

# MRI Procedure Information

For the St. Jude Medical™ MR Conditional Pacing System



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# Introduction

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 10) if you have any questions.

Refer to the Merlin™ PCS on-line 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 St. Jude Medical MR Conditional leads.

An 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.

## MRI Conditions for Use

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.

The St. Jude Medical MR Conditional pacing system can be scanned in patients under the following conditions:

- Horizontal closed bore clinical scanner working in the Normal Operating Mode or First Level Controlled Operating Mode, whole body specific absorption rate (SAR)  $\leq 4.0$  W/kg and head SAR  $\leq 3.2$  W/kg.
- Static magnetic field strength of 1.5 Tesla (T) only
- Maximum gradient slew rate of 200 T/m/s per axis.

## MR Conditional Contraindications

- Patients who do not have a complete St. Jude Medical™ MR Conditional pacing system, which includes a St. Jude Medical MR Conditional pulse generator and St. Jude Medical MR Conditional leads, are contraindicated for an MRI scan.
- Patients with broken or intermittent St. Jude Medical MR Conditional leads, or lead impedance measurements not within the programmed lead impedance limits are contraindicated for an MRI scan.
- Patients with abandoned cardiac hardware including leads, lead extenders, or lead adaptors are contraindicated for an MRI scan.
- Use of local transmit-only coils or local transmit and receive coils placed directly over the pacing system has not been studied and such use is contraindicated.
- All spectroscopy and imaging for atoms other than hydrogen are contraindicated.
- Patients with an implanted St. Jude Medical MR Conditional pacing system must not be positioned on his or her side within the MRI bore. This position is contraindicated for an MRI scan.
- Patients with a St. Jude Medical MR Conditional pacing system implanted in sites other than the left and right pectoral region are contraindicated for an MRI scan.

# 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 dislodgment
- Competitive pacing and potential for VT/VF induction due to asynchronous pacing when MRI Settings are enabled

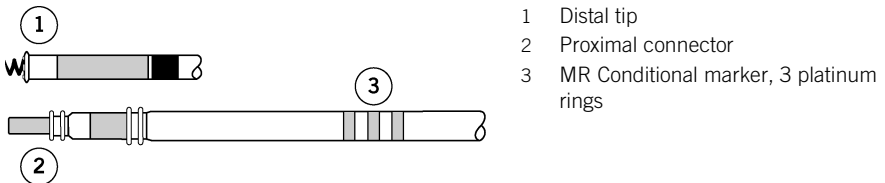
# Radiopaque MRI symbols

A radiopaque MRI symbol is present on all implanted St. Jude Medical™ MR Conditional pacing system components. Take an x-ray of the implanted system to verify the components of the St. Jude Medical MR Conditional pacing system. An x-ray can also indicate whether the patient has any additional active or abandoned implanted cardiac hardware.

Figure 1. Radiopaque MR Conditional marker, St. Jude Medical MR Conditional pulse generator



Figure 2. Radiopaque MR Conditional marker, St. Jude Medical MR Conditional lead



# Device Management Physician and Clinician Instructions

To safely perform an MRI scan on a patient with a St. Jude Medical™ MR Conditional pacing system:

1. Review the MRI Conditional Contraindications (page 1).
2. Review the Pacing System and Patient Considerations (page 3).
3. Select and Save MRI Settings (page 4).
4. Review the Checklist and:
  - Enable the MRI Settings Using the Merlin™ PCS (page 5).
  - Enable the Use of the SJM MRI Activator™ handheld device (page 5) for use at the time of the MRI scan.
5. Patient receives the MRI Scan.
6. Disable MRI Settings Using the Merlin PCS (page 6) or the SJM MRI Activator handheld device (page 9).

## Pacing System and Patient Considerations

### Implanted Hardware

**Confirm that the implanted pulse generator and leads are labeled as St. Jude Medical™ MR Conditional.** Only St. Jude Medical MR Conditional pulse generators and leads have been tested. Patients can be considered safe for an MRI scan only if the implanted system consists of a St. Jude Medical MR Conditional device connected to St. Jude Medical MR Conditional leads.

**Do not authorize a scan for or perform a scan on patients with previously implanted (active or abandoned) cardiac hardware which may include medical devices, leads, lead extenders, or lead adaptors.** Doing so may increase the risk of myocardial tissue damage due to heating and other MR RF field-related hazards. The interaction with other implantable devices has not been evaluated. Patients can be considered safe for an MRI scan only if no other implantable medical devices, leads, lead extenders, or lead adaptors are present.

### Lead Integrity

**Confirm that the implanted leads are electrically intact.** 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.

### Pacing Capture Threshold

**Stable pacing capture threshold values are recommended.**

**Do not scan patients with pacing capture threshold values of > 2.5 V at a pulse width of 0.5 ms.** MRI Settings require a pacing pulse output of 5.0 V or 7.5 V at a pulse width of 1.0 ms to ensure an adequate safety margin during the MRI scan.

### MRI Pacing Mode

**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.

## Competitive Pacing

**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.

## Diaphragmatic Stimulation

**Do not authorize a scan for or perform a scan on patients who experience diaphragmatic stimulation** at a pacing output of 5.0 V or 7.5 V and at a pulse width of 1.0 ms and whose device will be programmed to an asynchronous pacing mode when MRI Settings are enabled. It may be difficult for the patient to remain still in order to obtain a quality image.

## Suspended Pulse Generator Function

**When the MRI Settings are enabled, the following pulse generator functions are suspended:**

- Sensing
- Diagnostics
- Magnet mode
- Rate-responsive pacing

## Potential Interactions

**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.**

The St. Jude Medical™ MR Conditional pacing system has been designed to reduce these effects so that the mechanical stress on the implanted system and tissue interface is minimized. 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.** The St. Jude Medical MR Conditional pacing system has been designed to limit the voltages and pulse widths induced on the leads 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. St. Jude Medical MR Conditional leads have been designed to limit heating at the electrodes to minimize thermal damage of the surrounding cardiac tissue.

## Select and Save MRI Settings

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.

You can temporarily enable the MRI Settings to evaluate the patients hemodynamic status with the selected MRI parameter settings.

Select and program the MRI parameter settings at the time of implant or at any time before the patient requires an MRI scan.

The MRI Settings must be enabled before an MRI scan. See Review the Checklist and Enable the MRI Settings Using the Merlin™ PCS (page 5).

It is recommended that the MRI Settings be disabled immediately following an MRI scan. See Disable the MRI Settings Using the Merlin PCS (page 6) or Disable the MRI Settings Using the SJM MRI Activator™ Handheld Device (page 9).

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

## Review the Checklist and Enable the Use of the SJM MRI Activator™ Handheld Device

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### Note

It is optional to enable the use of the SJM MRI Activator™ handheld device.

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Review the MRI Checklist on the Merlin™ PCS. 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. It is recommended that all other conditions on the MRI Checklist are also confirmed.

Refer to the Merlin PCS on-screen help for information on the MRI Checklist and enabling the use of the SJM MRI Activator handheld device.

Refer to the SJM MRI Activator handheld device user's manual for instructions for use.

## Review the Checklist and Enable the MRI Settings Using the Merlin™ PCS

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### CAUTION

**Do not bring the Merlin™ Patient Care System (PCS) Model 3650 into Zone IV (MR scanner magnet room), as defined by the American College of Radiology. It is MR Unsafe.**

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Review the MRI Checklist on the Merlin PCS. Before MRI Settings can be enabled, in-range bipolar pacing lead impedance measurements from the current programming session are required. It is recommended that all other conditions on the MRI Checklist are also confirmed.

A summary report that includes the MRI parameter settings and the MRI Checklist information is available for printing.

Refer to the Merlin PCS on-screen help for information on the MRI Checklist and enabling MRI Settings.

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### Note

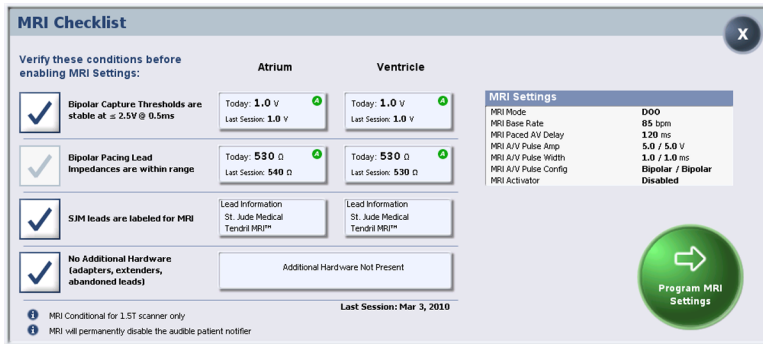
MRI Settings can also be enabled using the SJM MRI Activator™ Handheld Device (page 9).

When the MRI Settings are enabled, the pulse generator maintains these settings until the MRI Settings are disabled.

When the MRI Settings are disabled, the permanent parameter settings are restored to the pre-scan settings.

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Figure 3. An example of the MRI Checklist screen on the Merlin PCS



## Disable the MRI Settings Using the Merlin™ PCS

### CAUTION

Do not bring the Merlin™ Patient Care System (PCS) Model 3650 into Zone IV (MR scanner magnet room), as defined by the American College of Radiology. It is MR Unsafe.

### Note

When the MRI Settings are disabled, the permanent parameter settings are restored to the pre-scan settings.

When you interrogate the pulse generator using the Merlin PCS, the MRI parameter settings and permanent parameter settings are shown. You must disable the MRI Settings before you can proceed with the programmer session.

Confirm that the permanent parameter settings are as expected.

You can also Disable the MRI Settings Using the SJM MRI Activator™ Handheld Device (page 9).

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

## Radiologists and MRI Technologists Instructions

To safely perform an MRI scan on a patient with the St. Jude Medical™ MR Conditional pacing system:

1. Confirm the MRI Conditions for Use (page 1).
2. Review the MR Conditional Contraindications (page 1).
3. Review the MRI Scan Considerations (page 7).
4. Check the MRI Settings status using the SJM MRI Activator™ handheld device (page 8).
5. Enable the MRI Settings using the SJM MRI Activator handheld device (page 9).
6. Perform the MRI Scan.
7. Disable the MRI Settings using the SJM MRI Activator handheld device (page 9).

# MRI Scan Considerations

## Implanted Hardware

**Confirm that the implanted pulse generator and leads are labeled as St. Jude Medical™ MR Conditional.** Only St. Jude Medical MR Conditional pulse generators and leads have been tested. Patients can be considered safe for an MRI scan only if the implanted system consists of a St. Jude Medical MR Conditional device connected to St. Jude Medical MR Conditional leads.

**Do not authorize a scan for or perform a scan on patients with previously implanted (active or abandoned) cardiac hardware which may include medical devices, leads, lead extenders, or lead adaptors.** Doing so may increase the risk of myocardial tissue damage due to heating and other MR RF field-related hazards. The interaction with other implantable devices has not been evaluated. Patients can be considered safe for an MRI scan only if no other implantable medical devices, leads, lead extenders, or lead adaptors are present.

## Patient Monitoring

**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.**

## Patient Rescue

**Keep an external defibrillator available during the MRI scan.**

## Image Quality

**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.

## Potential Interactions

**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.**

The St. Jude Medical™ MR Conditional pacing system has been designed to reduce these effects so that the mechanical stress on the implanted system and tissue interface is minimized. 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.** The St. Jude Medical MR Conditional pacing system has been designed to limit the voltages and pulse widths induced on the leads so that the potential for capturing the heart is minimized.

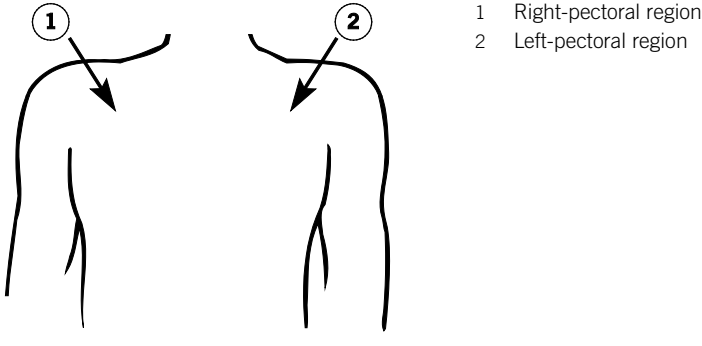
**The RF fields generated by an MRI scanner could induce voltages onto an implanted lead system that may cause heating at the lead electrodes.** This heating could damage the tissue surrounding the electrodes and compromise pacing and sensing thresholds at that site. St. Jude Medical MR Conditional leads have been designed to limit heating at the electrodes to minimize

thermal damage of the surrounding cardiac tissue.

## MR Conditional Pulse Generator Implant Location

The St. Jude Medical™ MR Conditional pulse generator is implanted under the skin in the right- or left-pectoral region.

Figure 4. Implant location



## Check MRI Settings Status Using the SJM MRI Activator™ Handheld Device

### CAUTION

Do not bring the SJM MRI Activator™ handheld device Model EX4000 into Zone IV (MR scanner magnet room), as defined by the American College of Radiology. It is MR Unsafe.

Refer to the SJM MRI Activator user's manual for additional information on the 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 (page 8).
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.

## Enable the MRI Settings Using the SJM MRI Activator™ Handheld Device

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### CAUTION

**Do not bring the SJM MRI Activator™ handheld device Model EX4000 into Zone IV (MR scanner magnet room), as defined by the American College of Radiology. It is MR Unsafe.**

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Refer to the SJM MRI Activator user's manual for additional information on the handheld device.

To enable 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 (page 8).
2. Press the MRI Settings On button.



The LEDs may flash before they illuminate continuously.

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

## Disable the MRI Settings Using the SJM MRI Activator™ Handheld Device

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### CAUTION

**Do not bring the SJM MRI Activator™ handheld device Model EX4000 into Zone IV (MR scanner magnet room), as defined by the American College of Radiology. It is MR Unsafe.**

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Refer to the SJM MRI Activator user's manual for additional information on the handheld device.

To disable 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 (page 8).
2. 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.

# Technical Support

St. Jude Medical Cardiac Rhythm Management Division 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.







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