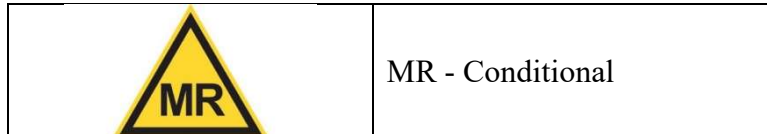


MRI SAFETY INFORMATION FOR OPTIMIZER SMART IPG



The Optimizer Smart 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 IPG must be implanted with two ventricular leads and an optional atrial lead, **where all leads are separately labeled MR conditional** and must have established conditions for safe use in the 1.5T MRI environment. When combined, the Optimizer Smart 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 IPG and/or lead implantation and/or any electrode revision or surgical modification.
- The device system is implanted pectorally.
- The Optimizer Smart IPG is programmed to OOO mode before the MR 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 Tesla**.
- There are no restrictions for positioning the Optimizer Smart 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 System.
- The spatial gradient of the magnetic field must not exceed 50 T/m or 5000 G/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 head absorption rate must not exceed 3.2 W/kg.
- The whole-body specific absorption rate must not exceed 2 W/kg.
- 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 1.5T and extends by approximately 5 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

