MRI SURESCAN™ SYSTEMS

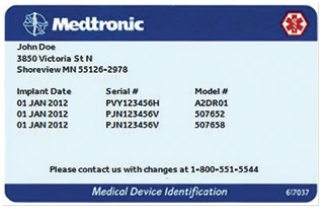
Patient Scanning Process
Transvenous Implantable Cardiac Systems

PATIENT PRESCREENING

SureScan™ Pacing, Defibrillation, and CRT (CRT-D and CRT-P) Systems Verification

Verify that patient has a complete SureScan™ pacing, defibrillation, or CRT 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


Medtronic

John Doe
3850 Victoria St N
Shoreview MN 55126-2978

Implant Date	Serial #	Model #
01 JAN 2012	PVY123456H	A2DR01
01 JAN 2012	PJN123456V	507652
01 JAN 2012	PJN123456V	507658

Please contact us with changes at 1-800-551-5544

Medical Device Identification 617037


For Medical Questions Contact Your Physician

I have a/an Advisa DR MRI SureScan Pacemaker implanted

This patient has a complete MR Conditional system implanted, consisting of a SureScan device and SureScan lead(s). For important MRI safety information, visit www.mrisurescan.com

If medical questions or emergency call:

Following Physician, MD
(763) 555-5555
Following Physician, MD
(763) 555-5555

My device may trigger metal detection systems.

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- 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 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**.

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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™ and Revo MRI™ 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 and CRT-P systems, Atrial and RV pace polarities must be set to bipolar to program MRI SureScan™ mode to On.
  - Note: For CRT systems, 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 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

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.

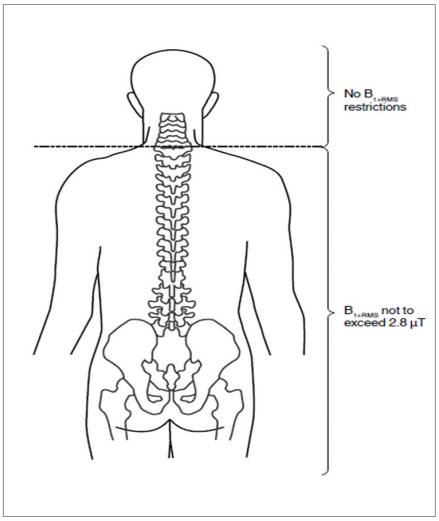

Figure 1: Illustration showing the new labeling for 3T MR conditionality.

Step 4: Provide appropriate patient monitoring and rescue

- **Pacemaker and CRT-P 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, CRT-P 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.

Indications

The SureScan MRI transvenous pacing systems are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Dual chamber SureScan pacing systems are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony.

The SureScan MRI defibrillation systems are indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the dual chamber devices are indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias.

The SureScan MRI CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications:

- New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration,
- Left bundle branch block (LBBB) with a QRS duration ≥ 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II,
- NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Claria/Amplia only: Some CRT-D systems are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias.

The SureScan CRT-P Systems are indicated for: NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal heart failure medical therapy and have a LVEF ≤ 35% and a prolonged QRS duration and for NYHA Functional Class I, II, or III patients who have a LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post-implant. Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity. Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications.

Micra™ Model MC1VR01 is indicated for patients with symptomatic paroxysmal or permanent high grade AV block in the presence of AF. It is also indicated in the absence of AF as an alternative to dual chamber pacing, or symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia/sinus pauses) when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy.

The Reveal LINQ™ Insertable Cardiac Monitor (ICM) is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated for patients with clinical syndromes or situations at increased risk of cardiac arrhythmias, or patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain that may suggest a cardiac arrhythmia.

Contraindications

The SureScan transvenous pacing and CRT-P systems are contraindicated for implantation with unipolar pacing leads (Revo MRI™ only), concomitant implantation with another bradycardia device or an implantable cardioverter defibrillator.

Micra IPG is contraindicated for patients who have the following types of medical devices implanted: an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, an implanted inferior vena cava filter, a mechanical tricuspid valve, or an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device or for patients who have the following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤ 12.5 cm (4.9 in), or known intolerance to the materials listed in the Instructions for Use, or to heparin, or sensitivity to contrast media that cannot be adequately pre-medicated.

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 reset, or device damage. Do not place transthoracic 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 anticoagulation protocols.

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

- SureScan transvenous 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 region. 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 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).
- SureScan Pacemaker and CRT-P specific: pace polarity parameters set to Bipolar for programming MRI SureScan to On (Advisa MRI™ and CRT-P [atrial and RV] only); or a SureScan pacing system with a lead impedance value of ≥ 200 Ω and ≤ 1,500 Ω (Advisa MRI and Revo MRI only). 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.
- Micra: 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:

Micra, Reveal LINQ, and transvenous system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. Revo MRI pacemakers can only be scanned using 1.5T systems.

Potential Adverse Events

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 tachycardia, and surgical complications such as hematoma, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, thrombosis, thrombotic and air embolism, 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 Micra 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 on leads resulting in continuous capture, 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 www.medtronic.com *or* www.mrisurescan.com.

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

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