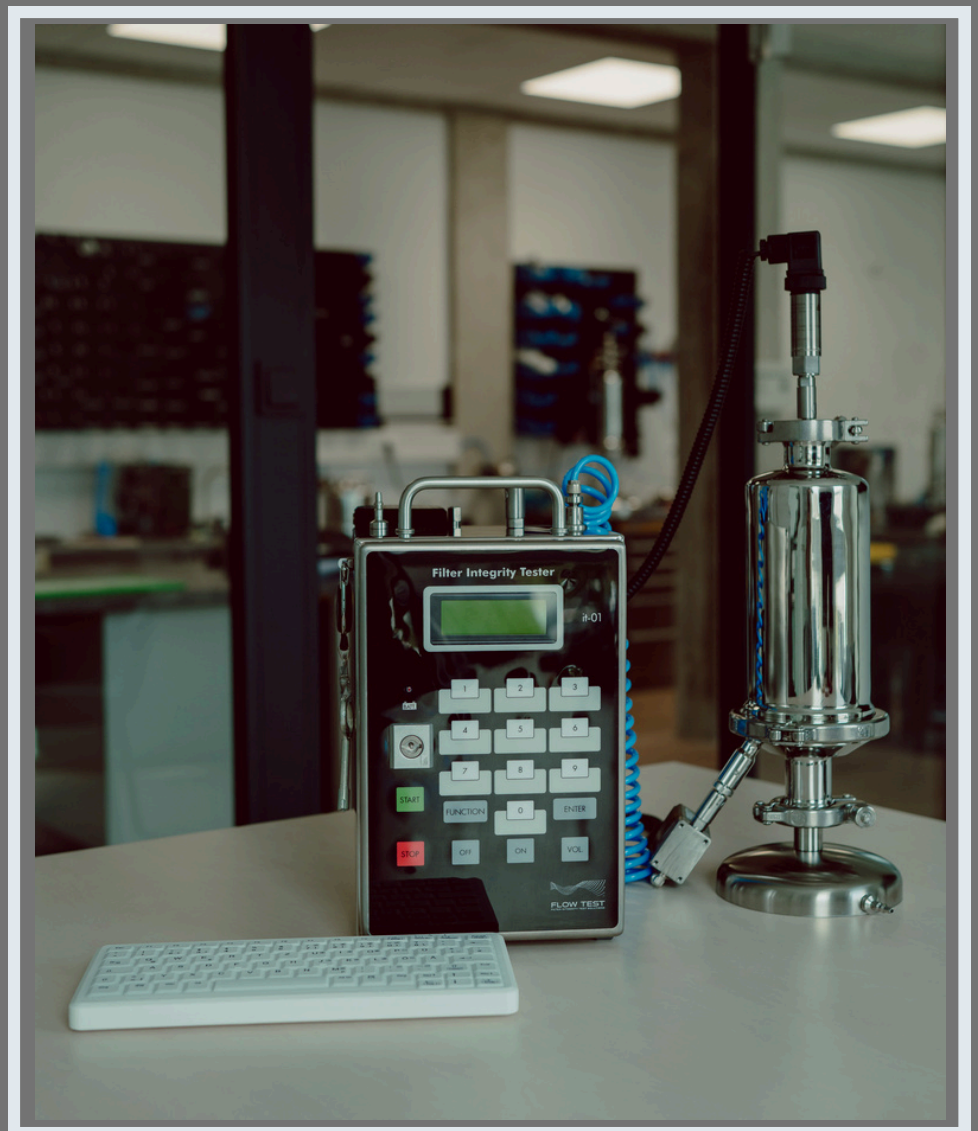


"it-01"

The portable Filter integrity tester



www.flow-test.com



info@flow-test.de

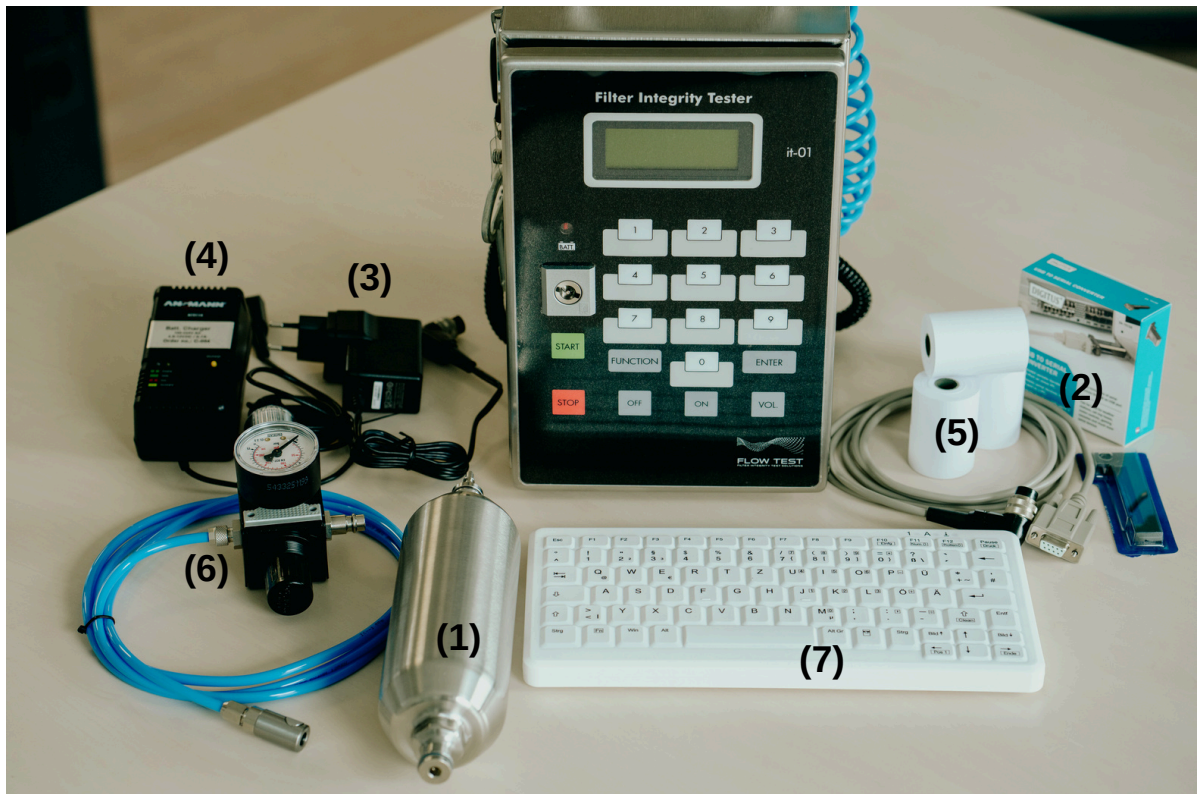


+49-5121 1023233



THE FILTER INTEGRITY TESTER "it-01"

SCOPE OF DELIVERY



1. Reference volume it-350-VA
2. Interface Data cable
3. Power Supply PS-18
4. Battery Charger (optional)
5. Set of paper rolls (x4) & ink ribbon
6. Compressed air regulator and inlet tube
7. USB-keyboard (Bluetooth or as cable option available)

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.

Filter Integrity Tester - Softwareversions:

- **it-01G** => Standardversion, capable to store till 400 Testresults.
- **it-01G-CFR** => CFR-Version, comply with FDA-standard 21CFR11.
- **it-01G-PLC** => PLC/LAN-version, PLC-interface for Remote controll and LAN-connection for data transfer!

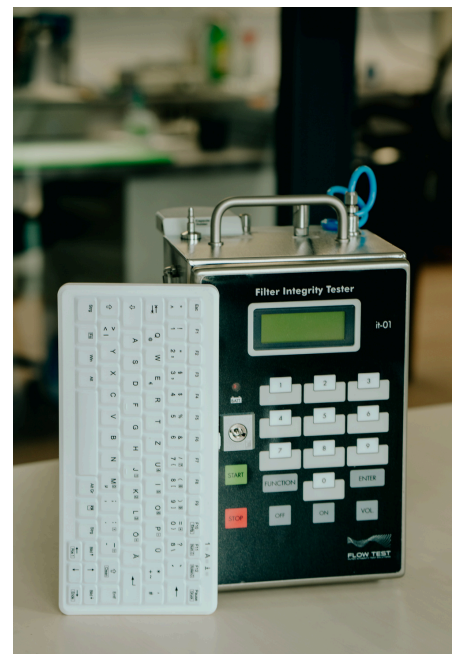
Power supply:

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)*
- Volume measurement (e.g. Upstream Vol.)

* - **Additional accessories necessary!**

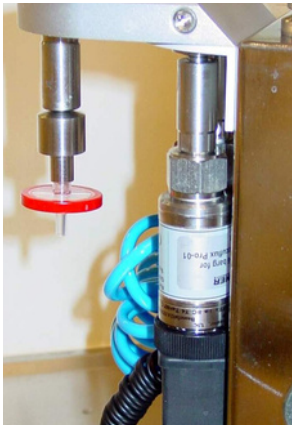




THE FILTER INTEGRITY TESTER "it-01"

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.



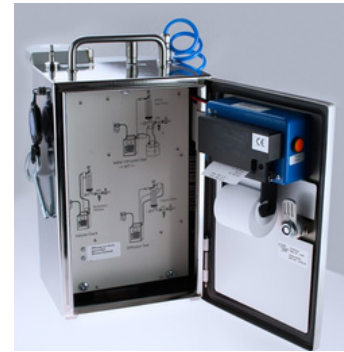
THE FILTER INTEGRITY TESTER "it-01"

PRINTER

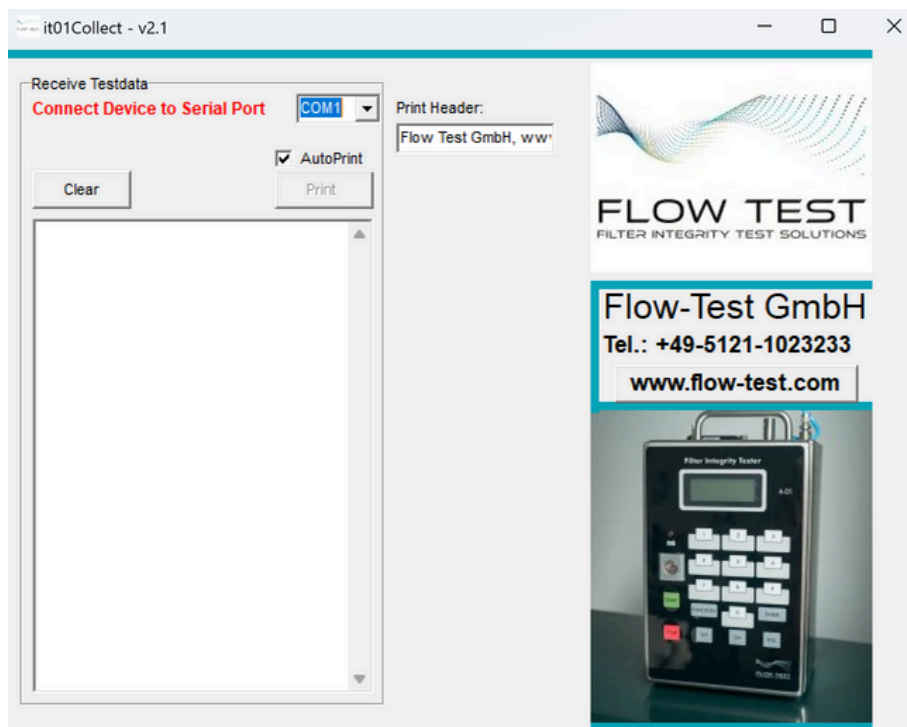
The integrated printer is splash protected and located inside the cabinet behind its front door.

It allows printing test results in the place of testing.

(No Thermal Printer!)



PC-SOFTWARE



"it-collect"

Software program "it-collect" is a part of delivery. It is delivered with the "it-01".
(System Software: Windows >XP/7/10/11.

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.



THE FILTER INTEGRITY TESTER "it-01"

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/7/10/11) 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 400 Filter Test Records can be stored in the instrument.

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.





THE FILTER INTEGRITY TESTER "it-01"



EXAMPLE: PRINTOUT

it-01- Filter Test

Serial No.: 01041434

Program No.: 1

Water Intrusion Test

Date: Time:
12.08.14 14:12

Filter System:
Freeze Dryer Hof

Filter Type:
PALL ABI-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: Time:
12.08.14 15:12

Filter System:
Washing Machine

Filter Type:
PALL ABI-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: Time:
12.08.14 16:12

Filter System:
Washing Machine

Volume:
1896 mL

Test Pressure:
2506 mbar

Sign. Operator:
Anja Gehne



THE FILTER INTEGRITY TESTER "it-01"



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:	mains adaptor: low voltage: 7,5V/3, 3A or rechargeable battery 7,2V/4,5 Ah
KEYBOARD:	cable linked keyboard
SOFTWARE PROTECTION:	stored in flash EPROM
MATRIX PRINTER:	normal paper, 24 characters/line
AMOUNT OF STORABLE TEST PROGRAMS:	400
PNEUMATIC CONNECTORS:	STÄUBLI RBE 03 /stainless steel: 1.4404
INTERNAL PRESSURE SENSOR:	0-6000 mbar. class: 0,2
BAROMETRIC PRESSURE SENSOR:	800-1070 mbar, rel- class: 0,5
EXTERNAL PRESSURE SENSOR:	0-6000 mbar CLASS 0,15
MAIN CPU -BOARD:	CPU-T (ARM-CORTEX 32bit)
PROGRAM LANGUAGE:	C
DISPLAY:	4 lines illuminated - 20 characters/line
DATA TRANSFER:	RS 232
LANGUAGES:	GERMAN, ENGLISH, FRENCH, ITALIAN, SPANISH, DANISH
MEASURING UNITS:	
PRESSURE :	mbar, resoluiton = +-0,1mbar
WATER FLOW:	µL/time (test time)
DIFFUSION:	mL/min (1000 mbar /20°C)
VOLUME:	mL
TEST CAPABILITIES:	THE WATER INTRUSION TEST (WIT) THE DIFFUSION/FORWARD 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
THE DIFFUSION TEST:	5% OF ACTUAL VALUE >= 5mL/min
THE BUBBLE POINT TEST:	1% F.S.
ENVIRONMENT TEMPERATURE:	5- 40°C
STORAGE TEMPERATURE:	2- 50°C
REL. HUMIDITY:	0-80%



THE FILTER INTEGRITY TESTER "it-01"



ACCESSORIES PRESSURE VESSEL

Stainless steel pressure vessel for the WIT-Test Water or wetting agent

Material: stainless steel 1.4571 e-polished

Vessel Volume: 5,7L -> 19,5L

- 5,7L Press. max:6 bar
Temp. max: 80 °C
- 10L Press. max:6 bar
Temp. max: 80 °C
- 19,5L Press. max: 6 bar
Temp. max: 80 °C

Connectors:

Inlet side:

Unvalved male Stäubli nipple with G1/4" thread

Outlet side:

Valved female Stäubli connector RBE 03 with G1/4" thread

Material: stainless steel 1.4404

Note:

It is delivered with all necessary documents for the EU Market.



Stainless steel pressure vessel (5,7L)
Order-Nr.: it-006L

Stainless steel pressure vessel (10 L)
Order-Nr.: it-010L

Stainless steel pressure vessel (19,5L)
Order-Nr.: it-020L



THE FILTER INTEGRITY TESTER "it-01"



ACCESSORIES ADAPTERS

Triclamp-Adapter for WIT tests:

Adp-TC 1,5" (50,5mm)

Triclamp-Adapter:

Adp-TC 34" (34 mm)

Triclamp-Adapter:

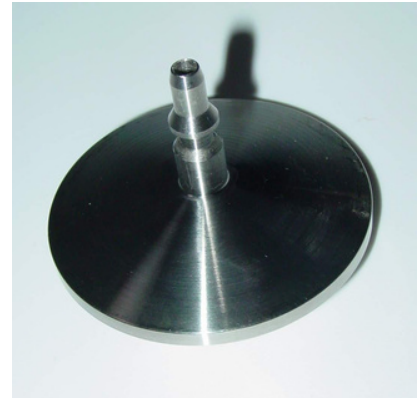
Adp-TC 0,5" (25mm)

Triclamp-Adapter big size with Stäubli-

RBE-03 closing nippel:

Adp-TC 1,5-St3z

Material: Stainless steel-1.4404



Order-Nr.: Adp-TC-1,5

Order-Nr.: Adp-TC-34

Order-Nr.: Adp-TC-0,5

Order-Nr.: Adp-TC-1,5-St3z

Twin-Stäuble-Triclamp adapter for test on liquid filters

1 x nippel

1 x Stäubli-closing nippel RBE 03

Triclamp-Adapter:

TC 1,5" (50,5mm)

Material:

Stainless steel-1.4404



Order-Nr.: Adp-St-TC-10



THE FILTER INTEGRITY TESTER "it-01"



ACCESSORIES/ UNITS FOR SPECIAL APPLICATIONS

Filter test unit for multiple testing of tank vent filters in the pharmaceutical and food industries



Order-Nr.: itB-10

The low-pressure test box "itb-LP" is an additional hardware component for the filter testing device "it-01". Controlled by the filter testing device, it allows for leak tests on sterile bag packages, small storage tanks, or fermenters. The test pressure range is from 50 to 500 mbar



Order-Nr.: itB-LP

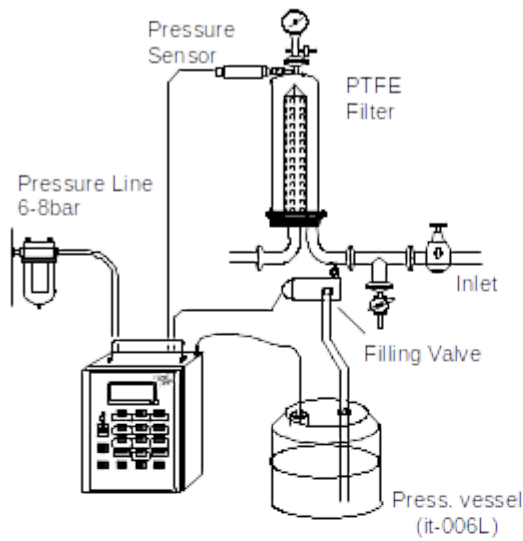


THE FILTER INTEGRITY TESTER "it-01"

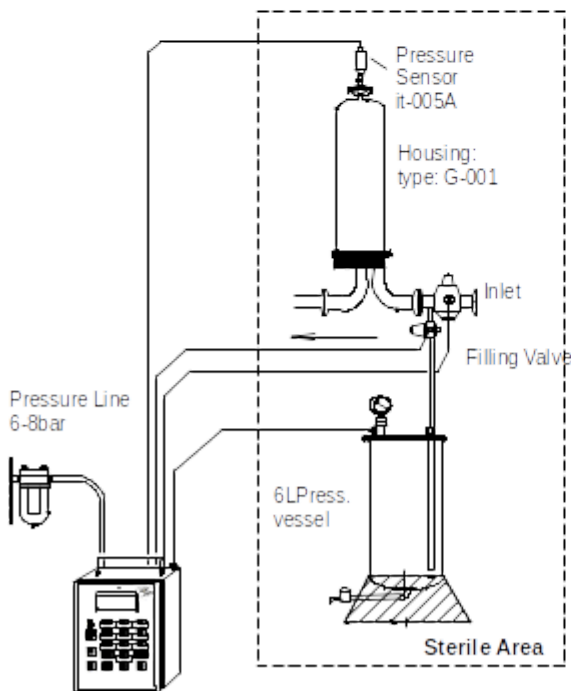
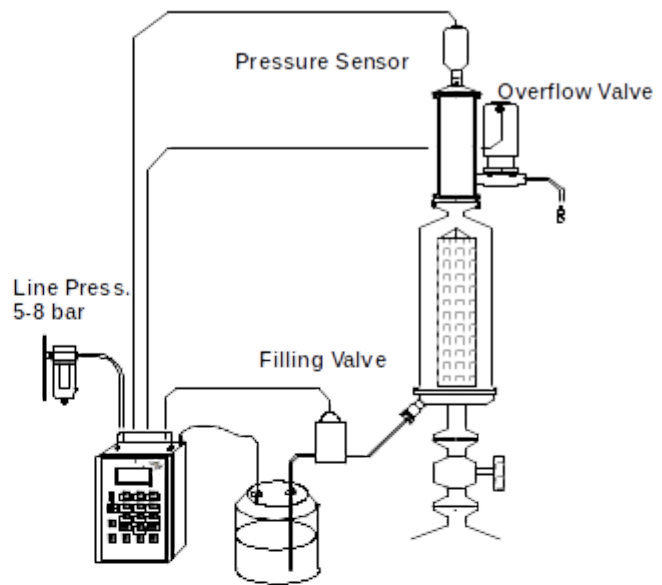


INSTALLATION: THE WATER INTRUSION TEST (WIT)

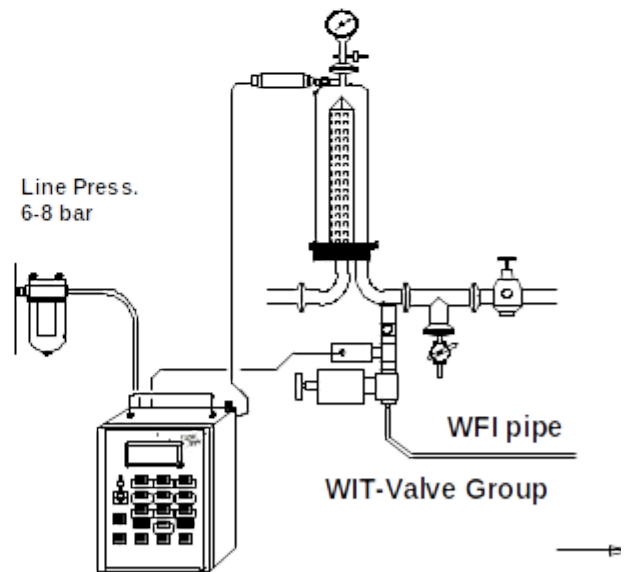
*Installation:
Standard Water Intrusion Test (WIT)*



*Installation:
Water Intrusion Test (WIT)
with filter cooling*



*Installation:
"Remote Controlled"*

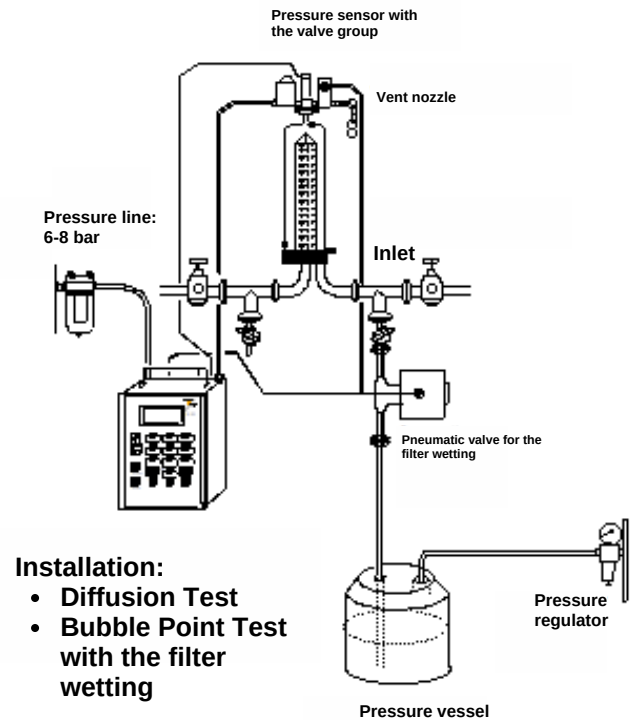
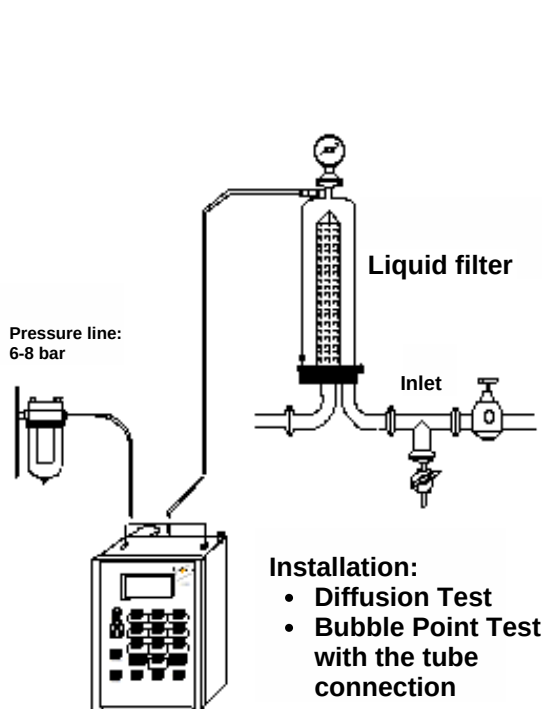
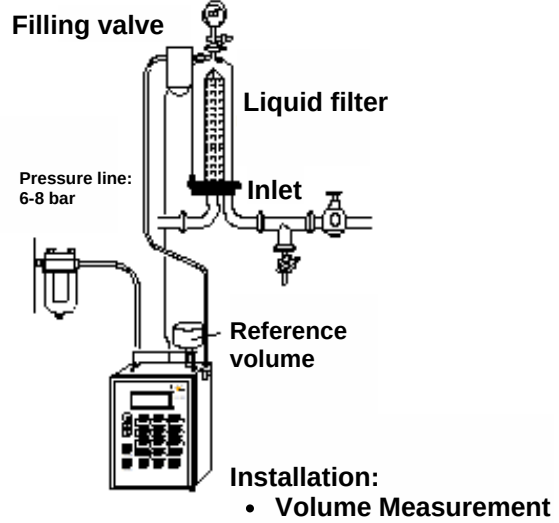
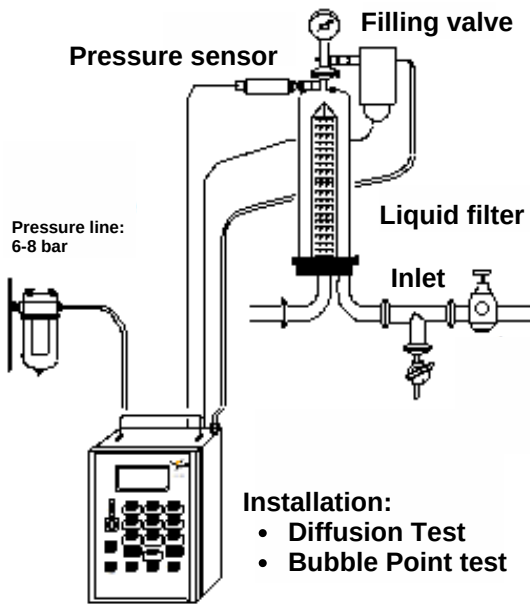


*Installation:
Water Intrusion Test
on huge filter systems*



THE FILTER INTEGRITY TESTER "it-01"

INSTALLATION: THE DIFFUSION - BUBBLE POINT TEST AND VOLUME MEASUREMENT





YOUR COMPETENT PARTNER IN FILTER
INTEGRITY TESTING



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