

## **Hitna sigurnosna obavijest**

**PrisMax** sustavi i **TherMax** grijači krvi

**FA broj:** FAV-2025-005

**Proizvođač:** Baxter Healthcare SA (CH-MF-000026124)

**Vrsta radnje:** Korekcija

DD. mjeseca 2025.

Poštovani,

Tvrtka Vantive izdaje korekciju za **PrisMax** sustave i **TherMax** grijače krvi navedenih u nastavku zbog sljedeća tri problema:

- **PrisMax** sustav alarm *T2309: Air Detected in Prime* se može javiti nakon punjenja s niskom razinom tekućine u komori za odzračivanje. Sustav ispravno detektira prisutnost zraka unutar jednokratnog seta i aktivira alarm na kraju ispiranja ako je stanje prisutno. Operateri trebaju slijediti upute na zaslonu za ponovno punjenje jednokratnog seta.
- **PrisMax** sustav alarm *T0830: Blood Leak Detected* se može javiti kada nema curenja krvi ili operater može imati poteškoća s normalizacijom detektora curenja krvi (engl. Blood Leak Detector (BLD)) što dovodi do alarma **PrisMax** sustava *1313: BLD Normalize Failed*, *T0853: Normalization Failed*, ili *T1205: BLD Self-Test Failure*. Operateri trebaju slijediti upute na zaslonu i vratiti krv u jednokratnom setu ako je spojen na bolesnika.
- **Thermax** sustav možda neće moći otkriti prisutnost vrećice na **Thermax** grijaču krvi što dovodi do poteškoća s postavljanjem terapije ili alarma sustava **PrisMax** *T2284: Thermax Disposable Not Inserted*. Operateri trebaju slijediti upute na zaslonu i vratiti krv u jednokratnom setu ako je spojen na bolesnika.

Ako operater nastavi primati bilo koji od ovih alarma ili je potrebna dodatna pomoć, obratite se lokalnom predstavniku tvrtke Vantive, [igor\\_svab@baxter.com](mailto:igor_svab@baxter.com) (+386 40 378 419). Vantive trenutno istražuje ove probleme i ispraviti će pogođene uređaje.

### **Zahvaćeni proizvod**

| Kataloški broj | Opis proizvoda                       | Brojevi serije |
|----------------|--------------------------------------|----------------|
| 955725         | <b>PrisMax</b> V3 Control Unit-ROW   | Svi            |
| 955515         | <b>TherMax</b> Blood Warmer Unit ROW | Svi            |

### **Uočena opasnost**

Pojava ova tri problema mogla bi dovesti do odgode ili prekida terapije, a u određenim situacijama i do gubitka krvi. Međutim, vraćanje krvi je moguće kako bi se izbjegao gubitak krvi. U slučaju gubitka krvi, količina gubitka krvi bila bi ograničena na količinu krvi sadržanu u jednokratnom setu. Vantive je svjestan da korisnici mogu odlučiti ne vraćati krv u skladu sa svojom kliničkom praksom. Bolesnici koji su hemodinamski nestabilni i anemični od samog početka nalaze se u skupini visokog rizika za gubitak krvi. Vantive je primio jednu pritužbu na ozbiljnu ozljedu povezanu s gubitkom krvi povezanim s gore navedenim problemima.

## Radnje koje trebaju poduzeti korisnici

1. Operateri mogu nastaviti sigurno koristiti **PrisMax** sustave i **TherMax** grijače krvi u skladu s pripadajućim priručnicima za uporabu i uputama na zaslonu. Za detalje pogledajte priloženi Dodatak A. Ako je potrebna dodatna pomoć, obratite se lokalnom predstavniku tvrtke Vantive, [igor\\_svab@baxter.com](mailto:igor_svab@baxter.com) (+386 40 378 419). Molimo Vas da se pobrinete da svi operateri ovih uređaja budu svjesni ove obavijesti. Vantive preporučuje da se kopija ove obavijesti objavi na odgovarajućoj lokaciji u Vašoj ustanovi.
2. Čim ispravci postanu dostupni, lokalni predstavnik tvrtke Vantive kontaktirat će Vašu ustanovu kako bi utvrdio plan ispravaka i zakazao povezane ispravke za pogođene uređaje.
3. Ako ste nabavili ovaj proizvod od tvrtke Vantive, ispunite priloženi obrazac o primitku obavijesti, skenirajte ga i pošaljite tvrtki Vantive putem e-pošte na [SEE.FieldAction@vantive.com](mailto:SEE.FieldAction@vantive.com) čak i ako nemate proizvod na stanju. Ako žurno ispunite i pošaljete obrazac, smatrat ćemo da ste potvrdili primitak ove obavijesti i time ćete spriječiti ponovljeno slanje ove obavijesti.
4. Ako ste nabavili ovaj proizvod od distributera, molimo uzmite u obzir da obrazac o primitku obavijesti tvrtke Vantive nije u tom slučaju primjenjiv. Ako je odgovor zatražio distributer ili veleprodaja, molimo odgovorite dobavljaču sukladno njihovim uputama.
5. Ako ste distribuirali ovaj proizvod u druge ustanove ili odjele unutar Vaše ustanove, molimo prosljedite im kopiju ove obavijesti.
6. Ako ste posrednik, veleprodaja, distributer ili originalni proizvođač opreme koji distribuira bilo koji od zahvaćenih proizvoda u druge ustanove, molimo pošaljite ovu obavijest Vašim korisnicima u skladu s vlastitim postupcima.

## Daljnje informacije i podrška

Za općenita pitanja u vezi ove obavijesti ili ako iskusite bilo koji problem s proizvodom, obratite se tvrtki Vantive na [SEE.FieldAction@vantive.com](mailto:SEE.FieldAction@vantive.com)

Ispričavamo se na svim neugodnostima koje to može uzrokovati Vama i Vašem osoblju..

S poštovanjem,

Petra Jurić, MPharm  
Sr Manager, Regulatory Affairs CEEI & Croatia  
Baxter Healthcare d.o.o.  
Hektorovićeve 2 / 10000 Zagreb / Hrvatska

Privici:      Obrazac o primitku obavijesti tvrtke Vantive  
                 Dodatak A: Priručnik za uporabu i upute na zaslonu (engl. Operator's Manual and Graphical User Interface (GUI) Guidance)

## PrisMax Operator's Manual:

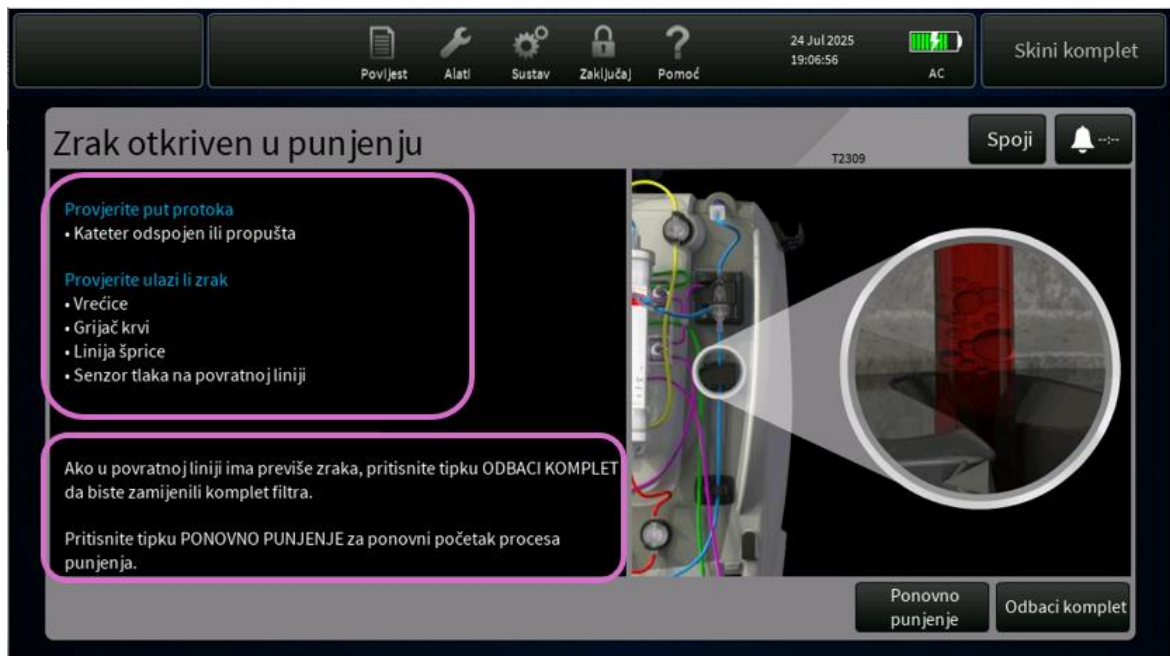
| Alarm                                                                                                            | PrisMax Operator's Manual , SW 3.XX, AW8046 Rev E                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|-------|-----------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------------------------------------------------------------|--------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------------------------------------------|
| T2309                                                                                                            | Section 3.1.8 Setup Alarms,<br>Page 172                                                                                                             | <table><tr><th>Air Detected in Prime</th><th>T2309</th></tr><tr><td><b>Cause</b></td><td><b>Operator Actions</b></td></tr><tr><td>Empty priming bag</td><td>Check priming bag.</td></tr><tr><td>Open tubing connection</td><td>Check line connections.</td></tr><tr><td></td><td>Reprime or discard the set.</td></tr><tr><td></td><td>If air continues discard the set.</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Air Detected in Prime | T2309 | <b>Cause</b>                | <b>Operator Actions</b> | 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                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| <b>Cause</b>                                                                                                     | <b>Operator Actions</b>                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| Empty priming bag                                                                                                | Check priming bag.                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| Open tubing connection                                                                                           | Check line connections.                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
|                                                                                                                  | Reprime or discard the set.                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
|                                                                                                                  | If air continues discard the set.                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| T0830                                                                                                            | Section 3.1.5 Medium-Priority Alarms,<br>Page 136                                                                                                   | <table><tr><th>Blood Leak Detected</th><th>T0830</th></tr><tr><td><b>Cause</b></td><td><b>Operator Actions</b></td></tr><tr><td>The Blood Leak Detector (BLD) detects blood in the effluent line, which can indicate a ruptured filter membrane.</td><td>Check for air bubbles in effluent line in the Blood Leak Detector (BLD).</td></tr><tr><td>Leak in filter membrane</td><td>Tap the <b>Alarm Off</b> button to dislodge bubble.</td></tr><tr><td>Tubing incorrectly installed in the Blood Leak Detector (BLD)</td><td>If air bubbles recur, check for kinked effluent line, or decrease Blood Flow Rate (BFR).</td></tr><tr><td>Tubing is cloudy or debris in the tubing path</td><td>Verify that effluent line is correctly installed in the Blood Leak Detector (BLD).</td></tr><tr><td>Air in the effluent line</td><td>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>The wrong section of tubing is installed in the Blood Leak Detector (BLD).</td><td>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>Dirty Blood Leak Detector (BLD) optics.</td><td>Tap the <b>Discard Set</b> button and change the set.</td></tr><tr><td>TPE: Formed elements of lipids in plasma discolored plasma.</td><td>Tap the <b>Continue</b> button to clear the alarm and return to normal operations.</td></tr></table> | Blood Leak Detected   | T0830 | <b>Cause</b>                | <b>Operator Actions</b> | 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 <b>Alarm Off</b> 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 <b>Discard Set</b> button and change the set. | TPE: Formed elements of lipids in plasma discolored plasma. | Tap the <b>Continue</b> button to clear the alarm and return to normal operations. |
| Blood Leak Detected                                                                                              | T0830                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| <b>Cause</b>                                                                                                     | <b>Operator Actions</b>                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| 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 <b>Alarm Off</b> 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 <b>Discard Set</b> button and change the set.                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| TPE: Formed elements of lipids in plasma discolored plasma.                                                      | Tap the <b>Continue</b> button to clear the alarm and return to normal operations.                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
|                                                                                                                  | Section 3.1.10 Alarm off / Override Alarms,<br>Page 194                                                                                             | <table><tr><th>Blood Leak Detected</th><th>T0830</th></tr><tr><td><b>Reaction to override</b></td><td><b>Override Action</b></td></tr><tr><td>Disables blood leak detector (BLD) for 60 seconds</td><td> <b>NOTE!</b><br/>Alarm detection delayed for up to 40 seconds.</td></tr><tr><td>Disables blood leak detection or renormalization, or both, when override is active.</td><td>Override shall be automatically cleared 60 seconds after it is set.</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Blood Leak Detected   | T0830 | <b>Reaction to override</b> | <b>Override Action</b>  | Disables blood leak detector (BLD) for 60 seconds                                                                |  <b>NOTE!</b><br>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                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| <b>Reaction to override</b>                                                                                      | <b>Override Action</b>                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |
| Disables blood leak detector (BLD) for 60 seconds                                                                |  <b>NOTE!</b><br>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.                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                       |       |                             |                         |                                                                                                                  |                                                                                                                                                     |                                                                                     |                                                                     |                                                               |                                                                                          |                                               |                                                                                    |                          |                                                                                                                                               |                                                                            |                                                                                                            |                                         |                                                       |                                                             |                                                                                    |

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|-------|---------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| T1313 | Section 3.1.8 Setup Alarms,<br>Page 173                 | <div> <div>BLD Normalize Failed</div> <div>T1313</div> <div> <div>Cause</div> <div>Transmission below expected values</div> <div>Effluent line incorrectly installed</div> <div>Air bubbles in the effluent line</div> <div>Dirty effluent line</div> <div>Dirty Blood Leak Detector (BLD) mirrors</div> <div>Effluent Line Clamped</div> </div> <div> <div>Operator Actions</div> <div>NOTE!</div> <div>Alarm detection delayed for up to 40 seconds.</div> <div>Slide the tubing back and forth in the Blood Leak Detector (BLD).</div> <div>Squeeze the air bubbles out of the return line.</div> <div>Remove and clean the effluent line with an alcohol swab. Clean Blood Leak Detector (BLD) mirrors.</div> <div>Tap the <b>Continue</b> button to retest.</div> <div>Tap the <b>Discard Set</b> button and change the front set.</div> </div> </div>                                                                                                                                                                                                                                                        |
| T0853 | Section 3.1.5 Medium-Priority Alarms,<br>Page 142       | <div> <div>Normalization Failure</div> <div>T0853</div> <div> <div>Cause</div> <div>BLD normalization failure during therapy.</div> <div>Tubing incorrectly installed in the BLD.</div> <div>Tubing is cloudy or debris in the tubing path.</div> <div>Air in the effluent line. The wrong section of tubing is installed in the BLD.</div> <div>Dirty BLD optics. Blood present in the effluent line.</div> </div> <div> <div>Operator Actions</div> <div>Verify that effluent line is correctly installed in the BLD.</div> <div>Remove air bubbles in effluent line.</div> <div>Slide the tube inside the BLD to increase detection signal.</div> <div>If displayed transmissivity (detection signal) &gt; 85%, tap the <b>Continue</b> button to retry.</div> <div>If displayed transmissivity (detection signal) &lt; 85%, change the set.</div> <div>Tap the <b>Alarm Off</b> button to override detection of this alarm.</div> <div>Tap the <b>Discard Set</b> button and change the set.</div> <div>Tap the <b>Continue</b> button to clear the alarm and return to normal operations.</div> </div> </div> |
|       | Section 3.1.10 Alarm off / Override Alarms,<br>Page 196 | <div> <div>Normalization Failure</div> <div>T0853</div> <div> <div>Reaction to override</div> <div>Disables BLD for 60 seconds</div> <div>Disables blood leak detection or renormalization, or both, when override is active.</div> </div> <div> <div>Override Action</div> <div>NOTE!</div> <div>Alarm detection delayed for up to 40 seconds.</div> <div>Override shall be automatically cleared 60 seconds after it is set.</div> </div> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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

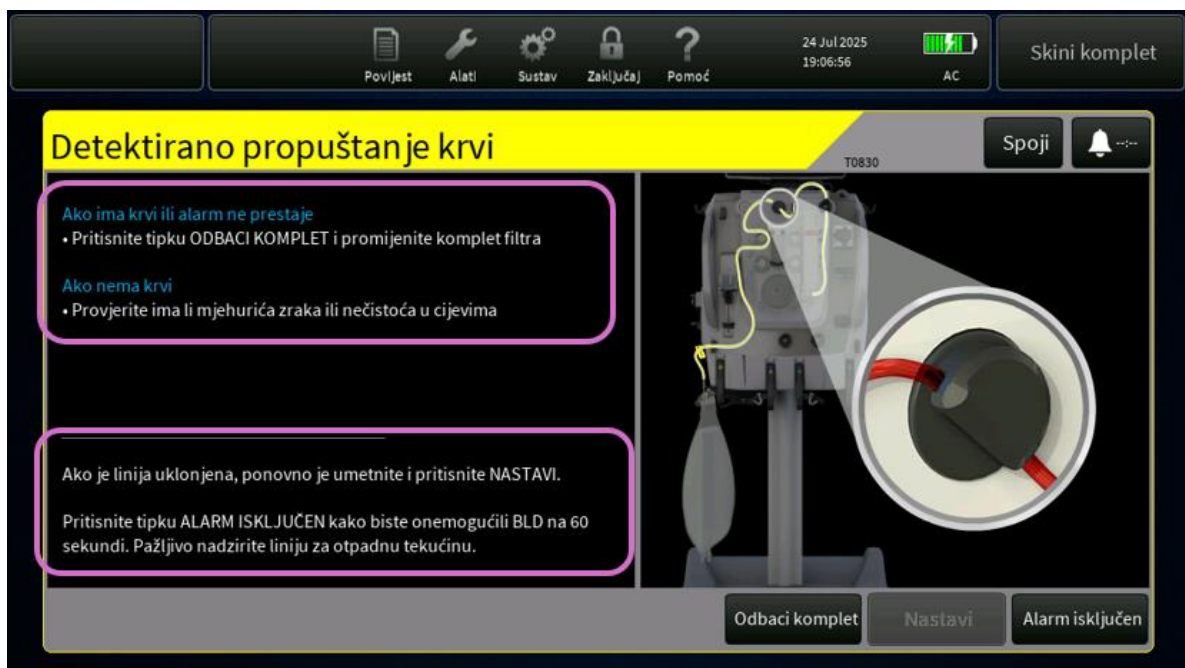
## PrisMax Graphical User Interface (GUI):

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*.

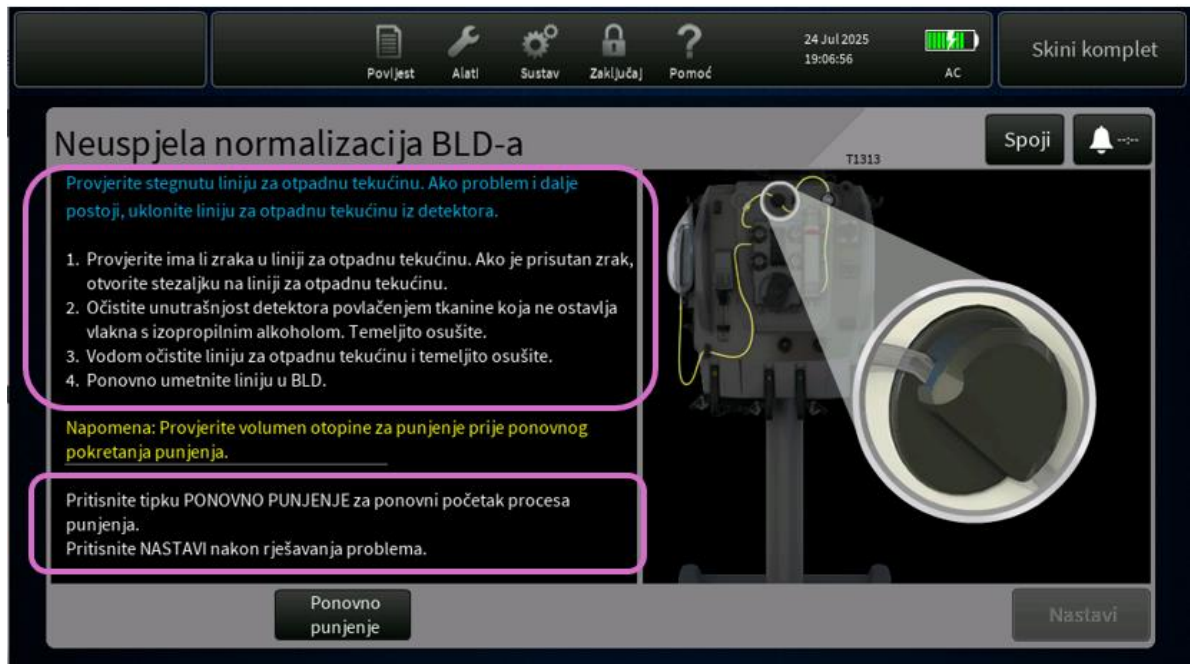
2. **Alarm T0830 : Blood Leak Detected** – The PrisMax system displays the following Alarm Screen when the alarm *T0830 : Blood Leak Detected* is active.





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 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.