prismaflex

Welcome to the Gambro Prismaflex®
system SW 7.1 US Key Notes!

These 'Key Notes' provide you with an
overview of the changes from SW 5.1 to SW
7.1

Following topics are included:
- Status screen improvements
- New soft keys design
- New pressure bar design
- Simplified pressure management
- History screen improvement
- Simplified weight/ flow alarms
- Changed alarm signals
- Other alarm improvements
- Usability improvements
- Other changes

Status screen: new design

The 'Status' screen is the main operating screen while a treatment is ongoing. It displays the pressure conditions in the set, the flow rates, the anticoagulation settings and calculated prescription parameters.

The operator is also notified (Info tab) when a next intervention is required, e.g. changing a bag or syringe empty.

If abnormal situations occur, an alarm screen will appear that provides information about action that needs to be taken.

prismafleX SW 7.1 Key Notes

Status screen: new symbols

Patient ID	
Patient Weight	
Filter time, time elapsed on current disposable set	
Treatment time, total treatment time for patient	
Current clock time	
Currently delivered therapy	
Prescribed therapy	
Information, lit orange during the self-test	

NOTE:
Filter time & Treatment time are including downtime

Status screen: Filtration Fraction & UFR Dose

Filtration fraction (FF): Indicator for % of fluid being removed (ml/min) relative to blood flow rate (ml/min) in the filter.

Excessive FF levels increase blood concentration (hemoconcentration) in the filter. This will reduce filter life.

FF is more accurate and considers all replacement flows (also PRE). The FF is now displayed on Status/ Prescription tab.

UFR Dose:

Improved logic for the display of the currently delivered therapy:

Display switches from SCUF or CVVHD to CVVH or CVVHDF if relevant ultrafiltration is present.

The threshold for displaying convective therapies (CVVH, CVVHDF,) is an UFR Dose of > 8 ml/h/kg.

Consult the Operator's Manual for the new FF (Filtration Fraction) calculation for CRRT & TPE

Status screen: Prescription Settings tab

Displays information about Prescription Settings and Prescription Indicators.

Press the ADJUST soft key in the lower right corner to change prescription settings on the 'Enter Flow Settings' screen.

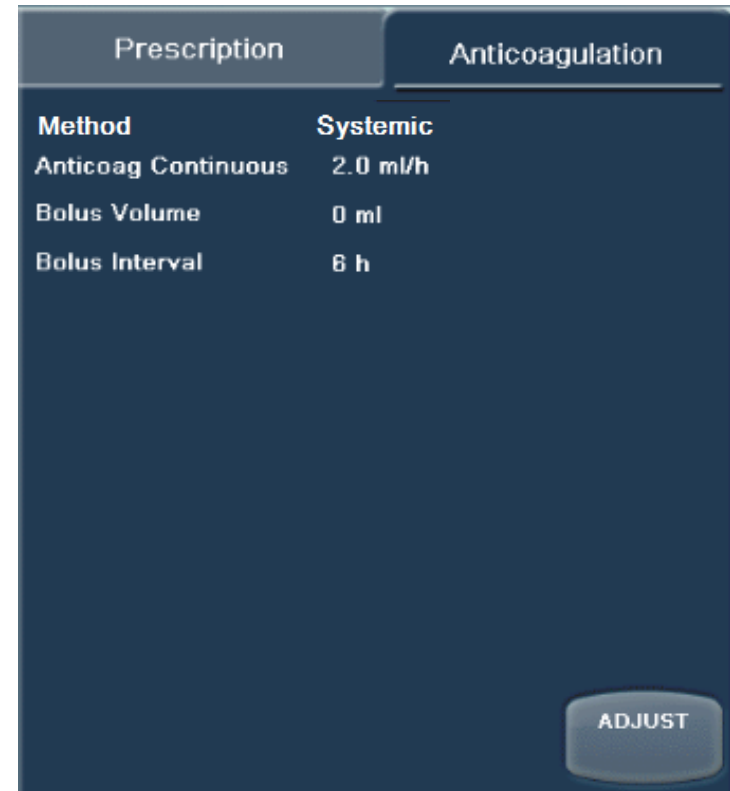| Prescription	Anticoagulation
Blood	200 ml/min
Pre Blood Pump	1200 ml/h
Dialysate	1000 ml/h
Replacement	800 ml/h
	Post
Pt Fluid Removal	100 ml/h
Effluent	3102 ml/h
Effluent Dose	38 ml/kg/h
UFR Dose	23 ml/kg/h
Filtration Fraction	35 %

ADJUST

Status screen: Anticoagulation tab

Displays information about Anticoagulation prescription settings.

Press the ADJUST soft key in the lower right corner to change prescription settings on the 'Enter Anticoagulation Settings' screen.

NOTE: The ADJUST soft key is not present in the anticoagulation tab when 'No anticoagulation' has been selected.

Prescription	Anticoagulation
Method	Systemic
Anticoag Continuous	2.0 ml/h
Bolus Volume	0 ml
Bolus Interval	6 h

ADJUST

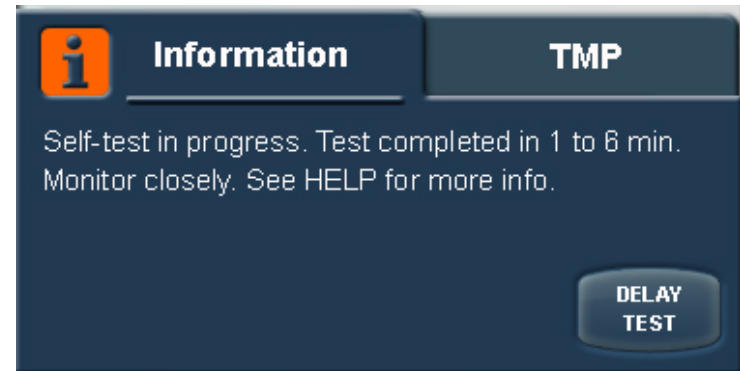## Status screen: Information & TMP tabs

Information tab:

Displays information about next intervention, self-test in progress, pressure operating point calculations in progress and waiting for stabilization of scales.

The DELAY TEST soft key is only available during the self-test. It stops and postpones the self-test for 10 minutes. When the periodic self-test hasn't successfully completed within the last 150 minutes of treatment, an 'ADVISORY: Self-Test Overdue' alarm will be issued.

NOTE: During the self-test, the following soft keys are disabled in the Status screen to avoid affecting the tests: CHANGE BAGS, CHANGE SYRINGE, ADJUST CHAMBER, SYSTEM TOOLS, HELP

TMP tab:

Displays a pressure graph; TMP and Pressure drop (CRRT), TMPa and pressure drop (TPE).
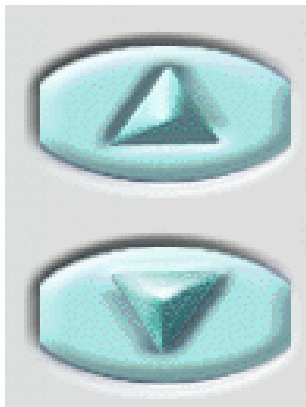

Information | **TMP**

Self-test in progress. Test completed in 1 to 6 min. Monitor closely. See HELP for more info.

DELAY TEST

Info | TMP

Pressure Drop: 52   TMP: 55

Status screen: Softkeys

STOP — Stops all pumps and navigates to the 'Stop' screen.

CHANGE BAGS — Navigates user to the 'Change Bags' screen.

CHANGE SYRINGE — Navigates user to the 'Change Syringe' screen. Only displayed when the Systemic method has been selected.

ADJUST CHAMBER — Navigates user to the 'Adjust Deaeration Chamber' screen.

SYSTEM TOOLS — Navigates user to the 'System Tools' screen.

HISTORY — Navigates user to the 'History' screen.

HELP — Navigates user to the 'Help' screens.

Status — Patient X — 0 kg — 12:38 — 43:16 — 19:26 — CVVHDF — CVVHDF

Prescription		Anticoagulation
Blood	200 ml/min	
Pre Blood Pump	1200 ml/h	
Dialysate	1000 ml/h	
Replacement	800 ml/h	
	Post	
Pt Fluid Removal	100 ml/h	
Effluent	3102 ml/h	
Effluent Dose	38 ml/kg/h	
UFR Dose	23 ml/kg/h	
Filtration Fraction	35 %	

Pressures (mmHg)

Access -104 ... -250 ... 300
Filter 101 ... 10 ... 450
Effluent -45 ... -500 ... 500
Return 122 ... 10 ... 450

Info — TMP

Next intervention: in 6 min.
Due to: Effluent bag empty.

ADJUST

STOP — CHANGE BAGS — CHANGE SYRINGE — ADJUST CHAMBER — SYSTEM TOOLS — HISTORY — HELP

prismaflex SW 7.1 Key Notes

New softkeys design

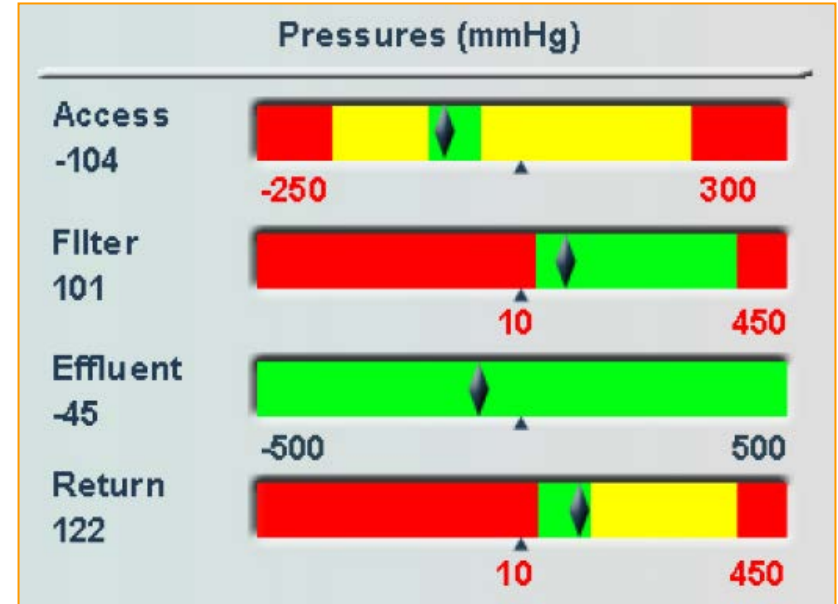| OLD DESIGN	NEW DESIGN
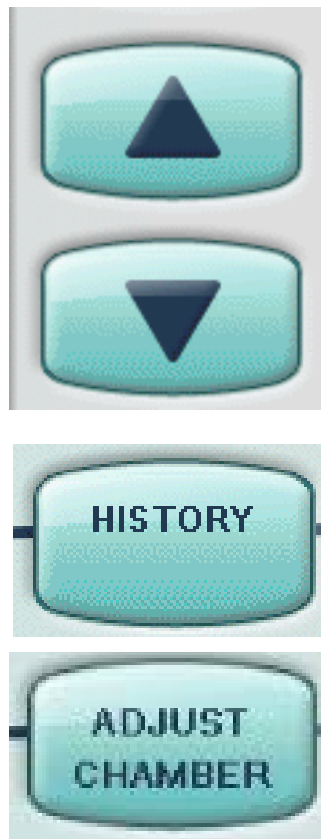
All soft keys are updated with a new, larger design (for all screens for all therapies)

New design of pressure bars

The pressure bars are enlarged for increased readability and consistently color coded with reference to the colors of the indicator light on top of the Prismaflex. Values representing the lower and upper limits of red alarm priority states are indicated by red numbers underneath each pressure bar.
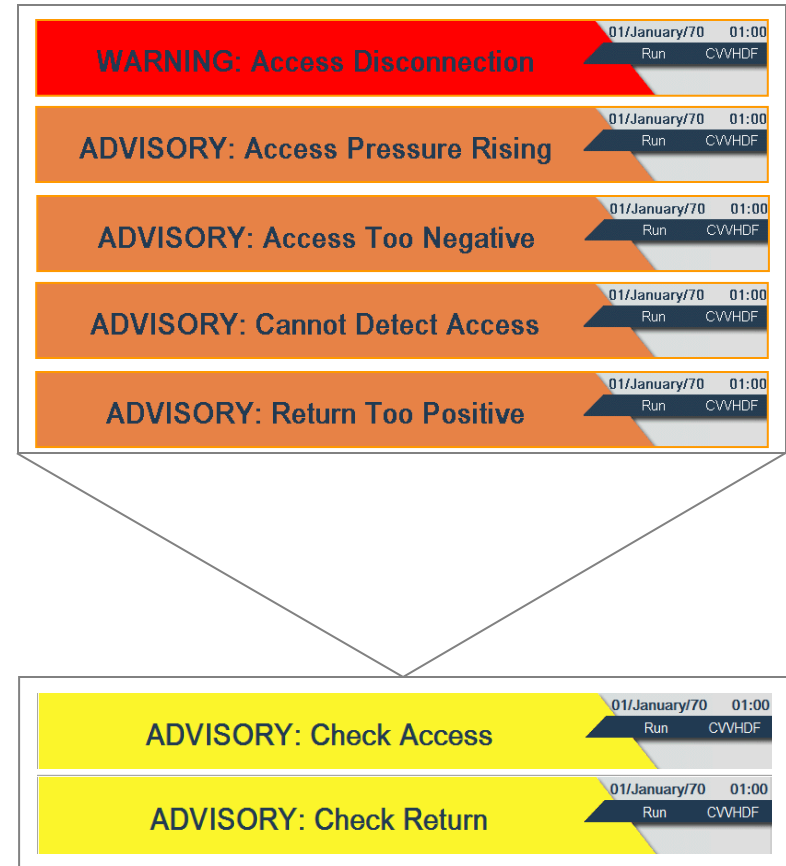

The new design is valid for all therapies.

prismafleX SW 7.1 Key Notes

Simplified pressure alarm management

To avoid multiple alarm situations, especially when the operating pressures for access and/or return are close to zero, in which the Prismaflex monitor is running with a yellow status light after the alarm is overridden, the pressure alarm management has been simplified. 5 alarms have been replaced by 2 simple alarms for both access and return pressures.

The alarm conditions are still detected and alarms accordingly issued.

The numbers of alarms are reduced and some alarm titles have been changed.

	01/January/70	01:00
WARNING: Access Disconnection	Run	CVVHDF

	01/January/70	01:00
ADVISORY: Access Pressure Rising	Run	CVVHDF

	01/January/70	01:00
ADVISORY: Access Too Negative	Run	CVVHDF

	01/January/70	01:00
ADVISORY: Cannot Detect Access	Run	CVVHDF

	01/January/70	01:00
ADVISORY: Return Too Positive	Run	CVVHDF

	01/January/70	01:00
ADVISORY: Check Access	Run	CVVHDF

	01/January/70	01:00
ADVISORY: Check Return	Run	CVVHDF

NOTE:
Consult the Operator's Manual for a detailed description and troubleshooting of the 2 'Advisory' alarms.

History screen

The software memory stores up to 96 hours of treatment / history data.

History data includes:

- Patient Fluid Removal or Patient Plasma Loss
- Doses and Solutions
- Pressures
- Events

Arrows to scroll between four 24-hour period.

- Circle to the right: current 24-hour period
- Filled circle: currently displayed 24 hour period
- Unfilled circles: data available for that period

Up and down arrows to scroll within the selected 24 hour interval (not available for Pressures).

NOTE:
Consult the 'Operator's Manual' for more detailed information on the different 'History' screens.

History screen: Patient Fluid Removal or Patient Plasma Loss

The 'Patient Fluid Removal' or 'Patient Plasma Loss' table has three columns:

- Time: chart time intervals
- Periodic: accumulated volume removed for time interval
- Total: accumulated volume removed for selected 24 hour

The footer in the table displays current values including time, current periodic volume removed and total volume removed.

In CRRT, this screen displays values for 'Unintended Patient Fluid Loss or Gain' volume and the limit selected in 'Setup' mode.

Starting time for the chart (i.e. when a new shift begins) and chart time interval can be configured in 'Custom' mode (Other Setting).

Chart reminder beep can be configured in run mode.

Alarm Management System: General

The Prismaflex control unit continually monitors itself and the Prismaflex disposable set for proper functioning during operation. If an abnormal situation occurs, the control unit signals a Warning, Malfunction, Caution, or Advisory alarm. The operator is notified of an alarm condition via a red or yellow status light, an audible alarm, and an alarm screen on the display. Each alarm screen provides instructions on how to respond to the alarm.
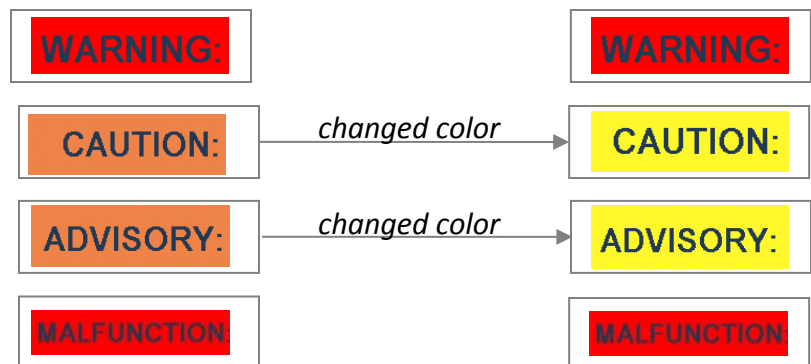
New MUTE soft key

Press the MUTE soft key to temporarily silence the audible alarm (for 2 minutes).

SW 5.1   SW 7.1

WARNING:		WARNING:
CAUTION:	changed color →	CAUTION:
ADVISORY:	changed color →	ADVISORY:
MALFUNCTION		MALFUNCTION

prismaflex SW 7.1 Key Notes

Alarm Management System: Signals

WARNING

Red flashing light

Recurring high sound, 10 sound pulses repeated approx. every 8 seconds until muted.

OVERRIDEN WARNING: Yellow constant light

CAUTION

Yellow flashing light

Recurring medium sound, 3 sound pulses repeated approx. every 11 seconds until muted.

ADVISORY

Yellow constant light

Recurring low sound, 2 sound pulses repeated approx. every 21 seconds until muted.

OVERRIDEN ADVISORY: Yellow light remains illuminated

MALFUNCTION

Red flashing light

Recurring high sound, 10 sound pulses repeated approx. every 8 seconds until muted.

OVERRIDEN MALFUNCTION: Yellow constant light

Alarms: CAUTION: Flow Problem (new)

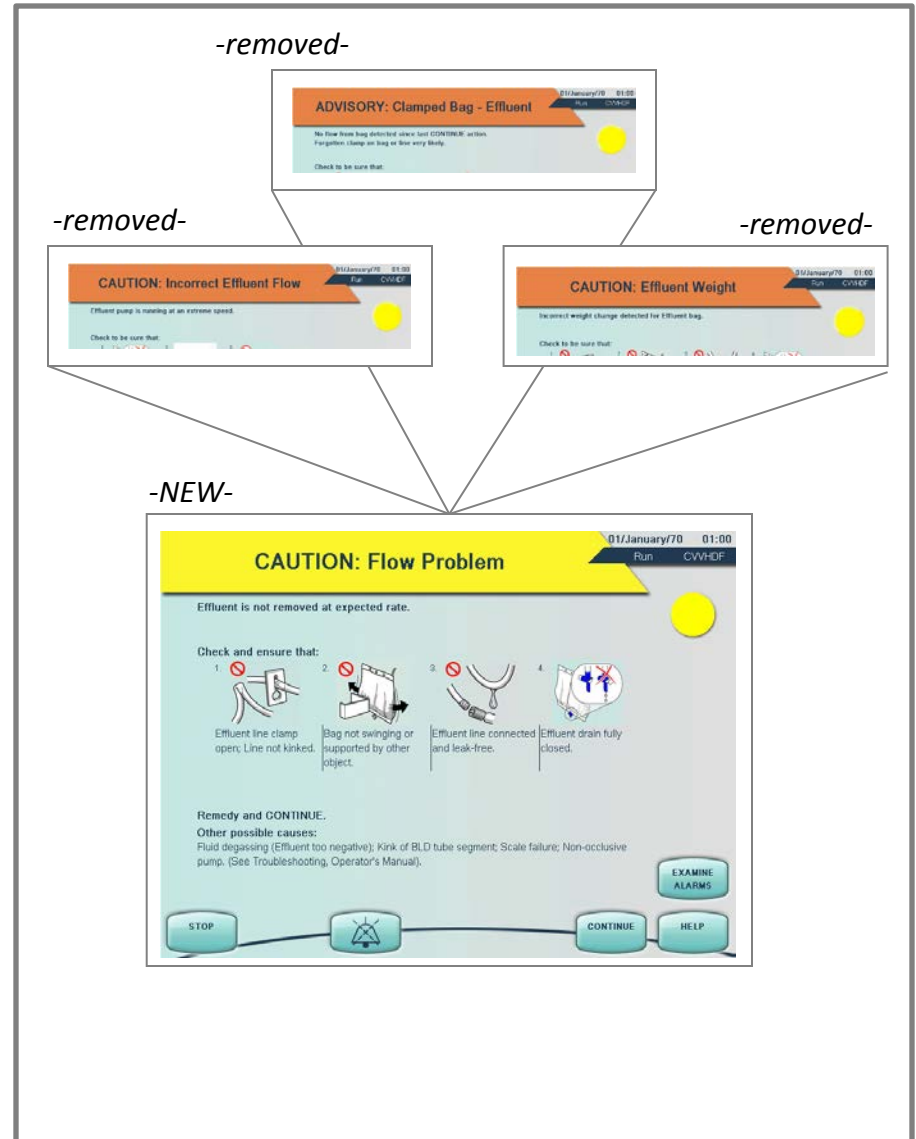Consolidation of weight & flow alarms

The 'CAUTION: Flow Problem' alarm replaces the following alarms:

ADVISORY: Clamped Bag – XXX (all scales)

CAUTION: Incorrect XXX flow (all scales)

CAUTION: XXX Weight (all scales)

The 'CAUTION: Flow Problem' alarm is issued when the actual weight of a bag varies more than 20 g from its expected value, or fluid pumps are not running at the appropriate speed. This applies to all 4 scales.

-removed-

ADVISORY: Clamped Bag - Effluent

-removed-

CAUTION: Incorrect Effluent Flow

-removed-

CAUTION: Effluent Weight

-NEW-

CAUTION: Flow Problem

Effluent is not removed at expected rate.

Check and ensure that:

1. Effluent line clamp open; Line not kinked.
2. Bag not swinging or supported by other object.
3. Effluent line connected and leak-free.
4. Effluent drain fully closed.

Remedy and CONTINUE.
Other possible causes:
Fluid degassing (Effluent too negative); Kink of BLD tube segment; Scale failure; Non-occlusive pump. (See Troubleshooting, Operator's Manual).

STOP   CONTINUE   HELP   EXAMINE ALARMS

Alarms: CAUTION: Bag Empty / Full

Renaming of alarm

Following CAUTION alarms are renamed:

Effluent Bag Full → Bag Full

PBP Bag Empty → Bag Empty

Dialysate Bag Empty → Bag Empty
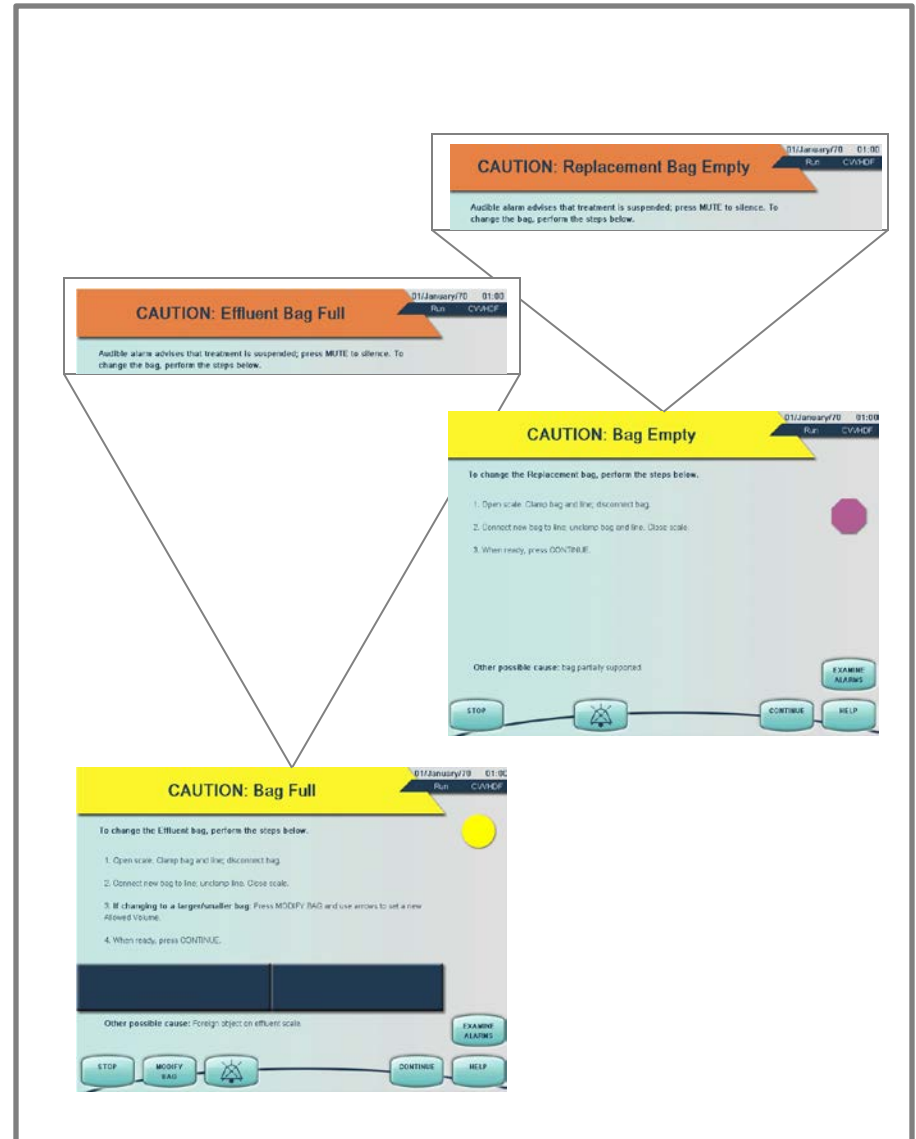
Replacement Bag 2 Empty → Bag Empty

Replacement Bag Empty → Bag Empty

All 'CAUTION: Bag Empty / Full' alarms are provided with a respective color-coded icon so the user can see which bag is empty or full when the Prismaflex control unit is alarming. This applies for all 4 scales.

NOTE:
The affected scale is mentioned in the subtitle of the alarm screen.

Alarms: Self-Test

Removed and new alarm

During patient treatment periodic self-test is conducted every two hours. The first periodic self-test starts 10 minutes after Run mode is entered.

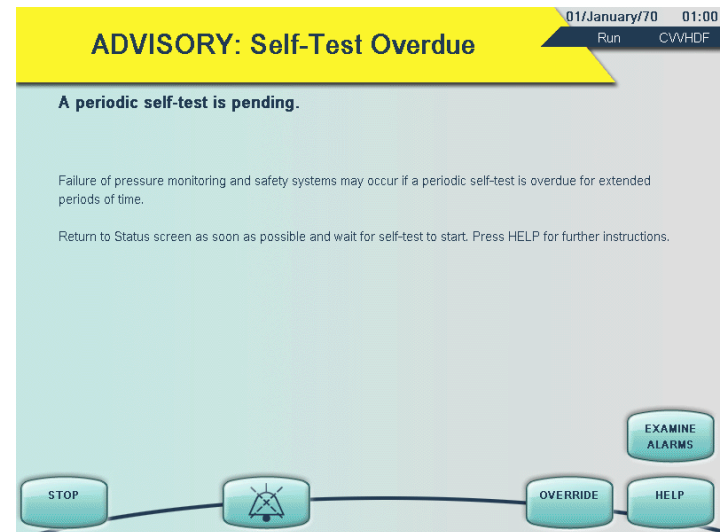Periodic self-test may be delayed 10 min by selecting the DELAY TEST soft key.
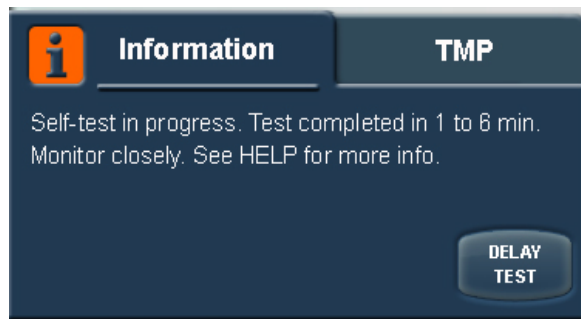
When the periodic self-test doesn't successfully complete within the last 150 minutes of treatment, an 'ADVISORY: Self-Test Overdue' alarm will be issued.
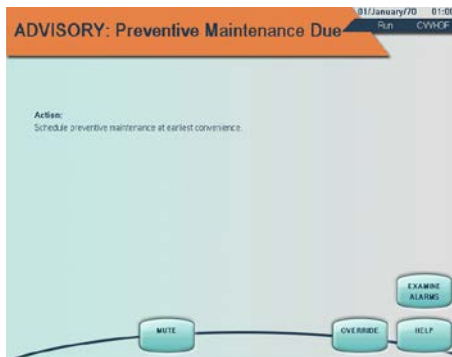
-removed-
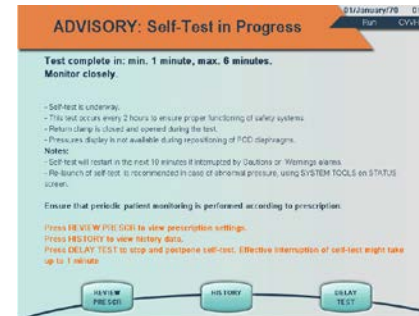
-NEW-

## Alarms: Preventive Maintenance

Alarm replaced by reminder screen

The 'ADVISORY: Preventive Maintenance Due' alarm no longer appears during treatment. The alarm is removed and override is not necessary anymore.
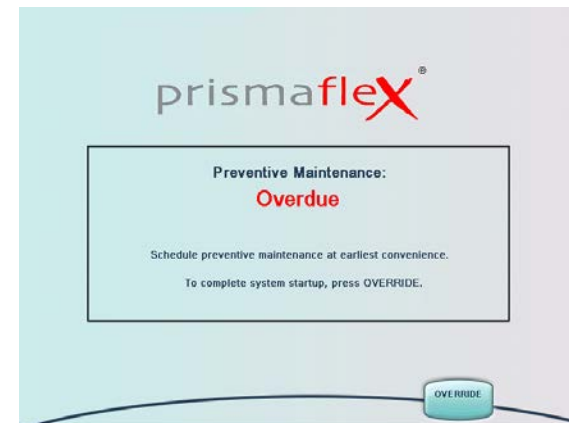
-removed-

Instead, the Prismaflex control unit will display a reminder that informs the user of the days or hours left until the nearest set PM due limit. In case of passing the nearest PM due limit, 'Overdue' is displayed, without day or hour information.

-NEW-
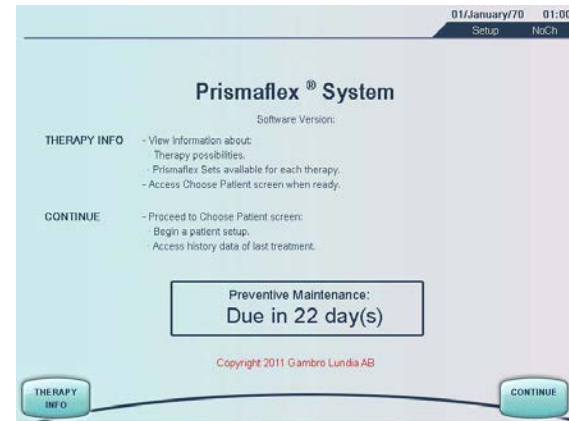
-NEW-

NOTE:
The monitor will no longer run with a yellow status light when OVERRIDE has been pressed.

Alarms: Additional

Some new alarms

## WARNING: Effluent Line Not in BLD (Blood Leak Detector)

Appears in setup mode when effluent line of new set is not installed in blood leak detector. Remedy and press RETEST.
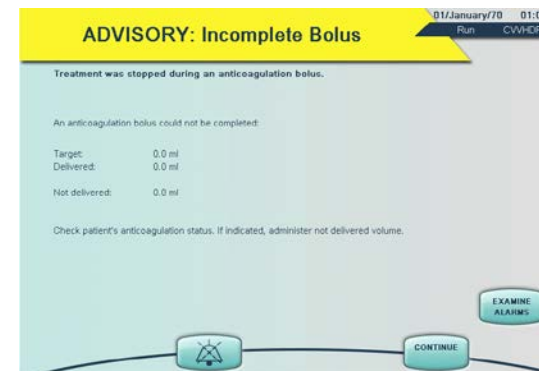
ADVISORY: Incomplete bolus

Appears when a bolus is interrupted, either by the operator or another alarm.

Check patient´s anticoagulation status. If indicated, administer not delivered volume.

-NEW-
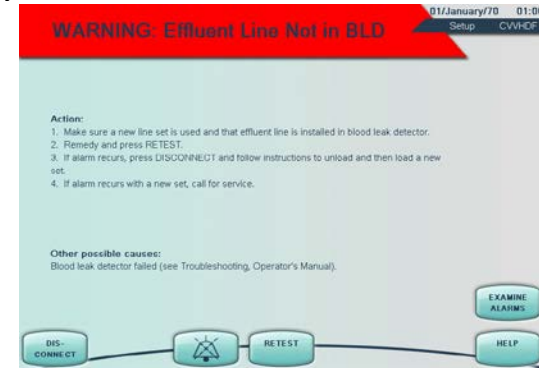
-NEW-

Usability: Anticoagulation Methods

For easier selection of the prescribed anticoagulation method, the 'Choose Anticoagulation Methods' screen has been updated.

Prescription delivery choices are clearer and as following:

Systemic (e.g. Heparin), Prismaflex syringe pump

No anticoagulation

This change has consequences for other screens as well, where the text has been updated. Such screens as 'Status', 'Review Prescription', 'Help' screens, confirmation screens, etc.
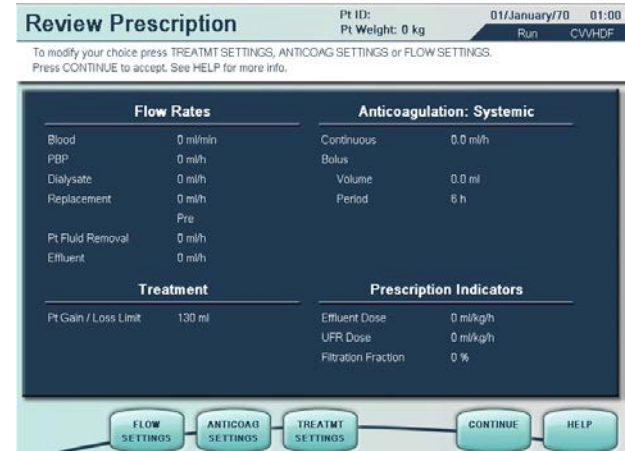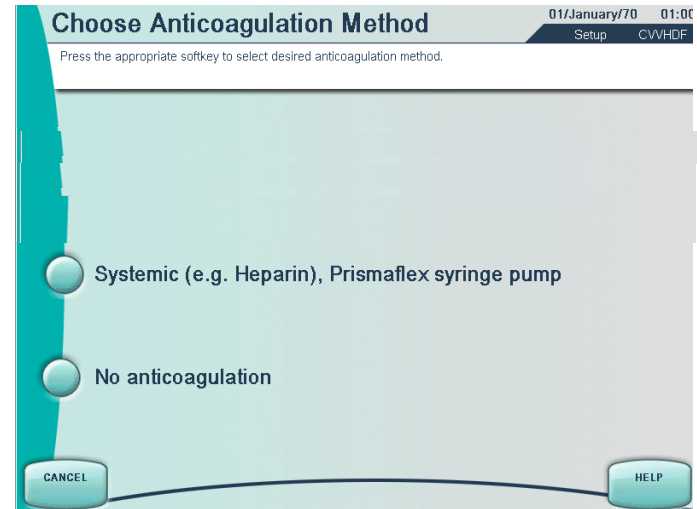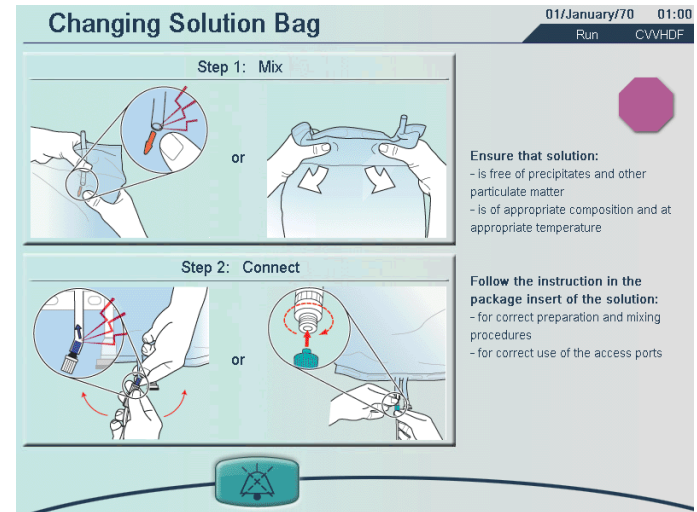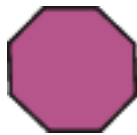
Usability: Change Solution Bags

Updated illustrations for improved handling

The steps to mix and connect a solution bag on the 'Changing Solution Bag' screen are clearer and updated to Gambro commercially available bags.
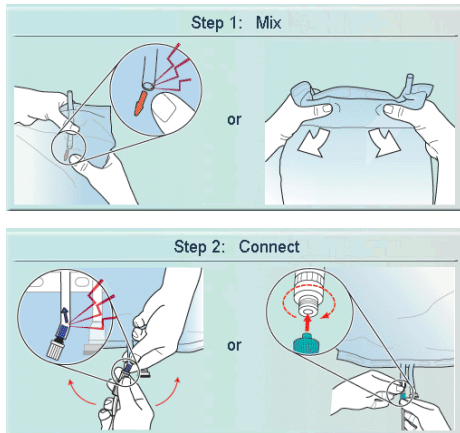
The procedure applies to all 3 solution delivery scales

NOTE:
The alarm sound is automatically muted for 2 minutes when the screen is entered.
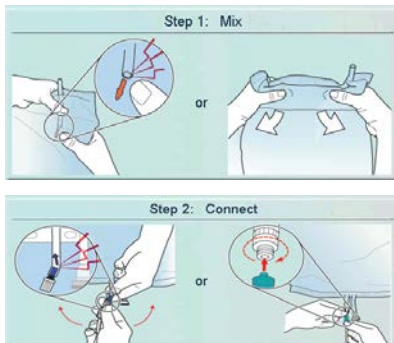
Usability: Change Solution Bags

Special: on the green scale

The solution prescribed for use on the green (dialysate) scale requires special attention. This scale can be used for either replacement or dialysate solution depending on the modality prescribed (i.e. CVVH or CVVHDF)

NOTE: The steps to mix and connect a solution bag on the 'Changing Solution Bag' screen for the green scale are identical.

CVVH:
A replacement solution is required during a bag change
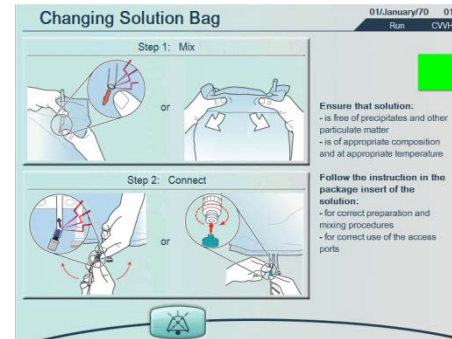
CVVHD:
A dialysate solution is required during a bag change

CVVHDF:
A dialysate solution is required during a bag change

Usability: Change Effluent Bag

Updated illustrations for improved handling

The steps to connect an effluent bag on the 'Changing Effluent Bag' screen are clearer and updated to the available bags.

NOTE:
The alarm sound is automatically muted for 2 minutes when the screen is entered.
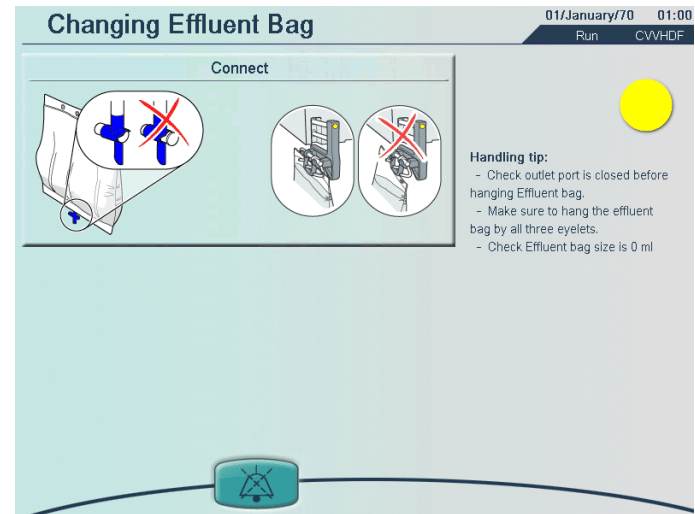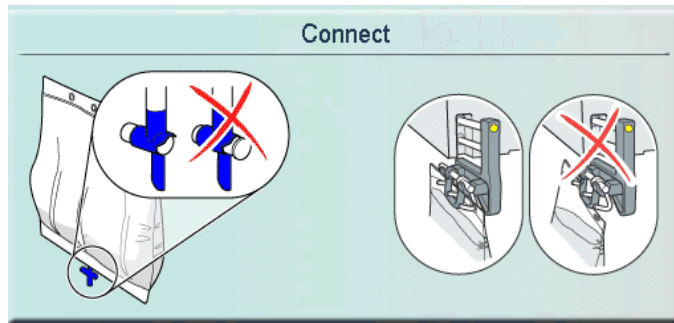
Usability: Auto Blood Return

Improved handling during 'End' mode

During 'Change Set', 'End Treatment' and 'Saline Recirculation', the user has the possibility to return the blood in the set to the patient. The user has two possibilities:
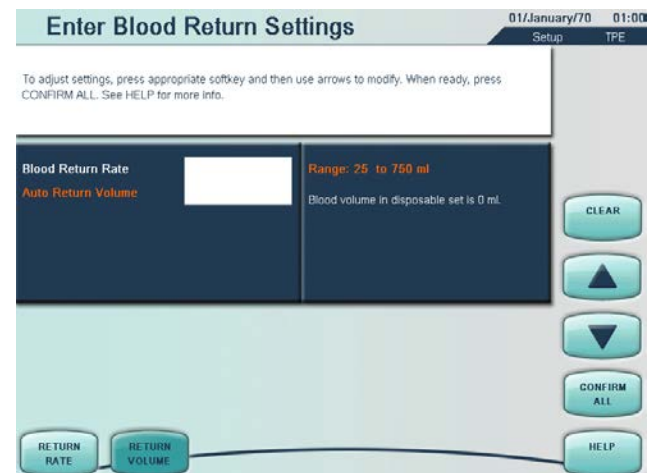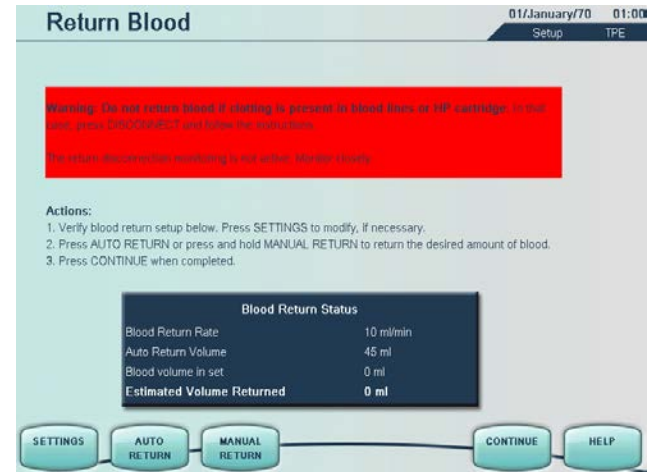
AUTO RETURN

MANUAL RETURN

Auto Return Volume: 75% of the filter set volume programmed into the Prismaflex.

The user has the possibility to increase 'Auto Return Volume' on the 'Enter Blood Return Settings' screen.

Range for Auto Return Volume: Depending on the set in use (example: 75 to 230 ml for M100 set).

Usability: Auto Blood Return

Improved handling during 'End' mode

By pressing the AUTO RETURN soft key the blood will be automatically returned at the programmed flow rate, until the 'Auto Return Volume' is reached.

When the set amount is reached, the AUTO RETURN soft key becomes inactive, unless user goes back to settings screen to increase the 'Auto return Volume'. The maximum volume that can be return automatically is 150% of the disposable set volume.

MANUAL RETURN remains active.

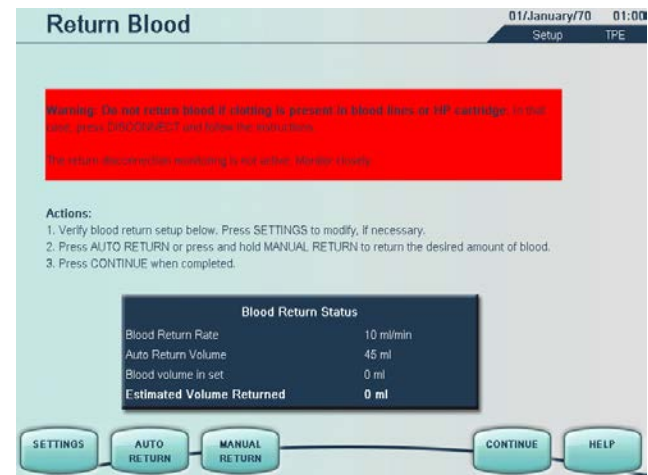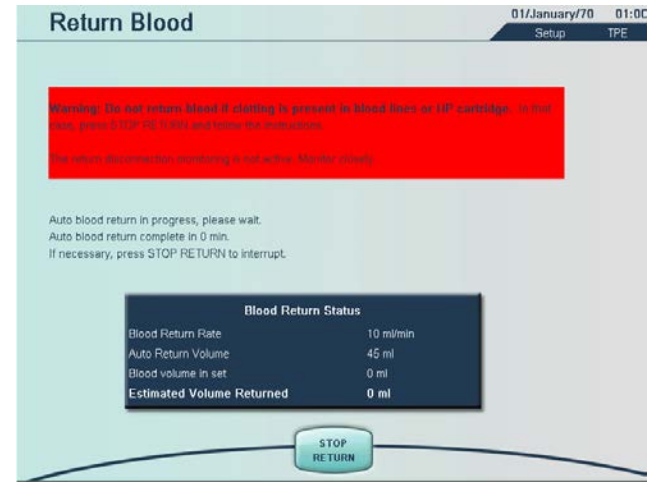Note: Automatic blood return is disabled when:

Cumulated Volume Returned is equal to/ greater than Auto Return Volume

The set has been blood primed

'Warning: Filter Clotted' alarm has been triggered

'Warning: Plasmafilter Clotted' alarm has been triggered

'Warning: HP Cartridge Clotted' alarm has been triggered

Return Blood — 01/January/70 01:00 — Setup — TPE

Warning: Do not return blood if clotting is present in blood lines or HP cartridge. In that case, press STOP RETURN and follow the instructions.

The return disconnection monitoring is not active. Monitor closely.

Auto blood return in progress, please wait.
Auto blood return complete in 0 min.
If necessary, press STOP RETURN to interrupt.

Blood Return Status

Blood Return Rate	10 ml/min
Auto Return Volume	45 ml
Blood volume in set	0 ml
Estimated Volume Returned	0 ml

STOP RETURN

Return Blood — 01/January/70 01:00 — Setup — TPE

Warning: Do not return blood if clotting is present in blood lines or HP cartridge. In that case, press DISCONNECT and follow the instructions.

The return disconnection monitoring is not active. Monitor closely.

Actions:
1. Verify blood return setup below. Press SETTINGS to modify, if necessary.
2. Press AUTO RETURN or press and hold MANUAL RETURN to return the desired amount of blood.
3. Press CONTINUE when completed.

Blood Return Status

Blood Return Rate	10 ml/min
Auto Return Volume	45 ml
Blood volume in set	0 ml
Estimated Volume Returned	0 ml

SETTINGS | AUTO RETURN | MANUAL RETURN | CONTINUE | HELP
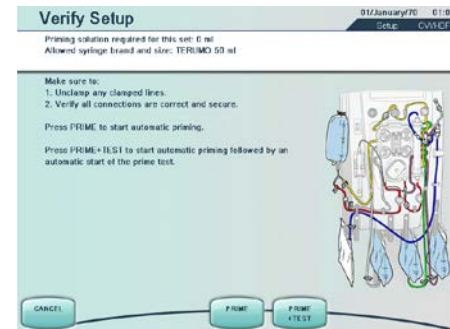
Other Changes

All bag/scale related alarms display the color coded shapes associated with the specific scale (see shapes right side).

Existing graphics are replaced with improved displays (see right side for example).

Updated 'Verify Setup' screen:

Displays a new soft key titled PRIME + TEST.

IMPORTANT: Selecting PRIME + TEST skips Priming, N of N Cycles Complete screen and Priming Complete screen. System moves directly from prime to self test without operator intervention.
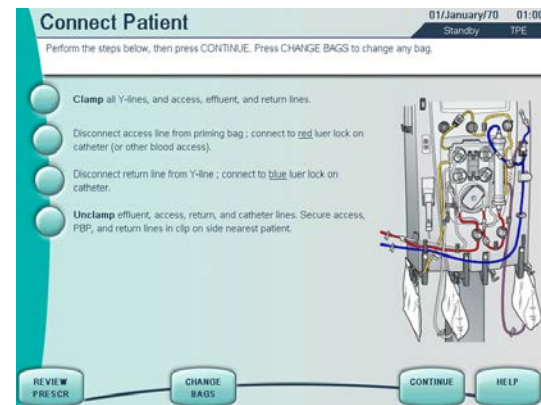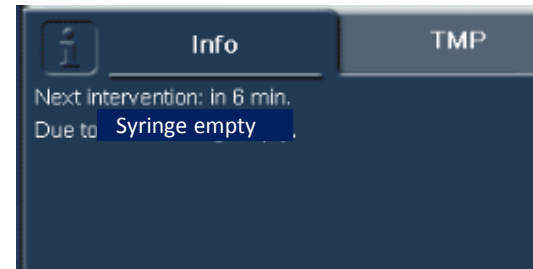
Other Changes

On the Info tab of the 'Status' screen, a message is displayed to indicate when the Prismaflex syringe will be empty under the 'Next Intervention' message.

NOTE: Always verify in 'Custom Mode' the displayed syringe brand/size is the same brand/size installed in the syringe holder.

The 'Connect Patient' screen now has a CHANGE BAGS soft key.

This allows the user to change a solution/effluent bag before the treatment starts. This is very useful during a TPE treatment.
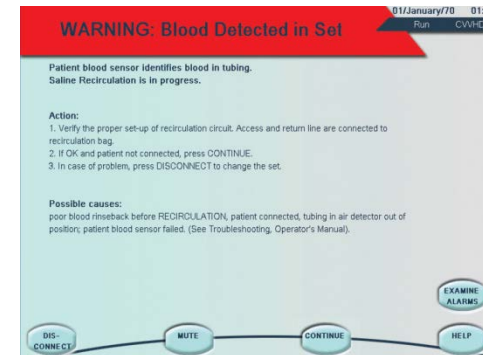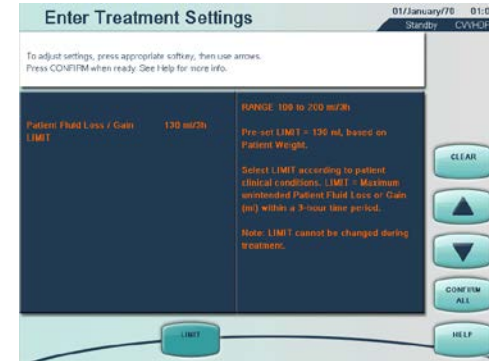
Other Changes

Because of the improved pressure alarm management, the 'Access Pressure Range' soft key is now obsolete and removed from the 'Enter Treatment Settings' screen.

NOTE: The LIMIT for the unintended patient Fluid loss or gain remains to be set on this screen.

The patient sensor is no longer enabled. All related alarms (i.e. Blood Detected in Set) and related calibration screens are removed.

prismaflex SW 7.1 Key Notes

Other Changes

Removal of 780 liters limit for sets.

Removal of pressure pod adjustment procedure from GUI and Operator's Manual.

Syringe pump can no longer be 'Disabled' during treatment.

Possibility to suspend the 'ADVISORY: Blood Flow Stopped' alarm for 1 minute (CONTINUE goes back to 'Stop' screen). The alarm will be generated again when >1 minute in 'Stop' screen.

Removed: 10cc syringe option.

Other Changes

OVERRIDE is no longer allowed in the following alarms:

- MALFUNCTION: No Line in Clamp
- MALFUNCTION: No Line in Air Detector
- MALFUNCTION: Line in Clamp
- MALFUNCTION: Line in Air Detector

Temporary suppression of 'Filter Is Clotting' and 'TMP Too High' advisory alarms after occurrence of 'Caution: Flow Problem' alarms on effluent.

PDMS Improvements:

- Dose added (ml/kg/h)
- PFR added (last completed interval, current interval, current day, ...)

prismaflex SW 7.1 Key Notes

Other Changes

Improvement to syringe rate adjustment (systemic anticoagulation method) – soft keys are more reactive to allow faster increase or decrease of syringe flow rate.

Priority of Warning Alarms improved. 'WARNING: Access Extremely Negative' is prioritized over 'WARNING: Return Pressure Extremely Positive'. This enables the RELEASE CLAMP button when 'WARNING: Return Extremely Positive' occurs simultaneously with 'WARNING: Access Extremely Negative'.

Specific scale alarms are removed
'ADVISORY: Scale Component Missing'
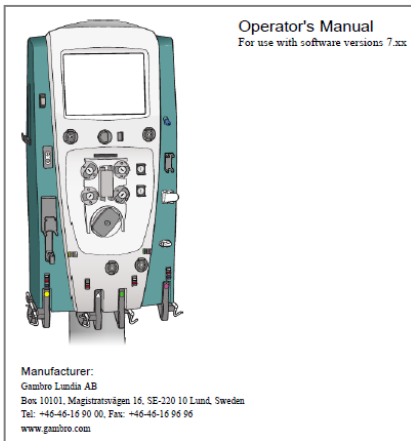'MALFUNTION: Scale Sensor (the alarm remains for Setup Mode)

Other Changes

Self-test Failure Code 20 root cause for the malfunction is displayed through sub codes in the History (Events) and on PCMCIA data cards.

Auditory alarm state remote connection
The remote alarm can now be coupled to the auditory alarm state. If chosen, the MUTE button will silence the (central) remote alarm. Also, the remote alarm will not be triggered during self-test

References

Operator's Manual
For use with software versions 7.xx

Manufacturer:
Gambro Lundia AB
Box 10101, Magistratsvägen 16, SE-220 10 Lund, Sweden
Tel: +46-46-16 90 00, Fax: +46-46-16 96 96
www.gambro.com

Prismaflex Operator's Manual SW 7.11
Prismaflex Service Manual SW 7.11
Prismaflex GUI SW 7.11