

Asahi Gold Particle Test System-II (AGPTS-II)

As a leading manufacturer of equipment for virus filtration of plasma derivatives and biopharmaceuticals, Asahi Kasei Bioprocess understands that manufacturing groups require fast turnaround times to maintain throughput within their facility. As such, we have developed a second generation Asahi Gold Particle Test System (AGPTS-II) to streamline and automate the post-use integrity testing of Planova™ filters. With an improved viewing angle, data historian and optimized flow design to minimize bubble entrapment, the AGPTS-II offers reliable integrity testing in a format that is ideal for manufacturing environments.



Implement fast and reliable post-use integrity testing for Planova 15N, 20N and 35N filters.

Gold Particle Test

The gold particle test (GPT) is a post-use integrity test of Planova filters, which confirms no shift in pore size distribution after virus filtration. Following filtration of a proprietary gold colloid solution matched to the Planova filter type, the pore size distribution of the filter can be assessed by using spectrophotometric absorbance readings of the diluted integrity test solution and a permeate fraction to calculate the Asahi gold particle logarithmic reduction value (AGP LRV).



Using the manual method, performing the GPT on Planova 15N, 20N and 35N filters is a time-consuming, labor-intensive process. Among other requirements, the user is responsible for supplying tanks to store the diluted integrity test solution and maintaining

a constant pressure set-up to deliver the diluted integrity test solution to the Planova filter. The manual test set-up introduces opportunities for operator error and access to a spectrophotometer is required to obtain the absorbance readings for the permeate test fraction, diluted integrity test solution and water used to dilute the concentrated integrity test solution (AGP-HA). Therefore, the AGPTS-II was engineered to overcome these obstacles.

Save Time, Reduce Risk

Compared to the manual GPT, the AGPTS-II increases efficiency with respect to execution and reporting. The novel in-line visual spectrometer measures the absorbance of the diluted integrity test solution and a permeate fraction, eliminating the need for sample handling and an offline spectrophotometer analysis. The control unit calculates the AGP LRV and produces a filter pass/fail result within seconds, improving turnaround time on the production floor.

In addition to time savings on every test, the AGPTS-II has several risk-mitigating features. A QR code scanner allows instantaneous capture and documentation of filter spinning series number and filter production number to ensure that the GPT will only start if the software method selected is paired with the corresponding Planova filter type.

Alarms and interlocks prevent initiation of the GPT if solutions or on-board sensors are out of specification. Automatic differential pressure control via the proportional-integral-derivative (PID) feedback controller ensures that appropriate pressure conditions required by the GPT standard operating procedure are always met. Lastly, the permeate sample fraction is collected and retained.

Flexibility

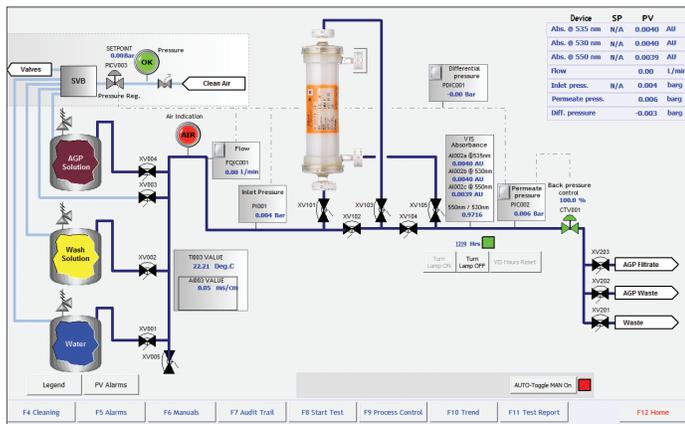
AGPTS-II control units are configured to handle Planova 15N, 20N or 35N filters. All AGPTS-II control units are delivered with a perpetual, non-exclusive software license to support testing of one Planova filter type. For greater flexibility, control units for Planova 15N or 20N filters can be configured with a second license to support testing of the other Planova filter. This is especially useful for multi-product environments, and it leverages the system's automation benefits against the need to purchase multiple testers. Planova 35N filter control units can only be licensed for Planova 35N filters.

The optional software phase for the pre-GPT wash step is included. This wash phase can be seamlessly programmed using the control unit, permitting the system to automatically step from the pre-GPT wash, to rinsing, to the GPT filtration without user input during the cycle.



Validated Control for Manufacturing

The AGPTS-II is designed to execute the GPT in compliance with the relevant standard operating procedures for the GPT. A traceability matrix that links the AGPTS-II steps with the manual GPT procedure is available.



A simple and intuitive Windows 7-based software interface allows the user to select the proper test program and initiate the GPT. Training on the unit can be completed in as little as 2 hours.

To minimize the validation burden to the end user, an IQ/OQ qualification package is executed on every AGPTS-II control unit at the factory prior to shipment. PQ was executed and validated on the original AGPTS system and the PQ package is included as a reference.

AGPTS-II units offer several improvements compared to manual GPT execution.

Single-Filter AGPTS-II Overview

After the pre-GPT wash solution and diluted integrity solution are prepared, one 4.0 or 1.0 m² Planova 15N, 20N or 35N filter is set in the automated Single-Filter AGPTS-II (1F AGPTS-II), which completes the GPT in less than 25 minutes and returns the AGP LRV and a pass/fail judgement. Intended for clinical and commercial manufacturing plants that have implemented Planova filters, the 1F AGPTS-II reduces handling, eliminates human error and improves turnaround times.

The 1F AGPTS-II is comprised of two units: a control unit and a feed unit. The control unit contains the programmable logic controller (PLC) and industrial PC which executes the appropriate GPT program. A non-metallic flow path includes a flow sensor, pressure sensors, valves and a fiber optic absorbance flow cell to direct the flow of each solution in defined volumes at a controlled pressure and flow rate.

The feed unit is a mobile cart with pressure tanks to supply water, pre-GPT wash solution and diluted integrity test solution to the filter. The hoses that connect the feed unit vessels to the control unit inlets are color-coded to prevent connection errors. Select the AGPTS-II feed unit corresponding to your individual needs.

As outlined below in Table 1, automating the GPT provides time-saving and risk-mitigating benefits relative to manual GPT operation.

Table 1. **Manual GPT vs AGPTS-II.**

	Manual Test	AGPTS-II	Improvement*
Permits the execution of the post-use Asahi Gold Particle integrity test to confirm membrane pore size distribution of the Planova filter	√	√	–
Complies with Asahi SOPs	√	√	–
Time to execute GPT is <25 minutes		√	~ 1 h per filter
Minimizes operator set-up time and shortens operator workload and training load in the plant		√	~ 0.5 h per filter
Provides an automatic and validated pass/fail report for the filter, obviating the need for offline spectrophotometric analysis by QC lab and shortening turnaround time		√	~ 1 to 4 h per filter
Provides a reproducible test & measurement method		√	Risk mitigation
Automatically verifies the suitability of the gold particle solution prior to the integrity test		√	Risk mitigation
Includes automated control of differential pressure during GPT filtration		√	Risk mitigation
Includes automated high pressure alarming to mitigate risk of test failure		√	Risk mitigation
Includes QR code reader for automated filter data entry to mitigate risk of data entry error		√	Risk mitigation
IQ/OQ/PQ protocols and test execution included; no user validation required		√	~ 4 weeks labor
Minimizes ongoing manual batch record maintenance by operators/QA		√	~ 0.5 h per filter
Eliminates the hidden cost of documenting and correcting a non-conformance associated with operator error in a manual test		√	~ 1 batch per year
Ensures that the appropriate test procedure is run on a Planova 15N, 20N or 35N filter		√	Risk mitigation

*Realized time savings may be more or less, depending on the facility, process or other factors.

Single-Filter AGPTS-II Mechanical System Description

- » Four-port inlet valve manifold (diluted integrity testy solution, air, pre-GPT wash solution, water)
- » Dry line detection
- » Planova differential pressure measurement
- » Feed side flow measurement and totalization
- » In-line VIS spectrometer
- » Backpressure control valve
- » Fractionation manifold for permeate collection
- » Cleaning by water rinse and air blowdown

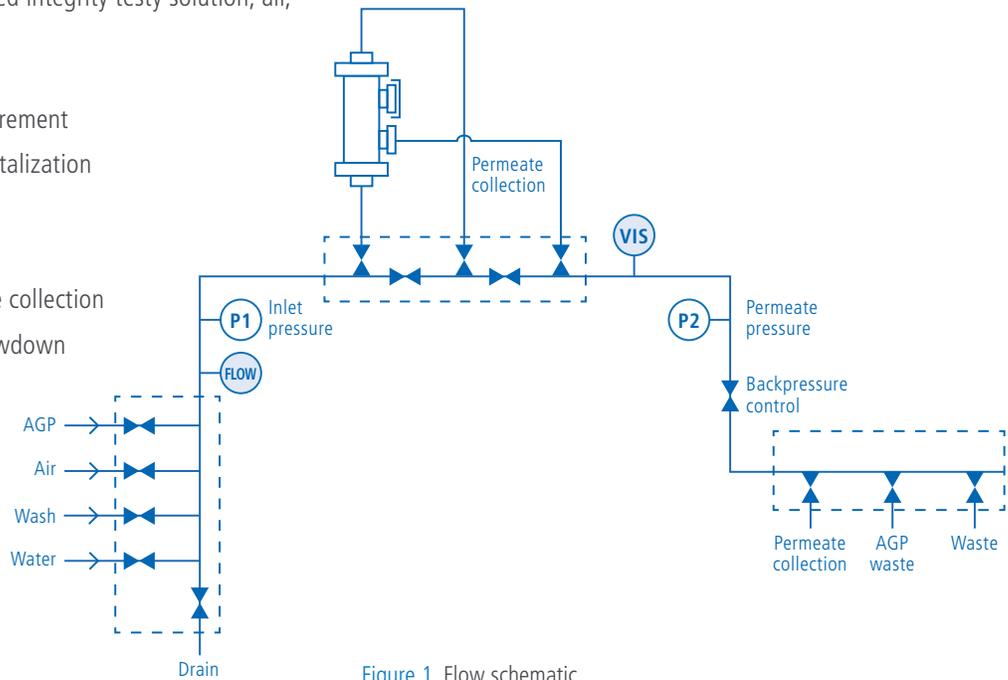


Figure 1. Flow schematic.

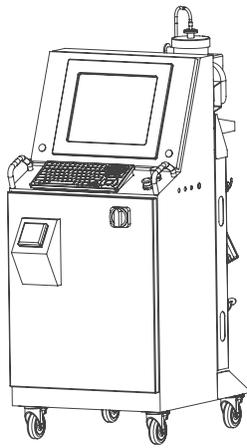
Single-Filter AGPTS-II Control Unit Specifications

Applicable filters	4.0 and 1.0 m ² Planova 15N, 20N and 35N filters
Number of filters connected	One filter
QR code scanner	For filter and integrity test solution identification prior to use
Process connections	Sanitary clamp (external), Flared tubing or sanitary clamp (internal)
Piping MOC	Smooth bore PFA tubing
Valve MOC	PTFE valve body; TFM™ PTFE diaphragm
VIS flowcell MOC	PEEK
VIS wavelength range	340 – 720 nm
wavelength accuracy	<1.0 nm
absorbance accuracy	±0.010 AU
noise	<0.05 mAU
drift	≤1.5 mAU/h
Pressure rating	0 to 3 barg
Temperature rating	4 – 30 °C (validated range for GPT)
Flow method	Pressure tank connected to compressed air (tank supplied separately)
Utility requirements	120 VAC 1-phase 60 Hz or 230 VAC 1-phase 50 Hz, 6.5 – 7.0 barg clean air
Electrical protection	NEMA 4X, IP55
Instrument rating	IP65
Dimensions	762 mm (30 in.) W x 940 mm (37 in.) D x 1625 mm (64 in.) H
Operator interface	Local display with keyboard
Control software	21CFR Part 11 compliant
Certificates	Certificates of Compliance, Material Certificates, Calibration Certificates, CE Declaration of Conformity available
Documentation	One print copy and one electronic copy provided
Qualification package	Asahi package included

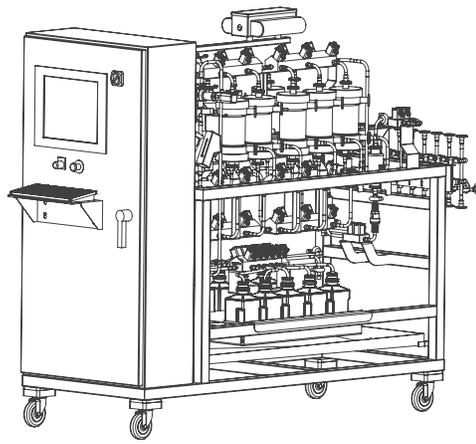
Multi-Filter AGPTS-II Control Units

Compared to the manual GPT, the 1F AGPTS-II reduces the time required for GPT set-up, operation and measurement for one Planova 20N 1.0 or 4.0 m² filter by over 50%. These time savings further increase with implementation of the 5F AGPTS-II, 6F AGPTS-II and 10F AGPTS-II Multi-Filter control units for 5, 6 and 10 Planova filters, accordingly.

For processes which utilize three or more Planova filters per batch, or in facilities that use more than 100 Planova filters per year, Multi-Filter AGPTS-II control units provide a way to perform the GPT even more efficiently. Multiple filters can be mounted on the system at once, and then the filters are automatically processed sequentially, reducing set-up time and labor costs (Figure 2). Multi-Filter AGPTS-II control units can be designed to accommodate one of two constant pressure operation modes: tank overpressure or pump-fed. The tank overpressure version is operated in conjunction with Asahi-supplied or user-supplied pressure tanks to supply the diluted integrity test solution, pre-GPT wash solution and water. Alternatively, the on-board pump version can be used to deliver the necessary solutions to the Planova filter from user-supplied bags or carboys.



Single-Filter AGPTS-II control unit



Multi-Filter AGPTS-II control unit

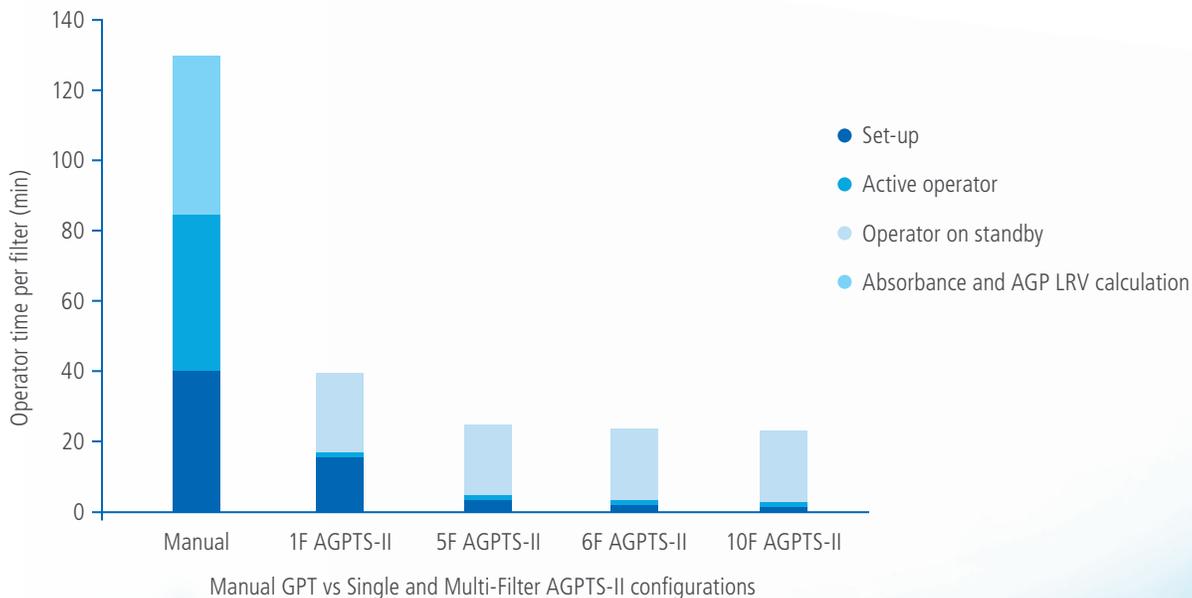


Figure 2. Time requirements for the manual GPT compared to automated options.

Ordering Information

Single-Filter AGPTS-II control units.

Catalog No.	Description	License Included	Add-on Licenses Available
GPT015	1F AGPTS-II control unit for 1.0 m ² and 4.0 m ² Planova 15N filters	P15N	P20N
GPT020	1F AGPTS-II control unit for 1.0 m ² and 4.0 m ² Planova 20N filters	P20N	P15N
GPT035	1F AGPTS-II control unit for 1.0 m ² and 4.0 m ² Planova 35N filters	P35N	None

Single-Filter AGPTS-II feed units.

Catalog No.	Description	Capacity	Filter Type	Water Tank Volume (L)	Pre-GPT Wash Tank Volume (L)	Tank Volume for Diluted Integrity Test Solution (L)
GPT003	Three tank Planova 15N/20N feed unit	One test	P15N or P20N	37	7.5	7.5
GPT004	Three tank Planova 15N/20N feed unit	Two tests	P15N or P20N	75	19	19
GPT005	Three tank Planova 15N/20N feed unit for use with the EZ GPT Kit	One test	P15N or P20N	37	7.5	Specially designed for EZ GPT Kit*
GPT033	Three tank Planova 35N feed unit	One test	P35N	37	7.5	7.5
GPT034	Three tank Planova 35N feed unit	Two tests	P35N	75	19	19
GPT035	Three tank Planova 35N feed unit for use with the EZ GPT Kit	One test	P35N	37	7.5	Specially designed for EZ GPT Kit*

*EZ GPT Kit is only available in the United States.

Single-Filter AGPTS-II spare parts.

Catalog No.	Description
GPT009	Spare parts kit (wear parts) for AGPTS-II
20023-0033	AKB VIS spectrometer, halogen lamp
KIT-FLOWCELL 3/8 PK	AKB PEEK VIS flow cell 3/8 in. (3/8 in. tri-clamp)
20023-0034	AKB fiber optic cable (AGPTS), 1.5 m
20024-0022	3/8 in. ultrasonic flowmeter, 0 – 6 LPM
20021-2017	3/8 in. flow-through pressure transmitter, 0 – 2 barg
20055-0010	1.0 m ² Planova filter holder adaptor
SFCU_CIP_Holder	Filter C.I.P. spool holder

Note: Wear parts and critical spare parts are stocked in the United States and Germany. All of the above spare parts with the exception of GPT009 are also compatible with Multi-Filter AGPTS-II control units.

Add-on licensing for Single-Filter and Multi-Filter AGPTS-II control units.

Catalog No.	Description
GPT120	Planova 20N software license add-on, point-of-sale
GPT115	Planova 15N software license add-on, point-of-sale
GPT220	Planova 20N software license add-on, after-sale
GPT215	Planova 15N software license add-on, after-sale

Technical Support

Asahi Kasei Bioprocess recommends annual maintenance to keep your AGPTS-II in proper working condition. We offer three different service options as described below.

Services for Single-Filter and Multi-Filter AGPTS-II control units.

	Silver Service Visit	Gold Service Visit	Platinum Service Contract
Features	Single-Filter SRV-221 Multi-Filter SRV-226	Single-Filter SRV-222 Multi-Filter SRV-227	Single-Filter SRV-223 Multi-Filter SRV-228
VIS spectrometer verification service	√	√	√
VIS lamp and fiber optic cable inspection	√	√	√
Replacement VIS lamp		√	√
Pressure regulator calibration		√	√
Pressure sensors verification		√	√
Flowmeter calibration		√	√
PLC battery replacement		√	√
Software patches			√
One emergency service visit			√
All spare wear parts for the year			√

Note: Technical support for Single-Filter and Multi-Filter AGPTS-II control units is available throughout the United States, Europe and Asia.

Multi-Filter AGPTS-II control units.

Catalog No.	Description	Filter Types Licensed	Compatible Filter Type Licenses	Operation Mode
GPT05FT150000	5F AGPTS-II control unit for one to five 4.0 or 1.0 m ² Planova 15N filters	P15N	P20N	Tank overpressure
GPT05FP150000				On-board pump
GPT05FT002000	5F AGPTS-II control unit for one to five 4.0 or 1.0 m ² Planova 20N filters	P20N	P15N	Tank overpressure
GPT05FP002000				On-board pump
GPT06FT150000	6F AGPTS-II control unit for one to six 4.0 or 1.0 m ² Planova 15N filters	P15N	P20N	Tank overpressure
GPT06FP150000				On-board pump
GPT06FT002000	6F AGPTS-II control unit for one to six 4.0 or 1.0 m ² Planova 20N filters	P20N	P15N	Tank overpressure
GPT06FP002000				On-board pump
GPT10FT150000	10F AGPTS-II control unit for one to ten 4.0 or 1.0 m ² Planova 15N filters	P15N	P20N	Tank overpressure
GPT10FP150000				On-board pump
GPT10FT002000	10F AGPTS-II control unit for one to ten 4.0 or 1.0 m ² Planova 20N filters	P20N	P15N	Tank overpressure
GPT10FP002000				On-board pump
GPT05FT000035	5F AGPTS-II control unit for one to five 4.0 or 1.0 m ² Planova 35N filters	P35N	Not available	Tank overpressure
GPT05FP000035				On-board pump
GPT06FT000035	6F AGPTS-II control unit for one to six 4.0 or 1.0 m ² Planova 35N filters	P35N	Not available	Tank overpressure
GPT06FP000035				On-board pump
GPT10FT000035	10F AGPTS-II control unit for one to ten 4.0 or 1.0 m ² Planova 35N filters	P35N	Not available	Tank overpressure
GPT10FP000035				On-board pump

Note: Pressure tanks for Multi-Filter AGPTS-II control units can be quoted upon request.

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