



Sartocheck[®] 4 plus Bag tester & Bag tester MultiUnit

Fully automatic bag testing device
for 2D and 3D bags

Product Information

The Sartocheck[®] 4 plus Bag tester is the result of a clear market request for testing single use bags and bioreactors, pre-use and post-use. It is based on the same market leading software and hardware platform as the Sartocheck[®] 4 plus Filter tester and assures full communication compatibility between the both.



As bags require lower test pressures and therefore also higher pressure accuracies than membrane filters, the pressure range has been reduced for an overall optimization of pressure accuracy and pressure drop measurement accuracy. The Sartocheck[®] 4 plus Bag tester provides the same combination of benefits as the Sartocheck[®] 4 plus Filter tester:

- Barcode Scanner for easy and reliable data entry (optional)
- Intelligent selection of test program after scanning the 1D or 2D label
- Combination of large, colour touch screen display with keypad
- Automated cleaning function eliminates expensive service calls
- Sophisticated Cleaning Kit available (optional)
- Multitasking menu
- Electronic test reports in PDF format

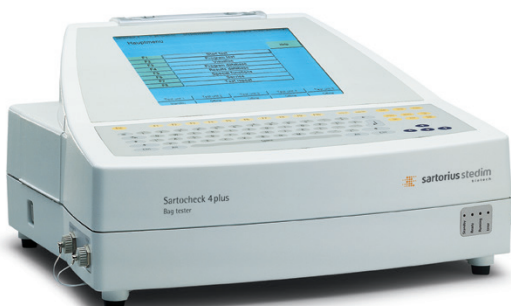
- No thermo paper but dot matrix printer (longer print preservation)
- Easy test program and user profile proliferation to other Sartocheck[®] testers via FTP or SD card
- Unparalleled accuracy and repeatability of results for all test types
- World class documentation, training, applications, and service support
- Allows real time parallel testing by controlling up to four additional test units (optional Bag tester and | or Filter tester MultiUnits)
- Fully compliant with 21 CFR Part 11
- Developed in accordance with GAMP5

Test Methods

- Pressure Drop Test of all 2D and 3D bag sizes having defined pressure drop parameters at a test pressure not higher than 300 mbar.

Barcode Scanning

Using the optional barcode scanner allows easy and error-free entry of bag | filter cartridge data into the unit. Sartocheck[®] 4 plus automatically locates the suitable test program that matches the scanned bag | filter cartridge.



Cleaning Function

The patented cleaning function of Sartocheck® 4 plus (Bag tester and Filter tester) allows the user to perform reliable cleaning of the complete internal pneumatics even with aggressive cleaning agents (up to 1 M NaOH). This unique feature provides highest security of the testing procedure while eliminating the need for costly down time and service calls. A fulfilled cleaning also generates a printout for full traceability.

Testing of Single-Use Bags

The Sartocheck® 4 plus Bag tester is the ideal tool for eliminating the risk of filling a defective single use bag. The STR Cultibag and Flexsafe® 3D bags are tested pre-use after installation into their holder before being filled with high valuable cell culture or bioprocessing fluids. Flexsafe® 2D and 3D bags, Flexboy® bags are used in a variety of process steps and applications:

- Buffer and media storage
- Harvest and storage
- Process intermediate storage
- Drug substance purification and storage
- Drug product formulation, storage and filling

The requirement for pre-use leak testing is more prevalent in the critical process steps of drug substance purification in downstream processing and drug product formulation in final fill and finish.

Technical Data

Specifications	
Power requirements	100 – 240 V AC 50 60 Hz
Max. Power Input	74 watts
Max. operating pressure	9999 mbar 145 psi
Min. inlet pressure	4000 mbar 58 psi
Dimensions (W × D × H1 × H2)	460 × 390 × 140 × 245
Measuring Ranges	
Test Pressure	10 – 300 mbar 0.145 – 4.350 psi
Pressure drop	0.1 – 300 mbar 0.001 – 4.350 psi
Measuring Accuracy	
Pressure	± 0.05 % full scale
Pressure drop	± 0.3 mbar ± 0.004 psi

Network Concept

The network solution for the Sartocheck® 4 plus incorporates the TCP-IP and FTP protocol standards, with data being transmitted via the Ethernet standard. Via standard RJ45 connection, all data can be easily up-loaded on a FTP server.

Multiunit Concept

In order to increase productivity through parallel system testing, up to four additional MultiUnits (Filter tester or Bag tester) can be easily connected to the Sartocheck® 4 plus. This provides the possibility to test both bags and filters within a limited footprint. Moreover it gives the equivalent testing capacity of five Sartochecks operating concurrently and significant cost savings to the end user.

Qualification

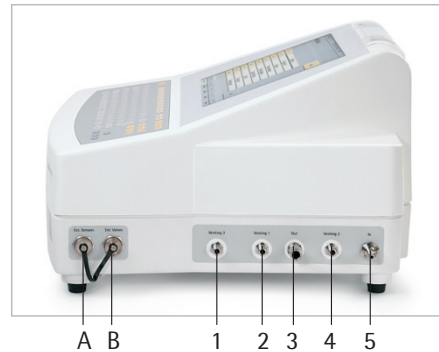
Sartocheck® 4 plus ensures that all tests are carried out with highest precision and accuracy. Our comprehensive Sartocheck® 4 plus validation documentation and world-class Service Team provide exemplary support for the user.

Operating Conditions	
Ambient temperature	+15 °C to +35 °C
Rel. humidity	10 – 80 %
Touch Screen	
Size	10.4" TFT
Features	256 colors
Communication Ports	
Serial Port TU	RS232
Serial Port MU	RS485
PLC Port binary signals	12 pins
Network	RJ45
Language Option	
English	
German	
French	
Spanish	
Italian	

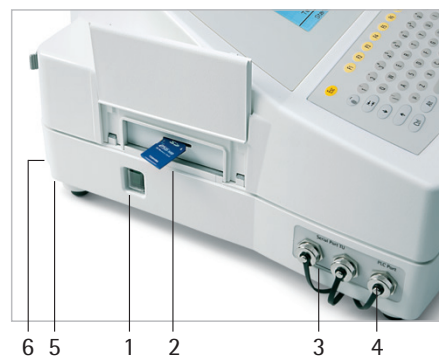
Equipment Supplied	
Sartocheck® 4 plus Bag tester	26288---BT
Inlet tubing for compressed gas	18104
Ribbon cassette	6982141
Rolls of printer paper	6982142
Test certificate	
Calibration certificate	
Installation and operating instructions	
Validation package Bag tester	26288---VPBT
Power cord	Region specific
External temperature sensor	26288---ETS

Accessories	
Barcode Scanner	26288---BS
Bag tester MultiUnit	26288---BM
Filter tester MultiUnit	26288---FM
Serial Port Interface cable TU TU	
0.5 m	1ZE---0008
2 m	1ZE---0009
5 m	1ZE---0010
Network Cable	
2 m	1ZE---0029
5 m	1ZE---0030
10 m	1ZE---0031
20 m	1ZE---0032
Cleaning Kit	26288---CK
Pressure Tank for Cleaning	26288---PV
Profibus Interface	16288---PI
Clean Room Venting Adapter	1ZE---0021
Validation packages:	
Filter tester	26288---VPFT
Filter tester MultiUnit	26288---VPFM
Bag tester	26288---VPBT
Bag tester MultiUnit	26288---VPBM
Outlet tubing for 2D bags	26288---BT2D
Outlet tubing for 3D bags	26288---BT3D
FlexAct® BT for testing of Flexboy® 2D Bag	26288---BTFA

Remark: outlet tubing has to be specified when ordered



- A: external sensor
- B: external valves
- 1: Venting 3
- 2: Venting 1
- 3: Out
- 4: Venting 2
- 5: Compressed Air In



- 1: Main switch
- 2: SD card reader
- 3: Serial Port TU
- 4: PLC Port
- 5: RJ45 Network
- 6: connection for optional barcode scanner

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