

# Certitest 20

## New Generation of Integrity testing



# Certitest™ 20

## All-New intelligent integrity tester

- The machine uses high tech hardware to ensure data stability and accuracy.
- Special structure design prevents water from drawing back into the instrument.
- Powerful windows system supports real-time display of test curves.
- 50G large memory capacity, backup data can be exported on user's demand.
- Supports multi-level user access settings to ensure data integrity and safety.

## Rigorous

- Powerful windows system and stable algorithm result in each test point being accurately displayed.
- Complete audit trail can use single-level or two-level signatures.
- Strict authority management, in full compliance with FDA 21CFR PART 11.

## Reliable

- IP54 standard against dust and water splashing.
- The whole machine adopts Stäubli interface, which is convenient for operation and has better air tightness for each connection.
- Complete self-check procedure during startup: including inlet pressure value display function, internal valve, internal pressure sensor.

## 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 accuracy and fast response.
- Pressure sensor: Digital pressure sensor made of ceramic substrate, with small temperature drift and pressure fluctuation.
- Solenoid valve: Certitest™ 20 features Burkert solenoid valve and customized valve, with few interfaces and high sealing performance, making the system stable and hard to leak.



## More Convenient

- Windows operating system is user friendly.
- Equipped with network interface, which can transfer data to the server.

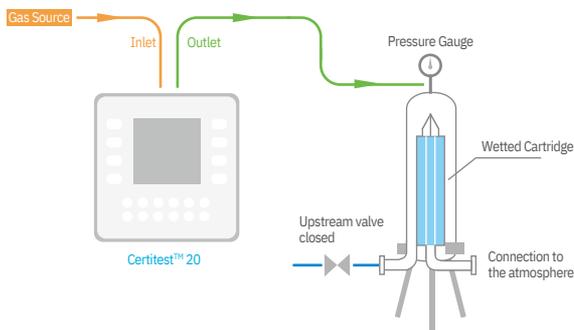
## Instrument parameters

Items	
Power	100-240V AC, 50/60Hz 120W
Display screen	10.1 inch high-definition color touch screen and resolution up to 1280*800
Test Range	Bubble point: 100-7000mbar Diffusion flow: 0.1-600ml/min Water intrusion: 0.01-100ml
Test Method	Bubble point test, Extensive Bubble point test(bubble point + diffusion flow), pressure hold test, diffusion/ forward flow test, water intrusion test;
Operation condition	Ambient temperature: 0°C ~ 40°C Relative humidity: ≤80%
Histry Record Function	50G large storage capacity easy to export or backup
Language options	English/Chinese

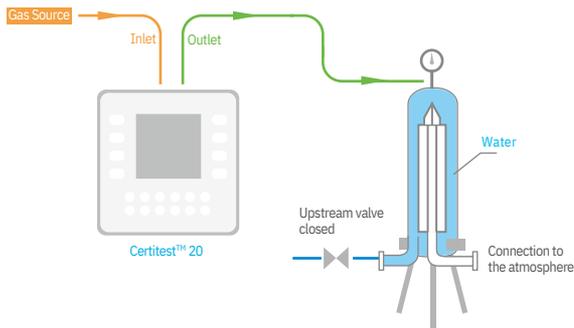
## Gas line connection of Integrity test

GMP requires that sterile grade filter elements need to be tested for integrity. Cobetter integrity Certitest™ 20, which is based on the GAMP (Good automated manufacturing practice) guidelines, fully complies with GMP requirements.

### A. Bubble Point, Diffuse Flow Test



### B. Water Immersion Test



#### Integrity testing Notes

1. Assure good gas tightness of the instrument and system;
2. Ensure that the filter element and the filter adapter are integral.
3. When performing Bubble Point and Diffusion Flow, ensure that the filter element is completely wetted; For Water Intrusion Test ensure filter element is has not been in contact with oil or alcohol and is dry.
4. Choose the right type of filter element, only absolute membrane filter elements can be used for integrity testing, such as: PES, PTFE, PVDF, NY66, etc.;
5. The gas source pressure must be at least 1000mbar higher than the value of bubble point.