

FAV-2025-005

T +41(0)44 908 56 00
switzerland.cqa@vantive.com
www.vantive.eu/de

Correction

Glattpark (Opfikon), 8. august 2025

FAV-2025-005: Urgent Field Safety Notice for PrisMax Systems and TherMax Blood Warmer Units

Dear Sir or Madam

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. Vantive is currently investigating these issues and will be correcting the impacted devices.

Affected Products:

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 2 for details. If further assistance is required, please contact your local Vantive account representative. 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 (switzerland.cqa@vantive.com), 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.
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.
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.

If you have general questions about this notice or a problem with a product, please contact your Vantive sales representative or email us at switzerland.cqa@vantive.com.

The competent authority has been informed of this measure.

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

Sincerely,

Vantive GmbH

i.V.

Renate Thut
Senior Specialist CQA/RA, FvP
Country Quality Assurance

Enclosure:

- 1) Attachment 1: Customer Reply Form
- 2) Attachment 2: Operator's Manual and Graphical User Interface (GUI) Guidance



**CUSTOMER REPLY FORM related to Product Correction letter dated August 2025
(FAV-2025-005)**

Product Name: PrisMax Systems and TherMax Blood Warmer Units

Product code: 955558, 955725, 955515

Serial Number: all

Please complete and return one copy of this form per facility by e-mail (switzerland.cqa@vantive.com) as confirmation that you have received this notification.

Facility Name and Address:	
Reply Confirmation Completed By <i>(Please Print):</i>	
Title <i>(Please print):</i>	
Email and/or Telephone Number <i>(including Area Code):</i>	

Please list the specific products and serial numbers in your facility below *:




Product Code	Serial number







* You may attach an additional sheet if required.

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date:	
------------------------	--

PrisMax Operator’s Manual:

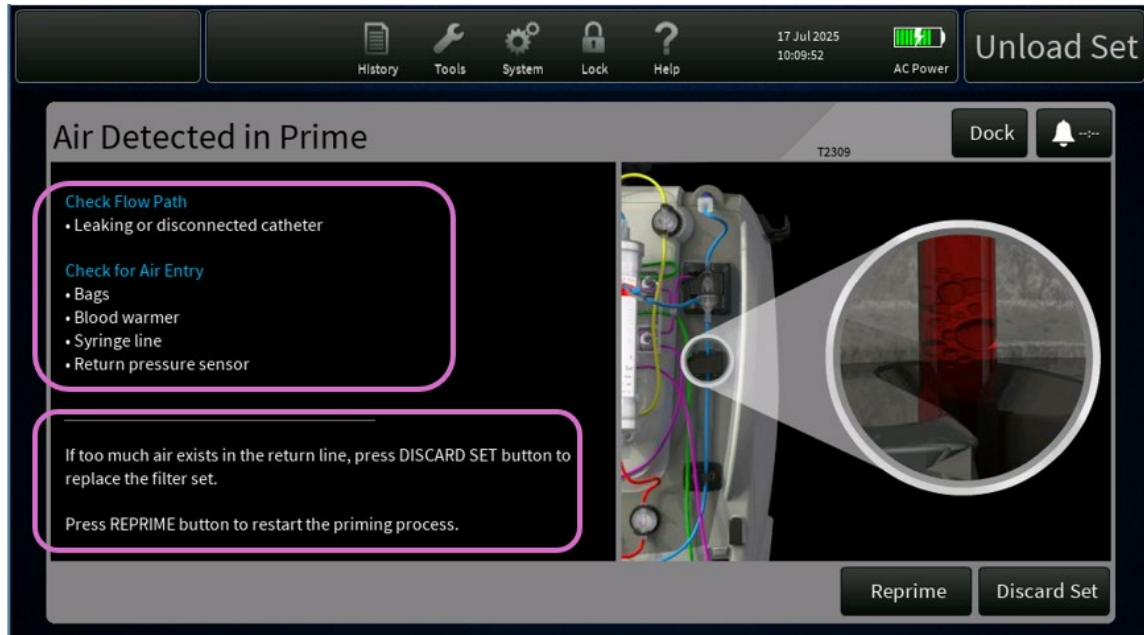
Alarm	PrisMax Operator’s Manual, AW8061 Rev E																					
T2309	<p>Section 3.1.8 Setup Alarms</p> <p>Page 165</p>	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="607 275 1369 310">Air Detected in Prime T2309</th> </tr> </thead> <tbody> <tr> <td data-bbox="607 310 980 338">Cause</td> <td data-bbox="980 310 1369 338">Operator Actions</td> </tr> <tr> <td data-bbox="607 338 980 365">Empty priming bag</td> <td data-bbox="980 338 1369 365">Check priming bag.</td> </tr> <tr> <td data-bbox="607 365 980 392">Open tubing connection</td> <td data-bbox="980 365 1369 392">Check line connections.</td> </tr> <tr> <td></td> <td data-bbox="980 392 1369 420">Reprime or discard the set.</td> </tr> <tr> <td></td> <td data-bbox="980 420 1369 447">If air continues discard the set.</td> </tr> </tbody> </table>	Air Detected in Prime T2309		Cause	Operator Actions	Empty priming bag	Check priming bag.	Open tubing connection	Check line connections.		Reprime or discard the set.		If air continues discard the set.								
Air Detected in Prime T2309																						
Cause	Operator Actions																					
Empty priming bag	Check priming bag.																					
Open tubing connection	Check line connections.																					
	Reprime or discard the set.																					
	If air continues discard the set.																					
T0830	<p>Section 3.1.5 Medium-Priority Alarms</p> <p>Page 136</p>	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="607 554 1369 590">Blood Leak Detected T0830</th> </tr> </thead> <tbody> <tr> <td data-bbox="607 590 980 617">Cause</td> <td data-bbox="980 590 1369 617">Operator Actions</td> </tr> <tr> <td data-bbox="607 617 980 743">The Blood Leak Detector (BLD) detects blood in the effluent line, which can indicate a ruptured filter membrane.</td> <td data-bbox="980 617 1369 743">Check for air bubbles in effluent line in the Blood Leak Detector (BLD).</td> </tr> <tr> <td data-bbox="607 743 980 770">Leak in filter membrane</td> <td data-bbox="980 743 1369 770">Tap the Alarm Off button to dislodge bubble.</td> </tr> <tr> <td data-bbox="607 770 980 848">Tubing incorrectly installed in the Blood Leak Detector (BLD)</td> <td data-bbox="980 770 1369 848">If air bubbles recur, check for kinked effluent line, or decrease Blood Flow Rate (BFR).</td> </tr> <tr> <td data-bbox="607 848 980 926">Tubing is cloudy or debris in the tubing path</td> <td data-bbox="980 848 1369 926">Verify that effluent line is correctly installed in the Blood Leak Detector (BLD).</td> </tr> <tr> <td data-bbox="607 926 980 953">Air in the effluent line</td> <td data-bbox="980 926 1369 953">Check for liquid or debris in the Blood Leak Detector (BLD) tubing path and effluent line: clean with a lint-free cloth, then dry thoroughly.</td> </tr> <tr> <td data-bbox="607 953 980 1031">The wrong section of tubing is installed in the Blood Leak Detector (BLD).</td> <td data-bbox="980 953 1369 1031">If blood is in the effluent line, change the set. Send sample of effluent to the blood lab for cell count.</td> </tr> <tr> <td data-bbox="607 1031 980 1108">Dirty Blood Leak Detector (BLD) optics.</td> <td data-bbox="980 1031 1369 1108">Tap the Discard Set button and change the set.</td> </tr> <tr> <td data-bbox="607 1108 980 1186">TPE: Formed elements of lipids in plasma discolored plasma.</td> <td data-bbox="980 1108 1369 1186">Tap the Continue button to clear the alarm and return to normal operations.</td> </tr> </tbody> </table>	Blood Leak Detected T0830		Cause	Operator Actions	The Blood Leak Detector (BLD) detects blood in the effluent line, which can indicate a ruptured filter membrane.	Check for air bubbles in effluent line in the Blood Leak Detector (BLD).	Leak in filter membrane	Tap the Alarm Off button to dislodge bubble.	Tubing incorrectly installed in the Blood Leak Detector (BLD)	If air bubbles recur, check for kinked effluent line, or decrease Blood Flow Rate (BFR).	Tubing is cloudy or debris in the tubing path	Verify that effluent line is correctly installed in the Blood Leak Detector (BLD).	Air in the effluent line	Check for liquid or debris in the Blood Leak Detector (BLD) tubing path and effluent line: clean with a lint-free cloth, then dry thoroughly.	The wrong section of tubing is installed in the Blood Leak Detector (BLD).	If blood is in the effluent line, change the set. Send sample of effluent to the blood lab for cell count.	Dirty Blood Leak Detector (BLD) optics.	Tap the Discard Set button and change the set.	TPE: Formed elements of lipids in plasma discolored plasma.	Tap the Continue button to clear the alarm and return to normal operations.
Blood Leak Detected T0830																						
Cause	Operator Actions																					
The Blood Leak Detector (BLD) detects blood in the effluent line, which can indicate a ruptured filter membrane.	Check for air bubbles in effluent line in the Blood Leak Detector (BLD).																					
Leak in filter membrane	Tap the Alarm Off button to dislodge bubble.																					
Tubing incorrectly installed in the Blood Leak Detector (BLD)	If air bubbles recur, check for kinked effluent line, or decrease Blood Flow Rate (BFR).																					
Tubing is cloudy or debris in the tubing path	Verify that effluent line is correctly installed in the Blood Leak Detector (BLD).																					
Air in the effluent line	Check for liquid or debris in the Blood Leak Detector (BLD) tubing path and effluent line: clean with a lint-free cloth, then dry thoroughly.																					
The wrong section of tubing is installed in the Blood Leak Detector (BLD).	If blood is in the effluent line, change the set. Send sample of effluent to the blood lab for cell count.																					
Dirty Blood Leak Detector (BLD) optics.	Tap the Discard Set button and change the set.																					
TPE: Formed elements of lipids in plasma discolored plasma.	Tap the Continue button to clear the alarm and return to normal operations.																					
	<p>Section 3.1.10 Alarm off / Override Alarms</p> <p>Page 194</p>	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="607 1554 1369 1589">Blood Leak Detected T0830</th> </tr> </thead> <tbody> <tr> <td data-bbox="607 1589 980 1617">Reaction to override</td> <td data-bbox="980 1589 1369 1617">Override Action</td> </tr> <tr> <td data-bbox="607 1617 980 1659">Disables blood leak detector (BLD) for 60 seconds</td> <td data-bbox="980 1617 1369 1659">  NOTE! Alarm detection delayed for up to 40 seconds. </td> </tr> <tr> <td data-bbox="607 1659 980 1743">Disables blood leak detection or renormalization, or both, when override is active.</td> <td data-bbox="980 1659 1369 1743">Override shall be automatically cleared 60 seconds after it is set.</td> </tr> </tbody> </table>	Blood Leak Detected T0830		Reaction to override	Override Action	Disables blood leak detector (BLD) for 60 seconds	 NOTE! Alarm detection delayed for up to 40 seconds.	Disables blood leak detection or renormalization, or both, when override is active.	Override shall be automatically cleared 60 seconds after it is set.												
Blood Leak Detected T0830																						
Reaction to override	Override Action																					
Disables blood leak detector (BLD) for 60 seconds	 NOTE! Alarm detection delayed for up to 40 seconds.																					
Disables blood leak detection or renormalization, or both, when override is active.	Override shall be automatically cleared 60 seconds after it is set.																					

Alarm	PrisMax Operator’s Manual, AW8061 Rev E					
<p>T1313</p>	<p>Section 3.1.8 Setup Alarms</p> <p>Page 173</p>	<table border="1"> <thead> <tr> <th data-bbox="605 218 971 254">BLD Normalize Failed</th> <th data-bbox="971 218 1373 254">T1313</th> </tr> </thead> <tbody> <tr> <td data-bbox="605 254 971 800"> <p>Cause</p> <p>Transmission below expected values</p> <p>Effluent line incorrectly installed</p> <p>Air bubbles in the effluent line</p> <p>Dirty effluent line</p> <p>Dirty Blood Leak Detector (BLD) mirrors</p> <p>Effluent Line Clamped</p> </td> <td data-bbox="971 254 1373 800"> <p>Operator Actions</p> <p> NOTE! Alarm detection delayed for up to 40 seconds.</p> <p>Slide the tubing back and forth in the Blood Leak Detector (BLD).</p> <p>Squeeze the air bubbles out of the return line.</p> <p>Remove and clean the effluent line with an alcohol swab. Clean Blood Leak Detector (BLD) mirrors.</p> <p>Tap the Continue button to retest.</p> <p>Tap the Discard Set button and change the front set.</p> </td> </tr> </tbody> </table>	BLD Normalize Failed	T1313	<p>Cause</p> <p>Transmission below expected values</p> <p>Effluent line incorrectly installed</p> <p>Air bubbles in the effluent line</p> <p>Dirty effluent line</p> <p>Dirty Blood Leak Detector (BLD) mirrors</p> <p>Effluent Line Clamped</p>	<p>Operator Actions</p> <p> NOTE! Alarm detection delayed for up to 40 seconds.</p> <p>Slide the tubing back and forth in the Blood Leak Detector (BLD).</p> <p>Squeeze the air bubbles out of the return line.</p> <p>Remove and clean the effluent line with an alcohol swab. Clean Blood Leak Detector (BLD) mirrors.</p> <p>Tap the Continue button to retest.</p> <p>Tap the Discard Set button and change the front set.</p>
BLD Normalize Failed	T1313					
<p>Cause</p> <p>Transmission below expected values</p> <p>Effluent line incorrectly installed</p> <p>Air bubbles in the effluent line</p> <p>Dirty effluent line</p> <p>Dirty Blood Leak Detector (BLD) mirrors</p> <p>Effluent Line Clamped</p>	<p>Operator Actions</p> <p> NOTE! Alarm detection delayed for up to 40 seconds.</p> <p>Slide the tubing back and forth in the Blood Leak Detector (BLD).</p> <p>Squeeze the air bubbles out of the return line.</p> <p>Remove and clean the effluent line with an alcohol swab. Clean Blood Leak Detector (BLD) mirrors.</p> <p>Tap the Continue button to retest.</p> <p>Tap the Discard Set button and change the front set.</p>					
<p>T0853</p>	<p>Section 3.1.5 Medium-Priority Alarms</p> <p>Page 142</p>	<table border="1"> <thead> <tr> <th data-bbox="605 848 971 884">Normalization Failure</th> <th data-bbox="971 848 1373 884">T0853</th> </tr> </thead> <tbody> <tr> <td data-bbox="605 884 971 1633"> <p>Cause</p> <p>BLD normalization failure during therapy.</p> <p>Tubing incorrectly installed in the BLD.</p> <p>Tubing is cloudy or debris in the tubing path.</p> <p>Air in the effluent line. The wrong section of tubing is installed in the BLD.</p> <p>Dirty BLD optics. Blood present in the effluent line.</p> </td> <td data-bbox="971 884 1373 1633"> <p>Operator Actions</p> <p>Verify that effluent line is correctly installed in the BLD.</p> <p>Remove air bubbles in effluent line.</p> <p>Slide the tube inside the BLD to increase detection signal.</p> <p>If displayed transmissivity (detection signal) > 85%, tap the Continue button to retry.</p> <p>If displayed transmissivity (detection signal) < 85%, change the set.</p> <p>Tap the Alarm Off button to override detection of this alarm.</p> <p>Tap the Discard Set button and change the set.</p> <p>Tap the Continue button to clear the alarm and return to normal operations.</p> </td> </tr> </tbody> </table>	Normalization Failure	T0853	<p>Cause</p> <p>BLD normalization failure during therapy.</p> <p>Tubing incorrectly installed in the BLD.</p> <p>Tubing is cloudy or debris in the tubing path.</p> <p>Air in the effluent line. The wrong section of tubing is installed in the BLD.</p> <p>Dirty BLD optics. Blood present in the effluent line.</p>	<p>Operator Actions</p> <p>Verify that effluent line is correctly installed in the BLD.</p> <p>Remove air bubbles in effluent line.</p> <p>Slide the tube inside the BLD to increase detection signal.</p> <p>If displayed transmissivity (detection signal) > 85%, tap the Continue button to retry.</p> <p>If displayed transmissivity (detection signal) < 85%, change the set.</p> <p>Tap the Alarm Off button to override detection of this alarm.</p> <p>Tap the Discard Set button and change the set.</p> <p>Tap the Continue button to clear the alarm and return to normal operations.</p>
Normalization Failure	T0853					
<p>Cause</p> <p>BLD normalization failure during therapy.</p> <p>Tubing incorrectly installed in the BLD.</p> <p>Tubing is cloudy or debris in the tubing path.</p> <p>Air in the effluent line. The wrong section of tubing is installed in the BLD.</p> <p>Dirty BLD optics. Blood present in the effluent line.</p>	<p>Operator Actions</p> <p>Verify that effluent line is correctly installed in the BLD.</p> <p>Remove air bubbles in effluent line.</p> <p>Slide the tube inside the BLD to increase detection signal.</p> <p>If displayed transmissivity (detection signal) > 85%, tap the Continue button to retry.</p> <p>If displayed transmissivity (detection signal) < 85%, change the set.</p> <p>Tap the Alarm Off button to override detection of this alarm.</p> <p>Tap the Discard Set button and change the set.</p> <p>Tap the Continue button to clear the alarm and return to normal operations.</p>					
	<p>Section 3.1.10 Alarm off / Override Alarms</p> <p>Page 196</p>	<table border="1"> <thead> <tr> <th data-bbox="605 1656 971 1692">Normalization Failure</th> <th data-bbox="971 1656 1373 1692">T0853</th> </tr> </thead> <tbody> <tr> <td data-bbox="605 1692 971 1896"> <p>Reaction to override</p> <p>Disables BLD for 60 seconds</p> <p>Disables blood leak detection or renormalization, or both, when override is active.</p> </td> <td data-bbox="971 1692 1373 1896"> <p>Override Action</p> <p> NOTE! Alarm detection delayed for up to 40 seconds.</p> <p>Override shall be automatically cleared 60 seconds after it is set.</p> </td> </tr> </tbody> </table>	Normalization Failure	T0853	<p>Reaction to override</p> <p>Disables BLD for 60 seconds</p> <p>Disables blood leak detection or renormalization, or both, when override is active.</p>	<p>Override Action</p> <p> NOTE! Alarm detection delayed for up to 40 seconds.</p> <p>Override shall be automatically cleared 60 seconds after it is set.</p>
Normalization Failure	T0853					
<p>Reaction to override</p> <p>Disables BLD for 60 seconds</p> <p>Disables blood leak detection or renormalization, or both, when override is active.</p>	<p>Override Action</p> <p> NOTE! Alarm detection delayed for up to 40 seconds.</p> <p>Override shall be automatically cleared 60 seconds after it is set.</p>					

Alarm		PrisMax Operator's Manual, AW8061 Rev E												
<p>T1205</p>	<p>Section 3.1.8 Setup Alarms</p> <p>Page 174</p>	<table border="1"> <thead> <tr> <th colspan="2">BLD Self-Test Failure</th> <th>T1205</th> </tr> <tr> <th>Cause</th> <th colspan="2">Operator Actions</th> </tr> </thead> <tbody> <tr> <td>Air in the effluent line</td> <td colspan="2">Check BLD</td> </tr> <tr> <td>Effluent line incorrectly installed in the BLD</td> <td colspan="2"> Verify that there are no air bubbles in the effluent line. Verify that effluent line is correctly installed in the BLD. Tap the Continue button to retry pinch valve position. If air is present in the entire return line, change the set. Tap the Discard Set button and change the set. </td> </tr> </tbody> </table>	BLD Self-Test Failure		T1205	Cause	Operator Actions		Air in the effluent line	Check BLD		Effluent line incorrectly installed in the BLD	Verify that there are no air bubbles in the effluent line. Verify that effluent line is correctly installed in the BLD. Tap the Continue button to retry pinch valve position. If air is present in the entire return line, change the set. Tap the Discard Set button and change the set.	
BLD Self-Test Failure		T1205												
Cause	Operator Actions													
Air in the effluent line	Check BLD													
Effluent line incorrectly installed in the BLD	Verify that there are no air bubbles in the effluent line. Verify that effluent line is correctly installed in the BLD. Tap the Continue button to retry pinch valve position. If air is present in the entire return line, change the set. Tap the Discard Set button and change the set.													
<p>T2284</p>	<p>Section 3.1.4.2 TherMax</p> <p>Page 133</p>	<table border="1"> <thead> <tr> <th colspan="2">TherMax Disposable Not Inserted</th> <th>T2284</th> </tr> <tr> <th>Cause</th> <th colspan="2">Operator Actions</th> </tr> </thead> <tbody> <tr> <td>Warmer disposable not detected during therapy</td> <td colspan="2"> Confirm that the warmer disposable is pushed in all the way. Tap the Discard Set button and change the set. Discontinue therapy if this can not be resolved. </td> </tr> </tbody> </table>	TherMax Disposable Not Inserted		T2284	Cause	Operator Actions		Warmer disposable not detected during therapy	Confirm that the warmer disposable is pushed in all the way. Tap the Discard Set button and change the set. Discontinue therapy if this can not be resolved.				
TherMax Disposable Not Inserted		T2284												
Cause	Operator Actions													
Warmer disposable not detected during therapy	Confirm that the warmer disposable is pushed in all the way. Tap the Discard Set button and change the set. Discontinue therapy if this can not be resolved.													

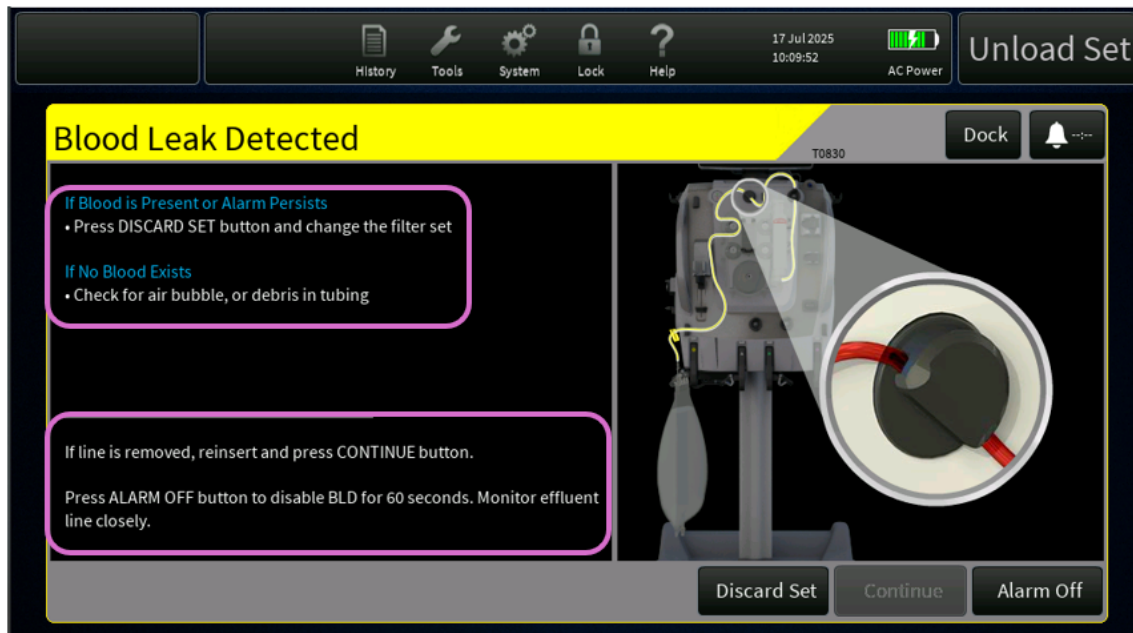
PrisMax Graphical User Interface (GUI):

1. **Alarm T2309: Air Detected in Prime** - The **PrisMax** System displays the following Alarm Screen when the alarm, *T2309: Air Detected in Prime*, is active.



The Alarm Screen guides the user to investigate potential sources of air in the circuit and provides mitigation options – *Reprime* or *Discard Set*.

2. **Alarm T0830: Blood Leak Detected** – The **PrisMax** System displays the following Alarm Screen when the alarm, *T0830: Blood Leak Detected*, is active.



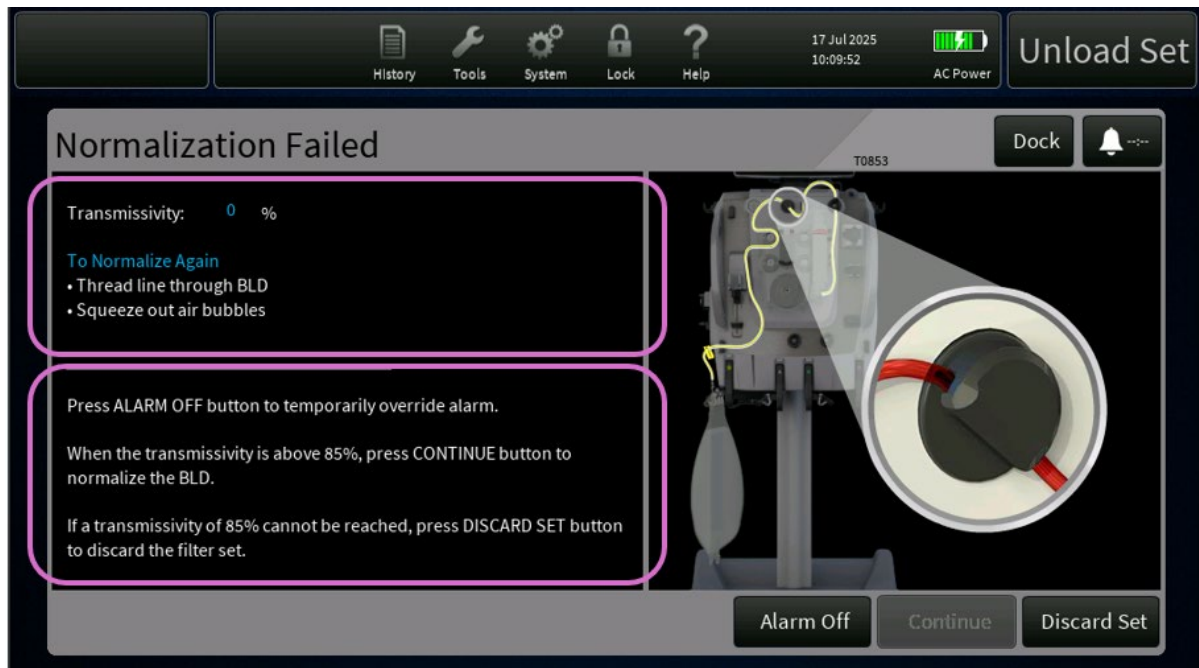
The Alarm Screen prompts the user to verify the presence of blood in the effluent line and provides options for next steps – *Discard Set*, *Continue* or *Alarm Off*.

- 3. **Alarm T1313: BLD Normalize Failed** – The **PrisMax** System displays the following Alarm Screen when the alarm, *T1313: BLD Normalize Failed*, is active.



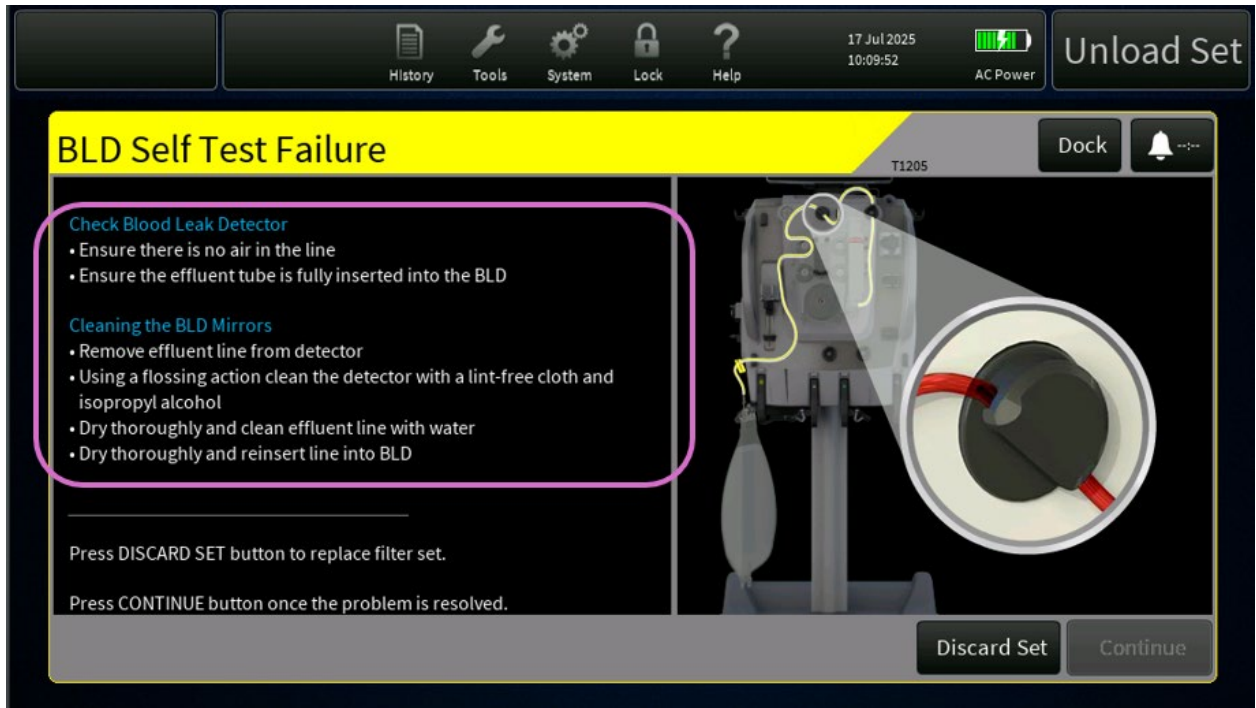
The Alarm Screen guides the user in resolving the BLD Normalization failure and provides possible next steps – *Reprime* or *Continue*.

- 4. **Alarm T0853: Normalization Failed** – The **PrisMax** System displays the following Alarm Screen when the alarm, *T0853: Normalization Failed*, is active.



The Alarm Screen provides information on current the Transmissivity value, instructions on how to normalize again, and possible next steps – *Alarm Off*, *Continue* or *Discard Set*.

- 5. **Alarm T1205: BLD Self-Test Failure** – The **PrisMax** System displays the following Alarm Screen when the alarm, *T1205: BLD Self-Test Failure*, is active.



The Alarm Screen guides the user to investigate the potential source of BLD Self-Test Failure and provides next steps – *Discard Set or Continue*.

- 6. **Alarm T2284: TherMax Disposable Not Inserted** – The **PrisMax** System displays the following Alarm Screen when the alarm, *T2284: TherMax Disposable Not Inserted*, is active.



The Alarm Screen guides the user in resolving the **TherMax** Blood Warmer Unit's disposables detection issue and provides an option to *Discard Set* if the problem is not cleared.