

AGPTS: ASAHI GOLD PARTICLE TEST SYSTEM SINGLE FILTER CONFIGURATION

The Gold Particle Test (GPT) is a post-use integrity test of the Planova™ virus removal filter, which uses gold particles in solution as a model virus. The test evaluates the gold particle removal rate of the filter by measuring the absorbance of both the pre-filtered and the filtered gold particle solution, and provides a pass/fail result based on an LRV calculation of the absorbances. The Asahi Gold Particle Test System (AGPTS) is a compact, automated control unit designed to execute the post-use GPT for 1m² and 4m² Planova™ filters with 15nm and 20nm pore sizes.

Save time, reduce risk

The control unit has been designed to reduce both operating time and risk for post-use integrity testing. A typical gold particle test can be executed and reported in less than 25 minutes, a dramatic time savings compared to manual testing. A novel in-line visual wavelength spectrometer measures the absorbance of filtered gold particle solution and provides calculated LRV and filter pass/fail result within minutes. This eliminates the need for sample handling and offline spectrometer analysis. Potential for operator error is minimized through several risk-mitigating features. Alarms and interlocks prevent a test from initiating if pre-set operating conditions are not met. A bar code scanner allows automatic storage of filter lot # and filter ID #. Automatic differential pressure control via PID feedback ensures that appropriate pressure conditions are always met.

Validated control for manufacturing

The control unit is validated for use within cGMP manufacturing areas. A simple and intuitive software interface allows the user to select the proper test program and initiate the test. As few as two hours of training are required to begin using the unit. And since the system is designed according to the Asahi gold particle testing SOP and delivered with an Asahi qualification package, the validation burden to the user is minimized.



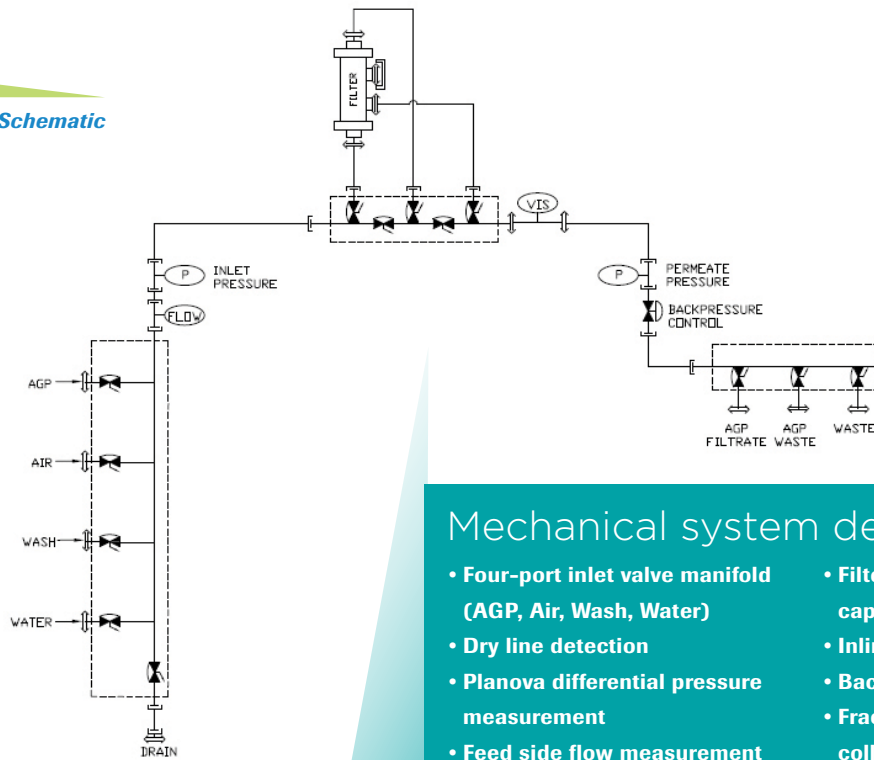
Fig. 1 Asahi Gold Particle Test System

Flexibility

The control unit includes an optional Triton-X/NaOH protein washing software phase. This wash phase can be seamlessly programmed into the control unit, permitting the machine to automatically step from protein washing, to rinsing, to the gold particle test without user intervention.

The control unit is also designed to execute the gold particle test on any of the four most common Planova™ filters used in manufacturing: 20N4-000, 20N1-000, 15N4-000, and 15N1-000. This proves especially useful for multi-product environments, and leverages the system's automation benefits against the need to purchase multiple testers.

Fig. 2 Flow Schematic



Mechanical system description

- Four-port inlet valve manifold (AGP, Air, Wash, Water)
- Dry line detection
- Planova differential pressure measurement
- Feed side flow measurement and totalization
- Filter up flow and down flow capability
- Inline VIS spectrophotometer
- Backpressure control valve
- Fraction manifold with AGPS collection bottle
- Cleaning by water rinse and air blow down

Control unit specifications

Applicable filters	— 20N4-000, 20N1-000, 15N4-000, and 15N1-000
# of filters connected	— One filter
Bar code scanner	— For filter identification prior to use
Process connections	— Triclamp (external), Flaretek or Triclamp (internal)
Piping MOC	— Smooth bore PFA tubing
Valve MOC	— PTFE
Flowcell MOC	— PEEK
VIS wavelength range	— 190-720 nm
wavelength accuracy	— ±0.5 nm
absorbance accuracy	— ±0.015 AU
noise	— <0.05 mAU
drift	— ≤1.5 mAU/h

Pressure rating	— 0 to 3 barg
Temperature range	— 4 - 30°C (validated range for GPT)
Flow method	— Pressurized tank by regulated air (tank supplied separately)
Utility requirement	— 120 VAC 1-phase 60 Hz or 230 VAC 1-phase 50 Hz, 5.5 barg instrument air, optionally 2.25 barg clean air
Electrical protection	— NEMA 4X, IP55
Instruments rating	— IP65
Dimensions	— 926 mm (36.5") W x 940 mm (37") D x 1600 mm (63") H
Operator Interface	— Local display with keyboard
Control Software	— 21CFR Part 11 compliant
Certificates	— Certificates of Compliance, Material Certificates 2.1 per EN 10204
Documentation	— One print copy and one electronic copy provided
Qualification package	— Asahi package included CE Declaration of Conformity available

Optional GPT feed unit

An optional feed unit cart is available, to provide pressurized feeds of gold particle solution, wash solution, and water to the control unit. Pressure regulation is achieved by the control unit.

// Two 10 L pressure tanks, one each for delivery of AGP and wash solutions, plus one 25 L pressure tank for delivery of water to the control unit

// Mounted on a portable cart

// Each tank includes air line and pressure relief valve

Software licensing

The Control Unit is designed to operate the post-use gold particle test for any of the following Planova™ filters: 20N4-000, 20N1-000, 15N4-000, and 15N1-000.

Software activations for 20N4 and 20N1 are bundled into the GPT020 control unit. Software activations for 15N4 and 15N1 are bundled into the GPT015 control unit. Both control units are capable of being upgraded to operate both the 15N and 20N filters with a one-time fee. Both control units are identical except for the software programs which are activated upon delivery. Please contact your local sales rep for assistance selecting the correct package for your intended usage.

Technical support and spare parts

Technical support for the unit is available from our U.S. headquarters in Glenview, Illinois, as well as from our European technical center in Köln, Germany.

Critical spare parts are maintained in stock at both the U.S. and German facilities.

Service contracts are also available for turnkey support. Custom engineered multi-filter AGPTS systems and VF systems are also available.

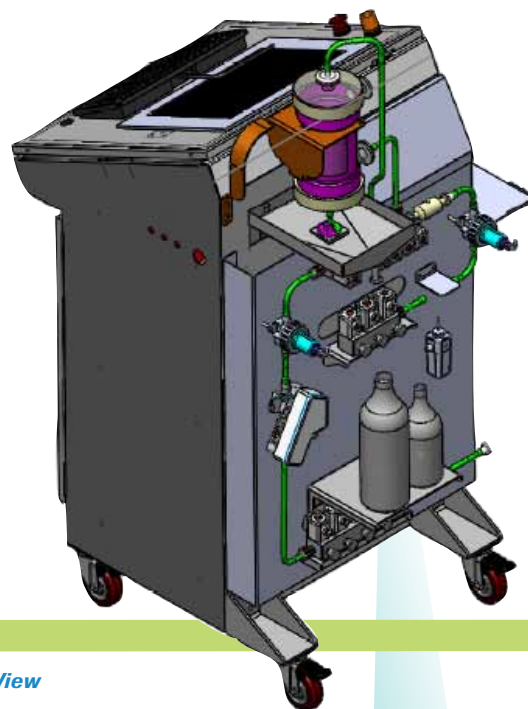


Fig. 3 Rear Isometric View

Catalog#	Description
GPT015	Control unit including license for 15N4-000 + 15N1-0000
GPT020	Control unit including license for 20N4-000 + 20N1-0000
GPT003	Feed unit, three tank configuration, 10L-10L-25L
GPT009	Control unit spare parts kit
GPT120	20N4-000 + 20N1-0000 license adder for GPT015, point-of-sale
GPT115	15N4-000 + 15N1-0000 license adder for GPT020, point-of-sale
GPT220	20N4-000 + 20N1-0000 license adder for GPT015, future upgrade
GPT215	15N4-000 + 15N1-0000 license adder for GPT020, future upgrade

Asahi**KASEI**

ASAHI KASEI BIOPROCESS

Please contact us for pricing and delivery information:

// **North America**

Asahi Kasei Bioprocess, Inc.
1855 Elmdale Ave.
Glenview, IL 60026 USA
+1 847 556-9700
info@ak-bio.com

// **Europe**

N.V. Asahi Kasei Bioprocess Europe S.A.
Rue Colonel Bourg, 122
1140 Brussels
Belgium
+32-2-526-0500
planova_de@om.asahi-kasei.co.jp

// **Asia**

Asahi Kasei Medical Co., Ltd.
Planova Division
1-105 Kanda Jinbocho
Chiyoda-ku, Tokyo 101-8101
+81-3-3296-3780
planova_jp@om.asahi-kasei.co.jp

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