NovaFlux

ClearFlux™

Dialyzer Regeneration System

"...recovers the total cell volume and the clearance of small and middle molecules of the dialyzers to levels that are approximately equivalent to those of new dialyzers."

FDA Cleared 510(k) # K091360

Indications For Use Per 510(k) # K091360:

The ClearFlux™ Dialyzer Reprocessing System is indicated for the reprocessing of polysulfone-based high-flux dialyzers for reuse, for preprocessing the dialyzers prior to their assignment to patients for first use, and for tracking the reprocessed dialyzer for use only by the patient to whom the dialyzer was initially assigned.

The steps used in reprocessing hemodialyzers with the ClearFlux™ System include:
(1) **Pre-cleaning**
(2) **Cleaning**
(3) **Rinsing**
(4) **Volume and Leak Testing** and
(5) **Disinfecting the Dialyzers** in accordance with the "AAMI Recommended Practice for Reuse of Hemodialyzers."

The ClearFlux™ System performs the patented *in-situ* two-phase cleaning cycle during reprocessing, which recovers the total cell volume and the clearance of small and middle molecules of the dialyzers to levels that are approximately equivalent to those of new dialyzers. The ClearFlux™ Dialyzer Reprocessing System is also indicated for performing record keeping of the dialyzer processing operation. The ClearFlux™ Dialyzer Reprocessing System is indicated to be used only with the ClearFlux Formula™ cleaning solution.

The Full ClearFlux™ System Components

ClearFlux™ Machine
Dialyzer Reprocessing Machine

System Computer
Ability to support up to 12 stations

Barcode Scanner
Perfect patient and dialyzer tracking

CRMS
ClearFlux™ Records Management Software

Air Compressor
Needed for ClearFlux™ operation

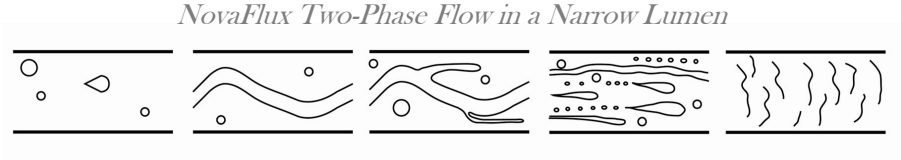
Label Printer
Prints labels for dialyzers, technicians and patients

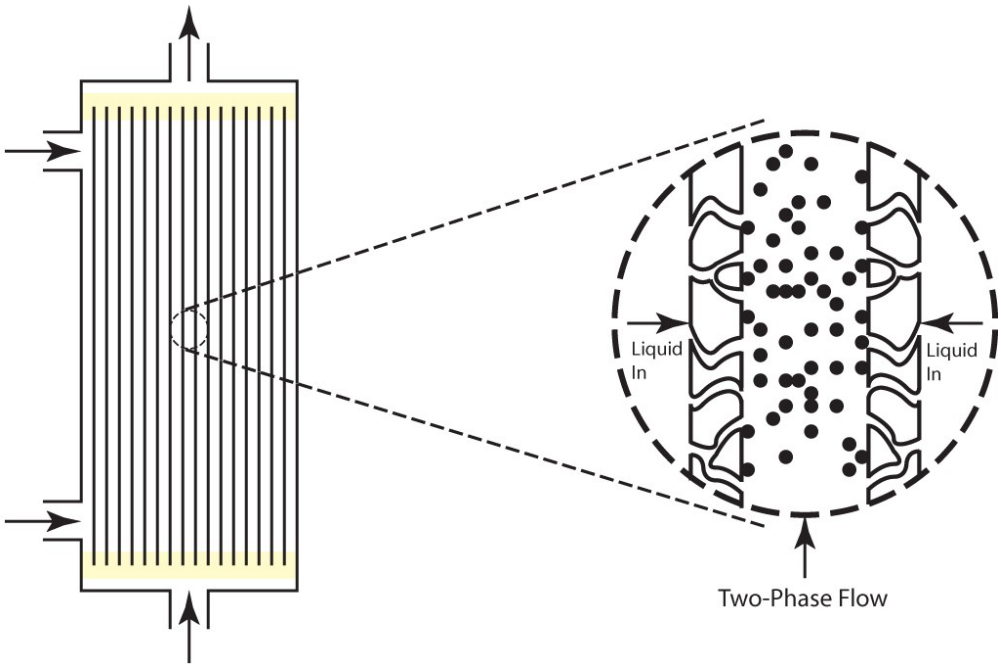
Dialyzer Regeneration Technology
No Manual Intervention
Sinkless Operation

NovaFlux integrated its proprietary Two-Phase Flow (TPF) technology into the design of the ClearFlux™. The ClearFlux™ incorporates intelligent operating and monitoring technologies, and performs validated cleaning and rinsing cycles using the Company's platform technology. The TPF (liquid and gas) completely removes biological contaminants and highly adhering substances from narrow passageways.

Dialyzer hollow fibers are more difficult to clean than lumens with impermeable solid surfaces. This is because the membrane pore structure of dialyzer hollow fibers must be cleaned as well, at the same time. Membrane pores are often cleaned by applying a reverse pressure gradient across the membrane wall such that precipitated proteins are pushed out into the lumen of fibers. The ClearFlux™ cleans membrane pores by backflushing, which is reverse ultrafiltration of a pressurized cleaning liquid from the dialysate side of the dialyzer, while simultaneously supplying HEPA-filtered air to the blood side (lumen) of the dialyzer, thus generating the two-phase mixture *in situ*, as depicted in the Figure below. This mode of *in situ* two-phase cleaning recovers the TCV and clearance of small and middle molecules, and at the same time eliminates the need for manual pre-cleaning. Accordingly, the ClearFlux™ standardizes "all" dialyzer regeneration processes, and eliminates manual intervention.

NovaFlux Two-Phase Flow in a Narrow Lumen



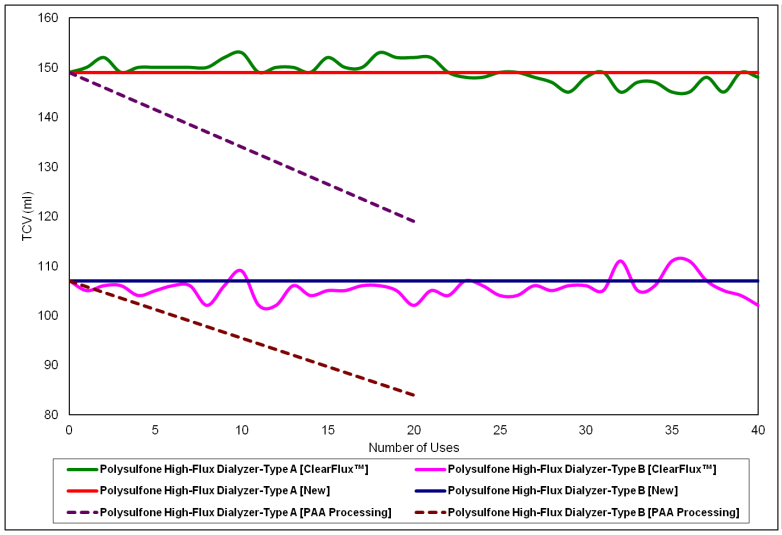


A schematic showing *in-situ* formation of the two-phase flow during dialyzer cleaning. The liquid flows from the dialysate side to the lumen side by backfiltration and is mixed with air to form the two-phase mixture in the fiber lumens. This process cleans the dialyzer membrane and headers at the same time.

We don't reuse, we recover...

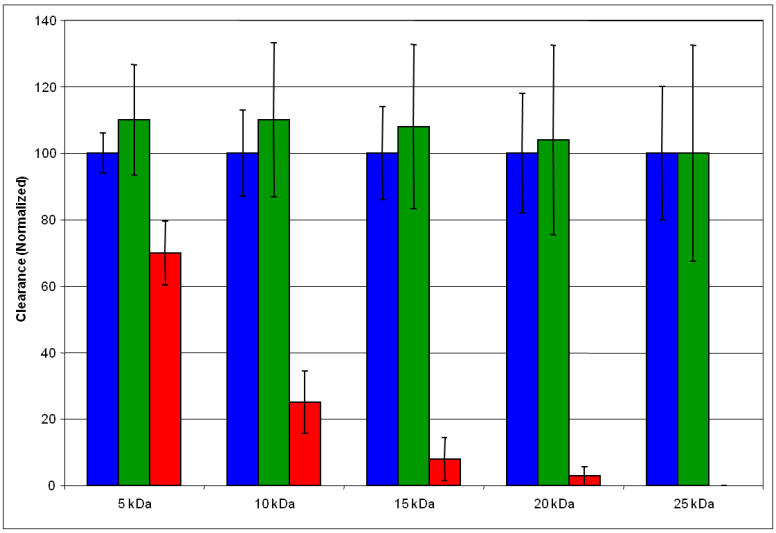
The ClearFlux™ fully restores dialyzer function to approximately its baseline value for each and every reuse, and achieves an average of 40 cycles per dialyzer. Unlike the existing devices, there is virtually no loss in dialyzer performance for up to 40 reuses with the ClearFlux™. Accordingly, a patient can be treated with the largest high-flux dialyzer possible, and can thus receive the highest possible dialysis dose as defined by Kt/V. Moreover, the middle molecules clearance of the dialyzer is maintained at approximately the optimal level of that of a new dialyzer for each treatment(see FDA 510(k) cleared label). This is highly desirable since improving the clearance of middle molecules has been linked to a reduction in cardiovascular disease and mortality.

TCV Performance Over 40 Cycles*
(New Dialyzer vs. ClearFlux™ Processed Dialyzer vs. Conventional PAA Processed Dialyzer)



*Data generated using simulated dialysis according to FDA and ISO recommended methods.

Recovery of Middle Molecules Clearance*
(New Dialyzer vs. ClearFlux™ Processed Patient Dialyzers vs. Current PAA Processed Dialyzers)



*Typical results of patient dialyzers using the ClearFlux™ compared to polysulfone high-flux dialyzers using dextran molecular probes. Clearance data shows that the ClearFlux™ processed dialyzers are approximately equivalent to new dialyzers within experimental variances of the method.

The ClearFlux™ recovers TCV for each treatment to a level approximately equivalent to that of a new dialyzer. The dashed line depicts TCV decline of the dialyzer processed with the current peracetic acid system.

The ClearFlux™ recovers middle molecules clearance for each treatment to a level approximately equivalent to that of a new dialyzer. See the significant decline in middle molecules clearance of dialyzers processed with the current peracetic acid system.

Features

Performance

- Fully Automated—No manual Pre-Cleaning
- 40 Treatments per Dialyzer (average)
- Maintains Total Cell Volume (TCV) (See FDA 510(k) Cleared Label)
- Recovers and maintains middle molecules clearance including Beta-2-microglobulin (See FDA 510(k) Cleared Label)
- 1 Dialyzer per Quarter per Patient

Cost Savings

- 40% Savings vs. high-flux disposable dialyzers
- 50% Labor reduction
- 66% Reduction in Peracetic Acid use
- 70% Reduction in RO water costs
- Ability to batch reprocess dialyzers
- Saving of 152 dialyzers per year vs. high-flux disposable dialyzers

User Friendly

- Reliable manufacturing and design
- Easy-to-use software and patient tracking
- Clear and defined operations
- Streamlined processing operations
- 24/7 stand-by technical support

Green Technology

- Provides long-term stability
- 97.5% waste reduction vs. high-flux disposable dialyzers
- Employs environmentally-safe reprocessing chemistry

Specifications

Equipment Specifications

Dimensions	Height: 20 inches Depth: 32 inches Width: 14 inches Weight: 50-55 pounds
Electrical Requirements	Electrical Supply: 50/60 Hz Max Consumption: 2200 watts Amperage: 15amps Chassis Current Leakage: <350 µa
System Computer Requirements	1GHz processor speed 256MB of memory 20GB hard disk drive Monitor (Size may vary) 4 USB ports 1 RS232 serial port 1 10MB/S Ethernet port
Water Requirements	Pressure: 30-70psi Quality: AAMI Water
Air Requirements	Pressure: 30-70psi Quality: HEPA Filter
Drain Requirements	Max. drainage: 4000 ml/min water Drain Capacity: 10 liters of water
Environmental Limits	Ambient Temp. Range: 15°C - 30°C (60°F-85°F) Relative Humidity: 5% - 95%

"It's the closest thing you can get to preparing the perfect dialyzer over and over..."
-Dr. M. Labib, Co-Inventor

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