

GLOBAL QUALITY SOLUTIONS



PACKAGE INTEGRITY | SEAL INTEGRITY | LEAK DETECTION

Redefining the standards for
accuracy and reliability.



ABOUT PTI

PTI - Packaging Technologies & Inspection is headquartered in Tuckahoe, New York, just outside New York City. We are a team of engineers, scientists and professionals serving the packaging industry as a leading equipment manufacturer of package inspection solutions for high risk applications.

PTI's inspection technologies are non-destructive, non-subjective and provide manufacturing operations with solutions to improve quality and process control, while reducing product waste and manufacturing cost. PTI continues to develop a powerful array of leading edge technologies, bringing patented and unique technologies to high risk packaging applications.

PTI's inspection technologies are deterministic test methods that produce reliable and robust quantitative test data. Our technologies conform to ASTM and other regulatory standards. We specialize in offering our customers comprehensive solutions including test method development, customized system design and equipment validation. In the case of our global clients, PTI's test methods are deployed at sites around the world, providing our clients with highly sensitive, reliable test results and leak detection capabilities. Our test methods have been established as truly "Globally Transferable Validated Test Methods." The measures PTI takes to assure quality of our test solutions make our technologies second to none.

Container Closure Integrity Testing (CCIT)



PTI's non-destructive inspection technologies verify container closure system integrity. Deterministic quantitative test methods for vials, ampoules, syringes, cartridges and auto-injectors. Applications include stability studies, clinical trials, quality assurance testing and statistical process control (SPC). PTI's leading technologies are referenced in the new USP <1207> Chapter on package integrity testing.

E-Scan

- MicroCurrent High Voltage Leak Detection (HVLD^{mc}) Technology
- Applications:
 - Liquid based products including products with suspensions, emulsions and proteins
 - Sterile Water for Injection (WFI)
- Non-conductive container materials can be glass, plastic or poly laminates
- Detects small pinholes, micro cracks and seal imperfections.
- Defect detection down to single digit microns

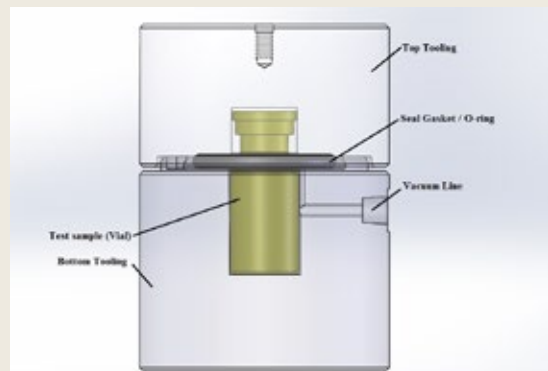
VeriPac[®]

- Vacuum Decay PERMA-Vac Technology
- ASTM Test Method F2338 and FDA Consensus Standard
- Defect detection down to 0.05 ccm
- Measures seal integrity of entire container or package
- Tests for gas leaks for dry products (lyophilized vials, powder filled)
- Tests for liquid leaks (liquid filled vials, ampoules, cartridges and pre-filled syringes)

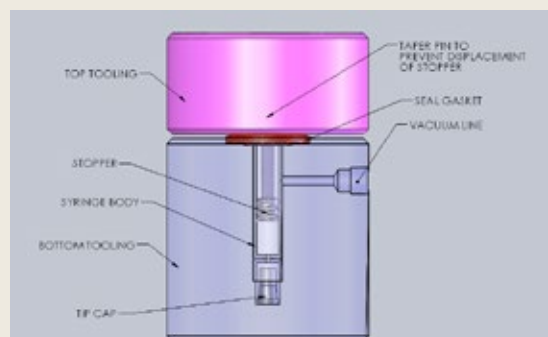
VeriPac 455



E-Scan 655



Test Chamber Concept for Vial



Test Chamber Concept for Syringe

Flexible Packaging

PTI is a well-established brand in the global market for inspection technologies that deliver accurate, efficient solutions for seal and package integrity testing of flexible packaging. With a focus on pharmaceutical, medical device, food and nutritional industries, as well as other markets, we're helping our customers improve their package quality every day.

Seal Quality Inspection with Airborne Ultrasound Technology

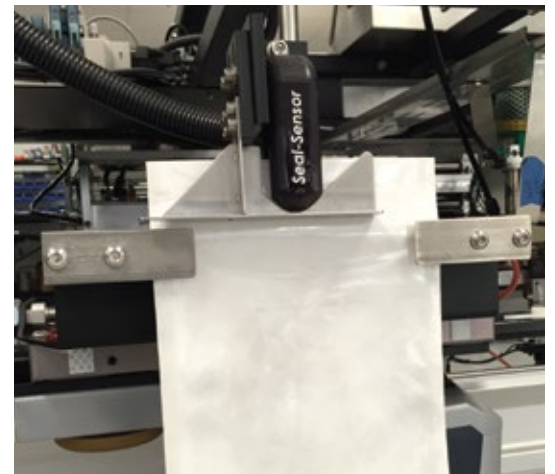
100% Online Pouch Seal Inspection

Seal-Sensor™ is an Airborne Ultrasonic Technology that inspects pouch seals non-destructively 100% online for defects. Seal-Sensor detects incomplete seals, partial or weak areas in seals, and common seal defects that affect product quality and shelf-life. A single linear scan (L-Scan) of the seal takes less than one second and produces a pass/fail result as well as quantitative, traceable data.

PTI is working closely with industry leaders in sealing equipment to integrate Seal-Sensor technology for immediate seal check and seal verification.

Seal-Sensor™

- Seal quality inspection
- Airborne Ultrasound Technology
- ASTM Test Method F3004-13
- Deterministic inspection method producing quantitative results
- Non-destructive, non-subjective, no sample preparation
- Works for any material and combinations, regardless of color, transparency, print, surface finish and porosity
- Fast - can be integrated for 100% online defect detection
- Repeatable and reliable results
- Eliminates subjective, manual vision inspection methods
- Cost effective solution for pouch seal integrity testing
- Offline systems available for in-depth seal quality and material analysis



OEM integration: Seal-Sensor can be integrated into pouch sealing systems and continuous band sealers



Stats	Avg	Min	Max	StD
	33.1	27.7	41.2	1.9



Stats	Avg	Min	Max	StD
	32.1	5.3	10.0	8.0

Channel Defect





Dry Filled Flexible Packaging Pouch Leak Testing

VeriPac FLEX Systems

The standards of quality for flexible packaging continue to be a challenge for manufacturers. PTI's VeriPac FLEX Systems has been established globally as a technology proven to reduce production waste and cost while improving package quality assurance and brand equity.

The VeriPac FLEX Systems are versatile package inspection systems for dry filled pouches and flexible packaging. VeriPac FLEX inspection systems provide a definitive PASS or FAIL as well as quantitative data that correlates to a leak rate.

VeriPac FLEX Systems provide unparalleled sensitivity, reliability and practicality in testing a wide range of flexible package formats and sizes with no change-over of settings or tooling. To accommodate various package specifications and test sensitivity requirements, VeriPac FLEX Systems are available in several configurations for both the leak test instrument and the test chamber capacity, with solutions to accommodate small format sachets and stick packs, up to very large bulk size pouches and bags. Defect detection down to the 10 to 20 micron range.

- Flexible package micro leak detection
- Vacuum Decay PERMA-Vac Technology
- ASTM Test Method F2338 and FDA Consensus Standard
- Testing is non-destructive allowing for increased sampling and testing frequency
- Capability to test different size pouches, stick packs or sachets without any changeover in parts or system settings.
- Deterministic, quantitative test method
- Non-destructive, non-subjective, no sample preparation
- Test multiple packages in a single test cycle
- Supports sustainable packaging and zero waste initiatives
- Simplifies the inspection and validation process
- Accurate and repeatable results



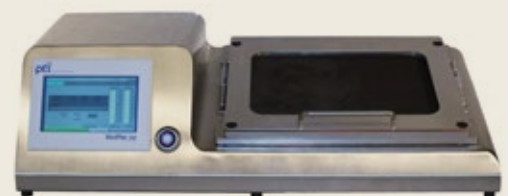
VeriPac D-Series
Large Drawer System



VeriPac D-Series
Small Drawer System

VeriPac Integrated FLEX Chamber

The test system with integrated flexible test chamber (IFC) is intended for sachets or stick packs with low headspace.

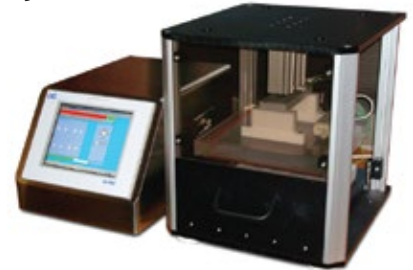


Integrated Flex Chamber (IFC)

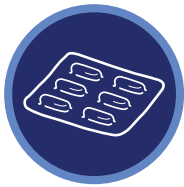
Low Headspace and Blister Packaging



The VeriPac systems for blister packs and low headspace packaging utilize a combination of vacuum decay technology and differential force measurement to identify defective packages. Depending on the package specifications, VeriPac provides the capability to test multiple packages in a single test cycle and also identifies which package or blister cavity is defective. Test results are quantitative and provide operators with a definitive pass/fail result. This precision technology is the perfect solution for testing blister packs, sachet packages, flat pouches such as suture pouches and transdermal patch packaging.



VeriPac UBV - UNIVERSAL BLISTER VERIFICATION



The VeriPac UBV Leak Detection System is a deterministic non-destructive technology designed specifically for multi-cavity blister packs. The VeriPac UBV utilizes volumetric imaging under vacuum to detect the presence and location of leaks.

It's a rapid test requiring no changeover or sample preparation. Operators simply input the number of blister cavities, place the blister pack on the inspection plate and press the START button. Within seconds, the operator sees a definitive pass/fail result, along with a volumetric measurement reading. The location of the defective cavity is presented to the operator with an image of the tested package. The small footprint kiosk design is ideal for positioning next to any production line. A clean and simple test approach makes it clean room compatible. The intuitive and simple method make it a practical solution giving rapid feedback to production line operators.



The UBV technology is unique in that it can provide rapid detection of defects as small as 10 microns with a fast test time, averaging 10-30 seconds depending on blister cavity volume. Test system requires no tools or test parameter changes for different blister formats. This technology is particularly advantageous for small to tiny blister cavities that are notoriously difficult to detect with a standard vacuum system due to the very low headspace.



Benefits

- Non-destructive technology
- Accurate and repeatable results
- Pass/fail results backed by quantitative test data
- Completely tool-less
- No changeover to test different blister formats
- Identifies which cavity is defective
- Eliminates destructive, subjective testing methods

Automated Package Quality Testing

In addition to PTI's line of offline laboratory instruments for leak detection and package quality testing, we offer configurations that provide the capability of automated statistical process control (SPC) testing. Systems have been designed using our VeriPac technology for applications that include semi-automated SPC testing up to 100% fully automated robotic pick and place package handling.



**INCREASED
SPC TESTING
Leads to
Greater Quality
Assurance**

Innovative Robotic Handling for Pre-Filled Syringe Testing

Container Closure Integrity Testing
of Pre-Filled Syringes

E-Scan 665 MicroCurrent HVLD

MicroCurrent HVLD technology is the optimal solution for all parenteral and biologic products.

The E-Scan 665 is an automated pre-filled syringe container closure integrity (CCI) test solution. Using the latest in High Voltage Leak Detection (HVLD^{mc}) technology, the system inspects an entire tray of pre-filled syringes in under three minutes.



The E-Scan 665 is an automated pre-filled syringe container closure integrity (CCI) test solution. Using the latest in High Voltage Leak Detection (HVLD^{mc}) technology, the system inspects an entire tray of pre-filled syringes in under three minutes. The technology provides reliable inspection and detection of leak sizes down to the critical to quality levels.

The nature of PTI's MicroCurrent HVLD allows the E-Scan 665 to inspect a wide range of product classes and delivery systems. Traditional HVLD systems may struggle to inspect low conductivity liquids or smaller diameter container formats. PTI's E-Scan 665 can perform a CCI inspection on syringes containing Water for Injection (WFI) on small diameter formats such as a 1 ml syringe. The E-Scan 665 delivers advanced automated CCI inspection to meet the guidelines of USP 1207 and ANNEX 1.



E-Scan 665 Robotic Test System

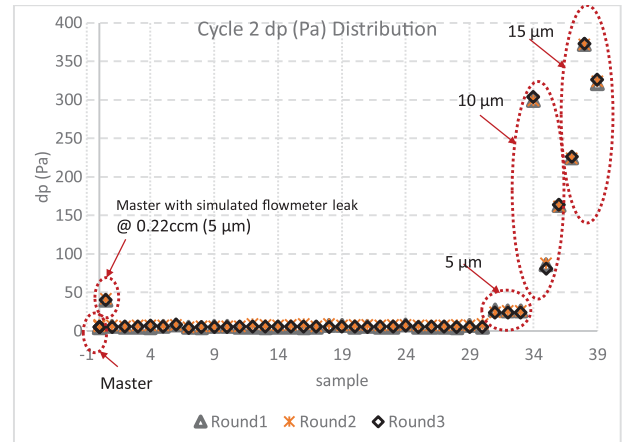
The E-Scan 665 is a fully automated robotic inspection system for container closure integrity testing of nested pre-filled syringes. A single, high speed compact 6-axis robotic arm picks & places rows of syringes from the nested trays into the HVLD^{mc} test position.

Feasibility Studies and Test Method Development

A variety of test methods exist to challenge package quality and performance. The goal of a feasibility study is to assure that the right technology and test method are applied to each product application to provide accurate, sensitive, and reliable data for definitive package integrity verification.

PTI's feasibility studies for package quality testing and test method development leave clients with raw data, statistical analysis of data sets and a full report on the test method to confirm the recommended approach related to a specific package or container. Known good test samples as well as positive control samples with defined defects are used. The report details the technology solution, specific leak test method, test parameters, test result data and acceptance criteria.

PTI's mission to provide complete package integrity test solutions begins with a client's problem statement and concludes with a definitive path to package integrity assurance. Our non-destructive deterministic inspection technologies bring clarity and actionable information to package testing requirements.





PTI ETHOS

21 CFR Part 11 Software Solution

PTI has developed a new standard for protecting, storing and presenting data generated from its line of non-destructive leak testers in the form of a software package called PTI Ethos

Data Integrity and 21 CFR Part 11 Compliance

The FDA is enforcing compliance regarding data integrity, in particular, concerning user access to equipment and electronic records management –CFR Title 21 Part 11. This regulation insures user accountability, traceability and full data protection. PTI ETHOS uses the client's active directory to allow for ease of operation while providing all the data controls and back-ups necessary of federal regulations. ETHOS has proven to be a very simple and highly effective solution to satisfy our customers' compliance needs.

PTI Technology Integration Sensory & Measurement Platforms



PTI's patented and unique inspection technology platforms for leak detection and sensory measurement are also designed for integration into a variety of packaging machines. Integrated inspection within the production line leads to increased quality and process control. With a strong focus on new test methodologies for high risk packaging applications, our R & D team develops custom solutions to meet unique client challenges.

Equipment Validation, Calibration and Maintenance

PTI offers equipment validation packages and validation assistance for each of our product lines. The purpose of validation is to verify and prove that a piece of equipment performs as specified and in accordance with the customer's required application.

PTI supplies the documentation package and qualification protocol to meet FDA standards and guidelines. Validation protocols include the following qualification procedures (IQ/OQ/PQ) that are specific to the technology to ensure compliance requirements:

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Standard Operating Procedures (SOP)
- Preventative Maintenance
- Calibration Procedures

NON-DESTRUCTIVE PACKAGE INSPECTION TECHNOLOGIES

PTI package test methods are centered on two fundamental principles;

- The method must be non-destructive
- The method must be quantitative

Accuracy and reliability of test data is important for many reasons. Six Sigma is based on Measure and Control of the process. Non-destructive methods allow for a deeper investigation into failures. Quantitative test results allow for a wide variety of statistical tools that provide unbiased and clear results.



NON-DESTRUCTIVE PACKAGE QUALITY TESTING

Applications:

- Parenteral/Injectibles:
 - Vial/Ampoule
 - Syringe/Cartridge/Auto-injector
- Low headspace and blister packaging
- Rigid containers (bottles, cups, trays)
- Pouches and other flexible packaging, stick packs and sachets
- Tyvek®/Porous
- Ophthalmic

Major Markets:

- Pharmaceutical
- Biological
- Medical Device
- Food & Beverage
- Nutrition/Oral Dose



Contact us

Get in touch to learn how we can help support your quality goals.

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