

# Guide to [pH] Sensor Selection

Sensor Solutions: A Series

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#### WHY CHOOSING THE RIGHT SENSOR MATTERS

Advances in medical devices are helping transition the healthcare industry from a subjective mindset to that of a quantitative mindset. Smarter medical devices are enabling physicians and healthcare workers to produce quantifiable data that lead to more supportive diagnosis and better data-driven treatments, thereby contributing to an overall improvement in patient quality of life. This transition is being largely enabled by advances in sensor technology.

With over 50 years of manufacturing knowledge and industry expertise, Millar is the pressure and pH sensor technology expert when customers need innovative, integrative solutions to take their medical device from concept to commercialization quickly, efficiently, and cost-effectively.

Our OEM partnership process is designed to uncover innovative ways to reduce risk, lower costs and reach patients faster – together. A key part in that OEM partnership is the selection of the sensor. One of the most frequently asked questions regarding sensor selection is: "Which sensor is the best?" Of course, there is no simple answer to this question. Each sensor has certain capabilities and limitations, so to choose the correct option, one must first consider the following factors.

#### WHY MEASURE PH?

Measuring pH is essential in a wide range of applications, particularly in medical devices and various industries, due to its direct correlation with chemical reactions, biological processes, and environmental conditions. It is a means of indicating the hydrogen ion (H+) activity in products, which in turn, is the direct availability of free H+. The commonly used pH scale is from 0 to 14: a pH level of 7 is neutral, values below 7 are acidic, and values above 7 are considered alkaline or basic.

In the medical field, pH measurement is critical for diagnosing and monitoring numerous health conditions. Medical devices that incorporate pH sensors can provide real-time monitoring of bodily fluids, such as blood, urine, and saliva, enabling healthcare professionals to detect imbalances indicative of diseases. pH measurement facilitates timely diagnosis, effective treatment, and continuous monitoring of patient health. Millar is the only known company to produce ISFET pH sensors used in clinically approved medical devices.

Beyond medical applications, pH measurement plays a pivotal role in environmental monitoring, ensuring water quality in bodies of water and wastewater treatment facilities. Industries such as food and beverage, pharmaceuticals, and agriculture also rely on pH measurements to ensure product quality, control chemical processes, and optimize growth conditions.



#### pH SENSORS

#### ISFET METHODOLOGY

The ISFET (Ion Selective Field Effect Transistor) pH sensor represents a pivotal innovation in sensor technology, originally pioneered by Professor Piet Bergveld from the University of Twente, the Netherlands. Initially conceived for neural investigation, the potential for pH sensing was discovered through early experimentation with the ISFET in 1970.

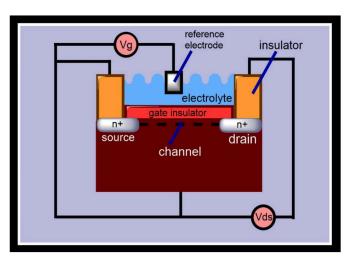
The ISFET methodology for ion measurement is developed on the basis of MOSFET (Metal Oxide Silicon Field Effect Transistor). The first attempts to use ISFET as pH sensors were made as early as 1970.

## FUNCTIONALITY OF ISFET SENSOR

An ISFET (Ion Selective Field Effect Transistor) pH sensor serves as a specialized field-effect transistor designed for measuring ion activity within a solution. Unlike conventional FETs where the gate is directly connected to the drain and source, the ISFET's components are arranged uniquely. In the ISFET, the gate is substituted with an external reference electrode, while a gate insulator ensures that the current passing through the drain and source is influenced solely by electrostatic means. This setup allows the amount of electrostatic charge buildup, and thus the current, to be contingent upon the quantity of H+ ions at the surface of the ISFET.

A circuitry is designed which steers the ISFET with a constant lds and Vds. The third parameter, the Vgs, is used as an output for pH.

Only a few components are needed for this circuitry to give an analog output. The speed of the signal is as fast as 10 microseconds and is dependent on the capacitors used in the circuit.



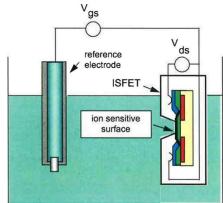


#### pH SENSORS

#### MOSFET VS. ISFET

The MOSFET's Gate, typically composed of a metallic coating, acts as an electrode to control the Drain-Source current using the external potential Vgs. However, in the ISFET, this metallic coating is replaced by a specialized oxide coating that is sensitive to hydrogen ion activity in fluids.

Millar employs aluminum oxide coatings in its pH sensors for the gate electrode, as this has proven to yield the best results for creating an H+ selective sensor. This technique is integrated seamlessly into the silicon sensor fabrication process. Additionally, an added "protection shield" further enhances sensor performance, providing significantly higher stability when exposed to incident light and even very high electrostatic discharges.

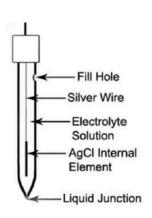


The principle of every MOSFET is the electrostatic control of the current flowing between the source and the drain via the potential of the gate electrode.

For the ISFET, this potential is mainly determined by the hydrogen ion concentration (H<sup>+</sup>activity) present at its gate.

#### REFERENCE ELECTRODE

Since the ISFET signal is floating and a changing element, there is a stable potential is required in the fluid to function as the Gate. The Reference system gives a stable potential of approximately 200mV in any aqueous solution and is not pH sensitive. The diaphragm (liquid junction) transports the ions between the Ag/AgCl wire and the liquid and therefore it has to be porous. The disadvantage of this is that the salty gel can migrate out over time and other substances can get in. Thermal cycling, and therefore expansion and contraction of the gel, can accelerate this effect. For medical applications, we have different solutions to prevent and or minimize this out flow.





#### pH SENSORS

#### **CONSIDERATIONS**

**Highly Accurate Measurement:** Millar's ISFET pH sensors offer exceptional accuracy, with a wide pH range spanning from 0 to 14. This expansive range ensures versatility across a spectrum of applications, from highly acidic to highly alkaline environments.

**Glass-Free Construction:** Millar's ISFET pH sensors are designed with glass-free construction, making them inherently more durable and resistant to breakage. This feature eliminates the risk of breakage during handling or use, ensuring long-term reliability in challenging environments.

**Robust Design:** Engineered for reliability, our ISFET pH sensors boast a robust design that can withstand the rigors of diverse medical devices and applications. This combination of durability and accuracy ensures consistent performance even in demanding conditions.

**Dry Storage Capability:** Unlike traditional electrodes that require wet storage to prevent drying out and degradation, Millar's ISFET pH sensors can be safely stored in a dry state. This simplifies handling and storage procedures, reduces the risk of contamination, and enhances ease of sterilization processes.

#### SENSOR SIZE

In the evolving landscape of medical devices, there is a growing emphasis on enhancing functionality through miniaturization and additional capabilities, including pressure & pH sensing components. Millar uses the French scale to denote our catheter casing requirements for sensor integration, where each French unit corresponds to a specific diameter.

One French (1Fr) is equivalent to 0.33mm (or  $330\mu$ m) in diameter, while Three French (3Fr) is equivalent to 1mm (or  $1000\mu$ m) in diameter. The most challenging applications require integrating a sensor into a 1F catheter body or inner lumen. Millar's sensors are commonly integrated into various medical devices, including catheters, probes, and monitoring devices.

#### **SENSOR FOUNDRY**

Tailoring solutions for small to medium-sized device manufacturers, our pure play sensor mircofoundry is the heart of Millar's sensor development process. We offer both off-the-shelf and custom solutions to meet our customers' unique needs, ensuring the fastest path from design to full device integration. Millar has strategic partnerships with leading MEMS sensor foundries for larger-scale projects. When you're ready to scale up, we'll be there to connect you with the right resources. Learn how our collaborations can drive growth for your sensor innovations.



#### **SENSOR FOUNDRY**

Whether you require low-volume, high-precision sensor manufacturing or rapid prototyping services, Millar's MEMS sensor foundry is your partner in sensor innovation. Our sensor portfolio includes Wheatstone bridge full and half-bridge pressure sensors, ISFET pH sensors, electrical conductivity sensors and more. Each step of the production process, from lithography to chemical vapor deposition, diffusion, and annealing, is carefully performed in-house. This meticulous approach ensures optimal sensor performance and reliability, backed by our state-of-the-art facilities including a testing factory, a fully equipped tooling shop, an electronic and PCB circuit design facility, and a comprehensive sensor and product assembly facility.

### PH SENSOR SPECIFICATIONS

Parameter	Value
Sensor	Glass-free Ion Sensitive Field Effect Transistor (ISFET) semiconductor
Range	0-14 pH
Size Range	Length 1600µm-3000µm Width 800µm-1000µm
Accuracy	+/- 0.02 pH
Resolution	0.01 pH
Drift Maximal (in pH7 @ 25° C.)	0.14 pH/day
Drift Typical (in pH7 @ 25° C.)	0.05 pH/day and lower
Calibration	1,2,3 and 5-point calibration
Automatic Temperature Compensated (ATC) calibration	Yes

Explore our Guide to Pressure Sensor Selection for more detailed pressure sensor specifications and an in-depth look at our pressure sensor technology. Ready to experience Millar's ISFET pH sensors firsthand? Our fully customizable R&D Evaluation pH Kit allows you to test integration with your existing medical devices and technology. Discover the possibilities and learn more here.



#### IN CONCLUSION

Millar has over 50 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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