Leak, Flow and Package Testing 101
Part 2. Package Testing

Part 2 of a 3 part paper designed to help you better understand why leak, flow and package testing is important. This series will enable you to make informed decisions as to the type and method of testing best suited to solving your issue.
Presented by TM Electronics, Inc.

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TM Electronics, Inc
SPECIALISTS IN LEAK, FLOW AND PACKAGE TESTERS

What's covered in Part 2

Part 1. Device / Product Integrity (Download separately)

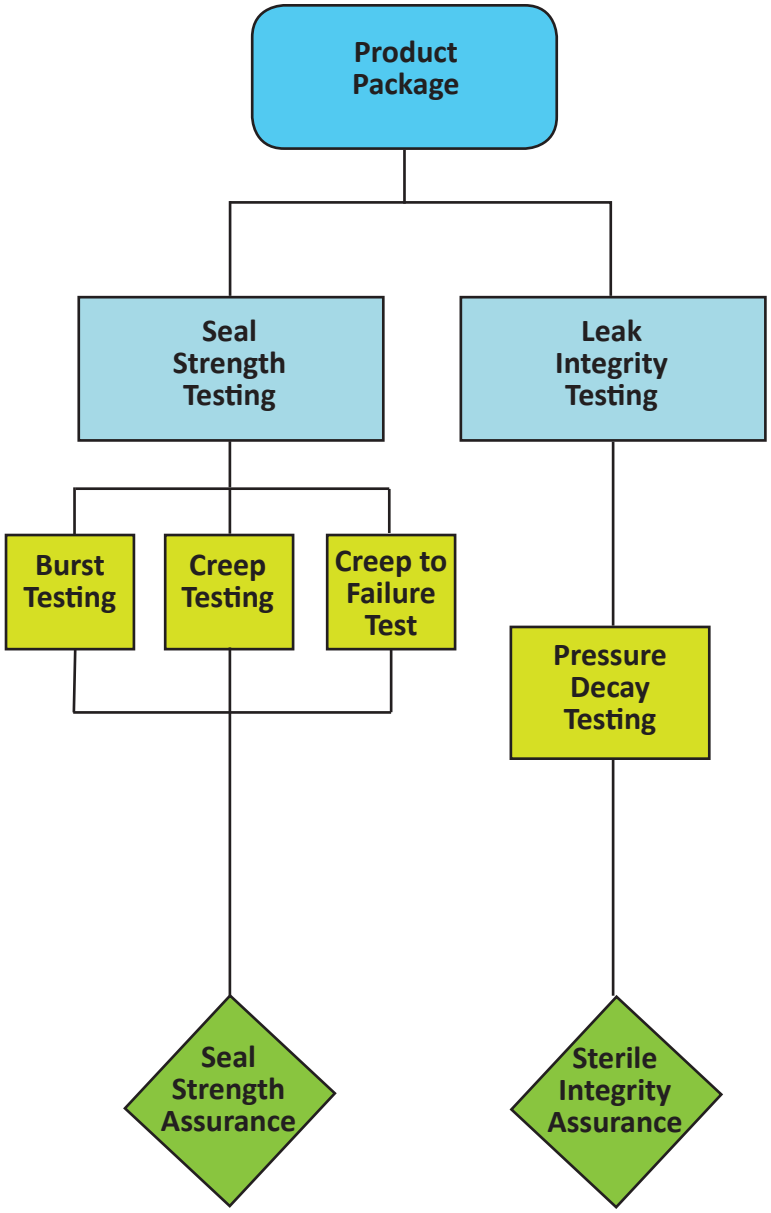
Overview of Device or Product Integrity Testing
What is a leak? Types of Leak Tests Quiz
Pressure Decay Leak Testing
Mass Flow Testing and Flow Testing for Occlusion/Obstruction
Statistics for Quality and Process Control
Instruments
Quiz

Part 2: Package Testing

Part 3: Non-Destructive Pressure/Vacuum Decay Chamber Testing for Sealed Products or Packages (Download separately)

Surrogate Chamber Testing
Understanding your Test Item
Designing your Test Chamber
Chamber Test Systems
Test Fixtures
Quiz

Package Testing: Overview



Package integrity testing is the next step for the device or product manufacturer.

There are two roads of testing - seal strength testing and leak integrity testing for non-porous packages.

Seal strength testing is valuable to ensure that package contents don't escape, and that sterile barriers remain intact, under stresses from transport, shelf life

Having completed and documented your device and packaging testing, you can now present your final product to the market.

Introduction to ANSI/AAMI/ISO 11607 – Essential for Medical Packaging, but Useful and Important Concepts for all.

International Standard

ISO 11607, "Packaging for Terminally Sterilized Medical Packaging", is an international standard providing a guideline for the design, processing and testing of primary product packages. Because the FDA considers ISO 11607 to be the paradigm for validation protocol for medical device packaging, it is important that manufacturers of these devices rely on guidance from this document as they seek FDA approval of their packaging system validation protocol.

Useful for non-medical device manufacturers

The concepts expressed in ISO 11607 are useful and helpful to non-medical device manufacturers, as well. Whether your product is food for people or pets, electronics, or automotive parts, if you package it, you could find some excellent guidance here.

Maintain sterility

According to ISO 11607, "the intention of packaging for terminally sterilized medical devices is to maintain the sterility of the product with respect to its intended use, the shelf life, transport, and storage conditions", i.e. to see that the packaging material and process provide a package that will withstand the sterilization and packaging processes and maintain that sterile barrier for the life of the product.

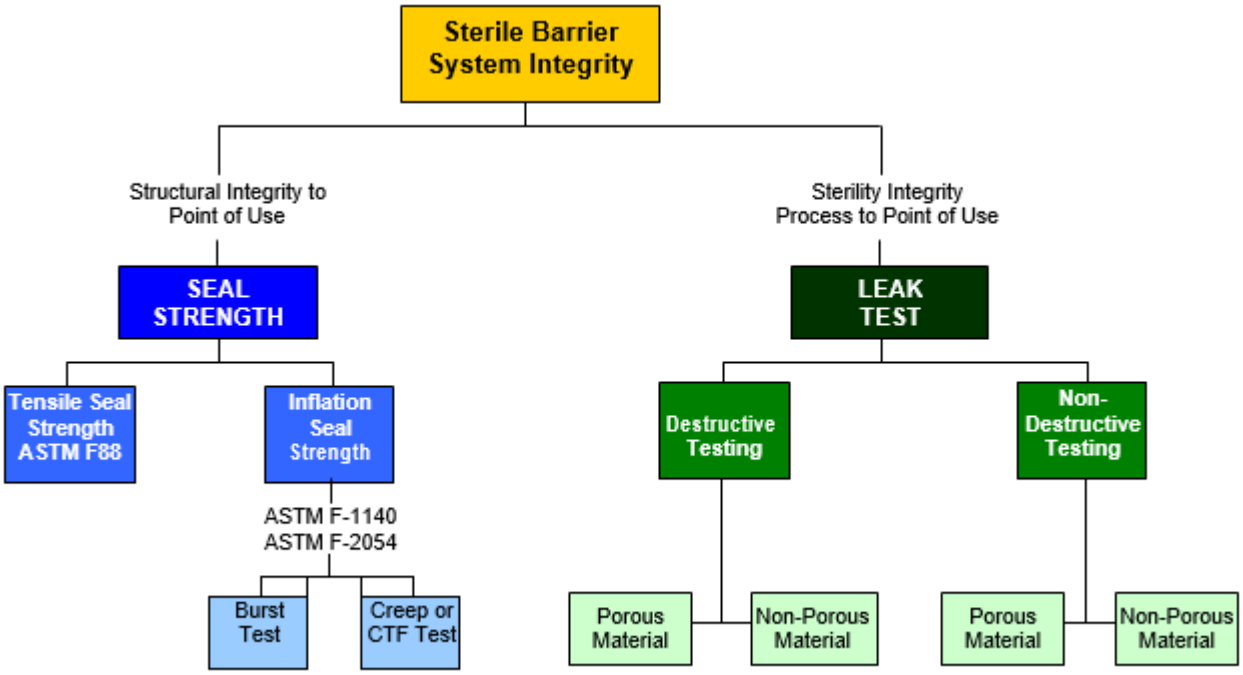
This is a twofold objective

First, to ensure the integrity of the sealed package, and second, to assure that no weaknesses in the sealed areas of the package permit leaks to develop with handling stresses and time. To assure that the package performs adequately, you must be sure that the package is able to maintain the integrity of both the seals and the materials under stress. This implies that your package testing system must include both package integrity testing and seal strength testing, two complementary but very different procedures.

Package integrity may be thought of as a "leak test" of the package – is there a failure in the materials or process that allows contamination to enter?

Seal strength testing, on the other hand, measures an attribute of the seal, which is designed to ensure that the seal presents a microbial barrier to at least the same extent as the rest of the packaging. Both testing streams are important in your final package analysis.

These two paths can be illustrated as follows:



Consensus Standards? ASTM Test Methods?

A note to medical device manufacturers and packagers:

Before deciding on specific package test methods, it is important to look ahead to the process you, as medical device packaging professionals, will have to deal with: validation of your chosen package test method.

What is a validatable test method?

A validatable test method is one for which the following characteristics have been defined by ASTM or FDA:

• ***Repeatability:*** what is the variation in results using the same operator, same equipment, in the same location?

• ***Reproducibility:*** what is the variation in results with different operators using different equipment in varying locations?

• ***Sensitivity:*** what is the smallest value of the tested variable that can be accurately identified by the test method?

Although you are not required to use a test method for which the above characteristics have already been defined and recognized by FDA, it is greatly to your advantage to do so.

Responsibility

If you design your own test method, YOU will be responsible for all the effort that has been done by others, such as ASTM, for validatable methods! ASTM is a consensus body made up of OEM users, suppliers, instrument and other manufacturers.

Standard methods

The ASTM process provides for the development of test methods using a standard procedure, and confirmation of methods using Interlaboratory Studies (ILS). These procedures provide the repeatability, reproducibility and sensitivity data necessary to validate your test method with your product. FDA Recognized Consensus Standards are by definition test methods developed by consensus bodies such as ASTM.

For more information about FDA consensus standards, check the following government websites: www.www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

and

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm

A note to the rest of you:

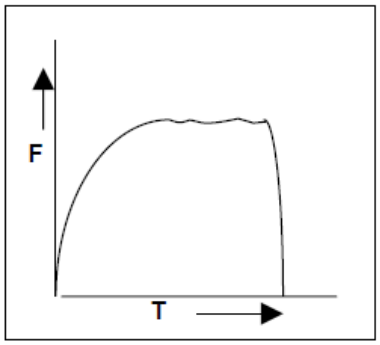
You may or may not be responsible to the government for validation of your test methods for leak or package testing. However, you are of course responsible for providing the best possible protection for your product, your customers, and yourself by selecting the most appropriate test method for your needs.

Benefit of ASTM test methods

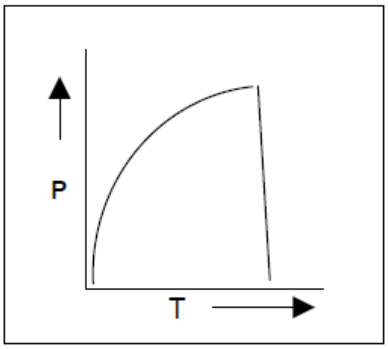
ASTM test methods, when appropriate to your product or package, provide information on repeatability, reproducibility and sensitivity that will enhance your confidence in the way you are testing your product.

Seal Strength Testing

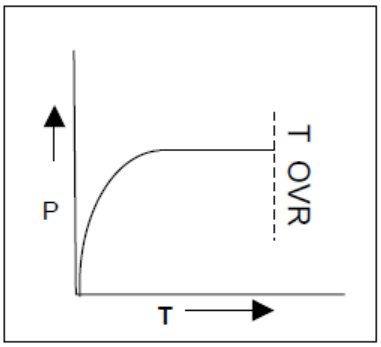
Types of Seal Strength Testing:



Tensile Test



Whole Package Burst Test



Whole Package Creep Test

F = Force
P = Pressure
T = Time

Tensile Testing

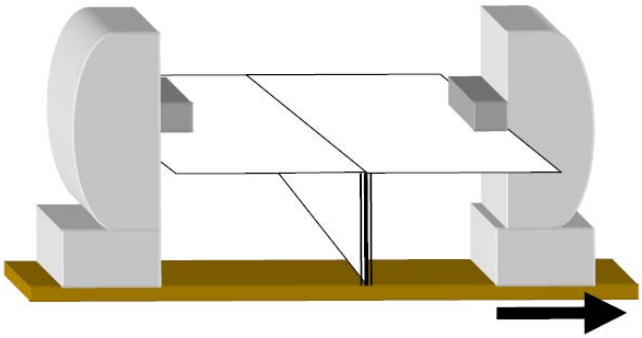
Tensile seal strength testing measures the ability of a package seal to resist separation – the simple peel strength of the seal. Using a defined width sample of a package perimeter seal, a moving jaw pulls the sample apart at a constant speed while measuring the resistance force during the seal separation. The tensile test is particularly suited to peel-open packages.

Sensitivity

A significant advantage to this test is its sensitivity.

Disadvantages

In the majority of cases a perimeter seal is sampled only at several locations and a total package seal strength measure is not obtained. Another disadvantage is that the effect of hoop and lateral stresses from inflation or non-perpendicular peel stress cannot be measured.



An example of a tensile test instrument

Inflation Seal Strength Testing

Inflation seal strength testing includes burst, creep and creep-to-failure testing.

Burst test

This test requires pressurizing the entire package and measuring the peak rupture pressure.

Creep and Creep-to-failure test

The time to failure at a constantly held pressure. This test provides three different components of stress to the package: peel stress with horizontal and vertical components, tension due to hoop stress in the vertical direction, and lateral stress due to package expansion.
(Circumferential stress or Hoop stress is a normal stress in the tangential direction. Radial stress is a stress in directions coplanar with, but perpendicular to the symmetry axis. “Coplanar” are points lying in the same plane.)

If these stresses are greater than the strength of the seal at any point within the package, the seal will rupture. This provides a more realistic representation of stresses to which your package will

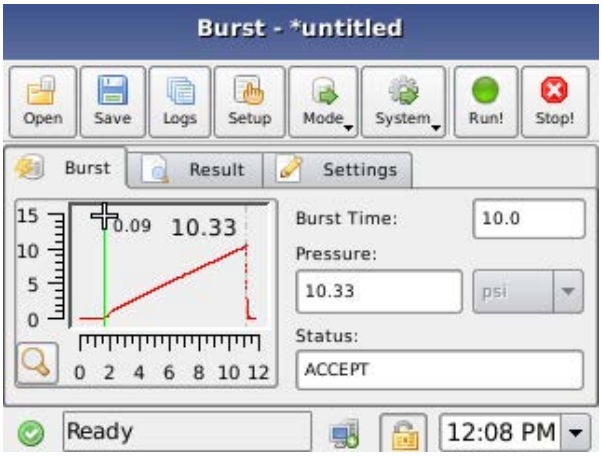
be subject than that provided by the tensile test.

Additional advantage
Another advantage to this type of testing is that it provides a whole-package minimum seal strength and also indicates the weakest seal area, and is equally applicable to peelable and non-peelable seals.

Using inflation tests
Inflation tests are applicable to most package forms such as pouches, header bags, lidded trays, flexible or rigid blisters and laminated or rolled tubes.

Burst Testing
Burst testing 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 screen shot below represents the output from the TM Electronics BT Integra-Pack Smart Package Tester showing a characteristic burst curve.

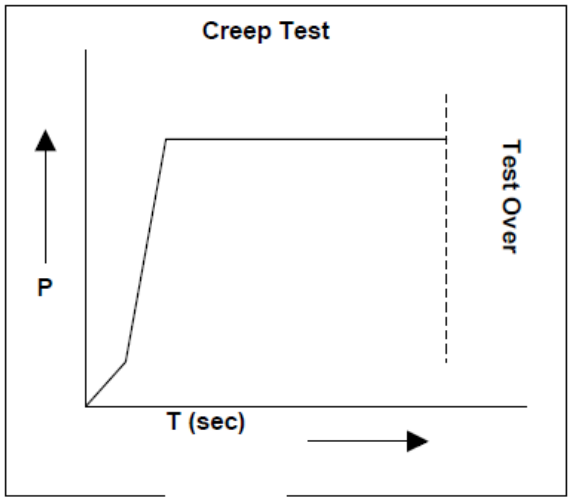


Example of a characteristic burst curve

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 (10.33 psi on our screen shot) 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.

Creep 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. This provides 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.

Disadvantages
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.

Creep to Failure Testing
This is a variation on the Creep Test that addresses its weaknesses. 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 Statistical Process Control (SPC) or Statistical Quality Control (SQC) methods.

How do I get pressure into the package?
To pressurize a closed package, a leak tight measuring path must be available between the package interior volume and the pressure source.

In Figure 5 we can see a simple, effective method of accomplishing this.

This is the TM Electronics' patented Package-Port™ system in which a reusable plastic entry port is secured and then accommodates the pressurizing probe.

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. Inexpensive, simple to use and reliable, this system makes in-process package inflation testing highly efficient and repeatable.

An example of a leak tight path to a package, enabling pressure to be inserted into the package

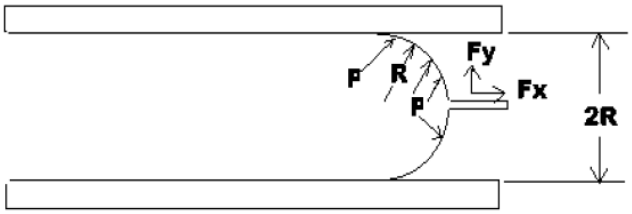
Restraining Plate Package Testing

Seal strength values are related to the package size, geometry, and materials. For example, pouches with a long side seal will generally fail on the long seal unless a heater failure has occurred on the shorter seal or chevron. Unsupported tray lid seals may fail at points only relative to their geometry. Very flexible package materials may deform with pressurization to an extent that makes seal testing difficult. To address these problems, it may be advisable to use restraining plates for your inflation testing.

Package geometry affect

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.

The diagram below illustrates the effect of restraining plates on the pouch under test:



Restraining plate test forces on pouch where **R** is the radius, **P** is the pressure exerted on the unrestrained edges of the pouch, and **Fy** and **Fx** are the force vectors on the seal.

Relationship of gap to pressure

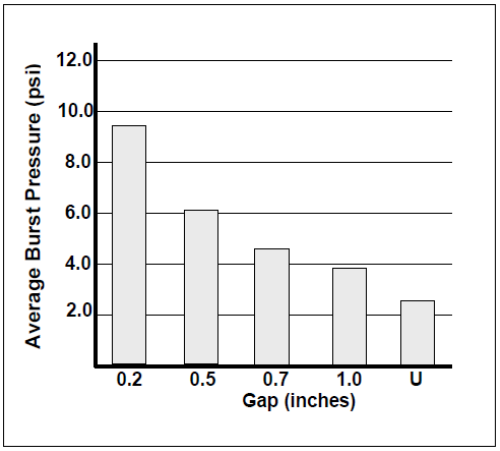
In addition, package restraint has a direct relationship to burst pressures: the wider the gap between plates, the lower the average burst pressure (Figure 7).

Consistency required

The most important factor when interpreting test results is that all conditions in the package test method are consistent. Establish a set of test conditions for each package and reproduce those conditions consistently.

Caution

Use of package restraints must be approached with caution; because of pressures exerted on the plates, extreme care must be taken that fixtures are designed to withstand the forces applied by the inflated package.



Graph demonstrating average burst pressure to gap width

Summary – Seal Strength Testing

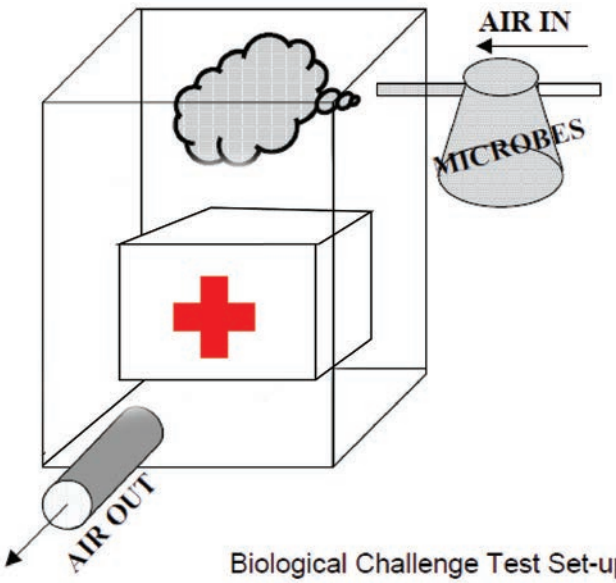
Inflation seal strength test results can be an excellent tool for process control. Burst test results, creep-to-failure and tensile data are all amenable to use in control charts and provide quantitative data required by ISO-11607 for package testing validation. A number of ASTM test methods, which are accepted FDA Consensus Standards, are available to aid in the design of these tests (see below).

ASTM Seal Strength Standard Test Methods	Reference#
Internal Pressurization Failure Resistance of Unrestrained Packages	F1140 - 13
Burst Testing of Flexibale Package Seals Using Internal Air Pressurization Within Restraining Plates	F2054 F2054M-13
Seal Strength of Flexible Barrier Materials (Tensile Test)	F88 F88M-15

But as we discussed earlier, seal strength testing is only half of the story. The other half is Physical Package Integrity Testing.

Package Integrity Testing

We have thoroughly examined the need and methods of seal strength testing. 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.



Biological Challenge Test Set-up.

Biological Challenge Tests vs. Physical Test Methods

Biological challenge tests, in which the package is isolated in a chamber, surrounded by microbe-laden atmosphere, and then examined after the microbes have been removed, are indicated by ISO-11607 for finished medical device packaging. Recent studies indicate that these high bio-burden aerosol tests may not be the most reliable indicators of leakage. Physical test methods, which are more reliable and more repeatable, present the best opportunity for determining the integrity of the package.

The ISO-11607 list of methods for physical integrity tests includes these methods:

Visual Inspection Method
Internal Pressure Method
Vacuum Leak Method
Dye Penetration Method

These methods have been reviewed and are recommended for use. A drawback of these methods is that they are not quantifiable, and that they require operator interpretation.

Consensus Methods

The FDA has accepted certain test methods produced by industry consensus organizations as being valid for medical device packaging. This means they have been evaluated for repeatability, reproduce-ability and sensitivity, and make the validation process much easier for the medical packaging professional.

Excellent starting point

These consensus standards are also an excellent place to start for those outside the medical packaging community as they begin the process of designing or selecting a package test method.

List of Methods

The table on page 11 gives an overview of currently used package test methods, their ASTM test method designation if applicable, appropriate usage circumstances, advantages and disadvantages.

Note: It is very important that you think about your package, your process and your end product's needs when evaluating test methods.

Among other things, you should consider:

- **Are your barrier materials porous or non-porous?**
- **Will you need to test the whole package, or just the seals?**
- **Is a destructive test or a non-destructive test more suitable to your needs?**
- **Are you able to consider an expensive test, or are you operating on a budget?**

The Alternative to Microbial Challenge: Physical Tests with ASTM Test

Test Method	Package Form	Barrier	Destructive or Non	Cost	Sensitivity
Dye Penetration (Blue Dye Test) ASTM F1929	**Pouch, tray**	**Porous or Non-porous**	**Destructive**	**$**	**50 um (.002) channel leak**
Advantages: Inexpensive, commonly used test		*Disadvantages: Messy, operator dependent, requires clear material on at least one side, difficult to use with papers and some porous materials that can absorb dye: qualitative*			
Visual Inspection ASTM F1886	**Pouch, tray**	**Porous or Non-porous**	**Destructive**	**$**	**75 um (.003) channels**
Advantages: Inexpensive, convenient		*Disadvantages: Operator dependent, materials, magnification can't rule out pinholes: qualitative*			
CO2 Trace Gas ASTM F2228	**Trays with porous lids**	**Porous**	**Destructive**	**$$$**	**100 um channel 50 um hole**
Advantages: Not operator dependent; will find leaks in rigid tray material as well as channels in seal		*Disadvantages: Not considered a whole package test: does not challenge the porous component of the package. limited use*			
Bubble Emission ASTM D3708	**Flexible material**	**Non-Porous**	**Destructive**	**$$**	**100 um hole or 1 x 10-5 cc/sec**
Advantages: Useful for gross leak detection; usable with a variety of package forms		*Disadvantages: May not detect small leaks: dependent on product contained, materials etc; Operator dependent: messy, qualitative*			
CO2 Trace Gas ASTM F2227	**UNLIDDED Rigid trays**	**Non-Porous**	**Non-Destructive**	**$$$**	**50 um (.002) pinholes**
Advantages: Not operator dependent		*Disadvantages: Not for whole package, applicable to empty trays only*			
Pressure decay with/without restraining plates ASTM F2095	**Flexible pouches, Foil sealed trays**	**Non-Porous**	**Destructive**	**$$**	**25 um pinholes or 1 x 10-4 sec**
Advantages: Quantitative, not operator dependent, fast, easy to use, wide range of applicability		*Disadvantages: Sensitivity dependent on package volume; doesn't show location of leaks, not amenable to porous barriers or liquid content*			
Bubble Test (Internal Pressurization) ASTM F2096	**Flexible material**	**Porous or Non-porous**	**Destructive**	**$**	**250 um holes**
Advantages: Useful for gross leak detection: usable with a variety of package forms, inexpensive		*Disadvantages: Messy, operator dependent, use with porous in certain circumstances only, long test time*			
Vacuum Differential ASTM F2338	**Trays (lid/no lid) and cups**	**Porous or Non-porous**	**Non-Destructive**	**$$$**	**Varies with application**
Advantages: Not operator dependent, amenable to a variety of package forms and materials		*Disadvantages: requires sealing of porous surfaces*			
Helium Tracer Gas ASTM F2391	**Flexible or rigid packages**	**Non-Porous**	**Non-Destructive**	**$$$4**	**10-10 sccs**
Advantages: Quantitative, can detect moderate ("Sniffer mode") to very fine ("Vacuum Mode") leaks		*Disadvantages: Expensive, high maintenance*			

Some other alternatives: Physical integrity test in use

Test Method	Package Form	Barrier	Destructive or Non	Cost	Sensitivity
Pressure/Vacuum decay Chamber test	**Sealed, flexible material**	**Non-Porous**	**Non-Destructive**	**$$$**	**5-10 um holes**
Advantages: Quantitative, fast, not operator dependent can be semi-automated		*Disadvantages: Not a consensus standard; requires custom fixture for greatest sensitivity*			
Ultrasonic Leak Detection	**Pouch, flexible packages**	**Porous or Non-porous**	**Non-Destructive**	**$$$$**	**25 um**
Advantages: No sample preparation; detects non-leaking seal defects; fast		*Disadvantages: Not a consensus standard*			
Force Decay	**Pouches**	**Non-Porous**	**Non-Destructive**	**$$$**	**25 -50 um**
Advantages: Not operator dependent; fast, quantitative		*Disadvantages: Not a consensus standard; requires custom fixture for greatest sensitivity*			

TME Statistics Packages: For Quality and Process Control

TM Electronics' leak testers and package testers contain a standard statistical package that provides not only quality documentation but also process control tools such as control charts, histograms and graphic presentation of each individual test.

Control Charts Aid Process Control

Control charts are commonly used to aid in manufacturing process control. The objective of control charts is to monitor the process in real time so if something goes wrong, it can be noted and corrected with the minimum of lost product. The concept behind control charts is as follows:

1. A process "in control" will result in pressure decay test values that fall consistently in a predictable range around the average (see Figure 4). In addition, the average test value will not change appreciably over time when the sealing process is "in control".

2. Because processes always vary slightly due to manufacturing and material variations, "good" product test values will go up and down within a range around the mean value. That range can be statistically predicted using the mean test value plus and minus three standard deviations (a measure of the variation inherent in the process). The "acceptable" range is the set of test values that fall between the upper and lower control limits. These control limits are automatically calculated in the TME test instrument from the previous test results in the Datalog.

3. In the TME Solution, the data points on the control chart consist of subgroups of test results. These subgroups can be as small as two tests (as in Figure 3), or as many as 20 tests. Subgroups are used to minimize the effect of a testing error or a single bad part.

Control charts for the mean (X-bar) can help the manufacturer in several ways.

Example

If, for example, a temperature problem in your sealing equipment is causing weaker than usual seals resulting in greater pressure decay, the upward trend in test values will be obvious on the control chart even before the product reaches the point of failures. This gives the machine operator

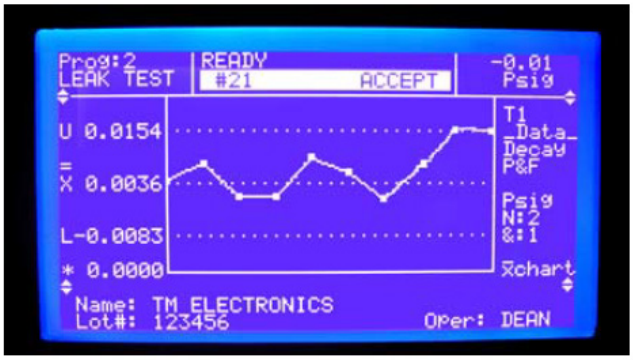


Figure 3. Control charts for leak results showing a process in control

an opportunity to correct the temperature problem with little or no loss of product.

Several data points outside of the control limits (Figure 4) may give the machine operator an indication that instability is developing in the process that needs to be investigated before a large quantity of bad product is produced.

Control charts for range (the difference between the maximum test value and the minimum test value within a subgroup) also have a place in identifying when the process is becoming erratic and inconsistent.

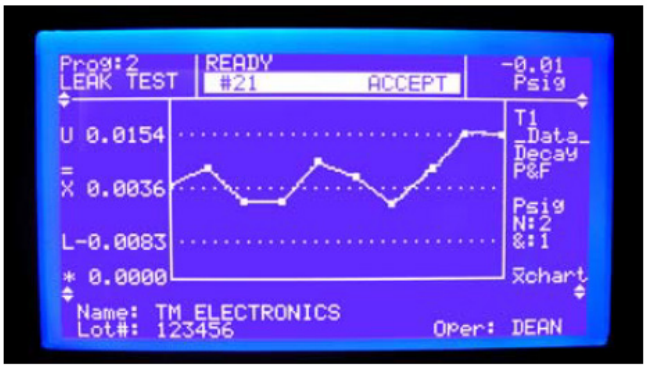


Figure 4. Control charts for process going out of control

TM Electronics, Inc. Leak and Flow Testers

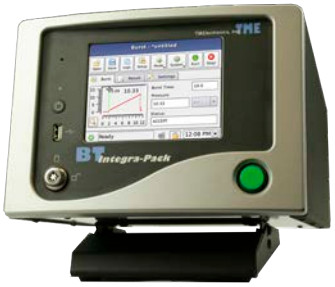
The TME SOLUTION™ Leak & Flow Tester
The TME SOLUTION is a high resolution leak and flow tester featuring one to four channel concurrent or multiple channel sequential leak and flow testing.

Sensitive, repeatable and reliable, the SOLUTION can be configured to perform ten different tests on product, including burst, occlusion, vacuum and pressure decay, crack, and differential pressure or vacuum. Touch screen menu-drive operation allows the operator to control the test parameters, examine statistical analysis of results or download data files easily.

The SOLUTION, in conjunction with custom fixtures, accessories and engineering support, provides a complete turnkey solution to your leak and flow testing problems.

The TME INDUSTRIAL SOLUTION
is available in a NEMA-4 enclosure for harsh environments. All TME Solution models are available with Ethernet capability

The TME Smart BT-Integra Pack for burst, creep, creep-to-failure and leak integrity tests. a small footprint and user-friendly ease of operation. Electronic pressure and flow controls provide precise and repeatable test conditions, while automatic and high flow output allow testing of large porous packages. Applications cover a range of flexible or rigid, porous and non-porous, open or sealed packages.



The TME Pressure Bubble Tester provides low pressure and controlled flow to apply to a pouch to meet the requirements of ASTM International F-2096 test method “Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)”.

The TME WORKER Integra™ Leak or Flow Flow and Occlusion-Tester a high resolution (as low as 0.0001 psig) leak and flow tester featuring one to four channels.

A small footprint and user-friendly ease of operation. The system can be configured to perform pressure or vacuum decay leak testing, flow and occlusion testing on non-porous, flexible or rigid products.

Models are available for pressure ranges from 15 to 150 psig, or vacuum, and flow rates from as little as 10 sccm to as much as 10 lpm.

Quiz

Test your understanding of the pages Part 2

Q.1. ISO 11607 is?
- A. More of guideline rather than a standard
- B. Only important in the USA
- C. An international standard for design, processing and testing

Q.2. Package integrity is?
- A. The moral uprightness of a package
- B. A leak test of a package
- C. A way of just testing seals

Q.3. Seal strength is?
- A. Important as a microbial barrier
- B. The measurement of the total aroma coming from a seal colony
- C. The time when the part is being pressurized

Q.4. A validatable test method must have which of following characteristics?
- A. Repeatability
- B. Reproducibility
- C. Sensitivity
- D. All of the above

Q.5. Which test is a seal test?
- A. Tensile Test
- B. Whole package burst test
- C. Whole package creep test
- D. B and C
- E. A, B and C

Q.6. A tensile seal strength test measures the ability of a package seal to resist separation?
- □ True
- □ False

Q.7. A burst test means having to pressurize the seals and measuring peak rupture pressure?
- □ True
- □ False

Q, 8. Hoop stress?
- A. Is also called circumferential stress
- B. Only suffered by adults with a hula-hoop
- C. Is determined with a creep and creep-to-failure test
- D. A and C

Q,9. A burst test determines the overall minimum seal strength of the package seals
- A. True
- B. False

Q,10. When using a creep test, you need to?
- A. Avoid filling to slowly as to create a long test time
- B. Use intermediate flows
- C. Fill the package in such a way as to not shock the seals
- D. A and C

Q, 11. Seal strength values are related to which?
- A. Package material
- B. Package size
- C. Package geometry
- E. A and C
- F. A, B and C

Q, 12. When using restraining plates, the wider the gap between the plates, the lower the average burst pressure ?
- A. True
- B. False

Q,13. Inflation seal strength test results cannot be used as a tool for process control?
- A. True
- B. False

Q14. Package integrity testing is not needed if seal strength testing has been done?
- A. True
- B. False

Answers:
Q1. C. Q2. B. A leak test of the package. Q3. A. The seal prevents a microbial barrier to the same extent as the rest of the package. Q4. D. All of the above. Q5. E. A, B and C Q6. True. Q7. False. The entire package is pressurized Q.8. D. Q9, A. Q10, D. A and C. Q11, F. A, B and C. Q12, A. True. Q13, False. They are an excellent tool. Q14. B False. Package integrity testing is a measure of the package's sterile barrier - A leak test of the whole package.

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Glossary of Terminology

Pressure Decay Test: an inflation leak test in which a non-porous package or product is pressurized to a preset level. After the package has stabilized, the decay in pressure over a preset test time is evaluated to determine if a leak is present.

Vacuum Decay Test: similar to the Pressure Decay Test, except that a preset vacuum is established inside the product or package, and the decay in the vacuum over a preset time is evaluated to determine if a leak is present.

Decay: refers to the change of pressure (Δ P) inside a pressurized containment during a pressure decay leak test. Decay can refer to either positive or negative (vacuum) pressure

Pressure/Vacuum Decay Test Cycle:
Consists of five consecutive steps:

1. Load (attach the test item to the test system)
2. Charge (pressurize the test item to a preset pressure, or create a predetermined vacuum level)
3. Settle (time allowed for the volume of the test item to stabilize to minimize the effects of material stretching, adiabatic heating, etc.)
4. Test (the time during which the decay in the pressure or vacuum is measured
5. Unload (removal of the test part from the test system).

Decay Curve: In a pressure decay leak test, the graph of the drop in pressure (Y axis) over time (x axis) is called the decay curve. TME uses the decay curve in its "Test Plot" graphic display and in its "Memory Reference Curve" technology, in which the decay curve for an acceptable test part is determined and reject decisions are made by the test instrument by comparing the test decay curve to the acceptable "memory reference curve" for the test part.

Resolution vs. Sensitivity:
Resolution is the least significant digit that an instrument is capable of measuring; for example, the TME Solution Leak Tester has a resolution of 0.0001 psi.
Sensitivity is the smallest volume leak rate your test system (including the air lines, fixtures, etc.) can detect.

Units of Measure:
Pressure units of measure include: psig (pounds per square inch gauge), Pascals, kg/cm2 and many others.

Flow rate units of measure include: liters/min, sccm (standard cubic centimeter per minute), sccs (standard cubic centimeters per second) – where standard refers to atmospheric pressure.

Transducer: Any sensor that converts a physical parameter (for example, pressure) into an electronic signal that can be utilized by an instrument.

Leak Rates:
Volume Leak Rate: change in volume per unit of time (measured in Flow Rate units of measure, see above)
Pressure Leak Rate: change in pressure per unit of time (measured in Pressure units of measure, see above)

Operating Test Parameters: the descriptive factors defining a leak, flow or package test. These may include:

Charge, settle, and test times for pressure or vacuum decay tests;
Test pressure;
Flow rate into the test item (very important in burst testing);
Maximum acceptable volume leak rate.

Sequential vs. Concurrent Testing:
Concurrent testing enables leak tests to be performed simultaneously on more than one and up to four test items in a Solution tester, with one test item connected to each port on the instrument. The tests must have identical test parameters (test time, pressure, decision point etc.), and the test results are discrete and identifiable to a specific test part. An instrument of this type has individual transducers for each test port.

Sequential testing involves performing a series of like tests on a test item through a single port. An example is a leak test followed by a flow occlusion test on a test item and/ or a series of leak and flow tests on multiple ports. An instrument of this type may have one port or multiple ports that are tested one at a time.

Occlusion Testing: An occlusion is a partial blockage of a flow path. An example is a crimp in a catheter. Occlusion testing can be done in several ways, including:

1. mass flow rate
2. back pressure measurement
3. pressure drop measurement.

Back pressure: the pressure forcing air through a leak path.

Package Testing: Based on international standards and FDA guidelines, thorough package testing should consist of both seal strength testing and leak integrity testing.

Seal Strength Testing: a destructive test that provides a measurement of the strength of a package seal of a porous or non-porous package. Seal strength testing can also identify the area of weakest seal. Seal strength testing can be done using inflation tests or tensile tests, but TME recommends using one or more of the following inflation seal strength tests:

1. Burst testing (recording the peak or ultimate strength of a package seal);
2. Creep Testing (measuring resistance to seal peel) – result is pass/fail only;
3. Creep-to-Failure (measuring resistance to seal peel) – result is variable statistic (time).

Integrity Testing: a measure of the quality of the package or product in general, including the seal areas and the package or product materials themselves. Leak Integrity Testing generally refers to product or package leakage measured by a leak test.

Fixtures: Fixtures are used to enable the test instruments to perform specified leak, flow or package tests on a variety of products or packages. Examples of fixtures commonly used by TME include: *Open Package Test Fixtures, Closed Package Test Fixtures, Restraining Plate Fixtures, Package Probe Assembly, Radial Sealing Fixtures.* Fixtures are often custom designed to accommodate a customer's very specific testing need.

Closed Package Entry System: a method to obtain a leak tight measuring path between the package interior volume and the instrument's pressure transducer. TME uses the patented Package-Port System, which consists of the following disposable items:

1. Package-Port – a reusable plastic entry port which accommodates the pressurizing sensor probe, and
2. Adhesive Disks that adhere the Package-Port to the surface of the test item which are supplied in rolls of 1000.

Non-Destructive (Chamber) Testing: a method to non-destructively test a sealed, non-porous package or product for leaks. It is necessary that the test item contain some air or other gas inside – this is called the "head space". The package or product is enclosed in a surrogate chamber that provides an interstitial air space around the test item. This air space is then pressurized and stabilized, and decay of the pressure in this air space (indicating air leaking into the head space of the package or product) is measured. A chamber test can also be done using vacuum.

Surrogate Chamber: the test chamber used in non-destructive chamber leak testing is called a "surrogate chamber" because the actual pressure or vacuum decay leak test is done on the air contents of the chamber surrounding the test item rather than on the test item itself.

NEMA-4: A designation in the USA which indicates that an item (such as case, components, or an assembly) can withstand damage from harsh industrial environments, including water or dust. The NEMA-4 designation corresponds to the IP-65 designation.

Verification/Qualification/Validation: These terms describe a process that is helpful when evaluating a new product or package manufacturing process:

1. Verification refers to the test and inspection results for each individual component and/or step involved in the manufacture and packaging of a medical device.
2. Qualification is a combination of verifications to determine how well equipment, materials, and a process can work together.
3. Validation is the combination of various qualifications and other objective evidence that the processes consistently produce prod uct meeting predetermined specifications.

IQ/OQ/PQ: Installation Qualification, Operation Qualification, Performance Qualification. These protocols are part of the validation process addressed above.