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White Paper: Challenges with MEMS Pressure Sensor Integration in Medical Devices

MEMS IN TODAY'S MEDICAL DEVICES

Today more value is being placed on enhancement of medical devices through miniaturization and added capabilities such as pressure sensing components. Proper integration of a MEMS pressure sensor in a medical device requires in-depth knowledge of sensor types, capabilities, validation and manufacturing requirements. The nuances of these processes to ensure quality and expected performance of the sensor requires in-depth knowledge from years of trial and error. By partnering with experts in this unique space, cost and time for sensor integration can be reduced dramatically.

BENEFITS OF MEMS SENSORS IN CLINICAL APPLICATIONS

MEMS pressure sensors offer a highly accurate and reliable method for measuring pressure in various clinical conditions including heart failure, brain injury, airway obstruction, compartment syndrome, and spinal tumor pressures. Drug delivery and neuromodulation devices can also benefit from integration of high-fidelity pressure sensors. Common medical applications include:

- Cardiovascular
- Critical care
- Oncology
- Respiratory
- Neurocritical care
- Emergency care

MEMS COMPARED TO ALTERNATIVE PRESSURE TECHNOLOGY

Fiber-optic sensors and fluid-filled sensors are alternatives to MEMS pressure sensors. Each technology presents different trade-offs that are necessary to be understood for proper use.

	MEMS	Fiber Optics	Fluid-Filled
High frequency response	YES	YES	NO
Measures pressure at source	YES	YES	NO
Robust design	YES	NO	YES
Accuracy during movement or bend	YES	NO	NO
No overshoot, true signal	YES	YES	NO

Fiber-optic sensors shine laser light into an optical fiber. The end of the fiber is often equipped with a flexible membrane that flexes in relation to applied pressure and temperature. Changes in the membrane are sensed by shifts in wavelength of reflected light. This sensor requires a reasonably complex receiving electronics system that also has to correct for temperature effects. Integration of these sensors requires care such that the bending of the catheter does not add additional strain over the signal being measured. Fiber optic cables within the catheters are fragile and may be prone to cracking, increasing integration costs. This is a known problem and most clinicians take adequate care to prevent such incidents.

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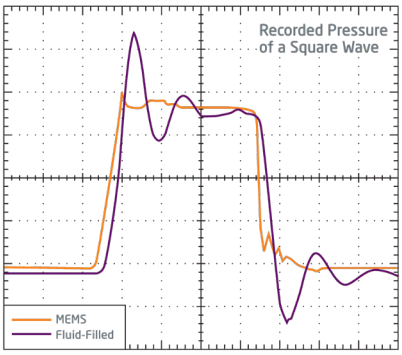
MEMS COMPARED TO ALTERNATIVE PRESSURE TECHNOLOGY

Fluid-filled sensors use an external transducer coupled by a fluid-filled catheter that communicates the pressure from the source. Problems associated with fluid-filled lines include viscous damping resulting from the long catheter and extension tubing. Further, dynamic pressure changes such as those produced in normal cardiac operation cause measured signals to peak much higher than the actual pressure. This results from resonance within the tubing system. Using fluid-filled systems is an art, and success depends on how the sensor is set-up and used.



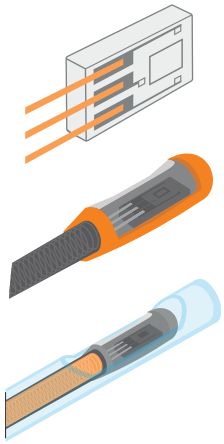
MEMS piezo-resistive sensors sense a change in resistance across a thin silicon diaphragm. This technology is widely used in industrial sensors and is well proven. The sensors are rugged and measure pressure only at the source. Over the years, Millar has perfected integration methods with these sensors to greatly reduce effects of drift resulting from manufacturing. Catheters built with sensor tips are robust and can navigate tortuous paths in the human vasculature. The interface electronics are fairly simple and can connect to commercially available monitors. Since pressure is measured only at the tip, this technology does not suffer from damping and resonance effects of fluid-filled lines.

MEMS SENSOR OPTIONS

The proper selection of a MEMS pressure sensor is critical to successful integration, functionality and manufacturabiity. There are a wide variety of features and options including size, configuration and gauge or sealed. Based on the application and required standards specifications, choosing the optimal sensor the first time provides great cost savings. A thorough understanding of testing protocols, knowledge of industry specifications and quality standards, and ease of manufacturability are all critical to the sensor selection and integration process. Millar offers 1F (0.014") to 3F (0.039") sensors but as an expert in MEMS sensors will also support the integration of a third party sensor.

SENSOR ENCAPSULATION AND INTEGRATION

Encapsulation and integration of the sensor are critical to the performance of the sensor and ultimately, the device. While the raw sensor specs may meet the requirements of the device usage and application, improper encapsulation could result in higher drift and lower accuracy of pressure measurements. There are also unique challenges to consider during wire stringing and attachment to the sensor. The miniaturization of medical sensors requires working with small wires, such as 50 AWG, and must be handled carefully to avoid breakage and increased manufacturing cost. Some devices may be more suitable to wall mounting the sensor while others perform better integrated directly into the device. Testing for biocompatibility and electrical leakage or fluid ingress in initial stages can ensure a higher rate of success for future pre-clinical studies and long-term commercialization.



MEMS Integration Stages - Catheter-based Sensor

MILLAR'S INTEGRATION PROCESS

While sensor integration can be a challenging path to navigate, Millar provides unique partnership opportunities to help guide companies through the process. Millar utilizes a staged approach to help confirm technology compatibility and long-term benefits of a continued partnership. Through feasibility studies, fit for purpose solutions and production of prototypes, Millar is quick to solve integration challenges and provide recommendations for the best path forward. *With nearly 50 years of sensor integration expertise and a dedicated engineering team, Millar is the partner of choice to bring new MEMS pressure sensor enabled medical devices to life.*

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