



## Transformative Shifts in Vacuum Decay Leak Testing

### Introduction to vacuum decay, how it works and what has made it a lasting solution

Vacuum decay is a test method that has been proven over decades and improved with new technology innovations. The test method is simple in principle and challenges container integrity based on fundamental physical properties. It involves drawing vacuum on a package within a test chamber and monitoring the vacuum level for any decay, which would indicate a leak. The method established itself as a non-destructive replacement to the water bath leak test. It provides significant savings by not wasting product for a leak test, and generates return on investment in under six months for many products.

Vacuum decay has been verified that it is the most practical and sensitive vacuum based leak test method. The test measurement creates a reliable and accurate quantitative result and a pass or fail determination. The standard vacuum decay leak test method (ASTM F2338), developed using PTI's VeriPac instruments, is recognized by the FDA as a consensus standard for container closure integrity (CCI) testing. The test method is listed in ISO 11607 and referenced in the United States Pharmacopeia Chapter on CCI (USP Chapter 1207).

Vacuum Decay's acceptance as a regulatory tool is evident, and continued development optimizes the technology so that it can do more, do it better and perform it faster. PTI's next generation of improvements are not an incremental improvement, but rather foundational shifts in how the technology will serve the food, pharmaceutical and medical device industries.

## VERIPAC VACUUM DECAY TECHNOLOGY

PTI brings a tradition of excellence and performance reliability to our line of VeriPac non-destructive package testing equipment. The next generation of VeriPac test systems has undergone a technology overhaul across the product line, improving each model to better perform for their respective applications. Innovation in the field of vacuum decay has often been focused on improving the practicality and sensitivity of the test method. The next generation of VeriPac systems combines both technological innovation and practical adjustments to current technology 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 technology is establishing itself as the foremost vacuum-based leak detection technology.

## Application Specific Technology Improvements

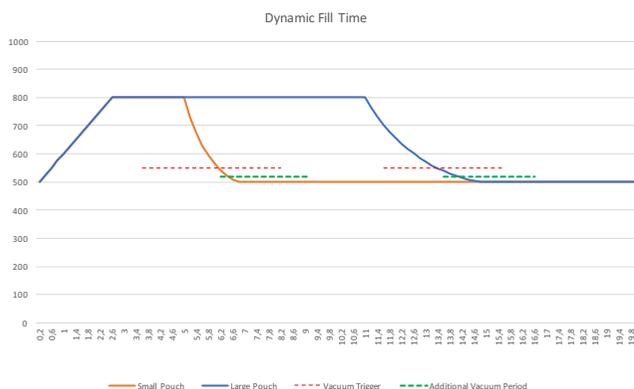
### DYNAMIC VACUUM CYCLE (Patent Pending)



VeriPac Flex

PTI's FLEX chambers have been a standard leak testing solution for flexible packaging manufacturers. The flexible test chamber conforms to the shape and size of different package formats, reducing test chamber headspace and maximizing sensitivity. PTI's series of flexible test chambers has always benefited from the ability to detect small leaks in a broad range of pouch formats and sizes. The fact that a single test chamber can be used for multiple flexible package sizes has been the most practical aspect of the FLEX chamber test systems.

PTI's latest developments for the FLEX chamber systems improve the flexibility and speed with which the systems operate. Programmatic and pneumatic developments have made it possible to use a single test cycle recipe on pouch formats and sizes ranging from stick packs to multi-kilo pouches. These same technological developments have increased the test cycle speed reducing cycle time by 50%.



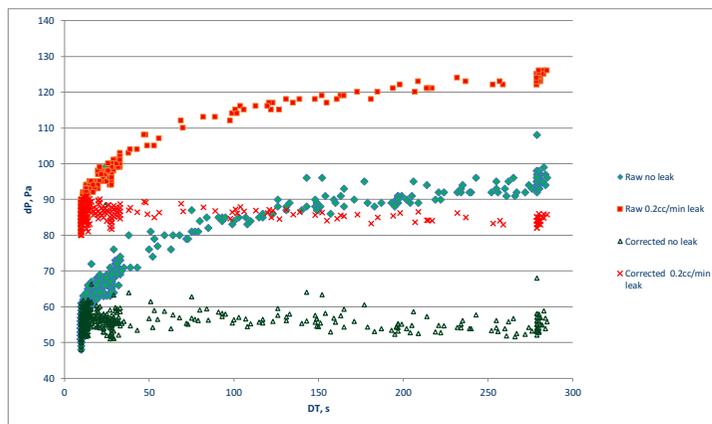
- Vacuum trigger is set above target vacuum level.
- On passing through the vacuum trigger a timer is initiated, with vacuum stopping upon timer completion.
- Provides single test cycle for multiple size pouches.

## AUTOMATIC SIGNAL PRIMER (Patent Pending)

In specific cases vacuum based test systems benefit from priming the test cycle to achieve the highest level of sensitivity. Priming the system can produce lower baseline test results for good samples, making defects more apparent. With a lower baseline in test results, smaller leaks can be detected faster.

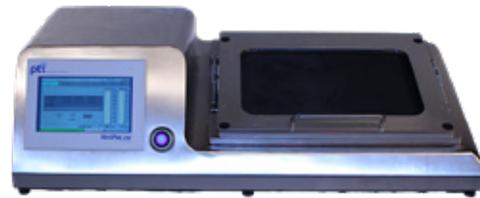
In applications where priming may have improved test sensitivity, PTI's next generation of vacuum test systems can use the Automatic Signal Primer (ASP) solution. The technology has the ability to dramatically reduce baseline test results, amplifying the detection capability of small defects. The test system is capable of producing extremely reliable and repeatable results, with greater detection of defects due to a very high Signal-to-Noise Ratio (SNR). This development has achieved a sensitivity improvement of approximately three-fold. Certain applications that only had a sensitivity of 15-20 microns can now achieve detection of leaks below 10 microns.

## ADJUSTING FOR TEST DELAY



Results Produced by Test

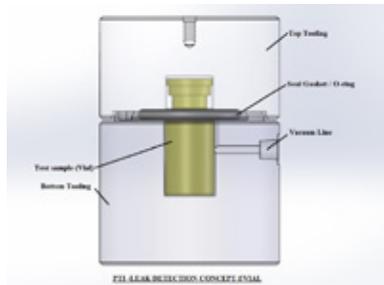
- Initial test cycles show higher test results. With subsequent tests the tester is primed and less variability occurs.
- ASP provides a digital adjustment to results to achieve reliable low baseline results for every test cycle.



VeriPac Integrated Flex Chamber

## PERMA-VAC TECHNOLOGY

PTI's VeriPac 455 has been a work horse in the field of parenteral and high vacuum leak testing. Parenteral leak testing requires the detection of both liquid and gas based leaks, and demands the highest level of reliability in producing accurate test results based on the high impact of the data.

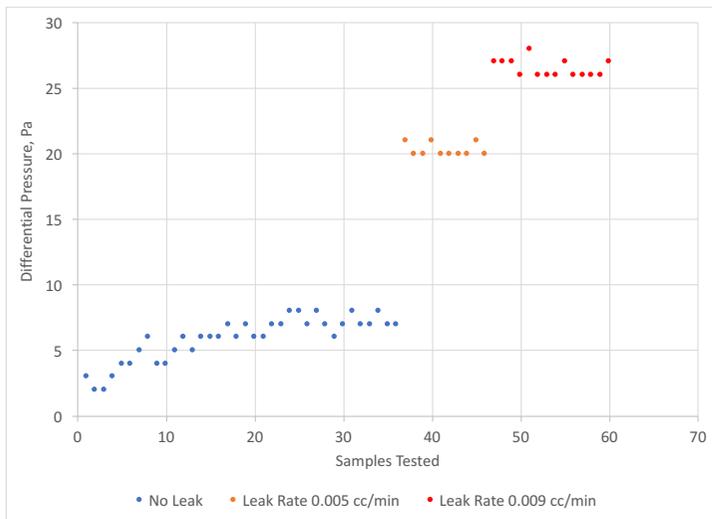


VeriPac 455

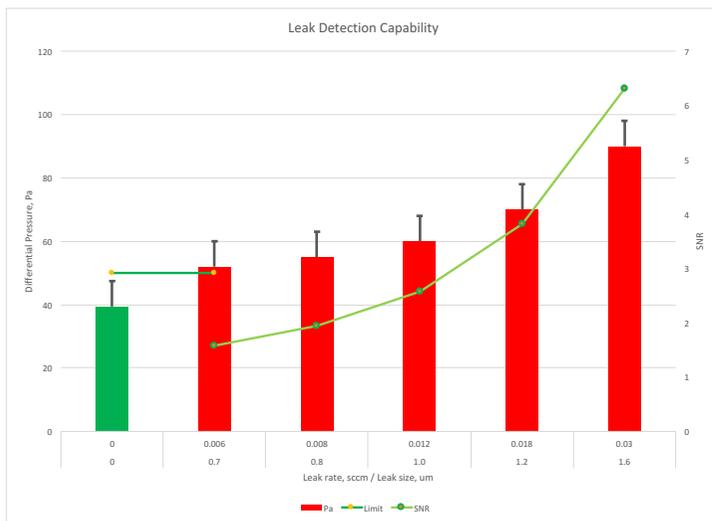
Parenteral applications also require the highest level of sensitivity with the maximum allowable leakage limit (MALL) that could still pose a risk to a patient being below the 1 micron level. The VeriPac 455 achieved reliable and sensitive test results, with the limit of detection of leak rates down to the 1 micron level.

PTI's 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 decay leak detection at the very core of the physical test measurement, controlling the test system volume and maximizing the SNR between good and defective samples. The technology provides the VeriPac series with the most stable test measurement ever achieved through vacuum decay. The technology reduces the baseline measurement for good samples and amplifies the test result for defective samples. The PERMA-VAC 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 PERMA-VAC technology improvements make the VeriPac line of test systems the most sensitive vacuum based leak test available on the market.



Treated Alu TC - Run 3			
Summary			
	MC Closed	0.005 CCM	0.009 CCM
Average	5.9	20.3	26.5
Standard Deviation	1.7		
SNR		2.8	4.1



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