Five Steps to Leak-Proof Testing Success

The testing of any medical device is critical to the overall design and development cycle in order to ensure its safety and effective performance. As such, companies need to be certain that the methods they use to perform these tests are as accurate and reliable as possible. With this in mind, this article focuses on leak-proof testing and outlines five steps device manufacturers should follow to verify proper testing.

Kendall 3142-A family of tubing sets are leak and flow tested within 50 seconds to stringent quality requirements.

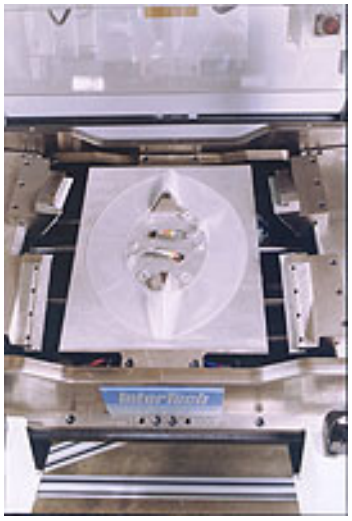
By Jacques Hoffmann
An array of medical products&#151blood collection kits, tubing, respiratory products, catheters, etc.&#151have "leak-proof" requirements. But when one is considering leaks on the molecular level as is sometimes required, while also designing manufacturing processes that will be fully FDA-compliant, the question arises as to just how "leak-proof" a particular medical product design is. Failsafe leak testing, where one never misclassifies a bad part as a good part, is achievable. Better still, good parts are never misclassified as bad parts and yield is maximized. However, this standard is possible only if one understands and manages all the factors that can undermine leak testing integrity. A discussion of relevant issues affecting mass flow leak testing&#151the best match leak test method for the widest range of medical applications&#151follows.

Step One: Define Specifications and Select Test Method Accordingly

In this catheter leak test system, balloon diameter gauging and lumen leakage tests are performed at a rate of 310 pph with an InterTech M-1045 Pressure Change Leak Detector.

GMP for medical devices begins with a clear understanding of compliance requirements and how that translates into testing specifications. If accuracy requirements are not too high and testing can be done at relatively low pressures (e.g., testing a plastic part/molding at 10 PSI), an upstream test will usually suffice.

In medical applications where the leak-proof requirement is 1 sccm or less, or where the part must function at higher pressures (e.g., catheters), there may be a need for the more accurate downstream test method, which involves added tooling and fixturing costs.
In downstream testing, the mass flow transducer is not exposed to the test part pressure and provides a very accurate measurement that is independent of test pressure. The test part is pressurized to test pressure. Any leakage from the test part flows into the test chamber through the mass flow transducer out to atmosphere. The output from the mass flow transducer is a direct measure of the leakage of the test part.

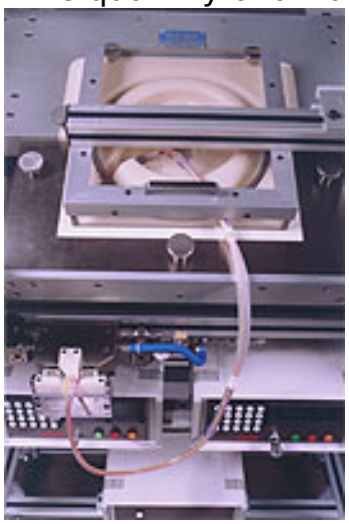


InterTech's mass flow leak detection technology permits

the fast and accurate testing of blood collection bags and similar large volume parts.

Step Two: Ensure Test Method Includes Appropriate Temperature Compensation

Thermal effects create virtual leaks that must be compensated for by test methods to achieve the failsafe leak test standard. Otherwise, virtual leaks will mask real leak rates.
Virtual leaks are caused by adiabatic heating or cooling, trapping, or part temperature effects. Typically, this occurs when a part is at atmospheric pressure and ambient temperature is pressurized. The internal volume heats up as the air is compressed and then cools down once pressure has been reached. If a part is at atmosphere and then evacuated, the reverse occurs.
Volume fillers will reduce both the quantity of air being compressed and the response time of the system.



The unique fixture design for leak testing this medical tubing set allows for accurate test measurements without problems such as seal creep.

Those who do not take the need for temperature compensation into account are apt to mistakenly think that mass flow leak testing methods are only viable for gross leaks. With appropriate temperature compensation, mass flow leak testing can be accurate for leaks as small as 0.05 sccm.

Step Three: Verify Leak Test System Functionality with Bias Leaks

In downstream mass flow testing where there is zero pressure from atmosphere, it is not possible to know if the valve used in testing is working or not unless extra

steps are taken. Otherwise, a zero leak measurement could be due to a valve not working or a line being plugged.

To compensate for this possibility, and to make the testing "failsafe," the more accurate systems employ a bias leak that verifies that the entire system is working and that the test circuit's integrity is not compromised. A bias leak is simply the introduction of a known leak as a self-check of the testing system. If valves are not operating properly and test seals are insufficient, the bias leak will not measure as a leak, indicating that remedial actions on the test system need to be taken. Ideally, introducing a bias leak should not affect test circuit design and test circuit volume.

Medical tube assemblies typically need to be leak tested during assembly.

Step Four: Adhere to FDA GMP and Other Requirements for Calibration and Validation of Test Systems

Medical device manufacturers must create detailed documentation that verifies correct processing and leak testing of parts. Leak test instrumentation must be able to adequately store data that includes logging parts by serial number for subsequent analysis.

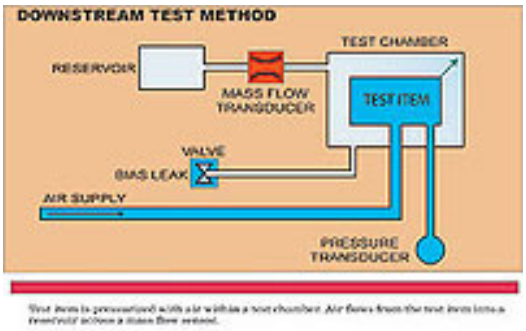
Beyond these industry standards, what many in the industry do not realize is that the failsafe leak testing standard can only be achieved with very frequent calibration and validation of test systems. Antiquated mechanically-based calibration and validation methods are insufficient. Practically speaking, frequent calibration and validation is only possible if one uses the updated electronic technology for self-calibration and automatic validation that is now available. Electronic calibration and validation can achieve an accuracy of &#1772% of reading or 0.02 sccm. Off-line mechanical calibrations not only are much slower, but they can only achieve a repeatable and reproducible accuracy of 0.1 sccm and have inherent limitations, such as pneumatic valves or other moving parts that can stick or wear, as well as small gaps or orifices that are likely to change due to clogging.

Moreover, mechanical methods have the inherent drawback of introducing the potential for operator error.

Step Five: Fixture Design

Blood collection kits are mass flow leak tested to a 1.0 sccm limit at 10 psig. at a rate of 60 pph.

Some make the mistake of thinking that expertise in assembly fixture design is the same as that required for designing fixtures for testing. In assembly, a fixture is meant to simply hold parts in place. Leak test fixtures need to take other factors into account, such as the volume and wall thickness of the part to be tested, the test pressure, and how the volume of the part relates to the size of the leak being measured. Those who do not understand these issues nor have extensive experience in designing test fixtures will often have problems achieving the failsafe leak testing standard. This is the case whether the part is made of plastic or metal&#151seal creep is often a problem whenever a nuanced understanding of test fixture design is not employed. This is one of the reasons why most medical device manufacturers are well-advised to add applications engineers with a singular focus on testing to their design team.



Downstream leak testing is used for difficult applications where there is a requirement for testing at pressures in excess of 150 psi, short test times, measurement of small

leaks, very accurate and repeatable results, and/or precise temperature compensation.

Conclusion

Real world requirements for leak testing take into account the needed temperature compensation methods, use of bias leak testing, need for electronic inline calibration and validation methods, and the skillsets of those with extensive experience in test fixture design. The failsafe leak testing standard is achievable and is precisely what GMP and overall FDA compliance requires.

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