IMPULSE DYNAMICS
Hope is Here

MRI SAFETY INFORMATION

OPTIMIZER® Smart Mini Implantable Pulse Generator
(Model: CCM X11)

MRI Safety Information

For Whole-Body MR Examinations: A person implanted with the OPTIMIZER Smart Mini System may be safely scanned anywhere in the body at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

<table>
<tr><th>Parameter</th><th>Condition</th></tr>
<tr><td>Device</td><td>The OPTIMIZER Smart Mini IPG must be implanted with two ventricular leads and an optional atrial MR-conditional lead from the list below. When combined, the OPTIMIZER Smart Mini IPG and such leads constitute an MR conditional device system.
<table>
<tr><th>Lead [Manufacturer, Model]</th><th>Length [cm]</th><th>Lead's whole-body SAR limit (See OEM lead MRI labeling for additional information)</th></tr>
<tr><td rowspan="2">Medtronic, CapSureFix Novus MRI™ SureScan 5076</td><td>52</td><td rowspan="2">1.5T: 2.0 W/kg
3T: $B_{1+RMS} \leq 2.8$ µT</td></tr>
<tr><td>58</td></tr>
<tr><td rowspan="2">Medtronic, SelectSecure MRI™ SureScan 3830</td><td>59</td><td rowspan="2">1.5T: 2.0 W/kg
3T: $B_{1+RMS} \leq 2.8$ µT</td></tr>
<tr><td>69</td></tr>
<tr><td rowspan="2">Abbott, 2088TC Tendril STS</td><td>52</td><td rowspan="2">2.0 W/kg</td></tr>
<tr><td>58</td></tr>
<tr><td>Boston Scientific, Ingevity+ 7841</td><td>52</td><td rowspan="2">2.0 W/kg</td></tr>
<tr><td>Boston Scientific, Ingevity+ 7842</td><td>59</td></tr>
<tr><td>Biotronik, Solia S-53</td><td>53</td><td rowspan="2">2.0 W/kg</td></tr>
<tr><td>Biotronik, Solia S-60</td><td>60</td></tr>
</table></td></tr>
<tr><td>Device Configuration</td><td>OOO mode (CCM Stimulation OFF, Sensing OFF)</td></tr>
<tr><td>Static Magnetic Field Strength (B_0)</td><td>1.5T and 3T</td></tr>
<tr><td>Type of Nuclei</td><td>Hydrogen</td></tr>
<tr><td>MR Scanner Type</td><td>Cylindrical closed-bore magnet</td></tr>
<tr><td>B_0 Field Orientation</td><td>Horizontal</td></tr>
<tr><td>Maximum Spatial Field Gradient</td><td>40 T/m</td></tr>
<tr><td>Maximum Gradient Slew Rate</td><td>200 T/m/s per axis</td></tr>
<tr><td>RF Excitation</td><td>Circularly Polarized (CP)</td></tr>
<tr><td>RF Transmit Coil Type</td><td>Integrated Whole Body Transmit Coil. Local transmit coils may be used but should not be placed directly over the OPTIMIZER Smart Mini System.</td></tr>
<tr><td>RF Receive Coil Type</td><td>Any</td></tr>
</table>

Parameter	Condition
Operating Mode	Normal Operating Mode
RF Conditions	Whole-body SAR ≤ 2.0 W/kg or ≤ 3.2 W/kg head absorption rate for local head transmit coil.
Scan Duration	Scan for up to 30 minutes. Wait 30 minutes before the next imaging session
Scan Regions	Any landmark is acceptable
Image Artifact	The presence of the OPTIMIZER Smart Mini System may produce an image artifact. In non-clinical testing, the maximum image artifact size was seen on the gradient echo pulse sequence at 1.5T and extends by approximately 6.7 cm from the boundary of the implant. At 3T the maximum image artifact extends by approximately 4.6 cm from the boundary of the implant. Some manipulation of scan parameters may be needed to compensate for the artifact.

Restrictions for the Patient and the Implanted System

- There are no other active or abandoned cardiac implants (e.g., lead extensions, lead adapters, or abandoned leads) in the patient's body.

WARNING: Do not bring any system components that are not marked MR-safe or MR-conditional into the MRI suite.

- Other active or passive implants are permitted if they are identified as MR conditional by the manufacturer.
- At least six (6) weeks have elapsed since the OPTIMIZER Smart Mini IPG and/or lead implantation and/or any electrode revision or surgical modification.
- The device system is implanted pectorally.
- Patient does not have elevated body temperature or compromised thermoregulation at time of scan.
- **WARNING:** Do not scan a patient with an elevated body temperature.

Restrictions During the MRI scan

- Emergency equipment for resuscitation must be kept at hand and properly certified staff must be available.
- Patient must be continuously monitored by pulse oximetry and electrocardiography (ECG).

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