PendoTECH Single Use Pressure Sensors™: Autoclave Study Results

Prelude

December 2020

Dear Valued Customer,

The purpose of this letter is to clarify the compatibility of PendoTECH's Single Use Pressure Sensors™ with autoclaving. This applies to all pressure sensors models, except those with a water-tight IP-67 Connector (-W), which cannot be autoclaved.

PendoTECH considers autoclaving to be an application for its pressure sensors, not a specification. That is, the compatibility of PendoTECH's sensors is highly dependent on the autoclave and the cycle conditions. Different cycle conditions will have different effects on the sensors, which impacts overall compatibility. PendoTECH has conducted a study to demonstrate compatibility with one specific set of autoclave conditions, which can serve as a baseline for customers. We strongly recommend prospective users of PendoTECH pressure sensors in autoclave applications consult the following Application Note. Ultimately, it is the end-user's responsibility to validate their specific autoclave conditions with PendoTECH pressure sensors.

Although not found in our validation testing, customers have reported that a very small percentage of sensors may fail, even after validating PendoTECH pressure sensors in their autoclave. The failures are seemingly random and infrequent, and are manifested by erratic readings, liquid in the sensor compartment, or liquid leaking from the test port at the end of the cable. Higher pressure applications seem to be at greater risk, while failures in low pressure applications, e.g., bioreactors, are exceptionally rare. PendoTECH is investigating the root cause of the failures, but in the meantime, it is best practice to verify the integrity of every sensor post-autoclave in order to have the utmost confidence in each individual sensor prior to use. For applications below 10 psi, sensors can be assessed non-invasively with a PendoTECH PressureChecker™ (see link to datasheet also below). For applications above 10 psi, ideally customers can perform an integrity test around 30 psi. This integrity test can be performed many ways, but the easiest method is to pressurize the system and inspect for air leakage at the sensor's test port with soapy water or Snoop® Leak Detector Solution.

Please contact PendoTECH if you have any further questions.

Sincerely,

Dennis Annarelli
Vice President, Operations
PendoTECH
(609) 799-2299
dennis@pendotech.com

PressureChecker Datasheet:
https://www.pendotech.com/wp-content/uploads/2019/10/PressureChecker.pdf

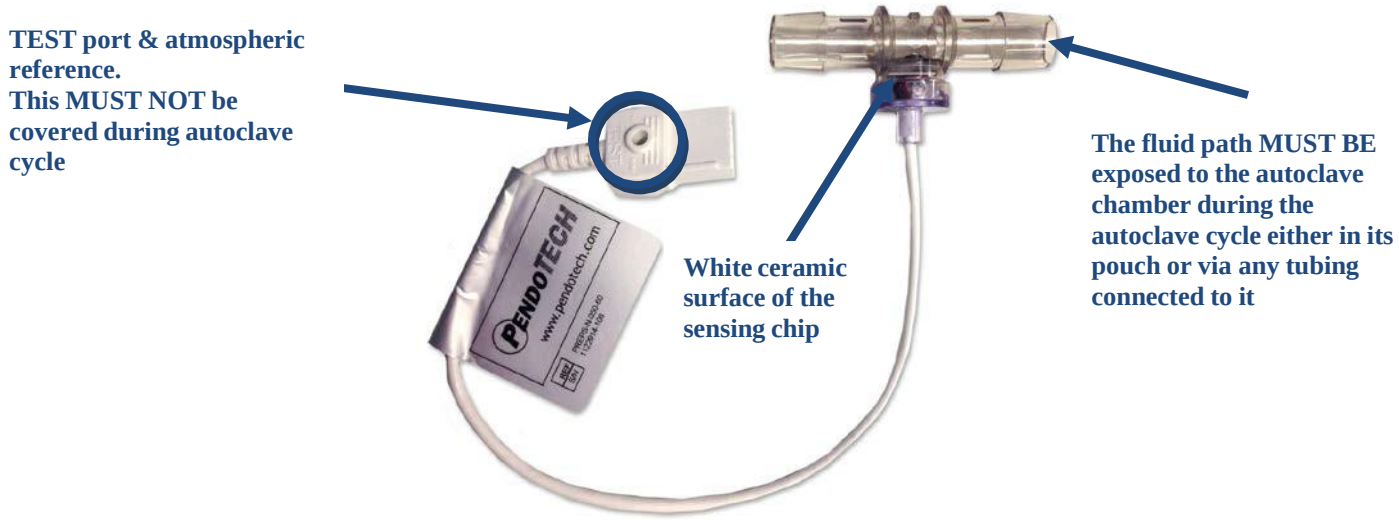
Technical Note

Introduction

Some users of PendoTECH single use pressure sensors desire to autoclave the pressure sensors prior to use with a glass bioreactor. 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.

Background on Sensor Design

The sensor, at its most basic level, is designed of the molded body with a pressure sensing chip affixed into a compartment on the molded body which accesses the fluid path of the body via about a 4mm opening in the molded body. There is a material called "dielectric silicone" that is part of the sensing chip that: 1) can transmit the force (pressure) in the fluid path and; 2) provide the required isolation of the fluid path from the micro-diaphragm in the pressure measurement circuit on the white ceramic surface of the sensing chip. The cable is attached to the electrical contacts on the white ceramic surface and transmits the electrical signals to/from the monitor. Also, what is critical in the design of pressure sensors that are measuring "gauge" pressure is an atmospheric reference. This reference of the micro-diaphragm to atmospheric conditions is via the TEST port of the cable^. When a sensor is connected to a monitor, the tare function should be used to set the fluid path pressure to zero versus the atmospheric conditions. It is ***critical*** that both the ***TEST port*** and ***fluid path*** are exposed to the chamber pressure (and hence to each other) to prevent pressure build-up under high temperature conditions. If the fluid path isolated, its pressure will rise/fall relative to the chamber pressure which can lead to damage to the sensing chip. If the TEST port (reference side) is covered, it can lead to damage to the cable and/or sensing chip as pressure in the cable will rise/fall relative to the chamber pressure.



^ The TEST port can be used to non-invasively test functioning of the pressure sensors and its monitor pre- and post-use with the PendoTECH PressureChecker™

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 liquid 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.

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

Gauge psi	Sensor 1	Sensor 2	Sensor 3	Sensor4	Sensor 5
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

Gauge psi	Sensor 1	Sensor 2	Sensor 3	Sensor4	Sensor 5
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

Technical Note

Lot 3

Gauge psi	Sensor 1	Sensor 2	Sensor 3	Sensor4	Sensor 5
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

Gauge psi	Sensor 1	Sensor 2	Sensor 3	Sensor4	Sensor 5
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

Gauge psi	Sensor 1	Sensor 2	Sensor 3	Sensor4	Sensor 5
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

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.