

LT-Pro Leak Tester

When versatility is precisely
the solution you need



Bonfiglioli Engineering LT-Pro Leak Tester

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The Bonfiglioli Engineering LT-Pro Leak Tester represents a new era in advanced package-testing design for multiple package types in leading pharmaceutical and laboratory applications.

Through a holistic approach to package inspection, our newest innovation provides you with everything necessary for your most demanding applications.

By combining our latest technology advancements in leak testing with flexible testing solutions for a variety of container types, you are now able to achieve your goals faster, more reliably, and with less effort.



Better Solutions for Optimal Testing

Able to perform the same package inspection tests as larger in-line machines – with a higher degree of accuracy – the LT-Pro Leak Tester is built upon Bonfiglioli Engineering expertise and incorporates innovations such as interchangeable tooling, a large memory capacity, and a flexible membrane all within a small footprint. Available with either 5µm or 1µm accuracy, choose the system that suits your application needs.

Enhanced Flexibility

With unparalleled flexibility, you can now test a wide variety of containers from ampoules, vials, and cartridges to syringes, sachets, and capsules without sacrificing capability or quality. Multiple test methods, including vacuum decay and pressure decay, and a wide-range of tooling options means you are always ready regardless of the application.

Total Simplicity

Designed as a compact benchtop unit that is easy-to-clean, easy-to-move, and easy-to-operate.

The LT-Pro Leak Tester delivers the performance, reliability, ease-of-operation, and value required to support a range of testing needs from basic food & beverage containers to leading-edge pharmaceutical applications, you're ready for whatever comes next.

Ease of Use

The LT-Pro Leak Tester is designed to fit into almost any lab or production line setup and be used by almost any member of your team.

- Record unlimited recipes for efficient changeover between tests
- Store and lock multiple test recipes so any colleague can use it
- Intuitive touchscreen interface provides test results in as few as 10 seconds with a simple click
- Screen layout is common across all test types, reducing the need for training and documentation
- Clear symbols reduce the need for translation
- Calibration kit included with easy-to-use instructions
- Ergonomic design that's lightweight, compact, and easy to clean
- Housing and one-piece cover designed to prevent contamination



User friendly interface for intuitive operation

Quality Assurance

Rapid, accurate, reproducible test results you can rely on and document. The LT-Pro Leak Tester is able to easily connect with your existing data management system and is fully compliant with a variety of international regulatory standards, including:

- ASTM Standards for Vacuum Decay (F2338-09) and Pressure Decay Testing
- USP General Chapter <<1207>>
- EU Guidelines to GMP Medicinal Products for Human and Veterinary Use – Annex 1, *Manufacturer of Sterile Medicinal Products*
- FDA 21 CFR part 11 as well as EMA Annex 11
*PDA Technical Report No. 27 *Pharmaceutical Package Integrity*



Various tooling options available for multiple application types



Applications

Bonfiglioli Engineering is a leader in non-invasive and non-destructive technologies, providing reliable, accurate leak testing solutions from in-line high-speed rotary machines to benchtop testers, across a range of test protocols and sensitivity needs.

As more complex treatments and therapies come online, increased use of specialized parenteral containers has driven the need for much lower Maximum Allowable Leakage Limits (MALL) and a higher level of sensitivity in CCIT methods. The innovative LT-Pro Leak Tester is able to reliably and repeatedly detect leak rates as small as $1\mu\text{m}$.

Whether you need to detect leaks of $5\mu\text{m}$ or $1\mu\text{m}$, Bonfiglioli Engineering offers a compact LT-Pro Leak Tester perfect for your applications:

- Small-batch testing
- Non-invasive, non-destructive testing of personalized medicine
- Feasibility testing of new products and concepts
- Random batch certainty testing
- Confirmation of packaging rejected from the line



Versatility

Space and functionality are key to efficiency, in the lab and on the production floor.

The LT-Pro Leak Tester is a sleek, standalone system that can provide package integrity assurance customized to your needs. Able to perform the same tests as larger in-line systems, the LT-Pro Leak Tester can also provide verification of in-line test results, and even higher sensitivity testing given longer test times.

- Compact, lightweight unit suitable for limited lab space or portable for temporary in-line or next-to-line use
- Customizable for your test types, data requirements, preferred unit of measure, and test time
- Runs both the vacuum decay method and the pressure decay method
- Accommodates a variety of container types: pouches, sachets, vials, syringes, ampoules, cartridges, cups, BFS, trays, bottles
- Tests liquids, pastes, powder and lyophilized materials
- Able to detect a variety of faults: weak seals, channel leaks, and pinholes



LT-Pro tester with flexible membrane attachment for testing pouches, sachets, and other flexible and semi-flexible filled-and-sealed packaging



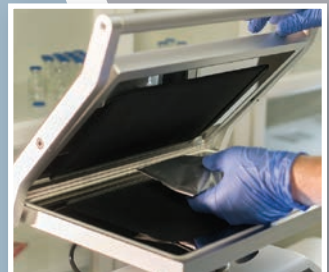
CCIT of vial, vacuum or pressure decay testing methods



CCIT of capsule, vacuum decay test combined with lid deflection method



CCIT of Blow, Fill, Seal containers, vacuum decay test method



CCIT of pouch using vacuum decay test method



Connectivity Made Simple

A customizable and intuitive interface, portable size, sleek and ergonomic design and quick connectivity make the LT-Pro Leak Tester a versatile and integral part of your workflow. Capable of storing and uploading results from multiple tests, the system easily connects to your existing information management system to provide quick data upload and documentation to confirm adherence to required regulations.

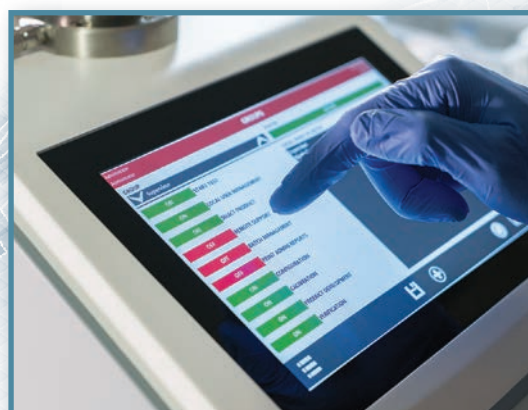
- Easy Ewon connection to OPC UA/DA
- Test results easily uploaded to LIS via onboard Ethernet port
- OPC UA/DA connection
- Crystal reports automatically generate user-friendly graphs for analysis



Designed for simple connectivity to various information management systems

The LT-Pro Leak Tester makes leak testing easier to access, with a bright screen, intuitive layout, and customizable menus clear enough for almost any colleague to navigate.

- 170 ° viewing angle for enhanced visibility and live results
- Touch screen is both fingerprint-resistant and can be used with latex gloves
- Privileges can be tailored to individual operators by the administrator
- Most screens and functions can be accessed within 3 clicks
- Ewon connection allows to provide remote support, assistance and troubleshooting in real-time
- Wi-Fi connectivity: the machine provides integrate WLAN connectivity (in addition to the classic LAN connection)



Easy-to-operate interface makes product testing stress-free

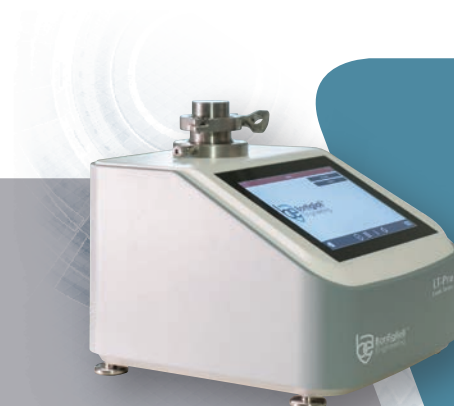
Specifications

Select the LT-Pro Leak Tester that best meets your container testing needs using the comparison chart below.



	LT-Pro SA (Standard Accuracy)	LT-Pro HA (High Accuracy)
Maximum Accuracy (In Most Conditions)	5µm	1µm
Vacuum Decay Test Method	Yes	Yes
Pressure Decay Test Method	Yes	Yes
External Vacuum Pump	Optional	Optional
Internal Vacuum Pump	Yes	Yes
Open Platform Communication (OPC)	Optional	Standard
Active Directory (AD) Integration	Yes	Yes
Electronic Signatures	Yes	Yes
Batch and Sub-Batch Management	Yes	Yes
Touch Screen	Yes	Yes
Reports	Yes	Yes
Backups	Yes	Yes
Cleaning Cycle	Yes	Yes
Calibrated Leak Test Mode	Yes	Yes
CFR 21 Part 11	Yes	Yes
Sensor Type	Single	Dual

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Learn more about the latest innovations
from Bonfiglioli Engineering at
www.bonfiglioliengineering.com

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