

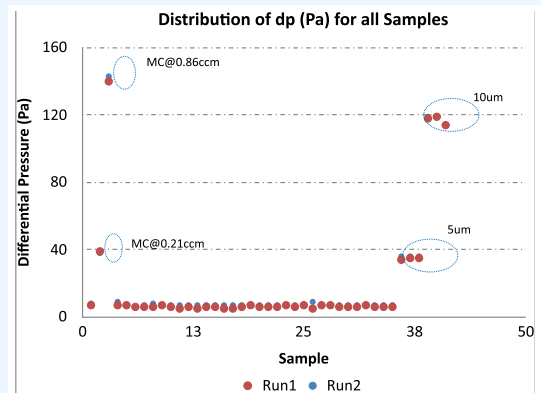
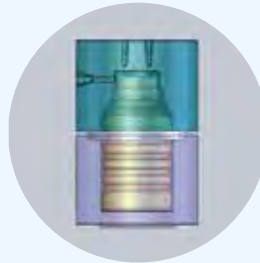
VeriPac 425

a PTI technology

Package Integrity Testing



VeriPac systems can be easily integrated into the packaging process to improve quality, reduce waste, and provide operators with a clear understanding of package quality.



Evaluate and Analyze Package Integrity with Precision and Repeatability

VeriPac test systems are non-destructive, non-subjective and require no sample preparation. Test fixtures are designed to inspect flexible, rigid and semi-rigid packaging. VeriPac inspection systems use cutting edge innovation to provide repeatable, more sensitive, and more robust detection of defects. VeriPac inspection systems utilize an ASTM approved vacuum decay leak test method F2338-24, which is listed in ISO 11607, USP <1207> and is a FDA recognized consensus standard for package integrity testing. This ASTM method was developed using VeriPac leak test instruments and has proven its capabilities under GMP regulatory guidelines. Applications for VeriPac technology include stability studies, clinical trials, quality assurance testing and statistical process control (SPC). VeriPac testers feature the patented PERMA-Vac manifold system and dynamic test modes that provide the ability to test a wide range of package formats. Leak detection of high risk applications requires the highest level of test measurement reliability. The VeriPac series has redefined the reliability and accuracy of test measurement systems.

Benefits



Cost effective with rapid return on investment



Deterministic, quantitative test method



Defect detection down to 2 microns



Highest level of repeatability and accuracy



Simplifies the inspection and validation process



Results proven superior to dye ingress



ASTM test method and FDA standard



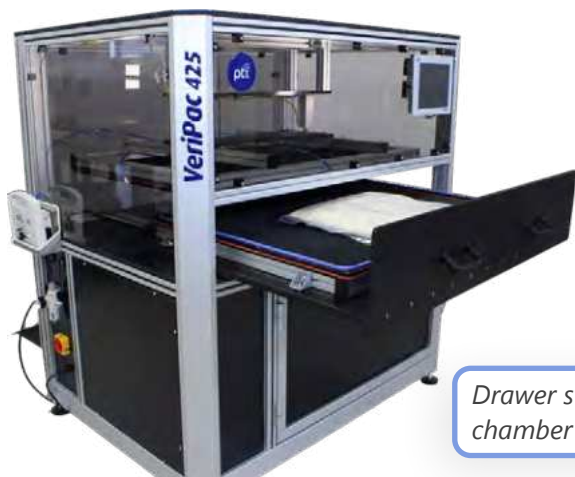
USP <1207> Compliant

Inspection Criteria

- Measures seal integrity of entire container or package
- Measures and verifies container closure integrity
- Altitude package testing

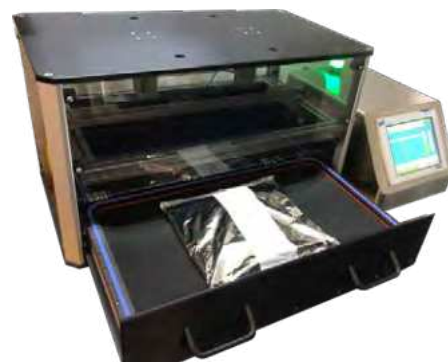
Technology

VeriPac leak testers connect to a test chamber that is specially designed to contain the package to be tested. The package is placed inside the test chamber to which vacuum is applied. The single or dual vacuum 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. The sensitivity of a test is a function of the package design, the package test fixture and critical test parameters of time and pressure. Test systems can be designed for manual or automatic operation. This inspection method is suitable for laboratory offline testing and production applications for QA/QC statistical process control. The test cycle takes only a few seconds, is non-invasive and non-destructive to both product and package.



Test Chamber
Configurations
can be for flexible or
rigid containers

*Drawer style FLEX
chamber examples shown*



Specifications

APPLICATION	- Non-destructive leak detection for packages with defect profile typically >5 microns - Altitude package testing
PACKAGE TYPE	- Filled & sealed bottles, cups, trays - Empty trays & cups - Pouches
PACKAGING MATERIALS & COMBINATIONS	Foil, Film, Aluminum, Plastic, Glass & Laminated Materials
TEST CONFIGURATION	Offline laboratory and Production line applications
TEST SYSTEM	Dual Transducer PERMA-Vac Technology*
TEST METHOD*	Differential Vacuum Decay
RECOGNIZED TEST METHOD	ASTM F2338-24 (astm.org), referenced in USP <1207>
OPERATOR INTERFACE	10" Color Touch Screen
TEST PARAMETER STORAGE	Up to 20 products (ETHOS 21 CFR, Part 11 software provides unlimited product storage)
TEST SENSITIVITY**	0.034 cc/min (Approximate hole size 2 micron)
TEST RESULTS/RESOLUTION	Pass/Fail Result in mBar and Pascal units
CFR SECURITY CAPABILITY	Yes (21 CFR, Part 11) PTI ETHOS Software
MANUFACTURING EXECUTION SYSTEMS (MES) INTEGRATION	Yes
DATA COLLECTION	View on HMI touch screen and electronic data collection
PRINTER OPTION	Yes
TEST CHAMBER	Manual or semi-automatic
RECOGNIZED TEST METHOD	- ASTM F2238-24—Non-destructive vacuum decay leak testing - ASTM D6653-13—Test method for high altitude package testing – www.astm.org - USP <1207> compliant
TEST INSTRUMENT ENCLOSURE	Stainless Steel
DIMENSIONS	14.5" W – 22" D – 12" H
WEIGHT	35 lbs.
POWER	100-240 VAC; 50/60 cycles
AIR	90 psi
OPTIONS	Validation Qualification Package (IQ/OQ/PQ) / Microcalibrator Flowmeter
CERTIFICATIONS	CE

* U.S. Patents 5,513,516 6,513,366 8,544,315

**Test results may vary according to application and package specifications.