



# Sartocheck<sup>®</sup> 5 Plus Filter Tester

Keeps Your Risk Factors under Control

## Product Information

The Sartocheck<sup>®</sup> 5 Plus represents the ideal intersection point of today's most relevant industry requirements for filter integrity testing within demanding GMP environments. A combination of a unique approach to Quality Risk Management as well as optimal data integrity, intuitive usability and minimized risk factors for Health, Safety and Environment (HSE) set a new standard for filter integrity test devices.



## Surpass the Requirements of QRM

The regulatory focus on QRM (cf. ICHQ9 and the new Annex 1 written by EMA in cooperation with the US-FDA, WHO and PICs) also applies to filter integrity testing, as a fundamental element of sterility assurance. The Sartocheck<sup>®</sup> 5 Plus Filter Tester uses program specific parameters allowing the automatic identification of testing anomalies before or during the test. This prevents time-consuming, costly variations, potential drug recalls and 483 warning letters.

## Experience the Comfort of Intuitive Usability

An optimal user experience speeds up process workflows due to intuitive guidance and ease of use. The high-quality touchscreen of the Sartocheck<sup>®</sup> 5 Plus Filter Tester provides a unique viewing angle, an intuitive user interface, a logical menu structure, and simple data entry options. This allows straightforward programming of tests and QRM enhancement features, as well as error-free operation in GMP production environments.

## Reach the Ultimate Level of Data Integrity

Devastating malware incidents and the continuing threat of computer-related virus infections have created an urgent need for data protection and security. The completeness, consistency and accuracy of data during its entire life-cycle are critical aspects of regulatory compliance in all systems that generate, store and retrieve it. The customized Linux Operating System and write protected root file system of the Sartocheck<sup>®</sup> 5 Plus, along with the unalterable data formats associated with test results and audit trail, protect against malware and virus infections, ensuring data integrity is always preserved.

## Discover the Simplicity of Health, Safety, and Environment (HSE)

Integrity testing often involves the use of chemicals and hazardous materials e.g. alcohol. The Sartocheck<sup>®</sup> 5 Plus is certified for use in explosion hazardous areas (ATEX) and is compatible with all current cleaning agents and VHP. This ensures maximum safety for operators and manufacturing facilities.

## Quality Risk Management

- Automatic detection of incorrect test setups
  - Program specific min and max values for volume determination
  - Program specific min diffusion/intrusion values
  - Program specific min flow at pressure end during a bubble point test
- Automatic detection of abnormal test conditions
  - Detection of abnormal pressure increase
  - Detection of environmental temperature outside prerequisite conditions and temperature changes (roadmap – free software upgrade – requires sensor)
  - Detection of unstable test values (roadmap – pat. pending – free software upgrade)
- Prevention of irregular test repeats (roadmap – pat. pending – free software upgrade)
- Self-test at booting and before each test
- Comprehensive Failure Mode Effects Analysis (FMEA) including instructions for setting of program specific QRM values
- Calculation tool for the impact of unlikely calibration offsets

## Usability

- Intuitive iF-Design rewarded Human Machine Interface (HMI)
- 12.1" bright touchscreen with a  $\pm 88^\circ$  viewing angle
- Large digital keypad - no need for a pen – compatible with glove use
- 10 system languages
- LDAP - Log on with network user credentials
- Automatic test time for faster testing
- Data transfer
- Automation



## Data Integrity

- Custom Linux-based Operating System
- Rare processors
- Write protected root file system
- All redundant inbound connections over the three Ethernet ports are disabled
- The device is programmed to ignore unrecognized commands
- Four eyes principle with electronic signature (September 2019 release – free software upgrade)
- Internal Double Data Backup
- Encrypted Data
- Time Zone synchronization
- Audit Trail with time stamped events
- User Matrix to generate individual user roles
- Mandatory fields for operator entries
- Data entry by barcode scanner
- Long-life printouts and sticker function

Request the Data Integrity statement for more details

## Health Safety and Environment (HSE)

- Splash-proof (IP64)
- Ex-proof (ATEX IECEx & FM certified)
- Safe testing and re-testing of alcohol wetted filters
- Continuous and clear visualization of pressure status
- Resistant to all current cleaning agents
- H<sub>2</sub>O<sub>2</sub>-vapor resistant (VHP)
- PFA tubes (FDA 21 CFR 177 and USP Class VI compliant)
- Automated cleaning of all pneumatics with up to 0.5 M NaOH at 50 °C/122 °F
- Optional accessory kit for backflow protection

## Technical Data

### Test Methods

Diffusion (DIN 58536 part 2)
Bubble Point (detection by over proportionality)
Combined diffusion and bubble point
Water Intrusion Test
Pressure drop   leak test
Multipoint diffusion (see roadmap)

### Measuring Ranges

Diffusion and intrusion test	50 – 6,600 mbar   0.73 – 95.7 psi pressure
Programmable max diffusion flow	0.01 – 4,800 ml/min
Programmable max intrusion water flow	0.005 ml/min – 60.000 ml/min
Max measurable   displayable diffusion flow	24,000 ml/min (5 times the max programmable value)
Max. measurable   displayable intrusion water flow	300 ml/min
Programmable minimum bubble point	250 – 6,550 mbar   3.63 – 95.0 psi
Programmable pressure drop (not higher than the test pressure)	0.1 – 6,600 mbar   0.002 – 95.7 psi
Sample net volume with volume measurement	
– with int. reference vessel	14 L
– with ext. reference vessel	150 L
Max. sample net volume for pressure drop test	1,000 L

### Power supply

Power requirements	100 – 240 V AC at 50   60 Hz
Max. Power Input	74 W
Average power usage	66 W
Power consumption in standby mode	14.8 W

A country specific cable is delivered with each device.

### Pneumatics

Max. inlet pressure	8,000 mbar   116 psi
Overpressure protection	Max inlet pressure + 4,000 mbar
Min. inlet pressure	4,000 mbar   58 psi
Internal reference volume	1,023 ml conforming to Pressure Equipment Directive 2014/68/EU Max. Pressure = 12 bar pressure certificate

### Measuring Accuracies

Measured pressure	± 0.1 % full scale (± 7.2 mbar   ± 0.104 psi)
Measured pressure drop	0.2 % of the measured value before rounding
Volume Determination	± 4 %
Diffusion and intrusion	± 5 %
Bubble Point	± 50 mbar   ± 0.7 psi
Accelerated bubble point	± 50 mbar   ± 0.7 psi from the starting pressure to one pressure step above the minimum bubble point

### Dimensions, weight and noise

Dimensions (W × D × H)	348 × 379 × 286 mm
Weight	16.6 kg
Weight of the packaging	2.4 kg
Cargo   gross weight	22 kg
Cargo volume	95,304 cm <sup>3</sup>
Cargo dimensions	570 × 440 × 380 mm
Max Noise at 1 m during depressurization at max test pressure	< 70dB(A)

### Materials of construction and roughness

All materials used for the external surfaces and the fluid paths are animal free.

### External surfaces

- Ra 1.6 µm or better
- Stainless steel 316L
- Heat strengthened glass (see "Screen and protective glass")
- Plastic polymer (Edistir® polystyrene PBBE free) painted with chemical resistant Alexit-lacquer 5300
- Aluminum painted with chemical resistant Alexit-lacquer 5300
- Rubber feet: Taber H-18 abrasion resistant (ASTM-501C)

### Pneumatic fluid path of the Sartocheck® 5 Plus

- Ra 1.6 µm or better
- Aluminum (inlet valve block, no potential product contact)
- Stainless steel 316L (process valve block)
- Stainless steel 316L (connectors)
- EPDM (connector gaskets), FDA 21 CFR 177 and USP Class VI (A)
- PFA tubes, FDA 21 CFR 177 and USP Class VI (A)
- PTFE (valve block membrane FDA 21 CFR 177 and USP Class VI (A))

### Pneumatic fluid path of the Accessory Kit for external venting

- Ra 1.6 µm or better
- Stainless steel 316L (valves)
- Stainless steel 316L (connectors)
- EPDM (connector gaskets) FDA 21 CFR 177 and USP Class VI (A)

### External tubes (inlet and test tube)

- PFA tubes, FDA 21 CFR 177 and USP Class VI (A)
- Stainless steel 316L (connectors)
- EPDM (connector gaskets) FDA 21 CFR 177 and USP Class VI (A)
- Sintered Polyethylene (inlet filter housing)
- Polypropylene (inlet filter)
- Stainless steel 316L Parker nipple

### Screen and protective glass

Size	12.1" (Format 16:10; 262.6 × 164.7 mm   10.34 × 6.48 inch)
Type	TFT LED-Backlit color
Resolution	1,280 × 800 pixels
Luminosity	400 CD/m <sup>2</sup>
Viewing angle vertical and horizontal	± 88° (total 176°)
Shock resistance	Thermally toughened glass DIN EN 12150-1; IEC 60068-2-75
Antiglare	LS Touch Gloss 85 ± 10   60° on front side

### Connectors and ports

All connectors and ports are located on the backside of the device to free up the working space.

### Pneumatic Connectors

Inlet tube towards pressurized line	Parker nipple (Parker reference 26SFAW13MXN)
Inlet tube towards device	Staubli RBE03 female
Test tube towards sample to be tested	Staubli RBE03 female

All connectors on the device are specifically defined in order to avoid mix up between different connections. E.g. the test tube can only be connected to the outlet of the device.

### Pneumatic tubes

All pneumatic tubes have been leak tested at the end of manufacturing.

Use only original test tubes of original length with original connectors to avoid any mix up.

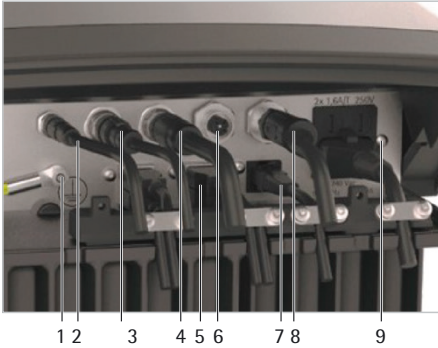
### Communication ports

- Modbus TCP for automation
- Ethernet RJ45 for networking and data transfer
- USB (4 ports) for software upgrades, barcode reader and USB printer

### Operating Conditions

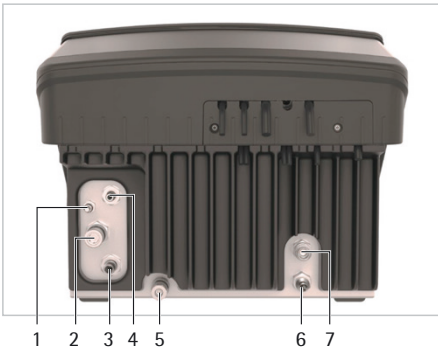
Environmental temperature and humidity according to IEC 61010-1	0 °C to 40 °C (32 – 104 °F) From 0 °C to 31 °C 80% RH From 31 °C to 40 °C linearly decreasing to 50% RH
Altitude	100 m below sea level to 3000 m above sea level
Ingress protection rating of the device as per EN 60529 / IEC 60529	IP64 under normal conditions IP4X for use in potentially explosive atmospheres
Ingress protection of the Accessory Kit for external venting as per EN 60529 / IEC 60529	IP65
Explosion prone areas (device only)	Zone 2, Groupe II-B (IECEX, ATEX)   Class 1 Zone 2 Group II-B (USA)
Explosion prone areas (Accessory Kit for venting)	Zone 1 Group II-B (IECEX, ATEX)   Class 1, Div. 1, Zone 1 Group II-B (USA)

### Connectors on the backside



- 1 Earth
- 2 Future environmental temperature sensor
- 3 External pressure sensor
- 4 External valves
- 5 4 x USB (e.g. printer)
- 6 Future extender box
- 7 RJ45
- 8 Modbus TCP
- 9 Power

### Back cover closed



- 1 Device cleaning
- 2 Outlet | Test tube
- 3 Sample vent
- 4 Device vent
- 5 Ext. reference tank
- 6 Inlet pressure max. 8 barg
- 7 External valves pressure supply

### Fixation of cables



### Operating system and memory

- Custom Linux Distribution made by Sartorius
- Flash memory 4 GB
- RAM 2 GB
- Internal inaccessible SD card 8 GB
- CPU MSC NanoRISC i.MX6 D 800 MHz

### Memory capacity

The memory can hold approximately 21,900 test results. In case of 10 tests per day, 365 days per year, the memory will be full after approximately 6 years.

### Test result calculation, evaluation and rounding

The test evaluation is done before the rounding meaning that e.g. a measured diffusion value with 16 decimals of 4.4000000000000001 ml/min will give a failed test if the max diffusion value is set to 4.40 ml/min. The test result rounding is done according to the tie-breaking rule called "round half to even". This is the default rounding mode used in IEEE 754 computing functions and operators.

### Storage and transportation conditions

From -10 °C to +60 °C (14–140 °F) at 90% RH noncondensing humidity.

The original cardboard box is single use shipping only. For subsequent shipping please use the solid transportation box 26787---ST (see accessories).

### Language Options

- English
- German
- French
- Spanish
- Italian
- Mandarin (simplified)
- Portuguese (Brazilian)
- Japanese
- Korean
- Russian

#### Cleaning and chemical compatibility of external surfaces (based on Alexit lacquer compatibility)

Do not use any abrasive cloth.

Only smooth cloths or towels are allowed.

- Spor-Klenz® Ready-To-Use Cold Sterilant
- 3% Hydrogen Peroxide WFI Sterile Solution
- Septihol® Sterile Alcohol Solution 70% IPA
- Water for injection
- Sodium hydroxide (NaOH) 10%
- Hydrochloric acid (HCL) 20%
- Sulfuric acid (H2SO4) 20%
- Acetic acid 10%
- Ammoniac 10%
- Quaternary ammonium compounds 0.2%
- Cleansinald (Quaternary ammoniums blended with alkyl amines)
- Bacterianos (Glutaraldehyde 0.5 mg/g and didecyldimethylammonium chloride 1.2 mg/g; pH 3 – 5, contact time > 15 min)
- Aniospray (Ethanol 226 mg/g, Chlorure de didécyldiméthylammonium 0.53 mg/g, chlorhydrate de polyhexaméthylène biguanide 0.64 mg/g contact time > 15 min)
- Amphospray (Ethanol 327.4 mg/g, N-(3-aminopropyl)-N-dodé- cylpropane- 1,3-diamine 0.33 mg/g), chlorure de didécyldiméthylammonium 1.09 mg/g), chlorhydrate de polyhexaméthylène biguanide 0.96 mg/g)
- Formaldehyde 37%
- Sodium hypochlorite 6%
- Ethanol (60%, 70% and pure)
- Acetone (pure)
- Ethyl acetate (pure)
- Minncare Cold Sterilant
- Vaporized Hydrogen Peroxide (VHP) at 1400 ppm

#### Cleaning of internal pneumatics

Only use the original Accessory Kit for cleaning 26787---AK---CL (cf. roadmap)

#### Warning!

Inflammable or explosion prone liquids must not be used for internal cleaning because the Accessory Kit for cleaning is not compliant to hazardous areas or liquids.

Use the following cleaning agents:

- Sodium hydroxide up to 0.5 M at 50 °C (122 °F)
- Water for injection 50 °C (122 °F)
- Citric acid 10% at 25 °C (77 °F)
- Sodium hypochlorite 10% at 25 °C (77 °F)
- 3% Hydrogen Peroxide at 25 °C (77 °F)

#### Sartocheck® 5 and 5 Plus Filter Tester comparison

Feature	Sartocheck® 5	Sartocheck® 5 Plus
QRM related program parameters	No	Yes
Automation (Modbus TCP)	No	Yes
Data Integrity	Identical	Identical
HSE – ATEX   IECEx   FM	Identical	Identical
Usability	Identical	Identical
Accuracy	Identical	Identical
Cleanability	Identical	Identical
Accessory kits (external venting kit and cleaning kit)	Compatible	Compatible
Free of charge software upgrades	Only 4 eyes principle and electronic signature release (September 2019)	Yes – All



## Ordering Information

Description	Article No.	Description	Article No.
Sartocheck® 5 Filter Tester	26787---FT	Tube for "device vent"	26787---VT---DE
Sartocheck® 5 Plus Filter Tester	26787---FT---P	Tube for "sample vent"	26787---VT---SA
<b>Equipment included in 26787---FT</b>		Environmental temperature sensor 2 m	26787---ES---02
Sartocheck® 5 Filter Tester		Environmental temperature sensor 5 m	26787---ES---05
Inlet tube for compressed gas 2m (26787---IT)		Environmental temperature sensor 10 m	26787---ES---10
Test tube 2 m (26787---TT---02)		Accessory kit for cleaning of the pneumatics	26787---AK---CL
Test certificate		Additional waste vessel for the accessory kit for cleaning	26787---AKWV---CL
Calibration certificate		Barcode Scanner (None ATEX)	26787---BS
Installation and operating instructions		External reference volume	26787---ER
Power cord Region specific		Additional tube for the external reference volume	26787---TE---RV
Screw driver (T20 × 100) for fixation of cables		Solid transportation box for the Sartocheck® 5   5 Plus	26787---ST
<b>Equipment included in 26787---FT---P</b>		Validation package (incl. IQ/OQ) for Sartocheck® 5/5 Plus	26787---V3---FT
Sartocheck® 5 Plus Filter Tester		Sartocheck® 5/5 Plus installation	S872QINST
Inlet tube for compressed gas 2 m (26787---IT)		Sartocheck® 5/5 Plus installation pack (incl. travel exp.)	S872QINSTP
Test tube 2 m (26787---TT---02)		Valve Kit installation	S873IINST
Test certificate		Valve Kit installation pack (incl. travel exp.)	S873IINSTP
Calibration certificate		Sartocheck® 5/5 Plus IQ/OQ	S872QIQOQ
Installation and operating instructions		Sartocheck® 5/5 Plus IQ/OQ service pack (incl. travel exp.)	S872QIQOQP
Risk Assessment for integrity testing   FMEA (PDF)		Valve Kit IQ/OQ	S873IIQOQ
Power cord region specific		Valve Kit IQ/OQ service pack (incl. travel exp.)	S873IIQOQP
Screw driver (T20 × 100) for fixation of cables		Service level agreement Advanced	S872QSLAA
<b>Accessories and spare parts</b>		Service level agreement Comprehensive	S872QSLAC
<b>Description</b>	<b>Article No.</b>	Service level agreement Essential	S872QSLAE
USB printer (without paper)	YDP30	Midisart Test Manifold for parallel bubble point	1Z-LB-0002
Standard paper 90m and ink ribbon set	69Y03285	Triclamp 25 mm – Staubli nipple RBE03 open	7ZML--0011
Self-adhesive paper 90 m and ink ribbon set	69Y03286	Triclamp 25 mm – Staubli nipple RBE03 closed	7ZML--0009
Standard thermal paper 5 rolls of 24 m	69Y03287	Tri Clamp 50.5 mm – Staebli nipple RBE03 closed	7ZML--0019
Self-adhesive thermal paper 5 rolls of 13 m	69Y03288		
Inlet tube for compressed gas 2 m	26787---IT		
Test tube 2 m	26787---TT---02		
Test tube 5 m	26787---TT---05		
Test tube 15 m	26787---TT---15		
Accessory kit for external venting	26787---AK---EV (max. 10 accessory kits per device due to calibration data)		

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