# Choosing the Ideal Integrity Test

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Introduction

Determining which medical package testing method to use involves a variety of independent considerations and decisions. To begin, it is important to understand the importance of medical device package testing. Making the right decision can benefit a company's manufacturing practices and quality of the products to its end users. After the importance is understood, there are several factors that must be considered when choosing the ideal integrity test, including:

- Material properties, such as whether they are a porous or non-porous
- Allocated testing budgets
- Appropriateness of a destructive or non-destructive test
- Desired level of accuracy
- Integration of testing into current packaging process
- Obtaining Food and Drug Administration (FDA) approval by following standards

**Importance of Medical Package Testing**

The U.S. has seen a recent spike in medical packaging growth. Demand is expected to climb 5.4 percent by 2005. The growth is a result of stricter infection control standards, an aging population that is requiring more medical services, and more convenient and flexible package designs (Sterile Packaging, 2001). With an increase in the number of medical products being packaged, companies are looking for ways to improve their processes, while at the same time maintaining costs and meeting the growing demand. This growth stresses the importance for companies to develop quality-manufacturing practices. These practices can help the company guarantee the integrity of their packages.

Package integrity is the "unimpaired physical condition of a final package" (Franks, 2002). Basically, it means that a package meets the required minimum physical properties and specified seal strength. Package integrity guarantees that a package's sterility is maintained. It is a measure of its sterile barrier (Franks, 2002).

Package leakage is also a measure of integrity. Any defect presents possible loss of product sterility, therefore these test methods are designed to detect material or process failures (Franks, 2002).

Package testing is essential in medical device manufacturing. If a package fails, the sterility of the product is at risk (Beagly, 1998). The two main reasons for testing are: to ensure integrity of a sealed package and to ensure no defects developed during sterilization, product handling, transportation, and/or storage. Testing can be done to find leakage resulting from large holes, pinholes, cracks in the materials, and/or failed seals (Franks, 2002). It also provides

insight into how the package/product will perform in real life situations. Testing of package integrity is also done to provide information on how effective a company's manufacturing processes are performing. When medical device manufacturers designate a product for use in the medical field, they must assure the user that the package has been examined and has passed testing standards set by the FDA (Franks, 1999).

Beyond understanding the importance of medical packaging, a packaging company must take various factors into consideration when choosing an appropriate test method.

**Package Compatibility**

Manufacturers, based on compatibility with the product, choose their own test methods. Medical packagers can use either non-porous materials, such as films, coextrusions or laminates (including foils). They can also use porous materials, such as Tyvek® or paper for part of the package barrier wall. Porous materials are predominant in the industry, due to extensive use of ethylene oxide (ETO) sterilization methods. The nature of porous materials may limit the amount of test methods and equipment. (Franks, 2002).

Using non-porous materials allows a packaging company to choose from many leak detection test methods. Leak testing would not be appropriate for a company that uses porous packaging materials, because by nature, porous materials leak. Although there are systems that can test for leaks in a porous package, they are generally too expensive for the average medical packaging company to afford. The most common test method for porous packages is visual inspection, which relies completely on the thoroughness of an individual. This, in turn, is not very reliable. Dye penetration, another example, involves injecting dye into the package. The inspector then observes to see if any dye leaks through the seal. This is generally a good choice for packagers that use porous materials because it is effective, inexpensive and fairly easy. However, it is also very messy and destructive to the product (Leventon, 2001).

For packaging companies that use both porous and non-porous materials, there are applicable tests for both types of packages. These methods are burst, creep, creep-to-failure, vacuum jar bubble and trace gas testing. Each method requires specific techniques and trained expertise to be performed properly (Variables, 2003).

**Cost Considerations**

Cost is one of the most important factors when choosing the ideal test. Purchasing and laboring expenses need to be considered. The price of equipment can range dramatically, depending on the test method and automation of the process. In general, more automated processes may result in lower operator costs. However, the highly automated systems may be even more expensive. Not only because they are more complex, because they may require more upfront costs in order to understand the equipment and train new operators.

The bubble tank method is one of the least expensive methods to purchase and set up. But it can result in high costs when the need for supplementary

equipment and extensive technician time are factored in. Examples of supplementary equipment are drying and conveying systems (Leak Detection, 2003).

The cost of pressure decay systems can range dramatically because the systems can be purchased at varying levels of automation. The highest of automated systems interface with process control computers and can cost as much as $100,000. Pressure decay systems also require supplementary equipment, such as special chambers or jig constructions that create a sealed environment (Leak Detection, 2003).

Trace gas leak detectors require the packaging company to construct positive pressure environments and exhaust systems. But unlike the two previously mentioned tests, the largest expense of this test comes from the gas itself. Choosing the right gas to use, such as helium, can reduce the cost. Helium is one of the least expensive gases and is also self-exhausting. Another cost reduction method includes purchasing a system that includes a gas recovery system. This system can usually recover up to 60 percent of the gas used (Leak Detection, 2003).

On the high end, mass spectrometers are the most costly test system to purchase. They require a vacuum environment, including vacuum pumps. These pumps add to the upfront costs and also increase the time necessary to complete each test (Leak Detection, 2003). Below, Figure 1 compares the cost of these tests with other common test systems.

*Figure 1: Cost of the Various Test Systems*

| Detector Type | Equipment Price Range | Operating Cost Perameters |
|---|---|---|
| Bubble Test | $1,500 - $50,000 | Operator, heat for water, heat to dry components |
| Helium Mass Spectrometer | $20,000 - $150,000 | Electrical power, helium gas, vacuum source |
| Pressure Decay | $5,000 - $20,000 | Factory compressed air systems, electrical power |
| Dynamic Flow | $3,000 - $15,000 | Operator, factory compressed air systems, electrical power |
| Electron Capture | $8,000 - $12,000 | Operator, argon ($1/day), trace gas 1-10% with dry air |
| Thermal Conductivity | $1,000 - $2,000 | Operator, trace gas (depends on application) |
| Acoustic | $1,000 - $4,000 | Operator |
| Hand Probe Mass | $10,000 - $20,000 | Electrical power spectrometer, helium gas, operator |

Overall, the costs related to package leak detection testing are incurred upfront. These costs include purchasing systems, set-up, and throughout time, the cost of operating and performing the test. Set-up expenses can include constructing supplemental systems, training the work force, and purchasing any additional test operating parameters.

**Destructive v. Non-Destructive**

When choosing a test method, another issue is deciding whether a destructive or non-destructive test is appropriate for the process and package/product. Cost is an important factor when making this choice. A non-destructive test is performed without harm to the product. A destructive test, on the other hand, is conducted in a manner that destroys the product, in order to prove package integrity. Cost becomes a major factor if the product contained in the package is expensive. Every package tested results in product loss. Using a non-destructive test method results in minimal product loss for the company. For example, the pressure decay test method is non-destructive to the product. However, it uses a port to inflate the package until it reaches an established pressure. This test measures the amount of pressure loss over time. Even though this test method is non-destructive to the product, using this port to inflate the package renders the package unusable after the test is complete. In other non-destructive test methods, such as the vacuum decay test method, the package is not harmed during testing. The package is placed in a vacuum chamber. There, the package is subjected to the vacuum and the pressure change is measured over time to indicate any leaks. The advantage to this test is it allows the packager to test 100 percent of their packages without any product loss (Allen, 2002).

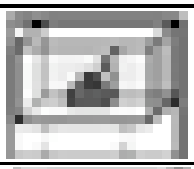
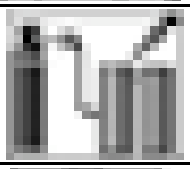
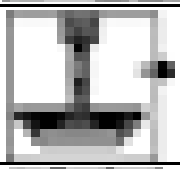
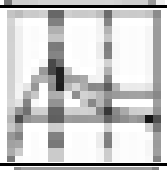
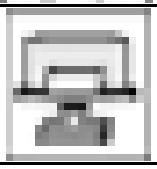
Although choosing a non-destructive test has many advantages, choosing a destructive test with a lower start-up cost may be more appropriate. When the company is packaging a relatively inexpensive product, destructive testing would not result in a large profit loss over time.

**Accuracy**

Another key factor to consider is the sensitivity of each test. Currently, there is no industry standard for testing sensitivity. It is up to manufacturers to consider their objective and determine which test is appropriate. Many companies assume that choosing the test that detects the smallest hole is the best decision. But in medical packaging, there has been no correlation found between the size of the defect and contamination when microbes are present. Choosing the test that detects the smallest hole is often more expensive and not necessary (Leventon, 2001). Choosing a test that is ultra-sensitive could, in effect, render a process incapable of producing packaged items that meet specification limits. Basically, according to ISO 11607 (Standard for Packaging Terminally Sterilized Medical Devices), manufacturers should show that their package will still be sterile after it has been through its normal process handling and aging cycle. Figure 2 compares the sensitivities of various common tests.

It is important to examine other considerations before choosing a test with a certain level of accuracy. As stated earlier, test sensitivities are important in making a choice on which test to use, but striving to use a test that finds that smallest possible holes may not be necessary or economical.

*Figure 2: Test Sensitivities*

| Detector Type | | Sensitivities |
|---|---|---|
| Bubble Test |  | 10^2 to 10^3 sccs with vacuum |
| Trace Gas Sensing |  | 10^4 to 10^5 sccs (helium) |
| Force Decay Test |  | 10^1 to 10^3 sccs |
| Pressure/Vacuum Decay Testing |  | 10^4 to 10^6 sccs |
| Mass Spectrometry |  | 10^9 to 10^11 sccs (helium) |

**Inline v. Offline**

When and where testing will occur are also factors to consider when choosing an appropriate testing method. If a company desires to test their packages inline during the packaging process, there are many logistical factors to consider. For example, how the newly purchased testing system will be integrated with existing equipment (In-line Versus, 2002). Many machines, such as the system for helium mass spectrometer, are very large and would require major changes in order to be integrated into a current packaging line. Some manufacturers are offering customized systems to make integration easier and less costly (Allen, 2002). A major advantage of this method is that it allows for 100 percent inspection without adding excessive time and labor to the existing

process. According to Steven Franks of T.M. Electronics, "One hundred percent inline testing is the ideal. It would be the most effective use of a non-destructive test. It would provide maximum use of technology, prevent waste, and provide lower costs by not requiring the use of large amounts of labor" (Allen, 2002). If inline testing is not an option, offline testing should occur. Space considerations will still need to be made and the process for moving the packages offline to the testing areas will need to be established.

**Supported by Standards**

When a medical device manufacturer designates a product for use, the end user must be assured that the product/package has been examined and has passed testing standards set by the FDA. Manufacturers must also follow guidelines set by either the International Standards Organization (ISO) or the American Society for Testing and Materials (ASTM) (Franks, 1999). ISO 11607 is an international standard that provides guidelines for designing, manufacturing and testing a package. ISO 11607 also provides a listing of supporting documentation necessary to validate the package design and its ability to meet standard specifications. Both the FDA and international regulatory bodies are increasingly requiring compliance with ISO 11607 (Regulatory Requirements, 2003). ISO 11607 includes a list of package tests in its appendix. The list gives a manufacturer a variety of choices when choosing a testing method.

When deciding on a test method, considering one that is supported by ISO and/or ASTM standards may be helpful. This allows the manufacturer to follow procedures that are consistent with other companies conducting the same test; it eases the validation process and helps gain FDA approval. FDA approval helps gain customer confidence, due to the standard's guarantee that a terminally sterilized package will maintain its designed performance over the intended life of the product and will not fail during transport or storage (Some Fundamentals, 2002).

**Conclusion**

In conclusion, medical device package testing has been discussed in many aspects. All these factors contribute to a manufacturer choosing the ideal integrity test. In the medical industry, it is important to maintain a high level of assurance that the integrity of the medical package may not be compromised. This integrity gives both the manufacturer and purchasers confidence that the sterility of the product will be maintained. Incorporating good manufacturing practices and utilizing the proper test methods can achieve this confidence. A medical device packager will benefit greatly from making the right choice, not only in the eyes of its customers, but to the end users as well.

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