

Palltronic Flowstar V

INTEGRITY TEST INSTRUMENT

The Palltronic Flowstar V filter integrity test instrument is an essential tool to support your contamination control strategy (CCS). The latest LGR version of the instrument can perform both integrity testing of filters and leak testing of single-use biocontainers and assemblies prior to committing valuable drug product. Capable of integrity testing filters at any point in your process, this system is critical for point-of-use testing at final sterile filtration, the last chance to produce and confirm a sterile drug product before filling.

The Palltronic Flowstar V system uses direct flow measurement to achieve highly accurate results. This system ensures high level data integrity with compliance to 21 CFR Part 11 and ALCOA+ principles, and strong cyber security with Linux-based software. It also provides advanced automation capabilities for centralized data management and control, in addition to a wide variety of options for network integration.

An extensive team of field engineers is available for responsive, on-site service and expertise.

Test capabilities

The Palltronic Flowstar V instrument system can perform a filter integrity test by forward flow (FF), bubble point (BP), and combined FF/BP. A gas filter can be tested by water intrusion test (WIT). Pressure decay is also available. Vessels such as filter housings can also be leak-tested.

It is recommended that the AquaWIT V system is used when testing gas filters. Leak testing of single-use assemblies and biocontainers can also be performed using direct flow with the Flowstar V LGR instrument.

Direct flow measurement

The Palltronic Flowstar V integrity tester uses direct flow measurement for accurate results. A chamber of known pressurized volumes are used to directly measure the flow of gas passing through a test filter membrane. The precise quantity of gas discharged can be derived from the volume size, the pressure inside the chamber before and after discharge, and the number of discharges over time. In comparison, the pressure decay method converts pressure measurements to flow using algorithms, which can be less accurate when compared to actual flow rates.

Flow is calibrated, which is ideal for GMP compliance when calibration test results are reported in flow units, the same units as reported on tests results.



Fig 1. Palltronic Flowstar V integrity test instrument.

Secures compliance to data integrity and 21 CFR part 11 requirements

Electronic Records and Electronic Signature (ERES) features

The instrument has all features and requirements required to be operated in accordance with 21 CFR Part 11 and other guidelines like the Medicines and Healthcare Products Regulatory Agency (MHRA) related to data integrity and electronic signature safety.

Access management helps prevent uncontrolled access to critical functions on the Palltronic Flowstar V integrity test instrument.

Access management and password management allows the electronic signing of test records. The Palltronic Flowstar V integrity test instrument allows:

- Configurable access control management (four access levels – Super Administrator, Administrator, Supervisor, and Operator)
- Configurable password management

Audit trail features

The instrument captures all data needed for audit purposes, facilitating the review process regardless of frequency, while complying with all data integrity requirements issued by the FDA, MHRA, and Pharmaceutical Inspection Cooperation Scheme (PIC/S). This ease of review plays a major role for regulated companies that are expected to regularly review data with a direct impact on batch release and patient safety. The Palltronic Flowstar V integrity test instrument fulfils ALCOA PLUS principles which require that data be attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available. ALCOA has served as a framework for guaranteeing data integrity and good documentation practice (GDP) by regulated industries.

In addition, the Palltronic Flowstar V integrity test instrument has an event audit trail which logs activities on the instrument and a record audit trail which includes test program records, access management records, user records, date/time change records and configuration records.

The primary records of the Palltronic Flowstar V integrity test instrument, including the test results, cannot be altered after generation and storage. Only signatures and any comments with the signature can be added. With this approach, the test result is a static record.

Finally, with the different data backup possibilities, including manual and automatic backup options, and the expanded data storage capacity on the instrument, the Palltronic Flowstar V integrity test instrument ensures compliance with all data backup, retention and retrieval requirements.



Fig 2. Integrity testing a filter capsule.

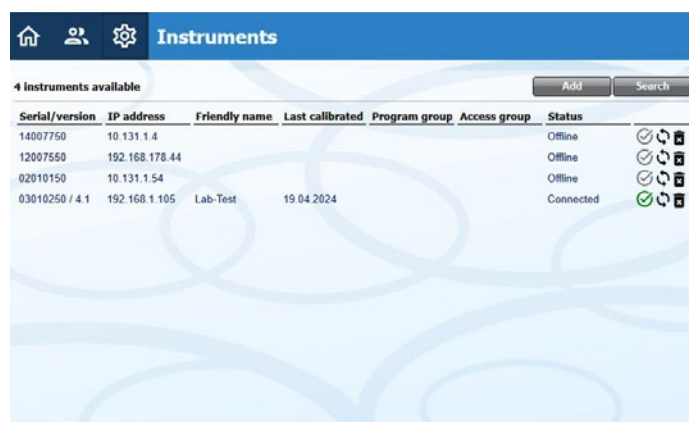
State-of-the-art automation protocols and remote control

Supplementary software

Data management system (DMS) Pro software

The DMS Pro software is designed for automated, centralized data back-up across multiple Palltronic Flowstar V instruments. Features include:

- Synchronization of date and time across instruments
- Synchronization of test programs across instruments
- Automated continuous backup audit trails, test records, programs, users, settings, audit trail, and results
- Use of domain log in for Active Directory passwords



Serial/version	IP address	Friendly name	Last calibrated	Program group	Access group	Status
14007750	10.131.1.4					Offline
12007550	192.168.178.44					Offline
02010150	10.131.1.54					Offline
03010250 / 4.1	192.168.1.105	Lab-Test	19 04 2024			Connected

Fig 3. DMS Pro software provides users with information on filter integrity test instruments from across their facility.

mPath™ operational insights software (OIS)

The mPath OIS is a browser-based analytics solution that monitors filter integrity test activity across multiple Palltronic Flowstar V instruments. It can improve productivity by providing insights into:

- Test results by instrument, filter product and individual operators
- Troubleshooting false-failure integrity test results
- Preventive maintenance and calibration scheduling

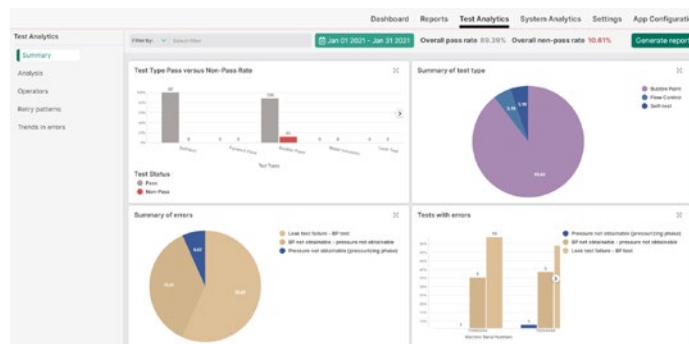


Fig 4. mPath operational insights software monitors filter integrity test activity across multiple instruments and provides insights on test results, troubleshooting, and other key analytics.

PAS-X MES software

The Palltronic Flowstar V instrument has been designed with manufacturing execution system compatibility in mind. Through the use of automation adaptors and software licenses, the instrument can work with a variety of protocols to:

- Remotely perform an integrity test
- Access real-time FIT progress and results
- Maintain traceability of filter products across batch and lot numbers
- Enforce individual FIT protocol rules
- Automated retrieval of test records

Supplementary hardware

Palltronic Flowstar V MUX instrument

The Palltronic Flowstar V MUX instrument connects to the Palltronic Flowstar V integrity test instrument⁽¹⁾ and allows a user to test up to 16 separate filter cartridges or capsules sequentially, reducing the need for a user to be present at frequent intervals to connect and disconnect filters to be tested.

⁽¹⁾ The Palltronic Flowstar V instrument must be operating on at least firmware version 2.1.



Fig 5. Palltronic Flowstar V MUX instrument.

Service

An extensive team of trained and certified field service engineers (FSE) are available globally to perform on-site service and maintenance. They can be on-site within days. System troubleshooting, inspection, functionality verification, on-site qualification, on-site calibration, and parts replacement can be performed. Additional engineers are available through our online call center to help you troubleshoot problems as they arise.

Protect your equipment and optimize productivity

Our range of service packages keeps your equipment protected and well-maintained, and includes itemized pay-as-you-go services, start-up care and training packages and a variety of post-warranty service plans that include priority response times, discounts for emergency repairs and flexible payment options. Our service plans provide total peace of mind and worry-free support throughout the coverage period.



Fig 6. Service team member performing routine maintenance on a Palltronic Flowstar V unit.

Features and benefits

	Features	Benefits
Technology Ease-of-use	Direct flow measurement	Faster testing High accuracy of test results Calibration based on traceable flow references
	Storage of test parameters and recipes	Reduced setup times Avoids input errors
	Light instrument with a small footprint	Portable Easy to locate close to point of use
	Intuitive user interface with 12 in. (1280 × 800 pixels) color touchscreen and adjustable screen angle	Enhanced readability Intuitive design improving ease of use for data entry and navigation Adjustable positioning of display angle to improve ease of interaction and aid comfort when in use
	LED alarm strip	Enables quick check of instrument status whilst in operation, even from a distance
Quality and regulatory	Developed in accordance with GAMP 5	Assurance instrument complies with GAMP standard
	IP54 rated design	Robust and easy to clean
	Compliance to 21 CFR Part 11	Meets regulatory requirements
	Electronic records and electronic signature	Requirement for electronic batch documentation
	Automated data entry through barcode reader	Mitigates risks of manual entry errors of test parameters (quality risk management)
	Test repeat control feature	Ensures compliance with the work instructions (SOP) Mitigates risks of entry errors Improves ease of use
	Data security and audit trail	Facilitates the detection of unauthorized record editing
	Test parameters and records can be stored electronically	Ensures permanent records
Network integration and automation	Fade-resistant printouts	Ensures permanent records
	Possibility to connect to OPC-UA, Profibus, DeviceNet, PROFINET, Serial, PAS-X MES	Faster and simplified integration to local network Improved flexibility for remote connection
	Lightweight Direct Access Protocol (LDAP)	Increased safety margins with lower risks in forgetting user ID and password
	USB, LAN, and Wifi networking connectivity	Connectivity ease of use for flash drives, printers and LAN networking

Technical specifications

Physical dimensions	Weight: 11 kg (24.3 lb) width × height × depth: 350 × 263 × 450 mm (13.8 × 10.4 × 17.7 in.)
Filter tests	Forward flow test (FF) Bubble point test (BP) Combined forward flow / bubble point test (FF/BP) Water intrusion test (WIT)
Leak tests	Single use leak test of bicontainers and assemblies up to 200 L with LGR option Pressure decay test (PD) (leak test for volumes up to 200 L)
Function tests	Self-test Flow check test
Other functions	Test program transfer function Configuration export/import function Access management export/import function User list export/import function Test result export function Full back up function (including all above functions) Audit trail backup function
Operating system	Linux ⁽¹⁾
Data capacity	Test program storage: > 500 programs Test result storage: > 10 000 tests Active user storage: > 250 users

Language options ⁽²⁾	Chinese Dutch English French German Italian Japanese Portuguese Russian Spanish US English
Communication ports	1× CAN 1× ethernet port (RJ45) 3× USB (can be deactivated with software setting) 1× custom printer interface 1× external valve power supply
Automation protocols	OPC UA Industry standard Profibus, PROFINET, Serial, and DeviceNet (via external USB modules)
Measuring range	Forward flow test: 0.1 to 1000 mL/min Water intrusion test: 0.03 to 50 mL/min water Bubble point test: 400 to 6500 mbar (5.8 to 94.3 psi) Single-use system leak test: 0.01 to 400 mL/min at 20 to 50 mbar
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
Resolution	Forward flow test 0.1 mL/min Water intrusion test 0.01 mL/min Bubble point test 50 mbar (0.7 psi) Pressure decay test: 1 mbar Single-use system leak test: 0.1 mL/min
Thermal printer	See <i>Thermal printer</i> for detailed description and specifications
Calibration limits	Flow measurement: ± 3% of measurement or ± 0.05 mL/min, whichever is greater Pressure measurement: ± 30 mbar (calibrated up to 7 bar) Pressure measurement LGR: ± 1 mbar (calibrated up to 290 mbar)
Electrical data	Voltage: automatically adjusted between 100 and 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 External pressure transducer: relative (to gauge) pressure measurement, 4 mA to 20 mA signal
Touchscreen	Size: 12.1 in. LCD (1280 × 800) Features: stylus pen, capacitive touch, 30° adjustable angle, color, illuminated background, adjustable contrast, enclosed multicolour LED strip
Pneumatic specifications	Maximum gas supply pressure: 8000 mbar (116 psi) Minimum gas supply: – Self-test: 3000 mbar (43.5 psi) – Flow range 0.01 to 149 mL/min 1000 mbar (14.5 psi) above test pressure – Flow range 150 to 1000 mL/min 2000 mbar (29.0 psi) above test pressure Test pressure range: 20 to 6500 mbar (0.7 to 94.3 psi)
Pneumatic connections	1× Staubli IN male 1× Staubli OUT female 1× Staubli bag return 1× external vent 1× internal vent
Accessory printer	Palltronic Flowstar printer accessory connected via custom thermal printer interface 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.)
Peripherals	Power supply for external vent valve CAN bus to connect the MUX unit Automation via USB and Ethernet (OPC-UA)
Environmental conditions	Splash-proof: IP54 ⁽³⁾ Operating temperature: +5 to +40°C Storage temperature: -20 to +50°C Humidity: 80% up to 31°C, 50% at 40°C Cleaning fluid compatibility – 70%/30% ethanol/water, 70%/30% isopropyl alcohol/water Altitudes up to 3000 m ⁽⁴⁾ (9800 ft)

⁽¹⁾ The source code which falls under the GNU General Public License (GPL) is stored on the USB flash drive supplied with the instrument.

⁽²⁾ Contact your local Cytiva representative for other languages.

⁽³⁾ To meet the full requirements of IP54, splash-proof electrical connections to the instrument are necessary. These are available as accessories; please contact us for details.

⁽⁴⁾ For altitudes higher than 2000 m, we recommend an on-site calibration for best accuracy of measurement.

Thermal printer

The thermal printer for the Palltronic Flowstar V integrity test instrument delivers accurate printouts on long-lifetime Mitsubishi HiTec thermal paper.

Printer installation

The printer can be used on a table next to the Palltronic Flowstar V instrument or be set in the indentation on the top of the Palltronic Flowstar V instrument.



Fig 7. Thermal printer as delivered.



Fig 8. Thermal printer installed on the top of the Palltronic Flowstar V instrument.

Technical specifications

Environmental conditions (printer only)

Operating	5 to 40°C, 20% to 85% relative humidity (RH) non-condensing
Storage	-40 to +70°C, 5% to 95% RH non-condensing
IP rating (when transparent lid closed)	IP 20
Overall maximum dimensions (without cable)	Width × height × depth: 184 × 77 × 165 mm
Printer language	Printer should be capable to handle the printer language PCL5e or PostScript Printer language is proprietary and compatible with Palltronic Flowstar V instrument

Ordering information

Main system

Product	Product code
Palltronic Flowstar V filter integrity tester	FFS05
Palltronic Flowstar V filter integrity tester with DMS Pro software	FFS-FFS05-DMS
Flowstar V LGR filter integrity tester	FFS05-LGR

Accessories and spare parts

Product	Product code
Palltronic Flowstar V MUX sequential filter integrity test accessory	FFS05MUX
Palltronic Flowstar V barcode reader	FFS-BARCODE
Palltronic Flowstar V thermal printer	FFS-PRNT
Palltronic Flowstar V thermal printer paper rolls	S44.5.05
Palltronic Flowstar V USB stick	FFS-USB
Palltronic Flowstar V touchscreen pen	FFS-PEN
Palltronic Flowstar V protective transportation case	FFS-TC

External vent valves

Palltronic Flowstar V external vent valve	FFS-BHVALVE
Palltronic Flowstar V External vent valve (10 m cable)	FFS-BHVALVE-10M
Palltronic Flowstar V External vent valve (5 m cable)	FFS-BHVALVE-5M

Flowstar V LGR accessories

Flowstar V LGR hose accessory	FFS-LGRHOSE1
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Power cables

Palltronic Flowstar V power cable EU	FFS-PCEU
Palltronic Flowstar V power cable UK	FFS-PCUK
Palltronic Flowstar V power cable US	FFS-PCUS
Palltronic Flowstar V power cable Japan	FFS-PCJP
Palltronic Flowstar V power cable Switzerland	FFS-PCCH
Palltronic Flowstar V power cable Australia	FFS-PC AUS
Palltronic Flowstar V power cable China	FFS-PCZH

Software and automation

Product	Product code
Palltronic Flowstar V DMS Pro software	FFS-DMS
Palltronic Flowstar V PAS/X software	FFS05-PASX

mPath OIS software and license keys

mPath operational insights software installation package	FFS-OIS
License key to activate software, expires after one year	FFS-OISKEY1
License key to activate software, expires after three years	FFS-OISKEY3
License key to renew subscription, expires after one year	FFS-OISKEY1 N
License key to renew subscription, expires after three years	FFS-OISKEY3N

Automation adapters

Profibus automation adapter	FFS-AUTADAPTBUS
DeviceNet automation adapter	FFS-AUTADAPTDNET
PROFINET automation adapter	FFS-AUTADAPTPNET
Serial automation adapter	FFS-AUTADAPTSBUS

Systems that use the Palltronic Flowstar V integrity tester

Product	Product code
AquaWIT V integrity test system	AW05
Allegro™ Connect bulk fill system	ACBFSULPLC
Manual drug product filtration system	MANPUPSIT-US
Automated drug product filtration system	DPFS-UL-LB

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