Medtronic

Advisa DR MRI™ A2DR01 and Advisa SR MRI™ A3SR01 SureScan™ pacing systems

MR Conditional dual chamber and single chamber SureScan pacing systems with SureScan leads

MRI Technical Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 Introduction

The Medtronic SureScan pacing system is MR Conditional and, as such, 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 mode 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 pacing system. Contact a Medtronic representative if you have further questions.

Refer to the appropriate Medtronic clinician manual or lead technical manuals for non-MRI related instructions for use.

2 MRI conditions for use

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan pacing system includes a Model A2DR01 device with two SureScan leads or a Model A3SR01 device with one SureScan lead. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during 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 pacing system.

Note: If a lead impedance measurement value is < 200 Ω or > 1500 Ω, the software prevents the MRI SureScan feature from being initiated.

Note: The MRI SureScan mode 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 pacing system is implanted in the left or right pectoral region.
- The pace polarity parameters are set to Bipolar for programming MRI SureScan to On
- The lead impedance value is ≥ 200 ohms (Ω) and ≤ 1500 Ω
- 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.

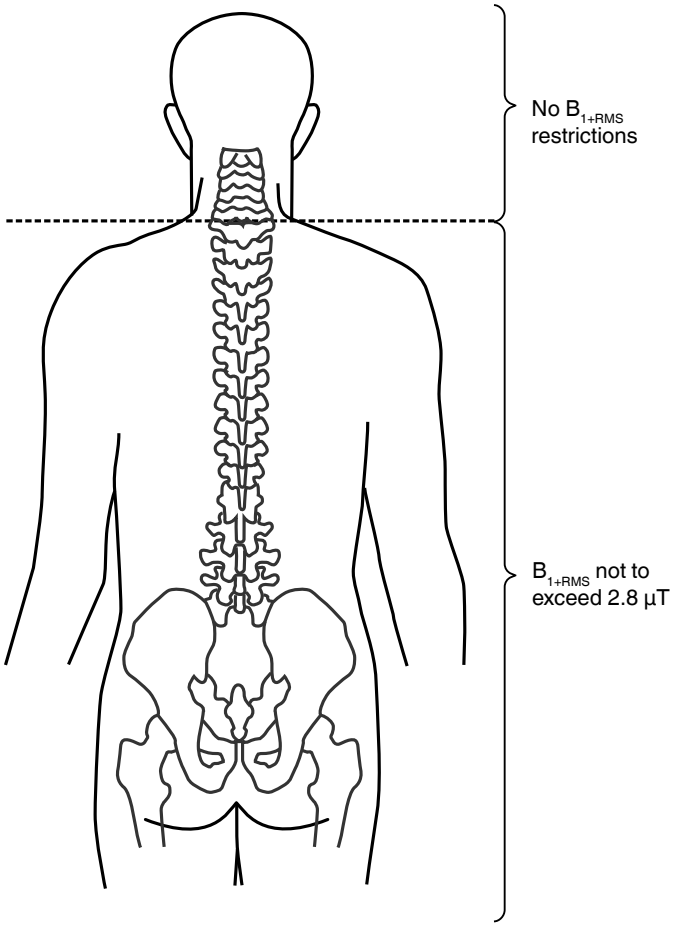
Caution: It is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms for pacemaker-dependent patients. A higher pacing capture threshold may indicate an issue with the implanted lead.

2.2 Radiology requirements

The safety and reliability of the SureScan pacing 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 restriction when the isocenter is at or superior to the C7 vertebra (see Figure 1).

Figure 1. 3T Scan location requirements



2.3 Patient monitoring and rescue requirements

Continuous patient monitoring is required during the MRI scan.

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

2.4 Training requirements

- A health professional who has completed cardiology SureScan training must be present during the programming of the MRI SureScan feature.
- A health professional who has completed radiology SureScan training must be present during the MRI scan.

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 pacing system.
- Do not scan patients who do not have a complete SureScan pacing system, which includes a Model A2DR01 DR IPG with two SureScan pacing leads, or a Model A3SR01 SR IPG with one SureScan pacing lead. Any other combination may result in a hazard to the patient during an MRI scan.
- 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 pacing 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 pacing 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.
- For pacemaker-dependent patients, it is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at a pulse width of 0.4 ms. A higher pacing capture threshold may indicate an issue with the implanted lead.
- Do not scan patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is on, and who have diaphragmatic stimulation at a pacing output of 5.0 V and at 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 MRI-related hazards, including myocardial tissue damage due to lead tip heating.
- 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 Zone 4 (MRI magnet room), as defined by the American College of Radiology. They are MR Unsafe.

4 Potential adverse events

The SureScan pacing system is 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
- 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
- potential for VT/VF induction when the patient is programmed to an asynchronous pacing mode during MRI SureScan mode

5 Patient monitoring requirements

Proper patient monitoring must be provided during the MRI scan and includes both of the following actions:

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

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

Note: If the patient's hemodynamic function is compromised during the MRI scan, discontinue the scan, remove the patient from the magnet room, 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) have not been prospectively studied by Medtronic and are not recommended.

Competitive pacing – If an asynchronous MRI SureScan pacing mode is selected, be aware that some patients may be susceptible to cardiac arrhythmia induced by competitive pacing. For these patients, it is important to first select an MRI SureScan pacing rate that avoids competitive pacing and then minimize the duration of the asynchronous pacing operation. For more information, contact a Medtronic representative.

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

System information and records – All pertinent information about the components of the implanted SureScan pacing 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 an ID card, should be provided to all patients with an implanted SureScan pacing system. These reference materials should indicate that the patient has a SureScan pacing device and SureScan leads.

Note: Be sure to advise the patient to notify medical personnel that they have an IPG before entering the MR environment and to present their patient ID card.

7 Radiology-specific considerations

7.1 MRI considerations

3 T whole-body transmit coil RF excitations – 3 T MRI systems using two transmit channels (or fewer) may operate in the following RF excitations: two transmit channels (known as Multichannel-2 (MC-2)) or Circularly Polarized (CP). Systems that use more than two transmit channels have not been studied, but such systems could be operated in CP or MC-2, if available.

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 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 pacing system components

Use the following methods to verify that a patient has a SureScan pacing 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 pacing 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. 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 pacing system. The patient may have other implanted devices that are not approved for use in the MRI environment, but not noted in the patient information on the programmer.

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 (OVO for single-chamber devices) when programming the MRI SureScan mode to On. Asynchronous pacing may increase the risk of arrhythmia. For pacemaker-dependent patients, it is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at a pulse width of 0.4 ms.

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.

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 pacing system.

Caution: Do not bring the Medtronic programmer, the Patient Assistant, or the patient monitor into Zone 4 (MRI magnet room), as defined by the American College of Radiology. They are MR Unsafe.

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 mode is programmed to On, regardless of the programmed mode. The device maintains the selected parameters until the MRI SureScan mode is programmed to Off after the MRI scan has been completed. After the MRI SureScan mode is programmed to Off, the permanent device parameters are restored.

9.1 SureScan pacing system integrity verification

The SureScan pacing system provides automatic verification that no device or lead issues that may compromise patient safety during an MRI scan are detected. Before allowing the user to initiate the MRI SureScan feature, the SureScan device application software checks for the following 2 situations:

Lead impedance is out of range – If a lead impedance measurement value is < 200 Ω or > 1500 Ω, or unavailable, the software prevents the MRI SureScan feature from being initiated.

Insufficient battery longevity – 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 feature to On

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

1. Select the Params icon from the tool palette.
2. Select Additional Features… on the Parameters screen.
3. Select the MRI SureScan… field (see Figure 2 or Figure 3, as applicable to the implanted device). The MRI SureScan Checklist window opens.

Figure 2. MRI SureScan… selection window for the dual chamber device

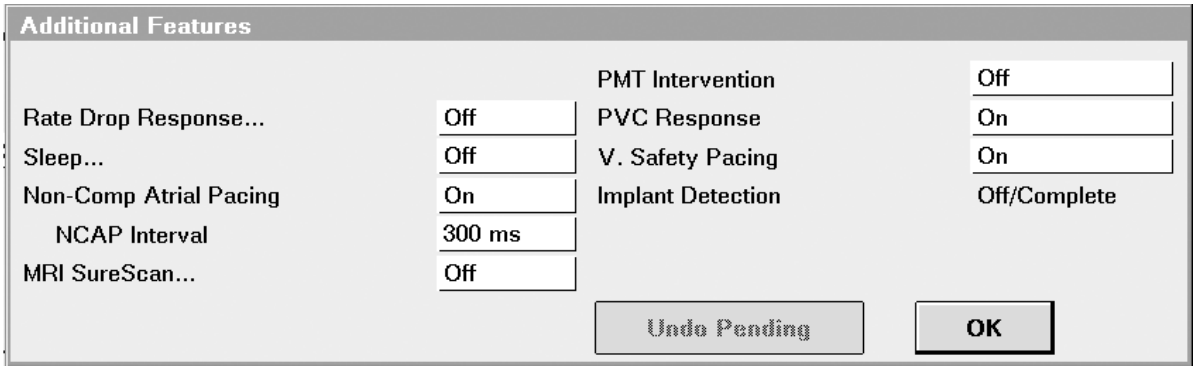
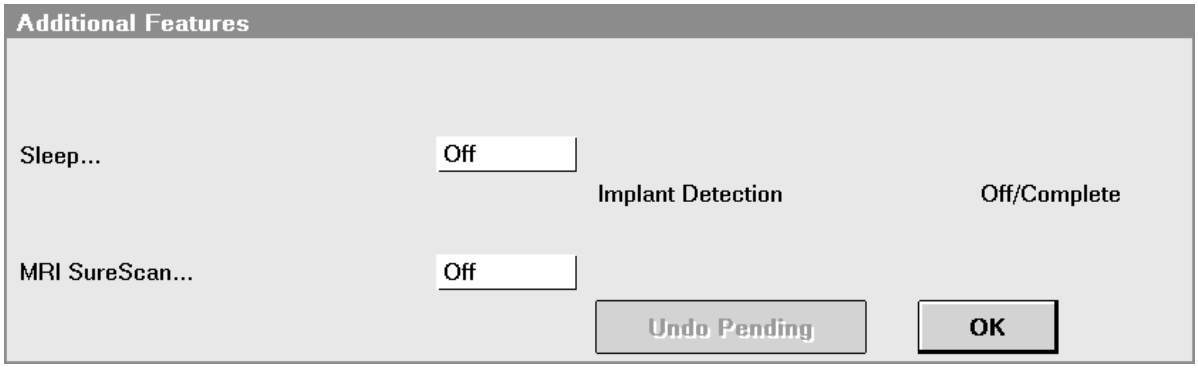
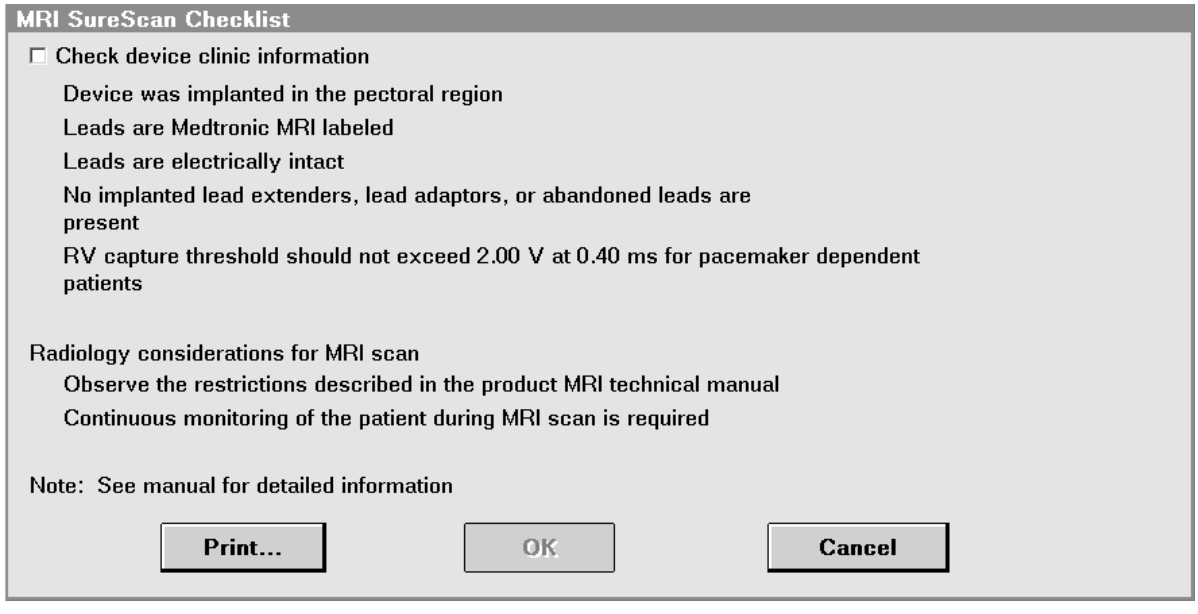


Figure 3. MRI SureScan… selection window for the single chamber device



4. Select the check box in the upper-left corner if all items on the MRI SureScan Checklist are satisfied for the patient (see Figure 4).
   Note: Print the MRI SureScan Checklist if desired.

Figure 4. MRI SureScan Checklist



5. Select [OK]. The MRI SureScan window opens.
6. Program MRI SureScan to On. See Figure 5 or Figure 6, as applicable to the implanted device.
7. 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 for a dual chamber device or VOO for a single chamber device).
     Note: An MRI SureScan pacing rate must be selected for the asynchronous pacing mode to avoid competitive pacing during the operation of MRI SureScan mode.
     Note: Pace polarity must be set to bipolar to program MRI SureScan mode to On.
   - For patients who do not require pacing support, program the device to the non-pacing mode (ODO for a dual chamber device or OVO for a single chamber device).
     Note: If the patient's device is programmed to the non-pacing (ODO or OVO) mode, the MRI SureScan pacing rate (Lower Rate) is not available for programming.

Figure 5. MRI SureScan settings for the dual chamber device

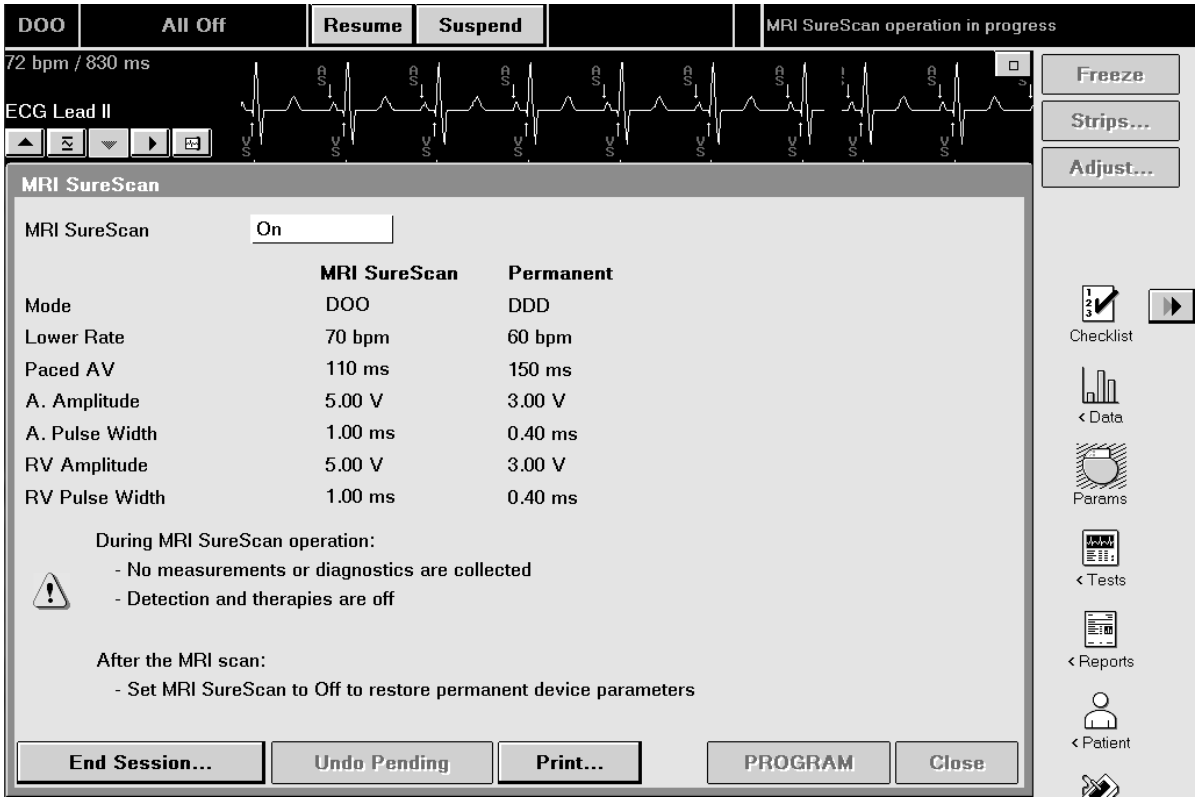
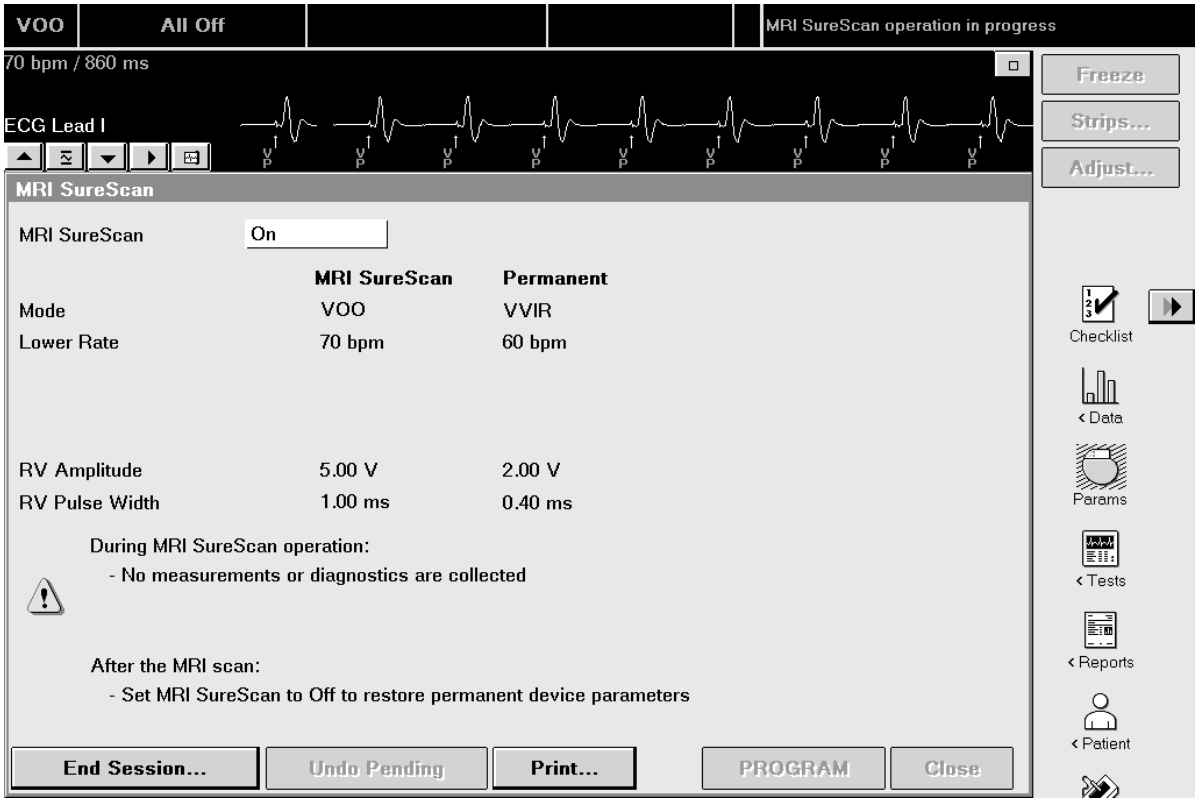


Figure 6. MRI SureScan settings for the single chamber device



8. Select [PROGRAM].
   Notes:
   - After the device is programmed for an MRI scan, available options are [Print…], [End Session…], and [Emergency]. The MRI SureScan parameter can also be programmed to Off.
   - Selecting the [Emergency] button while in MRI SureScan mode programs the MRI SureScan parameter to Off.
   - The status of MRI SureScan mode and the programmed parameters may be confirmed by printing the MRI SureScan parameter screen.

The device is now ready for the MRI scan.

9.3 Device considerations

Suspension of diagnostics and counters – When MRI SureScan mode is programmed to On, the following device diagnostics and counters are suspended:

- Daily Automatic EGM Amplitude Measurements
- Daily Automatic Lead Impedance Measurements
- Daily Atrial Lead Position Check in a dual chamber device
- Short Interval Counter
- Bradycardia Event Counters

Suspension of Magnet Mode – When MRI SureScan mode is programmed to On, the device does not initiate asynchronous, fixed-rate bradycardia pacing in the presence of a magnet.

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

If the permanently programmed A. Amplitude or RV Amplitude is less than 5.0 V, the amplitude is set to 5.0 V. If the permanently programmed A. Pulse Width or RV Pulse Width is less than 1.00 ms, the pulse width is set to 1.00 ms.

No RRT indication – When MRI SureScan mode is programmed to On, if the battery voltage falls below 2.83 V, the normal RRT indication does not occur.[1] If the feature is left on indefinitely, the patient will have no indication that the device has reached RRT.

Considerations specific to dual chamber devices:

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

Suspension of tachyarrhythmia detection – When MRI SureScan mode is programmed to On in a dual chamber device capable of tachyarrhythmia detection, the device does not detect atrial or ventricular tachyarrhythmias.

Suspension of tachyarrhythmia therapies – When MRI SureScan mode is programmed to On in a dual chamber device capable of providing tachyarrhythmia therapies, the device does not deliver these therapies. However, bradyarrhythmia pacing therapy is provided when an asynchronous pacing mode is selected for MRI SureScan operation.

Automatic PAV selection for DOO mode – If the DOO mode is selected when 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 MRI SureScan is programmed to On.

10 Following the MRI scan

Program the MRI SureScan mode to Off – Program the MRI SureScan mode to Off as soon as the scan is complete. If the mode is not programmed to Off, the device will remain in MRI SureScan mode indefinitely.

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 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.

[1] RRT indication consists of the following indicators: response to application of magnet = asynchronous pacing at 65 bpm; upon interrogation, an RRT warning message is displayed to the user.

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 pacing 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 call or write Medtronic at the appropriate telephone number or address listed on the back cover.

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

Medtronic USA, Inc.
Toll-free in the USA (24-hour technical consultation for physicians and medical professionals)
Bradycardia: +1 800 505 4636
Tachycardia: +1 800 723 4636

Europe/Middle East/Africa
Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale 84
CH-1131 Tolochenaz
Switzerland
+41 21 802 7000

Technical manuals
www.medtronic.com/manuals

M961531A001 B
2016-04-29

M961531A001