

Revised 3/8/08



Integrity Test Procedures

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Introduction

All integrity test procedures outlined below should be followed when performing integrity testing of membrane filters only. Use of other types of filters such as polypropylene or glass fiber cartridges will not give consistent or accurate results.

Cartridge Wetting

Prior to any integrity test procedure, the cartridge membrane must be thoroughly wetted otherwise hydrophobic or un-wetted spots will give an incorrect bubble point.

1. Cut off the polyethylene bag at the O-ring end of the cartridge. Be careful not to damage the O-rings.
2. Remove the polyethylene sleeve from the cartridge. The cartridge must be handled consistent with its intended use. For example, some applications may require special procedures such as, wearing of gloves, pre-sterilization of the cartridge, etc.
3. Place the cartridge into the housing and flow filtered water or the selected test fluid through the housing at 2 liters per minute for 10 minutes. Start closing down stream housing valve to reduce water flow and increase inlet pressure. Bring the inlet pressure up to **15-20 psi** by lowering the outlet flow. Be sure to vent the housing of air during this process or incomplete cartridge wetting may occur.

Cartridge Integrity Test – Bubble Point

Figure 1 represents a typical layout for an integrity test.

1. Remove the filter cartridge from the housing used for wetting the cartridge and drain all excess wetting solution from cartridge. Install it into the housing used for the integrity testing.
2. Starting with all valves in the close position, open V5.
3. Connect regulated air pressure line A to valve V2. Open V2 and purge the upstream water at 2 psig.
4. Close valve V5 and open valve V4.
5. Increase the pressure in increments of 2 psig holding for 5 seconds at each step until a continuous stream of bubbles is observed in the beaker. Record the pressure as the bubble point. Due to the subjectivity in the interpretation of this test, a 10 inch cartridge bubble point is arbitrarily defined as 50 ml per minute.

Note: If cartridge appears to fail the initial bubble point test, repeat Cartridge Wetting procedures increasing the rinse time to twice the initial amount to insure that the media has been properly wetted, and retest.

Pressure Hold Test

The Pressure Hold Test, also known as Pressure decay, is dependent on the diffusional flow and upstream volume. It can be calculated using the following equation:

$$\text{Pressure Hold Test Formula} = \frac{D(T)(Pa)}{V_h} = DP$$

Where:

D = Diffusion rate cc/min

T = Time (minutes)

Pa = Applied pressure

V_h = Upstream volume of apparatus (cc)

DP = Pressure Drop (psi)

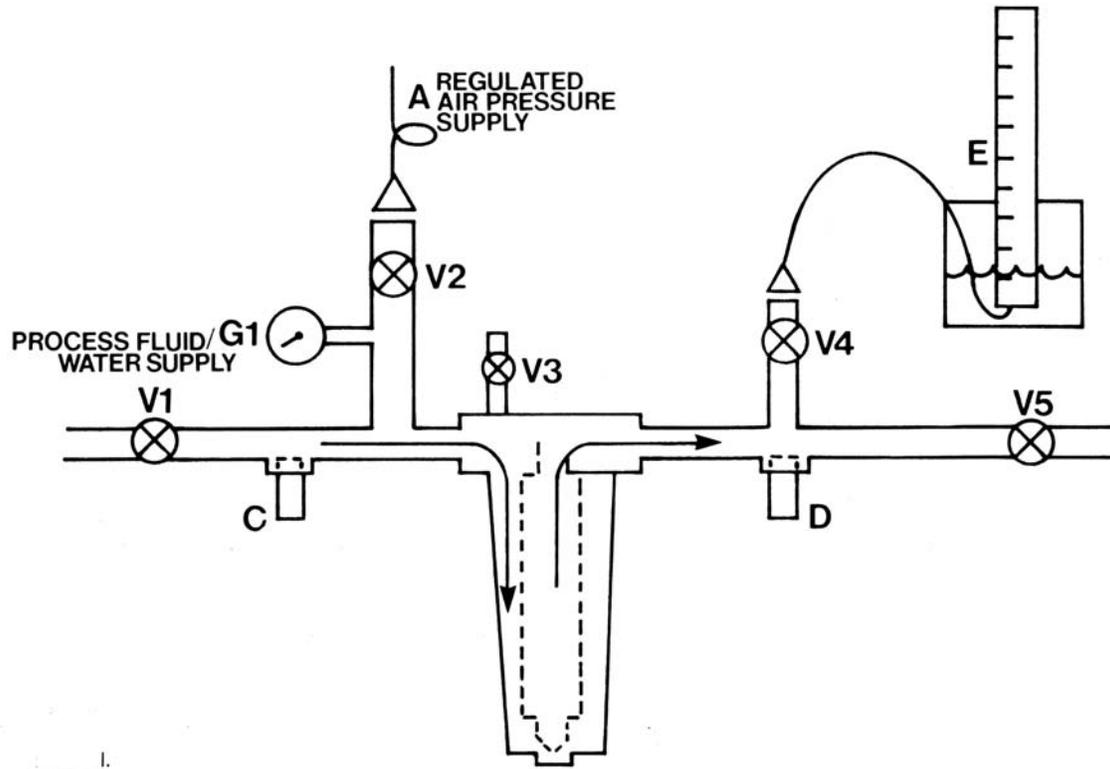
1. Install and rinse cartridges as per instructions
2. Starting with all valves in the closed position, open valve V5. Downstream must be open to ambient pressure
3. Connect gas pressure to line A and to valve V2. Open V2 and purge the upstream water at 2 psig.
4. Slowly increase pressure to the value specified and close V2. Note the pressure on G1. The system is considered integral when the measured pressure drop on gage G1 is less than the specified amount for the cartridge for the specified test time.

Note: If cartridge appears to fail the pressure hold test, repeat Cartridge Wetting procedures increasing the rinse time to twice the initial amount to insure that the media has been properly wetted, and retest.

Diffusive Flow Test

1. Install and rinse cartridges as per instructions
2. Starting with all valves in the closed position, open valve V5. Downstream must be open to ambient pressure
3. Connect gas pressure to line A and to valve V2. Open V2 and purge the upstream water at 2 psig.
4. Slowly increase the pressure, G1, to the specified amount, usually 80% of the bubble point.
5. Allow the system to equilibrate and maintain that pressure by adjusting the flow of air by adjusting the valve V2.
6. Measure the gas flow at the outlet for one minute with an inverted graduated cylinder (valve V4 open and V5 closed) or a flow meter at valve V5 or V4.
7. A diffusional flow reading higher than the specification is an indication that the system is not integral. Repeat Cartridge Wetting procedure increasing the rinse time to twice the initial amount to insure that the media is properly wetted, and retest. Also check the cartridge sealing in the housing.

Figure 1. Wetting and Integrity Test Set-up



Note:

Filter Integrity should be tested in accordance with current good manufacturing practice for all critical applications before and after use. It is up to each individual customer to determine the best method and protocol required. The information provided is a recommendation and guide for integrity testing procedures, and the importance of proper cartridge wet out.

For help determining the values or formulas needed, or additional information contact your local distributor or Critical Process Filtration direct.

Quality Standards

Our goal is to ensure our customers the greatest possible value for their filtration dollar. We achieve both low cost manufacture and high quality by employing state of the art manufacturing equipment. This computer controlled equipment is highly automated, reducing hand operations that compromise quality. Each operation including assembly, testing, cleaning, drying and packaging is done in appropriately rated clean rooms. Critical Process Filtration manages an ISO 9000 facility that produces validated products to rigorous standards. Manufacturing is controlled using sophisticated MRP software that is networked to work stations in manufacturing centers and inspection points. During the manufacturing and inspection processes, data is collected “real time” from machinery and measuring instruments. This allows variable and attribute data to be quickly and easily analyzed to facilitate constant improvements in both quality and cost.

Total Performance

Critical Process Filtration, Inc.® is a vertically integrated supplier of filtration products and services to industries in which filtration is considered to be a critical part of the manufacturing process. We manufacture a complete line of products to help you achieve all your filtration requirements from a single source.

