Intelligent Integrity Tester Certitest® 20 PLUS

The Certitest® 20 Plus ensures an accurate filter integrity testing with a reduction in test duration and complies entirely with the FDA 21 CFR Part 11 guidance on electronic records. Features as automation and network integration will save time and effort.

Designed to be used in cleanroom environment, the Certitest® 20 Plus has been developed and validated in accordance with the current GAMP guidelines. The Integrity tester includes the requisite controls and other features for operation in a 21 CFR Part 11 compliant environment. Data integrity controls, electronic records and signatures are available to support quality risk analysis.

Features

- High-level hardware to ensure data stability and accuracy
- Special structure design effectively prevents water from sucking back and self-check function
- Powerful windows system supports real-time display of test curves
- 128 GB hard disk drive capacity and 16 GB RAM
- Backup date can be exported on user demand
- Support multi-level user access settings to ensure data is integrated and safe
- Automated network function (optional)

Advantages

Solid

- The powerful Windows 10 system and stable algorithm make that each test point can be accurately displayed
- Complete audit trail can use single-level or two-level signature
- Strict authority management, in full compliance with FDA 21CFR PART 11

Reliable

- IP54 standard again dust and splashing of water
- The whole machine adopts Stäubli interface, which is convenient for operation and has better air tightness of each connection
- Complete self-check procedure after startup: including inlet pressure value display function, internal valve, internal pressure sensor, it can complete whether the whole system leak

Convenient

- Windows 10 operating system is very friendly to user's operation
- User can finish system updates independently, which can save the time and labour costs
- Equipped with network interface, which can realize automatic data upload to the server

Strong Hardware

- Pressure regulating valve: Advanced Festo piezoelectric pressure regulating valve with pressure feedback function can be used to automatically adjust the feedback pressure, which has the characteristics of high-pressure accuracy and fast response
- Pressure sensor: Digital pressure sensor made of ceramic substrate, with small temperature drift and pressure fluctuation, operational amplifier circuit has no effect on date test
- Solenoid valve: Certitest® 20 Plus features Burkert solenoid valve and customized valve, meanwhile with few interfaces and high sealing performance, the system is stable and not easy to leak

Automated Network Functions (Optional)

In addition to basic testing functions, Certitest® 20 Plus integrates advanced automated network functions, which can realize automatic archiving of all data and databases; and synchronize users, settings and multi-device management through the network framework, saving time; the device also supports Modbus TCP and OPC-UA protocols, and compatible with other automation network control protocols, such as PLC (programmable logic controller), SCADA system (supervisory control and data acquisition system), HMI (human-machine interface), etc.

Technical Parameters

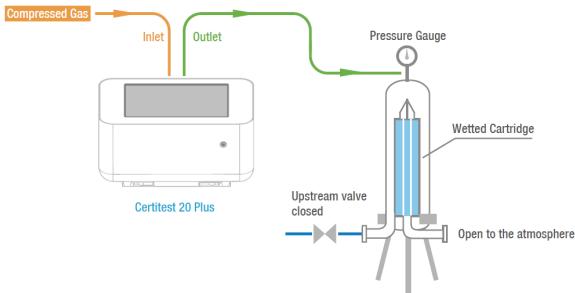|	
Dimensions	495 × 330 × 265 mm (L x W x H)
Weight	13 kg
Operating System	Windows 10
Hard Disk Drive	128 GB
RAM	16 GB
Screen	Type: Capacitance touch screen Size: 10.1 inch Screen resolution: 1280×800
Printer	Thermal / Needle dot matrix
Power Requirements	100 - 240 V/AC
Over-voltage Protection	Yes
Operating Environment	Temperature: 0 - 40 °C Relative humidity: 10 - 80 %
Max Inlet Pressure	3.000 to 8.000 mbar
Test Methods	Bubble Point Combined diffusion and bubble point Diffusion Water flow test Pressure decay
Measuring Ranges	Bubble Point: 100 - 7.000 mbar Diffusion: 0.1 - 1.000 ml/min Water flow test: 0.005 - 100 ml/min Pressure decay: 1 to 7.000 mbar
Measuring Accuracy	Bubble Point: ± 50 mbar Diffusion: ±4% or 2 ml/min, whichever is greater Water flow test: ±5% or 0.02 ml/min, whichever is greater Pressure decay: ± 5% or 3.5 mbar, whichever is greater
Resolution	Bubble Point: 1 mbar Diffusion: 0.01 ml/min Water flow test: 0.001 ml/min Pressure decay: 1 mbar
Pressure Units	Mbar / MPa / KPa / psi
Applicable Products	Membrane / Filter / Cassette / Hollow fiber
Export Data	Export tool: U disk Export file format: PDF
Data Capacity	Test data result storage: > 20.000 tests Test program storage: > 1.000 programs Active user storage: > 1.000 users
Audit Trail	Compliance to 21 CFR Part 11 and GAMP standard
Communication Ports	One Ethernet port (RJ45) One USB (standard)

Components

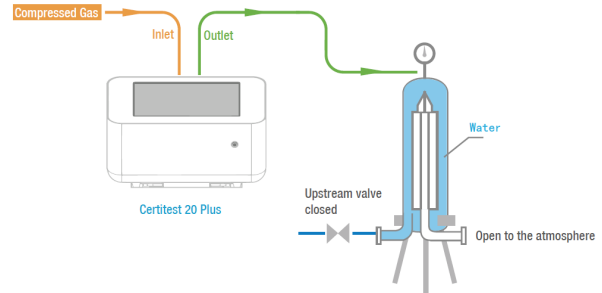|	
Certitest® 20 Plus Integrity Tester	Options: Thermal printer or Needle dot matrix printer
Inlet Gas Tube	Ø6x4 mm x 2 m with quick coupling (female/open end)
Outlet Gas Tube	Ø6x4 mm x 2 m with quick coupling (female/female end)
Quick Clamp	TC 50 mm to quick coupling (male end)
External Valve	External valve with quick couplings (male/female end)
Case for transportation	PP trolley case

Gas Line Connection of Integrity Test

GMP requires that sterile grade filter elements need to be tested for integrity. The Integrity Tester Certitest® 20 Plus, which is based on the GAMP (Good automated manufacturing practice) guidelines, fully complies with GMP requirements.
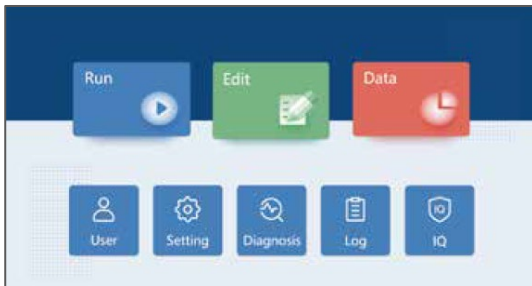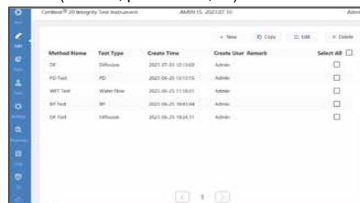
Bubble Point and Diffusion Test
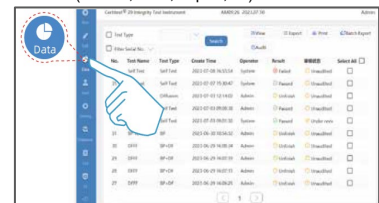

Water Flow Test

Main Interface

Run (select method, run test, curve, …)

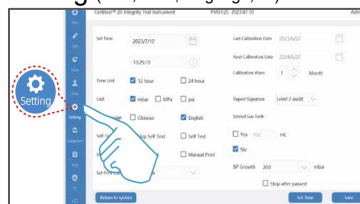
Edit (method, parameters, …)

Data (search, view, export, …)
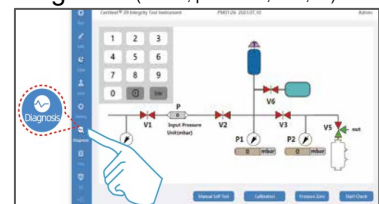

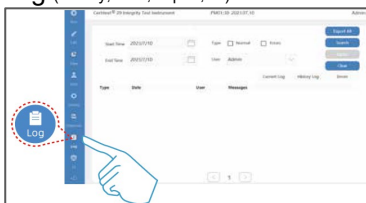### User (create, edit, delete, …)

Setting (time, units, language, …)

Diagnosis (valves, pressures, filter, …)

Log (history, user, export, …)

IQ (database, software, filter, back-up, …)

Contact Masterfilter: www.masterfilter.com