GUIDELINE 21 CFR PART 11

How to implement the MAS-100 Atmos® into your compliant workflow

English

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		OPTION 1	**OPTION 2**	**OPTION 3**
21 CFR Part 11		**Out-of-the-box non 21 CFR Part 11 compliant**	**Stand-alone 21 CFR Part 11 supporting instrument**	**Smart link to a 21 CFR Part 11 compliant LIMS/EM software**
User login for sampling		No user login on the instrument	21 CFR Part 11 compliant user management on the instrument	Logged in to LIMS/ EM software, but no user login on the instrument
Data handling		If needed: Manual export of the tamper-proof audit trail	Manual export of the tamper-proof audit trail	Error-free and direct transfer of data via sampling barcode directly to LIMS/EM software
Traceability		Limited traceability via Audit Trail Export: – No user data available – Instrument data (Sampling Archive/ Audit Trail) – No sampling environment data (no scanner)	Full traceability via Audit Trail Export: – User data – Instrument data (Sampling Archive/ Audit Trail) – Sampling environment (scanner connected to instrument)	Full traceability via external LIMS/EM software: – Instrument data (in sampling barcode) – Sampling environment (scanner connected to LIMS/EM software)
Benefits		– Out-of-the-box-operation – Maximum flexibility – For customers who work non-compliant (e.g. for customers outside pharma)	– Dedicated 21 CFR Part 11 compliant user management for MAS-100 Atmos – For customers who want to work compliant but do not use a LIMS/EM software	– Secure data transmission to higher-level systems – No additional user login required prior to sampling on the instrument – For customers using LIMS/EM software with connected peripheral devices (barcode scanner or tablet).

NOTE: MAS-100 Atmos allows individual configuration and thus optimal adaptation even to use cases between the options shown above.

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