

Medical Design

Resource Article

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Exploring the ways to buy sensors you design into medical devices.

The key to becoming and staying a leader in the booming medical device industry is to aggressively launch new, never before seen devices. These devices should perform a function not previously possible, be smaller, faster, less expensive and more multi-functional than their predecessors. With the \$100 billion market expected to explode to \$300+ billion over the next few years, it is safe to say there will be growing demand for these products. Conversely, there will be more competition, more FDA scrutiny, more competitive pricing pressure and more rattling from the financial sector to pump out more state-of-the-art devices to satisfy the Wall Street darlings.

So, how does a designer satisfy all these masters? Better, faster, cheaper products sure sound good, but we have always heard you can only have two of these three benefits. Maybe not.

There is a lot of chatter and speculation about new supercharged technologies that are poised to impact next generation designs. These include nanotechnology, bioabsorption, smart materials and the like. But what are some processes you can implement immediately to make existing and future designs more reliable, more multifunctional, more affordable and easier to manufacture?

The answer may be a relatively low technology soldier that can breathe new life into current, as well as future, designs. It does its job so well, sometimes it is overlooked when designers

are attempting to carve out a new niche of technological superstardom. It's the sensor.

Sensors have been used in medical devices since their beginning. But some new technologies, designs and manufacturing techniques have combined to create exciting ways to quickly incorporate multiple sensing technology into medical devices. Imagine the ability to sense two, three or more parameters without adding to the cost, weight or size of a device. This may not be as revolutionary as nanotechnology, but there are simple, easy ways to make more reliable devices multi-taskers right now.

There are dozens of parameters to sense and an equal number of ways to sense them. You are most likely sensing current, force, humidity, flow, infrared, liquid level, load, pressure, position, temperature, turbidity and ultrasound, to name a few. Then one can add other actuating, controlling and monitoring devices such as flexible or rigid heaters, thermostats, indicators, instruments and recorders. These components all need sealed, limit, pushbutton, key, relay, toggle or rocker switches or combinations thereof.

So, how do you as a designer sort it all out to come up with a new, differentiated product quickly and easily using sensor technology? With all the combinations and variations available, it may seem overwhelming.

Upgrading your current device's sensing performance may be done with some simple redesigning that adds very little cost and may streamline current manufacturing. But the answer to getting it done correctly is to choose a vendor who not only supplies the right sensor technology, but one who can provide the service, medical industry requirements, innovation, performance and regulatory expertise that may be required.

To learn more about Honeywell sensors and switches for the medical design field, visit www.honeywell.com/sensing.

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Let's say your current design senses only temperature, and adding flow and humidity sensing would make your device the only one in its class to sense all three parameters. You can choose one of three ways to obtain these sensors:

1. Buy 3 sensors from 3 vendors. Calibrate, mount and test the final assembly yourself in your own manufacturing plant.
2. Buy 3 sensors from 3 vendors. Then hire a contract house to assemble on a pc board, calibrate, test and ship back to you.
3. Buy 3 sensors from 1 vendor. This single source programs, incorporates intelligence into the chip and harmonizes the communications protocols to eliminate multiple communications platforms. Then they test, calibrate and ship to you a combination sensor with a connector that is a plug-and-play module ready to install in your device. Intelligence includes, but is not limited to, data transformation, signal filtering or conditioning, analog-to-digital conversions, self-diagnostics, control logic, memory, and bus communications compatibility.

If you are a medical device designer and you are purchasing your sensors using steps one or two above, beware. You may be shortchanging your designs, adding cost, adding weight, complicating your design and production cycles, diluting your competitive advantage and delaying FDA clearance. Let's look at the pros and cons of each of these methods.

Three sensors from three vendors.

Most sensor companies tend to specialize in one or two "measurands." This means they typically design and manufacture pressure sensors or humidity sensors. One perceived benefit of these vendors is they are temp sensor experts, so you will get the best temp sensor available at the lowest price because this is their specialty. A disadvantage to buying sensors in this manner is that three sensors bought from three vendors may not be able to communicate with each other. If this is the case, this disparity will need to be dealt with at some point in the device, the controller or the motherboard.

Something else to consider: If you source from three vendors who ship you the sensor, now you have the responsibility of testing, calibrating and mounting the individual sensors into the subsystem. This scenario involves multiple sources and divided responsibility for overall quality, delivery and reliability. So while the perceived expertise and price at first glance is appealing, you may have to deal with communications protocol and assembly work later.

Three sensors, three vendors, one contract manufacturing house.

The second choice is to source your three sensors from three separate measurand suppliers and have them ship the sensors directly to a contract manufacturer who does the testing, calibrating and mounting. The benefit here is this precludes the need for your operation to perform these tasks, so you are still able to keep sensor costs low. You receive a complete subassembly that is inspected and ready for final installation.

A disadvantage, however, is that you have added a fourth vendor into the mix. Now you have another project to manage, another company to qualify, certify, trace, supervise and pay. Not only are there more "bodies" requiring communication and supervision, but adding vendors tends to protract schedules, increase QA checks and cause other delays in shipping, paperwork and so on. And, you may still have a communications protocol issue as well as divided responsibility for overall quality, delivery and reliability.

Three sensors from one supplier who handles the whole project.

Your third choice is to acquire all three sensors from one vendor. This method may initially appear to be more costly and carry more risks. Also, you may not obtain the high level of operational and manufacturing experience of those companies that focus on one or two sensor types. Your management may consider using multiple sensor vendors a good strategic plan to avoid price hikes or stock-outs.

But choosing a single vendor who specializes in multiple sensor technology can make a designer's life simpler in many ways. First, it can eliminate the costs and time involved with using multiple vendors. Many companies are going through drastic vendor reduction programs, so reducing sensor vendor count can be a big plus. Not only will this save you time, it will save your company money and score points with your Procurement Department.

Second, there are numerous advantages to having multiple measurand capability on a single chip. Having a single communications protocol eliminates the need to accommodate disparate communications elsewhere. It can eliminate possible signal rationalization that is needed to control the device. A single communications protocol means the three sensors can act together to give your device a new level of sophistication without adding cost. A single chip is more reliable because there are fewer connections. It simplifies assembly because fewer connections mean less soldering and testing. A single connector on a combination sensor gives you plug-and-play capability. A single combo sensor can be hermetically sealed to give you moisture resistance. This is almost impossible to do using discrete sensors. A combination sensor can

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also consume less power than three separate sensors and can deliver multiple sensing ranges. It also yields a less complicated layout.

Third, this sensor company can mount the sensors to a PC board, calibrate them, and add intelligence, diagnostics and communications capability. They do final testing on the resulting sensor subsystem before shipping it to you. This scenario gives you a single sensor subsystem source completely responsible for the overall quality, delivery and reliability.

Fourth, forging a relationship with a single full-service supplier can help with your next generation of designs. In addition to helping you quickly upgrade the sensing performance of your existing design, having a supplier with depth, innovation and experience in the many disciplines that contribute to the end sensing technology product will be invaluable. Having such an affiliation, along with trust, respect, and knowledge of your short and long range goals for designs will enable this supplier to contribute a great deal of horsepower to your next generation of devices. Such a relationship also fosters collaboration among your other vendors, suppliers and associates. This relationship can also give you that valuable, critical outside expert perspective.

So, how do you choose this key supplier? Here are some of the traits to look for in a medical device sensor provider.

- A very broad sensor portfolio that encompasses the ability to sense many parameters in several ranges and environmental conditions. Companies specializing in one measurand can give you “monovision” that can limit your designs.
- A proven track record of providing sensors and value-added sensor subsystems to medical OEMs.
- A reputation for quality, reliability, on-time delivery, application expertise and creative problem solving. Get recommendations. Check for depth and expertise, in-house design, electronics intelligence, instrumentation, research, regulatory, engineering, communications protocol, testing, intellectual property and manufacturing.
- Financially strong and secure. Provides good sales, service and application support globally.
- Delivers value that adds to your bottom line. Remember, while a combination sensor might at first glance seem to be more expensive than individual measurands, to do an accurate comparison, be sure you are tallying up the processes, labor, time and other costs associated with using individual sensors.

- Devotes the proper engineering, regulatory and research resources to your project up front. Get this company involved early to get the best recommendations.
- Takes a holistic approach to your designs. They should be eager to know about your current and future plans so their designers can help you with your whole device, not just what the sensing portion touches. They should be willing to work with and augment the efforts of all of your associates and vendors.
- Offers a liberal sampling program. They should be willing and able to give you several styles of housings, sensing ranges, protocols and connecting options for you to try before you buy.
- Wireless technology capability. This may be the key ingredient in your next generation design.