



"ita-02"



**THE MOBILE FILTER
INTEGRITY TROLLEY**



- The Pharmaceutical Industry
- The Cosmetic Industry
- The Chemical Industry
- Biotech



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YOUR COMPETENT PARTNER IN FILTER INTEGRITY TESTING

MOBILE FILTER INTEGRITY TROLLEY "ita-02"

PRODUCT DESCRIPTION

The filter integrity test trolley "ita-02" is a compact, mobile filter integrity test instrument designed for membrane filter tests.

In addition to integrity testing the instrument can be used as a calibration pressure gauge (**0-4 or 0-8 barg**) and is capable of checking unknown volumes (e.g. the upstream volume of a filter housing (**from 0,1 to 35L**)).

TEST CAPABILITIES

- The Diffusion Test (Forward-Flow), based on the guideline DIN 58356 Part 2
- The Bubble Point Test
- The Diffusion and Bubble Point Tests
- The Pressure Drop Test (Pressure Hold Test)
- The Pressure Drop Test on huge vessels or fermenters up to 10 m³ *
- The Pressure Drop Test on Plastic Bags up to 50L*
- The Filter Integrity Tests with the automatic filter wetting*
- The Water Intrusion Test (WIT), based on the DIN guideline DIN 58356 Part 12
- The Water Intrusion Test (WIT) on huge filter systems up to 150L *
- The Water Intrusion Test (WIT) with the automatic cooling of the filter housing *
- The filter integrity testing can be conducted over a long distance (50m) with draining or venting directly on the filter housing (no contamination from exhaust gases) *

- - **Additional accessories necessary!**



MOBILE FILTER INTEGRITY TROLLEY "ita-02"

BENEFITS

- "ita-02" is compact and mobile, the flexible wheels allow a fast and easy moving between different filter systems.
- "ita-02" can easily carry all accessories, e.g. test adapters, cables or tubes as well as a water vessel for the WIT or for the wetting fluid.
- Two independent working test channels allow it to test a lot of filters at the same and within a short time.
Note: High Reliability by Redundancy!
- If any technical problems in one of the two instruments occur, the test device can be easily dismantled from the trolley and sent to a manufacturer to repair it. The second instrument can continue to run filter tests. In-place Tests can be easily handled up to 10 m around the trolley.
- Automated testing.
- User-friendly interface that requires minimal training of operations.



- Easy to use and program.
- Filters and extremely small filters (e.g. capsules, 50 mm disposables, mini cartridges and syringe filters) can be easily tested directly on the "ITA-02" due to a special filter holder installed on the rear of its cabinet. Configurable to automatically flush and drain filters.
- Maintains resolution and accuracy regardless of filter system size in the range of 0.1 to 35 litres.

- Capable of checking unknown volumes (e.g. the upstream volume of filter systems between 0,1-35L) and can be used as a calibration pressure gauge (0-4, 0-6 or 0-8 barg).
- Integrated printer allows printing test results in the place of testing.
- Up to 100 filter test programs can be stored in the instrument memory and an unlimited amount on a PC.
- Up to 40 filter test records can be stored in the instrument memory.
- Test results can be saved on a USB-flesh drive.
- Designed to 21 CFR Part II and delivered with an extensive qualification and documentation package.
- High reliability of the instrument guarantees its long operation.

MOBILE FILTER INTEGRITY TROLLEY "ita-02"

INTEGRATED PRINTER & SOFTWARE

The integrated printer is splash protected and located inside the cabinet behind its front door. **(No Thermal Printer!).**

Short Operation Instruction is shown inside the cabinet behind its front door.

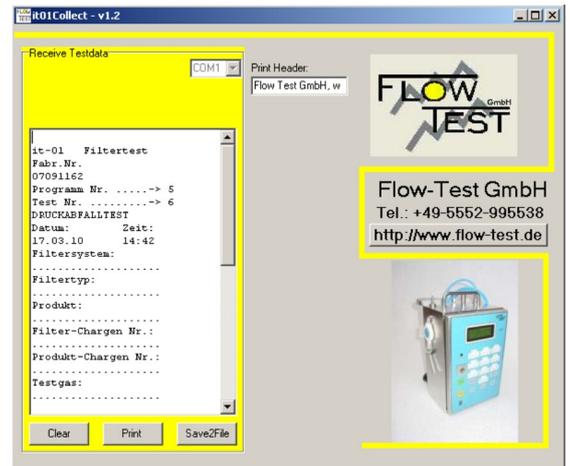
Up to 100 test programs can be stored in the instrument memory and an unlimited amount on a PC.

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

The Compliance to FDA 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).

The software "it-collect" is easy to use.



PNEUMATIC VALVES

Three pneumatic valves for each test channel can be directly controlled by the instrument (e.g. for the automatic wetting procedure, filter drying or filling of huge housings, remote controlled filling and draining of the filter housings or the pressure drop testing on huge containers (up to 10 m³)).

Electrical Power: 2x 7,5V 3,3A

Mains operated, with the medical mains adapter (100-240V AC).



MOBILE FILTER INTEGRITY TROLLEY "ita-02"

CALIBRATION, MAINTENANCE AND QUALIFICATION

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, separate the instrument from the trolley and send it 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.



QUALIFICATIONS (IQ, OQ, PQ)

"ita-02" was 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.

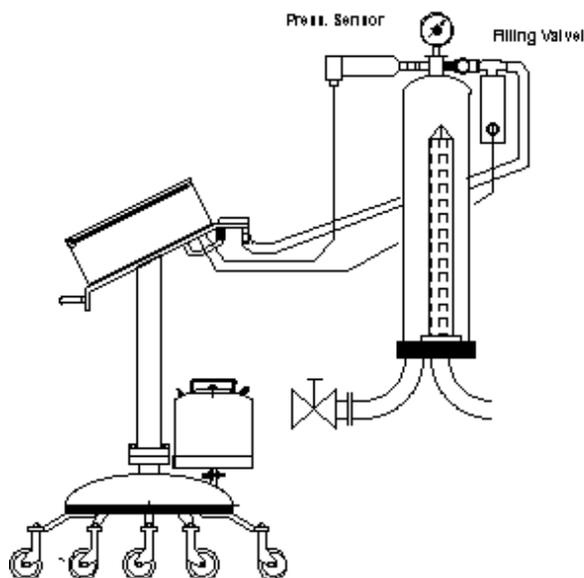
All the documents are prepared in English.



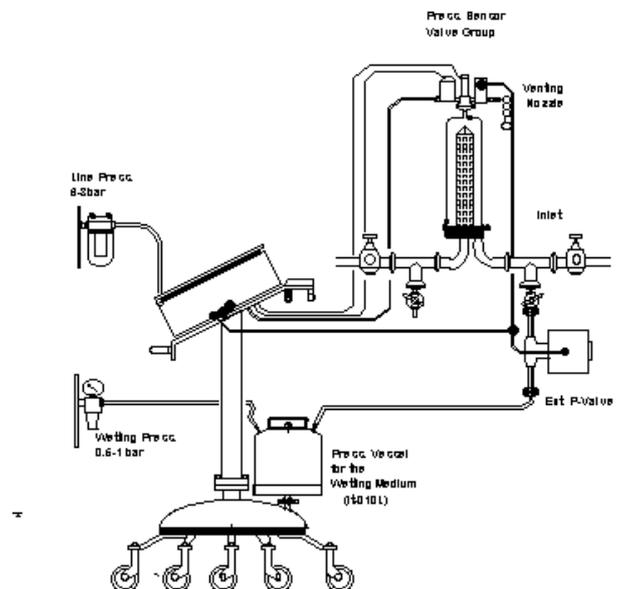
MOBILE FILTER INTEGRITY TROLLEY "ita-02"

Integrity tests on liquid filters (Leakage Tests on Huge Vessels or Huge Fermenters)

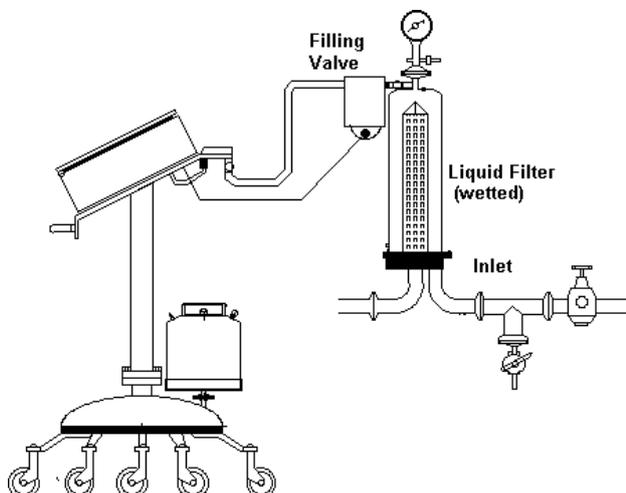
Filter Integrity Diffusion and Bubble Point Tests



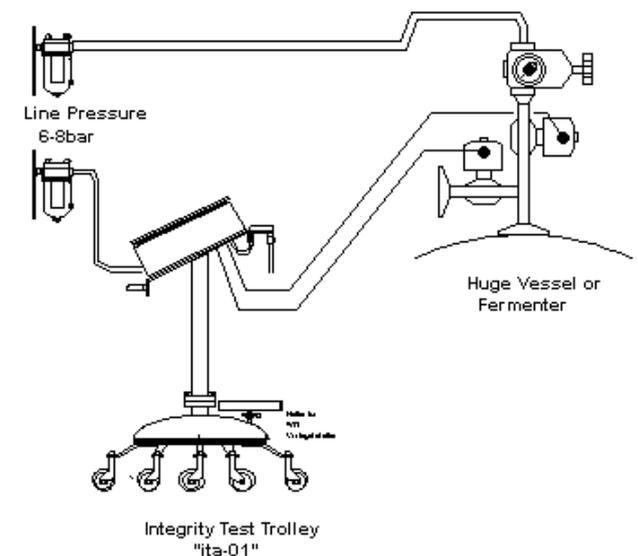
Filter Integrity Test with Wetting



Upstream Volume Measurement



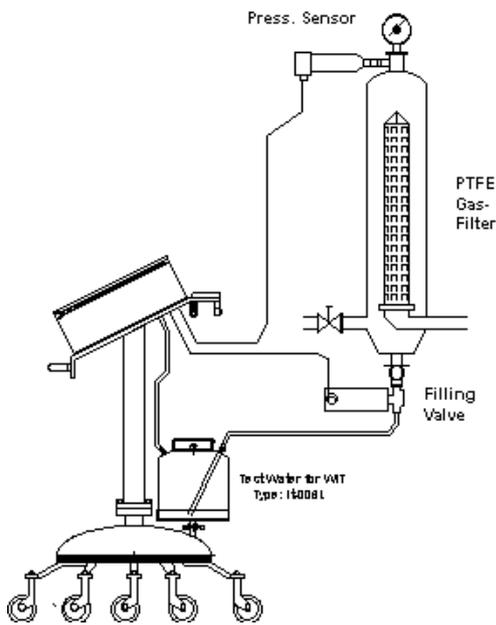
Leakage Tests on Huge Vessels



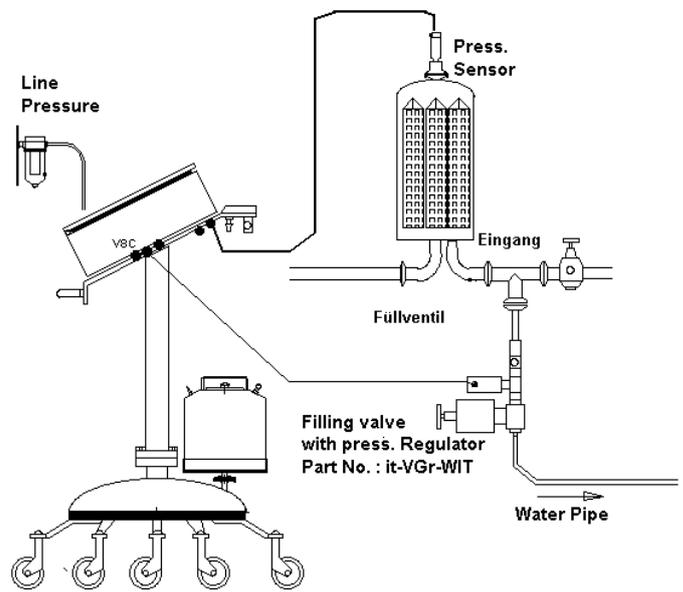
MOBILE FILTER INTEGRITY TROLLEY "ita-02"

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

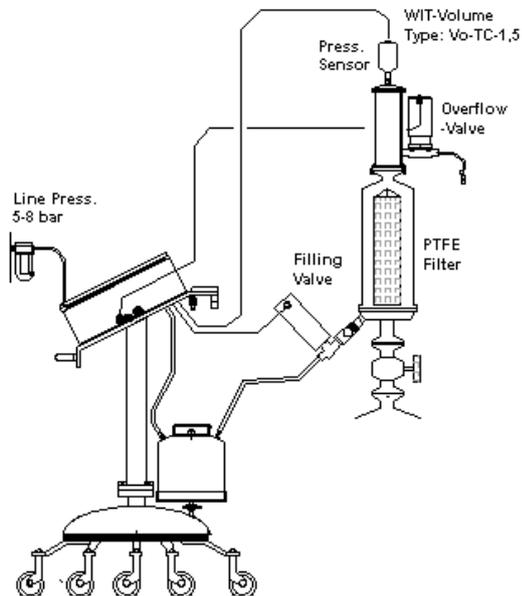
Water Intrusion Test Installation



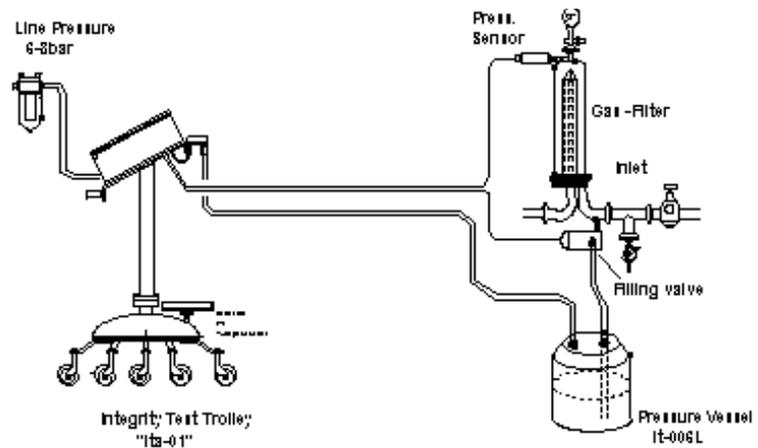
Water Intrusion Test on Huge Housings (approx. 150L)



Water Intrusion Test with filter Cooling



Remote controlled Water Intrusion Tests



MOBILE FILTER INTEGRITY TROLLEY "ita-02"

Printout

ITA-02- 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 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-02- FILTER TEST

SERIAL NO.: 0104434

PROGRAM NO.: 2

DIFFUSION TEST

DATE: 12.08.14 TIME: 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

ITA-02- 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

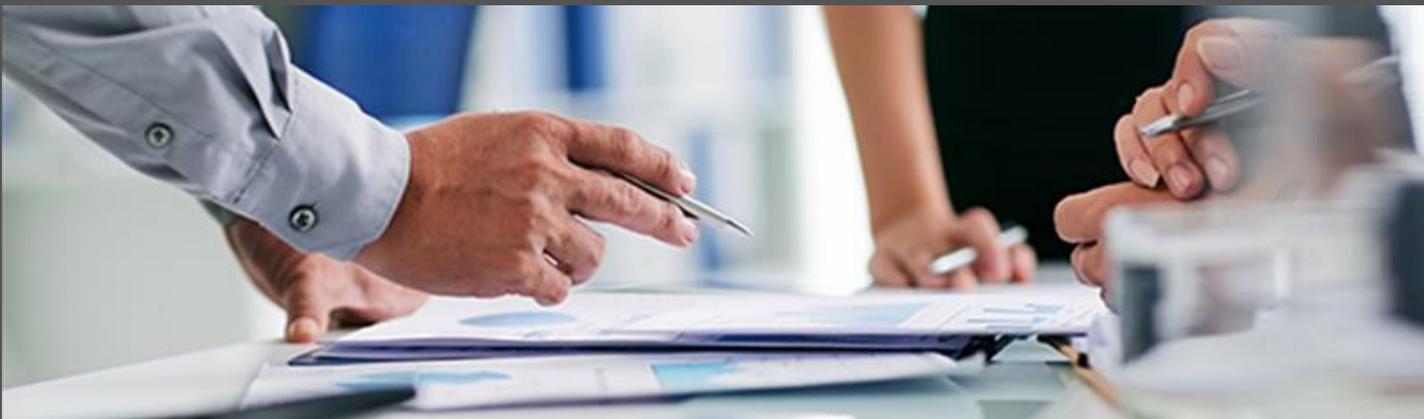
MOBILE FILTER INTEGRITY TROLLEY "ita-02"

SPECIFICATIONS

CABINET MATERIAL:	stainless steel 1.4301 (e-polished)
CABINET DIMENSION: (WITHOUT HANDHOLD, AND HOLDERS)	760x760x1111 mm
WEIGHT:	86 kg
PROTECTION CLASS:	IP 55
POWER SUPPLY:	mains adaptor 100-240 v/ac to 2x7,5V/3,3A
KEYBOARD:	infrared-alpha numeric (water protected)
SOFTWARE PROTECTION:	stored in Flash EPROM
MATRIX PRINTER:	normal paper, printout paper size: 58 mm
AMOUNT OF STORABLE TEST PROGRAMS:	2x100
AMOUNT OF STORABLE TEST RECORDS:	2x40 (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, 0-8barg)
BAROMETRIC PRESSURE SENSOR:	800-1090 mbar, rel. class 0,5
EXTERNAL PRESSURE SENSOR:	0-6 barg, rel. class 0,15 (alternative 0-4, 0-8barg)
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
VOLUME OF THE TEST PRESSURE VESSEL:	5.7L for each channel
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 >= 100mL/min max.resolution 5mL
THE DIFFUSION TEST:	5% of actual value >= 5mL/min max.resolution 0,1mL
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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