



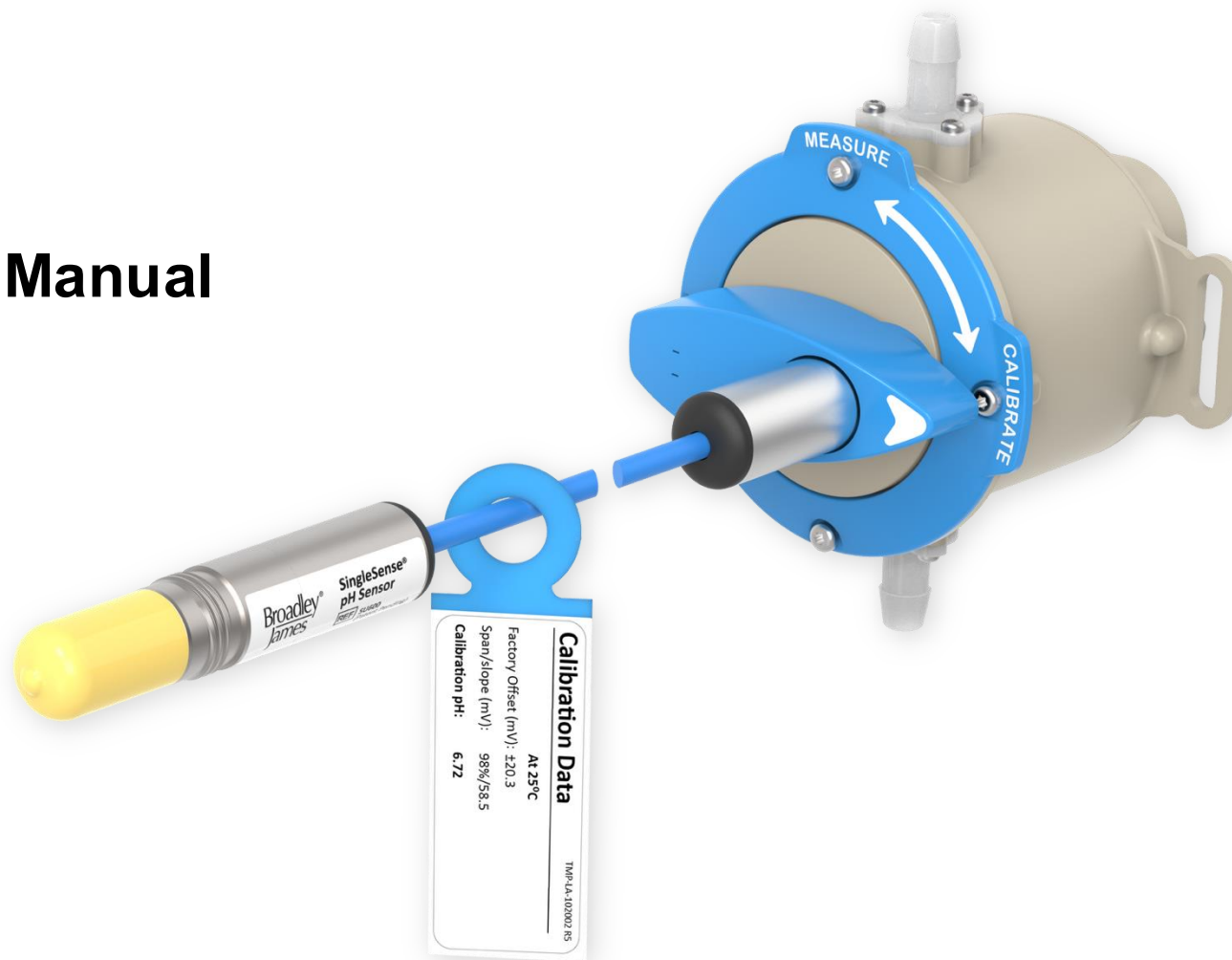
Specification and Installation Manual

SingleSense® Single-Use pH Sensor

Model SU600/SU680



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Purpose

This manual provides instructions on how to specify and install Models SU600/SU680 SingleSense® single-use pH sensors for use with a downstream bioprocess system.

Scope

This manual is for customers who purchase and use Models SU600/SU680 SingleSense® single-use pH sensors.

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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Compliance

Broadley-James Corporation confirms Models SU600/SU680 SingleSense® single-use pH sensors meet 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 SU600 and SU680 SingleSense® single-use pH sensors are designed for installation with a downstream bioprocess system.

Definition of Symbols

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

Contact your Broadley-James representative if you wish us to create a custom single-use assembly with your choice of: **flow cell size, barb size, type of tubing, length of tubing (cm), type of aseptic connector, and sterilization process.**

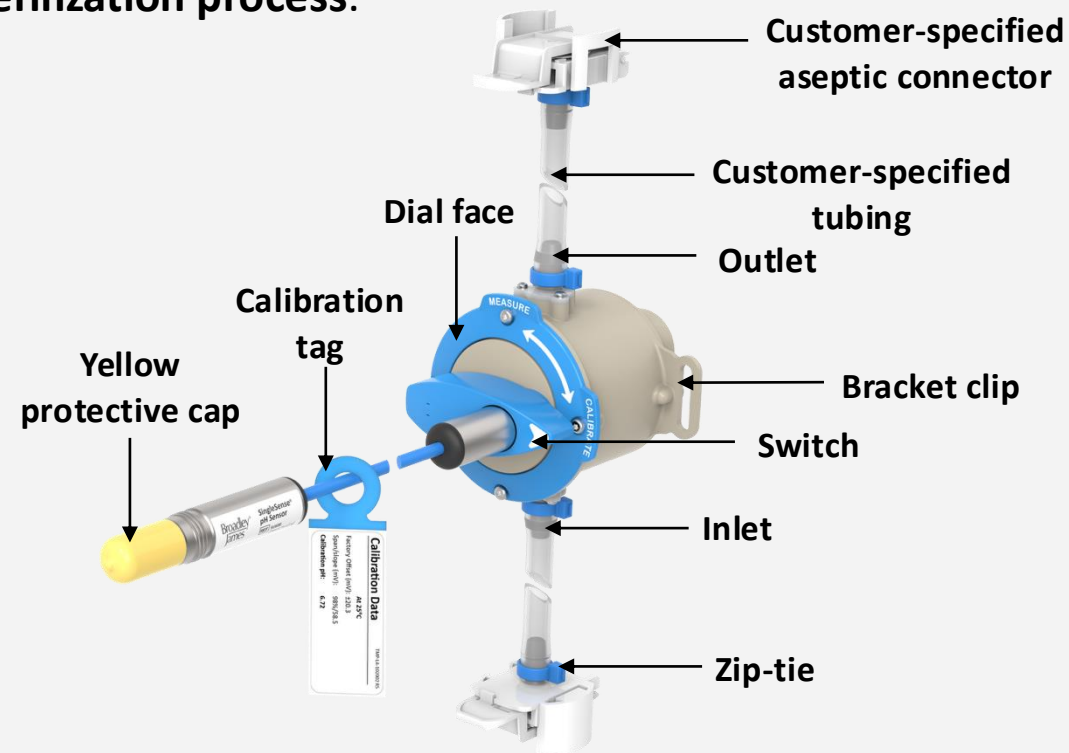


Figure 1. Single-use assembly description

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1.0 Installation

- Sensor Overview
- Installation Overview
- Installation Options
- Mounting to Recommended Bracket

1.1 Essential Terms and Definitions

This table outlines terms and definitions important for the installation process. See the next slides for their location on the sensor and single-use assembly.

Term	Definition
Aseptic connector (optional)	Attaches the sensor to the flow stream
Bracket clip	For attachment to an optional bracket
Calibration tag	Tag on the sensor’s cable that displays data specific to each sensor (do not remove)
Yellow protective cap	Protects the sensor’s VP8 connector during shipment
Dial face	Displays the position of the sensor in either measure or calibrate
Inlet	Allows process solution to pass through the sensor
Mounting bracket (optional)	An optional bracket to mount sensor in a vertical position
Outlet	Allows process solution to flow out of the sensor
Protective barb cover	Disposable cover protecting the barb (not shown)
Switch	Changes the position of the sensor between measure and calibrate
Tubing	Allows process solution to pass through the flow cell
Zip tie	Secures tubing to inlet and aseptic connector

1.2 Sensor Description

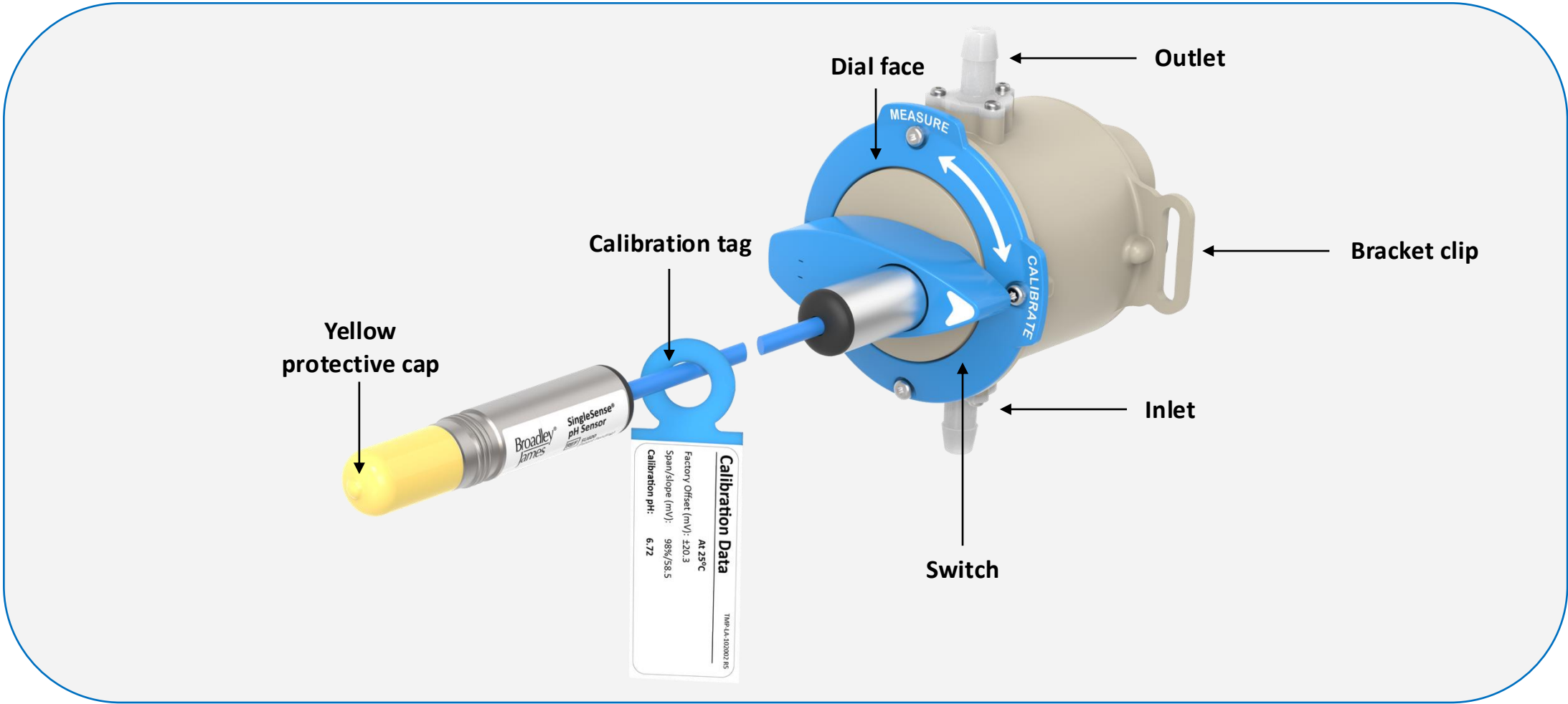


Figure 2. Sensor description

1.3 Single-use Assembly Description

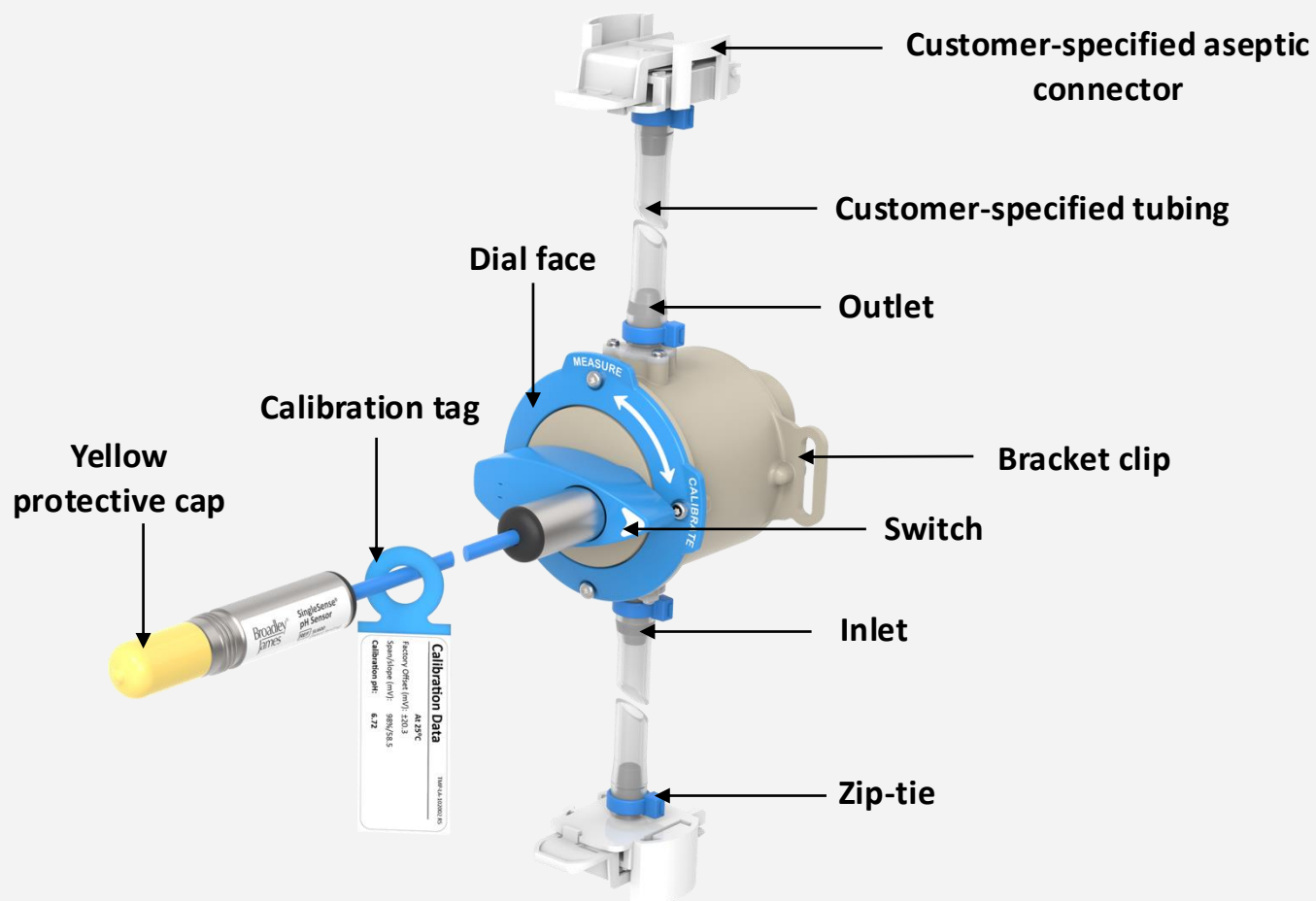


Figure 3. Single-use assembly description

1.5 Sensor Packaging Configuration

- The sensor is double bagged.
- The outer bag protects the inner bag. The inner bag is sealed in a Class 7 clean air hood.
- All labeling on the inner bag is legible through the outer bag.



If a sterilized single-use assembly was ordered, check to see if the gamma sterilization sticker is red. For unsterilized sensors, the sticker will be yellow.

Note: For demonstration purposes, this manual shows an unsterilized SU600 sensor only.



Figure 4. Sensor packaging configuration

1.6 Unpacking the Sensor

- Remove the outer bag from the sensor package and transfer the inner bag to a clean room.
- When inside a clean room, carefully open the inner bag and remove the sensor.

⚠ **Do not remove the calibration tag.**

Note: Do not damage the sensor's cable during removal. Only open the inner bag in a clean room.



Remove from outer bag

*Remove from inner bag only
when in a clean room*

Figure 5. Unpacking the sensor

1.7 Installation Options

Option 1:

For **unsterilized sensors**, tubing or tubing with aseptic connectors will need to be installed and sterilized.

Follow your standard operating procedures to install the sensor.



For correct process solution flow, position the sensor with the outlet and inlet as shown.

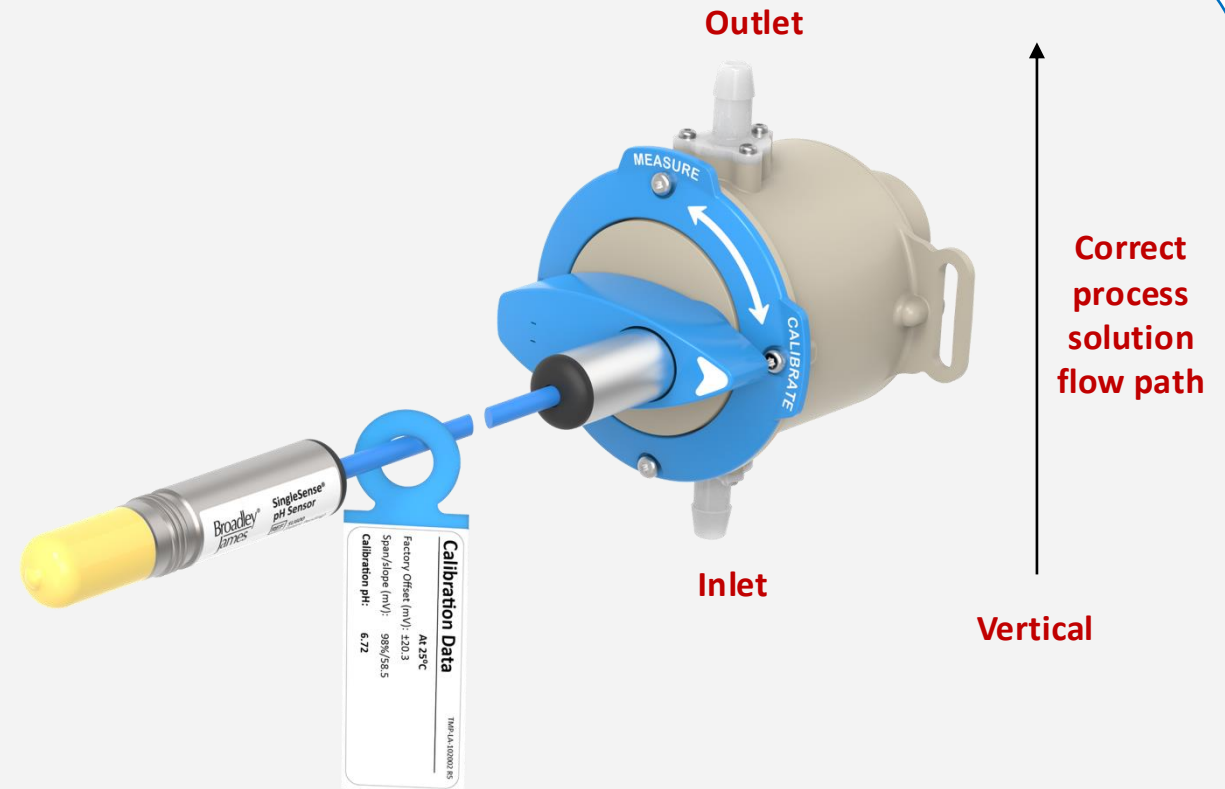


Figure 6. Unsterilized sensor installation option

1.8 Installation Options (cont.)

Option 2:

For **sterilized single-use assemblies**, the assembly is ready for installation into your downstream bioprocess system.



For correct process solution flow, position the sensor with the outlet and inlet as shown.

This completes the installation for a single-use assembly.

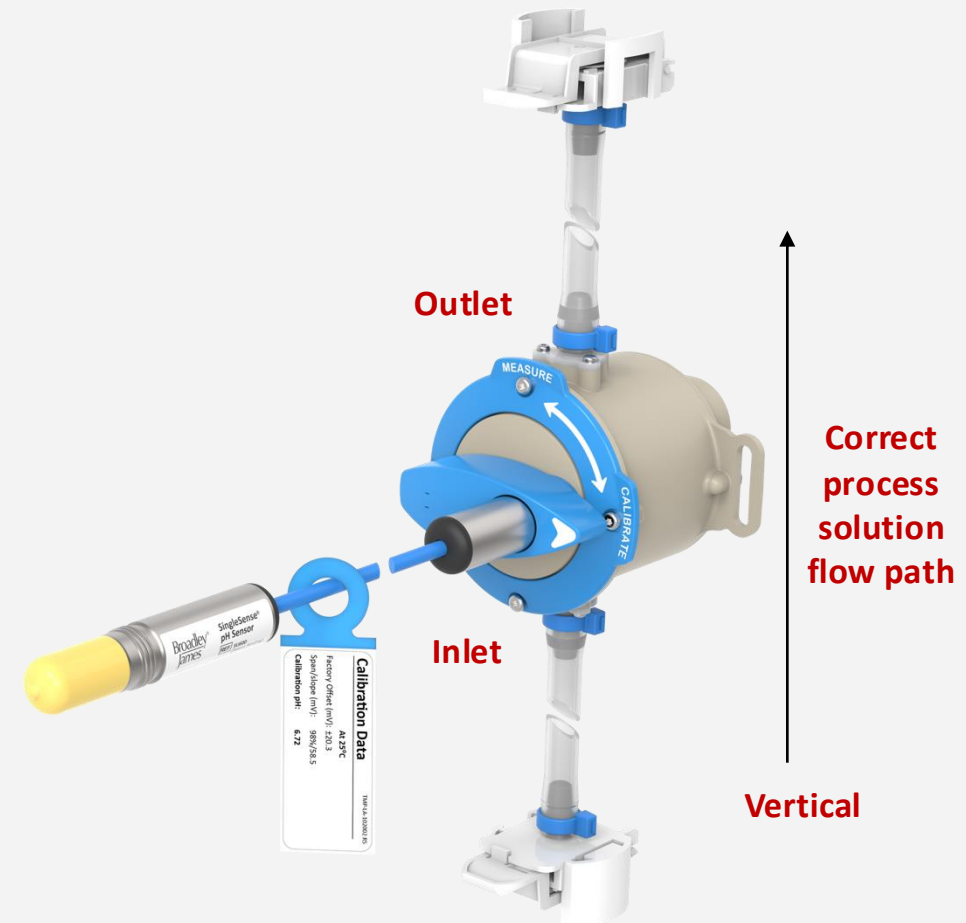


Figure 7. Sterilized single-use assembly installation option

1.9 Mounting to Optional Bracket

To mitigate inline bubbles, the recommended orientation for installing the sensor is vertical, with the outlet on the top and the inlet on the bottom.

Broadley-James offers an optional mounting bracket for this purpose. Contact Broadley-James sales for more information.

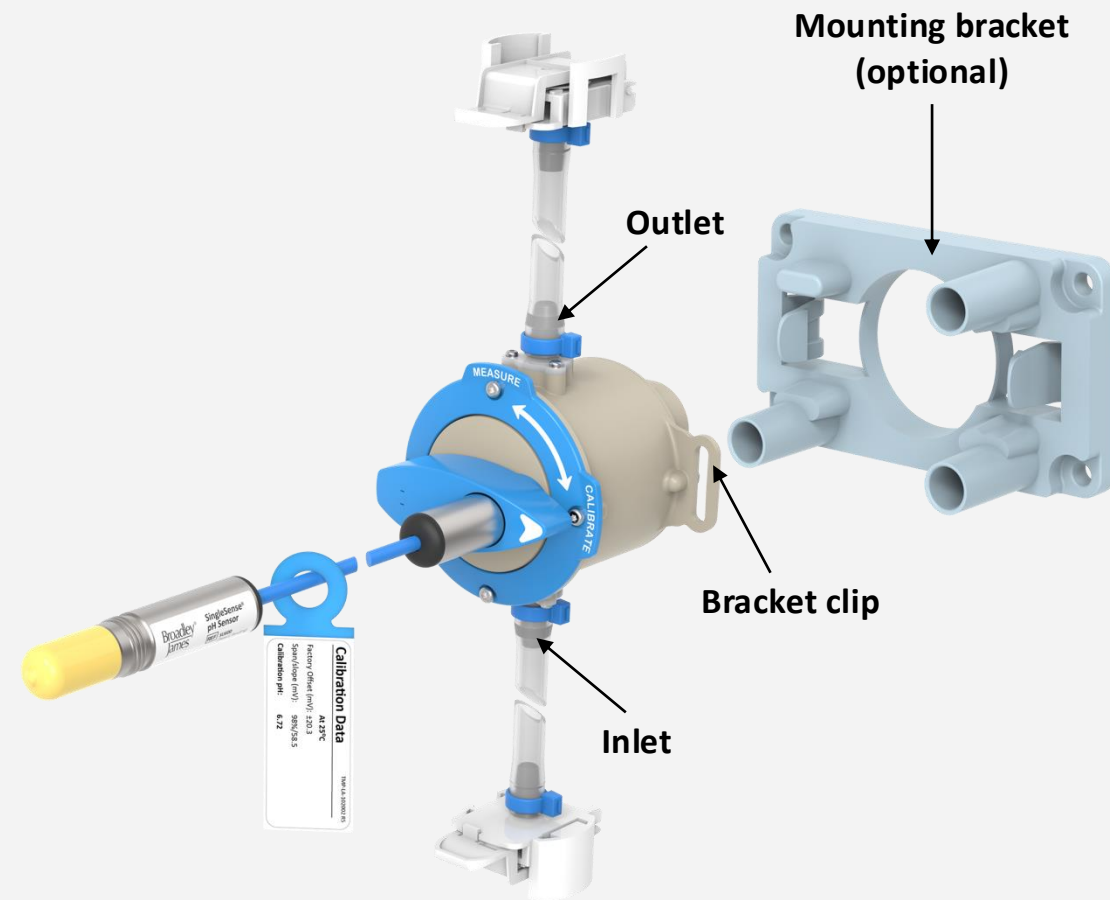


Figure 8. Mounting sensor to optional bracket

1.10 Mounting to Optional Bracket (cont.)

Follow these steps when using an optional mounting bracket:

- Align the bracket clips with the fasteners on the bracket.
- Push the sensor into the bracket to snap it into place.
- To detach the sensor from the bracket, bend back the fastener from the clips. The bracket stays part of the permanent installation.

This completes the recommended installation in the vertical position using the optional bracket.

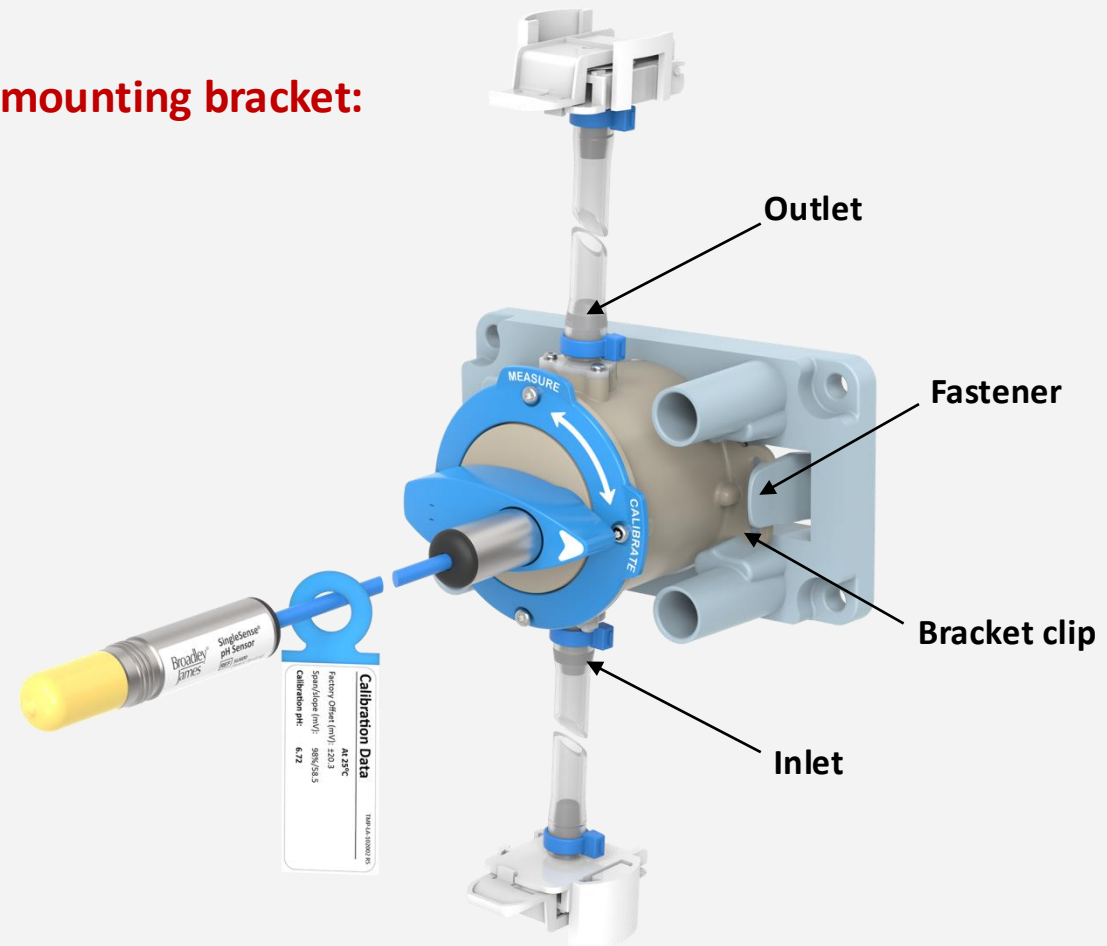


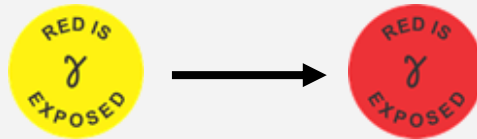
Figure 9. Mounting bracket installation

2.0 Post-Installation Inspection

- Post-installation Checklist
- Calibration Warning

2.1 Post-installation Inspection Checklist

- ☐ 1. Is the calibration tag still attached?
- ☐ 2. Is the switch in the calibrate position?
- ☐ 3. If it is a sterilized single-use assembly, was the sticker red when the sensor was taken out of the bag?



Do not move the dial to the **measure** position until ready to operate.

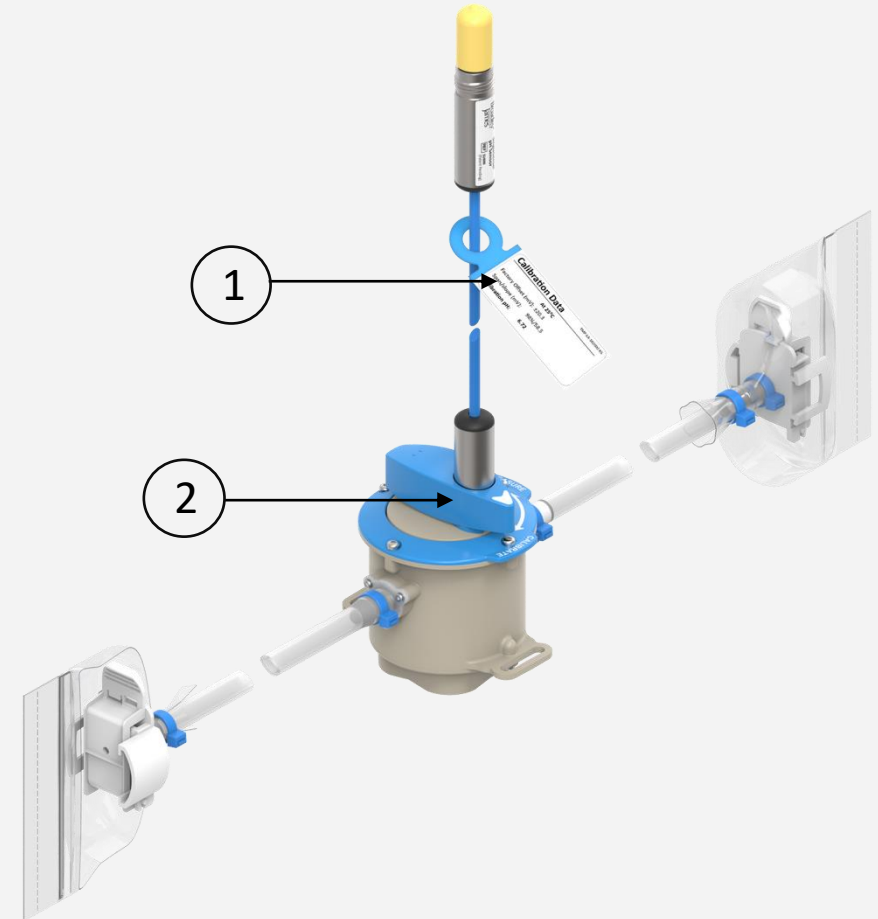


Figure 10. Post-installation inspection checklist

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