Sartocheck® 5 Plus Filter Integrity Tester
Keeps Your Risk Factors Under Complete Control
The Sartocheck® 5 Plus perfectly meets today's key industry requirements for filter integrity testing in demanding GMP environments.

It sets a new standard for filter integrity testing devices:

- Surpass the Requirements of Quality Risk Management (QRM)
- Reach the Ultimate Level of Data Integrity
- Experience the Comfort of Intuitive Usability
- Discover the Simplicity of Health, Safety, and Environment (HSE)

### Quality Risk Management

- Automatic detection of improper test setups
- Automatic detection of abnormal test conditions
- Supplied comprehensive FMEA documentation
- Calculation tool for unlikely pressure reading deviations

### Data Integrity

- Audit trail with time zone synchronized (NTP) events
- Custom Linux-based OS with SSB custom architecture
- Write protected and constantly monitored root file system
- Encrypted double data backup on internal inaccessible SD card

### Usability

- Large touch screen (12.1") with great viewing angle (+/- 88°)
- LDAP for log on with Windows credentials
- Easy data transfer
- Automation (September 2019 free upgrade)

### Health Safety and Environment

- High ingress protection IP64
- Ex-proof (ATEX|IECEx|FM) for safe testing of alcohol wetted filters
- Resistant to all current cleaning agents and H₂O₂ (VHP)
- Accessory kit for external venting prevents backflow
Surpass the Requirements of Quality Risk Management (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 in advance or during the test. This avoids time-consuming and costly deviations, potential drug recalls and 483 warning letters.

Automatic Detection of Incorrect Test Setups by...

... accurate volume determination
The Sartocheck® 5 Plus Filter Tester allows users to enter a specific expected upstream volume range for each individual program. If the volume measurement result falls outside this range, it is evidence that the system being tested is not the appropriate one i.e. the wrong filter setup is being tested with the wrong filter size. The test is therefore immediately aborted with an explicit error message which is also traceable in the audit trail.

... minimum expected flow
All diffusion and WIT programs can be defined with a minimum expected value. If the measured value falls below that setting it is evidence that, for example, the filter being tested is blocked, the wrong filter type is being tested or the downstream valve is closed.

The bubble point programs can be defined with a minimum flow expected to be achieved at the end pressure of the test ($P_{end}$). If this flow threshold is not reached, it may be an indication that the filter is blocked, the wrong filter type is being tested or that the downstream valve is closed.

$P_{end}$ is set in order not to exceed the pressure resistance of the filter setup and will terminate the test, even if the bubble point has not been reached.

... $BP_{max}$ versus $P_{end}$
A defined filter type under defined test conditions is expected to have an actual bubble point within a certain range. If the actual bubble point exceeds a certain level it is considered atypical. The $BP_{max}$ (if set to lower than $P_{end}$) allows detection of these atypical situations.

... BPmin versus Pend

Diffusion | WIT

- Failed test: broken filter
- Passed test: integral filter
- Failed test: too low value

Bubble point

- Normal
- Abnormal

Min flow

$BP_{max}$ $P_{max}$ $P_{end}$

Normal Abnormal
Automatic Detection of Abnormal Test Conditions From a Pressure Increase

When a filter is being tested, it always generates a certain pressure decay. If a pressure increase is detected instead of a pressure decay, it may indicate a temperature change or that the downstream side of the filter is being pressurized.

Prevention of Irregular Test Repeats (Roadmap)

It is generally recommended that a filter should be tested a maximum of three times at the user’s site (cf. PDA Technical Report 26 and PDA Points To Consider Part 2 Topic K).

If more tests are required to get a test pass, the integrity testing procedure can be considered not to be under control and, consequently may generate a Quality Assurance deviation.

By tracking the lot and individual number the Sartocheck® 5 Plus counts the number of test attempts and blocks test repeats when the defined number (e.g. 3) has been reached. Prematurely aborted tests by e.g. “upstream volume out of range” are not counted.

Self-test at Booting and Before Each Test

The Sartocheck® 5 Plus Filter Tester performs a system self-test at booting and also a mechanical self-test including a comparative pressure reading before every test. This further increases the device’s reliability.

Comprehensive Failure Mode Effects Analysis (FMEA)

The aim of the Sartocheck® 5 Plus FMEA is to identify operator hazards, risks of false passed and false failed test results and perils for the functionality of the device, as close as possible to its source.

It provides extensive information of how to improve the process around filter integrity testing from a general perspective and how to set the program specific safety parameters to avoid false passed test results. This guarantees the highest safety level (HSE) and the best Quality Risk Management.

Calculation Tool for the Impact of Unlikely Calibration Offsets

Quality Risk Management requires that all potential events that could have an impact on quality are evaluated and mitigated.

The evaluation tool for the Sartocheck® 5 is based on theoretical calculations that have been confirmed by empirical studies on intentionally decalibrated integrity test devices. The peer reviewed publication explains the calculation in detail and contributes to robust, regulatory compliant Quality Risk Management.
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® 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.

Custom Linuxbased Operating System

The Sartocheck® 5 Plus Filter Tester uses a custom Linux-based OS with Sartorius Stedim’s own custom architecture to provide inherent protection against virus and malware attacks. It runs its operating system on an ARM Cortex-A Family processor, which is a rare and unlikely target for malware. By not using a commonly available mainstream processor architecture, the Sartocheck® 5 Plus is different from the usual targets of malware and viruses. For maximum of security, the root file system is writeprotected, making it impossible for a virus to reside in the system.

Internal Double Data Backup

All data generated is instantly backed up on an internal inaccessible 8 GB SD card. This prevents any loss of data, even in the unlikely event of system crash or if the Sartocheck® 5 Plus is dropped or damaged. All data generated is encrypted to the highest standards for efficient protection against misuse and is stored simultaneously on a 4 GB flash memory and on an SD card.

Encrypted Data

Encryption protects data to prevent its disclosure, theft or misuse.

All internal data is encrypted to the highest standards for efficient protection against misuse.

Software updates and upgrades of the Sartocheck® 5 Plus are also encrypted (AES128) and cryptographically signed by Sartorius Stedim with RSA algorithms. This prevents the risk of virus infected updates and upgrades.

Audit Trail With Time Stamped Events

Data is only consistent if an event is reliably time stamped.

All GMP relevant actions are time stamped in the audit trail to comply with 21CFR part 11. When parameters are changed, before and after values are displayed so that full traceability of “who did what and when” is shown.
Data integrity also includes reliable time stamping of events. When the Sartocheck® 5 Plus is connected to the network and the NTP function is activated, automatic time zone synchronization occurs thus generating reliable time stamps in the audit trail.

If the Sartocheck® 5 Plus is not connected to the network, the time settings can only be changed if specific rights have been allocated to a specific user. If time settings are changed it is traceable in the audit trail.

User Matrix to Generate Individual User Roles

For maximum flexibility, the Sartocheck® 5 Plus Filter Tester offers the option to freely define user roles according to a matrix of all existing features. This ensures more process security, by allowing all users to access only the level they are entitled to.

Even the Sartorius Service team has restricted access to only service relevant features, thus keeping your data safe from accidental intrusion.

More than 1000 users and user roles can be defined and for total flexibility, each user can obtain a combination of different roles.

Mandatory Fields for Operator Entries

The Sartocheck® 5 Plus Filter Tester uses protocol data fields with mandatory data entries to avoid that data entry is accidentally omitted.

Data Entry by Barcode Scanner

A barcode scanner allows seamless data entry during programming of for example, the filter reference and additional information used to automatically select the program when a filter is being tested.

To further reduce the risk of operator errors when selecting a program the use of the barcode scanner can be set to mandatory. This assures a much safer, faster test procedure.

Additionally, user-generated barcodes assigned to SOPs or filter housings can also be used are to ensure the right program is selected by the operator.

Long-life Printouts and Sticker Function

Electronic records are now beginning to replace paper printouts, however where paper printouts are generated, they have to be archivable.

The optional external Sartocheck® 5 Plus printer (YDP30) automatically performs thermal transfer or direct thermal printing without the need to change any settings, depending on the specific paper.
Experience the Comfort of Intuitive Usability

An optimal user experience speeds up process workflows due to intuitive guidance and ease of use. The highquality 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 error-free operation in GMP production environments.

Intuitive iF-Design
Rewarded Human Machine Interface (HMI)

Straight forward menus, ergonomic design, formal language, user experience and user-friendly control system all contributed to start processes within seconds and winning the iF Design Award 2018.

12.1” Touchscreen With a + | - 88° Viewing Angle

A large bright screen with a great viewing angle contributes to ease of use, regardless of the operator’s height and position.

- Size 12.1”
- High luminosity and resolution
- Type TFT LED-Backlit color
- Optimal viewing angle + | - 88° (total 172°)
- Slight anti-glare
- Perfectly visible from a distance
- Compatible with gloves

Large Digital Keypad – no Need for a Pen – Compatible With Glove Use

The Sartocheck® 5 Plus digital keypad covers the entire width of the screen and its large touch zones do not require a digital pen. This easy to use keypad, prevents users typing the wrong letters or signs. It pops up automatically when needed and can easily be retracted.

Automation by Modbus TCP (September 2019)

The Modbus TCP protocol is a commonly used industrial automation protocol. Compatibility to other automation network control protocols like DeviceNet, Profinet, etc. can be achieved by using third-party gateways.

The Sartocheck® 5 Plus supports two automation modes:

- Semi-automated: A full test recipe can be sent to and stored on the device till an operator logs in and starts the test.
- Fully automated: A full test recipe can be sent to the device following which the test can be started and monitored by an MES.
LDAP – Log on With Network User Credentials

The Sartocheck® 5 Plus supports Lightweight Directory Access Protocol (LDAP) which allows all operators to utilize their network credentials to access the device. This ensures that all users have the same credentials on all devices, significantly reducing the risk of forgetting their IDs and passwords.

If the LDAP is deactivated, the Sartocheck® 5 Plus supports local users with the option to transfer users and user roles, while still assuring fulfillment of password complexity and supervised password aging.

Data Transfer

The generated data by the Sartocheck® 5 Plus can be conveniently transferred by file directory shares via Ethernet cable or Wi-Fi (optional Nano router), either automatically as soon as generated or manually, which requires user rights. It is possible to use separate folders for “Audit trail”, “Programs” and “Results”, and each folder can have separate usernames and passwords.

System Languages

The user interface is available in 10 widely spoken languages, helping to make it simple to use.

Faster Testing

The Sartocheck® 5 Plus test duration of diffusion and water intrusion testing can be significantly reduced by using the automatic test time. When activated, the test will be truncated if:

- The test value of 10 subsequent measurement points is stable within a pre-defined range
- The test value is below or equal to the defined maximum limit
- The test value is above or equal to the defined minimum limit

Measuring the actual bubble point value of a filter with a high bubble point may require substantial amounts of time and will reduce operator productivity.

In fact, as soon as the minimum bubble point has been exceeded the filter can be considered as integral, but it is still advisable to obtain the actual bubble point’s value.

The accelerated bubble point of the Sartocheck® 5 Plus Filter Tester uses progressively larger pressure steps once the minimum bubble point has been exceeded by one pressure step. This results in a faster bubble point test with fewer pressure steps, yet with the same stringent accuracy at the critical pass | fail threshold of the minimum bubble point.
Discover the Simplicity of Health, Safety, and Environment (HSE)

Integrity testing often involves the use of chemicals and hazardous materials. 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.

Splashproof (IP64)

The Sartocheck® 5 Plus is designed for IP64-compliance to perform under the most stringent conditions in wet environments such as filter preparation.

Ex-proof (ATEX IECEx & FM Certified)

The Sartocheck® 5 Plus is the only explosion proof filter integrity tester device on the market. This allows safe testing and re-testing of alcohol wetted filters according to recommended procedures (cf. PDA Technical Report 26 and Points To Consider part 2).

Using a Sartocheck® 5 Plus, which is certified for use in explosion hazardous areas provides maximum safety for operators and manufacturing facilities. Certified for explosion prone areas Zone 2, Groupe II-B (IECEx, ATEX) | Class 1 Zone 2 Group II-B (FM - USA)

Continuous and Clear Visualization of Pressure Status

Pressurized systems may harm operators if used incorrectly and must be handled with care.

The Sartocheck® 5 Plus Filter Tester displays the integrity test status at all times, even if the user logs out from the device. The large display can be clearly seen from a distance which helps operators avoid handling the pressurized filter system while it is being tested.
Resistant to all Current Cleaning Agents

The Sartocheck® 5 Plus is designed with smooth, chemical resistant external surfaces to support all currently used cleaning agents (based on Alexit lacquer, stainless steel and glass).

The Sartocheck 5 Plus is also designed to be compatible with VHP and can therefore be left in a cleanroom during fumigation.

H₂O₂- Vapor Resistant (VHP)

Vaporized hydrogen peroxide (VHP) is frequently used for decontamination of clean rooms. Electronics are generally not VHP resistant and all instruments that are not VHP resistant must either be covered by plastic or moved out of a clean room before fumigation.

The Sartocheck® 5 Plus is the only VHP compatible filter integrity tester on the market. It can conveniently be left in a clean room during fumigation and benefits from the scheduled decontamination.

PFA Tubes (FDA 21 CFR 177 and USP Class VI Compliant)

All flow paths of the Sartocheck® 5 Plus are made with grease free certified material and all tubes are manufactured to the highest quality to be FDA 21 CFR 177 and USP Class VI compliant.

Optional Accessory Kit for External Venting

The optional Accessory Kit for external venting consists of a venting valve and a blocking valve and includes a pressure sensor that is identical to the one used inside the Sartocheck® 5 Plus. The Accessory Kit can be used together with the Sartocheck® 5 Plus to avoid any undesirable liquid siphoning. This prevents cross-contamination between product-soaked filters being post-use tested and new filters being pre-use tested (e.g. PUPStit).

The Accessory Kit is certified for use in hazardous areas (ATEX | IECEx | FM) to an even higher class than the Sartocheck® 5 Plus device and can be used together with alcohol wetted filters combined with standard tube lengths of 2, 5 and 15 meters.
Sartocheck® 5 and Sartocheck® 5 Plus Filter Testers

The new Sartocheck 5 Series comes in two variants to ideally match the requirements of the customer with either model.

The Sartocheck® 5 Filter Tester performs all standard integrity tests combined with ultimate level of Data Integrity, intuitive Usability and top level Health and Safety Requirements.

The enhanced features of the Sartocheck® 5 Plus Filter Tester adds automation capabilities and the highest level of QRM through automatic detection of abnormal test conditions.

Should automation not be required, and if traditional QRM (data entry by bar code scanner, operator training...) is enough for your regulatory compliance, the Sartocheck® 5 Filter Tester would satisfy your needs.

However, if automation is needed, and or the highest level of QRM is required to achieve regulatory compliance, the Sartocheck® 5 Plus Filter Tester becomes the obvious choice.
<table>
<thead>
<tr>
<th>Feature</th>
<th>Sartochek® 5</th>
<th>Sartochek® 5 Plus</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usability</strong></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>All commonly used integrity test</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>methods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High quality 12.1” screen</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>iF-design rewarded user interface</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>LDAP</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Full Data transfer</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Automation</td>
<td>-</td>
<td>●</td>
</tr>
<tr>
<td><strong>Health Safety &amp; Environment</strong></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Ingress protection IP64</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Ex-proof (ATEX</td>
<td>IECEx</td>
<td>FM certified)</td>
</tr>
<tr>
<td>Resistant to all current cleaning</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H₂O₂-vapor resistant (VHP)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Automated cleaning of all pneumatics with up to 0.5 M NaOH at 50 °C</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td></td>
<td>(requires optional cleaning kit and free of charge software upgrade)</td>
<td></td>
</tr>
<tr>
<td>Optional accessory kit for external venting (backflow protection)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td><strong>Quality Risk Management</strong></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Traditional QRM</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>(bar code scanner, operator training...)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Optimized QRM through automatic detection of improper test setups, including free software upgrades upon periodic release</td>
<td>-</td>
<td>●</td>
</tr>
<tr>
<td>Comprehensive FMEA documentation</td>
<td>-</td>
<td>●</td>
</tr>
<tr>
<td><strong>Data Integrity</strong></td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Custom Linux-based OS with inherent virus and malware protection</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Write protected root file system for virus protection</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Encrypted double data backup</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Time zone synchronization for reliable time stamped audit trail</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>
The Sartocheck® 5 Plus Filter Tester is the new reference for filter integrity testing. The purchase of the Sartocheck® 5 Plus includes a pre-established roadmap of software upgrades on a bi-annual or more frequent basis. The software upgrades include valuable, patented and patent pending features for enhanced:

- **Usability**
  - Automation
  - Administration software
- **Quality Risk Management**
  - Improved detection of out of specification conditions
  - Test counting and blocking of irregular test attempts
- **Data Integrity**
  - 4 eyes principle
  - "Why" comment for changes
- **Health, Security & Environment**
  - Accessory kit for automated cleaning

Each software upgrade comes with a comprehensive risk assessment and development documentation, and can easily be executed by the device administrator and supported by Sartorius Stedim Application Specialists.
September 2019
- Automation
  - e-signature
  - 4 eyes principle
- Encrypted LDAP

Q1 2020
- Administration release

Q2 2020
- Accessory upgrade

Q3 2021
- Usability & automation upgrade

Q1 2021
- QRM upgrade

Q4 2021
- Administrative upgrade
Accessories

USB Printer YDP30

The YDP30 printer will automatically perform thermal transfer or direct thermal printing, depending on the particular paper you choose. You will not need to change any settings. For example, to meet the strict requirements for fade-resistant printouts in regulated areas of the pharmaceutical industry, just use paper for thermal transfer printing – either standard or self-adhesive – with up to 20 years of archiving.

Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolution</td>
<td>203 dpi</td>
</tr>
<tr>
<td>Max. print width</td>
<td>54 mm</td>
</tr>
<tr>
<td>Dimensions [L x W x H]</td>
<td>241.3 x 139.9 x 177.4 mm</td>
</tr>
<tr>
<td>Power supply</td>
<td>External universal switching power supply</td>
</tr>
<tr>
<td></td>
<td>• Input: 100 – 240 V~</td>
</tr>
<tr>
<td></td>
<td>• Output: 24 V~; 2.5 A</td>
</tr>
<tr>
<td>Ambient conditions</td>
<td>• Operation</td>
</tr>
<tr>
<td></td>
<td>5°C to 40°C (41°F to 104°F), 25% to 85%, non-condensing</td>
</tr>
<tr>
<td></td>
<td>• Storage</td>
</tr>
<tr>
<td></td>
<td>- 40°C to 60°C (-40°F to 140°F), 10% to 90%, non-condensing</td>
</tr>
<tr>
<td>Order code</td>
<td>YDP30</td>
</tr>
</tbody>
</table>
Barcode Scanner

The barcode scanner allows to select the right program by scanning the appropriate 1D or 2D barcode in a safer and much faster way than if done manually. "Homemade" barcodes can also be used that can be attached to SOPs or filter housings. Flawless data entry of e.g. the filter lot number, the product lot number and the start comment before starting the integrity test program is also achieved by using the scanner.

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions [L × W × H]</td>
<td>104 mm × 71 mm × 160 mm (4.1” × 2.8” × 6.3”)</td>
</tr>
<tr>
<td>Weight</td>
<td>54 mm</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>0°C to 50°C (32°F to 122°F)</td>
</tr>
<tr>
<td>Storage temperature</td>
<td>-40°C to 70°C (−40°F to 158°F)</td>
</tr>
<tr>
<td>Humidity</td>
<td>0% to 95% relative humidity, non-condensing</td>
</tr>
<tr>
<td>Environmental sealing</td>
<td>IP41</td>
</tr>
<tr>
<td>Light levels</td>
<td>0 to 100,000 lux (9,290 foot-candles)</td>
</tr>
<tr>
<td>Scan pattern area image</td>
<td>838 × 640 pixel array</td>
</tr>
<tr>
<td>Motion tolerance</td>
<td>Up to 610 cm/s (240 in/s) for 13 mil UPC at optimal focus</td>
</tr>
<tr>
<td>Scan angle HD focus</td>
<td>Horizontal: 41.4°; Vertical: 32.2°</td>
</tr>
<tr>
<td>SR focus: horizontal</td>
<td>42.4°; vertical: 33°</td>
</tr>
<tr>
<td>ER focus: horizontal</td>
<td>31.6°; vertical: 24.4°</td>
</tr>
<tr>
<td>Symbol contrast</td>
<td>20% minimum reflectance difference</td>
</tr>
<tr>
<td>Pitch, skew</td>
<td>45°, 65°</td>
</tr>
<tr>
<td>Order code</td>
<td>26787---BS</td>
</tr>
</tbody>
</table>
Optional Accessory Kit for External Venting

The optional Accessory Kit for external venting consists of a venting valve and a blocking valve and includes a pressure sensor that is identical to the one used inside the Sartocheck® 5 Plus. The Accessory Kit can be used together with the Sartocheck® 5 Plus to avoid any unwanted siphoning of liquid. This precludes cross-contamination between product-soaked filters being post-use tested and new filters being pre-use tested (e.g. PUPSIT). The use of the Accessory kit for external venting can be set to mandatory for specific programs, thus enhancing the Quality Assurance. Up to 10 Accessory Kits for external venting can be associated to one Sartocheck® 5 Plus and thereby allow the use of different Accessory Kits for pre-use testing and post use testing.

The Accessory Kit is certified for use in hazardous areas (ATEX | IECEx | FM) and can therefore be used together with alcohol wetted filters. It can be used with the standard tube lengths of 2, 5 and 15 meters. The pneumatic flow path of the Accessory Kit can be cleaned at the same time as the Sartocheck® 5 Plus with 0.5M NaOH at 50 °C when using the Accessory Kit for automated cleaning.

Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test accuracy when using the</td>
<td>Identical to the Sartocheck® 5 Plus</td>
</tr>
<tr>
<td>AK-EV</td>
<td></td>
</tr>
<tr>
<td>Dimensions [L × W × H]</td>
<td>159 × 147 × 163 mm</td>
</tr>
<tr>
<td>Weight (without cables)</td>
<td>2.7 kg</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>2 – 40 °C (environmental)</td>
</tr>
<tr>
<td>Power supply</td>
<td>Integrated from the Sartocheck® 5</td>
</tr>
<tr>
<td>Power consumption in operation</td>
<td>0.3 W (typical)</td>
</tr>
<tr>
<td>IECEx, ATEX</td>
<td>Zone 1 Group II-B</td>
</tr>
<tr>
<td>FM (USA)</td>
<td>Class 1, Div. 1, Zone 1 Group II-B</td>
</tr>
<tr>
<td>Order code</td>
<td>26787---AK---EV</td>
</tr>
</tbody>
</table>

For installation and maintenance see control drawing 2058868. | Pour installation et maintenance voir le diagramme de contrôle 2058868.
Transportation Box

The transportation box with wheels and a telescopic handle has been designed for easy transport of the Sartocheck® 5 and 5 Plus and its mandatory components from one building to another, but also for overseas shipping.

The following items can be put into the transportation box:

- Sartocheck® 5 Plus
- Power cable
- Test tube
- Inlet tube
- Instruction manual
- T20 screw driver for fixing of cables

Specifications

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials of construction</td>
<td>Polypropylene (case and wheels)</td>
</tr>
<tr>
<td></td>
<td>Polyethylene and polyurethane (Foam)</td>
</tr>
<tr>
<td>Dimensions [H × W × D]</td>
<td>670 mm × 510 mm × 372 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>12.3 kg</td>
</tr>
<tr>
<td>Total weight</td>
<td>30 kg</td>
</tr>
<tr>
<td>incl. Sartocheck® 5 Plus</td>
<td></td>
</tr>
<tr>
<td>Order code</td>
<td>26787---ST</td>
</tr>
</tbody>
</table>
## Technical Specifications

### Test Methods
- **Diffusion (DIN 58536 part 2)** with or without automatic test time
- **Bubble Point** (detection by over proportionality) standard or accelerated
- Combined diffusion and bubble point
- **Water Intrusion Test**
- **Pressure drop | leak test**
- **Multipoint diffusion** (see roadmap)

### Measuring Ranges

<table>
<thead>
<tr>
<th>Parameter</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>

### Power supply

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power requirements</td>
<td>100 – 240 V AC at 50</td>
</tr>
<tr>
<td>Max. Power Input</td>
<td>74 W</td>
</tr>
<tr>
<td>Average power usage</td>
<td>66 W</td>
</tr>
<tr>
<td>Power consumption in standby mode</td>
<td>14.8 W</td>
</tr>
</tbody>
</table>

A country specific cable is delivered with each device.

### Pneumatics

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. inlet pressure</td>
<td>8,000 mbar</td>
</tr>
<tr>
<td>Overpressure protection</td>
<td>Max inlet pressure + 4,000 mbar</td>
</tr>
<tr>
<td>Min. inlet pressure</td>
<td>4,000 mbar</td>
</tr>
<tr>
<td>Internal reference volume</td>
<td>1,023 ml conforming to Pressure Equipment Directive 2014/68/EU</td>
</tr>
<tr>
<td>Max. Pressure = 12 bar pressure certificate</td>
<td></td>
</tr>
</tbody>
</table>
### Measuring Accuracies

<table>
<thead>
<tr>
<th>Metric</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>

### Dimensions, weight and noise

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions (W × D × H)</td>
<td>348 × 379 × 286 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>16.6 kg</td>
</tr>
<tr>
<td>Weight of the packaging</td>
<td>2.4 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>
BPS Service

To keep your biopharmaceutical process robust and reliable, we provide a comprehensive range of services to ensure the highest reliability and uptime of your Sartocheck® 5 | 5 Plus Filter Tester, regulatory compliance and best quality of results. From installation and qualification to regular preventative maintenance: Our service team will be happy to assist you on site and will be with you quickly thanks to our worldwide service network.

- **Installation and Commissioning**: Safe and proper operation of your equipment — right from the start.
- **Qualification (IQ/OQ)**: Compliance with GMP requirements, easy integration into your quality management system.
- **Operator Training**: Quality through greater expertise: Sartorius trains the personnel operating our equipment.
- **Repairs and Spare Parts**: In the event of service requests, we are quickly at your side with the necessary spare parts — worldwide.
- **Maintenance and Contracts**: Optimal equipment operation and protection against potential downtimes.
- **Calibration**: Accurate results in the long term and compliance with regulatory requirements.
With our Bioprocess Service Program, Sartorius offers service contracts to protect your equipment through its entire lifetime. Based on your specific risk assessment and requirements, you can choose between three Service Level Agreements: Essential, Advanced and Comprehensive. Protect your Sartocheck\textsuperscript{\textregistered} 5 | 5 Plus Filter Tester by choosing the appropriate service contract. For maximum productivity and minimum downtimes.

**Essential**
You benefit from:
- A plannable annual maintenance
- A fast support at the technical helpdesk within one business day and priority on-site-response
- In case of repair: A discount on all time and material based cost elements

**Advanced**
You benefit from:
- A plannable annual maintenance
- Technical helpdesk reaction time within 8 hours and 72 hours on-site response
- In case of repair: labor and travel costs are covered, a discount of 10% on spare parts

**Comprehensive**
You benefit from:
- A plannable annual maintenance
- Technical helpdesk reaction time within 4 hours and 48 hours on-site response
- In case of repair: all costs are covered

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**Your Benefits**
- Process stability and minimized downtime
- Maximized system uptime, higher profitability
- Optimized total cost of ownership

For further details and the dedicated datasheets, please have a look at our website: [www.sartorius.com/service](http://www.sartorius.com/service)
Sales and Service Contacts

For further contacts, visit www.sartorius-stedim.com

Europe

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49.551.308.0

Sartorius Stedim Systems GmbH
Robert-Bosch-Strasse 5 – 7
34302 Guxhagen
Phone +49.5665.407.0

France
Sartorius Stedim FMT S.A.S.
ZI des Paluds
Avenue de Jouques – CS 91051
13781 Aubagne Cedex
Phone +33.442.845600

Sartorius Stedim France SAS
ZI des Paluds
Avenue de Jouques – CS 71058
13781 Aubagne Cedex
Phone +33.442.845600

Austria
Sartorius Stedim Austria GmbH
Modecenterstrasse 22
1030 Vienna
Phone +43.1.7965763.18

Belgium
Sartorius Stedim Belgium N.V.
Rue Colonel Bourg 105
1030 Bruxelles
Phone +32.2.756.06.80

Hungary
Sartorius Stedim Hungária Kft.
Kagyló u. 5
2092 Budakeszi
Phone +36.23.457.227

Italy
Sartorius Stedim Italy S.r.l.
Via dell’Antella, 76/A
50012 Antella-Bagno a Ripoli (FI)
Phone +39.055.63.40.41

Netherlands
Sartorius Stedim Netherlands B.V.
Phone +31.30.60.25.080
filtratie.nederland@sartorius-stedim.com

Poland
Sartorius Stedim Poland Sp. z o.o.
ul. Wreszinska 70
62-025 Koszalin
Phone +48.61.647.38.40

Russia
Sartorius Stedim RUS
Vasilyevsky Island
5th line 70, Lit. A
199178 St. Petersburg
Phone +7.812.327.53.27

Spain
Sartorius Stedim Spain, S.A.U.
Avda. de la Industria, 32
Edificio PAYMA
28108 Alcobendas (Madrid)
Phone +34.913.586.098

Switzerland
Sartorius Stedim Switzerland AG
Ringstrasse 24 a
8317 Tagelswangen
Phone +41.52.354.36.36

U.K.
Sartorius Stedim UK Ltd.
Longmead Business Centre
Blenheim Road, Epsom
Surrey KT19 9 QQ
Phone +44.1372.737159

Ukraine
LLC "Sartorius Stedim RUS"
Post Box 440 "B"
01001 Kiev, Ukraine
Phone +380.44.411.4918

Americas

USA
Sartorius Stedim North America Inc.
5 Orville Drive, Suite 200
Bohemia, NY 11716
Toll-Free +1.800.368.7178

Argentina
Sartorius Argentina S.A.
Int. A. Ávalos 4251
B1605ECS Munro
Buenos Aires
Phone +54.11.4721.0505

Brazil
Sartorius do Brasil Ltda
Avenida Senador Vergueiro 2962
São Bernardo do Campo
CEP 09600-000 - SP - Brasil
Phone +55.11.4362.8900

Mexico
Sartorius de México, S.A. de C.V.
Libramiento Norte de Tepozotlán s/n,
Colonia Barrio Tlacateco,
Municipio de Tepozotlán,
Estado de México,
C.P. 54605
Phone +52.55.5662.1102
leadsmex@sartorius.com

Asia and Pacific

Australia
Sartorius Stedim Australia Pty. Ltd.
Unit 5, 7-11 Rodeo Drive
Dandenong South Vic 3175
Phone +61.3.8762.1800

China
Sartorius Stedim (Shanghai)
Trading Co., Ltd.
3rd Floor, North Wing, Tower 1
No. 4560 Jinke Road
Zhangjiang Hi-Tech Park
Pudong District
Shanghai 201210, P.R. China
Phone +86.21.6878.2300

India
Sartorius Stedim India Pvt. Ltd.
#69/2-69/3, NH 48, Jakkasandra
Nelamangala Tq
562 123 Bangalore, India
Phone +91.80.4350.5250

Japan
Sartorius Stedim Japan K.K.
4th Fl., Daiwa Shimagawa North Bldg.
B1-11, Kita-Shinagawa 1-chome
Shinagawa-ku, Tokyo, 140-0001 Japan
Phone +81.3.4331.4300

Malaysia
Sartorius Stedim Malaysia Sdn. Bhd.
Lot L3-E-1B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur, Malaysia
Phone +60.3.8996.0622

Singapore
Sartorius Stedim Singapore Pte. Ltd.
10 Science Park Rd
The Alpha #02-13/14
Singapore Science Park II
Singapore 117684
Phone +65.6872.3966

South Korea
Sartorius Korea Biotech Co., Ltd.
8th Floor, Solid Space B/D,
PanGyo Yeok-Ro 220, Bundang-Gu
SeongNam-Si, GyeongGi-Do, 463-400
Phone +82.31.622.5700

www.sartorius-stedim.com

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