TM*Electronics*, Inc.

Specialists in Leak, Flow and Package Testers

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The following is an overview of Physical Inflation Package Leak Testing, including:
- Part 1: Destructive testing of flexible, non-porous packages and the use of appropriate accessories including restraining plates and sealing fixtures;
- Part 2: Non-destructive pressure or vacuum chamber testing; including methods to test induction welded bottle seals, filled and sealed bottles, and bottles containing fluids.

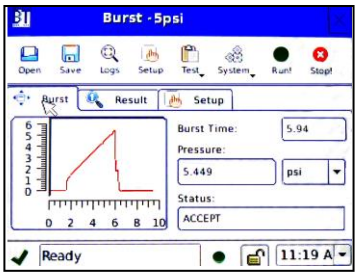
For more details, click *here* [link to "In-Depth Discussion of Package Testing"],
For a detailed look at *Leak Science*, visit the free *Leak, Flow and Package Testing 101* seminar pages.

Part 1: Inflation Seal Strength and Package Integrity Testing (Destructive Tests)

Seal strength and package integrity testing are two distinct test functions, both of which are important in determining the ability of the finished package to protect its contents from contamination or leakage. Inflation tests, such as *Burst Testing, Creep Testing, Creep-to-Failure Testing and Pressure Decay Leak Testing* can be used to meet both of these test functions. These test methods meet EN ISO 11607 guidelines and ASTM International standards. The TME BT-1000 Automated Package Tester and the BT *Integra-Pack* test instrument both perform all three of these tests in a wide variety of medical, food, and industrial packaging applications.

Burst Testing

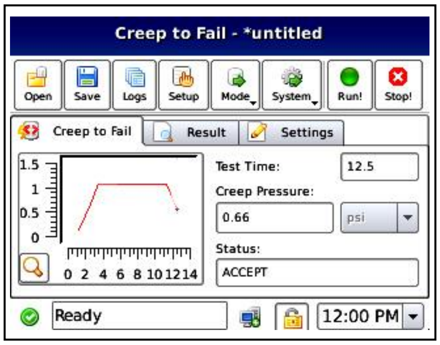
The burst test is a whole package test that determines the overall minimum seal strength of the package seals by inflating the package at a uniform rate until the seal separates at the point of greatest weakness. The burst test can be performed on porous or non-porous, sealed or unsealed pouches, trays, and other types of package forms. This is a destructive test.



The graph at left represents the output from the TM Electronics BT *Integra-Pack*© showing a characteristic burst curve. The Burst Test is a peak inflation pressure test; you can see how the pressure increases to a maximum pressure at which the pressure drops to zero. This drop represents the rupture of the seal. The pressure at which the package bursts (5.449 psig on our burst graph) is a variable statistic that can be utilized to document process development and process control through the use of tools such as upper and lower control limits.

Control of inflation rate is important in a burst test to ensure consistent conditions for the test method. The porosity (or lack thereof) of the package material helps to determine the inflation rate for the burst test. Because air escapes through the walls of a porous package during inflation, the BT-1000's operator can increase the flow rate to compensate for the lost air through the walls and create the back pressure in the porous package. The new BT *Integra-Pack*, unlike the BT-1000 and a number of competitive instruments, allows the operator to control the rate of pressure increase in the package by using a *ramp rate control.* For a detailed discussion on the functionality and advantages of ramp rate control, please click *here* [link to "In-Depth Discussion of Package Testing"].

Creep and Creep-to-Failure Testing

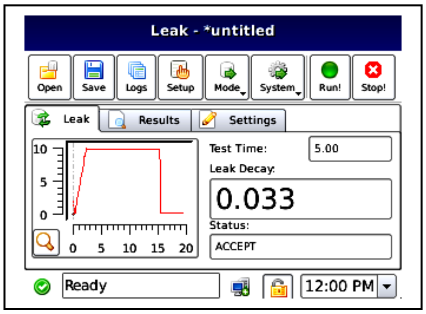


The Creep Test is a second general type of whole package inflation seal strength test. In the Creep Test, a whole package is inflated to a constant pressure, which is then held for a specified time, resulting in a pass/fail result. A typical Creep Test graph is shown in the left photo from the TME BT *Integra-Pack.* The creep test is a test for slow shear of the adhesive bond similar to a dead weight hanging on the seal. A suggested starting pressure for peelable seals is to begin evaluating your seal with a creep pressure that is about 80% of the burst value. The inflation rate is not critical, as long as the initial fill is not so fast as to shock the seal or so slow as to result in an overly long test time.

Shortcomings of this test are the need for the operator to visually examine the seal at the end of the test to determine the degree of seal peel, and the lack of a variable statistic upon which to perform process control analysis. An advantage of the creep test over the traditional tensile test is that whereas the tensile test is performed on only selected areas of the seal, the creep test examines the seal strength of the entire package.

Creep to Failure Testing is a variation on the Creep Test that addresses the weaknesses noted above. In the Creep-to-Failure test, the test pressure on the inflated package is held until the seal actually fails, yielding an end point value (a variable statistic), time to failure, and pinpointing the area of greatest weakness in the seal. Time to failure can then be used in SPC or SQC methods.

Package Integrity (Leak) Testing – Pressure Decay Method (Destructive)



Package integrity testing is purely a measure of the package's sterile barrier – a "leak test" of the whole package. In addition to seal bonding failures or disrupted seals, leakage can be the result of large holes, pinholes or cracks in package materials. Either source of leakage represents the potential for product contamination – elements of the ambient atmosphere outside of the package entering the package – or for the materials inside the package to escape. To perform a pressure decay leak test on a non-porous package, the package is pressurized to a predetermined test pressure and the air input is closed off. A drop in the internal pressure of the package, after taking into account influences like deformation of the package (change in volume) through stretching, is indicative of a leak. Unlike the bubble test, this test method yields quantitative information (pressure decay), hard data points that can be recorded and upon which decisions can be made. This removes the dependency upon the operator and allows specific accept/reject criteria to be set, and this method is quite simple to use. It is reasonably fast; 2-4 second cycles are achievable, keeping in mind that test time is volume dependent. Although more sensitive than bubble testing, pressure decay testing is as sensitive as the time available for the test.

A great deal of information on pressure decay leak testing, including description of the leak test cycle, leak limits and leak rates, and foundational equations to help design the leak test of your package, is available in the free mini-course *Leak, Flow and Package Testing 101*.

Restraining Plate Use

Another consideration when designing your package test procedure is the degree of flexibility of the barrier materials and the geometry of the package. The geometry of the package under test affects the distribution of internal pressure forces on the package surface and seals; for example, a pouch-form package unrestrained in any axis exhibits circumferential hoop stress when internal pressure is applied. When the package is restrained, the load application is distributed directly on the seal area and, because material stretching and deformation is minimized, the test forces are more uniformly applied. In addition, package restraint has a direct relationship to burst pressures: the wider the gap between plates, the lower the average burst pressure. The use of restraining plate fixtures is supported by ASTM F-2095.

Testing Open-Ended Packages

Flexible porous or non-porous peelable pouches that are sealed on three sides are often tested before filling and closure. TME provides two configurations of Open Package Test Fixtures, both consisting of a clamp that will seal the open end of a flexible package during the inflation testing for package seal strength in accordance with ASTM F-1140. The 12-inch open package fixture provides a pneumatically driven clamp that will seal the open end of the flexible package under test; a similar seal is obtained with a manual clamp on the 24-inch model. The flexible materials of the clamp surfaces conform to the

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installed supply and sensor tubes, sealing the package material and test assembly. The supply/sensor probe is sealed on its outer surface to the inside of the package while it communicates with the internal volume, establishing a direct flow path to the measuring instrument.

Testing Packages Sealed on All Sides
When the package to be tested has already been filled and sealed, a problem of how to access the package interior for the burst test pressurization presents itself. To pressurize a closed package, a leak tight measuring path must be available between the package interior volume and the pressure source. The TM Electronics' patented Package-Port© system, in which a reusable plastic entry port is secured and then accommodates the pressurizing and sensing probe, can accomplish this task. The probe tip pierces the package, enabling pressurization, and the Package-Port reinforces the package material to eliminate any possible leakage of gas around the penetration point, creating a leak-tight path connecting the package internal volume directly to the test instrument. Inexpensive, simple to use and reliable, this system makes in-process package inflation testing highly efficient and repeatable.

TME's closed package test fixture allows you to test flexible package Seal Strength and Leak Integrity on completely sealed packages. The fixture can accommodate packages up to 12" wide (with probe down) and up to 24" wide (with probe up). A variety of probe configurations is available to further customize your package integrity test system.

For more information on TME package test fixtures, click here.

Part 2: Non-Destructive Pressure or Vacuum Package Integrity (Leak) Tests

It is possible to perform a pressure or vacuum decay, whole-package leak test on a closed, filled package without destroying the package or damaging the contents. The *chamber test method* is applicable for non-porous packages including pouches, trays, and bottles, as long as there is some head space (air or gas-filled area) inside the package.

The methodology for the chamber leak test involves placing the test item in a chamber that has been specifically designed to minimize the space surrounding the package, then pressurizing (or evacuating) the chamber to the required test pressure and measuring the pressure or vacuum decay inside the chamber. Air entering the part through a leak (or in the case of a vacuum test, leaving the part through a leak) provides the measurement of leakage into the test part. A pressure differential can thus be created across the non-porous product or package walls or seal. Once stabilized, air movement from the higher pressure to the lower will indicate the presence of a leak path, providing a quantitative measure of package or product leak integrity without disrupting the package seals. This non-destructive method of testing will detect leaks from pinholes, cracks, seal and channel leaks in the walls or seals of common package materials such as films, foils and laminates.

Because air moves in or out of the package or closed product in the presence of a leak, the air volume around the test object must be adequate to create a detectable change in the chamber pressure. Keep in mind, though, that when you minimize the interstitial volume (the area around the package, which will be subject to pressure or vacuum during the test) and maximize the instrument resolution (within reason), about 10^{-4} sccs is an achievable sensitivity. The method is quantitative; your test results are amenable to SQC analysis for process control. High resolution instrumentation, such as the TME *Solution-C©,* can detect pressure changes as small as 0.0001 psi in the interstitial space (the space surrounding the closed product or package). In order to detect this pressure change in the interstitial space, there must be sufficient air in the head *space relative to the air in the interstitial space* to create this much of a change in pressure. TM Electronics engineers evaluate each potential application of chamber testing technology to assure that this condition is met.

For more detail on Non-Destructive Closed Chamber Package Integrity Testing, click *here* to take the free TME seminar, *Leak, Flow and Package Testing 101*.

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Some applications of closed chamber testing in current use include the following:

This TME *Solution-C* Vacuum Chamber Leak Test Systems comprised of a single port vacuum chamber tester is designed to perform a vacuum decay leak test on a sealed flexible pouch by means of a custom designed, single application test fixture. An internal vacuum generator is provided with the system. The TME vacuum chamber package leak test system meets ASTM-2338 requirements.

This package test system, consisting of an application-specific fixture and the TME *Solution-C* high-resolution pressure/vacuum leak tester, is configured to perform either vacuum or pressure decay tests at the customer's discretion, but will use vacuum decay for this application. This fixture is designed to perform a vacuum decay test on a two-chamber, thermoformed tray with a welded film cover that contains a medical device. leakage of air ("vacuum decay").

This TME *Solution-C* Chamber Leak Test System is comprised of a pressure decay chamber fixture with a TME *Solution*-C single port pressure decay leak test instrument. The product under test is a foil package containing a vacuum-packed food product. This test fixture is designed with manual toggle clamps as a safety feature.





Test systems are available for non-destructive pressure or vacuum testing of sealed bottles containing liquids (vertical fixtures) or solids (vertical or horizontal fixtures), as long as some air space is present inside the bottle. Fixtures can be semi-automated or manual, and the test systems, based around the TME *Solution-C* test instrument, are high resolution, repeatable, and have data storage capability that meets CFR Part 11 guidelines.