Purpose:
To define conditions that will allow a SureScan® Pacing System patient to receive an MRI.

Policy:
If a patient with a SureScan pacemaker meets the specific criteria as described in these instructions, they may obtain, at the discretion of the Medical Director or qualified physician, an MRI.

Definition:
It is recognized that most traditional pacemakers are contraindicated for MRI by the scanner equipment labeling. However, as pacemakers approved for MRI use enter the market, there will be requests for scanning pacemakers since MRI can be a conclusive and or less invasive way of obtaining important diagnostic information.

MR Specifications:
MR must be a 1.5T cylindrical bore magnet. The SureScan Pacing System is not approved to use with other magnetic field strengths. Gradient system with maximum gradient slew rate of less than or equal to 200 Tesla per meter per second (T/m/s) must be used. Static magnetic field with a spatial gradient ≤ 20 T/m (2,000 gauss/cm). Whole body averaged SAR must be less than or equal to 2W/kg, head averaged SAR less than or equal to 3.2W/kg.

Equipment Specifications:
Require MR compatible oximetry or ECG monitoring devices for use in scan room. External defibrillator needs to be accessible to qualified staff in control area.

Procedure for Approval of Exam:
Before the patient is scheduled for MRI exam, the following must occur or be verified by the Medical Director or surrogate:

- Interpreting physician (Radiologist) approves appropriateness of exam ordered to answer the clinical question.
- “Pacemaker 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. Refer to MRI Screening Questionnaire (Attachment B).
- If applicable, the patient is not contraindicated for gadolinium contrast (Attachment B).
- Patient’s Cardiologist approval and order for pacer settings (Attachment C).

Pre-Scan (day of exam):
Immediately available staff for the exam’s duration will be supervising physician, MR technologist, and healthcare professional trained to monitor the patient. The patient will arrive to the center 30 minutes before the scheduled scan time.

- The patient will be instructed to change out of street clothes and into scrubs.
- The MR screening questionnaire and consent will be reviewed with the patient by the MR technologist (Attachment B).
  Both patient and technologist will sign the questionnaire and consent. The patient will be given the opportunity to ask questions and receive clear answers.
- MRI Technologist will discuss scan parameters with the interpreting physician.
- The patient will be escorted to the MR control room and seated outside the MRI.

Medtronic SureScan® pacing systems are MR-Conditional and as such, are designed to allow patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. A complete SureScan pacing 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.
√ The MR-compatible oximetry or ECG will be attached to the patient and activated. Accurate readings will be confirmed and monitored by a trained healthcare professional.

√ All pacemakers will be checked by a qualified healthcare professional (please note the device programmer is NOT MRI safe). 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. Tachyarrhythmia functions will be disabled and pacemakers will be switched to Medtronic’s SureScan safe mode. Pacing mode will be set according to cardiology order (Attachment C). Report will be printed from device programmer confirming SureScan mode is On.

MR Scan:

√ The patient will be escorted to the MR table by the technologist.

√ The monitor readings will be rechecked by a trained healthcare professional for readability and accuracy.

√ Sequences will be limited or modified to achieve a whole body average SAR less than or equal to 2.0 W/kg and Head average SAR less than or equal to 3.2 W/kg. Static magnetic field with a spatial gradient ≤ 20 T/m (2,000 gauss/cm). Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 Tesla per meter per second (T/m/s) must be used.

√ Visual and voice communication will be maintained with the patient.

√ Continuous monitoring of oximetry or ECG will be done by a trained healthcare professional. (Note that oximetry is monitored closely during certain sequences which make the ECG unreadable.)

Post-Scan:

√ The patient will be moved from the scan room to the control area.

√ Monitor device will be removed from the patient.

√ SureScan mode will be switched off and pre-scan pacemaker settings will be restored.

Documentation:

√ Printed reports from the device programmer will become part of the patient’s medical record.

√ Exceptions to the performance of the routine MR exam will be documented by the technologist and added to the PAC’s archive.

Education and Training:

√ All staff will be trained according to the MRI Staff Safety Policy.

√ A healthcare professional present during the scan must complete Radiology SureScan training.

√ A healthcare professional present during programming of the pacemaker must complete Cardiology SureScan training.
## MRI SureScan® Checklist

### Patient Name:

<table>
<thead>
<tr>
<th>Pre-Exam</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received completed physician’s order for MRI</td>
<td></td>
</tr>
<tr>
<td>Referring physician authorized provider? If not, non-provider form faxed to and returned from referring physician’s office</td>
<td></td>
</tr>
<tr>
<td>Received completed Cardiology Clearance form for MRI</td>
<td></td>
</tr>
<tr>
<td>Pacemaker has been implanted for more than 6 weeks</td>
<td></td>
</tr>
<tr>
<td>Alternatives to MR have been considered</td>
<td></td>
</tr>
<tr>
<td>Chest x-ray Y or N Date:</td>
<td></td>
</tr>
<tr>
<td>No lead extenders, lead adaptors or abandoned leads.</td>
<td></td>
</tr>
<tr>
<td>Pacemaker conclusively identified? (Only patients with a complete SureScan Pacing System can undergo an MRI procedure – a complete SureScan pacing system, which consists of an approved combination (see <a href="http://www.mrisurescan.com/">http://www.mrisurescan.com/</a>) MRI SureScan device with SureScan lead(s), is required for use in the MRI environment.</td>
<td></td>
</tr>
<tr>
<td>Medical Director approved scan</td>
<td></td>
</tr>
<tr>
<td>Interpreter (if not medical director) approved scan</td>
<td></td>
</tr>
<tr>
<td>MRI screening questionnaire has been reviewed with patient over the phone</td>
<td></td>
</tr>
<tr>
<td>If contrast MRI: Renal issues? Diabetes? (If yes, recent Creatinine and GFR required)</td>
<td></td>
</tr>
</tbody>
</table>

### Day of Exam:

<table>
<thead>
<tr>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interpreting MD’s name</td>
</tr>
<tr>
<td>Medtronic patient ID card copied and placed on patient chart</td>
</tr>
<tr>
<td>Patient changes into scrubs and removes any ferrous objects from person</td>
</tr>
<tr>
<td>Patient consent for MRI checklist reviewed and signed by patient and qualified staff</td>
</tr>
</tbody>
</table>
## MRI SureScan® Checklist

### (Page 2/2)

<table>
<thead>
<tr>
<th>In Control Room</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG or Oximeter applied to patient and accessed for accuracy</td>
<td></td>
</tr>
<tr>
<td>Pacemaker interrogated and placed in SureScan mode, report printed from device programmer to document pacemaker configuration and put on patient’s chart</td>
<td></td>
</tr>
<tr>
<td>External defibrillator must be available in control room during the procedure</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In Scan Room</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ECG or Oximetry are continuously monitored by qualified staff member</td>
<td></td>
</tr>
<tr>
<td>Whole <strong>body</strong> averaged SAR must be less than or equal to <strong>2W/kg</strong>, <strong>head</strong> averaged SAR less than or equal to <strong>3.2W/kg</strong></td>
<td></td>
</tr>
<tr>
<td>Static magnetic field with a spatial gradient ≤ 20 T/m (2,000 gauss/cm)</td>
<td></td>
</tr>
<tr>
<td>Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 Tesla per meter per second (T/m/s) must be used</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Scan</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>In control area, SureScan setting will be turned off and pre-scan pacemaker settings will be restored</td>
<td></td>
</tr>
</tbody>
</table>

Signature: _____________________________________________________________________________________

Initials: ________________ Date:  ___________________________________________________

(Attachment A)
# Magnetic Resonance Imaging Patient Medical Questionnaire

**Name:** _________________________________  
**Date:** ____________  
**Patient Weight:** ___________

**Name of Person filling this out:** ______________________________  
**Relationship to Patient:** __________________________

## Medical History

### Prior MR Scans?
- **Facility:** ______________________________  
- **Year:** ______________________________

### Any imaging procedure related to today’s scan?
- **Facility:** ______________________________  
- **Year:** ______________________________

### On Dialysis?
- **Yes**  
- **No**  
- **If “YES”, STOP! Check with Nephrologist**

### Pacemaker or Pacemaker Wires?
- **Yes**  
- **No**

### Implanted Cardiac Defibrillator?
- **Yes**  
- **No**

### Artificial Cardiac Valve?
- **Yes**  
- **No**  
- **If “YES”, Model #: _____________________________**

### Cranial Surgery
- **Yes**  
- **No**  
- **If “YES”, aneurysm clips?**
  - **Yes**  
  - **No**

### Neurostimulator?
- **Yes**  
- **No**

### Infusion Pump?
- **Yes**  
- **No**

### Renal Disease?
- **Yes**  
- **No**  
- **If “YES”,** to any of these, must have **GFR within 6 WEEKS** (**GFR = Glomerular filtration rate**)

### > Age 60?
- **Yes**  
- **No**

### High Blood Pressure?
- **Yes**  
- **No**

### Diabetes?
- **Yes**  
- **No**

### Liver Disease, Transplant, or Pending Transplant?
- **Yes**  
- **No**

### Bone Stimulator?
- **Yes**  
- **No**

### Transdermal Patch?
- **Yes**  
- **No**

### Cochlear Implant?
- **Yes**  
- **No**

### Tattoos?
- **Yes**  
- **No**

### Any other implanted/swallowed mechanical/electronic device?
- **Yes**  
- **No**  
- **If yes, describe:** ________________________________________________________________________

### Any metallic foreign body? (Examples: surgical clips, bullets, stents, screws, dentures with metal, artificial joints, artificial limb)
- **Yes**  
- **No**  
- **If yes, describe:** ________________________________________________________________________

### Any metallic objects in the eyes? (Sheet metal worker, welder, accident, ANY possibility of shavings in the eye)
- **Yes**  
- **No**  
- **If yes, describe:** ________________________________________________________________________

### Allergies to food, medications, and/or contrast dye?
- **Yes**  
- **No**  
- **If yes, describe:** ________________________________________________________________________

### List all medications: ___________________________________________________________________________________

### List major surgeries: ___________________________________________________________________________________

### History of claustrophobia  
- **Yes**  
- **No**

**Patient Signature:** ______________________________________________________________________________

**Technologist Signature:** _________________________________________________________________________

(Attachment B)
MRI SureScan® Pacing System
Cardiology Order Form

Patient Name: ________________________________________________________________

DOB: ______________________________

1. Your patient has an MRI ordered. Please confirm that your patient has a complete SureScan Pacing System, which consists of an MRI SureScan device with SureScan lead(s).

☐ YES, my patient has a complete SureScan Pacing System and it has been implanted longer than 6 weeks in the pectoral region.

☐ NO, my patient does not have a complete SureScan Pacing System.

2. Before the scan your patient’s pacemaker will be placed in a SureScan mode. How would you like your patient’s pacer to be programmed?

☐ DOO Pacing rate: _____bpm  ☐ AOO Pacing rate: _____bpm

☐ VOO Pacing rate: _____bpm  ☐ ODO or OVO Pacing rate: OFF

3. Post-Scan, SureScan mode will be turned off and pre-scan pacemaker settings will be restored.

Physician Signature: __________________________________________________________

Physician Name: _____________________________________________________________

Date: ________________________________

Please FAX back to: __________________________________________
Antitachycardia pacing (AtP) is indicated for termination of atrial
• VVI intolerance (for example, pacemaker syndrome) in the presence of
• Various degrees of AV block to maintain the atrial contribution to
synchrony, which include:
• of conduction disorders that require restoration of both rate and AV
synchrony. Dual chamber modes are specifically indicated for treatment
tracking modes in patients who may benefit from maintenance of AV
the dual chamber systems are also indicated for dual chamber and atrial
• Vasovagal syndromes or hypersensitive carotid sinus syndromes
modality to control heart rate. the patient’s age and medical condition,
• Concomitant implantation with an implantable cardioverter defibrillator
• Concomitant implantation with another bradycardia device
Medtronic SureScan pacing systems are contraindicated for:
•  Single chamber atrial pacing is contraindicated in patients with an
•  Asynchronous pacing is contraindicated in the presence (or likelihood)
of competition between paced and intrinsic rhythms
• chronically or persistent supraventricular tachycardias, including atrial
fibrillation or flutter

Indications
Medtronic SureScan pacing systems are indicated for the following:
• Rate adaptive pacing in patients who may benefit from increased pacing
rates concurrent with increases in activity
•Accepted patient conditions warranting chronic cardiac pacing include:
– Symptomatic paroxysmal or permanent second- or third-degree
AV block
– Symptomatic bilateral bundle branch block
– Symptomatic paroxysmal or transient sinus node dysfunctions with or
without associated AV conduction disorders
– Bradyarrhythmia syndrome to prevent symptomatic bradycardia
or some forms of symptomatic tachyarrhythmias
• Note: The Advisa DR MRI® pacing system includes the following
additional indication:
• Vasovagal syndromes or hypersensitive carotid sinus syndromes
The dual chamber systems are also indicated for dual chamber and atrial
tracking modes in patients who may benefit from maintenance of AV
synchrony. Dual chamber modes are specifically indicated for treatment
of conduction disorders that require restoration of both rate and AV
synchrony, which include:
• Various degrees of AV block to maintain the atrial contribution to
cardiac output
• VVI intolerance (for example, pacemaker syndrome) in the presence of
persistent sinus rhythm
Antitachycardia pacing (ATP) is indicated for termination of atrial
tachyarrhythmias in bradycardia patients with one or more of the above
pacing indications.

Contraindications
Medtronic SureScan pacing systems are contraindicated for:
• Concomitant implantation with another bradycardia device
• Concomitant implantation with an implantable cardioverter defibrillator
There are no known contraindications for the use of pacing as a therapeutic
modality to control heart rate. The patient’s age and medical condition,
however, may dictate the particular pacing system, mode of operation,
and implant procedure used by the physician.
• Rate-responsive modes may be contraindicated in those patients who
cannot tolerate pacing rates above the programmed Lower Rate
• Dual chamber sequential pacing is contraindicated in patients with
chronic or persistent supraventricular tachycardias, including atrial
fibrillation or flutter
• Asynchronous pacing is contraindicated in the presence (or likelihood)
of competition between paced and intrinsic rhythms
• Single chamber atrial pacing is contraindicated in patients with an
AV conduction disturbance
• ATP therapy is contraindicated in patients with an accessory
antegrade pathway

Warning 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. Use of the
device should not change the application of established anticoagulation
protocols.

Patients and their implanted systems must be screened to meet the MRI
Conditions of Use. Do not scan patients who do not have a complete
Medtronic SureScan pacing system consisting of a SureScan device and two
SureScan leads; patients who have broken, abandoned or intermittent leads;
or patients who have a lead impedance value of < 200 Ω or > 1,500 Ω. Do not
scan patients with a SureScan pacing system implanted in sites other than
the left or right pectoral region.

Potential Complications
Potential complications include, but are not limited to, rejection
phenomena, erosion through the skin, muscle or nerve stimulation,
oversensing, failure to detect and/or terminate arrhythmia episodes,
acceleration of tachycardia, and surgical complications such as hematoma,
infection, 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. The SureScan system has been designed
to minimize potential complications in the MRI environment. 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
induced currents on leads resulting in continuous capture, VT/VF, and/or
hemodynamic collapse.

See the device manuals before performing an MRI Scan for detailed information
regarding the implant procedure, indications, MRI conditions of use,
contraindications, warnings, precautions, and potential complications/adverse
events. For further information, call Medtronic at 1 (800) 328-2518 and/or consult

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

www.medtronic.com

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(24-hour technical support for
physicians and medical professionals)