**Revo MRI® SureScan® Pacing System**

**PERFORMING THORACIC IMAGING WITH PHILIPS MRI**

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One of the MR conditions of use when performing an MRI on patients with the Revo MRI SureScan Pacing System is that the isocenter (center of the bore) must be above C-1 or below T-12 (Figure 1). This is accomplished by landmarking above C-1 or below T-12.*

It is possible, however, to safely scan and obtain diagnostic MR images of anatomic structures that are located within this “exclusion zone” without violating this condition of use.

Figure 2 shows a sample sagittal and coronal localizer acquired using a 3-plane localizer sequence (axial images have been omitted) with a FOV of 400 mm. If the acquisition of any images in any plane are desired and these images need to be centered within the exclusion zone, the operator must first begin with localizer images landmarked (centered) as shown in Figure 2. Using the large FOV localizers, the desired images can then be prescribed.

**Sagittal and/or Coronal Images**

Prescribing sagittal and/or coronal images (including oblique sagittal and/or coronal images) as shown in Figure 3, would normally require the table to move prior to initiating the scan (and any preparation measurements).


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A complete SureScan pacing system including a Revo MRI SureScan IPG and two CapSureFix MRI® leads is required for use in the MRI environment. Any other combination may result in a hazard to the patient during an MRI scan. The SureScan feature must be programmed to On prior to scanning a patient according to the specified conditions for use. Refer to the Revo MRI Pacing System Conditions for Use located in the device manuals prior to scanning a patient. Consult Medtronic’s website at www.medtronic.com or call Medtronic at 1 (800) 328-2518.
In order to stay within the conditions of use, the following steps can be taken to prevent the table from moving so as to center the FOV of the prescribed scan(s) in isocenter.

**From the scan list within the exam card**

1. Right-click anywhere within the list of series to invoke the following pop-up box

![Pop-up box](image1)

2. Insure “Automatically Start Scan” (yellow arrow) is **Deselected** as shown above (i.e., not checked)

3. When each subsequent scan enters the preparation phase, the following pop-up menu box will appear:

![Pop-up menu](image2)

4. Select “**No**” and the table will not move.

The same scenario would occur with axial/oblique images (2D or 3D) as illustrated in Figure 4.

As long as “**Automatically Start Scan**” is **unchecked**, the operator will have the opportunity to **not allow system-controlled tabletop movement**.

Imaging within the lower portion of the exclusion zone would, of course, be handled in the same fashion. Figure 5 is an example of a localizer scan acquired with the FOV center below T-12.

![Figure 5](image3)

**Figure 4.** 2D and 3D axial/oblique prescriptions **below** C-1.

**Figure 5.** Landmark (and therefore FOV center) is below T-12.
Figure 6 illustrates axial prescriptions (both 2D and 3D) with the center of the slice group above the level of T-12.

As with the cervical spine example, in order to stay within the conditions of use the table movement must be prevented. As long as “Automatically Start Scan” is un-checked, the operator will have the opportunity to not allow system-controlled table top movement. prior to performing any scan or pre-scan measurements.

The same would hold true for coronal or coronal/oblique MRA studies of the abdomen where the center of the 3D data set would be above the level of T-12 (Figure 7).

**Image Quality Considerations**

It should be stressed that the further the center of the 2D slice group or 3D data set is from isocenter, a reduction in image quality may be observed. This could include reduced SNR and/or image distortion. This would most likely be more problematic on short-bore systems.

**Summary**

Scanning within the conditions of use for the Revo MRI SureScan Pacing System can be accomplished on the Philips system as long as one is aware of the FOV center when prescribing coronal and/or sagittal acquisitions and the superoinferior center of slice group when prescribing axial or steep oblique acquisitions. Deselecting “Automatically Start Scan” followed by “No” to “allow system-controlled table top movement?” will fix the table position at the point of the original landmark. To be within the conditions of use, the original landmark would need to be above C-1 or below T-12.

**Brief Statement**

The Revo MRI® SureScan® pacing system is MR Conditional and as such is designed to allow patients to undergo MRI under the specified conditions for use.

**Indications**

The Revo MRI SureScan Model RVDR01 IPG is indicated for use as a system consisting of a Medtronic Revo MRI SureScan IPG implanted with two CapSureFix MRI® SureScan 5086MRI leads. A complete system is required for use in the MRI environment.

The Revo MRI SureScan Model RVDR01 IPG is 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
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

The device is 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.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch.
Overdrive Pacing (PMoP) are indicated for the suppression of atrial tachyarrhythmias in bradycardia patients with atrial septal lead placement and one or more of the above pacing indications.

**Contraindications**
The device is contraindicated for:
- Implantation with unipolar pacing leads
- 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 implantation 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
- Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance
- ATP therapy is contraindicated in patients with an accessory antegrade pathway

**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. 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 Revo MRI SureScan pacing system consisting of a SureScan device and two SureScan leads; patients who have previously implanted devices, or broken 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 and right pectoral region; or patients positioned such that the isocenter (center of MRI bore) is inferior to C1 vertebra and superior to the T12 vertebra.

**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 hematomata, 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 and/or device heating which may cause tissue damage, impact the pacing system functionality such as failure to detect/treat irregular heartbeats, or potential for VT/VF induction.

*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 Medtronic’s website at www.medtronic.com.*

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