

Principles of Operation For Force-Decay Leak Testing of Flexible Packages

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Non-destructive leak testing for flexible packages can be accomplished by several methods that utilize various properties of the package form and materials. Techniques include vacuum bubble test, pressure/vacuum decay, displacement change, trace gas and force-decay, and each method provides certain advantages for specific package forms such as pouch, tray, blister or tube. The *force-decay method* is particularly suited to pouch forms using non-porous materials such as films, foil or laminates in that this method presents advantages in speed and control for peel open package forms used in medical device and pharmaceutical products.

The principle of operation of the force-decay method for leak testing is quite straightforward. When a package with internal headspace is placed in a vacuum chamber, a differential pressure is created across the package walls of the non-porous materials. In an unrestrained state the package will expand until either the seals burst or the package reaches an equilibrium stress state with the internally applied pressure. Using a restraining plate to prevent the full expansion of the package results in forces being applied to the plate from the package walls. When the restraining plate is attached to a force transducer, then the applied force from the expanded package is measured relative to the differential pressure applied in the vacuum chamber (Figure 1).

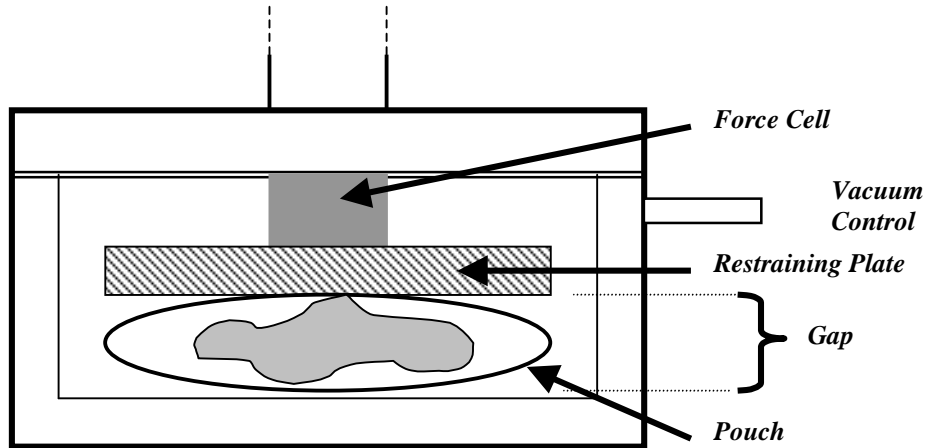


Figure #1- Force-Decay Leak Tester Principle

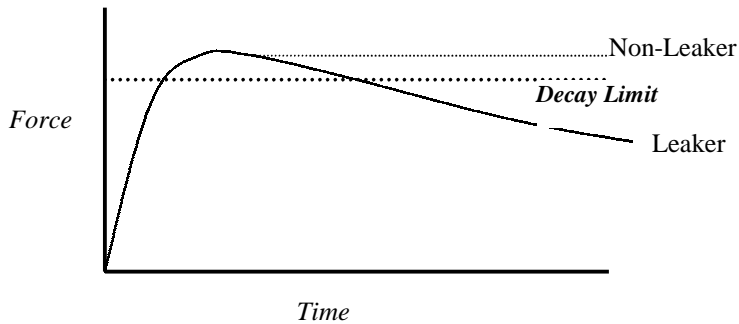


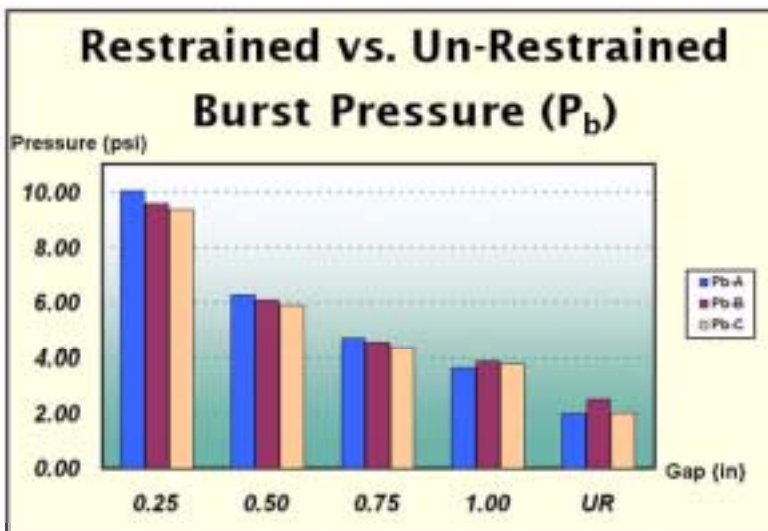
Figure #2 - Force Decay in Leaking Test Sample

For flexible packages that do not leak the applied force to the restraining plate is constant with time. When a leak occurs in the package the loss of air from the headspace decreases the pressure inside the package, thus reducing the applied force to the restraining plate. This change of force is measured with the force transducer and the force decay represents the leakage rate from the package (Figure 2).

The sensitivity of the force transducer in a properly designed fixture, vacuum chamber and the electronic amplification system provides resolution

and sensitivity to detect micron size holes in package walls or seals. TMElectronics customizes the vacuum chamber and restraining plate to optimize sensitivity according to each package form and material.

TMElectronics' force-decay leak test method also maximizes test sensitivity by optimizing the relationship between package seal strength and pressure differential. As the pressure differential increases, the sensitivity of the test to detect very small leaks is increased. A maximum pressure difference produces the highest leak rate from the package and will optimize leak test sensitivity while avoiding seal movement that may interfere with correct leakage indication. The use of a smaller restraining plate gap enables an increase in the pressure differential because package burst strength is increased (see data in Figure 3, taken from the published article by



Franks and Barcan in August 1999's Medical Device and Diagnostic Industries, "Comparing Tensile and Seal Strengths in Medical Packaging"). Using this information and the TMElectronics' BT-1000 Package Tester prior to leak testing, the restraining plate gap can be optimized to determine the maximum pressure differentials applied to the package that will not disrupt the package seals.

Qualification of the tester is best accomplished with packages of the intended form that have identified leakage in the magnitude of the intended detection limit. Packages that are identified from functional testing in the primary failure modes will best represent the response of the test system and identify sensitivity limits. TMElectronics can supply artificial leak standards by sealing a known leak orifice in the package walls or providing a standard leak container for the custom fixture.

Where adequate vacuum systems are available, force-decay testing is easily scalable to in-line package testing. Individual package cells can be measured and translated to PLC controlled systems for "Pass/Fail" indication of package integrity. Throughput speeds related to medical device and certain pharmaceutical products are accomplished by linear or rotary automation equipment.

The control parameters of the test system are simple to implement with little operator training. A timer for the cycle length and limit settings for the force-decay are provided. Vacuum indicator and test indicator status are provided along with "Pass and Fail" indicators. Cycle start and stop are provided as two hand opto-touch controls for operator safety in semi-automatic systems.