



Guide to Sensor Integration

Sensor Solutions: A Series

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Rev. A

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WHY CHOOSING THE RIGHT INTEGRATION PARTNER MATTERS

Choosing the right integration partner is a crucial decision for any company looking to develop and bring innovative sensor-based products to market. All devices come with their own unique restrictions and capabilities, making it essential to find the best way to make each device smarter. At Millar, our dedicated team of engineers understands this complexity and is here to guide our customers through the integration process. This thorough understanding allows us to suggest the best sensor and integration method tailored to your specific needs.

Partnering with a trusted and experienced sensor integrator like Millar ensures that the integration process is streamlined, risks are minimized, and the final product meets the highest standards of performance and reliability. With our expertise, you can accelerate your path to market success and confidently navigate the complexities of sensor integration. To best determine the optimal route of design, calibration, and testing, the following questions will need to be answered:

DEVICE DESIGN CONSIDERATIONS

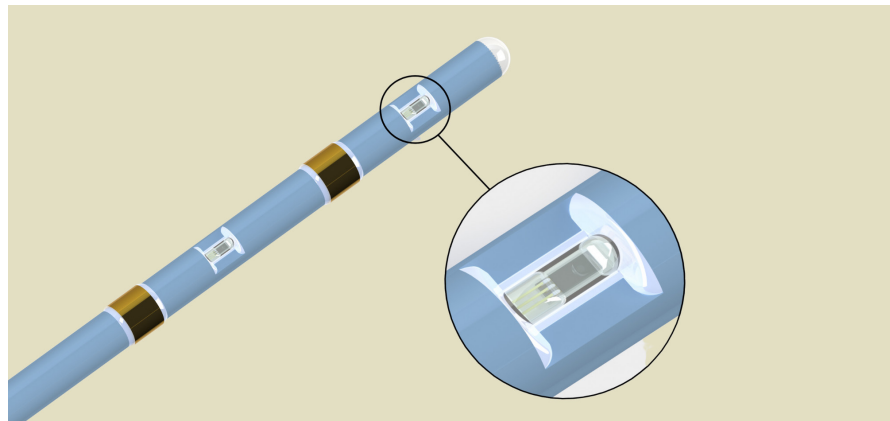
When embarking on the integration of sensors into medical devices, it's vital to consider several key aspects of device design. These considerations lay the foundation for successful sensor integration and the optimal performance of the final product. During the initial conversations, Millar's OEM engineers will conduct an investigation into the following device parameters:

- **Application Investigation:** Starting with a thorough understanding of the specific application for the device is essential for the integration team. Whether it's for cardiovascular or critical care applications, or even non-medical devices and uses, understanding the application drives the sensor selection and integration plan.
- **Implantation Duration:** The duration of device implantation directly influences testing protocols and sensor selection. Testing occurs for the planned duration of implantation, guiding decisions on sensor placement and functionality. Understanding this aspect is integral to both the sensor selection process and the overall device design.



DEVICE DESIGN CONSIDERATIONS

- **Single-Use vs. Reusable:** Understanding whether the device will be single-use or reusable impacts cost considerations and the type of sensors required. Millar has extensive experience with both types, ensuring that the integration process aligns with the device's intended use and lifecycle.
- **Insertion Method and Path:** Considering how the device will be inserted is crucial. Factors such as the type of introducer or guidewire required for catheter insertion play a role in the device's design. Millar's sensors, known for their small size, excel in navigating bends and curves, especially in cardiovascular applications. Understanding the intended procedures and the insertion method aids in defining the device design requirements.
- **Number of Sensors:** For devices requiring multiple sensors determining the quantity is essential. In catheter-based devices, the number of sensors affects the necessary lumens and the spacing between sensors, all of which are vital considerations.



- **Dimensional Requirements:** Specifications such as height, inner diameter (ID), and outer diameter (OD) of the device are important for designing the device around the sensors. These dimensions impact the sensor placement and the device's overall form factor and usability.
- **Additional Functionality:** Consideration must be given to whether the device requires electrodes for specific functions. Additionally, exploring the need for measuring pH, electrical conductivity (EC) or temperature opens possibilities for broader data collection and analysis.



DEVICE DESIGN CONSIDERATIONS

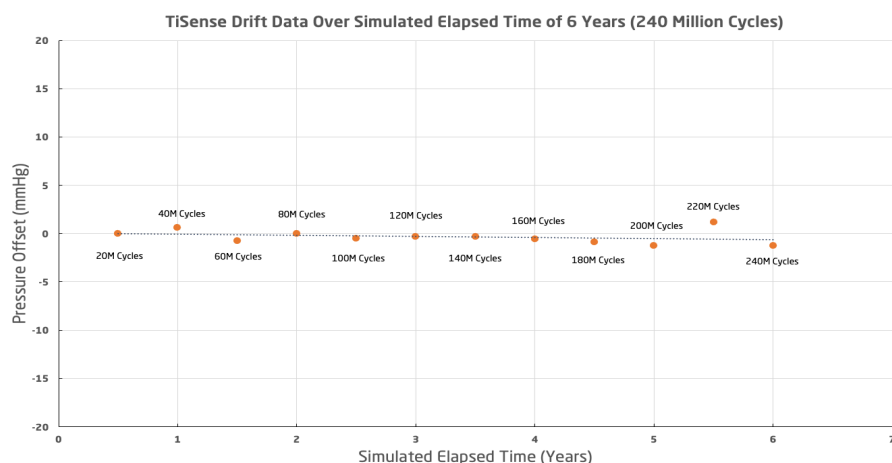
Taking these device design considerations into account ensures a comprehensive approach to sensor integration, leading to optimized device performance and enhanced patient outcomes. For a deeper dive into the importance of sensor selection, explore our [Guide to Pressure Sensor Selection](#) and [Guide to pH Sensor Selection](#).

CALIBRATION AND TESTING REQUIREMENTS

Ensuring sensor accuracy and reliability requires precise calibration and testing. Millar employs advanced techniques to minimize the impact of key variables, including temperature shift, drift, light sensitivity, nonlinearity, mechanical effects, and zeroing.

Addressing these requirements is important for successful sensor integration. Millar's dedication to advanced techniques and careful testing guarantees superior accuracy and reliability in sensor-enabled medical devices.

- **Temperature Shift:** Temperature sensitivity is inherent to MEMS sensors, leading to output deviations with even slight temperature changes. While sensors typically operate at stable temperatures, such as body temperature ($\sim 37^{\circ}\text{C}$), concerns arise during zeroing processes and temperature variations between zeroing and actual use. Both Millar's standard analog and digital board offer linear adjustment of temperature to minimize temperature sensitivity.
- **Drift:** Drift, the sensor output deviation over time, results from several factors like hydration of the sensor coating and equilibrium of sensor elements in new environments. Inherent changes in electrical components can also contribute. Millar collaborates closely with our customers to test for and minimize drift, a necessary step for long-term sensor stability.



Example of drift specifications for Millar's long-term sensor module, TiSense™



CALIBRATION AND TESTING REQUIREMENTS

- **Light Sensitivity:** Light exposure changes can affect sensor output, especially during zeroing. Since sensors often operate in dark cavities, zeroing conditions – whether in light or dark– can impact accuracy. Millar’s calibration processes account for these light effects to ensure consistent and accurate readings.
- **Mechanical Effects:** Mechanical forces on catheters or devices, such as bending, can influence pressure sensor readings. Design considerations must minimize these effects, especially on the sensor diaphragm. Millar draws from extensive design experience to address these mechanical challenges.
- **Zeroing Considerations:** Zeroing, the process of removing residual offsets, is crucial for accurate sensor readings. Factors like sensor temperature during zeroing versus use, duration of sensor operation before zeroing, light conditions, catheter orientation, and environmental factors (dry versus hydrated) all impact zeroing accuracy. Millar’s rigorous zeroing protocols ensure precise sensor calibration before integration into devices.

FULL DEVICE DESIGN

Millar is renowned for its expertise in sensor integration, but our capabilities extend far beyond. As an OEM partner, we offer a comprehensive range of in-house services, from wire stringing to custom design solutions, making us your ultimate one-stop-shop for full device design needs. We are committed to providing tailored solutions to support every aspect of full device design.

Our state-of-the-art headquarters facility in Pearland, TX has expanded our capabilities, enabling us to meet your requirements and guide you through the entire design-to-commercialization process. Throughout the integration journey, Millar ensures a thorough understanding of the steps to facilitate a seamless process:

- **Sensor Foundry:** Our pure-play microfoundry is the heart of our sensor development process. Whether you’re a small startup or a medium-sized device manufacturer, our microfoundry offers tailored solutions to meet your unique needs. With a focus on both off-the-shelf and custom solutions, we ensure the fastest path from initial design concepts to full device integration.
- **Project Management:** As your one-stop-shop OEM partner, Millar adapts its involvement to fit your project requirements. Our seasoned project management team oversees every aspect of your device design or manufacturing project, providing a seamless experience from inception to completion.



FULL DEVICE DESIGN

- **Commercialization Expertise:** Navigating the path to commercialization can be challenging and our team is here to guide you through the entire commercialization journey. As a Contract Development and Manufacturing Organization (CDMO), we have the expertise to assist at every step, from prototyping to final production.
- **Packaging Solutions:** The final packaging of your medical device is crucial for its safety, usability, and marketability. Millar's expertise extends to comprehensive packaging solutions tailored to your device's specific requirements.
- **Sterilization Protocols:** Sterilization is a critical consideration for medical devices, ensuring patient safety and regulatory compliance. Our team ensures that your device undergoes the appropriate sterilization protocols, meeting the highest standards of cleanliness and safety.
- **Regulatory Affairs and Quality Assurance (RA/QA):** Millar's RA/QA team is well-versed in industry regulations and standards, guiding your device through the approval process with confidence.

IN CONCLUSION

Millar has over 55 years of MEMS integration and catheter manufacturing expertise and our tested process is guaranteed to improve yields and relieve the challenges of integration, resulting in reduced costs and faster time to market. Proper integration of the sensor is critical to the performance of the sensor and ultimately, the device.

Therefore, many device companies are choosing to leverage the experience of sensor integrators like Millar. The integration of a MEMS pressure or pH sensor is an intricate and detailed process, but through feasibility studies, fit for purpose solutions and production of prototypes, Millar is quick to solve integration challenges to reduce the costs and timeline from concept to market. To learn more, or to speak with a member of our team, please don't hesitate to contact us at insights@millar.com.

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