

Sartocheck® 5 – Contamination Control Strategy

Protective and Curative
Solutions for Backflow –
How to Avoid Cross
Contamination

New Software Release Q1 2023 - Version 2.2.1



Portfolio Overview

Contamination Control Strategy

In the released Annex 1 version from August 2022, it is stated that, "Quality Assurance is particularly important, and manufacture of sterile products must strictly follow carefully established and validated methods of manufacture and control. 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 (design, procedural, technical and organisational) and monitoring measures employed to manage risks associated with contamination. The CCS should be actively updated and should drive continuous improvement of the manufacturing and control methods."

Accessory Kits

- Accessory Kit for External Venting
- Accessory Kit for Automated Cleaning of the Pneumatics

Key Benefits

- Meets the requirements for Contamination Control Strategy
- Provides traceability for the cleaning of the pneumatics in the audit trail
- Automated cleaning procedure
- Secure for the operator

The new Annex 1 also states, “The CCS should consider all aspects of contamination control and its life cycle with ongoing and periodic review resulting in updates within the quality system as appropriate.

The manufacturer should take all steps and precautions necessary to assure the sterility of the products manufactured within its facilities. Sole reliance for sterility or other quality aspects should not be placed on any terminal process or finished product test.

Elements to be considered within a documented CCS should include (but are not limited to):

- xii. Preventative maintenance – maintaining equipment, utilities, and premises (planned and unplanned maintenance) to a standard that will not add significant risk of contamination.
- xiii. Cleaning and disinfection.”

Interpretation of the Annex 1 Contamination Control Strategy

Testing a filter pre-use (e.g., during PUPSIT) may induce cross contamination if the filter integrity tester has been contaminated by backflow from a filter tested post-use. This cross contamination can be both chemical and microbiological, which represents a risk to the final product, and must therefore be part of the CCS.

Preventing backflow into the Sartochek® 5 averts cross contamination, and cleaning of the pneumatics should be part of the preventive maintenance.

Accessory Kit for External Venting

The optional Accessory Kit for External Venting (AKEV) consists of a venting valve and a blocking valve and includes a pressure sensor that is identical to the one used inside the Sartochek® 5. The kit can be used in conjunction with the Sartochek® 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).



Setup of Accessory Kit for External Venting

The use of the AKEV can be set to mandatory for specific programs, thus greatly reducing the risk of human errors. Up to 10 AKEVs can be associated with one Sartochek® 5, thereby 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 with alcohol-wetted filters. It can be used with the standard tubing length of 2 and 5 meters. The pneumatic flow path of the AKEV can be cleaned with up to 0.5 M NaOH at max 50 °C when using the Automated Cleaning Kit.



Accessory Kit for External Venting

Accessory Kit for Automated Cleaning

The optional automated Cleaning Kit (available in Q3 2022) consists of a valve box, a waste vessel, and tubing. Two pressure vessels are also needed and can be supplied separately.

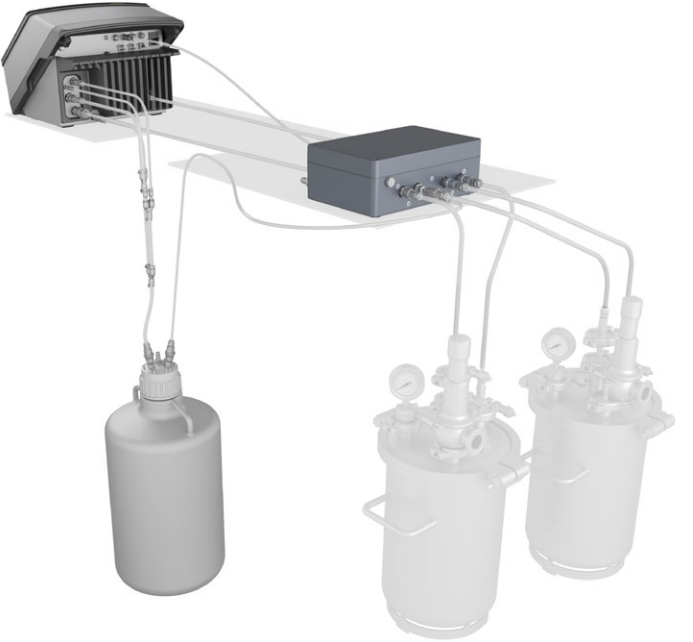
The Cleaning Kit can be used to clean the internal and external pneumatics of the Sartochek® 5 with 0.1 M NaOH, rinse it with water, and dry it with compressed air – all in one fully automated process step. Should depyrogenation be required, up to 0.5 M NaOH at max 50 °C can be used.

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

The pneumatics of the AKEV can also be cleaned with the kit, under identical conditions, and without the cleaning and rinsing fluids coming into contact with the pneumatics of the Sartochek® 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.



Setup of the Cleaning Kit

Contamination Control Strategy Assessment for the Sartocheck® 5

General Risk Assessment

- Cross-contamination is a legitimate concern for all integrity test systems performing pre-use integrity testing; however, as long as the integrity tester and connection tubing have not become contaminated, they cannot possibly cross-contaminate filters being tested.
- Filters being pre-use tested with actual product, or a buffer as a wetting liquid, or filters being post-use tested, may result in contamination of the integrity tester.
- Once the integrity tester has been contaminated, and if it is subsequently used for pre-use testing, there exists a risk for cross-contamination.
- Cross-contamination of a liquid filter being post-use tested is not a concern, as the filter will not be re-used. This assumes that cross-contamination does not affect the integrity test measurements, nor is it potentially hazardous to the operator.

Preventive Measures Using the AKEV:

- The AKEV is an automated valve manifold containing a calibrated pressure sensor, allowing the Sartocheck® 5 to work according to the “one-way” principle. The test gas travels from the Sartocheck® 5 towards the filter to be tested; however, the test gas is never allowed to flow in the reverse direction back towards the Sartocheck® 5. Rather, the test gas is diverted and vented directly from the AKEV, which is affixed to the top of the filter. If the AKEV is used for all post-use filter testing, it effectively prevents any backflow from entering the Sartocheck® 5.
- While protecting the Sartocheck® 5 during post-use testing, the AKEV itself can potentially become contaminated; however, if the AKEV remains dedicated only to post-use testing, cross-contamination is of no concern.
- If a test program is defined to be run with an AKEV, it cannot be executed without the AKEV connected, thereby preventing the operator from inadvertently running the test without the AKEV. Conversely, if a program is defined to be run without the AKEV, it cannot be executed with the AKEV connected, thereby preventing the operator from inadvertently running a pre-use test with a contaminated AKEV.
- In lieu of the AKEV, a single-use sterilizing-grade vent filter can be inserted between the Sartocheck® 5 and the filter to be tested to prevent cross-contamination.

Curative Measure Using the Cleaning Kit:

Should the Sartocheck® 5 ever become contaminated, the automated Cleaning Kit allows the cleaning, rinsing, and drying of all internal pneumatics within the Sartocheck® 5, including the AKEV, using up to 0.5 M NaOH at 50 °C. The executed cleaning procedure is fully captured within the audit trail of the Sartocheck® 5.



Ordering Information

Item	Description	Package	Order Number
Sartocheck® 5	Filter tester	1 pc.	26787---FT
Sartocheck® 5 Plus	Filter tester with highest QRM and automation	1 pc.	26787---FT---P
Accessory Kit for External Venting	Kit to prevent backflow	Kit	26787---AK---EV
Cleaning Kit (Germany)	Includes German manual and EU power cord	Kit	26787---AKDE-CL
Cleaning Kit (UK, India, and USA Canada)	Includes English manual and power cords for Europe, USA Canada, UK, and India	Kit	26787---AKEN-CL
Cleaning Kit (France)	Includes French manual and French power cord	Kit	26787---AKFR-CL
Cleaning Kit (Italy)	Includes Italian manual and Italian power cord	Kit	26787---AKIT-CL
Cleaning Kit (Spain and Argentina)	Includes Spanish manual and power cords for Europe and Argentina	Kit	26787---AKES-CL
Cleaning Kit (Portugal and Brazil)	Includes Portuguese manual and power cords for Europe and Brazil	Kit	26787---AKPT-CL
Cleaning Kit (China)	Includes Chinese manual and Chinese power cord	Kit	26787---AKCN-CL
Cleaning Kit (Japan)	Includes Japanese manual and Japanese power cord	Kit	26787---AKJP-CL
Cleaning Kit (Korea)	Includes Korean manual and Korean power cord	Kit	26787---AKKR-CL
Cleaning Kit (Russia)	Includes Russian manual and Russian power cord	Kit	26787---AKRU-CL
Cleaning Kit (Switzerland, Belgium, and Canada)	Includes English, German, French, and Italian manuals and power cords for Europe, USA Canada, Italy, and Switzerland	Kit	26787---AKVA-CL
Cleaning Kit (South Africa, Australia New Zealand, Israel, and Denmark)	Includes English manual and power cords for South Africa, Australia New Zealand, Israel, and Denmark	Kit	26787---AKVB-CL
Tubing and Cables in Wrap 2 m	Tubing and cable in wrap 2 m	Bundle	26787---02-AKEV
Tubing and Cables in Wrap 5 m	Tubing and cable in wrap 5 m	Bundle	26787---05-AKEV
Pressure Vessel 10 L Bundle EU	Stainless steel pressure vessel 10 L bundle including manometer and safety valve, certified for EU	Bundle	26787---AKPV-EU
Manometer	Manometer	1 pc.	7ZMA--0024
Safety Valve 4 bar	Safety angle valve up to 4 bar, DN25, included in the Pressure Vessel 10 L Bundle	1 pc.	3ZVIG-0124
Safety Valve 2 bar	Safety angle valve up to 2 bar, DN25	1 pc.	3ZVIG-0122
Pressure Vessel 10 L	Pressure Vessel 10 L including the necessary couplings and breech nipples	1 pc.	380AA0010ID020LN
Triclamp 50.5 mm - Staeubli-coupling (closed) RBE03 Alternative adapter with EPDM gasket	Closure coupling including the necessary clamp	1 pc.	7ZML--0019 7ZML--0056
Triclamp 50.5mm - Staeubli-nipple (closed) RBE03.7 Alternative adapter with EPDM gasket	Breech nipple including the necessary clamp	1 pc.	7ZML--0012 7ZML--0055
Plastic Waste Vessel 25 L	Waste Vessel modified for Cleaning Kit	1 pc.	26787---AKWV-CL
Lid with Connectors	Lid with connectors for the plastic waste vessel	1 pc.	Please Contact Service Department
Tagged Tubing with Connector	Tagged tubing with connector	1pc.	Please Contact Service Department

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