PASS

Test ID: PSMA-105
Pressure Hold: **Pass**
Test Pressure: 50.0 psi
Test Result: 51.8 psi

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Filter Integrity Tester

Solution Loading

Automated Filter Integrity Tester

for Radiopharmaceutical Quality Control

www.**lablogic**.com

LabLogic
EXPERIENCE & EXPERTISE

Fully automate the process of bubble-point testing

The iPhase Filter Integrity Tester is a compact standalone bench-top unit capable of fully automating the process of bubble-point testing commonly used vented and non-vented sterilising filters used in radiopharmaceutical quality control.

The Filter Integrity Tester is designed to replace manual bench top systems or manual methods of testing sterilising filters to enable the following:

- Automate testing with calibrated sensors.
- Eliminate operator subjectivity of mesurment.
- Minimise operators exposure to radioactivity.
- Record and store results in non-editable log.

Benefits

Calibrated pressure sensors are used to measure gas pressure and deliver the true bubble-point.

Filters are wetted prior to the test to standardise the test to the filter manufactures specifications which eliminates the need for any product specific bubble-point pressure calibration.

Installation independent results

No need to calibrate pressure drop between the test devices pressure meter and the filter if the filter is located some distance away from the test device.

3 simple steps

Step 1: Select parameter

Select pressure hold test time and bubble-point pressure as per filter manufacturer specification's along with Test ID.

Step 2a: Wet filter

Load up to 35 mL of wetting solution (usually water) into the solution reservoir. The solution will be pushed through the filter to wash off residual product which could alter the bubble point.

This step standardises testing and performs the process as per the filter manufactures recommended test procedure.
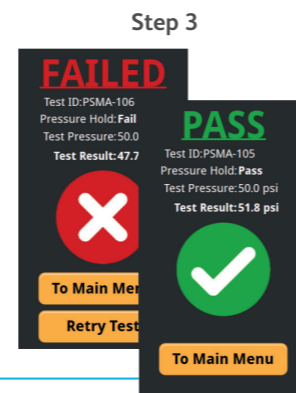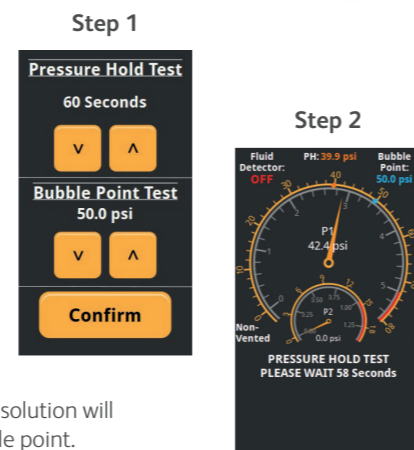
Step 2b: Pressure hold test

The test is started by pressure being slowly increased up to 80% of the bubble point pressure for a specific amount of time in which the system checks that there are no bubbles/pressure increase on the outlet of the filter.

Step 2c: Bubble Point Test

After the pressure hold test the Filter Integrity Tester slowly increases the pressure to check the bubble point. The Filter Integrity Tester will then record the pressure when bubbles appear/pressure increases on the filter outlet to determine the bubble point pressure.

Step 3: Results

Once the test is complete the filter integrity will display a pass or fail screen with the pressure result.

Solution Loading

Step 1

Pressure Hold Test
60 Seconds

Bubble Point Test
50.0 psi

Confirm

Step 2

Fluid Detector: **OFF** PH: 39.9 psi Bubble Point: 50.0 psi
P1 42.4 psi
Non-Vented P2 0.0 psi

PRESSURE HOLD TEST
PLEASE WAIT 58 Seconds

Step 3

FAILED
Test ID:PSMA-106
Pressure Hold:**Fail**
Test Pressure:50.0
Test Result:47.7

To Main Menu
Retry Test

PASS
Test ID:PSMA-105
Pressure Hold:**Pass**
Test Pressure:50.0 psi
Test Result:51.8 psi

To Main Menu

Sensor calibration

The Filter Integrity Tester requires the two internal pressure sensors to be calibrated once per year. This can be done in one of the two following ways.

Option 1:

Contact LabLogic's service support team at support@lablogic.com to schedule a service engineer to come out on site to calibrate your Filter Integrity Tester.

Option 2:

Ship the Filter Integrity Tester back to LabLogic and we will perform the calibration and have it shipped back to you.

Simple installation and data logging

Simply connect compressed air, power and waste bottle and its ready to go.

The Filter Integrity Tester is a non-shielded device, if testing radioactive filters then it needs to be located behind sufficient shielding.

Waste Bottle

Compressed Air

24 V Power Supply

Test history and data logging

Each test is logged with all details including Date, Time, Test ID, Bubble-point test pressure, Measured bubble-point and Test result.

Data is stored on the device and can be downloaded as a file onto a computer by USB connection.

Vented and Non-Vented Filters

The Filter Integrity Tester is compatible with both vented and non-vented filters as the device automatically detects the filter type and applies the applicable gas flow profile.

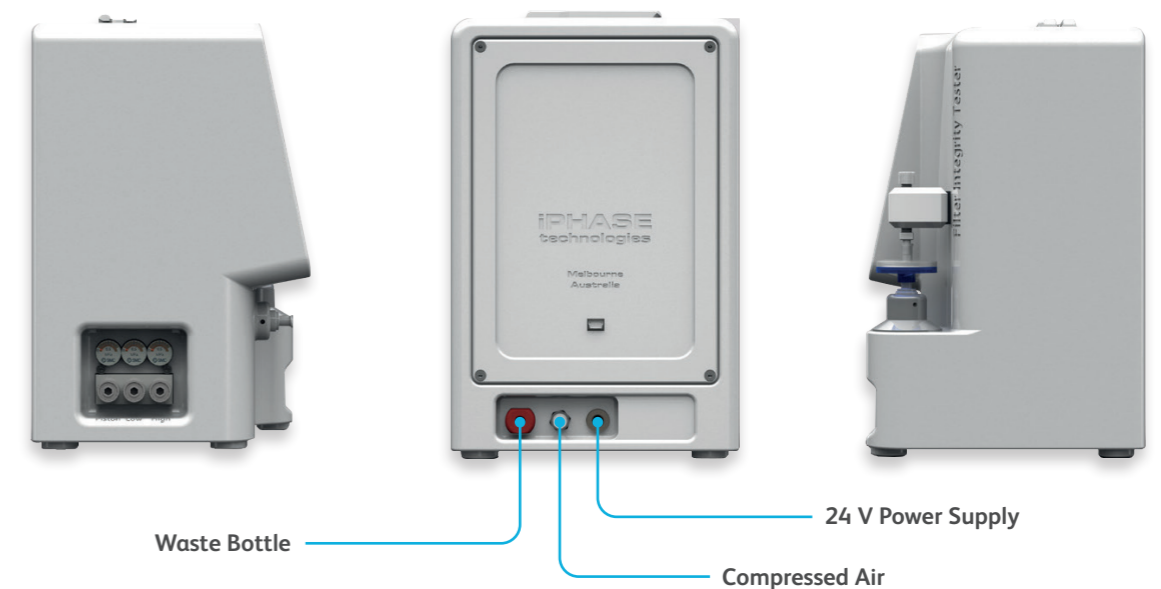This means that from the users perspective both types of filters are tested in the exact same way.

No need to seal vent holes!

Vented Filters

Non-Vented Filters

Technical Specifications	
Test Method	Non-destructive true bubble-point using calibrated pressure sensors
Sterile Filters	Non-vented and vented up to 35 mm diameter
Filter Wetting	Yes, by loading internal 40 mL reservior with desired solution volume
Gas Supply	Any gas 5 - 8 bar (73 - 116 psi), 1/8" OD push in connection
Power Supply	110 V-240 V, 50/60 Hz
Dimensions and Weight	15 cm (w) x h 23.5 cm (h) x 15 cm (d) (5.9" (w) x 9.3" (h) x 5.9" (d)) 1.9 kg (4.2 lbs)

Service and Support

Users of our systems can benefit from our comprehensive, fully inclusive service and support.

We can give reassurance that if things go wrong or you need expert advice, help is only an e-mail or phone call away.

Validation Services

Our Validation Service enables you to implement and get maximum value from your investments as soon as possible.

We work as a partner with your Quality Manager, System Manager and users to provide a tailored Validation Plan, suited to your needs. Our Validation Specialists who have many years' of experience in GLP system validation, detailed knowledge of our systems, together with other industry standard systems to help you meet company and regulatory requirements.

Training

LabLogic can provide a variety of training courses and workshops to help you get the most out of your instrument and software.

All training is performed by our expert Product and Support Specialists who have many years experience in the development and use of the instruments and software.

Certificates can be provided to complement your internal GLP training records.

LabLogic
EXPERIENCE & EXPERTISE

INVESTORS IN PEOPLE®
We invest in people Gold

Certificate No: 1535
ISO 9001

Certificate No: 10926
ISO 9001

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