A Fluid Process

A wave of new and modified flow technologies has helped to create effective solutions for manufacturers of medical devices. However, the maximum benefit of these advances can only be gained by working alongside an expert provider of fluidic technology from the early design stages, says Sherea Lizaso, Medical Marketing Manager for Gems Sensors & Controls.

The control of fluid flow – both gas and liquid – forms an essential part of many different types of medical equipment, from boiler control on steam sterilisers and reagent dispensing in *in vitro* diagnostic equipment, to bulk delivery of gases or precise gas delivery in products such as ventilators.

Increasingly, the drive is towards reduction in the size and weight of equipment, while at the same time increasing performance and reliability. For manufacturers, however, these demands create a dichotomy; for example, reducing size can have a significant effect on flow rate and dynamics, while component integration can lead to an increase in complexity and potential failure rates.

However, a wave of new and modified flow technologies, in conjunction with a fresh approach to equipment design, has helped to create effective solutions. Specific examples of product development illustrate this; for example a recent redesign of flow valves and manifolds on a transport ventilator has helped to reduce space requirements by 40%.

A major challenge for the providers of flow solutions for medical devices is to supply laboratories, hospitals and physicians with these increasingly complex yet compact systems while managing cost both internally and for customers. This has driven manufacturers to develop new design and production methods that deliver on all fronts to the benefit of both manufacturer and end user. For example, a smaller unit footprint represents a market opportunity for a manufacturer as it will be a popular choice for many commercial laboratories; these businesses are often measured by revenue per square foot, and technicians will therefore be inclined to choose more compact instruments when specifying equipment. Small, portable devices will also be preferred purchases for emergency medical services where equipment size is a key factor.

Size can be effectively reduced by consolidating components that are typically separate constituent parts into a single functional unit. This was recently proved in collaboration with a producer of respiratory equipment that wanted to offer a compact transport ventilator. When working on the gas mixing system for the ventilator, which controls the concentration of oxygen and room air that is delivered to the patient, the challenge was to reduce the physical size and power consumption of the blending system while still maintaining requisite flow parameters to comfortably manage oxygen delivery for patients ranging from neonates to adults.

The necessary size reduction was achieved by challenging the design of the existing gas blender. For instance, the existing system relied on needle valves that had to be manually adjusted to set the gas flow to a precise range; in contrast, the redesign of the system employs precision orifices that are pressed into the manifold and are controlled externally. The need to access valves was thus eliminated and the amount of space required to house the manifold was significantly reduced. This solution has the added benefits of decreasing the total number of parts and eliminating labour-intensive calibration. To reduce the size further, further functions were taken that had been located externally and relocated inside the manifold. Specifically, the nebuliser block (used to moisturise the gas mixture) and temperature sensor were placed within the body of the manifold block. With access constraints eliminated, the overall footprint of the device was reduced by 40%.

The success of this project was the result of carefully applied expertise and, though the solution may appear to be simple, this impression is deceptive. Reducing the physical size of equipment while still maintaining requisite performance is a difficult task and can introduce complications of its own, which is why it is so important for specialist technicians to collaborate in the early design stages. For example, where some equipment manufacturers have opted to produce smaller renal dialysis units without entering into an appropriate period of consultation with expert technologists, the benefit of gaining a small degree of added floor space around the unit has been offset by the complications this has introduced during maintenance. The optimisation of medical instruments and equipment always needs to strike the right balance between issues such as size and ease of maintenance, and it is the capability of component and equipment manufacturers to meet challenges such as this that ultimately wins the confidence of healthcare technicians and provides secure, reliable service for patients.

A business benefit of working with a specialist provider of fluidic solutions is that it frees up valuable time for staff who can then focus solely on maximising the performance of proprietary components or systems, rather than diluting their priorities with non-core technology that is not their forte. In small companies, where cash flow is especially critical, money can be saved by working with an external fluidics partner because although this will add a cost to the project it is nevertheless more cost-effective than employing permanent staff. A further benefit is that the cutting-edge expertise of a specialist partner is more likely to deliver an innovative solution to product development challenges and to do so with greater speed. Faster development will, in turn, mean a more efficient, focussed production process that achieves the best results and satisfies the specific needs of the marketplace. Design of the fluidics component can proceed in parallel with other system functions, enabling designers and engineers to focus on the development of their specialist area while sharing feedback with other teams. The process can result in the fluidics specialist team delivering a single, fully-constructed subassembly that is tested and ready, and after the product has been built the fluidics team can provide an expert source of support if performance issues arise.

Clearly, the key to a successful design and engineering project in this field is to involve a fluidics expert early in the development process. This not only speeds development but prevents wastage of time and resources at the end of a less collaborative design process when awkward and expensive changes can be required. By understanding the limitations and potential of components at the earliest stages, the most effective design can be achieved and any compulsory regulatory review, testing or validation that may necessitate modification can be considered and prepared for. Without an early consultation, project costs can significantly escalate; it is not uncommon, for example, that an OEM will approach a contract fluidics firm with a predefined specification and find that incompatibilities between the fluidics requirements and the overall product specification require an expensive and time-consuming exploratory pre-development phase.

In summary, involving a fluidics design partner early allows design requirements to be discussed as the piece of equipment is being created, enabling many potential problems to be seen and sidestepped early on in the design process. This of course requires the free sharing of information, and naturally some parties are reluctant to provide such information to an external source, even in the course of progress. The best way to minimise concern here is to enlist the services of a partner that is equally transparent and regularly engages in consultation and knowledge-sharing with manufacturers. When all parties do share information and work closely together, the results are typically impressive.

The technological expertise offered by the designers and developers of today's sensors offers great advantages to OEMs in the construction of custom, engineered fluid systems and, while personal attention and technical support is available to produce bespoke systems to customers' individual requirements, it is also true to say that, in many cases, sensor manufacturers have now considered so many problems that they may already have a product solution available off the shelf, saving further time and money. For example, the performance of dialysis machines, which provide a critical service to patients who have lost kidney function by purifying the blood and preventing overhydration, has been streamlined via the use of advanced flow sensors. Owing to the extremely high temperatures required during sterilisation cycles, the slow reaction times of some sensors within these machines has triggered equipment shutdown, an often unnecessary safety measure that has brought inconvenience, delay and disappointment to waiting patients. This problem has now been addressed by the designers and engineers of flow sensors, resulting in the manufacture of ultra-compact flow switches that are not adversely affected by high temperatures. These sensors are equipped with a magnetic piston that is displaced by liquid flow to magnetically actuate a hermetically-sealed reed switch isolated within the unit.

As we have seen, fluids play a role in many medical devices. From precision instruments such as *in vitro* diagnostic systems, medical lasers, drug-infusion pumps or ventilators, to equipment such as steam sterilisers or systems for bulk delivery of gases that require large-scale fluid transfer, fluid management is critical wherever a liquid or gas needs to be measured, monitored or controlled. Among these devices there is a wide range of fluid-management needs, each with its own set of functional requirements. The concerted, consistent, dedicated effort of market-leading sensor designers to continually consult with clients to enhance and improve processes is bringing clear and measurable results to medical science, results that reduce patient discomfort and stress and enable more efficient and successful healthcare.

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