

Recycled pressure cuffs must be tested prior to reuse to ensure they meet the standards. The medical company needed not only to improve the accuracy, repeatability and reliability of the test that was being done manually, but also had to collect test data records for each part. Sciometric developed a solution that automated the test, provided clear visibility into the process and complete part traceability.

Challenge

A medical device company collects and re-uses limb sleeve pressure cuffs used in arm and leg diagnosis. Each cuff must be tested to ensure proper pressure decay performance, and the test data must be traceable on a part by part basis when re-deployed in the field. The original tests involved a manual inflation followed by a manual measurement of the decay rate using pressure gauges and timers. While the tests were functional it yielded a number of false failures. The test itself was poorly validated and it was not known if the test time was too long or too short to ensure an accurate measurement. Creation and recording of serial numbers was awkward and time consuming. A more consistent, accurate test methodology was required.

Solution

The test was replaced by a fully automated test using a sigPOD Leak station. Where the original test provided only an average leak rate measurement, the sigPOD Leak was configured to record the entire pressure decay curve with high resolution. The sigPOD software also automatically generated serial numbers as the parts were tested, and stored the results versus serial number to provide traceability. To perfect the test, decay curves were obtained from known 'good' and 'bad' parts and these parts were re-tested 10 times in succession to characterize the repeatability of the measurement.

All of the waveforms were then imported into QualityWorX trend analysis software and it was discovered that the leak decay rates decreased between the initial and subsequent tests. It was determined that the initial inflation of the cuff caused it to stretch slightly,



BENEFITS

- Automated measurements provide improved accuracy and repeatability
- Complete data records and part traceability meets strict regulatory requirements
- Test parameters optimized to ensure consistent measurements
- Visibility into the process to identify and correct issues with the test



Leak Testing for Compressible Limb Sleeves

resulting in a change in the elasticity of the material, which then affected the measured decay rates. The test was adjusted to eliminate this source of variability in the measurement.

The decay curves were then analyzed to determine which section of the curves provided the most repeatable measurement of the decay rate, while also minimizing the test time. The objective was to maximize throughput without impacting the accuracy of the test. Using the data from the known 'good' and 'bad' parts, the distributions were analyzed to confirm that the test consistently isolated the 'bad' parts from the rest of the population. The test parameters developed in QualityWorX were then loaded into the test software on the sigPOD Leak station for real-time use on the production floor.

Achievement

The Sciometric technology provided a significant improvement in the accuracy and repeatability of the leak decay measurements. The run-to-run variation inherent in the manual, two-point measurement was eliminated, replaced by an optimized, automated test based on a high-resolution measurement of the leak decay curve. The new test procedure dramatically reduced the occurrence of false fails that had plagued the original methodology, resulting in higher throughput and improved yields. The manufacturer also now has a complete test record for complete traceability.

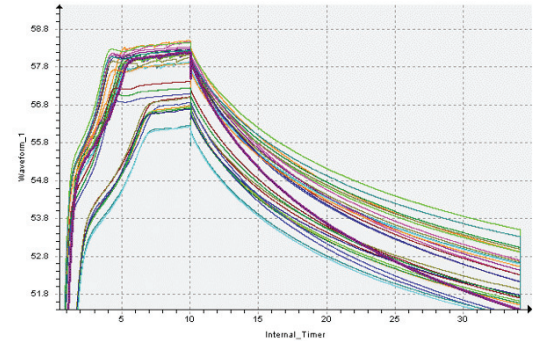


Figure 1: Multiple cuff pressure decay signatures showing the similar decay but different initial pressure.

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