**TECH TIPS**

**CARDIAC DEVICES UPDATED LABELING FOR 3.0 T**

Philips Specific

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**$B_{1+RMS}$ as a Condition of Use**

Because $B_{1+RMS}$ is now recommended as a supplemental metric to SAR, Medtronic has begun to have device labeling approved with $B_{1+RMS}$ limits. Table 1 lists all SureScan™ cardiac devices and leads and specifies if they are labeled for 1.5 and 3T or 1.5T only.

### 1.5T and 3T

#### Devices

- **Evera MRI™ XT DR (DDMB1D4, DDMB1D1)**
- **Advisa MRI SR (A3SR01)**

- **Evera MRI XT VR (DVMB1D4)**
- **Amplia MRI™ Quad (DTMB1QQ)**

- **Evera MRI S DR (DDMC3D4, DDMC3D1)**
- **Amplia MRI (DTMB1D4)**

- **Visia AF MRI™ VR (DVFB1D4, DVFB1D1)**
- **Compia MRI™ Quad (DTMC1QQ)**

- **Advisa MRI™ DR (A2DR01)**

#### Leads

- **6947: 58 and 65 cm**
- **4574: 45 and 53 cm**

- **6935: 58 and 65 cm**
- **4196 (bipolar) 78, 88 cm**

- **6947M: 55 and 62 cm**
- **4296 (bipolar) 78, 88 cm**

- **6935M: 55 and 62 cm**
- **4396 (bipolar straight) 78, 88 cm**

- **5086MR: 45, 52, and 58 cm**
- **4298 (quad dual cant) 78, 88 cm**

- **5076: 35, 45, 52, 58, 65, and 85 cm**
- **4398 (quad straight) 78, 88 cm**

- **4076: 35, 45, 52, 58, 65, and 85 cm**
- **4598 (quad S shaped) 78, 88 cm**

- **4074: 52 and 58 cm**
- **Pin Plug 6725**

### 1.5T only

#### Devices

- **Revo MRI™ (RVDR01)**

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**Table 1**: Devices and leads listed per 3T and 1.5T labeling

SureScan cardiac device 3T labeling is a little different than 1.5T labeling in that it uses $B_{1+RMS}$ rather than SAR when landmarking/centering below C7. When scanning these devices at 1.5 T, SAR must be limited to the Normal Operating Mode. It is important to remember that the $B_{1+RMS}$ limit applies to 3T ONLY. When utilizing $B_{1+RMS}$ as a condition of use at 3T, one can utilize either Normal or First Level Controlled Mode for SAR. However, the displayed $B_{1+RMS}$ value for each scan is not to exceed 2.8 $\mu$T (micro Tesla) when landmarking/centering below C7. When landmarking/centering above C7, either Normal or First Level Controlled mode may be used for SAR and there are no restrictions regarding $B_{1+RMS}$. If your 3T MR system does not display $B_{1+RMS}$, then only studies may be performed which are landmarked/centered above C7.

How one modifies scan parameters to affect the $B_{1+RMS}$ may vary slightly between MR system brands based on available options. However, in general, whatever you do to reduce SAR on your system will likely reduce the $B_{1+RMS}$. If your system displays $B_{1+RMS}$, you will find it in the same area in which you find SAR.

### Philips 3T MR Systems

On the Philips system, $B_{1+RMS}$ is displayed alongside the estimated SAR values as shown in Figure 1. In particular it is the “Max B1+RMS” that is to be monitored.
As previously mentioned, most parameters that affect SAR will affect the $B_{1+RMS}$. Therefore, setting the SAR mode to “low” will reduce the $B_{1+RMS}$. However, it is highly unlikely this will be necessary to stay below 2.8 µT. Once you have adjusted the parameters to obtain a $B_{1+RMS}$ value of 2.8 µT or less, you can save that sequence in your protocols. Unlike SAR, the $B_{1+RMS}$ value will be the same the next time you recall that sequence (provided none of the parameters are altered from when it was saved, including the number of slices).

### Specific Examples for Modifying $B_{1+RMS}$ on Philips 3T Systems

Reducing the number of slices without increasing the TR or increasing the TR without increasing the number of slices will reduce the $B_{1+RMS}$. Reducing the number of slices is often not practical so increasing the TR is the more likely choice between the two. Depending on other parameters, you may have to significantly increase the TR. Besides the impact on scan time, significant increases in TR are also not practical when T1-Weighted spin echo sequences are desired.

Fast spin echo series consist of a 90-degree pulse followed by a “train” of refocusing pulses, generally said to be 180-degree pulses. In reality these are rarely 180-degree pulses but rather 170-degrees or even less. The number of echoes generated by the refocusing pulses is referred to as the TSE factor. To reduce the $B_{1+RMS}$ you can reduce the TSE factor (leaving all other parameters unchanged).

You also have the option to alter the flip angle of the refocusing pulse. (Figure 2). You will find this option under the contrast tab. Selecting “yes” for Refocusing control will open up a selection to allow you to reduce the angle of the refocusing pulse. Care should be taken when reducing the refocusing angle. If it is reduced significantly, you may see a reduction in SNR and/or alteration of image contrast. Experimentation may be the best way to determine the lower limit for any given sequence. As you reduce either the TSE factor or the refocusing flip angle, the $B_{1+RMS}$ will be reduced.

Please note that as of 2016, all Philips 3T systems specify a maximum $B_{1+RMS}$ of 2.3 µT in their compatibility technical data sheet, thus any modifications of any kind are not expected to be needed.

### Summary

- Certain Medtronic SureScan cardiac devices (pacemakers and ICDs) now have expanded labeling to include 3T.
- 3T labeling uses $B_{1+RMS}$ as the condition of use relative to RF power when landmarking/centering below C7.
- When landmarking/centering above C7, there are no restrictions for $B_{1+RMS}$ and either Normal or First Level Controlled mode for SAR may be selected.
- When landmarking/centering below C7, the displayed $B_{1+RMS}$ value should be less than or equal to 2.8 µT (micro-Tesla). Either Normal or First Level Controlled SAR mode may be selected.
- In the event your 3T system software does not display $B_{1+RMS}$, only studies in which the landmark is above C7 may be performed on a 3T system.
- The use of $B_{1+RMS}$ as a metric for RF heating provides for greater flexibility in pulse sequence and parameter selection.
- Most parameters which affect SAR will affect $B_{1+RMS}$.
- Once a sequence has been modified to have a $B_{1+RMS}$ value of 2.8 µT or less, it can be saved in the site’s protocols.
- As long as the parameters affecting $B_{1+RMS}$ are not modified, sequences saved with a specific $B_{1+RMS}$ value will remain unchanged patient-to-patient.
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. When a single coil SureScan defibrillation lead is used, a Medtronic Defibrillation lead 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.misurescan.com. Any other combination may result in a hazard to the patient during or after MRI.

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

SureScan Micra MRI® and Compia 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 classifications detailed in the specific device manuals. 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 ≥ 150 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 is required for patients who are at significant risk for developing atrial tachyarrhythmias.

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 stored implantable cardiac monitor system powered by 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 who may suggest a cardiac arrhythmia.

Contraindications: The SureScan transvenous pacing systems are contraindicated for implantation with unpolar 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 obstruction 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 Instruction 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 transverse defibrillation paddles directly over the device. Additionally, for CRT-D devices, certain programming and device operations may not provide reliable cardiac resynchronization. Use of the device should not change the application of established anticoagulation. Patients and their implanted systems must be screened to meet the following requirements for MRI:

- SureScan transvenous pacing, ICD and CRT-D 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 require an issue with the implanted lead. No diaphragmatic stimulation at a pacing output of 0.5 V and at a pulse width of 1.0 ms in a Medtronic SureScan system is on. It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks).

- Pacemaker specific: pace polarity parameters set to Bipolar for programming MRI SureScan to On (Advisa MRI only); or a SureScan pacing system with a lead impedance value of ≤ 2.0 kΩ and ≤ 1.0 kΩ. 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:

- Transvenous system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging, maximum spatial gradient ≤ 20 T/m, and maximum peak slew rate ≤ 200 T/m/s. Do not place transverse defibrillation paddles directly over the device. The SureScan system should be operated in Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg; head SAR ≤ 3.2 W/kg). MRI scanners must be operated in First Level Controlled Operating Mode. B1+max must be ≤ 2.81 T when the isocenter (center of the bore) is inferior to the C7 vertebra. Scan can be performed without B1+max restriction when the isocenter is at or superior to the C7 vertebra. Revo MRI pacemakers can only be scanned using 1.5T systems.

- Micra and Reveal LINQ patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging, maximum spatial gradient ≤ 25 T/m and maximum gradient slew rate performance per axis ≤ 200 T/m/s. The Whole Body New Normal Operating Mode (B1+max ≤ 4.0 W/kg, head SAR as reported by the MRI equipment must be ≤ 3.2 W/kg). MRI scanners must be operated in First Level Controlled Operating Mode. B1+max must be ≤ 2.81 T when the isocenter (center of the bore) is inferior to the C7 vertebra. Scan can be performed without B1+max restriction when the isocenter is at or superior to the C7 vertebra.

- Patients scheduled for MRI should not have any body composition changes that would alter the size of the field of view or the body contour. The presence of body compositions that may alter the size of the field of view or the body contour should be noted.

Potential Complications: 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, fibration, 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 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.misurescan.com.

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