

# Integrity Test Services

Determining if a sterilizing grade filter is integral can be done via non-destructive integrity testing.

The test parameters for sterilizing grade membrane filters are based on correlating the test parameters with the LRV of the filter against a  $10^7$  CFU/cm<sup>2</sup> challenge with *Brevundimonas diminuta*.

The filter cartridges can be tested by industry standard procedures as recommended in PDA Technical Report 26.

The test parameters are dependent on the surface tension of the wetting fluid to be used. Therefore, the parameters used in the procedures, listed below, assume the wetting fluid to be water. For test values using wetting fluids other than water the adjusted parameters have to be determined.

Hall Pyke can carry out and advise on the following integrity test procedures:

- Bubble Point
- Water intrusion test
- Forward Flow Diffusion

Hall Pyke can carry out tests on site or in house, in our lab in Dublin. We can carry out tests on all makes of filters including PALL™, Parker Dominick Hunter™, Amazon™, Millipore™ and Sartorius™.

## Bubble point test

The basis for the integrity testing of filters depends upon the interpretation of airflows through membranes wetted by water or other fluids. The bubble point measurement identifies the largest (diameter) pores present in a membrane by the differential pressure required to empty them of their water. The largest (diameter) pores are vacated first. The pores thus sized are correlated with their ability to restrain the passage of organisms. It is this correlation that enables a filter to be characterized and selected for an application requiring a given pore retention value.

The differential pressure supplies the work function necessary to disrupt the bonding between the water molecules and the molecules of the hydrophilic pore surface that constitutes wetting, and to forcibly separate the water from the pore walls. The bonding strength of the wetting interaction to be overcome is peculiar to each filter/fluid combination

The utility of the bubble point derives from its identifying a filter's largest pores as measured by the differential pressure required to expel the water from a wetted filter

## Diffusion flow test

In the diffusive flow test the membrane is wet with water, and the upstream gas is then held constant at a specified pressure near, but somewhat below, the bubble point of an integral filter. A measurement is made of the flow rate of gas through the filter and compared to the manufacturer's specification.

A measured flow rate equal to or less than the specified value indicates that the filter is integral. A higher flow rate indicates that the filter being tested has pores or defects which were purged of water at the test pressure, resulting in bulk flow through the filter.

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## Water Intrusion Test (WIT)

The water intrusion test measures the decay rate of a pressure level imposed upon a hydrophobic filter enveloped by water. Using an automated integrity tester, a particular decay level is identified as the point at which water enters the largest pores of the filter.

## Hydrophilic Surface Deposits

The water intrusion test depends upon and measures the hydrophobicity of the filter. Only the experimentally demonstrated correlation of its values with the entrance of water into the hydrophobic pore structure establishes it as an integrity test. But the basic measurement of filter hydrophobicity is itself an inherent requirement in its pertinence to air filter reuse. Consider an integral air filter that contains hydrophilic deposits upon its surface. They may encourage microbial growth and ultimately, organism penetration. Solely ensuring air filter integrity, however essential, is not enough in air filter usage. The filter's full hydrophobicity must also be assessed to ensure freedom from compromising hydrophilic impurities.

