Leak Testing for
Medical and Diagnostic Equipment Explained

Two areas of medical device manufacture require leak detection for quality assurance: product testing and packaging testing. Product testing includes verifying the function of devices, flow paths, valves and assembly integrity. Pack testing is about ensuring the sterility of the devices, or other protective requirements such as low humidity, during their shelf lives. The test methods in common use are pressure decay and trace gas.

Pressure Decay

Method

Pressure decay testing can be conducted through positive internal pressurisation or negative (vacuum) external pressurisation. In positive pressure testing the product is pressurised via an access port and the pressure changes monitored. Similarly, for vacuum decay testing the pressure outside the product is reduced (inside a test chamber) and any leak from the pack or product monitored as a leak into the vacuum. Typically, pressure changes are monitored electronically. There is however one case in the medical industry where water immersion is used for leak detection, the 'blue dye test' for pharmaceutical blisters.

Vacuum immersion Test for Tablet Blister

Electronic Pressure Monitoring

Because the detection method is (normally) entirely electronic, pressure decay testing lends itself well to automated production systems. There is some restriction on this as cycle times can be 10 or 15 seconds, but multiple test stations may provide a solution to this.

In addition to leak testing MET testers decay can be used as a simple flow test. The most common use of this is following an integrity test. Once the leak test cycle is complete a valve is opened in the tooling which allows the pressure to escape through a specific route. Pressure loss confirms patency of the fluid path (occlusion test). The pressure transducer can be replaced by a mass flow transducer for more sophisticated flow tests and occlusion tests.

Suitable Applications for Pressure Decay

- Simple integrity tests for rigid components and vials
- Integrity tests for small flexible components
- Integrity and patency tests on multi-lumen or multi-flow-path products
- Investigating inter lumen or flow path cross talk
- Measuring valve opening and closing pressures
- Operation of stopcocks and flow controllers
- 100% and automated testing where cycle times are not too long
- Integrity testing of impermeable packs (large and small), non destructively

Advantages

- All electronic, no operator decision making required
- Simple to operate
- Can be programmed for a wide variety of tests and products
- Ideal for sequential tests such as multi-lumen catheters or inflation / deflation of balloons
- Equipment can often be adapted to conduct burst or creep and burst tests
- Simple calibration
- Data can usually be stored and analysed
- Compressed air is the only consumable

Drawbacks

- Large flexible components need restraint and have long cycles and large volume tests have lower sensitivity
- Viscous fluids (e.g. uncured adhesive) in the products mask leaks and may be drawn into vacuum tester
- Results are influenced by temperature changes in the components under test

Tracer Gas

Method


Trace Gas 'Soaking' Chamber

A variety of tracer gases are available, the ones most common being carbon dioxide (CO_2), hydrogen (H_2) and helium (He). The test method consists in loading the product with trace gas and then searching for leakage of that gas from the device or pack. Trace gas loading can be performed by low pressure flushing into a device or component. Alternatively, the finished test items can be 'soaked' in an atmosphere of trace gas prior to testing. Sub-assemblies can be sealed in an atmosphere enriched with the trace gas. Once the gas is loaded, specific detectors are used outside the test piece to 'sniff' for leakage.

The measurement techniques vary greatly according to which gas is utilised. CO_2 is detected by infrared absorbtion, H_2 by ion selective semiconductors and He by mass spectroscopy. Carbon dioxide is commonly used in the food industry. It has relatively higher natural abundance and is therefore less sensitive than the other methods, which are more suitable for sterile barrier testing. CO_2 is ideal when moisture ingress to a pack is of concern rather than microbial contamination. Both hydrogen and helium are excellent for testing medical devices and packs. They both allow testing with extreme sensitivity and dissipate rapidly to allow repeat or complex testing. The detection systems for He are somewhat more cumbersome and costly than those for H_2. Hydrogen also has the advantage of simplicity of use and accessibility with minimal training.


Hydrogen Trace Gas Analyser

Trace gas testing is not influenced by product volume or temperature. There are no toxicity or regularity concerns for the gases mentioned here, at the concentrations used.

Suitable Applications for Tracer Gas

- Simple integrity tests for rigid components
- Integrity tests for flexible components, including large volumes
- Integrity tests on multi-lumen or multi-flow-path products (extra flushing may be required)
- 100% testing and automated testing
- Testing of impermeable packs, non destructively
- Easily portable, in the case of hydrogen

Advantages

- Locates and quantifies leaks
- All electronic, no operator decision making required
- Simple to operate in cases of hydrogen and carbon dioxide
- Can usually be applied to a very wide variety of tests and products
- Data can usually be stored and analysed
- More sensitive (100 – 100,000X) than pressure and mass flow testing methods
- Ease of calibration

Drawbacks

- He detection is expensive (hydrogen detectors are in a similar price range to pressure detectors)
- 'Soaking' periods may exceed 24 hours for pre-sealed packs or product.
- Viscous fluids in the products mask leaks

Conclusion

Manufacturers have two practical alternatives for integrity testing of products and packs: tracer gas testing and pressure decay. Both are effective and easy to apply across a wide range of products.

The best sensitivity-to-cost ratio comes from hydrogen trace gas testing. This is also the method of choice for large packs and volumous products. Use helium when ultimate sensitivity is essential.

Pressure decay testing comes into its own when multiple tests are required on a single product, such as integrity and flow. Pressure testing also has the edge for testing finished packs when time is important.

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