BioSpectrum
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

SartocheckÂ® 5 Plus Filter Integrity Tester

09 December 2019 | Features | By Amit Khanna, Technical Manager â?? Separation Technologies, Sartorius Stedim India

Keeps Your Risk Factors Under Complete Control A biotechnologist by training, Amit has been a part of Sartorius Stedim Indiaâ??s Separation Technologies team for over a decade and a half and leads a team of Technical Specialists in India. Amitâ??s expertise lies in filter & filtration process optimization, virus filtration, integrity testing & trouble shooting

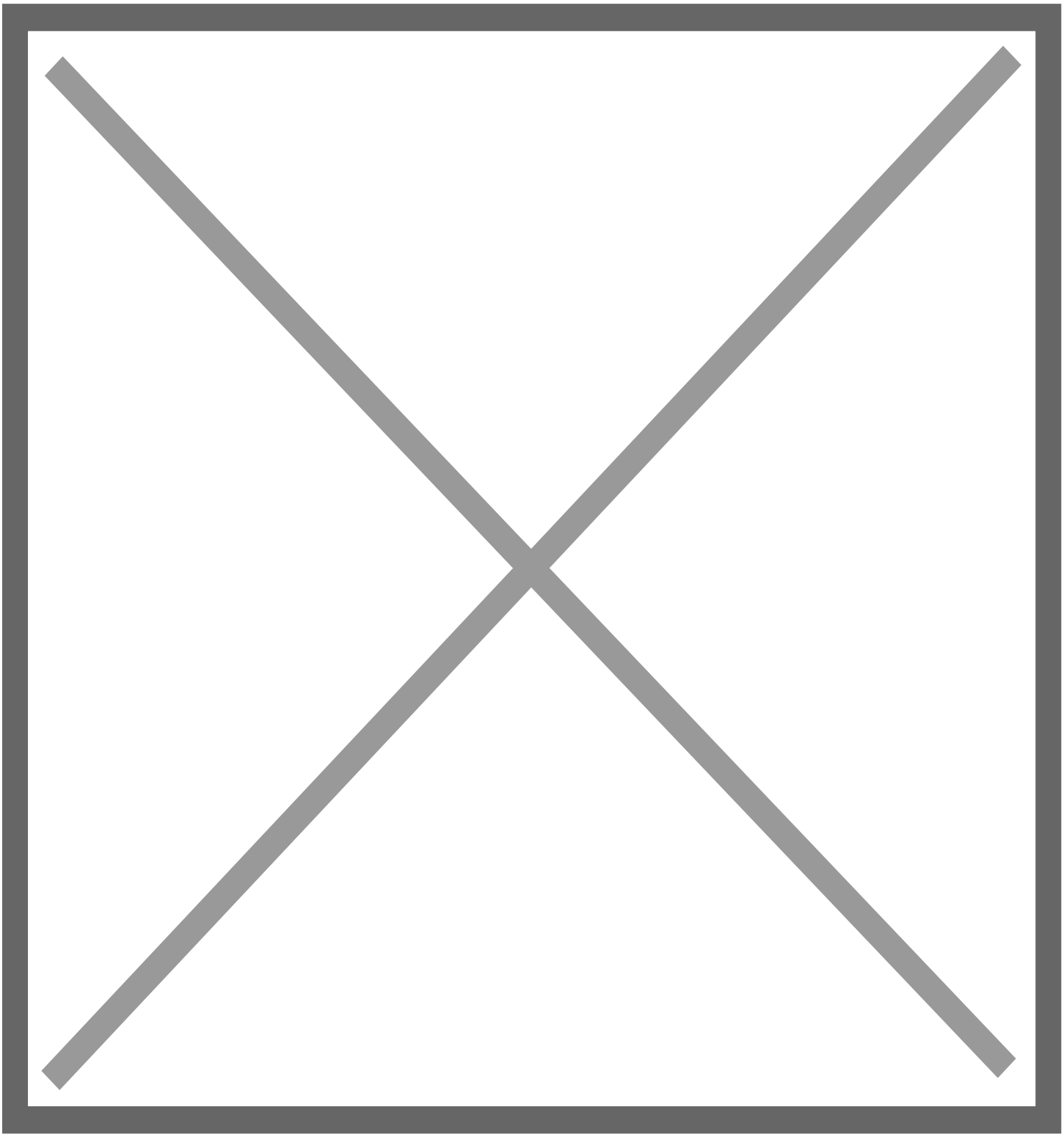


Sartorius introduced the very first Sartocheck® Filter Integrity Tester in 1980 and over a period spanning more than 3 decades, Sartocheck® Filter Integrity Tester evolved into an extremely sophisticated automated integrity test solution which is preferred by customers across the globe. Sartocheck® 5 Plus Filter Integrity Tester, the latest upgrade to the Sartocheck® product line, is the outcome of extensive research and customer-centric approach to optimize the detection of operator errors, improper test setups and out-of tolerance environmental conditions. Its patented software and sensor technologies make the new Sartocheck® 5 Plus Filter Integrity Tester the most advanced filter integrity tester yet that surpasses the requirements of Quality Risk Management (QRM). All these elements ensured that Sartocheck® 5 Plus Filter Integrity Tester wins the iF Design Award in 2018. This is how Sartocheck® 5 Plus Filter Integrity Tester meets key industry requirements for filter integrity testing even in the most demanding environments.

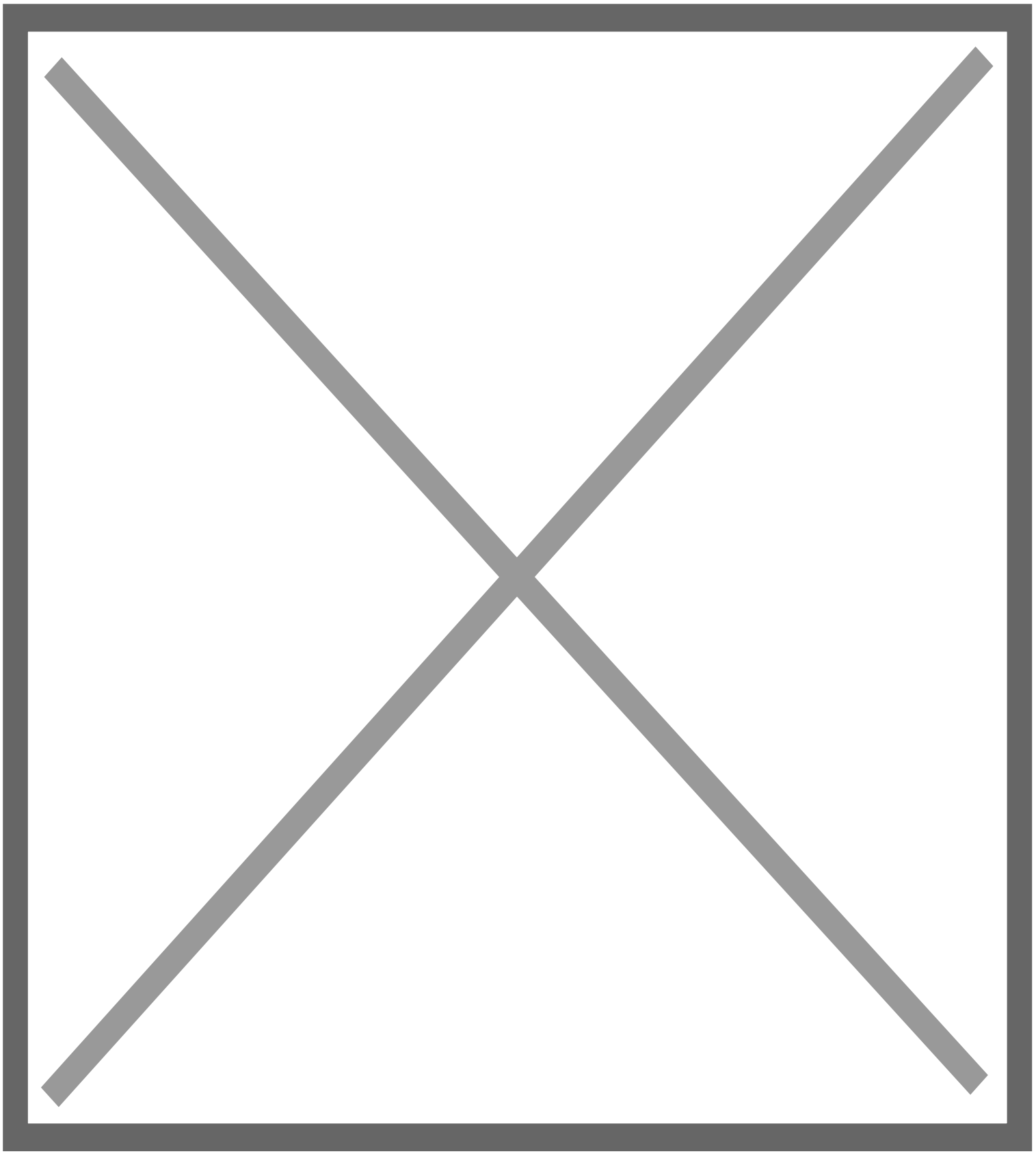
Automatic detection of incorrect test setups and test conditions

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 something is wrong, 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. (Image 1)

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. 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. (Image 2)

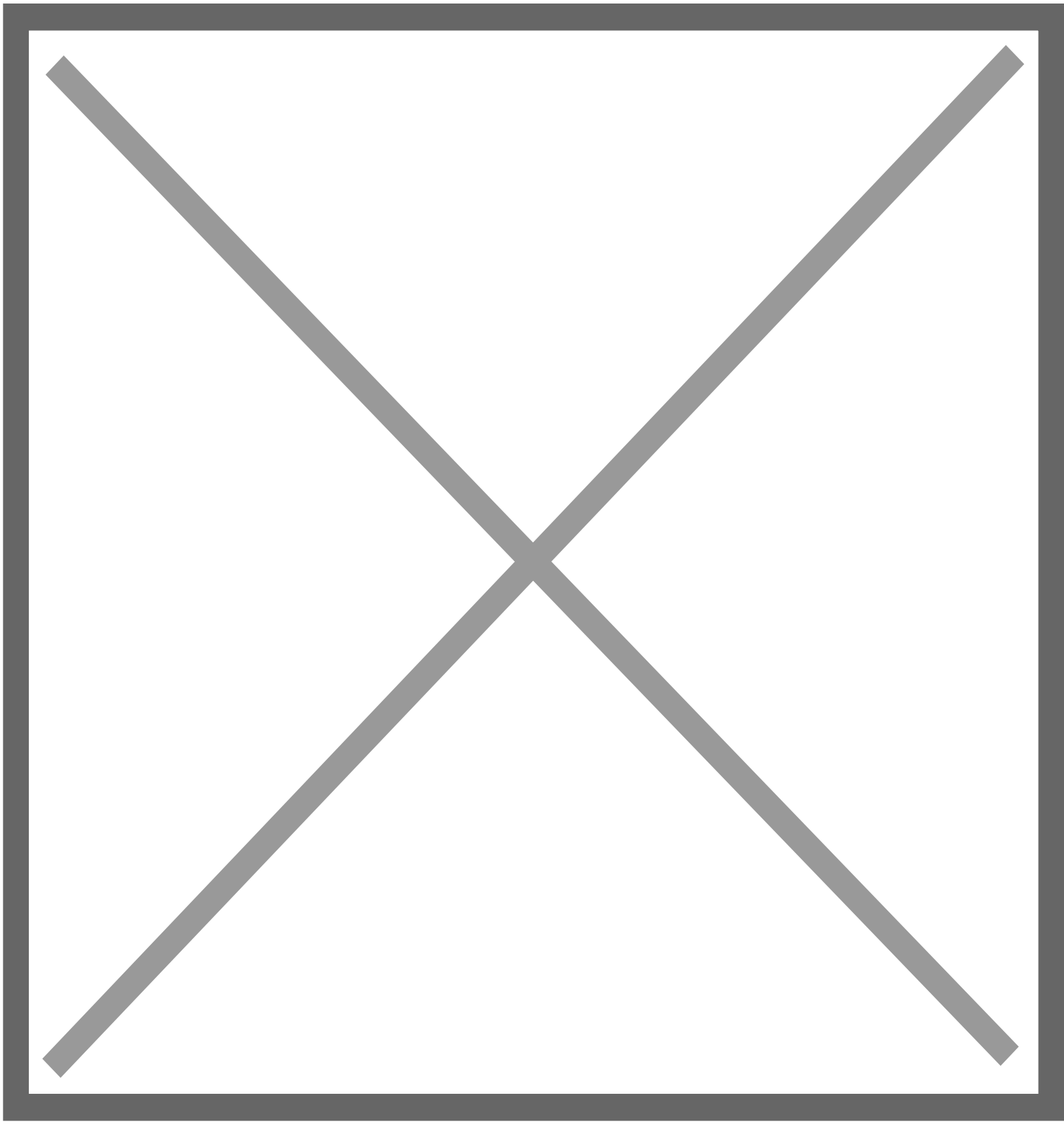


When a filter is being tested, it always generates a certain pressure decay. If a pressure increase is detected instead of a pressure decay, it may indicate a temperature change or that the downstream side of the filter is being pressurized. (Image 3)

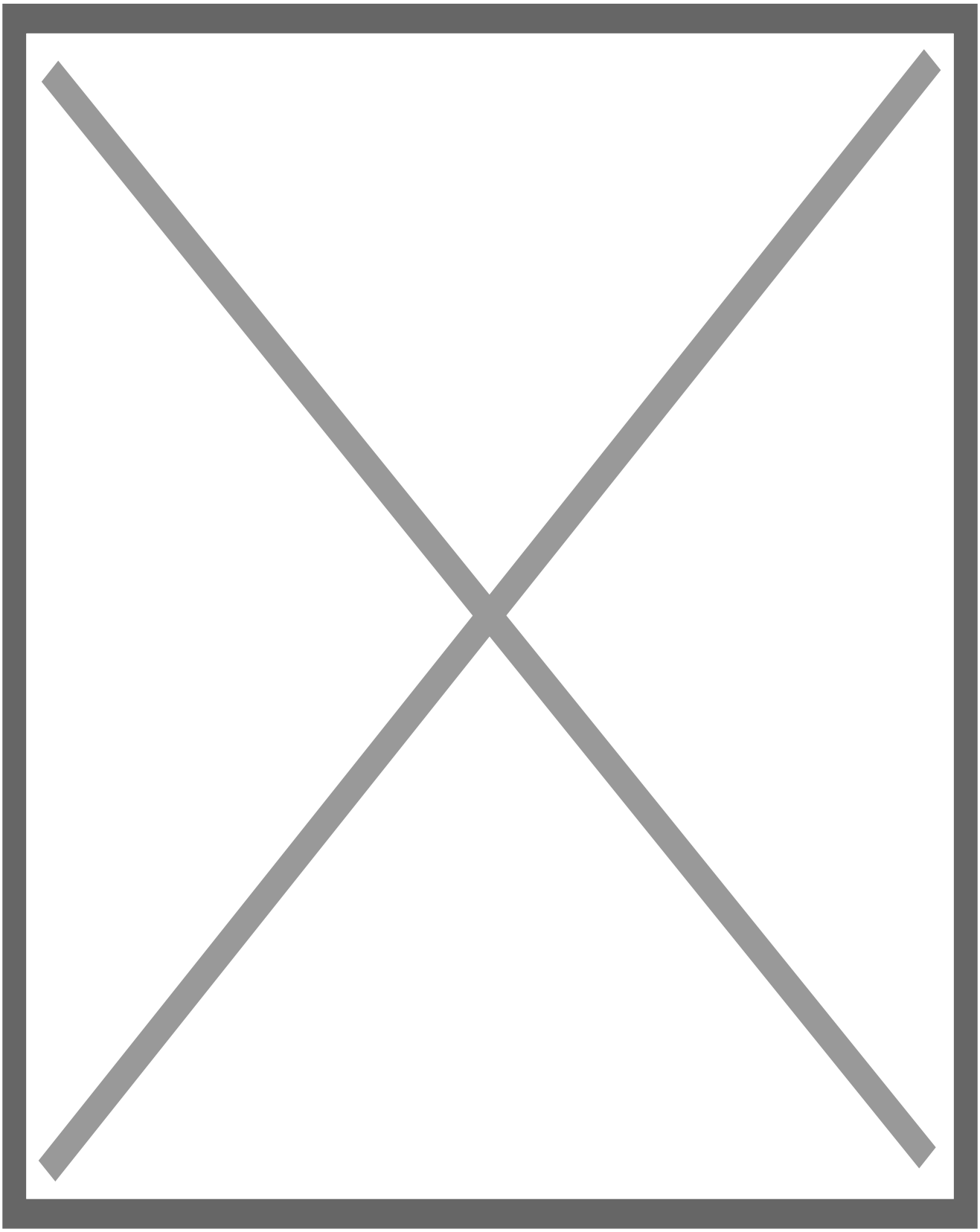


Faster Testing

The Sartocheck® 5 Plus Filter Integrity Tester tests the 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. (Image 4)



The accelerated bubble point of the Sartocheck® 5 Plus Filter Integrity 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. (Image 5)



Data Integrity

Sartocheck® 5 Plus Filter Integrity Tester uses a custom Linux-based OS with Sartorius Stedim Biotech custom architecture to provide inherent protection against virus and malware attacks for maximum security. The route file system is write protected making it impossible for a virus to reside in the system. All data generated is instantly backed up on the internal inaccessible 8 GB SD card. This prevents any loss of data even in the unlikely event of system crash. The encryption protects data to prevent its disclosure, theft or misuse. All GMP relevant actions are time stamped in the audit trail to comply with 21 CFR part 11. When parameters are changed, before and after values are displayed so that full traceability of “who did what and when” is sure data integrity also includes a reliable time stamping of the events.

When Sartocheck® 5 Plus Filter Integrity Tester is connected to the network and NTP function is activated, automatic time zone synchronization occurs thus generating reliable time stamps in the audit trail. Barcode scanner allows seamless data entry during programming of the test. The barcode scanner can be set to mandatory to ensure a much safer, faster test procedure.

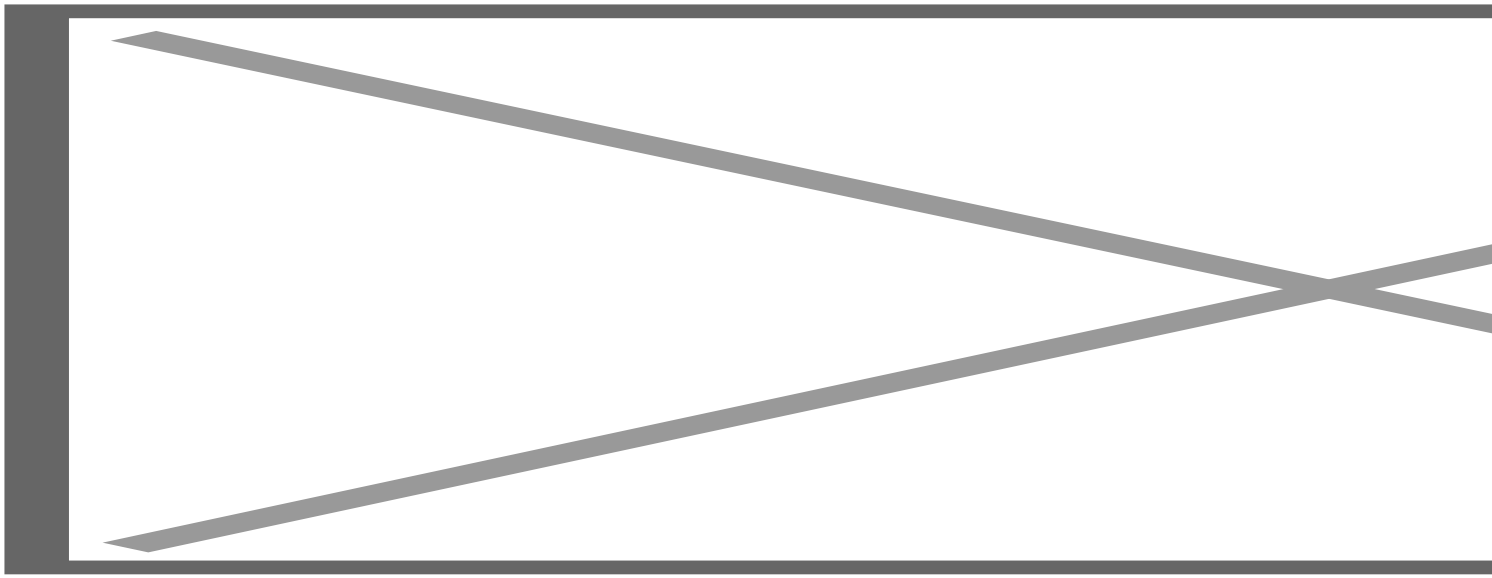
Ease of Use

12.1 inch touchscreen with a viewing angle of 88° contributes to ease of use regardless of the operators’ height and position. The screen is also compatible with gloves. Sartocheck® 5 Plus Filter Integrity Tester supports Lightweight Directory Access Protocol (LDAP) which allows all operators to utilize their network credentials to access the device. It supports local users with the option to transfer user and user roles, while still ensuring fulfilment of password complexity and supervised password ageing

Automation

The Modbus TCP protocol is a commonly used industrial automation protocol. Compatibility to other automation network control protocols like DeviceNet, Profinet, etc. can be achieved by using third-party gateways (Image 6). Sartocheck® 5 Plus Filter Integrity Tester supports two automation modes:

- Semi-automated: A full test recipe can be sent to and stored on the device till an operator logs in and starts the test.
- Fully automated: A full test recipe can be sent to the device following which the test can be started and monitored by an MES.



Health , Safety and Enviroment (HSE)

Integrity testing often involves the use of chemicals and hazardous materials. The Sartocheck® 5 Plus Filter Integrity Tester is certified for use in explosion hazardous areas (ATEX), this allows safe testing of IPA wetted filters and is also compatible with all current cleaning agents and VHP. This ensures maximum safety for operators and manufacturing facilities. It is also rated a splash-proof (IP64) for performance under the most stringent conditions in wet environment. Continuous and clear visualization of pressure status avoids mishandling by operator while system is under pressure. PFA tubes flow path of Sartocheck® 5 Plus Filter Integrity Tester are FDA 21 CFR 177 and USP Class VI compliant. Automated cleaning of all pneumatics with up to 0.5 M NaOH at 50 °C using an optional cleaning kit is possible.