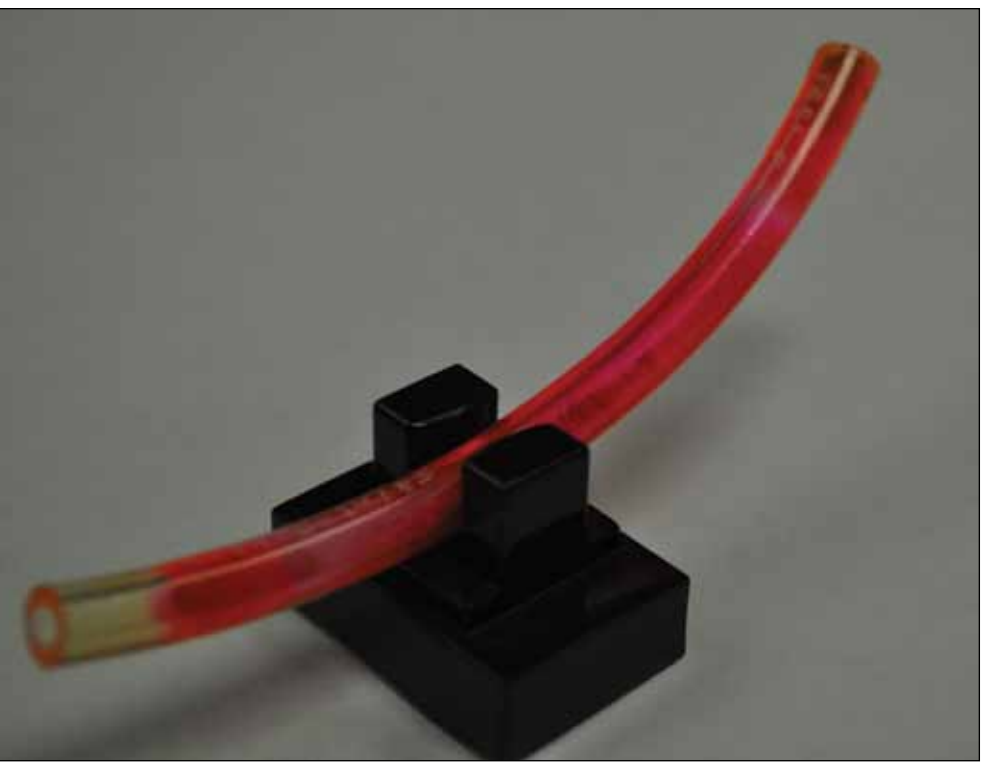
Medical Pumps with Uncommon Sens(ors)

NEW-GENERATION SENSORS IMPROVING OUR QUALITY OF LIFE

Jack McGuinn, Senior Editor



A series of ultrasonic, non-invasive air bubble and particle detectors (above and top, next page) from Cosense has a wide range of applications for the detection of air bubbles and particles in fluid-lines in the wafer etching process as well as in coolant lines. Standard sensors can detect air bubbles as small as 500 microns in size in tubing from 1 mm to 12 mm. Custom sensors for OEM customers can be designed to measure air bubbles down to 100 microns in size (photos courtesy Cosense).

Pumps and pumping applications have been around for millennia—longer, if you include those found in the breasts of most living creatures—great and small.

But the sensors that usually serve as the "brain" within today's pump systems are a much more recent technological advance.

The first known pump device is attributed to—who else?—the Greeks. Archimedes, a Renaissance man before there was a Renaissance, is credited with inventing the screw pump—a device used to remove a sailing vessel's bilge water. Its 21st century iteration is still used today in the coal and grain industries.

As for sensors, pressure and pressure management of some form have existed and been recognized since the 16th century, when Italian physicist and full-fledged Renaissance man, mathematician, astronomer and philosopher Galileo—secured a patent—who knew?—in Pisa to create a machine

for pumping (extracting) river water for irrigation use. But it was in 1967—according to most accounts—that what we know as the "modern" sensor was developed by the Honeywell Research Center via a patent awarded to Art R. Zias and John Egan for an "edge-constrained silicon diaphragm."

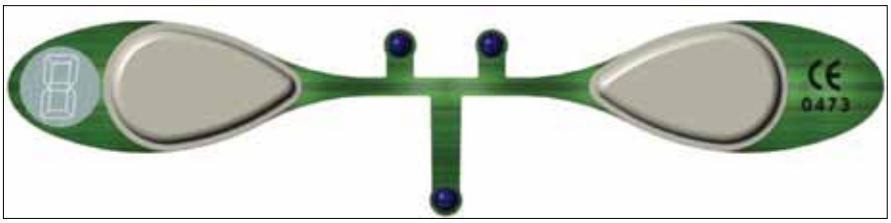
Today, dollar estimates of the U.S. market for sensors in general vary, with medical sensor applications pegged at around $5 billion and an annual growth rate of perhaps 10–15 percent through 2014. The overall sensors market is estimated to be around $12 billion per year, with an annual growth rate of about 5 percent.

Medical application sensor types include pressure, temperature, flow and level. In fact, according to a Freedonia Group study, "(Process variable) sensors will continue to be among the two largest product segments, given the numerous applications for these products."

But for now, let's concentrate on one niche in the medical sensor universe—pumps; more specifically, pumps with sensors.

Pete Smith, senior applications specialist for Hampton, VA-based Measurement Specialties, Inc. (MSI), provides a bit more background on sensor/pump applications.

"Medical equipment has always contained some degree of sensing technology, although often it has been rudimentary and fairly basic. For example, old-style blood pressure equipment used dial gauges to indicate the reading to the clinician. The dial gauge itself was a crude pressure sensor. Over the past couple decades, more and more sensors have found their way into medical machines. These sensors have added utility, new features, better indicators, more reliability and more patient safety to the equipment.



This MSI sensor is embedded in a sleep apnea patch used for monitoring airway flow during sleep. It features strain gage sensing of chest movement, contact microphone-sensing for snoring and pyroelectric sensing for exhalation monitoring (photo courtesy MSI).

"As an example, flow sensors in infusion pumps monitor for proper dosing and operation of the pump. If anything isn't working properly, the pump stops and alerts the nurse of the problem."

And beyond that, says Smith, sensor technology is improving patients' quality of life while shortening hospital stays, allowing for much less stressful home recovery time.

"In the past few years, there has been a move in the medical equipment industry to redesign machines so they will function well in 'home healthcare' applications. Rather than keeping patients in the hospital, they are sent home, but with sophisticated monitors that can continuously check on the patient's condition and quickly alert the doctor via a cell phone link, or over the internet. These 'home healthcare' machines are filled with sensors to add intelligence and safety, and make them foolproof."

As one might expect, with an industry dedicated to making small things even smaller—as specified by its OEMs and end-users—challenges abound.

Says U.S.-based HSI Sensing president David Posey, "The sensor has evolved by making them smaller, (but) the reduction in size cannot give up any performance in magnetic sensitivity. (Our customers) require high quality, customer service (audits, reports, visits). Nothing new to us; we welcome their challenges and opportunities."

Mustansir Faizullabhoy, director of business development for Hauppauge, NY-based Cosense, offers his take.

"There are challenges on multi-

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HSI manufactures what is claimed to be the world's smallest and most sensitive magnetically operated reed switch. At more than 50 percent smaller than the smallest reed switch currently on the market, this new switch was designed to address the need for smaller electronic components in the medical and healthcare industry, including hearing aids, pacemakers and other implantable devices,defibrillators, surgical instruments and test/ diagnostic equipment (photo courtesy HSI).

ple fronts—from sourcing the crystal material, manufacturing, meeting each specific customer's critical functional requirements and while still providing a cost-effective solution."

And back at MSI, Smith comments on perhaps the greatest challenge of all—time—or the lack of it.

"One challenge is the time and investment needed to be part of a medical product development project. Often, a new medical product takes several years from concept to a running production line.

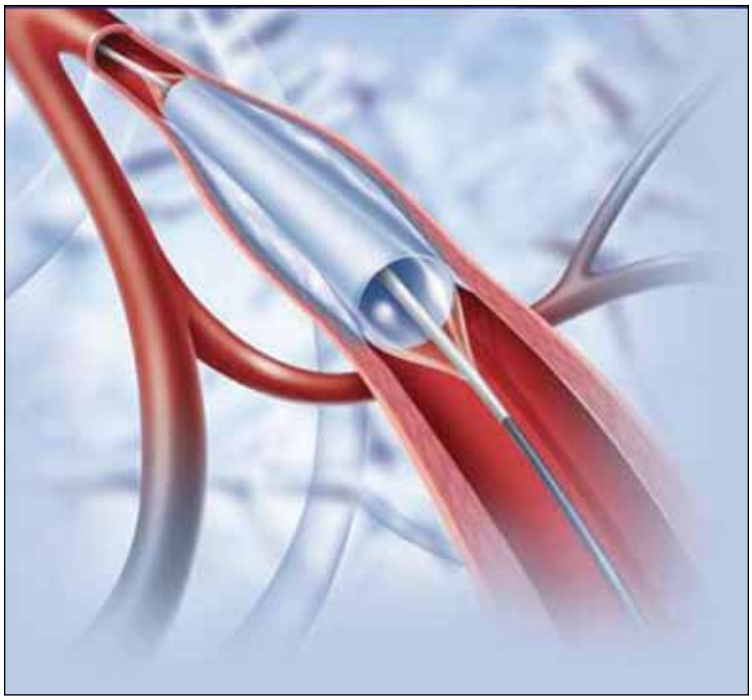
"Another challenge is that once in production, making changes, even very minor ones, is a significant effort. The effects of the change must be evaluated and studied to be certain there are no unintended consequences." As in, one might well assume, accidental injury or death.

But of course it doesn't stop there.

"The medical equipment industry spends a lot of resources implementing and operating quality control programs," says Smith. "Unlike most other types of customers, medical companies conduct periodic audits of their supply chain. These audits are highly detailed and rigorous. They occur at our facilities and can sometimes take a few days. In addition, there are any number of governmental and oversight groups that scrutinize the industry, and each of them have their own set of auditors. We have the FDA in the USA, and most other countries have an equivalent agency, but often with different standards. If a company wants to sell products in many countries, the regulatory maze is very complex."

Adds Cosense's Faizullabhoy, "We try to achieve the Six Sigma quality standard. Each customer has their own set of criteria. Testing specifications are mutually agreed upon prior to production launch so that customer expectations are met. Also, conforming to ISO9001 standards for design and manufacturing are a must. Sensors must be 100 percent-tested and offer fail-safe functionality."

"Fail-safe" means if a sensor malfunctions then it raises an alarm to the subsystem which automatically shuts down the system to prevent any unsafe conditions.



MSI's proprietary Microfused silicon strain gage pressure sensor measures pressure levels of cryogenic gases used in novel angioplasty procedures (photo courtesy MSI).

All three of the companies discussed in this article are OEM suppliers, and are involved in all of the things that such status incurs.

"Our medical customers work closely with us during the development of a sensor solution, says MSI's Smith. "They do extensive qualification and validation—not only of the sensor device we plan to sell them, but also of the factory and processes we plan to use to make them. Once in production, our customers perform regular audits of our entire company to insure we are maintaining quality standards that were outlined at the beginning of development.

"Our customers also make sure we conform to the Code of Federal Regulations, Title 21, which outlines requirements for medical products."

At Cosense, "We are an OEM manufacturer of sensors that are tailored to each customer's specifications," says Faizullabhoy. "The typical conditions that OEMs impose on manufacturers include meeting cost constraints while maintaining quality of components."

And says Posey at HSI, "Many OEM's require customization for their application; with the benefits of cell manufacturing they want the part 'ready to go'. They do not want to modify it for any reason. We welcome the opportunity to build different versions of the 'same' device (e.g.—longer wires, connectors, customization for specific application)."

As one might expect with one complex industry (sensors) working with others (device makers, medicine, etc.) equally complex, R&D is important. That means one's engineers working with the other's engineers, for example, in making something work to everyone's benefit.

But as Posey points out, R&D is a customer-to-customer dance.

"It (R&D) depends on the company," he says. "Some manufacturers design and build what are called 'standard products,' which are sold to everyone from a catalog, and everyone buys the same components. We not only have standard products, but we also work with a customer to develop and build custom products specifically designed to meet the customer's specifications. Custom products are typically not sold to anyone except the customer for whom they were designed."

Adds Faizullabhoy, "On all our special sensor development programs we work together in the R&D phase very closely with our customers, and this is typical in this industry."

HSI's Posey concurs, but points out that "(R&D) is not industry wide. Some manufacturers are not set up for low-volume customization like we are. We have a (department) called Product Development specifically dedicated to work with our customer engineers."

Getting back to specifics, i.e.—sensors for pumps. Is one type of sensor more difficult to produce than another? That probably depends on the sensor application. Remember, we're talking life-and-death here.

"In many applications, our customer is looking for a high level of performance from the sensors," says MSI's Smith. "Typically, they want sensors with good accuracy, repeatability, long term stability, etc. Basically, the pressure sensor that goes into a kidney dialysis machine needs to perform better than the one that goes into a refrigerator or irrigation pump."

Adds Faizullabhoy, "A medical-related sensor has to have much greater MTBF (mean time between failure) requirements, meet stringent regulatory approvals and is typically integrated in customer-designed pumps. Each has their own set of challenges of packaging and integration."

So what's next for sensors? Sure, we just *know* that they will get even smaller as the technology advances. But what else?

"There are a couple-dozen frontiers for sensors in medical applications," says Smith. "To name a few—sensors will be finding their way into implantable applications; more sensors in monitoring the home healthcare patients; sensors in providing well person monitoring to give very early indications of an impending medical problem. Also, very low power sensors that will operate for years from small batteries or from electrical power generated inside your body using biochemical cells."

At Cosense, Faizullabhoy says the Next Big Thing will be "Integrating other functions for monitoring as part of the ultrasonic sensor. For example, flow control and temperature. (There will be) demands for sensors to become smaller, more sensitive, multifunctional. Also, many devices are now employing Bluetooth technology, i.e.—no magnetic sensor involved in operation of the device. I hope the Bluetooth technology proves 'too costly' in regards to power consumption within the device. This will, over time, return (makers) to magnetic sensing devices."

And while the sensor industry is not experiencing any acute problems, it's not all clear sailing, according to MSI's Smith.

"The biggest problems confronting medical equipment manufacturers in general are meeting and keeping current with FDA requirements; managing their supply chain to maintain the high quality levels expected; avoiding and mitigating litigation from customers and patients; and trying to figure out how to navigate the health insurance maze, government-sponsored care and the evolution of patient care toward new paradigms in the next decade."

Today's various sensor-pump combinations have taken medical device capabilities and applications beyond the unimaginable. Better health, longer life and shorter hospital stays are just a few of the benefits (photo courtesy MSI).

But all of this aside, one paramount truth is that medical sensors are playing a revolutionary role in our improving quality of life and extended lifespan.

For example, "Portable infusion pumps for drug and pain therapy that can be worn by the patient on the hip are a good example of improving the quality of life," says Cosense's Faizullabhoy.

And at MSI: "Our sensors are being used in wearable insulin infusion pumps," says Smith. "They give patients freedom to conduct normal lives and avoid the periodic insulin injections that were used a decade ago. We've also been involved in wearable pumps that provide medication infusion to control chronic pain and even provide low-dose, continuous chemotherapy."

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