Urgent safety information

Commercial name of the affected product:	NEUROVENT PTO
Identifier (e.g. date):	FSN 01/2025
Type of action:	Field Safety Notice
Date:	7. April 2025
Sender:	RAUMEDIC AG Hermann-Staudinger-Str. 2 95233 Helmbrechts, Germany Germany

Recipient:
Distributors and clinical end-users of the medical devices specified below

Details on affected devices:
NEUROVENT-PTO (095008-001) with the following S/N:

E838 3803	E838 3809	E838 3815	E838 3821	E838 3837
E838 3804	E838 3810	E838 3816	E838 3832	E838 3838
E838 3805	E838 3811	E838 3817	E838 3833	E838 3839
E838 3806	E838 3812	E838 3818	E838 3834	E838 3840
E838 3807	E838 3813	E838 3819	E838 3835	E838 3841
E838 3808	E838 3814	E838 3820	E838 3836	

Description of the problem including root cause:
RAUMEDIC AG received a report that it was not possible to display the ICP on the associated NeuroSmart logO (095294-001) monitor using a NEUROVENT-PTO (095008-001) neurosurgical precision pressure catheter. The problem was reproduced and analyzed internally. Due to incorrect programming, a very small number of NEUROVENT-PTO catheters are not recognized by the NeuroSmart logO as precision pressure catheters with ICP measurement functionality, and only display the temperature and ptiO2 values.
The affected catheters can only be used with the DATALOGGER MPR2 logO (095254-002) and EASY logO (095264-002) monitors.

Advice on action be taken by the user:

1) Please review and understand the information provided in this letter.
2) Please immediately check your inventory for affected products.
3) If you do have affected products:
   a) Separate the products and attach a copy of this FSN
   b) Check the box on the enclosed form “I do have affected products” and enter the S/N of the affected products.
   c) The affected products can be used with a DATALOGGER MPR2 logO (095254-002) or EASY logO (095264-002).

4) If you no longer have any affected devices in your inventory, please check the box “I no longer have any affected devices” and indicate if the devices could be used without any incidents or complications.
5) Please return the completed reply form by email to neuromonitoring@raumedic.com. By filling the form, you confirm that you have received this Field Safety Notice and you intend to fully comply with this notification. We expect a response within 2 weeks. You also confirm that this Field Safety Notice has been forwarded to every concerned person in your organization.
6) We recommend that you retain a copy of the form for your records.

Please confirm receipt of this Field Safety Notice by using the enclosed reply form. Your organisation’s response is the evidence we need to monitor the progress of the corrective action. Please retain this notice until the affected devices have been used.

Please ensure that all users of the above-mentioned devices within your organisation and others who need to be informed are made aware of this Field Safety Notice. If you have handed over the products to third parties, please forward a copy of this information and inform the contact persons listed below.

The Competent Authority has received a copy of this Urgent Field Safety Notice.

Contact persons

RAUMEDIC AG
Dr Hannes Engelhardt
Head of Regulatory Affairs
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
Germany

Telephone: +49 – (0)9252-359-1530
Mobile: +49 – (0)175 7428393
Email: Hannes.Engelhardt@raumedic.com

RAUMEDIC AG
Ingo Bartels
Global Vice President Clinical Products
Hermann-Staudinger-Strasse 2
95233 Helmbrechts
Germany

+49 – (0)9252-359-1431
+49 – (0)151 51798654
Ingo.Bartels@raumedic.com

Availability: Monday to Friday between 08:00 and 17:00 (CET)

The undersigned confirms that this Field Safety Notice has been notified to the Competent Regulatory Authority.

i.V. Dr Hannes Engelhardt
Head of Regulatory Affairs
PRRC reporting obligations Art. 15 (3)d

Field Safety Notice
Reply form

1. Safety Information	
FSN Reference Number	FSN 01/2025
FSN Date	07.April 2025
Product information	NEUROVENT PTO
REF	095008-001
Affected S/N	E838 3803, E838 3810, E838 3817, E838 3834 E838 3804, E838 3811, E838 3818, E838 3835 E838 3805, E838 3812, E838 3819, E838 3836 E838 3806, E838 3813, E838 3820, E838 3837 E838 3807, E838 3814, E838 3821, E838 3838 E838 3808, E838 3815, E838 3832, E838 3839 E838 3809, E838 3816, E838 3833, E838 3840 E838 3841

2. Customers details	
Customer ID#	
Healthcare facility	
Address	
Department/area	
Delivery address, if different	
Contacts person	
Title or function	
Phone Number	
Email	

	3. Actions carried out by the healthcare facility		
☐	I confirm receipt of the Field Safety Notice and that I have read and understood its contents		
☐	The information and required actions have been communicated to all relevant users and implemented		
☐	Inventory has been checked		
☐	I no longer have any affected products in my inventory		
☐	Affected products were used without incidents or complications	S/N: S/N: S/N: S/N:	S/N: S/N: S/N: S/N:
☐	I have affected products		
☐	Affected products have been separated and provided with a copy of this Field Safety Notice	S/N: S/N: S/N: S/N:	S/N: S/N: S/N: S/N:
☐	I will only use the affected products with a DATALOGGER MPR2 logO (095254-002) or EASY logO (095264-002).		
	Name		
	Signature		
	Date		

4. Feedback to sender	
Email	neuromonitoring@raumedic.com
Customer Service Hotline	+49 – (0)9252-359-1587
Fax	+49 – (0)9252-359-513333
Address	RAUMEDIC AG Hermann-Staudinger Str. 2 95233 Helmbrechts Germany
Web Portals	www.raumedic.com
Deadline for returning the Customer Response Form	22 April 2025

It is important that your organisation takes the actions listed and confirms receipt of the FSN.

Your organisation’s response is the evidence we need to monitor the progress of the corrective action.