

Appendix 2

(Urgent safety information)

User information regarding the application of RAUMEDIC NEUROVENT precision pressure catheters during 1.5 and 3 Tesla MRT

It can be scanned safely under the following conditions:

- static magnetic field of 1.5 Tesla and 3 Tesla and less, with
- spatial gradient field of 72 T/m (value extrapolated) and less
- spatial gradient field product of 98 T²/m (value extrapolated) and less
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of

< 0.7 W/kg at 1.5 Tesla, (local SAR < 2.6 W/kg), Neurovent-PTO
< 0.5 W/kg at 3 Tesla, (local SAR < 3.1 W/kg), Neurovent-PTO with PTO cable for 15 minutes of continuous MR scanning (valid only for performed test configuration).

In non-clinical testing with test configuration \approx 34 cm straight implanted catheter parallel to static magnetic field B_0 the “Neurovent-PTO” produced a temperature rise of less than 1.9°C (with a background temperature increase of \approx 1.2°C) at a maximum whole body averaged specific absorption rate (SAR) of \approx 1.9 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 1.5 Tesla Intera, Philips (Software: Release 12.6.1.4) MR Scanner.

In non-clinical testing with test configuration \approx 34 cm straight implanted catheter parallel to static magnetic field B_0 with connected PTO cable coiled in a loop with 3.5 windings orthogonal with coil plane to static magnetic field B_0 the “Neurovent-PTO with PTO cable” produced a temperature rise of less than 3.1°C (with a background temperature increase of \approx 2.3°C) at a maximum whole body averaged specific absorption rate (SAR) of \approx 2.3 W/kg assessed by calorimetry for 15 min. of continuous MR scanning with whole body coil in a 3 Tesla Magnetom Trio, Siemens (Software: Numaris/4, syngo MR A30) MR Scanner.

No other RF heating testing than 1.5 & 3 Tesla only was performed.

MR image quality is compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this device.