



# Medical Device Industry Overview

Multi-Function Leak and Flow Testers





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.



Our leak testers capture vast amounts of data, for a clear view of how the manufacturing process is performing.



We support our customers throughout the life of the Uson leak tester.



Our leak testers accommodate multi-step processes for greater flexibility to meet quality demands.



Our leak testers deliver the assurance of quality, so bad parts don't leave the factory.

# 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.

## 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.

**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 number of product applications in the medical device industry is staggering — creating a unique set of 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.

## Intervention & Treatment



### Cardiology

There are a wide range of components used for cardiology intervention. Leak testing is important to ensure the device works properly as failure cannot happen during a procedure.

**Applications include:** High pressure balloons, Instrument delivery systems, Sheaths and Catheters, Sterile and Storage containers, Balloons, Stents, Heart replacement and repair valves.



### Urology

There are a variety of treatments in Urology. Leak testing is critical to ensure the navigation and steering systems are protected from the bodily fluids. Additionally, single use tubing sets and catch bags are tested for leaks as well as occlusion with functional tests for valves associated with them.

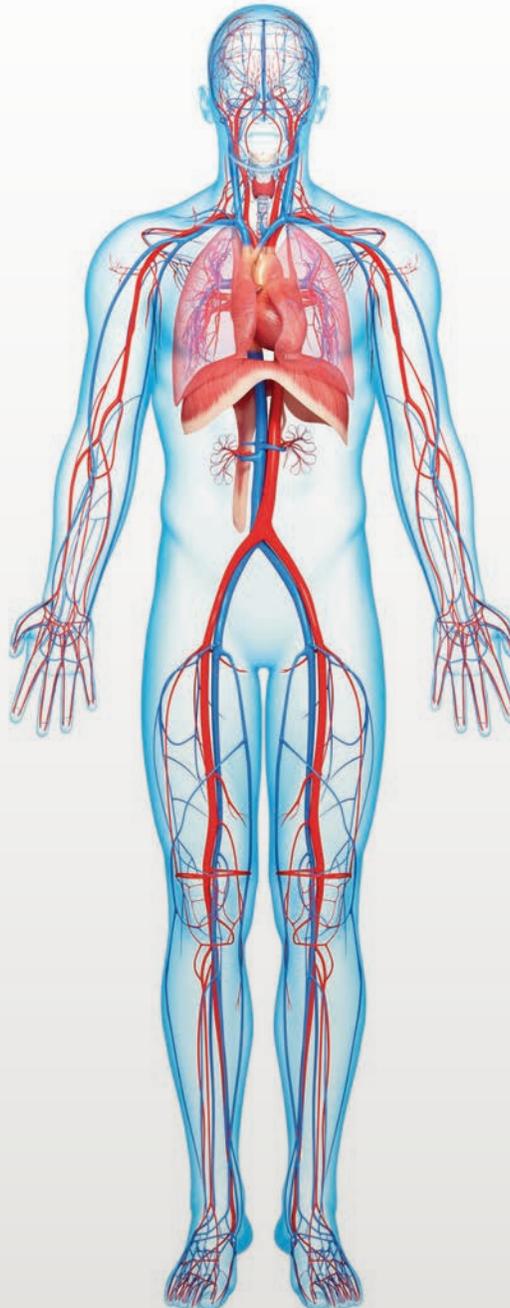
**Applications include:** Fluid management sets, Catheters, Steering systems, Viewing systems, Kidney stone treatments, Prostate treatments, Renal access urinary stent flow analysis.



### Diabetes

Treatment for diabetes has continued to advance rapidly. Along with pumps, dialysis, bags and tubing sets, advancement in wearable technology allows for continual monitoring and treatment improving the quality of life. These devices are checked for leaks, Ingress protection (IP) and weld joints sealing to ensure the patient receives the necessary care.

**Applications include:** IP ratings (Ingress Protection) of wearables, Dialysis treatment bags and Testing pumps, Monitors, Delivery systems.



## Surgical Equipment



### Surgery

During surgery there is a significant amount of equipment used to support the care of the patient. Any component that is used to contain or deliver a fluid should be tested to ensure there are no defects as well as functionally tested to verify performance.

**Applications include:** IV Bags, Heating pads, Needles, Breathing tubes, Ventilators, Fluid management sets.



### Endoscopy

Endoscopy applications are growing at a significant rate as technology gets smaller and the number of treatments approved increases. In an endoscopic procedure there are a variety of channels that need to be leak and flow tested. Testing ensures cameras can see and the tooling can get to where they need to be while the fluid paths for irrigations and insufflation have the correct flow patterns.

**Applications include:**

Scope: Trocars, Endoscopic instruments, Insufflation systems connections, Camera light source.



### Stents

Stents are tested to ensure they open at the right time and place. Both integrity and functional tests on these mechanisms and delivery systems is critical. Deployment systems must deliver the proper force to effectively apply the stents.

**Applications include:** Cardiology, Neurology, Biliary.

## Test Techniques

Pressure Decay, Vacuum Decay, Sealed Component, Occlusion, Functional, Flow, Burst.

# 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



**Sprint mD** - A flexible solution for leak testing a wide range of components using the pressure decay method.



**Optima vT** - 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.



**Qualitek mR** - An affordable, high-quality leak tester designed to set a new benchmark of accuracy and dependability for light- to medium-duty 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 L.P.

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

## 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

## 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.

