

# BAMS

## BioAerosol Monitoring System



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

## Features

- Real-time, continuous airborne microbial monitor
- Certified ISO particle detector
- Most efficient, user-oriented design
- First truly portable microbial monitor



## Application



### 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.



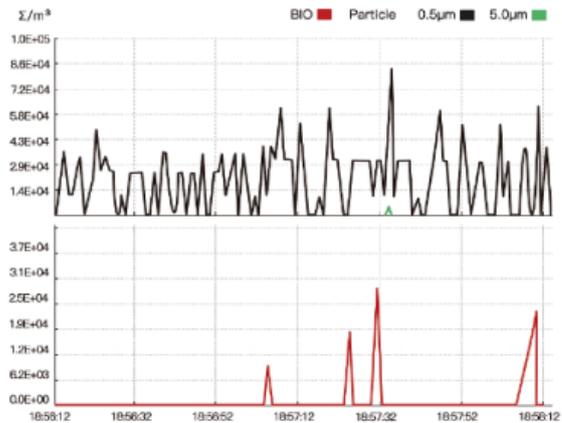
### Fill Line Quality

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

## 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
<b>Size range</b>	0.5µm to 25µm	<b>Export file</b>	PDF file or EXCEL file
<b>Size channels</b>	0.5µm,1.0µm,2.0µm,3.0µm, 5.0µm,10.0µm	<b>Data storage</b>	119GB
<b>Laser source</b>	Long life laser	<b>Data security</b>	Authority management, authority level divide into admin, operator and supervisor
<b>Size resolution</b>	<15% @ 0.5µm (meets ISO 21501-4)	<b>Data reliability</b>	Compliant with 21 CFR Part11
<b>Count efficiency</b>	50%±20% for 0.5µm,100%±10% for >0.75µm (meets ISO 21501-4 and JIS B9921 )	<b>Print</b>	Auto or Off-line
<b>Flow rate</b>	2.83LPM ±3%	<b>Dimensions (HxWxD)</b>	10(H) x7.87 (W) x 10.39(D) in 255(H) x 200(W) x 264(D) mm (with handle and foot mat)
<b>Flow rate control</b>	Electronic, automatic closed-loop	<b>Weight</b>	12.8lbs/5.8kg; 14.9lbs/6.8kg (incl. battery)
<b>Sampling time</b>	10 seconds-168 hours	<b>Enclosure</b>	316L Stainless Steel and anodized aluminum
<b>Delay</b>	0-99 hours 59 minutes 59 seconds	<b>Power</b>	AC 100-240V, 50 Hz/60 Hz
<b>Cycles</b>	1000 samples on one location	<b>Battery</b>	10.8V, 9000mAhX2, rechargeable lithium battery
<b>Interval</b>	5 seconds-99 hours 59 minutes 59 seconds	<b>Operating conditions</b>	Temperature: 5°C-35°C/41°F-95°F Relative humidity: 5-90%, non-condensing
<b>Sampling mode</b>	Manual, auto, cumulative count Σ / differential count Δ or concentration	<b>Storage conditions</b>	Temperature: 0°C-40°C/32°F-104°F Relative humidity: 5-95%, non-condensing
<b>Zero count</b>	<1count/5min	<b>Calibration frequency</b>	Once a year
<b>Concentration limit</b>	4,000,000 particles/ft <sup>3</sup> @10% coincidence loss	<b>Warranty</b>	12 months (calculated from the date of product activation or six months after the date of manufacture, whichever comes first).
<b>Exhaust</b>	Internal HEPA filter(>99.999% @ 0.3µm)	<b>Safety</b>	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
<b>Display</b>	8.0" LCD capacitive touch screen		
<b>Language</b>	English, Chinese		
<b>Communication</b>	RJ45, USB, SENSER-HUB, WIFI		
<b>Alarm</b>	Audible built-in alarm		
<b>Capture the biological contamination sample</b>	Connect the BioAerosol Sampler(BAS) via WIFI/USB to collect the biological contamination sample in real time		
<b>Reports</b>	Compliant with ISO/EUGMP/CHINESEGMP/Fed Std		

## Ordering Information

Name	Model	Order No.
BioAerosol Monitoring System   BAMS	M120	MACHM120

### Scientific & Environmental Monitoring Technologies



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