# Leak, Flow and Package Testing 101

## Part 1. Device and Product Integrity

**Part 1 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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SPECIALISTS IN LEAK, FLOW AND PACKAGE TESTERS

# Why is testing important?

***Leaks and faulty flow equal product failure.***

A leak or seal weakness may lead to material leakage, environmental contamination, loss of sterility or component failure.

***In all cases, leaks, seal weakness or faulty flow mean a waste of manufactured product and surely lead to customer complaints and a lose of reputation.***

Although Leak,Flow and Package Testing are different in their functional approach, the motivation for testing is the same

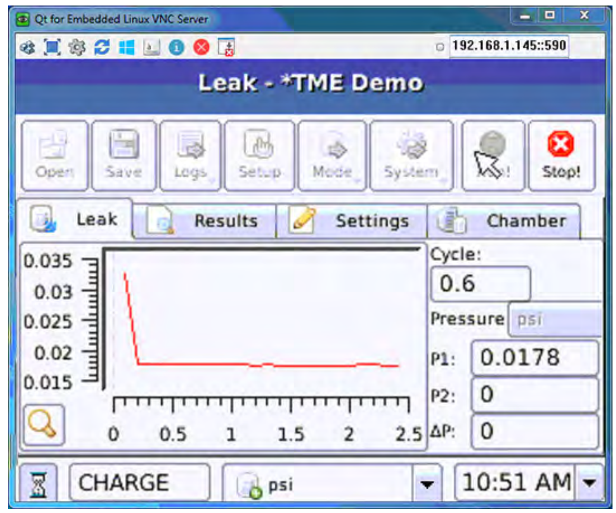
- To insure material supposed to remain in a package or product stays there,
- And that nothing in the outer environment that is not intended to get into the package or product can enter,
- Or insuring a substance flows at a specific rate from one point to another and arrives intact.

Your interest in this course is because you want to know more about basic leak, flow or package testing.

Perhaps your product is designed to contain a material without losing any of the contents or it's intended to transfer a material, solution or gas intact from one point to another.

Perhaps you are introducing a new product that is itself enclosed in a completely sealed package, sterile or otherwise, to protect the product from the world, or to protect the world from your product.

Whatever your concerns or needs, this course is designed to help you understand the fundamentals and guide you in selecting the appropriate testing.




Leaks, seal weakness and faulty flow equal product failure

## What's covered in Part 1

### Device / Product Integrity

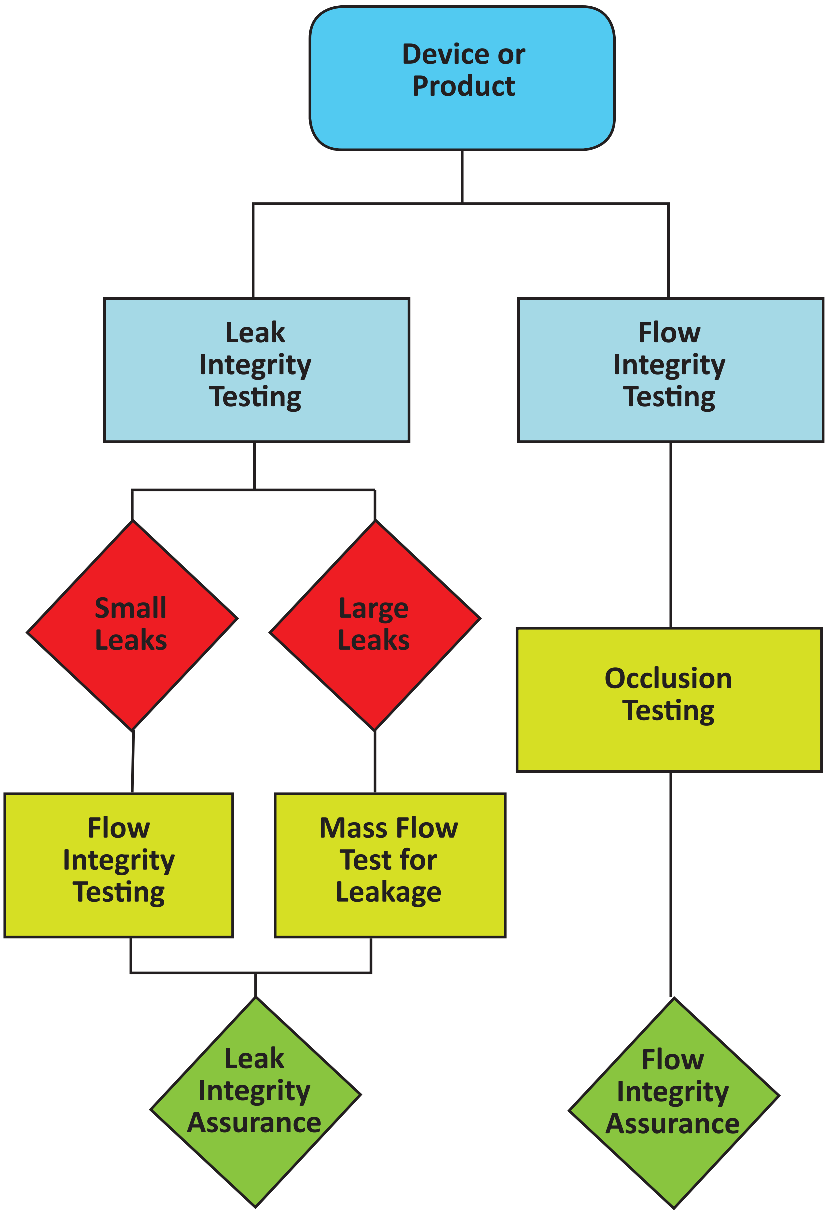


### Part 2: Package Testing (Download separately)



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

# Device or Product Integrity Testing Overview




Whether you manufacture medical devices, auto parts, or other products it's essential to provide assurance of product

Leak and flow testing are a valuable way to enable your QC department to provide assurance of your product's integrity.

Large or small leaks can be quantified using pressure decay and mass flow testing, and flow testing can also identify obstructions in flow-through parts.

The end result is that you, the manufacturer, will gain CONTROL over your manufacturing process, and QUALITY ASSURANCE in the field.

**What is a Leak?**

In this section, we will discuss:

- How leakage is measured and what is meant by "Leak Rate"
- Determining the appropriate standard or specification for your particular product,
- Practical issues involving leakage including typical product leakage ("leak rate")
- Leak rate conversions and the price of "no leaks"

Although important and fundamental in leak science, most information in this section relates to the identification and measurement of leaks; package integrity testing will be discussed in detail in a later module.

## *What is a Leak?*

Simply and directly, a leak is a hole or a path through which the package contents may escape, or through which ambient materials from the environment may enter. There are holes in everything; the issue you face is to decide how large a hole must be to cause a failure, and where that hole is likely to be located. Your answer to these questions will help to determine what kind of leak testing is most appropriate for your product.

There are two common methods of locating leaks:

- Bubble testing,
- Sniffer testing with trace gas.

We'll address these later.

A very important issue is the definition of the leakage – or leak rate – that must be found to avoid product failure. This definition will vary according to your product and its circumstances.

***Everything Leaks***

Remember that everything leaks, even if it is the permeation of gas molecules through a metal or plastic, or atoms leaking through a lead shield. It's just a matter of time. The important point is that leakage is relative to a standard or specification.

***How Much Leakage is Too Much?***

In order to define the specification or standard (how much leakage is too much leakage?), and indeed in order to measure leakage at all, we need to understand one basic relationship:

Leakage (or Leak Rate) = $\Delta V / \Delta t$

where V is the volume of the medium exiting or entering and t is the time period during which you are measuring the change in volume. Leak Rate is therefore the volume of material (air, fluid etc.) that escapes from a closed or sealed containment in a predetermined amount of time.

***Various Units of Measure***

You may see leak rate expressed in various units of measure, such as cc/min, cc/sec, or ft3/hr. The units will generally reflect whether you are measuring a relatively high or low leak rate; for example, leakage of air from a medical fluid container will be typically in the range of $1 \times 10^{-3}$ cc/sec (quite small) but air leakage from a water pump may be in the moderately high range of 8-10 cc/min and still be considered an acceptable part based on its use and test specifications. We will discuss the setting of test specifications later.

***Leak Measure as a Change of Pressure***

Note that some people will use a leak measure as a change in pressure over time (psi/sec, kPa/sec). These measures represent the result of the volume leakage rate for that specific application. However, unless the total volume of the part and measuring system are known, these measurements cannot be standardized against other instruments or measuring systems.

***Identifying Good and Bad Parts***

Using volumetric or mass measurements provides the best approach to defining leakage in a test system. Using the pressure drop method is most useful when a particular part can be identified as a "good" or "bad" part.

***Typical Product Leak Rates***

Having developed a very rudimentary sense of the meaning of "Leak Rate", let us take a look at some practical issues involving actual products. ***Table 1*** demonstrates typical leak rates for a variety of medical products.

**Table 1.** Typical allowable air leakage for medical applications

| Application | Pressure | Leak Rate | Cycle Time |
|---|---|---|---|
| Catheters | 30 psig | < cc/min ($1.6 \times 10^{-2}$ cc/sec) | 1 - 2 sec |
| Balloon Catheters | 200 psig | 0.6 cc/min ($1 \times 10^{-2}$ cc/sec) | 10 - 15 sec |
| Blood Bags | 2 psig | 1 - 4 cc/min ($1.6 - 6.4 \times 10^{-2}$ cc/sec) | 4 - 10 sec |
| Syringes | 10 -150 psig | 0.1-5 cc/min ($0.2 - 8 \times 10^{-2}$ cc/sec) | 3 - 10 sec |
| Insulin tester containers | | $1 \times 10^{-4}$ cc/sec | |
| Medical fluid containers | | $1 \times 10^{-3}$ cc/sec | |

You may note that some items with higher allowable leak rates, such as the syringes, have a relatively short test time. This is related in part to the degree of flexibility of the test part. A less flexible test item such as a syringe may require less time to “stabilize” before the actual leak test begins, whereas a more flexible item such as a blood bag may need a longer “settle” time. This issue will be discussed in greater detail later in the class.

***Typical Leak Rates in Industrial Applications***

Table 2 illustrates typical product leakage in industrial applications. Note again that variations in test specifications vary depending on the type of part. Several have a relatively high level of leakage to reach the critical point, but others are lower – in particular, the brake cylinders; consequently, a longer test time is needed to detect leakage at the desired critical level (remember our formula?).

***Size of Part Changes Test Time***

Another reason for variations in test time is the size of the part being tested. Even though the critical level of leak to be measured is larger, the volume of the part is larger. Most of these parts are not particularly flexible, as were many of the medical devices, but even these metal parts can be affected by temperature changes in the gas, and still need some stabilization time. In general, we can state that the lower the leakage rate, the longer the test time required.

***Further Discussion: Leak Rate through an Orifice***

Leak Rate through an orifice – a hole or a break – is a function of several variables: the pressure differential across the orifice; the diameter or size of the hole; the density of the test medium; the temperature.

The relationships can be defined as follows:

$$Q = k * d^2 * \text{Sqrt} ( P_1^2 – P_2^2 / \rho * T_a)$$

where Q is flow rate, d is the diameter of the orifice, P1 and P2 are the pressure on either side of the orifice, ρ is the specific density of the medium, k is a dimensional constant and T is the temperature of the system.

***Temperature Must be Constant***

To obtain consistent measurements of leak rate, the temperature must be constant. When dealing with gases, most measurements assume it is used in a state where it is considered incompressible.

Obviously, you can relate leakage with hole size, but several empirical factors are tied up in “k”. These factors come from geometry and fluid flow properties like the Reynolds number. Because of this, most leak rates are approximate, unless they are measured directly by mass flow.

As an aside, because matter can flow through an orifice in either direction, in general, leak rates can be assessed using either pressure or vacuum. This is a part-related issue, and in making this decision you need to consider several points: the function of the part, the structural integrity of the part, the degree of pressure change needed to

**Table 2.** Typical allowable industrial product leak rate

| Application | Pressure | Leak Rate | Cycle Time |
|---|---|---|---|
| Water Pumps | 15 psig | 4 - 6 cc/min | 10 - 15 sec |
| Oil Pumps | 30 psig | 8 - 10 cc/min | 5 - 10 sec |
| Thermostats | 80 psig | 1 cc/min | 2 sec |
| Radiators | 15 - 40 psig | 3 - 6 cc/min | 15 - 30 sec |
| Brake Cylinders | 80 psig | $1 \times 10^{-3}$ cc/sec | 30 sec |
| Hoses | 150 psig | 1 cc/min | 10 sec |
| Tube Sets | 15 psig | 2 cc/min | 5 sec |
| Faucets | 80 psig | 5 cc/min | 15 sec |
| Fuel Injection Units | | $5 \times 10^{-4}$ cc/sec | |
| Diesel Injection Units | | $1 \times 10^{-2}$ cc/sec | |
| Gas Filters | | $3 \times 10^{-3}$ cc/sec | |
| Diesel Filters | | $3 \times 10^{-2}$ cc/sec | |
| Gas Pressure Regulators | | $3 \times 10^{-2}$ cc/sec | |
| Gas Tubes | | $3 \times 10^{-3}$ cc/sec + high pressure test | |

find the leak, and whether the part will “out-gas” in a vacuum, giving false readings.

***Leak Rate Conversions***

A caveat to keep in mind when considering your test specifications: there are several common units of measure. Table 3 gives leakage and pressure conversion charts that may be helpful to you; note that these are volumetric leak rates at “Standard Conditions” – stated 70 degrees Fahrenheit, 14.7 psia (1 atm).

**Table 3.** Leakage & Pressure Conversions
All leak rate units at standard atmosphere conditions (70ºF, 14.7 psi)

| | To obtain → | cc/ss | cc/min | $in^3/min$ | $ft^3/hr$ | $Pam^3/min$ |
|---|---|---|---|---|---|---|
| Multiply | cc/sec | 1.000 | 60.0 | 3.66 | 0.127 | 10 |
| | cc/min | $1.67 \times 10^{-2}$ | 1.000 | $6.10 \times 10^{-2}$ | $2.12 \times 10^{-3}$ | 0.167 |
| | $in^3/min$ | 0.273 | 16.39 | 1.000 | $3.47 \times 10^{-2}$ | 2.73 |
| | $ft^3/hr$ | 7.87 | 471.9 | 28.80 | 1.000 | 78.7 |
| | $Pam^3/sec$ | 0.10 | 6.0 | 0.366 | $1.27 \times 10^{-2}$ | 1.000 |

Be careful to note on your specifications – or on specifications from others – what “their” standard conditions are. Many will use 0 degrees Celsius as a reference. The SI units are Pam3/sec (P*V/t). Note also that the following are not leakage measurements (psi/sec, Pa/sec, mbar/sec), but are pressure rates. The actual leak rate is a function of volume. These pressure measurements are only good for one part design, at specific conditions.

***The Price of “No Leaks”***

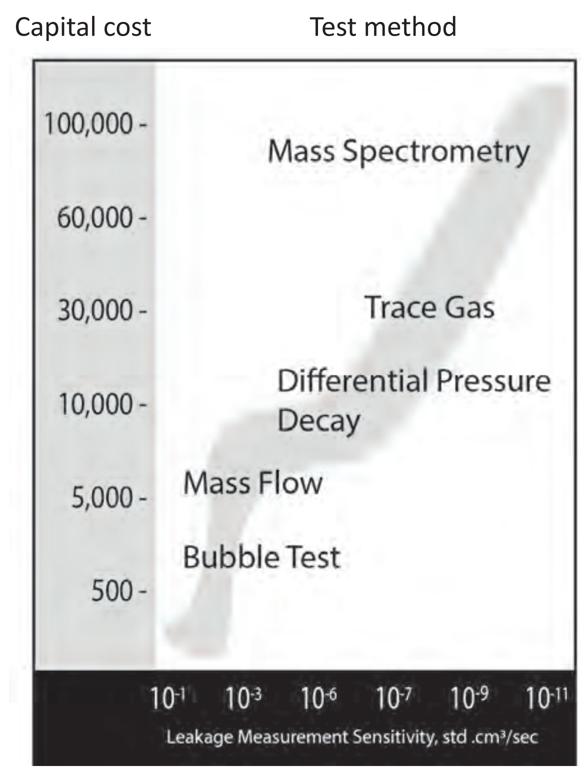
We have now developed a sense of the relationship between the size of a leak that is critical and the sensitivity of the test needed to find it. Once you have determined the size of the critical leak for your particular part or device, you can make a determination of your test specifications, and you can begin to research the test method to best serve your needs.

It is important to realize during this specification-setting period that there is a cost associated with instituting this quality control step. The table 4 shows a relative scale of different test methods. There are wide bands around each method to accommodate the different instrument type and the fixturing required to implement the test for your particular part.

As one would expect, the cost associated with greater sensitivity increases. If detection of very low leak rates is essential, the higher cost of equipment may be justified.

Only you can analyze your own best interests.

**Table 4.** The price of “No Leaks”

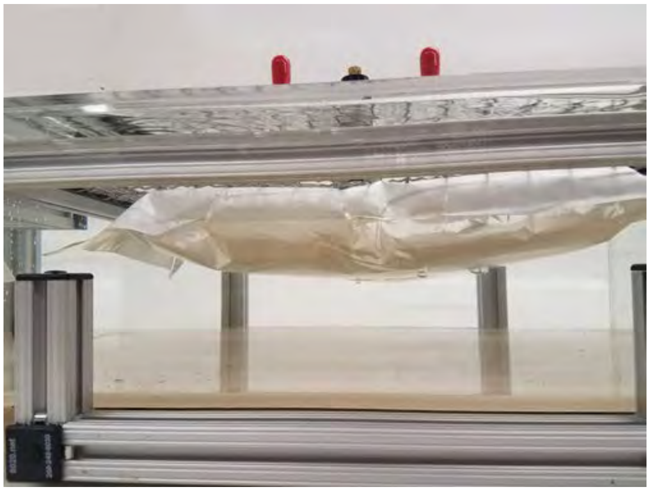


## *Types of Leak tests*

**Bubble ("Dunk") testing**
Bubble testing is the simplest, least expensive method of detecting and assessing leak rate.

The procedure is as the name implies: the part being tested is submerged in water, and the test operator visually observes and takes note of any bubbles escaping from the test part. Under the best test conditions, including good lighting, a very clear liquid, and a patient, alert operator, a leak rate of 10-2 to 10-3 sccs can be observed (a 1-2mm bubble escaping).

Disadvantages include a long test time (a minimum of 30 seconds per test), water contamination, and part clean-up time. The sensitivity of the test is not high, due to operator dependence.

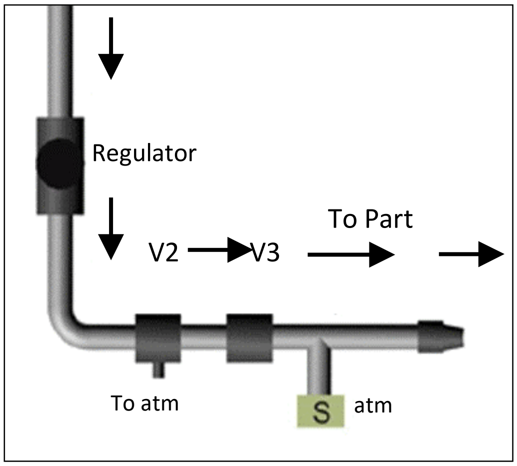


Bubble Testing

***Pressure Decay Testing***
Pressure decay testing measures the change in pressure between atmospheric pressure and your pressurized test sample.

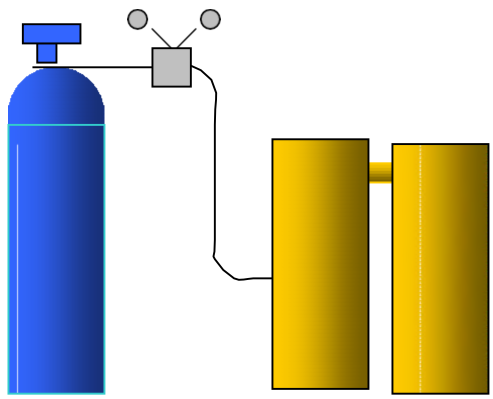
Unlike the bubble test, this test method yields quantitative information, hard data points that can be recorded and upon which decisions can be made. This removes the dependency upon the operator and allows specific accept/reject criteria to be set, and this method is quite simple to use. It is reasonably 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 variation uses a differential transducer for pressure on both sides of the membrane, which might give more sensitivity in some cases but adds more complication (differential pressure testing requires a reference volume, and is temperature dependent on both volumes; it is difficult or impossible to "standardize"). Pressure decay may include vacuum testing since a "vacuum" is merely a pressure below atmosphere. We will return to Pressure Decay Testing frequently during this course.




Pressure Decay Testing

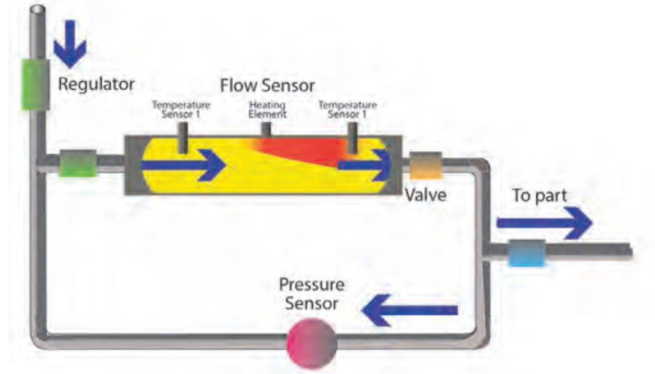
***Trace Gas Sensing***
There are several types of trace gas sensing systems on the market today. This diagram illustrates a simplified trace gas leak detector. The closed test part is pressurized with a tracer gas, and the sensor is moved around the part to determine if and where there is a detectable leakage of the tracer gas. A constant flow pump allows measurement



Trace Gas Sensing

of varying concentrations of gas. Of course, using this detector as a leak locater is easy, but using it as a quantitative leak detector requires skill! This instrument is also available for hazardous gases and work areas (intrinsically safe).

This method gives quantitative measurements so standards can be precisely described. It is straightforward and reasonably easy to use, and the cost is low. However, because it is dependent on sensing a gas other than air, gas sensing is not useful for sealed packages that cannot be pressurized with a trace gas.

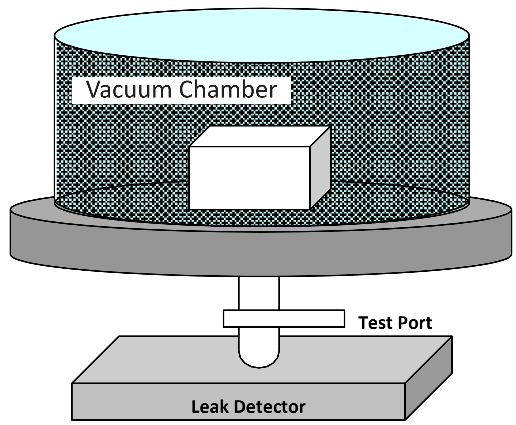


Mass Flow Sensing

***Mass Flow Sensing***

The Mass Flow test method uses a small sensor that heats air and then measures the change in temperature with regard to mass flow. Since mass flow is a function of the density of air, care must be taken to check that the calibration is for sea level pressure, otherwise small differences may occur from place to place.

The mass flow detector is less sensitive to temperature changes than pressure decay. Mass flow meters vary in their response time depending on the level of leak rate; low rates can be longer especially if maximum values are exceeded.



Mass Spectrometry

***Mass Spectrometry***

Mass Spectrometry is the most sensitive of all test methods, being capable of detecting 10-11 sccs using helium.

The helium-pressurized test part is placed in a chamber which is evacuated to a vacuum of 10-5 millibars, and any helium leakage is drawn into the mass spectrometer tube. The advantages to mass spectrometry include a very high level of sensitivity and a high degree of quantitative accuracy.

However, mass spectrometry is extremely expensive, with equipment costs in the range of $25,000 - $100,000. The method is slow, and the cost to run and maintain the equipment is significant.

***Types of leak tests - Advantages and Disadvantages.***

Chart 1 is a brief summary of several commonly used test methods, including advantages, disadvantages and the relative price of “No Leaks”.

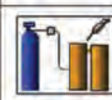
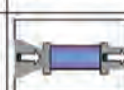
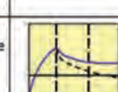
| | | Advantages | Disadvantages | Approximate Sensitivity | Relative Cost |
|---|---|---|---|---|---|
| Bubble Testing |  | Simple Inexpensive | Operator dependent non-quantitative | $10^{-2}$ to $10^{-3}$ sccs | $100 - $1,000 |
| Trace Gas Sensing |  | Low cost, Best as leak locator | Not usable for sealed packages | $10^{-4}$ to $10^{-5}$ sccs (helium) | $3,000 - $10,000 |
| Mass Flow Sensing |  | Fast response Quantitative | Ambient air pressure sensitive | $10^{-2}$ to $10^{-3}$ sccs | $4,000- $10,000 |
| Pressure Decay Testing |  | Quantitative 2 - 4 sec. tests | Sensitivity is dependant on part size and test time | $10^{-4}$ to $10^{-6}$ sccs | $5,000 - $12,000 |
| Mass Spectro-metry |  | Extremely sensitive | Slow, high cost to run and maintain | $10^{-9}$ to $10^{-11}$ sccs | $25,000 - $100,000 |

Chart 1. A comparison of test methods

## *Quiz*

Test your understanding of the previous pages.

Q.1. Everything leaks:
- □ True
- □ False

Q.2. A leak is defined when the contents of the package may escape but the definition does not include materials entering:
- □ True
- □ False

Q.3. Permeation is defined as penetration of a permeate (such as liquid, gas or vapor) through a solid.
- □ True
- □ False

Q.4. Material from a package can escape through:
- A. A large hole
- B. A pin hole
- C. A channel in a seal
- D. By permeation
- E. All of the above

Q.5. Leak rate is determined by:
- A. The size of the hole
- B. The size of the channel
- C. The volume of material that escapes from containment in a predetermined time

Q.6. A change of pressure cannot be used to determine a leak:
- □ True
- □ False

Q.7. To obtain a consistent measure of leak rate, the temperature must always be:
- A. 100º F
- B. 0º C
- C. Constant
- D. Ambient

Q, 8. Stabilization (settle time) is required by products that are:
- A. Flexible
- B. Inflexible

Q,9. Leak rate through a hole can be affected by which variables?
- A. Temperature
- B. Diameter of the hole
- C. Pressure differential across the hole
- D. All of the above

Q,10. Bubble Testing:
- A. Is the most expensive method
- B. Highly sensitive
- C. Requires a trained observer
- D. Is very fast

Q, 11. Pressure Decay testing:
- A. Provides quantitative information
- B. Is operator dependent
- C. Measures the change in atmosphere
- D. Is very slow

Q, 12. Trace Gas Sensing:
- A. Best used on sealed packages
- B. Works using ambient air
- C. Makes finding leaks easy
- D. Is very expensive

Q,13. Mass Flow Sensing:
- A. Can only be used calibrated to sea level
- B. Is very sensitive to temperature changes
- C. Cools the air
- D. Tests over a fixed time

Q, 14. Mass Spectrometry
- A. Is cheap to maintain
- B. Has the highest sensitivity
- C. Is very fast
- D. Has the lowest capital cost

Q,15. Testing for leak and flow is important because:
- A. A seal weakness may lead to loss of sterility.
- B. Leaks can lead to product failure
- C. Product failure can lead to lose of reputation
- D. Faulty flow can lead to product failure
- E. All of the above

**Answers:**

**Q1. True. Everything leaks. Q2. False. Leaks include material entering or leaving. Q3. True. Q4. E. Hope you got this one right. Q5. C. Leak rate is measured over a given time.**
**Q6. False. Pressure decay testing is an approved method.**
**Q7. C. Changes in temperature impact leak rates. Q.8. A. Flexible products volumes can change with pressurization.**
**Q9, D. All of the above impact leak rate. Q10, C. The operator needs to observe and take notes. Q11, A. The instrument will provide hard date points. Q12, C. Using trace gas sensing for leak detection is easy. Q13, A. Mass flow is a function of the density of air, so the instrument needs to calibrate to sea level. Q14, B. This is the most sensitive of all test methods.**
**Q15. E. All of the above.**

# *Pressure or Vacuum Decay Leak Testing*

***Pressure Decay Leak Test Cycles***
What is happening during a leak test? The leak test cycle is actually broken down into three distinct phases, not counting the load and unload phases. Figure 1 illustrates the relationship between these phases.

***Load and Unload*** are the times it takes to engage and disengage your part or package from the pressurizing and pressure decay measuring instrument. Although not technically part of the actual test cycle time, these periods must be taken into account in order to realistically project the time needed to test individual items.

***Charge*** is the period of time in which the part is being pressurized to the predetermined test pressure (or slightly above this pressure, so any stability changes can be taken into account).

***Settle*** is the period allowed for the volume of the pressurized part or package to change and stabilize due to the stresses introduced by pressurization. This is particularly crucial in the case of flexible materials whose volume may change substantially with pressurization. If this is an issue for your product, you will want to review the discussion on restraining plate fixtures in a later unit of this course.

The Settle period also allows time for the adiabatic temperature rise (the heat generated through compression of a gas) to stabilize.

***Test*** is the data taking period in which the measurement of the decay of pressure is taken.

***Acceptable and Unacceptable Leaks***

***Decay*** is a term used for the difference in pressure from its initial state of complete pressurization to the pressure at the end of the "test" phase of the leak test cycle previously discussed. Figure 2 shows examples of "acceptable" and "leak failure" decay.

Once pressurized and stabilized, the test instrument will measure the decay of the pressure inside the test part or package over a predetermined period of time. As we have already learned, everything leaks; there will be some amount of apparent background leakage, even if only molecules permeating a rigid container. This pressure decay becomes more significant as the test time increases. This decay may be related to the physical or mechanical properties of the product as well. This tendency is an important consideration when setting the Leak Limit.

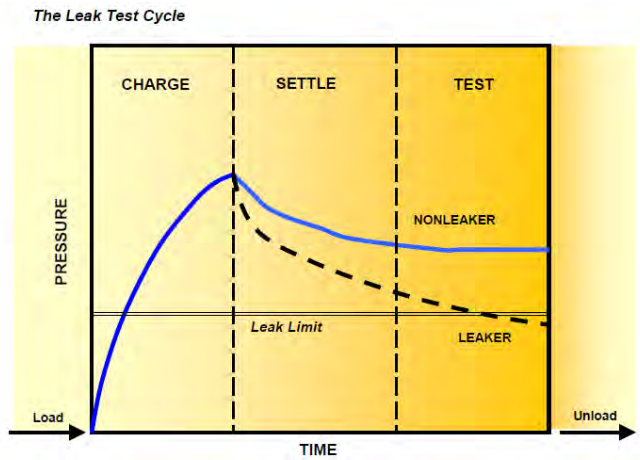


Figure 1. Leak Test Cycle

If the part or package you are testing possesses a gross leak, as for example an unsealed joint, that prohibits complete pressurization, the test may not complete the Charge phase of the test cycle, and the test may be terminated at this point.

If the part being tested can be completely pressurized but the decay of the internal pressure is greater than the expected background decay for that part, it may indicate an unacceptable level of leakage. This is a fine leak. The selection of an appropriate Leak Limit for the product being tested will differentiate between "normal" background pressure decay and an unacceptable fine leak in the test item.

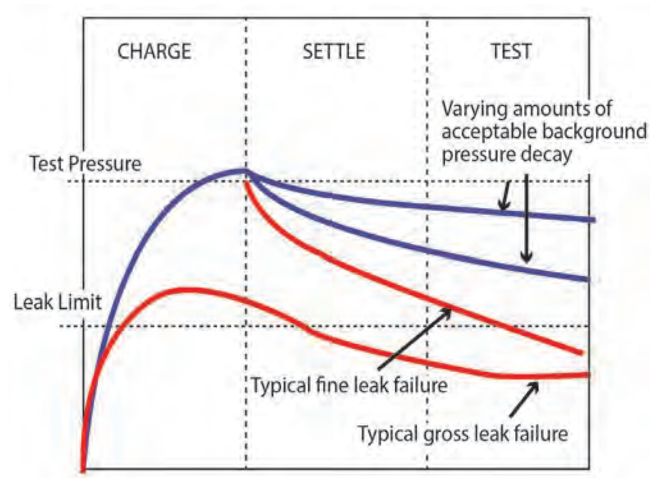


Figure 2. Examples of typical decay

## *Pressure Decay Testing: Choosing a leak rate*

### *Setting the Leak Limit*

The Leak Limit is set based on your need for sensitivity in detecting a pressure decay in your part or package that exceeds what has been determined to be "normal", acceptable leakage. You want to convert your pressure decay (ΔP) to leak rate. The guiding equation is:

**Q (sccs) = ΔP (atm) * V (cc) / Δt (sec)**

…where Q, leak rate, is expressed in standard cubic centimeters per second;
…where t is the test time in seconds;

The longer the test time, the smaller the leak rate you will be able to identify. Remember, we agreed that everything leaks; it's only a matter of time!

When considering the test cycle for production times, don't forget to include all phases of the test cycle (Load, Charge, Settle, Test and Unload) – see the unit on Pressure Decay Test Cycles for more information.
…and V is the internal volume of the pressurized system.

### *Pressure Decay Sensitivity*

Pressure decay sensitivity is also a volume function. When selecting your spec, remember to include all the volume in your test system – the instrument, the fixture and your part – in your calculations.

### *Instrument and Environmental Conditions*

To maximize the sensitivity of your test, it is also important to consider the stability of your instrument and its environmental conditions such as ambient temperature and temperature changes. However, most test cycles are short in seconds and temperature change may be negligible.

***EXAMPLE***.

You have performed a pressure decay test on your part and found the pressure decay (ΔP) to be 0.004 psi (.1 in $H_2O$). This translates to $2.5 \times 10^{-4}$ atm. Your part, plus the internal pressurized volume of the instrument and the fixture, has a volume of 100cc. Your test time was 10 seconds. Using our formula above, we calculate:

**Leak Rate = 2.5 x 10-4 atm * 100cc / 10 sec = 2.5 x 10-3 atm-cc/sec**

This is the leak rate for your part. Is it acceptable or a reject? That is a decision you must make as you set your Leak Limit.

If this is your Leak Limit, then it is the maximum acceptable leak rate for your part and your Pressure Decay Test should reject any parts with a greater pressure decay at this test time.

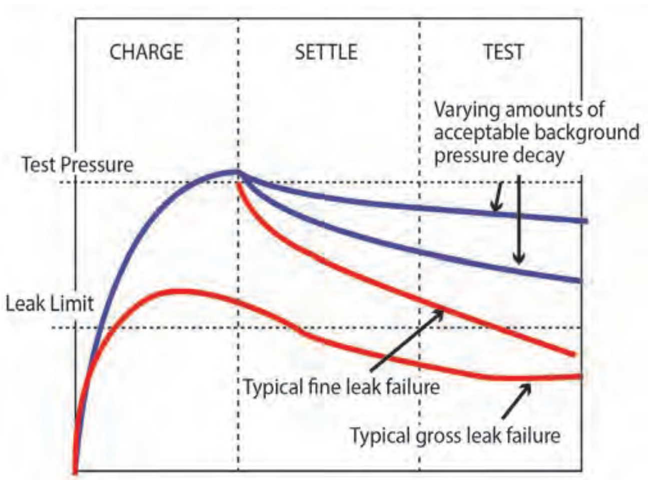



Figure 2 (Repeated). Examples of typical decay

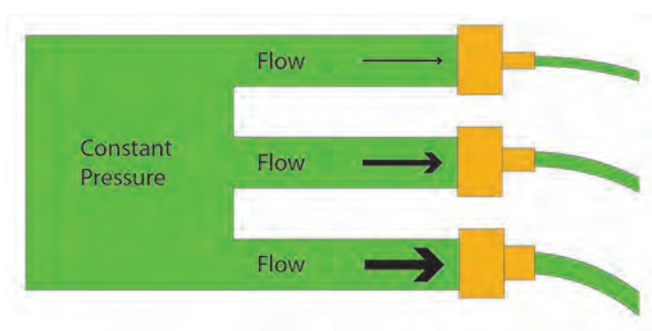



Figure 3. Graphic showing impact of orifice size on flow when arriving pressure is constant from an unlimited source

## *Mass Flow Testing and Flow Testing for Occlusions/Obstructions*

***Mass Flow Testing for Leakage***
Mass flow testing uses intrinsic properties of air to directly measure the amount of air escaping a closed system. A pressure regulator establishes the testing pressure, and then the sensor records any movement of air out of the test system. Mass flows are not affected by temperature changes due to pressurization. Mass flow sensors have limited low range sensitivity, generally usable at greater than one sccm (.02 sccs).

***Appropriate Criteria***
We have seen that either pressure decay or mass flow testing can be used for leak testing. What are the criteria for deciding which is appropriate for your particular need? Depending on the size of the leak you are searching for (and the volume of your product), mass flow leak testing can have several advantages, including speed of test. The mass flow test is not dependent on temperature change, which may be a difficulty for the pressure decay test.

## *Flow Testing for Obstructions/Occlusions*

***Mass flow testing***
Mass flow testing is available for identifying obstructions in an open-ended test part. Unlike mass flow testing for leakage, mass flow testing for obstructions uses a continual flow measure the blockage in an open-ended device, such as a medical catheter or refrigeration tubing.

***Pass or Fail***
Once the pressure sensor has indicated that the test part has reached the proper pressure, the flow sensor measures the continuous flow of air through the sensor assembly. Determination of whether the part passes or fails the test is made based on the flow rate through the part. If the flow sensor measures too low a flow rate at the desired pressure, the part will fail the test.

Any obstructions in the part, therefore, will restrict the flow of air through the device, thereby causing the part to fail the test.

***Back Pressure Occlusion Testing***
When a tube or device is pressurized with air, a flow will be established depending on the input pressure. If the flow path is obstructed, more pressure will be required to force flow through the product. Back pressure occlusion testing measures the input pressure to the device.

***Higher Pressure Indicates Blockage***
A blockage creates a higher pressure at the device. The instrument measures the input pressure, and limits on the pressure measurement are set in the instrument based on experience with the obstructed part. A higher pressure indicates a blockage.

***Pressure Drop Occlusion Testing***
A device will often need to vent its pressure in a given period of time for proper function.

Alternatively, a part may have a manufacturing defect that creates a flap or one-way obstruction that prevents air from venting the part. Pressure drop occlusion testing pressurizes the part, and then measures the change in pressure when the pressure is removed.

***Lack of Pressure Drop Indicates a Blockage***
The pressure must approach a value or zero in a fixed time. If the pressure does not drop a minimum amount, then the limit set in the instrument will not be met, thus indicating a blockage.

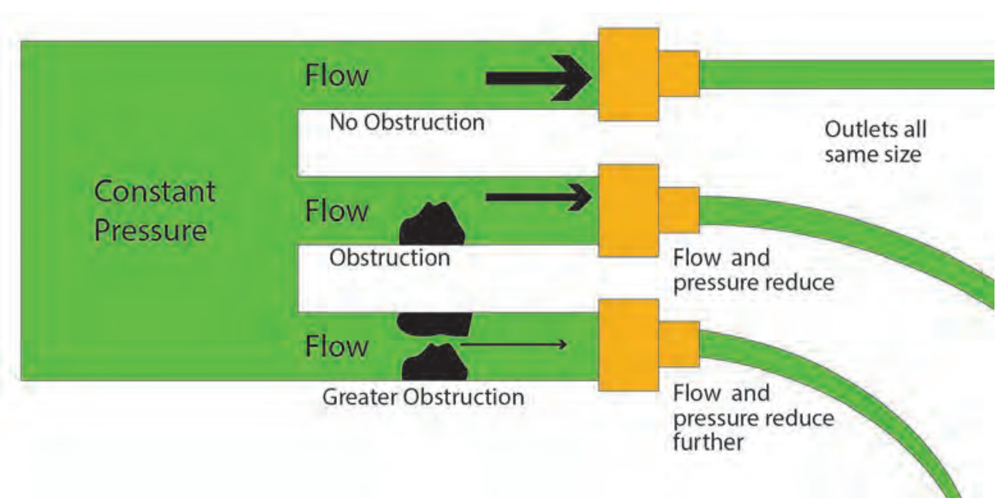



Figure 4. Graphic showing impact of an obstruction on flow and pressure when arriving pressure is constant from an unlimited source

## *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.

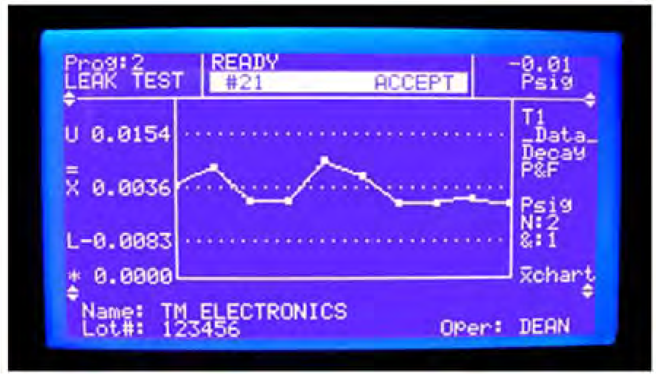


Figure 3. Control charts for leak results showing a process in control

***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 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.

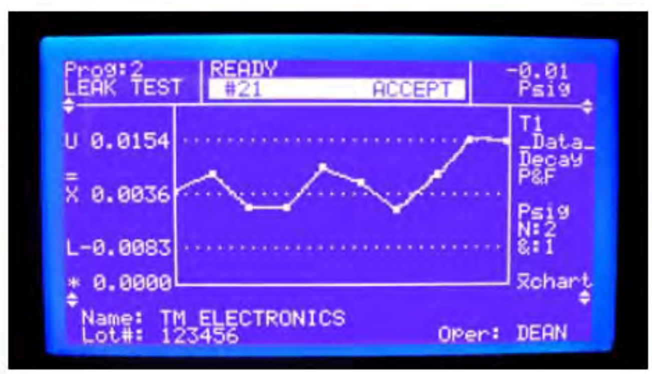


Figure 4. Control charts for process going out of control

## *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 11 -14.

Q.1. The three phases of a pressure decay or vacuum decay test are:
- A. Test, Charge, Settle
- B. Charge, Settle, Test
- C. Settle, Change, Test

Q.2. In order to predict the total time for an individual test you need to include the time to:
- A. Make coffee
- B. Connect the test instrument to power
- C. Connect and disconnect the product to the instrument

Q.3. Charge is defined as:
- A. The cost of doing the test
- B. The time for adiabatic temperature to cool
- C. The time when the part is being pressurized

Q.4. Settle is when:
- A. The instrument is actually testing
- B. An agreement on the test cost
- C. Adiabatic temps rise
- D. The pressurized part is stabilized

Q.5. When deciding if a pressure or vacuum decay leak test is acceptable you need to know:
- A. Only that the part has failed the test
- B. Decay may be related to the physical properties of the product
- C. What is considered acceptable back ground decay for your product
- D. B and C

Q.6. The term “decay” in testing means the difference in pressure from its initial state of complete pressurization to the press at the end of the “test” phase.
- □ True
- □ False

Q.7. When selecting your sensitivity spec you need to include all the volume in your test system, the instrument, fixture and part in your calculations.
- □ True
- □ False

Q, 8. The reason to conduct a pressure or vacuum test is to:
- A. Know the decay
- B. Eliminate failed parts or packages
- C. Determine the volume of the part

Q,9. Mass flow testing for leakage:
- A. Uses intrinsic properties of air to directly measure the amount of air escaping a closed system
- B. Does not require a regulator
- C. Has unlimited low range sensitivity

Q,10. Flow testing for obstructions:
- A. Can only be done on a close part
- B. Uses intermediate flows
- C. Uses continual flow

Q, 11. Back pressure occlusion testing:
- A. Measures the input pressure
- B. Is operator dependent
- C. Is indicated by a drop in pressure

Q, 12. Pressure drop occlusion testing
- A. Has no time limit
- B. Works using ambient air
- C. Measure the change in pressure when the pressure is removed
- D. Is very expensive

Q,13. The objective of control charts is to monitor the process in real time
- □ True
- □ False

**Answers:**

**Q1. B. Charge, settle, test. Q2. C. You are measuring total time to test. Q3. C. The time the when the part is being pressurized. Q4. D. It's when the pressurized part is stabilized. Critical with flexible parts or packages. Q5. D B and C. Q6. True. Q7. True. Q.8. B. Do you really want to ship defective parts? Q9, A. Q10, C. It's flow testing, it needs continuous flow. Q11, A. Back pressure is indicated by an increase in input pressure. Q12, C. Makes sense. Q13, True. The quicker you know something is going wrong the faster you can fix it.**

## 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.

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