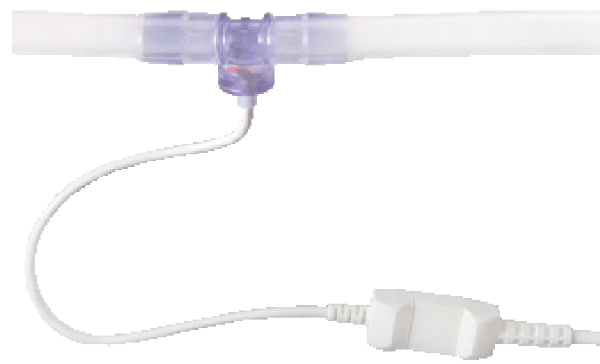
Technical Note

PendoTECH Single Use Pressure Sensors: Calibration, Accuracy, and Implementation

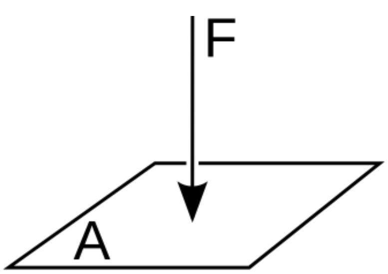
Introduction



The PendoTECH Single Use Pressure Sensors have proven to be a very valuable tool to measure pressure in many different process operations. They are shipped ready to use with no calibration required because the accuracy is manufactured into each sensor. Before release from manufacturing, they are verified by 100% testing of accuracy to be within the limits stated on the certificate of quality document for each sensor lot. And during use, the calibration does not change so they can be conveniently used with confidence of accurate data. From a calibration perspective, the approach to meeting calibration requirements for these sensors is different than that for more traditional pressure measurement devices that typically would be checked and calibrated on some periodic basis. This leads to a paradigm shift in the approach a company and its metrology group must take. This Technical Note is designed to provide some of the details on the design and manufacture of the sensors and approaches for implementation with respect to accuracy verification.

Primer on Pressure

Pressure is force measurement most often normalized to force per unit area. The force is exerted on an object by something in contact with it and in the case of a pressure measurement device, the force is often a static or dynamic fluid (either liquid or gas) extorting a force against the measurement device.



This force can be then normalized to force per unit area such as $\text{pounds}_{\text{force}}$ per square inch (psi) or in SI units as Newtons/m^2 or Pascal (Pa) or expressed as other relative measurements such as mm of Mercury (mmHg), Bar, or Atmospheres (atm). Standard atmospheric pressure (1atm) is defined as 1.013bar, 101.3 kPa, 760mmHg, and 14.7psi.

Since pressure is a force, pressure measurement of a fluid, either a liquid or gas, can be made with either static or dynamic fluid in touch with the pressure measurement element. Therefore, pressure can be measured of a fluid stationary in a vessel or fluid flowing through a tube.

Gauge Pressure Versus Atmospheric Pressure?

Absolute pressure is measured against absolute vacuum. The more commonly utilized *gauge* pressure is the pressure relative to the ambient air at the point of measurement. However, the ambient condition varies based on elevation and other environmental factors. For example, at 5000 feet elevation, the absolute atmospheric pressure is 12.2 psi versus 14.7 psi at sea level. Therefore, a pressure measurement device must have a means to tare to zero gauge pressure when prepared for use in order to have an accurate measurement of pressure in a vessel or liquid flowing through a tube because the relevant measurement of the force in the tube or vessel is *relative* to the ambient environment in which it resides.

Basic Applications of Pressure Measurement

In a *dynamic* system, a fluid (liquid or gas) flows typically through a tube and a pressure measurement device along the flow path measures the force. Since it is a force, there is no difference in whether a liquid or gas is in contact with the pressure measure device. In a dynamic liquid system, the force within the tube is most frequently created by a pump and liquid will flow from the highest pressure point at the pump to lower pressure points along the tube.

Pascal's principle: In a *stationary* vessel, a depth of a ***liquid*** creates a force directly proportional to the height and this principle is used to estimate a level of liquid. *Pascal's principle* is defined as measuring liquid level by hydrostatic pressure which is based on the difference in pressure at two points within a fluid column, due to the weight of the fluid.

This principle is stated mathematically as:

$$\Delta P = \rho g(\Delta h)$$

ΔP is the hydrostatic pressure (given in pascals in the SI system), or the difference in pressure at two points within a fluid column, due to the weight of the fluid;
ρ is the fluid density (in kilograms per cubic meter in the SI system);
g is the acceleration due to gravity (normally using the sea level acceleration due to Earth's gravity, in SI in meters per second squared);
Δh is the height of fluid above the point of measurement, or in the difference in elevation between the two points within the fluid column (in meters in SI)

Using this formula, fluid height of water can be approximated by 0.1 psi = 2.768 inches of water.

Ideal Gas Law: In a *stationary* vessel, ***a gas*** fills the shape of a container and exerts a relatively uniform force on the container wall. The behavior of a gas in a stationary vessel was initially defined by Boyle's Law and Charles' Law from the 17th Century and 18th century, respectively, that were later combined and stated as the "Ideal Gas Law". This law describes the behavior of a gas under certain conditions and is represented by the equation:

$$PV=nRT,$$

where the letters denote absolute pressure (P), volume (V), amount (n in moles), ideal gas constant (R), and absolute temperature (T) of the gas.

The principle can be used as the basis of determination of the estimation of a leak rate from a container. Because the drop of Pressure (ΔP) at constant temperature, means molecules (n) of gas have left the container. In a pressure-hold test, in a constant volume system at constant temperature, as the pressure drops, this indicates "n" is dropping as gas leaves the constant volume container. This can be readily converted to a leak rate by converting the ΔP in the system to ΔV at room conditions and applying the time over which the ΔP occurred and the known system volume. This is described by the equation:

$$\text{Rate} = (\Delta P * \text{Vsystem}) / (\text{test time} * \text{Patm})$$

which yields units of volume per unit time.

Accurate Measurement of Pressure- Quality By Design

In all PendoTECH Pressure sensors, the measurement element is the same which is the proprietary MEMS-HAP™ (MEMs- high accuracy pressure) sensing chip. At the core of this pressure sensor is a MEMS (Micro-Electro-Mechanical System) defined as the integration of micro-machined mechanical elements, sensors, actuators, and electronics on a common silicon substrate through microfabrication technology. They are manufactured in a high tech semiconductor fabrication facility.

The measurement is made by a piezoresistive micro- machined silicone diaphragm in a Wheatstone bridge circuit. The excitation voltage is 2-10V with less than 5V recommended for best performance, and an output of 0.2584mV/psi per Volt excitation. The accuracy claim is from -7 to 60psi and can be readily exposed from -13 to 75psi and intermittently to 150psi with no damage or failure.

Each sensing chip is manufactured to the same output specification of millivolts per psi so they can be read accurately on the manufacturing testers as well as end-user monitors. The chips are manufactured in lots of >5000 and are 100% tested to verify accuracy within 2% of reading at 30 psi (2 bar) and within 5% of the reading at 60 psi (4 bar). Any that fail the accuracy test are rejected.

Certificate of Quality with Each Sensor

The finished pressure sensor is manufactured by placing a sensing chip into a "sensor body" which is an injection molded part in any one of range of sizes. The assembly of the finished product takes place in a Class 10,000 (ISO Class 7) room where each sensor is assembled and then tested, and if passes, is placed into its Tyvek pouch as shown:

The chip inserted to a sensor body is shown in the following illustration:

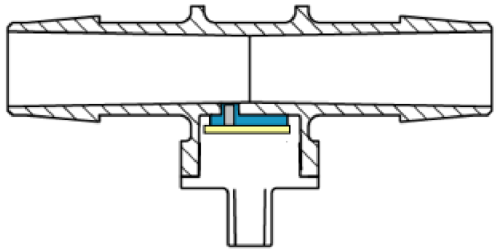


Figure 1. Illustration of pressure sensor body with chip inserted
Yellow: ceramic base of the chip which contains all electronics
Blue: Chip housing which bonds to sensor body
Gray: Dielectric silicone in chip housing that isolates fluid path from electronics and conveys pressure

The following photo shows the chip in a pressure sensor:

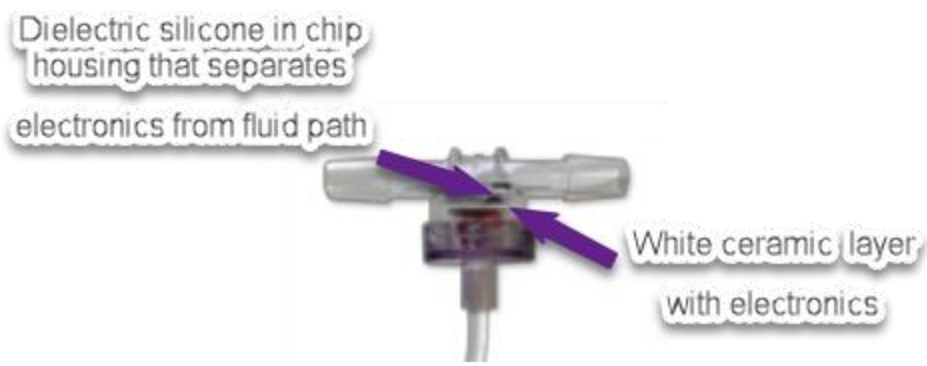


Figure 2. Photo of pressure sensor body with chip inserted

Each finished sensor is tested during manufacturing in an ISO13485/FDA registered facility where manufacturing equipment is maintained per facility SOPs, and comes with a lot-based certificate of quality with the following information on this testing (for complete certificate, see attachment 1):

- Each product is leak-tested on the liquid side to confirm integral assembly and leak-tested on the test port side
- Each product is tested electrically to confirm proper electrical performance and tested to confirm linearity of sensor output to +/- 2% of the specified sensitivity within the range of 0 psi (0 bar) to 5.8 psi (0.40 bar)
- Each sensor is tested to be accurate at 30 psi (2.07 bar) within +/- 2% of reading (+/- 0.6 psi / 0.04 bar)
- Each sensor is tested to be accurate at 60 psi (4.14 bar) within +/- 5% of reading (+/- 0.6 psi / 0.04 bar)

Both accuracy tests are conducted in manufacturing to +/- 1% but the certificate specifies a wider range of +/- 2% to provide additional margin.

If the sensor passes the final testing, it is placed into a Tyvek pouch (see Figure 3) then 25 sensors are placed into a polybag within a brown box and then go to the warehouse and are ready for shipment.

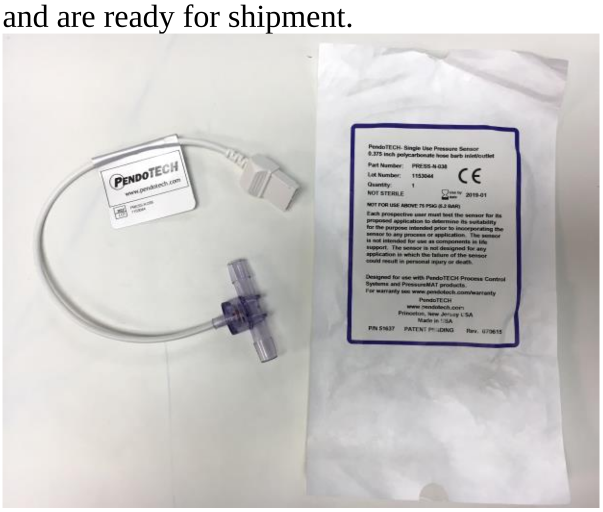


Figure 3. Picture of finished pressure sensor and Tyvek pouch with cable and pouch labels showing part number and lot number and expiration date.

Qualification on gamma irradiation compatibility and five year shelf life has been completed by PendoTECH and this data is available.

Serial Numbers and NIST Certificate

Depending on the implementation of the sensors and end-users preferences, documented values of a sensor reading across a range of applied pressures may be desired before use in a process. As an addition product option, each sensor is available with a serial number in addition to the lot number along with a NIST calibration report for each sensor with the NIST traceable reference used. Part numbers listed with suffix identifiers (such as -B or -30, -60 or -75) added to the part number include individual NIST Calibration Certificates. These sensors undergo an additional test and documentation of the actual readings at each applied pressure. The applied pressures and readings documented are based on the range of calibration required. Here is a list of the suffixes:

–B is for low pressure applications such as bioreactor and the certificate is in the range of 0 to 6psi

–30 is for moderate pressure applications in the range of 0 to 30psi

–60 is for higher pressure applications where the PressureMAT products^ are used and the certificate is in the range of 0 to 60psi

^ the PressureMAT products (both monitors and transmitter model PT-60) interprets the non-linear range of the sensor millivolt output in the range from 30 to 60psi; the PressureMAT monitor will read the sensors to 75psi whereas other monitors typically only read the linear range up to 30psi

Examples of these certificates are included as attachments 2 through 4 and the sensor label and pouch label with the suffix and the serial number following the lot number are shown in Figure 4.

Figure 4. Picture of finished pressure sensor and Tyvek pouch with cable and pouch labels showing part number and lot number followed by the serial number and expiration date.

The NIST certificate has the test date and along with the five year shelf life, which is qualified by test data generated, indicating no change in accuracy after five years on the shelf.[1]

[1]In general, NIST does not require or recommend any set recalibration interval for measuring instruments, devices, or standards. Specific recalibration intervals depend on a number of factors including:

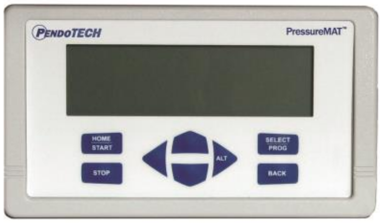
- Accuracy requirements set by customers
- Requirements set by contract or regulation
- Inherent stability of the specific instrument or device
- Environmental factors that may affect the stability

https://www.nist.gov/calibrations/recommended-calibration-interval

End User Options to Accurately Read the Pressure Sensors

The sensors come with an integral cable with a 4 pin overmolded connector at the end of the cable. The sensors connect to a receptacle on the cable that is connected to a number of monitoring devices offered by PendoTECH

1. PendoTECH PressureMAT® Monitor that can read up to four sensors:

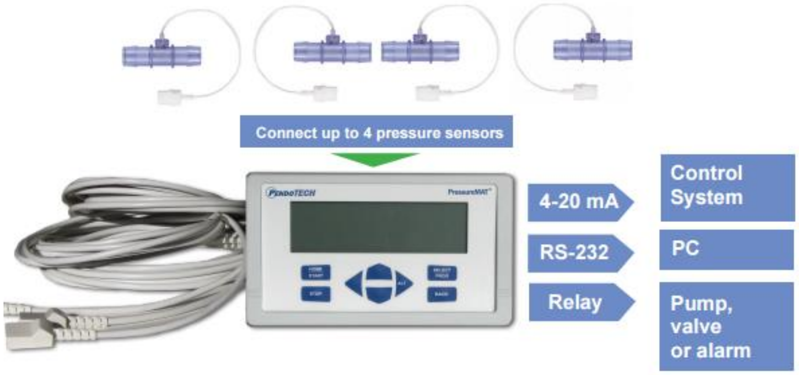


And the PressureMAT-S that can read one sensor:

The PressureMAT is a full featured monitor and there are models that read between one and four sensors:

Model PMAT-S has 1 input and for outputs 1 Relay / 1 Analog
Model PMAT2 has 2 inputs and for outputs 2 Relays / 2 Analog
Model PMAT3 has 3 inputs and for outputs 1 Relay / 3 Analog
Model PMAT4A has 4 inputs and for outputs 4 Analog
Model PMAT4R has 4 inputs and for outputs 4 Relays

The monitors feature the following:
- Tare button for atmospheric tare of a sensors
- Transmitter function
- Programmable alarm points tied to a relay signal output that can shut off a pump or switch a valve
- An RS232 to connect to the PendoTECH PC software for data collection or to a custom program



There are a number of options/accessories available to aide in installation including a benchtop stand, a panel mount kit, and a both benchtop and wall mount boxes.

2. PressureMAT-SHR High Resolution Monitor

This monitor is similar to the PressureMAT Model PMAT-S (with the below key differences) that make it ideal for these specialized applications:

- Measure pressure in bioreactors (both re-usable and single use types)
- Leak testing of a container or a fluid path

The PressureMAT-SHR monitors feature these key differences:

- A remote tare via a dry contact relay as well as a tare button for atmospheric tare
- Reads to a lower pressure range (7.5psi versus the full range of 75psi) however, can read the same sensor to a higher resolution of 0.001psi which makes it more capable to measure pressure decays that can be used to detect leaks.

3. PressureMAT Signal Conditioning Card

The PressureMAT Signal Conditioning Card is perfect for installations where no display is required. It converts the pressure sensor raw signal to a linear 4-20milliamp analog signal that can be easily read into a control system via an analog input. It can be mounted remotely inside of a control panel on a DIN rail. It features a remote tare that sets zero psi gauge to 4milliamp. The tare is initiated by a contact closure that could be either a mechanical button or an electrical relay actuated by the control system. There are several models available depending on the pressure range at which the sensors will be used. Use the narrowest range possible which will provide the highest resolution at the control system receiving the output signal.

The models available are:

Model PT-2: Pressure sensor transmitter with 4-20mA output, 0-2 psi (0.138 bar) DIN Rail mount, 24VDC, with calibration certificate and reusable sensor cable

Model PT-10: Pressure sensor transmitter with 4-20mA output, 10 psi (0.69 bar) DIN Rail mount, 24VDC, with calibration certificate and reusable sensor cable

Model PT-30: Pressure sensor transmitter with 4-20mA output, 30 psi (2.07 bar) DIN Rail mount, 24VDC, with calibration certificate and reusable sensor cable

Model PT-60: Pressure sensor transmitter with 4-20mA output, 60 psi (4.14 bar) DIN Rail mount, 24VDC, with calibration certificate and reusable sensor cable

4. PendoTECH Process Control Systems

TFF Process Control System

Normal Flow Filter Screening System

PendoTECH Control Systems read the pressure sensors and these are primarily used for Process Development activities. The TFF Process Control System and Normal Flow Filter Screening System both have a wide range of features such as graphical user interfaces, process control, trending and data acquisition features.

5. Third Party Monitors and Pumps

There are some 3rd party monitors that read the sensors and if they are designed to read the 0.2584mV/psi/V they can be used. If a 3rd party monitor has the ability to execute a calibration routine, apply 30psi on a calibrated gauge to a PendoTECH pressure sensor installed on the 3rd party unit. 3rd Party monitors cannot accurately read the pressure sensors above 30psi because there is some non-linearity in the raw sensors output that is not accounted for in non-PendoTECH products.

6. Custom Circuitry

For high volume OEM applications, custom circuitry can be used to excite the Wheatstone bridge, provide for the tare, and read the high resolution 0.2584mV/psi/V output from the circuit.

<u>Options to Handle the Sensor TARE When Integrating Transmitters to Control Systems</u>

Atmospheric gauge pressure varies depending on distance above sea level etc., and it is a relative number and not absolute pressure. When the pressure sensing chips are made, the piezoresistive micro-diaphragm is manufactured to about 0psig at atmospheric but the spec is +/-1.45psi (called the base sensor imbalance) but either way the sensor differs at different relative atmospheric pressures. Usually the imbalance is closer to 0.2psi or less at sea level. When trying to measure specifically low pressure, it becomes more important to zero the sensor via a tare before use at your exact conditions so there is accuracy relative to the environment. For the PressureMAT monitor and PendoTECH Control systems, the tare process is handled within the units themselves. When the tare routine is executed by the units' software, an *offset* is stored to create the zero value at the measurement when the tare routine was executed. So when the tare function is initiated, the software subtracts the current value from the raw reading and stores it in memory (stored value is called an *offset*) so there is a zero reading on the display and that value is used for all raw readings displayed. This is similar to how a scale works. There is a gross weight and a net weight (the net weight is calculated by subtracting the tare value from the raw gross scale reading). This same type of routine would be used for a 3rd party monitor/pump and for OEM custom circuitry with those units' software.

Assuming the keypad tare button on the PressureMAT will not be used or is inaccessible, when transmitting the value from a PressureMAT monitor or PT transmitter card the tare is handled in generally one of 2 ways:

1- In a software based system, use the 4 to 20mA transmitted value as it comes from the transmitter. So if the transmitter is not tared, at atmospheric pressure, the control system may receive a value, for example of 0.2 psi. The control system would store this offset in its memory and any value being received will have this offset applied.

2- For the PressureMAT-S and the PressureMAT PT cards, a dry contact relay connected to the units can remote tare them which sets atmospheric pressure to the correct corresponding milliamp transmitter signal corresponding to zero psi gauge (with PressureMAT-S this is 5.88mA, for the PressureMAT-SHR this is 8.00mA, and for the PT cards, this is 4.00mA). Use a dry contact relay activated by the control system user interface to achieve the tare by momentarily connecting the tare input signal to ground, or a mechanical button could also be used.

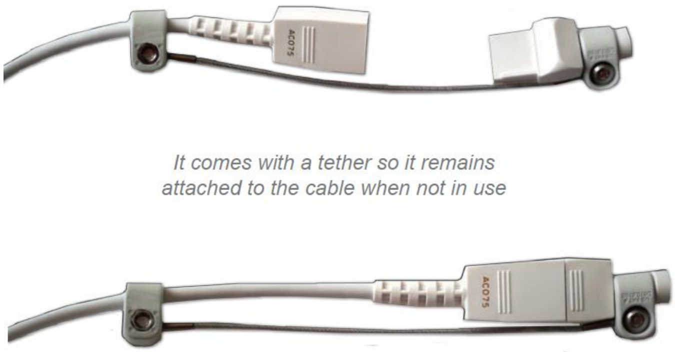
In the 2nd case, the control system would never store a tare value and strictly interpret the 4-20mA signal. In the first case, the option would be to program the control system to perform a tare and store the offset. But either way, a tare routine must be implemented. Again, neither is needed if using the PressureMAT, and the keypad is accessible, because in this case the tare button on the keypad can be used.

If a stored offset is implemented in the control system software relative to the value received from the PressureMAT (and since most likely the display will not be visible, there is no concern the values may differ slightly). The important thing is that the control system reads zero as the official present value when the sensor is exposed to atmospheric pressure.

What a Monitor May Read with No Sensor Connected

When there is no sensor connected to a monitor, there is no input signal to measure so the input floats in an "indeterminate state" so there is no signal to tare because there is no stable signal. Some monitors can account for this situation and go to a high value to indicate to the user that the sensor is disconnected (the PressureMAT Monitors perform in this manner). Some monitors remain around zero where the reading typically bounces around. Some custom monitors will measure the input resistance load and have a clear designation of sensors connected or disconnected.

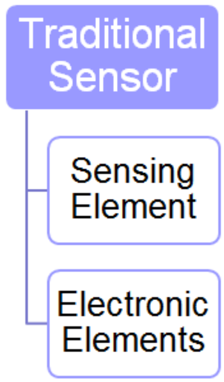
If it is desired to have a stable monitor reading when there is no sensor connected, one option if the PendoTECH Zero Plug/Dust Cover. A stable reading may be desired to prevent any alarming of a monitor which when being transmitted to a control system, may cause an alarm condition to be logged when there is no sensor connected. This product is shown in the following picture:



This can also serve the purpose to protect the re-usable monitor gold pins from the environment including some harsh cleaning chemicals that may be used on surrounding equipment.

Different Approach Required for Single Use Sensors Versus Traditional Instrumentation

Implementation of the single use sensors to a facility more accustomed to traditional sensors/instrument creates a paradigm shift in metrology procedures. The traditional instrument is replaced by a sensing element, which may be replaced with each use, and electronic elements which are re-used for many years and require periodic calibration verification.



So each element (sensor and re-usable electronics) must have its own approach.

Implementing the Sensors- Verification and Documentation Options

Depending on the implementation of the sensors, metrology heuristics at a particular company, and end-users process configuration and requirements, different options are available to verify accuracy.

These include a range of documentation and testing options that are available:

1. Lot Certificate Received with Each Sensor (Attachment 1)

2. Serialized Sensor Options (Attachments 2 through 4)

3. Apply Air to the Sensor(s) from a Calibrated Gauge via the fluid path

If the process has a step where pressure is being applied to the fluid path for a purpose such as filter integrity testing, the reference pressure of the tester can be compared to the sensor reading to confirm accuracy. Figure 5 gives an illustration of this type of setup.

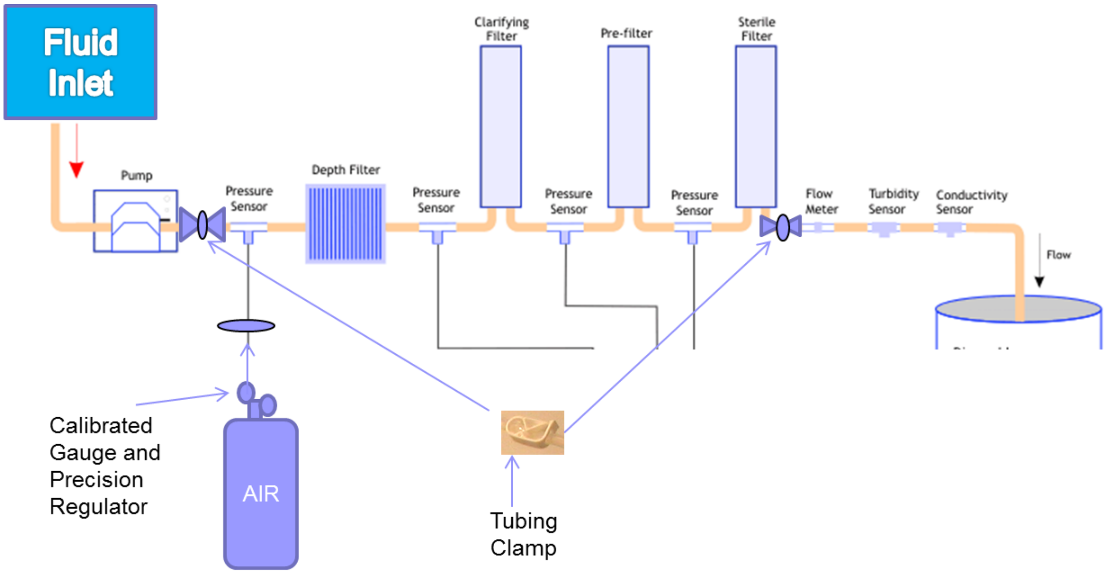
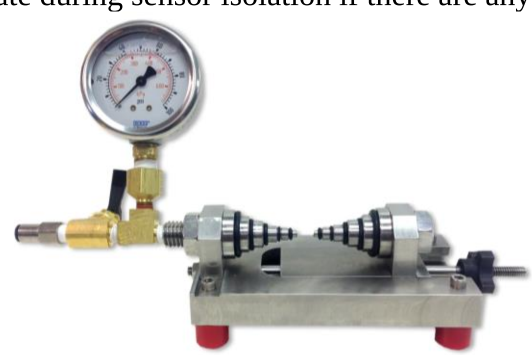


Figure 5. Illustration (for representation only) of a test set up where a calibrated reference pressure could be compared to pressure sensor readings.

4. Test fixture with precision regulator and calibrated gauge or calibrated Fluke pressure generator

PendoTECH offers a test fixture that can isolate the fluid path for the range of sensor sizes and inject air in one side. It has a quick release isolation valve and reference gauge (non-calibrated) to indicate during sensor isolation if there are any leaks from the sensor:



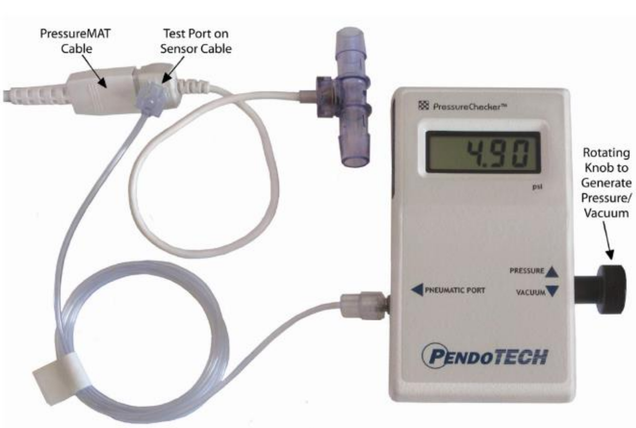
A precision regulator connected to an air source and calibrated gauge (calibrated gauge and precision regulator not shown) can be connected to inlet connection on the left side shown below. With the isolation valve open, the calibrated gauge reading can be compared to the sensor reading to tests its accuracy. Here is an example setup with a sensor in the fixture:

Because this involves testing the sensor only, it would be most useful for sensor qualification testing or post-use testing of a sensor removed from a disposable assembly.

To create a more portable test setup, a calibrated Fluke pressure generator (model shown is Fluke 718-100g - 100PSI model) with built in pump, can be used as the calibrated reference and as the means to generate pressure (shown below).

5. PressureChecker™

The PendoTECH PressureChecker is a calibrated device that uses the sensor TEST port on the sensor cable connector to non-invasively verify the sensor accuracy by comparing the PressureChecker reading to the sensor monitor reading (shown below).



The sensor TEST port accesses the atmospheric reference side of the pressure sensing chip, so when pressure is applied to the test port, it appears as the inverse value (vacuum) on the monitor. Because of this, it has a limitation to only verify to 7psi. For low pressure applications like bioreactor pressure monitoring, this may cover the entire process range to be verified. For higher pressure application, the PressureChecker can verify accuracy and linearity of the sensor to the monitor to a portion of the entire process range, and this in conjunction with the sensor certificate of quality may be adequate for verification to some users.

There are two models available:

PDKT-650-950 PressureChecker pressure sensor and monitor verification tool (psi)
PDKT-650-950B PressureChecker pressure sensor and monitor verification tool (millibar)

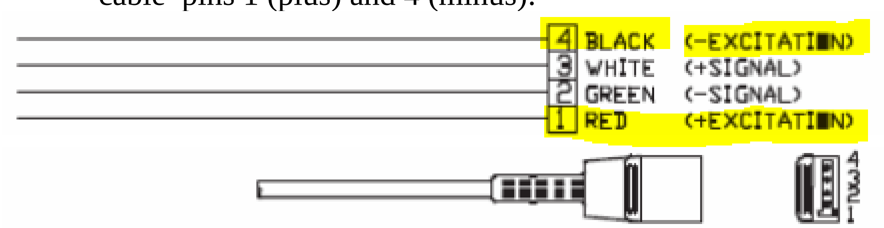
Verifying Monitor Performance and Calibration

Depending on the implementation of the sensors, metrology heuristics at a particular company, and end-users process configuration and requirements, different options are available to verify accuracy.

1. PendoTECH offers a test cable called a TCA cable to connect to a monitor where the sensor typically connects. It may look like a cable removed from a sensor however there is additional componentry within the connector that completes the required circuitry to enable this test method. This cable comes with a chart of the mV applied and corresponding pressure readings and requires a calibrated mV generator to simulate sensor input to monitor.

A basic millivolt generator such as the Martel Electronics model IVC-222HPII can be a useful tool:

2. Measure Excitation Voltage- in addition to generating an input with a mV generator to simulate pressure, the excitation voltage can also be verified. The sensor output is in units of mV per psi per volt excitation so this voltage is an important factor in overall sensor accuracy. The voltage appears on the monitor cable pins 1 (plus) and 4 (minus):



For the PressureMAT products, this is 4.096V +/- 0.009V

3. PressureChecker- The PressureChecker in addition to being able to test a pressure sensor non-invasively, it has a sensor simulator built-in. The monitor cable can be connected to the PressureChecker and the readings on the displays are compared for accuracy.

This has an upper test limit of 10 psi which is the PressureChecker limit because it is designed for high resolution readings and the limit of the calibrated internal reference pressure transducer (that reads on the LCD).

4. Standard Sensor- a sensor verified against a calibrated gauge on a periodic basis within its five year shelf-life can be used as a reference to check other monitors across the entire pressure range.
   Annually return monitor to PendoTECH- There is PressureMAT recertification option offered by PendoTECH where a unit can be returned and re-certified to be within accuracy specification. The part number for this is: PMAT-RECERT

   After a purchase order is placed for this service, PendoTECH customer service will issue and RMA to return the unit. The return shipping fees is included in the service (U.S.A. only).

Conclusion

This Technical Note was designed to help users better understand the PendoTECH Single Use Pressure Sensors and their accessories and how they differ from traditional technology and to enable confident implementation and maintenance of the technology. For further discussion or comments, please contact us at request@pendotech.com.

References:

Datasheets, Technical Notes and Product Movies available at: http://www.pendotech.com/pressure and http://www.pendotech.com/pressuremat

Validation Guide for PendoTECH Single Use Pressure Sensors, Revision x

ATTACHMENT 1

Princeton, New Jersey 08542
PH: 609-799-2299
FAX: 609-784-7889
www.pendotech.com

Certificate of Quality

PendoTECH- Single Use Pressure Sensor, non-sterile, 0.125 inch (3.75 mm) hose barb

Part Number: PREPS-N-012

Lot Number: 1221587

Date of Manufacture: September 2022

Country of Origin: United States

- The product was manufactured in an FDA Registered, ISO 13485 certified facility
- The product was assembled in a ISO 7 Cleanroom
- All materials in fluid path meet USP Class VI requirements
- All materials in fluid path are animal derived component free
- Each product is leak-tested on the liquid side to confirm integral assembly and leak-tested on the test port side
- Each product is tested electrically to confirm proper electrical performance and tested to confirm linearity of sensor output to +/- 2% of the specified sensitivity within the range of 0 psi (0 bar) to 5.8 psi (0.40 bar)
- Each sensor is tested to be accurate at 30 psi (2.07 bar) within +/- 2% of reading (+/- 0.6 psi / 0.04 bar)
- Each sensor is tested to be accurate at 60 psi (4.14 bar) within +/- 5% of reading (+/- 3.0 psi / 0.21 bar)*

Approved by: Tannia Jaramillo

Tannia Jaramillo, Quality Manager

****CHANGE NOTIFICATION 22-004: Pressure Sensor 60psi testing addition***

Details of this change can be found in our Customer Change Notification documentation at:
https://www.pendotech.com/pressure-sensor-60psi-testing-addition/

Rev 21 Sep 2022

ATTACHMENT 2

Certificate of Compliance and Calibration

Device Description: PendoTECH Single Use Pressure Sensor™ **Cal. Procedure:** MP-MK-20

Catalog Number: PRExS-N-000-B **Lot Number:** ____________ **Serial Number:** ____________

Date of Service: ____________

NIST CALIBRATION TEST RESULTS

CALIBRATION CHECK POINTS

Applied Pressure (psi) (Using Test Standard)	Sensor Under Test			Sensor Specification	Test Standard Specification (psi)
	Indicated Pressure Reading (psi)	Deviation (psi)	Allowed Deviation (psi)		
0.00	Adjusted to zero		N/A	N/A	± 0.01
1.00			± 0.02	± 0.02 psi	± 0.01
2.00			± 0.04	± 2% of applied pressure. T.U.R (Total Uncertainty Ratio) of 4:1 at 2.0 psi	± 0.01
3.00			± 0.06		± 0.01
4.00			± 0.08		± 0.01
5.00			± 0.10		± 0.01
6.00			± 0.12		± 0.01
0.00			± 0.02	± 0.02 psi	± 0.01

PendoTECH® certifies that the unit described above has been inspected and calibrated in accordance with the listed Calibration Procedure using standards and instruments whose accuracies are traceable to the National Institute of Standards and Technology, through equipment which is calibrated at planned intervals. The policies and procedures at this facility comply with ISO13485.

Test Equipment Used	*Make*	*Model*	*I.D. #*	*Cal Expires*
Pressure Gauge				
Multimeter				

Technician: ____________________ Date: ____________

Disclaimers: **NOT FOR USE ABOVE 75 PSIG (5.2 Bar)**

Each prospective user must test the sensor for its proposed application to determine its suitability for the purpose intended prior to incorporating the sensor into any process or application. The sensor is not intended for use as a component in life support. The sensor is not designed for any application in which the failure of the sensor could result in personal injury or death.

Change Notification: Elimination of Descending Readings
Dear Valued Customer: We are no longer measuring the descending pressure values for our individually tested sensors with NIST traceable certificates. The detailed justification for this change can be found at www.pendotech.com/notifications/nistcertcn.pdf

Designed for use with PendoTECH Process Control Systems and PressureMAT® products.

For warranty see www.pendotech.com/warranty
PendoTECH®
www.pendotech.com
Princeton, New Jersey USA
Made in USA

Form 74142
Rev. D

ATTACHMENT 3

Certificate of Compliance and Calibration

Device Description: PendoTECH Single Use Pressure Sensor™ **Cal. Procedure:** MP-MK-20

Catalog Number: PRExS-N-XXX-30 **Lot Number:** ____________ **Serial Number:** ____________

Date of Service: __________

NIST CALIBRATION TEST RESULTS

CALIBRATION CHECK POINTS

Applied Pressure (psi) (Using Test Standard)	Sensor Under Test			Sensor Specification	Test Standard Specification (psi)
	Indicated Pressure Reading (psi)	Deviation (psi)	Allowed Deviation (psi)		
0	Adjusted to zero		N/A	N/A	± 0.05
5			± 0.20	± 3% of applied pressure or ± 0.2 psi whichever is greater	± 0.05
10			± 0.30		± 0.05
15			± 0.45		± 0.05
20			± 0.60		± 0.05
25			± 0.75		± 0.05
30			± 0.90		± 0.05
0			± 0.20		± 0.05

SAMPLE

PendoTECH® certifies that the unit described above has been inspected and calibrated in accordance with the listed Calibration Procedure using standards and instruments whose accuracies are traceable to the National Institute of Standards and Technology, through equipment which is calibrated at planned intervals. The policies and procedures at this facility comply with ISO13485.

Test Equipment Used	*Make*	*Model*	*I.D. #*	*Cal Expires*
Pressure Gauge				
Monitor				

Technician: ____________________ Date: ____________

Disclaimers: **NOT FOR USE ABOVE 75 PSIG (5.2 Bar)**

Each prospective user must test the sensor for its proposed application to determine its suitability for the purpose intended prior to incorporating the sensor into any process or application. The sensor is not intended for use as a component in life support. The sensor is not designed for any application in which the failure of the sensor could result in personal injury or death.

Change Notification: Elimination of Descending Readings
Dear Valued Customer: We are no longer measuring the descending pressure values for our individually tested sensors with NIST traceable certificates. The detailed justification for this change can be found at www.pendotech.com/notifications/nistcertcn.pdf

Designed for use with PendoTECH Process Control Systems and PressureMAT® products.

For warranty see www.pendotech.com/warranty
PendoTECH®
www.pendotech.com
Princeton, New Jersey USA
Made in USA

Form 74143
Rev. C

ATTACHMENT 4

Certificate of Compliance and Calibration

Device Description: PendoTECH Single Use Pressure Sensor™ **Cal. Procedure:** MP-MK-20

Catalog Number: PRExS-N-XXX-60 **Lot Number:** ____________ **Serial Number:** ______________

Date of Service: __________

NIST CALIBRATION TEST RESULTS

CALIBRATION CHECK POINTS

Applied Pressure (psi) (Using Test Standard)	Sensor Under Test			Sensor Specification	Test Standard Specification (psi)
	Indicated Pressure Reading (psi)	Deviation (psi)	Allowed Deviation (psi)		
0	Adjusted to zero		N/A	N/A	± 0.05
10			± 0.30	± 3% of applied pressure	± 0.05
20			± 0.60		± 0.05
30			± 0.90		± 0.05
40			± 2.00	± 5% of applied pressure	± 0.05
50			± 2.50		± 0.05
60			± 3.00		± 0.05
0			± 0.20	± 0.2 psi	± 0.05

PendoTECH® certifies that the unit described above has been inspected and calibrated in accordance with the listed Calibration Procedure using standards and instruments whose accuracies are traceable to the National Institute of Standards and Technology, through equipment which is calibrated at planned intervals. The policies and procedures at this facility comply with ISO13485.

Test Equipment Used	*Make*	*Model*	*I.D. #*	*Cal Expires*
Pressure Gauge				
Monitor				

Technician: ______________________ Date: ______________

Disclaimers: **NOT FOR USE ABOVE 75 PSIG (5.2 Bar)**

Each prospective user must test the sensor for its proposed application to determine its suitability for the purpose intended prior to incorporating the sensor into any process or application. The sensor is not intended for use as a component in life support. The sensor is not designed for any application in which the failure of the sensor could result in personal injury or death.

Change Notification: Elimination of Descending Readings
Dear Valued Customer: We are no longer measuring the descending pressure values for our individually tested sensors with NIST traceable certificates. The detailed justification for this change can be found at www.pendotech.com/notifications/nistcertcn.pdf

Designed for use with PendoTECH Process Control Systems and PressureMAT® products.

For warranty see www.pendotech.com/warranty
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