

VALAIRDATA II

The most efficient test for sterile gas filters



Since 1990 and the launch of the unique VALAIRDATA aerosol integrity test system, the aerosol test method has become widely accepted in a variety of applications and industries as a routine method for integrity testing air filtration systems. The VALAIRDATA II integrity test instrument is a second generation design offering further practicality in air filter testing.

The VALAIRDATA II combines the sound principles of aerosol testing, as recommended in the 'PDA's Sterilising Filtration of Air - Technical Report #40', with a compact, portable and ergonomic design reducing test times and improving multi cartridge system sensitivity.

The VALAIRDATA II aerosol test is correlated to an aerosolised *Brevundimonas diminuta* and bacteriophage (such as *Enterobacteria phage MS2*) challenge.

Aerosol methods are rapid, can identify filter non-integrity on very large systems, allow immediate use of filter systems after testing as drying is not required and provides direct measurement of filter performance for gas filters.

- 30 second test time for a single 10" (250 mm) cartridge challenge
- Results correlated to aerosol bacterial and viral challenge
- Increased sensitivity compared to liquid based tests especially on multi-cartridge systems
- Built-in test instrument system integrity check
- Well established with over 200 current VALAIRDATA II users
- Fully validated secure option design to GAMP 4 Guidelines and meets the FDA's 21CFR11 requirements
- Stores up to 200 test results and supported with software for PC download
- PDA recommended for use where filtered gas not in direct contact with exposed sterile product or surfaces



Physical Parameters

Instrument Material.....	Moulded Robust Polyurethane Case & Non-Slip Feet
Instrument Size.....	363 mm x 155 mm x 308 mm : 14.3" x 6.1" x 12.1"
Weight.....	8 Kg : 18 lb
Ingress Protection Class.....	IP45
Power Supply.....	Re-chargeable Battery (12V / 3.8 Ah) & Mains (90 - 230 VAC : 50 / 60 Hz)
Keyboard.....	16 Tactile Keys with Alphanumeric Input
Inlet Pressure Required.....	3.5 - 7.0 barg (50 - 100 psig) (60 Al / min)
Operating Temperature.....	5 - 37 °C (40 - 95.6 °F)
Pneumatic Connectors.....	Rectus 21 KA Series
Ambient Humidity.....	10 - 95% RH (non-condensing)
Languages.....	English, French, German, Spanish, Italian, Danish, Portugese & Swedish
Programmed Tests.....	Up to 100
Storable Test Programmes.....	200

Instrument Options

	Standard	Secure Environment	Electronic Signature
PC Manager Software.....	ST - Standard	SE - Secure Environment	ES - Electronic Signature
PC Operating Platforms.....	Microsoft Windows 98, 2000, NT & XP	Microsoft Windows 98, 2000, NT & XP	Microsoft Windows XP
Design Environment Approvals.....	Hardware & Software Development to GAMP Guidelines	GAMP Hardware & Software Development 21CFR11 Compliant (PC data is users responsibility)	GAMP Hardware & Software Development 21CFR11 Compliant
Operator (max. 40).....	Open Access	Access Password & PIN	Access Password & PIN
Access ADMINISTRATOR.....	Open Access	Access Password & PIN	Access Password & PIN
Record Output.....	RS232 Transfer	RS232 Transfer	RS232 Transfer
Audit Trail Record.....	No	Yes	Yes