

PFM Medical, Inc.

Mr. Salvadore Palomares, RAC  
Director of Regulatory Affairs

1815 Aston Ave, Suite 106,  
Carlsbad, CA 92008, USA

**pfm medical mepro gmbh**

Christian Baumeister  
Am Söterberg 4  
66620 Nonnweiler, Germany  
T +49 (0)6873 9011-42  
F +49 (0)6873-9011-99  
christian.baumeister@pfmmedical.com

**www.pfmmedical.com**

10.01.2014

To whom it may concern.

**MRI Safety Information for the Nit-Occlud® PDA device**

The Nit-Occlud® PDA coil was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing demonstrated that the Nit-Occlud® PDA coil is MR conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- The maximum whole-body averaged specific absorption rate (SAR) shall be limited to 2.0 W/kg (normal operating mode only) for 15 minutes of scanning.

**MRI-Related Heating**

In non-clinical testing, the Nit-Occlud® PDA coil produced the following temperature rise during MRI performed for 15-min in the 3-Tesla (3-Tesla/128-MHz, Excite, HDX, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system: Highest temperature change +1.6°C.

Therefore, the MRI-related heating experiments for the Nit-Occlud® PDA coil at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C.

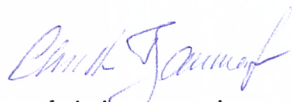
**Artifact Information**

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Nit-Occlud® PDAcoil. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. In non-clinical testing for different imaging sequences, the artifacts presented as signal voids of the following sizes:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	369 mm <sup>2</sup>	118 mm <sup>2</sup>	647 mm <sup>2</sup>	739 mm <sup>2</sup>
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Kindest Regards,

pfm medical mepro gmbh



i. A. Christian Baumeister  
Head of R&D

**pfm**medical

pfm medical mepro gmbh  
Am Söterberg 4 · 66620 Nonnweiler  
T +49 (0)6873 9011-0 · F -99  
[www.pfmmedical.com](http://www.pfmmedical.com)