Measurement Specialties, Inc. 1000 Lucas Way Hampton, VA 23666 www.meas-spec.com 757 766 1500 - Fax: 757 766-4297



Medical equipment manufacturers and sensor experts can create state-of-the-art technologies working together.

Figure 1: Miniature Piezo film sensor enlarged about 10x

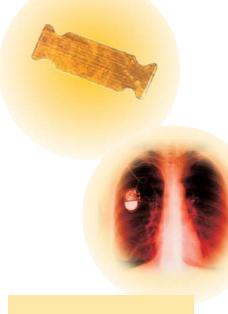


Figure 2: Pacemaker X-ray

The population is growing, people are aging, and modern medical miracles are available in plenty. To support this growth as more and more people seek medical help, there is a need to reduce manual labor and human error as well as to increase reliability and process automation.

The kind of intelligence needed to achieve these objectives can be provided with sensors. Sensors are used in equipment for surgical procedures, intensive care units, hospital recuperative care, and home care. There are many sensors already available in the market that could be integrated into medical equipment.

With medical equipment manufacturers and sensor experts working together, state-of-the-art technologies can be created. Selecting a sensor can be simple if the application and the parameters that need to be controlled are clearly understood.

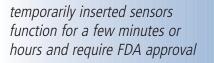
The most complicated sensors are implantables, followed by sensors used in catheters (through incision), sensors used in body cavities, sensors that are external but come in contact with body fluids, and sensors for external application. In this article, I describe sensor specifications for each of these levels and give examples of current devices being used.

#### **Implantable Sensors**

Implantable sensors need to be small, lightweight and compatible with body mass as well as require very little power. Most importantly, they cannot decay over time. Since these are Class III medical devices, they require FDA approval. Implantable sensors typically require two to four years for development and implementation. Generally, they are more expensive and require a specialist to surgically implant them.

The power requirement is one of the major challenges for working with implantable sensors. Sensors that can function with no power are perfect, but there are few in the market. Piezoelectric polymer sensors are small, reliable, require no power and last for a long time. Such sensors can be used in pacemakers that monitor activities of the patient.

The Piezo sensor is a tiny cantilever beam with weight attached on one end that flops with body movement. Every time the patient moves, the sensor generates a signal. The pacemaker gets these signals and makes the heart beat accordingly. If the patient is resting, the signal is zero and the pacemaker makes the heart beat at a nominal rate; for example, around 70 beats/minute. The sensor can differentiate between various activities such as walking, running, or other physical activities. The output of the sensor is proportional to the level of activity. A miniature Piezo film vibration sensor - 15/100 of an inch in length - and a pacemaker which houses it are show in Figures 1 and 2.



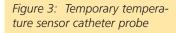




Figure 4: Intra-uterine Pressure Sensor There are other ways to power implanted sensors from external sources. When an RF energy wand is brought close to the location of a specially designed sensor located inside the body, the sensor wakes up, takes measurements, sends the data back to the wand by RF link, and goes back to sleep. A sensor with an antenna and a transpondent will do this job.

As an example, an abdominal aortic aneurysm requires a portion of the weak arteries to be removed and replaced with synthetic tubes. Such a sensor can be implanted during the procedure to monitor the pressure leaks at the surgical location.

#### "Temporary" Inserted Sensors

The requirements for sensors that can be inserted through an incision typically through a catheter—are less critical than those for implantables. This application is still sensitive and requires FDA approval. Depending on the surgical procedure, they need to function for few minutes to a couple of hours. Ideally, these sensors do not require external power to operate, but, if necessary, they can be powered by external means.

A pair of matched thermistors can be attached to the tip of a catheter, which can be guided to different locations of the heart to measure blood flow. Either they can be heated through the coil or flushed with cold saline to measure blood flow rates. When flushed with cold saline, the first sensor gets cooled more than the second because the blood flow warms up the saline that reaches the second sensor. Since the two temperature sensors are separated by a known distance and the temperature and the volume of saline is controlled, the blood flow can be calculated by reading the difference in the outputs of the two sensors. When cold saline is used, these thermistors don't require external power. Figure 3 shows this type of sensor.

Catheter ablation sensors are another example of sensors temporarily inserted through incision to effect specific treatments and/or to take measurements during treatment. Ablation is the process of selectively killing tissue to create scar tissue in order to re-route nerve impulse flow within the heart to correct abnormal arythmias. RF energy is often used in the ablation process. It is critical that the force applied by the catheter tip to the target tissue not exceed predetermined values to avoid any possibility of perforating the target tissue. Microfused sensor technology holds the promise of providing a triaxial force-sensing system able to measure tissue contact forces in all three dimensions simultaneously.

Silicon MEMS-based pressure sensors are used in intrauterine pressure (IUP) sensors to measure contraction pressure and frequency during childbirth. (See Figure 4.) This method is more reliable than conventional belts and is used in critical cases. Additional features can be built into these sensors such as amnion fluid infusion and extraction. These sensors are inserted through the uterus and reside in the amnion sack.



disposable blood pressure sensors, which are exposed to body fluids, provide continuous monitoring



Figure 5: Disposable blood pressure sensor

Figure 6: Infusion pump load cell to detect occlusion



Figure 7: Reusable NTC thermistors used to measure skin or body temperature

The sensor is taken out when the baby is ready to be delivered. These are disposable sensors.

Oral/rectal probes to measure body temperatures are designed to be small and rugged. The sensors are covered with a soft coating material to protect the inner layer of the organs from suffering damage.

#### **External Sensors Exposed to Fluids**

There are several disposable sensors where the sensor stays outside the body, but body fluids come in contact with it. One example is disposable blood pressure sensors (DPS). (See Figure 5.) These sensors are used in surgical procedures and ICU to continuously monitor the blood pressure of the patient. This is the ideal way to measure blood pressure when intravenous fluids (IV) are administered to the patient. These sensors are replaced once every 24 hours to maintain hygiene. This sensor module is plugged in to a monitor to log all information.

A few other sensors come in contact with medication and/or body fluids. One is the sensor used in the inflation of an angioplasty balloon. In this application, the pressure sensor needs to withstand more than 30 bars and monitor the pressure applied to inflate the balloon. Too much pressure can burst the balloon. Since medication and body fluids are coming in contact, a silicone gel barrier is used to isolate the rest of the sensor.

#### **Devices and External Applications**

Medical devices use sensors for external applications in which neither medication nor body fluids come in contact with the sensors. In most cases, these are non-disposables. They can either be used in hospital or home care applications. Examples include:

- load cells for infusion pumps that detect occlusion (tube blockage) (Figure 6)
- magnetic encoders in syringe pumps to detect flow rate, empty syringe and occlusion
- MEMS-based flow sensors used in spirometers to measure breathing strength of asthmatic patients
- extremely small MEMS-based accelerometers to study tremors in Parkinson patients
- Piezoelectric (and also pyroelectric) sensors for sleep apnea study
- MEMS pressure sensor array to monitor and measure the arterial pressures in the wrist
- MEMS and load cell-based sensors for the conservation of oxygen and also to monitor oxygen tank levels
- NTC temperature sensors to measure skin/body temperature (Figure 7)
- MEMS-based pressure sensors for cuff blood pressure sensor kits



About The Author	Bala Kashi is the Medical Products Manager at Measurement Specialties, Inc., in which capacity he designs sensors for many different medical applications. Mr. Kashi, who has worked with medical sensors for more than 20 years, is based out of Measurement Specialties' Fremont, CA design center and can be reached at bala.kashi@meas-spec.com.
About Measurement Specialties	Measurement Specialties offers multiple sensor technologies to medical device manufacturers, including: disposable and reusable silicon MEMS pressure sensors, low cost load cells, SpO2 Sensors, NTC thermistors for temperature sensing, thermopiles for non-contacting temperature sens- ing, capacitance-based humidity sensors, piezoelectric polymers as vibra- tion sensors, magnetic encoders, LVDTs, RVDTs, magneto resistive sen- sors, flow sensors, vibration and acceleration sensors. This broad capa- bility base allows the company to compare parallel technologies and bring the ideal solution for price and performance to the fore. Measurement Specialties has the ability to combine various sensor tech- nologies into one module which is unique in the industry. The company's experienced application engineers and product managers work with cus- tomers to achieve these goals.
	-