MRI SURESCAN™
SYSTEMS

Patient Scanning Process
Transvenous Implantable Cardiac Systems

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 devices), using one or more of the following methods:

- Use the patient records to verify a complete SureScan™ pacing, defibrillation, or CRT 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 mrisurescan.com*

- Call Medtronic at 1 (888) 660-4616 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 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 system has been implanted

For a full list of devices and leads approved for the MRI environment, download our MR-conditional Cardiac Device Summary Chart, which can be found on **MRISureScan.com***.

Medtronic

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 Advisa MRI™ , Ensura MRI™, and *Revo SureScan 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

- 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 pacemakers, Atrial and RV pace polarities must be set to bipolar to program MRI SureScan™ mode to On.

  - Note: For CRT -Dsystems, 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 systems, 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

* Revo is not approved in Canada. Please contact your local representative for further information.

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)
   - 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 system 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

Radiology Checklist, *cont'd.*

| 1.5T — MRI radiofrequency (RF) power	3T — MRI radiofrequency (RF) power
Normal Operating Mode • Whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg • Head SAR must be ≤ 3.2 W/kg	**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)

Table 2: MR Conditions of use for specific RF power.
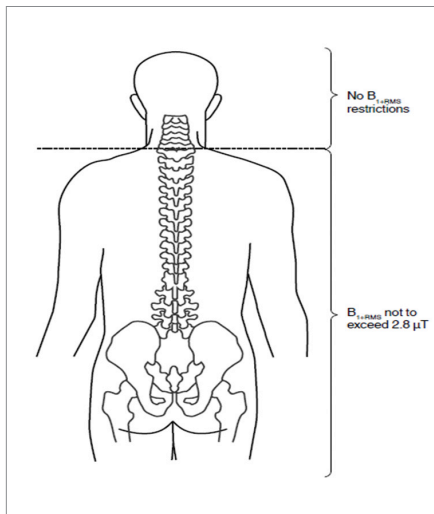
Figure 1: Illustration showing the new labeling for 3T MR conditionality.

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

Brief Statement
Medtronic SureScan™ Portfolio for 1.5T and 3T MR-conditional Use
Medtronic SureScan products and systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use.
Pacing, ICD, and CRT-D Systems: When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete transvenous SureScan system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. For ICD and CRT-D Systems, when a single coil SureScan defibrillation lead is used, a Medtronic DF-1 pin plug must be secured in the SVC port to make a complete SureScan DF-1 defibrillation system. 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.

See the Ensura MRI™ , Advisa MRI™, Evera MRI™, Visia AF MRI™ or Claria MRI™ /Amplia MRI™ SureScanTechnical Manual before performing an MRI Scan and Device Manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information consult Medtronic's website at www.medtronic.com* or www.mrisurescan.com*.

*Products that appear on this web site may not all be approved in your country. Please contact your local affiliate for further information