

# Fully Automatic Filter Integrity Tester 3000 Series



EPC / PRODUCTS / APPLICATION / SOFTWARE / ACCESSORIES / CONSUMABLES / SERVICES

**Analytical Technologies Limited**

An ISO 9001 Certified Company

[www.analyticalgroup.net](http://www.analyticalgroup.net)

## ►► FILTER INTEGRITY TESTER

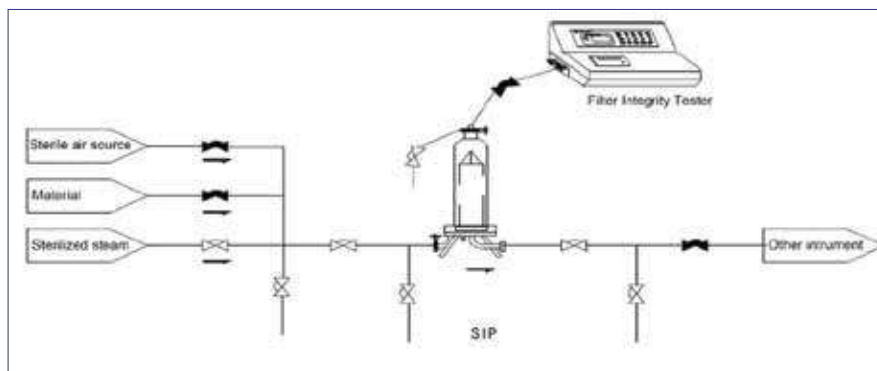
Filter Integrity Tester Integtest series are special instruments of integrity testing for sterile filtration membrane and filter system, where the testing method and instrument design fully meet the requirements for relevant laws and regulations in GMP, EP and USP.

### Regulatory Requirements:

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

### Solutions:

Connection diagram of online test



### Applied Range:

- Disc Membrane:  $\Phi 25\text{mm}$ - $\Phi 300\text{mm}$ ;
- Capsule & Mini Cartridge
- Ultrafiltration membrane
- Standard Cartridge: 2.5" - 40"
- Air filter test : 2.5" - 40"

▶▶ **Fully Automatic Filter Integrity Tester Integtest 3600**



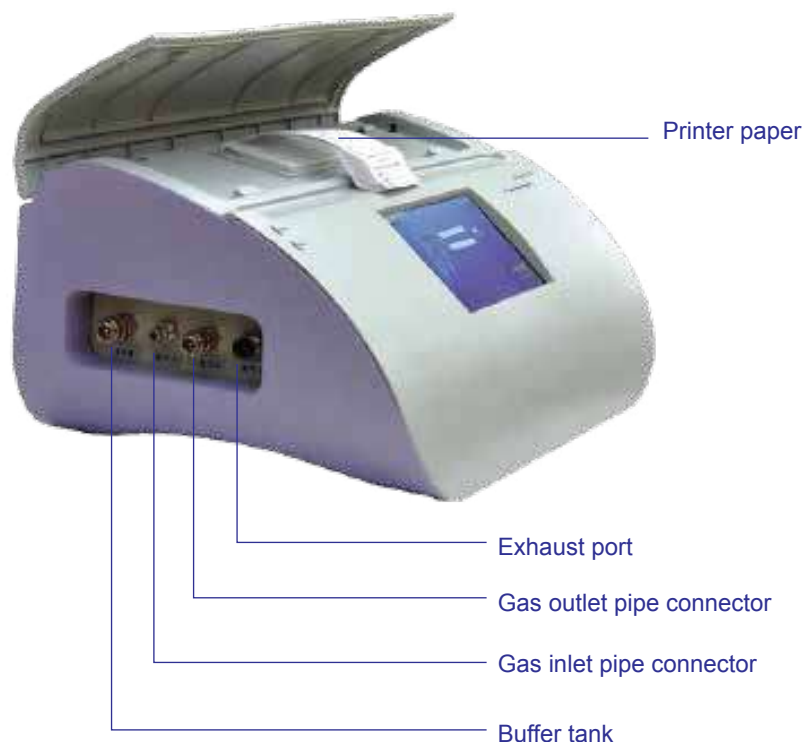
**Features**

- 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 P ART 11 requirements;
- It can create 80 groups of reservation solution, so the instrument is more simplistic and intelligent;
- It can carry out detection for up to 9-core 20-inch filter cartridge, greatly improving the work efficiency of the user;
- 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;

**Parameters:**

<b>Power Supply</b>	100 – 240 VAC, 50HZ, 120W Spare battery (Selection)
<b>Operation Pressure</b>	100-10000 mbar (145psi) ;
<b>Unit</b>	mbar
<b>Operation Condition</b>	Ambient Temperature : +5°C ~ +40°C ; Relative Humidity : 10-80%
<b>Dimension(mm)</b>	400 (Depth) *240 (Width) *270 (Height1) *220(Height2)
<b>Function</b>	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 : $\pm 4\%$ ; Bubble Point Test : $\pm 50\text{mbar}$ ; Diffusion Flow Test : $\pm 4\%$ ; Water Immersion : $\pm 0.01\text{ml}$
Test Scope	BP : 100-8000mbar DF : 1-600ml/min WI : 0.01-100ml/min
Applied Range	Symmetric and asymmetric membrane test, needle filter, filter bag, flat filter, filter cartridge (9 core within 20 inches), ultrafiltration membrane, ultrafiltration column, a variety of irregular filters
Authority Management	User Name and Password to Login ,4 Authority Grades, meeting the FDA 21CFR PART 11 requirements
Reservation Solution	80 sets
Print Function	Built-in printer
Historical Records	More than 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	English
Work Mode	Online/Offline
Applicable Environment	Above B level
Weight	7.5KG



▶▶ **Fully Automatic Filter Integrity Tester Integtest 3400**



**Features**

- Automatic air inlet design, to ensure efficiency and test accuracy at the same time;
- The instrument actually measures the up stream volume, so the test result is more accurate;
- Domestic first model to introduce water immersion method;
- Widely used by customers, with a high market share and cost performance;
- Automatic control of air intake level, with a smooth and safe air intake, to ensure the service life of filter.

**Parameters:**

Power Supply	100 – 240 VAC, 50HZ, 120W
Operation pressure	100-8000mbar (115psi)
Unit	mbar
Operation Condition	Ambient Temperature : +5°C ~ +40°C ; Relative Humidity : 10-80%
Dimension (mm)	400 (Depth) *240 (Width) *270 (Height1) *220(Height2)
Test Function	Manual Bubble point Test ; Basic Bubble Point Test ; Extensive Bubble Point Test ; Diffusion Flow Test ; Water Immersion Test
Test Accuracy	Upstream Volume : ± 4% ; Bubble Point : ± 50mbar ; Diffusion Flow Test : ± 4% ; Water Immersion Test : ± 0.01ml

Test Scope	Bubble Point : 590-6900mbar Diffusion Flow Speed : 1-180ml/min WI : 0.01-30ml/min
Applied Range	Symmetric and asymmetric membrane test, needle filter, filter bag, flat filter, filter cartridge (3 core within 20 inches)
Print Function	Built-in printer
Historical Records	500 sets
Display Screen	5.7" TFT, Single color
Serial Connection	RS232
Language	Chinese/English
Work Mode	Online/Offline
Applicable Environment	Above B level
Weight	7.5KG

### ►► Fully Automatic Filter Integrity Tester Integtest 3100



#### Features

- All English operation, mainly used for early exports;
- It has system self-checking 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



Power Supply	100 – 240 VAC, 50HZ, 120W
Operation Pressure	100-8000mbar (115psi)
Unit	mbar
Operation Condition	Ambient Temperature : +5°C ~ +40°C ; Relative Humidity : 10-80%
Dimension (mm)	400 (Depth) *240 (Width) *270 (Height1) *220(Height2)
Test Function	Pressure Holding Test ; Bubble Point Test ; Bubble Point Scanning Test
Test Accuracy	Bubble Point Test : ± 75mbar
Test Scope	Bubble Point : 590-6900mbar Diffusion Flow Speed : 1-180ml/min
Applied Range	Symmetric and asymmetric membrane , needle filter, filter bag, flat filter, filter cartridge (3 core within 20 inches)
Print Function	Built-in printer
Historical Records	20 sets
Display Screen	3.2” ,single color
Language	English
Work Mode	Online/Offline
Applicable Environment	Above B level
Weight	7.5KG

### Selection Guide

Model / Function	V6.0	V4.0	V1.1	Custom-made
Basic Bubble Point Test	√	√	√	Can be customized according to customer's actual require
Extensive Bubble Point Test	√	√		
Pressure Holding Test	√		√	
Diffusion Flow Test	√	√		
Water Immersion Test	√	√		
Ultrafiltration Test	√			
Input Method	English/Number	English/Number	English/Number	
Electronic Signature	√			
Reservation Solution	80sets			
Screen	Touch Screen			
Historical Records	more than 5000sets	500sets	20sets	
Records Print	√	√	√	
Export Data	√			

▶▶ **Glove Integrity Tester GT-3200**



**Introduction**

The on-line gloves Integrity Tester GT-3200 produced by Analytical Technologies is designed according to the positive pressure leak detector principle proposed by GB/T 25915.7- 2010/ISO 14644-7:2004, and it is a dedicated instrument to detect the gloves leakage. The simple and easy design won't need any additional equipment, no need to remove the gloves, with fast detection speed and high precision.

**Technical Parameters**

Working power supply	AC 220V 50Hz
Rated power	120W
Testing duration	2-8min
Pressure range	500-5000Pa
Response value	≤ 50Pa
Noise	≤ 50dB(A)
Working mode	Continuous work
External gas source	Compressed air, nitrogen, inert gas
Sealing pressure	≤ 0.8Mpa
Historical record	10000 groups
Print Function	Built-in Printer
Overall dimensions	370mm*220mm*210mm
Weight	7.5KG
On-line gloves tray	Custom-made



## Features

- The instrument adopts a small amount of frequent air inlet mode, with uniform inlet velocity in gloves, to avoid gloves deformation.
- It is equipped with color touch screen and humanized interface design, according to different test parameters, for automatic selection and matching, which can be most adaptive to the current gloves test procedure, date and time display;
- The authority management and electronic signature design is in line with the 21 CFR part 11 for certification requirements of electronic records and electronic signature;
- It is convenient to move, easy to carry and quick to connect;
- Historical records can be used for print, storage and query.

## ▶▶ Electronic Heater Jacket



To meet the requirements of the new version of GMP, our company has carried out independent research and development and designed the NEH series of electronic heater jacket; The instrument is composed of high performance composite heating material and control unit, and it has been widely used in biotechnology, pharmaceutical and electronics and other fields.

### **Application**

- The drying of condensate of breathing apparatus on the water storage tank in pharmaceutical industry;
- The temperature control of bioreactor and reaction kettle in biotech industry;
- The temperature control of the high viscosity material in the membrane separation;
- The temperature control of water system in electronics industry.

### **Main Features**

- It can fully meet the provisions of the new version of GMP;
- Modular design, which can facilitate the system upgrading and reconstruction;
- Good human-machine interface, which can facilitate the operation and control of personnel;
- Special protective performance, which can satisfy the uses in various environments;
- Customized insulation sheath, which can improve the heating efficiency and save the energy;
- Humanized design, which can greatly improve the security of the operation.

▶▶ **Servicing, Validation, Trainings and Preventive Maintenance :**

- Servicing : We have team of service engineers who can attend to any make of instrument promptly @the most affordable cost.
- Trainings :We also take up preventive maintenance to reduce downtime of instrument's Trainings.
- AMC's/CMC : We offer user training both in-House and at customer sites on instrument principles, operations, troubleshooting.
- Validations : We have protocols for carrying out periodic Validations as per GLP/ GMP/USFDA norms.
- Instruments : We offer instruments/Renting Services Modules like pumps, detector etc. on Rent.



▶▶ **About Analytical Technologies**

Analytical Technologies is synonymous for offering technologies for doing analysis and is the Fastest Growing Global Brand having presence in at least 96 countries across the globe. Analytical Technologies Limited is an ISO :9001 Certified Company engaged in Designing, Manufacturing, Marketing & providing Services for the Analytical, Chromatography, Spectroscopy, Bio Technology, Bio Medical, Clinical Diagnostics, Material Science & General Laboratory Instrumentation. Analytical Technologies, India has across the Country operations with at least 4 Regional Offices, 6 Branch Offices & Service Centers. Distributors & Channel partners worldwide.

▶▶ **Our Products & Technologies**

						
UV/VIS Spectro 2080+ Double Beam	Infra FTIR	Optima Gas Chromatograph 3007	Optima Gas Chromatograph 2979 Plus	Flash Chromatograph	Atomic Absorption Spectrophotometer	Liquid Partical Counter
						
Optical Emission Spectrophotometer	DSC/TGA	Semi Auto Bio Chemistry Analyzer	HEMA 2062 Hematology Analyzer	Micro Plate Reader/Washer	URINOVA 2800 Urine Analyzer	Total Organic Carbon 3800
						
Fully Automated CLIA	NOVA-2100 Chemistry Analyzer	PCR/Gradient PCR/ RTPCR	TOC Analyzer	Laser Particle Size Analyzer	Ion Chromatograph	Water purification system



▶▶ Regulatory compliances



▶▶ Corporate Social Responsibility

Analytical Foundation is a Nonprofit Organization (NGO) found for the purpose of:



# Analytical Foundation

1. Research & Innovation Scientist's awards / QC Professional Award : Quality life is possible by innovation only and the innovation is possible by research only, hence ANALYTICAL FOUNDATION is committed to identify such personalities for their contributions across various field of Science and Technology and awarding them yearly. To participate for award, send us your details of research / testing / publication at [info@analyticalfoundation.org](mailto:info@analyticalfoundation.org)

2. Improving quality of life by offering YOGA Training courses, Work shops / Seminars etc.

3. ANALYTICAL FOUNDATION aims to DETOXYFY human minds, souls and body by means of Yoga, Meditation, Ayurveda, Health Care, Awards, Media, Events, Camps etc.

▶▶ Reach us @



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