PrismaFlex

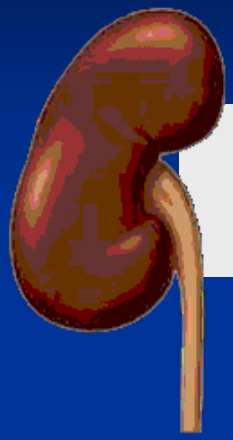
Basic CRRT Principles

Continuous Renal Replacement Therapy (CRRT)

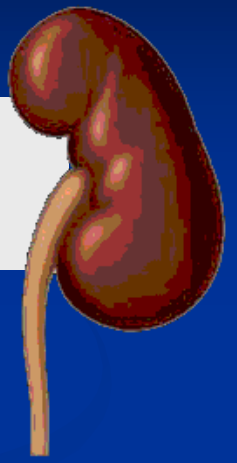
““Any extracorporeal blood purification therapy intended to substitute for impaired renal function over an extended period of time and applied for or aimed at being applied for 24 hours/day.”

Bellomo R., Ronco C., Mehta R, Nomenclature for Continuous Renal Replacement Therapies, AJKD, Vol 28, No. 5, Suppl 3, Nov 1996

Why CRRT?



CRRT closely mimics the native kidney in treating ARF and fluid overload



- Removes large amounts of fluid and waste products over time
- Tolerated well by hemodynamically unstable patients

CRRT Treatment Goals

- Maintain fluid, electrolyte, acid/base balance
- Prevent further damage to kidney tissue
- Promote healing and total renal recovery
- Allow other supportive measures; nutritional support

CRRT Transport Mechanisms

Molecular Transport Mechanisms

- Ultrafiltration → Fluid Removal
- Diffusion
- Convection
- Adsorption

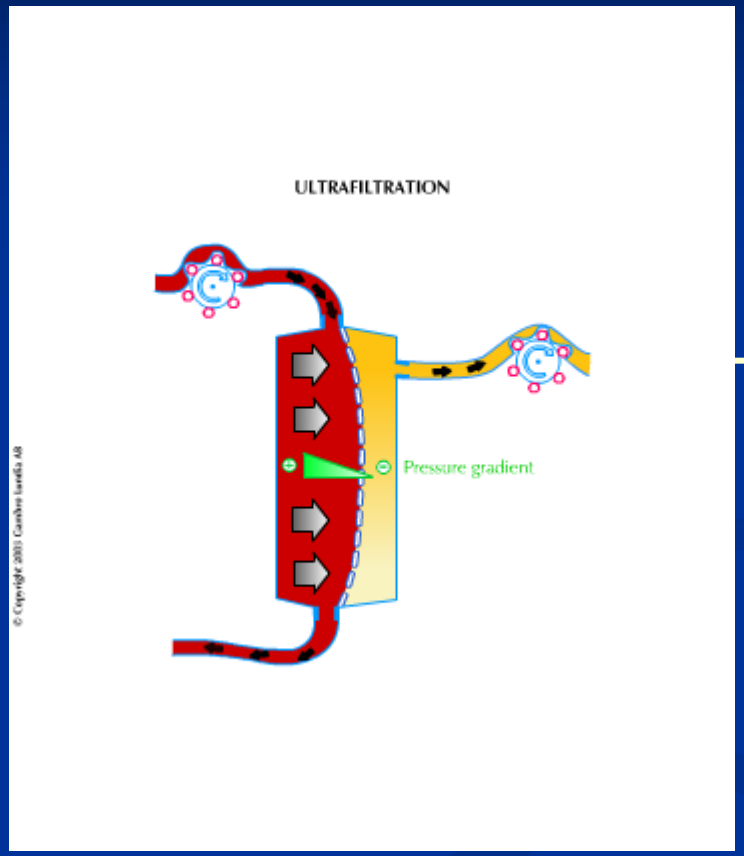
} Solute Removal

Ultrafiltration

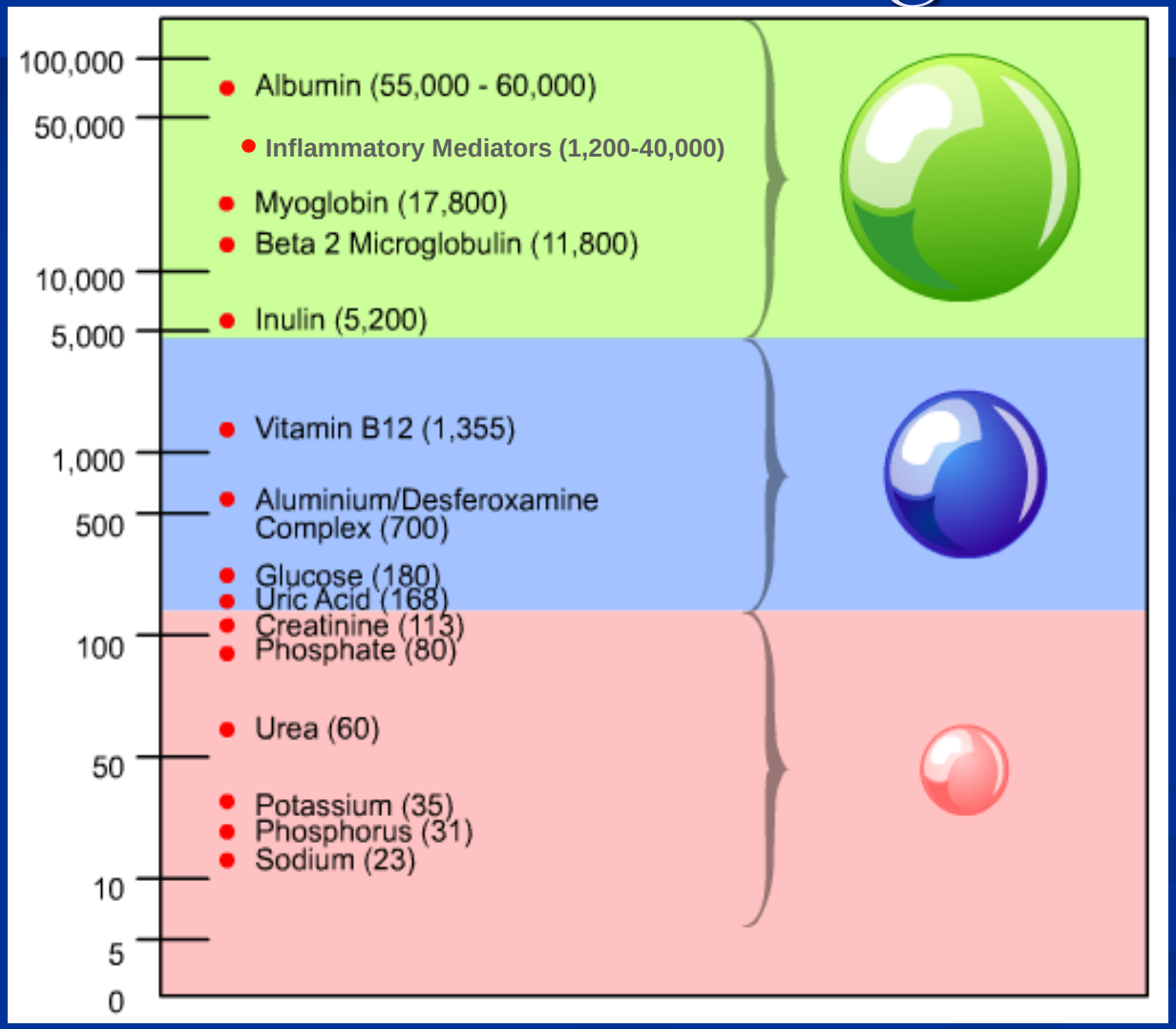
- Movement of **Fluid** through a semi permeable membrane caused by pressure gradient (TMP)
- A positive and negative pressure required

Ultrafiltration (UF) Applied to Prismaflex ®

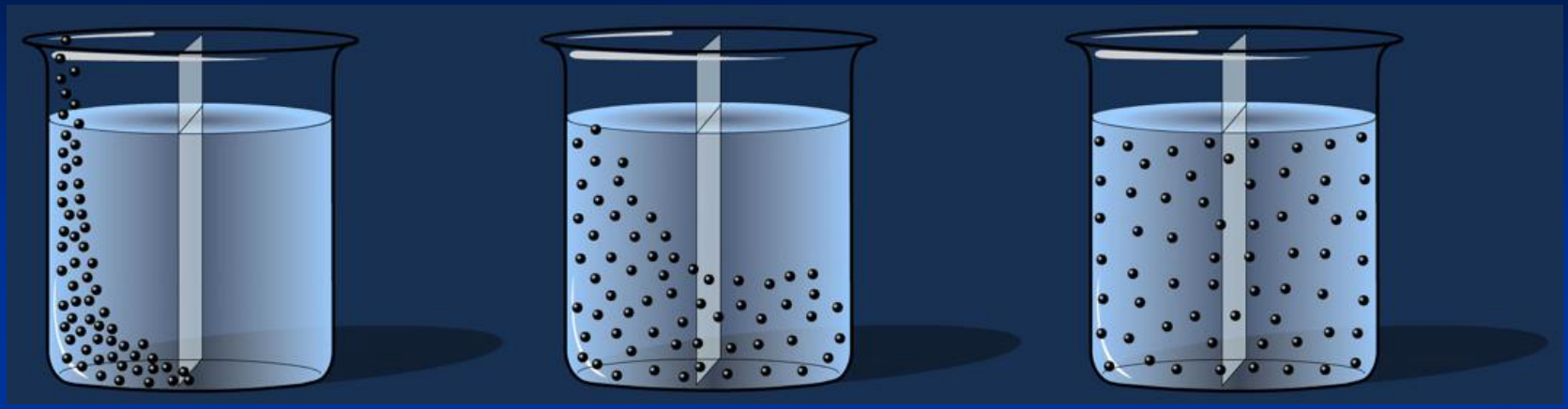
- **Positive pressure** in blood compartment will "push" fluid across the membrane
- **Negative pressure** in fluid compartment will "pull" plasma water across the membrane
- Combination of both pressures makes up the total gradient required to pull plasma water across the semi-permeable membrane
- The *effluent* pump on the Prismaflex® automatically controls the ultrafiltration rate (UFR)



Molecular Weights



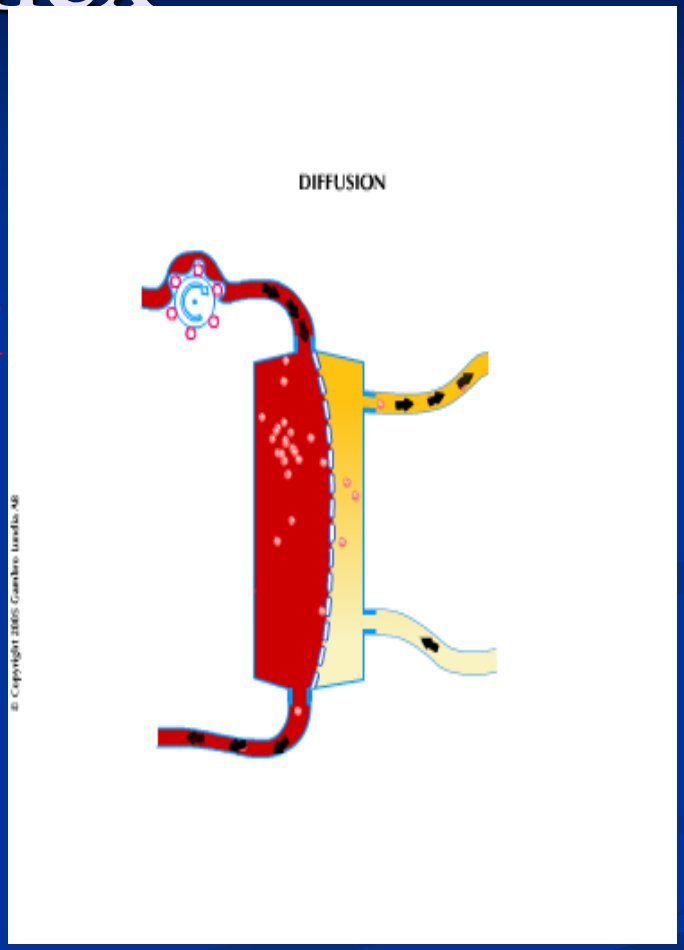
Diffusion



- Passive movement of small solutes from a higher to lower solute concentration area through a semi-permeable membrane
- Will continue until concentration equilibrium is achieved
- Concentration gradient between solutes in the blood and solutes in the dialysate solution is key to clearance
- Dialysate is used to create a concentration gradient across a semi-permeable membrane.

Diffusion Applied to the Prismaflex®

- Movement of solutes based upon a concentration gradient
- Solute removal depends on:
  - Solute size
  - Blood flow rate (BFR)
  - Dialysate flow rate
  - Concentration gradient between the blood and the dialysate



Convection (Hemofiltration)

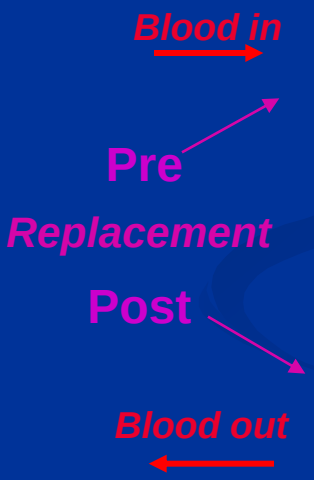
Positive pressure

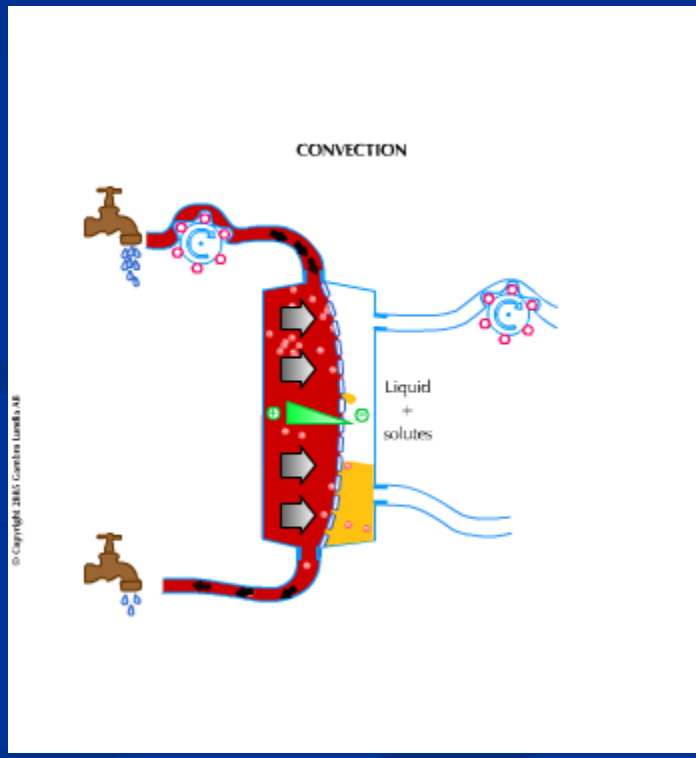
Negative pressure

- Movement of middle and large **solutes** <u>with</u> a water flow: "solvent drag"
- A positive and negative pressure required
- A Replacement solution must be added

Convection applied to the Prismaflex®

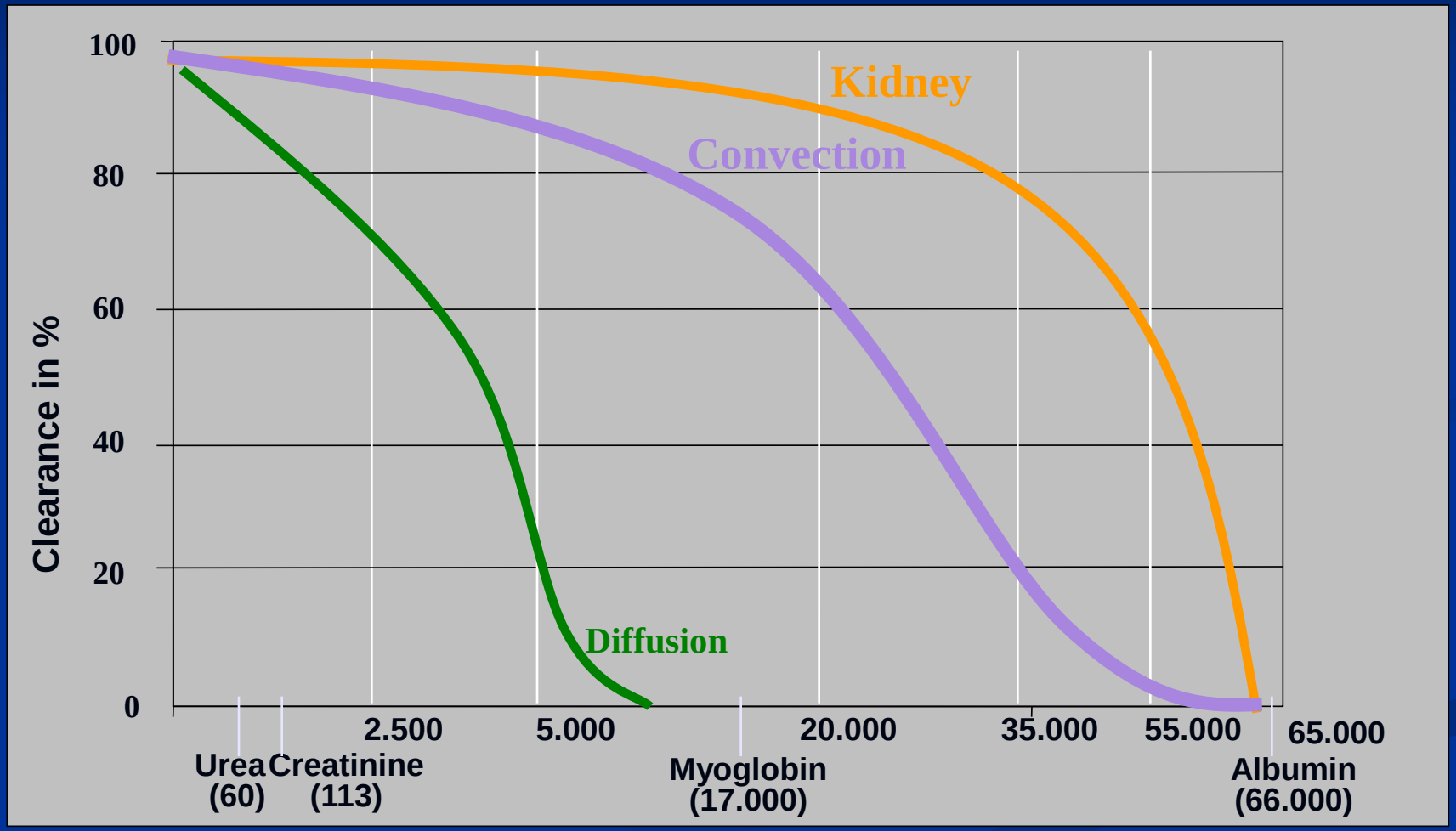
- Plasma water with solutes is removed as UF at set replacement rate
- Replacement solution is infused into blood flow path at the same rate as the UF pump is removing
  - No fluid bolus for patient
- Unwanted solutes are not replaced (e.g. BUN)
- Wanted solutes (e.g. HC03) & fluid are replaced



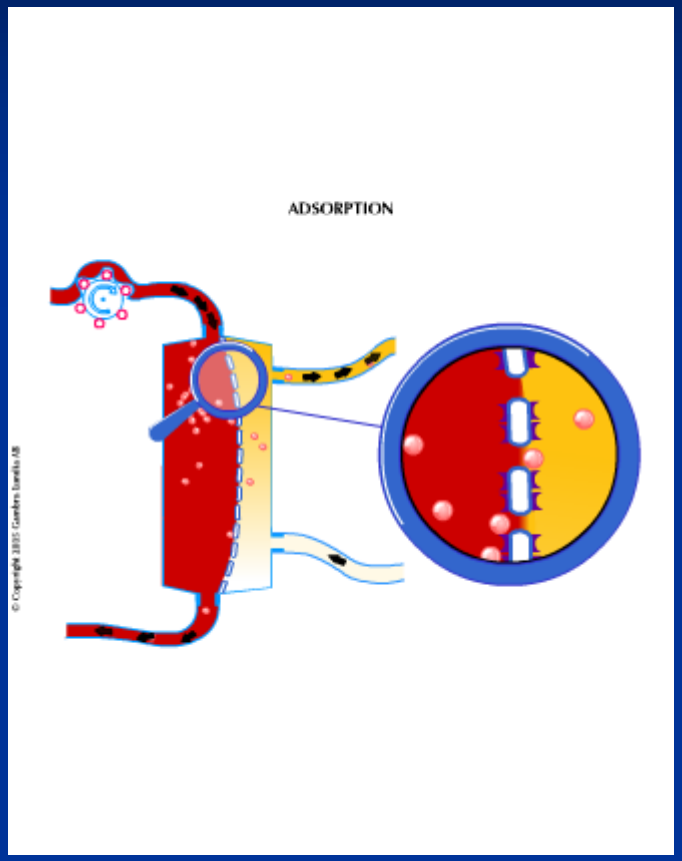


"Convection is Ultrafiltration with Replacement"

Small vs. Large Molecules Clearance



Adsorption



- Adsorption is
  - binding of molecules (e.g., protein coating, lipids) to the surface of the hollow fibers of the filter
  - and microclotting which occurs on the surface of the hollow fibers of the filter
- Adsorption plays a role in how quickly the pressure drop and/or the transmembrane pressure (TMP) will rise during treatment

CRRT Modes of Therapy

- **SCUF** - *Slow Continuous Ultrafiltration*
  - *Fluid removal only from the patient*
- **CVVH** - *Continuous Veno-Venous Hemofiltration*
  - *Removal of small, middle and large sized solutes by convection only and fluid volume management*
- **CVVHD** - *Continuous Veno-Venous HemoDialysis*
  - *Small solute removal by diffusion only and fluid volume management—no middle or large molecule removal*
- **CVVHDF** - *Continuous Veno-Venous HemoDiaFiltration*
  - *Solute removal by diffusion and convection and fluid volume management*

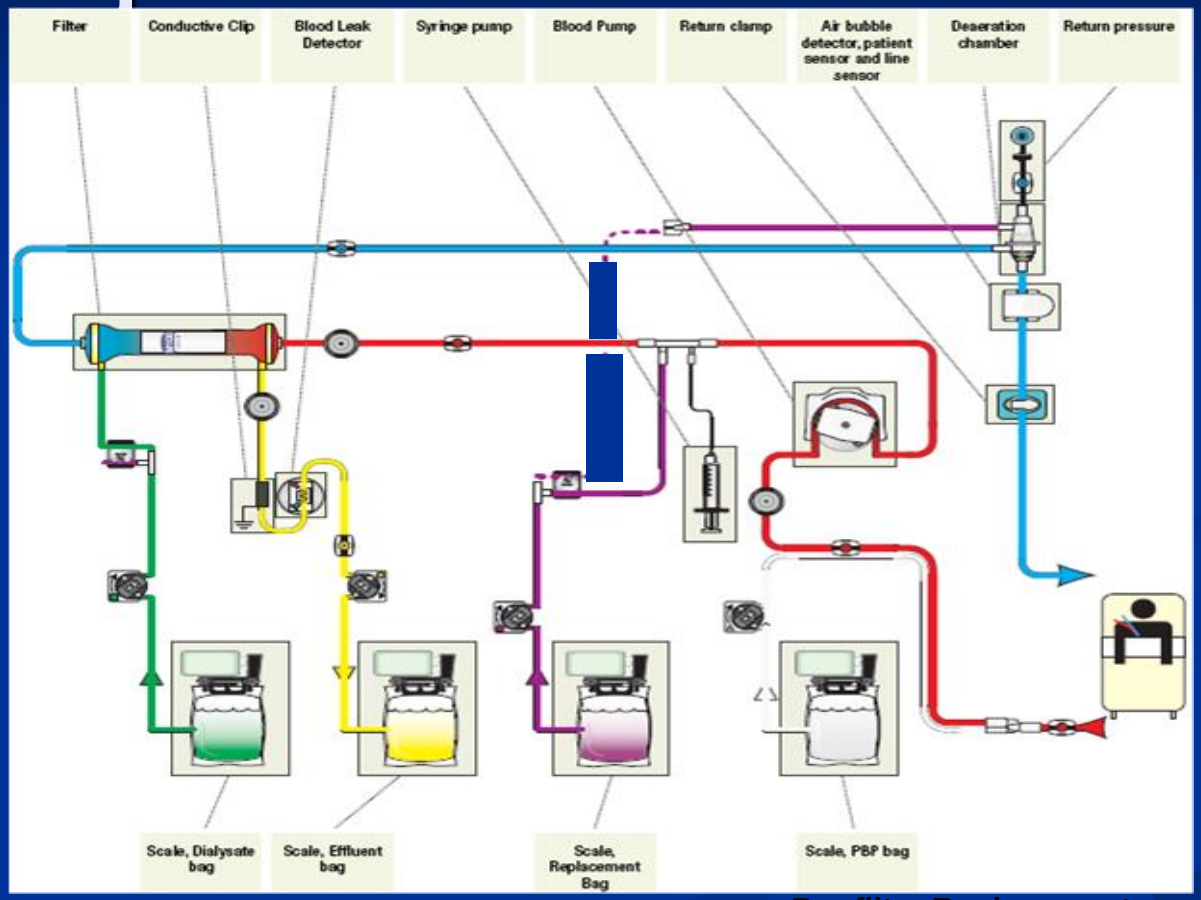
CVVHDF Pre-filter replacement

- Considerations:

- Lowers hematocrit
  - dilutes blood passing through the filter

- Higher UF capabilities

- Less efficient clearance then post-filter replacement



Pre-filter Replacement

Pre-filter Replacement or Anticoagulant

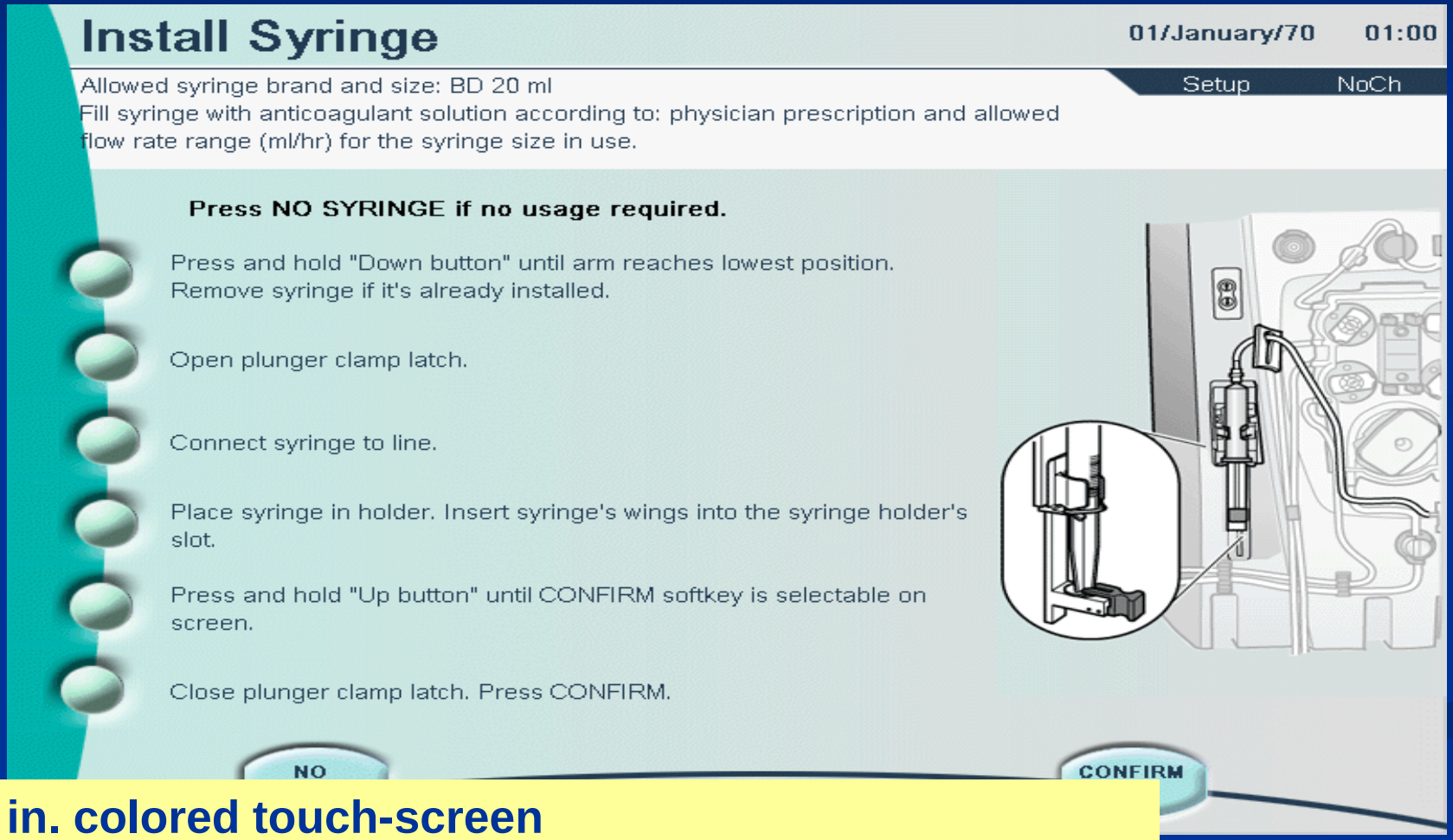
1. Which transport mechanism is used to remove excess plasma water?
2. Name the 3 solute transport mechanisms.
3. How does CVVH provide convection?
4. How does CVVHD provide diffusion?
5. Which therapies are most efficient when treating patients suffering from Systemic Inflammatory Response Syndrome (SIRS) and why?

Prismaflex System Overview

Communication Unit

- **Interactive, color, touch screen**
- **Machine status lights**

Interactive Display Screen Step-by-Step Instructions



- **12 in. colored touch-screen**
- **Displays a diagram of required actions**

Status Lights

Give a general indication of operating conditions.

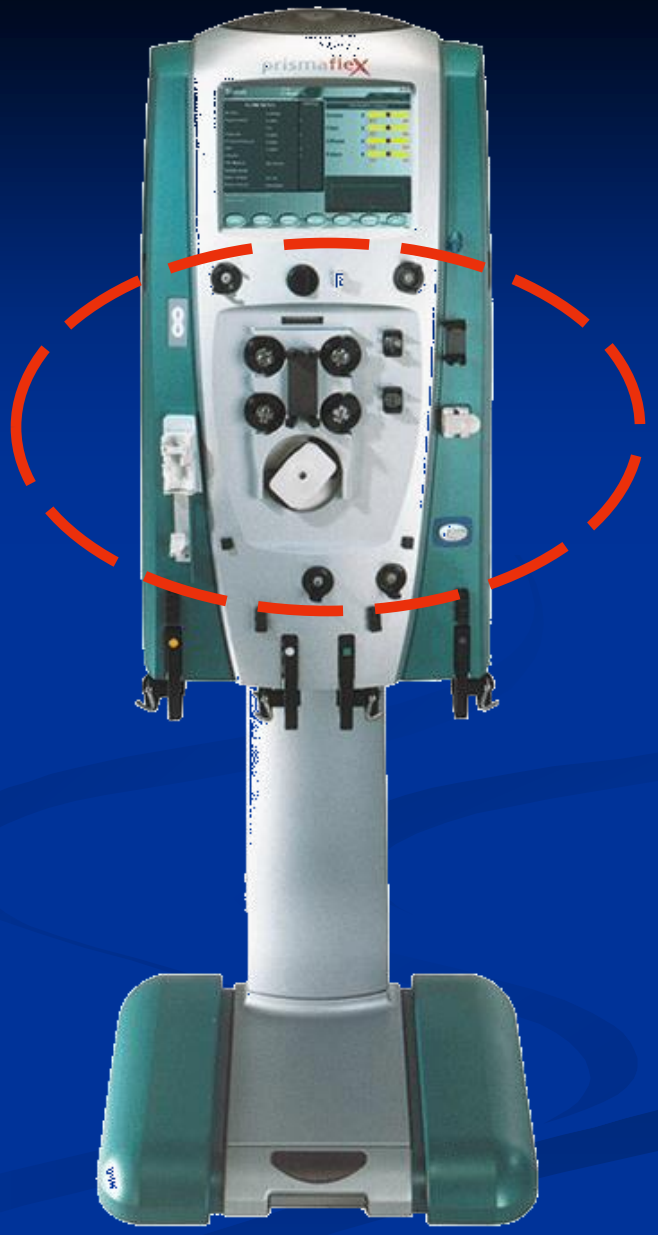
- **Green** - normal treatment conditions

- **Yellow** - advisory or caution alarm

- **Red** - highest priority alarm condition needing immediate intervention

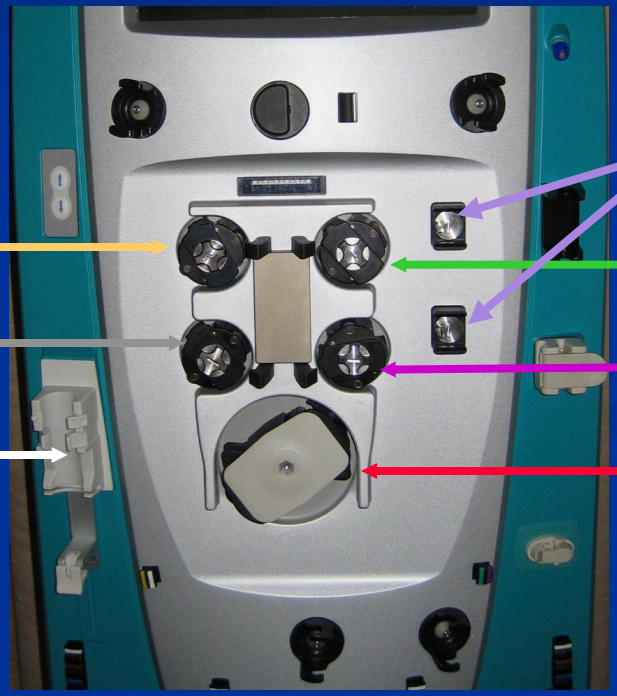
Flow Control Unit

- Blood and fluid pumps
- Syringe pump
- Pressure monitoring system
- Pinch valves
- Safety feature components



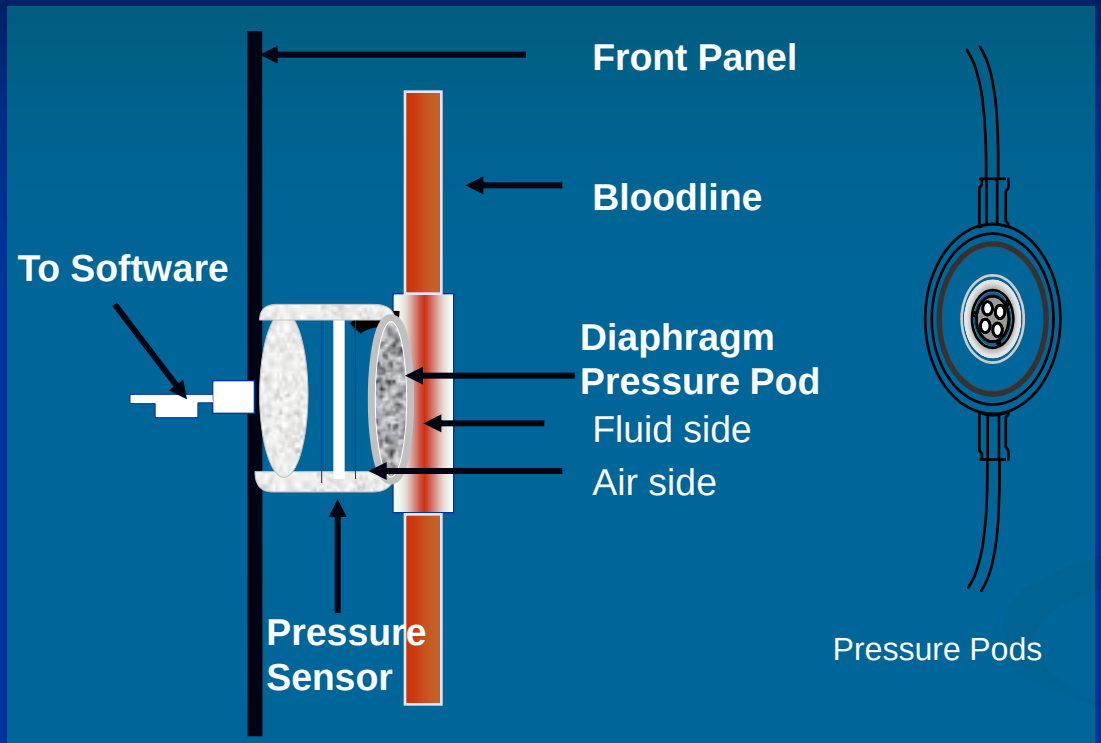
Prismaflex® Operator's Manual Chapter 1, p.1-2

Flow Control Unit – Pumps

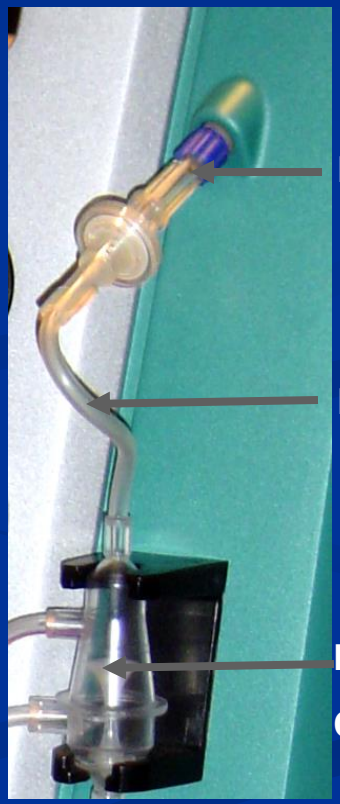


Flow Control Unit Pressure Monitoring

Pressure Monitoring



Pressure Pod System



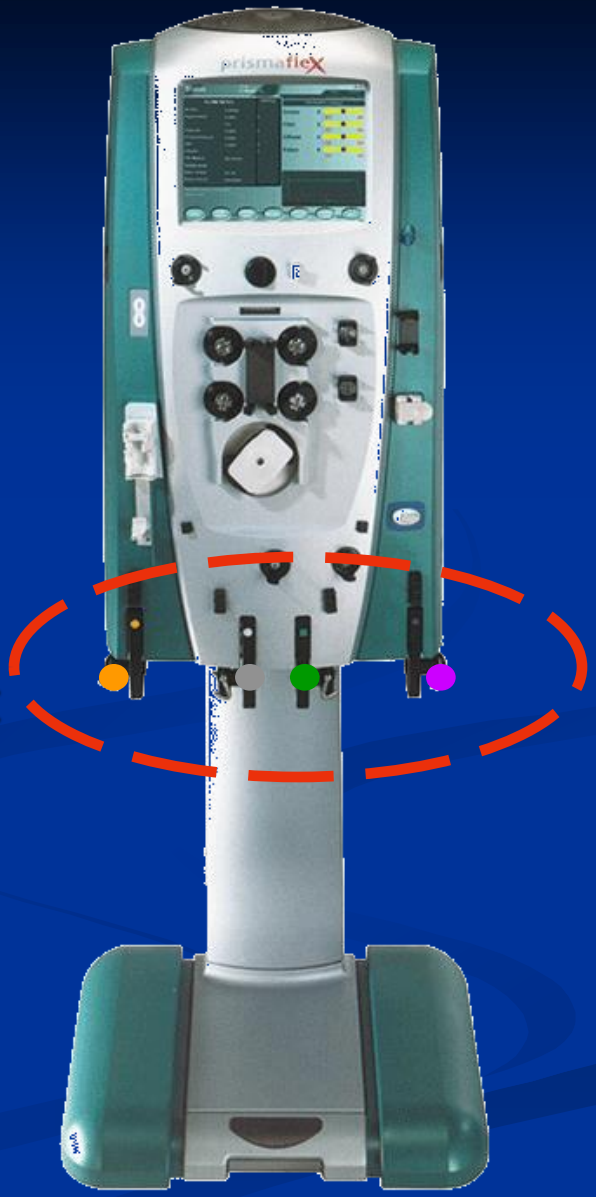
Return Pressure Monitor

Prismaflex® Operator's Manual Chapter 4-p52

Safety Components

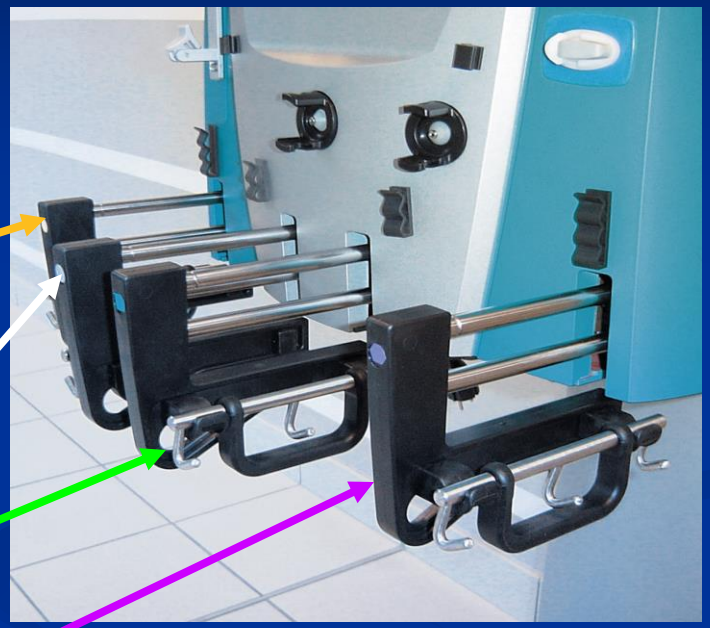
Fluid Control Unit

- Scales
  - Effluent
  - Replacement
  - Dialysate/2nd replacement
  - Pre-Blood Pump (PBP)
- Scale hook assemblies
- Color-coded tubing guides



Fluid Control Unit

- Scale hook assembly
  - Slide-out bar tray
  - Removable carrying bar
- Scales-
  - Effluent
  - Pre-blood pump (PBP)
  - Dialysate
  - Replacement



Prismaflex® System

Treatment Management

Status

Pt ID:
Pt Weight: 80 kg

01/January/70 01:00
Run CVVHDF
Currently Delivering: CVVHDF

Flow Settings

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

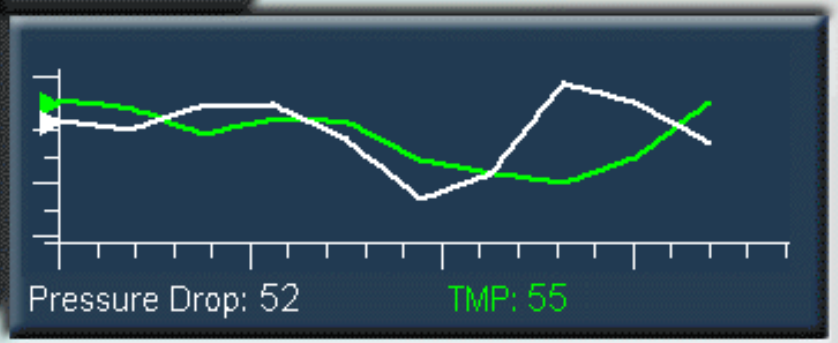
Anticoagulation Method STANDARD

Anticoag Continuous	2.0 ml/h
Bolus Volume	0.0 ml
Bolus Interval	6 h

I/O Data 30 of 60 min	
598 ml	
495 ml	
397 ml	
51 ml	
1541 ml	

PRESSURES (mmHg)

Access	-38	-500 500
Filter	127	-500 500
Effluent	18	-500 500
Return	57	-500 500

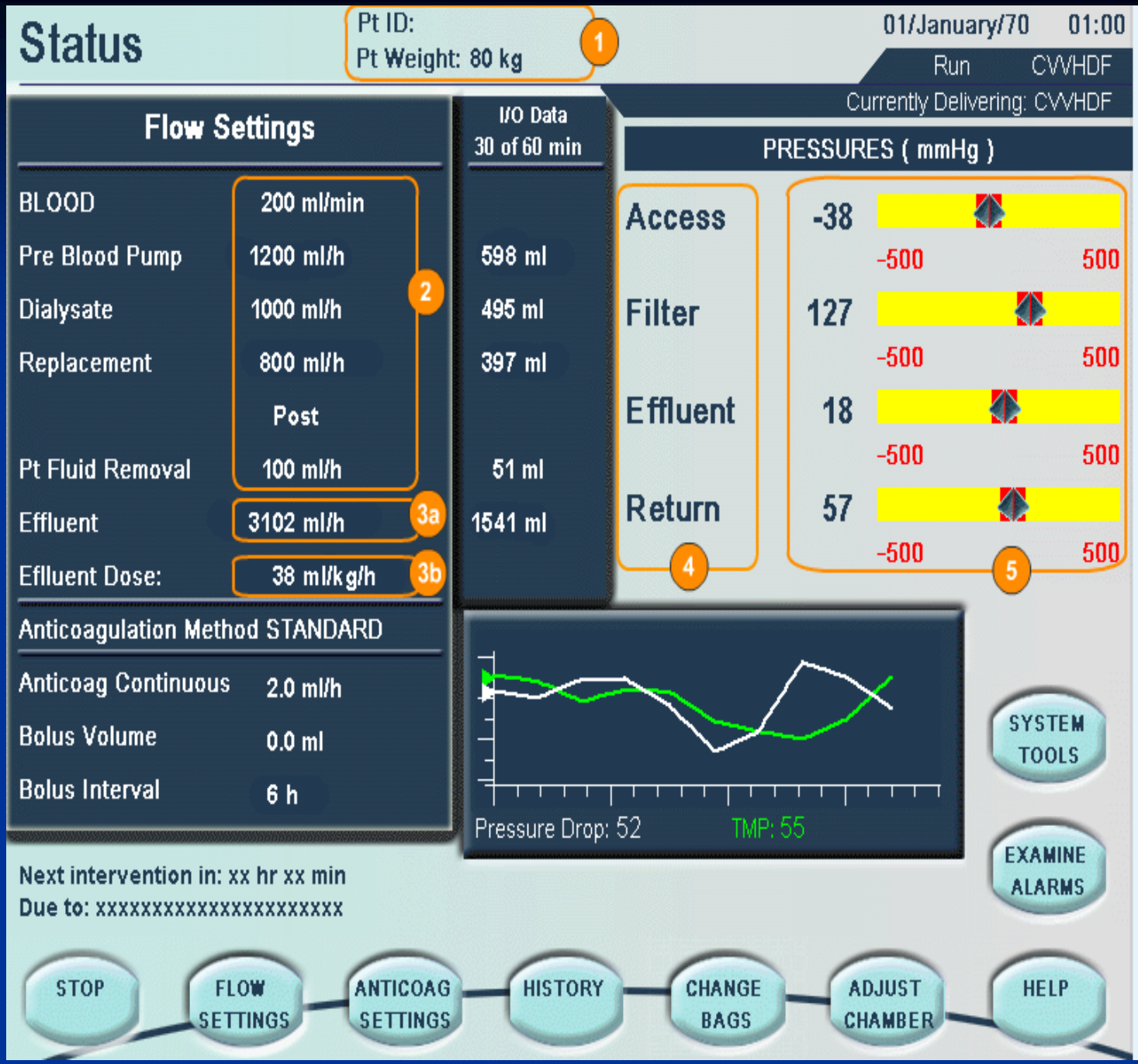


SYSTEM TOOLS

EXAMINE ALARMS

Next intervention in: xx hr xx min
Due to: xxxxxxxxxxxxxxxxxxxxx

STOP | FLOW SETTINGS | ANTICOAG SETTINGS | HISTORY | CHANGE BAGS | ADJUST CHAMBER | HELP



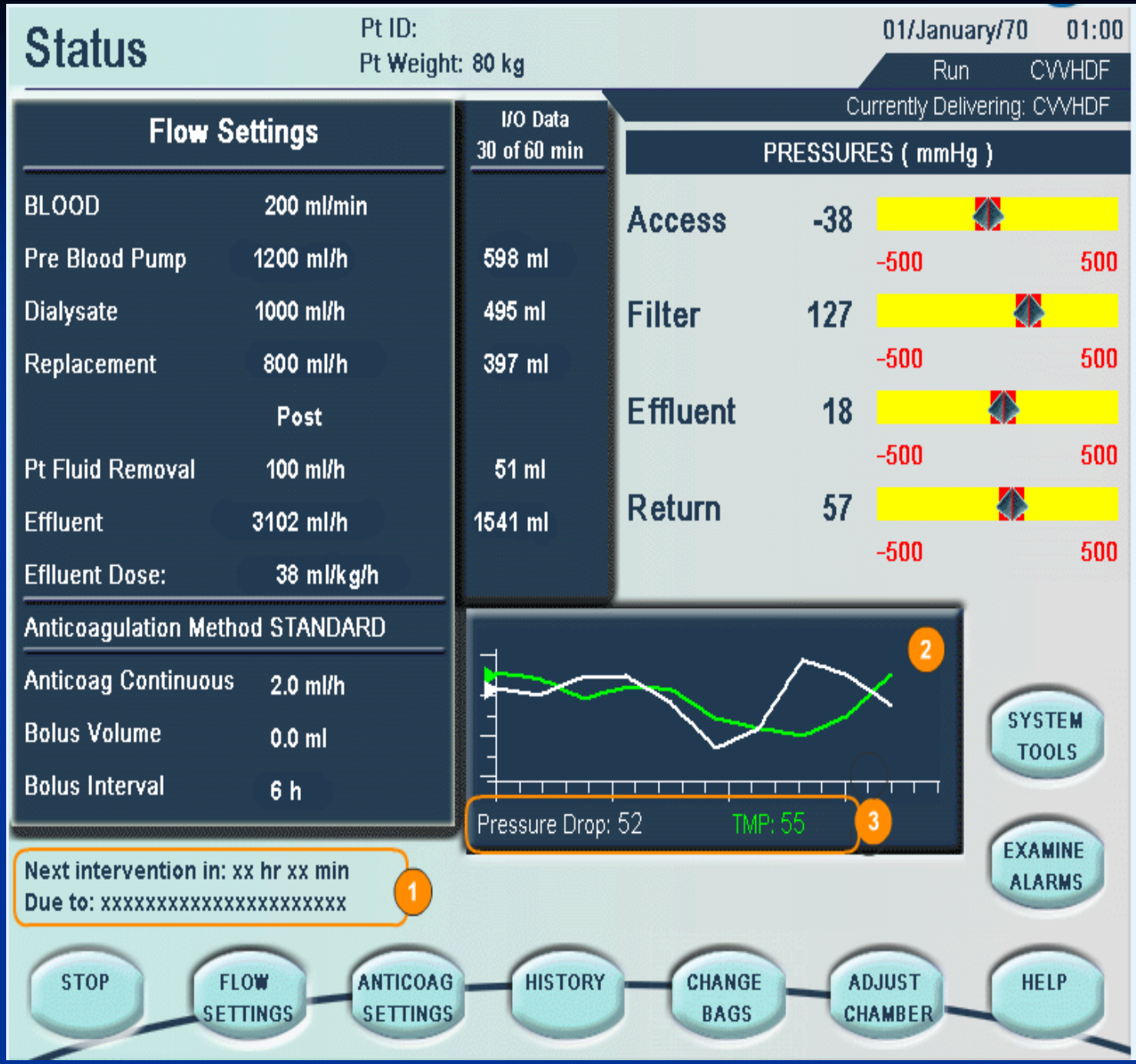
1. Patient information confirmed during Setup is displayed here.

2. Current flow rate settings are shown on this side of the screen.

3a. Effluent: is the effluent flow in ml/h

3b. Effluent dose: is the effluent flow per kg patient weight.

4. Current pressures.



1. This shows you the next activity you'll need to do and when!

2. This is the Status graph. It shows you a history of the pressures within the filter and can help you in assessing clotting trends.

3. These numbers are the current pressures within the filter.

Status

Pt ID:
Pt Weight: 80 kg

01/January/70 01:00
Run CVVHDF
Currently Delivering: CVVHDF

Flow Settings

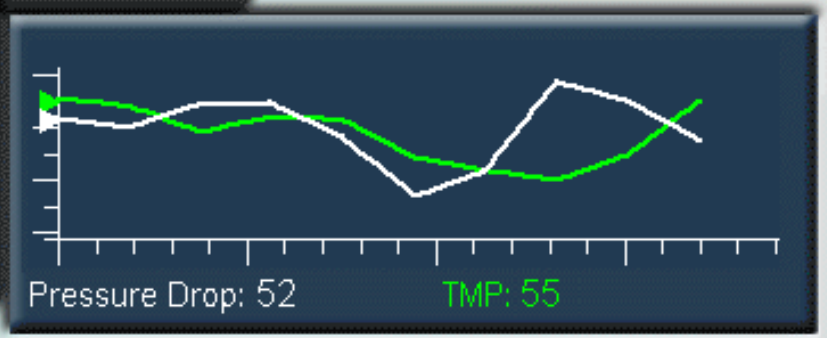
		I/O Data 30 of 60 min
BLOOD	200 ml/min	
Pre Blood Pump	1200 ml/h	598 ml
Dialysate	1000 ml/h	495 ml
Replacement	800 ml/h	397 ml
	Post	
Pt Fluid Removal	100 ml/h	51 ml
Effluent	3102 ml/h	1541 ml
Effluent Dose:	38 ml/kg/h	

Anticoagulation Method STANDARD

Anticoag Continuous	2.0 ml/h
Bolus Volume	0.0 ml
Bolus Interval	6 h

PRESSURES (mmHg)

		-500	500
Access	-38	-500	500
Filter	127	-500	500
Effluent	18	-500	500
Return	57	-500	500



Next intervention in: xx hr xx min
Due to: xxxxxxxxxxxxxxxxxxxxx

SYSTEM TOOLS

EXAMINE ALARMS

STOP | FLOW SETTINGS | ANTICOAG SETTINGS | HISTORY | CHANGE BAGS | ADJUST CHAMBER | HELP

Enter Flow Settings

01/January/70 01:00

Run CVVHDF

To adjust settings, press appropriate softkey, then use arrows.
Press CONFIRM when ready. See Help for more info.

Blood	200 ml/min
Pre Blood Pump	1200 ml/h
Dialysate	1000 ml/h
Replacement	800 ml/h
Pre or Post	Post
Patient Fluid Removal	100 ml/h

Range: 10 to 400 ml/min

PBP = Pre-blood pump

VIEW CHANGES

CLEAR

CONFIRM ALL

BLOOD | PBP | DIALYSAT | REPLACE | PRE or POST | PT. FLUID REMOVAL | HELP

Calculating Patient Fluid Removal

Non-Prismaflex intake (IV, TPN, etc.)

-Non-Prismaflex output (urine, etc.)

+Net fluid removal hourly (physician order)

=Patient Fluid Removal Rate (set in Prismaflex)

Enter Flow Settings

01/January/70 01:00
Run CVVHDF

To adjust settings, press appropriate softkey, then use arrows.
Press CONFIRM ALL when ready. See Help for more info.

Blood	200 ml/min
Pre Blood Pump	1200 ml/h
Dialysate	1000 ml/h
Replacement	1000 ml/h
Pre or Post	Post
Patient Fluid Removal	100 ml/h

Range: 0 to 5800 ml/h
Rate per Pt kg 13 ml/h
UFRpost% of BFR: 9 %
Total predilution 54 %

Use PRE or POST to select replacement solution delivery method.

PBP = Pre-blood pump
BFR = Blood flow rate
UFR = Ultrafiltration rate

VIEW CHANGES
CLEAR
CONFIRM ALL

BLOOD | PBP | DIALYSAT | REPLACE | PRE or POST | PT. FLUID REMOVAL | HELP

View Prescription Changes

Pt ID:
Pt Weight: 80 kg

01/January/70 01:00
Run CVVHDF

View highlighted settings. Press CONTINUE when ready.

Prescription Settings		Current	Changed
Blood Flow Rate:	ml/min	200	200
Pre Blood Flow:	ml/h	1200	1200
Dialysate Flow Rate:	ml/h	1000	1000
Replacement Flow Rate:	ml/h	800	1000
Replacement Pre/Post:		post	post
Pt Fluid Removal Rate:	ml/h	100	100

Prescription Indicators

Effluent Dose:	ml/h/kg	38	41
UFR Dose:	ml/h/kg	23	25
Filtration Fraction:	%	9	11

CONTINUE

Enter Flow Settings

01/January/70 01:00
Run CVVHDF

To adjust settings, press appropriate softkey, then use arrows.
Press CONFIRM ALL when ready. See Help for more info.

Blood	200 ml/min
Pre Blood Pump	1200 ml/h
Dialysate	1000 ml/h
Replacement	1000 ml/h
Pre or Post	Post
Patient Fluid Removal	100 ml/h

PBP = Pre-blood pump

VIEW CHANGES

CLEAR

CONFIRM ALL

BLOOD PBP DIALYSAT REPLACE PRE or POST PT. FLUID REMOVAL HELP

Status

Pt ID:
Pt Weight: 80 kg

01/January/70 01:00
Run CVVHDF
Currently Delivering: CVVHDF

Flow Settings

BLOOD	200 ml/min
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Dialysate	1000 ml/h
Replacement	1000 ml/h
	Post
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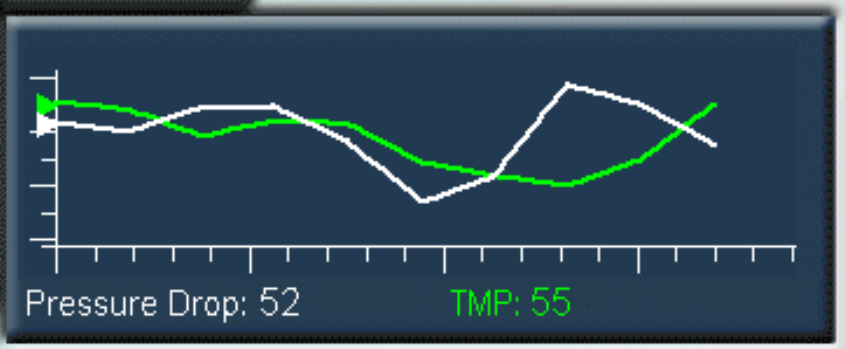
495 ml	
397 ml	
51 ml	
1541 ml	

PRESSURES (mmHg)

Access	-38	-500	500
Filter	127	-500	500
Effluent	18	-500	500
Return	57	-500	500



Next intervention in: xx hr xx min
Due to: xxxxxxxxxxxxxxxxxxxx

SYSTEM TOOLS

EXAMINE ALARMS

STOP | FLOW SETTINGS | ANTICOAG SETTINGS | HISTORY | CHANGE BAGS | ADJUST CHAMBER | HELP

Enter Anticoagulation Settings

01/January/70 01:00
Run CVVHDF

To adjust settings, press appropriate softkey, then use arrows.
Press CONFIRM ALL when ready. See Help for more info.

Syringe Pump

Continuous

Rate 2.0 ml/h

Choices: Continuous or Bolus

The software accounts for solution infused via the syringe pump in fluid balance.

CHANGE SYRINGE

CLEAR

Allowed Syringe Size: 50 ml
Allowed Syringe Brand: TERUMO

CONFIRM ALL

CONTINU-OUS DEL.

CONTINU-OUS RATE

BOLUS DELIVERY

HELP

Change Syringe

01/January/70 01:00

Allowed syringe brand and size: BRAUN 50 ml

Run CVVHDF

Caution:
Fill a new syringe with anticoagulant solution according to:

1. **Physician prescription**
2. **Allowed flow rate range (ml/h) for the syringe size in use.**

CANCEL	Deletes the choice and allows to exit the Change Syringe screen without performing the Change Syringe Procedure.
CONTINUE	Proceeds with the Change Syringe Procedure: - the installed syringe can be removed and a new (full) syringe loaded by following the step by step instructions ; - stops the syringe pump ; - activates the UP/DOWN buttons on the Syringe Pump Control Panel (on machine).

1

2

CANCEL

CONTINUE

Change Syringe

Allowed syringe brand and size: TERUMO 50 ml
Fill syringe with anticoagulant solution according to: physician prescription and allowed flow rate range (ml/h) for the syringe size in use.

Clamp syringe line. Open plunger clamp latch.

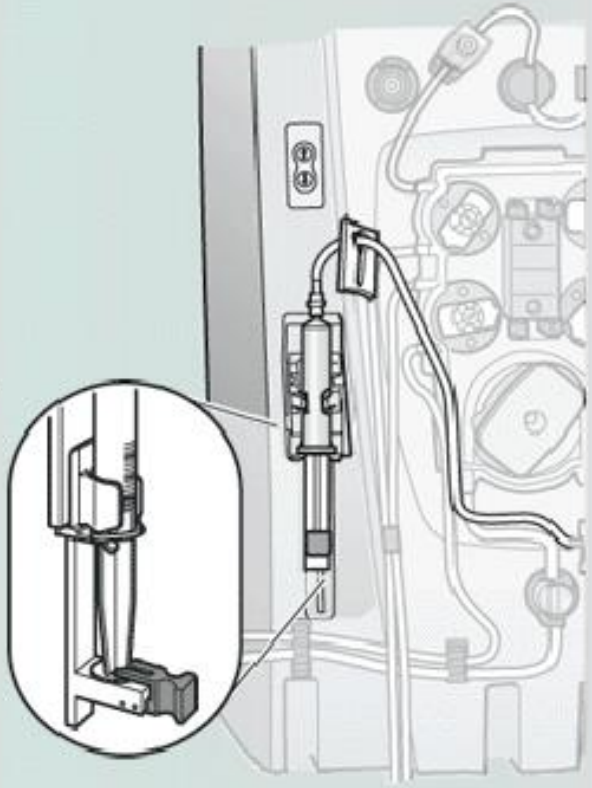
Press AUTO DOWN and wait until arm reaches lowest position.

Pull syringe out of holder, disconnect and discard. Connect new syringe to line.

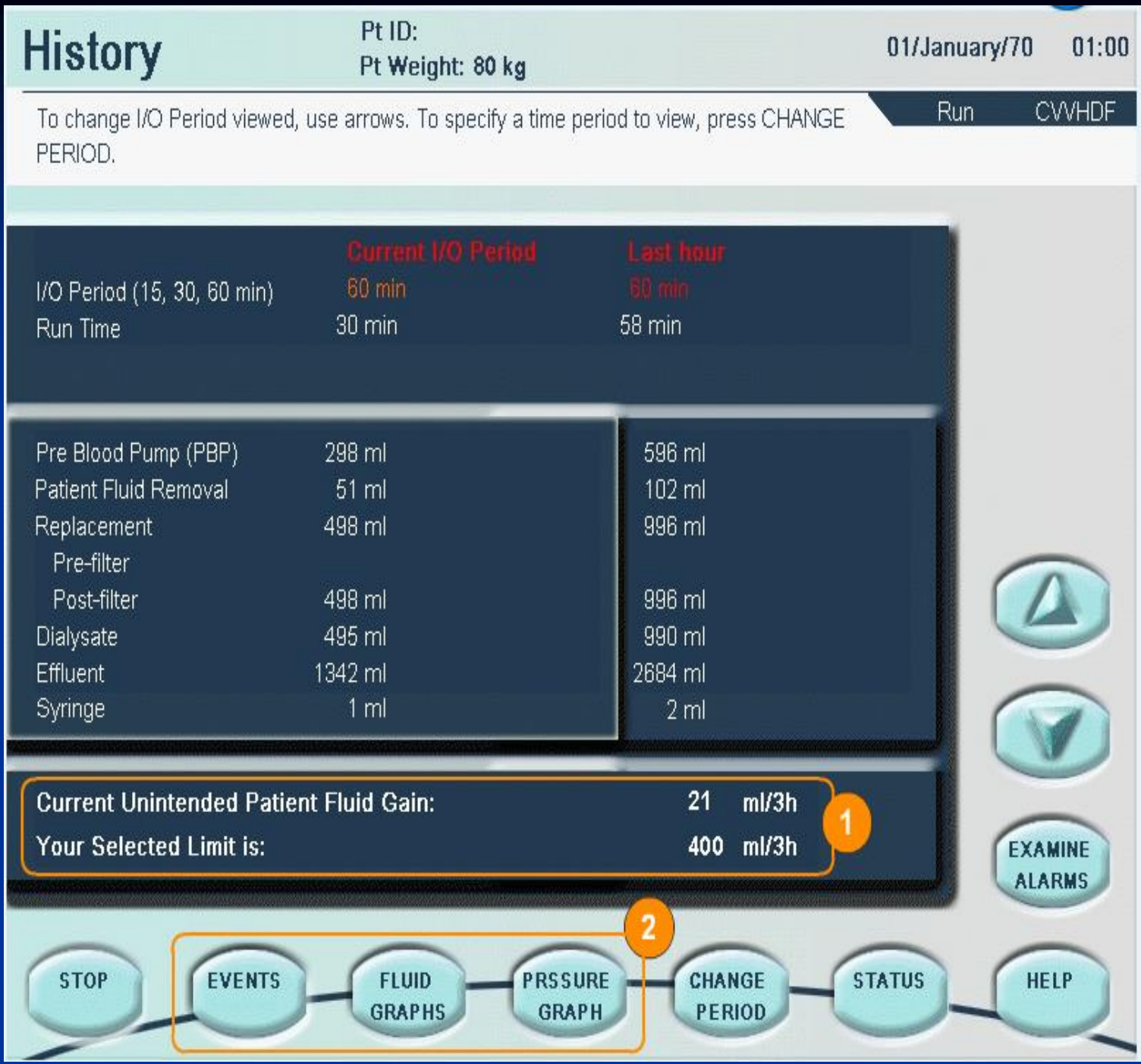
Place syringe in holder. Insert syringe's wings into the syringe holder's slot.

Press AUTO UP and wait until arm reaches the syringe's plunger.

Close plunger clamp latch. Unclamp syringe line. Press CONTINUE.



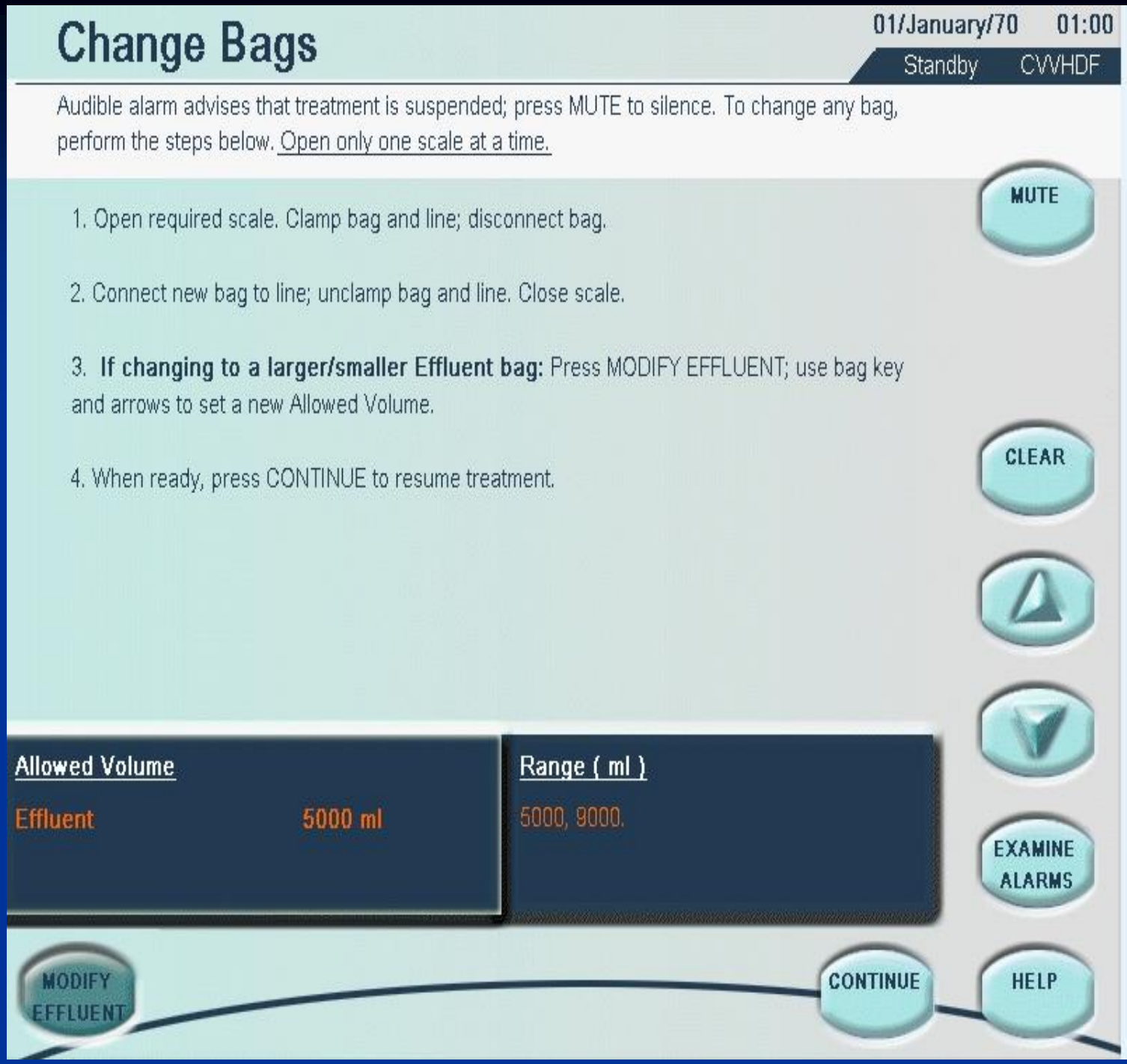
CANCEL | AUTO DOWN | AUTO UP | CONTINUE | HELP



The History screens give you alot of information about what's been happening!

1. This is your reminder about the Patient Fluid Loss or Gain LIMIT which has been set up at the beginning of the treatment.

2. These softkeys take you to other History screens. The same softkeys are available on all the History screens.



When you enter this screen, all fluid pumps stop.

Main Rule: You Should change a bag when the appropriate "Bag Full or Empty" alarm notifies you. The alarm screen provides instructions. If you need to change a bag for any other reason, you should use this Change Bags screen! To ensure accurate fluid reporting, you must always physically open/close the required scale. You can switch to a different size of effluent bag, if needed.

What happens when you open the scale?

Adjust Deaeration Chamber

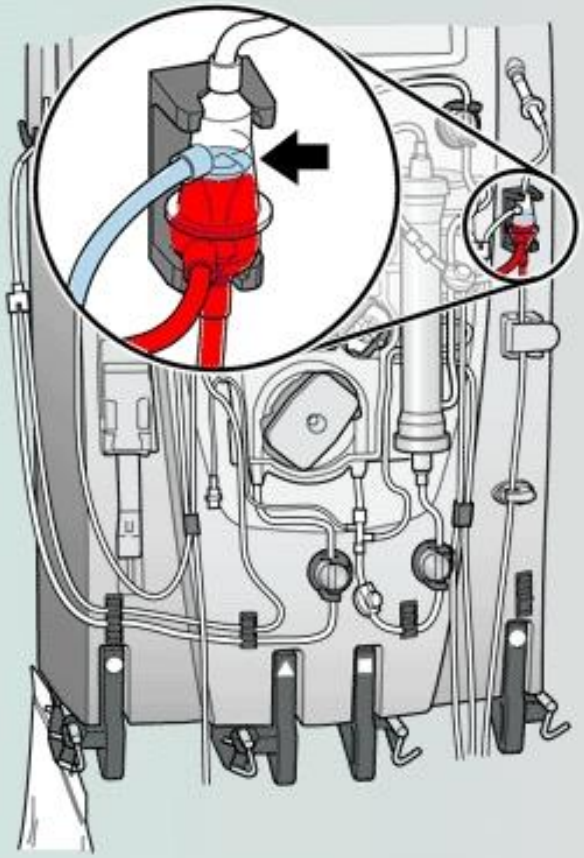
01/January/70 01:00

"Up" arrow raises the fluid level ; "Down" arrow lowers the fluid level.

Run CVVHDF

1. **Visually inspect fluid level in the deaeration chamber** – Fluid should be as shown on the illustration. If needed, use arrows to adjust the level.

2. **Visually confirm fluid is at desired level in the chamber.** When ready, press CONFIRM LEVEL to return to main screen.



EXAMINE ALARMS

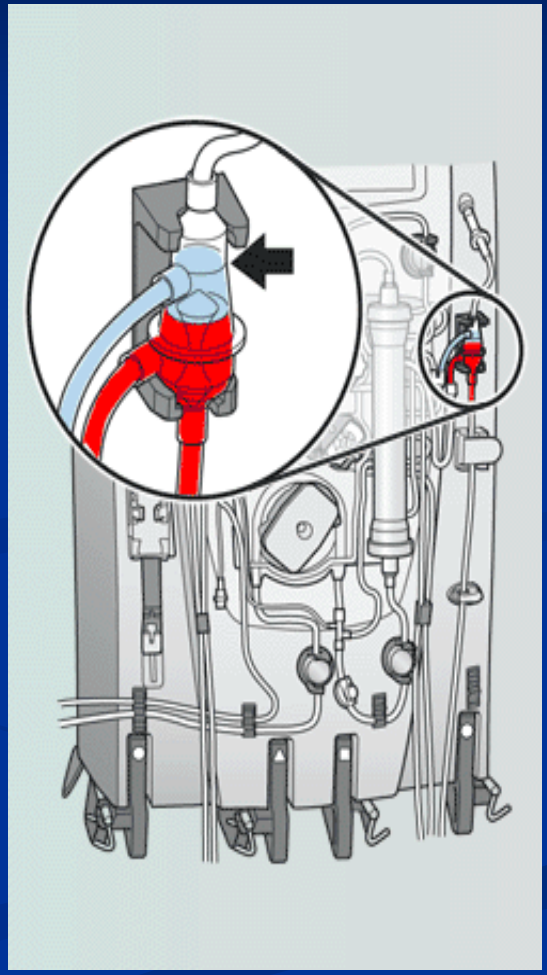
CANCEL

CONFIRM LEVEL

HELP

Deaeration Chamber

- Monitor chamber level hourly with routine I&O
  - Important NOTE:
- Keep Blood at designated level on deaeration chamber at all times.
  - If fluid level is too high and return line clamps off, fluid may enter machine through monitor line
  - If fluid level is too low, an “Air in Blood” alarm may occur



System Tools

- PRESSURE PODS
- MODIFY SETTINGS
- CLEAN SCREEN
- SELF TEST
- NORMALIZE BLD

SYSTEM TOOLS INFO

The System Tools allow adjustment of the system during treatment. (All pumps remain running when any softkey is pressed from System Tools screen.)

- PRESSURE PODS goes to Pod Adjustment Procedure screen. Provides instructions for moving pod diaphragms back to neutral (center) position and removing any debris between pod and sensor housing.

- CLEAN SCREEN goes to an empty cleaning screen for 10 s, in order to allow touch screen cleaning, avoiding unwanted pressing of action keys.

- SELF TEST goes to Self Test Request screen. Provides instructions for starts self test after 15 s.

- MODIFY SETTINGS goes to screen where is possible to

Prismaflex® System

Basic Alarm Overview

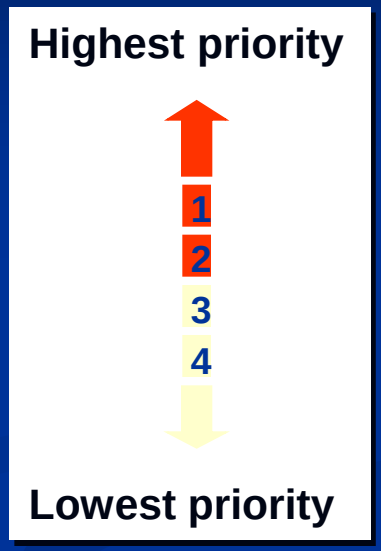
Prismaflex Types of Alarms

1. **Warning** - Patient hazard
   - Patient and System at risk
   - Needs immediate action
   - Treatment suspended

2. **Malfunction** - Failure of safety system
   - Patient and System at risk
   - Needs immediate action
   - Treatment suspended

3. **Caution** - Informs operator of an action
   - Patient and System not at immediate risk
   - Needs action
   - Treatment continues; Blood and syringe flows continue

4. **Advisory** - Informs operator of an action
   - Patient and System not at immediate risk
   - Treatment continues; Blood and syringe flows continue



The Troubleshooting Commandments

- **Read Screen**
- **Follow Steps**
- **Check Manual**
- **Call 1-855-292-3045**

Handling alarms: Alarm Screen Softkeys

Each alarm screen has its own specific combination of softkeys which may be needed to remedy the situation.

Alarm screens

Silences alarm beep for 2 minutes.

Retests for the alarm condition.

Overrides alarm for 60 seconds.

Clears alarm and restarts stopped pumps. If the problem still exists, alarm recurs.

Allows loading of a new set as part of remedying the alarm.

Opens the return line clamp as part of remedying the alarm.

Operating screens

Some softkeys on alarm screens also appear on the normal operating screens. These softkeys perform the same on the alarm screens as they do normally.

Here are some of these softkeys:

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.

Try it!

ADVISORY: Self-Test in Progress

01/January/70 01:00

Run CVVHDF

Test complete in: min. 1 minute, max. 6 minutes.
Monitor closely.
Auto Mute is OFF .

- 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.
- Pressures display is not available during repositioning of POD diaphragms.

Notes:

- Self-test will restart in the next 10 minutes if interrupted by Cautions or Warnings alarms.
- Re-launch of self-test is recommended in case of abnormal pressure, using SYSTEM TOOLS on STATUS screen.

Ensure that periodic patient monitoring is performed according to prescription.

Press REVIEW PRESCR to view prescription settings.
Press HISTORY to view history data.
Press DELAY TEST to stop and postpone self-test. Effective interruption of self-test might take up to 1 minute

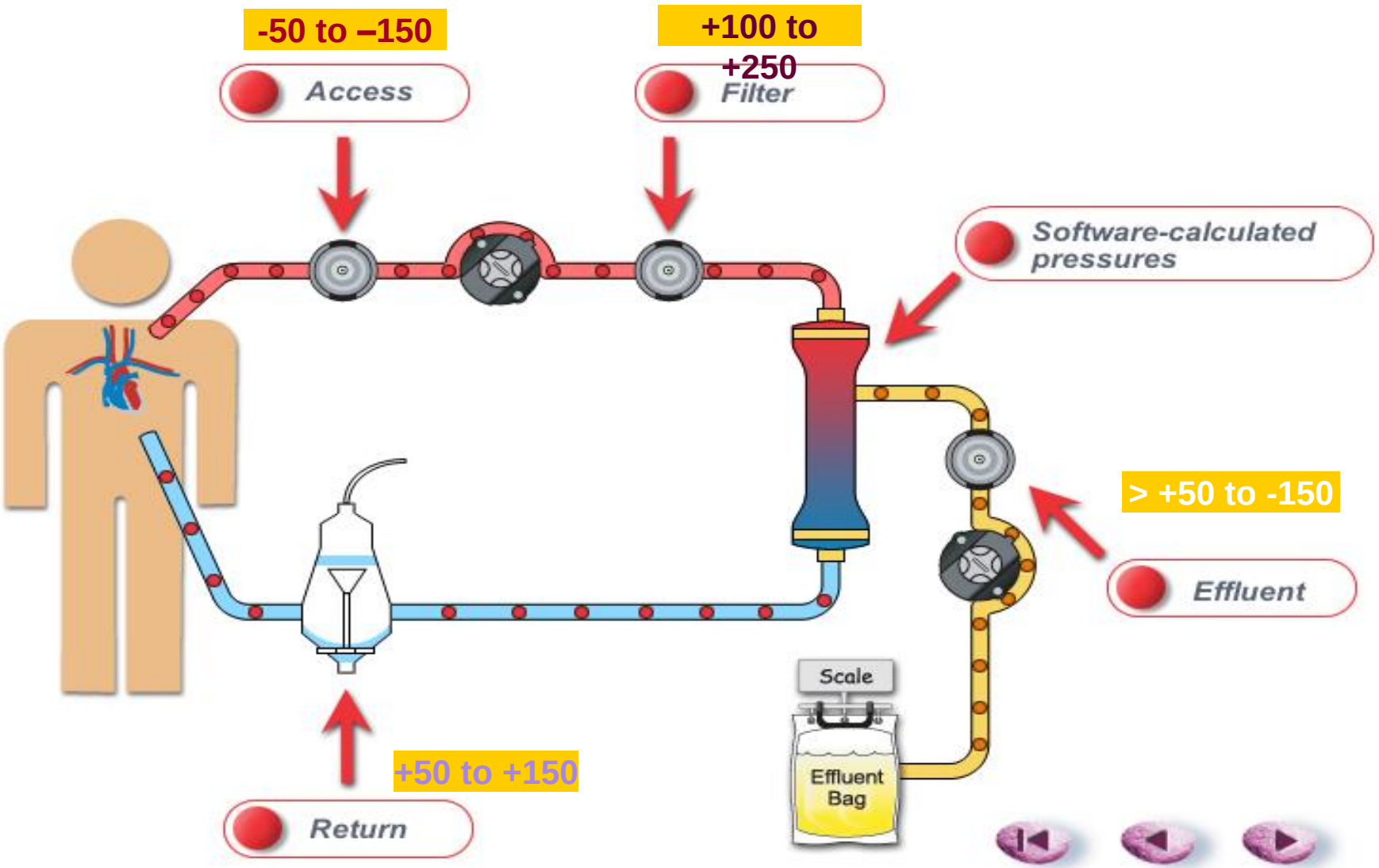
Every two hours, Prismaflex system does a self-test.

1. You can look at the Prescribed settings and History during the self-test, but any flow settings changes have to wait until the test is over!

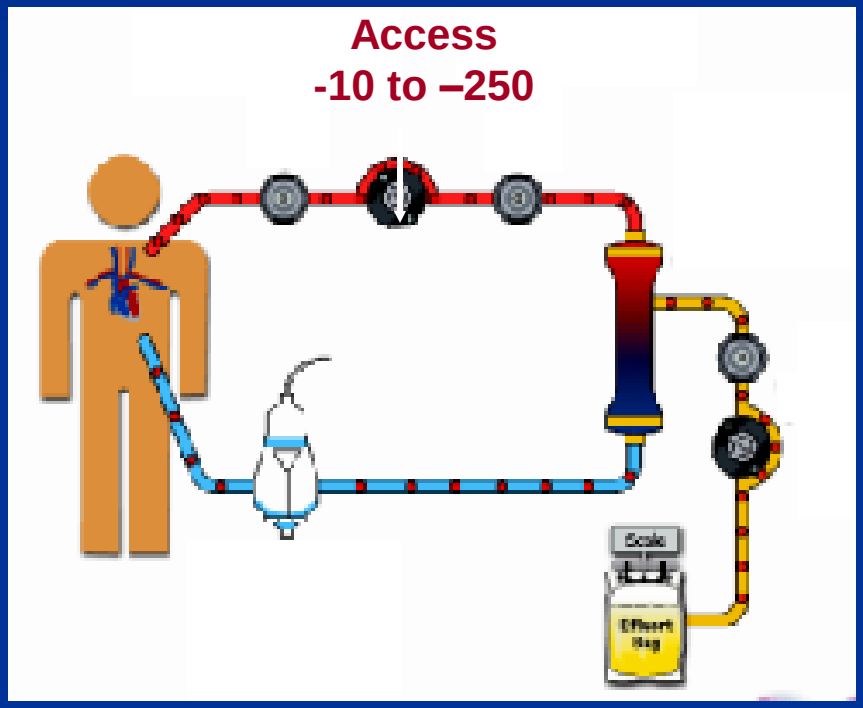
2. You may use "Delay test" one time, if you have some important check to do when this alarm occurs.

Self-Test is an important step for the control unit, Prismaflex system has to do its job properly.

Pressure Monitoring



Access Pressure



- Pressure created by pulling blood from patient through access
- Access pressure usually negative
  - Blood flow rate
  - Blood source
    - (e.g., CVC, AV Fistula, blood access device)
- Typical pressure:

  -50mmHg to -150mmHg

WARNING: Access Extremely Negative

01/January/70 01:00

Run CVVHDF

Self-clear attempt in progress.

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

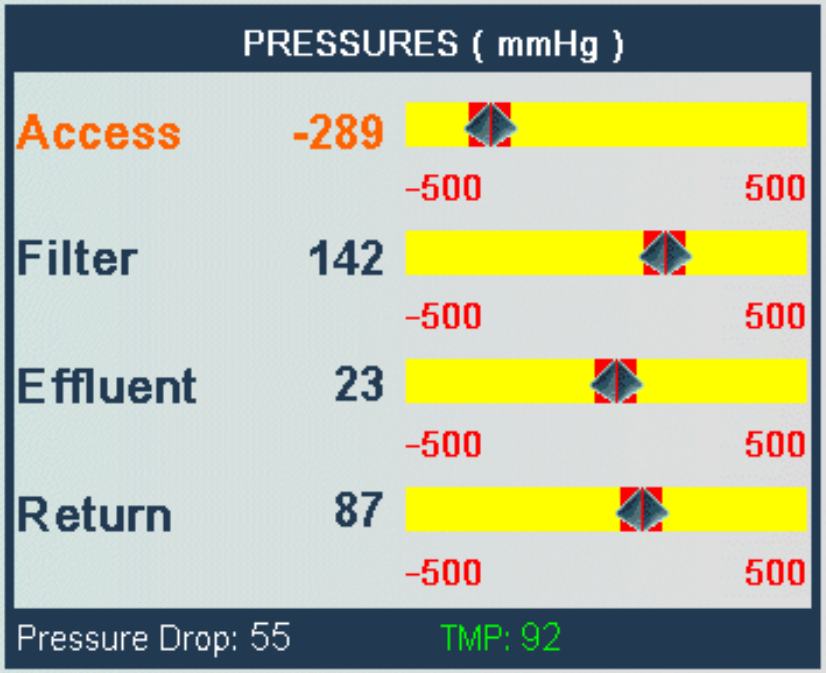
Action:

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:

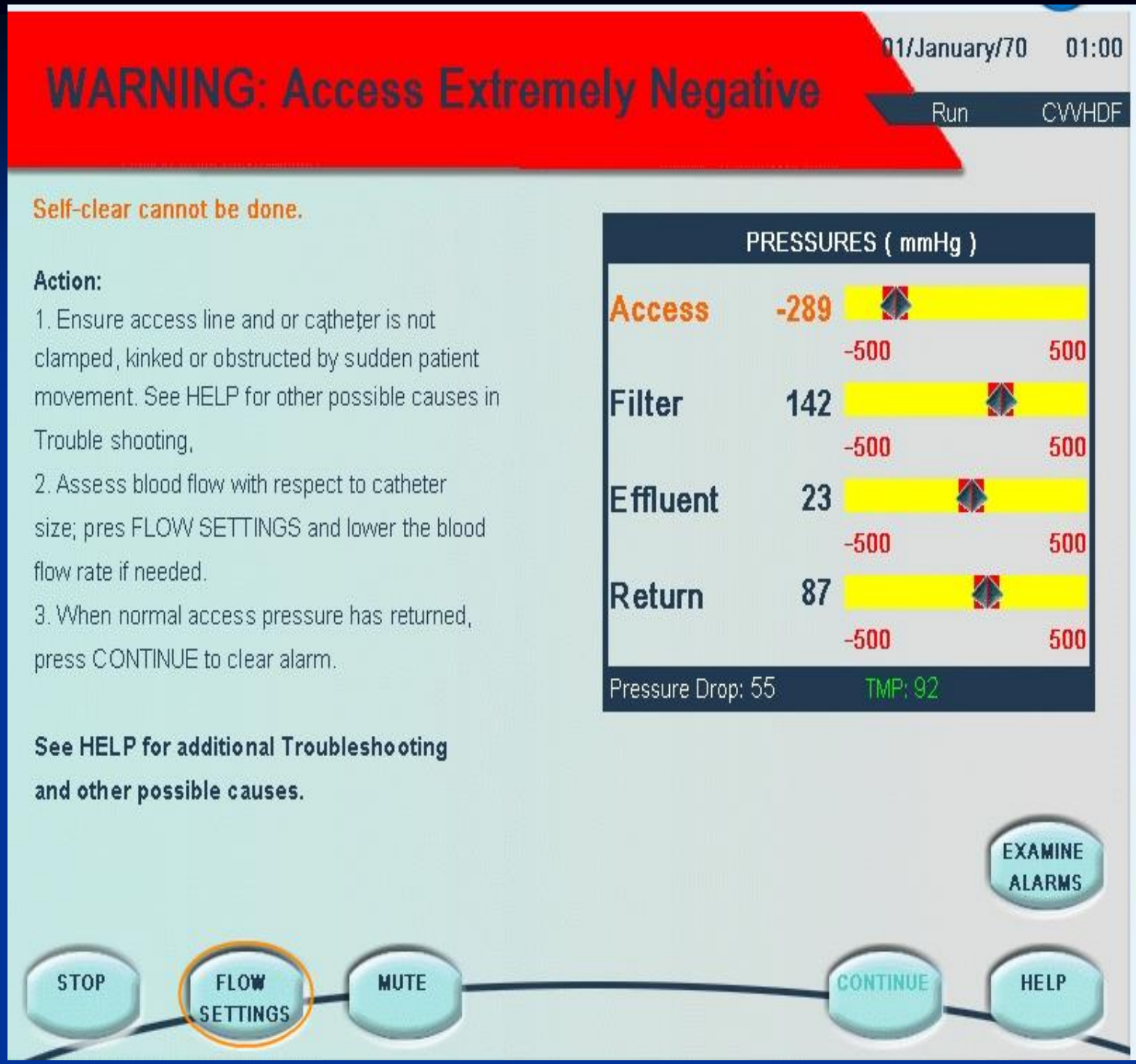
Access catheter clotted or out of position in vein ; patient is moving or being moved ; patient being suctioned ; blood rate too high ; access pressure sensor failed. (See Troubleshooting, Operator's Manual).



EXAMINE ALARMS

MUTE

HELP

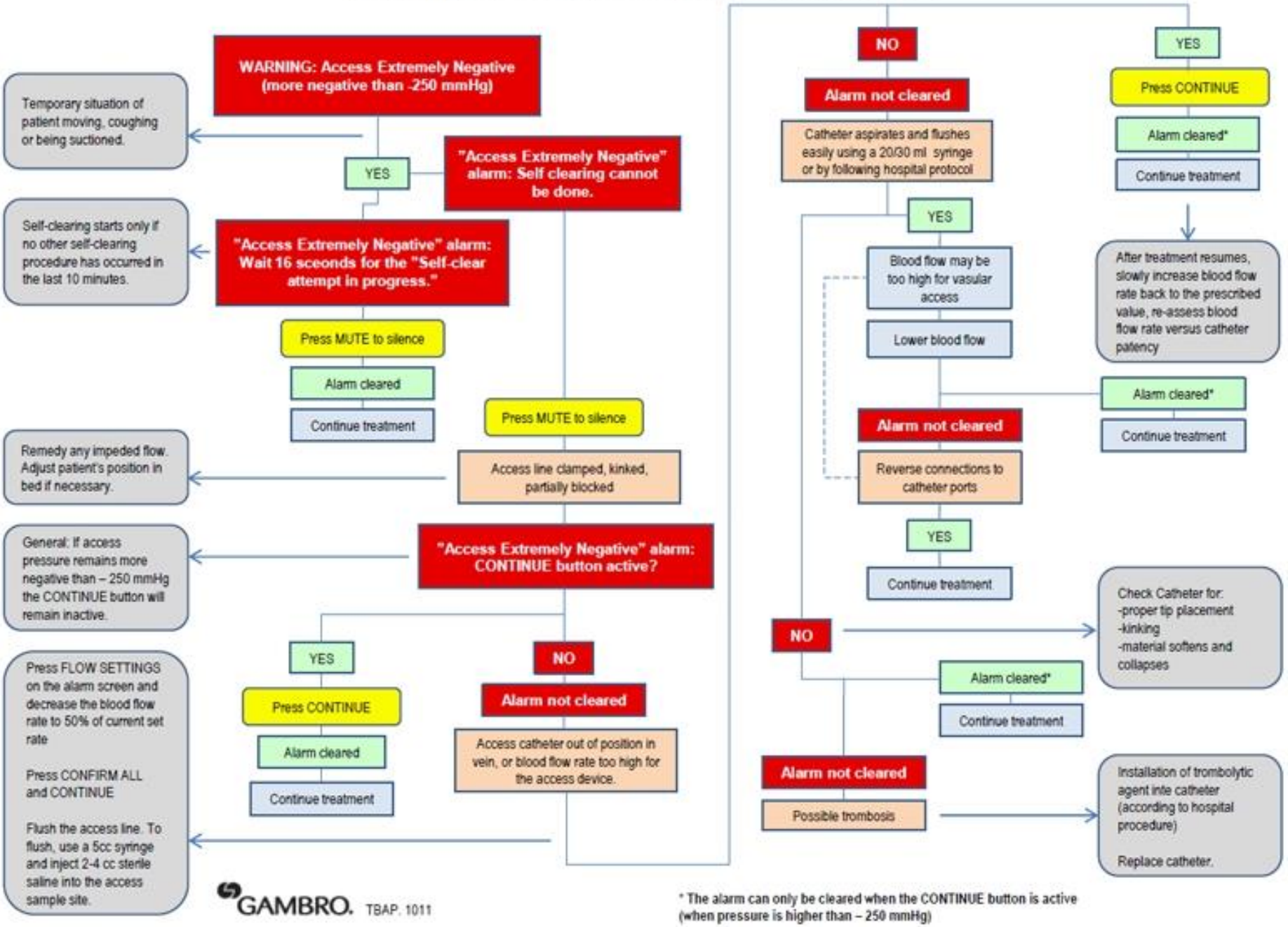


Rule out other possible causes: access catheter clotted or out of position in vein; patient is moving or being moved; patient being suctioned; blood rate too high; access pressure sensor failed. Self clear cannot occur because the access pressure remains more negative than -250 mmHg

The CONTINUE soft key will remain inactive (grey) until the access pressure has become less negative than -250 mmHg.

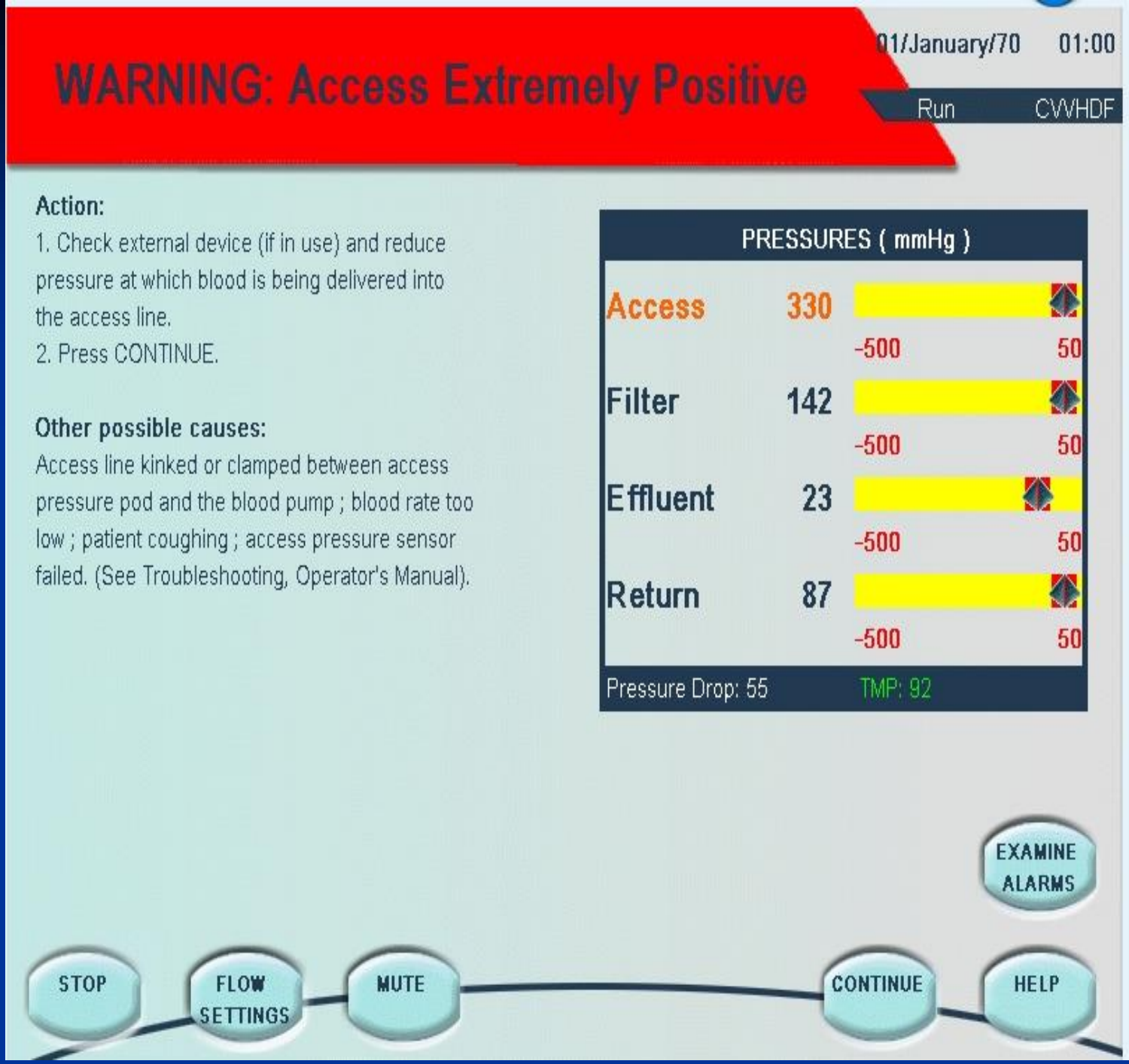
Press: FLOW SETTINGS

Warning: Access Pressure Extremely Negative



GAMBRO. TBAP. 1011

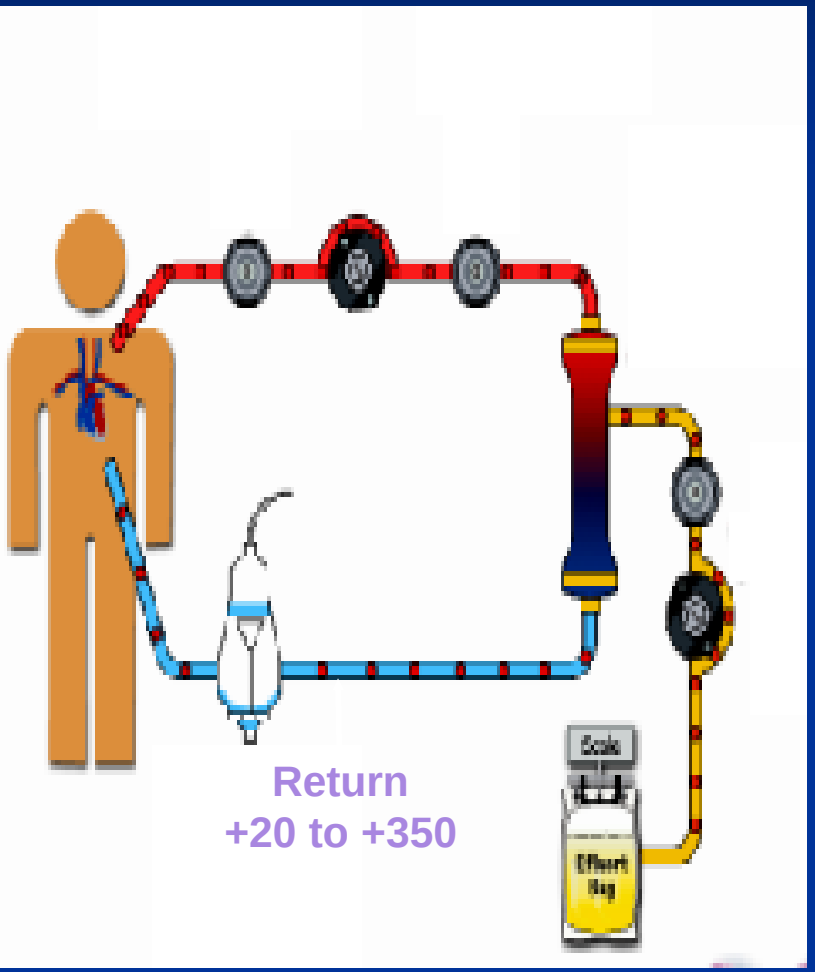
* The alarm can only be cleared when the CONTINUE button is active (when pressure is higher than – 250 mmHg)



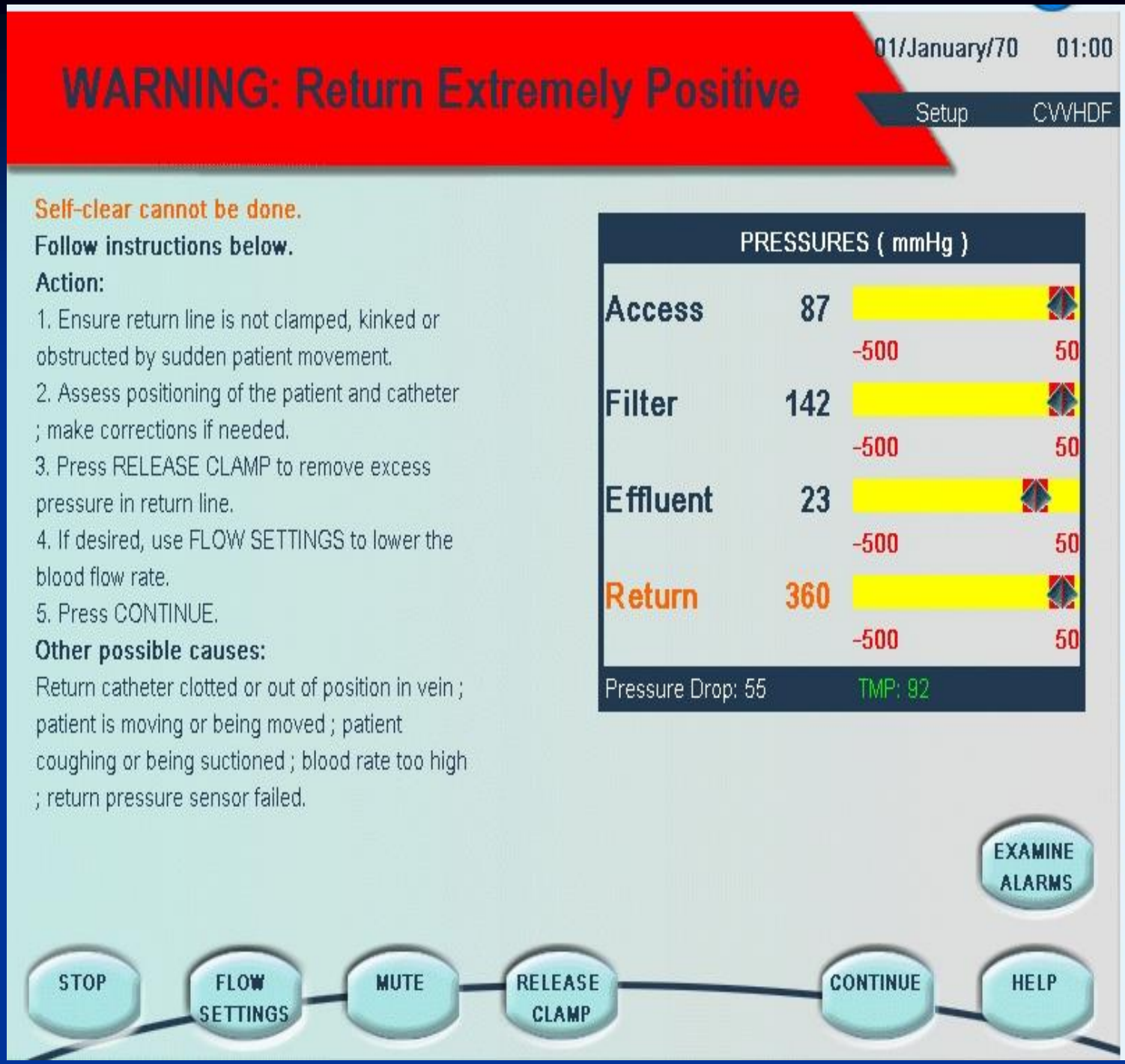
This alarm might occur when you're operating in positive access monitoring range, using an external device to deliver blood to Prismaflex set. This alarm is NOT self-clearing, so start right away on the action steps.

Rule out all possible causes and verify the access pressure becomes less positive than +300 mmHg before pressing CONTINUE
Otherwise select FLOW SETTINGS to modify rates.

Return Pressure



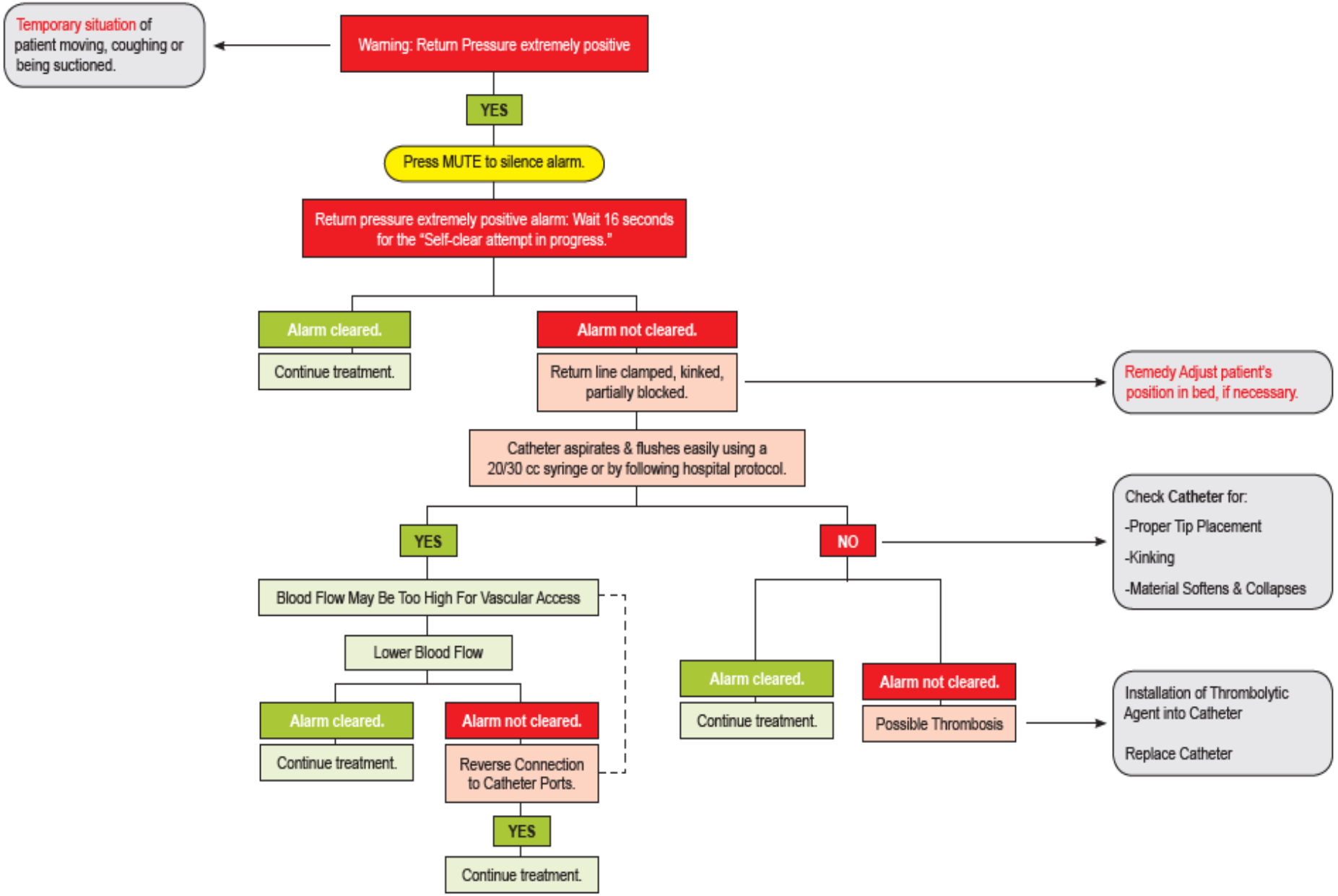
- Pressure created by returning blood to patient through access
- Uses internal pressure sensor/ deaeration chamber monitor line
- Always positive
- Typical pressure: +50mmHg to +150mmHg



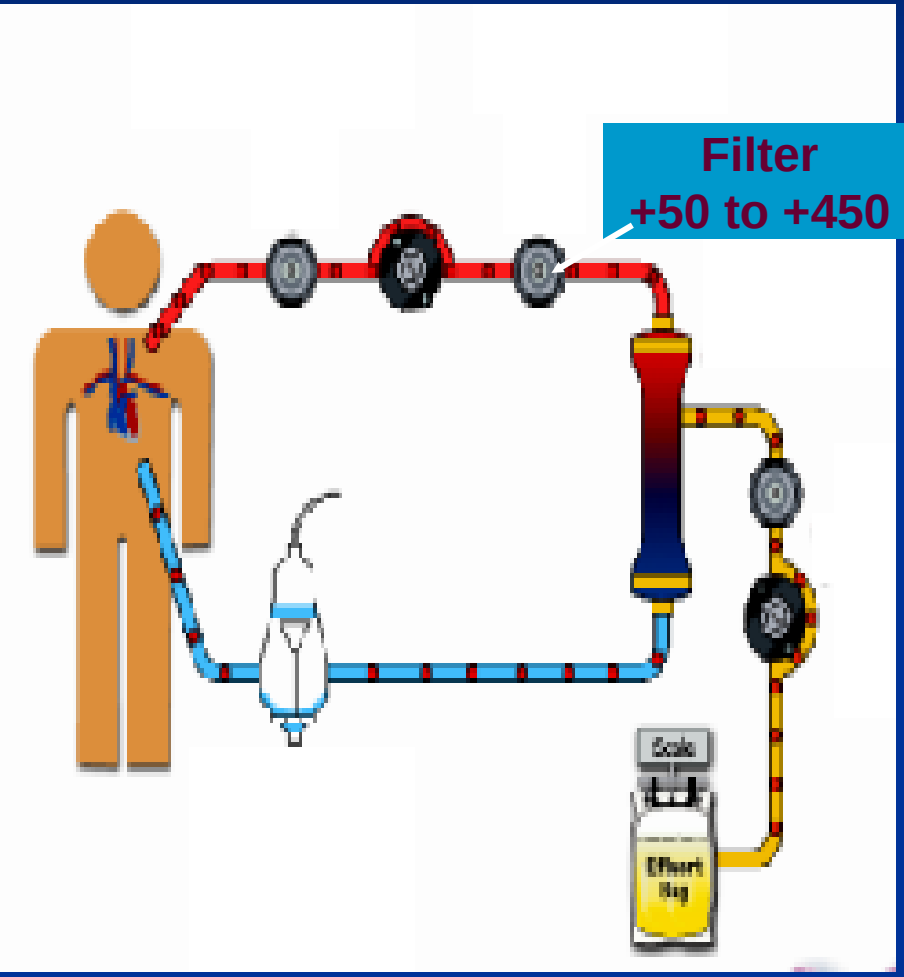
Rule out other possible causes: access catheter clotted or out of position in vein; patient is moving or being moved; patient being suctioned; blood rate too high; access pressure sensor failed. Self-clear cannot occur because the return pressure remains more positive than +350 mmHg

Press RELEASE CLAMP and verify the return pressure becomes less positive than +350 mmHg before pressing CONTINUE. Otherwise select FLOW SETTINGS to modify the rates.

Warning: Return Pressure extremely positive



Filter Pressure



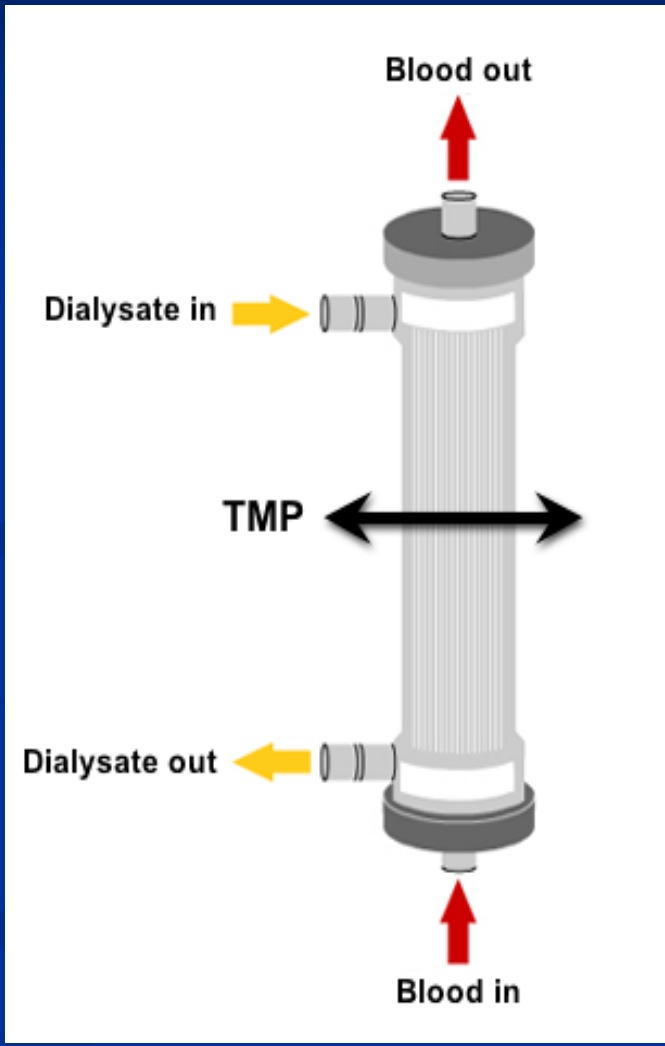
- Circuit pressure to push blood into filter
- Most positive pressure displayed
- Typical pressure:
  +100mmHg to +250mmHg

Trans-Membrane Pressure (TMP)

Calculated and automatically recorded:

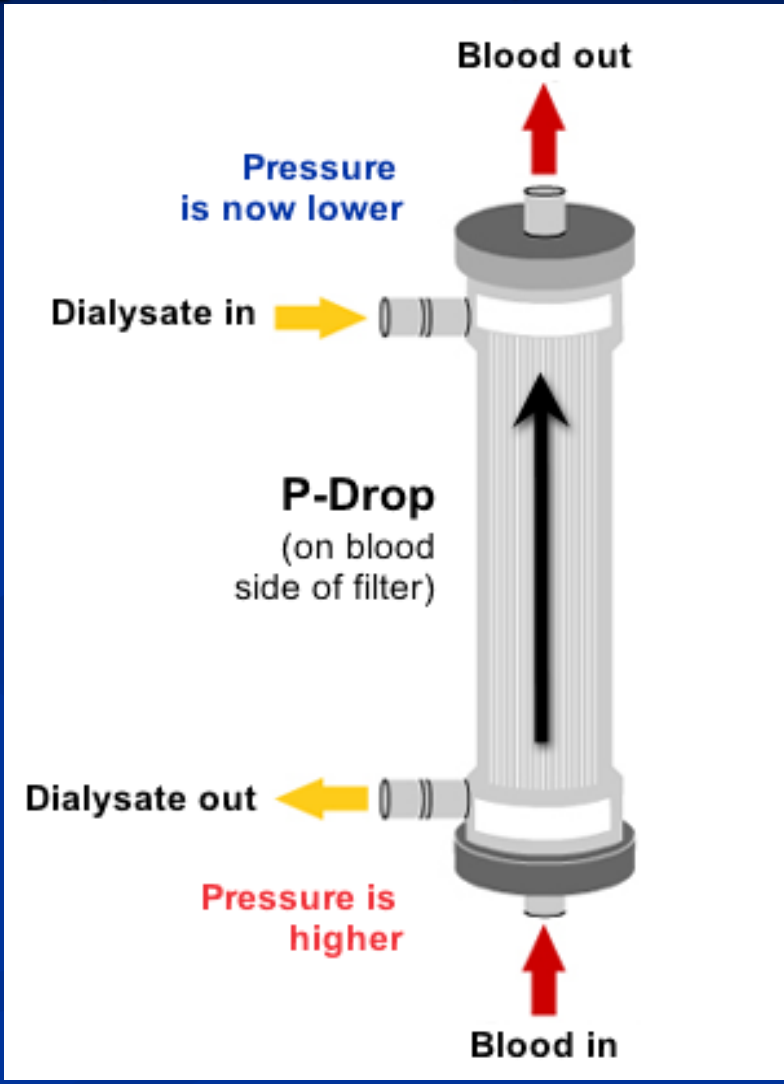
- **Entering Run mode- blood flow is stabilized**
- **Blood flow rate is changed**
- **Patient fluid removal rate is changed**
- **Replacement solution rate is changed**

Membrane permeability ↓ TMP ↑



Filter Pressure Drop (ΔP Filter)

- Change of pressure from blood entering filter and leaving filter
- Determines pressure conditions inside hollow fibers
- Calculated and automatically recorded:
  - Entering Run mode
  - Blood flow rate is changed
- Calculated by Prismaflex software



Clotting alarms
This notification occurs if internal pressures increase to certain limits where filter clotting or pore plugging are likely to be in progress.

Advisory: Filter is clotting:
(a) TMP is 100 mmHg above the last-calculated TMP value, and/or
(b) Pressure Drop is 100 mmHg above the last-calculated Pressure Drop value.

Warning: Filter Clotted:
(a) Filter pressure drop is greater than the limit value for the filter in use, or
(b) TMP Excessive Caution and Filter is Clotting Advisory conditions occur simultaneously

ADVISORY: Filter is Clotting

01/January/70 01:00

Run CVVHDF

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.

EXAMINE ALARMS

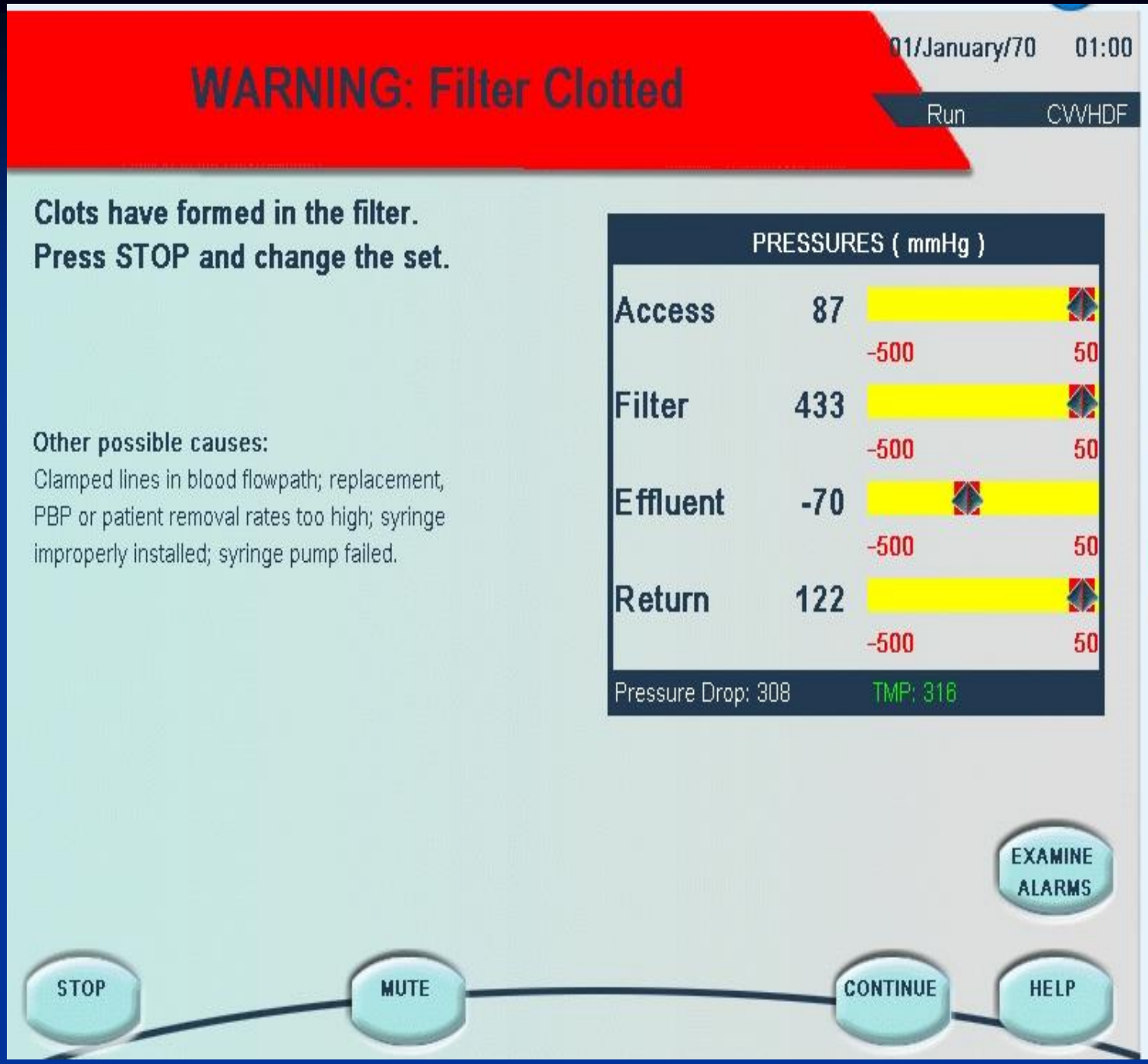
STOP

FLOW SETTINGS

MUTE

OVERRIDE

HELP



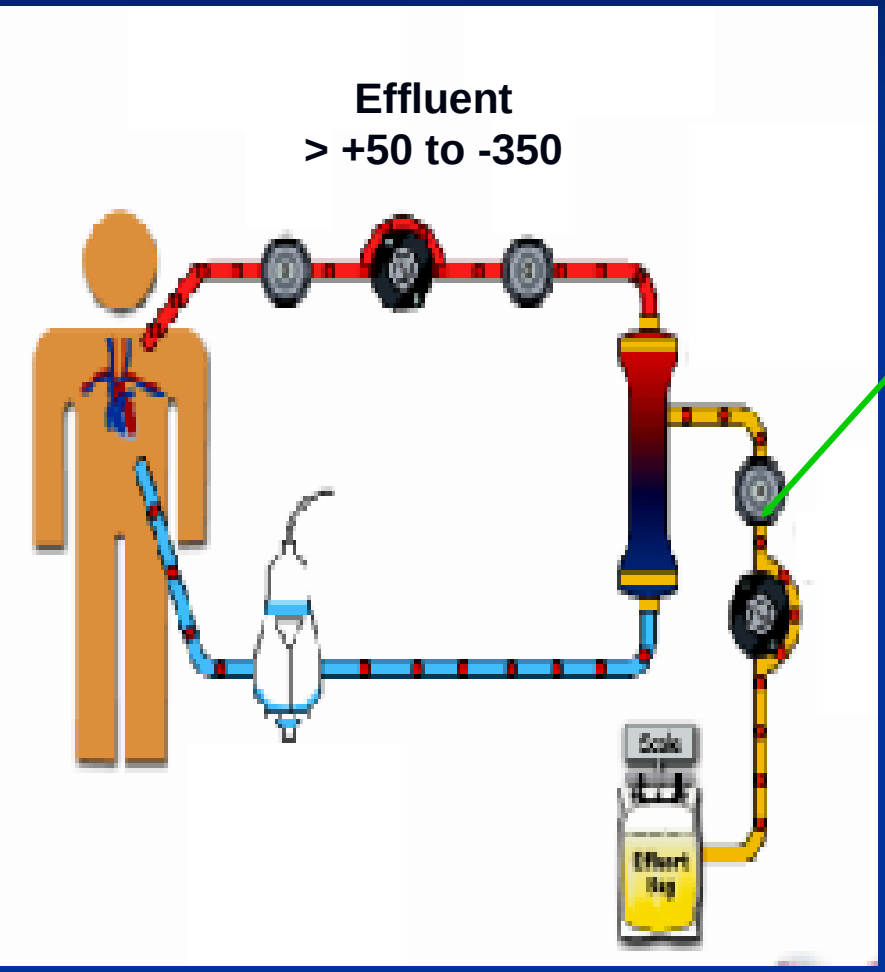
Inadequate anticoagulation is the top cause for filter clotting.

Make sure anticoagulation strategy is properly assessed.

Did this alarm occur suddenly, with no prior clotting advisory?

If yes, consider “Other possible causes”.

Effluent Pressure



- Pressure depends on:
  - Therapy and UFR
- Typical pressure:

  +50mmHg to
  -150mmHg

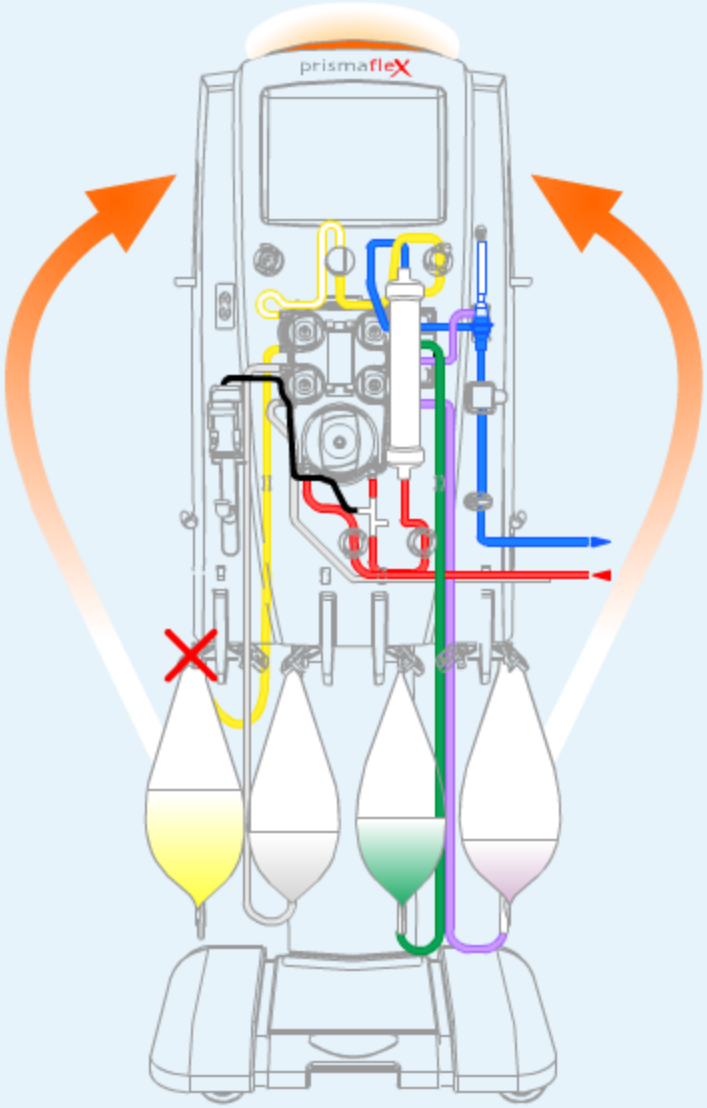
Safety Features

Fluid Control Unit

Continuous Monitor feedback Balances fluid between:

- Scales
- Software
- Pumps

"Incorrect Weight Change Detected" fluid variance in Patient Fluid Removal compare to the set Fluid Removal rate



Incorrect weight / Incorrect flow

Abnormal situations can cause a bag weight to differ from its expected weight. If this happens, an “Incorrect Weight” alarm notifies you!

Other situations can cause a fluid pump flow to differ from its expected flow. If this happens an "Incorrect flow" alarm notifies you.

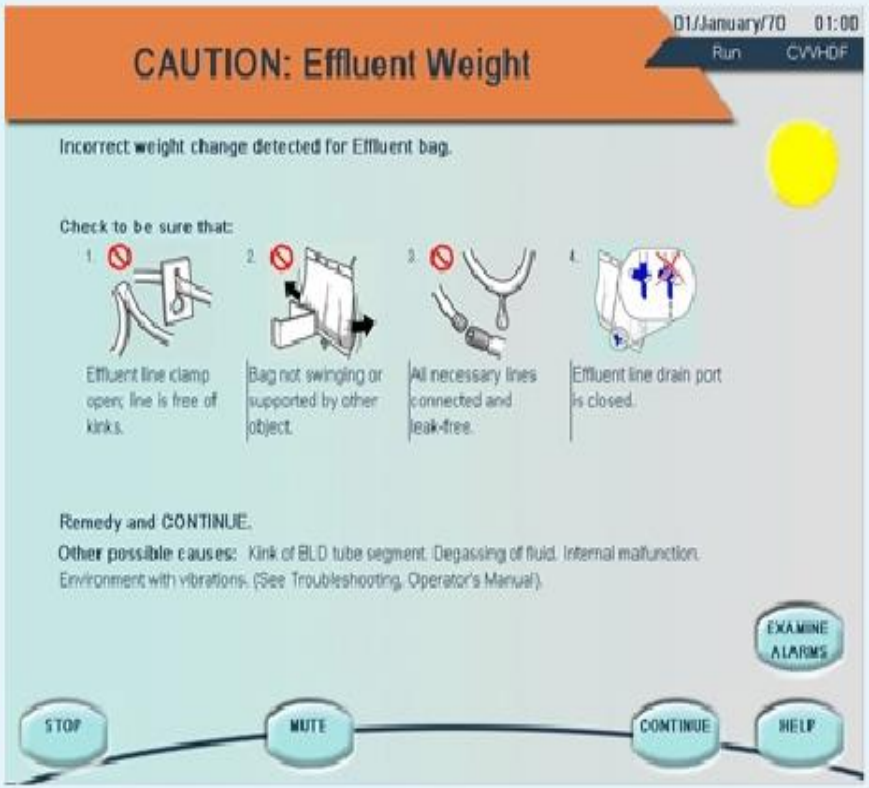
These two different situations result in unintended fluid loss or gain for the patient.

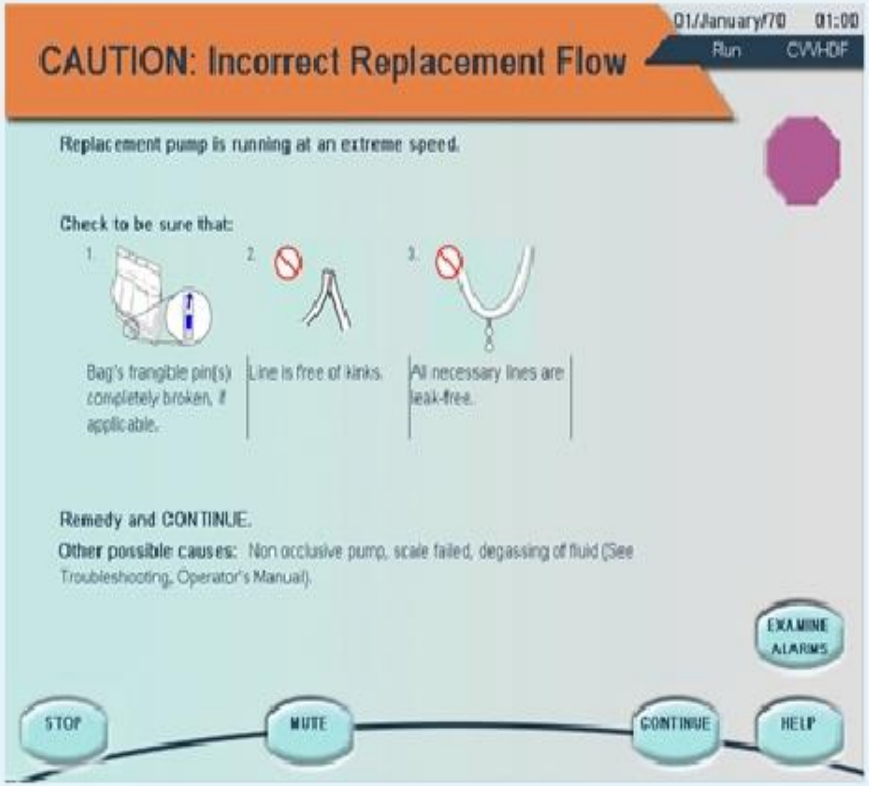
Meet the Fluid Safety Guard!

The guard’s job is to protect the patient from unintended fluid Loss or Gain in case of unresolved flow problems.

The guard constantly monitors how much excess (unintended) fluid Loss or Gain has occurred over the past 3 hours of Run Time.
If the limit is reached, the guard sets off an alarm that requires you to change the set or end the treatment.

During operation, the software compares the actual bag weights to the expected weights and monitors the speed of all solutions pumps. Two types of alarms can be triggered.





What triggers the Incorrect Weight Change Alarm?

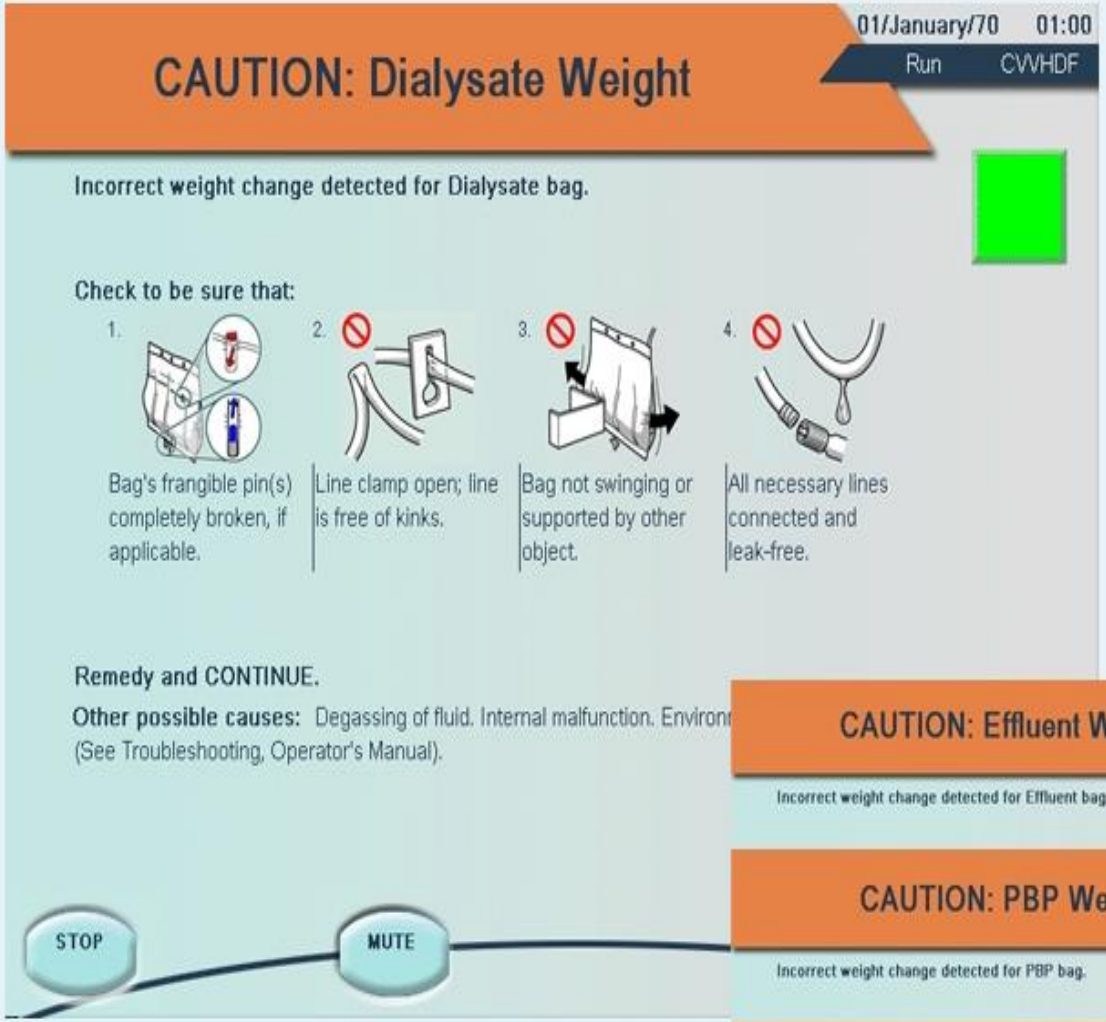
- 40ml+/- for immediate variance from operator set patient fluid removal
- 120ml variance in one hour from operator set patient fluid removal

Incorrect Weight Change Detected

Occurs when weight on one or more scales does not change according to set fluid flow rates.

Causes:

- Frangible pin(s) in solution bags not completely broken
- Kinked or clamped fluid line
- Bags swinging on scale hook
- Leaking bags or bag lines not properly connected
- Foreign object on scales
- Partially supported bags (not hanging freely)

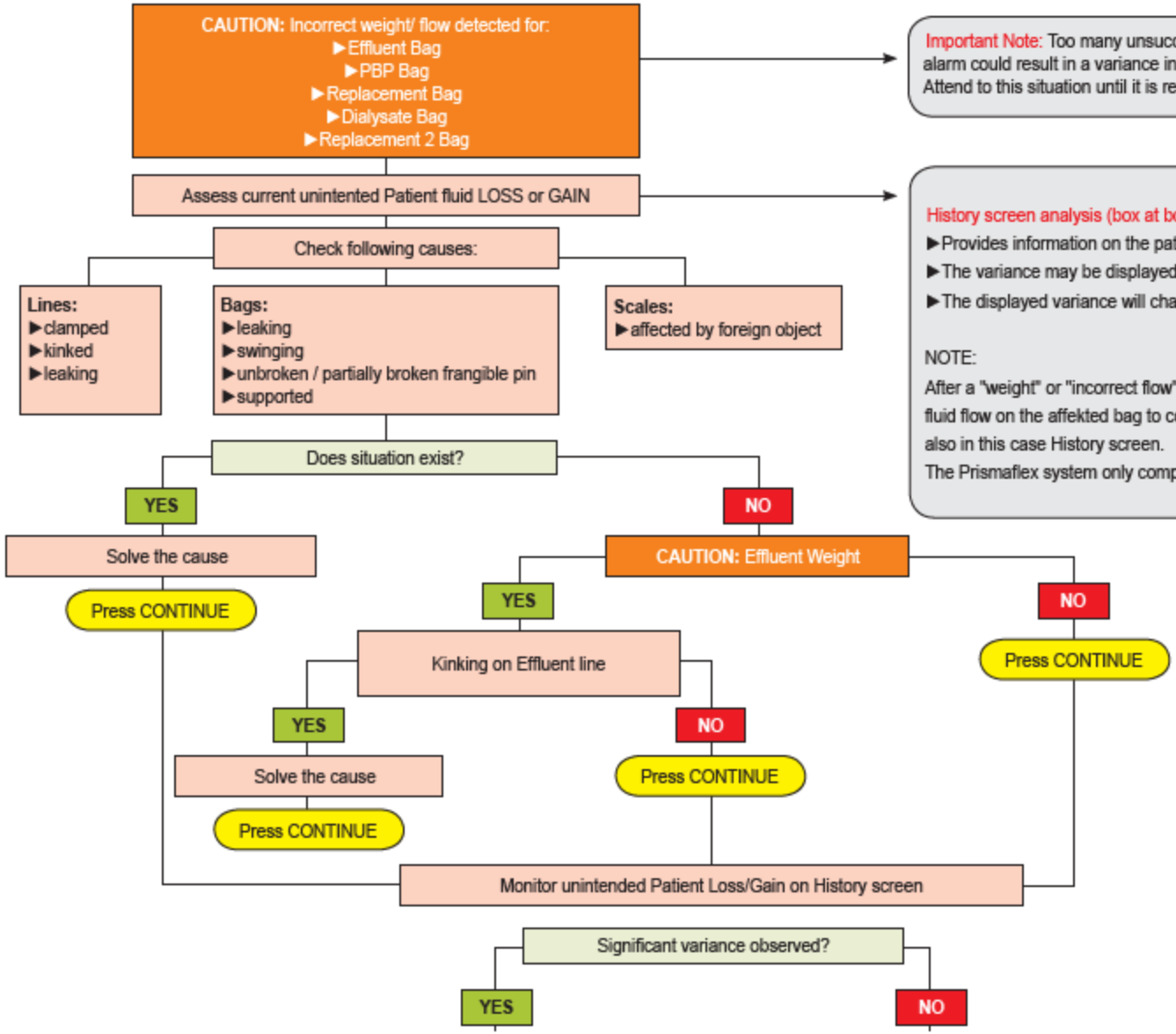


There is an "Incorrect Weight" alarm for each fluid bag.

Notice these alarms are Cautions. The blood pump still runs, but all fluid pumps are stopped.

CONTINUE restarts the fluid pumps. You should press it only after thoroughly troubleshooting all possible causes of the alarm.

Caution: Incorrect Weight/ Flow Alarms



Important Note: Too many unsuccesful attempts to clear an incorrect weight / Flow alarm could result in a variance in patient fluid removal / fluid balance.
Attend to this situation until it is resolved.

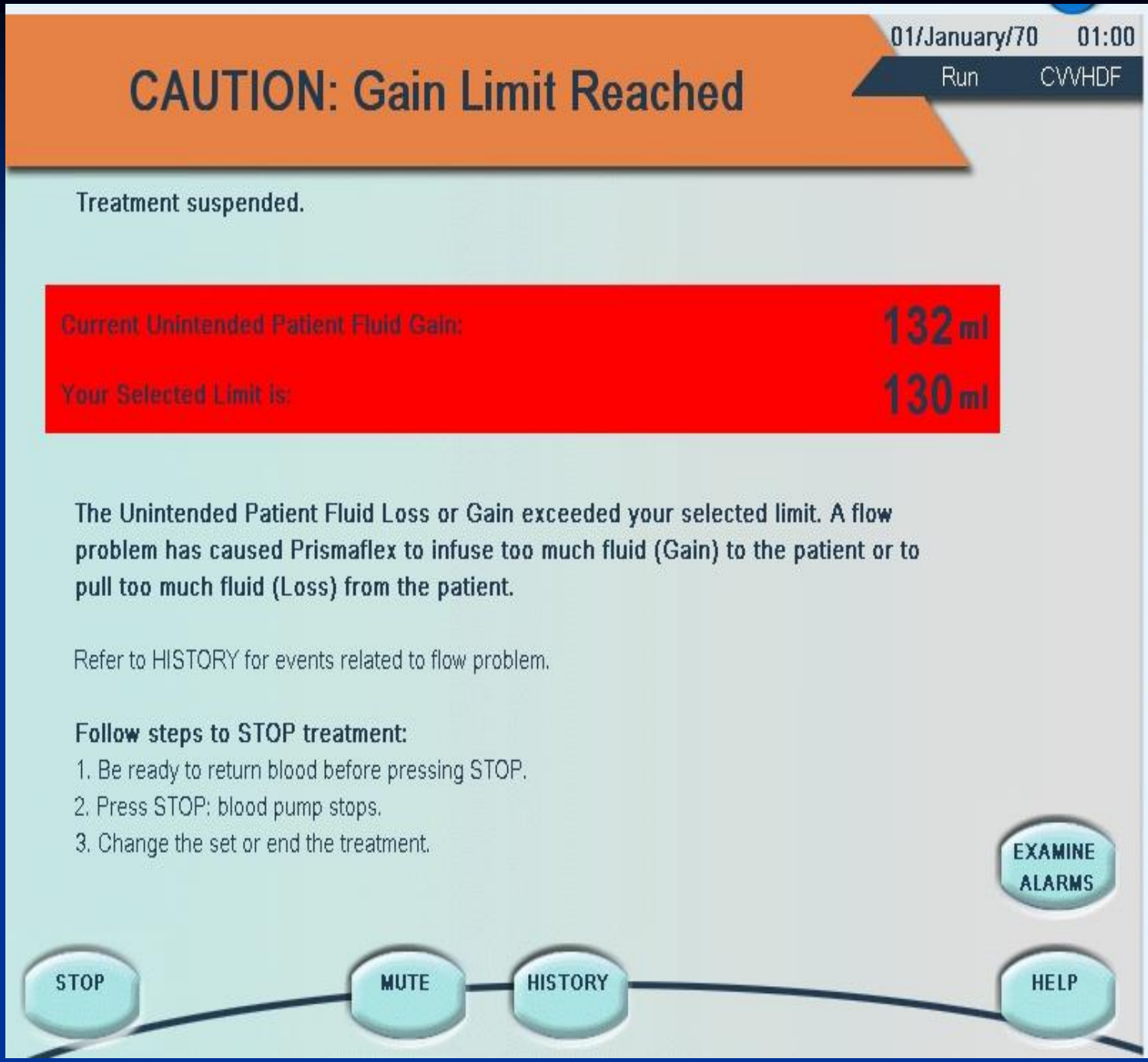
History screen analysis (box at bottom of screen):

- ▶Provides information on the patient fluid removal variance over a 3-hour period
- ▶The variance may be displayed as LOSS or GAIN.
- ▶The displayed variance will change each time a weight/ flow alarm occurs.

NOTE:

After a "weight" or "incorrect flow" event the Prismaflex will temporally increase the fluid flow on the affekted bag to compensate for the occured flow deviation. Consult also in this case History screen.

The Prismaflex system only compensates for errors up to 100 ml.



If unintended fluid LOSS or GAIN reaches the alarm limit, this alarm takes precedence over the situation.

The fluid pumps will not re-start until you either change the set or end the treatment. The fluid safety guard is on duty.

Before you begin these steps, assess your patient for symptoms of fluid imbalance. follow your facility's protocol for medical intervention.

The History screen has valuable information you will need to check afterwards.

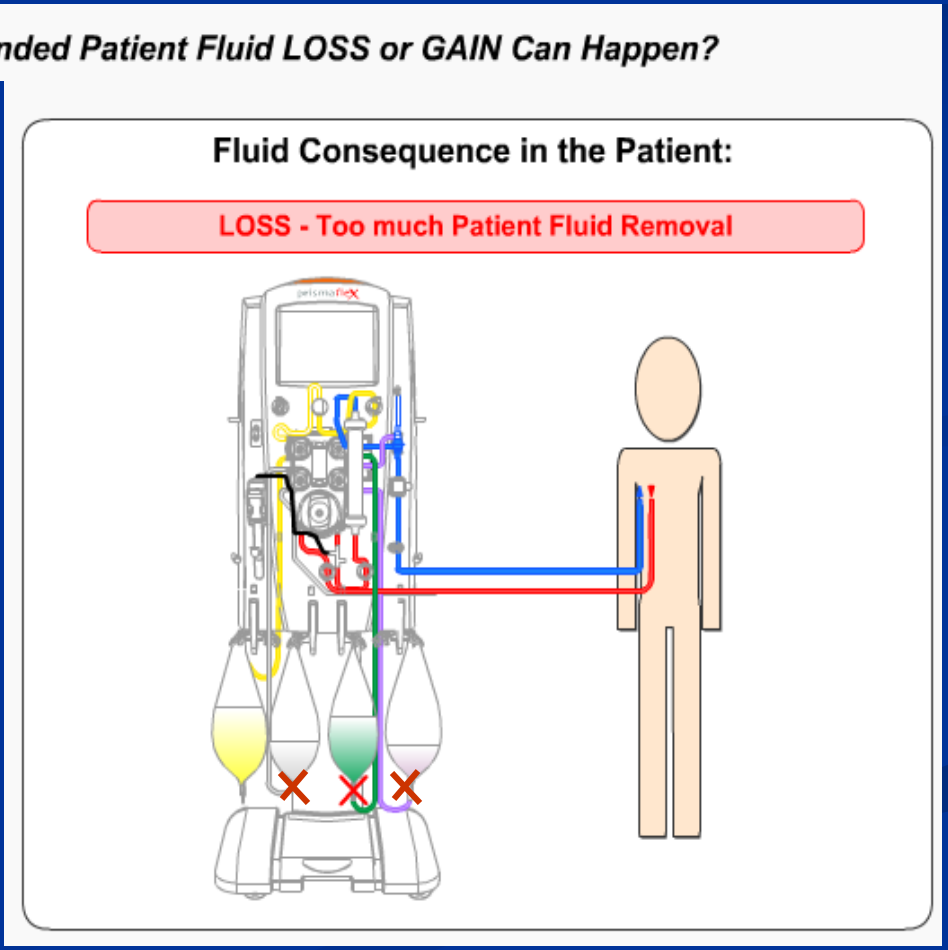
Incorrect Weight Change: Patient Fluid LOSS

If:

Dialysate, replacement, or PBP *flow is obstructed*

Then:

Fluid may be pulled from *patient* through blood side of filter



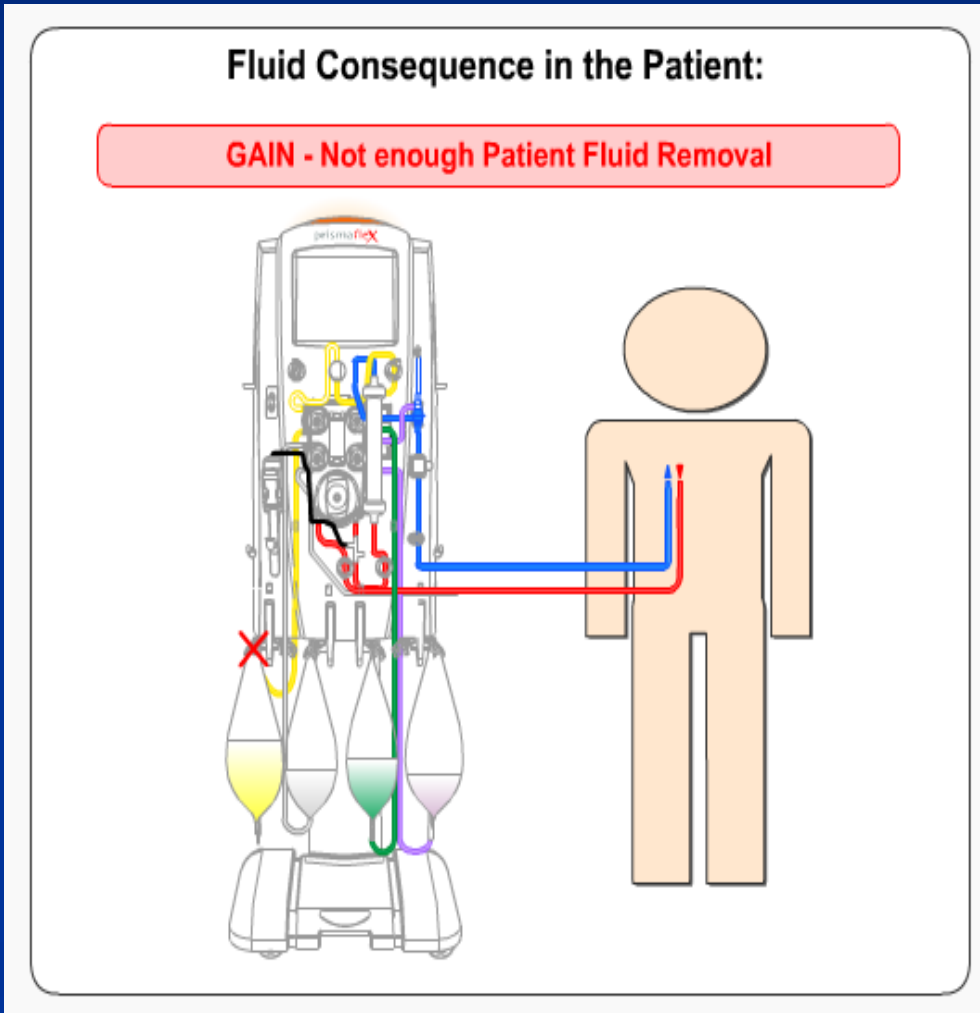
Incorrect Weight Change: Patient Fluid GAIN

If:

Effluent flow is obstructed

Then:

Fluid may be infused to *the patient* from blood side of filter



WARNING: Blood Leak Detected

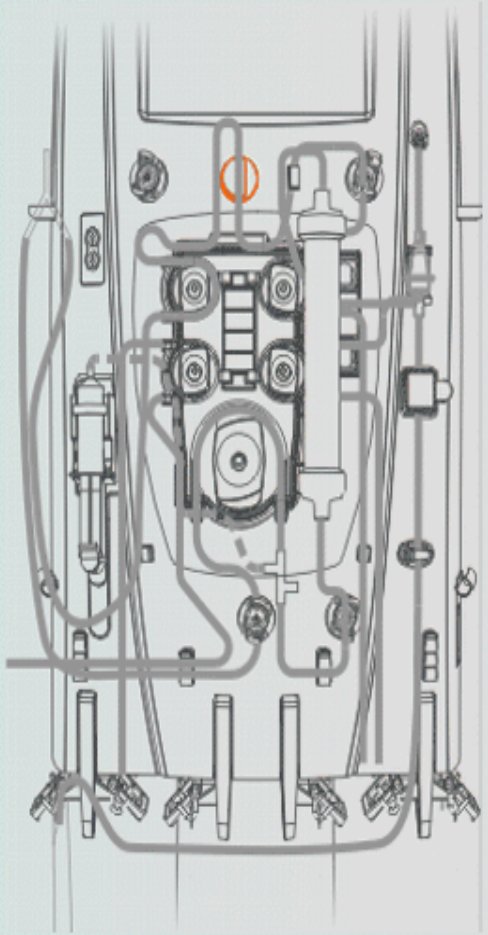
01/January/70 01:00

Run CWVHDF

OVERRIDE overrides this alarm for 60 seconds. Monitor closely.

Leak in filter membrane. Press STOP and change the set.

1



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:

2

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).

EXAMINE ALARMS

3

STOP MUTE OVERRIDE HELP

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

2. If effluent color is normal, inspect for these other possibilities, remedy, OVERRIDE. Send effluent sample to lab to confirm a filter blood leak.

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

Let's see how to do this.

Normalize Blood Leak Detector

01/January/70 01:00

Signal Value: 0

Run CVVHDF

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 important to verify that effluent line is free of blood or air at the time of normalization.

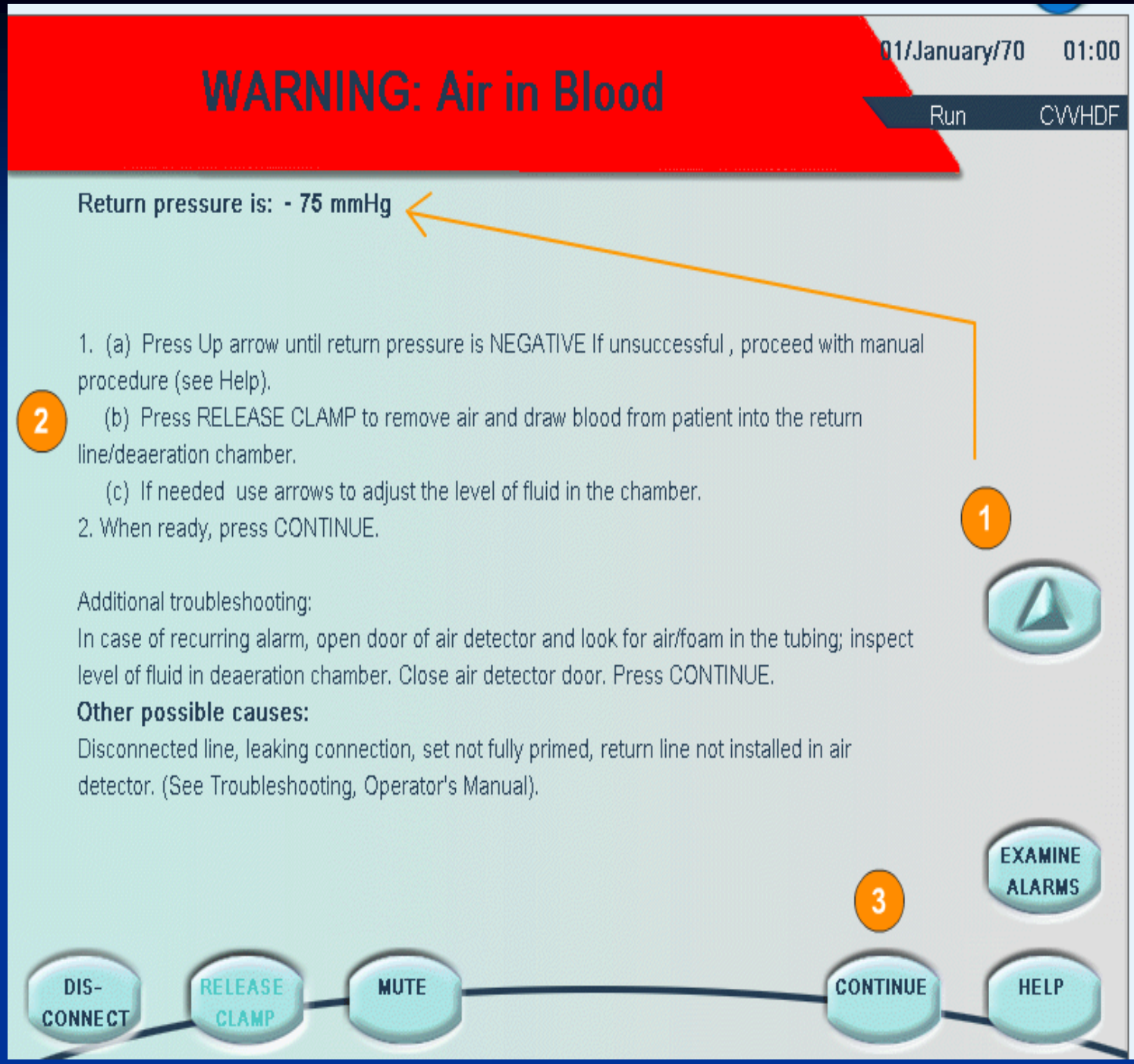
EXAMINE ALARMS

Blood Leak Detected (BLD)

- Leakage of blood to the fluid side of the hemofilter
- Other causes:
  - Air in effluent line
  - Effluent line not properly installed in BLD
  - Myoglobin (trauma, burn, Rhabdomyolysis)
  - Bilirubin (Liver failure, Hyperbilirubin) Conjugated only
  - Debris in sensor housing

Effluent Testing Do's & Don't's

- When testing effluent, **DO**:
  - Use a quantitative method:
    - Run effluent as though it were blood
    - Perform RBC count
    - Results should be zero
    - Run as Peritoneal cell count
- When testing effluent **DO NOT**:
  - Use Hem-a-Stix or other urine dipstix
  - Run effluent as urine sample



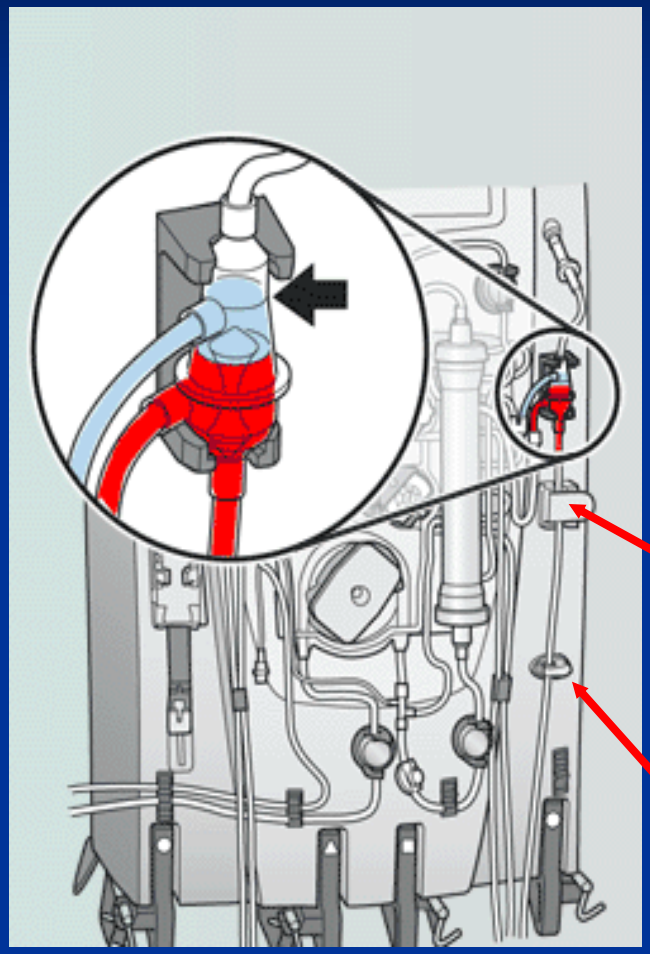
If this happens, follow the steps. Patient is safe because pumps are stopped and return clamp is closed.

1. Create a Negative pressure in the dearation chamber, by pressing the arrow key.

2. Press RELEASE CLAMP. This will release the air bubbles from the return line.

3. Press CONTINUE to restart the pumps, and clear the alarm. If alarm doesn't clear, look at "Other possible causes". You may need to disconnect and change the set.

Air Bubble Detector



- Ultrasonic
- Located along return line
- Alarm activated by:
  - air in blood
  - micro air

Prismaflex® System

End Treatment

Stop

Caution: Stopping pumps may cause clotting in the blood flowpath.

RESUME	- Restart pumps and resume treatment.
CHANGE SET	- Change the set.
RECIRC	- Temporarily disconnect patient. - Allow recirculation of blood or saline through the blood flowpath.
END TREATMT	- Terminate the treatment.

End Treatment

RETURN BLOOD - Return blood to patient, if desired.

Note: If blood return is not done, patient will lose the volume of blood in the blood flowpath. This volume depends on the filter in use. (For specific volume, see the Instructions for Use packaged with the set.)

DISCONNECT - Disconnect patient from set without returning blood.

CANCEL
- Cancel "End Treatment" choice.
- Return to the Stop screen.

Prepare to Return Blood

01/January/70 01:00

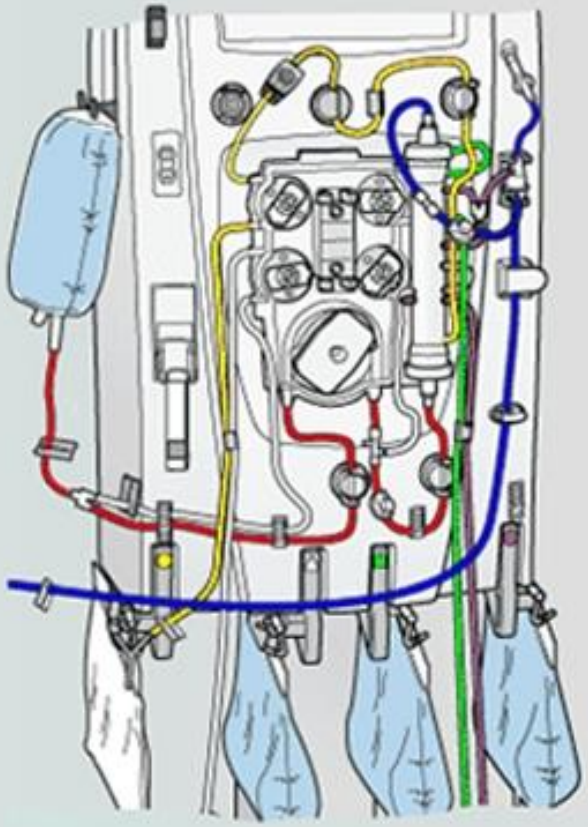
End CVVHDF

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

Hang a bag of sterile saline on priming hook.

Clamp access line.
Disconnect line from patient (or other blood access).

Connect access line to saline.
Unclamp access line.



Press CONTINUE when ready to proceed.

CANCEL

DIS-CONNECT

CONTINUE

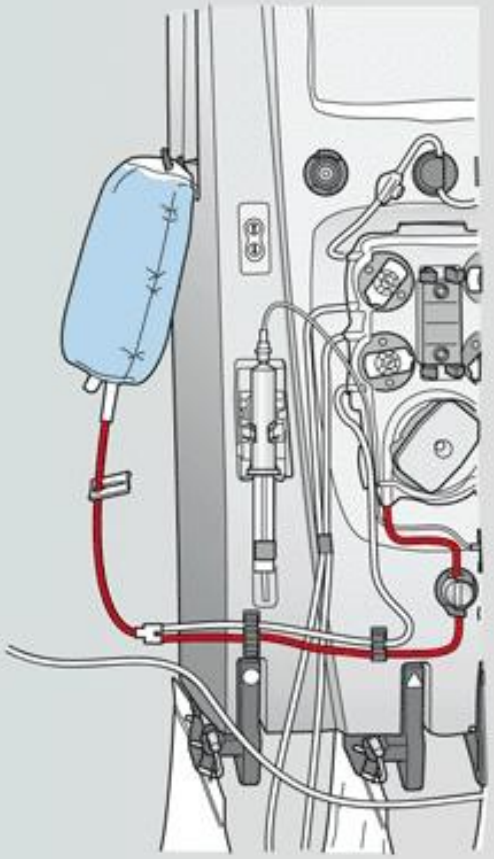
Prepare to Return Blood

01/January/70 01:00

End CVVHDF

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

- Hang a bag of sterile saline on priming hook.
- Clamp access line.
  Disconnect line from patient (or other blood access).
- Connect access line to saline.
  Unclamp access line.



Press CONTINUE when ready to proceed.

CANCEL DIS-CONNECT CONTINUE

Return Blood

01/January/70 01:00

End CVVHDF

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

Actions:

1. Verify blood return rate below. Press RETURN RATE to modify, if necessary.
2. 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
Blood volume in set	152 ml
Cumulated Volume Returned	**0 ml**

RETURN RATE | DIS-CONNECT | MANUAL RETURN | CONTINUE | HELP

Enter Blood Return Rate

Enter desired blood return rate (press BLOOD and use arrows to modify). When ready, press CONFIRM.

Blood	100 ml/min

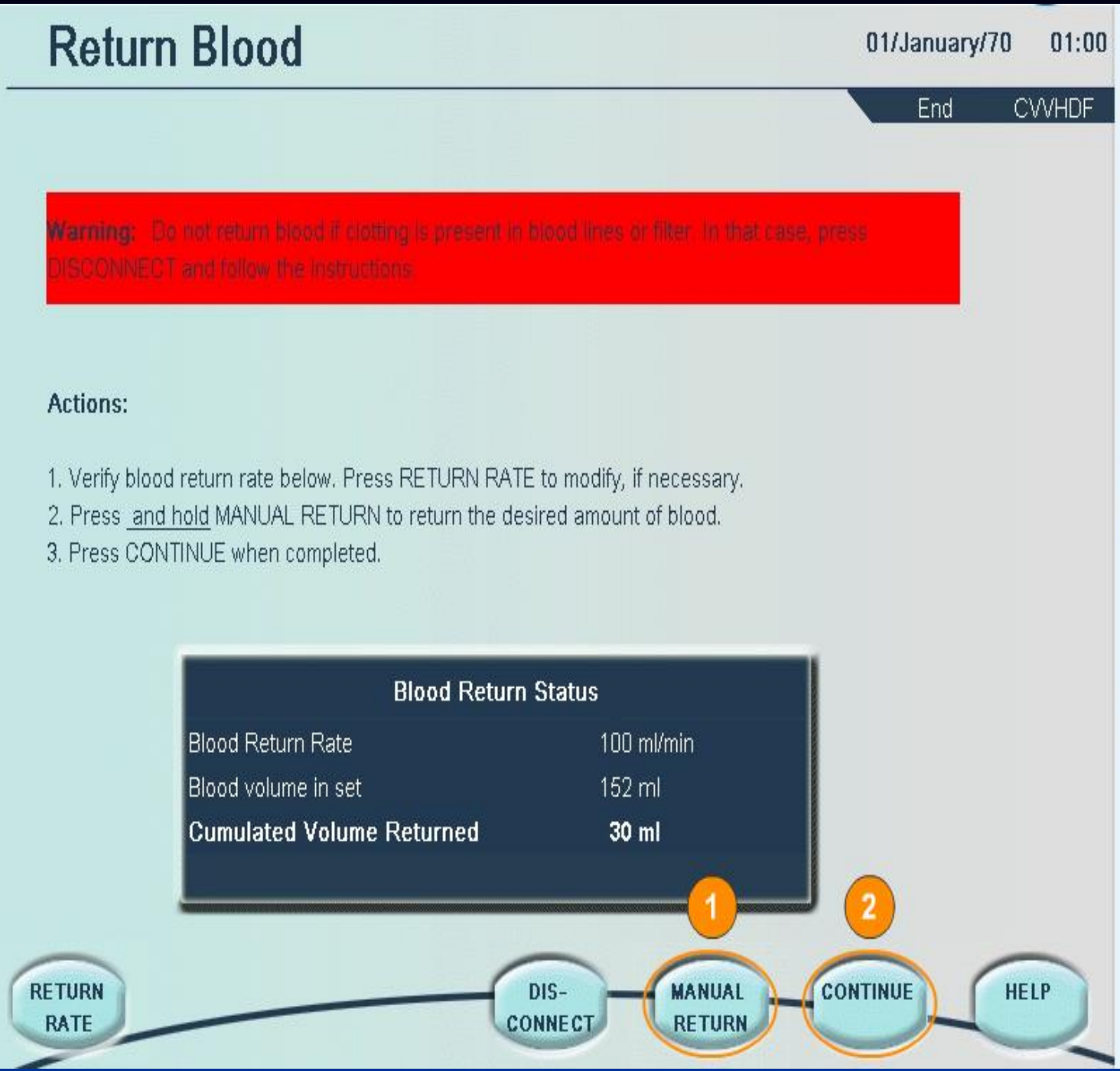
Range: 10 to 100 ml/min

CLEAR

CONFIRM

BLOOD

CANCEL



1. While you're pressing the MANUAL RETURN, check the estimate Cumulated Volume of blood returned to your patient.

That may become handy for your patient fluid management.

2. Press CONTINUE when ready to disconnect patient.

Disconnect Patient

Perform steps below:

1. Clamp all lines in the set.

2. Disconnect access and return lines.

3. Disconnect syringe line from syringe.

4. Press UNLOAD to unload pump segments from pump raceways.

Warning: UNLOAD disables air bubble detection and other patient protection alarms. **Ensure patient is disconnected before pressing UNLOAD.**

CANCEL

UNLOAD

QUESTIONS?