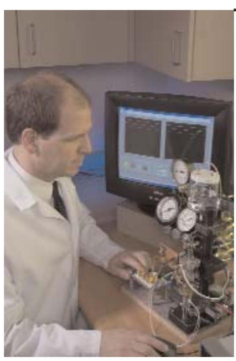
What's Happening With Pumps and Valves

Pumps and valves are subject to many of the same pressures from users and respond with similar technological changes. This exclusive article takes a look at recent changes influencing medical device manufacturers.

By Peter Cleaveland, West Coast Editor

Peter Cleaveland is an editor and writer with wide experience in science, engineering, and manufacturing. He received an AB, with a major in physics and a minor in math, from Dickinson College, followed by graduate studies in education at Temple University and work toward a master's in engineering at Penn State. He worked for 10 years as an engineer, first in military electronics and then in industrial control equipment. He then spent 19 years as an editor and was awarded a Jesse H. Neal certificate.



On the cover: Clippard engineer Rich Humason measures flow rate vs. current for one of the company's EVP proportional solenoid valves.

As with most technical products, users of both pumps and valves want products that are smaller, use less power, and cost less than their predecessors—yet have as good or better performance. How to achieve that is a challenge. As Ken Burtt, director of sales and marketing at Precision Dynamics Inc. in New Britain, CT, puts it: "How do we make a smaller valve but be able to meet higher pressure requirements and the higher flow requirements that we need?" Adds George Bednar, North American director of sales and marketing at Ismatec USA in Madison, WI: "They want to go to smaller pumps but they don't want to compromise performance."

One way peristaltic pump makers are improving performance, says Bednar, is by changing the shape of the rollers. He cites as an example new roller designs that allow pumping media containing live cells with much less damage to the cells. One roller, as depicted in Figure 1, has a convex surface and a concave tubing bed. "That tube gets squeezed in the middle first, and the edges of the tube are still open," he explains, so the cells escape shearing or crushing.

One area driving the push to smaller equipment is medical diagnostics, where there is a need for ever-smaller sample sizes. Burtt says, "They're trying to reduce the amount of sample size, so you don't have to draw three vials of blood out of the person's body to run a chem-7 test."

Reduced Power Consumption

Along with the move to smaller valves is a push toward reduced power consumption. Equipment is becoming smaller and smaller and, in some cases, becoming portable and running on batteries, which makes power consumption a critical issue.

Burtt cites the ventilator industry as an example. "You have companies making filing cabinet

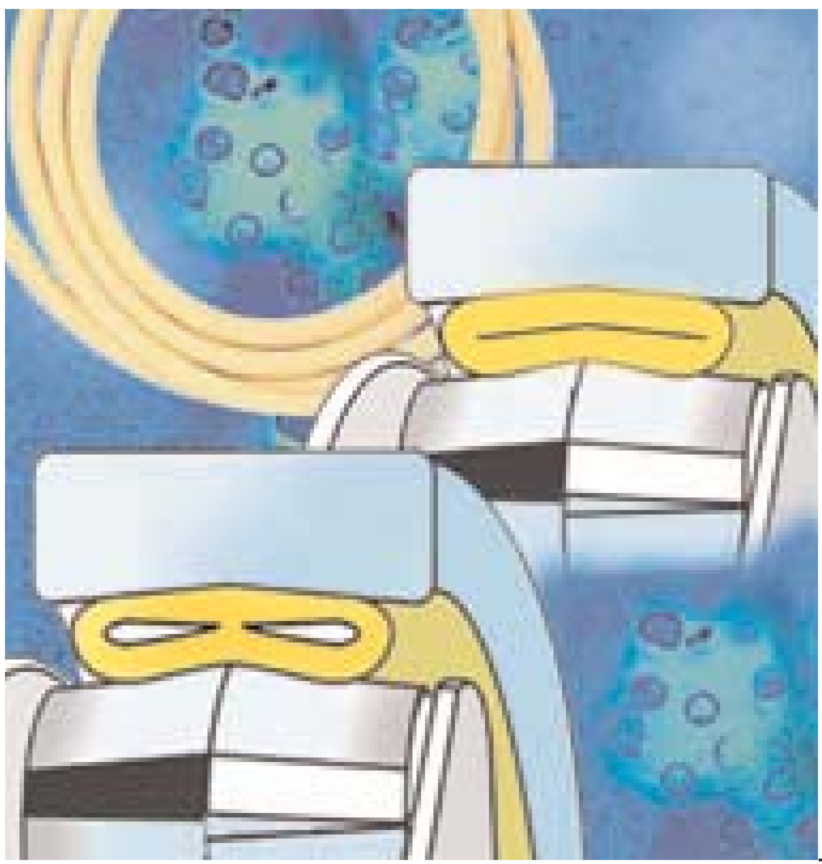


Figure 1. New peristaltic pump roller designs with a convex roller and concave tubing bed allow pumping media containing live cells with much less damage to the cells. The tube is squeezed in the middle first while the edges remain open, so the cells escape shearing or crushing.

size ventilators, but what they want to do is to design platforms that will make them the size of a laptop computer," which often means changing from a standard 2 inch by 1 inch valve down to something that's going to have to be quite considerably smaller. And because the unit is to run on batteries, they want more efficient coils. "So we are having to go back and redesign coils that will work at 1/2 watt or less. You need to maximize the amount of winding you get on the coil bobbin. There's always a trade-off. If you can't maximize your amp turns, you have to give up something on the valve performance side, whether it be flow or pressure."

Cutting Costs

Everywhere in the medical field, there is emphasis on cutting costs. Because valves are used in large numbers in some applications, their price becomes an important factor. Burtt cites immunoassay machines, which may contain between 20 and 30 valves, as an example. "Most of the time they're building these machines and essentially giving the machines away, so they can sell their reagents, consumables. So they want to make these machines as cost-effective as possible."

Many companies choose to cut costs by moving production overseas, to Ireland or China, but that can lead to problems, says Sid Hendry, sales manager for North America at **Clippard Instruments** in Cincinnati. "If you are to move things offshore, you're now distancing yourself in terms of quality." **Clippard's** answer, at least so far, has been to improve automation and quality testing processes, "where we have our on-site engineering and so forth." With increasing globalization, however, one wonders how long this can be kept up.

There is always a trade-off between reliability and cost, says Hendry. "We've tested [some] valves ... to billions of cycles, but you run into customers who don't want to pay for that; they just want to get through the warranty period. I understand that cost is an issue, but how close to the precipice do you want to walk?"

Burtt says it depends on the industry. "The people building small oxygen conservation devices want a valve that will work into the 200-300 million cycles. We have other applications where the valve only has

Figure 2. The Chem-S miniature isolation valve from Precision Dynamics is available with a choice of diaphragm materials from Viton to EPDM.

Solenoid Valves Help Automate Diagnostic Machine

Qualigen Inc. in Carlsbad, CA, manufactures the FastPack system, a portable diagnostic machine that allows a urologist to perform a blood test for PSA (prostate specific antigen) in the office in just 10 minutes. The system uses foil-and-Mylar pouches that contain all the required reagents heat-sealed in separate compartments. The doctor or nurse injects a blood sample into one compartment and puts the pouch into the machine, which then performs a series of mixing and rinsing steps, culminating in a chemiluminescent reaction that releases light in an amount proportional to the analyte in the mixture.

Thirteen **Clippard** ES-3T-12 valves mounted on an acrylic manifold feed compressed air to actuators (brass color, with O-rings) that move liquids within the sample pouch.

"If you go in for a PSA and you're concerned about whether you have prostate cancer, or maybe you've had prostate cancer and you've had your prostate removed, when you go in the office to get your next result, you'll be very anxious about what that result might be," says Bob Buchanan, Qualigen's vice president of marketing. "The physician normally brings the patient in a little early, blood is drawn, the test is run, and when the patient goes back into the exam room, the physician has the result in hand."

The manifold assembly, with supporting circuitry, mounts against the front panel of the FastPack.

All the testing is done within the pouch: computer-controlled pneumatic actuators squeeze the different compartments, and bursting chevron seals allow the sample and the reagents to flow from one compartment to the next. The pneumatic actuators are powered by compressed air from a built-in 45-50 psi compressor and are controlled by a set of **Clippard** Model ES-3T-12 valves mounted on an acrylic manifold. Materials are washed back and forth between the chambers while the actuators lock off other chambers so the material is localized.

"The disposable pouch is a great concept," says Jason Taylor, project engineer for the FastPack system. "The only thing the person administering the test has to do is put the patient sample inside the test pouch, write the patient's name on the label, put the packet in the machine, and hit one button. The machine reads the barcode label and then processes from there, and tells it which test to run, so the actuators know which ones to actuate at a given time. It's pretty simple for the user."

to work 30,000 cycles. It's on an application-by-application basis. Some people say our valves work 250 million cycles. Really you can make any valve work 250 million cycles; it's will it work 250 million cycles in that particular customer's application. That's the hard part."

New Materials

One of the challenges for makers of valves used in diagnostic equipment, says Burtt, is to maintain compatibility with the reagents used. "More and more of these medical companies are coming out with these reagents and you really don't know what's in the reagents and they won't tell you," he observes. Which, of course, increases costs to the valve manufacturer. How do you choose materials that will handle anything that might come along, yet do it at a reasonable price? While it's possible to design a valve that will handle almost anything an OEM may throw at it, it may cost $80, while the OEM is looking for one that costs $40 to $45.

For valve materials, says Burtt, "most of the time you go after a Teflon or a PEEK as far as the actual body materials. As far as seal materials, you always look at the higher-grade Vitons, the higher grade EPDM, or the perfluoroelastomers. Or the Teflons, too."

However, Burtt says Teflons aren't the ultimate answer because they don't make a very good dynamic seal. For that reason, more and more valve companies are looking at perfluoroelastomer materials, and some are even developing their own PFE material for valves in the medical industry.

For ceramic valves, Steve Szabo, the vice president of business development at Kloehn Ltd. in Las Vegas, says the choice is usually alumina or Teflon–alumina where the fluid contains particles and Teflon where it doesn't.

Steve Bello, product marketing engineer for Halkey-Roberts in St. Petersburg, FL, points out one interesting innovation on the materials side: valves that kill bacteria. Some makes, says Bello, are "trying to incorporate bacteria-fighting ingredients into the resin. The thing cleans itself. It's very expensive, but it's working its way into the industry. They're working towards having the resin of the device actually be able to kill bacteria that got onto it."

The choice of materials for a pump is a balancing act between inertness, longevity, and cost. In syringe pumps, for example, one gets longer life by using polyethylene instead of Teflon, which wears, says Szabo. Where the medium is compatible, he explains, a polyethylene syringe can last two to three times as long as a Teflon one. And sometime the choice comes down to where the equipment is sold; in Third World countries, for example, it may not be practical to make periodic service calls to replace components, so they have to last longer.

A peristaltic pump places great demands on its tubing. Silicone tubing, which is inert and has a very smooth inner surface, doesn't last very long under the harsh mechanical demands of a peristaltic pump. "C-Flex is another example of a good tubing for the application," he adds. "It can be welded. In the health care industry, they can fill it up once, weld it, maintain the sterility, and throw it away. And it's inexpensive. The catch here is that it, too, is relatively fragile; it doesn't have a long life in a peristaltic pump application."

Some tubing manufacturers have made significant strides in recent years. W.L. Gore, Newark, DE, recently came out with two new types called STA-PURE and CHEM-SURE. "They give long life," says Bednar, "which is a godsend to peristaltic tubing manufacturers and ... they get very little spallation ... a big concern to pharmaceutical manufacturers." The drawback, he adds, is price. Nobody would use such tubing where it isn't needed, but some pharmaceutical companies, for example, will see it as insurance. "You have millions of dollars worth of pills on your revenue stream, and for $600 worth of tubing you don't want to quibble about something like that," says Bednar.

Methods of Actuation

The motors used to drive pumps haven't been changing very quickly, although there have been a few shifts. Where the need is simply to get fluid from point A to point B, the preference is still for plain-vanilla 60 Hz AC motors. Where there is a need for variable speed, DC motors are used although some makers are shifting from brush-type to brushless DC, primarily because of longer operating life. You get "7,000-9,000 hours of life out of a brushless motor compared to 5,000 hours out of a standard motor with brushes," says Bednar.

In syringe pumps, on the other hand, you're more likely to see step motors such as the one shown in Figure 3. The big advantage of a step motor is that its motion can be precisely

Figure 3. The Kloehn Versa Pump 6 syringe pump is driven by a step motor.

controlled without using a feedback loop, so accurate dispensing is made simpler. Kloehn makes syringe pumps, for example, that give resolutions of 24,000:1 or 48,000:1. The big drawback to step motors is that the design of the drive electronics is a little more complex than for regular motors. Some designers swear by steppers, while others think of them as strange beasts that behave in mysterious ways.

While electric actuation for valves is gaining in popularity, pneumatic actuation is, and will continue to be, a very live option. Burtt mentions smaller dialysis machines and oxygen conservation devices as examples, as well as non-invasive blood pressure cuffs, which are using ever-smaller air valves.

Szabo points out that solenoid valves are not always the best answer. Although a solenoid valve uses no motor and is less costly than other types, he says a pinch valve may be

Figure 4. These valves from Halkey-Roberts help minimize the need for needles.

better when multiple samples are put through a tube separated by air gaps because a solenoid valve tends to mix up the interface.

What's Coming

While neither pumps nor valves are about to experience a revolution, there are some interesting developments on the horizon. For example, Ismatec is working on peristaltic pumps with easily replaceable pump heads, which neatly get around the problem of having to periodically disassemble a pump to replace the tubing.

On the valve side, Bello predicts that ever-growing safety concerns will lead to a rapid increase in the use of valves that eliminate the need for needles, such as those shown in Figure 4, "anywhere that you can minimize the use of a needle stick." But, he goes on, this won't happen unless manufacturing costs are reduced. "If it's a disposable, and the price isn't at that point where it's enticing for someone to buy, they're not going to buy it. So the efficiency in these types of things will be key."