

Xoft Routine Per Article Manufacturing Testing of the Axxent® Source

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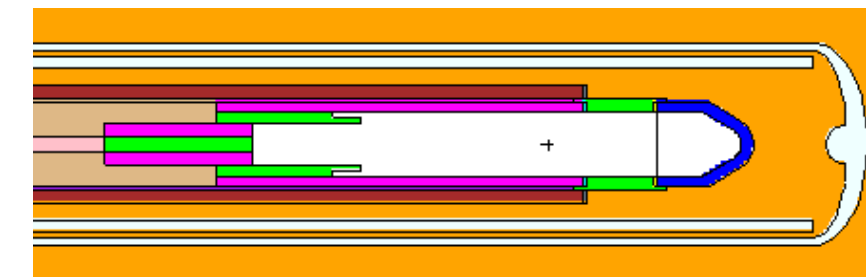
ABSTRACT

- Purpose:** To select sources during routine manufacturing which exhibit reliable stability and match TG-43 parameters to within the error budget criteria for patient treatment.
- Materials and Methods:** Two formally validated pieces of equipment consisting of hardware and software are used to measure a) the spatial characteristics azimuthal symmetry, polar anisotropy and depth-dose; and b) the x-ray output reproducibility and stability during repeated on-off cycling and an extended on period. Automated software runs the tests, analyzes and evaluates the results, and produces printed reports that form part of the permanent history for each source.
- Results:** All sources accepted for human use have azimuthal asymmetry $\leq 7\%$, normalized polar anisotropy in two orthogonal planes ≤ 0.10 of the TG-43 reference, and depth-dose behavior within 0.03 of the TG-43 reference. In addition, when cycled on and off, all sources reproduce their previous output within 2%, with an average standard deviation of $\leq 2\%$ during the "on" portion of the short cycles. During the 20 minute "on" period, the drift (maximum deviation from start) measured over four 5-minute intervals is $\leq 3\%$, and the noise (standard deviation of 0.5 second readings) at 10 second intervals is $\leq 0.25\%$.
- Conclusions:** Manufacturing testing of every source ensures that those accepted for human use will be stable and have spatial output characteristics consistent with the values used for treatment planning within established error ranges.

INTRODUCTION

- The Xoft Axxent® Electronic Brachytherapy system is based on a new micro-miniature x-ray source operating at 50 kVp and 300 μ A.
- The X-ray Source comprises an X-ray tube in a multi-lumen catheter that allows cooling fluid to circulate over the tube. The X-ray tube is approximately 2.25 mm in diameter x 15mm long and is attached to a high voltage cable and encapsulated within an electrical ground. See Figure 1.
- As a brachytherapy source it is characterized under the TG-43 protocol for use with treatment planning systems such as Varian BrachyVision.
- Each X-ray source shipped for patient use must have spatial and depth-dose characteristics that match the TG-43 parameters to within an overall error budget. Furthermore, as an x-ray source that can be turned on and off at will, establishing reproducibility and stability is of great importance.
- Xoft has established a manufacturing testing process to ensure that every source meets these requirements.

Figure 1. Xoft Axxent® model S700 Electronic Brachytherapy Source



METHODS

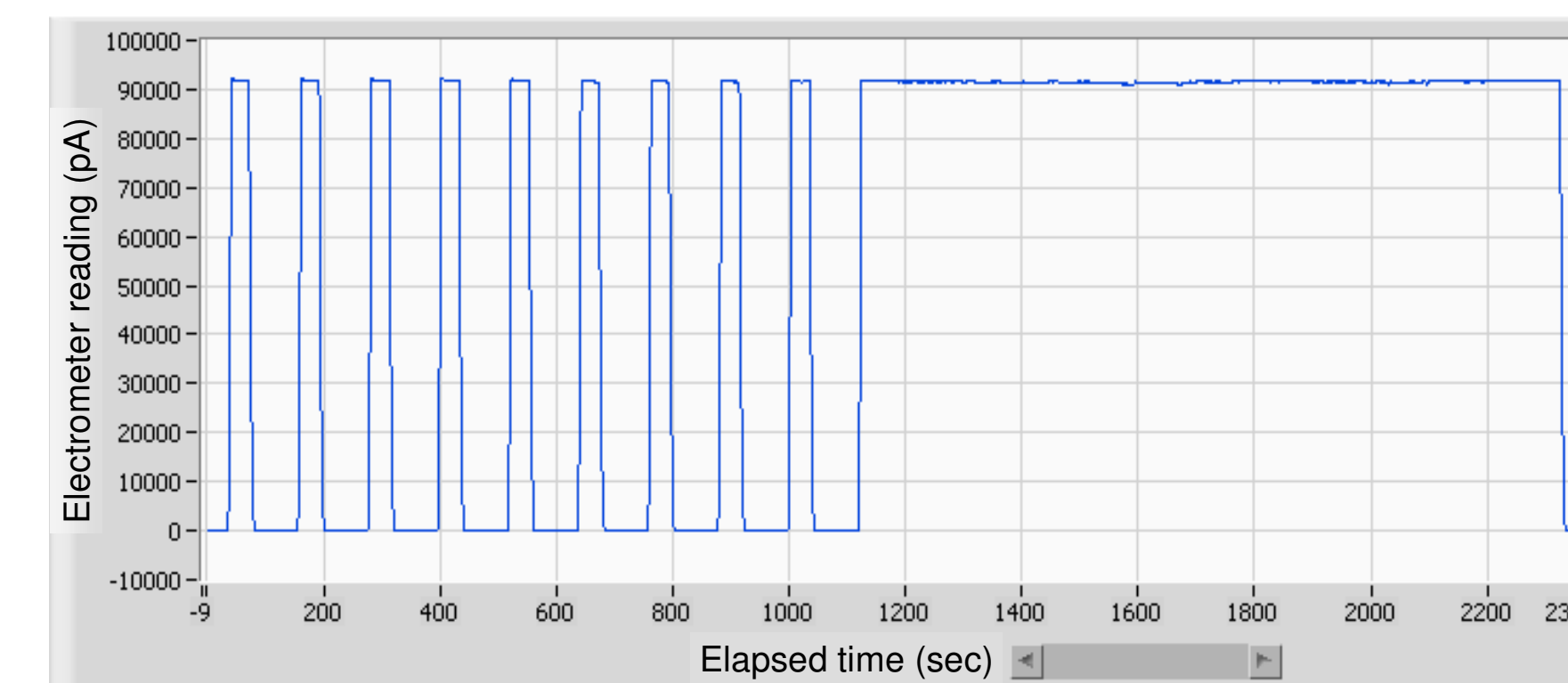
- Purpose:** This series of tests will demonstrate the manufacturing testing process for the Xoft X-ray source. The testing process measures the spatial and intensity characteristics of every source, rejecting any that fall outside the assigned specifications.
- Spatial characteristics:** These are measured in a specially constructed water tank system employing a PTW 34013 ion chamber encased in a water-tight solid water jacket. The system is mounted on ganged linear and rotary motion stages as described in Rivard, et al.
- Data points:**
 - Depth-dose data is taken at 5 mm intervals from 10mm to 70 mm.
 - Azimuthal asymmetry is measured at 20 degree intervals at 20 mm from the source, over 360 degrees, in two passes to ensure reproducibility.
 - Polar asymmetry data is taken in 20 degree intervals at 20 mm from the source, from -140 to +140 degrees, also in two passes and is run at two orthogonal angles.
- Stability and reproducibility:** These are measured in an apparatus that is based on a Standard Imaging HDR-1000+ well chamber with a custom insert. In the test named "Robustness" the source is turned on and off ten times, the first nine times for 30 seconds, the last time for 20 minutes. The average output for each of the nine cycles is calculated and analyzed for cycle to cycle and overall variation. The 20 minute "on" period is analyzed to determine both the short term (noise) and longer term (drift) variability. The average output over the 20 minute period is combined with the dose in water at 1 cm from the spatial test apparatus to determine the TG-43 dose rate constant Λ .
- Software:** Both systems are controlled by custom LabVIEW-based software which has been subjected to a rigorous validation process to verify the data acquisition, calculations and reports. In addition, the software was shown to have all features and performance capabilities recorded in the Software Requirements Specification document.
- References:** Rivard MJ, Davis SD, DeWerd LA, Rusch TW, Axelrod S., "Calculated and measured brachytherapy dosimetry parameters in water for the Xoft Axxent X-Ray Source: An electronic brachytherapy source," Med Phys 33, 4020-4032 (2006).

RESULTS

Robustness Test

- All sources accepted for human use have azimuthal asymmetry $\leq 7\%$, normalized polar anisotropy in two orthogonal planes ≤ 0.10 of the TG-43 reference, and depth-dose behavior within 0.03 of the TG-43 reference. Total output must be at least 55,000 U, and the dose rate constant must be within 7% of nominal.
- In addition, when cycled on and off, all sources reproduce their previous output within 2%, with an average standard deviation of $\leq 2\%$ during the "on" portion of the short cycles.
- During the 20 minute "on" period the drift (maximum deviation from start) measured over four 5 minute intervals is $\leq 3\%$, and the noise (standard deviation of 0.5 second readings) at 10 second intervals is $\leq 0.25\%$.
- Figure 2 (right) shows output from a source which has passed the Robustness test.

Figure 2. Sample output from the Robustness test used to measure stability and reproducibility.



Depth-Dose, Polar and Azimuthal Tests

- Figures 3, 4 and 5 (below) show depth-dose, polar and azimuthal test data, respectively, as examples of the data that are acquired for each source.
- Sources that fail any one of the tests are declared not eligible for patient use.

Figure 3. Normalized depth-dose readings for source sn100799 (red), with reference value (blue). Distances shown are in lab system; actual distances are 10 mm greater.

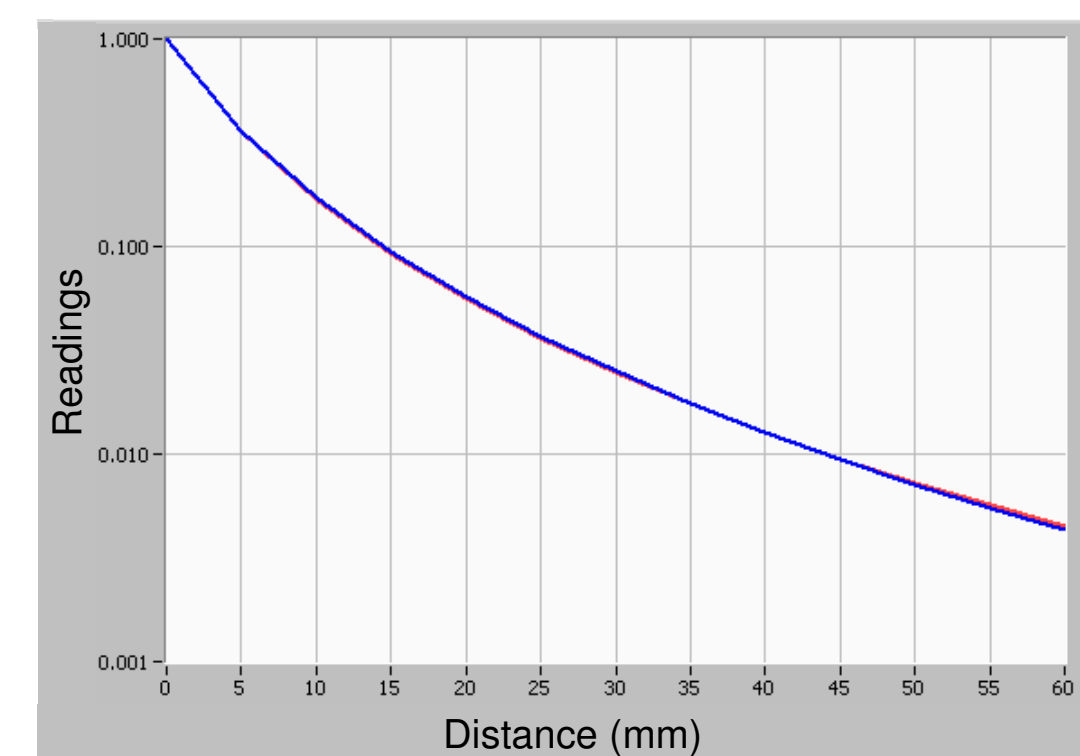


Figure 4. Normalized polar output source sn100799, along two orthogonal paths. Angles shown are in lab system, rotated 90° from the source axis.

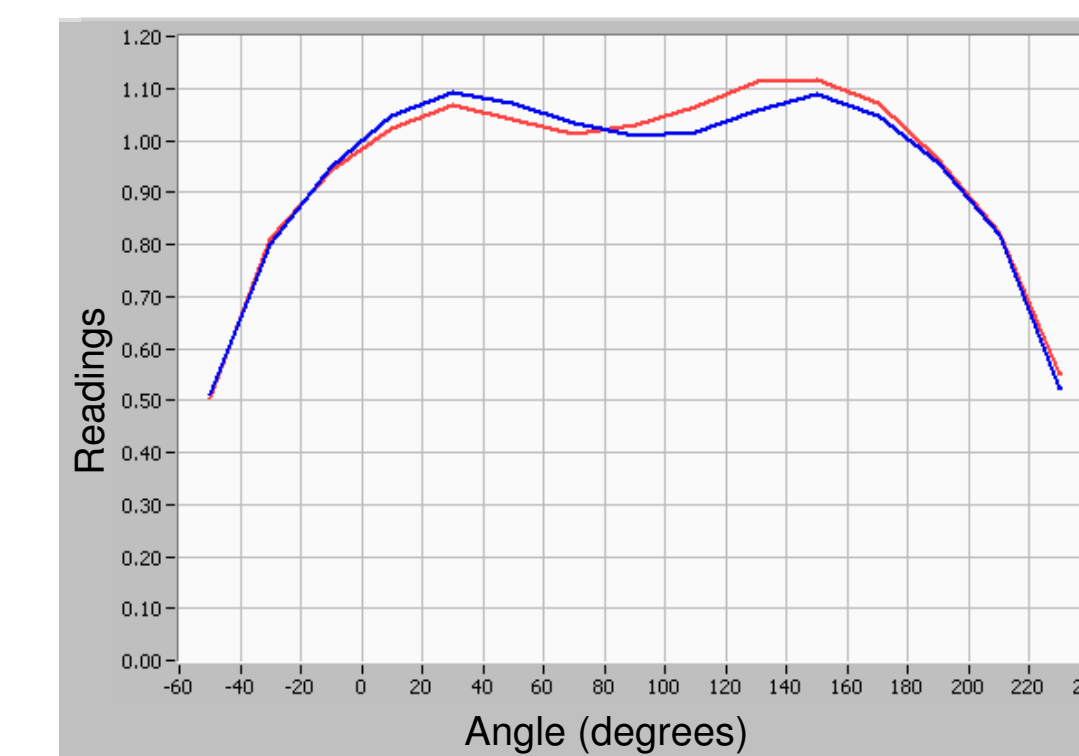
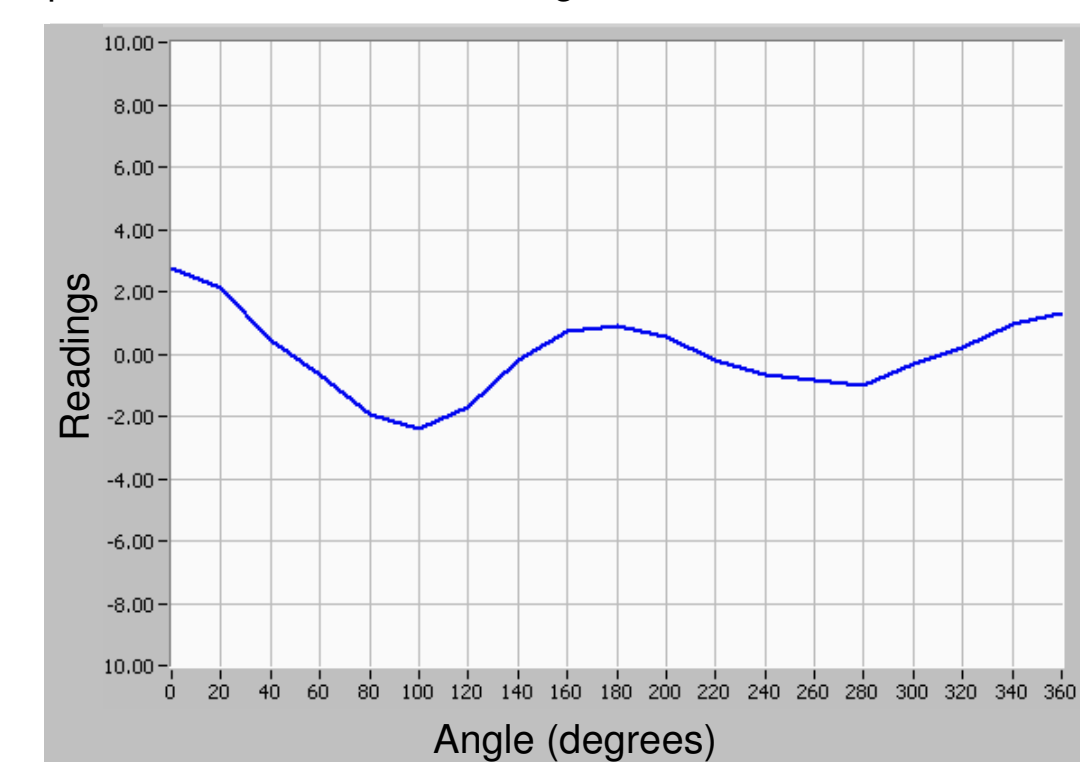


Figure 5. Azimuthal asymmetry of source sn100799, in percent deviation from average.



CONCLUSIONS

- This series of tests demonstrates the manufacturing testing process for the X-ray source used in the Xoft Axxent® Electronic Brachytherapy system.
- Manufacturing testing of every source ensures that those accepted for human use are stable and have spatial output characteristics consistent with the values used for treatment planning within established error ranges.

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