Advances in Additive Manufacturing and Material Science Accelerate Fluidic Manifold Delivery

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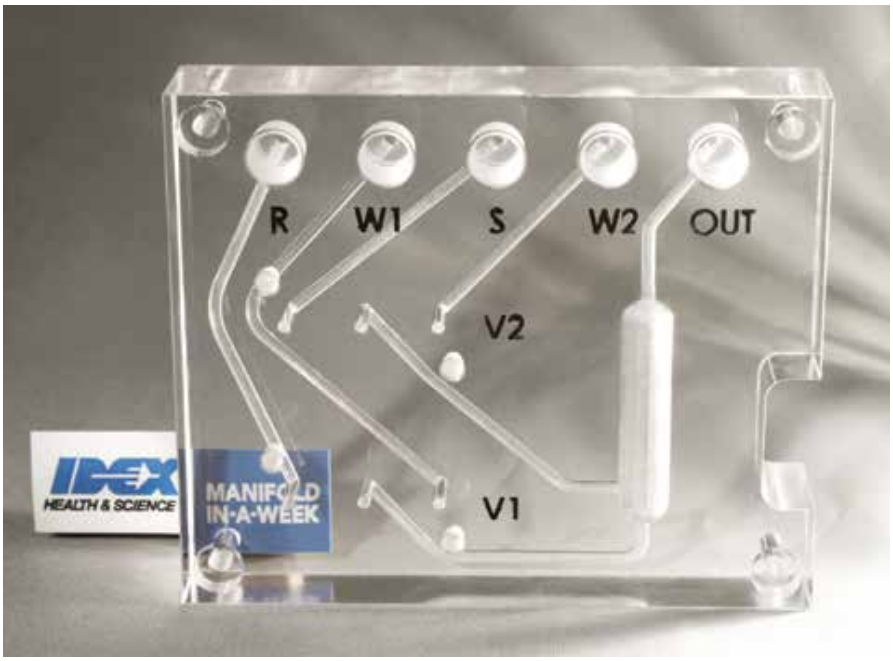
Many designers of in vitro diagnostic instruments embrace the concept of utilizing a fluidic manifold to minimize the size of a device, reduce leaks, improve the reliability of the flow path, and get consistent fluidic performance in every instrument. Certain process thresholds have made manifolds a practical solution for only large, established instrument manufacturers. Today, however, even startups on tight timelines and development budgets can acquire limited-run prototypes in materials suitable for proof-of-concept.

"It changes the whole discussion," said Sales Engineer Ed Beldowski of IDEX Health & Science (www.idex-hs.com), describing a recent manifold design project with a northeast biomedical startup developing a Point of Care (POC) device. *"The customer submitted the initial design request through our website for a very small, fast-turn manifold onto which they planned to assemble several small valves and a pressure regulator. He had been working with a European competitor of ours, but over time, some concerns arose about the smaller size of that company, the time-zone difference, and their responsiveness. Working with us, he liked the real-time availability of our engineers. Also, as a start-up, working with an established corporation like IDEX Health & Science increased his confidence in collaborating with us."*



"Speed was really the primary factor for us," emphasized the company's founder/chief technical officer (who prefers to remain anonymous for competitive reasons). *"If we'd done it the old-fashioned way, where we'd get the fluidics module in 6-8 weeks, the cycle times for making these iterations would have been a lot longer and would have cost a lot more. So, being able to get quick turnaround on fluidic modules was key."*

Laks Iyer, Ph. D., IDEX Health & Science Senior Product Manager for Manifolds, reviewed how the IDEX Health & Science team scoped the project. *"The customer had proven his concept at the breadboard stage, and came to us when he needed to shrink everything down into a very compact beta unit much closer to the final form that would go to market. We believed there were still iterations ahead; the instrument probably wasn't in final form yet — and he agreed — but the ideas were solid, and knew he needed manifold-based fluidics. After estimating the hard cost of making just one multi-layer bonded manifold, where the per-unit cost can be expensive because of production set-up time, process time, and finishing work, our team suggested, using an additive manufacturing processes. The customer was definitely interested, provided IDEX Health & Science could produce a very clear material that would fully expose the entire flow path. This was needed because he still wanted to visualize and improve his process. Like many start-ups, the incremental need for financing pushed his timeline, and of course, that pushed us."*

"The IDEX process gave us the flexibility to make iterative changes, and the ability to go fast. It was just fantastic."

Another strong feature that made the material ideal for the prototype manifold is that it offers the dimensional stability required to fabricate fluidic channels only thousandths of an inch wide.

The customer concurred: *"The IDEX Health & Science process gave us the flexibility to make iterative changes, and the ability to go fast. It was just fantastic."*

"When we talk to people about our process," Beldowski explained, "first they're shocked that it can give you a very clear manifold with very small tracks, because they typically have, maybe, a ten-year-old understanding of additive manufacturing. They don't realize that it's come very, very far in 10 years. So that's the first shock. The second question that usually follows is, 'what fluids is it compatible with?"

After the team had confirmed material compatibility with chemicals used, the customer next questioned whether the Manifold-in-a-Week process was capable of producing very small tracks. *"He wanted 0.030 inch (0.76 mm) diameter tracks which challenges the technology,"* added Dr. Iyer. *"That was the only area where I feared complications. These are very small tracks and I worried that they might close up during the process."*

Dr. Iyer went on to explain how additive manufacturing had historically been used to form larger objects with less sophisticated features. *"The IDEX Health & Science process starts with a liquefied resin in a vat. As the vat is raised incrementally of about 0.002 inch (0.05 mm) at a time, a laser describes a design on the surface. That design becomes the formed object as the laser cures and sets the material in the additive production process. Resin is cured only in the areas where you want material, leaving other areas where you want the channel open. The threshold of limitations that the industry has encountered up to now, has been around those very minute passages. The smaller the diameter of the channel, the harder it is to keep it open because the material outside the channel will collapse due to the heat energy surrounding it. After a couple of trials, we were successful in forming the tracks accurately, with absolutely no blockage or collapse."*

Once the piece was accurately formed and cured, manufacturing technicians at the IDEX Health & Science facility in Bristol, CT performed a series of specialized secondary processes. Fluidic ports were finished and sealing surfaces were smoothed to prevent leaks. Dr. Iyer further explained, *"To make the manifold functional, components such as valves and fluidic connections were added. Because this material is a thermoset, not a thermoplastic, it can be brittle. The IDEX expertise enabled the proper torque for sealing component ports and connections without introducing stress cracks in the process. We worked on that quite a lot, because it can create the critical difference and provide the level of precision that sets us apart from other Rapid Prototyping Services as the fluidic experts."*

"We were able to optimize his model for manufacturability at this very early stage."

In final form, the manifold assembly consolidates several pencil-tip-sized valves and a pressure regulator into a bench-top hematology instrument not much larger than a desktop telephone. The IDEX Health & Science team, in collaboration with the customer, was able to drive a roughly $4,000 investment using conventional process down to $300-$400 using the Manifold-in-a-Week process. *"The other advantage*, that is *probably less obvious at this point,"* added Beldowski, *"is that we were able to optimize his model for manufacturability at this very early stage. Our engineering team recommended some changes to some of the internal tracks that we knew could not be machined when we later convert over to production bonding technique for the final units. Now, the customer knows his manifold is production-ready."*

"I thought the finishing on the fluidic manifold was fantastic," added the customer. *"My other concerns had been around accommodating the additional fluidic components we were mating to the manifold and ensuring that the quality of the surface would be good enough to seal properly.*

In looking for success with our whole program, we try to get vendors who are invested in the development of the instrument because that way you're able to work through bugs together pretty easily. I would say with IDEX Health & Science, it's actually one of the two relationships that we've had in terms of going the extra mile to make sure that we're on track with our development."

What's Next for IDEX Health & Science?

"I have a call tomorrow," finished Beldowski, *"with a customer who wants one piece to qualify a design and it's a pretty complex manifold that would cost a lot of money and take a lot of time and resources on our end. Now, because of the clarity of this material, the compatibility with his benign chemicals and his short delivery window, Manifold-in-a-Week is a good option for him. Earlier, he told me that they've had SLA printing capability in-house for 5 or 10 years. So I asked him 'Do you think we could print your new manifold design on your machine?' But he said 'There's no way. The materials are not transparent, and it doesn't have very good resolution.' When I shared with him our ability in printing internal passages down to 0.030 inch,(0.76 mm) he said, 'Wow. I'm very interested. Show me.' It literally changes the entire discussion."*

Dr. Iyer added, *"There are Rapid Prototyping Service Bureaus out there that can produce a part. But that's not the real reason why customers come to us. The value that IDEX Health & Science provides to our customers is that when they transitions into production, they will save time and money. Our vast knowledge of entire fluidic systems combined with our understanding of design and production is a big advantage for both IDEX Health & Science and our customers."*

"Using Manifold -in-a-Week we are now able to produce manufacturable designs.
Only IDEX Health & Science provides this level of service and expertise—from fast prototypes all the way to production without having to go back and re-design or re-test."

- **Reduced time to market**
- **Cost Effective Prototypes**
- **Ease of prototyping multiple iterations**
- **Production Ready design**
- **Delight customers by delivering a quality part very quickly**

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