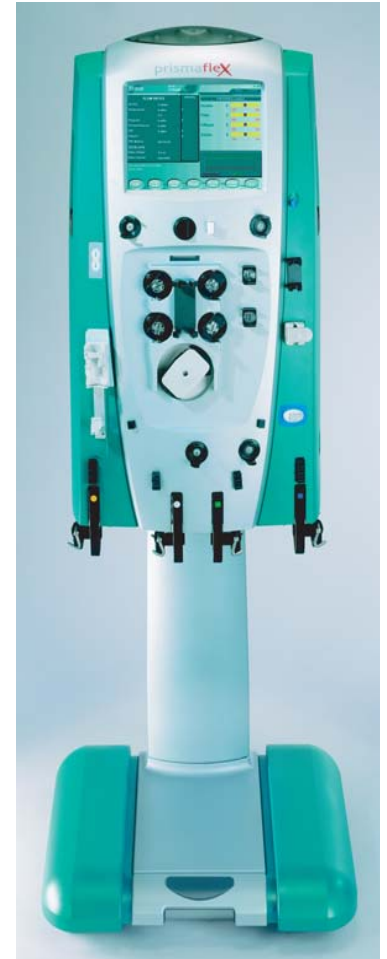


# Prismaflex Machine

prismaflex



# Prismaflex Schematic

# Communication Unit

- Give a general indication of operating conditions.
- **Status Lights**
  - **Green** Indicates all parameters are normal during treatment
  - **Yellow** Indicates advisory or caution alarm
  - **Red** Indicates highest priority alarm and needs immediate intervention.



# Load Set

01/January/70

01:00

You have chosen: **NoCh** . If incorrect, press CANCEL. Perform the steps below, then press LOAD.

Setup

NoCh

Snap cartridge into carrier. Route lines through tubing guides.

Attach all pressure pods.

Press effluent line into blood leak detector ; snap discharger ring into its guide.

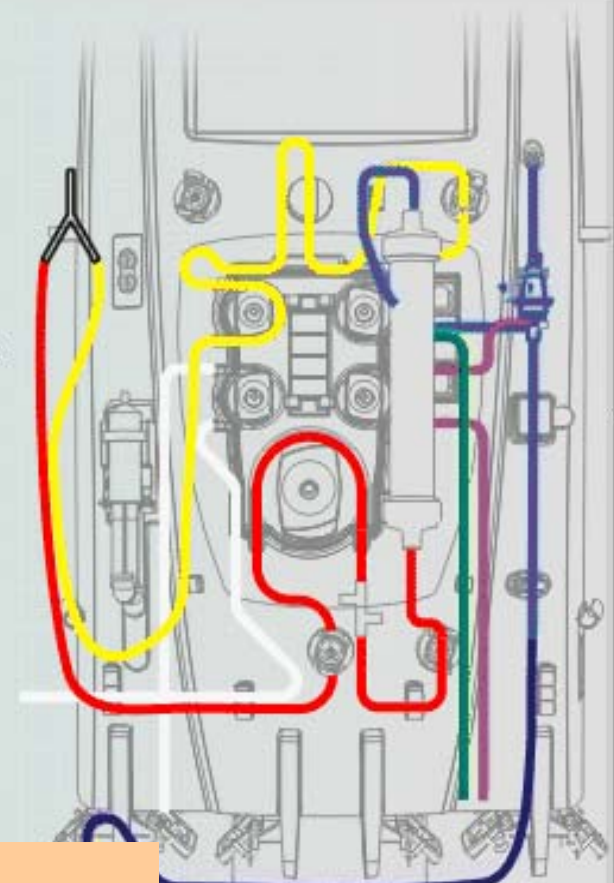
Temporarily hang access/effluent Y-line on priming hook.

Place deaeration chamber in its holder ; attach chamber monitor line to the return pressure port.

Insert return line into air detector and return line clamp.

Open

Interactive display is your command center. It provides screens to guide you through the functionalities of the machine. The contents of the display depend on the software mode and operations at the moment.



CANCEL

LOAD

HELP

# Status

Pt ID:  
Pt Weight: 0 Kg

01/January/70 01:00

Setup  NoCh  
Currently Delivering: SCUF

## FLOW RATES

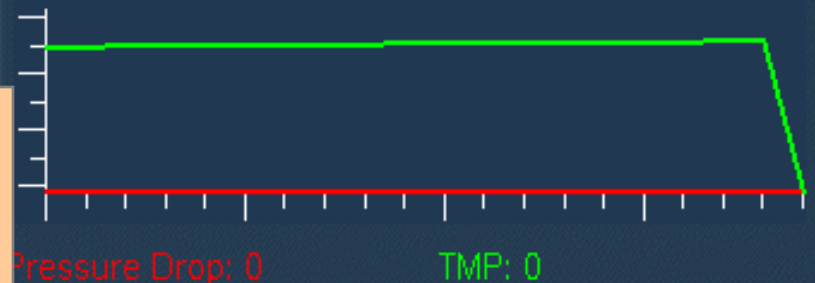
ml/hr/Kg

BLOOD	0 ml/min	
Replacement	0 ml/hr	0
	Pre	
Dialysate	0 ml/hr	0
Pt Fluid Removal	0 ml/hr	
PBP	0 ml/hr	0
Effluent		0
PBP Method	INFUSION	
<u>Syringe pump</u>		
Bolus Volume	0.0 ml	
Bolus Interval	Immediate	

## PRESSURES ( mmHg )

Access	0	
		-500 500
Filter	0	
		-500 500
Effluent	0	
		-500 500
Return	0	
		-500 500

The status screen is the main operating screen while a treatment is underway. You can see pressure conditions in the set and the flow rate settings at a glance.



STOP

FLOW RATES

CHANGE BAGS

HISTORY

SYSTEM TOOLS

EXAMINE ALARMS

HELP

# Flow Control Unit

# Control Unit

● Effluent pump: Pumps ultrafiltrate/dialysate.  
Automatically controls the ultrafiltration rate in the filter, based on the current patient fluid removal, pre-blood pump, replacement and dialysate pump rates. Max flow: 10,000ml/hr

● Pumps replacement solution into the blood flowpath. Max flow: 8000ml/hr



● Pumps dialysate into the fluid compartment of the filter. Max flow:



8000ml/hr.

Pinch Valves:

Mechanisms that hold the pinch valve segments of the Prismaflex Set. The valves open/close automatically and allow pre and post filter options for infusing replacement solution.



# Flow Control Unit

## Blood pump

Occlusive, peristaltic pump that conveys blood through the blood flowpath of the set and back to the patient. Blood source may be directly from patient, or from a device, such as an ECMO machine. Flow rate up to 450ml/min.

## Pre-blood pump (PBP)

△ Can be used to deliver a sterile infusion solution into the blood access line before the blood pump. May be used for anticoagulation strategies or for pre-dilution. Max flow rate: 8000ml/hr. Prismaflex does not allow the PBP rate to exceed the blood flow rate.





# Control Unit



## **Scale hook assembly**

Slide-out bar tray and removable carrying bar for hanging/removing fluid bags. Rotate the handle of the carrying bar downwards, then push the bar tray into the scale to close it.



## **Scales**

### **Effluent**

### **Pre-blood pump (PBP)**

### **Dialysate**

### **Replacement**

Precision scales independently monitor the weight of each bag and control ultrafiltration and patient fluid removal.

## **Tubing guides**

Secure the lines of the set in position on the control unit. The guide color matches the color of the set line it holds.

# Flow Control



**Pressure sensor housing**  
**Access**  
**Filter**  
**Effluent**  
**Unused (for future therapies)**

Each pressure sensor housing holds the corresponding pressure pod of the Prismaflex Set and provides a connection between the pod and an internal pressure sensor. This provides non-invasive pressure monitoring of the access line, filter, and effluent line. There are no air-blood interfaces.

# Control Unit



## **Syringe pump assembly**

Delivers anticoagulant or other solution into the blood flowpath via a syringe. Delivery can be continuous or in boluses (See Prismaflex Operator Manual for specification).

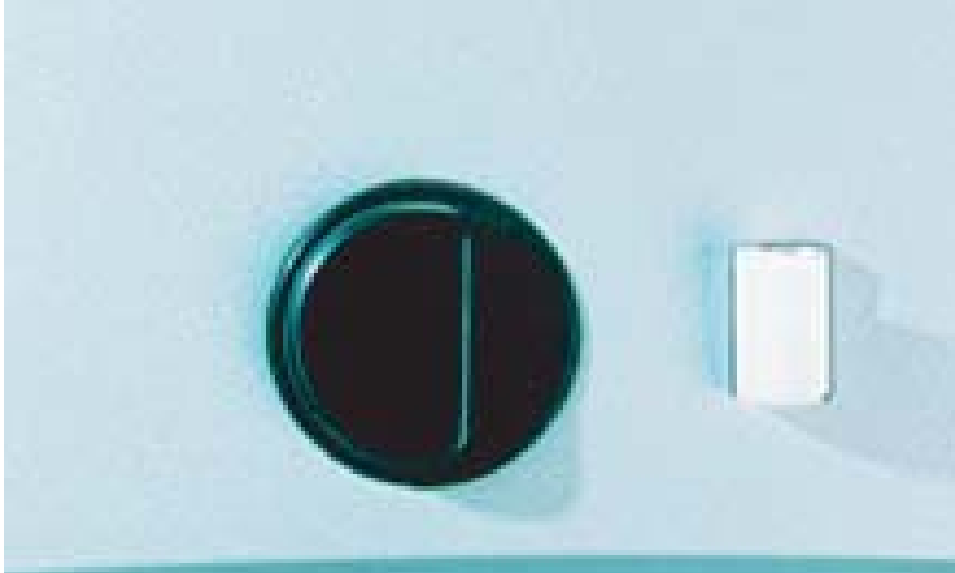
## **Syringe pump control panel**

UP and DOWN buttons on the machine allow you to install or remove a syringe.

## **Bar code reader**

Each type of Prismaflex Set has its own range of alarm limits and flow rate possibilities. When a set is loaded, the bar code reader automatically scans the identification code. The control unit then accesses the correct operating ranges and priming sequence. This is an important, proactive safety feature.

# Control Unit



## **Cartridge carrier**

Houses the cartridge of the Prismaflex Set and moves inward to automatically load the set into the pumps raceways.

## **Blood leak detector (BLD)**

Continuously monitors the effluent line for the presence of red blood cells.

## **Discharger ring guide**

Holds the discharger ring, located on the effluent line of the Prismaflex Set. Provides an electrical ground and minimizes electrical interference with other ICU devices.

# Control Unit



## **Return pressure port**

Provides a connection between an internal pressure sensor and the monitor line of the set's deaeration chamber. Non-invasive pressure monitoring of the deaeration chamber and return line is provided. A fluid barrier in the monitor line protects the interior of the control unit from accidental fluid entry.

## **Deaeration chamber holder**

Secures the deaeration chamber, which is located on the return line of the Prismaflex Set.

## **Ultrasonic air bubble detector (UABD)**

Continuously monitors the return line for air bubbles. Within the housing are also a tubing detection switch and a blood sensor. These sensors provide additional monitoring of return line conditions while you are setting up for treatment.

## **Return line clamp**

This occlusive safety clamp closes if any condition of possible patient hazard is detected. The clamp prevents blood and/or air from passing to the patient. A tubing detection switch is also in the clamp housing, allowing Prismaflex to notify you if the return line is not correctly installed in the clamp.

# Sets, Therapies and Bags



## **SAMPLE SITES**

- **Effluent line**
- **Access line** before the blood pump
- **Access line** (filter) after the blood pump
- **Return line** before the blood warmer connectors and deaeration chamber.

Sample sites are color-coded ports with a latex free plug that allows needle entry. You can use these to obtain fluid or blood samples, or to remove trapped air.

## **BLOOD WARMER CONNECTOR**

This luer-lock connector allows you to attach a disposable set for a blood warmer. The connection is made to the return line before the deaeration chamber. The warmer set must be connected during Setup procedures—it is automatically primed along with the Prismaflex Set.

# Sets, Therapies and Bags



## **DEAERATION CHAMBER**

Manages air

Bottom to top blood flow in the set promotes continuous elimination of air. In the return line, the deaeration chamber provides a unique conveyance path that works like a vortex to propel all air out of the blood. Post-filter replacement solution is added into the deaeration chamber on top of the blood. Using a minimum of 200 to 500 ml/hr of post filter replacement will prevent air/blood interface. This is recommended to minimize clotting and foaming into deaeration chamber.

## **Semi-automated fluid level adjustment**

Arrow keys on a special screen allow you to easily adjust the fluid level up or down in the chamber.

## **DEAERATION CHAMBER MONITOR LINE**

Connects the deaeration chamber to an internal pressure sensor, enabling return pressure monitoring and removal of air from the chamber, if needed. A **fluid barrier** at the end of the line protects the interior of the control unit from accidental blood/fluid entry.

**Tightening the connections is part of your usual setup and treatment management duties.**

# Sets, Therapies and Bags



## **PRESSURE PODS**

**Effluent**

**Access**

**Filter**

These integral pressure monitoring components connect with pressure sensors inside the machine. A diaphragm in the pod moves according to the pressure exerted by the fluid flowing in the line. The internal pressure sensor converts this motion to a pressure reading...

When treatment begins, access pressure is sensed to establish the type of blood source (negative or positive pressure). Software then activates the correct access pressure monitoring range.



# Sets, Therapies and Bags



## **Discharger ring**

This component on the effluent line installs in the ring guide on the control unit. Provides an electrical ground and minimizes electrical interference with other ICU devices.

## **Spike/Luer lock connector**

Located at the tip of each solution line, you may use either the spike or the luer lock to connect to the fluid bags. If you're using the luer lock, you need to remove the spike.





Warning: Patient Hazard

Needs immediate attention all pumps stop.



Malfunction: System Hazard

Needs immediate attention all pumps stop.



Caution: Condition requires stopping of fluid pumps. Patient safety and system not at immediate risk. Operator action is needed. Treatment suspended; blood and syringe flow continues.



Advisory: Informs of a condition or needed action. Patient and system not at immediate risk. Treatment continues.

# Alarm Screens

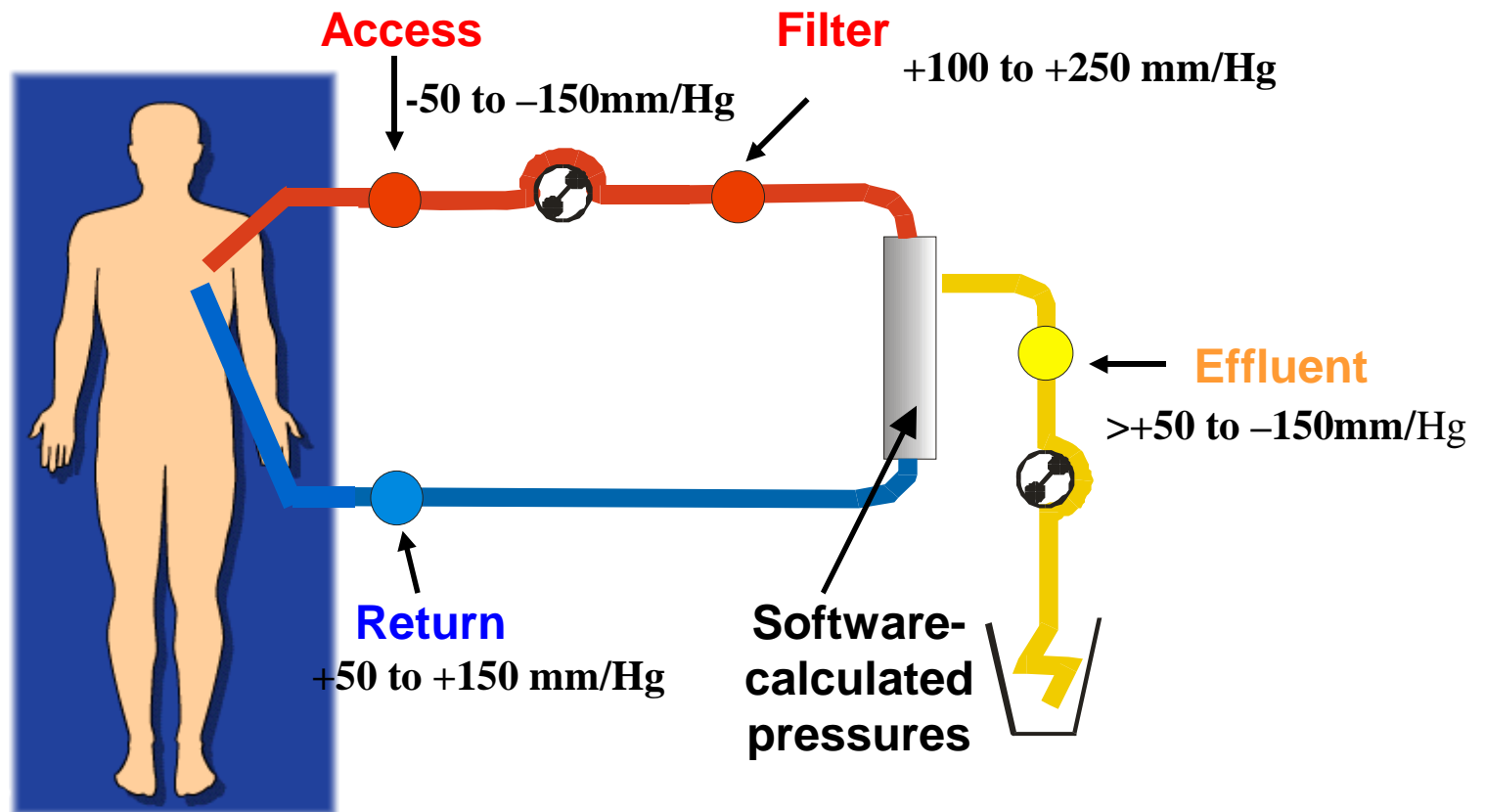
- Each alarm screen has its own specific combination of softkeys which may be needed to remedy the situation.
- Softkeys
  - Mute: Silences alarm beep for 2 minutes.
  - Retest: Retests for the alarm condition.
  - Override: Overrides alarm for 60 seconds. After the override period, if alarm condition is not present, the alarm clears.
  - Continue: Clears alarm and restarts stopped pumps. If the problem still exists, alarm recurs.
  - New Set: Allows loading of a new set as part of remedying the alarm.
  - Open Clamp: Opens the return line clamp as part of remedying the alarm.

# Examine Alarms

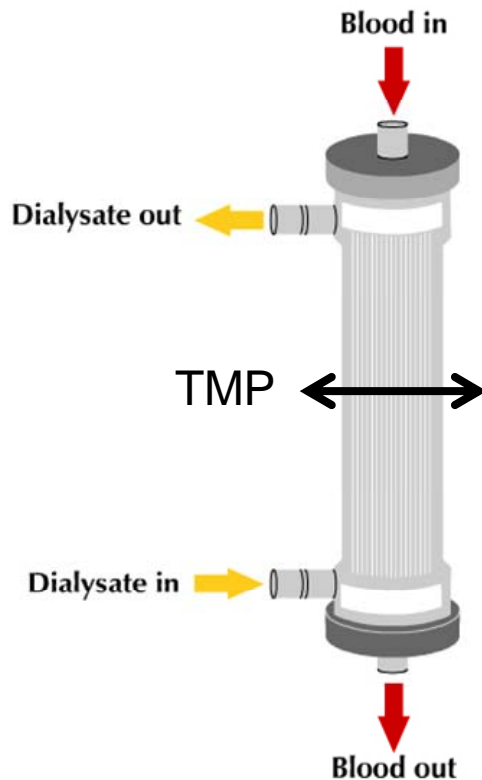
- An active alarm always causes the EXAMINE ALARMS key to appear on the currently displayed screen. Pressing this softkey accesses an Examine Alarms screen, which lists all active alarms in the order of their priority.

# Pressure Monitoring System

Pressure conditions are continually monitored in the access, effluent, and return lines, and in the filter.



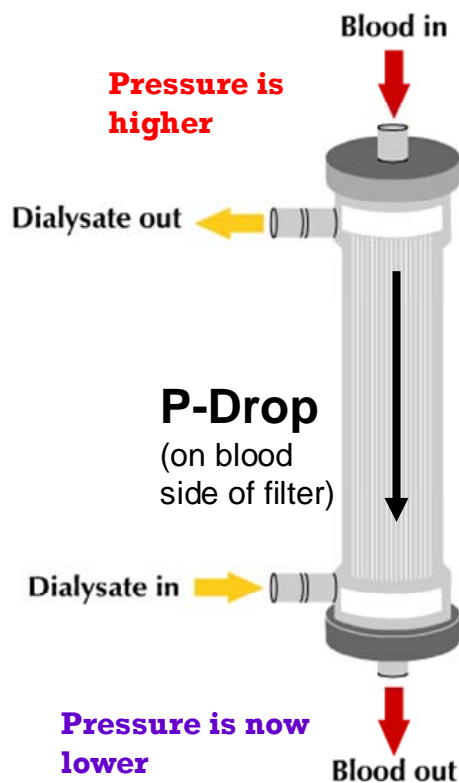
# Transmembrane Pressure (TMP)



- **TMP is the pressure exerted on the filter membrane during operation. It reflects the pressure difference between the fluid and blood compartments of the filter.**
- **During treatment, permeability of the membrane decreases due to protein coating on the blood side. This causes TMP to increase.**
- **TMP is calculated and automatically recorded when:**
  - **Entering Run mode (when pumps have attained proper speed and blood flow is stabilized).**
  - **Blood flow rate is changed**
  - **Pt. fluid removal rate is changed**
  - **Replacement solution rate is changed**

$$\text{TMP} = \frac{\text{Filter Press.} + \text{Return Press.}}{2} - \text{Effluent Press.}$$

# Filter Pressure Drop (P-Drop)



- **Pressure Drop is the pressure reduction that occurs as blood flows through the filter.**
- **Microclotting** can occur in the hollow fibers. This **creates resistance** as blood flows through, thus **Pressure Drop increases over time.**
- Microclotting eventually leads to a buildup of gross clotting and the need to change to a new Prismaflex Set.
- Pressure Drop is calculated and automatically recorded when:
  - Entering Run mode (when pumps have attained proper speed and blood flow is stabilized).
  - Blood flow rate is changed

## Example:

	<u>Start</u>	<u>After 24 Hours</u>
Filter :	100 mmHg	200 mmHg
Return :	<u>90 mmHg</u>	<u>110 mmHg</u>
Difference:	10 mmHg	90mmHg

**P-Drop increased by 80 mmHg**

## Formula:

**P-Drop = Filter Press. - Return Press.**



# Pressure During Operation

- **“Cannot Detect Disconnection”** Triggered when a pressure is too close to zero to be able to sense a line connection.
  - In order for this alarm not to occur the access pressure should be  $-10$  and the return pressure should be  $+10$ .
- **Pressure Trending** is triggered when a pressure changes from its established operating point by  $50\text{mm/Hg}$ 
  - For blood flow rates above  $200\text{ml/min}$ , the change must be  $70\text{ mm/Hg}$ .

# Start Treatment Troubleshooting

# ADVISORY: Identify Access Range

**Monitoring range for access pressure cannot be determined. Access line pressure is between -10 mmHg and +10 mmHg.**

Negative Access Pressure Range: -250 mmHg to 0 mmHg

Positive Access Pressure Range: 0 mmHg to 300 mmHg

**Action:**

1. Ensure access line is securely connected to the blood source.
2. Press appropriate softkey (right) to identify the access pressure range for the blood source.

**Negative Range** - Patient central venous catheter

**Positive Range** - External blood access device ; patient arterio-venous fistula ; patient arterial catheter

3. If the chosen pressure range is correct, press CONTINUE. If wrong, press CLEAR again.

NEGATIVE RANGE

CLEAR

POSITIVE RANGE

Positive range monitoring is less common. Pressing POSITIVE and CONFIRM requires a second confirmation from the operator.

BACK

MUTE

CONTINUE

HELP

# ADVISORY: Confirm Access Range

## Negative Access Pressure Range: -250 mmHg to 0 mmHg

**Negative Range** – Patient central venous catheter


**Positive Range** – External blood access device ; patient arterio-venous fistula ; patient arterial catheter

### Options:

- If the above pressure monitoring range is appropriate for the blood source, press CONFIRM to proceed with treatment.
- If range is not correct, resolve other possible causes ; press RETRY. If access pressure range cannot be resolved, press CHANGE SET, unload and try with a new set.

**Other possible causes:** Access pod removed after priming ; access pressure sensor failed.  
(See Troubleshooting, Operator's Manual).

**The machine measures the access pressure and reports its best “guess” for proper monitoring range. If guess is right, press CONFIRM. If guess is wrong, one RETRY measurement is allowed. Before retrying, resolve any other possible causes. If machine guess is again wrong, you’ll need to change the set.**

 EXAMINE  
ALARMS CHANGE  
SET MUTE RETRY CONFIRM HELP

# Manage Treatment Troubleshooting

**When troubleshooting, just  
remember  
the three “commandments”!**



**Read the screen  
Follow the steps  
Check your Operator's  
Manual**

# ADVISORY: Self-Test in Progress

**Test complete in: min. 1 minute, max. 6 minutes.  
Monitor closely.**

- Periodic self-test is underway.
- This test occurs every 2 hours to ensure proper functioning of safety systems.
- Return clamp is closed and opened during the test.

Ten minutes into treatment and every two hours, Prismaflex, does a self-test.

MUTE

# CAUTION: Dialysate Bag Empty

Setup

NoCh

**Audible alarm advises that treatment is suspended ; press MUTE to silence. To change the bag, perform the steps below.**

1. Open scale. Clamp bag and line ; disconnect bag.
2. Connect new bag to line ; unclamp bag and line. Close scale.
3. **If changing to a larger/smaller bag:** Press MODIFY BAG and use arrows to set a new Allowed Volume.
4. When ready, press CONTINUE.

You should wait for the alarm before changing any bag. An exception might be physician-ordered changes to a prescribed solution. In that case, you would use CHANGE BAGS on Status screen.

Always physically open and close the scale. This is required for accurate fluid flows and patient fluid removal.

Dialysate

0 ml

Volume ( ml )

-10000 to 10000 ( Increment: 1 ml )

Other possible cause: bag partially supported.

CLEAR



EXAMINE ALARMS

MODIFY BAG VOL

MUTE

CONTINUE

HELP



# CAUTION: Effluent Bag Full

**Audible alarm advises that treatment is suspended ; press MUTE to silence. To change the bag, perform the steps below.**

1. Open scale. Clamp bag and line ; disconnect bag.
2. Connect new bag to line ; unclamp bag and line. Close scale.
3. **If changing to a larger/smaller bag:** Press **MODIFY BAG** and use arrows to set a new Allowed Volume.
4. When ready, press **CONTINUE**.

Here's another "bag change" alarm. Be sure to physically open/close the scale when changing any bag. This is required for accurate fluid flows and patient fluid removal.

**Effluent** 5000 ml

**Other possible cause:** Foreign object on effluent scale.

CLEAR



EXAMINE ALARMS

MODIFY BAG VOL

MUTE

K4

CONTINUE

HELP

# Common Alarms

# WARNING: Access Extremely Negative

**Self-clear attempt in progress.**

Alarm self-clears if pressure goes back to normal limits within 8 s.

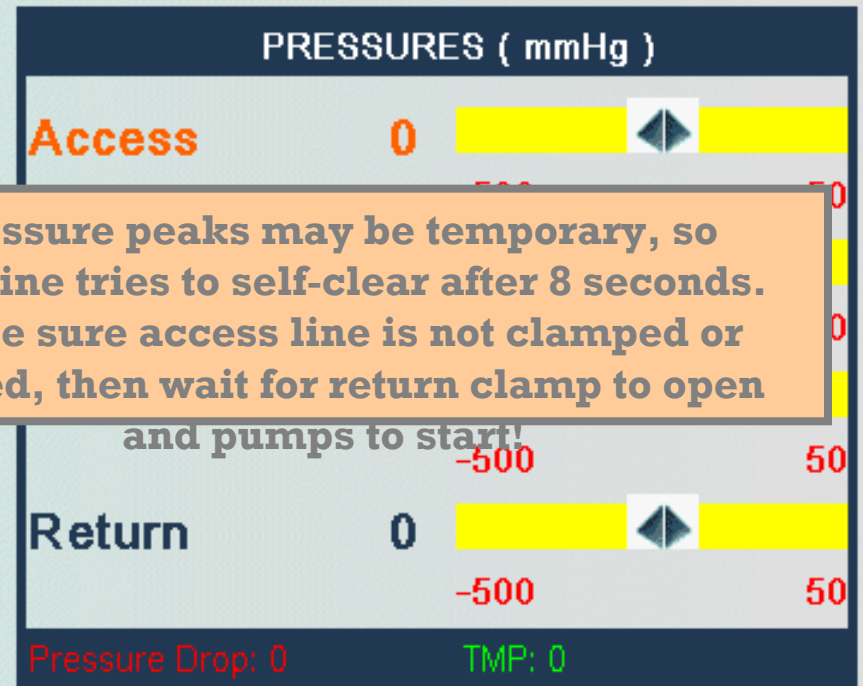
**Action:**

1. Ensure access line is not clamped, kinked or obstructed by sudden patient movement.
2. Assess positioning of the patient and catheter ; make corrections if needed.

Note: If self-clear fails, further instructions appear.

**Other possible causes:**

Access catheter clotted or out of position in vein ; patient is moving or being moved ; patient being suctioned ; blood rate too high ; access pressure sensor failed. (See Troubleshooting, Operator's Manual).



**Pressure peaks may be temporary, so machine tries to self-clear after 8 seconds. Make sure access line is not clamped or kinked, then wait for return clamp to open**

**and pumps to start!**

**If self-clear fails, your troubleshooting expertise is needed. Let's see how to do this!**


MUTE

EXAMINE ALARMS

HELP

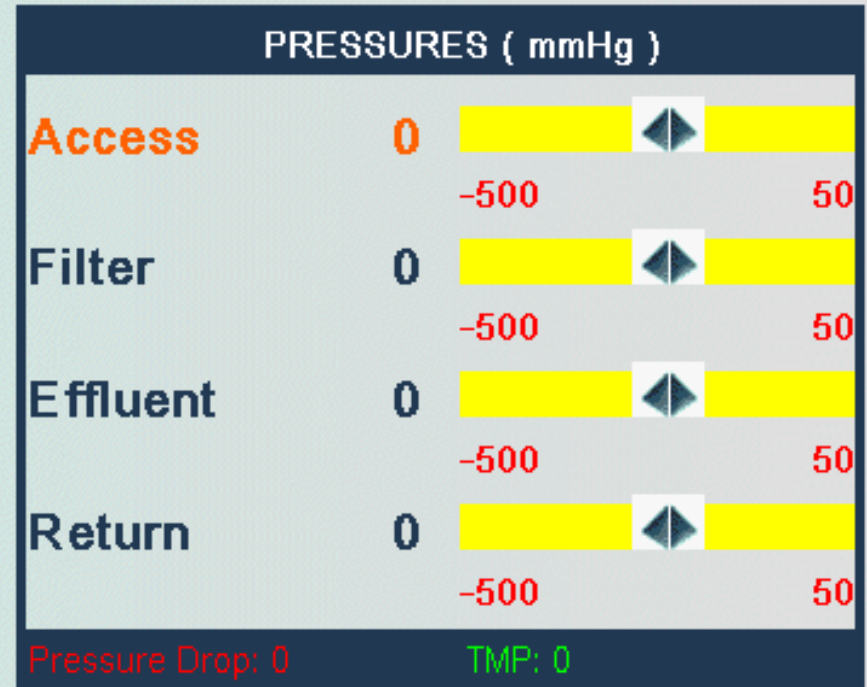
# WARNING: Access Extremely Positive

### Action:

1. Ensure access line connection is not clamped, kinked, or clotted. 
2. Check external device (if in use) and reduce pressure at which blood is being delivered into the access line.
3. Press CONTINUE.

### Other possible causes:

Access line kinked or clamped between access pressure pod and the blood pump ; blood rate too low ; patient coughing ; access pressure sensor failed. (See Troubleshooting, Operator's Manual).



STOP    FLOW RATES    MUTE    CONTINUE    EXAMINE ALARMS    HELP

# WARNING: Return Extremely Positive

## Self-clear attempt in progress.

Alarm self-clears if pressure goes back to normal limits within 8 s.

### Action:

1. Ensure return line is not clamped, kinked or obstructed by sudden patient movement.
2. Assess positioning of the patient and catheter ; make corrections if needed.



Note: If self-clear fails, further instructions appear.

### Other possible causes:

Return catheter clotted or out of position in vein ; patient is moving or being moved ; patient coughing or being suctioned ; blood rate too high ; return pressure sensor failed.

**PRESSURES ( mmHg )**

Pressure peaks may be temporary, so alarm self-clears if possible. Make sure return line is not clamped or kinked, then wait for clamp to open and blood pump to start!

<b>Effluent</b>	0	
	-500	50
<b>Return</b>	0	
	-500	50

Pressure Drop: 0      TMP: 0

**If self-clear fails, your expertise is needed!  
Let's learn a couple of special points about troubleshooting this alarm!**

EXAMINE ALARMS

MUTE

HELP

# ADVISORY: Filter is Clotting



## Increasing TMP and/or Pressure Drop.

TMP can be lowered by:

- Decreasing the replacement and/or patient fluid removal rates.
- Increasing the blood flow rate.

Increasing Pressure Drop may be due to:

- Kinked lines in blood flowpath.
- Inadequate anticoagulation of the extracorporeal circuit.
- Air leak or failure at return or filter pressure sensor.

Other possible causes: (See Troubleshooting, Operator's Manual).

This alarm self-clears if condition no longer exists.

**This notification occurs if internal filter pressures reach certain limits. OVERRIDE removes alarm screen.**

- Delay/prevent clotting:**
- Adequate anticoagulation
  - Lower ultrafiltration rates
  - Higher blood rates

EXAMINE ALARMS

STOP

FLOW RATES

MUTE

OVERRIDE

HELP

# WARNING: Filter Clotted

Setup

NoCh

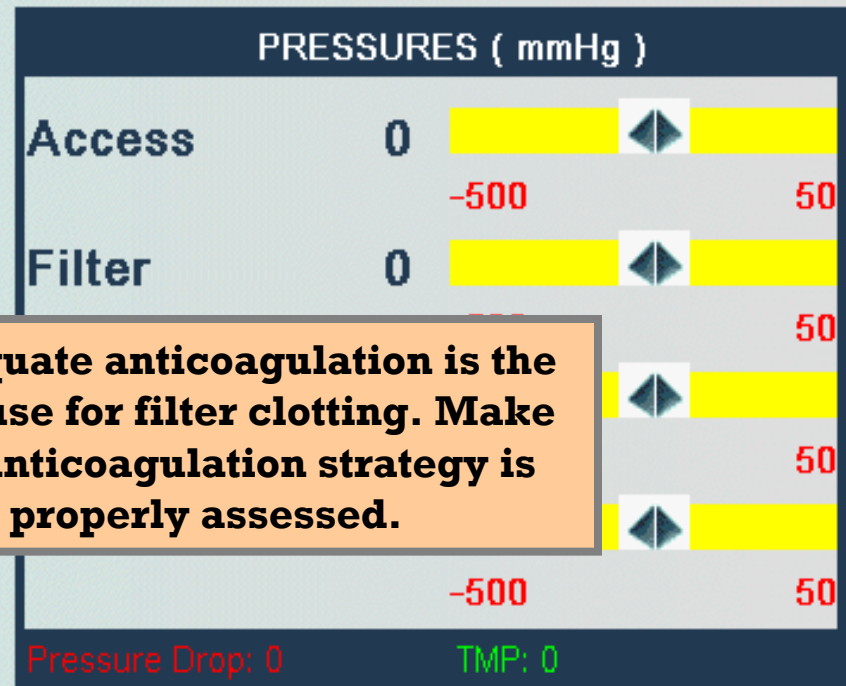
Clots have formed in the filter.  
Press STOP and change the set.

### Other possible causes:

Clamped lines in blood flowpath ; replacement solution flow rate too high ; syringe improperly installed ; syringe pump failed.

**Did this alarm occur suddenly, with no prior clotting advisory? If yes, consider Other possible causes.**

**Inadequate anticoagulation is the top cause for filter clotting. Make sure anticoagulation strategy is properly assessed.**

EXAMINE  
ALARMS

STOP

MUTE

CONTINUE

HELP

# Additional Troubleshooting



# WARNING: Air in Blood

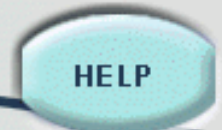
**Return pressure is: 0 mmHg**

Always stop and read instruction to solve alarms.

1. Open door of air detector and look for air/foam in the tubing ; inspect level of fluid in deaeration chamber. If necessary do Step 2, otherwise, proceed to Step 3.
2. **If air/foam is present OR if fluid level in chamber is abnormal, do the following:**
  - (a) Press Up arrow until return pressure is NEGATIVE ( 0 to -150 mmHg).
  - (b) Press RELEASE CLAMP to remove air and draw blood from patient into the return line/deaeration chamber.
  - (c) If needed, press ADJUST CHAMBER and use arrows to adjust the level of fluid in the chamber.
3. When ready, close air detector door ; press CONTINUE.

## Other possible causes:

Disconnected line, leaking connection, set not fully primed, return line not installed in air detector. (See Troubleshooting, Operator's Manual).



# WARNING: Blood Leak Detected

**VERRIDE overrides this alarm for 60 seconds. Monitor closely. Leak in filter membrane. Press STOP and change the set.**

Stop and change the set if blood is visualized in the effluent line/bag.

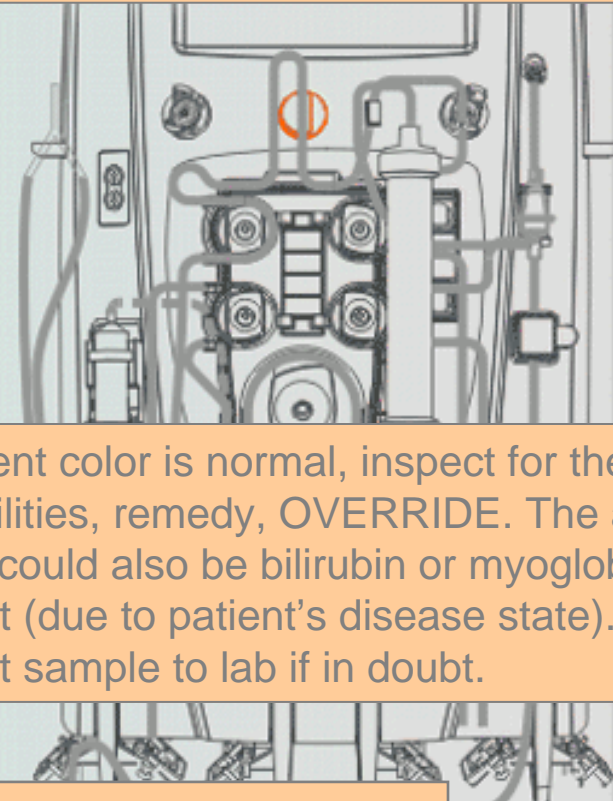
**WARNING: If effluent line is repositioned or removed/reinserted in blood leak detector, detector must be reset by pressing NORM BLD on System Tools screen after alarm clears.**

**Other possible causes:**

Air bubble in effluent line ; effluent line not properly installed in detector ; liquid or other debris in tubing path through detector, discolored plasma during a TPE procedure. (See Troubleshooting, Operator's Manual).

If effluent color is normal, inspect for these other possibilities, remedy, OVERRIDE. The alarm's cause could also be bilirubin or myoglobin in the effluent (due to patient's disease state). Send effluent sample to lab if in doubt.

Important. If you manipulate the effluent line in order to remedy the alarm, the blood leak detector must be reset (renormalized) before continuing with treatment.



STOP

MUTE

OVERRIDE

EXAMINE ALARMS

HELP

# Normalize Blood Leak Detector

01/January/70

01:00

Signal Value: 0

Setup

NoCh

**WARNING:** Before normalizing, fluid in effluent line must be tested and verified to be free of blood.

Perform the steps below.

- 1. Required** - Draw a sample from effluent line and test for blood. **If blood present, discontinue ; press CANCEL and change the set.** If no blood, go to Step 2.
2. Verify the signal value is 38.000 or greater. If necessary, move effluent line slightly up or down in the blood leak detector to raise the signal value.
3. When Steps 1 and 2 are complete, press START NORM. (When normalization finishes, control unit automatically returns to Status screen.)

Pumps run and treatment continues. The blood leak detector re-sets the “normal” signal value to match the signal value it is currently sensing. This is why it is vital to verify that effluent line is free of blood at the time of normalization.

CANCEL

START  
NORM

EXAMINE  
ALARMS

HELP

**IMPORTANT DETAILS**

# Important Detail

## PBP Rate and Blood Pump Speed

- Software increases the blood pump speed to maintain the BFR at the access site
- PBP scale limits: 250cc to 4000cc
- Flow rates 0-8L/hr (Specific to therapy and set)

# Important Detail

## Blood Pump and PBP Calculation

- Operator-set BFR + Operator-set PBP rate/min = Blood pump speed

Example:

$100 + (1000/60) = 117\text{cc/min}$  Blood pump speed

- You will not see the setting change, it calculates internally.

# Important Details

- To change a bag you must follow these steps:
  - Only open the scale when the machine alerts you to change a bag.
  - Or, when the change bag is selected.
- Always open and close scales to change a bag.





# Important Details

- When loading a new bag you must open the scale to hang the bag and then close scale.
  - This action let's the machine know that a new bag is being hung, when the scale is closed the software reweighs the bag.
- If the bag is hung without opening the scale the machine cannot accurately weigh the bag.
  - This can cause weight incorrect alarms!

# Important Details

- Weight incorrect alarms are important and should be taken seriously.
  - When you receive this alarm it is telling you to check that the bag is unclamped, frangible pin is broken or is fully spiked. After considering these interventions select change bag key open the indicated scale lift hook off scale place back on scale and close scale. This will allow the machine to reweigh bags.

# Important Details

- If weight incorrect alarms are not resolved and the operator continues treatment the patient fluid removal can be compromised.
- The operator is only allowed 10 attempts in 3 hours to correct weight incorrect alarms.
- Once the 11<sup>th</sup> attempt is activated the Prismaflex will suspend treatment and require operator to return blood to patient.
- Weight incorrect alarms can be caused by the Dialysate, Replacement, and PBP.

# Important Details

- **Deaeration Chamber**
  - **Always monitor chamber level during treatment.**
    - **Great way to remember to check level is to do it when you are doing hourly I/O values.**
  - **Keep fluid level at the line on the deaeration chamber at all times for the following reasons:**
    - **If the fluid level is too high and if the return line clamps off the fluid can be pushed into the machine.**
    - **If the fluid level is too low then an “Air in Blood” alarm will occur.**

# Recirculation

Discontinue Treatment