

Instruction for use

for neurosurgical precision pressure catheters

**with and without
additional temperature and oxygen measurement
(multi-parameter catheter)**

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Before using the medical device, please read the instruction for use carefully!

1 Intended purpose

The RAUMEDIC® Precision pressure catheters for use in Neurosurgery are used to directly measure brain parameters (intracranial pressure (ICP), oxygen partial pressure (ptiO₂) of the interstitial fluid and/or the brain temperature (TBr)). Depending on the version, up to three of the aforementioned functions can be measured with a catheter. Some versions also make liquor drainage possible at the same time. The Precision pressure catheters for use in Neurosurgery are divided according to their application sites (parenchyma, ventricle, dura), measurement site and their functions. The application-, measurement sites and functions of the respective catheters are listed in Chapter 5 – Overview of RAUMEDIC® Precision pressure catheters.

RAUMEDIC® Precision pressure catheters for neurosurgery may remain in the body for a maximum period of 29 days with cumulative application.

The RAUMEDIC® neurosurgical precision pressure catheters are intended for single use only. They are sterilised with ethylene oxide in accordance with ISO 11135.

The application of the RAUMEDIC® Precision pressure catheters for use in Neurosurgery must be carried out by qualified medical personnel including neurosurgery specialists or traumatologists with appropriate specialized training. Application shall follow aseptic techniques used in neurosurgery. Patient monitoring shall be performed by qualified medical personnel including neurosurgery specialists, anesthesiologists, nurses or other medical assistants with appropriate focus training.

RAUMEDIC® Precision pressure catheters for use in Neurosurgery may be used for adults, adolescents, children, babies and toddlers ≥ 1 year (≥ 3 years for NEUROVENT-Sleeve Housing and NEUROVENT VP 16, ≥ 12 years for NEUROVENT-TO).

2 Indications

The indications of the RAUMEDIC Precision pressure catheters for use in Neurosurgery are based on their functions, which can be found in Chapter 5 - Overview of RAUMEDIC Precision pressure catheters.

The measurement of intracranial pressure (ICP) and cerebral perfusion pressure (mean arterial blood pressure minus ICP) and where required the drainage of cerebrospinal fluid (CSF) are, according to the current state of knowledge, essential requirements for effective treatment of patients with suspected intracranial pressure increases (e.g. craniocerebral injury GCS ≤ 8 ; malignant media infarction; subarachnoid hemorrhage Hunt/Hess grade IV + V; cerebral oedema; hydrocephalus or for the catheters NEURODUR and NEURODUR-TEMP e.g. hydrocephalus, idiopathic intracranial hypertension, macrocephaly) or other patients amongst whom the clinical picture may be associated with an increase in the ICP.

The measurement of oxygen partial pressure ptiO₂ enables additional information about the patient's condition (secondary brain damage – detection of cerebral hypoxia and tissue damage). According to the general opinion in specialised literature, a good oxygen supply to the brain tissue correlates with a good outcome for patients.

The measurement of the brain temperature allows the direct measurement of the temperature in the brain tissue. This temperature can differ from the core body temperature. Measurement of the brain temperature allows the detection of episodes of cerebral hypothermia and the derivation of additional temperature information with hypothermia treatment.

The NEUROVENT-TO is used in particular to supplement an existing ICP measurement (e.g. in the case of traumatic brain injury) with the parameters temperature and oxygen partial pressure.

3 Contraindications

The following notes are no replacement for studying experience reports and recommendations in specialised medical literature that deal with techniques in pressure catheter application, failure and malfunctions as well as complications that occur.

There must be a particularly strong indication for the use of RAUMEDIC precision pressure catheters with:

- Reye's syndrome
- Clotting disorder (coagulopathies) due to an increased risk of haemorrhages
- Application with babies and toddlers < 1 year (with toddlers < 3 years for NEUROVENT-Sleeve Housing and NEUROVENT VP 16, with children < 12 years for NEUROVENT-TO)
- Sepsis, infection (especially in the catheter entry point area)
- Encephalitis
- Lysis therapy (haemorrhaging risk)

4 Side effects

Infections, liquor fistulas and neurological after-effects are potential complications of the process. Bone, meningeal, cortical or intraparenchymal haemorrhages can also occur around the application site.

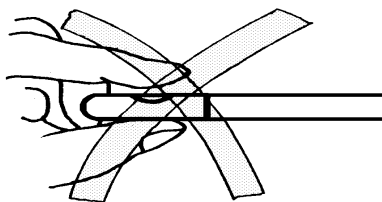
5 Overview of RAUMEDIC® precision pressure catheters

Catheter description			Application site (✓) Measuring site (x)			Functions				Application technique		
Catheter designation	Art.No.	Ø (CH)	Parenchyma	Ventricle	Dura	ICP	TEMP	p _t O ₂	Drainage	Bolt	Tunnel	Auxiliary devices
NEUROVENT®-P	092946-001	5 F	✓/ x			✓				✓	✓	
NEUROVENT®-PX	091580-001	5 F	✓/ x			✓				✓	✓	
NEUROVENT®-P-TEMP	094268-001	5 F	✓/ x			✓	✓			✓	✓	
NEUROVENT®-PX-TEMP	091431-001	5 F	✓/ x			✓	✓			✓	✓	
NEUROVENT®-PTO	095008-001	5 F	✓/ x			✓	✓	✓		✓		
NEUROVENT®-PTO 2L	095108-001	5 F	✓/ x			✓	✓	✓			✓	
NEUROVENT®-PTO 2L BOLT	095308-001	5 F	✓/ x			✓	✓	✓		✓		
NEUROVENT®-TO	095908-001	3 F	✓/ x				✓	✓		✓		
NEUROVENT®-Sleeve Housing	091576-001	9 F	x	✓		✓			✓	✓	✓	Mandrel (soft)
NEUROVENT® VP 16	096704-001	9 F	x	✓		✓			✓	see section 14.		Stilet
NEUROVENT®	092956-001	9 F		✓/ x		✓			✓		✓	Stilet
NEUROVENT®-TEMP	094278-001	9 F		✓/ x		✓	✓		✓		✓	Stilet
NEUROVENT®-IFD-S	091678-001	9 F		✓/ x		✓			✓	✓	✓	Mandrel (soft)
NEUROVENT®-TEMP-IFD-S	094288-001	9 F		✓/ x		✓	✓		✓	✓	✓	Mandrel (soft)
NEUROVENT®-IFD-R	095317-001	9 F		✓/ x		✓			✓	✓		Mandrel (hard)
NEUROVENT®-TEMP-IFD-R	095327-001	9 F		✓/ x		✓	✓		✓	✓		Mandrel (hard)
NEUROVENT® 6F	094678-001	6 F		✓/ x		✓			✓	✓	✓	Mandrel (soft)
NEURODUR®	092976-001	-			✓/ x	✓				see section 13.		
NEURODUR®-TEMP	094298-001	-			✓/ x	✓	✓			see section 13.		

* The NEUROVENT-TO is a special case due to its specific design (no titanium measurement head).

6 Precautionary measures / notes

- The application of the RAUMEDIC Precision pressure catheters for use in Neurosurgery must be carried out by qualified medical personnel including neurosurgery specialists or traumatologists with appropriate specialized training. Application shall follow aseptic techniques used in neurosurgery. Patient monitoring shall be performed by qualified medical personnel including neurosurgery specialists, anesthesiologists, nurses or other medical assistants with appropriate focus training.
- The neurosurgical precision pressure catheters are intended for **single use** only. If reused, there is a risk of prion transfer (Creutzfeldt-Jacob disease) as well as damage to the catheter from reuse processes.
- An optical check of packaging and of the pressure catheter for mechanical integrity as well as a check of the date of expiry must be carried out before use! Do not use the pressure catheter if checking indicates damage or evidence of incorrect handling! Use is also prohibited if the date of expiry is exceeded!
- Warning: During the application, a replacement catheter should always be available if the need arises.
- The catheter is sterile and must be applied under sterile conditions in the operation room!
- Prior and during the examination, the pressure catheter must not be bent, stretched or squeezed as well as manipulated by surgical tools. This is particularly true of catheters with an integrated partial oxygen pressure metering function. → **Caution: risk of glass fibre breakage!**
- If an unchanged ICP is indicated given the absence of an intracranial pressure pulse amplitude (breath-synchronously variabilities / pulse peaks) in a vigorous patient, the functionality of the pressure catheter has to be checked immediately by testing the reaction of the pressure channel on a slight movement of the head, for example. If the signal does not change, the defective precision pressure catheter has to be replaced.
- The pressure sensors may not be subjected to undefined pressures, e.g. by gripping the catheter with forceps to insert into a hole, because the sensors may be damaged with pressure values in excess of 1500 mmHg!



Do not touch the membrane and do not exert pressure with fingers!

- The catheter entry point has to be checked for any signs of a wound infection in regular intervals (such as swelling, reddening). If there are any signs of an infection, the catheter has to be removed.
- Since the infection rate for a catheterisation period of up to 3 days is very low, it is generally recommended to change a catheter after 5 days and no later than 10 days (see Citation 1, last page below).
- It must be insured with application that the sensor can be removed without problems with a slight pull.
- Extreme pull or damage to the catheter with sharp instruments has to be avoided – in particular during removal. Check for completeness after having removed the catheter.
- Bone, meningeal, cortical or intraparenchymal haemorrhages can occur around the operation area. If there is a suspicion of such occurrences, an imaging check-up procedure should be carried out!
- A therapy decision, based on the oxygen partial pressure value alone must not be made, rather it should always be backed up with another method, e.g. ICP measurement.
- Do not use the catheter connected to a device in an explosive environment. The catheter connected to a device must have a minimum distance of 25 cm to anaesthesia equipment and gas-filled hoses.

7 Precision pressure catheter connection to monitor systems

7.1 Pressure measurement

The measurement chain for pressure measurement comprises:

- RAUMEDIC precision pressure catheter (1)
- ICP-TEMP-Cabel (2)
- NPS2 (3)

Note: The zero point module NPS2 must be selected to match the configuration of the existing monitor system in the clinic.

→ see 20. Accessories

7.2 Temperature measurement

The measurement chain for additional temperature measurement comprises:

- RAUMEDIC precision pressure catheter (1)
- ICP-TEMP-Cabel (2)
- ICP-TEMP-Adapter (4)
- NPS2 (3)

For additional temperature measurement, an ICP-TEMP-Adapter is inserted between ICP-TEMP-Cable and NPS2.

Note: The ICP-TEMP-Adapter must be selected to match the configuration of the existing monitor system in the clinic.

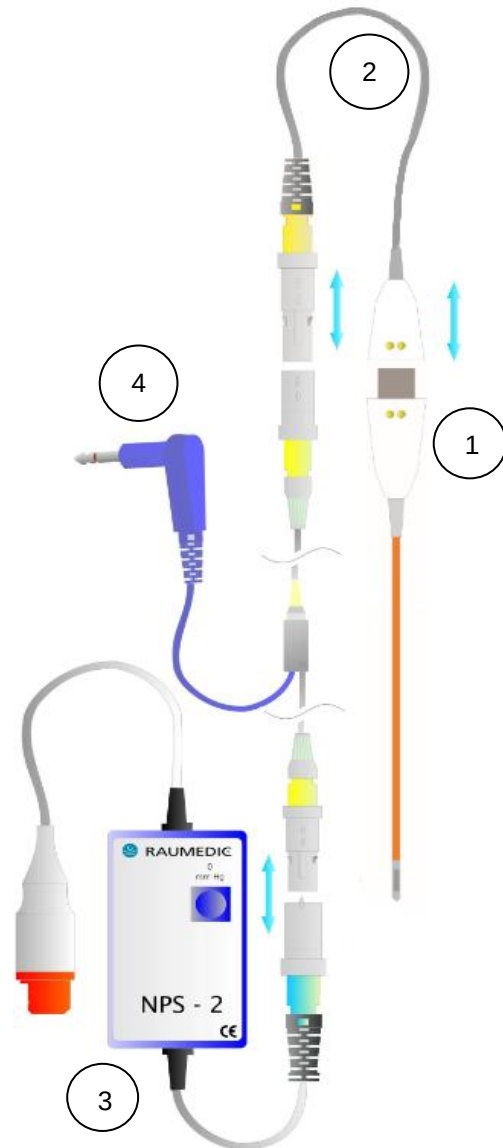
→ see 20. Accessories

7.3 Oxygen partial pressure measurement

The measurement chain for oxygen partial pressure measurement comprises:

- RAUMEDIC Präzisionsdruckkatheter (1)
- Cabel PTO
- Cabel LWL (Optical fibre cable)
- MPR2 logO DATALOGGER / EASY logO / RAUMED NeuroSmart logO

For additional oxygen partial pressure measurement, ICP-TEMP-Cable and Adapter are replaced with a Cable PTO. In addition, a LWL Cable (Optical fibre cable) is required for connection of the oxygen measurement channel.

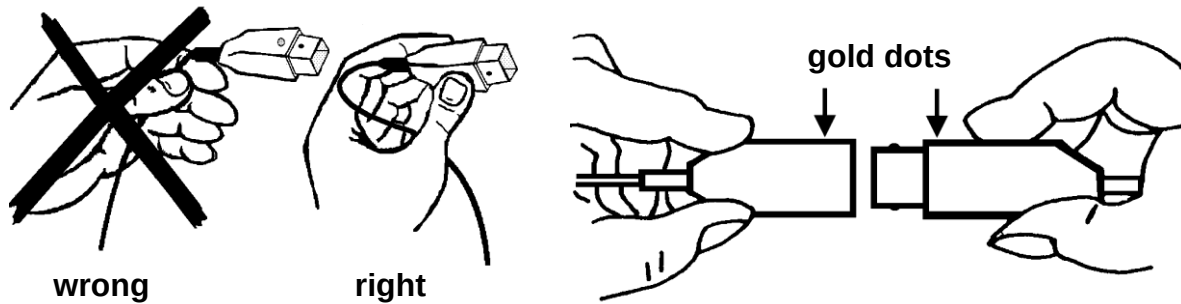


Note: The oxygen can be measured only with RAUMEDIC Datalogger MPR2 logO, RAUMED NeuroSmart logO or EASY logO. A NPS2 zero point module is no longer required.

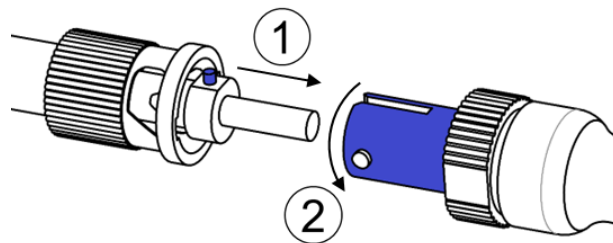
→ see 20. Accessories

8 Correct connection and removal

The gold dots on the plug connections of ICP-TEMP-Cable or Cable PTO and catheter must point to the same side.



When the optical plug connection comes into contact via LWL Cable (Optical fibre cable), the lateral nose on the male OF connector must be pushed into the appropriate recess of the counterpart all the way to the stop (1). Subsequently, the rim must be rotated clockwise 90° until it latches (2) to secure the plug connection. The plug connection is released in reverse order.



⚠ Caution: To avoid incorrect measurements, the optical fibre plug connection (OF contact) for $p_{ti}O_2$ measurement must be checked to ensure that is free from dirt!

9 Zeroing

Zeroing must be done according to the **NPS2 zero point module** instruction for use (zero offset adjustment of the monitor while pressing the blue button of the NPS2).

Oxygen partial pressure measurement via DATALOGGER MPR2 logO, RAUMED NeuroSmart logO or EASY logO does not require zero offset adjustment. All necessary calibration data for correct display of values are stored in the catheter connector and are automatically accepted by the particular monitor after the PTO connection cable is connected.

i Note: After catheter removal, a possible catheter drift during the recent application period can be detected by reading out the pressure value under zeroing conditions (immersion in fluid, no direct light).

10 Making a drill hole

Holes must be drilled into the skullcap according to the **BOLT KIT / DRILL KIT** instruction for use.

⚠ Caution: The operating area must be freed from bone splinters or treatment residue after every drilling process or any work on the drill hole (e.g. shaping a ramp) with rinsing. Possibly existing burrs at the base of the drill hole must be removed carefully.

11 Application with the BOLT(-DRILL) KIT

⚠ Caution: Please refer to the RAUMEDIC®- precision pressure catheter overview (see section 5.) to find out if the catheter that is used is compatible with the bolt system.

The BOLT(-DRILL) KIT version must be chosen according to the catheter to be used:

BOLT(-DRILL) KIT CH5	BOLT(-DRILL) KIT CH9	BOLT(-DRILL) KIT PTO	BOLT KIT PTO 2L	BOLT-DRILL KIT VP 16
for all catheters with a diameter of 5F and without p_{tiO_2} measurement function	for all catheters with a diameter larger than 5F	for NEUROVENT-PTO, NEUROVENT-TO	for NEUROVENT-PTO 2L BOLT	for NEUROVENT VP 16, NEUROVENT-Sleeve Housing

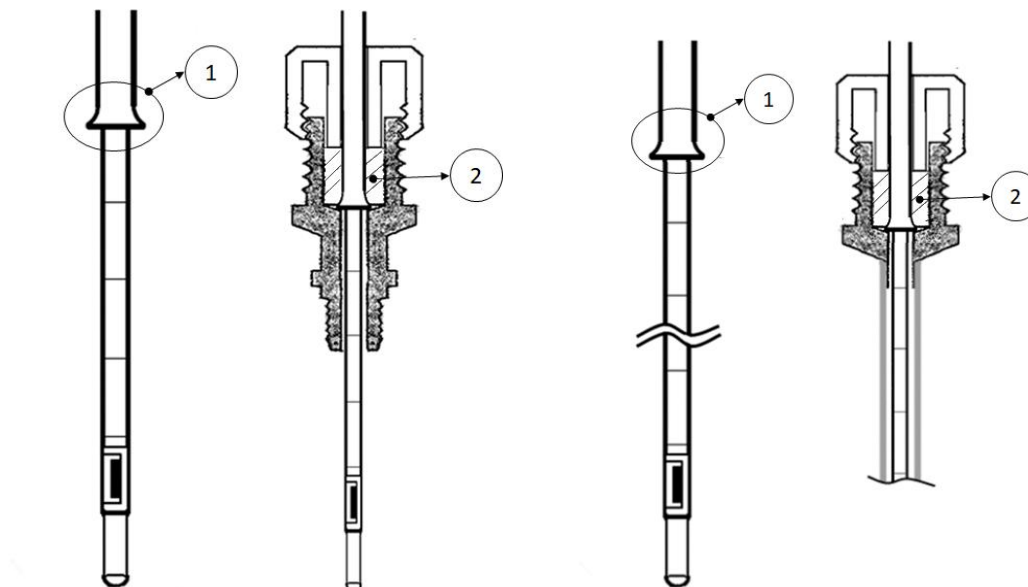
RAUMEDIC- precision pressure catheter application with BOLT(-DRILL) KIT must be done according to the **BOLT KIT / DRILL KIT** instruction for use. Additional notes to be observed during application depending on catheter type are described in the following sections. The BOLT KIT fixing cap must be turned until the catheter is secured and a complete seal is made. It must also be ensured that the catheter remains open for ventilation and drainage. To safely determine this position with a laid down mandrel, the crimp connection must be closed until the mandrel can still barely be pulled out.

11.1 Catheter type specific notes on application for NEUROVENT-PTO, -TO and -PTO 2L BOLT

These catheter models have a mechanical stop (lip 1) in the front region of the catheter. This serves to place the catheter tip at an ideal application depth (2.5 – 3.0 cm) if BOLT (-DRILL) KIT PTO or BOLT KIT PTO 2L is used:

The lip on the catheter outlet must be pushed forward by the silicone ring (shaded area (2), sealing cap not tightened). During passage of the silicone ring, a resistance must be felt against which the catheter must be pushed forward until the silicone ring has completely passed through and the base of the BOLT screw has been reached.

The following image illustrates the result (example illustration of the NEUROVENT-PTO in the BOLT (-DRILL) KIT PTO (left), NEUROVENT-PTO 2L BOLT in the Tuohy Borst adapter of the BOLT KIT PTO 2L (right)):



The catheter is subsequently fixed in place in the BOLT screw / Tuohy Borst adapter by tightening the fixing cap.

11.2 Catheter type specific notes on application for NEUROVENT-IFD-R and -TEMP-IFD-R

This catheter model may be applied only with the BOLT(-DRILL) KIT CH9. Tunnelling of this catheter is not permitted due to the strong restoring force of the mandrel that is inserted into the catheter! After reaching the desired application depth, the mandrel must be pulled out of the catheter lumen slowly and carefully.

⚠ Caution: These catheters are equipped with an additional lumen for the mandrel. It reaches into the metal tip of the catheter and thus allows precise guidance during application. Since this lumen also transmits the reference pressure to the pressure sensor chip, it may not be closed or come into contact with fluid!

11.3 Catheter type specific notes on application for NEUROVENT- IFD-S, -TEMP-IFD-S and 6F

⚠ Caution: These catheters are equipped with a mandrel that is taken through the drainage lumen. It must be ensured during application that the top of the guide wire does not push through a proximal drainage opening. After successful ventricle puncture, the guide wire is pulled back and removed.

12 Application with tunnelling sleeve

⚠ Caution: Please refer to the RAUMEDIC precision pressure catheter overview (see section 5.) to see if the catheter that is used is suitable for tunnelling.

The version of tunnelling sleeve must be chosen according to the catheter to be used:

Spliceable tunnelling sleeve CH8 Tunneling KIT CH8	Spliceable tunnelling sleeve CH12 Tunneling KIT CH12
for all catheters with diameter 5F	for all catheters with a diameter larger than 5F and the <u>NEUROVENT-PTO 2L</u>

Application of a RAUMEDIC- precision pressure catheter with tunnelling sleeve must be done according to the instruction for use for the **spliceable tunnelling sleeve with trocar** or **Tunneling KIT**. Additional notes to be observed during application depending on catheter type are described in the following sections.

After application of a catheter via tunnelling, it must be pulled back subcutaneously until it rests below a skin-galea flap and loops cannot form. It is then led from the point of exit at the stab incision to the fixation with a slight curve.

⚠ Caution: During the explantation of tunnelled catheters, the sutures over the drill hole must first be loosened fully. The catheters can subsequently be pulled out like wound drainage using suitable tools (e.g. forceps) for non-destructive drill hole passage.

⚠ Caution: If there is a plan not to open the stitches during removal of the catheter due to clinical requirements, this must be ensured with suitable measures such as those shown below:

- an appropriate choice of drill hole diameter using a suitable surgical tool (e.g. trepan, drill ... Depending on the anatomical conditions), but at least:
 - Ø 10 mm for the 5F catheter and
 - Ø 12 mm for all catheters with a diameter larger than 5F and the **NEUROVENT PTO 2L**
- placement of an angled drill hole (similar to Section 10)
- ramp-shaped deburring of the drill hole margin in the drainage direction of the catheter

⚠ Caution: To prevent the catheter from being torn off in the process, pull it slowly and not jerkily.

12.1 Catheter type specific notes on application for NEUROVENT-PTO 2L

i Note: NEUROVENT-PTO 2L can also be used for craniotomy patients.

The **drill hole** for the tunneling of this catheter must be made slanted **at an approx. angle of 30°**. The upper edge of the bone must be broken in the direction of the leading out of the catheter to avoid sharp edges.

⚠ Caution: The direction of introduction of the catheter should correspond with the direction of the sloping drill hole (30°). The catheter must be taken into the brain tissue straight through the drill hole. For craniotomy patients, the catheter must also be introduced into the brain tissue at an approx. angle of

30° to the surface of the brain. Bending the thin CH5 catheter tube must be avoided (danger of breakage of the O₂ glass fibre!).

12.2 Catheter type specific notes on application for NEUROVENT, -TEMP, -IFD-S, -TEMP-IFD-S, 6F and -Sleeve Housing

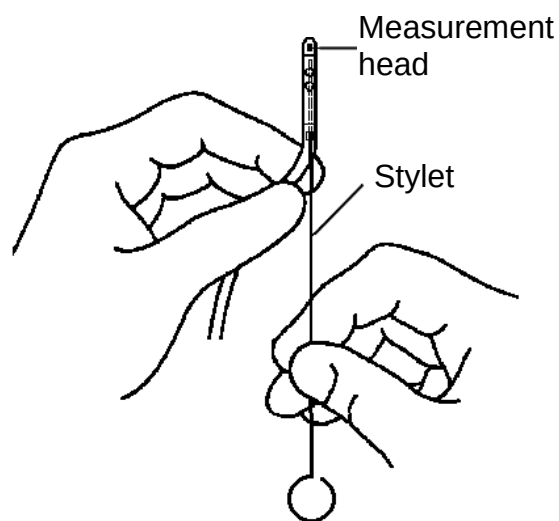
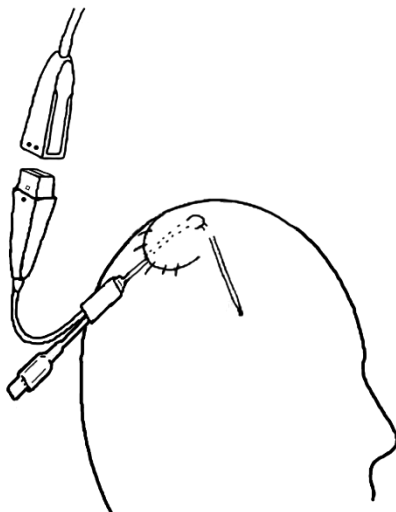
For ventricle pressure measurement, these catheters can be placed like external CSF drainage. The LL cap must first be removed for that. Leaking liquor indicates correct positioning of the pressure catheter. An external drainage system (e.g. RAUMEDIC®-Liquor-Drainage-Set) can now be connected or the lumen be closed again with the LL cap. Curved incision with tunnelling of the skin-galea flap prevents that skin incision and drill hole are directly above each other. After tunnelling, the catheter is pulled out about 30 cm on the drill hole side and inserted into the ventricle through the drill hole.

The catheter can be stiffened for ventricle puncture with a stylet or the internal mandrel:

Stylet	Mandrel
Carefully insert the stylet in the distal drainage opening and push it in up to the measurement head.	Carefully insert the guide wire (mandrel) through the Luer attachment, push it up to the measurement head and lock it in place with Luer cap.

⚠ Caution: Make sure that the stylet or mandrel tip does not push through a proximal drainage opening!

After successful ventricle puncture, stylets are pulled out and removed with a slight rotation around their longitudinal axis while guide wires are pulled out and removed **continuously holding the catheter above the drill hole**.



Example here: an NEUROVENT(-TEMP) with stylet

13 Notes on the application of NEURODUR, -TEMP

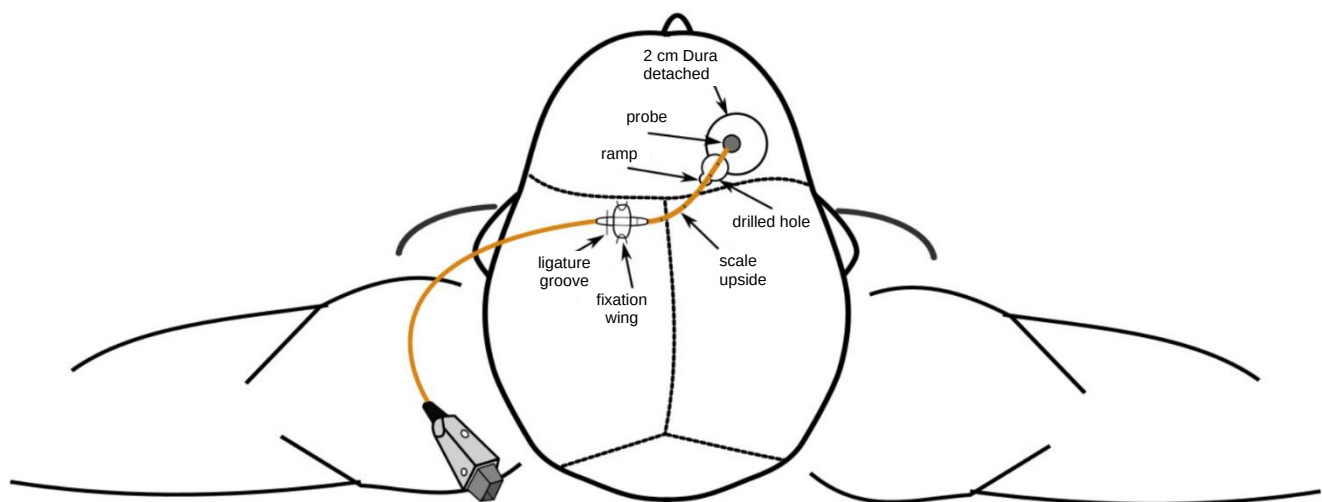
Placement of the brain pressure measurement probe between dura and skullcap. The measurement window is pointing toward the dura here. Correct alignment can be detected from the outside only with the catheter scale that faces upward.

The minimum size for the drill hole is 9 mm. The edge of the bone in the intended introduction and extraction direction is bevelled and smoothed off to form a tapered edge using milling hand piece, Luer bone rongeur, sharp curette or by creating a second drill hole down to the cancellous bone directly alongside the actual drill hole. Wax can be used for smoothing and haemostasis.

Detach a dura section of about 25 mm length and 25 mm width from the inside of the bone surface with a suitable instrument (e.g. spring probe) to avoid internal stress on the measurement window. A lateral stab incision is made a few centimetres from the drill hole. After tunnelling, the probe is carefully pushed through with atraumatic forceps (no sharp-edged instruments!) or with a finger and inserted subgaleal into the drill hole.

The measurement head must be inserted at least 5 mm below the edge of the bone between dura and skullcap without using force!

The pressure can be measured at any point on the skull. The present disease should be used for orientation when selecting the site of application. Epidural precision catheter application should be done on the side of the lesion to detect pressure changes early.



Note: Meaningful values can only be recorded after an adjustment period of about 2-6 hours. The dura requires this time to shape to the probe. Applanation quality is achieved if pulse and breath amplitudes are transmitted cleanly with bottom peaks.

After neurosurgical operations with trepanation, the NEURODUR /-TEMP can be used for postoperative brain pressure monitoring without further surgical effort. The measurement head must be pushed below the trepanation edge as far as possible. The dura must be detached here too so that the measurement head slides between dura and cranial bones easily and there are not measuring errors from internal dura tension.

Note: The NEURODUR /-TEMP can also be laid subdural on the surface of the brain. The catheter channel must be sealed against leaking liquor with deep sutures!

14 Notes on the application of NEUROVENT VP 16

Note: We recommend placing the NEUROVENT VP 16 with BOLT-DRILL KIT VP 16 (see section 11).

The application of NEUROVENT VP 16 can also be done with a sterile skin incision with a sufficiently large drill hole (> 6.0 mm) as an alternative to the recommended method.

The catheter can hereby be stiffened with the included stylet or another disposable stylet (diameter ≤ 1.1 mm, min. length 160 mm, maybe with the possibility for neuro-navigation) for ventricle puncture. The stylet is temporarily inserted in the drainage lumen for that. After successful puncture, the skin incision is closed and the stylet removed. The drainage lumen is connected with an external ventricle drainage system. When connecting to an external drainage system, please ensure that no rotations are performed on the side of the catheter's LUER connector. For this, fix the NEUROVENT VP 16 in place by hand and carry out the rotation from the drainage system side.

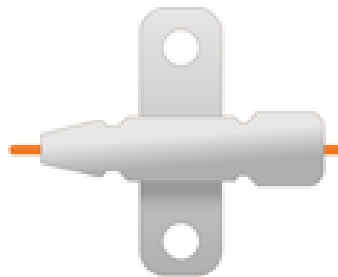
Caution: To avoid infection, the condition of the wound must be monitored especially closely with this application technique!

15 Fixing the catheter in place after application

RAUMEDIC precision pressure catheters must always be additionally fastened to the scalp with the included fixing wing to avoid manipulation of the position regardless of the application method used!

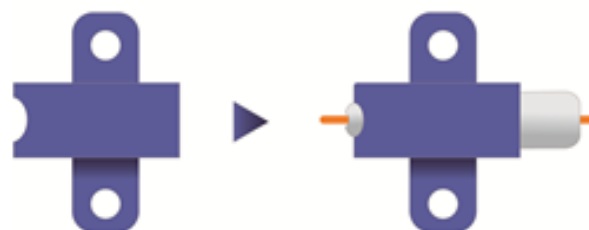
15.1 RAUMEDIC precision pressure catheters with a diameter larger than 5F

These catheters must be additionally fixed in place with two ligatures on the existing ligature grooves to protect against longitudinal displacement or rotation! It must be ensured that the ligature threads are not pulled too strongly to prevent the reference or drainage lumen from being closed.



15.2 NEUROVENT-P, -PX, -P-TEMP and -PX-TEMP

These catheter models have an additional blue fixing clip (see image), which is sutured to the scalp together with the white fixing wing.



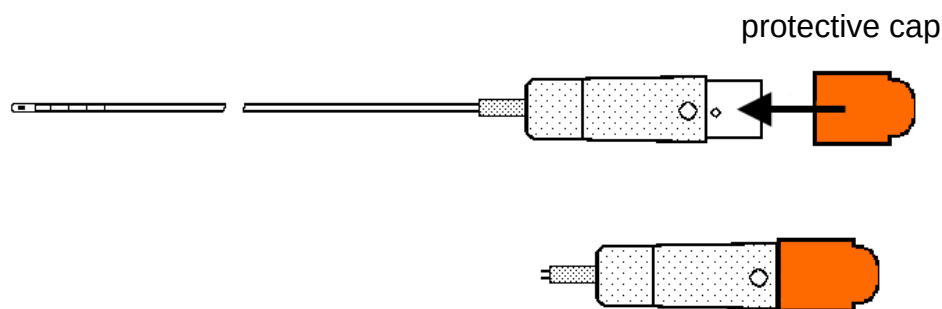
15.3 NEUROVENT-PTO 2L

Caution: The fixing wing may be fixed in place only on the thick part of the catheter hose (8F).

The thin part of the catheter hose (5F) must be laid in a loop $\varnothing$ approx. 20 mm for strain relief and covered with a plaster.

16 Safety information

- Use of the pressure catheter must take place according to the recognized rules of medical practice (therapy guidelines)!
- Only CF type (cardiac floating) measuring systems with the  symbol shall be used.
- The product is not equipped with protective measures to prevent the patient from being burnt when high-frequency surgical equipment is used.
- The ICP-TEMP-Cabel or Cabel PTO must be disconnected from the catheter:
 - before using a HF surgical device!
 - before using a defibrillator, as the catheter is not protected against defibrillation!
 - if disconnection is intended (e.g. during nursing procedures, patient transport)!
- High frequency interferences (e.g. from mobile phones or pagers) may, under unfavourable conditions, lead to disturbances in the signal and thus result in incorrect measurements!
- **NEUROVENT-PTO, NEUROVENT-PTO 2L, NEUROVENT-PTO 2L BOLT** and **NEUROVENT-TO** catheters may only be operated in conjunction with the MPR2 logO, RAUMED NeuroSmart logO or EASY logO monitor!
- Catheter models **NEUROVENT-PTO** and **NEUROVENT-TO** may only be used with **BOLT KIT PTO**!
- The catheter model **NEUROVENT PTO 2L BOLT** may only be used with the **BOLT KIT PTO 2L**.
- If ICP-TEMP-Cable or PTO-Cable are not connected, the catheter plug must always be closed with the included protective cap to protect it against moisture (see image)!



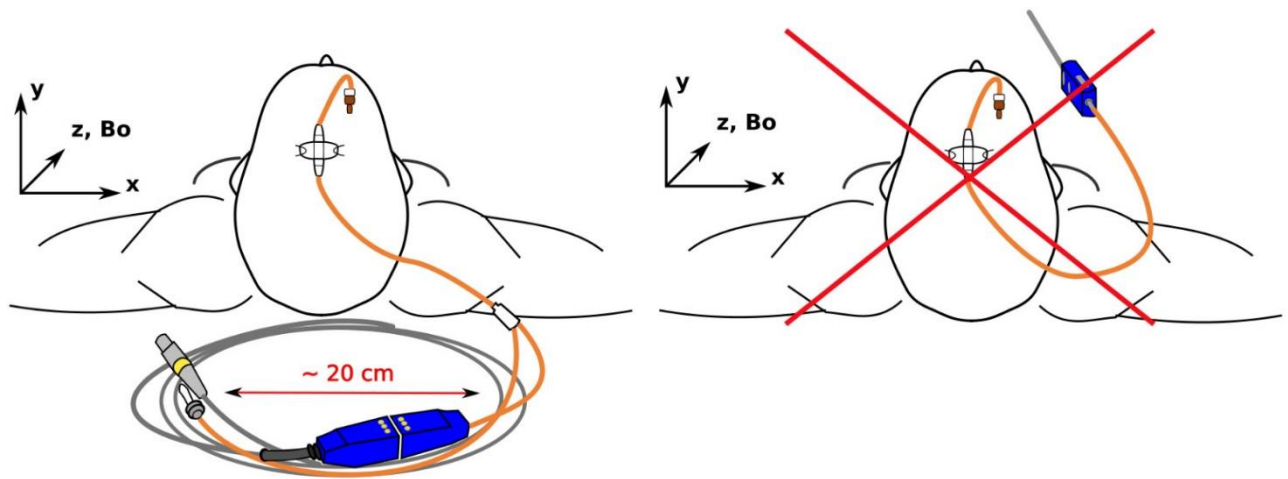
17 MRI safety RAUMEDIC Precision pressure catheters at 1,5 T / 3,0 T

Note: Within the scope of non-clinical laboratory tests according to ASTM F 2503 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 1.5 T and 3.0 T MRI procedures according to ASTM F 2503.

- 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 conditional can be guaranteed for the RAUMEDIC precision pressure catheter are listed in point **17.2. MRI parameters**. Deviations from these specifications can increase the risk of patient harm!
- 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 patient harm.
- In order to safely avoid a displacement of the RAUMEDIC precision pressure catheter due to the force effect of the spatial magnetic field gradients, the catheter fixation specified for each catheter type in this instruction must be used!
- MRI devices with field strengths other than 1.5 T and 3.0 T may not be used!
- If the region of interest for imaging is near the RAUMEDIC precision pressure catheter, the existing image corruption from the object surface (3.0 T spin echo: longitudinal artefact 0.6 mm, transversal artefact 25.6 mm and 3.0 T 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.

17.1 Use during MRI

- It must be ensured directly before the MRI examination that the RAUMEDIC precision pressure catheter functions correctly. If this is not the case, no MRI examination may be performed with the placed catheter!
- The RAUMEDIC precision pressure catheter requires a special positioning geometry for MRI examinations to safely prevent the probe tip from heating up.
- During the MRI examination, it must be ensured that before and during the examination in the MRI there is **no disconnection** of the RAUMEDIC PTO-Cable or ICP-TEMP-Cable used!
- 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.
- 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 B_0 (see image)! This positioning also prevents artefacts in the head of the patient from the electrical and optical plug.



⚠ Caution: If a deviation from the configuration specified above occurs, there is a clinically unacceptable risk of heating in MRI 1.5 T and 3.0 T under worst case conditions (cable stretched out beside the patient).

Heating that occurs under required configurations is shown in the table “Laboratory data for heating effects during MRI” in Section 19.

⚠ Caution: If the local conditions do not allow the coiled cable to be plugged into the external part of the catheter, the potentially higher heating if a cable is not plugged in (see table Laboratory data for heating effects during MRI) must be considered with appropriate reduction of the scanning time and/or the SAR.

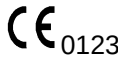
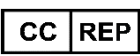
ℹ Note: With 1.5 T and 3.0 T MRI imaging, plugging the connecting cable in is not essential for safe use if the given instructions are observed. But we recommend plugging in the coiled cable in the sense of a uniform approach for 1.5 T and 3.0 T and the lower heating effects.

17.2 MRI parameters

The MRI examination must be carried out adhering to the following MRI device conditions:

Static magnetic field B_0 :	1.5 T or 3.0 T
Maximum of the spatial magnetic field gradient:	$ \nabla B \leq 25 \text{ T/m}$ (value extrapolated)
Maximum of the spatial magnetic field gradient of the product:	$ B \cdot \nabla B \leq 50 \text{ T}^2/\text{m}$ (value extrapolated)
Maximum, theoretically derived, specific absorption rate (SAR) averaged via the head:	for precision pressure catheters with cable plugged in as per section 17.1.: < 3.2 W/kg at 1.5 Tesla and 3.0 Tesla (normal mode of operation and initial-stage mode of operation)
	for precision pressure catheters without a plugged-in cable: 3.2 W/kg at 1.5 Tesla and 3.0 Tesla (normal mode of operation and initial-stage mode of operation)
Tested configurations (worst case):	NEUROVENT-PTO with Bolt and Cable PTO, application depth $\approx 3 \text{ cm}$, Cable PTO $\varnothing$ wound 20 cm, main level of the cable coil parallel to B_0 , see section 17.1., laser cross positioned on the head (head in the isocentre of the body coil)
	NEUROVENT-PTO with Bolt and no Cable PTO, application depth $\approx 3 \text{ cm}$, laser cross positioned on the head (head in the isocentre of the body coil)
	NEUROVENT-TEMP-IFD-S with skin tunnel and ICP-TEMP-Cable, application depth 8 cm (ventricle), ICP-TEMP cable $\varnothing$ wound 20 cm, main level of the cable coil parallel to B_0 , see section 17.1., laser cross positioned on the head (head in the isocentre of the body coil)
	NEUROVENT-TEMP-IFD-S with skin tunnel and no ICP-TEMP-Cable, application depth 8 cm (ventricle), laser cross positioned on the head (head in the isocentre of the body coil)
	NEUROVENT-TEMP-IFD-R with Bolt and ICP-TEMP-Cable, application depth 8 cm (ventricle), ICP-TEMP cable $\varnothing$ wound 20 cm, main level of the cable coil parallel to B_0 , see section 17.1., laser cross positioned on the head (head in the isocentre of the body coil)
	NEUROVENT-TEMP-IFD-R with Bolt and no ICP-TEMP-Cable, application depth 8 cm (ventricle), laser cross positioned on the head (head in the isocentre of the body coil)
Max. duration of continuous MRI scan:	15 min.

18 Indication and warning symbols on the label

	Sterilized using ethylene oxide		Consult instructions for use
	Do not re-use		Non-pyrogenic
	Do not re-sterilize		Date of manufacture
	Do not use if package is damaged		Use-by date
	Keep away from heat and sunlight		The RAUMEDIC® precision pressure catheter is MR conditional
	Keep dry		Quantity
	The product complies with the general safety and performance requirements of Regulation (EU) 2017/745.		Caution, consult the instructions for use for important cautionary information such as warnings and precautions!
	Serial number		Medical device
	Reference number		Unique Device Identification
	Single sterile barrier system with protective packaging inside		Manufacturer
	Importer		Authorized representative in the country CC (the letters "CC" correspond to the two-letter country code defined in ISO 3166-1).

19 Technical data

General	
Measurement head material	Titanium
Catheter material	Polyurethane
Material measurement window	Silicone

Pressure measurement information	
Pressure measurement range:	-40 to +400 mm Hg (53 kPa)
Maximum pressure:	1500 mm Hg (200 kPa)
Sensitivity:	5 $\mu\text{V/V/mm Hg} \pm 1\%$ (37.5 $\mu\text{V/V/kPa}$)
Zero point stability in physiolog. saline solution:	maximum drift of 3.0 mm Hg in 100 hours $\emptyset$ drift after 5 days 0.6 mm Hg*

* Bench test assessment of the new Raumedic NEUROVENT-P ICP sensor: a technical report by the BrainIT group Citerio G., Piper I., Cormio M., Galli D., Cazzaniga S., Enblad P., Nilsson P., Contant C., and Chambers I., BrainIT Group Acta Neurochirurgica (Wien). 2004, Aug; DOI: 10.1007/s00701-004-0351-z

Temperature measurement information (YSI400)	
Measured exit area (initial value range):	25°C to 45°C
Measured expanded exit area (initial value range):	15°C to 25°C
Accuracy in the range from 25°C to 45°C:	± 0.1 K
Accuracy in the range from 15°C to 25°C:	± 0.2 K
Minimum measurement time:	10 s
Temperature measuring method:	Direct mode, compatible with monitors that support the YSI 400 characteristic curve
Measuring point/reference body site:	Measurement of brain temperature

Oxygen partial pressure measurement p_{tiO_2} information	
Measurement range:	0-200 mmHg oxygen partial pressure
Measurement accuracy:	1) 0...120 mmHg $\rightarrow \pm 3\%$ of the measured value or ± 2.50 mmHg (the larger value applies) 2) 120...200 mmHg $\rightarrow$ max. 10% of the measured value
Time drift: (*)	max. 1.5 mmHg over 5 days (at a p_{tiO_2} of ≤ 10 mmHg)
p_{tiO_2} -sensitive area: (*)	> 13 mm ² for NEUROVENT-TO > 22 mm ² for NEUROVENT-PTO, -PTO 2L and -PTO 2L BOLT

Operating conditions		
Temperature range	Humidity range	Air pressure range
+10°C to +40°C	30% to 75% RH	540 to 1050 hPa

Laboratory data for heating effects during MRI				
Configuration	Max. temperature increase on the catheter	Max. temperature increase in the environment	Temperature difference	normalised to (WBA)-SAR
1,5 T *				
NEUROVENT-PTO with Bolt, application depth 3 cm (parenchymal), Cable PTO plugged in as per section 17.1.	2,0°C	0,4°C	1,6 K	2,4 W/kg
NEUROVENT-TEMP-IFD-S, skin tunnel, application depth 8 cm (ventricular), ICP-TEMP-Cable plugged in as per section 17.1.	0,9°C	0,6°C	0,3 K	3,2 W/kg
NEUROVENT-TEMP-IFD-S, skin tunnel, application depth 8 cm (ventricular), no cable plugged in	2,1°C	0,4°C	1,7 K	3,2 W/kg
3,0 T **				
NEUROVENT-PTO with Bolt, application depth 3 cm (parenchymal), Cable PTO plugged in as per section 17.1.	0,6°C	0,5°C	0,1 K	3,2 W/kg
NEUROVENT-TEMP-IFD-R, with Bolt, application depth 8 cm (ventricular), ICP-TEMP-Cable plugged in as per section 17.1.	0,9°C	0,5°C	0,4 K	3,2 W/kg
NEUROVENT-TEMP-IFD-R, with Bolt, application depth 8 cm (ventricular), no cable plugged in	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 for length x und guided in parallel to the static magnetic field B_0 . Connecting Cable PTO was, as described in 17.1. Use during MRI, coiled and plugged to the catheter. Analogous measurements are performed with the NEUROVENT-TEMP-IFD-S, skin tunnel, application depth 8 cm. 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 for length x und guided in parallel to the static magnetic field B_0 . Connecting Cable PTO was, as described in 17.1. Use during MRI, coiled and plugged to the catheter. Analogous measurements are performed with the NEUROVENT-TEMP-IFD-R, with Bolt, application depth 8 cm. The following heating was detected.

With regard to the heating effects, the catheters and types of application used for the laboratory tests constitute the worst-case configurations of the NEUROVENT catheter family shown in the Section 5 table.

20 RAUMEDIC Accessories

Cabels	
ICP-TEMP-Cable	094328-001
Cable LWL	095657-001
Cable PTO	095624-001
ICP-TEMP-Adapter	094323-001
ICP-TEMP-Adapter 2m	095226-001
ICP-TEMP-Adapter Philips/HP	094047-001
ICP-TEMP-Adapter Philips/HP 2m	095216-001
Monitors	
MPR 1 DATALOGGER	094474-002
MPR2 logO DATALOGGER	095254-002
EASY logO	095264-002
NPS 3	091656-001
RAUMED NeuroSmart	095284-001
RAUMED NeuroSmart logO	095294-001
Application aids	
BOLT KIT CH5	091868-002
BOLT KIT CH9	091688-002
BOLT KIT PTO	096026-001
BOLT KIT PTO 2L	096076-001
DRILL KIT CH5	091878-002
DRILL KIT CH9	091668-002
BOLT-DRILL KIT CH5	091888-001
BOLT-DRILL KIT CH9	091898-001
BOLT-DRILL KIT PTO	092380-001
BOLT-DRILL KIT VP 16	092969-001
Spliceable Tunneling Sleeve CH8	090506-002
Spliceable Tunneling Sleeve CH12	090717-001
Tunneling KIT CH8	090516-001
Tunneling KIT CH12	090727-001
NPS2	
NPS2 SpaceLabs	091715-001
NPS2 Spiegelberg CPP	091738-001
NPS2 CODMAN	091978-001
NPS2 Siemens/Dräger Infinity	092627-001
NPS2 Philips/HP	092637-001
NPS2 GE/MARQUETTE	093807-001
NPS2 Nihon Kohden BSM 41xx	094716-001
NPS2 Fukuda Denshi 8000	095007-001
NPS2 SpaceLabs 9X496 Module	095027-002
NPS2 Criticare nCompass	095037-001
NPS2 Datascope	095918-001
NPS2 Fukuda Denshi	096003-001
NPS2 Spiegelberg Compliance	096013-001

NPS2 Saadat	096023-001
NPS2 GE	093999-001
NPS2 Tempus Pro	095097-001

21 Liability and guarantee information

RAUMEDIC® precision pressure catheters (referred to in the following as catheters) are handled with extreme care during development, component selection, manufacturing and final testing prior to delivery.

The responsibility for the suitability of the type of catheter used and for the correct employment shall be borne by the user. Incorrect handling may lead to functional impairment which in turn could lead to damage and injury. RAUMEDIC® will not be responsible for any injuries of any type nor for any losses or damages, whether these be direct, indirect or consequential losses resulting from use of the catheter outside its intended use as described in the instruction for use.

As a matter of course however, medical complications cannot be ruled out, nor can functional faults and failures of the connected pressure measurement amplification and monitoring systems and the resulting functional faults and failures of the catheters.

Therefore, no guarantee can be provided, nor can it be warranted or guaranteed that no functional faults or failures of the catheters will occur, that the body will not display an immune reaction or that non-medical complications will not occur as a result of the use of the catheter.

Any guarantee or liability for defects which are not immediately detected during initial use of the catheters is excluded.

In accordance with the European Medical Devices Regulation (2017/745), Raumedic AG is obliged to point out the following:

All serious incidents that occur in connection with the product must be reported to Raumedic AG and the competent authority of the member state, in which the user and/or patient is based.

Please note:

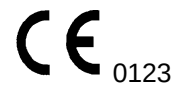
Serious incidents include the death of a patient, user or another person, or the temporary or permanent deterioration in the health of a patient, user or another person. It does not matter whether these have occurred or could occur. Article 2 (65) in Regulation (EU) 2017/745 contains the precise definition.

The contact details of your member state's competent authority are available online. Use the search term, **"Competent Authorities for Medical Devices EU"**.

The Summary of Safety and Clinical Performance (SSCP) is available in the European Database on Medical Devices (Eudamed), which can be accessed via the following URL: <https://ec.europa.eu/tools/eudamed>. The summary report can be retrieved by searching for the respective Basic UDI-DI (40578340009NDKU7 for all RAUMEDIC precision pressure catheters for neurosurgery, without drainage function or 40578340009NDKdrZD for all RAUMEDIC precision pressure catheters for neurosurgery, with drainage function). The SSCP is also available on <https://www.raumedic.com>.

22 Disposal

After use, the RAUMEDIC precision pressure catheters must be correctly disposed of in accordance with the applicable instructions for disposal of contaminated hospital waste.



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Literature:

- 1) Abdulla W. Intrakranielle Druckmessung. In: Abdulla W. Interdisziplinäre Intensivmedizin. 3. Auflage. München [u.a.]: Elsevier, Urban & Fischer 2007; 658-660