Together, we can take control of your process

... for accurate and reliable results

Parker domnick hunter

ENGINEERING YOUR SUCCESS.

Valairdata 3

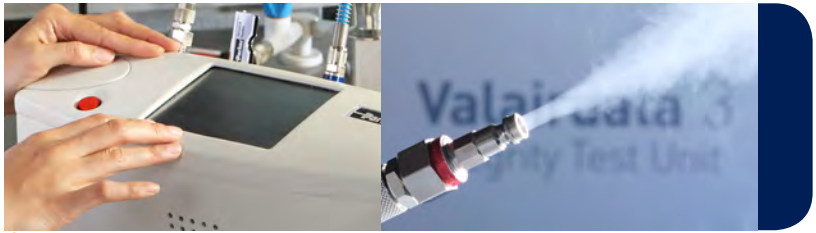
Setting the standards

The new Valairdata 3 has been designed utilizing state-of–the-art technologies and 40 years of experience in the provision of sterile air and gas filtration solutions. It is the quickest and easiest way to verify the integrity of sterile gas filter systems.

The Fast Solution

Fast

In process environments minimizing downtime and speed of production are key. The Valairdata 3 provides fast and reliable filter integrity testing in-situ, with results obtained in seconds. The test filter can be introduced back into process immediately after testing with no flushing or drying required.



Accurate

Verifying a sterile gas filter's ability to provide sterility is essential to ensure your process remains secure. The Valairdata 3 aerosol challenge is fully correlated to aerosolized bacterial and viral challenges and is an accurate, reliable method for detecting gas filter integrity. Test details are securely stored within the unit in accordance with FDA 21CFR part 11 requirements.

The Accurate Solution

Portable

The Portable Solution

Designed for use throughout your process, the Valairdata 3 incorporates state-of-the-art technologies to enhance the benefits offered by the aerosol challenge in comparison to other sterile gas filter test methods. The lightweight, portable design and long-life battery allows operators to test filters in-situ, safe-guard your process from potential contamination. Once testing is complete, results are easily transferred from the unit via a USB data stick for easy tracking, storage and transfer of test data.

Test Princliples

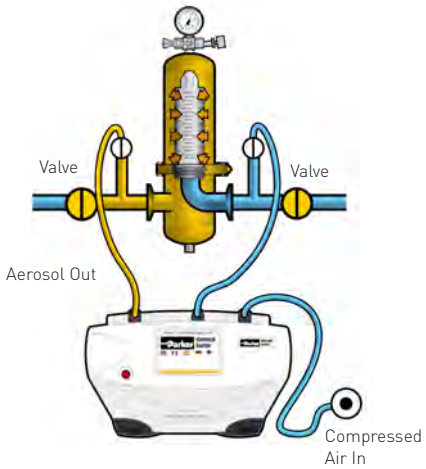
Increasing product quality requirements and processing standards has driven the need for greater control of aseptic process operations. Analysing the performance of sterile gas filter systems in-situ, quickly and with minimal disruption to the process is a key part of establishing process control.

The Valairdata 3 delivers on these requirements by performing an aerosol challenge of the test filters. Independent validation has correlated this method to aerosol challenges with *B.subtilis*, *P.aeruginosa* and MS2 coliphage according to ASTM guidelines. Any filter which passes Valairdata 3 testing is therefore capable of providing sterile gas to the process.

The test is performed in a matter of seconds. During the test, the sterile filter is challenged with an FDA approved aerosol containing particles in the size range 0.2µm to 0.3µm simulating an actual bacterial challenge under worst-case conditions.

The filtered gas is then passed through a laser particle counter and any aerosol penetration through the filter is measured and calculated as a percentage penetration. On this basis a pass or fail result is established. Test details and results are held securely in the internal memory of the unit. Data transfer to a computer is enhanced through the use of USB port, requiring no specific software to access the test data.

Advantages of Aerosol Challenge Testing	Limitations of Liquid Based Tests
Speed – the test is much quicker than liquid based tests, with no stabilization times involved.	Long stabilization and test times.
Speed – in a dry gas process no flushing or drying of the test filter is required, so the filter can be returned to process immediately after testing.	The requirement to fully wet out the test filter with low surface tension liquid (e.g. IPA). The requirement to dry filter cartridges after testing.
Accuracy – the test is more accurate for larger systems as the actual retention efficiency of the filter system is measured.	Inaccuracies for multi-cartridge times.



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 Ondina 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

Instrument Options	WVA-3-ST (Standard)	WVA-3-SE (Secure)
Design environment approvals	GAMP 5	GAMP 5
21CFR 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

Customer Support

Parker domnick hunter can offer full after sales support worldwide, whether it is commissioning of the instrument, calibration / service or full training of site operators.

For more information contact: dhprocess@parker.com

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