

Filter Integrity Testing Systems

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Sartocheck® mini

Filter Integrity Tester for Food & Beverage Applications



Description

The automatic filter integrity tester Sartocheck® mini can be used to verify the integrity of membrane filters which are used in the food & beverage environment.

Taken those specific needs into account, this unit offers the following main features:

- Automatic filter integrity tester
- Pressure Drop Test &
- Diffusion Test
- Small, portable unit
- 19 different test programs
- 100 test results to be stored
- LCD display
- Automatic venting after the test
- Thermo-printer (57 mm paper)
- Easy and reliable data transfer to PC
- High capacity batteries for up to 4 hrs work
- Protection rating IP50
- Incl. bag and case

Test Result Documentation

Test results are automatically printed using the built-in thermo printer. An additional port allows the connection of an external printer.

Data Storage

The unit stores up to 100 test results in the internal memory. To avoid the oldest data to be overwritten, electronic data can be stored on a connected PC with user-friendly software. The same software can be used for programming the device.

Equipment Supplied

- Sartocheck® mini integrity test unit
- Low volume adapter for net volumes < 5 l
- Printer paper (4 rolls)
- Pressure inlet tubing (18104)
- Pressure outlet tubing (18103)
- Carrier bag (soft case)
- Hard case

Order Information

26292---01

Specifications

Technical Specifications

Power Requirements	100–240 V AC, 50 60 Hz
Max. Power Input	20 W
Max. inlet pressure	4500 mbar
Dimensions W f H f D [mm]	315 f 150 f 280
Weight [g]	ca. 3,900
Languages	German, English, French, Italian, Spanish, Portuguese

Operating Conditions

Temperature	3–30 °C
Humidity	5–95% rel.

Measuring Ranges

Test pressure	0–3900 mbar
Max. inlet pressure	0–4500 mbar
Net volume	0.1–999 L

Measuring Accuracy

Rel. deviation pressure measurement	< 0.2%
Abs. deviation pressure measurement (@ 20 °C)	max. ± 4 mbar

Interfaces

External printer	Centronics 25 pol
Communication port	232,9 pole male

Sartocheck® 3 plus

Description

This unit supports all established integrity test methods and is characterized by its intuitive and easy handling. The Sartocheck® 3 plus is not encumbered by the 21 CFR part 11 code as it is a paper based system and does not store test results electronically.

Main Features

- Smart design
- Large colour TFT display
- User-friendly menu structure
- On-screen assistance
- Paper-based result documentation (21CFR part 11 not applicable)
- Up to 250 different test programs to be stored
- Password protected access
- Individual user profiles/rights to be defined
- SD card reader for storing/transferring test programs
- Reliable cleaning of the complete internal pneumatics

Sartocheck® 3 plus Performs the Following Tests:

- Bubble Point Test
- Diffusion Test
- Bubble Point and Diffusion Test (combined test)
- Pressure Drop Test
- Water Intrusion Test
- Water Flow Test
- Multipoint Diffusion Test

Data Storage

As a pure paper-based system the Sartocheck® 3 plus does not have an electronic result database. However, the system allows to store up to 250 test programs within its internal memory. Test programs can be stored/archived on standard SD cards (Secure Digital memory Card).

Cleaning Function Guarantees Highest Process Security

The cleaning function of Sartocheck® 3 plus allows you to flush all internal pneumatic parts completely. On-screen instructions guide you through all necessary steps. The automatic drying function guarantees that no cleaning liquid remains inside.

Because only stainless steel and PTFE is used for the internal pneumatic parts, the unit can be cleaned even with aggressive cleaning fluids (e.g. 1 M NaOH). This guarantees highest cleaning efficacy and therefore enhances the safety of the integrity testing procedure.



Specifications

Power requirements	100-240 V AC, 50 60 Hz
Max. Power Input	74 watts
Max. operating pressure [mbar psi]	9999 145
Minimum inlet pressure [mbar psi]	4000 58
Dimensions W f D f H [mm]	460 f 390 f 212

Measuring Ranges

Test pressure [mbar psi]	100–8000 1.5–116
Pressure drop [mbar psi]	1–2000 0.01–29
System inlet volume	
■ With internal ref. vessel	9000 ml
■ With external ref. vessel	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 [mbar psi]	± 50 ± 0.7

Operating Conditions

Ambient temperature	+15 °C to +35 °C
Rel. humidity	10–80%

Colour Display

Size	8.4"
Resolution	640 f 480 pixel

Language Option	English, German, French, Spanish, Italian
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Equipment Supplied

Order No.

Sartocheck® 3 plus	16290
Tubing for compressed gas inlet	18104
Tubing for compressed gas outlet	18103
Ribbon cassette	6982141
Rolls of printer paper	6982142
Test certificate	
Calibration certificate	
Operating instructions	
Validation package	16290---VP
Mains lead (country specific)	

Accessories

Cleaning kit	26288---CK
Ext. reference vessel (10 l)	16288---RV



- 1: External reference tank
- 2: Venting 1
- 3: Out
- 4: Venting 2
- 5: In



- 1: Main switch
- 2: Service TU
- 3: Service MU

Sartocheck® 4 plus

Fully Automatic Integrity Testing Device

Description

The Sartocheck® 4 plus is the result of Sartorius' 30 years experience in developing automatic filter integrity testers. Valuable productivity enhancing features and robust build quality have been combined with incredible ease of use to make the Sartocheck® 4 plus the only logical choice for integrity testing.

The Sartocheck® 4 plus provides the following unique combination of benefits:

- Barcode Scanner for easy and reliable data entry (optional)
- Intelligent selection of test program after scanning the filter
- Combination of large, color touchscreen display with keypad
- External pressure sensor and external valves (optional)
- Automated cleaning function eliminates expensive service calls
- Sophisticated Cleaning Kit available (optional)
- Automatic detection of improper test setup (e.g. disconnected filters)
- Multitasking menu
- Electronic test reports in PDF format (longer print preservation)
- SD card reader for easy test program proliferation to other Sartocheck® testers
- Profibus communication (interface as accessory)
- Unparalleled accuracy and repeatability of results for all test types
- World class documentation, training, applications, and service support
- Allows concurrent filter testing by controlling up to four additional test units (optional MultiUnits)
- Fully compliant with 21 CFR Part 11
- Developed in accordance with GAMP

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
- Automatic Test Time function for intelligent optimization of test times

Barcode Scanning

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

Cleaning Function

The patented cleaning function of Sartocheck® 4 plus 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 integrity testing procedure while eliminating the need for costly down time and service calls.

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. Profibus communication can be used to allow bidirectional communication with process control system as a basis for complete automation.

Multiunit Concept

In order to increase productivity through parallel filter testing, up to four additional MultiUnits can be easily connected to the Sartocheck® 4 plus. This provides the equivalent testing capacity of five Sartochecks® operating concurrently at a significant cost savings to the end user.

Qualification

Sartocheck® 4 plus ensures that all integrity 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.



Specifications

Technical Specification

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 f D f H1 f H2 [mm]	460 f 390 f 140 f 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 int. reference vessel	14 l
■ With ext. reference vessel	150 l

Measuring Accuracy

Pressure	± 0.1 % full scale
Pressure drop	± 1 mbar 0.015 psi
Volume determination	± 4 %
Diffusion	± 5 %
Water intrusion	± 5 %
Bubble point	± 50 mbar ± 0.7 psi

Operating Conditions

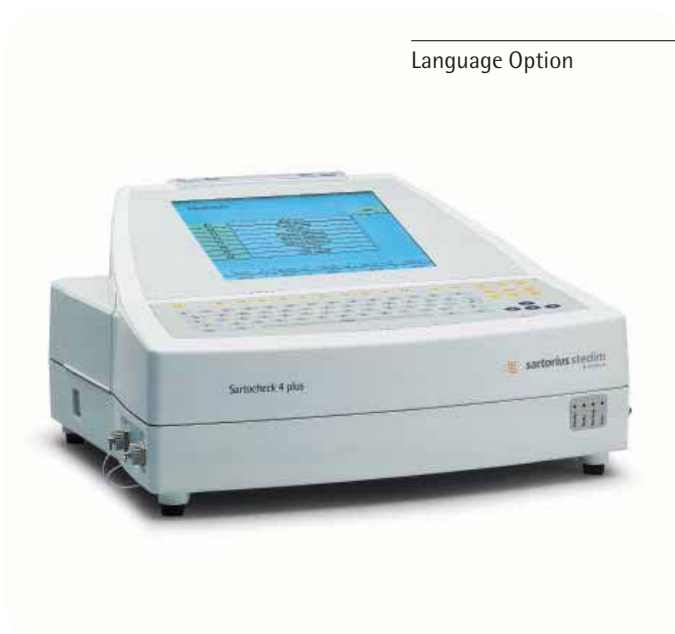
Ambient temperature	+15 °C to +35 °C
Rel. humidity	10–80%

Touch Screen

Size	10.4" TFT	
Features	256 colors	
Communication Ports	Serial Port TU Serial Port MU PLC Port Network	RS232 RS485 binary signals, 12 pins RJ45

Language Option

English, German, French, Spanish, Italian



Equipment Supplied	Order No.
Sartocheck® 4 plus	26288
Inlet tubing for compressed gas	18104
Outlet tubing	18103
Ribbon cassette	6982141
Rolls of printer paper	6982142
Test certificate	
Calibration certificate	
Installation and operating instructions	
Validation package	26288---VP
Power cord	
Accessories	
Barcode scanner	26288---BS
Multunit	16288---TU
External pressure transducer	1ZE---0018
Set for external venting (1 valve)	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
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
External reference vessel (10 l)	16288---RV
Profibus interface	16288---PI
Validation package	26288---VP
Clean room venting adapter	1ZE---0021
Midisart® test manifold 10 f	1Z-LB-0002



- 1: Ext. reference tank
- 2: Venting 1
- 3: Out
- 4: Venting 2
- 5: Compressed Air In
- A: External sensor
- B: External valves



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

Sartochek® 4 MultiUnit

Next Generation of Filter Integrity Testing



Description

The Sartochek® 4 MultiUnit has been developed to enable parallel integrity testing of multiple filters in the biopharmaceutical industry. The MultiUnit is an identical copy of the Sartochek® 4, without the user interface and the data management system. Each MultiUnit connected to a Sartochek® 4 or Sartochek® 4 plus is operated and controlled by this Sartochek® 4 (plus) via a RS485 connection.



Efficiency

Up to 4 MultiUnits can be connected to one Sartochek® 4 (plus) allowing to integrity test up to 5 different filter systems in parallel including the testing capabilities of the Sartochek® 4 (plus) itself. Testing up to 5 filters in parallel allows to reduce the time required for filter integrity testing in biopharmaceutical production significantly and increases the efficiency of your production process.

Flexibility

There is no relevant distance limitation between the Sartochek® 4 (plus) and the connected MultiUnits. The MultiUnits can be placed all over your production facility and are centrally controlled and operated by the Sartochek® 4 (plus). A printout of the test results of the MultiUnit is made by the printer of the Sartochek® 4 (plus) and the test data can be transferred to a network for review and archiving.

Data Transfer Security

The Sartochek® 4 MultiUnit is an independent test unit with its own power supply, electronics and pneumatics. It will maintain the test results even if switched off or if the connection is lost until the handshake communication with the Sartochek® 4 (plus) confirms that the test results have been transferred successfully. If the MultiUnit is switched off during the test it will transfer a corresponding error message as soon as the communication has been automatically reestablished.

Traceability

The Sartochek® 4 (plus) test result printout contains the serial number of the MultiUnit, the user name (log-on identity), a unique file name and all the information that has been entered in the batch protocol.

Patent Pending Thermal Insulation

The Sartochek® 4 (plus) and its MultiUnit feature a unique, patent pending separation of the electronic components and the temperature sensitive pneumatics in addition to the efficient vent fan. This superior solution avoids any thermal influence on the integrity test measurement from the unit itself.

Clean Room Venting Adapter

The Sartochek® 4 (plus) and its MultiUnit can be equipped with an optional venting fan adapter that allows to contain the outgoing air in order to avoid any dispersion of particles in a clean room.

Sartorius Stedim Biotech Validation Package

The MultiUnit is delivered with a comprehensive validation package including an IQ & OQ protocol that can be accomplished by qualified Sartorius Stedim Biotech personnel. Assistance for PQ can also be provided from the Sartorius Stedim Biotech Technical Support team.

Specifications

Technical Specifications

Power requirements	100–240 V AC , 50/60 Hz
Maximum operating pressure	9999 mbar 145 psi
Minimum inlet pressure	4000 mbar 58 psi

Measuring Ranges

Test pressure	100–8000 mbar 1.5–116 psi
Pressure drop	1–2000 mbar 0.01–29 psi
System net volume	
■ With int. reference vessel	14 l
■ With ext. reference vessel	150 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%
Max distance between SC4 and multiunit (RS485)	100 m

Order Information.

Order number	16288---TU
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Equipment Supplied

Order No

MultiUnit	16288---TU
Tubing for compressed gas inlet	18104
Tubing for test gas	18103
Test certificate	
Calibration certificate	
Installation and operating instructions	
Validation package	16288---VPTU
Mains lead (country specific)	

Accessories

Order No

External pressure transducer	1ZE---0018
Valve kit for ext. venting (1 valve)	1ZE---0025
Valve kit for WIT and/or external pressure sensor (3 valves)	1ZE---0026
Cleaning kit	26288---CK
Clean room venting adapter	1ZE---0021



1. MultiUnit RS485 in/out
2. MultiUnit RS485 in/out
3. MultiUnit PLC in/out
4. Sartocheck® 4 PLC in/out
5. Sartocheck® 4 RS485 in/out



- | | |
|------------------------|----------------------|
| A. Ext. sensor | E. Outlet (test gas) |
| B. Ext. valve | F. Venting 2 |
| C. Ext. reference tank | G. Inlet comp. gas |
| D. Venting 1 | |

WIT Trolley



Description

The WIT Trolley has been developed to make integrity testing of hydrophobic sterilizing grade filters safe and easy in the pharmaceutical industry. Both Water Intrusion and Water Flow tests can be performed. The Sartochek® 4 (plus) pilots all the pneumatic valves via the integrated SIEMENS PLC. A PT100 sensor measures the water temperature in the water tank and avoids testing with water out of the predefined temperature range.

Installation

Due to its unique design and its fully automatic two step filling procedure the WIT Trolley can test all HIMA correlated hydrophobic sterilizing grade membrane filters at a horizontal distance of more than 100 m and a vertical distance of more than 15 m. The external thermal compensated pressure sensor is installed on the top of the housing and measures the pressure drop exactly where the intrusion|water flow take place. Moving the WIT Trolley during the measurement will have no incidence on the test value.

No Cross Contamination

The Trolley uses the principle of one way flow. Once the Sartochek® 4 (plus) has pressurized the water tank and filled the housing to a stable pressure the filter housing is isolated by the filling valve. The gas overpressure in the water tank is vented directly at the water tank and does not go back via the Sartochek® 4 (plus).

At the end of the integrity test the test water is drained via the draining valve directly at the housing and does not get in contact with neither the filling tubing nor the water tank.

In-line Steam Decontamination

The Trolley can be steamed at max temperature of 134 °C (266 °F). The SIEMENS PLC supervises the steaming temperature at the lowest point using a second PT100 sensor. If the steaming temperature increases too much the inlet valve is closed. If the steaming temperature decreases too much the steaming cycle is interrupted and an error message is given. An optional extended steaming version of the Trolley allows for steaming of the filling hose.

Test Flexibility

Although connected to the Trolley the Sartochek® 4 (plus) can perform all types of standard integrity testing via the auxiliary output thus giving a total test flexibility. It can also be connected to up to four MultiUnits (please see separate data sheet) in order to perform an additional test in parallel.

PLC Connector and Integration

The Sartochek® 4 (plus) may be triggered by a 24V dry signal from a PLC. The Sartochek® 4 (plus) printout clearly shows the difference between an integrity test that has been started by an operator from the Sartochek® 4 (plus) touch screen|key-board and via the PLC contact.

The WIT Trolley can thus be integrated into an automated process and deliver a "GO" or a "NO GO" for the following process steps.

Sartorius Stedim Biotech Validation Package

The Sartochek® 4 (plus) and its Trolley are both delivered with a comprehensive validation package including an IQ & OQ protocol that can be accomplished by qualified Sartorius Stedim Biotech personnel. Assistance for PQ can also be provided from the Sartorius Stedim Biotech Technical Support team.

Specifications

Technical Specifications

Power requirements	110–230 V AC , 50 60 Hz
Maximum operating pressure	9999 mbar 145 psi
Minimum inlet pressure	4000 mbar 58 psi

Measuring Ranges

Test pressure	100–8000 mbar 1.5–116 psi
Pressure drop	1–2000 mbar 0.01–29 psi
System net volume	
■ With int. reference vessel	9000 l
■ With ext. reference vessel	100 l

Order Information

Order number	17005A---L--5301
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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%
Max distance between SC4 and filter housing (horizontal)	100 m
Max distance between SC4 and filter housing (SC4 below)	25 m
Max distance between SC4 and filter housing (SC4 above)	15 m

Equipment Supplied

- Trolley
- Hose with valve battery for filling
- Steam trap
- Installation and operating instructions
- Validation package
- Mains lead (country specific)

Accessories

External pressure transducer*	1ZE---0018
Sartocheck® 4 plus*	26288

Optional Version

Extended steaming version	17005A---L--5501
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*To be ordered separately; not part of 17005A---L--5301



- 1: Sartocheck® 4
- 2: Pneumatic & hydraulic compartment
- 3: Electrical compartment
- 4: OP7 screen