

8.7 Five Year shelf life: Sensor Integrity- Burst Testing

8.7.1 Procedure- In order to qualify the products for a five year shelf life, twelve polysulfone sensors from six different lots were tested for leaks or burst upon exposure to 150+ psi after storage for 5 years at ambient conditions and then gamma irradiation at 30-40 kGy.

8.7.1.1 Acceptance Criteria- No burst and leak rate less than 0.01 psi per second

8.7.2 Data Summary-

Sensor	Lot #	S/N	Final Test Pressure (psi)	Burst/ Leak Result
1	1132694	78	161.19	Pass
2	1132518	51	161.23	Pass
3	1132694	77	161.27	Pass
4	1132518	52	161.17	Pass
5	1132694	76	161.18	Pass
6	1132518	53	161.21	Pass
7	1132694	79	161.19	Pass
8	1133155	26	161.24	Pass
9	1132715	105	161.18	Pass
10	1132715	104	161.17	Pass
11	1131209	26	160.34	Pass
12	1132789	26	161.20	Pass

8.7.3 Conclusions- All sensors meet the acceptance criteria and therefore are qualified for a five year shelf life.

8.8 Five Year Shelf Life: Sensor Accuracy- Performance after 5 years storage, and following gamma radiation

8.8.1 Procedure- 12 of part number PREPS-N-050 were taken from 6 different lots and stored at room temperature. After 5 years, the sensors were retested for accuracy to compare with their original NIST traceable data. After at least 10 minutes warm-up, a calibrated gauge was used to measure applied pressure and the sensors were read by a PendoTECH Process Control System every 10 psi from 0 to 60 psi. These sensors were then gamma irradiated with a dose of 40 kiloGrays. Post gamma treatment, the same procedure was performed to measure sensor accuracy and compare with pre-gamma readings.

8.8.1.1 Calibrated Pressure Gauge: Model# Druck DPI 104, S/N 3674169 (Cert in Appendix T)

8.8.1.2 Acceptance Criteria- Repeatability target was ΔP less than 0.5 psi; Sensors remain within PendoTECH's standard accuracy claim:

Better than +/- 2% of reading in the range of 0 to 6 psi

Better than +/- 3% of reading in the range of 6 to 30 psi

In range of 30 to 60 psi, typically better than +/- 5% of reading

8.8.2 Data Summary

Single Use Sensor Pressure Difference in Readings After a 5 Year Shelf Life

Time Zero Test Date: 2013

Retest Date: February 2019

Gauge Pressure (psi)	Lot # 1132715 S/N: 104	Lot # 1132715 S/N: 105	Lot # 1132694 S/N: 76	Lot # 1132694 S/N: 77	Lot # 1132694 S/N: 78	Lot # 1132694 S/N: 79	Lot # 1132518 S/N: 51	Lot # 1132518 S/N: 52	Lot # 1132518 S/N: 53	Lot # 1132789 S/N: 26	Lot # 1133155 S/N: 26	Lot # 1131209 S/N: 26
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
10	0.04	0.05	0.02	0.00	-0.01	0.02	0.00	-0.03	0.02	-0.01	-0.04	0.04
20	0.06	0.05	0.08	-0.06	-0.04	0.01	0.02	-0.02	0.01	0.03	-0.04	0.01
30	0.04	0.06	0.05	-0.03	-0.02	0.00	0.01	-0.03	0.05	0.05	0.01	0.03
40	0.07	0.10	0.09	-0.02	-0.03	-0.03	0.03	0.03	0.05	0.12	-0.02	X
50	0.12	0.11	0.12	0.09	0.03	0.03	0.02	0.02	0.06	0.06	0.11	X
60	0.11	0.12	0.07	0.11	0.01	0.03	0.02	0.03	0.03	0.13	0.05	X

X = Data not available

All values are differences in pressure (ΔP)

Single Use Sensor Pressure Difference in Readings Post Gamma Irradiation after 5 Year Shelf Life

Pre Gamma Test Date: February 2019

Post Gamma Test Date: March 2019

Gauge Pressure (psi)	Lot # 1132715 S/N: 104	Lot # 1132715 S/N: 105	Lot # 1132694 S/N: 76	Lot # 1132694 S/N: 77	Lot # 1132694 S/N: 78	Lot # 1132694 S/N: 79	Lot # 1132518 S/N: 51	Lot # 1132518 S/N: 52	Lot # 1132518 S/N: 53	Lot # 1132789 S/N: 26	Lot # 1133155 S/N: 26	Lot # 1131209 S/N: 26
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
10	0.03	-0.01	0.00	0.03	0.02	0.01	0.07	0.07	0.03	0.02	0.06	-0.02
20	0.02	0.06	-0.01	0.12	0.11	0.02	0.09	0.10	0.06	0.00	0.09	0.03
30	0.03	0.06	0.04	0.13	0.06	0.08	0.08	0.06	0.06	0.03	0.07	0.05
40	0.05	0.07	0.05	0.15	0.15	0.11	0.14	0.09	0.10	0.01	0.14	0.11
50	0.08	0.13	0.08	0.11	0.17	0.16	0.20	0.15	0.14	0.08	0.07	0.10
60	0.14	0.16	0.19	0.14	0.20	0.20	0.22	0.17	0.18	0.04	0.11	0.06

All values are differences in pressure (ΔP)

- 8.8.3 Raw Data- The data below represents the raw data collected, which was used to generate the tables above. Original refers to the time zero data of the pressure sensors, which was taken from the NIST traceable certificates created during manufacturing in 2013. Pre Gamma denotes the pressure readings recorded following 5 years of storage at ambient conditions (February 2019). Lastly, Post Gamma represents the pressure readings measured after receiving 40 kGys of gamma irradiation dose (March 2019).

Lot Number	Serial Number	Time	Pressure Reading (psi)					
			10	20	30	40	50	60
1132715	104	Original	10.01	20.14	30.13	40.45	51.05	61.79
		Pre Gamma	10.05	20.20	30.17	40.52	51.17	61.90
		Post Gamma	10.08	20.22	30.20	40.57	51.25	62.04
1132715	105	Original	10.04	20.13	29.95	39.92	49.91	59.84
		Pre Gamma	10.09	20.18	30.01	40.02	50.02	59.96
		Post Gamma	10.08	20.24	30.07	40.09	50.15	60.12
1132694	76	Original	10.07	20.17	29.98	39.97	49.97	59.89
		Pre Gamma	10.09	20.25	30.03	40.06	50.09	59.96
		Post Gamma	10.09	20.24	30.07	40.11	50.17	60.15
1132694	77	Original	10.07	20.18	30.09	40.24	50.50	60.77
		Pre Gamma	10.07	20.12	30.06	40.22	50.59	60.88
		Post Gamma	10.10	20.24	30.19	40.37	50.70	61.02
1132694	78	Original	10.06	20.14	29.95	39.80	49.68	59.48
		Pre Gamma	10.05	20.10	29.93	39.77	49.71	59.49
		Post Gamma	10.07	20.21	29.99	39.92	49.88	59.69
1132694	79	Original	10.06	20.19	30.08	40.31	50.61	60.99
		Pre Gamma	10.08	20.20	30.08	40.28	50.64	61.02
		Post Gamma	10.09	20.22	30.16	40.39	50.80	61.22
1132518	51	Original	10.00	20.07	29.91	39.78	49.75	59.65
		Pre Gamma	10.00	20.09	29.92	39.81	49.77	59.67
		Post Gamma	10.07	20.18	30.00	39.95	49.97	59.89
1132518	52	Original	10.02	20.07	29.87	39.69	49.60	59.41
		Pre Gamma	9.99	20.05	29.84	39.72	49.62	59.44
		Post Gamma	10.06	20.15	29.90	39.81	49.77	59.61
1132518	53	Original	10.05	20.16	29.99	40.04	50.20	60.30
		Pre Gamma	10.07	20.17	30.04	40.09	50.26	60.33
		Post Gamma	10.10	20.23	30.10	40.19	50.40	60.51

1132789	26	Original	10.04	20.13	30.04	40.21	50.56	60.89
		Pre Gamma	10.03	20.16	30.09	40.33	50.62	61.02
		Post Gamma	10.05	20.16	30.12	40.34	50.70	61.06
1133155	26	Original	10.06	20.18	30.09	40.24	50.50	60.81
		Pre Gamma	10.02	20.14	30.10	40.22	50.61	60.86
		Post Gamma	10.08	20.23	30.17	40.36	50.68	60.97
1131209	26	Original	10.06	20.19	30.16	X	X	X
		Pre Gamma	10.10	20.20	30.19	40.44	51.02	61.74
		Post Gamma	10.08	20.23	30.24	40.55	51.12	61.80

X = Data not available

8.8.4 Conclusion: All sensors met acceptance criteria and are suitable for a 5 year shelf life