

# SpectraFlo™ Dynamic Dialysis Systems

## User Guide



SpectraFlo™ Lab System



SpectraFlo™ Process System



SpectraFlo™ Mobile System

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## SpectraFlo™ Dynamic Dialysis Systems

The SpectraFlo™ Dynamic Dialysis Systems assembly and operation may vary based on application. The instructions below are for general use. For questions about specific application set-up or customization, please contact your local Repligen representative.

### 1. General Precautions

- Remove the contents from the packaging. Check contents against the parts list (table 3). If a part is missing, contact Repligen before proceeding with assembly.
- Clean all fluid contact parts with appropriate cleaning agent prior to assembly
- No tools are required, hand tighten only

Optional: To ensure a leak-free seal, wet gasket surfaces with 50-100% isopropanol immediately prior to assembly

### 2. SpectraFlo™ Lab System

**Table 1. Tank Dimensions – SpectraFlo™ Lab System**

Part number	163106	163107	163108
Approximate volume	650 ml	1400 ml	2200 ml
Assembled tank height	23 cm	46 cm	70 cm
Minimum internal diameter	6.35 cm	6.35 cm	6.35 cm

**Table 2. Parts and Materials of Construction - SpectraFlo™ Lab System**

Part description	Material	Qty
Dialysis tank	Polysulfone	1
Tank stand	Polypropylene	1
3-inch end cap	Polypropylene	1
1.5-inch x 1/4-inch hose barb adaptor	Polypropylene	1
1.5-inch x 1/8-inch hose barb adaptor	Polypropylene	1
3-inch gasket	Silicone platinum-cured	2
1.5-inch gasket	Silicone platinum-cured	2
3-inch clamp	Nylon	2
1.5-inch clamp	Nylon	2
Size #16 Extended Life Tubing	Silicone platinum-cured	5 feet
Size #17 Extended Life Tubing	Silicone platinum-cured	5 feet

## 2.1 Dialysis Tank Assembly

**Figure 1. Dialysis Tank**



1. Polysulfone tank
2. Polypropylene stand
3. Polypropylene end cap
4. Nylon sanitary clamps
5. Silicone gaskets
6. Polypropylene hose barb adaptor

1. Place the tank stand on a stable surface. Align a 3-inch gasket on the top of the tank stand with the gasket's outer lip facing downward.
2. Place the dialysis tank on top of the tank stand and 3-inch gasket.
3. Secure a 3-inch clamp around the perimeter of the gasket and dialysis tank by hand tightening the wingnut.
4. Align 1.5-inch x 1/8-inch hose barb adaptor and a 1.5-inch gasket on the tank's lower inlet side-port. Secure a 1.5-inch clamp around adaptor and lower inlet port (hand tighten wingnut).
5. Repeat step 4 to connect 1.5-inch x 1/4-inch hose barb adaptor to the tank's upper outlet side-port.
6. Set aside remaining gasket, clamp, and 3-inch sanitary end-cap. Install after dialysis samples are placed into the assembled tanks.

## 2.2 System Assembly

1. Place the assembled dialysis tank near pump and feed reservoir.
2. Cut a piece of size #16 extended life tubing long enough to connect from feed reservoir through the KrosFlo® KR Jr pump head and to the lower inlet of the tank.
3. Cut one piece of size #17 extended life tubing long enough to reach drain or back to feed reservoir. Connect one end of the tubing to the upper outlet of the tank. For Single Pass mode, direct to drain. For recirculation mode, connect tubing back to feed reservoir.

## 2.3 Operating Instructions

### 2.3.1 General Pump Operation

1. To load tubing, open the pump head by moving the front knob counterclockwise.

**Figure 2. Load Tubing in the Open Pump Head**



2. Insert a loop pump tubing into one open tubing retainer, between the occlusion bed and the rollers and into the other tubing retainer.

**Figure 3. Closing the Loaded Pump Head**



3. Position the tubing so that it is firmly centered against the rollers and inside the tubing retainers.
4. Turn front knob clockwise to close tubing retainers. The pump head will grip the tubing.

Figure 4. Closed Pump Head



### 2.3.2 Operating the System

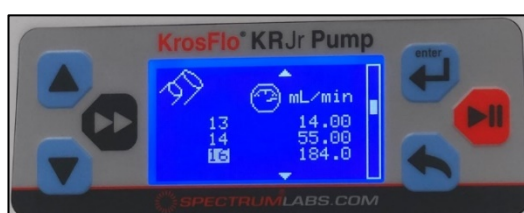
1. Plug in KrosFlo® KR Jr peristaltic pump and flip switch to the on position.
2. Using the up and down arrows highlight “settings”, ⚙️, and press “enter” ↵.



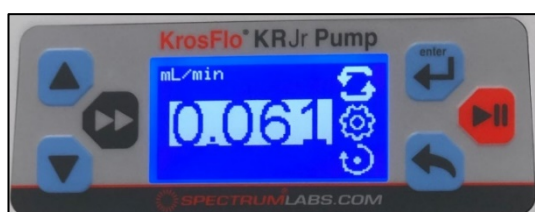
3. Press the “down arrow” to reach the “tubing selection” and press “enter” ↵.



4. Select #16 tubing and press “enter”, ↵, then press “back arrow”, ⬅️, until you reach the main screen.



5. Highlight the flow rate and press “enter” ↵.



6. Use the “enter” key to toggle between digits and the arrow keys to set the flow rate to 100 ml/minute.
7. Make sure that the flow is set in the correct direction, ↻.





8. Press “start stop key”, ▶ ||, to fill the dialysis tank  $\frac{3}{4}$  of the way up. Check to ensure that the tubing is installed correctly and not moving around in the pump head.
9. Once tanks are primed, press “start stop key”, ▶ ||.

### 2.3.3 Loading Dialysis Membrane

1. Carefully place the sample-filled dialysis membrane into each assembled tank by using the red hanger closure as a handle and supporting the weight of the bottom with the free hand.
2. Suspend dialysis membrane inside the top of the tank using the red hanging closure.
3. Seal tank with 3-inch gaskets, end caps, and clamps.
4. Reduce the pump flow rate per your application (5-50 ml/minute recommended), press “start stop key”, ▶ || and dialyze.
5. If running in single pass mode, make sure that the feed source volume is enough for duration of operation.
6. When dialysis is complete, turn off pump, remove cap.
7. Carefully remove dialysis membrane from the tanks.
8. Reverse the flow direction on the pump, ↶. Continue to run the pump until all fluid is drained from tanks.



### 3. SpectraFlo™ Process System

**Table 3. Tank Dimensions – SpectraFlo™ Process System**

Part number	163109	163110	163111
Approximate volume	5 L	7 L	10 L
Assembled tank height	68 cm	86 cm	126 cm
Minimum internal diameter	10.5 cm	10.5 cm	10.5 cm

**Table 4. Parts and Materials of Construction - SpectraFlo™ Process System**

Part description	Material	Qty
Dialysis tank	Polysulfone	1
Tank stand	Polypropylene	1
1.5-inch x 1/4-inch hose barb adaptor	Polypropylene	2
1.5-inch x 3/8-inch hose barb adaptor	Polypropylene	1
6-inch gasket	Silicone platinum-cured	1
1.5-inch gasket	Silicone platinum-cured	2
6-inch clamp	Nylon	1
1.5-inch clamp	Nylon	2
Size #73 Extended Life Tubing	Silicone platinum-cured	10 feet
Size #17 PharmaPure® Tubing	PharmaPure®	8 feet

#### 3.1 Dialysis Tank Assembly

1. Place the tank stand on a stable surface. Align a 6-inch gasket on the top of the tank stand with the gasket's outer lip facing downward.
2. Place the dialysis tank on top of the tank stand and 6-inch gasket.
3. Open a 6-inch clamp by first loosening both wingnuts and then pulling the locking wingnut away from the clamp. Secure the clamp around the perimeter of the gasket, tank stand and dialysis tank by hand tightening the wingnuts firmly.
4. Align 1.5-inch x 1/4-inch hose barb adaptor and 1.5-inch gasket on the tank's lower inlet side-port—on the tank stand side of dialysis tank. Open a 1.5-inch clamp, secure around adaptor and lower inlet (hand tighten wingnut).
5. Repeat step 4 to connect 1.5-inch x 3/8-inch hose barb adaptor to the tank's upper outlet side-port.

#### 3.2 System Assembly

1. Place the assembled dialysis tank near pump and feed reservoir.
2. Cut a piece of size #17 PharmaPure® tubing long enough to connect from feed reservoir through KR1 pump head and to the lower inlet of the tank.
3. Cut one piece of size #73 extended life tubing long enough to reach drain or back to feed reservoir. Connect one end of the tubing to the upper outlet side-port of the dialysis tank. For Single Pass mode, direct to drain. For recirculation mode, connect tubing back to feed reservoir.

### 3.2.1 Series Operation (optional)

**Figure 5. Series Operation - SpectraFlo™ Process System**



1. Depending on your processing requirements, up to 3 process tanks can be connected and operated in series using a single pump and buffer flow. For series operation, a Tank Cap Kit (PN 163001) will need to be purchased separately.
2. Arrange assembled tanks in a row as shown in Figure 5.
3. Cut a piece of size #17 extended life tubing long enough to connect from the upper outlet side-port of the first tank in the series to the bottom inlet side-port of the next tank. Repeat for the 3<sup>rd</sup> subsequent tank in the series.
4. Use size #73 extended life tubing to connect the upper outlet side-port of the last tank in the series to drain or back to feed reservoir.

**Note:** Use 1/4 in. hose barb adaptor for all #17 tubing and 3/8 in. hose barb adaptor for all #73 tubing.

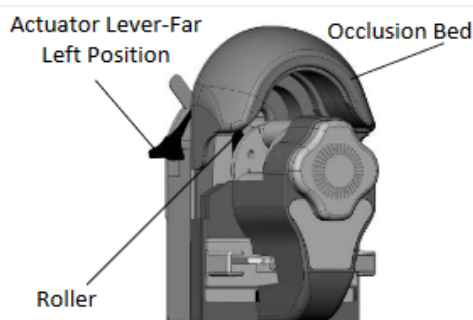
## 3.3 Operating Instructions

### 3.3.1 General Pump Operation

**Note:** For complete pump instructions, refer to the KR1 peristaltic pump operating instructions available at [repligen.com](http://repligen.com).

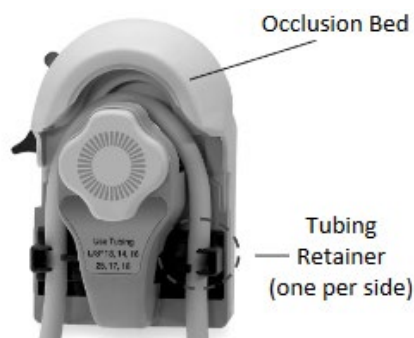
1. To load tubing, open the pump head by moving the actuator lever counterclockwise (left, if pump head is mounted facing down).

**Figure 6. Load Tubing in the Open Pump Head**



2. Insert a loop of pump tubing into one open tubing retainer, between the occlusion bed and the rollers and into the other tubing retainer.
1. Position the tubing so that it is firmly centered against the rollers and inside the tubing retainers.

**Figure 7. Closing the Loaded Pump Head**



2. While holding the tubing ends down, move the actuator lever back to the far clockwise (right) position. The pump head will grip the tubing.
3. Make sure INT/EXT function is set to “int”.



### 3.3.2 Operating the System

1. Connect size #17 PharmaPure® tubing to feed reservoir and thread through pump head. Close pump head.
2. Make sure that flow is set to the correct direction, ↻.
3. Set KR1 Pump to 600 rpm and press the “on” button, ⏻, to fill tanks to 2/3rd volume capacity.




**Note:** Check to ensure that the tubing is installed correctly and not moving around in the pump head.

4. Once Tanks are primed, turn off pump.

### 3.3.3 Loading Dialysis Membrane

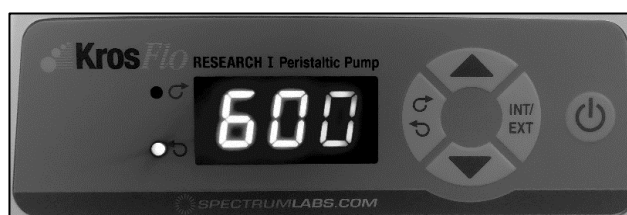
1. Carefully place the sample-filled dialysis membrane into the assembled dialysis tank by using the red hanger closure as a handle and supporting the weight of the bottom with a free hand.
2. Suspend membrane inside the top of the tank using the red hanging closure.


- Optional: for closed systems or series operation, seal all top of the tanks in the series with 6-inch gaskets, end caps, and clamps (PN 163001).
- Set the pump flow rate to per your application (50-200ml/min recommended), press “on” button, , and dialyze.
- For provided #17 tubing, calculate required RPM using the equation below:

**Figure 8. RPM Tubing Equation**

$$RPM = \frac{(flow\ rate\ x\ 6)}{17}$$

- If running in single pass mode, make sure that the feed source volume is sufficient for duration of operation.
- When dialysis is complete, turn off pump, remove caps.
- Carefully remove dialysis membrane from the tanks.



- Reverse the flow direction on the pump, . Continue to run the pump until all fluid is drained from tanks.

## 4. SpectraFlo™ Mobile System

**Table 5. Tank Dimensions - SpectraFlo™ Mobile System**

Part number	163309	163310	163311
Approximate volume	5 L	7 L	10 L
Assembled tank height	68 cm	86 cm	126 cm
Minimum internal diameter	10.5 cm	10.5 cm	10.5 cm

**Table 6. Parts and Materials of Construction - SpectraFlo™ Mobile System**

Part description	Material	Qty
Dialysis tank	Polysulfone	1
6-inch to 1.5-inch conical reducer	Polysulfone	1
6-inch end cap	Polypropylene	1
1.5-inch x ¼ inch hose barb adaptor	Polypropylene	3
1.5-inch x 3/8-inch hose barb adaptor	Polypropylene	1
6-inch gasket	Silicone platinum-cured	2
1.5-inch gasket	Silicone platinum-cured	3
6-inch clamp	Nylon	2
1.5-inch clamp	Nylon	3

### 4.1 Dialysis Tank Assembly

1. Align 1.5-inch x ¼-inch hose barb adaptor and 1.5-inch gasket on the 1.5-inch opening of the conical reducer. Secure connections with a 1.5-inch clamp (hand tighten wingnut).
2. Place dialysis tank upright on stable surface. Place a 6-inch gasket on the top of the dialysis tank with the gasket's outer lip facing downward.
3. Place 6-inch opening of the conical reducer on the dialysis tank making sure it seats firmly over the gasket ridge.
4. Open a 6-inch clamp by first loosening both wingnuts and then pulling the locking wingnut away from the clamp. Secure the clamp around the perimeter of the gasket, conical reducer and dialysis tank by hand tightening firmly—alternatively between wingnuts.
5. Align 1.5-inch x ¼-inch hose barb adaptor and 1.5-inch gasket on the tank's lower inlet port—on the conical reducer side of dialysis tank. Open a 1.5-inch clamp, secure around adaptor and lower inlet (hand tighten wingnut).
6. Repeat step 5 to connect a 1.5-inch x ¼-inch hose barb adaptor to the tank's upper outlet side-port.
7. Set aside remaining gasket, clamp, and 6 in cap. Install once system is ready and dialysis samples are placed into the tanks.
8. Repeat steps 1-7 for all tanks in the series. For the final tank in the series, install the 1.5-inch x ¾-inch hose barb adaptor instead of the 1.5-inch x ¼-inch hose barb adaptor on the tank's upper outlet side-port.

## 4.2 System Assembly

**Table 7. Dialysis Mobile System Components**

Description	4-position cart	6-position cart
Tubing pinch clamps	6	11
X connector	1	2
T connector	2	3
Size #17 Extended Life Tubing	3	3 X 10 feet
Size #73 Extended Life Tubing	1	10 feet
Size #17 PharmaPure® Tubing	1	8 feet
Tank straps	4	6
Dialysis cart	1	1

### 4.2.1 Tank Placement

1. Place cart in an area near buffer feed source, drain and power supply.
2. Lock caster wheels by stepping on black pedal.
3. Optional: Install pump shelf by inserting the hooks at the end of the shelf into the four bottom holes of the cart. Insert at a 45-degree angle and push down firmly until shelf is parallel with the floor and locked in to place
4. Optional: Follow the same procedure for the wet tray using the four top holes of the cart
5. Thread tank strap through each slot in the upper tank support.
6. Place dialysis tank reducer side down on lower support with the side ports facing outward.
7. Wrap strap around the tank and thread the loose end of the strap through the black nylon buckle and pull one of strap holes over the prong of the black nylon buckle.
8. Repeat for all tanks placing the tank with the 1.5 in x 3/8-inch hose barb adaptor in the last position.
9. Place KR1 Peristaltic Pump (PN 163902) on pump shelf (optional) with pump head oriented towards first tank in series.
10. Plug KR1 Peristaltic Pump into the power supply.

### 4.2.2 Installing Drain/Priming Manifold

**Table 8. 4-position Drain/Priming Manifold**

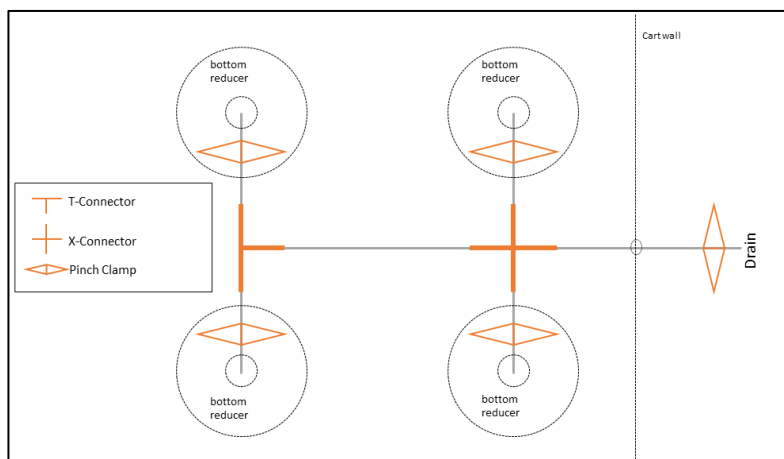
Length	4-position cart	Quantity
Tank to center	8"	4
Center to center	14"	1
To drain/fill	Per customer need	

**Table 9. 6-position Drain/Priming Manifold Tubing Cut List**

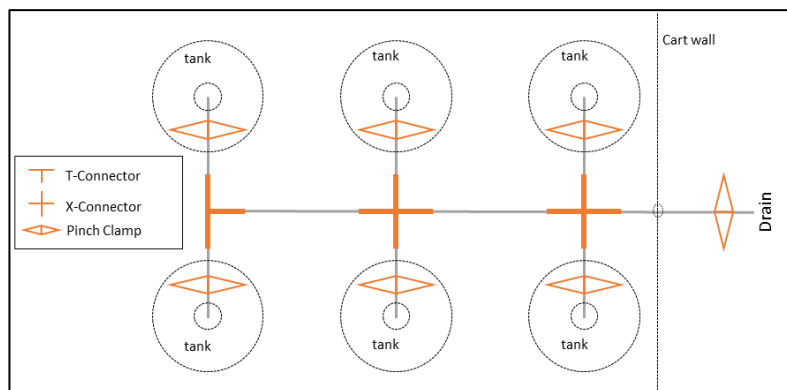
Length	6-position cart	Quantity
Tank to center	8"	6
Center to center	11"	2
To drain/fill	Per customer need	

1. Cut a piece of #17 extended life tubing that is long enough to connect through the pump head to reservoir and to drain. This manifold line will be used for priming and draining the system.
2. Cut Size #17 extended life tubing according to Table 8 or 9.
3. Connect tubing lengths together using T-connector and X-connector per Figure 8 and 9. below.
4. Thread tubing through pinch clamps, as shown. **Close pinch clamps.**
5. Place manifold on the bottom of the cart.
6. Connect each tube to the 1.5-inch x 3/4-inch hose barb adaptor beneath each assembled tank.
7. Thread the manifold line through the hole on the cart wall and then through a pinch clamp and close
8. Coil manifold line and hang on cart tubing hook.

**Figure 9. Fill/Drain Manifolds for 4-position Cart**



**Figure 10. Fill/Drain Manifolds for 6-position Cart**



#### 4.2.3 Connecting Tanks to Mobile System

**Table 10. 4-position SpectraFlo™ Mobile Dialysis System Tubing Cut List**

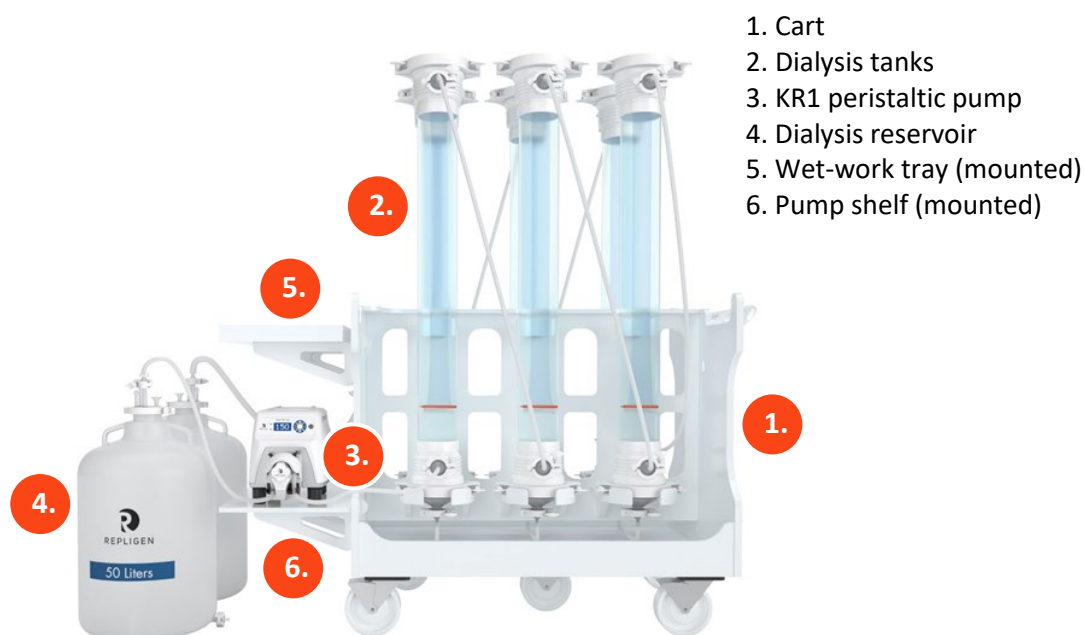
Qty	5 L tank	7 L tank	10 L tank
3	28"	32"	47"
1	37"	42"	56"



**Table 11. 6-position SpectraFlo™ Mobile Dialysis System Tubing Cut List**

Qty	5 L tank	7 L tank	10 L tank
5	26"	31"	46"
1	37"	42"	56"

1. Cut a piece of size #17 PharmaPure® tubing long enough to connect from feed reservoir through KR1 pump head and to the lower inlet of the first tank in the series.
2. Thread one end of the tubing through a pinch clamp and connect tubing to lower inlet port of first tank. **Close pinch clamp.**
3. Cut pieces of Size #17 extended life tubing according to Table 10 or Table 11.
4. Connect one of the short pieces of Size #17 extended life tubing from the first tank's upper outlet port to second tank's lower inlet port.
5. Repeat for all tanks in the series. Use the long piece to connect the tanks on opposite sides of cart.
6. Cut one piece of size #73 extended life tubing long enough to reach drain or back to feed reservoir. Connect one end of the tubing to the upper outlet of the last tank in the series. For Single Pass mode, direct to drain. For recirculation connect tubing back to feed reservoir.

**Figure 11. Fully Assembled SpectraFlo™ Mobile System**

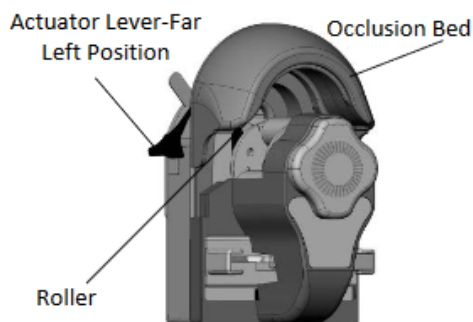
1. Cart
2. Dialysis tanks
3. KR1 peristaltic pump
4. Dialysis reservoir
5. Wet-work tray (mounted)
6. Pump shelf (mounted)

## 4.3 Operating Instructions

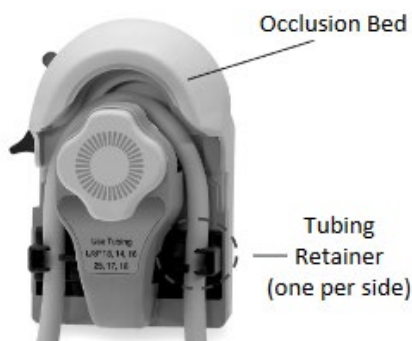
### 4.3.1 General Pump Operation

**Note:** For complete pump instructions, refer to the KR1 peristaltic pump operating instructions available on [www.repligen.com](http://www.repligen.com).

1. To load tubing, open the pump head by moving the actuator lever counterclockwise (left, if pump head is mounted facing down).

**Figure 12. Load Tubing in the Open Pump Head**

2. Insert a loop pump tubing into one open tubing retainer, between the occlusion bed and the rollers and into the other tubing retainer.
3. Position the tubing so that it is firmly centered against the rollers and inside the tubing retainers.

**Figure 13. Closing the Loaded Pump Head**

4. While holding the tubing ends down, move the actuator lever back to the far clockwise (right) position. The pump head will grip the tubing.
5. Make sure int/ext function is set to "int"



#### 4.3.2 Prime the System

1. Connect manifold line to feed reservoir and thread through pump head. Close pump head.
2. **Open all pinch clamps on manifold.**
3. Make sure that flow is set to the correct direction, ↻.
4. Set KR1 Pump to 600 rpm and press the "on" button, ⏻, to fill Tanks to 2/3rd volume capacity.



**Note:** Check to ensure that the tubing is installed correctly and not moving around in the pump head.

5. Once Tanks are primed, turn off pump and **close all pinch clamps on manifold.**
6. Disconnect manifold line from feed reservoir, coil and hang on cart tubing hook.

#### 4.3.3 Loading Dialysis Membrane

1. Open pump head and thread #17 PharmaPure® tubing through the pump head. Connect tubing to feed source and **open pinch clamp.**
2. Carefully place the loaded dialysis membrane in each tank by using the red hanger closure as a handle and supporting the weight of the bottom with the free hand.
3. Suspend membrane inside the top of the tank using the red hanging closure.
4. Seal all top of the tanks in the series with 6-inch gaskets, end caps, and clamps.
5. Reduce the pump flow rate per your application (50-200ml/min recommended) and dialyze.
6. For provided #17 tubing, calculate required RPM using the equation below:

**Figure 14. RPM Tubing Equation**

$$RPM = \frac{(flow\ rate\ x\ 6)}{17}$$

7. If running in single pass mode, make sure that the feed source volume is sufficient for duration of operation.
8. When dialysis is complete, turn off pump, remove caps.
9. Carefully remove dialysis membrane from the tanks.
10. To empty tanks, close pinch clamp near the lower inlet on first tank and remove tubing from pump head.
11. Thread manifold line through pump head and direct to drain. Open all pinch clamps on manifold. Reverse the flow direction on the pump. Continue to run the pump until all fluid is drained from tanks.

## 5. System Care and Use – SpectraFlo™ Dynamic Dialysis Systems

### 5.1 Cleaning/Sanitizing for SpectraFlo™ Systems

The following procedure is recommended for cleaning SpectraFlo™ Systems before and/or after each use. All fluid contact surfaces should also be cleaned prior to the initial system assembly. However, it is incumbent upon the operator to ensure that this cleaning procedure is suitable and the system has been appropriately cleaned for its intended use.

**Table 12. Cleaning Solution Options**

Cleaning solutions	Ingredients
Alcohol solution (for sanitizing)	Alcohol solution (50-70% ethanol or methanol; or 70-90% isopropanol)
Detergent solution (for cleaning)	Dilute lab anionic detergent (e.g. Liquinox)
NaOH (for cleaning and sanitizing)	0.1-0.5N NaOH
Water	Deionized water or water for Injection

#### 5.1.1 Unassembled System Parts

1. Wipe down all non-fluid contact parts with alcohol solution.
2. Soak, flush and/or wipe thoroughly all fluid contact parts and surfaces with preferred cleaning solution.
3. Rinse thoroughly with water.
4. Optional: additional rinse with alcohol solution.
5. Dry parts.
6. After system assembly, flush system with water.
7. Drain rinse water.

#### 5.1.2 Cleaning Fully Assembled System

1. Wipe down all non-fluid contact parts of assembled system with Alcohol solution.
2. Use peristaltic pump to thoroughly flush (1 LPM) the system with preferred cleaning solution from a feed reservoir.
  - a. For single-pass mode, operate system until approximately 0.5 L of cleaning solution is expelled to drain.
  - b. For recirculation mode, recirculate cleaning solution through feed reservoir and tank for 10-20 min.
3. After flushing, drain/empty as much cleaning solution as possible.
4. Optional: If initial flush with detergent or NaOH, an additional flush with alcohol solution.
5. Flush system with water
  - a. For single-pass mode, operate system until approximately 2-5 L of water is expelled to drain.
  - b. For recirculation mode, recirculate water through feed reservoir and tank for 10-20 min. Drain water, and repeat 1 more time.
6. After rinsing, drain/empty as much water as possible (without disassembling flow-path).

### 5.2 Steam Autoclaving Tanks

1. Loosen all sanitary clamps to avoid damaging during the autoclave cycle.
2. Pre-warm the tank to 102° C at 10 psi for 10 minutes.
3. Ramp up the autoclave by increasing pressure approximately 1.5 psi/min for 30 minutes to 121° C

4. Hold the autoclave at 121° C for 50 minutes, not to exceed 124.1° C.
5. Slowly ramp down the temperature of the autoclave by exhaust pressure release of approximately 0.75-1 psi/minute to 104° C.
6. Hold the autoclave at 104° C for at least 20 minutes.
7. Bring the tank to room temperature.
8. Tighten all sanitary clamps prior to use.

### 5.3 System Maintenance

1. Each customer application is different, and it is incumbent upon the customer to develop their own maintenance schedule.
2. After each use, all component should be inspected for general wear.
3. If autoclaving after each use, change all tubing, gaskets and hose barb adaptor at a minimum of every 5 cycles.
4. If you are planning on having a new flow path with each use, change all liquid contact surfaces including tubing, gaskets, hose barb adaptors after every use.
5. If cleaning in place, replace parts as needed depending on application (heat, solvents, time, etc.).