Suppliers Keep Pace with Changing Dialysis Needs and Fast-Moving Regulatory Environment

With global populations expanding and aging, the demand for advanced medical therapies like dialysis continues to grow, as do patients' expectations for convenient access to the procedure, shorter dialysis time frames, lower infection risks, and better medical outcomes. Dialysis equipment builders have steadily met these expectations, building hospital-quality hemodialysis machines that shorten clinic-based hemodialysis sessions from 12 hours to 4 hours and make home-based "in your sleep" peritoneal dialysis not only a reality but a preferred option.

But every advance in making dialysis technology safer, faster, more portable, and more effective for the patient has been hard-won. Dialysis equipment builders and their suppliers must not only manage the medical side of the process — a precise blood filtration and purification process made possible by physics — but also implement the technology through components and products that meet ever-higher regulatory standards while simultaneously improving process consistency, reliability and cost-effectiveness.

The European Union's (EU) new Medical Device Regulation (MDR) went into effect in May 2021. To meet stringent requirements, not only of Europe's MDR but also those of the U.S. Food and Drug Administration (FDA) and other global bodies, dialysis equipment manufacturers must rely on fluid-system automation and control suppliers that can help them meet these regulatory requirements, such as strict change controls, and offer the range of necessary valves and fluid controls.

Hemodialysis Challenges

Because the fluid pathways of hemodialysis machines directly handle human blood and related bodily fluids, MDR and FDA rules require every wetted surface of these pathways to be made of thoroughly tested biocompatible materials — subject to source-to-end-use change controls to ensure their consistency and purity. In addition, any mechanical flow-control components, such as pumps or valves, must incorporate biocompatible materials while ensuring complete isolation — a hermetic separation between their power/control/actuation mechanisms and the fluid path that carries the blood being purified. This isolation prevents the risk of contamination due to metallic particles or external pathogens.

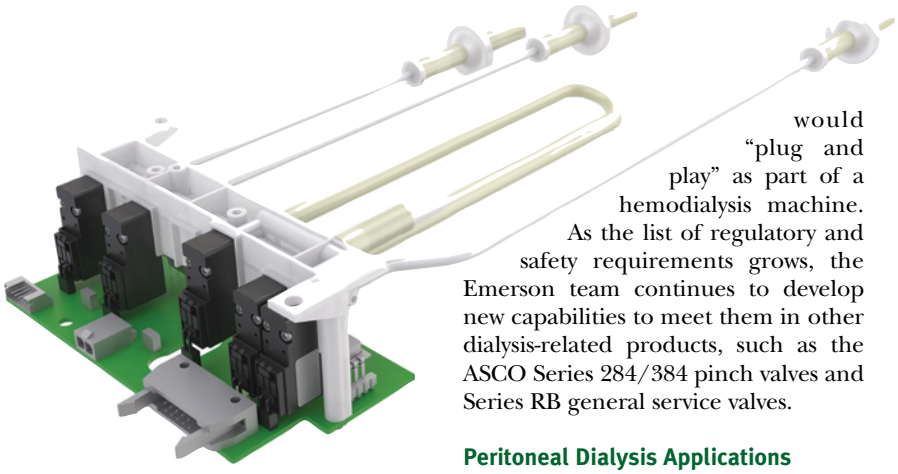
The ASCO Series 283/383 miniature fluid isolation valves are often used in dialysis equipment because they provide complete, hermetic isolation of the fluid path to reduce the risk of contamination. (Credit: Emerson)

Other key requirements include superior reliability and configurability. Reliability is essential since clinic-based hemodialysis machines are subject to constant use. In this context, improved reliability means flow-control valves that can realistically deliver life of 5 million to 6 million cycles over a three- to four-year period of use. Another requirement is configurability, since a large hemodialysis machine can require 20 or 30 valves, enough to run three or four identical dialysis/filtration circuits simultaneously.

Configurability means anything from modifying individual valve bodies to combining multiple valve flow paths — and associated actuators/controls/printed circuit boards (PCBs) — into compact manifolds that meet dimensional requirements. It can also mean modifications to controls, wire leads and connections, or a valve's noise output, since dialysis valves are typically actuated using pneumatics and must operate in a relatively quiet hospital or clinical environment, or even while a patient sleeps at home.

Only after a valve meets all of the above requirements — regulatory, materials, isolation, design, manufacturability, and assembly — does its actual function come into play. Within the hemodialysis process, the pressure and flow of fluids must be carefully and consistently managed through a series of dialyzing circuits. These circuits expose a volume of blood to physical filtration and a process of diffusion/osmosis, where wastes are transferred from blood to a dialysate fluid.

For analytical and medical specialists, the process of making better dialysis valves and ensuring their continued regulatory compliance never ends. Yet beyond engineering, quality, and regulatory requirements, these valves must also meet customer requirements: performance, configuration, flow rate, reliability, and ease of installation. For example, the ASCO 283/383 Series miniature solenoid valves met requirements for durability and biocompatibility, with valve bodies and fluid paths made of polyetherimide (PEI). However, a prospective customer and dialysis equipment builder asked Emerson to modify



This modular valve assembly for a hemodialysis machine contains multiple ASCO Series 188 general service valves. The base is a printed circuit board, complete with all electrical and communications connections and ready to install. (Credit: Emerson)

the valve to increase flow rates at required pressures (3–4 bars) and to provide a special coil with flying leads that would eliminate a manufacturing step and reduce product assembly costs.

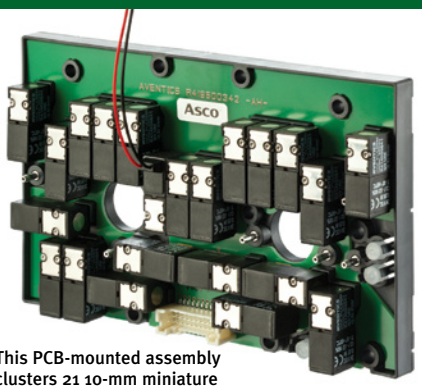
In other situations, customers might ask for a manifold assembly, which links a series of valves, such as ASCO Series 188 general service valves, into a single assembly mounted on a PCB along with customer-specified tubing. One such manifold design was produced for a dialysis equipment builder that sought a high-flow, low-leakage solution that would "plug and play" as part of a hemodialysis machine. As the list of regulatory and safety requirements grows, the Emerson team continues to develop new capabilities to meet them in other dialysis-related products, such as the ASCO Series 284/384 pinch valves and Series RB general service valves.

Peritoneal Dialysis Applications

In peritoneal dialysis, the blood is cleansed within the body, using the lining of the peritoneal cavity both as a filtration mechanism and as a container for dialyzing fluid. Because the procedure can be done at home — sometimes even while a patient sleeps — the latest ambulatory peritoneal dialysis (APD) machines feature compact design, lightweight componentry, low power consumption, and low noise. However, the fluid components in these machines are subject to the same biocompatibility and isolation requirements as hemodialysis equipment since the fluids they carry are in direct contact with the human body.

To simplify manufacturability of APD equipment while meeting the latest MDR and FDA requirements, Emerson often

In hemodialysis, human blood is filtered and cleansed outside the body using a dialysis machine, then returned to the patient. (Credit: iStock/saengsuriya13)



This PCB-mounted assembly clusters 21 10-mm miniature general-purpose valves, which together regulate the input and output of dialysate fluid used in peritoneal dialysis equipment. This ultracompact assembly reflects the importance of lower weight, cost, and power consumption in portable machines at home. (Credit: Emerson)

provides equipment builders with modular, multivalve manifolds or assemblies. Similar to those mentioned earlier, the manifolds or assemblies may be built atop a compact PCB that incorporates valve-mounted pneumatic connections, data links, and multi-pin electrical connectors.

In one case, a PCB-based modular assembly built to hold 21 modified 10 mm miniature general-purpose valves offered two key benefits for a maker of APD machines. First, the pneumatically actuated assembly is lightweight and easy to install yet fits within the tight confines of a tabletop APD machine. Second, and more important, the manifold functions reliably for patients by precisely managing the inflow and removal of dialysate within the peritoneal cavity, maintaining the fluid levels and pressures essential for an optimal dialysis process.

Conclusion

Through decades of effort, medical professionals, dialysis equipment makers, and equipment suppliers have collaborated amid the stringent requirements of regulators to develop and deliver newer, safer and more effective dialysis treatments, not only for clinics but also for at-home settings. With longer lifespans and aging populations worldwide, the need for and importance of dialysis technology will only grow, creating new treatment opportunities and technical challenges in the years ahead.

This article was written by Luca Raguzzi, Business Development Manager for ASCO Analytical and Medical at Emerson, St. Louis, MO. For more information, visit ***http://info.hotims.com/79419-343****.*