

Polysulfone Version of PendoTECH Single Use Pressure Sensors™: 1N NaOH Compatible 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 extended times. 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 thru mode is required, such as concentration/diafiltration in a tangential flow filtration (TFF) process operation.

Materials and Methods

All sensors used were made 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 thru) 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 camera-equipped 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 Sensors were withdrawn from the oven at 2 hours, 4 hours and 6 hours exposure.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: None of the sensors showed signs of leakage of caustic. 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 so that

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only the portions with chips remained. Visual and optical microscopy inspections showed no damage to the sensing materials.

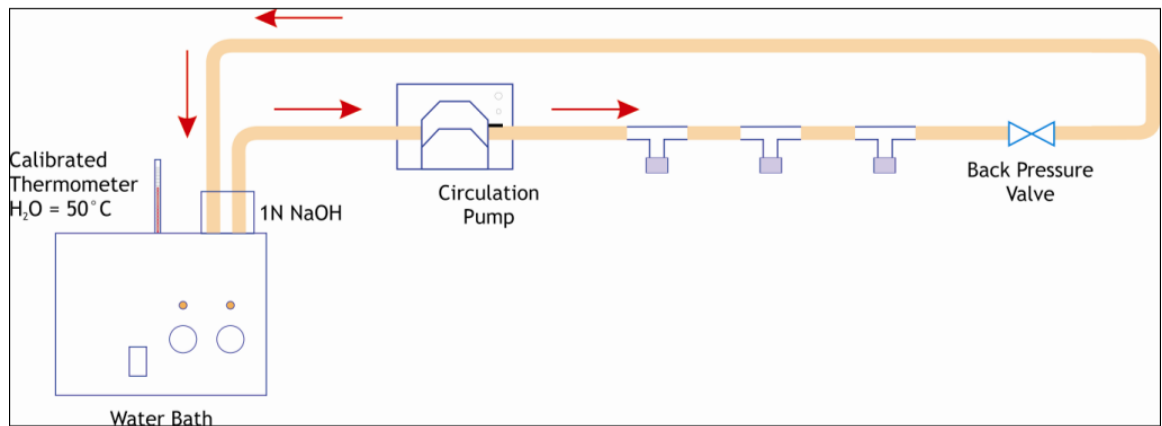
Conclusions: the hot caustic did not attack the polysulfone body or the sensing materials. The materials chosen for the sensor will maintain physical integrity when exposed to 1N NaOH at 50°C for 6 hours or longer at lower temperature.

Test 2: PendoTECH Polysulfone Flow Thru 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 for extended periods in a dynamic, i.e., flow thru 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 thru 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, and the system shut down. The sensors were removed from the caustic circuit and flushed with tap water before inspection.

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.

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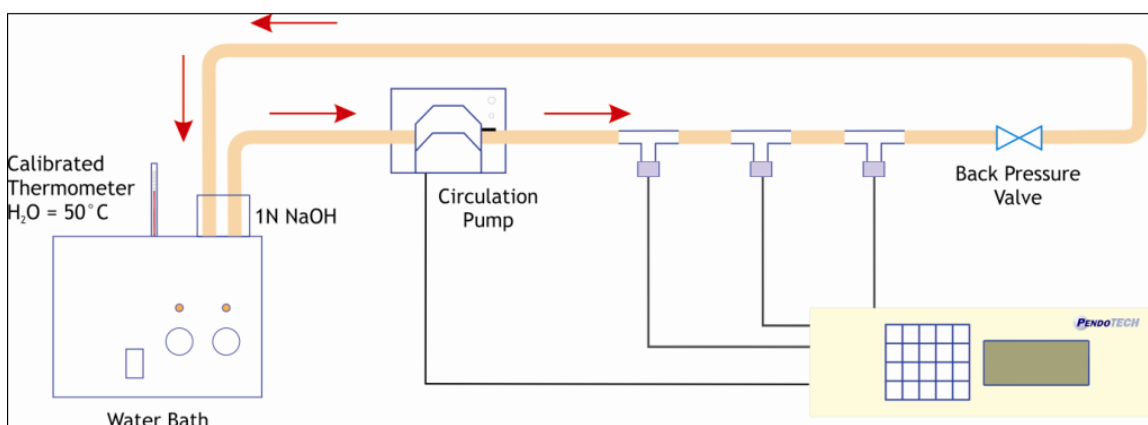
Test 3: PendoTECH Polysulfone Flow Thru of 1N NaOH w/Pressure Measurements

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 for extended periods in a dynamic, i.e., flow thru 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 thru 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 placed 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 thru the system for 3.5 hours and pressure readings were also taken approximately every 15 minutes. At the conclusion of 3.5 hours at 50°C, the system was shut down, sensors were removed and flushed with clean tap water and 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 attack by caustic and none were found. Pressure readings were generated during the entire experiment (because of the low pressure and pulsating of the peristaltic pump the readings fluctuated). 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.

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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 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 several hours.

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

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

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