



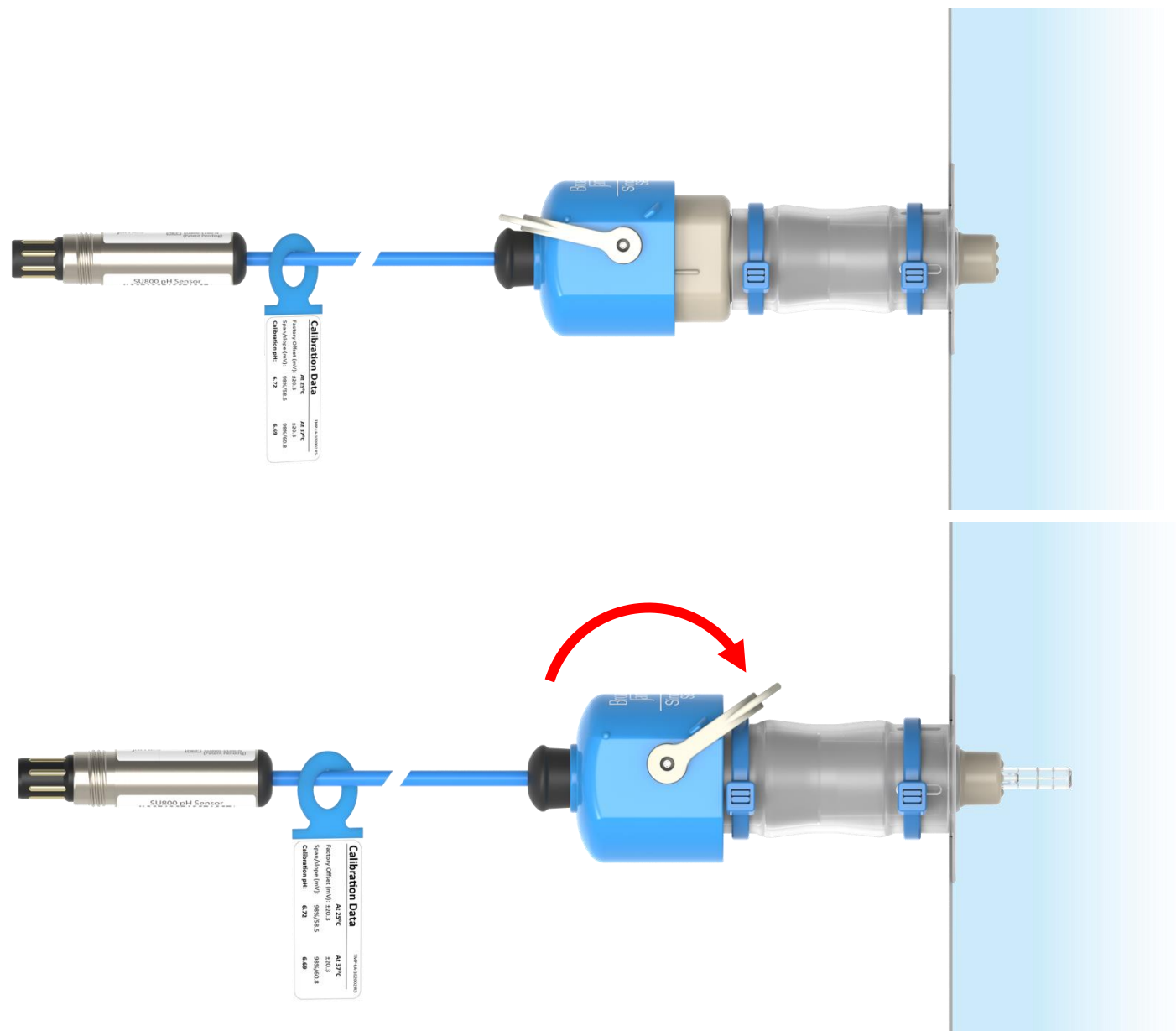
Operation Manual

SingleSense® Single-Use pH Sensor

Model SU800



Doc Nbr: OM-062103 R5
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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.

Disclaimers

Read all instructions prior to installing or operating this product. Save this manual for future reference.

If the instructions in this manual are unclear, contact Broadley-James. If this instruction manual is not for the product ordered, call (949) 829-5555.

Follow all warnings, cautions, and instructions marked on and supplied with the product.

To ensure proper performance, use qualified personnel to install, operate, update, calibrate, and maintain the product.

This product is designed for single-use.

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All sales are subject to our Terms and Conditions, available upon request. We reserve the right to revise or improve this publication at any time without notice. For the latest product documentation and specifications, please visit our website.

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 | Dimethyl Silicone Rubber: Pt Cure, USP Class VI, Extraction Tested 21 CFR, 177 | 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

	Catalogue number
	Serial number
	CE marking
	Use by date
	Temperature limit
	Quantity

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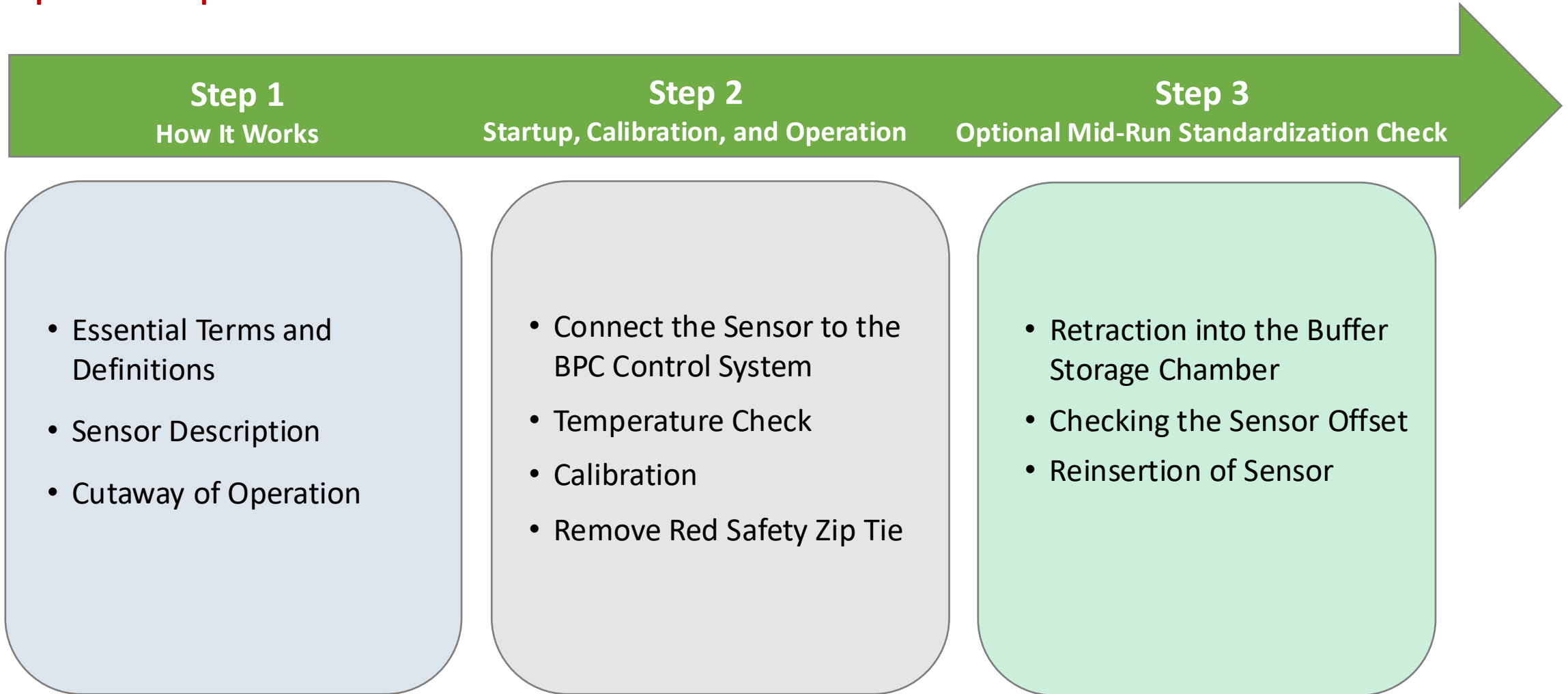
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Operation Steps



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

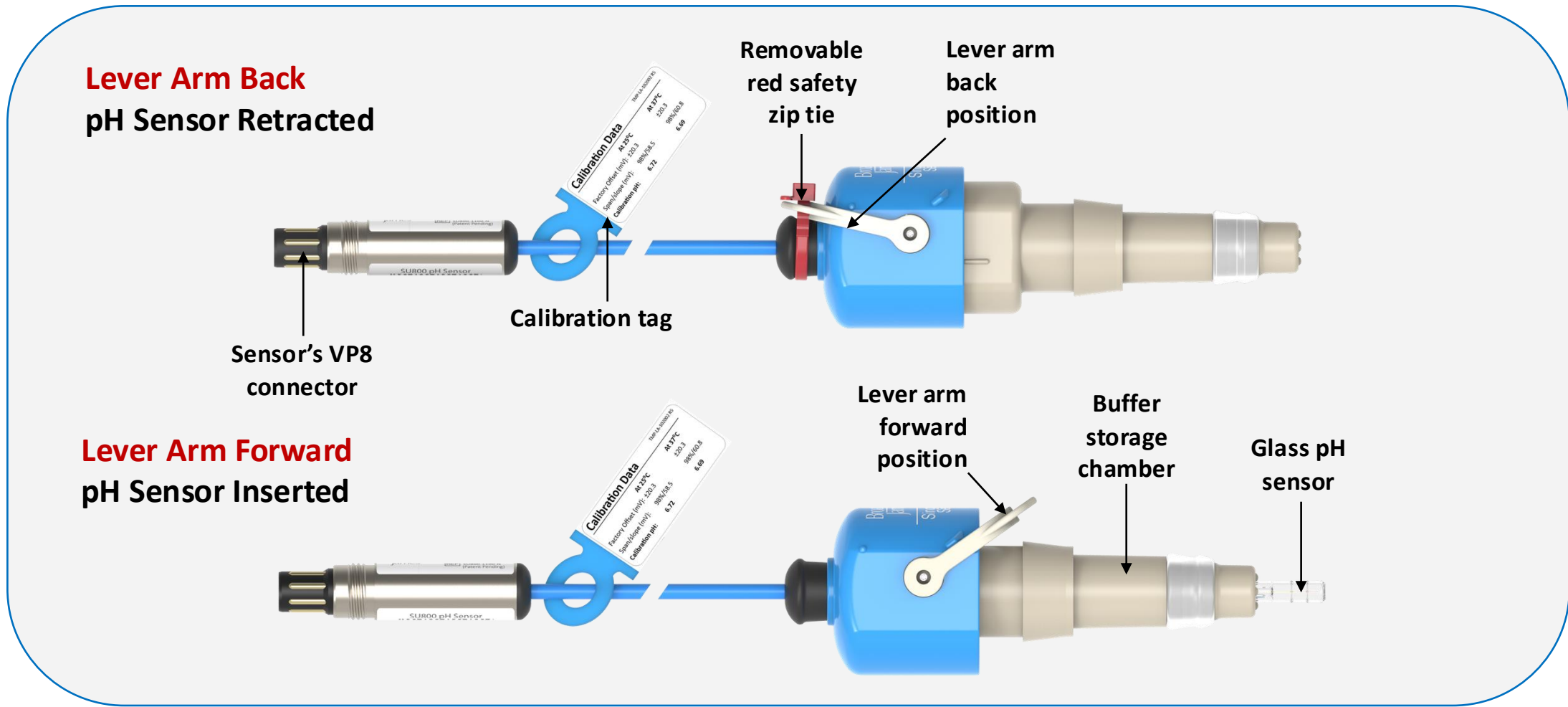


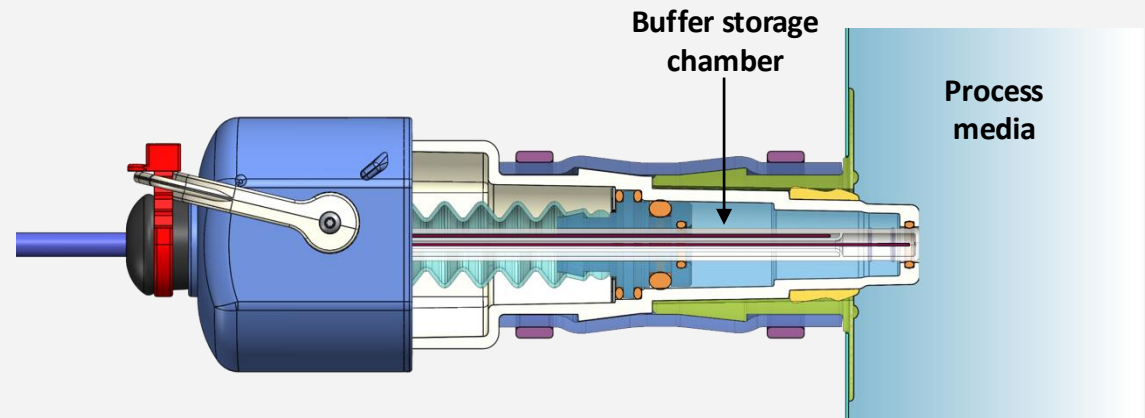
Figure 1. Sensor description

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.

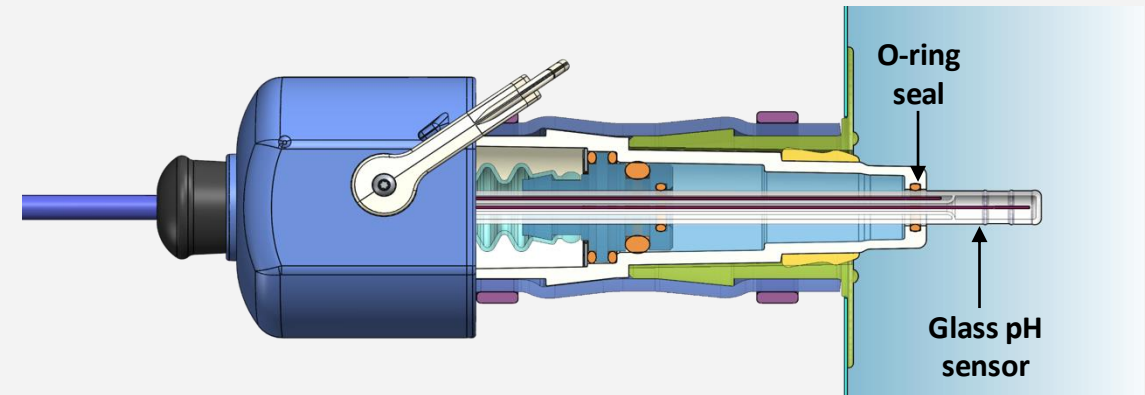
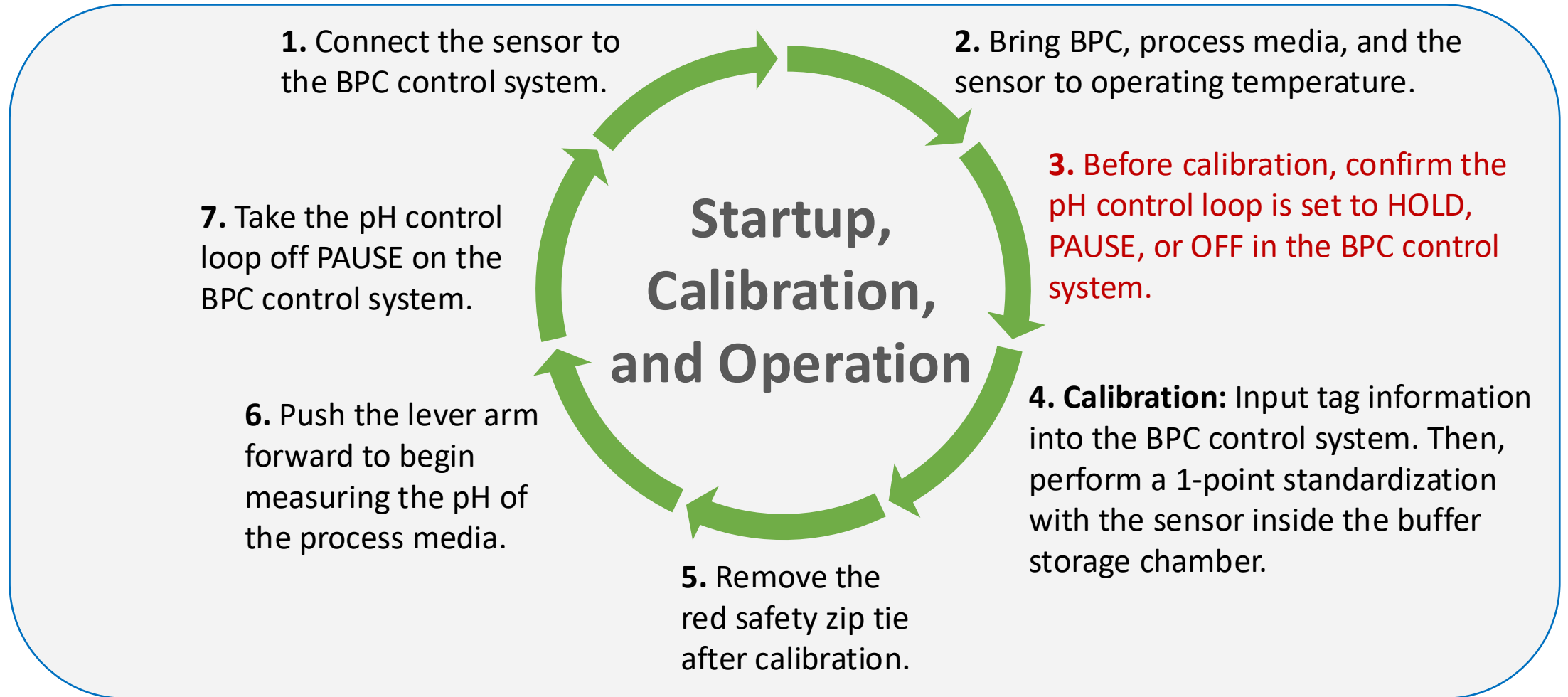


Figure 2. Lever arm back and forward

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.

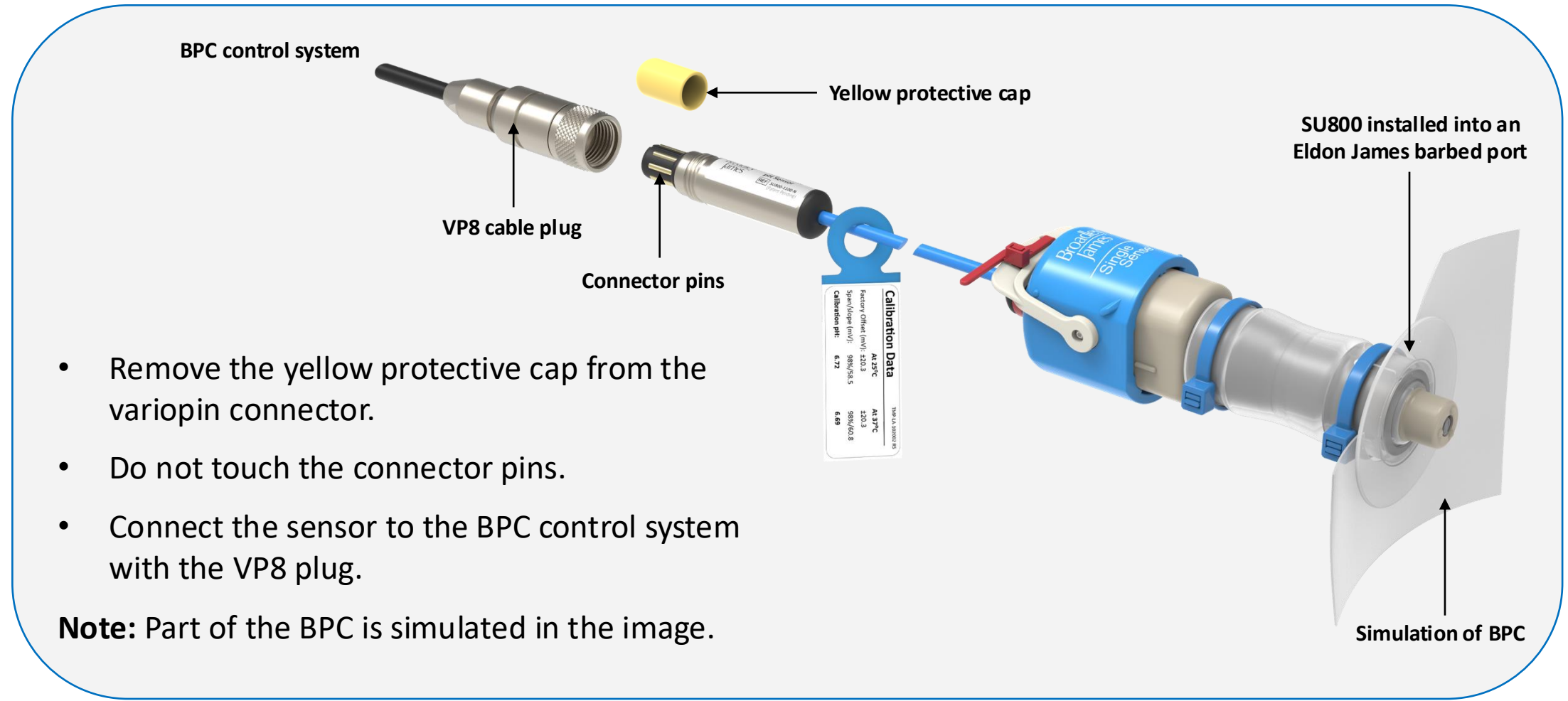


Figure 3. Connecting sensor to BPC control system

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.

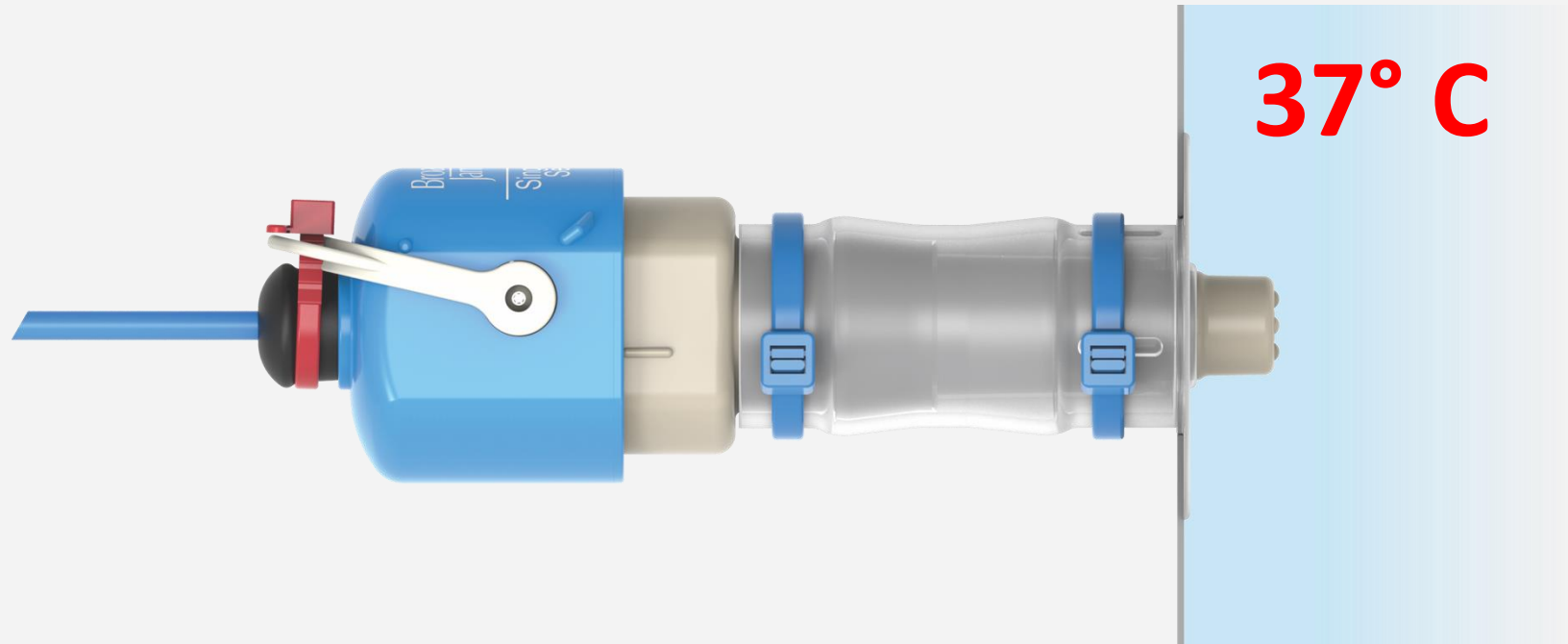


Figure 4. Process media at operating temperature

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.



Calibration Data			TMP-LA-102002 R5
	At 25°C	At 37°C	
Factory Offset (mV):	<u>±20.3</u>	<u>±20.3</u>	
Span/slope (mV):	<u>98%/58.5</u>	<u>98%/60.8</u>	
Calibration pH:	6.72	6.69	

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.



Calibration Data			TMP-LA-102002 R5
	At 25°C	<u>At 37°C</u>	
Factory Offset (mV):	±20.3	±20.3	
Span/slope (mV):	98%/58.5	98%/60.8	
Calibration pH:	6.72	<u>6.69</u>	



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.

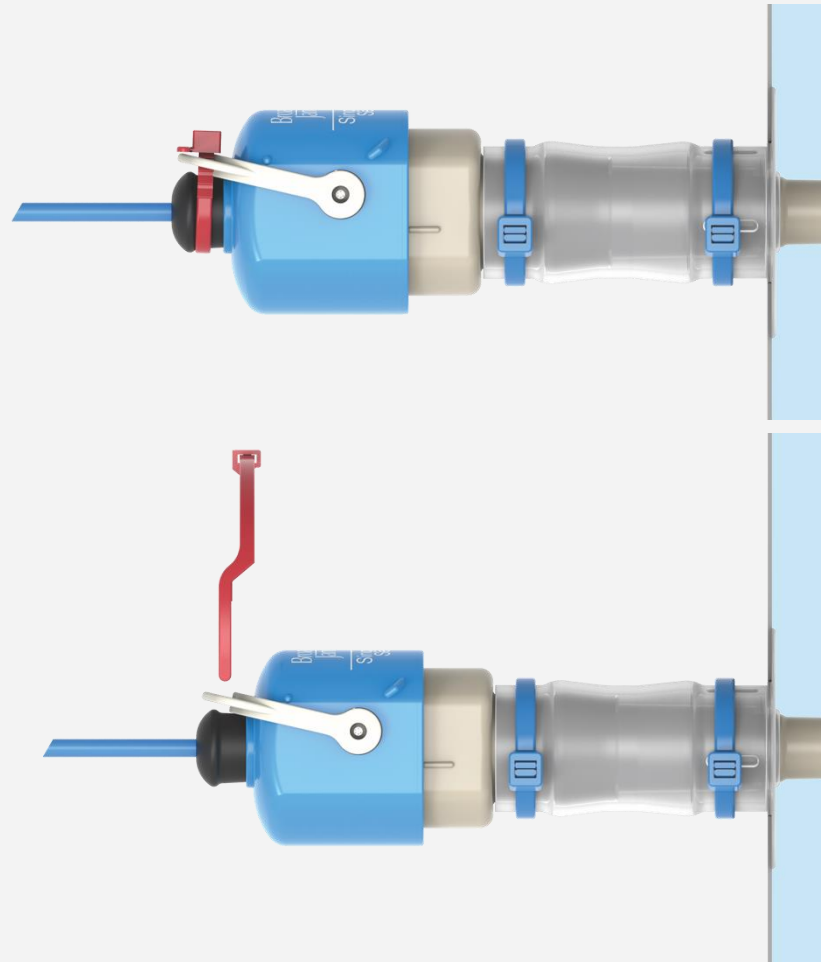


Figure 7. Red safety zip tie removed

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.

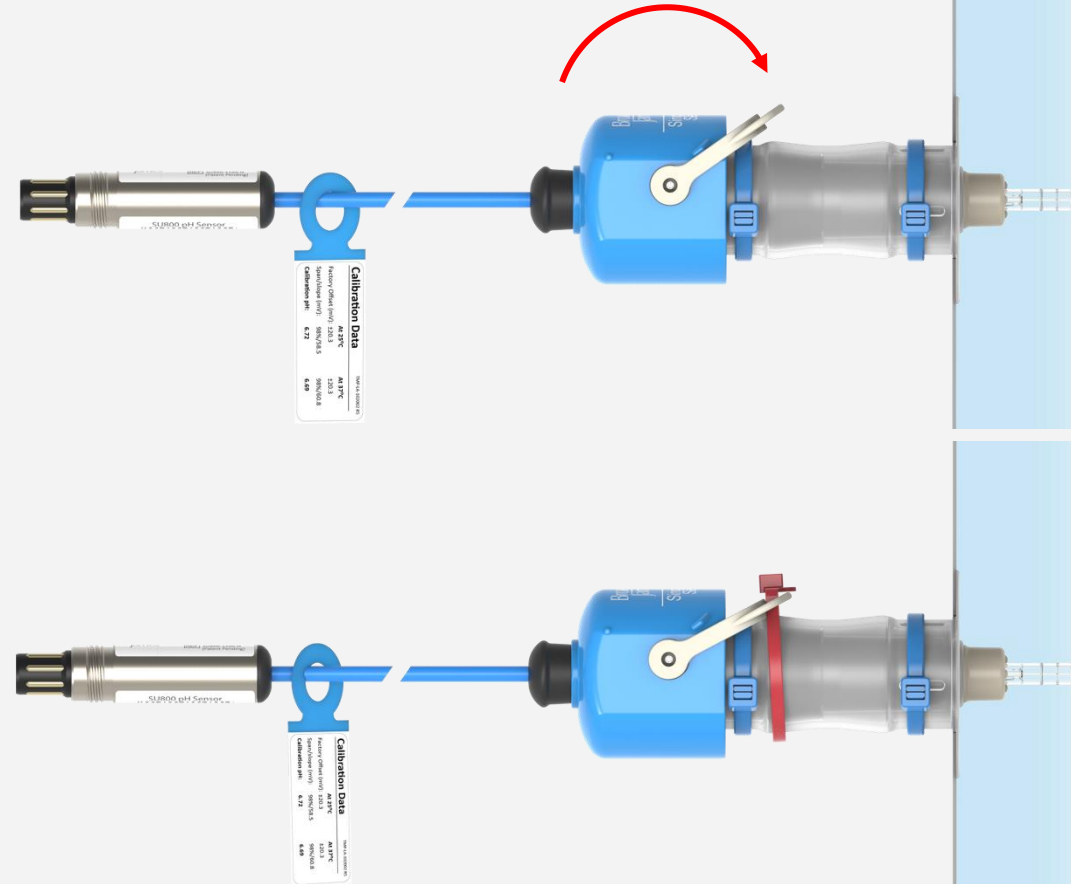


Figure 8. Lever arm inserted and secured

2.9 Reactivate the pH control loop.

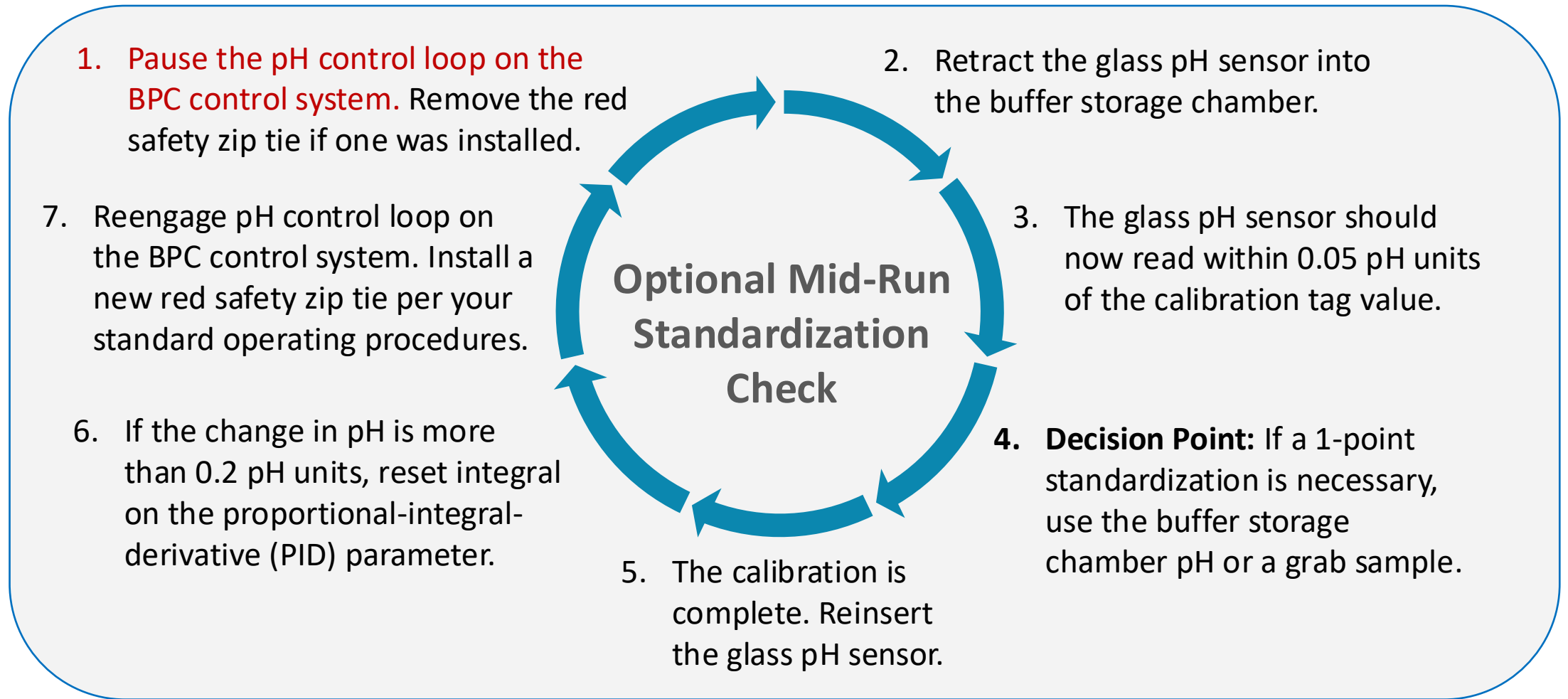


The pH control loop can be taken off HOLD, PAUSE, or OFF and made active again after the glass pH sensor has been inserted into the BPC media.

Step 3: Optional Mid-Run Standardization Check

- 1
 - Retraction into the Buffer Storage Chamber
 - Checking the Sensor Offset
 - Reinsertion of Sensor

3.1 Sequence of Optional Mid-Run Standardization Check



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.

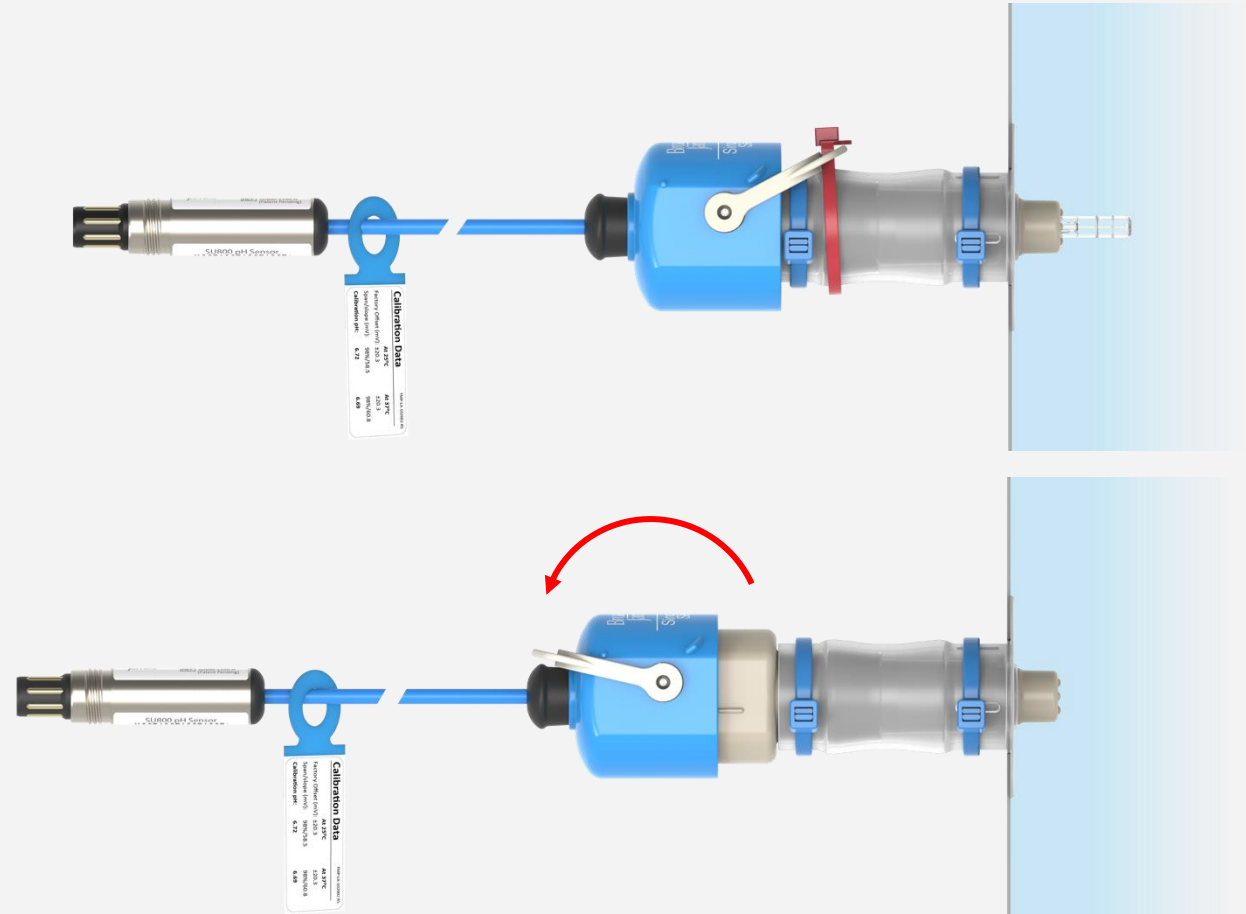


Figure 10. Preparation for optional mid-run standardization check

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.



Calibration Data		TMP-LA-102002 R5
	At 25°C	<u>At 37°C</u>
Factory Offset (mV):	±20.3	±20.3
Span/slope (mV):	98%/58.5	98%/60.8
Calibration pH:	6.72	<u>6.69</u>



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.

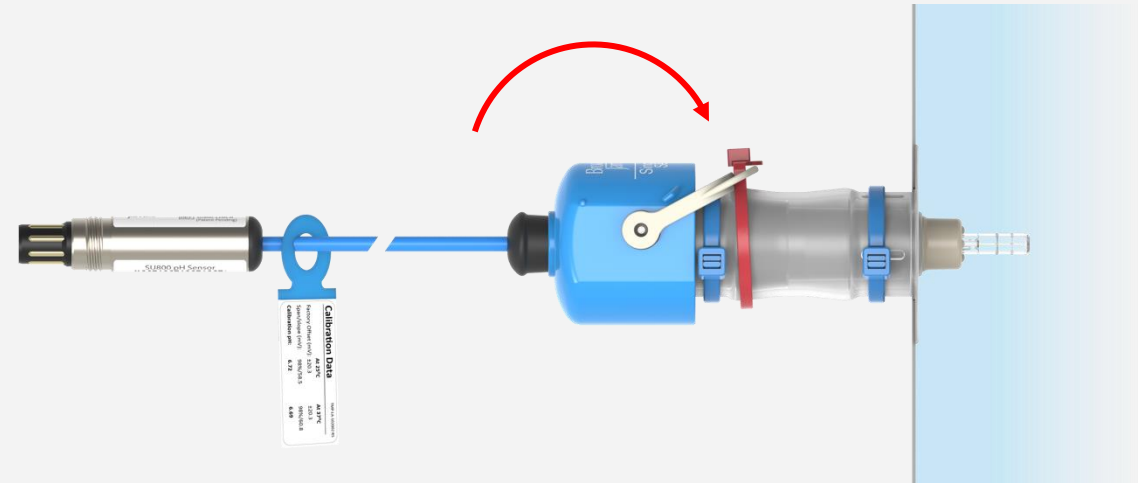


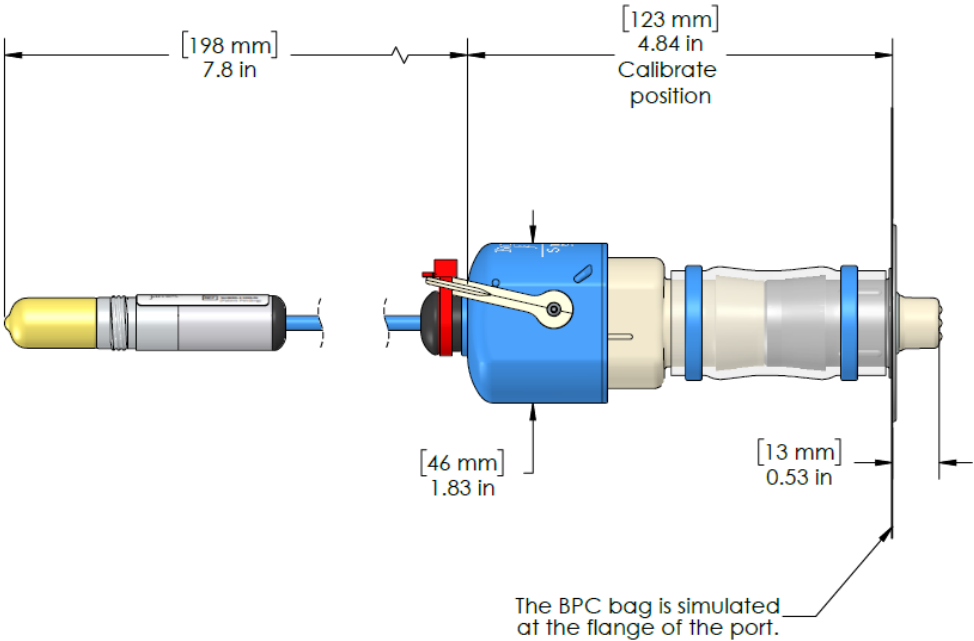
Figure 12. Reinsertion of the sensor

Appendices

- Appendix A – Dimensional Drawing of Sensor
- Appendix B – Buffer Storage Chamber
- Appendix C – Calibration Tag Data

Appendix A – Dimensional Drawing of Sensor

Lever Arm Back
pH Sensor Retracted



Lever Arm Forward
pH Sensor Inserted

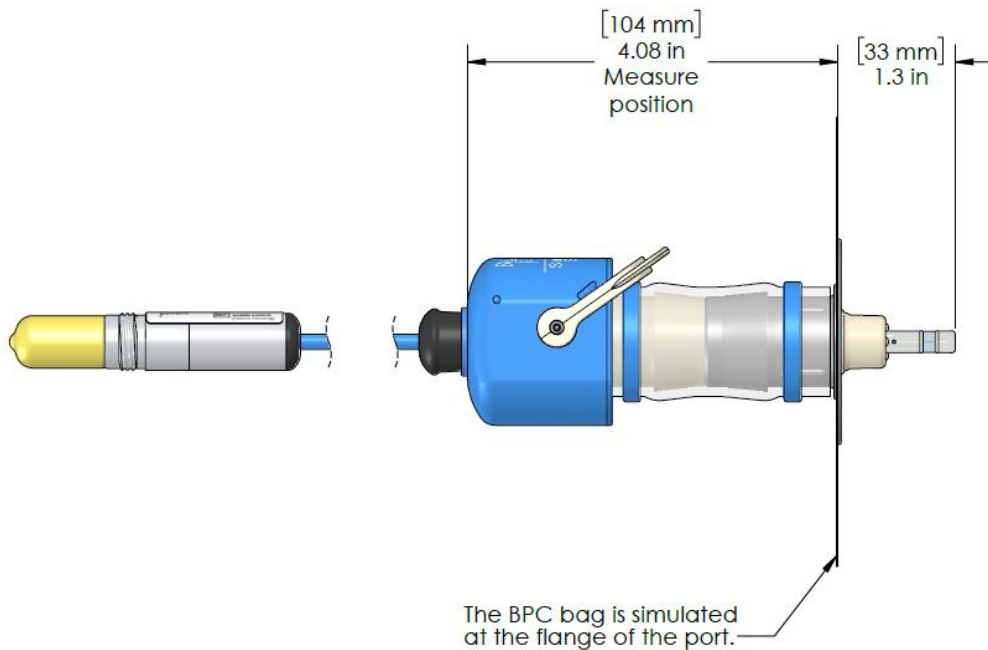
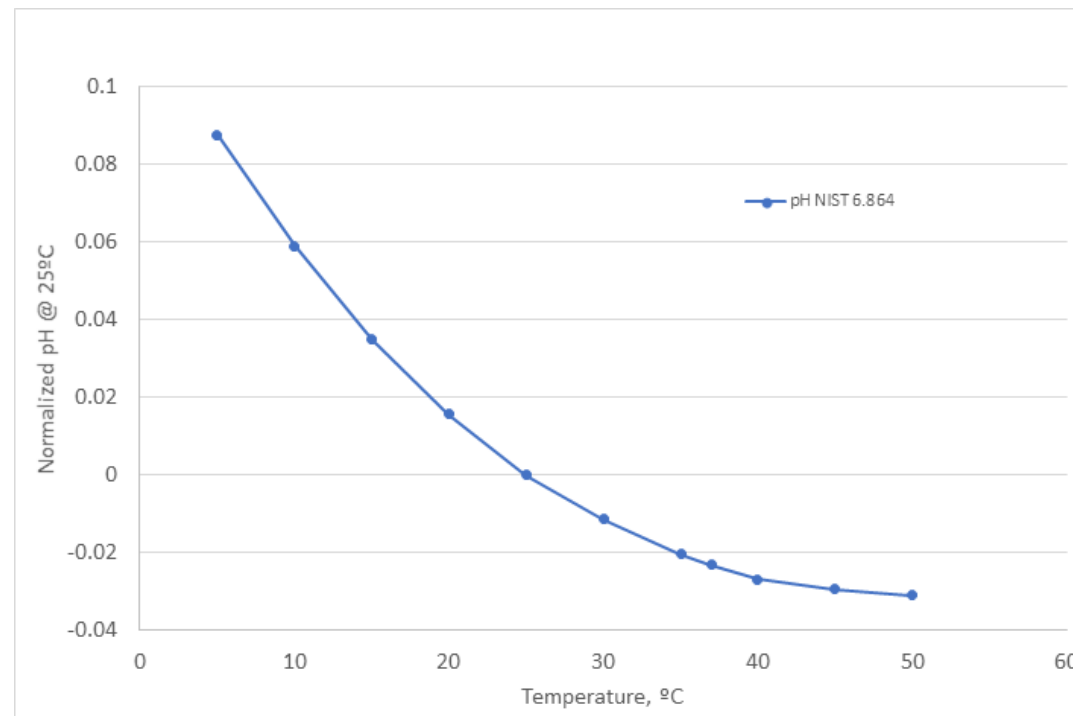


Figure 13. Dimensional drawing of sensor inserted and retracted with red safety zip tie

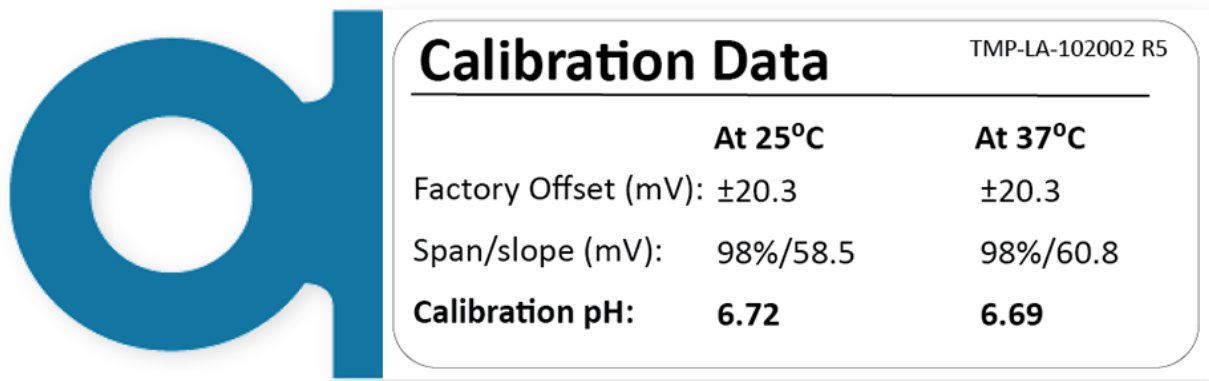
Appendix B – Buffer Storage Chamber Solution Table

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

T, °C	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

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