Medtronic

CLARIA MRI™/CLARIA MRI™ QUAD, AMPLIA MRI™/AMPLIA MRI™ QUAD, COMPIA MRI™/COMPIA MRI™ QUAD CRT-D SURESCAN™ SYSTEM

MR

MRI procedural information for SureScan™ defibrillators with cardiac resynchronization therapy and SureScan™ leads

MRI Technical Manual

CE 0123

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1 Introduction

1.1 About the system

The Medtronic SureScan implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT-D) system is MR Conditional. As such, it is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. It is important to read this manual before conducting an MRI scan on a patient with an implanted SureScan CRT-D system. Contact a Medtronic representative if you have further questions.

Refer to the appropriate Medtronic device and reference manuals or lead technical manuals for non-MRI related instructions for use.

Note: The images, button labels, and navigation instructions in this manual apply to the Claria/Amplia/Compia MRI Programmer Application Software Model SW034, used with a CareLink Encore™ Model 29901 programmer or a CareLink™ Model 2090 programmer. If you are using a tablet to program your device, please refer to the CareLink SmartSync™ Claria Amplia Compia Application help for programming information.

2 MRI conditions for use

A complete SureScan system is required for use in the MR environment. Any other combination may result in a hazard to the patient during an MRI scan.

A complete SureScan CRT-D system includes the following components:

- the Claria MRI, Claria MRI Quad, Amplia MRI, Amplia MRI Quad, Compia MRI, or Compia MRI Quad CRT-D device
- a SureScan right atrial pacing lead or a Model 6725 pin plug for the right atrial port
- a SureScan left ventricular pacing lead
- a SureScan defibrillation lead

A complete SureScan system only includes components that have been certified by Medtronic as being MR Conditional. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com.

Warning: Do not scan a patient without first programming MRI SureScan to On. Scanning the patient without programming MRI SureScan to On may result in patient harm or damage to the SureScan CRT-D system.

Note: MRI SureScan cannot be programmed to On if the device is recommended for replacement.

2.1 Cardiology requirements

Patients and their implanted systems must be screened to meet the following requirements:

- The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
- The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.
- The SureScan CRT-D system is implanted in the left or right pectoral region.
- The SureScan device is operating within the projected service life.
- For patients whose device will be programmed to an asynchronous pacing mode when the MRI SureScan mode is programmed to On, no diaphragmatic stimulation is present when the paced leads have a pacing output of 5.0 V and a pulse width of 1.0 ms.

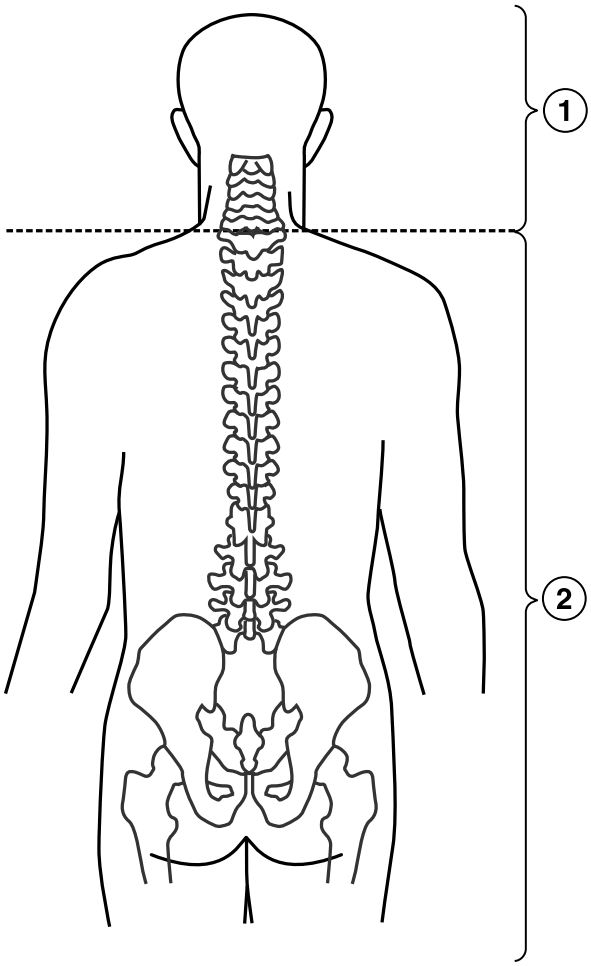
  Note: The LV lead is not paced during SureScan operation so the presence of diaphragmatic stimulation on the LV lead at a pacing output of 5.0 V and a pulse width of 1.0 ms does not need to be considered.

2.2 Radiology requirements

The safety and reliability of the SureScan CRT-D system has been evaluated for scanning patients using MRI equipment that has the following operating characteristics:

Scanner type	Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging
Scanner characteristics	• Static magnetic field of one of the following strengths: – 1.5 T – 3 T • Maximum spatial gradient of ≤ 20 T/m (2000 gauss/cm) • Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 T/m/s
Scanner operation	**1.5T –** MRI radio frequency (RF) power – Normal Operating Mode • The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg. • The head SAR must be ≤ 3.2 W/kg.
	3T – MRI radio frequency (RF) power – First Level Controlled Operating Mode or Normal Operating Mode: • B_{1+RMS} must be ≤ 2.8 µT when the isocenter (center of the MRI bore) is inferior to the C7 vertebra. • Scans can be performed without B_{1+RMS} restriction when the isocenter is at or superior to the C7 vertebra (see *Figure 1*).

Figure 1. 3T scan location requirements



1 No B_{1+RMS} restrictions
2 B_{1+RMS} not to exceed 2.8 µT

2.3 Patient monitoring and rescue requirements

Continuous patient monitoring is required while the MRI SureScan mode is programmed to On.

An external defibrillator must be immediately available in the event that patient rescue is required.

3 MRI warnings and precautions

Warnings:

- Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan CRT-D system.
- Do not leave the device in MRI SureScan mode after the scan is complete. While the MRI SureScan mode is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode, arrhythmia risk may be increased. Also, while the MRI SureScan mode is programmed to On, the patient receives no CRT support. This lack of CRT support might cause dizziness or shortness of breath. Be sure to program the MRI SureScan mode to Off as soon as the scan is complete.

- Do not scan patients who do not have a complete SureScan CRT-D system. A complete SureScan CRT-D system includes the following components. Any other combination may result in a hazard to the patient during an MRI scan.
  - the Claria MRI, Claria MRI Quad, Amplia MRI, Amplia MRI Quad, Compia MRI, or Compia MRI Quad CRT-D device
  - a SureScan right atrial pacing lead or a Medtronic IS-1 pin plug for the right atrial port
  - a SureScan left ventricular pacing lead
  - a SureScan defibrillation lead
- Do not scan patients with broken, abandoned, or intermittent leads. Lead fractures or other damage to the leads may cause changes in the electrical properties of the SureScan CRT-D system that will make the system unsafe for an MRI scan. Patients with damaged leads may be harmed if an MRI scan is performed.
- Do not scan patients with a SureScan CRT-D system implanted in sites other than the left and right pectoral region. Safety and effectiveness have been assessed for left and right pectoral implant locations only. Scanning of patients with devices implanted in other locations could lead to increased pacing capture threshold or unintended cardiac capture.

Cautions:

- Do not scan patients in a 1.5 T magnetic field with a whole body averaged SAR level > 2.0 W/kg. A scan above 2.0 W/kg may increase the risk of myocardial tissue damage due to lead tip heating, resulting in an increase in the pacing capture threshold.
- Do not scan patients in a 3 T magnetic field with a B_{1+RMS} value > 2.8 µT when the isocenter (center of the MRI bore) is inferior to the C7 vertebra. A scan above 2.8 µT may increase the risk of myocardial tissue damage due to lead tip heating, resulting in an increase in the pacing capture threshold.
- Do not scan patients whose device will be programmed to an asynchronous pacing mode when the MRI SureScan feature is on, and who have diaphragmatic stimulation when the paced leads have a pacing output of 5.0 V and a pulse width of 1.0 ms. It may be difficult for the patient to remain still in order to obtain a quality MRI scan.
- Do not scan patients with lead extenders or lead adaptors. Lead extenders and lead adaptors may increase the risk of myocardial tissue damage due to lead tip heating and other MRI-related hazards.
- It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks) because MRI scans during this period have not been prospectively studied by Medtronic.
- Scanning patients who have multiple MR Conditional devices present is acceptable as long as the MR labeling conditions for all implants can be satisfied.
- Do not bring the Medtronic programmer, Patient Assistant, or patient monitor into the examination room (MRI magnet room). They are MR Unsafe.
- Use caution if using wireless telemetry while the patient is in the MRI magnet room. Wireless telemetry may cause image distortion.

4 Potential adverse events

The SureScan CRT-D system has been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MR environment:

- lead electrode heating and tissue damage resulting in loss of sensing or capture or both
- spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while the MRI SureScan mode is programmed to On
- potential for ventricular tachycardia or ventricular fibrillation (VT/VF) induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan mode
- device heating resulting in tissue damage in the implant pocket or patient discomfort or both
- MR-induced stimulation 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 of the device to communicate with the programmer
- movement or vibration of the device or leads resulting in dislodgment

5 Patient monitoring requirements

While the MRI SureScan mode is programmed to On, tachyarrhythmia detection and therapy are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. At the same time, arrhythmia risk may be increased for patients who are programmed to an asynchronous pacing mode while the MRI SureScan mode is programmed to On. Also, while the MRI SureScan mode is programmed to On, the patient receives no CRT support. This lack of CRT support might cause dizziness or shortness of breath. Therefore, proper patient monitoring is required during the entire time when the MRI SureScan mode is programmed to On.

Proper patient monitoring is required during the entire time when the MRI SureScan mode is programmed to On and includes all of the following actions:

- continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography
- continuous visual monitoring of the patient, maintaining verbal contact if the patient can communicate

Preparation for patient rescue – An external defibrillator must be immediately available in the event that patient rescue is required.

Note: If the patient's hemodynamic function is compromised during the MRI scan, discontinue the scan, remove the patient from the magnet room, program the MRI SureScan mode to Off, and take the proper measures to restore the patient's hemodynamic function.

6 Cardiology-specific considerations

Lead maturation – MRI scans during the lead maturation period (approximately 6 weeks after implant) have not been prospectively studied by Medtronic and are not recommended.

Spontaneous tachyarrhythmia – Tachyarrhythmia detection and therapy are suspended while the MRI SureScan mode is programmed to On. Be sure to program the MRI SureScan mode to Off as soon as the MRI scan is complete.

VT/VF induction – If an asynchronous MRI SureScan pacing mode is selected for a patient, be aware that the patient may be susceptible to cardiac arrhythmia induced by competitive pacing and other mechanisms. To avoid VT/VF induction, confirm that the patient needs asynchronous pacing, select a pacing rate that avoids competitive pacing, and minimize the period of time during which the MRI SureScan mode is programmed to On.

Note: If the patient does not need pacing support, select a nonpacing mode (ODO).

System information and records – All pertinent information about the components of the implanted SureScan CRT-D system such as model names, model numbers, and serial numbers should be recorded in the patient record and on the Patient Information screen on the programmer. This information will help with system identification in the future.

Patient ID card – Reference materials, such as a patient ID card, should be provided to all patients with an implanted SureScan CRT-D system. These reference materials should indicate that the patient has a SureScan CRT-D device and SureScan leads.

Note: Be sure to advise the patient to notify medical personnel that they have a CRT-D device before entering the MR environment and to present their patient ID card.

7 Radiology-specific considerations

7.1 MRI considerations

Use of transmit/receive and receive-only coils – There are no restrictions on the use of local transmit/receive coils for MRI scanning of the head or of the extremities, and there are no restrictions on the placement of receive-only coils.

Image artifact and distortion – SureScan leads have demonstrated minimal MRI scan distortion for areas surrounding the implanted leads when the device is out of the field of view. Significant MRI scan distortion will result from the presence of the device within the field of view. MRI scan 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 the MRI scanning parameters. These factors must also be considered when interpreting the MRI scans.

Patient sensation during MRI – The device has been evaluated to ensure no risk of tissue damage. However, the patient may feel sensations of warmth or vibration in the implant site during the MRI scan. Tolerable levels of these sensations do not indicate that patient safety has been compromised.

8 Pre-MRI scan operations

The steps in the following sections are required before performing an MRI scan.

8.1 Identification of SureScan CRT-D system components

Use the following methods to verify that a patient has a SureScan CRT-D system:

- **Patient records or patient ID card (if applicable):** Patient records and the patient ID card, if applicable, are the most reliable record of the medical devices that have been implanted in the patient. These records are available to clinicians other than the device clinician and can be accessed without the presence of the patient or the use of a programmer. These records must be complete and accurate if they are to be used to determine whether the patient has a SureScan CRT-D system.
- **Patient information on the programmer:** The programmer Patient Information feature is intended to be used by the implanting clinician to document the components of the patient's SureScan system and to report the presence of any additional implanted medical devices. If the implanting clinician has entered the needed information completely and accurately, you can use the Patient Information feature to determine whether the patient has a SureScan CRT-D system.
    1. Click the Patient icon on the tool palette to open the Patient Information window.
    2. In the lower left area of the Patient Information window, select MRI SureScan System/Other Hardware … .
    3. View the MRI SureScan System fields for information about the patient's leads and whether or not they are MR conditional.
    4. View the Other Hardware fields for information about other lead extenders, lead adaptors, and abandoned leads.

8.2 Required patient care

Before programming the MRI SureScan mode to On, perform the following actions to help ensure patient safety:

Evaluate the patient to determine whether or not pacing support is needed while the MRI SureScan mode is programmed to On – For patients who require pacing support, set the MRI SureScan pacing mode to DOO, AOO, or VOO when programming the MRI SureScan mode to On. For patients who do not require pacing support, set the MRI SureScan pacing mode to ODO when programming the MRI SureScan mode to On. Asynchronous pacing may increase the risk of arrhythmia.

If the patient will require pacing support, ascertain an appropriate pacing rate – An appropriate pacing rate is one that will help avoid competitive pacing while the MRI SureScan mode is programmed to On.

Prepare to provide proper patient monitoring while the MRI SureScan mode is programmed to On – Proper patient monitoring includes maintaining continuous visual and verbal contact with the patient and continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography.

Prepare for patient rescue – In the event that patient rescue is required, an external defibrillator must be immediately available.

9 Performing an MRI scan

Warning: Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan CRT-D system.

Warning: Do not leave the device in MRI SureScan mode after the scan is complete. While the MRI SureScan mode is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode, arrhythmia risk may be increased. Also, while the MRI SureScan parameter is programmed to On, the patient receives no CRT support. This lack of CRT support might cause dizziness or shortness of breath. Be sure to program the MRI SureScan mode to Off as soon as the scan is complete.

Note: The system automatically programs the MRI SureScan mode to Off 6 hours after it is programmed to On. Before you program the MRI SureScan mode to On, ensure that the MRI scan will be completed before this 6-hour timeout occurs. Refer to the MRI SureScan report or the Quick Look II report for information about when the MRI SureScan mode was programmed to On.

Caution: Do not bring the Medtronic programmer, Patient Assistant, or patient monitor into the examination room (MRI magnet room). They are MR Unsafe.

Caution: Use caution if using wireless telemetry while the patient is in the MRI magnet room. Wireless telemetry may cause image distortion.

When programming the MRI SureScan mode to On, you must select parameters that are appropriate for the patient. Pacing mode and rate (if applicable) are to be programmed per the physician's discretion. Based on whether or not the patient needs pacing support, an asynchronous pacing mode (DOO, AOO, or VOO) or sensing only mode can be programmed. Sensed events will be ignored by the device when the MRI SureScan parameter is programmed to On, regardless of the programmed mode. The device maintains the selected parameters until the MRI SureScan parameter is programmed to Off after the MRI scan has been completed. After the MRI SureScan parameter is programmed to Off, the permanent device parameters are restored.

9.1 SureScan CRT-D system integrity verification

The SureScan CRT-D system 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 SureScan feature, the SureScan device application software checks for the following situations:

Pacing lead impedance is out of range – If either the Bipolar or the Tip to Coil pacing impedance is out of range, the software prevents the MRI SureScan feature from being initiated. The valid pacing lead impedance range is 200 Ω - 3000 Ω. For dual cathode LV pacing vectors, the impedance range applies to each individual vector. For example, for the LV1+4 to RVcoil pathway, both LV1 to RVcoil and LV4 to RVcoil must be in the 200 Ω - 3000 Ω range.

Note: If Atrial Sensitivity is programmed to Off, the software prevents the atrial lead impedance check so that patients without an atrial lead implanted can undergo an MRI scan.

Defibrillation lead impedance is out of range – If the RV Defib impedance is out of range, the software prevents the MRI SureScan feature from being initiated. If the SVC Defib impedance is out of range, the software displays a message indicating a potential issue with the SVC. If that happens, follow these steps:

1. Confirm that either there is no SVC coil electrode or that, if there is an SVC coil electrode, the defibrillation lead is electrically intact.
2. If you suspect an issue with the SVC coil electrode, select [Cancel] and do not proceed with the MRI scan. Otherwise, proceed with the following steps.
3. Select [Accept] in the message window.
4. Continue with MRI SureScan programming.

The valid defibrillation lead impedance range is 20 Ω - 200 Ω.

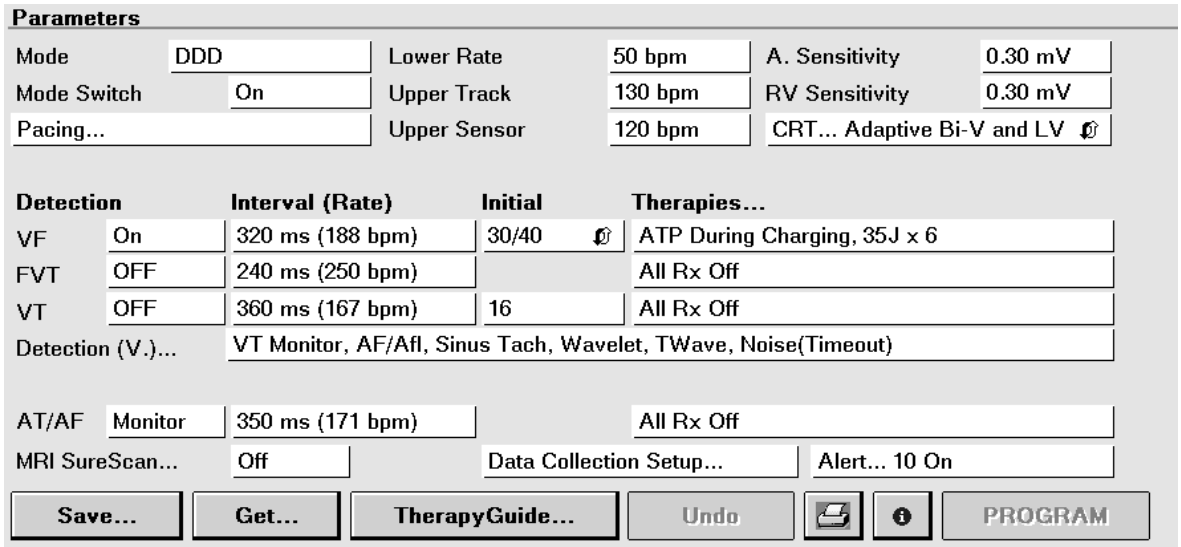
Limited device function – If the device is at Recommended Replacement Time (RRT) or End of Service (EOS), the software prevents the MRI SureScan feature from being initiated.

9.2 Programming the MRI SureScan parameter to On

Use the following steps to program the MRI SureScan parameter to On:

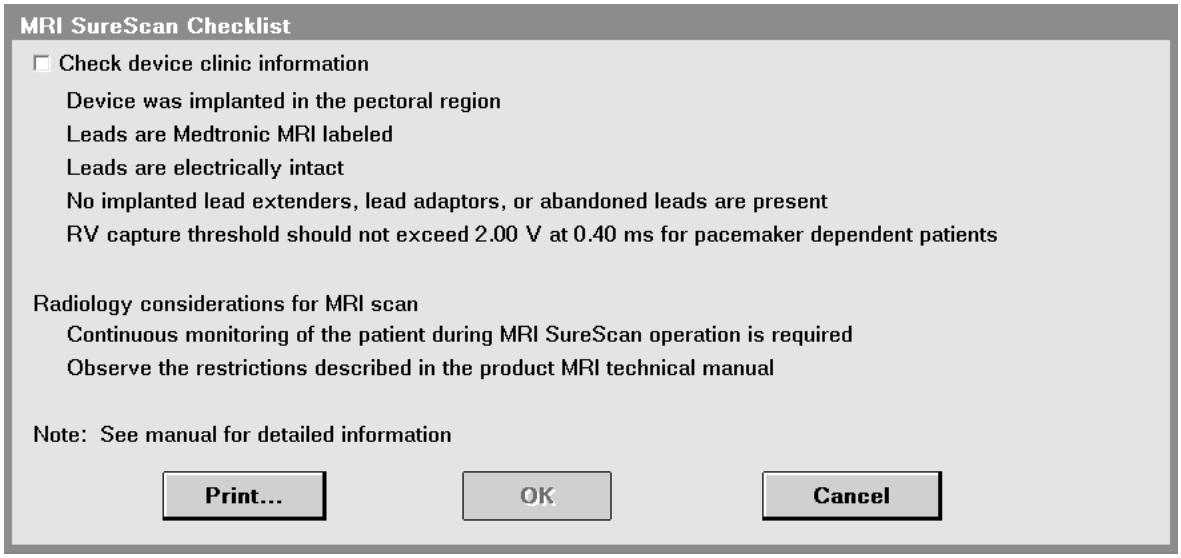
1. Click the Params icon on the tool palette to open Parameters screen.

Figure 2. Selecting the MRI SureScan… field



2. Click the MRI SureScan… field in the lower left corner of the Parameters screen to display the MRI SureScan Checklist. (You can also select MRI SureScan from the Additional Features window. Select Params > Pacing… > Additional Features…)

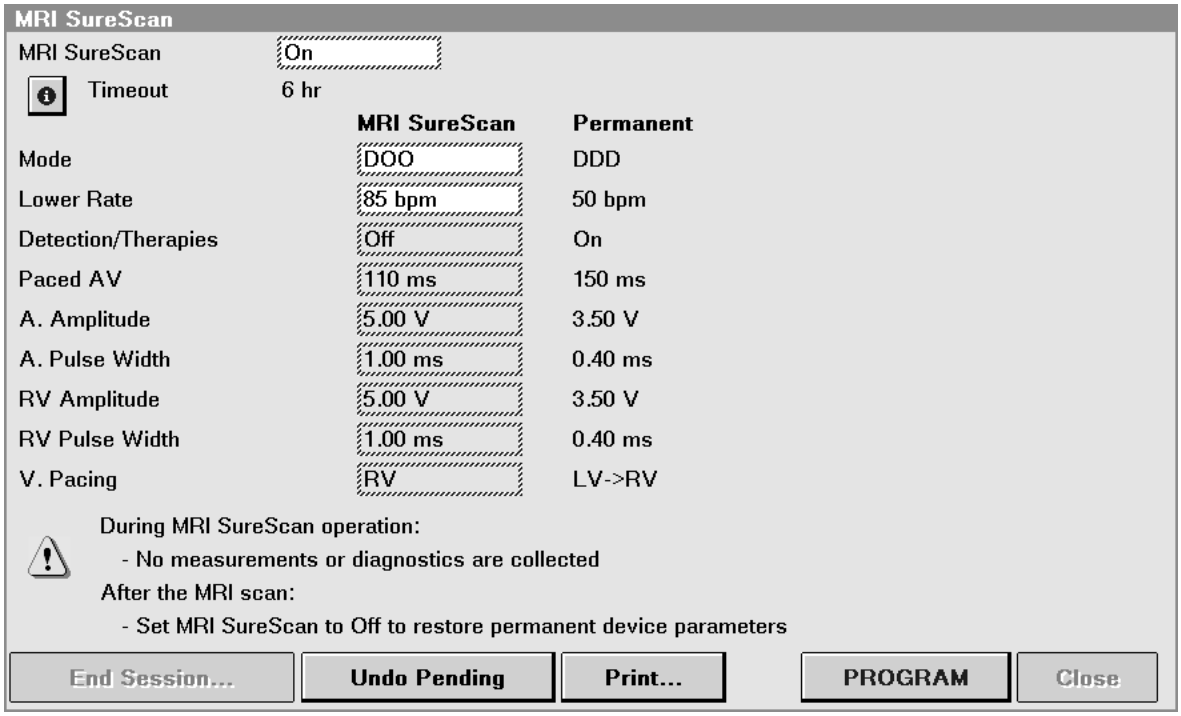
Figure 3. MRI SureScan Checklist



3. Select the check box in the upper-left corner if all items on the MRI SureScan Checklist are satisfied for the patient.

   Note: Print the MRI SureScan Checklist if desired.
4. Select [OK] to open the MRI SureScan screen.

Figure 4. Selecting MRI SureScan settings



5. Set the MRI SureScan parameter to On.
6. Select an appropriate MRI SureScan pacing mode and MRI SureScan pacing rate.
   - For patients who require pacing support, program the device to an asynchronous pacing mode (DOO, AOO, or VOO).

Note: If you select an asynchronous pacing mode, an appropriate MRI SureScan pacing rate must be selected to avoid competitive pacing while the MRI SureScan parameter is programmed to On.

- For patients who do not require pacing support, program the device to the nonpacing mode (ODO).

  Note: If the patient's device is programmed to the nonpacing (ODO) mode, the MRI SureScan pacing rate (Lower Rate) is not available for programming.

7. Select [PROGRAM].

   The system is now ready for the MRI scan. The status of the MRI SureScan parameter and the programmed parameters may be confirmed by printing the MRI SureScan parameter screen.

   After the device has been programmed for an MRI scan, available options are [Print…], [End Session…], and [Emergency]. The MRI SureScan parameter can also be programmed to Off.

9.3 Device considerations

Suspension of diagnostic data – When the MRI SureScan mode is programmed to On, all device diagnostic measurements and collection are suspended.

Suspension of tachyarrhythmia detection and therapies – While the MRI SureScan mode is programmed to On, the device does not detect tachyarrhythmias, and it does not deliver tachyarrhythmia therapies.

Note: When the MRI SureScan mode is programmed to On, the message, All Off, appears on the Device Status Line to indicate that all detection and therapy features are suspended.

Suspension of PVC detection – While the MRI SureScan mode is programmed to On, the device does not detect PVCs.

Asynchronous bradyarrhythmia pacing therapy – Asynchronous bradyarrhythmia pacing therapy is provided when an asynchronous pacing mode is selected for MRI SureScan operation.

Automatic PAV selection for DOO mode – If DOO mode is selected when the MRI SureScan mode is programmed to On, the device automatically sets the PAV to either the permanently programmed PAV interval or 110 ms, whichever is less. However, if the permanently programmed PAV is less than 50 ms, the device automatically sets the PAV to 50 ms when the MRI SureScan mode is programmed to On.

Automatic amplitude and pulse width selection for MRI SureScan pacing modes – When the MRI SureScan mode is programmed to On and the pacing mode is DOO, VOO, or AOO, the device automatically sets the pacing amplitude and pulse width values:

- The device sets A. Amplitude and RV Amplitude to 5.00 V or the permanently programmed value, whichever is higher.
- The device sets A. Pulse Width and RV Pulse Width to 1.00 ms or the permanently programmed value, whichever is higher.

Automatic canceling of the MRI SureScan mode with Emergency programming – If you deliver any emergency therapy when the MRI SureScan mode is programmed to On, the MRI SureScan mode is automatically programmed to Off. After an Emergency feature is programmed, the MRI SureScan mode must be programmed to On again before the patient can be scanned safely.

10 Following the MRI scan

Warning: Do not leave the device in MRI SureScan mode after the scan is complete. While the MRI SureScan mode is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. In addition, if the device is programmed to an asynchronous pacing mode, arrhythmia risk may be increased. Also, while the MRI SureScan mode is programmed to On, the patient receives no CRT support. This lack of CRT support might cause dizziness or shortness of breath. Be sure to program the MRI SureScan mode to Off as soon as the scan is complete.

Six-hour timeout period – The system automatically programs the MRI SureScan mode to Off 6 hours after it was programmed to On. This six-hour timeout period is provided to protect the patient from prolonged exposure to spontaneous tachyarrhythmia and VT/VF induction.

Check the pacing capture threshold – Check the pacing capture threshold after the scan is complete, and be sure that the pacing parameters are programmed adequately for the patient based on the threshold. There is a very slight risk that the MRI will cause lead tip heating, leading to increased pacing capture threshold and loss of capture.

Note: The Pacing Threshold Test measures capture thresholds in 0.25 V increments. The actual capture threshold change associated with a 0.25 V change is between 0.0 V and 0.5 V. For example, actual thresholds of 1.49 V and 1.51 V correspond to measured thresholds of 1.5 V and 1.75 V, respectively. In this case, an actual change of 0.02 V results in a measured change of 0.25 V. Similarly, actual thresholds of 1.01 V and 2.00 V correspond to measured thresholds of 1.25 V and 2.00 V. In this situation, an actual change of 0.99 V results in a measured change of 0.75 V.

Atrial, LV, and RV Capture Management measures capture thresholds in 0.125 V increments.

10.1 Returning the device to the pre-MRI configuration

After the MRI scan is complete, the MRI SureScan mode must be programmed to Off using the Medtronic programmer. Programming the MRI SureScan mode to Off restores the device parameter values to the pre-MRI SureScan mode configuration.

The device maintains the parameters that were set while initiating MRI SureScan operation until the MRI SureScan mode is programmed to Off after the MRI scan.

Perform the following steps to program the MRI SureScan mode to Off:

1. In the MRI SureScan field of the MRI SureScan screen, select [Off].
2. Select [PROGRAM].
3. Select [Close] to return to the Parameters window.

The device parameter values are now restored to the pre-MRI SureScan configuration.

Note: During each interrogation, the device is monitored for possible electrical reset conditions and disabled therapies. If a condition is detected that requires attention, the programmer displays a Device Status Indicator warning in a pop-up window and on the Quick Look II screen.

11 Medtronic warranty information

Please see the literature enclosed with the products for information regarding the product warranty or disclaimer of warranty as applicable.

12 Explanation of symbols

The following symbols are related to the magnetic resonance (MR) environment and are used to indicate the safety of devices and components in the MR environment.

SureScan symbol

MR Conditional symbol. The Medtronic SureScan CRT-D system is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MRI conditions for use.

13 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more information, contact your local Medtronic representative or contact Medtronic at the appropriate telephone number or address listed on the back cover of this manual.

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