



# Micro Leak Testing Container Closure Integrity Testing

## VeriPac 465

a PTI technology



The VeriPac 465 is a deterministic micro leak test system for container closure integrity testing for parenteral products and rigid containers that require precise measurement and detection of the smallest leaks.



The VeriPac 465 performs leak detection based on the basic principles of physics and does not require the use of trace gasses or sample preparation to perform the test. The VeriPac 465 core technology is based on the ASTM vacuum decay leak test method (F2338) recognized by the FDA as a consensus standard for package integrity testing. This test method was developed using VeriPac leak test instruments. The VeriPac 465 combines technological innovation and practical adjustments to patented dual vacuum transducer technology, PERMA-VAC, to make it the most sensitive and versatile vacuum-based leak detection technology to date. Through the introduction of unique test cycles, pneumatic controls and processing algorithms, the VeriPac 465 is establishing itself as the foremost vacuum-based leak test for parenteral products.

### BENEFITS

- Non-destructive, non-subjective, no sample preparation
- Defect detection down to 0.005 ccm
- Highest level of sensitivity, repeatability and accuracy
- Results proven superior to dye ingress
- Deterministic, quantitative test method
- ASTM test method and FDA recognized standard

### TECHNOLOGY

The VeriPac 465 advances in high vacuum testing has redefined what is achievable with a vacuum-based leak detection technology. The next generation PERMA-VAC technology addresses vacuum leak detection at the very core of the physical test measurement, controlling the test system volume and maximizing the Signal-to-Noise Ratio (SNR) between good and defective samples. VeriPac 465 technology reduces the baseline measurement for good samples and amplifies the test result for defective samples. This technology is geared towards detecting leaks in the MALL range for parenteral packaging and can also be applied to flexible and semi flexible package formats.

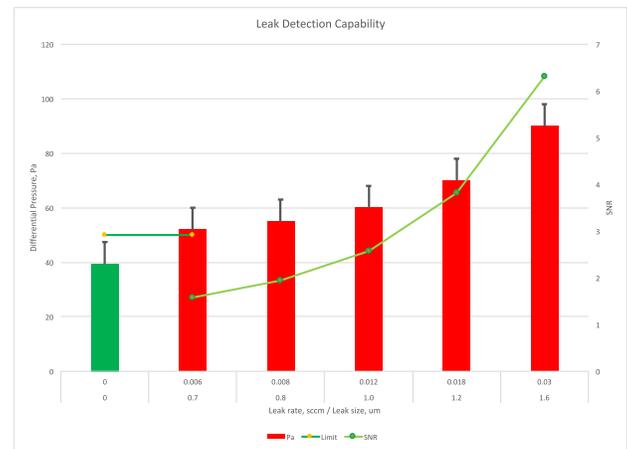
The VeriPac 465 leak tester connects to a test chamber that is specially designed for the package or container. The package is placed inside the test chamber to which vacuum is applied. The dual transducer technology is used to monitor the test chamber for both the level of vacuum as well as the change in vacuum over a predetermined test time. The changes in absolute and differential vacuum indicate the presence of leaks and defects within the package.

### TECHNOLOGY (CONT.)

Test systems can be designed for manual or automatic operation. This inspection method is suitable for laboratory offline testing and QA/QC statistical process control. The test cycle takes only a few seconds, results are non-subjective and testing is non-destructive to both product and package.

### INSPECTION CRITERIA

- Measures seal integrity of entire container or package
- Measures and verifies container closure system integrity
- Tests for gas leaks for dry products (lyophilized vials, powder filled)
- Tests for liquid leaks (liquid filled vials, pre-filled syringes)



### SPECIFICATIONS

Application	MICRO LEAK DETECTION	CONTAINER CLOSURE INTEGRITY TESTING
Package Type	<ul style="list-style-type: none"> <li>• Empty &amp; pre-filled syringes</li> <li>• Liquid filled &amp; lyophilized vials (glass or plastic)</li> <li>• Filled &amp; sealed bottles, FFS bottles</li> <li>• BPC (Bulk Pharmaceutical Chemical) containers</li> </ul>	<ul style="list-style-type: none"> <li>• API (Active Pharmaceutical Ingredient ) containers</li> <li>• BFS containers</li> <li>• Ophthalmic dropper tip bottles containing liquid materials</li> <li>• Glass or plastic ampoules containing liquid materials</li> <li>• Lidded (nonporous trays or cups) containing liquid materials</li> </ul>
Test Configuration	Offline laboratory and production line applications	
Test System*	Dual Transducer PERMA-VAC Technology*	
Technology*	Differential Vacuum Decay	
Operator Interface	10" Color Touch Screen	
Recognized Test Method	ASTM F2338-09, referenced in USP <1207>	
Test Parameter Storage	Up to 20 products (ETHOS 21 CFR, Part 11 software provides unlimited product storage)	
Base Unit Test Sensitivity**	0.002 cc/min/ (Approximate hole size 0.5 micron)	
Application Sensitivity***	0.005 cc/min (Approximate hole size 0.75 micron)	
Test Results/Resolution	Pass/Fail Result in mBar and Pascal units	
Manufacturing Execution Systems (MES) Integration	PTI's 21 CFR Part 11 Compliant Software - ETHOS	
Data Collection	Collects test data for view on HMI touch screen and electronic data collection	
Test Chamber Tooling	Manual or automatic	
ASTM Test Method	ASTM F2338-09 based on VeriPac leak testers - www.astm.org	
Test Instrument Enclosure	Stainless Steel	
Dimensions	14.9" W - 24.6" D x 23.6 H	
Weight	50 lbs	
Power	100-240 VAC; 50/60 Cycles	
Air	90 psi compressed air connection and high vacuum pump	
Options	Validation Qualification Package (IQ/OQ) / Microcalibrator Flowmeter	
Articles/Publications	<ul style="list-style-type: none"> <li>• PDA Journal of Pharmaceutical Science and Technology: Vacuum Decay Container/Closure Integrity Testing Technology. Part 1. ASTM F2338-09 Precision and Bias Studies <a href="http://journal.pda.org/cgi/content/abstract/63/5/472">http://journal.pda.org/cgi/content/abstract/63/5/472</a></li> <li>• PDA Journal of Pharmaceutical Science and Technology: Vacuum Decay Container/Closure Integrity Testing Technology. Part 2. Comparison to Dye Ingress Tests <a href="http://journal.pda.org/cgi/content/abstract/63/5/489">http://journal.pda.org/cgi/content/abstract/63/5/489</a></li> </ul>	

Certifications **CE**

MEMBER **DMMI**  
 \* U.S. Patents 5,513,516 6,513,366 8,544,315 | Test results may vary according to application and package specifications.  
 \*\*The base unit test sensitivity that can be compared with competitive vacuum based test equipment sensitivity claims.  
 \*\*\*The detection sensitivity of standard applications that provides a detection capability with at least a 4-Sigma Signal-Noise separation in real-world operating environments.