

Automated Filter Integrity Tester 2.0

For Radiopharmaceutical Quality Control



IPHASE
TECHNOLOGIES

Automated Filter Integrity Tester

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 measurement.
- ✓ 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 manufacturers 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 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!

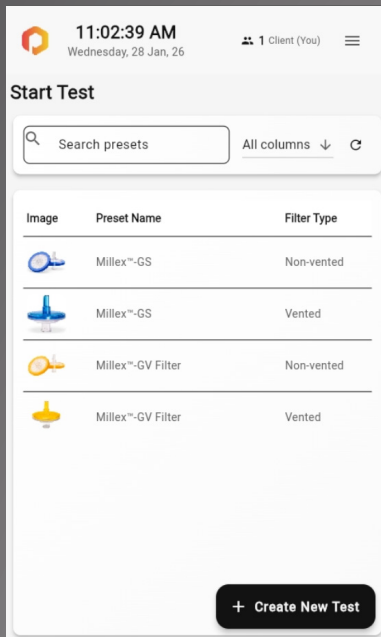


Vented filters



Non vented filters

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 35mL 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

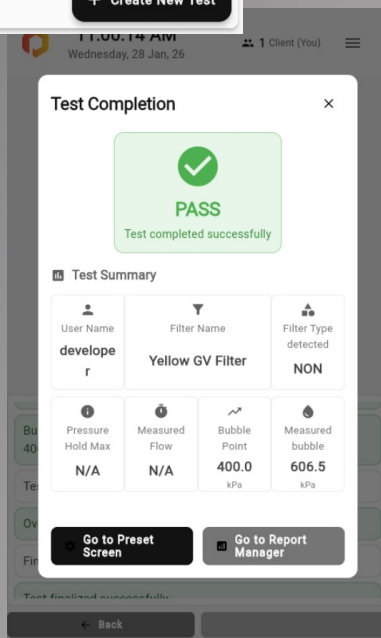
The test is started by pressure being slowly increased up to 80% of the bubble point pressure for a specific amount of time in which the system checks that there are no bubbles/pressure increase on the outlet of the filter.

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.



Key Benefits

- Simple Installation: Connect compressed air, power and waste bottle and its ready to go.
- Title 21 CFR Part 11 compliant software.
- Connectivity via WiFi, Bluetooth, Ethernet or USB 2.0 & 3.0.
- Remote access and control via network interface (Such as pc or tablet).
- Vaporized Hydrogen Peroxide (VHP) sterilization compatible .
- Compact dimensions: W 15cm x H 25.2cm x D 16.1cm
- Each test is logged with all details including user, Test ID, Bubble-point test pressure, Measured bubble-point and more.
- Print reports directly to networked printer.
- PETra LIMS support.
- Multiple languages such as English, German, Korean & more.
- Compatible with water, methanol & ethanol wetting solutions.

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.

FAQ

Can the Filter Integrity Tester be used inside an hotcell?

The FIT was designed as a standalone bench top device to replace manual bubble point testing rigs. The wetting solution needs to be loaded by syringe into the device, the touchscreen operated to start tests, and filters installed onto and removed from the device.

If wanting to operate the device inside a hotcell remotely, teletongs would be required so long as they can be used to install and remove filters from the device. If the filters has a luer lock outlet fitting, the filter would need to be screwed on/off whereas luer slip outlet fittings could be simply pushed on/off.

Technical Specifications

Specifications	
Test Method	Non-destructive true bubble-point using calibrated pressure sensors
Sterile Filters	Up to 35mm diameter Non-vented and vented Hydrophilic and Hydrophobic
Filter Wetting	Yes, by loading internal 40mL reservoir with desired solution volume
Gas Supply	Compressed Air, 5-7 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 25.2cm x d 16.2cm 1.9kg
Connectivity	WiFi, Bluetooth, 1 x Gigabit Ethernet, 2x USB 3.0, 2 x USB 2.0
Database	API based access to Relational SQL database, Relational SQL database SHA512 Password hashing, Test History, Audit logs, and settings remotely accessible Automatic rollover backups

