



Filter Integrity Tester it-02

- Compact and portable Integrity Tester
- Specifically developed for filter integrity testing in pharmaceutical and biotechnology applications
- Mains independent (Battery version)
- Testing on hydrophilic and hydrophobic membrane filters
- Comply with 21 CF Rpart 11 regulations





Product Description

The Filter Integrity Tester it-02 is the next generation of Van Borselen Filters proven integrity testing technology, designed for reliable filter integrity testing in pharmaceutical, biotechnology, food & beverage, and other GMP-regulated industries.

This compact, portable, and battery-operated instrument performs all standard integrity test methods for both hydrophilic and hydrophobic membrane filters. Thanks to its lightweight and ergonomic design, the instrument is ideally suited

for mobile applications and can be used conveniently in difficult-to-access locations such as large process vessels, autoclaves, freeze dryers, cleanrooms, and production areas. The it-02 features a high-resolution 7-inch capacitive touchscreen (1280 × 720 pixels) that provides an intuitive and modern user interface. A customizable Quick Access menu allows operators to launch their most frequently used test methods with a single touch, improving efficiency during routine operation.

Designed specifically for GMP-regulated environments, the system supports secure and compliant electronic documentation. Test results are displayed graphically in real time and can be exported as time-stamped and digitally signed PDF reports, ensuring complete traceability, data integrity, and compliance with regulatory requirements such as 21 CFR Part 11.

With its combination of advanced measurement technology, intelligent software, and user-friendly operation, the it-02 sets a new benchmark for reliable, accurate, and efficient membrane filter integrity testing.

Test Capabilities

- Diffusion Test (Forward Flow Test)
- Pressure Drop Test
- Low Pressure Drop Test on sterile bags*
- Diffusion and Bubble Point Test
- Diffusion Tests with the automatic filter wetting
- Water Flow Test (WFT, formerly known as Water Intrusion Test – WIT)
- Volume measurement (e.g. Upstream Vol.)

Power supply

Low-voltage: 67W, 20V/3,3A. Rechargeable battery or mains operation.

* – Additional accessories necessary!

Scope of Delivery



1. Filter Integrity Tester "it-02"

2. Reference volume it-350-VA

3. Power Supply 67W, 20V

4. Outlet tube

5. Air regulator with 8µm Filter and inlet tube

Capsule Holder and Ext. Vent-valve

Direct Connection of small filters to the Test Instrument

Filters and extremely small filters (e.g. capsules, 50mm disposables, mini cartridges and syringe filters) can be easily tested directly on the filter integrity tester "it-02" due to a special filter holder installed on the rear side of its cabinet.



Filter Testing with 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 Flow Test (WFT) can be carried out the same way.

Test Report Management

Printer

The integrated front-mounted thermal printer enables fast and reliable printing of test reports directly at the instrument. Since thermal printing technology is used, no ink or toner is required, minimizing maintenance and operating costs. Test reports can be printed automatically upon completion of a test or manually whenever required.

Thanks to the integrated SD memory card, the instrument can store more than 12,000 test reports, providing quick access to historical test data and allowing reports to be reprinted at any time.

PC Software "it-collector"

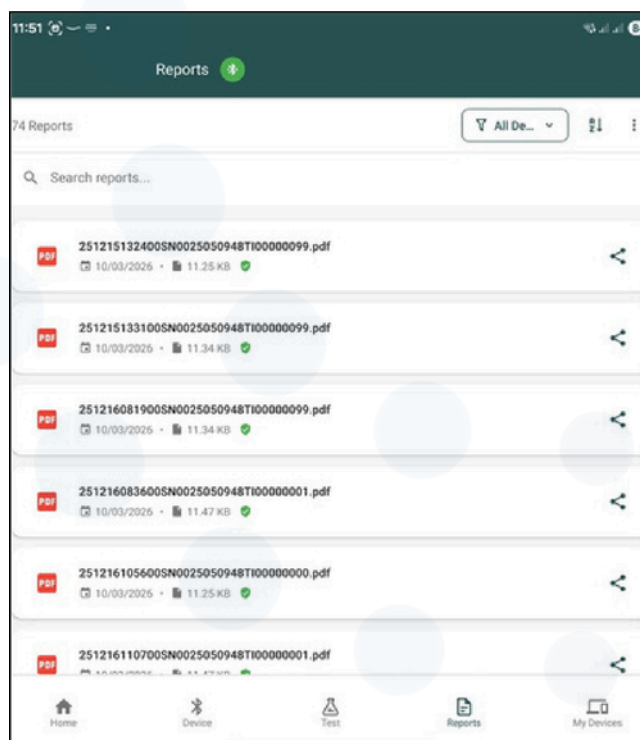
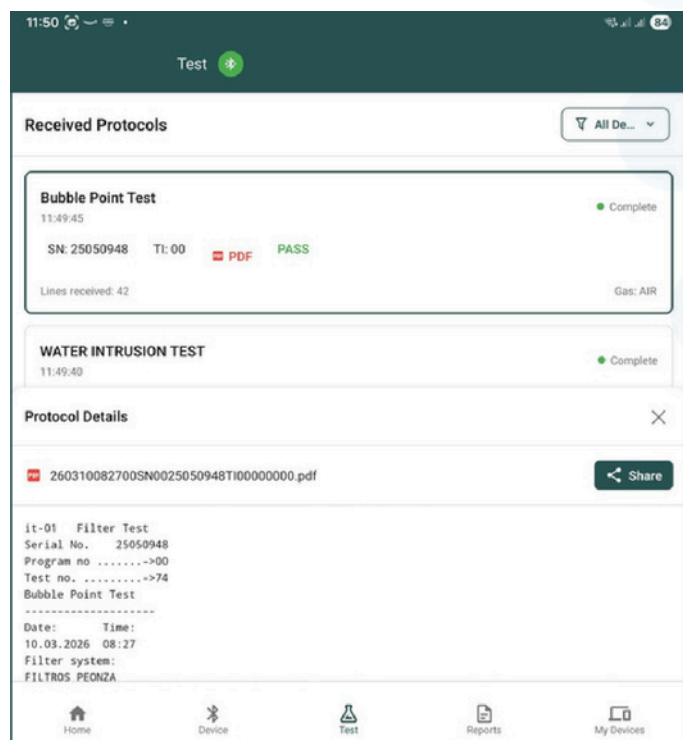
Software program "it-collector" is included in the standard delivery and supplied with the "it- 02". (Systems: Windows and iOS)

The "it-collector" software is a desktop application for PCs that allows test reports generated by the filter integrity test instrument to be received, managed, and archived. Test reports can either be saved as PDF files or printed directly via a customer provided printer.

The original test records remain stored on the filter integrity test instrument and are not transferred or deleted by the software.

Flow-Test "App-Collector"

The mobile app for smartphones and tablets is compatible with both iOS and Android devices. It enables users to conveniently receive, store, and manage test reports directly on their mobile devices. All test reports are automatically generated as PDF files and include a secure timestamp, ensuring data integrity and preventing any subsequent modification. This provides a documentation GLP-regulated reliable and compliant solution for GMP- and environments.



Filter Integrity Tester–Services

Calibration and Maintenance

To maintain measurement accuracy and support compliance with industry best practices, annual inspection and calibration of the sensors and pressure control system are recommended. Maintenance and calibration services can be performed either at the manufacturer's facility or, upon request, directly at the customer's site by our qualified service personnel.

All measuring equipment used for calibration is certified and traceable to DAkkS (German Accreditation Body) standards. Regular verification and monitoring of all calibration equipment are performed to ensure the highest level of measurement reliability and quality.



Qualification Services (IQ,OQ,PQ)

The Filter Integrity Testers "it-02" are designed to support qualification and validation activities in GMP-regulated environments.

Upon request, the instrument can be supplied with a comprehensive qualification documentation package, including Installation Qualification (IQ) and Operational Qualification (OQ) protocols and guidance. Performance Qualification (PQ) is typically performed at the customer's site. Upon request, Flow-Test can also provide on-site support for qualification activities. All qualification documents are provided in English or German



Printout Example

it-02- FilterTest

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 m bar

Water Flow:

1890 µL/t

Test passed

Programmer:

Heinz Rudolph

Sign. Operator:

Anja Gehne

it-02- 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

it-02- 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

Technical Specification

Cabinet Material:	Stainless steel 1.4301 (e-polished, splash protected)
Cabinet Dimension:	220x300x245 mm
Weight:	11,5 kg
Protection Class:	IP 65
Power Supply:	Mains adapter, low voltage: 20V/ 3,3A or rechargeable
HMI Touch:	battery 7-inch capacitive TFT touchscreen
Software Security:	Protected Linux operating system
Amount of Storable Test Programs:	>500
Amount of Storable Test Results:	>12.000
Pneumatic Connectors:	Stäubli RBE 03/ Stainless steel 1.4404
Internal Pressure Sensor:	0-6 bar. class: 0,2
Barometric Pressure Sensor:	800-1070 mbar, rel.- class: 0,5
External Pressure Sensor:	0-6 bar, rel.- class 0,05
Main CPU-Board	Raspberry Pi 5
Program Language:	Python
Display resolution:	1280 × 720 pixels
Data Transfer:	Serial communication via USB Type-C or Bluetooth®
Languages:	German, English
Measuring Units:	
- Pressure Drop Test:	0,1mbar
- Water Flow:	ml/min
- Diffusion:	mL/min (1000mbar, 20°C)
- Volume:	mL
Test Capabilities:	Water Flow Test (WFT), Diffusionstest, Pressure Drop Test, Bubble Point Test, Diff.+ Bubble Point Test, Volume Test
Pressure Vessels for WIT or Wetting:	5,7 Liter (also 10 Liter available)
Measuring Accuracy:	
- Pressure Drop Test:	+/-0,6mbar
- WFT:	≤ 3%
- Diffusion Test:	≤ 4%
- Bubble Point Test:	+/-50mbar
- Volume Test:	≤2 %
Environment Temperature:	5-40°C
Storage Temperature:	2-50°C
Rel. Humidity:	0-80°

Accessories and Adapters

Stainless steel pressure vessel

For the WFT-Test Water or wetting agent.
Material: stainless steel 1.4571 e-polished

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

5,7L Press. max:6 bar

10L Press. max:6 bar

19,5L Press. max: 6 bar

Connectors:

- Inlet side: Unvalved, G1/4"thread
- Outlet side: Valved female Stäubli connector RBE 03 with G1/4" thread

Material: stainless steel 1.4404

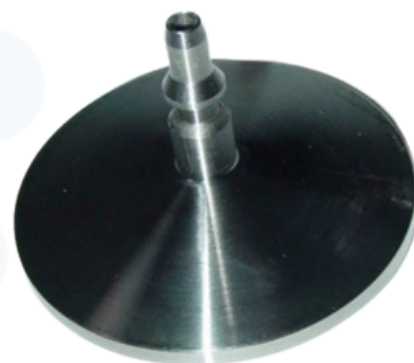


Tri-Clamp adapters

invarious sizes, equipped with a Stäubli RBE- 03 coupling nipple.

Material: Stainless steel 1.4404 (AISI 316L)

- 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)



Twin-Stäubli-Triclamp

TC1,5" (50,5mm)adapterfor 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



Accessories / Units for special Applications

Filter test unit "itB-10"

for multiple testing of tank vent filters in the pharmaceutical and food industries.

The low-pressure test box "itb-LP"

The Low Pressure Unit is an optional hardware accessory for the it-02 Filter Integrity Tester. Controlled directly by the integrity tester, it enables leak testing of sterile bag assemblies, small storage tanks, and fermenters. The test pressure range is 50 to 500 mbar. In addition, the Low Pressure Unit is equipped with a powerful vacuum pump that efficiently evacuates air from the test bag prior to testing, ensuring reliable and reproducible leak test results.



itB-10



itb-LP

"it-flush"

The Filter Integrity Tester it-02 features an integrated automatic wetting unit for hydrophobic membrane filters. The system utilizes pressure-assisted wetting technology to ensure fast, effective, and reproducible wetting of the membrane prior to integrity testing, minimizing operator intervention while maximizing process reliability. Depending on the filter configuration, individual wetting units are available for both cartridge filters and capsule filters, ensuring optimized wetting performance for a wide range of filter designs and applications.

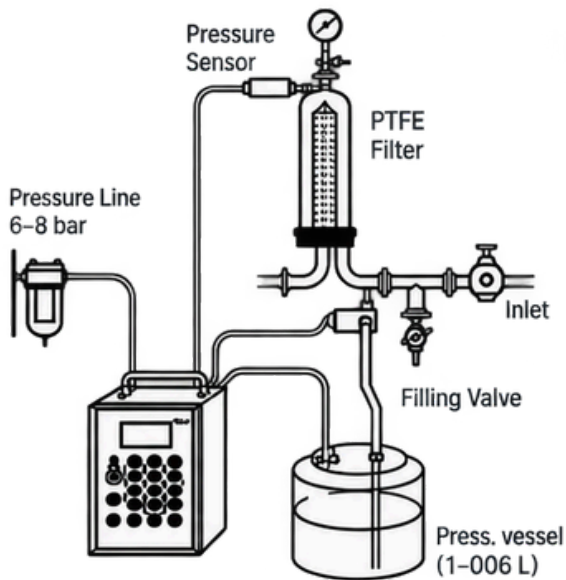
By combining automatic wetting and integrity testing in a single instrument, the it-02 significantly reduces handling time, improves process consistency, and increases operational efficiency.



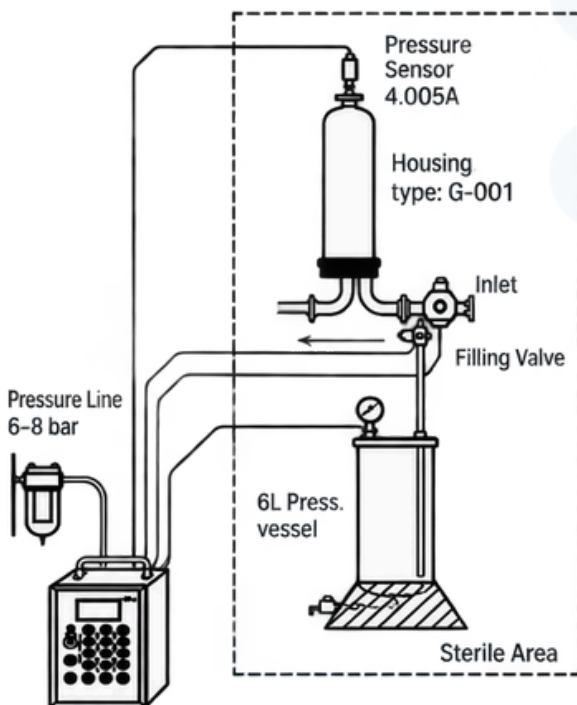
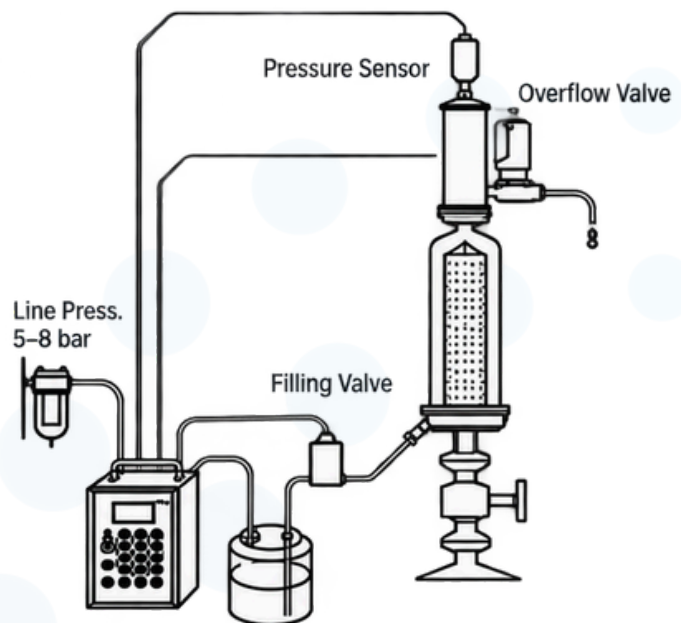
it-flush

Installation: Water Flow Test (Water Intrusion)

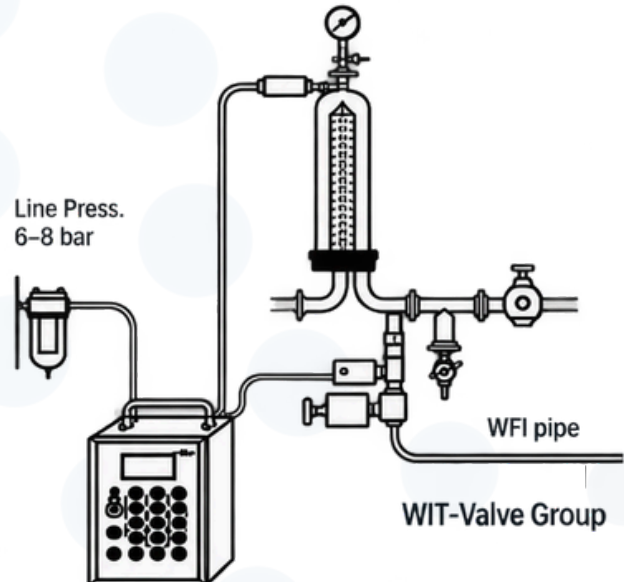
Installation: Standard Water Intrusion Test (WIT)



Installation: Water Intrusion Test (WIT) with filter cooling



Installation: "Remote Controlled"



Installation: Water Intrusion Test on huge filter systems

Installation: Diffusion Test, Pressure-Decay Test, Bubble-Point Test, and Volume Measurement

