

BAMS

BioAerosol Monitoring System



- Real-time, continuous airborne microbial monitoring
- No need to incubate; Immediate results

Features

- Real-time, continuous airborne microbial monitor
- ISO 21501-3 compliant particle counter
- Efficient, user-oriented design
- First truly portable microbial monitor



Applications



Alerts

Provides real-time continuous data with alert capabilities when counts surpass an acceptable level. Instant alerts reduce the risk of product loss.



Process & Training

BAMS real-time results serve as an ideal 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 root cause identification of contamination sources.



Sterility Test Isolators

BAMS enables enhanced coordination and control of sterility testing in isolators.



Fill Line Quality

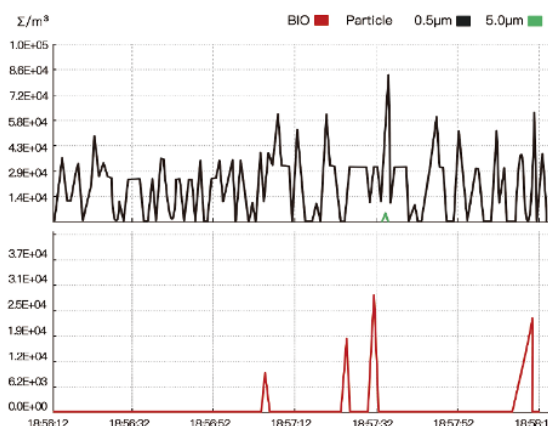
BAMS real-time continuous monitoring helps to ensure the cleanliness of fill line environments.

Wait Time vs. Real Time

Current airborne microbial monitoring relies on interval, ad-hoc, and event-driven sample collections, which necessitate incubation. This method takes 1-7 days to produce test results, causing delays and significantly hindering contamination root cause identification and doing little to prevent substantial production losses.

The current monitoring process also involves managing intricate schedules for collecting and manually examining many air samples each month. This is time-consuming and incurs significant labor and material costs.

BAMS offers a real-time, continuous viable and particulate monitoring solution that overcomes these limitations, providing immediate results and streamlining the entire monitoring process.



Testing Aspect	Compendial Method	BAMS Benefits
Time to Results	• 1-7 days • More scheduled/unscheduled breaks • Unlikely contamination identification • Increased cost and inefficiency risks	• Immediate • Likely contamination identification
Detection Frequency	• Sampled monitoring • Reduced accuracy • Limited trending • Greater contamination risk • Greater risk of production loss	• Continuous monitoring • Trend data and improved analysis • Reduced contamination and production loss risks
Coordination	• Resource intensive • Higher labor costs • Time delays	• Minimal costs and resources • Immediate and online

Increased Control

The Latest Technology

BAMS is designed to meet the stringent standards of pharmaceutical manufacturing, delivering real-time data for immediate action and preventing catastrophic losses. It is also engineered with end-users in mind: compact, lightweight, and user-friendly.

Optical Sensor Technology

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

- Particle sizing is achieved using the principle of Mie scattering in which the scatter pattern of light reflecting off a particle is measured.
- Concurrently, the instrument detects the presence or absence of intrinsic fluorescence from specific metabolites that indicate biological activity.

Specification Sheet

Specification		Specification	
BioAerosol Monitoring System BAMS		BioAerosol Monitoring System BAMS	
Size Range	0.5µm to 25µm	Export File	PDF file or EXCEL file
Size Channels	0.5µm,1.0µm,2.0µm,3.0µm, 5.0µm,10.0µm	Data Storage	119GB
Laser Source	Long life laser	Data Security	Authority management, authority level divide into admin, operator and supervisor
Size Resolution	<15% @ 0.5µm (meets ISO 21501-4)	Data Reliability	Compliant with 21 CFR Part11
Count Efficiency	50%±20% for 0.5µm,100%±10% for >0.75µm (meets ISO 21501-4 and JIS B9921)	Print	Auto or Off-line
Flow Rate	2.83LPM ±3%	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 control	Electronic, automatic closed-loop	Weight	12.8lbs/5.8kg; 14.9lbs/6.8kg (incl. battery)
Sampling Time	10 seconds-168 hours	Enclosure	316L Stainless Steel and anodized aluminum
Delay	0-99 hours 59 minutes 59 seconds	Power	AC 100-240V, 50 Hz/60 Hz
Cycles	1000 samples on one location	Battery	10.8V, 9000mAhX2, rechargeable lithium battery
Interval	5 seconds-99 hours 59 minutes 59 seconds	Operating Conditions	Temperature: 5°C-35°C/41°F-95°F Relative humidity: 5-90%, non-condensing
Sampling Mode	Manual, auto, cumulative count Σ / differential count Δ or concentration	Storage Conditions	Temperature: 0°C-40°C/32°F-104°F Relative humidity: 5-95%, non-condensing
Zero Count	<1count/5min	Calibration Frequency	Once a year
Concentration limit	4,000,000 particles/ft³ @10% coincidence loss	Warranty	12 months (calculated from the date of product activation or six months after the date of manufacture, whichever comes first).
Exhaust	Internal HEPA filter (>99999% @ 0.3µm)	Safety	EN 61010-1:2010+A1:2019, EN 61326-1:2013, EN 61326-2:2:2013, EN 60825-1:2014, EN 61000-6-1:2007, EN 61000-6-3:2007+A1, EN 62311:2008, EN 62479: 2010
Display	8.0" LCD capacitive touch screen		
Language	English, Chinese		
Communication	RJ45, USB, SENSER-HUB, WIFI		
Alarm	Audible built-in alarm		
Biologic Air Sample	Connect the BioAerosol Sampler(BAS) via WIFI/USB to the BAMS to collect a biological contamination sample in real time		
Reports	Compliant with ISO/EUGMP/CHINESEGMP/Fed Std		

Ordering Information

Name	Model	Order No.
BioAerosol Monitoring System BAMS	M120	MACHM120