Background
Medtronic's offering of MR-conditional implantable cardiac device systems (SureScan™ systems) includes pacemakers (IPG), defibrillators (ICD), and cardiac resynchronization defibrillators (CRT-D) that allowed for full body scans with 1.5T closed bore MR, a maximum whole body specific absorption rate (SAR) of 2W/kg, and a maximum head SAR of 3.2 W/kg.

Medtronic has expanded the MR-conditional labeling for selected SureScan™ systems to 3T in order to provide SureScan™ device patients with broader access to MRI with improved diagnostic imaging.

The new Medtronic MRI labeling for 3T specifies the maximum patient RF exposure in terms of the RF magnetic field used to create the image. This parameter is called 'B1+RMS' and is displayed on the console of newer MRI scanner models, or systems with updated software. For scans below C7 the maximum allowed B1+RMS is ≤ 2.8µT.

What is SAR?
SAR (Specific Absorption Rate) is a measure of the rate at which energy is absorbed by the body when exposed to a radio frequency (RF) electromagnetic field. It is measured in units of Watts per kilogram of body weight. These are the different modes available for the SAR level:

- Normal operating mode: Whole body SAR less than or equal to 2 W/kg, head SAR less than or equal to 3.2 W/kg. In the normal operating mode, no physiologic stress is expected.
- First level controlled operating mode: Whole body SAR greater than 2 W/kg but less than 4 W/kg, head SAR less than or equal to 3.2 W/kg. In the First Level Controlled mode, some patients who are unable to tolerate a thermal challenge may experience physiologic stress. Examples include: elderly, frail, obese, diabetic, etc.

SAR is very patient dependent; it varies depending on a patient's size and mass (weight) and there is no absolute direct measure of SAR that can be performed during an MRI scan. As a result, MRI manufacturers rely on numerical models to conservatively estimate the SAR for a particular scan. Each scanner manufacturer builds conservative assumptions into their SAR models to ensure that no patient exceeds the specified SAR limits.

The MRI system can measure the B1 field (the positively rotating RF magnetic field produced by the MRI scanner) needed for an imaging sequence, and uses the time averaged B1 field, or B1+RMS, to predict the estimated SAR that will occur due to that imaging sequence.

3T LABELING

The following terms and definitions will be utilized throughout the document.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>B0</td>
<td>The static magnetic field produced by the scanner. Units are Tesla (T)</td>
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<tr>
<td>B1 field</td>
<td>The rotating RF magnetic field produced by the MRI scanner. Units are micro-Tesla (µT).</td>
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<tr>
<td>B1+ field</td>
<td>The particular (positively rotating) component of the B1 Field useful for imaging</td>
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<tr>
<td>B1+RMS</td>
<td>The root-mean-square value of the MRI effective component of the B1 field. Units are micro-Tesla (µT).</td>
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<tr>
<td>RF</td>
<td>Radio frequency</td>
</tr>
<tr>
<td>SAR</td>
<td>Specific absorption rate. Units are watts per kilogram (W/kg)</td>
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<tr>
<td>SNR</td>
<td>Signal-to-noise ratio</td>
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What is the advantage of 3T over 1.5T?
3T provides superior Signal to Noise Ratio (SNR) which can result in improved image quality compared to 1.5T MRI imaging.1,2 This improved imaging quality has potential to provide superior diagnostics compared to 1.5T MRI imaging.1,5 In addition, the superior SNR can reduce the number of imaging averages required to produce images, which will reduce the overall scan duration.6,7
What is B$_{1+\text{RMS}}$?

B$_{1+\text{RMS}}$ is the time-averaged RF magnetic field component relevant for creating an MR image that is generated by the scanner during a scan and is measured in units of micro-Tesla (µT). Understanding the importance of B$_{1+\text{RMS}}$ to 3T MR-conditional labeling requires a brief overview of some basic MRI physics.

When a patient enters an MRI magnet, protons in the body align in the direction of the B$_0$ magnetic field similar to a compass aligning with the earth’s magnetic field. An MR imaging sequence is composed of a series of RF pulses that produce a magnetic field that interacts with these magnetically aligned protons and rotates them through a specific angle typically called the ‘flip angle’ or ‘tip angle.’ The RF magnetic field produced by the scanner is called the ‘B$_1$’ field of which only one part known as the positively rotating or ‘+’ component is useful for ‘flipping’ the magnetically aligned protons and allows images to be created. The maximum 10-second time averaged B$_1$ field strength of the RF pulses in the imaging sequence is the root-mean-square or ‘RMS’ B$_1$ value of the imaging sequence. Figure 1 defines each of the elements of the symbol B$_{1+\text{RMS}}$.

Another reason that B$_{1+\text{RMS}}$ is a more precise RF exposure metric than SAR is that it is patient independent. In contrast, SAR is a conservative estimate of the RF power deposited in a specific region of the patient under examination (head, whole-body, and partial-body) for a particular B$_{1+\text{RMS}}$ value. Predicting SAR from the known B$_{1+\text{RMS}}$ value is a complicated function of patient weight, morphology, tissue composition, posture, landmark location and averaging time. MRI scanners estimate the SAR for each scan and account for patient specific attributes using real-time RF power supervision combined with proprietary computational algorithms that have unknown safety margins.

The B$_{1+\text{RMS}}$ limit of ≤ 2.8µT identified in Medtronic SureScan™ systems’ MRI labeling is independent of such manufacturer specific approaches to SAR estimation and represents the actual RF field exposure that is safe for all patients implanted with Medtronic full-body eligible SureScan™ system using any 3T scanner that meets the requirements specified in the labeling.

Last but not least, imaging sequences that have been configured for a certain B$_{1+\text{RMS}}$ can be saved for future use and will be relatively consistent when recalled since B$_{1+\text{RMS}}$ isn’t patient dependent. However, if an imaging sequence was configured for a particular SAR value, when that sequence is recalled the SAR can often vary by large amounts depending on the patient.

“From my point of view, considering how troublesome SAR is for RF safety ‘predictions,’ the sooner we switch our approach throughout the industry away from SAR and to a more quantifiable and reproducible unit such as B$_{1+\text{RMS}}$ — the better.”

Emanuel Kanal, M.D., FACR, FISMRM, MRMD, AANG
Professor of Radiology and Neuroradiology
Director of Magnetic Resonance (MR) Service
University of Pittsburgh

“Setting parameters based on B$_{1+\text{RMS}}$ instead of SAR is a significant advance for patients and clinicians because B$_{1+\text{RMS}}$ is a more accurate and reproducible measure of potential implant heating in the MRI scanner. Utilising B$_{1+\text{RMS}}$ for implant labeling allows for the greatest possible performance of MRI scanning protocols while also ensuring patient safety.”

Yair Safriel, MBBCh, M.D.
Interventional & Diagnostic Spine and Neuroradiologist
Chief Medical Officer, Pharmascan Clinical Trials
Asst. Clin Professor, University of South Florida
If $B_{1+RMS}$ is a better measure of the RF field and SAR is based on this measure, why did Medtronic use SAR for their initial labeling?

Prior to 2010, manufacturers of MRI scanners weren’t required to display the value for $B_{1+RMS}$. Therefore, when Medtronic’s initial SureScan MRI cardiac systems were released in 2008, it was not practical to label these devices to $B_{1+RMS}$ since the MR technologist would have no means of verifying that they were conforming to the labeling.

What is the maximum RF output allowed under the 3T labeling?

As of May 2016, selected Medtronic SureScan™ cardiac systems are approved for a scan in a 3T scanner that can display $B_{1+RMS}$ with the following requirements:

- 3T closed bore clinical MRI used for hydrogen proton imaging
- Maximum spatial gradient of ≤ 20T/m (2,000 gauss/cm)
- Maximum gradient slew rate performance per axis ≤ 200 T/m/s
- No restriction if the isocenter is at or superior to the C7 vertebra
- $B_{1+RMS}$ must be ≤ 2.8µT when isocenter is inferior to the C7 vertebra

Why did Medtronic choose $B_{1+RMS}$ labeling for 3T MRI?

Medtronic’s 3T labeling (which utilizes $B_{1+RMS}$) allows for the greatest access to 3T MRI, without compromised performance. Medtronic arrived at the specified 3T labeling using $B_{1+RMS}$ in order to allow the greatest possible MR performance of 3T systems and reduce the impact on radiology staff, while simultaneously ensuring patient safety from implant heating.

Does this mean I need to change my scan sequences to stay within this limit?

The 2.8µT $B_{1+RMS}$ limit is not expected to limit current 3T scan protocols for scans below C7, thus no modification of scan sequences should be required. In most scenarios, basic SAR restrictions that are applied for all patients (associated with the limits imposed by First Level Controlled Operating Mode9) will prevent scan sequences from operating above 2.8µT when positioned inferior to the C7 vertebra. Scan sequences superior to the C7 vertebra have only First Level Controlled Operating Mode limits. The general principles that an MR technologist uses to reduce SAR can be used to reduce $B_{1+RMS}$.

If a scan sequence were to be encountered that is greater than 2.8µT for a landmark position inferior to the C7 vertebra, the general principles used to create reduced SAR protocols also apply to $B_{1+RMS}$ reduction.

Is the $B_{1+RMS}$ Display available on all 3T scanners?

No. The regulations that govern MRI equipment require that $B_{1+RMS}$ must be displayed on all new MRI scanners beginning in 20109 allowing a grace period until 2013. Some major manufacturers added this feature to scanners sold prior to 2013 as part of regular software upgrades. Medtronic estimates that more than 75% of installed 3T MRI scanners display $B_{1+RMS}$, and this percentage will continue to grow in the coming years.

Should the 3T scanner console not display the value for $B_{1+RMS}$ then the patient should not be scanned in said scanner. Consider finding a different 3T scanner with $B_{1+RMS}$ or scanning the patient at 1.5T instead. If you are unsure whether a scanner displays $B_{1+RMS}$, or is eligible for a software upgrade that enables this feature, contact the scanner manufacturer.

Where is $B_{1+RMS}$ displayed on the scanner console?

The location of the $B_{1+RMS}$ display on the scanner console is different for each manufacturer but is likely to be displayed in close proximity to SAR.
References
8. As specified in IEC 60601-2-33, “the maximum 30 second time averaged...”

Brief Statement
Medtronic SureScan™ Portfolio for 1.5T and 3T MRI-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 DF-1 pin plug must be secured in the SVC port to make a complete SureScan™ DF-1 defibrillation system.

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 HR Increase, DA increase, or post-dose increases. Dual chamber SureScan™ pacing systems are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of atrial tachyarrhythmias.

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.

SureScan™ Clara/Ampila/Compa CRT-D systems are indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. In addition, the dual chamber devices are indicated for use in the ambulatory patient with ventricular tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias.

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Contraindications: The SureScan™ transvenous pacing systems are contraindicated for implantation with unipolar pacing leads (Revo MRI™) or a complete SureScan™ DF-1 defibrillation system. 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.

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, induction of an arrhythmia, interruption of antibradycardia, and/or device reset, or device damage. Do not place transcutaneous defibrillation paddles directly over the device. Additionally, for CRT-D systems, certain programming and device operations may not provide reliable performance.

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 double 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 chronic atrial tachyarrhythmia with no concomitant VT or VF. For single chamber devices, the device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

RelevIQ™: There are no known contraindications for the implant of the RelevIQ™ ICM. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Clinically, a patient who is selected for implantation with an atrial tachyarrhythmia monitoring device may be 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 use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias.

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Contraindications: The SureScan™ transvenous pacing systems are contraindicated for implantation with unipolar pacing leads (Revo MRI™) only, concomitant implantation with another brachytherapy 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 cardiac conditions: femoral or iliac artery anatomy unable to accommodate a 7.8 mm (33 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 telemetry radiofrequency (RF) communication with the Micra™ device as outlined in the Instruction for Use, or to haphazard, or sensitivity to contrast media that cannot be adequately pre-medicated.

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