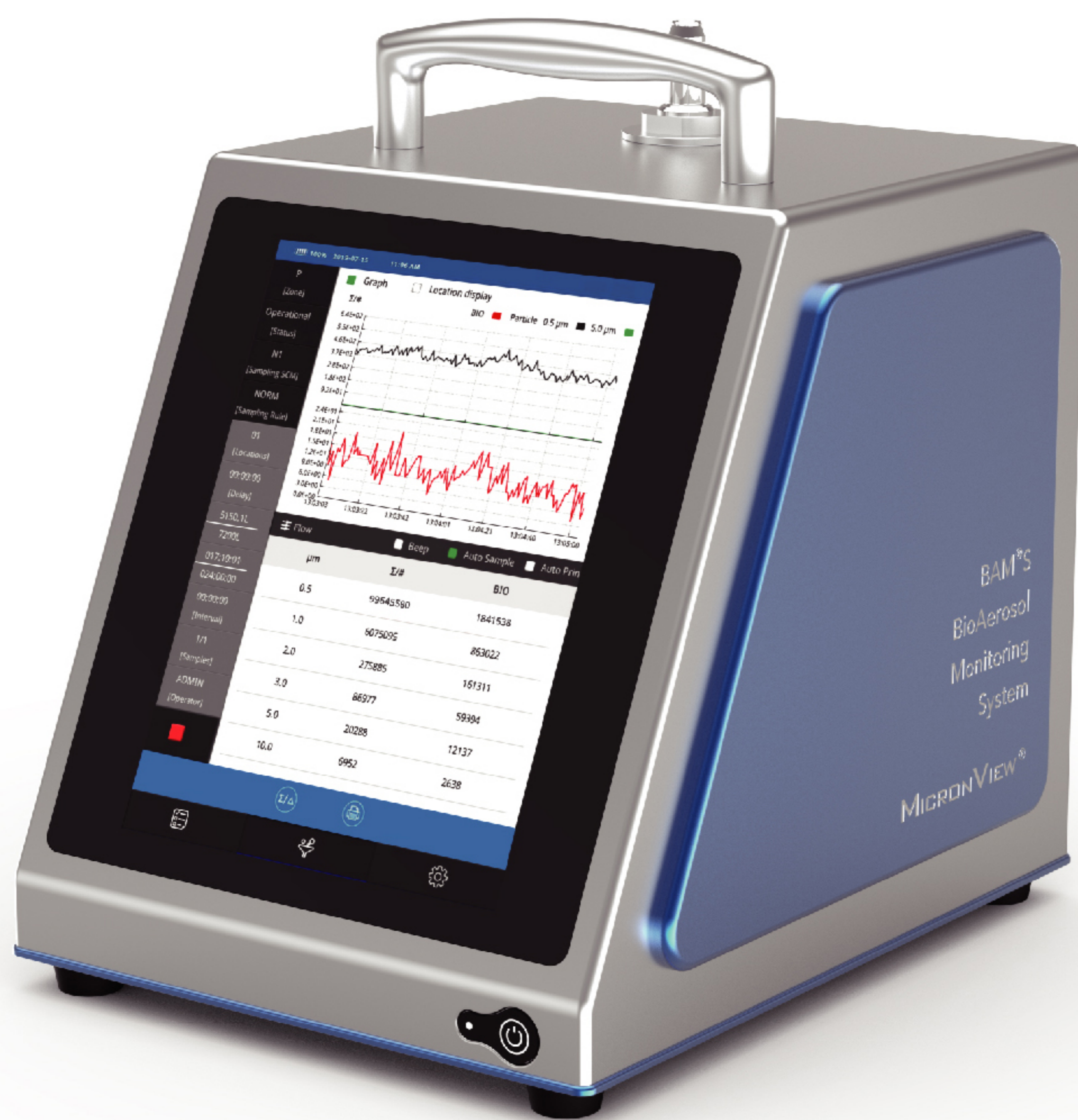


# BAMS: BioAerosol Monitoring System



- LOWER COST
- IMMEDIATE DATA
- CONTINUOUS MONITORING

Monitoring Airborne Microbes in Real Time



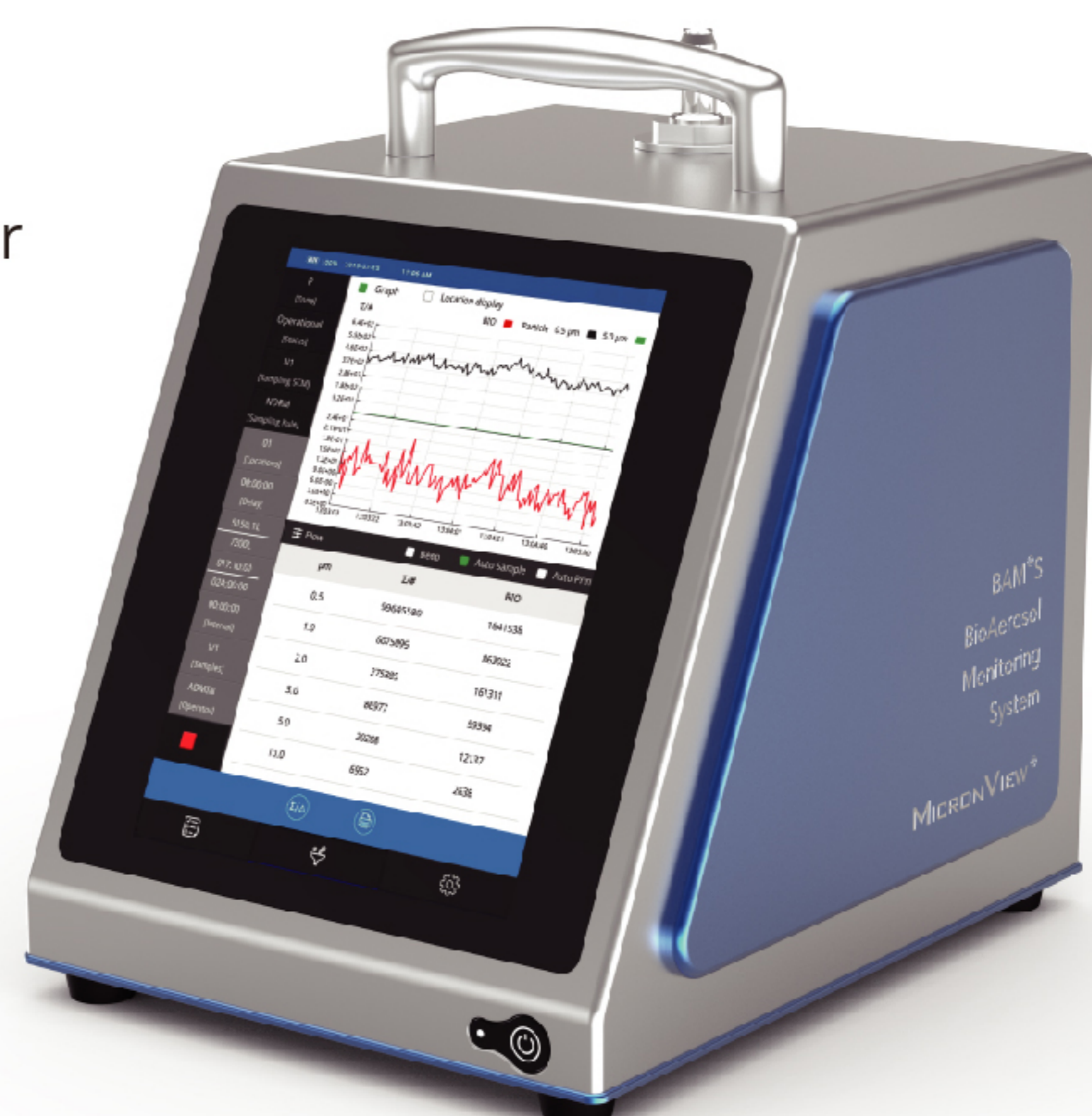
CONTINUOUS  
IMMEDIATE  
NO CONSUMABLES  
MOST EFFECTIVE

Real-time, continuous airborne microbial monitor

Certified ISO particle detector

Most efficient, user-oriented design

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.



### STERILITY TEST ISOLATORS

BAMS enables enhanced coordination and control of sterility test isolators.



### ROOT CAUSE

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



### FILL LINE QUALITY

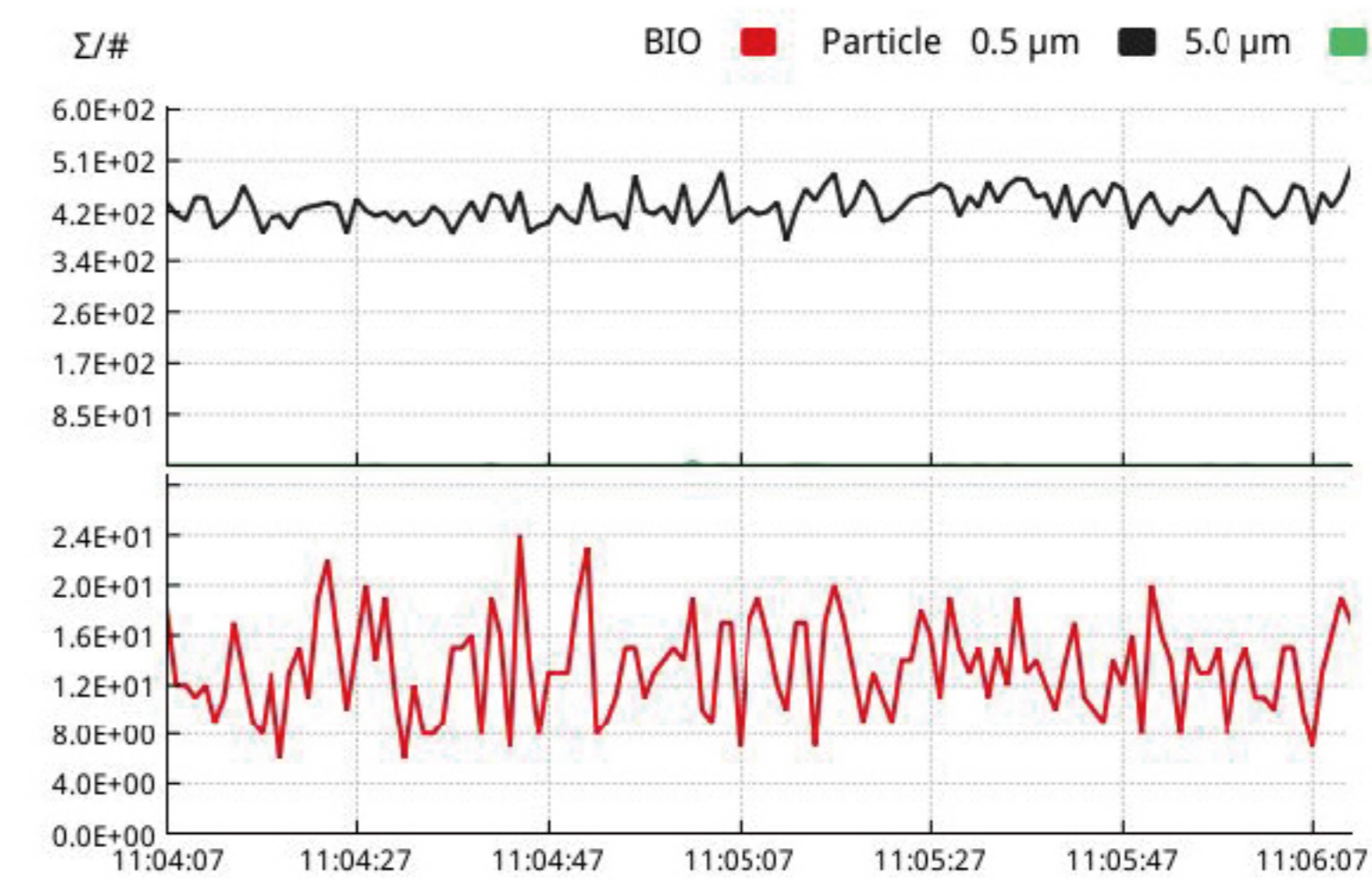
BAMS real-time continuous monitoring helps to ensure the cleanliness of this crucial quality environment.



# 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"> <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>
Detection Frequency	<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>• Trend data and improved analysis</li> <li>• Reduced contamination and production loss risks</li> </ul>
Coordination	<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	Specification	BioAerosol Monitoring System
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%	Alarm	Audible built-in alarm
Flow rate control	Electronic, automatic closed-loop	Calibration frequency	Once a year
Sampling time	0.1 seconds-999 hours 59 minutes 59seconds	Dimensions (HxWxD)	10x7.87x10.39 in/255x200x264mm (with handle and foot mat)
Delay	0-99 hours 59 minutes 59 seconds	Weight	12.8lbs/5.8Kg (without battery)
Cycles	1000 samples on one location	Enclosure	316L Stainless Steel and anodized aluminum
Interval	0-99 hours 59 minutes 59 seconds	Power	AC 100-240V, 50 Hz/60 Hz
Sampling mode	Manual, auto, cumulative count Σ / differential count Δ or concentration	Battery	10.8V, 9000mAh, rechargeable lithium battery
Zero count	<1count/5min	Operating conditions	Temperature: 5°C-35° C/41°F-95°F Relative humidity: 5-90% non-condensing
Concentration limit	4,000,000 particles/ft³at 10% coincidence loss	Storage conditions	Temperature: 0°C-40° C/32°F-104°F Relative humidity: 5-90% non-condensing
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 300 328 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-M110
Display	8.0" touch screen		
Language	Chinese, English		
Communication	RJ45, USB, SENSER-HUB, WIFI		
Capture the biological contamination sample	Connect the BioAerosol Sampler(BAS) via WIFI/USB to collect the biological contamination sample in real time		
Warranty	1 years after activation		
Reports	ISO/EUGMP/CHINESEGMP		

## Ordering Information

Name	Model	Order No.
BioAerosol Monitoring System   BAMS	M110	MACHM110

### Micron View Limited

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