## **HAMILT®N**

## Innovative Solutions for Process Analytics

Biotech and Biopharma Upstream and Downstream



# Continuous Innovation for Biotech and Biopharma

"With our pioneering sensor technology, we solve biopharma challenges» More measurement parameters and less measurement error yield tighter process control

#### **Complete Portfolio**

Measure all critical process parameters which enable the holistic understanding and control of your process.

#### **Seamless Integration**

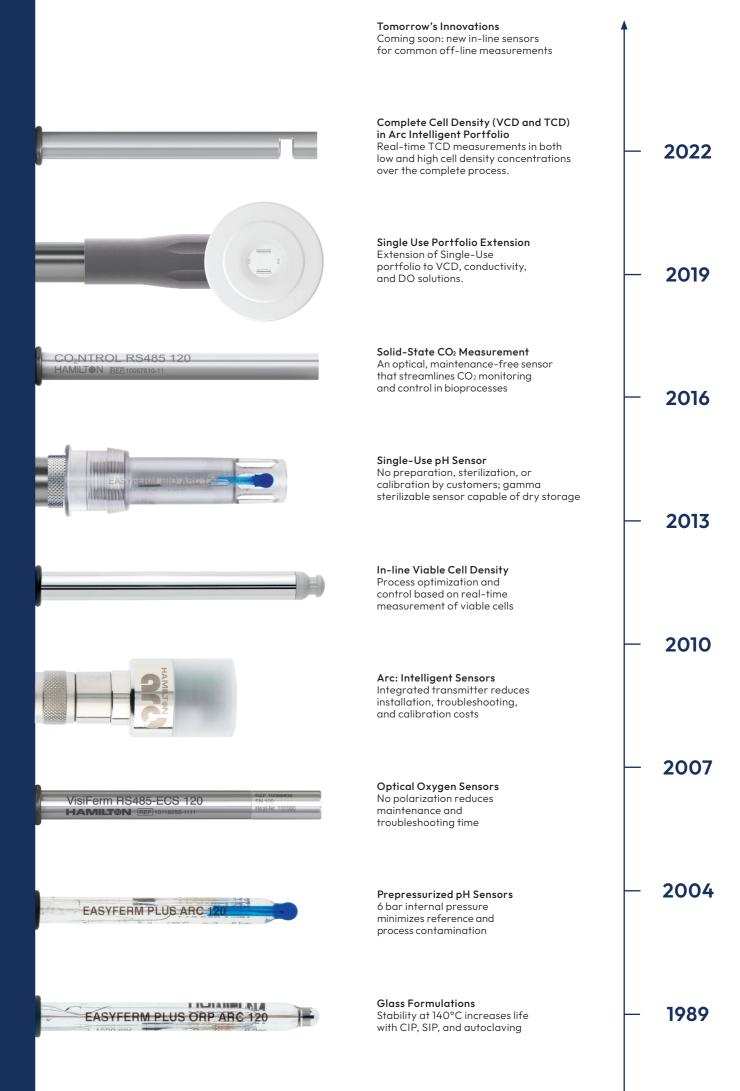
Minimize the time and effort required to discover, procure, validate, and effectively utilize a Hamilton sensor.

#### **Highest Quality**

Benefit from products with the highest manufacturing standards to meet or exceed all FDA and GMP regulatory requirements.

#### **Process Analytics Know-how**

Hamilton provides 30+ years of experience of process sensors developed for biopharma applications.

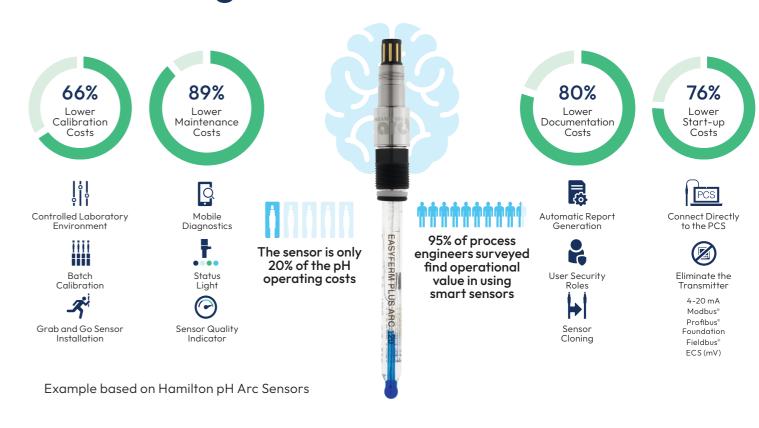


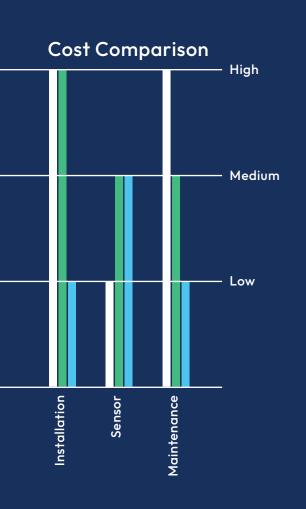
## The Intelligent Sensor Revolution

## Over 95% of process engineers surveyed find value in using intelligent sensors

Less than half of engineers felt they fully utilized their smart sensor. The key to getting the most out of your smart sensor is choosing the implementation that best fits your application. Hamilton offers two versions of smart sensors each equipped with our best-in-class measurement technology.

## Benefits of Replacing Analog with Intelligent Sensors





#### Analog Sensors ► Traditional analog sensors offer the lowest sensor cost which is ideal for implementations that discard the sensor after each run. They rely on a transmitter to read the 4-20 mA sensor's electrochemical signal (ECS) and transmit Analoa it to the process control system. Digital Sensors Memosens Digital sensors eliminate signal errors from electromechanical noise near the cable and reduce maintenance cost by enabling 4-20 mA **Proprietary** in-lab calibration instead of at-line. This is accomplished with Digital an integrated processor to convert the electrochemical signal to a digital output. Arc Intelligent Sensors • Intelligent sensors have the lowest start-up and operating costs. They provide advanced alarms, troubleshooting, quality 4-20 mA or Open Digital Protocol indicators, and diagnostics simultaneously to the control system and to an optional mobile device. An integrated micro-transmitter eliminates a point of failure by directly connecting the sensor to the PCS.

## A Trusted Partner

## The top bioreactor manufacturers deliver reactors with Hamilton sensors installed

Bioreactor and fermenter performance is dependent on having reliable access to actionable data. Manufacturers choose Hamilton's diverse product offering to deliver to their customers relevant process parameters with exceptional life and low maintenance.

#### **Retrofitting Existing Reactors**

Hamilton offers sensors that are compatible with any bioreactor and provide exceptional measurement stability and sensor life. Upgrading to an intelligent sensor will lower operating costs with automatic reporting, batched in-lab calibration, quality indicators, and wireless troubleshooting.

#### **Next Generation Systems**

In recent years bioreactor manufacturers have incorporated 4–20 mA inputs to enable direct input from intelligent sensors. Now they are taking the next step by incorporating digital control of the sensors. This enables the user to check the sensor health, calibrate, and troubleshoot all from the reactor controller.



## **New Tools**

#### Dissolved CO<sub>2</sub>

CO<sub>2</sub>NTROL

The first solid-state sensor designed to directly measure DCO<sub>2</sub> in bioprocesses. The sensor provides a low maintenance, in-line measurement for the control of DCO<sub>2</sub>. This parameter is useful for optimizing cell viability, product yield, and when scaling a process up or down.

#### **Cell Density Sensors**

Incyte Arc (VCD) and Dencytee Arc (TCD)
Real-time measurement of Viable Cell Density
and Total Cell Density provides continuous data
resulting in faster optimization of feeding and
harvesting strategies.

#### Single-Use pH, DO, VCD, and COND

Hamilton developed a gamma sterilizable glass pH sensor that arrives factory calibrated and can be stored dry for up to 18 months. This can be delivered in the bag ready to use alongside Hamilton's single-use DO, VCD, and Conductivity solutions.

## ArcAir Monitoring and Configuration Tools

Transform any Bluetooth-enabled iOS, Android, or PC device into a potent troubleshooting tool at no cost with ArcAir. Establishing a seamless Bluetooth connection, ArcAir grants comprehensive access to all your sensor data. For a more enriching experience, consider upgrading to our advanced version to unlock the full potential of our GMP package.

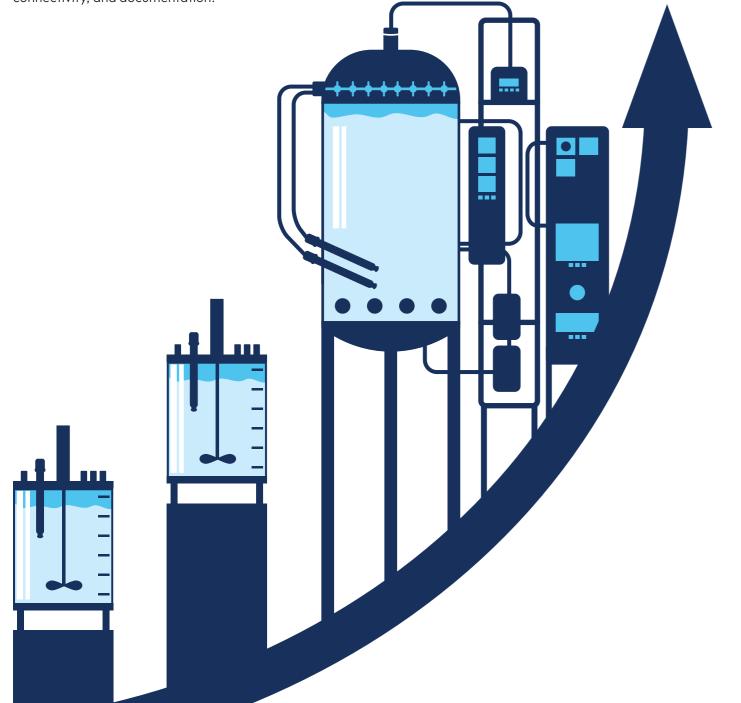




## Seamless Scale-up to Production

## Sensors that last longer and require less maintenance

Hamilton is known for high quality materials and craftsmanship that result in exceptional sensor life. With the introduction of the Arc sensors Hamilton took ownership of the measurement loop and pioneered advances in sensor calibration, troubleshooting, connectivity, and documentation.





#### Start Up

Hamilton assists you to better understand the functionality and use of your sensors with a familiarization demonstration. Trained service engineers are available to commission, qualify, and verify your sensor installation and deliver audit-quality reports that can be shared with your regulatory body.



#### Calibration

On-site calibrations require a lot of preparation and logistic effort. Arc sensors can be calibrated in the lab and stored ready to use on the shelf.



#### Cleaning

Cleaning in Place (CIP) and Sterilization in Place (SIP) are very challenging treatments for the functionality of sensors. Hamilton sensors are engineered to achieve no offset and no drift shortly after cleaning.



#### Maintenance & Troubleshooting

Wirelessly troubleshoot up to 30 sensors at a time without having to enter the production environment. The sensor's quality indicator as well as errors and warnings are easily accessible via the ArcAir App on the Arc View Mobile.



#### **Plant Expansion**

Arc sensors eliminate the need for costly transmitters and simplify wiring with a variety of analog and digital communication options.



#### Documentation

Best practices require documentation of sensor calibration, communication verification, and post-process sensor verification. This is normally a manual process, but with Arc reports are generated automatically. The reports are saved in an encrypted GMP-compliant database, printed, and signed for compliance to 21 CFR Part 11 and Eudralex Vol. 4 Annex 11.

## **Product Offering**

## Single-Use Sensors

Reusable sensors are commonly used in single-use applications but require additional handling, sterilization, and insertion devices. Hamilton adapted these proven sensor technologies into single-use options that come from your single-use supplier: pre-installed, precalibrated, and gamma sterilized.



#### **Factory Calibration Labels**

Every single-use sensor comes with factory calibration data printed on the sensor tag. This data can be scanned into ArcAir with the 2D barcode, manually input, or directly entered into the bioreactor control system.











VCD







Reusable **Electronic** 





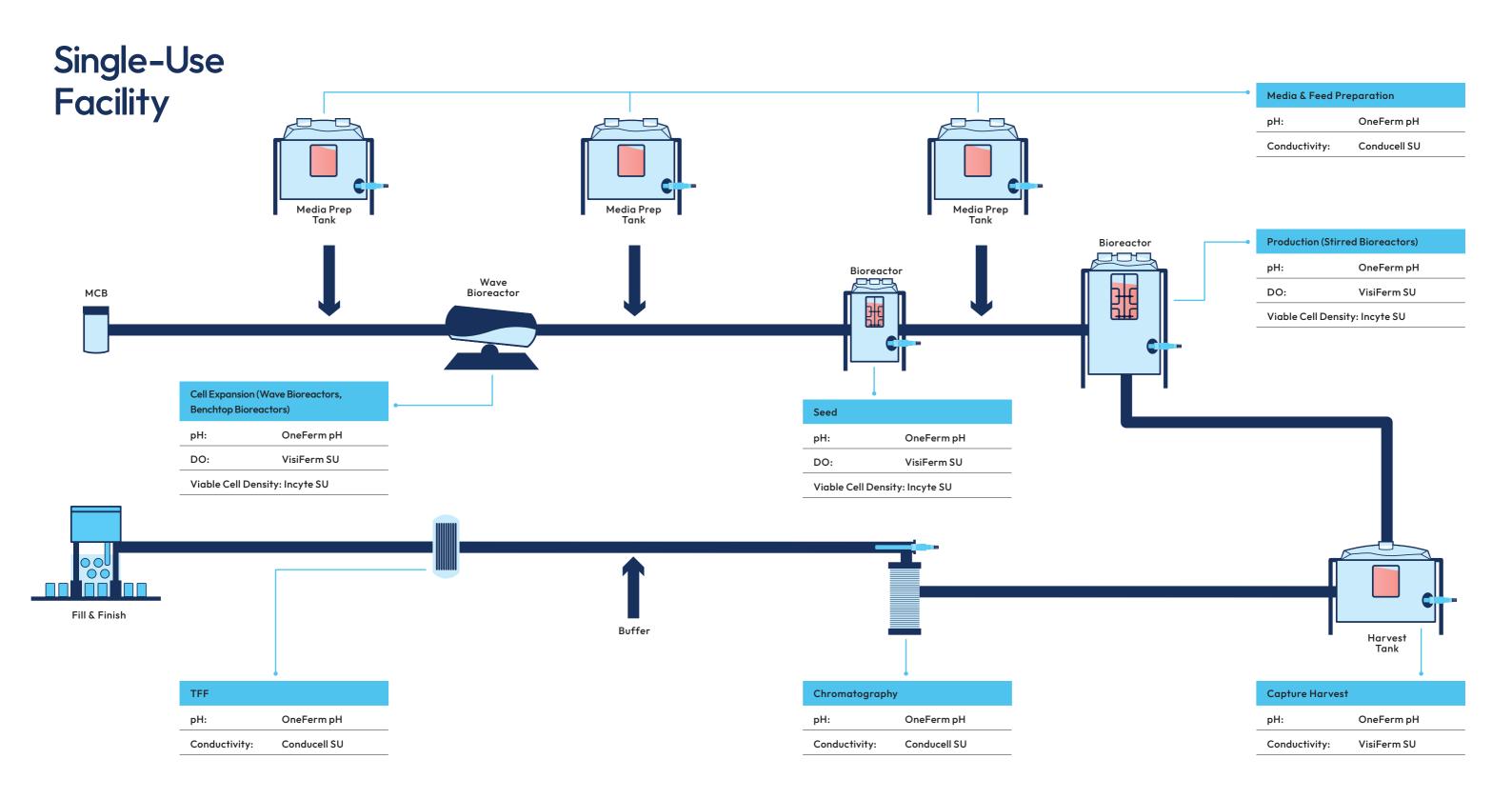
#### Compatible with Existing Single-Use Reactor

Hamilton's single-use solutions fit in a variety of different reactor styles and have already been evaluated for performance by many of the top single-use system providers.

Compatibility Options				
	рН	Dissolved Oxygen	Viable Cell Density	Conductivity
Rigid-Wall	~	<b>✓</b>	✓	~
Stirred-Tank	<b>~</b>	<b>✓</b>	✓	<b>√</b>

## Single-Use Sensors

## Biopharmaceutical CPPs and KPIs



## **Product Offering**

### Reusable Sensors

For more than 25 years, Hamilton has manufactured reusable sensors to meet the evolving needs of pharmaceutical and biotechnology upstream (USP) and downstream (DSP) customers. Our extensive product selection is certified to meet or exceed all FDA and GMP regulatory standards.





#### **Measurement Parameters**

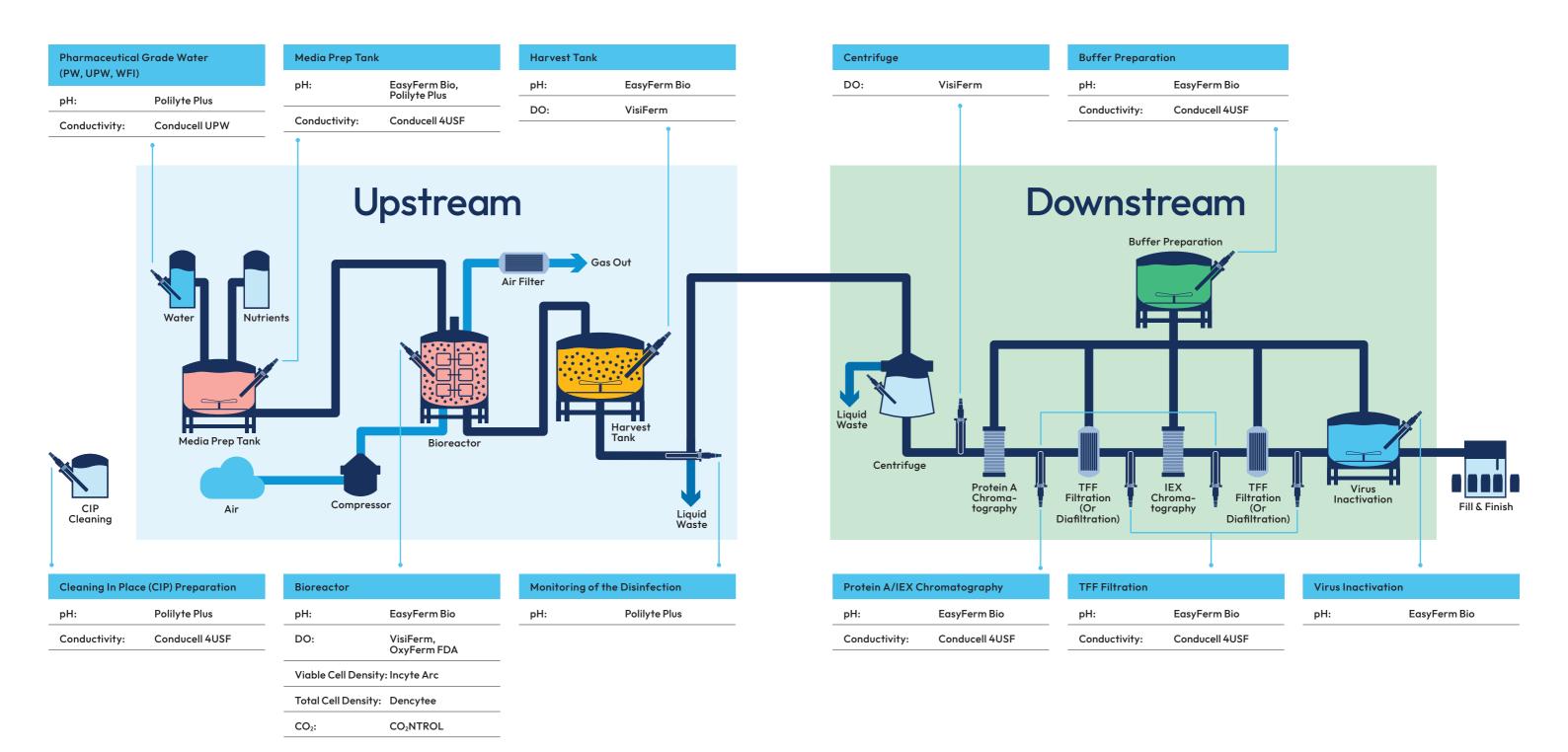
All relevant measurement parameters for BioPharma applications are part of the Hamilton portfolio.



## Reusable Sensors

### Biopharmaceutical CPPs and KPIs

Every step of the biopharmaceutical process has specific requirements for sensors to monitor and control it precisely. The roadmap below shows the individual recommendations from the Hamilton portfolio.

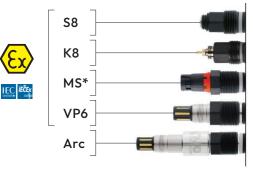


## **Sensor Families**



#### EasyFerm Bio

The Foodlyte electrolyte of the EasyFerm Bio sensors is Certified for bio-compatibility, making it the ideal choice for Food or Biopharma applications. Different glass membrane formulations are suitable for different applications, allowing the user to optimize their processes. Hamilton's clog-free diaphragm increases the stability and accuracy of readings, while increasing the lifetime of the sensor.



#### **Benefits**

- · Certified Bio-compatible
- Pre-pressurized reference design for accurate pH measurement
- Clog-free diaphragm ensures extremely low drift over the sensor's lifetime
- · Customizable to your application



#### \*Memosens

### pH

#### **Polilyte Plus**

18

Polilyte Plus sensors have been designed to withstand demanding industrial processes in chemical, petrochemical, process water, and wastewater treatment applications. The sensor has a maintenance–free design as clogging is eliminated by the two single pore junctions. The Polilyte sensors show good measurement accuracy in highly alkaline solutions as well as in samples with low conductivity. Additionally, the Everef–L reference cartridge ensures a long lifetime. The integrated Liquid Earth in the VP stabilizes sensor signal and extends sensor diagnosis.

#### **Benefits**

- Maintenance free design: elimination of clogging with two single pore junctions
- Good performance in highly alkaline solutions and in samples with low conductivity
- Suitable for demanding industrial applications in chemical, petrochemical, process water, and wastewater treatment



#### VisiFerm Family

The VisiFerm is delivered ready-to-use without polarization and low maintenance. It has improved measurement performance and no  $CO_2$  fouling issues, delivering the lowest drift of available Hamilton DO sensors and requires 80% less calibration. The VisiFerm performs real-time self-diagnostics on sensor and cap health to further ensure optimum performance and reduce process downtime or batch losses. The new generation of VisiFerm also has a 50% longer lifetime compared to the older generation of VisiFerm sensors.

#### **Benefits**

- · Ready-to-use
- · Real-time self-diagnostic capabilities
- Most stable and robust DO sensor: no CO<sub>2</sub> fouling issues





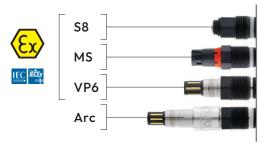
#### OxyFerm FDA

The OxyFerm FDA sensor is an electrochemical polarographic dissolved oxygen (DO) sensor capable of the detecting a wide range of concentrations. The FDA approved membrane is suitable for industries requiring sterile applications (e.g. biopharma, biotech, food & beverage) and is capable of withstanding intensive sterilization and cleaning procedures (steam sterilization, autoclaving, CIP cleaning). The traditional nanoamp (nA) current output offers multiple options for electrical connectors and process mounting connections.

#### **Benefits**

- Wide measuring range
- FDA approved hygienic design: ideal for biopharma, biotech, food and beverage applications
- Robust construction: compatible with steam sterilization, autoclaving, CIP cleaning
- Increased versatility through optional accessories

www.hamiltoncompany.com/dissolved-oxygen





## **Sensor Families**



#### Conducell 4UxF

The Conducell 4UxF is capable of measuring a broad range of conductivity (from 1 to 500'000  $\mu\text{S/cm}$  (Analog) and 1 to 300'000  $\mu\text{S/cm}$  (Arc)), making it suitable for both low and high conductivity measurements. All wetted parts (DIN 1.4435, PEEK, EPDM) are FDA compliant and are CIP, SIP and autoclaving compatible, with good linearity. Hamilton offers Conducell 4UxF sensors made from different materials which are suitable for various applications and come in Traditional or Arc models.

#### **Benefits**

- Can measure a broad range of conductivity (trace – very high)
- · Real-time self-diagnostic capabilities
- FDA compliant and suitable for CIP, SIP and autoclaving
- Compatible with wired or wireless transmission
- · Customizable to your application







#### Conducell UPW

The Conducell UPW sensor provides industry-leading, accuracy and sensitivity for producing pure and ultra-pure water in the pharmaceutical industry. The sensor is USP 645, EP, JP and FDA compliant, therefore appropriate for Pharmaceutical and pure water treatment applications. The Arc model can be directly integrated into standard control systems, eliminating the need for a transmitter. Arc technology allows calibrations, predictive diagnostics, automated documentation, as well as user and process assignment to be stored in the sensor. The Traditional model is suitable for use in hazardous areas and is ATEX and IECEx approved.

#### Benefits

- · Industry leading accuracy and precision
- · Exceptional temperature compensation
- · Seamless integration
- Easy cleaning USP 645, EP and JP compliant
- · All wetted parts are FDA compliant



#### Incyte Arc

When used on-line, the Incyte Arc sensor delivers real-time viable cell density measurements for deeper process insights and data driven process optimization and control.



#### Benefits

- Never miss an important event during your bioprocess by measuring viable cell density
- · Gain deeper process insights e.g., cell size and morphology
- Determine viability in real-time for data-driven process optimization.





#### **Dencytee Arc**

Hamilton's Dencytee Arc sensor is an on-line optical Transmittance and Reflectance sensor capable of accurately measuring the total cell density of cultures from 0-200 g/L.



- $\cdot$  1% accuracy over the whole measuring range from 0 to 200 g/L
- · Never miss an important event during your bioprocess
- · Robust design adapts to changes in ambient light and temperature
- Easy air verification with our Maintenance Tool Kit







#### CO<sub>2</sub>NTROL

Hamilton's CO<sub>2</sub>NTROL is a solid-state sensor (no electrolyte) that directly measures DCO<sub>2</sub> and provides maintenance free (no consumables), real-time, and in-line control of this important critical process parameter. Automated control of DCO<sub>2</sub> enables increased titer, better batch-to-batch reproducibility, and more consistency from R&D to production-scale bioreactors.

#### **Benefits**

- Automated control of DCO<sub>2</sub> in bioproduction.
- Maintenance Free (save cost and time)
- · Simple Calibration





## Housings

## Calibration

#### Retractex B

The retractable pneumatic or manual housing Retractex B was designed for sanitary applications in biotechnology, food & beverage and pharmaceutical industry. The Retractex B with its patented HyCIP cleaning principle offers the best available cleaning efficiency for Ingold sockets (G  $1\,\%$ "). Due to the availability of Various other process connections it can be used with all vessels used in these branches.



#### **Benefits**

- · Extremely compact design
- Integrated safety concept: no sensor
   no insertion
- Very low maintenance due to sterile safety and unique cleaning efficiency



#### **FlexiFit**

Easy and tailored integration for PG 13,5 enabling optimal positioning for the best measurement performance.



#### **Benefits**

- Easy integration for PG13,5 sensors in various stainless steel tanks or pipes
- Optimal sensor positioning for best measurement performance
- 185 versions (connection, insertion length, angeled, o-ring position, sensor protection) to meet all the requirements of process connections





#### **FlowCell**

22

Flexible and space saving two parameter measurement point for bypasses when inline measurement is not possible or desired. The FlowCells comes in two sizes, which in turn are available with various connections.



#### **Benefits**

- Flexible design for one or two measuring points
- PEEK insert of high chemical resistance
- · Low dead volume and self draining





#### pH Buffers

DuraCal Buffer pH are patented pH calibration solutions available in a wide range of independently verified pH values (pH 1.68 - pH 12). Their high buffering capacity accurately provides rapid and stable calibration (± 0.01 pH). Hamilton's pH calibration solutions are stable for up to 5 years and their unique bottle design ensure convenient calibration with minimal waste (15 mL per calibration) and contamination.

#### **Benefits**

- Convenient: bottle has a built-in calibration compartment
- · Economical: only 15 mL used per calibration
- Certified and traceable pH value from an accredited DakkS laboratory

#### **Conductivity Standards**

Hamilton's conductivity standards are high-quality, high-purity calibration solutions designed for accurate and consistent verification of (all) conductivity meters and electrodes. They are available in a range of values and are suitable for various applications in pharmaceutical, chemical, food and beverage, and environmental monitoring industries. These standards are NIST traceable and are stable for 12-36 months.

#### **Benefits**

- Unique certified conductivity standards of 1.3 and 5 µS/cm at an accuracy of ±1%
- NIST traceable and fulfills all requirements of United States Pharmacopia USP Chapter 625

www.hamiltoncompany.com/calibration

23

#### Unlock the Secrets of Bioprocessing Excellence

**Download and Find Out More** 





Measurement
Challenges
Optical Dissolved Oxygen
Sensors White Paper

Cell
Density
Applications eBook

Dissolved CO<sub>2</sub>
Series
White Paper, Part 1

Dissolved CO<sub>2</sub>
Series
White Paper, Part 2

www.hamiltoncompany.com/housings





#### • Headquarters / Manufacturing







To find a representative in your area, please visit: www.hamiltoncompany.com/contacts

**Web:** www.hamiltoncompany.com **USA:** 800-648-5950 **Europe:** +41-58-610-10-10 Hamilton Americas & Pacific Rim Hamilton Company Inc. 4970 Energy Way Reno, Nevada 89502 USA Tel: +1-775-858-3000 Fax: +1-775-856-7259 sales@hamiltoncompany.com Hamilton Europe, Asia & Africa Hamilton Bonaduz A.G. Via Crusch 8 CH-7402 Bonaduz, Switzerland Tel: +41-58-610-10-10 contact.pa.ch@hamilton.ch

