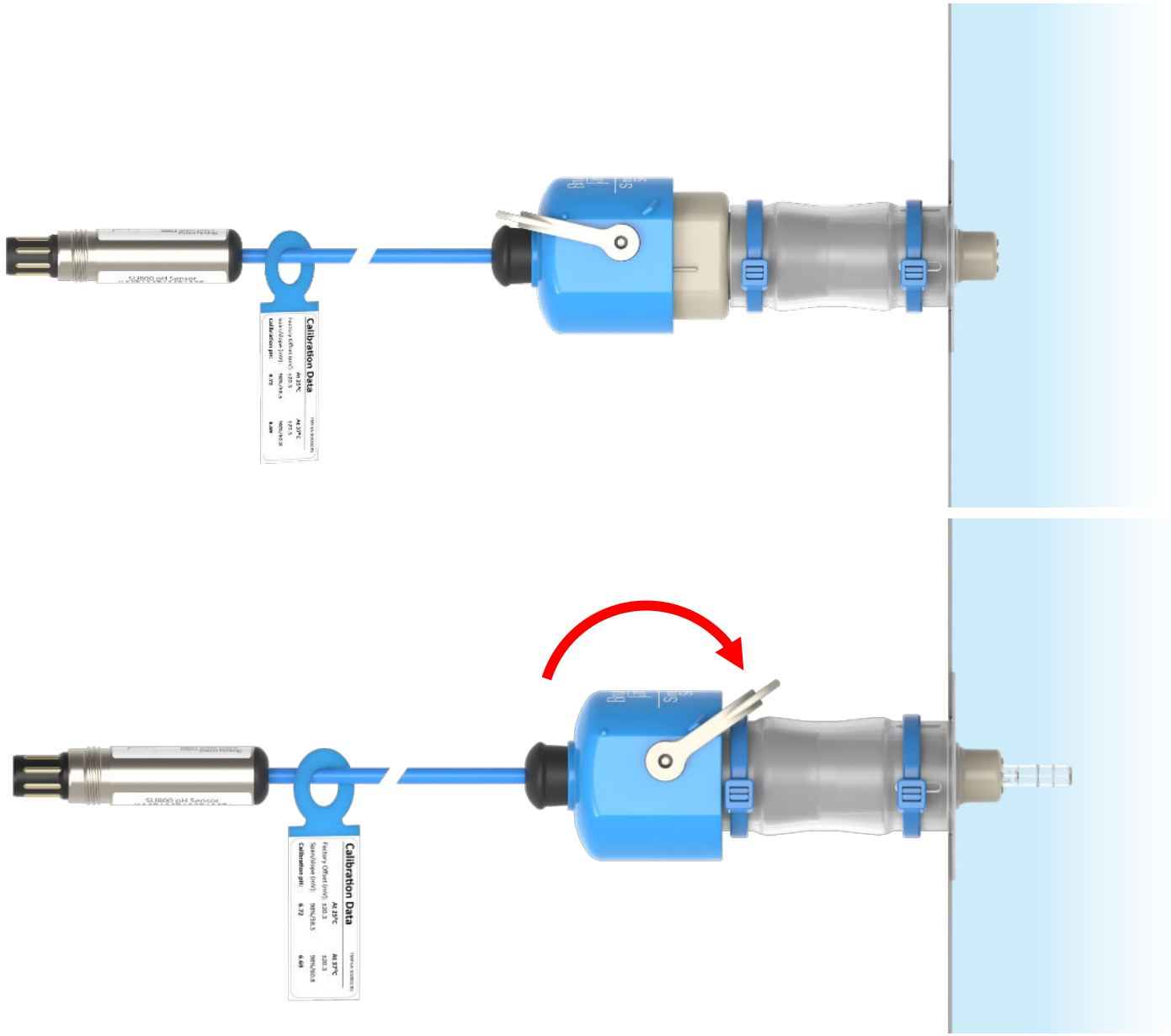
Broadley James
Manufacturers of Sensors for Science and Industry

Operation Manual

SingleSense® Single-Use pH Sensor

Model SU800



PATENTED
EU PATENT 3684906

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Purpose

This manual provides instructions on how to operate the SU800 SingleSense® Single-Use pH Sensor for use with a bioprocess container (BPC).

Scope

This manual is for customers who purchase and use the SU800 SingleSense® Single-Use pH Sensor.

Precautions

This product is intended for professional use only. Follow your standard operating procedures when using this product. Do not use the product if it is broken, defective, or visually damaged.

Compliance

Broadley-James Corporation confirms Model SU800 SingleSense® Single-Use pH Sensor meets the following regulatory and compliance standards:

CE Compliant	Yes
RoHS Compliant	Yes
REACH Compliant	Yes
CFR 21-11 Compliant	Not applicable
BSE/TSE/ADI Free	Yes
USP Class VI Compliant	Yes, all wetted parts
FDA Material Compliant	Yes, all wetted parts

Wetted Materials

PEEK: UPS Class VI, ADI-Free, Extraction Tested 21CFR, 177.2600 | Dimethyl Silicone Rubber: Pt Cure, USP Class VI, Extraction Tested 21 CFR, 177.2600 | EPDM: USP Class VI, FDA Compliant, ADI-Free | Lead-Free Glass | Alumina Silicate

Full scale extractable and leachable test based on BPOG extractable protocol and USP 665 pending.

Product Description

The SU800 SingleSense® Single-Use pH Sensor is gamma sterilizable and designed for use with a BPC.

Definition of Symbols

REF	Catalogue number
SN	Serial number
CE	CE marking
	Use by date
	Temperature limit
QTY	Quantity

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Operation Steps

Step 1
How It Works

- Essential Terms and Definitions
- Sensor Description
- Cutaway of Operation

Step 2
Startup, Calibration, and Operation

- Connect the Sensor to the BPC Control System
- Temperature Check
- Calibration
- Remove Red Safety Zip Tie

Step 3
Optional Mid-Run Standardization Check

- Retraction into the Buffer Storage Chamber
- Checking the Sensor Offset
- Reinsertion of Sensor

Step 1: How It Works

- Essential Terms and Definitions
- Sensor Description
- Cutaway of Operation

1.1 Essential Terms and Definitions

This table outlines terms and definitions important for the operation process. See the next slide for their location on the sensor.

Term	Definition
Buffer storage chamber	Houses and protects the glass pH sensor within the sensor body
Calibration tag	Tag on the sensor's cable that displays data specific to each sensor (do not remove)
Yellow protective cap	Protects the VP8 connector during shipment
Glass pH sensor	Measures the pH of the buffer storage chamber when in the lever arm is in the back position and the process media when the lever arm is in the forward position
Lever arm	Retracts and inserts the glass pH sensor
Lever arm back position	Glass pH sensor is retracted into the buffer storage chamber when the lever arm is in the back position
Lever arm forward position	Glass pH sensor is inserted into the process media and is measuring the process media's pH when the lever arm is in the forward position
Removable red safety zip tie	Designed to keep the sensor in the retracted position for shipment
Sensor's VP8 connector	Links the sensor to the BPC control system

1.2 Sensor Description

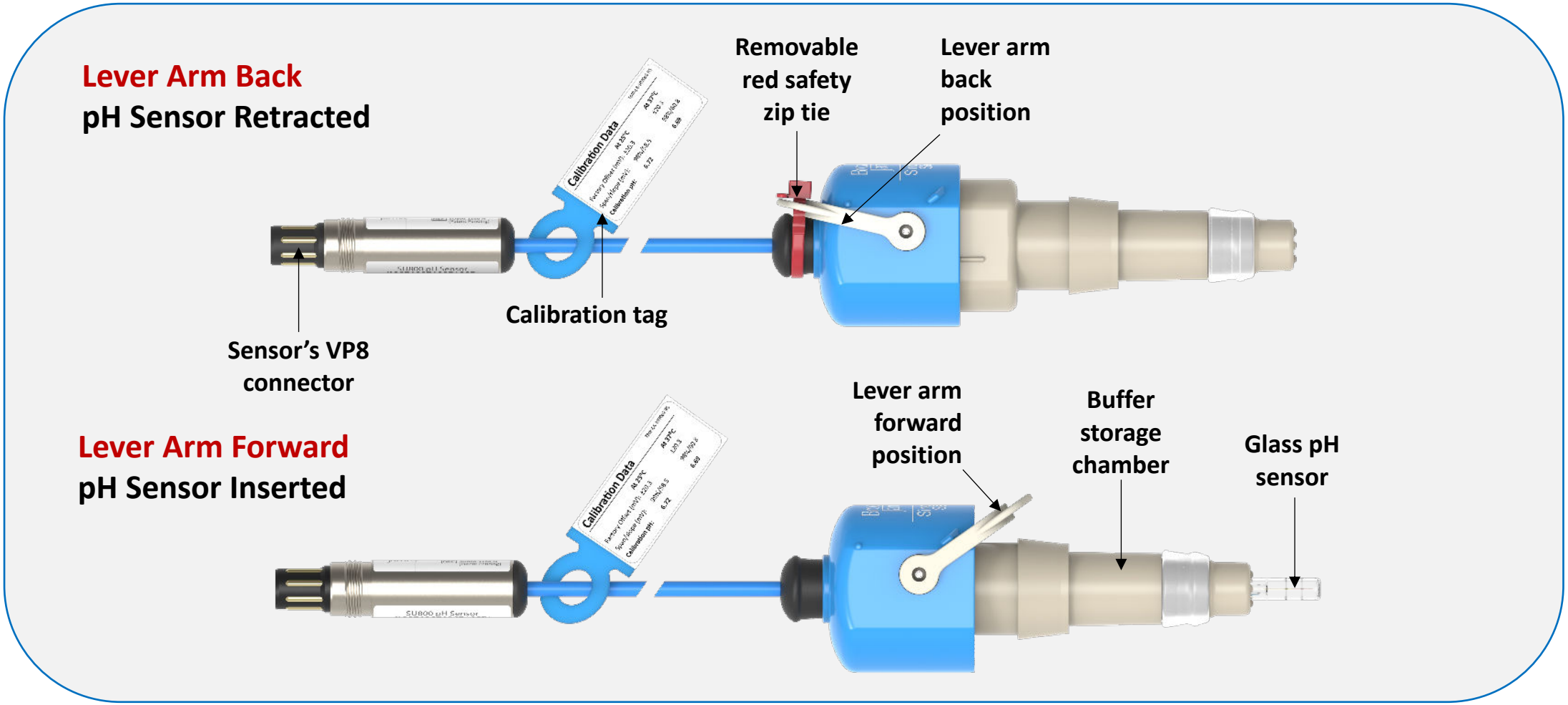


Figure 1. Sensor description

1.3 Cutaway of Operation

Lever Arm Back

pH Sensor Retracted Into Buffer Storage Chamber

The glass pH sensor is out of the process media and measuring the buffer storage chamber pH.

Lever Arm Forward

pH Sensor Inserted Into BPC

The glass pH sensor is inserted into the process media and measuring the pH of the process media.

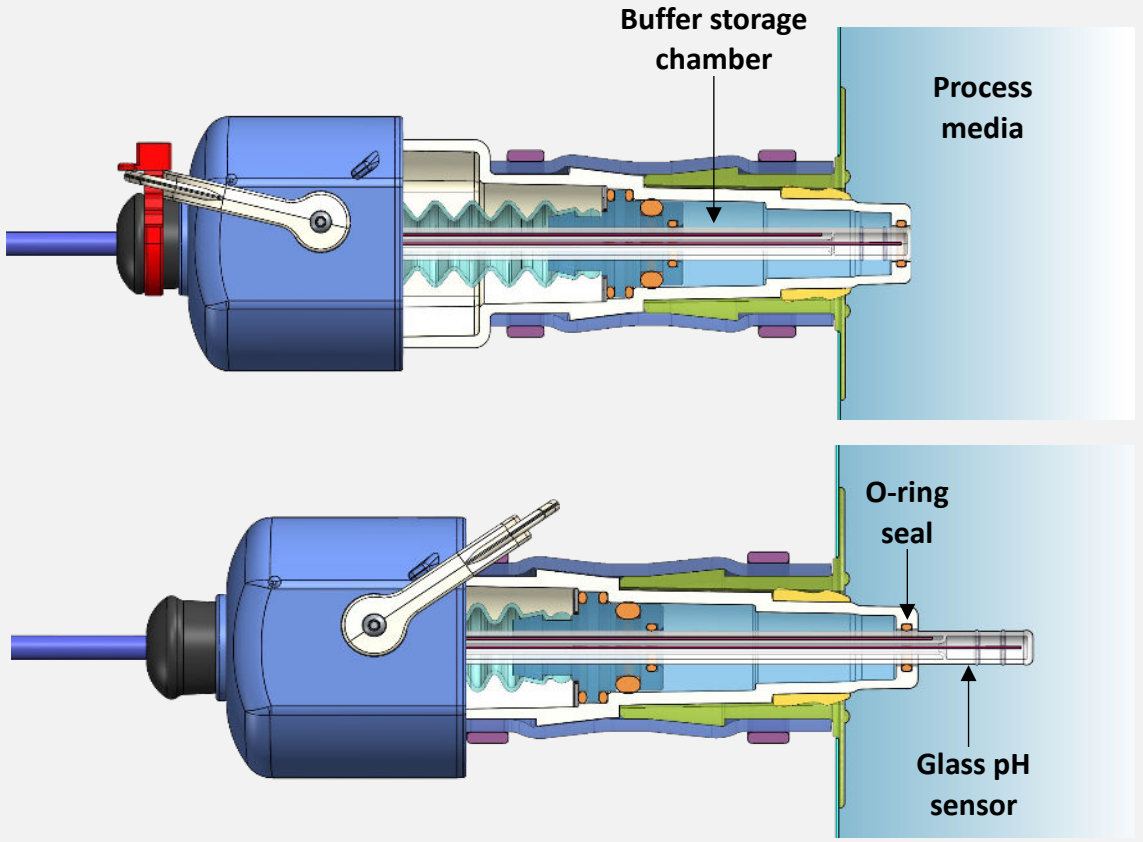
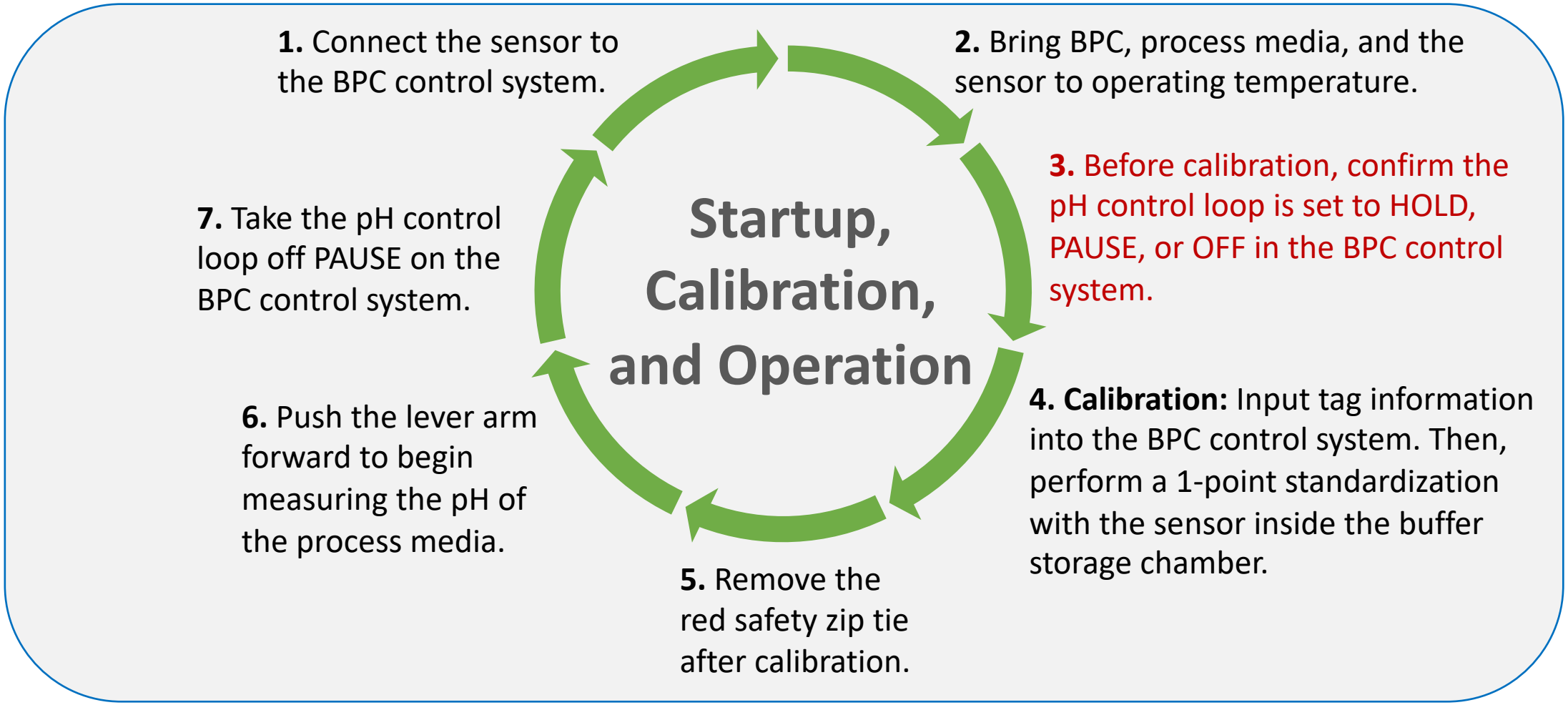


Figure 2. Lever arm back and forward

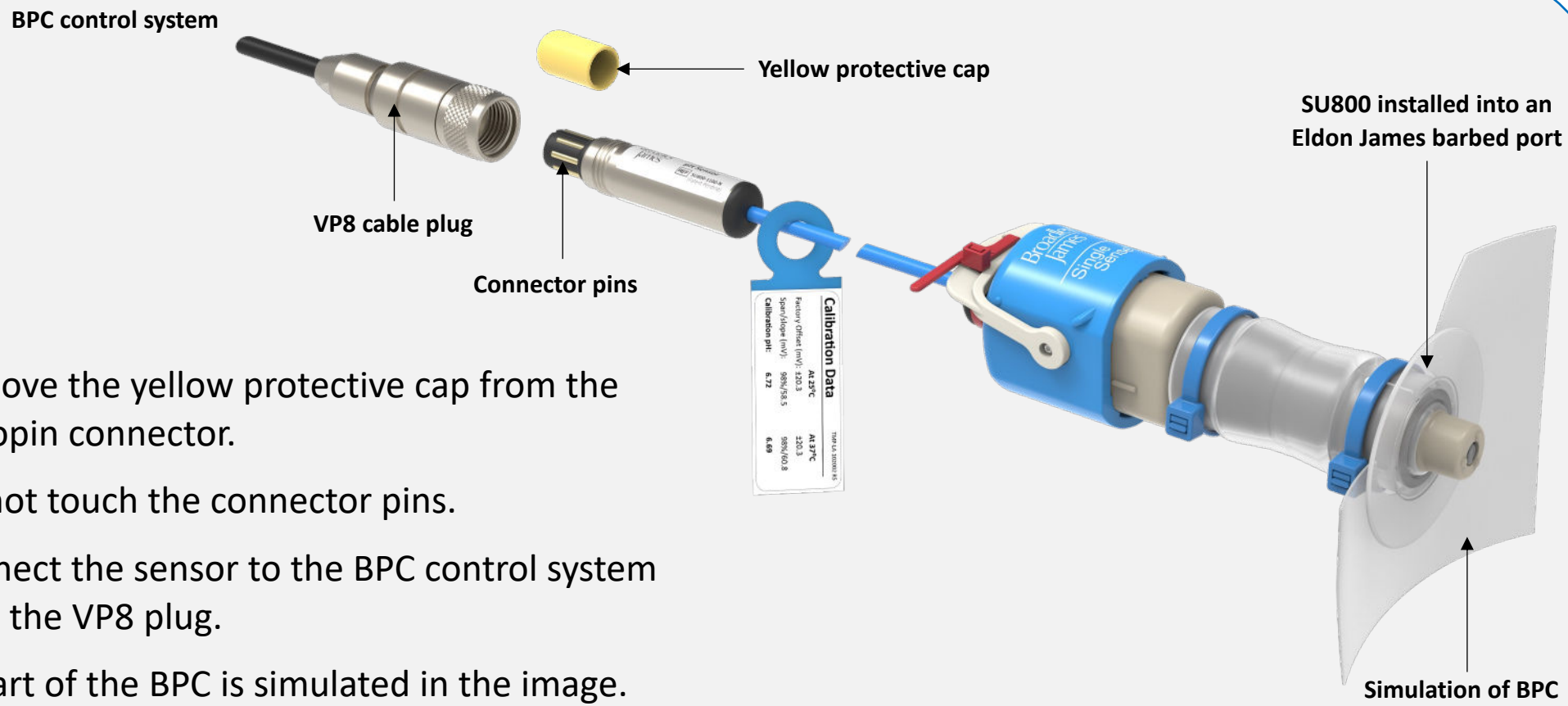
Step 2: Startup, Calibration, and Operation

- Sequence of Startup, Calibration, and Operation
- Connect the Sensor to the BPC Control System
- Temperature Check
- Calibration
- Remove the Red Safety Zip Tie

2.1 Sequence of Startup, Calibration, and Operation



2.2 Connect the sensor to the BPC control system.



- Remove the yellow protective cap from the variopin connector.
- Do not touch the connector pins.
- Connect the sensor to the BPC control system with the VP8 plug.

Note: Part of the BPC is simulated in the image.

Figure 3. Connecting sensor to BPC control system

2.3 Bring the process media to operating temperature.

- Bring the process media to operating temperature (37° C).
- Allow the sensor to reach thermal equilibrium with the process media.

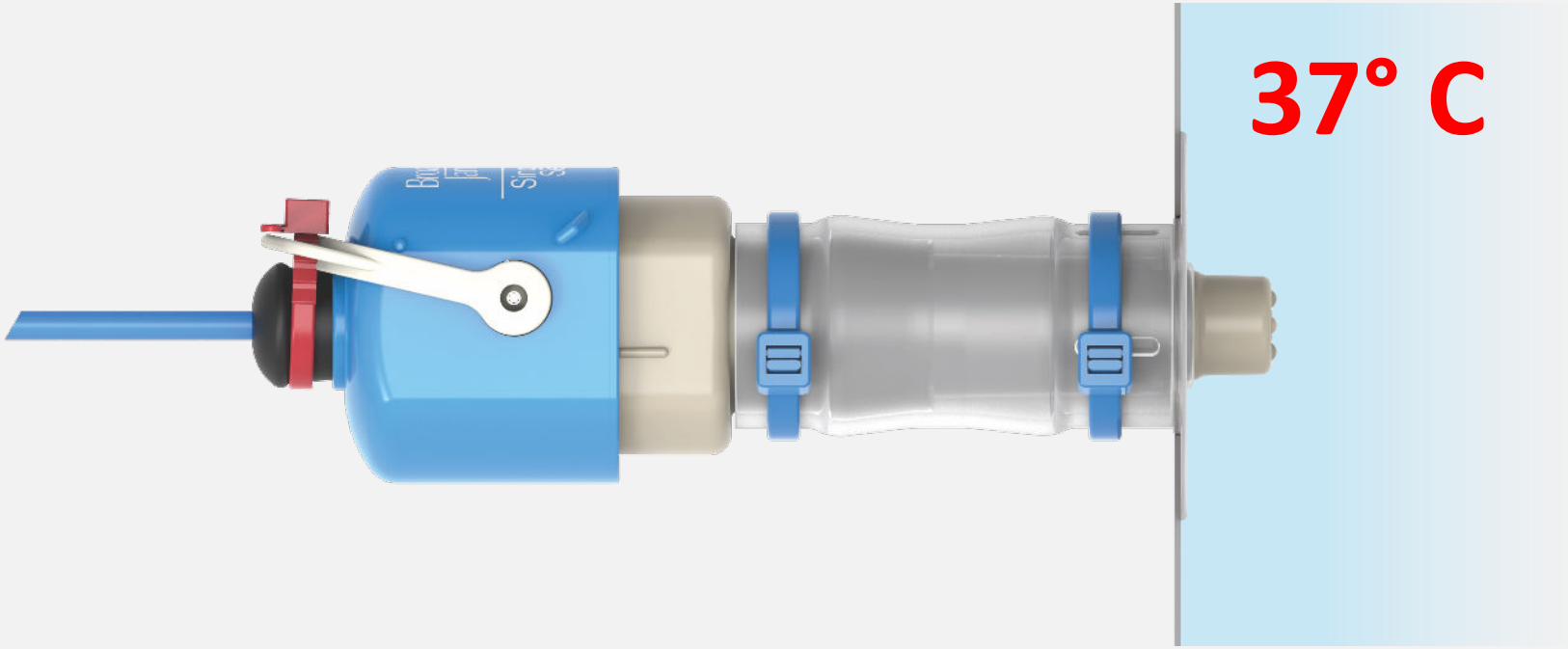


Figure 4. Process media at operating temperature

2.4 Pre-calibration Precaution

Before calibration, confirm the pH control loop is set to HOLD, PAUSE, or OFF in the BPC control system.

Do not retract the sensor if the closed loop control is active.

Note: Follow your standard operating procedure for sensor calibration.

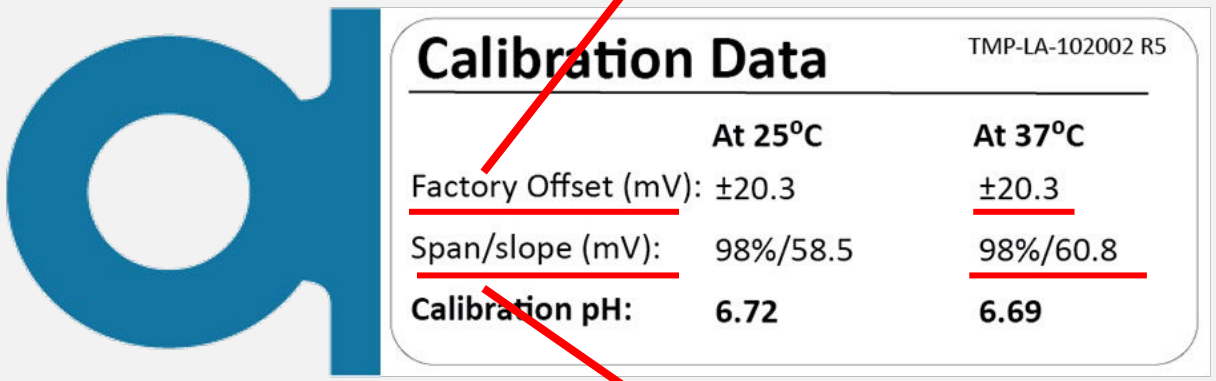
2.5 Calibration: Direct Input of Offset and Slope

1. Reference the data on the calibration tag.
2. Take the **Factory Offset** and **Span/slope (mV)** information and input it into the process instrumentation.

Note: The pH value should read within 0.05 pH units of the values on the calibration tag, correctly reflecting the buffer storage chamber pH.

See next slide to perform a 1-point standardization.

The **Factory Offset** is the sensor's offset (mV at pH 7) when measured at the factory before shipping.



The **Span/slope (mV)** is the sensor's mV to one pH units at a given temperature or the percentage of the theoretical value of the sensor's millivolts to pH units at a given temperature.

Figure 5. Direct input of offset and slope

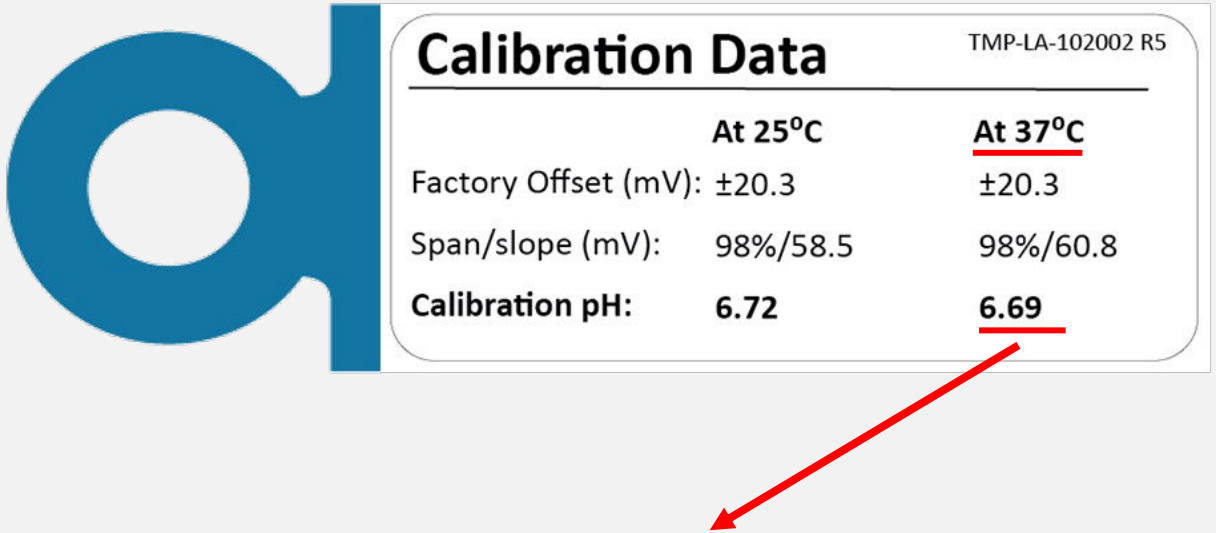
2.6 Calibration: 1-point Standardization

Perform a 1-point standardization.

Note: The pH value of the sensor's buffer chamber is indicated on the tag at 37° C.

Refer to **Appendix B – Storage Buffer Table** for a complete chart of storage buffer value versus temperature.

This completes the 1-point standardization process.



The **Calibration pH** refers to the pH of the buffer solution inside the sensor at 37° C.

Figure 6. Calibration: 1-point standardization

2.7 Remove the red safety zip tie.

- Tools are not needed to remove the zip tie.
- Pull red safety zip tie in opposite directions. The zip tie will separate along a prescored line.

Note: Do not push the lever arm forward until you are ready to operate.

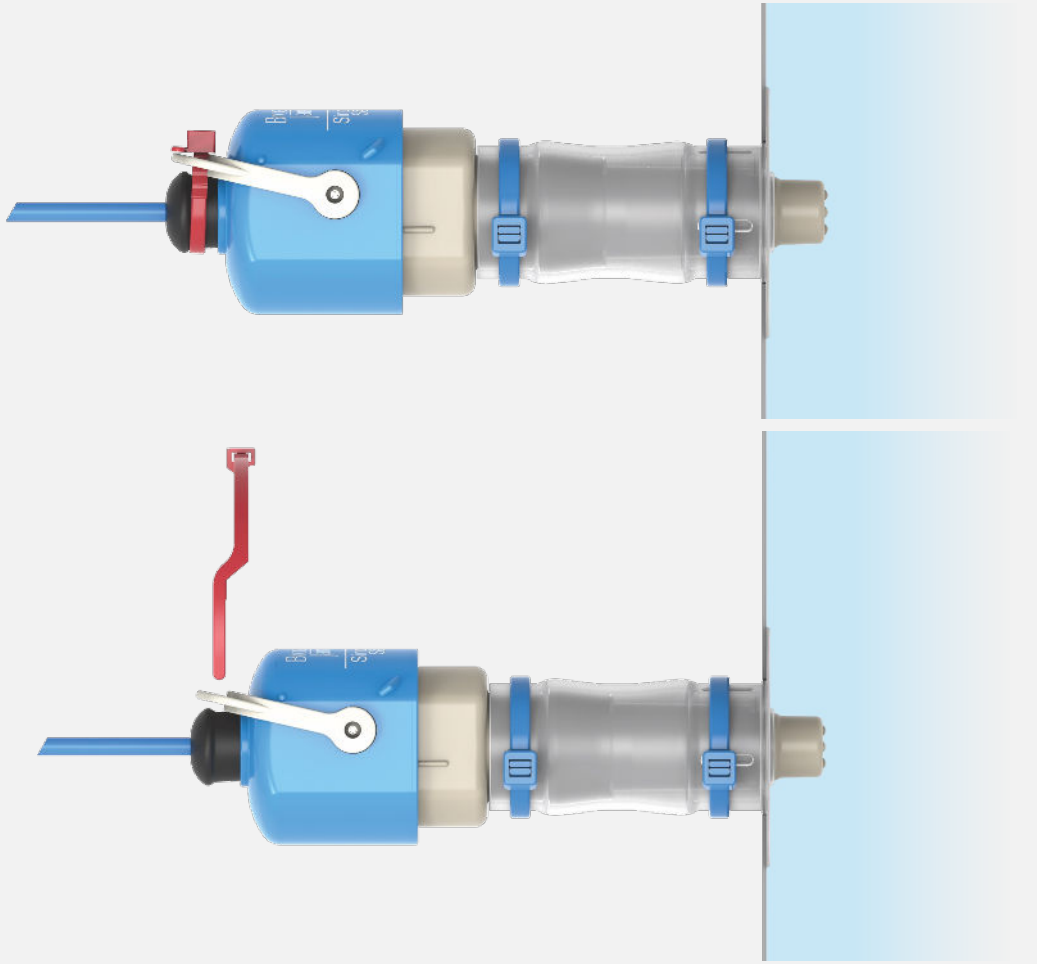


Figure 7. Red safety zip tie removed

2.8 Insert the pH sensor into the process media.

- Push the lever arm forward until the handle touches the silicone tubing. The glass pH sensor will insert into the process media.
- An audible click may occur as the lever arm is pushed forward.

Note: Securing the lever arm in forward position with a red safety zip tie as shown is recommended to prevent accidental retraction. Add a lockout tag per your standard operating procedures.

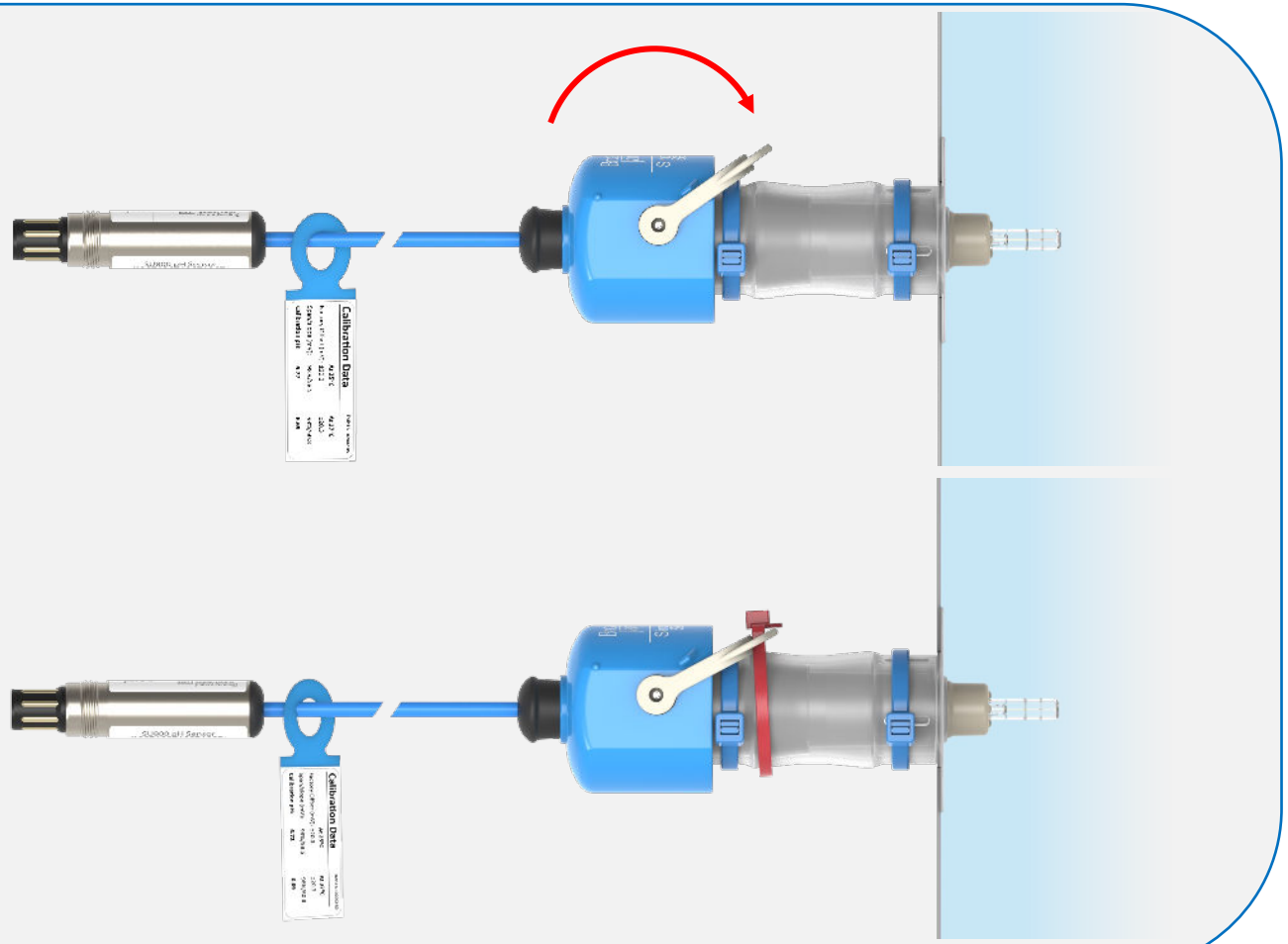


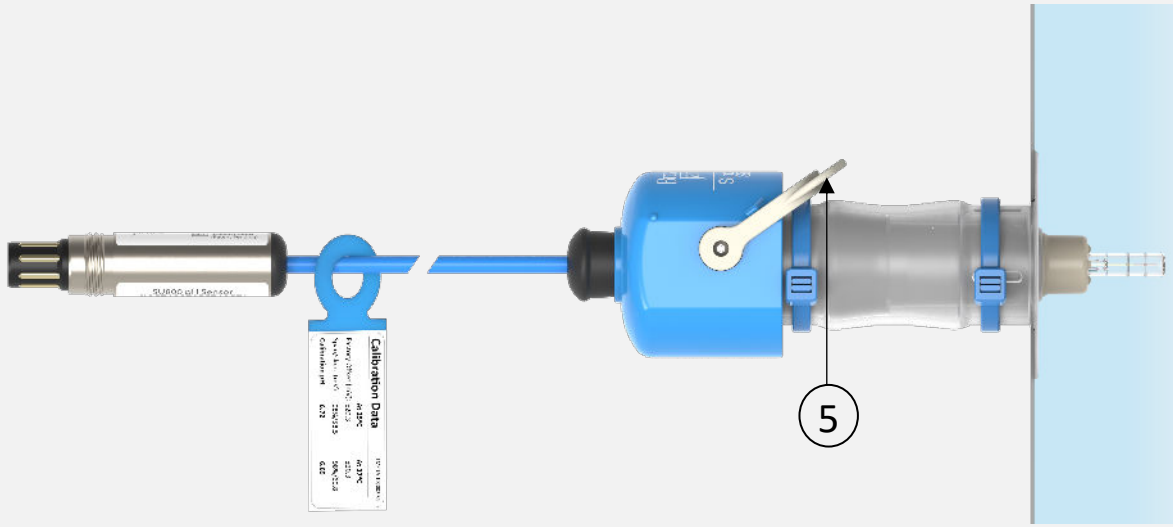
Figure 8. Lever arm inserted and secured

2.9 Reactivate the pH control loop.

The pH control loop can be taken off HOLD, PAUSE, or OFF and made active again after the glass pH sensor has been inserted into the BPC media.

2.10 Post-startup Checklist

BPC control system (not shown)



- ❑ **1.** Is the sensor connected to the BPC control system?
- ❑ **2.** Was the pH control loop on the BPC control system put on HOLD, PAUSE, or OFF prior to calibration?
- ❑ **3.** Is the sensor calibrated with the BPC control system?
- ❑ **4.** Is the red safety zip tie removed?
- ❑ **5.** Is the lever arm pushed forward?
- ❑ **6.** Is the pH control loop system reengaged?

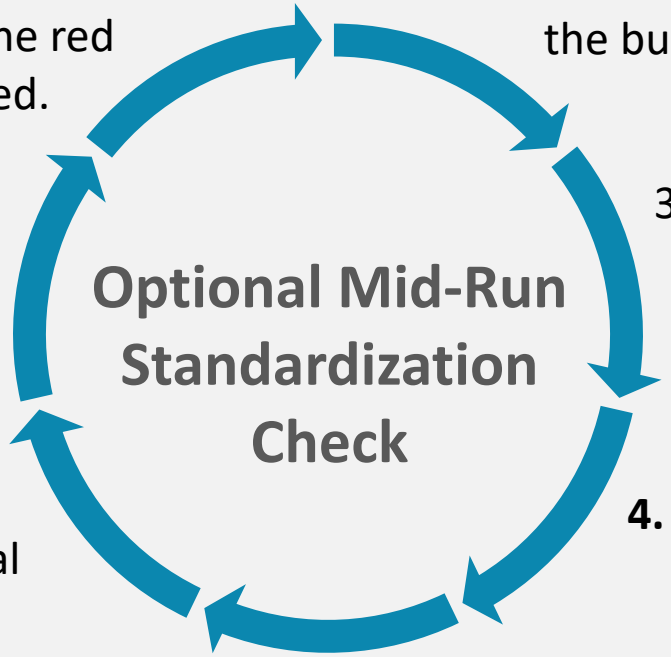
The startup is complete. The sensor is calibrated and operational.

Figure 9. Post-startup checklist

Step 3: Optional Mid-Run Standardization Check

- Retraction into the Buffer Storage Chamber
- Checking the Sensor Offset
- Reinsertion of Sensor

3.1 Sequence of Optional Mid-Run Standardization Check



1. Pause the pH control loop on the BPC control system. Remove the red safety zip tie if one was installed.
2. Retract the glass pH sensor into the buffer storage chamber.
3. The glass pH sensor should now read within 0.05 pH units of the calibration tag value.
4. **Decision Point:** If a 1-point standardization is necessary, use the buffer storage chamber pH or a grab sample.
5. The calibration is complete. Reinsert the glass pH sensor.
6. If the change in pH is more than 0.2 pH units, reset integral on the proportional-integral-derivative (PID) parameter.
7. Reengage pH control loop on the BPC control system. Install a new red safety zip tie per your standard operating procedures.

3.2 Retraction into the Buffer Storage Chamber

1. Pause pH control loop before you retract the sensor.
   Remove the red safety zip tie if one was installed.

2. Retract the sensor. The o-ring seal cleans the glass pH sensor as it is retracted into the buffer storage chamber.

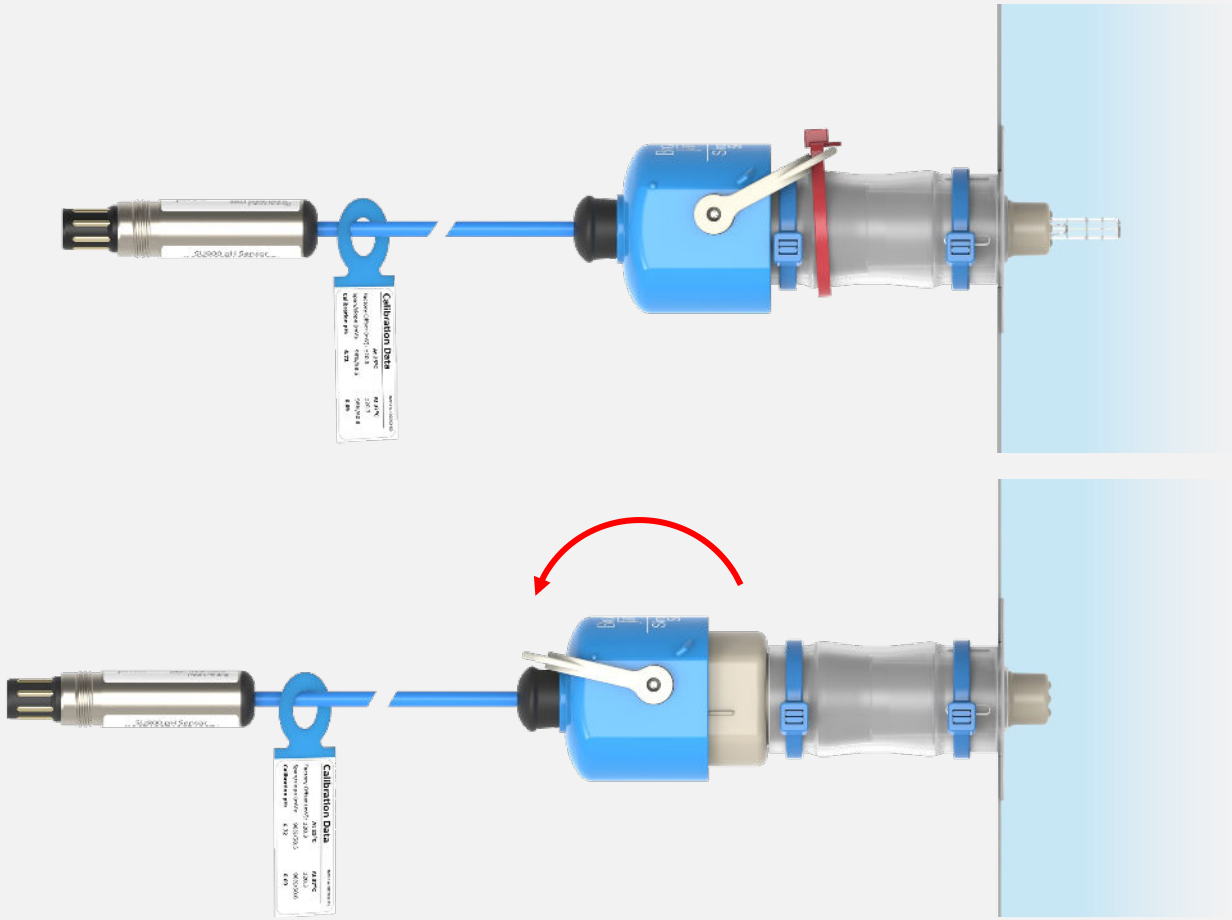


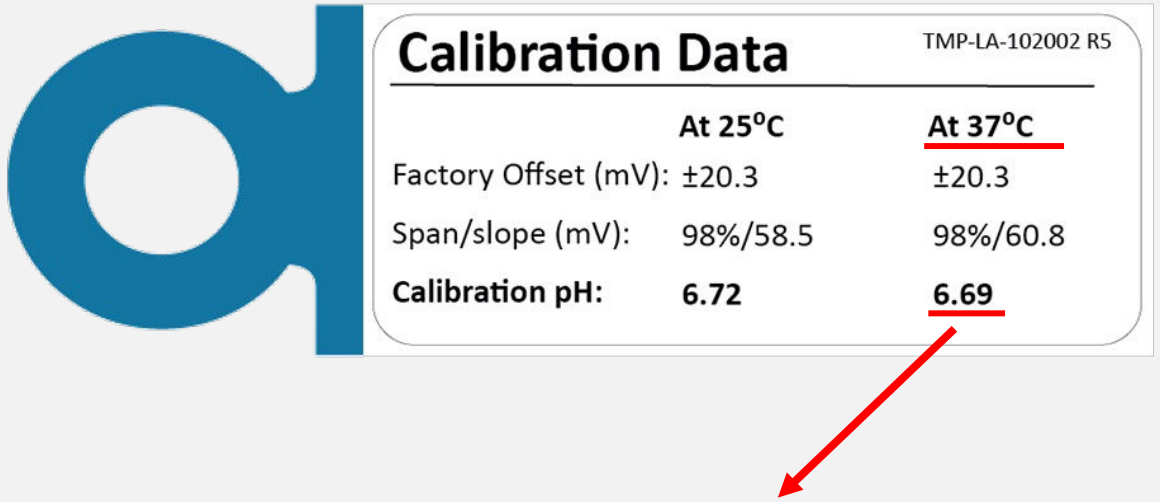
Figure 10. Preparation for optional mid-run standardization check

3.3 Checking the Sensor Offset

3. Check the pH value on the calibration tag. The sensor should now read within 0.05 pH units of the value on the calibration tag.

4. If a 1-point standardization is necessary, use the sensor's buffer storage chamber pH for the standardization value.

5. Refer to **Appendix B – Storage Buffer Table** for a complete chart of buffer storage chamber pH value versus temperature.



The **Calibration pH** refers to the pH of the buffer solution inside the sensor at 37° C.

Figure 11. Performing the mid-run standardization check

3.4 Reinsertion of Sensor

Caution: If the change in pH is more than 0.2 pH units, reset integral on the proportional-integral-derivative (PID) parameter before re-engaging pH control loop.

5. The 1-point standardization is complete. Reinsert the glass pH sensor.
6. The pH control loop can be taken off HOLD, PAUSE, or OFF and made active again after the glass pH sensor has been inserted into the BPC media.

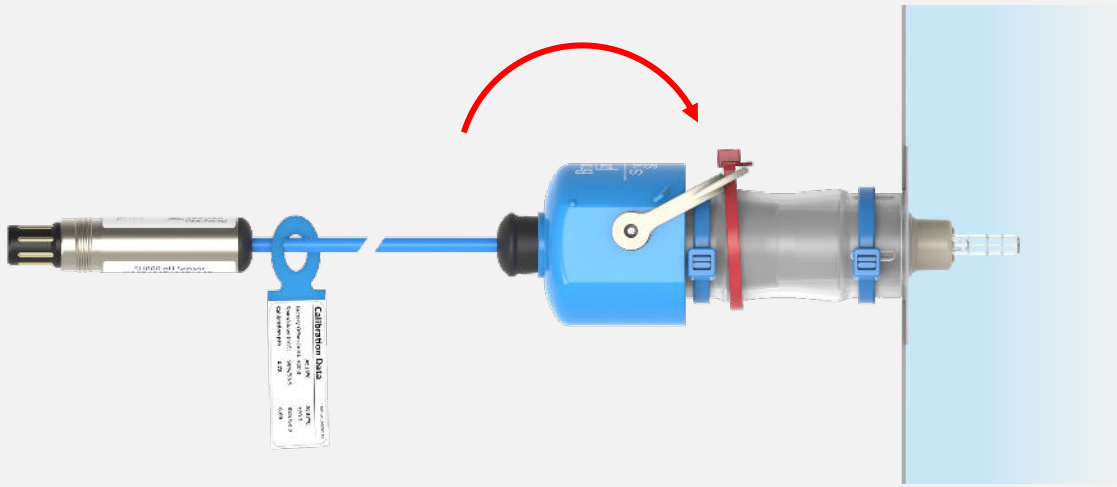


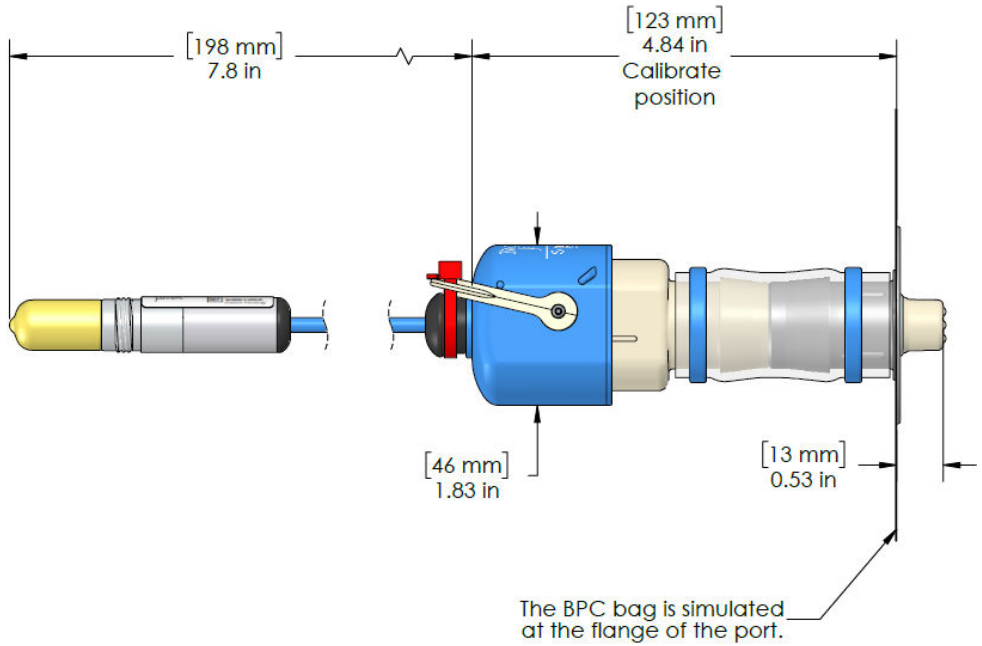
Figure 12. Reinsertion of the sensor

Appendices

- Appendix A – Dimensional Drawing of Sensor
- Appendix B – Buffer Storage Chamber
- Appendix C – Calibration Tag Data
- Appendix D – Specification Sheet
- Appendix E – Purchasing Sheet

Appendix A – Dimensional Drawing of Sensor

Lever Arm Back
pH Sensor Retracted



Lever Arm Forward
pH Sensor Inserted

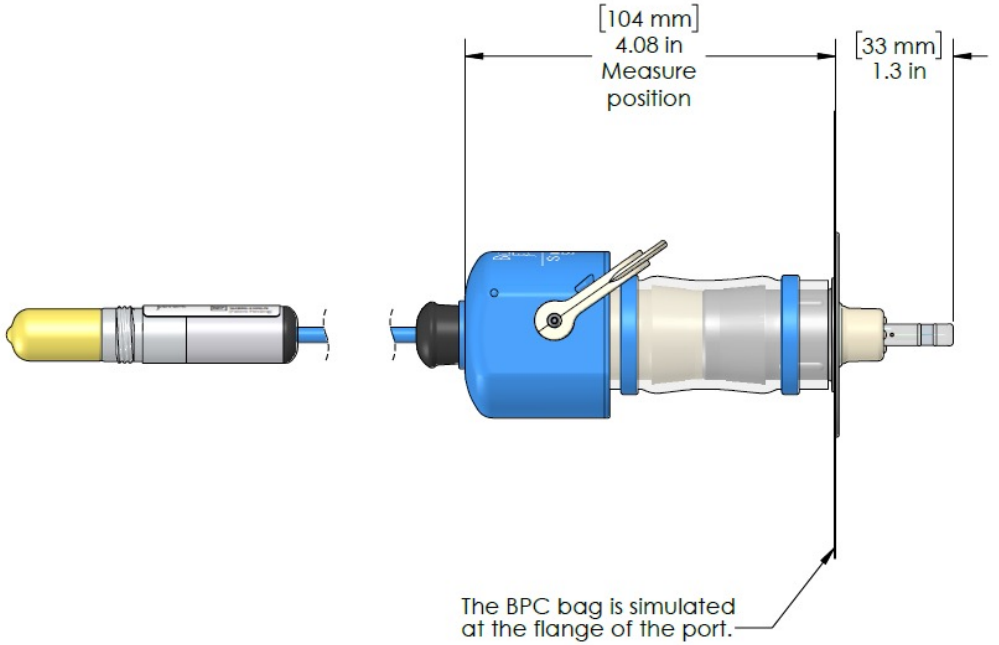
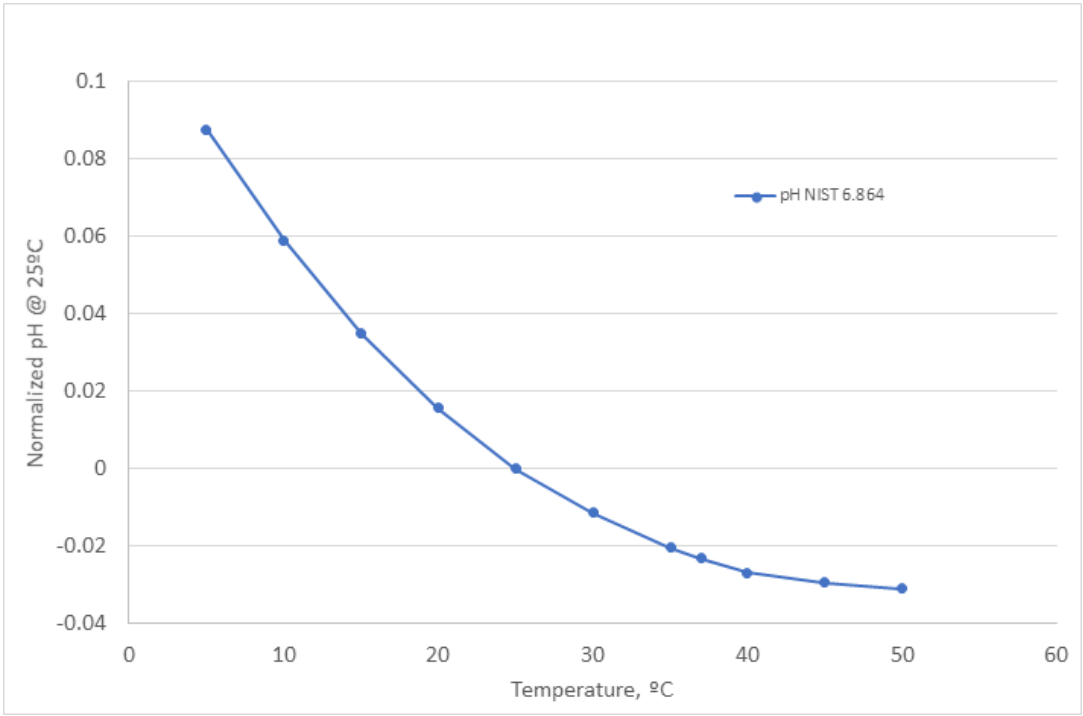


Figure 13. Dimensional drawing of sensor inserted and retracted with red safety zip tie

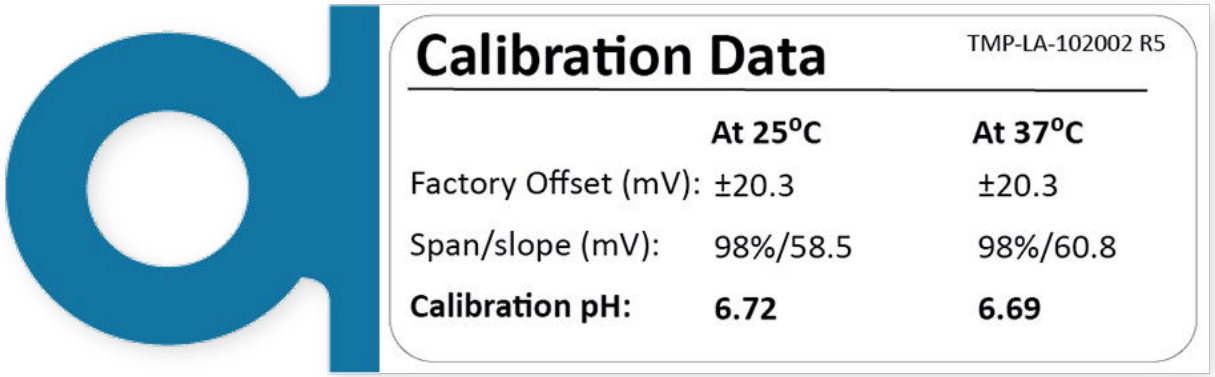
Appendix B – Buffer Storage Chamber Solution Table

This table outlines the nominal pH level of the sensor's buffer storage chamber solution in correlation with temperature.

T, ºC	Normalized pH (NIST 6.864)
5	0.0875
10	0.0589
15	0.0349
20	0.0156
25	0
30	-0.0114
35	-0.0205
37	-0.0232
40	-0.0268
45	-0.0294
50	-0.0309



Appendix C – Calibration Tag Data



Note: The data on the tag is for sample purposes only.

1. The **Calibration Data** is unique to each sensor. It gives the factory calibration principles and data for each sensor.
2. The **Factory Offset** is the sensor's offset (mV at pH 7) when measured at the factory before shipping.
3. The **Span/slope (mV)** is the percentage of the theoretical value of the sensor's millivolts to pH units at a given temperature.
4. The **Calibration pH** refers to the pH of the buffer solution inside the sensor at a given temperature.

Figure 14. Calibration tag data

Appendix D – Specification Sheet (Model SU800)

Product Specification Sheet
Doc Nbr: PSS-062101 R6
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REF SU800-16-V8
Single-Use pH Sensor
for BPC with 1-inch Hose Barb Port

Description

The SU800-16-V8 SingleSense® Single-Use pH Sensor is a gamma sterilizable and designed with a 1-inch hose barb for pre installation into a bioprocess container (BPC). The sensor can be used for upstream and downstream BPC applications including media mixing, buffer preparation, and large-scale cell culture bioreactors.

Rugged and always ready to use, no hydration time is required. The sensor can be installed horizontally and retracted during mid-run for a 1-point standardization check with the built-in buffer storage chamber.

Model	SU800
Part Number	SU800-16-V8

SU800-16-V8 Single-Use pH Sensor

Sensor Specifications

Measurement Range	2–12 pH
Operational Temp. Range	15°–40° C [60°–104° F]
Storage Temperature	5°–35° C [41°–95° F]
Shipping and Transportation	-25° C [-20° F] for up to 72 hours
Shelf Life	36 months Post Gamma: 30 months
Gamma Tolerance Level	50 kGy
Sensor/Tubing Interface	1 inch Hose Barb
Sensor Connector Cable	8-pin Variopin

Wetted Materials

Main Sensor Body	PEEK, USP 88 Class VI, USP 87, ADI Free
Port Gasket	Dimethyl Silicone Rubber Pt Cure, USP 88 Class VI, USP 87, ADI Free
O-ring	EPDM, USP 88 Class VI, USP 87, FDA Compliant Extraction Tested 21 CFR, 177.2600, ADI Free
pH Glass Electrode	Lead-free Glass
Ceramic Junction	Alumina Silicate

Features

- pH sensor retracts into the buffer storage chamber in the sensor body for long-term storage
- Sensor can be inserted and retracted multiple times without loss of buffer storage electrolyte

Benefits

- Sensor can be stored and protected in sensor housing until needed
- Always ready to use, no rehydration time required
- Sensor can be retracted into buffer storage chamber during mid-run for 1-point standardization check

PATENTED
EU PATENT 3064905

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Product Specification Sheet
Doc Nbr: PSS-062101 R6
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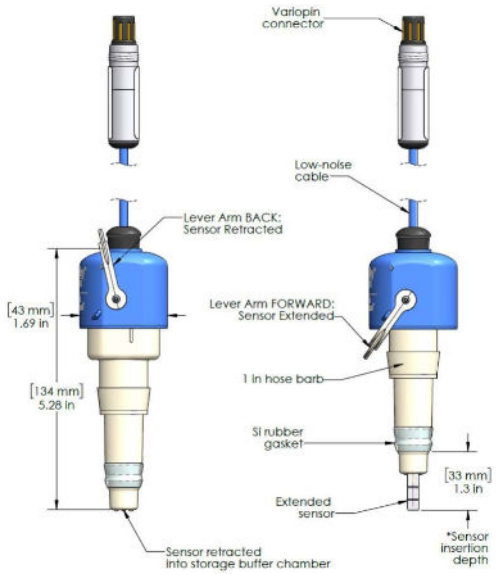
REF SU800-16-V8
Single-Use pH Sensor
for BPC with 1-inch Hose Barb Port

Dimensional Drawings of SU800-16-V8



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Appendix E – Purchasing Sheet (Model SU800)

Product Purchasing Sheet
Doc Nbr PDS-112007 R8
April 2024 – Page 1

SU800-16-V8
Single-Use pH Sensor
for BPC with 1-inch Hose Barb Port

Description

The SU800-16-V8 SingleSense® Single-Use pH Sensor is designed for horizontal preinstallation in a bioprocess container (BPC) with subsequent gamma sterilization.

Purchase Information

Part Number	SU800-16-V8
Description	Single-Use pH Sensor for pre-install in BPC

Classification

Model Type	SU8XX
Product Type	pH Sensor

Specifications

Measurement

Type	pH
Principle	Potentiometric
Range	2–12 pH
Drift	≤ 0.01 pH per day
Accuracy	±.05 pH units

Operational Range

Temperature	15°–40° C [60°–104° F]
Pressure	0–776 mmHg [0–15 psig]
Flow Rate	Not applicable

Signal

Input	Not applicable
Output	Sensor ±414 mV

Sterilization

Autoclavable	Not autoclavable
Steam Sterilizable	Not steam sterilizable
Gamma Sterilizable	Yes, up to 50 kGy

Connectors and Cables

Connector	8-pin Variopin
Cable Length	0.15 m [6 inches]

Process Interface

Insertion Method	1-inch Hose Barb
Insertion Length	13 mm when retracted, 33 mm when extended

SU800-16-V8 Single-Use pH Sensor

Wetted Materials

PEEK, USP 88 Class VI, USP 87, ADI-Free
Extraction Tested 21CFR, 177.2600, Dimethyl Silicone Rubber, Pt Cure, USP 88 Class VI, USP 87
Extraction Tested 21CFR, 177.2600, EPDM USP 88 Class VI, USP 87
FDA Compliant, ADI-Free Lead-Free Glass, Alumina Silicate

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Product Purchasing Sheet
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SU800-16-V8
Single-Use pH Sensor
for BPC with 1-inch Hose Barb Port

Packaging and Regulations

Packaging Information

Package Type .... Cardboard box with double-bagged sensor inside
Package Dimensions .... 30.48 x 30.48 x 5.08 cm [12 in x 12 in x 2 in]
Package Weight .... < 0.5 kg [1 lb]
Double Bagged .... Yes, sensor is double-bagged
Cleanhood Bagged .... Yes, inner bag only
Cleanhood Class .... Class 7 Clean Air Hood
Storage Conditions .... Temperature: 5°–35° C [41°–95° F]
Shipping and Transportation .... Temperature: -29° C [-20° F] for up to 72 hours
Included Accessories .... Not applicable
Quality Certificate .... Included
Shelf Life .... 36 months
Shelf Life Post Gamma Sterilization .... 30 months

Origination and Tariff Code

Harmonized Tariff Trade Code 9027803100
Country of Origin .... USA
MFR Location .... California, USA

Purchasing Information

Unit of Sale .... Each
Minimum Purchase Quantity .... Each

Regulatory and Compliance

CE Compliant .... Yes
RoHS Compliant .... Yes
REACH Compliant .... Yes
CFR 21-11 Compliant .... Not applicable
BSE/TSE/ADI Free .... Yes
USP 88 Class VI, USP 87 Compliant .... Yes, all wetted parts
FDA Material Compliant .... Yes, all wetted parts

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