

Filter Integrity Tester



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GVS filter integrity tester is a new-generation device signed according to the latest GAMP guidelines. It combines intelligent technology with high-sensitivity performance and features large-capacity accurate data recording, exporting, and printing functions. The tester's system is designed for greater stability, making it suitable for most cleanroom environments. The device is lightweight, compact, and ergonomic. Its 10-inch high-definition truecolor touch screen enhances usability and simplifies operation.

Additionally, the equipment complies with GMP guidelines and meets FDA 21 CFR Part 11 requirements for electronic records, and 21 CFR 820.72 for calibration.

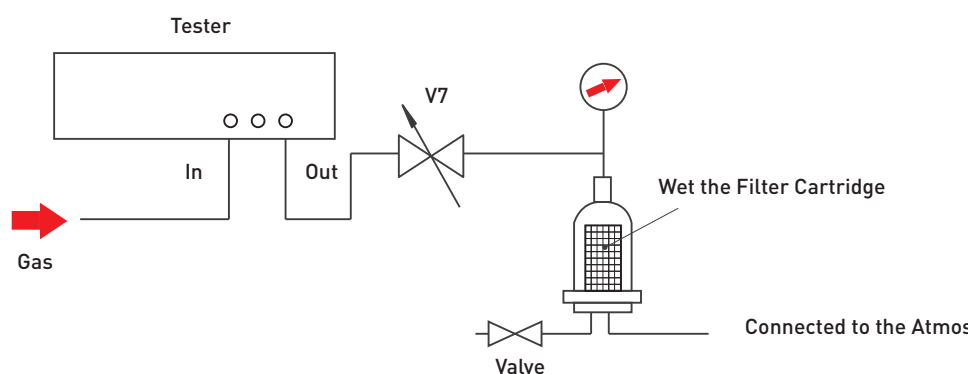


Diagram of Connection Between Tester and Filter

Product Code

ITMDG020

Features

◆ Innovation of Hardware Configuration

- The new high-performance industrial-grade dual-core design CPU significantly improves the data processing speed and capability to ensure the safety, reliability, and efficiency of the instrument during operation.
- The structure is optimized to achieve front IP65 level dust and splash protection, with superior internal sealing for reliable operation in wet environments, enhancing durability.
- The device features a 10-inch true-color touch screen design and a user-friendly interface, allowing for simple, quick, and reliable operation.
- The built-in thermal printer avoids the risk of particle and ink contamination, hardly produces any particles during the printing process, meets the FDA requirements for data recording, can maintain legible writing under the appropriate conditions for more than 10 years, and the printing paper outlet design is ergonomic.
- The instrument supports various industrial buses and analog control ports, tailored to customer needs. It features a rich data interface, including standard digital and analog interfaces (RS232/USB), and offers a USB disk data export function. This function exports not only the original test data but also source data and configuration data, enhancing flexibility.
- The equipment adopts compact and lightweight design, small size, light weight, less energy consumption, easy to carry.

◆ Flexible and Steady Operating System Design

- Optimize the Linux system, enhance the autonomy of the instrument, its stability has been fully verified, optimize test operation, and reduce the test time.
- With a perfect boot-up automatic self-check function and comprehensive diagnostic capabilities, the instrument ensures accurate operation.
- The scientific electronic signature system and user hierarchy management mechanism enhance responsibility division, reduce misoperations, and increase standardization and security in laboratory management.
- High-precision sensors and optimized algorithms can extend the gas path to 100m, make the upstream volume test more accurate, and the instrument can better meet the conditions of field use without affecting the test results.
- The operation interface displays the test data and process curve in real time, and monitors the test process throughout the process to ensure the accuracy and controllability of the test.
- Audit trail records can be exportable and be quickly queried record storage 5 years.
- Support database encryption export, which perfectly reflects the data integrity requirements of the instrument.
- Implemented an efficient calibration process to ensure accurate pressure and flow measurements within instrument test thresholds.

◆ Comprehensive Testing and Data Processing Capabilities

- Comprehensive and powerful, it covers all existing test methods for filter integrity, including the integrity testing of ultrafiltration systems.
- Advanced digital sensor technology is utilized to significantly enhance the accuracy and consistency of test results, ensuring precise evaluation of the performance indicators of the tested filter.
- Conduct both offline (with battery) and online testing using pressure sensors that provide higher accuracy and lower deviation.
- The tester provides detailed and comprehensive test data, along with complete test curves that accurately reflect various performance indicators of the filter being tested, delivering precise analytical information to users.
- Up to 12 20-inch filters can be tested, which greatly improves the user's work efficiency.

◆ Secure and Reliable Data Storage Capability

- Historical records can store up to 300,000 test results, support quick query and generate PDF test reports.
- "Reservation Solution (programs)" design simplifies operation, can establish 1000 sets of pre-stored programs, and fully meets multiple filter types and different test conditions in the field, which is more intelligent, simpler, and accurate.
- User-level management allows for the creation of up to 1,000 user accounts, which can be easily queried.
- The information base can store 5000 fault information and prompt information, and can be quickly queried.

Parameters

Dimension

- Weight: 8.2kg
- Depth x Width x Height:
350mm x 352mm x 178mm
(13.78in. x 13.86in. x 7.01in.)

Filter Test Methods

- Bubble point Test
- Extensive Bubble Point Test
- Pressure Holding Test
- Diffusion FLOW Test
- Water Intrusion Test
- Ultrafiltration Membrane Test

Function Test Methods

- Self-check
- Flow Check Test
- Printer Test
- Network Test

Other Functions

- Anti-backflow device (optional)
- Cleaning function
- Test program transfer functionality
- Set the transfer function
- Rights management transfer function
- Test result output function
- Backup function

Pressure Options

- mbar
- kPa
- psi
- kgf/cm²

Communication Ports

- USB
- RS232C
- Ethernet
- Wireless Ethernet Network (optional)

Test Accuracy

- Upstream Volume Test: $\pm 4\%$
- Bubble Point Test; $\pm 50\text{mbar}$
- Diffusion Flow Test: $\pm 4\%$
- Water Intrusion Test: $\pm 0.01\text{ml}$

Test Range

- Bubble Point; 100-8000mbar
- Diffusion Flow: 1-1000ml/min
- Water Intrusion: 0.01-100ml/min

Electrical Supply

- Voltage: Automatically adjusted between 100-240V AC, external power supply (including EU, UK, US, AU adaptors)
- Input Frequency: 50/60HZ
- Charging Power: 120W
- Spare Battery (optional)

Operation Conditions

- Operating Pressure: 100-10000 mbar (150psi)
- Dust and Splash Level: IP54, Front is IP65
- Operating Temperature: $+5^{\circ}\text{C}$ to $+40^{\circ}\text{C}$
- Storage Temperature: -20°C to $+70^{\circ}\text{C}$ Relative Humidity: 10-80%
- Applicable Environment: Above D level
- Usage: Online/Offline (with battery)

Display Screen

- Size: 10.1 inch
- Resolution: 1024x768 pixels
- Features: High definition, color, bright background, touch screen

Information Records

- Reservation Solution(programs): 1000 sets
- History Record Function: No limit on the number of records stored
- Result Backup: Support U disk export data (including test curve)

Audit Trial

- Audit trail records can exportable and irreversible
- Record storage 5 years

Printer

- Audit trail records can exportable and irreversible
- Record storage 5 years

User Management

- Authority Management: Login level 4 permission in full compliance with FDA 21CFR PART 11
- Number of Accounts : 1000

Operating System

- Linux System (more stable than Windows)

Applied Scope

- Symmetric and asymmetric membrane test, needle filters, capsule filters, flat filters, cartridge filters, ultrafiltration membrane packages, ultrafiltration columns, various irregular filters

Calibration Item

- Calibration limits for pressure sensors and flow measurements

Signal Output

- [4-20]mA, RS485, 12V alarm output

