

Validation Guide for PendoTECH® Single Use Temperature Sensors™

Revision 3



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CONFIDENTIAL

Validation Guide for PendoTECH Single Temperature Sensors

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

Revision 3

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1 INTRODUCTION

1.1 Product overview

- 1.1.1 PendoTECH Single Use Temperature Sensors measure temperature in processes accurately and cost effectively. They are low cost for single use applications, but may also be repeatedly cleaned and re-used. They are perfect for bioreactor, filtration and chromatography processes, filling operations, and general process monitoring. These sensors connect to monitors via a reusable cable. Suitable monitors include the handheld unit TEMP340, a PendoTECH Process Control System, a DIN Rail mountable transmitter with a 4-20 mA output, or other pre-qualified third-party monitors. They are the alternative solution for use with tubing to the existing temperature measurements devices on the market. To optimally adapt to tubing the sensors are available with either a hose barb fitting, or sanitary flange. Tubing can be secured directly to the hose barb fitting and the hose barb design imparts no obstruction on the fluid path that can cause a pressure drop and there is no dead-leg at the point where the temperature is measured. The temperature sensing element is a thermistor. No calibration is required because the temperature versus resistance for the thermistor element is well-defined within the specified accuracy range. Within the instrument, the measured resistance is converted to the temperature.

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 comment.

- 1.3.1 Testing was completed to qualify the product for use in bioprocess applications. In the product manufacturing process, stainless steel tubes and thermistors are installed into the polysulfone product bodies. Pre-existing specifications on certain materials used in the single use temperature sensors are noted.

2 PRODUCT CATALOG NUMBERS

PendoTECH Product Catalog Numbers Covered in This Document	
Part Number	Description
TEMPS-N-012	Single Use Temperature Sensor, Non-Sterile, 1/8 inch Hose Barb, Polysulfone
TEMPS-N-025	Single Use Temperature Sensor, Non-Sterile, 1/4 inch Hose Barb, Polysulfone
TEMPS-N-038	Single Use Temperature Sensor, Non-Sterile, 3/8 inch Hose Barb, Polysulfone
TEMPS-N-050	Single Use Temperature Sensor, Non-Sterile, 1/2 inch Hose Barb, Polysulfone
TEMPS-N-075	Single Use Temperature Sensor, Non-Sterile, 3/4 inch Hose Barb, Polysulfone
TEMPS-N-1-1	Single Use Temperature Sensor, Non-Sterile, 1 inch Sanitary Flange, 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 mm² in the fluid path. Maximum size of 0.2 mm² anywhere else.
- 3.3.2 Embedded Bubbles: Maximum 2 allowed per part. Maximum size of 0.08 mm² in the fluid path. Maximum size of 0.2 mm² 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 product contact side
- 3.5.2 Every product is tested electrically to confirm proper electrical performance
- 3.5.3 Each thermistor is tested to verify accuracy
- 3.5.3.1 Each thermistor is tested at 10°C to confirm 4482Ω ± 0.1°C
- 3.5.3.2 Each thermistor is tested at 25°C to confirm 2252Ω ± 0.1°C
- 3.5.3.3 Each thermistor is tested at 40°C to confirm 1200Ω ± 0.1°C
- 3.5.3.4 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 temperature 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 Temperature products.

4 MATERIALS

4.1 Wet Volume and Surface Area

Part Number	Wet Volume	Wet Surface
TEMPS-N-012	0.011in ³	0.45in ²
TEMPS-N-025	0.048in ³	0.91in ²
TEMPS-N-038	0.113in ³	1.88in ²
TEMPS-N-050	0.269in ³	3.10in ²
TEMPS-N-075	0.890in ³	6.14in ²
TEMPS-N-1-1	1.850in ³	8.53in ²

4.2 Fluid path components

- 4.2.1 Polysulfone product body: Solvay UDEL P1700; 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)
- 4.2.2 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)
- 4.2.3 Thermistor Sheath: 304 Stainless Steel; must contact fluid to measure temperature

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 42-51 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 temperature sensors as the fluid path components are 99% identical. The major difference is the presence of a 304 Stainless Steel sheath for the thermistor in temperature sensors, which is not a polymeric material and therefore not subject to USP Class VI testing.

5.2 USP 661 post gamma irradiation

- 5.2.1 Fully assembled temperature sensors meet the criteria of the USP Physicochemical Test for Plastics based upon Nonvolatile Residue, Residue on Ignition, and Buffering Capacity after exposure to 27.5 - 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. The sensors did not meet the criteria for Heavy Metals of the USP Physicochemical Test. These sensors contain stainless steel probes in the flow path, which likely contributed to this as USP<661> is intended for plastic parts. For more detailed information regarding the presence of heavy metals in this product, please contact PendoTECH directly. Testing was done with PendoTECH conductivity sensors, which are made of identical materials. Test Result Certificates are in Appendix B.

5.3 ISO 10993-5 post gamma irradiation

- 5.3.1 Fully assembled temperature sensors meet the requirements of ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity and are not considered to have a cytotoxic effect. Testing was done with PendoTECH conductivity sensors, which are made of identical materials. 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. These results also apply to temperature sensors as they are manufactured in the same location and consist of the same materials

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. These results also apply to temperature sensors as they are manufactured in the same location and consist of the same materials

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. These results also apply to temperature sensors as they are manufactured in the same location and consist of the same materials

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 temperature sensors as the fluid path components are 99% identical. The major difference is the presence of a 304 Stainless Steel sheath for the thermistor in temperature 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	0°C to 70°C: $\pm 0.2^\circ\text{C}$	Qualification Testing by PendoTECH, Specifications of Thermistor
Pressure Range	75 psi max	In Process Manufacturing Testing by PendoTECH
Gamma Irradiation	Up to 50 kiloGrays	Qualification Testing by PendoTECH
X-ray Irradiation	Up to 50 kiloGrays	Qualification Testing by PendoTECH
Post Irradiation Accuracy	0°C to 2°C: $\pm 0.5^\circ\text{C}$ 2°C to 50°C: $\pm 0.2^\circ\text{C}$ 50°C to 70°C: $\pm 0.5^\circ\text{C}$	Qualification Testing by PendoTECH
Operating Temperature	0°C to 70°C	Raw Material Specifications
Storage Temperature	-25°C to 65°C	Raw Material Specification
Shelf life	5 years	Qualification Testing by PendoTECH

7 PENDOTECH TEST METHOD SUMMARY

7.1 Pressure limit of 75 psi

- 7.1.1 In order to further qualify temperature sensors to be physically compatible at pressures of 75 psi, high pressure leak and burst testing was carried out. Testing was performed on PendoTECH Single Use Conductivity 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 conductivity sensors have two additional electrodes for measuring conductivity. Nine 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 Temperature Sensor Accuracy

- 7.2.1 PendoTECH has carried out a study challenging the thermistors manufacturing claim of “better than +/- 0.2°C (typically better than +/- 0.1°C)”, in the range 0°C to 70°C. 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. The result of the study 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 $\pm 0.2^\circ\text{C}$ tolerance band/specification across the entire 0°C to 70°C range. Only a few measurements were even outside of the $\pm 0.1^\circ\text{C}$ 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.

7.3 Shelf life of 5 years and Gamma Compatibility

- 7.3.1 PendoTECH has validated a 5-year shelf life and gamma compatibility for its temperature sensor by performance testing real time aged and gamma irradiated sensors. Samples of temperature sensors that were stored on the shelf under ambient conditions for 2 years, gamma irradiated, and then stored for 3+ more years were tested for accuracy at 2, 10, 20, 50, and 70°C. The sensors were submerged in a calibrated MEAS Brand Temperature Bath, which controlled the temperature setpoint. The raw resistance readings were measured with a calibrated multimeter and then converted to degrees Celsius using the Steinhart-Hart equation. The temperature reading and error for each point are reported here.
- 7.3.2 In order to validate sensor integrity after a 5 year shelf life and gamma irradiation, leak testing was performed on sensors that were gamma irradiated and stored on the shelf under ambient conditions for a total of 5+years. These were the same temperature sensors used for the accuracy testing described above. A 90 second pressure decay test was performed at 60 psi. The pressure decay of each sensor is reported here.

7.4 X-ray Compatibility

- 7.4.1 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 Temperature Sensors for X-ray irradiation for a dose > 50 kiloGrays (Certificate in Appendix K). 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 was performed on PendoTECH single Use Conductivity 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 conductivity sensors have two additional electrodes for measuring conductivity. Testing procedures and results are documented below.

7.5 Operating Temperature range 0 to 70°C

- 7.5.1 PendoTECH has determined a 0 to 70°C operating temperature range for Single Use Temperature sensors based on thermistor qualification and raw material specifications. PendoTECH has on file information from all sensor component material suppliers stating operating temperature ranges that are congruent with a 0 to 70°C claim.

7.6 Storage Temperature -2 to 65°C

- 7.6.1 PendoTECH has determined a -25° to 65°C storage temperature range for Single Use Temperature 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: Burst Testing

- 8.1.1 Procedure: Testing was conducted with conductivity sensors, which are made of identical components and assembled in the same facility by the same operators using the same procedure. 9 conductivity 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
- 8.1.1.1 Calibrated Pressure Gauge: Model: Druck DPI 104 S/N: 2936090 (Cert in Appendix I)
- 8.1.1.2 Acceptance Criteria: No identifiable leaks after exposure to 90 psi for 100 seconds and no burst.
- 8.1.2 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

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

8.2 Temperature Sensor Accuracy

8.2.1 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: $\pm 0.2^{\circ}\text{C}$ 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 $\pm 0.2^{\circ}\text{C}$ tolerance band/specification across the entire 0 °C to 70 °C range. Only a few measurements were even outside of the $\pm 0.1^{\circ}\text{C}$ 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 ($\pm 0.2^{\circ}\text{C}$)	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

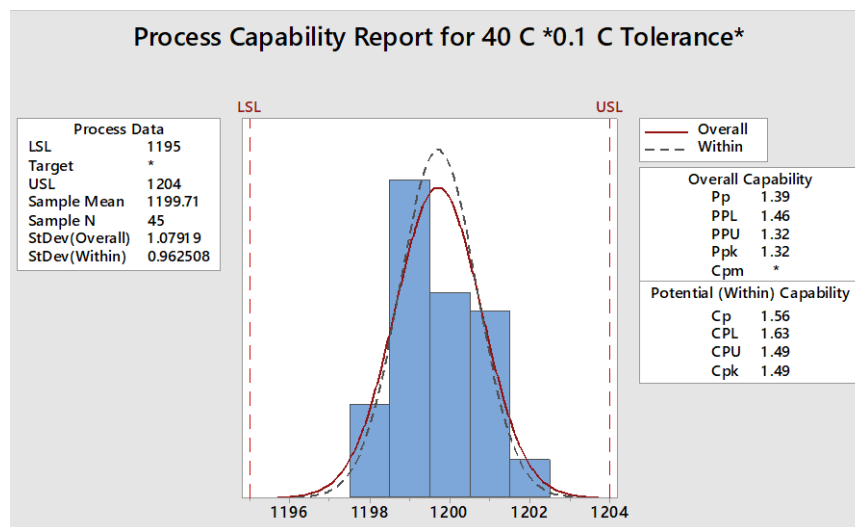
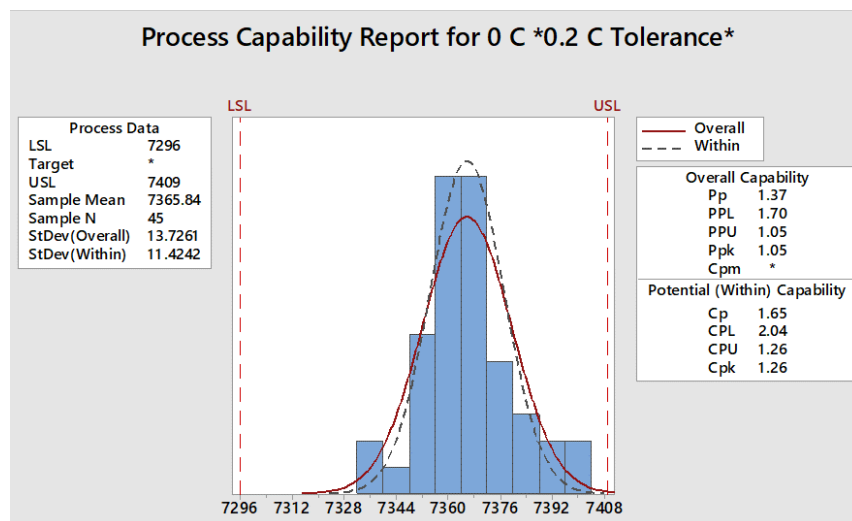
RESULTS

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.



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

8.3 Shelf life of 5 years and Gamma Compatibility

8.3.1 Real Time Aged and Gamma Irradiated Sensor Accuracy Testing

8.3.1.1 Procedure- 15x temperature sensors from Lot# 15L29128 that were stored on the shelf under ambient conditions for 2 years, gamma irradiated with a dose of 60-77 kGy (Certificate in Appendix H), and then stored in the same conditions for 3+ more years were tested for accuracy at 2, 10, 20, 50, and 70°C. The sensors were submerged in a calibrated bath, which controlled the temperature setpoint. The raw resistance readings were measured with a calibrated multimeter and then converted to degrees Celsius using the Steinhart-Hart equation. The temperature reading and error for each point are reported here.

8.3.1.2 Calibrated Equipment:

Device	Manufacturer	Model	Serial Number	Last Calibration Date
Digital Multimeter	Keithley	197A	3201	5/2/2020
Precision Bath	TE	MEAS	2617	7/28/2020
Precision Bath Probe	TE	MEAS	2925	7/28/2020

8.3.1.3 Acceptance Criteria: All sensors within accuracy specification:

0°C to 2°C: $\pm 0.5^\circ\text{C}$
 2°C to 50°C: $\pm 0.2^\circ\text{C}$
 50°C to 70°C: $\pm 0.5^\circ\text{C}$

8.3.1.4 Data Summary:

Sensor	2°C		10°C		20°C		50°C		70°C	
	Temp °C	Error °C	Temp °C	Error °C	Temp °C	Error °C	Temp °C	Error °C	Temp °C	Error °C
1	2.11	0.11	9.86	-0.14	19.86	-0.14	49.83	-0.17	69.80	-0.20
2	1.91	-0.09	10.11	0.11	19.93	-0.07	49.88	-0.12	70.02	0.02
3	1.90	-0.10	9.91	-0.09	19.92	-0.08	49.90	-0.10	69.90	-0.10
4	1.96	-0.04	9.97	-0.03	19.98	-0.02	49.96	-0.04	69.98	-0.02
5	1.85	-0.15	9.88	-0.12	19.96	-0.04	49.84	-0.16	69.90	-0.10
6	1.86	-0.14	9.85	-0.15	19.92	-0.08	49.83	-0.17	70.00	0.00
7*	1.79	-0.21	9.79	-0.21	19.78	-0.22	49.73	-0.27	69.68	-0.32
8	1.93	-0.07	9.94	-0.06	19.96	-0.04	49.94	-0.06	70.13	0.13
9	2.00	0.00	9.91	-0.09	19.92	-0.08	49.91	-0.09	69.96	-0.04
10	2.04	0.04	9.91	-0.09	19.93	-0.07	49.92	-0.08	69.91	-0.09
11	1.89	-0.11	9.97	-0.03	19.95	-0.05	49.93	-0.07	69.91	-0.09
12	2.07	0.07	9.94	-0.06	19.97	-0.03	49.91	-0.09	69.97	-0.03
13	1.91	-0.09	9.94	-0.06	19.99	-0.01	49.92	-0.08	70.07	0.07
14	1.98	-0.02	10.11	0.11	19.95	-0.05	49.93	-0.07	69.97	-0.03
15	1.92	-0.08	9.93	-0.07	19.96	-0.04	49.94	-0.06	69.96	-0.04

*One out of the 15 sensors was marginally outside its specification. Based on the consistent results of the other sensors, sensor #7 is considered to be an outlier that does not reflect the typical performance of a temperature sensor post 5 year shelf life or gamma irradiation.

8.3.1.5 Conclusion: 14/15 temperature sensors were within PendoTECH's accuracy specification. The one sensor not within specification is considered to be an outlier, thus validating post 5-year shelf accuracy and post gamma irradiation accuracy for PendoTECH temperature sensors.

8.3.2 Real Time Aged and Gamma Irradiated Sensor Leak Testing:

8.3.2.1 Procedure- The same 15x real time aged and gamma irradiated temperature sensors used for the accuracy testing above were also subjected to leak testing. One at a time the sensors were connected a PendoTECH custom test rig, where 60 psi was applied to the system. The sensor was then isolated and the pressure drop over the next 90 seconds was measured. The pressure decay is reported below.

8.3.2.2 Calibrated Pressure Gauge- Model: Druck DPI 104 S/N: 5380820 (Cert in Appendix J)

8.3.2.3 Acceptance criteria- Pressure decay less than 0.03 psi/sec

8.3.2.4 Data Summary:

Sensor	Initial Pressure (psi)	Final Pressure (psi)	ΔP (psi)	Pressure Decay (psi/sec)
1	60.21	60.16	0.05	0.0006
2	60.09	60.03	0.06	0.0007
3*	60.12	57.86	2.26	0.0251
4	60.15	60.08	0.07	0.0008
5	60.12	60.05	0.07	0.0008
6	60.11	60.05	0.06	0.0007
7	60.2	60.14	0.06	0.0007
8	60.16	60.1	0.06	0.0007
9	60.15	60.06	0.09	0.0010
10	60.16	60.08	0.08	0.0009
11	60.14	60.06	0.08	0.0009
12	60.15	60.07	0.08	0.0009
13	60.13	60.07	0.06	0.0007
14	60.15	60.06	0.09	0.0010
15	60.11	60.04	0.07	0.0008

*Although in specification, a liquid leak check was performed to double check sensor integrity since the pressure decay was larger than all the other samples. The sensor was confirmed to not leak any liquid.

8.3.2.5 Conclusion: No leaks were identified, validating sensor integrity post gamma irradiation and 5-year shelf life

8.4 X-ray Compatibility

8.4.1 Post X-ray Functionality Testing

8.4.1.1 Procedure: 29x Conductivity sensors from 3 different lots (CONDS-N-025 from Lot numbers 0222442687, 0222742463, and 0222589479), which use the same thermistor as PendoTECH's single use temperature sensors, were tested for temperature accuracy across their full range of 0-70°C. Half of the sensors were X-ray irradiated with a dose >50 kGy (Certificate in Appendix K), and the other half were not irradiated to act as a control group. The sensors were tested at the following temperature test points: 2, 10, 20, 50 and 70°C. The sensors were submerged in a calibrated temperature bath to control the temperature setpoint as the raw resistance readings were measured with a calibrated multimeter. The temperature reading and error for each test point are reported here.

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8.4.1.2 Calibrated Equipment:

Device	Manufacturer	Model	Serial Number	Last Calibration Date
Digital Multimeter	Keithley	197A	3413	4/1/2022
Precision Bath	TE	MEAS	3045	1/28/2022
Precision Bath Probe	TE	MEAS	2924	1/28/2022

8.4.1.3 Acceptance Criteria:

All Sensor's within PendoTECH Temperature Sensor Accuracy Specification:

0°C to 2°C: $\pm 0.5^\circ\text{C}$; 2°C to 50°C: $\pm 0.2^\circ\text{C}$; 50°C to 70°C: $\pm 0.5^\circ\text{C}$

8.4.1.4 Data Summary:

Serial Number	Condition	Temperature Setpoint (°C)									
		2		10		20		50		70	
		Reading (°C)	Error (°C)	Reading (°C)	Error (°C)	Reading (°C)	Error (°C)	Reading (°C)	Error (°C)	Reading (°C)	Error (°C)
1	Control	1.95	0.05	9.96	0.04	19.97	0.03	49.90	0.10	69.85	0.15
2	Control	1.96	0.04	9.97	0.03	20.00	0.00	49.95	0.05	69.90	0.10
4	Control	1.95	0.05	9.94	0.06	19.97	0.03	49.97	0.03	69.92	0.08
5	Control	1.95	0.05	9.94	0.06	19.98	0.02	49.96	0.04	69.94	0.06
11	Control	1.94	0.06	9.92	0.08	19.96	0.04	49.95	0.05	69.96	0.04
14	Control	1.94	0.06	9.93	0.07	19.97	0.03	49.97	0.03	69.93	0.07
18	Control	1.94	0.06	9.92	0.08	19.96	0.04	49.97	0.03	69.90	0.10
19	Control	1.94	0.06	9.93	0.07	19.97	0.03	49.96	0.04	69.97	0.03
20	Control	1.95	0.05	9.94	0.06	19.96	0.04	49.89	0.11	69.87	0.13
22	Control	1.91	0.09	9.93	0.07	19.95	0.05	49.97	0.03	69.87	0.13
25*	Control	1.60	0.40	9.50	0.50	19.54	0.46	49.95	0.05	69.91	0.09
27	Control	1.94	0.06	9.91	0.09	19.96	0.04	50.00	0.00	69.92	0.08
28	Control	1.95	0.05	9.94	0.06	19.99	0.01	49.96	0.04	69.93	0.07
30	Control	1.95	0.05	9.94	0.06	19.97	0.03	49.96	0.04	69.93	0.07
6	X-ray	1.94	0.06	9.96	0.04	19.98	0.02	49.96	0.04	69.90	0.10
7	X-ray	1.93	0.07	9.94	0.06	19.95	0.05	49.94	0.06	69.99	0.01
8	X-ray	1.87	0.13	9.90	0.10	19.90	0.10	49.88	0.12	69.84	0.16
9	X-ray	1.97	0.03	9.94	0.06	19.97	0.03	49.97	0.03	69.91	0.09
10	X-ray	1.97	0.03	9.92	0.08	19.95	0.05	49.97	0.03	69.91	0.09
12	X-ray	1.91	0.09	9.94	0.06	19.95	0.05	49.95	0.05	69.95	0.05
13	X-ray	1.95	0.05	9.94	0.06	19.98	0.02	49.93	0.07	69.95	0.05
15	X-ray	1.91	0.09	9.94	0.06	19.95	0.05	49.96	0.04	69.91	0.09
16	X-ray	1.94	0.06	9.94	0.06	19.94	0.06	49.90	0.10	69.90	0.10
17	X-ray	1.94	0.06	9.94	0.06	19.95	0.05	49.93	0.07	69.87	0.13
21	X-ray	1.91	0.09	9.94	0.06	19.96	0.04	49.96	0.04	69.95	0.05
23	X-ray	1.91	0.09	9.93	0.07	19.94	0.06	49.98	0.02	69.95	0.05
24	X-ray	1.90	0.10	9.92	0.08	19.93	0.07	49.93	0.07	69.91	0.09
26*	X-ray	1.72	0.28	9.61	0.39	19.67	0.33	49.91	0.09	69.81	0.19
29	X-ray	1.94	0.06	9.93	0.07	19.94	0.06	49.95	0.05	69.90	0.10

*Two sensors, sensor# 25 (control) and sensor#26 (X-ray irradiated) were out of specification. These sensors were then re-tested, and both reported extremely high resistance values, indicating an open circuit. Therefore, these sensors were damaged during the initial exposure to the water bath, likely from mishandling, and thus their results should be omitted from the X-ray compatibility analysis.

8.4.1.5 Conclusion: With the exception of the two outliers described in the footnote, all of the sensors, both control and x-ray irradiated, were within PendoTECH's temperature sensor accuracy claim, thus validating the performance of PendoTECH single use temperature sensors post x-ray irradiation.

8.4.2 Post X-ray Integrity Testing

8.4.2.1 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 (Certificate in Appendix K). 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.

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

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

8.4.2.4 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

8.4.2.5 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 Temperature Sensors post X-ray Irradiation.

9 APPENDICES

9.1 Appendix A- Assembled Sensor Certificate: Class VI post 40kGy gamma irradiation



TEST RESULT CERTIFICATE

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

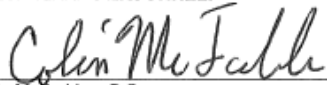
The extraction conditions were performed as stated above. The test article extracts and corresponding blanks were injected systemically and intracutaneously in mice and rabbits, respectively. The injections were in the amounts and routes set forth by USP, including the further dilution of the extracts 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.

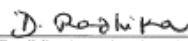
RESULTS AND CONCLUSION:

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



**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

TOXIKON

Class VI Test – USP (With 14 Day Subcutaneous Implant)

Final GLP Report: 19-00538-G1 Amended

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

STUDY SUMMARY

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

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




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

QUALITY ASSURANCE STATEMENT

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

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

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


 Colin McFadden, B.S.
 Quality Assurance

6/17/19
 Date



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

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

Prepared for EMD MILLIPORE – BEDFORD



Gamma Process Run ID 117005A

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

PO Number: N1402721

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

Minimum Specified Dose (kGy):	40.0	Minimum Delivered Dose (kGy):	42.1
Maximum Specified Dose (kGy):	60.0	Maximum Delivered Dose (kGy):	50.8
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.			

<u>Signature Manifest</u>	
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.
---	--



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)
	1	1 OC1	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
			0BR600257866	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 cm ² /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**




Gamma Process Run ID **179365C**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
GROUP 89	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.

STERIS Isomedix Services Dosimetry Record

Prepared for ADVANCED SCIENTIFICS INC -- Process Run ID 179355C
 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)	5A30364003	MX 700989	0.7050	2.748	30.7	
1	2	0C3	NR (09/15/2015)	5A30364003	MX 700989	0.7742	3.049	30.1	
1	3	0CEOB	NR (09/15/2015)	5A30364003	MX 700989	0.8206	3.228	30.2	
1	4	1C1	NR (09/15/2015)	5A30364003	MX 700989	0.7697	2.877	33.0	
1	5	1CEOB	NR (09/15/2015)	5A30364003	MX 700989	0.8630	3.249	32.6	
1	6	TBAEOB	NR (09/15/2015)	5A30364003	MX 700989	0.8840	3.236	34.3	
1	7	TBEOB	NR (09/15/2015)	5A30364003	MX 700989	0.7782	2.842	34.5	
2	1	0CEOB	NR (09/15/2015)	5A30364003	MX 700989	0.7542	2.962	30.3	
2	2	TBA5	NR (09/15/2015)	5A30364003	MX 700989	0.8315	2.894	37.7	
2	3	TBE5	NR (09/15/2015)	5A30364003	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: 11/12/2015 4:21:38 AM

Signature Manifest

Prepared By:
Zephoni Rose (Material Handler)

Approved By:
Tracy Wild (QS/RC Technician)

Document Content Revision: 1

Signed On 11/12/2015 at 4:22 AM
 UTC / GMT Offset (hr:mm): -5:00

Signed On 11/22/2015 at 10:47 AM
 UTC / GMT Offset (hr:mm): -5:00

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

Certificate Of Processing
 Prepared for **ADVANCED SCIENTIFICS INC**




Gamma Process Run ID **179655E**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
GROUP 89	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.

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**

<u>Carrier</u>	<u>Seq</u>	<u>Coordinate</u>	<u>Batch - Cal Dt</u>	<u>Spectro S/N</u>	<u>Micrometer S/N</u>	<u>ABS</u>	<u>Thick (mm)</u>	<u>Final Dose (kGy)</u>	<u>Comment</u>
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	0.8988	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

PROC-0003/01350 Last Rev DMA 1.0.2.1 & RT 3.6.2.1

Release Date: **10-Aug-2015**

Page 1 of 2

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



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 (CO₂). 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

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**



Gamma Process Run ID **75899A**


<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
GROUP 89	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.

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	Seg	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 DateTime: 8/2/2015 12:33:08AM

Signature Manifest

Prepared By:  Ronald Slack (Supervisor I)	Signed On 8/2/2015 at 12:33 AM UTC / GMT Offset (hr:mm): -4:00
Approved By:  Maria H Greco (QS/RC Technician) Document Content Revision: 1	Signed On 8/3/2015 at 7:49 AM UTC / GMT Offset (hr:mm): -4:00

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

9.4 Appendix D: Assembled Sensor Certificate: Particulates



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 :

$$Particles\ per\ unit = \frac{T_a * P_a - T_b * P_c}{N_{dev}}$$

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





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.

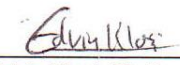
TABLE 2
 Particles per unit of device
 Calculated Results

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

TOXIKON

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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

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 °C 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 °C 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 °C 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



Bioburden Validation – Spore Inoculation – AAMI

Final Non-GLP Report: 19-00165-N1

Test Article Name: PendoTECH Single Use Conductivity Sensors

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

Aparajita Mukherjee
Aparajita Mukherjee, M.S.
Study Director

9.6 Appendix F: Assembled Sensor Certificate: Endotoxin



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	<p>Pouches containing devices tested included the following information:</p> <p>Test Article 1: Lot 17M6516 Test Article 2: Lot 17C51224 Test Article 3: Lot 18G75420</p> <p>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.</p> <p>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.</p>		

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.



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

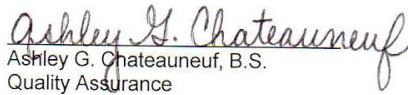
RESULTS:

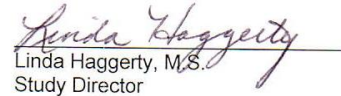
TABLE 1:
Endotoxin Inhibition and Enhancement Results

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. Chateaufort, B.S.
Quality Assurance


Linda Haggerty, M.S.
Study Director



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	<p>The test article was labeled with Lot # 18G75420.</p> <p>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.</p> <p>The pH of the test article was 7.24 and did not need to be adjusted.</p>		

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 °C 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 °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 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

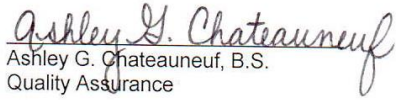


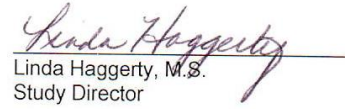
Chromogenic Endotoxin Testing
Final Non-GLP Report: 19-01946-N2

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. Chateauf, B.S.
Quality Assurance


Linda Haggerty, M.S.
Study Director

Certificate Of Processing

Prepared for **EMD MILLIPORE – BEDFORD**



Gamma Process Run ID 117005A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF1TN05	0020499759	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRF4HN05	0021039308	1	CS
40-60 SAMPLES Cust Item ID: CAT. NO. CDRM3HN05	0022897176	1	CS
40-60 SAMPLES Cust Item ID: 20277484/00123958DR	MGBF620/MGDM180	1	CS
40-60 SAMPLES Cust Item ID: PENDOTECH POLYSULFONE SENSORS	NA	1	CS

PO Number: N1402721

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

Minimum Specified Dose (kGy):	40.0	Minimum Delivered Dose (kGy):	42.1
Maximum Specified Dose (kGy):	60.0	Maximum Delivered Dose (kGy):	50.8
Product meets Customer specifications, zero nonconformities occurred during this irradiation run.			

<u>Signature Manifest</u>	
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

<u>Processing Location:</u> STERIS 435 Whitney Street Northborough, MA 01532 Phone: 508-393-8323 Fax: 544-688-8778	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 DA QSR, EN/ISO 13485, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11133. 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.
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STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for EMD MILLIPORE - BEDFORD

Process Run ID 117905A

Date Prepared: 1/21/2019 8:47:34AM

Processing Location: Northborough

Irradiator / Method: 128, Norclon Cobalt-60 Irradiator #126, ON-STD

Carrier	Seq	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
Final Dose Measurements							
1	1	OC1	08R600268204	TH0049	0484	28.7	42.1
			08R600257902	TH0048	0481	13.4	
1	2	TA5	08R600288439	TH0040	0484	34.4	50.5
			08R600257878	TH0048	0431	16.1	
1	3	TE5	08R600288499	TH0049	0434	34.7	50.8
			08R600257866	TH0048	0481	16.1	

Minimum Dose for Record (kGy): 42.1
 Maximum Dose for Record (kGy): 50.8

Signature Manifest

Prepared By:  **Hector Baez (Material Handler)**

Approved By:  **Francine Miranda (QS & RC Analyst)**

Document Content Revision: 1

Signed On 1/21/2019 at 8:23 AM
UTC: GMT Offset (hr:min): -0:00

Signed On 1/21/2019 at 8:47 AM
UTC: GMT Offset (hr:min): -0:00

9.7 Appendix G: Assembled Sensor Certificate: B&F

TOXIKON

ADVANCING YOUR INNOVATION

TEST RESULT CERTIFICATE

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

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

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

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

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

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

As positive controls, an equivalent number of TSB and FTM vessels were inoculated with the respective organisms. One TSB and one FTM vessel were un-inoculated and served as negative controls. A volume of 20 mL of PBS and 20 mL of Fluid D of the same lot used was membrane filtered and the filters were put in respective containers containing 100 mL of TSB each. All TSB vessels were incubated aerobically at 20-25 °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 anaerobically 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	Organism						Negative Control	Fluid D	PBS
	<i>B. subtilis</i>		<i>C. albicans</i>		<i>A. brasiliensis</i>				
	With TA	Without TA	With TA	Without TA	With TA	Without TA			
1	W	W	W	W	W	W	W	W	
2	W	W	W	W	W	W	W	W	
3	+	+	+	+	+	+	-	-	
4	+	+	+	+	+	+	-	-	
5	+	+	+	+	+	+	-	-	

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

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

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)

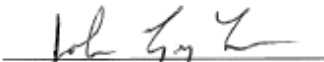
TABLE 2:
 Sterility Validation Results – FTM
 Growth (+/-) per Medium

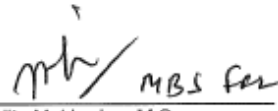
Day	Organism						Negative Control	Fluid D	PBS
	<i>C. sporogenes</i>		<i>S. aureus</i>		<i>P. aeruginosa</i>				
	With TA	Without TA	With TA	Without TA	With TA	Without TA			
1	W	W	W	W	W	W	W	W	
2	W	W	W	W	W	W	W	W	
3	+	+	+	+	+	+	-	-	
4	+	+	+	+	+	+	-	-	
5	+	+	+	+	+	+	-	-	

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


 Aparajita Mukherjee, M.S.
 Study Director

Certificate Of Processing

Prepared for EMD MILLIPORE – BEDFORD



Gamma Process Run ID 117005A

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

PO Number: N1402721

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

Minimum Specified Dose (kGy):	40.0	Minimum Delivered Dose (kGy):	42.1
Maximum Specified Dose (kGy):	60.0	Maximum Delivered Dose (kGy):	50.8
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.			

<u>Signature Manifest</u>	
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/AAMISO 11137 or EN ANSI/AAMISO 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.
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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)
	1	1 OC1	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
			0BR600257866	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: Gamma Certificate for Temperature Sensors used in 7.3/8.3

Certificate Of Processing



Prepared for **ADVANCED SCIENTIFICS INC**

Gamma Process Run ID **91935A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
GROUP 69	JASON P SAMP / JASON P-SAMP	1	CS
GROUP 69	NA / JULIE-SAMP	1	CS

Processing Run Start Date/Time: 13-Jan-2018 07:25:00 am Approx. Downtime (hours): 0.00
 Processing Run End Date/Time: 13-Jan-2018 08:42:00 am

Minimum Specified Dose (kGy):	27.5	Minimum Delivered Dose (kGy):	30.4
Maximum Specified Dose (kGy):	45.0	Maximum Delivered Dose (kGy):	35.1
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.			

Signature Manifest

Reviewed and E-Signed By Signed On 1/13/2018 at 3:57 PM
 Caitlin Davies (QS/RC Technician) UTC / GMT Offset (hh:mm): -5:00
 Document Content Revision: 1

Processing Location:
 STERIS
 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, ENISO 13485, and in alignment with EN ANSIAAMIISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.



STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for ADVANCED SCIENTIFICS INC

Process Run ID 91935A

Date Prepared: 1/13/2018 3:56:41PM

Processing Location: Whippany
 Irradiator / Method: 131, Nordion Cobalt-60 Irradiator #131, ON-STD

Carrier	Seg	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
	1	1 2C1	08G5920388541	TH0096	0482	31.5	31.5
	1	2 2C5	08G592038836	TH0096	0482	31.1	31.1
	1	3 2C8.8	08G5920388532	TH0096	0482	30.4	30.4
	1	4 3A5	08G592038835	TH0096	0482	35.1	35.1
	1	5 3E5	08G592038833	TH0096	0482	34.9	34.9
	1	6 TBA5	08G592038732	TH0096	0482	33.4	33.4
	1	7 TBE5	08G592038830	TH0096	0482	34.3	34.3

Minimum Dose for Record (kGy): 30.4

Maximum Dose for Record (kGy): 35.1

Signature Manifest

Prepared By: **Thomas Meier (Cell Operator)**
 Approved By: **Caitlin Davies (QS/RC Technician)**
 Document Content Revision: 1

Signed On 1/13/2018 at 9:00 AM
 UTC / GMT Offset (hh:mm): -5:00

Signed On 1/13/2018 at 3:56 PM
 UTC / GMT Offset (hh:mm): -5:00

Certificate Of Processing

Prepared for **ADVANCED SCIENTIFICS INC**




Gamma Process Run ID **205239D**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
GROUP 501	B109735-I / 97MNV-0000	10	CS
GROUP 501	B109735-I / 97MNV-0000	10	CS
GROUP 69	JASON P SAMP / JASON P-SAMP	1	CS
GROUP 7	100001926 / 97MSE-0000	5	CS
GROUP 7	B106522-I / 97LRX-0000	1	CS
GROUP 7	B108295-I / 97LXH-0000	22	CS
GROUP 7	B109173-I / 97MCJ-0000	1	CS
GROUP 7	B109174-I / 97MCK-0000	1	CS
GROUP 7	B109344-I / 97K2U-0000	5	CS
GROUP 7	B109606-I / 97MCL-0000	1	CS
GROUP 7	B109606-I / 97MG3-0000	1	CS
GROUP 7	B113538-I / 97LXL-0000	1	CS
GROUP 7	B114444-I / 9/MMZ-0000	1	CS
GROUP 7	B114958-I / 97KBX-0000	7	CS

Processing Run Start Date/Time: 22-Jan-2018 08:34:28 am Approx. Downtime (hours): 0.00
 Processing Run End Date/Time: 22-Jan-2018 10:34:09 am

Minimum Specified Dose (kGy): 27.5	Minimum Delivered Dose (kGy): 29.0
Maximum Specified Dose (kGy): 45.0	Maximum Delivered Dose (kGy): 42.1
Product meets Customer specifications; zero nonconformities occurred during this irradiation run.	

Signature Manifest

Reviewed and E-Signed By  **Tracy Wild (QS/RC Technician)** Signed On 1/23/2018 at 12:44 PM
 Document Content Revision: 1 UTC / GMT Offset (hh:mm): -5:00

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

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, ENISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

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STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for ADVANCED SCIENTIFCS INC

Process Run ID 205239D

Date Prepared: 1/23/2018 12:17:21PM

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

Carrier	Seg	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
Final Dose Measurements							
1	1	OCEOB	0BJ600007427	TH0057	0491	29.8	29.8
1	2	1A3	0BJ600007440	TH0057	0491	38.1	38.1
1	3	1E3	0BJ600007213	TH0057	0491	39.5	39.5
4	1	OCEOB	0BJ600007173	TH0057	0491	29.0	29.0
4	2	1A3	0BJ600007485	TH0057	0491	38.8	38.8
4	3	1E3	0BJ600007238	TH0057	0491	38.7	38.7
6	1	TBA5	0BJ600007351	TH0057	0491	37.7	37.7
6	2	TBE5	0BJ600007466	TH0057	0491	37.2	37.2
7	1	TBAEOB	0BJ600007447	TH0057	0491	36.1	36.1
7	2	TBEEOB	0BJ600007235	TH0057	0491	36.3	36.3
8	1	OC1	0BJ600007437	TH0057	0491	30.9	30.9
8	2	OC3	0BJ600007481	TH0057	0491	31.8	31.8
8	3	OC5	0BJ600007053	TH0057	0491	30.7	30.7
8	4	OC7	0BJ600007051	TH0057	0491	31.9	31.9
8	5	OCEOB	0BJ600007261	TH0057	0491	31.3	31.3
8	6	1A3	0BJ600007472	TH0057	0491	40.2	40.2
8	7	1A5	0BJ600007471	TH0057	0491	40.7	40.7
8	8	1A7	0BJ600007375	TH0057	0491	40.0	40.0
8	9	1E3	0BJ600007005	TH0057	0491	38.5	38.5
8	10	1E5	0BJ600007082	TH0057	0491	39.3	39.3



STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for ADVANCED SCIENTIFCS INC

Process Run ID 205239D

Date Prepared: 1/23/2018 12:17:21PM

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

Carrier	Seg	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final	
							Dose (kGy)	Dose (kGy)
8	11	1E7	OBJ600007259	TH0057	0491	38.6	38.6	38.6
8	12	2A3	OBJ600007032	TH0057	0491	42.1	42.1	42.1
8	13	2A5	OBJ600007025	TH0057	0491	40.0	40.0	40.0
8	14	2A7	OBJ600007430	TH0057	0491	39.8	39.8	39.8
8	15	2E3	OBJ600007263	TH0057	0491	40.5	40.5	40.5
8	16	2E5	OBJ600007055	TH0057	0491	39.4	39.4	39.4
8	17	2E7	OBJ600007044	TH0057	0491	39.9	39.9	39.9
9	1	0C1	OBJ600007042	TH0057	0491	30.6	30.6	30.6
9	2	0C3	OBJ600007132	TH0057	0491	31.6	31.6	31.6
9	3	0C5	OBJ600007298	TH0057	0491	31.3	31.3	31.3
9	4	0C7	OBJ600007010	TH0057	0491	31.5	31.5	31.5
9	5	0CE0B	OBJ600007114	TH0057	0491	31.4	31.4	31.4
9	6	1A3	OBJ600007490	TH0057	0491	39.9	39.9	39.9
9	7	1A5	OBJ600007126	TH0057	0491	40.9	40.9	40.9
9	8	1A7	OBJ600007290	TH0057	0491	40.3	40.3	40.3
9	9	1E3	OBJ600007245	TH0057	0491	39.9	39.9	39.9
9	10	1E5	OBJ600007221	TH0057	0491	39.9	39.9	39.9
9	11	1E7	OBJ600007500	TH0057	0491	40.2	40.2	40.2
9	12	2A3	OBJ600007335	TH0057	0491	40.0	40.0	40.0
9	13	2A5	OBJ600007246	TH0057	0491	40.4	40.4	40.4
9	14	2A7	OBJ600007462	TH0057	0491	40.0	40.0	40.0
9	15	2E3	OBJ600007420	TH0057	0491	39.6	39.6	39.6

WI-00074 Last Rev DMA 2.0.1.0 & RT 3.6.5.1

Release Date: 05-Jun-2017



STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for ADVANCED SCIENTIFICS INC

Process Run ID 206239D

Date Prepared: 1/23/2018 12:17:21PM

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

Carrier	Seg	Coordinate	Barcode ID	Insert	Instrument	Dose (kGy)	Final Dose (kGy)
9	16	2E5	0BJ600007049	TH0057	0491	39.1	39.1
9	17	2E7	0BJ600007412	TH0057	0491	39.7	39.7
10	1	0C1	0BJ600007106	TH0057	0491	30.5	30.5
10	2	0C3	0BJ600007333	TH0057	0491	31.5	31.5
10	3	0C5	0BJ600007376	TH0057	0491	30.8	30.8
10	4	0C7	0BJ600007280	TH0057	0491	31.4	31.4
10	5	0CE0B	0BJ600007414	TH0057	0491	31.2	31.2
10	6	1A3	0BJ600007077	TH0057	0491	41.1	41.1
10	7	1A5	0BJ600007096	TH0057	0491	41.2	41.2
10	8	1A7	0BJ600007499	TH0057	0491	39.8	39.8
10	9	1E3	0BJ600007292	TH0057	0491	39.2	39.2
10	10	1E5	0BJ600007196	TH0057	0491	38.6	38.6
10	11	1E7	0BJ600007062	TH0057	0491	40.0	40.0
10	12	2A3	0BJ600007357	TH0057	0491	41.1	41.1
10	13	2A5	0BJ600007200	TH0057	0491	40.3	40.3
10	14	2A7	0BJ600007131	TH0057	0491	39.5	39.5
10	15	2E3	0BJ600007014	TH0057	0491	39.6	39.6
10	16	2E5	0BJ600007226	TH0057	0491	39.0	39.0
10	17	2E7	0BJ600007287	TH0057	0491	39.9	39.9
11	1	TBA5	0BJ600007057	TH0057	0491	38.5	38.5
11	2	TBE5	0BJ600007300	TH0057	0491	37.4	37.4



STERIS Dosimetry Record (Alanine Dosimetry System)

Prepared for ADVANCED SCIENTIFICS INC

Process Run ID 205239D


Date Prepared: 1/23/2018 12:17:21PM


Processing Location: Chester
 Irradiator / Method: 239, Nordion Cobalt-60 Irradiator #239, Cont Batch

<u>Carrier</u>	<u>Sag</u>	<u>Coordinate</u>	<u>Barcode ID</u>	<u>Insert</u>	<u>Instrument</u>	<u>Dose (kGy)</u>	<u>Dose (kGy)</u>	<u>Final</u>
						29.0		
						42.1		

Minimum Dose for Record (kGy):
 Maximum Dose for Record (kGy):

Signature Manifest

Prepared By:
 **James Calone (Material Handler II)**

Approved By:
 **Tracy Wild (QS/RC Technician)**

Document Content Revision: 1

Signed On 1/22/2018 at 12:40 PM
 UTC / GMT Offset (hh:mm): -5:00

Signed On 1/23/2018 at 12:17 PM
 UTC / GMT Offset (hh:mm): -5:00

9.9 Appendix I: Certificate of Calibration for Pressure Gauge Used in 8.1



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**NIST Traceable
 Calibration Report**



Reference Number: 1374549
 PO Number: RANDD

PendoTECH
 3490 US Route 1
 Building 15F
 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 Druck DPI 104 0-100PSI

Calibration Date: 06/10/2019
Calibration Due Date: 06/10/2020
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
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 4.6:1]
	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 0.011 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		18.95 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:	
Name	ID #	Title	Phone	Name	Date
Ziegler, Jeff	335	Metrologist	847-327-5335	Pietronico, Mike	06/10/2019

This report may not be reproduced, except in full, without written permission of InVivoCal. The results stated in this report relate only to the items tested or calibrated. Measurements reported herein are traceable to SI units via national standards maintained by NIST and were performed in compliance with MIL-STD-45653A, ANSI/NCSL Z540-1-1994, 10CFR85, Appendix B, ISO 9002:94, and ISO 17025:2005. Guard Banding, if reported on this certificate, is applied at a Z-factor of 30% for test points with a test uncertainty ratio (TUR) below 4:1. In Tolerance conditions are based on test results falling within specified limits with no reduction by the uncertainty of the measurement. The estimated measurement uncertainty (EMU), if reported on this certificate, is being reported at a confidence level of 95% or K=2 unless otherwise noted in the remarks section.

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 8.3



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NIST Traceable
Calibration Report



Reference Number: **1389873**
 PO Number: **RANDD**

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

Manufacturer: Druck Inc.	Calibration Date: 06/22/2020
Model Number: DPI 104 0-100 PSIG	Calibration Due Date: 06/22/2021
Description: Pressure, Digital Gauge 100psig	Condition As Found: In Tolerance
Asset Number: CP307734	Condition As Left: In Tolerance, No adjustment
Serial Number: 5380820	
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	06/03/2020	06/30/2021

Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
Increasing	0.0000 psi	0.00		Same		-0.0500 to 0.0500 psi [EMU 0.00011 psi][TUR 468.1]
	10.0000 psi	10.00		Same		9.9500 to 10.0500 psi [EMU 0.0013 psi][TUR 38.1]
	20.0000 psi	20.01		Same		19.9500 to 20.0500 psi [EMU 0.0054 psi][TUR 9.3.1]
	30.0000 psi	30.01		Same		29.9500 to 30.0500 psi [EMU 0.0059 psi][TUR 8.5.1]
	40.0000 psi	40.01		Same		39.9500 to 40.0500 psi [EMU 0.0069 psi][TUR 7.2.1]
	50.0000 psi	50.01		Same		49.9500 to 50.0500 psi [EMU 0.0079 psi][TUR 6.3.1]
	60.0000 psi	60.02		Same		59.9500 to 60.0500 psi [EMU 0.0089 psi][TUR 5.6.1]
	70.0000 psi	70.02		Same		69.9500 to 70.0500 psi [EMU 0.0099 psi][TUR 5.1.1]
	80.0000 psi	80.02		Same		79.9500 to 80.0500 psi [EMU 0.011 psi][TUR 4.6.1]
	90.0000 psi	90.03		Same		89.9500 to 90.0500 psi [EMU 0.012 psi][TUR 4.2.1]
Decreasing	100.0000 psi	100.03		Same		99.9500 to 100.0500 psi [EMU 0.013 psi][TUR 3.9.1]
	90.0000 psi	90.03		Same		89.9500 to 90.0500 psi [EMU 0.012 psi][TUR 4.2.1]
	80.0000 psi	80.03		Same		79.9500 to 80.0500 psi [EMU 0.011 psi][TUR 4.6.1]
	70.0000 psi	70.02		Same		69.9500 to 70.0500 psi [EMU 0.0099 psi][TUR 5.1.1]
	60.0000 psi	60.02		Same		59.9500 to 60.0500 psi [EMU 0.0089 psi][TUR 5.6.1]
	50.0000 psi	50.02		Same		49.9500 to 50.0500 psi [EMU 0.0079 psi][TUR 6.3.1]
	40.0000 psi	40.02		Same		39.9500 to 40.0500 psi [EMU 0.0069 psi][TUR 7.2.1]
	30.0000 psi	30.01		Same		29.9500 to 30.0500 psi [EMU 0.0059 psi][TUR 8.5.1]
	20.0000 psi	20.01		Same		19.9500 to 20.0500 psi [EMU 0.0054 psi][TUR 9.3.1]



Calibration Data

FUNCTION TESTED	Nominal Value	As Found	Out of Tol	As Left	Out of Tol	CALIBRATION TOLERANCE
	10.0000 psi	10.00		Same		9.9500 to 10.0500 psi [EMU 0.0013 psi][TUR 38.1]
	0.0000 psi	0.00		Same		-0.0500 to 0.0500 psi [EMU 0.0011 psi][TUR 468.1]

Temperature: 21° C
 Humidity: 63% RH
 Rpt. No.: 1620311

Calibration Performed By:				Quality Reviewer:	
Name	ID #	Title	Phone	Name	Date
Davis, Lou	373	Metrologist	847-327-5324	Ziegler, Jeff	06/22/2020

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Report Number: 1620311

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



9.11 Appendix K: X-ray Certificate of Processing for section 7.4/8.4

STERIS

Manual Certificate of Processing

Prepared For: PENDOTECH

Processing Run ID: 10834-40001554

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
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
<p>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.</p>			
<p>Latrice Sutherland, <i>[Signature]</i> 08/23/2021, 07:27AM CST QA Manager Approval / Date / Time (Print and Sign)</p>			
<p>Michael Ezzo, <i>[Signature]</i> 8/23/2021 10:42AM EST Quality Zone Director Approval / Date / Time (Print and Sign)</p>			
<p>Processing Location: 2500 Commerce Drive Libertyville, IL. 60048 847-247-4782</p>		<p>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.</p>	

**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	'0040	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 actual 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 significant figure.

Prepared By Print Name / Title / Sign and Date: *Latrice Sutherland, OSC Manager, 8/23/21*
QA Approved Print Name / Title / Sign and Date: *Halley Mayer, QA Tech I, NMMR 8/23/21*

9.12 Appendix L: Certificate of Calibration for Pressure Gauge used in 8.4



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

**NIST Traceable
 Calibration Report**

PendoTECH
 3490 US Route 1
 Princeton, NJ 08540 United States



Reference Number: 1408403
 PO Number: RANDD

*OK to use
 JMC
 Sept 7, 2021*

Manufacturer: Digi-Sense
Model Number: 68349-06
Description: Pressure, Digital Gauge, 0 to 100 psi
Asset Number: CP355333
Serial Number: 1912310225
Procedure: DS Universal Pressure Gauge-10

Calibration Date: 08/24/2021
Calibration Due Date: 08/24/2022
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
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]
Decreasing	100.000 psi	100.02		Same		99.750 to 100.250 psi [EMU 0.013 psi][TUR 19.1]
	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]



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

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Report Number: 1662895

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

