CODAN pvb Critical Care GmbH

Telefon +49(0)8121 · 98 02 0
www.codancompanies.com

CODAN pvb · Römerstraße 18 · D-85661 Forstinning

FSN Ref: FSN_26-09-098

FSCA Ref: FSCA_26-09-098

> Customer <

27.10.2026

URGENT SAFETY INFORMATION

FOR ATTENTION OF:

To the responsible persons in medical management, purchasing management, intensive care units, accident and emergency departments, surgery, nursing management, materials management, continuing nursing education (and all other departments which may possibly have received and be using these products).

REGARDING:

CODAN pvb Critical Care GmbH requests that all users follow the instructions set out in point 3 when using invasive pressure monitoring sets. This safety notice applies to all sets fitted with Xtrans® and DPT-6000 series pressure transducers with a **3 ml/h flushing system**, which have a date of manufacture between **March and August 2026**.

CONTACT DETAILS OF LOCAL REPRESENTATIVE:

Distributor:	CODAN DEHA ApS Lykkebaekvej 22 DK - 4600 Køge

Contact Name:	**Tel.:**	**Email:**
Tina Hansen	+45 49121191	tih@codandeha.dk
Andreas Mülverstedt	+45 49121190	am@codandeha.dk

1 Information on Affected Devices

Device Type(s)

Invasive Pressure Monitoring Sets with Xtrans® or DPT-6000 with Flushing System **3 ml/h**.

Commercial name(s)

Pressure Monitoring Sets, x-fold, Xtrans®, **3 ml/h**

Pressure Monitoring Sets, x-fold, DPT-6000, **3 ml/h**

Production Date: 02.03.2026 - 31.08.2026

Expiry date: 02.02.2029 - 31.07.2029

The production and expiry dates can be found on each individual package and on each packaging unit (cardboard box).

Handelsregister: München HRB 156382
Ust-IdNr./VAT NO: DE 814 304 932
Sitz der Gesellschaft: 85661 Forstinning

Sydbank A/S, Flensburg · BLZ 215 106 00 · Konto-Nr. 10 001 483 41
IBAN DE 792 151 060 010 001 483 41/SWIFT SYBKDE22
Geschäftsführer:
Deirdre Husted-Andersen, Alexandra Husted-Andersen, Stefanie Husted-Andersen

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Primary clinical purpose of device(s)

The pressure monitoring set is intended for use on a patient requiring continuous monitoring of their blood pressure via one or more vascular access ports (IBPM) and/or requiring blood withdrawals.

2 Reason for Field Safety Corrective Action (FSCA)

Description of the product problem

A manufacturing fault during the assembly of the flushing system may result in an increased flushing rate.

Hazard giving rise to the FSCA

If the user fails to notice the increased flushing rate when setting up the pressure monitoring set, this may result in an overdose of the flushing solution used.

Probability of problem arising

Based on the figures currently available, the error rate stands at 1.68 ppm (parts per million).

Predicted risk to patient/users

Given the potentially increased likelihood of this occurring during the production period in question, we consider it necessary to draw explicit attention to the potential risk.

To date, the fault has not resulted in any harm to patients.

Background on Issue

A very rare human error during the assembly of the flushing system can lead to an increased flushing rate. Under normal circumstances, such defective parts would be detected and rejected during the final inspection. During the production period in question, our supplier suspended this final inspection of its own accord due to staff shortages and capacity issues. Consequently, it cannot be ruled out that pressure transducers with this fault were placed on the market during this production period.

The fault has been verified as being limited to the specified production period (March - August 2026).

Since September, following a change of supplier, the final inspection has once again been carried out in accordance with the specifications (100 % inspection).

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3 Type of Action to mitigate the risk	
Action To Be Taken by the User ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification: ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None **When commissioning a pressure monitoring set, it is essential to observe the following:** If the fluid does not flow freely during flushing or an increased flow rate is observed after flushing, the pressure monitoring set is not functioning properly and must not be used. A continuous flow of approximately 3 ml/h at 300 mmHg should be observed in the drip chamber. When using a microdrip chamber, the drop rate should be approximately 3 drops per minute. When using a macrodrip chamber, the drop rate should be approximately 1 drop per minute. An excessively high flow rate may result in an overdose of the flushing solution used.	
By when should the action be completed?	This note must always be observed, but particularly in the case of pressure monitoring sets manufactured between 2 March 2026 and 31 August 2026.
Is customer Reply Required? **(If yes, form attached specifying deadline for return)**	No
Action Being Taken by the Manufacturer ☐ Product Removal ☐ On-site device modification ☐ Software upgrade ☒ IFU or labelling change ☐ None ☐ Other:	
By when should the action be completed?	From November 2026, the above warning will be supplied with all pressure monitoring sets fitted with a 3 ml/h flushing system, in addition to the current instructions for use. Furthermore, this warning will be incorporated as soon as possible into a new version of the instructions for use supplied with the pressure monitoring sets (from January 2027).

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4 General Information	
FSN Type	New
Further advice or information already expected in follow-up FSN?	No
A copy of this „URGENT SAFETY INFORMATION“ has been submitted to the competent higher federal authority, Lægemiddelstyrelsen (DKMA).	
Name/Signature	 Dr. Stefanie Klingenhagen Head of Quality Management

Transmission of this Field Safety Notice

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

Please transfer this notice to other organisations on which this action has an impact (as appropriate).

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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