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Fluid Handling in Medical Device Design

Issues and Challenges

Fluid Handling in Medical Device Design: Issues and Challenges

The proliferation of advanced medical devices and diagnostic instruments continues to accelerate. Laboratories, hospitals and physicians are demanding a growing array of increasingly complex yet smaller, faster and more reliable systems. At the same time cost pressures on both original equipment manufacturers (OEM) and end-users continue to grow. To meet these demands, device manufacturers must increasingly find new ways to innovate design and production, while improving efficiency of resource utilization.

Fluids play a role in most medical devices. Wherever a liquid or gas needs to be measured, monitored or controlled, fluid handling is critical. This includes such diverse operations as boiler control on steam sterilizers, reagent dispensing in in-vitro diagnostic equipment, and bulk delivery of gases in hospitals. Fluid handling also plays a role in applications such as cooling of medical lasers and drug delivery in infusion pumps, as well as precise gas delivery in products such as ventilators. Among these devices, there is a range of fluid management needs, such as liquid monitoring, mixing and dispensing, wash systems, and waste control, each with its own unique functional properties.

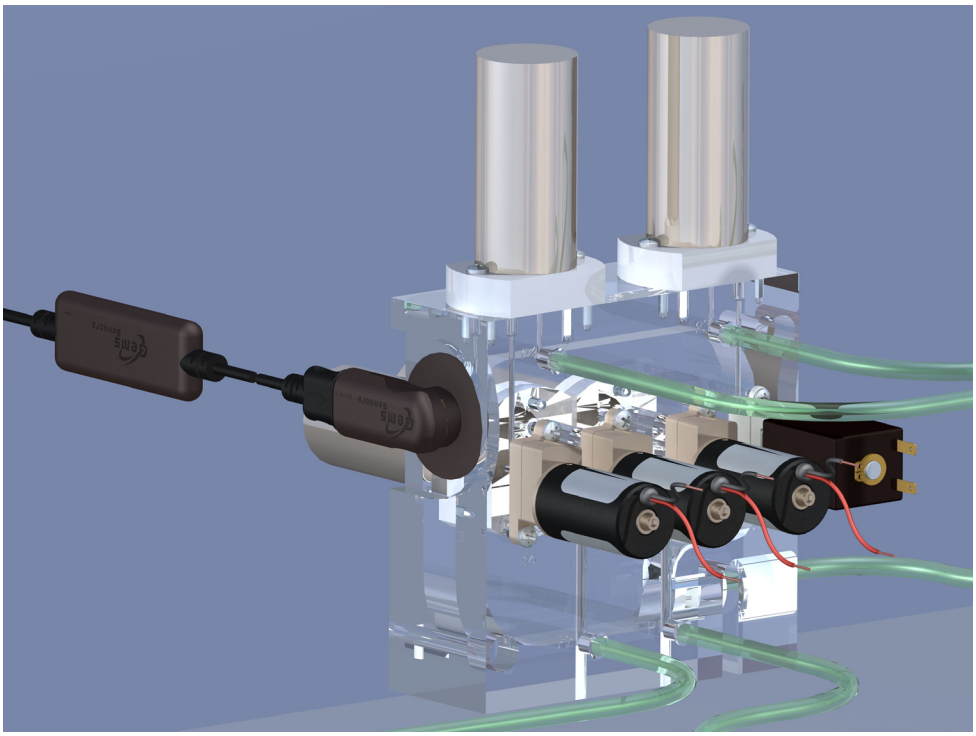
The field of fluidics may broadly be divided into macro- and micro-applications. The former encompasses situations where moderate or bulk quantities of material must be moved through an instrument, such as tank filling or waste disposal; the latter applies to applications that require delivery of small, precise quantities. Fluidics, especially macrofluidics, often represents a necessary but non-core function in medical device design; that is, it falls outside of a company's proprietary expertise. While internal engineering staff is highly adept at driving an OEM's core technology, they may not have the in-depth knowledge or the time required to develop ancillary systems. Consequently, when an application requires the inclusion of fluid management, OEMs may be best served by engaging an external engineering resource with specialized expertise in this field.

This white paper will review key challenges and emerging trends in fluidics design, and will explore considerations for achieving the best results when working with contract design and manufacturing firms.

Challenge 1: Consolidate and Simplify

The current trend in medical devices and equipment is towards ever-smaller products. In fact, reducing instrument size or complexity can create significant new market opportunities. First, a smaller footprint may provide a competitive edge for an OEM. Commercial laboratories, for example, are often measured by revenue per square foot, and will, therefore, choose more compact instruments when making buying decisions. Second, reducing a device's size and weight can open new market segments. The smaller the device, the more easily it can be transported for use in non-traditional environments

such as disaster zones or field emergency medical services. Finally, smaller size can increase the user base. For example, diagnostic equipment reduced to tabletop size can be sold to physician offices unable to house large-scale systems.



Gems Medical Sciences redesigned the manifold of a transport ventilator, reducing space requirements by 40%.

The challenges of consolidating and simplifying systems are myriad. Flow management becomes more critical as volumes decrease. Tolerance variances likewise become more critical. In addition, a device must consume less energy and resources, especially if it is to be used in applications where portability is important.

Reduction in size and weight can be achieved in numerous ways. One approach is to consolidate components by combining multiple constituent parts into a single functional unit. Gems Medical Sciences has applied this strategy for a respiratory-products company that sought to revolutionize transport ventilators. By taking various components, such as a nebulizer and temperature sensor, and incorporating them directly into the manifold block, the team produced a new design that occupied much less space.

In some cases, the size of an instrument may be constrained by operational considerations. When this occurs, the answer may lie in automating functions. In the above ventilator case, for example, flow valves in the original design had to be set manually. Access to the flow adjustment on the needle valves limited how small the device could be. To overcome this problem, Gems Medical Sciences re-engineered the

manifold design, replacing the adjustable valves with precision orifices pressed directly into the manifold. With access constraints eliminated, the overall footprint of the device was reduced by 40 percent.

In another situation, a medical laser manufacturer wanted to redesign its large fixed-location device into a unit small enough to be easily moved within a doctor's office. This required, among other factors, reducing the size of the device's cooling system. Gems Medical Sciences fluidics experts were able to significantly reduce space requirements by consolidating a level sensor and a temperature sensor into a single component. The new combination sensor required less access space in the fluid reservoir, enabling the use of smaller containers. These changes, combined with the use of smaller pumps and smaller sensors, cut the footprint in half.

Challenge 2: Cost Control

Pressure to reduce production costs is a reality throughout the medical industry, but is particularly strong among medical device manufacturers, for whom the cost of goods is generally very high. Yet OEMs are understandably cautious about adopting cost-based modifications to core technologies that are the foundation of a device's performance. This is less of a concern in relation to ancillary functions. By driving costs out of non-core systems, such as a fluid handling system, an OEM can preserve cost-flexibility in proprietary technologies.

Control of equipment costs is also a particular concern for IVD and other device manufacturers whose business is based on driving use of consumables (razor/razorblade model). The success of such models hinges on maximizing the base of installed instruments. To execute this strategy, OEMs must keep upfront costs low to reduce barriers to installation. Given that manufacturers frequently offer the core instrument at minimal or even no cost, strong pressure exists to pull costs out of equipment production wherever possible.

Benefits of Working with Fluidics Specialists

When considering whether to partner with a fluidics specialist, an OEM must weigh the suitability and short-term cost of employing an outside firm against the potential for improved product performance and for cost and resource savings in the long run. Benefits of such partnerships may include:

Optimizing Staff Utilization

In an era where efficiency is the name of the game, and even large companies increasingly have leaner organizations, working with a fluidics partner can free up valuable staff time. Rather than dilute their priorities with non-core technology, internal engineers can focus solely on maximizing performance of proprietary components or systems. This is true for companies of any size.

Small or early-stage companies may find it particularly advantageous to work with an outside fluidics firm. Often such enterprises have only a handful of staff, and perhaps not even that. At the very earliest stages of development, the company may consist only of the founders who have the requisite clinical, but not engineering, expertise to take a concept from drawing board to production. When cash flow is critical, as it is for many start-ups, working with an external fluidics partner is often more cost-effective than adding head count, especially if the need falls outside the company's core focus.

External fluidics specialists offer cutting-edge expertise that can help OEMs find innovative solutions to product development challenges.

Shortening Development Time

External fluidics experts, by definition, keep abreast of the latest advances in fluidics technology and have extensive knowledge of the field. As such, they can quickly see through design challenges and identify approaches to solve them, more so than internal engineers who may lack depth of experience in such matters.

Another advantage of working with an external fluidics is that design of the fluidics component can proceed in parallel, rather than in sequence, with design of other system functions. This can accelerate the upfront development timeline and may also save time later in the process when design conflicts are more difficult to correct.

Streamlining Risk- and Data-Management

When there is a need for a fluid handling system, an external fluidics partner can deliver a single, fully assembled unit, with a single part number. The subassembly is produced and tested by the contractor, and continuity of test data is maintained back to the component level. Since the contractor assumes responsibility for the complete subassembly, there is a ready source of support if performance issues arise. All of this reduces risk for the OEM.

Value-engineering and Troubleshooting

Beyond original product design, the expertise of an outside fluidics partner can be valuable when an OEM seeks to modify a device already in commercial distribution. This may include situations where a device is not performing to expectations or when a company is seeking to eliminate cost from the manufacturing process. In the first situation, a manufacturer is in reactive mode, trying to identify root cause in response to customer complaints. There is a need for a rapid, effective solution, and the specialized expertise of a fluidics partner can help an OEM quickly diagnose the problem and/or find a fix.

Objectivity is another benefit of working with a fluidics contractor. An external specialist can bring a fresh perspective to the table, and may see things that are not obvious to internal engineering staff who are very close to the project. Furthermore, because it is not invested in a company's current practices, an external specialist can help an OEM distinguish effective practices from those that need improvement.

Improving Cost-Efficiency

An external fluidics provider can help an OEM realize significant cost savings. The firm's ability to identify straightforward solutions, together with its knowledge of sourcing, access to volume pricing, and the infrastructure to readily produce custom parts if necessary, all contribute to cost reduction. For its clients, Gems Medical Sciences has often been able to shave as much as 40 percent off of component parts.

Early Involvement is Key

The best time to seek fluidics support is early in the development process. Doing so can not only shorten upfront development time, but can also save time – and expense – at the back end of the process, when changes can be expensive to implement. This consideration is especially relevant in the medical device industry, where products and manufacturing are subject to regulatory review and where modifications to a product can require significant testing and validation.

Involving a contract firm early in the development process increases design flexibility and helps ensure that fluidics specifications and solutions will be compatible with overall device performance.

In many cases, an OEM will approach a contract fluidics firm with a predefined specification. The contractor then begins its work by developing an in-depth understanding of the assignment and its challenges. This includes reviewing the design specification and clarifying with the OEM any open questions or concerns. From this process, a list of exceptions or concerns may be generated. Fixed and flexible specifications (ie, needs vs wants) will also be explored to create a cost-benefit analysis. Unfortunately, when the process follows this route, incompatibilities between the fluidics requirements and the overall product specification are not uncommon. The findings from

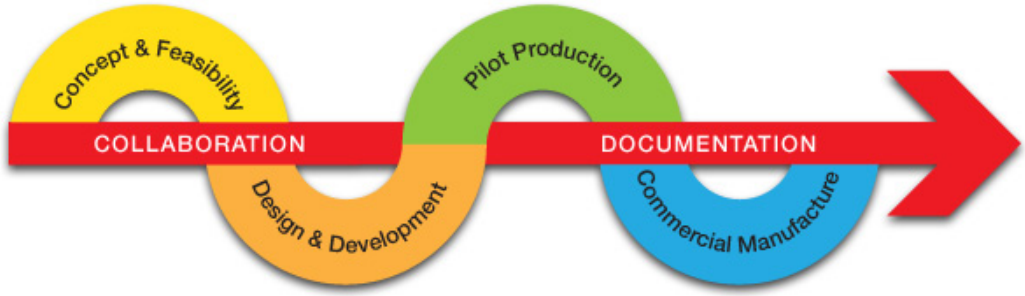
fluidics analyses could mandate a revision to the specification or a very expensive and time-consuming exploratory pre-development phase, only to discover that the specification must be revised further or, worse yet, is not technically feasible. Furthermore, remedial options later in development may be limited by fixed design parameters.

Involving a design partner early in the creation of the design/product specification will most often prevent these complications. Design requirements are discussed as the specification is being created. Specifications and solutions are developed early on to be compatible with overall device performance. If necessary, preliminary testing and development can be completed in parallel with the creation of the specification. Technical hurdles will be identified and possibly mitigated up front. The result is the release of a more complete design/product specification that has already been validated and accepted by both the OEM and the design partner. With this as a starting point, execution of the assignment proceeds more expeditiously and with greater confidence of success.

Maximizing Partnership Value

The value derived from partnering with a fluidics firm will be influenced by how the internal team approaches the relationship.

The best results from partnering with a fluidics specialist will come when companies are forthcoming in the sharing of information. This may require overcoming a reluctance to provide detailed data to an external source. Therefore, it is essential to select a team with which the OEM feels a level of trust. Better results will also come when the company is open to providing the outside team with a well-defined set of desired specifications and requirements. In some cases, a company might have already assembled this list prior to approaching the fluidics partner. In other cases, this may be developed in conjunction with the specialist's input, drawing from the latter's expertise in design, manufacturing and outsourcing. In either case, a company must be prepared to invest time and attention in setting project parameters.



Gems Medical Sciences offers a unique array of intelligent sensors, world-class lean manufacturing tools and ISO-certified quality processes to significantly increase efficiency, productivity and quality through all stages of design and manufacture.

On the other side of the partnership, a manufacturer should expect a partner to be transparent in its execution. At Gems Medical Sciences, for example, we regularly invite a client's engineers onto the production floor during our Kaizen event—a continuous-quality exercise to develop, test, evaluate and optimize the manufacturing cell. This creates a collaborative environment in which both parties are invested in the process and outcome. In fact, willingness to expose its processes to client scrutiny is one indicator of the kind of partner a contract firm will be. When such openness is not offered, an OEM should consider seeking an alternative provider.

Conclusion

Today's competitive marketplace requires medical device companies to be more flexible than ever in their approach to product design and production. The demand for devices that are smaller, less expensive, and more reliable requires increasingly novel solutions. Regardless of size, many companies will benefit from working with an external fluidics contractor to address these challenges. The advantages of such partnerships include freeing employees to work on core technologies, shortening development time, and reducing manufacturing costs. By working with an outside fluidics specialist, companies can also hand-off potentially time-consuming validation and test data-management burdens. Whether for the development of new products or for value-engineering improvements to existing ones, medical device companies will find that an outside fluidics contractor can be a valuable partner to the company's own development and engineering teams.

Gems Medical Sciences is a focused division of Gems Sensors & Controls providing a dedicated resource to medical OEM customers. Gems is a global leader in the design and manufacture of fluid sensors and controls from individual components to complete fluid handling systems.

Built on Gems' 50+ years of application engineering experience and a broad portfolio of sensing and control products, Gems Medical Sciences has the resources to quickly design, prototype, build and deliver components, subassemblies and fluid handling systems to our customer's critical requirements.

Our team of sales and engineering professionals in North America, Europe and Asia provide direct access to the highest level of individual support and attention to our OEM customers. Gems has five manufacturing facilities across the US, Europe and Asia to reduce lead-times and allows us to cost-effectively ship ready-to-use systems throughout the world.

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