PATIENT PRESCREENING

SureScan™ Pacing, Defibrillation, and CRT-D Systems Verification

Verify that patient has a complete SureScan™ pacing, defibrillation, or CRT-D system, which consists of an approved combination MRI SureScan™ device with SureScan™ lead(s) (Note: The model 6725 Pin Plug is MR conditional only for use in the atrial port on CRT-D devices), using one or more of the following methods:

- Use the patient records to verify a complete SureScan™ pacing, defibrillation, or CRT-D system has been implanted and MR conditions are met
- Use the patient ID card to identify the device and leads implanted, then verify MR conditional at http://www.mrisurescan.com
- Call Medtronic at 1 (800) 551-5544 to verify the patient’s current implanted system

The following are two optional methods that rely on complete and accurate information being entered:

- Use the Patient Details page on the CareLink™ network to verify a complete SureScan™ pacing, defibrillation, or CRT-D system has been implanted
- Use the Patient Information window [for ICD: select MRI SureScan™ system/Other Hardware] on the programmer to verify a complete SureScan™ pacing, defibrillation, or CRT-D system has been implanted

The table below provides an overview of devices and leads labeled for 1.5 and 3 Tesla covered by this checklist:

### 1.5T and 3T

#### Devices

<table>
<thead>
<tr>
<th>1.5T</th>
<th>3T</th>
</tr>
</thead>
<tbody>
<tr>
<td>SureScan™ XT DR (DDMB1D4, DDMB1D1)</td>
<td>Claria MRI™ Quad (DTMA1QQ, DTMA1Q1)</td>
</tr>
<tr>
<td>SureScan™ XT VR (DVMB1D4)</td>
<td>Claria MRI™ (DTMA1D4, DTMA1D1)</td>
</tr>
<tr>
<td>SureScan™ S DR (DDMC3D4, DDMC3D1)</td>
<td>Amplia MRI™ Quad (DTMB1QQ, DTMB1Q1)</td>
</tr>
<tr>
<td>SureScan™ VR (DVFC3D4, DVFC3D1)</td>
<td>Amplia MRI™ (DTMB1D4, DTMB1D1)</td>
</tr>
<tr>
<td>SureScan™ S VR (DVFB1D4, DVFB1D1)</td>
<td>Compia MRI™ Quad (DTMC1QQ)</td>
</tr>
<tr>
<td>SureScan™ DR (A2DR01)</td>
<td>Compia MRI™ (DTMC1D1)</td>
</tr>
<tr>
<td>SureScan™ SR (A3SR01)</td>
<td></td>
</tr>
</tbody>
</table>

#### Leads

<table>
<thead>
<tr>
<th>1.5T only</th>
</tr>
</thead>
<tbody>
<tr>
<td>6947: 58 and 65 cm</td>
</tr>
<tr>
<td>6935: 58 and 65 cm</td>
</tr>
<tr>
<td>6947M: 55 and 62 cm</td>
</tr>
<tr>
<td>6935M: 55 and 62 cm</td>
</tr>
<tr>
<td>5086MRI: 45, 52, and 58 cm</td>
</tr>
<tr>
<td>5076: 35, 45, 52, 58, 65, and 85 cm</td>
</tr>
<tr>
<td>4076: 35, 45, 52, 58, 65, and 85 cm</td>
</tr>
<tr>
<td>4074: 52 and 58 cm</td>
</tr>
</tbody>
</table>

**Table 1:** Devices and leads listed per 3T and 1.5T labeling
Cardiology Checklist

**Step 1: Patient prescreening 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. (Note: For pacemakers, the lead impedance value is ≥ 200 ohms (Ω) and ≤ 1,500 Ω)
- The SureScan™ system is implanted in the left or right pectoral region
- Revo pacemaker system has been implanted for more than 6 weeks; all other systems post-lead maturation period (approximately 6 weeks)
- 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: For pacemakers, the pace polarity parameters must be set to Bipolar for programming MRI SureScan™ to On)
- Pacing capture thresholds ≤ 2.0 V at 0.4 ms (Revo MRI™)

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.

**Step 2: Pre-scan programming requirements**
- A health professional who has completed cardiology SureScan™ training must be present during the programming of the SureScan™ mode
- Provide doctor’s order for pacing support needed and the appropriate pacing rate during SureScan™ operation
  - For patients who require pacing support, the MRI pacing mode must be set to DOO, AOO, or VOO while the MRI SureScan™ feature is programmed On
  - Tip: If an asynchronous pacing mode is selected, an appropriate MRI SureScan™ pacing rate must be selected to avoid competitive pacing during the operation of MRI SureScan™.
  - Note: For Advisa MRI™ devices, pace polarity must be set to Bipolar to program MRI SureScan™ mode to On.
  - Note: For CRT-D devices, when 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.
  - For patients who do not require pacing support, the MRI pacing mode should be set to ODO (OVO, for single chamber devices) while the MRI SureScan feature is programmed On

**Step 3: Post-scan programming requirements**
- Program SureScan™ mode Off after the MRI procedure; device returned to previous settings (see next page)
  - Note: Do not leave the device in MRI SureScan™ mode after the scan is complete. For CRT-D and ICD devices, 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.
  - Note: For CRT-D devices, 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.
- Check the pacing thresholds to ensure that there is a proper safety margin
SureScan™ Programming Steps

Prior to the MRI procedure
1. After accessing the Parameters screen, navigate to the MRI SureScan™ feature.
2. Select the check box in the upper-left corner to indicate all items on the MRI SureScan™ checklist are satisfied.
3. Select MRI SureScan™ programming field to On.
   Note: When MRI SureScan™ is programmed to On, all device diagnostic measurements and collection are suspended; the ICD or CRT-D system does not detect tachyarrhythmias and does not deliver tachyarrhythmia therapy.
4. From here, you will need to:
   ▪ Program a mode (DOO, VOO, AOO, ODO, or OVO)
   ▪ Program a rate (for asynchronous modes only; Pacemaker 30-120 bpm, ICD/CRT-D systems 60-120 bpm)
   ▪ Touch [PROGRAM] to complete the steps
   ▪ Touch [Print...] for documentation

Refer to the SureScan™ Programming Tip Card for more details.

After the MRI procedure
1. Interrogate the device, and you will be automatically brought to the SureScan™ programming screen.
2. Program SureScan™ Off. Pre-scan parameters are automatically restored.
3. Check the pacing capture threshold to ensure that there is a proper safety margin.

Radiology Checklist

Step 1: Schedule
- Contact cardiology to obtain clearance documents, including SureScan™ Programming Order, and the applicable SureScan™ conditions for use (including whether or not the patient is eligible for a 1.5T or a 3T MRI scan)
- Schedule a health professional who will monitor heart rate of patient during MRI exam (with ECG or pulse oximetry). A patient with a defibrillator or a CRT-D device must be monitored the entire time SureScan™ mode is programmed to On.
- Schedule a trained cardiology professional who will program the patient’s pacemaker, defibrillator, or CRT-D device in and out of SureScan™ mode

Step 2: Prep patient for scan
- Confirm a health professional who has completed radiology SureScan™ training is present
- Ensure device is programmed in SureScan™ mode prior to the MRI examination

Step 3: Conduct MRI scan using the following guidelines
- Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging
- Static magnetic field of one of the following strengths (Refer to table 2 on the following page):
  - 1.5T
  - 3T
- 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

Step 4: After the MRI procedure
- Contact cardiology to verify clearance documents are updated with any new programming changes
- Confirm that the patient’s heart rate is normal and stable
- Ensure that all device diagnostic measurements and collection are enabled
- Check the pacing capture threshold to ensure that there is a proper safety margin

SureScan™ Programming Tip Card

[Table 2: List of MRI parameters and their corresponding strengths]
Radiology Checklist, cont’d.

<table>
<thead>
<tr>
<th>1.5T — MRI radiofrequency (RF) power</th>
<th>3T — MRI radiofrequency (RF) power</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Normal Operating Mode</strong></td>
<td><strong>First Level Controlled Operating Mode or Normal Operating Mode:</strong></td>
</tr>
<tr>
<td>• Whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg</td>
<td>• ( B_{1+RMS} ) must be ≤ 2.8 ( \mu )T when the isocenter (center of the MRI bore) is inferior to the C7 vertebra</td>
</tr>
<tr>
<td>• Head SAR must be ≤ 3.2 W/kg</td>
<td>• Scans can be performed without ( B_{1+RMS} ) restriction when the isocenter is at or superior to the C7 vertebra (see Figure 1)</td>
</tr>
</tbody>
</table>

Table 2: MR Conditions of use for specific RF power.

**Step 4: Provide appropriate patient monitoring and rescue**

- **Pacemaker Requirements:** Proper patient monitoring* must be provided during the MRI scan. An external defibrillator must be available nearby during the MRI procedure.

- **ICD and CRT-D Requirements:** Proper patient monitoring* must be provided the entire time SureScan™ is programmed to On. An external defibrillator must be immediately available the entire time MRI SureScan™ is programmed to On.

*This includes visual and verbal contact with the patient, and monitoring heart rate using instrumentation such as pulse oximetry or electrocardiography.

**Step 5: Manage patient post-scan**

Ensure a trained professional programs the patient’s device back to previous settings.

Figure 1: Illustration showing the new labeling for 3T MR conditionality.
Contraindications: The SureScan™ transvenous pacing systems are contraindicated for implantation with unipolar pacing leads (Revo™ MRI only), concomitant implantation with another brachytherapy device or an implantable cardioverter defibrillator.

SureScan™ defibrillation and CRT-D systems are contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes, or patients with incessant VT or VF. For dual chamber and CRT-D devices, the device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF. For single chamber devices, the device is contraindicated for patients whose primary disorder is atrial tachyarrhythmia.

Reveal LINQ™: There are no known contraindications for the implant of the Reveal LINQ™ ICM. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings and Precautions: Changes in patient’s disease and/or medications may alter the efficacy of the device’s programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical failure, or device damage. Do not place transvenous defibrillation paddles directly over the device. Additionally, for CRT-D devices, certain programming and device operations may not provide cardiac resynchronization. Use of the device should not change the application of established antiarrhythmia protocols.

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

- SureScan™: transvenous pacing, ICD and CRT-D systems: no lead extenders, lead adaptors, or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; and the system must be implanted in the left or right pectoral or subclavicular region.
- For patients who are scheduled to undergo an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms. A higher pacing capture threshold may indicate an issue with the implanted lead. 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. It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks).
- Patientspecific: place polarity parameters set to Bipolar for programming MRI SureScan™ or On (Advista™ MRI only) or a SureScan™ pacing system with a lead impedance value of ≥ 200 Ω and ≤ 500 Ω. Revo MRI™ patients must have pacing capture thresholds of ≤ 2.0 V at a pulse width of 0.4 ms and a SureScan™ pacing system that has been implanted for a minimum of 6 weeks.
- Micro™: no abandoned leads are present; device is operating within the projected service life; pacing amplitude is ≤ 4.5 V at the programmed pulse width; no diaphragmatic stimulation is observed when MRI SureScan™ is programmed to On.

MR Scanning Conditions:

- Transvenous system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging, maximum spatial gradient ≤ 25 G/cm, and maximum gradient slew rate per axis ≤ 200 T/m/s. The 1.5T or 3T MRI system must be used in Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg). JT scanners must be operated in First Level Controlled Operating Mode or Normal Operating Mode. B, must be ≤ 2.8 μT when the isocenter (center of the bore) is inferior to the C7 vertebra. Scans can be performed without B, restriction when the isocenter is at or superior to the C7 vertebra. Revo MRI™ pacemakers can only be scanned using 1.5T systems.
- Micro™ and Reveal LINQ™: patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging, maximum spatial gradient ≤ 25 G/cm, and maximum gradient slew rate per axis ≤ 200 T/m/s. The whole Body Specific Absorption Rate (SAR) as reported by the MRI equipment must be ≤ 4.0 W/kg; the head SAR as reported by the MRI equipment must be ≤ 3.2 W/kg.
- Reveal LINQ™: Do not use local transmit coils on the chest, trunk, or shoulder region.
- For all SureScan™ pacing systems, proper patient monitoring must be provided during the MRI scan. For SureScan™ defibrillation and CRT-D systems, continuous patient monitoring is required while MRI SureScan™ is programmed to On. Do not scan a patient without first programming MRI SureScan™ to On and do not leave the device in MRI SureScan™ mode after the scan is complete. While MRI SureScan™ 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.

Potential Complications: Potential complications include, but are not limited to, rejection phenomena, device migration, infection, or erosion through the skin. Potential complications associated with cardiac rhythm devices include muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachyarrhythmias, and surgical complications such as hematoma, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibration, thrombosis, thromboembolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myocardial irritability, and pneumothorax. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. Other potential complications related to Micro™ are access site hematoma, AV fistulae, and vessel spasm. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or MR-induced stimulation resulting in continuous runaway, VT/VF, and/or hemodynamic collapse. Potential complications of the Reveal LINQ™ device include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

See the appropriate product MRI SureScan™ Technical Manual before performing an MRI Scan and see the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com or www.mrisurescan.com.

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