

Preliminary Evaluation of PendoTECH® Single Use Sensors Post X-Ray Irradiation

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Abstract

This poster details a preliminary study performed on PendoTECH Single Use Pressure, UV/Turbidity, and Temperature sensors. A small sample size of sensors were X-ray irradiated at 41.5 to 44.6 kGy, and then checked for physical integrity (via leak testing) and accuracy to validate the performance of the sensors. All pressure, UV/turbidity, and temperature sensors were demonstrated to be reliable, and were within specification post X-ray irradiation. Although this is a preliminary study, these results suggests that PendoTECH sensors are compatible with X-ray irradiation.

Introduction

As the biopharmaceutical industry continues to rapidly grow, so does the demand for sterilization capacity. Currently gamma irradiation is the primary sterilization technique of the industry for materials required in manufacturing processes, however, with increasing lead times and potential capacity issues, many companies have been exploring alternative sterilization methods [1]. X-ray sterilization is one of the more popular and promising techniques currently being investigated. In fact, the Bioprocess System's Alliance (BPSA) has recently published a white paper on the value, requirements, and risk of X-ray Sterilization on all Single Use Bioprocessing Equipment, including sensors. PendoTECH is an active contributor to the committee tasked with investigating X-ray sterilization and has already taken independent action towards qualifying its sensors. This poster summarizes the preliminary study that PendoTECH has completed to evaluate the X-ray compatibility of its Single Use Pressure, Temperature, and UV/Turbidity sensors. These sensors were all irradiated with a dose of 41.5 to 44.6 kGy. Following irradiation, all the sensors were checked for accuracy and leak tested to evaluate physical integrity. The test methods and results are detailed below.

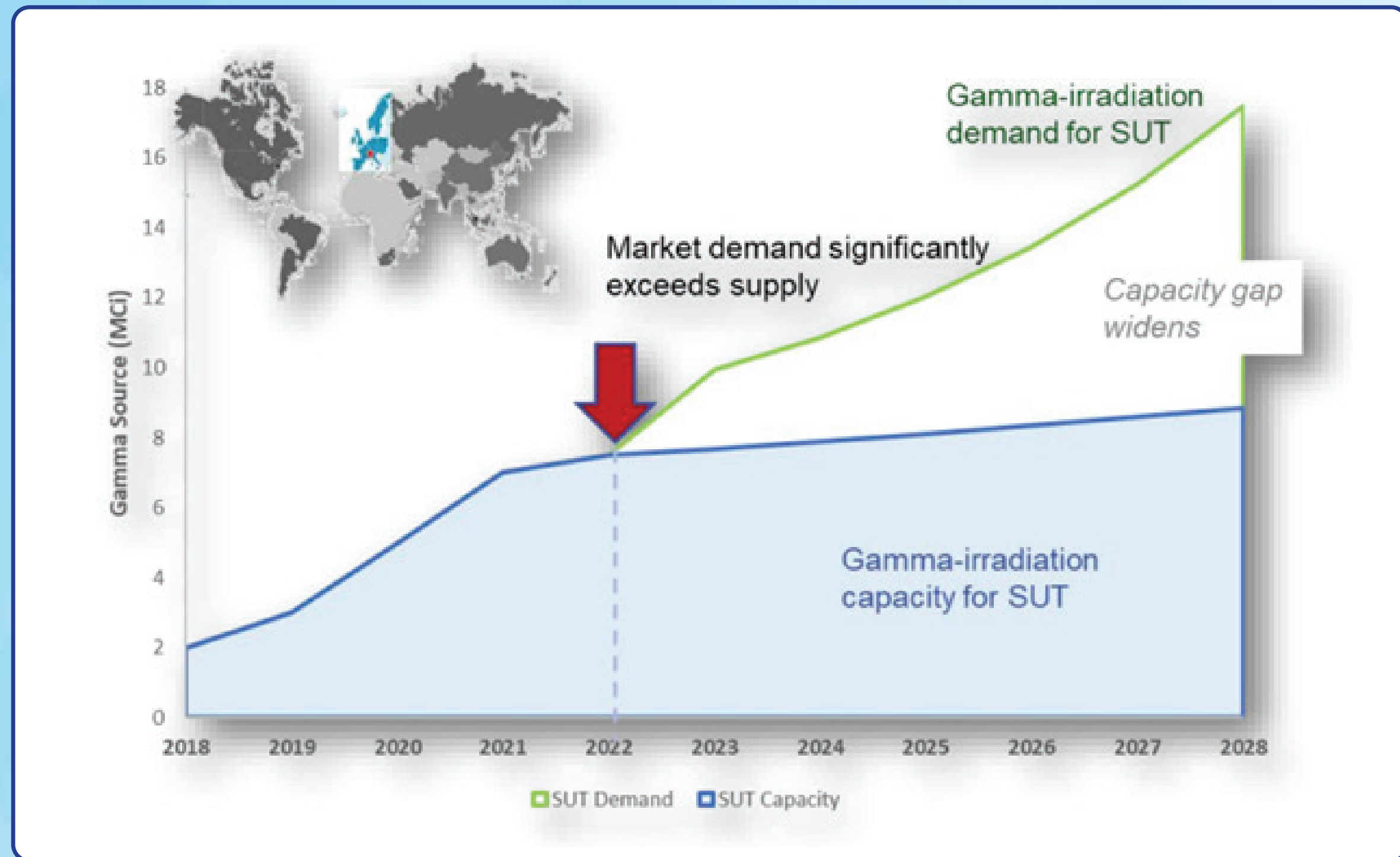


Figure 1: Figure from the BPSA's white paper on X-ray Sterilization [1] on the anticipated supply, demand, and capacity, of gamma irradiation for Single Use Technologies over the next several years.

Pressure Sensor Results

Procedure: Six PendoTECH Single Use Pressure Sensors™ consisting of 3 different part numbers from 5 different lots were accuracy and leak checked following X-ray irradiation. The sensors tested consisted of both Polycarbonate (PRESS) and Polysulfone (PREPS) pressure sensors. For the leak test, the sensors were isolated on a PendoTECH custom test fixture at 60 psi for 60 seconds. Soapy water was used to visually identify any leaks, while a pressure drop was measured with a calibrated pressure gauge. A full range accuracy check (0 to 60 psi) was performed using the same test fixture. The sensor readings were measured with a PendoTECH Pressure Monitor Model PMAT2P (SN: 19914) and compared against the reference calibrated pressure gauge. The detailed sensor information and results from both tests can be found in the tables below.

Acceptance Criteria:

Leak: Pressure Decay less than 0.03 psi/second

Accuracy: Within PendoTECH's Pressure Sensor Accuracy Specification -

0 to 6 psi: ± 2% of reading

6 to 30 psi: ± 3% of reading

30 to 60 psi: Typically ± 5% of reading

Table 1: Pressure Leak Test Results

| Sensor | Part Number | Lot Number | Serial Number | Initial Pressure (psi) | Final Pressure (psi) | ΔP (psi) | Pressure Decay (psi/sec) |
|--------|----------------|------------|---------------|------------------------|----------------------|----------|--------------------------|
| 1* | PREPS-N-000P | 1192826 | 1 | 62.24 | 60.45 | 1.79 | 0.0298 |
| 2* | PREPS-N-000P | 1192826 | 2 | 61.44 | 59.57 | 1.87 | 0.0312 |
| 3 | PREPS-N-038-60 | 1160339 | 62 | 60.07 | 60.04 | 0.03 | 0.0005 |
| 4 | PREPS-N-038-60 | 1132573 | 26 | 60.15 | 60.12 | 0.03 | 0.0005 |
| 5 | PREPS-N-038-60 | 1152888 | 27 | 60.11 | 60.09 | 0.02 | 0.0003 |
| 6 | PRESS-N-038-30 | 1160644 | 51 | 60.10 | 60.08 | 0.02 | 0.0003 |

*Small leak detected from Luer connections, which accounted for the large pressure decay.

No liquid or fluid path leaks detected

Table 2: Pressure Accuracy Results

| Gauge Pressure (psi) | Sensor Reading | | | | | | | | | | | |
|----------------------|----------------|---------|---------------|---------|---------------|---------|---------------|---------|---------------|---------|---------------|---------|
| | 1 | | 2 | | 3 | | 4 | | 5 | | 6 | |
| | Reading (psi) | % Error | Reading (psi) | % Error | Reading (psi) | % Error | Reading (psi) | % Error | Reading (psi) | % Error | Reading (psi) | % Error |
| 0 | 0.00 | 0.00% | 0.00 | 0.00% | 0.00 | 0.00% | 0.00 | 0.00% | 0.00 | 0.00% | 0.00 | 0.00% |
| 10 | 9.99 | -0.10% | 10.02 | 0.20% | 10.01 | 0.10% | 9.98 | -0.20% | 10.05 | 0.50% | 10.02 | 0.20% |
| 20 | 19.99 | -0.05% | 20.01 | 0.05% | 20.05 | 0.25% | 20.02 | 0.10% | 20.07 | 0.35% | 20.03 | 0.15% |
| 30 | 30.19 | 0.63% | 30.15 | 0.50% | 30.23 | 0.77% | 30.00 | 0.00% | 30.30 | 1.00% | 30.20 | 0.67% |
| 40 | 40.66 | 1.65% | 40.48 | 1.20% | 40.61 | 1.53% | 40.04 | 0.10% | 40.80 | 2.00% | 40.59 | 1.48% |
| 50 | 51.52 | 3.04% | 51.07 | 2.14% | 51.24 | 2.48% | 50.07 | 0.14% | 51.60 | 3.20% | 51.20 | 2.40% |
| 60 | 62.69 | 4.48% | 61.90 | 3.17% | 62.08 | 3.47% | 60.15 | 0.25% | 62.73 | 4.55% | 62.11 | 3.52% |

All sensors performed as expected and passed the accuracy and leak check. Although the calculated leak rate for Sensor 2 was greater than the acceptance criteria, this was attributed to the Luer lock connection. Both Sensors 1 and 2 are Luer style, which can experience small leaks around the Luer connection, especially at higher pressures. Therefore, PendoTECH Single Use Pressure Sensors maintain integrity and accuracy post X-ray irradiation.

UV Absorbance/Turbidity Flow Cell Results

Procedure: Four PendoTECH Single Use UV/Turbidity Flow cells of 2 different sizes and lots were checked for accuracy and leaks post X-ray irradiation. The same leak test procedure was used to evaluate the integrity of these flow cells. One at a time the flow cells were isolated on a PendoTECH custom test fixture at 60 psi for 60 seconds, while soapy water was used to inspect for leaks and a pressure drop was measured. The accuracy of the flow cells was evaluated by confirming that the absorbance value at 0 AU (only ambient air inside flow cell fluid path) did not change significantly post X-ray irradiation. The flow cells were placed in a small flow cell stand (PendoTECH SPEC-FCH-S SN: FCHS80820) and connected to a single channel photometer (PendoTECH SPEC-280L SN: 472079314). A blank cuvette from PendoTECH's UV/VIS/NIR Photometer Test Rig (PendoTECH SPEC-280-TRS) was also inserted into the stand and the absorbance readings were read from the photometer with a PMAT2P (SN: 19914). The detailed sensor information and results from both tests can be found in the tables below.

Acceptance Criteria:

Leak: Pressure Decay less than 0.03 psi/second

Accuracy: Absorbance with blank cuvette inserted less than 0.20 AU

Table 3: UV/Turbidity Leak Test Results

| Sensor | Part Number | Lot Number | Serial Number | Initial Pressure (psi) | Final Pressure (psi) | ΔP (psi) | Pressure Decay (psi/sec) |
|--------|--------------|------------|---------------|------------------------|----------------------|----------|--------------------------|
| 1 | SPECPS-N-025 | 1191428 | 246 | 60.09 | 60.05 | 0.04 | 0.0007 |
| 2 | SPECPS-N-025 | 1191428 | 63 | 60.10 | 60.07 | 0.03 | 0.0005 |
| 3 | SPECPS-N-050 | 1201618 | 90 | 60.09 | 59.98 | 0.11 | 0.0018 |
| 4 | SPECPS-N-050 | 1201618 | 87 | 60.06 | 59.97 | 0.09 | 0.0015 |

Table 4: UV/Turbidity Accuracy Results

| Sensor | Absorbance (AU) | In Spec? |
|--------|-----------------|----------|
| 1 | 0.10 | Yes |
| 2 | 0.10 | Yes |
| 3 | 0.11 | Yes |
| 4 | 0.12 | Yes |

All flow cells met the acceptance criteria for both the accuracy and leak test, therefore demonstrating reliable performance post X-ray sterilization.

Temperature Sensor Results

Procedure: Accuracy and leak testing was performed on ten PendoTECH Single Use Temperature Sensors™ of 3 different sizes from 3 different lots post X-ray irradiation. Once again, the same leak test procedure was used to evaluate the temperature sensors. They were connected to a PendoTECH custom test fixture at 60 psi for 60 seconds. A pressure decay over this time was calculated and soapy water was used for an additional qualitative inspection. Due to the lack of a controlled temperature environment, or calibrated temperature bath, the sensors were only checked for accuracy in ambient air conditions. All sensors were left in the same location at ambient conditions, alongside a calibrated temperature probe. A temperature measurement was then taken from each sensor using a PendoTECH TEMP340 temperature monitor and compared against the reference probe. The detailed sensor information and results from both tests can be found in the tables below.

Acceptance Criteria:

Leak: Pressure Decay less than 0.03 psi/second

Accuracy: Temperature reading within 0.2°C of calibrated probe measurement

Table 5: Temperature Leak Test Results

| Sensor | Part Number | Lot Number | Initial Pressure (psi) | Final Pressure (psi) | Final Pressure (psi) | ΔP (psi) | Pressure Decay (psi/sec) |
|--------|-------------|------------|------------------------|----------------------|----------------------|----------|--------------------------|
| 1 | TEMPS-N-025 | 20F107240 | 60.19 | 60.18 | 60.05 | 0.01 | 0.0002 |
| 2 | TEMPS-N-025 | 20F107240 | 60.16 | 60.11 | 60.07 | 0.05 | 0.0008 |
| 3 | TEMPS-N-025 | 20F107240 | 60.22 | 60.18 | 59.98 | 0.04 | 0.0007 |
| 4 | TEMPS-N-025 | 20F107240 | 60.11 | 60.10 | 59.97 | 0.01 | 0.0002 |
| 5 | TEMPS-N-038 | 19F92902 | 60.10 | 60.07 | 2 | 0.03 | 0.0005 |
| 6 | TEMPS-N-038 | 19F92902 | 60.11 | 60.07 | 22 | 0.04 | 0.0007 |
| 7 | TEMPS-N-038 | 19F92902 | 60.17 | 60.15 | 2 | 0.02 | 0.0003 |
| 8 | TEMPS-N-050 | 17G59300 | 60.31 | 60.25 | 2 | 0.06 | 0.0010 |
| 9 | TEMPS-N-050 | 17G59300 | 60.19 | 60.08 | 2 | 0.11 | 0.0018 |
| 10 | TEMPS-N-050 | 17G59300 | 60.21 | 60.10 | 2 | 0.11 | 0.0018 |

Table 6: Temperature Accuracy Results:

| Sensor | Sensor Reading °C | Calibrated Probe Reading °C | Error °C |
|--------|-------------------|-----------------------------|----------|
| 1 | 23.84 | 24.02 | -0.18 |
| 2 | 24.19 | 24.00 | 0.19 |
| 3 | 24.17 | 23.99 | 0.18 |
| 4 | 24.26 | 24.08 | 0.18 |
| 5 | 23.87 | 24.05 | -0.18 |
| 6 | 24.12 | 24.09 | 0.03 |
| 7 | 24.21 | 24.10 | 0.11 |
| 8 | 24.17 | 24.11 | 0.06 |
| 9 | 24.28 | 24.12 | 0.16 |
| 10 | 24.16 | 24.14 | 0.02 |

All of the temperature sensors passed both the accuracy and leak check. Although, the accuracy test did not challenge the full range of the sensor, it did suggest that the sensor remains within its accuracy specification. Therefore, these results suggest that the sensors are compatible with X-ray sterilization.

Conclusion

PendoTECH Single Use Pressure, UV/Turbidity, and Temperature sensors all performed within specification post X-ray sterilization. Every sensor passed the associated leak and accuracy check, suggesting that X-ray irradiation does not impact sensor integrity or performance. This study incorporated only a small sample size of sensors as it was intended to be an initial feasibility study. A larger, full-scale X-ray validation plan will be completed in the future. The results of this preliminary study suggest that PendoTECH's Single Use Sensors will have no issues meeting validation requirements for X-ray irradiation. The full validation results will be accessible through the Validation Guides offered by PendoTECH on its single use sensor product lines.

References

[1] Bio-Process Systems Systems Alliance (BPSA). (2021, May). X-Ray Sterilization of Single Use Bioprocess Equipment. Part I- Industry Need, Requirements, and Risk Evaluation. https://bpsalliance.org/wp-content/uploads/2021/X-Ray-White-Paper/FINAL-BPSA-X-Ray-Sterilization-of-SU_051321.pdf