Leak Testing Considerations for Medical Devices

Automatic leak detection is now a common occurrence and part of the quality control process for many companies. There is a wide choice of equipment available and techniques from which to choose. With such a choice one may think that the selection becomes something of a formality and the solution a commodity. In some cases that may be so, but it is most certainly not the truth when it comes to testing medical devices.

The medical device testing market probably has more challenges than any other field, and there are special considerations that make leak testing in this field so challenging.

Successful leak testing depends in all cases upon careful consideration and evaluation of the potential application. Here are some of the factors that must be considered:

**Part Volume**
Medical devices vary from the extremely small and rigid to large (greater than two liters), and very flexible and soft. The tester must be flexible enough to have a test volume that will remain sensitive for testing while keeping the restriction of the filling circuit low to handle larger parts.

**Part Geometry**
Frequently, medical devices have very unusual geometry; one often encounters tubes, valves, stopcocks, transducers, enclosures and components within components. This not only makes the test itself challenging, but emphasizes the critical nature of fixturing and control.

**Part Material**
Polymers and plastics can behave in strange ways. Elasticity can make repeatable testing very difficult wherein some parts continue to expand after reaching the desired test pressure, taking a long time to stabilize. Sometimes this effect is referred to as “compliance.” One of the ways to minimize the effect of elasticity is fixturing or part control to minimize part movement. However, caution should be exercised in the design of such fixtures because the parts can seal themselves either through inherent elasticity or under pressure against the fixture. For this reason fixtures often have a porous surface or are textured in such a way that air may escape from the product into what is a small cavity or cavities built into the fixture.
**Leak Rate**

Medical devices have a critical role in patient safety and comfort. Cross contamination, air or gas ingress/egress almost certainly must be avoided to minimize infection or improper medication. In personal long-term care products, leakage is detrimental to patient comfort. For this reason, accurate determination and measurement of leaks is vital and the specifications for medical devices, while varying tremendously from one device to another, are amongst the tightest specifications leak test experts deal with.

**Environment**

Clean room manufacturing and testing means that the leak tester and fixturing must comply with clean room conditions. Leak testers must not release contaminates into the part or clean room environment. Components inside should be of non-corrosive material. Fittings that require sealant should not have any off-gassing into either part or room.

**Cycle Time**

High-volume production is commonly found amongst manufacturers of medical devices. This has a significant effect on the type and quantity of test equipment required. Reliability and repeatability must never be sacrificed for speed. The laws of physics upon which leak testing is based are inflexible. These factors are at odds with one another and may be countered by deployment of multiple testers or the use of multi-channel test equipment.

**Complexity of Testing Requirements**

Quite often a medical device will require more than one type of test, sometimes several. This will naturally increase the cycle time and reduce throughput. To some extent, modern leak test equipment can mitigate the effect by combining more than one technique in a single tester and utilizing sequential or step programming. For example, a check valve would require testing from both directions to test opening and closed seat, as well as flow, at design specification. This would require three discrete tests and each one could be programmed to abort the test sequence on failure, if desired.

**Use of the Tester**

Much medical device leak testing is labor intensive. The devices often do not lend themselves to fully automated part delivery, handling, testing and sorting. For this reason, the design of the tester should be such that it is easy to use so that operator fatigue is minimized, and the results should be non-subjective and clearly displayed to minimize the occurrence of false rejection or acceptance. Many parts have the requirement of only undergoing one test maximum, so the part needs to be handled correctly the first time and the tester must produce an accurate result such that undue scrap is not created. Parts that include materials with no elastic memory might only test satisfactorily once. Furthermore, the nature of the test may require a destructive test, as is the case with burst testing.

**Tester Features**

Increasingly, customers are looking for advanced tester features such as data handling, network communication, and security protection for programs, while increased speed and resolution are always sought after. To improve cycle time and throughput, independently started test channels can help. One leak tester can then be shared by several operators, each of whom may start their own test or sequence independently.

For more information contact:
Uson L.P.
Phone: 281 671 2000
Email: info@uson.com