

Exact-Air™ II Automatic, Water-based Integrity Testing Option

Regulatory agencies require that bioprocessing equipment with critical sterilizing-grade vent filters, such as blow-fill-seal systems, autoclaves, freeze dryers, WFI vessels, production tanks, washing machines and fermenters, must be periodically integrity-tested. In fact, many biopharmaceutical manufacturers are increasingly testing filters before and after use. This production step requires a fast, reliable and validatable test method that is widely accepted by the industry and regulatory agencies. Unfortunately, many of the gas-based test methods used are highly sensitive to the effects of temperature. Additionally, the access to the vent filters is often difficult, due to their position in technical areas or on the dome of large tanks.

Automatic, water-based integrity test unit for hydrophobic vent filters used in:

Critical processes

- Lyophilisation (vacuum filter)
- Blow Fill Seal (BFS) machine (sterile air blow, sterile air shower, liquid transfer, plastic container blow filter)
- Gas and vent filter in aseptic filling operations
- Bioreactor gas inlet filter and exhaust

Long term applications

- Vent filter on WFI/purified water tank
- Vacuum filter on autoclave



In order to provide easy, safe and validatable integrity testing, we have developed the Exact-Air™ II System option to the Integritest® 5 tester. Based on Remote Volume Technology, the Exact-Air™ II System is an automatic device with an intermediate volume located between the filter to be tested and the testing device. This improves test accuracy and reproducibility under extremely critical temperature conditions.

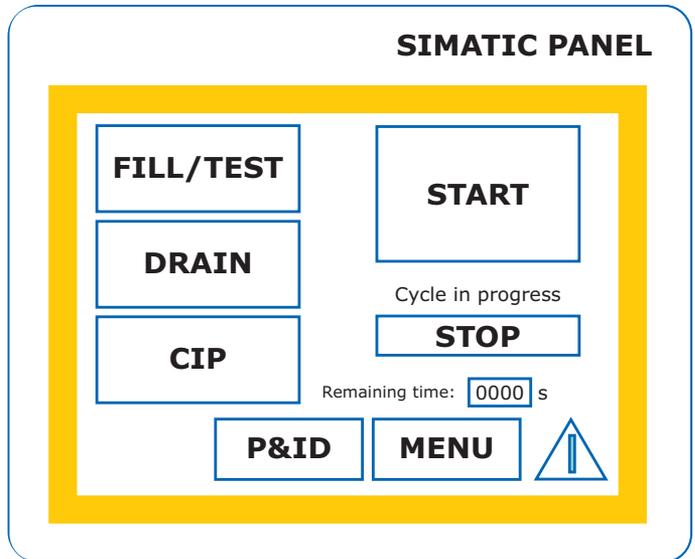
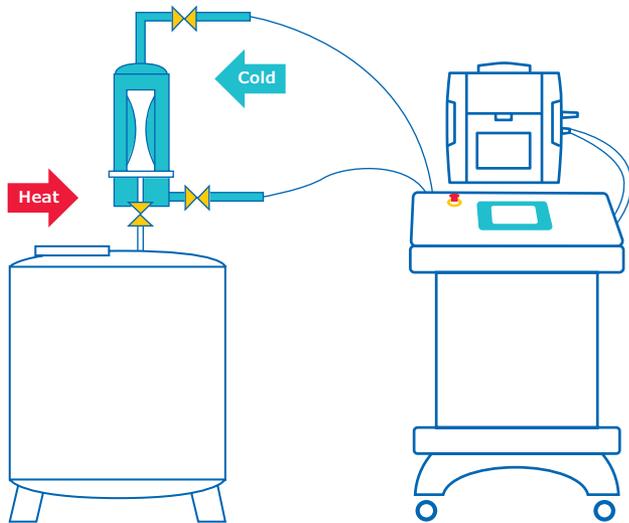
In the Exact-Air™ II System, both the filter and the tubing connected to the testing device are filled with water, minimizing the effect of temperature on the test. The gas volume, which is very sensitive to temperature, is housed separately in a protected area, inside the Exact-Air™ II System. This way, the remote gas volume can be maintained at constant room temperature, and the tests yield reliable results, even in the case of significant temperature changes.

Using an automatic and mobile system also improves ease and frequency of integrity testing since only the connection to the filter is required. Operators just need to launch the test sequence, using the touch screen control panel. All the valves are then automatically actuated by the Process Logic Controller (PLC).

HydroCorr™ Integrity Testing Method

The Exact-Air™ II System, paired with the Integritest® 5 tester, uses the HydroCorr™ method, a highly sensitive water-based integrity test for hydrophobic membrane filters. Due to its high heating capacity, water acts as a buffer to external temperature changes. Unlike gas, water does not expand or compress if a temperature variation occurs, resulting in more accurate test results. Based on the fact that water is repelled by the pores of hydrophobic filters, the HydroCorr™ test is conducted at a pressure below the water-intrusion pressure, after filling the upstream side of the filter with water. In addition, the HydroCorr™ test eliminates the use of alcohol, lowering handling requirements, safety concerns and material costs.

By using the HydroCorr™ test method, the Exact-Air™ II System offers users a unique opportunity to improve reliability, accuracy, reproducibility and frequency of air filter testing, even under challenging operating conditions. Since all connections and operations are made upstream of the filter, the system can be used to conduct pre-use integrity testing even after the filter has been sterilized, without compromising the sterility of the filter system. The Exact-Air™ II skid is designed to fulfill biopharmaceutical industrial requirements. It can be cleaned in place (CIP) easily for use in a Class C environment.



HydroCorr™ Test Benefits

No alcohol required

- Eliminates special handling requirements and safety concerns
- Avoids validation of alcohol elimination

Validatable test

- Cartridge specifications correlated to bacterial retention test
- Referee test with a calibrated hydrometrometer available for on-site IQ/OQ

Uses water as the test media

- No passage of test liquid downstream of the filter
- Filters can be tested in-line after SIP and before use, eliminating the risk of processing with a damaged filter

Exact-Air™ II System Benefits

Ease of use

- User-friendly software with touch screen display
- Control of filling, testing, draining and cleaning-in-place operations
- Ease of validation
- Encourages more frequent integrity testing
- Can be used for bubble point and diffusion test on hydrophilic filters

Remote volume control

- Designed for adverse temperature environment
- Can be used outside the clean room, using air or water

Complete validation

The validation of the Exact-Air™ II System is executed on-site according to cGMP standards. Provantage® services provide customized protocols and assistance in completing IQ/OQ/PQ validation efforts.

Industrial and sanitary design

- Mobile rugged frame, water- and splash-resistant (IP 54)
- Feed water tank (10 L or 20 L) can be removed for autoclaving
- CIP program
- Universal design can be used with different integrity-testing devices

Specifications

The Integritest® 5 tester has been qualified to the following performance specifications, under typical operating conditions:

Parameter	HydroCorr™ Range	Accuracy and Reproducibility
Accuracy	< 0.4 mL/min. ≥ 0.4 mL/min.	0.02 mL/min. +/- 5%
Reproducibility	< 0.4 mL/min. ≥ 0.4 mL/min.	0.04 mL/min. +/- 10%

Operating Parameters

Electrical	90 – 264 VAC, 50/60 Hz
Power	200 W
System inlet pressure	≥ 6 bar
Gas type	Nitrogen or air
Gas condition	Clean and dry
Storage temperature	0 °C to +40 °C (32 °F to 104 °F), dry
Operating temperature	4 °C to +40 °C (39.2 °F to 104 °F)
Humidity range	20% to 80%, non-condensing
IP rating	Front of the unit (including PLC panel): IP54 Electrical connections: IP40

Dimensions

Height (nominal)	1.014 m
Width (nominal)	600 mm
Depth (nominal)	600 mm
Weight	100 kg

Accessories

The following documentation and accessories are included with the Exact-Air™ II System:

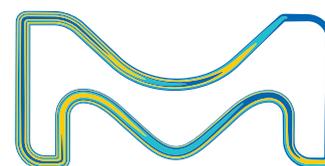
- User's Manual
- Mechanical drawings, P&ID and component data sheets
- Quality assurance records and certificates
- This product is currently CE marked and self declared compliant to the applicable European Union Directives. For details on which directives and compliance standards have been used, please refer to the products Declaration of Conformity
- Exact-Air™ II power cord 220V
- Flexible tubing, blue 6 mm x 20 m
- Flexible tubing, grey 6 mm x 20 m
- Bypass tubing
- Quick-connect RBE03 male and female for 6 mm tubing
- Water temperature measurement in testing tank*

*This option can be ordered separately.
See Ordering Information section for details.

Ordering Information

Description	Cat. No.
Exact-Air™ II System with 10 L water tank (without temperature sensor)	XEXAIR210
Exact-Air™ II System with 10 L water tank (with temperature sensor)	XEXAIR210T
Exact-Air™ II System with 20 L water tank (without temperature sensor)	XEXAIR220
Exact-Air™ II System with 20 L water tank (with temperature sensor)	XEXAIR220T
Exact-Air™ II IQOQ service	SSVIOQEXA

MilliporeSigma
400 Summit Drive
Burlington, MA 01803



For more information, please visit
EMDMillipore.com