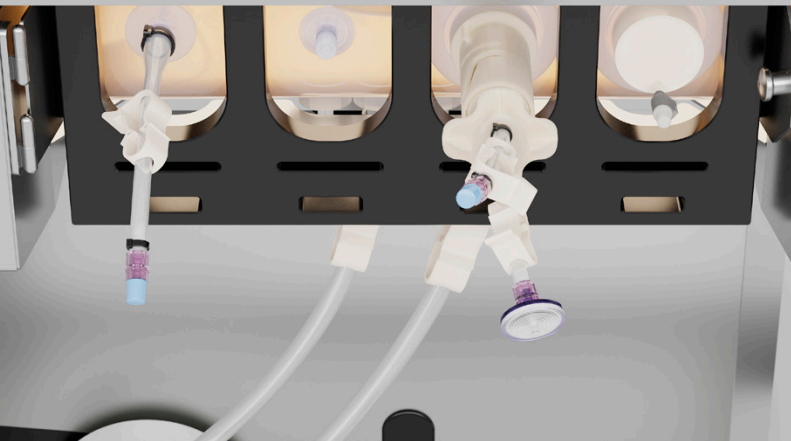


Integrated Single-use Sensors

for pH, Conductivity and
Temperature Control During
Mixing Operations

Benefits

- Delivers continuous real-time monitoring and process control.
- Enables consistent product quality and process efficiency.
- Eliminates the risk of errors and cross-contamination
- Saves operator time



Product Information

There are many mixing steps in both upstream and downstream processes where pH, conductivity and temperature are key process parameters to control to meet PAT and cGMP requirements. Our pre-assembled single-use sensors offer inline control and monitoring of pH, conductivity and temperature that are essential for cGMP biomanufacturing. On top of delivering continuous and real-time measurement, our integrated single-use sensors eliminate the risk of contamination associated with reusable probes and reduce operator time by eliminating sample withdrawal.

The single-use pH sensor, conductivity sensor and thermowell are available on:

- Flexsafe® Pro Mixer bag
- Flexsafe® for Magnetic Mixer and Levmixer® bags
- Flexel® for Magnetic Mixer and Levmixer® bags

Single-use pH Sensor

Measurement Principle

The single-use pH sensor is based on an electrochemical pH glass electrode with an integrated temperature sensor (Pt1000).

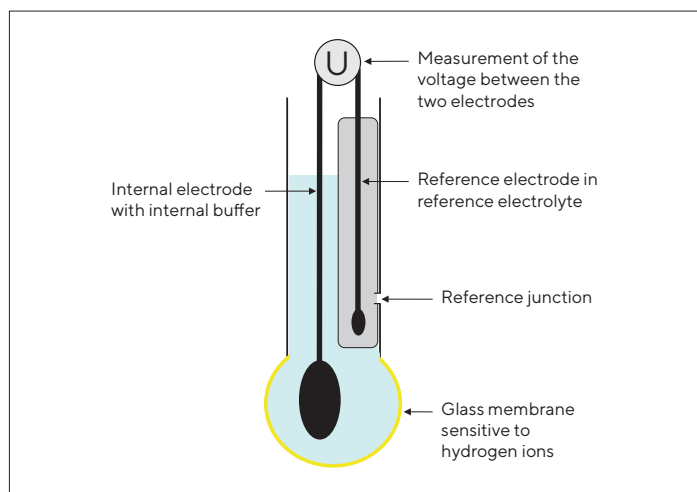


Figure: working principle of a pH electrode

The electrochemical pH glass electrode is assembled with an insertion device composed of high purity USP Class VI High Density Polyethylene (HDPE) and silicone components. The electrode tip is made of alkali lead free glass. This Single-use pH sensor is designed to isolate the glass electrode from the bag interior during storage and calibration and to insure sterile insertion of the electrode inside the bag following calibration. 3 activations (2 insertions, 1 withdrawal) are authorized to maintain sterility into the bag.



Picture: pH electrode and pH sensor

The glass pH electrode is stored in a pH = 6.5 ± 0.3, sterile, gamma stable, buffered solution.

Chemical	CAS-No	Concentration [g/L]
Potassium chloride(KCl)	7447-40-7	224
Potassium dihydrogen phosphate (KH ₂ PO ₄)	7778-77-0	8
Sodium hydrogen phosphate (Na ₂ HPO ₄)	7558-79-4	15

Table: Composition of the Buffer Storage Solution

Data read-out

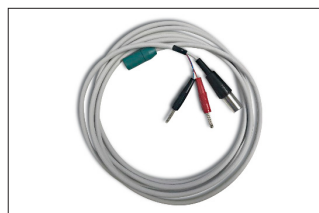
The single-use pH sensor can be read-out using different options:

- **Flexact®.** The single-use pH sensor is fully integrated in the hardware and software of the Sartorius single-use upstream and downstream Flexact® platform.



Picture: Lab-6 to VP-8 Cable to connect the single-use pH sensor to the Flexact® (BPP0013)

- **Handheld reading device.** The single-use pH sensor can be connected to the Portavo 907 Multi reader from Knick allowing a direct read-out of the pH on the display



Picture: cable Lab-6 to Knick reader (BPP0012)



Picture: Knick reader

- **Direct connection to 3rd party automation** using a connection cable Lab-6 to open-ends

Single-use Conductivity Sensor

Measurement Principle

The single-use conductivity sensor is based on a thick film system which is sealed into a ceramic module.

The single-use conductivity sensor is based on 4 electrodes system with an integrated temperature sensor (Pt1000).

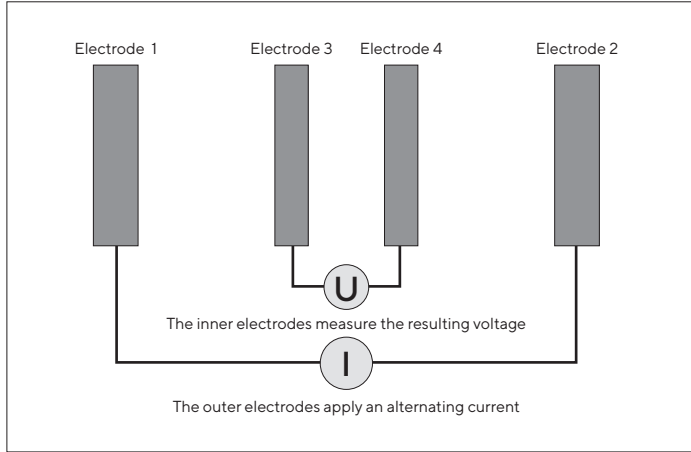


Figure: working principle of the single-use conductivity sensor

Knowing voltage U (in Volt) and the current I (in Ampere), the resistance R (in Ohm) can be calculated using Ohm's law ($U=IR$). Knowing the geometry of the electrodes (the cell constant), the resistivity of the solution (in Ohm \times meters) can be calculated. Conductivity (in Siemens per meter) is then determined as it is the reciprocal value of the resistivity.

The housing of the single-use conductivity sensor is composed of high purity USP Class VI High Density Polyethylene (HDPE). The sensor is pre-calibrated and each sensor has its individual cell constant (calibration factor) on the back side. An additional (extended) certificate can be provided on request.



Picture: single-use conductivity sensor

Data read-out

The single-use conductivity sensor can be read-out using different options:

- **Flexact®.** The single-use conductivity sensor is fully integrated in the hardware and software of the Sartorius single-use upstream and downstream Flexact® platform.



Picture: ODU to VP-8 cable to connect the single-use conductivity sensor to the Flexact® (BPT0031)

- **Handheld reading device.** The single-use conductivity sensor can be connected to the Portames® 913 reader from Knick allowing a direct read-out of the conductivity on the display



Picture: cable ODU to Knick reader (BPT0033)



Picture: Knick reader

- **Direct connection to 3rd party automation** using a connection cable ODU to open-ends



Picture: cable ODU to open-ends (BPT0032)

Thermowell

The single-use thermowell is manufactured with high purity USP Class VI Low Density Polyethylene (LDPE) and silicone components. The thermowell allows the insertion of a reusable temperature probe for measuring the temperature of the liquid inside the mixing bag.

Technical Specifications

Single-use pH Sensor

Measurement technology	Electrochemical pH electrode
Measurement range	pH 2-11, 4-50°C
System accuracy	±0.08 pH over entire measurement range
Drift	<0.03 pH per 24h
Working temperature	4-50°C
Maximum application time	2 days
Temperature compensation	Given through integrated Pt-1000
pH electrode storage solution	pH = 6.5 ± 0.3 sterile buffered conservation solution
Sterilization	by Gamma irradiation (pre-assembled to bag assembly)
Shelf life after γ-irradiation	1 year
Calibration	2-point calibration within port possible: once before process, once during process
Signal output	Analog signal in mV
pH probe holder	Inlet: 0.2 μm Minisart® Syringe Filter Outlet: 1 L waste bag Main body and sensor holder: HDPE O-ring gaskets: Silicone
Cable & Connector	BPP0015: cable pH sensor handhelds with BNC BPP0014: cable pH sensor DCU GEN1 BPP0013: cable pH sensor DCU BPP0012: cable pH sensor Knick handheld BPP0011: cable pH sensor open ends (direct connection to 3rd party automation)

Thermowell

Thermowell dimensions	Compatible with reusable temperature probe of 3 mm diameter
Shelf life after γ-irradiation	3 years
Sterilization	by Gamma irradiation (pre-assembled to bag assembly)

Single-use Conductivity Sensor

Measurement technology	4-electrodes conductivity-meter
Measurement range	0.1-200 mS/cm
System accuracy	3% of current value for 0.1-100 mS/cm 5% of current value for 100-200 mS/cm
Drift	<0.5% in 24h
Working temperature	4-40°C
Maximum application time	5 weeks continuous measurement
Temperature compensation	Given through integrated Pt-1000 sensor
Shelf life after γ-irradiation	2 years
Calibration	pre-calibrated
Cell constant	0.5-1 cm ⁻¹ (the exact value of the cell constant is written on the back of every sensor and in its documentation)
pH resistance	pH 1-12
Sterilization	by Gamma irradiation (pre-assembled to bag assembly)
Probe Holder	HDPE Housing Thick film sealed into a ceramic module
Cable & Connector	BPT0031: cable Conductivity DCU BPT0032: cable Conductivity open ends (direct connection to 3rd party automation) BPT0033: cable Conductivity Knick handheld

Ordering Information


Order Number	Description	Pieces per Pack
Single-use pH Sensor		
BPP0001	Knick handheld Portavo 907 Multi	1
BPP0011	Cable LAB6 - open ends	1
BPP0012	Cable LAB6 - Knick handheld	1
BPP0013	Cable LAB6 - DCU	1
BPP0014	Cable pH sensor DCU GEN1	1
BPP0015	Cable pH sensor handhelds with BNC	1
Single-use Conductivity Sensor		
BB 8800005	Knick handheld Portamess 913	1
BPT0031	Cable Conductivity DCU	1
BPT0032	Cable Conductivity open ends	1
BPT0033	Cable Conductivity Knick handheld	1

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