Sartocheck® 5 Plus
Filter Tester

Keeps Your Risk Factors Under Complete Control

New Software Release Q2 2020

Product Information

The Sartocheck® 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 (QRM) 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® 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® 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 errorfree-operation in GMP production environments.

Reach the Ultimate Level of Data Integrity
Filter integrity test values are part of the batch protocol and are used to justify the drug release. Long-term reliable data is crucial to avoid quality deviations and potential 483 warning letters.

The integrity and security of filter integrity test data must not be seen only as an IT problem, but also as a potential global business risk. Low standards of data integrity and security may not only jeopardize the activities of the drug manufacturing company, but more critically, endanger the health of patients.

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® 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 to avoid false passed and false failed test results
- Calculation tool for the impact of unlikely calibration offsets

**Usability**
- Intuitive iF-Design rewarded
- Human Machine Interface (HMI)
- 12.1” bright touchscreen with a ± 88° 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 by OPC UA or Modbus TCP
- Additional keyboards (Korean and Cyrillic)
- LDAP group-based role management

**Data Integrity**
- Custom Linux-based OS with SSB custom architecture
- Audit trail with time zone-synchronized (NTP) events
- Write-protected and constantly monitored root file system
- Encrypted double data backup | Redundant data storage
- 4 eyes principle | Electronic signatures
- Comprehensive and flexible role management
- Locking out user after X number of unsuccessful login attempts
- Serial number of the device in every audit trail entry

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
- H₂O₂-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 (Q3 2020)
- Optional accessory kit for backflow protection (26787---AK---EV)
### Technical Data

#### Test Methods

- **Diffusion**
- **Bubble point (detection by over proportionality)**
- **Combined diffusion and bubble point**
- **Water intrusion test**
- **Pressure drop | leak test**
- **Multipoint diffusion (see roadmap)**

#### Measuring Ranges

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diffusion and intrusion test pressure</td>
<td>50 – 6,600 mbar</td>
</tr>
<tr>
<td>Programmable max diffusion flow</td>
<td>0.01 – 4,800 ml/min</td>
</tr>
<tr>
<td>Programmable max intrusion water flow</td>
<td>0.005 ml/min – 60,000 ml/min</td>
</tr>
<tr>
<td>Max measurable</td>
<td>displayable diffusion flow</td>
</tr>
<tr>
<td>Max. measurable</td>
<td>displayable intrusion water flow</td>
</tr>
<tr>
<td>Programmable minimum bubble point</td>
<td>250 – 6,550 mbar</td>
</tr>
<tr>
<td>Programmable pressure drop (not higher than the test pressure)</td>
<td>0.1 – 6,600 mbar</td>
</tr>
<tr>
<td>Sample net volume with volume measurement</td>
<td></td>
</tr>
<tr>
<td>- with int. reference vessel</td>
<td>14 L</td>
</tr>
<tr>
<td>- with ext. reference vessel</td>
<td>150 L</td>
</tr>
<tr>
<td>Max. sample net volume for pressure drop test</td>
<td>1,000 L</td>
</tr>
</tbody>
</table>

#### Measuring Accuracies

<table>
<thead>
<tr>
<th>Measuring Type</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measured pressure</td>
<td>± 0.1 % full scale (± 7.2 mbar</td>
</tr>
<tr>
<td>Measured pressure drop</td>
<td>0.2 % of the measured value before rounding</td>
</tr>
<tr>
<td>Volume determination</td>
<td>± 4 %</td>
</tr>
<tr>
<td>Diffusion and intrusion</td>
<td>± 5 %</td>
</tr>
<tr>
<td>Bubble point</td>
<td>± 50 mbar</td>
</tr>
<tr>
<td>Accelerated bubble point</td>
<td>± 50 mbar</td>
</tr>
</tbody>
</table>

### 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

### Dimensions, Weight, and Noise

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (W × D × H)</td>
<td>348 × 379 × 286 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>16.8 kg</td>
</tr>
<tr>
<td>Weight of the packaging</td>
<td>2.2 kg</td>
</tr>
<tr>
<td>Cargo</td>
<td>gross weight</td>
</tr>
<tr>
<td>Cargo volume</td>
<td>95,304 cm³</td>
</tr>
<tr>
<td>Cargo dimensions</td>
<td>570 × 440 × 380 mm</td>
</tr>
<tr>
<td>Max noise at 1 m during depressurization at max test pressure</td>
<td>&lt; 70dB(A)</td>
</tr>
</tbody>
</table>

### 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.

### Manufacturing Site

- Designed, developed, and manufactured in Germany
- Otto-Brenner Strasse 20
- Goettingen, Germany

### End-user Training

The Sartocheck® comes with end-user training.
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 304L
- 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 304L (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 304L (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)
- Polypropylene (inlet filter housing)
- Stainless steel 316L Parker nipple

Screen and Protective Glass

Size

12.1” (Format 16:10; 262.6 x 164.7 mm | 10.34 x 6.48 inch)

Type

TFT LED-Backlit color

Resolution

1,280 x 800 pixels

Luminosity

400 CD/m²

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 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 Connectors

Inlet tube towards pressurized line
Parker nipple (Parker reference 265FAW13MXN)

Inlet tube towards device
Staubli RBE03 female

Test tube towards sample to be tested
Staubli RBE03 female

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

- Industrial automation for OPC UA and Modbus TCP
- 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, Group II-B (IECEx, ATEX) | Class 2 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 × USB (e.g. printer)
6 Future extender box
7 RJ45
8 Industrial automation
9 Power

Back cover closed

Fixation of cables

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

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. At a rate 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 didecylidimethyl-ammonium chloride 1.2 mg/g, pH 3 – 5, contact time > 15 min)
- Aniospray (Ethanol 226 mg/g, Chlorure de didécylidiméthyl-ammonium 0.53 mg/g, chlorhydrate de polyhexaméthyléne biguanide 0.64 mg/g, contact time > 15 min)
- Amphospray (Ethanol 327.4 mg/g, N-(3-aminopropyl)-Ndé-cylpropane-1,3-diamine 0.33 mg/g, chlorure de didécylidiméthylammonium 1.09 mg/g, chlorhydrate de polyhexaméthyléne 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

Use only the original Accessory Kit for cleaning 26787---AK---CL (available Q3 2020)

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
- 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

<table>
<thead>
<tr>
<th>Feature</th>
<th>Sartocheck® 5</th>
<th>Sartocheck® 5 Plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>QRM-related program parameters</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Automation (OPC UA and Modbus TCP)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Data integrity</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>HSE – ATEX</td>
<td>IECEx</td>
<td>FM</td>
</tr>
<tr>
<td>Usability</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Accuracy</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Cleanability</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Accessory kits (external venting kit and cleaning kit)</td>
<td>Compatible (cleaning kit available in Q3 2020)</td>
<td>Compatible (cleaning kit available in Q3 2020)</td>
</tr>
<tr>
<td>Free software upgrades</td>
<td>Upgrades related to data integrity, usability, and HSE are included. Not included: automation and QRM-related features</td>
<td>Yes – All</td>
</tr>
</tbody>
</table>
## Ordering Information

### Sartocheck® Filter Tester

<table>
<thead>
<tr>
<th>Description</th>
<th>Article No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sartocheck® 5 Filter Tester</td>
<td>26787---FT</td>
</tr>
</tbody>
</table>

**Equipment included in 26787---FT**

- Sartocheck® 5 Filter Tester
- Inlet tube for compressed gas 2m (26787---IT)
- Test tube 2 m (26787---TT---02)
- Test certificate
- Calibration certificate
- Installation and operating instructions
- Power cord (region-specific)
- Screw driver (T20 × 100) for fixation of cables
- Networking cable (RJ45)
- Printer cable (USB)

### Sartocheck® Plus Filter Tester

<table>
<thead>
<tr>
<th>Description</th>
<th>Article No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sartocheck® 5 Plus Filter Tester</td>
<td>26787---FT---P</td>
</tr>
</tbody>
</table>

**Equipment included in 26787---FT---P**

- Sartocheck® 5 Plus Filter Tester
- Inlet tube for compressed gas 2 m (26787---IT)
- Test tube 2 m (26787---TT---02)
- Test certificate
- Calibration certificate
- Installation and operating instructions
- Risk assessment for integrity testing | FMEA (PDF)
- Power cord (region-specific)
- Screw driver (T20 × 100) for fixation of cables
- Networking cable (RJ45)
- Printer cable (USB)
### Accessories and Spare Parts

<table>
<thead>
<tr>
<th>Description</th>
<th>Article No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>USB printer (without paper)</td>
<td>YDP30</td>
</tr>
<tr>
<td>Archivable paper 90 m and ink ribbon</td>
<td>69Y03285</td>
</tr>
<tr>
<td>Archivable self-adhesive paper 90 m and ink ribbon</td>
<td>69Y03286</td>
</tr>
<tr>
<td>Thermal paper 5 rolls of 24 m</td>
<td>69Y03287</td>
</tr>
<tr>
<td>Self-adhesive thermal paper 5 rolls of 13 m</td>
<td>69Y03288</td>
</tr>
<tr>
<td>Inlet tube for compressed gas 2 m</td>
<td>26787---IT</td>
</tr>
<tr>
<td>Test tube 2 m</td>
<td>26787---TT---02</td>
</tr>
<tr>
<td>Test tube 5 m</td>
<td>26787---TT---05</td>
</tr>
<tr>
<td>Test tube 15 m</td>
<td>26787---TT---15</td>
</tr>
<tr>
<td>Accessory kit for external venting</td>
<td>26787---AK---EV (max. 10 accessory kits per device due to calibration data)</td>
</tr>
<tr>
<td>Tube for “device vent”</td>
<td>26787---VT---DE</td>
</tr>
<tr>
<td>Tube for “sample vent”</td>
<td>26787---VT---SA</td>
</tr>
<tr>
<td>Accessory kit for cleaning of the pneumatics (available Q3 2020)</td>
<td>26787---AK---CL</td>
</tr>
<tr>
<td>Additional waste vessel for the accessory kit for cleaning (available Q3 2020)</td>
<td>26787---AKWV-CL</td>
</tr>
<tr>
<td>Barcode Scanner (None ATEX)</td>
<td>26787---BS</td>
</tr>
<tr>
<td>External reference volume</td>
<td>26787---ER</td>
</tr>
<tr>
<td>Additional tube for the external reference volume (available Q3 2020)</td>
<td>26787---TE—RV</td>
</tr>
<tr>
<td>Solid transportation box for the Sartocheck® 5</td>
<td>5 Plus</td>
</tr>
<tr>
<td>Midisart® Test Manifold for parallel bubble point</td>
<td>1Z-LB-0002</td>
</tr>
<tr>
<td>Triclamp 25 mm – Staubli nipple RBE03 open</td>
<td>7ZML---0009</td>
</tr>
<tr>
<td>Triclamp 25 mm – Staubli nipple RBE03 closed</td>
<td>7ZML---0015</td>
</tr>
<tr>
<td>Triclamp 50.5 mm – Staeubli nipple RBE03 closed</td>
<td>7ZML---0012</td>
</tr>
<tr>
<td>Luer lock male – Staubli nipple RBE03 open</td>
<td>7ZV---0115</td>
</tr>
</tbody>
</table>

### Services

<table>
<thead>
<tr>
<th>Description</th>
<th>Article No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validation package for Sartocheck® 5</td>
<td>5 Plus</td>
</tr>
<tr>
<td>Sartocheck® 5</td>
<td>5 Plus installation Sartocheck® 5</td>
</tr>
<tr>
<td>Sartocheck® 5</td>
<td>5 Plus IQ</td>
</tr>
<tr>
<td>Valve Kit IQ</td>
<td>OQ service pack (incl. travel exp.)</td>
</tr>
<tr>
<td>Service level agreement Advanced Sartocheck® 5</td>
<td>5 Plus</td>
</tr>
<tr>
<td>Service level agreement Comprehensive Sartocheck® 5</td>
<td>5 Plus</td>
</tr>
<tr>
<td>Service level agreement Essential Sartocheck® 5</td>
<td>5 Plus</td>
</tr>
</tbody>
</table>