

How to use MAS-100® Air Samplers with BioTrends EM® System

Introduction

Environmental monitoring plays an important role in the contamination control strategy of pharmaceutical manufacturing lines. The Environmental monitoring program consists of several main elements including viable air, surface, and personnel monitoring, but also monitoring of total particles, temperature, relative humidity, and Aseptic Process Simulation (APS). The data are used for routine trending. These trends should include:

- Increasing numbers of excursions
- Consecutive excursions from alert levels
- Regular but isolated excursion from action limits that may have a common cause as well as changes in microbial flora type
- Numbers and predominance of specific organisms

Based on the huge number of samples tested, digitalization of tracking and managing data is helpful.

The MAS-100® air sampler family, irradiated ICR settle and contact plates, and ICR swabs offer a complete portfolio to perform all viable environmental monitoring. All of which are suitable for cleanrooms as well as isolators.

Archilex offers the BioTrends EM® software system developed for managing microbiological data of environmental monitoring programs. The system is compatible with mobile devices having barcode readers that support operators and/or analysts, speeding up and facilitating all the previously mentioned operations. The software is compliant with FDA 21 CFR part 11. It is a management system for the entire microbiological monitoring process, from planning and execution of sampling to incubation, plate reading, CFUs identification, and finally data trending and reports.

During environmental monitoring, it is essential for the equipment and consumables used to “communicate” with the computerized systems to complete the digital process.

The BioTrends EM® system is developed to collect necessary information from the following air samplers (**Figure 1**) and culture media (**Figure 2**).



Figure 1: From left to the right: portable air samplers MAS-100 NT® and MAS-100 VF® and installed air sampler MAS-100 Iso NT®



Figure 2: From left to right: ICR 90 mm settle plate, ICR Contact Plate, and ICR Swab

Description of the Workflow

The BioTrends EM® software system with the use of mobile devices (PDAs) equipped with a barcode reader and BioTrends EM® Mobile application, allows the recording of all activities performed in the field without using paper. It can also retrieve all necessary data from the MAS-100 NT®, MAS-100 VF®, and MAS-100 Iso NT® air samplers of interest for investigation, trending, and demonstrating the integrity of the acquired data.

Workflow

The sampling workflow with BioTrends EM® Mobile is very intuitive and can be summarized in the following steps (see **Figure 3**):

1. Select the point to sample*
2. Select the MAS in use* (for active air samples)
3. Acquire the serial number of the plate (or swab) used, scanning the datamatrix code
4. Confirm the sampling by selecting "Save"
5. Repeat steps 1-4 for all points to sample. All activities are recorded in real time within the central system.

* The sampling point and the sampling device (steps 1-2) can be selected from the list or by scanning the identification datamatrix code with the PDA.



Figure 3: BioTrends EM® Mobile acquires data about media and devices used from the scanner for datamatrix codes integrated into the PDA.

After the sampling process, it is possible to download the data recorded by the MAS100® air samplers allowing the BioTrends EM® system to combine the data from the two sources (MAS and PDA), giving the user more accurate qualitative information.

For example, using the data from the device, it is possible to confirm the volume of sampled air.

The BioTrends EM® system can also compare the sampled amount versus the one expected and defined in the sampling plan – highlighting any discrepancies or errors that occurred during instrument setup.

The workflow to download data from MAS in BioTrends EM® (see **Figure 4**) is very intuitive:

1. Connect the MAS-100® air sampler to a PC in which BioTrends EM® is installed.
2. In BioTrends EM® select the menu item “Devices → MAS → Import Data”.
From this window, the user has a complete overview of the data present in the MAS memory.
3. Proceed to launch the “Import” function. The imported data are recorded in BioTrends EM® and cleaned from the MAS memory.
4. By selecting the menu item “Devices → MAS → View Data” it is possible to analyze the outcome of previously imported data and highlight any anomalies.



Figure 4: Data from PDA and MAS-100® air samplers are collected in BioTrends EM® to perform deep analysis

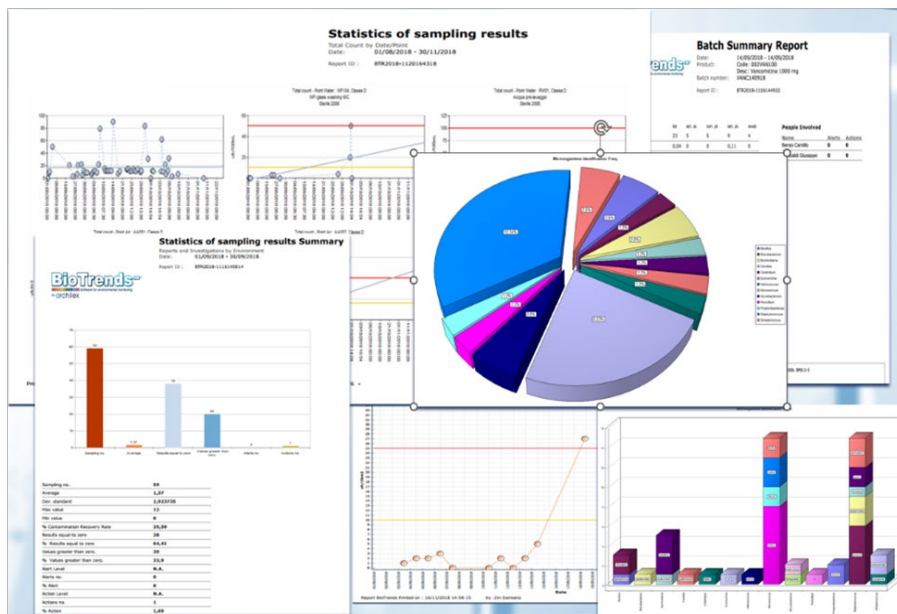
Data Analysis with BioTrends EM® Software:

At the end of the monitoring process, it is possible to analyze data in a fast and reliable way, thanks to BioTrends EM® software.

The software allows you to perform searches by applying filters for classes, environments, rooms, personnel, and all the other relevant characteristics associated with the sampling points.

The automatic generation of statistics associated with the search carried out facilitates the review of the alert limits.

The outcomes thus obtained can be used to generate trends, reports, and graphs in a few "clicks".



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