MBV

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USER MANUAL

MAS-100 Atmos® microbial compressed gas sampler

English

The life science business of Merck KGaA, Darmstadt, Germany
operates as MilliporeSigma in the US and Canada.

Millipore®

THANK YOU VERY MUCH!

Dear customer

congratulations and thank you very much for choosing a product from MBV AG. We are pleased to make a contribution to your success.

MBV AG develops and produces precision microbial air and gas samplers for more than 20 years. Our uncompromising quest for the best possible quality has convinced globally leading companies to rely on our solutions for their most demanding applications. Our superior product quality is backed by global availability of application and service support.

For best performance of your product please read this instruction manual carefully. The manual will provide you with the necessary information for correct and safe use of your new instrument.

If you need additional technical or application information, do not hesitate to contact us at welcome@mbv.ch or find more information on www.mbv.ch.

MANUFACTURER

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DISTRIBUTION PARTNER (WORLDWIDE EXCEPT SWITZERLAND)

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D-64239 Darmstadt
Germany

> **Note**
>
> Up-to-date product information – such as Service Information Letters (SIL) – are available in the expert center section of the MBV AG website: www.mbv.ch and Downloads for compressed gas sampler MAS-100 Atmos (mbv.ch) (https://www.mbv.ch/en/expert-center/downloads/mas-100-atmos/).
>
> Moreover, important product after-sales information about changes, issues, instructions as well as news are provided.

DOCUMENT HISTORY

VERSION	RELEASED	HISTORY
6.0	2024-10-03	Chapter Trademarks: Updated (old instruments removed) Chapter Applicability: Software Version 1.9.1 added Chapter 1.2.4: Updated to (EU) 2021/821 Chapter 1.4.1: Link to MBV website added to icon description Chapter 2.9.1: Instrument status Switch off screen Y/N added Chapter 3.1.2: Note regarding battery charging added Chapter 3.5: Updated and note regarding pressure gauge added Chapter 4.1.2 Computer time and note regarding time zone updated Chapter 4.8.1: Automated test time to 60 seconds adjusted Chapter 6.2: Error E-74551 added Chapter 6.3: Instrument can be unlocked by: User administrator added Chapter 7.4: Link updated Chapter 9: Charging time: Note regarding battery charging added
5.0	2024-03-21	Page 2: Link to instrument website added Chapter 1.1.2: Hazard of damage to the instrument and/or wrong results updated Chapter 1.4.1: Type label updated Several links corrected Footer: Document name and version integrated Chapter 2.5: Transport Packaging updated & Article numbers added to parts
4.0	22.08.2022	Chapter 6.1 and 6.2: Updated Chapter 4.4.2: Updated Chapter 6.3:Updated Incorrect cross-references updated
3.0	14.07.2022	Branding template: Update
2.0	04.05.2022	Chapter 4.4.2: File integrity check statement corrected
1.0	26.04.2022	First released version

TRADEMARKS

The following product names are used for identification purposes only. They remain the exclusive property of their respective owners.

EXTERNAL
The vibrant M® is a registered trademark of Merck KGaA, Darmstadt, Germany.
Opticap® is a registered trademark of Merck KGaA, Darmstadt, Germany.
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Safari® is a registered trademark of Apple Inc. in the U.S. and other countries.
Firefox® is a registered trademark of the Mozilla Corporation in the U.S. and other countries.
Chrome™ is a trademark of Alphabeth Inc. in the U.S. and other countries.

MBV AG	
MAS-100 Eco®	Switzerland
MAS-100 VF®	Switzerland and other countries
MAS-100 NT®	Switzerland and other countries
MAS-100 NT Ex®	Switzerland and other countries
MAS-100 Iso NT®	Switzerland and other countries
MAS-100 Iso MH®	Switzerland and other countries
MAS-100 Regulus®	Switzerland
MAS-100 Atmos®	Switzerland and other countries

ABBREVIATIONS

The microbial compressed gas sampler MAS-100 Atmos® is hereafter referred to as «instrument».

A comprehensive list of all used abbreviations can be found in Annex D – Glossary.

APPLICABILITY

The information in this manual is valid for the following configurations:

COMPONENT	VERSION
Application software MAS-100 Atmos	1.9.1
Application software MAS-100 Atmos	1.7

RELATED USER MANUALS

The following user manuals provide additional information:

DOCUMENT	SCOPE
None	N/A

TABLE OF CONTENTS

1. GENERAL INFORMATION

This chapter provides information of general interest regarding the instrument.

1.1. SAFETY INFORMATION

IT IS IMPORTANT TO READ THESE INSTRUCTIONS BEFORE USING THIS INSTRUMENT.

Please read the safety data sheet and the instrument-specific safety information in this manual carefully before using the instrument and/or any accessory supplied with this product.

1.1.1. SEVERITY LEVELS

Warning

Symbols in red boxes indicate hazardous situations which could result in danger to life and/or serious injury and/or irreparable damage to the instrument.

Attention

Symbols in yellow boxes indicate critical situations which could result in light injuries and/or damage to the equipment and/or unreliable air sampling results.

Note

Symbols in green boxes indicate information which may be of major interest for the user.

1.1.2. SPECIFIC SAFETY INFORMATION FOR THE INSTRUMENT

Hazard of explosion and/or fire

Do not use the instrument in explosion hazard areas.

Hazard of damage to the instrument and/or wrong results

The microbial compressed gas sampler is a precision instrument for industrial and laboratory use.

The instrument shall only be operated by trained, qualified and authorized personnel as stated in chapter 1.2.1.

Hazard of damage to the instrument and/or wrong results

Ensure that the instrument does not drop on the floor.

Any exposure of the instrument to conditions outside the specified limits and approved uses in the user manual may result in invisible damage and deviations of the instrument. Therefore, after such an incident, an instrument must be checked for correct functioning by trained personnel or an MBV certified service centre.

Any application other than the intended use is not covered by warranty.

For additional information, please consult warranty chapter 1.2.2 and chapter 1.3.

	Hazard of damage to the instrument
!	Read the instructions in this User Manual carefully before using the instrument and pay attention to all warnings. Keep this manual in a designated place, accessible for all users for future reference. Ensure that all personnel have read and understood the content of this manual.
!	**Hazard of damage to the instrument** There are no user-serviceable parts inside the instrument. Do not perform any intervention inside the instrument. Only trained, qualified and authorized technicians can perform repair and maintenance activities.
!	**Hazard of damage to the instrument** The instrument is not IP-protected. Do not spill liquids into the electric connections or into the gas duct.
!	**Hazard of damage to the instrument** Any cleaning/disinfection solution must be completely dried before using the instrument.
!	**Hazard of wrong results** Do not use an uncalibrated instrument. It is recommended to adjust and calibrate the instrument in a periodicity of 12 months.
!	**Hazard of cross contamination** The FDA considers the separation of penicillin production from other drug products for human use as a GMP requirement (21 CFR 211.46(d)), therefore MBV AG recommends taking any precaution for installing and handling the instrument accordingly.

1.2.   OPERATION

1.2.1.   PERSONNEL QUALIFICATION

The microbial compressed gas sampler is a precision instrument for industrial and laboratory use. Its use should be restricted to trained, qualified and authorized personnel only.

1.2.2.   INTENDED PRODUCT USE

The MAS-100 Atmos is used during microbiological quality control as part of a risk-based quality assurance. The instrument is used to determine the microbial contamination of compressed air and compressed gases via impaction on a nutrient plate. For details about the application and its restrictions refer to chapter 2.1.

1.2.3.   OPERATING CONDITIONS

The instrument must be operated in defined environmental conditions. Please consult the operating conditions in chapter 9 «Technical specifications»).

1.2.4.   «DUAL-USE» STATEMENT

The instrument is designed solely for civilian purposes. It is excluded in the scope of the European «Dual-Use» regulation (EU) 2021/821.

1.3. WARRANTY

1.3.1. GENERAL

This chapter informs about the warranty of the instrument and the procedures to follow if the instrument isn't working as described in the user manuals.

For products listed in this publication purchased via the life science business of Merck KGaA, Darmstadt, Germany, the applicable warranty may be found at: Terms and Conditions (sigmaaldrich.com).

For products listed in this publication purchased directly from MBV AG the applicable warranty may be found at: www.mbv.ch/about-us/gtc.

1.3.2. QUALITY STATEMENT

The instrument has been designed and manufactured to the highest quality levels.

The manufacturer guarantees the instrument's impeccable quality for a period of 24 months (starting from shipping date).

The quality of original MBV AG spare parts is guaranteed by the manufacturer for a period of 3 months after the repair or service.

1.3.3. CONTACT

If a warranty case occurs, customers may contact the life science business of Merck KGaA, Darmstadt, Germany or the instrument manufacturer directly:

| MBV AG (manufacturer) | Worldwide | www.mbv.ch/en/services/support/ |
| Merck KGaA, Darmstadt, Germany and/or its affiliates | Worldwide | www.sigmaaldrich.com/support/customer-support |

1.3.4. EXCLUSION CLAUSES

The warranty covers exclusively material and manufacturing defects which occurred during the above described periods of time. The warranty does not cover the natural wear and tear of parts or any damage caused by improper handling, negligence, or non-observance of the user manuals or the Service Information Letters. The warranty expires immediately if any of the following conditions are infringed:

– The instrument shall only be serviced or repaired by qualified, trained and authorized technicians. A list of certified service centers can be found on www.mbv.ch/en/services/support/

– The instrument shall only be serviced or repaired as described in the MBV AG service manual.

– The instrument shall only be serviced or repaired using original MBV AG spare parts.

– The instrument shall only be operated according to the defined intended use.

– The instrument shall only be operated and updated with original application software from MBV AG.

– The instrument shall not be modified physically in any way.

	Hazard of damage to the instrument
	There are no user-serviceable parts inside the instrument.
	Do not perform any intervention inside the instrument.
	Only trained, qualified and authorized technicians can perform repair and maintenance activities.

	Risk of warranty loss
	Every instrument is secured with an anti-tamper (warranty) seal. Breaking the warranty seal on the bottom plate for disassembly of the instrument will break the seal and render the warranty void.

1.4. PRODUCT LABELING

1.4.1. PRODUCT TYPE PLATE

The information imprinted on the type plate identifies the instrument and its manufacturer. The information includes:
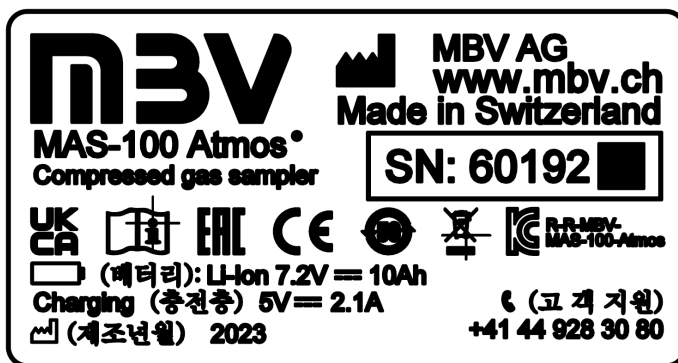
– Instrument description

– Instrument type

– Instrument serial number

– Manufacturer name, address and contact data

– Country of origin

– Regulatory information

– Date of manufacture

– Battery type

Signifance of the icons on the type plate

SN	Indicates the serial number of the instrument
	Identifies the manufacturer of the instrument
CE	With the CE symbol the manufacturer declares conformity with the relevant directives of the European Union as stated on the «Declaration of Conformity» which can be found on the MBV AG website: Downloads for compressed gas sampler MAS-100 Atmos (mbv.ch)

UKCA	With the UK Conformity Assessed (UKCA) marking the manufacturer declares conformity with the relevant directives of Great Britain as stated on the «Declaration of Conformity» which can be found on the MBV AG website: Downloads for compressed gas sampler MAS-100 Atmos (mbv.ch)
EAC	With the EAC symbol the manufacturer declares conformity with the relevant directives of the Eurasian Trade Union as stated on the «Declaration of Conformity» which can be found on the MBV AG website: Downloads for compressed gas sampler MAS-100 Atmos (mbv.ch)
50	This symbol indicates that product does contain any toxic or hazardous substances or elements above the maximum concentration value established by the Chinese standard SJ/T11363-2006 as stated in chapter 8.2, and can be recycled after being discarded and should not be casually discarded
	Read the instructions before using the instrument
	With this symbol the manufacturer declares conformity with the WEEE directive as described in the «Declaration of Conformity» which can be found on the MBV AG website: Downloads for compressed gas sampler MAS-100 Atmos (mbv.ch). It should not be disposed of as household waste at the end of its life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this instrument from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources. Users should either send the instrument back to the supplier or dispose it locally in accordance with the applicable local waste legislations
	Indicates the date of manufacture
	Indicates the type of battery used in the instrument
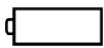
1.4.2. HOUSING LABELS

The electronical interfaces which are placed on the right side of the instrument are labelled with product icons.

Significance of the icons on the housing

	Indicates the connecting terminals of the computer network. In the case of MAS-100 Atmos the Ethernet interface for the update of the time via network time protocol is labelled.
	Indicates ports as meeting the generic requirements of the Universal Serial Bus (USB). In the case of MAS-100 Atmos the USB-A and USB-C ports are labelled.

2. INSTRUMENT DESCRIPTION

2.1. APPLICATION/INTENDED USE

The microbial compressed gas sampler is a highly accurate instrument used for taking samples from compressed gases, such as air, Nitrogen (N_2), carbon dioxide (CO_2), 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 (O_2), toxic, flammable or combustible gases or mixtures.

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. WORKING PRINCIPLE

2.3.1. 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.

2.3.2. 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.

2.3.3. 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.

### 2.3.4. 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.

2.3.5. FUNCTIONAL DESCRIPTION

The following figure shows the instrument's gas flow path and the essential functional components:
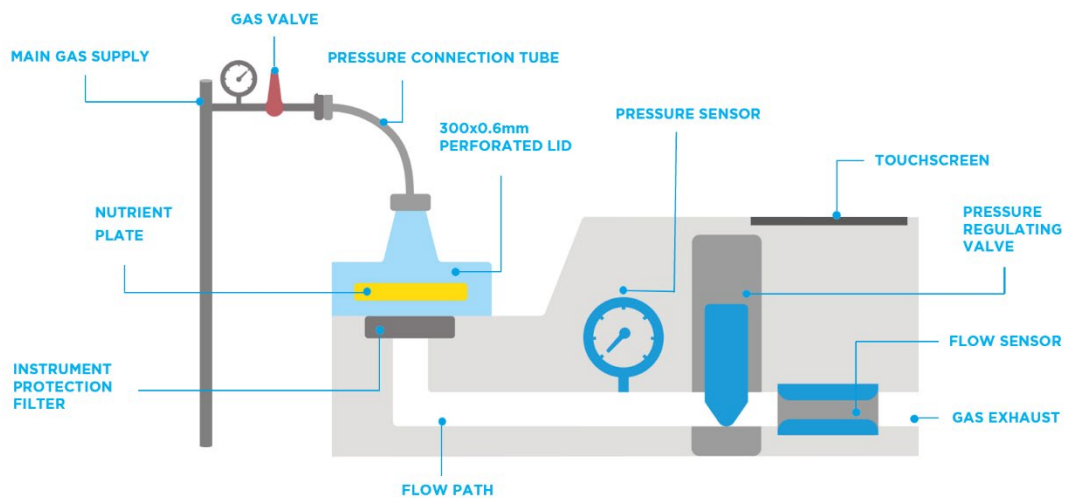
During sampling with the MAS-100 Atmos the following happens inside the instrument:

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.

2.4. 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)

2.5. SCOPE OF DELIVERY

The instrument is shipped in a membrane packaging. The packaging can be reused for shipping if handled with care:
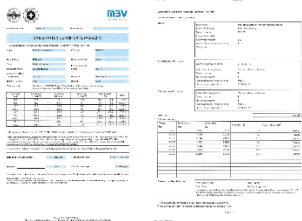
NOTE: However, for regular transport for calibration we recommend to acquire the robust transport case for MAS-100 Atmos (see list below)

Unpack the instrument carefully and verify whether all items listed below are present. Contact your local representative immediately if items are missing or show signs of defect.

DESCRIPTION	ARTICLE NUMBER		PICTURE
	MBV AG	MERCK KGAA, DARMSTADT, GERMANY	
MAS-100 Atmos® sampler for compressed gases with HEPA H13 (ISO 35H) filter and nutriente plate holder	200162	1173280001	

1 x perforated lid MAS-100 Atmos 300x0.6 mm	130.4457	1173570001
1 x pressure connection tubing 2m PTFE with tri-clamp connector	130.4285	1173540001
1 x tri-clamp Ø34mm	130.4461	1173670001
1 x silicone gasket 34/10 mm	130.4318	1173640001
1 x dust cover (polypropylene, white)	130.4328	1173400001
1 x power supply incl. USB-C cable and region-specific adapters	130.4258	1173290001
1 x hardware key system administrator (black)	n/a	n/a
5 x additional hardware keys for MAS-100 user management (various colors)	130.4459	1173330001
Documents: - Quick Start Guide MAS-100 Atmos - Global Safety data sheet - Flow and pressure calibration certificates MAS-100 Atmos - Flow and pressure calibration certificates calibration unit of MAS-100 Atmos	n/a	n/a

2.6. ACCESSORIES FOR MAS-100 ATMOS

DESCRIPTION	ARTICLE NUMBER		PICTURE
	MBV AG	**MERCK KGAA, DARMSTADT, GERMANY**	
Wheeled case for MAS-100 Atmos	130.4468	1173340001	
Perforated lid 300x0.6 mm (anodized aluminum) with blue sieve and individual black marking (3 letter code for lid type)	130.4457	1173570001	
Perforated lid 300x0.47 mm (anodized aluminum)	130.4458	1173630001	
Pressure connection tubing 2m, PTFE, with fixed tri-clamp Ø34 mm and universal 3/8 inch thread part (female)	130.4285	1173540001	
1 x gas exhaust tubing set, 5m tubing (Ø40 mm) with tri-clamp (Ø50.5 mm) connector	130.4271	1173490001	
1 x adapter for gas exhaust tubing	130.4147	1173480001	
5 x hardware keys for MAS-100 user management (various colors)	130.4459	1173330001	
Power supply incl. USB-C cable and region-specific adapters (US/JPN, AUS, UK)	130.4258	1173290001	
Tri-clamp Ø34 mm	130.4461	1173670001	

Instrument protection filter: HEPA H13 (ISO 35H) Ø74 mm	130.2652	1172780001	
Nutrient plate holder (stainless steel) for 90mm nutrient plates	130.4190	1173350001	
1 x dust cover (polypropylene, white)	130.4328	1173400001	
Filter cover (anodized aluminum)	130.4159	1173360001	

2.7. PARTS DESIGNATION

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

2.8. COMMUNICATION

The electrical interfaces are located below the handle on the right:
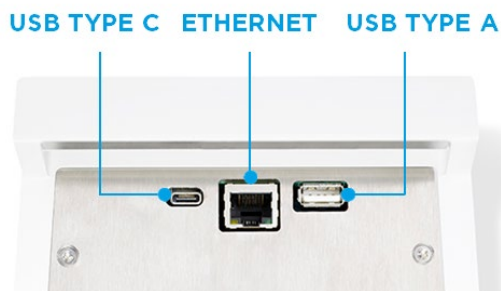
To prevent the ports from dust, the less frequently used Ethernet and USB type A interfaces are protected with protecting caps.

NOTE: According to regulatory, the length for the USB cable must not exceed 1m and that of the ethernet cable must not exceed 30m.

2.8.1. USB TYPE C PORT

– To charge the internal battery of the instrument, the cable is connected with the USB Type-C to the instrument and with the USB-A to the power supply

– It is also used to connect the instrument to a computer for accessing the instrument by means of the browser-based user interface

2.8.2. ETHERNET PORT

The Ethernet connection is used for automatic time synchronisation via the local network if the unit is configured accordingly (network time protocol = NTP).

2.8.3. USB TYPE A PORT

– The USB type A port is used for connecting a barcode/QR code scanner/reader to the MAS-100 Atmos in order to capture the ID of a sampling head, a nutrient plate or the sampling location (depending on the instrument configuration, see chapter 4.1 «Setting up the instrument configuration»). In this case, the scanner/reader will be automatically recognized as a USB keyboard.
NOTE: To ensure correct working a set of configurations of the barcode scanner are advised (see chapter 4.5 «Data transmission to an installed LIMS or EM software»).

– To perform service tasks, the USB type A port is used to connect the instrument to the calibration instrument during the calibration procedure.

– Furthermore, the USB type A port can be used to download the service file by connecting a USB stick to the port.

2.9. LOCAL USER INTERFACE

POWER BUTTON   HARDWARE KEY READER

DISPLAY (TOUCHSCREEN)

2.9.1. POWER BUTTON

The power button is used to switch between on, standby and off and has an integrated LED indicator:

ACTION	INSTRUMENT STATUS	LED INDICATION
Tap power button once	Starting up Switched on	Blue flashing Blue
Connect instrument to power supply via USB-C cable (display switched off)	Instrument is charging	Blue flashing
	Instrument is fully charged	Blue
Connect instrument to power supply via USB-C cable (display switched on)	Instrument is charging	None
	Instrument is fully charged	Indication on display only see chapter 2.9.2
Pressure on the instrument	Under pressure	Yellow
Tap power button once while the instrument is switched on	On standby	None
Tap power button once while the instrument is in standby	Instrument awakened	Blue
Tap power button twice while instrument is switched on	Switch off screen Y/N Switched off	Blue None
Tap and hold power button (until instrument is switched off)	Hard reset then switched off	None
System error occurred, e.g. instrument was connected to overpressure (>7 bar.a), battery overheated or sensor connection lost (complete list see chapter 6)	System error	Red

2.9.2. TOUCHSCREEN

A color-type LED screen with touchscreen function is the local user interface for the operator. It enables user login and guides the operator through the sampling process:
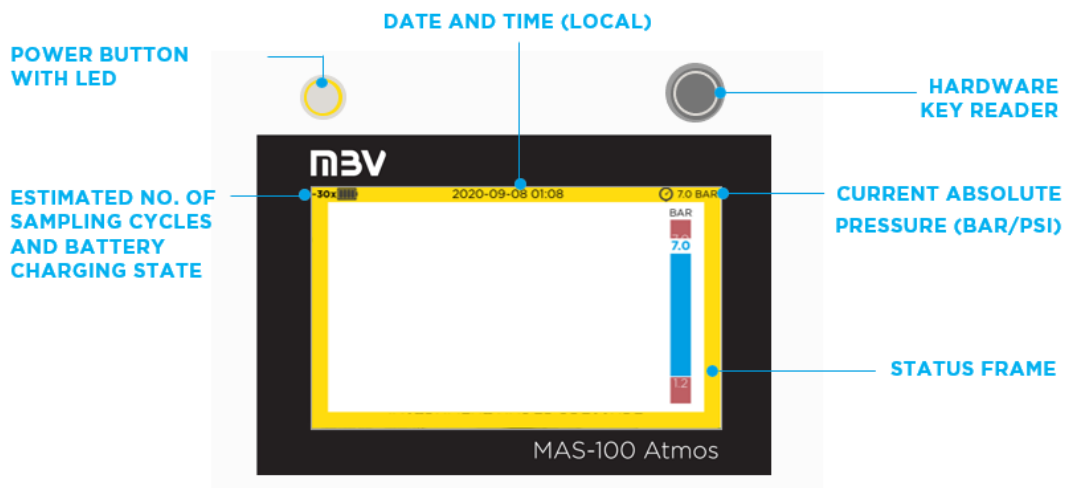
– Battery charging state

~[n]x	Estimated number of sampling cycles that can be run with the remaining battery capacity (calculated by a default value of 1000 NL compressed air at 2 bar.a)
▮▮▮▮	Battery full
▮▮	Half of battery capacity remaining
▮	Battery almost empty
⚡	Battery charging (instrument connected to power supply and display switched on)

– Status frame colour code

Yellow: system under pressure

Blue: sampling ongoing

Red: system error

More details about the local user interface can be found in the corresponding instructions. Refer to chapter 3.3 «Taking a sample».

2.9.3. HARDWARE KEY READER

The hardware key reader allows users to log on to the instrument using a personal security key called hardware key.

Hardware keys are available for each user role, in different colors to make identification of the corresponding user easy. The hardware key is a data carrier based on single-wire technology. It contains the login data for accessing the instrument function according to the user management.

If a user management on the instrument is required (see chapter 2.11.1 «User management use cases») a login can be setup to access the local user interface of the instrument (see chapter 4.1 «Setting up the instrument configuration»).

To access the browser-based user interface for advanced functions a login with PIN is always required. In case no user management was initialized use the supplied preset black instrument administrator hardware key shown on the left, in case the user management was initialized use the newly written hardware key (see chapter 4.2 «Setting up the optional user management»).

The user will be prompted to present the hardware key. For programming and reading out, the hardware key is presented to the hardware key reader on top right of the touchscreen.

Depending on the configuration set, the user must enter a personal PIN. This PIN is set during the first login on the instrument, whereby the user is prompted to set a personal PIN and to confirm it a second time.

NOTE: After three unsuccessful attempts the instrument will be locked. To unlock the instrument see chapter 6.3 «Other Troubleshooting».

2.10. BROWSER-BASED USER INTERFACE

With a computer connected to the instrument, the user has access to the internal software of the instrument via a web browser to for example view information (all user roles) and to change instrument settings (system administrator), according to the assigned rights (refer to chapter 2.11.2 «User roles»).

2.10.1. ACCESSING THE BROWSER-BASED USER INTERFACE

To use the browser-based user interface a computer must be connected with an installed web browser to the instrument by means of an UBS type C (instrument side) to USB type A (computer side) cable. The instrument must be switched on one of the following web browsers must be opened:

– Google Chrome

– Mozilla Firefox

– Microsoft Edge (Chromium)

To use the browser-based user interface no internet connection is required. Type the IP address **http://192.168.254.1** in the address bar of the browser and tap 'Enter'.

NOTE: The access to the browser-based user interface can be installed as browser app and thus gets even more easy. How to configure this see Annex A – browser App Installation.

2.10.2. HOME SCREEN FOR LOGGED-OUT USERS

The start page of the browser-based user interface that is accessible without user login looks as follows:

User Manual MAS-100 Atmos en.docx, Version: 6.0

Language

In the upper right corner of the page, select the display language of the browser-based user interface. The default setting is English.

Moreover, you can choose between:
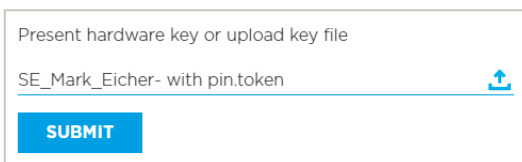
– French

– German

– Italian

– Russian

– Spanish

NOTE: This setting does not affect the display language of the instrument local user interface. To change the language of the local user interface, please go to the sub-menu instrument settings (see chapter 4.1 «Setting up the instrument configuration»).
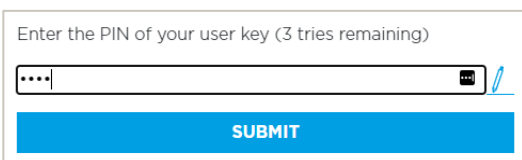
User login with key file

In addition to hardware keys, all user roles except the operator, can alternatively use a key file (.token) to login on the browser-based user interface. These key files have the same data content as hardware keys. They are created by the user administrator after setting up the user management (see chapter 4.2 «Setting up the optional user management»).

Note: The token file name shows the user level UA for user administrator, SA for system administrator as well as the first and last name of the user.

Present hardware key or upload key file	
SE_Mark_Eicher- with pin.token	⬆
SUBMIT	

1. Click on the login option on top right of the page and load the key file.

Enter the PIN of your user key (3 tries remaining)	
••••	▣ /
SUBMIT	

2. Select a key file and submit it.

3. Enter a personal PIN (4 up to 10 digits) and click the submit button

4. The browser-based user interface shows now the home screen for the corresponding user

Support links available to every user

Click on the headset symbol to call up the MBV service and support website.

Click on the FAQ symbol to access the section of frequently asked questions.

Click on the user manual symbol to download this user manual

General Information

On the home screen each logged-our user role has access to general information such as instrument, serial number and customer instrument label (if configured), to the remaining calibration validity period and to the contact data of the manufacturer and its affiliates.

Submenu Instrument Information

INSTRUMENT INFORMATION

Instrument type	MAS-100 Atmos
Instrument serial number	127435
Custom instrument label	
Application software version	1.5.3

Submenu Copy Key File (only accessible when logged out)

This function enables to copy the login data from a key file to a hardware key.

Possible use cases for this function:

– Service engineers who have been authorized by the manufacturer after success-ful training (or re-training after training validity period has expired) will receive a key file that can be copied to a hardware key with this function

– If the black 'system administrator hardware key' that is supplied with the instru-ment got lost. Download a backup file key from the MBV website and copy it to a hardware key (see chapter 6.3 «Other Troubleshooting»)

Open the submenu 'Copy Key File' and load the corresponding key file. Then click SUBMIT. The user will be prompted to present a hardware key on the local user in-terface.

NOTE: If a hardware key that is already in use is presented, it will be overwritten.

Submenu File Integrity Check (only accessible when logged out)

With this checker tool every .zip folder or .xml file (except individual sampling files (sampling archive)) generated by the instrument can be checked for its file integrity. Possible use cases for this function:

– Checking if an exported audit trail was manipulated on the level of the zip ar-chive and on individual file level

– Checking the integrity of an instrument settings export file before upload to other instruments

Open the corresponding file, click 'UPLOAD' and the file checker will indicate either if the file is valid or if the file is invalid/ has been modified.

2.10.3. ADVANCED FUNCTIONS

For the advanced functions, performed by the user administrator of system adminis-trator, access to the browser-based user interface is always protected. To login a hardware key (see 2.9.3 «Hardware key reader») or a key file (see 2.10.2 «Home screen for logged-out users») and a PIN is required.

List of available submenus

Submenu	Instrument Settings	Audit Trail Display	Audit Trail/ Sampling Archive Export
Description	– Configuration of the instrument – Set up the optional 21 CFR part 11 compliant instrument mode	View and filter audit trail	– View sampling archive – Export/clear audit trail
Reference chapter	4.10	4.4.1	4.4.4 4.4.2-4.4.3
Submenu	PIN Change	Settings Approval	Diagnostics
Description	Change personal PIN	Approve setting changes	– Perform diagnostics – Set up the optional user management
Reference chapter	4.6	4.7	4.8 2.11 and 4.2
Submenu	Adjustment and Calibration		
Description	Perform adjustment and calibration		
Reference chapter	4.9		

2.11. USER MANAGEMENT

The instrument is delivered without an initialized user management and can be used immediately for sampling and configuration (with the preset black system admin hardware key).

However, depending on the use case of the instrument, a user management may be required, for example in order to follow the 21 CFR part 11 compliance or data integrity guidelines or for traceability of user activities.

2.11.1. USER MANAGEMENT USE CASES

Depending on the use case 'no user management', 'a user management' on the instrument' or 'covered by a LIMS or EM software' will be required:

USE CASE	NO USER MANAGEMENT	21 CFR PART 11 COMPLIANT USER MANAGEMENT ON INSTRUMENT	21 CFR PART 11 COMPLIANT USER MANAGEMENT BY LIMS/ EM SOFTWARE
User management	None	User management on instrument	User management of LIMS or EM software
Instrument login configuration	No operator login on instrument	Operator login with user key and PIN	No operator login on instrument

To set up the optional 21 CFR Part 11 compliant user management and to define a new user group on the instrument, refer to chapter 4.2 «Setting up the optional user management». After initialization of the user management change the login configuration according to chapter 4.1 «Setting up the instrument configuration».

NOTE: For traceability of users outside of 21 CFR part 11 compliance there is also the possibility to set up the user management on the instrument with user key but without PIN (for configuration see chapter 4.1 «Setting up the instrument configuration»).

2.11.2. USER ROLES

After the user management has been initialized on the instrument each user is assigned one of the following user roles to perform corresponding tasks on the instrument:

– Operator: Sampling

– System administrator: Responsible for managing the instrument configuration

– User administrator: Responsible for managing all instrument users

The user role is distributed to the user via a hardware key (see chapter 2.9.3) or a key file (see chapter 2.10.2).

Access rights

The following table shows which tasks (access rights) are assigned to the corresponding user role and on which type of user interface of the instrument the task can be performed (LUI = Local user interface or BUI = browser-based user interface):

TASK	OPERATOR	USER ADMINISTRATOR	SYSTEM ADMINISTRATOR
General			
Unlock calibration validity seal	LUI	LUI	LUI
View instrument information	BUI	BUI	BUI
Sampling			
Run a sampling	LUI	-	LUI
View and export audit trail	-	-	BUI
View and export sampling archive	-	-	BUI
Configuration			
Configure instrument	-	-	BUI
Create new user (file or hardware key)	-	BUI	-
Add user to list of blocked users	-	BUI	-

Rem. user from list of blocked users		BUI	-
Approve setting changes	-	-	BUI
Export/import instrument settings file	-	-	BUI
Service			
Export service file	LUI	LUI	LUI and BUI
Export calibration certificate	-	-	BUI
Diagnostics			
Run diagnostics	-	-	BUI
Update application software	-	-	BUI

2.12. SUPPORTING A 21 CFR PART 11 COMPLIANT WORKFLOW

In addition to a 21 CFR part 11 compliant user management, additional instrument settings are required to support a gas sampling workflow that is compliant with 21 CFR part 11 and meets data integrity requirements.

The instrument offers two optional instrument modes for a workflow without or with LIMS/EM software. A list of all required instrument configurations can be found in chapter 4.3 «21 CFR part 11 supporting instrument modes»).

2.13. DATA HANDLING IN ACCORDANCE WITH DATA INTEGRITY

2.13.1. AUDIT TRAIL AND SAMPLING ARCHIVE

All data generated by the instrument and by user events are stored in the audit trail of the instrument. Additionally, there is a sampling archive with all performed samplings. Both recordings were built according to 21 CFR part 11 requirements and are tamper-proof.

Depending on the intended use the audit trail data can be viewed and filtered on the browser-based user interface or exported together with a dedicated sampling archive as tamper-proof XML files. See all available options in the user manual chapter 3.4 «Data reporting».

NOTE: If a LIMS or EM software is in use the instrument offers also the possibility to send sampling data directly to these systems using the sampling barcode (see chapter 2.13.2 «Sampling barcode»).

2.13.2. SAMPLING BARCODE

The sampling barcode is a feature for error-proof and easy data transmission to a connected LIMS or EM software without the need to install a foreign software. If configured, after each sampling, a QR code is displayed on the display of the instrument that contains all sampling-related parameters. With a barcode scanner, which is connected to a LIMS or EM software, this QR code is than scanned.

This feature is part of supporting a 21 CFR part 11 compliant workflow with an existing LIMS or EM software. The complete list of all required instrument settings for this use case can be found in chapter 0 «

21 CFR part 11 supporting instrument modes».

3. OPERATION

3.1. GETTING STARTED

3.1.1. INSTRUMENT POSITIONING

The instrument shall only be stored, transported and used in an upright position. Use both handles when holding the instrument.

3.1.2. BATTERY CHARGING

Make sure that the battery is charged before starting a sampling. Connect the power supply to the USB type C port of the instrument to charge the battery. Charge the battery until the symbol on the local user interface indicates that the battery is full. See chapter 2.9.2 «Touchscreen».

NOTE: The main battery should be fully charged every 6 months to protect it from deep discharge. This further ensures that the internal real-time backup battery is not discharged prematurely.

3.1.3. CALIBRATION VALIDITY SEAL

To allow for a delay between manufacturing or recalibration and first use of the instrument the countdown for the calibration validity period only starts when the instrument is started up for the first time. This enables the customer to make use of the entire calibration validity period of 12 months.

To start the calibration interval, the calibration validity seal must be unlocked and confirmed the first time the instrument is started. To do this, tap the 'UNLOCK' button on the screen of the instrument and confirm with 'OK'.

3.1.4. OPTIONAL 21 CFR PART 11 SUPPORTING WORKFLOW

The instrument offers two optional instrument modes for customers that need a workflow supporting 21 CFR part 11 and meets data integrity requirements (for configuration see chapter 4.3 «21 CFR part 11 supporting instrument modes»):

– For customers that have no LIMS or EM software

– For customers that have a LIMS or EM software that should be used in combination with the gas sampler

3.1.5. CLEANING AND DECONTAMINATION

Make sure that the instrument (at rest) and its accessories have been properly disinfected and that the disinfectant has dried completely. Refer to chapter 5.2 «Cleaning and decontamination».

NOTE: In case the perforated lid is dismantled for autoclaving, it is recommended to protect the instrument with the dust cover during this time.

3.1.6. SWITCHING THE INSTRUMENT ON

To switch the instrument on, proceed as follows:
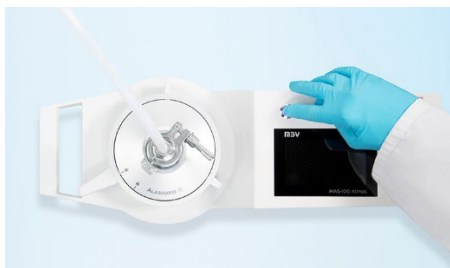
1. Tap the power button once. The power button indicator LED now flashes in blue color.
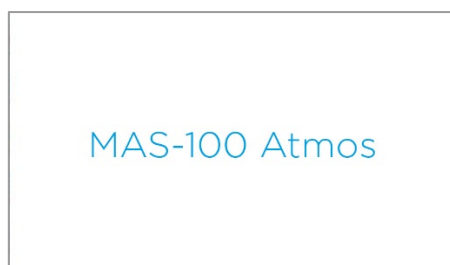
2. The instrument starts up.
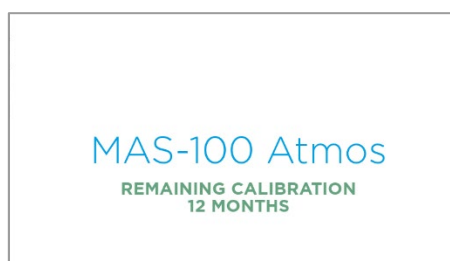
3. The instrument displays the remaining calibration validity, both in text and with a color code:

   Green: valid (within the 12 months)

   Yellow: <1 month

   Red: < 1 day
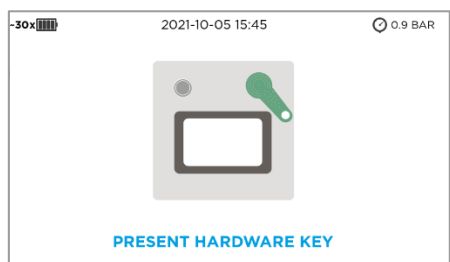
4. The power button indicator LED lights up in blue color

5. OPTIONAL: If the user management on the instrument was set up (see chapter 4.2) and the configuration was configured (see chapter 4.1), the operator is prompted to login by presenting the hardware key and optionally also to enter the personal PIN.
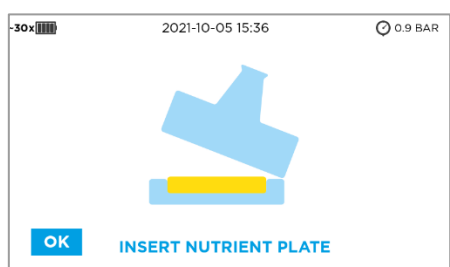
6. The instrument software is now ready to insert a nutrient plate and to start sampling.

3.2. CONNECTING THE INSTRUMENT TO THE GAS SUPPLY

3.2.1. CONNECTING THE INSTRUMENT

1. Connect the end of the pressure connection tubing with the universal 3/8 inch connector (female) to the closed gas supply at your sampling location. The gas supply must be equipped with a male 3/8 inch connector to fit to the pressure connection tubing of MAS-100 Atmos. Make sure that the connection is tight.

2. Remove the dust cover and connect a sterilized perforated lid (clockwise). Place a silicone gasket on top of the closed sampling head and fix the pressure connection tubing with the 34mm tri-clamp to the sampling head.

3.2.2. APPLYING THE OPTIONAL GAS EXHAUST TUBING

When sampling gases that can be potentially hazardous or toxic in high concentrations, it may be necessary to guide the sampled gas to a dedicated exhaust. For the safe removal of sampled gases from the room, a 5 meter long gas exhaust tubing (refer to chapter 2.5 «Scope of delivery») can optionally be connected to the gas outlet of the instrument. This exhaust tubing can as well be used to prevent potential contamination of the environment.

For the available options for cleaning and decontamination consult chapter 5.2.3. Connect the adapter piece to the air exhaust outlet on the instrument and fix the tubing with the tri-clamp:
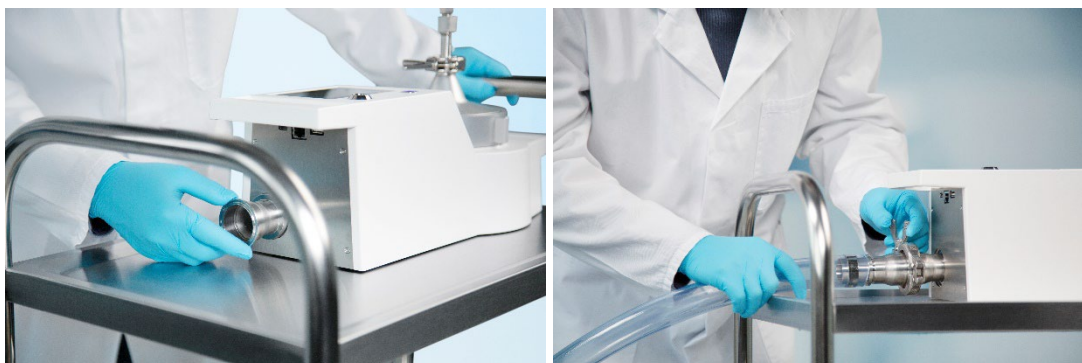
The end of the tubing is open and can be adapted by the customer to the respective application.

NOTE: In case only the adapter for gas exhaust tubing was ordered for a customized solution, it must be ensured that the customer tubing that is used has a minimum inner diameter of 32mm and a maximum length of 5m. A longer tubing must be tested by the customer in an own validation and own pass criteria must be defined.

3.3. TAKING A SAMPLE

Choking hazard due to gas accumulation.

Gases can accumulate in a room, displace oxygen in the air and may cause intoxication or suffocation. If no gas exhaust tubing is used, provide for sufficient ventilation and a big room size.

Occupational safety

It is advised to work with safety goggles and ear protection when operating with pressurized gases.
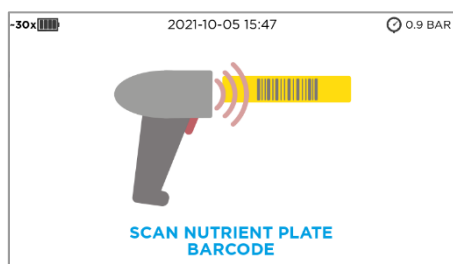
OPTIONAL: In case a 21 CFR part 11 supporting workflow without LIMS/EM software (see chapter 4.3.1) is followed, the setting to scan sampling environmental barcodes is configured (see chapter 4.1 «Setting up the instrument configuration»). The operator is then prompted to scan/read the barcode/QR code of the nutrient plate, sampling head and/or sampling location

1. Scan the barcode/ QR code

2. The input works automatically via the carriage return function (auto enter) of the scanner (see chapter 2.8.3)
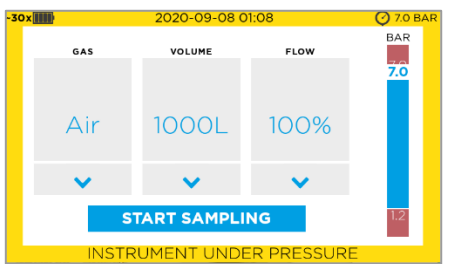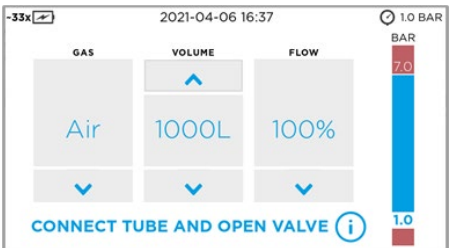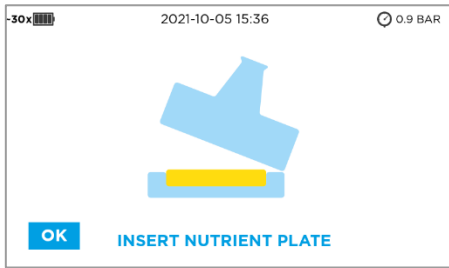
3. Open the sampling head: Hold the long handle with your left hand and the short handle with your right hand and turn the head counter-clockwise until the long handle points to the "lock open" marking

4. Insert a new nutrient plate aseptically and remove its lid

5. Insert the perforated lid with the marking pointing to the front. Close the sampling head securely (turn clockwise until the long handle points to the "lock closed" marking)

6. Confirm by tapping 'OK' on the touchscreen

   NOTE: This reminder screen is optional and can be deactivated (see chapter 4.1).

7. Select the gas type by tapping the up or down arrow of the 'GAS' column.

8. Select the sampling volume by tapping the up or down arrow of the 'VOLUME' column.

9. In the 'FLOW' column select the volume flow. The default is 100% (100 L/min), with the down arrow also 50% (50 L/min) can be selected. By default, an additional automatic fallback of the flow mode from 100 to 50% is configured. This takes effect if the gas pressure is not sufficient to reach the default flow, for example in gas lines with limited flow.

   NOTE: The flow mode fallback has an impact on the nominal d50 value (see chapter 9)

   NOTE: The gas types, volumes and flow modes selectable on the local user interface can be configured by the system administrator (see chapter 4.1).

10. Make sure that the gas connection is tight.

11. Open the main valve of the gas supply line.

12. The yellow frame and the yellow LED indicate that the system is under pressure. The current pressure on the system is displayed in the pressure bar on the right.

    NOTE: The pressure unit can also be configured to be displayed in «psi» (see chapter 4.1).

    NOTE: The sampling head has a built-in pressure safety lock and cannot be opened while the system is under pressure.
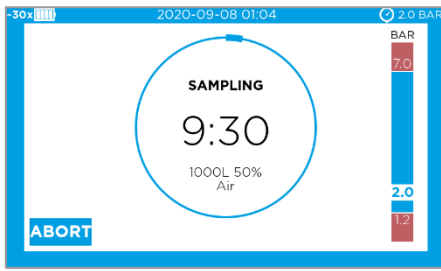
13. To start a sampling, tap 'START SAMPLING'. The sampling has started and the LED lights up in blue.

14. During the sampling cycle, the selected parameters and the remaining sampling time are displayed inside the circle, a progress indicator is also displayed graphically around the circle in a clockwise direction.

    If you tap 'ABORT' the sampling is interrupted. You can either press the prompt button 'YES', in which case the instrument aborts the sampling and shows 'CANCELLED', or 'NO' to proceed with the sampling. After abortion you will need to close the valve of the gas supply line and confirm with the 'OK' button.
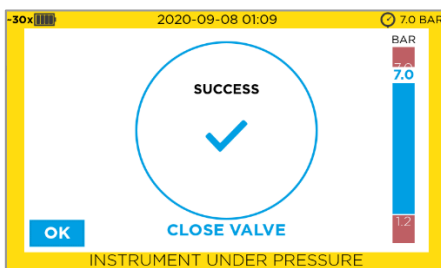
15. If the sampling has been completed and performed correctly the instrument displays 'SUCCESS'.

    Instead, 'SUCCESS WITH FALLBACK' means that the sampling has taken place with a reduced flow rate (only possible if fallback to the 50% flow configuration is enabled).

16. Close the valve of the gas supply line.

17. Confirm with the OK button.

18. The instrument starts with the automatic decompression cycle.

    NOTE: If the gas valve has not been closed properly the instrument displays 'PRESSURE NOT RELEASED'. Check the gas valve and confirm with the OK button after closure.

19. Open the sampling head (turn counterclockwise)

20. Carefully remove the nutrient plate, making sure that the plate is not contaminated during removal.
    NOTE: This reminder screen can be deactivated (see chapter 4.1)

21. Confirm with the OK button.

    OPTIONAL: If configured, a sampling barcode (QR code) to be scanned will be displayed containing all sampling-related data.
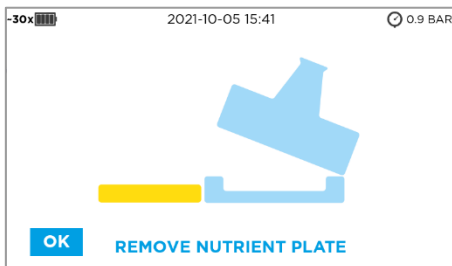
22. Scan the code with your QR code reader. After scanning, tap the 'OK' button.

```
-30x▥▥▥    2021-10-05 15:36    ⏱ 0.9 BAR




              ▭
   OK    INSERT NUTRIENT PLATE
```
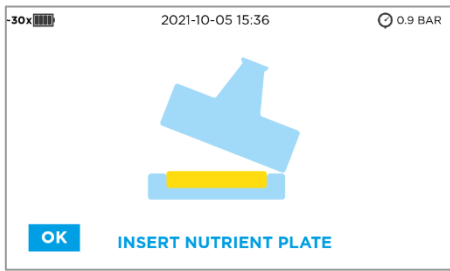
23. The instrument has completed the sampling procedure and is now ready for the next sampling.

At the end of the sampling day the nutrient plate is incubated under appropriate conditions for several days and finally the colonies (CFU) are counted. In case of ≥ 18 CFU per plate a statistical correction according to Feller must be performed. Make use of the positive hole conversion table for 300x0.6 and 300x0.47mm perforated lids (see Annex B – Feller conversion table). After correction, the CFU/1000 Liter (m^3) can be calculated based on the actual sampling volume.

3.4.   DATA REPORTING

All data generated by the instrument and by user events are stored tamper-proof in the audit trail and sampling archive of the instrument. Depending on the intended use, the data can be viewed, exported or transmitted to higher-level LIMS or EM software systems:

Display

– View the complete list of performed samplings with the newest entry on top in the submenu 'Sampling archive' (see chapter 4.4.4 «Viewing and exporting the sampling archive»)

– View the audit trail (filterable according to different categories) on the browser-based user interface (see chapter 4.4.1 «Viewing the audit trail»)

– Gain a quick overview over the data set by opening any exported XML file in a browser (see chapter 4.4.2 «Exporting the audit trail»)

Export for archiving and official audits

– Export of a tamper-proof .zip file containing the complete audit trail as well as a dedicated file of the sampling archive and the error/warning list (all tamper-proof XML files) (see chapter 4.4.2 «Exporting the audit trail»)

– Export of sampling data for a specific sampling in .xml or .csv format or display as a QR code (content configurable see chapter 4.1). See chapter 4.4.4 «Viewing and exporting the sampling archive»4.4.4

Data trending and analysis

– Import a true copy of the archived .XML to a program (e.g. Excel) (see chapter 4.4.2 «Exporting the audit trail»)

Direct data transmission to an installed LIMS or EM software

– If a LIMS or EM software is installed and a barcode scanner connected to such a system is used (see chapter 4.5 «Data transmission to an installed LIMS or EM software»), data transmission can be achieved using the sampling barcode that can be displayed on the instrument display. By scanning this barcode, the sampling data can be transferred to this higher-level system directly after sampling (see chapter 4.3.2 «Use case with installed LIMS/EM software» and for configuration see chapter 4.1 «Setting up the instrument configuration»)

3.5. SHUTDOWN

Standby mode

To put the instrument in standby mode (e.g. for a short break of operation), press the power button once.

NOTE: A switch to the standby mode automatically logs off a user.

Switching the instrument off

To switch the instrument off completely, tap the power button twice.

NOTE: During charging, the instrument cannot be switched off, it remains in standby mode.

NOTE: While being under pressure the instrument cannot be switched off or go to standby mode. In this case the user is prompted to first decompress the instrument.

NOTE: If the instrument's pressure gauge fails, the pressure can not be measured. Sofware version 1.9.1 and higher: The instrument shows the the pressure sensor warning and presents the depressurize button. After the decompression, the instrument can be switched off normally.
Software version 1.7: follow SIL 2023-11-30.
With both versions, after a sensor error a service intervention is needed.

4. SETTINGS AND CONFIGURATION

4.1. SETTING UP THE INSTRUMENT CONFIGURATION

The user roles system administrator and service engineer have the user rights to change the instrument settings. If required, for example to work in a 21 CFR part 11 supporting mode, the instrument can be configured in a way that setting changes made by a service engineer need to be approved by the system admin before becoming effective (see chapter 4.7 «Settings approval»).

To change the instrument settings set up a connection to the browser-based user interface either with the supplied black system administrator hardware key (without initialized user management, see chapter 2.9.3 «Hardware key reader») or with the newly created user key (hardware key or key file) of a new user group (see chapter 4.2 «Setting up the optional user management»). Then open the submenu 'Instrument settings'.

4.1.1. IMPORTING INSTRUMENT SETTINGS

To easily replicate settings from one instrument to another, instrument settings can be imported. To import a settings file click on the 'UPLOAD SETTINGS FROM FILE' button at the bottom right of the page.

The Windows file explorer appears. Navigate to and select the .zip file that contains the instrument settings you want to upload and then click the open button in the file explorer.

NOTE: For settings to take effect on the local user interface a logout and login sequence is required.

4.1.2. CHANGING INSTRUMENT SETTINGS
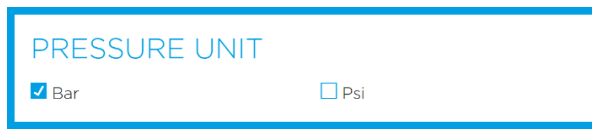
The following list shows the individual items of the instrument settings that can be configured by the system administrator:

NOTE: To make them effective, any changed settings need to be stored by tapping 'SAVE ALL SETTINGS' at the lower end of the window.

INSTRUMENT LANGUAGE

English ∨

With this selection the instrument language can be defined in which the instrument generates reports and displays texts on the local user interface.

The default setting is English. Moreover, German, French, Spanish, Italian and Russian can be selected.

PRESSURE UNIT

☑ Bar   ☐ Psi

Defines the unit in which the pressure values are displayed and reported.
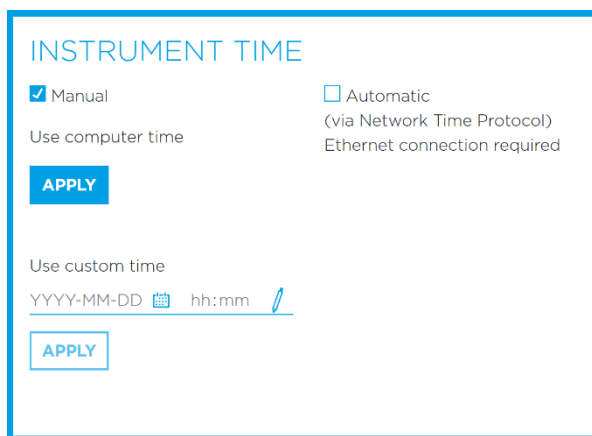
Bar
The pressure values are represented in bar (100 kPa).

Psi
The pressure values are represented in pounds per square inch (psi).

DISPLAY BRIGHTNESS

100   ⬩ %

Adjusts the brightness of the display. A value between **0%** and **100%** can be entered. 100% results in max. brightness.

INSTRUMENT TIME

☑ Manual   ☐ Automatic
                  (via Network Time Protocol)
Use computer time   Ethernet connection required

APPLY

Use custom time
YYYY-MM-DD 📅   hh:mm ⬩

APPLY

.

With this configuration the instrument time can be set. Select one of the following options and save the settings before proceeding:

– **Manual**

 Allows to take over the computer system time or to enter the date and time manually (custom time). Choose the option and tap 'APPLY'

 Computer time

 Tap 'APPLY' to copy/paste time/date as seen. The time zone information is not copied.

 Custom time

 Click on the calendar symbol and select month and day.
 In the field hh:mm, enter the time in the 24 h format.
 Tap ' APPLY'.

– **Automatic**
 Synchronizes the time via Network Time Protocol (possible if the instrument is connected to a local network via Ethernet cable).

NOTE: For each option, shifting between summer and winter time takes place automatically, depending on the selected time zone.

TIME ZONE

Europe/Zurich ▾

With this configuration, the time zone of the location where the instrument is used can be selected. The different time zones show the time difference to UTC (Universal Time Coordinated) e.g. America/New_York (-05:00 h).

NOTE: The selected time zone is the basis for the display on the local user interface and for reporting in the audit trail. To avoid confusion, it is advisable to have your PC and the instrument on the local time zone.

TIME UNTIL STANDBY MODE (LOGOUT)

15 min ▾

Defines the tolerated time period of inactivity before the instrument switches to standby mode and logs off the user. 15 minutes is the default setting. Additionally, select between

– **1, 5 or 30 minutes**
The instrument switches to standby mode after the specified time of inactivity.

– **Never**
The instrument runs continuously.

NOTE: While being under pressure the instrument cannot go to standby mode. In this case the user is prompted to first decompress the in-strument.

BEHAVIOUR UPON EXPIRY OF CALIBRATION VALIDITY

☐ Lock instrument
☑ Warn operator
☐ No validity indication

With this configuration it can be de-fined how the instrument reacts when the calibration validity (12 months) has expired.

– **Lock instrument**
When the calibration validity has expired, the instrument will be locked and it cannot be used for sampling anymore until it has been re-calibrated by a service engi-neer. The expiration will be logged in the audit trail.

– **Warn operator**
The operator will be alerted on the instrument start screen as well as on the home screen of the browser-based user interface about the status of the remaining time until re-calibration:

Green: valid (within the 12 months)

Yellow indication: <1 month

Red: < 1 day

In case the calibration has expired the instrument will not be locked,

but the operator will be alerted that the calibration has expired. The exceeding will be logged in the audit trail.

– **No validity indication**
If the calibration period is tracked in another tool or no indication is needed. With this configuration there will be no warning and no locking of the instrument.

NOTE: The manufacturer recommends to calibrate the instrument in time and not to use it beyond the calibration validity.

APPROVAL OF SETTING CHANGES

☐ Yes   ☑ No

Defines if changes to the instrument settings made by a service engineer take a formal approval by the system administrator. This may be a requirement of specific regulations in your environment (e.g. 21 CFR Part 11).

– **Yes**
The system administrator needs to check and approve all settings changes before they become effective. Refer to chapter 4.7 «Settings approval».

– **No**
Changes done by the service engineer are accepted automatically without formal approval by the system administrator.

INSTRUMENT ACCESS

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

Defines the login procedure on the local user interface for the operator to perform a sampling:

– **No login**
The operator does not require any login and can take samples at any time.

NOTE: This configuration is the default setting and is applied both for use cases outside of 21 CFR part 11 compliance and in the case that the 21 CFR part 11 compliant user authentication is handled by a LIMS or EM software (see chapter 4.3.2 «Use case with installed LIMS/EM software»)

– **Login with user key**
The operator needs a hardware key for login and sampling.

NOTE: This configuration is recommended for use cases outside of 21 CFR part 11 compliance but in case you want to log user actions.

– **Login with user key and PIN**
  The operator needs a hardware key and must enter his personal PIN for login and sampling (see chapter 2.9.3 «Hardware key reader»).

NOTE: This configuration is selected if the 21 CFR Part 11 compliant user management on the instrument is to be used (see chapter 4.2 «Setting up the optional user management»).

GAS TYPES

☑ Air
☑ Nitrogen (N_2)
☑ Carbon dioxide (CO_2)
☑ Argon (Ar)
☐ Name of custom gas

$f(x) = 0.0000 \ x^2 + 0.0000 \ x + 1.0000$

NOTE: The user must take care to comply with local law. The instrument is not intended to take samples from oxidizing (O_2), toxic, flammable or combustible gases or mixtures.

This box defines the gas types that are available for selection on the local user interface. A gas factor for automatic gas amount compensation was determined for the following gas types using compressed air (gas factor = 1) as a reference:

– **Nitrogen**

– **Carbon dioxide**

– **Argon**

NOTE: When sampling CO_2 at pressures <1.5 bar.a. sampling is only possible in 50% flow mode (d_{50} = 1.6μm). Change to the 300x0.47mm perforated lid if the d_{50} of 1.1μm is to be maintained (see chapter 9 «Technical specifications»)

– **Custom gas**
  As advanced function even complex mixed gas compositions (as long as not oxidizing, flammable or combustible) can be mapped in the software. If this applies to you, please contact us for a talk with our experts.

NOTE: Do not change the default value of the custom gas factor if this function is not needed!

SAMPLING VOLUMES

Volume 1	☑ 2000	Liter
Volume 2	☑ 1000	Liter
Volume 3	☑ 500	Liter
Volume 4	☑ 250	Liter
Volume 5	☑ 125	Liter

Defines the sampling volumes that can be selected on the local user interface before sampling. A sampling volume between 50 up to 3000 normal liter (NL) can be entered and a volume is activated for selection on the local user interface after ticking.

FLOW MODE

☑ 100% mode
☑ 50% mode
☑ Enable automatic flow mode fallback

The following flow mode settings can be pre-defined for selection on the local user interface:

– **100% mode**
This mode corresponds to the full flow rate (100 L/min) for sampling.

If the pressure difference between the gas supply line and the atmosphere pressure is not large enough to reliably achieve the required gas flow rate, the instrument offers the option of halving the flow rate for sampling (50% mode). In this case the instrument needs the double time for sampling the selected gas amount, accordingly. The system administrator can choose between 2 options:

– **50% mode**
When selecting this mode on the local user interface the sampling continuously runs at 50% flow mode. The reduced gas flow has an influence on the impaction speed on the nutrient plate and as a consequence the physical efficiency d_{50} (see Annex C – Physical sampling efficiency) will be decreased (d50=1.6µm).

NOTE: To exclude a possible biological efficiency loss, for routine sampling at this mode, it is recommended to use the dedicated 50 L/min perforated lid.

– **Enable automatic flow mode fallback**
If this option is selected in addition to the 50% mode any initiated sampling at 100% (100 L/min) can be terminated without stopping because the instrument can automatically reduce the flow rate to 50 L/min.

DECOMPRESSION SPEED

☑ Slow
☐ Moderate
☐ Fast

Defines at which speed the venting of the gas duct is performed.

Select from

– **Slow (default and legacy setting)**

– **Moderate**

– **Fast**

It is recommended to keep the standard decompression speed (slow). However, if a faster decompression is desired, for example at very low pres-

sures, the instrument can be reconfigured to moderate or fast decompression.

BARCODE SCANNING OPTIONS

☐ Nutrient plate
☐ Perforated lid
☐ Sampling location

With this configuration the scanning of the sampling environment can be activated. This configuration is chosen when a 21 CFR supporting workflow is to be followed without the use of a LIMS/EM software (see chapter 4.3.1 «Use case without LIMS/EM software»). Connect a barcode/QR code scanner directly to the instrument using USB-A (see chapter 2.8.3 «USB type A port»).

– **Nutrient plate**
  The operator will be asked to scan the barcode of the nutrient plate.

– **Sampling head**
  The operator will be asked to scan the barcode on the perforated lid.

  NOTE: Each perforated lid is marked with an individual 3-letter and six-digit serial number for unique identification (black marking). This information is also displayed in the form of a scannable barcode. A matrix for the decomposition of the letter code can be found on our website:
  https://www.mbv.ch/media/mbv_marking_of_perforated_lids_black_marking.pdf

– **Sampling location**
  The operator will be asked to scan the barcode of the sampling location where the sampling takes place.

  NOTE: If one or more scanning options are ticked, a barcode/ QR code scanner is mandatory to be able to start a sampling.

OPTIONAL DATA OF SAMPLING BARCODE

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

If configured, after a sampling, the instrument displays a QR code (sampling barcode) including all sampling-related data: Date and time, sampling start and stop time, gas type, sampling volume, flow mode, sampling success/failure.

The following additional data can optionally be included in the sampling barcode (QR-code):

– **Instrument serial number and instrument label**
 Includes the instrument serial

number as well as the optionally defined customer instrument label (see below in this chapter) in the QR-code.

– **Calibration date and time**
Includes the instrument's last calibration date in the QR code.

– **User data**
Includes the logged in user name and user role in the QR code.

The selected data is both included in the displayed sampling barcode on the local user interface as well as in the sampling barcode that can be downloaded from the browser-based software (see chapter 4.4.4 «Viewing and exporting the sampling archive») (see pictures on the left).
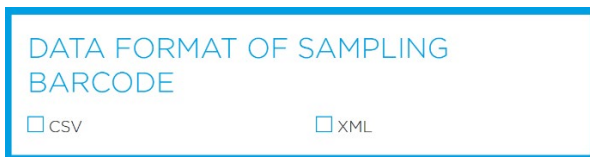
As default no data format of sampling barcode is selected. This means that no sampling barcode will be shown on the display after a sampling has been performed.

If a barcode scanner shall be connected to a customer LIMS or EM software (see chapter 4.3.2 «Use case with installed LIMS/EM software» and 4.5 «Data transmission to an installed LIMS or EM software»)), the format in which the sampling barcode (QR-code) will be displayed for direct scanning on the display can be defined:

– **CSV**
The sampling data is issued in variable length element strings whereby a comma serves as the separator.

– **XML**
The sampling data is issued in XML values separated by angle brackets.

If none of both formats is selected, no QR-code will be issued when sampling is completed

NOTE: The barcode that can be displayed in the sampling archive after the sampling (see chapter 4.4.4 «Viewing and exporting the sampling archive») will have the same format as defined here.

CUSTOM INSTRUMENT LABEL

There is the option of assigning a customized instrument label for identification purposes.

Enter the name in the corresponding line. The defined custom instrument label will be displayed on the browser-based user interface start page and on the calibration certificates, additionally, if configured, as well in the sampling barcode (see above).

NOTE: The certificates will not be updated when changing the custom instrument label. The selected fields take effect only on the next calibration certificates.

COMPANY ADDRESS

This box allows to enter a company address which will be shown on the calibration certificates.

NOTE: The certificates will not be updated when changing the company address. The selected fields take effect only on the next calibration certificates.

DISPLAY REMINDERS

☑ Enable   ☐ Disable

By default, the display reminders are shown on the local user interface. They are reminder screens to insert and/ or remove the nutrient plate which have to be confirmed with 'OK'. It is recommended to let them activated, especially if the nutrient plate scanning function is used, however, they can be disabled, for example for very practiced operators.

Exporting instrument settings

To easily save instrument settings or to transfer them from one instrument to another, the settings can be written to a file. To export a settings file, tap 'EXPORT SETTINGS TO FILE' at the end of the page. The instrument creates a .zip file that contains a text file with the selected instrument settings.

NOTE: The settings file is automatically sent to the Windows «Downloads» folder.

Check for the file «InstrumentSerialNumber_Settings_yyyyMMdd-hhmmss.zip».

NOTE: If the exported settings file is manipulated, the file will become invalid and can no longer be imported into an instrument. The data integrity of a file can be checked using the tile 'File Integrity Check' on the start screen of the browser-based user interface (see chapter 2.9.3 «Hardware key reader »).

4.2.   SETTING UP THE OPTIONAL USER MANAGEMENT

This chapter describes how to set up the 21 CFR part 11 compliant user management on the instrument. This is relevant whenever no LIMS or EM software is present or in case the user management of such a software shall not be used for login (see chapter 2.11.1 «User management use cases»).

4.2.1. INITIALIZING THE MAS-100 USER MANAGEMENT

To initialize the MAS-100 user management on the instrument for the first time log in with the black system administrator hardware key that is supplied with the instrument (see chapter 2.10.1 «Accessing the browser-based user interface»). A personal PIN is required and must be set in the beginning.

To set up a new user group

A user group is a set of defined users for an instrument. If a new user group is setup on an instrument it is private and users outside this group will not have access. This applies to advanced functions on the browser-based user interface. Users outside this user group have no access to the local user interface in case the optional operator login has been configured according to chapter 4.1.2. Follow the following steps to set up a new user group on the instrument:

1. On the browser-based user interface click on the submenu 'DIAGNOSTICS'.

2. In the 'USER MANAGEMENT RESET' box on bottom right, tap the 'RESET' button.

3. In the 'CREATE NEW USER GROUP' box, enter the first and last name of the new system administrator.

NOTE: It is recommended to set up a second backup system administrator for the case that the key is unavailable or the instrument blocked.

4. Tap the 'CREATE HARDWARE KEY' button.

5. Present the hardware key you want to use for this login on the hardware key reader.

NOTE: The system does not check if there is data on the presented hardware key. Existing data will be overwritten

6. Next, create two user administrator hardware keys. For backup reasons two user administrators need to be defined).

7. Log in as user, set a personal PIN and follow the instructions described in chapter 4.2.2 «Creating new users» to add new additional users such as operators to this newly defined user group.

Additional instruments can be adopted into the same user group and therefore a user key can be used on multiple instruments. In this case use one of the upper

boxes 'ACCESS WITH EXISTING USER GROUP'. Either click on the left box in case you want to use an existing system administrator hardware key or on the top right box in case you want to login with a system administrator key file and follow the indicated steps.

4.2.2. CREATING NEW USERS

Log in with the user administrator hardware key. On the browser-based user interface page for the user administrator click on the submenu 'USER MANAGEMENT'.

To add a user proceed as follows:

1. Select the user role (User Administrator, system administrator or operator).

2. Select the instrument type (MAS-100 Atmos).

3. Enter the first name and last name in the corresponding boxes.

   Example for an operator:

USER MANAGEMENT

ADD USER

User role	☐ User administrator ☐ System administrator ☑ Operator
Instrument type	☑ MAS-100 Atmos
First name	John
Last name	Smith
Set PIN validity period	12 months

Warning: Hardware keys will be overwritten

CREATE HARDWARE KEY   CREATE KEY FILE

4. Select the duration of the PIN validity according to your IT security guideline. Choose between 1 up to 12 months, or alternatively no limit if the validity shall not be restricted. If the PIN validity period has expired, the user will be prompted to renew the PIN directly on the screen of the instrument.

5. Create a hardware key or a key file (depending on the selected user role)

Creating a hardware key (for all user roles)

1. Tap the button 'CREATE HARDWARE KEY'. The local user interface prompts the user with 'PRESENT HARDWARE KEY'.

2. Present the hardware key to the hardware key reader. The login data are written onto the hardware key.

Creating a key file (all user roles except operator)

1. Alternatively, tap the button 'CREATE KEY FILE'.

NOTE: The key files are automatically sent to the Windows «Downloads» folder.

Example for a system administrator:

Generation of the personal identification number (PIN)

The user administrator does not define the PIN for other users. Upon first login the user is asked to set a personal PIN. This is done either on the local user interface (hardware key and operator in general) or on the browser-based user interface (key file). This applies to the user roles user administrator and system administrator in general and for the operator only if required by the instrument configuration (see chapter 2.11.1 «User management use cases» and 4.1.2 «Changing instrument settings»).

NOTE: After login, either on the local user interface of the instrument with a hardware key, or on the browser-based user interface with a key file, the page of the browser-based user interface reloads automatically to show the current login state. Otherwise, reload the page manually with the keyboard combination «CTRL+F5».

4.2.3. BLOCKING AND UNBLOCKING A USER

It is not possible to delete users from the instrument, but the user administrator can block a user to prevent them from future log in.

NOTE: The name of blocked users is case sensitive. Moreover, this setting is only stored on an individual instrument. To make it effective on all instruments within a user group, the blocking of users must be replicated on all instruments.

To block a user, type the first and last name in the corresponding boxes and tap the 'BLOCK' button:

The names of blocked users appear in the 'UNBLOCK USER' list.

If a blocked user tries to log in, the instrument denies access and an error message appears on the instrument screen.

NOTE: When a user is blocked, both hardware keys and file keys are blocked (same name).

To unblock a user, select the name in the 'UNBLOCK USER' list and tap the 'UN-BLOCK' button.

4.3. 21 CFR PART 11 SUPPORTING INSTRUMENT MODES

The instrument offers two optional instrument modes for and without LIMS or EM software, that can support a workflow that needs to be compliant with 21 CFR Part 11 and needs to meet data integrity requirements:

4.3.1. USE CASE WITHOUT LIMS/EM SOFTWARE

– Initialize the MAS-100 user management with dedicated user roles (see chapter 2.11 «User management» and follow user manual chapter 4.2 «Setting up the optional user management»)

– Connect a barcode/QR code scanner via USB type A port (see user manual chapter 2.8.3 «USB type A port» and 4.1.2 «Changing instrument settings») for scanning of the sampling environment (perforated lid, nutrient plate and sampling location)

– Change the instrument configuration to 'approval of setting changes' (user manual chapter 4.1.2 «Changing instrument settings» and chapter 4.7 «Settings approval»).

4.3.2. USE CASE WITH INSTALLED LIMS/EM SOFTWARE

– Use the user management of the installed LIMS/EM software (instrument configuration: no login) as described in chapter 2.11 «User management».

– Define the data format of the sampling barcode and the data content of the sampling barcode in the instrument configuration submenu (user manual chapter 4.1.2 «Changing instrument settings»).

– Use a barcode/QR code scanner that is connected with your LIMS/EM software. Ensure with your LIMS/EM supplier that the data structure of the sampling barcode is detected correctly by the system (see chapter 4.5 «Data transmission to an installed LIMS or EM software») and scan the displayed sampling barcode (sampling-related data) on the instrument screen after each sampling.

– Change the instrument configuration to 'approval of setting changes' (user manual chapter 4.1.2 «Changing instrument settings» and chapter 4.7 «Settings approval»).

4.4. AUDIT TRAIL AND SAMPLING ARCHIVE

The audit trail is a chronological record that provides documentary evidence of the sequence of all instrument and user activities.

The sampling archive lists all performed samplings with the corresponding sampling parameters.

4.4.1. VIEWING THE AUDIT TRAIL

On the browser-based user interface page for the system administrator, click on the submenu 'AUDIT TRAIL DISPLAY':

Audit trail display

The audit trail display lists all messages in chronological order. The newest entry appears on top. Each entry consists of the following information:

HEADER	INFORMATION
Local date / time	Date and time stamp, indicated in local time zone (currently selected) and in the format yyyy-mm-dd hh:mm defined according to ISO 8601
Category	Each entry is divided into one of the ten different categories
User	The name of the user who was logged in when the message was issued
User Type	The user role of the logged in person
Message	A plain text message that describes the entry
Parameter	If applicable, it shows a value along with its unit, or other parameters

Filter for category

The display allows you to filter the entries for their category. Check the box(es) to display the entries of the corresponding category:

CHECKBOX	CATEGORY
All	Shows all entries, no filter is selected

Login / Logout	Shows all login events of the corresponding users. The logout entries do not provide user names (can also be done automatically by the system, according to configuration).
Information	Shows informative messages, such as 'sampling completed', etc.
Warn	Shows warning messages with a clear warning ID, which are not critical to the sampling process results.
Error	Shows error messages with a clear error ID, which may be critical to the sampling process.
Sampling parameters	Shows all process-related value changes that have been done on the local user interface.
Setting change	Shows all changes made via the browser-based software in the 'Instrument settings' submenu.
Settings approval	If the corresponding setting is activated according to chapter 4.1.2 «Changing instrument settings») this category lists all activities of formal approval of setting changes.
User	Shows all events pertaining to the user management.
Action	Shows messages that represent an action, such as «sampling started», etc.
Technical	Shows messages that are related to internal technical aspects of the instrument, such as «battery charging started».

Filter for user

The display allows you to filter the entries by user role. Check the box(es) to display the messages related to the corresponding user role.

USER ROLE	EXPLANATION
Operator, User Administrator and System Administrator	These are the standard user roles at a customer's site.
Service Engineer	Refers to a technician authorized by the manufacturer, e.g. to perform calibration or repairs on the instrument. The interpretation of the specific messages may require special knowledge.
Unknown User Type	Relates to messages, where the user role cannot be identified. For example technical or logout messages are allocated to the unknown user type. This also applies to non-user-specific messages when no user management is set up or when no login on the local user interface is required according to the instrument configuration.

Additionally, you can also filter the messages for a specific person. For this, enter the first and last name in the corresponding fields.

Filter by date

The display allows you to filter the messages by date and time. To do this, click the calendar icon and select the date and enter the time in hours and minutes in the corresponding fields.

NOTE: The filtered audit trail display can either be saved as a pdf or printed (if a printer is installed on the computer that is used) by using the browser print function («ctrl+p»). However, this is not intended for official audits, in this case export the complete audit trail as XML as described in the following chapter 4.4.2.

4.4.2. EXPORTING THE AUDIT TRAIL

NOTE: The storage capacity of the audit trail and sampling archive is larger than 100 MB which corresponds to at least 10'000 samplings including errors/warnings. However, it is recommended to perform the export regularly, at least once per year, before sending the instrument for re-calibration, in order to prevent an irreversible data loss which can happen in case of an unlikely failure of the instrument memory.

Open the submenu 'AUDIT TRAIL / SAMPLING ARCHIVE EXPORT' on the browser-based user interface:

Tap the 'EXPORT AUDIT TRAIL' button to export the data currently stored on the instrument.

Content of the file export

The export file is a .zip archive with the file name «instrumentSerialNumber_Audit-Trail_yyyyMMdd-hhmmss.zip». This .zip file contains .xml files of the audit trail and the sampling and error/warning list. It also contains a signature and a public-key file which protect the complete archive from manipulations. This .zip archive is recommended for archiving at the customer's site.

NOTE: After export from the instrument, the customer takes full responsibility for archiving and ensuring data authenticity of the files.

NOTE: Data authenticity of .zip and .xml files can be checked at any time using the file integrity check on the home screen of the browser-based user interface (see chapter 2.10.2 «Home screen for logged-out users»).

Browser view

The XML format of all exported files ensures universal readability. Therefore, to gain a quick overview on the data set, the files can be opened in a standard internet browser (list of browsers see chapter 2.10.1 «Accessing the browser-based user interface»). The data will be displayed in form of a simple table.

NOTE: These tables in the browser viewer can also be saved as pdf or printed (if a printer is installed on the computer that is used) by using the browser print function («ctrl+p»). However, we recommend to use the tamper-proof XML files for archiving and official audits.

Official audits

For an official audit it is recommended to unzip the zip folder and use the audit trail file contained in it. This document contains the complete audit trail with all entries since the last clearance of the instrument. Since this file contains a secure W3C XML signature, it is still protected from tampering even after unzipping the .zip file.

Included in the .zip file are as well the complete sampling archive and a separate complete error/warning list. These files contain filtered subsets of the audit trail and serve to quickly gain an overview of all performed samplings and problems that encountered in this timeframe. All files are encoded as tamper-proof XML files with a secure W3C XML signature and can as well be used for official audits.

Trending and analysis

For trending and analysis a true copy of the XML or CSV files can be imported into data analysis tools.

Import process for XML file

To open the file in Excel, for example, import the XML via the path 'Data' >'Retrieve Data' > 'from XML'. Select 'entries' in the navigator. In the opened Power Query Editor, tap 'Table' under the column 'Entry'. After selection of the predefined filters then click on 'close and load' at the top left. The complete data set is now displayed in a clear and filterable Excel table.

Import process for CSV file

The file can be opened directly in Excel. However, change the separator if necessary, so you have a nice tabular view of the CSV data content. Import the CSV via the path 'Data' >'Retrieve Data' > 'from text/CSV'. Select then the separator 'comma' instead of 'separator' and tap 'Load'.

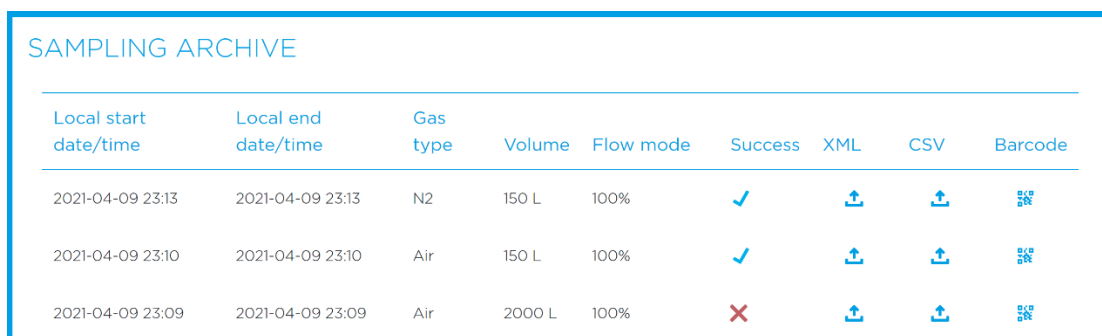### 4.4.3. CLEARING THE AUDIT TRAIL

NOTE: The audit trail can only be deleted from the instrument if the .zip file has been successfully exported before.

Make sure that you do not need the local data on the instrument anymore and that you have exported and saved the .zip file at a safe place for archiving before irrevocably clearing the data from the instrument.

Tap on the activated 'CLEAR AUDIT TRAIL' button and confirm to clear all audit trail data from the instrument.

4.4.4. VIEWING AND EXPORTING THE SAMPLING ARCHIVE

To get an overview of all samplings carried out, open the submenu 'AUDIT TRAIL/SAMPLING ARCHIVE EXPORT':

SAMPLING ARCHIVE

Local start date/time	Local end date/time	Gas type	Volume	Flow mode	Success	XML	CSV	Barcode
2021-04-09 23:13	2021-04-09 23:13	N2	150 L	100%	✓	⬆	⬆	▦
2021-04-09 23:10	2021-04-09 23:10	Air	150 L	100%	✓	⬆	⬆	▦
2021-04-09 23:09	2021-04-09 23:09	Air	2000 L	100%	✗	⬆	⬆	▦

The list shows all data associated with a sampling with the newest entry on top. This includes information about date, start and stop time, the selected gas type, the sampling volume and the flow mode.

Moreover, the list shows if a sampling was successful or not. Depending on the import requirements of a customer, there is the possibility to download/display the data for a corresponding sampling in different formats:

Click on the corresponding download or display icon:

– **XML**
  The sampling report contains XML values separated with angle brackets for corresponding data handling.

– **CSV**
  The sampling report is issued in the form of simple comma-separated value text.

– **Sampling barcode (QR code)**
  In case the barcode scanning was missed on the instrument screen it can be displayed again later in the browser-based user interface. The barcode contains the content in the format that was defined in chapter 4.1.2 «Changing instrument settings»):

NOTE: Scale the page in the browser with ctrl+scroll or in the menu in the upper right corner if the displayed barcode is too big or too small.

## 4.5. DATA TRANSMISSION TO AN INSTALLED LIMS OR EM SOFTWARE

The prerequisite for using this function is that a LIMS or EM software is installed and that a connected device is available which can read barcodes/QR codes. The following settings of the barcode scanner are advised:

– Input is American keyboard (otherwise signs and z/y may be wrong)

– Carriage return function (also known as 'auto enter'): Important as this is the only way for the instrument to get feedback if a barcode has been successfully scanned and to thereby switch to the next instrument screen.

– If signs are to be used, also make sure to select UTF-8 code page for the country keyboard type

To ensure a smooth integration of the data of the scanned barcode to the software, the LIMS or EM software supplier must be contacted and provided with the structure of the encrypted data of the sampling barcode:

CSV data format

If the data format of the sampling barcode is set to CSV (according to chapter 4.1.2 «Changing instrument settings») the data structure that uses a comma as delimiter looks the following:
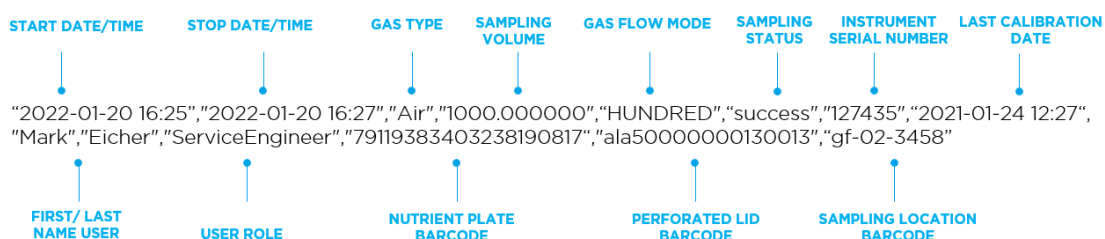
XML data format

Here an example of the data structure in XML format, if the sampling barcode format was configured to XML according to chapter 4.1.2 «Changing instrument settings»:

User Manual MAS-100 Atmos en.docx, Version: 6.0

```
<measurement>
<start_time>2022-02-07 16:25</start_time>              START TIME
<end_time>2022-02-07 16:27</end_time>                  STOP TIME
<gas_type>Air</gas_type>                               GAS TYPE
<volume>1000.000000</volume>                           SAMPLING VOLUME
<flow_mode>HUNDRED</flow_mode>                         GAS FLOW MODE
<status>success</status>                               SAMPLING STATUS
<instrument>127435</instrument>                        INSTRUMENT SERIAL NUMBER
<cal_time>2021-04-09 22:27</cal_time>                  LAST CALIBRATION DATE/TIME
<first_name>Walther</first_name>                       USER FIRST NAME
<last_name>Bauman</last_name>                          USER LAST NAME
<user_type>Operator</user_type>                        USER ROLE
<petri_dish>79119383403238190817</petri_dish>         NUTRIENT PLATE BARCODE
<head>ala50000000130013</head>                         PERFORATED LID BARCODE
<location>ala50000000130013</location>                 SAMPLING LOCATION BARCODE
</measurement>
```

As soon as the LIMS was taught how to handle the data, set up the instrument configuration to display the sampling barcode, according to chapter 4.1.2 «Changing instrument settings». The default content of the sampling barcode can optionally be supplemented with data of the sampling environment such as perforated lid, nutrient plate and/or sampling location (if configured according to chapter 4.1.2 «Changing instrument settings»).

Upon a successful setup, from now on, a sampling barcode will be displayed after each sampling. After scanning the barcode, the instrument will automatically switch to the next screen via 'auto enter' (see above).


The sampling barcode is available for later display and scanning by accessing the submenu 'SAMPLING ARCHIVE' on the browser-based user interface. The data of the sampling barcode can also be exported as .CSV or .XML file (can be configured according to chapter 4.1.2 «Changing instrument settings»).

4.6. CHANGING THE PIN

The PIN can be changed on the local user interface if the personal identification number (PIN) validity period of a hardware key of a user expired (if set by the user administrator, see chapter 4.2.2).

In addition, to change the PIN of a hardware or a file key independent of the optional PIN validity period, all user roles except the operator can access the submenu 'PIN CHANGE' on the browser-based user interface:
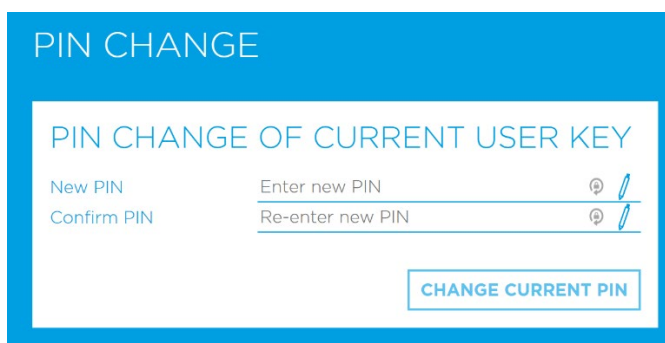
NOTE: The PIN of hardware key and file key are independent. Changes to either login option do not transfer to another.

1. Enter the new PIN (4 up to 10 digits) on the line 'New PIN' and repeat entering the same number on the lint 'Confirm PIN'.

2. Tap the 'CHANGE CURRENT PIN' button.

3. Writing of the user key

   – Hardware key: If a hardware key was used for login, the instrument prompts to present the hardware key to the hardware key reader in order to write the new PIN onto it.

   – Key file: If a key file was used for login, a new key file will be generated containing the new PIN.

NOTE: If the PIN validity has not expired, the previous key file with the old PIN is still valid.

4.7. SETTINGS APPROVAL

If the system administrator has activated this setting (see chapter 4.1.2 «Changing instrument settings»), he needs to approve all setting changes that have been made by the service engineer. The instrument issues the message 'INSTRUMENT SETTINGS NOT APPROVED. CONNECT TO COMPUTER' and needs to be unblocked by the system administrator before further actions with the instrument are possible.

If there are setting changes to be approved, it is neither possible to change instrument settings nor to perform a calibration and adjustment. The corresponding tiles are locked on the browser-based user interface. It is recommended to perform the approval as soon as possible:



Therefore, open the submenu 'SETTINGS APPROVAL':
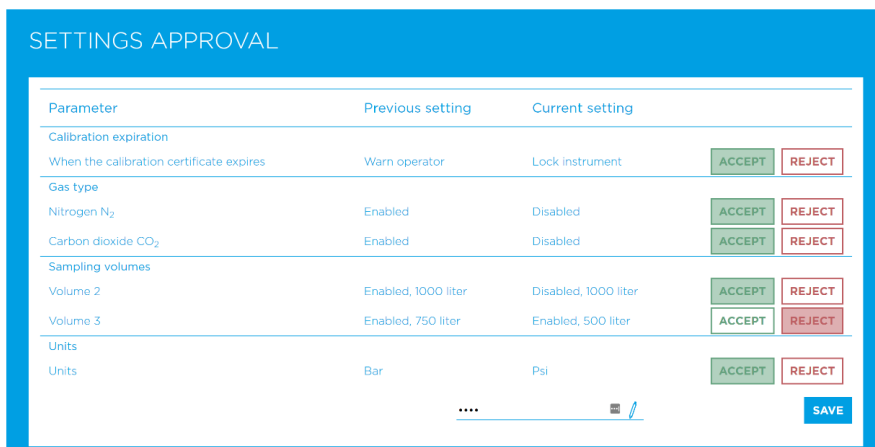
1. Review the changes and tap the 'ACCEPT' button for all changes that should be accepted.

2. If you do not agree with the change, tap the 'REJECT' button.

1. Enter your personal PIN and click on the 'SAVE' button.

NOTE: Settings that have not been accepted will not take effect.
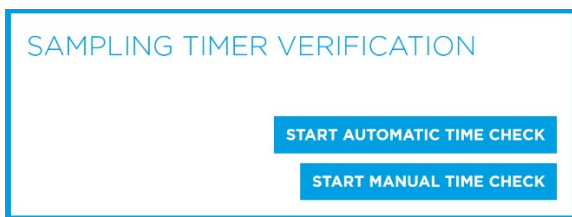

4.8. PERFORMING DIAGNOSTICS

On the browser-based user interface page for the system administrator, click on the submenu 'DIAGNOSTICS':
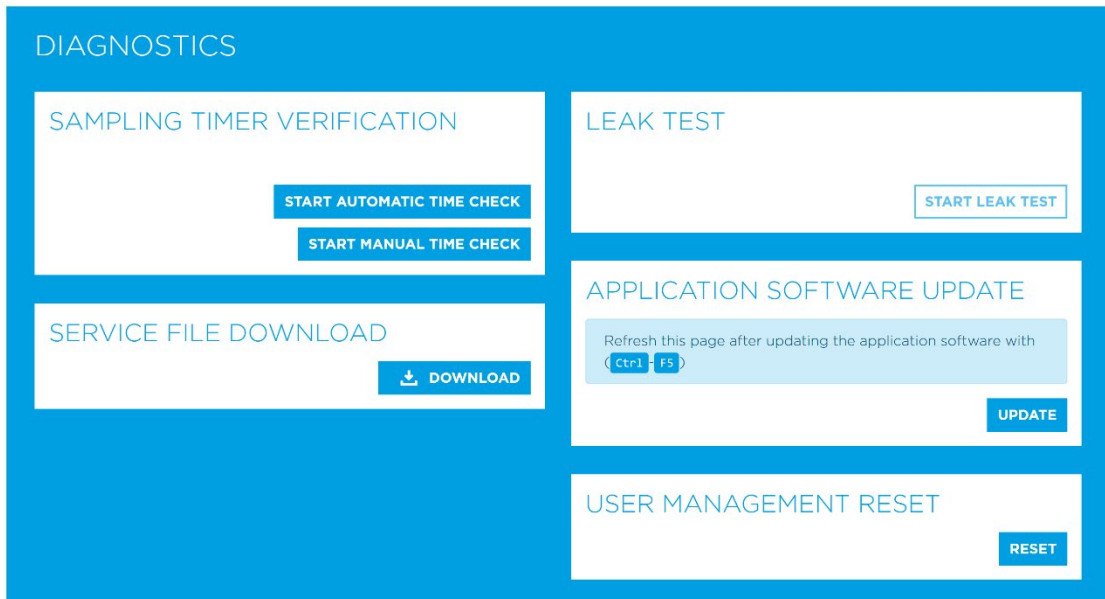
4.8.1. VERIFYING THE SAMPLING TIMER

This function is used to verify the correctness of the time base for the sampling timer.

There are two optional methods to carry out the test:

– With the automated timer verification procedure the instrument compares the internal system time with the computer system time.

– With the manual timer verification procedure the user compares the instrument's internal system time with an external time measuring device, e.g. a calibrated stopwatch.

Automated test

1. Tap the 'START AUTOMATIC TIME CHECK' button to start the automated test. The test runs for 60 seconds.

2. The browser-based user interface informs the user about the test results: The test result will be indicated as «passed» or «failed». The pass criterion for this test

is a deviation of <±0.25 %. With this deviation no detectable influence on the sampling volume is expected.

Manual test

The instrument emits a marker beep when the test has started and another beep after the time has elapsed. The test runs for 120 seconds.

To carry out the manual test, proceed as follows:

1. Prepare to be ready to start and stop the stopwatch at the sound of the marker beeps.

2. Tap the 'START MANUAL TIME CHECK' button to start the manual test.

– A countdown from 10 to 0 seconds starts and the browser-based user interface shows the remaining time until the initial marker beep. Start the stopwatch at the first marker beep.

– A countdown from 120 to 0 seconds starts and the user interface shows the remaining time until the second marker beep. Stop the stopwatch at the second marker beep.

NOTE: For the manual time check, the instrument-internal audio signal should be used to trigger the start and stop on an external stop-watch, as the display on the browser might be delayed due to the communication time from the instrument to the computer.

3. Note and compare the measured time with the instrument's 120-second time base.

4. Test evaluation: The manual test result is outside the control of the manufacturer. Therefore the pass criteria for this test must be defined by the customer himself based on in-house equipment and tolerance expectations.

4.8.2. TESTING FOR LEAKS

With this test the instrument is checked for gas leaks. It is used for troubleshooting purposes.

NOTE: For this test a dedicated calibration instrument is required, which is only available to authorized service engineers. Please contact your local service organization.

4.8.3. DOWNLOADING THE SERVICE FILE

The service file contains information that can be helpful for troubleshooting and diagnostic purposes, such as adjustment and calibration data and its parameters, information about instrument components and current application software versions. It does not contain any user information or other sensitive information such as the audit trail. MBV advises the system administrator to attach a service file of the instrument when issuing a service request, for simplified error analysis.

In the box 'SERVICE FILE DOWNLOAD' tap the 'DOWNLOAD' button to generate and download the service file. The service file is automatically sent to the Windows «Downloads» folder. Check for the .zip file «InstrumentSerialNumber_Service_yyyyMMdd-hhmmss.zip».

NOTE: Alternatively, the USB type A port can be used to download the service file by connecting a USB stick to the port.

4.8.4. UPLOADING THE APPLICATION SOFTWARE

Before carrying out an application software update, make sure that all relevant data from the instrument is downloaded and saved.

Check the MBV AG website www.mbv.ch for the latest application software and software updates.

NOTE: The firmware update should be managed under change control, according to the company's quality policy. If applicable, an impact assessment on the qualification status of the instrument is recommended.

To update the application software of the instrument, tap the 'UPDATE' button. A new browser page is opened:
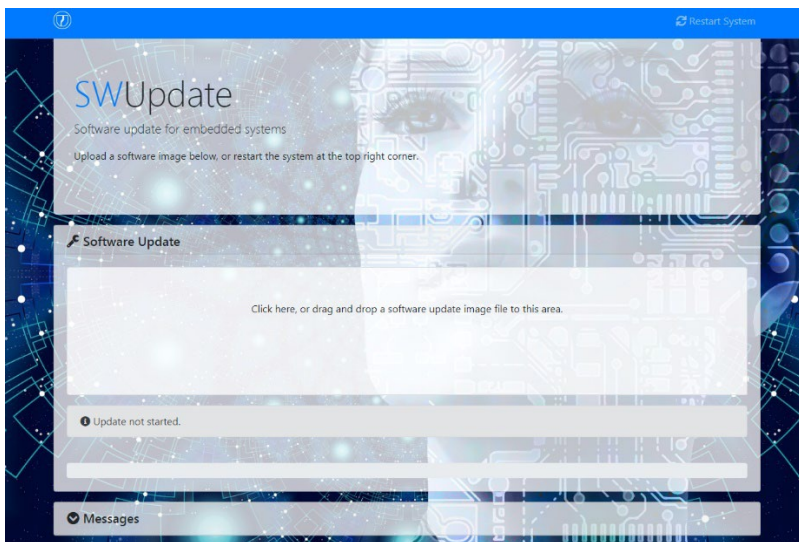
Follow the instructions on the screen. After a firmware update has been carried out, it is necessary to reload the page manually with «Ctrl+F5» to see the updated data on the browser-based user interface.

4.8.5. RESETTING THE USER MANAGEMENT

This function is used to initialize the 21 CFR part 11 compliant user management on the instrument or to apply the already initialized user management on a new instrument of the fleet. For details refer to chapter 4.2.1 «Initializing the MAS-100 user management».

4.9. ADJUSTMENT & CALIBRATION

Although adjustment and calibration are normally not performed by a system administrator, this user role has also access to the function, to have access to the current calibration certificates. The digital versions comply with the printed version supplied with the standard delivery. It is advised to store a digital version of the certificates on the server in addition.

To perform an adjustment and calibration of the instrument a dedicated calibration unit is required, which is only available to authorized service engineers. Please contact your local service organization in this case.

For general information about calibration refer to chapter 7 «Calibration and adjustment».

4.9.1. DISPLAYING THE LAST CALIBRATION CERTIFICATE

In the 'CALIBRATION AND ADJUSTMENT' submenu, all current calibration certificates can be viewed by the system administrator: As-found and as-left calibration certificates, both for mass flow and pressure. To view the current as-found or as-left

calibration certificate, tap the 'LAST MASS FLOW CALITBRATION CERTIFICATE' or 'LAST ABSOLUTE PRESSURE CALIBRATION CERTIFICATE' button in the corresponding box:

Example of a calibration certificate:

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
	Adjustment equipment	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		
	Calibration equipment	Venus Reference Device
	Serial number	1
	Hardware version	2
	Application software version	V1.0.0
	Date of last calibration [1]	2022-03-28

Leak test[2]   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%.

It shows all tests that have been performed and the corresponding results. The certificates can be printed our or saved as pdf by tapping the 'PRINT' button in the top left corner.

NOTE: The print function of the browser may automatically add a header and a footer (showing the URL address, for example), which is not desirable. Check your browser's print options, accordingly.

NOTE: The creation of this certificate required a digital authentication by the service engineer and it is therefore valid without manual signature.

5. CARE AND MAINTENANCE

5.1. GENERAL

The instrument does require moderate care and maintenance to remain in good working condition. Please pay attention to the following aspects:

– Follow the general safety information (see chapter 1.1)

– Always follow the cleaning and decontamination procedures (see chapter 5.2)

– The instrument must be calibrated periodically (see chapter 7.3).

– It is recommended to cover the lower sampling head with the dust cover when the perforated lid is in the autoclave or when changing the sampling location.

5.2. CLEANING AND DECONTAMINATION

(!)	**Hazard of damage to the instrument** Only perform disinfection when the instrument is at rest.
(!)	**Hazard of damage to the instrument** The instrument is not IP-protected. Do not pour any liquids into the electrical connections or into the gas duct.
(!)	**Hazard of damage to the instrument** Any remaining cleaning/disinfection solution must be properly removed/wiped off before using the instrument.

5.2.1. INSTRUMENT HOUSING

The housing is an injection molded high impact polystyrene with plastic primer and texture varnish. The following disinfectants can be used for wiping:

ACTIVE INGREDIENT	CONCENTRATION (V/V)	DILUTION
Ethyl alcohol	– 70%	Ready to use
Propan-2-ol	– 70%	Ready to use
– Benzalkonium chloride – Poly(hexamethyienebigua-nide) hydrochloride	– 10 – 30% – 10 – 30%	Ready to use
– Hydrogen peroxide – Acetic acid	– 1% – 5.2%	Ready to use

Clean the housing of the instrument using a clean tissue moistened with surface sanitizer listed in the table above. Carry out a wipe down of the air sampler housing. Use the pull and lift technique and do overlap paths to make sure no surface area is missed. Wait until the disinfectant has dried completely.

5.2.2. SAMPLING HEAD

The disinfection procedure of the sampling head of MAS-100 Atmos is similar to other mobile MAS-100® air samplers.

The perforated lid

Remove the perforated lid from the instrument. The perforated lid (anodized aluminum) can be disinfected or autoclaved with the following techniques:

METHOD	ACTIVE INGREDIENT	CONCENTRATION (V/V)	CONDTIONS
Dry or moist heat sterilization (autoclaving)	– Moist heat (steam)	– Saturated	– 121°C for 20 mins or 134°C for 5 mins
	– Dry heat		– ≤ 180 °C for <60 mins **Note:** Autoclave the material according to your validated cycle
Vaporized H_2O_2	– Hydrogen peroxide	– up to 840 ppm	Sterilize the material according to your validated cycle.
Disinfectant	– Ethyl alcohol	– 70%	Follow the instructions of the manufacturer
Disinfectant	– Propan-2-ol	– 70%	Follow the instructions of the manufacturer

NOTE: It is recommended to protect the instrument with the dust cover while autoclaving/disinfecting the perforated lid.

In case of the use of a disinfectant, spray the perforated lid with sufficient disinfectant. Allow the disinfectant to take effect (according to supplier recommendation), then wipe over it with a clean tissue.

Another possibility is to either use ready-to-use tissues soaked with disinfectants or a pre-sprayed tissue for wipe disinfection according to the pull and lift technique.

Lower sampling head

The lower part of the sampling head is fixed, such as with other mobile MAS-100® air samplers. Above are the instrument protection filter, the filter holder and the base for the nutrient plate. For routine application it is recommended to not remove these components before cleaning. Apply wipe disinfection with a clean tissue using either 70% Ethanol or 70% IPA:

Optionally, the base for nutrient plates can be removed for autoclaving. In this case make sure to protect the sampling head base with the dust cover. While removing the nutrient plate holder, take care not to touch nor damage the instrument filter, if in doubt, it is recommended to replace the filter (see chapter 5.3 «Replacing the instrument filter»).

NOTE: When autoclaving the base for nutrient plates (stainless steel), stains may appear. They can easily be removed with a little IPA, without damaging the material.

5.2.3. ACCESSORIES

The available accessories can be cleaned and decontaminated as follows:

ACCESSORY	MATERIAL	METHODS
Dust cover	Polypropylene	– Steam sterilization (autoclaving) at 134°C for 5mins or 121°C for 20 mins **NOTE:** The dust cover will slightly shrink after the first autoclaving cycle, resulting in some clearance. This should be taken into account during transport, but has no effect on the protective capacity of the cover. – Spray or wipe disinfection with 70% Ethanol or 70% IPA
Pressure connection tubing	PTFE, stainless steel, brass, silicone	– Steam sterilization (autoclaving) at ≤134°C for 5mins or 121°C for 20 min – Outside: Spray or wipe disinfection with 70% Ethanol or 70/30% IPA
Tri-clamp and silicone gasket	Anodized aluminum and silicone	– Dry or moist heat sterilization (autoclaving) at ≤180°C for <60 mins – Spray or wipe disinfection with 70% Ethanol or 70% IPA
Gas exhaust tubing set with tri-clamp connector	PVC, stainless steel, galvanized steel, silicone	– Spray or wipe disinfection with 70% Ethanol or 70% IPA
Single adapter for gas exhaust tubing	Stainless steel or aluminum	– Steam sterilization (autoclaving) at ≤134°C for 5mins or 121°C for 20 min

5.3. REPLACING THE INSTRUMENT FILTER

Upon delivery a HEPA H13 (ISO 35H) instrument protection filter is installed in the instrument. When used as described in this manual, the filter in the sampling head takes no maintenance between the yearly service intervals. However, if the sampled gas contains a high amount of debris, replacement of the filter may be necessary more often. The same applies if there is a risk that the filter got damaged, for example due to remaining disinfectants. In such cases the filter is easily accessible and can be replaced by the user:

Open the filter cover with a screwdriver. Remove the underlying filter carefully.
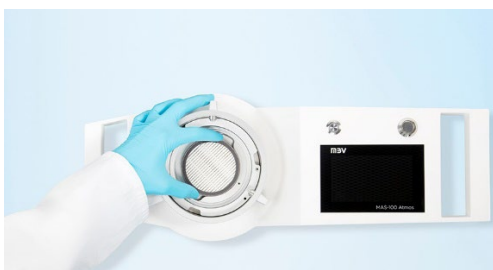
Insert a fresh HEPA H13 filter (see chapter 2.6 «Accessories for MAS-100 Atmos»). Pay attention not to touch the filter membrane because of risk of damaging it. Carefully apply the filter cover and attach it with the three screws.

NOTE: Pay attention not to forget to place the nutrient plate holder before starting to sample!

6. ERRORS AND WARNINGS

The instrument issues warning and error messages to alert the user of conditions that may have an impact on the sampling results. This information can also be helpful for troubleshooting purposes.

6.1. WARNING LIST

All warnings are displayed on the local user interface. All warning events indicated as [W-XXXX] are logged in the audit trail of the instrument (see chapter 4.4 «Audit trail and sampling archive»). Warning screens can be quit by tapping the 'OK' button on the touchscreen. The following table lists the errors and warnings and gives information on how to handle them:

	ID	NAME	POSSIBLE CAUSE	TROUBLESHOOT-ING
General				
Sampling				
	[W-74967]	Decompression aborted because pressure was not successfully released	The gas valve was not closed.	Please close the main gas valve and try again.
User Management				
	[W-10418]	Blocked user tried to login	A user key of a blocked user was used for login on the instrument.	A user on the list of blocked users cannot log in. A user administrator must first unlock the locked user.
Power manage-ment				
	[W-11245]	Insufficient battery charge for operation	n/a	
	[W-74281]	The pressure exceeded the maximum limit	The input pressure is out of specifications! **POTENTIAL SAFETY HAZ-ARD!** Relieve pressure immediately	Send the MAS-100 Atmos to your local service contact to check for internal damage.

6.2. ERROR LIST

All errors are displayed on the local user interface. Once such an event occurs, the instrument is in a special state (red screen). To skip the error screen further investigation is needed. All errors events indicated as [E-XXXX] are logged in the audit trail of the instrument (see chapter 4.4 «Audit trail and sampling archive»). The following table lists all possible errors and information on how to handle them:

	ID	NAME	TROUBLESHOOTING
Sampling			
	[E-74779]	Failed to start sampling since instrument not ready	Restart MAS-100 Atmos and try again. If the error persists please contact your local service contact.

	[E-74716]	Failed to start process because instrument is not idle	Restart MAS-100 Atmos and try again. If the error persists please contact your local service contact.
	[E-74726]	Failed to start decompression because instrument is busy	Restart MAS-100 Atmos and try again. If the error persists please contact your local service contact.
	[E-74632]	Decompression could not be started	Restart MAS-100 Atmos and try again. If the error persists please contact your local service contact.
	[E-74947]	Sampling aborted because target flow not reached	The pressure line could not deliver the target flow, even with maximum valve opening. Please try again with the 50% flow mode (50 L/min). If the error persists please contact your local service contact.
	[E-74104]	Pressure during sampling exceeded	The input pressure is out of specifications! **POTENTIAL SAFETY HAZARD!** Relieve pressure immediately! Send the MAS-100 Atmos to your local service contact to check for internal damage.
	[E-74551]	Pressure sensor failure	The system reads no valid pressure information! **POTENTIAL SAFETY HAZARD!** Close pressure supply: Software version 1.9.1 and higher: Press DEPRESSURIZE. The valve is slowly opened and then closed after approx. 20 secs. Repeat if air flow hasn't stopped during the open phase. Software version 1.7 follow SIL 2023-11-30. Send the MAS-100 Atmos to your local service contact to check for internal damage.
	[E-74699]	Unable to access regulating valve	Restart MAS-100 Atmos and try again. If the error persists please contact your local service contact.
	[E-74730]	Connection to pressure sensor lost	Please contact your local service contact.
User Management			
	[E-10205]	Wrong PIN entered	**ATTENTION:** The instrument will be locked after three incorrect entries! If you forgot your personal PIN please contact the user administrator to reset your PIN.
	[E-10817]	User key of foreign user group tried to login	The user key used is not activated for the user group recorded on this instrument. Please use an appropriate user key and try again.

	[E-10254]	User key data could not be read correctly or might be corrupted	The user key was either not presented correctly or is damaged. Present the user key one more time to the hardware key reader. If this repeatedly does not work the user key might be damaged. The user administrator can program a new hardware key (if spare is available), otherwise order a new set of hardware keys.
	[E-10553]	User key is not valid for this instrument type	The user key used is not registered for this instrument type. Contact a user administrator to change the settings of your user key.
	[E-10418]	Blocked user tried to login	Contact the user administrator to unblock the user or use another user key to login.
Power management			
	[E-11495]	Unable to set 12V DCDC converter GPIO	Restart MAS-100 Atmos and try again. If the error persists please contact your local service contact.
	[E-11671]	Unable to start charging	Try again and check the power supply. If the error persists please contact your local service contact.
	[E-11394]	Unable to access USB PD chip	Instrument internal error. Please contact your local service contact.
	[E-11681]	Unable to stop charging	Try again and check the power supply. If the error persists please contact your local service contact.
	[W-11385]	Battery temperature too high	The battery must be replaced. Please contact your local service contact

6.3. OTHER TROUBLESHOOTING

This list gives an overview of other problems that may occur and their possible solutions:

	PROBLEM	TROUBLESHOOTING
Sampling		
	Instrument crashes and local user interface (display) cannot be operated anymore	Slowly open either a vent valve at the main gas supply or the tri-clamp to cautiously relieve the pressure from the instrument.
	Instrument crashes and local user interface (display) cannot be operated anymore	Restart the instrument. If this does not work then connect the instrument to the power supply, wait shortly and restart the instrument again. If unsuccessful, carefully vent the tubing to relieve the pressure from the instrument.
User Management		

Default 'system administrator hardware key' (black, delivered with instrument)		
	The PIN of the default 'system administrator hardware key' was forgotten or instrument is blocked because PIN was entered wrong for 3 times	– Go to the MBV website to download a backup 'file key' for the system administrator: https://www.mbv.ch/en/expert-center/downloads/mas-100-atmos/ – Use this file key to log in to the browser-based user interface (see chapter 2.10.2) and to unlock the instrument
	The default 'system administrator hardware key' was lost	– Go to the MBV website to download a backup 'file key' for the system administrator: https://www.mbv.ch/en/expert-center/downloads/mas-100-atmos/ – Use this file key to log in via the browser-based user interface – Store this file key at a save place on your server – Optionally: Copy this file key to an empty hardware key (see chapter 2.6 and 2.10.2) **NOTE:** The lost hardware key is still protected with a personal PIN so the security risk is considered low.
User keys of a newly defined user group		
	Operator or system administrator forgot personal PIN	The user administrator can overwrite the affected user key by following the process of creating a new user (see chapter 4.2.2).
	User administrator forgot the PIN	The second user administrator can overwrite the affected user admin key by following the process of creating a new user (see chapter 4.2.2).

	Both user administrators forgot personal PINs	If available: Log in with a user administrator file key and write new hardware or file keys for the affected user administrators.
	Instrument is blocked because PIN was entered wrong for 3 times	For unlocking of the instrument the corresponding person (see table below) has to login either with a hardware key or a key file: After unlocking, the user key that locked the instrument will still have the old PIN. If a user forgot the PIN in the meantime, the user administrator must rewrite the hardware key.

INSTRUMENT LOCKED BY	INSTRUMENT CAN BE UNLOCKED BY
Operator	System administrator*
System administrator	Second system administrator* User administrator* (available from FW version 1.9.1) If no second system admin hardware or file key is available please contact your local service organization to unblock the instrument.
User administrator	System administrator*

*either using a hardware key or a key file

NOTE: The old PIN for the user role will still be valid.

	Operator or system or user administrator lost personal hardware key	(Second) user administrator can write a new hardware or file key for the affected user. **NOTE:** The lost hardware key is still protected with a personal PIN so the security risk is considered low.
	All hardware keys are lost	If available: Log in with a user administrator file key and write new hardware or file keys for the affected users. Otherwise, please contact your local service organization to reset the user management.
Company re-structuring		
	User leaves company (without handing in the hardware key)	It is advisable to block the user (see chapter 4.2.3). **NOTE:** Blocking a user must be repeated on every individual instrument.
	Instrument is sold or given to other plant	The system administrator shall reset the user management (see chapter 4.8.5). If needed, reinitialize the user management according to chapter 4.2.1.

7. CALIBRATION AND ADJUSTMENT

7.1. GENERAL

Adjustment = Adjust an instrument to a reference instrument

Calibration = Compare an instrument to a reference instrument

> The instrument is adjusted and calibrated prior to shipping from the factory.

7.2. FACTORY CALIBRATION CERTIFICATES

The instrument is calibrated by means of a dedicated reference instrument that is calibrated in the MBV calibration laboratory for airflow. The MBV calibration laboratory has been accredited by the Swiss Accreditation Service SAS according to ISO 17025:2017.

MBV AG
Industriestrasse 9
CH-8712 Stäfa
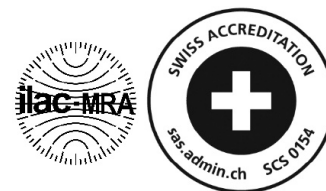
| Certificate Number | 16115-20190709161559 | Order Number | 11364 |

7.3. CALIBRATION PERIODICITY

Calibration is a key aspect of the process. Always ensure that the instrument calibration is still valid.

> **Hazard of wrong sampling results**
>
> Do not use an uncalibrated instrument. It is recommended to adjust and calibrate the instrument in a periodicity of 12 months.
>
> **NOTE:** Improper handling of the instrument such as mechanical damage or impact or inappropriate cleaning procedures may alter the accuracy of any calibrated instrument regardless of the time since the last calibration.

7.4. CALIBRATION SERVICE

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

– Send the instrument to the manufacturer:

  Contact address

  MBV AG
  Service
  Industriestrasse 9
  CH-8712 Stäfa
  Switzerland

– Contact your local life science business of Merck KGaA, Darmstadt, Germany service contact for local service (workshop or on-site whereas available), or visit the

website to request more information: https://www.sigmaaldrich.com/CH/en/services/product-services/maintenance-and-service-plans/microbiology-maintenance-and-service-plans

NOTE: The membrane packaging received at the time of purchase might be reused if handled with care. However, it is recommended to use the robust wheeled case, available as accessory (MBV article number: 08.8105.01, Merck KGaA, Darmstadt, Germany article number: 1173340001), for repeated shipping.

8. REGULATORY INFORMATION

8.1. ATEX

Hazard of explosion and/or fire
Do not use the instrument in explosion hazard areas.

8.2. SUBSTANCES SUBJECT TO CHINESE ROHS

Hazardous substances
This product contains certain hazardous substances and can be used safely during its environmental protection use period in years (typically 50 years and indicated by the number in the center of the logo on the type label) which should enter into the recycling system after its environmental protection use period.

The instrument is compliant with the Chinese RoHS regulation SJ/T11363 2006.

The table below lists the instruments' hazardous substances.

部件名称 Component name	有害物质或元素 Hazardous substances or elements					
	铅 Pb	汞 Hg	镉 Cd	六价铬 Cr(VI)	多溴联苯 PBB	多溴联苯醚 PBDE
Main PCB	x	o	o	o	o	o
Sensor PCB	x	o	o	o	o	o
Display	x	o	o	o	o	o

O: **表示**该有毒有害物质在该部件所有均质材料中的含量均在 SJ/T11363-2006 规定的限量要求以下

X: **表示**该有毒有害物质至少在该部件所用均质材料之一中含量超出 SJ/T11363-2006 规定的限量要求（公司可对标记"X"**的技**术原因进行说明）

O: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006

X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006 (Company can explain technical reason to mark «X»).

8.3. AIR TRANSPORTATION (IATA)

No special provisions necessary.

9. 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):

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

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. 7.5 hrs **NOTE:** The main battery should be fully charged every 6 months to protect it from deep discharge. This further ensures that the internal real-time backup battery is not discharged prematurely
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 by-stander	<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

ANNEX A – BROWSER APP INSTALLATION

MICROSOFT EDGE CHROMIUM

STEP	IMAGE	DESCRIPTION
1		Go to the browser tab http://192.168.254.1/dashboard with the name MAS-100 Atmos.
2		Click on the three dots (...) > Apps > 'Install this site as an app'.
3		Define the application name (for example "MAS-100 Atmos") and tap 'install'.
4		Select whether you want to pin the application to the taskbar, to the start menu, to create a desktop shortcut or to auto-start the app on device login. Confirm with the 'Allow' button.

MOZILLA FIREFOX

This feature is currently not available.

GOOGLE CHROME
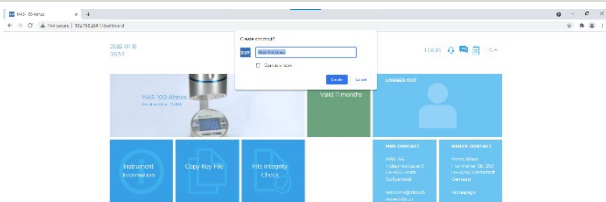
STEP	IMAGE	DESCRIPTION
1		Go to the browser tab http://192.168.254.1/dashboard with the name MAS-100 Atmos.
2		Click on the three dots (…) > Apps > 'install this site as an app'
3		Define the application name (for example "MAS-100 Atmos") and tap 'create'
4		Open chrome//:apps in a new tab. There you will now find the installed app, in this example 'MAS-100 Atmos'. Right click on the icon and select 'create shortcuts'. Optionally, tap 'open as window' to open the app in a separate window when using the shortcuts.
5		Select the shortcuts according to your preferred solution and tap 'create'.
6		You can now start MAS-100 Atmos as an app from the created shortcuts on your desktop or the start menu.
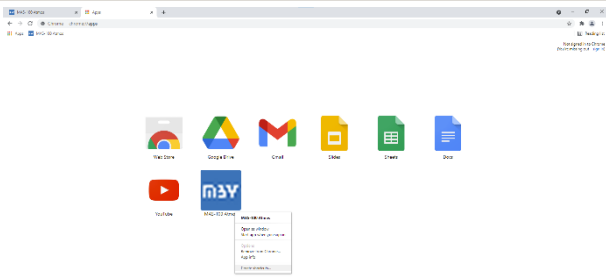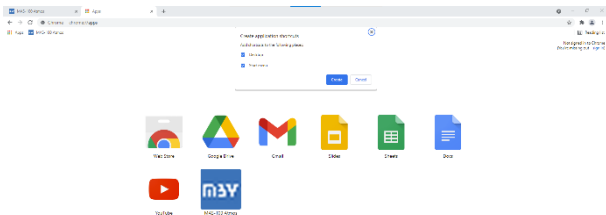
ANNEX B – FELLER CONVERSION TABLE

Positive hole conversion table according to Feller for perforated lids with **300** holes:

r = Number of colony forming units counted on nutrient plate						Pr = Probable statistical total					
r	**Pr**	**r**	**Pr**	**r**	**Pr**	**r**	**Pr**	**r**	**Pr**	**r**	**Pr**
1	1	51	56	101	123	151	209	201	332	251	541
2	2	52	57	102	124	152	211	202	335	252	547
3	3	53	58	103	126	153	213	203	338	253	553
4	4	54	59	104	127	154	216	204	341	254	560
5	5	55	61	105	129	155	218	205	344	255	566
6	6	56	62	106	131	156	220	206	347	256	573
7	7	57	63	107	132	157	222	207	350	257	580
8	8	58	64	108	134	158	224	208	353	258	587
9	9	59	66	109	135	159	226	209	357	259	594
10	10	60	67	110	137	160	228	210	360	260	601
11	11	61	68	111	138	161	230	211	363	261	609
12	12	62	69	112	140	162	232	212	367	262	616
13	13	63	71	113	142	163	235	213	370	263	624
14	14	64	72	114	143	164	237	214	374	264	632
15	15	65	73	115	145	165	239	215	377	265	641
16	16	66	74	116	146	166	241	216	381	266	649
17	17	67	76	117	148	167	243	217	384	267	658
18	19	68	77	118	150	168	246	218	388	268	667
19	20	69	78	119	151	169	248	219	391	269	677
20	21	70	80	120	153	170	250	220	395	270	686
21	22	71	81	121	155	171	253	221	399	271	696
22	23	72	82	122	156	172	255	222	403	272	707
23	24	73	83	123	158	173	257	223	407	273	717
24	25	74	85	124	160	174	260	224	410	274	728
25	26	75	86	125	161	175	262	225	414	275	740
26	27	76	87	126	163	176	264	226	418	276	752
27	28	77	89	127	165	177	267	227	422	277	765
28	29	78	90	128	167	178	269	228	427	278	778
29	30	79	92	129	168	179	272	229	431	279	791
30	32	80	93	130	170	180	274	230	435	280	805
31	33	81	94	131	172	181	277	231	439	281	820
32	34	82	96	132	174	182	279	232	444	282	836
33	35	83	97	133	175	183	282	233	448	283	853
34	36	84	98	134	177	184	284	234	452	284	871
35	37	85	100	135	179	185	287	235	457	285	889
36	38	86	101	136	181	186	289	236	462	286	909
37	39	87	103	137	183	187	292	237	466	287	931
38	41	88	104	138	184	188	295	238	471	288	954
39	42	89	105	139	186	189	297	239	476	289	979
40	43	90	107	140	188	190	300	240	481	290	1006
41	44	91	108	141	190	191	303	241	486	291	1036
42	45	92	110	142	192	192	306	242	491	292	1069
43	46	93	111	143	194	193	308	243	496	293	1107
44	47	94	113	144	196	194	311	244	501	294	1150
45	49	95	114	145	198	195	314	245	507	295	1200
46	50	96	115	146	200	196	317	246	512	296	1260
47	51	97	117	147	202	197	320	247	518	297	1335
48	52	98	118	148	203	198	323	248	523	298	1435
49	53	99	120	149	205	199	326	249	529	299	1585
50	55	100	121	150	207	200	329	250	535	300	1885

The values in the table are calculated from the basic formula (Feller, 1950):

$$Pr = N\left[\frac{1}{N} + \frac{1}{N-1} + \frac{1}{N-2} + \cdots + \frac{1}{N-r+1}\right]$$

ANNEX C – PHYSICAL SAMPLING EFFICIENCY

B.1 THE D50 VALUE

The physical sampling efficiency of an air sampler is influenced by inlet or extraction efficiency and by separation efficiency.

Inlet or extraction efficiency is a function of the inlet design of the sampler and its ability to collect particles from the air in a representative way and transport the particles to the impaction nozzle or the filter.

The physical sampling efficiency is the same whether the particles consist of single microorganisms, carry microorganisms, or are nonviable (inanimate). The physical sampling efficiency is based on the physical characteristics of the sampling instrument, such as airflow, orifice shape, and orifice size.

Detailed information how to calculate the d_{50} value may be found in specific publications [2,3].

An approximation for calculating the d_{50} value in µm is given by the following formula:

$$d_{50} = \sqrt{\frac{40 * D_h}{U}}$$

Where:

40 = Constant factor for air viscosity.

D_h = Hydraulic diameter of the air inlet nozzle [mm].

U = Impact velocity [m/s].

The lower the d_{50} value, the better the physical sampling efficiency for small particles.

In the MAS-100 product family the d_{50} value is governed by the perforated lid configuration and flow rate:

300 x 0.6 mm perforated lid ➔ d_{50} = 1.1 µm (at 100 L/min)

300 x 0.6 mm perforated lid ➔ d_{50} = 1.6 µm (at 50 L/min)

300 x 0.47 mm perforated lid ➔ d_{50} = 1.1 µm (at 50 L/min)

300 x 0.47 mm perforated lid ➔ d_{50} = 0.8 µm (at 100 L/min)

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[2] Willeke K, Baron PA, eds. Aerosol Measurement: Principles, Techniques and Applications. New York: Van Nostrand Reinhold, 1993

[3] Nevalainen A, Willeke K, Liebhaber F, Pastuszka J, Burge H, Henningson E. Bioaerosol sampling. In: Willeke K, Baron PA, eds. Aerosol Measurement: Principles, Techniques and Applications. New York: Van Nostrand Reinhold, 1993: 471-492.

ANNEX D – GLOSSARY

TERM	MEANING
ATEX	European directive for equipment in explosive environments
BAR.A	Bar absolute
CFR	Code of Federal Regulations (USA)
CFU	Colony Forming Units
DC	Direct Current
EAC	Eurasian conformity mark
EMC	ElectroMagnetic Compatibility
EM (Software)	Environmental Monitoring (Software)
FDA	Food and Drug Administration (USA)
FDS	Functional and Design Specifications
GAMP	Good Automated Manufacturing Practice,
GMP	Good Manufacturing Practice
IATA	International Air Transport Association
ID	IDentification number
IEC	International Electrotechnical Commission
IP	International Protection marking
ISO	International Organization for Standardization (standards)
LED	Light-Emitting Diode
LIMS	Laboratory Information Management System
MS	Module Specifications
NL	Normal Liters
NL/min	Normal Liters per minute
PIN	Personal Identification Number
QR (code)	Quick Response code (2D barcode)
RoHS	Restriction of Hazardous Substances (directive)
SIL	Service Information Letter (MBV AG)
SJ	Chinese standard for electronic equipment
S/N	Serial Number

URS	User Requirements Specification
USA	United States of America
USB	Universal Serial Bus
WEEE	Waste Electrical and Electronic Equipment (European directive)