

Single-use pH sensor METTLER TOLEDO

Now available in custom Thermo Scientific Single-Use Bioreactor and Single-Use Mixer BioProcess Containers

The METTLER TOLEDO InSUS 307 pH sensor, offers unique benefits:

- Single-use sensor which is pre-calibrated and pre-assembled prior to sterilization
- Allows the sensor to be provided in SUB BPCs as a closed system thereby reducing risk of contamination
- Wide pH range (3 to 10)
- Rapid sensor response time and robust sensor stability
- Compatible with most standard pH transmitters, avoiding the need to invest in dedicated hardware
- Resistant to photo-bleaching and most chemicals
- Standard 6 pin variable pole cable connection



Thermo Scientific Single-Use Bioreactor (S.U.B.) and Mixer (S.U.M.) BioProcess Containers (BPCs) are now available with the METTLER TOLEDO InSUS 307 pH sensor.

The METTLER TOLEDO InSUS 307 pH Sensor, is a classical pH electrode in single use format. It encompasses all the benefits of a classical pH electrode in a gamma stable format for use in single-use applications both, upstream and downstream.

Single-use sensors avoid the need to calibrate, sterilize and make connections to the bag, thereby saving time, labor and avoiding process risks by increasing efficiencies and significantly reducing contamination risk.

The probe assembly consists of a METTLER TOLEDO InSUS 307 pH sensor mated to a 1" port. The probe is inserted to the 1" port and retained using a tamper-proof snap retainer. Sealing is provided by use of 2 conventional o-rings. The integrated assembly is rated to process pressures of 15 psi (1 bar). The probe consists of a resistance temperature detector; pH electrode and a reference electrode. It is suitable for dry storage conditions up to 12 months from date of manufacture.

Calibration

The METTLER TOLEDO single-use sensor is supplied with a calibration certificate (Figure 2). Simply enter the values for slope and zero point from the certificate supplied with your probe into the controller software.

Once in use, the calibration value of the sensor can be offset to match an external reference value at any time using traditional one point calibration methods.

InSUS307	Serial No. 2140625
Value at 25°C Messgröße bei 25°C	Specification Spezifikation
Slope pH 4...7 Steilheit pH 4...7	-58.4 mV/pH
Zero point / Nullpunkt	7.20 pH
Membrane resistance Membranwiderstand	710 MOhm
Response time (90% between pH 4...7) Ansprechzeit (90% zwischen pH 4...7)	8 s
Temperature at 25°C Temperaturmessung bei 25°C	24.7°C
Quality Control passed. Qualitätsprüfung bestanden.	

Figure 2. Sample calibration certificate.

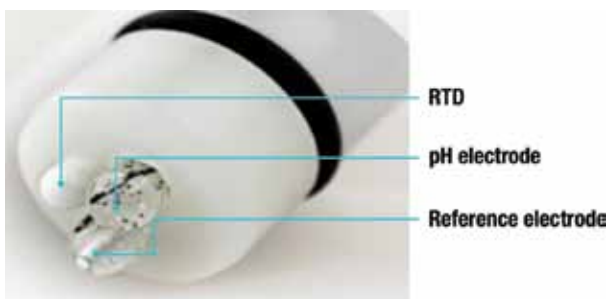


Figure 1. METTLER TOLEDO InSUS 307 pH sensor

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Connections & Communication

The METTLER TOLEDO InSUS 307 pH sensor is compatible with the METTLER TOLEDO M300 & M400 transmitter and can be readily adapted to most classical transmitters or controllers available in the industry today. The sensor calibration requires a slope and zero point to be entered into the transmitter for calibration verification. If your controller does not have

the ability to accept the slope and zero point values through the HMI – contact your local controller manufacturer for more information.

The METTLER TOLEDO InSUS 307 pH sensor works with a Pt 1000 RTD. If using the integrated temperature detector for compensation, the settings in your transmitter may need to be adjusted from Pt 100 to Pt 1000 range in order to work

correctly. If your controller does not have the ability to accept this value through the HMI – contact your local controller manufacturer for more information.

The METTLER TOLEDO InSUS 307 pH sensor requires a standard VarioPin™ cable (VP6) connection. This is a standard industry cable which can be purchased from your controller manufacturer.

Probe Schematic

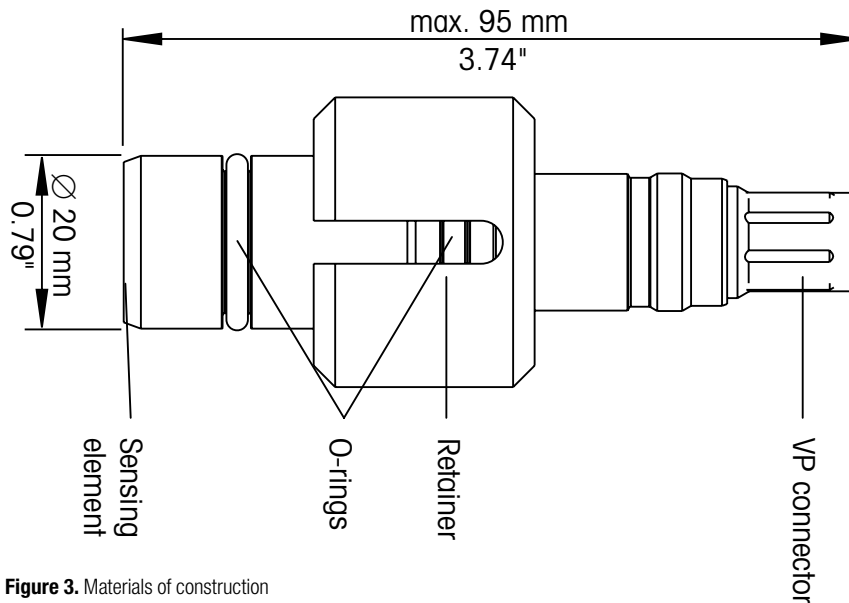


Figure 3. Materials of construction

Specification

Sensor Specification

pH range	3 to 10
Operating temperature	0-60°C (32-140°F)
Zero point	7.20 ± 0.25 pH
Calibration	Factory supplied, optional 1-pt process calibration
Integrated temperature probe	Pt 1000 (1000 ohm platinum RTD)
Sensing elements	Glass pH and reference electrodes, lead-free
Pressure resistant	Rated in SUB BPC final assembly up to 15 psi gauge pressure in the bag
Shelf life	12 months from date of sensor manufacture (6 months final S.U.B. BPC)
Storage	Dry storage capability
Documentation	USP class VI certified polymer materials Calibration certificate included
Gamma irradiation sterilizable	25-45 kGy
Compatible transmitters	M300 & M400 single- and dual-channel versions and most standard transmitters for classical electrodes when equipped with the proper cable connector
Compatible cable	VarioPin™ 6 (METTLER TOLEDO part # 52 300 109 or equivalent)

NOTE: please see SUB data sheet for BPC specification

Characterization Data:

In order to qualify the performance of the METTLER TOLEDO pH sensor after irradiation, 10 x samples were gamma irradiated in SUB BPCs with a dose 25-40kGy. Testing utilized the supplier's recommended conventional pH transmitter and the factory-supplied calibration values provided for each probe. A certified reference buffer of pH 7 was used to demonstrate sensor accuracy after exposure to sterilizing dose of gamma irradiation.

After sterilization all samples demonstrated that the factory calibration is accurate and repeatable:

- Results show a minimal pH shift after sterilization, well below the manufacture specification of $\pm 0.25\text{pH}$ (test results show the average being less than 0.05pH)

- Excellent slope stability after sterilization was achieved; the magnitude of slope difference did not exceed $\pm 1\text{mV/pH}$, which would correlate to a standard error of less than 0.02pH over a typical cell culture bioreactor process control range of $6.5\text{-}7.5\text{pH}$

In order to demonstrate the long term performance of the METTLER TOLEDO pH sensors after irradiation, 6 x samples were gamma irradiated with a dose exceeding 25kGy and aged for a period exceeding 1 year. The probes were tested using manufacturer's recommended conventional pH transmitter and factory supplied calibration values, test results were referenced by way of certified calibration buffers.

Dry storage conditions often degrade conventional pH sensors performance; however, test results confirm the robust characteristics of this sensor's factory calibration after a 14-month dry storage interval:

- The raw mV signal at the sensor zero point was measured, zero point shift magnitude did not exceed 4mV and this correlates to a factory calibration shift of less than $\pm 0.07\text{pH}$ after extended dry storage conditions
- The shift in slope offset did not exceed a magnitude of 1mV/pH . This would correlate to a drift of less than 0.02pH when used in a bioreactor cell culture process control range of $6.5\text{-}7.5\text{pH}$.

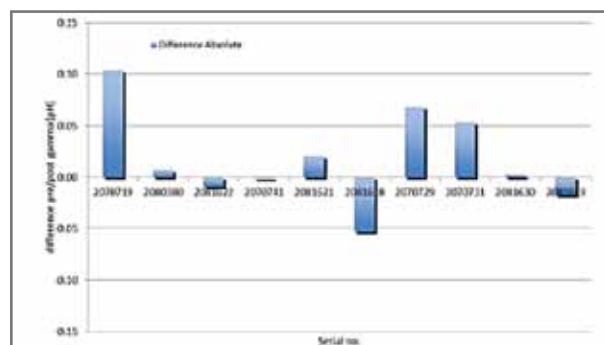


Figure 4. Difference of measured pH value in buffer pH 7, pre/post gamma

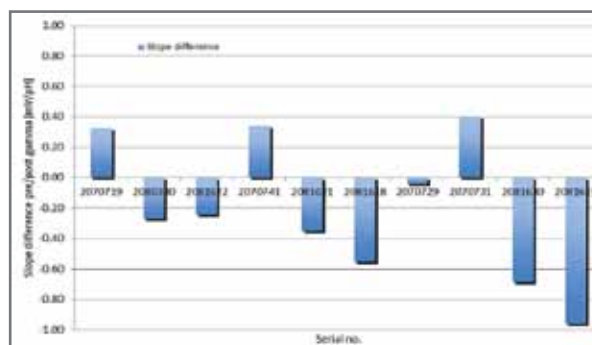


Figure 5. Slope difference pre/post gamma

Cell Culture Run

This experiment was performed to evaluate the effectiveness of the Single-Use METTLER TOLEDO electrochemical pH probe in a high intensity fed-batch cell culture process when compared to a conventional METTLER TOLEDO electrochemical pH probe sterilized via autoclave. This process utilized a CHO cell line in chemically-defined media. The process duration was 17 days. A Siemens Blood Gas Analyzer was used as an offline reference standard and the adjustment criteria for the process pH was ± 0.05 pH units away from the offline reference. During the experiment only one correction was made on day 5 and it was applied to both the conventional MT probe, as well as, the single-use probe marked in red.

This data shows that the single-use METTLER TOLEDO InSUS 307 pH sensor performs as well as the electrochemical re-usable probe, requiring, minimal intervention by single point offset to provide the equivalent level of confidence over cell culture processes. The METTLER TOLEDO InSUS 307 pH sensor is a true alternative to classical reusable sensors, offering all the benefits of single-use.

Ordering Information

The METTLER TOLEDO InSUS 307 pH Sensor is available on all Thermo Scientific single-use products, including S.U.B. and S.U.B. BPCs.

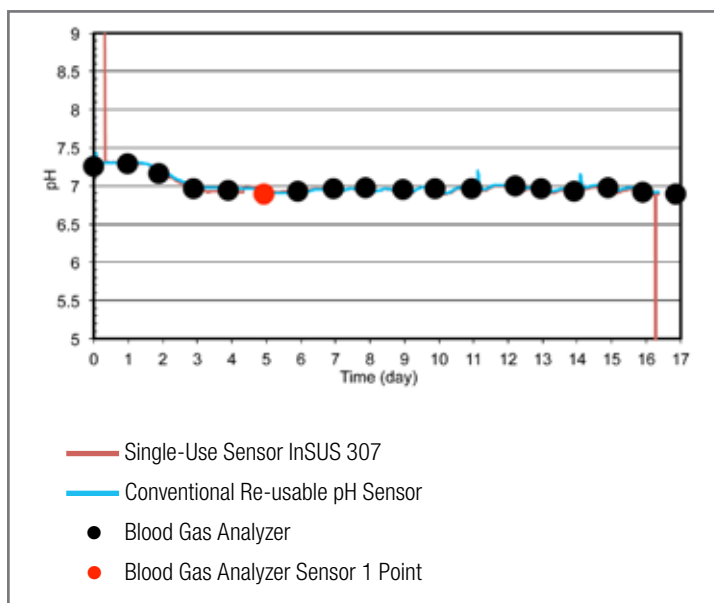


Figure 6. Comparison of conventional reusable pH and single-use InSUS 307 pH in a CHO cell culture run

Part	Description	Details
InSUS 307 pH sensor	METTLER TOLEDO pH sensor SV21223.01	Contact your local Thermo representative
Cable	VarioPin™ (VP) cable	Contact your local Thermo representative
Transmitter	M300/400 or other standard transmitters	Contact your local Thermo representative

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Cell Culture & BioProcessing 925 West 1800 South **In Americas/Asia** 435-792-8000 **In Europe** +32 53 85 71 80 www.thermoscientific.com/bioprocessing
 Logan, UT 84321 435-792-8001 fax +32 53 85 74 31 fax

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