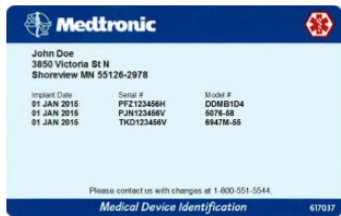


MRI SCANNING CHECKLIST

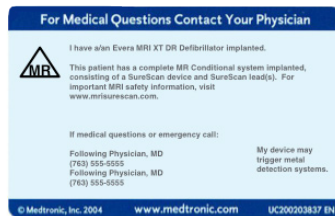
PATIENT PRE-SCREENING

SureScan™ Pacing and Defibrillation Systems Verification

- Verify that patient has a complete SureScan Pacing or Defibrillation System, which consists of an approved combination MRI SureScan device with SureScan lead(s), using one or more of the following methods:
- Use the patient ID card to identify the device and leads implanted, then verify MR conditional at <http://www.mrisurescan.com>.



Evera MRI Patient ID Card



- Use the patient records to verify a complete SureScan Pacing or Defibrillation System has been implanted.
- 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 or Defibrillation 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 or Defibrillation System has been implanted.
- Confirm that the patient does not have any lead extenders, lead adaptors, or abandoned leads.

Cardiology Checklist

Step 1: Patient pre-screening requirements

- Pacemaker System has been implanted for more than 6 weeks; ICD System post-lead maturation period (approximately 6 weeks).
- Pulse generator was implanted in the pectoral region.
- No lead extenders, lead adaptors, or abandoned leads.
- Leads are electrically intact (Pacemaker: pacing lead impedance between 200 and 1,500 ohms; ICD: pacing lead impedance between 200 and 3,000 ohms; defibrillation lead impedance between 20 and 200 ohms).
- No broken or abandoned leads or leads with intermittent electrical contact as confirmed by lead impedance history.
- 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.

Step 2: Pre-scan programming requirements

- A health professional who has completed cardiology SureScan training must be present during the programming of the SureScan feature.
- Provide 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.
 - 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.

Cardiology Checklist, *continued*

- Perform threshold check to confirm that atrial and ventricular thresholds do not exceed 2.00 V at 0.4 ms.
- Confirm SureScan is programmed On prior to scan (see sample device programming below).
- Print SureScan programming report for documentation to accompany patient to the MRI procedure.

SureScan Programming Steps

Prior to the MRI procedure

1. After accessing the Parameters screen, select [Additional Features].
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 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 60-120 bpm).
 - Touch [PROGRAM] to complete the steps.
 - Touch [Print...] for documentation.

Step 3: Post-scan programming requirements

- Program SureScan Off after the MRI procedure; device returned to previous settings (see below).
- Check the pacing thresholds to ensure that there is a proper safety margin.

	MRI SureScan	Permanent
Mode	DOO	DDD
Lower Rate	85 bpm	60 bpm
Paced AV	110 ms	180 ms
A. Amplitude	5 V	3 V
A. Pulse Width	1.0 ms	0.4 ms
RV Amplitude	5 V	3 V
RV Pulse Width	1.0 ms	0.4 ms

During MRI SureScan operation:
- No measurements or diagnostics are collected
- Detection and therapies are off

After the MRI scan:
- Set MRI SureScan to Off to restore permanent device parameters

End Session... Undo Pending Print... PROGRAM Close

Advisa DR MRI™ SureScan programming screen

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.
- Schedule a health professional who will monitor patient during MRI exam. Patients with defibrillators must be monitored the entire time SureScan Mode is programmed to On.
- Schedule a trained professional who will program the patient's pacemaker or defibrillator 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 cylindrical bore magnet MRI system of 1.5 Tesla must be used in Normal Operating Mode (Whole body averaged SAR must be $\leq 2\text{W/kg}$, head averaged SAR must be $\leq 3.2\text{W/kg}$).
- Static magnetic field of 1.5 T operating at a frequency of 64 MHz, maximum spatial gradient of $< 20\text{ T/m}$ (2,000 gauss/cm).
- Gradient systems with maximum gradient slew rate performance per axis of $\leq 200\text{ Teslas per meter per second (T/m/s)}$.

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 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 patient's device back to previous settings.

Brief Statement

Medtronic SureScan™ pacing and defibrillation systems are MR Conditional and, as such, are designed to allow patient to be safely scanned by an MRI machine when used according to the specific MRI conditions for use. A complete SureScan pacing or ICD system, which consists of an approved combination (see <http://www.mrisurescan.com/>) MRI SureScan device with SureScan lead(s), is required for use in the MRI environment. Consult the device manuals to ensure all system components are MR Conditional. For complete MRI Conditions for Use, operation and programming guidelines, and restrictions, refer to the SureScan Pacing or ICD System Reference Manual, call 1 (800) 505-4636, or visit www.emanuals.medtronic.com.

See the Advisa MRI™, Revo MRI®, or Evera 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, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com or www.mrisurescan.com.

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

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