

Pressure-Sensing Systems for Medical Devices

Combining sensors with microcontrollers and communications technology can create new devices that enhance patient care and lower healthcare costs.

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TODAY'S HEALTHCARE environment is characterized by what seem to be irreconcilable demands: patients are calling for better care, while healthcare providers and insurance companies are seeking increasingly cost-effective diagnoses and treatments. The challenge to the medical product industry thus becomes how to design more-intelligent devices that offer benefits to both constituencies. Fortunately, the industry can incorporate unprecedented sophistication in its products by using innovative new sensing technologies and wireless communications. For optimal patient care, the manipulation of a patient's critical-care information is an absolute necessity for today's medical devices.

One industry response has been the development of portable systems designed to perform multiple complicated tasks and to operate in a home or other nonhospital environment. Studies have shown that patients recover faster and respond better to ongoing treatment in the comfort and familiarity of their own homes than in a hospital. On the other hand, healthcare providers see home care as a significant cost-cutting measure, because it reduces or eliminates the hospital's or healthcare facility's overhead.

Systems that can manipulate patient data and be fully integrated within the patient-provider network also offer multiple benefits. Insurance companies in particular are very interested in tracking whether and how well a patient complies with his or her doctor's orders. They argue that lack of patient compliance is a primary reason for multiple and prolonged hospital stays—thereby driving up insurance premiums for everyone. For example, the inclusion of tracking capabilities in drug-delivery devices can provide an accurate record of when medications are taken and whether correct dosages have been administered. With enhanced communications technology, it is possible for patients to routinely relay this information to healthcare providers over the Internet. After a review of pressure-sensor functionality and levels of sophistication,

this article discusses how intelligent pressure-sensing systems can play a key role in medical devices designed for a variety of applications.

PRESSURE SENSOR TECHNOLOGY

Many diagnostic and therapeutic devices incorporate pressure sensors made with piezoresistive semiconductor technology. The manufacture of these solid-state sensors involves bulk micromachining and surface etching of silicon wafers to create chips capable of producing a voltage output that depends fairly linearly on applied pressure. This linear dependency allows for time-varying output signals that effectively map the applied pressure. Figure 1 depicts a typical cross section of a pressure sensor, and the graph in Figure 2 shows the typical relationship between applied pressure and output voltage.

Sensor manufacturers typically offer three types of pressure sensors: uncompensated basic elements, temperature-compensated and calibrated sensors, and integrated sensors. Depending on the requirements of a particular device, a designer or engineer may specify any one of the three.

An uncompensated pressure sensor is a bare-bones part, usually chosen to minimize cost when accuracy is not a critical factor. It requires



Chip-Pak medical-grade temperature-compensated pressure sensor packages from Motorola's Sensor Products Division (Phoenix).

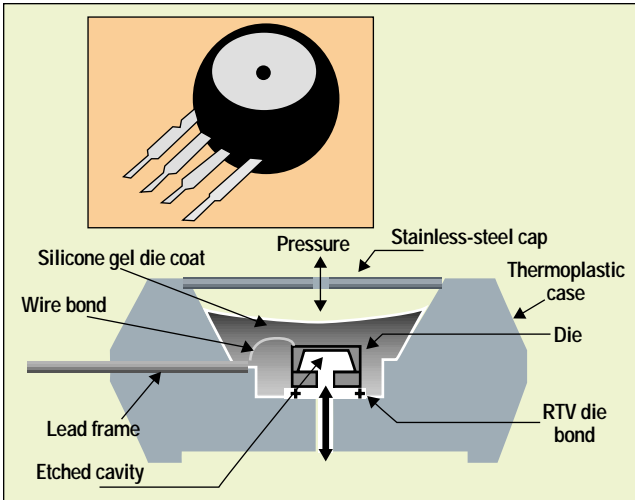


Figure 1. Cross section of a basic pressure sensor die, showing etched cavity and top circuitry.

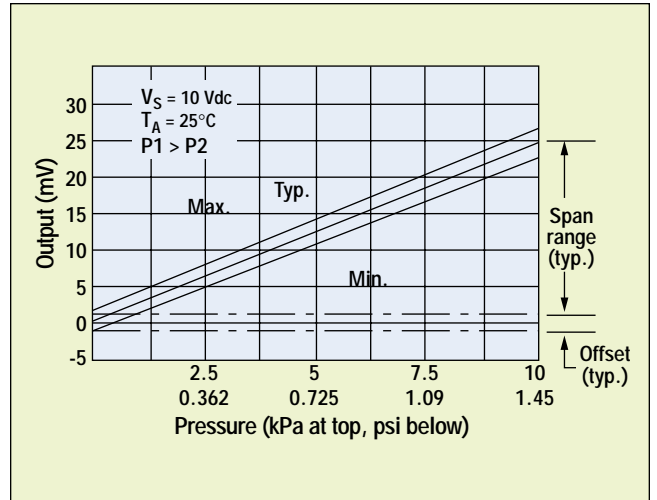


Figure 2. Graphic representation of typical pressure and voltage signals.

signal conditioning, such as amplification and noise filtering, to produce usable output signals.

Temperature-compensated and calibrated devices are manufactured with minimal offset and compensated for temperature with a built-in resistive network. As with uncompensated devices, these products require signal conditioning, because output voltages are in the low-millivolt range.

Integrated devices are also temperature compensated and calibrated, but in addition they are signal conditioned, producing a signal that is anywhere between 0 and 5 V.

Temperature-compensated and integrated sensors are the most widely used in medical devices. When very specific signal-conditioning and resolution requirements must be met, a temperature-compensated device affords the designer full signal control. For ease of implementation and reduction in board space, an integrated device is appropriate and may actually provide the least expensive system-level solution.

INTELLIGENT PRESSURE-SENSING SYSTEMS

Intelligent pressure sensing is a system solution that combines pressure sensors with microcontrollers and communications technology to create devices that can aid in providing better patient care and lowering healthcare costs. Digital manipulation of a real-time pressure signal can enable physicians and caregivers to monitor drug administration, vital signs, and patient compliance. In devices for the

home-use market, intelligent pressure-sensing systems are allowing physicians to remotely measure blood pressure, administer precise quantities of drugs or oxygen, and track patient compliance, all in a closed-loop system via the Internet.

The pressure sensor is the critical element of any intelligent pressure-sensing system because it provides the fundamental analog signal that is either processed by an analog-to-digital converter (ADC) or fed directly to a microcontroller.

Figure 3 depicts the building blocks of such a system. In a typical application, pressure is sensed by placing the sensor near the source of pressure. In a dynamic pressure-sensing application, the sensor port can be located inside a tube to

measure the pressure of moving fluid, for example. For static pressure, a common method is to sense a column of air. In both of these cases, the resultant signal is a voltage. This voltage signal is then fed into an ADC, which produces a certain number of digital counts that are read by a microcontroller and interpreted as a pressure value. Depending on the specific application, the microcontroller can simply provide data to a display or it can use the pressure signal and appropriate software to control a mechanical or electrical device, such as an alarm, valve, or data-acquisition system. The microcontroller can also be used to drive data-transmission hardware, such as radio-frequency telemetry systems.

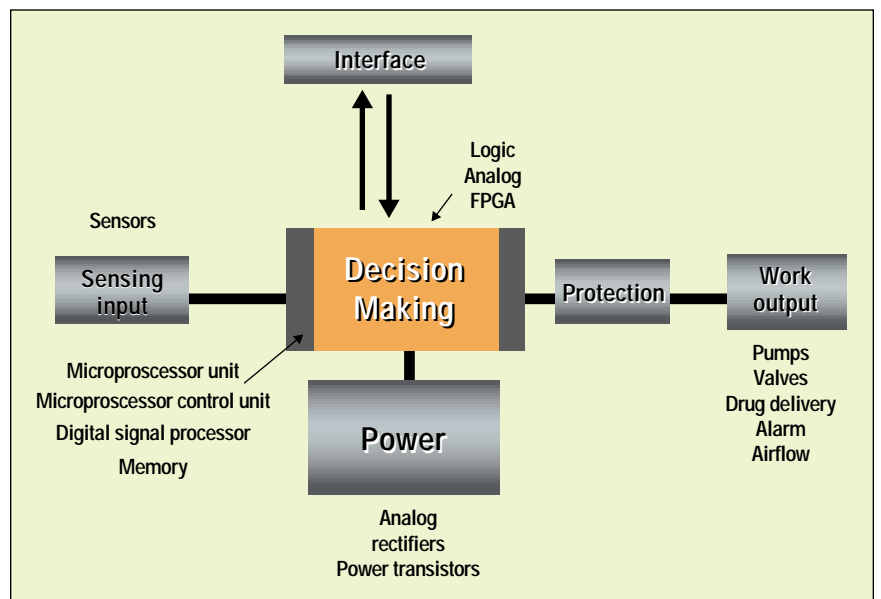


Figure 3. Schematic diagram of an intelligent pressure-sensing system.

MEDICAL DEVICE APPLICATIONS

In most medical applications, sensors are used to measure either gauge or differential pressure. Several physical parameters can be extracted or calculated from these pressure measurements, including volumetric flow rates and total fluid volume transferred. Pressure-sensing systems can also act as switches when a certain pressure threshold is reached, thereby performing subsequent functions. Among medical applications for which intelligent pressure-sensing systems are appropriate are respiratory devices, drug-delivery systems, and patient monitors. As technological advances continue, wireless systems will extend such products' capabilities.

Respiratory Devices. The respiratory device market comprises both diagnostic and therapeutic equipment. Diagnostic devices include spirometers, peak expiratory flow-rate meters, plethysmographs, and ergometers, while therapeutic equipment includes nebulizers, humidifiers, oxygen therapy equipment, continuous positive-airway pressure equipment, and ventilators. Together, these devices serve patients with three major respiratory disorders: asthma, chronic obstructive pulmonary disease, and sleep apnea (a cessation of breathing during sleep). A recent Clinica Reports study estimates the worldwide respiratory device industry segment will increase from \$1.6 billion in 1998 to \$1.9 billion by 2003.¹

Intelligent pressure-sensing systems are playing an increasing role in portable respiratory devices. For example, airflow rates, which are typically expressed in liters per minute, can be calculated by measuring pressure and using known fluid dynamic principles. One such device is a handheld spirometer developed by Micro Medical Ltd. (Gillingham, Kent, UK). In addition to measuring peak flow rate, this device is capable of storing information and downloading it to a computer program with graphics and analysis capabilities. The data can also be downloaded from a patient's device and viewed by a healthcare practitioner to assess progress between encounters.

Drug-Delivery Systems. In recent years, the U.S. market for controlled drug-delivery systems has increased significantly, from an estimated \$2.3 billion in

revenues in 1994 to an estimated \$3.2 billion in 1999, according to USData.com. As in other device industry market segments, increasing concerns over rising healthcare costs have led to the development of novel drug-delivery systems that are also cost-effective. One example is an inhaler that delivers drugs orally to asthmatics. Often these patients do not have the lung capacity or manual dexterity to operate a purely mechanical device. An electronic device that can sense a very low inspiratory pressure can activate a mechanism that automatically delivers medication into a person's lungs. With an intelligent pressure-sensing system, controlled dosages are possible, together with complete patient tracking.

Patient Monitors. Used to determine alterations in a patient's condition, patient-monitoring systems provide continuous measurement of clinical parameters such as heart rate, blood pressure, temperature, respiration, and oxygenation. The trend in this approximately \$2 billion market has been toward the development of multiparameter systems that are portable, modular, and able to interface and integrate with healthcare information systems. Additionally, some systems offer users the flexibility to customize the parameters measured, while the most sophisticated monitors possess the ability to respond to changes in vital signs. For example, Siemens Medical Systems (Iselin, NJ) has introduced an interactive function to its Automode ventilator, which automatically takes over if the patient's breathing ceases.² In such interactive devices, an intelligent pressure-sensing system is essential, particularly for full control of respiration and oxygenation functions.

Both invasive and noninvasive blood pressure monitors are currently available. Although noninvasive systems are preferred—because their use is less costly, poses less risk of patient infection, and offers patients greater mobility—invasive monitors are more accurate. Thus, there has been a push toward achieving improved accuracy and performance with noninvasive methods. With clever placement and enhanced packaging schemes, solid-state pressure sensors, by nature of their real-time response, can provide device designers with the means to create such monitors.

Future Solutions. As wireless technology continues to advance, the medical device industry will no doubt incorporate this capability in many of its new products. Indeed, medical technologists have described the hospital room of tomorrow as one with few or no wires attached to either the patient or the equipment. Bluetooth—a technology which provides for short-range 2.4-GHz radio networking—is expected to play a major role in the migration to wireless medical systems that would enable remote real-time patient monitoring. With such systems, critical parameters could be recorded on a continuous basis while the patient experiences full mobility.

Pressure-sensing technology will also evolve, and sensors are expected to be further integrated into medical devices, with the goal of providing more functionality in increasingly smaller packages. Solutions are possible, for example, in which a pressure sensor die will be merged with microcontroller functionality in creative packages to provide enhanced systems solutions.

CONCLUSION

To meet the demands of the patient community and of the healthcare and insurance industries, medical device manufacturers must continue to develop more-intelligent and more-capable healthcare products. One way they are achieving this goal is with the use of intelligent pressure-sensing systems. When integrated with the latest microcontroller and communications technologies in respiratory, drug-delivery, and patient-monitoring devices, solid-state pressure sensors can significantly increase product capability and patient compliance while reducing healthcare costs.

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