

Application Note

Technical Application Publication

Assuring the Performance of Sterile Gas Filtration in Drinks Packaging



Summary

The performance of sterile gas filter systems is critical to a plant's Quality Assurance objective of protecting their product from contamination during production and packaging. The on-going performance of a plant's sterilizing grade gas filters can be checked by routine integrity testing as part of their HACCP plan. Most integrity testing methods are time consuming and difficult to perform, thus conflicting with the demand for efficient operation for leading beverage processes.

The aerosol challenge test, performed by Parker domnick hunter's Valairdata 3 provides a number of process advantages by being capable of testing both depth and membrane style sterile gas filters in-situ, quickly and easily.



Key Benefits:

- **Speed** – The Valairdata 3 can be used to test filters in situ quickly and easily, with results obtained in a matter of seconds. This drives cost savings in comparison to other testing methods by saving valuable production time.
- **Accuracy** – The Valairdata 3 aerosol challenge is fully correlated to aerosolized bacterial challenge with *Brevundimonas diminuta*, *Bacillus subtilis* and MS-2 Coliphage under ASTM guidelines. The ability to accurately detect minor filter flaws increases process control and helps safeguard the product from contamination.
- **Portability** – The lightweight, portable design and enhanced battery allows operators to test filters in-situ. This negates the repeat removal and re-installation of test filters, thus reducing potential filter damage through mishandling.

Introduction

The growth of aseptic filling within the soft drinks industry has seen a significant increase in recent years, driven by a demand for fresh, healthy, natural products which are low in fats, salts, sugars and preservatives. Unfortunately, reducing the level of these constituents provides the ideal environment for bacterial growth.

Bacterial contamination presents a significant processing problem which, if not addressed appropriately, could result in product re-work, wastage or recall, all of which contribute to significant processing costs. As a result, manufacturers employ microbial stabilization or sterilization techniques throughout their production processes to eliminate

contamination and reduce the levels of microorganisms in their products for safe consumption.

In aseptic filling, the microbial content of the product is stabilized before it is packaged, typically using one or a combination of methods such as pasteurization and filtration. Stabilizing the product before packaging creates the need for a completely sterile environment when packaging, to prevent any other microorganisms from entering the product. A key consideration in doing this is the compressed air or other gases that come into direct contact with the product or packaging. The gas used to dispense the product into its container and the gas

used to blow containers serve as the two key examples of where sterility is absolutely essential to maintain product quality. To achieve food grade compressed air sterility, a range of filtration and separation techniques are typically employed to remove each contaminant before final sterile filtration² (see table 1 below).

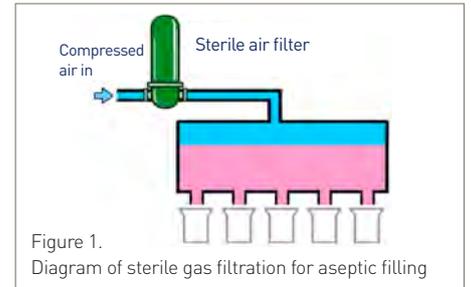


Figure 1. Diagram of sterile gas filtration for aseptic filling

| Contamination Reduction / Removal | | | | | | | | |
|-------------------------------------|----------------------|--------------|----------------|--------------------------------------|-----------------|------------|-----------------------------|--------------------|
| Purification Equipment Technologies | Bulk Condensed Water | Water Vapour | Water Aerosols | Atmospheric Dirt & Solid Particulate | Micro-organisms | Oil Vapour | Liquid Oil and Oil Aerosols | Rust and Pipescale |
| Water Separators | • | | | | | | | |
| Coalescing Filters | | | • | • | • | | • | • |
| Adsorption Filters | | | | | | • | | |
| Adsorption Dryers | | • | | | | | | |
| Refrigeration Dryers | | • | | | | | | |
| Dust Removal Filters | | | | • | • | | | • |
| Microbiological Filters* | | | | | • | | | |

*To ensure the highest level of beverage safety and shelf life, Parker domnick hunter recommends that all contact and non-contact high risk is treated with a sterilizing grade filter to remove all microbial contamination.

Table 1. Summary of purification technologies applicable to eliminate the main contaminants of compressed air²

The sterile filtration of compressed gases is an essential consideration in the HACCP (Hazard Analysis of Critical Control Points) framework. HACCP is an internationally recognised approach for the systematic identification, control and on-going monitoring of potential hazards in a beverage production process, principally aimed at protecting consumer health. Sterile filtration of gases which come into direct contact with the product or packaging are highlighted as Critical Control Points in the HACCP plan. As such, a monitoring programme is required to make sure the filter system is fit for purpose and is capable of delivering sterility throughout its entire service life.

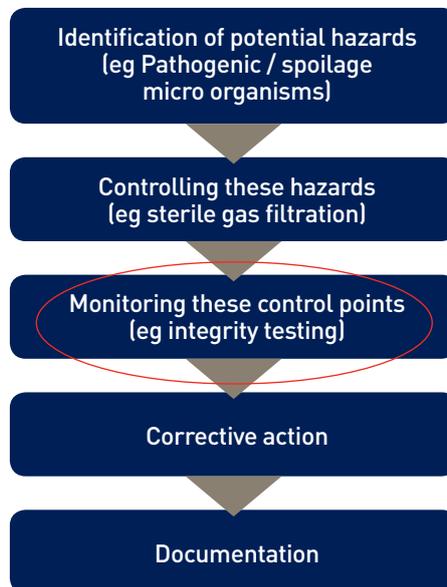


Figure 2. Summary of HACCP plan adopted by beverage producers

Sterile Gas Filter Integrity Testing

Assurance of Hazard Elimination

The ability of sterile gas filter systems to provide sterility during use will have been validated by the filter manufacturer. Typically, this will have been done through extensive bacterial challenge testing, where the filter will have been exposed to high levels of bacterial cells per square centimetre (typically 10^7 cfu *B.diminuta* or *B.subtilis* per cm^2). This validation is used to demonstrate that a sterile gas filter will deliver sterility under set operating conditions¹. However, gas filters can be damaged in situ, termed as having 'lost their integrity', if exposed to conditions outside their validated limits. Various factors can cause or contribute to filter damage, such as mishandling on installation, stress during steam sterilization (SIP), contact with aggressive chemicals or puncturing from finings in the pipework.

In order to reduce the impact of processing with a filter failure as best possible, any filter failure needs to be detected as soon as it occurs. This is done through integrity testing; a means of verifying the ability of a filter to provide the required quality of filtrate. Through correlation of an integrity test to a live bacterial challenge, integrity testing is used to give assurance of filter performance within an application¹.

Currently, sterile gas filter systems are engineered to provide extended service lifetimes to suit the demand for increased process efficiency and reduced operational costs required by leading beverage

processes. An increase in service lifetime of the filter further drives the need for routine integrity testing, so that the performance of the filter system can be monitored and assured throughout its complete operational life. As most beverage processes are also fast paced production environments driven by efficient operations, there is also a demand for filter integrity testing to be a quick procedure, requiring little process downtime or operator input.

There are various traditional integrity test methods available to monitor the performance of a sterilizing gas filter. Such methods (Diffusional Flow, Pressure Decay, Bubble Point, Water Intrusion) are widely accepted methods which have been developed in-line with pharmaceutical processes¹. Although they are reliable in terms of determining filter integrity, they have significant disadvantages when employed to integrity test sterile air filters for fast-paced beverage production

The main disadvantage of these methods for the beverage industry usually arises from the time-consuming operations required to prepare the filter for the test and to restore the filter system back into the process. Such operations include wetting the filter medium with a suitable solvent and the subsequent flushing and / or drying of the filter after testing. Another disadvantage of the liquid based methods is that they are not compatible with sterilizing gas filters which use a depth style filter matrix as opposed to a membrane as the

filter layer.

Gas sterilizing filter systems which use depth style media as the filtration layer, such as Parker domnick hunter's HIGH FLOW BIO X⁴, are suited to beverage operations due to the superior flow rates which can be achieved over membrane style filters, such as Parker domnick hunter's HIGH FLOW TETPOR II⁵. A superior flow rate per given pressure drop will improve filter system and process economics by two main mechanisms:

1. Smaller filter systems can be used for a given flow rate, which can reduce replacement element costs.
2. Reduced demand from the compressors, will yield a reduction in energy costs.

As many beverage production processes use sterilizing grade filters which have a depth media as the filter layer, there is a need for an integrity test which can also be used for this format of filter. The aerosol challenge test method performed by the Valairdata 3 satisfies this requirement as the method is applicable to filters using both membrane and depth materials.

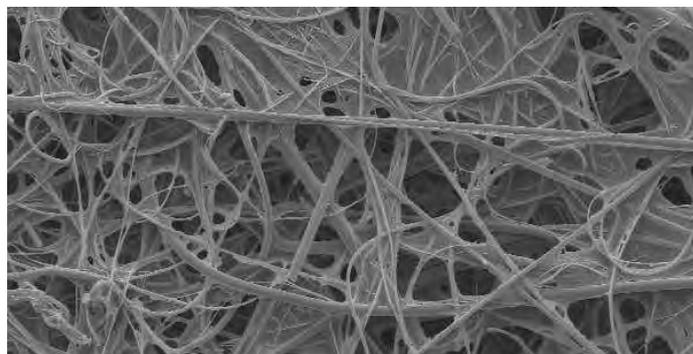
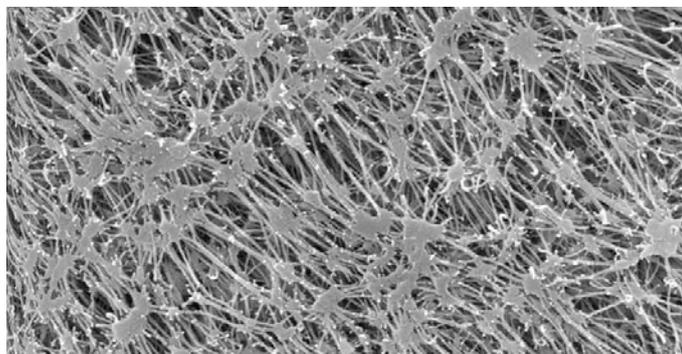


Figure 3. SEM images of sterile gas filter media, PTFE membrane (left) and depth media (right)

Aerosol Challenge Testing with the Valairdata 3

Test Principles

During the aerosol challenge, the Valairdata 3 challenges the test filter with a high concentration of aerosolized oil droplets (FDA approved for food use) within the 0.2µm - 0.3µm size range (figure 4).



Figure 4.

This size is considered the most penetrating particle size (MPPS) for a sterilizing air filter, as retention mechanisms in gas are also influenced by

electrostatic interactions, Brownian motion and inertial impaction, aside from size exclusion. The test simulates an aerosolized bacterial challenge under high loading, worst-case conditions. Any aerosol which passes through the filter to the downstream, sterile side is directed through a laser particle counter which directly detects the presence of any oil and calculates a percentage penetration value. On this basis a pass or fail result for the test filter is established.

As the retention ability of the test filter is actually tested during an aerosol challenge, the method can easily be applied to both depth and membrane style sterilizing grade gas filters. In addition to this, the method also carries the following process advantages.

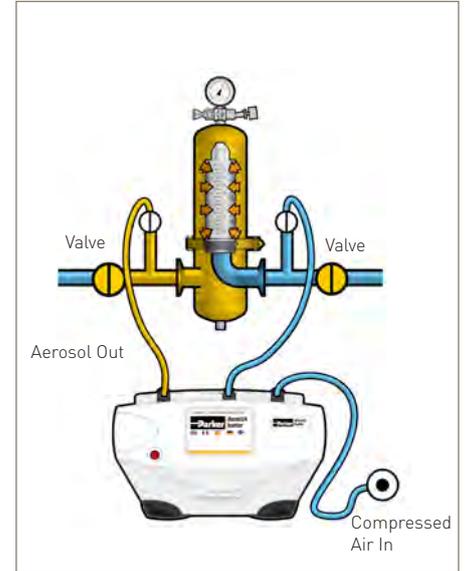


Figure 5.
Schematic diagram of Valairdata 3 test set-up³

The Fast Solution

The Valairdata 3 can be used to test filters in-situ quickly and easily; the test time for a 10 inch filter is just 30 seconds. The test filter can be returned to process immediately following testing with no flushing or drying required, significantly reducing system downtime.



The Accurate Solution

The Valairdata 3 aerosol challenge is fully correlated to aerosolised bacterial challenge with *Brevundimonas diminuta*, *Bacillus subtilis* and MS-2 Coliphage under ASTM guidelines, providing assurance of retention of all bacteria, spores and viruses in an airborne state. The unit offers increased test sensitivity versus traditional liquid based methods, particularly on larger filter systems.



The Portable Solution

The lightweight, portable design and long-life battery allows operators to test filters in-situ. This eliminates the risk of filter damage during removal / re-installation whilst transferring the test filter to a testing station. Once testing is complete, the results are easily transferred from the unit via a USB data stick for easy traceability of the Critical Control Point performance.



Conclusion

Monitoring the performance of sterile gas filters used at critical control points is recommended to safeguard the bottling process from the risks of microbial contamination and is a requirement of the plant's HACCP plan. The aerosol challenge test performed by the Valairdata 3 can be used for both depth and membrane construction filter elements and provides accurate filter integrity results quickly and easily. The Valairdata 3 therefore fits well within a beverage producer's HACCP framework and production objectives of maintaining product quality and increasing operational efficiency.

For further information, please contact your Parker domnick hunter representative.

References:

1. PDA Technical Report 40, Sterilizing Filtration of Gases
2. High Quality Compressed Air for the Beverage and Bottling Industries, Parker domnick hunter
3. Valairdata 3 brochure, Parker domnick hunter
4. HIGH FLOW BIO X data sheet, Parker domnick hunter
5. HIGH FLOW TETPOR II data sheet, Parker domnick hunter

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