

PULSION Medical Systems SE • Hans-Riedl-Str. 21 • D-85622 Feldkirchen, Germany

- Distributor Information -

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Date  
07 November 2014

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**Urgent Field Safety Notice**

**ProAQT Sensor, REF PV8810**  
**FSCA-Identifier: CAPA-2014-034**  
**Type of action: Removal**

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Dear Ladies and Gentlemen,

Unfortunately we have to inform you that PULSION Medical Systems SE reported BfArM and other local authorities a product recall.

Details on affected devices

The ProAQT Sensor is a special single-use cardiac output (CO) sensor, designed for continuous haemodynamic monitoring with suitable PULSION monitors mainly used in the ICU and a perioperative setting.

Manufacturer Reference: PV8810

Affected LOTs: 13JK21, 13KD13, 14AK20, 14AL20, 14BD10, 14CM25, 14EF08, 1420, 14FL25

*Description of the problem*

Internal packaging tests revealed occasional damages in the primary packaging of ProAQT sensors. This could lead to product contamination and could possibly cause a patient infection. Even though PULSION did not receive any customer complaints about the packaging system of ProAQT Sensors, we decided to take preventative measures. Herewith PULSION Medical Systems SE recalls the above listed batches of ProAQT sensors:

*Immediate actions to be taken by distributors*

- Please check your local stock if you have products of the above listed batches.
- If applicable quarantine above listed batches.
- Inform sub-distributors and end users immediately about the product recall (as a reference see PULSION customer letter attached)

- Collect products of above listed batches from your customers and quarantine them in your local stock
- Collect from all customers who received products of above listed batches written and signed confirmation letters documenting the whereabouts of the affected batches (as a reference see PULSION customer letter attached).
- Fill out and sign attached confirmation form and send all products of the above batches back to PULSION Medical Systems SE, Hans-Riedl-Str. 17, 85622 Feldkirchen, Germany
- We will provide a credit note for returned products

*Transmission of this Field Safety Notice (if appropriate)*

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation / department where the potentially affected devices have been transferred.

*Contact reference person*

PULSION Medical Systems SE  
Dr. Volker Humbert  
Hans-Riedl-Straße 21  
85622 Feldkirchen  
Phone +49 89-459914-503  
Email: recall@pulsion.com

The undersigns confirm that this notice has been notified the appropriate Regulatory Agency.

We kindly ask for your support on these tasks. To confirm that all goods relevant for this recall are sent back, please fill out and return the attached form.

We apologise for any inconvenience caused.

With kindest regards  
PULSION Medical Systems SE

i.V. Dr. Volker Humbert  
Safety Officer

i. V. Aleksandra Wagner  
Head of Quality Management

Enclosures:

- Confirmation Form for Medical Device Recall – Distributor
- PULSIONs Field Safety Notice for end users / customers

Confirmation Form for MEDICAL DEVICE RECALL  
ProAQT Sensor, PULSION REF PV8810



Customer Data
Distributor Name:
Contact name
Address
Country

Please state in this table the quantity of unused ProAQT Sensors in your local stock / organisation.

Pro AQT (PV8810) in stock	Batch	Qty in stock	Qty returned from customers	Total to be returned to PULSION
	13JK21			
	13KD13			
	14AK20			
	14AL20			
	14BD10			
	14CM25			
	14EF08			
	14EK20			
	14FL25			

We herewith declare that

- We informed all of our customers about the PULSION product recall
- we do not have any ProAQT Sensors of the recalled batches in stock with the exception of the listed above,
- all above listed quantities will be returned to PULSION Medical Systems SE.

\_\_\_\_\_  
Date, City

\_\_\_\_\_  
Signature

Please send a scan of this form to [e-order@pulsion.com](mailto:e-order@pulsion.com) or fax to +49 89 45 99 14 – 18 and attach the signed original document to your return shipment. The delivery address for the return shipment is:

PULSION Medical Systems SE  
Christof Kunz  
Hans-Riedl-Straße 17  
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Germany