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.

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 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 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 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. Centering/Landmarking and/or scanning below C7 is not allowed for 3T systems that do not display B_{1+RMS}.

At 3T, most of your current protocols will need little to no modification to comply with the 2.8 µT B_{1+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 B_{1+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 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.

![Figure 1](image)

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).

![Figure 2](image)

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

- **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-compatible conditions

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, CRT-P and CRT-D Systems: When programmed to On, the MRI SureScan feature allows the patient to be safely imaged while the device continues to provide appropriate pacing. A complete transvenous SureScan system, which is a SureScan device with appropriate SureScan leads(s), is required for use in the MR environment. For ICD and CRT-D Systems, when a single coil SureScan device 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.mrisurescan.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 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 MRI defibrillation systems are indicated to provide 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 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) or a QRS duration > 130 ms, left ventricular ejection fraction ≤ 30%, and NYHA Functional Class II.
- NYHA Functional Class I, II, III or IV and who have left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of 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. Some CRT-D systems are also indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias.

The SureScan CRT-D system is 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 following classifications:
- NYHA Functional Class III or IV and who have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration and for NYHA Functional Class II, III, or IV and who have a left ventricular ejection fraction ≤ 50% and atrioventricular block (AV block) that are expected to require a high percentage of 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 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. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in patients with one or more of the above pacing indications.

Micra: Model M1CVRI01 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 pause) 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 (Revo MRI® only), concomitant implantation with another bradycardia device or an implantable card over defibrillator.

Micra ICP 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 obstructions or severe tortuosity), morbid obesity that prevents the implanted device from obtaining the device position in the heart, or significant intolerance to the materials listed in the Instructions for Use, or to heparin, or sensitivity to contrast media that cannot be adequately pre-medicated.

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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.mrisurescan.com.

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