

Wireless Communication Between MAS-100 Atmos® Sampler & Novatek EM Software

Introduction

The new EU GMP Annex 1 is about gaining an understanding of the bigger picture. This can only be achieved if we access and use all types of digital sample data for trending analyses.

Using cGMP guidelines, data integrity of the sample information must be ensured. It is essential that all the equipment and consumables used for environmental monitoring can interact with the computerized systems to complete the digital process.

We offer a broad portfolio of products and solutions to perform all microbial environmental monitoring tasks, including the MAS-100® NT air sampler, irradiated ICR settle and contact plates as well as ICR swabs, all of which can be managed by the **Novatek Environmental Monitoring Management Software**. The newly launched MAS-100 Atmos® microbial compressed gas sampler is compatible as well. Along with its 21 CFR Part 11 compliant software, it offers the new unique feature of displaying barcodes with all sample data to facilitate wireless data transfer into the Novatek Environmental Monitoring Management Software (Novatek EM software).

The Novatek EM software has been developed for digitalization of the entire environmental monitoring process. The software includes everything from planning and execution, sampling, results, microbial ID, and finally data trending and reports. The software is compliant with both EU GMP Annex 11 and 21 CFR part 11. The system also works in association with cleanroom compatible mobile devices for real-time data capturing. This ensures data integrity is built into your EM sampling process.

The software is available as on premise or hosted installation, which include mobile tablets. The tablet is cleanroom-ready for immediate data collection. This device, which works in both online and offline mode, provides access to the sample plan, receives the sample's data via the barcode scanner after sampling, and forwards the captured data to the Novatek EM software's database for storage. This application note shows how to set up the unique wireless communication between the MAS-100 Atmos® sampler and the Novatek EM software.

For a general introduction to the MAS-100 Atmos® microbial compressed gas sampler and how it is operated, see the user manual.

How to use MAS-100 Atmos® Compressed Gas Samplers with the Novatek EM Software?

Workflow description

The MAS-100 Atmos® microbial compressed gas sampler offers an easy way to transmit all sample data into the Novatek EM software's database. After each sampling process a barcode containing all the sampling information is displayed on the touchscreen for tracking via the barcode reader (see **figure 1**).



Figure 1: Sampling barcode on the display of the MAS-100 Atmos® microbial compressed gas sampler

Settings in the MAS-100 Atmos® sampler

The data to be included in the QR code can be selected.

In order to create seamless communication between the MAS-100 Atmos® and the Novatek EM software, some settings must be activated. The System Administrator is allowed to make these changes.

1. The “**INSTRUMENT ACCESS**” setting determines if the user must login onto the instrument. The username and role will be coded in the resulting barcode (QR code displayed on the MAS-100 ATMOS® display after sampling) only if one of the bottom two options in **figure 2** is selected.
 - If it is sufficient that only the Novatek EM software tracks the user, select “No login (for operator)”.
 - If the MAS-100 Atmos® instrument itself must also track the complete workflow, select either “Login with user key (for operator)” or, for maximum access security, “Login with user key and PIN”. The choice should depend on the security policy of the organization. For Annex 11 / 21 CFR Part 11 compliant login please tick “Login with user key and PIN”.

INSTRUMENT ACCESS

- ☐ No login (for operator)
- ☐ Login with user key (for operator)
- ☒ Login with user key and PIN

Figure 2: Instrument access options

2. The settings “**BARCODE SCANNING OPTIONS**” are for use cases where a barcode scanner is directly connected to the MAS-100 Atmos® instrument and the Novatek EM software is not being used.
 - If the sampler is used in combination with the Novatek EM software it is recommended not to select any of the options in **figure 3** as the data are scanned and tracked by the Novatek barcode reader, which connects to the mobile device. This mobile device forwards the data to the Novatek EM software.

BARCODE SCANNING OPTIONS

- ☐ Nutrient plate
- ☐ Perforated lid
- ☐ Sampling location

Figure 3: Barcode scanning options

3. In case you would like to transfer the data of instrument serial number and calibration date as well as user information, please tick the boxes under “**OPTIONAL DATA OF SAMPLING BARCODE**” indicated in **figure 4**.

OPTIONAL DATA OF SAMPLING BARCODE

- ☐ Instrument serial number and label
- ☐ Calibration date/ time
- ☐ User data

Figure 4: Optional data to be included in the samples’ barcodes

4. Select whether the sample data should be saved in CSV or XML format after scanning the barcode. Both are compatible with the Novatek EM software.

DATA FORMAT OF SAMPLING BARCODE

- ☐ CSV
- ☐ XML

Figure 5: Format of the data to be saved after barcode scanning

Once the above settings have been made, the following sample data are transferred to the database of the Novatek EM software after scanning the barcode:

- Start Date (YYYYDDMM) and time.
- Stop Date (YYYYDDMM) and time.
- Gas type (indicates either “Air”, “Nitrogen”, “Argon” or “Carbon dioxide”)
- Sampling volume in normal liters
- Gas flow mode (“HUNDRED” = 100 LPM; “FIFTY” = 50 LPM or “Fallback” = automatic switch from 100 LPM to 50 LPM)
- Sampling status: “success” or “fail”
- Instrument serial number (6 digits)
- Last calibration date and time
- User (only when selected in settings for login, see **figure 2**)

Workflow with the Novatek EM software and mobile device:

The workflow of the operator who performs sampling is described in **figure 6**.

Advantages of this workflow:

- Sampling locations and frequencies based on risk
- Rapid analysis and data management
- Data integrity compliance

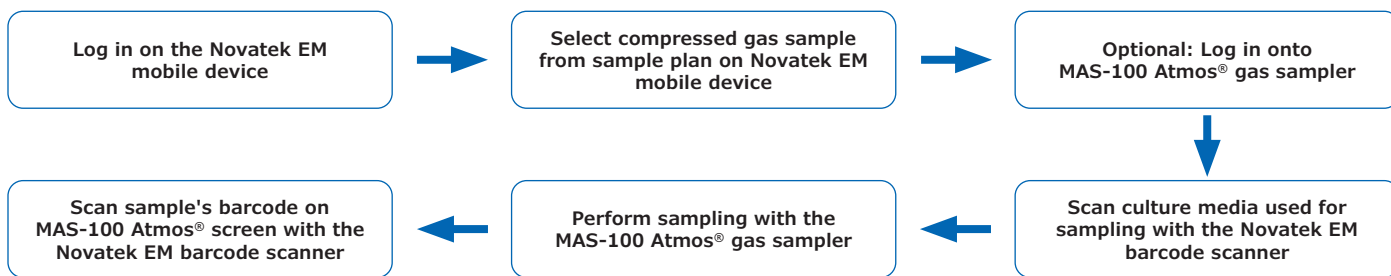


Figure 6: Workflow for data tracking with MAS-100 Atmos® gas sampler

A typical view of Novatek EM software's interface on the mobile device:



Figure 7: The Novatek EM mobile device's interface

Advantages of Novatek EM software's user interface for MAS-100 Atmos® operations:

- **True touch screen design:** The large, ergonomically designed buttons are easy to read and operate while wearing any cleanroom glove, so there is no need for a pen.
- **Clear visual sample status:** Visual color coding of the sampling status supports quick work list evaluation and gives notifications for samples to be collected.
- **Quick sampling updates:** Pressing a single button lets you add, update, or change a sampling location.

Benefits of Data Analysis with Novatek EM Software and MAS-100 Atmos® sampler

Fast and reliable data analysis

- The software allows you to perform data entries and searches, 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 makes reviewing both alert level and action limit excursions easier.
- The data retrieved in this way can be used to generate trends, reports and graphs with only a few clicks (see **figure 8**).

Rapid data retrieval, summarization, and report generation:

- Report by microorganism distribution
- Report by recovery rates
- Report by dispersion
- Report by sample locations

Scanning the barcodes of samples taken by the microbial MAS-100 Atmos® compressed gas sampler allows the wireless transfer of data into the Novatek EM software's data pool.

This feature ensures that all microbial samples of compressed gases can be easily planned, performed, and their data used for trending analyses.

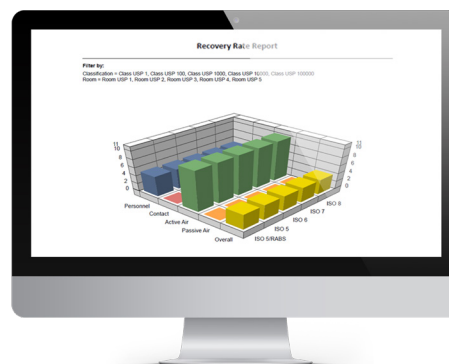


Figure 8: Illustrated recovery rate report in Novatek EM software.

Conclusion

The MAS-100 Atmos® gas sampler and the Novatek EM Software seamlessly work together. Their streamlined workflows enable secure wireless data transfer, real-time data capturing in compliance with data integrity guidelines, robust access control, compliance with 21 CFR Part 11 and EU GMP Annex 11, and versatile online and offline modes. In combination, the MAS-100 Atmos® gas sampler and the Novatek EM Software offer end-to-end digitalization, regulatory compliance, utmost convenience and maximum efficiency to ensure faster results and less manual input.

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