Üson
for good measure

Medical Device Industry Overview

Multi-Function Leak and Flow Testers

Uson

Pioneer of Modern Leak and Flow Testing

When Your Process Needs to Keep Up with the Pace of Innovation —

Uson leak testers support unique design and testing criteria, so you can meet strict product performance requirements.

In the medical device industry, the pace of product innovation has created unique challenges. In order to ensure compliance with regulations, every part of a product requires unique design and testing criteria. Product performance requirements are becoming stricter. This means that test procedures are complex, and multifunctional testing and part integrity testing capabilities are required.

- Uson has more than 50 years of experience to support manufacturers in the medical device industry.
- We support our customers throughout the life of the Uson leak tester.
- Our leak testers deliver the assurance of quality, so bad parts don't leave the factory.
- Our leak testers capture vast amounts of data, for a clear view of how the manufacturing process is performing.
- Our leak testers accommodate multi-step processes for greater flexibility to meet quality demands.

Medical device manufacturers must navigate a highly regulated and fast-changing industry

No leak test manufacturer understands the dynamics of the medical device industry as well as Uson. Leak detection plays a critical role in medical device manufacturing, as many medical devices have fluid management functions that can be dangerous to the patient if compromised. Non-destructive tests are essential to product integrity. Air-based methods, such as pressure decay and mass flow, are most commonly used in the medical device industry.

We have identified three key market drivers within the medical device industry.

1) The pace of product innovation
2) Compliance with regulations
3) Industry consolidation

Product innovation is a key performance indicator (KPI) for the medical device industry. Medical device companies are driven to continuously innovate their processes, to ensure quality, regulatory compliance, and short time-to-market for new products.

Regulatory compliance and the push for faster time-to-market also heavily impact the development, launch, and manufacture of products. Because of the highly regulated nature of this industry, manufacturers face a regulatory process that is lengthy and unpredictable and can impact whether a product is approved for the market, which impacts profitability.

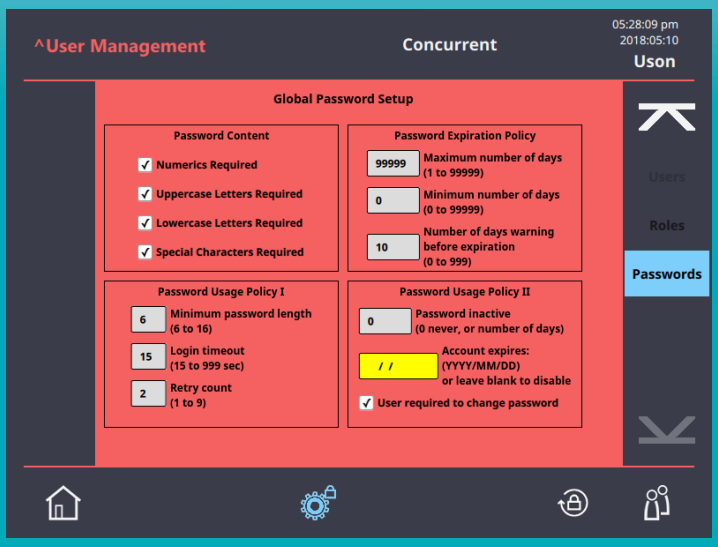
Finally, ***industry consolidation*** is an ongoing trend that makes it challenging to maintain profitability in the context of a global business, so companies are trying to optimize processes and elevate production amidst varying challenges that occur in different world areas.

Medical device manufacturers demand a lot from their leak testers—very fast cycle times, the ability to accommodate a wide range of multi-functional and part integrity tests, and test methods to accommodate many applications. Uson's leading leak testers are ideal to meet the needs of medical device product development and product manufacturing.

The Cost of Non-Compliance is High

Uson delivers solutions that are specifically designed for medical device manufacturers.

Guidelines for storing and protecting electronic records—such as 21 CFR Part 11 (U.S.) and others—have been in place for more than 20 years. Advancements in technology and innovation, combined with the sheer volume of data being generated, means these regulations are even more relevant for medical device manufacturers. Leak testers like Uson's Sprint^{mD} make it possible for medical device manufacturers to move new products into manufacturing quickly and support the instrument qualification and operational qualification (IQ/OQ) processes with greater efficiency.



The number of product applications in the medical device industry is staggering —and this creates its own set of unique challenges.

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.

Application	Description	Common Test Method(s)
Non-Compliant Balloon Catheters	Used in stent delivery, PTA, & dilation	Often performed using positive pressure and/or vacuum decay testing and verification of inflation/deflation
Compliant Balloon Catheters	Used in enteral feeding, tracheotomy tubes, occlusion, and drainage	A combination of pressure and vacuum decay for verification of inflation/deflation, ramp to burst event, and dilation curve information
Multi-Lumen Catheters	Used in hemodialysis, diagnostics, pacing drug delivery, CVC, and PICC	Often performed using both pressure decay for leak testing and mass flow for blockage on each lumen individually, using multi-port instruments when testing medical equipment
Bags	Used in IV/saline, hemodialysis, blood transfer, and urinary/waste collection	Often performed using pressure decay utilizing restraining plates and bag functional testing using ramp to burst event
Check Valves & Pressure Relief Valves	Used in drug/fluid delivery, hemodialysis, and blood transfer	Often performed using pressure decay and cracking/opening pressure utilizing ramp to open event
Tubing	Used in drug and solution delivery, and blood transfer	Pressure and/or vacuum decay testing and occlusion testing
Sheath Introducers	Used for guidewire and catheter entry into blood vessels	Pressure and vacuum decay testing and occlusion testing

Count On Uson's Expertise & Quality —

For customer-driven test specifications built with proven technology for ease of use

Our in-house manufacturing and calibration capabilities give us unsurpassed experience in designing customized test solutions for automated or semi-automated leak testing systems.

- Pressure decay leak testers
- Differential pressure leak testers
- Mass flow testers
- Burst, occlusion, and sealed-component techniques
- Combination instruments—pressure decay mass flow + burst or other combinations
- Multi-channel concurrent or sequential test instruments
- Leak testers for flexible packaging
- Data collection—USB network (Ethernet I/P, TCP I/P, QDas, etc.)
- Service and support—calibration, instrument selection, and repairs

Uson's Sprint^{mD}—A flexible solution for leak testing a wide range of components using the pressure decay method.

Uson's Optima vT is designed to be highly configurable. With a choice of one or two test channels, optional enclosures, a wide range of test types and custom pneumatics, the Optima is highly versatile.

Uson's QmR leak tester is an affordable, high-quality leak tester designed to set a new benchmark of accuracy and dependability for light- to medium-duty applications.

Uson's Raptor is a single-channel pressure decay leak tester that is ideal to help reduce recalls and increase efficiencies for a wide range of applications.

Uson's 628 differential pressure decay leak tester—A cost-effective solution for leak testing a wide range of components using the differential pressure decay method.

Uson

www.uson.com

Support and Commitment —
At all stages of your process

Uson maintains a global service and support team, with field service experts located all over the world. This network of specialists ensures highly trained, local support experts in leak testing are available, no matter where your factory is located. As part of its aftermarket program, Uson provides calibration, predictive maintenance, and modification services to keep the tester running in optimal condition.

Uson is fully committed to its products and does not obsolete legacy products until technology has progressed to the point that getting replacement parts is absolutely impossible. Even after spare parts aren't available, Uson's service team will continue to support the product.

Our Sales & Support Offices

With our strong, global team of sales representatives and support offices, Uson provides our customers with exceptional services in all world areas.

Uson L.P.
8640 N. Eldridge Parkway
Houston, TX 77041
USA
Phone: +1-281-671-2000
Fax: +1-281-671-2001
www.uson.com

Detroit Office
31471 Utica Road
Fraser, MI 48026
USA
Phone: +1-248-589-3100
Fax:+1-248-589-3103

Uson China
Room 601, 567 Lan Gao Road
Shanghai, 200333
P.R. China
Main: 021-583 65859
021-583 59187
Fax: 021-583 59185
021-337 73559
www.uson.com.cn

Uson Ltd.
Western Way
Bury St. Edmunds
Suffolk, IP33 3SP
United Kingdom
Phone: +44-1284-760606
Fax: +44-1284-763049