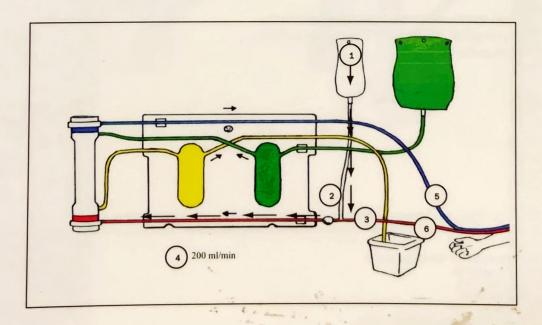
Return of the Blood (Rinseback)

If you experience difficulties in resolving alarms after 2 or 3 attempts, consider returning the blood (if the blood circuit is not clotted) for *A-emergent rinseback*, then contact your center or NxStage Technical Support for additional assistance. Hopefully, this will prevent you from losing your blood circuit during troubleshooting. If you experience a cycler or power failure, proceed to *B-Manual Rinseback*.

A: Emergent rinseback (procedure is similar to a manual fluid bolus)

- 1.) Make sure enough saline is available to rinse back the blood (300-500ml).
- 2. Open the saline clamps (red and white) and ensure saline is flowing.
- 3) Occlude (or clamp) the arterial patient line (red clamp) before the saline "T".
- 4. Decrease the blood flow rate to 200ml/min (you may first need to decrease the therapy fluid pump rate to decrease BFR).
- (5.) When the venous patient line is clear, press STOP.
- 6. If desired, (and there is enough saline) return the remaining blood in the rest of the arterial patient line, by unclamping the arterial patient line (red clamp), and allowing saline to flow by gravity to return blood through the arterial access. **Monitor carefully for air.**



Disclaimer: This is not intended to replace the NxStage User's Guide or cartridge Instructions for Use. Always follow the User's Guide and applicable instructions for troubleshooting, end of treatment, and returning the blood.

B: Manual rinseback for cycler or power failure

- Make sure enough saline is available to rinseback the blood 300-500ml.
- 2. Turn the power switches to both the Cycler and the Fluid Warmer off.
- 3. Clamp the waste line (yellow clamp) and the Dialysate line inlet (green clamp).
- 4. Clamp and disconnect the arterial patient line (red clamp), reconnect it to the priming spike (red port), then unclamp (see fig. 1).
- 5. Lift the handle up completely (until it clicks) and pull to open the Cycler door.
- 6. Squeeze the saline bag until the patient lines have rinsed clear. If pressure exists, or air is present in the venous patient line (blue clamp), DO NOT attempt to Rinseback (see fig. 2).
- 7. Clamp and disconnect the venous patient line from the patient's vascular access.
- Open the Fluid Warmer door and remove the disposables. Discard the Cartridge and Fluids appropriately.

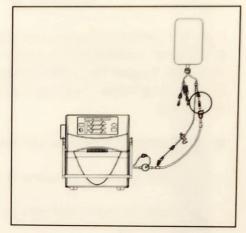


Fig. 1



Fig. 2

Disclaimer: This is not intended to replace the NxStage User's Guide or cartridge Instructions for Use. Always follow the User's Guide and applicable instructions for troubleshooting, end of treatment, and returning the blood.

COMPANY CONTACT INFORMATION

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Detailed reference list provided upon request. FOR PRESCRIPTION USE ONLY.

List of alarms and cautions

000 - End of TREATMENT/RINSEBACK (Yellow Caution)

000 - Alarm Test Passed (Red Alarm)

Priority

- Yellow caution Low
- Red alarm High

Alarm event

The system has reached the end of a process.

Check for	Do
The system has successfully reached the end of a major process (prime, treatment, rinseback).	No action required. Press STOP if you want to go to the next mode, such as: • From prime to treatment • From treatment to rinseback

1 - Infusing Fluid Bolus (Yellow Caution)

Priority

• Yellow caution - Low

Alarm event

ADD FLUID was pressed during the treatment and an automated fluid bolus is underway.

Check for	Do
This feature is only active when System Setting #9 is set to a value greater than 0. System Setting #9 determines the volume of the fluid bolus (see Changing system settings, page 9-2).	No action required. Press STOP if you want to stop infusing the bolus.



PRECAUTION -



The default value for System Setting #9 is zero (0) for hemodialysis which disables the automatic bolus feature. In certain geographic areas outside of the US, additional labeling provides more information on using the NxStage System One to deliver an automatic fluid bolus.

2 - Fluid Balance System Check Underway (Yellow Caution)

Priority

• Yellow caution - Low

Alarm event

The system is conducting a normal automated fluid balancing system check, which takes approximately two minutes.

Check for	Do -
The fluid balancing system check is performed at an interval determined by System Setting #43.	No action required. If the check fails, a balancing system red alarm occurs.

3 - Parameter Limit Exceeded (Yellow Caution)

Priority

• Yellow caution - Low

Alarm event

A setting is too low or too high.

Check for	Do
	Confirm the system settings. See the list of default settings in this user guide on page 9-6 for allowable settings.

4 - Blood Pump Off Caution (Yellow Caution)

Priority

• Yellow caution - Medium

Alarm event

The blood pump is stopped.

Check for	Do
stopped. Blood flow rate equals zero	 If you are using an external infusion pump, turn it off. Press TREATMENT to continue the treatment.
(0).	If you are using an external infusion pump, turn it back on again. OR
	 Press ADD FLUID to continue rinseback mode. The risk of clotting increases if the blood pump is stopped for a long time.

5 - Target Volume Achieved (Yellow Caution)

Priority

• Yellow caution - Low

Alarm event

The target volume has been reached.

Check for	Do
Dialysate or ultrafiltration volume target has been reached.	
	2. Press MUTE (x) to clear the caution.

6 - Blood Circulation Only (Yellow Caution)

Priority

• Yellow caution - Medium

Alarm event

No therapy is being delivered, but the target volume has not been reached.

Check for	Do
The dialysate and the ultrafiltration rates are set to zero (0), but at least one target volume is not zero. Blood is flowing through the cartridge, but no therapy is being delivered.	Reset rates or end the treatment and perform an automated rinseback, page 4-33, as appropriate.

7 - Alarms Overridden Caution (Yellow Caution)

Priority

· Yellow caution - Low

Alarm event

The system is stabilizing.

Check for	Do
One or more alarms are temporarily overridden as the system stabilizes, such as after a change to flow rates.	Monitor the treatment closely until a green operating condition returns.

8 - Pressure Limits Not Locked (Yellow Caution)

Priority

• Yellow caution - Low

Alarm event

The system is adjusting to a change in flow rates.

Check for	Do
The user has changed flow rates and the adjustable pressure limit windows have not yet "locked." See Chapter 9, System Settings for more information.	Monitor the treatment closely until a green operating condition returns.

9 - Automated High Pressure Recovery (Yellow Caution)

Priority

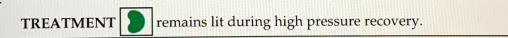
• Yellow caution - Low

Alarm event

Pressure-related alarm recovery

Check for	Do
Alarm resetting after a pressure-related alarm condition (Red alarm 20–39).	No action required. Do not press STOP during the alarm recovery process.

NOTE



10 - Check for Venous Air During PRIME, not including recirculation step 23.0 (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp). All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Air entering the blood circuit due to one	e of the following:
The tip of the priming spike is not fully inserted into the saline bag.	Push the priming spike into the saline bag using a twisting motion until the tip is visible.
The saline bag is empty.	Replace the empty saline bag.
The saline "T" cap is loose.	Secure the cap on the saline "T."

After the cause is fixed

- 1. Press **STOP** to clear the alarm.
- 2. Remove the air using a luer lock syringe (for a small amount of air) or reprime the cartridge, page 5-4.



PRECAUTION .



Do not reprime a cartridge that has been used on a patient. Failure to follow the instructions for repriming a cartridge may cause damage to the cartridge or misloading, and may impact system performance.

To remove the air using a syringe

- 1. Close the blue clamp on the post-dialyzer port.
- 2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp.
- 3. Slowly pull back on the syringe to remove air. When the air is removed, close the blue clamp.
- 4. If you do not see air, press ADD FLUID to resume treatment.
- 5. Check the blood circuit lines and venous header for air. Repeat steps 1 and 2 if you see any air.

10 - Check for Venous Air During TREATMENT (Red Alarm)

Priority

· Red Alarm - High

Alarm event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp).

All pumps stop and air must be removed before continuing with the treatment. If there is air in the venous blood line, **do not** rinse back blood.

Air in the blood circuit during treatment can be dangerous. If air enters the blood stream, it can lead to an air embolism that can result in serious injury or even death.

If you suspect an air embolism, follow the emergency interventions according to your center's policy. Call emergency medical personnel immediately, and then notify the doctor and the center.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do	
Air is entering the blood circuit due	e to one of the following reasons:	
An arterial line connection is loose or disconnected between the patient and blood pump.	Secure and/or reconnect all arterial connections.	
The arterial access is dislodged.	Re-establish arterial access following your center's procedure.	
There is air in the saline line from an empty saline bag.	Remove air from the saline line by doing one of the following:	
	1. Replace the saline bag.	
	2. Make sure the saline "T" is clamped.	
	3. If you see any air in the saline line, disconnect the saline line from the saline "T."	
	 Open the clamp on the saline line to fill the line with saline. 	
	Close the clamp on the saline line and reconnect it to the saline "T."	
The air was not removed during priming.	Follow the instructions below to remove air from the venous line.	
The air was not completely removed from the venous header.	Follow the instructions below to remove air from the venous line.	



WARNING



Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

After the cause is fixed, remove air from the venous line as follows

- 1. Press **STOP** to clear the alarm.
- 2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp. Slowly pull back on the syringe to remove the air.
- 3. Inject the blood (but not the air) back through the post-dialyzer port, then close the blue clamp on the port securely.
- Hold the luer lock syringe upright to prevent the return of air.
- When complete, check that the post-dialyzer port is clamped securely.
- 4. Press **TREATMENT** . The yellow caution window shows the number **12**.



- This means the blood pump is running slowly (50 ml/min) so that you can make sure there is no air.
- Check for air is in the venous blood line (blue clamp).
- 5. If you see any air, press STOP immediately. Repeat steps 2 through 4.
- If necessary, disconnect the blood lines and recirculate the blood to remove air.
- If you cannot remove air from the venous blood line, press **STOP** and end the treatment. Do **not** rinse back blood.
- 6. If you do not see air, press **TREATMENT** again to continue with the treatment.
- The blood flow returns to the previous rate.
- 7. Flush the post-dialyzer port with 3 ml of saline to clear the blood, and then close the clamp on the port securely. Continue to check the venous header of the dialyzer for air.

10 - Check for Venous Air During RINSEBACK (Red Alarm)

Priority

· Red Alarm - High

Alarm event

Air is detected in the cartridge tubing after the dialyzer and before the venous blood line (blue clamp).

All pumps stop and air must be removed before continuing with the treatment. If there is air in the venous blood line, **do not** rinse back blood.

Air in the blood circuit during treatment can be dangerous. If air enters the blood stream, it can lead to an air embolism that can result in serious injury or even death.

If you suspect an air embolism, follow the emergency interventions according to your center's policy. Call emergency medical personnel immediately, and then notify the doctor and the center.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for

Air is entering the blood circuit due to one of the following reasons:

- The air is not completely removed from the dialyzer's venous header.
- The air entered the blood circuit while making the cartridge connections for rinseback.

Do

To remove the air with a syringe:

- . Press **STOP** to clear the alarm.
- 2. Attach a 20 ml luer lock syringe to the post-dialyzer port, then open the blue clamp. Slowly pull back on the syringe to remove air.
- 3. Inject the blood (but not the air) back through the post-dialyzer port, then close the blue clamp on the port securely.
- 4. Press **ADD FLUID** . The yellow caution window shows the number **12** (air recovery underway).
- 5. Check for air is in the venous blood line (blue clamp). Repeat steps 1 through 4 if air you see any air.
- 6. If you do not see air, press **ADD FLUID** again to resume treatment.
- If you cannot remove air from the venous blood line, press STOP and end the treatment. Do not rinse back blood.

11 - Check for Arterial Air During PRIME, Not Including Recirculation Step 23.0 (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Air is detected in the arterial blood line (red clamp) before the dialyzer. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Air is entering the blood circuit due to one	of the following:
The tip of the priming spike is not visible in the saline bag.	Push the priming spike into the saline bag using a twisting motion until the tip is visible.
Kinked/clamped saline or arterial blood line.	Unkink or unclamp the saline or arterial blood line.
	NOTE -
	Air is pulled out of solution (saline/blood) when negative pressure is increased from the kinked or clamped arterial blood line.
The saline bag is empty.	Replace the empty saline bag.
The saline "T" cap is loose.	Secure the "T" cap.

After the cause is fixed

- 1. Press **STOP** to clear the alarm.
- 2. Press ADD FLUID to resume priming.

11 - Check for Arterial Air During TREATMENT (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Air is detected in the cartridge tubing before the dialyzer.

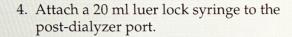
All pumps stop and air must be removed before continuing with the treatment.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Air is entering the blood circuit due to one of the following:	Secure the connections and make sure no air is in the saline line.
 Loose connection at the arterial vascular access. 	
Arterial vascular access disconnection.	
Reversing patient blood lines.	
Poor flow through arterial vascular access or clamped blood line.	Adjust the vascular access or unclamp the blood line.
The access pressure pod is clotted.	Perform a manual fluid bolus , page 5-5, to view the access pressure pod.
	If the pod is clotted, end the treatment and do not rinse back blood.
	• If pod is not clotted, follow the instructions to perform arterial air recovery, page 5-37.
Air is in the saline line from empty saline bag.	Remove air from the saline line by doing one of the following:
	1. Replace the saline bag.
	2. Make sure the saline "T" is clamped.
	3. If you see any air in the saline line, disconnect the saline line from the saline "T."
	Open the clamp on the saline line to fill the line with saline.
	Close the clamp on the saline line and reconnect it to the saline "T."

After the cause is fixed, perform arterial air recovery

- 1. Press **STOP** to clear the alarm.
- 2. Identify and correct the source of air in the arterial blood line (red clamp).
- 3. Press TREATMENT
- The yellow caution window shows the number 12.
- The blood pump runs at 100 ml/min.
- Check the arterial blood line (red clamp) for air for 5 to 10 seconds to make sure that the source of air was corrected.





- 5. Press **TREATMENT** . The blood pump returns to the pre-alarm rate.
- 6. If you see air in the venous header of the dialyzer:
- Open the clamp on the post-dialyzer port. Slowly pull back on the syringe to remove air.
- Hold the syringe upright to allow bubbles to rise. Inject the blood (but not the air) back through the post-dialyzer port, then close the blue clamp on the port securely.
- 7. Flush post-dialyzer port with 3 ml of saline to clear the blood and then close the clamp on the port securely.
- Continue to observe the venous header of the dialyzer for air and remove as needed.
- If this alarm occurs again, lower the blood flow rate. The arterial vascular access may not be able to deliver the set blood flow.

11 - Check for Arterial Air During RINSEBACK (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Air is detected in the arterial blood line before the dialyzer.

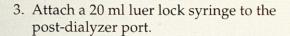
All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
The clamp is closed on the arterial blood line, or the arterial blood line is kinked.	Open the clamp or unkink the arterial blood line.
	NOTE —
	Air is pulled out of solution (saline / blood) when negative pressure is increased from the kinked or clamped arterial blood line.
The saline bag is empty or has too little fluid remaining for programmed rinseback.	Replace the saline bag.
After disconnection from the arterial vascular access, the arterial blood line tip may have a small air bubble that travels past and is detected by the arterial air detector when rinseback begins.	Remove air using the instructions below.

After the cause is fixed, remove air

- 1. Press STOP
- 3
- 2. Press ADD FLUID
- The yellow caution window shows the number 12.
- The blood pump runs at 100 ml/min.
- Check the arterial blood line (red clamp) for air for 5 to 10 seconds to make sure that the source of air was corrected.







- 4. Press **ADD FLUID** . The blood pump returns to the pre-alarm rate.
- 5. If you see air in the venous header of the dialyzer:
- Open the clamp on the post-dialyzer port. Slowly pull back on the syringe to remove air.
- Hold the syringe upright to allow bubbles to rise. Inject the blood (but not the
 air) back through the post-dialyzer port, then close the blue clamp on the port
 securely.
- 6. Flush the post-dialyzer port with 3 ml of saline to clear the blood, and then close the clamp on the port securely.
- Continue to observe the venous header of the dialyzer for air and remove as needed.
- 7. If unable to remove air, press **STOP** and end rinseback mode.

12 - Air Recovery Underway (Yellow Caution)

Priority

Yellow Caution - Medium

Alarm event

Previous red alarm 10 or 11 in treatment or rinseback mode.

The system reduces the blood flow rate to allow time to confirm successful air removal.

Check for	Do
This caution always occurs after a red alarm 10 or 11 in treatment or rinseback mode.	Check the following sites for air entering the system:
	Arterial blood line (red clamp) (red alarm 11).
	Venous blood line (blue clamp) (red alarm 10).
	2. If you see air, press STOP and
	repeat the air removal process. If no air
	is observed, press TREATMENT
	to resume treatment or press ADD
	FLUID to resume rinseback.

NOTES

- A low venous pressure caution or alarm (20, 21) may occur before TREATMENT or ADD FLUID is pressed due to the reduced blood flow rate.
- Do not adjust the blood flow rate at this time unless resetting the rates is desired. Prior rates will be restored once treatment or rinseback mode is resumed.

13 - Check Fluid Line Inlet: Air Detected in Fluid Line Inlet (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Air is detected in the dialysate circuit during the prime and alarms test. Prime and alarms tests are stopped until the situation is resolved.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Insufficient priming fluid.	Verify that enough priming fluid is available.
Blocked or kinked tubing.	Unblock or unkink the fluid inlet tubing.
Incorrectly loaded cartridge.	Prime a new cartridge. Firmly press all cartridge lines into the air detectors.

3. When the cause is fixed, press STOP to clear the alarm, and then press ADD FLUID to resume.

14 - Check Fluid Line Inlet: Air Detected in Fluid Line Inlet (Yellow Caution)

Priority

Yellow Caution - Medium

Alarm event

Air is detected in the dialysate circuit.



PRECAUTION ———



Make sure that premixed dialysate is at room temperature before using. If it is not at room temperature, outgassing of air may occur as the fluid is warmed, which may cause NxStage System One cycler air alarms.

The blood pump and the ultrafiltration pump continue to run. The dialysate pump stops until the situation is resolved and you press **TREATMENT**

- 1. Press **MUTE** to silence the caution.
- 2. Identify and fix the cause.

Check for	Do
The dialysate source is empty or low.	 Add more dialysate: If using a warmer, replace the dialysate bags. If using PureFlow SL, check the following: Sufficient fluid volume in the SAK. The line inlets must be at or near the base of the tub. If not, reposition the SAK by carefully lifting up the back end.
Loose dialysate line connection(s).	Tighten the dialysate line connection(s).
Occluded, kinked, or clamped dialysate line(s).	Check the dialysate line(s) and unkink, unclamp, or unfold the affected lines. On the cartridge: Cartridge dialysate inlet (green clamp) If using a warmer: Warmer disposable (green clamps) If using PureFlow SL: Dialysate outlet (green clamp) SAK lines within the PureFlow SL tub Dialysate line filter. If it is plugged, discard the SAK and make another batch

Check for	Do
Improperly hung dialysate bags, if using a fluid warmer.	Verify that the dialysate bags are hung using both corner holes (two holes in each bag) and that the dialysate outlet port is located at the very bottom of the bag.
If using ComfortMate Fluid Warmer, check the following: • Warmer air trap is full of air. • Warmer bag fitments are not seated correctly in the fluid warmer.	Property of the Air Vent on the disposable: 1 - Air Vent Line 2 - Air Trap 3 - Warmer Outlet Line a. Open the clamp on the air vent line. b. Loosen the protective cap to release the air. c. Tighten the cap and close the clamp. Make sure bag fitments are seated correctly in the fluid warmer.
If using PureFlow SL, check the following: • TREATMENT on the cycler was pressed before pressing the GO key on the PureFlow SL. • PureFlow SL was paused. • Air in the SAK lines.	 Verify that the PureFlow SL is in 'Batch in Use' mode. If not, press the GO key on the PureFlow SL twice to go to 'Batch in Use' mode. Then press TREATMENT on the cycler. If PureFlow is paused, press the GO key to enter 'Config To Use Batch' mode. If there is air is in the SAK lines, slightly open the connection between the SAK and cartridge dialysate inlet line to remove air.

Check for	Do	
When the cause is fixed, press TREATMENT on the cycler to resume the treatment.		
The cartridge was not loaded correctly.	End the treatment and rinse back the patient's blood unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.	

20 - Check Blood Circuit: Venous Pressure Low During RINSEBACK (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The pressure is lower than expected at the venous pressure detector.

All pumps continue to run. If the venous pressure drops further during the treatment, then a red alarm (20, 21) occurs.

Check for	Do
Arterial vascular access flow problem.	Reposition the arterial vascular access.
Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.

When the venous pressure increases, the caution clears automatically.

20 - Check Blood Circuit: Venous Pressure Low (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The pressure is lower than expected at the venous pressure detector.
All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
The blood pump speed is lower than the prescribed rate. For example, too much time is taken to increase the blood flow rate at the start of the treatment or during air alarm recovery.	Increase the speed of the blood pump.
Arterial vascular access flow problem.	Reposition the arterial vascular access.
The arterial blood line (red clamp) is kinked or clamped.	Unkink or unclamp the arterial blood line (red clamp).
Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
Manual fluid bolus caused a decrease in venous pressure.	Resume the prescribed blood flow.
Clotted dialyzer.	If clotting is suspected, press STOP to clear the alarm, then press TREATMENT and flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.

- 3. When the cause is fixed, press **STOP** to clear the alarm.
- 4. Press **TREATMENT** to resume the treatment.

21 - Check Blood Circuit: Venous Pressure Decreasing (Yellow Caution)

Priority

Yellow Caution - Medium

Alarm event

The pressure is lower than expected at the venous pressure detector.

All pumps continue to run. If the venous pressure drops further during the treatment, then a red alarm (20, 21) occurs.

Check for	Do
Arterial vascular access flow problem.	Reposition the arterial vascular access.
Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous vascular access and/or the venous blood line (blue clamp).
Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.

When the venous pressure increases, the caution clears automatically.

21 - Check Blood Circuit: Venous Pressure Decreasing (Red Alarm)

Priority

• Red Alarm - High

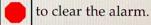
Alarm event

The pressure is lower than expected at the venous pressure detector. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Arterial vascular access flow problem. The arterial blood line (red clamp) is kinked or clamped.	 Reposition the arterial vascular access. Unkink or unclamp the arterial blood line (red clamp).
Venous blood line (blue clamp) leak, disconnection, or access extraction.	Secure the venous access and/or the venous blood line (blue clamp).
Clotted dialyzer.	If clotting is suspected, press STOP to clear the alarm then press TREATMENT and flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.

3. When the cause is fixed, press **STOP**



4. Press **TREATMENT** to resume the treatment.

22 - Check Blood Circuit: Effluent Pressure Low (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The pressure is lower than expected at the effluent pressure circuit. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Arterial vascular access flow problem. The arterial blood line (red clamp) is kinked or clamped.	 Reposition the arterial vascular access. Unkink or unclamp the arterial blood line (red clamp).
The effluent line is clamped or disconnected from the dialyzer.	Reconnect or unclamp and secure the effluent line.
Clotted dialyzer.	If clotting is suspected, press STOP to clear the alarm then press TREATMENT and flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
The flow fraction is too high.	Decrease the flow fraction by reducing the dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.

- 3. When the cause is fixed, press **STOP** to clear the alarm.
- 4. Press **TREATMENT** to resume the treatment.

23 - Check Blood Circuit: Effluent Pressure Decreasing (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The pressure is lower than expected in the effluent pressure circuit.

All pumps continue to run. If the effluent pressure drops further, a red alarm (22 or 23) occurs.

Check for	Do
Arterial vascular access flow problem.	Reposition the arterial vascular access.
Clotting dialyzer.	If clotting is suspected, flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
The flow fraction is too high.	Decrease the flow fraction by reducing dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.

When the venous pressure increases, the caution clears automatically.

23 - Check Blood Circuit: Effluent Pressure Decreasing (Red Alarm)

Priority

• Red Alarm - High

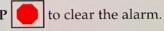
Alarm event

The pressure is lower than expected in the effluent circuit. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Arterial vascular access flow problem. The arterial blood line (red clamp) is kinked or clamped	 Reposition the arterial vascular access. Unkink or unclamp the arterial blood line (red clamp).
The effluent line is clamped or disconnected from the dialyzer.	Reconnect or unclamp and secure the effluent line.
Clotted dialyzer.	If clotting is suspected, press STOP to clear the alarm then press TREATMENT and flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
The flow fraction is too high.	Decrease the flow fraction by reducing the dialysate exchange or ultrafiltration rate, or by increasing the blood flow rate.

3. When the cause is fixed, press STOP



4. Press **TREATMENT** to resume the treatment.

24 - Check Arterial Access: Access Pressure Decreasing to Low Limit (Yellow Caution)

Priority

Yellow Caution - Medium

Alarm event

The pressure is lower than expected in the arterial blood circuit.
All pumps continue to run. If the arterial pressure decreases further, a red alarm 24 occurs.

• Identify and fix the cause.

Check for	Do
Arterial vascular access flow problem.	Reposition the arterial vascular access or reduce the blood flow.

When the arterial pressure increases, the caution clears automatically.



WARNING -



Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

24 - Check Arterial Access: Access Pressure at Low Limit (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Pressure is lower than expected in the arterial blood circuit. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause

Check for	Do
Arterial vascular access flow problem. The arterial blood line (red clamp) is kinked or clamped.	 Reposition the arterial vascular access. Unkink or unclamp the arterial blood line (red clamp).
Access or access pressure pod clotting.	Follow your center's procedures to assess and treat access pressure pod or vascular access clotting. You may perform rinseback unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
The tip of the vascular access needle or catheter touching the vascular wall.	Consider repositioning vascular access catheter or needle to improve blood flow.
If using a catheter for vascular access, compromised blood flow may be related to the patient's position.	Consider repositioning the patient to improve blood flow.

- 3. When the cause is fixed, press STOP to clear the alarm.
- 4. Press TREATMENT to resume the treatment.



WARNING



Do not disconnect and reverse patient blood lines during treatment. This may cause an infusion of air into the patient blood lines, which may lead to an embolism.

25 - Access Pressure Pod Error: Reset Access Pressure Pod (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The pressure in the arterial blood circuit is stagnant.

All pumps continue to run. However, access pressure readings may not be available until the situation is fixed.

Check for	Do
The access pressure pod monitoring line is kinked.	Unkink the monitoring line of the access pressure pod.

Check for	Do
Access pressure pod connection error: the monitoring line is leaking, poorly connected, or not connected.	Reset the access pressure pod as follows: 1. Disconnect the access monitoring line from the cycler. The access pressure pod deflates. 2. Press STOP If the pod fills immediately, go directly to step 3. If the pod does not fill immediately do the following:
	Close the red clamp on the arterial blood line.Open the white clamps on the saline line
	 and saline "T." The pod fills with blood. Close the white clamps on the saline line and saline "T."
	Open the red clamp on the arterial blood line.
	3. Attach the monitoring line of the access pressure pod to the connection point located below the front handle on the right side of the cycler as instructed below:
	Hold the line behind the locking collar.
	Insert the tip into the connection point until it stops.
	Maintain firm pressure and twist the tip ¼ turn counterclockwise to properly seal the connection.
	Tighten the locking collar.
	4. Press TREATMENT .
	5. Check that the arterial pressures are within range.

30 - Check Blood Circuit: Venous Pressure Approaching High Alarm Limit (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The pressure is higher than expected in the venous blood circuit.

All pumps continue to run. If the venous pressure increases further, a red alarm 30 occurs.

Check for	Do
Venous blood line (blue clamp) or venous access problem.	Reposition the venous access.
Venous access infiltration.	Correct the venous access infiltration.
The blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
Fluid imbalance or ultrafiltration removed too quickly leading to hemoconcentrated blood.	Perform a manual fluid bolus, page 5-5, to check the dialyzer for clotting. If there is no clotting, adjust the ultrafiltration rate or goal accordingly. If clotting is present, end the treatment and do not rinse back the blood.

- When the venous pressure decreases, the caution clears automatically.
- Consider weighing the patient after the treatment is restarted to evaluate ultrafiltration status.

30 - Check Blood Circuit: Venous Pressure High During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The pressure is higher than expected in the venous blood circuit. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Kinked or clamped venous blood line (blue clamp) or the priming line (blue clamp).	Unkink or unclamp the venous blood line (blue clamp) or the priming line (blue clamp).
The priming spike is occluded or the tip is bent.	Replace the priming line.

3. When the cause is fixed, press **STOP**



to clear the alarm.

4. Press ADD FLUID to resume.

30 - Check Blood Circuit: Venous Pressure High During TREATMENT (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The pressure is higher than expected in the venous blood circuit.

All pumps stop when this alarm occurs.

- 1. Press MUTE to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Kinked or clamped venous blood line (blue clamp) or venous access.	Unkink or unclamp the venous blood line (blue clamp) or the venous access.
Venous access infiltration.	Correct the venous access infiltration.
Clotted venous blood line (blue clamp) or the venous access.	If the venous blood line (blue clamp) or venous access is clotted, end the treatment. Do not attempt to rinse back blood through the venous access.
The blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
Fluid imbalance or ultrafiltration was removed too quickly leading to hemoconcentrated blood.	End the treatment. Do not rinse back the blood. Weigh the patient to assess ultrafiltration status.

3. When the cause is fixed, press **STOP** to clear the alarm.



4. Press TREATMENT



to resume the treatment.

30 - Check Blood Circuit: Venous Pressure High During RINSEBACK (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The pressure is higher than expected in the venous blood circuit. All pumps stop when this alarm occurs.

- 1. Press MUTE to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Kinked or clamped venous blood line (blue clamp).	Unkink or unclamp the venous blood line (blue clamp). • Press STOP to clear the alarm. • Press ADD FLUID to resume rinseback.
Clotted venous blood line (blue clamp).	Press STOP and end the treatment. Do not rinse back the blood.
Clotted venous vascular access.	Press STOP and end the treatment. Do not rinse back the blood.

32 - Check Blood Circuit: Venous Pressure Increasing (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The pressure is higher than expected in the venous blood circuit.

All pumps continue to run. If the venous pressure increases further, a red alarm 30 occurs.

• Identify and fix the cause.

Check for	Do
Venous blood line (blue clamp) or venous access problem.	Reposition the venous access.
Venous access infiltration.	Correct the venous access infiltration.
The blood flow rate is too high for the vascular access.	Decrease the blood flow rate.
Fluid imbalance or ultrafiltration was removed too quickly leading to hemoconcentrated blood.	Perform a manual fluid bolus, page 5-5 to check the dialyzer for clotting. If there is no clotting, adjust the ultrafiltration rate or goal accordingly. If clotting is present, end the treatment and do not rinse back blood.

- When the venous pressure decreases, the caution clears automatically.
- Consider weighing the patient after the treatment is restarted to evaluate ultrafiltration status.

33 - Check Dialyzer: High TMP During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The transmembrane pressure (TMP) is higher than expected. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
The cartridge is not aligned correctly in the cycler.	Reprime the cartridge, page 5-4.

33 - Check Dialyzer: High TMP During TREATMENT (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The transmembrane pressure (TMP) is higher than expected.

- 1. Press MUTE to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Venous blood line is kinked between the dialyzer and the cartridge venous air detector.	Unkink the venous blood line between the dialyzer and the cartridge venous air detector.
Blood is pooling or clotting in the venous header of the dialyzer.	If clotting is suspected, press STOP to clear the alarm then press TREATMENT and flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.

- 3. When the cause is fixed, press **STOP** to clear the alarm.
- 4. Press **TREATMENT** to resume the treatment.
- Consider weighing the patient after the treatment is restarted to evaluate ultrafiltration status.

34 - Check Dialyzer: High TMP During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The transmembrane pressure (TMP) is higher than expected. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
The cartridge is not aligned correctly in the cycler.	Reprime the cartridge, page 5-4.

34 - Check Dialyzer: High TMP During TREATMENT (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The transmembrane pressure (TMP) is higher than expected.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Venous blood line is kinked between the dialyzer and the cartridge venous air detector.	Unkink the venous blood line between the dialyzer and the cartridge venous air detector.
Blood is pooling or clotting in the venous header of the dialyzer.	If clotting is suspected, press STOP to clear the alarm then press TREATMENT and flush the dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.

- 3. When the cause is fixed, press **STOP** to clear the alarm.
- 4. Press **TREATMENT** to resume the treatment.
- Consider weighing the patient after the treatment is restarted to evaluate ultrafiltration status.

35 - Check Waste Line: Waste Line Pressure High (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The waste line pressure is higher than expected.

All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Waste or drain lines or SAK dialysate line is kinked, clamped, pinched, occluded, submerged, or not connected.	Check the waste and drain lines to clear the occlusion. Reposition, unkink, or unclamp, and connect as required to ensure the free flow of waste fluid to the drain. The affected line(s) may include:
	• The waste line (yellow clamp)
	• The waste line extension (yellow clamp)
	2. If using PureFlow SL, check the following:
	Control unit adapter (yellow clamp)
	Drain line - Reposition the drain line.
	If necessary, flush the drain line. If unsuccessful, disconnect the cartridge waste line from the PureFlow SL and connect it to waste line extension
	 SAK dialysate line: Check all lines and connections in the SAK for leaks or kinks and adjust any line that is kinked Slide the line collars all the way towards the SAK. Verify the SAK has been installed and unfolded
	correctly.
	3. Lower the dialysate rate.
If using a waste bag, it is full.	Replace the waste bag.
Low effluent pressure due to poor arterial flow.	Adjust the vascular access to improve the blood flow.

to resume the treatment.

5. Press TREATMENT

For software version 4.13 and higher

If you need more time to resolve the cause, do the following

- 1. Press and hold STOP ...

 The blood pump starts to run at the treatment rate.
- 2. When you resolve the cause, press **TREATMENT** to resume the treatment.

If you cannot resolve the cause

• Press **STOP** to end the treatment and begin rinseback.

36 - Check Dialysate Source: Dialysate Inlet Pressure Exceeded (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The dialysate inlet pressure is too high.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
If using a warmer, this alarm is unlikely to occur.	End the treatment and rinse back the patient's blood unless otherwise directed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
If using PureFlow SL: kinked SAK line.	1. Open the cabinet door and slide out the tub so you can see the SAK lines.
	2. Check all lines and connections on the PAK and SAK for leaks or kinks. Adjust any line that is kinked.
	3. Slide the line collars all the way towards the SAK.
	4. Verify the SAK has been installed and unfolded correctly.
	5. Press the GO key twice on the PureFlow SL to go to
	'Batch In Use' mode before you press TREATMENT
	on the cycler.
	6. Press STOP on the cycler to clear the alarm
	7. Press TREATMENT to resume the treatment.
	If you cannot recover from the alarm after multiple attempts, or a SAK leak is found, you must drain the SAK.

37- Check Fluid Circuit: High Balance Chamber Pressure **During PRIME, Including Recirculation Step 23.0** (Red Alarm)

Priority

· Red Alarm - High

Alarm event

The pressure is higher than expected in the fluid balance chambers. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Kinked or clamped cartridge lines.	Unkink or unclamp the cartridge lines.
The priming spike is occluded or the tip is bent.	Replace the priming line.
The tip of the priming spike is not fully inserted into saline bag.	Push the priming spike into the saline bag using a twisting motion until the tip is visible.
Air in fluid balance system from an empty saline bag.	Hang a new saline bag.

3. When the cause is fixed, press **STOP**



to clear the alarm.

4. Press ADD FLUID | to resume.



NOTES

- A yellow caution 9 may be displayed indicating the system is recovering from a high pressure condition. Do not press STOP at this time. Prime resumes when the yellow caution 9 disappears.
- The red alarm 37, 38 may recur a few times after the yellow caution 9 disappears if the pressure remains high. Repeat steps above to fix the alarm condition.

37- Check Fluid Circuit: High Balance Chamber Pressure During TREATMENT (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Pressure is higher than expected in the fluid balancing circuit.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Occluded, kinked or clamped fluid line(s).	Check the fluid lines and clear the occlusion. Unkink or unclamp the affected line(s):
	On the cartridge check the following: Cartridge dialysate inlet (green clamp) Cartridge dialysate outlet (green clamp) Waste line (yellow clamp) (following alarm 35) If using a warmer, check the following: Warmer disposable (green clamps) Waste line extension (yellow clamp) If using the PureFlow SL, check the following: Dialysate outlet (green clamp) SAK lines within the PureFlow SL tub Control unit adapter (yellow clamp)
	 Control unit adapter might be plugged; replace the control unit adapter.
	 Dialysate line filter. If it is plugged, discard the SAK and make another batch.

Check for	Do
The dialysate source is low or empty.	Add more dialysate.
	If using a warmer, replace the empty dialysate bags.
	If using the ComfortMate Fluid Warmer, remove air from the air vent of the disposable:
	a. Open the clamp on the air vent line.
	b. Loosen the protective cap to release the air.
	c. Tighten the cap and close the clamp.
	If using PureFlow SL check the following:
	- Sufficient fluid volume in the SAK.
	 The line inlets must be at or near the base of the tub. If not, reposition the SAK by carefully lifting up the back end.
TREATMENT on	Verify the PureFlow SL is in 'Batch In Use' mode. If it is not
	press GO twice on the PureFlow SL to enter 'Batch In Use'
the cycler was pressed before pressing GO on the PureFlow SL.	mode before pressing TREATMENT on the cycler.
The wrong SAK type is	Lower the dialysate rate on the cycler to 12 L/hr or
being used in the PureFlow SL while	less.
running the cycler at	Load a 400 series SAK into the PureFlow SL for the next treatment to return to higher flow rates.
dialysate rates higher than 12 L/hr.	heat treatment to return to higher now rates.
Clotted dialyzer.	If clotting is suspected, press STOP to clear the
	alarm then press TREATMENT and flush the
	dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
Air in the fluid balancing system.	Verify that the dialysate is flowing from the warmer or PureFlow SL to the cartridge.

- 3. When the cause is fixed, press **STOP** to clear the alarm.
- 4. Press TREATMENT to resume the treatment.

For software version 4.13 and higher

If you need more time to resolve the cause, do the following

1. Press and hold **STOP**

The blood pump starts to run at the treatment rate.

2. When you resolve the cause, press **TREATMENT** to resume the treatment.

If you cannot resolve the cause

• Press STOP to end the treatment and begin rinseback.

NOTES

- A yellow caution 9 may be displayed indicating the system is recovering from a high pressure condition. **Do not** press **STOP** at this time. Treatment resumes when the yellow caution 9 disappears.
- The red alarm 37, 38 may recur a few times after the yellow caution 9 disappears if the pressure remains high. Repeat steps above to fix the alarm condition.

38 - Check Fluid Circuit: High Balance Chamber Pressure During PRIME, Including Recirculation Step 23.0 (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The pressure is higher than expected in the fluid balance chambers.

All pumps stop when this alarm occurs.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Kinked or clamped cartridge lines.	Unkink or unclamp the cartridge lines.
The priming spike is occluded or the tip is bent.	Replace the priming line.
The tip of the priming spike is not fully inserted into saline bag.	Push the priming spike into the saline bag using a twisting motion until the tip is visible.
Air in fluid balance system from an empty saline bag.	Hang a new saline bag.

3. When the cause is fixed, press **STOP**



to clear the alarm.

4. Press ADD FLUID to resume.

NOTES

- A yellow caution 9 may be displayed indicating the system is recovering from a high pressure condition. Do not press STOP
 at this time. Prime resumes when the yellow caution 9 disappears.
- The red alarm 37, 38 may recur a few times after the yellow caution 9 disappears if the pressure remains high. Repeat steps above to fix the alarm condition.

38 - Check Fluid Circuit: High Balance Chamber Pressure During TREATMENT (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Pressure is higher than expected in the fluid balancing circuit.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Occluded, kinked or clamped fluid line(s).	Check the fluid lines and clear the occlusion. Unkink or unclamp the affected line(s):
	 On the cartridge check the following: Cartridge dialysate inlet (green clamp) Cartridge dialysate outlet (green clamp) Waste line (yellow clamp) (following alarm 35)
	 If using a warmer, check the following: Warmer disposable (green clamps) Waste line extension (yellow clamp)
	 If using the PureFlow SL, check the following: Dialysate outlet (green clamp) SAK lines within the PureFlow SL tub Control unit adapter (yellow clamp) Control unit adapter might be plugged; replace the control unit adapter.
	 Dialysate line filter. If it is plugged, discard the SAK and make another batch.

Check for	Do
The dialysate source is low or empty.	Add more dialysate.
	If using a warmer, replace the empty dialysate bags.
	If using the ComfortMate Fluid Warmer, remove air from the air vent of the disposable:
	a. Open the clamp on the air vent line.
	b. Loosen the protective cap to release the air.
	c. Tighten the cap and close the clamp.
	If using PureFlow SL check the following: Sufficient fluid volume in the SAK.
	 The line inlets must be at or near the base of the tub. If not, reposition the SAK by carefully lifting up the back end.
TREATMENT on	Verify the PureFlow SL is in 'Batch In Use' mode. If it is not press GO twice on the PureFlow SL to enter 'Batch In Use'
the cycler was pressed before pressing GO on the PureFlow SL.	mode before pressing TREATMENT on the cycler.
The wrong SAK type is being used in the PureFlow SL while running the cycler at dialysate rates higher than 12 L/hr.	 Lower the dialysate rate on the cycler to 12 L/hr or less. Load a 400 series SAK into the PureFlow SL for the next treatment to return to higher flow rates.
Clotted dialyzer.	If clotting is suspected, press STOP to clear the
	alarm then press TREATMENT and flush the
	dialyzer by performing a manual fluid bolus, page 5-5. If the dialyzer is clotted, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis or thromboembolism.
Air in the fluid balancing system.	Verify that the dialysate is flowing from the warmer or PureFlow SL to the cartridge.

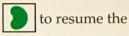
- 3. When the cause is fixed, press **STOP** to clear the alarm.
- 4. Press TREATMENT | to resume the treatment.

For software version 4.13 and higher

If you need more time to resolve the cause, do the following

1. Press and hold STOP ...
The blood pump starts to run at the treatment rate.

2. When you resolve the cause, press **TREATMENT** treatment.



If you cannot resolve the cause

Press STOP to end the treatment and begin rinseback.

NOTES -

- A yellow caution 9 may be displayed indicating the system is recovering from a high pressure condition. **Do not** press **STOP** at this time. Treatment resumes when the yellow caution 9 disappears.
- The red alarm 37, 38 may recur a few times after the yellow caution 9 disappears if the pressure remains high. Repeat steps above to fix the alarm condition.

39 - Check Fluid Inlet: Dialysate Inlet Occlusion (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The pressure is lower than expected at the dialysate inlet.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
During priming: The tip of the priming spike is not fully inserted into the saline bag.	Push the priming spike into saline bag using a twisting motion until tip is visible.
Kinked, clamped or folded dialysate fluid line(s).	Check the fluid lines and unkink or unclamp the affected line(s) which may include:
	 On the cartridge check the following: Cartridge dialysate inlet (green clamp)
	If using a warmer, check the following:Warmer disposable (green clamps)
	 If using the PureFlow SL, check the following: Dialysate outlet (green clamp) SAK lines within the PureFlow SL tub
The dialysate source is low or	Add more dialysate:
empty.	If using a warmer, replace the empty dialysate bags.
	If using the ComfortMate Fluid Warmer, remove air from the air vent of the disposable:
	a. Open the clamp on the air vent line.
	b. Loosen the protective cap to release the air.
	c. Tighten the cap and close the clamp.
	 If using the PureFlow SL check the following: Sufficient fluid volume in the SAK. The line inlets must be at or near the base of the tub. If not, reposition the SAK by carefully lifting up the back end.

Check for	Do
If using PureFlow SL: TREATMENT on the cycler was pressed before pressing GO on the PureFlow SL.	Verify the PureFlow SL is in 'Batch In Use' mode. If not, press the GO key on the PureFlow SL twice to go to 'Batch In Use' mode before pressing TREATMENT on the cycler.
If using PureFlow SL: Plugged filter in the SAK dialysate line.	Discard the SAK and make another batch.
The wrong SAK type is being used in the PureFlow SL while running the cycler at dialysate rates higher than 12 L/hr.	 Lower the dialysate rate on the cycler to 12 L/hr or less. Load a 400 series SAK into the PureFlow SL for the next treatment to return to higher flow rates.
Air in fluid balancing system.	Verify that the dialysate is flowing through the warmer or PureFlow SL to the cartridge.

- 3. When the cause is fixed, press **STOP** to clear the alarm.
- 4. Press **TREATMENT** to resume the treatment.

For software version 4.13 and higher

If you need more time to resolve the cause, do the following

- 2. When you resolve the cause, press **TREATMENT** to resume the treatment.

If you cannot resolve the cause

Press STOP to end the treatment and begin rinseback.

NOTES

- A yellow caution 9 may be displayed indicating the system is recovering from a high pressure condition. Do not press STOP

 at this time. Treatment will resume when the yellow caution 9 disappears.
- The red alarm 37, 38 may recur a few times after the yellow caution 9 disappears if the pressure remains high. Repeat steps above to fix the alarm condition.

40 - Perform Power Recovery: Power Failure (Yellow Caution)

Priority

· Yellow Caution - Medium



WARNINGS



The risk of blood clotting in the cartridge and dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the cartridge and dialyzer for clotting by looking closely at the cartridge and dialyzer, and periodically flushing the dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the cartridge and dialyzer or administering medication through the Post-dialyzer port when clotting is present in the dialyzer venous header may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the cartridge and dialyzer if they are clotted.

Alarm event

Previous loss of power to the cycler.

Check for	Do
During the recirculation step of prime mode (000 in red alarm window, 23.0 in top window): Power is restored following a power failure or cycler being turned off during recirculation and the cartridge life has not expired.	 Press TREATMENT Monitor the cycler screen (20.0 to 23.0 in top window) indicating the system is rechecking the fluid balance system. When 23.0 appears, continue with air removal steps as instructed in Removing air from the blood circuit, page 5-11.
During treatment or rinseback mode: Power is restored following a power failure or cycler being turned off for less than the preset number of minutes allowed (set by System Setting #16; see Chapter 9).	 During treatment mode, press TREATMENT to resume. During rinseback mode, press ADD FLUID to resume.

41 - Failed Power Recovery During TREATMENT or RINSEBACK (Red Alarm)

Priority

• Red Alarm - High



WARNING -



The risk of blood clotting in the cartridge and dialyzer is higher during long treatments, when no anticoagulation is used, in certain patients who are more prone to excess clotting, or any time when the blood flow stops, including when the NxStage System One cycler loses power or during an unrecoverable alarm. The risk of blood clotting increases the longer treatment continues and the longer blood flow is stopped. To reduce the risk of blood clotting and identify the early signs of clotting:

- Follow your center's instructions to give and monitor anticoagulant.
- During treatment, regularly check the cartridge and dialyzer for clotting by looking closely at the cartridge and dialyzer, and periodically flushing the dialyzer with a manual fluid bolus.

Failure to respond to blood clotting in the cartridge and dialyzer or administering medication through the post-dialyzer port when clotting is present in the dialyzer venous header may result in a blood clot being released into the patient's bloodstream and causing a blockage (thromboembolism). Failure to respond to clotting may also lead to sustained high pressures in the blood circuit and cause a dialyzer blood leak or hemolysis. These conditions may cause serious injury or death if not responded to promptly and appropriately. Regularly check the dialyzer for any evidence of a leak. Do not return the blood if the blood flow is stopped for a long time. Discard the cartridge and dialyzer if they are clotted.

Alarm event

Previous loss of power to the cycler.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.
- 3. Regardless of the cause, the treatment must be ended.

Check for	Do
Power failure or the cycler was turned off during treatment or rinseback mode for longer than the time allowed by System Setting #16 (see Chapter 9) after recovering from a power failure.	If the circuit is not clotted, perform a manual rinseback, page 5-10, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
The cycler door was opened during a power failure or while the cycler power was turned off during treatment or rinseback mode and remained open when the power returned.	If the circuit is not clotted, perform a manual rinseback, page 5-10, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.

50 - Check Fluid Temp: Fluid Temp High (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The fluid temperature is above the fluid temperature alarm point.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
The heater setting is too high on the fluid warmer or PureFlow SL.	 Reduce the dialysate heater setting: If using the Express Fluid Warmer: – Press the DOWN ARROW to decrease the comfort setting. If using PureFlow SL: Reduce the heater setting. Open the PureFlow SL cabinet door to help the fluid cool.
The dialysate bags are too warm prior to set up.	Cool or replace the dialysate bags.
The treatment environment is too warm.	Cool the room with air conditioning or fan.

- 3. When the cause is fixed, press **STOP**
- P to clear the alarm.
- 4. Press **TREATMENT** to resume the treatment.

51 - Fluid Cooldown Underway (Yellow Caution)

Priority

Yellow Caution - Medium

Alarm event

Previous red alarm 50. The fluid temperature is cooling down.

The blood pump and ultrafiltration pump continue to run. However, the dialysate pump stops until the temperature of the dialysate has cooled down.

Check for	Do
Previous alarm 50.	No action required. Look for yellow caution 52.

NOTE

If yellow caution 52 does not occur within a reasonable amount of time, this means the dialysate temperature remains too high. Consider ending the treatment and rinsing back blood.

52 - Continue Treatment: Fluid Cooldown Complete (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The dialysate has cooled down sufficiently following a previous red alarm 50 and vellow caution 51.

The dialysate pump remains stopped.

Check for	Do
The fluid temperature has dropped 0.5 °C or more below the fluid temperature alarm point after a red alarm 50 and subsequent yellow caution 51.	Press TREATMENT to resume the

53 - Low Fluid Temperature (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The fluid temperature is below 33.3 °C.

The blood pump and the ultrafiltration pump continue to run. This caution occurs if the fluid temperature is less than 17.1 °C or remains between 17.1 °C and 24.4 °C for at least 20 minutes.

Check for	Do
The fluid warmer is not turned on, is set too low or is not working.	Turn on the fluid warmer or increase the dialysate heater setting:
	If using the ComfortMate Fluid Warmer: Turn the Fluid Warmer knob clockwise.
	If using the Express Fluid Warmer: Press the UP ARROW to increase the comfort setting.
	If using the PureFlow SL: Refer to the PureFlow SL User Guide to change the heater setting.
The dialysate is too cold prior to set- up.	Allow the warmer enough time to warm the fluid. Press TREATMENT to continue. If the patient is experiencing discomfort, end the treatment.
The room temperature is too low.	Increase room the temperature.

When the cause is fixed, press TREATMENT



to resume the treatment.

54 - Low Temperature Monitor Disabled (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The System Setting #79 has been set to 0.

Check for	Do
System Setting #79 has been set to 0.	Press MUTE to acknowledge the caution. OR If low temperature monitoring should be enabled, see the instructions in Chapter 9 to
	change System Setting #79 to 1.

60 - Check for Blood Leak: Blood Detected in Waste Line (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The system suspects that blood may be present in the effluent.

- 1. Press MUTE 💢 to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Dialyzer fiber leak.	Check the color of your waste fluid. Follow your center's instructions for testing waste fluid for the presence of blood.
	If you see blood, which may appear as red streaks as the fluid leaves the dialyzer, or if testing shows that blood is present, end the treatment and perform a manual rinseback, page 5-10, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
	• If you see pink-tinged effluent in the drain line and testing shows that blood is present, end the treatment and perform a manual rinseback, page 5-10, unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.
	If you see normal yellow colored effluent and if testing does not show that blood is present, see the next probable cause.
Air is in the effluent or the	Do one or both of the following:
flow fraction is set too high.	Correct the source of air entering the effluent.
	Lower the flow fraction.
	If the alarm recurs, end the treatment and perform a manual rinseback, page 5-10, unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.

Check for	Do	
The ultrafiltration rate is at zero (0).	Press STOP , then press TREATMENT . Set	
	the ultrafiltration rate to at least 0.1 L/hr for approximately two minutes and reset the alarm.	

NOTE

Pink tinged or red effluent not associated with a blood leak and confirmed by testing may be attributed to certain medical conditions, medications, or treatment-related hemolysis. In any case, discuss the presence of pink effluent with your health care provider (HCP). See **Observation of pink waste fluid**, page 5-18, for additional information.

61 - Check BLD: Failed Blood Leak Detector (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The blood leak detector or blood leak detector mirror are not clean.

All pumps stop when this alarm occurs.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Dirty blood leak detector	1. Turn off the cycler.
Dirty blood leak detector mirror	2. Lower the saline bag below the cycler.
	3. Open the cycler door and allow the fluid to flow back into the saline bag.
	4. Clean the mirror and detector, following the instructions in the maintenance chapter of the user guide.
	5. Turn on the power switch to the cycler with the door open and the handle raised.
	6. When the yellow caution window flashes, insert the cartridge, close the door, and hang the saline bag.
	7. When ADD FLUID is lit, restart prime.



PRECAUTION -



Do not reprime a cartridge that has been used on a patient. Failure to follow the instructions for repriming a cartridge may cause damage to the cartridge or misloading, and may impact system performance.

62 - Check Dialyzer for Clotting (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The arterial pressure is unstable.

All pumps stop when this alarm occurs.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
The arterial blood line is kinked between the cartridge and the dialyzer.	 Unkink the arterial blood line between the cartridge and the dialyzer. Press STOP to clear the alarm. Press TREATMENT to resume.
A clot has formed in the arterial header of the dialyzer.	 Press STOP to clear the alarm. Press TREATMENT and perform a manual fluid bolus, page 5-5 to observe the arterial header of the dialyzer for clotting.
	 3. If clotting is seen, end the treatment and do not rinse back blood. Failure to appropriately respond to a clotted dialyzer or blood circuit may contribute to hemolysis. 4. If no clotting is seen, continue the treatment. If the alarm recurs, end the treatment and do not rinse back blood.

NOTE

System Setting #53 must be set to 1 and System Setting #78 must be set to 1 to enable this alarm.

70 - Change Cartridge: Cartridge Life Exceeded (Yellow Caution)

Priority

Yellow Caution - Low

Alarm event

The cycler has determined that the cartridge has exceeded its life expectancy.

All pumps stop when this alarm occurs.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
The cartridge has been used for greater than 864 L of blood processed or for longer than 72 hours of operation.	If the caution is due to exceeded cartridge life, press MUTE to clear or end the treatment and replace the cartridge.
The saline bag was spiked before the cycler door was closed after a new cartridge was inserted and the tubing pressed into all three air detectors.	If the caution occurred with a new cartridge as priming was initiated, clear the caution and reprime the same cartridge, page 5-4.

71 - Schedule Preventive Maintenance: Preventive Maintenance Due (Yellow Caution)

Priority

· Yellow Caution - Medium

Alarm event

Preventive maintenance is due on the cycler.

Check for	Do
Normal maintenance notification.	Complete the treatment. Schedule preventive maintenance with Technical Support.

72 - Treatment Complete (Yellow Caution)

Priority

• Yellow Caution - Low

Alarm event

The cycler door was opened at the end of rinseback mode.

All keys and alarms are disabled. The user may not resume treatment or rinseback.

Check for	Do
The cycler door opened at end of rinseback mode.	Turn the cycler off. Prime a new cartridge if additional treatment is desired.

80 - Reconfigure Cartridge Line (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The venous blood line of a cartridge without a pre-attached dialyzer must be reconfigured.

Check for	Do
The cycler has paused during the priming of a cartridge without a pre-attached dialyzer and System Setting #25 is set to 1.	Move the venous blood line (blue clamp) of the cartridge without a pre-attached dialyzer. See the cartridge without a pre-attached dialyzer instructions for use.

• Press ADD FLUID to continue.

81 - Tap Dialyzer to Remove Air (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

Priming procedure.

Check for	Do
 System Setting #64 (Air Removal Required) is set to 1. Air in the dialyzer. 	Tap the dialyzer to dislodge the trapped air until the yellow caution disappears. For specific priming directions for the cartridge without pre-attached filter, refer to cartridge without pre-attached filter instructions for use.

85 - Check Cartridge Loading: Waste Line Check Failure (Red Alarm)

Priority

• Red Alarm - High

Alarm event

During prime, the cycler determined that the cartridge is not properly loaded. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Improperly loaded cartridge.	1. Press STOP , then press ADD FLUID .
	2. If the alarm recurs, reprime the cartridge, page 5-4.
	3. If the alarm occurs again, replace the cartridge and restart prime.
	4. If the alarm recurs a third time, record the alarm number and prime step when the alarm occurs, then call Technical Support.

86 - Reprime (Replace) Cartridge: Failed Alarm Test (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The system failed an alarm test during prime.

- 1. Press MUTE to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Improper priming.Faulty cartridge.Cycler malfunction.	For all causes, follow the instructions below: 1. Press STOP , and then press ADD FLUID
	2. If the alarm recurs, reprime the cartridge, page 5-4.
	3. If the alarm occurs again, replace the cartridge and restart prime.
	4. If the alarm recurs a third time, record the alarm number and prime step when the alarm occurs, then call Technical Support.

87 - Check Cartridge Loading: UF Occlusion Test Failure (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The system failed an alarm test during prime.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Loose post-dialyzer port cap.	Tighten the post-dialyzer port cap.
Improperly loaded cartridge.	1. Press STOP , and then press ADD FLUID .
	2. If the alarm recurs, reprime the cartridge, page 5-4.
	3. If the alarm occurs again, replace the cartridge and restart prime.
	4. If the alarm recurs a third time, record the alarm number and prime step when the alarm occurs, then call Technical Support.

88 - Pressure Offset Rezeroing Needed (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

Priming cannot begin until the pressure offset rezeroing procedure is done. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do	
The cycler was turned on with the door closed.	Rezero pressure offset by doing the following:	
	1. Turn off the cycler.	
	Lift the front door handle up completely until it clicks.	
	3. Open the cycler door.	
	4. Turn on the power switch to the cycler with the door open and handle raised. Pressure offset rezeroing will be done automatically.	
	5. When the yellow caution window flashes, insert the cartridge and close the cycler door.	
A used cartridge was installed before turning the cycler on.	Discard the cartridge and prime a new cartridge. Pressure offset rezeroing will b done automatically.	
A partially primed cartridge was installed before turning the cycler on.	Reprime the cartridge, page 5-4. Pressure offset rezeroing will be done automatically.	

88 - Pressure Offset Rezeoing Needed (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The system failed when trying to lower the pressures during prime. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Blocked or kinked dialysate lines.	Unblock or unkink the dialysate line.
Pressure offset error.	Press STOP then press ADD FLUID
	If the alarm recurs, reprime the cartridge, page 5-4.
	If the alarm recurs a second time, record the alarm number and prime step when the alarm occurs, then call Technical Support.

89 - Pressure Offset Rezeroing Failed (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The cycler was unable to rezero the pressure sensor offsets on startup. All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Variable pressure offset on startup of cycler.	Rezero the pressure offset by doing the following:
	1. Turn off the cycler.
	2. Lift the front door handle up completely until it clicks.
	3. Disconnect the access pressure pod monitoring line (if present) from the side of the cycler.
	4. Open the cycler door.
	5. Turn on the cycler with the door open and handle raised. Pressure offset rezeroing will be done automatically.
	6. When the yellow caution window flashes, insert the cartridge and close the cycler door.

90 - Check Cartridge For Leak: Fluid Circuit Test Failure (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The cycler detected a malfunction in the fluid balancing system.

All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Malfunction in the fluid balancing system.	 End the treatment and perform an automated rinseback, page 5-6. Thoroughly check the cartridge for fluid
	leaks, for example, at the bottom of the cartridge. If it is leaking, contact Technical Support.

NOTES .

- For all fluid balance failure alarms, check the patient's weight.
- Setting the ultrafiltration rate to 0 will not fix a fluid balance system problem.

91 - Check Fluid Balance: Fluid Circuit Leak Probable (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The cycler detected a malfunction in the fluid balancing system.

All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Malfunction in the fluid balancing system.	1. End the treatment and perform an automated rinseback, page 5-6.
	2. Thoroughly check the cartridge for fluid leaks, for example, at the bottom of the cartridge. If it is leaking, contact Technical Support.

NOTES

- For all fluid balance failure alarms, check the patient's weight.
- Setting the ultrafiltration rate to **0** will not fix a fluid balance system problem.

92 - Check for Cartridge Leak, During PRIME or Recirculation (Red Alarm)

Priority

• Red Alarm - High

Alarm event

During priming or recirculation, the cycler detected a malfunction in the fluid balancing system.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Compromised cartridge integrity.	1. Thoroughly check the cartridge for fluid leaks, for example, at the bottom of the cartridge.
	Notify Technical Support of cartridge leak.
	Return or discard the cartridge as directed.
	2. If you do not see a leak, press STOP
	and then press ADD FLUID
	to continue.

93 - Correct Parameters: System Settings Conflict (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The cycler detected conflicting settings.

This caution can only occur in service or system setting mode — not during regular start-up or prime.

Check for	Do
A setting set to a value that conflicts with the values of other settings.	Re-enter or review the system settings, as listed in the user guide.

99 - Fluid Balance System Failed: Terminate Treatment (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The system detected a malfunction in the fluid balancing system.

All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Malfunction in the fluid balancing system.	1. Press STOP , then press
	TREATMENT and observe 000
	in the yellow caution window.
	2. End the treatment and perform an
	automated rinseback, page 5-6.

NOTE

For all fluid balance failure alarms, check the patient's weight.

100 - 999 System Alarm (Red Alarm) Except for alarm numbers 600, 601, 602, 603, 715 and 721

Priority

• Red Alarm - High

Alarm event

The cycler detected a system or communications error or it may be in service mode.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
System error or internal communications error.	During prime mode before step 23.0 • Reprime the cartridge, page 5-4.
Service mode.	During recirculation of prime (23.0 in top window), treatment or rinseback mode:
1	Note alarm number displayed in the red alarm window.
	2. Write down the alarm number for future reference.
	If 999 is shown in the yellow caution window, the cycler is in service mode. Call Technical Support immediately. Do not initiate or continue treatment.

Check for	Do
	3. Turn the cycler off, and then turn it on again immediately.
	Watch for the number 40 in the yellow caution window.
	4. If the cycler repeats the alarm or has a blank window after step 2, turn off the power, wait approximately one minute, and then turn on the power again.
	5. If 40 appears in the yellow caution window, press TREATMENT or ADD FLUID to continue.
	6. If the system alarm recurs, or red alarm 41 appears, perform a manual rinseback, page 5-10, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. Contact Technical Support and provide the system alarn number.

600 - System Alarm (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The cycler detected pump movement while the cycler door was closing.
All pumps stop when this alarm occurs.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
After spiking the saline bag, a pump might have moved while the cycler door was being closed.	Reprime the cartridge, page 5-4.
Before spiking the saline bag, a pump	1. Turn off the cycler.
might have moved while the cycler door was being closed.	Lift the front door handle up completely until it clicks.
	3. Open the door.
	4. Remove the cartridge completely from the cycler.
	5. Turn on the cycler.
	6. When the yellow caution window flashes, insert the cartridge and close the cycler door.
	7. Press ADD FLUID .
	8. If the alarm recurs, contact Technical Support.

601, 602, 603 - System Alarm (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The cycler detected that the pumps are not running at the proper speed.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do
Kinked, clamped, or pinched	During prime mode before step 23.0:
fluid or blood lines.	Check and fix any kinked, clamped, or pinched fluid or blood lines.
	Reprime the cartridge, page 5-4.
	• If unable to fix, contact Technical Support. During recirculation of prime (23.0 in top window), in treatment or rinseback mode:
	Check and fix any kinked, clamped, or pinched fluid or blood lines.
Pump failure.	1. Turn the cycler off.
	2. Wait for three seconds and then turn the cycler on.
	3. When the number 40 appears in the yellow caution window, press TREATMENT to continue.
	4. If the alarm recurs, repeat steps 1 through 3. Press
	and hold STOP . Perform an automated
	rinseback, page 5-6.
	5. If the alarm occurs a third time, perform a manual rinseback, page 5-10 unless otherwise instructed by the center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines. Contact Technical Support.

715 - Check Blood Leak Detector (Red Alarm)

Priority

• Red Alarm - High

Alarm event

The cycler detected a problem with the blood leak detector.

- 1. Press **MUTE** to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do	
Blood leak detector malfunction. Fluid has interfered with the blood leak detector signal.	Turn the cycler off, then on again immediately. When the grapher 40 engage in the	
detector signal. Improper automated calibration of the blood leak detector during prime.	2. When the number 40 appears in the yellow caution window, press TREATMENT to continue.	
	3. If the alarm recurs, or a leak is observed, end the treatment and perform a manual rinseback, page 5-10, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.	
	After rinseback is complete, check the cartridge for leaks. If you see a leak, clean and dry all cycler surfaces affected by the leak. Weigh the patient to assess ultrafiltration status.	
	Even if no leak is observed, clean the mirror and detector, following the instructions in the maintenance chapter of the user guide.	
	Prime a new cartridge.	

721 - Door is Ajar (Red Alarm)

Priority

• Red Alarm - High

Alarm event

Door movement.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Cl	Check for		Do	
	Door handle in the upright position. The door handle was lifted any time after priming began. Damaged door locking mechanism.	1. 2. 3.	Clamp dialysate inlet line immediately. Turn the cycler off. Perform a manual rinseback, page 5-10, unless otherwise instructed by your center, as long as the blood circuit is not clotted or hemolyzed and air is not seen in the blood circuit or in the patient blood lines.	
		4.	Call Technical Support and report the alarm number.	

999 - Service Mode Active (Yellow Caution)

Priority

• Yellow Caution - Medium

Alarm event

The cycler is in service mode.

- 1. Press MUTE of to silence the alarm.
- 2. Identify and fix the cause.

Check for	Do	
Service mode.	Do not start the treatment.	
	Call Technical Support immediately.	

SECTION 6

ALARMS AND TROUBLESHOOTING



WARNINGS:

If any Alarms generated by the PureFlow SL cannot be remedied by the operator, discontinue use of the PureFlow SL and call NxStage Customer Service. If any setup or Alarm test fails or audible Alarm cannot be remedied by the operator, do not use the NxStage PureFlow SL and call NxStage Customer Service.

PureFlow SL Alarms are communicated through a series of lights on the Control Panel of the Pump Controller and an audible Alarm. Alarms will also be accompanied by a text message displayed on the Control Panel. Consult the Alarm Chart in this manual for Alarm descriptions and corrective measures.

If the PureFlow SL fails during the initial start up Self Test, power down, wait 10 seconds, and power on again.

For Alarms that cannot be resolved after the corrective measure has been attempted, call NxStage Technical Service.

POWERING UP AFTER A POWER FAILURE

If power is interrupted to the PureFlow SL, the PureFlow SL will attempt to recover and return to its previous mode when power is restored.

Upon resumption of power, the PureFlow SL will indicate:

POWER FAIL RECOVERY FROM: (MODE)

Press GO to initiate Power Fail Recovery.

POWER FAIL RECOVERY
Cancel:STOP Cont:GO

Press GO to return the PureFlow SL to its previous mode.

If the PureFlow SL cannot return to its previous mode, the PureFlow SL will enter **DRAIN MODE** and any partial or completed Batch must be drained and discarded per the **DRAIN** procedure.

FLUID LEAKS

If a fluid leak is detected, there is a potential for contamination of the dialysate line and dialysate. Therefore, the process of making, using, or holding a Batch must be discontinued and the Batch must be drained and unloaded. Refer to Section 5 for draining and unloading the Dialysate Sack.

If the leak alarm is from the Dialysate Sack:

- 1. Discard the Dialysate Sack.
- 2. All fluid in the Dialysate Tub must be absorbed and removed.
- 3. Refer to Section 5 for loading a new Dialysate Sack.

If the leak is from the Purification Pack:

- 1. Disconnect the three lines coming from the Purification Pack.
- 2. Slide out and remove Purification Pack.

NOTE:

The Purification Pack may be heavier if water has been filtered.

- 3. All fluid in the Purification Pack Compartment must be absorbed and removed.
- 4. Refer to Section 5 to load a new Purification Pack.

MANUAL DRAINING OF THE DIALYSATE SACK

When the Dialysate Sack cannot be drained by the PureFlow SL, the Dialysate Sack must be drained manually:

- Locate a container in which to empty the dialysate from the Dialysate Sack.
- Shut off the main power switch on the back of the PureFlow SL.
- 3. Open the door.
- Open the door of the Control Panel.
- Lift the cover on the Dialysate Pump.
- 6. Close the orange clamp on the Dialysate Sack line and disconnect from the Conductivity Sensor Connector.
- 7. Remove the filter and lines of the Dialysate Sack from the Control Panel and hang the assembly on the outside of the Dialysate Tub.
- 8. Slide out the Dialysate Tub.
- 9. With the green clamp open, place the Dialysate Sack Outlet Line into the container.
- 10. Press the Dialysate Sack while it is inside the Dialysate Tub to empty the Batch into the container.
- 11. When the container is full, close the green clamp on the Dialysate Sack Outlet Line. Empty the full container into the drain and repeat steps #9 and #10 until the Dialysate Sack is nearly empty.
- 12. Discard the Dialysate Sack once enough fluid had been drained so it can be removed safely.



WARNING:

Do not attempt to lift the Dialysate Sack disposable from the PureFlow SL when it is full. The Dialysate Sack must be drained as much as possible prior to lifting. If fluid still remains, two people are required to lift it.

CAUTION AND ALARM TROUBLESHOOTING TABLES

The following two tables indicate Alarms that may be encountered while using the PureFlow SL, their potential cause, and corrective measure. The first table, "PureFlow SL Alarms," addresses Alarms from the PureFlow SL. Some cycler Alarms may also be caused by the PureFlow SL. These Alarms are listed in the table, "Cycler Alarms," with the potential cause and corrective action with the PureFlow SL.

Table 1: PureFlow SL Alarms

PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure
Caution 1	PAK Expires in hh hr	Preventive Maintenance timer indicates the Purification Pack (PAK) timeout is nearing.	Verify that the batch can be completed prior to Purification Pack expiration. Press GO to continue. Prepare to replace Purification Pack prior to initiating next batch.
Caution 2	UVLt Exp. in dd days	Preventive Maintenance timer for the UV Light is near expiration.	Verify that the batch can be completed prior to UV-Light expiration. Press GO to continue. Control unit needs to be replaced soon.
Caution 3	UV Light Expired	Preventive Maintenance timer for the UV Light indicates that the UV Light has expired.	Press GO to acknowledge the caution. Control Unit needs to be replaced. Call NxStage Technical Support.

PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure
Caution 4	Batch Expires: hh:mm	The current batch is nearing its expiration time.	Verify that the treatment can be completed prior to Batch expiration. Press GO to continue using the batch or discard batch by pressing STOP to transition to DRAIN.
Caution 5	Last Batch: Cont: GO	The resistivity sensor has indicated that the Purification Pack is near exhaustion and that this was the last batch prepared with this Pack.	Press GO to acknowledge the caution and use the batch. However, the Pack needs to be replaced before creating the next batch.
Alarm 10	Batch Expired	The 72 hour batch timer has expired.	Batch must be discarded. Press STOP to acknowledge the alarm. Press GO to transition to DRAIN and drain the batch.
Alarm 11	PAK Expired	Preventive Maintenance timer for the Purification Pack has elapsed.	The Purification Pack needs to be replaced before creating the next batch. Press STOP to acknowledge alarm and follow the instructions on the display to replace and prime a new Purification Pack.

PureFlow SL	PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure	
Alarm 12	PAK Exhausted	Resistivity readings show that the Pack is beyond its useful life.	The Pack needs to be replaced and batch cannot be completed. Press STOP to acknowledge the alarm. Press GO to transition to DRAIN and drain the batch.	
Alarm 13	Replace UV Light	UV-Light Monitor has detected a UV-Light malfunction.	The Control Unit needs to be replaced. Pressing STOP and GO allows the user to continue in the event of a false alarm. If there is a malfunction of the UV Light, the alarm will recur. Contact NxStage Technical Support.	
Alarm 14	Compromised SAK	Output Pressure read is below the minimum allowable parameterized limit.	Press STOP to acknowledge the alarm. a) Inspect all Dialysate Sack to Purification Pack connections for leaks or kinks. b) Check that Dialysate Sack has been unfolded properly. Press GO to continue. If alarm persists, discard the batch and transition to DRAIN.	

PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure
Alarm 15	Door is Open	The Control Panel door is open when it should be closed.	Press STOP to acknowledge the alarm. Close the Control Panel door if it is open. PRESS GO and unit will transition to DRAIN if a partially made or used batch is present that needs to be drained.
Alarm 16	Connect PAK	Purification Pack connection sensor shows that the Pack is not connected.	Verify that the Pack cable is connected to the left hand side of the UV Light. Pressing STOP and GO allows the user to continue in the event of a false alarm. If the Pack is not connected, the alarm will recur and the user will have to discard a partially made batch and prime a new Pack.
Alarm 20	Prime PAK Failed	Failure occurred during PAK Alarm Test.	Press STOP to acknowledge the alarm. The Purification Pack needs to be replaced before creating the next batch.
Alarm 21, 22, and 23	PAK Init.: FAILED	Failure to initialize priming of the Purification Pack.	Press STOP and GO. If alarm persists contact NxStage Technical Support.

PureFlow SL	PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure	
Alarm 24, 25, 26, and 27	PHASE 1: FAILED PHASE 2: FAILED PHASE 3: FAILED PHASE 4: FAILED	Failure to verify and reach water quality during the priming of the Purification Pack.	Press STOP and GO. If alarm persists contact NxStage Technical Support.	
Alarm 28	ction sensor cable is or that the the loft ha that the UV Light is	Failure to prime the Purification Pack.	Press STOP to acknowledge the Alarm. Priming of the Purification Pack has failed and the Pack needs to be replaced and primed before creating the next batch.	
Alarm 31	HDW Test: FAILED	Failure to pass hardware alarm test during Dialysate Sack P&AT	Press STOP to acknowledge the alarm. Press GO to retry test. Verify that all electrical connections on the back of the units have been made.	
Alarm 32		Inlet water pressure is below the minimum acceptable pressure during Inlet Water Pressure Test.	Press STOP to acknowledge the alarm. Verify that a) the PureFlow SL is connected to the water source as described in the User's Guide, b) the water is turned on, and c) that the water supply line is not kinked. Press GO to retry test.	

PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure
Alarm 33	Condo.Low AT: FAILED	Conductivity alarm test failed.	Press STOP to acknowledge the alarm. Verify that a) the conductivity sensor line of the Dialysate Sack is connected to the conductivity sensor connector on the front of the unit, b) the orange clamp on the conductivity sensor line of the Dialysate Sack is open, c) Verify that drain line is connected to the back of the unit. Press GO to retry test.
Alarm 34	Encoder Test: FAILED	Encoder test failed.	Press STOP to acknowledge the alarm. Press GO to retry test.
Alarm 35 and 36	Ini Press AT: FAILED	Inlet pressure low alarm test failed.	Press STOP to acknowledge the alarm. Press GO to retry test. Check clamps, specifically the white clamp on the Water Inlet Line.
Alarm 38	Out Press AT: FAILED	Output pressure high alarm test failed.	Press STOP to acknowledge the alarm. Press GO to retry test.

PureFlow SL Alarms

PureFlow SL Alarms				
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure	
Alarm 39, 40, and 41	Load Test: FAILED	Pressure could not be increased to desired value for Dialysate Sack Loading Verification Test.	Press STOP to acknowledge the alarm. Verify that a) Dialysate Sack is loaded properly, b) blue clamps on the Pack to Dialysate Sack lines are open, c) tubing on Dialysate Sack has not been kinked d) check that Dialysate Sack has been unfolded properly Press GO to retry test.	
Alarm 42	CSC Test: FAILED	Conductivity sensor clamp failed to occlude.	Press STOP to acknowledge the alarm. Verify Dialysate Sack is loaded properly. Press GO to retry test.	
Alarm 43	Conduct. Test Failed	Verification of the batch conductivity failed.	Press STOP to acknowledge the alarm. a) Check lines for clamps and kinks. b) Push on the bag to mix fluid. Press GO to retry test.	

PureFlow SL Alarms

Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure
Alarm 44	No Flow Detected	Fluid flow through the conductivity sensor line has not been detected.	Press STOP to acknowledge the alarm. Verify that: a) the conductivity sensor line is connected to the conductivity sensor connector and that the conductivity sensor clamp (orange clamp) is open b) the tubing on Dialysate Sack has not been kinked c) the Dialysate Sack has unfolded properly d) the drain line on the back of the Control Unit is connected properly and can drain without obstructions Press GO to continue.

PureFlow SL	PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure	
Alarm 50	Inlet Pressure Low	Inlet Pressure is lower than the pre-set limits. This could be caused by low supply water pressure or a exhausted Replacement Sediment Filter.	Press STOP to acknowledge the alarm. Verify that a) the PureFlow SL is connected to the water source as described in the User's Guide, b) the water is turned on, and c) that the water supply line is not kinked. Press GO continue. If problem persists, replace Replacement Sediment Filter.	
Alarm 51	Output Pressure High	Output Pressure exceeds the pre-set limits.	Press STOP to acknowledge the alarm. Verify that blue clamps on the water inlet line and the white clamp on the inlet to the Pack are open. Check that the Dialysate Sack is unfolded properly and there are no kinks in the lines. Press GO to continue. If necessary, relieve pressure from the Purification Pack: Disconnect the Water Inlet Line from the Control Panel and drain a little water.	

PureFlow SL	PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure	
Alarm 52	Fluid Leak in CU	A fluid leak has been sensed in the Control Unit.	Press STOP to acknowledge the alarm. Press GO to continue. If alarm persists, contact NxStage Technical Support.	
Alarm 53	Fluid Leak in Tub	Fluid has been detected in the Dialysate Tub indicating a leak in the Dialysate Sack.	Press STOP to acknowledge the alarm. Press GO to continue. If alarm persists, discard the batch and transition to DRAIN . See Manual Draining of the Dialysate Sack.	
Alarm 54	Fluid Leak in PAK	A fluid leak has been sensed in the Purification Pack Compartment.	Press STOP to acknowledge the alarm. Press GO to continue. If alarm persists, remove Purification Pack and dry leak sensor in Purification Pack Compartment. If Purification Pack is wet, Purification Pack needs to be discarded and a new Purification Pack primed.	
Alarms 55	Fluid Temp Too High	Temperature of fluid in the Dialysate Sack exceeds parameterized limits.	Press STOP to acknowledge the alarm. Open door and let fluid cool down. Press GO to continue. If alarm persists, contact NxStage Technical Support.	

PureF	low	SL	Alarm
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Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure
Alarms 56	Heater Error	The temperature did not increase as expected.	Press STOP to acknowledge the alarm. Verify that the heater cable is connected properly. Press GO to continue. If alarm persists, contact NxStage Technical Support.
Alarm 60 and 61	Dialysate Pump Error	Indicates that the system has detected an error with the Dialysate Pump	Press STOP to acknowledge the Alarm. Press GO to continue. If the Alarm persists, discard the Batch and transition to DRAIN.
Alarms 62 through 67	Water Pump Error	Indicates that the system has detected an error with the Water Pump.	Press STOP to acknowledge the Alarm. Verify that the water line inlet is not clamped or kinked. Press GO to continue. If the Alarm persists and a partially made Batch is present, discard the Batch and transition to DRAIN.
Alarm 68	UNSUCCESSFUL	Could not complete a power failure recovery operation.	Press STOP and GO. Unit will either transition to STANDBY or to DRAIN if a partially made or used batch is present that needs to be drained.

PureFlow SL	PureFlow SL Alarms			
Caution/ Alarm Number	Line 2 of Display	Probable Cause	Corrective Measure	
Alarm >199	Turn Power OFF/ON	Indicates system error or internal communication error.	Note alarm number. Turn power off and on again. If POWER FAIL RECOVERY is displayed press GO to continue. If system alarm reappears, contact NxStage Technical Support.	
Caution 999	NxStage Medical C999 (Line 1) Enter Password	Unit is in Service Mode.	Call NxStage Technical Support immediately.	

Table 2: NxStage System One Cycler Alarms

Cyc	ler	Al	a	rms	,
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Cycler Display	Description	Probable Cause	Corrective Measure
Yellow 14	Check Fluid Line Inlet: Air Detected in Fluid Line Inlet	 Empty Batch TX on cycler was initiated before use of Batch on PureFlow SL Air in tubing Kinked or occluded line on Dialysate Sack Plugged filter on Dialysate Outlet Line Fluid volume in Dialysate Sack is low 	 Check for sufficient fluid volume in Dialysate Sack Initiate Use Batch on PureFlow SL Slightly open connection between Dialysate Sack and Cartridge Therapy Fluid Line to remove air Check bag for folded over or kinked line Reposition Dialysate Sack by lifting up the back end; tubing inlets must be at or near the base of the tub Check for clamped lines on the Therapy Fluid Inlet Lines and Dialysate Outlet Lines (green clamps) Discard Batch
Red 35	Check Waste Line: Waste Line Pressure High	 Waste Line is occluded Drain Line is not connected to PureFlow SL 	 Remove occlusion on Waste Line Connect Drain Line to PureFlow SL. Ensure proper connection to drain

Cycler Alarms			
Cycler Display	Description	Probable Cause	Corrective Measure
Red 37, 38	Check Fluid Circuit: High Balance Chamber Pressure	 Empty Batch TX on cycler was initiated before use of Batch Kinked or occluded line on Dialysate Sack Plugged filter on Dialysate Outlet Line Fluid volume in Dialysate Sack is low 	 Check for sufficient fluid volume in Dialysate Sack Initiate Use Batch on PureFlow SL Slightly open connection between Dialysate Sack and Cartridge Therapy Fluid Line to remove air Check Dialysate Sack for folded over or kinked line Reposition Dialysate Sack by lifting up the back end; tubing inlets must be at or near the base of the tub Check for clamped lines on the Therapy Fluid Inlet Lines and Dialysate Outlet Lines (green clamps) Discard Batch

Cycler Alarm	Cycler Alarms			
Cycler Display	Description	Probable Cause	Corrective Measure	
Red 39	Check Fluid Inlet: Therapy Fluid Inlet Occlusion	 Empty Batch TX on cycler was initiated before use of Batch Kinked or occluded line on Dialysate Sack Plugged filter on Dialysate Outlet Line Fluid volume in Dialysate Sack is low 	 Check for sufficient fluid volume in Dialysate Sack Initiate Use Batch on PureFlow SL Slightly open connection between Dialysate Sack and Cartridge Therapy Fluid Line to remove air Check Dialysate Sack for folded over or kinked line Reposition Dialysate Sack by lifting up the back end; tubing inlets must be at or near the base of the tub Check for clamped lines on the Therapy Fluid Inlet Lines and Dialysate Outlet Lines (green clamps) Discard Batch 	
Red 50	Check Fluid Temp: Fluid Temp High	Heater setting is too high	Reduce heater setting by 1 and let fluid cool down by opening the cabinet door	
Yellow 51	Fluid Cooldown Underway	System recovery after Red Alarm 50 is cleared	None required. Wait for Yellow Caution 52	

Cycler Alarms			
Cycler Display	Description	Probable Cause	Corrective Measure
Yellow 52	Continue Treatment: Fluid Cooldown Complete	Fluid temperature has dropped below 38.5 degrees Celsius after a Red Alarm 50 and subsequent Yellow Caution	Press TREATMENT to resume therapy

51. Therapy Fluid Pump remains off

TREATMENT is

until

pressed