PendoTECH
PressureChecker™

Model PDKT-650-950

Revision 1

www.pendotech.com

User Guide

PendoTECH PressureChecker™ User Guide

Revision 1

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The information in this *User Guide* is believed to be accurate and reliable for use and operation of the monitor, however, PendoTECH assumes no responsibility for the use of this product except for what is covered in the Limited Warranty and Terms and Condition of Sale.

WARNING: "WARNING" is used to indicate the presence of a hazard which can cause severe personal injury, death, or substantial property damage if the warning is ignored

NOTE: "NOTE" is used to notify the user of installation or operation information which is important but not hazard related.

⚠️	Warning potential shock hazard. Do not submerge this product. Protect the product before cleaning with any liquids by covering openings that expose the internal components.

Goods and software are not designed, intended or authorized for use as components in life support or medical devices. They are not designed for any application in which the failure of the product could result in personal injury, death or property damage.

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1. Overview of the PressureChecker

The PressureChecker™ is a calibrated device that can be used to verify proper functioning and accuracy of PendoTECH Single Use Pressure Sensors and monitors non-invasively. It can be used to test the sensors in-situ without the requirement to access the fluid path. In its small, hand-held enclosure are all the devices necessary to perform the required function. PendoTECH Pressure Sensors are 100% tested at several points in the manufacturing process, however, this device gives the ability to verify the performance of the sensor by the end-user. PendoTECH Pressure Sensors are also frequently used on single use bioreactors to measure pressure in the bag. The required resolution is often less than 1 psi and the PressureChecker has the readability and ability to regulate pressure in this range. It also has an internal pressure sensor simulator and can be used to verify proper functioning of monitors such as the PressureMAT™, PendoTECH Process Control Systems, or 3rd party monitors.

There are numerous applications in biopharmaceutical production processes where the device can be used.

System Components Supplied:

- PDKT-650-950 PressureChecker pressure sensor and monitor verification tool (with 9V alkaline battery)

- PDKT-650-905 4 foot connecting tube with luer slip

- Calibration Certificate

1.1. Key Features

The PressureChecker incorporates a specially designed pressure cylinder and precision solid-state transducer for generating and measuring static pressure from -7 to +10.5 psi. The adjustment knob is used to regulate the pressure, and the pressure value is shown on the liquid crystal display. A built-in pneumatic port provides the external connection for fittings to connect to the sensor test port.

- Verify proper functioning of sensor and monitors
- Verify proper function of sensor in-situ by accessing the atmospheric reference side of sensor
- NIST Traceable
- Can be returned for annual calibration
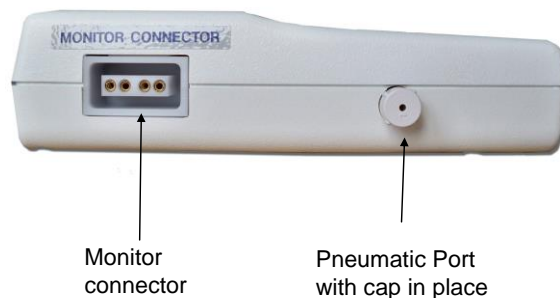- Battery operated for portability

1.2. Device Details
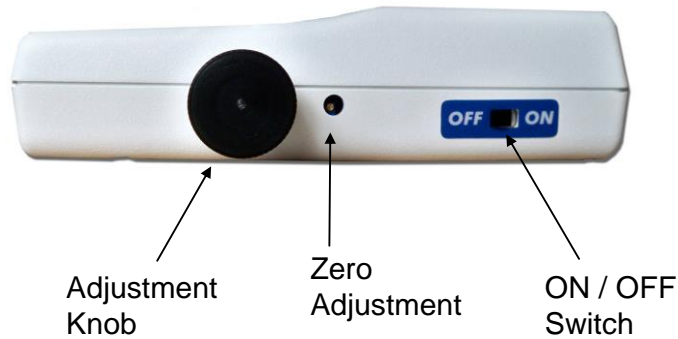
1.2.1. Hardware Details

Device details are as shown:

The connections on the left side panel are as shown below:

The control functions are on the right side panel as shown below:

Adjustment Knob   Zero Adjustment   ON / OFF Switch

1.2.2.Specifications

|	
Operating Pressure Range	-7 to +10.5 psi, 0.01 psi resolution Certified Range: -6 to +6 psi, 0.01 psi resolution
Temperature	Operating 15C to 40C Storage -20C to 65C
Operating Humidity	80% RH Max., Non-condensing
Accuracy	+/- 1% of reading or 0.01 psi, whichever is greater
Repeatability / Hysteresis	+/- 0.15% of Full Scale Output
Over Pressure Rating	14.5 psi
Pressure Sensor Simulator	Sensitivity: 0.2584mV/psi/volt +/- 1% Excitation: 2 to 10 VDC Input Impedance: 350 Ohms +/- 10% Output Impedance: <400 Ohms Asymmetry: < 1% Unbalance: 1.45 psi
Power Requirements	One 9 Volt battery
Battery Life	150 hours constant use, 15 months intermittent use, low battery indicator (BAT) appears when voltage drops below 7.2 volts
Display	3.5 inch LCD with 0.5 inch high digits and negative polarity indicator (for vacuum indication)
Dimensions	5.75 x 1.5 x 3.1 inches (L x D x W) 146 x 38 x 79 mm
Weight	9.7 Ounces (275 grams)

1.2.3.Theory of Operation

Positive and vacuum pressures can be generated within the PressureChecker and applied to a system under test. The pressure delivered is indicated on PressureChecker's liquid crystal display for quick comparison to the monitor. By applying a vacuum to the sensor test port, the linearity, and accuracy of the pressure sensor can be tested. Since the pressure sensor is a true differential device (measures gauge pressure relative to atmosphere), applying vacuum is equivalent to applying a pressure to the fluid path so the system can be checked to verify calibration very easily without accessing the fluid path or breaking sterility if a sterile fluid path. Even though it may not be possible to test the entire range of the pressure sensor, the proper function and sensor output accuracy of 0.2584 mV/psi/V can be verified to be within accuracy specification because this applies across the range of sensor pressures.

The pressure sensor simulator, which is housed inside PressureChecker's monitor connector, is a pressure sensor of the same type as that used in the PendoTECH Single User Pressure Sensor . When using the exclusive simulator feature of the PressureChecker, the pressure sensor is replaced with a device having the same operating characteristics and not with a device which "simulates" only some of its operating characteristics. A pressure (or vacuum) generated internally by PressureChecker's pneumatic pump, is applied to both the precision pressure transducer (which is connected to the 3.5 inch display) and to the pressure sensor simulator. Referencing the diagram, the signal from the precision pressure transducer is sent to the panel meter circuit, where it is converted from an analog voltage to a digital number and displayed in psi on the LCD readout. The signal from the sensor simulator is sent to the monitor to which it is connected, and from which it receives its excitation power. The monitor and LCD are then compared.
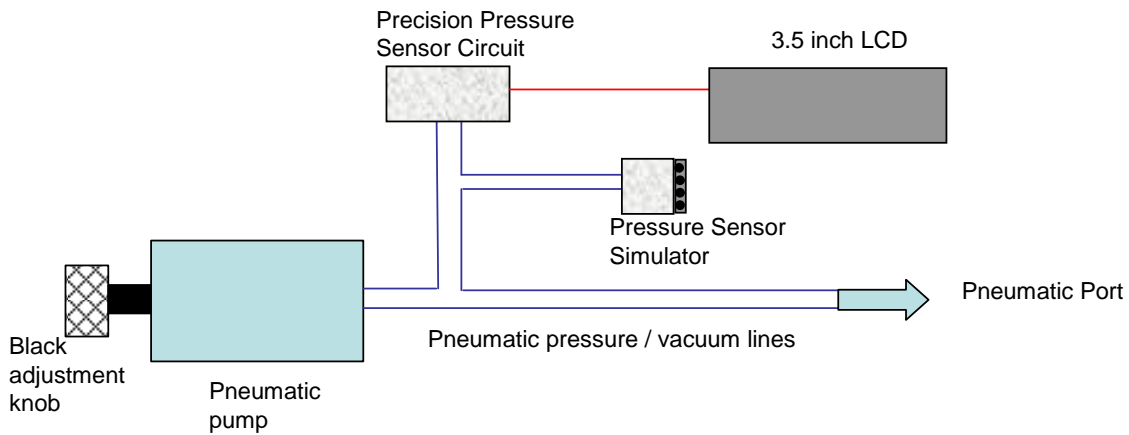
2. Using the Device

2.1. Testing sensors non-invasively

Positive and vacuum pressures can be generated within PressureChecker and applied to a sensor under test. The pressure delivered is indicated on PressureChecker's liquid crystal display for quick comparison to the monitor. By applying a vacuum to the sensor test port, the linearity and accuracy of the pressure sensor can be tested. Since the pressure sensor is a true differential device (measures gauge pressure relative to atmosphere), applying vacuum is equivalent to applying a pressure to the fluid path so the system can be checked to verify calibration very easily without accessing the fluid path or breaking sterility if a sterile fluid path. Even though it may not be possible to test the entire range of the pressure sensor, the proper function and sensor output accuracy of 0.2584 mV/psi/V can be verified to be within accuracy specification because this applies across the range of sensor pressures to 30 psi. Beyond the 30 psi, there is a non-linear output that both the PressureMAT and PendoTECH Control Systems can interpret and display the actual pressure reading. Regardless, the PressureChecker only can be used in its specified range which is below 30 psi.

NOTE: During the following steps the fluid path of the sensor must be exposed to atmosphere

Steps:
1. Connect the sensor to the monitor cable
2. Connect the 4 foot air tube with stop cock and slip luer on one end to the sensor test port and the PressureChecker pneumatic port on the other end.
3. Zero the system- properly zeroing the system is important for accuracy determination. To zero do the following:
   a. Position the handle on the stopcock to vent both the sensor and pneumatic port to atmosphere.
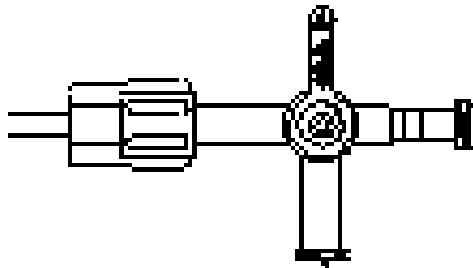
   b. Tare the sensor at the monitor per its operating instructions
   c. If the PressureChecker display does not read 0.00, turn the zero adjustment located on the right side using a small screwdriver

d.   When both the monitor and PressureChecker read zero, position the stop cock as shown and the sensor and setup is ready for testing:
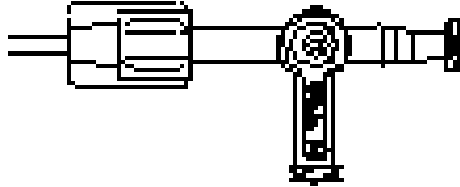
WARNING: IF THE SYSTEM APPEARS TO BE LOSING PRESSURE, CAREFULLY CHECK ALL FITTINGS AND CONNECTIONS

WARNING: DURING THIS TESTING DO NOT EXCEED +7 PSI OR THE SENSOR UNDER TEST MAY BE DAMAGED.

WARNING: DURING THIS TESTING DO NOT APPLY LESS THAN -7 PSI OR THE PRESSURE SENSOR SIMULATOR MAY BE DAMAGED.

4.   As pressure is generated by turning the adjustment knob, the pressure applied to the sensor is indicated on the PressureChecker display. This pressure reading is compared to the reading on the monitor to determine the sensor and setup accuracy.
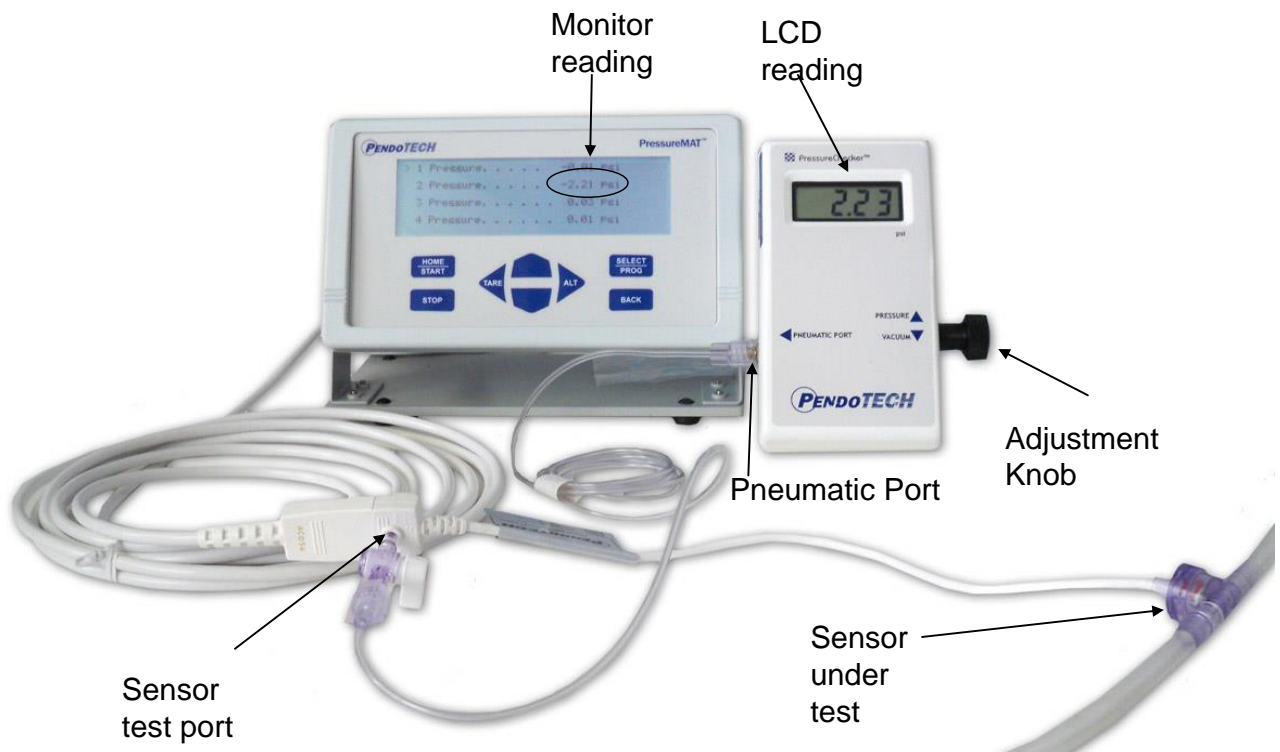
5. Interpretation of Results

Determining if a pressure sensor it accurate requires only one measurement at a known amount of applied pressure. This involves the following steps:
    a. Apply a pressure from -6 psi to +6 psi as indicated on the PressureChecker display
    b. Record the pressure from the monitor display
    c. From the accuracy specification on each item in the setup (sensor, monitor, PressureChecker) determine the maximum allowable deviation in pressure.
    d. Compare the results from step "b" with step "c". If the results from "b" fall into the range calculated in "c", the sensor under test is within the specification.

      Example on calculation of allowable deviation:

PressureChecker accuracy specification:	1% of reading
Pressure Sensor accuracy specification:	2% of reading
PressureMAT monitor accuracy specification:	1% of reading
ALLOWABLE DEVIATION =	4% of reading

    e. A linearity graph may also be plotted to verify linearity. Plot the results of monitor reading versus PressureChecker reading in the range of 0 psi to 6 psi (0 psi to -6 psi on the PressureChecker) to verify the linearity.

2.2. Using as a monitor simulator to test a monitor

The pressure sensor simulator, which is housed inside PressureChecker's monitor connector, is a pressure sensor of the same type as that used in the PendoTECH Single User Pressure Sensor. When using the exclusive simulator feature of the PressureChecker, the pressure sensor is replaced with a device having the same operating characteristics and not with a device which "simulates" only some of its operating characteristics. A pressure (or vacuum) generated internally by PressureChecker's pneumatic pump, is applied to both the precision pressure transducer (which is connected to the 3.5 inch display) and to the pressure sensor simulator.

NOTE: During the following steps the fluid path of the sensor must be exposed to atmosphere

Steps:
1. Remove the 4 foot air tube with stop cock from the PressureChecker pneumatic port and place the cap on the pneumatic port and tighten in place (or the stop cock may be closed by turning handle parallel with tubing and positioned under the tubing)
2. Connect the monitor cable to the PressureChecker Monitor Connector port
3. Zero the system- properly zeroing the system is important for accuracy determination. To zero do the following:
    a. Zero the PressureChecker with the Adjustment Knob
    b. Tare pressure simulator per the monitor operating instructions
    c. If the PressureChecker display does not read 0.00, turn the zero adjustment located on the right side using a small screwdriver
    d. When both the monitor and PressureChecker read zero, the sensor and setup is ready for testing

      WARNING: IF THE SYSTEM APPEARS TO BE LOSING PRESSURE, CHECK TO SEE THE PNEUMATIC PORT IS CLOSED TO ATMOSPHERE
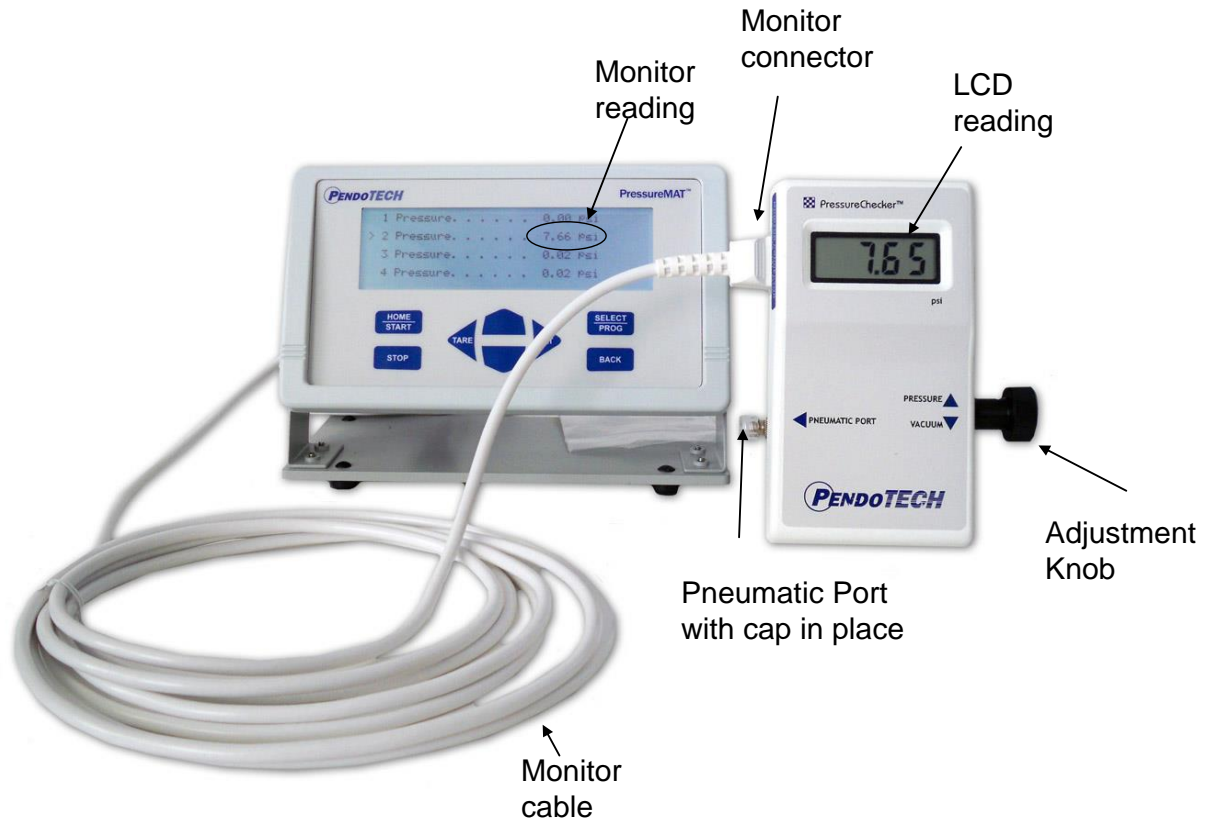
      WARNING: DURING THIS TESTING DO NOT EXCEED 10.5 PSI OR THE INTERNAL PRECISION PRESSURE TRANSDUCER MAY BE DAMAGED.

      WARNING: DURING THIS TESTING DO NOT APPLY LESS THAN -7 PSI OR THE PRESSURE SENSOR SIMULATOR MAY BE DAMAGED.

4. To test the following is an example set-up

5. Interpretation of Results

Determining if the monitor and interface cable are functioning properly requires only one measurement at a known amount of applied pressure. This involves the following steps:

    a. Apply a pressure from -6 psi to +6 psi as indicated on the PressureChecker display
    b. Record the pressure from the monitor display
    c. From the accuracy specification on each item in the setup (monitor, PressureChecker, and pressure sensor simulator) determine the maximum allowable deviation in pressure.
    d. Compare the results from step "b" with step "c". If the results from "b" fall into the range calculated in "c", the monitor and interface cable are within the specification.
       Example on calculation of allowable deviation:

PressureChecker accuracy specification:	1% of reading
Pressure sensor simulator accuracy specification	1% of reading
PressureMAT monitor accuracy specification:	1% of reading
ALLOWABLE DEVIATION =	3% of reading

    e. If the readings differ by more than allowable, first replace the monitor cable to make sure it is not faulty. If this is not the problem, it may be the monitor and contact PendoTECH for further assistance (see Appendix B).

3. Key System Components

3.1.   Power Supply and Low Battery Indicator

The solid state electronics of the PressureChecker are powered by a 9 volt alkaline battery. Because it uses CMOS circuitry, a 9 volt alkaline battery will last over a year in normal use. A low battery indicator is activated to alert the user when battery voltage drops below 7.2 VDC. When the "BAT" (low battery indicator) comes on, the battery must be replaced within a couple of hours of use for operation within specifications. Slide the battery compartment door open and replace the battery with an equivalent 9 volt alkaline battery.

WARNING: Remove battery from unit before storing for an extended period of time. If the unit has not been used for 12-15 months, replace the battery (see "Battery Life" in Specification Table).

3.2.   Precision Pressure Transducer

The PressureChecker's precision miniature piezoresistive pressure transducer generates electrical signals proportional to the pressure (or vacuum) generated by the internal pneumatic pump or applied externally to the pneumatic port. The certified operating pressure range is from -6 to +6 psi. The maximum allowable test pressure is from -7 to +10.5 psi (+7 psi if a sensor test port is connected to pneumatic port because the creates a vacuum on the sensor under test and -7 psi is the sensor lower limit). The maximum allowable (overpressure) limit is 14 psi. If more than 14 psi is applied to, or generated by the pneumatic pump, its calibration accuracy could be affected and the precision pressure transducer could be permanently damaged.

WARNING: Do not apply greater than 14 psi to the precision pressure transducer. It may be permanently damaged or accuracy may be affected.

3.3.   Display

The LCD Digital Panel Meter is a multi-purpose device that converts analog voltages from the transducer into digital information and simultaneously displays it on the 3½ digit liquid crystal display.

3.4.   Pressure Generating Cylinder

Static pressure (or vacuum) levels are generated using a unique piston and cylinder arrangement. Turning the adjustment knob clockwise will generate pressure. Turning the adjustment knob counterclockwise will generate vacuum at the connection port. The pump is internally connected to the PressureChecker's precision pressure transducer, the pressure sensor simulator, and the pneumatic port. The pressure generating cylinder incorporates precision parts with controlled assembly techniques and testing. Therefore, if defective, it is not user serviceable and should be returned to the factory for repair or replacement.

APPENDIX A: PRODUCT WARRANTY

PENDOTECH LIMITED WARRANTY

LIMITED WARRANTY: Subject to the limitations contained in <u>LIMITATION OF REMEDY AND LIABILITY</u> and except as otherwise expressly provided herein, PendoTECH LLC ("Seller") warrants that the Software will execute the programming instructions provided by Seller, and that the products, systems and goods ("Goods") manufactured by Seller will be free from defects in materials or workmanship under normal use and service until the expiration of twenty-four (24) months from the date of shipment by Seller. Expendable items are warranted to be free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of shipment by Seller. Products purchased by Seller from a third party for resale to Buyer ("Resale Products") shall carry only the warranty extended by the original manufacturer. Buyer agrees that Seller has no liability for Resale Products beyond making a reasonable commercial effort to arrange for procurement and shipping of the Resale Products. If, within thirty (30) days after Buyer's discovery of any warranty defects during the applicable warranty period, Buyer notifies Seller thereof in writing, Seller shall, at its option and as Buyer's sole and exclusive remedy hereunder, promptly correct any errors that are found by Seller to exist in the Software, or repair or replace F.O.B. point of manufacture, that portion of the Goods or Software found by Seller to be defective. All replacements or repairs necessitated by inadequate preventive maintenance, or by normal wear and usage, or by fault of Buyer, or by unsuitable power sources or by attack or deterioration under unsuitable environmental conditions, or by abuse, accident, alteration, misuse, improper installation, modification, repair, storage or handling, or any other cause not the fault of Seller are not covered by this limited warranty, and shall be at Buyer's expense. Seller shall not be obligated to pay any costs or charges incurred by Buyer or any other party except as may be agreed upon in writing in advance by an authorized Seller representative. All costs of dismantling, reinstallation and freight and the time and expenses of Seller's personnel for site travel and diagnosis under this warranty clause shall be borne by Buyer unless accepted in writing by Seller. Failure by Buyer to give such written notice of defects within the applicable time period shall be deemed an absolute and unconditional waiver of Buyer's claim for such defects. Goods repaired and parts replaced during the warranty period shall be in warranty for the remainder of the original warranty period or ninety (90) days, whichever is longer. All warranties, either express or implied, extend to BUYER only. All descriptions, representations and/or other information concerning Goods on the PendoTECH website and/or contained in PendoTECH's advertisements, brochures, promotional material, or statements made by employees or sales representatives of PendoTECH are solely for general informational purposes only and are not binding upon PendoTECH. No employee or sales representative of PendoTECH shall have any authority to establish, expand or otherwise modify PendoTECH's warranty associated with the sale of Goods. SELLER shall not be liable to BUYER in any manner with respect to Goods sold. SELLER MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY TYPE, EXPRESS OR IMPLIED, AND EXPRESSLY DISCLAIMS AND EXCLUDES ANY REPRESENTATION OR WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR USE, NON-INFRINGEMENT OR WARRANTY ARISING FROM USAGE OF TRADE, COURSE OF DEALING OR PERFORMANCE. PendoTECH, LLC makes no warranty or representation regarding whether or not a customer's end use of any PendoTECH product, system or good infringes the valid intellectual property rights of others.

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APPENDIX B: Service Information

A PressureChecker which is under warranty must be returned to PendoTECH for repair. If out of warranty, the user should call PendoTECH for over-the-phone assistance and our service staff will help determine if the should be returned for repair.

The PressureChecker should be checked for calibration every twelve months, or as often as company policy requires. The calibration service is available from PendoTECH for a fee and a new calibration certificate will be issued.

For factory service or calibration, please contact PendoTECH at request@pendotech.com or call +1-609-802-1262 for a return authorization number.

Then pack the unit carefully, preferably in the original shipping container, insure, and ship to PendoTECH.