameter settings are automatically stored in the St. Jude Medical MR Conditional pulse generator. If you change the MRI parameter settings from the default values, you must save the modified MRI settings in the pulse generator.

It is recommended that the MRI Settings be disabled immediately following an MRI scan.

Refer to the Merlin PCS on-screen help for information on selecting, testing, and saving the MRI parameter settings.

1. From the MRI Settings window of the Merlin™ PCS, you can modify the default values of five of the MRI parameters that are in effect when the MRI Settings are enabled.
2. You can temporarily test the settings if you select the Test MRI Settings button. Use this function to evaluate the patient's hemodynamic status with the proposed MRI parameter settings.
3. Select the Cancel Test button to return to permanently programmed settings.
4. Select the Save Test button to save any changed parameters.
5. If you are using the SJM MRI Activator™ handheld device to program MRI Settings, select the Setup MRI Activator button. This opens the MRI Checklist. Refer to the SJM MRI Activator handheld device user's manual for instructions for use.

   NOTE

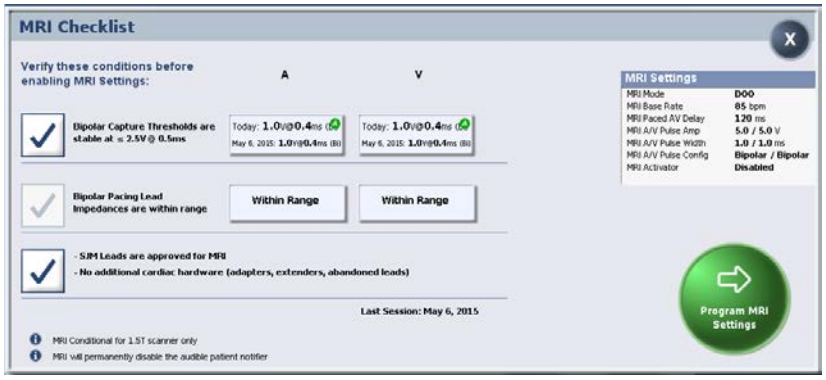
   Before the use of the SJM MRI Activator handheld device can be enabled, in-range bipolar pacing lead impedance measurements from the current programming session are required.
6. When you are satisfied with the MRI Settings, select the Setup for MRI Now button to open the MRI Checklist.

   NOTE

   Regardless of the programmed permanent pacing mode, sensed events are ignored by the pulse generator when MRI Settings are enabled. Determine whether or not pacing support is needed during the MRI scan. When pacing support is needed, set the MRI pacing mode to an asynchronous pacing mode (DOO, AOO, or VOO). When pacing support is not needed, set the MRI pacing mode to Pacing Off.
   Some patients may be susceptible to cardiac arrhythmia induced by competitive pacing when an asynchronous MRI pacing mode is selected. For these patients, it is important to select an appropriate MRI pacing rate to avoid competitive pacing and then minimize the duration of the asynchronous pacing operation.

VI. Review the MRI Checklist

Figure 4. An example of the MRI Checklist screen on the Merlin PCS



1. Review each condition on the checklist and check off each one that applies. You will not be able to program MRI settings until all checkboxes are checked.

   NOTE

   If the programmer has recorded that the leads are not MR Conditional, the leads button will be grayed out.
2. If you are using the SJM MRI Activator™ handheld device to program MRI Settings, close the Checklist window and return to the MRI Settings window. Before the use of the SJM MRI Activator handheld device can be enabled, in-range bipolar pacing lead impedance measurements from the current programming session are required.
3. If you are using the MRI Activator handheld device, select "Set Up Activator" button from the MRI Settings window. Refer to the SJM MRI Activator handheld device user's manual for instructions for use.
4. If you are using the Merlin PCS, once you have selected the MRI Settings and completed the checklist, select the Program MRI Settings button to enable the MRI Settings.
5. Select End Session.

The patient is now ready for the MR scan.

VII. Disable the MRI Settings

CAUTION
Do not bring the Merlin™ Patient Care System (PCS) Model 3650 or the SJM MRI Activator™ handheld device Model EX4000 into Zone IV (MRI scanner magnet room), as defined by the American College of Radiology. Each device is MR Unsafe.

Immediately following the MRI procedure, the patient's device management physician or clinician must:

1. Interrogate the pulse generator using the Merlin™ PCS or the SJM MRI Activator handheld device.
2. For the Merlin PCS, disable the MRI Settings by selecting Parameters > MRI Settings > Disable MRI Settings. This restores the permanently programmed settings.
3. For the SJM MRI Activator handheld device, select the MRI Settings Off button.
4. Confirm the permanently programmed settings are appropriate.
5. To ensure that an accurate lead impedance measurement, perform a device lead impedance test by selecting Tests > Battery & Leads > Update leads.
6. Print or save an MRI Summary Report.

Refer to the Merlin PCS on-screen help for information on selecting and programming parameter settings.

Instructions for Radiologists and MRI Technicians

The role of the radiologist or MRI Technician is to:

- Confirm that the patient has an MR Conditional pacing system (page 6)
- Confirm that no adverse conditions to MR scanning are present (page 6)
- Review the potential interactions between the MR scanner and the pacing system (page 7)
- Select the Correct Scan Parameters (page 7)
- Check the MRI Settings status (page 7)
- Perform the Scan and Monitor the Patient (page 8)
- Disable the MRI Settings (page 8)

I. Confirm that the Patient has an MR Conditional Pacing System

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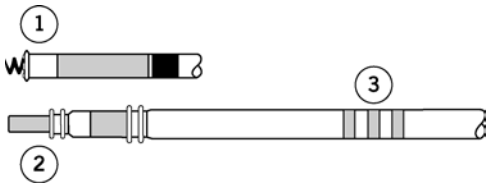

1. Distal tip
2. Proximal connector
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- Broken or intermittently functioning St. Jude Medical MR Conditional leads
- Lead impedance measurements not within the programmed lead impedance limits
- Abandoned cardiac hardware, including leads, lead extenders, or lead adaptors
- St. Jude Medical MR Conditional pacing system implanted in sites other than the left and right pectoral region (see figure below)
- Unstable capture thresholds or capture threshold values of > 2.5 V at a pulse width of 0.5 ms
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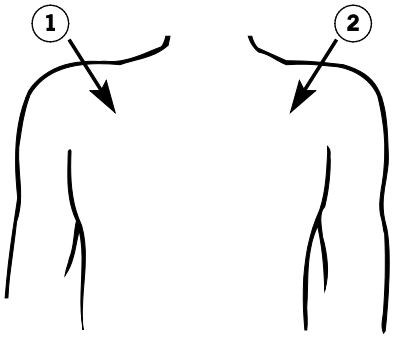
Figure 7. Correct locations for pulse generator implant



1. Right-pectoral region
2. Left-pectoral region

III. Review the Potential Interactions

Potential interactions between the MR scanner and the pacing system include:

- The magnetic material of an implanted system may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. These effects have been shown to be minimal in St. Jude Medical™ MR Conditional pacing systems. Patients may feel a mild tugging or vibration sensation at the site of the device implant while in or near the MRI scanner.
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IV. Select the Correct Scan Parameters

1. Refer the St. Jude Medical™ Conditional Pacing Systems table at the beginning of this manual and identify which MR scan parameter set can be used in this patient.
2. Make sure that you identify the **combination** of both the pulse generator and the lead(s) to properly select the MR Scan Parameter Set.
3. Refer to the MR Scan Parameter Sets table (page 2) to locate the relevant scan parameters.

V. Check the MRI Settings Status

CAUTION

Do not bring the Merlin™ Patient Care System (PCS) Model 3650 or the SJM MRI Activator™ handheld device Model EX4000 into Zone IV (MRI scanner magnet room), as defined by the American College of Radiology. Each device is MR Unsafe.

If you do not have an SJM MRI Activator™ handheld device Model EX4000, see, Check the MRI Setting Status without the SJM MRI Activator™ Handheld Device. (page 8)

If you do have an SJM MRI Activator™ handheld device Model EX4000 available, see, Check the MRI Settings Status with the SJM MRI Activator™ Handheld Device (page 8).

Check the MRI Settings Status without the SJM MRI Activator™ Handheld Device

1. Refer to the MRI Summary Report generated by the Merlin™ PCS.
2. Confirm these settings with the device management physician or clinician.

   The currently programmed settings should include:

Table 6. Pacemaker MRI Settings[1]

Parameter	Setting
MRI Mode	DOO, VOO, AOO, Pacing Off
MRI Base Rate	30 - 120 min^{-1}
MRI Paced AV Delay	25 - 120 ms (excluding Accent MRI pacemaker) 25 - 350 ms (Accent MRI pacemaker)
MRI Pulse Amplitude	5.0 or 7.5 V
MR Pulse Width	1.0 ms
MRI Pulse Configuration	Bipolar

Check the MRI Settings Status with the SJM MRI Activator™ Handheld Device

To check the status of the MRI Settings:

1.Place the activator over the implanted pulse generator.

The activator should be touching the patient's clothing directly over the implanted pulse generator. See MR Conditional Pulse Generator Implant Location.

2.Press the MR Status button.

- MRI Settings Enabled. The green LEDs illuminate continuously for 5 seconds.
- MRI Settings Disabled. The red LEDs illuminate continuously for 5 seconds.

VI. Perform the Scan and Monitor the Patient

Proper patient monitoring must be provided during the MRI scan. This includes continuous monitoring of the patient's hemodynamic function. Since the MR environment may interfere with the patient monitoring system, it is recommended that more than one of the following systems be used: electrocardiography, pulse oximetry, noninvasive blood pressure measurements. If the patient's hemodynamic function is compromised during the MRI scan, discontinue the MRI scan and take the proper measures to restore the patient's hemodynamic function.

Verbal communication with the patient during the MRI scan is recommended.

Ensure an external defibrillator and the specialist personnel certified to use it are available during the MRI scan.

St. Jude Medical MR Conditional leads have demonstrated minimal image distortion for areas surrounding the implanted leads when the pulse generator is out of the field of view. Significant image distortion can result from the presence of the pulse generator within the field of view. Image artifacts and distortion resulting from the presence of the pulse generator and the leads 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.

VII. Disable the MRI Settings

1. If you are using the SJM MRI Activator handheld device, place the activator over the implanted pulse generator.

   The activator should be touching the patient's clothing directly over the implanted pulse generator.

   1.Press the MRI Settings Off button.

   

   The LEDs may flash before they illuminate continuously.

   - MRI Settings Disabled. The red LEDs illuminate continuously for 5 seconds.
2. If you are not using the activator, the MRI settings must be disabled by the patient's device management physician or clinician.

Technical Support

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

- 1 818 362 6822

[1] This is the entire range of all possible settings for this parameter.

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

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

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