AIR SAMPLERS

BAMS: BioAerosol Monitoring System

Real-time Microbial Monitoring

MicLev
Quality Products for Microbiology

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BAMS: BioAerosol Monitoring System

GREATER CONTROL

IMMEDIATE DATA

LOWER COST

...TRULY PORTABLE

MICRONVIEW

Leaders in Real-time Microbial Monitoring Technology

The New Baseline…

Compendial Method Issues	vs. Real-time Microbial Monitoring
Lost Time	☑ Immediate, real-time results
	☑ Microbe presence/count
	☑ Microbe sizes in microns
Excessive Resources	☑ No consumables
Limited Control	☑ Continuous data history
	☑ Parametric release facilitation
	☑ Rapid dynamic solution
Regulatory Demands	☑ Root cause analysis
	☑ Reduced product loss

…with the BAMS Difference

BAMS	vs. Market
Just 20 lbs.	☑ Lightest
< 1ft^3 [¼ to ½ other units]	☑ Smallest
Built to truly be carried	☑ Only one
Near silent when running	☑ Only one
8-inch touch-screen interface	☑ Largest
AC power & 4-hour battery	☑ Only one
Six detection channels	☑ Most
Price	☑ ***Lowest***

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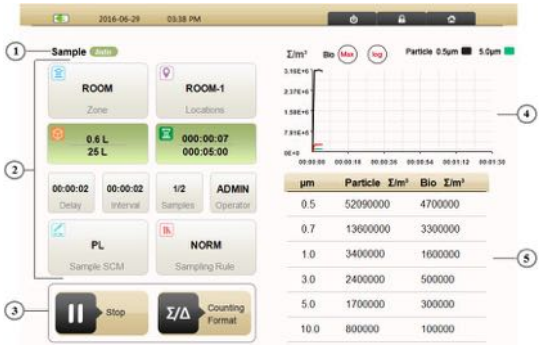
BAMS User Interface

IMMEDIATE ON-SCREEN DATA

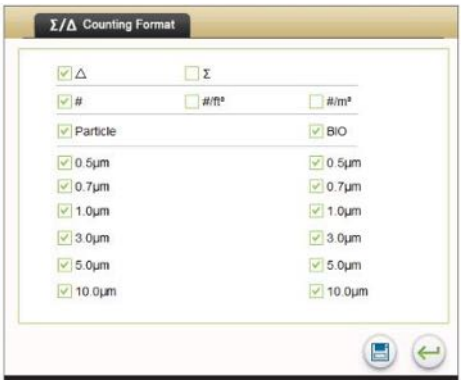
BAMS' intuitive visual displays and audio alerts communicate user-defined, particle contamination parameters and sampling status. BAMS' authority settings also enable situation-specific access.



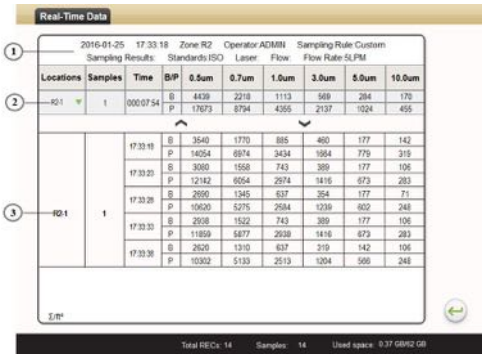
Sampling Display

USER-DEFINED, SIX-CHANNEL PARTICLE SEGMENTATION

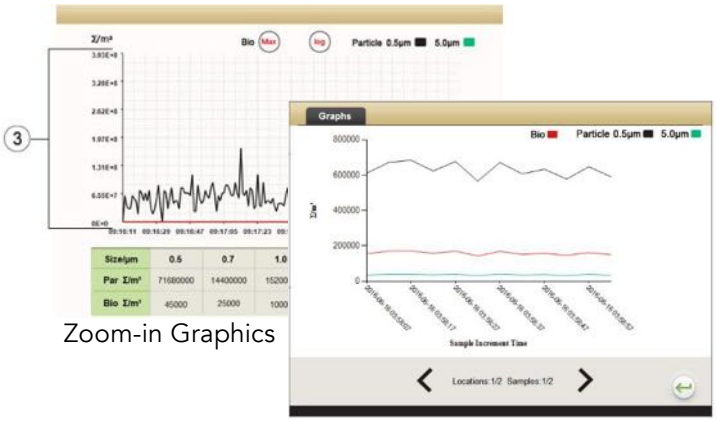
Users can choose to review inert and biologic particles in BAMS' six channels, from 0.5 to 10 µm and review results in customized parameter-driven data and graphic displays.



Counting Parameters



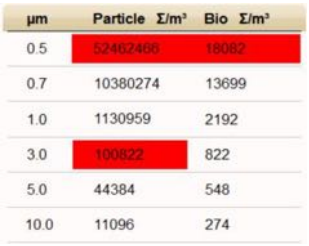
Real-time Data



Zoom-in Graphics

USER-DEFINED ALERTS

BAMS allows you to easily set, save and add location-specific biologic and particle size/volume alert parameters. Coupled with its compact size, this reinforces BAMS true functional, mobility.



Counting Alarm

Flow Alert

MULTI-MODE APPLICATIONS

Auto: On one location, sampling will stop after all cycles are complete

Manual: On one location, sampling will continue once *Start* is pressed

Differential: Counting the number of particles between the selected and adjacent channels

Cumulative: Counting the number of particles above the selected channel.

Normal: Sampling per ISO/EUGMP/ChineseGMP. Parameters cannot be modified once the room and sampling scheme is selected.

Custom: Sampling parameters can be modified and sampling can be stopped at any moment.

BAMS Uses

ALERTS

Regardless of the sampling mode, BAMS instantaneously detects contamination.

- There is no 1-7 day waiting period to know when and excursion occurs.
- On-screen or remotely accessible data facilitates immediate reaction.
- Production losses are significantly mitigated.
- Stored, user-defined alert parameters enable location-specific flexibility while also providing increased efficiency in repetitive processing.

TRENDS

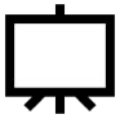
Given delays and time lapses inherent to compendial testing methods, trend analysis is all but prohibited. BAMS changes that.

- Providing real-time and continuous data immediately available for any excursion, BAMS makes trends analysis truly possible.
- In addition to facilitating internal regulatory and compliance demands, BAMS also provides invaluable process analysis in executing the FDA's PAT initiative.

ROOT CAUSE

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

- The continuous sampling data—with corresponding time stamps—can be rerun and analyzed either on-screen or via data exports.
- The analysis capabilities provide immediate insight into an excursion, representing revolutionary access to root cause identification and remediation.
- Post-remediation, BAMS can then validate success to ensure ongoing operation with certainty and confidence.



PROCESS & TRAINING

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

- Providing instantaneous results, BAMS can confirm proper technique or remediate improper technique on-the-spot.
- BAMS' immediate data also facilitates testing new techniques, procedures and enhance process with far greater efficiency in advance of disseminating new processes.

STERILITY TEST ISOLATORS

BAMS enables an enhanced coordination and control with sterility test isolators.

- BAMS assesses the isolator pre-test, post-test and during testing, simply by connecting BAMS' intake tube.
- Any pre-test alerts enable decontamination and instantaneous validation, essentially eradicating a degraded test environment.
- In-process testing alerts enable also help root issue identification and immediate remediation or mitigation actions.

FILL LINE QUALITY

BAMS can help ensure the crucial quality environment for this process.

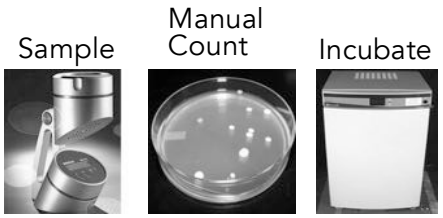
- Continuous real-time data feeds, alerts and trend/root cause analysis all significantly reduce the chance and cost of product loss.
- Pre-production alerts exponentially mitigate certain product loss risks while alerts in the midst of production enable immediate reaction and remediation for current and future batch production.
- BAMS helps reduce scrap rates and production downtime while increasing a preventative learning curve.

◦ CONTINUOUS DATA ◦ MINIMAL LABOR ◦ NO CONSUMABLES ◦ PORTABLE ◦

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.



Real Time
Real Data

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 • Desired location placement

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.

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Technical Specifications

Specification	Description
Detection Methods	Mie Scatter for Particle Size / Fluorescence
Size channels	0.5μm, 1.0μ, 2.0μm, 3.0μm, 5.0μm, 10.0μm
Detectors	Photodiode and PMT
Light source	laser diode
Laser wavelength	405 nm
Flow rate	5L/min with ≤±5%
Sampling time	5 seconds-500 hours
Delay	0-99 hours 59 minutes 59 seconds
Cycles	100 samples on one location
Interval	0-99 hours 59 minutes 59 seconds
Sampling mode	Manual, auto, cumulative count, differential count, or concentration
Zero count	<1 count/5 minutes
Exhaust	Internal HEPA filter
Display	8.0 inch touch screen
Communication mode	USB, WIFI or Ethernet
Reports	ISO/EUGMP/CHINESEGMP
Export file	PDF file or EXCEL file
Data storage	128G
Key Software features	Historical data playback
Print	Auto, off-line
Language	English
Data security	Password protected
Alarm	Audible built-in alarm
Calibration frequency	Once a year recommended
Power	AC 100-240V, 50 Hz/60 Hz
Battery	11.1v, 7800mAh Lithium battery, over 4-hour run-time
Power consumption	120W
External surface	Aluminum alloy
External Surface Chemical Resistance	Isopropyl alcohol
Dimensions	255(L) x 265.35(W) x 287(H) mm / 10.04(L) x 10.45(W) x 11.3(H) in (with handle and foot mat)
Weight	9.15Kg / 20.17 lb
Operating conditions	Temperature: 5°C -30°C / 41°F - 86°F, relative humidity up to 80%. Pressure: 70-106Kpa / 10.15-15.37psi
Storage conditions	Temperature: 0°C -40°C / 32°F - 104°F, relative humidity up to 80%.
Operating Humidity Range	10-85% RH, non-condensing
Safety	IEC 61010-1:2010。

FOR MORE INFORMATION

To discover how BAMS can help to protect your environment, call 520.261.5105.

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