

**Together, we can take
control of your process**
... for accurate and reliable results



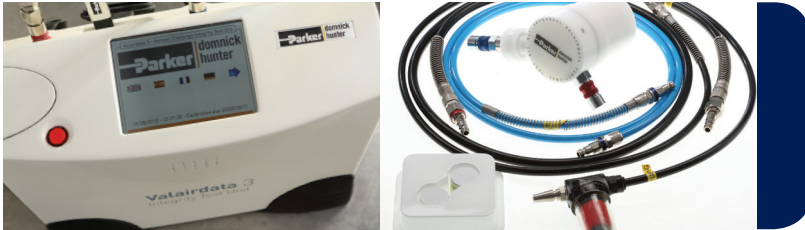
Valairdata 3

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.



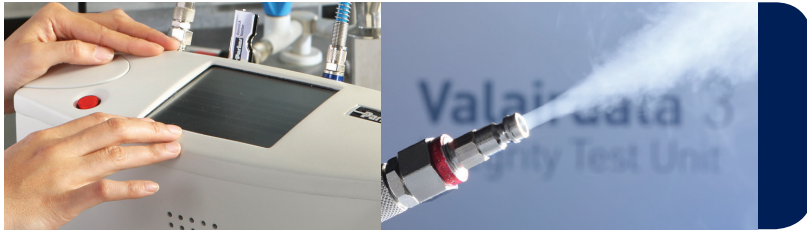
The Fast Solution



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

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 allow operators to test filters in-situ, to safeguarding your process from potential contamination. Once testing is complete the results are easily transferred from the unit via a USB data stick for easy tracking, storage and transfer of test data.

The Portable Solution



Test Principles

Increasing product quality requirements and processing standards have 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.

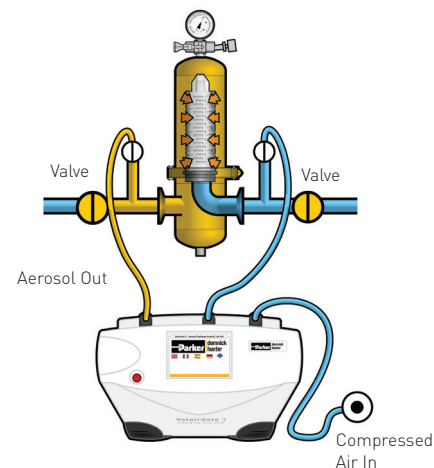
The Valairdata 3 delivers on these requirements by performing an aerosol challenge of the test filters. Independent validation has correlated this method to aerosol challenges with *B.subtilis*, *Paeruginosa* and MS2 coliphage according to ASTM guidelines. Any filter which passes Valairdata 3 testing 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 $0.2\mu\text{m}$ to $0.3\mu\text{m}$, simulating an actual bacterial challenge under worse 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: 155mm
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 Purity™ W015 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

Parker Worldwide

AE – UAE, Dubai
Tel: +971 4 8127100
parker.me@parker.com

AR – Argentina, Buenos Aires
Tel: +54 3327 44 4129

AT – Austria, Wiener Neustadt
Tel: +43 (0)2622 23501-0
parker.austria@parker.com

AT – Eastern Europe,
Wiener Neustadt
Tel: +43 (0)2622 23501 900
parker.easteurope@parker.com

AU – Australia, Castle Hill
Tel: +61 (0)2-9634 7777

AZ – Azerbaijan, Baku
Tel: +994 50 2233 458
parker.azerbaijan@parker.com

BE/LU – Belgium, Nivelles
Tel: +32 (0)67 280 900
parker.belgium@parker.com

BR – Brazil, Cachoeirinha RS
Tel: +55 51 3470 9144

BY – Belarus, Minsk
Tel: +375 17 209 9399
parker.belarus@parker.com

CA – Canada, Milton, Ontario
Tel: +1 905 693 3000

CH – Switzerland, Etoy
Tel: +41 (0)21 821 87 00
parker.switzerland@parker.com

CL – Chile, Santiago
Tel: +56 2 623 1216

CN – China, Shanghai
Tel: +86 21 2899 5000

CZ – Czech Republic, Klecany
Tel: +420 284 083 111
parker.czechrepublic@parker.com

DE – Germany, Kaarst
Tel: +49 (0)2131 4016 0
parker.germany@parker.com

DK – Denmark, Ballerup
Tel: +45 43 56 04 00
parker.denmark@parker.com

ES – Spain, Madrid
Tel: +34 902 330 001
parker.spain@parker.com

FI – Finland, Vantaa
Tel: +358 (0)20 753 2500
parker.finland@parker.com

FR – France, Contamine s/Arve
Tel: +33 (0)4 50 25 80 25
parker.france@parker.com

GR – Greece, Athens
Tel: +30 210 933 6450
parker.greece@parker.com

HK – Hong Kong
Tel: +852 2428 8008

HU – Hungary, Budapest
Tel: +36 1 220 4155
parker.hungary@parker.com

IE – Ireland, Dublin
Tel: +353 (0)1 466 6370
parker.ireland@parker.com

IN – India, Mumbai
Tel: +91 22 6513 7081-85

IT – Italy, Corsico (MI)
Tel: +39 02 45 19 21
parker.italy@parker.com

JP – Japan, Tokyo
Tel: +81 (0)3 6408 3901

KR – South Korea, Seoul
Tel: +82 2 559 0400

KZ – Kazakhstan, Almaty
Tel: +7 7272 505 800
parker.easteurope@parker.com

MX – Mexico, Apodaca
Tel: +52 81 8156 6000

MY – Malaysia, Shah Alam
Tel: +60 3 7849 0800

NL – The Netherlands,
Oldenzaal
Tel: +31 (0)541 585 000
parker.nl@parker.com

NO – Norway, Asker
Tel: +47 66 75 34 00
parker.norway@parker.com

NZ – New Zealand, Mt Wellington
Tel: +64 9 574 1744

PL – Poland, Warsaw
Tel: +48 (0)22 573 24 00
parker.poland@parker.com

PT – Portugal, Leca da Palmeira
Tel: +351 22 999 7360
parker.portugal@parker.com

RO – Romania, Bucharest
Tel: +40 21 252 1382
parker.romania@parker.com

RU – Russia, Moscow
Tel: +7 495 645-2156
parker.russia@parker.com

SE – Sweden, Spånga
Tel: +46 (0)8 59 79 50 00
parker.sweden@parker.com

SG – Singapore
Tel: +65 6887 6300

SK – Slovakia, Banská Bystrica
Tel: +421 484 162 252
parker.slovakia@parker.com

SL – Slovenia, Novo Mesto
Tel: +386 7 337 6650
parker.slovenia@parker.com

TH – Thailand, Bangkok
Tel: +662 717 8140

TR – Turkey, Istanbul
Tel: +90 216 4997081
parker.turkey@parker.com

TW – Taiwan, Taipei
Tel: +886 2 2298 8987

UA – Ukraine, Kiev
Tel: +380 44 494 2731
parker.ukraine@parker.com

UK – United Kingdom,
Warwick
Tel: +44 (0)1926 317 878
parker.uk@parker.com

US – USA, Cleveland
Tel: +1 216 896 3000

VE – Venezuela, Caracas
Tel: +58 212 238 5422

ZA – South Africa,
Kempton Park
Tel: +27 (0)11 961 0700

parker.southafrica@parker.com

European Product Information Centre
Free phone: 00 800 27 27 5374
(from AT, BE, CH, CZ, DE, DK, EE, ES, FI,
FR, IE, IL, IS, IT, LU, MT, NL, NO, PL, PT,
RU, SE, UK, ZA)

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Parker Hannifin Manufacturing Ltd
domnick hunter
Process Filtration – Europe
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

Parker Hannifin Corporation
domnick hunter
Process Filtration – North America
2340 Eastman Avenue
Oxnard, California, USA 93030
toll free: +1 877 784 2234
phone: +1 805 604 3400
fax: +1 805 604 3401
email: dhpsales.na@parker.com
www.parker.com/processfiltration