Urgent Field Safety Notice

PRISMAFLEX SETS, OXIRIS SETS (to be adapted locally)
FA Number: FAV-2025-010
Manufacturer:
Gambro Industries (SRN: FR-MF-000017812)
Baxter Healthcare SA (CH-MF-000026124)
Type of Action: Correction

DD January 2026 (to be adapted locally)

Dear **Prismaflex** Control Unit Customer:

Vantive is issuing a Correction to **all Prismaflex Control Unit users** due to the potential dislodgement of the **Prismaflex** Set deaeration chamber from the **Prismaflex** Control Unit, as shown in Figure 3 below. **This issue does not affect PrisMax Control Units and may occur only when the Prismaflex Sets are being used with the Prismaflex Control Unit**, as the two machines have different deaeration chamber holder designs.

While Vantive is actively working on correcting this issue with the sets, you may continue to perform therapy using the **Prismaflex** Sets, keeping in mind the precautions included below.

Fig 1: Prismaflex chamber holder

Fig 2: Secure deaeration chamber in holder

Fig 3: Dislodged deaeration chamber in holder

Affected Product Prismaflex Sets (to be adapted)

Product Code	Product Description	Lot Numbers
106697	PRISMAFLEX M100 SET	All lots including and manufactured after 24F0077CA
107140	PRISMAFLEX HF1000 SET	All lots including and manufactured after 24G0034CA

107142	PRISMAFLEX HF1400 SET	All lots including and manufactured after 24F0094CA
107144	PRISMAFLEX TPE 2000 SET	All lots including and manufactured after 24E0067CB
107636	PRISMAFLEX ST100 SET	All lots including and manufactured after 24F0069
107640	PRISMAFLEX ST150 SET	All lots including and manufactured after 24E0059
109990	PRISMAFLEX M150 SET	All lots including and manufactured after 24F0100CA

Affected Product Oxiris Sets (to be adapted)

Product Code	Product Description	Lot Numbers	UDI Number
112016	OXIRIS SET	All lots including and manufactured after 24G0041Z	N/A
973002	OXIRIS SET GL	All lots including and manufactured after 24G0041	00085412813752
973003	OXIRIS SET ROW	All lots including and manufactured after 24F0087	00085412813769

Hazard Involved

A dislodged deaeration chamber may lead to an "Air in Blood" alarm on the **Prismaflex** Control Unit. The alarm may occur during the priming phase prior to initiating therapy, or during therapy—resulting in a delay/interruption of therapy, and in some cases blood loss due to clotting/failure to return blood manually. Vantive has not received any reports of serious patient injury related to this issue.

Actions to be Taken by Customers

1. **You may continue to perform therapy using the Prismaflex sets listed above.** Please monitor the deaeration chamber during therapy to ensure it remains in an upright position within the holder.
2. Vantive is aware of customers who have experienced this issue and attempted to further secure the deaeration chamber in an upright position. If attempting to secure the deaeration chamber in an upright position, please consider the following:

    - Ensure there are no kinks in the tubing and that the deaeration chamber remains visible.
    - If the **Prismaflex** Control Unit issues an "Air in Blood" alarm, check if air is present. If there is no air present, check if the deaeration chamber is dislodged from the holder and ensure there are no clots present.
        1. If no dislodgement, please follow the operator's manual instructions for "Air in Blood" alarm.

2. In case of dislodgement with clotting, follow the associated instructions within the **Prismaflex** Control Unit operator's manual to stop the therapy and replace the set.
3. Only in case of dislodgement without clotting or any other alarms, if the chamber is secured in an upright position, follow the associated instructions within the **Prismaflex** Control Unit operator's manual to proceed with treatment.

3. Complete enclosed customer reply form and return it to Vantive by either scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information), even if you don't have any inventory left. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeated notices.

4. If you purchased this product from a distributor, please note that the Vantive customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

5. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this notification in accordance with your customary procedures.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Vantive at (insert local contact information), between the hours of (insert local information).

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Pascal Pollet (to be adapted)
Senior Director, Quality (to be adapted)
Vantive US Healthcare LLC (to be adapted)

Enclosures: Customer Reply Form