

C690H Nondestructive Package Leak Detector

C690H Nondestructive Package Leak Detector is based on the testing principle of the vacuum decay method, designed and manufactured according to ASTM F2338 and other standards. It is professionally suitable for batch sealing leak detection of vials, and trace leakage detection of ampoule, cartridge bottles, infusion bottles, prefilled syringes and other pharmaceutical packaging.



Features ^{Note 1}

Batch Testing

- Equipped with fully-automatic gravity fed sample feeder, which is Labthink's latest scientific and technological achievement that can facilitate continuous testing of 20 to 120 samples.
- A & B dual-channel design can test samples of two different specifications simultaneously.
- The target vacuum degree can be set by the operator to meet testing requirements of different samples.
- Dual methods of vacuum decay and pressure decay provide the flexibility to accommodate various types of package samples.

Precise Data

- Advanced pressure detection technology, using world renowned components for data stability which is not affected by ambient environment.
- Advanced microflow automatic flow control technology that can accurately simulate different sizes of leakage holes without manual adjustment.
- Both the differential pressure transducer and flow meter are traceable to NIST.
- The system can achieve a higher test repeatability of $\pm 1\mu\text{m}$.

Intelligent Control

- 15.6" embedded touch tablet computer with Windows OS.
- New longitudinal interface layout, and easy to use graphic user interface.

- Automatic alarm, automatic capture, automatic collection of unqualified samples.
- The pressure curve is displayed in real time, and the test results are counted automatically.
- Leakage rates are calculated automatically.
- The system is equipped with various sensors as intelligent reminders for safer operation and control.
- Universal printer can be connected for test results output.
- The system features embedded with USB and network ports to facilitate the external access and data transmission of the system, which can be upgraded remotely.

Security Compliance

- Verified by compensation and calibration methods.
- The leak tester meets GMP requirements for data traceability and meets the needs of the pharmaceutical industry.
- User operation permission is managed at multiple levels, and the permission content can be configured on demand.
- Electronic signature is designed according to the standard requirements of 21 CFR Part11.

Test Principle

The sample is placed in the sample feeder and automatically delivered into the test cell. The leak rate and other results can be calculated and obtained by analyzing pressure changes measured by the sensor.

Reference Standards

ASTM F2338, YY-T 0681.18, and USP<1207>

Applications

Basic Applications	Vials	Various vial sealing test.
Extended Applications	Ampoule	Various ampoule bottle sealing tests.
	Cartridge Bottles	Various cartridge bottle sealing tests.

Injection bottles

Various injection bottles sealing test.

Flexible Packaging Bags

Various IV bags and flexible packaging bags

Technical Parameters

 Table 1: Test Parameters ^{Note 2}

Parameter \ Model	C690H
Testing Range	um(Reference aperture size USP1207) 2~8~great leakage
Detection Lower Limit	um ≤2
Resolution	um 0.1
Repeatability	um ±1
Pressure Range	kPa -100~0~+100
Extended Functions	21 CFR Part11 Optional
	GMP computer system requirements Optional

Table 2: Technical Specifications

Testing Cell	1 set for A group and 1 set for B group
Sample Feeder	1 set for A group and 1 set for B group
Sample Size	≤Φ45 mm×80mm ^{Note3}
Sample Quantity	20~120 pieces
Gas Specifications	Compressed Air (Gas source is provided by the user)
Gas Source Pressure	0.5 MPa~0.7 MPa (72.5PSI~101.5PSI)
Port Size	Φ6 mm Polyurethane tube
Dimensions	33.4" H x 19.6" W x 28.7" D (85cm× 50cm× 73cm)
Power	120VAC±10% 60Hz / 220VAC±10% 50Hz (select one from the two)
Net Weight	209Lbs (95kg)

Table 3: Product Configuration

Standard Configuration	Mainframe, embedded tablet computer, software, flow meter, European vacuum pump, Φ6 mm polyurethane tube
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Customization	Test cell and sample feeder of group A, test cell and sample feeder of group B, negative standard reference sample and positive standard reference sample designed according to sample specifications
Optional Parts	GMP computer system requirements, 21 CFR Part11, air compressor , IQ/OQ/PQ documents

Note 1: The described product characteristics are subject to the specific annotation of the "Technical Parameters" table.

Note 2: The parameters in the table are measured in the Labthink laboratory by professional operators according to the requirements and conditions of the relevant laboratory environmental standards.

Note 3: Group C test cell can be customized for samples beyond the "Sample Size", but the lower detection limit and test range will change according to the sample size, and the actual delivery shall prevail.