

PendoTECH Single Use Pressure Sensors: Autoclave Study Results

Introduction

Many users of PendoTECH single use pressure sensors desire to sterilize disposable process assemblies containing the pressure sensors prior to use. Often gamma irradiation is the sterilization method of choice. PendoTECH single use pressure sensors have been qualified for exposure to gamma irradiation up to 50 KGy with no changes in either physical integrity or functional performance. However, other users prefer an autoclave cycle for sterilization. The study described in this Application Note was carried out to determine the impact, if any, of one typical autoclave cycle on the functional performance of PendoTECH single use pressure sensors.

Materials and Methods

Sensors: PendoTECH PRESS-S-000 Single Use Pressure Sensors

Autoclave: BetaStar Model # 243660-SRM-HHR-GMP

Calibrated Pressure Gauge: GE/Druck Model DPI 104

Five sensors from 5 different lots (total of 25 sensors) were randomly selected for the study. Pressure readings for these sensors were recorded from 5 to 75 psi in 5-psi increments using the calibrated pressure gauge. The sensors were then packaged in groups of 5 and sealed inside an autoclave pouch. The pouches were then exposed to the following autoclave cycle conditions twice, in succession without opening the pouches, allowing the pouches to cool to room temperature overnight between cycles:

Condition	Cycle 1	Cycle 2
Purge time	5 min	5 min
Time in sterilize	1 hour	1 hour
Minimum temperature (°C)	120	119.8
Maximum temperature (°C)	121.3	121.3
Minimum pressure (psi)	28.8	28.6
Maximum pressure (psi)	30.1	30.1
Cool time	30 min	30 min

Following autoclave cycle 2, the sensors were removed from the pouches and pressure readings were taken again from 5 to 75 psi in 5-psi increments using the calibrated gauge.

Application Note

Results

The following tables present the difference in pressure readings between before and after the exposure to 2 autoclave cycles for each of the 5 sensors from the 5 lots.

Lot 1

<u>Gauge psi</u>	<u>Sensor 1</u>	<u>Sensor 2</u>	<u>Sensor 3</u>	<u>Sensor4</u>	<u>Sensor 5</u>
5	0.0	0.0	0.0	0.0	0.0
10	0.0	-0.1	0.0	0.0	0.0
15	0.0	0.0	0.0	0.0	0.0
20	-0.1	0.0	0.0	0.0	0.0
25	-0.1	-0.1	0.0	0.0	0.0
30	0.0	0.0	0.0	0.0	0.0
35	0.0	0.0	0.0	0.0	0.0
40	0.0	0.0	0.0	0.0	0.0
45	-0.1	-0.1	0.0	-0.1	0.0
50	-0.1	0.0	0.0	0.0	0.0
55	-0.1	0.0	0.0	0.0	0.0
60	-0.1	0.0	0.0	0.0	0.0
65	-0.1	-0.1	-0.1	-0.1	-0.1
70	-0.1	0.0	0.0	0.0	0.0
75	-0.1	-0.1	0.0	-0.1	-0.1

Lot 2

<u>Gauge psi</u>	<u>Sensor 1</u>	<u>Sensor 2</u>	<u>Sensor 3</u>	<u>Sensor4</u>	<u>Sensor 5</u>
5	0.0	0.0	0.0	0.0	0.0
10	0.0	0.0	0.0	0.0	0.0
15	0.0	-0.1	0.0	0.0	0.0
20	0.0	0.0	-0.1	0.0	0.0
25	0.0	0.0	0.0	0.0	-0.1
30	0.0	-0.1	-0.1	0.0	-0.1
35	0.0	0.0	0.0	0.0	-0.1
40	0.0	0.0	0.0	0.0	0.0
45	0.0	-0.1	0.0	-0.1	0.0
50	0.0	-0.1	-0.1	0.0	-0.1
55	0.0	0.0	0.0	0.0	-0.1
60	0.0	-0.1	-0.1	0.0	-0.1
65	-0.1	0.0	-0.1	-0.1	-0.1
70	0.0	0.0	0.0	0.0	0.0
75	0.0	0.0	0.0	0.0	0.0

Application Note

Lot 3

<u>Gauge psi</u>	<u>Sensor 1</u>	<u>Sensor 2</u>	<u>Sensor 3</u>	<u>Sensor4</u>	<u>Sensor 5</u>
5	0.0	0.0	0.0	0.0	0.0
10	0.0	-0.1	-0.1	-0.1	0.0
15	0.0	0.0	0.0	0.0	0.0
20	0.0	-0.1	0.0	0.0	0.0
25	0.0	-0.1	0.0	0.0	0.0
30	-0.1	-0.1	0.0	0.0	0.0
35	0.0	0.0	-0.1	0.0	0.0
40	0.0	0.0	-0.1	0.0	0.0
45	0.0	-0.1	0.0	0.0	0.0
50	0.0	-0.1	0.0	0.0	0.0
55	0.0	-0.1	0.0	-0.1	0.0
60	0.0	-0.1	0.0	0.0	0.0
65	0.0	-0.1	0.0	0.0	0.0
70	0.0	-0.1	-0.1	0.0	-0.1
75	0.0	-0.1	0.0	0.0	0.0

Lot 4

<u>Gauge psi</u>	<u>Sensor 1</u>	<u>Sensor 2</u>	<u>Sensor 3</u>	<u>Sensor4</u>	<u>Sensor 5</u>
5	0.0	0.0	0.0	0.0	0.0
10	0.0	0.0	0.0	0.0	0.0
15	0.0	0.0	0.0	0.0	0.0
20	0.0	0.0	0.0	0.0	0.0
25	0.0	0.0	0.0	0.0	0.0
30	0.0	0.0	0.0	0.0	0.0
35	0.0	0.0	0.0	0.0	0.0
40	0.0	0.0	0.0	-0.1	0.0
45	0.0	0.0	0.1	0.0	0.0
50	-0.1	0.0	-0.1	0.0	0.0
55	0.0	0.0	0.0	0.0	0.0
60	0.0	0.0	0.0	0.0	-0.1
65	0.0	0.0	0.0	0.0	-0.1
70	0.0	0.0	0.0	0.0	0.0
75	-0.1	0.0	0.0	0.0	-0.1

Lot 5

<u>Gauge psi</u>	<u>Sensor 1</u>	<u>Sensor 2</u>	<u>Sensor 3</u>	<u>Sensor4</u>	<u>Sensor 5</u>
5	0.0	0.0	0.0	0.0	0.0
10	0.0	0.0	0.0	0.0	0.0
15	-0.1	-0.1	0.0	0.0	0.0
20	0.1	0.0	0.0	-0.1	-0.1
25	-0.1	0.0	0.1	0.0	0.0
30	-0.1	-0.1	0.0	-0.1	0.0
35	-0.1	0.0	0.1	-0.1	0.0
40	-0.1	0.0	0.0	0.0	0.0
45	0.0	0.0	-0.1	0.1	0.0
50	-0.1	0.0	0.0	0.0	0.0
55	0.0	0.0	0.0	0.0	0.0
60	-0.1	0.0	0.0	0.0	0.0
65	0.0	0.0	0.0	0.0	0.0
70	-0.1	-0.1	0.1	-0.1	0.0
75	-0.1	-0.1	0.0	-0.1	0.0

Application Note

Inspection of the data reveals there is no significant difference in pressure readings between before and after autoclave exposure with the greatest difference 0.1 psi.

This study was carried to investigate functional performance of sensors, but more specifically, the impact of autoclave conditions on the pressure sensing chips contained within the sensors. While this study used one type of PendoTECH pressure sensor, all PendoTECH pressure sensors utilize the same pressure sensing chip. Thus, we believe the results from this study are applicable to all PendoTECH pressure sensors.

Conclusions

Based on the conditions that were used in this experiment, the functional performance of the sensors was not impacted, as it was within anticipated experimental variation. It needs to be emphasized, however, that only one set of conditions in the autoclave were tested, and conditions specific to the end user must be tested to ensure similar results.