AquaWIT V

FILTER INTEGRITY TEST SYSTEM

The water intrusion test (WIT) is widely used in the pharmaceutical industry to integrity test gas filters on equipment such as hold tanks, autoclaves, and bioreactors. Testing with automated equipment supports a robust contamination control strategy.

Manual procedures related to integrity testing of gas filters can be time consuming and prone to error. If an organic solvent such as alcohol is used, the filter must be removed from the process, brought to a safe environment for testing, then cleaned and dried before reinstallation. Removal of filters from elevated locations can be a challenge for the operator. Temperature fluctuations in the environment can also affect test results, particularly with smaller filters.

With the latest Palltronic Flowstar V integrity test instrument at its core, the AquaWIT V system performs an automated, *in-situ* water intrusion test, saving time, and reducing the risk of manual error. The system will fill, test, drain, and air flush your gas filter, providing greater reproducibility of procedure. The use of a solvent is not necessary; therefore, removing the filter from the process is not required.

The AquaWIT V system can also test liquid sterilizing grade filters by forward flow or bubble point test procedures. The flush set extension enables thorough water rinsing for complete and consistent wetting.

Fig 1. AquaWIT V system front view.

Target applications

Integrity testing of gas filters installed on:

- Aseptic tanks for formulation and filling
- Water for injection (WFI) systems
- Autoclaves
- Freeze dryers and lyophilizers
- Bioreactors
- Isolators

Integrity testing of liquid filters used for:

- Bulk drug substance
- Buffer and media at formulation site

Functions of the AquaWIT V system

The AquaWIT V system is delivered ready-to-use. To get started, an electrical connection and a stable source of pressurized air of at least 5.0 bar must be supplied (Fig 4). The system can be connected to a water source to fill the onboard 16 L working volume water tank.

Water source and filling

Water intrusion tests are normally performed with de-ionized (DI) water, or water of comparable quality. The removable watertank of the AquaWIT V system can either be filled manually or automatically. The system can recognize if the water level is too low or if the tank is full, and can close the water supply. If an appropriate water supply is permanently connected to the system, it is capable of refilling the water automatically.

Fully automated water intrusion testing

The AquaWIT V system can perform a fully automated water intrusion test. 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 system can perform a fully automated forward flow and bubble point test. The system draws water from the internal tank to fill the filter housing or capsule (Fig 2), flushes it through the membrane to the downstream side, and the filter is then tested using the programmed integrity test. This wetting procedure is carried out within controlled parameters, allowing reproducible wetting of hydrophilic filters. Filter wetting is achieved with a very small amount of water – a huge advantage for small processing systems or processing with single-use equipment.

Auto test time

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.

Fig 2. Internal water tank.

Electronic records and signatures (21 CFR Part 11)

The AquaWIT V 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 four levels of access – operator, supervisor, administrator, and viewer. Operators have access to the test functions only, supervisors can modify test programs, and viewers have viewing rights. Administrators have full access to all functions including system configuration and 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. Configuration, test programs, user data, and test results are easily and quickly exported to a network or external USB drive.

External connections

A number of connections on the system allow interaction with external control systems (Fig 5). The USB port can be used to connect USB devices such as a barcode reader or flash drive, and the field bus port allows connection to a process programmable logic controller (PLC). The ethernet (LAN) port or onboard wireless network adapter can be used to link the system to an external network. Two additional ports for external pressure or temperature sensor are provided.

Remote operation

The AquaWIT V 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 using the accessory 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.

Fig 3. AquaWIT V system side view.

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 AquaWIT V 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 AquaWIT V system checks the temperature of the water before the test and will display a warning if it drops below 18°C to 25°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 gas temperature to be stable and within validated limits for the duration of the test. This cannot be guaranteed in a pharmaceutical process. Air conditioning outlets or steam lines close to the filter housing can change the temperature during the test. The AquaWIT V system performs the gas measurement in a more controlled internal environment, minimizing the affect of external 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. The AquaWIT V system can control the filling pressure, enabling more controlled filling, and eliminating the risk of trapped air.

Fig 4. Side view with connections shown.

Flow measurement

Very small flow rates must be measured accurately in a water intrusion test. As the water flow rate is measured, the upstream gas volume changes over the course of the test. The AquaWIT V system uses volume dosing flow measurement technology. This unique measurement principle was developed by Cytiva 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.

Increasing process safety

Even if the critical test parameters are well controlled, there is still a small risk of filter integrity test failure. The AquaWIT V system 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 AquaWIT V 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’, which indicates an invalid test. The AquaWIT V 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 AquaWIT V 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 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.

Fig 5. Rear view with communication connections shown.

AquaWIT V system MUX extension

Available separately, the AquaWIT V system MUX extension is an innovative, time-saving companion to the AquaWIT V system. Up to four hydrophilic or hydrophobic filter cartridges or capsules can be installed in the unit directly. This prepares and integrity tests the installed filters independently, automatically, and sequentially without further operator involvement, saving time, and vastly improving process efficiency.

Fig 6. AquaWIT V system with MUX extension.

Key advantages

The AquaWIT V system MUX extension provides a four-channel extension to the AquaWIT V filter integrity test system – saving operator time.

- Either filter capsules or filter housings can be installed – offering total flexibility.
- System software and hardware enable multiple tasks to be performed at once – improving test efficiency.
- Parameters for preparing filters are stored together with the test result – all test information is fully documented.
- Filters prepared and tested independently, and in an automated sequence – saving time and costs compared with manual operation.
- LEDs on each channel help the operator quickly identify the test status.
- MUX can be automatically cleaned and sanitised at the same time as the main system.

Simply connect up the water lines and the pneumatic control connections from the system to the AquaWIT V system MUX extension, and install the filter cartridges or capsules as required. Next, the system is programmed to perform any desired filter integrity test on those four channels, in the preferred order. Not only will the system automate the process of filling hydrophobic filters with water before the test, but it will also use minimal amounts of water during the complete, reliable wetting of hydrophilic filters. Results are stored on the test system and can be easily exported or printed. Parameters programmed to prepare the filters are also stored together with the filter test result, keeping critical information stored safely and securely.

The MUX extension is an ideal solution for production areas and facilities where large amounts of filters are tested offline. All four channels can be programmed and activated independently. They also enable the user to exchange filters and select new test programs while existing channels are undergoing integrity tests. These features combine to provide a simple, reliable yet highly-efficient method for high-throughput filter testing.

AquaWIT V system flush set extension

The AquaWIT V system flush set is an extension of the AquaWIT V system that ensures complete wetting of hydrophilic sterilizing grade filters, minimizing the need for repeated flushing. It allows you to install, flush, and integrity test one hydrophilic filter (T-style or in-line style) by using water from the AquaWIT V system. The flush set prevents back flow to avoid potential cross-contamination.

With the flush set you will acheive:

- Reduction of false integrity test failures.
- Implementation of validated and reproducible filter flush processes.
- Avoidance of product cross contamination of the AquaWIT V system.

Key advantages of the flush set:

- The flushing step can be controlled by fixed amount of flush cycles or by target conductivity in the flush water.
- The flush set can be automatically cleaned and sanitised at the same time as the main system.

Fig 7. AquaWIT V system with flush set.

Service and support

Qualification

The AquaWIT V system has been designed following the current good automated manufacturing practice (GAMP) 5 guidelines and can be used in a manner compliant with 21 CFR part 11. The internal components have been carefully selected for long-term availability and reliable functionality. All relevant functions have been verified. An extensive documentation package with all the relevant documents is available on request.

Calibration and preventative maintenance

The system can be calibrated at any Cytiva-certified service center or directly on site. Calibration equipment, procedures, and training are available. Cytiva 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. Cytiva has established calibration procedures to verify the system's pressure and flow measurement, which are qualified over the full measurement range of the system. AquaWIT V systems can be calibrated by certified engineers either in a Cytiva-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 for the product, the related systems, and filter integrity testing. For this and any other technical topic, we are happy to assist you with a custom-designed training program.

Technical specifications

AquaWIT V system, AW05

Process specifications

Equipment	Specification
Functionality	Automated preparation, integrity testing and draining of filters
Filter configurations	Single
Compatible filter format/size	Please contact Cytiva
Vessel size	20 L
Vessel working volume	16 L
Maximum integrity test pressure	6.5 bar* for maximum exposure ≤ 10 h
Number of inlets	1 (line to connect to vent of filter housing) 1 (water/clean-in-place (CIP)/ steam-in-place (SIP) media inlet) 1 (manual filling port on the vessel)
Number of outlets	1 (line to connect to inlet of filter housing) 1 (line to connect to filtrate side of filter housing) 1 (AquaWIT V system drain) 1 (AquaWIT V system vent)
Maximum flow path operating pressure	6.5 bar
Temperature sensor	1 (vessel)
Level switches	5 (2 in vessel, 2 before and after test chamber, 1 in line to filter housing)
Pressure sensor	1 (before test chamber)
External connections	9 (air in, air out, CANBus, Input/output (I/O) sensor ×1, I/O sensor ×2, external valve connection ×6)

* 1 bar = 14.5 psi = 0.1 MPa.

System specifications

System	Specification
Main system dimensions (W × D × H)	72.1 × 80.1 × 113.2 cm (28 × 32 × 45 in.)
Main system mass (empty)	125 kg (275 lb.)
Environmental conditions	4°C to 40°C[1], RH 25% to 80% (non-condensing)
Materials of construction	Piping, vessel: stainless steel 1.4435/1.4404 Frame, metal sheets, control box Housings: stainless steel 1.4301 Clamp gaskets, vessel gasket valve Membranes: EPDM (FDA) Wetted hoses: PTFE (FDA) Staubli couplings (liquid wetted parts): Stainless steel + EPDM (FDA)
Surface finish	Piping, vessel (liquid wetted parts): inner: Ra < = 0.38 µm (SF4), electro-polished outer: Ra < = 0.80 µm, electro-polished Frame, metal sheets: grinded, electro-polished, Ra < = 1.6 µm, weldings (without fillet welds) smooth grinded
Ingress protection rating	IP54 (electrical control box, power-supply box)
Additional certifications	CE cTÜVus (NRTL) certified KC certified

[1] For standard operating conditions – this does not include cleaning or sanitization operations.

Utility specifications

Utilities	Specification
Electrical supply	100 to 240 V AC, 50 to 60 Hz
Operating voltage control	24 V DC
Recommended FI switch	RCD 30 mA, type B
Power consumption	Max. 150 W
Max. fuse	T3.15A L 250 V
Amperage	10 A
Process air	Minimum: 5 bar for valve actuation, expected integrity/leak test pressure plus 1 bar Maximum: 8 bar Clean, dry and oil free recommended according to ISO 8573-1:2010 Class 3.4.4 or better[2]
Process medium	Deionised water (max. 3 bar)
CIP / SIP medium	Caustic solution 0.5 to 1 M (max. 4 bar) or hot water up to 90°C (max. 4 bar) or saturated steam between 121°C (1 bar) to 135°C inlet (2.1 bar)

[2] Requirements for the process air quality to be defined by the operating company.

Component specifications

Component specifications, sensor range, and accuracies are as per OEM datasheets and correct at the time of compiling this proposal. Cytiva does not accept any responsibility in the case of deviation to the specifications outlined below.

Process equipment	Type	Specification
Temperature	Resistance thermometer with thermowell, process connection 25 mm TC, IO-link	Sensor range: -50°C to 200°C Measurement range: 15°C to 140°C Accuracy: class A DIN EN 60751
Pressure (vessel)	Pressure gauge with mechanical seal NG63, process connection TC 25 mm	Range: 0 to 16 bar Accuracy: class 1.6 per EN837-1
Process valves	Gemü type 650	Pneumatically operated valve
Pressure	Pressure sensor with mechanical seal, process connection TC 50.5 mm, IO-link	Sensor range: -1 to 12 bar Measurement range: 0 to 12 bar Accuracy: < = 0.3%
Level detector	Capacitive sensor, process connection EPA-8	Capacitive level switch for aqueous solutions with Er < 20
Integrity test instrument	Palltronic Flowstar V filter integrity test instrument	Forward flow test: Range: 0.1 to 1000 mL/min Accuracy: ± 3% of value or ± 0.05 mL/min, whichever is greater Water intrusion test: Range: 0.03 to 50 mL/min Accuracy: ± 3% of measurement or ± 0.02 mL/min, whichever is greater Time accuracy: ± 1000 ppm
External pressure sensor (optional)	Pressure sensor with mechanical seal, process connection TC 50.5 mm, IO-link	Sensor range: -1 to 12 bar Measurement range: 0 to 12 bar Accuracy: < = 0.3%
External temperature sensor (optional)	Resistance thermometer with thermowell, process connection 25 mm TC, IO-link	Sensor range: -50°C to 200°C Measurement range: 15°C to 140°C Accuracy: class A DIN EN 60751

AquaWIT V system MUX extension, AW05-MUX

Process specifications

Equipment	Specification
Functionality	Filter integrity testing
Filter configurations	Up to four in serial testing
Compatible filter format/size	Please contact Cytiva
Number of inlets	1 (line to connect to port B of AW05)
Number of outlets	1 (line to connect to port A of AW05) 1 (drain)
Maximum flow path operating pressure	6.5 bar for maximum exposure ≤ 10 h
Temperature sensor	1 (drain)
External connections	2 (air in, CANBus)

System specifications

System	Specification
MUX extension dimensions (without filter housings) (W × D × H)	70 × 67 × 107.6 cm (28 × 27 × 42 in.)
MUX extension mass (empty)	63 kg (139 lb.)
Environmental conditions	4°C to 40°C, RH 25% to 80% (non-condensing)
Materials of construction	Piping: stainless steel 1.4435/1.4404 frame, metal sheets, control box Housings: stainless steel 1.4301 Clamp gaskets: EPDM (FDA) Wetted hoses: PTFE (FDA) Staubli couplings: stainless steel
Surface finish	Piping: inner: Ra < = 0.38 µm (SF4), electro-polished outer: Ra < = 0.80 µm, electro-polished frame, metal sheets: grinded, electro-polished, Ra < = 1.6 µm, weldings (without fillet welds) smooth grinded
Ingress protection rating	IP54 (electrical control box)

Utility specifications

Utilities	Specification
Electrical supply	24 V DC
Operating voltage control	24 V DC
Recommended FI switch	RCD 30 mA, type B
Max. fuse	T3.15A L 250 V
Power consumption	Max. 60 W
Amperage	10 A
Process air	Minimum: 5 bar for valve actuation, expected integrity/leak test pressure plus 1 bar Maximum: 8 bar Clean, dry and oil free recommended according to ISO 8573-1:2010 class 3.4.4 or better[1]
Process medium	Deionised water (3 bar)
CIP/SIP medium	Caustic solution 0.5 to 1 M (4 bar) or hot water up to 90°C (4 bar) or saturated steam between 121°C (1 bar) to 135°C inlet (2.1 bar)

[1] Requirements for the process air quality to be defined by the operating company.

Component specifications

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Process equipment	Type	Specification
Temperature	Resistance thermometer with thermowell, process connection 25 mm TC, IO-link	Sensor range: -50°C to 200°C Measurement range: 15°C to 140°C Accuracy: class A DIN EN 60751
Process valves	Gemü type 650	Pneumatically operated valve
Pressure (vent)	Pipe manometer NG63, process connection TC 25 mm	Range: 0 to 6 bar Accuracy: class 1.6 per EN837-1

AquaWIT V system flush set, AW05-FLST

Process specifications

Equipment	Specification
Functionality	Filter integrity testing
Filter configurations	Single
Compatible filter format/size	Please contact Cytiva
Number of inlets	1 (line to connect to port B of AW05)
Number of outlets	1 (line to connect to port A of AW05) 3 (vent, 2× drain)
Maximum flow path operating pressure	6.5 bar
Temperature sensor	1 (drain in maintenance manifold)
Level switches	1 (vent)
External connections	2 (air in, CANBus)

System specifications

System	Specification
Flush set extension dimensions (without filter housing) (W × D × H)	47 × 60 × 110.9 cm (19 × 24 × 44 in.)
Flush set extension mass (empty)	40 kg (88 lb.)
Environmental conditions	4°C to 40°C, RH 25% to 80% (non-condensing)
Materials of construction	Piping: stainless steel 1.4435/1.4404 frame, metal sheets, control box Housings: stainless steel 1.4301 Clamp gaskets: EPDM (FDA) Wettedhoses: PTFE (FDA) Staubli couplings: stainless steel
Surface finish	Piping: Inner: Ra < = 0.38 µm (SF4), electro-polished Outer: Ra < = 0.80 µm, electro-polished Frame, metal sheets: grinded, electro-polished, Ra < = 1.6 µm, weldings (without fillet welds) smooth grinded
Ingress protection rating	IP54 (electrical control box, power-supply box)

Utility specifications

Utilities	Specification
Electrical supply	24 V DC
Operating voltage control	24 V DC
Recommended FI switch	RCD 30 mA, type B
Power consumption	Max. 36 W
Max. fuse	T3.15A L 250 V
Amperage	10 A
Process air	Minimum: 5 bar for valve actuation, expected integrity/leak test pressure plus 1 bar Maximum: 8 bar clean, dry and oil free recommended according to ISO 8573-1:2010 Class 3.4.4 or better[1]
Process medium	Deionised water (3 bar)
CIP/SIP medium	Caustic solution 0.5 to 1 M (4 bar) or hot water up to 90°C (4 bar) or saturated steam between 121°C (1 bar) to 135°C inlet (2.1 bar)

[1] Requirements for the process air quality to be defined by the operating company.

Component specifications

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Process equipment	Type	Specification
Temperature	Resistance thermometer with thermowell, process connection 25 mm TC, IO-link	Sensor range: -50°C to 200°C Measurement range: 15°C to 140°C Accuracy: class A DIN EN 60751
Process valves	Gemü type 650	Pneumatically operated valve
Level detector	Capacitive sensor, process connection EPA-8	Capacitive level switch for aqueous solutions with Er < 20
Conductivity (flush set extension)	4 electrode conductivity sensor with analogue 1-channel transmitter, process connection 50.5 mm TC	Range: 0 to 500 µS/cm (optional with 0 to 20 mS/cm) Accuracy: ≤ 2% of measurement value (1 µS/cm to 1 mS/cm) ≤ 4% of measurement value (1 to 500 mS/cm)

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