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Single Use Sensors in Continuous Bioprocessing

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Abstract

With the expansion of continuous processing in biopharmaceutical development and manufacture using single use components, sensors and monitors that are qualified for continuous longer service life will be required. This poster presents accuracy data for pressure, conductivity, and UV sensors that have been in continuous use up to 93 days.

Introduction:

The growth of continuous processing in bioprocessing coupled with the benefits of single use technology (SUT) creates demand for SUT sensors that have proven performance in long term use. To demonstrate the performance of SUT sensors over time, laboratory studies on PendoTECH Single Use Pressure SensorsTM and also on SUT conductivity sensors were carried out to provide data showing that the sensors will maintain their accuracy in continuous use. In a related study, the long term stability of PendoTECH UV/Vis/NIR photometer was determined and is reported here

PendoTECH Single Use Pressure Sensors

To demonstrate the long term accuracy of PendoTECH Single Use Pressure Sensors two 7-day and one 93-day experiments were carried out: (1) accuracy over 7 days with a constant pressure of 3.5 bar (2) accuracy over 7 days with a constant pressure of 0.5 bar with twice per day pressure spikes to 3 bar, and (3) 93 days with constant pressure of 10 psi.

Accuracy at Constant 3.5 bar Over 7 Days

* = Polysulfone
All others = PC

Sensor ID	Elapsed Time = 0 Hours					Sensor Performance	Elapsed Time = 168 Hours					Sensor Performance
	Applied Pressure (bar)						Applied Pressure (bar)					
	0	0.5	1	2	4		0	0.5	1	2	4	
1152607-01	0.00	0.51	1.01	2.01	4.07	Pass	0.00	0.51	1.01	2.01	4.07	Pass
1152607-02	0.00	0.51	1.01	2.02	4.14	Pass	0.00	0.51	1.01	2.01	4.14	Pass
1152607-03	0.00	0.50	1.01	2.02	4.20	Pass	0.00	0.51	1.01	2.02	4.19	Pass
1152607-04	0.00	0.50	1.01	2.01	4.17	Pass	0.00	0.50	1.01	2.01	4.17	Pass
1161066-01*	0.00	0.50	1.01	2.02	4.14	Pass	0.00	0.50	1.01	2.01	4.13	Pass
1161066-02*	0.00	0.51	1.01	2.02	4.14	Pass	0.00	0.50	1.01	2.02	4.13	Pass
1161066-03*	0.00	0.51	1.01	2.02	4.15	Pass	0.00	0.51	1.01	2.02	4.15	Pass
1161066-04*	0.00	0.50	1.01	2.01	4.13	Pass	0.00	0.50	1.01	2.01	4.13	Pass
1151819-01	0.00	0.50	1.01	2.01	4.14	Pass	0.00	0.50	1.01	2.01	4.14	Pass
1151819-02	0.00	0.50	1.01	2.02	4.14	Pass	0.00	0.50	1.01	2.02	4.15	Pass
1151819-03	0.00	0.51	1.01	2.02	4.16	Pass	0.00	0.51	1.01	2.02	4.16	Pass
1151819-04	0.00	0.50	1.01	2.02	4.16	Pass	0.00	0.51	1.01	2.02	4.16	Pass
Acceptance Criterion (+/-)	2% 0.00	3% 0.02	3% 0.03	3% 0.06	5% 0.20	All within specifications	2% 0.00	3% 0.02	3% 0.03	3% 0.06	5% 0.20	All within specifications

Accuracy at Constant 3.5 bar Over 7 Days with Pressure Spikes to 3 bar

* = Polysulfone
All others = PC

Sensor ID	Elapsed Time = 0 Hours					Sensor Performance	Elapsed Time = 176 Hours					Sensor Performance
	Applied Pressure (bar)						Applied Pressure (bar)					
	0	0.5	1	2	4		0	0.5	1	2	4	
1152607-05	0.00	0.50	1.01	2.01	4.12	Pass	0.00	0.51	1.01	2.01	4.12	Pass
1152607-06	0.00	0.51	1.01	2.02	4.16	Pass	0.00	0.51	1.02	2.02	4.16	Pass
1152607-07	0.00	0.51	1.01	2.01	4.13	Pass	0.00	0.51	1.01	2.01	4.14	Pass
1152607-08	0.00	0.50	1.01	2.01	4.17	Pass	0.00	0.50	1.01	2.02	4.18	Pass
1161066-05*	0.00	0.51	1.01	2.01	4.12	Pass	0.00	0.51	1.01	2.02	4.12	Pass
1161066-06*	0.00	0.51	1.01	2.01	4.15	Pass	0.00	0.51	1.01	2.02	4.15	Pass
1161066-07*	0.00	0.50	1.01	2.02	4.14	Pass	0.00	0.51	1.01	2.02	4.15	Pass
1161066-08*	0.00	0.50	1.01	2.01	4.12	Pass	0.00	0.51	1.01	2.01	4.12	Pass
1151819-05	0.00	0.51	1.01	2.02	4.16	Pass	0.00	0.51	1.02	2.03	4.16	Pass
1151819-06	0.00	0.51	1.01	2.02	4.14	Pass	0.00	0.51	1.02	2.02	4.14	Pass
1151819-07	0.00	0.51	1.01	2.02	4.15	Pass	0.00	0.51	1.02	2.02	4.15	Pass
1151819-08	0.00	0.51	1.01	2.01	4.13	Pass	0.00	0.51	1.01	2.02	4.14	Pass
Acceptance Criterion (+/-)	2% 0.00	3% 0.02	3% 0.03	3% 0.06	5% 0.20	All within specifications	2% 0.00	3% 0.02	3% 0.03	3% 0.06	5% 0.20	All within specifications

Accuracy at Constant 10 psi After 93 Days

* = Polysulfone

Sensor ID	Test Duration: 10/25/2016 - 1/26/2017			
	Average Pressure (psi)	Minimum Range (psi)	Maximum Range (psi)	Sensor Performance
1152607-01	10.03	9.94	10.12	Pass
1152607-02	10.01	9.92	10.10	Pass
1152607-03	10.00	9.91	10.09	Pass
1152607-04	9.93	9.85	10.04	Pass
1161066-01*	10.02	9.95	10.11	Pass
1161066-02*	10.01	9.94	10.11	Pass
1161066-03*	10.04	9.97	10.15	Pass
1161066-04*	10.01	9.93	10.09	Pass
1151819-01	9.99	9.88	10.08	Pass
1151819-02	10.00	9.89	10.10	Pass
1151819-03	10.01	9.90	10.11	Pass
1151819-04	10.01	9.91	10.10	Pass
Acceptance Criterion (+/-)	3% 0.30	3% 9.70	3% 10.30	All Within Specifications

Pressure Accuracy Verification Post 93 Days

* = Polysulfone
All others = PC

Sensor ID	Test Duration: 10/25/2016 - 1/26/2017							Sensor Performance
	Applied Pressure (psi)							
	0	5	10	20	30	40	50	60	
1152607-05	-0.03	4.99	10.10	20.17	30.09	40.29	50.58	61.09	Pass
1152607-06	-0.04	4.97	10.05	20.19	30.09	40.56	51.22	62.15	Pass
1152607-07	-0.04	4.95	10.08	20.22	30.21	40.85	51.78	62.99	Pass
1152607-08	-0.05	4.93	10.01	20.05	30.10	40.49	51.52	62.67	Pass
1161066-05*	-0.02	4.99	10.07	20.20	30.15	40.48	51.29	62.17	Pass
1161066-06*	-0.03	4.99	10.07	20.19	30.13	40.50	51.26	62.14	Pass
1161066-07*	-0.02	4.99	10.13	20.19	30.28	40.72	51.33	62.32	Pass
1161066-08*	-0.03	4.98	10.07	20.12	30.17	40.41	51.11	61.93	Pass
1151819-05	-0.01	4.98	10.03	20.12	30.17	40.46	51.26	62.14	Pass
1151819-06	-0.04	4.98	10.09	20.14	30.16	40.67	51.35	62.29	Pass
1151819-07	-0.03	5.00	10.10	20.16	30.18	40.72	51.44	62.52	Pass
1151819-08	-0.01	5.00	10.06	20.19	30.27	40.72	51.44	62.42	Pass
Acceptance Criterion (+/-)	2% 0.10	3% 0.30	3% 0.60	3% 0.90	5% 2.00	5% 2.50	5% 3.00		All within specifications

Conclusion:

After 7 days exposure to 3.5 bar, PendoTECH Single Use Pressure Sensors remained accurate when tested up to 4 bar at specified intervals within the 168 hours of exposure.

Similarly in another experiment, after 7 days of exposure to 0.5 bar and periodic (twice per day) pressure spikes to 3 bar within 5 seconds, the pressure sensors remained accurate when tested up to 4 bar at specified intervals within the 176 hours.

After 93 days exposure to 10 psi the pressure sensors remained accurate.

Overall, the test results clearly show the PendoTECH Single Use Pressure Sensors remain well within their stated accuracy specification over the life of the experiments.

PendoTECH Single Use Conductivity Sensors

A 35 day static continuous laboratory test was carried out on PendoTECH Single Use Conductivity SensorsTM to provide data demonstrating that the sensors will maintain their accuracy in long term use.

Accuracy at Conductivity Standards 2 mS & 15 mS After 35 Days
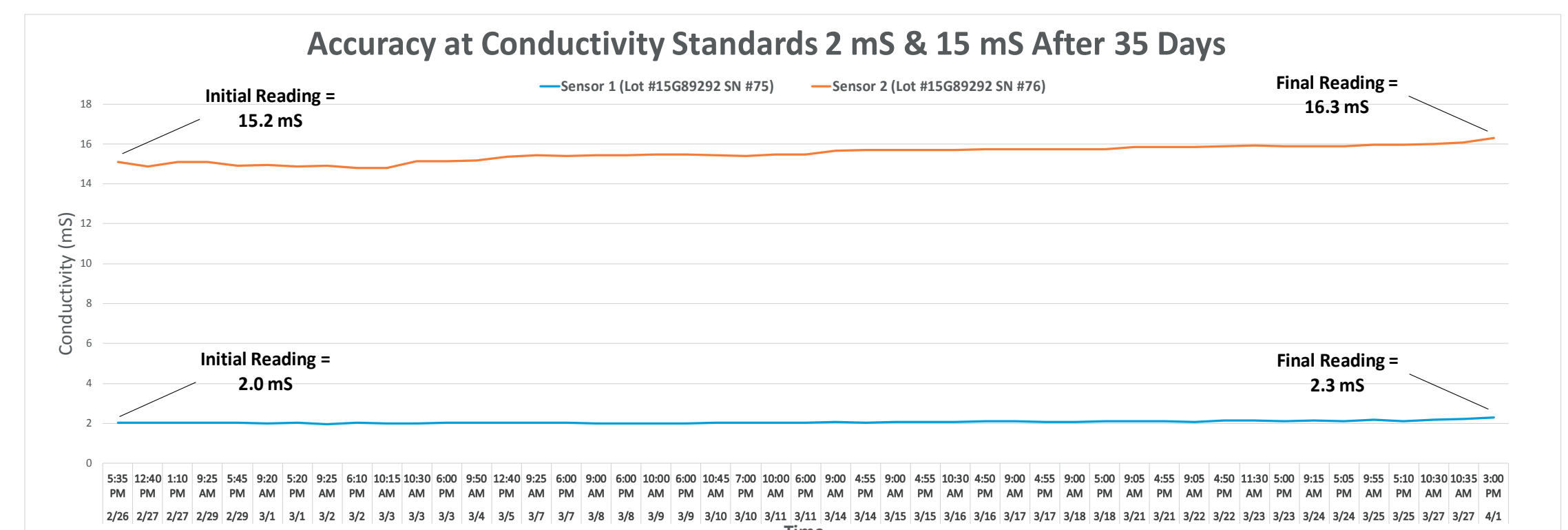
Conclusion:

While a slight drift upward in readings was noted over 35 days, it is clear that the solutions used in this 35 days test study experienced an increase in concentration, very likely due to some evaporation of water during the test. Taking that into consideration, the conductivity sensors showed no change in reading over 35 days at ambient temperatures.

PendoTECH UV/VIS/NIR Photometer

The PendoTECH UV/Vis/NIR system consists of a photometer with wavelength specific LED light source, fiber optic cables and optical couplers, and flow cell.

Accuracy of 280 nm UV Photometer After 93 Days

280 nm Standard	UV (AU)
Test Duration: 10/25/2016 - 1/26/2017	
0.46 AU Standard	0.45
1.01 AU Standard	0.99
1.51 AU Standard	1.50
> 2.00 AU Standard	2.03

Conclusion:

After 93 days powered on and in-service, the PendoTECH UV transmitter continued to test within specifications for the entire output range of the unit.