

PendoTECH Single Use Pressure Sensors™: For Single Use and Glass Bioreactor Monitoring and Control

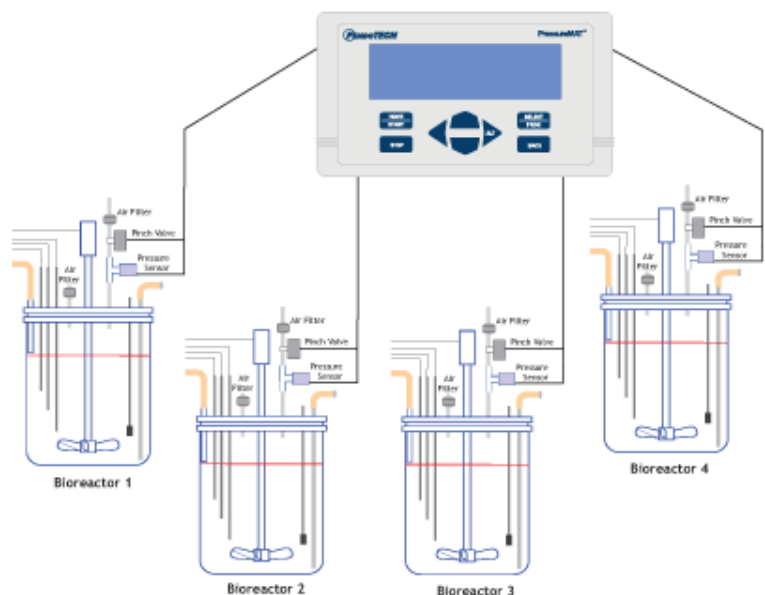
Introduction

In bioreactors, gases are introduced to the sterile vessel to both the liquid phase of the media and the gas phase in the head space to both supply the cells with the required oxygen and to control process conditions. The exhausted gas exits via a vent filter from the head space and it is important to use a filter of adequate size and construction to prevent it from clogging or becoming occluded with water. Also, pressure is used as a means of influencing mass transfer and mitigating contamination. However, an over pressure situation in a glass or single use bioreactor can occur at rather low pressures and a clogged vent filter on a bioreactor can cause a vessel to rupture, particularly on a single use bioreactor bag, spilling the contents of the reactor and exposing the operators to unprocessed bulk creating a potentially hazardous situation. Classic stainless steel bioreactors typically have pressure monitoring and also a pressure relief function to prevent accidents. For single use bioreactors, PendoTECH Single Use Pressure Sensors are an ideal solution in this application for monitoring the pressure in the range of 1 psi and less. They are compatible with gamma irradiation up to 50 KGy so they can be placed on the bioreactor before it is gamma sterilized. Also, they are available pre-sterile so they can be connected to a glass bioreactor that has been autoclaved. The sensors connect to the PendoTECH PressureMAT™, which in addition to reading the sensors has 4-20 mA signal outputs, an RS-232 output, and alarm relay outputs. The relay can be tied directly to a valve to relieve an over-pressure situation and even direct the air flow to a back-up filter so the process can continue.

Figure 1. Pressure Sensor on Single Use Bioreactor



Figure 2. Pressure Sensors on Glass Bioreactors



Technical Note

Product specifications that are highlighted for this application are as follows*:

- Accuracy within +/- 2% of reading from 0-6 psi (i.e., at 1 psi +/- 0.02 psi)
- Raw signal from sensor chip compensated for temperature changes from 15-40°C
- Qualified for gamma-irradiation up to 50 KGy
- Each sensor is tested for accuracy and leaks before being released from manufacturing
- No calibration is required- the sensors come ready to use

* 10 minute warm-up of sensor is recommended for best accuracy

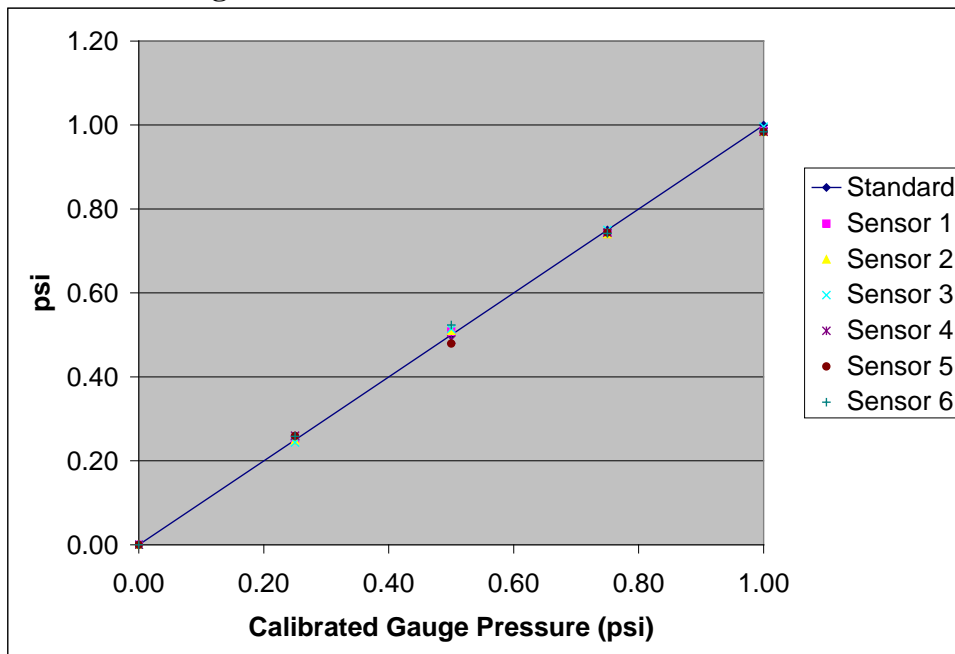
Low Pressure Testing Method

The sensors are very accurate in the critical range of measurement. To demonstrate the accuracy, six sensors were randomly selected from a production lot of 210 sensors with the new PendoTECH MEMs High Accuracy Pressure (MEMS-HAP™) chips for the testing. The six sensors were installed onto a common manifold where they could be pressurized with air. After a 10 minute warm-up, pressure readings for these sensors were recorded from 0.00 to 1.00 psi in 0.25-psi increments set by using the calibrated NIST traceable pressure gauge. The sensors were read using a PendoTECH Process Control System.

Results

The results are shown in figure 1. There was a limitation of the testing by the accuracy specification on the calibrated reference pressure gauge of +/- 0.03 psi. Results indicate that within the resolution of the measurement equipment, the sensor readings results fell within +/- 2% of the calibrated gauge.

Figure 3. Six Random Sensors Tested at Low Pressures*



* Sensors: PendoTECH PREPS-N-000 Single Use Pressure Sensors
Calibrated Pressure Gauge: PressureChecker™, Serial #1090521-001, NIST Traceable with accuracy of +/- 0.03 psi

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Conclusions

The PendoTECH Single Use Pressure Sensors come in a wide variety of sizes and two materials but the sensing chip is the same in all of the sensors- the PendoTECH MEMS-HAP chip. The chips feature temperature compensation from 15 to 40°C that gives them accurate readings across the range of temperature where bioreactors are typically operated.

Based on the conditions that were used in this experiment, the sensors clearly meet the requirement to accurately measure pressure in the low ranges required for glass and single use bioreactor pressure monitoring.

Appropriate interlocks can be put on process equipment so operations staff are not exposed directly to over-pressurized glass or single use bioreactor vessels. The relay output on the PressureMAT can be tied directly to a valve to relieve an over-pressure situation and even direct the air flow to a back-up filter so the process can continue. Either a pneumatic or electric pinch valve can be actuated directly by the PressureMAT and the relay can be configured as normally open or normally closed.

Figure 4. Pneumatic pinch valve with signal from PressureMAT and power supplied via connector on rear for remote control of valve



Figure 5. Electric pinch valve with signal from PressureMAT and power supplied via connector on rear for remote control of valve



The sensors are qualified for exposure to gamma, therefore, they can be connected to a single use bioreactor bag during assembly and sterilized with the bioreactor bag assembly. The part # PRESS-S-000 comes sterile in its pouch and can be connected to either an autoclaved glass bioreactor or a gamma irradiated single use bioreactor. A separate Application Note exists titled “Autoclave of Single Use Pressure Sensors” that demonstrates under certain conditions, they can be successfully autoclaved.