

Urgent Medical Device Correction

July 28, 2025

Dear Healthcare Provider:

Vantive is issuing an Urgent Medical Device 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 Vantive Customer Care helpline 1700-81-6565 or your Vantive sales representative. Vantive is currently investigating these issues and will be correcting the impacted devices.

Affected Product

Product Code	Product Description	Serial Numbers	UDI Number
955725	Prismax	All	07332414126025
955515	Thermax Blood Warmer Unit	All	07332414123925

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 Vantive Customer Care helpline 1700-81-6565 or your Vantive sales representative. Please ensure that all operators of these devices are made aware of this Urgent Medical Device Correction notification. A copy of this notification may be 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. If you received this communication directly from Vantive, **please acknowledge receipt of this letter by completing the Customer Reply Form (Enclosed)**. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
4. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. 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 Urgent Medical Device Correction in accordance with your customary procedures and acknowledge receipt of this letter by completing the Customer Reply Form (Enclosed).

Further Information and Support

For general questions regarding this communication, please contact Vantive Customer Care helpline 1700-81-6565 or your Vantive sales representative. Vantive Customer Care is available 24 hours a day, seven days a week.

The Medical Device Authority (MDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported via contacting Vantive Product Surveillance by navigating to the Product Feedback Portal at <https://productfeedback.vantive.com>.

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

Sincerely,












Electronically signed by: Wensze
Sharon Ding
Reason: I am the author of this
document
Date: Aug 15, 2025 20:02:21 GMT+8

Sharon Ding
QA/RA Manager/Pharmacist
Vantive Sdn Bhd
B-21-3, Level 21, The Ascent Paradigm,
No 1, Jalan SS7/26A, Kelana Jaya,
47301, Petaling Jaya, Selangor

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

PrisMax Operator's Manual:

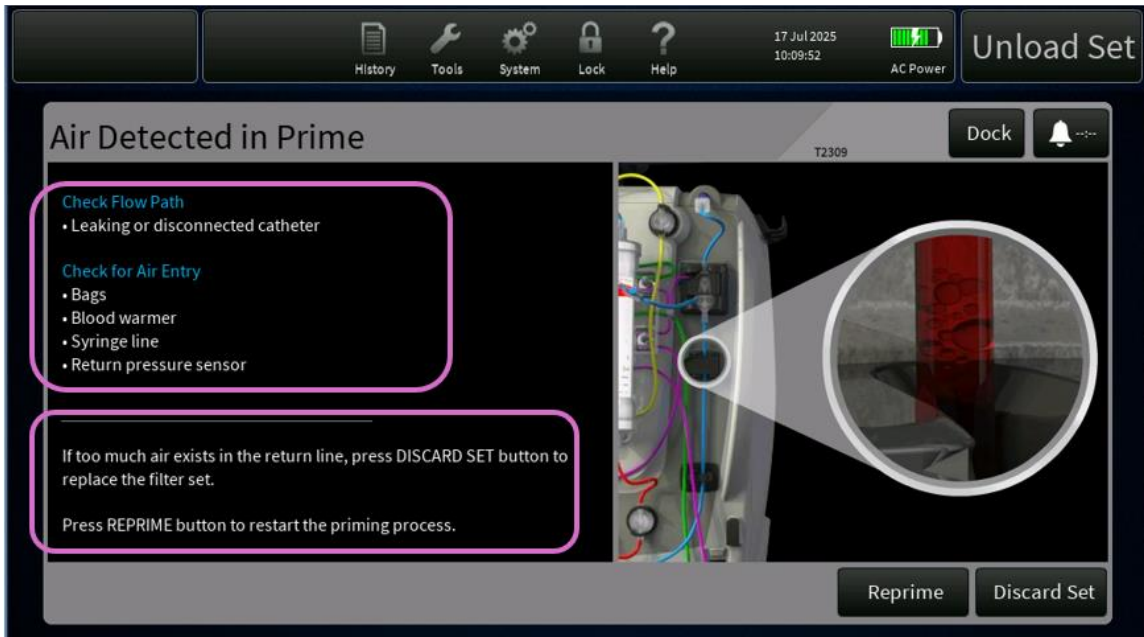
Alarm	PrisMax Operator's Manual , SW 3.XX, AW8046 Rev E																					
T2309	Section 3.1.8 Setup Alarms, Page 172	<table border="1"> <thead> <tr> <th data-bbox="654 302 1019 331">Air Detected in Prime</th> <th data-bbox="1019 302 1396 331">T2309</th> </tr> </thead> <tbody> <tr> <td data-bbox="654 331 1019 361">Cause</td> <td data-bbox="1019 331 1396 361">Operator Actions</td> </tr> <tr> <td data-bbox="654 361 1019 390">Empty priming bag</td> <td data-bbox="1019 361 1396 390">Check priming bag.</td> </tr> <tr> <td data-bbox="654 407 1019 436">Open tubing connection</td> <td data-bbox="1019 407 1396 436">Check line connections.</td> </tr> <tr> <td></td> <td data-bbox="1019 453 1396 483">Reprime or discard the set.</td> </tr> <tr> <td></td> <td data-bbox="1019 499 1396 529">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.								
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<p>T0853</p>	<p>Section 3.1.5 Medium-Priority Alarms, Page 142</p>	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="646 835 1398 869"> Normalization Failure T0853 </th> </tr> </thead> <tbody> <tr> <td data-bbox="646 869 1024 898"> Cause </td> <td data-bbox="1024 869 1398 898"> Operator Actions </td> </tr> <tr> <td data-bbox="646 898 1024 974"> BLD normalization failure during therapy. </td> <td data-bbox="1024 898 1398 974"> Verify that effluent line is correctly installed in the BLD. </td> </tr> <tr> <td data-bbox="646 974 1024 1029"> Tubing incorrectly installed in the BLD. </td> <td data-bbox="1024 974 1398 1029"> Remove air bubbles in effluent line. </td> </tr> <tr> <td data-bbox="646 1029 1024 1104"> Tubing is cloudy or debris in the tubing path. </td> <td data-bbox="1024 1029 1398 1104"> Slide the tube inside the BLD to increase detection signal. </td> </tr> <tr> <td data-bbox="646 1104 1024 1180"> Air in the effluent line. The wrong section of tubing is installed in the BLD. </td> <td data-bbox="1024 1104 1398 1180"> If displayed transmissivity (detection signal) > 85%, tap the Continue button to retry. </td> </tr> <tr> <td data-bbox="646 1180 1024 1255"> Dirty BLD optics. Blood present in the effluent line. </td> <td data-bbox="1024 1180 1398 1255"> If displayed transmissivity (detection signal) < 85%, change the set. </td> </tr> <tr> <td data-bbox="646 1255 1024 1293"></td> <td data-bbox="1024 1255 1398 1293"> Tap the Alarm Off button to override detection of this alarm. </td> </tr> <tr> <td data-bbox="646 1293 1024 1331"></td> <td data-bbox="1024 1293 1398 1331"> Tap the Discard Set button and change the set. </td> </tr> <tr> <td data-bbox="646 1331 1024 1369"></td> <td data-bbox="1024 1331 1398 1369"> Tap the Continue button to clear the alarm and return to normal operations. </td> </tr> </tbody> </table>	Normalization Failure T0853		Cause	Operator Actions	BLD normalization failure during therapy.	Verify that effluent line is correctly installed in the BLD.	Tubing incorrectly installed in the BLD.	Remove air bubbles in effluent line.	Tubing is cloudy or debris in the tubing path.	Slide the tube inside the BLD to increase detection signal.	Air in the effluent line. The wrong section of tubing is installed in the BLD.	If displayed transmissivity (detection signal) > 85%, tap the Continue button to retry.	Dirty BLD optics. Blood present in the effluent line.	If displayed transmissivity (detection signal) < 85%, change the set.		Tap the Alarm Off button to override detection of this alarm.		Tap the Discard Set button and change the set.		Tap the Continue button to clear the alarm and return to normal operations.
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<p>T1205</p>	<p>Section 3.1.8 Setup Alarms, Page 174</p>	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="646 205 1382 237"> BLD Self-Test Failure T1205 </th> </tr> </thead> <tbody> <tr> <td data-bbox="646 237 1019 268">Cause</td> <td data-bbox="1019 237 1382 268">Operator Actions</td> </tr> <tr> <td data-bbox="646 268 1019 300">Air in the effluent line</td> <td data-bbox="1019 268 1382 300">Check BLD</td> </tr> <tr> <td data-bbox="646 300 1019 373">Effluent line incorrectly installed in the BLD</td> <td data-bbox="1019 300 1382 373">Verify that there are no air bubbles in the effluent line.</td> </tr> <tr> <td></td> <td data-bbox="1019 373 1382 447">Verify that effluent line is correctly installed in the BLD.</td> </tr> <tr> <td></td> <td data-bbox="1019 447 1382 520">Tap the Continue button to retry pinch valve position.</td> </tr> <tr> <td></td> <td data-bbox="1019 520 1382 594">If air is present in the entire return line, change the set.</td> </tr> <tr> <td></td> <td data-bbox="1019 594 1382 688">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.
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<p>T2284</p>	<p>Section 3.1.4.2 TherMax Page 133</p>	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="646 741 1382 772"> TherMax Disposable Not Inserted T2284 </th> </tr> </thead> <tbody> <tr> <td data-bbox="646 772 1019 804">Cause</td> <td data-bbox="1019 772 1382 804">Operator Actions</td> </tr> <tr> <td data-bbox="646 804 1019 877">Warmer disposable not detected during therapy</td> <td data-bbox="1019 804 1382 877">Confirm that the warmer disposable is pushed in all the way.</td> </tr> <tr> <td></td> <td data-bbox="1019 877 1382 951">Tap the Discard Set button and change the set.</td> </tr> <tr> <td></td> <td data-bbox="1019 951 1382 1024">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.						
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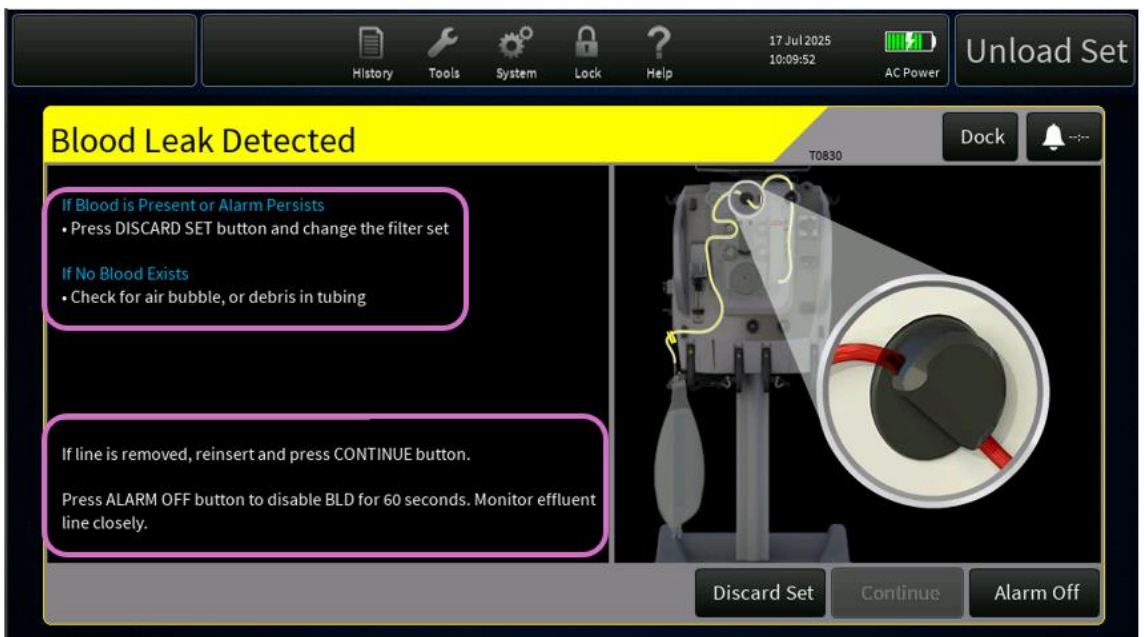
PrisMax Graphical User Interface (GUI):

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.



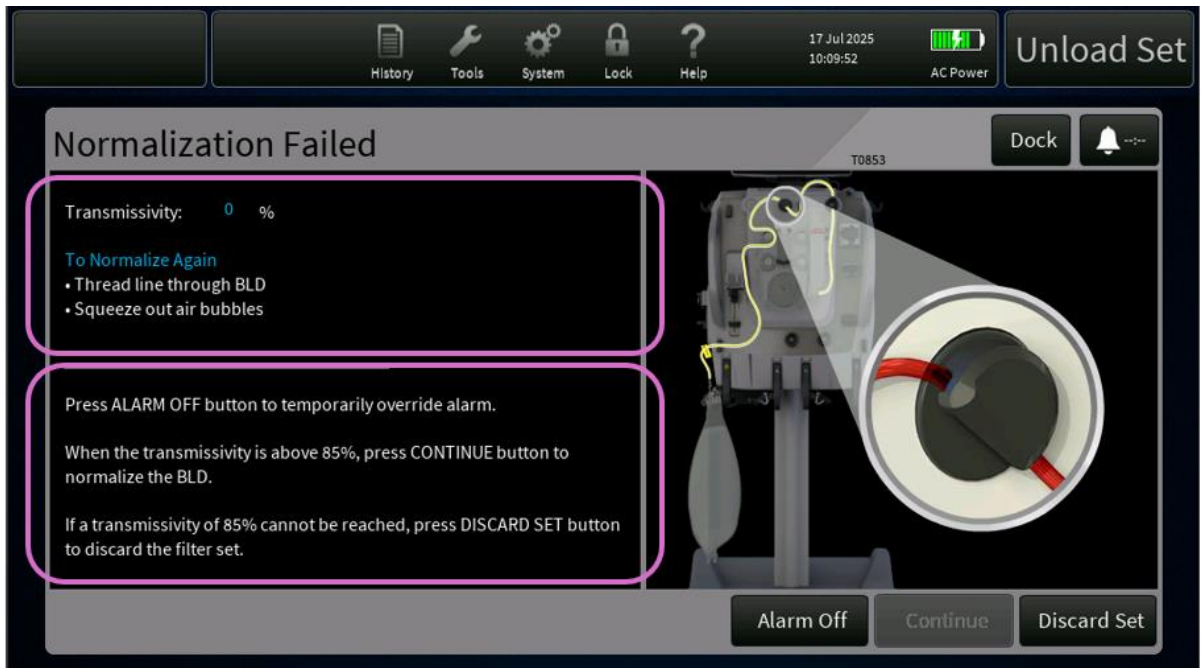
The Alarm Screen prompts the user to verify the presence of blood in the effluent line and provides options for next steps – *Discard Set*, *Continue* or *Alarm Off*.

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



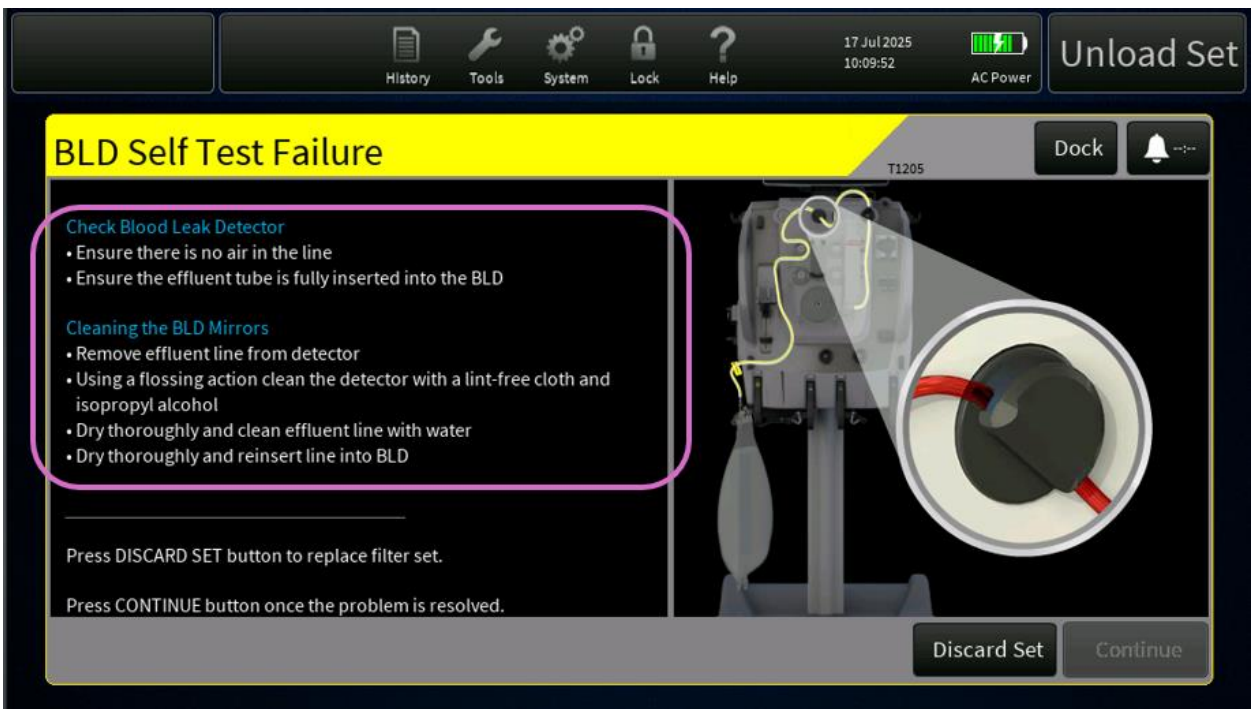
The Alarm Screen guides the user in resolving the BLD Normalization failure and provides possible next steps – *Reprime* or *Continue*.

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



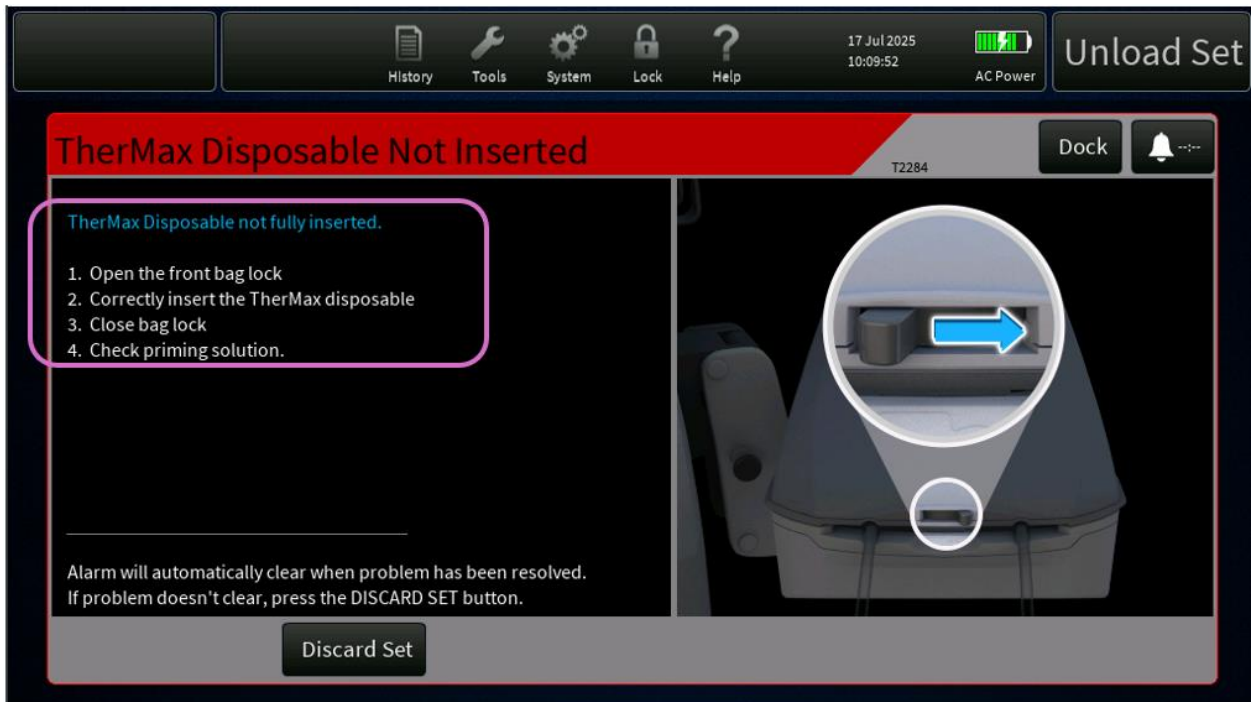
The Alarm Screen provides information on current Transmissivity value, instructions on how to normalize again and possible next steps – *Alarm Off*, *Continue* or *Discard Set*.

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 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 TherMax disposables detection issue and provides an option to *Discard Set* if the problem is not cleared.