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Application Note

Leak Testing for Medical Devices

Seven Key Leak Testing Considerations for Medical Devices

In the medical device industry, the pace of product innovation has created unique challenges and opportunities.

Manufacturers are beginning to understand the benefits of accessible and actionable data and analytics within their R&D and manufacturing processes, which allow them to introduce competitive advantages into an industry that is concerned with the cost of testing, the amount of time required to test, and risk abatement.

The medical device industry is facing pricing pressures, as insurers attempt to contain costs and hospitals operate with tighter budgets. This is leading medical device manufacturers toward a renewed focus on quality and value.

Regulations continue to be of highest importance. In order to ensure compliance with regulations, every part of a product requires unique design and testing criteria, and product performance requirements are becoming stricter. This means that test procedures are complex, and multifunctional testing and part integrity testing capabilities are required.

Automatic leak testing using the right instrument for the application provides solutions for many of these challenges within the medical device industry.

Automatic leak testers are essential parts of the quality control processes for many medical device manufacturers. Because there is a wide choice of equipment available and techniques from which to choose, it's important to understand the application, so the right method or combination of methods can be selected.

Because medical devices can directly impact lives, the industry faces more challenges than most. 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. This paper outlines seven of the factors that should be considered.

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#1 Cycle Time is Impacted by Multiple Variables

Most medical device manufacturers have high-volume production lines and want fast cycle times to ensure the most efficient manufacturing process. A shorter cycle time can negatively impact reliability and repeatability, which should never be sacrificed for speed. Cycle time is also impacted by many factors, including test part volume, geometry, materials, test pressure, leak rate, and environment. All of these factors can have a significant effect on the type and quantity of test equipment required.

Part Volume

Part volume can have a tremendous impact on the achievable cycle time, as well as on the sensitivity to detect the leakage at specified levels. The higher the part volume, the longer it might be necessary to stay connected to the part and measure for pressure changes. Higher part volumes also require a higher number of channels, or even a second tester. Because medical devices within the same manufacturing process can vary from extremely small and rigid to very large and elastic, it is important to select a tester that is flexible enough to accommodate different volumes accurately, without sacrificing sensitivity.

Part Geometry

It is not unusual for medical devices have unusual geometries. Examples of these include tubes, valves, stopcocks, transducers, enclosures, and components within components. This not only makes leak testing challenging, but emphasizes the critical nature of fixturing and control. The geometry of the part often determines how repeatable the parts are manufactured. For instance, if the part to part volume varies then the leak tester may start rejecting good parts because the internal volume is different from one part to the next. Also some leak test setups see differences in part performance depending on what cavity of a multi-cavity mold is being tested. Part geometry can also influence the parts capability to transfer heat due to the parts internal surface areas. Parts that transfer heat well will typically stabilize faster which then means a faster cycle time.

Part Material

Polymers and plastics can behave in strange ways. It can take a much longer time for pressure to stabilize when testing materials with elastic properties, as with products like balloons, IV bags, mixing bags, and anything with a bit of give. Elasticity can make repeatable testing very difficult, as some parts continue to expand after reaching the desired test pressure, which leads to a long time to stabilize. Sometimes this effect is referred to as “compliance.”

One of the ways to minimize the effect of elasticity is to minimize part movement through fixturing or part control. 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.

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Leak Rate

Accurate determination and measurement of leaks is vital for medical devices, which have a critical role in patient safety and comfort. Because of this, the medical device industry requires tighter leak test specifications than any other industry. Even so, the leak rate specifications medical devices can vary tremendously from one device to another. One of the biggest considerations is avoiding cross contamination (air or gas ingress/egress) to minimize the chance of infection or improper medication.

Some medical devices present greater challenges when it comes to testing for leaks. If a leak rate is extremely small, a part is highly elastic and flexible, and the volume is large, testing a leak to customer specifications can be complex. It's important to work with a leak test expert who has the facilities to lab-test the medical device product to actually hook it up to a tester to analyze the physics of the part to see how it reacts. This can ensure the right leak tester configuration for the specific application.

Test Pressure

Test pressure can have a significant impact on the performance of a leak tester, so it is very important that the pressure used within the test process is at the right levels for the intended application. Cycle time and sensitivity can both be impacted by the test pressure. When the pressure is higher, more adiabatic heat is generated, which means a leak tester will require more time to stabilize. High pressures may cause parts to flex, which is a situation that also requires a longer time to stabilize. Higher pressures require a larger range sensor, which can reduce sensitivity to the leak and lead to a longer period of measurement to get an accurate result. Higher pressures can also lead to increased leak rates in holes and can weaken welds or glue joints.

Environment

Most medical devices are manufactured in a clean-room environment, which means 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.

Many clean rooms have constant air flow and filters, which can impact the leak testers. Air flow means temperature change, and temperature change can impact the pressure change in relation to temperature. It is necessary to minimize rapid temperature changes, so pressure remains as constant as possible.

#2 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 a body test, along with 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.

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#3 Use of the Tester

Medical device leak testing can be labor intensive, with operators often responsible for manual part delivery, handling, testing, and sorting. It's important that testers are designed for maximum ease of use, with an intuitive user interface and simplified menu structure. The results should be non-subjective and clearly displayed to avoid the risk of false rejection or acceptance. Many parts can only undergo a single test, so the part needs to be handled correctly the first time. 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. It is important the tester produce an accurate result to avoid unnecessary waste.

#4 Tester Features

Increasingly, customers are looking for advanced tester features such as data handling, fieldbus communication protocols, network communication, onboard data, analytics, statistics, and security protection for programs, user authentications and individual passwords. Furthermore, increased speed and resolution continue to be a requirement. 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.

#5 Tester Flexibility

Because a leak tester may be used to test multiple medical device product lines, the tester should accommodate a wide range of multifunctional testing, including pressure, vacuum, flow, occlusion, burst, and crack, without sacrificing high performance, fast cycle times, and exceptional repeatability. Also, the ability to perform both part integrity and performance tests in a single instrument is helpful, because it simplifies maintenance and makes scaling operations easier.

#6 Regulatory Compliance

Within the medical device manufacturing industry, regulations have been becoming increasingly more stringent since the late 1990s, and that trend continues today. The cost of not complying with local regulations can be very high, including the loss of a certificate of compliance. Standards such as 21 CFR Part 11, MHRA/EU Annex 11, and others address electronic record keeping and signatures, including time stamps, user authorization, audit trails, historical tracking, work flows, and traceability. It's important to make sure that all new testing equipment is in compliance with these guidelines, as it is very expensive to upgrade non-compliant equipment to current standards.

#7 Global Support

Widespread consolidation of companies within the medical device industry has created challenges relating to the manufacture of products in multiple world areas. Leak testers must accommodate multiple languages, and be easy to use for a wide variety of skillsets. Leak tester manufactures must have the ability to duplicate testers so they can be installed in manufacturing facilities in multiple locations. Medical devices can be manufactured in remote facilities, making it hard to ship testers across borders, which translates into challenges with shipping testers back for calibration. Testers should incorporate self-diagnostics that monitor the health of the instrument and include built-in communications protocols to make remote monitoring and troubleshooting easy. Instruments should be designed to minimize tolerance errors and include the ability to change out ports – NPT or BSPP – for international flexibility.

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Conclusion

Choosing the right leak tester requires a solid understanding of the application and goals for the manufacturing process. Because quality can't be compromised with medical devices, it's important to select a leak tester manufacturer who is highly experienced in the medical device field, with years of documented successes in the industry and a commitment to meeting the highest standards for leak testing. The right leak tester should offer accuracy and reliability, without compromising cycle time. It should be able to connect with your existing manufacturing and IT systems seamlessly, while delivering improved process insights and advanced security features, to ensure your compliance requirements are met.

In addition to providing an excellent product, the right leak tester manufacturer should be able to provide top-notch aftermarket support. They should maintain a network of specialists to provide calibration, predictive maintenance, and modification services designed to keep your leak tester running at optimum levels, no matter where the factory or laboratory is located.

At Uson, we work closely with our customers to understand their unique and changing needs. We combine this insight with the knowledge of cutting-edge technologies to predict the future needs of our customers and their industries. With the largest installed base of leak testers in the medical device industry, we build leak testers and accessories to the highest standards, as demanded by the world's leading manufacturers. This unrivaled experience and expertise is complemented by global sales and support.

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