WHY IS RADIOFREQUENCY (RF) POWER IMPORTANT FOR MR CONDITIONAL LABELING OF IMPLANTS?

Magnetic resonance imaging (MRI) uses a combination of static magnetic field, time varying gradient magnetic field and RF field to generate an image. MR Conditional implant labeling includes the MRI environment conditions under which the implant has been tested and demonstrated as safe for use.

The potential hazards related to the RF field interacting with an active implantable medical device include heating (typically at the lead electrodes), unintended stimulation and damage to the implant. RF power limits in MR Conditional labeling indicate the safe conditions for use.

WHAT IS SAR?

SAR (Specific Absorption Rate) is defined as radio frequency power absorbed per unit of mass. SAR is expressed in units of watts per kilogram of patient tissue mass (W/kg). Estimated SAR is displayed on the MRI scanner user interface for each sequence prior to and during a scan.

RF Power restrictions may be present in MR Conditional implant labeling as a SAR limit or a specified RF operating mode. For clinical purposes, the international standard IEC 60601-2-33 defines two RF operating modes by which the MRI scanner enforces the SAR limits during the scan: Normal Operating Mode (whole body SAR ≤ 2 W/kg) and First Level Controlled Operating Mode (whole body SAR ≤ 4 W/kg).

• To determine the RF Power restrictions for the Abbott neurostimulation implants, users can obtain the most recent version of the Abbott MRI Procedure manual online at manuals.sjm.com.

FOR IMPLANTS WITH RF POWER RESTRICTIONS, HOW DO I ENSURE THE RF POWER LIMIT IS MET?

It is very important to not exceed any SAR limit included in MR Conditional labeling to ensure patient safety and proper device functioning in the MRI environment. Clinically relevant SAR restricted scans have been used successfully for patients with MR Conditional implants.1-3

Estimated SAR is displayed on the MRI scanner user interface for each sequence prior to and during a scan. Important factors that go into SAR estimation include the MRI scan parameters and patient demographics. It is vital to enter accurate patient information to facilitate accurate SAR estimations. Personnel knowledgeable in MRI safety should be involved to optimally plan the scan and actively monitor SAR levels during the scan.

In recent years some of the MRI vendors have incorporated imaging workflows to facilitate SAR restricted scans for patients with MR Conditional implants. Examples include ScanWise® implant by Philips,4 Low SAR Mode by GE5 and the Low SAR RF pulse type option by Siemens.6 Please consult the user manual on your MRI system or contact your MRI manufacturer’s applications support/clinical education specialists for information about your specific system.

WHAT CHANGES CAN BE MADE TO MRI SCAN PARAMETERS TO REDUCE SAR?

There are multiple ways to reduce the SAR of an MRI sequence such that the estimated SAR level does not exceed the SAR limit stated in the MR Conditional implant labeling. Parameters to change include repetition time, flip angle of the RF pulse, number of imaging slices and number of echoes. These options may vary based upon the MRI systems, vendors and software versions.

Some commonly used approaches to reduce the SAR of a MRI sequence include:7,8

• Utilize a SAR restricted or implant mode when available
• Use a local RF transmit-receive coil and keep the implant out of the coil coverage
• Prefer Gradient Echo sequences over Spin Echo and Fast Spin Echo sequences
• Reduce the flip angle of refocusing RF pulse when using Fast Spin Echo sequences
• Increase the repetition time (TR) when appropriate for sequence parameters
• Reduce the number of echoes (Echo Train length/Turbo factor/Shot factor) for Fast Spin Echo sequences when appropriate for sequence parameters
• Reduce the number of imaging slices for a given TR when appropriate for sequence parameters
• Use fewer RF Saturation Bands as appropriate for sequence parameters

NOTE: The approaches mentioned above are only suggestions for reducing SAR. Each of these selections may impact your image quality or contrast. Please refer to the educational resources and references provided at the end of this document to develop a better understanding about RF safety and SAR restriction. Please consult with your Radiologist and the MR manufacturer applications support for further guidance.
IS HIGHER SAR ALWAYS NECESSARY FOR HIGHER IMAGE QUALITY?

Higher SAR does not always guarantee higher MR image quality. Clinical value of an MR image depends largely on the diagnostic information provided by the MR image regarding the patient's underlying condition. Clinical studies have shown that SAR restricted MR images can still provide diagnostic information.1,2,9,10

WHERE CAN I FIND MORE INFORMATION REGARDING ABBOTT MR CONDITIONAL IMPLANTS?

Obtain the most recent version of Abbott's MRI Procedure manual online at manuals.sjm.com.

For more information about MR Conditional products, visit the product information page at sjm.com/MRIReady.

Examples of Low SAR Clinical Scans of the Lumbar Spine

Low SAR (0.8W/kg) MRI scans on patient with an Abbott MR Conditional Spinal Cord Stimulation System. Images were obtained on a Siemens' 1.5 T scanner.

Board-certified Radiologist's diagnosis based on complete sequence of MR images acquired following the sequence parameters.
Examples of Low SAR Clinical Scans of the Thoracic Spine

Low SAR (0.8W/kg) MRI scans on patient with an Abbott MR Conditional Spinal Cord Stimulation System. Images were obtained on a Siemens' 1.5 T scanner.

Board-certified Radiologist’s diagnosis based on complete sequence of MR images acquired following the sequence parameters.

Sequence Parameters at 1.5 T Siemens‡ (syngo‡ MR E11)

<table>
<thead>
<tr>
<th></th>
<th>THORACIC T1 WEIGHTED TURBO SPIN ECHO</th>
<th>THORACIC T2 WEIGHTED TURBO SPIN ECHO</th>
<th>THORACIC SHORT TI INVERSION RECOVERY (STIR)</th>
<th>LUMBAR T1 WEIGHTED TURBO SPIN ECHO</th>
<th>LUMBAR T2 WEIGHTED TURBO SPIN ECHO</th>
<th>LUMBAR SHORT TI INVERSION RECOVERY (STIR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Siemens</td>
<td>Siemens</td>
<td>Siemens</td>
<td>Siemens</td>
<td>Siemens</td>
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<tr>
<td>Low SAR RF pulse</td>
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<td>on</td>
<td>on</td>
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<tr>
<td>Slice thickness (mm)</td>
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<tr>
<td>Repetition time (ms)</td>
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<td>2620</td>
<td>4500</td>
<td>650</td>
<td>3100</td>
<td>5300</td>
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<tr>
<td>Echo time (ms)</td>
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<td>8.7</td>
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<td>35</td>
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<td>Inversion time (ms)</td>
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<tr>
<td>Number of Averages (NEX)</td>
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<td>2</td>
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<tr>
<td>Acquisition Matrix</td>
<td>320 x 256</td>
<td>384 x 250</td>
<td>320 x 240</td>
<td>320 x 256</td>
<td>384 x 250</td>
<td>320 x 240</td>
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<tr>
<td>Echo Train Length (ETL)</td>
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<td>11</td>
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<td>Flip angle</td>
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<td>140</td>
<td>180</td>
<td>180</td>
<td>140</td>
<td>180</td>
</tr>
</tbody>
</table>

*Bold items directly affect SAR power levels
Educational Resources:


References:


7. Allison, J., & Yanasak, N. (2015). What MRI sequences produce the highest specific absorption rate (SAR), and is there something we should be doing to reduce the SAR during standard examinations? *American Journal of Roentgenology*, 205(2), W140-W148.


Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use: Spinal cord stimulation as an aid in the management of chronic, intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following failed back surgery syndrome and intractable low back and leg pain.

Contraindications: Patients who are unable to operate the system or who have failed to receive effective pain relief during trial stimulation.

Warnings/Precautions: Diathermy therapy, implanted cardiac systems, magnetic resonance imaging (MRI), explosive or flammable gases, theft detectors and metal screening devices, lead movement, operation of machinery and equipment, postural changes, pediatric use, pregnancy, and case damage. Patients who are poor surgical risks, with multiple illnesses, or with active general infections should not be implanted.

Adverse Effects: Painful stimulation, loss of pain relief, surgical risks (e.g., paralysis). Clinicians manual must be reviewed for detailed disclosure.

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