

PULSION Medical Systems SE | Hans-Riedl-Str. 21 |
85622 Feldkirchen | Germany

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Urgent Field Safety Notice – Medical Device Recall

FEB-01-2022 | REF 574697 | Rev 01

Subject: 574697 – Field Action Tyvek Issue

Products affected:

PiCCO Monitoring Kit	catalogue #: 6882815, 6882817, 6882818, 6886184, 6886185
ProAQT Sensor	catalogue #: 6882824, 6886188
PiCCO Kit	catalogue #: 6885056, 6885059, 6885060, 6885062, 6885063, 6885065, 6885082, 6885083, 6885084, 6885085, 6886153

Description of the issue and root cause

We have identified that the listed products have been produced with packaging material that is suspected to have an uncoated area. The absence of coating on the inner material surface leads to a weak seal between blister and lid of the sterile packaging. Due to the vacuum process within ETO-sterilization or transportation, the lid will be detached from the blister.

As a consequence, it cannot be excluded that there are open packages in the field resulting in non-sterile products.

Pulsion Medical Systems SE has not received any complaints or reports of adverse events related to a deficient sterile barrier system for the products listed above.

Potential health consequences

Exposure to a non-sterile medical device may result in infection with local reaction, local infection with systemic reaction or sepsis (Systemic infection): This would constitute a serious deterioration of the patient's clinical state.

Identification of the affected medical devices

PiCCO Monitoring Kit

The PiCCO Monitoring Kit consists of a single use pressure monitoring kit and an injectate temperature sensor housing. The PiCCO Monitoring Kit is designed for use with the PULSION PiCCO. With the PULSION PiCCO, the arterial blood pressure curve is utilized to determine the patient's cardiovascular status and to support decisions regarding clinical interventions.

The single use pressure monitoring kit is intended for detection and measurement of blood pressure through an indwelling vascular catheter providing a direct uninterrupted access to the intravascular space.

ProAQT Sensor

The ProAQT Sensor is a special single-use cardiac output (CO) sensor, designed for continuous haemodynamic monitoring with suitable PULSION monitors (PulsioFlex PC4000). The arterial blood pressure curve is utilized to determine the patient's cardiovascular status and to support decisions regarding clinical interventions.

The ProAQT Sensor is intended for pressure curve analysis. The sensor is integrated into an installed arterial blood pressure measurement system which is needed for the pressure transfer to the patient monitor and the flushing in order to ensure the patency of the catheter.

PiCCO Kit

The PiCCO Kit itself is not a medical device. It can be bought as a combination of the medical devices PiCCO Monitoring Kit and PiCCO Catheter.

Affected batch numbers

Our records indicate that the below listed products were delivered to your location. Please verify if you have any of the listed products.

Item number	Getinge Order Reference	Batch number	Manufacturing date

Record the total number of affected products currently located at your facility in the attached reply form and check the appropriate boxes below.

Which actions are required by the customer?

Getinge will initiate an immediate field action of all affected device units. Please

- immediately separate products with batches listed above to prohibit any further use.
- contact your Getinge sales or service representative to plan the return and replacement of the device.
- complete and return the attached acknowledgement form and maintain awareness of this notice and related actions until the involved product has been replaced to ensure effectiveness of the corrective action.
- immediately closely monitor the health status of any patient currently monitored with any of the devices from the listed batches for signs of deterioration related to infection and inflammatory response.

Distribution of the provided Information

This Getinge **Field Safety Notice** needs to be distributed to those individuals within your organization who need to be aware of the issue - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and the resulting action until closure of this action.

In the case that you as customer choose not to proceed with completion of the action requirements described above, Getinge cannot accept any responsibility for safety-related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. The [enter name competent authority here] has been informed about this communication and issue.

We apologize for any inconvenience this may cause. We will do our utmost to carry through with this action as swiftly as possible.

Should you have questions or require additional information, please let us know.

Sincerely,

Name
Product Manager
Pulsion Medical Systems SE

Name
Head of Quality
Pulsion Medical Systems SE

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recall.pulsion@getinge.com
www.getinge.com, www.pulsion.com

Contact data local Getinge representative per country

Contact Name

Contact e-mail

Contact phone

Contact office address

Reply Form

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Affected batch numbers

Our records indicate that the below listed products were delivered to your location.

Item number	Getinge Order Reference	Batch number	Manufacturing date	Status

1. Please verify if you have any of the listed products and complete the information in this reply form.
2. Please complete the table above with the relevant device status:
 1. Products have been used
 2. The devices are in our storage and located at the address this communication was sent to.
 3. The devices are in our storage but in a location different from where this communication was sent to, namely (please add contact information to Annex I)
 4. We have sold / moved our devices to another facility. Namely (please add contact information to Annex I)

Confirmation:

Please make sure to tick the box below. Should you not understand the communication please contact us for guidance. Your organisation's reply is the evidence needed to monitor the progress of the corrective actions.

- We have read the Field Safety Notice and we understand the communication and the required actions.

For device distributors only:

- We have checked our stock and quarantined inventory. We have reviewed the list of devices to identify any affected customers.
- We will share the list of devices, updated with customer details with Getinge in order to be able to report this information to the applicable authorities that request this information.

- We will share the list of devices with Getinge after finalizing the field action and identify the state of each device in the list.

Please return your completed form to:

Getinge market organization

Contact name / title

e-Mail address

Address (no PO box)

City, State, ZIP/Postal code

Phone number (Fax number)

Name, Date, Signature customer contact

Annex I - New device location (if applicable)

Serial numbers at this new location:		
New Facility Name	New Facility Name	New Facility Name
New Address (no PO box)	New Address (no PO box)	New Address (no PO box)