

Sartorius Stedim Biotech Launches New Sartocheck® 5 Plus Filter Tester

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-Highest level of data integrity as requested by regulatory authorities -State-of-the-art quality risk management to comply with the upcoming EMA Annex 1 -Optimal operator protection to minimize health, safety and environmental risks



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-- [Sartorius Stedim Biotech](#) (SSB), a leading international supplier for the biopharmaceutical industry, has announced the launch of its new [Sartocheck® 5 Plus](#) filter integrity tester. Designed for use in downstream processing, this new integrity tester is the latest development in the established line of Sartocheck® units already recognized throughout the pharmaceutical industry. Based on extensive research of customers' needs to confirm the integrity of filters in pharmaceutical production, Sartocheck® 5 Plus features the most advanced functions for ensuring maximum data integrity and compliance with future requirements of quality risk management, such as the upcoming Annex 1 of the European Medicines Agency (EMA).

The new filter tester greatly improves the detectability of operator errors, improper test set-ups and out-of-tolerance environmental conditions. It is also more reliable and easier to use than ever before. With the Sartocheck® 5 Plus, false passed and false failed test results are therefore relegated to the past.

Where other devices are limited in their flow measurement capability, this advanced filter tester has been designed to cover the complete range of integrity testing from small syringe filters up to large multi-round housings and crossflow cassettes, with diffusion rates of up to thousands of milliliters per minute.

In addition, the automatic test time feature for diffusion and water intrusion, along with accelerated bubble point testing, reduces overall test time. Parallel bubble point testing is also a significant time saver as this function enables up to 10 small filters to be checked with one Sartocheck® 5 Plus.

User benefits include the biggest and brightest screen currently available on the market (12") for integrity testers, along with an ergonomic interface, an easy-to-clean design, improved data integrity and inherent virus protection. Sartocheck® 5 Plus is also the only integrity tester that is ATEX | IECEx | FM compliant. It protects operators by allowing safe integrity testing of

alcohol-wetted filters. To prevent cross-contamination, the device can be used together with an accessory kit for external venting.

The filter integrity tester comes with comprehensive quality risk management documentation, including an FMEA (Failure Mode and Effects Analysis). Qualification protocols are available and operational qualification can be performed by SSB's Service team for maximum security and peace of mind. The company also provides on-site annual or biannual calibration along with preventive maintenance.

The Sartocheck® 5 Plus is set to become the new reference standard for filter integrity testing. The purchase of this device includes a pre-established roadmap of software upgrades that come with comprehensive risk assessments. Add-on features do not require re-qualification. The software upgrades include valuable patented and patent-pending features for the highest data integrity, QRM, HSE and usability, throughout the entire life cycle of the filter integrity tester.