

# Guidance for Adjusting MRI scan Sequence SAR and B1+rms Values

Medtronic

## Note to MRI equipment operators:

Carefully review the *MRI Guidelines for Medtronic Deep Brain Stimulation Systems* before attempting to scan any patient with an implanted Medtronic Deep Brain Stimulation (DBS) system. Go to [www.medtronic.com/mri](http://www.medtronic.com/mri) or contact Medtronic at 1-800-707-0933 for a copy of the guidelines. Also, carefully review the MRI scanner labeling before proceeding with the scan.

This document is intended to provide general guidance on how to adjust MRI scan protocols in accordance with the Specific Absorption Rate (SAR) and B1+rms limits identified in the MRI Guidelines for Medtronic Deep Brain Stimulation Systems. The scan protocol adjustments described in this document should only be used by qualified MRI scanner operators. The scanner operator and/or radiologist are responsible for ensuring compliance with the *MRI Guidelines for Medtronic Deep Brain Stimulation Systems*.

The SAR and B1+rms reduction strategies described in this document are based on publicly available MRI scanner information collected in 2015. Medtronic has verified the accuracy of the information for the specific scanner models summarized in this document but does not guarantee the output of any MRI scanner. The third party scanner information and technical details contained in this document are subject to change and Medtronic cannot guarantee their accuracy at the time this document is used. In addition, scanners of different models or manufacturers than those described below may have different scan setting options than described here.

## Introduction

Medtronic has labeling for specific DBS systems that allow head scans with a transmit/receive (T/R) head coil and a maximum SAR of 0.1W/kg. In addition, Medtronic recently obtained approval for expanded labeling for certain DBS systems to enable scanning of implanted patients anywhere in the body at significantly greater radio frequency (RF) power than was previously allowed. The new labeling specifies the maximum patient RF exposure in terms of the RF magnetic field used to create the image in addition to SAR. This parameter is called B1+rms and is displayed on the console of newer model MRI scanners. This document describes SAR and B1+rms, and provides guidance for adjusting MRI scan sequence SAR and B1+rms values.

The following sections also cover why B1+rms has a number of advantages over SAR with regard to MR Conditional implantable device labeling and where the B1+rms parameter is likely to be displayed on the MRI scanner console. Because supervision of the applied RF power is critical for ensuring safety of patients implanted with MR Conditional medical devices, guidance for modifying the B1+rms of imaging protocols is provided using examples from certain Siemens, Philips, and General Electric MRI scanners that display this new parameter. These examples are intended to provide general guidance regarding the typical work flow associated with modifying MRI scan protocols for B1+rms to comply with the *MRI Guidelines for Medtronic Deep Brain Stimulation Systems*.

**MRI scanner operator and/or radiologists are responsible for verifying compliance with all scan conditions identified in the product labeling.**

## Terms & Definitions

Term	Definition
B0	The static magnetic field produced by the scanner. Units are Tesla (T).
B1	The RF magnetic field produced by the MRI scanner. Units are micro-Tesla ( $\mu$ T).
B1+rms	The root-mean-square value of the MRI effective component of the B1 field. Units are micro-Tesla ( $\mu$ T).
DBS	Deep brain stimulation.
ETL	Echo train length. Also may be called the 'turbo factor'.
Refocusing Pulse	The spin-echo RF pulse used to refocus the MR signal.
RF	Radio frequency.
SAR	Specific absorption rate. Units are watts per kilogram (W/kg).
SNR	Signal-to-noise ratio.
TE	Echo time.
TR	Repetition time.
T/R	Transmit/Receive.

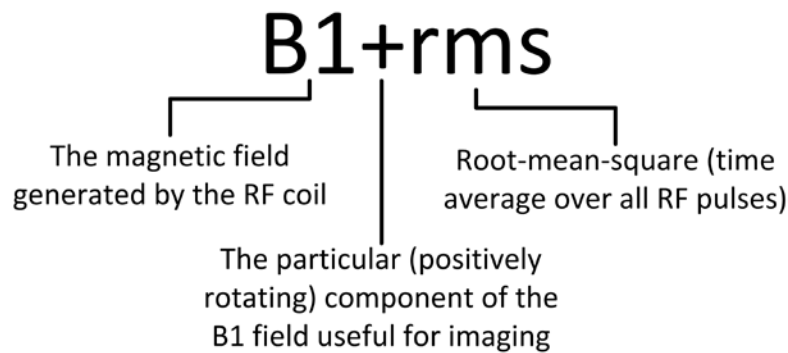
## What is SAR?

The Specific Absorption Rate (SAR) is a measurement of RF energy deposition in the body expressed in watts per kilogram (W/kg). The *MRI Guidelines for Medtronic Deep Brain Stimulation Systems* manual identifies specific DBS systems that allow patients to receive an MRI scan of the head only using a T/R head coil and a maximum head SAR of 0.1W/kg. Other DBS systems listed in the *MRI Guidelines for Medtronic Deep Brain Stimulation Systems* allow patients to be scanned anywhere in the body using the whole body coil at a maximum SAR of 0.1W/kg.

## What is B1+rms?

B1+rms is the time-average MRI effective RF magnetic field that is generated by the scanner during a scan and is measured in units of micro-Tesla ( $\mu$ T). Understanding the importance of B1+rms to DBS 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 B0 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 "B1" field. One part of the B1 field is known as the positively rotating (or "+") component and is useful for "flipping" the magnetically aligned protons and allows images to be created. The time averaged B1+ field strength for all RF pulses in the imaging sequence is the root-mean-square or "rms" B1+ value of the imaging sequence. The meaning behind the symbol that represents this parameter is summarized in Figure 1.



**Figure 1.** The definition of 'B1+rms'

## What is the Advantage of Using B1+RMS for DBS MR Conditional Labeling?

B1+rms is a more precise RF exposure metric than SAR because B1+rms is the fundamental RF field parameter related to MR image creation. The scanner calibrates the RF pulse B1+ field strength during pre-scan and the B1+rms value for an imaging sequence is determined by the scan parameters needed to produce the desired tissue contrast. The B1+rms for a scan protocol is a fundamental electromagnetic field parameter that is patient independent. In contrast, SAR is a conservative estimate of the RF power deposited in a specific region of the patient under examination (e.g., head, whole-body, and partial-body) for a particular B1+rms value. Predicting SAR from the known B1+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 B1+rms limit of 2.0 $\mu$ T identified in *MRI Guidelines for Medtronic Deep Brain Stimulation Systems* 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 DBS devices using any 1.5T scanner that meets the requirements specified in the labeling.

## Is B1+rms Displayed on All 1.5T Scanners?

No. The standards that govern MRI scanner manufacturers mandate that B1+rms must be displayed on all new MRI scanners beginning in 2013<sup>1</sup>. However, several major manufacturers added this feature to scanners sold prior to 2013 as part of regular software upgrades. If you are unsure whether your scanner displays B1+rms, or is eligible for a software upgrade that enables this feature, contact the scanner manufacturer.

<sup>1</sup> International Electro technical Commission. IEC 60601-2-33:2010+A11:2011 and Corrigendum 1:2012. Medical electrical equipment. Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis. 3rd. Geneva: International Electro technical Commission, 2010

## What Scan Sequences will be Compatible with the 2.0 $\mu$ T B1+rms Limit?

Many standard Normal Operating Mode MRI protocols are likely to comply with the 2.0 $\mu$ T B1+rms limit without modification. Other standard Normal Operating Mode MRI protocols are likely to be executable under the 2.0 $\mu$ T B1+rms limit following minor modification. The portfolio of scan sequences suitable for imaging at 2.0 $\mu$ T B1+rms is dependent on scanner manufacturer and on specific clinical indications. **In general, however, standard gradient echo (spoiled gradient echo) and echo planar sequences are likely to comply with the 2.0 $\mu$ T B1+rms limit with little or no modification. Most conventional spin-echo and fast spin-echo sequences can be expected to comply with the 2.0 $\mu$ T B1+rms limit after modifications that may result in increased scan time and/or some change in tissue contrast. Single-shot fast spin echo and Steady State Free Precession (Un-spoiled gradient echo) sequences are inherently RF power intensive and may be difficult or impossible to implement under the 2.0 $\mu$ T B1+rms limit.** Table 1 summarizes some common sequence classes and their relative usability at a B1+rms of  $\leq$  2.0 $\mu$ T.

**This list is not comprehensive and is only intended to provide general guidance and a starting point for protocol optimization. The scanner operator and/or radiologists are responsible for verifying compliance with all scan conditions identified in the product labeling.**

**Table 1.** Representative MRI sequence classes and their relative suitability at  $\leq$ 2.0 $\mu$ T B1+rms

Sequence Type	Siemens	Philips	General Electric
<b>Sequence Classes Likely to Comply with 2.0<math>\mu</math>T B1+rms Limit with Minimal or No Modification</b>			
Gradient Echo	GRE	Fast Field Echo (FFE)	GRE
Spoiled Gradient Echo	FLASH	T1-FFE	SPGR
Ultra-Fast Spoiled Gradient Echo	Turbo FLASH	TFE	Fast GRE/Fast SPGR
Ultra-Fast Spoiled Gradient Echo 3D	MPRAGE	3D TFE	3D FGRE/3D Fast SPGR
Volume Interpolated Spoiled Gradient Echo	VIBE	THRIVE	LAVA-XV
Echo Planar Imaging	EPI	EPI	EPI
3D TSE with Variable Flip Angle	SPACE	VISTA	CUBE
Susceptibility Weighted Imaging	SWI	SWAN	Venous BOLD
<b>Sequence Classes Likely to Comply with 2.0<math>\mu</math>T B1+rms Limit with Moderate Modification</b>			
Spin Echo	SE	SE	SE
Fast Spin Echo	TSE	TSE	FSE
Inversion Recovery	IR/ TIR	IR-TSE	IR/ Fast IR
Short Tau Inversion Recovery	STIR	STIR	STIR
Long Tau Inversion Recovery	Turbo Dark Fluid	FLAIR	FLAIR
<b>Sequence Classes That May Be Unsuitable with 2.0<math>\mu</math>T B1+rms Limit</b>			
Single Shot Fast Spin Echo	HASTE	Single Shot TSE	Single Shot FSE
Un-Spoiled Gradient Echo/ Steady State Free Precession	PSIF/FISP/True-FISP	T2-FFE/Balanced FFE	GRASS/SSFP/FIESTA

## Where is B1+rms Displayed on the Scanner Console?

The location of the B1+rms display on the scanner console is different for each manufacturer but is likely to be displayed in close proximity to where the SAR parameters are displayed.

## How Do I Reduce the SAR or B1+rms of a Protocol to Comply with the Labeling?

Medtronic's *MRI Guidelines for Medtronic Deep Brain Stimulation Systems* manual identifies specific device and lead configurations that are eligible for scans using T/R head coil with a maximum head SAR of 0.1W/kg. It also describes the device and lead configurations that are eligible for full-body scans at a maximum B1+rms of 2.0 $\mu$ T. If the B1+rms variable is not available on the MRI scanner console, eligible full-body scans can use a displayed average whole body or head SAR of  $\leq 0.1$ W/kg. Always consult the **Medtronic DBS MRI Guidelines for Medtronic Deep Brain Stimulation Systems** before attempting to scan any patient with a DBS system.

Because SAR is proportional to B1+rms squared ( $SAR \propto B1+rms^2$ ), the same basic sequence adjustments can be used to reduce the B1+rms or SAR of a scan protocol to comply with the appropriate device labeling. These protocol adjustments are summarized below, and examples of using these adjustments for Siemens, GE, and Philips scan protocols are provided in the following section.

### Adjustments that Reduce the Scan Protocol B1+rms and SAR

- When possible, increase the RF pulse duration. This option, when available, is usually offered as a low SAR imaging mode. In this mode, the RF pulse duration is increased with a corresponding reduction in the pulse amplitude. The low SAR RF pulse option increases the minimum TE and T/R and may result in modified tissue contrast. Moreover, depending on how the scanner modifies the RF pulse waveform, the low SAR option may increase inter-slice cross-talk.
- Acquire only the minimum number of slices necessary for the clinical application using the longest acceptable TR.
- Minimize the refocusing pulse flip angle when using spin-echo sequences. This reduces the protocol B1+rms and SAR but may decrease the SNR and modify the tissue contrast.
- Reduce the number of echoes (turbo factor or ETL) when using fast spin-echo sequences. This reduces the B1+rms and SAR by increasing the scan time.
- Increase the T/R when using T2 or proton density (PD) weighted spin-echo sequences. This reduces the B1+rms without SNR or tissue contrast penalty but increases the scan time.
- Use the longest acceptable T/R to achieve the desired contrast when using T1 weighted spin-echo sequences. Consider using gradient echo sequences for T1 weighted imaging rather than spin-echo sequences, particularly for scanners that do not have a low SAR RF pulse option.

## What is the Procedure for Modifying the B1+rms for My Scan Protocols?

The procedure will vary with scanner manufacturer, software revision and specific diagnostic requirements. The following sections provide examples of accessing the B1+rms display and adjusting the RF pulse amplitude and tip angle for one particular model and software revision of certain Siemens, Phillips, and GE scanner that display B1+rms. **These brief examples are not comprehensive and are only intended to provide general guidance and to provide a starting point for protocol optimization.** Always consult the *MRI Guidelines for Medtronic Deep Brain Stimulation Systems* and verify compliance with all scan conditions identified in the product labeling before scanning any patient with an implanted DBS system. Always consult the applicable scanner product instructions and guidelines before scanning any patient with an implanted DBS system.

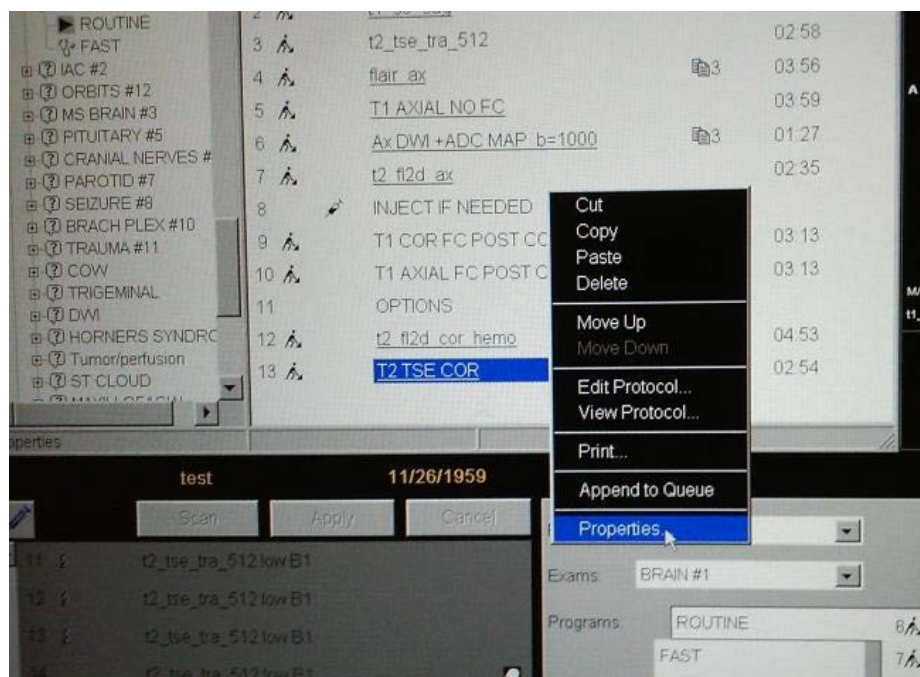
### Note to MRI equipment operators

Medtronic is providing this guidance to you in connection with certain scans of patients implanted with Medtronic DBS systems. The information contained in this guidance document should be used only by qualified MRI equipment operators. The MRI equipment operator and/or radiologist are responsible for the MRI equipment operation.

## Siemens Magnetom Avanto<sup>®</sup> 1.5T Scanners with Syngo Version B19<sup>2</sup>

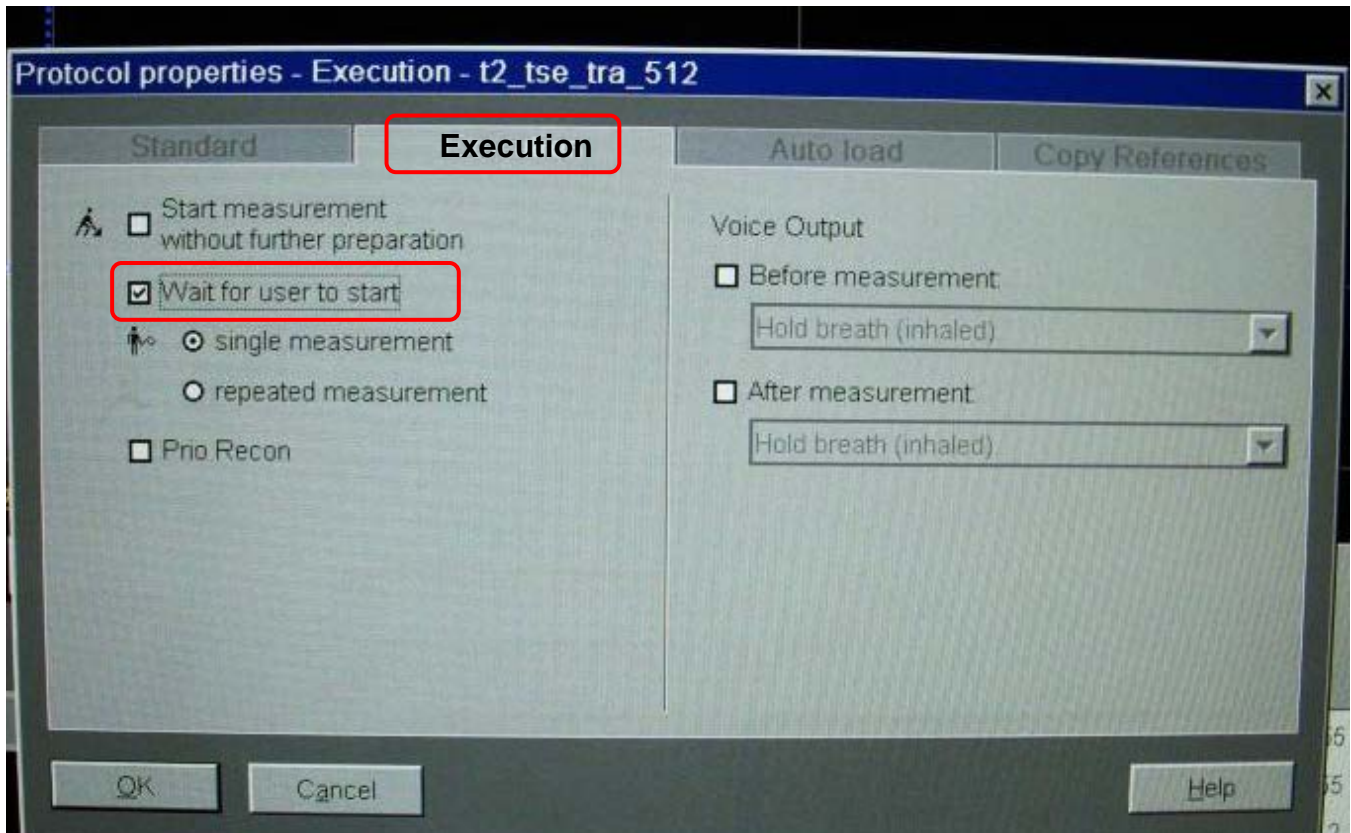
### Configure the Protocol to Start Manually

Configuring the protocol to start in manual mode will allow the predicted B1+rms value to be updated and displayed without executing the scan. Select the protocol **Properties** dialog window for the desired protocol.

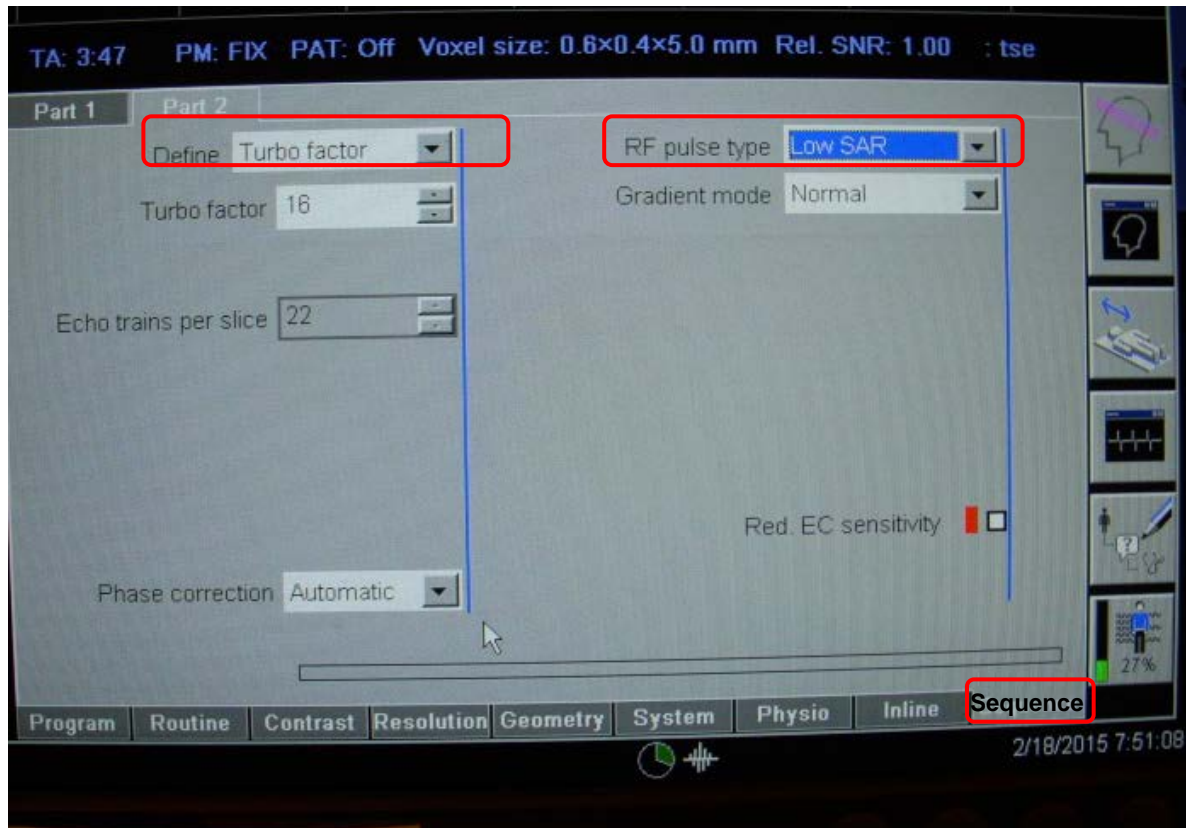


<sup>2</sup> Registered mark of Siemens Aktiengesellschaft. Corporation. Screen images are the property of Siemens.

Select **Wait for user to start** on the **Execution** tab and select **OK**. The protocol is now configured to start in manual mode.



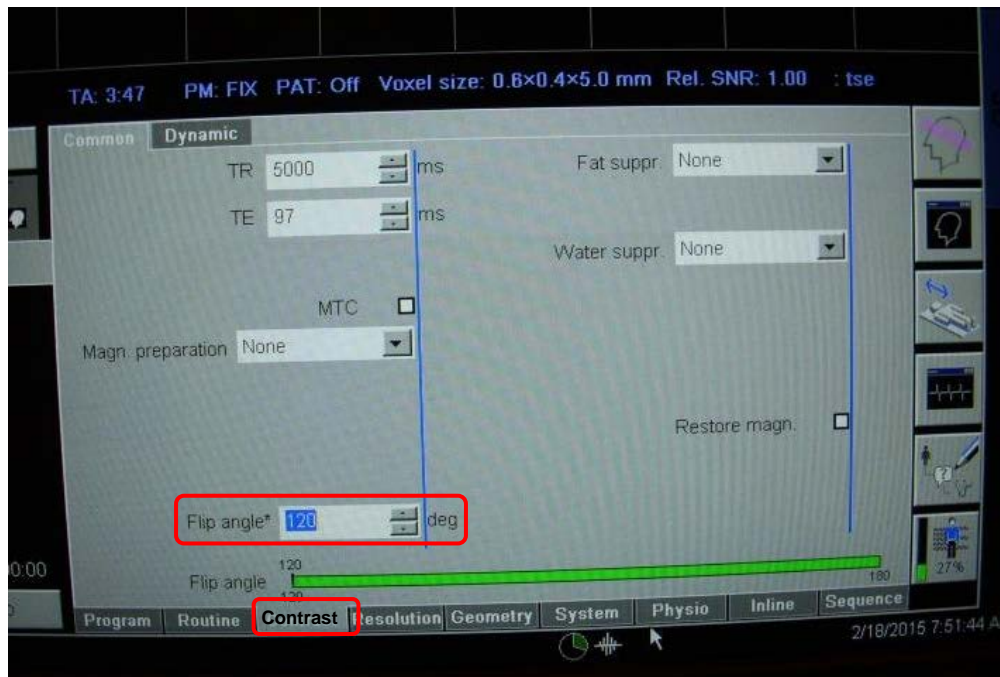
On the **Sequence** tab, select **Low SAR** from the **RF pulse type** drop-down list. This selects an RF pulse that is longer in duration but has a lower B1+ amplitude that reduces the B1+rms of the protocol relative to Normal or Fast RF pulse configurations. Minimize the **Turbo factor** when using fast spin-echo protocols. Reducing the Turbo factor (number of echoes) will decrease the B1+rms at the expense of an increased scan time.





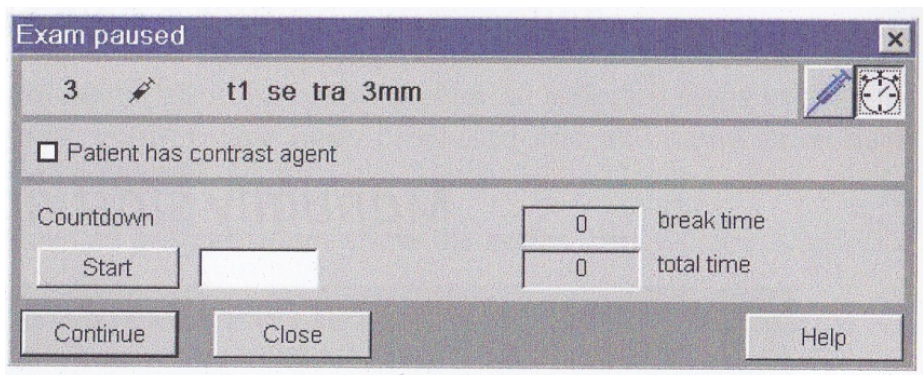
## Minimize the Refocusing Flip Angle for Spin-Echo Sequences.

In the **Contrast** tab, minimize the refocusing pulse **Flip angle**. Large reductions of the refocusing flip angle may result in reduced SNR.



## Proceed to Scan

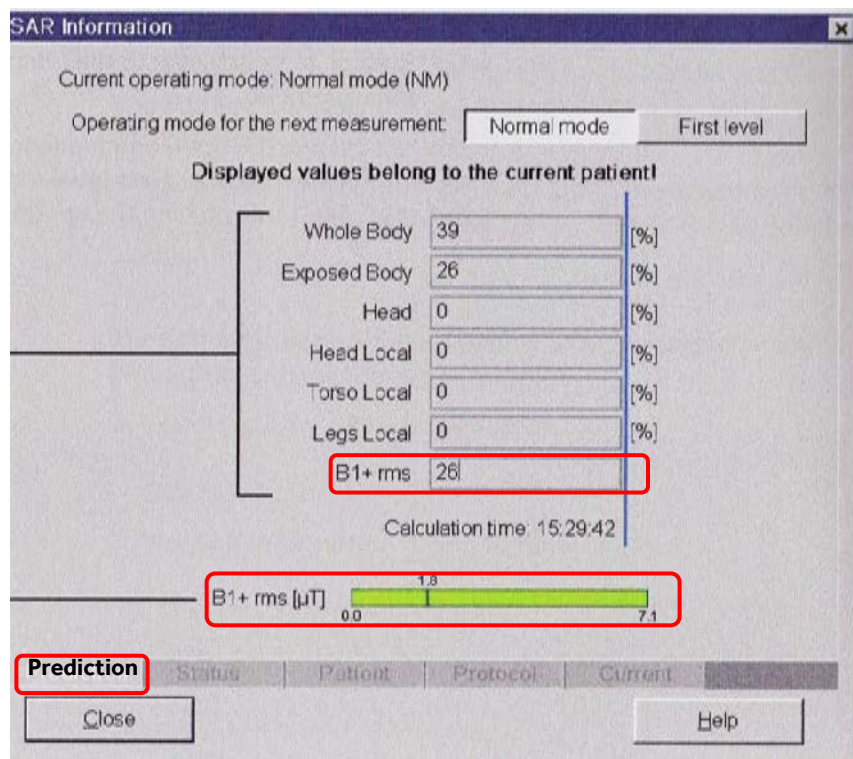
When a protocol is configured in manual mode, proceeding to scan loads the sequence, updates the B1+rms and SAR predictions, and pauses the exam until the operator manually selects **Continue** on the **Exam Paused** dialog.



## Verify the Predicted B1+rms Value

Open the SAR information dialog and verify the B1+rms value on the **Prediction** tab. Note that the B1+rms value is reported below the predicted SAR values as the percentage of the value at the SAR limit. Selecting the B1+rms percentage field with the cursor toggles the green bar chart at the bottom of the field from SAR to B1+rms and shows the numerical value. If the predicted B1+rms value is  $2.0\mu\text{T}$ , then the scan may be executed or the protocol can be saved. If the B1+rms value is greater than  $2.0\mu\text{T}$  then abort the scan by selecting **Close** on the **Exam Paused** dialog and continue to adjust the parameters and repeat the previous steps.

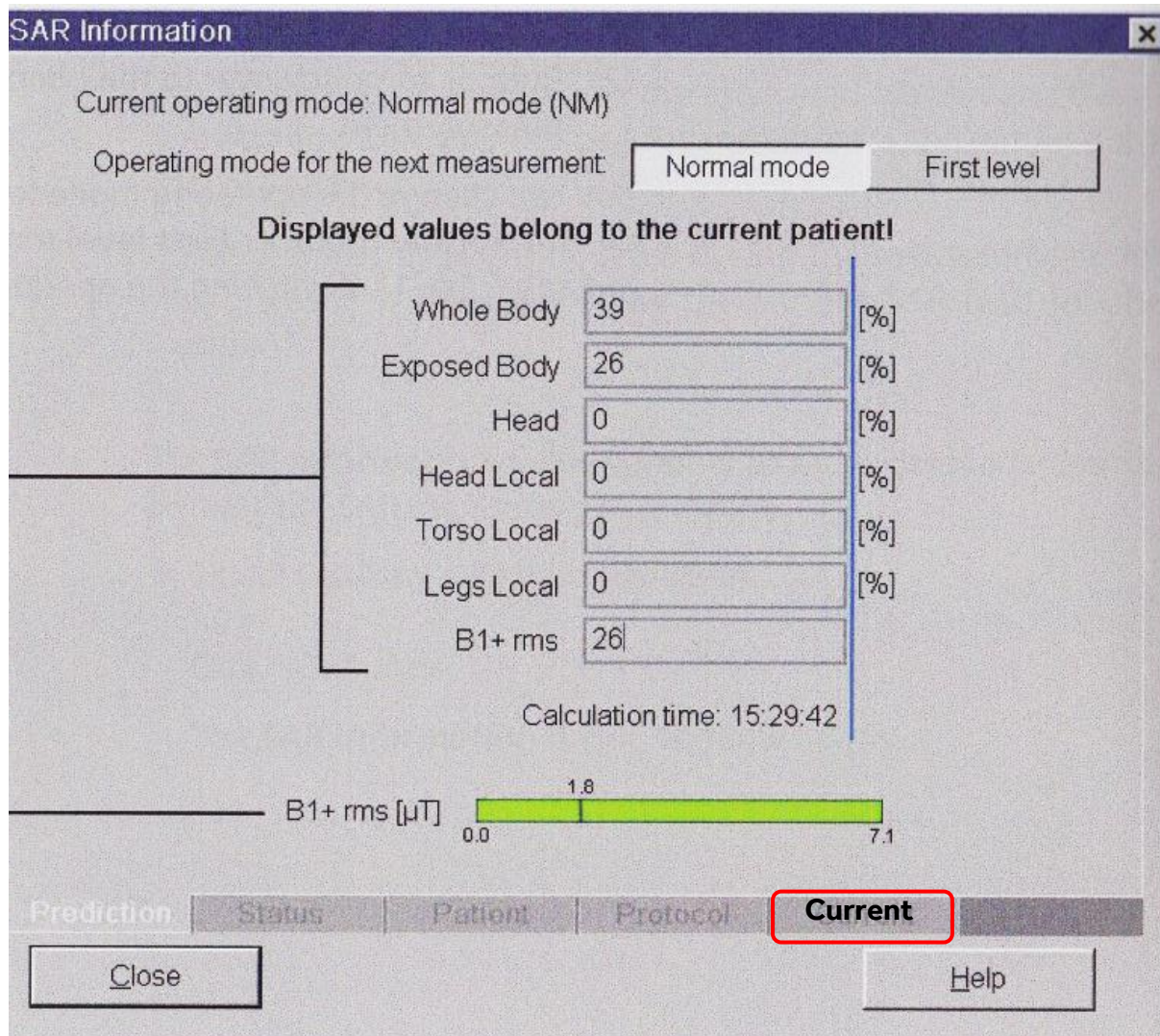
**Note:** some software versions may not include the "+" in Units and report only "B1rms". This is equivalent to B1+ rms.



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## Real-Time B1+rms Display

The actual B1+rms value based on real-time RF power measurements can be displayed during scanning by selecting the **Current** tab on the **SAR Information** dialog. The actual B1+rms value may differ slightly from the predicted value due to small variability in the flip angle calibration. The *MRI Guidelines for Medtronic Deep Brain Stimulation Systems* manual requires only that the predicted B1+rms value for the protocol is  $\leq 2.0\mu\text{T}$ . The uncertainty associated with the ability of the scanner to deliver the predicted B1+rms is accounted for in the Medtronic safety margin.



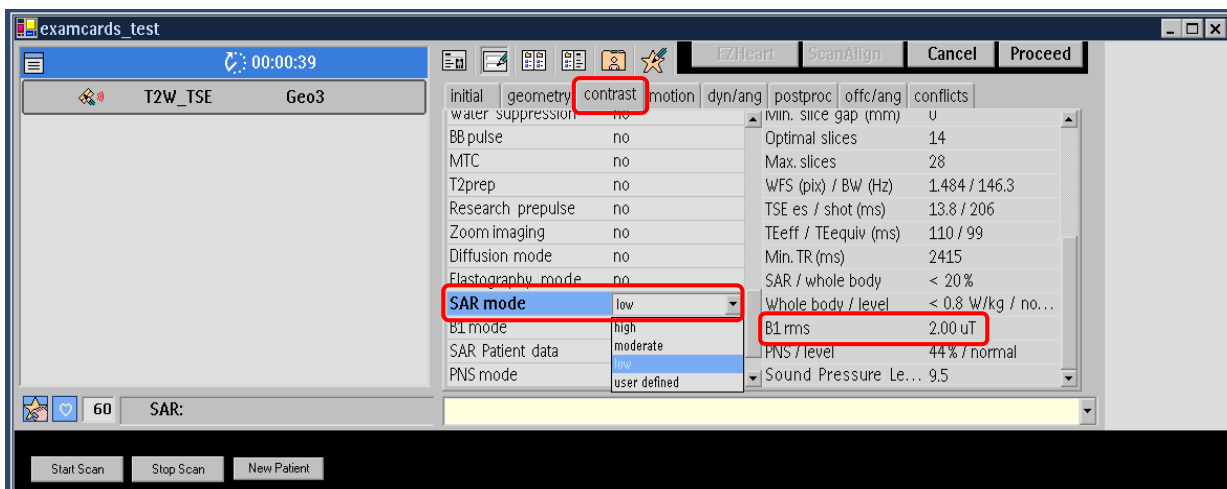
## Philips Scanners (Ingenia Software Version 4.1.1.2)<sup>3</sup>

On Philips scanners that display B1+rms, the B1+rms value is reported on the right hand panel of the scan parameter data field and is updated in real time as scan parameters are changed.

### Select RF Pulse Type

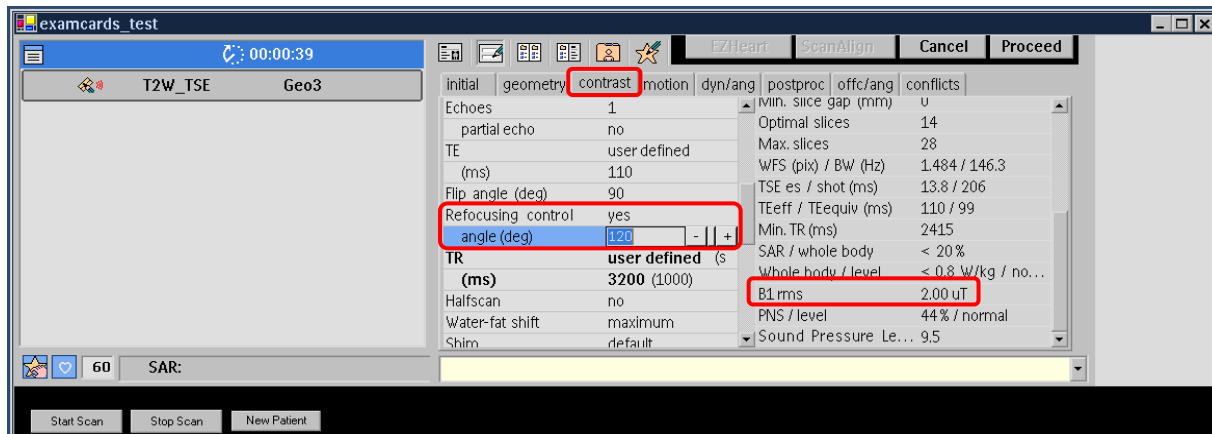
Under the **contrast** tab, set the **SAR mode** to **low**. This selects an RF pulse that is longer in duration but a lower B1+ amplitude and reduces the B1+rms of the protocol relative to **high** or **moderate** RF pulse configurations.

**Note:** some software versions may not include the "+" in units and report only "B1rms". This is equivalent to "B1+rms".



### Minimize the Refocusing Flip Angle for Spin-Echo Sequences

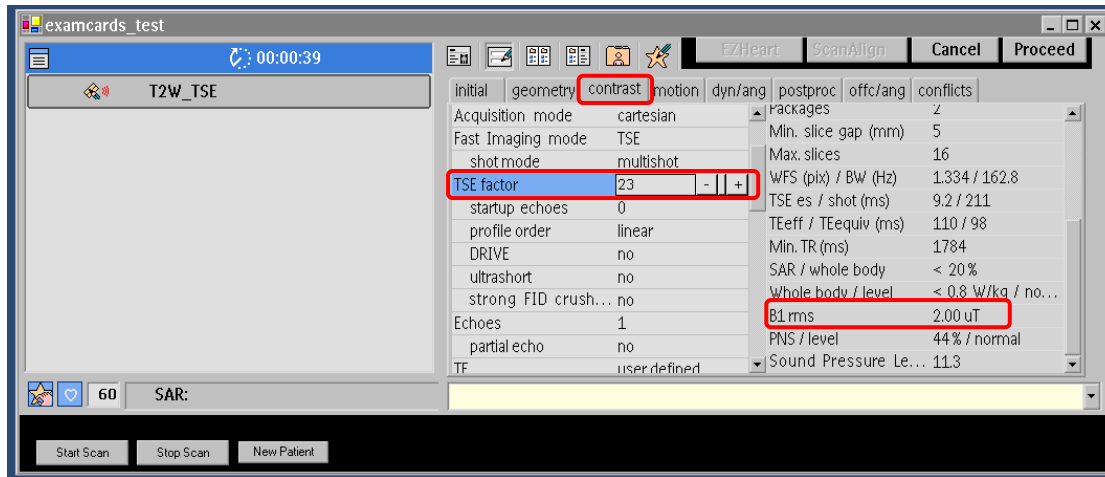
On the **contrast** tab, turn on **Refocusing control** by selecting **yes** from the drop-down list and minimize the refocusing angle. Large reductions of the refocusing flip angle may result in reduced SNR.



<sup>3</sup>Screen images are the property of Philips.

## Reduce the TSE Factor for Fast Spin-Echo Sequences

Reduce the **TSE factor** on the **contrast** tab. Reducing the TSE factor (number of echoes) for a turbo spin-echo protocol will decrease the B1+rms at the expense of an increased scan time.

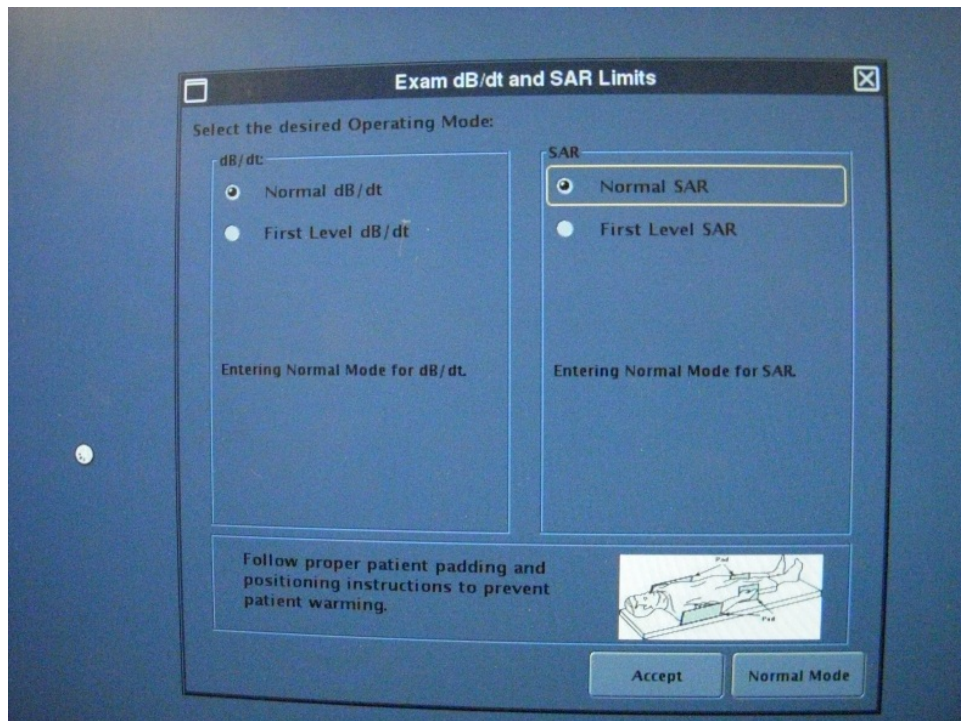


## GE Scanners (MR450W Software Version DV24.0)<sup>4</sup>

On GE scanners that display B1+rms, the B1+rms value is displayed on the bottom of the main dialog panel in addition to the SAR data for the protocol. The B1+rms value is updated in real time as scan parameters are changed. GE scanners do not allow control over the RF pulse width.

## Set Normal Operating Mode Limits

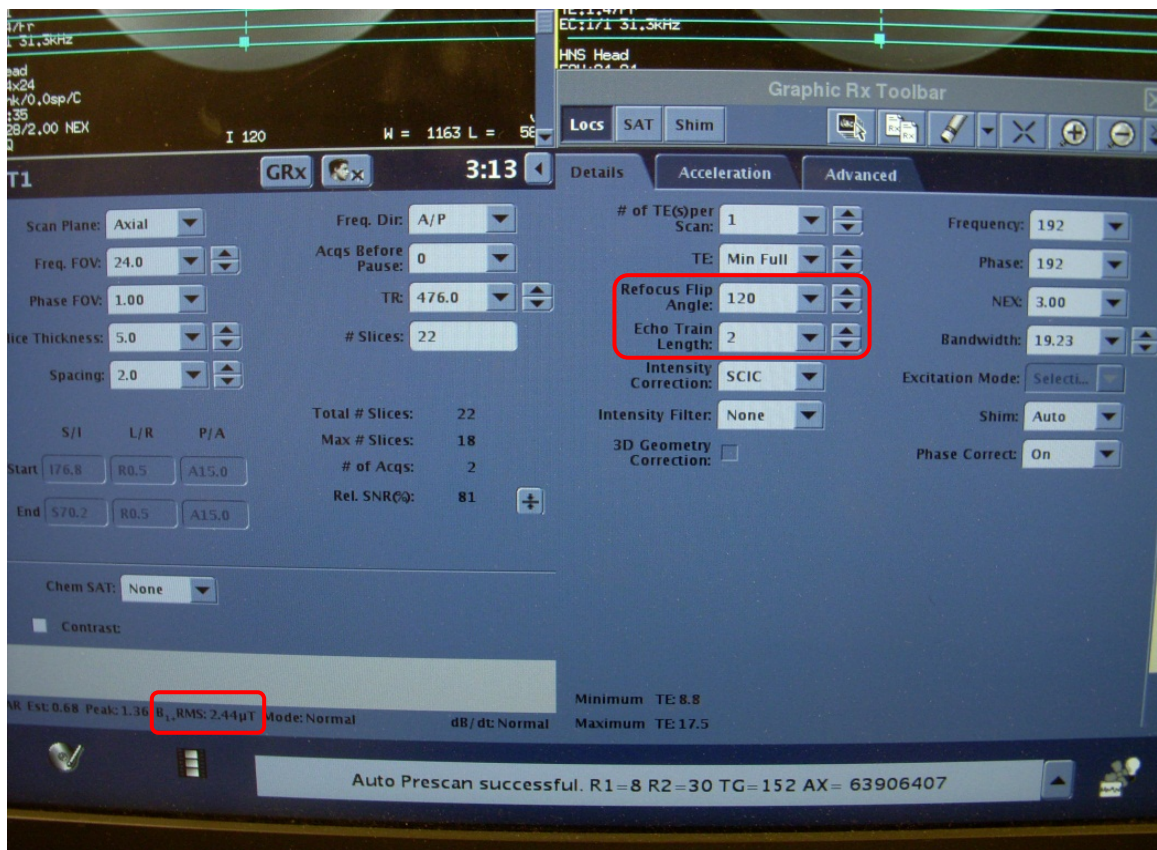
Select both the **Normal dB/dt** and **Normal SAR** limits in the Exam dialog.



## Minimize Refocusing Flip Angle and Echo Train for Fast Spin-Echo Protocols

On the **Details** tab, minimize the **Refocus Flip Angle** and **Echo Train Length** when using fast spin-echo protocols. Large reductions of the refocusing flip angle may result in reduced SNR. Reducing the echo train length (number of echoes) will decrease the B1+rms at the expense of an increased scan time.

**Note:** This image is for purposes of illustration only. The B1+rms value for the protocol shown here is  $>2\mu\text{T}$  and additional modifications would be required to comply with the *MRI Guidelines for Medtronic Deep Brain Stimulation Systems*.



<sup>4</sup>Screen images are the property of General Electric.

## References

All protocol adjustments that reduce SAR will also be effective at reducing B1+rms. The following articles summarize strategies to modify scan protocols to comply with the displayed average head SAR of 0.1W/kg or less. Although the 2.0 $\mu$ T B1+rms limit is significantly less restrictive, the general principles used to create low SAR protocols also apply to B1+rms reduction.

1. Sarkar SN, Alsop DC, Madhuranthakam AJ, et al. Brain MR imaging at ultra-low radiofrequency power. *Radiology*. 2011;259(2):550-557.
2. Sarkar SN, Papavssilliou E, Hackney DB, et al. Three-dimensional brain MRI for DBS patients with ultra-low radiofrequency power limits. *Mov Disord*. 2014;29(4):546-549.
3. Sarkar SN, Sarkar PR, Papavssilliou E, Rojas RR. Utilizing fast spin echo MRI to reduce image artifacts and improve implant/tissue interface detection in refractory Parkinson's patients with deep brain stimulators. *Parkinson's Dis*. 2014;2014:1-6.
4. Sarkar SN, Papavssilliou E, Rojas R, et al. Low-power inversion recovery MRI preserves brain tissue contrast for patients with Parkinson disease with deep brain stimulators. *Am J Neuroradiol*. 2014;35(7):1325-1329.

## Brief Summary Disclosure: Use of Magnetic Resonance Imaging (MRI) in Patients with Medtronic DBS Systems

Medtronic DBS systems are MR Conditional which means they are marked to indicate they are safe in the MR environment as long as certain conditions are met. Read and fully understand the *MRI Guidelines for Medtronic Deep Brain Stimulation Systems* before conducting the MRI examination. Go to [www.medtronic.com/mri](http://www.medtronic.com/mri) or contact Medtronic at 1-800-707-0933 for a copy. Also review current MRI manufacturer labeling before conducting the MRI.

### Indications:

**Medtronic DBS Therapy for Parkinson's Disease:** Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson's Disease is indicated for adjunctive therapy in reducing some of the symptoms in individuals with levodopa-responsive Parkinson's disease of at least 4 years' duration that are not adequately controlled with medication, including motor complications of recent onset (from 4 months to 3 years) or motor complications of longer-standing duration.

**Medtronic DBS Therapy for Tremor:** Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) using Medtronic DBS Therapy for Tremor is indicated for the suppression of tremor in the upper extremity. The system is intended for patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

**Medtronic DBS Therapy for Dystonia\*:** Medtronic DBS Therapy for Dystonia is indicated for unilateral or bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) to aid in the management of chronic, intractable (drug refractory) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia (torticollis), in patients 7 years of age or above.

**Medtronic Reclaim DBS Therapy for Obsessive-Compulsive Disorder\*:** Bilateral stimulation of the anterior limb of the internal capsule, AIC, using Medtronic Reclaim DBS Therapy is indicated as an adjunct to medications and as an alternative to anterior capsulotomy for treatment of chronic, severe, treatment-resistant obsessive-compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs).

**Contraindications/Warnings/Precautions:** Use of a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area is contraindicated for patients with the following implanted DBS systems or system components: Soletra Model 7426 Neurostimulator; Kinetra Model 7428 Neurostimulator; Activa SC Model 37602 Neurostimulator; and Model 64001 and Model 64002 pocket adaptors. Tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death, can occur if a contraindicated MRI scan is performed on a patient with these DBS systems. Other conditions that may cause excessive heating at the lead electrodes which can result in serious injury or death, or that may cause device damage, include: neurostimulator implant location other than pectoral and abdominal regions; unapproved MRI parameters; partial system explants ("abandoned systems"); misidentification of neurostimulator model numbers; and broken conductor wires (in the lead, extension or pocket adaptor). Active scan time >30 minutes within a 90 minute window, elevated core body temperature due to fever or use of blankets, or patient position within the MRI bore other than prone or supine, may cause excessive tissue heating. Leaving therapy on during the scan could increase the potential for uncomfortable, unintended stimulation. Failure to cap a lead-only system may result in unintended stimulation during the scan. External control devices such as the patient programmer, recharger, external neurostimulator and clinician programmer, are MR Unsafe and not allowed in the MRI scanner (magnet) room.

**\*Humanitarian Device:** The effectiveness of this device for the treatment of dystonia and obsessive-compulsive disorder has not been demonstrated.

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