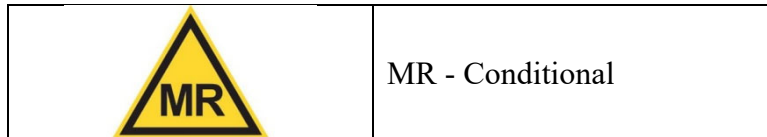


MRI SAFETY INFORMATION

OPTIMIZER Smart Mini Implantable Pulse Generator



The OPTIMIZER Smart Mini IPG is Magnetic Resonance (MR) Conditional, and patients with this device may be scanned safely with magnetic resonance imaging (MRI) **if all the requirements for the implanted components and for scanning are met.**

Restrictions for the Patient and the Implanted System

- The OPTIMIZER Smart Mini IPG must be implanted with two ventricular leads (and one optional atrial lead), **where all leads are separately labeled MR conditional** and must have established conditions for safe use in the 1.5T and 3T MRI environment. When combined, the OPTIMIZER Smart Mini IPG and such leads constitute an MR conditional device system.

WARNING: Not all lead lengths of a specific model may be MR-Conditional. Each lead needs to be checked for MRI compatibility and individual scan parameters.

- 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.
- The OPTIMIZER Smart Mini IPG is programmed to OOO mode before the MRI scan.
- 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.

Requirements of the MRI Scanner

- Use of a clinical, hydrogen-atom MRI scanner with horizontal cylindrical closed-bore magnet, and a static magnetic field strength of **1.5 or 3 Tesla**.
- There are no restrictions for positioning the Optimizer Smart Mini System within the integrated body coil of the MRI scanner. The use of receive-only coils is not restricted. Local transmit coils may be used, but should not be placed directly over the Optimizer Smart Mini System.
- Maximum spatial gradient of the magnetic field of 50 T/m or 5000 Gauss/cm.
- The slew rate of the MRI scanner's gradient fields must not exceed 200 T/m/s per axis.

WARNING: scanning under other conditions may result in severe patient injury, death, or device malfunction.

Restrictions During the MRI scan

- The specific absorption rate must not exceed limits as defined in IEC 60601-2-33, for example 3.2 W/kg for the head.
- 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).

Image Artifacts

In non-clinical testing, the maximum image artifact size was seen on the gradient echo pulse sequence at 1.5 T and extends by approximately 6.7 cm from the boundary of the implant.

In non-clinical testing, the maximum image artifact size was seen on the gradient echo pulse sequence at 3 T and extends by approximately 4.6 cm from the boundary of the implant.

Impulse Dynamics (USA), Inc.
50 Lake Center Executive Parkway
401 Route 73 N, Building 50, Suite 100
Marlton, NJ 08053-3449
(856) 642-9933 - www.impulse-dynamics.com



© 2022 Impulse Dynamics