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ISOKINETIC MICROBIAL AIR SAMPLING ON MAS-100 INSTRUMENTS

APPLICATION NOTE

ABSTRACT

Microbial air sampling in controlled environments should be performed in a manner that does not disrupt the surrounding airflow. Also, the EU GMP Annex 1 emphasizes the need for isokinetic sampling for total particles.
MAS-100® instruments sample air at a rate of 100 L/min, which is isokinetic. This application note explains the sampling process using MAS-100 instruments and compares it to sampling at a lower flow rate of 25 L/min. The calculation of the air velocity over the sampling area is complemented by a CFD data simulation and a smoke study that visualizes the air flow to the human eye. The data and experiment show that at a flow rate of 100 L/min under laminar flow conditions, the MAS-100 instruments sample the air isokinetically, ensuring a representative sample, while this is not the case at a flow rate of 25 L/min.

INTRODUCTION

Microbial air sampling in low turbulence unidirectional airflow environments such as cleanrooms, isolators, RABS or other controlled environments should be performed with minimal interference between the sampling process and the surrounding airflow.
Volumetric air samplers remove a specific volume of the air and transfer it to an agar surface. To achieve a representative sample of the air supply, the velocity of the air collection should match the velocity of the supplied air and only then air is sampled isokinetically (Figure 1). Likewise, it is important to sample air in the same direction as the air flows.
The fact that EU GMP Annex 1 requests isokinetic sampling for total particles (§5.9, EU GMP Annex 1), further strengthens the importance of collecting particles from the air over a defined time and area without disturbing the air path.
In case of hypokinetic sampling the flow rate of the sampler is slower than the external air supplied. A faster sampling flow rate compared to the external flow leads to hyperkinetic sampling. Both scenarios generate a histogram shift of the sampled particles and lead to under- or oversampling of microbe-carrying particles and disturb the uni-directional air flow pattern (Figure 1).

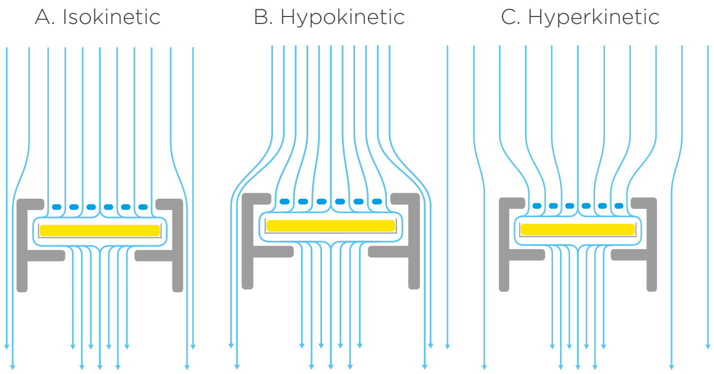


FIGURE 1: Schematic representation of different sampling modes regarding isokinesis. A. isokinetic sampling, B. hypokinetic sampling and C. hyperkinetic sampling.

Continuous viable air monitoring in grade A is a new Annex 1 requirement and must be performed during critical processing and equipment assembly (§9.24, EU GMP Annex 1). MAS-100® instruments sample air with a flow rate of 100 liters/minute (L/min) and thus collect 1'000 L in 10 minutes. MBV recommends combining active air sampling with MAS-100 instruments together with settle plates for continuous monitoring to meet Annex 1 conformity (MBV, Expert view 2023). Other strategies exist to cover continuous viable air monitoring. By reducing the air flow from 100 L/min to 25 L/min, active air monitoring can be extended from 10 to 40 minutes to collect 1'000 L of air. This document explains the isokinetic sampling process on all MAS-100 instruments and compares it to sampling with 25 L/min.

CALCULATION OF ISOKINETIC SAMPLING SPEED

The mobile air samplers MAS-100 NT® and MAS-100 VF® which are mainly used in unidirectional air flow cleanrooms are designed to exhaust air in the same direction as they aspirate. This avoids introducing turbulence into the airstream. The microbial air samplers MAS-100 Iso MH® and MAS-100 Iso NT® are integrated into isolators or RABS. Only their sampling heads must be considered for airflow integrity as only those are located inside the containment while the control unit is placed outside.
All microbial air samplers of the MAS-100 family aspirate air at a rate of 100 L/min with the highest precision. Thanks to precisely manufactured perforated lids with either 300 or 400 holes they allow an ideal physical and biological sampling efficiency. In some instruments this air flow is controlled by a built-in temperature and pressure-compensated mass-flow sensor (MAS-100 NT, MAS-100 Iso MH, MAS-100 Iso NT).
For isokinetic air sampling the air volume per surface area supplied by the filter fan unit (FFU) of the controlled environment must be very similar to the air volume aspirated by the microbial air sampler on the same area. The inner diameter of MBVs perforated lids is 7 cm. The outer dimension of all sampling heads is 11 cm (Figures 2 & 3).

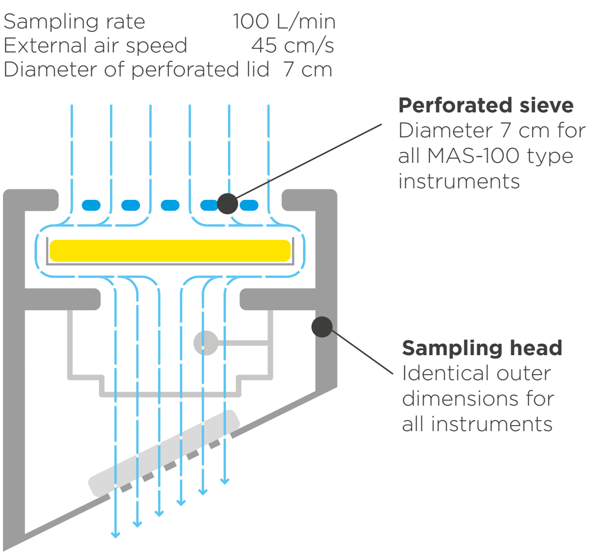


FIGURE 2: Schematic of sampling head with external airflow velocity (0.45 m/s) and volumetric sampling rate (100 L/min). For isokinetic sampling the air sampler aspires the identical volume of air supplied to the surface of the perforated sieve.

FIGURE 3: Top view of 300 x 0.6 mm stainless steel perforated lid. More on perforated lids and the difference between different types of lids including sampling efficiency can be found here: www.mbv.ch/perforated-lids.

TABLE 1: CALCULATION OF AIR SPEED ON SAMPLING AREA OF THE MAS-100 WITH 100 L/MIN

Parameter	Unit	FFU	MAS-100	Comments
Air flow	cm^3/s		1667	Equals 100 L/min
Sampling surface diameter	cm		7	Diameter of sampling sieve
Sampling surface area	cm^2		38.48	$A = \pi r^2$
Air speed on sampling area	cm/s	45±20%	43.3	Typical air speed 0.45 m/s
Difference to nominal isokinetic velocity			-4%	

TABLE 2: CALCULATION OF AIR SPEED ON SAMPLING AREA WITH 25 L/MIN

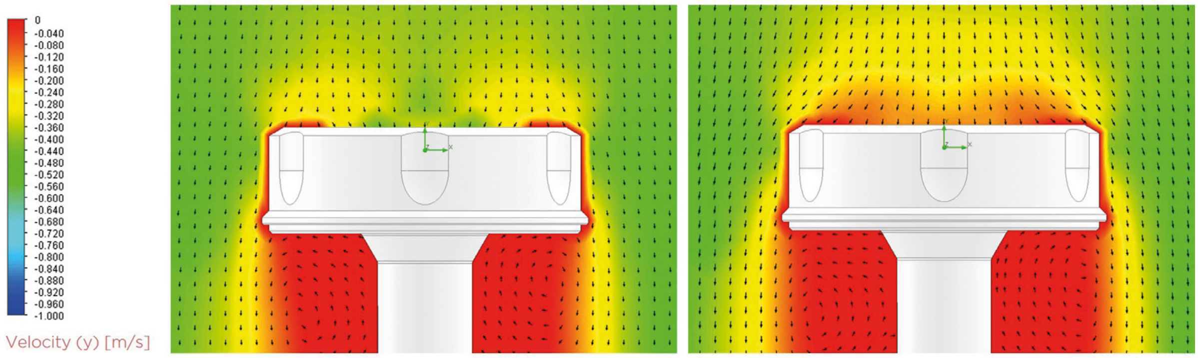
Parameter	Unit	FFU	25 L/min	Comments
Air flow	cm^3/s		417	Equals 25 L/min
Sampling surface diameter	cm		7	Diameter of sampling sieve
Sampling surface area	cm^2		38.48	$A = \pi r^2$
Air speed on sampling area	cm/s	45±20%	11.0	Typical air speed 0.45 m/s
Difference to nominal isokinetic velocity			-76%	

A laminar flow velocity of 0.45 m/s at the FFU is typical for isolators and cleanrooms. The MAS-100 family of microbial air samplers aspirate air with a speed of about 0.43 m/s over the sampling area (calculated in Table 1). Whereas an aspiration rate of 25 L/min with a perforated lid with identical diameter, an air speed of 0.11 m/s is reached on the sampling area giving a 76 % difference to the isokinetic flow rate (calculated in Table 2).

CFD SIMULATION OF ISOKINETIC SAMPLING SPEED

To visualize the air flow pattern of the calculated sampling speed computational fluid dynamics (CFD) was performed under laminar flow conditions. CFD compared flow rates of 100 L/min and 25 L/min of an MAS-100 Iso head in a laminar flow environment with an air velocity of 0.45 m/s.

A sampling flow rate of 1666.667 cm^3/s for 100 L/min and 416.667 cm^3/s for 25 L/min were set, respectively. This air flow visualizations supports the calculated data demonstrating that with a flow rate of 100 L/min the external air supplied was collected by the air sampler (Figure 4A). At 25 L/min the collection flow rate is too low compared to the supplied air leading to slowdown of the air flow above the sampling head and thus disturbs the air flow pattern (Figure 4B).



A. 100 L/min

B. 25 L/min

FIGURE 4: CFD data comparing A. 100 L/min with B. 25 L/min flow rate under laminar flow conditions with 0.45 m/s.

SMOKE STUDY

In a laminar flow study ultrapure water was nebulized via ultrasound under laminar flow conditions and air was aspirated with 100 L/min. The test confirms the CFD data and shows that the MAS-100 perforated lids sample air isokinetically at 100 L/min. The overall laminar flow around the air sampler head remains largely undisturbed.

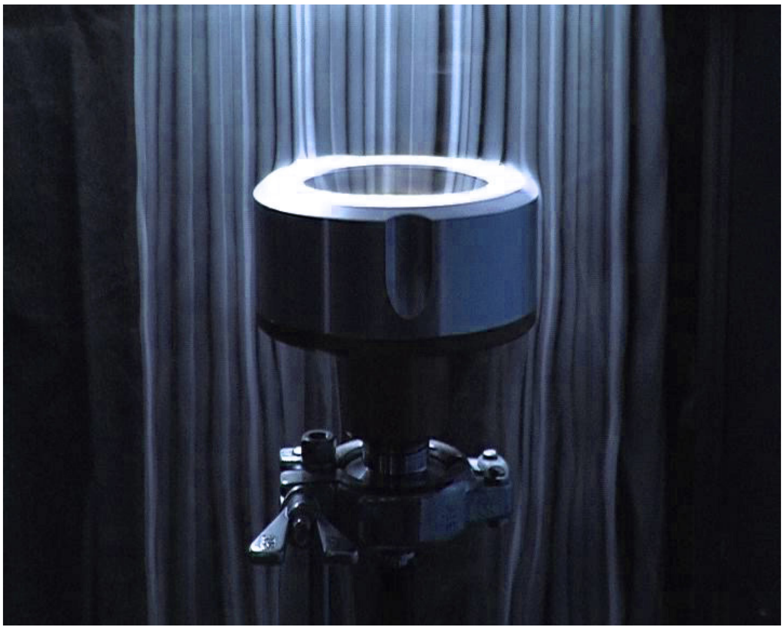


FIGURE 5: Real air visualization study under laminar flow conditions at a sampling flow rate of 100 L/min.

CONCLUSION

In this application note we demonstrate that with a flow rate of 100 L/min under laminar flow conditions MAS-100 instruments sample air isokinetically. This assures that a representative sample of the air supplied above the sampling point is taken. This is in conformity with the requirement that the sampling equipment should not interfere with the laminar airflow in the controlled environment. If air is sampled with a perforated lid with the same inner diameter and with a flow rate of 25 L/min, then the sampling is hypokinetic leading to a disturbance of the supplied air and no representative sample of particles from the air can be collected.

ABOUT THE AUTHORS

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Miriam Schönenberger is a microbiologist and holds a PhD in cancer research from ETH Zurich.
She has many years of experience in business development and after sales of laboratory equipment and channeled customer needs into concrete product portfolio strategies.
At MBV AG, she is responsible for the products for microbial air monitoring in isolators and RABS and develops convincing solutions for aseptic production together with interdisciplinary teams.

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Alwinder Singh is a design engineer with a bachelor's degree in biotechnology from the ZHAW Wädenswil. He has worked over 10 years in product development for various companies, ranging from waste burning plants, implants to novel surgical robots.
At MBV AG, he is responsible for product development, fluid dynamic simulations and hands on testing of possible new features for further products.

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- MBV (2023) Expertview. ERP Article

FURTHER INFORMATION

We offer you additional information on our products on these channels:

- Expert Focus: EU GMP Annex 1
  www.mbv.ch/en/expert-center/expert-focus-EU-GMP-annex-1

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