



Fig. 1 – MEMS ultraminiature sensors are well suited for integration into cardiovascular medical devices, including catheters and guidewires.

MEDICAL DESIGN BRIEFS

Ultraminiature MEMS Sensors for Improved Patient Outcomes

Ultraminiature sensors (<1 mm in size) enable instrumentation of medical devices in order to advance monitoring capabilities, deliver new insight into complex cardiovascular cases, and optimize targeted treatment therapies. These high-performance medically proven sensors can advance medical devices with real-time monitoring capabilities with less invasive access and more reliable results. Whether integrated directly into an existing medical device or added to a complementary delivery system or procedural accessory, ultraminiature sensors can enable new

revenue streams by increasing reimbursement opportunities or adding a new component to an existing sales channel.

MEMS Technology

Ultraminiature sensors are enabled by microelectromechanical systems (MEMS) technology, which integrates sensors or actuators, and sometimes its readout electronics, into a single, tiny silicon chip. Used in applications as varied as aerospace, oil exploration, and automobiles, MEMS sensors are proven for challenging environmental

conditions such as within the human body.

MEMS sensors have been developed to measure a wide variety of phenomena, including pressure, acceleration, sound, ultrasound, fluid flow, temperature, light, and many others. Moreover, many types of MEMS actuators have also been developed, including micropumps, tweezers, electrodes, ultrasonic stimulators, and more. These sensors and actuators can be combined into a single device to stimulate and understand the object of observation in multiple ways.

Ultraminiature Sensor Applications

An example of a MEMS sensor used in medical applications is the pressure sensor. As small as 0.25 mm on a side, MEMS pressure sensors offer a highly accurate and reliable method for measuring pressure in situ in various clinical conditions including heart failure, brain injury, airway obstruction, compartment syndrome, and spinal tumor pressures. Novel drug delivery, neuromodulation, and cardiac assist devices can also benefit from integration of high-fidelity pressure sensors. Sensors can provide closed-loop feedback, enabling increased device responsiveness and improved therapy outcomes, reducing facility costs and increasing the device value proposition. Medical specialties that benefit from pressure sensor-enabled medical devices include:

- Cardiology.
- Critical and emergency care.
- Oncology.
- Pulmonology.
- Neurocritical care.
- Ophthalmology.

Highlight on Sensors within Cardiac Guidewires and Catheter-Based Devices

MEMS ultraminiature sensors are well suited for integration into cardiovascular medical devices, including catheters and guidewires. For example, a device made by Millar can be seen in Figure 1. Understanding changes in pressure within the human circulatory system supports diagnostic decisions and reveals information about disease severity. With sensors on board, catheter-based devices provide a robust tool to navigate difficult paths in the human vasculature. Because pressure may be measured at the desired location only, this technology does not suffer from damping and resonance effects of fluid-filled measurement lines. Catheters incorporating MEMS sensors provide a more accurate measurement of pressure gradients — for example, across a heart valve to assess disease — and can diagnose and moni-

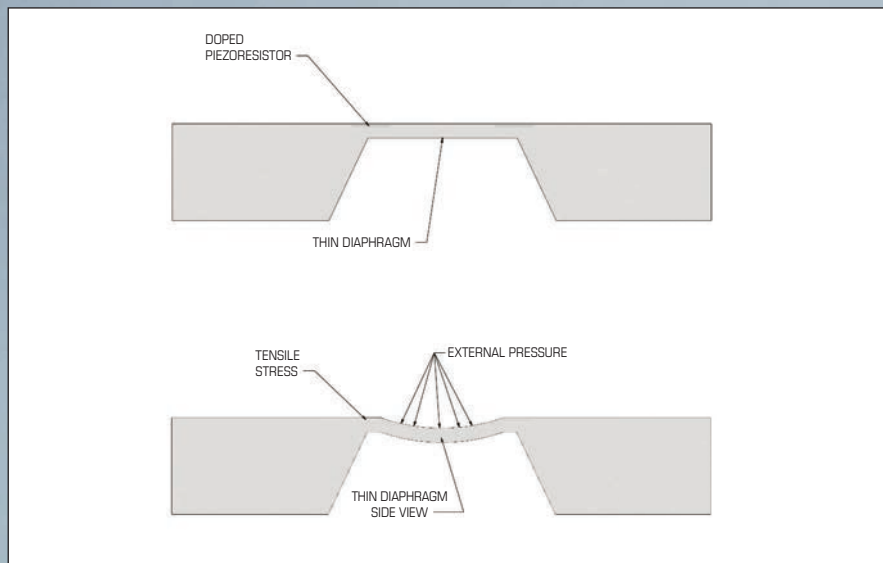


Fig. 2 – A MEMS sensor converts pressure signals into electrical signals by having implanted small strain gages, called piezoresistors, in a thin silicon membrane.

tor conditions like congestive heart failure and hypertension.

A MEMS pressure sensor operates by converting pressure signals into electrical signals by having implanted small strain gages, called piezoresistors, in a thin silicon membrane (see Figure 2). As pressure deflects the membrane, it creates mechanical strain. The piezoresistors, in turn, convert mechanical strain into a change in electrical resistance. Using a Wheatstone bridge, the electrical resistance can then be read out as a change in voltage.

The interface electronics are fairly simple and can connect to commercially available monitors and leverage existing device circuitry. This reduces system complexity, lowers overall project costs and increases speed to market.

Challenges

Biocompatible encapsulation and integration of the sensor are critical to the performance of the sensor and ultimately, the medical device. While sensor specs may meet the requirements of the medical device usage and application, improper sensor encapsulation could result in higher drift and lower accuracy of pressure measurements. Furthermore, sensors from the same wafer can vary slightly in performance and require compensation circuitry that effectively corrects for any manufacturing differences in the sensor signal.

There are also unique challenges to

consider during electrical interconnect and attachment to the sensor. Miniature sensors require working with small wires, such as 50 AWG, and must be handled carefully to avoid breakage and increasing manufacturing cost.

Integration into guidewires introduces added challenges to both sensor integration and sensor selection. Due to the small sizes required to navigate the coronary arteries of the heart, adding a MEMS pressure sensor to an existing guidewire or designing a new guidewire that incorporates a sensor requires specialized capability and MEMS manufacturing knowledge. The unique guidewire construction limits real estate for sensor wires, vent tubes and sensor housings. As a result, selecting the right sensor design at the start of the project can improve project success.

Testing for biocompatibility and electrical leakage or fluid ingress in initial stages can ensure a higher rate of success for future preclinical studies and for long-term commercialization. These are included in the rigorous testing and validation protocols for compliance to the IEC 60601 and AAMI BP-22 standards.

Finally, in comparison with consumer electronics, biomedical devices have lower annual unit volume, but higher per unit value. Due to the nature of their manufacture, MEMS sensors pose businesses challenges when manufacturing volumes less than one million

MEMS Sensors

units per year. The correct partners and vendors can create a supply chain to meet the needs of low-volume, high-value specialty medical devices.

Similar to working with an experienced architect and builder to build a home, working with an experienced development group for both the MEMS sensor and its integration into a medical device can reduce timelines, cost, and risk.

Conclusion

The applications for ultraminiature MEMS pressure sensors are numerous. MEMS sensors can provide significant improvements to the medical understanding of existing patient conditions, increase therapy efficacy and increase device capability. This can be achieved without the need to develop a new

high-cost interface circuit or stand-alone device, further reducing barriers to rapid market adoption of the MEMS enabled device.

Ultraminiature sensors also create the potential to combine multiple sensor modalities into one super device or procedure kit. The integration of a MEMS sensor can provide real time feedback on therapy efficacy, thereby reducing long term costs for end users. The addition of a new MEMS enabled device to a product kit can enable new revenue streams to existing sales channels by delivering capability that is not enhanced by sensing capabilities.

Ultimately, capitalizing on the potential of MEMS pressure sensors requires challenging many of the assumptions involved in the original

device development and an increased awareness of the total procedure in which the device is utilized. As more large medical device companies acquire compatible technologies to complement their existing devices and sales channels, new combined innovative devices may become the next step in advanced device development.

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