sciemetric

# Medical Device Leak Testing

## SCIEMETRIC MEDICAL SOLUTIONS

**While traditional methods of leak testing have improved with technology, Sciemetric's SigPOD advanced leak platform meets and exceeds more demanding rigors of smaller internal volume medical component testing.**

## Challenge

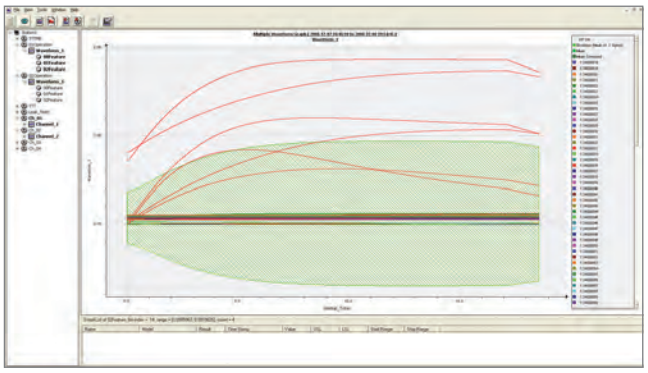
A major challenge when leak testing medical components is the very small internal volume of the parts under test. Depending on the component, the internal plumbing manifold can be greater than ten times the volume of the part. This disparity in volume puts a much greater demand on the precision of leak equipment to ensure repeatability. Additionally, any thermal impacts from things such as valve operating electrical coils have to be considered, as heat can affect stability over hours of production testing.

## Solution

The Sciemetric SigPOD Leak platform was specifically designed to meet the demands of precision medical component testing. From an extremely small internal manifold volume, to air piloted valves, SigPOD Leak offers a unique leak testing solution for both lab and production testing.

## Achievement

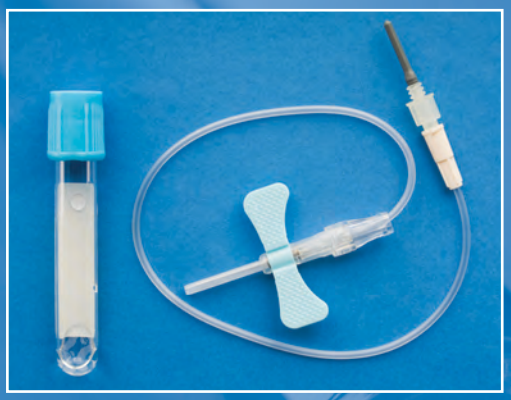
Achieving reliability and stability in a production environment requires proper development of the part, but also the test process itself. From an initial DOE concept to a production ready station, the SigPOD leak platform is ideal in that the encrypted stored waveform and scalar data can be utilized to "tune" for the best stability using thousands of parts for active review. Once in production, the SigPOD/QualityWorx platform acts as a process over-seer to ensure continued quality assurance and traceability.



QualityWorx overlay of hundreds of serialized parts

## BENEFITS

- CFR 21 Part 11 Security Supported
- Signature analysis reliably catches more defects
- Smaller test station footprint
- Best in class stability & repeatability
- Integral Operator ID & training record verification
- Capture, display and analyze complete waveform
- Integral SPC analysis for multiple feature checks
- Commonality from inception to production
- Full serialized traceability
- Greater thermal and dynamic stability



the science of quality

**www.sciemetric.com**
**inquiries@sciemetric.com**
**1-877-931-9200**

© 2009 Sciemetric Instruments, Inc. All brand and product names are trademarks or registered trademarks of their respective companies.
ANM110