Automated Filter Integrity Tester

For Radiopharmaceutical Quality Control

iPHASE technologies

www.iphase.com.au

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

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

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

Key Benefits

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

Filters are wetted prior to the test to standardize 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.

Vented & Non-Vented Filters

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

Vented filters

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

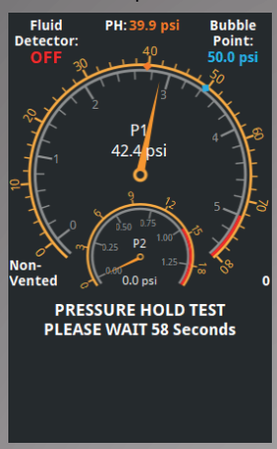
No need to seal vent holes!

Non vented filters

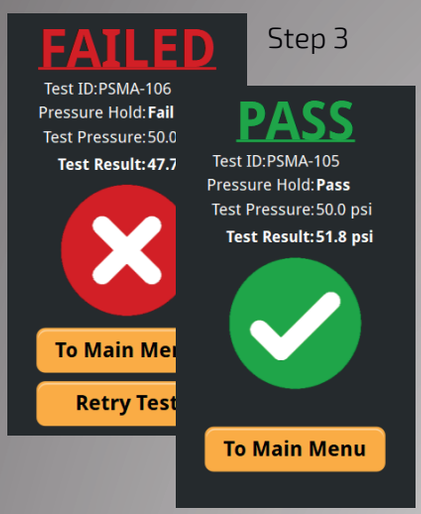
3 simple steps

Step 1

Step 2



Step 3



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 35mL of wetting solution (usually water) into the solution reservoir. The solution will be pushed through the filer 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.

Simple Installation & 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.

Compact dimensions
23cm (H) x 17cm (L) x 17cm (W)

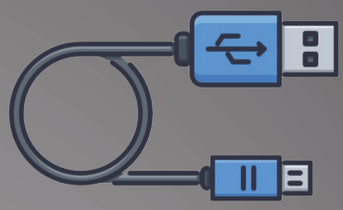
Sensor Calibration

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:
Attach a calibrated pressure meter to the device and calibrate the 2 internal pressure sensors using the calibration wizard (this takes about 5-10 minutes)

Option 2:
Ship the Filter Integrity Tester back to iPHASE and we will perform the calibration and have it shipped back to you in no time.

Test History & 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.

Technical Specifications

Specifications	
Test Method	Non-destructive true bubble-point using calibrated pressure sensors
Sterile Filters	Non-vented and vented up to 35mm diameter
Filter Wetting	Yes, by loading internal 40mL 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 & Weight	w 15cm x h 23.5cm d 15cm (w 5.9" x h 9.3" x d 5.9") 1.9kg (4.2 lbs)

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