Regulation Requirement

Good Manufacturing Practices (2010 version)
Sterile Medicinal Products

The integrity of the sterilised filter should be tested and recorded immediately after use by an appropriate method. The common methods include Bubble Point test, Diffusion Flow test or Pressure Hold test.

Testing Principle

Bubble Point Test

When the filter membrane is wetted by a proper liquid; the liquid will be held in the pore of the filter by surface tension and capillary forces. The minimum pressure required to force liquid out of the biggest pores is a bubble point pressure. The formula is as followed:

$$P = \frac{4 \times K \times Y \times \cos\theta}{D}$$

P *bubble point pressure*
Y *surface tension*
θ *liquid-solid contact angle*
K *shape correction factor*
D *pore diameter*

Diffusion Flow Test/ Pressure Hold Test

At the 80% pressure of the minimum bubble point,the gas flow rate is measured diffusing through the liquid-filled pores of a wetted membrane to downstream.

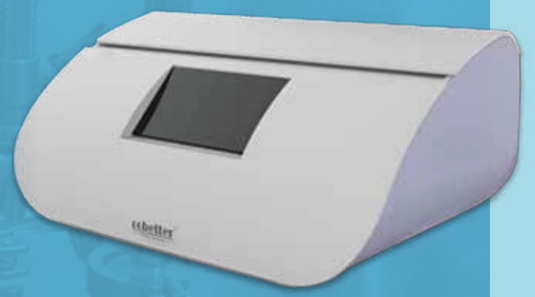
Water Intrusion Test

Under a low differential pressure, the smaller flow is squeezed into the filter membrane to form a certain flow rate despite of the preventing force caused by a hydrophobic membrane.

Integrity Test Instruments
CF 7.2 Integrity Test

Features and Benefits

- All Integrity Test Methods Are Present: Basic Bubble Point, Enhance Bubble Point, Diffusion Flow Test, Water Intrusion Test, Pressure Decay Test, and Manual Bubble Point
- HD 7" Color Touchscreen Allow for Easy Selection of Testing Parameters
- Testing Accuracy Has Been Significantly Improved By Using Advanced Digital Sensors and Brand New Hardware Design
- Dual Core CPU Features Include High Speed and Stability Which Ensure the Efficiency, Safety, and Stability of the Device While in Use
- Detailed Testing Data and Integral Testing Curve Provide An Objective Analysis Report
- User-friendly Display Design Make it Easy to Use Including Chinese/English Language Option
- Electronic Signature and User Classification Managing Function Help to Eliminate Erroneous Operation
- Optional Data Interface Includes Standard RS232/USB Port and Simulation Control Port
- Customized Communication Protocol Provides Automatic Centralized Management for Customers



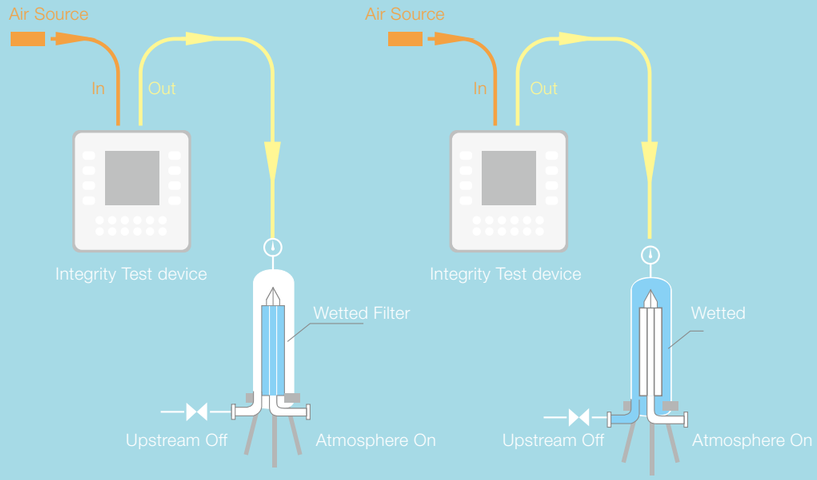
cobetter® filtration

Product Parameters

Required Power Supply	100-240V AC; 50/60Hz; 120W
Max. Operating Pressure	10000 mbar (150psi)
Min. Intake Pressure	100 mbar (1.5psi)
Dimension	450mm x 280mm x 190mm
Testing Range	Max. Testing Pressure: 100 - 8000mbar
Testing Methods	Manual Bubble Point / Basic Bubble Point / Enhanced Bubble Point / Pressure Hold Test / Diffusion Flow Test / Water Intrusion Test
Testing Accuracy	Net-volume Testing ± 2% ; Bubble Point : ± 25mbar ; Diffusion Flow : ± 2%
Operating Conditions	Ambient Temperature : +5℃ ~ + 40℃ Relative Humidity: 10 - 80%
Testing Time	Net-Volume Testing: 4 min ± 2min Diffusion Flow: 8 min ± 2min Basic Bubble Point: 10 min ± 2min Enhanced Bubble Point: 15 min ± 2min Water Intrusion Test: Set-Time ± 2min
Print Function	Line Printing ; Testing Parameters and Results ; Manual/Automatic Print
Storage Function	No Storage Limit ; Able to Use SD Card and U-Disk to Export Data
Display Screen	HD 7 inch Color Touchscreen
Signal Interface	Serial Port; RS232; USB
Language	English/Chinese

Please Note the Following

- Ensure that the Device and Testing System Are Sealed Tightly
- Ensure that the Connection Between the Cartridge End Cap and Housing Adapter Are Sealed Tightly
- Ensure that the Filter Cartridge is Prewetted for Bubble Point and Diffusion Flow Tests
- Ensure that the Filter Cartridge is Hydrophobic and Dry for Water Intrusion Test
- To Complete the Integrity Test, the Filter Cartridge Must Have Absolute Rating and Be of PES, PTFE, PVDF, or Nylon 66
- Air Source Pressure Must Be at Least 1000mbar Higher Than the Testing Value



A **Bubble Point Test** B **Diffusional Flow Test**