



# FILTER INTEGRITY TESTER BUBBLE POINT TESTER

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# Introduction

SHUOBODA Filter Integrity Testers are special instruments of integrity testing for sterile filtration membrane and filter system, where the testing method and instrument design fully meet the requirements for relevant laws and regulations in GMP, EP, FDA and USP.

## Regulatory requirements

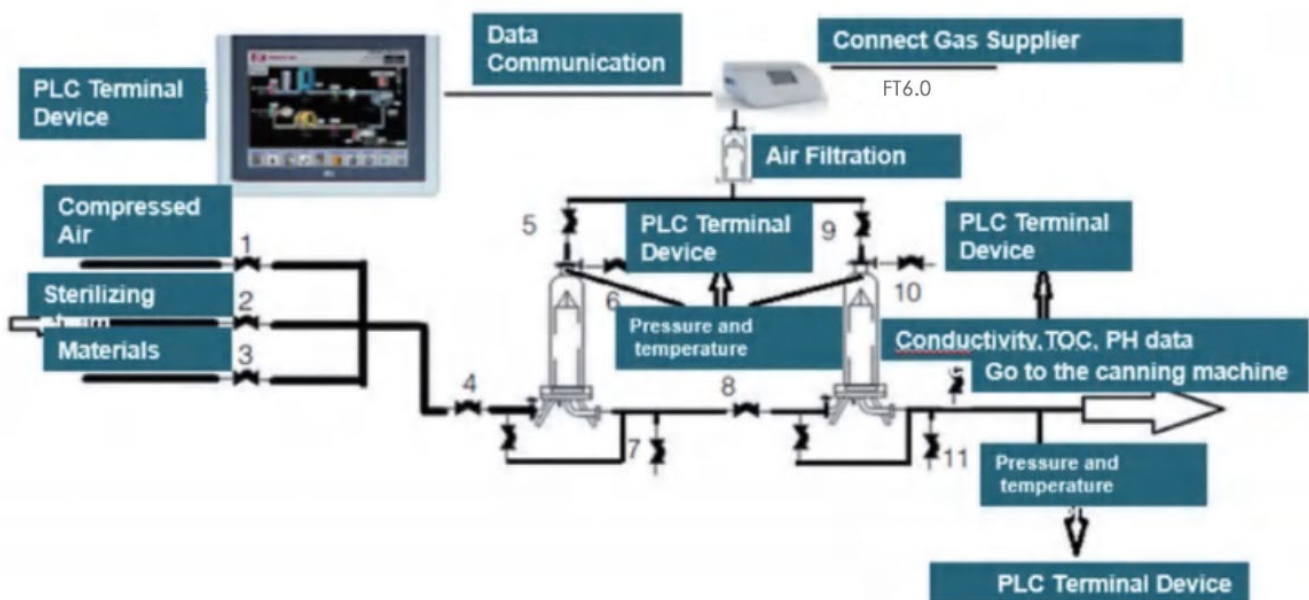
1. Chinese GMP and EU EP have made specific provision for the integrity testing of sterile filter on the test method, where the commonly used methods include bubble point test, diffusion flow test or pressure holding test. GMP regulates that the test is required after the use of sterile filtration. EP regulates that the test is required before and after the use, and at the same time EP regulates that the critical gas and air filter must be confirmed after use, while other filters must be tested on a regular basis.

2. According to Drug Manufacturing Quality Management Standard (revised in 2010) Article 310, two appendices of Computerized System and Confirmation and Validation are now issued, as the supportive documents for Drug Manufacturing Quality Management Standard (revised in 2010), effective as of December 1, 2015.

3. The requirements for electronic records and electronic signatures as specified in 21 CFR Part 11.

## Solutions

Connection diagram of online test



## Applied range

- 1. Disc Membrane:  $\phi 25\text{mm}-\phi 300\text{mm}$ ;
- 2. Standard Cartridge: 2.5" - 40"
- 3. Capsule & Mini Cartridge
- 4. Air filter test :2.5"- 40"
- 5. Ultrafiltration membrane

## Model Selection Guide

Model Function	FT8.0	FT6.5	FT4.0	FT1.2	Customer-made
Manual Bubble Point Test	√				Can be customized according to customer's actual require
Basic Bubble Point Test	√	√	√	√	
Extensive Bubble Point Test	√	√	√		
Pressure Holding Test	√	√			
Diffusion Flow Test	√	√	√		
Water( intrusion) Test	√	√	√		
Ultrafiltration Test	√	√			
Input Method	Chinese/English/Number	English/Number	English/Number	English/Number	
Electronic Signature	√	√			
4 level user management	√	√			
Users' quantity	1000 sets	80 sets			
Audit trail	√	operational			
Reservation Solution	1000sets	80sets			
Screen	Touch Screen	Touch Screen			
Historical Records	300000sets	5000 sets	500s sets	20sets	
Records Print	√	√	√	√	
Export Data	√	√			
Password lock screen after setting time	√				
More unit (mbar, kpa, psi, kgf/cm2)	√				
Blow sweeping inside tube	√				

# 1. FT-1.2 Filter Integrity Tester



## Features

- Online testing, does not interfere the downstream aseptic conditions
- It has system self-check function, with an error report function for the system tightness and wrong operation;
- It is microcomputer control of automatic detection, with many kinds of test functions such as bubble point scanning, fast bubble point test and pressure holding method;
- Real-time print of test results;
- It can be used to test the single core filter and multi-core filter.

## Performance Parameter

Model	FT-1.2
Power requirements / power	100 – 260 VAC, 50HZ, 120W
Operating pressure	100-8000 mbar (115psi);
sensor	U.S. imported sensors
unit	mbar
Self-check function	not support
Operating conditions	Ambient temperature: + 5 °C ~ + 40 °C; relative humidity: 10-80%
Dimensions (mm)	400 (L) × 240 (W) × 270 (H 1) × 220 (H 2)
Test function	Basic bubble point test; diffusion flow test (semi-automatic);
Test accuracy	Bubble point: ± 75mbar; Diffusion flow: ± 4%;
Test Range	Bubble point: 590-6900mbar Diffusion flow rate: 1-180ml / min
Scope of application	Symmetric and asymmetric membrane testing, needle filter, bladder filter, flat filter, cartridge filter (with 3 cores within 20 inches);
Audit trail	not support
authority management	not support
Pre-existing solutions	not support

Print function	built-in micro printer;
History records	20 sets
Record backup	not support
Display	3.2 ", single color
Serial connection	not support
Language	Chinese / English
How to use	Online / offline
Applicable environment	Grade B or above
weight	7.5KG
Audit trail storage	not support
operating system	Stand-alone mechanical nesting system
number of users	not support
Anti-backflow device	Matching
Dust and splash resistance	IP22

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## 2.FT-4.0 Filter Integrity Tester



FT Series Integrity Tester are designed for testing integrity of filters and filter systems. The test meets to verify the sterilizing filter in the FDA, the State Pharmacopoeia and GMP specification requirements. FT series Integrity Tester is compact, handy to use, and fully automated integrity test instrument, which performs bubble point, diffusion flow, enhanced bubble point, and water-based test for hydrophobic filters. The first domestic launch of integrity test for water-based test for hydrophobic filters to meet different customer needs.

### Main features

- The scientific electronic signature and classification to distinguish the responsibility easily, and to prevent false operation.
- Display of test data and curves in real time, monitoring the whole process of testing.
- Provides automatic printing set function, the user can operate simpler and more convenient.
- Water Based test (WH) for Hydrophobic Filter: using purified water as test liquid instead of IPA and Ethanol, thus it can avoid trace quantity of ethanol or IPA contamination when testing filters.
- The instrument can store 500 history record and curve.
- Advanced "water intrusion method" has solved the disadvantage that the hydrophobic filter can only be tested immersed in organic solvent.
- Advanced automatic control system, no need of manual adjusting pressure, to ensure the accuracy and precision.
- Real-time displaying test data and curve, monitoring the whole testing process.
- Dual-core operation, with PC software.
- Covers all of the functions of foreign similar instruments.
- More perfect user extension management, users can change the password according to need.
- Add the automatic protection function for tested filters, to avoid doing harm to the filter because of overvoltage testing.
- Provide automatic printing setting, and make the operation easier and more convenient.
- 5.7 " backlight digital LCD, display clearly.
- Testing the Diffusion flux of the disc membrane is of important significance for judging the characteristics of the membrane.

## Specifications

<b>Model</b>	<b>FT-4.0</b>
Power requirements / power	100 – 260 VAC, 50HZ, 120W
Operating pressure	100-8000 mbar (115psi);
sensor	U.S. imported sensors
unit	mbar
Self-check function	not support
Operating conditions	Ambient temperature: + 5 °C ~ + 40 °C; relative humidity: 10-80%
Dimensions (mm)	400 (L) × 240 (W) × 270 (H 1) × 220 (H 2)
Test function	Manual bubble point test; basic bubble point test; enhanced bubble point test; diffusion flow test; water immersion test;
Test accuracy	Net volume test: ± 4%; bubble point: ± 50mbar; diffusion flow: ± 4%; water immersion method: ± 0.01ml
Test Range	Bubble point: 590-6900mbar Diffusion flow rate: 1-180ml / min Water immersion: 0.01-30ml / min
Scope of application	Symmetric and asymmetric membrane testing, needle filter, bladder filter, flat filter, cartridge filter (with 3 cores within 20 inches);
Audit trail	not support
authority management	not support
Pre-existing solutions	not support
Print function	built-in micro printer
history record	500 sets of record storage
Record backup	not support
Display	5.7 ", TFT, Single color
Serial connection	RS232 serial port
Language options	Chinese / English
How to use	Online / offline
Applicable environment	Grade B or above
weight	7.5KG
Audit trail storage	not support
operating system	Stand-alone mechanical nesting system
number of users	not support
Anti-backflow device	Matching
Dust and splash resistance	IP22



### 3. FT-6.5 Filter Integrity Tester



#### Features

- Powerful functions, covering all the existing test methods for the filter integrity testing;
- The first domestic implementation of integrity testing for the ultrafiltration system;
- Scientific authority management design, password, permissions, authority grading, electronic signature, etc., in full compliance with FDA 21 CFR PART 11 requirements;
- It can create 120 groups of reservation solution, so the instrument is more simplistic and intelligent;
- With rich data interface, the instrument not only includes the standard configuration of digital and analog interface (RS232/USB), but also can customize a variety of industrial bus and simulation control port according to customer's need, in preparation for the intelligent system upgrade, such as the complete set of online automatic sterilization control system;
- Independent research and development team can carry out the design of specific solutions according to the needs of customers; Many years of field experience and strong professional services can not only ensure that the customers use the instrument at ease, but also can provide the technical support for the design and configuration of the filter system of the customers;



1-4 connector from left to right:

In the figure:

- 1) External tank interface : For connecting external tank;
- 2) Gas inlet: the gas inlet is connected to the gas source (such as gas pump, nitrogen bottle and etc.);
- 3) Gas outlet: the gas outlet is connected to the filter;
- 4) Exhaust port: the exhaust port is used for exhausting the gas in the instrument and the filter.

Back View of Integrity Tester

**Specifications**

Model	FT-6.5
Power Supply	100 -260 VAC,50HZ,120W
Operation Pressure	100-10000 mbar(1.5-145psi)
Pressure Unit	mbar
Operation Condition	Ambient Temperature: +5C - +40C; Relative Humidity: 10-80
Dimension (mm)	400 (Depth)*240 (Width)*270 (Height1) *220(Height2)
Function	Manual Bubble point Test; Basic Bubble Point Test; Extensive Bubble Point Test; Pressure Holding Test; Diffusion Flow Test; Water Intrusion Test; Ultrafiltration Membrane Test
Test Accuracy	Upstream Volume Test: + 4%; Bubble Point Test: s+50mbar Diffusion Flow Test: ≤ ±% ; Water Immersion: s+001m
Test Scope	BP: 100-8000mbar DF: 1-600ml/min WI: 001-100ml/min
Applied Range	Symmetric and asymmetric membrane test, needle filter, filter bag, flat filter, filter cartridge (big filter volume), ultrafiltration membrane, ultrafiltration column, a variety of irregular filters
Authority Management	User Name and Password to Login ,electronic signature to meeting the FDA 21CFR PART 11 requirements
Reservation Solution	120 sets
Audit trail (customization)	More subject logs
Print Function	Built-in printer;
Historical Records	More than1 5000 sets unlimited sets records
Records Copy	Support USB disk to export (Include test curve )
Display Screen	7-inch, color touch screen
Serial Connection	RS232/USB
Language	Chinese/English
Work Mode	Online/Offline

Other functions	One/two-dimension cods, Scanning gun; Lithium battery (customization)
Applicable Environment	Above D level
Weight	8KG
Anti-liquid level	Front IP65
Signal output	(4-20)MA,RS485,12V Alarm output



## 4. FT-8.0 Filter Integrity Tester



### Features:

- Powerful, covers all existing test methods regarding the integrity of the filter;
- Adopt optimized Linux system;
- Optimized test operation and shortened test time;
- 10-inch true-color touch screen design, friendly human-machine interface, simple, fast and reliable operation;
- To meet offline online testing, using pressure sensors with higher accuracy and lower deviation bands to improve the test accuracy of the instrument;
- Automatic self-test function, self-test of multiple performance functions of the instrument itself, after turning on the instrument has instrument self-test function, report faults in time.
- The first domestic company to implement the integrity test of an ultrafiltration system.
- Scientific user management, password login, user classification, electronic signature, etc., in compliance with GMP and FDA CFR 21 part 11, support multi-level user access permission settings, ensure data integrity, have comprehensive audit trail functions, and support manual or electronic signature;
- The instrument comes with an audit trail function, truly meets the requirements of data integrity;
- Can establish 1000 sets of pre-stored programs, which can fully meet multiple filter types and different test conditions in the field, and the instrument is more simple and intelligent;
- Increased the display curve of diffusion flow-pressure, realized the display and printing function of three curves, optimized the air intake control unit, and greatly increased the air intake speed and stability;
- Support USB disk data export function, which can not only export the original test data, but also the source data and configuration data, so that the data integrity requirements are perfectly reflected in the instrument; if single data can export PDF style directly;
- Can expand data communication and network interface requirements according to customer requirements, and support wireless communication functions;
- Optimize the structure of the instrument so that its dustproof and splashproof level reaches IP54, and use quick connectors (Staubli connectors can be used) to avoid incorrect

connection of the inlet and outlet pipes

- Test records and audit trails of the instrument both can be queried and exported;
- High-precision sensors and optimized algorithms can extend the gas path to 100m, make the upstream volume test more accurate, and the instrument can better meet the conditions of field use without affecting the test results;
- The built-in thermal printer avoids the risk of particle and ink contamination, and can keep the handwriting clear for more than 10 years under appropriate conditions;
- External interfaces can be customized according to customer requirements, which is convenient for customers' automated control and management;
- Using Chinese and English bilingual interface;
- Multiple pressure units can be switched flexibly (mbar,kpa,psi,kgf/cm<sup>2</sup>) ;
- 1000 user accounts, four level of user management, and each user's authority can be determined by default or customized methods, more flexible to meet the needs of on-site production and laboratory management, and perfect user information and authority configuration;
- Can test most up to 12-core 20-inch filter cartridges, which greatly improves the user's work efficiency;
- Rich data interface, the instrument not only includes standard digital and analog interfaces (RS232 / USB), but also can customize a variety of industrial buses and analog control ports according to customer needs to prepare for intelligent upgrade of the system, such as online full automation supporting bacteria control system;
- The independent R & D team can design specific solutions according to the needs of customers. Many years of field experience and strong professional services not only ensure that customers can use the instrument at ease, but also provide technical support for the design and configuration of customer filtration systems.

## Specifications

Model	FT-8.0
Power Supply	100–240 VAC, 50HZ, 120W
Operation Pressure	100-10000 mbar (150psi)
Unit	Mbar, kpa, psi, kgf/cm <sup>2</sup>
Operation Condition	Ambient Temperature: +5°C ~ +40°C; Relative Humidity: 10-80%
Dimension(mm)	480(Depth) ×300 (Width) × 210(Height1)
Function	Manual Bubble point Test; Basic Bubble Point Test; Extensive Bubble Point Test; Pressure Holding Test; Diffusion Flow Test; Water Immersion Test; Ultrafiltration Membrane Test
Test Accuracy	Upstream Volume Test: ± 4%; Bubble Point Test: ± 50mbar ; Diffusion Flow Test: ± 4% ; Water Immersion: ± 0.01ml
Test Scope	BP: 100-8000mbar DF: 1-900ml/min WI: 0.01-100ml/min
Applied Range	Symmetric and asymmetric membrane test, needle filters, capsule filters, flat filters, cartridge filters (within 12 cores and 20 inches), ultrafiltration membrane packages, ultrafiltration columns, various irregular filters
Audit Trial	Audit trail records can exportable and irreversible

Authority Management	User Name and Password to Login ,4 Authority Grades, meeting the FDA 21CFR PART 11 requirements
Reservation Solution(programs)	1000sets
Audit trail record storage	≥5 years storage
Anti-backflow(liquid) device	Customization
Number of users	1000sets
Operating System	Linux system
Operation Interface	Chinese and English bilingual operation interface
Dust and splash level	IP54, Front is IP65
Print Function	Built-in printer, can control on PC; choose subject
Historical Record	300000 sets records storage
Records Copy	Support USB disk to export (include test curve) ;
Display Screen	High definition 10-inch, color touch screen;
Serial Connection	RS232/USB/Support wireless connection;
Language	Chinese/English
Work Mode	Online/Offline
Applicable Environment	Above D level
Weight	10KG