AIR. NOTHING ELSE.

AIRFLOW VISUALIZATION WITH THE MAS-100 LIBRA®

APPLICATION NOTE

ABSTRACT

The MAS-100 Libra® is a cutting-edge instrument designed to automate passive air sampling using settle plates in pharmaceutical cleanrooms. Ensuring that the device does not interfere with critical laminar airflow is essential for maintaining the reliability of microbial air sampling in controlled environments.

This application note presents the results of a computational fluid dynamics (CFD) study performed to analyze the airflow patterns around the MAS-100 Libra. The study demonstrates that the airflow profiles around the exposed agar plate are consistent with those of a free-floating settle plate, confirming that the MAS-100 Libra does not disrupt laminar flow or compromise sampling integrity around the settle plate. These findings underline its suitability for cleanroom environments, where airflow stability is crucial for accurate and reproducible air monitoring.

INTRODUCTION

Monitoring air quality is critical in pharmaceutical environments and cleanrooms to ensure compliance with cleanliness and safety standards. Among the most-used methods, passive air sampling with settle plates involves exposing a nutrient medium to ambient air for a defined period. It is currently the most widely used technique to monitor the air in cleanrooms continuously thereby complying with the requirements of the new EudraLex Annex 1 (EudraLex 2022). Airborne microorganisms settle on the agar surface, where they can be incubated to form countable colonies. This straightforward and effective method is widely applied to assess microbial contamination in the air.

The MAS-100 Libra® automates this process, enhancing precision and repeatability while minimizing manual intervention (see Figure 1). It is specifically designed for sensitive environments, such as pharmaceutical cleanrooms, where airflow control and the prevention of cross-contamination are paramount.

This application note outlines the results of a computational-fluid-dynamics (CFD) study conducted to evaluate the instrument's impact on surrounding airflow and to demonstrate its ability to preserve the integrity of passive air sampling.

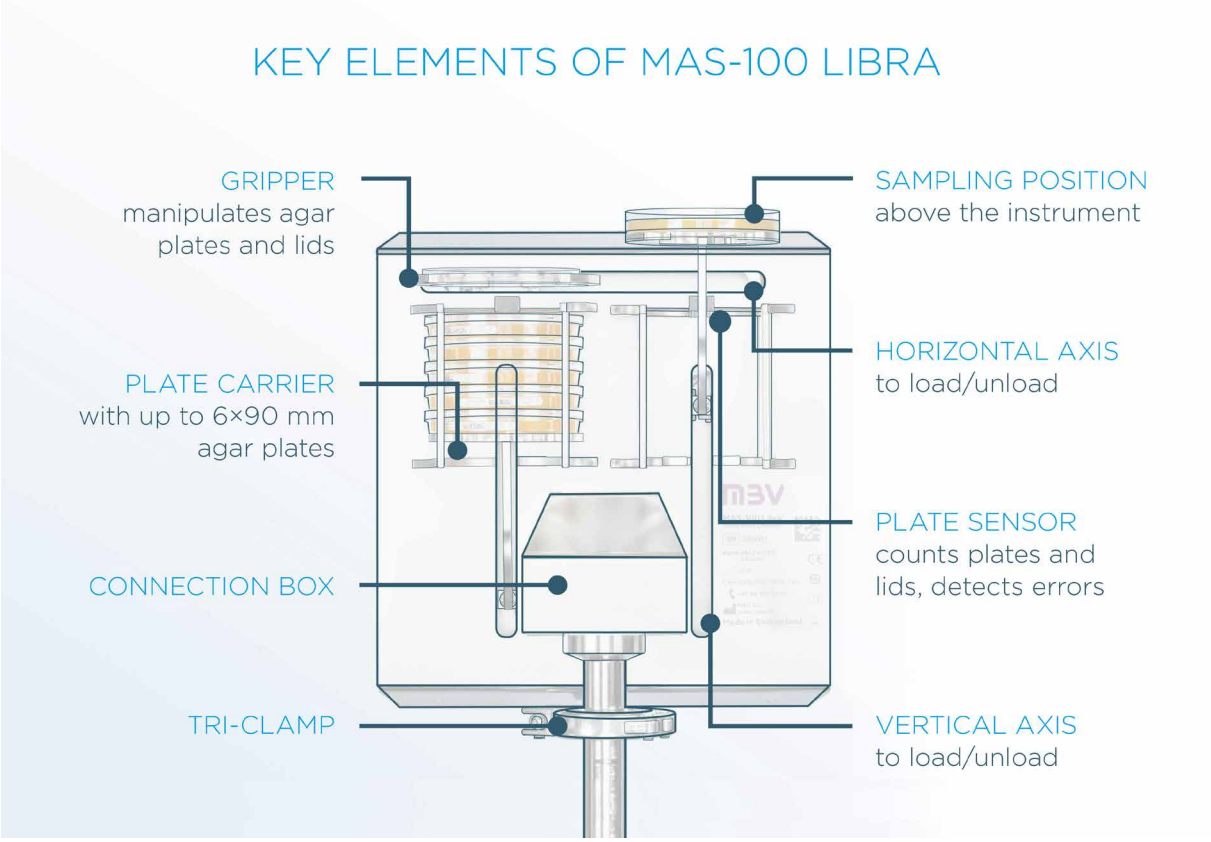

FIGURE 1: Schematic presentation of the MAS-100 Libra explaining its key components and their function.

AIRFLOW ANALYSIS

The airflow around the MAS-100 Libra was analyzed using computational-fluid-dynamics (CFD) simulations to assess the instrument's impact on laminar airflow in cleanroom environments. This analysis was essential to ensure that the MAS-100 Libra does not interfere with the passive air sampling process or compromise cleanroom standards.

CFD METHODOLOGY

The CFD study simulated airflow streamlines around the MAS-100 Libra in an idealized setup under controlled conditions, including an airflow velocity of 0.45 m/s, representative of typical Grade A cleanroom conditions. Various cross-sections of the device were analyzed to visualize airflow patterns, identify potential turbulence formations, and evaluate flow uniformity.

This approach was intentionally simplified to focus on airflow behavior around the agar plate, specifically to determine whether any backflow from the equipment reaches the agar plate. To isolate this effect, both the MAS-100 Libra instrument with agar plate and the isolated agar plate were modeled without their respective lids.

Figure 2 illustrates the cross-sections used for the analysis, which include the region around the agar plate as well as areas below and above the MAS-100 Libra housing.

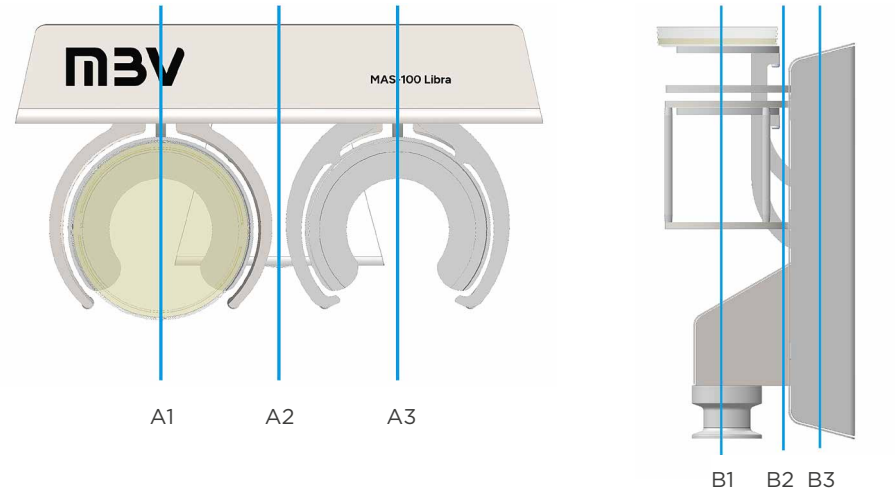

FIGURE 2: Various cross-sections used to perform CFD analysis.

RESULTS AND OBSERVATIONS

Figure 3 shows an example of the CFD analysis, namely the cross-section B1 from Figure 2. It demonstrates a comparison of airflow patterns between a standard agar plate setup – representing a traditional settle plate in a simple holder – and the MAS-100 Libra. The side-by-side analysis confirms that the airflow above the agar plate is comparable for both approaches. Specifically, the MAS-100 Libra demonstrates airflow above the agar plate similar to that under standard conditions, ensuring the validity of microbial sampling results. Beneath the agar plate and around the MAS-100 Libra housing, the airflow differs between the two systems, which is unsurprising given the distinct designs of the agar plate and the MAS-100 Libra. Interestingly, turbulence beneath the agar plate of the MAS-100 Libra is less pronounced than to that under the single agar plate. However, the turbulence around the MAS-100 Libra has a larger overall extent due to the size of the equipment.

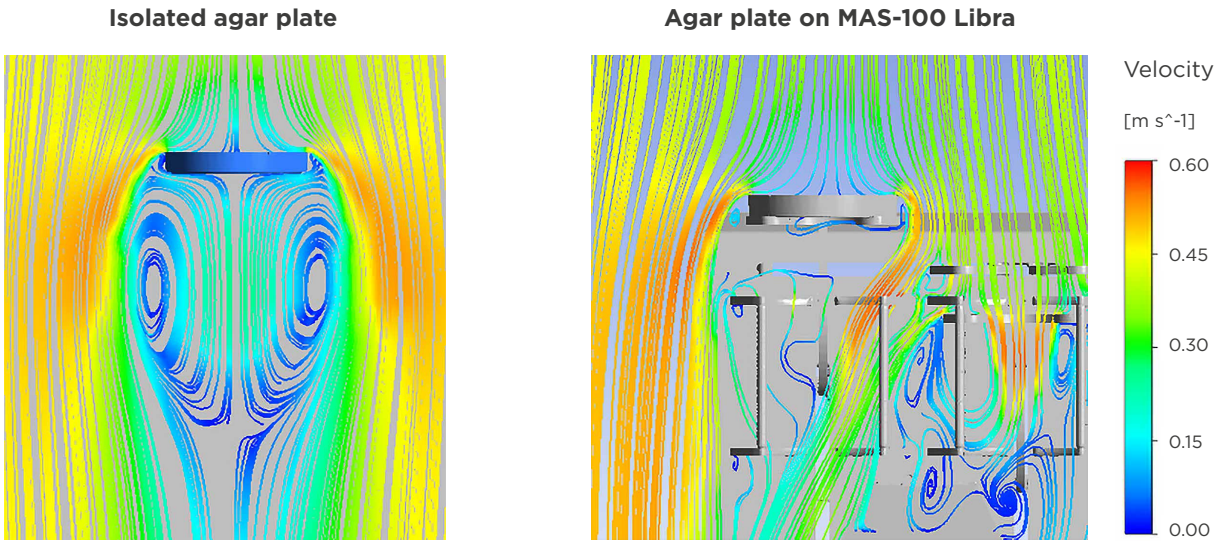

FIGURE 3: CFD results for the front view of a standard agar plate setup (left) and the MAS-100 Libra (right).

Figure 4 shows the side view of the airflow around and into the MAS-100 Libra and demonstrates that the airflow enters the instrument. To further evaluate the airflow within the housing of the MAS-100 Libra, the airflow pattern inside the instrument was simulated and is shown in Figure 5. This observation highlights the potential for vaporized hydrogen peroxide (VHP) to penetrate the interior during decontamination. This insight was critical in defining control points for the validation of VHP decontamination, ensuring that the internal components of the MAS-100 Libra are also effectively decontaminated (see Application Note MBV, Validation of VHP decontamination of MAS-100 Libra).

Agar plate on MAS-100 Libra

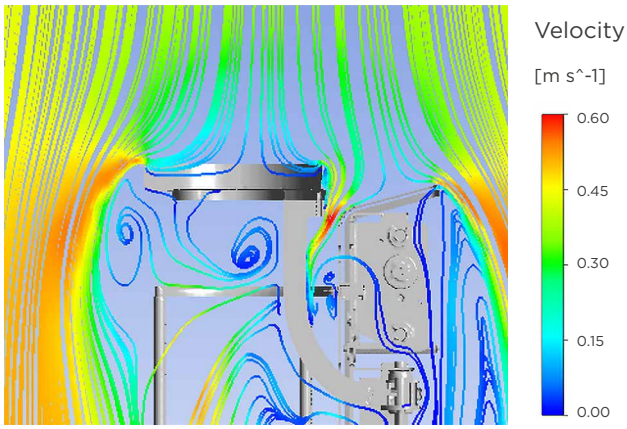

FIGURE 4: A side view illustration of the airflow streamlines around the MAS-100 Libra agar plate (cross-section A2 in Figure 2).

Inside MAS-100 Libra

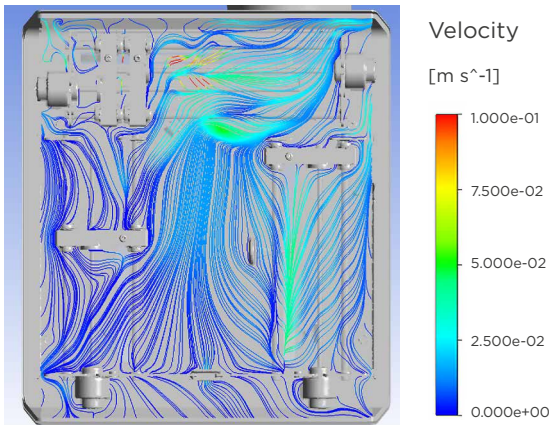

FIGURE 5: Illustration of the airflow streamlines inside the MAS-100 Libra.

In summary, the results of the CFD simulations revealed the following:

1. **Airflow similarity:** The airflow profiles around the agar plate on the MAS-100 Libra were comparable to those around a standard agar plate setup (Figure 3). The air mass flux reaching the agar plate is the same as the isolated agar plate case. The streamlines were consistent, indicating that the instrument does not obstruct or redirect airflow significantly.
2. **Laminar flow integrity:** The MAS-100 Libra maintained laminar airflow integrity, crucial for ensuring reliable settle plate sampling. No significant turbulence or disruptions were observed near critical sampling areas. This ensures first air sampling and that no air enters the agar plate from the nearby recirculation region.
3. **Turbulence formation:** Turbulence formations were observed under both the standard agar plate setup and the plate in the MAS-100 Libra exposure setup. These did not adversely affect the flow towards the agar plate nor the plate's ability to capture airborne microorganisms.
4. **Decontamination of the MAS-100 Libra:** The CFD airflow study indicates that air from the environment enters the housing and is well distributed within the instrument. Consequently, the inner components should also be effectively decontaminated during VHP treatment. This was confirmed in a separate study using biological indicators during VHP decontamination cycles.

CONCLUSION

The CFD analysis of MAS-100 Libra demonstrates that the instrument does not disturb airflows during passive sampling. The airflow streamlines around the agar plates positioned on the MAS-100 Libra closely resemble those of a standard agar plate setup, ensuring that the instrument preserves the laminar flow essential for cleanroom applications. Additionally, the study confirmed that there is no backflow from the instrument onto the sampling agar plate. The open agar plate on the instrument is exposed to first air. This ensures that the sampled air is representative of the air within the cleanroom and the integrity of microbial monitoring is maintained.

Furthermore, the study revealed that airflow pathways within the instrument allow vaporized hydrogen peroxide (VHP) to enter during decontamination cycles. This finding was instrumental in identifying critical control points for validating the VHP decontamination process.

In summary, the MAS-100 Libra maintains airflow integrity and shows a comparable airflow without backflow compared to the standard agar plate setup. Therefore, it is ideally suited for passive air sampling in pharmaceutical and cleanroom environments, ensuring accurate, reliable, and automated microbial monitoring.

ABOUT THE AUTHORS

Dr. Miriam Schönenberger, Product Manager

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.

Dr. Lucas Armbrecht, Project Leader

Lucas Armbrecht is a microsystems engineer and holds a PhD in bioanalytics from ETH Zurich.
At MBV AG, he is responsible for the development of new products and technologies for microbial contamination control and accurate air flow sensing solutions.

REFERENCES

- EudraLex (2022). Annex 1 – Manufacture of Sterile Medicinal Products. The Rules Governing Medicinal Products in the European Union, Volume 4, EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use. 2022

- MBV (2025). Validation of VHP decontamination of MAS-100 Libra. Application Note.

FURTHER INFORMATION

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

- Additional information can be found on our FAQ page.

We love to hear from you. Write to us: welcome@mbv.ch or call: +41 44 928 30 80.

ORDERING INFORMATION

MBV article number	Description
201120	MAS-100 Libra settle plate changer The following accessories are included in the scope of delivery for the MAS-100 Libra®: 1 x Tri-clamp connector 1 x Tri-clamp sealing gasket 1 x Safety sheet 1 x Quick start guide 1 x Test report

MORE INFORMATION ABOUT THE MAS-100 LIBRA

SUBSCRIBE TO OUR NEWSLETTER

MBV AG makes every effort to include accurate and up-to-date information within this publication; however, it is possible that omissions or errors might have occurred. Information contained in this publication regarding device applications and the like is provided only for your convenience, MBV AG cannot make any representations or war-ranties, expressed or implied, written or oral, statutory or otherwise as to the accuracy or completeness of the in-formation provided in this publication. Changes in this publication can be made at any time without notice. All mentioned trademarks are protected by law. For technical details and detailed procedures of the specifications provided in this document please contact your MBV representative.

All mentioned trademarks are protected by law. In general, the trademarks and designs referenced herein are trademarks, or registered trademarks, of MBV AG, Staefa, Switzerland. Product names and company names that are not contained in the list but are noted herein may be the trademarks of their respective owners.

For disclaimer please visit: www.mbv.ch/en/about-us/privacy-policy

MBV AG, Industriestrasse 9, CH-8712 Stäfa, T +41 44 928 30 80, welcome@mbv.ch, www.mbv.ch
© 2025 MBV AG Switzerland, all rights reserved

AIR. NOTHING ELSE