C690M Nondestructive Package Leakage Detector is based on the vacuum decay method and pressure decay method, and is designed and manufactured according to ASTM F2338 and other standards. It is professionally suitable for the trace leakage detection of various drug packaging such as vials, ampoule bottles, cartridge bottles, infusion bottle, and prefilled syringes and so on.



Features Note 1

Multi-stage Vacuum

- Dual methods of vacuum decay and pressure decay provide the flexibility to accommodate various types of package samples.
- The system features automatic clamping method to fasten test chamber reliably.
- The target vacuum degree can be set by the operator to meet detection requirements of different samples.
- A custom made transparent test chamber facilitates easy observation of the sample state.
- Built-in European oil-free vacuum pump, which is maintenance-free and pollution-free (optional).

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 ±1um.

Intelligent Control

- 12.1" embedded touch tablet computer with Windows OS.
- The pressure curve is displayed in real time, and the test results are counted automatically.

- Leakage rates are calculated automatically.
- 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 the 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 sealed in the test cell, and the sealed test cell is vacuumized. By analyzing the pressure change measured by the sensor, the leakage rate of the sample can be calculated.

Reference Standard

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

Applications

Basic Applications	**Vials**	Various vial sealing tests.
Extended Applications	**Ampoule**	Various ampoule bottle sealing tests.
	Cartridge Bottle	Various cartridge bottle sealing tests.
	Injection Bottle	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		C690M
Test 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

Test Cell	1 set
Sample Size	≤Φ45 mm×80mm[Note 3]
Sample Quantity	1 piece
Gas Specification	Compressed air (Air 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	12” H x 22” W x 15” D (30cm x 56cm x 37cm)
Power	120VAC±10% 60Hz / 220VAC±10% 50Hz（select one from the two）
Net Weight	58Lbs（26kg）

Table 3: Product Configuration

Standard Configuration	Mainframe, embedded tablet computer, software, flow meter, vacuum pump, Φ6 mm polyurethane tube
Customization	Test cell, negative standard reference sample and positive standard reference sample designed according to the sample specifications
Optional Parts	GMP computer system requirements, 21 CFR Part11, air compressor, built-in European vacuum pump , 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: Samples beyond the "Sample Size" can be customized, but the lower detection limit and test range will change according to the sample size, the actual delivery shall prevail.