



CLINICALLY PROVEN THERAPY FOR TREATING FLUID OVERLOAD



AQUADEX SMARTFLOW® SYSTEM IS A CLINICALLY PROVEN SOLUTION FOR MANAGING FLUID OVERLOAD

- Simplified form of ultrafiltration that can be prescribed by any physician trained in extracorporeal therapy
- Deliver safe and precise therapy with the ability to adjust the fluid removal rate and volume to meet each patient's clinical need
- Approximately 35 ml of extracorporeal blood volume in our patented blood circuit
- No significant change to electrolyte balance
- Easy set-up and monitoring allowing for a 4:1 nurse to patient ratio
- New Hematocrit and SvO2 features provide clinical insights and may help guide therapy decisions

LOOP DIURETICS¹

to eliminate hypotonic urine

- ⚠ Unpredictable elimination of sodium and water
- ⚠ Development of diuretic resistance
- ⚠ Risk of hypokalemia (low potassium levels) and hypomagnesemia (low magnesium levels)
- ⚠ Insufficient symptom relief: Persistent congestion, failure to lower sodium levels
- ⚠ Worsening heart failure, increased mortality after discharge, increase in re-hospitalization rates

ULTRAFILTRATION¹

to remove isotonic plasma water

- ✓ Predictable removal of sodium and fluids
- ✓ Restoration of diuretic responsiveness
- ✓ No change in electrolytes, particularly potassium and magnesium
- ✓ More effective decongestion and fewer heart failure events compared to loop diuretics
- ✓ Improved glomerular filtration rate
- ✓ Efficacy, and improved outcomes

Aquadex SmartFlow System

Simplified approach to ultrafiltration for the removal of isotonic fluid.



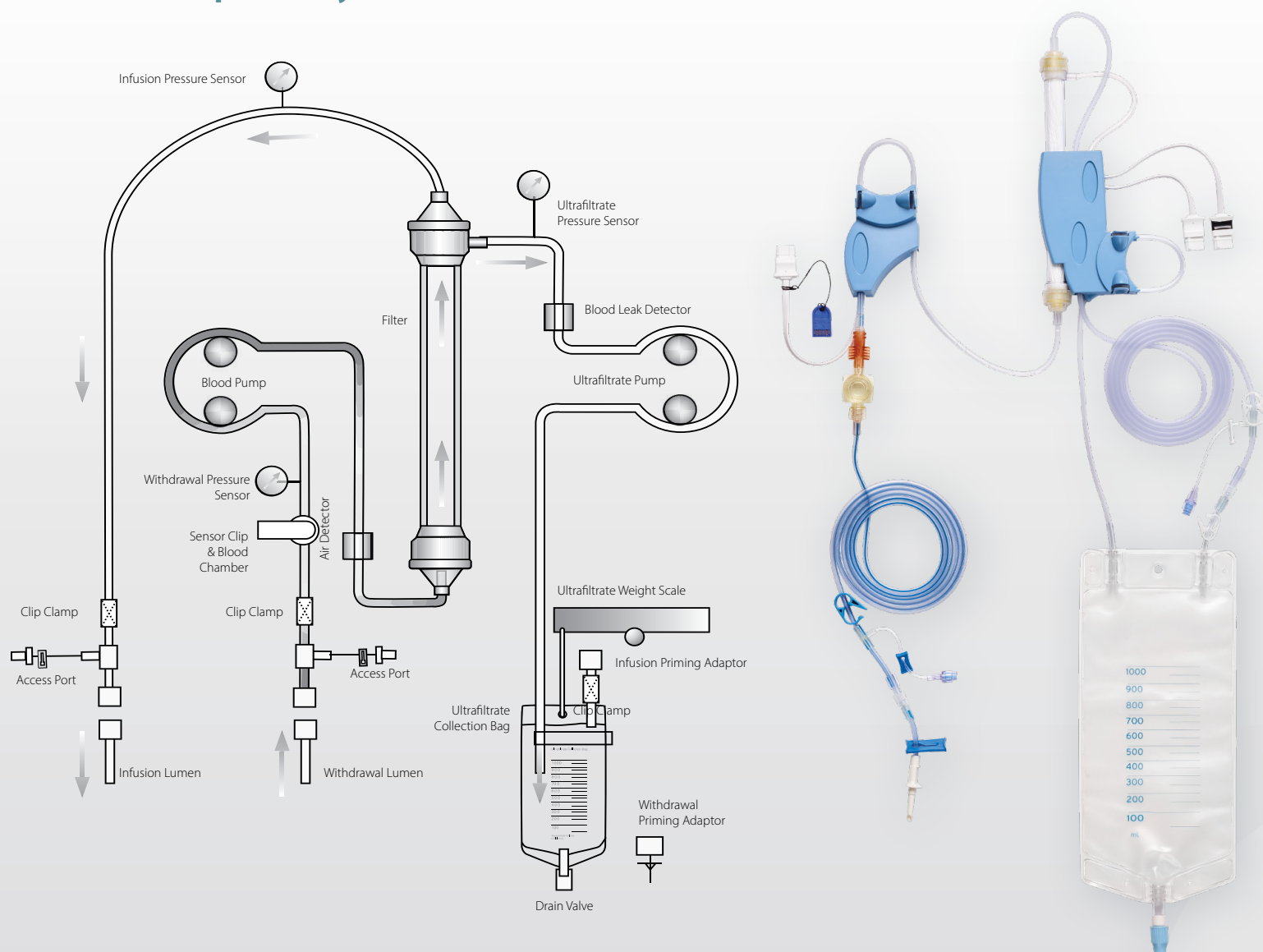
Easy to Operate, Safe to Use

- Controllable fluid reduction and individualized patient fluid removal
- Perform therapy through peripheral or central venous access
- Highly automated with only one setting required to begin
- Hematocrit sensor provides real time measurement of % blood volume change
- User defined hematocrit limit
- SvO2 monitoring provides insights into tissue oxygen delivery

Blood Circuit Set

Uniquely designed for the removal of isotonic fluid with a low extracorporeal blood volume of approximately 35 ml.

Aquadex System Fluid Path



Fully Integrated Blood Circuit Set

- Patented filter designed to reduce clotting
- Air and blood leak detectors to ensure correct operation
- Needleless access ports for aspiration or infusion of fluids
- Filter Resistance Alert prompts action to help extend circuit life

RX ONLY

INDICATION: The Aquadex SmartFlow System is indicated for: Continuous ultrafiltration therapy for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kilograms or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a healthcare provider, within an outpatient or inpatient clinical setting, under physician prescription, both of whom having received training in extracorporeal therapies.

ORDERING DETAILS

MODEL		PRODUCT DESCRIPTION	QUANTITY
English (US)	120100	Aquadex SmartFlow Console	1
English (UK)	120200		
French	120300		
German	120400		
Portuguese	120500		
Italian	120600		
Spanish	120700		
420000		Aquadex SmartFlow Cart/Stand	1
114156		Aquadex Blood Set with Hematocrit Monitoring	1 Box of 5
114153		Coiled Dual Lumen Catheter (Not shown)	1 Box of 5
115463		Coiled Dual Lumen Catheter with Insertion Kit (Not shown)	1 Box of 5 Each

Blood Flow Rate

Run and Manual modes operational range: 10 to 40 ml/min, automatically adjusted by the Aquadex SmartFlow. User settings: 10, 15, 20, 25, 30, 35, 40 ml/min. Reversals are at half the set blood flow.

Fluid Removal Rate

UF RATE ultrafiltrate flow:

Range: 0 to 500 ml/h.

User settings: 0 through 500 ml/h in 10 ml/h increments.

Accuracy: \pm 10% of setting.

Source: ^[1] Costanzo MR, et al. J Am Coll Cardiol. 2017;69(19):2428-2445.

Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

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