

MRI-Ready Systems Manual

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

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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 system. Contact Technical Support (page 18) if you have any questions.

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

The St. Jude Medical MR Conditional system includes a St. Jude Medical MR Conditional device connected to one or more St. Jude Medical MR Conditional leads. For a list of the device/lead combinations that have been tested, see the device/lead combinations tables (page 2).

Testing has demonstrated that the St. Jude Medical™ MR Conditional 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 system to be safely scanned by an MRI scanner when used according to the instructions in this manual.

CAUTION

Not all of the products listed as MR Conditional are approved for MR Conditional use in all countries or regions. Before performing an MRI scan on patients implanted with any of these devices, contact St. Jude Medical or consult your regulatory authorities to determine if the products have been certified as MR Conditional.

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.
	MRI environment and conditions specified for device/lead combinations using 1.5 Tesla, full body scan, with a SAR (specific absorption rate) of 4 W/kg.
	MRI environment and conditions specified for device/lead combinations using 1.5 Tesla, restricted body scan, with a SAR (specific absorption rate) of 2 W/kg.

For a complete list of parameters, restrictions, and conditions for each device/lead combination, see MRI Scan Parameters table (page 1).

St. Jude Medical MR Conditional Systems

Personnel planning or performing an MRI scan of a patient with an MR Conditional system 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 Scan Parameters for St. Jude Medical Conditional Systems

When performing an MRI scan on a patient with a St. Jude Medical MR Conditional system, the following scan parameters must be followed.

Table 2. MRI scan parameters

Scan Parameters	Setting
Scanner Type	Cylindrical-bore magnet, horizontal field orientation
Magnet Strength	1.5 Tesla/64 MHz excitation frequency (hydrogen atom).
Spatial Field Gradient	≤30 T/m (3000 G/cm)
RF Power SAR	Varies for each device/lead combination. See the device/lead combinations tables below (page 2).
Head SAR	≤3.2 W/kg

Table 2. MRI scan parameters

Scan Parameters	Setting
Gradient Slew Rate	≤200 T/m/s
Scan Regions	Varies for each device/lead combination. See the device/lead combinations tables below (page 2).
Scan Time	Varies for each device/lead combination. See the device/lead combinations tables below (page 2).

NOTE

The above settings refer to full body transmit-only coils.

Use of some local transmit/receive RF coils has been found to be conditionally safe for use in the MRI environment, including:

- Head coil¹
- Lower extremity coil²
- Upper extremity coil³

Use of local transmit-only coils or local transmit and receive coils placed directly over the device has not been studied and such use is contraindicated.

CAUTION

Multiple leads can be connected to MR Conditional devices. Each lead needs to be checked for MRI compatibility and individual scan parameters.

Not all lead lengths are MR Conditional. The device/lead combinations tables below (page 2) lists the MR Conditional lead lengths.

In the device/lead combinations tables below (page 2), if the implantable system is comprised of a combination of leads that have different scan parameters [RF power (SAR)], scan region and/or additional considerations), use the most restrictive of each scan parameter to determine the overall set of scan conditions applicable for the total system.

St. Jude Medical MR Conditional Systems Device/Lead Combinations

Table 3. St. Jude Medical MR Conditional Systems Device/Lead Combinations for Accent MRI™ Devices

Device model	Lead model	RF Power (SAR)	Scan regions	Additional considerations
Accent MRI PM1124 PM1224 PM2124 PM2224	Tendril MRI LPA1200M (all lead lengths)	First-level controlled operating mode	Full body	N/A
	IsoFlex 1944 (lengths: 46 cm, 52 cm) 1948 (lengths: 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
	Tendril STS 2088TC (lengths: 46 cm, 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter 10 cm above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions

Table 4. St. Jude Medical MR Conditional Systems Device/Lead Combinations for Assurity MRI™ Devices

Device model	Lead model	RF Power (SAR)	Scan regions	Additional considerations
Assurity MRI PM1272 PM2272	Tendril MRI LPA1200M (all lead lengths)	First-level controlled operating mode	Full body	N/A

¹ Quadrature only, normal operating mode.

² Quadrature only, safe for all extremities except the hip, normal operating mode.

³ Quadrature only, safe for wrist area, normal operating mode.

Table 4. St. Jude Medical MR Conditional Systems Device/Lead Combinations for Assurity MRI™ Devices

Device model	Lead model	RF Power (SAR)	Scan regions	Additional considerations
	IsoFlex 1944 (lengths: 46 cm, 52 cm) 1948 (lengths: 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
	Tendril STS 2088TC (lengths: 46 cm, 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter 10 cm above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions

Table 5. St. Jude Medical MR Conditional Systems Device/Lead Combinations for Endurity™ Devices

Device model	Lead model	RF Power (SAR)	Scan regions	Additional considerations
Endurity MRI PM1172 PM2172	Tendril MRI LPA1200M (all lead lengths)	First-level controlled operating mode	Full body	N/A
	IsoFlex 1944 (lengths: 46 cm, 52 cm) 1948 (lengths: 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
	Tendril STS 2088TC (lengths: 46 cm, 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter 10 cm above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
Endurity PM1162 PM2162	Tendril MRI LPA1200M (all lead lengths)	Normal operating mode	Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
	IsoFlex 1944 (lengths: 46 cm, 52 cm) 1948 (lengths: 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
	Tendril STS 2088TC (lengths: 46 cm, 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter 10 cm above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
Endurity Core PM1140 PM1152 PM2140 PM2152	Tendril MRI LPA1200M (all lead lengths)	Normal operating mode	Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
	IsoFlex 1944 (lengths: 46 cm, 52 cm) 1948 (lengths: 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions
	Tendril STS 2088TC (lengths: 46 cm, 52 cm, 58 cm)	Normal operating mode	Superior: Isocenter 10 cm above the eye level Inferior: Isocenter at or below the L4 vertebra	30 min of total active scan time per session 30 min wait between sessions

Table 6. St. Jude Medical MR Conditional Systems Device/Lead Combinations for Ellipse™ Devices

Device model	Lead model	RF Power (SAR)	Scan regions	Additional considerations
Ellipse CD1377-36Q CD1377-36QC CD2377-36Q CD2377-36QC	Durata 7120Q (lengths: 58 cm, 65 cm)	Normal operating mode	If MRI Mode is "Pacing Off" : Full body	30 min of total active scan time per session 30 min wait between sessions
	7122Q (length: 58 cm, 65cm)			
	Optisure LDA220Q (lengths: 58 cm, 65 cm) LDA210Q (length: 58 cm, 65 cm)		Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L2 vertebra	
	Tendril MRI LPA1200M (all lead lengths)			
	Tendril STS 2088TC (lengths: 46 cm, 52 cm)	Normal operating mode	For MRI Mode "Pacing Off" , "VOO" , "AOO" or "DOO" : Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L2 vertebra	

Table 7. St. Jude Medical MR Conditional Systems Device/Lead Combinations for Fortify Assura™ Devices

Device model	Lead model	RF Power (SAR)	Scan regions	Additional considerations
Fortify Assura CD1359-40Q CD1359-40QC CD2359-40Q CD2359-40QC	Durata 7120Q (length: 58 cm, 65 cm)	Normal operating mode	If MRI Mode is "Pacing Off" : Superior: Isocenter at or above the eye level Inferior: Isocenter at or below the L2 vertebra	30 min of total active scan time per session 30 min wait between sessions
	7122Q (length: 58 cm)			
	7122Q (lengths: 65 cm)	Whole body SAR ≤1.6 W/kg		
	Optisure LDA220Q (lengths: 58 cm, 65 cm) LDA210Q (length: 58 cm)	Normal operating mode	Superior: Isocenter 10 cm above the eye level Inferior: Isocenter at or below the L4 vertebra	
	LDA210Q (length: 65 cm)			Whole body SAR, ≤1.6 W/kg
	Tendril MRI LPA1200M (all lead lengths)	Normal operating mode		
	Tendril STS 2088TC (lengths: 46 cm, 52 cm)	Normal operating mode		

Table 8. St. Jude Medical MR Conditional Systems Device/Lead Combinations for Quadra Assura™ and Quadra Assura MP™ Devices

Device model	Lead model	Whole body SAR	Scan regions	Additional considerations			
Quadra Assura CD3367-40Q CD3367-40QC	Quartet 1456Q (length: 86 cm) 1457Q (length: 86 cm) 1458Q (length: 86 cm) 1458QL (length: 86 cm)	Normal operating mode	Full body	30 min of total active scan time per session 30 min wait between sessions			
					Quadra Assura MP CD3371-40Q CD3371-40QC	Durata 7120Q (length: 58 cm, 65 cm) 7122Q (length: 58 cm, 65 cm)	
							Optisure LDA220Q (lengths: 58 cm, 65 cm) LDA210Q (lengths: 58 cm, 65 cm)

Instructions for Physicians and Clinicians

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

- Confirm that the Patient has an MR Conditional System (page 5)
- Confirm that No Adverse Conditions to MRI Scanning are Present (page 7)
- Review the Potential Adverse Events (page 7)
- Generate a Report of the Patient's Permanently Programmed Parameters (page 8)
- Select and Save MRI Settings (page 8)
- Review the MRI Checklist and Program the MRI Settings (page 11)
- Disable the MRI Settings (page 12)

I. Confirm that the Patient has an MR Conditional System

1. Review the patient's ID card or Parameter report (generated by the Merlin™ PCS) to obtain the model numbers for both the implanted lead(s) and device.
2. Check the model numbers against the appropriate device/lead combinations tables (page 2).

NOTE

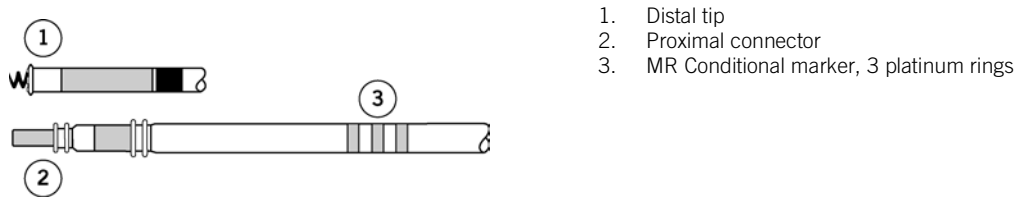
Not all lead lengths are MR Conditional. Check the lead lengths listed in the device/lead combinations tables (page 2) for MR Conditional lead lengths. Lead lengths not listed are untested.

3. Certain MR Conditional leads and devices 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. To further verify or confirm the presence of MR Conditional leads, you may wish to take an x-ray. The table below provides 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



NOTE

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 the appropriate St. Jude Medical MR Conditional leads.

Table 9. Presence of radiopaque MR Conditional marker in St. Jude Medical MR Conditional devices and leads

Model Name and Number	Radiopaque MR Conditional X-ray marker
Pacemakers	
Accent MRI PM1124 PM1224 PM2124 PM2224	Yes
Assurity MRI PM1272 PM2272	Yes
Endurity MRI PM1172 PM2172	Yes
Endurity PM1162 PM2162	Yes
Endurity Core PM1140 PM1152 PM2140 PM2152	Yes
CRT-Ds	
Quadra Assura CD3367-40Q CD3367-40QC	No
Quadra Assura MP CD3371-40Q CD3371-40QC	No
ICDs	
Ellipse CD1377-36Q CD1377-36QC CD2377-36Q CD2377-36QC	No
Fortify Assura CD1359-40Q CD1359-40QC CD2359-40Q CD2359-40QC	No
Pacing leads	
IsoFlex 1944 (lengths: 46 cm, 52 cm) 1948 (lengths: 52 cm, 58 cm)	No

Table 9. Presence of radiopaque MR Conditional marker in St. Jude Medical MR Conditional devices and leads

Model Name and Number	Radiopaque MR Conditional X-ray marker
Quartet 1456Q (length: 86 cm) 1457Q (length: 86 cm) 1458Q (length: 86 cm) 1458QL (length: 86 cm)	No
Tendril MRI LPA1200M (all lead lengths)	Yes
Tendril STS 2088TC (lengths: 46 cm, 52 cm, 58 cm)	No
Defibrillation leads	
Durata 7120Q (lengths: 58 cm, 65 cm) 7122Q (lengths: 58 cm, 65 cm)	No
Optisure LDA210Q (lengths: 58 cm, 65 cm) LDA220Q (lengths: 58 cm, 65 cm)	No

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

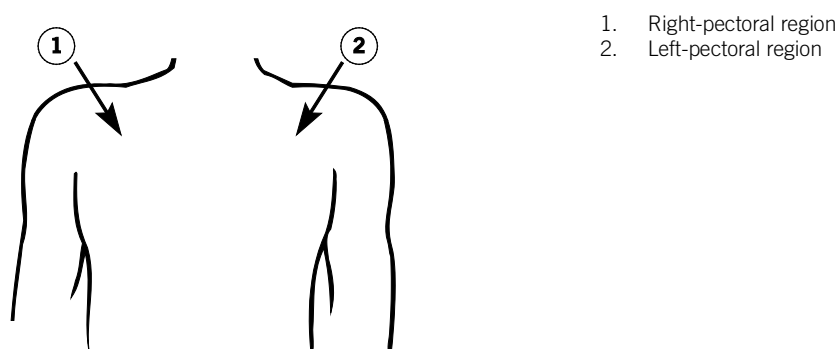
If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- Patient has elevated body temperature or compromised thermoregulation at time of scan, and if system includes any of 1944/1948/2088 lead or Ellipse/Fortify Assura/Quadra Assura/Quadra Assura MP device
- The device is at End-of-Life
- A combination of lead (s) and device that is not listed as MR Conditional in the device/lead combinations tables (page 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
- A St. Jude Medical MR Conditional 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 for RA and RV leads
- Capture threshold of >2.0V at a pulse width of 0.5ms for the LV lead
- 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
- Capacitor has not been prepared for the MRI scan (see VI. Review the MRI Checklist (page 11))

NOTE

Lead fractures or other damage to the leads may cause changes in the electrical properties of the St. Jude Medical MR Conditional 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 device implant



III. Review the Potential Adverse Events

The St. Jude Medical™ MR Conditional 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 if asynchronous pacing is programmed when MRI Settings are enabled
- Syncope due to loss of pacing if no pacing support is programmed with MRI settings
- Death due to untreated spontaneous arrhythmia because tachy therapy is disabled when MRI settings are programmed.

Potential interactions between the MRI scanner and the 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 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 MR Conditional 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 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™ Summary 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).

NOTE

Device diagnostic data may be suspended or cleared when MRI Settings are enabled. Refer to the table below for the behavior of each system.

Table 10. Diagnostic Data during MRI Settings

Device Family	Diagnostics
Accent MRI	Suspended with MRI Settings
Assurity MRI	Suspended with MRI Settings
Ellipse	Cleared from memory when MRI Settings are programmed
Endurity	Suspended with MRI Settings
Endurity Core	Suspended with MRI Settings
Endurity MRI	Suspended with MRI Settings
Fortify Assura	Cleared from memory when MRI Settings are programmed
Quadra Assura	Cleared from memory when MRI Settings are programmed
Quadra Assura MP	Cleared from memory when MRI Settings are programmed

For any device, it is recommended that the clinician perform a complete follow-up prior to the MRI procedure to save all diagnostic data.

V. Select and Save MRI Settings

NOTE

The Merlin PCS must be operating with software version 21.1.2 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 device.

Table 11. Default ICD MRI Settings

Parameter	Setting
MRI Mode	Pacing Off
MRI Base Rate	n/a
MRI Paced AV Delay	n/a
MRI Pulse Amplitude	n/a
MR Pulse Width	n/a
MRI Pulse Configuration	n/a
Tachy Therapy	Disabled

Table 12. Default MRI Settings for Pacing

Parameter	Setting
MRI Mode (dual-chamber devices)	DOO
MRI Mode (single-chamber devices)	VOO
MRI Base Rate	85 min [§]
MRI Paced AV Delay	120 ms
MRI Pulse Amplitude	5.0V
MR Pulse Width	1.0 ms
MRI Pulse Configuration	Bipolar

Table 13. Default MRI Settings for CRT-Ds

Parameter	Setting
MRI Mode	DOO
MRI Base Rate	85 min ⁻¹
MRI Paced AV Delay	120 ms
MRI Pulse Amplitude	5.0V
MR Pulse Width	1.0 ms
MRI Pulse Configuration	Bipolar
MRI V Pacing Chamber	RV Only
Tachy Therapy	Disabled

If you change the MRI Settings from the default values, you must save the modified MRI Settings in the device as described below. Refer to the Merlin PCS on-screen help for information on selecting, testing, and saving the MRI parameter settings.

1. After you interrogate the device with the Merlin PCS, select the Parameters button on the right to open the Parameters window. Then, select the MRI Settings tab. This opens the MRI Settings window.
2. From this window, you can modify the default values of the MRI parameters that are in effect when the MRI Settings are enabled.
3. For ICDs and CRT-Ds, select the appropriate HV lead type implanted in the patient
 - For patients implanted with dual coil defibrillation lead, select Dual Coil value
 - For patients implanted with single coil defibrillation lead, select the Single Coil value

NOTE:

Selecting the correct HV lead type ensures appropriate testing during MRI setup.

4. 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.
5. Select the Cancel Test button to return to permanently programmed settings.
6. Select the Save MRI Settings button to save any changed parameters.

NOTE:

MRI Pacing Chamber defaults to RV only in CRT devices. Left Ventricular pacing will be turned off when MRI settings are programmed

- If you plan to use the SJM MRI Activator™ handheld device to implement the MRI Settings, you must review the MRI Activator Checklist and enable the pulse generator to communicate with the handheld device. See Enabling the Device to Communicate with the SJM MRI Activator handheld device below.

NOTE

Only certain devices can be programmed by the SJM MRI Activator handheld device. For a list of these devices, see the table below.

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.

- When you are satisfied with the MRI Settings, select the Setup for MRI Now button to run the system integrity tests required for MRI setup.

CAUTION

Regardless of the programmed permanent pacing mode, sensed events are ignored by the device 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 Mode to an available asynchronous pacing mode (DOO, AOO, or VOO). When pacing support is not needed, set the MRI Mode to Pacing Off.

Some patients may be susceptible to cardiac arrhythmia induced by competitive pacing when an asynchronous MRI 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.

In MR Conditional ICDs and CRT-Ds, tachycardia therapy is disabled when the MRI settings are programmed.

Enabling the Device to Communicate with the SJM MRI Activator™ handheld device

To use the SJM MRI Activator™ handheld device, you must first enable the pulse generator to communicate with the handheld device. This is done through the MRI Settings window on the Merlin™ PCS.

NOTE

Before communication between the SJM MRI Activator handheld device and the pulse generator can be enabled, you must obtain in-range bipolar pacing lead impedance measurements from the current programming session.

To enable the pulse generator to communicate with the handheld device:

- Determine the appropriate MRI Settings as described above.
- From the MRI Settings window, select the Setup MRI Activator button.
The MRI Activator Checklist window opens.
- Review each condition on the checklist and check off each one that applies. You will not be able to enable the pulse generator to communicate with the handheld device until all boxes are checked.
Once you have verified each condition, the Enable MRI Activator button becomes available.
- Select the Enable MRI Activator button.
The device can now communicate with the handheld device.

Table 14. St. Jude Medical MR Conditional pulse generators⁴ with SJM MRI Activator™ device functionality

Model Name and Number	Operates with the SJM MRI Activator handheld device Model EX4000
Pacemakers	
Accent MRI PM1124 PM1224 PM2124 PM2224	Yes
Assurity MRI PM1272 PM2272	Yes
Endurity MRI PM1172 PM2172	Yes
Endurity PM1162 PM2162	Yes
Endurity Core PM1140 PM1152 PM2140 PM2152	Yes
CRT-Ds	

⁴ Not all device models are available in all countries.

Table 14. St. Jude Medical MR Conditional pulse generators⁴ with SJM MRI Activator™ device functionality

Model Name and Number	Operates with the SJM MRI Activator handheld device Model EX4000
Quadra Assura CD3367-40Q CD3367-40QC	No
Quadra Assura MP CD3371-40Q CD3371-40QC	No
ICDs	
Ellipse CD1377-36Q CD1377-36QC CD2377-36Q CD2377-36QC	No
Fortify Assura CD1359-40Q CD1359-40QC CD2359-40Q CD2359-40QC	No

VI. Review the MRI Checklist

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

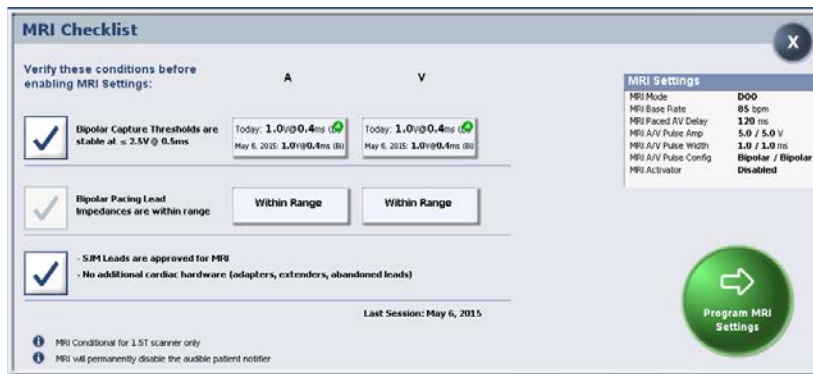


Figure 5. An example of the MRI Checklist screen for ICDs on the Merlin PCS

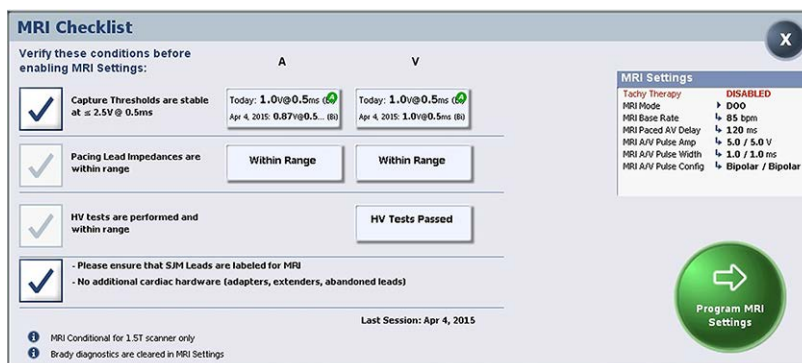


Figure 6. An example of the MRI Checklist screen for CRT-Ds on the Merlin PCS



1. After you have selected the appropriate MRI Settings, from the MRI Settings window on the Merlin PCS, select the Setup for MRI Now button.

After the system performs test measurements required for MRI setup, the MRI Checklist window opens.

2. 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.

The MRI software provides automatic verification that no device or lead issues are detected that may compromise patient safety during an MRI scan. Before allowing the user to initiate the MRI Settings, the MRI software ensures:

- Pacing lead impedance is within range - If bipolar pacing lead impedance for RA, RV, or LV leads is out of range, the software prevents the MRI Settings from being enabled.
- Defibrillation lead impedance is within range - If the lead impedance for any of the implanted coils on the defibrillation lead is out of range, the software prevents the MRI Settings from being enabled.
- Capacitor maintenance is postponed - For ICDs and CRT-Ds, the software prepares the capacitor to prevent automatic capacitor maintenance from occurring during an MRI scan.

3. If any of the system integrity tests required for MRI setup is incomplete, Perform Test will be displayed on the test panel in the MRI Checklist. Click on the panel to manually run the incomplete test before enabling MRI settings.

4. Once you have completed the checklist, select the Program MRI Settings button to enable the MRI Settings.

MRI Settings: MRI Summary Report window appears. This window confirms the programmed changes. Use this window to print the MRI Summary report and end the session (recommended) before performing the MRI scan. MRI Settings can also be disabled in this window.

NOTE

If the programmer Shock button is selected when MRI settings are enabled, the system will disable the MRI settings and display the emergency shock dialog box. After an emergency shock, restore the MRI settings before scanning the patient.

5. Select Print MRI Report button to print the report.
6. Select End Session.

The patient is now ready for the MR scan.

CAUTION:

An ICD or CRT-D patient must be hemodynamically monitored while MRI settings are programmed, and an external defibrillator must be kept continuously ready.

Be sure to disable the MRI Settings as soon as the MRI scan is complete.

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 device using the Merlin™ PCS or the SJM MRI Activator handheld device.
2. For the SJM MRI Activator handheld device, select the MRI Settings Off button.

For the Merlin PCS, disable the MRI Settings by selecting the Disable MRI Settings button. This restores the permanently programmed settings.

- a. Confirm the permanently programmed settings are appropriate.
- b. To ensure that an accurate lead impedance measurement, perform a lead impedance test by selecting Tests > Battery & Leads > Update leads.
- c. Check the pacing capture thresholds after the scan is complete and ensure that the pacing parameters are programmed adequately for the patient based on the threshold.

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

NOTE

If the device performs an automatic lead impedance measurement during the procedure, the results may be inaccurate. The magnetic field exerted by the MRI scanner can sometimes result in an inaccurate lead impedance measurement.

Instructions for Radiologists and MRI Technicians

The role of the radiologist or MRI Technician is to:

- Confirm that the Patient has an MR Conditional System (page 13)
- Confirm that No Adverse Conditions to MRI Scanning are Present (page 14)
- Review the Potential Adverse Events between the MRI Scanner and the MR Conditional System (page 15)
- Select the Correct Scan Parameters (page 15)
- Check the MRI Settings Status (page 15)
- Perform the Scan and Monitor the Patient (page 17)
- Disable the MRI Settings (page 18)

I. Confirm that the Patient has an MR Conditional System

1. Review the patient's ID card or the MRI Summary Report (generated by the Merlin PCS) to obtain the model numbers for both the implanted lead(s) and device.
2. Check the model numbers against the appropriate device/lead combinations tables (page 2).

NOTE

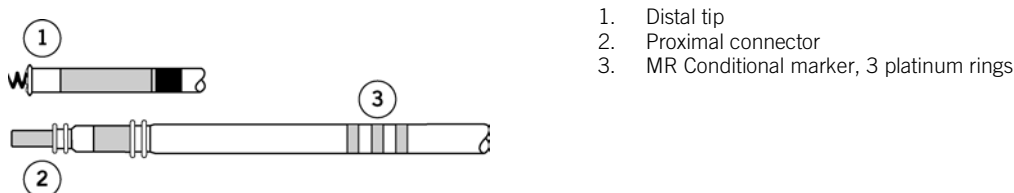
Not all lead lengths are MR Conditional. Check the lead lengths listed in the device/lead combinations tables (page 2) for MR Conditional lead lengths. Lead lengths not listed are untested.

Certain MR Conditional leads and devices 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. To further verify or confirm the presence of MR Conditional leads, you may wish to take an x-ray. The table below provides information on which products contain the MR Conditional radiopaque marker.

Figure 7. Radiopaque MR Conditional marker in pacemaker models



Figure 8. Radiopaque MR Conditional marker in Tendril MRI lead models



NOTE

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 the appropriate St. Jude Medical MR Conditional leads.

Table 15. Presence of radiopaque MR Conditional marker in St. Jude Medical MR Conditional devices and leads

Model Name and Number	Radiopaque MR Conditional X-ray marker
Pacemakers	
Accent MRI	Yes
PM1124	
PM1224	
PM2124	
PM2224	
Assurity MRI	Yes
PM1272	
PM2272	

Table 15. Presence of radiopaque MR Conditional marker in St. Jude Medical MR Conditional devices and leads

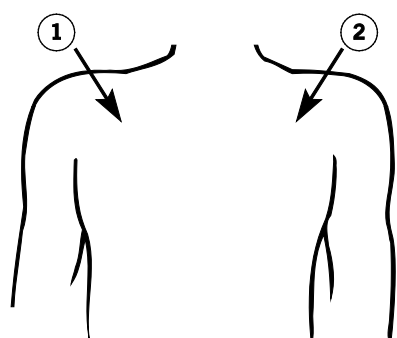
Model Name and Number	Radiopaque MR Conditional X-ray marker
Endurity MRI PM1172 PM2172	Yes
Endurity PM1162 PM2162	Yes
Endurity Core PM1140 PM1152 PM2140 PM2152	Yes
CRT-Ds	
Quadra Assura CD3367-40Q CD3367-40QC	No
Quadra Assura MP CD3371-40Q CD3371-40QC	No
ICDs	
Ellipse CD1377-36Q CD1377-36QC CD2377-36Q CD2377-36QC	No
Fortify Assura CD1359-40Q CD1359-40QC CD2359-40Q CD2359-40QC	No
Pacing leads	
IsoFlex 1944 (lengths: 46 cm, 52 cm) 1948 (lengths: 52 cm, 58 cm)	No
Quartet 1456Q (length: 86 cm) 1457Q (length: 86 cm) 1458Q (length: 86 cm) 1458QL (length: 86 cm)	No
Tendril MRI LPA1200M (all lead lengths)	Yes
Tendril STS 2088TC (lengths: 46 cm, 52 cm, 58 cm)	No
Defibrillation leads	
Durata 7120Q (lengths: 58 cm, 65 cm) 7122Q (lengths: 58 cm, 65 cm)	No
Optisure LDA210Q (lengths: 58 cm, 65 cm) LDA220Q (lengths: 58 cm, 65 cm)	No

II. 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:

- Patient has elevated body temperature or compromised thermoregulation at time of scan, if system includes any of 1944/1948/2088 lead or Ellipse/Fortify Assura/Quadra Assura/Quadra Assura MP device.
- A combination of lead(s) and device that is not listed as MR Conditional in the device/lead combinations tables (page 2).
- A St. Jude Medical MR Conditional system implanted in sites other than the left and right pectoral region (see figure below)
- Positioning patients on their side (lateral recumbent) within the MRI bore

Figure 9. Correct locations for device implant



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

III. Review the Potential Adverse Events

The St. Jude Medical™ MR Conditional 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 if asynchronous pacing is programmed when MRI Settings are enabled
- Syncope due to loss of pacing if no pacing support is programmed with MRI settings
- Death due to untreated spontaneous arrhythmia because tachy therapy is disabled when MRI settings are programmed.

Potential interactions between the MRI scanner and the 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 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 MR Conditional 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 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. Select the Correct Scan Parameters

1. See the MRI Scan Parameters table (page 1) for the applicable scan parameter settings for approved MR Conditional device/lead combinations.
2. Refer the St. Jude Medical™ MR Conditional Systems in the device/lead combinations tables (page 2) to identify the settings for RF power (SAR) and scan regions and to note any additional considerations for specific device/lead combinations.
3. Make sure that you identify the **combination** of both the device and the lead(s) to select the correct settings
4. If the implantable system is comprised of a combination of leads that have different scan parameters [RF power (SAR)], scan region and/or additional considerations), use the most restrictive of each scan parameter to determine the overall set of scan conditions applicable for the total system.
5. For ICD devices, identify the programmed MRI Mode setting using the MRI Summary Report to properly select the scan parameter settings.

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 16).

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 16).

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 16. MRI Settings⁵

Parameter	Setting
Tachy Therapy (ICD and CRT-D patients)	Disabled
MRI Mode	DOO, VOO, AOO, ⁶ Pacing Off
MRI Base Rate	Pacemakers: 30 - 120 min ⁻¹ ICDs and CRT-Ds: 30-100 min [§]
MRI Paced AV Delay	25 - 120 ms
MRI Pulse Amplitude	5.0 or 7.5 V
MR Pulse Width	1.0 ms
MRI Pulse Configuration	Bipolar
MRI V. Pacing Chamber (CRT-D patients)	RV only

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

To check the status of the MRI Settings:

1. Refer to the table below to determine if the device can communicate with the handheld device.
 2. Place the handheld device over the implanted device.
- The handheld device should be held against the patient's chest directly over the implanted pulse generator. For the proper location, see the figure above.
3. Press the MR Status button.



- MRI Settings Enabled. The green LEDs (on the right side of the handheld device) illuminate continuously for 5 seconds.
- MRI Settings Disabled. The red LEDs (on the left side of the handheld device) illuminate continuously for 5 seconds.

Figure 10. SJM MRI Activator handheld device



1. MR Status button
2. MRI Settings On button
3. Green LED
4. MRI Settings Off button
5. Red LED

If the MRI Settings are not enabled and the patient is ready for the MRI scan, enable the settings with the handheld device.

To enable the MRI Settings:

1. Place the handheld device over the implanted pulse generator.

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

See MR Conditional Pulse Generator Implant Location.

⁵ This is the entire range of all possible settings for this parameter.

⁶ Available only in single chamber pacemakers.

2. Press the MRI Settings On button.



The LEDs may flash before they illuminate continuously.

- MRI Settings Enabled. The green LEDs (on the right side of the handheld device) illuminate continuously for 5 seconds.
- MRI Settings Disabled. The red LEDs (on the left side of the handheld device) illuminate continuously for 5 seconds.

Table 17. St. Jude Medical MR Conditional pulse generators⁷ with SJM MRI Activator™ device functionality

Model Name and Number	Operates with the SJM MRI Activator handheld device Model EX4000
Pacemakers	
Accent MRI PM1124 PM1224 PM2124 PM2224	Yes
Assurity MRI PM1272 PM2272	Yes
Endurity MRI PM1172 PM2172	Yes
Endurity PM1162 PM2162	Yes
Endurity Core PM1140 PM1152 PM2140 PM2152	Yes
CRT-Ds	
Quadra Assura CD3367-40Q CD3367-40QC	No
Quadra Assura MP CD3371-40Q CD3371-40QC	No
ICDs	
Ellipse CD1377-36Q CD1377-36QC CD2377-36Q CD2377-36QC	No
Fortify Assura CD1359-40Q CD1359-40QC CD2359-40Q CD2359-40QC	No

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.

Keep an external defibrillator available during the MRI scan.

⁷ Not all device models are available in all countries.

CAUTION

In MR Conditional ICDs and CRT-Ds, tachycardia therapy is disabled when the MRI settings are programmed.

CAUTION

An ICD or CRT-D patient must be hemodynamically monitored while MRI settings are programmed, and an external defibrillator must be kept constantly ready.

Be sure to disable the MRI Settings as soon as the MRI scan is complete.

St. Jude Medical MR Conditional leads have demonstrated minimal image distortion for areas surrounding the implanted leads when the device is out of the field of view. Significant image distortion can result from the presence of the device within the field of view. Image artifacts and distortion resulting from the presence of the device 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 handheld device over the implanted device.
The handheld device should be touching the patient's clothing directly over the implanted device.
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.

3. If you are not using the handheld device, the MRI settings must be disabled by the patient's device management physician or clinician using the Merlin PCS programmer.

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.

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