

Application Note

The Role of Pressure Sensors in Medical Devices

October 2009

The current state of healthcare today in the US is one which focuses upon cost containment, while at the same time, providing the advancements of modern technology to an aging population. Finding effective treatment methods at affordable levels, while at the same time providing patients with high quality care is certainly a tightrope act many healthcare providers walk.

So, what is the industry to do?

Not providing care and services is certainly not an option; therefore, the medical industry must find innovative solutions, incorporating the latest technology, thereby providing the most effective level of healthcare, both in and out of the hospital environment.

One solution is to integrate various sensors into intelligent medical devices. The focus here is to address pressure sensing technologies to monitor, control or measure key patient parameters with higher accuracy and reliability.

Typical pressure sensing applications range from common everyday uses and life support to exotic investigational devices. Devices addressing measurements as blood pressure cuffs, sleep apnea detection, respirometers, anesthetic control, air concentration, Swan-Ganz catheters, implanted cardiac measurement, gastrointestinal pressure sequencing, and other applications benefit from advancing sensor technology.

Typically, medical pressure sensors are used to measure gage or differential pressures. Measurement of these pressures can then be used to calculate volumetric flow rates as well as fluid, gas or air volumes. In fact, a pressure sensor can also act as a switch, communicating to a control unit as to when a preset pressure threshold is being met in order to cease, continue or change a treatment method.

Pressure sensors are generally used to monitor a patient's condition, be installed within respiratory devices, or be utilized with drug delivery systems.

The ultimate goal for medical device manufacturers' is to continue the development of intelligent devices that enhance the effectiveness of patient care while keeping the cost of that care or treatment method one that the healthcare provider can justify to the insurance industry and the patient.



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By making devices more intelligent while at the same time, decreasing size and increasing capability, more options become available to medical device manufacturers, allowing them to integrate sensors with micro-controllers and communication technologies, patient monitoring, respiratory devices, and drug-delivery systems, fully automating to the point of providing 24/7 information. Patients could possibly have increased mobility due to the smaller size of the devices and therefore not be required to be hospitalized during treatments, keeping the cost of healthcare down.

Here are several examples of pressure applications and pressure sensor technologies.

• Blood Pressure:

The market for blood pressure sensors is the largest medical pressure sensor market. There are two common types of blood pressure sensors; the standard manual or automatic sphygmomanometer better known as a blood pressure cuff. The second type of blood pressure measurement monitors pressure during surgery. Every time a patient goes under anesthetics, 2-3 external, disposable pressure sensors are used. A small IV similar to those used to draw blood samples is inserted in a vein in the arm and the sensor is typically located externally at the end of the blood filled tube.

• Cardiac Catheters:

The US National Institute of Health (NIH) estimates that there are 23M adults in the US with diagnosed heart disease. Each year, there are over a half million percutaneous coronary angioplasty procedures performed and 80,000 heart valve repair procedures. The overall market for cardiac catheters in the US alone is \$13B. Current state of the art uses a catheter filled with a saline solution and an external disposable pressure sensor. Sensors such as wedge pressure measure for cardiac diagnosis provide a natural application for pressure sensing.

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Investigation into permanent implanted sensors for devices such as optimum hemodynamic pacemakers, titrated drug dosages, or combined treatment effects are developing.

• Neonatal Catheters:

Approximately 3million babies are delivered in hospitals annually in the US. 20% of those require Cesarean Sections. Obstetrics presents the highest risk medical profession with obstetricians in many states and areas leaving the profession due to the high degree of professional risk of lawsuits. In all induced and complicated deliveries, an intrauterine catheter is inserted to measure the pressure on the infant's head during contractions. Some products also monitor the fetal heartbeat. The most common catheters are filled with a saline solution by the physician and connected to an external pressure sensor. According to several physicians, they have significant accuracy and ease of use problems with these sensors. A simple, easy to use solution would quickly find wide adoption in this area. Practicing physicians have estimated that the right solution would be used on every delivery and that the cost adder in the context of the total cost of the procedure is simply not an issue.

• Laparoscopic Devices:

Virtually all abdominal surgical procedures today are performed laparoscopically. A small incision is made, the abdomen is extended by filling with pressurized CO₂, and surgical cameras and instruments are inserted to perform the procedures. Procedures performed in this manner include appendectomies, gynecologic procedures, gall bladder surgery, hernia repair, tubal ligation, and general exploratory surgery among other procedures. Monitoring of GI internal pressure, force concentration, sequential stimulation could limit surgical damage, or aid in diagnosis of medical conditions.

• Endoscopic Procedures

Literature exists that describes the use of endoscopic tools to measure pressure in the esophagus. Some of these tools are described in technical application notes covering reflex forces with up to 32 pressure sensors mounted on a tube that is swallowed by patients. This information is useful in the diagnosis of acid reflux and other diseases of the stomach and upper GI track.

• Respiratory

Pressure sensors are used in applications targeting three major respiratory disorders: asthma, chronic obstructive pulmonary disease and sleep apnea. They are used in both diagnostic equipment to measure the pressure of air expelled from the lungs and in therapeutic equipment such as nebulizers, oxygen therapy equipment and ventilators. This market is primarily a non-invasive application of pressure sensing and could be supported by small, low cost devices.

• Other applications

Many other applications may be adapted to measure effects only now being investigated, including devices such as implanted systems that have a reservoir of drugs where dose delivery is controlled by measuring pressure. New types of air cushioned artificial limb interface with adjustable or controllable force can improve comfort as well as function.

So what sensing devices can make these applications possible?

Implantable sensors must be fully sealed with bio-compatibility and high cycle life. Sensors like these may be sealed with metal diaphragms or encapsulated with robust coatings. Signals can be passed through wire interfaces to devices such as pacemakers. Diagnostic sensors may pass signals through wireless connections to external receivers.

Miniaturization and low cost sensors can make dynamic measurement of breath in sleep apnea masks, or nasal cannula a possibility. Small, replaceable, and low cost units can enable OEM's to move the sensor to the mask for optimum sensitivity.

The use of MEMS devices with high sensitivity small size integral amplification and digital interface provide an opportunity to reduce cost and miniaturize high accuracy pressure sensing.

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