Application Note

PENDOTECH
Leading Process Analytics

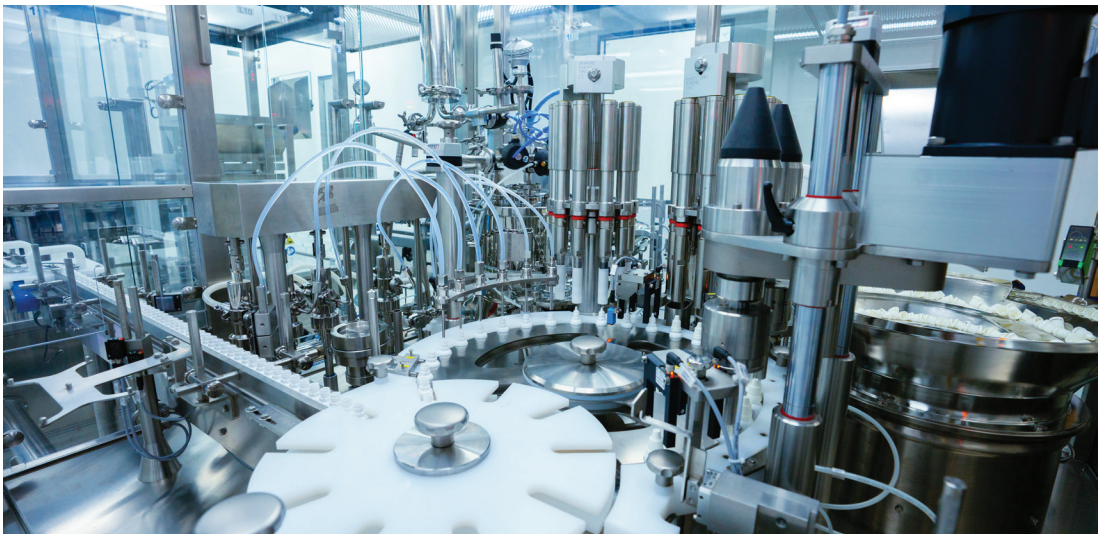
Versatile Sensor Solutions

Seamless Scale-Up in Biopharmaceuticals

The transition from small-scale research to full-scale GMP manufacturing in biopharma is frequently hindered by limitations in existing sensor technologies, such as limited line sizes and insufficient accuracy. These restrictions can impede product development and manufacturing and impact quality. To overcome these problems, versatile single-use sensor solutions with broad compatibility and precise monitoring capabilities are essential.

Background

In the evolving landscape of biopharmaceutical manufacturing, the transition from Research & Development (R&D) to full-scale Good Manufacturing Practice (GMP) production presents significant challenges. As processes move from small-scale experiments to large-scale manufacturing, equipment and components must be adaptable and scalable to maintain efficiency, quality, and regulatory compliance. However, current solutions often fall short, with limitations in line size options, a narrow range of connection types, and measuring instruments that lack the necessary range and precision. These constraints create bottlenecks that can delay development timelines, increase costs, and compromise product quality, highlighting the urgent need for more versatile, scalable, and accurate solutions to support process development and manufacturing.



METTLER TOLEDO

Application Note

Challenges

Customers in industries that demand precise and scalable measurement solutions often face key challenges that affect both their operational efficiency and the quality of their products. One major issue is the limited availability of line size options, which restricts their ability to smoothly transition processes from the early stages of R&D to large-scale production under GMP conditions. This gap often forces compromises or additional investments to bridge the scale-up process. Moreover, the lack of versatile connection types, such as hose barb, sanitary flanges, and luer fittings, further complicates system integration and reduces flexibility, as users may need to work with multiple incompatible components or invest in adapters.

Another major challenge is that current measurement solutions often have limited measuring ranges or lack the accuracy needed to satisfy the strict demands of diverse applications, which can vary from highly precise low-volume dosing to large-scale, high-throughput operations. These limitations can lead to inaccurate data, inconsistent product quality, and ultimately, increased operational risks. Therefore, addressing these pain points is essential for supporting seamless scale-up, enhancing system adaptability, and ensuring reliable performance.

METTLER TOLEDO Pendotech Solutions

METTLER TOLEDO Pendotech provides a range of single-use sensors with extensive line sizes and connection options designed to seamlessly integrate with a variety of downstream processing (DSP) unit operations. Recognizing the critical importance of accurately monitoring key process parameters such as pressure, conductivity, temperature, and UV absorbance in DSP, these sensors are offered with multiple fitting configurations. This versatility ensures that users can select the most appropriate sensor fittings to match their specific system requirements, tubing sizes, and process conditions, thereby optimizing installation flexibility, process reliability, and overall operational efficiency.

Single-Use Pressure Sensor

Measuring pressure in bioprocessing is essential for maintaining optimal process conditions, ensuring product quality, and safeguarding system integrity. Accurate pressure monitoring helps prevent equipment damage, detect leaks or blockages, and maintain sterile conditions critical for sensitive biological processes.

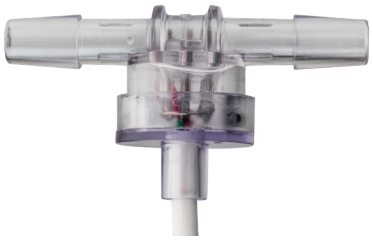
METTLER TOLEDO Pendotech Single-Use Pressure Sensors are designed to seamlessly integrate with transmitters such as the PressureMAT™ and Pendotech Process Control System, offering reliable data transmission and high accuracy up to 75 psi. Their design features—such as an unobstructed flow path, reduced hold-up volume, and compatibility with various tubing sizes and connection types—make them ideal for flexible tubing applications. The hose barb design secures tubing effectively and can easily integrate with retainers such as BarbLock and Oetiker clamps to provide additional security for higher pressure needs. Sanitary flange connections are available in multiple sizes (½, 1, and 1½ inches), allowing direct connection to filters.

Additionally, hybrid sanitary flanges with hose barb connections are offered for improved, seamless integration into systems. For smaller scale processes, polycarbonate and polysulfone luer connectors offer versatility and sterile connections, supporting a wide range of bioprocessing requirements.

Single-Use Conductivity Sensor

Ensuring complete buffer exchange is critical for maintaining process efficiency and product quality. METTLER TOLEDO Pendotech Single-Use Conductivity Sensors are specifically designed to support this need with a measurement range of 0.1 to 100 mS/cm, providing high accuracy across different conductivity levels.

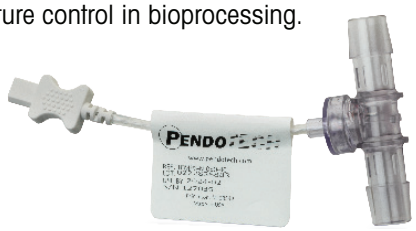
These sensors withstand pressures up to 75 psi (5 bar) and are made from fluid path materials that are gamma compatible. Additionally, they feature integrated temperature measurement for normalization, enhancing data reliability. Available in a range of polysulfone tubing options, along with hose barbs in various sizes, they provide flexibility to meet different process needs.



Single-Use Temperature Sensor

Accurate temperature measurement is vital in bioprocessing to maintain optimal conditions, ensure product consistency, and protect delicate biological systems. METTLER TOLEDO Pendotech Single-Use Temperature Sensors provide a cost-effective and reliable solution for single-use applications, with the added benefit of being autoclavable and reusable. These sensors are well-suited for bioreactor, filtration, chromatography, filling, and general process monitoring operations. They easily connect to a variety of monitors including the handheld TEMP340, the Pendotech Process Control System, and other pre-qualified third-party devices, with options available for standalone 4-20mA transmitters and benchtop transmitters for lab data acquisition.

Designed specifically for tubing integration, the sensors come with hose barb or luer connectors that ensure an unobstructed fluid path, eliminating pressure drops and dead legs at the measurement point. Sensors with hose barb connectors use a 10-foot reusable cable with molded connectors compatible with common monitors, while sensors with luer connectors have custom molded connectors with alignment guides to prevent incorrect connections. Quick-disconnect features and transmitter options enable seamless integration with PLC or control systems, making these sensors a versatile and effective choice for precise temperature control in bioprocessing.



Single-Use UV Absorbance

METTLER TOLEDO Pendotech offers a dual wavelength version of the PM2 Photometer, featuring two LED light sources that can output wavelengths of 260 nm, 280 nm, 300 nm, or 880 nm and measure two wavelengths simultaneously. This capability provides significant advantages in biopharmaceutical development and manufacturing by allowing for precise monitoring of sample absorbance at multiple wavelengths. For example, in bioprocessing, turbidity measurements at 880 nm can assess filter performance by detecting unclarified material directly from bioreactors or fermentors, indicating potential filter breakthrough and loss of capacity. When combined with pressure data during constant flow filtration, this offers a comprehensive evaluation of filter efficiency.

The Pendotech Turbidity Flow Cell enables continuous on-line turbidity measurement, eliminating the need for discrete, off-line sampling. Additionally, Pendotech's Single-Use UV Absorbance Sensors facilitate non-invasive detection of molecules of interest, typically measured at 280 nm, using a compact photometer and fiber optic cables. These flow cells integrate seamlessly into tubing systems via hose barb fittings, available in various sizes (1/2 inch with 1 cm path length, 1/4 inch with 5 mm path length, and 1/8 inch with 2 mm path length), and are cost-effective for single-use applications while being cleanable and reusable. This design includes a special glass window and compartments for the light source and detector, allowing accurate in-line absorbance measurements through the flowing sample.

Conclusion

Single-use sensor solutions are engineered to enable a truly seamless scale-up from R&D to GMP manufacturing by overcoming the key challenges encountered throughout biopharmaceutical process development and commercialization. Offering a wide selection of scalable line sizes and versatile connection options—ranging from hose barbs and sanitary flanges to luer connectors—these sensors ensure smooth integration across various system configurations and production scales. Combined with high-precision measurement capabilities for critical parameters such as pressure, conductivity, temperature, and UV absorbance, they provide reliable monitoring and control throughout every stage of production. This flexibility not only simplifies the transition from small-scale experimental setups to full-scale GMP production but also enhances operational efficiency, maintains consistent product quality, and supports strict regulatory compliance.

The comprehensive sensor portfolio from METTLER TOLEDO Pendotech empowers biopharmaceutical manufacturers to optimize their processes confidently, delivering a cost-effective, adaptable, and dependable solution for seamless scale-up across the entire product lifecycle.

METTLER TOLEDO Pendotech
Process Analytics

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