

Certitest™ Bag Integrity Tester

Integrity testing of full size 2D/3D Single-use bags



Function

- Integrity testing of Single-use bags before or after use
- Support custom pressure parameters within 300 mbar
- Two stage inflation control, free combination of fast charging and fine tuning
- Support custom stabilization time and testing test, and flexibly adapt to various testing scenarios
- Equipped with high-precision sensors, real-time display of pressure drop curve
- Confirmation when start and stop test, safe and controllable test operation

Fully Compliant with Data Integrity Requirements

- Developed in accordance with GAMP5, fully compliant with 21 CFR Part 11
- Multi level permission settings, supporting customer customization of user groups, assigning user permissions, and fully compliant with quality management system requirements
- Multi level password policy, supporting customized password policies for users, meeting the verification requirements of computerized system
- Complete audit trail function, supporting PDF file export of data and logs, easy traceability, and traceable operation
- One-click backup and restore, easily cope with disaster recovery
- Support Electronic Signatures, with first/second level audit function, release compliance

Easy to Operate

- Application software developed based on Windows 10 operating system, user-friendly for operators
- Easy to switch between Chinese and English, and can customize other languages according to needs
- Support USB updates, client can update independently without returning to the factory, saving costs
- Support power-on self test, automatically determine whether internal communication, air source pressure, and control detection functions are normal
- Quick inlet/outlet connectors, plug and test

Accessory & Hardware

- Computer memory capacity 16G, smoothly-operation
- Configure 128G solid-state drive with large storage capacity and fast read and write capabilities
- Equipped with piezoelectric control components, accurate and fast pressure control, support temperature control
- Integrated valve terminal design, with few interfaces, high sealing performance, stable system and low leakage risk

Services

- Support 3Q documents drafting and validation, and provide comprehensive application technology training services
- Provide remote/on-site technical support

Instrument Parameters

Brand	Certitest™
Operating voltages & power input	100 ~ 240 V AC, 50/60 Hz 120W
Screen	10.1-inch high-definition full view color touch screen: 1280 * 800px
Size	500* 330* 270 mm (Length * Width * Height)
Weight	11.5 kg
Test pressure range	0~300 mbar
Pressure unit	mbar/Kpa/psi
Pressure display resolution	0.1mbar/0.01Kpa/0.1psi
Applicable scope	50mL~3000L 2D/3D Single-use bags
Pressure accuracy	Max ± 0.3 mbar
Pressure drop accuracy	Max ± 0.3 mbar
Detection limit	Can detect 30 µm equivalent aperture leakage holes
Temperature	0~40°C
Humidity	≤ 80% RH (No condensation)
External interface	RJ45 USB COM Serial port
Accessory information	Pressure reducing valve (standard) Barcode Scanner (optional)

Ordering Information

Product Name	Model	Specifications
Certitest™ Bag Integrity Tester	CTBA0 (Thermal Printer)	1 pcs
Certitest™ Bag Integrity Tester	CTBA1 (Dot Matrix Printer)	1 pcs



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* Specifications subject to change without notice.