Bonfiglioli™ Engineering

LT-Pro

Leak Tester

A Compact, Ergonomic, Flexible Benchtop Leak Tester for CCIT Methods

Non-Invasive, Non-Destructive leak tester for laboratory and in-process control applications. Provides accurate and reliable Closed Container Integrity Testing (CCIT) for rigid and flexible packaging.

HIGHLIGHTS

- **Enhanced flexibility**
- **Interchangeable tooling for testing a wide variety of containers**
- **Multiple test methods: vacuum and pressure decay**
- **Available with either 5 µm or 1 µm test accuracy**
- **Non-invasive, non-destructive testing of personalized medicine**
- **Small-batch testing**
- **Ergonomic design: lightweight, compact, easy to operate, clean, and move**
- **Simple Ewon connection makes it easy to store, analyze, and document test results**

TECHNICAL FEATURES

Container Application: Vials, ampoules, BFS, FFS, bottles, prefilled syringes, carpoules, cartridges, trays, pouches, sachets, flowpacks, cups, and other flexible and semiflexible filled-and sealed packaging

Products: Lyo, liquid, powder, pastes, solid, semi-solid

Container Dimensions: From 0.1 mL to 1 L

Testing Time: From a few seconds to approximately 1 minute depending on container size

Technology: CCIT

Inspection Features: Non-Invasive, Non-Destructive CCIT based on Vacuum & Pressure Decay Test Method

Inspection Capabilities: Weak seals, channel leaks, and pinholes, leaking cracks, inappropriate welds, improper sealing, tears

ADDITIONAL BENEFITS

- **Feasibility testing** of new products and concepts
- **Random batch certainty testing**, and even higher sensitivity testing given longer test times
- **Customizable and intuitive HMI**
- **Customizable** test types, data requirements, preferred unit of measure, and test time
- **Screen layout is common across all test types**, reducing the need for training and documentation
- **Fingerprint-resistant touchscreen is latex glove compatible**
- **Easy Ewon connection to OPC UA/DA** for remote support, assistance and troubleshooting in real-time
- **Integrated WLAN connectivity** (in addition to the classic LAN connection)
- Housing and one-piece cover designed to **prevent contamination**
- Suitable for **limited lab space or portable** for temporary **in-line or next-to-line use**
- **Calibration kit included** with easy-to-use instructions

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Available with either 5 µm or 1 µm accuracy, 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)	5 µm	1 µm
Vacuum Decay Test Method	Yes	Yes
Pressure Decay Test Method	Yes	Yes
External Vacuum Pump	Optional	Optional
Internal Vacuum Pump	Yes	Yes
Manufacturing Execution System (M.E.S.)	Optional	Optional
Active Directory (AD) Integration	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
Electronic Signature CFR 21 Part 11	Yes	Yes
Sensor Type	Single	Dual

TECHNOLOGY

Container Closure Integrity Testing is a non-destructive measurement technology based on the following methods:

Vacuum Decay Test Method
Pressure Decay Test Method

Measurement is achieved by applying a pressure differential into an airtight testing chamber enclosing the container.

The test objective is to detect container leakages by measuring the reached pressure level as well as the pressure change over test time.

QUALITY ASSURANCE

Equipment test method refers to:

- Approved industry standard "**ASTM F2338-09**": "Standard Test Method for Non-Destructive Detection of Leaks in Packages"
- United States Pharmacopoeia – **USP General Chapter «1207»** "Packaging Integrity Evaluation"
- EU Guidelines to **GMP** Medicinal Products for Human and Veterinary Use – **Annex 1** "Manufacture of Sterile Medicinal Products"
- **PDA Technical Report No. 27** "Pharmaceutical Package Integrity"
- **FDA 21 CFR part 11** as well as **EMA Annex 11**