RAUMEDIC
Lifeline to Health

NEUROVENT – Precision Pressure Catheters

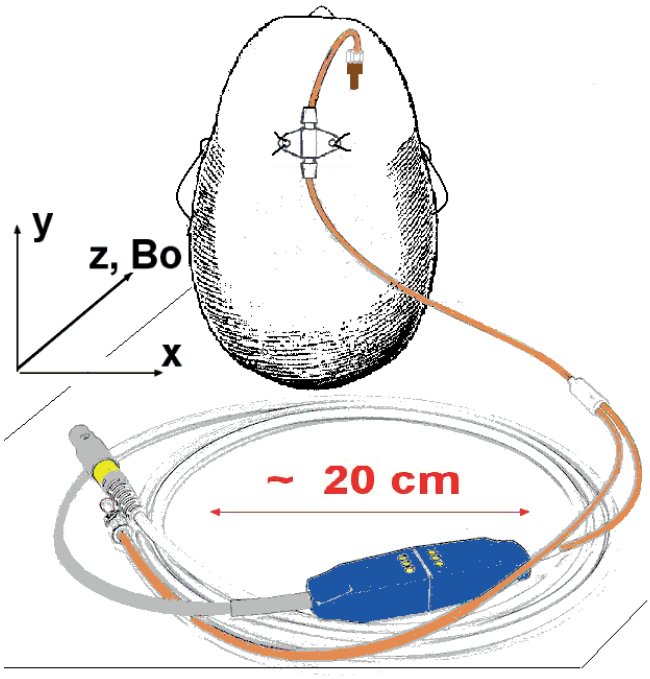
Within the scope of non-clinical laboratory tests it was demonstrated that with observance of the following notes and parameters, RAUMEDIC® precision pressure catheters are safe in the sense of MR conditionally in 1.5T and 3.0T MRI procedures according to ASTM F 2503-08 and IEC 62570.

MR Conditional

A theoretical estimated head averaged (HA) SAR limit of 3.2 W/kg (normal/first level operating mode) limit has been used for extrapolating the temperature increases based on in vitro test results. Measurement inaccuracies and additional safety margins should be taken into account.

A patient with this device can be safely scanned in an MR system meeting the following conditions:

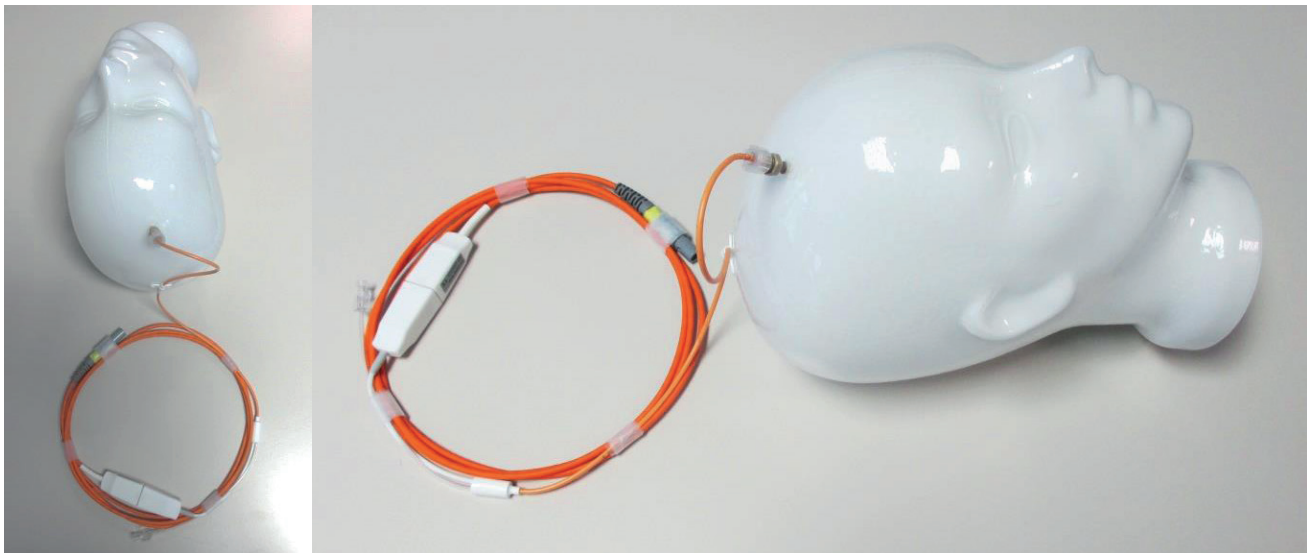
→ Static magnetic field of:	1.5 Tesla and 3 Tesla
→ Maximum spatial field gradient of:	72 T/m
→ Maximum force product of:	98 T^2/m
→ Maximum switched gradient slew rate per axis of:	200 mT/m/ms
→ Maximum switched gradient amplitude per axis of:	45 mT/m
→ Theoretically estimated maximum head averaged (HA) specific absorption rate (SAR) of:	< 3.2 W/kg (First Level Controlled Operating Mode)



Picture 1: Configuration MRI - coiled cable 01

The cable **and the part of the catheter outside the patient** must be positioned in coiled condition (loop-diameter approx. 20 cm, complies with approx. 3.0…3.5 coils) at the head of the patient.

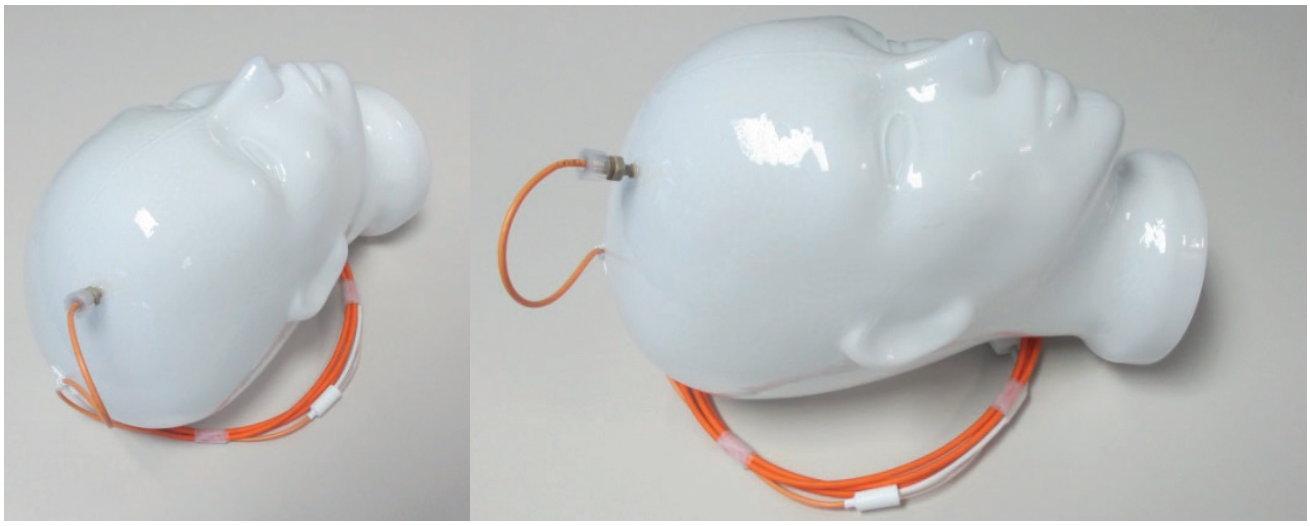
The cable coil must be set down at the headboard of the patient table in parallel (horizontally) to the static main magnetic field B0! (see image) This positioning also prevents artefacts in the head of the patient from the electrical and optical plug.



Picture 2: Configuration MRI - coiled cable 02

- → Different MRI systems with different methods to calculate the scan parameters (e.g. SAR) and individual, technical features of different MRI systems cannot be copied in laboratory tests. The conditions under which the feature MR can be conditionally guaranteed for the RAUMEDIC® precision pressure catheter are listed above. Deviations from these defaults can increase the risk of danger to patients!
- → Before the examination, the doctor must assess the risk whether the same information could not also be gained with other imaging methods with a lower risk of danger to the patient.
- → If the region of interest for imaging is near the RAUMEDIC® precision pressure catheter, then the existing image corruption from the object surface (3T spin echo: longitudinal artefact 0.6 mm, transversal artefact 25.6 mm and 3T gradient echo: longitudinal artefact 2.5 mm, transversal artefact 19.6 mm) must be taken into consideration. The scan parameters may have to be optimised for minimal image artefacts or another imaging method may have to be used.
- → It must be ensured directly before the MRI examination that the RAUMEDIC® precision pressure catheter functions correctly. If this is not the case then the positioned catheter may not be used for an MRI examination!
- → It must be ensured during the MRI examination that, before and during the examination during MRI, there is **no disconnection** of the RAUMEDIC® accessories, Cable PTO or ICP-TEMP-Cable used for the respective catheter!
- → The low magnetic components of the plugs (on the cable and on the RAUMEDIC® precision pressure catheter) can lead to image artefacts of approx. 70 mm starting from the surface of the object. These components must be placed with sufficient distance to the anatomical regions of interest for imaging.

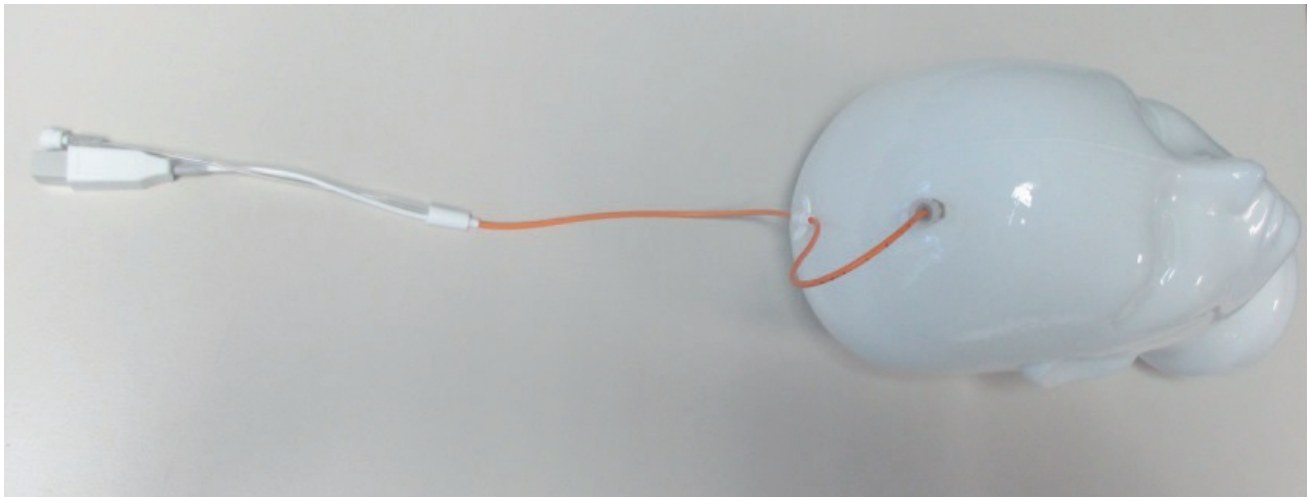
If the local setup does not allow application of coiled cable acc. to picture 1 (e.g. by using a Birdcage Coil), the coiled cable can also be placed under the patient's head (see picture 3).



Picture 3: Configuration MRI – with coiled cable in tight head coils (e.g. Birdcage Coil)

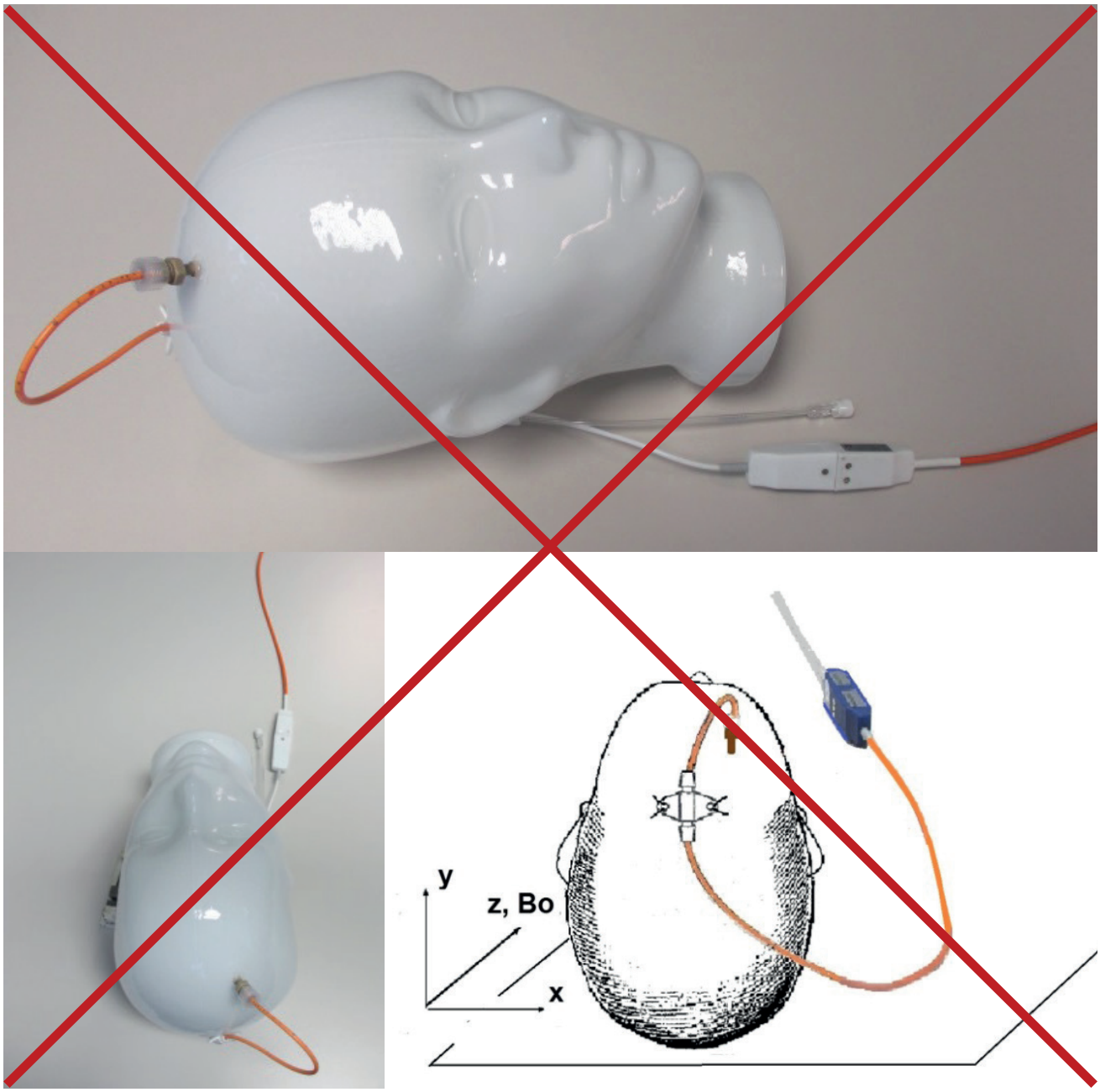
Putting the cable coil under the patient's head might affect the image quality of adjacent body parts by metal components in the cable.

With **1.5 T MRI imaging**, plugging the connecting cable in is not essential for safe use. But we recommend plugging in the coiled cable in the sense of a uniform approach for 1.5 T and 3.0 T.



Picture 4: Configuration MRI – without cable in tight head coils (e.g. Birdcage Coil)

It is not allowed to guide the cable alongside the patient's body towards the entry of the MRI scanner (see picture 5). There is an increased risk of warming.



Picture 5: Do not guide cable of catheter alongside the patient's head and body!

It is not allowed for any part of the catheter or cable to have contact with the housing of the MRI scanner. There is an increased risk of sparking.

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Laboratory data on heating effects in MRI				
Configuration	**Max. temperature increase at catheter**	**Max. temperature increase in surrounding area**	**Temperature difference**	**Normalized to (WBA)-SAR**
1,5 T *				
NEUROVENT®-PTO with **BOLT**, Implantation depth: 3 cm (parenchymal), Cable PTO attached and coiled (see pic.1 + 2)	2,0 °C	0,4 °C	1,6 K	2,4 W/kg
NEUROVENT®-TEMP-IFD-S **tunneled**, Implantation depth: 8 cm (Ventricle), ICP-TEMP-Cable attached and coiled (see pic.1 + 2)	0,9 °C	0,6 °C	0,3 K	3,2 W/kg
NEUROVENT®-TEMP-IFD-S **tunneled**, Implantation depth: 8 cm (Ventricle), no cable attached (see pic.4)	2,1 °C	0,4 °C	1,7 K	3,2 W/kg
3,0 T **				
NEUROVENT®-PTO with **BOLT**, Implantation depth: 3 cm (parenchymal), Cable PTO attached and coiled (see pic.1 + 2)	0,6 °C	0,5 °C	0,1 K	3,2 W/kg
NEUROVENT®-TEMP-IFD-R with **BOLT**, Implantation depth: 8 cm (Ventricle), ICP-TEMP-Cable attached and coiled (see pic.1 + 2)	0,9 °C	0,5 °C	0,4 K	3,2 W/kg
NEUROVENT®-TEMP-IFD-R with **BOLT**, Implantation depth: 8 cm (Ventricle), no cable attached (see pic.4)	4,6 °C	0,2 °C	4,4 K	3,2 W/kg

*) *Non-clinical examination on the head phantom with body coil with 64 MHz (1.5 Tesla equivalent) RF laboratory system „Medical Implant Test system MITS 1.5“, Zurich Medtech AG (software: MITS-DUALBAND 1.2.5.2),* **15 minutes of continuous MR scanning**. *The NEUROVENT®-PTO catheter is elongated and guided in parallel to the static magnetic field B0. Connecting cable PTO was, as described in picture 1, coiled and plugged to the catheter. The following heating was detected.*

) *Non-clinical examination on the head phantom with body coil, MR Scanner 3 Tesla Magnetom Trio, Siemens (software: Numaris/4, syngo MR A30),* **15 minutes of continuous MR scanning. *The NEUROVENT®-PTO catheter is elongated and guided in parallel to the static magnetic field B0. Connecting cable PTO was, as described in picture 1, coiled and plugged to the catheter. The following heating was detected.*