Valairdata 3

Validation Guide, Revision 1.0

aerospace
climate control
electromechanical
filtration
fluid & gas handling
hydraulics
pneumatics
process control
sealing & shielding

Parker | domnick hunter

ENGINEERING YOUR SUCCESS.

Contents

1. Introduction

The Valairdata 3 is an aerosol based challenge test unit used to verify the integrity of a sterile gas filter. As such the test method is required to correlate with an aerosolised bacterial challenge. The Valairdata 3 is shown to be a far more searching test than actual aerosol bacterial / phage challenge with the following organisms:

- *Brevundimonas diminuta*
- *Bacillus subtilis* spores
- MS-2 Coliphage

The reason for performing correlation work with three organisms is that it provides a broad range of particle sizes from 0.02µm to 1.0µm. This also allows comparison with the classic theory of capture mechanisms. This guide provides all the information required for the support of the Valairdata 3 as a valid method for integrity testing sterile gas cartridges.

The data to support the correlation is taken from an original independent test report (ref 510185) on the Valairdata 1 performed by the Centre for Applied Microbiology, Porton Down. The two Valairdata systems are based on identical aerosol generation systems, operate at comparable flow rates and only differ in the use of a higher sensitivity aerosol detection system in the Valairdata 3. It is therefore possible to correlate the two systems albeit that the Valairdata 3 will provide enhanced sensitivity of detection in actual use.

NOTE

If printed with the banner UNCONTROLLED COPY, this validation document has not been registered. If you wish to receive amendments and updates automatically, then please contact the department below or fax this page with your name and address and we will send you a registered copy:

The Quality Assurance Department
Parker Hannifin Manufacturing Ltd
Durham Road
Birtley, Co. Durham
DH3 2SF, England
phone +44 (0)191 4105121
fax +44 (0)191 4105312
email: dhprocess@parker.com
www.parker.com/processfiltration

Registered Holder Information

Name: .....

Company: .....

Department: .....

Address: .....

.....

.....

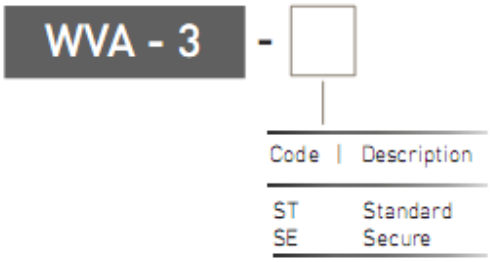
Registered No. .....

Date Issued: .....

Signed .....

2. Product Coding

Each variant can be uniquely identified using the following coding system:

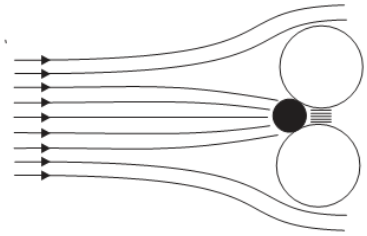


Instrument Options	WVA-3-ST (Standard)	WVA-3-SE (Secure)
Design environment approvals	GAMP 5	GAMP 5
21 CFR Part 11	No	Yes (transferred data is user's responsibility)
Security user levels	Operator Administrator	Operator - password protected Administrator - password protected
Audit trail	No	Yes

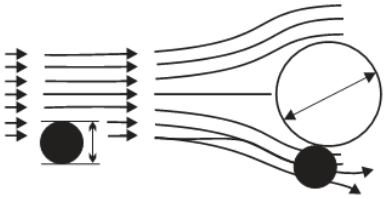
Technical Specifications	
Weight	8kg
Instrument size	Width: 363mm Height: 308mm Depth: 155 mm
Electrical requirement	Battery operated 3.2V / 16Ah & mains 100-240 VAC : 50/60 Hz
Laser	Type: Solid state laser diode Power: 24 Volts DC Sample flow rate: 0.1cfm
Aerosol generator	Aerosol generated from Shell Ordina EL white mineral oil FDA:178-3620
CE standards	LVD - EN61010-1-1 EMC - EN61326-1
Pneumatic requirements	Input pressure: 4.5 to 7 barg clean dry air or nitrogen Pneumatic Rectus 21 KA connections
Packaging	Waterproof and airtight solid case for transportation Padded carry bag for site portability
Languages	English, German, French, Swedish, Italian, Portuguese, Danish and Spanish

3. Theoretical basis of test

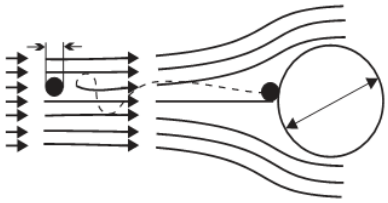
Gas filter efficiency is dependent on three different capture mechanisms. These are;



Direct Interception: Exclusion is due to the particle / micro-organism size being greater in size than the average pore diameter or inter-fibre distance of the filtration medium. Typically, particles in the size range of 1.0µm and above are removed by this mechanism.



Inertial Impaction: Particles of a certain size are carried around the fibres / pore walls of the filter matrix in the gas stream line. However, particles of a certain mass will exit the streamline due to their inertia. They then impact on individual fibres and remain captured due to electrostatic forces (e.g. Van de Waals). Retention by this mechanism is generally accepted to be in the range of 0.3µm – 1.0µm.



Diffusion: When particles are small enough they are acted upon by the molecules of the gas being filtered. This means that even though the particles may be as small as 0.02µm they have an effective diameter much larger. Also, due to their size, they travel at a lower speed than that of the carrier gas. These two phenomena mean that a very small particle can be removed from a gas stream using filtration media with an average pore size much larger than that of the particle being removed.

Most Penetrating Particle Size (MPPS)

The overall efficiency of a gas filter is the result of a combination of all these three mechanisms, and each mechanism has a particle size for which it is most efficient. This results in a particle size that is the most difficult to remove because its size is between the ideal size for removal by a combination of diffusion and inertial impaction. This particle size is referred to as the MPPS. For a sterile gas filter this is recognised during normal process conditions as being in the order of 0.2µm – 0.3µm. As the gas velocities are substantially increased through the membrane the MPPS can reduce to around 0.07µm but this is at trans-filtration medium velocities outside those experienced in a correctly designed system. The Valairdata method is based on a stringent filter challenge using an aerosol at the most penetrating particle size.

3.0 Description of test

The basis of the Valairdata 3 test is to challenge the sterile filter under test with a high concentration of aerosol in the size range of 0.2µm to 0.3µm (the most penetrating particle size MPPS). The presence or absence of aerosol on the sterile side of the filter is determined using a laser particle counter and the % penetration correlated to an aerosol bacterial challenge methodology. Unlike liquid based integrity test methods the Valairdata 3 tests filters in the gas phase and is therefore more representative of the true efficiency of the gas filter. The other major benefit of this method is that the test times are a fraction of those required for a liquid based test.

The test has three key phases that are all automatically controlled by the Valairdata 3; aerosol generation, sensing and data collection. A typical test set up is shown below:

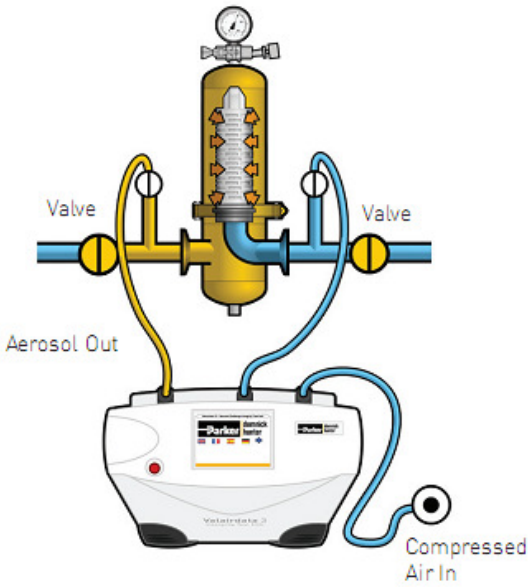


Fig 1 Typical Test Set Up

3.1 Aerosol Generation phase

Aerosol containing a narrow distribution of particles within the most penetrating particle range is generated via a proprietary aerosol generator utilising a submerged Laskin nozzle. Sterile compressed air is pumped through the nozzle at 14.5l/min that generates a polydispersed aerosol. Aerosol of the desired distribution (see section 4.1) preferentially passes through a separation layer in the aerosol generator and the larger removed particles return to the challenge fluid sump. Air pressure, viscosity of the challenge fluid and fluid level, govern the specification of the distribution. Internal pressure and level sensors are therefore incorporated to ensure the conditions for aerosol generation is retained during operation. A cross section of the aerosol generator is shown below.

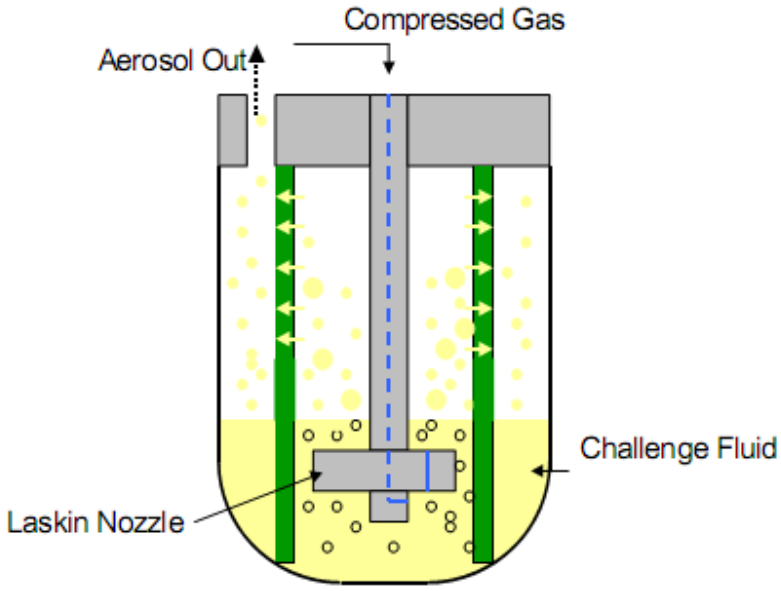


Figure 2. Cross Section of Aerosol Generator

3.2 Sensing phase

High concentrations (approximately 1 x 10^{11} per minute) of the aerosol generated as described above then challenge the upstream surface of the test filter. Any aerosol that passes through the filter is then detected using a sensitive laser particle counter. Within the particle counting system, light from the laser is scattered by any penetrating aerosol particles onto the parabolic mirrors that focus the light onto a photodiode. The output from this diode is proportional to the size and number of particles in the air stream. Software in the Valairdata 3 calculates the number of particles and compares this to the number typically generated in the challenge stream. The result is then displayed as a “PASS” if the filter under test is integral and has retained the aerosol challenge. If the filter has allowed penetration of aerosol, the system displays ‘Fail’ and the percentage penetration. Pass / Fail limits are determined by the correlation to an aerosol bacterial challenge. A cross section of the laser particle counter is shown below:

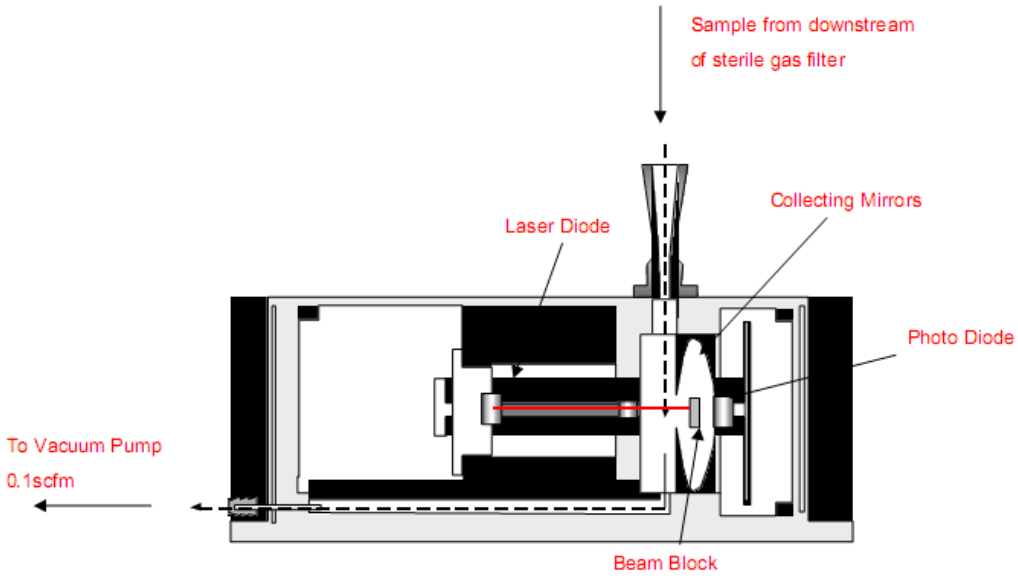


Figure 3. Cross section of laser particle counter

4.0 Validation

4.1 Verification of particle size distribution from the aerosol generator

A key parameter in conducting the Valairdata 3 test is the consistent generation of aerosol at the required concentration and within the set particle size range (most penetrating particle size). The particle size distribution from the aerosol generator has been verified using a custom designed PALAS LPC test system (ref: domnick hunter ltd test report 7722).

The aerosol generated is of too high a concentration to pass directly into a laser particle counter and is therefore diluted in such a way as to maintain the distribution. This is accomplished using a dilution system from the company PALAS (model VKL-10).

The aerosol is diluted by a factor of 100,000 before being passed through a TSI-FMS 1C particle counter that measures particles in the range of 0.1µm to 0.9µm.

Results & conclusion

The recorded aerosol distribution is figure 4 below. These data indicate that the system generates an aerosol with a tight distribution centred on the target particle size of 0.2µm - 0.3µm.

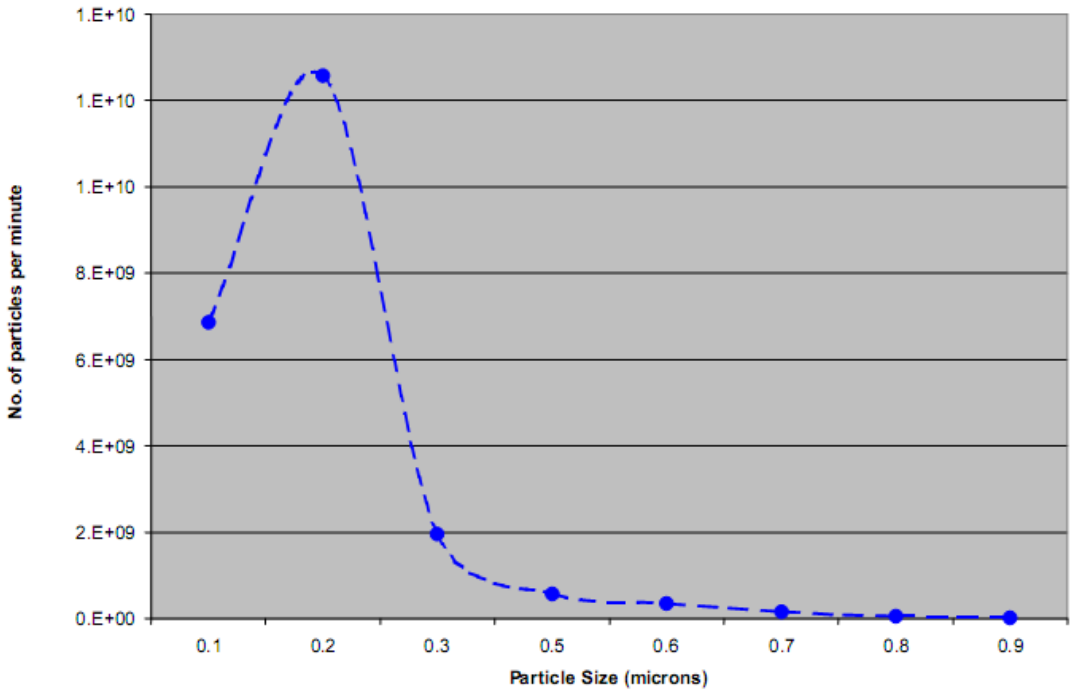


Figure 4. Mean particle size range from Valairdata 3 aerosol generator

4.2 Correlation of the Valairdata 1 aerosol integrity test to aerosol bacterial & coliphage challenge

The correlation tests were performed on both fully retentive and marginally failed HIGHFLOW TETPOR (ZCHT) sterile gas cartridges. These are standard sterile gas cartridges from the Parker domnick hunter range and utilise PTFE membrane as the sterilising membrane. The correlation was performed on both 2.5" and 5" product.

Each filter was tested using the Valairdata 1 prior to the aerosol bacterial and phage challenges. The penetration values recorded on the Valairdata 1 were then correlated to the actual bacterial / phage penetrations. The Valairdata 1 % aerosol penetration values were then correlated to penetration values for the new Valairdata 3 (see section 4.4)

4.2.1 Methods

Bacterial challenge

Aerosol containing very large numbers of viable organisms per unit volume of air was produced by a Collision spray (CAMR Porton Down, UK ref test report 510185) to provide high microbial challenges.

The following organisms were used for bacterial challenge;

• washed suspensions of spores of *Bacillus subtilis* var niger in distilled water.

• washed suspensions of *Brevundimonas diminuta* in distilled water.

The temperature and relative humidity of the air were 20℃ and 60%, respectively. Under these conditions, any water associated with a single bacterial cell will rapidly evaporate and the filters are therefore challenged by monodispersed particles equivalent to the size of single bacterial cells. The organisms used were determined, under the growth and preparation conditions outlined below, to be as follows;

- *Bacillus subtilis* 1.0µm by 0.7µm
- *Brevundimonas diminuta* 0.8µm by 0.2µm

Coliphage challenge

A series of filters were challenged with high concentrations of aerosolised MS-2 Coliphage and these results were correlated with the % aerosol penetration measured with the Valairdata 1 system. MS-2 is an unenveloped single stranded RNA coliphage, 23 nanometres in diameter with a molecular weight of 3.6 x 10^6 Da. This coliphage is fairly resistant to inactivation during aerosolisation and partly because of this, and partly due to its more compact and smaller size it was preferred to the T-Coliphage in these filter penetration studies.

4.2.1.1 Preparation of Test Organisms

***Bacillus subtilis* var niger** - Stock suspensions containing washed spores of *Bacillus subtilis* var niger suspended in distilled water were prepared and stored at CAMR (Porton Down). A spore suspension containing 1.5 x 10^9 colony forming counts/mL was prepared and heated to 60°C for 30 min before use.

The heating step ensures that any vegetative organisms that are present are inactivated (as these are more sensitive to inactivation by aerosolisation that spores). In all cases, it was found that there was no significant decrease in bacterial count after heating and prior to aerosolisation indicating that the majority of cells were in the spore form.

Brevundimonas diminuta - A lyopholized vial of *Brevundimonas diminuta* obtained from The National Collection of Industrial and Marine Bacteria, Torry Research Station, Aberdeen (NCIMB), was reconstituted in 1 mL of nutrient broth. 0.1 mL of this suspension was spread over the surface of a nutrient agar plate that was then incubated overnight at 30°C ± 2°C. A single colony from this plate was then inoculated on to a fresh nutrient agar plate that was then at 30°C ± 2°C for 40 hours. After 24 hours incubation at this temperature, pin-point colonies were obtained and after 40 hours dull beige coloured colonies of about 2mm diameter were formed. The cells from a single colony were examined under the microscope. The microscope examination showed that the bacterial cells were small gram-negative rods that correspond to the description of the *Brevundimonas diminuta* in Bergey's Manual of Determinative Bacteriology. Another colony from the same plate was used to inoculate a 250mL flask containing 50mL of nutrient broth. The fluid was shaken for 40hrs at 30°C ± 2°C. The cells were harvested by centrifugation at 8300g for 30 min and were washed by re-suspension in an equal volume of distilled water. The washed cells were recentrifuged again at 8300g for 30 minutes. The final suspension of *Brevundimonas diminuta* in water contained approximately 2 x 10^{10} cfu/mL.

MS-2 Coliphage - Suspensions of MS-2 Coliphage were obtained from the NCIMB. A stock suspension of coliphage was prepared by inoculating 0.1mL of the 10^{11} plaque-forming units (pfu)/mL coliphage suspension into 500mL nutrient broth containing 1 x 10^9 CFU *Escherichia coli* in the logarithmic growth phase. The suspension was mixed in a shaking incubator at 37°C. The bacterial cells lysed within 30 minutes to form a clear suspension. The suspension was centrifuged to remove the cell debris. The supernatant was transferred to a fresh flask and 10 drops of chloroform was added to kill any viable bacteria. The concentration of coliphage was determined by diluting the lysate in 1:1 mixture of nutrient broth and distilled water and adding 0.1mL of suitably diluted sample of 3mL of molten nutrient agar at 45°C containing 10^9 *E.coli* in the logarithmic phase of growth. After mixing, this was added as an overlay to phage typing agar plate. Each plate was incubated at 37°C overnight and the clear plaques formed were counted.

4.2.1.2 Methodology for bacterial aerosol challenge

A schematic of the apparatus used for bacterial challenges of filter cartridges with either *Bacillus Subtilis* or *Brevundimonas diminuta* is shown in Figure 5. The assembly consists of a Collison nebulizer for the generation of microbial aerosols in a chamber, connecting steel pipework, a filter housing containing the test cartridge, compressed air supply, aerosol sampling devices, flow meters and a powerful vacuum pump to draw the air containing the microbial aerosols through the test filters installed in the housing. The air exhausted by the vacuum pump is then passed through a High Efficiency Particulate Air (HEPA) filter before being finally exhausted to the environment. The microbial suspension (containing either 3 x 10^9 cfu/mL *Bacillus Subtilis* or 2 x 10^{10} cfu/ml *Brevundimonas diminuta* was nebulized by a 3-jet Collison spray by applying compressed air at a pressure of 180 kPa to the inlet. This resulted in the production of a fine aerosol of aqueous suspensions containing viable micro-organisms. Most of the droplets formed are unlikely to contain more than one bacterial cell. In these conditions the water associated with each droplet will evaporate so that "naked" monodispersed bacterial cells challenge the test filter. ZCHT-AZ (5" Demi cartridge) and ZCHT-BZ (2.5" Demi cartridge) were challenged at flow rates of 600 and 350 L/min, respectively.

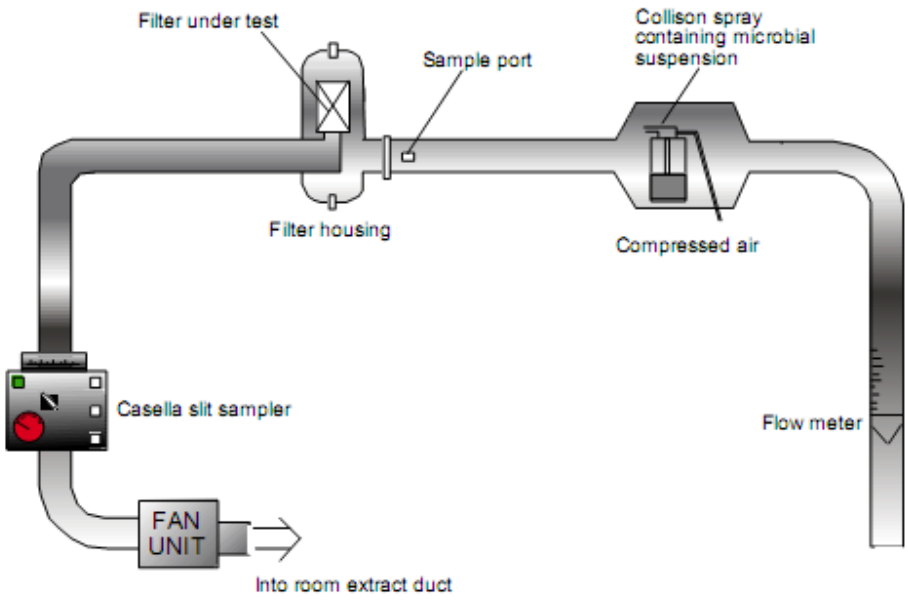


Figure 5. Schematic of aerosolised bacterial challenge

The actual level of bacteria challenging the filter was determined by taking a one minute sample upstream of the filter through a port linked to a Porton all-glass impinger (CAMR, Porton Down) operating at 11 L/min using 10 mL of PBMA as the collecting fluid.

Any organisms penetrating the test filter were collected using a large capacity Casella slit sampler (Casella London Ltd, London, UK). The sampler was fitted with a large volume sampling head and sampled air at approximately 300L/min (measured with a rotameter) with two of the four slits sealed with the strips provided. Prior to bacterial challenge, the system sterility was confirmed (with the filter installed in the housing) by slit sampling on a rotating 150-mm Tryptone Soya Broth Agar (TSBA) plate for 3 min.

Immediately after this process, the test filter was challenged with the appropriate organism and samples collected.

4.2.1.3 Methodology for coliphage aerosol challenge

A schematic of the apparatus used for bacterial challenges of filter cartridges with MS-2 Coliphage is shown in Figure 6. The test system is similar to that used for bacterial aerosol challenge although it was necessary to replace the slit sampler with a cyclone sampler to determine coliphage challenge and penetration levels.

Prior to filter challenge the concentration of MS-2 was determined by running the system without the test filter installed in the housing. The cyclone sampler is linked to a vacuum pump which draws air through the system at a rate of around 600ml (linear air velocity into the inlet aperture was measured by an Airflow anemometer). Collection fluid (PBMA) is fed into the cyclone inlet at a rate of 2ml/min and particles in the air stream are deposited by centrifugal force on the cyclone wall and are collected by the swirling liquid. The liquid was then withdrawn by a syringe after a 4 minute assay period, the exact volume of liquid collected measured by weighing and the collected fluid assayed for MS-2 Coliphage.

Following installation of the test filter in the test housing and system sterilisation, the MS-2 culture was nebulized in the Collison nebulizer. This system produces a range of droplet sizes. After rapid evaporation of water from the droplets it was shown experimentally that a range of particles from the limits of optical microscopic analysis (less than 0.2µm) to 30µm micron were produced. The probability of MS-2 phage present in a particular size distribution depends on the size and number of the aerosol particle size. Analysis of the particle size distribution of the MS-2 nebulized in this way by the Andersen sampler showed that 55% of viable MS-2 were collected in the lowest stage (6th) of the sampler (corresponding to the particle size range 0.65µm - 1.1µm); 36% were collected in the 5th stage (corresponding to the size range 1.1µm - 2.1µm); 6% in the 4th stage (2.1µm - 3.3µm) and 3% in the top three stages (greater than 3.3µm). ZCHT-AZ (5” Demi cartridge) and ZCHT-BZ (2.5” Demi cartridge) were challenged at flow rates of 600 and 350 L/min, respectively.

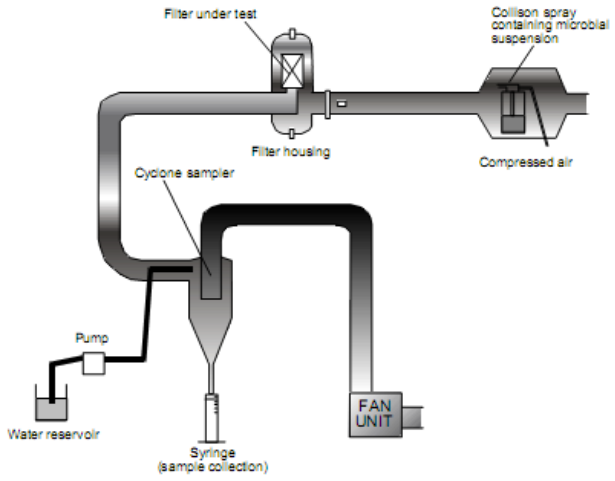


Figure 6. Schematic diagram of the Coliphage challenge apparatus

4.2.1.4 Microbial Assay Methods

Bacillus Subtilis var Niger - The collection fluid from the impingers and cyclone were serially diluted (if required) in PBMA, and 0.1ml of the diluent was spread on TSBA plates. TSBA plates containing *Bacillus subtilis* were incubated at 37°C for more than 18hrs. Aerosolisation had no effect on the size of the colonies formed. TSBA plates used in the slit sampler were incubated in the same way and the colonies counted.

Brevundimonas diminuta - The assay of the impinger samples were carried out as described above except that the diluent was spread on nutrient agar plates which were subsequently incubated for 48hrs at 30°C. The beige colonies formed were counted. All *Brevundimonas diminuta* colonies counted were beige and their colony morphology was similar to the colonies produced by the original suspension. Nutrient agar plates used in the slit sampler were also incubated for 48 hrs at 30°C, and the colonies counted.

MS-2 coliphage - The number of viable MS-2 Coliphage particles collected by the impingers and the cyclone samplers were determined, as described earlier in this article (Test Organisms: MS-2Coliphage), by adding 0.1 mL of the suitably-diluted sample in PBMA to molten agar at 45°C containing 10^{11} *E.coli* in the logarithmic phase of growth.

4.2.2 Results

Using challenge solution at 3 x 10^9 cfu/mL *B.subtilis* and 2 x 10^{10} cfu/ml *Brevundimonas diminuta* suspended in distilled water, it was found that filters under test were actually challenged with bacterial aerosol at 1.5 x 10^6 and 1.0 x 10^6 bacterial cells/L, respectively. The results of these tests using both 2.5 and 5 inch HIGH FLOW TETPOR air sterilisation filter cartridges are shown in Table 1.

Similarly, using the MS-2 Coliphage suspension at 10^{11} pfu/ml it was found that the filters were actually challenged with 5 x 10^6 pfu/mL aerosolised phage.

Table 4 shows the number of organisms detected downstream of the filter cartridge under test after challenge with high concentrations of aerosolised bacteria. In all cases, cartridges were tested with the Valairdata 1 to determine the % aerosol penetration prior to bacterial challenge. These values are shown for each cartridge. It can be seen that the number of organisms penetrating the cartridges reduces broadly in line with falling % penetration values on the Valairdata 1. From cartridge 45088 and all subsequent cartridges that demonstrated no aerosol penetration during the Valairdata 1 test there was also zero bacterial penetration with either aerosolised *Bacillus subtilis* or *Brevundimonas diminuta*. The first challenge failure was recorded with a cartridge exhibiting a Valairdata 1 % penetration of 0.00023% (filter serial # 45195). On this basis the PASS / FAIL limit for the Valairdata I (allowing a safety margin) was set at a penetration of 0.00005%.

Similarly, the data for the MS-2 coliphage challenge (see Table 2) shows that the minimum fail limit was 0.0004% (filter serial # 43814). The above PASS / FAIL limit is therefore also applicable to coliphage challenge.

Filter No	Filter Type / Size	Valairdata I % Penetration	Bacterial penetration per 10^8 (cfu)	
			B.subtilis	*Brevundimonas diminuta*
1	ZCHT-AZ (5)	0.098	507.0	5264
2	ZCHT-AZ (5)	0.018	44.0	1860
3	ZCHT-BZ (2.5)	0.0074	63.0	122
4	ZCHT-AZ (5)	0.0032	3.5	Not done
5	ZCHT-AZ (5)	0.0029	12.0	445
6	ZCHT-BZ (2.5)	0.0026	11.0	6.75
7	ZCHT-AZ (5)	0.0018	18.0	215
8	ZCHT-BZ (2.5)	0.0017	4.0	5.75
9	ZCHT-BZ (2.5)	0.0010	3.5	96
10	ZCHT-AZ (5)	0.0004	2.6	52.5
11	ZCHT-BZ (2.5)	0.00038	13.0	87
12	ZCHT-BZ (2.5)	0.00023	9.3	13.75
13	ZCHT-BZ (2.5)	0	0	0
14	ZCHT-BZ (2.5)	0	0	0
15	ZCHT-AZ (5)	0	0	0
16	ZCHt-AZ (2.5)	0	0	0
17	ZCHT-BZ (2.5)	0	0	0
18	ZCHT-AZ (5)	0	0	0
19	ZCHT-AZ (2.5)	0	0	0

Table 1. Aerosol bacterial challenge results

Filter No	*Filter Type / Size*	*Valairdata I % Penetration*	*MS-2 Penetration per 10^8 challenge (pfu)*
1	ZCHT-AZ (5)	0.098	182
2	ZCHT-AZ (5)	0.018	15
5	ZCHT-AZ (5)	0.0029	9.4
10	ZCHT-AZ (5)	0.0004	4.3
15	ZCHT-AZ (5)	0	0
18	ZCHT-AZ (5)	0	0
Flow rate through filter = 600Nl/min **MS-2 Aerosol challenge = 5 x 10^8pfu/ml** **Sampling time for each filter = 4 minutes**			

Table 2. Aerosol Coliphage challenge results

4.2.3 Discussion

These data indicate that the Valairdata 1 was able to detect very low penetrations of both bacterial and phage aerosol challenges passing through marginally failed cartridges. Similarly, intact cartridges were clearly identified by the Valairdata 1 allowing a PASS / FAIL limit to be set with a high degree of safety margin.

4.3 Correlation of Valairdata 1 and Valairdata 3 penetration values

The two Valairdata systems are based on identical aerosol generation systems, operate at comparable flow rates and only differ in the use of a higher sensitivity aerosol detection system in the Valairdata 3. It is therefore possible to correlate the two systems albeit that the Valairdata 3 will provide enhanced sensitivity of detection in actual use.

Figure 7 shows the relationship between the % penetration values from the two units when they were sequentially used to test a range of filter cartridges. These cartridges were selected as they represent a good range of marginal integrity test fails. It can be seen that the relationship between the % penetration from each instrument is not linear at very low penetrations. This is because the Valairdata 3 uses a significantly more sensitive particle detector than the original system. With larger penetrations the relationship between the two systems becomes increasingly linear.

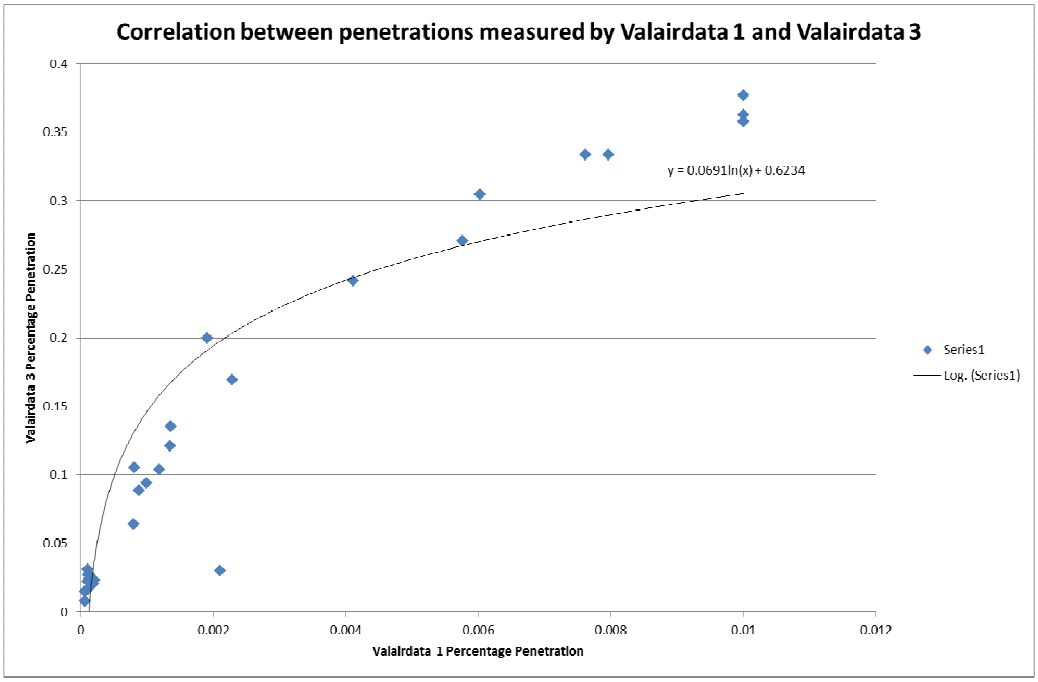


Figure 7. Correlation between Valairdata 1 and Valairdata 3 instruments

4.4 Correlation of Valairdata 3 to aerosolised Brevundimonas diminuta challenge

As shown in section 4.3, it is possible to determine the relationship between % aerosol penetration values from the Valairdata 1 and Valairdata 3. These values have then been used to correlate the % penetration values from the Valairdata 3 to the bacterial challenge data described in section 4.2. In all cases, the correlation associated with the Valairdata 3 is fail safe as this system is significantly more sensitive than the original Valairdata 1 used for the bacterial correlation studies.

Table 6 shows the correlation of the Valairdata 3 aerosol penetration data to the bacterial aerosol challenge results. From the original test work performed the number of bacteria penetrating the various filters has been correlated to the comparative penetrations obtained from the Valairdata 1. The initial fail point was identified at a penetration of 0.0446%. The actual PASS / FAIL limit for the Valairdata 3 has been set at 0.0004%. This gives a factor of safety in the order of 100.

Filter No	*Filter Code / Size*	*Percentage Penetration*		*Bacterial Penetration per 10^8 (cfu)*	
		Valairdata 1	**Valairdata 3 (correlated)**	***Bacillus subtilis***	***Brevundimonas diminuta***
1	ZCHT-AZ (5)	0.098	0.2522		5264
2	ZCHT-AZ (5)	0.018	0.1941		1860
3	ZCHT-BZ (2.5)	0.0074	0.1636		122
4	ZCHT-AZ (5)	0.0032	0.1315		Not done
5	ZCHT-AZ (5)	0.0029	0.1349		445
6	ZCHT-BZ (2.5)	0.0026	0.1277		6.75
7	ZCHT-AZ (5)	0.0018	0.1151		215
8	ZCHT-BZ (2.5)	0.0017	0.1132		5.75
9	ZCHT-BZ (2.5)	0.0010	0.0950		96
10	ZCHT-AZ (5)	0.0004	0.0635		52.5
11	ZCHT-BZ (2.5)	0.00038	0.0618		87
12	ZCHT-BZ (2.5)	0.00023	0.0446		13.75
13	ZCHT-BZ (2.5)	0	0		0
14	ZCHT-BZ (2.5)	0	0		0
15	ZCHT-AZ (5)	0	0		0
16	ZCHt-AZ (2.5)	0	0		0

17	ZCHT-BZ (2.5)	0	0		0
18	ZCHT-AZ (5)	0	0		0
19	ZCHT-AZ (2.5)	0	0		0

Table 3. Summary of correlated % penetrations for Valairdata 3 against bacterial challenge

4.4.1 Discussion

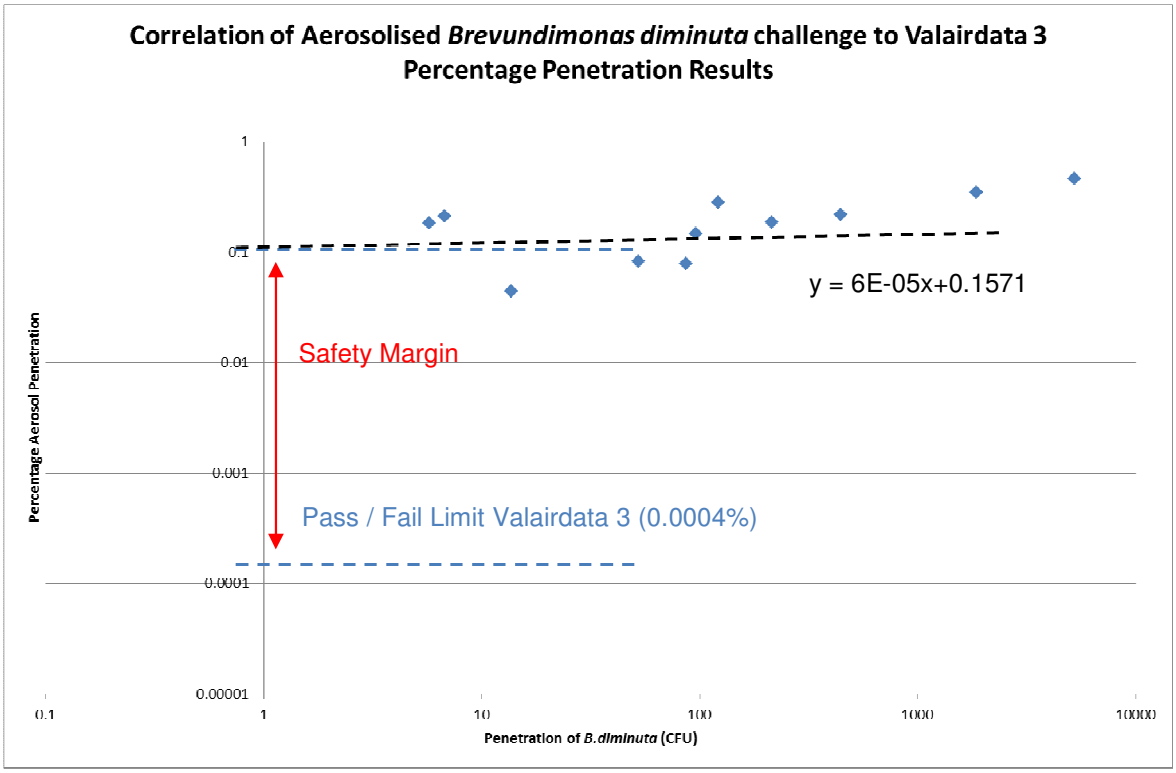


Figure 8. Correlation of Valairdata 3 to aerosolised Brevundimonas diminuta challenge

The penetration values detailed above show large penetrations of test aerosol compared to actual aerosolised bacteria, indicating that the Valairdata 3 test is potentially more challenging than an actual bacterial challenge. Due to the high challenge concentration level from the Valairdata 3 the numbers of particles penetrating a very minor fault in the membrane structure equate to tens of thousands rather than one or two. This is highlighted as a step change in penetration values rather than the linear relationship expected on traditional liquid based correlation.

It should be expected that a filter with a fully retentive membrane or media would pass zero particles when tested by the Valairdata 3. This is the case, but indicating a failed filter based on the passage of one or two particles is essentially testing the downstream system for particulate contamination rather than the ability of the filter to provide sterile gas. This potential background 'noise' is the reason the pass/ fail limit for the Valairdata 3 is set at 0.0004% and not 0%. Using this limit still ensures a very high margin of safety.

Documentation Approval Section

Approved By: Martin Newman

Title: Senior Quality Engineer

Date: January 2013

Durham Road, Birtley, Co. Durham
England, UK. DH3 2SF
Tel: +44 (0)191 4104450
Fax: +44 (0)191 4105312
Website: www.domnickhunter/process filtration.com