



BAMS

BioAerosol Monitoring System

Monitoring Airborne Microbes in Real Time

- Continuous Monitoring
- Immediate Data
- Lower Cost

CONTINUOUS

Real-time, continuous airborne microbial monitor

IMMEDIATE

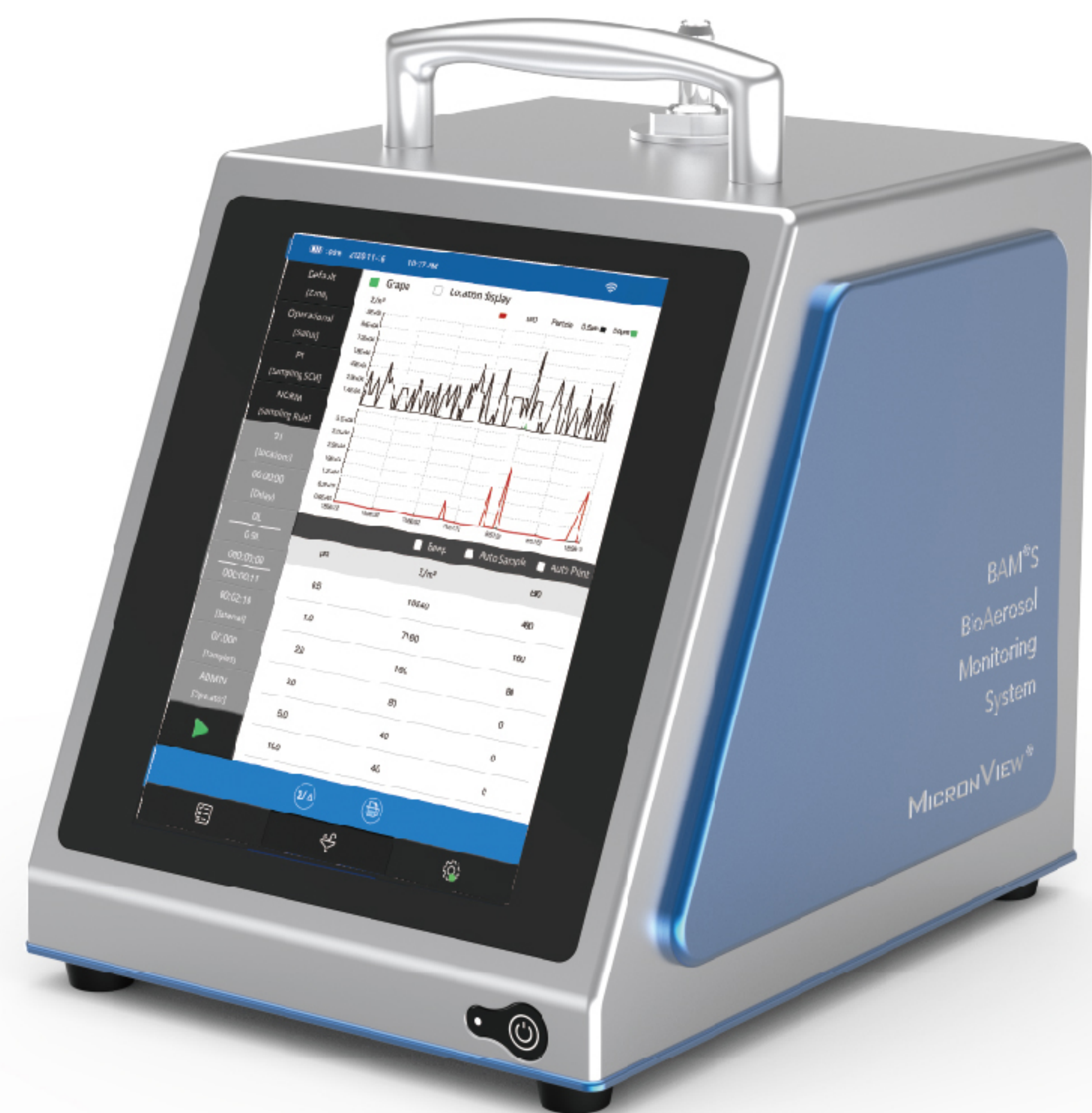
Certified ISO particle detector

NO CONSUMABLES

Most efficient, user-oriented design

MOST EFFECTIVE

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

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



STERILITY TEST ISOLATORS

BAMS enables enhanced coordination and control of sterility test isolators.



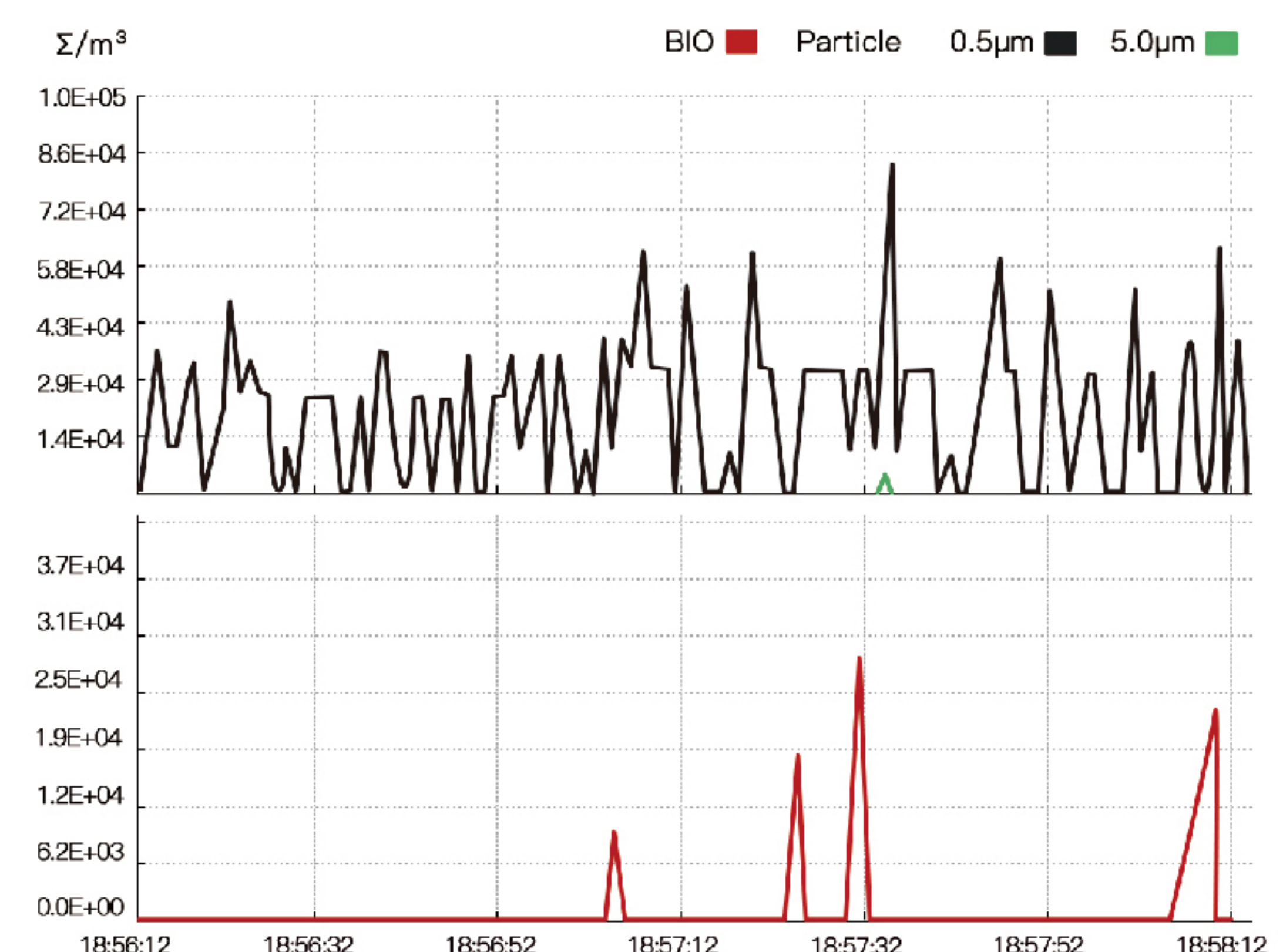
FILL LINE QUALITY

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.



Real Time ,Real Data

| 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 • Trend 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 | Export file | PDF file or EXCEL file |
| Size channels | 0.5µm, 1.0µm, 2.0µm, 3.0µm, 5.0µm, 10.0µm | Data storage | 119G |
| 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 21CFR Part11 |
| Count efficiency | 50%±20% for 0.5µm, 100%±10% for >0.75µm (meets ISO 21501-4 and JIS B9921) | Print | Auto, off-line |
| Flow rate | 5L/min with±3% | Dimensions (HxWxD) | 10 (H) x 7.87 (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 (without battery) |
| Sampling time | 0.1 seconds-999 hours 59 minutes 59 seconds | 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, 9000mAh, rechargeable lithium battery |
| Interval | 0-99 hours 59 minutes 59 seconds | Operating conditions | Temperature: 5°C-35° C/41°F-95°F Relative humidity: 5-90% noncondensing |
| Sampling mode | Manual, auto, cumulative count Σ / differential count Δ or concentration | Storage conditions | Temperature: 5°C-35° C/41°F-95°F Relative humidity: 5-90% noncondensing |
| Zero count | <1count/5min | Calibration frequency | Once a year |
| Concentration limit | 4,000,000 particles/ft³at 10% coincidence loss | Warranty | 1 year after activation |
| Exhaust | Internal HEPA filter (>99.997%@0.3µm) | 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 301 48917 V3.2.0: 2017, EN 62311:2008 EN 62479: 2010, EN 60825-1: 2014 ASTM D 4169 DC13,FCC IDENTIFIER: 2AV6V-M110 |
| 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 | | |

Ordering Information

| Name | Model | Order No. |
|-------------------------------------|-------|-----------|
| BioAerosol Monitoring System BAMS | M110 | MACHM110 |

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