

# EXAMPLE PROTOCOL FOR PATIENT SCANNING PROCESS

MRI SureScan™ Pacing, ICD, and CRT-D  
Transvenous Implantable Cardiac Systems

## Purpose:

To define conditions that will allow a patient with a Medtronic SureScan™ Pacing/ICD/CRT-D System to receive an MRI.

## Policy:

If a patient with a Medtronic SureScan™ Pacing/ICD/CRT-D System meets the specific criteria as described in these instructions, they may obtain, at the discretion of a qualified physician, an MRI.

## Definitions:

It is recognized that most traditional pacemakers/ICD/CRT-D systems are contraindicated for MRI by the scanner equipment labeling. However, as MR-Conditional pacemakers/ICD/CRT-D systems enter the market, there will be requests for scanning these patients since MRI can be a conclusive and/or less invasive way of obtaining important diagnostic information.

## MR Specifications:

Depending on the specific SureScan™ device, the MR must be a 1.5T or 3T cylindrical bore magnet; different conditions of use exist for 1.5T versus 3T field strength. See the information in Table 1 for the specific conditions of use for either 1.5T or 3T field strength for devices covered with this protocol.

For a full list of devices and leads approved for the MRI environment, refer to our MR-conditional Cardiac Device Summary Chart.

- Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging
- Maximum spatial gradient of  $\leq 20$  T/m (2,000 gauss/cm)
- Gradient systems with maximum gradient slew rate performance per axis of  $\leq 200$  T/m/s

3T — MRI radiofrequency (RF) power	1.5T — MRI radiofrequency (RF) power
<b>First Level Controlled Operating Mode OR Normal Operating Mode</b> <ul style="list-style-type: none"> <li>▪ Scans can be performed without <math>B_{1+RMS}</math> restriction when the isocenter (center of the MRI bore) is at or superior to the C7 vertebra (see Figure 1).</li> <li>▪ <math>B_{1+RMS}</math> must be <math>\leq 2.8</math> <math>\mu</math>T when the isocenter is inferior to the C7 vertebra.</li> </ul>	<b>Normal Operating Mode</b> <ul style="list-style-type: none"> <li>▪ Whole body averaged specific absorption rate (SAR) must be <math>\leq 2.0</math> W/kg.</li> <li>▪ Head SAR must be <math>\leq 3.2</math> W/kg.</li> </ul>
<ul style="list-style-type: none"> <li>▪ Full body scanning: No MRI Exclusion Zone</li> </ul>	

Table 1: Specific conditions of use for 1.5T and 3T.

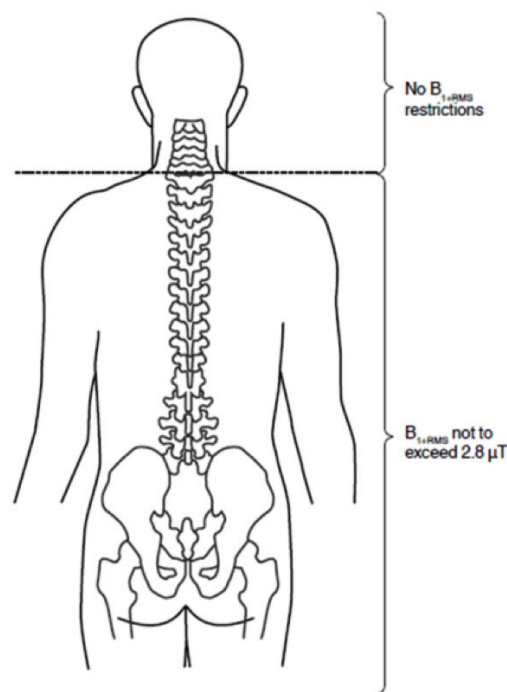


Figure 1: 3T scan location requirements.

## Equipment Specifications:

Require MR compatible oximetry or ECG monitoring devices for use in scan room (pacemaker) or for use when SureScan™ is programmed ON (ICD/CRT-D device). External defibrillator should be accessible in control area.

## Procedure for Approval of Exam:

Before the patient is scheduled for MRI exam, the following must occur:

- Interpreting physician (radiologist) approves appropriateness of exam ordered to answer the clinical question.
- "Pacemaker/ICD/CRT -D Systems Checklist" form (Attachment A) is started for this patient. This form ensures all screening requirements and steps in this procedure are followed.
- The patient is not otherwise contraindicated for an MRI. MRI safety screening should be completed per center's protocol.
- Patient's Cardiologist approval and order for pacer settings (Attachment B).

## Procedure:

### Pre-scan (day of exam):

Ensure availability of staff to be present during the exam. This should include the MR Technologist and a healthcare professional (not a Medtronic employee) trained to monitor the patient.

- Standard MRI screening questionnaire and consents will be obtained.
- MRI Technologist will discuss scan parameters with the interpreting physician. Any modifications to sequences will be done, when possible, before the patient is in the scan room. Special attention will be made to ensure SAR or  $\mu\text{T}$  limits are not exceeded.
- All pacemakers/ICD/CRT-D systems will be checked by a Medtronic representative or qualified healthcare professional. (Please note the device programmer is NOT MRI safe).
  - If pacemaker dependency is unknown, the device will be transiently switched to VVI at a backup rate of 30 to assess for device dependence. Information on battery voltage, lead capture threshold, lead impedance, and sensing signal amplitude will be obtained and recorded in a printout and copied to patient's medical record.

- While the device is in the SureScan™ mode, the tachyarrhythmia functions will be disabled (for the ICD/CRT-D) and CRT support is also disabled; pacing mode and rate will be set according to the cardiology order (Attachment B).

- Healthcare provider will print report from device programmer confirming SureScan™ mode is turned ON and copied to patient's medical record.

- For patients with ICD or CRT-D systems, monitoring of the patient by a qualified health professional is required from the time SureScan™ is programmed ON to it being programmed OFF. For pacemaker patients, monitoring is required during the MRI scan.
- External defibrillation should be immediately available during the MRI procedure, and for an ICD/CRT-D patient, the entire time SureScan™ Mode is programmed ON.
- Patient Monitoring:
  - Pacemaker: Either prior to entering the MRI room or once in the MRI, the MR-compatible pulse oximetry or ECG will be attached to the patient and activated. Accurate readings will be confirmed by a trained healthcare professional.
  - ICD/CRT-D: When SureScan™ is programmed ON, the MR-compatible pulse oximetry or ECG will be attached to the patient and activated. Accurate readings will be confirmed by a trained healthcare professional. Monitoring is required for the duration that SureScan™ is programmed ON.

## MR Scan:

- The patient will be prepared for the exam according to exam protocol with location guidelines followed.
- Scanning sequences for MR-conditional pacemaker/ICD/CRT-D systems may be limited or modified to respect the respective limits per conditions of use as stated above.
- Visual and voice communication will be maintained with the patient by the MR tech.
- Monitoring will be done via pulse oximetry or ECG by a trained healthcare professional.

## Post-Scan:

- The patient will be moved from the scan room to the control area by a qualified healthcare professional.
- Pacemaker/ICD/CRT -D function is reassessed and SureScan™ mode will be switched OFF and pre-scan device settings will be restored by a Medtronic representative or a qualified healthcare professional.
  - Pacemaker: Monitor systems may be removed from the patient after final oximetry or ECG monitor reading is recorded and after MRI scan is completed.
  - ICD/CRT-D: Monitor systems will be removed from the patient after SureScan™ has been programmed OFF and pre-scan device settings have been restored.
- Pacing capture threshold is reassessed post-scan by a Medtronic representative or a qualified healthcare professional to ensure the pacing parameters are programmed adequately for the patient based on the threshold.

## Education and Training:

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

**Training tutorials have been created for all systems and specifically for Cardiology and Radiology health professionals.**

Please visit

**[www.medtronicacademy.com](http://www.medtronicacademy.com)**. Search "MRI SureScan™ Training for Cardiology/Radiology."

## Documentation:

- Printed device rhythm and threshold reports from the device programmer will become part of the patient's medical record.
- Pre- and post-oximetry or ECG readings may be recorded.
- Exceptions to the performance of the routine MR exam will be documented by the technologist or qualified healthcare professional and added to the patient's chart.

# CHECKLIST FORM FOR MRI

Pacemaker/ICD/CRT-D Systems (Page 1/2)

## Patient Name:

Pre-Exam:	Initials
Received completed physician's order for MRI?	
Received completed cardiology clearance form for MRI?	
<p>*Revo™ Pacemaker: Has been implanted for more than 6 weeks? (contraindication for pacemakers)</p> <p>All others: Is post-lead maturation period (approximately 6 weeks)? (This is a caution, not a contraindication.) Confirm adequacy of lead maturation with cardiology.</p> <p><b>MRI scans during the lead maturation period (approximately 6 weeks) have not been prospectively studied by Medtronic and are not recommended.</b></p>	
<p>*Revo Pacemaker: Atrial (if applicable) and right ventricular thresholds do not exceed 2.0 V at 0.4 ms.</p> <p>All others: Right ventricular threshold does not exceed 2.0 V at 0.4 ms for pacemaker dependent patients. (This is a caution, not a contraindication.)</p>	
<b>Confirm that patient does not have any lead extenders, lead adaptors, abandoned leads, or leads that are not electrically intact.</b>	
<p><b>Pacemaker/ICD/CRT-D and implanted leads conclusively identified?</b></p> <p>(Only patients with a complete MRI SureScan™ Pacing/ICD/CRT-D System can undergo an MRI procedure.)</p> <p><b>Note: Only CRT systems may have a 6725 pin plug used in the atrial port as part of an MR-Conditional system.</b></p>	
MRI screening questionnaire has been reviewed with patient over the phone?	
Day of Exam:	
In Control Room (Outside MRI Suite)	
MRI Safe ECG or pulse oximeter applied to patient and assessed for accuracy; baseline blood pressure taken.	
Pacemaker/ICD/CRT-D system programmed into SureScan™ mode.	
An external defibrillator is available in the control room.	
For ICD/CRT-D: Patient ECG or oximetry monitoring will be initiated prior to SureScan™ mode being turned ON and prior to entering the magnet. Monitoring should be continuously done by a qualified staff member until SureScan™ mode is turned OFF.	
For patients with CRT-D systems, the patient receives no CRT support while SureScan™ mode is ON. Patient should be monitored for symptoms of dizziness and shortness of breath.	
In MRI Scan Room	
Patient ECG or pulse oximetry will be continuously monitored during the scan by qualified staff member.	
<p><b>3T — MRI radiofrequency (RF) power</b></p> <p>First Level Controlled Operating Mode OR Normal Operating Mode</p> <ul style="list-style-type: none"> <li>Scans can be performed without B<sub>1+RMS</sub> restriction when the isocenter (center of the MRI bore) is at or superior to the C7 vertebra (see Figure 1).</li> <li>B<sub>1+RMS</sub> must be ≤ 2.8 μT when the isocenter is inferior to the C7 vertebra.</li> </ul>	<p><b>1.5T — MRI radiofrequency (RF) power</b></p> <p>Normal Operating Mode</p> <ul style="list-style-type: none"> <li>Whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg.</li> <li>Head SAR must be ≤ 3.2 W/kg.</li> </ul>
Post-Scan (Outside MRI Suite)	
Post-MRI vital signs will be taken and documented.	
Patient's pacemaker/ICD/CRT-D SureScan™ setting is programed OFF (device parameters automatically restored to pre-MRI SureScan™ configuration).	
For CRT-D patients: Be sure to program MRI SureScan™ mode to OFF as soon as scan is complete to resume CRT support.	
Threshold check: Update programming outputs if necessary.	

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

# CARDIOLOGY ORDER FORM

Medtronic SureScan™ Pacing, ICD, and CRT-D Systems

Patient Name: \_\_\_\_\_

DOB: \_\_\_\_\_

1. Your patient has an MRI ordered. Please confirm that your patient has a Medtronic SureScan™ Pacing/ICD/CRT-D System, with SureScan™ lead(s). (Refer to <http://wwwp.medtronic.com/mrc> for a current listing of Medtronic MR-Conditional products. Note: Only CRT-D systems may have a 6725 pin plug used in the atrial port as part of an MR-Conditional system.)

**YES**, my patient has a complete Medtronic SureScan™ Pacing/ICD/CRT-D System and it has been implanted longer than 6 weeks in the pectoral region (\*Revo MRI™ IPG) or post-lead maturation period of approximately 6 weeks (all others).

**NO**, my patient does not have a complete SureScan™ IPG/ICD/CRT-D System.

2. Please confirm your patient's leads are electrically intact. (For Advisa™ MRI , Ensura™ MRI and \*Revo: to activate SureScan mode, the impedance range must be between 200-1,500 ohms. For other pacemakers, ICDs and CRT-D Systems; pacing leads must be between 200-3,000 ohms, defibrillation lead impedance must be between 20-200.

**YES**, I confirm that my patient's lead(s) are electrically intact.

**NO**, my patient's lead(s) are not electrically intact.

3. Confirm your patient's pacing threshold(s) do not exceed 2.0 V at 0.4 ms for \*Revo Pacing system, or right ventricular pacing threshold does not exceed 2.0 V at 0.4 ms for pacemaker dependent patients for all other systems.

**YES**, I confirm that my patient's threshold(s) do not exceed 2.0 V at 0.4 ms.

**NO**, my patient's threshold(s) exceed 2.0 V at 0.4 ms.

4. Before the scan, your patient's IPG/ICD/CRT-D will be placed in a SureScan mode. How would you like your patient's device to be programmed? Please select a pacing rate to avoid competitive pacing. (Note that post-scan, device programming will be restored to original settings.)

DOO Pacing rate: \_\_\_\_\_ bpm

AOO Pacing rate: \_\_\_\_\_ bpm

VOO Pacing rate: \_\_\_\_\_ bpm

ODO or OVO

(no pacing, for patients who do not require pacing support)

Physician Signature: \_\_\_\_\_

Physician Name: \_\_\_\_\_

Date: \_\_\_\_\_

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**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 MRI SureScan Technical 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](http://www.medtronic.com) or [www.mrisurescan.com](http://www.mrisurescan.com).

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