



Van Borselen
FILTERS



Portable filter integrity test devices
for the pharmaceutical industry



The portable filter tester "it-01"



The filter tester "it-01" is used to check the integrity of membrane filters. In addition, unknown volumes can be measured (eg the net volume of filter systems between 0.1-32L). The test device can also be used as a calibration manometer to check pressure transducers (possible measuring ranges 0-4, 0-6, 0-8bar).

The following filter integrity tests can be performed:

- Diffusion test (forward flow)
 - Pressure drop test
 - Pressure drop test sterile bag test *)
 - Diffusion and bubble point test
 - Tests with automatic filter wetting
 - Water intrusion test (WIT)
 - WIT on large filter systems (150L) *)
 - WIT with automatic filter drying *)
 - WIT with automatic housing cooling *)
- *) additional hardware required

The filter tester "it-01" is small and portable, (housing dimensions 20x30x15cm). It can also be used for filter tests in inaccessible places, eg. On tanks, in autoclave rooms, on freeze dryers etc.

Power supply:

Low voltage 7,5V / 3,3A Optional battery or mains operation

Filter holder:

At the back of the device is a special filter holder. Here, all standard filters can be adapted directly on the device, from syringe filters to standard capsules.

Control of external compressed air valves:

For automatic filter wetting, for filter drying, for external venting or for filling large housings, the test device can directly control an external compressed air valve.





The plain paper printer is waterproof and placed behind the front opening/door. Even under the most adverse circumstances, the printer's paper always stays dry

A quick installation guide

is printed inside the device and can be viewed when opening the front door.

Up to 100 test programs

can be stored permanently in the device, and unlimited numbers in a PC. A corresponding software

for test program management is available.

FDA Standard 21 CFR 11:

A software version to meet this standard is available.

Up to 40 filter test protocols

can be stored in the device (CFR version only).

Central administration of filter test programs in a PC (System Software: Windows> XPprof.)

With the software "it-trans" large quantities of filter test programs can be managed in a central location.

All necessary filter test programs shall be created on a PC. The created programs for the application are loaded to the Integrity tester through the included transfer cable. So that the responsible QA employee is certain that the right programs are used.



Filter test with a vent on the filter system

In order to avoid contamination of the filter test device by refluxing test gas, it is possible to vent the filter housing directly on site after the end of the test via a compressed air valve. A gas filter can be placed behind the valve, so that the environment of the filter housing is not polluted. Since the filling hose does not affect the measurement, the filter test can be performed over long distances.



Maintenance, Calibration, Qualification and Inline Filter Tests:



Maintenance and calibration:

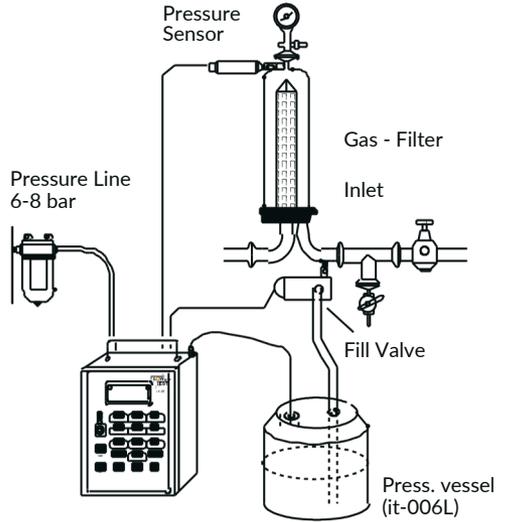
In order to guarantee a high quality standard, all sensors and the pressure regulation are checked and calibrated after 6 months (initial delivery only) thereafter the checks shall be performed every 12 months. The calibration check can be done at customer site or at Van Borselen, Zoetermeer. All required measuring equipment have DKD or PTB calibration certificates and are subject to regular measuring equipment monitoring.

Qualification (IQ, OQ, PQ):

Our qualification service will carry out qualification of the filter tester in accordance with the qualification plan prepared and approved by the operator.

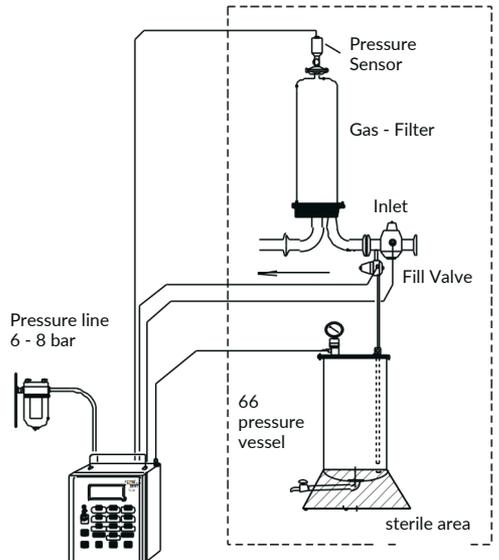
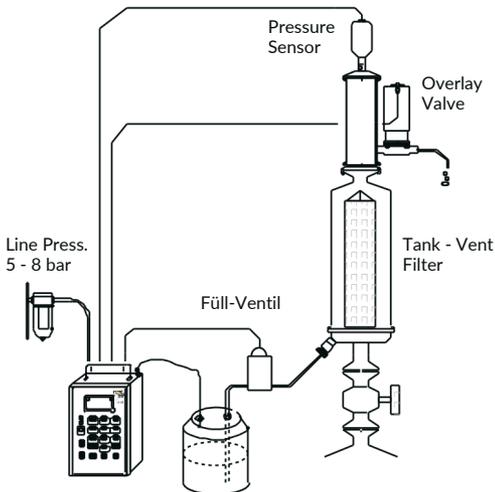
Test Setup: Water Intrusion Test

Test Setup: Water Intrusion Test (WIT)



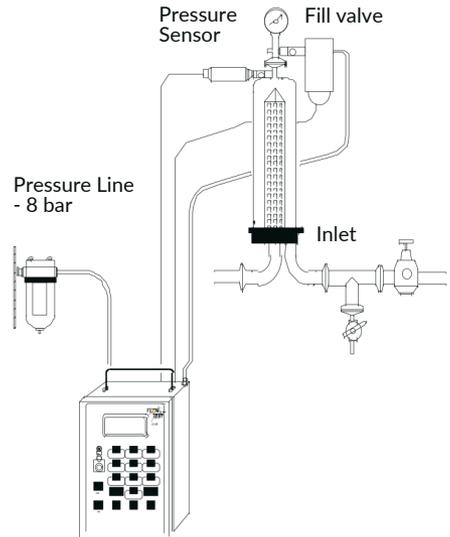
Test setup: Water intrusion test (WIT) with filter cooling

Test setup: "Remote Controlled" Waters intrusion test



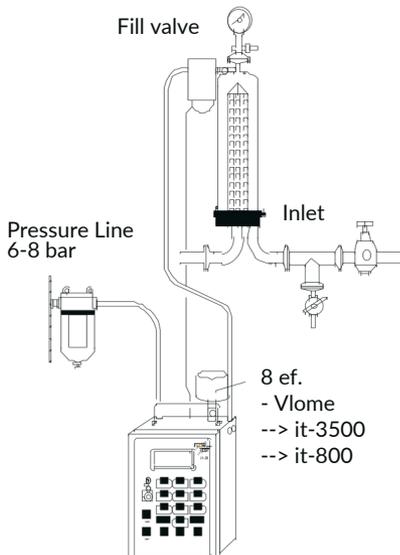
Test setup: Diffusion bubble point test and volume measurement

Diffusion Test Bubble point Test

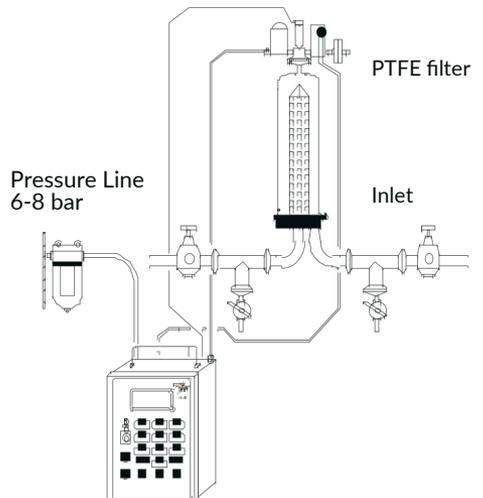


Volume measurement

Filter test with external vent filter (Remote Controlled)



Pressure sensor with Filling valve and Ext. Ventilation valve



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:
Van Borselen BPB17SP002
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
Kind of Water:
Tap-Water
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:
VVan Borselen BPF27SP002
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
Kind of Water:
Tap-Water
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.: 01041434

Volume Measurement:

Date: 12.08.14 Time: 16:12

Filter System:
Washing Machine

Volume:
1896 mL

Test Pressure:
2506 mbar

Sign. Operator:
Anja Gehne

Technical specifications:

Test device housing (see picture)	: Stainless steel 1.4301 (e-polished)
Housing dimensions (without handle)	: 200x300x155
Mass	: 8,6Kg
Protection	: IP 55 (optional IP65)
Power supply	: 230V /30W
Input keyboard	: Infrared alphanumeric (water-protected)
Software assurance	: Secured EPROM
Dot matrix printers	: Plain paper, 24 characters / line
Number-storable test programs	: 100
Backup of the test program, and test protocols	: Flash EPROM
Pneumatic connections	: Stäubli RBE 03 / stainless steel 1.4404
Pressure sensor - internal	: 0-6 bar; rel. CI 0.5
Pressure sensor	: 800-1090 mbar KI 0,5
Barometric	: 0-6 bar, rel. KI 0,15
Pressure sensor external computer	: HC-12 Motorola
Programming language	: C
Display	: 4 rows - 20 columns - backlight
Interface	: RS 232 (19,200 bd) (optional Ethernet)
Languages	: German-English-French-Spanish-Italian-Danish
Tests	: Water Intrusion Test (WIT) Diffusion Test Pressure Drop Test Bubble-Point Test, Diff + Bubblepoint Test, Net Volume Measurement
Cleaning the sensors and valves	: Evaporation of the external pressure sensor and the filling valve. Flushing internal valves (80 ° C)
Accuracy	: 4% of measured value $\geq 0.1 \text{ ml} / \text{min} = 100\mu\text{L} / \text{min}$ max. Resolution 0.005 mL = 5 μL
Water Intrusion Test (WIT)	: 5% of the measured value $\geq 5 \text{ ml} / \text{min}$
Diffusion	: Measurement according to DIN 58356 Part 2 max. Resolution 0.1 mL
Bubblepoint	: 1% FS
Ambient temperature	: 5- 40°C
Storage temperature	: 2- 50°C
Rel. Humidity	: 0-80%

Van Borselen Filters B.V.

Argonstraat 66
2718SN,
Zoetermeer

T +31 (0) 793412314
E info@vanborselen.nl
W www.vanborselen.nl



Van Borselen Filters BV reserve the right to change specification without prior notice, as part of their continuous product development programme.