

MICRONVIEW

Cleanroom Air Monitoring Solution



BAMS

BioAerosol Monitoring System

Continuous

Real-time, continuous airborne microbial monitor

Efficient

Most efficient, user-oriented design

Compliant

Certified ISO particle detector

Portable

First truly portable microbial monitor



BAMS Uses



Alerts

Provides real-time continuous data to help with the root cause identification of contamination. Alerts in time to reduce the risk of product loss.



Process & Training

BAMS real-time results are a perfect training aid to drive immediate technique correction and process improvement.



Trends

Given delays and time lapses inherent to compendial testing methods, trend analysis is all but prohibited. BAMS changes that.



Root Cause

Provides real-time continuous data to help with the root cause identification of contamination. Alerts in time to reduce the risk of product loss.



Sterility Test Isolators

BAMS enables enhanced coordination and control of sterility test isolators.



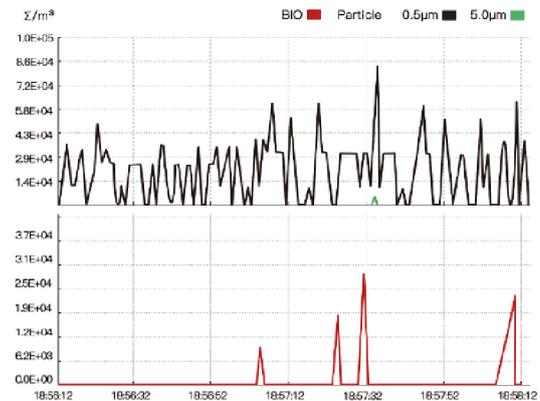
Fill Line Quality

BAMS real-time continuous monitoring helps to ensure the cleanliness of this crucial quality environment.

Wait Time vs. Real Time

Current airborne microbial monitoring uses interval, ad-hoc and event-driven sample collections, which require incubation. This process takes 1-7 days to generate test results, delaying and, at best, inhibiting, contamination root cause identification. This also does little, if anything, to prevent major production scrappage.

The current monitoring process also requires managing complex collection and manual growth examination schedules for thousands, even tens of thousands, of air samples per month. This is expensive, requiring significant labor and material costs.



Testing Aspect	Compendial Method	BAMS benefits
Time to Results	<ul style="list-style-type: none"> • 1-7 days • More scheduled/unscheduled breaks • Unlikely contamination identification • Increased cost and inefficiency risks 	<ul style="list-style-type: none"> • Immediate • Likely contamination identification
Detection Frequency	<ul style="list-style-type: none"> • Sampled monitoring • Reduced accuracy • Limited trending • Greater contamination risk • Greater risk of production loss 	<ul style="list-style-type: none"> • Continuous monitoring • Real data and improved analysis • Reduced contamination and production loss risks
Coordination	<ul style="list-style-type: none"> • Resource intensive • Higher labor costs • Time delays 	<ul style="list-style-type: none"> • Minimal costs and resources • Immediate and online

Increased Control The Latest Technology

BAMS was designed to meet exacting, pharmaceutical manufacturing standards while providing real-time data for immediate action and catastrophic loss avoidance. It was also designed for end-users. Small. Light. Easy to use.

Optical Sensor Technology

BAMS' principle of operation is the simultaneous measurement of an individual particle's size and its ultraviolet (UV)-induced intrinsic fluorescence signal:

- Particle sizing is possible through the widely utilized principle of Mie Scattering.
- Simultaneously, the instrument detects the presence or absence of the intrinsic fluorescence of certain metabolites that indicate biologic activity.

Specification Sheet

Specification	BioAerosol Monitoring System BAMS	Specification	BioAerosol Monitoring System BAMS
Size range	0.5µm to 25µm	Data storage	119G
Size channels	0.5µm, 1.0µm, 2.0µm, 3.0µm, 5.0µm, 10.0µm	Data security	Authority management, authority level divide into admin, operator and supervisor
Laser source	Long life laser	Data reliability	Compliant with FDA 21CFR Part11
Size resolution	<15% @ 0.5µm (meets ISO 21501-4)	Print	Auto, off-line
Count efficiency	50%±20% for 0.5µm, 100%±10% for >0.75µm (meets ISO 21501-4 and JIS B9921)	Dimensions (HxWxD)	10(H)x7.87 (W)x 10.39(D) in 255(H) x 200(W) x 264(D) mm (with handle and foot mat)
Flow rate	5L/min with ±3%	Weight	12.8lbs/5.8Kg (without battery)
Flow rate control	Electronic, automatic closed-loop	Enclosure	316L Stainless Steel and anodized aluminum
Sampling time	0.1 seconds-999 hours 59 minutes 59 seconds	Power	AC 100-240V, 50 Hz/60 Hz
Delay	0-99 hours 59 minutes 59 seconds	Battery	10.8V, 9000mAh, rechargeable lithium battery
Cycles	1000 samples on one location	Operating conditions	Temperature: 5°C-35°C/41°F-95°F Relative humidity: 5-90% noncondensing
Interval	0-99 hours 59 minutes 59 seconds	Storage conditions	Temperature: 0°C-40°C/32°F-104°F Relative humidity: 5-90% noncondensing
Sampling mode	Manual, auto, cumulative count Σ / differential count Δ or concentration	Calibration frequency	Once a year
Zero count	<1count/5min	Warranty	1 year after activation
Concentration limit	4,000,000 particles/ft ³ @10% coincidence loss	Safety	FCC Part 15, Subpart B, EN 61010-1:2010, EN 61326-1:2013, EN 61326-2-2:2013, EN 61000-6-1:2007 EN 61000-6-3:2007+A1, EN 300328 V2.1.1: 2016, ETSI EN 301489-1 V2.2.0: 2017, ETSI EN 301489-17 V3.2.0:2017, EN 62311:2008, EN 62479: 2010, EN 60825-1: 2014, ASTM D 4169 DC13, FCC IDENTIFIER: 2AV6V-M110
Exhaust	Internal HEPA filter(>99.997%@0.3µm)		
Display	8.0" touch screen		
Language	Chinese, English		
Communication	RJ45, USB, SENSER-HUB, WIFI		
Alarm	Audible built-in alarm		
Capture the biological contamination sample	Connect the BioAerosol Sampler(BAS) via WIFI/USB to collect the biological contamination sample in real time		
Reports	ISO/EUGMP/CHINESEGMP		
Export file	PDF file or EXCEL file		



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