MED/INSTITUTE

B₁+RMS: What is it and How Does it Impact MRI Safety Labeling?

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INTRODUCTION

Over 40 years of experience,

providing medical device development services to accelerate your product.





- 1. Background on radiofrequency (RF)-induced heating
- 2. Specific absorption rate (SAR) and SAR labeling
- 3. B_1 +RMS and B_1 +RMS labeling
- 4. Potential benefits and considerations for B_1^+RMS labeling
- 5. Towards adoption of B₁+RMS limits



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Background on RF-Induced Heating

MRI Safety Evaluations for (Most) Electrically Passive Devices





Background on RF-Induced Heating

Types of Magnetic Fields in MRI

Magnetic Field	Source	Presence	Amplitude	Frequency	Associated Safety Considerations for Electrically Passive Devices
Static Magnetic Field (B ₀)	Superconducting coils	Static, constant presence	Tesla (T)	N/A	Force Torque Image artifact
Gradient Magnetic Field (B _G)	Three gradient coils	Time-varying	mT	kHz	Gradient-induced heating Gradient-induced vibration
RF Magnetic Field (B ₁)	RF transmit coil	Time-varying	μΤ	MHz	RF-induced heating



Background on RF-Induced Heating

Physics of RF-Induced Heating

- Time-varying B₁ magnetic field induces currents on electrically conductive devices
- Induced currents create a scattered electric field in the tissue around the implant that can become highly focalized
- Scattered electric field can lead to high magnitudes of local specific absorption rate (SAR)
- SAR contributes to temperature rise





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SAR and SAR Labeling What is SAR?

- <u>SAR (specific absorption rate)</u> radiofrequency (RF) power absorbed per unit of mass [W/kg]
- SAR is:
 - present in the absence of a device
 - mostly restricted to the volume of the patient within the RF transmit coil
 - dependent on patient habitus and positioning within the RF coil and the scanning parameters
 - the major source of tissue heating in MRI





SAR and SAR Labeling SAR and Tissue Heating

SAR acts as the heat source term (q) in the Pennes' Bioheat Equation

$$k\left(\frac{\partial^2 T}{\partial r^2} + \frac{\omega}{r}\frac{\partial T}{\partial r}\right) + q + \rho_{bl}\omega_{bl}c_{bl}(T_{bl} - T) = \rho c\frac{\partial T}{\partial t}$$

Heat Source (SAR)

 Focused, high levels of SAR can lead to high temperature rises





Types of SAR and Use in MR Conditional Labeling

- Whole body, partial body, and local SAR
- Partial body and local SAR scale linearly with whole body SAR
- Limiting whole body averaged SAR directly limits local SAR associated with device heating
 - e.g., heating at 1 W/kg would be half that at 2 W/kg
- Whole body averaged SAR limits are what are typically listed on MR Conditional labeling





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B₁+RMS and B₁+RMS Labeling What is B₁+RMS?

- B₁+: The component of the RF magnetic field that is generated by the RF transmit coil during scanning that is used to positively rotate the protons used for imaging [µT]
 - Evaluated in an adjustment volume about isocenter
- B₁+RMS: The root mean square (RMS) of B₁+, which represents the highest average value for any 10s period, evaluated over the duration of a sequence







Relationship Between B₁+RMS and SAR

- B₁+RMS is a measure of the amplitude of the RF field, while SAR is a measure of the power absorbed from the RF field
- SAR is proportional to B₁+RMS²
- Limiting B₁+RMS limits temperature rise



Why are B₁+RMS Limits Being Requested Now?

- The 2022 edition of IEC 60601-2-33 introduced MR Equipment Output Conditioning (MROC)
- MROC allows operators to specify conditions to specific outputs during an MR examination
- Parameters listed in Table 201.107 are mandatory for the operator to have ability to limit
- SAR is not listed, while B₁+RMS is

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User controlled parameters Units Selectable options Any of the following birdcage transmit RF coils. RF transmit coil type if supported in the MR EQUIPMENT: · Integrated body coil Integrated head coil DETACHABLE head coil Other DETACHABLE coils at the discretion of the MANUFACTURER RF polarization Where applicable: • CP MC-2 MC-N μΤ Maximum B₄⁺RMS MAXIMUM GRADIENT SLEW RATE per axis T/m/s

Table 201.107 – User selectable control parameters for MROC implementation

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Comparison Between SAR and B₁+RMS Labeling

MRI Scanner-Reported SAR and B₁+RMS

RF Metric	Variables	Patient-Dependent?	Calculation Method
SAR	Patient habitus Patient positioning Scanning parameters	Yes – patient and patient positioning can result in different wbSAR for same scanning sequence	Proprietary algorithms that have been shown to overestimate SAR by 2-3x
B₁⁺RMS	Scanning parameters	No – given sequence will result in same B ₁ ⁺ RMS regardless of patient or patient positioning	Accurately calculated from scanning sequence during pre-scan using a standardized equation



Comparison Between SAR and B₁+RMS Labeling

Simulation Calculation of SAR and B₁+RMS

- Whole body SAR is calculated as the average SAR in the entire mass of the patient
- B₁+RMS is calculated as the spatially averaged B₁+ in an axial adjustment volume of the patient about the isocenter of the RF coil





Comparison Between SAR and B1+RMS Labeling Virtual Human Landmark Studies

 B_1^+RMS Limit for Hour Continuous Scan at 3 T: 2.75 μT





Comparison Between SAR and B₁+RMS Labeling

Implications on MR Conditional Labeling

- Since SAR is typically overestimated by 2-3x at MR scanners, simulated temperature rise at an exact calculated wbSAR value may be overly conservative
 - Can result in unnecessarily restrictive labeling
- Scanner-reported B₁+RMS and simulated B₁+RMS are both accurately calculated
 - Simulated B₁+RMS condition is representative of actual scanning condition; potential for more appropriate labeling
- A sequence that is within the B₁+RMS limit for a device can be safely applied to any patient with the device

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Challenges/Roadblocks for Implementation of B₁+RMS Labeling

- SAR has been the precedent for MR Conditional labeling for decades
 - More literature, familiarity, and comfort with it over B_1 +RMS
- Presence of metallic implant near isocenter may skew the scanner-reported B₁+RMS value
- Solution: publish on the topic to have more universal understanding for researchers, industry, and regulators
 - This will also inherently come with the shift towards regulatory bodies requesting B₁+RMS limits



Questions?



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