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Single-Use pH sensor via a coplanar pH glass electrode design

CD Feng
Broadley-James Corp., USA, cfeng@broadleyjames.com

Robert Garrahy
Broadley-James Corp., USA

Realization of Single-Use pH Sensor : Via a Coplanar pH Glass Electrode Design

CD Feng and Robert Garrahy | Broadley-James Corporation, 19 Thomas, Irvine, CA 92618 | www.broadleyjames.com

1. Introduction

The elimination of high temperature and high pressure sterilization processes by the advent of Single-Use-Systems (SUS) opens up a new era for the glass electrode based pH sensor. Without the requirement for pretreatment of a pH glass electrode by Autoclaving or SIP, we can revert to established sensing technology to deliver a more reliable, more rugged, and more accurate pH measurement.

From A Sensor Point of View

Conventional Bioprocessing
Caustic solution
High temperature
High pressure

Single Use Technology (SUT)
Neutral media
Body temperature
Ambient pressure

However, the innovative and unique SUT approach also posts new challenges, such as a long shelf-life requirement and the limitation of access to the sensor for calibration.

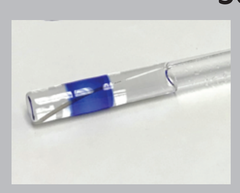
At Broadley-James Corporation®, a new manufacturing technology has been developed to allow a coplanar pH glass electrode design. This innovative sensor design will allow the sensing surface to transfer from a storage/calibration position to a measurement position while maintaining a fully closed and sterile system status. A single-use pH sensor based on this design will exhibit features such as a shelf life up to 2.5 years, on site calibration capability, and post-use validation capability. This poster presents a coplanar tubular glass electrode design for upstream (bag) installation, as well as a coplanar flat glass electrode design for downstream (flow path) installation. Sensor accuracy verification, design details, and preliminary test results are also presented.

2. Sensor Design

Conventional Electrode

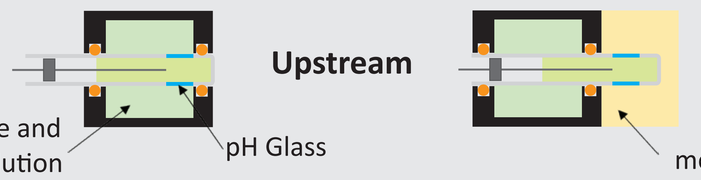
Glass Bulb Electrode

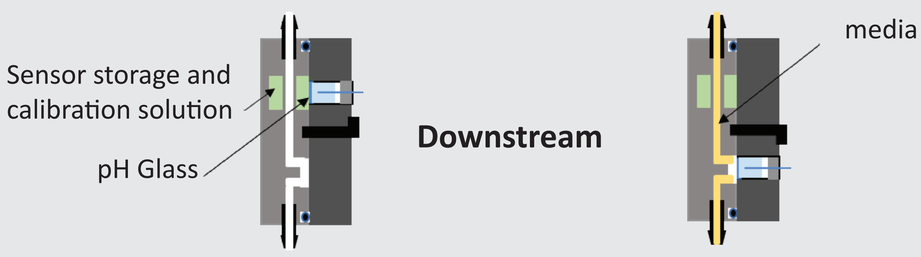
SUT Electrodes



Tubular Glass Bulb Electrode for upstream

Flat Glass Bulb Electrode for downstream



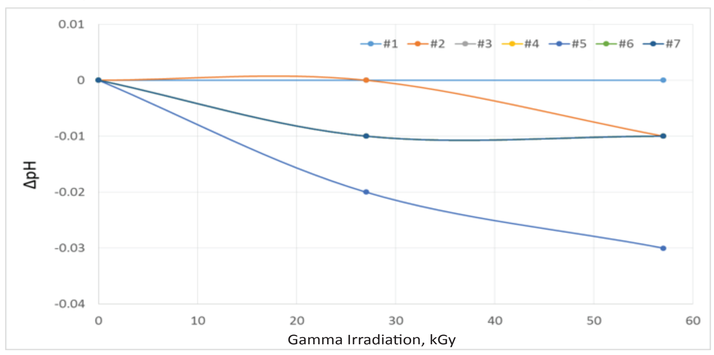


Sensor storage/calibration position

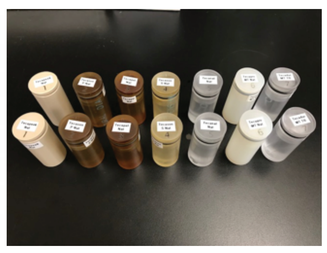
Sensor operation position

3. Storage Solution

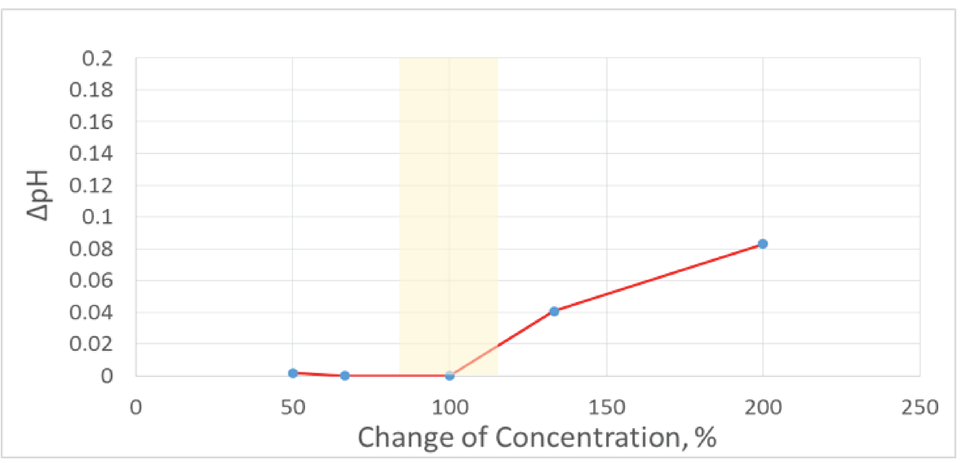
- Buffer Stability in different plastic container after gamma irradiation



Raw Material Choices
Polycarbonate
Polyphenylene Sulphone
Polyetherimide
Polyetheretherketone
Polysulphone
Polypropylene
TecaDur MT



- Buffer Capacity



4. Electrode Performance after Gamma Irradiation

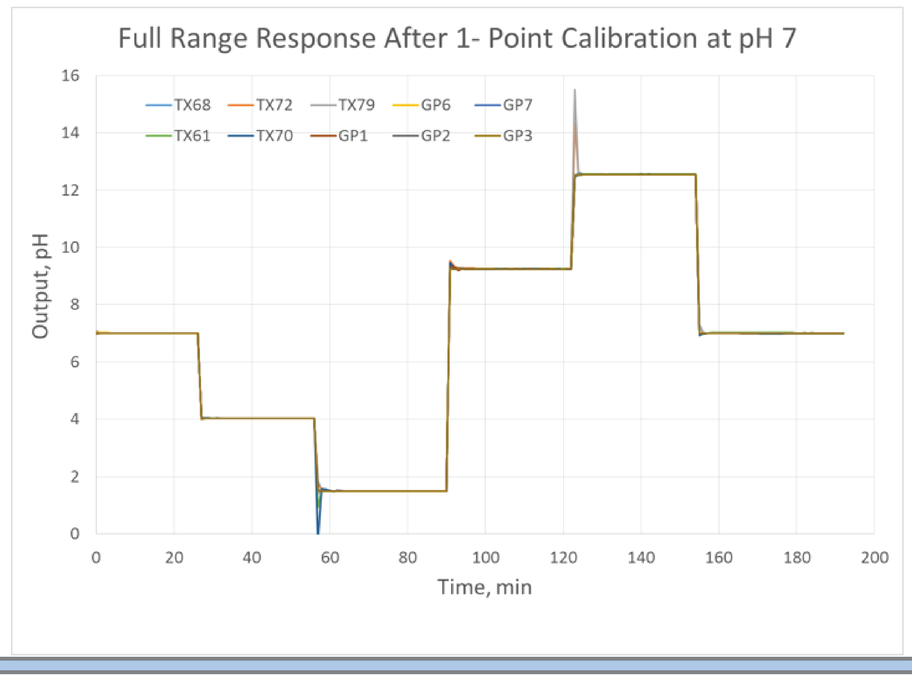
Electrodes were tested after gamma irradiation with no deterioration in slope, accuracy, response time and pH sensing range.

Tubular Glass Electrode slope after Gamma Irradiation

	After gamma irradiation at 26 kGy										
Electrode ID	A-1	A-2	A-3	A-4	A-5	A-6	A-7	A-8	A-9	A-10	A-11
Slope, mV/pH	58.2	58.2	58.3	58.0	58.0	57.9	58.3	58.3	58.2	58.0	57.6
Loss of slope, %	0.5	0.5	0.4	0.8	0.9	1.0	0.3	0.3	0.6	0.8	1.6
	After gamma irradiation at 57 kGy										
Electrode ID	B-1	B-2	B-3	B-4	B-5	B-6	B-7	B-8	B-9	B-10	B-11
Slope, mV/pH	58.3	58.3	58.3	58.2	58.1	58.1	58.4	58.4	58.4	58.2	58.2
Loss of slope, %	0.4	0.3	0.4	0.5	0.7	0.6	0.1	0.2	0.2	0.5	0.6

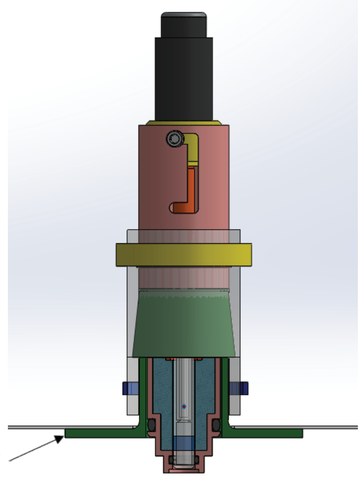
The measurement error caused by a 2% loss of slope when one point calibration is carried out at pH 7

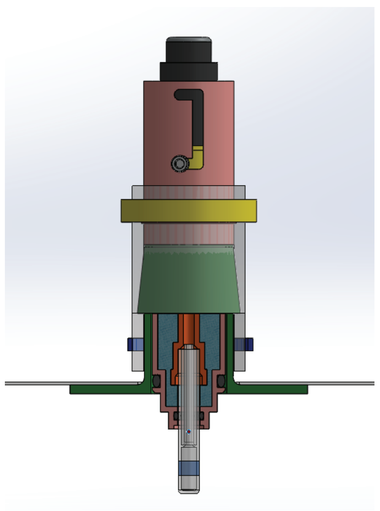
@ pH value	2	3	4	5	6	7	8	9	10	11	12
Error, pH	0.1	0.08	0.06	0.04	0.02	0.00	-0.02	-0.04	-0.06	-0.08	-0.1



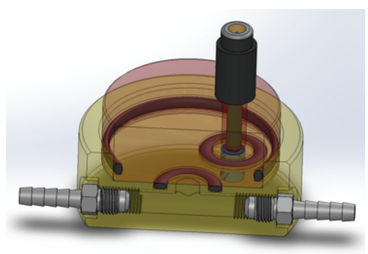
5. 3-D Model of Prototype Sensor

Upstream

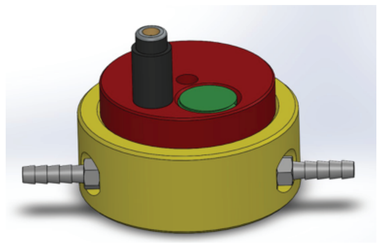




Downstream



Storage/Calibration Position



Operation Position

6. Conclusion

The coplanar glass electrode proves to be accurate and rugged for pH measurement after gamma irradiation. The pH sensor based on the coplanar feature is designed to deliver the following sensor features:

1. Shelf life up to 2.5 Years
2. Withstand gamma irradiation up to 50 kGy
3. Plug and Play with built-in calibration capability
4. Compatible with legacy transmitter and connection
5. Facilitate autoclave-free and sample-free operation

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