**B₁+RMS as a Condition of Use**

Because B₁+RMS is now recommended as a supplemental metric to SAR, Medtronic has begun to have device labeling approved with B₁+RMS limits.

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.

SureScan™ cardiac device 3T labeling is a little different than 1.5T labeling in that it uses B₁+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 B₁+RMS limit applies to 3T ONLY.

When utilizing B₁+RMS as a condition of use at 3T, one can utilize either Normal or First Level Controlled Mode for SAR. However, the displayed B₁+RMS value for each scan is not to exceed 2.8 µT (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 B₁+RMS. If your 3T MR system does not display B₁+RMS, then only studies may be performed which are landmarked/centered above C7. Centering/Landmarking and/or scanning below C7 is not allowed for 3T systems that do not display B₁+RMS.

At 3T, most of your current protocols will need little to no modification to comply with the 2.8 µT B₁+RMS condition of use. As a rule of thumb, the higher the estimated SAR, the higher the likelihood that some modifications may need to be made. However at 3T, the likelihood that a sequence would need modification to comply with the 2.8 µT limit is still very low.

It should also be noted that there are no restrictions on the use of local transmit/receive coils for imaging of the head or the extremities, which includes no B₁+RMS restrictions. For example, if one is using a knee transmit/receive coil with a sequence requiring > 2.8 µT, this would be acceptable since the whole body coil is not being used as the transmit coil.

How one modifies scan parameters to affect the B₁+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 B₁+RMS. If your system displays B₁+RMS, you will find it in the same area in which you find SAR.

**Siemens 3T MR Systems**

On the Siemens system, B₁+RMS is displayed on the prediction tab in the SAR information dialog box (Figure 1). The yellow box in Figure 1 displays the B₁+RMS as a percentage of an arbitrary maximum B₁+RMS, defined such that scanner performance will not be limited due to B₁+RMS. This percentage of limit does not correspond to the B₁+RMS limit per the Medtronic labeling. To display a bar graph with the absolute B₁+RMS value in µT (red box in Figure 1), click in the B₁+RMS field. It is important to note that the B₁+RMS value is not updated in real time as scan parameters are changed. The predicted value for the scan will not be displayed until after the measurement phase. Therefore, the series should be configured so that the scan pauses after the measurement phase. This will allow the operator to verify the B₁+RMS value prior to manually initiating the scan.

![Figure 1](image-url)
To configure the scan so the operator manually initiates the scan, follow these steps:

1. Right-click on the series you wish to configure and select “Edit Properties” (Figure 2).

2. Select “Execution” on the left; then select “Wait for user to start” along with “Single measurement” and then “OK” (Figure 3).

The system will then perform the pre-scan measurement. Following the pre-scan measurement, you will be able to verify the predicted value of $B_{1+RMS}$ as shown previously in Figure 1. This should be done for each sequence being performed where landmarking/centering is below C7. Please note that the value of $B_{1+RMS}$ shown on the “Prediction” tab should be used to verify that the scan sequence follows the 2.8 μT labeling limit. During the actual scan sequence, the current $B_{1+RMS}$ is shown on the “Current” tab of the SAR information dialog box; the current value can vary in some instances due to the timing in gated scans and may even display values larger than the predicted value. However, this is acceptable as uncertainty of the predicted $B_{1+RMS}$ in comparison to the real-time $B_{1+RMS}$ has been accounted for in Medtronic’s 3T safety assessments.

As previously mentioned, most parameters that affect SAR will affect the $B_{1+RMS}$. Also remember that 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 Siemens 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.

Turbo 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 Turbo factor. To reduce the $B_{1+RMS}$ you can reduce the Turbo factor (leaving all other parameters unchanged). Figure 4 shows the selection for Turbo factor.

Siemens also allows the user to select the RF pulse type (Figure 4). Selecting the “Low SAR” option will also reduce the $B_{1+RMS}$. However, it is highly unlikely that selecting the “Low SAR” option will be necessary to stay below 2.8 μT.
Altering the flip angle is another option for reducing $B_{1+RMS}$. This is actually the flip angle of the refocusing pulses. Figure 5 shows the screen where you will find the flip angle adjustment. As you reduce either the Turbo factor or the refocusing flip angle, the $B_{1+RMS}$ will be reduced. It should be noted that at some point, reducing the refocusing flip angle can result in reduced SNR and altered image contrast. As a general rule of thumb, use caution when selecting a refocusing flip angle below 130.

**Summary**

- 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.

**Figure 5**

Remember, 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).
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. For CIED - CRT-P 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.mrissurescan.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 require atrioventricular 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 CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias and for providing antitachycardia 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, III, or IV who 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. Claria/Ampia only. Some CRT-D system are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias. The SureScan MRI CRT-F 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 II, III, or IV 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. Anti-tachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications.

Micra™-Model MCVR10 is indicated for patients with symptomatic paroxysmal or permanent high grade AV block in the presence of AF. It is also indicated 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 (Reva MRI™ only), concomitant implantation with another bradycardia device or an implantable cardioverter defibrillator. Micra IGP 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 (2.3 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions following conditions: femoral venous anatomy unable to accommodate a 7.8 mm (23 French) implant). An implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician, or an implantable cardioverter defibrillator.

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. 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.

**Warming Precaution**

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 transhoracic 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 anticogulation 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 at 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 is observed 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 [atral and RV] only); or a SureScan pacing system with a lead impedance value of ≥ 200 Q and ≤ 1,500 Q (Advisa MRI and Revo MRI CRT-P only). Micra, Claria/Ampia, or Clarity only: some CRT-D systems are not ideal for scanning in the MRI environment. For ICD and CRT-D Systems, 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.

**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, fibrosis, thrombus, 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, VTV, 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.

**Reference**

1. It should be noted that the maximum B max of 10 µT shown in Figure 1 is not representative of the maximum B max that will be utilized by the whole body transmit coil. In practice, it should be very rare that a sequence will reach the 2.8 µT labeling limit when using the whole body transmit coil and landmarking/centering below C7.