



BAMS: Market Comparison Review

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1. Specification Comparison

1.1 FLOW RATE

- ▶ BAMS: Features a flow rate of 5L/min \pm 3%, meeting the minimum requirement for viable particle detection. This enables real-time assessment of the environment and potential contamination risks.
- ▶ Competitor: Offers a flow rate of 28.3L/min \pm 5%, which exceeds the necessary flow rate but does not specifically meet the 5L/min requirement for viable particle detection.

1.2 THE UNIT

- ▶ BAMS: Dimensions of 255(h) x 200(w) x 264(d) and weighing 5.8kg. Constructed with stainless steel and anodized aluminium, providing a compact and lightweight design. The materials used ensure durability and resistance to harsh cleaning disinfectants.

These robust materials prevent deterioration of the instrument from harsh cleaning disinfectants such as QUAT, Biguands, IPA and hydrogen peroxide. The inlet to the BAMS device must be covered or valved to prevent ingress of VHP as it will damage the internal mechanism.

- ▶ Competitor: Dimensions of 483(h) x 267(w) x 343(d) and weighing 18.6kg, made solely of stainless steel. The unit is larger and heavier compared to BAMS.
- ▶ BAMS: Sample time is 0.1 sec to 100 hrs to fulfil the interpretation of GMP Annex 1 guidance on continuous monitoring. The customer can then monitor throughout setup, through a campaign and clear down processes.
- ▶ Competitor: Sample time is 1 sec to 99 hrs.

1.3 REGULATIONS

Both BAMS and the competitor unit meet the following regulations:

- ▶ Particle size requirements are met for the ISO14644 cleanroom classification and GMP Annex 1 on viable particles of 0.5 to 5 μ .
- ▶ ISO 21501-4 regarding size resolution (<15% @ 0.5 μ m).
- ▶ ISO 21501-4 and JIS B9921 for counting efficiency (50% at 0.5 μ m; 100% for particles >0.75 μ m).

1.4 DATA

- ▶ BAMS: Provides the ability to export files in PDF or Excel format. PDF ensures secure information retrieval, preventing manipulation. Excel format facilitates data trending, if required, for compliance with GMP Annex 1 and 21 CFR part 11. The unit also offers a storage capacity of 119G, allowing for the retrieval of historical data for trending or regulatory inspections.
- ▶ Competitor: Requires bespoke software to export files. Storage capacity limited to 10,000 samples.

1.5 CONNECTIVITY

- ▶ BAMS: Offers multiple connectivity options, including USB, WiFi, Ethernet, and SENSER-HUB. This allows IT departments to establish secure connections in accordance with 21 CFR part 11 compliance. The unit's neutral platform ensures compatibility with any Laboratory Information Management System (LIMS) and supports communication through the MODBUS protocol, commonly used in facility IT systems.
- ▶ Competitor: Limited to USB and Ethernet connectivity. Requires bespoke software for connectivity.

In summary, BAMS meets the GMP Annex 1 requirement for viable particle detection with an appropriate flow rate. It has a smaller and lighter design, employing durable materials for resistance to harsh cleaning disinfectants. Both units comply with relevant regulations. BAMS offers more flexible data export options and higher storage capacity. Additionally, BAMS provides a wider range of connectivity avenues, enabling secure connections and compatibility with various software and communication protocols.



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