BioVigilant®
Instantaneous Microbial Detection

IMD-A® Series

Rapid Biologic Detection System for Air

The IMD-A family of Real-Time, Rapid Biologic Detection Systems for Environmental Air Monitoring can continuously guard aseptic pharmaceutical environments to instantly warn when microbes are present

- *Real-time operation*
- *Measures particle size and biologic status simultaneously*
- *Immediate results without staining or reagents*
- *Continuous monitoring, or by specified sample volume*
- *Visual status indicator*
- *Built-in system self test*
- *USP<1223> compliant*
- *21 CFR Part 11 compliant*
- *Stainless steel enclosure*
- *Sanitary flange for easy removal and re-installation*
- *Flexible communications interface for networking*

www.metrovalidpharma.com

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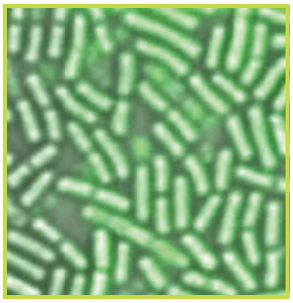
BioVigilant's IMD-A rapid biologic detection system revolutionizes environmental air monitoring for microbial contamination.

Using patented optical technology, the IMD-A system is capable of simultaneously detecting both size and biologic fluorescence of airborne particulates. The technology offers an eloquent yet robust method for determining the microbial content of an aerosol sample on a particle-by-particle basis, thereby providing a continuous, real-time analysis of environmental bioburden.

The IMD-A system requires no reagents and minimal human operator involvement, so it is particularly well-suited for rigorous environmental monitoring applications where time, cost, and cleanliness are of greatest concern.

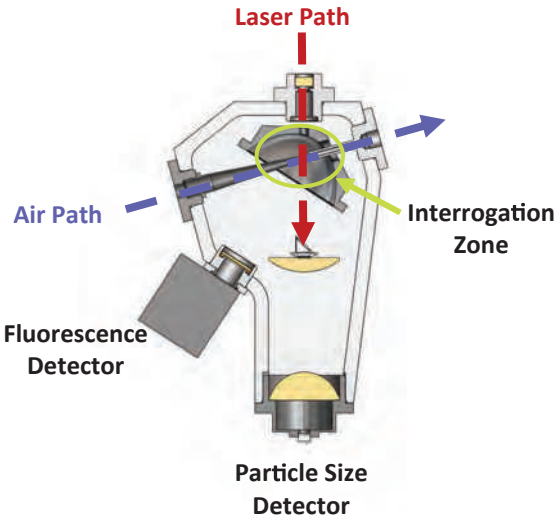


Microbes contain metabolites or chemical compounds such as NADH, riboflavin, and dipicolinic acid (DPA). When excited by a certain wavelength of light, these compounds emit an intrinsic fluorescence signal that serves as a marker for biological content of the sample.

Bacillus Atrophaeus under Confocal Microscope

When a particle enters the IMD-A system's interrogation zone, it intersects the beam of a single laser light source.

The scattering of the laser light determines the size of each individual particle. At the same time, the presence or absence of intrinsic fluorescence determines whether the particle is biologic or inert.

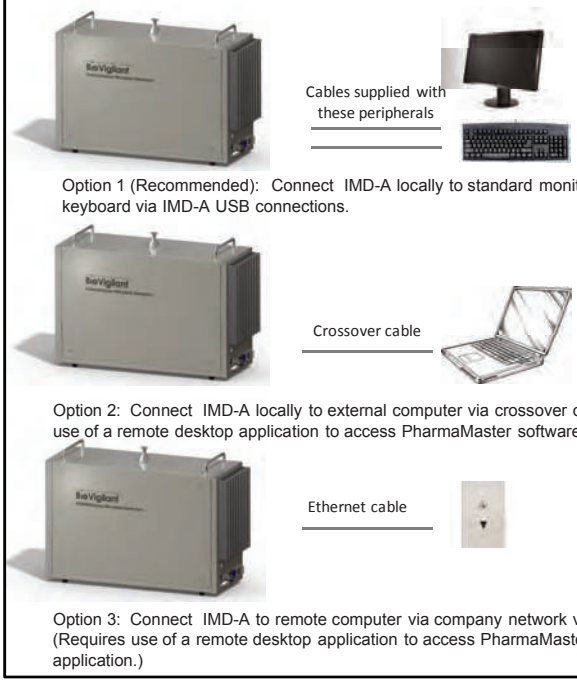


IMD-A's Optical Subsystem

The supplied sanitary flange clamp at the inlet of the IMD-A system allows for easy connection to tubing, and quick disconnection during cleaning.

The IMD-A system also features a video option that allows simultaneous video capture of the environment being measured for precise correlation of physical events with detected microbial or particulate excursions.

Communicating with IMD-A System



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The IMD-A system is supplied with PharmaMaster software.

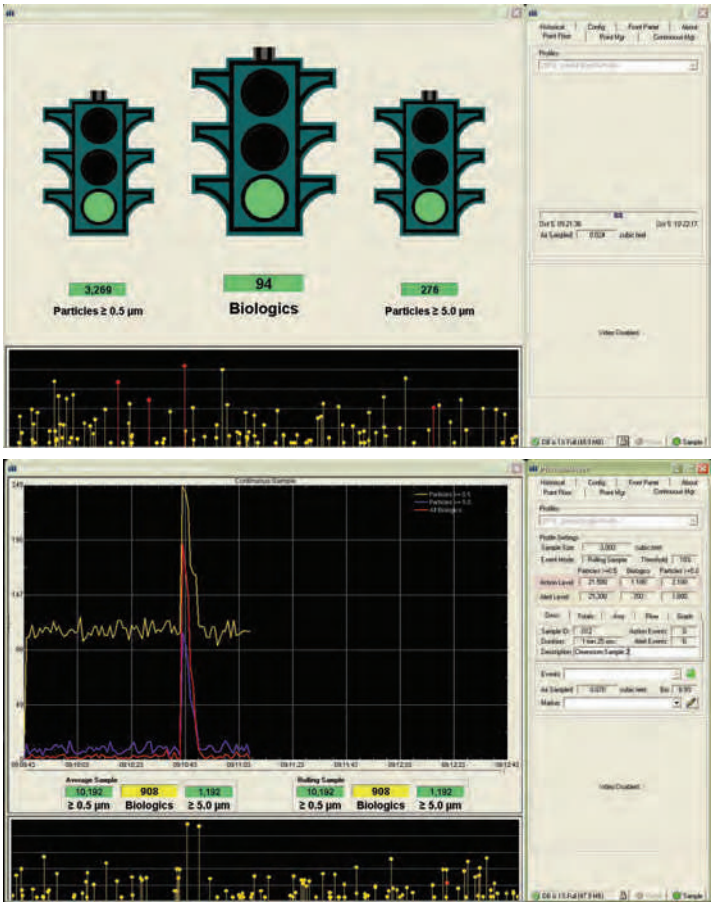
Instant-Read Interface
The system's sophisticated PharmaMaster software offers different levels of functionality based on user need and authority. For environmental control, the software features graphic displays that visually communicate custom-defined limits of particle contamination. A green light indicates that operation is safely within defined limits, yellow warns that an Alert level has been exceeded, and red indicates that an Action level has been exceeded. Alert and Action levels can trigger alarms, if desired.

User-Defined Alert Protocols
PharmaMaster software enables users to create a library of alert protocols with sensitivity levels to match different applications and environments.

Results Displayed by Particle Size
With PharmaMaster software (as shown in the display at right), users can view independently controlled line graphs to display results for all particles greater than 0.5 µm, all particles larger than 5.0 µm, and all biologic particles. An alarm alerts managers when a user-defined level is exceeded.

Five-Channel Sorting
With the PharmaMaster software, users can choose to review biologic particles in five data bins, from 0.5 µm to >10 µm.

Two Operational Modes for Application Flexibility
The PharmaMaster software offers both a continuous detection mode and a point sample mode for a sampling a specified volume or time duration, allowing users to determine the method of environmental sampling that best fits their application.



Graphical User Interface

Ordering Information

Systems

IMD-A 300:	IMD-A with 1.15 LPM (±5%) sample flow rate
IMD-A 350:	IMD-A with 28.3 LPM (±5%) sample flow rate utilizing virtual impaction concentration method

Accessories

A01000	Panasonic Toughbook computer
A02000	Monitor, DVI-compatible
A02010	Sealed keyboard with mouse
A02020	Crossover cable, 6ft.
A03000	Sanitary flange kit
A03001	Isokinetic probe for IMD-A 300
A03002	Isokinetic probe with stand for IMD-A 300
A03003	Isokinetic probe for IMD-A 350
A03004	Isokinetic probe with stand for IMD-A 350
A04001	Bev-A-Line XX tubing, 3/8", 100ft. (recommended)
A04002	Bev-A-Line XX tubing, 1/2", 100ft.
A04003	Disposable HEPA filter with Polypropylene housing

Services and Support

System Verification Templates
Pre-printed documentation sets for system functional design specification (DQ), installation qualification (IQ), and operational qualification (OQ) are available for completion without the need to recreate these documents.

Onsite Support Services
BioVigilant's highly trained applications and service personnel can streamline maintenance, implementation and validation work. Our experts can assist with any of these activities:

- Calibration
- Preventive maintenance
- Equipment installation
- Test plan development
- Data analysis
- Operator training
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Contact your sales person to learn more.

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Technical Specifications

Detection Method:	Optical, Mie Scatter (particle size) Optical, Auto-fluorescence (biologic status)
Biologic Detection Capability:	Vegetative cells, bacterial spores, fungi
Biologic Counting Efficiency:	Meets USP<1223> and EP 5.1.6
Incubation time:	None required
Particle Size Range:	0.5µm to ≥10µm
Particle Sizing Bins:	Grouped by size into 5 bins: 0.5µm to 1µm 1µm to 5µm 5µm to 7µm 7µm to 10µm ≥10 µm
Sampling Mode:	Continuous or Point sampling for specified duration or volume
Particle Threshold:	0.5µm
System Dimensions:	9" W x 18 1/8" H x 24 1/4" D
Weight:	54.0 lbs (24.6kg) (IMD-A 300); 55.5 lbs (25.2 kg) (IMD-A 350)
Enclosure material:	304 stainless steel, Nickel-plated aluminum
External chemical resistance:	Isopropyl alcohol (91%), chlorinated solution (2500ppm), hydrogen peroxide (3%)
Operating temperature range:	15-30 degrees Celsius
Operating Humidity Range:	10-80 % RH Non-condensing @ 15-25 degrees Celsius, 10-60% RH Non-condensing @ 25-30 degrees Celsius
Altitude:	< 6000 feet (1830m)
Power Requirements:	100-240 VAC, 50-60 Hz
Power consumption:	90 Watts, max.
Air Outlet filtering:	HEPA filtering (Internal)
Light source:	405nm laser
Detectors:	Photodiode, Photo Multiplier Tube
CPU:	Embedded Intel® dual core 1.5GHz, 4MB L2 cache
Data storage:	Peripheral hard drive (≥80GB)
Communications output options:	(1) Ethernet 10/100-base T (4) USB 2.0 ports (1) Digital Video Interface (DVI)
User interface:	Compatible with standard DVI/SVGA monitor, mouse, and keyboard. Remote access and control via network
Software:	Windows® XP Operating System, PharmaMaster® Bio-Detection Software, VNC® Server Enterprise Edition, and SQL Server® Express Edition
Data export:	ASCII, CSV
Languages supported:	English, Japanese
Regulatory compliance:	Electromagnetic compatibility 2004/108/EEC CE/GS Mark RoHS 2002/95/EC WEEE 2002/96/EC 21 CFR Part 11 FDA Type V Drug Master File
Standards met:	USP<1223> Validation of Alternative Microbiological Methods EP 5.1.6 Alternative Methods for Control of Microbiological Quality Manufactured in accordance with ISO 13485
Accessories included:	Bev-A-Line XX tubing (3/8" ID), (8) feet Sanitary flange kit for 3/8" tubing Inlet HEPA filter Web camera Inlet and outlet caps User manual

LI005 December 4, 2013