



# AQUADEX FLEXFLOW® SYSTEM

chf solutions™

QUICK REFERENCE GUIDE



## AQUADEX FLEXFLOW SYSTEM

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### DISCLAIMER

The quick reference guide is not intended to replace CHF Solutions, Inc. Aquadex FlexFlow Direction For Use (DFU). Always follow the appropriate and applicable local, institutional, and/or hospital policies, procedures, and requirements.

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### PURPOSE OF QUICK REFERENCE GUIDE

Provides an overview on workflow and setup of Aquadex FlexFlow system.



**Rx  
ONLY**

**INDICATION:** The Aquadex FlexFlow® System is indicated for temporary (up to 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy; and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies.



## AQUADEX FLEXFLOW SYSTEM

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### LIST OF SUGGESTED ITEMS

- Aquadex FlexFlow Console
- UF 500 Blood Circuit Set
- 500cc NaCl bag
- Preloaded NaCl syringes
- Empty 10 – 12cc syringe
- Alcohol preps
- Extra Luer caps
- Graduated cylinder

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### KEY CONCEPTS FOR AQUADEX FLEXFLOW SYSTEM THERAPY

**The following must be achieved, confirmed, and maintained throughout therapy:**

- Catheter patency
- Recommended blood flow (20-40 mL/min)
- Therapeutic levels of anticoagulation

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**WARNING** It is important for the clinician to balance the risks of anticoagulation with the potential benefit when deciding to use anticoagulation therapy (for example, heparin) in conjunction with Aquadex FlexFlow system therapy.

## PRE-THERAPY PREPARATION

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- 1 Ensure anticoagulation has begun (minimum 30 minutes), per physician order
- 2 Gather the required items listed
- 3 Check for venous access patency using 10-in-10 test:
  - Ensure Withdrawal of 10ml over 10 seconds then re-infuse in 10 seconds without resistance (10-in-10 patency test)
  - Aspirate and flush each catheter port
  - If resistance is encountered, consider the following catheter corrections, such as:
    - Re-position catheter, per hospital protocol
    - Contact PICC team or Interventional Radiology as needed

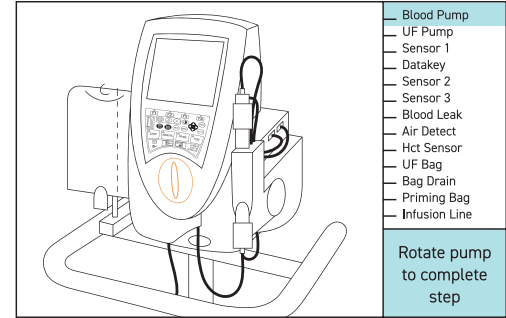
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**WARNING** Do not use heparin for anticoagulation in patients with intolerance or allergy to heparin.

## PRE-THERAPY PREPARATION

### 4 Load and Prime the Circuit:

- a. Press **PRIME** then **HELP**
- b. Follow prompts on screen to load the UF 500 Blood Set
- c. On Prime mode screen, press **ACCEPT** to enter Prime mode
- d. Follow prompts on screen during Prime
- e. To prime access ports, use an empty syringe to withdraw saline from the Withdrawal (blue) access port and use the same syringe to infuse saline into the Infusion (clear) access port







Attach the front cartridge and push until it clicks. Rotate the pump clockwise until the console beeps.

**WARNING** To avoid risk of introducing air into the patient, do not connect the patient to the circuit until priming is complete.



## INITIATING THERAPY

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- 1** Connect lines to venous access catheter/lumen(s):
  - Disconnect Withdraw (blue) line from priming bag and connect to catheter
  - Disconnect Infusion (clear) line from UF bag and connect to catheter
  - Open all clamps
  - No caps or plugs – HUB to HUB connection
- 2** Set  and  Rate, then Press 
- 3** Press the  key
- 4** Determine whether automatic Hematocrit monitoring will be enabled on console
- 5** Monitor Venous Access:
  - Check Pw and Pi pressures and frequency of Occlusions / Disconnects
  - Consider adjusting patient/catheter position in order to maximize blood flow
  - Setting blood flow lower than 20 ml/min is not recommended
- 6** Monitor the patient per hospital standing orders and per the DFU



## THERAPY COMPLETION

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- 1** To return blood (35 mL with Hct and 33mL without), connect blue Withdrawal line to saline and press and hold Manual button until blood is returned to patient
- 2** Close clamps and disconnect blood set from venous access/catheter(s)
- 3** Remove blood set from device
- 4** Care for catheter and dispose of set according to institutional policies

## PRESSURE READINGS: ACCESS

### Pw

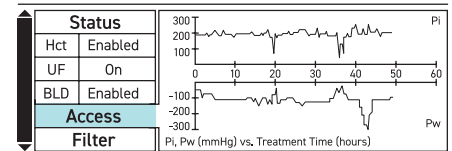
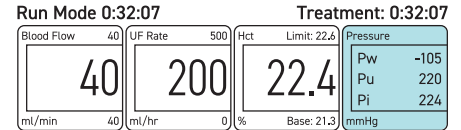
#### WITHDRAWAL PRESSURE:

- Measures patency of the Withdraw (blue) side of the set
- Negative pressures -20 to -300 mmHg (greater negative number means greater resistance)
- If Pw trends in a more negative direction, consider flushing the access ports and/or re-positioning patient

### Pi

#### INFUSION PRESSURE:

- Measures patency of the Infusion (clear) side of the circuit
- Positive pressures +20 to +300 mmHg (greater number means greater resistance)



UF 500 Hct

Total Fluid: 6.400L

To view graph – from the main screen, use the down arrow until the **Access** status bar is highlighted



## PRESSURE READINGS: FILTER

### Pu

#### ULTRAFILTRATE PRESSURE:

- Measures patency of the filter
- Pressure range: -250 to +200 mmHg (greater negative number indicates potential clot)

#### FILTER LIFE:

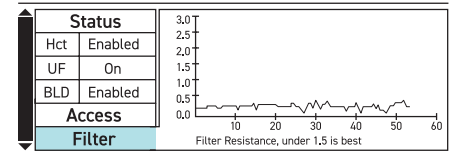
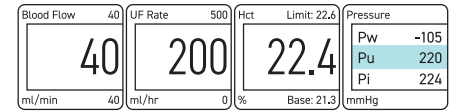
- If the blood pump has been stopped for 4-5 minutes and the filter resistance is greater than 1.0, consider re-priming Blood Set

### FILTER STATUS:

- Measures resistance of the filter
- If resistance is trending upward towards 1.0, consider re-priming filter, checking that anticoagulation level is appropriate, reducing UF rate
- Greater than 1.5, may indicate a clotted filter. Consider re-priming or change out filter

Run Mode 0:32:07

Treatment: 0:32:07



UF 500 Hct

Total Fluid: 6.400L



To view graph — from the main screen, use the down arrow until the **Filter** status bar is highlighted

## ADDITIONAL TIPS


### PATIENT SHOWING CLINICAL SIGNS OF HYPOVOLEMIA:

- These could include: decrease urine output, hypotension, tachycardia
- Contact prescriber
- Consider setting UF rate to "0" while awaiting prescriber response

### REPORTS AND SYSTEM EVENTS HISTORY:

- Press the  key
- Choose "Alarms and Events" for a history of recent events
- Choose "Measurements" for a history of settings and pressure readings (logged every  20 minutes)

### AMBULATING THE PATIENT:

- Disconnect power cord from outlet
- Console can operate for no more than "30 minutes" on battery power alone
- Device will alert – press 
- Ensure stability of catheter and lines
- Hct measurement may be affected by patient movement


**WARNING** Ignoring and/or indiscriminately pressing the CLEAR key as a response to an alarm may result in serious patient injury or death. Always identify and solve the originating cause of an alarm before pressing the CLEAR key.



## HEMATOCRIT (HCT) SENSOR – OPTIONAL

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### IF HEMATOCRIT SENSING IS NOT DESIRED:

- Leave the Hematocrit sensor on the dock on the back of the machine
- When prompted with "Confirm Hct System Disabled" at start-up, press the  key

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### ENABLING HEMATOCRIT SENSING:

- Move the Hematocrit sensor from the dock to the blood chamber cuvette
- Set the Hct limit by pressing the Hct button and using the arrows to adjust
- Upon startup, Hct sensor will automatically establish the patient's baseline Hct
- Once the automatic baseline process is complete, Hct level will be displayed on the main screen

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### HEMATOCRIT MONITORING:

- To view graph – from the main screen, press the down arrow until the Hct screen is highlighted
- When Hct limit is reached, the UF pump will stop without stopping the blood pump
- If Hct limit sustained, system will alert

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**WARNING** The setting of a Hct Limit is an adjunct to standard medical practice and is not a replacement. It has the ability to prevent excessive volume depletions and allow the medical practitioner to provide an additional level of safety while treating fluid overloaded patients.

# COMMON ALARMS AND ALERTS

ALARM/ALERT	DESCRIPTION	POSSIBLE REMEDY
<p>The device is beeping</p>	<p>ALARM (red LED, audible alarm sounds once per second)</p> <p>ALERT (yellow LED, audible alarm sounds once every two seconds)</p>	<ul style="list-style-type: none"> <li>• Press the Alarm Silence key (Silence for 2 minutes)</li> <li>• Follow prompts on screen for troubleshooting alarms/alerts</li> <li>• Press the CLEAR key when ready to advance</li> <li>• If pump was stopped, press run to continue</li> </ul>
<p><b>Withdrawal Line Occlusion or Infusion Line Occlusion</b></p>	<p>The withdrawal line or infusion line pressure is higher than expected</p>	<ul style="list-style-type: none"> <li>• Consider position of patient, catheter and lines</li> <li>• Consider flushing catheters</li> <li>• Consider switching the lumens (Infusion and Withdrawal), per institutional policy</li> <li>• Consider repositioning catheter, per institutional policy</li> <li>• If persistent, reduce blood flow rate in increments of 5 mL/min until consistent blood flow is maintained</li> </ul>
<p><b>Withdrawal Line Disconnect or Infusion Line Disconnect</b></p>	<p>The withdrawal line pressure is lower than expected Infusion line is not connected to the ultrafiltrate bag during Prime Mode</p> <p>The console did not see the expected ultrafiltrate bag weight increase during Prime Mode</p>	<ul style="list-style-type: none"> <li>• Consider connection to catheter</li> <li>• Consider size of catheter – resistance may be too low (consider adding resistance)</li> <li>• Ensure blood flow rate is at maximum of 40 mL/min</li> <li>• Press CLEAR and then RUN to continue</li> </ul>
<p><b>UF Bag Full</b></p>	<p>The ultrafiltrate bag is full. If in Run Mode, ultrafiltrate pump stops but blood pump continues operation to prevent clotting</p> <p>The amount of fluid removed is approximate</p>	<ul style="list-style-type: none"> <li>• Drain bag completely into graduated cylinder or urinal and discard</li> <li>• Ensure the bag drain is fully closed</li> <li>• Press CLEAR to continue</li> </ul>
<p><b>Ultrafiltrate Bag Weight Mismatch</b></p>	<p>The fluid measured by the weight scale does not match the amount expected to be delivered by the ultrafiltrate pump</p> <p>The amount of fluid removed is approximate</p> <p>If the alarm persists and the ultrafiltrate bag full alarm does not occur at 1.1 liters contact customer service</p> <p>Repeated occurrence of this alert can result in the Excessive Weight Mismatch alert</p>	<ul style="list-style-type: none"> <li>• Can occur if fluid collection bag is emptied prematurely</li> <li>• Ensure bag is hanging freely on weight scale hook, and the bag drain is fully closed</li> <li>• Press CLEAR to continue</li> </ul>



## COMMON ALARMS AND ALERTS

ALARM/ALERT	DESCRIPTION	POSSIBLE REMEDY
<b>Air Detected</b>	Air detected in the circuit during Run Mode Blood and ultrafiltration pumps stop, system enters Stop Mode	<ul style="list-style-type: none"> <li>· PROMPTLY assess amount of air in the air detector</li> <li>· Press the CLEAR key</li> <li>· Press and hold the MANUAL key to advance the air past the detector</li> <li>· For large air bubbles, continue to advance the air bubble until it reaches the Infusion access port and remove with a syringe</li> <li>· Press RUN to continue</li> </ul>
<b>Excessive Withdrawal Pressure or Excessive Infusion Pressure</b>	System detected out of range withdrawal or infusion pressure Blood and ultrafiltrate pumps stop, system enters stop mode	<ul style="list-style-type: none"> <li>· If obstruction due to compressed vein, re-position patient and catheter position</li> <li>· If obstruction due to clot, flush catheter/lumen per institutional policy</li> <li>· Disconnect line to relieve pressure and then reconnect</li> </ul>
<b>Excessive UF Pressure</b>	System detected out of range ultrafiltrate pressure Blood and ultrafiltrate pumps stop, system enters stop mode	<ul style="list-style-type: none"> <li>· Check the line from the filter to the UF bag for any kinks or obstructions</li> <li>· Flush catheter/lumen per institutional policy</li> <li>· Disconnect line to relieve pressure and then reconnect</li> </ul>
<b>Unexpected Pressure Difference</b>	An unexpectedly high pressure difference over 100 mmHg is detected between the withdrawal and infusion pressures at the beginning of Run or Manual Mode	<ul style="list-style-type: none"> <li>· Ensure ALL clamps are open</li> <li>· Consider patient and catheter position</li> <li>· Verify anticoagulation is at appropriate level</li> <li>· Flush catheter/lumen per institutional policy</li> <li>· Manually turn the pumps by hand to achieve desired pressure levels</li> </ul>
<b>Motion Detected</b>	The console is having difficulty measuring pressures	<ul style="list-style-type: none"> <li>· Press CLEAR</li> <li>· Restrict patient movement</li> <li>· Press RUN to continue</li> </ul>

## COMMON ALARMS AND ALERTS

ALARM/ALERT	DESCRIPTION	POSSIBLE REMEDY
<b>Circuit Life Exceeded / Expired</b>	The indicated life of the circuit has been exceeded Less than 10 minutes remain in current circuit life before therapy using the current circuit will be disabled	<ul style="list-style-type: none"> <li>• Prepare and replace with a new blood set if treatment is to continue</li> </ul>
<b>Circuit Clotted</b>	The system has detected a higher than expected infusion pressure and an inadequate blood flow Blood and ultrafiltration pumps stop, system enters stop mode	<ul style="list-style-type: none"> <li>• Avoid prolonged or frequent periods in stop mode</li> <li>• Verify appropriate anticoagulation levels</li> <li>• Flush catheter/lumen per institutional policy</li> <li>• Consider re-priming the circuit (see pg 15)</li> <li>• Replace the circuit if necessary</li> </ul>
<b>Large increase in Hematocrit (Hct)</b>	The current patient Hct reading is significantly above the HCT limit Ultrafiltration has stopped	<ul style="list-style-type: none"> <li>• Ensure that Hct sensor is properly connected to blood chamber cuvette</li> <li>• Limit excessive patient movement</li> <li>• Clean the Hct sensor of any dust or debris</li> <li>• If persistent, consider lowering UF rate (per prescriber's order), raising Hct limit or disabling feature</li> <li>• Remove air bubble or saline from blood chamber</li> </ul>
<b>Hct Limit Not Set</b>	The Hct limit has not been set, ultrafiltration is prevented	<ul style="list-style-type: none"> <li>• Press CLEAR, then set the Hct limit using the Hct key</li> <li>• If disabling, place the Hct sensor on the dock</li> </ul>
<b>Hct No Blood Detected</b>	The HCT sensor clip is not currently detecting blood in the blood chamber	<ul style="list-style-type: none"> <li>• Remove Hct sensor from blood chamber and reconnect</li> <li>• Remove any air bubble or saline from blood chamber using the MANUAL key</li> </ul>

Please refer to additional warnings, alarms, and alerts listed in the DFU.



## RE-PRIMING THE CIRCUIT

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### CONSIDER RE-PRIMING THE CIRCUIT IF:

- Device is in Stop mode for more than a few minutes
- Pu is trending negatively or Filter resistance is reaching critical range
- “Circuit Clotted” alarm occurs

## RE-PRIMING STEPS

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- 1 Empty and document current amount of fluid in UF bag
- 2 Pause anticoagulation Infusion
- 3 Disconnect Withdrawal (blue) line and connect to saline bag using spike
- 4 [OPTIONAL] Press and hold the  key to return blood to patient
- 5 Disconnect Infusion (clear) line and connect to UF bag
- 6 Press , then  and follow prompts on screen
- 7 Press  and  for a second prime cycle
- 8 Reconnect Withdrawal and Infusion line to patient catheters
- 9 Resume anticoagulation
- 10 Press





## CONTACT INFORMATION

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For more information, refer to the Aquadex FlexFlow User's Guide.

For customer and technical support, please call 1-855-786-2778.

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