2025-12-16

URGENT FIELD SAFETY NOTICE

Manufacturer SRN:	DE-MF-000020091
FSCA Reference:	1427918 - Bubble Sensor - Bad contact in sensor cable
FSN Type:	New
Affected Product:	BS 3/8x3/32 L1.7 Mat. 701055720 (Bubble Sensor for 3/8" x 3/32" tubing, length 1,7 m)
Unique Device Identifier:	04037691816432
Affected Serial No.:	All serial numbers are potentially affected.
For Attention of:	Users of the medical device listed above

Dear valued customer,

Maquet Cardiopulmonary GmbH (MCP) would like to inform users about a corrective action related to the cable durability of the Venous Bubble Sensor.

The Venous Bubble Sensor (BS 3/8x3/32 L1.7) is an accessory used in ROTAFLOW II (mandatory) and CARDIOHELP-i (optional) extracorporeal membrane oxygenation (ECMO) circuits. The Venous Bubble Sensor is attached to the venous/drainage tubing and alerts the user when Bubbles are detected. Bubble detection can also trigger an intervention when the setting is enabled by the user.

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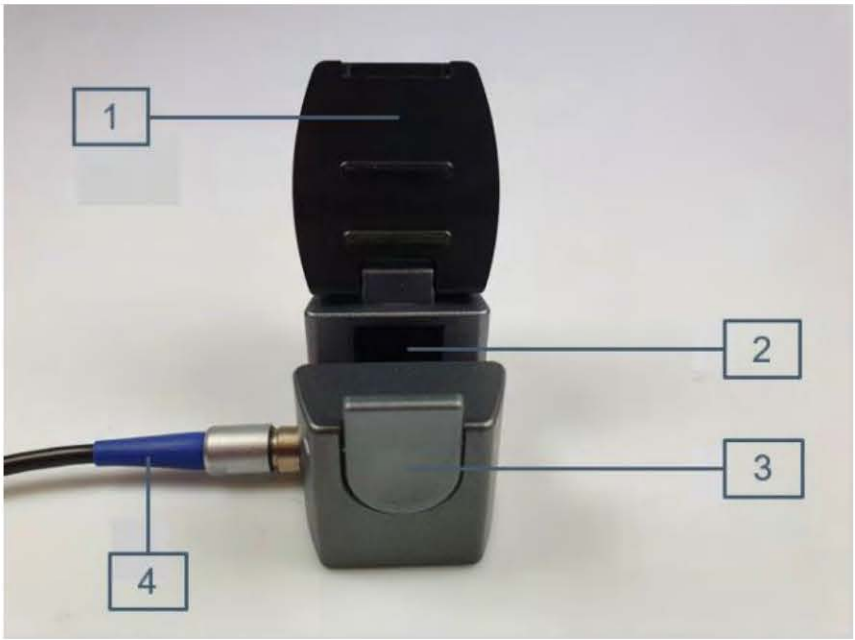

Figure 1 Picture of a Venous Bubble Sensor

1	Cover
2	Tube retainer
3	Locking device
4	Connecting Cable

Problem Description

Internal investigations have identified an issue with the durability of the connecting cable (See Fig. 1 position [4]) near the connection to the Bubble Sensor. Excessive bending of the cable can lead to poor contact, which may trigger the errors "Ven. bubble sensor defective" or "Ven. bubble sensor disconnected" on the connected medical device (ROTAFLOW II or CARDIOHELP-i). These errors can occur temporarily when the cable is moved or permanently if the connection is fully compromised.

Hazardous Situation

In course of a Health Hazard Evaluation (HHE), Maquet Cardiopulmonary GmbH determined the following hazardous situations that may arise:

- Patient exposed to inappropriately low blood flow[a]
- Patient exposed to Bubbles / particles / embolism

a. A delay in support/treatment, assumedly, may expose a patient to ischemia especially in an "at risk population" in whom support is required and a delay of support may not be tolerated.

Potential harm

The possible immediate and/or long-range health consequences and risk levels of the nonconformance include the following (for further information please refer to Annex I):

- Ischemia

Patient Management Recommendations

Patients should be monitored as appropriate according to your facility's standard of care.

Recommended Mitigations

An additional sensor is used for bubble detection:
- The **{FLOW/BUBBLE Sensor}** (**Not affected** by this Field Safety Notice)

Bubble interventions by the **{FLOW/BUBBLE Sensor} should not be deactivated.** This sensor is **mandatory for both systems** and attached to the arterial/return tubing.

The **Venous Bubble Sensor** (**affected** by this Field Safety Notice) is Mandatory in ROTAFLOW II and optional in CARDIOHELP-i systems.

Until availability of unaffected sensor:
- **The Venous Bubble Sensor remains functional until error (**"Ven. bubble sensor defective" or "Ven. bubble sensor disconnected") displays on the main device.
- **To prevent error occurrence please follow these guidelines when handling Venous Bubble Sensors:**
  1. **Avoid roll up or coiling of the sensor cable!** When storing affected products, place them loosely in a box or bag to prevent damage.
  2. **Avoid excessive bending** of the Venous Bubble Sensor.
  3. **Handle the Sensor cable with care during cleaning.** Do not pull with excessive force while wiping the cable.

Upon availability of unaffected sensor:
Replacement of affected with unaffected devices.

Corrective Action:

Until availability of unaffected sensor:

- **The Venous Bubble Sensor remains functional until error (**"Ven. bubble sensor defective" or "Ven. bubble sensor disconnected") occur on the main device.
- **To prevent error occurrence please follow these guidelines when handling Venous Bubble Sensors:**
  1. **Avoid roll up or coiling of the sensor cable!** When storing affected products, place them loosely in a box or bag to prevent damage.
  2. **Avoid excessive bending** of the Venous Bubble Sensor.
  3. **Handle the Sensor cable with care during cleaning.** Do not pull with excessive force while wiping the cable.

Upon availability of unaffected sensor:

- **Replacement of affected with unaffected devices.**

Action to be taken by user:

☒ Identify Device
☐ Quarantine Device
☐ Return Device
☐ Destroy Device

Details on further action(s):

- According to our post-market surveillance documentation, you may have products affected by this action. Please examine your inventory immediately to determine, if you have any affected product in your inventory.
- **Optional for CARDIOHELP-i accessories only:** Instead of replacement, the affected accessory may be returned for credit. Upon return of the affected product, please contact your local Getinge representative for credit.
- Please always report any adverse events potentially related to the affected products to your Getinge representative.
- Duly fill out the enclosed Letter of Acknowledgement and return it to your local Getinge representative as soon as possible, latest by 2026-01-24 by mentioning FSCA - 1427918 as reference in the subject line of your mail.

Actions to be taken by the manufacturer:

☐ Product Removal
☐ Software Upgrade
☒ Other
☐ On-site device modification/ inspection
☐ IFU or labeling change
☐ None

- Inform all customers possessing the affected products promptly about this Field Action by sending the Field Safety Notice for Customers
- Upon availability of unaffected replacement products:
  Replace customer devices

Enclosed documents:
- Letter of Acknowledgment Customer
- Annex I Further information regarding Hazardous situation, Harms and Risk Levels

Transmission of the Field Safety Notice:

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

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

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Vice President

Signature: Electronically signed by: Dieter Engel
Reason: I approve this document.
Date: Dec 18, 2025 15:38:32 GMT+1

Email: dieter.engel@getinge.com

Person Responsible for Regulatory Compliance (PRRC)

Signature: Electronically signed by: Alexander Bernhardt
Reason: I approve this document.
Date: Dec 18, 2025 14:42:02 GMT+1

Email: alexander.bernhardt@getinge.com

Contact details of manufacturer
Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
GERMANY
Phone: +49 7222 932 - 0
Email: FSCA.cp@getinge.com

CUSTOMER RESPONSE FORM

FSCA Reference:	1427918 - Bubble Sensor - Bad contact in sensor cable
Affected Product:	701055720 - BS 3/8x3/32 L1.7 (Bubble Sensor for 3/8" x 3/32" tubing, length 1,7 m)
Affected Serial No.:	All serial numbers are potentially affected.

Please send this form at the latest by 2026-01-24, to your local Getinge representative.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice. We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

☐ I do not have any affected products in my inventory:

☐ I have the following affected products in my inventory

- ☐ and would like to opt for replacement upon availability.
- ☐ and would like to return to you for credit (CARDIOHELP-i accessory only).

Article Number	Description	Serial Number

Your Comments:

Country	Hospital / Clinic (full address)
Date	Name (Function)
	Signature

Please return the completed form to your local Getinge representative by email enter local Getinge mail address or via post enter local Getinge address or FAX:

Annex I Further information regarding Hazardous situation, Harms and Risk Levels

This Annex I Further information regarding Hazardous situation, Harms and Risk Levels is considered a supplementary attachment to the 1427918 Field Safety Notice.

Hazardous situation	Harm	S from Medical	P from above	Risk		
				Low	Med	High
[Patient] exposed to inappropriately low blood flow	Ischemia (Blood flow)	4	3	☐	☒	☐
[Patient] exposed to bubbles, particles, embolism	Ischemia (Air embolism)	4	3	☐	☒	☐
Exchange or replacement of product/device	User inconvenience	1	1	☒	☐	☐

Severity Definitions (S):
Negligible (1): Inconvenience or temporary discomfort.
Minor (2): Results in transient or self-limiting illness or injury not requiring professional medical intervention.
Major (3): Results in injury or impairment that is reversible with professional medical intervention.
Serious (4): Results in permanent impairment or life-threatening injury.
Critical (5): Results in death.

Probability Definitions (P):
Improbable (1) Harm is not likely.
Remote (2) Harm occurs infrequently.
Occasional (3) Harm may occur occasionally / intermittent.
Probable (4) Harm may occur often.
Frequent (5) Harm will occur repeatedly.