

ABSTRACT OF INTEGRITY TESTS

- As filter products are widely used by a number of industries to achieve required levels of purity in liquids and gases, verification of filter performance has become an important issue in several industries. This has led to the development of Integrity testing of filters.
- We conduct Integrity testing of various media filters using different Test methods via an automated integrity tester i.e. FIT it-01(Filter integrity tester, manufacturer- Flow Test GmbH), which offers non-destructive methods for proving the capability of a filter product to meet its stated performance when it is installed in an application.



Various Integrity Test conducted using FIT it-01 are as follows –

- ◇ The **Water Intrusion Test (WIT)** measures the volumetric flow rate of water that intrudes into a hydrophobic media /membrane of the cartridge at an applied pressure per 10 minutes. It is a highly sensitive, integrity test only for hydrophobic sterile air filters, which is carried out without the use of solvents such as Iso-propanol. The pores of hydrophobic filters will resist the passage of water up to a certain pressure. The pressure at which water will pass through the pores of a hydrophobic filter is inversely proportional to the size of the pore.

The **Hardware Volume** is a parameter of a water intrusion test program. It is the volume between the Top end of the filter membrane and the pressure sensor situated at the top end of the housing

Merits

- Only water required as the test liquid, no alcohol needed.
- No need to handle flammable liquid.
- Contaminants such as solvent mixtures are avoided.
- The test can be performed in place after steam sterilization.
- Filter is not wetted ready for use immediately after testing.
- No time – consuming for wetting procedure.

Demerits

- This test is very sensitive test, if there is a change in average pore size of membrane the WIT value may differ.
- Temperature of water should be at room temperature.
- It can be used only with difficulty as an in situ test.
- Solvent residue can contaminate the filtrate side and create hydrophilic areas.
- The drying procedure is time consuming.
- Any contaminant, creating hydrophilic areas, will not be detected.
- Specific test areas and equipment is required due to solvent vapour.

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- ◇ **Bubble Point Test (BPT)** measures the minimum differential pressure required to form a bubble through its largest pores present in wetted filter media / membrane of the cartridge. It is generally used to identify the presumed pore rating of a membrane. It represents the force necessary to break the bond of the intermolecular attractions that characterize the wetting of the filters solid surface by the liquid. There is always a diffusion of air before the bubble point test initialized. For every 10° C there is approx 2% change in the bubble point value.

Bubble point shows the flow of air forming a bubble through its largest pores present in the membrane of the cartridge.

Merits

- One of the great advantages of the bubble point test is that it can be performed on filters under actual use conditions and with any filter.
- It is a non-destructive test, thus it does not contaminate the filter and so can be used to determine the integrity of a filter at any time, as well as establishing the absolute rating.
- In the future, with further advantages in computer software and control, it may be possible to use the data on flow rate or pressure increases to more accurately determine what happens in a sample before the bubble point is reached, such as diffusion.

Demerits

- Ensure that the filter is thoroughly and uniformly wet as per wetting procedure. Any dry pores in the membrane will result in test failure.
- Contamination of the filter should be avoided as it can adversely affect the wetting of the membrane thus resulting in a false failure.
- There is always a diffusion of air before the bubble point test, this pre-mature air flow should not be assumed as bubble flow observation while performing manual test.
- Failure to wet the filter may result in premature air flow resulting in false failure. Rewetting is required in such case.
- Test parameters may vary by change in wetting fluid due to change in surface tension of the liquids.

- ◇ The **Diffusion Test (DFT)**, also known as **Forward Flow Test** represents the gas flow rate resulting from diffusion of gas across a wetted filter media/membrane of the cartridge at an applied differential pressure of (approx. 80%) of the bubble point for that cartridge. It is generally recognized as a non-destructive integrity test for membrane filters. When the Trans membrane pressure increased the diffusive gas flow through the wetted membrane pores will

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also increase proportionally that is diffusion range. For the test only non soluble gases can be used, normally air or nitrogen.

The observed rate of diffusion measured is actually the total volume of the flow from the pores. The **Upstream Volume** is a parameter of a Diffusion test program. It is the volume between the inlet valve of a filter system and the wetted filter cartridge. To reach high volume test accuracy it is necessary to adapt the reference volume to the size of the volume which should be measured.

Merits

- It is a non destructive test.
- It is a non-destructive test, thus it does not contaminate the filter and so can be used to determine the integrity of a filter at any time, as well as establishing the absolute rating.

Demerits

- Ensure that the filter is thoroughly and uniformly wet as per wetting procedure. Any dry pores in the membrane will result in test failure.
- Test parameters may vary by change in wetting fluid due to change in surface tension of the liquids.
- Contamination of the filter should be avoided as it can adversely affect the wetting of the membrane thus resulting in a false failure.

Note - The filter manufacturer has to specify for every kind of filter the necessary integrity test parameters and limits. Please refer reference document, validation guide, data sheet to check the test values to input during test.

The filter element is intact if the test results are in the limit. Temperature variations will result in test failures; entry and exit through any outside doors that result in temperatures changes during testing should be restricted.