# Validation Guide for PendoTECH<sup>®</sup> Single Use Pressure Sensors

**Revision** 4



# Validation Guide for PendoTECH Single Use Pressure Sensors

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#### **1** INTRODUCTION

#### 1.1 Product overview

PendoTECH's Single Use Pressure Sensors<sup>TM</sup> can be integrated virtually into any bioprocess. They are the alternative low-cost solution for use with tubing and bioprocess containers to the existing stainless steel pressure sensors on the market and are compatible with both gamma and ETO sterilization. They can be integrated for pressure measurement and control with both a PendoTECH Process Control System and PressureMAT products. The data collected by the control systems can be output to a PC or another data monitoring device. The pressure sensors are very accurate in the pressure ranges typically used with flexible tubing and disposable process containers and are qualified for use to 75 psi.

#### **1.2 Purpose of this document**

The purpose of this document is to assist end users in qualifying the sensors for use in their process. Each prospective user must test the sensor for its proposed application to determine its suitability for the purpose intended prior to incorporating the sensor to 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 product could result in property damage, personal injury, or death. Proper safeguards must be put into place for the process in which the sensor is used.

#### **1.3 Qualification testing comments**

Testing was completed to qualify the product for use in bioprocess applications. In the product manufacturing process, pressure sensing chips are affixed into molded product bodies. Pre-existing specifications of the MEMS-HAP<sup>™</sup> pressure sensing chips and specifications on certain materials used in the pressure sensor devices are as noted.

#### **2 PRODUCT CATALOG NUMBERS**

PendoTECH Product Catalog Numbers Covered in this Document									
Part Number*	Description								
PRESS-S-000	Single Use Pressure Sensor, Sterile, polycarbonate, luer inlet/outlet								
PRESS-N-025	Single Use Pressure Sensor, non-sterile, polycarbonate, 1/4 inch hose barb								
PRESS-N-038	Single Use Pressure Sensor, non-sterile, polycarbonate, 3/8 inch hose barb								
PRESS-N-050	Single Use Pressure Sensor, non-sterile, polycarbonate, 1/2 inch hose barb								
PRESS-N-075	Single Use Pressure Sensor, non-sterile, polycarbonate, 3/4 inch hose barb								
PRESS-N-100	Single Use Pressure Sensor, non-sterile, polycarbonate, 1 inch hose barb								
PTPL-PRESS	Single Use Pressure Sensor Insert for Port Plate, non-sterile, polycarbonate								
PREPS-N-000	Single Use Pressure Sensor, non-sterile, polysulfone, luer inlet/outlet								
PREPS-N-012	Single Use Pressure Sensor, non-sterile, polysulfone, 1/8 inch hose barb								
PREPS-N-025	Single Use Pressure Sensor, non-sterile, polysulfone, 1/4 inch hose barb								
PREPS-N-038	Single Use Pressure Sensor, non-sterile, polysulfone, 3/8 inch hose barb								
PREPS-N-050	Single Use Pressure Sensor, non-sterile, polysulfone, 1/2 inch hose barb								
PREPS-N-075	Single Use Pressure Sensor, non-sterile, polysulfone, 3/4 inch hose barb								
PREPS-N-100	Single Use Pressure Sensor, non-sterile, polysulfone, 1 inch hose barb								
PREPS-N-100ST	Single Use Pressure Sensor, non-sterile, polysulfone, 1 inch hose barb for soft tubing								
PREPS-N-1-1	Single Use Pressure Sensor, non-sterile, polysulfone, 1 inch Sanitary Flange Inlet/Outlet								
PREPS-N-5-5	Single Use Pressure Sensor, non-sterile, polysulfone, 3/4 inch Sanitary Flange Inlet/Outlet								
PREPS-N-15-15	Single Use Pressure Sensor, non-sterile, polysulfone, 1.5 inch Sanitary Flange Inlet/Outlet								
PREPS-N-5-038	Single Use Pressure Sensor, non-sterile, polysulfone, 3/4 inch Sanitary Flange to 3/8 hose barb								
PREPS-N-5-050	Single Use Pressure Sensor, non-sterile, polysulfone, 3/4 inch Sanitary Flange to 1/2 hose barb								
PREPS-N-1-100	Single Use Pressure Sensor, non-sterile, polysulfone, 1 inch Sanitary Flange to 1" hose barb								
PTPL-PREPS	Single Use Pressure Sensor Insert for Port Plate, non-sterile, polysulfone								

\* This Guide also applies to part numbers listed with suffix identifiers (such as -B or -30, -60 or -75 added to the part number for individual serial numbers and individual NIST Certificates; or –W added to the part number for sensors with a IP-67 Binder electrical connector; or V added to the part number for sensors with a vented cap)

#### **3** MANUFACTURING INFORMATION

- 3.1 Product is manufactured in an FDA Registered, ISO 13485:2016 certified facility
- 3.2 Product manufacturing environment
  - 3.2.1 Product is manufactured is a clean/controlled environment internally monitored to ensure less than 10,000 0.5 micron particles per cubic foot (ISO Class 7).
- **3.3** Product is manufactured with the proprietary 100% tested MEMs High Accuracy Pressure Chips (MEMS-HAP chips)
  - 3.3.1 Each pressure sensing chip is 100% tested to be within ±2% of reading at 30psi and ±5% of reading at 60 psi.

#### 3.4 Each product is tested during manufacturing to verify proper performance:

- 3.4.1 Leak-tested on the product contact side to confirm integral assembly at 5.8 psi
- 3.4.2 Each product is tested electrically to confirm proper electrical performance
- 3.4.3 Each product is tested to be within +/- 2% of the sensor output specification of 0.2584 mV/psi/V within the range of 0 psi to 5.8 psi
- 3.5 Polycarbonate (PRESS) molded product body- 100% visual inspection
  - 3.5.1 Embedded Particulate- Maximum 2 allowed per part. Maximum size of 0.08 mm2 in the fluid path. Maximum size of 0.2 mm2 anywhere else.
  - 3.5.2 Embedded Bubbles- Maximum 2 allowed per part. Maximum size of 0.08 mm<sup>2</sup> in the fluid path. Maximum size of 0.2 mm<sup>2</sup> anywhere else.
  - 3.5.3 Additional Inspection Criteria- Proprietary information on file at PendoTECH
- 3.6 Polysulfone (PREPS) molded product body- 100% visual inspection
  - 3.6.1 Embedded Particulate- Maximum 2 allowed per part. Maximum size of 0.08 mm<sup>2</sup> in the fluid path. Maximum size of 0.2 mm<sup>2</sup> anywhere else.
  - 3.6.2 Embedded Bubbles- Maximum 2 allowed per part. Maximum size of 0.08 mm<sup>2</sup> in the fluid path. Maximum size of 0.2 mm<sup>2</sup> anywhere else.
  - 3.6.3 Additional Inspection Criteria- Proprietary information on file at PendoTECH
- 3.7 Luer molded product body by lot sampling
  - 3.7.1 Embedded Particulate Maximum allowable size of 0.20mm<sup>2</sup>. Total in .25 in<sup>2</sup> area not to exceed 0.20mm<sup>2</sup>
  - 3.7.2 Embedded Bubbles Maximum allowable of an estimated 1/3 wall thickness or 0.40mm<sup>2</sup>, whichever is less

#### 4 PRODUCT CONTACT MATERIALS 4.1 Wet Volume and Surface Areas

Part Number	Wet Volume	Wet Surface
PRESS-S-000	0.015 in <sup>3</sup>	0.55 in <sup>2</sup>
PRESS-N-025	0.048 in <sup>3</sup>	0.98 in <sup>2</sup>
PRESS-N-038	0.113 in <sup>3</sup>	1.87 in <sup>2</sup>
PRESS-N-050	0.269 in <sup>3</sup>	3.21 in <sup>2</sup>
PRESS-N-075	0.890 in <sup>3</sup>	6.50 in <sup>2</sup>
PRESS-N-100	2.011 in <sup>3</sup>	10.48 in <sup>2</sup>
PTPL-PRESS	N/A	0.39 in <sup>2</sup>
PREPS-N-000	0.015 in <sup>3</sup>	0.55 in <sup>2</sup>
PREPS-N-012	0.011 in <sup>3</sup>	0.45 in <sup>2</sup>
PREPS-N-025	0.048 in <sup>3</sup>	0.98 in <sup>2</sup>
PREPS-N-038	0.113 in <sup>3</sup>	1.87 in <sup>2</sup>
PREPS-N-050	0.269 in <sup>3</sup>	3.21 in <sup>2</sup>
PREPS-N-075	0.890 in <sup>3</sup>	6.50 in <sup>2</sup>
PREPS-N-100	2.011 in <sup>3</sup>	10.48 in <sup>2</sup>
PREPS-N-100ST	2.560 in <sup>3</sup>	11.99 in <sup>2</sup>
PREPS-N-1-1	1.850 in <sup>3</sup>	8.12 in <sup>2</sup>
PREPS-N-5-5	0.220 in <sup>3</sup>	2.18 in <sup>2</sup>
PREPS-N-15-15	4.350 in <sup>3</sup>	12.94 in <sup>2</sup>
PREPS-N-5-038	0.200 in <sup>3</sup>	2.18 in <sup>2</sup>
PREPS-N-5-050	0.240 in <sup>3</sup>	2.58 in <sup>2</sup>
PREPS-N-1-100	2.020 in <sup>3</sup>	9.37 in <sup>2</sup>
PTPL-PREPS	N/A	0.39 in <sup>2</sup>

#### 4.2 Product body and pressure sensor housing

- 4.2.1 Product body- Polycarbonate is Bayer Makrolon<sup>™</sup> Rx1805 and Polysulfone is Solvay Udel® P-1700 : Data provided by suppliers state that they meet USP Class VI; claimed to be animal derived component free by suppliers (letters on file at PendoTECH); Material testing by PendoTECH meets USP Class VI post 40 kGy gamma irradiation (see Appendix A & B)
- 4.2.2 Pressure Sensor Chip Housing- Proprietary polycarbonate plastic formulation; Data provided by supplier states meets USP Class VI; claimed to be animal derived component free by suppliers (letters on file at PendoTECH); Material testing by PendoTECH meets USP Class VI post 40 kGy gamma irradiation (see Appendix A & B)

#### 4.3 Adhesive

4.3.1 Proprietary formulation: Data provided by supplier states meets USP Class VI; claimed to be animal derived component free by supplier (letter on file at PendoTECH); Material testing by PendoTECH meets USP Class VI post 40 kGy gamma irradiation (see Appendix A & B)

#### 4.4 Dielectric silicone

4.4.1 Proprietary formulation: Material testing by PendoTECH meets USP Class VI; claimed to be animal derived component free (letters on file at PendoTECH); Material testing by PendoTECH meets USP Class VI post 40 kGy gamma irradiation (see Appendix A & B)

#### 4.5 Port Plate Exclusive Materials (PTPL-PRESS and PTPL-PREPS Only)

- 4.5.1 O-Rings- Silicone, 70A, Translucent, Medical grade; Material testing by PendoTECH meets USP Class VI post 40kGy gamma irradiation (see Appendix B). Claimed to be animal derived component free by suppliers (letters on file at PendoTECH)
- 4.5.2 Port Plates
  - 4.5.2.1 Dow HDPE DMDA-8007 Health+<sup>TM</sup> Data provided by supplier state that they meet USP Class VI are animal derived component free, and REACH/RoHS compliant (letters on file at PendoTECH)

#### **5** ASSEMBLED SENSOR CERTIFICATIONS

#### 5.1 Class VI post gamma irradiation

5.1.1 Fully assembled sensors and sensor components meet the acceptance criteria for Class VI Test-USP (with 14 day subcutaneous implants) after exposure to 43-47 kGy (polycarbonate sensors) or 42-51 kGy (polysulfone sensors) of gamma irradiations. Study Summaries are in Appendix A & B and full reports are on file at PendoTECH.

#### 5.2 USP 661 post gamma irradiation

5.2.1 Fully assembled polycarbonate and polysulfone sensors meet the criteria of the USP Physicochemical Test for Plastics based upon Nonvolatile Residue, Residue on Ignition, Heavy Metals, and Buffering Capacity after exposure to 60-77 kGy of gamma irradiation. The study was conducted based upon the following references: USP 38, National Formulary33, 2015. Monograph <661> Containers, Physicochemical Tests-Plastics. Test Result Certificates are in Appendix C & D.

#### 5.3 ISO 10993-5 post irradiation (Gamma and X-ray)

- 5.3.1 Fully assembled polycarbonate and polysulfone sensors were tested for cytotoxicity after exposure to 35-38 kGy of *gamma* irradiation. All sensors were determined to meet the requirements of ISO 10993-5, Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity and are not considered to have a cytotoxic effect. Test Result Certificates are in Appendix E & F and full reports are on file at PendoTECH.
- 5.3.2 Fully assembled polycarbonate and polysulfone sensors were also tested for cytotoxicity after exposure to >50 kGy of *X-ray* Irradiation. All sensors were determined meet the requirements of ISO 10993-5, Biological Evaluation of Medical Devices Part 5: Tests for In Vitro Cytotoxicity and are not considered to have a cytotoxic effect. Test Result Certificates are in Appendix X and full reports are on file at PendoTECH.

#### 5.4 Particulates

- 5.4.1 Fully assembled polysulfone sensors were tested for particulates according to Nelson Laboratories STP0011 Rev 07 (Lynx Non-Visible Particle Test Method). All test method criteria were met. Test Study Final Report is in Appendix G.
- 5.4.2 Fully assembled polysulfone port plate pressure sensors (PTPL-PREPS) were tested for particulates according to Nelson Laboratories STP0011 Rev 11. Testing was performed using the HIAC Royco Liquid Particle Counting System (LPC) Model #9703. Testing was also completed in compliance with U.S. FDA good manufacturing practices (GMP) regulations 21 CFR Parts 210, 211, and 820. All test method criteria were met. Test Study Final Report is at the end of Appendix G.

#### 5.5 Bioburden

5.5.1 Three samples are randomly selected from production every quarter and tested for bioburden by Nelson Laboratories according to their Standard Test Protocol Number STP0036 Rev15. Testing is performed in accordance with ANSI/AAMI/ISO 11737-1:2018. Testing is performed in compliance with U.S. FDA good manufacturing practices (GMP) regulations 21 CFR Parts 210, 211, and 820. An example of a recent quarterly report and historical results from 2013 to Q2 2019 are in Appendix H. For the latest data please contact PendoTECH.

#### 5.6 Endotoxins

- 5.6.1 Samples of polysulfone sensors that had been gamma irradiated between 42 and 51 kGy were submitted for Chromogenic Endotoxin Testing. The study was based upon the following references: USP 42 NF 37, 2019. <85> Bacterial Endotoxin Test. ISO 10993-12, 2012. Following test validation, three test articles gave the following results: < 0.00500 EU/mL and < 0.6 EU/device of bacterial endotoxin and meets USP <85>, Bacterial Endotoxin Test. Study validation and sample testing reports are in Appendix I.
- 5.6.2 Samples polycarbonate luer sensors sterilized with ethylene oxide (PRESS-S-000) were submitted to Nelson Laboratories for Bacterial Endotoxins Testing (*Limulus* Amebocyte Lysate (LAL) test). Testing was performed according to their Standard Test Protocol Number STP0046 Rev 15. The study was based on the following references: ANSI/AAMI DT72:2011(R)2016, USP <161>, and USP <85>. Additionally, the test was completed in compliance with the U.S. FDA good manufacturing practices (GMP) regulations 21 CFR Parts 210, 211, and 820. Study results can be found at the end of Appendix I.

#### 5.7 Bacteriostasis and Fungistasis (B&F)

5.7.1 B&F testing was carried out by the method suitability test via membrane filtration – USP. The study was conducted with accordance to the following references: USP 41, NF 36, 2018. <71> Sterility Tests. ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories. Testing determined the sensors are considered non-bacteriostatic and non-fungistatic, according to the USP guidelines. Test reports are in Appendix J.

#### 6 PERFORMANCE SPECIFICATIONS

Attribute	Qualification Test Information				
Accuracy	0 to 6 psi: ± 2% of reading 6 to 30 psi: ± 3% of reading 30 to 60 psi: ± 5% of reading	Qualification Testing by PendoTECH			
Vacuum Accuracy	0 to -7 psi: ± 3% of reading -7 to -10 psi: ± 5% of reading	Qualification Testing by PendoTECH			
Gamma Irradiation	Up to 50 kiloGrays	Qualification Testing by PendoTECH			
X-ray Irradiation	Up to 50 kiloGrays	Qualification Testing by PendoTECH			
Pressure Range	-11.5 to 75 psi	Qualification Testing by PendoTECH; Specifications of pressure sensing chip			
Shelf Life	5 Years	Qualification Testing by PendoTECH			
Operating Temperature	2°C to 40°C	Qualification Testing by PendoTECH; Specifications of pressure sensing chip			
Storage Temperature	-25°C to 65°C	Specifications of pressure sensing chip			
Connector	Custom molded water-tight 4 pin connector Rating: IP67 when connected to reusable cable	Qualification Testing by certified test lab; Reports on file at PendoTECH			

#### 7 PENDOTECH TEST METHOD SUMMARY

#### 7.1 Accuracy

- 7.1.1 The pressure sensing chips are manufactured in very large batch sizes in a highly automated semiconductor-type manufacturing process. A manufacturing run of more than 5000 sensor chips (PendoTECH MEMS-HAP chips) was made using over 40 silicon wafers. The chips from these wafers were aggregated to yield 7 wafer lots. These sensor chips were each tested at the following 3 pressures to be within an accuracy of +/- 1% at 1.93 psi, 5.80 psi, and 29.00 psi (as is done with all MEMS-HAP sensor chips used in production). Those sensor chips that pass the accuracy test are used in production of finished sensors. From these 7 lots of chips, 200 finished sensors were produced and tested per the normal manufacturing process. Then 100 were randomly selected for testing of measured pressure versus a calibrated pressure gauge at room temperature (72°F). Data was analyzed to confirm all finished sensors are well within the specifications from 0 to 30 psi. Graphs and summary statistics are presented below.
- 7.1.2 PendoTECH's pressure sensor accuracy claim from 30-60 psi was previously based on a statistical analysis of the data collected in 7.1.1, which resulted in a specification of *Typically better than*  $\pm$  5% of reading. This original statistics can be found in Appendix Y. Following an improvement to the manufacturing procedure to include 100% testing at 60 psi, the accuracy claim from 30-60psi was re-evaluated. The new accuracy claim,  $\pm$  5% of reading is based on an analysis of the latest empirical data collected from 2624 NIST traceable tested sensors across nine different lots. Data was analyzed to confirm all finished sensors are within  $\pm$  5% from 30 to 60 psi. Graphs and summary statistics are presented below.

#### 7.2 Vacuum Accuracy

7.2.1 The performance of PendoTECH pressure sensors in a vacuum was evaluated in order to develop a vacuum accuracy claim. 120x PREPS-N-000P from 5 different lots were tested from -1 to -10 psi using a vacuum pump, special vacuum regulator, and a calibrated pressure gauge. Data was collected using a PendoTECH Normal Flow Filtration System (NFFSS). Statistical analysis was performed on the data to characterize the accuracy of PendoTECH sensors down to -10 psi.

#### 7.3 Gamma compatibility

7.3.1 In order to qualify the gamma compatibility of the sensors to 50 kiloGrays to enable their use on disposable assemblies of bioprocess containers, tubing, fittings, filters etc., the sensors were exposed to two gamma radiation processing cycles which resulted in a minimum dose of >50 kiloGrays. Gamma Certificate can be found in Appendix K.

#### 7.4 Sensor reading performance 53 months post gamma

7.4.1 In order to qualify the gamma compatibility of the sensors to 50 kiloGrays to enable their use on disposable assemblies of bioprocess containers, tubing, fittings, filters etc., the sensors were exposed to two gamma radiation processing cycles which resulted in a minimum dose of >50 kiloGrays. Sensors were tested for accuracy, stored at ambient conditions for 53 months, and then tested again for accuracy. Gamma Certificate can be found in Appendix K.

#### 7.5 Pressure limit of 75 psi

7.5.1 In order to qualify the products to be physically compatible with a pressure of 75 psi, 9 pressure sensors from 3 different lots, (1 lot of PRESS-N-050, 1 lot of PRESS-N-100, and 1 lot of PREPS-N-000) were tested for leaks or burst upon exposure to 150 psi. These specific sensor types were chosen to cover both material options and a range of sizes.

#### 7.6 Lower pressure limit of -11.5 psi

7.6.1 In order to qualify the products to be physically compatible with a lower pressure limit of -11.5 psi, gamma treated luer style pressure sensors were used for the following experiment. A manifold of 4 sensors from 3 different lots (12 total) was connected to a PendoTECH Filter Screening System, which accepts 12 pressure inputs. Using a vacuum pump, all 12 sensors were exposed to -11.5 psi for 6 hours. These sensors were then taken to 60 psi and isolated to check for leaks. The sensors were also tested for functionality at 60 psi.

#### 7.7 Temperature range to 2°C

7.7.1 In order to qualify the accuracy of pressure readings to a lower temperature limit of 2 °C, 12 gamma treated luer pressure sensors, four each from three lots, were assembled end to end (Luer male to female) in a manifold configuration and connected to a PendoTECH Filter Screening System. Baseline pressure data was recorded at room temperature with a calibrated pressure gauge at 0, 5, 10, 20, 30, 50, and 60 psi. After recording pressure values at room temperature, these sensors were then placed in a freezer (approximately -18 °C) for 3 hours. To keep the sensors cold during further testing, an ice water bath was created and a temperature sensor was attached in line with the pressure sensors to monitor the flow path temperature during the experiment. The sensor manifold was then submerged into the ice water bath, and pressure readings were recorded at the same pressure test points as before.

#### 7.8 Five Year shelf life: Sensor Integrity- Burst Testing

7.8.1 The sensor Tyvek packaging has previously been qualified for 5 year performance to maintain integrity. In order to verify product integrity for a minimum of 5 years, PendoTECH carried out leak and burst testing using twelve polysulfone sensors from a total of six different lots. Acceptance criteria is no burst upon exposure to 150 psi and a leak rate less than 0.01 psi per second.

#### 7.9 Five Year shelf life: Sensor Accuracy- Performance after 5 years storage, and following gamma radiation

7.9.1 In order to qualify the accuracy of pressure sensors after 5 years of storage, 12 pressure sensors from 6 different lots were kept in storage for 5 years at room temperature. Then, the sensors were retested using a calibrated pressure gauge and a PendoTECH Filter Screening System every 10 psi from 0 – 60 psi. NIST traceable certificates were used to gather time zero data for each of the 12 sensors. Furthermore, to qualify the accuracy of pressure sensors after receiving gamma irradiation treatment after 5 years of storage, the same 12 sensors received 40 kiloGrays of gamma and then were retested. Gamma certificate can be found in Appendix L.

#### 7.10 Sensor Use in Continuous Bioprocessing

7.10.1 Two experiments were performed in order to validate the robustness of PendoTECH's single use pressure sensors and qualify them for use in continuous bioprocesses. In the first experiment, gamma irradiated pressure sensors were checked for accuracy during and after continuous exposure to 3.5 bar (50.76 psi) for 7 days. In a second experiment, the same pressure sensors were kept under a constant pressure of 10 psi (0.69 bar) for 93 consecutive days. Afterwards, the performance and accuracy of the sensors was evaluated. The results of the accuracy tests are reported here. Gamma Certificate can be found in Appendix T.

#### 7.11 X-ray Compatibility

7.11.1 In order to qualify PendoTECH Pressure sensors for compatibility with X-ray Irradiation up to 50 KiloGrays, post X-ray functionality and physical testing was conducted. Three different lots of Polycarbonate (PRESS) and Polysulfone (PREPS) pressure sensors were evaluated after exposure to >50kGy of X-ray irradiation. These sensors were subject to leak and burst testing to validate sensor integrity and accuracy testing confirm proper functionality post X-ray Irradiation. X-ray certificate can be found in Appendix V.

#### 8 PENDOTECH TEST RESULTS

#### 8.1 Accuracy

8.1.1 Accuracy from 0 to 30 psi

- 8.1.1.1 Procedure- A manufacturing run of more than 5000 sensor chips (PendoTECH MEMS-HAP chips) was made using over 40 silicon wafers. The chips from these wafers were aggregated to yield 7 wafer lots. These sensor chips were each tested at the following 3 pressures to be within an accuracy of +/- 1% at 1.93psi, 5.80psi, and 29.00psi (as is done with all MEMS-HAP sensor chips used in production). Those sensor chips that pass the accuracy test are used in production of finished sensors. From these 7 lots of chips, 200 finished sensors were produced and tested per the normal manufacturing process. Then 100 were randomly selected for testing of measured pressure using a PendoTECH Filter Screening System versus a calibrated pressure gauge at room temperature (72°F).
- 8.1.1.2 Calibrated Pressure Gauge Used: Model# Druck DPI 104, Serial #: 2936090 (Cert in Appendix M)
- 8.1.1.3 Acceptance criteria:
  - 1. Each sensor reads within +/- 2% of gauge reading in the range of 0 to 6 psi; within +/- 3% of reading in the range of 6 30 psi
- 8.1.1.4 Data Summary



#### Graph of 100 Random Sensors from 0 to 60 psi with MEMS-HAP Chips

			All in PSI
Std. Dev.	Average	6 SDs/Avg	Gauge Pressure
	0		0.00
0.01	5.02	1.48%	5.00
0.02	10.08	0.94%	10.00
0.02	15.16	0.81%	15.00
0.02	20.19	0.72%	20.00
0.04	25.19	1.03%	25.00
0.06	30.07	1.24%	30.00
0.10	34.98	1.67%	35.00
0.14	39.99	2.16%	40.00
0.21	45.00	2.86%	45.00
0.28	50.01	3.41%	50.00
0.37	55.01	4.00%	55.00
0.46	59.97	4.60%	60.00

#### Statistical Summary of 100 Random Sensors from 0 to 60 psi with MEMS-HAP Chips

- 8.1.1.5 Conclusion- All sensors meet the acceptance criteria of better than +/- 2% of reading in the range of 0 to 6 psi and better than +/-3% of reading in the range of 6 - 30 psi
- 8.1.2 Product Accuracy Verification in the range 30 to 60 psi following an improvement to the manufacturing procedure to include 100% sensor chip testing at 60 psi
  - 8.1.2.1 Procedure- Data was collected from 2624 NIST traceable sensors across 9 different lots that were all built following the latest manufacturing procedure with 100% testing at 60 psi.
  - 8.1.2.2 Acceptance Criteria:



8.1.2.3 Data Summary:



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Statistical Summary of an 1151 Traceable Sensors from o to ou pr							
Gauge Pressure (psi)	Min	Max	Average	% Error	Std. Dev.		
10	9.93	10.12	10.03	0.31%	0.019		
20	19.92	20.27	20.09	0.47%	0.050		
30	29.55	30.19	29.91	-0.30%	0.119		
40	39.10	40.54	39.88	-0.29%	0.280		
50	48.55	51.33	49.93	-0.13%	0.528		
60	57.80	62.34	59.93	-0.11%	0.854		

Statistical Summarv	of all NIST Traceable	Sensors from 0 to 60 psi
	· <b>j</b> · · · · · · · · · · · · · · · · · · ·	

8.1.2.1 Conclusion- 100% of sensors meet the acceptance criteria of  $\pm$  3% of reading in the range of 6 - 30 psi and  $\pm$  5% in the range of 30 to 60 psi, thus validating the new accuracy claim.

#### 8.2 Vacuum Accuracy

- 8.2.1 Procedure- 120x PREPS-N-000P from Lot #'s 1190285, 1190183, 1190774, 1190285, and 1190935, were connected to a high vacuum pump. Using a Tescom vacuum regulator, the sensors were exposed to pressures ranging from -1 to -10 psi. Data was collected using a PendoTECH Normal Flow Filtration System (NFFSS). Statistical analysis was performed on the data to characterize the accuracy of PendoTECH sensors down to -10 psi.
  - 8.2.1.1 Calibrated Pressure Gauge- Model: Crystal XP2i S/N: 692233 (Cert in Appendix P)

8.2.2	Data Summary:
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Gauge Pressure	-1.00	-2.00	-3.00	-4.00	-5.00	-6.00	-7.00	-8.00	-9.00	-10.00
Average	-1.00	-1.99	-2.99	-3.98	-4.98	-5.97	-6.96	-7.94	-8.91	-9.88
<b>Standard Deviation</b>	0.01	0.01	0.01	0.02	0.02	0.02	0.02	0.02	0.03	0.03

Statistical Analysis of all 120 sensors



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8.2.3

Raw Data:

		Pressure Reading (psi)									
Lot #	Sensor	-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
	1A	-1.01	-1.99	-2.99	-3.96	-4.95	-5.96	-6.94	-7.94	-8.89	-9.87
	1B	-1.01	-2.00	-2.99	-3.97	-4.96	-5.96	-6.94	-7.94	-8.89	-9.89
	1C	-1.02	-2.00	-3.00	-3.97	-4.96	-5.95	-6.95	-7.94	-8.90	-9.89
	2A	-1.02	-1.99	-2.98	-3.98	-4.98	-5.98	-6.97	-7.97	-8.92	-9.91
	2B	-1.02	-1.99	-3.00	-3.98	-4.98	-5.97	-6.96	-7.95	-8.89	-9.90
1190285-	2C	-1.03	-2.02	-3.00	-3.99	-4.99	-5.98	-6.98	-7.97	-8.95	-9.93
A	3A	-1.01	-2.00	-2.99	-3.98	-4.97	-5.96	-6.97	-7.94	-8.90	-9.89
	3B	-1.01	-1.99	-2.98	-3.97	-4.97	-5.95	-6.94	-7.93	-8.88	-9.87
	3C	-1.01	-1.99	-3.00	-3.97	-4.98	-5.97	-6.98	-7.96	-8.93	-9.91
	4A	-1.01	-2.00	-3.00	-4.00	-4.99	-5.98	-6.98	-7.97	-8.94	-9.93
	4B	-1.01	-1.99	-2.99	-3.98	-4.98	-5.98	-6.97	-7.96	-8.92	-9.91
	4C	-1.02	-1.99	-3.00	-3.99	-4.99	-5.98	-7.00	-7.97	-8.95	-9.94
	1A	-1.00	-2.00	-3.00	-3.98	-5.01	-5.99	-6.99	-7.97	-8.94	-9.91
	1B	-1.01	-2.01	-3.00	-4.00	-5.02	-5.99	-6.99	-7.98	-8.95	-9.93
	1C	-1.00	-1.99	-2.99	-3.98	-4.99	-5.97	-6.96	-7.94	-8.89	-9.87
	2A	-1.00	-1.99	-2.98	-3.98	-4.98	-5.96	-6.97	-7.92	-8.89	-9.86
	2B	-1.01	-2.00	-3.00	-3.99	-4.99	-5.98	-6.98	-7.95	-8.91	-9.89
1190183-	2C	-1.01	-2.00	-2.99	-4.00	-4.98	-5.97	-6.96	-7.92	-8.91	-9.88
A	3A	-0.99	-1.98	-2.99	-3.98	-4.97	-5.97	-6.97	-7.93	-8.89	-9.87
	3B	-1.00	-1.99	-2.99	-4.00	-4.97	-5.97	-6.97	-7.93	-8.91	-9.89
	3C	-0.99	-1.98	-2.99	-3.98	-4.96	-5.97	-6.98	-7.93	-8.92	-9.90
	4A	-1.00	-1.99	-2.99	-3.98	-4.98	-5.98	-6.97	-7.92	-8.90	-9.86
	4B	-0.99	-1.99	-3.00	-4.01	-4.99	-6.01	-7.01	-7.98	-8.95	-9.94
	4C	-0.98	-1.97	-2.97	-3.96	-4.94	-5.94	-6.94	-7.90	-8.88	-9.84
	1A	-1.00	-1.99	-3.01	-3.99	-5.00	-5.99	-6.98	-7.97	-8.95	-9.93
	1B	-1.01	-1.99	-3.00	-3.99	-4.97	-5.97	-6.97	-7.94	-8.91	-9.89
	1C	-1.01	-2.00	-3.00	-3.99	-4.98	-5.99	-6.97	-7.97	-8.96	-9.93
	2A	-1.01	-2.00	-3.02	-4.01	-4.99	-5.98	-6.98	-7.97	-8.93	-9.91
	2B	-0.98	-1.98	-2.98	-3.98	-4.97	-5.95	-6.95	-7.93	-8.91	-9.88
1190183-	2C	-1.01	-1.99	-2.99	-3.98	-4.99	-5.97	-6.97	-7.94	-8.93	-9.90
В	3A	-1.01	-1.99	-3.00	-3.98	-4.98	-5.98	-6.98	-7.96	-8.94	-9.92
	3B	-1.01	-2.00	-2.99	-3.99	-4.99	-5.99	-6.97	-7.97	-8.95	-9.92
	3C	-0.99	-1.99	-2.98	-3.98	-4.99	-5.98	-6.95	-7.95	-8.92	-9.88
	4A	-1.00	-1.99	-2.99	-3.98	-4.98	-5.96	-6.95	-7.93	-8.91	-9.88
	4B	-0.99	-1.98	-2.99	-3.98	-4.98	-5.98	-6.98	-7.96	-8.95	-9.92
	4C	-1.00	-1.99	-2.99	-3.99	-4.98	-5.97	-6.96	-7.94	-8.92	-9.88
1190774-	1A	-0.99	-1.98	-2.98	-3.97	-4.96	-5.96	-6.94	-7.93	-8.89	-9.86
Α	1B	-1.01	-1.98	-2.99	-3.98	-4.98	-5.96	-6.95	-7.91	-8.90	-9.86

	1C	-1.00	-1.99	-2.99	-3.97	-4.97	-5.96	-6.94	-7.92	-8.90	-9.86
	2A	-1.01	-1.99	-3.00	-3.98	-4.98	-5.98	-6.98	-7.95	-8.93	-9.92
	2B	-1.01	-1.98	-2.97	-3.97	-4.96	-5.95	-6.94	-7.93	-8.91	-9.86
	2C	-1.02	-1.99	-2.99	-3.98	-4.98	-5.97	-6.96	-7.94	-8.90	-9.86
	3A	-1.01	-2.01	-3.00	-3.99	-5.00	-5.99	-6.97	-7.96	-8.93	-9.89
	3B	-1.02	-2.01	-3.00	-4.01	-5.00	-5.98	-6.97	-7.96	-8.93	-9.90
	3C	-1.01	-1.98	-3.00	-3.97	-4.98	-5.97	-6.96	-7.95	-8.92	-9.89
	4A	-0.99	-1.98	-2.98	-3.97	-4.98	-5.97	-6.95	-7.93	-8.90	-9.88
	4B	-1.01	-2.00	-2.97	-3.89	-4.96	-5.97	-6.82	-7.91	-8.88	-9.87
	4C	-0.98	-1.99	-2.99	-3.99	-4.97	-5.98	-6.97	-7.94	-8.94	-9.92
	1A	-1.01	-2.00	-2.99	-4.00	-5.00	-5.99	-6.98	-7.96	-8.92	-9.90
	1B	-1.02	-2.00	-2.99	-4.00	-4.99	-5.98	-6.96	-7.91	-8.89	-9.86
	1C	-1.02	-2.00	-2.99	-3.98	-4.98	-5.97	-6.95	-7.94	-8.91	-9.88
	2A	-1.01	-1.98	-3.00	-3.99	-4.99	-5.98	-6.98	-7.96	-8.92	-9.91
	2B	-1.00	-1.99	-2.98	-3.97	-4.97	-5.96	-6.93	-7.91	-8.88	-9.85
1190774-	2C	-0.99	-1.98	-2.99	-4.00	-4.98	-5.99	-6.98	-7.96	-8.94	-9.93
В	3A	-1.00	-1.99	-2.98	-3.97	-4.97	-5.96	-6.95	-7.91	-8.90	-9.86
	3B	-1.01	-2.00	-3.00	-4.01	-5.00	-5.98	-6.97	-7.96	-8.93	-9.90
	3C	-1.01	-2.00	-2.98	-4.00	-4.99	-5.99	-6.98	-7.94	-8.92	-9.89
	4A	-1.00	-2.00	-2.99	-3.99	-4.99	-5.98	-6.97	-7.96	-8.93	-9.91
	4B	-1.01	-2.01	-3.00	-3.99	-4.98	-5.98	-6.96	-7.93	-8.90	-9.88
	4C	-1.00	-2.00	-3.00	-4.00	-5.01	-6.00	-6.99	-7.97	-8.95	-9.95
	1A	-1.00	-1.98	-2.99	-3.98	-4.99	-5.99	-6.97	-7.95	-8.91	-9.93
	1B	-1.00	-1.98	-2.97	-3.95	-4.95	-5.95	-6.93	-7.89	-8.84	-9.86
	1C	-0.99	-1.99	-2.98	-3.98	-4.97	-5.97	-6.96	-7.92	-8.88	-9.91
	2A	-0.99	-1.98	-2.98	-3.96	-4.95	-5.95	-6.93	-7.90	-8.86	-9.86
	2B	-1.00	-1.99	-2.99	-3.98	-4.98	-5.97	-6.97	-7.95	-8.91	-9.90
1190285-	2C	-0.99	-1.98	-2.98	-3.99	-4.96	-5.98	-6.96	-7.92	-8.90	-9.90
В	ЗA	-1.00	-1.99	-2.99	-3.98	-4.98	-5.98	-6.98	-7.94	-8.92	-9.92
	3B	-1.00	-1.99	-2.98	-3.99	-4.98	-5.98	-6.96	-7.92	-8.89	-9.91
	3C	-0.99	-1.96	-2.98	-3.97	-4.96	-5.96	-6.95	-7.91	-8.88	-9.88
	4A	-0.99	-1.98	-2.99	-3.98	-4.98	-5.97	-6.95	-7.94	-8.91	-9.90
	4B	-0.99	-1.99	-2.99	-3.98	-4.99	-5.98	-6.97	-7.96	-8.91	-9.91
	4C	-0.99	-1.99	-2.98	-3.98	-4.97	-5.96	-6.94	-7.92	-8.88	-9.86
	1A	-0.96	-1.99	-2.98	-3.97	-4.97	-5.96	-6.94	-7.93	-8.89	-9.87
	1B	-0.98	-1.99	-2.99	-3.98	-4.97	-5.97	-6.95	-7.94	-8.91	-9.89
1100025	1C	-0.98	-2.00	-2.98	-3.97	-4.97	-5.95	-6.93	-7.92	-8.89	-9.86
Σ 1130332-	2A	-0.98	-1.98	-2.97	-3.97	-4.97	-5.95	-6.94	-7.93	-8.89	-9.85
~	2B	-0.99	-2.00	-3.00	-3.98	-4.98	-5.96	-6.94	-7.94	-8.92	-9.88
	2C	-0.97	-1.98	-2.97	-3.97	-4.97	-5.95	-6.93	-7.91	-8.88	-9.86
	3A	-1.01	-2.01	-3.02	-4.01	-5.00	-6.00	-6.98	-7.98	-8.93	-9.91

	3B	-0.98	-1.98	-3.00	-3.99	-4.98	-5.98	-6.96	-7.94	-8.91	-9.88
	3C	-0.94	-1.95	-2.95	-3.94	-4.96	-5.94	-6.92	-7.93	-8.88	-9.86
	4A	-0.99	-2.00	-2.99	-3.99	-4.99	-5.98	-6.97	-7.96	-8.92	-9.90
	4B	-0.99	-1.99	-2.98	-3.98	-4.98	-5.97	-6.95	-7.93	-8.91	-9.87
	4C	-0.97	-1.97	-2.97	-3.95	-4.95	-5.95	-6.95	-7.93	-8.88	-9.85
	1A	-0.98	-1.98	-2.98	-3.98	-4.97	-5.96	-6.92	-7.91	-8.88	-9.84
	1B	-0.99	-1.99	-2.99	-3.99	-4.98	-5.97	-6.96	-7.94	-8.91	-9.88
	1C	-0.99	-1.98	-2.99	-3.97	-4.98	-5.97	-6.95	-7.94	-8.92	-9.89
	2A	-1.01	-2.00	-2.99	-3.99	-4.96	-5.96	-6.93	-7.91	-8.88	-9.86
	2B	-0.97	-1.96	-2.96	-3.97	-4.97	-5.95	-6.94	-7.94	-8.93	-9.90
1190526-	2C	-0.99	-1.97	-2.97	-3.96	-4.95	-5.95	-6.93	-7.92	-8.89	-9.86
А	3A	-1.00	-2.00	-2.99	-4.00	-4.99	-5.99	-6.97	-7.95	-8.93	-9.92
	3B	-1.01	-1.99	-2.99	-3.99	-4.99	-5.98	-6.96	-7.95	-8.91	-9.89
	3C	-1.00	-2.00	-2.99	-3.97	-4.95	-5.94	-6.88	-7.85	-8.79	-9.70
	4A	-0.99	-1.97	-2.98	-3.98	-4.96	-5.95	-6.93	-7.93	-8.89	-9.87
	4B	-1.00	-1.98	-2.99	-4.00	-4.99	-5.98	-6.97	-7.96	-8.92	-9.92
	4C	-1.00	-2.00	-3.00	-4.00	-4.99	-6.00	-6.98	-7.96	-8.95	-9.92
	1A	-1.01	-1.98	-2.96	-3.95	-4.94	-5.93	-6.93	-7.93	-8.85	-9.82
	1B	-1.01	-1.97	-2.98	-3.96	-4.95	-5.95	-6.97	-7.97	-8.89	-9.86
	1C	-1.01	-1.98	-2.97	-3.98	-4.96	-5.96	-7.00	-8.00	-8.89	-9.89
	2A	-0.99	-1.96	-2.94	-3.95	-4.92	-5.91	-6.95	-7.92	-8.88	-9.85
	2B	-1.01	-1.98	-2.97	-3.96	-4.95	-5.92	-6.95	-7.94	-8.87	-9.85
1190935-	2C	-1.01	-1.98	-2.97	-3.96	-4.95	-5.91	-6.96	-7.93	-8.89	-9.85
В	3A	-1.02	-1.99	-2.98	-3.97	-4.97	-5.95	-6.98	-7.93	-8.91	-9.90
	3B	-1.00	-1.98	-2.97	-3.95	-4.97	-5.94	-6.96	-7.91	-8.90	-9.88
	3C	-1.04	-2.00	-3.01	-4.00	-5.01	-5.99	-7.02	-7.96	-8.96	-9.93
	4A	-1.01	-1.99	-2.96	-3.96	-4.95	-5.93	-6.93	-7.92	-8.89	-9.87
	4B	-1.00	-1.98	-2.96	-3.96	-4.96	-5.94	-6.92	-7.91	-8.87	-9.85
	4C	-1.00	-1.99	-2.98	-3.97	-4.96	-5.94	-6.97	-7.90	-8.91	-9.88
	1A	-1.00	-2.00	-2.99	-3.98	-4.97	-5.97	-6.94	-7.93	-8.91	-9.87
	1B	-1.00	-1.99	-2.98	-3.97	-4.97	-5.97	-6.92	-7.93	-8.89	-9.86
	1C	-1.00	-1.99	-2.98	-3.98	-4.97	-5.96	-6.95	-7.94	-8.91	-9.87
	2A	-1.00	-2.00	-2.98	-3.98	-4.99	-5.98	-6.95	-7.96	-8.93	-9.89
	2B	-1.00	-1.99	-2.99	-3.97	-4.97	-5.97	-6.95	-7.94	-8.93	-9.89
1190526-	2C	-1.00	-1.97	-2.98	-3.97	-4.97	-5.96	-6.95	-7.94	-8.91	-9.88
В	3A	-1.00	-2.02	-3.00	-3.99	-4.98	-5.97	-6.95	-7.94	-8.92	-9.88
	3B	-1.00	-2.00	-3.00	-3.97	-4.97	-5.97	-6.94	-7.93	-8.89	-9.87
	3C	-0.99	-1.99	-2.97	-3.98	-4.97	-5.95	-6.92	-7.90	-8.88	-9.83
	4A	-1.00	-2.00	-2.99	-3.98	-4.99	-5.99	-6.97	-7.97	-8.94	-9.91
	4B	-0.99	-1.99	-2.99	-3.97	-4.96	-5.97	-6.94	-7.94	-8.91	-9.86
	4C	-1.00	-2.00	-2.98	-3.97	-4.97	-5.97	-6.94	-7.93	-8.90	-9.86

8.2.4 Conclusion- PendoTECH sensors can accurately measure pressure down to -10 psi

#### 8.3 Gamma compatibility

- 8.3.1 Procedure- 16 sensors from 4 different lots were tested with a high accuracy gauge. Each sensor was connected to the PendoTECH TFF Process Control System and after at least 10 minutes, the sensor readings were taken as compared to the gauge pressure at pressures up to 75 psi. All of the sensors were then exposed to a minimum gamma radiation dose of 25 kGy and then the pressure readings were measured again. The two actual doses were minimum of 30.6 and 27.9 kGy for a cumulative exposure of minimum of 58.5 kGy.
  - 8.3.1.1 Calibrated Pressure Gauge Used: Model# Druck DPI104, Serial #: 2460830 (Cert in Appendix N)
  - 8.3.1.2 Acceptance criteria- Repeatability target was less than 0.5psi
- 8.3.2 Data Summary (raw data on file at PendoTECH).

	Lot #1	- senso	r #1	Lot #1	- senso	r #2	Lot #1	- sensor	r #3	Lot #1	- sensor	r #4
Gauge Pressure (psi)		1 X Gamma (psi)	2X Gamma (psi)									
0.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.00
5.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
6.00		0.0	-0.1		0.0	0.0		0.0	-0.1		0.0	0.0
10.00		0.0	0.0		0.0	0.0		0.0	-0.1		0.0	0.0
15.00		-0.1	0.0		0.0	0.0		0.0	0.0		0.0	-0.1
20.00		-0.1	-0.1		0.0	0.0		-0.1	-0.1		0.0	-0.1
22.00		-0.1	0.1		0.0	-0.1		-0.1	-0.1		0.0	-0.1
25.00		0.0	-0.1		0.0	-0.1		0.0	-0.1		-0.1	-0.2
30.00		0.0	-0.1		0.0	-0.1		0.0	-0.1		0.0	-0.1
35.00		-0.1	-0.1		0.0	-0.1		-0.1	-0.2		-0.1	-0.1
40.00		0.0	-0.2		0.0	-0.1		0.0	-0.1		0.0	-0.1
45.00		0.0	-0.1		0.0	-0.1		0.0	-0.1		0.0	-0.1
50.00		-0.1	-0.2		-0.1	-0.2		-0.1	-0.1		0.0	-0.1
55.00		0.0	-0.1		0.0	-0.1		0.0	-0.1		0.0	-0.1
60.00		0.0	-0.1		0.0	-0.1		0.0	-0.1		0.0	-0.1
65.00		-0.1	-0.1		-0.1	-0.1		0.0	0.0		0.0	-0.2
70.00		0.0	-0.1		0.0	-0.1		0.0	-0.1		0.0	-0.2
75.00		-0.1	-0.1		0.0	-0.1		0.0	-0.1		0.0	-0.1

Sensor Pressure Difference After 1X and 2X Gamma Exposure at Set Gauge Pressure

	Lot #2	2- senso	r #1	Lot #2	- senso	r #2	Lot #2	- sensor	: #3	Lot #2	- senso	r #4
Gauge Pressure (psi)		1 X Gamma (psi)	2X Gamma (psi)									
0.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
5.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
6.00		0.0	0.0		-0.1	0.0		0.0	0.0		0.0	0.0
10.00		0.0	0.0		-0.1	0.0		0.0	0.0		0.0	0.0
15.00		0.0	-0.1		-0.1	0.0		0.0	0.0		0.0	-0.1
20.00		0.0	-0.1		0.0	0.0		0.0	0.0		0.0	0.0
22.00		0.0	0.0		-0.1	0.0		0.0	0.0		0.0	-0.1
25.00		0.0	-0.1		-0.1	0.0		0.0	0.0		0.0	-0.1
30.00		0.0	0.0		-0.1	0.0		0.0	0.0		0.0	-0.1
35.00		0.1	0.0		0.0	0.0		0.0	0.0		0.0	-0.1
40.00		0.0	-0.1		0.0	0.0		0.0	0.0		0.0	-0.1
45.00		0.0	-0.1		0.0	0.0		0.0	0.1		0.0	-0.1
50.00		0.1	-0.1		0.0	-0.1		0.0	0.0		0.0	-0.1
55.00		0.1	0.0		-0.1	0.0		0.1	0.0		0.1	-0.1
60.00		0.1	0.0		0.0	0.0		0.1	0.0		0.0	-0.1
65.00		0.1	0.0		0.0	0.0		0.1	0.0		0.0	-0.1
70.00		0.1	-0.1		0.0	-0.1		0.1	0.1		0.0	-0.1
75.00		0.1	0.1	-	0.0	0.0		0.1	0.1		0.0	-0.1

#### Sensor Pressure Difference After 1X and 2X Gamma Exposure at Set Gauge Pressure

	Lot #3	- senso	r #1	Lot #3	- senso	r #2	Lot #3	- senso	r #3	Lot #3	- senso	r #4
Gauge Pressure (psi)		1 X Gamma (psi)	2X Gamma (psi)									
0.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
5.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
6.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
10.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
15.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
20.00		0.0	-0.1		0.0	0.0		0.0	0.0		0.0	0.0
22.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
25.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
30.00		0.0	0.0		0.1	0.0		0.0	0.0		0.0	0.0
35.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	-0.1
40.00		0.0	0.0		0.0	0.0		0.0	0.0		0.0	0.0
45.00		0.0	0.0		0.0	-0.1		0.0	-0.1		0.1	0.0
50.00		0.1	0.0		0.1	0.0		0.0	0.0		0.0	0.0
55.00		0.0	0.0		0.1	-0.1		0.1	0.0		0.1	0.0
60.00		0.0	-0.1		0.1	0.1		0.1	0.1		0.1	0.0
65.00		0.1	0.0		0.1	0.0		0.1	0.0		0.1	0.0
70.00		0.1	0.0		0.1	0.0		0.1	0.0		0.1	0.0
75.00		0.1	0.0		0.1	0.0		0.1	0.0		0.1	0.0

#### Sensor Pressure Difference After 1X and 2X Gamma Exposure at Set Gauge Pressure

	Sensor	r Pressu	ire Diff	erence	After 1	X and 2	2X Gan	nma Ex	posure	at Set	Gauge.	Pressur
	Lot #4	- senso	r #1	Lot #4	- senso	r #2	Lot #4	- senso	r #3	Lot #4	- senso	r #4
Gauge Pressure (psi)		1 X Gamma (psi)	2X Gamma (psi)									
0.00		0.0	0.0		0.0	0.0		0.0			0.0	0.0
5.00		0.0	0.0		0.0	0.0		0.0			0.0	0.0
6.00		0.0	0.0		0.0	0.0		0.0			0.0	0.0
10.00		0.0	0.0		0.0	0.0		0.0			0.0	0.0
15.00		0.0	0.0		0.0	0.0		0.0			0.0	0.0
20.00		0.0	0.0		0.0	0.0		0.0			0.0	0.0
22.00		0.1	0.0		0.0	0.0		0.0			0.0	0.0
25.00		0.0	0.0		0.0	0.0		0.0			0.0	0.0
30.00		0.0	0.0		0.1	0.0		0.0			0.0	0.0
35.00		0.1	0.0		0.1	0.0		0.0			0.0	0.0
40.00		0.1	0.0		0.1	0.0		0.0			-0.1	0.0
45.00		0.1	0.0		0.1	0.1		0.0			0.0	0.0
50.00		0.1	0.0		0.1	0.1		0.0			0.0	-0.1
55.00		0.1	0.0		0.1	0.1		0.0			0.1	0.0
60.00		0.2	0.0		0.2	0.0		0.0			0.1	0.0
65.00		0.1	0.1		0.2	0.1		0.1			0.1	0.1
70.00		0.0	0.1		0.2	0.1		0.1			0.0	0.1
75.00		0.2	0.1	~	0.2	0.2		0.2			0.1	0.1

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8.3.3

Conclusions- All sensors meet the acceptance criteria after exposure to at least 58.5 Kgy, therefore they are compatible with up to 50 kGy.

#### 8.4 Sensor reading performance 53 months post gamma

- 8.4.1 Procedure- The same sensors that were exposed to > 50 kilograys and used in the initial gamma compatibility qualification testing (data in Section 8.2), were then retested after 53 months on the shelf at room temperature. After at least 10 minutes warm-up, a calibrated gauge was used to measure applied pressure and the sensors were read by a PendoTECH Process Control System up to their specified accuracy range of 60 psi.
  - 8.4.1.1 Calibrated Pressure Gauge: Model# Druck DPI104, Serial #: 2936090 (Cert in Appendix R)
  - 8.4.1.2 Acceptance Criteria- Repeatability target was less than 0.5psi

8.4.2	Data Summary	(raw dat	a on file a	t PendoTECH)-
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Single Use Sensor Pressure Differences in Readings 53 months After Receiving a Gamma Irradiation Exposure of Greater than 58.5 kGy Time = Zero is August 5, 2007 Retest Date is January 7, 2012

PSI-												
Gauge		Lot # 1			Lot # 2			Lot # 3			Lot # 4	
Pressure	1	2	3	1	2	3	1	2	3	1	2	3
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
5	-0.03	-0.02	-0.01	-0.01	-0.03	0.00	0.02	0.00	0.01	0.02	0.00	0.01
10	-0.02	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
15	-0.07	-0.07	-0.05	-0.03	0.00	0.02	0.03	0.01	0.02	0.04	0.06	0.02
20	-0.11	-0.09	-0.11	-0.07	-0.04	0.03	0.04	-0.01	-0.01	0.03	0.02	0.00
25	-0.09	-0.06	-0.03	-0.03	0.02	0.07	0.06	0.01	0.04	0.07	0.10	0.04
30	-0.07	-0.06	-0.06	0.01	0.01	0.06	0.05	0.01	0.04	0.07	0.11	0.05
35	-0.09	-0.11	-0.12	0.02	0.03	0.04	0.08	0.03	0.04	0.10	0.10	0.05
40	-0.12	-0.09	-0.10	-0.03	0.01	0.08	0.11	0.04	0.08	0.12	0.13	0.06
45	-0.11	-0.09	-0.05	0.00	0.01	0.10	0.04	-0.01	0.05	0.09	0.15	0.03
50	-0.13	-0.11	-0.04	0.06	0.06	0.11	0.09	0.09	0.10	0.13	0.23	0.12
55	-0.10	-0.08	-0.07	0.03	0.02	0.09	0.07	0.04	0.11	0.14	0.20	0.11
60	-0.12	-0.09	-0.05	0.06	0.08	0.10	0.09	0.09	0.14	0.17	0.21	0.12

8.4.3 Conclusions- All sensors meet the acceptance criteria after exposure to >50 kGy and aged 53 months and therefore are compatible with up to 50 kGy and function correctly after 53 months of aging.

#### 8.5 Pressure limit of 75 psi

- 8.5.1 Procedure- Nine sensors from 3 different lots were tested with a high pressure testing system to 150 psi. The final test pressure for sensors that did not burst or leak was recorded.
  NOTE: Data does not qualify the sensors with luer inlet/outlet- fitting susceptible to disengagement at higher pressures.
  - 8.5.1.1 Acceptance criteria- All must past test
- 8.5.2 Raw Data and Data Summary

Part Number: PRESS- Product Description:	N-050										
Single Use Pressure Sens	Single Use Pressure Sensor, non-sterile, polycarbonate, 0.50 inch hose barb										
Lot Number	Final test pressure-	Final test pressure-	Final test pressure-								
	Sensor #1- all in psi	Sensor #2- all in psi	Sensor #3- all in psi	Result for Lot							
1070088	151.19	156.20	158.38	All pass- no burst or							
				leak							
1070444	156.87	158.07	158.36	All pass- no burst or							
				leak							
1070568	158.03	158.80	157.98	All pass- no burst or							
				leak							

Part Number: PRESS-	N-100			
Product Description:				
Single Use Pressure Sens	sor, non-sterile, polycarb	oonate, 1 inch hose barb		
Lot Number	Final test pressure-	Final test pressure-	Final test pressure-	
	Sensor #1- all in psi	Sensor #2- all in psi	Sensor #3- all in psi	Result for Lot
1070663	160.20	160.20	160.17	All pass- no burst or
				leak
1070664	160.29	160.26	160.24	All pass- no burst or
				leak
1070665	154.73	160.49	155.06	All pass- no burst or
				leak

Part Number: PREPS-N-000												
Product Description:												
Single Use Pressure Sen	sor, non-sterile, polysulf	one, luer inlet/outlet										
Lot Number	Final test pressure-	Final test pressure-	Final test pressure-									
	Sensor #1- all in psi	Sensor #2- all in psi	Sensor #3- all in psi	Result for Lot								
1080555	155.11	152.58	152.50	All pass- no burst or								
				leak								
1081636	159.99	160.02	160.00	All pass- no burst or								
				leak								
1090538	160.06	159.94	159.99	All pass- no burst or								
				leak								

8.5.3 Conclusions- All sensors meet the acceptance criteria and therefore can handle exposure to 75 psi.

#### 8.6 Lower pressure limit of -11.5 psi

- 8.6.1 Procedure- Gamma treated luer style pressure sensors were used for this experiment. A manifold of 4 sensors from 3 different lots (12 total) was connected to a PendoTECH Filter Screening System, which accepts 12 pressure inputs. Using a vacuum pump, all 12 sensors were exposed to -11.5 PSI for 6 hours. These sensors were then taken to 60 PSI, isolated to check for leaks, and also tested for functionality.
  - 8.6.1.1 Calibrated Pressure Gauges Used: Model# Druck DPI104, Serial #: 2936090 and Model# Crystal XP2i, Serial# 364027 (Certs in Appendix O &P)
  - 8.6.1.2 Acceptance criteria- All must past leak test, and still function (read pressure)
- 8.6.2 Raw Data and Data Summary

Part Number: PRESS-S-000 3 lots of 4 sensors each gamma irradiated in the range of 40-45 kGy. Product Description:

Disposable Pressure Sensor, polycarbonate, luer connection

Lot Number	Sensor #1	Sensor #2	Sensor #3	Sensor #4	Result for Lot
1131140	Pass	Pass	Pass	Pass	All pass- no leaks
					and sensor still
					functioning
1131350	Pass	Pass	Pass	Pass	All pass- no leaks
					and sensor still
					functioning
1132283	Pass	Pass	Pass	Pass	All pass- no leaks
					and sensor still
					functioning

8.6.3 Conclusions- All sensors meet the acceptance criteria therefore can handle exposure to -11.5 psi.

#### 8.7 Temperature Range of 2° C

- 8.7.1 Procedure- In order to qualify the accuracy of pressure readings to a lower temperature limit of 2° C, 12 gamma treated luer pressure sensors, four each from three lots, were assembled end to end (Luer male to female) in a manifold configuration and connected to a PendoTECH Filter Screening System, which has a 2.5V excitation. Baseline pressure data was recorded at room temperature with a calibrated pressure gauge at 0, 5, 10, 20, 30, 50, and 60 psi. After recording pressure values at room temperature, these sensors were then placed in a freezer (approximately -18 °C) for 3 hours. To keep the sensors cold during further testing, an ice water bath was created and a temperature sensor was attached in line with the pressure sensors to monitor the flow path temperature during the experiment. The sensor manifold was then submerged into the ice water bath, and pressure readings were recorded at the same pressure test points as before.
  - 8.7.1.1 Calibrated Pressure Gauge Used: Model# Druck DPI104, Serial #: 2936090 (Cert in Appendix Q)
  - 8.7.1.2 Calibrated Temperature Monitor Used: Model# OAKTON TEMP340, Serial #: 570165 (Cert in Appendix S)
  - 8.7.1.3 Acceptance criteria- All sensors must remain within pressure accuracy specifications.
- 8.7.2 Raw Data and Data Summary-

#### Part Number: PRESS-S-000

Product Description: Single Use Pressure Sensor, sterile, polycarbonate, luer inlet/outlet

Test Co	est Condition. Room remperature (22 C)											
		Lot 11.	32283			Lot 11.	31350		Lot 1131140			
PSI-	1	2	2	4					1	0	0	4
Gauge	1	2	3	4		2	3	4	1	2	3	4
Pressure												
5.00	5.03	5.04	5.03	5.02	4.98	5.01	5.02	5.02	5.02	5.01	5.00	5.02
10.00	10.08	10.13	10.12	10.12	10.04	10.08	10.12	10.10	10.10	10.08	10.09	10.10
20.00	20.19	20.23	20.23	20.23	20.14	20.21	20.25	20.25	20.21	20.15	20.23	20.25
30.00	30.10	30.13	30.18	30.12	30.05	30.14	30.13	30.21	30.17	30.00	30.21	30.16
50.00	50.73	50.66	50.93	50.32	50.72	50.78	50.37	51.01	51.05	50.36	51.21	50.56
60.00	61.21	61.06	61.52	60.38	61.27	61.27	60.50	61.58	61.70	60.65	62.02	60.79

Test Condition: Room Temperature (22 °C)

Part Nu	Part Number: PRESS-S-000											
Product	Product Description: Single Use Pressure Sensor, sterile, polycarbonate, luer inlet/outlet											
Test Condition: Cold Temperature (both fluid path and ambient at 2 °C)												
Lot 1132283 Lot 1131350 Lot 1131140												
PSI-												
Gauge	1	1 2 3 4 1 2 3 4 1 2 3 4										
Pressure												
5.00	5.01	5.04	5.05	5.03	5.02	5.03	5.06	5.04	4.99	4.95	5.07	5.03
10.00	10.08	10.12	10.14	10.14	10.09	10.12	10.15	10.15	9.85	9.91	10.16	10.14
20.00	20.16	20.21	20.24	20.30	20.26	20.39	20.52	20.48	19.89	19.99	20.37	20.24
30.00	30.10	30.15	30.21	30.13	30.10	30.17	30.16	30.23	29.86	29.72	30.28	30.17
50.00	50.00 50.76 50.74 51.04 50.38 50.82 50.88 50.44 51.08 50.77 50.13 51.35 50.64											
60.00	61.29	61.16	61.65	60.47	61.39	61.39	60.62	61.70	61.49	60.45	62.20	60.93

Data Su	Data Summary of Change in Pressure from Room temperature to 2 °C											
		Lot 11.	32283			Lot 11.	31350		Lot 1131140			
PSI- Gauge Pressure	1	2	3	4	1	2	3	4	1	2	3	4
5.00	-0.02	0.00	0.02	0.01	0.04	0.02	0.04	0.02	-0.03	-0.06	0.07	0.01
10.00	0.00	-0.01	0.02	0.02	0.05	0.04	0.03	0.05	-0.25	-0.17	0.07	0.04
20.00	-0.03	-0.02	0.01	0.07	0.12	0.18	0.27	0.23	-0.32	-0.16	0.14	-0.01
30.00	0.00	0.02	0.03	0.01	0.05	0.03	0.03	0.02	-0.31	-0.28	0.07	0.01
50.00	0.03	0.08	0.11	0.06	0.10	0.10	0.07	0.07	-0.28	-0.23	0.14	0.08
60.00	0.08	0.10	0.13	0.09	0.12	0.12	0.12	0.12	-0.21	-0.20	0.18	0.14

8.7.3 Conclusions- All sensors meet the acceptance criteria and therefore are accurate at 2° C. There is no significant deviation in pressure reading.

#### 8.8 Five Year shelf life: Sensor Integrity- Burst Testing

- 8.8.1 Procedure- In order to qualify the products for a five year shelf life, twelve polysulfone sensors from six different lots were tested for leaks or burst upon exposure to 150+ psi after storage for 5 years at ambient conditions and then gamma irradiation at 30-40 kGy.
  - 8.8.1.1 Acceptance Criteria- No burst and leak rate less than 0.01 psi per second
- 8.8.2 Data Summary-

Sensor	Lot #	S/N	Final Test Pressure (psi)	Burst/ Leak Result
1	1132694	78	161.19	Pass
2	1132518	51	161.23	Pass
3	1132694	77	161.27	Pass
4	1132518	52	161.17	Pass
5	1132694	76	161.18	Pass
6	1132518	53	161.21	Pass
7	1132694	79	161.19	Pass
8	1133155	26	161.24	Pass
9	1132715	105	161.18	Pass
10	1132715	104	161.17	Pass
11	1131209	26	160.34	Pass
12	1132789	26	161.20	Pass

8.8.3 Conclusions- All sensors meet the acceptance criteria and therefore are qualified for a five year shelf life.

## 8.9 Five Year Shelf Life: Sensor Accuracy- Performance after 5 years storage, and following gamma radiation

- 8.9.1 Procedure- 12 of part number PREPS-N-050 were taken from 6 different lots and stored at room temperature. After 5 years, the sensors were retested for accuracy to compare with their original NIST traceable data. After at least 10 minutes warm-up, a calibrated gauge was used to measure applied pressure and the sensors were read by a PendoTECH Process Control System every 10 psi from 0 to 60 psi. These sensors were then gamma irradiated with a dose of 40 kiloGrays. Post gamma treatment, the same procedure was performed to measure sensor accuracy and compare with pre-gamma readings.
  - 8.9.1.1 Calibrated Pressure Gauge: Model# Druck DPI 104, S/N 3674169 (Cert in Appendix S)
  - 8.9.1.2 Acceptance Criteria- Repeatability target was ΔP less than 0.5 psi; Sensors remain within PendoTECH's standard accuracy claim:

Better than +/- 2% of reading in the range of 0 to 6 psi

Better than +/- 3% of reading in the range of 6 to 30 psi

In range of 30 to 60 psi, typically better than +/- 5% of reading

8.9.2 Data Summary :

#### Single Use Sensor Pressure Difference in Readings After a 5 Year Shelf Life

Gauge Pressure (psi)	Lot # 1132715 S/N: 104	Lot # 1132715 S/N: 105	Lot # 1132694 S/N: 76	Lot # 1132694 S/N: 77	Lot # 1132694 S/N: 78	Lot # 1132694 S/N: 79	Lot # 1132518 S/N: 51	Lot # 1132518 S/N: 52	Lot # 1132518 S/N: 53	Lot # 1132789 S/N: 26	Lot # 1133155 S/N: 26	Lot # 1131209 S/N: 26
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
10	0.04	0.05	0.02	0.00	-0.01	0.02	0.00	-0.03	0.02	-0.01	-0.04	0.04
20	0.06	0.05	0.08	-0.06	-0.04	0.01	0.02	-0.02	0.01	0.03	-0.04	0.01
30	0.04	0.06	0.05	-0.03	-0.02	0.00	0.01	-0.03	0.05	0.05	0.01	0.03
40	0.07	0.10	0.09	-0.02	-0.03	-0.03	0.03	0.03	0.05	0.12	-0.02	Х
50	0.12	0.11	0.12	0.09	0.03	0.03	0.02	0.02	0.06	0.06	0.11	X
60	0.11	0.12	0.07	0.11	0.01	0.03	0.02	0.03	0.03	0.13	0.05	Х

Time Zero Test Date: 2013 Retest Date: February 2019

X = Data not available

All values are differences in pressure ( $\Delta P$ )

#### Single Use Sensor Pressure Difference in Readings Post Gamma Irradiation after 5 Year Shelf Life

Pre Gamma Test Date: February 2019 Post Gamma Test Date: March 2019

Gauge Pressure (psi)	Lot # 1132715 S/N: 104	Lot # 1132715 S/N: 105	Lot # 1132694 S/N: 76	Lot # 1132694 S/N: 77	Lot # 1132694 S/N: 78	Lot # 1132694 S/N: 79	Lot # 1132518 S/N: 51	Lot # 1132518 S/N: 52	Lot # 1132518 S/N: 53	Lot # 1132789 S/N: 26	Lot # 1133155 S/N: 26	Lot # 1131209 S/N: 26
0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
10	0.03	-0.01	0.00	0.03	0.02	0.01	0.07	0.07	0.03	0.02	0.06	-0.02
20	0.02	0.06	-0.01	0.12	0.11	0.02	0.09	0.10	0.06	0.00	0.09	0.03
30	0.03	0.06	0.04	0.13	0.06	0.08	0.08	0.06	0.06	0.03	0.07	0.05
40	0.05	0.07	0.05	0.15	0.15	0.11	0.14	0.09	0.10	0.01	0.14	0.11
50	0.08	0.13	0.08	0.11	0.17	0.16	0.20	0.15	0.14	0.08	0.07	0.10
60	0.14	0.16	0.19	0.14	0.20	0.20	0.22	0.17	0.18	0.04	0.11	0.06

All values are differences in pressure ( $\Delta P$ )

8.9.3 Raw Data- The data below represents the raw data collected, which was used to generate the tables above. Original refers to the time zero data of the pressure sensors, which was taken from the NIST traceable certificates created during manufacturing in 2013. Pre Gamma denotes the pressure readings recorded following 5 years of storage at ambient conditions (February 2019). Lastly, Post Gamma represents the pressure readings measured after receiving 40 kGys of gamma irradiation dose (March 2019).

<b>X</b> ( <b>X</b> )					Pressure Re	eading (psi)		
Lot Number	Serial Number	Time	10	20	30	40	50	60
		Original	10.01	20.14	30.13	40.45	51.05	61.79
1132715	104	Pre Gamma	10.05	20.20	30.17	40.52	51.17	61.90
		Post Gamma	10.08	20.22	30.20	40.57	51.25	62.04
		Original	10.04	20.13	29.95	39.92	49.91	59.84
1132715	105	Pre Gamma	10.09	20.18	30.01	40.02	50.02	59.96
		Post Gamma	10.08	20.24	30.07	40.09	50.15	60.12
		Original	10.07	20.17	29.98	39.97	49.97	59.89
1132694	76	Pre Gamma	10.09	20.25	30.03	40.06	50.09	59.96
		Post Gamma	10.09	20.24	30.07	40.11	50.17	60.15
		Original	10.07	20.18	30.09	40.24	50.50	60.77
1132694	77	Pre Gamma	10.07	20.12	30.06	40.22	50.59	60.88
		Post Gamma	10.10	20.24	30.19	40.37	50.70	61.02
		Original	10.06	20.14	29.95	39.80	49.68	59.48
1132694	78	Pre Gamma	10.05	20.10	29.93	39.77	50      60        51.05      61.79        51.17      61.90        51.25      62.04        49.91      59.84        50.02      59.96        50.15      60.12        49.97      59.89        50.02      59.96        50.15      60.12        49.97      59.89        50.09      59.96        50.17      60.15        50.50      60.77        50.50      60.77        50.50      60.77        50.50      60.78        50.70      61.02        49.68      59.48        49.71      59.49        49.88      59.69        50.61      60.99        50.64      61.02        50.80      61.22        49.75      59.65        49.77      59.67        49.97      59.89        49.60      59.41        49.62      59.44        49.77      59.61        50.20      60.30        50.26	
		Post Gamma	10.07	20.21	29.99	39.92	49.88	59.69
		Original	10.06	20.19	30.08	40.31	50.61	60.99
1132694	79	Pre Gamma	10.08	20.20	30.08	40.28	50.64	61.02
		Post Gamma	10.09	20.22	30.16	40.39	50.80	61.22
		Original	10.00	20.07	29.91	39.78	49.75	59.65
1132518	51	Pre Gamma	10.00	20.09	29.92	39.81	49.77	59.67
1152516		Post Gamma	10.07	20.18	30.00	39.95	49.97	59.89
		Original	10.02	20.07	29.87	39.69	49.60	59.41
1132518	52	Pre Gamma	9.99	20.05	29.84	39.72	49.62	59.44
		Post Gamma	10.06	20.15	29.90	39.81	49.77	59.61
		Original	10.05	20.16	29.99	40.04	50.20	60.30
1132518	53	Pre Gamma	10.07	20.17	30.04	40.09	50.26	60.33
		Post Gamma	10.10	20.23	30.10	40.19	50.40	60.51

		Original	10.04	20.13	30.04	40.21	50.56	60.89
1132789	26	Pre Gamma	10.03	20.16	30.09	40.33	50.62	61.02
		Post Gamma	10.05	20.16	).16 30.12 40.34	50.70	61.06	
		Original	10.06	20.18	30.09	40.24	50.50	60.81
1133155	26	Pre Gamma	10.02	20.14	30.10	40.22	50.61	60.86
	20	Post Gamma	10.08	20.23	30.17	40.36	50.68	60.97
		Original	10.06	20.19	30.16	Х	Х	Х
1131209	26	Pre Gamma	10.10	20.20	30.19	40.44	51.02	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$
		Post Gamma	10.08	20.23	30.24	40.55	51.12	61.80

#### X = Data not available

8.9.4 Conclusion: All sensors met acceptance criteria and are suitable for a 5 year shelf life

#### 8.10 Sensor Use in Continuous Bioprocesses

8.10.1 Procedure- Two experiments were performed in order to validate the robustness of PendoTECH's Single Use Pressure Sensors and qualify them for use in continuous bioprocesses. In the first experiment, 12x post > 40 kGy gamma irradiated pressure sensors from 3 different lots (PRESS-S-000 Lot#'s 1152607 and 1151819 and PREPS-N-000 Lot # 1161066), were exposed to a constant 3.5 bar (50.76 psi) for 7 days. The sensors were checked for accuracy at 0.5, 1, 2, and 4 bar (7.25, 14.5, 29, and 58 psi) after 0, 80, and 168 hours of exposure. In a second experiment, same exact pressure sensors were continuously exposed to 10 psi (0.69 bar) for 93 consecutive days. Afterwards, the sensors were evaluated across their entire pressure range (0-60 psi). Both experiments used a PendoTECH Normal Flow Filtration System (NFFSS) to read the pressure sensors with a calibrated pressure gauge used as a reference. Gamma Certificate can be found in Appendix T.

8.10.1.1 Calibrated Pressure Gauge: Model# Druck DPI 104, S/N 4396848 (Cert in Appendix U)

8.10.1.2 Acceptance Criteria: Pressure sensor accuracy specifications-

0 to 6 psi:  $\pm 2\%$  of reading 6 to 30 psi:  $\pm 3\%$  of reading 30 to 60 psi: Typically better than  $\pm 5\%$  of reading

Accuracy at Constant 3.5 Bar- Time = 0 hours										
Songor ID		Applie	d Pressur	e (bar)		Sensor				
Selisor ID	0	0.5	1	2	4	Performance				
1152607-01	0.00	0.51	1.01	2.01	4.07	Pass				
1152607-02	0.00	0.51	1.01	2.02	4.14	Pass				
1152607-03	0.00	0.50	1.01	2.02	4.20	Pass				
1152607-04	0.00	0.50	1.01	2.01	4.17	Pass				
1161066-01	0.00	0.50	1.01	2.02	4.14	Pass				
1161066-02	0.00	0.51	1.01	2.02	4.14	Pass				
1161066-03	0.00	0.51	1.01	2.02	4.15	Pass				
1161066-04	0.00	0.50	1.01	2.01	4.13	Pass				
1151819-01	0.00	0.50	1.01	2.01	4.14	Pass				
1151819-02	0.00	0.50	1.01	2.02	4.14	Pass				
1151819-03	0.00	0.51	1.01	2.02	4.16	Pass				
1151819-04	0.00	0.50	1.01	2.02	4.16	Pass				
Acceptance	2%	3%	3%	3%	5%	All within				
Criterion (+/)	0.00	0.02	0.03	0.06	0.20	specifications				

#### 8.10.2 Data summary:

#### Accuracy at Constant 3.5 Bar- Time = 80 hours

Sensor ID		Applie	d Pressur	re (bar)		Sensor
Selisor ID	0	0.5	1	2	4	Performance
1152607-01	0.00	0.51	1.01	2.01	4.07	Pass
1152607-02	0.00	0.51	1.01	2.01	4.14	Pass
1152607-03	0.00	0.51	1.01	2.02	4.19	Pass
1152607-04	0.00	0.50	1.01	2.01	4.17	Pass
1161066-01	0.00	0.50	1.01	2.01	4.13	Pass
1161066-02	0.00	0.50	1.01	2.02	4.13	Pass
1161066-03	0.00	0.51	1.01	2.02	4.15	Pass
1161066-04	0.00	0.50	1.01	2.01	4.13	Pass
1151819-01	0.00	0.50	1.01	2.02	4.14	Pass
1151819-02	0.00	0.51	1.01	2.02	4.14	Pass
1151819-03	0.00	0.51	1.01	2.02	4.16	Pass
1151819-04	0.00	0.51	1.01	2.02	4.15	Pass
Acceptance	2%	3%	3%	3%	5%	All within
Criterion (+/)	0.00	0.02	0.03	0.06	0.20	specifications

Accuracy at Constant 3.5 Bar- 11me = 168 nours										
Songor ID		Applie	d Pressur	e (bar)		Sensor				
Selisor ID	0	0.5	1	2	4	Performance				
1152607-01	0.00	0.51	1.01	2.01	4.07	Pass				
1152607-02	0.00	0.51	1.01	2.01	4.14	Pass				
1152607-03	0.00	0.50	1.01	2.02	4.19	Pass				
1152607-04	0.00	0.50	1.01	2.01	4.17	Pass				
1161066-01	0.00	0.50	1.01	2.01	4.13	Pass				
1161066-02	0.00	0.50	1.01	2.02	4.13	Pass				
1161066-03	0.00	0.51	1.01	2.02	4.15	Pass				
1161066-04	0.00	0.50	1.01	2.01	4.13	Pass				
1151819-01	0.00	0.50	1.01	2.02	4.14	Pass				
1151819-02	0.00	0.50	1.01	2.02	4.15	Pass				
1151819-03	0.00	0.51	1.01	2.02	4.16	Pass				
1151819-04	0.00	0.51	1.01	2.02	4.16	Pass				
Acceptance	2%	3%	3%	3%	5%	All within				
Criterion (+/)	0.00	0.02	0.03	0.06	0.20	specifications				

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Accuracy at Constant 10 psi over 93 Days

Sensor ID	Average Pressure (psi)	Minimum Range (psi)	Maximum Range (psi)	Sensor Performance
1152607-01	10.03	9.94	10.12	Pass
1152607-02	10.01	9.92	10.10	Pass
1152607-03	10.00	9.91	10.09	Pass
1152607-04	9.93	9.85	10.04	Pass
1161066-01	10.02	9.95	10.11	Pass
1161066-02	10.01	9.94	10.11	Pass
1161066-03	10.04	9.97	10.15	Pass
1161066-04	10.01	9.93	10.09	Pass
1151819-01	9.99	9.88	10.08	Pass
1151819-02	10.00	9.89	10.10	Pass
1151819-03	10.01	9.90	10.11	Pass
1151819-04	10.01	9.91	10.10	Pass
Acceptance	3%	3%	3%	All Within
(+/-)	0.30	9.70	10.30	Specifications

Pressure Accuracy Verification Post 93 Days*										
Sangar ID			A	pplied P	ressure (j	psi)			Sensor	
Sensor ID	0	5	10	20	30	40	50	60	Performance	
1152607-05	-0.03	4.99	10.10	20.17	30.09	40.29	50.58	61.09	Pass	
1152607-06	-0.04	4.97	10.05	20.19	30.09	40.56	51.22	62.15	Pass	
1152607-07	-0.04	4.95	10.08	20.22	30.21	40.85	51.78	62.99	Pass	
1152607-08	-0.05	4.93	10.01	20.05	30.10	40.49	51.52	62.67	Pass	
1161066-05	-0.02	4.99	10.07	20.20	30.15	40.48	51.29	62.17	Pass	
1161066-06	-0.03	4.99	10.07	20.19	30.13	40.50	51.26	62.14	Pass	
1161066-07	-0.02	4.99	10.13	20.19	30.28	40.72	51.33	62.32	Pass	
1161066-08	-0.03	4.98	10.07	20.12	30.17	40.41	51.11	61.93	Pass	
1151819-05	-0.01	4.98	10.03	20.12	30.17	40.46	51.26	62.14	Pass	
1151819-06	-0.04	4.98	10.09	20.14	30.16	40.67	51.35	62.29	Pass	
1151819-07	-0.03	5.00	10.10	20.16	30.18	40.72	51.44	62.52	Pass	
1151819-08	-0.01	5.00	10.06	20.19	30.27	40.72	51.44	62.42	Pass	
Acceptance	-	2%	3%	3%	3%	5%	5%	5%	All within	
Criterion (+/)	-	0.10	0.30	0.60	0.90	2.00	2.50	3.00	specifications	

\*Sensors not re-tared prior to accuracy verification

8.10.3 Conclusion: PendoTECH pressure sensors remain well within their accuracy specifications after use for extended periods of time, qualifying them for use in continuous bioprocess applications.

#### 8.11 X-ray Compatibility

8.11.1 Accuracy Testing

- 8.11.1.1 Procedure- 22x Pressure sensors from 3 different lots (7x PREPS-N-000 from Lot#1203163, 8x PRESS-S-000 from Lot# 1210050, and 7x PREPS-N-025 from Lot#1191570) were tested for accuracy across their full pressure range (0 to 60 psi). All sensors were X-ray irradiated with a dose >50 kGy. Sensors were connected inline with a calibrated pressure gauge as a reference for the pressure readings. The pressure sensors were read using a PendoTECH PressureMAT (Model PMAT2P, SN:22935).
- 8.11.1.2 Calibrated Pressure Gauge: Model# DigiSense, Serial# 1912310225 Last Cal: 8/24/2021 (Cert in Appendix W)

8.11.1.3 Acceptance Criteria:

All readings within PendoTECH's Pressure Sensor Accuracy Specification:

0 to 6 psi:  $\pm 2\%$  of reading

6 to 30 psi:  $\pm 3\%$  of reading

30 to 60 psi: Typically better than  $\pm 5\%$  of reading\*

\*Sensors used for qualification were manufactured according to previous accuracy specification

						Post X	-ray Results	Gougo Pro	scuro (nci)					
Part Number	Lot Number	Serial Number	10		20		30		40		50		60	
			Reading (psi)	% Error	Reading (psi)	% Error	Reading (psi)	% Error	Reading (psi)	% Error	Reading (psi)	% Error	Reading (psi)	% Erro
PREPS-N-000	1203163	35	10.03	0.30%	20.16	0.80%	30.17	0.57%	40.59	1.48%	51.29	2.58%	62.25	3.75%
PREPS-N-000	1203163	36	10.02	0.20%	20.02	0.10%	30.17	0.57%	40.50	1.25%	51.06	2.12%	61.86	3.10%
PREPS-N-000	1203163	37	10.05	0.50%	20.02	0.10%	30.14	0.47%	40.50	1.25%	51.20	2.40%	62.10	3.50%
PREPS-N-000	1203163	38	10.04	0.40%	20.14	0.70%	30.14	0.47%	40.50	1.25%	51.13	2.26%	62.00	3.33%
PREPS-N-000	1203163	39	10.01	0.10%	19.98	-0.10%	30.07	0.23%	40.43	1.08%	51.11	2.22%	61.99	3.32%
PREPS-N-000	1203163	40	10.00	0.00%	19.96	-0.20%	30.11	0.37%	40.53	1.33%	51.34	2.68%	62.37	3.95%
PREPS-N-000	1203163	41	10.03	0.30%	19.99	-0.05%	30.21	0.70%	40.75	1.88%	51.80	3.60%	63.21	5.35%
PRESS-N-000	1210050	26	10.01	0.10%	19.98	-0.10%	30.18	0.60%	40.72	1.80%	51.64	3.28%	62.94	4.90%
PRESS-N-000	1210050	27	10.04	0.40%	20.02	0.10%	30.18	0.60%	40.58	1.45%	51.20	2.40%	62.07	3.45%
PRESS-N-000	1210050	28	10.02	0.20%	20.00	0.00%	30.10	0.33%	40.30	0.75%	50.67	1.34%	61.18	1.97%
PRESS-N-000	1210050	29	10.01	0.10%	20.00	0.00%	30.19	0.63%	40.57	1.43%	51.25	2.50%	62.22	3.70%
PRESS-N-000	1210050	30	10.04	0.40%	20.07	0.35%	30.21	0.70%	40.52	1.30%	51.06	2.12%	61.74	2.90%
PRESS-N-000	1210050	31	10.03	0.30%	20.08	0.40%	30.31	1.03%	40.86	2.15%	51.81	3.62%	63.04	5.07%
PRESS-N-000	1210050	32	10.03	0.30%	20.04	0.20%	30.15	0.50%	40.44	1.10%	50.91	1.82%	61.58	2.63%
PRESS-N-000	1210050	33	10.04	0.40%	20.06	0.30%	30.22	0.73%	40.62	1.55%	51.29	2.58%	62.25	3.75%
PREPS-N-025	1191570	26	10.06	0.60%	20.06	0.30%	30.16	0.53%	40.33	0.82%	50.67	1.34%	61.08	1.80%
PREPS-N-025	1191570	27	10.06	0.60%	20.08	0.40%	30.22	0.73%	40.50	1.25%	51.00	2.00%	61.62	2.70%
PREPS-N-025	1191570	28	10.02	0.20%	20.02	0.10%	30.21	0.70%	40.65	1.63%	51.41	2.82%	62.47	4.12%
PREPS-N-025	1191570	29	10.04	0.40%	20.07	0.35%	30.23	0.77%	40.62	1.55%	51.32	2.64%	62.21	3.68%
PREPS-N-025	1191570	30	10.05	0.50%	20.07	0.35%	30.23	0.77%	40.62	1.55%	51.32	2.64%	62.21	3.68%
PREPS-N-025	1191570	31	10.04	0.40%	20.05	0.25%	30.20	0.67%	40.55	1.37%	51.21	2.42%	62.12	3.53%
PREPS-N-025	1191570	32	10.01	0.10%	20.01	0.05%	30.01	0.03%	40.14	0.35%	50.45	0.90%	60.81	1.35%

#### 8.11.2 Leak and Burst Testing

- 8.11.2.1 Procedure- The integrity of 22x Pressure sensors from 3 different lots (7x PREPS-N-000 from Lot#1203163, 8x PRESS-S-000 from Lot# 1210050, and 7x PREPS-N-025 from Lot#1191570) was challenged following exposure to an X-ray Irradiation dose >50kGy. All sensors were evaluated with a leak test that consisted of a 90 second pressure decay test at 60 psi as well as a visual inspection for leaks using soapy water. Additionally, a subset of these sensors were burst tested a 150 psi while also being inspected for leaks.
- 8.11.2.2 Calibrated Pressure Gauge: Model# DigiSense, Serial# 1912310225, Last Cal: 8/24/2021 (Cert in Appendix W)
- 8.11.2.3 Acceptance Criteria:

Leak Test: Pressure Decay less than 0.03psi/second and no visual detection of leaks Burst Test: No evidence of leaks or sensor damage after exposure to 150 psi

8.11.2.4 Data Summary:

Post X-ray Results						
Part Number	Lot Number	Serial Number	Initial Pressure (psi)	Final Pressure (psi)	ΔР	Pressure Decay (psi/sec)
PREPS-N-025	1191570	29	62.24	62.21	0.03	0.0003
PREPS-N-025	1191570	28	62.51	62.46	0.05	0.0006
PREPS-N-025	1191570	27	61.63	61.60	0.03	0.0003
PREPS-N-025	1191570	32	60.88	60.85	0.03	0.0003
PREPS-N-025	1191570	30	62.25	62.18	0.07	0.0008
PREPS-N-025	1191570	26	61.35	61.33	0.02	0.0002
PREPS-N-025	1191570	31	62.20	62.13	0.07	0.0008
PRESS-S-000	1210050	33	62.26	61.50	0.76	0.0084
PRESS-S-000	1210050	32	61.58	60.76	0.82	0.0091
PRESS-S-000	1210050	31	63.05	62.31	0.74	0.0082
PRESS-S-000	1210050	29	62.29	61.49	0.8	0.0089
PRESS-S-000	1210050	26	62.92	62.02	0.9	0.0100
PRESS-S-000	1210050	27	62.04	61.20	0.84	0.0093
PRESS-S-000	1210050	28	61.27	60.65	0.62	0.0069
PRESS-S-000	1210050	30	61.72	60.97	0.75	0.0083
PREPS-N-000	1203163	41	63.29	63.00	0.29	0.0032
PREPS-N-000	1203163	39	62.01	61.75	0.26	0.0029
PREPS-N-000	1203163	35	62.10	61.87	0.23	0.0026
PREPS-N-000	1203163	36	61.75	60.97	0.78	0.0087
PREPS-N-000	1203163	40	62.46	62.28	0.18	0.0020
PREPS-N-000	1203163	38	61.90	61.67	0.23	0.0026
PREPS-N-000	1203163	37	62.11	61.89	0.22	0.0024

David Niewali au	Lot	Carial Number	Ohannationa
Part Number	Number	Serial Number	Observations
PRESS-S-000	1210050	29	No leaks or bursts
PRESS-S-000	1210050	27	No leaks or bursts
PRESS-S-000	1210050	30	No leaks or bursts
PRESS-S-000	1210050	32	No leaks or bursts
PRESS-S-000	1210050	28	No leaks or bursts
PREPS-N-000	1203163	35	No leaks or bursts
PREPS-N-000	1203163	36	No leaks or bursts
PREPS-N-000	1203163	37	No leaks or bursts
PREPS-N-000	1203163	38	No leaks or bursts
PREPS-N-000	1203163	39	No leaks or bursts

8.11.2.5 Conclusion: No leaks were identified in any of the leak or burst testing and all pressure decay tests were within the acceptable limit, thus validating the sensor integrity of PendoTECH Single Use Pressure Sensors post X-ray Irradiation.
### 9 APPENDICES

9.1 Appendix A- Assembled Sensor Certificate: Class VI post 40kGy gamma irradiation- Polycarbonate (PRESS)



#### TEST RESULT CERTIFICATE

Sponsor	PendoTECH		echnical Initiation	9/17/2013	
Address	3490 US Highway 1, Building 15F	US Highway 1, Building 15F Technical Completion eton, NJ 08540 Troise Certificate Date 174 Final Non-GLP Report		10/18/2013	
Contact P.O. Number	Princeton, NJ 08540 Nick Troise 2007374			5/18/202 13-03587-G	
Test Article	PendoTECH Polycarbonate Pressure Sensor after gamma irradiation at 43.3- 47.7 kGy	Ratio	120 cm <sup>2</sup> /20 mL		
Lot/Batch #	1131266		USP 0.9% Sodium C	9% Sodium Chloride for	
Sterility	Sterile	Vehicles	Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl		
Storage Condition	Room Temperature		(EtOH), and Polyeth 400 (PEG)	ylene Glycol	
Study	Class VI Test – USP	Extraction Conditions	70 ± 2 °C for 24 ± 2 h	nours	

#### REFERENCES:

The study was conducted based upon the following references:

United States Pharmacopeia 36, National Formulary 31, 2013. <88> Biological Reactivity Tests, In Vivo.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

#### GENERAL PROCEDURE:

The extraction conditions were performed as stated above. Per Sponsor request, the device was not cut in areas that would expose any internal wires. The sample was prepared so that the white cable did not come into contact with the extract vehicle. Prior to extraction, the test article was washed two times with 70 mL of sterile water for injection (SWFI). The test article sample prepared for extraction with CSO was dried at 50 +/- 2 C for 1 +/- 0.1 hour. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted subcutaneously into rats for 14 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection. Per Sponsor request, the test article was implanted as two components (T1 = snout portion of pressure sensor and T2 = polycarbonate main body. For T1, the white chip backing was removed from the clear polycarbonate and discarded. The snout portion of the polycarbonate containing black silicone was cut from the polycarbonate component.

#### **RESULTS AND CONCLUSION:**

None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, or edema in both test and control sites and no signs of clinical toxicity. In both the Systemic and Intracutaneous Tests, the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI - 70°C.

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#### FINAL GLP REPORT: 13-03587-G1 AMENDED

#### CLASS VI TEST – USP (WITH 14 DAY SUBCUTANEOUS IMPLANT)

Test Article PendoTECH Polycarbonate Pressure Sensor after gamma irradiation at 43.3 -47.7 kGy

21 CFR Part 58 Compliance GLP for Nonclinical Laboratory Studies

> Report Date October 18, 2013

Amended Report Date November 1, 2013

Study Director Cheng A. Kwok, M.S.

<u>Sponsor</u> PendoTECH 3490 US Highway 1, Building 15F Princeton, NJ 08540

Toxikon Corporation 15 Wiggins Ave., Bedford, MA 01730 USA 1.800.458.4141 Main: 1.781.275.3330

## τοχικοη

Project# 13-03587-G1 Amended PendoTECH Polycarbonate Pressure Sensor after gamma irradiation at 43.3 -47.7 kGy

Class VI Test - USP

#### STUDY SUMMARY

The USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG) extracts of the test article, following Intracutaneous Injection in rabbits and Systemic Injection in mice, and the test article, following implantation in rats, did not produce a biological response.

Based on the criteria of the protocol and the USP guidelines for Class VI Plastics – 70 °C, the test article, PendoTECH Polycarbonate Pressure Sensor after gamma irradiation at 43.3 -47.7 kGy, meets the requirements of the test.

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## τοχικοπ

Class VI Test - USP Project# 13-03587-G1 Amended PendoTECH Polycarbonate Pressure Sensor after gamma irradiation at 43.3 -47.7 kGy

#### QUALITY ASSURANCE STATEMENT

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

Phase	Inspection Date	Date Reported to Study Director	Date Reported to Management
CLINICAL OBSERVATIONS	10/10/13	10/10/13	10/10/13
DATA	10/16/13	10/16/13	10/16/13
FINAL REPORT	10/18/13	10/18/13	10/18/13
AMENDED REPORT	11/01/13	11/01/13	11/01/13

Jeffrey Freedman, B.S. Quality Assurance Signature <u>11/1/2013</u> Date

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### τοχικοπ

Class VI Test - USP Project# 13-03587-G1 Amended PendoTECH Polycarbonate Pressure Sensor after gamma irradiation at 43.3 -47.7 kGy

#### **GLP COMPLIANCE STATEMENT**

This study meets the technical requirements of the protocol.

This study was conducted in compliance with the current U.S. Food and Drug Administration 21 CFR, Part 58 Good Laboratory Practices for Nonclinical Laboratory Studies.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article, 21 CFR, Part 58.105, and its mixture with carriers, 21 CFR, Part 58.113.

#### SIGNATURES

Signature Information				
Protocol Number	P13-1935-00B			
Study Director	Cheng A. Kwok, M.S.			
Study Supervisor	Allan Sleger, A.S., LAT			
Company	Toxikon Corporation			

### **VERIFICATION DATES**

Fhe study initiation day is the date th	e protocol is signed by the Study Director.
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Verification Dates				
Test Article Receipt	09/16/13			
Project Log	09/16/13			
Study Initiation	09/17/13			
Study Completion	10/18/13	2 1 313333324734134 3		

woh

Cheng A. Kwok, M.S. Study Director Signature

11/12013

Date

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### Prepared for EMD MILLIPORE - DANVERS

# STERIS

### Gamma Process Run ID 83375A

Product Code	Product Lot Number	Quantity	UOM
MILLIPORE	1131266	1	CS
Cust Item ID: PRESS-N-050			00
MILLIPORE	L3KA97331	1	00
Cust Item ID: SPOUT_PORT_ASM1-SP			05

PO Number: N1236752

Data Reviewed By: Signature: Date: 10 10 2013

Time: 08- ose (kGy): ose (kGy): meets Customer	Sep-2013 ( 40.0 55.0 specification	05:06:00 am	Minimum Delivered Dose (kGy):	43.3
ose (kGy): ose (kGy): meets Customer	40.0 55.0 specification		Minimum Delivered Dose (kGy):	43.3
ose (kGy): meets Customer	55.0 specification		Maximum Delivered Dose (kGv):	
meets Customer	specification		bentered bose (ROJ).	47.7
		ns; zero nonco	onformities occurred during this irradiation run.	
E Classif D		Signature	Manifest	
ato (QS/RC A	(nalvst)		Signed On 9/8/2013 at 11. UTC / GMT Offset (httraum)4:	:57 AM
itent Revision: 1	, , ,			
5	Operating facil and OSHA) an EN/ISO 13485 11137 2006 or S1ERIS Isome accuracy of the	likes are in compl of provide service 2003/2012, and EN ANSI/AAM// dbx certifies that a dosimetry syste	Innce with applicable state and federal regulations (FDA. NF is under a quality system which meets the requirements of F in alignment with the applicable standard. EN ANSI/AAA9/IS ISO 11135 2007. For items processed with germa imadatio these items received the indicated doses within the proclass in used.	RC, EPA, DA OSR, XO In, In and
	E-Signed By sato (QS/RC A itent Revision: 1	E-Signed By sato (QS/RC Analyst) itent Revision: 1 Operating fact and OSHA) ar ENISO 13482 11137 2006 or STERIS Isome accuracy of the	Signature E-Signed By sato (QS/RC Analyst) itent Revision: 1 Operating facilities are in ceres and OSHA) and provide service ENISO 13485-2003/2012, and 11137 2006 or EN ANSI/AAM// STERIS Isometix cerefice that accuracy of the dosirretry syste	Signature Manifest           E-Signed By         Signed On 9/8/2013 at 11           sato (QS/RC Analyst)         UTC / GMT Offsel (htmm)4/3           intent Revision: 1         Operating facilities are in compliance with applicable state and federal regulations (FDA, NE and OBHA) and provide services under a quality system which meets the requirements of T ENISO 13/48/2003/2012, and in alignment with the applicable standard. EN ANSUAAMUS 11137/2006 or EN ANSUAAMUSO 11135/2007. For terms processed with general insolation S1ERIS (somedix comforts that these terms received the indicated doses withen the proclass accuracy of the dostreetry system used

Prepared for EMD MILLIPORE - DANVERS

# STERIS

molt lerror.

Gamma Process	Run	ID	83245A
---------------	-----	----	--------

Product Code	Product Lot Number	Quantity	UOM
MILLIPORE	L3KA00001	1	CS
Cust Item ID: PARTICULATE TEST-SP			
MILLIPORE	L3KA92202	1	CS
Cust Item ID: NS1XBAG_PROTN-SP			0.000
MILLIPORE	L3KA92203	1	CS
Cust Item ID: NS6XBA_GPROTN-SP			
MILLIPORE	L922704	1	CS
Cust Item ID: 00109697PU-SP		115	
MILLIPORE	L922705	1	CS
Cust Item ID: 00109698PU-SP			00

PO Number: N1236752

Data Reviewed by:

Signature for aller Date: JE-SEA-2013

	30-Aug-2013 11:50:00 pm	Approx. Downtime (hours):	1.15
Processing Run End Date/Time:	31-Aug-2013 02:58:00 am		
Minimum Specified Dose (kGy):	40.0	Minimum Delivered Dose (kGy):	43.1
Maximum Specified Dose (kGy)	: 55.0	Maximum Delivered Dose (kGv):	48.8
	Signature	Manifest	
Povintual and E. Sianoi D.	Signature	Manifest	
Roviewed and E-Signed By	Signature	Manifest Signed On 9/2/2013 at 10 UTC / GMT 05iset fib.com4	18 AM

Processing Location: STERIS Isomedix Services 435 Whitney Street Northborough, MA 01532 Phone: 508-393-9323 Fax: 508-393-3685 Operating facilities are in compliance with applicable state and faderal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, ENISO 13465 2003/2012, and in alignment with the applicable standard, EN ANSVAAMUISO 11137 2006 or EN ANSVAAMUISO 11135 2007. For items processed with gamma imagilition, STERIS isometic certifies that these items necessed with other processed within the precision and accuracy of the dosimetry system used.

PROC-00034 Last Revised in Rolease 3.6.0.0

Release Date: 06-Mar-2013

Page 1 of 1

9.2 Appendix B- Assembled Sensor Certificate: Class VI post 40kGy gamma irradiation- Polysulfone (PREPS) and Port Plate O-Ring



GHT. FROM THE START."

Sponsor Address Contact P.O. Number	PendoTECH 174 Nassau Street Suite 256 Princeton, NJ 08542 Dennis Annarelli 2013094	Tech Tech Repo Ame Fina	nnical Initiation nnical Completion ort Date nded Report Date I GLP Report	4/12/2019 5/29/2019 6/3/2019 6/17/2019 19-00538-G1
Test Article	Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation	Ratio	60 cm <sup>2</sup> /20 mL	
Lot/Batch #	1171477	Vehicles	USP 0.9% Sodium Ch Injection (NaCl), Cotto (CSO), 1 in 20 Ethano (EtOH), and Polyethy 400 (PEG)	nloride for onseed Oil ol in NaCl lene Glycol
Study	Class VI Test – USP (With 14 Day Subcutaneous Implant)	Extraction Conditions	$70\pm2^{\circ}\text{C}$ for $24\pm2$ ho	ours

### TEST RESULT CERTIFICATE

#### REFERENCES:

The study was conducted based upon the following references:

United States Pharmacopeia 41, National Formulary 36, 2018. <88> Biological Reactivity Tests, In Vivo.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

#### GENERAL PROCEDURE:

The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts prepared with PEG. The animals were observed for signs of toxicity and skin reactivity for up to 72 hours post treatment. In addition, the test article was implanted subcutaneously into rats for 14 days and observed macroscopically for signs of hemorrhage, necrosis, discoloration, encapsulation, and infection.

#### RESULTS AND CONCLUSION:

None of the mice injected with the test article extracts exhibited any signs of toxicity in the Systemic Injection Test. In addition, none of the rabbits injected intracutaneously with the test article extracts exhibited any signs of erythema, or edema in both test and control sites and no signs of clinical toxicity. In both the Systemic and Intracutaneous Tests, the controls were normal through 72 hours. Also, the implant sites exhibited no significant signs of hemorrhage, necrosis, discoloration, encapsulation, or infection compared with the control sites.

The test article meets the requirements of the guidelines for the Biological Test for Plastics, Class VI - 70°C.

AUTHORIZED PERSONNEL:

adden, B.S. Colin Mc

Quality Assurance

<u>)</u> Radhika Devalaraja, Ph.D. Study Director

> 15 Wiggins Ave., Bedford MA 01730 > 800.458.4141 > Main: 781.275.3330

Toxikon.com



#### FINAL GLP REPORT: 19-00538-G1 AMENDED

#### CLASS VI TEST – USP (WITH 14 DAY SUBCUTANEOUS IMPLANT)

Test Article Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation

> 21 CFR Part 58 Compliance Good Laboratory Practice for Nonclinical Laboratory Studies

> > Final Report Date 6/3/2019

Amended Final Report Date 6/17/2019

Study Director Radhika Devalaraja, Ph.D.

Sponsor PendoTECH 174 Nassau Street Suite 256 Princeton, NJ 08542

> 15 Wiggins Ave., Bedford MA 01730 > 800.458.4141 > Main: 781.275.3330

Toxikon.com

Class VI Test – USP (With 14 Day Subcutaneous Implant) Final GLP Report: 19-00538-G1 Amended Test Article Name: Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation

#### STUDY SUMMARY

The USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG) extracts of the test article, Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation, following Intracutaneous Injection in rabbits, Systemic Injection in mice, and the test article, following Subcutaneous Implantation in rats, did not produce a biological response.

Based on the criteria of the protocol and the USP guidelines for Class VI Plastics - 70 °C, the test article meets the requirements of the test.

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Page 6 of 30 Toxikon Use Only: 000 τοχικοη Class VI Test - USP (With 14 Day Subcutaneous Implant) Final GLP Report: 19-00538-G1 Amended Test Article Name: Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation

#### QUALITY ASSURANCE STATEMENT

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase	Inspection Date	Date Reported to Study Director	Date Reported to Management
EXPLANT	5/29/2019	5/29/2019	5/29/2019
DATA	6/3/2019	6/3/2019	6/3/2019
FINAL REPORT	6/3/2019	6/3/2019	6/3/2019
AMENDED REPORT	6/17/2019	6/17/2019	6/17/2019

in McJula Colin McFadden, B.S.

Quality Assurance

6/17/19 Date

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Page 7 of 30 Toxikon Use Only: 000 TOXIKON Test Article Name: Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation

#### GLP COMPLIANCE STATEMENT

This study meets the technical requirements of the protocol.

This study was conducted in compliance with the current U.S. Food and Drug Administration 21 CFR, Part 58 Good Laboratory Practices for Nonclinical Laboratory Studies.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article, 21 CFR, Part 58.105, and its mixture with carriers, 21 CFR, Part 58.113.

#### SIGNATURES

	Signature Information
Protocol Number	p19-0161-00b
Study Director	Radhika Devalaraja, Ph.D.
Study Supervisor	Catherine Maciaszek, B.S., LAT
Company	Toxikon Corporation

#### VERIFICATION DATES

The study initiation day is the date the protocol is signed by the Study Director.

		Verification Dates
Test Article Receipt	1/23/2019	
Project Log	2/11/2019	
Study Initiation	3/25/2019	
Study Completion	6/3/2019	

D. Rodhike

Radhika Devalaraja, Ph.D. Study Director

6/17/2019 Date

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Page 8 of 30 Toxikon Use Only: 000

Prepared for EMD MILLIPORE - BEDFORD

# STERIS

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### Gamma Process Run ID 117005A

Product Code	Product Lot Number	Quantity	
40-60 SAMPLES	0020499769	Guantity	UOM
Cust Item ID: CAT. NO. CDRF1TN05		1	CS
40-60 SAMPLES	0021039608		
Cust Item ID: CAT. NO. CDRF4HN05		1	CS
40-60 SAMPLES	0022897176	82	12.2
Cust Item ID: CAT. NO. CDRM8HN05		1	CS
40-60 SAMPLES	MGBE620/MGDM180	22	
Cust Item ID: 20277484/00123958DR		1	CS
40-60 SAMPLES	NA		
Cust Item ID: PENDOTECH POLYSULFONE SENSORS	27.7.5%	1	CS

PO Number: N1402721

vered Dose (kGy): 42. Ivered Dose (kGy): 50. during this irradiation run.	.1
vered Dose (kGy): 42. Ivered Dose (kGy): 50. during this irradiation run.	.1
ivered Dose (kGy): 50. during this irradiation run.	.8
during this irradiation run.	8
Signed On 1/21/2010 -t 0.40 AM	-
UTC / GMT Offset (hh.mm) -5:00	
and federal regulations (FDA, NRC, EPA which meets the requirements of FDA QSR, and, EN ANSI/AAM/ISO 11137 or EN irradiation, STERIS certifies that these d accuracy of the dosimetry system used.	
	Signed On 1/21/2019 at 8:48 AM UTC / GMT Offset (hh.mm) -5:00 and federal regulations (FDA, NRC, EPA which meets the requirements of FDA QSR and, EN ANSI/AAM/ISO 11137 or EN irradiation, STERIS cartifies that these d accuracy of the dosimetry system used.

1	ation:	Northbol	rough				
1	:001	126, Nor	dion Cobalt-60 Irradia	stor #126, ON	STD		
1000	Coordin	ate	<u>Barcode ID</u>	Insert	Instrument	Dose (kGv)	Final Dose (kGy)
3	rements						
-	0C1		0BR600288204	TH0049	0484	28.7	42.1
			08R600257802	TH0048	0481	13.4	
N	TAS		0BR600288439	TH0049	0484	34.4	50.5
			0BR600257878	TH0048	0481	16.1	
3	TES		0BR600288499	TH0049	0484	34.7	50.8
			0BR600257886	TH0048	0481	16.1	
	Minim	num Dose	for Record (kGy):	42	1		
	Maxim	num Dose	for Record (kGy):	35	8.		
					Signature A	Manifest	
-	Ś	Prepare Baez, J	d By: Hector (Material I	Handler)			Signed On 1/21/2019 at 6:23 Al UTC / GMT Offset (hittmn): -5:00
-	Ś	Approve	vd By: ne Maranda (QS	& RC Analy	(15		Signed On 1/21/2019 at 8:47 AM UTC / GMT C#54 (httmm): -5:00
-		Docume	int Content Revision:	-			

### 9.3 Appendix C- Assembled Sensor Certificate: USP 661 post gamma irradiation- Polycarbonate (PRESS)



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#### TEST RESULT CERTIFICATE

Sponsor	PendoTECH	Technic	al Initiation	11/18/2015
Address	Ste. 256	Technic	a completion	11/20/2015
<b>~</b>	Princeton, New Jersey 08542			
Contact P.O. Number	Dennis Annarelli 2009258	Report Final N	Date	11/24/2015 15.04023 N1
1.0. Number	2003200	T mai no	on-our Report	13-04023-111
	PendoTECH Single Use			
Test Article	PressureSensor – Polycarbonate	Ratio	120 cm <sup>2</sup> /20 mL	
	Post Gamma Irradiation			
Lot/Batch #	1151138	Vehicle	Purified Water	
Study	Physicochemical Test for Plastics – USP	Extraction Conditions	$70 \pm 2^{\circ}$ C for $24 \pm 2$ hours	
Comments	Cable not included in extraction.			

**REFERENCES:** The study was conducted based upon the following references: United States Pharmacopeia 38, National Formulary 33, 2015. Monograph <661> Containers, Physicochemical Tests–Plastics.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

**GENERAL PROCEDURE:** The test article was extracted in purified water after rinsing in purified water. The following tests were conducted in order to determine physical and chemical properties of the test article's extracts: Nonvolatile Residue, Residue on Ignition, Heavy Metals, and Buffering Capacity.

#### **RESULTS:**

TEST	ACCEPTABLE LEVEL	TEST RESULT
Nonvolatile Residue	≤ 15 mg	2.4 mg, Meets Criteria
Residue on Ignition*	≤ 5 mg	Not Applicable
Heavy Metals	≤ 1 ppm	< 1 ppm, Meets Criteria
Buffering Capacity	≤ 10 mL	0.31 mL, Meets Criteria

\*The Residue on Ignition test is only performed if the nonvolatile residue is 5 mg or above.

**CONCLUSION:** The test article meets criteria of the USP Physicochemical Test for Plastics based upon the methods employed.

AUTHORIZED PERSONNEL:

charly

Lakshmi Chandrasekaran, M.S. Quality Assurance

Amtul Qamar, M.S.

Study Director

Toxikon Corporation 15 Wiggins Ave., Bedford, MA 01730 USA 1.800.458.4141 Main: 1.781.275.3330

## Prepared for ADVANCED SCIENTIFICS INC





Isomedix Services

Product Lot Number	Quantity	UOM
SAMPLE JASON / SAMPLE JASON-0000	1	CS
140080 / 85174-0000	2	CS
622014-0602 / 84931-ENDO	1	CS
B110032-I / 85048-0000	1	CS
B110522-I / 86408-0000	1	CS
	Product Lot Number SAMPLE JASON / SAMPLE JASON-0000 140080 / 85174-0000 622014-0602 / 84931-ENDO B110032-1 / 85048-0000 B110522-1 / 86408-0000	Product Lot Number         Quantity           SAMPLE JASON / SAMPLE JASON-0000         1           140080 / 85174-0000         2           622014-0602 / 84931-ENDO         1           B110032-1 / 85048-0000         1           B110522-1 / 86408-0000         1

Processing Run End Date/Time:       01-Nov-2015 03:25:16 am         Minimum Specified Dose (kGy):       27.5       Minimum Delivered Dose (kGy):       30.1         Maximum Specified Dose (kGy):       45.0       Maximum Delivered Dose (kGy):       37.7         Product meets Customer specifications; zero nonconformities occurred during this irradiation run.       37.7         Product meets Customer specifications; zero nonconformities occurred during this irradiation run.       37.7         Signature Manifest       Signed On 11/2/2015 at 11:07 AM UTC / GMT Offset (nh:mm): -6:00         Document Content Revision: 1       Signed On 11/2/2015 at 11:07 AM UTC / GMT Offset (nh:mm): -6:00	
Minimum Specified Dose (kGy):       27.5       Minimum Delivered Dose (kGy):       30.1         Maximum Specified Dose (kGy):       45.0       Maximum Delivered Dose (kGy):       37.7         Product meets Customer specifications; zero nonconformities occurred during this irradiation run.       37.7         Signature Manifest       Signed On 11/2/2015 at 11:07 AM UTC / GMT Offset (hh:mm): -5:00         Document Content Revision: 1       1	
Maximum Specified Dose (kGy):       45.0       Maximum Delivered Dose (kGy):       37.7         Product meets Customer specifications; zero nonconformities occurred during this irradiation run.       37.7         Signature Manifest       Signed On 11/2/2015 at 11:07 AM UTC / GMT Offset (hh:mm): -5:00         Document Content Revision: 1       1	
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.           Signature Manifest           Reviewed and E-Signed By         Signed On 11/2/2015 at 11:07 AM           Tracy Wild (QS/RC Technician)         UTC / GMT Offset (hh:mm): -5:00           Document Content Revision: 1         1	
Signature Manifest         Reviewed and E-Signed By       Signed On 11/2/2015 at 11:07 AM         Image: Tracy Wild (QS/RC Technician)       UTC / GMT Offset (hh:mm): -5:00         Document Content Revision: 1       1	
Signature Manifest         Reviewed and E-Signed By       Signed On 11/2/2015 at 11:07 AM         Image: Tracy Wild (QS/RC Technician)       UTC / GMT Offset (hh:mm): -5:00         Document Content Revision: 1       1	
Reviewed and E-Signed By Signed On 11/2/2015 at 11:07 AM UTC / GMT Offset (hh:mm): -5:00 Document Content Revision: 1	
Image: Signed By     Signed By       Image: Signed By     UTC / GMT Offset (hh:mm): -5:00       Document Content Revision: 1     1	
Document Content Revision: 1	
Processing Location: Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR,	
23 Elizabeth Drive EN/ISO 13485:2003/2012, and in alignment with EN ANSI/AAMI/ISO 11137:2006. STERIS isomedix certifies that these processed items received the indicated doses within the precision and accuracy	
Chester, NY 10918 of the dosimetry system used. Phone: 845-469-4087	
Fax: 845-489-7512	
PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 P	

diator / N	fethod:	239, Nordio	on Cobalt-60 Iri	radiator #239, Cor	rt Batch				
								Final	
r Se	g Coordi	nate Batc	ch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Dose (kGy)	Comment
	18	NR	(09/15/2015)	5A3O364003	MX 700989	0.7050	2.748	30.7	
	2 0C3	NR	(09/15/2015)	5A3O364003	MX 700989	0.7742	3.049	30.1	
	3 0CEOE	3 NR (	(09/15/2015)	5A3O364003	MX 700989	0.8206	3.228	30.2	
	4 1C1	NR	(09/15/2015)	5A3O364003	MX 700989	0.7697	2.877	33.0	
	5 1CEOE	3 NR (	(09/15/2015)	5A3O364003	MX 700989	0.8630	3.249	32.6	
	6 TBAEO	B NR(	(09/15/2015)	5A3O364003	MX 700989	0.8840	3.236	34.3	
	7 TBEEO	B NR(	(09/15/2015)	5A3O364003	MX 700989	0.7782	2.842	34.5	
	1 0CEOE	3 NR (	(09/15/2015)	5A3O364003	MX 700989	0.7542	2.962	30.3	
	2 TBA5	NR	(09/15/2015)	5A3O364003	MX 700989	0.8315	2.894	37.7	
	3 TBE5	NR	(09/15/2015)	5A3O364003	MX 700989	0.8871	3.124	36.9	
Minimur	n Dose for Re	scord (kGy):	~ *	30.1					
Aaximur	n Dose for R	ecord (kGy):		37.7					
ast Dosir	nefer Absorbano	a Measurement D	Date/Time: 11/1/2	015 4:21:38 AM					
					Signature Mani	ifest			
		Preparet	d By: <b>ni Rose (M</b> a	sterial Handler)	_		Signed On 11/1/201 UTC/GMT Offiset (hhrmm	5 at 4:22 AM n): -5:00	
	Ŵ	Approve Tracy I Docume	ed By: Wild (QS/R( int Content Rev	<b>C Technician)</b> ision: 1			Signed On 11/2/201 UTC/GMT Offeet (nhtm	5 at 10:47 AM n): -5:00	

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC

#### Gamma Process Run ID 179655E



Isomedix Services

Product Lot Number	Quantity	UOM
SAMPLE JASON / SAMPLE JASON-0000	1	CS
B104620-I / 86635-0000	50	CS
HM00170-I / 86606-0000	1	CS
	Product Lot Number SAMPLE JASON / SAMPLE JASON-0000 B104620-I / 86635-0000 HM00170-I / 86608-0000	Product Lot Number         Quantity           SAMPLE JASON / SAMPLE JASON-0000         1           B104620-I / 86635-0000         50           HM00170-I / 86606-0000         1

Processing Run Start Date/Time:	08-Nov-2015	07:22:48 am	A	pprox. Downtime (hours):	0.09
Processing Run End Date/Time:	08-Nov-2015	09:28:01 am			
Minimum Specified Dose (kGy):	27.5		Minimum Del	ivered Dose (kGy):	30.3
Maximum Specified Dose (kGy):	45.0		Maximum De	livered Dose (kGy):	39.8
Product meets Custo	mer specificati	ons; zero nono	conformities occurred	I during this irradiation run.	
		Signature	e Manifest		
Reviewed and E-Signed By				Signed On 11/10/2015 at	3:45 PM
Tracy Wild (QS/RC Te	echnician)			UTC / GMT Offset (nn:mm): -5	100
Document Content Revision	1: 1				
Processing Location:	Operating fa	clittles are in comp	pliance with applicable sta	te and federal regulations (FDA, N	RC, EPA,
STERIS Isomedix Services	EN/ISO 134	85:2003/2012, and	d in alignment with EN AN	SI/AAMI/ISO 11137:2006. STERIS	S Isomedix
Chester, NY 10918	of the dosim	etry system used.	Items received the indicati	ed doses within the precision and a	iccuracy
Phone: 845-469-4087					
Fax: 040-408-7012					
PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1			Release Date:	02-Apr-2014	Page 1 of 1

				to the second seco				
radiator / Metho	d: 239,	Nordion Cobalt-60 Ir	radiator #239, Col	nt Baton				
ier Sea	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGv)	Comment
-	5	NR (09/15/2015)	5A3O364003	MX 700989	0.7962	3.125	30.3	
1 2	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8975	3.108	38.1	
1 3	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.7923	2.818	36.2	
2	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.7922	2.925	33.8	
2 2	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8764	3.213	34.2	
3	OCEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8139	3.171	30.7	
3 2	1A5	NR (09/15/2015)	5A3O364003	MX 700989	0.8954	3.032	39.8	
3	1E5	NR (09/15/2015)	5A3O364003	MX 700989	0.9176	3.131	39.2	
-	OCEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7704	2.963	31.4	
5	1A5	NR (09/15/2015)	5A3O364003	MX 700989	0.8998	3.084	38.9	
3	1E5	NR (09/15/2015)	5A3O364003	MX 700989	0.9223	3.137	39.5	
-	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8509	3.033	36.1	
3 2	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8184	2.863	37.4	
Minimum Dog	te for Record (	kGy):	30.3					
Maximum Do	se for Record	(kGv):	39.8					
Maximum Do	se for Record	(kGy):	39.8					

STERIS Isomedix Services Dosimetry Record Prepared for ADVANCED SCIENTIFICS INC – Process Run ID 179655E

### 9.4 Appendix D- Assembled Sensor Certificate: USP 661 post gamma irradiation- Polysulfone (PREPS)



ADVANCING YOUR INNOVATION

#### TEST RESULT CERTIFICATE

Sponsor	PendoTECH	Technic	al Initiation	11/18/2015
Address	174 Nassau Street Ste. 256 Princeton, New Jareau 08542	Technic	al Completion	11/20/2015
Contact	Dennis Annarelli	Report	Date	12/1/2015
P.O. Number	2009258	Final No.	on-GLP Report	15-04025-N1
Test Article	PendoTECH Single Use Pressure Sensor Polysulfone	Ratio	120 cm²/20 mL	
	Post Gamma Irradiation			
Lot/Batch #	1151748	Vehicle	Purified Water	
Study	Physicochemical Test for Plastics - USP	Extraction Conditions	$70 \pm 2^{\circ}$ C for 24	± 2 hours
Comments	Cable not included in extraction.			

REFERENCES: The study was conducted based upon the following references: United States Pharmacopeia 38, National Formulary 33, 2015. Monograph <661> Containers, Physicochemical Tests-Plastics.

ISC/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: The test article was extracted in purified water after rinsing in purified water. The following tests were conducted in order to determine physical and chemical properties of the test article's extracts: Nonvolatile Residue, Residue on Ignition, Heavy Metals, and Buffering Capacity.

#### RESULTS:

TEST	ACCEPTABLE LEVEL	TEST RESULT
Nonvolatile Residue	≤ 15 mg	2.7 mg, Meets Criteria
Residue on Ignition*	≤5 mg	Not Applicable
Heavy Metals	≤1 ppm	< 1 ppm, Meets Criteria
Buffering Capacity	≤ 10 mL	0.3 mL, Meets Criteria

\*The Residue on Ignition test is only performed if the nonvolatile residue is 5 mg or above.

CONCLUSION: The test article meets criteria of the USP Physicochemical Test for Plastics based upon the methods employed.

AUTHORIZED PERSONNEL:

i chapped ٦ akshmi Chandrasekaran, M.S.

Quality Assurance

amar mtul Qamar, M.S. Study Director



### Prepared for ADVANCED SCIENTIFICS INC



Isomedix Services

#### Gamma Process Run ID 179365C

Product Code	Product Lot Number	Quantity	UOM
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS
GROUP 82	140080 / 85174-0000	2	CS
GROUP 82	622014-0602 / 84931-ENDO	1	CS
GROUP 82	B110032-I / 85048-0000	1	CS
GROUP 82	B110522-I / 86408-0000	1	CS

Processing Run Start Date/Time:	01-Nov-2015	01:31:29 am	A	pprox. Downtime (hours):	0.00
Processing Run End Date/Time:	01-Nov-2015	03:25:16 am			
Minimum Specified Dose (kGy):	27.5		Minimum Deli	ivered Dose (kGy):	30.1
Maximum Specified Dose (kGy)	: 45.0		Maximum Del	ivered Dose (kGy):	37.7
Product meets Custo	omer specificati	ons; zero nono	onformities occurred	during this irradiation run.	
		Signature	Manifest		
Reviewed and E-Signed B	/			Signed On 11/2/2015 at 1	1:07 AM
Tracy Wild (QS/RC T	echnician)			UTC / GMT Offset (hh:mm): -5	:00
Document Content Revisio	n: 1				
Processing Location:	Operating fa	clities are in comp	llance with applicable sta	te and federal regulations (FDA, N	RC, EPA,
STERIS Isomedix Services	EN/ISO 134	and provide service 85:2003/2012, and	in alignment with EN AN	SVAAMI/ISO 11137:2006. STERIS	S Isomedix
Chester, NY 10918	certifies that of the dosim	these processed it etry system used.	tems received the indicate	ed doses within the precision and a	iccuracy
Phone: 845-469-4087					
Fax: 845-469-7512					
PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1			Release Date:	02-Apr-2014	Page 1 of 1

19 Loca / Meth 2 3 3 5 6 7 7	od: Cloordinate 0c1 23 0c1 0c1 0c1 0c3 0c1 0c1 1c1 0c1 1cE0B 1bAE0B 0cE0B 1BAE0B 0cE0B	Prepared fo thester 39, Nordion Cobalt-60 Irra 39, Nordion Cobalt-60 Irra NR (09/15/2015) NR (09/15/2015)	r ADVANCED SCI Date Prepare Spectro S/N 5A30364003 5A3003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A3003 5	<ul> <li>IENTIFICS INC Proceed: 11/2/2015 10:47:31</li> <li>Batch</li> <li>Micrometer SiN</li> <li>MK 700989</li> </ul>	ABS Run ID 1 1AM ABS 0.7742 0.7742 0.8206 0.7697 0.8840 0.8840 0.7782 0.7782 0.7782 0.7782	179365C Thick (mm) 2.748 3.049 3.228 3.249 3.236 2.847 2.842 2.894 2.894	Final Dose (kGV) 30.7 30.7 33.0 33.0 34.5 34.5 37.7 37.7	Comment
ig Locc / Meth 2 3 3 5 6 7 7	ation: Ct od: Coordinate 0C1 23 0C1 0C1 0C1 0C1 0C1 0C1 1C1 0C1 1CE0B 1CE0B 1CE0B 1CE0B 1BAE0B 0CE0B 1BA5 1CE0B	hester 39, Nordion Cobalt-60 Irra 89, Nordion Cobalt-60 Irra NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015)	diator #239, Cont Spectro S/N 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003	: Batch Micrometer <u>S/N</u> MK 700989 MK 700989 MK 700989 MK 700989 MK 700989 MK 700989 MK 700989	ABS 0.7742 0.7742 0.8206 0.8840 0.8840 0.7782 0.7782 0.7782 0.8315	Thick (mm) 2.748 3.049 3.228 3.236 3.236 3.236 2.849 2.894 2.894	Final Dose (KGV) 30.7 30.7 30.1 33.0 34.5 34.5 37.7 37.7 36.9	Comment
/ Meth 5 9 2 2 4 1 7 7 6 5 5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	od: 23 Coordinate 0C1 0C1 0C1 0C20B 1C10 1CE0B 1CE0B 1CE0B TBA5 0CE0B TBA5 TBA5	<ul> <li>39, Nordion Cobalt-60 Irra</li> <li>Batch - Cal Dt</li> <li>NR (09/15/2015)</li> </ul>	diator #239, Cont Spectro S/N 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003	Batch Mic ro meter SN MX 700989 MX 700989 MX 700989 MX 700989 MX 700989 MX 700989 MX 700989	ABS 0.7050 0.7742 0.7697 0.8840 0.8840 0.7782 0.7782 0.7782 0.7782	Thick (mm) 2.748 3.049 3.228 3.236 3.236 3.236 2.849 2.894 2.894	Final Dose (KGV) 30.7 30.7 30.1 33.0 34.5 34.5 34.5 37.7 37.7	Comment
Seq 5 4 3 2 1 4 2 1 4 2 1 4 2 2 1 4 2 2 2 1 4 2 2 2 1 4 2 2 2 1 4 2 2 2 1 4 2 2 2 1 4 2 2 2 2	Coordinate 0C1 0C3 0C508 1C1 1C1 1C108 1CE08 TBA5 0CE08 0CE08 TBA5 TBA5	<ul> <li>Batch - Cal Dt NR (09/15/2015)</li> <li>NR (09/15/2015)</li> </ul>	Spectro S/N           5A30364003	Mic ro meter S/N MX 700989 MX 700989 MX 700989 MX 700989 MX 700989 MX 700989 MX 700989	ABS 0.7050 0.77697 0.7697 0.8840 0.8840 0.7782 0.7782 0.7782 0.7782 0.8315	Thick (mm) 2.748 3.049 3.228 3.236 3.236 3.236 2.842 2.842 2.842 2.894	Final Dose (kGy) 30.7 30.7 30.2 34.5 34.5 34.5 37.7 37.7 36.9	Comment
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0 0 4 0 0 0	0C3 0CEOB 1C1 1CEOB 1CEOB TBAEOB 0CEOB 0CEOB	NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015)	5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003	MX 700989 MX 700989 MX 700989 MX 700989 MX 700989 MX 700989 MX 700989	0.7742 0.8206 0.7697 0.8630 0.8840 0.7840 0.7782 0.7782 0.7782	3.049 3.228 3.249 3.236 2.842 2.842 2.894	30.1 33.0 34.5 37.7 37.7 37.7	
6 4 6 6 F − 0	00000000000000000000000000000000000000	NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015)	5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003	MX 700989 MX 700989 MX 700989 MX 700989 MX 700989 MX 700989	0.8206 0.7697 0.8630 0.8840 0.7782 0.7782 0.7542 0.8315	3.228 2.877 3.249 3.236 2.842 2.842 2.894	90 93 93 93 93 93 93 93 93 93 93 93 93 93	
40000	1C1 1CEOB TBAEOB TBEEOB 0CEOB TBA5 TBA5	NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015)	5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003	MX 700989 MX 700989 MX 700989 MX 700989 MX 700989	0.7697 0.8630 0.8840 0.7782 0.7782 0.7542 0.8315	2.877 3.249 3.236 2.842 2.962 2.894	33.0 24.5 37.7 37.7 29	
0 0 V T 0	1CEOB TBAEOB TBEEOB 0CEOB TBA5 TBA5	NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015)	5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003	MX 700989 MX 700989 MX 700989 MX 700989 MX 700989	0.8630 0.8840 0.7782 0.7542 0.8315	3.249 3.236 2.842 2.894 2.894	22.6 24.5 29.5 29.3 29.3 29.3 29.3 29.3 29.3 29.3 29.3	
9 0	TBAEOB TBEEOB 0CEOB TBA5 TBE5	NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015)	5A30364003 5A30364003 5A30364003 5A30364003 5A30364003 5A30364003	MX 700989 MX 700989 MX 700989 MX 700989	0.8840 0.7782 0.7542 0.8315	3.236 2.842 2.894 2.894	34.5 37.7 37.7 38.9	
~ + 0	TBEEOB 0CEOB TBA5 TBA5	NR (09/15/2015) NR (09/15/2015) NR (09/15/2015) NR (09/15/2015)	5A3O364003 5A3O364003 5A3O364003 5A3O364003	MX 700989 MX 700989 MX 700989	0.7782 0.7542 0.8315	2.842 2.962 2.894	34.5 30.3 37.7 36.9	
÷ (	0CEOB TBA5 TBA5	NR (09/15/2015) NR (09/15/2015) NR (09/15/2015)	5A3O364003 5A3O364003 5A3O364003	MX 700989 MX 700989 MX 700989	0.7542 0.8315	2.962 2.894	30.3 37.7 36.9	
0	TBA5 TRE5	NR (09/15/2015) NR (09/15/2015)	5A3O364003 5A3O364003	MX 700989 MX 700989	0.8315	2.894	37.7 36.9	
N	TRES	NR (09/15/2015)	5A3O364003	MX 70080	0 0074		36.9	
e					0.0071	3.124		
um De	se for Recor	rd (kGy): 30	14					
um D	ose for Recor	vrd (kGy): 37						
osimeter	r Absorbance Mei	asument Date/Filme: 11/1201	15 4 21 38 AM					
				Signature Manif	fest			
	8	Prepared By: Zephoni Rose (Mat	erial Handler)			Signed On 11/1/2015 UTC/GMT Offset (hitrmm):	at 4:22 AM -5:00	
	ŝ	Approved By: <b>Tracy Wild (QS/RC</b> Document Content Revis	<b>Technician)</b> sion: 1			Signed On 11/2/2015 UTC / GMT Offset (hhrmm)	at 10:47 AM : -5:00	
		Comment Legend OU'	T = Calc Dose Out of L	imits; PID = Pre-Irradiated (	Dosimeter; GR	e = Dosimeter Group		
50 Last	Rev DMA 1.0.2.1	18. RT 3.6.2.1	Rele	lase Date: 10-Aug-2015				Page 1 of
	osimetet	num Dose for Reco num Dose for Reco osimeter Absolutance Mi	num Dose for Record (kGy): 3 num Dose for Record (kGy): 3 osimeter Absoltance Measumment Date/Time: 11/1/201 osimeter Absoltance Measumment Date/Time: 11/1/201 Prepared By: Zephoni Rose (Mat Approved By: Tracy Wild (QS/RC Document Content Revis	um Dose for Record (kGy):       30.1         num Dose for Record (kGy):       37.7         num Dose for Record (kGy):       37.7         osimeter Absolutance Measurement Date/Time:       11/12015 4.21.38 AM         osimeter Absolutance Measurement Date/Time:       11/12015 4.21.38 AM         Repared By:       Repared By:         Repared By:       Zephoni Rose (Material Handler)         Retrial For the Content Revision:       1         Document Content Revision:       1         Comment Lagend:       OUT = Calc Dose Out of L         Retext By:       Comment Lagend:       OUT = Calc Dose Out of L	3     IDEC     INCLUENT DATA     INCLUENT DATA       Num Dose for Record (kGy):     30.1       Num Dose for Record (kGy):     37.7       Signature Mani     11/12015 421:38 AM       Prepared By:     Signature Mani       R     Prepared By:       R     Approved By:       Approved By:     Comment Content Revision: 1       Document Content Revision: 1     Document Content Revision: 1	3 TBE5       NR (09/15/2015)       5A30364003       MX 700989       0.8871         num Dose for Record (kGy):       30.1       30.1         num Dose for Record (kGy):       37.7       0.1         osimeter Absolutance Measument Date/filme:       11/12015 4.21:38 AM       0.1         Approved By:       Ephoni Rose (Material Handler)       Approved By:       0.1         Approved By:       Tracy Wild (QS/RC Technician)       0.1       0.1         Document Content Revision:       1       0.1       0.1       0.1         Comment Legent:       0.1       Content Legent:       0.1       0.1       0.1	um Dose for Record (kGy):       30.1         num Dose for Record (kGy):       37.1         num Dose for Record (kGy):       37.1         osimoter Absorbance Measurement Date/Time:       11/12015 4.21.38 AM         osimoter Absorbance Measurement Date/Time:       11/12015 4.21.38 AM         Signed On 11/12015:       Signed On 11/12015:         Image: Signed On 11/12015:       Signed On 11/12015:         Image: Signed On 11/12015:       UTC/ GMT Offset (httm):         Image: Signed On 11/12015:       UTC/ GMT Offset (httm)	tum Dose for Record (KGy):     30.1       num Dose for Record (KGy):     37.7       num Dose for Record (KGy):     37.7       num Dose for Record (KGy):     37.7       osimeter Absolution:     11/12/015 4.21:38 M       noise for Record (KGy):     51/12/015 4.21:38 M       noise for Record (KGy):     51/12/015 4.21:38 M       noise for Record (KGy):     51/12/015 4.21:38 M       noise for Record (KG):     51/12/015 4.21:28 M       Image: Signed District Manifest     51/12/12/015 4.4:22 AM       Image: Record Material Handler)     51/11/12/015 4.14:22 AM       Image: Record Material Handler)     51/11/12/015 4.14:22 AM       Image: Record Material Handler)     51/11/11/2015 4.14:22 AM       Image: Record Material Handler)     10/11/11/2015 4.14:22 AM       Image: Record Material Handler)     10/11/11/11/2015 4.14:20 A       Image: Record Material Handler)     10/11

### Prepared for ADVANCED SCIENTIFICS INC



Isomedix Services

### Gamma Process Run ID 179655E

Product Code	Product Lot Number	Quantity	UOM
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS
GROUP 82	B104620-I / 86635-0000	50	CS
GROUP 85	HM00170-I / 86606-0000	1	CS

Processing Run Start Date/Time:	08-Nov-2015 07:22:48 am	Approx. Downtime (hours):	0.09
Processing Run End Date/Time:	08-Nov-2015 09:28:01 am		
Minimum Specified Dose (kGy):	27.5	Minimum Delivered Dose (kGy):	30.3
Maximum Specified Dose (kGy)	: 45.0	Maximum Delivered Dose (kGy):	39.8
Product meets Custo	mer specifications; zero nor	conformities occurred during this irradiation run.	
	Signatur	e Manifest	
Reviewed and E-Signed By	/	Signed On 11/10/2015 at 3	:45 PM
📝 Tracy Wild (QS/RC T	echnician)	UTC / GMT Offset (hh:mm): -5:0	0
Document Content Revisio	n: 1		
Processing Location:	Operating facilities are in cor	npliance with applicable state and federal regulations (FDA, NR)	C, EPA,
STERIS Isomedix Services	and OSHA) and provide serv	loss under a quality system which meets the requirements of FD and in alignment with EN ANSI/AAM/ISO 11137-2005 STERIS I	A QSR,
23 Elizabeth Drive	certifies that these processed	d Items received the indicated doses within the precision and ac	curacy
Chester, NY 10918 Phone: 845-469-4087	of the dosimetry system used	1.	
Fax: 845-469-7512			
PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1		Release Date: 02-Apr-2014	Page 1 of 1

Processing Location: Chester Irradiator / Method: 239, Nordion Cobal Carrier Seg Coordinate Batch - Cal I	lt-60 Irradiator #239, Co					
Irradiator / Method: 239, Nordion Cobal Zarrier Seg <u>Coordinate Batch - Cal I</u>	It-60 Irradiator #239, Co					
Carrier Seg Coordinate Batch-Cal I		nt Batch				
Carrier Seq Coordinate Batch - Cal I					Final	
	Dt Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Dose (kGy)	Comment
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	015) 5A3O364003	MX 700989	0.7962	3.125	30.3	
1 2 TBA5 NR (09/15/20	015) 5A3O364003	MX 700989	0.8975	3.108	38.1	
1 3 TBE5 NR (09/15/20	015) 5A3O364003	MX 700989	0.7923	2.818	36.2	
2 1 TBA5 NR (09/15/20	015) 5A3O364003	MX 700989	0.7922	2.925	33.8	
2 2 TBE5 NR (09/15/20	015) 5A3O364003	MX 700989	0.8764	3.213	34.2	
3 1 0CEOB NR (09/15/20	015) 5A3O364003	MX 700989	0.8139	3.171	30.7	
3 2 1A5 NR (09/15/20	015) 5A3O364003	MX 700989	0.8954	3.032	39.8	
3 3 1E5 NR (09/15/20	015) 5A3O364003	MX 700989	0.9176	3.131	39.2	
5 1 0CEOB NR (09/15/20	015) 5A3O364003	MX 700989	0.7704	2.963	31.4	
5 2 1A5 NR (09/15/20	015) 5A3O364003	MX 700989	0.8998	3.084	38.9	
5 3 1E5 NR (09/15/20	015) 5A3O364003	MX 700989	0.9223	3.137	39.5	
6 1 TBA5 NR (09/15/20	015) 5A3O364003	MX 700989	0.8509	3.033	8.1	
6 2 TBE5 NR (09/15/2(	015) 5A3O364003	MX 700989	0.8184	2.863	37.4	
Minimum Dose for Record (kGy):	30.3					
Maximum Does for Decord (b.G.).	0.00					

STERIS Isomedix Services Dosimetry Record

Page 60 of 109

# 9.5 Appendix E- Assembled Sensor Certificate: ISO 10993-5 post gamma irradiation- Polycarbonate (PRESS)

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	/		

ADVANCING YOUR INNOVATION

#### TEST RESULT CERTIFICATE

Sponsor	PendoTECH	Technical	Initiation	8/18/2015
Address	174 Nassau Street Ste. 256 Princeton, New Jersey, 08542	Technical	Completion	8/21/2015
Contact P.O. Number	Dennis Annarelli 2008960	Report Dat Final GLP	te Report	9/1/2015 15-02763-G1
Test Article	PendoTECH polycarbonate pressure sensor	Ratio	3 cm <sup>2</sup> /mL	
Lot/Batch #	See Attachment A	Vehicle	Serum-Sup (complete) M Essential Me	plemented Ainimum edium (MEM)
Study	L929 Neutral Red Uptake Test (1 Concentration) – ISO	Extraction	$24 \pm 2$ hours	at 37 ± 1 °C
Comments	Per Sponsor request, the test article was extracte	d intact and wires	were excluded	from testing

REFERENCES: The study was based upon the following references: ISO 10993–5, 2009, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. ISO 10993–12, 2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

**GENERAL PROCEDURE:** The biological reactivity of a mammalian cell monolayer, L929 mouse fibroblast, in response to the test article extract was determined. The test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles and an untreated control were prepared to verify the proper functioning of the test system. The test article and control article extracts were used to replace the maintenance medium of the cell culture. The test article extract was tested at the 100% (neat) concentration. All cultures were incubated in, at least, 6 replicates for 24 to 26 hours, at  $37 \pm 1$  °C, in a humidified atmosphere containing  $5 \pm 1\%$  carbon dioxide (CO<sub>2</sub>). The viability of cells following the exposure to the extracts was measured via their capacity to uptake a vital dye, Neutral Red. This dye was added to the cells to be actively incorporated in viable cells. The number of viable cells correlates to the color intensity determined by photometric measurements at 540 nm after extraction.

EVALUATION CRITERIA: The viability of cells exposed to the negative control article and positive control article extracts need to be greater and less than 70% of the untreated control, respectively, to confirm the validity of the assay. The test article meets the requirements of the test if the viability % is greater than or equal to 70% of the untreated control.

RESULTS:

	Untreated	Negative	Projitive Control	Test Article	
	Control	Control	Positive Control	100% (neat)	
Average OD	0.532	0.571	0.214	0.479	
Viability %	100%	107%	40%	90%	

CONCLUSION: The test article meets the requirements of the test and is not considered to have a cytotoxic effect.

#### AUTHORIZED PERSONNEL:

abette Elizabeth Hogan, B.S. Quality Assurance

Sruthi Sundaram, Ph.D Study Director

Toxikon Corporation 15 Wiggins Ave., Bedford, MA 01730 USA 1.800.458.4141 Main: 1.781.275.3330

Prepared for ADVANCED SCIENTIFICS INC



Isomedix Services

Gamma Process	Run I	ID 75899A
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Product Code	Product Lot Number	Quantity	UOM
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS

Processing Run Start Date/Time:	01-Aug-2015	09:52:00 pm	Approx. Downtime (hours):	0.15
Processing Run End Date/Time:	01-Aug-2015	11:27:00 pm		
Minimum Specified Dose (kGy):	27.5		Minimum Delivered Dose (kGy):	34.8
Maximum Specified Dose (kGy)	: 45.0		Maximum Delivered Dose (kGy):	37.8
Product meets Custo	omer specificat	ions; zero nonce	onformities occurred during this irradiation run.	
		Signature	Manifest	
Reviewed and E-Signed B	у		Signed On 8/3/2015 at 7:	51 AM
Maria H Greco (QS/R	C Technicia	nn)	UTC / GMT Offset (hh:mm): -4	:00
Document Content Revisio	n: 1			
Processing Location: STERIS Isomedix Services 9 Apollo Drive Whippany, NJ 07981 Phone: 973-887-2754 Fax: 973-887-6591	Operating fa and OSHA) EN/ISO 134 certifies that of the dosin	aclities are in comp and provide service 85:2003/2012, and these processed it letry system used.	lance with applicable state and federal regulations (FDA, N is under a quality system which meets the requirements of In alignment with EN ANSI/AAMI/ISO 11137:2006. STERIS ems received the Indicated doses within the precision and a	RC, EPA, FDA QSR, 3 isomedix ccuracy
PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1			Release Date: 02-4pr-2014	Page 1

Idiator #131, Nordion Cobalt-60 Irradiator #131, Oxa7100         Icidiator / Method:       131, Nordion Cobalt-60 Irradiator #131, Oxa7100       Icidiator #130, Oxa7	rradiator / Method: rier <u>Seq</u> <u>Coordi</u> 1 2C5 1 2C5 1 2 2A5 1 4 TBA5 1 5 TBE5 Minimum Dose for Re	131, Nordion Cobalt-60 inate Batch - Cal Dt NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) ecord (kGy): tecord (kGy): tecord (kGy):	rradiator #131, ON-5 Spectro <u>SIN</u> 4324039 4324039 4324039 4324039 4324039 37.8	5TD Micrometer S/N MX 700987 MX 700987 MX 700987 MX 700987	ABS 0.8148 0.7661 0.9126 0.8675 0.8675	Thick (mm) 2.856 2.602 3.060 2.926 2.949	Final Dose (kGy) 34.8 36.8 37.4 37.6 37.6	Comment
Inter         Serie         Descrie         Batch-Call Dr         Spectro SNI         Micrometer SNI         ABS         Thick (mm)         Dose (KGN)         Commeter SNI           1         205         NM (0527/2015)         4324039         NX 700987         0.8148         2.856         3.4.8           1         2         2         AB         NM (0527/2015)         4324039         NX 700987         0.8148         2.856         3.4.8           1         3         ZE5         NM (0527/2015)         4324039         NX 700987         0.9126         3.060         3.7.8           1         4         TBAS         NM (0527/2015)         4324039         NX 700987         0.8776         2.926         3.7.8           1         5         TBE5         NM (0527/2015)         4324039         NX 700987         0.8776         3.7.6         3.7.8           1         3         2E5         NM (0527/2015)         4324039         NX 700987         0.8776         2.949         3.7.6           1         3         TBE5         NM (0527/2015)         4324039         NX 700987         0.8776         2.949         3.7.4           1         3         3         4324039         NX 700987 <td< th=""><th>rier <u>Seq</u> <u>Coordi</u> 1 1 2C5 1 2 2A5 1 3 2E5 1 4 TBA5 1 5 TBE5 Minimum Dose for Re</th><th>Inate Batch - Cal Dt NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) ecord (kGy): tecord (kGy):</th><th>Spectro SIN 4324039 4324039 4324039 4324039 4324039 337.8</th><th><u>Micrometer S/N</u> MX 700987 MX 700987 MX 700987 MX 700987</th><th>ABS 0.8148 0.7661 0.9126 0.8675 0.8675</th><th>Thick (mm) 2.856 2.602 3.060 2.926 2.949</th><th>Final Dose (kGy) 34.8 36.8 37.4 37.6 37.6</th><th>Comment</th></td<>	rier <u>Seq</u> <u>Coordi</u> 1 1 2C5 1 2 2A5 1 3 2E5 1 4 TBA5 1 5 TBE5 Minimum Dose for Re	Inate Batch - Cal Dt NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) ecord (kGy): tecord (kGy):	Spectro SIN 4324039 4324039 4324039 4324039 4324039 337.8	<u>Micrometer S/N</u> MX 700987 MX 700987 MX 700987 MX 700987	ABS 0.8148 0.7661 0.9126 0.8675 0.8675	Thick (mm) 2.856 2.602 3.060 2.926 2.949	Final Dose (kGy) 34.8 36.8 37.4 37.6 37.6	Comment
1         2.55         NM (0527/2015)         4324039         MX 700987         0.8148         2.856         34.8           1         2         2.45         NM (0227/2015)         4324039         MX 700987         0.7651         2.602         36.8           1         3         ZE5         NM (0327/2015)         4324039         MX 700987         0.9126         3.060         37.8           1         4         TBA5         NM (0327/2015)         4324039         MX 700987         0.8176         2.926         37.4           1         5         TBA5         NM (0327/2015)         4324039         MX 700987         0.8776         2.949         37.4           Minimu Cost         NM (0327/2015)         4324039         MX 700987         0.8776         2.949         37.4           Maximu Dost of Record (KG):         3.4          3.75         3.74           Maximur Dost of Record (KG):         3.7         3.7         3.74         3.74	1 1 2C5 1 2 2A5 1 3 2E5 1 4 TBA5 1 5 TBE5 Minimum Dose for Re	NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) ecord (kGy): tecord (kGy):	4324039 4324039 4324039 4324039 4324039 34.8 37.8	MX 700987 MX 700987 MX 700987 MX 700987	0.8148 0.7651 0.9126 0.8675 0.8776	2.856 2.602 3.060 2.949 2.949	34.8 36.8 37.6 37.6	
1         2         2A5         NM (05/27/2015)         4324039         NX 700987         0.7651         2.602         36.8           1         3         2E5         NM (05/27/2015)         4324039         NX 700987         0.9126         3.060         37.8           1         4         TBA5         NM (05/27/2015)         4324039         NX 700987         0.8756         2.926         37.4           1         5         TBE5         NM (05/27/2015)         4324039         NX 700987         0.8756         2.926         37.6           1         5         TBE5         NM (05/27/2015)         4324039         NX 700987         0.8756         2.926         37.6           1         3         1         2         2.949         2.949         37.6         37.6           1         3         4         2         2.940         0.8775         2.949         37.6           1         3         4         3	1 2 245 1 3 2E5 1 4 TBA5 1 5 TBE5 Minimum Dose for Re	NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) ecord (kGy): tecord (kGy):	4324039 4324039 4324039 4324039 34.8 37.8	MX 700987 MX 700987 MX 700987 MX 700987	0.7651 0.9126 0.8675 0.8776	2.602 3.060 2.926 2.949	36.8 37.4 37.6	
1         2         E5         NM (05/27/2015)         4324039         MX 700987         0.9126         3.060         37.8           1         4         TBA5         NM (05/27/2015)         4324039         MX 700987         0.8675         2.926         37.4           1         5         TBE5         NM (05/27/2015)         4324039         MX 700987         0.8776         2.926         37.4           Mnimut         7         4324039         MX 700987         0.8776         2.949         37.6           Mnimut         7         3.4          2.940         37.6         37.6           Mnimut         7         3.4           2.943         37.6           Maximut         7         3.4           2.943         37.6           Maximut         7         3.7           37.6           Maximut         7         3.7           37.6           Maximut         7         3.7           37.6	1 3 2E5 1 4 TBA5 1 5 TBE5 Minimum Dose for Re	NM (05/27/2015) NM (05/27/2015) NM (05/27/2015) ecord (kGy): tecord (kGy): a Measumment Date/Trime. 8/2/2	4324039 4324039 4324039 <b>34.8</b> <b>37.8</b>	MX 700987 MX 700987 MX 700987	0.9126 0.8675 0.8776	3.060 2.926 2.949	37.8 37.6 37.6	
1         4         TBA5         NM (0527/2015)         4324039         MX 700987         0.8675         2926         37.4           1         5         TBE5         NM (0527/2015)         4324039         MX 700987         0.8776         2.949         37.6           Mnimur         Dest For Cord (KGy):         34         MX 700987         0.8776         2.949         37.6           Mnimur         Dest For Cord (KGy):         34         MX         1.4         1.4         1.4           Maximur         Dest For Record (KGy):         34.8         1.4         1.4         1.4         1.4           Maximur         Dest For Record (KGy):         34.8         1.4         1.4         1.4         1.4	1 4 TBA5 1 5 TBE5 Minimum Dose for Re	NM (05/27/2015) NM (05/27/2015) ecord (kGy): tecord (kGy): a Maasumment Date/Time. 8/2/2	4324039 4324039 <b>34.8</b> 37.8	MX 700987 MX 700987	0.8675 0.8776	2.949	37.6	
1         5         TBE5         NM (05/27/2015)         4324039         NX 700987         0.8776         2.949         37.6           Minimu Dose for Record (KGy):         34.8         34.8         37.8         37.8         37.6<	1 5 TBE5 Minimum Dose for Re	NM (05/27/2015) ecord (kGy): tecord (kGy): a Maasument Date/Time: 8/2/2	4324039 34.8 37.8	MX 700987	0.8776	2.949	37.6	
Minimum Dose for Record (kGy):     34.8       Maximum Dose for Record (kGy):     37.8       Last Dosimmer Absorbance Measumment Dash/Time:     8/2/2015 12:30.08 AM	Minimum Dose for Re	ecord (kGy): tecord (kGy): » Maasumment Date/Time: 8/2/2	34.8 37.8					
Maximum Dose for Record (KGy):     37.8       Last Dosimmeter Absorbance Measurement Date/Time:     8/2/2015 12:30:08.AM		tecord (kGy): te Measumment Date/Time: 8/2/2	37.8					
Last Dosimeter Absorbance Measumment Date/Time: 8/2/2015 12:33:08 AM	Maximum Dose for Re	20 Measurement Date/Time: 8/2/2						
	Last Dosiméer Absorbance		015 12 33.08 AM					
				Signature Mani	ifest			
Signature Manifest		Prepared By: Ronald Slack (St	upervisor I)			Signed On 8/2/2015 at UTC/GMT Offset (hhrmm):	12:33 AM -∉∞	
Prepared By: Prepared By: Ronald Stack (Supervisor I) Proc / GMT Official 12:33 AM Proc / GMT Official 12:33 AM		Approved By: Maria H Greco (C Document Content R	<b>NS/RC Technicia</b> evision: 1	ſ		Signed On 8/3/2015 at UTC / GMT Offset (hfr.mm):	7:49 AM -4:00	

#### 9.6 Appendix F- Assembled Sensor Certificate: ISO 10993-5 post gamma irradiation- Polysulfone (PREPS)



TEST RESULT CERTIFICATE

Sponsor Address	PendoTECH 174 Nassau Street	Technical Technical	Initiation Completion	8/18/2015 8/21/2015
Contact P.O. Number	Ste. 255 Princeton, New Jersey 08542 Dennis Annarelli 2008960	Report Dat Final GLP	te Report	9/1/2015 15-02861-G1
Test Article	polysulfone pressure sensor	Ratio	3 cm <sup>2</sup> /mL	
Lot/Batch #	See Attachment A	Vehicle	Serum–Sup (complete) M Essential M	plemented Minimum edium (MEM)
Study	L929 Neutral Red Uptake Test (1 Concentration) – ISO	Extraction	24 ± 2 hours	at 37 ± 1 °C
Comments	Per Sponsor request, the test article was e	extracted intact and wires	were excluded	from testing.

REFERENCES: The study was based upon the following references: ISO 10993–5, 2009, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity. ISO 10993–12, 2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.

ISO/IEC 17025, 2005, General Requirements for the Competence of Testing and Calibration Laboratories.

**GENERAL PROCEDURE:** The biological reactivity of a mammalian cell monolayer, L929 mouse fibroblast, in response to the test article extract was determined. The test article extract was prepared as stated above. Positive control (Natural Rubber) and negative control (Negative Control Plastic) articles and an untreated control were prepared to verify the proper functioning of the test system. The test article and control article extracts were used to replace the maintenance medium of the cell culture. The test article extract was tested at the 100% (neat) concentration. All cultures were incubated in, at least, 6 replicates for 24 to 26 hours, at 37  $\pm$  1 °C, in a humidified atmosphere containing 5  $\pm$  1% carbon dioxide (CO<sub>2</sub>). The viability of cells following the exposure to the extracts was measured via their capacity to uptake a vital dye, Neutral Red. This dye was added to the cells to be actively incorporated in viable cells. The number of viable cells correlates to the color intensity determined by photometric measurements at 540 nm after extraction.

EVALUATION CRITERIA: The viability of cells exposed to the negative control article and positive control article extracts need to be greater and less than 70% of the untreated control, respectively, to confirm the validity of the assay. The test article meets the requirements of the test if the viability % is greater than or equal to 70% of the untreated control.

#### RESULTS:

	Untreated	Negative	Positive Control	Test Article
	Control	Control	Positive Control	100% (neat)
Average OD	0.532	0.571	0.214	0.578
Viability %	100%	107%	40%	109%

CONCLUSION: The test article meets the requirements of the test and is not considered to have a cytotoxic effect.

AUTHORIZED PERSONNEL:

arch zabeth Hogan, B.S. Quality Assurance

Sruthi Sundaram, Ph.D. Study Director

Toxikon Corporation 15 Wiggins Ave., Bedford, MA 01730 USA 1.800.458.4141 Main: 1.781.275.3330

Prepared for ADVANCED SCIENTIFICS INC



Isomedix Services

Gamma Process	Run I	ID 75899A
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Product Code	Product Lot Number	Quantity	UOM
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS

Processing Run Start Date/Time:	01-Aug-2015 0	09:52:00 pm	Approx. Downti	ime (hours):	0.15
Processing Run End Date/Time:	01-Aug-2015 1	11:27:00 pm			
Minimum Specified Dose (kGy):	27.5		Minimum Delivered Dos	e (kGy):	34.8
Maximum Specified Dose (kGy)	: 45.0		Maximum Delivered Dos	e (kGy):	37.8
Product meets Custo	omer specificatio	ns; zero nonco	nformities occurred during this in	radiation run.	
		Signature	<u>Manifest</u>		
Reviewed and E-Signed B	y	-	Signed On	8/3/2015 at 7:51	1 AM
Maria H Greco (QS/R	C Technician	)	UTC / GMT O	ffset (hh:mm):   -4:0	D
Document Content Revisio	in: 1				
Processing Location: STERIS Isomedix Services 9 Apollo Drive Whippany, NJ 07981	Operating faci and OSHA) ar EN/ISO 13485 certifies that th of the dosimet	lities are in compli nd provide service 5:2003/2012, and i hese processed its ry system used.	ance with applicable state and federal re s under a quality system which meets the n alignment with EN ANSI/AAM//ISO 111 ms received the indicated doses within th	guiations (FDA, NR) requirements of FC 37:2006. STERIS I he precision and ac	C, EPA, DA QSR, isomedix curacy
Phone: 973-887-2754 Fax: 973-887-6591					
ROC-00034/01354/01369 Last Rev in Rel. 3.6.2.1			Release Date: 02-Apr-2014		Page 1

ITAIL INTEGRATION I	rradiator / Met	thod: 1: <u>Coordinat</u> 2 245 3 2E5 4 TBA5 5 TBE5	I31, Nordion Cobalt-60 Irr           Iae         Batch - Cal Dt           NM (05/27/2015)         NM (05/27/2015)           NM (05/27/2015)         NM (05/27/2015)           NM (05/27/2015)         NM (05/27/2015)           NM (05/27/2015)         NM (05/27/2015)           ord (kGy):         3           ord (kGy):         3	radiator #131, ON-S Spectro S/N 4324039 4324039 4324039 4324039 4324039 31.8	51D Micrometer S/N MX 700987 MX 700987 MX 700987 MX 700987	ABS 0.8148 0.9126 0.9126 0.8675 0.8776	Thick (mm) 2.856 2.602 3.060 2.926 2.949	Final Dose (kGy) 34.8 37.8 37.4 37.6	Comment
Trie         Sea         Coordinate         Batch- Cal Dt         Spectro SIN         Micrometer SIN         Micro meter SIN         Micro meter SIN         Thick (mm)         Dise (KSM)         Commany           1         2         245         NM (0527/2015)         4324039         MX 700987         0,8148         2.856         3.4.8         Commany         9.4.8         0.0.4.8<		Coordinat 2 245 3 2E5 4 TBA5 5 TBE5	Image: Teal Dt         Batch - Cal Dt           NM (05/27/2015)         NM (05/27/2015)           NM (05/27/2015)         NM (05/27/2015)           NM (05/27/2015)         NM           NM (05/27/2015)         3           ord (kGy):         3	Spectro S/N 4324039 4324039 4324039 4324039 4324039 4324039 34.8 37.8	Micrometer <u>SN</u> MK 700987 MK 700987 MK 700987 MK 700987	ABS 0.8148 0.7651 0.9126 0.8675 0.8776	Thick (mm) 2.856 2.602 3.060 2.926 2.949	Final Dose (kGy) 34.8 37.8 37.6 37.6	Comment
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Prepared By: Signed On 8/2/2015 at 12:33 AM UTC / GMT Official (Supervisor I)		) ()	Approved By: Maria H Greco (QS Document Content Revi	S/RC Techniciar	ſ		Signed On 8/3/2015 al UTC / GMT Offset (hlr.mm):	. 7:49 AM -4:00	

### 9.7 Appendix G Assembled Sensor Certificate: Particulates

	Lynx No	n-visible	Particle Test Met	nod Final Re	ероп
				••••••••••	
	Test Article:	Test via EMI	D Millipore Method		
		Lot: 114053	B-XXX		
	Durchase Order	(1140538-03	31, 032)		
	Laboratory Number:	768241			
	Study Received Date:	21 Jul 2014			
	Test Procedure(s):	Standard Te	st Protocol (STP) Number:	STP0011 Rev 07	
		Protocol Nur Sponsor Pro	nber: tocol Number:	201203604 Rev 01 00081563TM	
		00011301110		0000100011	
9	Immary: Particulate ma	atter is defined	in the USP as extraneous mo	bile undissolved sul	ostances other than
ga	as bubbles, unintentional	ly present in or	on a solution or device. All te	est method acceptan	ce criteria were met.
Te	esting was performed in	compliance w	ith US FDA good manufactu	ring practice (GMP)	regulations 21 CFR
Pa	arts 210, 211 and 820.				
Li	ght Obscuration: The te	st articles were	tested using the HIAC Rovco	b Liquid Particle Cou	nting System (LPC),
	1 1 10 700 71				1 5 61
M	odel #9703. The counter	r detects and s	izes particles using a light-obs	scuration sensor. Th	e LPC's sensor was
M	odel #9703. The counte alibrated by the manufact ze ranges listed in the	r detects and s turer in accord results tables.	izes particles using a light-obs ance with ASTM F 658 using Testing was conducted to	scuration sensor. Th polystyrene latex pa ensure compliance	e LPC's sensor was rticles, including the with the applicable
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******	Lynx Non-Visibl	Laboratory Number 768241 e Particle Test Method Final Report
LABORATORIES		
Acceptance Criteria: Light Obscuration: Test Method: Controls are wi	thin range.	
USP <788> and EP 2.9.19 R in/on medical devices.	equirements: There are no USP or EP spec	ifications for particulate matter found
Volume	≥ 10 µm	≥ 25 µm
Large	≤ 25 Particles/mL	≤ 3 Particles/mL
Small	≤ 6,000 Particles/Container	≤ 600 Particles/Container
		dh FRT0011-0001 Pay 5
		FRIDUIT-DUDI Rev 5



Sponsor: Nick Troise PendoTECH 3490 US-1 Building 15F Princeton, NJ 08540

### Sizing and Counting Particulate Matter: Light Obscuration Method Final Report

Test Article:	PTPL-PREPS- Single Use Port Plate Pressure Sensor with O-rings / Lot #1192002 Lot #1192003
Purchase Order	L0L#1192004
Purchase Order:	2014579
Study Number:	1269654-S01
Study Received Date:	20 Feb 2020
Testing Facility:	Nelson Laboratories, LLC
	6280 S. Redwood Rd.
	Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0011 Rev 11
Deviation(s):	None

Summary: Particulate matter is defined in the USP as extraneous, mobile, undissolved substances, other than gas bubbles, unintentionally present in a solution (or in/on a device). All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Light Obscuration: Testing was performed using the HIAC Royco Liquid Particle Counting System (LPC), Model #9703. The counter detects and sizes particles using a light-obscuration sensor. The LPC's sensor was calibrated by the manufacturer using polystyrene latex particles from 2  $\mu$ m – 100  $\mu$ m. Testing was conducted to ensure compliance with the applicable standard listed in the interpretation of results section.



Sho Asai electronically approved for Study Director

Nereyda Avelar

27 Feb 2020 18:30 (+00:00) Study Completion Date and Time

801-290-7500 nelsonlabs.com sales@nelsonlabs.com

FRT0011-0001 Rev 11 Page 1 of 2



Study Number 1269654-S01 Sizing and Counting Particulate Matter: Light Obscuration Method Final Report

Results: Values are rounded to the nearest whole number. If present, results reported as "0" do not necessarily indicate that zero particles were detected.

Light Obscuration: Test Article:

Test Article	Particles/Device						
Test Article	≥ 10 µm	≥ 25 µm					
S1, 1192002	174	16					
S2, 1192002	49	2					
S3, 1192002	92	20					
S1, 1192003	242	24					
S2, 1192003	66	10					
S3, 1192003	158	4					
S1, 1192004	46	0					
S2, 1192004	125	20					
S3, 1192004	39	6					

#### Control:

Environment Contr	ol (Particles/25 mL)	Positive Control (Particles/mL)					
Identification	≥ 10 µm	≥ 10 µm	≥ 25 µm				
S1-S3, 1192002	10						
S1-S3, 1192003	5	120	30				
S1-S3, 1192004	4						

#### Test Method Acceptance Criteria:

Light Obscuration: The environment control must have no more than a total of 25 particles ≥ 10 µm when adding the counts of all five aliquots (25 mL total). The positive control must exceed the USP <788> large volume criteria.

#### Interpretation of Results:

#### Light Obscuration:

USP <788> and EP 2.9.19 Requirements: There are no USP or EP specifications for particulate matter found in/on medical devices.

Volume	≥ 10 µm	≥ 25 µm
Large	≤ 25 Particles/mL	≤ 3 Particles/mL
Small	≤ 6,000 Particles/Container	≤ 600 Particles/Container

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### 9.8 Appendix H- Assembled Sensor Certificate: Bioburden (Sample Report & Q4 2021 Summary)



Sponsor: Russell Pope Utah Medical Products, Inc. 7043 S. 300 W. Midvale UT 84047

### **Bioburden Final Report**

Study Number:	1180131-S01
Test Article:	Press - N-050 1190034 Qty. = 3
Purchase Order:	N/A
Study Received Date:	07 May 2019
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 201801596 Rev 1
Deviation(s):	None
Testing Facility: Test Procedure(s): Deviation(s):	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A. Standard Test Protocol (STP) Number: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 201801596 F None

Summary: The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in accordance with ANSI/AAMI/ISO 11737-1:2018. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results: When bioburden results are calculated using a validated software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms.

Unit Number	Aerobic	Fungal
1	3	<3
2	3	<3
3	3	<3
Averages	3.1	<3.2

< = No Organisms Detected

Note: The results are reported as colony forming units per test article.

Note: Method Suitability testing was performed under Nelson Laboratories study #1157573, 1126674, 1091884. The test article was not inhibitory using this test method.

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results.

#### Procedure:

Extract Fluid:	Peptone Tween®
Extract Method:	Manual Shaking
Plating Method:	Membrane Filtration



Rob	ert J. Putna	m e	lectronically a	opro	ved		15 May 2019 20:3	6 (+00:00)
Study	y Director				Robe	rt J. Putnam	Study Completion D	ate and Time
8	801-290-7500	Т	nelsonlabs.com	1	sales@nelsonlabs.com			Page 1 of 2
Results	apply to the samples a	a receiv	ed and relate only to the tea	t article	isted in this report. Reports may not be reproduced except in the	eir entirety. Subject to NL te	ma & conditions at www.nelsonlabs.com.	Rev. 3.6.0

Study Number 1180131-S01 Bioburden Final Report



Agar Medium: Potato Dextrose Agar Tryptic Soy Agar Aerobic Bacteria: Plates were incubated 3 - 7 days at 30-35°C, then enumerated. Fungal: Plates were incubated 5 - 7 days at 20-25°C, then enumerated.

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P/NUsed			PRESS	-N-025	PBESS-	- N-050	PRESS	-N-050	PREPS	N-050	PBEPS-	- N-050	SPREPS	S-N-000	PRESS-	N-050	PRESS	-N-050	PRESS	-N-050	PBES	S-N-025	PRESS	-N-050
			Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fundal	Aerobic	Fungal
Unit Number 1			38	<3	11	<3	3	<3	12	<3	3	<3	13	<3	11	<3	<3	<3	<3	<3	19	<3	5	<2
2			22	<3	72	<3	3	<3	19	6	12	3	28	<3	6	<3	<3	<3	<3	<3	39	3	<3	<3
3			46	<3	83	<3	<3	<3	3	3	3	<3	37	<3	<3	<3	<3	<3	<3	<3	12	3	2	<2
Averages			35.2	<3.0	55.5	<2.9	<2.8	<2.8	11.2	<4.1	5.9	<3.1	25.8	<2.9	< 6.7	<3.1	<2.9	<2.9	<3.0	<3.0	23.2	<3.0	<3.4	<2.6
Year				20	16							20	17				2018							
Quarter	G	ŭ	G	12	Q	3	G	14	G	Q1 Q2 Q3 Q4						(	21	0	22		Q3	G	)4	
P/NUsed	DDECC	-N-050	PREPS	-N-025	PRESS-	N-050	DDDDCC	AL OF O		N-025			DDDDC	-N-025	PREPS-	N-075	DDFSS	-NL025	Inneed			C N OFO	PRESS	-N-050
1	PRESS	-14-030	THEFT			14 000	PHEDD	-14-050	PREPS	14-025	PREPS-	N-025	PREPS	-14-025			FHEUG	-14-025	FRESS	5-N-075	PRES	000-010-000		
	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	N-025 Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal
Unit Number 1	Aerobic 9	Fungal <3	Aerobic <3	Fungal <3	Aerobic <3	Fungal <3	Aerobic 6	Fungal <3	Aerobic 3	Fungal <3	Aerobic <3	N-U25 Fungal <3	Aerobic 8	Fungal <3	Aerobic 6	Fungal <3	Aerobic 3	Fungal <3	Aerobic 3	Fungal 3	PRES Aerobic <3	Fungal <3	Aerobic 5	Fungal <3
Unit Number 1 2	Aerobic 9 3	Fungal <3 <3	Aerobic <3 <3	Fungal <3 <3	Aerobic <3 3	Fungal <3 <3	Aerobic 6 6	-IN-050 Fungal <3 <3	Aerobic 3 3	Fungal <3 <3	Aerobic <3 18	N-025 Fungal <3 <3	Aerobic 8 6	Fungal <3 <3	Aerobic 6 10	Fungal <3 <3	Aerobic 3	Fungal <3 <3	Aerobic 3 <3	-N-U75 Fungal <3 <3	Aerobic <3 6	Fungal <3 <3	Aerobic 5 <3	Fungal <3 <3
Unit Number 1 2 3	Aerobic 9 <3	Fungal <3 <3 <3	Aerobic <3 <3 <3 <3	Fungal <3 <3 <3	Aerobic <3 3 3	Fungal <3 <3 11	Aerobic 6 6 6	-IN-050 Fungal <3 <3 <3	Aerobic 3 3 3 3	Fungal <3 <3 <3	Aerobic <3 18 16	N-U25 Fungal <3 <3 <3	Aerobic 8 6 <3	Fungal <3 <3 3	Aerobic 6 10 <3	Fungal <3 <3 <4	Aerobic 3 5 <3	Fungal <3 <3 <3	Aerobic 3 <3 <3	-N-U75 Fungal <3 <3 <3	Aerobic <3 6 9	Fungal <3 <3 <3	Aerobic 5 <3 9	Fungal <3 <3 <3
Unit Number 1 2 3 Averages	PHE35 Aerobic 9 <3 3 <b>&lt;4.9</b>	Fungal <3 <3 <3 <2.9	Aerobic <3 <3 <3 <2.9	Fungal <3 <3 <3 <b>&lt;2.9</b>	Aerobic <3 3 3 <b>&lt;2.9</b>	Fungal <3 <3 11 <b>&lt;5.8</b>	PRE35 Aerobic 6 6 6 6	-N-050 Fungal <3 <3 <3 <b>&lt;3</b>	Aerobic 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Fungal <3 <3 <3 <3 <2.8	PREPS- Aerobic <3 18 16 <b>&lt;12.4</b>	N-U25 Fungal <3 <3 <3 <b>&lt;3</b>	PREPS Aerobic 8 6 <3 <b>&lt;5.7</b>	Fungal <3 <3 <3 <b>3</b> <2.8	Aerobic 6 10 <3 <b>&lt;6.5</b>	Fungal <3 <3 <4 <3.2	Aerobic 3 5 <3 <b>&lt;3.6</b>	Fungal <3 <3 <3 <3 <3.0	Aerobic 3 <3 <3 <2.9	-N-U75 Fungal <3 <3 <3 <b>&lt;2.9</b>	PRES Aerobic <3 6 9 <b>&lt;6</b>	Fungal <3 <3 <3 <3 <3.3	Aerobic 5 <3 9 <b>&lt;5.7</b>	Fungal <3 <3 <3 <3
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### 9.9 Appendix I- Assembled Sensor Certificate: Endotoxins



RIGHT. FROM THE START."

### TEST RESULT CERTIFICATE

Sponsor Address	PendoTECH 174 Nassau St. Suite 256		Technical Initiation Technical Completion	6/5/201 6/5/201
Contact P.O. Number	Princeton, NJ 08542 Dennis Annarelli 2013567		Report Date Final Non-GLP Report	6/12/201 19-01947-N
Test Article	PendoTECH Single Use Pressure Sensors Post 40 kGy Gamma Irradiation	Ratio	1 Unit/120.0 mL	
Lot/Batch #	Not Supplied by Sponsor	Vehicle	USP Sterile Water for Inje	ection (SWFI)
Sterility	Sterile	Storage Condition	Room Temperature	
Study	Chromogenic Endotoxin Testing			
	Pouches containing devices tested includ Test Article 1: Lot 1181571 Test Article 2: Lot 1171477 (pouch open Test Article 3: Lot 1171477 (pouch open	ded the followi ) )	ing information:	
Comments	Sponsor Request: Suspend device by ca liquid to get barbed "T" section fully imme of the white cable/wire that is attached to	ble thus imme ersed, includin the device.	ersing sensors' clear polysul ng device's fluid path. Avoid i	fone body in immersing any
	The pH of Test Article 1 (Lot 1181571) w Article 2 (Lot 1171477 (pouch open)) was Article 3 (Lot 1171477 (pouch open)) was	as 7.51 and d s 7.32 and did s 7.32 and did	id not need to be adjusted. I not need to be adjusted. Ti I not need to be adjusted.	The pH of Test he pH of Test

REFERENCES: The study was conducted based upon the following references: USP 42, NF 37, 2019. <85> Bacter Endotoxins Test. ISO 10993-12, 2012 Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials. ANSI/AAMI ST72:2011 Bacterial Endotoxins - Test Methods, Routine Monitoring, and Alternatives to Batch Testing.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

**GENERAL PROCEDURE:** The test articles (3 units) were identified by information on the product packaging provider by the Sponsor. The barbed "T" section and fluid path of each test article were individually immersed in 120.0 mL of SWFI heated to  $37 \pm 1$  °C and extracted at room temperature for  $60 \pm 2$  minutes. The extract was assayed in duplicat at the neat concentration. A standard curve of endotoxin was prepared in duplicate with concentrations of 0.005, 0.05 0.5, and 5 EU/mL. A positive product control (PPC) for each dilution was prepared containing 0.09 mL of the extract a 0.01 mL of the 5 EU/mL endotoxin standard to give a final concentration of 0.5 EU/mL. Water for Bacterial Endotoxins Test (BET) and SWFI served as the negative controls. The microtiter plate was pre–incubated in the plate reader at  $37 \pm 1$  °C for  $\ge 10$  minutes. After incubation, Lysate (0.1 mL) was added to each well and the absorbance of each well 405 nm was read every 150 seconds for a total of 40 data points or until the concentration eached 0.2 absorbance units. The Kinetic QCL reader used the initial reading of each well as its own blank. The absolute value of the correlation coefficient (r) must be  $\ge 0.980$  in order for the test to be valid. The study and its design employed methodology to minimize uncertainty of measurement and control of bias for data collection and analysis.

> 15 Wiggins Ave., Bedford MA 01730 > 800.458.4141 > Main: 781.275.3330

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Chromogenic Endotoxin Testing Final Non-GLP Report: 19-01947-N2 Test Article Name: PendoTECH Single Use Pressure Sensors Post 40 kGy Gamma Irradiation

RESULTS:

			TABLE 1: Endotoxin Quar	ntity		
Test Article	Sample	pН	Dilution	EU/mL	EU/Device	Valid PPC (Yes/No)
PendoTECH	Test Article 1: Lot 1181571	7.51	Neat	< 0.00500	< 0.6	Yes
Pressure Sensors Post	Test Article 2: Lot 1171477 (pouch open)	7.32	Neat	< 0.00500	< 0.6	Yes
Gamma	Test Article 3: Lot 1171477 (pouch open)	7.32	Neat	< 0.00500	< 0.6	Yes

CONCLUSION: The absolute value of the correlation coefficient for the linear regression was calculated to be 0.997. Each test article, PendoTECH Single Use Pressure Sensors Post 40 kGy Gamma Irradiation, contains < 0.00500 EU/mL and < 0.6 EU/Device of bacterial endotoxin and meets the requirements of USP <85>, Bacterial Endotoxins Test.

### AUTHORIZED PERSONNEL:

<u>Ashley H. Chateauneuf</u> Ashley G. Phateauneuf, B.S. Quality Asburance

Linda Haggerty, M.S Study Director

www.toxikon.com



Sponsor: Ryan Usgaard Utah Medical Products, Inc. 7043 S. 300 W. Midvale UT 84047

### Bacterial Endotoxins Test Final Report

Study Number:	1247118-S01
Test Article:	Retort# 112719-1
	DPT Kits
	PRESS-S-000 - 1191776 (1)
	ABC-328NP - 1192177 (2)
Purchase Order:	55533
Study Received Date:	04 Dec 2019
Testing Facility:	Nelson Laboratories, LLC
	6280 S. Redwood Rd.
	Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0046 Rev 15
	Customer Specification Sheet (CSS) Number: 201700276 Rev 7
Deviation(s):	None

Summary: The Bacterial Endotoxins Test (BET), or *Limulus* Amebocyte Lysate (LAL) test, is an *in vitro* assay to detect and quantify bacterial endotoxin, a component of the cell wall of Gram negative bacteria. Standard controls and a positive product control (PPC) demonstrate a compliant assay. A PPC recovery within the 50%-200% range indicates that the test solution is free of interfering factors given the specific conditions of the test. If applicable, dilutions are calculated into the reported endotoxin level. All test method acceptance criteria were met.

The testing was conducted in accordance with the following regulatory documents: ANSI/AAMI ST72:2011/(R)2016, USP <161>, USP <85>, EP 2.6.14, and JP 4.01. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Kinetic Turbidimetric Results:

Quantity	Extraction Volume	Detected Endotoxin	PPC Recovery
3 (Pooled)	30 mL/device	<0.00500 EU/mL or <0.149 EU/device	143%

Endotoxin Limit: The endotoxin limit provided by the sponsor is not more than 20 EU/device.

Maximum Extraction Volume: With an endotoxin limit of 20 EU/device, tested with an assay sensitivity of 0.005 EU/mL, the maximum amount of extraction liquid that can be used is 4000 mL/device.



Shauna Gowans electronically approved for		09 Dec 2019 20:46 (+	+00:00)
Study Director	Christine Lundgreen	Study Completion Date	and Time
801-290-7500   nelsonlabs.com   sales@nelsonlabs.com		P	age 1 of 2
Results apply to the samples as recieved and relate only to the test article listed in this report. Reports may no	t be reproduced except in their entirety. Subject to NL term	a & conditions at www.neisoniaba.com.	Rev. 3.4.0

Study Number 1247118-S01 Bacterial Endotoxins Test Final Report

Test Method Acceptance Criteria: The following conditions were met as part of a compliant assay:

- The absolute value of the correlation coefficient of the standard curve is ≥0.980
- The blank value is less than the endotoxin detection limit of the lysate reagent employed
- The coefficient of variation (CV) between replicates is ≤10%

Nelson Labs.

Validation: The validity of the test requires demonstration that the test solution does not inhibit or enhance the assay. Validation of the kinetic BET is accomplished with the PPC. The PPC recovery must be between 50-200%. A PPC recovery of <50% suggests inhibition and a recovery of >200% suggests enhancement.

Preparation: The fluid pathway was flushed with endotoxin free water that had been heated to  $37 \pm 1^{\circ}$ C. The extraction liquid was kept in contact with the relevant fluid pathway for greater than one hour at room temperature (18-25°C). Additional components were extracted under the same parameters as the fluid pathway extraction. However, they were immersed in the extraction liquid. The extraction liquid from the fluid pathway and the additional components were combined for testing.

Test Procedure: The assay was performed at a sensitivity of 0.005 EU/mL using Charles River reagents.

801-290-7500 nelsonlabs.com sales@nelsonlabs.com

Page 2 of 2 Rev. 3.4.0

### 9.10 Appendix J- Assembled Sensor Certificate: Bacteriostasis & Fungistasis Testing

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### TEST RESULT CERTIFICATE

Sponsor	PendoTECH	Technical Initiation	2/8/2019
Address	174 Nassau Street	Technical Completion	2/13/2019
	Ste.256		
	Princeton, New Jersey 08542		
Contact	Dennis Annarelli	Report Date	2/15/2019
P.O. Number	2013094	Final Non-GLP Report	19-00365-N1

Test Article	PendoTECH Single Use Pressure Sensor Polysulfone Post Gamma Irradiation (>40KGy)
Lot/Batch #	Not Supplied by Sponsor
Study	Method Suitability Test via Membrane Filtration – USP
Comments	None

REFERENCES: The study was conducted based upon the following references: USP 41, NF 36, 2018. <71> Sterility Tests.

ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

GENERAL PROCEDURE: Six (6) test articles were supplied by the Sponsor for testing. A quanticult of Bacillus subtilis (B. subtilis), Aspergillus brasiliensis (A. brasiliensis, formerly known as Aspergillus niger), Pseudomonas aeruginosa (P. aeruginosa), Staphylococcus aureus (S. aureus), Candida albicans (C. albicans), and Clostridium sporogenes (C. sporogenes) all consisting of 10-100 CFU were used. Cultures were rehydrated according to manufacturer's instructions.

Each test article were individually immersed in 100 mL of sterile Fluid D in a sterile bag. A volume of 98 mL of extract was recovered and aseptically membrane filtered. Following membrane filtration and rinse with 10 mL of sterile Phosphate Buffered Saline (PBS), the filters were directly transferred (one unit per vessel) into 100 mL of sterile Trypticase Soy Broth (TSB) and 100 mL of sterile Fluid Thioglycollate medium (FTM). One TSB vessel was inoculated with *Bacillus subtilis*. One TSB vessel was inoculated with *Candida albicans*. The third TSB vessel was inoculated with *Aspergillus brasiliensis*. One FTM vessel was inoculated with *Pseudomonas aeruginosa*. One FTM vessel was inoculated with *Staphylococcus aureus*. The remaining FTM vessel was inoculated with *Clostridium sporogenes*.

As positive controls, an equivalent number of TSB and FTM vessels were inoculated with the respective organisms. One TSB and one FTM vessel were un-inoculated and served as negative controls. A volume of 20 mL of PBS and 20 mL of Fluid D of the same lot used was membrane filtered and the filters were put in respective containers containing 100 mL of TSB each. All TSB vessels were incubated aerobically at 20-25 °C for 5 days. All FTM vessels except *C. sporogenes* were incubated aerobically at 30-35 °C for 5 days. FTM vessels with *C. sporogenes* were incubated ananerobically at 30-35 °C for 5 days. Growth was visually compared between test and control articles at specific time points.

RESULTS: The growth of each organism was independent of the presence of the test article. Growth was observed for all organisms and test article media conditions in TSB by Day 3. No growth was observed in the negative control, Fluid D, and PBS.

			Sie	mity valuation	Nesuits 1	50			
				Growth (+	/-) per Mediu	ım			
David	Constant States		Orga	nism			Magating		
Day	B. si	ubtilis	C. al	bicans	A. bra	siliensis	Control	Fluid D	PBS
	With TA	Without TA	With TA	Without TA	With TA	Without TA	Control		
1	W	W	W	W	W	W	W	W	W
2	W	W	w	W	w	W	W	W	W
3	+	+	+	+	+	+	-	-	-
4	+	+	+	+	+	+	-	-	-
5	+	+	+	+	+	+	-	-	-

TABLE 1: Sterility Validation Results – TSB

TA = Test article, W = Weekend, (-) = No Growth, (+) = Growth

### Toxikon Corporation 15 Wiggins Ave., Bedford, MA 01730 USA 1.800.458.4141 Main: 1.781.275.3330

# τοχικοπ

### Method Suitability Test via Membrane Filtration – USP Final Non-GLP Report: 19-00365-N1 Test Article Name: PendoTECH Single Use Pressure Sensor Polysulfone Post Gamma Irradiation (>40KGy)

and the second	Les Portes and	Contraction of the	NE O THE ST	Growth (+	/-) per Mediu	ım			S. Barrent
			Orga	inism	Selection of		Mogativo		112.65
Day	C. spo	rogenes	S. a	ureus	P. aer	uginosa	Control	Fluid D	PBS
	With TA	Without TA	With TA	Without TA	With TA	Without TA	control		1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.
1	W	W	W	W	W	W	W	W	W
2	w	W	w	W	W	W	W	W	w
3	+	+	+	+	+	+	-	-	-
4	+	+	+	+	+	+	-	-	-
5	+	+	+	+	+	+	-	-	-

CONCLUSION: The test articles are considered non-bacteriostatic and non-fungistatic, according to the USP guidelines.

### AUTHORIZED PERSONNEL:

Johr Lugo-Toro,/B.S Quality Assurance

MBS For

Aparajita Mukherjee, M.S. Study Director

www.toxikon.com

# **Certificate Of Processing**

Prepared for EMD MILLIPORE - BEDFORD



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### Gamma Process Run ID 117005A

Product Code	Product Lot Number	Quantity	
40-60 SAMPLES	0020499769	Guantity	UOM
Cust Item ID: CAT. NO. CDRF1TN05		.1	CS
40-60 SAMPLES	0021039608		
Cust Item ID: CAT. NO. CDRF4HN05		1	CS
40-60 SAMPLES	0022897176	82	100
Cust Item ID: CAT. NO. CDRM8HN05		1	CS
40-60 SAMPLES	MGBE620/MGDM180		2
Cust Item ID: 20277484/00123958DR		1	CS
40-60 SAMPLES	NA		
Cust Item ID: PENDOTECH POLYSULFONE SENSORS		1	CS
	6		

PO Number: N1402721

Processing Run Start Date/Time:	20-Jan-2019	10:07:00 pm	Approx. Downtime (hours):	3.82
Processing Run End Date/Time:	21-Jan-2019	04:04:00 am		
Minimum Specified Dose (kGy):	40.0		Minimum Delivered Dose (kGy):	42.1
Maximum Specified Dose (kGy):	60.0		Maximum Delivered Dose (kGy):	50.8
Product meets Custor	mer specificat	ions; zero nonci	onformities occurred during this irradiation run.	
Reviewed and E-Signed By		Signature	Manifest Signed On 1/21/2019 at 8	48 AM
. Francine Maranda (Q	S & RC Ana	lyst)	UTC / GMT Offset (hh.mm) -5:0	0
Document Content Revision	: 1			
Processing Location: STERIS 435 Whitney Street Northborough, MA 01532 Phone: 508-393-9323 Fax: 844-698-9776	Operating fa and OSHA) EN/ISO 134 ANSI/AAMI/ items receive	cilities are in compli and provide service 55, and in elignmen SO 11135. For iten ad the indicated dos	ance with applicable state and federal regulations (FDA, NR s under a quality system which meets the requirements of FD with the applicable standard, EN ANSI/AAM/ISO 11137 or is processed with gamma irradiation, STERIS cartifies that th ras within the precision and accuracy of the dosimetry system	C. EPA DA QSR. EN Hese h usød.
1-00034/01354/01369 Last Rev in Rel. 3.6.5.1			Release Date 05. http://www.snar	Base 1

9 ÷							
1	tod:	Northbo 126, Nor	orough rdion Cobalt-60 Irradia	ttor #126, ON-	STD		
12000	Coordin	nate	Barcode ID	Insert	Instrument	Dose (kGv)	Final Dose (KGV)
3	rements						
-	0C1		0BR600288204	TH0049	0484	28.7	42.1
			0BR600257802	TH0048	0481	13.4	
N	TAS		0BR600288439	TH0049	0484	34.4	50.5
			0BR600257878	TH0048	0481	16.1	
3	TES		0BR600288499	TH0049	0484	34.7	50.8
			0BR600257886	TH0048	0481	16.1	
	Minim	num Dose	for Record (kGy):	42	5		
	Maxim	num Dose	e for Record (kGy):	5	8.		
					Signature A	Manifest	
-	\$	Baez,	ed By: Hector (Material I	Handler)			Signed On 1/21/2019 at 6:23 AM UTC/ GMT Offset (Intimul): -5:00
-	\$	Approv	ed By: ine Maranda (QS	& RC Analy	()st		Signed On 1/21/2019 at 8:47 AM UTC/ GMT Offset (httmm): -5:00
-		Docume	ent Content Revision:	-			

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### 9.11 Appendix K- Certificates of Gamma Irradiation for Sensor Accuracy Testing (7.2 & 7.3)

		STERIS Ison	nedix Service	es Dosimetr	y Record	
		Dat	• Prepared: 6/6/20	Process Run I 007 9:36:02AM	D 44637A	
Processir	ng Location:	Northborough				
Irradiator	/ Method:	126, Nordion Co	balt-60 Irradiator	#126, ON-STD		
Dosimete	er Batch:	Harwell, Batch	IH, Calibration Dat	te 10/24/2006 5	:00:00AM	
Spectrop	hotometer	Beckman, DU-6	40, Serial #432435	5		
Digital Mi	icrometer:	Mitutoyo, Micro	meter, Serial #010	04		
				Calc	Final Doge (kGy)	Comment
Carrier	Seq Coordi	nate <u>ABS</u>	Thick (mm)	Dose (KGV)	DOSETROM	
<u>Carrier</u> 1	Sea Coordi 1 0C1	nate <u>ABS</u> 0.7006	<u>Thick (mm)</u> 2.968	27.9	27.9	
Carrier 1 1	Seq Coordi 1 0C1 2 3A1	inate <u>ABS</u> 0.7006 0.7917	<u>Thick (mm)</u> 2.968 2.959	27.9 34.3	27.9 34.3	

Last Dosimeter Absorbance Measurement Date/Time: 6/6/2007 6:24:17 AM

		Signature Manif	est		)
	Repared By: Jason Perry	Signed	l On: 6/6/2007 At:	5:26 AM GMT:-4:0	oc.
	S Approved By: Francine Mara	i <i>nda</i> Signed	0n: 6/6/2007 At:	9:36 AM GMT:-4:0	0
L	Document Content Revision:	1			
	Comment Legend: OUT = Calc	Dose Out of Limits; PID = Pre-	Irradiated Dosimeter, GR	P = Dosimeter Group	
Form:	00036.1 Rev: 2	Effective Date:	05-Mar-2007		Page 1 of 1

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			Date P	repared: 8/27/2	Process Run II 007 9:40:22AM	D 45954A	
Proces	ssing Loc	ation:	Northborough				
Irradia	tor / Meth	nod:	126, Nordion Cob	alt-60 Irradiator	#126, ON-STD		
Dosim	eter Bato	h:	Harwell, Batch JH	, Calibration Dat	e 10/24/2006 5:	00:00AM	
Spectr	ophotom	eter:	Beckman, DU-640	, Serial #432435	5		
Digital	Microme	ter:	Mitutoyo, Microme	eter, Serial #010	04		
					Calc	Final	
Carrier	Seq	Coordina	ate ABS	Thick (mm)	Dose (kGy)	Dose (kGy)	<u>Comment</u>
1	1	341	0.7621	3.048	30.6	30.5	
2	- 1	TAS	0.7269	2 603	37.0	37.3	
2	2	TE5	0.7954	2.904	35.7	35.7	

Last Dosimeter Absorbance Measurement Date/Time: 8/25/2007 6:38:46 PM

 Signature Manifest

 Prepared By:
 Pfty Ly

 Signed On:
 8/25/2007

 Approved By:
 Ken Moore

 Signed On:
 8/27/2007

 Approved By:
 Ken Moore

 Signed On:
 8/27/2007

 Approved By:
 Ken Moore

 Signed On:
 8/27/2007

 At:
 9:40 AM

 GMT:-4:00
 At:

 Document Content Revision:
 1

Comment Legend: OUT = Calc Dose Out of Limits; PID = Pre-Irradiated Dosimeter; GRP = Dosimeter Group

PROC-00036 Last Revised in Release 2.0.0.2

Release Date: 24-Jul-2007

Page 1 of 1

### 9.12 Appendix L- Certificate of Gamma Irradiation for 5 Year Shelf Life (7.9)

### Certificate Of Processing Prepared for ADVANCED SCIENTIFICS INC



Gamma Process Run ID 218180E

Product Code	Product Lot Number	Quantity	UOM
GROUP 63	B107340-I / 986D0-0000	1	CS
GROUP 69	JASON P SAMP / JASON P-SAMP	1	CS
GROUP 7	B108815-I / 9812S-0000	1	CS
GROUP 7	B108821-I/97Z0F-0000	1	CS
GROUP 7	B114909-I/981GD-0000	6	CS
GROUP 7	CTC-1730 / 982J6-0000	1	CS
GROUP 7	HM00018-1/985JF-0000	1	CS
GROUP 7	R8EVM / 9818Q-0000	1	CS
GROUP 82	B109704-I / 982RX-0000	1	CS
GROUP 82	B109718-I / 982RW-0000	1	CS

Processing Run Start Date/Time:	18-Mar-2019	06:06:03 am	Approx. Downtime (hours)	0.19
Processing Run End Date/Time:	18-Mar-2019	08:13:02 am		
Minimum Specified Dose (kGy):	27.5		Minimum Delivered Dose (kGy):	30.2
Maximum Specified Dose (kGy):	45.0		Maximum Delivered Dose (kGy):	40.2
Product meets Custor	ner specificat	ions, zero nonce	onformities occurred during this irradiation run.	
		Signature	Manifest	
Victoria Mullings (QS	& RC Tech	nician)	Signed On 3/19/2019 at 10 uTC / GMT Offset (Mr.mm) -4.0	:32 AM
Document Content Revision	c 1			
Processing Location:	Onersting f	volitios are a come	inner with amiliauble state and federal requisitour (EDA INB)	- EDA
STERIS 23 Elizabeth Drive Chester, NY 10918 Phone: 845-469-4087 Fax: 845-469-7512	end OSHA) EN/ISO 134 processed i system use	and provide service (85 and in alignment tems received the in d.	is under a quality system which meets the requirements of FO is with EN ANSUAAMUISO 11137 STERIS certifies itself there dicated doses within the precision and accuracy of the dosm	A QSR. 4 ety
-00034/01354/01368 Last Rev In Rel. 3.6.5.1			Revenue Date 05-Jun-2017	Page 1

### 9.13 Appendix M- Calibration Certificate for Pressure Gauge Used in 8.1

<b>36</b>	CALIBRATIC	ON CEJ	RTIFICATE	PAGE 1 of
GE Druck UNIT UNDER TEST (UUT)			CALIBRATOR INFORM	IATION
Manufacturer	Druck	(*i)	Calibration Instrument	: DPI515
Type Number	DP1104		Serial Number	: 51501984
Serial Number	2936090		Calibrated Against	: UKAS 0221
Pressure Range	: 0 to 100 psi g	(*1)	Calibration Instrument	: Agilent 34401A
Pressure Connector	: 54 NPT Male		Serial Number	: MY45020018
Calibration Date	: 09 February 2009		Calibrated Against	: UKAS 0221

### PRESSURE PERFORMANCE 20°C (\*1)

Actual Applied Value psi	Unit Under Test Reading psi (*2)	Unit Under Test Deviation (*5)	Permissible Deviation (*4)
-0.00	-0.00	0.000 %6	±0.035 %ß
20.00	20.00	0.000 %ds	+0.035 %6
39.99	40.00	0.010 %fs	±0.035 %fa
59.99	60.00	0.010 %fs	±0.035 %fs
79.99	79.99	0.000 %E	±0.035 %6s
99.99	99.99	0.000 %/6	±0.035 %6s
50.00	50.00	0.000 %6	±0.035 %fs
0.01	0.00	-0.010 %/s	±0.035 %fs

### ANALOGUE PERFORMANCE 20°C (\*1)

Voltage Setpoint %	Analogue Output Reading V (*2)	Unit Under Test Deviation	Pennisable Deviation (*4)
2	0.100	-0.001 %fs	±0.095 %fs
20	0.999	-0.013 %fs	±0,095 %fs
40	2.000	-0.009 %fs	±0.095 %fs
60	2.999	-0.016 %ifs	40.095 %fs
80	3.999	-0.011 %fs	±0.095 %fs
100	4.999	-0.012 %45	±0.095 %ifs

Certified by:

10 FEB 2009 Date:

### NOTES

- (\*1) Tracable to relevant International Standards (recluding NSST).
- (\*2) Actual recorded values. For specification, see Permissible Deviation column.
- (\*3) Deviation calculated from UUT Reading minus Actual Applied Value
- (\*4) Non linearity, hysterisis, temperature effects and repeatability.

### P51074 V1.02

Druck Ltd., Fir Tree Lawe, Groby, Leicestershire Ltd: OPH.

www.gesensing.com

### 9.14 Appendix N- Calibration Certificate for Pressure Gauge Used in 8.2

### CALIBRATION CERTIFICATE



그는 말 같은 것 같은 것 같은 것 같은 것 같이 많이 많이 많이 했다.		
GE Dargkunder TEST (UUT)	CALIBRATOR INFORM	IATION
Manufacturer : Druck Type Number : DPI104 Serial Number : 2460830	Calibration Instrument Serial Number (*1) Calibrated Against	: DPI515 : 51501984 : UKAS 0221
Pressure Range: 0 to 100 pPressure Connector: ¼ NPT MCalibration Date: 10 Januar	si g ale Calibration Instrument / 2007 Serial Number (*1) Calibrated Against	: Aligent 34401A : MY45020018 : UKAS 0221

### PRESSURE PERFORMANCE 20°C (\*1)

psi	psi	(*2) Deviation	(*3)	(*4)
0.00	0.00	0.000 %fs		±0.035 %fs
19.99	20.00	0.010 %fs		$\pm 0.035$ %fs
39.99	39.99	0.000 %fs		±0.035 %fs
59.99	59.99	0.000 %fs		±0.035 %fs
79.98	79.99	0.010 %fs		±0.035 %fs
99.98	99.98	0.000 %fs		±0.035 %fs
50.00	50.00	0.000 %fs		±0.035 %fs
0.01	0.01	0.000 %fs		±0.035 %fs

ANALOGUE PERFORMANCE 20°C (\*1)

Voltage Setpoint %	Analogue Output Reading V (*2)	Unit Under Test Deviation	Permissible Deviation (*4)
2	0.100	0.005 %fs	±0.095 %fs
20	1.000	0.002 %fs	±0.095 %fs
40	2.000	-0.001 %fs	±0.095 %fs
60	2.999	-0.022 %fs	±0.095 %fs
80	3.999	-0.019 %fs	±0.095 %fs
100	4.999	-0.026 %fs	±0.095 %fs

Certified by:

Date: [1/107

### NOTES

- (\*1) Traceable to relevant International Standards (including N.I.S.T.).
- (\*2) Actual recorded values. For specification, see Permissible Deviation column.

MS

- (\*3) Deviation calculated from UUT Reading minus Actual Applied Value.
- (\*4) Non linearity, hysterisis, temperature effects and repeatability.

### PS1074 V1.01.00

Druck Ltd, Fir Tree Lane, Groby, Leicestershire LE6 OFH. www.gesensing.com

### 9.15 Appendix O- Calibration Certificate for Pressure Gauge Used in 8.5 and 8.6

		®	NIST	Frace	able		AEPORT NUMBER	
Fast Bunke	or Court	C	alibrat	ion F	Report	D.	former Number 400024	
non Hills, Ill	inois 60061	o t.			P	K	PO Number: RANDD	
847-327-2993 Innocalsolutio	3 ons.com γ 7	263183-00 P	Per 3490 B rinceton, NJ	ndotech ) US Rte 1  dg 15 F 08540 Uni	ted States			
Ianufacture Iodel Numb Jescription: sset Numbe erial Numbe	er: Druck Inc. ber: DPI 104 0-1 Pressure, D er: CP21618 er: 2936090	00 PSI igital Gauge, 0-100 PS	\$1		Calibratio Calibratio Condition Condition	n Date: n Due Date: As Found: As Left:	04/25/2014 04/25/2015 In Tolerance In Tolerance, No adjust	ment
Procedure: Remarks: NIST-trad lab's stand	DS Universa ceable calibration pe dard operating proce	al Pressure Gauge-10 erformed on the unit reference adures. No adjustments w	renced above vere made to t Standa	in accorda he unit. r <b>ds Ut</b> i	nce with custo	omer requireme	nts, published specificatio	ns and the
Asset No.	Manufacturer	Model N	lo.	Descrip	tion		Cal. Date	Due Dat
CP05091	DH Instruments In	nc. PPC3-70 A700KS/	OK G100KS	Pressure	, -14.7 to 100	psi Calibrator	12/31/2013	12/31/20
			Calibr	ation I	Data			
FUNCTI	ON TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tal	CALIBRATION TOLER	ANCE
Inc	reasing	0.000 psi	0.00		Same		-0.050 to 0.050 psi	57-11
	I 10.000 p		10.00		Same		9.950 to 10.050 psi [EMU 0.0012 psi][TUR 41:1]	
1 20.0		20.000 psi	20.00		Same		19.950 to 20.050 psi [EMU 0.0031 psi][TUR 16:1]	
	4	30.000 psi	30.00		Same		29.950 to 30.050 psi [EMU 0.0031 psi][TUR 1	6:1]
	1	40.000 psi	40.00		Same		39.950 to 40.050 psi [EMU 0.0040 psi][TUR 1	2:1]
	1	50.000 psi	50.00		Same		49.950 to 50.050 psi [EMU 0.0050 psi][TUR 9	.9:1]
	1	60.000 psi	60.01		Same		59.950 to 60.050 psi [EMU 0.0060 psi][TUR 8	3:1]
	1	70.000 psi	70.01		Same		69.950 to 70.050 psi [EMU 0.0070 psi][TUR 7	1:1]
	1	80.000 psi	80.01		Same		79.950 to 80.050 psi [EMU 0.0080 psi][TUR 6	2:1]
	3	90.000 psi	90.01		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5	.5:1]
	1	100.000 psi	100.00		Same		99.950 to 100.050 ps [EMU 0.010 psi][TUR 5.1	0:1]
Dec	reasing	90.000 psi	90.00		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5.	5:1]
	1	80.000 psi	80.01		Same		79:950 to 80.050 psi [EMU 0.0080 psi][TUR 6.	2:1]
		70.000 psi	70.01		Same		69.950 to 70.050 psi [EMU 0.0070 psi][TUR 7.	1:1]
		60.000 psi	60.01		Same		59.950 to 60.050 psi [EMU 0.0060 psi][TUR 8.	3:1]
	1	50.000 psi	50.01		Same		49.950 to 50.050 psi [EMU 0.0050 psi][TUR 9.	9:1]
		40.000 psi	40.00		Same		39.950 to 40.050 psi [EMU 0.0040 psi][TUR 1.	2:1]
	1	30.000 psi	30.00		Same		29.950 to 30.050 psi [EMU 0.0031 psi][TUR 10	B:1]
		20.000 psi	20.00		Same		19.950 to 20.050 psi [EMU 0.0031 psi][TUR 1/	5:1]





Thermo



Calibration Data						
FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
	10.000 psi	10.00		Same		9.950 to 10.050 psi [EMU 0.0012 psi][TUR 41:1]
1	0.000 psi	0,00		Same		-0.050 to 0.050 psi [EMU 0.00075 psi][TUR 67:1]

Temperature:	20° C	Calibration Performed By:			Quality Reviewer:		
Rot No :	41% HH	Santos, Daniel	Metrologist	847-327-5837	Pietronicco, Mike	4/25/2014	
rept. 11044	010000	Name	Title	Phone	Name	Date	

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Report Number: 578968



Druck Inc. / DPI 104 0-100 PSI, Pressure, Digital Gauge, 0-100 PSI







### 9.16 Appendix P- Calibration Certificate for Vacuum Gauge used in 8.2 and 8.5



625 East Bunker Court Vernon Hills, Illinois 60061 PH: 866-466-6225 Fax: 847-327-2993 www.innocalsolutions.com





Reference Number: 578526 PO Number MHUJBER102814

Pendotech 3490 US Rte 1 Bldg 15 F Princeton, NJ 08540 United States

**Crystal Engineering** Manufacturer: Model Number: 15PSIXP2I Pressure, Digita Description: Asset Number: CP140081 364027 Serial Number: Procedure: DS Universal Pressure Gauge-10

al Gauge 15 PSI	
raccura Gauga 10	

Calibration Date:	10/28/2014
Calibration Due Date:	10/28/2015
Condition As Found:	In Tolerance
Condition As Left:	In Tolerance, No a

-----

djustment

Remarks: NIST-traceable calibration performed on the unit referenced above in accordance with customer requirements, published specifications and the lab's standard operating procedures. No adjustments were made to the unit. Standards Utilized

Standards Offized							
Asset No.	Manufacturer	Model No.	Description	Cal. Date	Due Date		
CP05091	DH Instruments Inc.	PPC3-700K A700KS/G100KS	Pressure, -14.7 to 100 psi Calibrator	12/31/2013	12/31/2014		

UNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Increasing	-13.5000 psi	-13,500		Same		-13.5360 to -13.4640 psi [EMU 0.00070 psi][TUR 51:1]
1	-11.1000 psi	-11,101		Same		-11.1360 to -11.0640 psi [EMU 0.00070 psi][TUR 51:1]
1	-8.2000 psi	-8.201		Same		-8.2360 to -8.1640 psi [EMU 0.00070 psi][TUR 51:1]
1	-5,3000 psi	-5.301		Same		-5.3360 to -5.2640 psi [EMU 0.00070 psi][TUR 51:1]
1	-2.4000 psi	-2.401		Same		-2.4360 to -2.3640 psi [EMU 0.00070 psi][TUR 51:1]
1	0.5000 psi	0,500		Same		0.4970 to 0.5030 psi [EMU 0.00049 psi][TUR 6.1:1]
1	3.4000 psi	3.400		Same		3.3966 to 3.4034 psi [EMU 0.00055 psi][TUR 6.2:1]
I	6.3000 psi	6.300		Same		6.2937 to 6.3063 psi [EMU 0.00073 psi][TUR 8.6:1]
1	9.2000 psi	9.201		Same		9.1908 to 9.2092 psi [EMU 0.00099 psi][TUR 9.3:1]
1	12.1000 psi	12.100		Same		12.0879 to 12.1121 psi [EMU 0.0013 psi][TUR 9.7:1]
1	15.0000 psi	15.001		Same		14.9850 to 15.0150 psi [EMU 0.0015 psi][TUR 9.9.1]
Decreasing.	12.1000 psi	12,101		Same		12.0879 to 12.1121 psi [EMU 0.0013 psi][TUR 9.7:1]
1	9.2000 psi	9.201		Same		9.1908 to 9.2092 psi [EMU 0.00099 psi][TUR 9.3:1]
1	6.3000 psi	6.301		Same		6.2937 to 6.3063 psi [EMU 0.00073 psi][TUR 8.6:1]
1	3.4000 psi	3.401		Same		3.3966 to 3.4034 psi [EMU 0.00055 psi][TUR 6.2:1]
1	0.5000 psi	0.501		Same		0.4970 to 0.5030 psi [EMU 0.00049 psi][TUR 6.1:1]
1	-2.4000 ps	-2.400		Same		-2.4360 to -2.3640 psi [EMU 0.00070 psi][TUR 51:1]
T.	-5.3000 psi	-5.300		Same		-5.3360 to -5.2640 psi

P Cole-Parmer



(D) DIGI-SENSE.



FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
	-8.2000 psi	-8.201		Same		-8.2360 to -8.1640 psi [EMU 0.00070 psi][TUR 51:1]
98	-11,1000 psi	-11.101		Same		-11.1360 to -11.0640 psi [EMU 0.00070 psi][TUR 51:1]
A.	+13.5000 psi	+13.501		Same		-13.5360 to -13.4640 psi [EMU 0.00070 psi][TUR 51:1]

Temperature:	21° C	<b>Calibration Perform</b>	ed By:		Quality Reviewer:		
Rot No :	46% HH 668824	Santos, Daniel	322	Metrologist	847-327-5837	Pietronicco, Mike	10/28/2014
Kpt. No.:	000024	Name	1D #	Title	Phone	Name	Date

 Name
 Diff
 Table
 Phone
 Name
 Date

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 The results stated in this report relate only to the items tested or

 calibrated.
 Measurements reported herein are traceable to S1 units via relional standards maintained by NIST and were performed in compliance with

 MIL\_STD-45682A, ANSI/NCSL Z540-1-1994, 10CFR50, Appendix B, ISO 9002-94, and ISO 17025-2005, Guard Banding, if reported on this certificate is

 applied at a Z-factor of 30% for test points with a test uncertainty ratio (TUR) below 4:1. The estimated measurement uncertainty (EMU), if reported on

 this certificate, is being reported at a confidence level of 95% or K=2 unless otherwise noted in the remarks section

Report Number: 668824









### 9.17 Appendix Q- Calibration Certificate for Temperature Monitor Used in 8.7

	NIST Traceable	685467		
625 East Bunker Court Vernon Hills, Illinois 60061	Calibration Report	Reference Number: 591452 PO Number: RANDD		
Ph. 804-406-6225 Fax: 847-327-2993 www.innocalisclutions.com	Pendotech 3490 US Rte 1 Bidg 15 F Princeton, NJ 08540 United States			
Manufacturer: Oakton	Calibration Date:	12/29/2014		

Calibration Date:	12/29/2014
Calibration Due Date:	12/29/2015
Condition As Found:	In Tolerance
Condition As Left:	In Tolerance, No adjustment

Remarks: NIST-traceable calibration performed on the unit referenced above in accordance with customer requirements, published specifications and the Tab's standard operating procedures. No adjustments were made to the unit.

# Standards Utilized Asset No. Manufacturer Model No. Description Col. Date Due Date

ADDEL IND.	Internation-ration	moder no.	Description	Our Duto	DOC DUIC
CP50148	Fluke Corporation	5522A	Calibrator, Multifunction	07/23/2014	07/23/2015
	and the second	and the second sec	And in the design of the second state of the s		

FUNCTION TESTED	Nominal Value	As Found	Out at Ial	As Left	Out of Tel	CALIBRATION TOLERANCE
Temperatura Accuracy	-35.00 °C	-35.00		Same		-35.03 to -34.07 "C (EMU 0.0058 "C[[TUR 5 1:1]
1	0.00 °C	0.00		Same		-0.03 to 0.03 °C JEMU 0.0568 °C JUH 5 2-1
1	75.00 °C	75.00		Same		74.97 to 75.00 °C [EMU 0.0061 °C][TUR 4.9.1]
1	150.0 %	119.9		Same		119.9 to 120.1 "C [EMU 0.056 "C][TUR 1.7:1]
1	145.0 °C	144.5		Same		144.5 to 145.5 'C [EMU 0.058 'C][TUR 8.6 1]

Temperature:	21° C
Humidity:	30% RH
Rpt. No.:	685467

 Calibration Performed By:
 Quality Reviewer;

 Tayag, Asher A
 305
 Metrologist
 847-327-6305
 Pietronicco, Mike
 12/29/2014

 Name
 10.8
 Take
 Name
 Bate

RpL No.1 069-467 1939s, restart is 340 intertempting Bit Valchesus Intertempting Bit Intertemptis Bit Intertempting Bit I









Page 1 of 1

### 9.18 Appendix R- Calibration Certificate for Pressure Gauge Used in 8.4



625 East Bunker Court Vernon Hills, Illinois 60061 PH: 866-466-6225 Fax: 847-327-2993 www.innocalsolutions.com

NIST Traceable **Calibration Report** 



Reference Number: 128806 PO Number: 2006026

No adjustment

Pendotech 3490 US Hwy 1 Bldg 15 E Princeton, NJ 08540

	Developed and	Calibration Data	06/07/2011
Manufacturer:	Druck Inc.	Calibration Date:	00/07/2011
Model Number:	DPI 104 0-100 PSI	Calibration Due Date:	06/07/2012
Description:	Pressure, Digital Gauge, 0-100 PSI	Condition As Found:	In Tolerance
Asset Number:	CP21618	Condition As Left:	In Tolerance,
Serial Number:	2936090		
Procedure:	Compass for Pressure		
Remarks:			

NIST-traceable calibration performed on the unit referenced above in accordance with customer requirements, published specifications and the lab's standard operating procedures. No adjustments were made to the unit. Measured data can be found on page 2.

### Standards Utilized

Asset No.	Manufacturer	Model No.	Description	Cal. Date	Due Date
CP05091	DH Instruments Inc.	PPC3-7MA7KSG100KS	Calibrator, Pressure, Master 30-0-100psi	11/02/2010	11/02/2011

		Calibration Performed By:			Quanty Keviewer:	PERMITS PRODUCTS SUS
Temperature:	21° C					
Rpt. No.:	162225	Santos, Daniel	Metrologist	847-327-5837 Phone	Ziegler, Jeff Name	6/7/2011 Date

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Page 1 of 2



625 East Bunker Court Vernon Hills, Illinois 60061 PH: 866-466-6225

PH: 866-466-6225 Fax: 847-327-2993 www.innocalsolutions.com NIST Traceable

### Calibration Report As Found / As Left Data



Test Number 162225

# As Found / As Left Data

<b>UUT</b> Informa	tion					
Manufacturer:	Druck			Identification:	CP21618	
Model:	DPI 104 0-100PSI			Senal Number:	5836080	
Range:	0.000 to 100.000 psi			Data Acquisition Method	: Manual	
Accuracy:	0.05 %FS			Date Tested:	Jun 7 2011	
Technician:	Daniel Santos					
Test Data				12723	1973/32	
	Reference	UUT	Abs.	% Span	UUT	
Set Pt	Pressure	Pressure	Error	Error	Tolerance	Status
psi	psi	psi	psi	%	psi	-
0.000	0.000	0.0000	0.0000	0.0000	0.0500	Pass
10.000	10.000	10.0000	0.0000	0.0000	0.0500	Pass
20.000	20.000	20.0000	0.0000	0.0000	0.0500	Pass
30.000	30.000	30.0000	0.0000	0.0000	0.0500	Pass
40.000	40.000	40.0000	0.0000	0.0000	0.0500	Pass
50.000	50.000	50.0000	0.0000	0.0000	0.0500	Pass
60.000	60.000	60.0100	0.0100	0.0100	0.0500	Pass
70.000	70.000	70.0100	0.0100	0.0100	0.0500	Pass
80.000	80.000	80.0100	0.0100	0.0100	0.0500	Pass
90.000	90.000	90.0100	0.0100	0.0100	0.0500	Pass
100.000	100.000	100.0000	0.0000	0.0000	0.0500	Pass
90.000	90.000	90.0100	0.0100	0.0100	0.0500	Pass
80.000	80.000	80.0100	0.0100	0.0100	0.0500	Pass
70.000	70.000	70.0100	0.0100	0.0100	0.0500	Pass
60.000	60.000	60.0100	0.0100	0.0100	0.0500	Pass
50.000	50.000	50.0100	0.0100	0.0100	0.0500	Pass
40.000	40.000	40.0000	0.0000	0.0000	0.0500	Pass
30.000	30.000	30.0000	0.0000	0.0000	0.0500	Pass
20.000	20.000	20.0000	0.0000	0.0000	0.0500	Pass
10.000	10.000	10.0000	0.0000	0.0000	0.0500	Pass
0.000	0.000	0.0000	0.0000	0.0000	0.0500	Pass

### Calculations

First Order Fit Equation: y = 9.998857E-01x + 1.155301E-03 Linearity: 0.0082 %UUTSpan Hysteresis: 0.0100 %UUTSpan

Measurement Uncertainty: 0.0251 psi



Data report may bel comporteduced instant to the instruction permission of history. The results stated in this report rearies and you me must perform a calibration of the DUT. Measurements tuborted tenses are instructed to SI under via realized and another tenses are instructed to set of the results and under a state of the DUT. Measurements tuborted tenses are instructed to SI under via realized and an operation of the DUT. Measurements tuborted tenses are instructed to SI under via realized and another tenses are instructed to set of the DUT. Measurements tuborted tenses are instructed to SI under via realized and another tenses are instructed to set of the DUT. Measurements tuborted tenses are instructed to set of the DUT. Measurement to NUSC and tenses are instructed to set of the DUT. Measurement to NUSC and tenses are instructed to set of the DUT. Measurement to NUSC and tenses are instructed to set of the DUT.

### 9.19 Appendix S- Calibration Certificate for Pressure Gauge Used in 8.8

625 East Bunke Vernon Hills, III	BRATIC er Cour inois 6	N SOLUTIONS		C	NIST Calibra	<i>Trace</i> tion F	able Report		Reference Ni PO Ni	1457083 imber: 126990 imber: RANDD	1
Fin: 800-468-6225 Fax: 847-327-2993 www.innocalsolutio	3 ons.com	1			P 349	endotech 0 US Route Bldg 15F	1				
					Princeton, N.	08540 Uni	led States				
Manufacture Model Numb Description: Asset Numbe Serial Numbe	er: C F F F: C	Druck Inc. DPI 104 Pressure, Dig DP91719 8674169	tal Pressu	ire Indica	itor		Calibratio Calibratio Condition Condition	n Date: n Due Date: As Found: As Left:	07/30/2 07/30/2 In Tolera In Tolera	2018 2019 ance ance, No adjust	ment
Procedure: Remarks: NIST-trac lab's stan	E cable c dard op	DS Universal alibration performanced	Pressure ( ormed on th ures. No a	G <b>auge-1</b> he unit ref djustment	erenced above s were made t Standa	e in accordar o the unit. urds Uti	nce with custo	mer requiren	ients, publis	hed specification	ons and the
Asset No.	Man	ufacturer		Model	No.	Descrip	tion	1000		Cal. Date	Due Dat
CP05091	DH In	struments Inc.		PPC3-7 A700KS	00K //G100KS	Pressure,	-14.7 to 100	osi Calibrator		04/24/2018	04/30/201
-					Calib	ration l	Data				
FUNCTI	ON TES reasing	STED	Nominal 0 000	Value	As Found	Out of Tel	As Left	Out of Tol	CALIBR	ATION TOLER	ANCE
	1				0.01		aame		[EMU	0.00075 ps)[TUR	67:1]
	÷		10.000	pasi	9.99		Same		9 (EMU	950 to 10.050 ps 0.0012 psil[TUR	41:11
	<u>1</u>	_	20.000	psi	19.99		Same		19 [EMU	0.950 to 20.050 ps 0.0031 psi][TUR	ii 16:1]
			30.000	psi	29.99		Same		29 [EMU	0.0031 psi[[TUR 1	ü 16.1]
	10		40.000	psi	39.98		Same		39 [EMU	950 to 40.050 ps 0.004 psi[[TUR 1	i 2.1]
			50.000	psi	49.98		Same		49 (EMU	950 to 50.050 ps 0.005 psi][TUR 9	i 9:1]
	1		60.000	psi	59.96		Same		59 [EMU	950 to 60.050 ps 0.006 psi)[TUR 8	i 3.1]
			70.000	psi	69.98		Same		69 IEMU	950 to 70.050 ps	i 1-11
	1		80.000	psi	80.01		Same		79	950 to 80.050 ps	9.41
	1		90.000	psi	90.01		Same		89	950 to 90.050 ps	2.11
	1		100.000	psi	100.01		Same		1(EMU 99	950 to 100.050 ps	0.1) I
Dec	easing		90.000 j	osi	90.01		Same		(EMU 89	950 to 90.050 ps 0.009 oslittue s	5:11
	1		80.000 p	iei	80.01		Same		79	950 to 80 050 ps	
	1		70.000 g	isi	70.01		Same		[EMU	950 to 70.050 psi	£1]
	1		60.000 p	15	60.01		Same		(EMU 59	0 007 psi)[TUR 7. 950 to 60 050 psi	1:1]
	I		50.000 p	si	50.01		Same	-	[EMU 49	0 006 psi][TUR 8 : 950 to 50 050 psi	3:1]
	1		40.000 p	si	40.01		Same		[EMU 0 39	0.005 psi][TUR 9.9 950 to 40.050 psi	9:1]
	1		30.000 p	si	30.00		Same		[EMU 29	0.004 psi][TUR 12 950 to 30.050 psi	E1]
	-								(EMU C	0.0031 psiliTUR 1	5(1)

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tel	CALIBRATION TOLERANCE
	20 000 psi	20.00		Same		19.950 to 20.050 psi [EMU 0.0031 psi][TUR 16.1]
	10.000 psi	10.00		Same		9.950 to 10.050 psi [EMU 0.0012 psi][TUR 41:1]
	0.000 psi	0.00		Same		-0.050 to 0.050 psi

Temperature:	21º C	Cali
Humidity:	54% KH	
Rpt. No.:	1457083	Gon

<b>Calibration Performe</b>	d By:		and a start	Quality Reviewer:	and the second
Gonzalez, Jaime	303	Metrologist	847-327-5322	Szplit, Tony	07/30/2018
Name	ID #	Title	Phone	Name	Date

This report may not be reproduced, exoch in full without writen permission of monocil. The results stated in file from the feeled or centrated Measurements reported hyrein are traceable to SL units we result and and the feeled by NIST and wree performed in compliance with ML-STD-456624. AVXIVOSL 2540-1-1994 10CFR90 Appendix BLISD 9003-94 and 180 17075 2005 Guard Bending. If reported on this service with ML-STD-456624. AVXIVOSL ancertainty rate (TUR) below 4.1. In Television confidence are based on least failing within specified with results with no reduction by the uncertainty of the measurement. The estimated measurement uncertainty (EMU), if reported on this performance are officience areas failing.

Report Number: 1457083



Druck Inc. / DPI 104. Pressure, Digital Pressure Indicator



(D) DIGI-SENSE



### 9.20 Appendix T- Gamma Certificate for sensors used in 7.10/8/10

Gamma Process Run ID 1	87014C		
Product Code	Product Lot Number	Quantity	UON
BROUP 62	B108761-I / 92059-0000	8	CS
BROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS
ROUP 7	B105146-I / 90879-0000	39	CS
ROUP 7	B105421-I / 92696-0000	1	CS
ROUP 7	B110621-I / 92968-0000	1	CS
ROUP 82	7201R / 92944-0000	1	CS
ROUP 82	7202R / 92945-0000	1	CS
ROUP 82	B102828-I / 92994-0000	1	CS
ROUP 82	B103135-I / 92995-0000	2	CS
ROUP 82	B105206-I / 90950-0000	1	CS
ROUP 82	B108824-I / 92963-ENDO	1	CS
Processing Run Start Date/Time: Processing Run End Date/Time:	13-Jun-2016 01:06:12 am Approx. Downtime (hours): 13-Jun-2016 03:21:09 am	0.08	Long PL Destructured
Processing Run Start Date/Time: Processing Run End Date/Time: Minimum Specified Dose (ku	13-Jun-2016       01:06:12 am       Approx. Downtime (hours):         13-Jun-2016       03:21:09 am         Gy):       27.5       Minimum Delivered Dose (kGy):	0.08	an Colorence Proc Provinsi and
Processing Run Start Date/Time: Processing Run End Date/Time: Minimum Specified Dose (ku Maximum Specified Dose (ku	13-Jun-2016       01:06:12 am       Approx. Downtime (hours):         13-Jun-2016       03:21:09 am         Gy):       27.5       Minimum Delivered Dose (kGy):         Gy):       45.0       Maximum Delivered Dose (kGy):	0.08 30.9 40.1	a Split During Co. McLevels. PDC & Providential
Processing Run Start Date/Time: Processing Run End Date/Time: Minimum Specified Dose (ku Maximum Specified Dose (ku Product meets (	13-Jun-2016       01:06:12 am       Approx. Downtime (hours):         13-Jun-2016       03:21:09 am         Gy):       27.5       Minimum Delivered Dose (kGy):         Gy):       45.0       Maximum Delivered Dose (kGy):         Customer specifications; zero nonconformities occurred during this irradiation run         Signature Manifest	0.08 30.9 40.1	mention figures contractivity constrained and the conductor
Processing Run Start Date/Time: Processing Run End Date/Time: Minimum Specified Dose (ki Maximum Specified Dose (ki Product meets ( Product meets ( Product meets ( Content Reviewed and E-Sign Tracy Wild (QS/R Document Content Re	13-Jun-2016       01:06:12 am       Approx. Downtime (hours):         13-Jun-2016       03:21:09 am       Approx. Downtime (hours):         Gy):       27.5       Minimum Delivered Dose (kGy):         Gy):       45.0       Maximum Delivered Dose (kGy):         Customer specifications; zero nonconformities occurred during this irradiation run         Signature Manifest         ad By       Signed On 6/14/2016 a         C Technician)       UTC / GMT Offset (hh:mm):         vision:       1	0.08 30.9 40.1 1. t 8:31 AM -4:00	Speed for spicitum of prevention

Commo Process F	Pup ID 187290D			
Broduct Code	F	Product Lot Number	Quantity	UON
Product Code		SAMPLE JASON / SAMPLE JASON	I-0000 1	CS
GROUP 69		B103911-I / 93000-0000	1	CS
GROUP 7		B105122-I / 93538-0000	1	CS
GROUP 7		B106519-I / 93405-0000	1	CS
		B110708-I / 93402-0000	1	CS
		B103522-I / 91941-0000	1	CS
		B110706-I / 93401-0000	1	CS
SROUF 02				
Processing Run Start D	ate/Time: 21-Jun-2016 04:20	:15 pm Approx. I	Downtime (hours): 0.1	56
Processing Run Start D Processing Run End Da	ate/Time: 21-Jun-2016 04:20 ate/Time: 21-Jun-2016 07:00	:15 pm Approx. I :08 pm Minimum Delivered	Downtime (hours): 0.0	66
Processing Run Start D Processing Run End Da Minimum Specified	ate/Time: 21-Jun-2016 04:20 ate/Time: 21-Jun-2016 07:00 I Dose (kGy): 27.5	:15 pm Approx. I :08 pm Minimum Delivered	Downtime (hours): 0.1	56
Processing Run Start D Processing Run End Da Minimum Specified Maximum Specifie	ate/Time: 21-Jun-2016 04:20 ate/Time: 21-Jun-2016 07:00 d Dose (kGy): 27.5 d Dose (kGy): 45.0	:15 pm Approx. I :08 pm Minimum Delivered Maximum Delivered	Downtime (hours): 0.0	36
Processing Run Start D Processing Run End Da Minimum Specified Maximum Specifie Proc	ate/Time: 21-Jun-2016 04:20 ate/Time: 21-Jun-2016 07:00 d Dose (kGy): 27.5 d Dose (kGy): 45.0 duct meets Customer specifications; z	:15 pm Approx. I :08 pm Minimum Delivered Maximum Delivered tero nonconformities occurred during	Downtime (hours): 0.0 I Dose (kGy): 31.1 d Dose (kGy): 40.0 g this irradiation run.	66
Processing Run Start D Processing Run End Da Minimum Specified Maximum Specifie Proc	ate/Time:       21-Jun-2016       04:20         ate/Time:       21-Jun-2016       07:00         d Dose (kGy):       27.5         d Dose (kGy):       45.0         duct meets Customer specifications; z	:15 pm Approx. 1 :08 pm Minimum Delivered Maximum Delivered tero nonconformities occurred during tero nonconformities occurred during	Downtime (hours): 0.1	66
Processing Run Start D Processing Run End Da Minimum Specified Maximum Specifie Proc	ate/Time: 21-Jun-2016 04:20 ate/Time: 21-Jun-2016 07:00 d Dose (kGy): 27.5 d Dose (kGy): 45.0 duct meets Customer specifications; z	:15 pm Approx. I :08 pm Minimum Delivered Maximum Delivered tero nonconformities occurred during tero nonconformities occurred during	Downtime (hours):         0.1           I Dose (kGy):         31.1           d Dose (kGy):         40.0           this irradiation run.	36
Processing Run Start D Processing Run End Da Minimum Specifie Maximum Specifie Proc	ate/Time:       21-Jun-2016       04:20         ate/Time:       21-Jun-2016       07:00         d Dose (kGy):       27.5         d Dose (kGy):       45.0         duct meets Customer specifications; z	:15 pm Approx. 1 :08 pm Minimum Delivered Maximum Delivered tero nonconformities occurred during tero nonconformities occurred during unature Manifest Sign urc /	Downtime (hours): 0.1 I Dose (kGy): 31.1 d Dose (kGy): 40.0 this irradiation run. ed On 6/22/2016 at 9:36 AM (GMT Offset (hh:mm): -4:00	36
Processing Run Start D Processing Run End Da Minimum Specified Maximum Specifie Proc	ate/Time:       21-Jun-2016       04:20         ate/Time:       21-Jun-2016       07:00         d Dose (kGy):       27.5         d Dose (kGy):       45.0         duct meets Customer specifications; z         Sig         and E-Signed By         helmke (QS/RC Technician)         content Revision:	:15 pm Approx. 1 :08 pm Minimum Delivered Maximum Delivered tero nonconformities occurred during tero nonconformities occurred during tero nonconformities occurred during	Downtime (hours):         0.1           I Dose (kGy):         31.1           d Dose (kGy):         40.0           this irradiation run.           ed On 6/22/2016 at 9:36 AM           'GMT Offset (hh:mm):         -4:00	66
Processing Run Start D Processing Run End Da Minimum Specified Maximum Specifie Proc Reviewed Brandon Document	ate/Time:       21-Jun-2016       04:20         ate/Time:       21-Jun-2016       07:00         d Dose (kGy):       27.5         d Dose (kGy):       45.0         duct meets Customer specifications; z         duct meets Customer specifications; z         since         and E-Signed By         and E-Signed By	15 pm Approx. 1 08 pm Minimum Delivered Maximum Delivered tero nonconformities occurred during unature Manifest Sign urc.	Downtime (hours):         0.1           I Dose (kGy):         31.1           d Dose (kGy):         40.0           t this irradiation run.	36

### 9.21 Appendix U- Calibration Certificate for Pressure Gauge used in 8.10

INN	0	C		8
INNOVATIVE	CALIBRA	TION SO	LUTIO	NS

625 East Bunker Court Vernon Hills, Illinois 60061 PH: 866-466-6225 Fax: 847-327-2993 www.innocalsolutions.com NIST Traceable Calibration Report



Reference Number: 734817 PO Number: RANDD

PendoTECH 3490 US Route 1 Princeton, NJ 08540 United States

Manufacturer:	Druck Inc.
Model Number:	DPI 104
Description:	Pressure, Digital Pressure Indicator
Asset Number:	4396848
Serial Number:	4396848
Procedure:	DS Universal Pressure Gauge-10
Remarks:	

<b>Calibration Date:</b>	03/21/2016
Calibration Due Date:	03/21/2017
Condition As Found:	In Tolerance
Condition As Left:	In Tolerance, No adjustment

NIST-traceable calibration performed on the unit referenced above in accordance with customer requirements, published specifications and the lab's standard operating procedures. No adjustments were made to the unit.

	Standards Othized											
Asset No.	Manufacturer	Model No.	Description	Cal. Date	Due Date							
CP05091	DH Instruments Inc.	PPC3-700K A700KS/G100KS	Pressure, -14.7 to 100 psi Calibrator	03/11/2016	03/31/2017							

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Increasing	0.000 psi	0.00		Same		-0.050 to 0.050 psi [EMU 0.00075 psi][TUR 67:1]
1	10.000 psi	10.00		Same		9.950 to 10.050 psi [EMU 0.0012 psi][TUR 41:1]
	20.000 psi	20.00		Same		19.950 to 20.050 psi [EMU 0.0031 psi][TUR 16:1]
4	30.000 psi	30.00		Same		29.950 to 30.050 psi [EMU 0.0031 psi][TUR 16:1]
,	40,000 psi	40.00		Same		39.950 to 40.050 psi [EMU 0.0040 psi][TUR 12:1]
J.	50.000 psi	50.00		Same		49.950 to 50.050 psi [EMU 0.0050 psi][TUR 9.9:1]
1	60.000 psi	60.00		Same		59.950 to 60.050 psi [EMU 0.0060 psi][TUR 8.3:1]
1	70.000 psi	70.01		Same		69.950 to 70.050 psi [EMU 0.0070 psi][TUR 7.1:1]
	80.000 psi	80.01		Same		79.950 to 80.050 psi [EMU 0.0080 psi][TUR 6.2:1]
1	90.000 psi	90.01		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5.5:1]
1	100.000 psi	100.01		Same		99.950 to 100.050 psi [EMU 0.010 psi][TUR 5.0:1]
Decreasing	90.000 psi	90.01		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5.5:1]
1	80.000 psi	80.01		Same		79.950 to 80.050 psi [EMU 0.0080 psi][TUR 6.2:1]
4	70.000 psi	70.01		Same		69,950 to 70.050 psi [EMU 0.0070 psi][TUR 7.1:1]
1	60.000 psi	60.01		Same		59,950 to 60.050 psi [EMU 0.0060 psi][TUR 8.3:1]
	50.000 psi	50.01		Same		49.950 to 50.050 psi [EMU 0.0050 psi][TUR 9.9:1]
	40.000 psi	40.00		Same		39.950 to 40.050 psi [EMU 0.0040 psi][TUR 12:1]
	30.000 psi	30.00		Same		29.950 to 30.050 psi (EMU 0.0031 psi/TUB 16.1)









Page 1 of 2

	Calibration Data											
FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE						
	20.000 psi	20.00		Same		19.950 to 20.050 psi [EMU 0.0031 psi][TUR 16:1]						
1	10.000 psi	10.00		Same		9.950 to 10.050 psi [EMU 0.0012 psi][TUR 41:1]						
1	0.000 psi	0.00		Same		-0.050 to 0.050 psi [EMU 0.00075 psi][TUR 67:1]						

Temperature:	21° C	<b>Calibration Perform</b>	ed By:	G, CUSHIC	Sale Sale	Quality Reviewer:	10.20
Rot No :	859693	Santos, Daniel	322	Metrologist	847-327-5837	Szplit, Tony	3/21/2016
tepte r ton	000000	Nome	ID 4	Tirle	Phone	Namu	Date

This report may not be reproduced, except in full, without written permission of Innocal. The results stated in this report relate only to the items tested or calibrated. Measurements reported herein are traceable to SI units via national standards maintained by NIST and were performed in compliance with MIL-STD-45662A, ANSI/NCSL 2540-1-1994, 10CFR50, Appendix B, ISO 9002-94, and ISO 17025/2005. Guard Banding, if reported on this certificate, is applied at a Z-lactor of 30% for test points with a test uncertainty ratio (TUR) below 4:1. The estimated measurement uncertainty (EMU), if reported on this certificate. Is being reported at a confidence level of 95% or K=2 unless otherwise noted in the remarks section.

Report Number: 859693









9.22 Appendix V – X-ray Certificate of Processing for section 7.11/8.11

■STERIS

# **Manual Certificate of Processing**

Prepared For: PENDOTECH

Processing Run ID: 10834-40001554

Product Code	Product Lot Number	Quantity	UOM
N/A	NA	1	cs

Other Information: Description: Single Use Sensors. PO # 2016692

Processing Run Start Date/Time:	07/14/2021, 7:24AM CST
Processing Run End Date/Time:	08/19/2021, 7:28AM CST
Approximate Downtime (Hours):	0.00

Minimum Specified Dose (kG	y): 50.0	Minimum Delivered	Dose (kGy):	61.8									
Maximum Specified Dose (k0	3y): 70.0	Maximum Delivered	Dose (kGy):	64.5									
A nonconformity occurred during this irradiation run - Reference Customer Disposition.													
Reference: NC-23394													
Comments: Dose added to meet requested dose range. Dose range within Customer													
requested dose range.													
Latrice Sutherland, & Jutton 08/23/2021, 07:27AM CST													
QA Manager Approval / Date	/ Time (Print and	Sign)											
Michael Ezzo 2020 8/23/2021 10:42AM EST Quality Zone Director Approval / Date / Time (Print and Sign)													
Processing Location: 2500 Commerce Drive Libertyville, IL. 60048 847-247-4782Operating facilities are in compliance with applicable state and federal regulations 													
WI-01678 Form: 2 Rev	: 0 Eff Date:	Oct 19, 2018 Status:	07b. Completed: All Gamma Facilities	Page 1 of 1									

		Measurement Source	13.1	49.8	12.5	49.3	13.5	50.3	12.8	49.0	13.6	50.9				10-20-20	
		<u>Final</u> Dose (kGy)	62.9	0.0	61.8	0.0	63.8	0.0	61.8	0.0	64.5	0.0			inal dose reports nificant figure.	12161	
cord n) s4 6:55AM		<u>Initial</u> Dose (kGy)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.8	4.5	ster location, the fi record is one sign	112 AUUN	
Oosimetry Re metry Systen PENDOTECH 10834-4000155 ed: 08/23/2021		Instrument	11-0186	11-0186	11-0186	11-0186	11-0186	11-0186	11-0186	11-0186	11-0186	11-0186	9	6	e for each dosime s reported on this	HTECH 1, 1	
IS Manual I anine Dosli Prepared For: ocess Run ID: J Time Prepar		Insert	.0040	.0040	,0040	.0040	.0040	.0040	.0040	.0040	.0040				is the acutal dos cation. The dose	sutherlan	
STER (AI Pro		Barcode ID	0BX592076386	0BX592026099	0BX592076219	0BX592020042	0BX592076365	0BX592020005	0BX592076319	0BX592020069	0BX592076103	0BX592026490	Record (kGy):	Record (kGy):	rement Source show osimeters for each loo	" Hauley M	
	5	Coordinate	-	-	2	2	ę	ň	4	4	9	ŝ	um Dose for	um Dose for	NC-23394. Measual devices the second of the second	e / Sign and Date tie / Sign and Da	
	ion:RTC d:EBIR-0;	Seq	÷	-	÷	-	÷	-	-	***	~	-	Minim	Maxim	Refer to the tot	Vame / Titl Name / Ti	
	Processing Locat Irradiator / Methou	Carrier	-	-	-	-	-	-	-	-	-	-			Other Information:	Prepared By Print I QA Approved Print	

Page 1 of 1

Eff Date: Oct 19, 2018 Status: 07b, Completed All Gamma Facilities

WI-01678, Form 1, Revision: 0

### 9.23 Appendix W- Calibration Certificate for Pressure Gauge Used in 8.11

VATIVE CALIBRATION SOLUTIONS 625 East Bunker Court Vernon Hills, Illinois 60061 PH: 866-466-6225

Fax: 847-327-2993

www.innocalsolutions.com

NIST Traceable **Calibration Report** 

PendoTECH 3490 US Route 1 Princeton, NJ 08540 United States

REPORT NUMBER 1662895 Reference Number: 1408403

Calibration Due Date: **Condition As Found:** Condition As Left:

In Tolerance In Tolerance, No adjustment

Manufacturer: Digi-Sense 68349-06 Pressure, Digital Gauge, 0 to 100 psig CP355333 1912310225 DS Universal Pressure Gauge-10



Model Number: Description: Asset Number: Serial Number: Procedure:

Remarks: NIST-traceable calibration performed on the unit referenced above in accordance with customer requirements, published specifications and the

	Standards Utilized											
Asset No.	Manufacturer	Model No.	Description	Cal. Date	Due Date							
CP144959	Fluke Corporation	PM600-A700K	Pressure, Measurement Mod -12.1 -100PSI	07/08/2021	07/31/2022							

Increasing	0.000 psi	0.00	Same	-0.250 to 0.250 pei
	10 000 psi			[EMU 0.00058 psi][TUR 428 1]
		9.98	Same	9.750 to 10.250 psi [EMU 0.0014 psi][TUR 175.1]
	20.000 psi	20.01	Same	19.750 to 20.250 psi [EMU 0.0054 psi][TUR 48.1]
1	30 000 psi	30.02	Same	29.750 to 30.250 psi [EMU 0.0059 psi][TUR 42.1]
	40 000 psi	40.02	Same	39 750 to 40 250 psi [EMU 0.0069 psi][TUR 36 1]
1	50.000 psi	50.01	Same	49.750 to 50.250 psi [EMU 0.0079 psi][TUR 32.1]
1)	60.000 psi	60.01	Same	59 750 to 60 250 psi [EMU 0.0089 psi][TUR 28 1]
1	70.000 psi	70.02	Same	69 750 to 70 250 psi [EMU 0.0099 psi][TUR 25:1]
1	80.000 psi	80.01	Same	79.750 to 80.250 psi [EMU 0.011 psi][TUR 23.1]
T.	90.000 psi	90.01	Same	89 750 to 90 250 psi [EMU 0.012 psi][TUR 21:1]
L.	100 000 psi	100.02	Same	99.750 to 100.250 psi [EMU 0.013 psi][TUR 19:1]
Decreasing	90.000 psi	90.02	Same	89.750 to 90.250 psi [EMU 0.012 psi][TUR 21:1]
	80.000 ps	80.02	Same	79 750 to 80 250 psi [EMU 0.011 psi][TUR 23 1]
L.	70.000 psi	70.02	 Same	69.750 to 70.250 psi [EMU 0.0099 psi][TUR 25.1]
1	60.000 psi	60.03	Same	59 750 to 60 250 psi [EMU 0 0089 psi][TUR 28 1]
1	50.000 psi	50.02	Same	49.750 to 50.250 psi [EMU 0.0079 psi][TUR 32.1]
1	40.000 psi	40.02	Same	39 750 to 40 250 psi [EMU 0.0069 psi][TUR 35 1]
1	30.000 psi	30.03	Same	29 750 to 30 250 psi [EMU 0.0059 psi][TUR 42 1]
1	20.000 psi	20.01	Same	19 750 to 20 250 psi [EMU 0.0054 psi][TUR 46:1]

Page 1 of 2

Calibration Data							
FUNCTION TESTED Nominal Value As Found Out of Tol As Left Out of Tol CALIBRATION TOLERAN							
	10.000 psi	9.99		Same		9.750 to 10.250 psi [EMU 0.0014 psi][TUR 175.1]	
1	0.000 psi	0.00		Same		-0.250 to 0.250 psi [EMU 0.00058 psi][TUR 428.1]	

Temperature:	19º C	Calibration Performed By:			Quality Reviewer:		
Rot. No.:	1662895	Fitzsimons, Sean	357	Metrologist	847-327-5305	Alexander, James	08/24/2021
		Name	ID #	Title	Phone	Name	Date



1







# 9.24 Appendix X- Assembled Sensor Certificate: ISO 10993-5 post X-ray irradiation- Polycarbonate (PRESS) and Polysulfone (PREPS)



### TEST RESULT CERTIFICATE

Sponsor Address	Pendo TECH 174 Nassau Street, Suite 256 Princeton New Jersey 08540	Techn Techn	ical Initiation ical Completion	1/4/2022 1/27/2022
Contact P.O. Number	Nick Troise 2017300	Report Final G	t Date GLP Report	3/16/2022 21-03845-G1
Test Article	PendoTECH Single Use Polycarbonate Pressure Sensors Post X-ray Irradiation (> 50kGy)	Ratio	3 cm <sup>2</sup> /mL	
Lot/Batch #	1210050	Vehicle	Serum-Supplemer (complete) Minimu Medium (MEM)	nted m Essential
Study	L929 MEM Elution Test - ISO			
Expiration Date	February 2026	Extraction Conditions	24 ± 2 hours at 37	± 1°C
Sterility Condition	Not Sterile	Storage Condition	Room Temperatur	e
Intended Use	Research and development - device	Safety Precautions	Standard Laborato Precautions	ry Safety
Comments	None			
Reference Article	PendoTECH Single Use Polycarbonate Pressure Sensors	Ratio	3 cm <sup>2</sup> /mL	
Lot/Batch #	1163277	Vehicle	Serum–Suppleme (complete) Minimu Medium (MEM)	nted m Essential
Study	L929 MEM Elution Test - ISO			
Expiration Date	January 2022	Extraction Conditions	24 ± 2 hours at 37	± 1°C
Sterility Condition	Sterile	Sterilization Conditions	Ethylene Oxide Sterilization	
Intended Use	Research and development – device	Storage Condition	-80°C ± 12°C	
Safety Precautions	Standard Laboratory Safety Precautions	1		
Comments	None			

REFERENCES: The study was conducted based upon the following reference: ISO 10993-5, 2009, Biological Evaluation of Medical Device – Part 5: Tests for *in vitro* cytotoxicity. ISO 10993–12, 2021, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials. ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

**GENERAL PROCEDURE:** The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. The test article extract was prepared as stated above. A positive control (Natural Rubber) article, negative control (Negative Control Plastic) article, and untreated control (blank) were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 ± 2 hours, at  $37 \pm 1$  °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity).

> 15 Wiggins Avenue, Bedford MA 01730 > 800.458.4141 > Main: 781.275.3330

Toxikon.com

# TOXIKON

L929 MEM Elution Test – ISO Final GLP Report: 21-03845-G1 Test Article Name: Pressure Sensors Post X-ray Irradiation (> 50kGy)

### EVALUATION CRITERIA:

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present, only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules, no extensive cell lysis; not more than 50% growth inhibition observable.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable.
4	Severe	Nearly complete or complete destruction of the cell layers.

The test article meets the requirements of the test if none of the cultures exposed to the test article extract show greater than a Mild Reactivity (Grade 2).

### **RESULTS:**

Time	Test Article	Control Article	Untreated Control	Negative Control	Positive Control
24 Hours	0	0	0	0	3
48 Hours	0	0	0	0	4

CONCLUSION: The test article meets the requirements of the test and is not considered to have a cytotoxic effect.

AUTHORIZED PERSONNEL:

Elizabeth Zamparelli, B.S. Quality Assurance

Nora Barakat, B.S. Study Director

### 

### TEST RESULT CERTIFICATE

Sponsor Address	PendoTECH 174 Nassau Street, Suite 256 Princeton, N.L. 08540	Tech Tech	3/4/2022 3/17/2022			
Contact P.O. Number	Nick Troise 2017300	Repo Final	5/20/2022 21-03844-G2			
Test Article	PendoTECH Single Use Polysulfone Pressure Sensors Post X-ray Irradiation (> 50kGy)	Ratio	3 cm <sup>2</sup> /mL			
Lot/Batch #	1191570	Vehicle	Serum–Supplemented (complete) Minimum Essentia Medium (MEM)			
Study	L929 MEM Elution Test - ISO					
Physical State	Not Supplied by Sponsor (N/S)	Color	N/S			
Expiration Date	July 2024	Stability	N/S			
Sterility	Not Sterile	Extraction Conditions	37 ± 1 °C for 24 ± 2 hours			
Sterility Condition	N/S	Storage Condition	n Room Temperature			
Intended Use	Research and development - device					
Comments	Per Sponsor request, only the Sensor Body was included for testing and the white cable was excluded from testing.					

REFERENCES: The study was conducted based upon the following reference: ISO 10993-5, 2009, Biological Evaluation of Medical Device – Part 5: Tests for *in vitro* cytotoxicity. ISO 10993–12, 2021, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials. ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

**GENERAL PROCEDURE:** The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article extract was determined. The test article extract was prepared as stated above. A positive control (Natural Rubber) article, negative control (Negative Control Plastic) article, and untreated control (blank) were prepared to verify the proper functioning of the test system. The test article or control article extracts were used to replace the maintenance medium of the cell culture. All cultures were incubated in triplicate for 48 ± 2 hours, at 37 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity).

### EVALUATION CRITERIA:

Grade	Reactivity	Conditions of all cultures
0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.
1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present, only slight growth inhibition observable.
2	Mild	Not more than 50% of the cells are round and devoid of intracytoplasmic granules, no extensive cell lysis; not more than 50% growth inhibition observable.
3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observable.
4	Severe	Nearly complete or complete destruction of the cell layers.

The test article meets the requirements of the test if none of the cultures exposed to the test article extract show greater than a Mild Reactivity (Grade 2).

> 15 Wiggins Avenue, Bedford MA 01730 > 800.458.4141 > Main: 781.275.3330

Toxikon.com

# тохікоп

L929 MEM Elution Test – ISO Final GLP Report: 21-03844-G2 Test Article Name: PendoTECH Single Use Polysulfone Pressure Sensors Post X-ray Irradiation (>50kGy)

**RESULTS:** 

Time Date		Те	ot Artic	alo				0	Control	s			
		Test Article		Untreated		Negative			Positive				
		A	В	С	A	В	С	A	В	С	Α	В	С
24 Hours	3/16/2022	0	0	0	0	0	0	0	0	0	4	4	4
48 Hours	3/17/2022	0	0	0	0	0	0	0	0	0	4	4	4

CONCLUSION: The test article meets the requirements of the test and is not considered to have a cytotoxic effect.

AUTHORIZED PERSONNEL:

Eliza h Zampai

Assurance Qualit

Nora Barakat, B.S. Study Director

www.toxikon.com

**STERIS** 

# **Manual Certificate of Processing**

## Prepared For: PENDOTECH Processing Run ID: 10834-40001554

Product Code	Product Lot Number	Quantity	UOM
N/A	NA	1	cs

Other Information: Description: Single Use Sensors. PO # 2016692

Processing Run Start Date/Time:	07/14/2021, 7:24AM CST
Processing Run End Date/Time:	08/19/2021, 7:28AM CST
Approximate Downtime (Hours):	0.00

Minimum Specified Dose (kGy	/): 50.0	Minimum Delivered Dose (kGy):	61.8					
Maximum Specified Dose (kG	Maximum Specified Dose (kGy): 70.0 Maximum Delivered Dose (kGy): 64.5							
A nonconformity occurred du	ring this irradiat	ion run – Reference Customer Dispo	sition.					
Reference: NC-23394								
Comments: Dose added to m	eet requested d	ose range. Dose range within Custon	ner					
requested dose range.								
Latrice Sutherland, X Juite	n 08/23/2021, 07:	27AM CST						
QA Manager Approval / Date /	Time (Print and	Sign)						
Michael Ezzo 200 B/23/2021 10:42AM EST Quality Zone Director Approval / Date / Time (Print and Sign)								
Processing Location:       Operating facilities are in compliance with applicable state and federal regulations         2500 Commerce Drive       (FDA, NRC, EPA, and OSHA) and provide services under a quality system which         Libertyville, IL. 60048       meets the requirements of FDA QSR, EN/ISO 13485, and with EN ANSI/AAMI/ISO         847-247-4782       11137. STERIS certifies that these processed items received the indicated doses         within the precision and accuracy of the dosimetry system used and/or Customer approval.								

|--|

			STERI: (Ala P P Pro	S Manual I anine Dosii repared For: cess Run ID: Time Prepar	Dosimetry Re metry Syster : PENDOTECH : 10834-400015/ ed: 08/23/2021	ecord m) 54 6:55AM			
ocessing Locat adiator / Methoo	ion:RTC d:EBIR-00								
Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	<u>Initial</u> Dose (kGv)	Final Dose (kGy)	Measurement Source	
÷	-	-	0BX592076386	.0040	11-0186	0.0	62.9	13.1	
-	-	-	0BX592026099	.0040	11-0186	0.0	0.0	49.8	
-	-	2	0BX592076219	,0040	11-0186	0.0	61.8	12.5	
	-	2	0BX592020042	0040	11-0186	0.0	0.0	49.3	
	-	100	0BX592076365	00400.	11-0186	0.0	63.8	13.5	
	-	6	0BX592020005	.0040	11-0186	0.0	0.0	50.3	
	-	4	0BX592076319	.0040	11-0186	0.0	61.8	12.8	
	-	4	0BX592020069	.0040	11-0186	0.0	0.0	49.0	
• •	. <del>.</del>	· vc	0BX592076103	0040	11-0186	0.0	64.5	13.6	
		o uc	0BX592026490		11-0186	0.0	0.0	50.9	
	Minim	um Dose for	· Record (kGv):		P	1.8		_	
	Mavin	um Dose for	Bacord (kGv)-		9	4.5			
	Maxim	um Dose Tol	Record (Key):			0.4		-	
ther Information:	Refer to the tot	NC-23394. Meas al dose for both d	turement Source shows sosimeters for each loca	s the acutal dos ation. The dose	se for each dosim s reported on this	eter tocation, the record is one sign	final dose reports nnificant figure.	_	
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## 9.25 Appendix Y- Statistical Analysis validating previous accuracy claim from 30 to 60 psi

9.25.1 Statistical Analysis of Data from 35 to 60 psi:

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9.25.1.1 Conduct Normality Test- The t-test assumes that data is sampled from a normally distributed population. A W\* statistic and a P value are computed, from which a statistical decision can be made by comparison with a level of significance. It has been observed that each sensor observes a similar pattern in the form of parallel lines at pressures above 30 psi. Therefore, the Normality Test was conducted at 60 psi only.

Normality Test (Shapiro-Wilk)

N W P Value Decision

100 0.97856 0.45327 Normal at 0.05 level

\* The W value reported by Origin Pro Software is computed using the NAG function nag\_shapiro\_wilk\_test (g01ddc) that implements the Applied Statistics Algorithm AS 181 described in Royston (1982).

9.25.1.2 Since the data sample is Normal, the t-statistic based on 99 degrees of freedom (sample size – 1) and a 0.000001 probability of a sensor being outside the population was calculated:

Gauge	Sample	Standard				Predicted	Predicted	Product Claim	
Pressure	Size	Deviation	Mean	6SDs/Avg	t-statistic*	Upper Interval	Lower Interval	+5% value	-5%value
35	100	0.097	34.98	1.67%	5.217	35.49	34.47	36.75	33.25
40	100	0.144	39.99	2.16%	5.217	40.74	39.23	42.00	38.00
45	100	0.214	45.00	2.86%	5.217	46.12	43.88	47.25	42.75
50	100	0.285	50.01	3.41%	5.217	51.50	48.53	52.50	47.50
55	100	0.366	55.01	4.00%	5.217	56.92	53.10	57.75	52.25
60	100	0.459	59.97	4.60%	5.217	62.37	57.57	63.00	57.00

\* degrees of freedom = 99, P = 0.000001

9.25.2 Conclusions- All sensors meet the acceptance criteria of better than +/- 2% of reading in the range of 0 to 6 psi and better than +/- 3% of reading in the range of 6 - 30 psi. All sensors meet the acceptance criteria of in the range of 30 to 60 psi, typically better than 5% of reading because the predicted interval is within the product claim.