Sartocheck® 5 Plus Universal

New Software Release Q3 2025 – Version 3.1.1

Simplifying Progress

SARTORIUS


SARTORIUS
Restart test
Print results
SARTOCHECK® 5

Sartocheck® 5 Plus Universal

Keeps Your Risk Factors Under Complete Control

The Sartocheck® 5 Plus Universal perfectly meets today's key industry requirements for filter integrity testing and bag testing in demanding GMP environments. It sets a new standard for testing devices, allowing users 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 health, safety and environment (HSE) | occupational safety and health (OSH)

Quality Risk Management
- Automatic detection of improper test setups
- Automatic detection of abnormal test conditions
- Comprehensive FMEA documentation available and updated with 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 Sartocheck® 5 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
- Combined with the Accessory Kit for Bag Testing, single-use bags can be tested

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
- Explosion proof (ATEX | IECEx | FM)

Surpass the Annex 1 Requirements of Quality Risk Management (QRM)

The regulatory focus on QRM (as outlined in ICH Q9 and the new Annex 1, developed by the EMA in collaboration with the US FDA, WHO, and PIC/S) also applies to filter integrity testing as a fundamental element of sterility assurance. The Sartocheck® 5 Plus Filter Tester and the Sartocheck® 5 Plus Universal use 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 and Sartocheck® 5 Plus Universal allow 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.

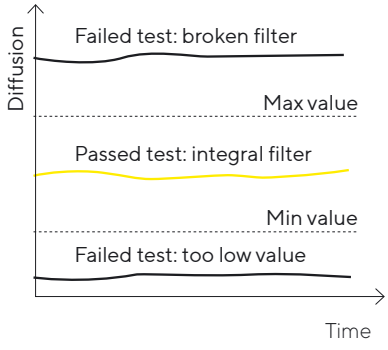
The bubble point programs can be defined with a minimum flow expected to be achieved at the end pressure of the test (P_{end}). If this flow threshold is not reached, it may be an indication that the filter is blocked, the wrong filter type is being tested, or that the downstream valve is closed.

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

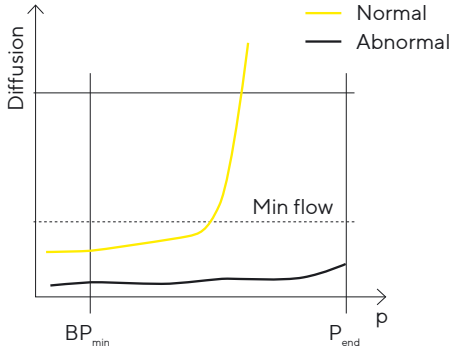
BP_{max} Versus P_{end}
A defined filter type under defined test conditions is expected to have an actual bubble point within a certain range. If the actual bubble point exceeds a certain level, it is considered atypical. The BP_{max} (if set to lower than P_{end}) allows detection of these atypical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

Automatic Detection of Abnormal

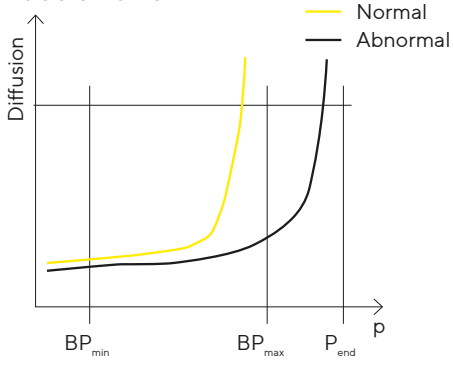
Diffusion | WIT



Bubble Point



Bubble Point



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
It is generally recommended that a filter should be tested a maximum of three times at the user's site (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 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 pass and false fail 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 QRM. This documentation is available on request.

Calculation Tool for the Impact of Unlikely Calibration Offsets
QRM 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[1], explains the calculation in detail and contributes to robust, regulatory-compliant QRM.

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. Reliable long-term 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 critically, endanger the health of patients.

Data Integrity Statement | ALCOA+ Principles

The Sartocheck® 5 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 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 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 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 | Four-Eyes Principle

The ability to electronically sign test results according the four-eyes principle further enhances the trust-worthiness 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 are also encrypted (AES-128) and cryptographically signed by Sartorius 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 is connected to the network, and the NTP function is activated, automatic time zone synchronization occurs, generating reliable time stamps in the audit trail. If the Sartocheck® 5 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.

User Matrix to Generate Individual User Roles

For maximum flexibility, the Sartocheck® 5 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, keeping your data safe from accidental intrusion. More than 1,000 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 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 three times before being declared as non-conforming. Too many tests can be seen as a serious deviation by regulatory bodies. The Sartocheck® 5 allows users 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 through intuitive guidance and ease of use. The high-quality touchscreen of the Sartocheck® 5 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, intuituve user experience, and a user-friendly control system all contributed to rapid process initiation and winning the iF Design Award.

12.1" Touchscreen With a ± 88° Viewing Angle
A large, bright screen with an optimal 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 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 starting, parameter setting, and results retrieval. Compatibility with other automation network control protocols like DeviceNet, Profinet, etc., can be achieved by using third-party gateways.

For details, please ask for the individual manuals.

Memory Management
Although the Sartocheck® 5 can hold more than 22,000 test results, it will eventually be necessary to free memory space. The memory management allows users to erase the memory in a secure manner, in compliance with 21CFR Part 11.

LDAP – Log on With Network User Credentials
The Sartocheck® 5 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 forgotten 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 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 be conveniently managed directly on the LDAP server without the need for intervention on the Sartocheck® 5.

Data Transfer
The data generated by the Sartocheck® 5 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 versions can be administrated via OPC UA. Many administrative tasks can now be handled remotely, without the need to be physically in front of the device, e.g., programming..

Faster Testing
Test durations for diffusion and water intrusion on the Sartocheck® 5 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 predefined 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 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

The Annex 1 version released in August 2022 states 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 builds up over the years of usage.

HSE | OSH: Integrity testing may involve the use of chemicals (e.g., isopropanol for restesting) and hazardous materials. The Sartocheck® 5 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. The Accessory Kit can be used together with the Sartocheck® 5 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 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 0.1 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.

The combination of the Accessory Kit for External Venting and the Accessory Kit for Cleaning gives a solid CCS in compliance with the new Annex 1.

Please ask for our separate CCS documentation.

CCS - VHP Resistant
Vaporized hydrogen peroxide (VHP) is frequently used for decontamination of cleanrooms. Electronics are generally not VHP-resistant, and all instruments that are not VHP-resistant must be covered by plastic or moved out of a cleanroom before fumigation.

The Sartocheck® 5 is the only VHP-compatible filter integrity tester on the market. It can remain in a cleanroom during fumigation and contributes to the global CCS of the production area.

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

Explosion-Proof (ATEX, IECEx, and FM certified)
The Sartocheck® 5 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 (PDA Technical Report 26 and Points To Consider, Part 2).

The Sartocheck® 5 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 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 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.

Three Versions of the Sartocheck® 5

The new Sartocheck® 5 Series comes in three variants to match different user requirements.

Sartocheck® 5 Filter Tester
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 (e.g, data entry by bar code scanner, operator training) is enough for regulatory compliance, the Sartocheck® 5 Filter Tester is sufficient.

Sartocheck® 5 Plus Filter Tester
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 right choice.

Sartocheck® 5 Plus Universal
Combined with the Accessory Kit for Bag Testing, the Sartocheck® 5 Plus Universal offers the capacity to perform point of use leak testing of bags up to 2,000 L*. Combined with the FlexAct® BT it also allows integrity testing of 2D bags up to 50 L.

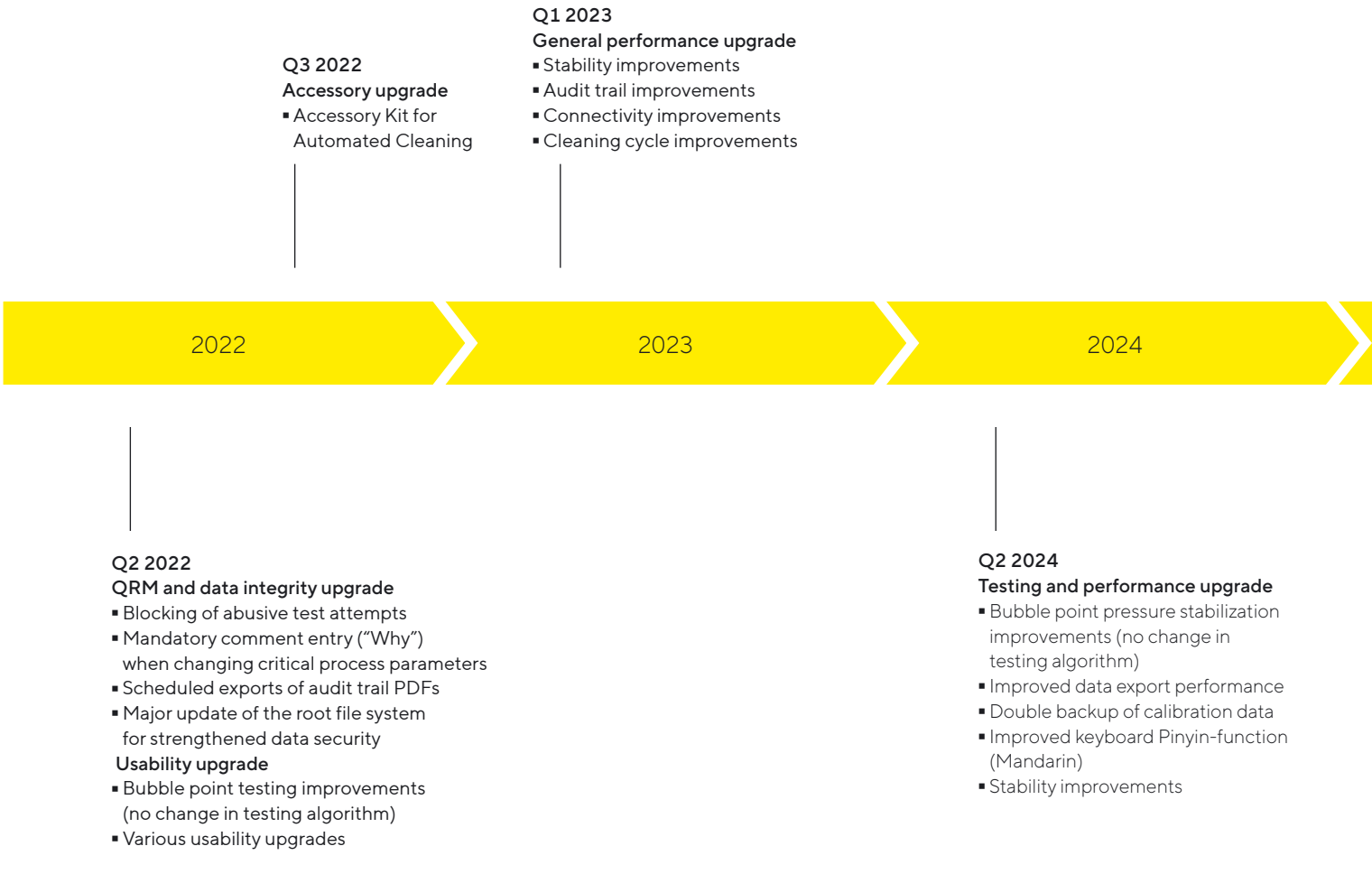
If bag testing or both filter and bag testing with the highest level of QRM are needed, the Sartocheck® 5 Plus Universal is the appropriate choice.

*Please refer to the point of use leak test data sheet of the corresponding bag.

	Sartocheck® 5	Sartocheck® 5 Plus	Sartocheck® 5 Plus Universal
Order code	26787---FT	26787---FT---P	26787---UN---P
Usability			
All commonly used filter integrity test methods	■	■	■
LDAP and user management	■	■	■
Full data transfer in JSON and PDF	■	■	■
Automatic (continuous) manual and scheduled exports of the audit trail	■	■	■
Automation (Modbus TCP and OPC UA)		■	■
PAS-X compatibility via OPC UA (software version 3.2.0 Q4 2025)		■	■
Remote administration via OPC UA		■	■
Memory management	■	■	■
Compatibility to the Accessory Kit for Bag Testing			■
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 for filter testing (backflow protection)	■	■	■
CCS - H_2O_2-vapor resistant (VHP)	■	■	■
Ingress protection IP64	■	■	■
Explosion proof (ATEX | IECEx | FM)	■	■	■
External resistance to all current cleaning agents	■	■	■
Quality Risk Management			
Traditional QRM (optional barcode scanner and operator training)		■	■
QRM - Automatic detection of improper test setups (min. and max. values)		■	■
Roadmap with additional QRM parameters			■
Comprehensive FMEA documentation (QRM Handbook)		■	■
Standard PQ protocol		■	■
Data Integrity and Software			
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	■	■	■
Network time protocol for reliable time-stamped audit trail	■	■	■
“Why comment” for program changes	■	■	■
Blocking of abusive test attempts (test counting)		■	■
Software maintenance	■	■	■
Roadmap with additional features beyond SW version 3.2.0		■	■

Roadmap

- The purchase of the Sartocheck® 5 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 HSE | OSH.
- An operational requalification is typically not required, as the added features are not part of the operational qualification, and do not alter the primary function of the Sartocheck® 5.



Q3 2025 – 3.1.1
Interface and performance upgrade
- New accelerated interface
- Rebranding of the interface
- General improvements
- Accessory Kit for Bag Testing (Sartocheck® 5 Plus Universal)

Q4 2027
Software maintenance

2025 2026 2027

Q4 2025 – 3.2.0
Automation upgrade
- PAS-X compatibility (Valid for the Sartocheck® 5 Plus versions)

Q3 2026
Software maintenance and automation upgrade
- OPC UA variable based communication (Valid for the Sartocheck® 5 Plus versions)

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 – 40 °C (41 – 104 °F), 25 – 85%, non-condensing ▪ Storage – 40 – 60 °C (– 40 – 140 °F), 10% – 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 – 50 °C (32 – 22 °F)
Storage temperature	-40 – 70 °C (-40 – 158 °F)
Humidity	0 – 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

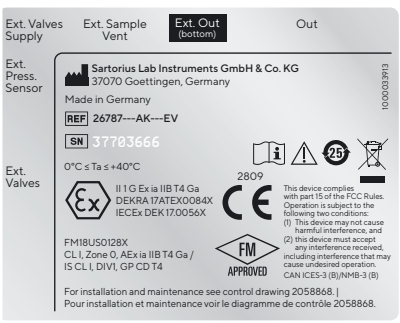
The barcode scanner enables selection of the right program by scanning the appropriate 1D or 2D barcode in a safer and much faster way than if done manually. “Homemade” barcodes can also be used that can be attached to SOPs or filter housings. Flawless data entry of, e.g., the filter lot number, the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

Contamination Control Strategy: 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. The Accessory Kit can be used together with the Sartocheck® 5 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, enhancing quality assurance. Up to 10 Accessory Kits for External Venting can be associated with one Sartocheck® 5, allowing 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 CCS in compliance with Annex 1.

Specifications	
Test accuracy when using the AK-EV	Identical to the Sartocheck® 5
Dimensions [L × W × H]	159 × 147 × 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) | 1.7 W (peak)
IEXEx, ATEX	Zone 1 Group II – B
FM (USA)	Class1, Div. 1, Zone1 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	5,000 g (Cleaning Kit Box)
Operating temperature	between 0 – 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. two 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 to disconnect any tubing, avoiding the risk of 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 CCS in compliance with the Annex 1.

The optional Accessory Kit for Bag Testing consists of a Sartorius-specific, highly accurate low-pressure sensor. The Accessory Kit can be used together with the Sartocheck® 5 Plus Universal to perform point-of-use leak testing of 3D bags, e.g., single-use bags for mixing and fermentation. If the Sartocheck® 5 Plus Universal is combined with the FlexAct® BT (see next page), integrity testing of 2D bags can be performed.

The combination of the Sartocheck® 5 Plus Universal, the Accessory Kit, and the FlexAct® BT allows users to build a holistic strategy for testing of filters and bags.

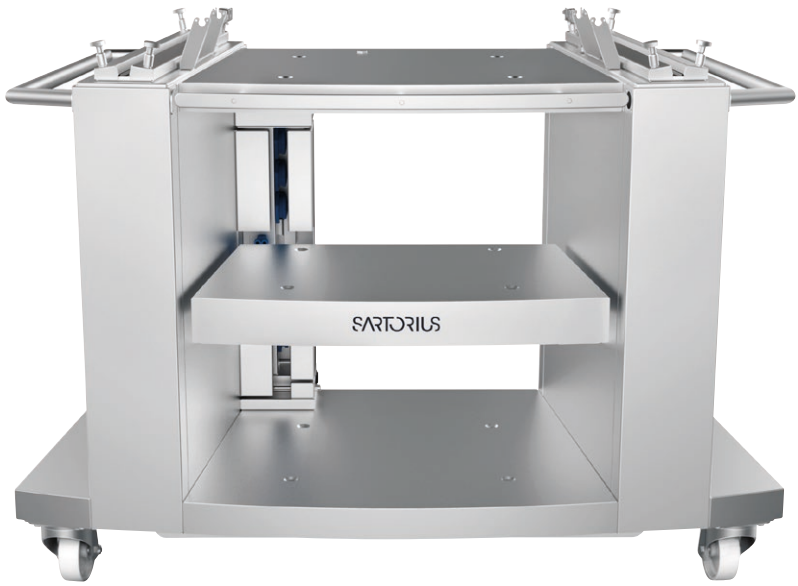
Note: Always verify that official testing parameters are available before testing bags. Exposing single-use bags to excessive pressures will damage the bag and may harm the operator in case of explosion.

Point-of-Use Leak and Integrity Testing of Single-Use Bags: Optional Accessory Kit for Bag Testing

Specifications	
Pressure range	0 – 400 mbar
Pressure test range	20 – 360 mbar
Pressurea accuracy	± 0.05% FS
Pressure drop accuracy	± 0.1% before rounding
Dimensions	190 × 155 × 37 mm
Weight	1 kg
Power supply	Integrated in the Sartocheck® 5
IECEx, | ATEX | FM	No
IP rating	44
Order code	26787---AK---BT

Integrity Testing of 2D Single-Use Bags: FlexAct® BT

Specifications	
Pressure test range	Max. 300 mbar (4.351 psi)
Bag type	2D
Bag volumes	Flexsafe® and Flexboy® up to 50 L
Dimensions [W×D×H]	1405×699×1043 cm (Cleaning Kit Box)
Weight	375 kg
Fleeces | porous spacer	DZ050L---SIT
Order codes	26288---BTFA



The FlexAct® BT is equipped with two plate holders, each of them consisting of two metal plates with porous spacer between which single-use bags are inserted for inflation and integrity testing. By using porous spacers, the film surface of the bag is not in direct contact with the stainless-steel holder during the test. Any potential masking effect is eliminated. The masking effect will occur when a leak in the plastic film is pressed against a smooth surface, blocking the leak.

The holders protect the bag from mechanical stress and reduce heat transfers. They allow users to perform the integrity test with a small and reproducible inflating bag volume and at a high test pressure (300 mbar), thus increasing the test sensitivity.

Note: Always verify that official testing parameters are available before testing bags. Exposing single-use bags to excessive pressures will damage the bag and may harm the operator in case of explosion.

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

The following items can be put into the transportation box:
- Sartocheck® 5
- 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


SARTORIUS
John Operator
08.01.2020
09:00:01 am
Run new test
Administration
SARTOCHECK® 5

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	
Bag Test Installed (BTI) - Only for the Sartocheck® 5 Plus Universal when equipped with the Accessory Kit for Bag Testing	
Bag Test Holder (BTH) - Only for the Sartocheck 5® Plus Universal when equipped with the Accessory Kit for Bag Testing and the FlexAct® BT	
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
Bag test installed (BTI)	20 – 50 mbar | 0.290 – 0.725 psi
Bag test holder (BTH)	20 – 360 mbar | 0.290 - 5.220 psi
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 Filter Testing	
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, 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®5. 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 by choosing the appropriate service contract for maximum productivity and minimum downtime.

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

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

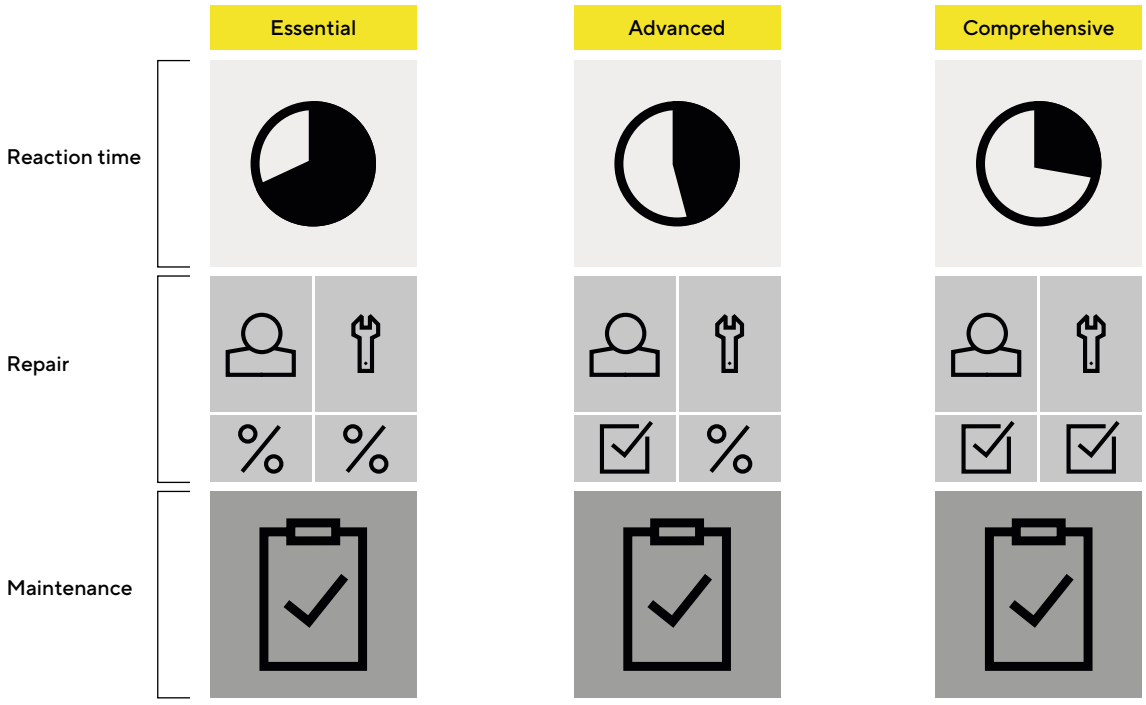
You benefit from:

- 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% 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



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