

MOBILE FILTER- INTEGRITY TEST UNIT "ita-02"




FLOW TEST
FILTER INTEGRITY TEST SOLUTIONS

- Pharmacy
- Cosmetic industry
- Chemical industry
- Biotech



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YOU COMPETENT PARTNER IN FILTER INTEGRITY TESTING



MOBILE FILTER- INTEGRITY TESTING UNIT "ita-02"

Product details:

The **Testing Unit "ita-02"** is used for the integrity testing of membrane filters. The two test channels operate completely independently, allowing a large number of filters to be checked in a short amount of time.

Key feature: High test reliability through redundancy!

The two testing units are mounted in a way that they can be easily removed from the chassis. In case of equipment failure, the faulty testing unit can be quickly detached and sent for repair, while the second unit can continue to operate.



Test methods:

The following filter tests can be performed independently on both test channels.

- Diffusion Test (Forward-Flow) regarding DIN 58356 Teil 2
- Bubble-Point Test
- Diffusions- and Bubble-Point Test
- Pressure Drop Test
- Pressure Drop Test- on Big vessels and fermenters till 10 m³*
- Pressure Drop Test- Plastic bags till 50L volume*
- Integrity Testing mit automatic Wetting of the filter*
- Water Intrusionstest (WIT) regarding DIN 58356 Teil 12
- WIT on big Filtersystems (150L) *



* Additional hardware required!



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Characteristics

- Mobile and easy portable
- Splash proof
- The two test channels operate completely independently
- Short testing cycle due redundance!
- High accuracy and reproducibility of test results. Pipes and cables do not affect the test outcome.
- User-friendly - minimal operation training required



- Thanks to a special filter holder at the back of the device, all common filters ranging from splash pre-filters (50 mm disposable capsules, mini cartridges, injection/syringe filters, etc.) to standard capsules can be directly adapted to the device.
- To prevent contamination of the filter testing device from backflowing test gas, there is the option to purge the filter housing on-site after the test using a compressed air valve.
- Maintenance friendly
- Up to 100 test programs can be stored permanently in the device.
- Up to 400 Testprotocolls can be stored at the device.
- If requested, we offer the device in a CFR-version that is compatible with 21 CFR Part II.
- Developed regarding **GAMP**



MOBILE FILTER- INTEGRITY TESTING UNIT "ita-02"

PRINTER & SOFTWARE

The printer is located in a waterproof compartment within the housing (non-thermal printer).

Up to 100 test programs can be stored in the system, and an unlimited number on a PC. Special software for centralized management of test programs is available.

A software version to comply with this standard is available (CFR version). Storage of test records:

FDA Standard 21 CFR 11:

A software version to comply with this standard is available (CFR-version).

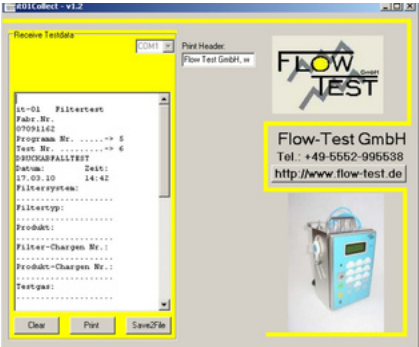
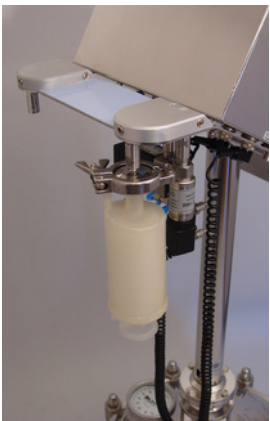
Saving of the test records:

Up to 400 Testresults can be stored at the Integrity Te.



Filter Holder

At the back of the system, there is a special filter holder where all common filters can be directly adapted to the system, ranging from syringe filters to 10" filter systems.



Software "it-collect"



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Calibration and Maintenance

To ensure a high quality standard, all sensors and the pressure control system are checked and calibrated for the first time after six months, and then annually. The work is carried out on-site within Germany and in neighboring countries. All necessary measuring instruments have DKD or PTB calibration certificates and undergo regular instrument monitoring.



Qualification (IQ, OQ, PQ)

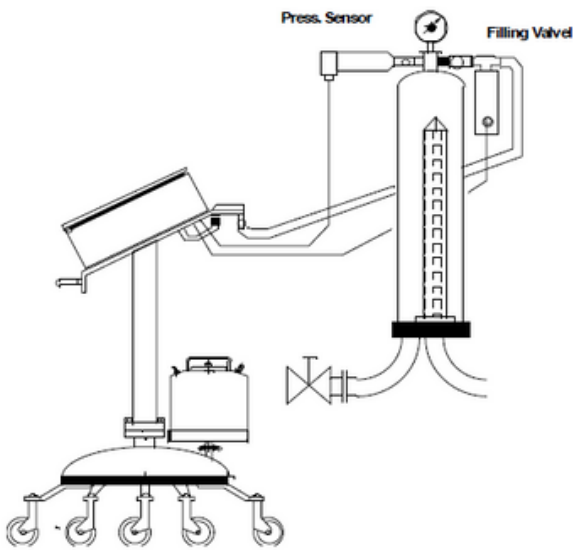
If the filter testing device is to be qualified, our qualification service will perform these tasks in accordance with the qualification plan prepared and approved by the operator.



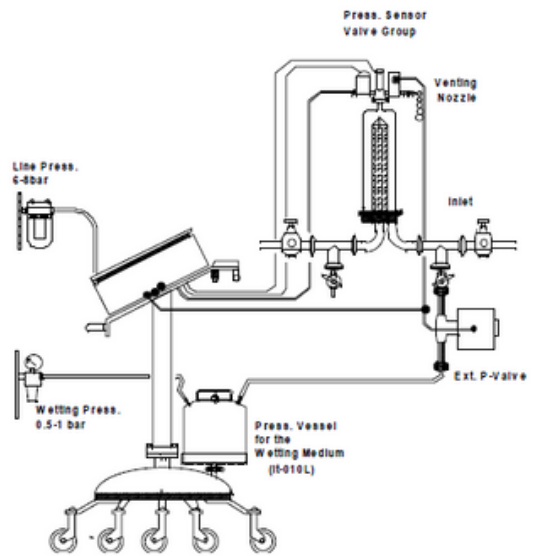
MOBILE FILTER- INTEGRITY TESTING UNIT "ita-02"

Integrity Tests on Liquid Filters (Calibration of external pressure gauges)

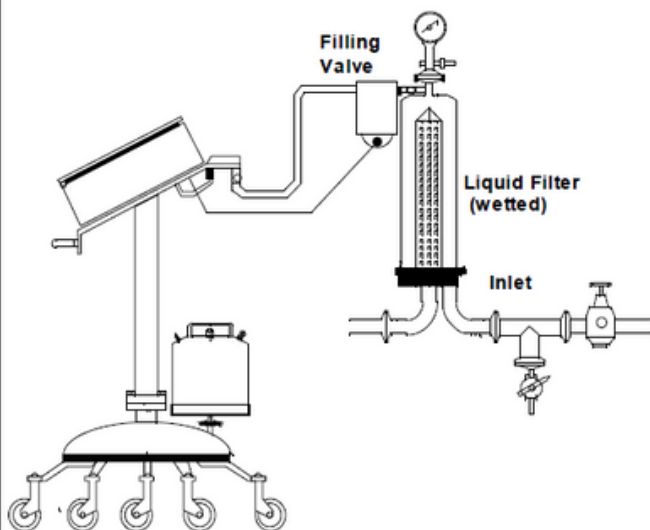
Filter Integrity Test Diffusion and Bubblepoint



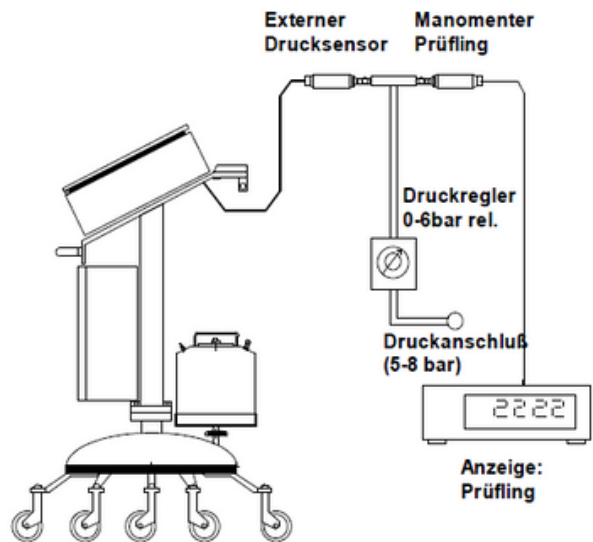
Filter Integrity Test with Wetting



Upstream Volume Measurement



Calibration of external pressure gauges

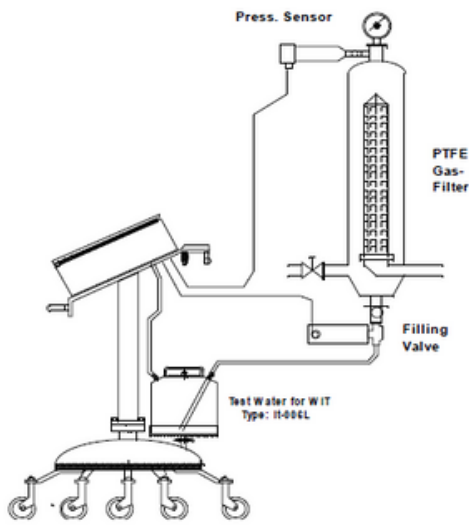




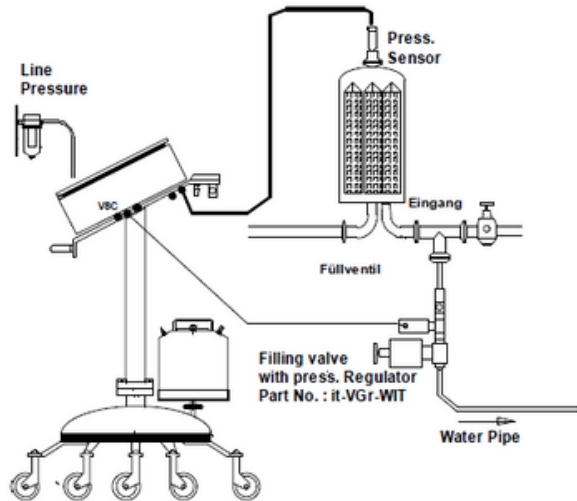
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Integrity Tests on Gas Filters with the Water-Intrusion Test (WIT)

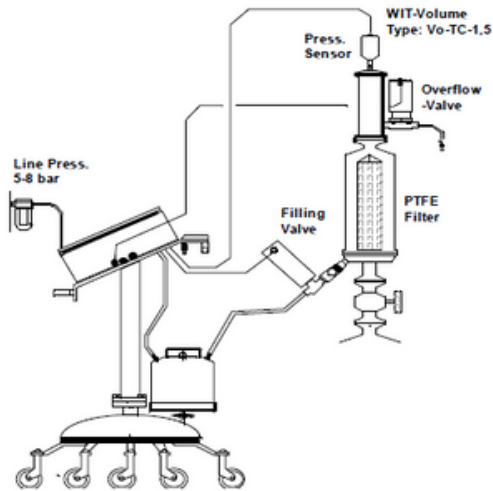
Water Intrusion Test Installation



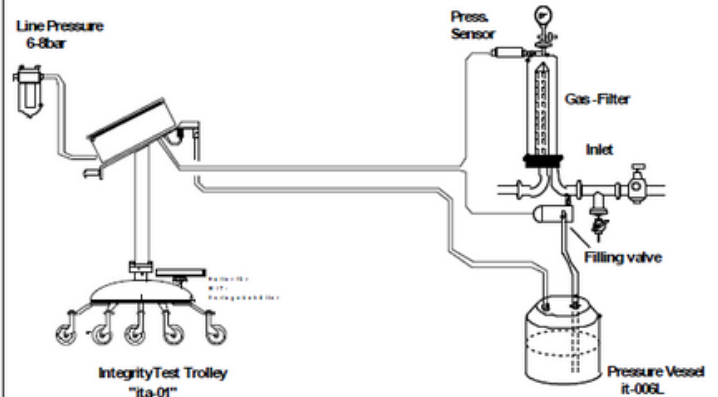
Water Intrusion Test on huge Housings (approx. 150L)



Water Intrusion Test with filter cooling



Remote controlled Water Intrusion Tests





MOBILE FILTER- INTEGRITY TESTING UNIT "ita-02"

EXAMPLE: PRINTOUT

ITA-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 ML/T

TEST RESULTS:

TEST PRESSURE:
2505 MBAR

PRESSURE DROP:
61 MBAR

WATER FLOW:
1890 ML/T

TEST PASSED

PROGRAMMER:
HEINZ RUDOLPH

SIGN. OPERATOR:
ANJA GEHNE

ITA-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



MOBILE FILTER- INTEGRITY TESTING UNIT "ita-02"

Technical Specification

CABINET MATERIAL:	stainless steel: 1.4301 (e-polished, splash protected)
CABINET DIMENSION:	760x760x111mm
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:	infrared, alphanumeric (splash protected)
SOFTWARE PROTECTION:	stored in flash EPROM
MATRIX PRINTER:	normal paper, 24 characters/line
AMOUNT OF STORABLE TEST PROGRAMS:	100 Testprogramms & 400 Testresults
PNEUMATIC CONNECTORS:	STÄUBLI RBE 03 /stainless steel: 1.4404
INTERNAL PRESSURE SENSOR:	0-6 barg. class: 0,2
BAROMETRIC PRESSURE SENSOR:	800-1070 mbar, rel- class: 0,5
EXTERNAL PRESSURE SENSOR:	0-6 barg 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
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%



Notes

Lined area for taking notes, consisting of numerous horizontal dashed lines.



IHR KOMPETENTER PARTNER IN INTEGRITÄTSPRÜFUNG VON MEMBRANFILTERN



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