MRI procedural information for Revo MRI® SureScan®, RVDR01, CapSureFix MRI® SureScan® 5086MRI

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CapSureFix, CapSureFix MRI, CareLink, Medtronic, Medtronic CareLink, Quick Look, Revo MRI, SureScan
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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 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 pacing system. Clinical and pre-clinical testing has demonstrated that the SureScan pacing system is safe for use in the MRI environment when used according to the instructions in this manual. Contact a Medtronic representative if you have further questions.

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

2 MRI conditions for use

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.

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.

MR Unsafe symbol. An item that is known to pose hazards in all MR environments. The Patient Assistant, Medtronic CareLink 2090 Programmer and the Medtronic CareLink Home Monitor are MR Unsafe.

Cautions:
● Instruct the patient not to take the Patient Assistant (handheld activator) into Zone 4 (magnet room), as defined by the American College of Radiology. Doing so could damage the Patient Assistant or the MR scanner. The Patient Assistant is MR Unsafe.
● Instruct the patient not to take the Medtronic CareLink Home Monitor into Zone 4 (magnet room). The Medtronic CareLink Home Monitor is MR Unsafe.
● Do not bring the Medtronic CareLink Model 2090 Programmer into Zone 4 (magnet room). The Medtronic CareLink Model 2090 Programmer is MR Unsafe.

A complete SureScan pacing system, including the Revo MRI SureScan IPG and two SureScan leads is required for use in the MRI environment. Any other combination may result in a hazard to the patient during an MRI scan. The SureScan feature must be programmed to On prior to scanning a patient according to the specified conditions for use.

Cardiology requirements:
● Patients and their implanted systems must be screened to meet the following requirements:
  – no lead extenders, lead adaptors or abandoned leads
  – no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history
  – a SureScan pacing system that is implanted for a minimum of 6 weeks
  – a SureScan pacing system implanted in the left or right pectoral region
  – pacing capture thresholds of ≤ 2.0 volts (V) at a pulse width of 0.4 milliseconds (ms)
  – a lead impedance value of ≥ 200 ohms (Ω) and ≤ 1500 Ω
  – no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is on
Radiology requirements:
- Horizontal cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5 Tesla (T) must be used.
- Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 Tesla per meter per second (T/m/s) must be used.
- The scanner must be operated in Normal Operating Mode:
  - The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 watts per kilogram (W/kg).
  - The head SAR must be ≤ 3.2 W/kg.
- Proper patient monitoring must be provided during the MRI scan. This includes visual and verbal contact with the patient, and monitoring heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography.

Training requirements:
- A health professional who has completed cardiology SureScan training must be present during the programming of the 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 patients who do not have a complete SureScan pacing system, which includes a SureScan device and two SureScan leads. 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. This device implant location helps to prevent lead electrode heating due to RF energy and unintended cardiac capture due to the gradient magnetic fields.
- Do not scan patients with a lead impedance measurement value of < 200 Ω or > 1500 Ω. If a lead impedance measurement value is < 200 Ω or > 1500 Ω, or unavailable, the device software prevents the MRI SureScan feature from being initiated.

Cautions:
- Do not scan patients 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 with pacing capture threshold values of > 2.0 V at a pulse width of 0.4 ms. The higher pacing capture threshold indicates there may be 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 image.
- The use of lead extenders or lead adaptors is not recommended as they may increase the risk of myocardial tissue damage due to lead tip heating and other MRI field-related hazards.
- Scanning patients who have multiple MR Conditional devices present is acceptable as long as the MR labeling conditions for all implants can be satisfied.
4 Potential adverse events

The SureScan pacing 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 of the device to communicate with the programmer
- movement or vibration of the device or leads resulting in dislodgment
- competitive pacing and potential for VT/VF induction due to ambulatory asynchronous pacing in MRI SureScan mode

5 Cardiology-specific considerations

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.

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.

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 IPG and two SureScan leads.

6 Radiology-specific requirements

6.1 MRI requirements

The MRI requirements listed in this section must be satisfied during all MRI scans performed on patients with a SureScan pacing system. If you are unsure of the capabilities of your MRI machine, contact the MRI manufacturer.

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

- hydrogen proton magnetic resonance imaging equipment with a static magnetic field of 1.5 T, operating at a frequency of 64 MHz
- cylindrical bore magnet, clinical MRI systems
- gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less

MRI radio frequency (RF) power – The MRI scanner must be operated in Normal Operating Mode:

- The whole body averaged SAR must be ≤ 2.0 W/kg.
- The head SAR must be ≤ 3.2 W/kg.

6.2 Patient safety during the MRI scan

Patient monitoring – Proper patient monitoring must be provided during the MRI scan. This includes visual and verbal contact with the patient, and monitoring heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography.

Preparation for patient rescue – An external defibrillator must be available nearby during the MRI scan.
Note: If the patient’s hemodynamic function is compromised during the MRI scan, discontinue the MRI scan, remove the patient from the magnet room, and take the proper measures to restore the patient’s hemodynamic function.

6.3 MRI considerations

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

Multiple MRI scans – The effect of multiple MRI scans on a patient has not been evaluated clinically. While the clinical study was not designed to evaluate the effects of multiple MRI scans, 15 patients received multiple MRI scans due to medical need during the course of the clinical trial. In these 15 patients, there was no observed impact on electrical performance due to multiple MRI scans and there were no MRI-related complications.

Image artifact and distortion – SureScan leads have demonstrated minimal image distortion for areas surrounding the implanted leads when the device is out of the field of view. Significant image distortion can result from the presence of the device within the field of view. Image artifacts and distortion resulting from the presence of the device and the leads within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

7 Pre-MRI scan operations

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

7.1 Identification of SureScan pacing system components

The following are three ways to verify that a patient has SureScan pacing system components:

- **Radiopaque MRI symbols**: A radiopaque MRI symbol is present on all implanted SureScan pacing system components. By taking an x-ray of the implanted system, the clinician can verify whether the components have SureScan technology. An x-ray also indicates whether the patient has any additional active implantable devices.
  
  The device radiopaque MRI symbol is located in the header of the can. The radiopaque MRI symbol is a wavy line located in the upper portion of the full device radiopaque. A similar wavy line is visible on the lead, adjacent to the can and lead interface. See Figure 1 for the device and lead radiopaque MRI symbols and their locations.

  **Figure 1.** Radiopaque MRI symbols and their locations

  1 Location of the device radiopaque symbol  
  2 Device radiopaque MRI symbol  
  3 Lead radiopaque MRI symbol

- **Patient records or patient ID card (if applicable)**: The patient records or patient ID card, if applicable, must be complete and accurate if they are to be used to verify that the patient has a SureScan pacing system and to determine whether the patient has any additional active implantable devices.
Patient information on the programmer: The patient information must be complete and accurate on the programmer if this feature is to be used to determine whether the patient has a SureScan pacing system and to determine whether the patient has any additional active implantable devices.

7.2 Preparing a SureScan device for an MRI scan

The following tasks must be completed before performing an MRI scan on a patient with a SureScan pacing system:

- **Check that the SureScan pacing system has been implanted for more than 6 weeks:** The 6-week post-implant waiting period allows the device and lead to become fixated in the patient. Maturation of the lead and tissue interface increases the stability of the pacing capture threshold.

- **Check that the device was implanted in the pectoral region:** A device that is implanted in the pectoral region limits the lead loop area. This device implant location helps to prevent lead electrode heating due to RF energy and unintended cardiac capture due to the gradient magnetic fields.

- **Check that no lead extenders or lead adaptors are present:** The use of lead extenders or lead adaptors may increase the risk of myocardial tissue damage due to lead tip heating and other MRI field-related hazards.

- **Check that the leads are labeled as SureScan leads:** Leads other than SureScan leads have not been tested by Medtronic. Patients can be considered safe for an MRI scan only if the implanted system consists of a SureScan device connected to two SureScan leads.

- **Check that the leads are electrically intact:** 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.

- **Check that abandoned or additional leads are not present:** Abandoned or additional leads have not been tested by Medtronic. Patients can be considered safe for an MRI scan only if no other implanted leads are present.

7.3 Required patient care

Verify that the pacing capture threshold values are \( \leq 2.0 \text{ V} \) at a pulse width of 0.4 ms.

**Note:** Patients experiencing atrial fibrillation may be scanned if all other pre-MRI scan requirements are satisfied.

**Maximum pacing capture threshold** – The patient’s atrial and ventricular pacing capture thresholds must be evaluated before performing an MRI scan. If either the atrial or ventricular capture threshold exceeds 2.0 V at a pulse width of 0.4 ms, there may be an issue with the implanted lead.

**Pacing therapy during MRI scans** – Each patient must be evaluated to determine whether or not pacing support is needed during the MRI scan. For patients that require pacing support, the MRI SureScan pacing mode must be set to DOO, AOO, or VOO while MRI SureScan is programmed to On. For patients that do not require pacing support, the MRI SureScan pacing mode should be set to ODO while MRI SureScan is programmed to On.

**Pacing rate** – The appropriate pacing rate for patients who require pacing support must be determined before performing the MRI scan. The pacing rate must be selected to avoid competitive pacing during MRI SureScan operation.

8 Performing an MRI scan

**Caution:** Do not bring the Medtronic CareLink Model 2090 programmer into Zone 4 (magnet room), as defined by the American College of Radiology. It is MR Unsafe.

To safely perform an MRI scan on a patient with the SureScan pacing system, MRI SureScan must be programmed to On using the 2090 programmer. To program MRI SureScan, the user must select parameters that are appropriate for the patient when the MRI scan is performed.
Note: Pacing mode and rate (if applicable) are to be programmed per the physician’s discretion. Based on whether the patient needs pacing support or not, an asynchronous pacing mode (DOO, AOO, or VOO) or sensing only mode (ODO) can be programmed. Sensed events will be ignored by the device when MRI SureScan is programmed to On, regardless of the programmed mode.

The device maintains the selected parameters until MRI SureScan is programmed to Off after the MRI scan is done. After MRI SureScan is programmed to Off, the permanent device parameters are restored.

8.1 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 SureScan feature, the SureScan device application software checks for the following situations:

Lead impedance is out of range – If either of the bipolar lead impedance measurements is greater than 1500 Ω, is less than 200 Ω, or is unavailable, the software prevents the 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 SureScan feature from being initiated.

Note: If the battery voltage is at or below 2.85 V, the user is notified that the device is nearing the RRT threshold. (See Figure 2.) The MRI SureScan feature may be programmed to On; however, prolonged use of the MRI Model 3 feature may lead to an early, undetected RRT.

Figure 2. Programmer display: Device is nearing the RRT threshold

Attention

Measured battery voltage is nearing the RRT threshold.

Leaving MRI SureScan On may lead to an early, undetected RRT condition.

Make sure MRI SureScan is set to Off as soon as possible after the imaging session.

OK

8.2 Programming MRI SureScan 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 3 ). The MRI SureScan Checklist appears.
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 appears.
6. Program MRI SureScan to On.
7. Select an appropriate MRI SureScan pacing mode and MRI SureScan pacing rate (see Figure 5).
   - For patients who require pacing support, program the device to an asynchronous pacing mode (DOO, AOO, or VOO).
     **Note:** An MRI SureScan pacing rate must be selected for these pacing modes to avoid competitive pacing during the operation of MRI SureScan.
   - For patients who do not require pacing support, program the device to the non-pacing mode (ODO).
     **Note:** An MRI SureScan pacing rate is not necessary for patients whose device is programmed to ODO.
Figure 5. Selecting MRI SureScan settings

8. Select [PROGRAM].

Note: 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.

Note: The status of MRI SureScan and the programmed parameters may be confirmed by printing the MRI SureScan parameter screen.

The device is now ready for the MRI scan.

8.3 Device considerations

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

- Daily Automatic EGM Amplitude Measurements
- Daily Automatic Battery Measurement
- Daily Automatic Lead Impedance Measurements
- Daily Atrial Lead Position Check
- Short Interval Counter
- Bradycardia Event Counters

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

Suspension of tachyarrhythmia and PVC detection – When MRI SureScan is programmed to On, the device does not detect atrial or ventricular tachyarrhythmias or PVCs.

Suspension of tachyarrhythmia therapies – When MRI SureScan is programmed to On, the device does not deliver tachyarrhythmia therapies. However, bradycardia pacing therapy is provided when an asynchronous pacing mode is selected for MRI SureScan operation.

Automatic PAV selection for MRI DOO mode – If DOO mode is selected when MRI SureScan 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.

Automatic amplitude and pulse width selection for MRI SureScan pacing modes – When MRI SureScan is programmed to On and the pacing mode is DOO, VOO, or AOO, the device may automatically reset the amplitude and pulse width values. If the permanently programmed RA Amplitude or RV Amplitude is less than 5.0 V, the amplitude is reset to 5.0 V. If the permanently programmed RA Pulse Width or RV Pulse Width is less than 1.0 ms, the pulse width is reset to 1.0 ms.
**Increased current drain** – When MRI SureScan is programmed to On, the current drain from the battery is increased. Therefore, the feature should be programmed off following the MRI scan to prevent significant reduction in battery longevity.

**No RRT indication** – When MRI SureScan is programmed to On, if the battery voltage falls below 2.81 V, the normal RRT indication may not be displayed.\(^1\) If the feature is left on indefinitely, the patient will have no indication that the device has reached RRT.

### 8.4 Radiology considerations during the MRI scan

**Patient monitoring** – Proper patient monitoring must be provided during the MRI scan. This includes visual and verbal contact with the patient, and monitoring heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography.

**Preparation for patient rescue** – An external defibrillator must be available nearby during the MRI scan.

**Note:** If the patient’s hemodynamic function is compromised during the MRI scan, discontinue the MRI scan, remove the patient from the magnet room, and take the proper measures to restore the patient’s hemodynamic function.

### 9 Following the MRI scan

**Required patient care** – The following steps are required after performing an MRI scan:

- Program MRI SureScan to Off.
- Check the pacing capture threshold to ensure that there is a proper safety margin.

**IPIG capture output resolution** – The Medtronic Revo MRI SureScan RVDR01 IPG measures pacing capture threshold in 0.5 V increments. The actual pacing capture threshold change associated with a 0.5 V change is between 0.0 V and 1.0 V. For example, actual thresholds of 1.49 V and 1.51 V correspond to measured thresholds of 1.5 V and 2.0 V respectively. In this case, an actual change of 0.02 V results in a measured change of 0.5 V. Similarly, actual thresholds of 1.01 V and 2.00 V correspond to measured thresholds of 1.5 V and 2.0 V. In this situation, an actual change of 0.99 V results in a measured change of 0.5 V.

### 9.1 Returning the device to the pre-MRI configuration

**Note:** The device maintains the parameters that were set while initiating the SureScan feature until the MRI SureScan parameter is programmed to Off after the MRI scan.

After the MRI scan is complete, MRI SureScan must be programmed to Off using the 2090 programmer. This restores the device parameter values to the pre-MRI SureScan configuration.

Perform the following steps to program MRI SureScan to Off:

1. Program the MRI SureScan parameter to Off.
2. Select [PROGRAM].
3. Select [Close] to return to the Additional Features window. Select [OK] to return to the Parameters screen.

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.

\(^1\) automatic mode programming to VVI; automatic Lower Rate programming to 65 bpm; atrial ATP automatically disabled; response to application of magnet = VOO, 65 bpm; upon interrogation, an RRT warning message is displayed to the user
10  Explanation of symbols

The labeling for Medtronic SureScan pacing system components contains the SureScan symbol and symbols related to safety in the magnetic resonance (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.

MR Unsafe. An item that is known to pose hazards in all MR environments. The Patient Assistant, Medtronic CareLink Programmer and the Medtronic CareLink Home Monitor are MR Unsafe.

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 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.