



sartorius stedim
biotech

Sartocheck® 4 plus Integrity Testing at its Best



turning science **into solutions**

Sartocheck® –

30 Years Experience in Integrity Testing

Sartorius introduced the very first Sartocheck® filter integrity tester in 1980. Over the 30-year period of continual enhancement that followed, the Sartocheck® product line evolved into the most sophisticated automated integrity test solution and the preferred choice of critical customers who insist on the best in performance and quality. Sartorius' unique innovations, such as the Water Intrusion Test, introduced revolutionary new concepts and paved the path for others to follow. With the Sartocheck® 4 plus, Sartorius remains firmly at the forefront of integrity testing and continues to extend its three-decade tradition of unmatched innovation and experience.



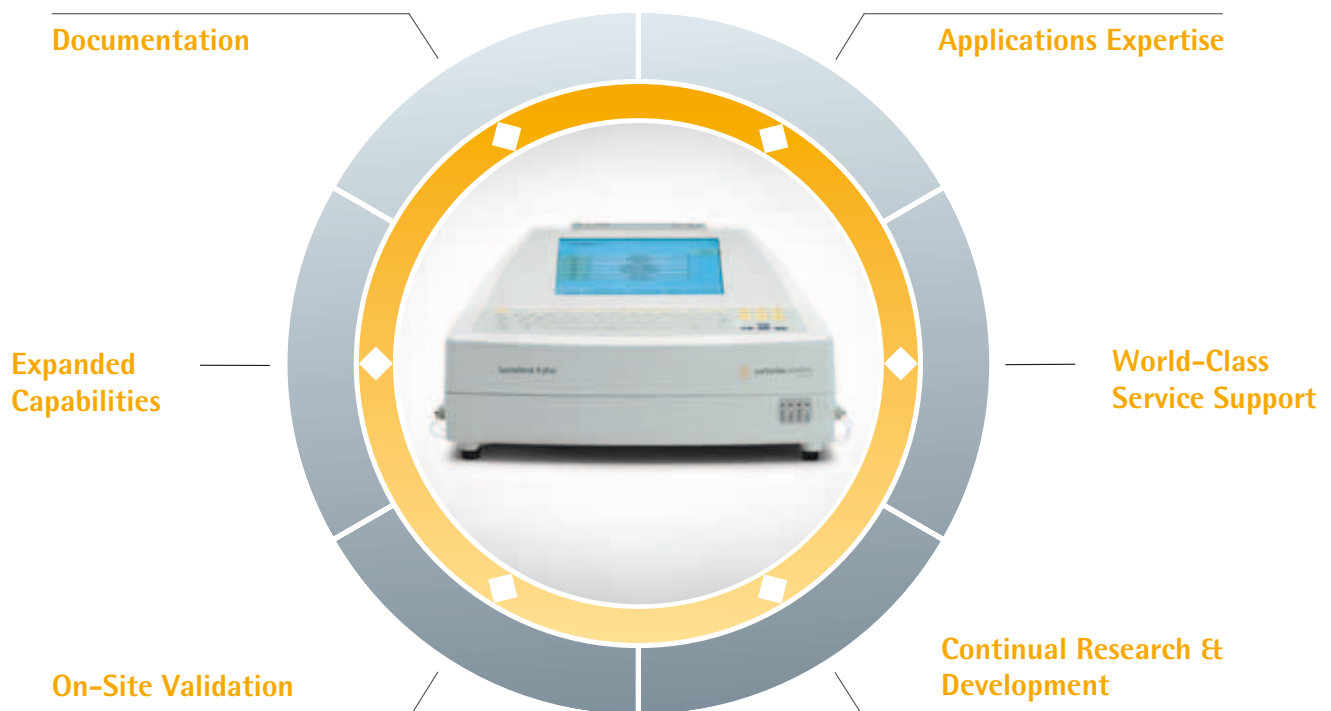
Sartocheck® 4 plus –

So Much More than Just a Great Product

Total customer satisfaction can only be realized when an outstanding product like the Sartocheck® 4 plus is surrounded by extraordinary service and support that enhances its overall value. We at Sartorius ensure that our customers experience the highest return on investment by placing equal emphasis on the many complementary factors as we do on the product itself.

A global team of Applications Specialists are in place ready to provide immediate assistance with integrity test

questions and troubleshooting. A dedicated service group ensures maximum system uptime to enhance productivity and equipment longevity. Comprehensive documentation in the form of manuals, validation guides, and applications notes provide the user with up-to-date documentation covering all aspects of the Sartocheck®. A tireless R&D department continues to create new and innovative ways to perform integrity testing that ensures Sartocheck's® leading edge status.



Sartochek[®] 4 plus – Benefits that Count

GMP Production Proven

Full compliance with 21 CFR Part 11, individual user access rights, intuitive programming and operation, and reliable Sartochek[®] performance over many years of use in production are just some of the key benefits that make the Sartochek[®] 4 plus an invaluable member of your production team – from the moment of installation throughout its extended life cycle.

Lowest Cost-of-Ownership

The extraordinary benefits that come with features such as the automated cleaning function, on-site calibration, and MultiUnit expansion serve to minimize the operating costs while maximizing the return on investment over the years. The Sartochek[®] 4 plus ensures that your wise decision to invest in the industry leader for integrity test equipment is continuously rewarded.

World-Class Support

Sartorius' commitment to fully support the Sartochek[®] product line – by providing on-site and factory Applications expertise, unparalleled Service and detailed documentation just as examples – is perfectly aligned with our customers' needs and expectations for quality and productivity. To that end, Sartorius is dedicated and fully equipped to furnish the level of responsiveness that our customers require to achieve their primary objectives.



Designed to Minimize Service Costs

The patented cleaning function of Sartochek[®] 4 plus allows the user to easily perform cleaning of the complete internal pneumatics as required without the need for costly down time and factory service calls. This unique automated cleaning feature provides the highest security without the burden of additional service costs that can add up over time.

Highest Process Safety

The optional use of external valves and pressure sensor precludes any risk of potential cross-contamination during the daily routine of filter integrity testing. CMOs, in particular, have come to appreciate the inherent safety of the Sartochek[®] when integrity testing a broad range of filters.

Error-Free Data Entry

Using the optional barcode scanner allows for simple and error-free entry of filter data into the Sartochek[®] 4 plus. After scanning a filter cartridge, only the relevant test program(s) that exactly match the scanned cartridge are displayed, thereby making test program selection far easier and void of risk.

Intuitive Operation

A well organized menu structure and clear on-screen instructions allow any user to operate the Sartochek[®] 4 plus with minimal training. First time users acquire an immediate knowledge and comfort in programming and running the unit, ultimately resulting in enhanced productivity and error-free operation.

Parallel Filter Integrity Testing

In order to maximize productivity in the most economical manner possible, up to four companion MultiUnits can be seamlessly connected to the Sartochek[®] 4 plus. This provides the equivalent testing capacity of five Sartocheks[®] operating concurrently at a significant cost savings to the end user.



Sartocheck® 4 plus –

Precision Down to the Last Detail.

Sartocheck® 4 plus Unique Combination of Features

- Barcode Scanner for easy and error-free data entry (optional)
- Intelligent selection of test program after scanning the filter
- Combination of large, color touch screen display with keypad
- Automated cleaning function eliminates expensive service costs
- Sophisticated Cleaning Kit available (optional)
- Automatic detection of improper test setup (e.g. disconnected filters)
- External valves (optional) for highest process security
- Multitasking menu
- Electronic test reports in PDF format
- No thermo printer but dot matrix printer (longer print preservation)
- SD card reader
- Automatic Test Time Function for intelligent optimization of test times
- Real-time graphing of tests in progress

Sartocheck® 4 plus Broad Variety of Integrity Test Methods

- Bubble Point Test (BPT)
- Diffusion Test (DIFF)
- Combined Test (DIFF + BPT)
- Pressure Drop Test
- Water Intrusion Test (WIT)
- Water Flow Test (WFT)
- Multipoint Diffusion Test
- Customer Specific Tests

Sartocheck® 4 plus – User Management in Compliance with 21 CFR Part 11

- Individual user access rights assigned by the system administrator
- Access rights assigned for authorized steps and procedures
- Only authorized persons may program tests
- All user action recorded in an audit trail
- User log-off function



With Service all Down the Line.



Sartochek® 4 plus Data Integrity and Security in Compliance with 21 CFR Part 11

- Up to 250 test programs and 999 test results are saved in the integrated database
- Test results with user access rights assigned
- Test 999 blocked if earlier tests have not been archived
- No data overwriting
- No data loss
- Test reports in PDF format

Sartochek® 4 plus Practical Peripherals (as Options)

- Autonomously performs up to 5 tests in parallel with one Sartochek® 4 plus
- Easily overcomes distances using the flexibility of an external pressure transducer
- Reliable procedure due to external venting
- Easy automatic remote control of external valves by Sartochek® 4 plus during WIT
- Network connection via RJ45 to FTP server
- Profibus Interface which allows the integration of Sartochek® 4 plus directly into process control systems

World-class Service not Just an Empty Catchphrase, but Practiced Everyday

- On-site support through dedicated engineers
- Technical phone support
- Highly professional and extensive qualification
- On-site calibration and maintenance
- Fast delivery times on replacement parts



Sartocheck® 4 plus - Just Look at the Benefits

SC 4 plus



Pall Flowstar IV



Millipore IT4



	SC 4 plus	Pall Flowstar IV	Millipore IT4
Footprint single unit	1794 cm ²	1680 cm ²	1057 cm ²
Footprint for 2 units Multiunits	1794 cm ² (due to stackability)	3360 cm ²	2114 cm ²
Operating System software stability	Linux ++	Linux ++	Windows XP --
Internal cleaning function (using up to 1 M NaOH)	++	--	--
Barcode Reader with automated test program selection	++	--	--
Automated detection of improper test setup	++	--	--
All established Integrity Tests	++	++	++
Testing Multiround Housings with Multipoint Diffusion Test	++	--	--
Concurrent, independent tests of up to 5 filters	++	--	--
21 CFR Part 11 compatible?	++	++	+/- (only version IT4N)
Lifetime of printout	unlimited (dot matrix printer)	10 years (thermo printer)	unlimited (dot matrix printer)
Recalibration interval	12 months	12 months	6 months
Touch Screen + Keypad	++	--	--
Splash protection	IP 44	IP 54	IP 22
PDF files	++	++	++

	SC 4 plus	Pall Flowstar IV	Millipore IT4
Test Accuracy			
Diffusion Test	±5%	±3% or ±0.05 mL/min (whichever is greater)	≤5%
Bubble Point Test	±50 mbar and better (using special program settings) (±0.73 psi)	±50 mbar (±0.73 psi)	±70 mbar (±1.02 psi)
WIT	±5%	±3% or 0.02 mL/min (whichever is greater)	≤5%
Pressure Drop Test	±1 mbar (±0.01 psi)	±1 mbar (±0.01 psi)	±3.5 mbar (±0.05 psi)
Measuring Range			
Diffusion	0.1 – 3000 mL/min	0.1 – 1000 mL/min	1 – 600 mL/min
Bubble Point Test	100 – 8000 mbar (1.45 – 116 psi)	400 – 6500 mbar (5.8 – 94 psi)	345 – 6205 mbar (5-90 psi)
WIT	0.01 – 99.9 mL/min	0.03 – 50 mL/min	0.01 – 10 mL/min
Pressure Drop	1 – 2000 mbar (0.01 – 29 psi)	50 – 6500 mbar (0.73 – 94 psi)	Not defined
Overall Customer Benefits			
Cost of ownership	++	--	--
Ease of use	++	--	--
30 years' experience integrity test innovation	++	--	--
Service and application support	++	--	--