Validation Guide for PendoTECH® Single Use Pressure Sensors

Revision 4

PENDOTECH
Adding Value To Your Process

www.pendotech.com

CONFIDENTIAL

Validation Guide for PendoTECH Single Use Pressure Sensors

Copyright © 2007-2022, PendoTECH

All rights reserved. No part of this publication may be reproduced, stored in an electronic retrieval system, or transmitted, in any form or by any means, whether electronic, mechanical, by photocopying, or otherwise, without the written consent of PendoTECH.

PendoTECH assumes no responsibility for the use of the products represented in this guide except for what is covered in the Limited Warranty and Terms and Conditions of Sale for products. The products are not designed, intended or authorized for use as components in life support or medical devices. They are not designed for any application in which the failure of the product could result in personal injury, death or property damage.

The sensors are designed for use with the PendoTECH Process Control Systems and PressureMAT® products offered by PendoTECH. Other sensor monitors must be tested for compatibility and PendoTECH assumes no responsibility of compatibility of performance with other instruments. The end user must take proper precautions required to make sure there is no damage their monitor.

PressureMAT is a Registered Trademark of PendoTECH

Revision 4
Latest Revision Date Printed: September 21, 2022

CONFIDENTIAL

Table of Contents

CONFIDENTIAL

CONFIDENTIAL

1 INTRODUCTION

1.1 Product overview

PendoTECH's Single Use Pressure Sensors™ 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™ pressure sensing chips and specifications on certain materials used in the pressure sensor devices are as noted.

CONFIDENTIAL

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.

CONFIDENTIAL

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^2 in the fluid path. Maximum size of 0.2 mm^2 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^2 in the fluid path. Maximum size of 0.2 mm^2 anywhere else.

3.6.2 Embedded Bubbles- Maximum 2 allowed per part. Maximum size of 0.08 mm^2 in the fluid path. Maximum size of 0.2 mm^2 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^2. Total in .25 in^2 area not to exceed 0.20mm^2

3.7.2 Embedded Bubbles - Maximum allowable of an estimated 1/3 wall thickness or 0.40mm^2, whichever is less

CONFIDENTIAL

4 PRODUCT CONTACT MATERIALS

4.1 Wet Volume and Surface Areas

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

4.2 Product body and pressure sensor housing

4.2.1 Product body- Polycarbonate is Bayer Makrolon™ 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)

CONFIDENTIAL

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+™ - 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.

CONFIDENTIAL

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.

CONFIDENTIAL

6 PERFORMANCE SPECIFICATIONS

Attribute	Specification	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

CONFIDENTIAL

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 (72ºF). 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 ± 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, *± 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 *± 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.

CONFIDENTIAL

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 ºC, 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 ºC) 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.

CONFIDENTIAL

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 (72ºF).

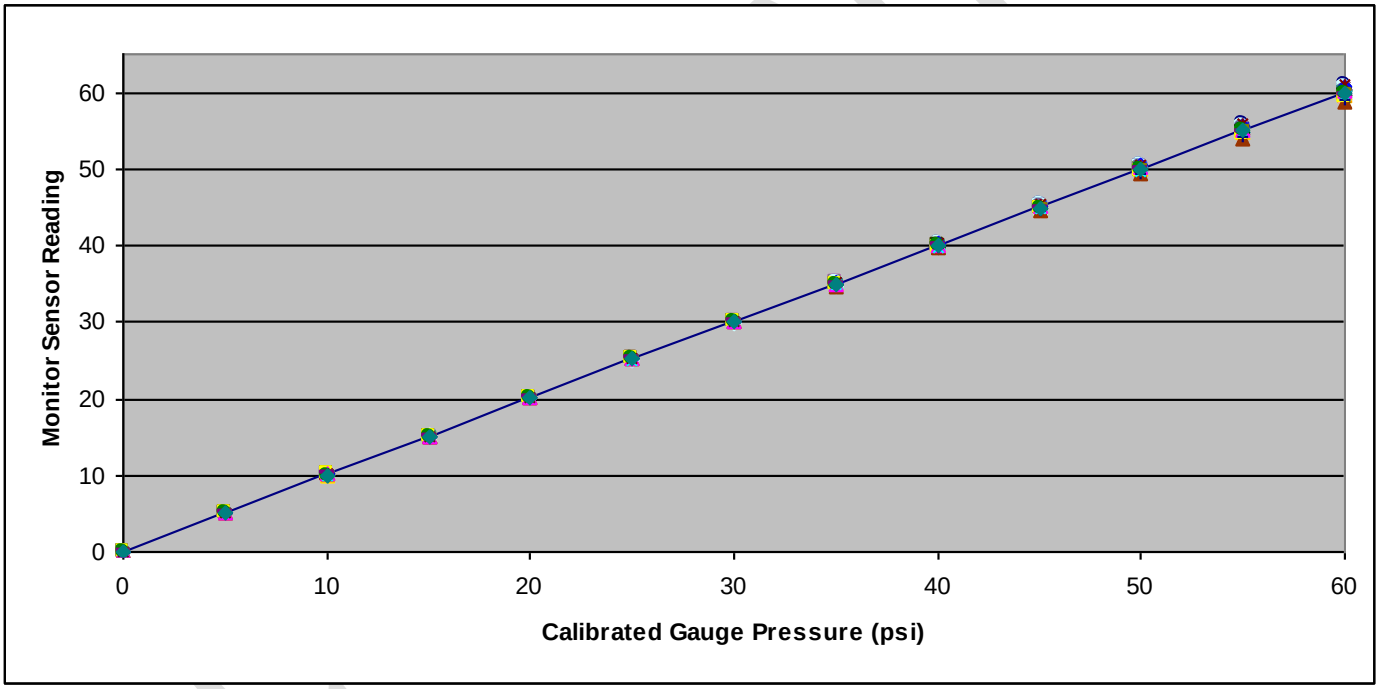
8.1.1.2 Calibrated Pressure Gauge Used: Model# Druck DPI 104, Serial #: 2936090 (Cert in Appendix M)

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



Statistical Summary 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

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

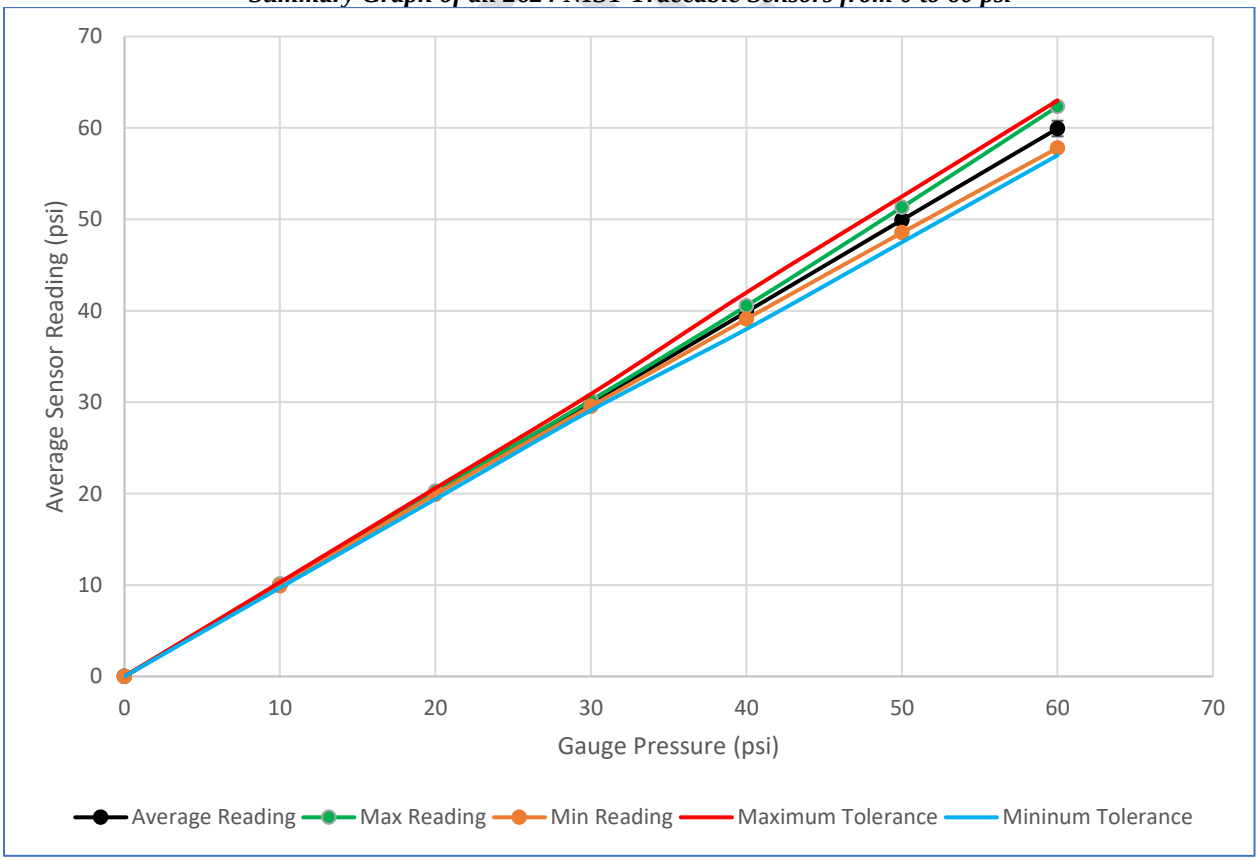
8.1.2.1 Procedure- Data was collected from 2624 NIST traceable sensors across 9 different lots that were all built following the latest manufacturing procedure with 100% testing at 60 psi.

8.1.2.2 Acceptance Criteria:

6 to 30 psi: ± 3% of reading
30 to 60 psi: ± 5% of reading

8.1.2.3 Data Summary:

Summary Graph of all 2624 NIST Traceable Sensors from 0 to 60 psi



Statistical Summary of all NIST Traceable Sensors from 0 to 60 psi

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

8.1.2.1 Conclusion- 100% of sensors meet the acceptance criteria of ± 3% of reading in the range of 6 - 30 psi and ± 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.

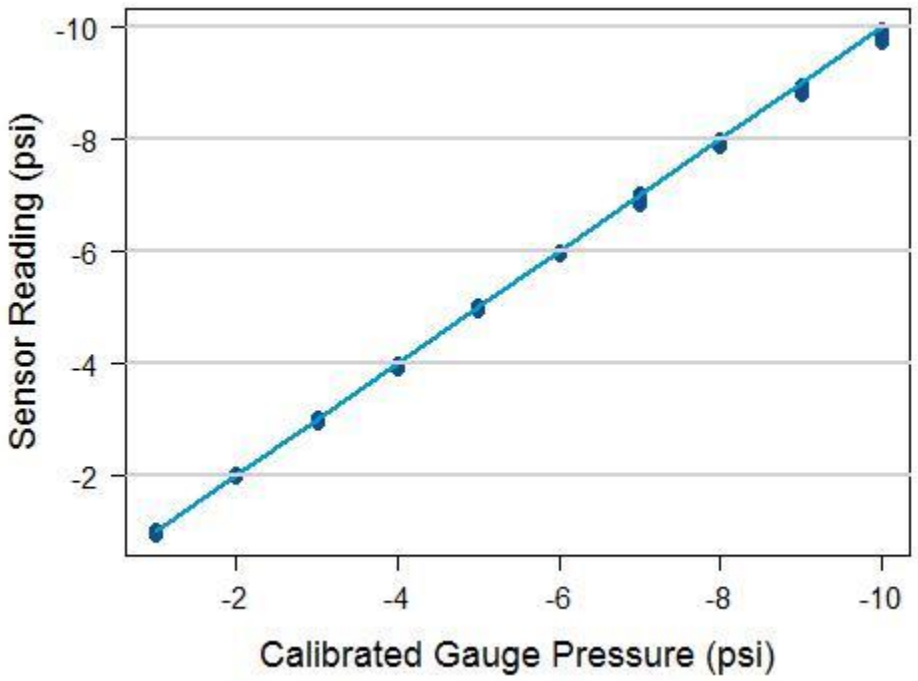
8.2.1.1 Calibrated Pressure Gauge- Model: Crystal XP2i S/N: 692233 (Cert in Appendix P)

8.2.2 Data Summary:

Statistical Analysis of all 120 sensors

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
Standard Deviation	0.01	0.01	0.01	0.02	0.02	0.02	0.02	0.02	0.03	0.03

All readings in PSI



8.2.3 Raw Data:

Lot #	Sensor	Pressure Reading (psi)									
		-1	-2	-3	-4	-5	-6	-7	-8	-9	-10
1190285-A	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
	2C	-1.03	-2.02	-3.00	-3.99	-4.99	-5.98	-6.98	-7.97	-8.95	-9.93
	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
1190183-A	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
	2C	-1.01	-2.00	-2.99	-4.00	-4.98	-5.97	-6.96	-7.92	-8.91	-9.88
	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
1190183-B	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
	2C	-1.01	-1.99	-2.99	-3.98	-4.99	-5.97	-6.97	-7.94	-8.93	-9.90
	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-A	1A	-0.99	-1.98	-2.98	-3.97	-4.96	-5.96	-6.94	-7.93	-8.89	-9.86
	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
1190774-B	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
	2C	-0.99	-1.98	-2.99	-4.00	-4.98	-5.99	-6.98	-7.96	-8.94	-9.93
	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
1190285-B	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
	2C	-0.99	-1.98	-2.98	-3.99	-4.96	-5.98	-6.96	-7.92	-8.90	-9.90
	3A	-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
1190935-A	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
	1C	-0.98	-2.00	-2.98	-3.97	-4.97	-5.95	-6.93	-7.92	-8.89	-9.86
	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

CONFIDENTIAL

	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
1190526-A	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
	2C	-0.99	-1.97	-2.97	-3.96	-4.95	-5.95	-6.93	-7.92	-8.89	-9.86
	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
1190935-B	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
	2C	-1.01	-1.98	-2.97	-3.96	-4.95	-5.91	-6.96	-7.93	-8.89	-9.85
	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
1190526-B	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
	2C	-1.00	-1.97	-2.98	-3.97	-4.97	-5.96	-6.95	-7.94	-8.91	-9.88
	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).

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

	Lot #1- sensor #1			Lot #1- sensor #2			Lot #1- sensor #3			Lot #1- sensor #4		
Gauge Pressure (psi)		1 X Gamma (psi)	2X Gamma (psi)		1 X Gamma (psi)	2X Gamma (psi)		1 X Gamma (psi)	2X Gamma (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

CONFIDENTIAL

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

	Lot #2- sensor #1			Lot #2- sensor #2			Lot #2- sensor #3			Lot #2- sensor #4		
Gauge Pressure (psi)		1 X Gamma (psi)	2X Gamma (psi)		1 X Gamma (psi)	2X Gamma (psi)		1 X Gamma (psi)	2X Gamma (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

CONFIDENTIAL

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

	Lot #3- sensor #1			Lot #3- sensor #2			Lot #3- sensor #3			Lot #3- sensor #4		
Gauge Pressure (psi)		1 X Gamma (psi)	2X Gamma (psi)		1 X Gamma (psi)	2X Gamma (psi)		1 X Gamma (psi)	2X Gamma (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

CONFIDENTIAL

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

	Lot #4- sensor #1			Lot #4- sensor #2			Lot #4- sensor #3			Lot #4- sensor #4		
Gauge Pressure (psi)		1 X Gamma (psi)	2X Gamma (psi)		1 X Gamma (psi)	2X Gamma (psi)		1 X Gamma (psi)	2X Gamma (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

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

CONFIDENTIAL

8.4.2 Data Summary (raw data on file at PendoTECH)-

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 Pressure	Lot # 1			Lot # 2			Lot # 3			Lot # 4		
	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-N-050
Product Description:
Single Use Pressure Sensor, non-sterile, polycarbonate, 0.50 inch hose barb

Lot Number	Final test pressure- Sensor #1- all in psi	Final test pressure- Sensor #2- all in psi	Final test pressure- 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

CONFIDENTIAL

Part Number: PRESS-N-100 Product Description: Single Use Pressure Sensor, non-sterile, polycarbonate, 1 inch hose barb				
Lot Number	Final test pressure- Sensor #1- all in psi	Final test pressure- Sensor #2- all in psi	Final test pressure- 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 Sensor, non-sterile, polysulfone , luer inlet/outlet				
Lot Number	Final test pressure- Sensor #1- all in psi	Final test pressure- Sensor #2- all in psi	Final test pressure- 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.

CONFIDENTIAL

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 ºC) 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 Condition: Room Temperature (22 °C)

	Lot 1132283				*Lot 1131350*				*Lot 1131140*			
PSI-Gauge Pressure	1	2	3	4	1	2	3	4	1	2	3	4
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

Part Number: PRESS-S-000
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 Pressure	1	2	3	4	1	2	3	4	1	2	3	4
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	50.76	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

CONFIDENTIAL

Data Summary of Change in Pressure from Room temperature to 2 °C												
	Lot 1132283				*Lot 1131350*				*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.

CONFIDENTIAL

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

Time Zero Test Date: 2013 Retest Date: February 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	0.04	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	X
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	X

X = Data not available

All values are differences in pressure (ΔP)

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 (ΔP)

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).

Lot Number	Serial Number	Time	Pressure Reading (psi)					
			10	20	30	40	50	60
1132715	104	Original	10.01	20.14	30.13	40.45	51.05	61.79
		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
1132715	105	Original	10.04	20.13	29.95	39.92	49.91	59.84
		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
1132694	76	Original	10.07	20.17	29.98	39.97	49.97	59.89
		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
1132694	77	Original	10.07	20.18	30.09	40.24	50.50	60.77
		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
1132694	78	Original	10.06	20.14	29.95	39.80	49.68	59.48
		Pre Gamma	10.05	20.10	29.93	39.77	49.71	59.49
		Post Gamma	10.07	20.21	29.99	39.92	49.88	59.69
1132694	79	Original	10.06	20.19	30.08	40.31	50.61	60.99
		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
1132518	51	Original	10.00	20.07	29.91	39.78	49.75	59.65
		Pre Gamma	10.00	20.09	29.92	39.81	49.77	59.67
		Post Gamma	10.07	20.18	30.00	39.95	49.97	59.89
1132518	52	Original	10.02	20.07	29.87	39.69	49.60	59.41
		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
1132518	53	Original	10.05	20.16	29.99	40.04	50.20	60.30
		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

CONFIDENTIAL

1132789	26	Original	10.04	20.13	30.04	40.21	50.56	60.89
		Pre Gamma	10.03	20.16	30.09	40.33	50.62	61.02
		Post Gamma	10.05	20.16	30.12	40.34	50.70	61.06
1133155	26	Original	10.06	20.18	30.09	40.24	50.50	60.81
		Pre Gamma	10.02	20.14	30.10	40.22	50.61	60.86
		Post Gamma	10.08	20.23	30.17	40.36	50.68	60.97
1131209	26	Original	10.06	20.19	30.16	X	X	X
		Pre Gamma	10.10	20.20	30.19	40.44	51.02	61.74
		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: ± 2% of reading
6 to 30 psi: ± 3% of reading
30 to 60 psi: Typically better than ± 5% of reading

CONFIDENTIAL

8.10.2 Data summary:

Accuracy at Constant 3.5 Bar- Time = 0 hours

Sensor ID	Applied Pressure (bar)					Sensor Performance
	0	0.5	1	2	4	
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 Criterion (+/)	2%	3%	3%	3%	5%	All within specifications
	0.00	0.02	0.03	0.06	0.20	

Accuracy at Constant 3.5 Bar- Time = 80 hours

Sensor ID	Applied Pressure (bar)					Sensor Performance
	0	0.5	1	2	4	
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 Criterion (+/)	2%	3%	3%	3%	5%	All within specifications
	0.00	0.02	0.03	0.06	0.20	

Accuracy at Constant 3.5 Bar- Time = 168 hours

Sensor ID	Applied Pressure (bar)					Sensor Performance
	0	0.5	1	2	4	
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 Criterion (+/)	2%	3%	3%	3%	5%	All within specifications
	0.00	0.02	0.03	0.06	0.20	

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 Criterion (+/-)	3%	3%	3%	All Within Specifications
	0.30	9.70	10.30	

Pressure Accuracy Verification Post 93 Days*

Sensor ID	Applied Pressure (psi)								Sensor Performance
	0	5	10	20	30	40	50	60	
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 Criterion (+/)	-	2%	3%	3%	3%	5%	5%	5%	All within specifications
	-	0.10	0.30	0.60	0.90	2.00	2.50	3.00	

*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.

CONFIDENTIAL

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: ±2% of reading
6 to 30 psi: ±3% of reading
*30 to 60 psi: Typically better than ±5% of reading**

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

8.11.1.4 Data Summary:

Post X-ray Results													
Part Number	Lot Number	Serial Number	Gauge Pressure (psi)											
			10		20		30		40		50		60	
			Reading (psi)	% Error	Reading (psi)	% Error	Reading (psi)	% Error	Reading (psi)	% Error	Reading (psi)	% Error	Reading (psi)	% Error
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%

8.11.1.5 Conclusion: All sensors were within PendoTECH's accuracy claim and performed as expected, thus qualifying the performance of PendoTECH Single Use Pressure Sensors Post X-ray Irradiation

CONFIDENTIAL

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)**	**ΔP**	**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

CONFIDENTIAL

Part Number	Lot 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.

CONFIDENTIAL

9 APPENDICES

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

TOXIKON
RIGHT. FROM THE START.℠

TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	9/17/2013
Address	3490 US Highway 1, Building 15F Princeton, NJ 08540	**Technical Completion**	10/18/2013
Contact	Nick Troise	**Certificate Date**	5/18/2021
P.O. Number	2007374	**Final Non-GLP Report**	13-03587-G1

Test Article	PendoTECH Polycarbonate Pressure Sensor after gamma irradiation at 43.3-47.7 kGy	**Ratio**	120 cm^2/20 mL
Lot/Batch #	1131266	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Sterility	Sterile		
Storage Condition	Room Temperature		
Study	Class VI Test – USP	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours

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.

TOXIKON
ADVANCING YOUR INNOVATION

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.

Sponsor
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

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.

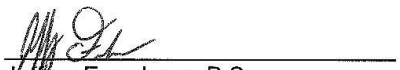
TOXIKON

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

11/1/2013
Date

TOXIKON

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

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

Verification Dates	
Test Article Receipt	09/16/13
Project Log	09/16/13
Study Initiation	09/17/13
Study Completion	10/18/13

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

11/1/2013
Date

Certificate Of Processing

STERIS

Prepared for **EMD MILLIPORE - DANVERS**

Gamma Process Run ID **83375A**

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

PO Number: N1236752

Data Reviewed By:
Signature:
Date: 10 Sep 2013

Processing Run Start Date/Time:	08-Sep-2013 02:05:00 am	Approx. Downtime (hours):	1.07
Processing Run End Date/Time:	08-Sep-2013 05:06:00 am		

Minimum Specified Dose (kGy):	**40.0**	**Minimum Delivered Dose (kGy):**	**43.3**
Maximum Specified Dose (kGy):	**55.0**	**Maximum Delivered Dose (kGy):**	**47.7**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Bryan Sposato (QS/RC Analyst)
Document Content Revision: 1

Signed On 9/8/2013 at 11:57 AM
UTC / GMT Offset (hh:mm): -4:00

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 federal regulations (FDA, NRC, EPA and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2003/2012, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137:2006 or EN ANSI/AAMI/ISO 11135:2007. For items processed with gamma irradiation, STERIS Isomedix certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.

PROC-00034 Last Revised in Release 3.6.0.0 Release Date: 06-Mar-2013 Page 1 of 1

Certificate Of Processing

STERIS

Prepared for **EMD MILLIPORE - DANVERS**

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			
MILLIPORE	L3KA92203	1	CS
Cust Item ID: NS6XBA_GPROTN-SP			
MILLIPORE	L922704	1	CS
Cust Item ID: 00109697PU-SP			
MILLIPORE	L922705	1	CS
Cust Item ID: 00109698PU-SP			

PO Number: N1236752

Data Reviewed by:

Signature:

Date: 3-SEP-2013

Processing Run Start Date/Time:	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 (kGy):**	**48.8**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Francine Maranda (QS/RC Analyst)
Document Content Revision: 1

Signed On 9/2/2013 at 10:18 AM
UTC / GMT Offset (hh:mm): -4:00

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 federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2003/2012, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137:2006 or EN ANSI/AAMI/ISO 11135:2007. For items processed with gamma irradiation, STERIS Isomedix certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.

PROC:00034 Last Revised in Release 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

TOXIKON
RIGHT. FROM THE START.℠

TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	4/12/2019
Address	174 Nassau Street Suite 256	**Technical Completion**	5/29/2019
	Princeton, NJ 08542	**Report Date**	6/3/2019
Contact	Dennis Annarelli	**Amended Report Date**	6/17/2019
P.O. Number	2013094	**Final GLP Report**	19-00538-G1

Test Article	Polysulfone Pressure Sensor Body, Pressure Sensing Chip, Port Plate o-Ring Post 40 kGy Gamma Irradiation	**Ratio**	60 cm^2/20 mL
Lot/Batch #	1171477	**Vehicles**	USP 0.9% Sodium Chloride for Injection (NaCl), Cottonseed Oil (CSO), 1 in 20 Ethanol in NaCl (EtOH), and Polyethylene Glycol 400 (PEG)
Study	Class VI Test – USP (With 14 Day Subcutaneous Implant)	**Extraction Conditions**	70 ± 2 °C for 24 ± 2 hours

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:

Colin McFadden, B.S.
Quality Assurance

Radhika Devalaraja, Ph.D.
Study Director

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

TOXIKON
RIGHT. FROM THE START.SM

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

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.

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

Colin McFadden, B.S.
Quality Assurance

6/17/19
Date

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. Radhika
Radhika Devalaraja, Ph.D.
Study Director

6/17/2019
Date

Certificate Of Processing

STERIS

Prepared for **EMD MILLIPORE – BEDFORD**

Gamma Process Run ID **117005A**

Product Code	Product Lot Number	Quantity	UOM
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF1TN05	0020499769	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF4HN05	0021039608	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRM8HN05	0022897176	1	CS
40-60 SAMPLES Cust Item ID: 20277484/00123958DR	MGBF620/MGDM180	1	CS
40-60 SAMPLES Cust Item ID: PENDOTECH POLYSULFONE SENSORS	NA	1	CS

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 Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Francine Maranda (QS & RC Analyst)
Document Content Revision: 1

Signed On 1/21/2019 at 8:48 AM
UTC / GMT Offset (hh:mm) -5:00

Processing Location:
STERIS
435 Whitney Street
Northborough, MA 01532
Phone: 508-393-9323
Fax: 844-698-9776

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, EN/ISO 13485, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.

WI-00034/01354/01369 Last Rev in Rel. 3.6.5.1 Release Date 05-Jun-2017 Page 1 of 1

STERIS

STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for EMD MILLIPORE – BEDFORD
Process Run ID 117005A
Date Prepared: 1/21/2019 8:47:34AM

Processing Location: **Northborough**

Irradiator / Method: **126, Nordion Cobalt-60 Irradiator #126, ON-STD**

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
Final Dose Measurements							
1	1	0C1	0BR600288204	TH0049	0484	28.7	42.1
			0BR600257802	TH0048	0481	13.4	
1	2	TA5	0BR600288439	TH0049	0484	34.4	50.5
			0BR600257878	TH0048	0481	16.1	
1	3	TE5	0BR600288499	TH0049	0484	34.7	50.8
			0BR600257886	TH0048	0481	16.1	

Minimum Dose for Record (kGy): 42.1

Maximum Dose for Record (kGy): 50.8

Signature Manifest

Prepared By:
Baez, Hector (Material Handler)
Signed On 1/21/2019 at 6:23 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Francine Maranda (QS & RC Analyst)
Signed On 1/21/2019 at 8:47 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

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

TOXIKON
ADVANCING YOUR INNOVATION

TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	11/18/2015
Address	174 Nassau Street Ste. 256 Princeton, New Jersey 08542	**Technical Completion**	11/20/2015
Contact	Dennis Annarelli	**Report Date**	11/24/2015
P.O. Number	2009258	**Final Non-GLP Report**	15-04023-N1

Test Article	PendoTECH Single Use PressureSensor – Polycarbonate Post Gamma Irradiation	**Ratio**	120 cm²/20 mL
Lot/Batch #	1151138	**Vehicle**	Purified Water
Study	Physicochemical Test for Plastics – USP	**Extraction Conditions**	70 ± 2°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.

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:

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

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS
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	Approx. Downtime (hours):	0.00
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.

Signature Manifest

Reviewed and E-Signed By
Tracy Wild (QS/RC Technician)
Document Content Revision: 1

Signed On 11/2/2015 at 11:07 AM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS Isomedix Services
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

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, 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 of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC -- Process Run ID 179365C
Date Prepared: 11/2/2015 10:47:31AM

Processing Location: **Chester**

Irradiator / Method: **239, Nordion Cobalt-60 Irradiator #239, Cont Batch**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	0C1	NR (09/15/2015)	5A3O364003	MX 700989	0.7050	2.748	30.7	
1	2	0C3	NR (09/15/2015)	5A3O364003	MX 700989	0.7742	3.049	30.1	
1	3	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8206	3.228	30.2	
1	4	1C1	NR (09/15/2015)	5A3O364003	MX 700989	0.7697	2.877	33.0	
1	5	1CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8630	3.249	32.6	
1	6	TBAEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8840	3.236	34.3	
1	7	TBEEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7782	2.842	34.5	
2	1	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7542	2.962	30.3	
2	2	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8315	2.894	37.7	
2	3	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8871	3.124	36.9	

Minimum Dose for Record (kGy): **30.1**

Maximum Dose for Record (kGy): **37.7**

Last Dosimeter Absorbance Measurement Date/Time: 11/1/2015 4:21:38 AM

Signature Manifest

Prepared By:
Zephoni Rose (Material Handler)
Signed On 11/1/2015 at 4:22 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Tracy Wild (QS/RC Technician)
Signed On 11/2/2015 at 10:47 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

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

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS 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 Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Tracy Wild (QS/RC Technician)
Document Content Revision: 1

Signed On 11/10/2015 at 3:45 PM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS Isomedix Services
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

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, 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 of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC – Process Run ID 179655E
Date Prepared: 11/9/2015 12:19:36PM

Processing Location: **Chester**

Irradiator / Method: **239, Nordion Cobalt-60 Irradiator #239, Cont Batch**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	0C1	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	1	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	1	0CEOB	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	3	1E5	NR (09/15/2015)	5A3O364003	MX 700989	0.9176	3.131	39.2	
5	1	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7704	2.963	31.4	
5	2	1A5	NR (09/15/2015)	5A3O364003	MX 700989	0.8998	3.084	38.9	
5	3	1E5	NR (09/15/2015)	5A3O364003	MX 700989	0.9223	3.137	39.5	
6	1	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8509	3.033	36.1	
6	2	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8184	2.863	37.4	

Minimum Dose for Record (kGy): **30.3**

Maximum Dose for Record (kGy): **39.8**

Last Dosimeter Absorbance Measurement Date/Time: 11/8/2015 11:27:16 AM

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

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

TOXIKON
ADVANCING YOUR INNOVATION

TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	11/18/2015
Address	174 Nassau Street Ste. 256 Princeton, New Jersey 08542	**Technical Completion**	11/20/2015
Contact	Dennis Annarelli	**Report Date**	12/1/2015
P.O. Number	2009258	**Final Non-GLP Report**	15-04025-N1

Test Article	PendoTECH Single Use Pressure Sensor – Polysulfone Post Gamma Irradiation	**Ratio**	120 cm^2/20 mL
Lot/Batch #	1151748	**Vehicle**	Purified Water
Study	Physicochemical Test for Plastics – USP	**Extraction Conditions**	70 ± 2°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.

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	2.7 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:

Lakshmi Chandrasekaran, M.S.
Quality Assurance

Amtul Qamar, M.S.
Study Director

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS
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	Approx. Downtime (hours):	0.00
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.

Signature Manifest

Reviewed and E-Signed By
Tracy Wild (QS/RC Technician)
Document Content Revision: 1

Signed On 11/2/2015 at 11:07 AM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS Isomedix Services
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

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, 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 of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC -- Process Run ID 179365C
Date Prepared: 11/2/2015 10:47:31AM

Processing Location: **Chester**

Irradiator / Method: **239, Nordion Cobalt-60 Irradiator #239, Cont Batch**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	0C1	NR (09/15/2015)	5A3O364003	MX 700989	0.7050	2.748	30.7	
1	2	0C3	NR (09/15/2015)	5A3O364003	MX 700989	0.7742	3.049	30.1	
1	3	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8206	3.228	30.2	
1	4	1C1	NR (09/15/2015)	5A3O364003	MX 700989	0.7697	2.877	33.0	
1	5	1CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8630	3.249	32.6	
1	6	TBAEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.8840	3.236	34.3	
1	7	TBEEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7782	2.842	34.5	
2	1	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7542	2.962	30.3	
2	2	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8315	2.894	37.7	
2	3	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8871	3.124	36.9	

Minimum Dose for Record (kGy): **30.1**

Maximum Dose for Record (kGy): **37.7**

Last Dosimeter Absorbance Measurement Date/Time: 11/1/2015 4:21:38 AM

Signature Manifest

Prepared By:
Zephoni Rose (Material Handler)
Signed On 11/1/2015 at 4:22 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Tracy Wild (QS/RC Technician)
Signed On 11/2/2015 at 10:47 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

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

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS
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 Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Tracy Wild (QS/RC Technician)
Document Content Revision: 1

Signed On 11/10/2015 at 3:45 PM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS Isomedix Services
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

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, 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 of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC – Process Run ID 179655E
Date Prepared: 11/9/2015 12:19:36PM

Processing Location: **Chester**

Irradiator / Method: **239, Nordion Cobalt-60 Irradiator #239, Cont Batch**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	0C1	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	1	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	1	0CEOB	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	3	1E5	NR (09/15/2015)	5A3O364003	MX 700989	0.9176	3.131	39.2	
5	1	0CEOB	NR (09/15/2015)	5A3O364003	MX 700989	0.7704	2.963	31.4	
5	2	1A5	NR (09/15/2015)	5A3O364003	MX 700989	0.8998	3.084	38.9	
5	3	1E5	NR (09/15/2015)	5A3O364003	MX 700989	0.9223	3.137	39.5	
6	1	TBA5	NR (09/15/2015)	5A3O364003	MX 700989	0.8509	3.033	36.1	
6	2	TBE5	NR (09/15/2015)	5A3O364003	MX 700989	0.8184	2.863	37.4	

Minimum Dose for Record (kGy): 30.3

Maximum Dose for Record (kGy): 39.8

Last Dosimeter Absorbance Measurement Date/Time: 11/8/2015 11:27:16 AM

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

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

TOXIKON
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	Dennis Annarelli	Report Date	9/1/2015
P.O. Number	2008960	Final GLP Report	15-02763-G1

Test Article	PendoTECH polycarbonate pressure sensor	Ratio	3 cm^2/mL
Lot/Batch #	See Attachment A	Vehicle	Serum-Supplemented (complete) Minimum Essential Medium (MEM)
Study	L929 Neutral Red Uptake Test (1 Concentration) – ISO	Extraction Conditions	24 ± 2 hours at 37 ± 1 °C
Comments	Per Sponsor request, the test article was 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 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide (CO_2). 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 Control	Negative Control	Positive Control	Test Article 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:

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

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS Isomedix Services

Gamma Process Run ID **75899A**

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 Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Maria H Greco (QS/RC Technician)
Document Content Revision: 1

Signed On 8/3/2015 at 7:51 AM
UTC / GMT Offset (hh:mm): -4:00

Processing Location:
STERIS Isomedix Services
9 Apollo Drive
Whippany, NJ 07981
Phone: 973-887-2754
Fax: 973-887-6591

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, 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 of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC – Process Run ID 75899A
Date Prepared: 8/3/2015 7:49:48AM

Processing Location: **Whippany**

Irradiator / Method: **131, Nordion Cobalt-60 Irradiator #131, ON-STD**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	2C5	NM (05/27/2015)	4324039	MX 700987	0.8148	2.856	34.8	
1	2	2A5	NM (05/27/2015)	4324039	MX 700987	0.7651	2.602	36.8	
1	3	2E5	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	2.949	37.6	

Minimum Dose for Record (kGy): **34.8**

Maximum Dose for Record (kGy): **37.8**

Last Dosimeter Absorbance Measurement Date/Time: 8/2/2015 12:33:08 AM

Signature Manifest

Prepared By:
Ronald Slack (Supervisor I)
Signed On 8/2/2015 at 12:33 AM
UTC / GMT Offset (hh:mm): -4:00

Approved By:
Maria H Greco (QS/RC Technician)
Signed On 8/3/2015 at 7:49 AM
UTC / GMT Offset (hh:mm): -4:00

Document Content Revision: 1

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

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

TOXIKON
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	Dennis Annarelli	Report Date	9/1/2015
P.O. Number	2008960	Final GLP Report	15-02861-G1

Test Article	polysulfone pressure sensor	Ratio	3 cm^2/mL
Lot/Batch #	See Attachment A	Vehicle	Serum–Supplemented (complete) Minimum Essential Medium (MEM)
Study	L929 Neutral Red Uptake Test (1 Concentration) – ISO	Extraction Conditions	24 ± 2 hours at 37 ± 1 °C
Comments	Per Sponsor request, the test article was 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 ± 1 °C, in a humidified atmosphere containing 5 ± 1% carbon dioxide (CO_2). 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 Control	Negative Control	Positive Control	Test Article
				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:

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

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**

STERIS Isomedix Services

Gamma Process Run ID **75899A**

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 Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By

Maria H Greco (QS/RC Technician)

Document Content Revision: 1

Signed On 8/3/2015 at 7:51 AM
UTC / GMT Offset (hh:mm): -4:00

Processing Location:
STERIS Isomedix Services
9 Apollo Drive
Whippany, NJ 07981
Phone: 973-887-2754
Fax: 973-887-6591

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, 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 of the dosimetry system used.

PROC-00034/01354/01369 Last Rev In Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC – Process Run ID 75899A
Date Prepared: 8/3/2015 7:49:48AM

Processing Location: **Whippany**

Irradiator / Method: **131, Nordion Cobalt-60 Irradiator #131, ON-STD**

Carrier	Seq	Coordinate	Batch - Cal Dt	Spectro S/N	Micrometer S/N	ABS	Thick (mm)	Final Dose (kGy)	Comment
1	1	2C5	NM (05/27/2015)	4324039	MX 700987	0.8148	2.856	34.8	
1	2	2A5	NM (05/27/2015)	4324039	MX 700987	0.7651	2.602	36.8	
1	3	2E5	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	2.949	37.6	

Minimum Dose for Record (kGy): **34.8**

Maximum Dose for Record (kGy): **37.8**

Last Dosimeter Absorbance Measurement Date/Time: 8/2/2015 12:33:08 AM

Signature Manifest

Prepared By:
Ronald Slack (Supervisor I)
Signed On 8/2/2015 at 12:33 AM
UTC / GMT Offset (hh:mm): -4:00

Approved By:
Maria H Greco (QS/RC Technician)
Signed On 8/3/2015 at 7:49 AM
UTC / GMT Offset (hh:mm): -4:00

Document Content Revision: 1

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

9.7 Appendix G Assembled Sensor Certificate: Particulates

NELSON LABORATORIES

Sponsor:
Dennis Annarelli
PendoTECH
174 Nassau St., Ste. 256
Princeton NJ 08542

Lynx Non-Visible Particle Test Method Final Report

Test Article:	Test via EMD Millipore Method P/N: PREPS-N-050-60 Lot: 1140538-XXX (1140538-031, 032)	
Purchase Order:	2008061	
Laboratory Number:	768241	
Study Received Date:	21 Jul 2014	
Test Procedure(s):	Standard Test Protocol (STP) Number:	STP0011 Rev 07
	Protocol Number:	201203604 Rev 01
	Sponsor Protocol Number:	00081563TM

Summary: Particulate matter is defined in the USP as extraneous, mobile, undissolved substances, other than gas bubbles, unintentionally present in or on a solution or 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: The test articles were tested 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 in accordance with ASTM F 658 using polystyrene latex particles, including the size ranges listed in the results tables. Testing was conducted to ensure compliance with the applicable standard listed in the acceptance criteria section.

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	≥ 10 µm Particles/Device	≥ 25 µm Particles/Device
#1	320	20
#2	310	230

Control:

Environment Control	Positive Control	
≥ 10 µm Particles/25 mL	≥ 10 µm Particles/mL	≥ 25 µm Particles/mL
0	582	127

Technical Reviewer

Study Director Ryan Lunceford, B.S.

ACLASS ACCREDITED TESTING

24 Jul 2014
Study Completion Date

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. · 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.
www.nelsonlabs.com · Telephone 801 290 7500 · Fax 801 290 7998 · sales@nelsonlabs.com

dh FRT0011-0001 Rev 5
Page 1 of 2

These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NLI terms and conditions at www.nelsonlabs.com.

NELSON LABORATORIES

Laboratory Number 768241
Lynx Non-Visible Particle Test Method Final Report

Acceptance Criteria:
Light Obscuration:
Test Method: Controls are within range.

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

dh FRT0011-0001 Rev 5
Page 2 of 2

P.O. Box 571830 | Murray, UT 84157-1830 U.S.A. · 6280 South Redwood Road | Salt Lake City, UT 84123-6600 U.S.A.
www.nelsonlabs.com · Telephone 801 290 7500 · Fax 801 290 7998 · sales@nelsonlabs.com

Nelson Labs.
A Sotera Health company

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 Lot #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 µm – 100 µm. Testing was conducted to ensure compliance with the applicable standard listed in the interpretation of results section.

Sho Asai electronically approved for Nereyda Avelar	27 Feb 2020 18:30 (+00:00)
Study Director	Study Completion Date and Time

Nelson Labs
A Sotera Health company

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

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

Nelson Labs
A Sotera Health company

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

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

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Robert J. Putnam electronically approved
Study Director Robert J. Putnam

15 May 2019 20:36 (+00:00)
Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com
Page 1 of 2

Results apply to the samples as received and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms & conditions at www.nelsonlabs.com.
Rev. 3.6.0

Nelson Labs
A Sotera Health company

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.

PENDOTECH
Adding Value To Your Process

Bioburden Results

Year		2013						2014								2015							
Quarter		Q2		Q3		Q4		Q1		Q2		Q3		Q4		Q1		Q2		Q3		Q4	
P/N Used		PRESS-N-025		PRESS-N-050		PRESS-N-050		PREPS-N-050		PREPS-N-050		SPREPS-N-000		PRESS-N-050		PRESS-N-050		PRESS-N-050		PRESS-N-025		PRESS-N-050	
		Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	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		2016								2017								2018							
Quarter		Q1		Q2		Q3		Q4		Q1		Q2		Q3		Q4		Q1		Q2		Q3		Q4	
P/N Used		PRESS-N-050		PREPS-N-025		PRESS-N-050		PRESS-N-050		PREPS-N-025		PREPS-N-025		PREPS-N-025		PREPS-N-075		PRESS-N-025		PRESS-N-075		PRESS-N-050		PRESS-N-050	
		Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal
Unit Number	1	9	<3	<3	<3	<3	<3	6	<3	3	<3	<3	<3	8	<3	6	<3	3	<3	3	<3	<3	<3	5	<3
	2	<3	<3	<3	<3	3	<3	6	<3	3	<3	18	<3	6	<3	10	<3	5	<3	<3	<3	6	<3	<3	<3
	3	3	<3	<3	<3	3	11	6	<3	<3	<3	16	<3	<3	3	<3	<4	<3	<3	<3	<3	9	<3	9	<3
Averages		**<4.9**	**<2.9**	**<2.9**	**<2.9**	**<2.9**	**<5.8**	**6**	**<3.0**	**<2.8**	**<2.8**	**<12.4**	**<3.0**	**<5.7**	**<2.8**	**<6.5**	**<3.2**	**<3.6**	<3.0	**<2.9**	**<2.9**	**<6**	<3.3	**<5.7**	<3

Year		2019								2020								2021							
Quarter		Q1		Q2		Q3		Q4		Q1		Q2		Q3		Q4		Q1		Q2		Q3		Q4	
P/N Used		PRESS-N-050		PRESS-N-050		PRESS-N-050		PRESS-S-000																SS-N-050, Lot 1210	
P/N Used				PREPS-N-025		PREPS-N-050		PREPS-N-050																PS-N-075, Lot 221	
		Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal	Aerobic	Fungal
Unit Number	1	3	<3	**<3,** 3	**<3,** 3	<3, <3	<3, <3	<3, 3	<3, <3	3,3	<3,3	<3<3	<3<3	12	<3	<3, 6	<3,<4	3, <3	<3, <3	5, 3	<3, <3	3, <3	<3, <3	12, 3	<3, <3
	2	3	<3	**<3,** 3	**<3,** 3	<3, 3	<4, <3	3, 25	<3, <3	6,21	<3,6	<3<3	<3<3	14	<3	3,7	<3,<3	<3, 12	<3, 12	<3, 3	<3, <3	<3, 9	<3, 3	9, 9	<3, <3
	3	<3	<3	**<3,** 3	**<3,** 3	<3, 3	<3, <3	6, 5	<3, <2	<3,41	3,<3	<3<3	<3<3	8	3	<3, 6	<3,<3	3, <3	<3, <3	<3, 6	<3, <3	3, <3	<3, <3	3, 12	6, <3
Averages		**<3**	**<3**	**3.1**	**<3.2**	<3.2, <3	3.5, <3.0	**<4, 11**	**<2.7**	**<3.9,21.5**	**<3,<4**	**2.6<2.7**	**2.9<2.8**	**11.2**	**<2.9**	**2.9,6.1**	**<3.2**	**<2.9, <6.0**		**5, 3.8**	**2.8, <3**	**3.5, < 5**	**<2.8, <2.9**	**7.9, 8.2**	**4, <2.9**

CONFIDENTIAL

9.9 Appendix I- Assembled Sensor Certificate: Endotoxins

TOXIKON
RIGHT. FROM THE START.℠

TEST RESULT CERTIFICATE

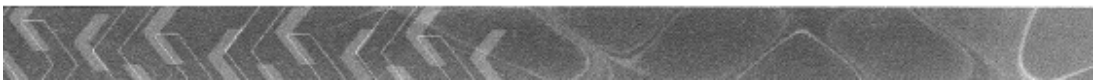
Sponsor	PendoTECH	**Technical Initiation**	6/5/201
Address	174 Nassau St. Suite 256 Princeton, NJ 08542	**Technical Completion**	6/5/201
Contact	Dennis Annarelli	**Report Date**	6/12/201
P.O. Number	2013567	**Final Non-GLP Report**	19-01947-N

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 Injection (SWFI)
Sterility	Sterile	**Storage Condition**	Room Temperature
Study	Chromogenic Endotoxin Testing		
Comments	Pouches containing devices tested included the following information: Test Article 1: Lot 1181571 Test Article 2: Lot 1171477 (pouch open) Test Article 3: Lot 1171477 (pouch open) Sponsor Request: Suspend device by cable thus immersing sensors' clear polysulfone body in liquid to get barbed "T" section fully immersed, including device's fluid path. Avoid immersing any of the white cable/wire that is attached to the device. The pH of Test Article 1 (Lot 1181571) was 7.51 and did not need to be adjusted. The pH of Test Article 2 (Lot 1171477 (pouch open)) was 7.32 and did not need to be adjusted. The pH of Test Article 3 (Lot 1171477 (pouch open)) was 7.32 and did not need to be adjusted.		

REFERENCES: The study was conducted based upon the following references: USP 42, NF 37, 2019. <85> Bacte 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 provide 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 ± 1 °C and extracted at room temperature for 60 ± 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 ± 1 °C for ≥ 10 minutes. After incubation, Lysate (0.1 mL) was added to each well and the absorbance of each wel 405 nm was read every 150 seconds for a total of 40 data points or until the concentration reached 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 ≥ 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.



TOXIKON

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 Quantity

Test Article	Sample	pH	Dilution	EU/mL	EU/Device	Valid PPC (Yes/No)
PendoTECH Single use Pressure Sensors Post 40 kGy Gamma Irradiation	Test Article 1: Lot 1181571	7.51	Neat	< 0.00500	< 0.6	Yes
	Test Article 2: Lot 1171477 (pouch open)	7.32	Neat	< 0.00500	< 0.6	Yes
	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:

Ashley G. Chateauneuf
Ashley G. Chateauneuf, B.S.
Quality Assurance

Linda Haggerty
Linda Haggerty, M.S.
Study Director

Nelson Labs
A Sotera Health company

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
Study Director — Christine Lundgreen

09 Dec 2019 20:46 (+00:00)
Study Completion Date and Time

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

Results apply to the samples as recieved and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms & conditions at www.nelsonlabs.com.
Rev. 3.4.0

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%

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 ± 1°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.

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

TOXIKON
ADVANCING YOUR INNOVATION

TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	2/8/2019
Address	174 Nassau Street Ste.256 Princeton, New Jersey 08542	**Technical Completion**	2/13/2019
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 ºC for 5 days. All FTM vessels except *C. sporogenes* were incubated aerobically at 30-35 ºC for 5 days. FTM vessels with *C. sporogenes* were incubated ananerobically at 30-35 ºC 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.

TABLE 1:
Sterility Validation Results – TSB

Day	Growth (+/-) per Medium								
	Organism						Negative Control	Fluid D	PBS
	B. subtilis		*C. albicans*		*A. brasiliensis*				
	With TA	Without TA	With TA	Without TA	With TA	Without TA			
1	W	W	W	W	W	W	W	W	W
2	W	W	W	W	W	W	W	W	W
3	+	+	+	+	+	+	–	–	–
4	+	+	+	+	+	+	–	–	–
5	+	+	+	+	+	+	–	–	–

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

TOXIKON

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)

TABLE 2:
Sterility Validation Results – FTM

Day	Growth (+/-) per Medium								
	Organism						Negative Control	Fluid D	PBS
	C. sporogenes		*S. aureus*		*P. aeruginosa*				
	With TA	Without TA	With TA	Without TA	With TA	Without TA			
1	W	W	W	W	W	W	W	W	W
2	W	W	W	W	W	W	W	W	W
3	+	+	+	+	+	+	–	–	–
4	+	+	+	+	+	+	–	–	–
5	+	+	+	+	+	+	–	–	–

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

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

AUTHORIZED PERSONNEL:

John Lugo-Toro, B.S.
Quality Assurance

MBS for
Aparajita Mukherjee, M.S.
Study Director

Certificate Of Processing

STERIS

Prepared for **EMD MILLIPORE – BEDFORD**

Gamma Process Run ID **117005A**

Product Code	Product Lot Number	Quantity	UOM
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF1TN05	0020499769	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF4HN05	0021039608	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRM8HN05	0022897176	1	CS
40-60 SAMPLES Cust Item ID: 20277484/00123958DR	MGBF620/MGDM180	1	CS
40-60 SAMPLES Cust Item ID: PENDOTECH POLYSULFONE SENSORS	NA	1	CS

PO Number: N1402721

Processing Run Start Date/Time: 20-Jan-2019 10:07:00 pm
Processing Run End Date/Time: 21-Jan-2019 04:04:00 am
Approx. Downtime (hours): 3.82

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 Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Francine Maranda (QS & RC Analyst)
Document Content Revision: 1

Signed On 1/21/2019 at 8:48 AM
UTC / GMT Offset (hh:mm): -5:00

Processing Location:
STERIS
435 Whitney Street
Northborough, MA 01532
Phone: 508-393-9323
Fax: 844-698-9776

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, EN/ISO 13485, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.

WI-00034/01354/01369 Last Rev in Rel. 3.6.5.1 Release Date 05-Jun-2017 Page 1 of 1

STERIS

STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for EMD MILLIPORE – BEDFORD
Process Run ID 117005A
Date Prepared: 1/21/2019 8:47:34AM

Processing Location: **Northborough**

Irradiator / Method: **126, Nordion Cobalt-60 Irradiator #126, ON-STD**

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
Final Dose Measurements							
1	1	0C1	0BR600288204	TH0049	0484	28.7	42.1
			0BR600257802	TH0048	0481	13.4	
1	2	TA5	0BR600288439	TH0049	0484	34.4	50.5
			0BR600257878	TH0048	0481	16.1	
1	3	TE5	0BR600288499	TH0049	0484	34.7	50.8
			0BR600257886	TH0048	0481	16.1	

Minimum Dose for Record (kGy): 42.1

Maximum Dose for Record (kGy): 50.8

Signature Manifest

Prepared By:
Baez, Hector (Material Handler) Signed On 1/21/2019 at 6:23 AM
UTC / GMT Offset (hh:mm): -5:00

Approved By:
Francine Maranda (QS & RC Analyst) Signed On 1/21/2019 at 8:47 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

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

STERIS Isomedix Services Dosimetry Record

Process Run ID 44637A
Date Prepared: 6/6/2007 9:36:02AM

Processing Location:	**Northborough**
Irradiator / Method:	**126, Nordion Cobalt-60 Irradiator #126, ON-STD**
Dosimeter Batch:	**Harwell, Batch JH, Calibration Date 10/24/2006 5:00:00AM**
Spectrophotometer:	**Beckman, DU-640, Serial #4324355**
Digital Micrometer:	**Mitutoyo, Micrometer, Serial #01004**

Carrier	Seq	Coordinate	ABS	Thick (mm)	Calc Dose (kGy)	Final Dose (kGy)	Comment
1	1	0C1	0.7006	2.968	27.9	27.9	
1	2	3A1	0.7917	2.959	34.3	34.3	
2	1	TA5	0.7087	2.741	32.3	32.3	
2	2	TE5	0.7362	2.916	31.1	31.1	

Minimum Dose for Record (kGy): **27.9**
Maximum Dose for Record (kGy): **34.3**

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

Signature Manifest

Prepared By: *Jason Perry*	Signed On: 6/6/2007	At: 6:26 AM	GMT:-4:00
Approved By: *Francine Maranda*	Signed On: 6/6/2007	At: 9:36 AM	GMT:-4:00

Document Content Revision: 1

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

Form: 00036.1 Rev: 2 Effective Date: 05-Mar-2007 Page 1 of 1

STERIS Isomedix Services Dosimetry Record

Process Run ID 45954A
Date Prepared: 8/27/2007 9:40:22AM

Processing Location:	**Northborough**
Irradiator / Method:	**126, Nordion Cobalt-60 Irradiator #126, ON-STD**
Dosimeter Batch:	**Harwell, Batch JH, Calibration Date 10/24/2006 5:00:00AM**
Spectrophotometer:	**Beckman, DU-640, Serial #4324355**
Digital Micrometer:	**Mitutoyo, Micrometer, Serial #01004**

Carrier	Seq	Coordinate	ABS	Thick (mm)	Calc Dose (kGy)	Final Dose (kGy)	Comment
1	1	0C1	0.7621	3.048	30.6	30.6	
1	2	3A1	0.8661	3.088	37.3	37.3	
2	1	TA5	0.7269	2.603	37.0	37.0	
2	2	TE5	0.7954	2.904	35.7	35.7	

Minimum Dose for Record (kGy): **30.6**
Maximum Dose for Record (kGy): **37.3**

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

Signature Manifest

Prepared By: *Phy Ly*	Signed On: 8/25/2007	At: 6:42 PM	GMT:-4:00
Approved By: *Ken Moore*	Signed On: 8/27/2007	At: 9:40 AM	GMT:-4:00

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

STERIS

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-I / 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 Customer specifications, zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Victoria Mullings (QS & RC Technician)
Document Content Revision: 1

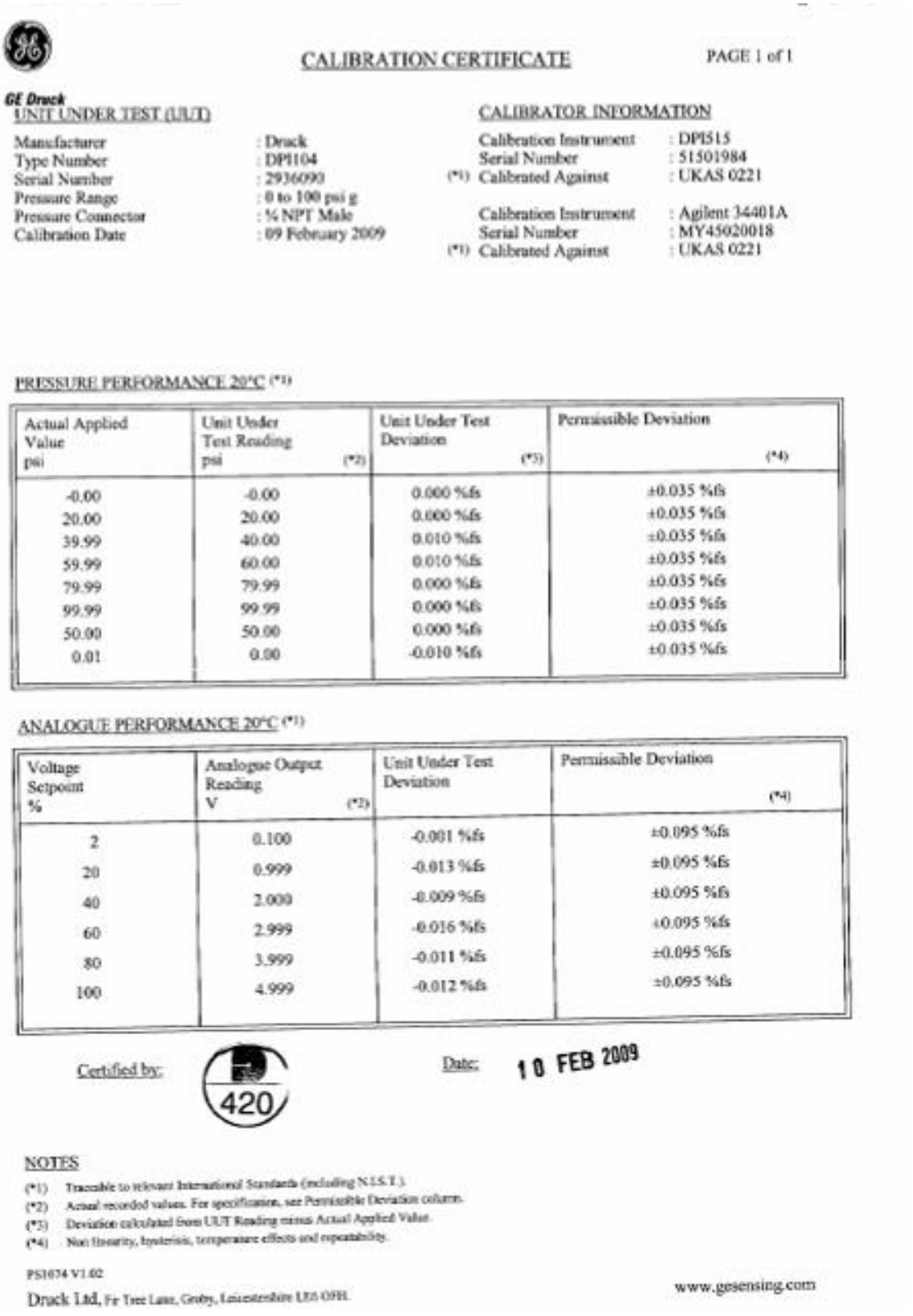
Signed On 3/19/2019 at 10:32 AM
UTC / GMT Offset (hh:mm): -4:00

Processing Location:
STERIS
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

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, EN/ISO 13485 and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

WI-00034/01354/01368 Last Rev In Rel. 3.6.5.1 Release Date 05-Jun-2017 Page 1 of 1

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



CALIBRATION CERTIFICATE

PAGE 1 of 1

GE Druck

UNIT UNDER TEST (UUT)

Manufacturer	: Druck
Type Number	: DPI104
Serial Number	: 2936090
Pressure Range	: 0 to 100 psi g
Pressure Connector	: ¼ NPT Male
Calibration Date	: 09 February 2009

CALIBRATOR INFORMATION

	Calibration Instrument	: DPI515
	Serial Number	: 51501984
(*1)	Calibrated Against	: UKAS 0221
	Calibration Instrument	: Agilent 34401A
	Serial Number	: MY45020018
(*1)	Calibrated Against	: UKAS 0221

PRESSURE PERFORMANCE 20°C (*1)

Actual Applied Value psi	Unit Under Test Reading psi (*2)	Unit Under Test Deviation (*3)	Permissible Deviation (*4)
-0.00	-0.00	0.000 %fs	±0.035 %fs
20.00	20.00	0.000 %fs	±0.035 %fs
39.99	40.00	0.010 %fs	±0.035 %fs
59.99	60.00	0.010 %fs	±0.035 %fs
79.99	79.99	0.000 %fs	±0.035 %fs
99.99	99.99	0.000 %fs	±0.035 %fs
50.00	50.00	0.000 %fs	±0.035 %fs
0.01	0.00	-0.010 %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	-0.001 %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 %fs	±0.095 %fs
80	3.999	-0.011 %fs	±0.095 %fs
100	4.999	-0.012 %fs	±0.095 %fs

Certified by: 420 Date: 10 FEB 2009

NOTES

(*1) Traceable to relevant International Standards (including N.I.S.T.).
(*2) Actual recorded values. For specification, see Permissible Deviation column.
(*3) Deviation calculated from UUT Reading minus Actual Applied Value.
(*4) Non linearity, hysteresis, temperature effects and repeatability.

PS1074 V1.02

Druck Ltd, Fir Tree Lane, Groby, Leicestershire LE6 0FH.

www.gesensing.com

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

GE Druck

CALIBRATION CERTIFICATE

PAGE 1 of 1

UNIT UNDER TEST (UUT)

Manufacturer	: Druck
Type Number	: DPI104
Serial Number	: 2460830
Pressure Range	: 0 to 100 psi g
Pressure Connector	: ¼ NPT Male
Calibration Date	: 10 January 2007

CALIBRATOR INFORMATION

	Calibration Instrument	: DPI515
	Serial Number	: 51501984
(*1)	Calibrated Against	: UKAS 0221
	Calibration Instrument	: Aligent 34401A
	Serial Number	: MY45020018
(*1)	Calibrated Against	: UKAS 0221

PRESSURE PERFORMANCE 20°C (*1)

Actual Applied Value psi	Unit Under Test Reading psi (*2)	Unit Under Test Deviation (*3)	Permissible Deviation (*4)
0.00	0.00	0.000 %fs	±0.035 %fs
19.99	20.00	0.010 %fs	±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: 420 MS Date: 11/1/07

NOTES

(*1) Traceable to relevant International Standards (including N.I.S.T.).
(*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.

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

INNOCAL®
INNOVATIVE CALIBRATION SOLUTIONS

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

Reference #: 7263183-00

NIST Traceable
Calibration Report

REPORT NUMBER
578958

Reference Number: 499231
PO Number: RANDD

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

Manufacturer:	Druck Inc.	**Calibration Date:**	04/25/2014
Model Number:	DPI 104 0-100 PSI	**Calibration Due Date:**	04/25/2015
Description:	Pressure, Digital Gauge, 0-100 PSI	**Condition As Found:**	In Tolerance
Asset Number:	CP21618	**Condition As Left:**	In Tolerance, No adjustment
Serial Number:	2936090		
Procedure:	DS Universal Pressure Gauge-10		

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

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

Calibration Data

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]
	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]
	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]
	50.000 psi	50.00		Same		49.950 to 50.050 psi [EMU 0.0050 psi][TUR 9.9:1]
	60.000 psi	60.01		Same		59.950 to 60.050 psi [EMU 0.0060 psi][TUR 8.3:1]
	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]
	90.000 psi	90.01		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5.5:1]
	100.000 psi	100.00		Same		99.950 to 100.050 psi [EMU 0.010 psi][TUR 5.0:1]
Decreasing	90.000 psi	90.00		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5.5:1]
	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]
	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][TUR 16:1]
	20.000 psi	20.00		Same		19.950 to 20.050 psi [EMU 0.0031 psi][TUR 16:1]

Cole-Parmer Delivering Solutions You Trust | Dalis Instruments | Thermo SCIENTIFIC | Fisher Scientific

Page 1 of 2

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]
	0.000 psi	0.00		Same		-0.050 to 0.050 psi [EMU 0.00075 psi][TUR 67:1]

Temperature: 20° C
Humidity: 41% RH
Rpt. No.: 578968

Calibration Performed By:			Quality Reviewer:	
Santos, Daniel	Metrologist	847-327-5837	Pietronicco, Mike	4/25/2014
Name	Title	Phone	Name	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 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: 578968

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

Cole-Parmer Delivering Solutions You Trust
Davis Instruments
Thermo SCIENTIFIC
Fisher Scientific

Page 2 of 2

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

INNOCAL®
INNOVATIVE 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

REPORT NUMBER
668824

Reference Number: **578526**
PO Number: **MHUJBER102814**

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

Manufacturer:	Crystal Engineering	**Calibration Date:**	10/28/2014
Model Number:	15PSIXP2I	**Calibration Due Date:**	10/28/2015
Description:	Pressure, Digital Gauge 15 PSI	**Condition As Found:**	In Tolerance
Asset Number:	CP140081	**Condition As Left:**	In Tolerance, No adjustment
Serial Number:	364027		
Procedure:	DS Universal Pressure Gauge-10		

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

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

Calibration Data

FUNCTION 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]
	-11.1000 psi	-11.101		Same		-11.1360 to -11.0640 psi [EMU 0.00070 psi][TUR 51:1]
	-8.2000 psi	-8.201		Same		-8.2360 to -8.1640 psi [EMU 0.00070 psi][TUR 51:1]
	-5.3000 psi	-5.301		Same		-5.3360 to -5.2640 psi [EMU 0.00070 psi][TUR 51:1]
	-2.4000 psi	-2.401		Same		-2.4360 to -2.3640 psi [EMU 0.00070 psi][TUR 51:1]
	0.5000 psi	0.500		Same		0.4970 to 0.5030 psi [EMU 0.00049 psi][TUR 6.1:1]
	3.4000 psi	3.400		Same		3.3966 to 3.4034 psi [EMU 0.00055 psi][TUR 6.2:1]
	6.3000 psi	6.300		Same		6.2937 to 6.3063 psi [EMU 0.00073 psi][TUR 8.6:1]
	9.2000 psi	9.201		Same		9.1908 to 9.2092 psi [EMU 0.00099 psi][TUR 9.3:1]
	12.1000 psi	12.100		Same		12.0879 to 12.1121 psi [EMU 0.0013 psi][TUR 9.7:1]
	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]
	9.2000 psi	9.201		Same		9.1908 to 9.2092 psi [EMU 0.00099 psi][TUR 9.3:1]
	6.3000 psi	6.301		Same		6.2937 to 6.3063 psi [EMU 0.00073 psi][TUR 8.6:1]
	3.4000 psi	3.401		Same		3.3966 to 3.4034 psi [EMU 0.00055 psi][TUR 6.2:1]
	0.5000 psi	0.501		Same		0.4970 to 0.5030 psi [EMU 0.00049 psi][TUR 6.1:1]
	-2.4000 psi	-2.400		Same		-2.4360 to -2.3640 psi [EMU 0.00070 psi][TUR 51:1]
	-5.3000 psi	-5.300		Same		-5.3360 to -5.2640 psi [EMU 0.00070 psi][TUR 51:1]

Cole-Parmer Delivering Solutions You Trust | Dwyer Instruments | DIGI-SENSE | OAKTON INSTRUMENTS

Page 1 of 2

Calibration Data

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]
	-11.1000 psi	-11.101		Same		-11.1360 to -11.0640 psi [EMU 0.00070 psi][TUR 51:1]
	-13.5000 psi	-13.501		Same		-13.5360 to -13.4640 psi [EMU 0.00070 psi][TUR 51:1]

Temperature: 21° C
Humidity: 46% RH
Rpt. No.: 668824

Calibration Performed By:				Quality Reviewer:	
Santos, Daniel	322	Metrologist	847-327-5837	Pietronicco, Mike	10/28/2014
Name	ID #	Title	Phone	Name	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 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

Crystal Engineering Corp / 15PSIXP2I, Pressure, Digital Gauge 15 PSI

Cole-Parmer Delivering Solutions You Trust

Davis Instruments

DIGI-SENSE

OAKTON INSTRUMENTS

Page 2 of 2

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

INNOCAL®
INNOVATIVE 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

REPORT NUMBER 685467
Reference Number: 591482
PO Number: RANDD

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

Manufacturer:	Oakton	**Calibration Date:**	12/29/2014
Model Number:	91426-50	**Calibration Due Date:**	12/29/2015
Description:	Temperature, Thermistor, Temp 340 Datalogger	**Condition As Found:**	In Tolerance
Asset Number:	CP100677	**Condition As Left:**	In Tolerance. No adjustment
Serial Number:	570165		
Procedure:	DS Oakton 91426-50		

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

Asset No.	Manufacturer	Model No.	Description	Cal. Date	Due Date
CP50148	Fluke Corporation	5522A	Calibrator, Multifunction	07/23/2014	07/23/2015

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Temperature Accuracy	-35.00 °C	-35.00		Same		-35.03 to -34.97 °C [EMU 0.0058 °C][TUR 5.1:1]
|	0.00 °C	0.00		Same		-0.03 to 0.03 °C [EMU 0.0058 °C][TUR 5.2:1]
|	75.00 °C	75.00		Same		74.97 to 75.03 °C [EMU 0.0061 °C][TUR 4.9:1]
|	120.0 °C	119.9		Same		119.9 to 120.1 °C [EMU 0.058 °C][TUR 1.7:1]
|	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	ID #	Title	Phone	Name	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 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.

Cole-Parmer · Davis Instruments · DIGI-SENSE · OAKTON INSTRUMENTS

Page 1 of 1

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

INNOCAL®
INNOVATIVE 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

REPORT NUMBER
162225

Reference Number: **128806**
PO Number: **2006026**

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

Manufacturer:	Druck Inc.	**Calibration Date:**	06/07/2011
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, No adjustment
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

Temperature: 21° C
Humidity: 62% RH
Rpt. No.: 162225

Calibration Performed By:			Quality Reviewer:	
Santos, Daniel	Metrologist	847-327-5837	Ziegler, Jeff	6/7/2011
Name	Title	Phone	Name	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 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.

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

Test Number
162225

NIST Traceable

Calibration Report

As Found / As Left Data

UUT Information

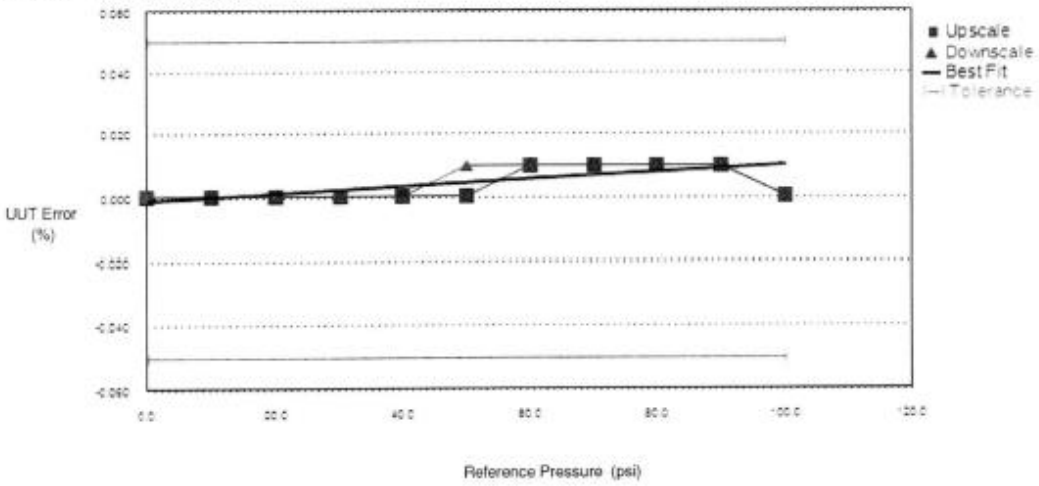
Manufacturer:	Druck	Identification:	CP21618
Model:	DPI 104 0-100PSI	Serial Number:	2936090
Range:	0.000 to 100.000 psi	Data Acquisition Method:	Manual
Accuracy:	0.05 %FS	Date Tested:	Jun 7 2011
Technician:	Daniel Santos		

Test Data

Set Pt	Reference Pressure	UUT Pressure	Abs. Error	% Span Error	UUT 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



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. Fullscale may be rounded due to the resolution of the UUT. Measurements recorded herein are traceable to SI units via national standards maintained by NIST and were performed in compliance with MIL-STD-45662A, ANSI/NCSL Z540-1-1994, 10CFR50, Appendix B, ISO 9001:94, and ISO 17025:2005.

Page 2 of 2

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

INNOCAL®
INNOVATIVE 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

REPORT NUMBER
1457083

Reference Number: **1269901**
PO Number: **RANDD**

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

Manufacturer:	Druck Inc.	**Calibration Date:**	07/30/2018
Model Number:	DPI 104	**Calibration Due Date:**	07/30/2019
Description:	Pressure, Digital Pressure Indicator	**Condition As Found:**	In Tolerance
Asset Number:	CP91719	**Condition As Left:**	In Tolerance, No adjustment
Serial Number:	3674169		
Procedure:	DS Universal Pressure Gauge-10		

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

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	04/24/2018	04/30/2019

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Increasing	0.000 psi	0.01		Same		-0.050 to 0.050 psi [EMU 0.00075 psi][TUR 67:1]
	10.000 psi	9.99		Same		9.950 to 10.050 psi [EMU 0.0012 psi][TUR 41:1]
	20.000 psi	19.99		Same		19.950 to 20.050 psi [EMU 0.0031 psi][TUR 16:1]
	30.000 psi	29.99		Same		29.950 to 30.050 psi [EMU 0.0031 psi][TUR 16:1]
	40.000 psi	39.98		Same		39.950 to 40.050 psi [EMU 0.004 psi][TUR 12:1]
	50.000 psi	49.98		Same		49.950 to 50.050 psi [EMU 0.005 psi][TUR 9.9:1]
	60.000 psi	59.98		Same		59.950 to 60.050 psi [EMU 0.006 psi][TUR 8.3:1]
	70.000 psi	69.98		Same		69.950 to 70.050 psi [EMU 0.007 psi][TUR 7.1:1]
	80.000 psi	80.01		Same		79.950 to 80.050 psi [EMU 0.008 psi][TUR 6.2:1]
	90.000 psi	90.01		Same		89.950 to 90.050 psi [EMU 0.009 psi][TUR 5.5:1]
	100.000 psi	100.01		Same		99.950 to 100.050 psi [EMU 0.01 psi][TUR 5.0:1]
Decreasing	90.000 psi	90.01		Same		89.950 to 90.050 psi [EMU 0.009 psi][TUR 5.5:1]
	80.000 psi	80.01		Same		79.950 to 80.050 psi [EMU 0.008 psi][TUR 6.2:1]
	70.000 psi	70.01		Same		69.950 to 70.050 psi [EMU 0.007 psi][TUR 7.1:1]
	60.000 psi	60.01		Same		59.950 to 60.050 psi [EMU 0.006 psi][TUR 8.3:1]
	50.000 psi	50.01		Same		49.950 to 50.050 psi [EMU 0.005 psi][TUR 9.9:1]
	40.000 psi	40.01		Same		39.950 to 40.050 psi [EMU 0.004 psi][TUR 12:1]
	30.000 psi	30.00		Same		29.950 to 30.050 psi [EMU 0.0031 psi][TUR 16:1]

Cole-Parmer Delivering Solutions You Trust | Davis Instruments | DIGI-SENSE | OAKTON INSTRUMENTS

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]
	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 [EMU 0.00075 psi][TUR 67:1]

Temperature: 21° C
Humidity: 54% RH
Rpt. No.: 1457083

Calibration Performed By:				Quality Reviewer:	
Gonzalez, Jaime	303	Metrologist	847-327-5322	Szplit, Tony	07/30/2018
Name	ID #	Title	Phone	Name	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 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. In Tolerance conditions are based on test results falling within specified limits with no reduction by the uncertainty of the measurement. The estimated measurement uncertainty (EMU), if reported on this certificate, is being reported at a confidence level of 99% or K=2 unless otherwise noted in the remarks section.

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

Certificate Of Processing

STERIS
Isomedix Services

Prepared for **ADVANCED SCIENTIFICS INC**

Gamma Process Run ID **187014C**

Product Code	Product Lot Number	Quantity	UOM
GROUP 62	B108761-I / 92059-0000	8	CS
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS
GROUP 7	B105146-I / 90879-0000	39	CS
GROUP 7	B105421-I / 92696-0000	1	CS
GROUP 7	B110621-I / 92968-0000	1	CS
GROUP 82	7201R / 92944-0000	1	CS
GROUP 82	7202R / 92945-0000	1	CS
GROUP 82	B102828-I / 92994-0000	1	CS
GROUP 82	B103135-I / 92995-0000	2	CS
GROUP 82	B105206-I / 90950-0000	1	CS
GROUP 82	B108824-I / 92963-ENDO	1	CS

Processing Run Start Date/Time: 13-Jun-2016 01:06:12 am
Processing Run End Date/Time: 13-Jun-2016 03:21:09 am
Approx. Downtime (hours): 0.08

Minimum Specified Dose (kGy): **27.5**
Minimum Delivered Dose (kGy): **30.9**
Maximum Specified Dose (kGy): **45.0**
Maximum Delivered Dose (kGy): **40.1**

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Tracy Wild (QS/RC Technician)
Document Content Revision: 1

Signed On 6/14/2016 at 8:31 AM
UTC / GMT Offset (hh:mm): -4:00

Processing Location:
STERIS Isomedix Services
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

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, 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 of the dosimetry system used.

PROC-00034/01354/01369 Last Rev in Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

Certificate Of Processing

STERIS
Isomedix Services

Prepared for **ADVANCED SCIENTIFICS INC**

Gamma Process Run ID **187290D**

Product Code	Product Lot Number	Quantity	UOM
GROUP 69	SAMPLE JASON / SAMPLE JASON-0000	1	CS
GROUP 7	B103911-I / 93000-0000	1	CS
GROUP 7	B105122-I / 93538-0000	1	CS
GROUP 7	B106519-I / 93405-0000	1	CS
GROUP 7	B110708-I / 93402-0000	1	CS
GROUP 82	B103522-I / 91941-0000	1	CS
GROUP 82	B110706-I / 93401-0000	1	CS

Processing Run Start Date/Time: 21-Jun-2016 04:20:15 pm
Processing Run End Date/Time: 21-Jun-2016 07:00:08 pm
Approx. Downtime (hours): 0.66

Minimum Specified Dose (kGy): 27.5
Minimum Delivered Dose (kGy): 31.1
Maximum Specified Dose (kGy): 45.0
Maximum Delivered Dose (kGy): 40.0

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By
Brandon Helmke (QS/RC Technician)
Document Content Revision: 1

Signed On 6/22/2016 at 9:36 AM
UTC / GMT Offset (hh:mm): -4:00

Processing Location:
STERIS Isomedix Services
23 Elizabeth Drive
Chester, NY 10918
Phone: 845-469-4087
Fax: 845-469-7512

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, 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 of the dosimetry system used.

PROC-00034/01354/01369 Last Rev in Rel. 3.6.2.1 Release Date: 02-Apr-2014 Page 1 of 1

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

INNOCAL®
INNOVATIVE 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

REPORT NUMBER
859693

Reference Number: 734817
PO Number: RANDD

PendoTECH
3490 US Route 1
Princeton, NJ 08540 United States

Manufacturer:	Druck Inc.	**Calibration Date:**	03/21/2016
Model Number:	DPI 104	**Calibration Due Date:**	03/21/2017
Description:	Pressure, Digital Pressure Indicator	**Condition As Found:**	In Tolerance
Asset Number:	4396848	**Condition As Left:**	In Tolerance, No adjustment
Serial Number:	4396848		
Procedure:	DS Universal Pressure Gauge-10		

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

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

Calibration Data

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]
|	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]
|	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]
|	50.000 psi	50.00		Same		49.950 to 50.050 psi [EMU 0.0050 psi][TUR 9.9:1]
|	60.000 psi	60.00		Same		59.950 to 60.050 psi [EMU 0.0060 psi][TUR 8.3:1]
|	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]
|	90.000 psi	90.01		Same		89.950 to 90.050 psi [EMU 0.0090 psi][TUR 5.5:1]
|	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]
|	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]
|	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][TUR 16:1]

Cole-Parmer Delivering Solutions You Trust | Davis Instruments | DIGI-SENSE | OAKTON INSTRUMENTS

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]
	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 [EMU 0.00075 psi][TUR 67:1]

Temperature: 21° C
Humidity: 26% RH
Rpt. No.: 859693

Calibration Performed By:				Quality Reviewer:	
Santos, Daniel	322	Metrologist	847-327-5837	Szplit, Tony	3/21/2016
Name	ID #	Title	Phone	Name	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 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: 859693 *Druck Inc. / DPI 104, Pressure, Digital Pressure Indicator*

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 (kGy):	50.0	**Minimum Delivered Dose (kGy):**	61.8
Maximum Specified Dose (kGy):	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, 08/23/2021, 07:27AM CST
QA Manager Approval / Date / Time (Print and Sign)

Michael Ezzo 8/23/2021 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 (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and with EN ANSI/AAMI/ISO 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.
2500 Commerce Drive Libertyville, IL. 60048 847-247-4782	

WI-01678 Form: 2 Rev: 0 Eff Date: Oct 19, 2018 Status: 07b. Completed: All Gamma Facilities Page 1 of 1

STERIS Manual Dosimetry Record
(Alanine Dosimetry System)

Prepared For: PENDOTECH
Process Run ID: 10834-40001554
Date and Time Prepared: 08/23/2021 6:55AM

Processing Location:RTC
Irradiator / Method:EBIR-03

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Initial Dose (kGy)	Final Dose (kGy)	Measurement Source
1	1	1	0BX592076386	'0040	11-0186	0.0	62.9	13.1
1	1	1	0BX592026099	'0040	11-0186	0.0	0.0	49.8
1	1	2	0BX592076219	'0040	11-0186	0.0	61.8	12.5
1	1	2	0BX592020042	'0040	11-0186	0.0	0.0	49.3
1	1	3	0BX592076365	'0040	11-0186	0.0	63.8	13.5
1	1	3	0BX592020005	'0040	11-0186	0.0	0.0	50.3
1	1	4	0BX592076319	'0040	11-0186	0.0	61.8	12.8
1	1	4	0BX592020069	'0040	11-0186	0.0	0.0	49.0
1	1	5	0BX592076103	'0040	11-0186	0.0	64.5	13.6
1	1	5	0BX592026490		11-0186	0.0	0.0	50.9

Minimum Dose for Record (kGy): ***61.8***
Maximum Dose for Record (kGy): ***64.5***

Other Information:	Refer to NC-23394. Measurement Source shows the acutal dose for each dosimeter location, the final dose reports the total dose for both dosimeters for each location. The dose reported on this record is one signnificant figure.

Prepared By Print Name / Title / Sign and Date: Latrice Sutherland, OSEC Manager, [signature] 8-23-21

QA Approved Print Name / Title / Sign and Date: Hailey Mayer, QA Tech I, [signature] 8/23/21

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

INNOCAL®
INNOVATIVE 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

REPORT NUMBER
1662895

Reference Number: **1408403**
PO Number: **RANDD**

OK TO USE
JMC
Sept 7, 2021

PendoTECH
3490 US Route 1
Princeton, NJ 08540 United States

Manufacturer:	Digi-Sense	**Calibration Date:**	08/24/2021
Model Number:	68349-06	**Calibration Due Date:**	08/24/2022
Description:	Pressure, Digital Gauge, 0 to 100 psig	**Condition As Found:**	In Tolerance
Asset Number:	CP355333	**Condition As Left:**	In Tolerance, No adjustment
Serial Number:	1912310225		
Procedure:	DS Universal Pressure Gauge-10		

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

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

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Increasing	0.000 psi	0.00		Same		-0.250 to 0.250 psi [EMU 0.00058 psi][TUR 428:1]
	10.000 psi	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 46:1]
	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]
	50.000 psi	50.01		Same		49.750 to 50.250 psi [EMU 0.0079 psi][TUR 32:1]
	60.000 psi	60.01		Same		59.750 to 60.250 psi [EMU 0.0089 psi][TUR 28:1]
	70.000 psi	70.02		Same		69.750 to 70.250 psi [EMU 0.0099 psi][TUR 25:1]
	80.000 psi	80.01		Same		79.750 to 80.250 psi [EMU 0.011 psi][TUR 23:1]
	90.000 psi	90.01		Same		89.750 to 90.250 psi [EMU 0.012 psi][TUR 21:1]
	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 psi	80.02		Same		79.750 to 80.250 psi [EMU 0.011 psi][TUR 23:1]
	70.000 psi	70.02		Same		69.750 to 70.250 psi [EMU 0.0099 psi][TUR 25:1]
	60.000 psi	60.03		Same		59.750 to 60.250 psi [EMU 0.0089 psi][TUR 28:1]
	50.000 psi	50.02		Same		49.750 to 50.250 psi [EMU 0.0079 psi][TUR 32:1]
	40.000 psi	40.02		Same		39.750 to 40.250 psi [EMU 0.0069 psi][TUR 36:1]
	30.000 psi	30.03		Same		29.750 to 30.250 psi [EMU 0.0059 psi][TUR 42:1]
	20.000 psi	20.01		Same		19.750 to 20.250 psi [EMU 0.0054 psi][TUR 46:1]

Cole-Parmer Traceable DIGI-SENSE OAKTON

Page 1 of 2

Calibration Data

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

Temperature: 19° C
Humidity: 61% RH
Rpt. No.: 1662895

Calibration Performed By:				Quality Reviewer:	
Fitzsimons, Sean	357	Metrologist	847-327-5305	Alexander, James	08/24/2021
Name	ID #	Title	Phone	Name	Date

This report may not be reproduced, except in full, without written permission of Ametek. The results stated in this report apply 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 Z540-1-1994, ISO/IEC Accredit to ISO 9001:94 and ISO 17025:2017 Guard Banding: If applied on this certificate, is applied at a 2 factor or 95% for test points with a test uncertainty ratio (TUR) below 4:1. In "pass-only" conditions are based on test results falling within specified limits only with no reduction by the uncertainty of the measurement. 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: 1662895

Digi-Sense / 68349-06, Pressure, Digital Gauge, 0 to 100 psig

Cole-Parmer® Traceable® DIGI-SENSE OAKTON®

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

TOXIKON
RIGHT. FROM THE START.℠

TEST RESULT CERTIFICATE

Sponsor	Pendo TECH	**Technical Initiation**	1/4/2022
Address	174 Nassau Street, Suite 256 Princeton, New Jersey 08540	**Technical Completion**	1/27/2022
Contact	Nick Troise	**Report Date**	3/16/2022
P.O. Number	2017300	**Final GLP Report**	21-03845-G1

Test Article	PendoTECH Single Use Polycarbonate Pressure Sensors Post X-ray Irradiation (> 50kGy)	**Ratio**	3 cm^2/mL
Lot/Batch #	1210050	**Vehicle**	Serum–Supplemented (complete) Minimum Essential Medium (MEM)
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 Temperature
Intended Use	Research and development – device	**Safety Precautions**	Standard Laboratory Safety Precautions
Comments	None		
Reference Article	PendoTECH Single Use Polycarbonate Pressure Sensors	**Ratio**	3 cm^2/mL
Lot/Batch #	1163277	**Vehicle**	Serum–Supplemented (complete) Minimum Essential Medium (MEM)
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		
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 ± 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

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

TOXIKON
RIGHT. FROM THE START.SM

TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	3/4/2022
Address	174 Nassau Street, Suite 256 Princeton, NJ 08540	**Technical Completion**	3/17/2022
Contact	Nick Troise	**Report Date**	5/20/2022
P.O. Number	2017300	**Final GLP Report**	21-03844-G2

Test Article	PendoTECH Single Use Polysulfone Pressure Sensors Post X-ray Irradiation (> 50kGy)	**Ratio**	3 cm^2/mL
Lot/Batch #	1191570	**Vehicle**	Serum–Supplemented (complete) Minimum Essential 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**	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

TOXIKON

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	Test Article			Controls								
					Untreated			Negative			Positive		
		A	B	C	A	B	C	A	B	C	A	B	C
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:

Elizabeth Zamparelli, B.S.
Quality Assurance

Nora Barakat, B.S.
Study Director

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 (kGy):	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, 08/23/2021, 07:27AM CST
QA Manager Approval / Date / Time (Print and Sign)

Michael Ezzo 8/23/2021 10:42AM EST
Quality Zone Director Approval / Date / Time (Print and Sign)

Processing Location:	
2500 Commerce Drive Libertyville, IL. 60048 847-247-4782	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, EN/ISO 13485, and with EN ANSI/AAMI/ISO 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.

WI-01678 Form: 2 Rev: 0 Eff Date: Oct 19, 2018 Status: 07b. Completed: All Gamma Facilities Page 1 of 1

STERIS Manual Dosimetry Record
(Alanine Dosimetry System)

Prepared For: PENDOTECH
Process Run ID: 10834-40001554
Date and Time Prepared: 08/23/2021 6:55AM

Processing Location:RTC
Irradiator / Method:EBIR-03

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Initial Dose (kGy)	Final Dose (kGy)	Measurement Source
1	1	1	0BX592076386	'0040	11-0186	0.0	62.9	13.1
1	1	1	0BX592026099	'0040	11-0186	0.0	0.0	49.8
1	1	2	0BX592076219	'0040	11-0186	0.0	61.8	12.5
1	1	2	0BX592020042	'0040	11-0186	0.0	0.0	49.3
1	1	3	0BX592076365	'0040	11-0186	0.0	63.8	13.5
1	1	3	0BX592020005	'0040	11-0186	0.0	0.0	50.3
1	1	4	0BX592076319	'0040	11-0186	0.0	61.8	12.8
1	1	4	0BX592020069	'0040	11-0186	0.0	0.0	49.0
1	1	5	0BX592076103	'0040	11-0186	0.0	64.5	13.6
1	1	5	0BX592026490		11-0186	0.0	0.0	50.9

Minimum Dose for Record (kGy): *61.8*
Maximum Dose for Record (kGy): *64.5*

Other Information:	Refer to NC-23394. Measurement Source shows the acutal dose for each dosimeter location, the final dose reports the total dose for both dosimeters for each location. The dose reported on this record is one signnificant figure.

Prepared By Print Name / Title / Sign and Date: Latrice Sutherland, OSEC Manager, [signature] 8-23-21

QA Approved Print Name / Title / Sign and Date: Hailey Mayer, QA Tech I, [signature] 8/23/21

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:

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 Pressure	Sample Size	Standard Deviation	Mean	6SDs/Avg	t-statistic*	Predicted Upper Interval	Predicted Lower Interval	Product Claim +5% value	Product Claim -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.

CONFIDENTIAL