PULSION Medical Systems

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

- Customer Information -

Direct number:	Fax	E-Mail	Date
+49 89-459914-0	+49 89-459914-18	info@pulsion.com	07 November 2014

Urgent Field Safety Notice

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

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, 14EK20, 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 the user / customer

- Please check your stock if you have products of the above listed batches.
- Remove above listed batches of the product from use.

- 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

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

PULSION Medical Systems

Customer Data
Customer Name:
Hospital name / Department
Address
State

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

Pro AQT (PV8810) in stock	
Batch	**Quantity**
13JK21	
13KD13	
14AK20	
14AL20	
14BD10	
14CM25	
14EF08	
14EK20	
14FL25	

We herewith declare that

- 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 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
85622 Feldkirchen
Germany