

MAS-100 ATMOS

SERVICE INFORMATION LETTER 2022_04

Product affected: MAS-100 Atmos / MAS-100 CG Ex

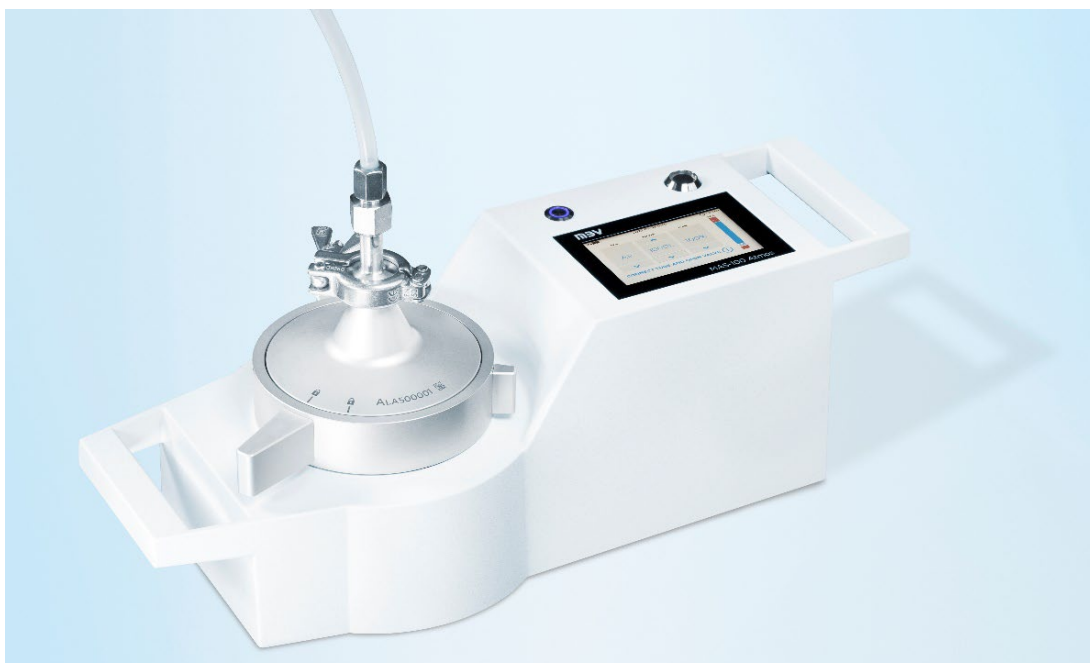
Change level:

- optional
- recommend by MBV
- mandatory
- for information only

1. REASON

This SIL introduces the MAS-100 Atmos® compressed gas sampler to the market. The MAS-100 Atmos replaces the MAS-100 CG Ex® which is not available any longer (see [sil_2021_11_production_discontinuation_of_mas-100_cg_ex.pdf](#)). The MAS-100 Atmos is used for taking samples from compressed gasses by impaction of microorganisms on a suitable growth medium and subsequent incubation and formation of colony forming units (CFU's).

2. THE MAS-100 ATMOS



2.1. APPLICATION/INTENDED USE

The microbial compressed gas sampler is an instrument used for taking samples from compressed gases, such as air, Nitrogen (N₂), carbon dioxide (CO₂), Argon (Ar) or a customer-defined gas (mixture) to assess the colony forming unit (CFU) count in a specific gas amount.

The instrument is not intended to take samples from oxidizing (O₂), toxic, flammable or combustible gases or mixtures thereof.

2.2. MAIN FEATURES

- Portable and lightweight instrument
- 21 CFR Part 11 compliant user management with easy login via user key
- Various configuration options via easily accessible browser-based user interface (no internet and foreign software needed)
- Easy-to-use sampling head with pressure safety lock
- Sampling takes place under pressure
- Automated pressure and flow regulation as well as decompression cycle
- Connection possibility to existing LIMS or EM softwares via use of sampling barcode
- Integrated audit trail function
- Optional exhaust tubing
- Developed according to GAMP 5

2.3. PARTS DESIGNATION

The figure below shows the main components of the instrument and their designation:



2.4. WORKING PRINCIPLE

2.4.1. IMPACTION-BASED MICROBIAL SAMPLING

During sampling the gas passes through a perforated lid, where the gas stream is accelerated in such a way that the microorganisms carried in the gas stream get impacted on a 90 mm standard nutrient plate positioned below the perforated lid. Therefore, the sampling principles remains the same as with all other MAS-100 instruments. The relevant sampling parameters, such as impaction velocity and the diameter of microorganisms impacted depend on the volume flow through the sampling head.

2.4.2. SAMPLING UNDER PRESSURE

With the MAS-100 Atmos microbial sampler for pressurized gases, the microorganisms are sampled in their usual environment under pressure. This means that the microorganisms in the gas are not exposed to rapid changes in pressure and temperature or to shear stress, all of which are not conducive to growth.

2.4.3. MAKING USE OF THE GAS PRESSURE

In order to use the instrument, its gas inlet needs to be connected to a pressurized gas supply line. At the gas exhaust, the sampled gas will be released at ambient pressure. The resulting pressure drop across the instrument propels the gas flow through the instrument.

2.4.4. MASS-FLOW-BASED SAMPLING OF GAS VOLUME

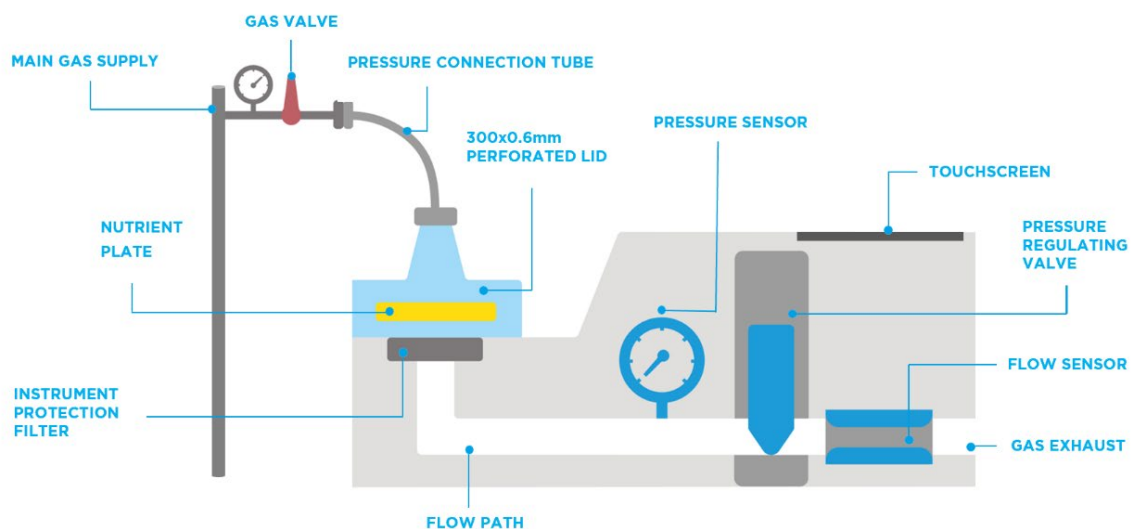
The instrument is equipped with a mass flow sensor in order to measure the amount of gas sampled, which is represented as a standardized volume.

In this way, samples performed under different conditions (temperature, ambient pressure, altitude from sea level, etc.) are reproducible and comparable.

The instrument's control system integrates the gas amount passing through the mass flow sensor until the target amount of standardized volume has been reached and then stops the sampling process.

2.5. FUNCTIONAL DESCRIPTION

The following figure shows the instrument's gas flow path and the essential functional components:



During sampling with the MAS-100 Atmos the following happens inside the instrument:

As soon as the gas valve is opened, the compressed gas from the pressurised supply system enters the instrument via the pressure connecting tubing. Since the flow regulation valve is initially closed, the internal volume of the sampling head gets pressurized and the current pressure is monitored with an integrated absolute pressure sensor.

When starting a sampling, the compressed gas passes through the sampling head, which directs the gas flow to the underlying nutrient plate. The gas flows past the plate and through the HEPA filter, which is designed to protect the instrument from contamination by particles in the gas line. Thereafter, the gas flows through the flow control valve, where the system pressure is reduced to near ambient conditions. Behind the flow control valve is the integrated mass flow sensor (Venturi tube type). This sensor measures the temperature and flow rate of the gas in NL/min (norm liters per minute). Together with the absolute pressure at the sampling location, as determined by the pressure sensor, the effective flow of gas in L/min through the sampling head is continuously observed. In order to maintain a flow rate of 100 L/min (or

50 L/min), the opening of the flow control valve is constantly adjusted. Lastly, the gas exits the instrument through the gas exhaust.

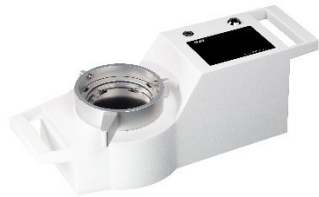


When the desired standard volume of gas is sampled, the flow regulation valve is closed and the instrument requests for automatic decompression. This requires the user to close the gas valve in order to prevent additional pressurized gas from entering the instrument. During decompression, the remaining pressurized gas in the instrument is slowly released. This process guarantees gentle transition of the captured microorganisms from the pressurized environment to ambient conditions. The decompression speed can be selected from three levels – slow (default and legacy setting), moderate and fast.








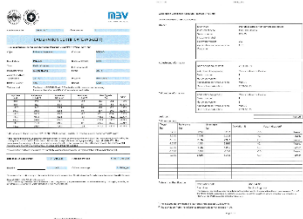
2.6. VALIDATION AND CLASSIFICATION







The instrument has been developed and validated according to GAMP 5, which includes the following development activities:

- Planning & specification (URS, FDS, MS)
- Design (hardware & software design specifications)
- Construction (assembly, software, electronics)
- Testing (module testing, functional and integration testing, requirements testing)
- Installation & hardware acceptance tests (EMC, ESD...)
- Operation (maintenance, change control)

2.7. SCOPE OF DELIVERY AND ACCESSORIES

DESCRIPTION	ARTICLE NUMBER	PICTURE
SD: SCOPE OF DELIVERY A: ACCESSORY	MBV AG	MERCK KGAA, DARMSTADT, GERMANY
MAS-100 Atmos® sampler for compressed gases with HEPA H13 (ISO 35H) filter and nutrient plate holder SD / A	200162	1173280001 
Perforated lid 300x0.6 mm (anodized aluminum) with blue sieve and individual black marking (3 letter code for lid type) SD / A	130.4457	1173570001 
Perforated lid 300x0.47 mm (anodized aluminum) A	130.4458	1173630001 

DESCRIPTION	ARTICLE NUMBER	PICTURE
SD: SCOPE OF DELIVERY A: ACCESSORY	MBV AG MERCK KGAA, DARMSTADT, GERMANY	
Pressure connection tubing 2m, PTFE, with fixed tri-clamp Ø34 mm and universal 3/8 inch thread part (female)	130.4285	1173540001
SD / A		
Tri-clamp Ø34 mm	130.4461	1173670001
SD / A		
1 x silicone gasket 34/10 mm	n/a	n/a
SD		
1 x dust cover (polypropylene, white)	130.4328	1173400001
SD / A		
Power supply incl. USB-C cable and region-specific adapters (US/JPN, AUS, UK)	130.4258	1173290001
SD / A		
1 x hardware key system administrator (black)	n/a	n/a
SD		
5 x additional hardware keys for MAS-100 user management (various colors)	130.4459	1173330001
SD / A		
Documents:	n/a	n/a
<ul style="list-style-type: none"> - Quick Start Guide MAS-100 Atmos - Safety sheet - Declaration of conformity - Flow and pressure calibration certificates MAS-100 Atmos - Flow and pressure calibration certificates calibration unit of MAS-100 Venus 		
SD		

DESCRIPTION	ARTICLE NUMBER		PICTURE
SD: SCOPE OF DELIVERY A: ACCESSORY	MBV AG	MERCK KGAA, DARMSTADT, GERMANY	
Wheeled case for MAS-100 Atmos A	130.4468	1173340001	
1 x gas exhaust tubing set, 5m tubing (Ø40 mm) with tri-clamp (Ø50.5 mm) connector A	130.4271	1173490001	
1 x adapter for gas exhaust tubing A	130.4147	1173480001	
Instrument protection filter: HEPA H13 (ISO 35H) Ø74 mm SD / A	130.2652	1172780001	
Nutrient plate holder (stainless steel) for 90mm nutrient plates SD / A	130.4190	1173350001	
Filter cover (anodized aluminum) SD / A	130.4159	1173360001	

3. TECHNICAL SPECIFICATIONS

GENERAL																			
Gas types	Default: Compressed air, Nitrogen (N ₂), carbon dioxide (CO ₂), Argon (Ar) Advanced: customized gas type (no oxidizing or combustible gases) if the gas factor is known																		
Gas flow rates	Default: 100 L/min Optional: 50 L/min Optional: Automatic fallback from 100 to 50 L/min (if needed)																		
Sampling volume	Configurable between 50 up to 3000 normal liter (NL). Standard conditions for normal liter: 20°C, 1013.25mbar(a), 0% relative humidity. Under these conditions, the air density is 1.2041 kg/m ³																		
Measurement precision of flow sensor	+/- 5% NOTE: For highest measurement precision it is advised to adjust the instrument as close to its intended operating temperature as possible.																		
Gas pressure range (bar absolute)	The dynamic input pressure range (line pressure during sampling) is 1.2 bar.a to 7 bar.a (17.4 psi to 101 psi). Depending on the gas type, the flow rate has to be adapted to the current pressure (see table below):																		
	<table border="1"> <thead> <tr> <th>GAS TYPE</th> <th>PRESSURE RANGE 50% FLOW MODE (50 L/MIN)</th> <th>PRESSURE RANGE 100% FLOW MODE (100 L/MIN)</th> </tr> </thead> <tbody> <tr> <td>Compressed air</td> <td>1.2-7 bar.a (17.4-101 psi)</td> <td>1.5-7 bar.a (21.8-101 psi)</td> </tr> <tr> <td>N₂</td> <td>1.2-7 bar.a (17.4-101 psi)</td> <td>1.5-7 bar.a (23.2-101 psi)</td> </tr> <tr> <td>CO₂</td> <td>1.2-7 bar.a (17.4-101 psi)</td> <td>1.5-7 bar.a (23.2-101 psi)</td> </tr> <tr> <td>Ar</td> <td>1.5-7 bar.a (23.2-101 psi)</td> <td>1.5-7 bar.a (23.2-101 psi)</td> </tr> <tr> <td>Custom gas</td> <td>Unknown</td> <td>Unknown</td> </tr> </tbody> </table>	GAS TYPE	PRESSURE RANGE 50% FLOW MODE (50 L/MIN)	PRESSURE RANGE 100% FLOW MODE (100 L/MIN)	Compressed air	1.2-7 bar.a (17.4-101 psi)	1.5-7 bar.a (21.8-101 psi)	N ₂	1.2-7 bar.a (17.4-101 psi)	1.5-7 bar.a (23.2-101 psi)	CO ₂	1.2-7 bar.a (17.4-101 psi)	1.5-7 bar.a (23.2-101 psi)	Ar	1.5-7 bar.a (23.2-101 psi)	1.5-7 bar.a (23.2-101 psi)	Custom gas	Unknown	Unknown
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Custom gas	Unknown	Unknown																	
	When sampling in 50% flow mode the d ₅₀ is 1.6µm. Change to the 300x0.47mm perforated lid if a d ₅₀ of 1.1µm is to be maintained.																		
Measurement precision of pressure sensor	+/- 2%																		

Standard perforated lid	
Material	Anodized aluminum
Weight	750g
Perforated sieve geometry	300 orifices, Ø0.6mm

Dimensions perforated sieve	Ø109 x 90mm
Physical sampling efficiency (nominal d ₅₀ value)	Nominal d ₅₀ value of 1.1µm (e.g. according to ISO 14698/ EN 17141) at 100 L/min using the 300x0.6mm perforated lid Nominal d ₅₀ value of 1.6µm at 50 L/min using the 300x0.6mm perforated lid Nominal d ₅₀ value of 1.1 µm at 50 L/min using the 300x0.47mm perforated lid
Autoclaving	20 mins at 121°C 5 mins at 134°C

Lower sampling head

Compatible nutrient plates	Standard 90mm nutrient plates with a lower plate diameter up to 93mm, centering of the nutrient plate via the upward pointing pins on the nutrient plate holder
Instrument filter	HEPA H13 (ISO 35H) filter with a diameter of 74mm

Physical instrument

Length	500mm
Width	210mm
Height	180mm
Weight (with perforated lid)	7.3kg
Housing material	Injection-molded high-performance polystyrene with acrylic plastic primer and acrylic texture varnish

Power supply

Supply data external power supply	Input: 100-240V, 1A max, 50-60 Hz Output: 5V, 2.1A max, 10.5W max
Mains supply voltage	Fluctuations must not exceed ± 5 percent of the nominal value
Transient overvoltage	Overvoltage category: Category II Pollution Degree: 2
Battery pack	Chemical system: Li-ion Total capacity: 9.6Ah, 72Wh Nominal voltage: 7.2V Weight: 300g NOTE: The battery pack cannot be exchanged by the customer. Please contact your local service organisation.
Charging time	Full recharge time approx. 7.5hrs
Sampling time	Minimum sampling time approx. 2 hrs Maximum sampling time approx. 5 hrs Depending on the chosen settings and the valve opening.

ENVIRONMENTAL CONDITIONS

Altitude	Up to 3'000 m above sea level ¹
Temperature	Storage: -10 to +50 °C Operation: +4 to +45 °C
Relative humidity	Max. 80 %RH for temperatures up to 31 °C, decreasing linearly to 50 % relative humidity at 40 °C; non-condensing
Electromagnetic compatibility	EMC (CISPR 11) Group 1, Class B (Domestic location)
Sound level for operator and bystander	<80 dB at highest pressure point (7 bar.a)

Miscellaneous

Display	Type: colored LED touchscreen Display diagonal: 4.3 inch Display resolution: 800x400
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¹ Altitude was calculated from pressure vs. altitude formulae given in ISO 2533

4. CALIBRATION AND ADJUSTMENT

4.1. FACTORY CALIBRATION CERTIFICATES

The MAS-100 Atmos is delivered with one calibration certificate for the instrument and one for the reference device (MAS-100 Venus). The certificates are stored on the MAS-100 Atmos and can be accessed any time via the browser-based user interface:

Calibration Certificate Absolute Pressure (As-Left)

Certificate number: 60022-202203300426

Object	Examinee	Microbial sampler for compressed gases
	Instrument type	MAS-100 Atmos
	Serial number	60022
	Instrument label	
	Hardware version	2.3
	Application software version	1.7.0
	Customer	

Adjustment information	Date of last adjustment ¹	2022-03-30
	<u>Adjustment equipment</u>	Venus Reference Device
	Serial number	1
	Hardware version	2
	Application software version	V1.0.0
	Date of last calibration ¹	2022-03-28

Calibration information	<u>Calibration equipment</u>	Venus Reference Device
	Serial number	1
	Hardware version	2
	Application software version	V1.0.0
	Date of last calibration ¹	2022-03-28

Leak test² Passed

Calibration data

Target bar	Reference bar	Examinee bar	Deviation %	Pass indication ³
1.200	1.288	1.283	-0.4	Passed
2.000	1.992	1.991	0.0	Passed
3.000	3.019	3.016	-0.1	Passed
4.000	4.039	4.044	0.1	Passed
5.000	5.003	4.999	-0.1	Passed
6.000	5.981	5.983	0.0	Passed
7.000	6.945	6.949	0.1	Passed

Date and authentication	Calibration date ¹	2022-03-30
	Examiner	Default User

The creation of this certificate required a digital authentication and it is therefore valid without manual signature. The MAS-100 Atmos calibration results are traceable to international standards through the use of a calibration tool calibrated in MBV's own ISO 17025 accredited calibration laboratory.

¹ The date is displayed in the format YYYY-MM-DD.

² The leakage determined at 5 bar does not exceed 0.25NL/min.

³ The deviation from the reference pressure does not exceed +2%.

The MAS-100 Atmos was calibrated fully automatically using the reference instrument MAS-100 Venus. The reference instrument was calibrated in our own ISO 17025:2017 accredited calibration laboratory.

4.2. CALIBRATION PERIODICITY

Calibration is a key aspect of the process. Always ensure that the instrument calibration is still valid. It is recommended to adjust and calibrate the instrument in a periodicity of 12 months.

4.3. CALIBRATION SERVICE

For adjustment and calibration of MAS-100 Atmos® there are the following options:

- Send the instrument to the manufacturer:

Contact address

MBV AG
Service
Industriestrasse 9
CH-8712 Stäfa
Switzerland

- Contact your local Merck KGaA, Darmstadt, Germany service contact for local service (workshop or on-site whereas available), or visit the homepage to request more information:

<https://www.sigmaaldrich.com/services/product-services/maintenance-and-service-plans/microbiology-maintenance-and-service-plans>

5. AVAILABILITY

The MAS-100 Atmos compressed gas sampler is available from:

Switzerland:

MBV AG, Industriestrasse 9, CH-8712 Staefa, sales@mbv.ch, +41 44 928 30 80

Outside Switzerland:

Merck KGaA, Frankfurter Strasse 250, D-64239 Darmstadt, Germany, www.sigmaaldrich.com

MBV AG

Stäfa, April 14, 2022/RDU