3T LABELING
B_{1+RMS}

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

Term	Definition
B_0	The static magnetic field produced by the scanner. Units are Tesla (T)
B_1 field	The rotating RF magnetic field produced by the MRI scanner. Units are micro-Tesla (μT).
B_{1+} field	The particular (positively rotating) component of the B1 Field useful for imaging
B_{1+RMS}	The root-mean-square value of the MRI effective component of the B1 field. Units are micro-Tesla (μT).
RF	Radiofrequency
SAR	Specific absorption rate. Units are watts per kilogram (W/kg)
SNR	Signal-to-noise ratio

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 'B_{1+RMS}' and is displayed on the console of newer MRI scanner models, or systems with updated software. For scans below C7 the maximum allowed B_{1+RMS} is ≤ 2.8μT.

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 SAR?

SAR (Specific Absorption Rate) is a measure of the rate at which energy is absorbed by the body when exposed to a radiofrequency (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 B_{1+} field (the positively rotating RF magnetic field produced by the MRI scanner) needed for an imaging sequence, and uses the time averaged B_{1+} field, or B_{1+RMS}, to predict the estimated SAR that will occur due to that imaging sequence.

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What is B_{1+RMS}?

B_{1+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+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[8] 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+RMS}.

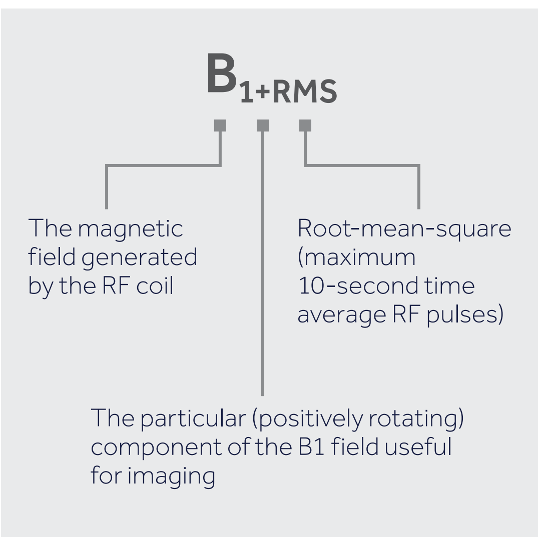


Figure 1: Definition of B_{1+RMS}

What is the Advantage of using B_{1+RMS} over SAR?

B_{1+RMS} is a more precise RF exposure metric than SAR.

- One reason for this is because B_{1+RMS} is the time averaged fundamental RF field parameter related to MR image creation. The scanner calibrates the RF pulse B_{1+} field strength during pre-scan and the B_{1+RMS} value for an imaging sequence is determined by the scan parameters needed to produce the desired tissue contrast.
- Another reason that B_{1+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+RMS} value. Predicting SAR from the known B_{1+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+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+RMS} can be saved for future use and will be relatively consistent when recalled since B_{1+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+RMS} — the better."

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

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

Yair Safriel, MBBCh, MD
Interventional & Diagnostic Spine and Neuroradiologist
Chief Medical Officer, Pharmascan Clinical Trials
Asst. Clin Professor, University of South Florida

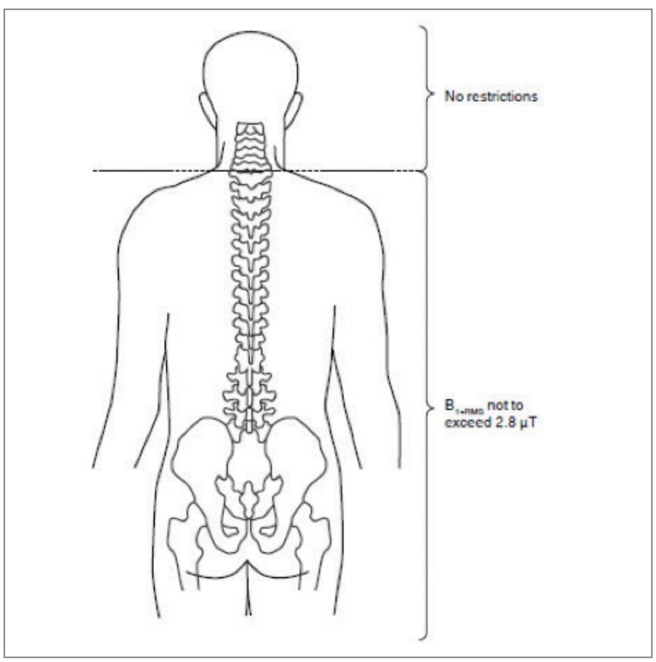
If B_{1+RMS} is a better measure of the RF field and SAR is based on this measure, why did Medtronic use SAR for their initial labeling?

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 Mode[9]) 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 2010[9] 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

[1] Kamada K, Kakeda S, Ohnari N, Moriya J, Sato T, Korogi Y. Signal intensity of motor and sensory cortices on T2-weighted and FLAIR images: intraindividual comparison of 1.5T and 3T MRI. *Eur Radiol*. December 2008;18(12):2949-2955.

[2] Stankiewicz JM, Glanz BI, Healy BC, et al. Brain MRI lesion load at 1.5T and 3T versus clinical status in multiple sclerosis. *J Neuroimaging*. April 2011;21(2):e50-e56.

[3] Lucchichenti G, Giugni E, Péran P, et al. 3 Tesla is twice as sensitive as 1.5 Tesla magnetic resonance imaging in the assessment of diffuse axonal injury in traumatic brain injury patients. *Funct Neurol*. Apr-Jun 2010;25(2):109-114.

[4] Craven I, Griffiths PD, Hoggard N. Magnetic resonance imaging of epilepsy at 3 Tesla. *Clin Radiol*. March 2011;66(3):278-286.

[5] Alvarez-Linera J. 3T MRI: advances in brain imaging. *Eur J Radiol*. September 2008;67(3):415-426.

[6] http://www.ncbi.nlm.nih.gov/pubmed/16555259Multicontrast black-blood MRI of carotid arteries: comparison between 1.5 and 3 tesla magnetic field strengths.

[7] http://www.biomedsearch.com/article/Cardiovascular-MRI-at-3T/209239236.html and http://www.medscape.com/viewarticle/566817 Cardiovascular MRI at 3T.

[8] As specified in IEC 60601-2-33, "the maximum 10 second time averaged..."

[9] IEC 60601-2-33 (Third edition – 2010).

Brief Statement
SureScan™ Pacing, Defibrillation, and Cardiac Resynchonization Therapy Defibrillation (CRT-D) Systems

The SureScan systems are MR Conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. 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 SureScan system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. 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.

See the Advisa MRI™, Evera MRI™, Visia AF MRI™ or Claria MRI™ /Amplia MRI™ SureScan Technical Manual before performing an MRI Scan and Device Manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information consult Medtronic's website at www.medtronic.com or www.mrisurescan.com.

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