



Sartocheck[®] 4

Fully automatic integrity testing device



Description

The latest state-of-art filter integrity tester Sartocheck 4 is the consequent further development of the most successful integrity tester of its class, the Sartocheck 3. Incorporating the well-known features of its predecessor, the user-friendliness of Sartocheck 4 was even more improved by the following features:

- Touch screen
 - Rapid and direct program selection and data entry on the display
- Large, color TFT display
 - Clear and easy-to-read display data
- Standard PC keyboard design
- Online assistance
 - Immediate and direct help available on the display
- Straightforward menu guidance
 - Quick and reliable handling
- External Pressure transducer and external valves
 - Flexible operation
- Easy to clean
 - Cleaning and drying of the internal valve block and internal reference vessel

Sartocheck 4 performs the following tests:

- Bubble Point
- Diffusion
- Bubble Point and Diffusion (combination test)
- Pressure Drop Test
- Water Intrusion Test (WIT)
- Water Flow Test (WFT)
- Multipoint Diffusion Test

Fully compliant with 21 CFR Part 11

The requirements in terms of electronic data capturing, handling and archiving are clearly ruled in 21 CFR Part 11. Sartocheck 4 is fully compliant to that guidance in all relevant points, e.g.:

- System developed according to current GAMP-guidelines
- Individual access authorization (user log-in), user profile and password to be defined by Sartocheck 4 system administrator
- Automatic user inactivity log-off (inactivity time programmable)
- Periodical expiration of passwords
- Secure time stamped audit trail to store all GMP-relevant user actions
- Data security: up to 250 test programs and 999 test results are stored in an internal database, data can be archived on a floppy disk.

Network Concept

The network solution for the Sartocheck 4 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 allow time- and cost-saving parallel integrity testing of several filters, up to four additional MultiUnits (complete Sartocheck 4 Test Units without Managing Unit, please see different data sheet) can be easily connected to the Sartocheck 4.

Qualification

Sartocheck 4 qualification ensures that integrity tests to be conducted are carried out with high precision and accurate reproducibility. Our comprehensive Sartocheck 4 validation documentation provides the necessary support for the user. Our Technical Support Specialists are additionally available to help on-site.

Technical Specification

Power requirements	100–240 V AC, 50/60 Hz
Maximum power input	74 watts
Maximum operating pressure	9999 mbar 145 psi
Minimum inlet pressure	4000 mbar 58 psi
Dimensions (W × D × H1 × H2)	460 × 390 × 140 × 245
Measuring ranges	
Test pressure	100–8000 mbar 1.5–116 psi
Pressure drop	1–2000 mbar 0.01–29 psi
System inlet volume -with internal ref. Vessel -with external ref. Vessel	9000 ml max. 100 l
Measuring accuracy	
Pressure	± 0.1 % full scale ± 9.5 mbar
Pressure drop	± 1 mbar
Volume determination	± 4 %
Diffusion	± 5 %
Water-Intrusion	± 5 %
Bubble Point	± 50 mbar ± 0.7 psi
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	16288
Tubing for compressed gas inlet	18104
Tubing for compressed gas outlet	18103
Ribbon cassette	6982141
Rolls of printer paper	6982142
Sartocontrol CD	
Test certificate	
Calibration certificate	
Installation and operating instructions	
Validation package	16288---VP
Mains lead (country specific)	

- 1: external reference tank
- 2: Venting 1
- 3: Out
- 4: Venting 2
- 5: In
- A: external Sensor
- B: external Valve



A B 1 2 3 4 5

Accessories

External pressure transducer	1ZE---0018
Valve set for external venting	1ZE---0025
Valve set for external filling (WIT)	1ZE---0026
Serial Port Interface cable TU/TU:	
0,5 m	1ZE---0008
2 m	1ZE---0009
5 m	1ZE---0010
Validation Package	16288---VP
Multiunit	16288---TU
Cleaning Kit	16288---CK

- 1: main switch
- 2: 3,5" floppy drive
- 3: Serial Port TU
- 4: PLC Port
- 5: RJ45 Network



5 1 2 3 4

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