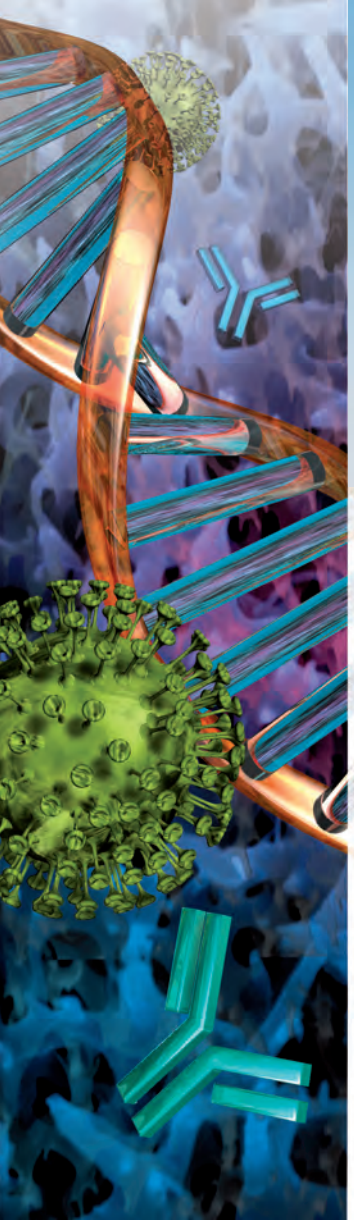
PALL Life Sciences

USD 2834

The Palltronic® AquaWIT IV Filter Integrity Test System



Accurate, reproducible, reliable automatic integrity testing of liquid or gas filters

Features

- Fully automated test preparation and integrity test cycle for hydrophobic filters
- Fully automated filter wetting and testing sequence for hydrophilic filters
- Automated control of the key parameters that influence Water Intrusion Test results
- Designed for use in GMP environments subject to controls on Electronic Records and Signatures (21 CFR Part 11)
- Sanitary design with removable internal water tank

Benefits

- Saves operator time, delivers a fully-controlled test sequence
- Enables accurate and reliable testing of sterile liquid filters
- Ensures reproducible test results
- Assures and protects the safety of paperless test records
- Simple to clean, trouble-free maintenance

Filtration. Separation. Solution.SM

Introduction

With the Water Intrusion Test (WIT) fast becoming the *in situ* integrity test of choice for hydrophobic filters, the Palltronic AquaWIT IV system is the latest in the line of Pall's state-of-the-art products developed specifically to perform crucial filter integrity testing - accurately, reproducibly and reliably.

The system fills the housing of a hydrophobic filter with water, performs a Water Intrusion Test, then drains the housing. A new feature to this latest version of the Palltronic AquaWIT system is the option to wet hydrophilic liquid filters with water prior to integrity testing by the Forward Flow or Bubble Point test. A clear and well-defined wetting procedure that uses minimal water can be of real benefit for the pre-use testing of filters, for example in Allegro™ single-use systems.

Front view

Water Intrusion Testing – The Basics

A detailed description of the physical basics of water intrusion testing can be found in PDA Technical Report 40 *Sterilizing Filtration of Gases* or at www.pall.com/wit. In summary, a hydrophobic membrane is completely covered with water and air pressure is applied to the water. The water will evaporate through the hydrophobic membrane, and the rate of water evaporation (vapor flow) can be measured indirectly. The apparent water/vapor flow rate is correlated to bacterial retention tests carried out on the hydrophobic filter.

Water Intrusion Test versus Alternative Methods

Alternative methods for integrity testing of hydrophobic gas filters include the Forward Flow Test or the Bubble Point Test. In these cases, hydrophobic filters first need to be wetted with a low surface-tension wetting liquid, usually a mixture of alcohol and water. In many processes, however, this alcohol:water wetting liquid is not compatible with the process fluid, and needs to be completely removed prior to process fluid introduction. This requirement can make *in situ* integrity testing very difficult to perform, and pre-use testing almost impossible. The filter is still wetted after Forward Flow or Bubble Point testing and must be subsequently dried before operation as an air, gas or vent filter. Furthermore, appropriate measures for addressing the use of flammable liquids such as alcohol need to be put in place, often only because of the integrity test.

By using the Water Intrusion Test however, all of these issues can be avoided. The test filter does not need to be wetted, only covered with water. After the water is drained, the filter is fully operational immediately and there is no risk of introducing unwanted liquids to the process.

Key Advantages of Performing the Water Intrusion Test

- Only water required as the test liquid - no alcohol needed
- No need to handle flammable liquids
- Filter is not wetted – ready for use immediately after testing
- No time-consuming wetting procedure needed

Functions of the Palltronic AquaWIT IV System

The Palltronic AquaWIT IV system is delivered ready-to-use. To get started, an electrical connection and a stable source of pressurized air of at least 4.5 bar (58 psi) must be supplied. The system can be connected to a water source to fill the onboard 18 L (4.5 gallon) water tank.

Water Source and Filling
Water Intrusion Tests are normally performed with de-ionized (DI) water, or water of comparable quality. The removable water tank of the Palltronic AquaWIT IV system can either be filled manually or automatically. The system can recognize if the water level is too low or that the tank is full, and can close the water supply. If an appropriate water supply is permanently connected to the system, the system is also capable of refilling the water automatically.

Fully Automated Water Intrusion Testing
The Palltronic AquaWIT IV system can also perform a complete Water Intrusion Test fully automatically. Once the filter housing is connected to the system and the relevant test parameters are programmed, the system can control up to three pneumatic valves around the filter housing in order to isolate the filter from the process, fill the housing with water, perform the integrity test and drain the housing after the completed test. The test result can then be printed, or saved as an electronic record.

Fully Automated Forward Flow and Bubble Point Test
The Auto Test Time function is available for the Forward Flow Test and the Water Intrusion Test in order to shorten test times while maintaining the reliability of the result. Results of Forward Flow or Water Intrusion Tests are interpreted by this algorithm during the test.

If the measured flow rate is evidently below the test limit and the measurement is stable, the system will interpret this as a passed test. Filter integrity test times can be reduced by over 50%, without any risk of false pass results.

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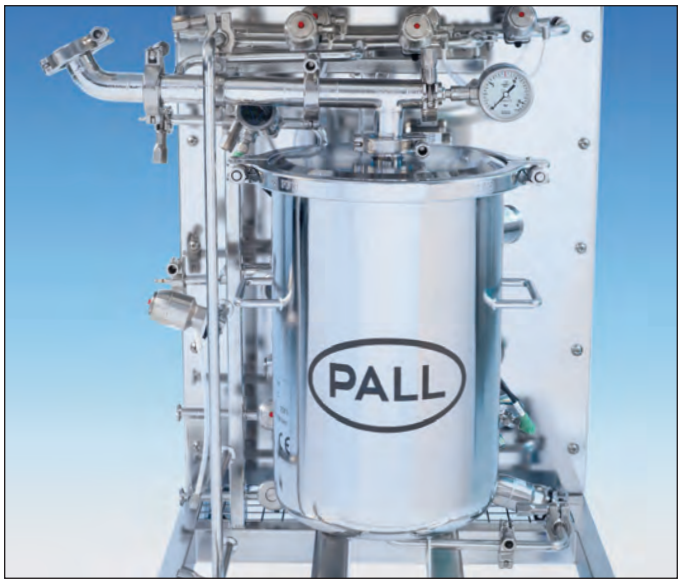


Internal water tank

Electronic Records and Signatures (21 CFR Part 11)

The Palltronic AquaWIT IV system has been designed to be used in an environment subject to the regulations of 21 CFR Part 11 for the storage of electronic records and signatures.

The system presents three levels of access – Operator, Supervisor or Administrator. Operators have access to the test functions only, supervisors can modify test programs in addition, but only administrators have full access to all functions, also performing changes to the system configuration or access management. The system can also be used in two different modes to limit access to the protected functions. When the password-controlled access function is activated, supervisor and administrator levels are each protected by a password. In the login-controlled access mode, each user must log in to the instrument with an individual user name and password before having access to its functions. The level of access can be defined for each person separately. All the changes performed on the system or the programs are recorded for audit purposes. For increased flexibility, test results can be electronically signed, and configuration, test programs, user data and test results easily and quickly exported to a network or external USB drive.

External Connections

A number of connections at the side of the Palltronic AquaWIT IV system allow interaction with external control systems. The USB port can be used to connect USB devices such as a printer, barcode reader or flash drive, and the Field Bus port allows connection to a process PLC (Programmable Logic Controller). The Ethernet (LAN) port or onboard wireless network adapter can be used to link the system to an external network, and an additional port for an external pressure sensor is provided.

Remote Operation

The Palltronic AquaWIT IV system can be quickly and simply connected to a remote PLC, thanks to its onboard internal adaptors. The PLC can fully control the system, with adapters available for all common communication protocols. The instrument can also be fully controlled via a Supervisory Control And Data Acquisition (SCADA) system by simply connecting it to the OPC UA server that is running on the system.

Remote Printing

As an alternative to use of the integrated printer, print data can be exported to an external printer, either networked or connected via USB. Print data can easily be exported electronically in a variety of standard formats including PDF or XML.

Lid raised to show Palltronic Flowstar instrument inside

Controlling Critical Test Parameters

With several factors potentially having an adverse effect on the Water Intrusion Test result, some (e.g. water quality) can be easily controlled and need not be monitored by the test system. Others, like potential contamination of the filter with a low surface tension liquid, need to be controlled in the processing system. The Palltronic AquaWIT system controls the remaining parameters and assures meaningful, reproducible results.

Water and Environmental Temperature

The temperature of the test water directly influences the water evaporation rate through the hydrophobic filter membrane. If the test water is much colder than the water used for filter validation, the flow rate will be lower than in the validated system. This needs to be avoided, as it could lead to a false positive result. The Palltronic AquaWIT IV system checks the temperature of the water before the test and will display a warning if it drops below 18 °C.

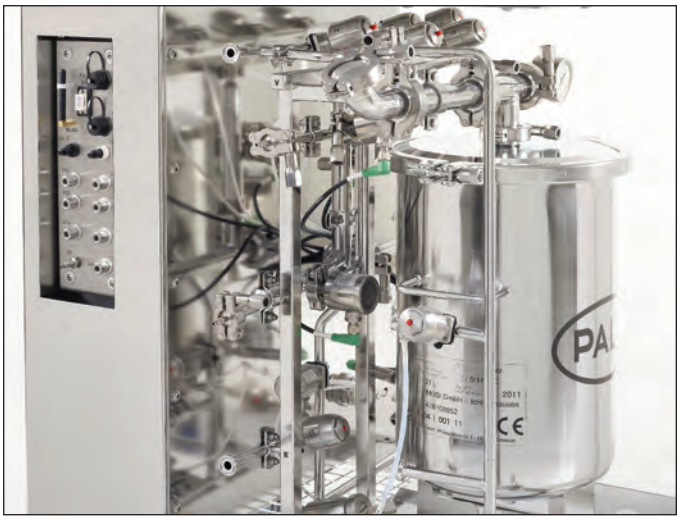
While the water temperature can directly influence the test conditions, environmental temperature will have an influence on the measurement conditions. All instruments that use a gas flow measurement to determine the flow rate require that the gas temperature is stable and within validated limits for the duration of the test. In a pharmaceutical process, this cannot always be assured – air conditioning outlets or steam lines close to the filter housing could potentially change the temperature during the test. The Palltronic AquaWIT IV system transfers the gas measurement into a better-controlled, internal environment, minimizing the affect of environmental factors.

Controlled Filling

The filter system must be filled with water in order to perform a Water Intrusion Test, but test results can be affected if air is trapped in unwanted places in the filter system during filling. However, the Palltronic AquaWIT IV system can control the filling pressure, enabling a very controlled filling step and eliminating the risk of trapped air.

Flow Measurement

Very small flow rates must be measured accurately in a Water Intrusion Test. As a water flow rate is measured, the upstream gas volume changes over the course of the test. The Palltronic Flowstar IV instrument inside the Palltronic AquaWIT IV system uses a special volume-dosing flow measurement technology. This unique measurement principle was developed by Pall to improve the accuracy and reproducibility of the filter integrity test relative to other test instruments, eliminating the need to validate system-specific correction factors.



Side view with communication ports shown

Increasing Process Safety

Even if the critical test parameters are well controlled, there is still a small risk of filter integrity test failure. The Palltronic Flowstar instrument can detect inconsistencies and reduce the risk of false positive test results.

Fault Detection
In some cases, pneumatic conditions for a successful test are not met. These may be caused by leaks in the test system or an unstable pressure source. The Palltronic AquaWIT IV system can identify such conditions and prompts the user by providing specific screen messages on where to locate the problem.

Low Flow Rate
In a Forward Flow Test, the gas diffusion rate is measured across a wetted filter membrane, along with any bulk flow through open pores, and in the Water Intrusion Test a water evaporation rate through a hydrophobic membrane is measured, along with any bulk water flow. With integral filters, both values must have a certain amount, and cannot be zero. 'Zero' or 'Undetectable Flow' indicates an invalid test. The Palltronic AquaWIT IV system compares the measured flow rate to an expected minimal flow rate. If this measure is lower than the expected minimal flow, the instrument will terminate the test and notify the user.

Downstream Pressure Sensor
In certain cases, the volume downstream of the filter cannot be as large as required. If so, there is a risk that the pressure on the downstream side could rise during the test so that differential pressure over the filter membrane cannot be maintained. As a consequence the measured flow rate could decrease, increasing the risk of a false pass result. The Palltronic AquaWIT IV system can help to avoid this, as a pressure sensor can be installed downstream of the filter and connected. If the downstream pressure should rise above a specified value, the test is aborted and the user notified.

Self Test
The Palltronic AquaWIT IV system will automatically run an internal Self Test once per day when it is switched on. This Self Test can also be initiated manually by a user at any time. During the Self Test the instrument carries out a full check 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 for internal leaks
- Internal communication
- Integrity of the operating system and its 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 along with a regular calibration and preventive maintenance program can help to assure continuous, reliable operation of the system.

Rear-side view

Service and Support

Qualification
The system has been designed following the current Good Automated Manufacturing Practice (GAMP 5) guidelines. The Palltronic AquaWIT IV system has accordingly been classified in software category 3 and hardware category 1. The internal 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 operations qualification (OQ) are usually sufficient to qualify the system, and an extensive documentation package with all the relevant documents is available on request.

Calibration and Preventative Maintenance
The Palltronic AquaWIT IV system can be calibrated at any Pall-certified service center or directly on site. Calibration equipment, procedures and training are available. Pall recommends calibration and preventive maintenance of the system at least once a year in one of our global service centers.

Accuracy
Requirements on test equipment calibration are described in 21 CFR 820.72: 'Inspection, Measuring, and Test Equipment' and the European GMP guide, Chapter 4. Pall has established calibration procedures to verify the Palltronic AquaWIT system's pressure and flow measurement, which are qualified over the full measurement range of the system. Palltronic AquaWIT IV systems can be calibrated by certified engineers either in a Pall-qualified laboratory or at your manufacturing site. Our traceable references allow us to confirm accuracy of 0.33% for pressure measurement and 3% for flow measurement, in all parts of the world.

Training
On-site training is available on the product itself, instrument validation, filter validation, integrity testing basics and regulatory requirements. Pall is happy to assist you with a custom-designed training program.

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Technical Specifications

Part Number
AW04

Physical Dimensions
Size: 1189 x 575 x 856 mm
Weight: approx 120 kg (tank empty)
Tank volume: 18 L (up to level switch 'L3' in the tank)

Filter Tests
Forward Flow Test (FF)
Bubble Point Test (BP)
Combined Forward Flow/Bubble Point Test (FF+BP)
Water Intrusion Test (WIT)

Functional and Diagnostic Tests
Leak Test (LT)
Pressure Decay Test (PD)
Self Test
Flow Check Test
Network Test
Printer Test

Operating System
Linux (the source code which falls under the GNU General Public License is stored on the USB flash drive supplied with the instrument)

Data Capacity
Test Program Storage: > 500 programs
Test Result Storage: > 10,000 tests
Active User Storage: > 250 users

Language Options
US English
English
French
German
Italian
Spanish
(Ask your Pall representative for other languages not listed)

Communication Ports
USB
RS232
Ethernet (RJ45)
Wireless Ethernet

Measuring Range
Forward Flow Test: 0.1 – 1000 mL/min
Water Intrusion Test: 0.02 - 50 mL/min water
Bubble Point Test: 400 - 6500 mbar (0.725 – 94.2 psi)

Resolution
Forward Flow Test: 0.1 mL/min (0.01 mL/min for a flow < 10 mL/min)
Water Intrusion Test: 0.01 mL/min
Bubble Point Test: 50 mbar (0.7 psi)

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

See Pall publication 'USTR2710: Validation Guide for the Palltronic Flowstar IV Integrity Test Instrument' for details

Calibration Limits
Flow Measurement: +/- 3% of measurement
Pressure Measurement: +/- 0.33% of full scale

Electrical Data
Voltage: Automatically adjusted between 100 - 240 V AC
Input Frequency: 50 Hz/60Hz
Power: Typically 150 W
Fuse: 3.15 A, slow blow (Palltronic Flowstar)
External Vent Valve: 24 V DC
External Pressure Transducer: Relative (relative to gauge) pressure measurement, 4 – 20 mA signal

Touchscreen
Size: Diagonal 26.4 cm (10.4 in.), 1024 x 768 pixels
Features: Color, illuminated background, adjustable contrast

Pneumatic Specifications
Maximum Gas Supply Pressure: 8000 mbar (116 psi)
Minimum Gas Supply: 4500 mbar (58 psi)
- Flow Range 0.01 - 149 mL/min 1000 mbar (14.5 psi) above test pressure
- Flow Range 150 - 1000 mL/min 2000 mbar (29.0 psi) above test pressure

Test Pressure Range: 50 to 6500 mbar (0.7 to 94.2 psi)

Pneumatic Connections
Compressed Air Inlet: Stäubli® Nipple RBE03
Compressed Air Outlet: Stäubli Coupling RBE03
Vent: Hose Connection 8 mm Outer Diameter

Integrated Printer
Type: Thermal
Lifetime of the Printout: > 10 years depending on storage conditions
Paper Width: 112 mm (4.4 in.)
Paper Roll Diameter: 50 mm (1.9 in.)

Environmental Conditions
Splash Proof: To IP54*
Operating Temperature: +5 °C to +50 °C
Storage Temperature: -20 °C to +70 °C
Humidity: 95% rh (no condensation)

**To meet the full requirements of IP54, splashproof electrical connections to the instrument are necessary. These are available as accessories, please contact your local Pall representative for details.*

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