Preliminary MRI Safety Information


MR Conditional

Non-clinical testing has demonstrated the Implantable Infusion Pumps IP2000V are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla**, with**
- Maximum spatial field gradient of 700 G/cm (7 T/m)
- **Maximum force product of** 13,000,000 $G^2$/cm **(13 $T^2$/m)**
- **Maximum switched gradient slew rate per axis of 100 mT/m/ms**
- **Maximum switched gradient amplitude per axis of 45 mT/m**
- **Calculated** maximum whole body averaged (WBA) specific absorption rate (SAR) of

  0.4 W/kg (Normal Operating Mode) for 1.5 Tesla

  0.5 W/kg (Normal Operating Mode) for 3 Tesla

- **Calculated maximum $B1^+_{rms}$ of**

  3.4 µT for 1.5 Tesla

  1.8 µT for 3 Tesla

Under the scan conditions defined above, the Implantable Infusion Pumps are expected to produce a maximum temperature rise of less than

6 °C **(0.4 W/kg, 1.5 Tesla) RF-related temperature increase**

6 °C **(0.5 W/kg, 3 Tesla) RF-related temperature increase**

after 15 minutes of continuous scanning.

**Under the scan conditions defined above, the Implantable Infusion Pumps are expected to produce a maximum temperature rise of less than**

**6.0°C at a time rate of change of the theoretical maximum of 21.4 T/s**

**during 30 min. of continuous exposure in a test laboratory system (Pulsed Magnetic Field Generator).**

MR-induced malfunction testing with device exposure to the static field $B_0$, the switched gradient field (dB/dt) and the RF field ($B_1$, E) in 1.5 Tesla and 3 Tesla MR systems passed all tests according to tricumed Medizintechnik GmbH testing procedure.

In non-clinical testing, the image artifact caused by the device extends approximately 67.6 mm from the IP2000V implantable infusion pump when imaged with a spin echo pulse sequence and a 3 Tesla MR system.



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