FAST AND RELIABLE POST-USE INTEGRITY TESTING

DATA SPECIFICATION SHEET

FOR PLANOVA 15N, 20N AND 35N FILTERS

BIOPROCESS FILTRATION

VANTIJ™ GPTS

VANTIJ GOLD PARTICLE TEST SYSTEM

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 VANTIJ Gold Particle Test System 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 GPTS offers reliable integrity testing in a format that is ideal for manufacturing environments.

SAVE TIME & REDUCE RISK

Compared to the manual GPT, the GPTS 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 GPTS 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-integralderivative (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.

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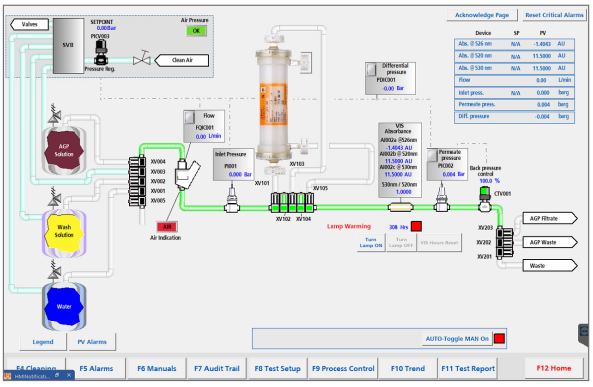
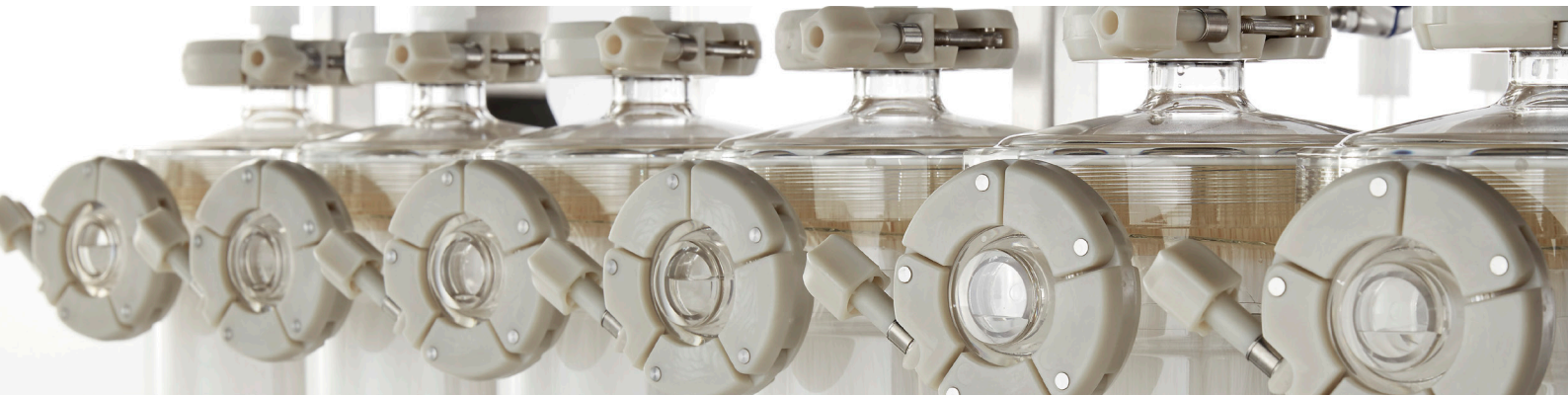
Flexibility

VANTIJ™ GPTS control units are configured to handle Planova 15N, 20N or 35N filters. All GPTS 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 used on the same unit. 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 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 GPTS is designed to execute the GPT in compliance with the relevant standard operating procedures for the GPT. A traceability matrix that links the GPTS steps with the manual GPT procedure is available. Our simple OCELOT System Control 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 two (2) hours.





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Single Filter Overview

AAfter the pre-GPT wash solution and diluted integrity solution are prepared, one Planova 15N, 20N or 35N filter is set in the automated Single-Filter VANTIJ GPTS (1F GPTS), 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 GPTS reduces handling, eliminates human error and improves turnaround times. The 1F GPTS 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 GPTS 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.

	Manual Test	VANTIJ	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		√	~ 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.*

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Single-Filter VANTIJ™ GPTS Mechanical System Description

- Four-port inlet valve manifold (diluted integrity test 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

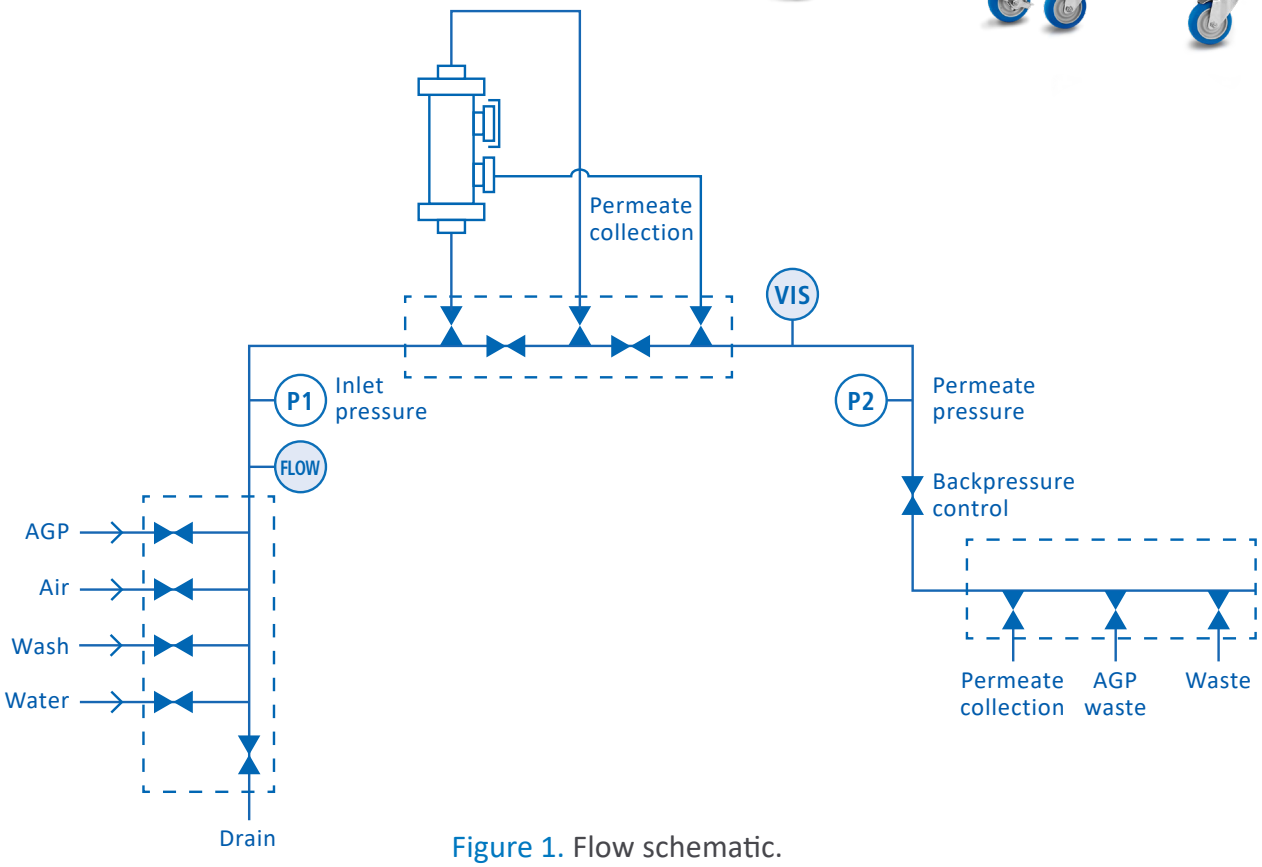

Figure 1. Flow schematic.

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Single-Filter VANTIJ™ GPTS Control Unit Specifications

Applicable filters	15N/20N filters: 4.0 and 1.0 m^2 35N filters: 0.3 and 0.12 m^2
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 types	Pressure tank connected to compressed air (tank supplied separately) Diaphragm pump
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	21 CFR Part 11 compliant
Certificates	Certificates of Compliance, Material Certificates, Calibration Certificates, EU Declaration of Conformity available
Documentation	One electronic copy provided
Qualification package	Asahi package included

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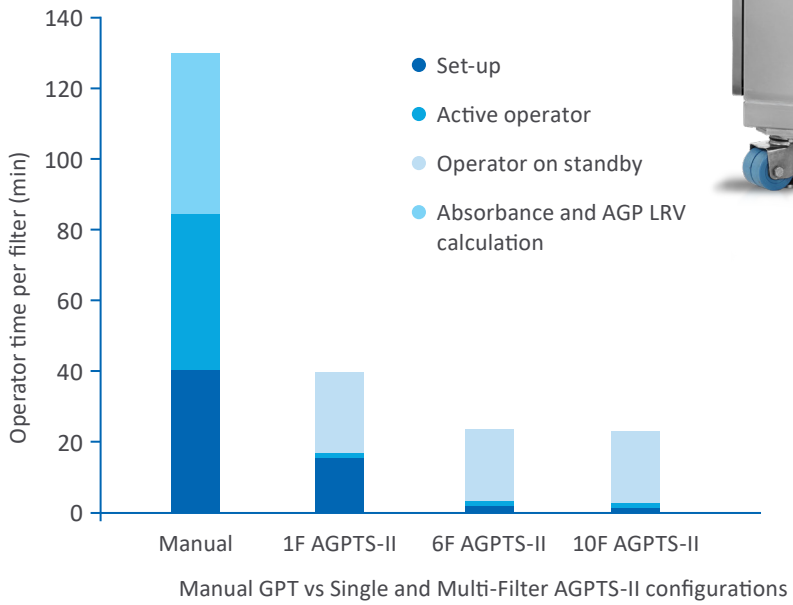
Multi-Filter AGPTS-II Mechanical System

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 6F GPTS or 10F GPTS Multi-Filter control units for 6 or 10 Planova filters, respectively.

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 GPTS 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 GPTS control units are designed to operate with an on-board pump that is used to deliver the necessary solutions to the Planova filter from user-supplied bags or carboys.



Manual GPT vs Single and Multi-Filter AGPTS-II configurations

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

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ORDERING INFORMATION

SINGLE FILTER VANTIJ GPTS

Catalog No.	Description	Filter Type	Operation Mode
AGPTS-01F-T	1F AGPTS-II control unit for 1.0 m^2 and 4.0 m^2 Planova 15N/20N filters	P15N	Overpressure tank
AGPTS-01F-P	1F AGPTS-II control unit for 1.0 m^2 and 4.0 m^2 Planova 15N/20N filters	P20N	On-board pump
AGPTS-01F-T	1F AGPTS-II control unit for 0.3 m^2 and 0.12 m^2 Planova 35N filters	P35N	Overpressure tank
AGPTS-01F-P	1F AGPTS-II control unit for 0.3 m^2 and 0.12 m^2 Planova 35N filters	P35N	On-board pump

SINGLE FILTER 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 feed unit	One test	P15N / P20N / P35N	37	7.5	7.5
GPT004	Three tank Planova feed unit	Two tests*	P15N / P20N / P35N	75	19	19

**Works with EZ GPT Kit (available only in the United States).*

Single-Filter VANTIJ Spare Parts

All AGPTS preventative maintenance parts kits include:

- Valve diaphragms
- Valve actuator
- Spectrometer bulb
- Tubing and fittings
- CIP spool
- Air filters

PM-KIT-AGPTS-03 (w/ cond.) includes:

- Conductivity flow cell O-rings

PM-KIT-AGPTS-04 (w/o cond.) includes:

- Nothing additional

PM-KIT-AGPTS-05 (w/ pump) includes:

- Diaphragm pump head

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.

Features	Silver Service Contract	Gold Service Contract	Platinum Service Contract
Unlimited phone/email support	√	√	√
Remote software support	√	√	√
Annual preventative maintenance (PM) visit	√	√	√
Spare parts included (PM)		√	√
One emergency support visit			√

Multi-Filter AGPTS-II control units.

Catalog No.	Description	Filter Types	Operation Mode
AGPTS-06F-P	6F AGPTS-II control unit for one to six 4.0 or 1.0 m^2 Planova 15N or 20N filters	P15N / P20N	On-board pump
AGPTS-10F-P	10F AGPTS-II control unit for one to ten 4.0 or 1.0 m^2 Planova 15N or 20N filters	P15N / P20N	On-board pump

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