MRI-Ready Systems Manual

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

Abbott

Contents

Introduction

This manual explains the procedures and precautions that must be followed when scanning a patient who is implanted with a St. Jude Medical™ MR Conditional system. St. Jude Medical is a wholly-owned subsidiary of Abbott. Products, functions, and facilities within St. Jude Medical are referenced as Abbott Medical within this manual.

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 if you have any questions (page 13).

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, refer to the 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 a St. Jude Medical port plug is placed in an unused port of the device header.

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 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 Abbott Medical or consult your regulatory authorities to determine if the products have been certified as MR Conditional.**

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, switched gradient magnetic field, and 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 St. Jude Medical™ MR Conditional systems within the scope of this manual 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 a St. Jude Medical™ 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 [T] and Type of Nuclei	3 Tesla/128 MHz excitation frequency (hydrogen atom only)
Magnet Type and Static Magnetic Field Orientation	Cylindrical-bore magnet, horizontal field orientation
Maximum Spatial Field Gradient [T/m] and [Gauss/cm]	30 T/m (3000 Gauss/cm)
Maximum Gradient Slew Rate per axis [T/m/s]	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
Patient Landmarking Criteria	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 6) Refer to Instructions for Radiologists and MRI Technologists to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 11) ▪ Perform the Scan and Monitor the Patient (page 12)
Patient Position in Scanner	Supine; 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 6) ▪ Instructions for Radiologists and MRI Technologists (page 11)
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.

ICDs

Table 3. 3T MR Conditional Systems device/lead combinations for Avant™, Neutrino™ NxT, Gallant™, and Entrant™ ICDs

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Avant VR CDVRA700Q **Avant DR** CDDRA700Q **Neutrino NxT VR** CDVRA800Q CDVRA600Q **Neutrino NxT DR** CDDRA800Q CDDRA600Q **Gallant VR** CDVRA500Q **Gallant DR** CDDRA500Q **Entrant VR** CDVRA300Q **Entrant DR** CDDRA300Q	**Durata™** 7120Q 7122Q **Optisure™** LDA220Q LDA210Q **Tendril™ STS** 2088TC	58 cm, 65 cm 46 cm, 52 cm	Normal Operating Mode Integrated Whole Body RF Transmit coil with RF excitation: – Circularly polarized (CP), or – Multichannel-2 (MC-2)	Full-body

CRT-Ds

Table 4. 3T MR Conditional Systems device/lead combinations for Avant™, Neutrino™ NxT, Gallant™, and Entrant™ CRT-Ds

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Avant HF CDHFA700Q **Neutrino NxT HF** CDHFA800Q CDHFA600Q **Gallant HF** CDHFA500Q **Entrant HF** CDHFA300Q	**Durata™** 7120Q 7122Q **Optisure™** LDA220Q LDA210Q **Tendril™ STS** 2088TC **Quartet™** 1456Q 1457Q 1458Q 1458QL	58 cm, 65 cm 46 cm, 52 cm 86 cm	Normal Operating Mode Integrated Whole Body RF Transmit coil with RF excitation: – Circularly polarized (CP), or – Multichannel-2 (MC-2)	Full-body

1.5T MRI Scan Parameters for MR Conditional Systems

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

Table 5. 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 [T] and Type of Nuclei	1.5 Tesla/64 MHz excitation frequency (hydrogen atom only)
Magnet Type and Static Magnetic Field Orientation	Cylindrical-bore magnet, horizontal field orientation
Maximum Spatial Field Gradient [T/m] and [Gauss/cm]	30 T/m (3000 Gauss/cm)
Maximum Gradient Slew Rate per axis [T/m/s]	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
Patient Landmarking Criteria	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 6) Refer to Instructions for Radiologists and MRI Technologists to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 11) ▪ Perform the Scan and Monitor the Patient (page 12)
Patient Position in Scanner	Supine; 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 6) ▪ Instructions for Radiologists and MRI Technologists (page 11)
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.

ICDs

Table 6. 1.5T MR Conditional Systems device/lead combinations for Avant™, Neutrino™ NxT, Gallant™, and Entrant™ ICDs

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Avant VR CDVRA700Q **Avant DR** CDDRA700Q **Neutrino NxT VR** CDVRA800Q CDVRA600Q **Neutrino NxT DR** CDDRA800Q CDDRA600Q **Gallant VR** CDVRA500Q **Gallant DR** CDDRA500Q **Entrant VR** CDVRA300Q **Entrant DR** CDDRA300Q	**Durata™** 7120Q 7122Q **Optisure™** LDA220Q LDA210Q **Tendril™ STS** 2088TC **Tendril™ MRI** LPA1200M	58 cm, 65 cm 46 cm, 52 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

CRT-Ds

Table 7. 1.5T MR Conditional Systems device/lead combinations for Avant™, Neutrino™ NxT, Gallant™, and Entrant™ CRT-Ds

Device model	Lead model	Lead lengths	RF Transmit Conditions	Scan region
Avant HF CDHFA700Q **Neutrino NxT HF** CDHFA800Q CDHFA600Q **Gallant HF** CDHFA500Q **Entrant HF** CDHFA300Q	**Durata™** 7120Q 7122Q **Optisure™** LDA220Q LDA210Q **Tendril™ STS** 2088TC **Tendril™ MRI** LPA1200M **Quartet™** 1456Q 1457Q 1458Q 1458QL	58 cm, 65 cm 46 cm, 52 cm 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

Instructions for Cardiac Physicians and Clinicians

NOTE: Radiologists and MRI technologists should see Instructions for Radiologists and MRI Technologists (page 11).

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 6)
- Confirm that No Adverse Conditions to MRI Scanning are Present (page 6)
- Review the Potential Adverse Events (page 6)
- Generate a Report of the Patient's Permanently Programmed Parameters (page 7)
- Select and Save MRI Settings (page 7)
- Review the MRI Checklist and Program MRI Settings (page 9)
- Disable MRI Settings (page 10)

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 or leads, and device.
2. Check the model numbers against the 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.

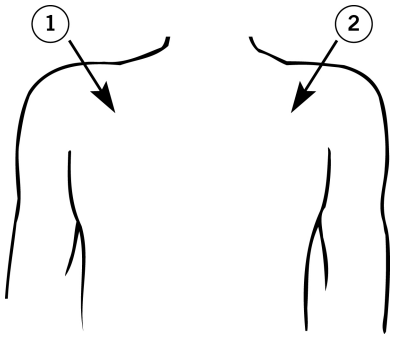
II. Confirm that No Adverse Conditions to MRI Scanning are Present

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
- The device is at End-of-Life
- A combination of one or more leads and a device that is not listed as MR Conditional in the MR Conditional Systems Device/Lead Combination tables (3T MRI tables (page 3) or 1.5T MRI tables (page 5)).
- Broken or intermittently functioning St. Jude 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 sites 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-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 in patients whose devices 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)

  NOTE: Lead fractures or other damage to the leads may cause changes in the electrical properties of the 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.

Figure 1. 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 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
- 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 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.

  NOTE: If LV pacing is enabled in MRI Settings, the RF or Gradient fields may interact with the LV pacing output. This could result in LV pulse cancellation leading to worsening of heart failure symptoms, or LV pulse enhancement leading to diaphragmatic stimulation during the MRI scan.
- 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 any external control devices, such as a programmer, or a smart phone or tablet running a mobile application, into the scanner magnet room (Zone IV). These devices are considered 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 will be suspended when MRI Settings are enabled. For any device, it is recommended that the clinician performs 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 25.0.2 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 8. 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 RV/RA Pulse Amplitude	n/a
MRI RV/RA Pulse Width	n/a
MRI RV/RA Pulse Configuration	n/a
MRI Timeout	6 hours

Table 9. Default MRI Settings for CRT-Ds

Parameter	Setting
Tachy Therapy	Disabled
MRI Mode	DOO
MRI V Pacing Chamber	RV Only
MRI Base Rate	85 min^{-1}
MRI Paced AV Delay	110 ms
MRI RV/RA Pulse Amplitude	5.0 V
MRI RV/RA Pulse Width	1.0 ms
MRI RV/RA Pulse Configuration	Bipolar
MRI Timeout	6 hours

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 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 MRI Settings are enabled.

   NOTE: For CRT-Ds: LV+RV (Simultaneous) Pacing may be enabled for MRI Settings if certain restrictions are met:

   - LV Pulse Configuration is permanently programmed to a bipolar LV pulse configuration only. For example, LV+RV (Simultaneous) Pacing with the RV coil as part of the Pulse Configuration is not allowed for MRI Settings. If both LV1 and LV2 vectors are bipolar, LV1 will be used.
   - DOO or VOO is programmed for MRI Settings.
   - When LV+RV (Simultaneous) Pacing is enabled, MRI LV Pulse Configuration, MRI LV Pulse Amplitude, and MRI LV Pulse Width default to Permanent Settings. These are the LV settings recommended for MRI programming.
3. 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.
4. Select the Cancel Test button to return to permanently programmed settings.
5. Select the Save MRI Settings button to save any changed parameters.
6. 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.
7. Program MRI Timeout. MRI Timeout automatically restores permanent settings after MRI Timeout duration expires. MRI Timeout duration starts after MRI Settings are programmed.
   - When MRI Settings are programmed, Tachy therapy is disabled, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. MRI Timeout option protects the patient from prolonged exposure to spontaneous tachyarrhythmia and VT/VF induction post-MRI scan.
   - MRI Timeout options are 3, 6, 9,12 or 24 hours with 6 hours being the nominal value upon MRI Settings programming. The other MRI Timeout option is Off if you are not using the feature.
   - The patient must be out of the MRI scanner before the MRI Timeout duration expires. Refer to the printed reports and Merlin PCS for the MRI Timeout duration information.
   - If MRI Timeout is enabled, it is recommended you enable V. AutoCapture (ICDs) or V. Cap Confirm (CRT-Ds) for the right ventricle prior to enabling MRI Settings. The AutoCapture or Cap Confirm feature will provide a safety margin against increased pacing capture thresholds that may occur post-MRI scan due to lead tip heating.
8. When you are satisfied with 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.

   Tachy therapy is disabled when MRI Settings are programmed.

VI. Review the MRI Checklist and Program MRI Settings

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

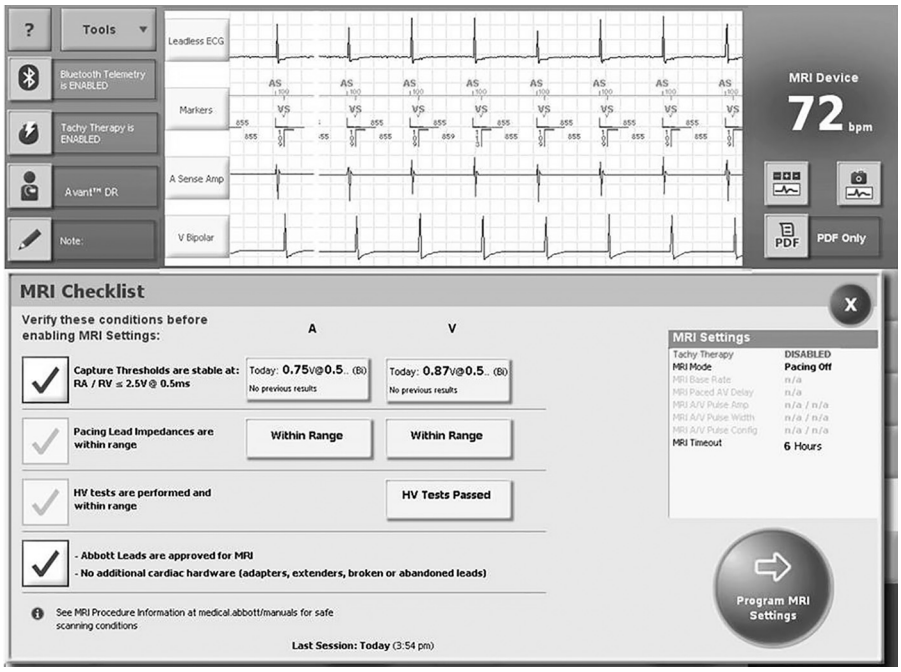
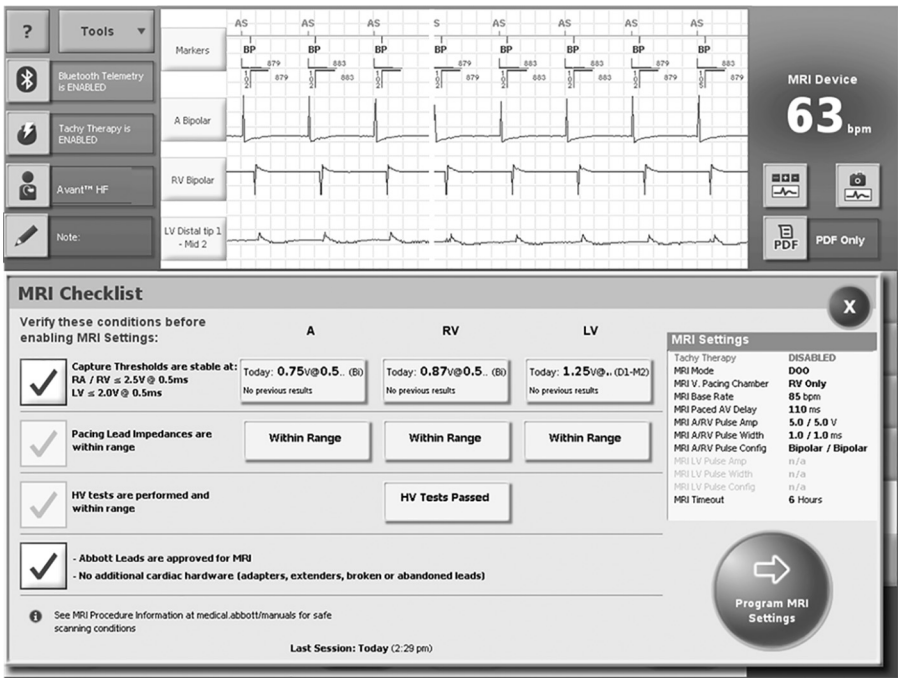


Figure 3. An example of the MRI Checklist screen for CRT-Ds on the Merlin™ PCS



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 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 - 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 maintenance is postponed. The software prevents 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 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 (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 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. If MRI Timeout is enabled, the report includes the time and date when MRI Settings will expire.

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.

If MRI Timeout is enabled, ensure that the patient is out of the MRI scanner before MRI Timeout expiration occurs.

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

VII. Disable MRI Settings

CAUTION: Do not bring any external devices, such as a programmer, or a smart phone or tablet running a mobile application, 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.

2. Disable MRI Settings by selecting the Disable MRI Settings button. This restores the permanently programmed settings.

   a. Confirm the permanently programmed settings are appropriate.

   b. 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.

CAUTION: MRI Settings must be disabled immediately after the MRI scan is complete using the Merlin PCS to minimize the time in MRI Settings, even if the MRI scan is completed before MRI Timeout expiration or if MRI Timeout is not enabled. When MRI Settings are programmed, Tachy therapy is disabled, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia.

If the device automatically exits MRI Settings due to MRI Timeout expiration, it is recommended that you interrogate the device using the Merlin PCS and perform the tests outlined in Step 2 above.

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

Instructions for Radiologists and MRI Technologists

NOTE: Cardiac physicians and clinicians should see Instructions for Cardiac Physicians and Clinicians (page 6).

The role of the radiologist or MRI technologist is to:

- Confirm that the Patient has an MR Conditional System (page 11)
- Confirm that No Adverse Conditions to MRI Scanning are Present (page 11)
- Review the Potential Interactions (page 11)
- Select the Correct Scan Parameters (page 12)
- Check MRI Settings Status (page 12)
- Perform the Scan and Monitor the Patient (page 12)

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 or leads and device.
2. Check the model numbers against the 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

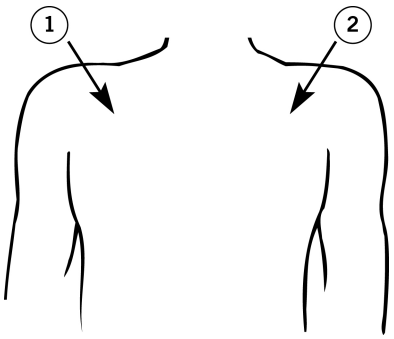
If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- 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 St. Jude Medical™ MR Conditional leads
- Additional cardiac hardware including lead extenders, lead adapters, or abandoned leads
- A device implanted in sites other than the left or right pectoral region (see figure below)
- Any patient position in scanner other than supine, 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 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 non-cardiac MR Conditional devices is acceptable provided all MR Conditional requirements for each implanted device are met.

Figure 4. 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 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.

NOTE: If LV pacing is enabled in MRI Settings, the RF or Gradient fields may interact with the LV pacing output. This could result in LV pulse cancellation leading to worsening of heart failure symptoms, or LV pulse enhancement leading to diaphragmatic stimulation during the MRI scan.

- 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. Refer to the MRI scan parameters table (3T MRI table (page 2) or 1.5T MRI table (page 4)) for the applicable scan parameter settings for approved MR Conditional device/lead combinations.
2. Refer to the section on 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 a programmer, or a smart phone or tablet running a mobile application, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.

1. Refer to the MRI Summary Report generated by the Merlin™ PCS.
2. Confirm these settings with the device management physician or clinician.
3. Review MRI Timeout programmed settings. MRI Timeout automatically restores permanent settings after MRI Timeout duration expires. MRI Timeout duration starts after MRI Settings are programmed.
   - When MRI Settings are programmed, Tachy therapy is disabled, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. MRI Timeout option protects the patient from prolonged exposure to spontaneous tachyarrhythmia and VT/VF induction post-MRI scan.
   - MRI Timeout is programmable with options of Off; and 3, 6, 9,12 or 24 hours with 6 hours being the nominal value upon MRI Settings programming. The patient must be out of the MRI scanner before the MRI Timeout duration expires. Refer to the printed reports for the MRI Timeout duration information.

   CAUTION: If MRI Timeout is enabled, verify there is adequate time to complete the scan before MRI Timeout expiration occurs. The MRI Summary report includes the date and time when MRI Timeout expires.

   The currently programmed settings should include:

Table 10. MRI Settings[1]

Parameter	Setting
Tachy Therapy	Disabled
MRI Mode	DOO, VOO, AOO, Pacing Off
MRI V Pacing Chamber	ICDs: RV only CRT-Ds: RV only, LV+RV (Simultaneous)
MRI Base Rate	30 - 100 min^{-1}
MRI Paced AV Delay	ICDs: 25 - 120 ms CRT-Ds: 25 - 110 ms
MRI RV and RA Pulse Amplitude	5.0 or 7.5 V
MRI RV and RA Pulse Width	1.0 ms
MRI RV and RA Pulse Configuration	Bipolar
MRI LV Pulse Configuration (CRT-Ds only)	LV Bipolar (for example, D1-M2)
MRI LV Pulse Amplitude (CRT-Ds only)	0.25 V to 7.5 V
MRI LV Pulse Width (CRT-Ds only)	0.05 ms - 1.5 ms
MRI Timeout	Options: Off; and 3, 6, 9, 12 or 24 hours

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.

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

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

Keep an external defibrillator available during the MRI scan.

CAUTION: 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.

The presence of this device may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact.

Immediately following the MRI procedure, the patient's device management physician or clinician must disable MRI Settings using the Merlin™ PCS programmer.

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 incidents related to a device should be reported to Abbott Medical and the European Union competent authority in your member state.

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