iDP Controls Aggressive Media for Dialyzer Reprocessing

Kidney Dialysis | Life Science Group | Engineered Solutions

MEDICAL | SIC:3841

THE CUSTOMER'S PRODUCT

The customer had developed an improved reprocessing machine to restore dialyzer function between treatments in hemodialysis. This machine is a major advancement as it streamlines clinical operations and replaces outdated processes. It is fully automated, does not require pre-cleaning, and extends dialyzer life up to 40 treatments.

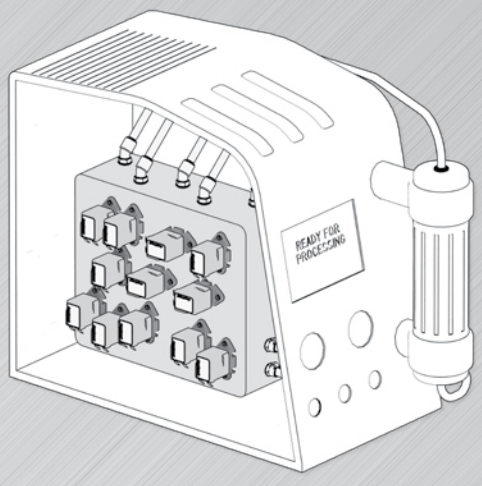
The machine cleans the dialyzer to near baseline performance for each reuse. It's proven to maintain optimal small and middle-molecule clearance for ideal treatment.

THE PROBLEM

- The machine's original valve and manifold design resulted in system leakage, unsatisfactory performance relating to handling the aggressive media and temperature, and unreliable critical disinfectant cycles.
- An aggressive disinfection cycle used a solution of water, acetic acid and other proprietary aggressive agents at temperatures higher than 90°C (194°F).
- Consequently, the customer was unable to enter its equipment in the qualifications stage of clinical trials.

REQUIREMENTS

- Inert design that incorporates FDA-approved materials for resistance to bodily fluids, hazardous liquids and aggressive cleaning agents.
- Zero leakage
- A minimum of four SLPM flow for various liquids at a pressure of 40 PSI.
- Quiet operation for patient comfort.
- Compact design while maintaining performance and reliability at elevated temperatures.
- Encapsulated coil to protect against outside moisture.



Dialyzer Reprocessing Machine

351 iDP Valve

THE CHALLENGE

The complexity of the device requires 22 valves for media control, but in a small space. This created an abundance of leak points that were problematic for inline valves and traditional barbed or push-to-connect valve fittings.

THE PROCESS

Engineer to Engineer Collaboration

- Understand current problems and issues.
- Understand current interface and control logic.
- Understand physical parameters and constraints of the existing machine.
- Develop a series of prototypes to dial in valves to the exact performance required.

Develop Production Readiness

- Initial pre-production valves identified a difference in Humphrey test and machine performance.
- A second pre-production quantity corrected the inconsistency and performance.
- Machine was qualified with FDA and released for production.

SCAN

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THE CONCEPT

The manifold mount design, in contrast to a tube-barb valve design, reduced assembly time, eliminated potential leak paths and miniaturized the assembly.

HUMPHREY ENGINEERED SOLUTION

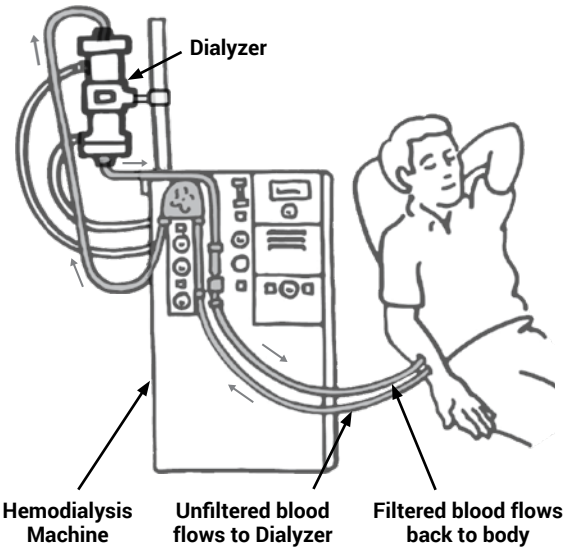
- Humphrey's industry-proven 350 iDP valve was purposely engineered to control aggressive media in harsh environments while maintaining critical performance and reliability.
- Using the 350 iDP valve as a foundation, Humphrey redesigned the liquid interface and reduced the overall valve profile. The size reduction maintained proven performance and accommodated the need for more valves in a small space. The revised design provided ideal valve integration, reduced leak points, improved reliability and allowed total media control.
- This new valve became Humphrey Products' 351 iDP valve.

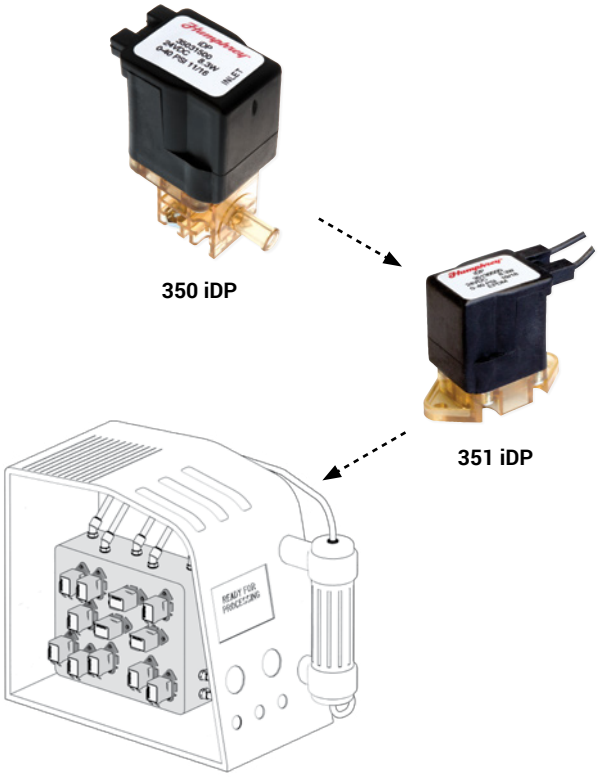
SOLUTION FEATURES

- New compact footprint allowing more valves in a smaller area.
- Soft seat diaphragm poppet design results in zero leakage.
- Design features allow for aggressive media use with no compromise in performance.
- A valve rated for 4 SLPM at working pressure of 40 PSI and working temperature of 90°C.
- Robust design allowing continuous duty for long periods reducing the PM cycle.

RESULTS

- Improved chemical compatibility.
- Improved equipment performance and lifespan.
- Equipment passed clinical trials and received FDA approval.





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