Sartocheck® 5 Plus Filter Tester

New Software Release
Q2 2024 — Version 2.3.1

Simplifying Progress

SARTORIUS

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 Annex 1 Requirements of Quality Risk Management (QRM)
- Reach the Ultimate Level of Data Integrity
- Experience the Comfort of Intuitive Usability
- Discover the Simplicity of Annex 1 Contamination Control Strategy and HSE | OSH

Quality Risk Management
- Automatic detection of improper test setups
- Automatic detection of abnormal test conditions
- Available comprehensive FMEA documentation – updated for every release
- 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
- A major update for the root file system of the SC5 in the Q2 2022 release further strengthened the data security aspects of the software
- Mandatory "Why" comment when modifying program parameters
- Blocking of abusive test attempts

Usability
- Large touch screen (12.1") (± 88° viewing angle)
- Easy data transfer via file share
- Automation by Modbus TCP and OPC UA
- LDAP group-based role management
- Export of the audit trail and digitally signed write-protected PDF format
- Improved filtering of displayed audit trail events
- Printing via network printer, direct IP address, DNS name and printer server
- Scheduled export of the audit trail in in PDF and JSON format
- Bubble point pressure stabilization improvement (BP_{min} and BP_{max})

CCS, HSE | OSH
- Pneumatics cleanable with NaOH to comply with the CCS of Annex 1
- Accessory Kit for external Venting prevents backflow and improves the CCS
- Resistant to VHP and all current cleaning agents for best CCS
- High ingress protection IP64
- Ex-proof (ATEX | IECEx | FM)

Surpass the Annex 1 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.
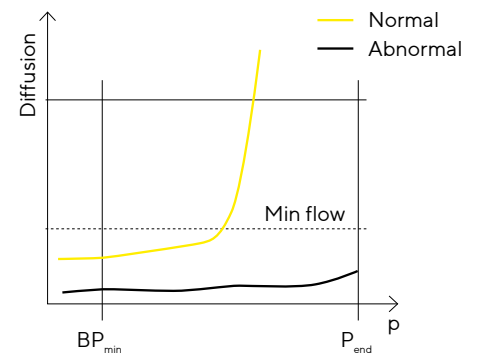
… BP$_{max}$ Versus P$_{end}$
A defined filter type under defined test conditions is expected to have an actual bubble point within a certain range. If the actual bubble point exceeds a certain level, it is considered atypical. The BP$_{max}$ (if set to lower than P_{end}) allows detection of these atypical situations.
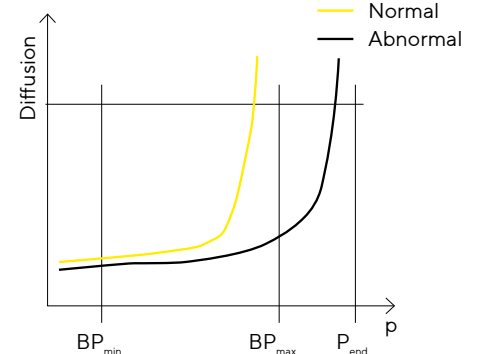
Diffusion | WIT
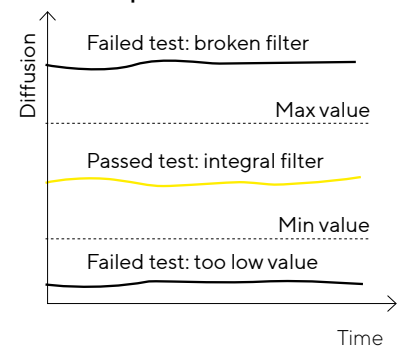
Bubble Point

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 (Q2 2022)

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. In addition, before every test a mechanical self-test is performed, including a comparative pressure reading. 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. A major update of the root file system in the Q2 2022 release further strengthened the data security aspects of the software.

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.

"Why" comment

When modifying a program, entering a "why" comment is mandatory. The comment is traced in the audit trail.

Consistent file names and harmonized time representations

Exported files have consistent names and time stamps (ISO 8601) for easy manual identification of the type of event and improved integration into data historians. The time representation is harmonized throughout the Sartocheck® 5 Plus.

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. The pre-programmed default users can easily be modified or deleted by the device administrator.

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.

Blocking of abusive test attempts

Typically, a filter should not be tested more than 3 times before being declared as non-conforming. Too many tests can be seen as a serious deviation by regulatory bodies. The Sartocheck® 5 Plus allows to define a max number of consecutive test attempts per filter. Only conclusive tests are counted. Faulty setups e.g. the wrong filter being tested or the filter being tested in reverse direction, detected by the QRM parameters of the Sartocheck® 5 Plus, are not counted.

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.

- High luminosity and resolution
- Type TFT LED-Backlit color
- Optimal viewing angle ±88°
- 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

OPC UA and Modbus TCP are two commonly used industrial automation protocols for remote start and setting of parameters, and retriving of results. 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.

Memory Management

Even if the Sartocheck® 5 Plus can hold more than 22,000 test results it will sooner or later be necessary to free memory space. The memory management gives the posibility to erase the memory in a secure manner, in compliance with 21CFR Part 11.

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", "Results", and "Backups", and each folder can have separate usernames and passwords.

System Languages

The user interface is available in 10 languages.

Remote Administration

The Sartocheck® 5 Plus can be administrated via OPC UA. Many administrative task can now be handled without the need of getting in front of the device e.g. programming.

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

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.

Export of the Audit Trail

The Sartocheck® 5 supports automatic (continuous), manual and scheduled exports of the audit trail in PDF (for eye readability) and JSON format (for machine readability). If filters are applied to the exported audit trail, they are clearly indicated on the header.

Discover the Simplicity of Annex 1 Contamination Control Strategy and HSE|OSH

In the released Annex 1 version from August 2022, it is stated that, "A Contamination Control Strategy (CCS) should be implemented across the facility in order to define all critical control points and assess the effectiveness of all the controls." Preventing backflow and perform cleaning of the internal pneumatics of the integrity tester assure that no contamination is building up over the years of usage.

HSE | OSH: 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.

CCS - Prevention: 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.

CCS - Curative: Automated Cleaning

The Cleaning Kit, can be used to clean the internal and external pneumatics of the Sartocheck® 5 with 0.1M NaOH, rinsed with water and dried with compressed air, all in one fully automated process step. Should depyrogenation be required, up to 0.5M NaOH at max 50° C can be used.

The combination of the Accessory Kit for External Venting and the Accessory Kit for automated cleaning gives a solid contamination control strategy (CCS) in compliance to the new Annex 1.

Please ask for our separate CCS documentation.

CCS - VHP Resistant

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 contributes to the global CCS of the production area.

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, Group 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 for highest level of HSE | OSH.

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).

FDA 21 CFR Part 177 and USP Class VI Compliant Tubing

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.

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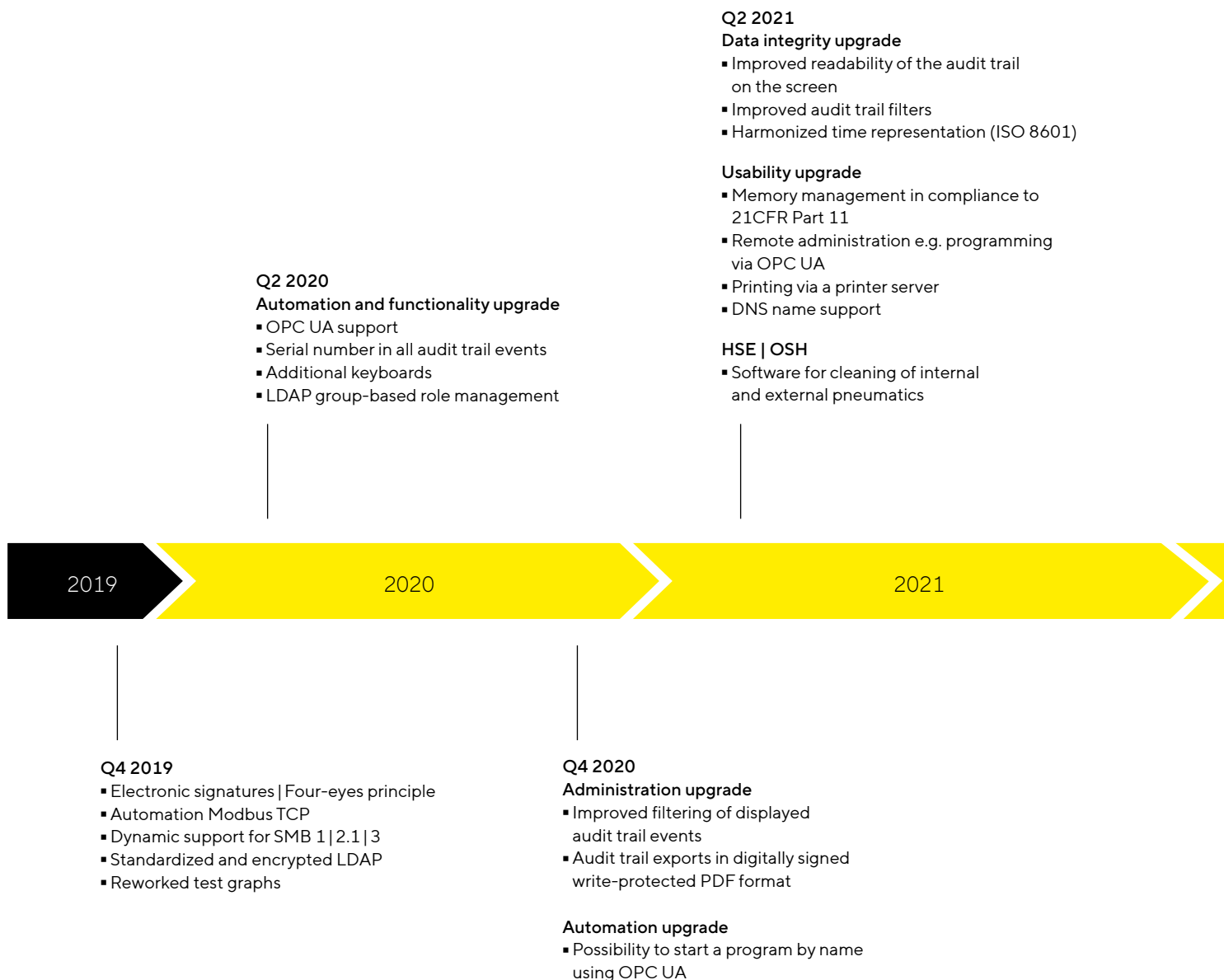
If automation is needed, and | or the highest level of QRM is required to achieve regulatory compliance, the Sartocheck® 5 Plus Filter Tester is the obvious choice.

	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	■	■
Automatic (continuous), manual & scheduled exports of the audit trail	■	■
Automation		■
Remote administration		■
Memory management	■	■
Contamination Control Strategy and HSE | OSH		
CCS - Automated cleaning of all pneumatics with up to 0.5 M NaOH (requires optional cleaning kit)	■	■
CCS - Optional Accessory Kit for External Venting (backflow protection)	■	■
CCS - H_2O_2-vapor resistant (VHP)	■	■
Ingress protection IP64	■	■
Ex-proof (ATEX|IECEx|FM certified)	■	■
Resistant to all current cleaning agents	■	■
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		■
Standard PQ protocol		■
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	■	■
Major update to the root file system in Q2 2022	■	■
"Why" comment for program changes	■	■
Blocking of abusive test attempts		■

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 an annual or more frequent basis.
- Each software upgrade comes with a comprehensive risk assessment and development documentation.
- The software upgrades include valuable improvements for data integrity, quality risk management (QRM), usability, contamination control strategy (CCS) and health, safety and environment (HSE) | occupational safety and health (OSH).
- The software upgrades are included in the price of the Sartocheck® 5 Plus until the software release in Q2 2025. The last included upgrade will benefit from a maintenance program.
- A roadmap of additional software upgrades including patented QRM parameters and improved usability will be implemented.
- A re-OQ is typically not required as the added features are not part of the OQ and do not alter the primary function of the Sartocheck® 5 Plus.

Q2 2021
Data integrity upgrade
- Improved readability of the audit trail on the screen
- Improved audit trail filters
- Harmonized time representation (ISO 8601)

Usability upgrade
- Memory management in compliance to 21CFR Part 11
- Remote administration e.g. programming via OPC UA
- Printing via a printer server
- DNS name support

HSE | OSH
- Software for cleaning of internal and external pneumatics

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

2019	2020	2021	

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

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

Q2 2022
QRM & Data Integrity upgrade
- Blocking of abusive test attempts
- Mandatory comment entry ("Why") when changing critical process parameters
- Scheduled exports of Audit trail PDFs
- Major update of the root file system for further strengthened data security

Usability upgrade
- Bubble point testing improvements (no change in testing algorithm)
- Various usability upgrades

Q1 2023
General Performance Upgrade
- Stability improvements
- Audit trail improvements
- Connectivity improvements
- Cleaning cycle improvements

Q2 2025 – 3.1.0
Interface & Performance upgrade
- New accelerated interface
- Rebranding of the interface
- General improvements

2022 2023 2024 2025

Q3 2022
Accessory upgrade
- Accessory Kit for Automated Cleaning

Q2 2024
Testing & Performance upgrade
- Bubble point pressure stabilization improvements (no change in testing algorithm)
- Improved data export performance
- Double backup of calibration data
- Improved keyboard Pinyin-function (Mandarin)
- Stability improvements

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 0.5 M NaOH when using the Accessory Kit for Automated Cleaning.

The combination of the Accessory Kit for External Venting and the Accessory Kit for automated cleaning gives a solid contamination control strategy (CCS) in compliance to Annex 1.

Contamination Control Strategy: 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 x 147 x 136 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

Contamination Control Strategy: Accessory Kit for Automated Cleaning of the Pneumatics

Specifications

Dimensions [L × W × H]	29 × 22 × 10.5 cm (Cleaning Kit Box)
Weight	5000 g (Cleaning Kit Box)
Operating temperature	between 0 °C and 40 °C
Max temperature of the cleaning liquid (0.5M NaOH)	Max. of 50 °C
Power consumption in operation	11 W (max. 60 W)
IECEx, ATEX, FM	No
Order codes (region specific)	26787---AKDE-CL 26787---AKEN-CL 26787---AKFR-CL 26787---AKIT-CL 26787---AKES-CL 26787---AKPT-CL 26787---AKCN-CL 26787---AKJP-CL 26787---AKKR-CL 26787---AKRU-CL 26787---AKVA-CL 26787---AKVB-CL

The optional Cleaning Kit consists of a valve box, a waste vessel and tubing. 2 pressure vessels are also needed and can be supplied separately.

The Cleaning Kit can be used to clean the internal and external pneumatics of the Sartocheck® 5 with 0.1 M NaOH, rinsed with water and dried with compressed air, all in one fully automated process step. Should depyrogenation be required, up to 0.5 M NaOH at max 50 °C can be used.

Once the connections are made and the cleaning cycle has been started, there is no need for disconnecting any tubing, thus avoiding the risk for spraying of cleaning liquid.

The pneumatics of the Accessory Kit for External Venting can also be cleaned with the Cleaning Kit, under identical conditions, without the cleaning and rinsing fluids getting in contact with the pneumatics of the Sartocheck® 5.

Each cleaning cycle is composed of soaking and cleaning, rinsing, and drying.

The execution and fulfillment of the cleaning cycle is traced in the audit trail.

The combination of the Accessory Kit for External Venting and the Accessory Kit for automated cleaning gives a solid contamination control strategy (CCS) in compliance to the Annex 1.

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

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

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	
Measuring Ranges	
Diffusion and intrusion test pressure	50.0 – 6,000.0 mbar | 0.725 – 95.725 psi
Programmable max diffusion flow	0.011 – 4,800.00 mL/min
Programmable max intrusion water flow	0.006 mL/min – 60.000 mL/min
Max measurable | displayable diffusion flow	24,000.00 mL/min (5 times the max programmable value)
Max measurable | displayable intrusion water flow	300.00 mL/min (5 times the max programmable value)
Programmable minimum bubble point	250.0 – 6,550.0 mbar | 3.626 – 95.000 psi
Programmable pressure drop (not higher than the test pressure)	0.5 – 6,600.0 mbar | 0.007 – 95.725 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	±5% or 0.05 mL/min, whichever is higher
Intrusion	±5% or 0.05 mL/min, whichever is higher
Bubble point	±50 mbar | 0.73 psi, can be improved to ±25 mbar | 0.36 psi (configurable pressure steps)
Accelerated bubble point	±50 mbar | ±0.73 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.

🌐 **For further details and the dedicated datasheets, visit our website**
www.sartorius.com/en/services

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 covered with 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 more information, visit**
sartorius.com