Validation Guide for PendoTECH® Single Use Conductivity Sensors

Revision 2

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CONFIDENTIAL

Validation Guide for PendoTECH Single Use Conductivity Sensors

PendoTECH assumes no responsibility for the use of this product except for what is covered in the Limited Warranty and Terms and Condition of Sale 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 property damage, personal injury, or death.

The sensors are designed for use with the PendoTECH products. 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.

Revision 2
Latest Revision Date Printed: September 26, 2022

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1 INTRODUCTION

1.1 Product Overview

1.1.1 PendoTECH's Single-Use Conductivity Sensors™, conductivity monitor (CMONT), and transmitter (CT-2) integrate for highly accurate conductivity and temperature measurement without the need to calibrate the conductivity electrode, because of its predetermined cell constant. For use in critical bioprocess operations, the CMONT reads conductivity and temperature for up to two sensors. No calibration is required because the cell constant must be entered when a new sensor is connected. There is temperature normalization to 25°C with an adjustable mS/ °C factor. The monitor has 4 – 20mA analog outputs for both conductivity and temperature and an RS232 output for data collection to a PC. For easy integration with bioprocessing skids, the CT-2 transmitter has a convenient DIN rail mountable and compact design. The transmitter reads the raw conductivity and the temperature value from a single conductivity sensor and calculates the normalized value at 25°C. The normalized conductivity value is transmitted via the 4-20mA signal. The analog output must be multiplied by the cell constant to determine the corrected reading.

1.2 Purpose of this Document

1.2.1 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

1.3.1 Testing was completed to qualify the product for use in bioprocess applications. In the product manufacturing process, stainless steel tubes are installed into the polysulfone product bodies. Pre-existing specifications on certain materials used in the Conductivity sensor devices are as noted.

2 PRODUCT CATALOG NUMBERS

PendoTECH Product Catalog Numbers Covered in this Document	
Part Number	**Description**
CONDS-N-012	Single Use Conductivity Sensor, non-sterile, 0.125 inch hose barb, Polysulfone
CONDS-N-025	Single Use Conductivity Sensor, non-sterile, 0.25 inch hose barb, Polysulfone
CONDS-N-050	Single Use Conductivity Sensor, non-sterile, 0.50 inch hose barb, Polysulfone

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 Final assembly of the flow path components is performed in a laminar flow hood (Class 5 clean/controlled environment)

3.3 Polysulfone molded product body- 100% visual inspection

3.3.1 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.

3.3.2 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.

3.3.3 Additional Inspection Criteria: Proprietary information on file at PendoTECH

3.4 Biocompatibility

3.4.1 All plastic materials in contact with product fluid path meet USP Class VI requirements

3.4.2 All plastic materials in contacts with product fluid are ADCF (Animal Derived Component Free)

3.5 Each product is tested during manufacturing to verify proper performance

3.5.1 100% leak testing on the liquid side

3.5.2 Every product is tested electrically to confirm proper electrical performance

3.5.3 100% accuracy testing to determine unique cell constant for each sensor

3.5.3.1 Every sensor is tested with NIST traceable conductivity standards to calculate cell constants

3.5.4 Each thermistor is tested to verify accuracy

3.5.4.1 Each thermistor is tested at 10°C to confirm 4482Ω ± 0.1°C

3.5.4.2 Each thermistor is tested at 25°C to confirm 2252Ω ± 0.1°C

3.5.4.3 Each thermistor is tested at 40°C to confirm 1200Ω ± 0.1°C

3.5.4.4 Each product is tested to confirm 500VDC isolation minimum between thermistor assembly and stainless steel tube

3.6 RoHS Statement

3.6.1 All sensors are in conformity with RoHS 3, EU Directive 2015/863.

3.7 REACH Statement

3.7.1 PendoTECH hereby certifies that its single use conductivity sensors meet the requirements of Directive EC 1906/2006 commonly known as REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) and that to the best of its knowledge its products are free of any materials on the Candidate List of Substances of Very High Concern (SVHC) as stated by the European Chemical Agency (ECA) and that none of these materials are added or used in any of its manufacturing processes. This declaration is effective with production after September 11, 2015 for all Conductivity products.

4 MATERIALS

4.1 Wet Volume and Surface Area

Part Number	Wet Volume	Wet Surface
CONDS-N-012	0.030 in^3	0.80 in^2
CONDS-N-025	0.048 in^3	0.91 in^2
CONDS-N-050	0.269 in^3	3.10 in^2

4.2 Fluid path components

4.2.1 Product body- 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)

4.2.2 Stainless Steel Electrode: 304 Stainless Steel, also houses temperature sensing element (thermistor)

4.2.3 Adhesive: 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)

5 ASSEMBLED SENSOR CERTIFICATIONS

5.1 USP Class VI Statement

5.1.1 All polymeric materials in contact with product fluid path meet the acceptance criteria for USP Class VI Test (with 14 day subcutaneous implants) after exposure to 42 to 51 kGy of gamma irradiation. Study Summaries are in Appendix A and full reports are on file at PendoTECH. The test articles evaluated were polysulfone pressure sensors, however, the qualification holds true for conductivity sensors as the fluid path components are 99% identical. The only difference is the presence of 304 Stainless Steel probes in conductivity sensors, which are not polymeric materials and therefore not subject to USP Class VI testing.

5.2 USP 661 post gamma irradiation

5.2.1 Fully assembled Single Use Conductivity 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 27.5 to 45 kGy of gamma irradiation. The study was conducted based upon the following references: USP 38, National Formulary 33, 2015. Monograph <661> Containers, Physicochemical Tests-Plastics. Test Result Certificates are in Appendix B.

5.3 ISO 10993-5 post gamma irradiation

5.3.1 Fully assembled Single Use Conductivity sensors meet the requirements of ISO 10993-5, Biological Evaluation of Medical Devices – Part5: Tests for In Vitro Cytotoxicity and are not considered to have a cytotoxic effect. Test Result Certificates are in Appendix C and full reports are on file at PendoTECH.

5.4 Particulates

5.4.1 Samples of conductivity sensors were randomly selected and sent to Toxikon for particulate testing. Testing was conducted in accordance with the following references: USP 41, National Formulary 36, 2018. <788> Particulate Matter in Injections. The resulting extracts were analyzed using a Particle Measuring System, Automated Parenteral Syringe Sample (APSS)-200 with channel settings of 10 μm and 25 μm. See Test Report in Appendix D for counts of each particle size.

5.5 Bioburden

5.5.1 Samples of conductivity sensors were randomly selected and sent to Toxikon for bioburden testing. Testing was performed in accordance with ANSI/AAMI/ISO 11737-1:2018. Following validation, the following results were obtained: Average Colony Forming Units (CFU)/Plate = 15.0 and average CFU/Device = 31. Test reports are in Appendix E.

5.6 Endotoxins

5.6.1 Samples of Conductivity sensors post 40 kGy gamma irradiation 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 F.

5.7 Bacteriostatic and Fungistatic (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. The test articles evaluated were polysulfone pressure sensors, however, the qualification holds true for conductivity sensors as the fluid path components are 99% identical. The major difference is the presence of 304 Stainless Steel probes in conductivity sensors, which would not affect the bacteriostatic and fungistatic properties of the sensor. Test reports are in Appendix G.

6 PERFORMANCE SPECIFICATIONS

Attribute	Specification	Qualification Test Information
Accuracy	From 0.1 to 2 mS/cm +/- 0.1 mS/cm; 2 to 50 mS/cm +/- 5% of reading; 50 to 100 mS/cm typically +/- 5% of reading	Qualification Testing by PendoTECH
Temperature Accuracy	Better than +/- 0.2°C	Qualification Testing by PendoTECH
Pressure Range	75 psi max	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
Shelf life	3 years	Qualification Testing by PendoTECH
Operating Temperature	2°C to 50°C (other ranges with process qualification)	Qualification Testing by PendoTECH
Storage Temperature	-25°C to 65°C	Raw Material Specification
Connector	Custom molded 4 pin connector- Rating: IP67 when connected to reusable cable	Qualification Testing by certified test lab Reports on file at PendoTECH

7 PENDOTECH TEST METHOD SUMMARY

7.1 Pressure limit of 75 psi

7.1.1 In order to further qualify conductivity sensors to be physically compatible at pressures of 75 psi, high pressure leak and burst testing was carried out. 9 sensors, 3 each from 3 different lots, were randomly selected for testing. These sensors were first exposed to 100 psi and visually inspected for leaks using soapy water. Afterwards, 150+ psi was applied to the sensors to verify sensor integrity by checking for bursts. The final test pressure and result for each sensor was recorded.

7.2 Accuracy and Cell Constant Determination

7.2.1 During manufacturing every Conductivity sensor is tested across its full-scale range (0–100mS). This data is used to calculate the Cell Constant (K), unique to every conductivity sensor. For testing, every sensor is initially assigned a K of 1.000 and conductivity readings are recorded using a CMONT and NIST traceable conductivity standard solutions. Then, a MATLAB script is used to determine the optimal cell constant for each sensor using the data collected. If the MATLAB script cannot calculate a Cell Constant that will bring the sensor within PendoTECH's accuracy specifications, then that sensor is rejected.

7.2.2 In order to validate the accuracy of PendoTECH conductivity sensors and the procedure for determining each sensor's cell constant, conductivity testing was carried out. 10 Conductivity sensors were retested after their initial testing and cell constant determination. Each sensor was connected to a CMONT that was different from the original CMONT it was initially tested on. The sensors were then retested using conductivity standard solutions ranging from 2 mS to 100 mS. The results were recorded and compared to the sensor's accuracy specification.

7.3 Temperature Accuracy

7.3.1 PendoTECH has carried out a study challenging the thermistors manufacturing claim of "better than +/- 0.2ºC (typically better than +/- 0.1ºC)", in the range 0 to 70°C. Testing was performed on PendoTECH Single Use Temperature sensors, which have the same design, consist of the same materials, are manufactured in the same location, and use the same temperature sensing element. The only difference is that temperature sensors do not have the two additional electrodes for measuring conductivity. This report covers the results of special testing requested by PendoTECH to verify the temperature accuracy claimed on the thermistor. The normal production process measures the thermistor prior to assembly into the full sensor, and between 25°C and 45°C. This testing covers the full range traditionally claimed by PendoTECH: 0°C to 70°C. This report addresses special testing on fully assembled PendoTECH temperature sensors, which possess the same thermistor in conductivity sensors. The raw resistance measurements demonstrate that the sensors are well within the ± 0.2°C tolerance band/specification across the entire 0°C to 70°C range. Only a few measurements were even outside of the ± 0.1°C tolerance band. Capability analysis shows that the thermistor manufacturing process is capable of consistently meeting the requirement. Results of the study are detailed in the report below.

7.4 Shelf life of 3 years

7.4.1 PendoTECH has determined a 3 year shelf life for its Single Use Conductivity sensors by validating the performance of real time aged sensors. Samples of conductivity sensors were placed in real time storage, and over a 3 year window, periodically removed for accuracy testing. Reported here are the results after 12 months, 24, month, 32 months, and 36 months of real time storage. All sensors were checked for accuracy across their full conductivity range of 0 to 100 mS using the cell constant determined prior to storage and conductivity standards.

7.4.2 To validate sensor integrity after 3 years of storage, samples of conductivity sensors were randomly selected for accelerating aging and leak testing. 9 Conductivity sensors from two different lots were gamma irradiated at 37 kGy. The sensors were then accelerated aged at 60°C for 14 weeks, simulating 3 years of aging. The sensors were then checked for leaks at 100 psi.

7.5 Gamma compatibility

7.5.1 PendoTECH has performed internal experiments with its Single Use Conductivity Sensors to qualify their use post gamma irradiation (Certificate in Appendix H). In order to confirm functionality, sensors were tested pre and post gamma irradiation and the results were compared to ensure that they did not change significantly. Additionally, leak testing was performed to validate sensor integrity following gamma irradiation. Sensors from the same lot were also gamma irradiated and then checked for leaks at 60 psi.

7.6 X-ray Compatibility

7.6.1 In accordance with the BioProcess System's Alliance (BPSA) white paper on the requirements and risk evaluation of the X-ray sterilization of single use equipment, a risk assessment was performed to identify the tests required to qualify PendoTECH Single Use Conductivity Sensors for X-ray irradiation for a dose > 50 kiloGrays (Certificate in Appendix L). As these sensors contain no active electronics and are composed of robust, gamma compatible materials, they were deemed to be very low risk. Basic functionality and leak testing was still performed to demonstrate compatibility as a precaution. Testing procedures and results are documented below.

7.7 Sensor Use in Continuous Bioprocessing

7.7.1 PendoTECH carried out a continuous 35 day static experiment on its Single Use Conductivity sensors to evaluate their performance in a continuous bioprocess. Two sensors were placed in known conductivity standards, and closely monitored over the course of 35 days. The sensors' performances were trended throughout the experiment to validate compatibility for continuous bioprocessing.

7.8 Operating Temperature range 2 to 50°C

7.8.1 PendoTECH has determined a 2 to 50°C operating temperature range for Single Use Conductivity sensors based on thermistor qualification. PendoTECH has on file information from all sensor component material manufacturers stating very wide operating temperature ranges well outside the 2 to 50°C claim. Other operating temperature ranges may be viable with proper end user process qualification. PendoTECH monitors are set to a default temperature normalization to 25°C with a factor of 2.1% per °C.

7.9 Storage Temperature -25 to 65°C

7.9.1 PendoTECH has determined a -25 to 65°C storage temperature range for Single Use Conductivity sensors based on raw material specifications. PendoTECH has on file information from all sensor component material manufacturers stating very wide storage temperature ranges well outside the -25 to 65°C claim. For consistency and a healthy safety factor, PendoTECH has narrowed the range to be the same as other PendoTECH single use sensors. Other storage temperature ranges may be viable with proper end user process qualification.

8 PENDOTECH TEST RESULTS

8.1 Pressure limit of 75 psi

8.1.1 Leak and Burst Testing

8.1.1.1 Procedure- 9 sensors, 3 each from 3 different lots, were randomly selected for testing. First, the sensors were exposed to 100 psi and visually inspected for leaks. Soapy water was placed on the sensor test port and around the sensor cap to easily identify any leaks. Afterwards, these sensors were exposed to pressures of 150+ psi and checked for bursts to verify sensor integrity. The final test pressure and burst/leak result for each sensor is reported here.

8.1.1.2 Calibrated Pressure Gauge: Model: Druck DPI 104 S/N: 2936090 (Cert in Appendix I)

8.1.1.3 Acceptance Criteria: No identifiable leaks after exposure to 90 psi for 100 seconds and no burst.

8.1.1.4 Data Summary:

Sensor	Lot #	Leak Result	Burst Result	Final Burst Pressure (psi)
1	19G96991	Pass	Pass	160.62
2	19G96991	Pass	Pass	160.64
3	19G96991	Pass	Pass	160.65
4	19D86473	Pass	Pass	160.65
5	19D86473	Pass	Pass	160.65
6	19D86473	Pass	Pass	160.63
7	19D90369	Pass	Pass	160.64
8	19D90369	Pass	Pass	160.65
9	19D90369	Pass	Pass	160.64

8.1.1.5 Conclusion: All sensors passed leak and burst testing and are therefore suitable for exposure up to a maximum pressure of 75 psi

8.2 Accuracy and Cell Constant Determination

8.2.1 Accuracy Testing:

8.2.1.1 Procedure- 10 Conductivity sensor were retested after their initial testing and cell constant determination. Each sensor was connected to a CMONT that was different from the original CMONT it was initially tested on. The sensors were then retested using conductivity standard solutions ranging from 2 mS to 100 mS.

8.2.1.2 Acceptance Criteria- All sensors within accuracy specification

Conductivity Sensor Accuracy Specification:

From 0.1 to 2 mS/cm +/- 0.1 mS/cm;
2 to 50 mS/cm +/- 5% of reading;
50 to 100 mS/cm typically +/- 5% of reading

8.2.1.3 Data Summary:

Raw Data for Calculating Cell Constants

Sensor	Lot #	CMONT S/N	Original Conductivity Reading (K = 1) mS						Calculated K Value
			2	10	15	30.1	50	100	
1	19D86473	3270	2.13	10.64	15.89	31.46	53.15	105.62	0.947
2			2.28	11.23	16.71	33.00	55.48	110.58	0.894
3			2.18	10.90	16.30	32.00	54.48	107.77	0.929
4			2.23	11.18	16.59	32.89	55.71	109.47	0.905
5			2.29	11.22	16.69	32.84	55.25	107.67	0.894
6			2.21	10.99	16.41	32.13	54.55	106.92	0.920
7			2.25	11.02	16.40	32.19	54.53	106.72	0.911
8			2.20	10.91	16.30	32.18	54.42	107.66	0.922
9			2.21	10.92	16.31	32.08	54.25	106.91	0.921
10			2.32	11.05	16.15	32.37	54.58	106.39	0.895

Cell Constant Validation

Sensor	CMONT S/N	Calculated K Value	Corrected Reading	Corrected Conductivity Reading mS					
				2	10	15	30.1	50	100
1	3136	0.947	Reading (mS)	2.02	9.97	14.92	28.97	48.04	92.08
			% Error	1.00%	-0.30%	-0.53%	-3.75%	-3.92%	-7.92%
2	3136	0.894	Reading (mS)	1.95	9.93	14.83	29.06	49.01	97.67
			% Error	-2.50%	-0.70%	-1.13%	-3.46%	-1.98%	-2.33%
3	3098	0.929	Reading (mS)	2.06	10.15	15.1	29.61	49.58	97.84
			% Error	3.00%	1.50%	0.67%	-1.63%	-0.84%	-2.16%
4	3098	0.905	Reading (mS)	1.94	9.96	14.86	29.2	48.94	97.12
			% Error	-3.00%	-0.40%	-0.93%	-2.99%	-2.12%	-2.88%
5	3136	0.894	Reading (mS)	2.01	9.92	14.83	29.06	48.71	96.42
			% Error	0.50%	-0.80%	-1.13%	-3.46%	-2.58%	-3.58%
6	3098	0.92	Reading (mS)	2.05	10.12	15.03	29.39	49.18	96.16
			% Error	2.50%	1.20%	0.20%	-2.36%	-1.64%	-3.84%
7	3098	0.911	Reading (mS)	1.99	9.81	14.79	29	48.35	95.19
			% Error	-0.50%	-1.90%	-1.40%	-3.65%	-3.30%	-4.81%
8	3136	0.922	Reading (mS)	2.03	9.96	14.93	28.97	47.76	91.22
			% Error	1.50%	-0.40%	-0.47%	-3.75%	-4.48%	-8.78%
9	3136	0.921	Reading (mS)	1.94	9.89	14.86	29.18	48.96	97.79
			% Error	-3.00%	-1.10%	-0.93%	-3.06%	-2.08%	-2.21%
10	3098	0.895	Reading (mS)	1.95	9.78	14.73	29.07	48.61	96.2
			% Error	-2.50%	-2.20%	-1.80%	-3.42%	-2.78%	-3.80%

8.2.1.4 Conclusion: All sensors were within PendoTECH's accuracy specification using the calculated cell constant determined for each sensor.

8.3 Temperature Accuracy

8.3.1 See Report below

Special Test Report for PendoTECH Single Use Temperature Sensor™ TEMP-N-050

TESS-ANDO-502-R000017
Revision: A

PURPOSE

This report covers the results of special testing requested by PendoTECH to verify the temperature accuracy claimed on the thermistor. The normal production process measures the thermistor prior to assembly into the full sensor, and between 25 °C and 45 °C. This testing covers the full range traditionally claimed by PendoTECH: ± 0.2°C from 0°C to 70 °C.

SCOPE

This report addresses special testing on fully assembled PendoTECH sensors. TEMP-N-050 was chosen as the representative part, since it has the largest flow path making it the most practical to measure in a controlled bath.

EXECUTIVE SUMMARY

The raw resistance measurements demonstrate that the sensors are well within the ± 0.2 °C tolerance band/specification across the entire 0 °C to 70 °C range. Only a few measurements were even outside of the ± 0.1 °C tolerance band. Capability analysis shows that the thermistor manufacturing process is capable of consistently meeting the requirement.

DEVIATIONS

One sensor was damaged during testing and could not be measured at 70 °C. Therefore, only 44 data points were used in that particular analysis.

TEST LOCATION

Testing was performed at TESS.

EXPERIMENTAL SETUP

TEST DESCRIPTION

This test shall verify sensor performance in terms of temperature accuracy.

Test Category	Description/Criteria	Measurement
Temperature Accuracy (±0.2 °C)	Resistance @ 0°C = 7278 – 7428 Ω	Resistance (Ω)
	Resistance @ 40°C = 1189 – 1209 Ω	Resistance (Ω)
	Resistance @ 70°C = 391.8 – 397.2 Ω	Resistance (Ω)

SUPPORTED EQUIPMENT AND MATERIALS

1. Constant Temperature Bath System:

a. A 3M Novec 7200 Bath (asset number 1436) suitable for use at 0°C - 70°C.

b. Agilent Autoranging Microvolt Digital Multimeter (asset number 3367) with calibration traceable to NIST.

c. Check resistor with calibration traceable to NIST.

d. Temperature bath setup probe Fluke 5616-12 (asset number 32175) with calibration traceable to NIST.

e. Measurement cables suitable for use with product.

ORIGIN OF SAMPLES

Samples were built according to the normal TEMP-N-050 process, but with an attached Temporary Deviation Authorization stating that the parts would be handed over to R&D prior to the final labeling and packaging steps. Three lots of 15 parts each were used for the test. The corresponding work order numbers were 59300, 59301, and 59302.

PROCEDURE

1.0 3M Novec Bath set to 0 °C or adjust and calibrate one according to SOP900-1027.

2.0 Connect the sensor to the Ohmmeter using a 2-pin Molex adaptor cable.

3.0 Place the sensor in the holding fixture and orient the flow path to the direction of fluid flow in the bath. Immerse the bottom part of the sensors in the fluid, but leave the upper portion out of the bath.

4.0 Wait for the resistance reading to settle, then record the measured resistance. This may take several minutes.

5.0 Repeat 2.0 through 4.0 for all sensors.

6.0 Recalibrate the bath to 40 °C and repeat all steps.

7.0 Recalibrate the bath to 70 °C and repeat all steps.

PASS / FAIL CRITERIA

Test Category	Description/Criteria	Lower Limit	Nominal	Upper Limit	**Cpk**
Temperature Accuracy	Resistance @ 0°C = 7315 – 7391 Ω	7278	7353	7428	0.85
	Resistance @ 40°C = 1195 – 1204 Ω	1189	1200	1209	0.85
	Resistance @ 70°C = 393.1 – 395.8 Ω	391.8	394.5	397.2	0.85

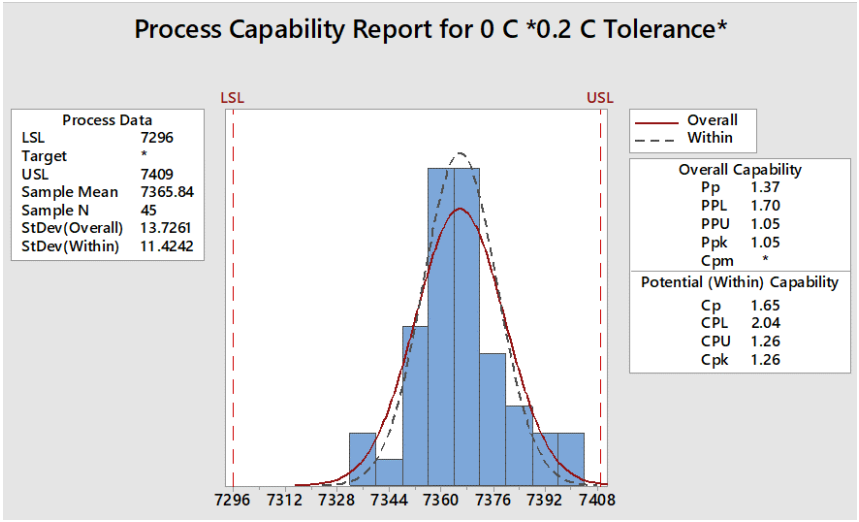
RESULTS

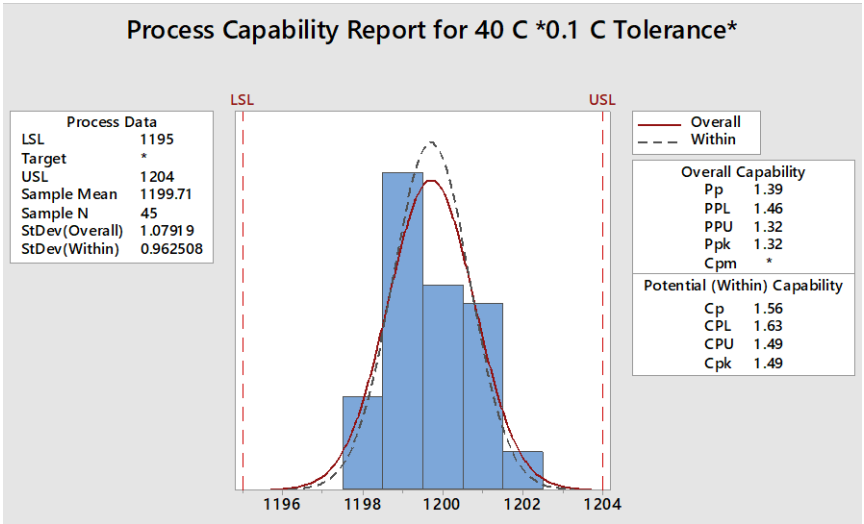
In the 0 °C bath, 45 of 45 sensors measured within the 0.2 °C acceptable range of 7278 Ω - 7428 Ω, and 42 of 45 sensors measured within the tighter 0.1 °C range of 7315 Ω - 7391 Ω.

In the 40 °C bath, 45 of 45 sensors measured within the tighter 0.1 °C range of 1195 Ω - 1204 Ω.

In the 70 °C bath, 44 of 44 sensors measured within the tighter 0.1 °C range of 393.5 Ω - 395.8 Ω.

Capability analysis on these measurements revealed that the current thermistor manufacturing process and testing regimen is quite capable of consistently delivering sensors meeting the ± 0.2 °C accuracy limit. Figures 1, 2, and 3 below represent the capability analysis from Minitab for measurements at 0 °C, 40 °C, and 70 °C respectively. Note that the tolerance used in Figures 1 & 3 is the full range, while Figure 2 uses the tighter ± 0.1 °C tolerance. All three charts show Cpk numbers of 1.26 and greater. The measurements at 40 °C actually have the highest Cpk value despite using the tighter tolerance. This is a feature of the thermistor testing regimen, which requires very high accuracy in the middle of the range in order to maintain acceptable accuracy at the edges of the range.





8.3.1 Conclusion: All sensors were within the thermistor specification of ± 0.2°C from 0 °C to 70°C, validating the accuracy of the thermistor

8.4 Shelf life of 3 years

8.4.1 3 Year Real Time Aging Accuracy Testing

8.4.1.1 Procedure- CONDS-N-025 sensors from Lot# 16M46192 were stored in ambient conditions and real time aged to validate the shelf life of PendoTECH's single use conductivity sensors. After determining the cell constant for each sensor, the sensors were sealed in moisture barrier bags, and kept in storage for 3 years. Over this 3 year window, sensors were periodically removed for performance testing. The sensors were checked for accuracy across their full range using conductivity standard solutions with values of 2, 10, 15, 30.1, 50, and 100 mS. Sensors were connected to a CMONT and the Cell constant determined during manufacturing was entered. Below are the results for sensors after 12 months, 24 months, 32 months, and 36 months of real time storage.

8.4.1.2 Acceptance Criteria- All sensors within accuracy specification

Conductivity Sensor Accuracy Specification:

From 0.1 to 2 mS/cm +/- 0.1 mS/cm;
2 to 50 mS/cm +/- 5% of reading;
50 to 100 mS/cm typically +/- 5% of reading

8.4.1.3 Data Summary:

Serial Number	Time in storage	CMONT S/N	Conductivity Reading (mS)						
			2	10	150	30.1	50	100	Result
1	6 months	3270	2.00	10.13	15.21	29.66	50.09	103.36	Pass
2	6 months	3270	2.00	10.23	15.12	29.84	49.99	102.87	Pass
3	6 months	3099	2.05	10.29	15.40	29.77	49.39	98.47	Pass
4	6 months	3099	2.03	10.30	15.37	29.92	49.95	101.39	Pass
5	12 months	3270	1.95	10.04	15.10	29.34	48.99	99.23	Pass
6	12 months	3270	1.99	10.20	15.24	29.54	49.05	98.41	Pass
7	12 months	3099	1.99	10.13	15.07	28.99	48.10	94.89	Pass
8	12 months	3099	2.00	10.21	15.24	29.64	49.48	100.99	Pass
21	24 months	3270	1.96	10.01	14.88	29.53	48.04	91.88	Pass
22	24 months	3270	1.97	10.12	15.20	30.35	50.07	99.24	Pass
23	24 months	3099	1.98	10.16	15.14	30.40	50.43	100.32	Pass
24	24 months	3099	1.94	9.94	14.89	29.93	48.81	95.98	Pass
29	32 months	3270	1.97	10.01	15.10	29.93	49.92	98.58	Pass
30	32 months	3270	2.01	10.19	15.37	30.36	50.25	99.61	Pass
31	32 months	3099	2.00	9.99	15.00	29.29	47.65	90.74	Pass
32	32 months	3099	2.01	10.11	15.19	29.55	49.01	94.45	Pass
37	36 months	3270	1.99	10.01	15.07	29.41	48.19	93.05	Pass
38	36 months	3270	2.06	10.13	15.26	29.73	48.34	92.79	Pass
39	36 months	3099	2.03	10.08	15.13	29.58	48.07	92.13	Pass
40	36 months	3099	1.99	9.95	15.13	29.44	48.04	92.19	Pass

8.4.1.4 Accuracy Testing Conclusion- Conductivity Sensor remained accurate over the duration of a 3 year shelf life

8.4.2 Post Accelerated Aging and Gamma Irradiation Leak Testing

8.4.2.1 Procedure- 9 Conductivity sensors from two different lots were gamma irradiated at 37 kGy. The sensors were then accelerated aged at 60 °C for 14 weeks, simulating 3 years of aging. The sensors were exposed to 100 psi and visually inspected for leaks. Soapy water was placed on the sensor test port and around the sensor cap to easily identify any leaks

8.4.2.2 Calibrated Pressure Gauge: Model: Druck DPI 104 S/N: 2936090 (Cert in Appendix J)

8.4.2.3 Acceptance Criteria: No leaks after exposure to 100 psi for 90 seconds

8.4.2.4 Data Summary:

Lot #	Serial #	Burst/Leak Result
14C80221	1	Pass
14C80221	2	Pass
14C80221	6	Pass
14A78639	6	Pass
14A78639	14	Pass
14A78639	20	Pass
14A78639	35	Pass
14A78639	46	Pass
14A78639	60	Pass

8.4.2.5 Leak Testing Conclusion: Conductivity sensors will not leak or burst after 3 years of storage and gamma irradiation

8.4.3 Conclusion: Conductivity sensors maintain their accuracy and integrity after 3 years of storage and are therefore suitable for a 3 year shelf life.

8.5 Gamma compatibility

8.5.1 Functionality Testing

8.5.1.1 Procedure- 10x CONDS-N-050 (Lot# 19M100661) conductivity sensors were tested for accuracy from 0 to 50 mS following gamma irradiation. The sensors were tested at the exact same test points used to determine the cell constant (K value), 2, 10, 15, 30.1, and 50 mS, before and after gamma irradiation (Certificate in Appendix H). The conductivity readings were compared to confirm that gamma irradiation does not significantly change the sensor performance. NIST traceable conductivity standards were used as a reference. All readings were made using a PendoTECH Conductivity Monitor (CMONT), which is used to determine the cell constant for every PendoTECH Conductivity sensor.

8.5.1.2 Acceptance Criteria: No substantive changes in any individual sensor reading, the group average, or standard deviation, before and after gamma irradiation

8.5.1.3 Data Summary:

Conductivity Sensors Post Gamma Results								
Part number	Lot Number	Serial Number	K Value	Conductivity Standard (mS)				
				2	10	15	30.1	50
				Pre vs Post Change (mS)	Pre vs Post Change (mS)	Pre vs Post Change (mS)	Pre vs Post Change (mS)	Pre vs Post Change (mS)
CONDS-N-050	19M100661	79	0.720	-0.03	-0.07	-0.07	-0.75	-2.21
CONDS-N-050	19M100661	113	0.698	-0.14	0.05	-0.06	-0.65	-2.08
CONDS-N-050	19M100661	65	0.704	-0.03	-0.05	-0.16	-0.93	-2.21
CONDS-N-050	19M100661	101	0.731	-0.19	-0.15	-0.42	-0.67	-1.08
CONDS-N-050	19M100661	91	0.697	-0.06	-0.26	-0.31	-1.07	-2.55
CONDS-N-050	19M100661	87	0.711	-0.04	-0.08	-0.18	-0.67	-1.43
CONDS-N-050	19M100661	96	0.705	-0.11	-0.14	-0.22	-0.84	-1.89
CONDS-N-050	19M100661	80	0.718	-0.14	-0.34	-0.20	-0.71	-1.90
CONDS-N-050	19M100661	69	0.693	-0.15	-0.12	-0.23	-0.95	-2.21
CONDS-N-050	19M100661	59	0.723	-0.08	-0.12	-0.10	-0.71	-2.47
*Group Average**				0.10	0.14	0.19	0.79	2.00
Group Standard Deviation				0.06	0.11	0.11	0.15	0.45

**Average of the absolute value of the change for each test point*

8.5.1.4 Conclusion: Given the variability introduced by different operators, conductivity standards, monitors, etc., the changes in the group average, standard deviation, or any individual sensor reading following gamma irradiation, are not considered to be substantive, thus demonstrating the performance of PendoTECH Single Use Conductivity Sensors post gamma Irradiation

8.5.1 Post Gamma Integrity Testing

8.5.1.1 Procedure: The integrity of 10x CONDS-N-050 (Lot# 19M100661) conductivity sensors was challenged following gamma irradiation. 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.

8.5.1.2 Calibrated Pressure Gauge: Model# DigiSense, Serial# 1912310225, Last Cal: 8/4/2021 (Cert in Appendix K)

8.5.1.3 Acceptance Criteria: Pressure Decay less than 0.03psi/second and no visual detection of leaks

8.5.1.4 Data Summary:

Conductivity Sensors Post Gamma Leak Results						
Part Number	Lot Number	Serial Number	Initial Pressure (psi)	Final Pressure (psi)	ΔP	Pressure Decay (psi/sec)
CONDS-N-050	19M100661	67	60.05	59.99	-0.06	-0.0007
CONDS-N-050	19M100661	70	60.05	59.95	-0.10	-0.0011
CONDS-N-050	19M100661	63	60.00	59.94	-0.06	-0.0007
CONDS-N-050	19M100661	83	60.02	59.96	-0.06	-0.0007
CONDS-N-050	19M100661	99	60.06	60.01	-0.05	-0.0006
CONDS-N-050	19M100661	89	60.01	59.95	-0.06	-0.0007
CONDS-N-050	19M100661	68	60.01	59.94	-0.07	-0.0008
CONDS-N-050	19M100661	62	60.03	59.68	-0.35	-0.0039
CONDS-N-050	19M100661	81	60.04	60.00	-0.04	-0.0004
CONDS-N-050	19M100661	78	60.04	59.98	-0.06	-0.0007

8.5.1.5 Conclusion: No leaks were identified in any of the leak testing and all pressure decay tests were within the acceptable limit, thus validating the sensor integrity of PendoTECH Single Use Conductivity Sensors post gamma irradiation.

8.6 X-ray Compatibility

8.6.1 Post X-ray Functionality Testing

8.6.1.1 Procedure: 14x Conductivity sensors from 3 different lots (CONDS-N-025 from Lot #'s 0222442687, 0222742463, and 0222589479) were tested for accuracy from 0 to 50 mS. All sensors were X-ray irradiated with a dose >50 kGy (Certificate in Appendix L). The sensors were tested at the exact same test points used to determine the cell constant (K value), 2, 10, 15, 30, and 50 mS, before and after X-ray irradiation. The conductivity readings were compared to confirm that X-ray irradiation does not significantly change the sensor performance. NIST traceable conductivity standards were used as a reference. All readings were made using a PendoTECH Conductivity Monitor (CMONT), which is used to determine the cell constant for every PendoTECH Conductivity sensor.

8.6.1.2 Acceptance Criteria: No substantive changes in any individual sensor reading, the group average, or standard deviation, before and after X-ray irradiation

8.6.1.3 Data Summary:

Conductivity Sensors Post X-ray Results								
Part number	Lot Number	Serial Number	K Value	Conductivity Standard (mS)				
				2	10	15	30.1	50
				Pre vs Post Change (mS)	Pre vs Post Change (mS)	Pre vs Post Change (mS)	Pre vs Post Change (mS)	Pre vs Post Change (mS)
CONDS-N-025	0222442687	6	0.909	-0.04	-0.62	-0.77	0.09	-0.13
CONDS-N-025	0222442687	7	0.931	-0.02	-0.29	-0.95	-0.86	-0.47
CONDS-N-025	0222442687	8	0.938	-0.05	-0.24	-0.99	-0.36	-0.19
CONDS-N-025	0222442687	9	0.925	-0.13	-0.21	-0.87	-0.88	1.58
CONDS-N-025	0222442687	10	0.909	-0.15	-0.32	-1.12	-1.43	0.05
CONDS-N-025	0222742463	12	0.923	-0.07	-0.16	-1.13	0.59	0.16
CONDS-N-025	0222742463	13	0.952	-0.10	-0.23	0.00	-0.37	0.98
CONDS-N-025	0222742463	15	0.951	-0.05	-0.13	-0.45	-0.15	-1.02
CONDS-N-025	0222742463	16	0.904	-0.02	0.15	-0.20	0.26	0.23
CONDS-N-025	0222742463	17	0.954	0.00	-0.14	-0.07	0.44	0.53
CONDS-N-025	0222589479	23	0.966	-0.10	-0.18	-0.57	0.60	1.33
CONDS-N-025	0222589479	24	0.951	-0.06	-0.18	-1.15	0.59	1.02
CONDS-N-025	0222589479	26	0.970	-0.06	-0.12	-0.72	0.57	1.34
CONDS-N-025	0222589479	29	0.956	-0.10	-0.18	-0.77	-0.43	0.46
*Group Average**				0.07	0.23	0.70	0.54	0.68
Group Standard Deviation				0.00	0.05	0.22	0.46	0.49

**Average of the absolute value of the change for each test point*

8.6.1.4 Conclusion: Given the variability introduced by different operators, conductivity standards, monitors, etc., the changes in the group average, standard deviation, or any individual sensor reading following X-ray irradiation, are not considered to be substantive, thus demonstrating the performance of PendoTECH Single Use Conductivity Sensors Post X-ray Irradiation.

8.6.2 Post X-ray Integrity Testing

8.6.2.1 Procedure: The integrity of 14x Conductivity sensors from 3 different lots (CONDS-N-025 from Lot #'s 0222442687, 0222742463, and 0222589479) 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.

8.6.2.2 Calibrated Pressure Gauge: Model# DigiSense, Serial# 1912310225, Last Cal: 8/4/2021 (Cert in Appendix K)

8.6.2.3 Acceptance Criteria: Pressure Decay less than 0.03psi/second and no visual detection of leaks

8.6.2.4 Data Summary:

Post X-ray Leak Results						
Part Number	Lot Number	Serial Number	Initial Pressure (psi)	Final Pressure (psi)	ΔP	Pressure Decay (psi/sec)
CONDS-N-025	222442687	6	59.99	59.95	-0.040	-0.0004
CONDS-N-025	222442687	7	60.14	60.08	-0.060	-0.0007
CONDS-N-025	222442687	8	59.99	59.95	-0.040	-0.0004
CONDS-N-025	222442687	9	59.95	59.92	-0.030	-0.0003
CONDS-N-025	222442687	10	60.10	60.04	-0.060	-0.0007
CONDS-N-025	222742463	12	60.01	59.96	-0.050	-0.0006
CONDS-N-025	222742463	13	59.98	59.94	-0.040	-0.0004
CONDS-N-025	222742463	15	60.06	59.99	-0.070	-0.0008
CONDS-N-025	222742463	16	60.14	60.12	-0.020	-0.0002
CONDS-N-025	222742463	17	60.17	60.17	0.000	0.0000
CONDS-N-025	222589479	21	60.00	59.93	-0.070	-0.0008
CONDS-N-025	222589479	23	60.05	59.99	-0.060	-0.0007
CONDS-N-025	222589479	24	60.08	60.04	-0.040	-0.0004
CONDS-N-025	222589479	26	60.10	60.07	-0.030	-0.0003
CONDS-N-025	222589479	29	60.11	60.06	-0.050	-0.0006

8.6.2.5 Conclusion: No leaks were identified in any of the leak testing and all pressure decay tests were within the acceptable limit, thus validating the sensor integrity of PendoTECH Single Use Conductivity Sensors post X-ray Irradiation.

8.7 Sensor Use in Continuous Bioprocessing

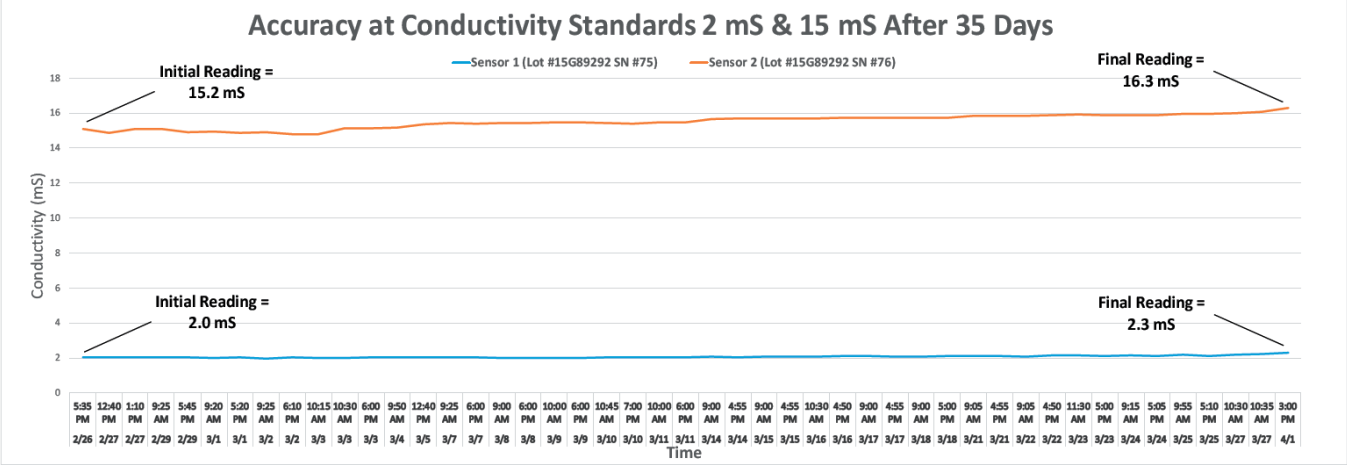
8.7.1 Procedure- PendoTECH carried out a continuous 35 day static experiment on its Single Use Conductivity sensors to evaluate their performance in a continuous bioprocess. Two CONDS-N-025 sensors from Lot #15G89292 were placed in known conductivity standards. One was placed in a 2 mS solution and connected to a CMONT (SN: 3047). The other was placed in a 15 mS solution and connected to a separate CMONT (SN: 3070). Both sensors were closely monitored over the course of 35 days. The sensors' performances were trended throughout the experiment to demonstrate that the sensors maintain their accuracy in long term use. At the end of the 35 days, fresh conductivity sensors were used to measure the conductivity of the standards to measure any drift caused by evaporation during the study.

8.7.2 Acceptance Criteria- All sensors remain within accuracy specification. No significant drift.

Conductivity Sensor Accuracy Specification:

From 0.1 to 2 mS/cm +/- 0.1 mS/cm;
2 to 50 mS/cm +/- 5% of reading;
50 to 100 mS/cm typically +/- 5% of reading

8.7.3 Data Summary:



Conductivity Standard values measured with fresh sensors after 35 days

Standard (mS)	CMONT SN: 3047	CMONT SN: 3070
2.00	2.27	2.25
15.00	16.38	16.27

8.7.4 Conclusion: The readings remained stable and accurate, but a slight drift upwards was observed over the 35 days. However, a fresh conductivity sensor confirmed that the actual conductivity of the solution had increased over the duration of the experiment. This was likely caused by a steady evaporation over the course of the study. With this in mind, the conductivity sensors showed no significant change in reading over 35 days, supporting their use for continuous bioprocessing.

9 APPENDICES

9.1 Appendix A- Assembled Sensor Certificate: Class VI post 40kGy gamma irradiation- Sensor Body and Port Plate O-Ring

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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

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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
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

9.2 Appendix B- Assembled Sensor Certificate: USP 661 post gamma irradiation

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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**	15-04024-N1

Test Article	PendoTECH Single Use Conductivity Sensor Post Gamma Irradiation	**Ratio**	120 cm²/20 mL
Lot/Batch #	15B89295	**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	3.5 mg, Meets Criteria
Residue on Ignition*	≤ 5 mg	Not Applicable
Heavy Metals	≤ 1 ppm	> 1 ppm, Does not meet Criteria
Buffering Capacity	≤ 10 mL	0.76 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 for nonvolatile residue and Buffering Capacity based upon the methods employed. It does not meet the criteria for Heavy Metals of the USP Physicochemical Test for Plastics based on the method 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

9.3 Appendix C: Assembled Sensor Certificate: ISO 10993-5 post gamma irradiation

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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**	15-02864-G1

Test Article	conductivity 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	0.541
Viability %	100%	107%	40%	102%

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**

Gamma Process Run ID **75899A**

STERIS Isomedix Services

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

9.4 Appendix D: Assembled Sensor Certificate: Particulates

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TEST RESULT CERTIFICATE

Sponsor	PendoTech	**Technical Initiation**	03/05/2019
Address	174 Nassau Street, Ste. 256 Princeton, NJ, 08542, USA	**Technical Completion**	03/06/2019
Contact	Dennis Annarelli	**Report Date**	03/26/2019
P.O. Number	2013020	**Final Non-GLP Report**	19-00167-N1

Test Article	PendoTECH Single Use Conductivity Sensors	**Ratio**	Fluid Path
Lot/Batch #	18G75422, 18B68526, 18E72698, 18D71380, 18AG5416	**Vehicle**	Purified Water
Study	Particulate Matter by Light Obscuration of Extract from a Solid Test Article	**Extraction Conditions**	37 ± 2 °C for 24 ± 2 hours
Comments	None		

REFERENCES: The study was conducted based upon the following references: United States Pharmacopeia 41, National Formulary 36, 2018. <788> Particulate Matter In Injections. Particle Measuring System. Operations Manual for "SLS-FAMILY Syringe Liquid Sampler" publication no. 1000014034, Rev G. Particle Measuring System. Operations Manual for "LiQuilaz® -E20 Particle Counter" publication no. M10179, Rev G. Sponsor specifications.

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

GENERAL PROCEDURE: The test article was extracted by filling the fluid path of all the devices (connected in series with tubing) with purified water at 37 ± 2 °C for 24 ± 2 hours. A control solution of purified water in the tubing only was also collected for analysis. Finally, a control solution of purified water was also collected . The resulting extracts were analyzed using the Particle Measuring System, Automated Parenteral Syringe Sampler (APSS)-2000. Particles were analyzed using channel settings of 10 and 25 µm. The differential count results were recorded directly from the instrument.

CALCULATIONS: Calculation of number of particles (of each size) per device :

$$Particles\ per\ unit = \frac{Ta*Pa - Tb*P_c}{N_{dev}}$$

Where:

Ta = Total Volume of Test Articles + Tubing = 71 mL
Tb = Amount of volume corresponding to Tubing = 60 mL
Pa = Number of particles / mL obtained in the extraction of Test Articles + Tubing
Pc = Number of particles / mL obtained in the tubing control experiment
N_{dev} = Number of devices = 10

TOXIKON

Particulate Matter by Light Obscuration of Extract from a Solid Test Article
Final Non-GLP Report: 19-00167-N1
Test Article Name: PendoTECH Single Use Conductivity Sensors

RESULTS: The results are presented in Table 1 and Table 2.

TABLE 1
Results of Particle Size Analysis
Instrumental Results

Sample ID	Replicate	(Particles per mL)	
		≥ 10 µm	≥ 25 µm
Control (Purified Water)	1	Discarded Sample	
	2	0.2000	0.2000
	3	0.6000	0.0000
	4	0.2000	0.0000
	5	0.2000	0.4000
	Average	**0.3000**	**0.1500**
Tubing Control	1	Discarded Sample	
	2	5.4000	0.2000
	3	8.0000	0.4000
	4	6.0000	0.8000
	5	6.4000	0.2000
	Average	**6.4500**	**0.4000**
Test Article + Tubing	1	Discarded Sample	
	2	5.6000	0.8000
	3	6.2000	1.0000
	4	8.4000	1.2000
	5	6.6000	0.2000
	Average	**6.7000**	**0.8000**

Each replicate was a 5 mL aliquot of the sample.

TABLE 2
Particles per unit of device
Calculated Results

Sample ID	Replicate	(Particles per unit)	
		≥ 10 µm	≥ 25 µm
Test Article (corrected for the control)	1	Discarded Sample	
	2	7.3600	4.4800
	3	0.0000	4.7000
	4	23.6400	3.7200
	5	8.4600	0.2200
	Average	**8.8700**	**3.2800**

CONCLUSION: The test article contained the amounts of each particle size as presented in Table 2, when tested based on the methods employed.

AUTHORIZED PERSONNEL:

Vanessa M. Dubay, B.S.
Quality Assurance

Edvin Klosi, Ph.D.
Study Director

9.5 Appendix E: Assembled Sensor Certificate: Bioburden

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TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	1/21/2019
Address	174 Nassau Street Ste.256 Princeton, New Jersey 08542	**Technical Completion**	1/28/2019
Contact	Dennis Annarelli	**Report Date**	2/1/2019
P.O. Number	2013020	**Final Non-GLP Report**	19-00165-N2

Test Article	PendoTECH Single Use Conductivity Sensors
Lot/Batch #	18H78452, 18K81350, 17M65167
Study	Aerobic, Anaerobic, Heat Shock and Yeast & Mold Bioburden by Membrane Filtration – AAMI
Comments	One (1) unit from each of the three (3) lots supplied by sponsor was tested. Refer to Toxikon Project Number 19-00165-N1 for bioburden validation.

REFERENCES: The study was conducted based upon the following references: ANSI/AAMI/ISO 11137–1, 2006/(R) 2010 & A1: 2013 (Consolidated Text) Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices. ANSI/AAMI/ISO 11737–1:2018 Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of the Population of Microorganisms on Product.

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

GENERAL PROCEDURE: The Sponsor submitted three (3) lots, one (1) unit from each lot was tested for total bioburden. Each test article was individually placed in a sterile bag and the fluid pathway was flushed with 100 mL of sterile Fluid D. The bag was shaken for 30 seconds. A volume of 96 mL of Fluid D was recovered and four (4) equal aliquots were made. One (1) aliquot was heat shocked at 80 °C for 15 minutes, then allowed to cool down. Following membrane filtration (4 × 24 mL) and wash with 10 mL of Phosphate Buffered Saline (PBS), the filters (one per plate) were aseptically placed onto Trypticase Soy Agar (TSA) plates and incubated aerobically and anaerobically at 30–35 °C for 4 days and onto Sabouraud Dextrose Agar (SDA) plates and incubated aerobically at 20–25 °C for 7 days. Samples of Fluid D and PBS, used as negative controls, were similarly filtered, plated and incubated. Colony Forming Units (CFU) were determined for each filter. The study and its design employed methodology to minimize uncertainty of measurement and control of bias for data collection and analysis.

RESULTS:

TABLE 1:
Bioburden Results

Test Article	CFU/Plate			
	TSA (Aerobic)	TSA (Anaerobic)	TSA (Heat Shock)	SDA (Yeast & Mold)
18H78452	NOC	NOC	1 Cream CI, FL	NOC
18K81350	1 Yellow CI, RA 1 Yellow IR, FL	NOC	NOC	NOC
17M65167	1 Cream CI, FL	NOC	NOC	NOC
Average CFU/Plate	**1.0**	**0**	**0.3**	**0**
CFU/Device	**4**	**< 1**	**1**	**< 1**

CFU = Colony Forming Units
NOC = No Observable Colonies = < 1 ≡ 0 for calculations
CI = Circular, FL = Flat, IR = Irregular, RA = Raised

Average CFU/Plate = Sum of CFU/plates ÷ Number of Plates

$$\text{CFU/Device} = \frac{\text{Average CFU/Plate} \times \text{Fluid D used (100 mL)}}{\text{Volume Filtered (24 mL)}}$$

Corrected CFU/Device = Total CFU/Device × Recovery Factor = 5 × 2.5 = 13

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

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TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	1/21/2019
Address	174 Nassau Street Ste.256 Princeton, New Jersey 08542	**Technical Completion**	1/25/2019
Contact	Dennis Annarelli	**Report Date**	2/1/2019
P.O. Number	2013020	**Final Non-GLP Report**	19-00165-N1

Test Article	PendoTECH Single Use Conductivity Sensors
Lot/Batch #	18H78452, 18K81350, 17M65167
Study	Bioburden Validation – Spore Inoculation – AAMI
Comments	One (1) unit from each of the three (3) lots supplied by sponsor was tested.

REFERENCES: The study was conducted based upon the following references: ANSI/AAMI/ISO 11137–1, 2006/(R) 2010 & A1: 2013 (Consolidated Text) Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices. ANSI/AAMI/ISO 11737–1:2018 Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of the Population of Microorganisms on Product.

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

GENERAL PROCEDURE: The Sponsor submitted three (3) units for bioburden validation by spore inoculation. Each test article was individually placed in a sterile bag and inoculated with 0.1 mL of *Bacillus atrophaeus* (*B. atrophaeus*) and allowed to dry for thirty (30) minutes. A volume of 100 mL of Fluid D was used to flush each test article. The bag was shaken for 30 seconds. The recovered extract (96 mL) was then membrane filtered. Following membrane filtration (2 × 48 mL) and wash with 10 mL of Phosphate Buffered Saline (PBS), the filters were aseptically placed onto Trypticase Soy Agar (TSA) plates and incubated aerobically at 30–35 ºC for 4 days. For the positive control, 0.1 mL of *B. atrophaeus* was added to a sterile bag and allowed to dry for thirty (30) minutes. A volume of 100 mL of Fluid D was added, bag was shaken for 30 seconds, membrane filtered (2 × 48 mL), washed with 10 mL of PBS, and aseptically placed onto TSA plates and incubated aerobically at 30–35 ºC for 4 days. Samples of Fluid D and PBS, used as negative controls, were similarly filtered, plated and incubated. The spore suspension concentration was verified by plate count utilizing membrane filtration method with 0.1 mL per plate, in duplicate, and incubated aerobically at 30–35 ºC for 4 days.

RESULTS:

TABLE 1:
Inoculation Verification
Microorganism: *B. atrophaeus*

Concentration	CFU/Plate/0.1 mL		Average CFU/Plate	Challenge Suspension (CFU/0.1 mL)
	1	2		
Neat	75	79	77.0	77.0

CFU = Colony Forming Units
Average CFU/Plate = Sum of CFU/Plate ÷ Number of Plates
Challenge Suspension (CFU/0.1 mL) = Average CFU/Plate = Population Inoculated

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TABLE 2:
Bioburden Validation
Test Article Results

CFU/Plate						Average CFU/Plate	CFU/Device	% Recovery	Recovery Factor
TA 1		TA 2		TA 3					
16	13	5	11	22	23	15.0	31	40%	2.5

CFU = Colony Forming Units
Average CFU/Plate = Sum of CFU/Plate ÷ Number of Plates
CFU/Device (Population Recovered) = Average CFU/Plate × (Volume of Fluid D used ÷ Volume Filtered)
% Recovery = (Population Recovered ÷ Population Inoculated) × 100
Recovery Factor = 100% ÷ Percent Recovery

TABLE 3:
Bioburden Validation
Positive Control Results

CFU/Plate		Average CFU/Plate	CFU/Device	% Recovery	Recovery Factor
32	36	34.0	71	92%	1.1

CFU = Colony Forming Units
Average CFU/Plate = Sum of CFU/Plate ÷ Number of Plates
CFU/Device (Population Recovered) = Average CFU/Plate × (Volume of Fluid D used ÷ Volume Filtered)
% Recovery = (Population Recovered ÷ Population Inoculated) × 100
Recovery Factor = 100% ÷ Percent Recovery

TABLE 4:
Negative Control Results

Fluid D	PBS
NOC	NOC

NOC = No Observable Colonies

CONCLUSION: For the Test Article Results, the average CFU/Plate was 15.0 and the CFU/Device was 31. Using the spore inoculation method, the percent recovery was 40% and the recovery factor was 2.5. For the Positive Control Results, the average CFU/Plate was 34.0 and the CFU/Device was 71. Using the spore inoculation method, the percent recovery was 92% and the recovery factor was 1.1. The Fluid D and PBS plates (negative controls) showed no growth.

AUTHORIZED PERSONNEL:

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

Aparajita Mukherjee
Aparajita Mukherjee, M.S.
Study Director

9.6 Appendix F: Assembled Sensor Certificate: Endotoxin

TOXIKON
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TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	6/4/2019
Address	174 Nassau St. Suite 256 Princeton, NJ 08542	**Technical Completion**	6/4/2019
Contact	Dennis Annarelli	**Report Date**	6/10/2019
P.O. Number	2013567	**Final Non-GLP Report**	19-01946-N1

Test Article	PendoTECH Single Use Conductivity 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	Endotoxins Test Validation (I & E) - USP		
Comments	Pouches containing devices tested included the following information: Test Article 1: Lot 17M6516 Test Article 2: Lot 17C51224 Test Article 3: Lot 18G75420 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 17M6516) was 8.18 and was adjusted to 7.60. The pH of test article 2 (Lot 17C51224) was 8.16 and was adjusted to 7.38. The pH of test article 3 (18G75420) was 7.29 and did not need to be adjusted.		

REFERENCES: The study was conducted based upon the following references: USP 42, NF 37, 2019. <85> Bacterial 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 provided by the Sponsor. The barbed "T" section and fluid path of each test article was individually immersed in 120.0 mL of SWFI heated to 37 ± 1 °C and extracted at room temperature for 60 ± 2 minutes. Each extract was assayed in duplicate 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 and 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 well at 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 study and its design employed methodology to minimize uncertainty of measurement and control of bias for data collection and analysis.

VALIDATION CRITERIA: The absolute value of the correlation coefficient (r) must be ≥ 0.980 in order for the test to be valid. The PPC value must be within the range of 50-200% of the known spike concentration, to show neither inhibition nor enhancement of the assay.

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

TOXIKON

Endotoxins Test Validation (I & E) - USP
Final Non-GLP Report: 19-01946-N1
Test Article Name: PendoTECH Single Use Conductivity Sensors Post 40 kGy Gamma Irradiation

RESULTS:

TABLE 1:
Endotoxin Inhibition and Enhancement Results

Test Article	Sample	Dilution	pH	EU/mL	% PPC Recovery	Valid PPC (Yes/No)
PendoTECH Single Use Conductivity Sensors Post 40 kGy Gamma Irradiation	Test Article 1: Lot 17M6516	Neat	7.60	< 0.00868	103%	Yes
	Test Article 2: Lot 17C51224	Neat	7.38	< 0.00500	82%	Yes
	Test Article 3: Lot 18G75420	Neat	7.29	< 0.00500	104%	Yes

CONCLUSION: The absolute value of the correlation coefficient for the linear regression was 0.998. Neat extracts from PendoTECH Single Use Conductivity Sensors Post 40 kGy Gamma Irradiation do not inhibit or enhance endotoxin detection and satisfy the USP requirements for Amoebocyte Lysate Chromogenic Validation.

AUTHORIZED PERSONNEL:

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

Linda Haggerty
Linda Haggerty, M.S.
Study Director

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TEST RESULT CERTIFICATE

Sponsor	PendoTECH	**Technical Initiation**	6/4/2019
Address	174 Nassau St. Suite 256 Princeton, NJ 08542	**Technical Completion**	6/4/2019
Contact	Dennis Annarelli	**Report Date**	6/10/2019
P.O. Number	2013567	**Final Non-GLP Report**	19-01946-N2

Test Article	PendoTECH Single Use Conductivity 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	The test article was labeled with Lot # 18G75420. 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 the test article was 7.24 and did not need to be adjusted.		

REFERENCES: The study was conducted based upon the following references: USP 42, NF 37, 2019. <85> Bacterial 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 article (1 unit) was identified by information on the product packaging provided by the Sponsor. The barbed "T" section and fluid path of the test article was individually immersed in 120.0 mL of SWFI heated to 37 ± 1 ºC and extracted at room temperature for 60 ± 2 minutes. The extract was assayed in duplicate 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 and 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 ºC for ≥ 10 minutes. After incubation, Lysate (0.1 mL) was added to each well and the absorbance of each well at 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.

RESULTS:

TABLE 1:
Endotoxin Quantity

Lot/Batch #	pH	Dilution	EU/mL	EU/Device	Valid PPC (Yes/No)
18G75420	7.24	Neat	< 0.00500	< 0.6	Yes

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Chromogenic Endotoxin Testing
Final Non-GLP Report: 19-01946-N2
Test Article Name: PendoTECH Single Use Conductivity Sensors Post 40 kGy Gamma Irradiation

CONCLUSION: The absolute value of the correlation coefficient for the linear regression was calculated to be 0.998. The test article, PendoTECH Single Use Conductivity 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

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	0021039808	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRM8HN05	0022897176	1	CS
40-60 SAMPLES Cust Item ID: 20277484/0012395BOR	MGBF62D/MGDM150	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: 844-698-8776

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.

STERIS

STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for END MILLIPORE – BEDFORD
Process Run ID 1179065A
Date Prepared: 1/21/2019 6:47:34AM

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	OC1	0BR600268204	TH0049	0484	28.7	42.1
			0BR600257802	TH0048	0481	13.4	
1	2	TA5	0BR600288439	TH0049	0484	34.4	50.5
			0BR600257878	TH0048	0431	16.1	
1	3	TE5	0BR600268469	TH0049	0434	34.7	50.8
			0BR600257866	TH0048	0431	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 6:47 AM
UTC / GMT Offset (hh:mm): -5:00

Document Content Revision: 1

WI-0937-4 Last Rev DMA 2.0.1.3 & RT 3.5.1.1 Release Date: 15-Jun-2017 Page 1 of 1

9.7 Appendix G: Assembled Sensor Certificate: B&F

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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 °C for 5 days. All FTM vessels except *C. sporogenes* were incubated aerobically at 30-35 °C for 5 days. FTM vessels with *C. sporogenes* were incubated ananerobically at 30-35 °C for 5 days. Growth was visually compared between test and control articles at specific time points.

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

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

9.8 Appendix H: Certificates of Gamma Irradiation for Gamma Compatibility Investigation (7.5)

Sterigenics
A Sotera Health company

Certificate of Processing

STERIGENICS 108 Lake Denmark Rockaway NJ 07866
TEL 973 625-8400 FAX 973 625-7820 www.sterigenics.com

R55480102

04/05/2021 15:57:34 GMT
Page 1 of 1

Customer Name: Flexbiosys, Inc.
P.O.# 2807

Processing Facility: Rockaway

Work Order # 2858627
Sales Order # 2736359

25-40 kGy

FLX, Gamma Treatment

Received Date/Time: 03/30/2021 16:34:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	20	CA	9# CT 22X17X8		1902447, 1902422	FXK-0003-0006, FXM-0020-0066
102.000	22	CA	9# CT 22X17X8		1902400, 1902422	FXK-0003-0006, FXM-0020-0066
103.000	8	CA	9# CT 22X17X8		1902400, 1902844	FXK-0003-0006, FXM-0020-0066
104.000	10	CA	9# CT 22X17X8		1902400, 1902409	FXK-0003-0006, FXL-0300-0002
105.000	1	CA	9# CT 22X17X8		1902399, 1902536	FXK-0003-0006, FXM-500M-0013
106.000	2	CA	9# CT 22X17X8		1902399, 1902595	FXK-0003-0006, FXB-500M-0021
107.000	12	CA	9# CT 22X17X8		1902399, 1902398	FXK-0003-0006, FXK-0001-0393
108.000	10	CA	9# CT 22X17X8		1902399, 1902773	FXK-0003-0006, FXL-0400-0002
109.000	10	CA	9# CT 22X17X8		1902399, 1902774	FXK-0003-0006, FXL-0400-0002
110.000	9	CA	9# CT 22X17X8		1902399, 1902775	FXK-0003-0006, FXL-0400-0002
111.000	1	CA	9# CT 22X17X8		1902399, 1902849	FXK-0003-0006, GAMMA22X17X08_A
	105	CA	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	Signed By - User	Signed By - Date /Time
450.00	Minimum Dose	25.0 kGy Reason Code Test	40.0 kGy	27.4 KGY	Pass	DRITCHIE DWAYNE RITCHIE	04/03/2021 14:46:34 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	40.0 kGy	35.1 KGY	Pass	DRITCHIE DWAYNE RITCHIE	04/03/2021 14:46:52 GMT

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: CONRAD WEISS
Reason: Work Order Completions

Date: 04/05/2021 15:56:05 GMT

ISO 9001 and ISO 13485 Registered

9.9 Appendix I: Certificates of Calibration for Pressure Gauge used in 8.1

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
1583957

Reference Number: **1374549**
PO Number: **RANDD**

PendoTECH
3490 US Route 1
Building 15F
Princeton, NJ 08540 United States

Manufacturer:	Druck Inc.	**Calibration Date:**	06/10/2019
Model Number:	DPI 104 0-100 PSI	**Calibration Due Date:**	06/10/2020
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 Druck DPI 104 0-100PSI		

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
CP144957	Fluke Corporation	PM600-G100K	Pressure, Measurement Module 0 - 15PSI	05/24/2019	05/31/2020
CP144959	Fluke Corporation	PM600-A700K	Pressure, Measurement Mod -12.1 -100PSI	05/23/2019	05/31/2020

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Zero Reference	0.00	0.00		Same		Reference Only
Increasing Pressure Accuracy	10.00 psi	10.00		Same		9.95 to 10.05 psi [EMU 0.007 psi][TUR 7.1:1]
	20.00 psi	20.00		Same		19.95 to 20.05 psi [EMU 0.031 psi][TUR 1.6:1]
	30.00 psi	30.01		Same		29.95 to 30.05 psi [EMU 0.0092 psi][TUR 5.5:1]
	40.00 psi	40.00		Same		39.95 to 40.05 psi [EMU 0.01 psi][TUR 4.8:1]
	50.00 psi	50.01		Same		49.95 to 50.05 psi [EMU 0.011 psi][TUR 4.4:1]
	60.00 psi	60.01		Same		59.95 to 60.05 psi [EMU 0.013 psi][TUR 4.0:1]
	70.00 psi	70.01		Same		69.95 to 70.05 psi [EMU 0.014 psi][TUR 3.7:1]
	80.00 psi	80.01		Same		79.95 to 80.05 psi [EMU 0.015 psi][TUR 3.4:1]
	90.00 psi	90.01		Same		89.95 to 90.05 psi [EMU 0.015 psi][TUR 3.3:1]
	100.00 psi	100.01		Same		99.95 to 100.05 psi [EMU 0.016 psi][TUR 3.1:1]
Decreasing Pressure Test	90.00 psi	90.01		Same		89.95 to 90.05 psi [EMU 0.015 psi][TUR 3.3:1]
	80.00 psi	80.01		Same		79.95 to 80.05 psi [EMU 0.015 psi][TUR 3.4:1]
	70.00 psi	70.01		Same		69.95 to 70.05 psi [EMU 0.014 psi][TUR 3.7:1]
	60.00 psi	60.01		Same		59.95 to 60.05 psi [EMU 0.013 psi][TUR 4.0:1]
	50.00 psi	50.01		Same		49.95 to 50.05 psi [EMU 0.011 psi][TUR 4.4:1]
	40.00 psi	40.01		Same		39.95 to 40.05 psi [EMU 0.01 psi][TUR 4.8:1]
	30.00 psi	30.00		Same		29.95 to 30.05 psi [EMU 0.0092 psi][TUR 5.5:1]

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
	20.00 psi	20.00		Same		19.95 to 20.05 psi [EMU 0.031 psi][TUR 1.6:1]
	10.00 psi	10.00		Same		9.95 to 10.05 psi [EMU 0.007 psi][TUR 7.1:1]
Zero Reference	0.000 psi	0.00		Same		Reference Only

Temperature: 21° C
Humidity: 42% RH
Rpt. No.: 1583957

Calibration Performed By:				Quality Reviewer:	
Ziegler, Jeff	335	Metrologist	847-327-5335	Pietronicco, Mike	06/10/2019
Name	ID #	Title	Phone	Name	Date

Report Number: 1583957

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

9.10 Appendix J: Certificate of Calibration 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 578968

Reference Number: 499231
PO Number: RANDD

Reference # : 7263183-00

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

Manufacturer: Druck Inc.
Model Number: DPI 104 0-100 PSI
Description: Pressure, Digital Gauge, 0-100 PSI
Asset Number: CP21618
Serial Number: 2936090
Procedure: DS Universal Pressure Gauge-10

Calibration Date: 04/25/2014
Calibration Due Date: 04/25/2015
Condition As Found: In Tolerance
Condition As Left: In Tolerance, No adjustment

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

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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

Report Number: 578968

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

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9.11 Appendix K: Certificate of Calibration for Pressure Gauge used in 8.5 and 8.6

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NIST Traceable
Calibration Report

REPORT NUMBER
1662895

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

OK TO USE
UNE
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

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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

Report Number: 1662895

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

Cole-Parmer® Traceable® DIGI-SENSE OAKTON®

9.12 Appendix L: X-ray Certificate of Processing for Section 8.6

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