PALL Life Sciences

USD 2555

Palltronic® Flowstar IV

Filter Integrity Test Instrument

Filtration. Separation. Solution.SM

The Next Generation Filter Integrity Test Instrument

The Palltronic® Flowstar IV filter integrity test instrument is the result of Pall's long experience and expert technical knowledge in producing successful, top-quality test instruments. The Flowstar IV instrument introduces many new features, enabling users to test even more filters, reliably and reproducibly, in less time, saving time and money.

Lightweight, compact and ergonomic, the instrument features an enhanced, touch screen and user-friendly interface, requiring minimal training of operators.

Improved pressure/flow calibration preserves measurement accuracy while ensuring faster tests.

The latest networking capabilities are also incorporated for easy integration within a network, and the optional WLAN adaptor, USB connectivity plus an extended range of remote control/automation options enable even greater flexibility.

Developed in accordance with GAMP (Good Automated Manufacturing Practices) guidelines, and offering full compliance with 21 CFR Part 11, the Palltronic Flowstar IV instrument is supported by an extensive qualification documentation package, including guides for Installation and Operational Qualification (IQ/OQ)

Volume-Dosed Flow Measurement

The Palltronic Flowstar IV integrity test instrument is a highly sensitive measurement instrument for gas pressure and flow. Highly sensitive pressure sensors are available from many sources, but highly accurate gas flow sensors for a measurement range of 0.01 to 1000 mL/min are not. However, such a range is required for an integrity test in pharmaceutical production.

The Palltronic Flowstar IV integrity test instrument utilizes a method that was developed by Pall for use in integrity test instruments and patented as “volume-dosed flow measurement technology”. The current version of this flow meter consists of a valve block with three high precision pressure sensors, a pressure regulator, three defined volumes and a specific control algorithm.

One pressure sensor constantly measures the gas pressure of the filter system, while the other two sensors are used to verify the pressure of the internal volumes. As gas diffuses through the wetted filter (as in the Forward Flow test) the integrity test instrument constantly refills gas into the filter system. The amount of gas that is dosed in the defined volumes is accurately determined and equals the diffusion rate of the filter.

In Pall’s standard calibration procedure, the measurement part of the instrument is calibrated as a whole using accurate flow references. This confirms that all flow measurement components are working correctly and produce accurate results.

The benefits of this technology are:

- Integrity test is much faster, as upstream volume does not have to be measured
- The flow measurement loop is directly calibrated
- The flow rate does not need to be calculated out of volume determination and pressure decay measurement
- The Forward Flow and Water Intrusion Tests are run at constant pressure over the complete test time

The instrument offers full compliance with regulatory demands on filter integrity testing.

Accuracy and Calibration

The requirements on calibration are described in 21 CFR 820.72 and the European GMP guide, chapter 4. Pall has established calibration procedures to verify pressure and flow measurement which are qualified over the full measurement range of the instrument. Palltronic Flowstar IV integrity test instruments can be calibrated in a Pall-qualified laboratory or within your manufacturing site. Our traceable references allow us to confirm an accuracy of 0.33% for pressure measurement and of 3% for flow measurement, in all parts of the world.

Test Capabilities

Automatic Self Test

When the Palltronic Flowstar IV instrument is switched on, an automatic self test is run. This test can be repeated any time during operation of the instrument. During the self test, the instrument does a full diagnosis of its functions:

- Inlet gas pressure
- Function of the internal valves
- Function and signal of the internal pressure sensors
- Function of the internal pressure regulator
- Check on internal leaks
- Internal communication
- Integrity of the operating system and the software
- Data integrity of user lists, test programs and test results

The full result of each self test is saved and can be printed at any time. The combination of the self test and a regular calibration and service guarantee a continuous reliable operation of the instrument for many years.

Auto Test Time

The Auto Test Time function is available for the Forward Flow Test and the Water Intrusion Test. It has been developed and validated to shorten test times while maintaining the reliability of the result. The results of a Forward Flow or Water Intrusion test are interpreted by this algorithm during the test.
If the measured flow rate is evidently below the limit, and the measurement is stable, the instrument will interpret this as a passed test. The filter integrity test times can be shortened by more than 50% without any risk of false pass results.

Forward Flow Test

The Forward Flow test is the filter integrity test that is most common in pharmaceutical manufacturing. All major filter suppliers recommend the Forward Flow test as the method of choice for integrity testing of filter cartridge or capsule assemblies.

The Palltronic Flowstar IV instrument performs the Forward Flow test quickly and with extreme accuracy. The volume dosed flow meter can perform a Forward Flow test in a range of 0.1 to 1000 mL/min within minutes and with an accuracy of 0.1 mL/min or 3%.

The features of the Forward Flow test function are:

- The test is performed at constant pressure
- A volume dosed flow sensor is used
- Progress of the test is shown on screen while other operations can be performed on the instrument
- Validated Auto Test Time function to shorten test times

All relevant data for the test result is stored on the instrument and can be printed or transferred to a network location.

The benefits provided by these features compared to other integrity test instruments are:

- No need for time consuming volume measurement before testing
- No loss of accuracy due to inexactly determined volume
- Filters with asymmetric membranes can be tested more reliably at constant pressure
- Test times are very short, usually below 10 minutes
- Progress of the test can be monitored in real time
- Unstable test conditions are detected
- Accurate and reproducible test results are obtained

Water Intrusion Test

The Water Intrusion test is widely spread in pharmaceutical manufacturing to perform inline integrity testing of sterilizing grade gas filters with hydrophobic membranes. The Palltronic Flowstar IV instrument is specially made and validated to perform this very sensitive water intrusion test. The water intrusion test profits from the features and benefits of the Forward Flow test.

The additional benefits are:

- The undefined upstream volume has no influence on the accuracy of the test result
- The change in water level during the test does not influence the accuracy of the result
- The very sensitive volume dosed flow measurement technology accurately measures a water flow as low as 0.03 mL/min

Bubble Point Test

The Palltronic Flowstar IV integrity test instrument can determine the Bubble Point of a filter. The gas flow rate is measured at increasing pressure steps, and the Bubble Point is the transition of diffusive gas flow through wetted filter pores to bulk gas flow through de-wetted filter pores.

The features of the Bubble Point test are:

- A gross leak test is performed at the beginning of the test phase
- Gas flow is measured very fast in incremental steps
- Full Bubble Point curve is determined
- All test parameters are documented with test results

The benefits of this are:

- False pass results due to insufficient filter wetting are avoided
- False pass results in filters with small defects are avoided
- Test result is obtained very quickly
- Reproducible test results are obtained
- All types of membranes from small disc to cartridge can be tested

Combined Forward Flow and Bubble Point Test

The instrument can also determine the Forward Flow and Bubble Point value in a single test. The test procedure has been refined to shorten test times of the combined test without compromising the accuracy of the result.

Leak Test and Pressure Decay Test

The leak test can be used to test for leaks in filter systems or processing systems. It is not an integrity test, since there is no correlation to bacterial retention. The leak rate can be measured either as pressure drop (mbar/min), using the Pressure Decay Test or as flow rate (mL/min), using the Leak Test function of the instrument. Possible applications are:

- Diagnosis of filter systems after failed tests
- Installation check on filter systems or processing systems
- Leak tests on processing equipment during qualification

The Palltronic Flowstar IV integrity test instrument can perform all kinds of gas pressure tests. It is capable of performing those tests reliably and accurately and of providing reproducible results.

Unique Design

The Palltronic Flowstar IV instrument is a highly sensitive measurement instrument which is designed for use in all locations including the laboratory or inside the process suite or cleanroom.

Splash and Dust Proof

The use of powder or liquid chemicals in close proximity to an instrument is very common in a laboratory. The Palltronic Flowstar IV integrity test instrument has been tested to be splash and dust proof (IP54 rated). The outside of the instrument can be easily cleaned.

Cleanroom Environment

The instrument has been specifically designed to be used in any kind of cleanroom. There is no cooling fan that would disturb the air in a cleanroom. The internal printer is a thermal printer, generating almost no particles during printing. All external components are compatible with common cleaning liquids to reduce surface bioburden.

User Interface

The user interface is one of the major benefits of the Palltronic Flowstar IV integrity test instrument. The 10.4 in. (264 mm) color touch screen displays all functions that are needed for routine use of the instrument. Use of the instrument is straightforward and intuitive, and all the most common language options are available.

The menu has been optimized for routine use of the instrument, and all relevant parameters are displayed on the screen at all times. This allows the operator to easily access the required functions and to avoid mistakes that can occur if relevant data is spread over too many screens.

Operators who are trained users of existing Palltronic Flowstar instruments can use the Palltronic Flowstar IV integrity test instrument without further training.

Electronic Data Handling and Remote Control

The Palltronic Flowstar IV integrity test instrument has been designed to be used in a facility that complies with 21 CFR Part 11 for electronic storage of data.

There are three levels of access - Operator, Supervisor and Administrator. Operators have access to the test functions only, Supervisors can also modify test programs, and Administrators have full access to all functions and can also perform changes to the system configuration or to the access management.

The instrument can be used in two different modes to limit access to the protected functions. When the password controlled access is activated, the supervisor level and the administrator level are each protected by a password. In the login-controlled access mode, each user needs to login to the instrument before having access to its functions. The level of access can be defined for each person separately.

All the changes that are performed on the system or the programs are recorded in the audit trail. The test results can be electronically signed. Configuration, test programs, user data and test results can be easily exported to a computer network or an external flash drive.

Interface Connections

A number of connections at the back of the instrument allow interfacing with different systems. The USB port can be used to connect an external printer, mouse, keyboard, barcode reader or a flash drive. The serial ports can be used to interface with other Palltronic instruments or a PLC.
An ethernet port and a wireless network adapter can be used to link to a computer network. There are also additional ports for an external pressure sensor and an external vent valve on the side of the instrument.

Remote Operation

The Palltronic Flowstar IV integrity test instrument is equipped with a number of interface connections, and it can be connected to a PLC using the internal adapters. The integrity test instruments can then be fully controlled by the PLC, and adapters are available for all common communication protocols.

The instrument can also be connected to a computer network using the on-board ethernet port or the on-board wireless LAN adapter. Data can be transferred to the network in a controlled manner. The instrument can also be fully controlled from a SCADA system using the available OPC server protocols.

Remote Printing

Instead of using the internal printer, the print data can be directed to an external printer. Either a printer that is connected directly to the instrument via the USB port or a network printer can be used. The instrument is also capable of generating the printout as a file, using common data formats, such as PDF or XML or both.

Service and Support

Qualification

The instrument has been designed following the GAMP guidelines. The Palltronic Flowstar IV integrity test instrument is classified as a software category 3 and hardware category 1 instrument in accordance to GAMP 5. The components have been carefully selected for long term availability and reliable functionality. All relevant functions have been thoroughly validated. A description of the main functions and an operational qualification (OQ) are usually sufficient to qualify the instrument. An extensive documentation package with all the relevant documents is available.

Calibration and Service

The Palltronic Flowstar IV integrity test instrument can be calibrated at any Pall-certified service center or directly on site. Calibration equipment, procedures and training are available. Pall recommends calibration of the instrument at least once a year, with a full service after three years.

There are Pall-qualified service centers throughout the world. Please contact your local representative to find the most suitable way to calibrate and service your instruments.

All components used in the Palltronic Flowstar IV integrity test instrument have been carefully selected and tested for quality.

Training

On-site training is also available for the Palltronic Flowstar IV integrity test instrument. Training is also available on instrument validation, filter validation, integrity testing basics and regulatory requirements. We are happy to assist you with a custom-designed training program.

Options

The Palltronic Flowstar IV integrity test instrument is available in three different versions. The basic version is designed as a standalone integrity test instrument. The standard version offers all the networking options and can be fully automated. The wireless version includes an internal WLAN adaptor.

Features of the Palltronic Flowstar IV Instruments

	Basic	Standard	Wireless
Part Number	**FFS04B**	**FFS04S**	**FFS04R**
Optimized user interface	✔	✔	✔
Multitasking menu	✔	✔	✔
Designed for use in highly demanding pharmaceutical production	✔	✔	✔
Suitable for use in cleanroom	✔	✔	✔
Splash and dust proof (IP54)	✔	✔	✔
Self test	✔	✔	✔
Volume dosed flow measurement	✔	✔	✔
Calibration for flow and pressure	✔	✔	✔
Basic integrity test capability (FF, BP, combined FF/BP, WIT, Leak Test, Pressure Decay Test)	✔	✔	✔
Password access control	✔	✔	✔
USB port (keyboard, mouse, printer, flash drive)	✔	✔	✔
Printing to USB printer	✔	✔	✔
PDF printing to USB flash memory	✔	✔	✔
Serial port	✔	✔	✔
Login-based access control		✔	✔
Electronic signatures in compliance with 21 CFR part 11		✔	✔
Configuration of test parameters		✔	✔
Configuration of main menu		✔	✔
Fieldbus◆ adapter for automation		✔	✔
OPC server for automation		✔	✔
Ethernet port		✔	✔
Printing to network printer		✔	✔
PDF printing to network drive		✔	✔
WLAN adapter			✔

Technical Specifications

Physical Dimensions

- (nominal) Weight: 10 kg (21.6 lbs)
- Width, height, depth: 348 mm x 205 mm x 483 mm (13.7 in. x 8. in. x 19 in.)

Filter Tests

- Forward Flow Test
- Bubble Point Test
- Combined Forward Flow / Bubble Point Test
- Water Intrusion Test

Other Tests

- Leak Test (Flow measurement based for volume < 50 L)
- Pressure Decay Test (Leak test for volumes up to 200 L)

Function Tests

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

Other Functions

- Cleaning function
- Test program Transfer function
- Configuration Transfer function
- Access management Transfer function
- Test result export function
- Backup function

Language Options

- English, French, German, Italian, Spanish, US English, Japanese
- Language files on the instrument are constructed such that other languages may be added as necessary.

Communication Ports

- USB
- RS232C
- Ethernet
- Wireless ethernet network (optional)

Accuracy

- Forward Flow test: ± 3% of value or ± 0.05 mL/min, whichever is the greater
- Water Intrusion Test: ± 3% of value or ± 0.02 mL/min, whichever is the greater

Measuring Range

- Forward Flow Test: 0.1 - 1000 mL/min
- Water Intrusion Test: 0.03 - 50 mL/min
- Bubble Point Test: 400 - 6500 mbar (5.8 - 94 psi)
- Leak Test: 0.1 – 1000 mL/min
- Pressure Decay Test: 50 – 6500 mbar

Resolution

- Forward Flow Test: 0.1 mL/min (0.01 mL/min for flows below 10 mL/min)
- Water Intrusion Test: 0.01 mL/min
- Bubble Point Test: 50 mbar (0.7 psi)
- Pressure Decay Test: 1 mbar

Calibration

The calibration of the Palltronic Flowstar IV instrument includes a calibration of the pressure transducers and the flow measurement calibration limits:

- Pressure measurement: ± 0.33% of full scale
- Flow measurement: ± 3% of measurement

Electrical Data

- Voltage: automatically adjusted between 100 - 240 V AC
- Input Frequency: 50 Hz / 60 Hz
- Power: typically 75 W (peak 150 W)
- Fuse: 3.15 A slow blow
- External Vent Valve: 24 V DC

Screen

- Size: diagonal 264 mm (10.4 in.)
- Resolution: 1024 x 768 pixels
- Features: Color, illuminated background, adjustable contrast, touch screen

Pneumatic Connections

- Compressed air inlet: Stäubli® Nipple
- Compressed air outlet: Stäubli Coupling
- Vent: Hose connection 8 mm outer diameter

Pneumatic Specifications

- Maximum gas supply pressure: 8000 mbar (116 psi)
- Minimum gas supply above test pressure (Standard):
  - Flow range: 0.01 - 150 mL/min 1000 mbar (14.5 psi)
  - Flow range: 150 - 1000 mL/min 2000 mbar (29.0 psi)
- Test pressure range: 50 - 6500 mbar (0.7 - 94 psi)

Internal Printer

- Thermal printer
- Printer resolution: 832 dots/line
- Lifetime of printout: >10 years depending on storage conditions
- Printer Speed: 12 mm/sec (0.5 in./sec) printout with graphic
- Paper Width: 112 mm (4.4 in.)
- Paper roll diameter: 50 mm (1.9 in.)

External printing function

- External USB printer
- External Network printer (A printer type HP P1505N or compatible is recommended. The printer should be capable of handling the printer language PCL5e)
- Virtual printing to PDF or XMF file format

Environmental Conditions

- Splash Proof: IP54
- Operating Temperature: +5 °C to +50 °C
- Storage temperature: -20 °C to +70 °C
- Humidity: 95% RH (no condensation)

Operating System

- Linux (The source code which falls under the GNU General Public License (GPL) is stored on the USB flash disk supplied with the instrument).

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

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