

5 Factors to Identifying the Best Leak Tester for You

Joe Pustka

The laws of physics that determine the best match leak test methods have not changed. What has changed is the technology available—both the leak testers and the automation for full or semi-automated test and assembly machinery—that make one or another leak tester the best match technology. This article reviews five factors that need to be considered to ensure the best choice is made.



Cradle-to-grave customer support from manufacturers of leak testers should be considered a necessity.

Many in the medical device industry are unwilling to trade up to faster and more accurate leak test technology given the pain and costs of redoing process validations required by the FDA. While that is always a factor, reputable leak tester manufacturers have worked with device manufacturers to validate leak test assemblies or leak detectors used in cleanroom environments many times and can be called upon to minimize the time required for validations. Further, the calculation of return-on-investments for newer leak detectors is a relatively straightforward proposition. In fact, reputable manufacturers of leak test systems should keep customers apprised of technology options as part of the cradle-to-grave support to which they are entitled.

1. Be Prepared

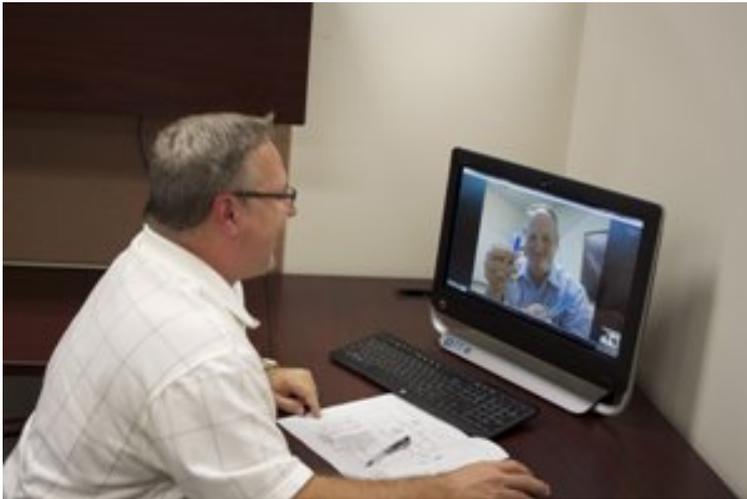
Be prepared to discuss the application with a leak testing specialist in detail. Figure 1 shows how different classes of leak testers match up to these requirements.

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Following are the factors and questions that need to be addressed prior to speaking with a leak test technology specialist:

- Physical parameters—What is the internal volume of the part to be tested? At which test pressure(s)? At what leak or flow rate specifications? What is the part made of? How much give or flexibility is in the product material?
- Details of how the part or device functions—In what type environment will the part or device be used? Is it a device that is operated in a controlled environment, pressurized room, or operated by a patient in a home or other uncontrolled situation?



USON's video consultations facilitate precise recommendations for seals or other fixturing in automated machinery that matches the geometry, flexibility, and other physical characteristics that bear on testing efficiencies.

Leak test environment—Cleanliness does impact the way in which a leak tester enclosure needs to be chosen. Will testing be done in a cleanroom environment or an industrial one where NEMA enclosures are required?

- Stage of manufacturing—At what point in the assembly process will the test take place? Is it directly after a glue weld or molding process such that temperature compensation will need to be figured in for the part to be tested?
- Production targets—What is the expected throughput of the manufacturing operation? In turn, this will help determine the optimal test cycle targets per component at the desired production rate, as well as the number of testing stations, test channels, and/or test sensors.
- Range of NDT (non-destructive testing) tests required—Many medical devices need a combination of related NDT tests (e.g., flow, leak, burst,

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occlusion, crack pressures, sealed component tests and more). Similarly, many devices have numerous subassemblies that need to be tested.

	Multichannel Benchtop	Single Channel Benchtop	Two Channel Multi-sensor	10 Channel Multi-sensor
Lifetime Support	Yes	Yes	Yes	Yes
Validation Assistance	Yes	Yes	Yes	Yes
Test Part Volume Recommendation	Small <1.5 Liter	Medium <4 Liters	All Sizes	All Sizes
Optimized for Fast Small Volume Testing	Yes	Yes	Configuration-Dependent	Configuration-Dependent
Ideal for Integration into Automated Systems	No	Yes	Yes	Yes
Optimized for Concurrent (Synchronous) Testing	Yes	N/A	Yes	Yes
Optimized for Asynchronous Testing	No	N/A	Yes	Yes
Handles Millions of possible Combinations of test types And sequences	No	No	Yes	Yes

Figure 1: Possible leak test solutions for any medical device are unlimited; this shows a few of the choices or test specifications that help leak testing specialists zero in on the best match. USON leak testing specialists will help companies find the best leak detector for their application at no charge.

2. Visual Inspection

Always give priority to consulting with the leak test specialist in a manner that enables detailed visual inspection and, in some cases, dissection of the device. In many cases, the patent-pending medical device for which a test system is being created cannot leave a manufacturer's facility. Videoconferencing makes that obstacle moot. Face-to-face discussions (even via video conference) are always a better option than simply trying to explain something over the phone. What these video consultations enable are precise recommendations for seals or other fixturing in automated machinery that matches the geometry, flex, and other physical characteristics that bear on testing efficiencies.

3. Testing Sequence

Make sure that the discussions include detailed analyses of whether parts of components can be leak tested simultaneously or whether the sequence of tests required makes asynchronous multi-channel leak testing a better match. This is not simply a matter of looking at lower costs, though that is one inevitable byproduct when getting into this level of detail. It is also a matter of test accuracies afforded by sensors that are tuned to different pressures as well as the cycle time for tests

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with particular sensors. Multi-channel and multi-sensor leak testers are the types where the most recent innovations have occurred.

For example, consider today's standard blood oxygenator. In these types of devices, the circulating blood, oxygen, and warm saline chambers operate at different pressures. If using a leak tester with three sensors scaled to operate at maximum efficiency at these three distinct pressures, a more efficient system is created. Note that the upfront cost of any leak detector is not the same as the real testing costs. Cycle times factor in and, in turn, relates back to the sensitivity and pressures to which the sensors being used are tuned. Testing costs per channel and testing costs per sensor are factors that create significant forks in the purchasing decision trees.

4. Features and Options

There is a wide variety of options among leak testers, such as those relating to I/O sophistication and the number of test steps that can be programmed. If flexibility is important, there are leak testers that have been designed with that requirement as core. Similarly, some leak detection equipment has numerous data communication options. These types of factors are always important with any system, but they are critical to blueprint in detail when enlisting a leak detector manufacturer to provide a total turnkey leak test solution.



USON's multichannel VECTOR Leak Tester, here being used to leak test check valves, can be configured with up to 10 independent test channels and I/O capability up to 72/122 different programmable steps.

5. Configurability

The necessary configurability of the leak tester needs to be identified. Today's technology improvements allow engineers to pick leak testers with totally

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customizable pneumatics, test methods, data communications, and storage. For example, with a system capable of performing more than a dozen types of NDT tests in any order, the number of permutations reaches into the millions; it is easy to see how flexibility needs to be a focal point. Additionally, configurability enables the engineer to not only have the best leak test technology for the application at hand, but also for the next device that is only on the drawing board.

Perhaps the biggest mistake device manufacturers make is when an antiquated leak tester that was built with one pressure and sensor range in mind for an earlier generation device is used for a new application. While it will work in some fashion, it is certainly not optimal. Typically, the regulators and flow sensor ranges are off and the tester “limps” to the finish line during every test cycle. Often, it will only take 48 hours to get a no-cost detailed application analysis to determine if a leak tester is suitable for a specific task.

Joe Pustka is the medical device leak testing technical support manager for USON, which first developed high accuracy leak testing methods for NASA, and for nearly half a century has been at the forefront of leak detection, leak testing, and non-destructive testing for the medical device and medical packaging industries.

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