Short Term NaOH Exposure Evaluation: PendoTECH® Polysulfone Pressure Sensor™ Compatibility

Abstract

PendoTECH conducted the following experiments to evaluate the compatibility of its single use polysulfone pressure sensors for short term exposure to sodium hydroxide (NaOH). NaOH is commonly used in the biopharmaceutical industry to sanitize equipment before product is introduced into the system. The experimental condition used for this testing was 1N NaOH at 50˚C, as this best models the most extreme customer applications. For the first experiment, a static soak was performed to assess the physical integrity of the sensor's polysulfone body and sensor chip. In the second experiment, the physical integrity of the sensor was analyzed upon exposure to NaOH dynamically flowing through the fluid path. The final test investigated sensor performance also following exposure to dynamically flowing NaOH. Overall, these experiments validated that PendoTECH polysulfone pressure sensors are suitable for short term exposure to 1N NaOH at 50˚C.

Introduction

This work was carried out to demonstrate PendoTECH Polysulfone Single Use Pressure Sensors will maintain physical and functional integrity when exposed to 1N NaOH at 50˚C for up to 24 hours. The intended application of these sensors is in environments where sodium hydroxide is used to sanitize equipment prior to introduction of product and where pressure measurement in a flow through mode is required, such as concentration/diafiltration in a tangential flow filtration (TFF) process operation.

Materials and Methods

All sensors used were molded from Solvay Udel polysulfone. One liter of a 1N NaOH stock solution was prepared from caustic pellets and distilled water, and stored in an airtight container. All required tubing connections were made from polyethylene connectors and either Pharmed or silicone tubing.

Static tests were carried out in Blue M oven monitored by a calibrated thermometer. MasterFlex pump drive with Easy Load II pump head 77201-66 was used for dynamic (flow through) tests. Caustic temperature was maintained at 50°C by a Precision Water Bath Model 183. A PendoTECH TFF Process Control System with 3 single use pressure sensor inputs was used to record sensor pressure reading. A GE/Druck Model DPI 104 calibrated pressure gauge was used to verify pressure readings before and after exposure for the quantitative testing. Optical microscopy for qualitative inspection was carried out with a Nikon microscope.

Test 1: PendoTECH Polysulfone Sensor Static Soak

The purpose of the test was to qualitatively ascertain the physical integrity of the sensor's polysulfone construction and sensor chip materials in static soak with 1N NaOH at 50°C.

Procedure: Using a 5 ml syringe, approximately 2 ml of 1N NaOH was added to each PendoTECH sensor to fill the cavity and then stoppered at each end. The sensors were placed in a pre-heated oven at 50°C oriented so that the chips were facing down (to ensure maximum contact of caustic with the chip). Sensors were withdrawn from the oven at 2 hours, 4 hours and 6 hours exposure. Power was then turned off and the remaining sensors in the oven were allowed to slowly return to room temperature over 24 hours (30 hours total). Sensors were removed from the oven, the caustic solution was drained from each, and they were thoroughly rinsed with clean tap water and then allowed to air dry.

Results: No caustic leakage or damage was observed in any of the sensors. All polysulfone sensors from each of the soak times (2, 4, 6, and 30 hours) showed no signs of physical degradation upon visual inspection. Sensors were then cut apart using a band saw to observe the portions with pressure chips. Visual and optical microscopy inspections showed no damage to the sensing materials.

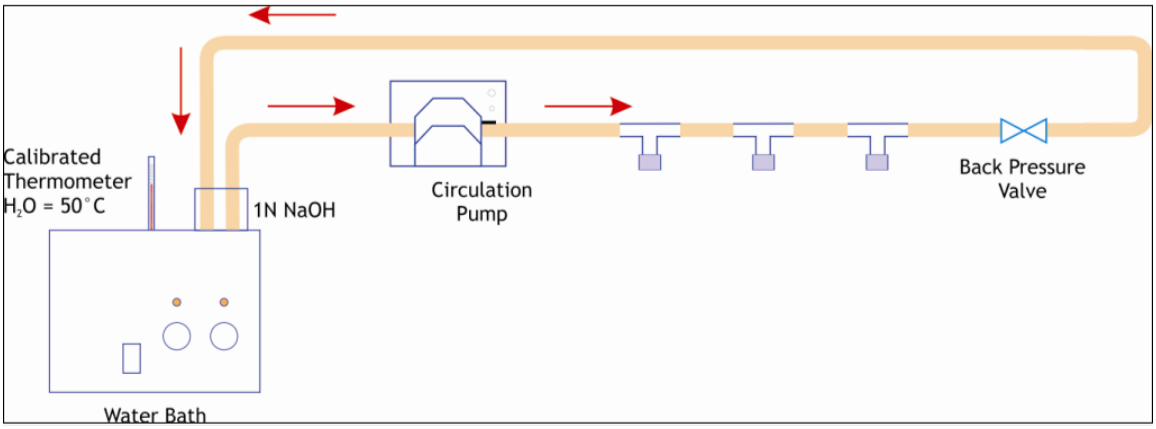
Conclusions: The hot caustic did not attack the polysulfone body or the sensing materials. The materials chosen for the sensor will maintain physical integrity when exposed to 1N NaOH at 50°C for at least 6 hours at lower temperature.

Test 2: PendoTECH Polysulfone Flow Through of 1N NaOH

The purpose of this test was to qualitatively assess the physical integrity of PendoTECH polysulfone pressure sensors that have been exposed to 1N NaOH at 50°C in a dynamic, i.e., flow through mode. Pressure readings were not taken, as there were no cables attached to the sensors.

Procedure: Using the equipment arrangement as in Figure 1, three polysulfone sensors were placed in series and 1N NaOH was flowed through them using the MasterFlex pump and tubing.

Figure 1. Test 2 Set Up



Flow rate was set at 340 ml/min with size 16 tubing in the pump head and transitioned to 3/8" ID tubing with a plastic reducer fitting. Pressure in the system was <5 psi. Caustic flow was

continued for 4 hours at 50°C, before the system was shut down. The sensors were removed from the caustic circuit and flushed with tap water before visual inspection with the Nikon microscope.

Results: There were no leaks or system failures during the operation at 50°C.

Conclusions: Polysulfone bodies and sensing materials will maintain their physical integrity with 1N NaOH for at least 4 hours in a dynamic system.

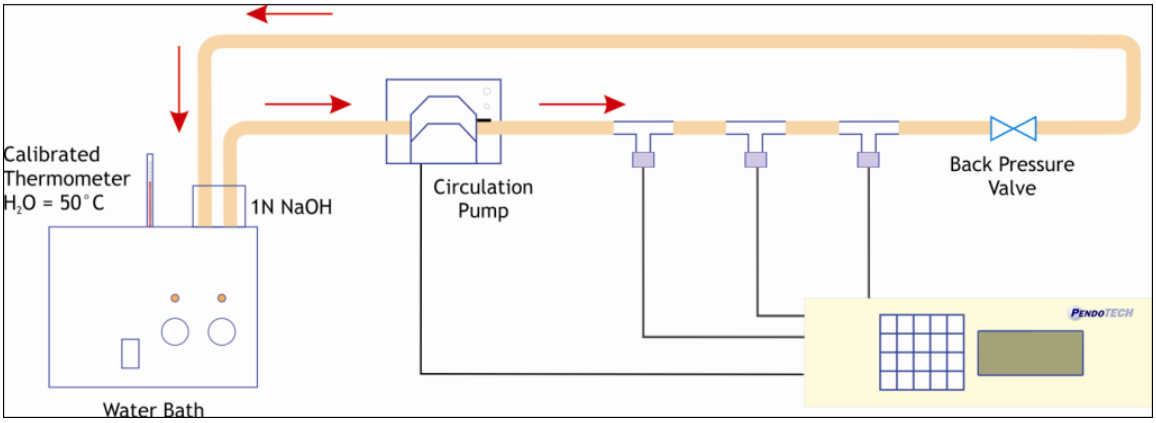
Test 3: PendoTECH Polysulfone Flow Through of 1N NaOH with Pressure Measurements

The purpose of this experiment was to quantitatively test the before, during and after pressure readings of polysulfone sensors and sensing materials that have been exposed to 1N NaOH at 50°C in a dynamic, i.e., flow through mode.

Sensor Materials: PendoTECH polysulfone pressure sensors were manufactured with the standard manufacturing process so they could be connected to the control system to acquire pressure readings.

Procedure: Three sensors were connected to a PendoTECH TFF Process Control System™, and pressure readings were taken from 5-75 psi before exposure to caustic. Using the equipment arrangement as in Figure 2, the three sensors were then placed in series and 1N NaOH was flowed through them using the Masterflex pump and tubing.

Figure 2. Test 3 Set Up



Flow rate was set at 340 ml/min with size 16 tubing in the pump head and transitioned to 3/8" ID tubing with a plastic reducer fitting. Sensors were place chip side down with the exposed part of the chip positioned toward the caustic inlet side of the sensor. A throttled pinch valve was set on the caustic return line to achieve approximately 5-psi backpressure in the system. 1N NaOH at 50°C was flowed through the system for 3.5 hours and pressure readings were taken approximately every 15 minutes. At the conclusion of 3.5 hours at 50°C, the system was shut

down, sensors were removed, flushed with clean tap water, and then allowed to dry. Pressure readings of the sensors were then recorded and compared to those prior to caustic exposure.

Results: Sensors were visually inspected for signs of leak or caustic damage and no evidence of either was found. Pressure readings were generated during the entire experiment. Table 1 reports pressure reading from the 3 sensors taken pre and post caustic exposure. There was no change in the reading, within the tolerance of the measurement equipment, when comparing pre and post data, indicating the sensing materials maintained their physical and functional integrity.

Table 1. Difference of Pre and Post Testing Pressure Readings (all in psi)

Gauge Pressure	Difference Sensor 1	Difference Sensor 2	Difference Sensor 3
0	0.0	0.0	0.0
5	0.0	0.0	0.0
10	0.0	0.0	0.0
20	0.0	0.0	0.0
22	0.0	0.0	0.0
30	0.0	0.0	0.0
40	0.0	0.0	0.0
50	0.0	0.0	0.0
60	0.0	0.0	0.0
70	0.0	0.0	0.0
75	0.0	0.0	0.0

Conclusions: The results shown in Table 1 provide strong evidence that the sensor materials maintain their functional integrity under the conditions of exposure to 1N NaOH for 3.5 hours at 50°C. Thus, the PendoTECH polysulfone single use pressure sensors can be recommended for service under these conditions, such as sanitization of a TFF step. In process pressure readings also support this assertion.

Overall Summary of Experimentation

As summarized in Table 2 below, testing indicates that the PendoTECH Polysulfone Single User Pressure Sensors can withstand typical exposure to 1N NaOH at 50°C for approximately 24 hours.

Table 2. Summary of Testing with 1N NaOH at 50°C

Test #	Purpose	Mode	Sensor	Conclusions
1	Physical Integrity	Static Soak	PendoTECH polysulfone w/o cables	Physical integrity confirmed
2	Physical Integrity	Dynamic flow through	PendoTECH polysulfone w/o cables	Physical integrity confirmed
3	Physical and Functional Integrity	Dynamic flow through	PendoTECH polysulfone w/cables	Functional and physical integrity confirmed