Sartocheck® 5 Plus Filter Tester

New Software Release Q4 2020

Simplifying Progress

SARTORIUS


SARTORIUS
John Operator
Restart test
Print results
SARTOCHECK® S

Sartocheck® 5 Plus Filter 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, allowing you to:

- 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
- Available comprehensive FMEA documentation
- Calculation tool for unlikely pressure reading deviations

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
- Four-eyes principle | electronic signatures
- Comprehensive and flexible role management
- Automatic user logout after X unsuccessful login attempts
- Serial number of the device in every audit trail entry

Usability

- Large touch screen (12.1") (± 88° viewing angle)
- Easy data transfer via file share
- Automation by Modbus TCP and OPC UA
- Additional keyboards (Korean and Cyrillic)
- LDAP group-based role management
- Export improvements of the audit trail and digitally signed write-protected PDF format
- Improved filtering of displayed audit trail events
- Possibility to start a program by name for OPC UA

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 H_2O_2 (VHP)
- Accessory Kit for External Venting prevents backflow

DESIGN AWARD 2018

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 of 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 that is also traceable in the audit trail.

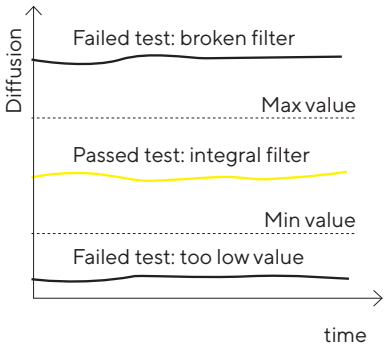
… Minimum Expected Flow
All diffusion and WIT programs can be defined with a minimum expected value. If the measured value falls below that setting it is evidence that, for example, the filter being tested is blocked, the wrong filter type is being tested or the downstream valve is closed.

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.

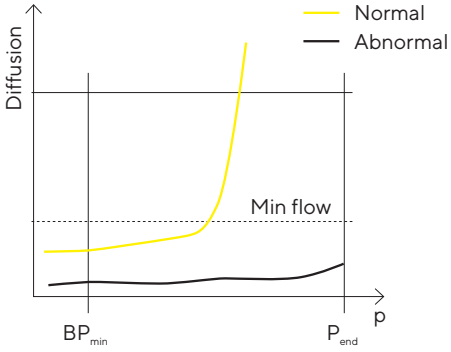
P_{end} is set in order not to exceed the pressure resistance of the filter setup and will terminate the test, even if the bubble point has not been reached.

… 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.

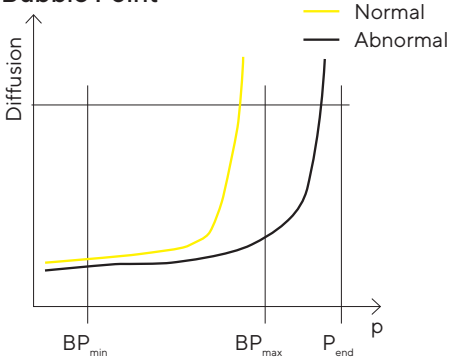
Diffusion | WIT



Bubble Point



Bubble Point



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 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 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 on 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.

This documentation is available on request.

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

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 FDA 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, even more critical, endanger the health of patients.

Data Integrity Statement | ALCOA+ Principles

The Sartocheck® 5 Plus Filter Tester has been designed in accordance with the ALCOA principles as mentioned in the FDA *"Data Integrity and Compliance with Drug CGMP Questions and Answers: Guidance for Industry"* from December 2018 and the ALCOA+ principles as referred to in the MHRA *"GXP' Data Integrity Guidance and Definitions"* from March 2018.
Ask for our Data Integrity Statement for details.

Data Security

The Sartocheck® 5 Plus Filter Tester is a closed system and uses a custom Linux-based OS with Sartorius' 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 an unlikely target for malware. By not using commonly available mainstream processor architecture, the Sartocheck® 5 Plus is different from the usual targets of malware and viruses.

For maximum security, the root file system is write-protected and continually monitored, making it impossible for a virus to reside in the system. Also, all non-relevant, inbound network connections are blocked.

Internal Double-Data Backup

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

Electronic Signatures | 4 Eyes Principle

The ability to electronically sign test results according the 4 eyes principle further enhances the trustworthiness of data. The parameter settings allow you to define 0, 2, or 3 signatures as required to validate a test result.

Encrypted Data and Encrypted LDAP

Encryption protects data to prevent its disclosure, theft or misuse. All internal data and LDAP communication are encrypted to the highest standards for efficient protection against misuse. Software updates and upgrades of the Sartocheck® 5 Plus are also encrypted (AES-128) and cryptographically signed by Sartorius Stedim with RSA algorithms. This prevents the risk of virus infected updates and upgrades.

Traceability | Audit Trail and Time Stamps

Data is only consistent if an event is reliably time-stamped and can be traced back to a specific device.
All GMP-relevant actions contain the serial number of the device and are time-stamped to comply with 21CFR Part 11. When parameters are changed, values before and after are displayed so that full traceability of "who did what and when" is shown.

Time Zone Synchronization

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 ensuring that user access is commensurate with the level of responsibility. 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 be assigned 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 data entry being 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 safer, faster test procedure. Additionally, user-generated barcodes assigned to SOPs or filter housings can also be used to ensure that the right program is selected by the operator.

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 error-free operation in GMP production environments.

Intuitive iF-Design Rewarded Human Machine Interface (HMI)
Straightforward 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 Using Modbus TCP or OPC UA
The OPC UA and Modbus TCP are two commonly used industrial automation protocols. Compatibility with other automation network control protocols like DeviceNet, Profinet, etc., can be achieved by using third-party gateways.

For details, please ask for separate manuals.

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 IDs and passwords.

Even if the Ethernet connection is lost, the LDAP user accounts stored on the device can be used until they expire. An administrator can define how many days the LDAP user accounts should be kept on the device

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.

LDAP Group-Based Role Management
Users can conveniently be managed directly on the LDAP server without the need for intervention on the Sartocheck® 5 Plus.

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 languages.

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.

New!
Export Improvements of the Audit Trail and PDF Format
The audit trail can be exported in JSON for optimal machine readability. It can also be exported in a digitally signed write protected PDF for optimal eye readability. If filters are applied to the exported audit trail they are clearly indicated on the header.

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).

The Sartocheck® 5 Plus is certified for explosion-prone areas Zone 2, Groupe II-B (IECEx, ATEX) | Class 1 Zone 2 Group II-B (FM – USA). This provides maximum safety for operators and manufacturing facilities.

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 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 compatible with VHP and can be left in a clean room during fumigation.

PFA Tubings (FDA 21 CFR 177 and USP Class VI Compliant)
All connectors are grease-free, and all tubings are manufactured to the highest quality to be FDA 21 CFR 177 and USP Class VI compliant.

H_2O_2- 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 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 scheduled decontamination.

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., PUPSIT).

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 tubing 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 match the requirements of the customer with either model.

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

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

Sartocheck® 5 Plus
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.

If automation is needed, and | or the highest level of QRM is required to achieve regulatory compliance, the Sartocheck® 5 Plus Filter Tester is the obvious choice.

	Sartocheck® 5	Sartocheck® 5 Plus
Order code	26787---FT	26787---FT---P
Usability	■	■
All commonly used integrity test methods	■	■
High quality 12.1" screen	■	■
iF-design rewarded user interface	■	■
LDAP	■	■
Full data transfer in JSON and PDF	■	■
Automation		■
Health, Safety and Environment	■	■
Ingress protection IP64	■	■
Ex-proof (ATEX | IECEx | FM certified)	■	■
Resistant to all current cleaning agents	■	■
H_2O_2-vapor resistant (VHP)	■	■
Automated cleaning of all pneumatics with up to 0.5 M NaOH (requires optional cleaning kit and free software upgrade in Q2 2021)	■	■
Optional Accessory Kit for External Venting (backflow protection)	■	■
Quality Risk Management		
Traditional QRM (bar code scanner, operator training ...)	■	■
Optimized QRM through automatic detection of improper test setups, including free software upgrades upon periodic release		■
Comprehensive FMEA documentation		■
Data Integrity		
Designed according to ALCOA+ principles	■	■
Custom Linux-based OS with inherent virus and malware protection	■	■
Write-protected root file system for virus protection	■	■
Encrypted double-data backup	■	■
Time zone synchronization for reliable time-stamped audit trail	■	■

Roadmap

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.

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.

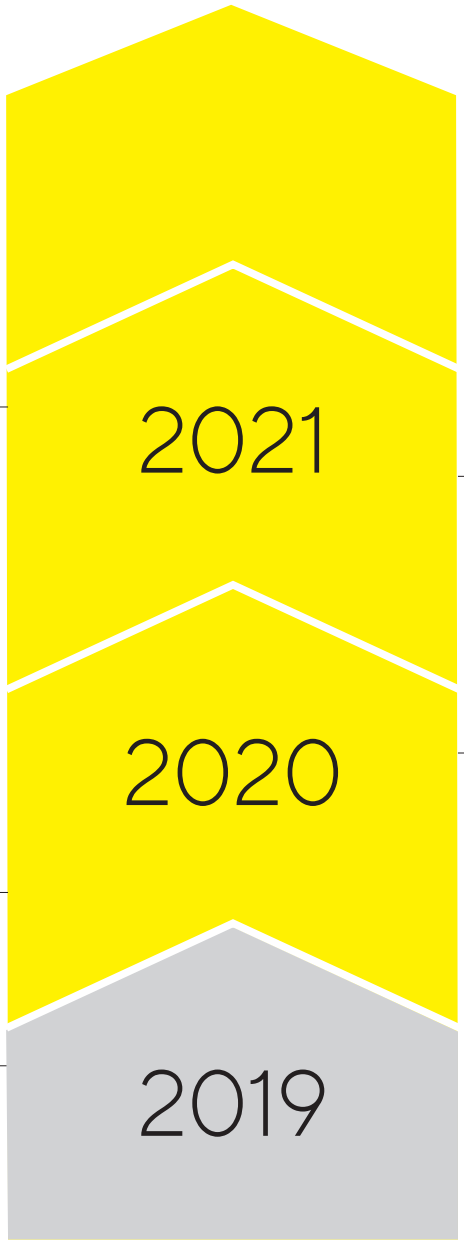
The software upgrades include valuable, patented, and patent-pending features for the following enhanced features:

Usability
- Additional integrated automation protocols
- Software for remote administration

Quality Risk Management
- Improved detection of out-of-specification conditions
- Test counting and blocking of irregular test attempts

Data Integrity
- "Why" comment for changes

Health, Safety and Environment
- Accessory Kit for Automated Cleaning



Q4 2021
QRM and Usability upgrade

Q2 2020
Automation and functionality upgrade
- OPC UA support
- Serial number in all audit trail events
- Additional keyboards
- LDAP group-based role management

Q4 2019
- Electronic signatures | Four-eyes principle
- Automation Modbus TCP
- Dynamic support for SMB 1 | 2.1 | 3
- Standardized and encrypted LDAP
- Reworked test graphs

Q2 2021
Administration upgrade
- Ability to administrate the Sartocheck® 5 Plus remotely using OPC UA
- Memory management of the device

Accessory upgrade
- Automatic cleaning kit

Q4 2020
Administration upgrade
- Improved filtering of displayed audit trail events
- Audit trail exports in digitally signed write-protected PDF format

Automation upgrade
- Possibility to start a program by name using OPC UA

Accessories

The printer automatically performs thermal transfer or direct thermal printing, depending on the selected paper. No settings need to be changed. For example, to meet the strict requirements for fade-resistant printouts in regulated areas of the pharmaceutical industry, paper for thermal transfer printing – either standard or self-adhesive – with up to 30 years of archiving should be used.

USB Printer

Specifications

Resolution	203 dpi
Max. print width	54 mm
Dimensions [L × W × H]	241.3 × 139.9 × 177.4 mm
Power supply	External universal switching power supply ▪ Input: 100 – 240 V~ ▪ Output: 24 V–; 2.5 A
Ambient conditions	▪ Operation 5°C to 40°C (41°F to 104°F), 25% to 85%, non-condensing ▪ Storage - 40°C to 60°C (- 40°F to 140°F), 10% to 90%, non-condensing
Order code	YDP30

Barcode Scanner

Specifications

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

The barcode scanner enables selection of 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.

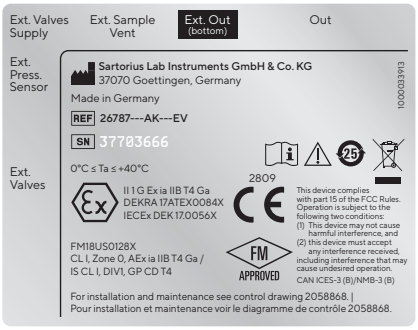
The optional Accessory Kit for External Venting consists of a venting valve and a blocking valve and includes a pressure sensor that is identical to the one used inside the Sartocheck® 5 Plus. The Accessory Kit can be used together with the Sartocheck® 5 Plus to avoid any unwanted siphoning of liquid. 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 Quality Assurance. Up to 10 Accessory Kits for External Venting can be associated with one Sartocheck® 5 Plus and thereby allow the use of different Accessory Kits for pre-use and post-use testing.

The Accessory Kit is certified for use in hazardous areas (ATEX | IECEx | FM) and can be used together with alcohol- wetted filters. It can be used with the standard tubing lengths of 2, 5, and 15 meters. The pneumatic flow path of the Accessory Kit can be cleaned with 0.5M NaOH when using the Accessory Kit for Automated Cleaning.

Optional Accessory Kit for External Venting

Specifications

Test accuracy when using the AK-EV	Identical to the Sartocheck® 5 Plus
Dimensions [L × W × H]	159 × 147 × 163 mm
Weight (without cables)	2.7 kg
Operating temperature	2 – 40 °C (environmental) 2 – 50 °C (cleaning and rinsing agent depending on chemical compatibility)
Power supply	Integrated from the Sartocheck® 5
Power consumption in operation	0.3 W (typical) | 0.7 W (peak)
IECEx, ATEX	Zone 1 Group II-B
FM (USA)	Class 1, Div. 1, Zone 1 Group II-B
Order code	26787---AK---EV



Transportation Box

Specifications

Construction materials	Polypropylene (case and wheels) Polyethylene and polyurethane (foam)
Dimensions [H × W × D]	670 × 510 × 372 mm
Weight	12.3 kg
Total weight incl. Sartocheck® 5 Plus	30 kg
Order code	26787---ST

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, as well as overseas shipping

The following items can be put into the transportation box:

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

Technical Specifications

Test Methods	
Diffusion 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	
Diffusion and intrusion test pressure	50 – 6,600 mbar | 0.73 – 95.7 psi
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 (5 times the max programmable value)
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 ▪ with ext. reference vessel	 14 L 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	16.8 kg
Weight of the packaging	2.2 kg
Cargo | gross weight	20.6 kg
Cargo volume	95,304 cm^3
Cargo dimensions	570 × 440 × 380 mm
Max noise at 1 m during depressurization with venting tubings	68 dB(A) at 6,600 mbar (95.7 psi) 51 dB(A) at 3,000 mbar (47.9 psi)

Services

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

Installation & Commissioning

Safe and proper operation of your equipment right from the start

Qualification (IQ | QQ)

Compliance with GMP requirements, easy integration into your quality management system

Operator Training

Quality through greater experience: Sartorius trains the personnel operating your equipment

Installation Phase

Utilization Phase

Repairs & Spare Parts

In the event of service requests, we are quickly at your side with the necessary spare parts – worldwide

Maintenance & Contracts

Optimal equipment operation and protection against potential downtimes

Calibration

Accurate results in the long term and compliance with regulatory requirements

Service Contracts for the Entire System Lifecycle

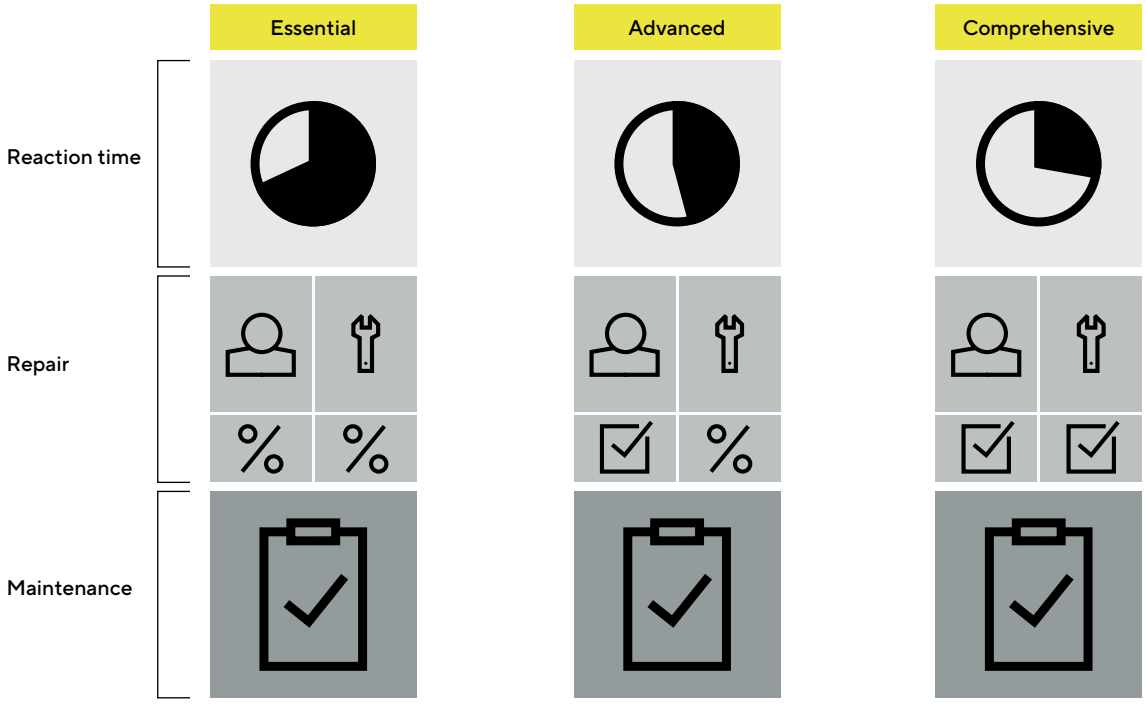
With our Bioprocess Service Program, Sartorius offers service contracts to protect your equipment through its entire lifetime. Based on your specific risk assessment and requirements, you can choose among three Service Level Agreements: Essential, Advanced, and Comprehensive. Protect your Sartocheck® 5 | 5 Plus Filter Tester by choosing the appropriate service contract for maximum productivity and minimum downtime.

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

Essential
You benefit from:
- A plannable annual maintenance
- Fast support at the technical helpdesk within one business day and priority on-site-response
- In case of repair, a discount on time and materials

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

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



For further details and the dedicated datasheets, visit our website
www.sartorius.com/service

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