

"it-01"

THE PORTABLE FILTER INTEGRITY TESTER



THE FILTER INTEGRITY TESTER "it-01"

SCOPE OF DELIVERY



- 1. Reference volume it-800-AL
- 2. Interface Data cable
- 3. Outlet tube
- 4. Power supply PS 18
- 5. Set of paper rolls (x4)
- 6. Ink ribbon cassette
- 7. Compressed air regulator and inlet tube
- 8. IR- keyboard

Additional accessories on request!

By ordering this filter integrity tester, please contact us to select the right version according to your production needs.

THE FILTER INTEGRITY TESTER "it-01"

PRODUCT DESCRIPTION

The Filter Integrity Tester "it-01" is a handy portable and mains independent filter integrity test instrument, which is used for all standard integrity tests on both **hydrophilic** and **hydrophobic membrane filters**.

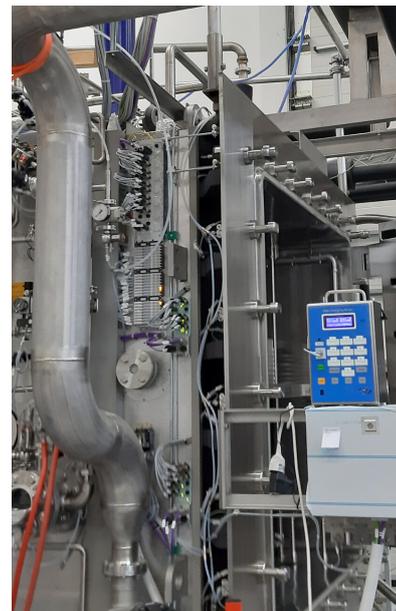
In addition to integrity tests the Filter Integrity Tester "it-01" is capable of checking unknown volumes (e.g. the upstream volume of filter systems in the range of **0,1-35L**) and can be used as a calibration pressure gauge (**0-4, 0-6 or 0-8 barg**).

Due to its design and weight, it can be easily used in inaccessible places, e.g. on huge vessels, in autoclave rooms and on Freeze Drying Systems.

Power supply:

Low-voltage: 7,5V/3,3A.

Rechargeable battery or mains operation.



TEST CAPABILITIES

- The Diffusion Test (Forward Flow Test)
- The Pressure Drop Test
- The Low Pressure Drop Test on sterile bags*
- The Diffusion and Bubble Point Test
- The Diffusion Tests with the automatic filter wetting
- The Water Intrusion Test (WIT)
- The Water Intrusion Test on huge filter systems (150L)*
- The Water Intrusion Test with automatic housing cooling*
- Volume measurement (e.g. Upstream Vol.)

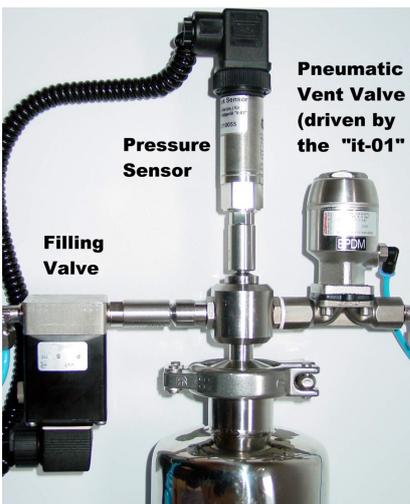


* - **Additional accessories necessary!**

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FILTER TESTING DIRECTLY ON THE INSTRUMENT

Filters and extremely small filters (e.g. **capsules, 50 mm disposables, mini cartridges** and **syringe filters**) can be easily tested directly on the filter integrity tester "it-01" due to a special filter holder installed on the rear side of its cabinet.



FILTER TESTING WITH THE EXTERNAL VENTING ON THE FILTER SYSTEM

To avoid any contamination of the Filter Integrity Tester, e.g. after **"In-line Testing"**, there is a possibility to vent the filter housing after the test directly in place, with a pneumatic vent valve controlled by the instrument.

The draining of the filter housing after the Water Intrusion Test (WIT) can be carried out the same way.

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PRINTER

The integrated printer is splash protected and located inside the cabinet behind its front door.

It allows printing test results in the place of testing.

(No Thermal Printer!)

The short operation instruction is shown inside the cabinet behind its front door.



PC-SOFTWARE

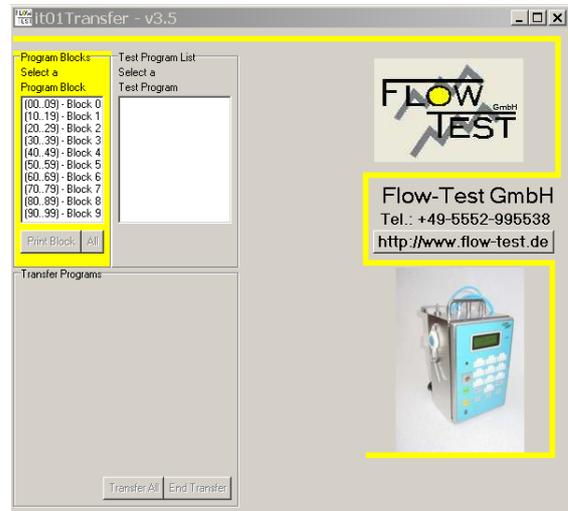


"it-collect"

Software program "it-collect" is a part of delivery. It is delivered with the "it-01".

(System Software: Windows >XP/7/10. Not valid for CFR Versions)

Due to the "it-collect" Software Program a lot of filter test programs can be created, changed and managed from the Central Administration Console within your local area network.



"it-trans"

PC-Program for the administration of filter test programs (System Software: Windows>X Pprof.7/10).

The "it-trans" is used to create and administrate filter test programs.

It can only be used with the RS 232 installed in the hardware of the computer.

STORAGE OF FILTER TEST PROGRAMS AND RECORDS



Up to **100 Filter Test Programs** can be stored in the instrument memory and an unlimited amount on a PC.

Software (**Windows – XP/7/10**) for the Central Administration of Filter Test Programs is available.

The FDA guideline 21 CFR 11: A Software version for this standard is available.

Up to **40 Filter Test Records** can be stored in the instrument memory (**only with CFR-version**).

CALIBRATION AND MAINTENANCE

For the first time the sensors and the pressure control system must be checked and calibrated after half a year of their usage then only once a year.

For maintenance and calibration the instrument must be sent back to the manufacturer.

All necessary measuring devices are calibrated and certified by **DKD (Deutscher-Kalibrier-Dienst)**.

A regular control of all calibration devices is guaranteed.



QUALIFICATION (IQ, OQ, PQ)

The Filter Integrity Tester "it-01" has been developed in accordance with **GAMP guidelines**, hence it is delivered (if it is required) with an extensive qualification documentation package, including guides for **Installation and Operational Qualifications (IQ/OQ)**. The **Performance Qualification (PQ)** is usually carried out at customer`s.

All documents are prepared in English.

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EXAMPLE: PRINTOUT

it-01- Filter Test

Serial No.: 01041434

Program No.: 1

Water Intrusion Test

Date: 12.08.14 Time: 14:12

Filter System: Freeze Dryer Hof

Filter Type: PALL AB1-PFR

Filter Batch No.: CT-234567

Product Batch No.: without

Test Parameters:

Test Gas: Air

Kind of Water: Tap-Water

Type of Housing: Flow-Test G-001

Hardware Volume: 646 mL

Test Pressure: 2500 mbar

Stabilization Time: 600 s

Test Time- t: 600 s

Water Flow max.: 3300 µL/t

Test Results:

Test Pressure: 2505 mbar

Pressure Drop: 61 mbar

Water Flow: 1890 µL/t

Test passed

Programmer: Heinz Rudolph

Sign. Operator: Anja Gehne

it-01- Filter Test

Serial No.: 0104434

Program No.: 2

Diffusion Test

Date: 12.08.14 Time: 15:12

Filter System: Washing Machine

Filter Type: PALL AB1-Nylon

Filter Batch No.: CT-2-RT-67

Product Batch No.: without

Test Parameters:

Test Gas: Air

Wetting Medium: Water

Type of Housing: Flow-Test G-001

Upstream Volume: 1896 mL

Test Pressure: 2500 mbar

Stabilization Time: 300 s

Test Time- t: 300 s

Diffusion max.: 13 mL/min

Test Results:

Test Pressure: 2505 mbar

Pressure Drop: 61 mbar

Diffusion: 8,9 mL/min

Test passed

Programmer: Heinz Rudolph

Sign. Operator: Anja Gehne

it-01- Filter Test

Serial No.: 0104434

Volume Measurement:

Date: 12.08.14 Time: 16:12

Filter System: Washing Machine

Volume: 1896 mL

Test Pressure: 2506 mbar

Sign. Operator: Anja Gehne

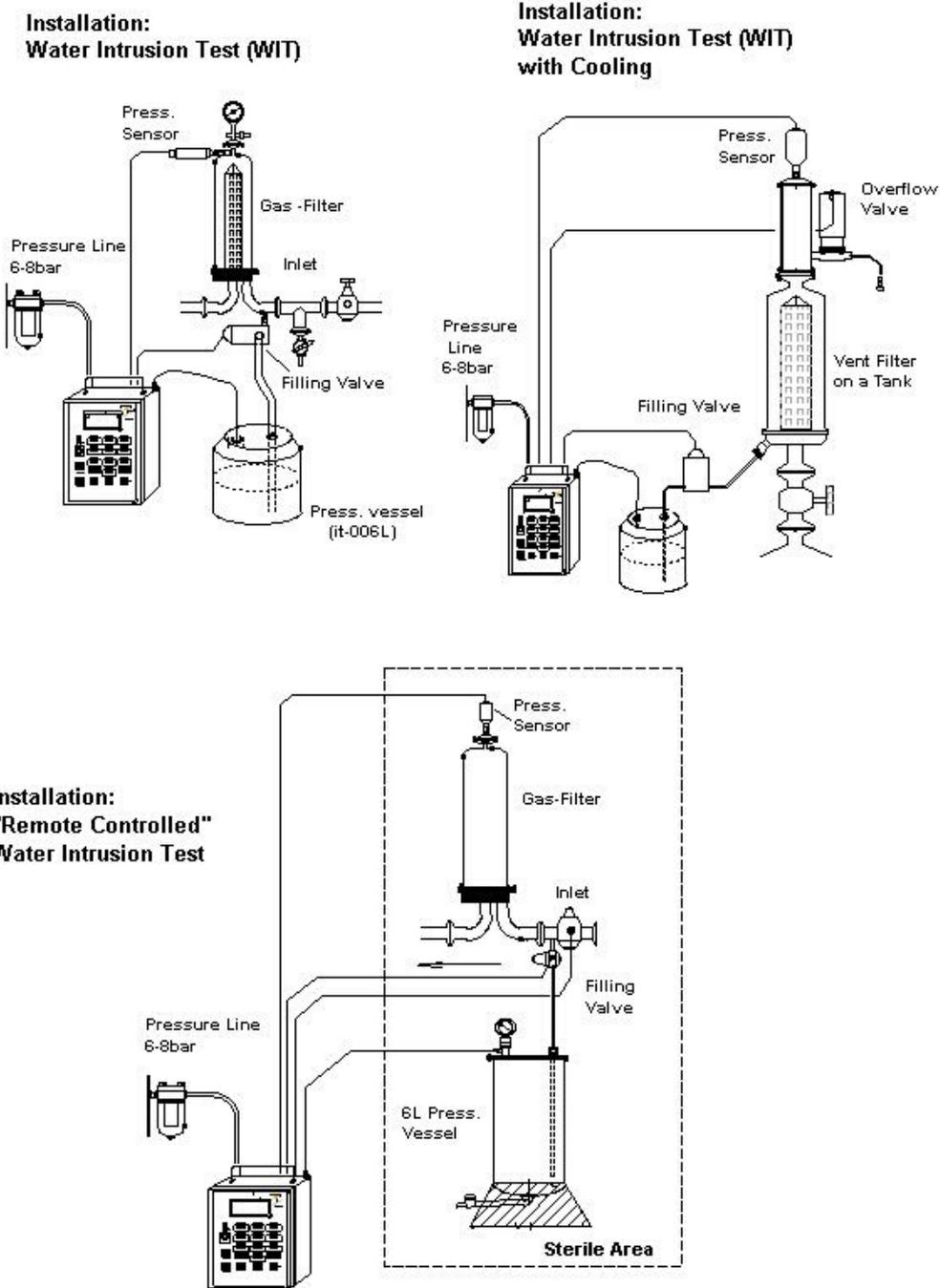
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TECHNICAL SPECIFICATIONS

CABINET MATERIAL:	stainless steel 1.4301 (e-polished, splash protected)
CABINET DIMENSION:	200x300x155
WEIGHT:	8,6 kg
PROTECTION CLASS:	IP 55
POWER SUPPLY:	low voltage 7,5V/3,3A
KEYBOARD:	infrared-alpha numeric (splash protected)
SOFTWARE PROTECTION:	stored in Flash EPROM
MATRIX PRINTER:	normal paper, 24 characters/ line
AMOUNT OF STORABLE TEST PROGRAMS:	100
AMOUNT OF STORABLE TEST RECORDS:	40 (depending on the instrument Software)
PNEUMATIC CONNECTORS:	Stäubli RBE 03 /stainless steel 1.4404
INTERNAL PRESSURE SENSOR:	0-6 barg, rel. class 0.2 (alternative: 0-4 or 0-8 barg)
BAROMETRIC PRESSURE SENSOR:	800-1090 mbar, rel. class 0,5
EXTERNAL PRESSURE SENSOR:	0-6 barg, rel. class 0,15 (alternative: 0-4 or 0-8 barg)
MAIN CPU -BOARD:	HC-12 Motorola
PROGRAM LANGUAGE:	C
DISPLAY:	4 lines illuminated - 20 characters/line
DATA TRANSFER:	RS 232 or LAN (19.200 bd)
LANGUAGES:	German, English, French, Italian, Spanish, Danish
MEASURING UNITS:	
PRESSURE :	mbar
WATER FLOW:	µL/ t (test time)
DIFFUSION:	mL/min (1000 mbar /20°C)
VOLUME:	mL
TEST CAPABILITIES:	the Water Intrusion Test (WIT) the Diffusion Test, the Pressure Drop Test the Bubble Point Test, the Diff.+Bubble Point Test Volume Measurement
CLEANING OF PNEUMATIC PARTS:	steaming of the external sensor and Filling valve flushing of the internal valves (80°C)
MEASURING ACCURACY:	
THE WIT:	4% of actual value >= 0.1mL/min max.resolution 0,005mL
THE DIFFUSION TEST:	5% of actual value >= 5mL/min max.resolution 0,1mL Measurement according to DIN 58356 Part II
THE BUBBLE POINT TEST:	1% F.S.
ENVIRONMENT TEMPERATURE:	5- 40°C
STORAGE TEMPERATURE:	2- 50°C
REL. HUMIDITY:	0-80%

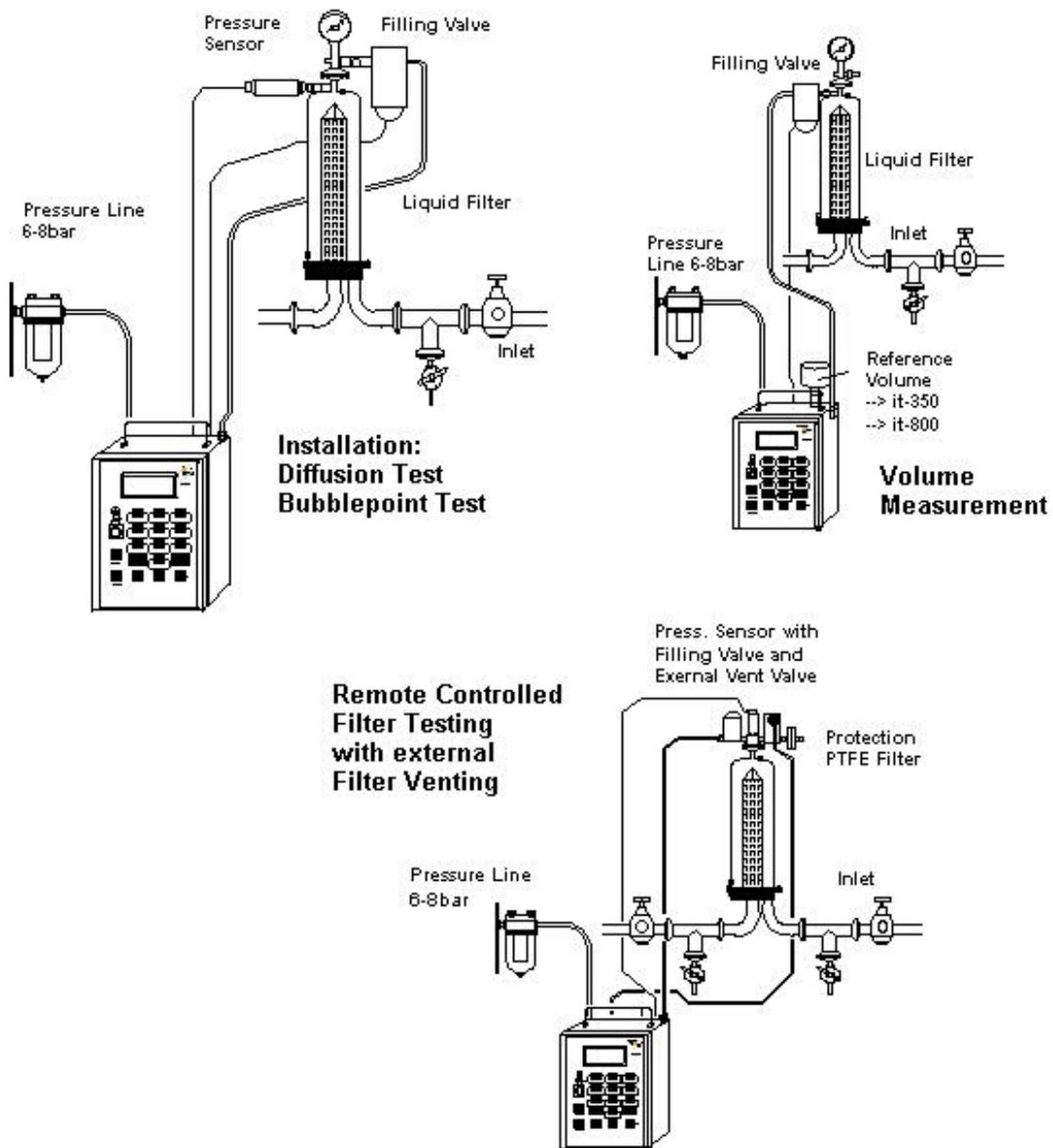
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INSTALLATION: THE WATER INTRUSION TEST (WIT)



THE FILTER INTEGRITY TESTER "it-01"

INSTALLATION: THE DIFFUSION - BUBBLE POINT TEST AND VOLUME MEASUREMENT





YOUR COMPETENT PARTNER IN FILTER INTEGRITY TESTING

