

Turnkey Service for Medical Device Leak Testing Automation and Validation



Global medical device manufacturers seeking to eliminate the risk of releasing defective products to market that do not adhere to the device's leak rate specifications can now rely on USON-Innovative Systems, a newly created joint venture between USON's best-in-class leak testers and Innovative Products and Equipment's automation systems expertise. UIS is a single source turnkey solution for semi-automated and fully automated leak testing applications.

Sophisticated automation systems such as state-of-the-art robotic part handling are tightly integrated with the USON leak detector best suited for a particular leak testing application challenge by the industry leading engineering talent comprising the UIS service. All UIS production line designs are 21 CFR Part 11-compliant and built with IQ/OQ/PQ factory acceptance tests and FDA validation front-of-mind.

Dave Foran, President of USON comments, "UIS marries a deep bench of mechanical and control engineering talent from Innovative Products and Equipment with USON's unsurpassed leak testing applications engineering team. Our customers seeking to automate or semi-automate their NDT leak testing operations will be able to get a turnkey single source custom clean assembly design that is not only tuned to their leak detection needs but is also the most efficient production line design possible. This means lower costs, faster throughputs, simple regulatory validation and compliance and faster time-to-market—the top level concerns of all medical device manufacturers worldwide."

Dale Beaver, [President of Innovative Products and Equipment \(IPE\)](#), further explains, "UIS is an extension of a collaboration that began many years ago to develop

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elegant designs for production lines that include best-in-class USON leak detection equipment. There is very little in terms of leak testing production lines that we haven't encountered before. We bring a number of state-of-the-art automated assembly designs to give medical device manufacturers a tried and true solution and when they have unique needs we have the team in place to create new solutions in rapid order. We understand what FDA compliance requires and we make it very straightforward for medical device manufacturers to validate their processes accordingly."

In most cases, UIS will provide a detailed application quote within two weeks of request.

USON

www.uson.com [1]

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