Urgent Field Safety Notice

PrisMax Systems and **TherMax** Blood Warmer Units
FA Number: FAV-2025-005
Manufacturer: Baxter Healthcare SA (CH-MF-000026124)
Type of Action: Correction

DD Month 2025 (to be adapted locally)

Dear Dialysis Provider: (to be adapted)

Vantive is issuing a Correction for the **PrisMax** Systems and **TherMax** Blood Warmer Units listed below due to the following three issues:

- **PrisMax** System alarm *T2309: Air Detected in Prime* may be raised after priming with a low liquid level in the deaeration chamber. The system correctly detects the presence of air within the disposable set and raises the alarm at the end of priming if the condition is present. Users should follow the on-screen instructions to reprime the disposable set.

- **PrisMax** System alarm *T0830: Blood Leak Detected* may be raised when no blood leak is present, or the operator may have difficulty normalizing the Blood Leak Detector (BLD) leading to **PrisMax** System alarms *T1313: BLD Normalize Failed, T0853: Normalization Failed,* or *T1205: BLD Self-Test Failure.* Operators should follow the on-screen instructions and return the blood in the disposable set if connected to a patient.

- **Thermax** System may be unable to detect the presence of a bag on the **Thermax** Blood Warmer Unit leading to difficulty setting up therapy, or **PrisMax** System alarm *T2284: **Thermax** Disposable Not Inserted*. Operators should follow the on-screen instructions and return the blood in the disposable set if connected to a patient.

If the operator continues to receive any of these alarms or further assistance is required, please contact your local Vantive account representative. (to be adapted) Vantive is currently investigating these issues and will be correcting the impacted devices.

Affected Product (to be adapted)

Product Code	Product Description	Serial Numbers
955558	**PrisMax** V2-ROW	All
955725	**PrisMax** V3 Control Unit-ROW	All
955515	**TherMax** Blood Warmer Unit ROW	All

Hazard Involved

The occurrence of these three issues could lead to a delay or interruption of therapy, and in certain situations could result in blood loss. However, blood return is possible to avoid blood loss. In the event of blood loss, the amount of blood loss would be limited to the amount of blood contained in the disposable set. Vantive is aware that users could decide to not return the blood in accordance with their clinical practices. Patients that are hemodynamically unstable and anemic from the onset are in the high-risk group for blood loss. Vantive has received one complaint of serious injury related to blood loss associated with the above issues.

Actions to be Taken by Customers

1. Operators may continue to safely use the **PrisMax** Systems and **TherMax** Blood Warmer Units per the associated Operator's Manuals and on-screen instructions. Refer to the enclosed Attachment A for details. If further assistance is required, please contact your local Vantive account representative. (to be adapted) Please ensure that all operators of these devices are made aware of this notification. Vantive recommends that a copy of this notification is posted within the appropriate location of your facility.

2. As corrections become available, a local Vantive representative will contact your facility to determine the correction plan and schedule the associated correction(s) for impacted devices.

3. Complete the 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. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices. (to be adapted)

4. If you purchased this product from a distributor, please note that responding using the Vantive Customer Reply Form is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions. (to be adapted)

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. (to be adapted)

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).

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

Sincerely,

Name (to be adapted locally)
Title (to be adapted locally)
Vantive Health GmbH (to be adapted locally)

Enclosures: Vantive Customer Reply Form
Attachment A: Operator's Manual and Graphical User Interface (GUI) Guidance