MRI-Ready Systems Manual

MRI Procedure Information for the Abbott Medical MR Conditional System

Abbott

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.

Contents

Introduction

This manual explains the procedures and precautions that must be followed when scanning a patient who is implanted with an Abbott 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 Abbott Medical MR Conditional system. Contact Technical Support if you have any questions (page 16).

Refer to the Merlin™ Patient Care System (PCS) or Merlin™ 2 Patient Care System (PCS) on-screen help or to the appropriate device or lead user's manual for non-MRI related information.

The Abbott Medical MR Conditional system includes an Abbott Medical MR Conditional device connected to one or more Abbott Medical MR Conditional leads. For a list of the device/lead combinations that have been tested, refer to the Abbott Medical MR Conditional Systems Device/Lead Combination tables (3T MRI tables (page 3) or 1.5T MRI tables (page 5)). The system remains MR Conditional when an Abbott Medical port plug is placed in an unused port of the device header.

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

Enable 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.

Refer to the appropriate device 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.

MRI Safety Information

A patient with this system may be safely scanned under the conditions given in this manual.

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

NOTE: All Abbott Medical MR Conditional systems can be scanned using 1.5 Tesla (1.5T) MRI scanners and some MR Conditional systems can also be scanned using 3 Tesla (3T) MRI scanners. Refer to the sections below to identify the MRI scanner type and scan parameters for the MR Conditional device/lead combinations.

3T MRI Scan Parameters for MR Conditional Systems

When performing a 3T MRI scan on a patient with an MR Conditional system, the following scan parameters must be followed.

Table 2. 3T MRI scan parameters

Scan Parameter	Setting
Item Name/Identification	Refer to 3T MR Conditional Systems Device/Lead Combination tables (page 3)
Static Magnetic Field Strength 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	30 T/m (3000 Gauss/cm)
Maximum Gradient Slew Rate per axis	200 T/m/s
RF Transmit Conditions	Refer to 3T MR Conditional Systems Device/Lead Combination tables (page 3)
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 to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 7) Refer to Instructions for Radiologists and MRI Technologists to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 13) ▪ Perform the Scan and Monitor the Patient (page 15)
Patient Position in Scanner	Supine or prone; patient's arms must be at his or her sides.
Device Configuration	**CAUTION: Multiple leads can be connected to an MR Conditional device. Confirm that each individual lead meets MRI conditions for use. The 3T MR Conditional Systems Device/Lead Combination tables below (page 3) list the MR Conditional leads.** **CAUTION: Not all lead lengths are MR Conditional. The 3T MR Conditional Systems Device/Lead Combination tables below (page 3) list the MR Conditional lead lengths.** Device implanted in the left or right pectoral region.
Instructions to be followed before and after the MRI exam	Device programming is required for safe scanning: MRI Settings must be enabled before start of scan and disabled after completion of scan. Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 7) ▪ Instructions for Radiologists and MRI Technologists (page 13)
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.

3T MR Conditional Systems Device/Lead Combinations

CAUTION: Only the lead lengths in the tables below are MR Conditional with the devices listed.

Pacemakers

Table 3. 3T MR Conditional Systems device/lead combinations for Assurity MRI™ and Endurity MRI™ pacemakers

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Assurity MRI PM1272 PM2272 **Endurity MRI** PM1172 PM2172	**UltiPace™** LPA1231	46 cm, 52 cm, 58 cm, 65 cm	Normal Operating Mode Integrated Whole Body RF Transmit coil with RF excitation: ▪ Circularly polarized (CP), or ▪ Multichannel-2 (MC-2)	Full-body
	Tendril™ STS 2088TC	46 cm, 52 cm, 58 cm		
	IsoFlex™ 1944 1948	46 cm, 52 cm 52 cm, 58 cm		

1.5T MRI Scan Parameters for MR Conditional Systems

When performing a 1.5T MRI scan on a patient with an MR Conditional system, the following scan parameters must be followed.

Table 4. 1.5T MRI scan parameters

Scan Parameter	Setting
Item Name/Identification	Refer to 1.5T MR Conditional Systems Device/Lead Combination tables (page 5)
Static Magnetic Field Strength 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	30 T/m (3000 Gauss/cm)
Maximum Gradient Slew Rate per axis	200 T/m/s
RF Transmit Conditions	Refer to 1.5T MR Conditional Systems Device/Lead Combination tables (page 5)
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 to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 7) Refer to Instructions for Radiologists and MRI Technologists to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 13) ▪ Perform the Scan and Monitor the Patient (page 15)
Patient Position in Scanner	Supine or prone; patient's arms must be at his or her sides.
Device Configuration	**CAUTION: Multiple leads can be connected to an MR Conditional device. Confirm that each individual lead meets MRI conditions for use. The 1.5T MR Conditional Systems Device/Lead Combination tables below (page 5) list the MR Conditional leads.** **CAUTION: Not all lead lengths are MR Conditional. The 1.5T MR Conditional Systems Device/Lead Combination tables below (page 5) list the MR Conditional lead lengths.** Device implanted in the left or right pectoral region.
Instructions to be followed before and after the MRI exam	Device programming is required for safe scanning: MRI Settings must be enabled before start of scan and disabled after completion of scan. Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 7) ▪ Instructions for Radiologists and MRI Technologists (page 13)
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 MR Conditional Systems Device/Lead Combinations

CAUTION: Only the lead lengths in the tables below are MR Conditional with the devices listed.

Pacemakers

Table 5. 1.5T MR Conditional Systems device/lead combinations for Accent MRI™ pacemakers

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Accent MRI PM1224 PM2218	**Tendril MRI™** LPA1200M	46 cm, 52 cm, 58 cm	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)	Full-body

Table 6. 1.5T MR Conditional Systems device/lead combinations for Assurity MRI™ and Endurity MRI™ pacemakers

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Assurity MRI PM1272 PM2272 **Endurity MRI** PM1172 PM2172	**UltiPace™** LPA1231	46 cm, 52 cm, 58 cm, 65 cm	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)	Full-body
	Tendril MRI™ LPA1200M	46 cm, 52 cm, 58 cm		
	Tendril™ STS 2088TC			
	IsoFlex™ 1944 1948	46 cm, 52 cm 52 cm, 58 cm		

CRT-Ps

Table 7. 1.5T MR Conditional Systems device/lead combinations for Quadra Allure™ and Quadra Allure MP™ CRT-Ps

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Quadra Allure PM3542 **Quadra Allure MP** PM3562	**Quartet™** 1456Q 1457Q 1458Q 1458QL	86 cm	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)	Full-body
	Tendril™ STS 2088TC	46 cm, 52 cm, 58 cm		

ICDs

Table 8. 1.5T MR Conditional Systems device/lead combinations for Ellipse™ ICDs

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Ellipse CD1311-36Q CD1411-36Q CD1411-36QC CD2311-36Q CD2411-36Q CD2411-36QC	**Durata™** 7120Q 7122Q	58 cm, 65 cm	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)	Full-body
	Optisure™ LDA220Q LDA210Q			
	Tendril MRI™ LPA1200M	46 cm, 52 cm		
	Tendril™ STS 2088TC			

Table 9. 1.5T MR Conditional Systems device/lead combinations for Fortify Assura™ ICDs

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Fortify Assura CD1357-40Q CD1357-40QC CD2357-40Q CD2357-40QC	**Durata™** 7120Q 7122Q	58 cm, 65 cm	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)	Full-body
	Optisure™ LDA220Q LDA210Q			
	Tendril MRI™ LPA1200M	46 cm, 52 cm		
	Tendril™ STS 2088TC			

CRT-Ds

Table 10. 1.5T MR Conditional Systems device/lead combinations for Quadra Assura™ and Quadra Assura MP™ CRT-Ds

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Quadra Assura CD3365-40Q CD3365-40QC **Quadra Assura MP** CD3369-40Q CD3369-40QC	**Quartet™** 1456Q 1457Q 1458Q 1458QL	86 cm	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)	Full-body
	Durata™ 7120Q 7122Q	58 cm, 65 cm		
	Optisure™ LDA210Q LDA220Q			
	Tendril MRI™ LPA1200M	46 cm, 52 cm		
	Tendril™ STS 2088TC			

Instructions for Cardiac Physicians and Clinicians

NOTE: Radiologists and MRI technologists should see Instructions for Radiologists and MRI Technologists (page 13).

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

- Confirm that the Patient has an MR Conditional System (page 7)
- 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 MRI Settings (page 10)
- Disable MRI Settings (page 11)

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 or Merlin™ 2 PCS) to obtain the model numbers for both the implanted lead or leads, and device.
2. Check the model numbers against the Abbott Medical MR Conditional Device/Lead Combination tables (3T MRI tables (page 3) or 1.5T MRI tables (page 5)).

   NOTE: Multiple leads can be connected to an MR Conditional device. Not all lead lengths are MR Conditional. Confirm that each individual lead meets MRI conditions for use.

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

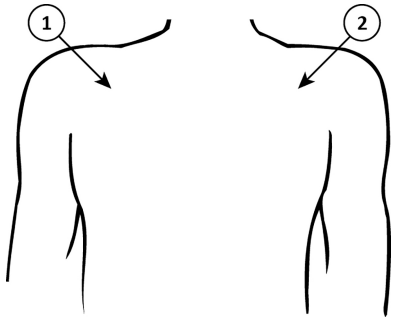
If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- Patient has elevated body temperature or compromised thermoregulation at time of scan
- Device is at End-of-Service
- A combination of one or more leads and a device that is not listed as MR Conditional in the Abbott Medical MR Conditional Systems Device/Lead Combination tables (3T MRI tables (page 3) or 1.5T MRI tables (page 5))
- Broken or intermittently functioning Abbott Medical MR Conditional leads
- Lead impedance measurements not within the programmed lead impedance limits
- Additional cardiac hardware including lead extenders, lead adapters, or abandoned leads
- A device implanted in a location other than the left or right pectoral region (see figure below)
- Patients with unstable capture thresholds
- Patients with capture threshold values >2.5 V at a pulse width of 0.5 ms for RA and RV leads
- For CRT-Ps and CRT-Ds, patients with capture threshold values >2.0 V at a pulse width of 0.5 ms for the LV lead
- Complaints of diaphragmatic stimulation with a pacing output of 5.0 V or 7.5 V 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
- For ICDs and CRT-Ds, capacitor has not been prepared for the MRI scan (see Review the MRI Checklist & Program MRI Settings (page 10))

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

  Scanning patients who have other MR Conditional devices that are not implanted in cardiac tissue is acceptable provided all MR Conditional requirements for each implanted device are met.

Figure 1. Correct locations for device implant



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

III. Review the Potential Adverse Events

The Abbott 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 dislodgement
- 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

- For ICDs and CRT-Ds, death due to untreated spontaneous arrhythmia because Tachy therapy is disabled when MRI Settings are programmed

Potential interactions between the MRI scanner and the MR Conditional 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 Abbott 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 currents induced on the leads of the Abbott 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 potentially interact with the device, resulting in heating. 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, Abbott 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 any external control devices, such as the Merlin™ Patient Care System (PCS) Model 3650 or Merlin™ 2 Patient Care System (PCS) Model MER3700, or SJM MRI Activator™ handheld device Model EX4000, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.

1. Interrogate the device with the Merlin PCS or Merlin 2 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 or Merlin 2 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 11. Diagnostic data during MRI Settings

Device family	Diagnostics
Pacemakers	
Accent MRI™ pacemakers	Suspended with MRI Settings enabled
Assurity MRI™ pacemakers	Suspended with MRI Settings enabled
Endurity MRI™ pacemakers	Suspended with MRI Settings enabled
CRT-Ps	
Quadra Allure™ CRT-Ps	Suspended with MRI Settings enabled
Quadra Allure MP™ CRT-Ps	Suspended with MRI Settings enabled
ICDs	
Ellipse™ ICDs	Cleared from memory when MRI Settings are programmed
Fortify Assura™ ICDs	Cleared from memory when MRI Settings are programmed
CRT-Ds	
Quadra Assura™ CRT-Ds	Cleared from memory when MRI Settings are programmed
Quadra Assura MP™ CRT-Ds	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 25.2.1 or greater, and the Merlin™ 2 PCS with version 1.2.1 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 Abbott Medical MR Conditional device.

Table 12. Default MRI Settings for Pacemakers

Parameter	Setting
MRI mode (dual-chamber pacemakers)	DOO
MRI mode (single-chamber pacemakers)	VOO or AOO (as applicable)
MRI base rate	85 bpm
MRI paced AV delay	120 ms
MRI pulse amplitude	5.0 V
MRI pulse width	1.0 ms
MRI pulse configuration	Bipolar

Table 13. Default MRI Settings for CRT-Ps

Parameter	Setting
MRI mode	DOO
MRI base rate	85 bpm

Table 13. Default MRI Settings for CRT-Ps

Parameter	Setting
MRI paced AV delay	120 ms
MRI pulse amplitude	5.0 V
MRI pulse width	1.0 ms
MRI pulse configuration	Bipolar
MRI V pacing chamber	RV only

Table 14. Default MRI Settings for ICDs

Parameter	Setting
Tachy therapy	Disabled
MRI mode	Pacing Off
MRI base rate	n/a
MRI paced AV delay	n/a
MRI pulse amplitude	n/a
MRI pulse width	n/a
MRI pulse configuration	n/a

Table 15. Default MRI Settings for CRT-Ds

Parameter	Setting
Tachy therapy	Disabled
MRI mode	DOO
MRI base rate	85 bpm
MRI paced AV delay	120 ms
MRI pulse amplitude	5.0 V
MRI pulse width	1.0 ms
MRI pulse configuration	Bipolar
MRI V pacing chamber	RV only

If you change MRI Settings from the default values, you must save the modified MRI Settings in the device as described below.

Refer to the Merlin PCS or Merlin 2 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 or Merlin 2 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 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-P and CRT-D devices. Left Ventricular pacing will be turned off when MRI Settings are programmed.
7. If you plan to use the SJM MRI Activator™ handheld device to implement MRI Settings, you must review the MRI Activator Checklist and enable the pulse generator to communicate with the SJM MRI Activator handheld device. See Enabling the Device to Communicate with the SJM MRI Activator handheld device (page 9).
8. When you are satisfied with MRI Settings, select the Setup for MRI Now button to open the MRI Checklist.

   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.

   For ICDs and CRT-Ds, Tachy therapy is disabled when MRI Settings are programmed, leaving the patient at risk of death from spontaneous tachyarrhythmia. Disable MRI Settings immediately after the MRI scan is complete using the Merlin PCS or Merlin 2 PCS.

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 SJM MRI Activator handheld device. This is done through the MRI Settings window on the Merlin™ PCS or Merlin™ 2 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. If you plan to use the SJM MRI Activator handheld device to implement MRI

Settings, program V. AutoCapture "on" prior to enabling MRI Settings. The AutoCapture feature will provide a safety margin against increased pacing capture thresholds that may occur post-MRI due to lead tip heating.

To enable the pulse generator to communicate with the SJM MRI Activator handheld device:

1. Determine the appropriate MRI Settings as described above.
2. From the MRI Settings window, select the Setup MRI Activator button.
   The MRI Activator Checklist window opens.
3. 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 SJM MRI Activator handheld device until all boxes are checked.
   Once you have verified each condition, the Enable MRI Activator button becomes available.
4. Select the Enable MRI Activator button.
   The device can now communicate with the SJM MRI Activator handheld device.

Table 16. Abbott Medical MR Conditional pulse generators with SJM MRI Activator™ handheld device functionality

Model name and number	Operates with the SJM MRI Activator handheld device Model EX4000
Pacemakers	
Accent MRI™ pacemakers PM1224, PM2218	**Yes**
Assurity MRI™ pacemakers PM1272, PM2272	**Yes**
Endurity MRI™ pacemakers PM1172, PM2172	**Yes**
CRT-Ps	
Quadra Allure™ CRT-Ps PM3542	**No**
Quadra Allure MP™ CRT-Ps PM3562	**No**
ICDs	
Ellipse™ ICDs CD1311-36Q, CD1411-36Q, CD1411-36QC, CD2311-36Q, CD2411-36Q, CD2411-36QC	**No**
Fortify Assura™ ICDs CD1357-40Q, CD1357-40QC, CD2357-40Q, CD2357-40QC	**No**
CRT-Ds	
Quadra Assura™ CRT-Ds CD3365-40Q, CD3365-40QC	**No**
Quadra Assura MP™ CRT-Ds CD3369-40Q, CD3369-40QC	**No**

VI. Review the MRI Checklist and Program MRI Settings

Figure 2. An example of the MRI Checklist screen for pacemakers on the **Merlin**™ PCS or **Merlin**™ 2 PCS

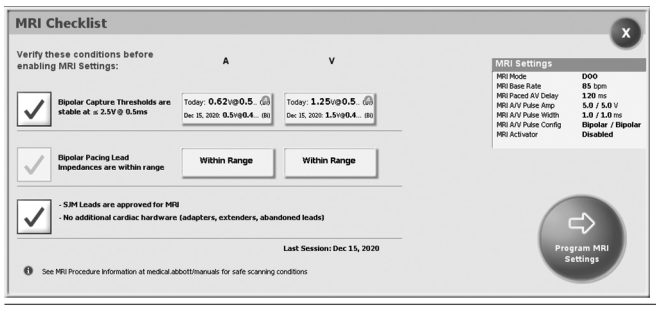


Figure 3. An example of the MRI Checklist screen for CRT-Ps on the **Merlin**™ PCS or **Merlin**™ 2 PCS

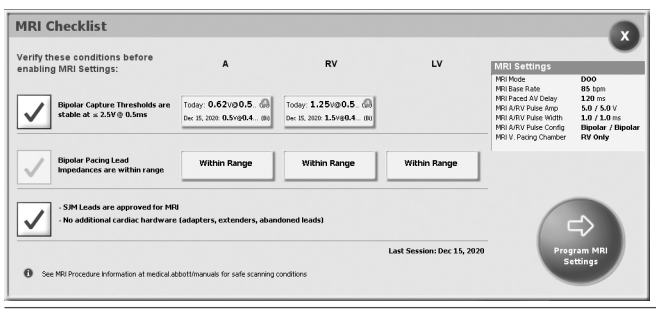


Figure 4. An example of the MRI Checklist screen for ICDs on the **Merlin**™ PCS or **Merlin**™ 2 PCS

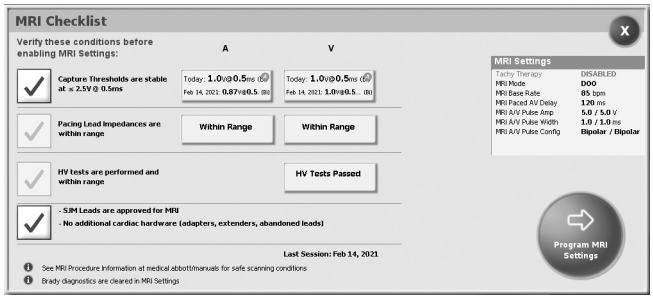
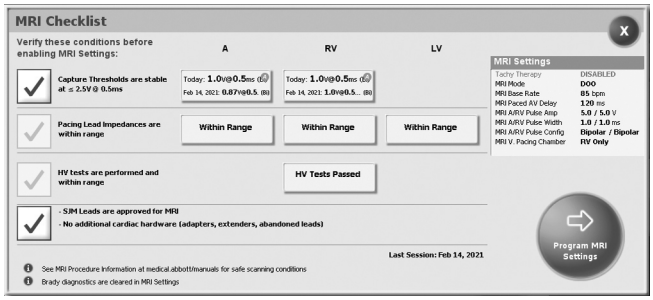


Figure 5. An example of the MRI Checklist screen for CRT-Ds on the **Merlin**™ PCS or **Merlin**™ 2 PCS



1. After you have selected the appropriate MRI Settings, from the MRI Settings window on the Merlin™ PCS or Merlin™ 2 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 boxes 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 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 MRI Settings from being enabled.
   - Defibrillation lead impedance is within range - For ICDs and CRT-Ds, if the lead impedance for any of the implanted coils on the defibrillation lead is out of range, the software prevents MRI Settings from being enabled.
   - Capacitor prepared - For ICDs and CRT-Ds, the software prevents imminent automatic capacitor maintenance from occurring during an MRI scan, and discharges the capacitor.

     CAUTION: For ICDs and CRT-Ds, be sure to enable MRI Settings just before the MRI scan, and disable MRI Settings immediately after the MRI scan to minimize the time in MRI Settings. When MRI Settings are enabled, Tachy therapy is disabled, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia.
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 MRI Settings.

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

   NOTE: For ICDs and CRT-Ds, if the programmer Shock button is selected when MRI Settings are enabled, the system will disable MRI Settings and display the emergency shock dialog box. After an emergency shock, restore MRI Settings before scanning the patient. Once you have completed the checklist, select the Program MRI Settings button to enable MRI Settings.
5. Select Print MRI Report button to print the report.
6. Select End Session.

The patient is now ready for the MRI scan.

CAUTION: An ICD or CRT-D patient must be hemodynamically monitored and an external defibrillator must be available and ready while MRI Settings are programmed.

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

VII. Disable MRI Settings

CAUTION: Do not bring any external control devices, such as the Merlin™ Patient Care System (PCS) Model 3650 or Merlin™ 2 Patient Care System (PCS) Model MER3700, or SJM MRI Activator™ handheld device Model EX4000, into the scanner magnet room (Zone IV). These devices are considered 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 Merlin™ 2 PCS, or the SJM MRI Activator™ handheld device.
2. For the SJM MRI Activator handheld device, select the MRI Settings Off button.
3. For the Merlin PCS or Merlin 2 PCS, disable MRI Settings by selecting the Disable MRI Settings button. This restores the permanently programmed settings.

- Confirm the permanently programmed settings are appropriate.
- For ICDs and CRT-Ds, to ensure an accurate lead impedance measurement, perform a lead impedance test by selecting Tests > Battery & Leads > Update leads.
- 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 or Merlin 2 PCS on-screen help for information on selecting and programming parameter settings.

CAUTION: MRI Settings must be disabled immediately after the MRI scan is complete using the Merlin PCS or Merlin 2 PCS to minimize the time in MRI Settings. When MRI Settings are programmed, Tachy therapy is disabled, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia.

NOTE: For ICDs and CRT-Ds, 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 Technologists

NOTE: Cardiac physicians and clinicians should see Instructions for Cardiac Physicians and Clinicians (page 7).

The role of the radiologist or MRI technologist is to:

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

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 or Merlin™ 2 PCS) to obtain the model numbers for both the implanted lead or leads and device.
2. Check the model numbers against the Abbott Medical MR Conditional Device/Lead Combination tables (3T MRI tables (page 3) or 1.5T MRI tables (page 5)).

   NOTE: Multiple leads can be connected to an MR Conditional device. Not all lead lengths are MR Conditional. Confirm that each individual lead meets MRI conditions for use.

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

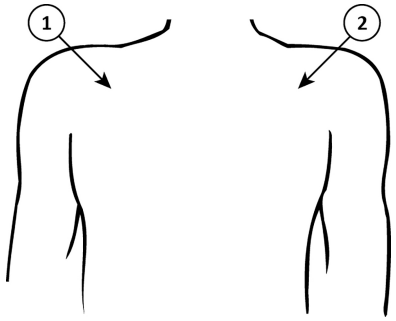
If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- Patient has elevated body temperature or compromised thermoregulation at time of scan
- A combination of one or more leads and a device that is not listed as MR Conditional in the device/lead combination tables (3T MRI tables (page 3) or 1.5T MRI tables (page 5)).
- Broken or intermittently functioning Abbott Medical MR Conditional leads
- Additional cardiac hardware including lead extenders, lead adapters, or abandoned leads
- A device implanted in a location other than the left or right pectoral region (see figure below)
- Any patient position in scanner other than supine or prone, with patient's arms at his or her sides

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

  Scanning patients who have other MR Conditional devices that are not implanted in cardiac tissue is acceptable provided all MR Conditional requirements for each implanted device are met.

Figure 6. Correct locations for device implant



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

III. Review the Potential Interactions

Potential interactions between the MRI scanner and the MR Conditional 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 Abbott 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 currents induced on the leads of the Abbott 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 potentially interact with the device, resulting in heating. 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, Abbott 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. Refer to the MRI scan parameters table (3T MRI table or 1.5T MRI table) for the applicable scan parameter settings for approved MR Conditional device/lead combinations.
2. Refer to the section on Abbott Medical MR Conditional Systems Device/Lead Combinations (3T MRI tables (page 3) or 1.5T MRI tables (page 5)) to identify the settings for RF Transmit Conditions for specific device/lead combinations.
3. Make sure that you identify the combination of one or more leads and a device to select the correct settings.
4. If the implantable system is comprised of a combination of leads that have different scan parameters, use the most restrictive of each scan parameter to determine the overall set of scan conditions applicable for the total system.

V. Check MRI Settings Status

CAUTION: Do not bring any external control devices, such as the Merlin™ Patient Care System (PCS) Model 3650 or Merlin™ 2 Patient Care System (PCS) Model MER3700, or SJM MRI Activator™ handheld device Model EX4000, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.

If you do not have an SJM MRI Activator™ handheld device Model EX4000, see Check MRI Settings Status without the SJM MRI Activator Handheld Device (page 14).

If you do have an SJM MRI Activator handheld device Model EX4000 available, see Check MRI Settings Status with the SJM MRI Activator Handheld Device (page 14).

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

1. Refer to the MRI Summary Report generated by the Merlin™ PCS or Merlin™ 2 PCS.
2. Confirm these settings with the device management physician or clinician.
   The currently programmed settings should include:

Table 17. MRI Settings [1]

Parameter	Setting
Tachy therapy (ICD and CRT-D patients)	Disabled
MRI mode	DOO, VOO, AOO, Pacing Off
MRI base rate	Pacemakers and CRT-Ps: 30–120 bpm ICDs and CRT-Ds: 30–100 bpm
MRI paced AV delay	25–120 ms
MRI pulse amplitude	5.0 or 7.5 V
MRI pulse width	1.0 ms
MRI pulse configuration	Bipolar
MRI V pacing chamber (CRT-P and CRT-D patients)	RV only

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

To check the status of MRI Settings:

1. Refer to the table below to determine if the device can communicate with the SJM MRI Activator™ handheld device.
2. Place the SJM MRI Activator handheld device over the implanted pulse generator. The SJM MRI Activator handheld device should be held against the patient's chest directly over the implanted pulse generator (see figure for correct locations for device implants).
3. Press the MR Status button (see figure of SJM MRI Activator handheld device).

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

Figure 7. **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

Enable MRI Settings with the SJM MRI Activator™ Handheld Device

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

To enable MRI Settings:

1. Place the SJM MRI Activator handheld device over the implanted pulse generator. The SJM MRI Activator handheld device should be held against the patient's chest directly over the implanted pulse generator (see figure for correct locations for device implant).

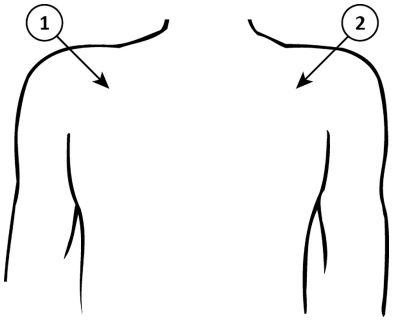
[1] This is the entire range of all possible settings for each parameter.

2. Press the MRI Settings On button.

The LEDs may flash before they illuminate continuously.

- When MRI Settings are enabled, the green LEDs illuminate continuously for 5 seconds to indicate that the device MRI Setting is enabled and the patient can proceed with the MRI scan.
- When MRI Settings could not be enabled, the red LEDs illuminate continuously for 5 seconds to indicate that an error occurred while enabling MRI Settings in the implanted MR Conditional pacing system, or that the implanted pacing system did not satisfy the conditions for an MRI scan. In this case, the patient should NOT proceed with the MRI scan. Contact the referring physician for further instruction.

Figure 8. Correct locations for device implant



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

Table 18. Abbott Medical MR Conditional pulse generators with SJM MRI Activator™ handheld device functionality

Model name and number	Operates with the SJM MRI Activator handheld device Model EX4000
Pacemakers	
Accent MRI™ pacemakers PM1224, PM2218	**Yes**
Assurity MRI™ pacemakers PM1272, PM2272	**Yes**
Endurity MRI™ pacemakers PM1172, PM2172	**Yes**
CRT-Ps	
Quadra Allure™ CRT-Ps PM3542	**No**
Quadra Allure MP™ CRT-Ps PM3562	**No**
ICDs	
Ellipse™ ICDs CD1311-36Q, CD1411-36Q, CD1411-36QC, CD2311-36Q, CD2411-36Q, CD2411-36QC	**No**
Fortify Assura™ ICDs CD1357-40Q, CD1357-40QC, CD2357-40Q, CD2357-40QC	**No**
CRT-Ds	
Quadra Assura™ CRT-Ds CD3365-40Q, CD3365-40QC	**No**
Quadra Assura MP™ CRT-Ds CD3369-40Q, CD3369-40QC	**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, or 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.

CAUTION: For ICDs and CRT-Ds, Tachy therapy is disabled when MRI Settings are programmed.

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

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

VII. Disable MRI Settings

1. If you are using the SJM MRI Activator™ handheld device, place the SJM MRI Activator handheld device over the implanted device.
   The SJM MRI Activator 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 SJM MRI Activator handheld device, MRI Settings must be disabled by the patient's device management physician or clinician using the Merlin™ PCS or Merlin™ 2 PCS.

CAUTION: For ICDs and CRT-Ds, be sure to disable MRI Settings immediately after the MRI scan to minimize the time in MRI Settings. When MRI Settings are enabled, Tachy therapy is disabled, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia.

Technical Support

Abbott 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)
- medical.abbott/manuals

For additional assistance, call your local Abbott Medical representative.

Any serious incident related to a device should be reported to Abbott Medical and the FDA.

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