

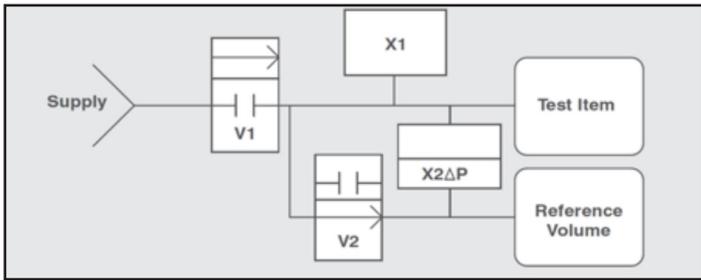


## Leak Testing – A faster and more cost effective approach

New product innovations in the medical device industry drive an ever increasing demand for faster and more reliable leak testing. From legacy products such as catheters to the modern developments in pressurised wound dressings, the challenge always remains to find more efficient and reliable test methods in order to reduce cycle times while still maintaining reliability in the quality of the test method.

One approach to achieving this goal is to consider the application of mass flow detection over traditional pressure decay. Many in the industry treat pressure decay and leak testing as interchangeable terms. Indeed, pressure decay has been the most common technology used to test for leaks in products for many years. So what is the difference between mass flow and pressure decay in the context of leak detection?

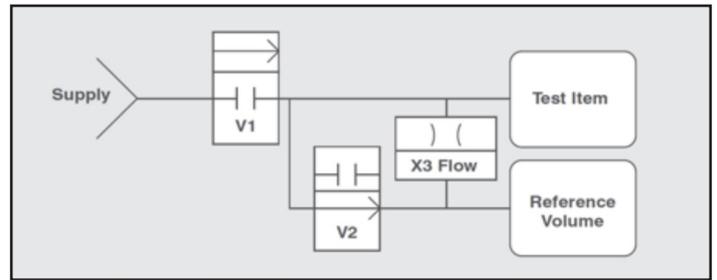
### Pressure Decay



Pressure Decay/Differential Pressure: Test item and non-leaking reference volume are pressurized from the same air supply, then both are isolated by closing V1. The reference volume is isolated from the test item by closing V2. The pressure transducer X2ΔP reads the pressure differential between reference volume and test item. Pressure differential is then converted by calculations to provide a measure of leak rate.

The primary draw back to this solution is that two measurements are required, one at the start of the cycle and the other at the end. Time is needed between these intervals to allow the system to equalise after the introduction of pressure into the test item. The longer the interval required, the longer the test cycle takes. Also, longer intervals lead to a decrease in accuracy as the rate of change in pressure decay reduces over time.

The other issue that needs to be accounted for with pressure decay is the influence of adiabatic effects on the system. Because a measurement system based on pressure is intrinsically linked to the temperature and volume of the system, any changes in temperature will affect the accuracy of the system. As a consequence, a longer test time can result in less repeatability in the system.



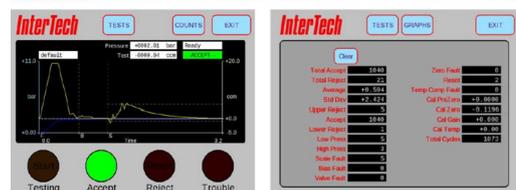
### Mass Flow Detection

Mass Flow: Test item and non-leaking reference volume are pressurized from the same air supply line, then both are isolated by closing V1. The reference volume is isolated from the test item by closing V2. Then the mass flow sensor X3 reads flow of air moving from the reference volume into leak test items, thus providing a direct reading of leak rate in standard cubic cm per second.

This approach yields two advantages over pressure decay testing. The first being that this method only requires a single measurement, so it eliminates any inaccuracies resulting from rate of change of decay over time. Also, the instantaneous reading means that the method is not as sensitive to changes in uncontrolled variables such as temperature over time.

The other advantage of this approach is a significant reduction in test cycle times. The two measurement requirement for pressure decay followed by a calculation to produce a leak rate, not only creates added opportunity for inaccuracy, but also takes more time. Updated mass flow sensors give the most rapid and direct measurement of leak rate because they can be finely tuned to be more responsive and quicker in any given application. Test cycle time reductions of up to 30% have been achieved.

To see if your leak test cycle times can be reduced, saving you time and money, why not contact us to find out more information. We offer a range of Intertech solutions using advanced mass flow sensors that can offer fast and accurate leak testing.



To find out more, or arrange an appointment with your local Technical Sales Manager, email Laura Sheahan at [lsheahan@ippgrouppltd.com](mailto:lsheahan@ippgrouppltd.com)



# GINOLIS: Keeping up with the Change



In a market that is regularly exposed to new commerce, medical device manufacturers need to revamp and update their products to suit the season's requirements," says Teijo Fabritius, CEO of Ginolis, as he touches upon how innovation and the rapid advancement of technologies are transforming the medical

device market. Having spent more than two decades in various leadership roles, Fabritius knows what it takes for the companies fairly entrenched in the medical device space to become flexible, limber, and able to roll with the tides of change. With a vision to provide effective healthcare to patients across the globe and eliminate manual intensive process in the diagnostic industry, Fabritius and his team at Ginolis provide unique and innovative automation solutions for precision liquid handling and micro assembly to ensure high product quality in the medical device industry.

The company offers modular automation platforms with extensive solutions ranging from standard products to customized systems. As the industry leaps to digital services, Ginolis' automated production systems keep pace with the change and can be modified effectively to meet customer specifications and provide quality healthcare to patients.

Established in 2010, the company's commitment to revolutionizing the healthcare consumables industry is fuelled by its laser focus on high-quality modular desktop automation solutions that utilize machine vision technology and high-precision liquid handling. Ginolis' service offerings fulfil customer requirements from the development of the product all way to its validation, support the entire process with its resources, encourage feasibility studies, and provide technical support. What sets the company apart from other players in the market is its low exchange time for products, even when they have to incorporate changes into standard solutions to meet customer specifications on a regular basis. The company's products, Ginolis Pixie and Lateral Flow Device Assembly, make this reduction in exchange time possible. While the former offers automated optical quality

inspection enabling high throughput on any surface, the latter serves as a standard system for the fully automated assembly and packaging of rapid tests. Ginolis' product automation solutions use high-quality manufacturing equipment to produce and process medical and diagnostic devices, while its standard automation platforms provide exceptional operation within a compact footprint. In order to operate and control the product automation solutions, Ginolis leverages the Ginger Software Platform. Besides its centralized machine vision and RFID capability, Ginger comes with an easy-to-use graphical user interface that provides process guidance, real-time information, and critical alerts and notifications

Patents in dispensing, micro-fabrication, and precision robotics have also proved invaluable to Ginolis' customers. The company has patented the Piezo Motor Bellows (PMB) pump technology and modular automation platforms to enable high precision liquid handling solutions for standard products as well as fully customized systems. Ginolis has developed the compact high-precision, non-contact dispensing and aspirating Cecilia-L platform to facilitate microfluidic chip/cartridge printing, lateral flow membrane striping, and microtiter plate liquid handling. Cecilia-L can have up to four PMB dispensing pumps to ensure smooth and consistent dispensing of fluids and reagents, and delivers precision and accuracy within a compact desktop module. On the other hand, the production and processing of micro-components, diagnostics and medical device products are managed by the company's modular compact automation platform, Xanthia.

This desktop automation platform offers fast, accurate and precise operations using the company's Intelligent Transfer Unit system.

Together with the Ginger software, sensors, cameras, and a plethora of techniques, each solution provided by Ginolis is equipped with an improved machine vision system for robot guidance, quality inspection, and process control. The company keeps pace with changing market trends by using a limited amount of product-specific components that can be altered as required.

With an extensive global presence, Ginolis aims to shift to the cloud for active maintenance and provide remote monitoring in addition to quality assurance, analytics, and reporting.

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# NEWS

## IPP brings Super Dry® Totech's dry cabinets to Ireland

IPP Ireland became the Irish distributor of Super Dry® Totech. Super Dry® Totech began nearly a decade ago as a distribution and technical support channel for ultra-low humidity dry cabinets with patented Zeolite technology.

Rapid growth was fuelled by European RoHS legislation that magnified the need to carefully control product failures caused by moisture sensitive devices (MSDs). Since then, Super Dry® Totech has become an independent design and manufacturing organization serving global markets with leading edge MSD solutions.

Unlike clay or silica, Super Dry® Totech's patented technology uses a crystal known as Zeolite. A molecular sieve, water molecules are literally sifted from the air inside the cabinet. The desiccant is never touched by operators, and it never needs replacing.

Managing Director of IPP Jack Daly is pleased to partner with Super Dry® Totech, a member of the ASYS Group, "Having partnered with ASYS for many years, we are delighted to grow our relationship and distribute Super Dry® Totech's ultra-low humidity dry cabinets with patented Zeolite technology in Ireland."

Super Dry® ToTech's Managing Director Jos Brehler is excited to bring its dry cabinets to Ireland through its IPP partnership, "Our development efforts have produced new levels of drying performance as well as environmentally responsible, industry-leading solutions such as our XSD & XSDB series."

For more, please visit our website at [www.ippgroupltd.com](http://www.ippgroupltd.com)

# EVENTS

## Making Pharmaceuticals, 30 April to 1 May 2019, Ricoh Arena, Coventry, UK

Join Industrial Production Processes (IPP) Ltd at Making Pharma 2019, stand 200.

We will have live demos on a range of packaging equipment, packaging inspection equipment and serialisation equipment.

PTI - Packaging Technologies & Inspection's Sales and Applications Engineer, Jason Sciarabba, will present on the *Advances in Deterministic Parenteral Container Closure Integrity* on Wednesday 1 May at 2.40pm.

Register for free today to secure your place at [www.makingpharma.com](http://www.makingpharma.com)

## MedTech Innovation Expo, 15 and 16 May 2019, NEC Birmingham, UK



IPP will be exhibiting at MedTech Innovation Expo 2019, stand D3.

We will have live demos on a range of packaging equipment, packaging testing equipment, and manufacturing and automation equipment.

IPP's Director of Life Sciences Donal Harrington will present on *Stent Package Integrity - Regulatory Shifts and the Technological Drivers* on Wednesday 15 May at 3.20pm.

Register for free today to secure your place at [www.med-techexpo.com](http://www.med-techexpo.com)



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