BioAerosol Monitoring System

BAMS

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an analytichem company

1. BioAerosol Monitoring System (BAMS)

1.1 MONITORING AIRBORNE MICROBES IN REAL TIME

Continuous
Real-time, continuous airborne microbial monitor

Immediate
Certified ISO partible detector

No Consumables
Most efficient, user-oriented design

Most Effective
First truly portable microbial monitor

1.2 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.

Trends

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

Root Cause

A uniquely effective diagnostic tool, BAMS can instantaneously help detect excursions and help identify the root cause.

Process & Training

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

Sterility Test Isolators

BAMS enables enhanced coordination and control of sterility test isolators.

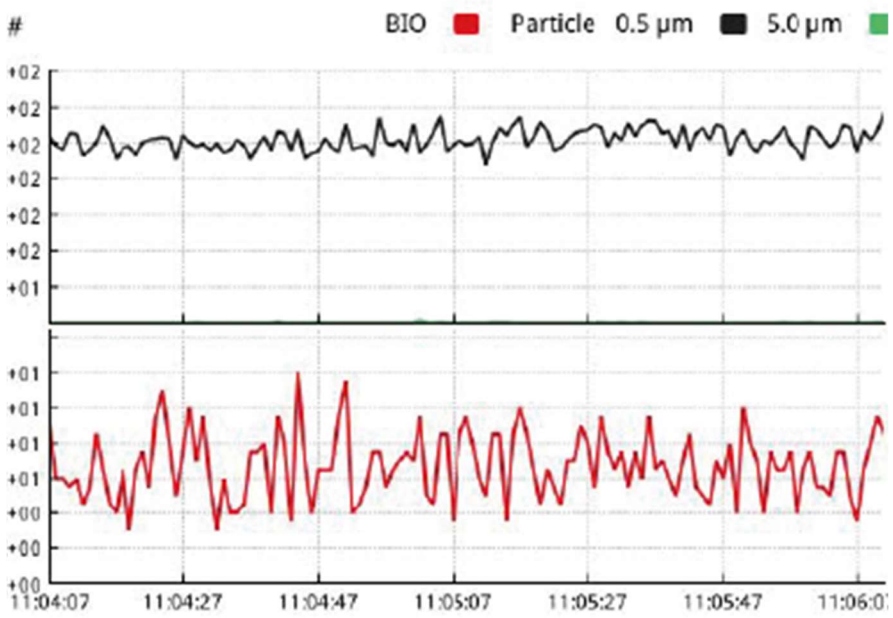
Fill Line Quality

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

1.3 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 labour and material costs.



Real time, Real data

Testing Aspect	Compendial Method	BAMS Benefits
Time to Results	1-7 days More scheduled / unscheduled breaks Unlikely contamination identification Increase 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 labour costs Time delays	Minimal costs and resources Immediate and online

1.4 INCREASED CONTROL

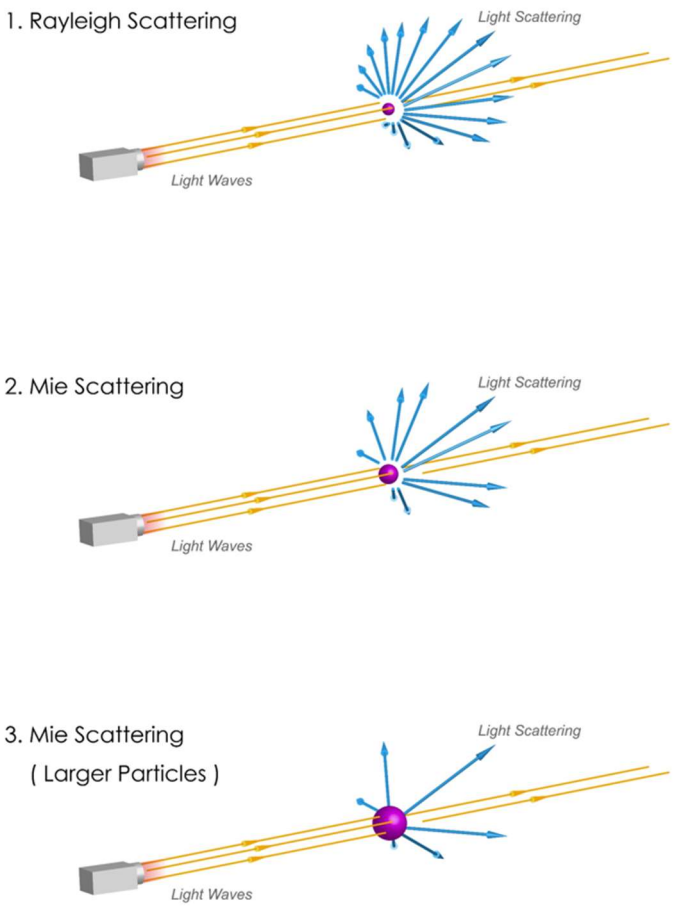
The Latest Technology

- BAMS was designed to meet exacting, pharmaceutical manufacturing standards while providing real-time data for immediate action and catastrophic loss avoidance
- Designed for end-users
- It is small, light and easy to use

1.5 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 utilised principle of Mie scattering
- Simultaneously, the instrument detects the presence or absence of the intrinsic fluorescence of certain metabolites that indicate biologic activity



Particle detecting: Mie scattering

2. Specification Sheet

Specification	BioAerosol Monitoring System	Specification	BioAerosol Monitoring System
Alarm	Audible built-in alarm	Battery	10.8V, 9000mAh, rechargeable lithium battery
Calibration frequency	Once a year	Capture the biological contamination sample	Connect the BioAerosol Sampler (BAS) via WIFI/USB to collect the biological contamination sample in real-time
Communication	RJ45, USB, SENSER-HUB, WIFI	Concentration limit	4,000,000 particles/ft^3 at 10% coincidence loss
Count efficiency	50% ± 20% for 0.5µm, 100% ± 10% for > 0.75µm (meets ISO 21501-4 and JIS B9921)	Cycles	1,000 samples on one location
Data reliability	Compliant with 21CFR Part 11	Data security	Authority management, authority level divide into admin, operator and supervisor
Data storage	119G	Delay	0-99 hours 59 minutes 59 seconds
Dimensions (HxWxD)	1O (H) x 7.87 (W) x 10.39 (D) in 255 (H) x 200 (W) x 264 (D) mm (with handle and foot mat)	Display	8.0" touch screen
Enclosure	316L Stainless Steel and anodized aluminium	Exhaust	Internal HEPA filter (>99.997% @ 0.3µm)
Export file	PDF file or EXCEL file	Flow rate	5L/min with ± 3%
Flow rate control	Electronic, automatic closed-loop	Interval	0-99 hours 59 minutes 59 seconds
Language	Chinese, English	Laser source	Long life laser
Operating conditions	Temperature: 5°C - 35°C / 41°F - 95°F Relative humidity: 5 - 90% non-condensing	Power	AC 100 - 240V, 50 Hz / 60 Hz
Print	Auto, off-line	Reports	ISO / EUGM P / CHINESEGM P

Specification	BioAerosol Monitoring System	Specification	BioAerosol Monitoring System
Safety	FCC Part 15, Subpart B, EN 61010 - 1:2010, EN 61326-1:2013, EN 6132 6-2-2:2013, EN 61000-6-1:2007, EN 61000-6-3:2007+A1, EN 300 32 8 V2.1.1: 2016, ETSI EN 301 489-1 V2.2.0: 2017, ETSI EN 301 489-17 V3.2.0: 2017, EN 62311:2008, EN 62479: 2010, EN 60825-1 :2014, ASTM D 4169 DC13, FCC IDENTIFIER: 2AV6V-M 110	Sampling mode	Manual, auto, cumulative count ∑/ differential count Δ or concentration
Sampling time	0.1 seconds - 999 hours 59 minutes 59 seconds	Size channels	0.5µm, 1.0µm, 2.0µm, 3.0µm, 5.0µm, 10.0µm
Size range	0.5µm to 25µm	Size resolution	<15% @ 0.5µm (meets ISO 21501-4)
Storage conditions	Temperature: 5°C - 35°C / 41°F - 95°F Relative humidity: 5 - 90% non-condensing	Warranty	1 year after activation
Weight	12.81bs / 5 .8kg (without battery)	Zero count	<1 count / 5 min

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