USER MANUAL

AIR. NOTHING ELSE.

MAS-100 Sirius® Microbial Air Sampler

English

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 instruments for active and passive microbial air and gas monitoring 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 our homepage www.mbv.ch.

MANUFACTURER

MBV AG
Industriestrasse 9
CH8712 Stäfa
Switzerland

Note

Up-to-date product information – such as Service Information Letters (SIL) – are available in the expert center section of the MBV AG homepage: www.mbv.ch

Moreover, important product after-sales information about changes, issues, instructions as well as news are provided in the corresponding expert center of MAS-100 Sirius.

DOCUMENT HISTORY

VERSION	RELEASED	CHANGE HISTORY
1.0	2025-07-15	Initial release

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.	
Millipore® is a registered trademark of Merck KGaA, Darmstadt, Germany.	
Windows®, Excel® and Internet Explorer® are registered trademarks of the Microsoft Corporation in the U.S. and other countries.	
PDF® is a registered trademark of Adobe Systems Inc. in the U.S. and other countries.	
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MBV AG	
MAS-100®	Switzerland
MAS-100 NT®	Switzerland and other countries
MAS-100 NT Ex®	Switzerland and other countries
MAS-100 Sirius®	Switzerland and other countries
MAS-100 Regulus®	Switzerland and other countries

TABLE OF CONTENTS

1. GENERAL INFORMATION

1.1. SCOPE OF THIS DOCUMENT

This document provides a comprehensive guide to use the hardware and software of the following instruments for active microbial air sampling:

INSTRUMENT	SOFTWARE VERSION
MAS-100 Sirius®	2.0.3

In the context of this document “Instrument” refers to “MAS-100 Sirius” air sampler.

1.2. RELATED DOCUMENTS

The following related documents provide additional information and are available via the dedicated Sirius download page www.mbv.ch/sirius/files:

DOCUMENT	SCOPE
Global Safety Datasheet for MAS-100 Sirius	Important safety information related to the use of the instrument.
Tripod for MAS-100® Microbiological Air Sampler Hardware Manual	Information for use of the Tripod
User Manual MAS-100 Regulus®	Information for calibration of the instrument
IQ/OQ template MAS-100 Sirius® (MBV article number 201938)	Installation qualification and operational qualification of the instrument
Declaration of Conformity (DoC) for MAS-100 Sirius®	Information on compliance to regulatory requirements.

1.3. SAFETY

1.3.1. SYMBOLS

	**Warning**
	**Prohibition**
	**Mandatory Action**

1.3.2. SEVERITY LEVELS

	Danger A red box indicates hazardous situations that, if not avoided, will result in death or serious injury.
	Warning An orange box indicates a hazardous situation that, if not avoided, could result in death or serious injury.
	Caution A yellow box indicates a hazardous situation that, if not avoided could result in minor or moderate injury.
	Safety Instructions A green box indicates specific safety related instructions or procedures that are related to safe work practices.
	Note A blue box indicates information considered important but not hazard-related. This may be situations resulting in irreparable damage to the instrument or unreliable sampling results.

1.3.3. SAFETY INFORMATION

	**Refer to user manuals** Read the safety data sheet and user manual of this instrument carefully before using the instrument and/or any accessory supplied with this instrument. Ensure that all users have read and understood the content of the safety data sheet and this manual and (where applicable) of related manuals. Keep this manual in a designated place, accessible for all users for future reference.
	**Instrument operation only by authorized and trained personnel** The Microbial Air Sampler MAS-100 Sirius 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 1.4.
	**Hazard of explosion and/or fire** The MAS-100 Sirius may not be used in explosion hazard areas.
	**Hazard of explosion and/or fire** Use the instrument only with the original battery delivered with the instrument or available as an accessory.
	**Hazard of explosion and/or fire** The instrument contains a Lithium-Ion battery which is regulated for air transportation. Please respect IATA labeling rules in case your instrument should travel by air.

	**Hazard of falling instrument (parts)** When using the instrument over-head (e.g. when placed on the optional tripod), wear a protective helmet and follow the safety instructions included in the user manual of the tripod for MAS-100 microbiological air samplers.
	**Hazard of microbiological or toxic contamination** When using the instrument in connection with potentially harmful substances, follow all relevant regulations to prevent personal injury. Before sending an instrument to service or anywhere outside of your jurisdiction, ensure necessary decontamination.
	**Hazard of wrongful service** With the exception of the battery pack (see chapter 7.2.2) and the filter (see chapter 7.2.1) there are no user-serviceable parts inside the instrument. Only trained, qualified and authorized technicians are allowed to perform repair and maintenance activities.
	**Caution of hand injuries** Hold the magnetic lid on its handle and be careful not to pinch your fingers.
	**Avoid instrument handling with moist or wet hands** Avoid manipulating the instrument with moist or wet hands/gloves to avoid slipping and dropping the instrument, the risk to drip liquid onto the agar plate, the risk to wet the exhaust filter (and affect its integrity).
	**Avoid skin irritation** Follow cleaning instructions, use appropriate cleaning agents and follow necessary safety precautions to prevent skin irritation.
	**Risk of instrument damage due to overheating** Do not operate the blower of the instrument while airflow through the perforated lid and the instrument is obstructed (e.g. do not start a sampling while the dust cover is placed on the perforated lid). The only exemption is the use of the dust cover in connection with the leak test feature of the instrument.
	**Follow storage and operating conditions** Do not store instrument outside of specified storage conditions (see chapter 4.1) nor operate the instrument outside the specified operating conditions (see chapter 9.2).
	**Wipe-disinfect instrument surfaces** Prevent cross-contamination by wipe-disinfecting all instrument surfaces regularly.
	**Protect instrument from entering liquids** The instrument is not IP 65 ingress protected. Do not spill nor spray liquids onto the instrument, in particular into the electric connections or into the air duct (see chapter 7.1.4). Any disinfection/sanitization solution must be completely dried before using the instrument for a sampling.

	**Do not touch the instrument filter** Risk to affect the filter integrity and damage the filter.
	**Keep instrument calibration valid** Do not use an instrument with an invalid or outdated calibration. It is recommended to calibrate the instrument in a periodicity of 12 months.
	**Risk of lost warranty claim** Every instrument is protected with an anti-tamper (warranty) seal placed on the battery compartment. Breaking the warranty seal will render the warranty void. Any application other than the intended use is not covered by warranty.

1.4. INTENDED USE

1.4.1. AREA OF APPLICATION

The instrument is active microbial air sampler intended for industrial and laboratory use. It can be used in non-controlled and controlled environments. The latter includes cleanrooms qualified according to ISO 14644 classes 5 to 8 and according to GMP grades A to D, respectively.

1.4.2. INTENDED USERS

The instrument is a precision instrument and must be handled with care. Its use should be restricted to any trained, qualified and authorized personnel.

The instrument is intended for professional use, therefore this user manual is available in English only.

1.4.3. OPERATING CONDITIONS

The instrument must be operated in defined environmental conditions (see chapter 9.2).

1.4.4. «DUAL-USE» STATEMENT

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

1.5. WARRANTY

1.5.1. GENERAL

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

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 at sigmaaldrich.com.

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

1.5.2. QUALITY STATEMENT

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

The manufacturer guarantees the instruments 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.

1.5.3. EXCLUSION CLAUSES

The warranty covers exclusively material and manufacturing defects that become apparent during the warranty period as described above.

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.

Following conditions need to be met for the warranty to remain intact:

- The warranty seal be intact.
- 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 its intended use.
- The instrument shall only be operated and updated with original application software from MBV AG.
- The instrument shall not be modified in any way.

1.5.4. CONTACT

If a warranty case occurs, customers may contact the life science business of Merck KGaA, Darmstadt, Germany or the instrument manufacturer directly: www.sigmaaldrich.com/support/customer-support

For instruments sold in Switzerland, contact MBV AG (manufacturer): www.mbv.ch/en/services/support/

1.6. PRODUCT MARKING

1.6.1. PRODUCT TYPE PLATE

SYMBOL	DESCRIPTION
	Specification of the battery
	Year of manufacture
	Instrument manufacturer
	Telephone number of the manufacturer
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 instrument specific download page www.mbv.ch/sirius/files.
EAC	Conformity to Eurasian market regulations.
FC	Conformity to Federal Communication Commission regulation.
	Conformity to South Korean standards.
MBV-MAS-100-Sirius	South Korean SDoC (Supplier's Declaration of Conformity) confirmation number.

SYMBOL	DESCRIPTION
CAN ICES-1(B) / NMB-1(B)	Conformity to Canadian Interference-Causing Equipment Standard (in French Norme Matériels Brouilleurs) Class 1 referring to industrial, scientific, and medical (ISM) equipment or commercial-grade equipment, Class B limits compliant to residential or domestic environments.
	Read the instructions before using the instrument.
	Conformity with the WEEE directive as described in the «Declaration of Conformity» of the instrument. 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.
	Product does contain toxic or hazardous substances or elements above the maximum concentration value established by the Chinese standard SJ/T113632006 as stated on the Declaration of Conformity and can be recycled after being discarded and should not be casually discarded.

1.6.2. HOUSING MARKING

(sample picture)

The 6 digits instrument serial number is laser marked on the front side of the lower part of the housing. Additionally, that serial number is encoded in a machine-readable 2D data matrix with a white background (to improve readability on the highly reflective stainless steel surface, see chapter 3.4).

1.7. REGULATORY AND COMPLIANCE INFORMATION

Refer to the Declaration of Conformity (DoC) for MAS-100 Sirius®.

1.7.1. 21 CFR PART 11

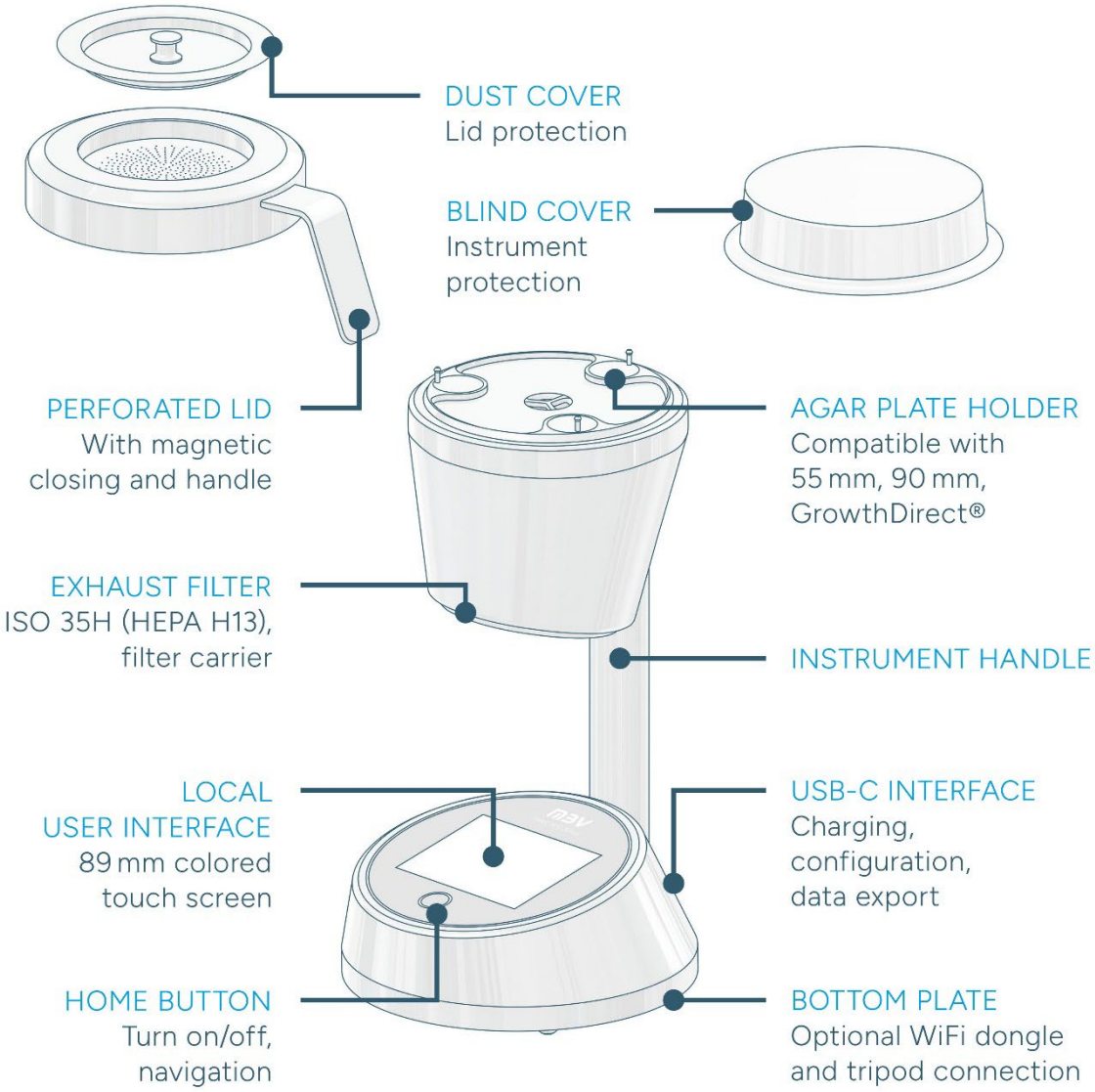
The instrument has been successfully validated to comply with 21 CFR part 11. Details about each paragraph of the guideline can be found in the validation summary for MAS-100 Sirius please visit www.mbv.ch/sirius/files.

2. INSTRUMENT DESCRIPTION

The instrument is a portable air sampler designed for active microbial monitoring of airborne viable microorganisms, including bacteria, yeast, and mold. It collects microorganisms onto an agar plate using impaction, allowing subsequent incubation and counting of colony-forming units (CFU). The instrument provides a reliable method for detecting and quantifying airborne microbial contamination in various environments.

2.1. PARTS DESIGNATION

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



2.2. MAIN FEATURES AND BENEFITS

FEATURE	BENEFITS
Seamless stainless-steel design	– Easy to clean, no dirt traps – Compatibility with a wide range of disinfectants including sporicidals (see chapter 7.1.1)
Perforated lid with magnetic closing mechanism and handle	– Supports aseptic handling in line with EU GMP Annex 1 independent of hand size – Intuitive handling requiring less force improves usability – Increased efficiency as no more turning and no fixed positioning (see chapter 4.5.5)
Leakage test (see chapter 4.5.5)	– Helps to detect leakage and replace damaged lids/surfaces early – Easily and anytime accessible via the local interface
Open system design compatible with a wide range of different agar plates from 55 up to 90mm	Tool-free adjustment to corresponding agar plate size (see chapter 3.2)
Automated check for presence of exhaust filter and correct lid type (see chapter 4.5.4)	– Operator is warned early – Error is documented in audit trail
Multiple flow rates available, 100 or 200 SLPM	-Configurable on the same instrument (see chapter 5.5.14)
Highly configurable instrument e.g. as customized one-button-sampler (see chapters 5.5.14, 5.5.15, 5.5.16 and 5.5.17)	– Tailored configuration that fits into an existing workflow – Simplified training – Minimized operation errors
Two redundant mass flow sensors	– Best in class reliability – Early detection of sensor drifts
Supports data integrity and ALCOA+ requirements with a tamper proof/tamper evident Audit trail (see chapter 5.7) (among many other features)	Compliance with data integrity and ALCOA+
Supports a FDA 21 CFR Part 11 compliant workflows with a user management (see chapter 5.9.6 and 5.10) (among many other features)	Compliance with FDA 21 CFR Part 11
Traceable flow and timer calibration according to ISO 17025 or NIST (see chapter 6)	– Calibrated sampling volume – Traceability

2.3. APPLICATION

The instrument is an active microbial air sampler that can be used during microbiological quality control as part of a risk-based quality assurance. Typical applications are in highly regulated environments such as pharmaceutical manufacturing, hospitals and medicinal products. Moreover, the instrument can be used in less highly regulated environments such as food and beverage as well as cosmetics production and as part of indoor air quality monitoring.

2.3.1. INSTRUMENT USE CASES

Whether used in a less or higher regulated environment, thanks to its high degree of configurability the instrument may be configured to fit a specific workflow (even if not explicitly shown in the below table):

	PAPER BASED	INSTRUMENT BASED	LIMS/EM BASED	LIMS/EM AUTOMATED
Master for data traceability and integrity	Paper	Instrument	LIMS/EM software	LIMS/EM software
User Identification (optional)	No Operator login. Manual signature User management on instrument for System Administrator only (protect instrument settings)	Operator login on instrument using a local user list or Active Directory System Administrator login on instrument using a local user list	Operator login at LIMS/EM software (Redundant Operator login on Instrument via local user list or Active Directory possible) Login on instrument for System Administrator only	
Scanning of sampling environment barcodes (agar plate and/or, perforated lid and/or sampling location) (optional)	Manually noted on paper	barcode reader connected to instrument. Data logged as part of sampling results and in Audit Trail within the instrument.	barcode reader connected to LIMS/EM SW (separate barcode reader or tablet that offers corresponding functionality)	
Recording sampling result	Visual check on instrument display and manually noted on paper.	Visual check on instrument display, logged in instrument Audit Trail. Manual download of Excel file containing sampling data via browser-based user interface	Scanning Result QR code from instrument display with barcode reader connected to LIMS/EM software	LIMS/EM software reading results from instrument automatically via Rest API commands via wireless access (WIFI accessory required)

2.3.2. USE CASE OUTSIDE 21 CFR PART 11

In an environment no or few regulatory boundaries, a small group of users might perform Operator as well as System Administrator functions. The instrument might be used with the out-of-the-box configuration (without user management).

2.3.3. USE CASE COMPLIANT WITH DATA INTEGRITY AND 21 CFR PART 11

A configuration for operation in a highly regulated pharma environment compliant with data integrity, ALOCA+ and 21 CFR part 11 (US Code of Federal Regulation relating to Electronic Records and Electronic Signatures under FDA) may include the following:

Configuration to support data integrity and ALCOA+ compliance:

- Configuration as “one-button sampler” (limit options available on the local user interface to only those that the Operator needs for a specific workflow), thereby significantly reducing the risk of mis manipulation (see chapters 5.5.14, 5.5.15, 5.5.16 and 5.5.17).
- Scanning of sampling environment (location, agar, perforated lid) with barcode reader connected to instrument (see chapter 3.4 and chapter 4.5.4) OR via barcode reader of existing LIMS/EM system (no configuration needed).
- Recording sampling notes (see chapter 4.5.4) for documentation of sampling errors.
- Error-proof data transfer using sampling result QR code (see chapter 4.5.4) or remote control through API interface (see chapter 5.12).

Configuration to support an FDA 21 CFR Part 11 compliant workflow:

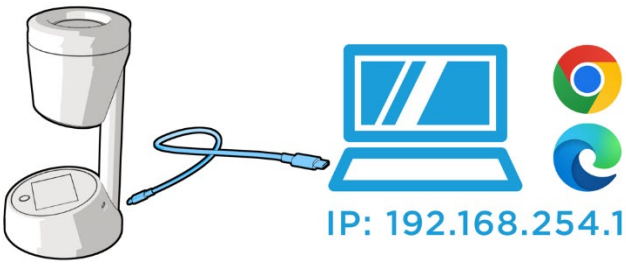
- User login on instrument either setup local user management (see chapter 5.9.6 and 5.10) or connection to existing active directory (see chapter 5.5.9) OR user login via existing LIMS/EM system (no user management configured, factory default).
- Approval of setting changes (see chapter 5.6).
- Automatic time/date synchronization (see chapter 5.5.6).

2.4. FUNCTIONAL DESCRIPTION

The instrument draws in a defined amount of air through its inlet where airborne microorganisms are impacted onto an agar plate. The volume flow and impaction speed are well controlled using a mass flow sensor to prevent damage to the microorganisms and not affecting their viability.

Once collected on the agar plate, the plate is removed and transferred to an incubator. There, the microorganisms multiply, forming visible colonies. The colonies can then be counted and analyzed, with results reported as colony-forming units per cubic meter (CFU/m³) of the sampled air. This process allows for accurate and reliable assessment of microbial contamination in the air.

A concept with two user interfaces dedicated to different user roles, allows to keep the instrument screen free of clutter and thereby reducing the risk of mis-manipulation by the Operator:



Local User Interface

- consists of the touch display and the Home button on the lower part of the instrument body
- dedicated to Operator
- limited to the functionality the Operator needs in operation

refer to chapter 4.5

Brower-based User Interface

- accesses the instrument via a standard browser from a PC (no internet / no SW)
- dedicated to System Administrator, User Administrator and Service Engineer
- limited to administrator functionality

refer to chapter 5

2.5. SCOPE OF DELIVERY

Unboxing:

Remove the transport case from the outer cardboard packaging. Place the transport case in front of you with the logo print facing upwards. Open the transport case by lifting the blue clamps from below. Carefully lift the instrument out of its transport case and place it on a clean, stable, horizontal surface.

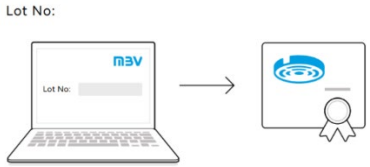
NOTE: Do not throw away the transport case and always place the instrument in its transport case if transported outside of its area of use (e.g. when transferring the instrument between buildings or shipping it to the service center).

Remove the tape or elements that secure the instrument during transport.

Article inspection:

Verify whether all items are present in the packaging, according to the scope of delivery for the article number you have ordered. Contact your local representative immediately if items are missing or show signs of defect.

Exhaust filter traceability:



The Quick Start Guide contains a sticker with the exhaust filter lot number. At https://certificate.mbv.ch/ the filter lot number can be entered and the corresponding filter certificate downloaded.

NOTE: Do keep the Quick Start Guide with the instrument or log the filter lot number matching the instrument elsewhere. The filter lot number may change when the filter is exchanged (see chapter 7.2.1).

DESCRIPTION	ARTICLE NUMBER		PICTURE REMARKS
	MBV AG	MERCK KGAA	
MAS-100 Sirius® 1x MAS-100 Sirius® Air Sampler 1x perforated lid type A for 90mm settle plates and sampling at 100 SLPM with a d_{50} of 1.1um 1x Dust cover 1x Exhaust filter (mounted) 1x Reduction screw 1/4" / 3/8" (mounted) 1x USB-C cover (mounted) 1x USB-C cable 1.5m 1x Transport case Documents: – Global Safety Datasheet – Clamp adjustment gauge – Quick Start Guide, incl. lot number of exhaust filter – Timer calibration certificate – Flow calibration certificate (as-left) 100 SLPM lid type A, 100 SLPM lid type B, 200 SLPM lid type B – Calibration certificate (as-left) of reference anemometer	200515	1178800001	 **NOTE:** A power supply is not included in the scope of delivery. The transport case offers a pocket to store the power supply ordered as an accessory (see chapter 2.7).

DESCRIPTION	ARTICLE NUMBER		PICTURE REMARKS
	MBV AG	MERCK KGAA	
MAS-100 Sirius® Flex 1x MAS-100 Sirius® Air Sampler 1x Blind lid 1x Exhaust filter (mounted) 1x Reduction screw 1/4" / 3/8" (mounted) 1x USB-C cover (mounted) 1x USB-C cable 1.5m 1x Transport case Documents: – Global Safety Datasheet – Clamp adjustment gauge – Quick Start Guide, incl. lot number of exhaust filter – Timer calibration certificate – Flow calibration certificate (as-left) 100 SLPM lid type A, 100 SLPM lid type B, 200 SLPM lid type B – Calibration certificate (as-left) of reference anemometer	201371	1178810001	 **NOTE:** Does not include a perforated lid. Combine this item with any of the lid types available as accessories (see chapter 2.6). **NOTE:** A power supply is not included in the scope of delivery. The transport case offers a pocket to store the power supply ordered as an accessory (see chapter 2.7).

2.6. PERFORATED LIDS

A marking is clearly identifying every individual perforated lid:

(example picture)

- 1st character: identifying the type of sieve (which relates to flow rate and D_{50} value), used as a reference for calibration and sampling settings.
- 2nd and 3rd character: identifying the type and material of the perforated lid.
- 6-digit number: Unique serial number of the lid

The 3 characters and 6 digits (as listed above) are encoded in a machine-readable 2D data matrix with a white background (to improve readability on the highly reflective stainless-steel surface). To set up a barcode reader see chapter 3.4.

For more details on the lid marking please refer to the MBV SERVICE INFORMATION LETTER 2023_04 available on www.mbv.ch/de/expertencenter/downloads/

Following table lists all perforated lids compatible with the instrument:

MATE-RIAL	LOCKING MECHA-NISM	FLOW RATE AND D50	SIEVE	LID MARKING		NUTRIENT PLATE TYPE	ARTICLE NUMBER	
				1st char-acter	2nd/3rd char-acter		MBV	MERCK KGAA
Stainless steel	magnetic	100 SLPM with D50 = 1.1um	300 holes of Ø 0.6mm	A	NS	90 mm	201139	1178830001
					NR	55 mm, Growth Direct® cassettes	201152	1178850001
		200 SLPM with D50 = 1.1um 100 SLPM with D50 = 1.6um (legacy)	400 holes of Ø 0.7mm	B	NS	90 mm	201263	1178840001
					NR	55 mm, Growth Direct® cassettes	201267	1178860001

2.7. ACCESSORIES

DESCRIPTION	ARTICLE NUMBER		PICTURE REMARKS
	MBV AG	MERCK KGAA	
Tripod 366cm	06.6054.03	1176560001	
Quick-release plate set Tripod adapter plate	201646	1176570001	
Quick release plate cpl. (complete) Tripod adapter and adapter plate (Quick change)	201706	1174520001	
Reduction screw 1/4" / 3/8" To connect the instrument directly to the tripod, without using the tripod adapter	101.355	1193800001	
Blind lid cpl. Protective cover for instrument whenever perforated lid is not applied e.g. during lid autoclaving	201376	1178880001	
Dust cover cpl. Protective cover applied to perforated lid whenever no sampling or flush is running	201377	1178870001	

DESCRIPTION	ARTICLE NUMBER		PICTURE REMARKS
	MBV AG	MERCK KGAA	
Filter packed cpl. HEPA H13 (ISO 35H) exhaust filter Ø74 mm Filter membrane from polypropylene.	201500	1176550001	
Power supply unit USB-C set complete Power supply unit with region-specific adapters for US/JPN, EU, GB, AUS	201318	1173600001	
USB-C cable 1.5m	201348	1178890001	
USB-C cover (1 pack with 5 pcs)	201532	1174530005	
WiFi dongle	200266	1176530001	
Battery MBV type H2B661.4 rechargeable Li-Ion battery pack 7.4Vdc, 9.6Ah	200372	1179800001	

DESCRIPTION	ARTICLE NUMBER		PICTURE REMARKS
	MBV AG	MERCK KGAA	
Transport case	201253	1176540001	
Tube adapter	101.528	1092240001	
Tube 1m Silicone, inner diameter 16mm	06.6057.01	n/a	

3. INSTALLATION

3.1. INSTALLING THE WIRELESS DONGLE

The following instrument features requires network access:

- Automated date/time synchronization (see chapter 5.5.6)
- Automated timer calibration (see chapter 6.3)
- Automated user synchronization (see chapter 5.10.7)
- AD login (see chapter 5.5.9)
- Wireless access to the browser-based user interface (e.g. audit trail review) and remote control (see chapter 5.12)

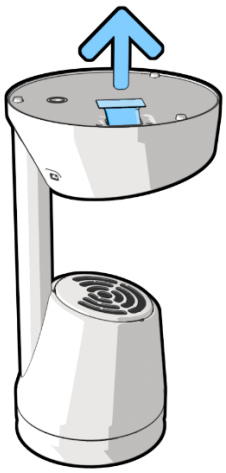
If you have ordered a WiFi Dongle as an accessory, mount it into the instrument.

NOTE: Do not remove the wireless dongle unless for replacement. Do not insert or remove the dongle while the instrument is turned on.

NOTE: Only use the recommended wireless dongle available as an accessory (see chapter 2.7).

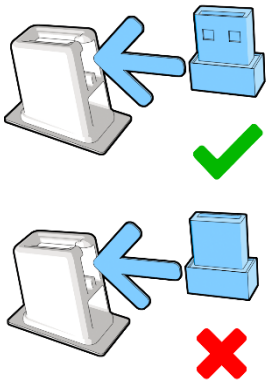
Follow handling instructions for dongle installation

Avoid applying excessive force, as this could damage the dongle or the instrument. If you encounter difficulty mounting the dongle, double-check the orientation of the parts. The asymmetrical design of the carrier prevents incorrect installation.



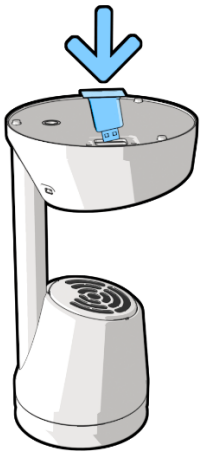
Turn off the instrument and place it upside down on the lid. Firmly grasp the small metal insert on the bottom plate from both sides and gently pull upwards in an even motion. Continue pulling until the dongle carrier is released from the base plate.

Position the adapter in front of you, leaning to the left. If a wireless dongle is already installed, slide it out to the right to remove it from the carrier.



Unpack the new dongle and ensure that the two square holes in the metal are facing you. Slide the plastic part of the dongle from right to left into the top section of the carrier.

Verify that the two square holes in the metal of the dongle are facing you, with the carrier leaning to the left. Carefully place the carrier back into the base plate in the same orientation as when you removed it.



Gently wiggle it if necessary, until the dongle is properly connected. Then, press down gently on the carrier until its metal insert lies flat on the bottom plate. The rubber carrier should create a tight seal in the hole on the bottom plate.

For configuration of the WiFi refer to section (see chapter 5.5.7).

3.2. ADJUSTING THE AGAR PLATE HOLDER

The instrument is compatible with a wide variety of different agar media from 55 up to 90mm size. The plate holder may be adjusted either to center or gently clamp the plate, without the need for tools or adapters:

- Place the clamp adjustment gauge (delivered with the instrument) onto the plate holder. **NOTE:** additional gauges can be printed from Appendix B – Clamp Adjustment Gauge
- The agar plate holder consists of three round clamps with excentric pins. To adjust a clamp, grab it by the pin, gently lift it up to the stop (about 3mm) to unlock it, rotate the pin into the desired position and gently drop the clamp back down to its lock position (when released, clamps may fall down into position or might require some gentle wiggle/push to do so – do not push down with force.)
- Preset all three pins (i.e. lift-rotate-drop) to the markers corresponding to your type of agar plate.
- Remove the clamp adjustment gauge and place your agar plate on the holder. Is the ager plate centered or clamped the way you desire?
- Starting with clamp **a**, adjust it by only one step tighter (rotating the pin inwards) or looser (rotating the pin outwards).
- Repeat this with clamp **b** then **c** then back to **a** and so forth, until your plate is centered or gently clamped just the way you desire.

3.3. MOUNTING THE TRIPOD ADAPTER PLATE

Hazard of falling instrument (parts)

When using the instrument over-head (e.g. when placed on the optional tripod), wear a protective helmet and follow the safety instructions included in the user manual of the tripod for MAS-100 microbiological air samplers.

Place the instrument in front of you with access to the bottom plate.

Take the adapter plate, the screw is fixed in the plate. Position the adapter plate in the indicated direction so that the screw points towards the thread. Turn the screw clockwise to fix it.

NOTE: To achieve optimum weight distribution, it is recommended using the adapter and not attaching the instrument directly to the tripod via the socket.

On the tripod side screw the quick-change adapter to the tripod clockwise.

NOTE: refer to the user manual of the tripod for more information.

3.4. SETTING UP A BARCODE SCANNER

The use of the barcode scanner is optional. There are two ways to use a barcode reader in connection with the instrument:

Option 1: Connect a barcode reader to the USB type C port of the instrument
Capture the ID of the sampling location, and/or the agar plate, and/or the perforated lids prior to starting a sampling (for instrument settings see chapter 5.5.17). The scanned information will be part of the meta data of the sampling entry in the audit trail
(see instrument-based workflow according to chapter 2.3.1).

Option 2: Use a barcode reader that is connected to your superordinate computer system (e.g. a EM or LIMS software)
Capture the ID of the sampling location, and/or the agar plate, and/or the perforated lids prior to starting a sampling (for instrument settings see chapter 5.5.17) and/or scan the sampling result QC-code see chapter 4.5.4) to transfer sampling results directly to your superordinate computer system (see EM/LIMS-based workflow according chapter 2.3.2).

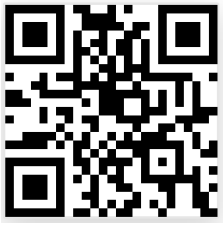
In either of the two cases, the barcode reader must be correctly configured to ensure correct data transmission from the. Follow these steps:

- Select a barcode reader able to read 1D and 2D barcodes. If you want to read sampling results according above option 2 the barcode reader must be able to read QR codes as well. Select a quality camera-based scanner that work well on the highly reflective stainless-steel housing and provides you the features according to below points.

  NOTE: MBV does not supply nor recommend barcode readers. MBV used barcode reader models Zebra DS3678 and Symbol DS4308 to validate barcode related functionality.

– Set the barcode reader to the correct keyboard type. For above option 1 set barcode reader to US English keyboard, for above option 2 set the barcode reader keyboard to match the keyboard setting on your connected computer.

  NOTE: In case of a mismatched keyboard setting between barcode reader and connected system, characters may not be correctly scanned (e.g. z/y are inversed and special characters may be wrong).



  For a quick test, scan this QR code. It should return the string

  QuincyMazon1234567890

– Set 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.

  NOTE: If this function is not activated on the barcode scanner, the instrument will not be able to jump to the next screen and continue with the sampling workflow.

– Connect the barcode reader, in case of above option 1 to the instrument or in case of above option 2 to your superordinate computer system.

  NOTE: In case of above option 1, the barcode scanner will be automatically recognized as a USB keyboard and may be supplied from the battery of the instrument (USB On-The-Go). If your barcode reader is only available with USB type A connector, a USB type C to USB type A adapter may be used.

– Only in case of above option 2 where you do want to scan the sampling result QR code, your superordinate computer system must be programmed to correctly parse the data. You may want to get in contact with your EM/LIMS supplier to support you with the integration.

  The sampling result QR code model 2 is encoded in .xml format and the structure look as follows (here shown with example data):

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<sampling>
        <start_time>2025-05-21 09:48:47</start_time>
        <end_time>2025-05-21 09:58:48</end_time>
        <timezone>Europe/Zurich</timezone>
        <username>Mustermann, Max (mma)</username>
        <userrole>Operator</userrole>
        <volume>1000 SL</volume>
        <cycles>1</cycles>
        <inter_delay>0 s</inter_delay>
        <flowrate>100 SLPM</flowrate>
        <initial_delay>30 s</initial_delay>
        <sn>220034</sn>
        <lid_type>Lid A</lid_type>
        <status>SUCCESS_WITH_W-82018</status>
        <label>ProdUnit7</label>
</sampling>
```

  NOTE: start_time and end_time identify the time window of the actual sampling/collection. Hence, the difference between the two time stamps corresponds to the blower run time.

NOTE: status may have the values 'ABORT', 'FAILED', 'SUCCESS' or 'SUCCESS_WITH-' followed by one or multiple warning IDs, e.g. 'SUCCESS_WITH_ W-82019_W-82018' (see chapter 8.2).

NOTE: barcodes that are read with a barcode scanner connected to the instrument are not part of the sampling result QR code (but of the audit trail entry), as it is assumed, that the system is only operated with one barcode scanner, either connected to the instrument or to a superordinate system such as LIMS or EM software.

3.5. VALIDATION AND QUALIFICATION

Validation consists of a series of tests to show the instrument consistently meets quality standards, product requirements, specifications and produces reproducible sampling results.

Validation is in the responsibility of MBV as manufacturer of the instrument. All validation activities follow good engineering practices and development is compliant with GAMP®5.

The following relevant validation criteria have been selected:

- Hardware validation including robustness, performance and lifetime testing
- Electromagnetic compatibility (EMC) including emission and emission/immunity
- Software validation including 21 CFR part 11 assessment
- Physical and biological sampling efficiency according to ISO 14698/EN 17141

The validation summary is available for download from here: www.mbv.ch/sirius/files

Qualification of the instrument for the intended use, the verification of the suitability or applicability of the method in a given customer situation is the responsibility of the customer. However, following support is available for installation qualification (IQ) and operational qualification (OQ) of the instrument:

- Order an on-site IQ/OQ service, performed by a Service Engineer expert from MBV or Merck.
  - For MBV service: Please go to https://www.mbv.ch/en/services/iq-oq-service/ for more information or write service@mbv.ch to make an appointment
  - For Merck service: Please go to: www.sigmaaldrich.com/EM-services
- Order a comprehensive IQ/OQ document template to perform IQ/OQ independently. Get in contact with sales@mbv.ch to order your IQ/OQ documents.

4. OPERATION

4.1. STORAGE

Follow storage conditions

Store the instrument in a dry, non-condensing environment at temperatures between -10°C and +50°C.

To extend the battery life it is recommended to store the instrument (as well as spare batteries) under cool conditions (+10°C to +25°C).

The instrument can be stored as follows

- In the transport case

- In an upright position with a protection
  - The blind lid can be placed on the instrument from either side. The magnetic attraction helps with alignment and provides haptic feedback to confirm correct positioning.

  - The dust cover can simply be placed on the perforated lid.

    NOTE: As the dust cover is not held in place, the instrument must remain in an upright position.

4.2. CHARGING

Preserve Battery and Clock

To extend battery life, it is recommended to charge the battery to over 50% every six months to prevent deep discharge and ensure the clock continues running with the correct date and time.

Ensure sufficient battery capacity for sampling

Make sure that the battery is charged before starting a sampling day (see chapter 4.5.2 and 4.2). It is recommended to charge the instrument overnight. If the battery is low a sampling cannot be started.

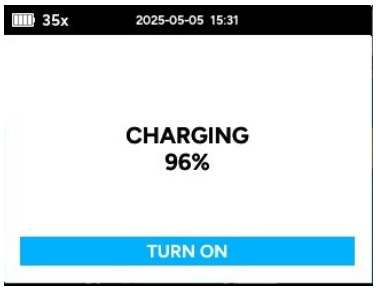
Protect the instrument during charging with a blind lid or a dust cover (see chapter 4.1).

To charge the internal battery of the instrument, plug the USB-C cable into the USB-C port of the instrument and connect it to the USB Power Delivery power supply.

NOTE: If the charger is connected while the instrument is off, the instrument automatically starts and enters charging-only mode. While the instrument is charging in the background the display turns off (dimming) and when disconnecting the charger, the instrument turns off automatically.

NOTE: If the user confirms to shut down the instrument while the charger is still connected the instrument will enter charging-only mode and will shut down once the charger is disconnected.

While the battery is charging, the charging symbol is displayed on the local user interface of the instrument (see chapter 4.5.2 and 4.5.2). For troubleshooting refer to chapter 8.3.2.



NOTE: While the instrument is charging, in the background, the display is turned off. To enable the screen, touch the Home button. The instrument may be turned on by clicking TURN ON. Otherwise, the display will turn off again after a few seconds.
The TURN ON button is only available when the battery has a minimal charge (i.e. is not available while the instrument is bringing a deep discharged battery to a minimal charge level).

NOTE: While the charger is connected the instrument can still be used for measurements. The power supplied is used for the instrument operation and any excess current will charge the battery. The charging current is limited to max 30W. For 200 SLPM the charger alone may not be able to supply the current for the motor and the battery must provide the remaining power, hence may drain not charge.

Charge the battery until the symbol for a full battery appears.

NOTE: the instruments' date and time is supplied by the main battery. With a fully charged battery and the instrument turned off, date and time are kept for approximately 24 months. If the battery is disconnected, date and time are kept for 48 hrs.

[n]x

While in operation and while charging, the estimated number of remaining sampling cycles for the current battery charge is displayed. This number is an estimate based on sampling with lid A, 100 SLPM, 1000L.

NOTE: The number of cycles applies to low altitude and may be less than indicated for locations at high altitude. To allow for accurate estimation of sampling cycles, a new battery should be discharged

below 25% and then charged until full without disconnecting the charger. This may also be done to recalibrate the battery indicator if it seems to be inconsistent.

Half of battery capacity remaining

Battery almost empty

4.3. TRANSPORT

Hazard of explosion and/or fire

The instrument contains a Lithium-Ion battery which is regulated for air transportation. Please respect IATA labeling rules in case your instrument should travel by air.

Ensure instrument is acclimatized

To ensure correct accuracy and functionality (e.g. checks during sampling) provide the instrument sufficient time to acclimatize to the temperature and humidity of the environment in which the instrument is to be operated in. This particularly applies after transferring the instrument between different areas/environments.

Instrument protection

Protect the instrument by placing either a blind lid or a perforated lid with dust cover while transporting the instrument to a new sampling location (see chapter 4.1).

NOTE: Always place the instrument in its transport case if transported outside of its area of use (e.g. when transferring the instrument between buildings). Please overpack the transport case when shipping the instrument for Service or shipping it to the service center).

Transport by hand

Transport the instrument by hand by holding it on the handle in an upright position. Make sure it sits well and safe in your hand(s).

NOTE: Tilting the instrument from its upright position may lead to the magnetic lid falling off.

With a transport aid

Place the instrument e.g. on a stainless-steel trolley. Ensure a level and dry surface. Base feet with plastic tops (POM) make sure that the instrument will not leave scratches. Due to its firm stand, the instrument will not tip over easily but may glide on the surface in the event of sudden acceleration.

4.4. INSTRUMENT POSITIONING

Place the instrument on a flat and stable surface at the defined location according to your sampling plan.

Place the instrument on a flat, dry and stable surface

Prevent the instrument from damage.

4.4.1. TRIPOD AND TRIPOD ADAPTER

Hazard of falling instrument (parts)

When using the instrument over-head (e.g. when placed on the optional tripod), wear a protective helmet and follow the safety instructions included in the user manual of the tripod for MAS-100 microbiological air samplers.

To allow flexible placement of the instrument across different rooms and to ensure sampling at working height, a tripod is recommended. It provides a stable and vibration-free set-up for accurate and reproducible sampling results.

In addition, for some sampling positions, e.g. near air outlets of HVAC systems, sampling must take place at a certain height. The stand can be extended up to 3.66m for this purpose.

Follow chapter 3.3 of this user manual for installation and chapter 3.3 and 3.4 of the tripod user manual for attaching/detaching the instrument to the quick change adapter.

NOTE: The instrument offers a stable stand, even when the adapter plate is mounted, e.g. for transport on a cleanroom trolley.

4.4.2. TUBE AND TUBE ADAPTER

A tube adapter with tube can be useful for special applications such as sampling at sampling points that are difficult to access as part of indoor air quality monitoring of ventilation and air conditioning systems (HVAC systems) in accordance with the requirements of SWKI VA104-01/VDI 6022.

Connect the tube adapter with the 1m tube.

Attach the tube adapter via the mounted perforated lid to the instrument.

Hold/position the tube at the difficult to access sampling location, for example at a HVAC opening, and start the sampling procedure according to chapter 4.5.4.

NOTE: The adjustment should always be performed with the configuration that is used during sampling, e.g. if sampling with tube and tube adapter), as otherwise, the lid detection warning may not work reliably (chapter 8.2.3).

4.5. LOCAL USER INTERFACE

4.5.1. HOME BUTTON

A Home button surrounded by a blue LED is built into the cover glass and located below the display.

The Home button is touch sensitive. To operate it, gently place the fingertip flat onto the whole area of the button.

NOTE: Do not apply force onto the button.

The button may be operated with single or multi- layer gloves. The thicker the gloves the less sensitive is the response of the button. To improve detection, place the fingertip flat to covering as much of the area of the button as possible.

The following table explains the LED states and corresponding button functions:

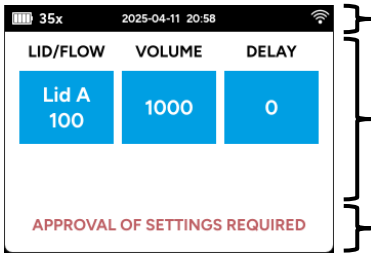
LED STATE	BUTTON FUNCTION	INSTRUMENT STATE
off		The instrument is **off**.
	Power on	Touch the Home button for >0.8 sec to **turn on** the instrument. **NOTE**: If the instrument does not turn on, charge the battery first (see chapter 4.2).
on		The instrument is **on** but not busy with delay, sampling, flush, leak test or cleaning mode.
	Show menu	Navigate to the **menu** screen and toggle between menu screens.
on		The instrument is in **cleaning mode** (see chapter 4.5.5).
	(none)	The Home button is blocked for 5 seconds, before the instrument reverts to the menu screen.
on		The instrument is in **standby with the power supply** connected (see chapter 4.5.5).
	Wake up	Touch the Home button to **wake up** the instrument.
on		The instrument is in **charging-only** mode (charging in the background with the power supply connected)
	Screen on	Turn on the screen (to see the charging state or to then turn on the instrument via touchscreen.)
Blinking (0.5 sec on, 0.5 sec off)		A **delay, sampling or leak test** is ongoing.
	Abort	Touch the Home button to **abort the process**. A confirmation screen appears, where the operator can still cancel the abort (in which case the process will continue) or conform the abort.
Blinking (0.5 sec on, 0.5 sec off)		The **flush mode** is running.
	Stop	Touch the Home button to **stop the flush mode** and return so the menu.

LED STATE	BUTTON FUNCTION	INSTRUMENT STATE
Pulsing (pulse every 2.6 sec)		The instrument is in **standby** mode without power supply connected (see chapter 4.5.5). Power consumption is reduced, USB ports (including WiFi dongle) are disabled to reduce energy consumption from the battery. After 1h in standby mode the instrument shuts down to further reduce power consumption.
	Wake up	Touch the Home button to **wake up** the instrument. Wake-up from standby take about 7 seconds.
Any state (except off)	Hard reset	If the instrument should not be responding anymore, touching the Home button for >6.4s to **force the instrument to shut down**. **NOTE:** Performing a hard reset may result in data loss, so only perform hard shutdown if unavoidable. Whenever possible turn-off the instrument via the 'OFF' function on the menu screen (see chapter 4.5.5). **NOTE:** If a charger is connected, the instrument will start-up again immediately after hard reset.

4.5.2. DISPLAY ARRANGEMENT

The local user interface is a 3.5" (89mm) colored liquid crystal display (LCD) with capacitive touchscreen which may be operated with single/double and some triple-layered latex gloves as well as single-layered nitrile gloves. It guides the Operator in a simple and intuitive way through a sampling. The language of the local user interface may be configured by the System Administrator (see chapter 5.5.19).

The screen is divided in three main sections:



The information bar on top displays general information and is available on all screens except on the sampling result screen.

The middle section displays information and options relevant to the current step of the process.

Bottom part includes information and warnings (text line) as well as call to actions.

A simple color scheme guides the user:
- Cyan: active field
- Grey: inactive field (read only)
- Black: Information (read only)
- Red: Warning or Error

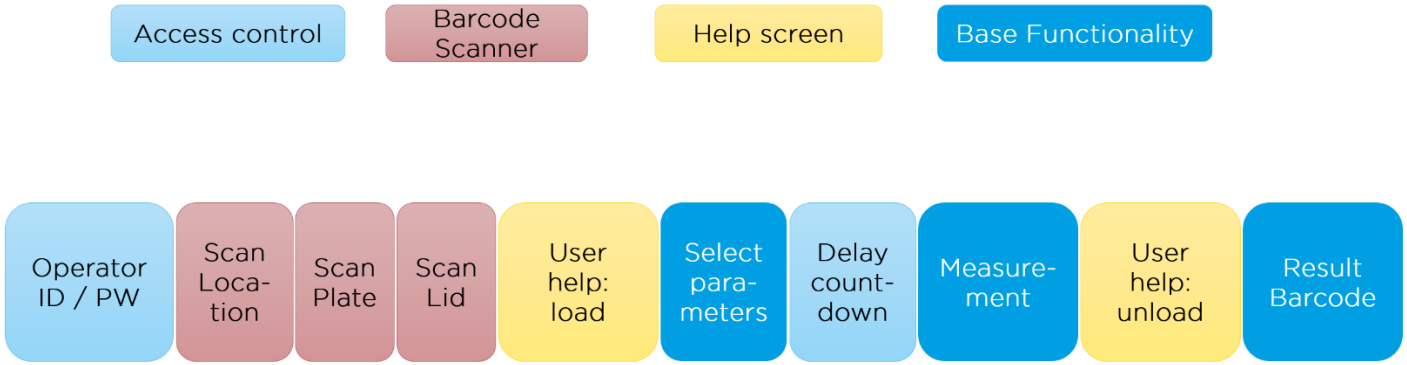
The information bar contains the following information (from left to right):
- Battery status (see chapter 4.2)
- Number of sampling cycles remaining. This ist an estimate and based on the assumption of sampling with lid A, 100 SLPM, 1000L. Also see chapter 4.2.
  NOTE: The information bar turns red when the remaining number of sampling cycles equals 0x.
- Date and time (local)
  NOTE: the date is shown in the format YYYY-

MM-DD and time is shown as hh:mm in 24h format according to ISO 8601. The format is not configurable.

- Logged-in user (if configured see chapter 5.5.7)
- WiFi icon (if configured see chapter 5.5.19) shown in case sufficiently strong connection to the network (if not shown, signal is weak but connection might still be present, if blinking intermittently the signal is just at the limit to be considered weak)

4.5.3. OVERVIEW ON AVAILABLE SCREENS

The following graphic shows which different local user interface screens are available on the instrument and how they are linked with each other:



4.5.4. SAMPLING WORKFLOW

Protect instrument from liquids ingress

Follow the sanitization and disinfection instructions according to chapter 7.1. Any disinfection/sanitization solution must be completely dried before using the instrument for a sampling.

Ensure sufficient battery charge for sampling

Before starting a sampling verify that there is sufficient battery to perform the sampling (see chapter 4.5.2 and 4.2).

It is recommended to charge the instrument overnight. If the battery is low a sampling cannot be started.

For higher flow rates, larger sampling volumes and SQS mode the user is responsible to ensure sufficient battery to complete a sampling. If in doubt, it is recommended to connect the power supply while performing a sampling (see chapter 4.2).

Ensure instrument is acclimatized

To ensure correct accuracy and functionality (e.g. checks during sampling) provide the instrument sufficient time to acclimatize to the temperature and humidity of the environment in which the instrument is to be operated in. This particularly applies after transferring the instrument between different areas/environments.

Turn on instrument

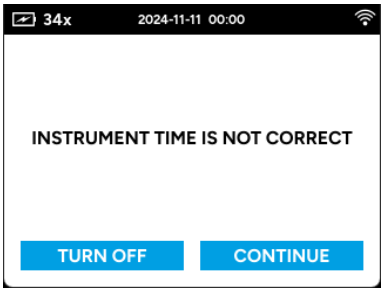
Touch and hold the round Home button near the lower edge of the instrument screen for approximately 1 second, until the blue LED lights up (see chapter 4.5.1). The instrument will then begin booting.

NOTE: if the instrument is not booting, connect a power supply and ensure the battery has sufficient charge (see chapter 4.2).

Instrument booting

Wait while the instrument is booting.

NOTE: To skip the longer booting time the instrument standby function (see chapter 4.5.5), can be used e.g. during lunch break.



Instrument warnings (optional)

After every calibration an instrument is sealed. Follow the instructions in chapter 6.1 to unseal it.

If the instrument issues a memory warning, proceed according to chapter 8.2.1 to prevent run out of memory during sampling.

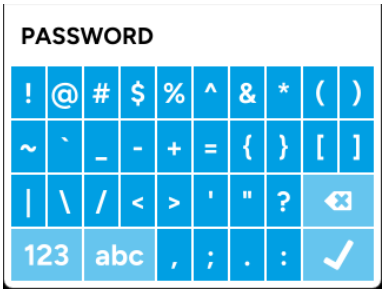
If the instrument issues a clock warning, proceed according to chapter 8.2.2 to prevent audit trail entries with wrong time stamps, before confirming to CONTINUE.

Operator login (optional)

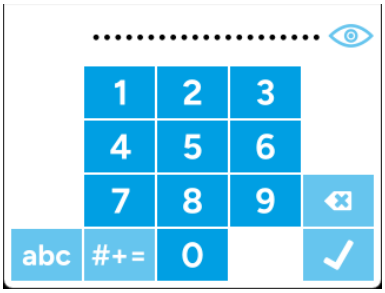
If configured by the System Administrator (see chapter 5.5.7) the Operator must login before sampling.

Enter the username followed by your personal password.

- tap 123 to switch to the number screen.
- tap #+= to switch to the special character screen.
- tap abc to switch back to the screen with alpha characters.
- tap ⇧ to enter capital letters.
- tap ⌫ to clear the last character (back-space).
- Tap the ✓ to confirm your entry.

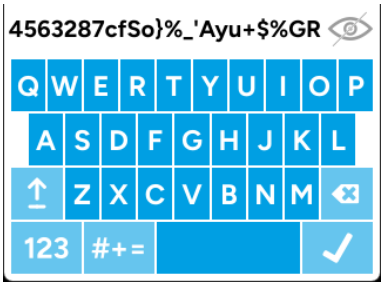


NOTE: The keyboard is available in English only.



NOTE: When the instrument is first switched on, the username field is empty. After a user logs in for the first time, the last logged-in username is automatically displayed for faster future logins. To log in with a different account, simply delete the displayed username and enter a new one.

While entering the password all characters are displayed as '*'. Tap the eye icon in the top right corner to show the actual characters. Tap it again to hide them.

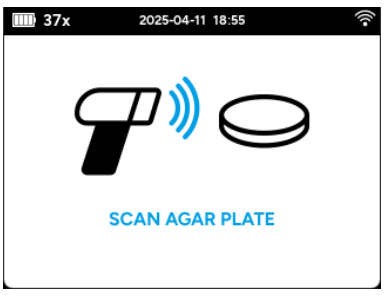


NOTE: The login remains active until the user actively logs out or enters standby (see chapter 4.5.5) or the instrument automatically enters standby after a time-out (for configuration see chapter 5.5.13).

NOTE: For login with Active Directory credentials, the instrument must be connected to the server via WiFi (see chapter 5.5.9).

NOTE: Entering a wrong password for three times, the user will be blocked. Approach the User Administrator to unblock users (see chapter 5.10.4).

NOTE: System Administrator and User Administrator login is via the browser-based user interface (see chapter 5.3).



Scan agar plate (optional)

If configured by the System Administrator (see chapter 5.5.17) the barcode on the agar plate must be scanned with a barcode reader connected to the instrument (see chapter 3.4).

NOTE (applies for all subsequent scanning screens): Once the instrument detects the scanner

input (scanner configuration see chapter 3.4), the display automatically advances to the next screen.

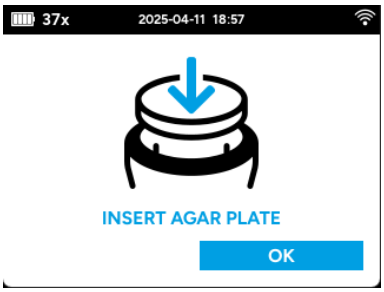
NOTE (applies for all subsequent scanning screens): The scanned information is logged together with the sampling result in the audit trail (see chapter 5.7).

Reduce risk of secondary contamination during handling

Follow SMPs/cGMP and internal SOP guidelines for aseptic handling. When inserting the agar plate, ensure that you do not reach over the agar plate. Operate the perforated lid only from the side using the handle to reduce the risk of a secondary contamination according to EU GMP Annex 1.

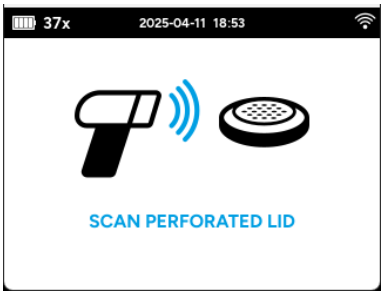
Instrument protection from particles and dust

The instrument should always be covered with a lid. The only exception is the moment where an agar plate is loaded or unloaded. This to reduce the risk of particles/dust to settle on the instrument and possibly entering it once the blower is turned on.



Insert agar plate

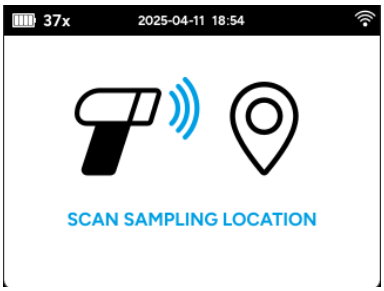
- **Remove the perforate lid:** Hold the lid by the handle with one hand. Tilt your hand slightly downwards to overcome the magnetic force. Then lift the lid sideways. No rotation is required.
- **Place the agar plate:** With the other hand, place the agar plate onto the agar plate holder. Carefully remove the agar cover and keep it in your hand.
- **Replace perforated lid:** Place the perforated lid back onto the instrument. Make sure not to collide with the open agar plate. A magnetic pull will assist in positioning it and provides haptic feedback to confirm it is properly placed. Once positioned, release the handle and remove the dust cover.
- **Store the agar plate cover:** Place the agar plate cover in your hand with the open side facing down on the dust cover in your other hand. Alternatively, place it on a sterile work surface with the opening facing down.
- **Confirm agar plate reminder screen (optional)** If configured by the System Administrator (see chapter 5.5.17): Click OK.



Scan perforated lid (optional)

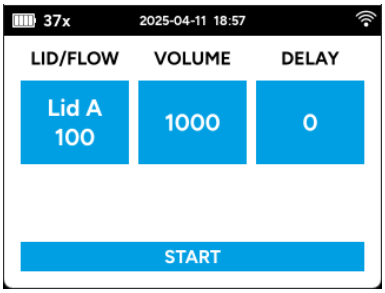
If configured by the System Administrator (see chapter 5.5.17) the 2D-datamatrix on the perforated lid (see chapter 2.6) is scanned with a barcode reader connected to the instrument (see chapter 3.4).

NOTE: When scanning the perforated lid, pay attention not to move over the exposed sieve with the scanner and/or your hand



Scan sampling location (optional)

If configured by the System Administrator (see chapter 5.5.17) the corresponding sampling location e.g. indicated on a paper/digital sampling plan is scanned with a barcode reader connected to the instrument (see chapter 3.4).

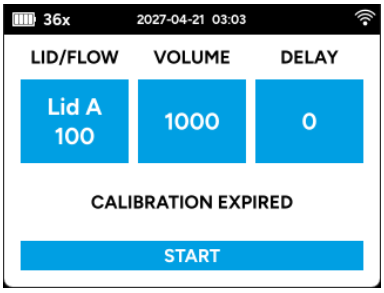


Sampling parameter selection

NOTE: it is recommended, if possible, to configure the instrument as one-button-sampler (see chapter 2.3.3 and 5.5)

If configured by the System Administrator (see chapter 5.5.14, 5.5.15 and 5.5.16), tap the blue field to step through the available options to select sampling settings:

- **LID:** Describes the lid typ used for the sampling. The indicated letter characterizes the sieve (see chapter 2.6). It must match the first letter of the 3-character code labelled on the perforated lid placed on the instrument.
- **FLOW:** the air flow rate in standard **liters per minute (SLPM)**
- **VOLUME:** corresponds to the sampling volume in **standard liters (SL)**
- **DELAY:** sampling delay in **seconds (s)** prior to starting the actual sampling.

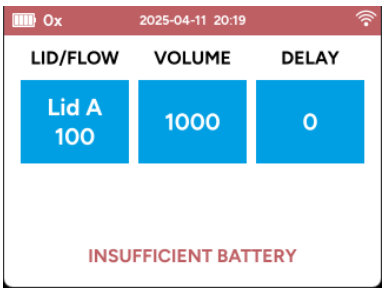


Calibration warning (optional)

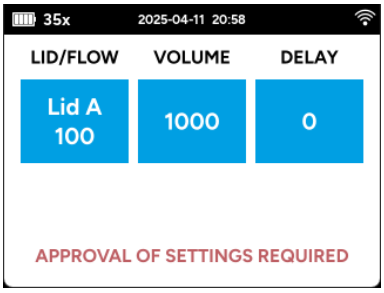
- Calibration validity expired (see chapter 5.5.18)

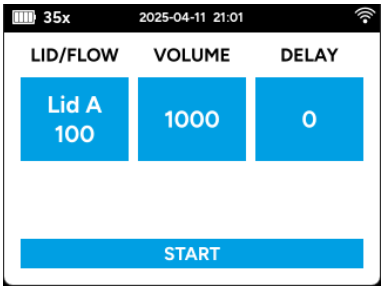
NOTE: Possible reasons that prevent sampling

In this case the 'START' button is replaced by a warning message until the corrective action has been carried out



- Low battery. Estimated number of remaining sampling cycles equals 0x (charge instrument battery according to chapter 4.2)
- Call for approval of setting changes (follow instructions according to chapter 5.5.11 and 5.6).



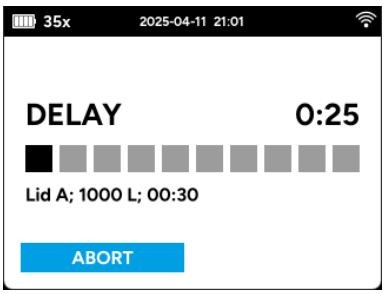


Start a sampling

After selection tap START to start the sampling.

Avoid risk of air turbulences

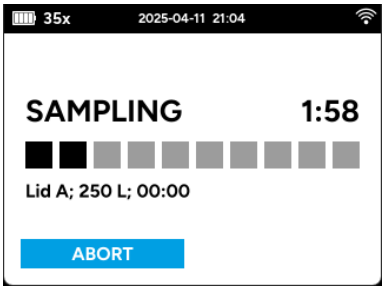
Avoid being near the instrument during sampling to avoid secondary contamination of the sample and air turbulences jeopardizing isokinetic sampling in laminar flow conditions.



Sampling delay (optional)

If a delay was selected on the previous screen, the sampling will be preceded by a corresponding delay. The timer on the right-hand side shows the remaining time for the delay and the bar shows the progress.

The information below the status bar shows the selected sampling parameters (perforated lid type and flow rate; sampling volume; delay time).



Sampling

Sampling will start automatically as soon as the delay (if any) is completed.

While the sampling is ongoing, timer and progress bar indicate the remaining duration. During sampling, the instrument automatically performs several safety checks to alert the Operator to possible misconfigurations. This allows the Operator to abort a sampling early and repeat it immediately.

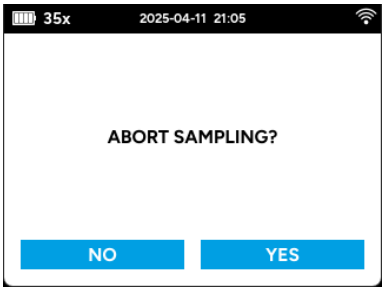
NOTE: The instrument may require several seconds to detect an inconsistent setup.

Following warning icons are shown in case a sanity check fails:

- **LID CHECK:** the lid seems inconsistent with the type of lid selected during sampling parameter selection.
- **FILTER CHECK:** the exhaust filter might be missing or inappropriately mounted

In addition to the displayed sanity check icons, corresponding warnings are logged in the audit trail (separate entry from the sampling result). And the buzzer sounds for 4 seconds with (only) the first warning.

NOTE: Due to the nature of the checks, which are depending on factors outside of the instrument, they may not be 100% accurate in all cases. The warnings intend to highlight potential issues. It is in the responsibility of the user to judge whether (considering the circumstances) a warning is relevant or may be ignored. Refer to chapter 8.2.3 and 8.2.5 for troubleshooting.



Abort a sampling delay or sampling

If tapping ABORT or tapping the Home button on either the sampling delay or sampling screens, a confirmation screen will appear requesting to confirm the wish to abort.

If tapping NO or tapping the Home button the sampling will proceed unaffected. Equally, if the abort is not confirmed until the regular end of the delay or sampling, the process continues to the next step.

If tapping YES, you will be required to select a reason for aborting.

Record a sampling note

To document sampling errors in accordance with data integrity requirements (see chapter 2.3.3).

Click on the button CHOOSE REASON to toggle between different options:

- **NO AGAR PLATE:**
  sampling started without agar plate
- **AGAR PLATE CONTAMINATED:**
  in case of a potential risk of secondary contamination of agar plate
- **WRONG SETTING:**
  wrong setting chosen
- **STARTED BY MISTAKE:**
  unintentional start of a sampling
- **OTHER:**
  In case none of the options seems appropriate,

select ‘OTHER’ and make sure to leave a note elsewhere in your sampling documentation.

NOTE: It is not possible to type a free text.

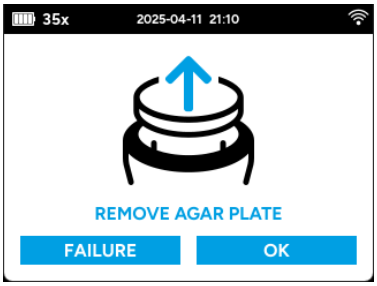
Confirm your selection by tapping OK. The chosen sampling note will be logged in the audit trail together with the sampling result which will be rated as aborted.

Remove agar plate

Once the sampling has completed, open the perforated lid analog to the loading of the agar (see above). Make sure to not grip over the open agar plate to avoid any contamination.

Submit your agar plates for incubation.

- **Place dust cover:** Use one hand to place the dust cover back onto the perforate lid on the instrument.
- **Open perforated lid:** With the same hand, hold the perforated lid by the handle. Tilt your hand slightly downwards to overcome the magnetic force. Then lift the lid sideways. No rotation is required.
- **Remove agar plate:** With the other hand, replace the cover on the agar plate and remove the agar, keep it in your hand.
- **Replace perforated lid:** With the other hand, place the perforated lid back onto the instrument. A magnetic pull will assist in positioning it and provides haptic feedback to confirm it is properly placed.
- **Check the impaction pattern on the agar plate**
- **Store agar plate:** Stack the agar plate for later incubation



Remove agar reminder screen and report a failure (optional)

If configured by the System Administrator (see chapter 5.5.17).

- In case the agar plate removal was successful confirm the reminder tapping OK
- In case the agar plate was contaminated during removal, or another failure renders the sampling invalid choose FAILURE. A reason for the failure may then be selected, as described above in ‘record a sampling error’. The sampling will be logged as failed in the audit trail.

Sampling result and barcode

After every sampling the result is indicated.

Every sampling result is logged in the audit trail. The same information is displayed on the instrument screen in the form of

- **A scannable QR code (model 2):** The QR code may be scanned with a barcode reader to easily transfer sampling results into a third-party software (e.g. a LIMS or EM software, see chapter 3.4).

NOTE: the display of the QR code cannot be disabled.

NOTE: Alternatively, a sampling result may be read out remotely (see chapter 5.12)

- **A visual indication:** Additionally, the overall result of the sampling is indicated through the following icons:

  - **SUCCESSFUL:**
    Sampling completed without warning, error or abort. Accompanied by a buzzer sound of 1 second.

  - **SUCCESSFUL WITH WARNING:**
    Sampling completed without error or abort, but LID CHECK and/or FILTER CHECK resulted in a warning. The corresponding icons as described in the 'sampling' section are shown. There is a buzzer sound of 4 seconds.

    NOTE: The warning ID (see chapter 8.2) is part of the sampling result.

    FAILED or ABORTED:
    An error was encountered; the user aborted the sampling or reported it as a failure. Additional warnings may or may not be present. There is a buzzer sound of 4 seconds.

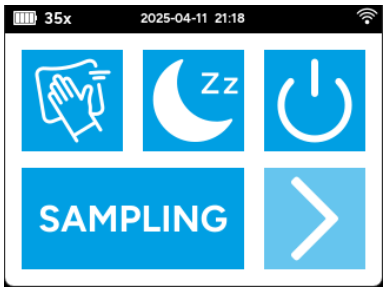
    NOTE: The error ID (see chapter 8.1) is part of the sampling result.

    Confirm the sampling result by tapping OK.

4.5.5. FURTHER FEATURES

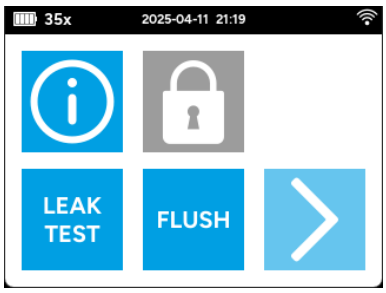
At any point before tapping START on the sampling preparation screen, the menu can be accessed by pressing the Home button.

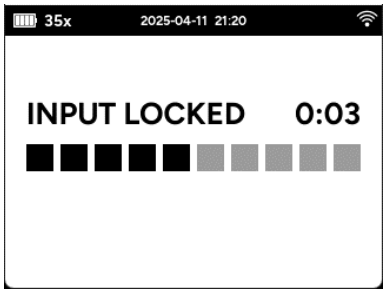
NOTE: A login is not required to access the menu screens.



Menu screens

There are two menu screens. Toggle between the screens by either tapping **>** or by tapping the Home button.





Cleaning mode

Use this feature for cleaning the instrument display according to chapter 7.1.3.

Tap the icon to lock the touchscreen and the Home button for 5 seconds. The LED is on.

A progress bar and a countdown timer indicate the remaining time until the touchscreen as well as Home button are reactivated, and the instrument reverts to the home screen.

Activate the cleaning mode multiple times in sequence if the time is not sufficient to properly clean the display.

NOTE: the hard reset after 6 sec on the Home button is not locked!

Standby

Tap the icon to enter standby mode. A brief confirmation message appears while the display turns off. Unless the power supply is connected the blue LED starts pulsing (see chapter 4.5.1).

NOTE: Entering standby mode enforces a user logout.

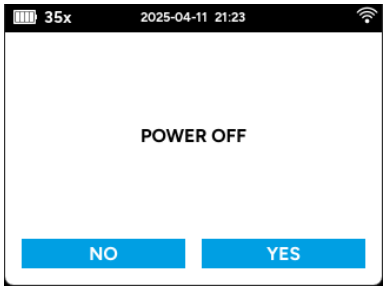
NOTE: In standby mode WiFi and USB-C are disabled, unless a power supply is connected to the instrument

It is recommended to use this feature whenever the instrument will not be used again right away but again within an hour. Wakeup from standby saves time compared to shutting down and restarting the instrument e.g. after lunch break.

NOTE: The instrument enters standby mode automatically after a certain number of minutes (as configured by the System Administrator according to chapter 5.5.13). To prevent unnecessarily discharging the battery it is recommended to manually enter standby mode whenever appropriate.

Exit standby mode by tapping the Home button.

NOTE: The instrument automatically shuts down after 1 hour in standby.



Shutdown

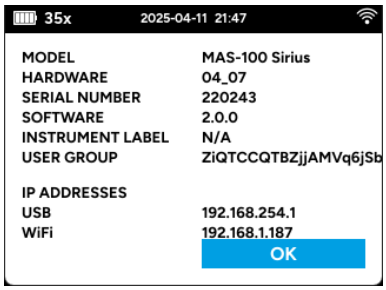
Tap the icon to turn the instrument off. A confirmation screen will appear requesting to confirm the wish to power down the instrument. If confirmed the screen goes dark, the LED goes off and the instrument turns off.

It is recommended to manually turn off the instrument if it will not be used for 3 hours or more. This prevents the battery from being discharged unnecessarily.

NOTE: While a charging device (power supply unit) is connected the instrument will not shut down but switch to charging only mode (to manage charging of the battery in the background). The instrument turns off once the charging device is disconnected.

Sampling

Tap the icon to initiate the sampling workflow (see chapter 4.5.4).



Instrument information

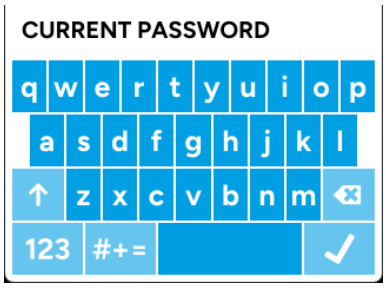
Tap the icon to access the instrument information screen.

The information shown is corresponding with the corresponding tile in the browser-based user interface. Refer to chapter 5.4 for more information on the contents.

NOTE: The user group information is truncated on the local user interface. If needed, refer to the information on the browser-based user interface (chapter 5.4).

NOTE: The information screen is static. If anything changes (e.g. IP address) while the screen is shown, the screen will not be updated. In this case leave the screen and open it again.

Click OK to return to the menu screen.



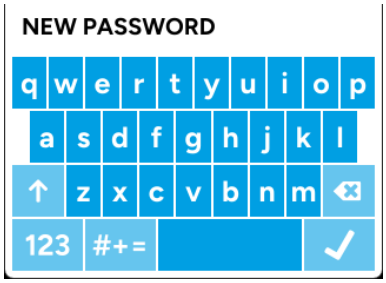
Change Operator password

The tile is deactivated (grey) if no user management has been setup or no user is logged in.

Tap the icon to change the operator password. A change of password is enforced depending on the configured password validity period (see chapter 5.10.2) or may be done freely at any time.

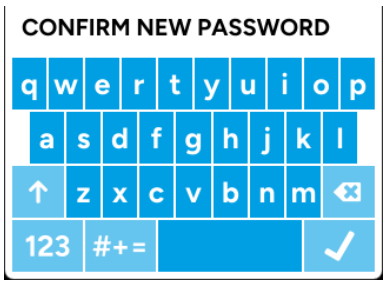
Enter the current password, followed by the new password and the confirmation of the new password.

For details regarding the keyboard, refer to chapter 4.5.4.



NOTE: The password constraint options (see chapter 5.5.8) may prevent users from choosing a weak password.

NOTE: Operator using Active Directory credentials (see chapter 5.5.9) cannot change their password on the instrument (use office computer to change password).



Leak test

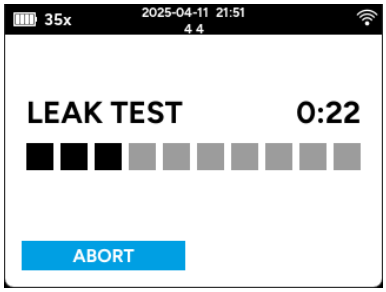
The leak test provides a quick test to assess the seal between the perforated lid and the instrument to detect lids that might have been damaged (e.g. after being dropped).

Tap the icon to perform a leak test:

- Place the perforated lid on the instrument.
- Place the dust cover on the perforated lid, making sure it is well placed.

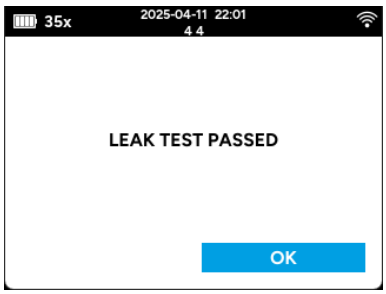
  NOTE: a dust cover that is sealing well onto the perforated lid is a necessary precondition to rate a leakage between the instrument and the perforated lid

- Start the leak test by tapping OK.
- The instrument will count-down 35 seconds. The LED is blinking, and the blower will turn on during the sequence



- Acknowledged the result be tapping OK.

A leak test result 'PASSED' confirms that there is no relevant leakage between the perforated lid and the instrument (and the necessary precondition of a dust cover sealing well onto the perforated lid was met).



A leak test result 'INVESTIGATE LEAK' implies that further steps need to be taken to rate the lid (i.e. conclusion of such investigation may be the lid is either okay or should no longer be used). Follow chapter 8.3.1 to investigate further.

While a passed leak test is logged as a technical event in the audit trail a leak test resulting in 'INVESTIGATE LEAK' is logged as a warning.

NOTE: This feature may be accessed by any user without login. Consequently, the corresponding audit trail entries may not be linked to a specific user. In case this risk shall be mitigated, it needs to be specified in the internal SOP that this feature shall only be initiated after successful login.

Flush mode

Use the flushing mode for active decontamination inside the instrument head according to chapter 7.1.4.

The flush mode may be used with or without perforated lid. Ensure to not operate it with the blind lid or dust cover.

Tap the icon to activate the flush mode.

10 seconds of activated blower are followed by 50 seconds with the blower at rest. This 60 second cycle is repeated until the user taps STOP, taps the Home button or will stop automatically after a total of 4 hours (240 cycles, thereafter the instrument will enter standby mode).

The LED is blinking while the flush mode is active.

NOTE: This feature may be accessed by any user without login. Consequently, the corresponding audit trail entries may not be linked to a specific user. In case this risk shall be mitigated, it needs to be specified in the internal SOP that this feature shall only be initiated after successful login.

5. CONFIGURATION

The instrument features may be accessed and configured via its browser-based user interface. A computer with web browser as well as a connection to the instrument is required, but no additional software or internet access.

5.1. CONNECTION TO THE INSTRUMENT

For access to the instrument, a connection either via USB or network is required. The same connection may be used to access the browser-based user interface (chapter 5.2) as well as the remote control of the instrument (see chapter 5.12).

Connecting via USB is required for (at least) the initial setup of WiFi. Once WiFi has been setup, both connections may be used. Consider using WiFi for better access speeds (see chapter 5.5.19). USB connection may always be used as a backup in case of network problems.

5.1.1. CONNECTION VIA USB

Connect the instrument to your computer using the USB type C cable included with the instrument and available as an accessory (see chapter 2.7). If your computer is lacking a USB type C port you may use a cable (not included) with USB type A (on PC side) to USB type C (on instrument side).

When the 'IP address USB' on the instrument information screen (see chapter 4.5.5) is indicated as **192.168.254.1** the connection to the PC has been correctly established.

Open a Google Chrome or Microsoft Edge Chromium browser window on your computer. Enter the IP address **192.168.254.1** to the address bar of the browser window and press enter to load the browser-based user interface.

NOTE: You may experience your computer losing connection to your network while being connected to the instrument via USB. This however is not a limitation of the instrument but depends on the network security settings of your computer/network.

5.1.2. CONNECTION VIA WIFI

Once the WiFi has been installed (see chapter 3.1) and configured (see chapter 5.5.7) the instrument may be connected to via wireless network (alternatively to USB).

Check the 'IP address WLAN' on the instrument information screen (see chapter 4.5.5) for the IP address that your network has assigned to the instrument. If no IP address is displayed the instrument is not connected to the WLAN (refer to chapter 8.3.5 for troubleshooting).

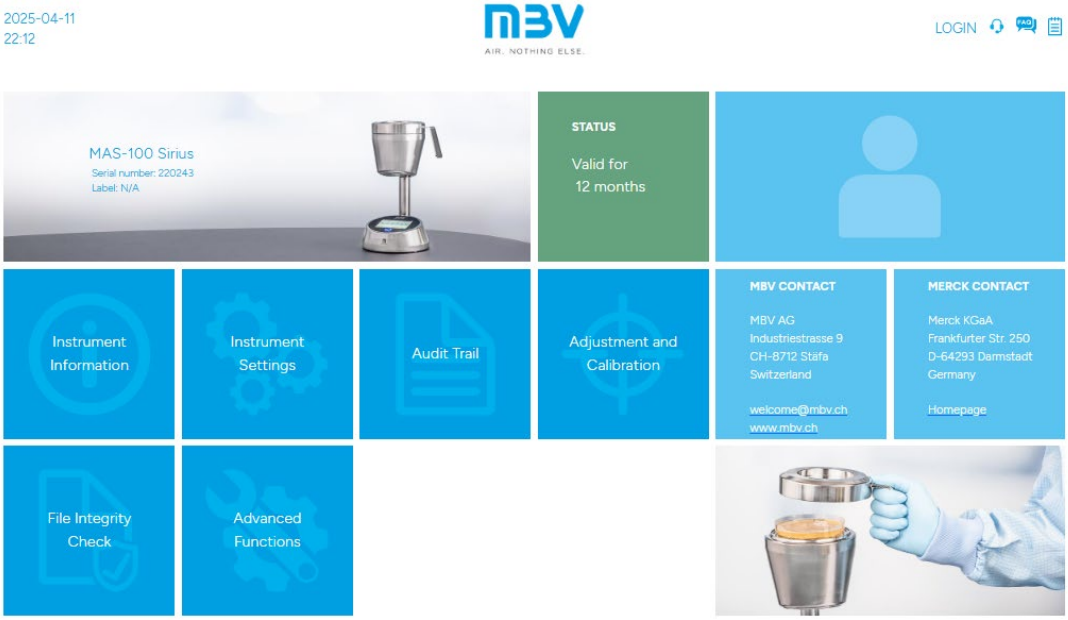
Open a Google Chrome or Microsoft Edge Chromium browser window on your computer. Enter the IP address WLAN to the address bar of the browser window and press enter to load the browser-based user interface.

5.2. BROWSER-BASED USER INTERFACE

The dashboard appears in the browser window.

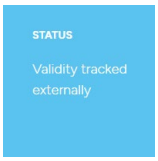
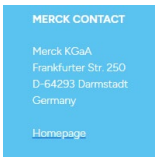
NOTE: it may happen that loading the page for the first time takes a bit longer because the font and pictures need to be loaded as well. Those will stay in the cache of your browser and ensure a faster loading time in the future.

NOTE: in case of loading issues perform a hard refresh (Ctrl+F5 on most browsers). In case of further connection problems, consult the troubleshooting in chapter 8.3.3 or chapter 8.3.5.



NOTE: the interface has been tested with Google Chrome browser 135 and Microsoft Edge Chromium 135. Compatibility issues with older or newer versions of these browser cannot be excluded.

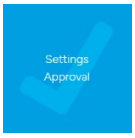
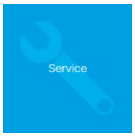
The dashboard shows some general information:

ICON	DESCRIPTION
2025-04-01 15:09	Instrument date and time (local)
LOGIN / LOGOUT	Login/Logout to the browser-based user interface (see chapter 5.3)
	Link to MBV website, service and support (Internet access required)
	Link to MBV website, Frequently Asked Questions (FAQ) (Internet access required)
	Link to MBV website, MAS-100 Sirius download page (Internet access required)
	Instrument Status - green : Calibration valid - red : Calibration Expired - blue : Calibration validity tracked externally (see chapter 5.5.19)
	User tile displaying name and role of the user currently logged in. If no information is displayed in the field, no user is currently logged in.
	Contact informant of the instrument manufacturer MBV (Links require internet access)
	Contact information of the global distributor Merck KGaA (Links require internet access)

The main features of the browser-based user interface are organized in different tiles (submenus). Click a tile to access the corresponding page. Which tiles/pages are available depends on whether a user management has been setup on the instrument (see chapter 5.9.6) and of the user role currently logged in.

The following table provides an overview:

TILE		WITHOUT USER MANAGEMENT (USERLESS MODE = FACTORY DEFAULT)	WITH USER MANAGEMENT AND USER LOGGED-IN:			SE[1] LOGGED IN
			none	SA[1]	UA[1]	
	Instrument information (see chapter 5.4)	X	X	X	X	X
	Instrument settings (see chapter 5.5)	X	-	X	-	X

TILE		WITHOUT USER MANAGEMENT (USERLESS MODE = FACTORY DEFAULT)	WITH USER MANAGEMENT AND USER LOGGED-IN:			SE[1] LOGGED IN
			none	SA[1]	UA[1]	
	Settings approval (see chapter 5.6)	- (feature not relevant in userless mode)	-	X	-	-
	Audit Trail (see chapter 5.7)	X	(X) (view only, if configured see chapter 5.5.12)	X	-	X (with restrictions, unless configure accordingly, see chapter 5.5.12)
	File integrity check (see chapter 5.8)	X	X	-	-	-
	Advanced func-tions (see chapter 5.9)	X	-	X	-	X
	Local User Management (see chapter 5.10)	- (feature not relevant in userless mode)	-	-	X	-
	Password change (see chapter 5.11)	- (feature not relevant in userless mode)	-	X	X	X
	Adjustment and calibration (see chapter 5.12)	X	-	X	-	X
	Service [2]	-	-	-	-	X
	Component man-agement [2]	-	-	-	-	X

1) for explanation of user roles, refer to chapter 5.10.1
2) Corresponding functionality is described in the service manual that is available to certified service engineers only (i.e. not covered in this user manual).

After clicking onto a tile, there is a navigation bar at the top of the page, to navigate back to the dashboard or directly to one of the tiles.

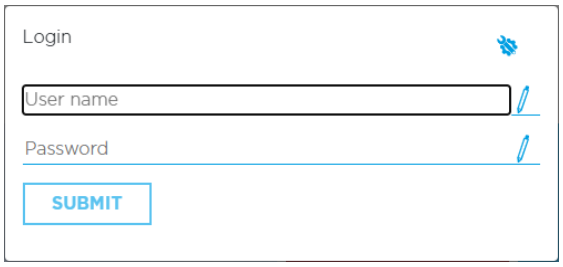
5.3. LOGIN TO THE BROWSER-BASED USER INTERFACE

If a user management has been set up (i.e. the instrument is part of a user group, see chapter 5.9.6), System Administrator and User Administrator need to login to the instrument via the browser-based user interface to access certain functions.

NOTE: Operator login is via the local user interface (see chapter 4.5.5).

To login follow these steps:

- Ensure the local user interface on the instrument shows a menu screen (see chapter 4.5.5).
- Connect to the instrument (see chapter 5.1) to access the browser-based user interface (see chapter 5.2).
- Verify that no user is currently logged in, by checking that no name is shown in the user tile (or on the information bar on the local user interface).
  To log out any user on the instrument enter the standby mode (see chapter 4.5.5) and wake-up the instrument (see chapter 4.5.5). The user has been logged-out and the username has disappeared from the information bar.
- In the browser window, click LOGIN. A pop up will appear which requests to enter the username/password credentials. Click on the fields to fill in username and password and click SUBMIT:



NOTE: Entering a wrong password three consecutive times, the user will be blocked. Approach the User Administrator to unblock users. This not only applies to role Operator and System Administrator but to User Administrator as well. It is therefore important to maintain more than one User Administrator to prevent being locked-out from the instrument fleet (see chapter 5.10.1)

NOTE: The icon is used for Service Engineer login only (described in the service manual).

5.4. INSTRUMENT INFORMATION

In the tile 'Instrument Information' the following information is shown:

NOTE: The instrument information is identical with the display on the local user interface of the Operator (see chapter 4.5.5):

NAME	DESCRIPTION
Instrument model	Product name of the instrument
Instrument serial number	The number corresponds to the number in front of the housing of the instrument base (written in full and as part of the QR code)
Customer instrument label	If the System Administrator has configured the customized instrument label (see chapter 5.5.2) that label is displayed here.
Software version	Version of the application software currently installed on the instrument
Hardware version	Version of the electronic hardware e.g. 06_02 or 06_04 (functionally equivalent) for initial manufacturing batches
IP address USB	IP address required to address the instrument when communicating via the instrument's USB type C port. It is only shown when the instrument detects a connection to a PC on its USB type C port (see chapter 5.1.1).
IP Address WLAN	IP address required to address the instrument when communicating via wireless network. It is only shown when the WiFi dongle is mounted, correctly configured and while connected to the network (see chapter 5.1.2).
Instrument user group	If a user management is setup on the instrument (see chapter 5.9.6), this is the unique identifier of the corresponding user group. This key is automatically generated and cryptic (see chapter 8.3.7). **NOTE**: In the instrument information on the local user interface the information is truncated.

5.5. INSTRUMENT SETTINGS

Please refer to the table in chapter 5.2 to see when/to which user role this tile is visible.

Settings allow the System Administrator to configure the instrument to match a specific customer workflow and limit the choices available on the local user interface to only those required by the Operator. Whenever possible it is recommended to do so to avoid the risk of operational errors. In this sense, it is possible to configure the instrument as a one-button sampler, pre-configured to one specific setting, protecting the Operator and the operation using wrong settings unintentionally.

Graphics in this section always show the factory default settings (out-of-the-box).

NOTE: Setting changes only take effect after clicking SAVE ALL SETTINGS (at the bottom of the page) and additionally, if configured accordingly (see chapter 5.5.11), only after being approved (see chapter 5.6).

Settings may be exported and imported (see chapter 5.5.21).

5.5.1. COMPANY ADDRESS

Three address lines allow entering a customer/owner company address. This address will be is here for information only and not used elsewhere.

NOTE: This field may not be edited by role Service Engineer.

5.5.2. CUSTOM INSTRUMENT LABEL

While the serial number is a predefined identifier for each instrument, this one line allows to assign a customer specific identification to the instrument. This label shows in the instrument information (see chapter 5.4 and 4.5.5) and the calibration certificates (see chapter 6.4).

NOTE: This field cannot be edited by the Service Engineer role

5.5.3. DISPLAY BRIGHTNESS

The brightness of the instrument display may be set between 0 and 100%. A higher brightness provides a better contrast but equally increases the power consumption of the instrument.

5.5.4. DISPLAY LANGUAGE

The languages on the local user interface may be selected from: English, German, French, Spanish, Italian, Russian).

NOTE: The language of the browser-based user interface is available in English only (not affected by this setting).

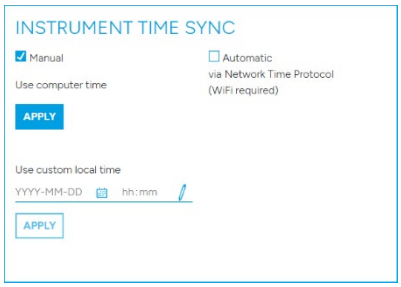
5.5.5. TIME ZONE

Select the time zone of where you operate the instrument from the dropdown list.

Change to and from daylight saving time (summer/wintertime) will happen automatically based on the selected time zone and the current date and time.

NOTE: As this is a long list, it takes a bit longer to load than the other elements in the instrument settings tile.

5.5.6. INSTRUMENT TIME SYNC



Ensure the instrument date and time are always correct. This may be done in different ways:

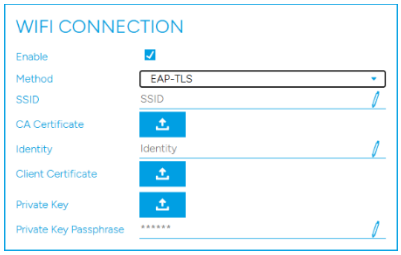
- **Automatic:**
  This setting ensures the instrument time is continuously synchronized with an NTP (Network Time Protocol) server. A wireless connection to the network (see chapter 5.5.7) and a Network Time Protocol (NTP) server in the network are required.
- **Manual:**
  NOTE: Manual time synchronization is not continuous and only happens once every time the 'APPLY' button is clicked.
  - Either use the upper 'APPLY' button to set the instrument time to the momentary time of the computer that is connected to the

instrument (often the computer time itself is synchronized to an NTP server).

- Or enter the desired date and time in the format YYYY-MM-DD and hh:mm and click the lower 'APPLY' button.

NOTE: If the instrument has network access, automatic mode is recommended.

5.5.7. WIFI CONNECTION



If a WiFi dongle has been installed (see chapter 3.1) configure the wireless connection as follows.

- **Enable:**
  Tick the box to allow a WiFi connection, untick the box to disable it (e.g. for data protection reasons, without having to physically remove the WiFi dongle).
- **Method (dropdown):**
  Chose PSK (Personal WPA2)
  or EAP-TLS (Enterprise WPA2).
- **SSID:**
  Enter the name of the network.

If Method PSK is chosen, the network must be configured to be protected by WPA2 standard. Additional configuration is required:

- **Passphrase:**
  Enter the password of the network.

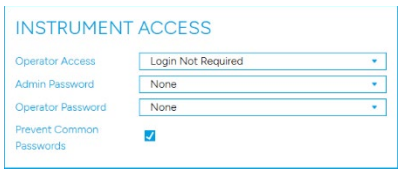
If Method EAP-TLS is chosen, the network must be configured to be protected by WPA2 eap-tls standard. The following additional configurations are required:

- **CA-Certificate:**
  Upload the Public SSL Certificate of your Radius server. Upload as base64 encoded text file.
- **Identity:**
  Enter the Identity used to authenticate into the WiFi Network (e.g. technical user)
- **Client Certificate:**
  Upload the Public SSL Certificate of the client (instrument) that was generated outside of the instrument and must be stored in Radius Server as well. Upload as base64 text file.
- **Private Key:**
  Private Key for client certificate to prove Identity. It is protected by the passphrase. Upload as base64 text file.
- **Private Key-Passphrase:**
  Enter the passphrase for the private key.

NOTE: For security reasons, the passphrase and private key are not part of a settings export and must be re-entered after a settings import (see

chapter 5.5.21). The passphrase is sent encrypted from the browser to the instrument.

5.5.8. INSTRUMENT ACCESS



NOTE: These settings are only visible (and relevant) if instrument is part of a user group (see chapter 5.9.6).

Configure the login and password constraints of the user management:

- **Operator Access:**
  Defines whether Operator 'Login Required' on the local user interface to perform a sampling or if 'Login not required'

  NOTE: System Administrator and User Administrator always need to login, if the instrument is part of a user group.

- **Admin Password:**
  Sets the password policy for login to the browser-based user interface by System Administrator and User Administrator. Select from:

  - **None:** no checks are performed on the password (i.e. there are no restrictions applied on the password, a password of at least one character is required).
  - **Easy:** at least 4 characters
  - **Medium:** at least 8 characters
  - **Secure:**
    - at least 12, maximum 20 characters
    - at least 1 lower case letter
    - at least 1 upper case letter
    - at least 1 number
    - at least 1 special character

- **Operator Password:**
  If above 'Operator Access' is set to 'Login Required' this sets the password policy for login to the local user interface by Operator. Select between none, simple, medium and secure (see list above).

  NOTE: this setting is only relevant, if Active Directory is not enabled (chapter 5.5.9).

  Whenever a new user is created, or a new password is set the instrument enforces compliance to the selected password policy.

- **Prevent common passwords:**
  Tick the box to prevent the use of some of the most frequently used passwords (such as '123456')

5.5.9. ACTIVE DIRECTORY

The instrument can be configured to use Microsoft's Active Directory (AD). When AD user management is enabled, operators can log in on instruments with their AD

credentials, i.e., the same username and password used on any other computer linked to the organization's AD:

- Operators can log in on the instrument by entering their AD username and credentials on the touch screen.
- Adding or removing users and changing usernames and passwords can be done using your organization's AD.
- The instrument access rights can be configured by the IT administration by adding users to a dedicated user group or removing them.
- Instruments need to be rebooted to apply AD setting changes fully!

This part explains what conditions must be fulfilled to use the instrument with AD, what limitations exist, and how the instrument and the AD need to be configured to function properly. Please note that an advanced understanding of AD in general as well as an in-depth knowledge of your company's AD structure is required for configuring the instruments AD settings. Therefore, this part of the manual addresses IT professionals.

- Your organization's AD setup must meet certain technical requirements and needs to be configured appropriately.
- At the time of login, the instrument must be able to establish a network connection to the pre-configured AD domain controller.
- A dedicated technical AD user whose credentials are stored on the instrument is required to find the other users on the AD.
- An Active Directory domain controller that adopts the LDAP protocol version 3. Any of the following systems are compatible:
  - Windows Server 2000
  - Windows Server 2003
  - Windows Server 2003 R2
  - Windows Server 2008
  - Windows Server 2008 R2
  - Windows Server 2012
  - Windows Server 2012 R2
  - Windows Server 2016
  - Windows Server 2019
  - Windows Server 2022
  - Azure AD Domain Services (further requirements, see below).

NOTE: If your organization uses Azure AD Domain Services, you need to make sure it is configured to allow LDAP authentication over the internet. For security reasons, it is strongly recommended to use secure LDAP (LDAPS).

NOTE: If your organization uses a hybrid AD architecture where AD domain controllers are synchronized to Azure AD, you can use one of the domain controllers for LDAP authentication.

For the instrument to connect to your organization's AD, you need to enter the address of an AD domain controller that meets the specifications.

Enter the IP address or URL of an AD domain controller as LDAP server as shown in the example. Make sure that your network and firewall rules allow the instrument to connect to the configured AD domain controller.

The instrument can use the standard LDAP protocol or secure LDAP (LDAP over SSL). For security reasons, it is highly recommended to use secure LDAP. If you want to use standard LDAP, you can disable the checkbox for secure LDAP.

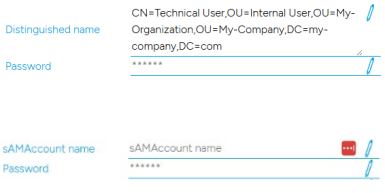
In the current version, SASL bind is not implemented and cannot be used with Sirius. Use simple authentication paired with TLS encryption to have a secure authentication flow.

NOTE: If you choose to use secure LDAP, you have to upload the base64 encoded public SSL certificate corresponding with the Server as a file (including the complete chain of trust, meaning server certificate, then intermediate certificate if needed and as lastly the root-CA certificate) so that Sirius recognizes the server as trusted.
You can get the public SSL certificate as a file by using this OpenSSL (openssl-library.org) command (replace My-Company.com with URL or IP of your LDAP server):

```
openssl s_client -connect My-Company.com:636 -showcerts </dev/null 2>/dev/null | awk '/-----BEGIN CERTIFICATE-----/,/-----END CERTIFICATE-----/' > ldap-root.crt
```

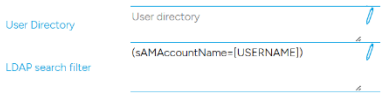
NOTE: If you want to use Azure AD Domain Services instead of a domain controller, you need to enter its external LDAP IP address as LDAP server.

NOTE: After changes of settings for Active Directory / LDAP, the instrument has to be rebooted for the changes to apply completely.



The instrument needs a technical AD user (i.e., an AD user that represents the device itself) to access and query the AD for operator's usernames. Therefore, your organization's IT needs to add a technical user in the AD. Please enter the technical user's distinguished name and password in the corresponding text fields. The example below shows the distinguished name for a technical user named Technical User belonging to an organization called “MyCompany”. Please note that this example is for illustrative purposes only, the exact structure of distinguished names depends on an organization's AD configuration.

If concurrent user logins are allowed in your organization's AD, you can add only one technical user for all your instruments. If concurrent user



logins are not allowed, you may need to add a distinct technical user for each instrument.

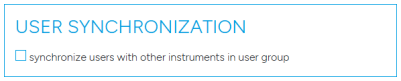
When a user tries to log in on an instrument, the instrument will query the AD for the user's entry. You need to specify where in your AD users are stored so that the instrument can find the correct AD entry.

You need to configure which attribute of a user's AD entry shall be used as username for login procedures, so that the instrument can identify the correct user entry based on the entered username. For example, user John Doe is used to log in with the username j.doe and his password. For him to be able to log in on an instrument with this username, you need to determine which attribute of John Doe's AD entry stores the value j.doe. [USERNAME] represents what is typed as username in the localUI username keyboard screen. Usually, the username is stored in the attribute "sAMAccountName". If you want users to be able to log in with a different identifier, you may choose another attribute (e.g., you could choose the mail attribute if you want users to be able to log in using their e-mail address).

Using those two parameters, you can define exactly which AD user can log into the instrument as operator.

NOTE: After changing and saving Active Directory settings, the instrument needs to be restarted before the settings take effect.

5.5.10. USER SYNCHRONIZATION



NOTE: These settings are only visible (and relevant) if instrument is part of a user group (see chapter 5.9.6).

Tick 'synchronize users with other instruments' to automatically and continuously synchronizes the user list (see chapter 5.10.3) between instruments of the same user group (see chapter 5.9.6) to allow all Operator, System Administrator and User Administrator users of that user group to login to all instruments of the user group.

To ensure the user automatic synchronization works as desired make sure that all instruments:

- are part of the same user group (see chapter 5.9.6)
- have 'instrument time sync' set to 'automatic' (see chapter 5.5.6).
- Have a WiFi dongle installed (see chapter 3.1) and are configured to the same WiFi network (see chapter 5.5.7)
- are connected to the WiFi network (see chapter 8.3.5)

- have ‘synchronize users with other instruments’ enabled (see chapter 5.5.10).
- the network Firewall needs to allow the communication between instruments over port 1025.

NOTE: Synchronization between instruments will require several seconds. With increasing number of instruments in a user group the time required for synchronization will increase.

5.5.11. APPROVAL OF SETTING CHANGES

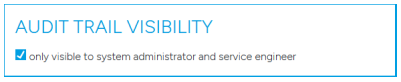
NOTE: This setting is only visible (and relevant) if the instrument is part of a user group (see chapter 5.9.6).

This setting allows you to safeguard the instrument against unintended and unvalidated setting changes (by System Administrator or Service Engineer). This feature supports working according to 21 CFR part 11.

- Box not ticked: setting changes take effect immediately after clicking ‘SAVE’ and sampling remains possible.
- Box ticked: after clicking ‘SAVE’ setting changes do take effect immediately but sampling is blocked until every setting change has been explicitly approved or rejected/reverted (see chapter 5.6) before Operator are able to start samplings again.

NOTE: This field cannot be edited by Service Engineer.

5.5.12. AUDIT TRAIL VISIBILITY



NOTE: This setting is only visible (and relevant) if the instrument is part of a user group (see chapter 5.9.6).

- **Box ticked (default):** the audit trail tile (see chapter 5.7) is only visible to the System Administrator and Service Engineer user roles. The Service Engineer can see and export the audit trail to allow debugging if needed.
- **Box not ticked:** the System Administrator provides view-only access of the audit trail, to all users without the need to login (i.e. the audit trail tail is visible on the dashboard of the browser-based user interface). This setting allows users other than the System Administrator to perform audits of the audit trail.

5.5.13. TIME UNTIL STANDBY

Configure delay for automatic logout to 1 min, 5min, 15min, 30min, or 120min of inactivity. Activities considered are user interactions, sampling process, flush mode and leak test.

If no power supply is connected, the instrument additionally enters standby mode (see chapter 4.5.5).

If a power supply is connected the instrument will go into (background) charging mode (see chapter 4.2).

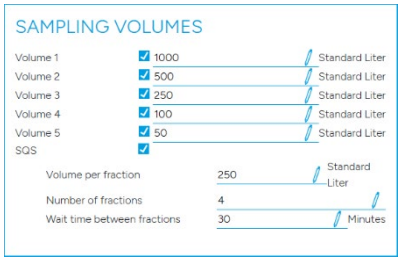
5.5.14. SAMPLING AIR FLOW AND LID TYPE

All the sampling flow rate and lid combinations the instrument is calibrated for (as-left calibration, see chapter 6) are listed in this setting. For a list of all available perforated lids see chapter 2.6.

Select the calibration that shall be available to the Operator on the local user interface 'sampling selection' screen (see chapter 4.5.4). Multiple selections can be made, but at least one must be selected.

NOTE: all flow rates that were not adjusted/calibrated are displayed as n/a. As soon as an as-left calibration was performed the corresponding sampling flow rate will be reflected here.

5.5.15. SAMPLING VOLUMES



Configure the sampling volumes that are available to the Operator on the 'sampling selection' screen (see chapter 4.5.4). Multiple selections can be made, but at least one must be selected.

The sampling volume may be configured in a range between 50 and 4000 standard liters (SL).

Additionally, there is the option to configure a sequential sampling (SQS) which consists of the following parameters:

- Volume per fraction: 25 up to 2'000 SL
- Number of fractions: 2 up to 50
- Wait time in between fractions: 1 up to 720 minutes

NOTE: the user is responsible to choose settings where a fraction lasts at least 30 seconds (depending on the selected flow rate), the total SQS sequence lasts no longer than 24 hours and the total volume is suitable for the agar plate used. The instrument software is not performing these checks.

NOTE: If more flexibility is required than the SQS settings here offer, a sequence of samplings may be executed via instrument remote control (see chapter 5.12)

NOTE: The configured sampling volumes are nominal values. Hence, the actual sampled volume may vary within the tolerance of the allowed deviation of flow and timer. In case the user wants to compensate for the specified accuracy and make sure at least the desired volume is sampled, the sampling volume may be increased by the specified ac-

curacy of the instrument at that flow rate (i.e. sampling of 1025 SL instead of 1000SL to counteract the 2.5% accuracy specification at 100SLPM flow rate).

5.5.16. SAMPLING DELAYS

Configure the sampling delays that are available to the Operator on the 'sampling selection' screen (see chapter 4.5.4). Multiple selections can be made, but at least one must be selected.

The delay time must be between 0 and 7'200 seconds.

NOTE: for application in pharmaceutical cleanrooms, according to EU GMP Annex 1 § 4.31, it is recommended to set delays of 900 seconds (15 minutes) for measuring cleanroom 'in operation' and 1200 seconds (20 minutes) for measuring cleanroom 'at rest'.

5.5.17. SAMPLING REMINDERS AND BARCODES

Optional screens of the sampling workflow (see chapter 4.5.4) may be enabled and disabled here to customize the sampling workflow:

Reminder screens:

- Show reminder screen 'insert agar plate'
- Show reminder screen 'remove agar plate' with the option to report a failure
  NOTE: if a failure is reported on this reminder screen, the process is the same as when aborting a sampling (see chapter 4.5.4).

Barcode scanning screens for use with a barcode reader connected to the instrument (see chapter 3.4) in order to scan the sampling environment and support data integrity/ALCOA+ requirements:

- Scan agar plate
- Scan perforated lid
- Scan sampling location

NOTE: Sampling environment information can also be stored directly in the LIMS/EM system. For this, use a barcode reader connected to the LIMS/EM system and disable the fields here (use case see chapter 2.3.1 and 2.3.3)

5.5.18. CALIBRATION REMINDER

Configure how to handle upcoming expiration of instrument calibration validity.

- **Warn Operator:**
  During the last 30 days prior to the calibration expiring, a warning message will be shown on the 'sampling selection' screen on the local user interface (see chapter 4.5.4), indicating the remaining number of days until calibration expiry.

NOTE: upon expiration of calibration, the sampling will not be blocked. It is in the responsibility of the Operator to appropriately respond to the warning message.

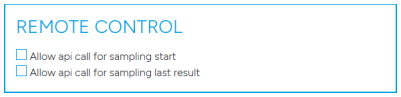
Refer to chapter 6.1 for information on calibration validity.

- **Track externally:**
  The instrument does not warn the Operator upon (upcoming) expiration of calibration validity. The assumption is, that the instrument calibration is managed entirely external to the instrument (e.g. in a customer calibration management tool or database).

5.5.19. CALIBRATION INDICATOR

Choose whether the pass/fail indication of the calibration result will be shown (tick) on the calibration certificate or not (no tick). This removes the pass/fail statement on the calibration certificate in case you want to apply your own criterias.

5.5.20. REMOTE CONTROL



Configure whether you want to allow 'start sampling' and/or 'reading the last sample result' command via remote control API (see chapter 5.12).

If you do not use the remote control feature of the instrument, it is recommended to disable these commands (boxes not ticked), to prevent interfering with the Operator performing a sampling.

If you do want to use the two commands (boxes ticked), consider how to potentially limit the access to the instrument within your network to prevent unauthorized users potentially interfering with your operation.

5.5.21. EXPORT/UPLOAD INSTRUMENT SETTINGS

Instrument settings as described in the previous sections are stored in an internal settings file. Click EXPORT SETTINGS TO FILE to export the settings file (.zip folder containing a .json file).

Exported settings serve as a backup and to replicate the same settings on other instruments. It is recommended to export and safeguard the settings file when changes are made to the instrument settings.

To import settings, click UPLOAD SETTINGS FROM FILE and upload .zip folder that was previously exported from an instrument.

NOTE: All existing settings, including settings not accessible by Service Engineer, will be overwritten with the imported settings, no matter which role triggers the import. If necessary, some fields e.g. custom instrument label (see chapter 5.5.2), may need

to be adapted manually after the import. Consult the audit trail to see which settings have changed.

NOTE: settings with sensitive data such as the WiFi password as well as the technical user password of active directory settings are not part of the exported file due to potential data security concerns. Consequently, these settings will not be overwritten upon upload and may have to be entered manually after the file import.

NOTE: Instrument settings are not synchronized between instruments of a user group (only user lists may be automatically synchronized, see chapter 5.5.10). It is strongly recommended that the System Administrator ensures consistent instrument settings among instruments within the same user group (see chapter 5.9.6) by exporting Instrument Settings from a master instrument and import to other instruments of the user group.

The integrity of the downloaded .zip folder may be checked (see chapter 5.8).

5.6. SETTINGS APPROVAL

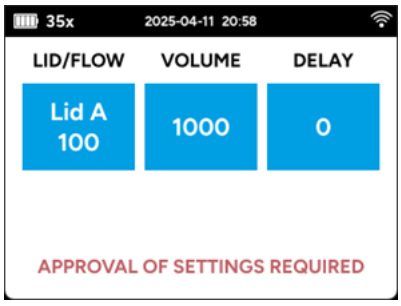
This section is only relevant if the instrument is part of a user group (see chapter 5.9.6). Please refer to the table in chapter 5.2 to see when/to which user role this tile is visible.

If configured accordingly (see chapter 5.5.11), a System Administrator must approve setting changes done by a Service Engineer or a System Administrator, based on a four-eyes principle. This feature allows to ensure that no critical (intentional or unintentional) change to the instrument settings is taking effect on sampling without dedicated approval by a System Administrator. This is for example mandatory for a use case that needs to be compliant with 21 CFR part 11.

NOTE: Sampling is blocked for the Operator while approvals are pending.

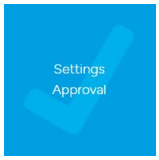
NOTE: Setting changes become active on the instrument as soon as they are saved. The instrument may be used by System Administrator, User Administrator and Service Engineer normally, including sampling performed by the Service Engineer. Only sampling by the Operator is blocked while approvals are pending. If changes are rejected (see below) the setting is changed back to its previous value.

While approval of changes to instrument settings (see chapter 5.5) are pending:



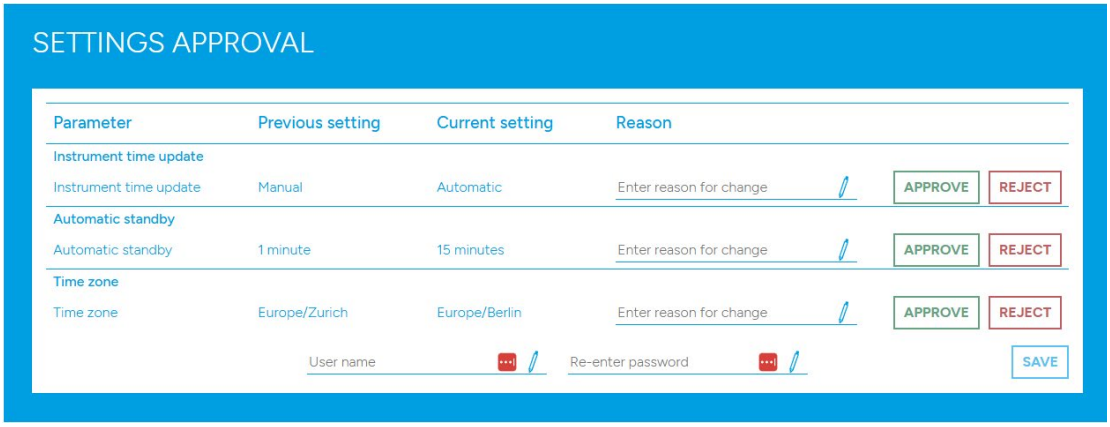
On the local user interface, the message 'Approval of setting changes required' is being displayed. In this state the Operator is prevented from starting a sampling.

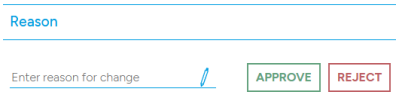
Further setting changes and calibrations may not be performed by the System Administrator, until all pending setting changes have been approved or declined.



A System Administrator (same or different System Administrator from the one that made the changes) needs to open the 'SETTINGS APPROVAL' tile. A list of all pending approvals is listed with previous and new values.

NOTE: When there are no new settings to be approved, the 'Settings Approval' tile is displayed inactive (in a brighter shade of blue).

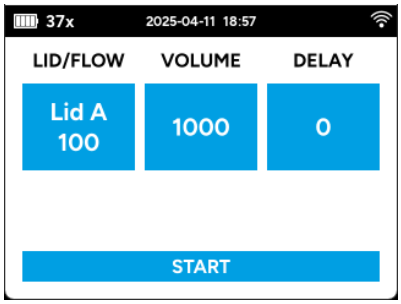




For each item:

- compare the previous as well as the Current (new) setting
- click APPROVE or REJECT (the corresponding button gets highlighted)
- log a reason/justification for the change (important 21 CFR part 11 requirement)

At the bottom of the window: enter username and password and click SAVE to authenticate the approval.



Upon logout of the System Administrator, the message on the local user interface disappears and the instrument allows sampling again.

NOTE: Adjustment and calibration are not part of the instrument settings and can therefore not be approved nor rejected. Please refer to chapter 6.1 for more information on the calibration routine and certificates.

5.7. AUDIT TRAIL

Please refer to the table in chapter 5.2 to see when/to which user role this tile is visible.

All user actions on the local user interface as well as on the browser-based user interface, all sampling results, warning, errors and further technical data are logged within the audit trail. It is an essential feature for many use cases requiring compliance with CFR 21 part 11 (see chapter 2.3.3). The audit trail is tamper proof within the instrument and tamper evident outside the instrument.

NOTE: For reasons of data integrity the audit trail cannot be disabled. So even if you do not actively use the audit trail in your workflow, data is getting logged and may be used for reference, and needs to be deleted (see chapter 5.7.3) from time to time to free up instrument memory (and exported beforehand, see chapter 5.7.2).

5.7.1. AUDIT TRAIL DISPLAY

The upper part of the audit trail tile offers different filter options.

In the center are the export and delete buttons.

The lower part shows the actual audit trail list.

Audit trail list

The audit trail list shows one row per entry, with the newest entry on top. Initially only the top entries are loaded into the view. Scrolling down on the list loads further (older) entries on the fly.

NOTE: New entries which are logged to the audit trail while the audit trail tile is open are not displayed automatically. Change a filter setting or reload the audit trail tile in the browser window to display the latest entries.

Each entry contains:

- Column 1 - Date and Time (including time zone) when the event was logged.
- Column 2 - Category of the entry:
  - Sampling: entries related to the sampling cycle (see chapter 4.5.4).
  - Settings: changes to instrument settings (see chapter 5.5), as well as their approvals (see chapter 5.6).
  - Warnings: warnings (for further information, refer to chapter 8.2).
  - Errors: errors (for further information, refer to chapter 8.1).
  - Calibration: events related to adjustment and calibration (see chapter 6).
  - User: events related to users, such as login, logout, change of password, user being blocked, creation and modifications of users.
  - Technical: entries not falling on any of the above categories. These may be useful during troubleshooting (see chapter 8.3).
- Column 3 - First name, Last name, Username (in brackets) as well as user role of the user that is associated with the event.

  NOTE: In case no user was logged in (instrument is in 'userless mode', see chapter 5.9.6 or function that is accessible without login), 'none' will be indicated for first, last and username as well as user role.

  NOTE: To protect sensitive personal data, first/last/user names are only visible to the System Administrator. Service Engineer and other users (in case the System Administrator made the audit trail visible to everyone, see chapter 5.5.12) can see user role only.
- Column 4 – Type of event that was registered.
- Column 5 - Parameters and meta-data associated with the event
- Column 6 - For events of category 'Sampling' only: the corresponding QR code (as it had been shown on the local user interface at the end of that sampling cycle, see chapter 4.5.4).

Filter options

Following filter options allow to display entries of interest only. Only entries that pass all filters are displayed (i.e. filters are connected with an AND logic).

NOTE: only the audit trail display is affected by the filters, not the export or deletion of the audit trail.

- Filter display by category: select the categories that shall be displayed
- Filter display by user: select user role, and/or username, and/or user first name, and/or user last name that shall be displayed.

  NOTE: Filter using the name fields require exact match of the name and are case-sensitive.
- Filter display by time period: define date and time for the beginning and the end of the period of interest.

  NOTE: the defined start and end date/time are included when filtering events.

Audit trail printing

Using the printer function of the browser (i.e. this is not a function of the instrument, but a function of your browser), to print a static version of the current audit trail display with the current filters active, for all entries that have been loaded into the window (use the browser scroll function to scroll down further on the audit trail list in order to load more entries).

It is recommended to have 'Headers and footers' enabled in the 'More settings' section of the browser's print menu in order to get page indicators (n of X) printed.

5.7.2. AUDIT TRAIL EXPORT

Click the EXPORT ALL DATA button, to download the complete, unfiltered (i.e. unaffected by the filters settings in the audit trail display shown in chapter 5.7.1) audit trail to your computer, as a file in .xml format wrapped in a tamper evident .zip folder.

After a completed export, the button CLEAR ALL DATA becomes available (except when exported by Service Engineer). With the successful download of the audit trail, the responsibility for its integrity, safekeeping and data protection is transferred from the instrument to the user.

The integrity of the downloaded .zip folder may be checked (see chapter 5.8).

The audit trail storage capacity is sufficient to typically store more than 7'300 sampling entries (this is an estimated, typical value only, as this depends on how the instrument is used and how much storage space is taken up by other events, besides sampling).

NOTE: To protect from an irreversible data loss, in case of a failure of the instrument memory or electronics, it is strongly advised to back up the internal audit trail on a regular basis.

NOTE: The audit trail exported by the Service Engineer has the same limitations on first/last/user names as apply to the audit trail display (see chapter 5.7.1). Therefore, the Service Engineer cannot make a full export of the audit trail (containing first/last/user names) on behalf of the customer, unless configured by the System Administrator accordingly (chapter 5.5.12).

5.7.3. AUDIT TRAIL DELETING

To prevent from unintended data loss, deletion is only possible after a successful export (see chapter 5.7.2). Click CLEAR ALL DATA to delete the complete audit trail from the instrument.

To free internal disk space, the audit trail must be deleted from time to time. It is advised to delete the audit trail latest when the memory warning shows on the local user interface, to prevent that the instrument blocks operation (see chapter 8.2.1).

NOTE: The Service Engineer cannot delete the audit trail.

5.7.4. OPEN EXPORTED AUDIT TRAIL IN A BROWSER

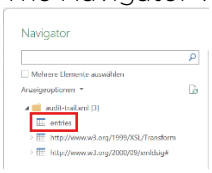
The .xml file (that is packed in the .zip folder) may be opened directly using an up-to-date browser and will be displayed in a user-friendly table format.

Date and Time Timezone	Category	FirstName LastName (Username) Userrole	Action	Parameter
2000-02-01 02:19:12 Europe/Zurich	Technical	NA (NA) Undefined	Battery charging stopped	
2000-02-01 02:19:12 Europe/Zurich	Technical	NA (NA) Undefined	Instrument switched off	
2000-02-01 02:19:12 Europe/Zurich	Technical	NA (NA) Undefined	Power source attached	
2000-02-01 02:19:13 Europe/Zurich	Technical	NA (NA) Undefined	Instrument switched on	Config_files_changed-6-g9f9064666
2000-02-01 02:19:14 Europe/Zurich	Technical	NA (NA) Undefined	Battery charging started	
2000-02-01 02:22:05 Europe/Zurich	Technical	NA (NA) Undefined	Files synchronized to disk	
2000-02-01 02:22:10 Europe/Zurich	Settings	NA (NA) Undefined	Using automatic network time setting changed	Old value: enabled; New value: disabled
2025-04-07 17:26:55 Europe/Zurich	Settings	NA (NA) Undefined	Instrument time changed	+794671484s

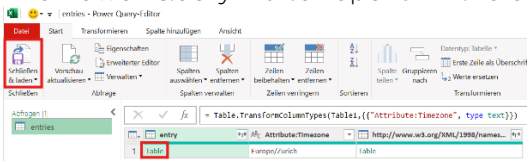
5.7.5. OPEN EXPORTED AUDIT TRAIL IN A SPREADSHEET

The exported audit trail in .xml format may be imported into a large range of data analysis tools for further data analysis. Follow these steps to open the audit trail into Microsoft Excel (for other analysis tools, please consult the manual of that specific tool):

- **NOTE:** due to the mentioned integrity check, it is recommended to copy the file before potentially altering it (e.g. for the purpose of data analysis).
- Unpack the file audit-trail.xml file from the .zip folder (exported audit trail)
- Open an empty spreadsheet in Microsoft Excel
- Select ‘Data’ >’Retrieve Data’ > from file > ‘from XML’ and select the audit-trail.xml
- The Navigator window opens. Under ‘display options’ double-click on ‘entries’



- The Power Query-Editor opens. In the column ‘entry’ click on ‘Table’.



- Click on ‘close and load’ at the top left of the menu bar.
- The data from the audit trail is now loaded in the Excel spreadsheet. Apply your Excel skills to filter and analyze the data as you wish.

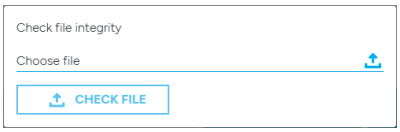
5.8. FILE INTEGRITY CHECK

Any file which is downloaded from the instrument is packed in a .zip file containing a signature. This feature allows you to validate the integrity of exported file (audit trail,

instrument settings, user list), in order to identify if the file has been modified/corrupted since its export. This makes the exported files tamper evident.

By using the file integrity check, it is possible to check the integrity of the .zip folders and detect whether it has been modified (intentionally or intentionally) since the moment it was exported.

Click the tile 'File Integrity Check', click on Choose file and select a .zip folder that was previously exported and click CHECK FILE.



The system will then report automatically if ✓ File is valid or ✗ File is invalid or has been modified

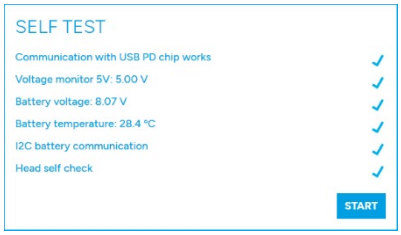
NOTE: If the file is reported invalid, it is not possible to identify who modified what when, just that it has been modified since export.

5.9. ADVANCED FUNCTIONS

Please refer to the table in chapter 5.2 to see when/to which user role this tile is visible.

5.9.1. INSTRUMENT SELF TEST

A self-test allows to automatically check key parameters of the electronic system.



Click START to run the self-test. A list of the results of the self-test will be shown once the test has been completed. Pass will be indicated with a ✓ while fail will be indicated with a ✗.

- **Communication with USB PD chip works:**
  Checks if the communication to the USB power delivery chip is working.
- **Voltage monitor 5V:**
  Measures the system voltage and checks if it is in the required range.
- **Battery voltage:**
  Measures the battery voltage and checks if it is in the required range.
- **Battery temperature:**
  Measures the battery temperature and checks if it is in the required range.
- **I2C battery communication:**
  Checks if the communication to the charger chip is working.
- **Head self-check:**
  Checks the communication between the instrument base and head, whether the head responds without errors and the sensor communication functions without problems.

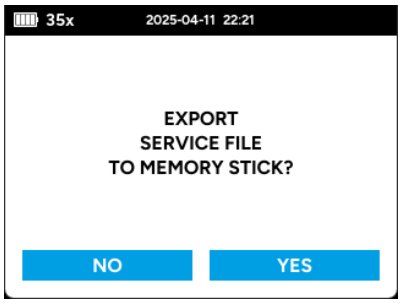
5.9.2. MANUAL TIMER CHECK

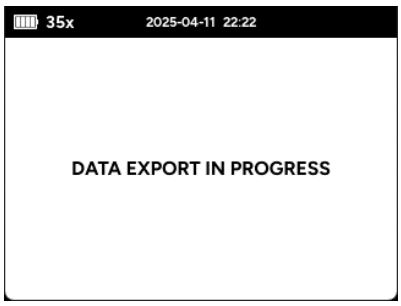
This is a manual, less accurate alternative to the recommended automated timer calibration (see chapter 6.3.1). For details, please refer to chapter 6.3.2.

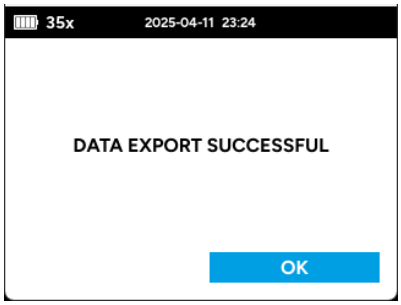
5.9.3. SERVICE FILE DOWNLOAD

In case you need a service engineer (see chapter 7.2.3) to investigate the status of the instrument remotely, you may send a copy of the audit trail (see chapter 6.3) and the service file. The service file may be downloaded in two ways:

- When logged into the instrument as System Administrator or Service Engineer, the service file export is triggered in the 'Advanced Functions' tile by clicking on the corresponding DOWNLOAD button
- As an alternative, the service file download can be triggered by plugging in a USB memory stick (formatted for the FAT32 file system) to the USB type C port of the instrument. Upon connection a dialog is displayed on the local user interface. Click YES to trigger the export (or NO to cancel). After successful export, click OK and unplug the USB memory device from the instrument.







A downloaded service file is a .zip archive that includes multiple text files documenting the status of the instrument. It is of interest for trained service engineers only.

NOTE: The Home button (see chapter 4.5.1) and automatic timeout are non-functional during the service file export routine.

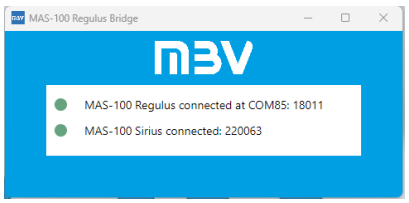
NOTE: The name of the .zip file may be changed but not the content which would render the file invalid.

5.9.4. REGULUS BRIDGE

Regulus bridge is an executable file (.exe) that can be run on a PC. It may be convenient when performing sampling flow adjustment/calibration on an instrument that does not have WiFi connection (see chapter 3.1). It enables you to have an UBS connection of the instrument to the PC and the calibration unit at the same time by routing the data from the anemometer via PC to the instrument (see chapter 6.2).

By clicking ACCESS DOWNLOAD a popup window will appear where the file can be downloaded (internet access required).

Run the .exe on your PC to allow the instrument and MAS-100 Regulus to communicate with each other via your PC. Connect both the instrument



and the MAS-100 Regulus calibration unit to your PC via USB. Perform adjustment/calibration according to chapter 6.2.

NOTE: Regulus needs to be unplugged and plugged back in prior every adjustment or calibration step.

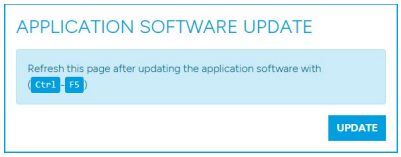
5.9.5. SOFTWARE UPDATE

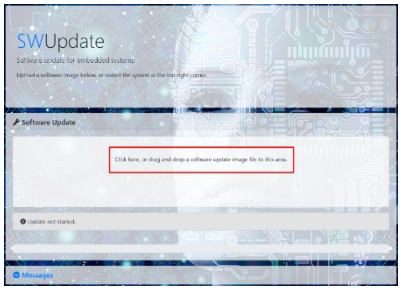
The application software of the instrument should be updated when a new SW version is available to ensure optimal instrument performance. The trigger for this is a newly published service information letter (SIL), published on the MBV webpage and via the MBV newsletter.

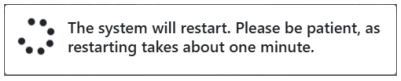
NOTE: Make sure that the audit trail is exported and saved prior to a SW update. In rare cases, the new application version may introduce changes to the audit trail structure and require a reset of the audit trail database. Such cases however will be communicated in the application software release notes (SIL).

NOTE: It is recommended to perform an as-found calibration before the update and an as-left calibration after the update. In rare cases, the new application version may introduce changes to the calibration memory structure and require a new calibration or even a new adjustment. Such cases however will be communicated in the application software release notes (SIL).

NOTE: Ensure the battery state of charge is sufficient to complete the software update process and reboot.







Upon clicking the 'UPDATE' button, a new browser window opens, where the update file can be selected or placed via drag-and-drop.

Once the new software has been downloaded to the instrument, the instrument will automatically restart. At this point you may close the software update tab in the browser. The update and restart may take several minutes. **Please be patient** while the instrument is booting and while it might display 'Preparation, please wait' for an extended time. Wait until the local user interface shows the first screen of your sampling cycle (depending on 'Instrument Settings').

NOTE: Do not shut-down the instrument during the update process as this might corrupt the instrument software and make the instrument unusable.

Check the Instrument information on the local user interface (see chapter 4.5.5) to confirm the desired SW version is now installed.

NOTE: If the SW update does not seem to have taken effect on the browser-based user interface, hard refresh the page without using cached data (Ctrl+F5 on most browsers). A simple reload may not be sufficient.

5.9.6. USER GROUP SETUP

Out-of-the-box (factory default) there is no user management activated on the instrument. The instrument is in userless mode and not part of a user group. The instrument can be operated and configured without the need to authenticate with

username and password. This mode might be suitable in a non-regulated environment (e.g. training center or non-Pharma environment).

NOTE: Service Engineer needs to login, independent whether or not a customer user management is setup.

However, to protect against unauthorized access to instrument configuration, for example in the scope of compliance with 21 CFR part 11 within the pharma industry, it is recommended to set up the user management. Even in a non-regulated environment, it might be desirable to password protect at least the instrument settings and advanced features. When setting up a user management, the instrument is assigned to an existing or a new user group.

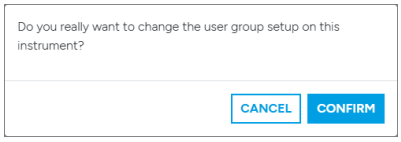
Refer to chapter 5.4 to see, whether or not an instrument is currently assigned to a user group.

Multiple instruments may be grouped into a user group. This group may for example be all MAS-100 Sirius instruments of e.g. a company, a department or a team. There is neither a limit to the number of user groups nor a limit to the number of instruments in a specific user group.

Instrument within the same user group share their local user list, hence users (Operator, System Administrator and User Administrator) may login on all instruments of the user group but not to instruments of any other user group. The synchronization between instruments may be set to happen automatically (see chapter 5.5.10) or, in absence of a network connection, may be performed manually by the User Administrator through export/import of user lists (see chapter 5.10.7) across instruments.

Click CHANGE if you want to setup or change the user group of the instrument.

NOTE: If a user management is currently setup (i.e. the instrument is assigned to a user group, see chapter 6.45.4), this function is only available to the existing System Administrator and Service Engineers.



CONFIRM the pop-up message to continue.

The user management reset may be aborted any time by clicking CANCEL.

NOTE: If a user management is currently setup on the instrument the local user list will be deleted upon clicking CONFIRM. It is recommended to export the local user list prior to proceeding (see chapter 5.10.5).

Choose among one of three options:

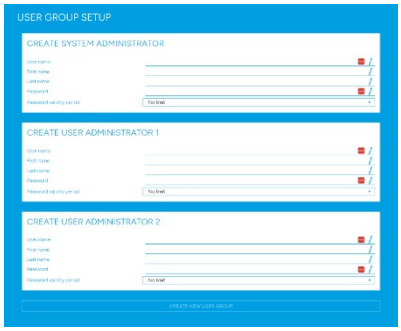
Option 1: Remove user management

Select 'No User Management' if you want to remove an existing user management and revert the instrument back into userless mode (i.e. instru-

ment no longer part of a user group). This will render the instrument operation open to any user. Login will (no longer) be required, even for advanced functions/settings.

Option 2: Setup user management by creating a new user group

Select 'Create new user group' if you want to setup a new user group, either because this is your first instrument, or you don't want to add the instrument to an already existing user group.



Create the first System Administrator user and two User Administrator users for the newly created user group. Per user provide:

- Username (used for login)
- First name
- Last name
- Password (preliminary password)
- Password validity period (no limit, 1, 3, 6, 12 months)

Click CREATE NEW USER GROUP.

NOTE: Password constraints apply. For a new instrument the constraints are set to 'none'. For an instrument where a user group was previously setup, the previous setting takes effect (see chapter 5.5.8)

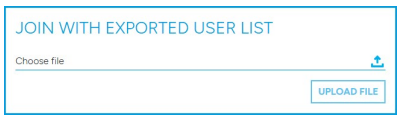
Hand-over the newly generated usernames and preliminary passwords to the respective users and ask them to change their passwords immediately (see chapter 5.11).

Configure the instrument access settings as needed (see chapter 5.5.8).

The User Administrator may login and create new users (Operator, further User Administrators and System Administrators) to the user group (see chapter 5.10.2).

Option 3: Setup user management by joining an existing user group

Select 'Join existing user group' if this is not your first instrument and you want to join this instrument to your existing user group.



Select a local user group list (.zip file) that you have downloaded from another instrument of the target user group (see chapter 5.10.5) and click UPLOAD FILE.

The instrument is now added to this existing user group. All users from the imported local user group list can login on the instrument.

NOTE: If the automatic user synchronization is activated (see chapter 5.5.10) user lists will continuously and automatically be synchronized between all instruments of the user group that are connected to the same network.

NOTE: It is recommended import the instrument settings (see chapter 5.5.21) from another instrument, to ensure consistent settings across all instruments in your user group.

5.10. LOCAL USER MANAGEMENT

This section is only relevant if the instrument is part of a user group (see chapter 5.9.6). Please refer to the table in chapter 5.2 to see when/to which user role this tile is visible.

This chapter explains how to manage the local users.

5.10.1. USER ROLES

Under the user management every user is assigned one specific user role. The same role may be assigned to multiple users, but every user may be assigned to one user role only. User rights are strictly separated by user role:

- The **Operator (OP)** role is dedicated to using the instrument to performing air sampling. The Operator is using the local user interface (see chapter 4.5) to interact with the instrument.
- The **System Administrator (SA)** role is dedicated to configuring the instrument settings, managing the audit trail and initializing the user management. The System Administrator is using the browser-based user interface (see chapter 5.2) to interact with the instrument.
- The **User Administrator (UA)** role creates and manages Operator, System Administrator and (other) User Administrator users. The User Administrator is using the browser-based user interface (see chapter 5.2) to interact with the instrument.
- The **Service Engineer (SE)** role is only available to authorized service engineers of the MBV/Merck service organizations. The Service Engineer is mainly using the browser-based user interface (see chapter 5.2) to interact with the instrument.

While Operator, System Administrator and User Administrator roles only exist when a user management has been setup (i.e. if the instrument is part of a user group), Service Engineer role exists independent of a user management. Service Engineer needs to authenticate with a key file and password even if the instrument is in userless mode.

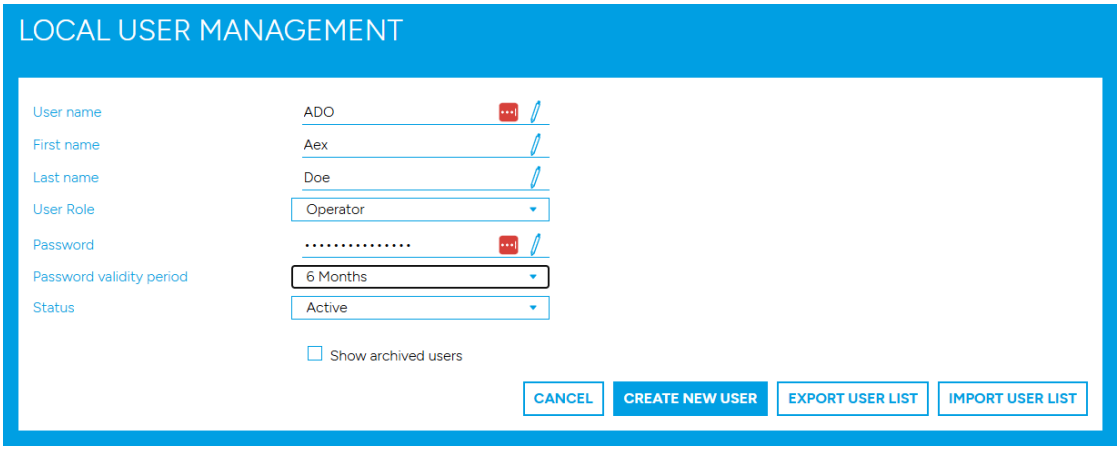
NOTE: The definition of the user roles and their access rights are not configurable.

NOTE: If the same person has multiple roles or changes roles, different users need to be created for each role. Suggestion: add '_OP' '_SA' or '_UA' to the username to clearly distinguish the different users per role.

NOTE: It is **strongly recommended to maintain at least two valid User Administrators at all times** to ensure there is a backup in case one of the User Administrator can no longer login. It may be advisable to generate an extra User Administrator and store the corresponding username and password in a (virtual or physical) safe. Neither the Service Engineer nor the manufacturer have a backdoor to rescue a user group if all User Administrator are locked-out. In case of problems with login please refer to the troubleshooting in chapter 8.3.6.

5.10.2. CREATE NEW USERS

The User Administrator can generate multiple User Administrators and multiple System Administrators for the same user group. Operators are managed as local users, unless Active Directory login has been enabled (see chapter 5.5.9)



To create a new user the User Administrator must complete the following parameters:

- **Instrument type:**
  Defines on which instruments the generated user will have access to
  - MAS-100 Atmos (sampler for compressed gases)
  - MAS-100 Sirius
- **Username:**
  Used for login. Must be unique within a user group. To allow for a fast login, it is recommended to use short abbreviations rather than long names.

  NOTE: The instrument will not allow a username already existing in the user list (including archived users). However, the instrument cannot prevent creating a username that is available on another instrument only.

  NOTE: Once a user has been created, the unique username as well as the user role cannot be changed. If the same person has multiple roles, different users/usernames must be created for each role. Suggestion: add '_OP' '_SA' or '_UA' to the username to clearly distinguish the different users per role.
- **First name / Last name:**
  NOTE: Several users may have the same first and last name, but their usernames must be different.
- **User role:**
  Operator, System Administrator or User Administrator

  NOTE: Service Engineers can only be created by the MBV service organization. They are not part of the user list.
- **Password:**
  This field is used to set an initial password.

  NOTE: Make sure to only use characters available on the English language keyboard of the Local User Interface (see chapter 4.5.4).

  NOTE: Communicate the username along with the initial password to the user and request the user to change the password immediately to a personal and confidential password (for Operators see chapter 4.5.5, for System/User Admin-

istrators see chapter 5.11). The instrument does not enforce a change of password upon first login. Every user must safeguard their personal username and password.

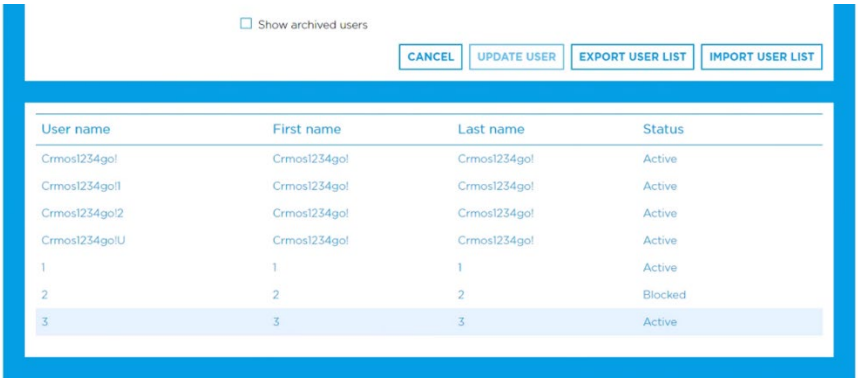
- **Password validity period:**
  Sets the duration of password validity (password needs to be renewed thereafter). Available options are: no limit, 1 month, 3 months, 6 months, 12 months
- **Status:**
  Each individual user can have one of the following states:
  - Active: the user is able to login on the instrument. Select this status when creating a new user.
  - Blocked: The user has been blocked, e.g. due to repeated (three times) entry of the wrong password or by being blocked by the User Administrator. User has no more access to instrument(s) of user group.
  - Archived: If a user is no longer active (e.g. has left the company or changed roles), that user may be archived (to ensure consistency with existing audit trail entries, user cannot be deleted, just archived). An archived user has no more access to instrument(s) of the user group.

    NOTE: When switching Operators from a local user list to active directory login, all Operators on the local user list will be automatically marked as archived.

Once finished the selection, click CREATE NEW USER to add the user to the local user list.

5.10.3. VIEW USER LIST

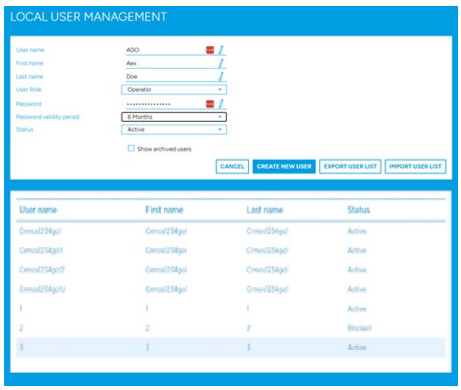
Users are listed on the user list in the lower section of the USER MANAGEMENT tile:



To include archived users active the show archived users checkbox.

5.10.4. MODIFY EXISTING USERS

The User Administrator can modify listed users and their properties as follows:



- Select an existing user by clicking on the corresponding entry in the user list (lower section of the window). The data is then automatically transferred to the fields in the upper section of the window.
- Make the required changes (e.g. blocking/unblocking a user or set a new password) and click the UPDATE USER button. The information will then be updated in the user list.

NOTE: The unique usernames as well as the user roles cannot be changed. If the same person has multiple roles or changes roles, different users need to be created for each role. Suggestion: add '_OP' '_SA' or '_UA' to the username to clearly distinguish the different users per role.

5.10.5. EXPORT USER LIST

The exported user list may be used to restore a backup of the user list, for manual user synchronization (see chapter 5.5.10) between instruments as well as to join an instrument to an existing user group (see chapter 5.9.6).

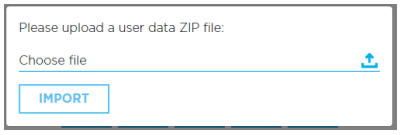
To avoid potential data loss, it is recommended to export and safeguard the local user list on a regular basis and whenever changes are made to the user list.

Click EXPORT USER LIST to download the user list as a .zip folder to the hard drive of your computer.

NOTE: This file contains unencrypted user data. The password itself is not part of the file (it only contains a password_hash that does not allow to re-engineer the password itself). It is in the responsibility of the User Administrator to handle this file in accordance with company policy and it is recommended to save the file at a safe place.

NOTE: the name of the .zip file may be changed but not the content. Changing the content invalidates the file integrity. The integrity of the downloaded .zip folder may be checked (see chapter 5.8).

5.10.6. IMPORT USER LIST



In the pop-up window select a user list .zip file that has previously been exported from an instrument within the same user group and confirm the file selection by clicking IMPORT.

NOTE: Import of a user list is only possible if the instrument from where the list got exported belongs to the same user group as the instrument where you want to import. If needed, join both instruments to the same user group first (see chapter 5.9.6).

NOTE: It is not possible to import user lists from e.g. text files or spreadsheet files.

NOTE: The imported list will replace the existing list, i.e. the existing and imported lists will not be merged!

5.10.7. USER SYNCHRONIZATION

User information needs to be synchronized between instruments, for the creation of a new user, a password change or a blocking/unblocking/archiving of users on one instrument to become effective on the other instruments of the user group.

Automatic synchronization is recommended. For automatic synchronization to work, several conditions need to be met, and the instrument needs to be configured accordingly (see 5.5.10).

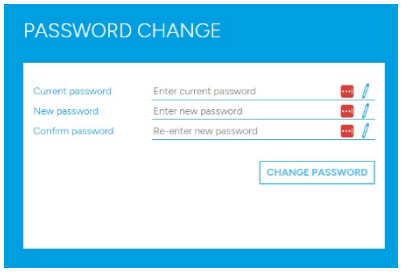
Alternatively, **manual synchronization** may be performed by following these steps:

- The User Administrator defines a master instrument. The User Administrator performs all user management tasks on this master instrument and all users are changing passwords only on this master instrument.
- The User Administrator exports the user list from the master instrument (see chapter 5.10.5).
- The User Administrator logs in on all other instruments of the user group (one after another) and imports the user list .zip file that has previously been exported from the master instrument (see chapter 5.10.6).

5.11. PASSWORDS CHANGE

This section is only relevant if the instrument is part of a user group (see chapter 5.9.6), as this tile allows the System Administrator and User Administrator to change their password.

NOTE: Password change for Operator is via the local user interface (see chapter 4.5.5).



Enter the current password, then the new password, confirm the new password and click CHANGE PASSWORD.

Passwords must match the setting for password constraints (see chapter 5.5.8). The local user is updated automatically.

The password validity is defined by the User Administrator upon setting up a new user (see chapter 5.10.2).

5.12. REMOTE CONTROL

The instrument may be controlled remotely and fully automated using a RESTful API. This is a Representational State Transfer Application Programming Interface (API or web API) that conforms to the constraints of REST architectural style and allows for interaction with RESTful web services.

With the use of the built-in documentation (see chapter 5.12.2) it is easy to make some first steps with this feature without much prior knowledge. However, this is an advanced feature and integrating the instrument into an automated environment does require experience in programming and a good understanding of the instrument (i.e. this user manual and the built-in documentation do not intend to teach programming software).

5.12.1. FUNCTIONALITY

Most functionality described in this manual may be controlled remotely by sending API commands to the instrument via USB or WiFi instead of manually clicking on the local user interface or the browser-based user interface.

Please note following restrictions and guidelines:

- The instrument cannot receive API commands when turned off. Turn the instrument on manually. Connect a power supply or ensure that the instrument battery is sufficiently charged to not run out of power while being controlled remotely.
- There is no command to remotely power-off the instrument.
- There is no command to remotely enter Standby-Mode. Note however, that the instrument will enter stand-by mode by itself, if time of activity reaches the configured 'Time until Standby' (see chapter 5.5.13).
- The instrument cannot receive API commands when in standby without power supply connected. Connect a power supply to prevent the instrument to become unresponsive if it enters standby without power. You may prevent the instrument from entering standby (with or without power) by ensuring activity is more frequent than the duration configured 'Time until Standby' (see chapter 5.5.13). If the instrument is entering standby with power supply connected, use the API call 'hardware button' (i.e. Home button) to wake-up the instrument.
- Sample, leak and flush work in 'standby with power' and 'charging-only' modes.
- As in manual operation, sequence of commands needs to be respected, and the instrument accepts commands only if it is ready and in an appropriate state.
- If a user management is setup on the instrument (see chapter 5.9.6) the instrument will accept commands only, if the appropriate user is logged in.
- If a user management is set up on the instrument (see chapter 5.9.6) the System Administrator has the possibility to enable starting a sampling and getting the last sampling result without login (see chapter 5.5.20).
- If optional sampling barcode screens are enabled (see chapter 5.5.17) the corresponding barcodes need to be scanned with a barcode reader connected to the instrument (see chapter 3.4) and cannot be sent to the instrument remotely.
- Sampling Result screen can currently not be confirmed remotely.

5.12.2. COMMANDS

From a computer connected to the instrument either via USB (see chapter 5.1.1) or via WLAN (see chapter 5.1.2) use the corresponding IP address for all communication with the instrument.

Please consult the comprehensive built-in documentation of the interface at the IP address http://192.168.254.1:9000/swagger/ui assuming the instrument is connected via USB. (If connected via WLAN instead, simply use the IP address of the network connection instead – see chapter 5.1). You may try out the commands in the swagger documentation by clicking on the corresponding command and click Try it out and then Execute. The corresponding action will be triggered, and the command syntax displayed:

- You may copy the cURL command into a Windows command window to execute the same command from there.
- You may copy the Request URL into the address line of the browser window to execute the same command from there.

If you want to implement remote control of advanced functions such as login or change of password, it is recommended to perform the corresponding actions manually from the browser-based user interface and observe in the browser debug window the actual commands exchange with the instrument. The sequence of commands may then be used to implement your own script for remote control.

Some commands (all commands marked with a lock symbol in the built-in documentation) required the correct session key to be used (to prevent the instrument from accepting the command from a computer other than the one that established the connection). If no user management is setup (userless mode) a default session key '**FFFFFFFF**' is used/must be used.

In order to execute the command from any programming language of your choice (e.g. when integrating the remote control of the instrument on a superordinate computer system like a LIMS), translate cURL command to the programming language of your choice. Artificial Intelligence or dedicated online tools may help in the translation process for inexperienced users (Convert curl commands to code e.g. curlconverter.com).

Example 1

To request the instrument information (see chapter 5.4) from an instrument connected via USB

- copy this cURL into a windows command window:
  curl -X GET "http://192.168.254.1:9000/api/information" -H "accept: application/json"
- or copy this Request URL into a browser command line:
  http://192.168.254.1:9000/api/information

Example 2

To start a sampling on an instrument connected via USB, with a delay of 10 seconds, sampling volume 50 liters, flow rate of 100 SLPM with lid A

- copy this cURL into a windows command window:
  curl -X GET "http://192.168.254.1:9000/api/sampling/start?delay=10&volume=50&flow_rate=100&lid=A" -H "accept: text/plain"
- or copy this Request URL into a browser command line:
  http://192.168.254.1:9000/api/sampling/start?delay=10&volume=50&flow_rate=100&lid=A

NOTE: for this command the instrument must be calibrated for 100 SLPM with lid A

Parameters may be adjusted in the above example as needed (as long as they are valid).

Example 3

To get the results from the last sampling via USB

- copy this cURL into a windows command window:
  curl -X GET "http://192.168.254.1:9000/api/sampling/last-result" -H "accept: text/plain"
- or copy this Request URL into a browser command line:
  http://192.168.254.1:9000/api/sampling/last-result

6. CALIBRATION

Calibration determines the measurement deviation of an instrument to a reference (calibration unit). Adjustment is used to adjust the instrument to a reference, useful e.g. in the event of a calibration deviation that exceeds the specification of the instrument. A valid adjustment is the precondition for a calibration.

Adjustment and calibration of the instrument are crucial to ensure correct performance. As the sampling volume is the integration (multiplication) of sampling flow rate and sampling duration/time, it is important to calibrate both, the sampling flow rate (see chapter 6.1) and the sampling timer (see chapter 6.3).

Both, sampling flow and sampling timer may be calibrated automatically. Traceable calibration certificates are generated on the instrument and may be authenticated electronically.

An as-found calibration should be performed when the instrument is taken out of operation (e.g. before service or maintenance tasks are performed on the instrument). The goal is to assess the state of the instrument in which it was last used. It is recommended perform this as the same conditions as the last as-left calibration to provide a best basis for comparison.

An as-left calibration should be performed before the instrument is handed back to operation (e.g. after service or maintenance tasks have been performed on the instrument) to ensure instrument accuracy. It is recommended to perform as close as possible to the conditions in operation (e.g. altitude, temperature, accessories, ...). As-left calibration extends the calibration validity (see chapter 6.1).

The instrument is adjusted and calibrated prior shipping from the factory. **It is recommended to perform a new as-left calibration before commissioning the instrument into operation** (independent of the remaining calibration validity indicated).

There are options for adjustment and calibration of MAS-100 Sirius:

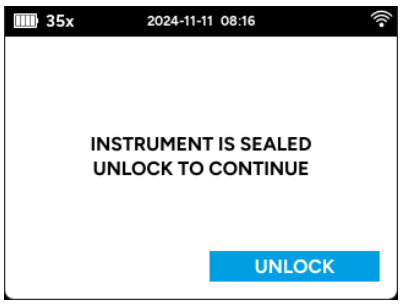
- Perform them yourself, using a MAS-100 Regulus as calibration unit by following the instructions in chapter 6.2 and for timer calibration in chapter 6.3.
- Send the instrument to a service center (see chapter 7.2.3).

6.1. CALIBRATION VALIDITY

A new instrument calibration will be sealed. Equally an as-left flow calibration performed by an authenticated System Administrator or Service Engineer will seal the instrument upon logout of that user.

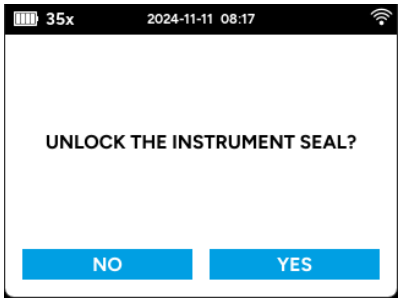
NOTE: As-left calibrations performed without login in the userless mode or calibrations with a deviation exceeding the accuracy specifications (see section 5.9.6) do not trigger a calibration seal.

The instrument needs to be unsealed before it can be operated.



To unseal the instrument, start the instrument.

On the 'calibration seal' screen on the local user interface tap 'UNLOCK'.



And confirm to unlock the instrument seal by pressing 'YES'.

NOTE: if the user does not unlock the instrument, it will turn off automatically after two minutes.

After breaking the calibration seal, the calibration certificate may be viewed on the browser-based user interface (see chapter 6.4). You may want to double-check that the calibration meets your requirements.

Calibration validity is limited as components of the instrument may age and drift over time. Calibration must be repeated at regular intervals, to ensure the instrument (still) performs within specification. It is strongly recommended to operate the instrument only with a valid instrument calibration. The instrument calibration is valid, if both sampling flow and automatic sampling timer calibration are valid:

- sampling timer as-left calibration is valid for 24 months from the last as-left sampling timer calibration.
- sampling flow as-left calibration is valid for 12 months from the moment the instrument is unsealed, but no longer than 24 months from the last as-left sampling flow calibration.

  NOTE: If the instrument has not been manually unsealed within 12 months in transportation or storage, the calibration validity period of 12 months will start automatically. This is to ensure the instrument calibration validity expires latest 24 months after the last as-left calibration, safeguarding against potential instrument drifts or degradation, e.g. due to unknown storage conditions.

Specified storage and operating conditions (see chapter 4.1 and 9.2) must be observed for as-left calibration to remain valid. It is strongly recommended to perform a calibration as part of the instrument commissioning to operation, in order to ensure the instrument is performing within specifications.

The instrument may be configured to warn the Operator of an upcoming expiration of the calibration (see chapter 5.5.18). If the manual timer check is used instead of the automatic timer calibration, the instrument cannot determine the calibration validity. In these cases, the corresponding user setting shall be set to "tracked externally" (see chapter 5.5.18).

6.2. PERFORMING SAMPLING FLOW CALIBRATION

A dedicated calibration unit, MAS-100 Regulus, is required for air flow calibration. This provides a traceable calibration:

Traceability: MAS-100 Sirius **>>** MAS-100 Regulus **>>** MBV's ISO17025 calibration lab and from there to national standards that are aligned to international standards

NOTE: a valid as-left calibration of the MAS-100 Regulus (supported by the corresponding as-left certificate [Part 2/2]) is a requirement for a valid MAS-100 Sirius as-found/as-left flow calibration. An as-found certification [Part 1/2] of MAS-100 Regulus is not relevant in this regard.

Refer to user manuals

Read the safety data sheet and the user manual of the MAS-100 Regulus carefully before using the instrument and/or any accessory supplied with the anemometer.

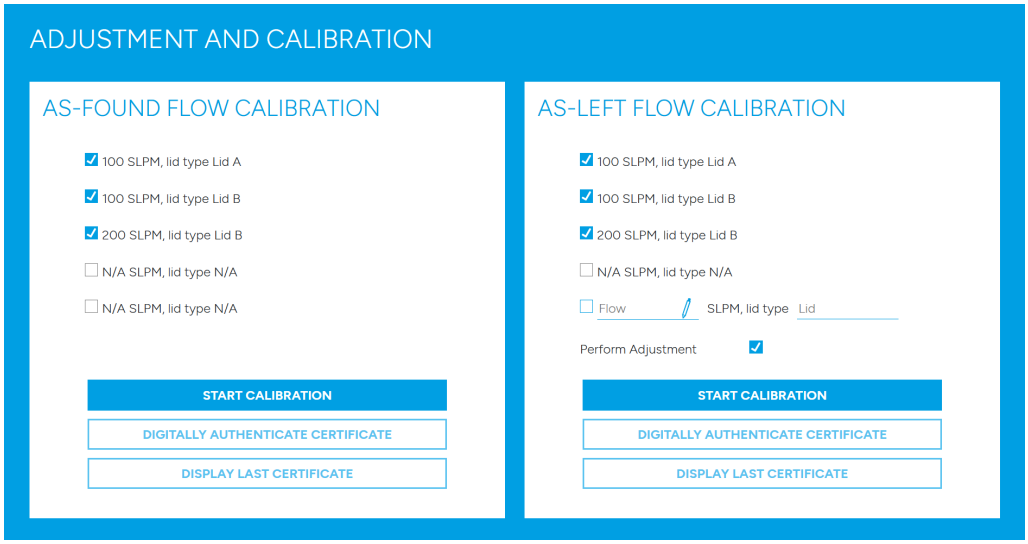
MAS-100 Regulus is portable. It can be used in a local service center or directly at the customer site.

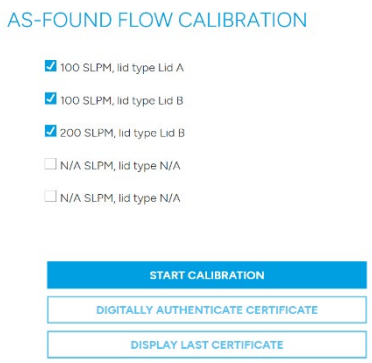
NOTE: To achieve optimal performance during sampling, it is advised to perform adjustment/calibration in the configuration and at a temperature as close as possible to those used for sampling in operation and to have the air sampler as well as the anemometer tempered to that temperature.

Perform the following steps in a clean place free of draft air, with the instruments placed on a stable surface. Keep the instrument out of direct sunlight. Avoid turbulences or movement during calibration.

6.2.1. AUTOMATIED FLOW CALIBRATION WITH OPTIONAL ADJUSTMENT

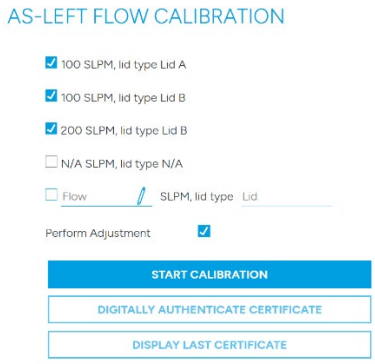
- On the local user interface: navigate to the menu screen (see chapter 4.5.5).
- If a user management is setup (see chapter 5.9.6), login to the browser-based user interface as System Administrator (see chapter 5.3) or Service Engineers (see MAS-100 Sirius Service Manual).
- Access the 'ADJUSTMENT AND CALIBRATION' tile on the browser-based user interface (see chapter 5.2). The upper part of the window refers to flow calibration.





Choose whether you want to perform an as-found or an as-left calibration

- For performing an as-found calibration, refer to the left side of the window: the flow/lid combinations of the last as-left calibration are selected by default (boxes ticked). Unselect any flow/lid combinations that you do not want to include in the as-found calibration. At least one flow/lid combination must be selected.



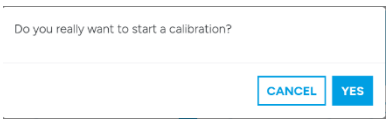
- For performing an as-left calibration refer to the right side of the window: select all flow/lid combinations that you wish to calibrate the air sampler for. There is one customizable slot where a user-defined flow/lid combination can be set. Flow must be in the range between 50 and 200 SLPM. Lid type must correspond the first letter of the lid marking (see chapter 2.6).

  By default the 'Perform Adjustment' box is ticked so that an adjustment of the instrument is performed prior the as-left calibration. If the instrument is already well adjusted for all selected flow/lid combinations the adjustment may be skipped (untick the 'Perform Adjustment' box).

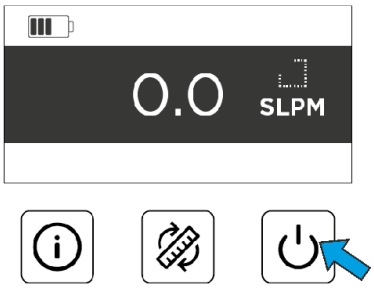
For information on the available lid types see chapter 2.6.

Click START CALIBRATION for as-found calibration (left side of the window) or as-left calibration (right side of the window)

NOTE: Performing an as-found/as-left calibration will overwrite the previous as-found/as-left calibration (including the corresponding calibration certificate) and a new adjustment will overwrite a previous adjustment. Overwritten adjustment and calibration data cannot be recovered.



Click YES in the in the pop-up window to confirm that you want to start the adjustment/calibration.



MAS-100 Regulus interface

If the MAS-100 Regulus was used with air samplers other than the MAS-100 Sirius turn off the MAS-100 Regulus by pressing the ON/OFF button (otherwise there is a risk communication problem during the calibration sequence).

Connect the MAS-100 Regulus to the MAS-100 Sirius using the USB-C cable supplied with the MAS-100 Sirius. The anemometer will switch on automatically.

NOTE: Alternatively, you may connect both the air sampler and the anemometer to your PC via USB cables and run the Regulus Bridge Software on you PC (see chapter 5.9.4).

(example)

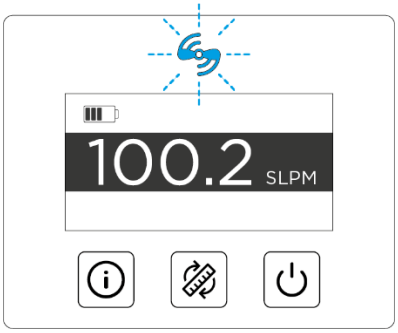
Follow the step-by-step instructions on the local user interface that will guide you through the adjustment/calibration sequence.

The instrument will ask you to place a specific perforated lid type onto the instrument and to place the MAS-100 Regulus on top of that perforated lid. Confirm by clicking OK on the local user interface.

If the message 'WAITING FOR ANEMOMETER' is displayed for more than 5 seconds on the local user interface of the air sample, try following trouble shooting steps:

- Ensure you use a cable compliant to USB standard. We recommend using the USB type C cable delivered together with the MAS-100 Sirius and available as an accessory.
- Disconnect the cable for at least 5 seconds before reconnecting.
- For MAS-100 Regulus up to serial number 18710: disconnect the USB cable from USB-C connector of the MAS-100 Regulus, flip the USB-C connector on the cable upside down and reconnect it to the MAS-100 Regulus.

NOTE: In case the Calibration of the MAS-100 Regulus has expired, the calibration can be continued with the connected anemometer or aborted.



MAS-100 Regulus interface

As soon as the instrument detects the connection to the MAS-100 Regulus the adjustment/calibration sequence will start. The local user interface is indicating the current step of the sequence.

The above sequence is repeated for each flow/lid combination that were selected (step in the sequence above). Just follow the instructions on the local user inter-face.

NOTE: Aborting an ongoing adjustment will leave the instrument without valid adjustment and therefore in a state that does not allow sampling.

NOTE: Do not remove the MAS-100 Regulus from the air sampler as long as its impeller running LED is on or flashing.

Once all flow/lid combinations were processed, a PASSED/FAILED result will be shown on the local user interface of the air sampler. Confirm by clicking OK.

Reconnect the PC to the instrument (USB or WiFi) and reload/refresh the 'ADJUSTMENT AND CALIBRATION' tile on the browser-based user interface (see chapter 5.2).

To view the calibration certificate, click DISPLAY LAST CERTIFICATE, for as-found on the left side of the window, for as-left on the right side of the window.

For information related to the certificates, refer to chapter 5.5.19.

NOTE: Logout after the calibration activity to allow the calibration seal to be set (see chapter) before starting to perform further operation or using the instrument.

To investigate the cause of a failed as-found calibration, perform a leak test (see chapter 4.5.5) and if necessary, follow the corresponding trouble shooting.

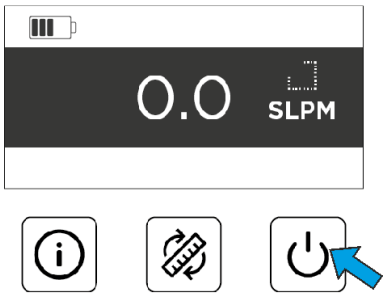
Do the same in case of a failing as-left calibration and/or repeated the as-left calibration including an adjustment.

6.2.2. MANUAL FLOW CALIBRATION

Manual flow calibration provides an alternative to the recommended automated flow calibration (refer to chapter 6.2.1). Only the automated as-left flow calibration allows to perform an adjustment (i.e. manual adjustment is not possible).

NOTE: The air sampler will not generate a calibration certificate and will not be able to reach a valid calibration state based on manual calibration. If this case is your standard calibration process, consider configuring the Instrument Setting 'calibration reminder' of the air sampler to 'tracked externally' (chapter 5.5.18).

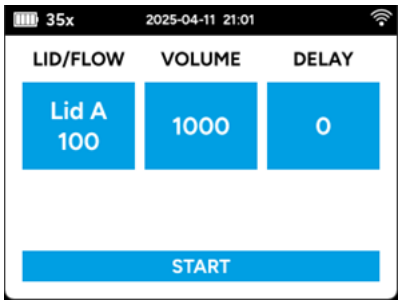
Manual flow calibration does not required access to the browser-based user interface and may therefore be executed by any user.



MAS-100 Regulus interface

Start the anemometer by pressing the ON/OFF button.

The anemometer is in mass flow mode, showing SLPM on the display.



Start a regular sampling on the instrument (see chapter 4.5.4).

MAS-100 Regulus interface

Wait for the display of the anemometer to stabilize before manually reading off multiple flow values and calculating the average of those values. Follow your own calibration procedure in doing so.

6.3. PERFORMING SAMPLING TIMER CALIBRATION

While synchronizing current date/time (see chapter 5.5.6) is concerned about the absolute date/time (e.g. it is 2025-06-12 16:05:24), here we are interested whether the internal timer that is controlling the sampling duration runs at the correct speed (e.g. if 10 minutes on the instrument are actually 10 minutes).

NOTE: there is no adjustment of the timer (calibration only).

6.3.1. AUTOMATED TIMER CALIBRATION

The automated time calibration provides convenient and accurate calibration of the internal sampling timer. It does so by comparing time expired on the internal sampling timer with the time expired on a NTP (Network Time Protocol) server.

For the automated timer calibration to function the instrument requires a stable connection to a wireless network (see chapter 3.1 and 5.5.19; WiFi icon should be stable ON, see chapter 4.5.2) and from there to the specified NTP server on the internet (unless an internal NTP server is used, see below). I.e. the timer calibration does not work via USB connection to a PC.

NOTE: If your instrument does not have connection to a NTP server in the network, a 'manual timer calibration' (see chapter 6.3.2) may be performed instead. However, without a successful automated 'timer calibration' the instrument state will not show the state of valid calibration. To address this, set the calibration reminder to 'tracked externally' (see chapter 5.5.18).

NOTE: The NTP server must support NTPv1 protocol.

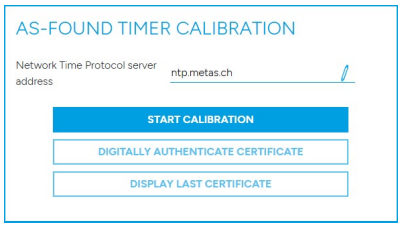
The IP address of the NTP server that shall be used for the automated calibration you may selected from the below list. By configuring a NTP server operated by a national standard organization you obtain a full calibration **traceability:** MAS-100 Sirius **>>** national standards that are aligned to international standards
Following list provides the selection of such NTP servers supporting NTPv1 protocol (as of July 2025):

ORGANIZATION	IP ADDRESS
METAS Federal Institute of Metrology, SWITZERLAND	e.g. ntp.metas.ch
NPL National Physical Laboratory, UNITED KINGDOM	e.g. ntp1.npl.co.uk
VSL VSL National Metrology Institute, NETHERLAND	e.g. ntp.vsl.nl
INRIM Istituto Nazionale di Ricerca Metrologica, ITALY	e.g. ntp1.inrim.it
LRTE Laboratório de Referências de Tempo e Espaço, BRAZIL	e.g. lrtest1.ntp.ifsc.usp.br
KRISS Center for Time and Frequency, REPUBLIC OF KOREA	time.kriss.re.kr
NAO Time Keeping Office, JAPAN	s2csntp.miz.nao.ac.jp
NPLI Time and Frequency Metrology Section, INDIA	e.g. time.nplindia.in

NOTE: Alternatively, any other NTP-Server may be specified (available on the internet or within the customers internal network), however the customer is responsible for traceability.

- On the local user interface: navigate to the menu screen (see chapter 4.5.5).
- If a user management is setup (see chapter 5.9.6) login to the browser-based user interface as System Administrator (see chapter 5.3) or Service Engineers (see MAS-100 Sirius Service Manual).

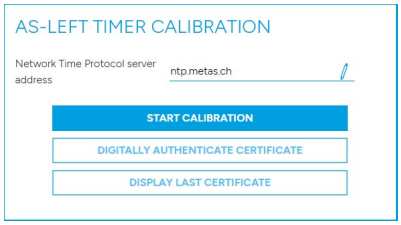
– Access the ‘ADJUSTMENT AND CALIBRATION’ tile on the browser-based user interface (see chapter 5.2). The lower part of the window refers to timer calibration



Choose whether you want to perform an as-found or an as-left calibration

– For performing an as-found calibration, refer to the left side of the window: NTP server address of the last as-left calibration is set by default but may be changed.

  NOTE: Changes to the NTP address will not be stored (i.e. are lost upon reloading the page).

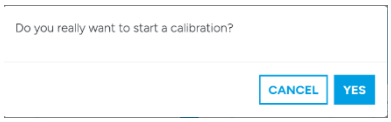


– For performing an as-left calibration refer to the right side of the window: specify the IP address of NTP server you would like to use as a calibration reference (for details see above).

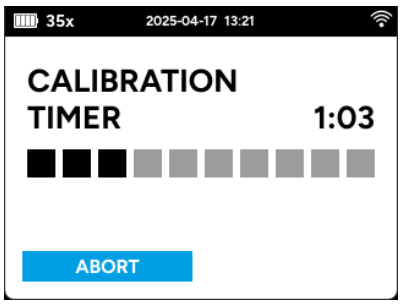
  NOTE: Changes to the NTP address will not be stored (i.e. are lost upon reloading the page).

Click START CALIBRATION for as-found calibration (left side of the window) or as-left calibration (right side of the window)

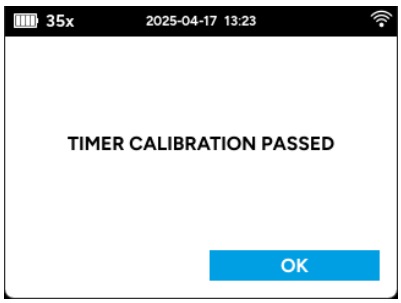
NOTE: Performing an as-found/as-left calibration will overwrite the previous as-found/as-left calibration (including the corresponding calibration certificate) and a new adjustment will overwrite a previous adjustment. Overwritten adjustment and calibration data cannot be recovered.



Click YES in the in the pop-up window to confirm that you want to start the adjustment/calibration.



The local user interface displays a count-down for 1 minute 40 seconds.



Once the 100 seconds have expired, a PASSED/FAILED result will be shown on the local user interface of the air sampler. Confirm by clicking OK.

To view the calibration certificate, on the browser, click DISPLAY LAST CERTIFICATE, for as-found on the left side of the window, for as-left on the right side of the window.

For information related to the certificates, refer to chapter 5.5.19.

The most likely cause for a failed timer calibration is an overloaded internet connection causing unusual lags on the response of the NTP. Simply re-execute the calibration.

6.3.2. MANUAL TIMER CALIBRATION

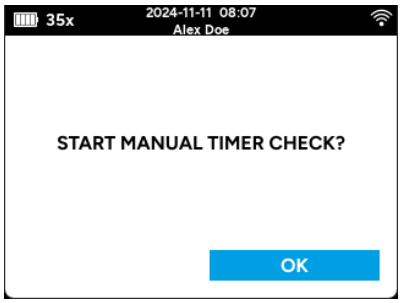
Manual timer calibration provides an alternative to the recommended automated timer calibration (refer to chapter 6.3.1). It may be useful, if the requirements for the automated timer calibration are not met.

NOTE: The air sampler will not generate a calibration certificate and will not be able to reach a valid calibration state based on manual calibration. If this case is your standard calibration process, consider configuring the Instrument Setting 'calibration reminder' of the air sampler to 'tracked externally' (chapter 5.5.18).

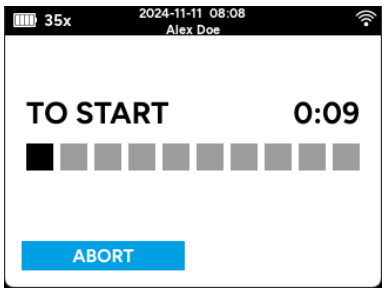
By using a calibrated stopwatch, you may obtain a traceable calibration of the timer manually. However, due to variation of the human reaction time, the manual process is inherently less accurate than the automatic one.

On the browser-based user interface navigate to the 'ADVANCED FUNCTIONS tile (see chapter 5.9).

In the section 'Manual Timer Check' click START.



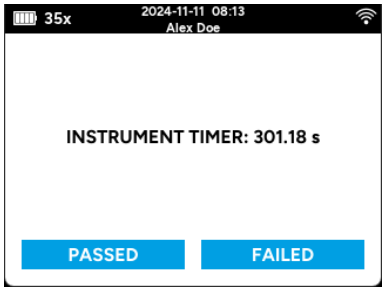
Get ready with your manual stopwatch and click START on the local user interface.



The local user interface will show a count-down to the start of the test. Start your manual stopwatch on the sound of the buzzer at the end of the countdown.

Wait for the counter counting down 300 seconds. As the count-down approaches 0 seconds, get ready again with your manual stopwatch and stop it on the sound of the buzzer at the end of the countdown.

NOTE: To minimize the influence of the reaction time of the user operating the stopwatch, the test duration is 300 seconds (as compared to 100 seconds using the automatic option).



The local user interface now displays the exact time expired on the instrument. Compare this to the time you have measured with the manual stopwatch and derive a passed/failed result based on your own criteria.

Click PASSED or FAILED to create the appropriate audit trail entry (category 'Technical').

Alternatively, to the manual process as described here above (e.g. in case you want to perform a timer calibration without accessing the browser based user interface) you may simply run a sampling and start and stop your manual stop watch on the start and stop of the blower. Please note however, that this will provide an even less accurate result, as the blower is not starting/stopping abruptly.

6.4. CALIBRATION CERTIFICATES

6.4.1. VIEWING CALIBRATION CERTIFICATE

A digital version of the latest calibration certificates is stored on the instrument. Executing an automated calibration (see chapter 6.2.1 for flow and chapter 6.3.1 for timer) will overwrite the previous certificate.

A digital version of the latest flow flow/timer as-found/as-left calibration certificates is stored on the instrument and may be viewed by clicking the corresponding DISPLAY LAST CERTIFICATE in the 'ADJUSTMENT AND CALIBRATION' tile on the browser-based user interface (see chapter 5.2).

NOTE: For a new instrument the digital version corresponds to the printed version of the as-left calibration certificate delivered with the instrument.

PRINT CLOSE

Certificate number 220038-20250408-183508-130886

CALIBRATION CERTIFICATE FLOW (AS-LEFT)

Object

Examinee	Microbial Air Sampler	Hardware version	04_02
Instrument type	MAS-100 Sirius	Application software version	Config_files_changed-6-g9f9084666
Instrument serial number	220038	Customer instrument label	Prototype D
Last adjustment date[1]	2025-04-08		

Reference instrument

Calibrated in an ISO 17025 or NIST accredited calibration laboratory, providing traceability to international standards.

Target flow	(100...200) SLPM	Anemometer	MAS-100 Regulus
Last calibration date[1]	2024-12-07	Serial number of reference	18012

Ambient conditions

Temperature	24.9 °C	Pressure	966.5 mbar

Calibration data

Lid type[2]	Target flow [SLPM]	Examinee [SLPM]	Reference [SLPM]	Deviation [%]	Passed indication[3]
A	100.0	100.0	100.4	0.4	Passed
B	100.0	100.0	100.2	0.2	Passed
B	200.0	200.0	200.4	0.2	Passed

Calibration date	2025-04-08	Examiner	

[1] The date is displayed in the format YYYY-MM-DD.
[2] Corresponds to the first letter of the sampling lid identification code.
[3] The deviation of the reference air flow does not exceed +-2.5% for a target flow ≥100SLPM or +-5.0% for a target flow <100SLPM.

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PRINT CLOSE

Certificate number 220038-20250412-205219-130886

CALIBRATION CERTIFICATE TIMER (AS-FOUND)

Object

Examinee	Microbial Air Sampler	Hardware version	04_02
Instrument type	MAS-100 Sirius	Application software version	Config_files_changed-6-g9f9084666
Instrument serial number	220038	Customer instrument label	Prototype D

Reference instrument

Calibration against a specific NTP reference server may provide traceability to national standards.

NTP reference server	ntp.metas.ch

Calibration data

Target duration [s]	Examinee [s]	Reference [s]	Deviation [%]	Passed indication[2]
100.000	100.308	100.368	-0.060	Passed

Calibration date	2025-04-12	Examiner	

[1] The date is displayed in the format YYYY-MM-DD.
[2] The deviation of the internal timer does not exceed +-0.25%.

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Each calibration certificate contains

- **Certificate number:**
  A unique certificate number
- **Title:**
  identifying the document as a flow or timer certificate, for as-found or as-left calibration.

  NOTE: In case of a flow calibration, the last flow adjustment date is indicated.
- **Object:**
  identifying the instrument that was the object of the calibration.
- **Reference Instrument:**
  identifying the instrument that was used as the reference for calibration:
  - for flow: the anemometer, including its last calibration date
  - for timer: the NTP server
- **Calibration data:**
  the actual values logged during calibration
  - for flow: one line per flow/lid combination
  - Examinee corresponds to the Object (see above)
  - Reference corresponds to the Reference instrument (see above)

  NOTE: deviations are indicated in % (i.e. not in SLPM or seconds)

  If the calibration indicator was enabled (see chapter 5.5.19) at the time the calibration was performed, each line includes a passed/failed, based on the instrument specification.
- **Calibration Date:**
  the date the calibration was performed
- **Examiner:**
  name of the user that authenticated the certificate (if applicable, see) and/or filed for a manual signature after printing
- **Footnotes:**
  clarifications related to the contents of the certificate

PRINT

The certificate can be exported by clicking the PRINT on top left corner and using the print functionality of the web-browser to e.g. print the certificate to a file in PDF format.

NOTE: Certificate print/export is not performed by the instrument but by the web-browser. For the blue fields to be printed you might have to adjust your browser's printer settings to include printing of background graphics.

The certificate view may be closed by clicking the CLOSE on top left corner or hitting 'Esc' on your keyboard.

6.4.2. DIGITALLY AUTHENTICATE CALIBRATION CERTIFICATE

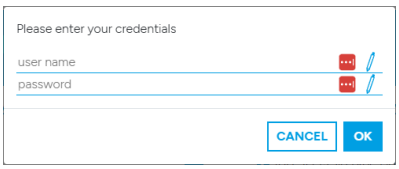
Digital authentication places first and last name of the logged-in user in the 'Examiner' field of the corresponding certificate. This functionality is only available to a logged-in System Administrator (user management required, see chapter 5.9.6)

NOTE: Authentication is optional and instrument calibration validity (see chapter 6.1) is independent of authentication.

NOTE: Calibration of new instruments and in service at MBV are performed and digitally authenticated by a user logged-in onto the instrument. Therefore, calibration certificates issued by MBV are valid with digital authentication and without manual signature.

Click the corresponding DIGITALLY AUTHENTICATE CERTIFICATE in the 'ADJUSTMENT AND CALIBRATION' tile on the browser-based user interface (see chapter 5.2).

NOTE: If the button is inactive, there is either no certificate to authenticate (perform the corresponding calibration first) or no user management is setup on the instrument (see chapter 5.9.6) and therefore the user is not logged in.



Enter your username and password in the pop-up window and click OK.

The 'Examiner' field on the calibration certificate now shows the first and last name of the user that authenticated.

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7. CARE AND MAINTENANCE

7.1. CLEANING AND DECONTAMINATION

Please carefully read the safety instructions in chapter 1.3.3 before performing any cleaning and decontamination of the instrument.

Avoid skin irritation

Follow cleaning instructions, use appropriate cleaning agents and follow necessary safety precautions to prevent skin irritation.

7.1.1. LIST OF COMPATIBLE INGREDIENTS

The following active ingredients have been tested and are compatible with the specified instrument parts:

INSTRUMENT	METHOD	ACTIVE INGREDIENT	CONCENTRATION (V/V)	CONDITIONS
Housing (incl. display and bottom plate) Accessories: perforated lid, blind lid, dust cover	Wipe cleaning	Ethyl alcohol	70%	Follow the disinfectant manufacturer's recommendations
	Wipe cleaning	Propan-2-ol	70%	
	Wipe cleaning	Benzalkonium chloride	0.5%	
	Wipe cleaning	Polyhexamethyien Biguanide hydro chloride	0.25%	
	Wipe cleaning	Hydrogen peroxide	1%	
	Wipe cleaning	Acetic acid	<10%	
	Wipe cleaning	Peracetic acid	0.08%	
Instrument at rest or in flush mode (see chapter 4.5.5)	Gas cleaning	Vaporized hydrogen peroxide (condensing and non-condensing)	up to 600 ppm	Validated with skanfog® setup. Repeat with own setup to confirm effectiveness.
Perforated lid, blind lid, dust cover	Dry or moist heat sterilization (autoclaving)	Moist heat (steam) Dry heat	Saturated	121°C for 20 mins (recommended) or 134°C for 5 mins ≤180 °C for ≤60 mins **NOTE:** Autoclave the material according to your validated cycle and use either autoclaving bag or box **NOTE**: Avoid handling lids when still hot. Do not drop or impact (hot) lids to prevent mechanical damage.

7.1.2. AUTOCLAVING

Do not autoclave the instrument.

Instrument may be permanently damaged.

Autoclaving is limited to the perforated lid, dust cover and blind lid.

Remove the perforated lid and dust cover from the instrument for autoclaving.

Summarized recommendations:

- Protect the instrument with a blind lid (see chapter 4.1) until the perforated lid is placed back onto the instrument.
- Do not place the dust cover on the perforated lid during autoclaving.
- Use autoclaving boxes, reusable autoclaving bags (soft type) or durable single use bags. In any case make sure the bag or box is large enough.
- Positioning of the handle towards the more resistant side of the bag and on the side of the sealed side of the autoclave bag to allow easy and aseptic removal of the lid from the bag after autoclaving

7.1.3. WIPE DISINFECTION

The instrument, including the perforated lid, is made of stainless steel and a glass cover on the display, which makes it very robust and compatible with a wide range of disinfectants (list see chapter 7.1.1). The seamless design with smooth surfaces and no visible screws or edges enables thorough cleaning and decontamination of the instrument.

As preparation, to protect the USB-C interface it is recommended to apply the USB-C cover.

As well, before wiping the display, select the cleaning mode in the menu (see chapter 4.5.5) to disable the touch functionality for 5 seconds, to prevent any mis manipulation on the instrument when wiping across the display or Home button.

NOTE: As this is a sensitive electronic equipment, we recommend not to spray any liquids to prevent any accidental harm to the instrument.

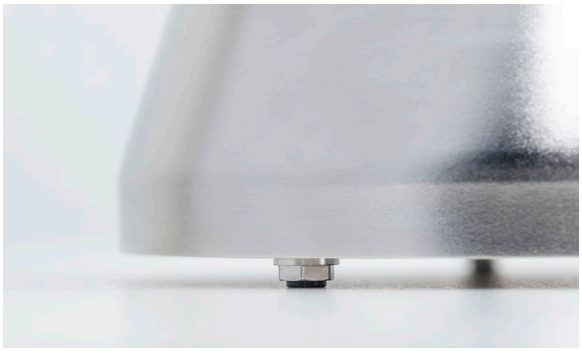
Do not touch the instrument filter during wiping
Risk to affect the filter integrity and damage the filter

Protect instrument from entering liquids
The instrument is not IP 65 ingress protected. Do not spill nor spray liquids onto the instrument, in particular into the USB-C interface or into the blower opening.

For wiping, use a pre-saturated non-woven wipe moistened with surface sanitizer with active ingredients as listed in chapter 7.1.1. Use the pull and lift technique and ensure wiping strokes overlap 10-25% to make sure no surface area is missed. Wait until the disinfectant has dried completely before using the instrument.

Protect instrument from entering liquids
Any disinfection/sanitization solution must be completely dried before using the instrument for a sampling so that the holes of the perforated lid are not blocked by dried disinfectant.

NOTE: The instrument feet keep the instrument above the supporting surface to prevent liquids entering the instrument via the bottom plate.



7.1.4. FLUSH DECONTAMINATION

In general, cleaning the inside of the instrument (e.g. the air flow channel) is not necessary. The exhaust filter ensures that nothing would be blown into the environment in case of any impurities inside the instrument head.

If needed, the inner path of the instrument can be decontaminated. Possible use cases include the transfer of the instrument between cleanroom grades or before/after instrument service.

Instrument flushing with clean air, ethanol, IPA or volatile hydrogen peroxide (VHP):

- Position the instrument in a VHP chamber/lock or laminar flow hood cabinet
- Start the instrument flushing mode as described in chapter 4.5.5.
- Run the VHP cycle

NOTE: Both passive (at rest) as well as active (instrument flush mode see chapter 4.5.5). VHP decontamination of the instrument was tested, and complete microbial inactivation (6-log reduction) confirmed using the skanfog® technology. The validity for a different decontamination cycle with other VHP dosing quantities and contact times must be checked confirmed.

OR

Spray two short strokes of 70-90 % ethanol/water (or IPA/water) from a spray bottle in front of the sampling head with the perforated lid installed. Repeat it after some time.

Protect instrument from entering liquids

The instrument is not IP 65 ingress protected. Do not spill nor spray liquids onto the instrument, in particular into the USB-C interface or into the blower opening.

– Stop the flushing mode after the VHP cycle has ended or the spray intervals have been completed.

7.2. SERVICE

Before reporting a problem to your service contact, please check if chapter 8 already proposes a solution to your problem.

Several service tasks can be performed by the customer such as the exchange of a filter (see chapter 7.2.1) or the replacement of the instrument battery (see chapter 7.2.2).

For any other service tasks such as calibration and repair, get in touch with your local service contact (see chapter 7.2.3).

7.2.1. FILTER EXCHANGE

A new instrument comes with an exhaust filter already installed. Follow these steps only if you want to exchange the filter.

We recommend replacing the exhaust filter once a year.

Hazard of falling instrument (parts)

There is a risk of damage to the cover glass should the filter carrier fall on the display. Follow the described filter exchange workflow.

Risk of biocontamination

Used filters may be biologically contaminated. Handle with appropriate personal protective equipment and dispose of according to your biosafety protocols.

Risk of filter/instrument damage

During the whole process do not apply excessive force for not potentially damaging the filter, filter carrier or instrument.

Do not touch the filter surface with hands or tooling to prevent it being punctured and damaged.

Ensure that the instrument is used according to the specified humidity environment (see chapter 9.2). Using the instrument in a high humidity environment increases the risk of a biofilm.

Correct filter mounting for filter efficiency

The filter needs to be correctly mounted for the instrument to meet the specification with respect to filter efficiency and particle contamination. Follow the described filter exchange workflow.

Dismount filter only for replacement with original accessory

Only dismount the filter in case of replacing it with a new one (risk of spreading particles that have collected on the inside of the used filter). Only use the recommended filter available as an accessory (see chapter 2.7).

Dismount the filter

The filter is held in a filter carrier, which is secured in the housing via a bayonet lock.

To remove the filter, follow these steps:

- Place the instrument upright and hold down with one hand, without pressing down.
- Gently press up onto the filter carrier (about 0.5 mm into the head) with the other hand and turn it in clockwise direction (approximately 15°) until it unlocks from the bayonet.
- Lower the hand to remove the filter carrier with the filter from the head.
- Remove the old filter from the carrier (discard the old filter).

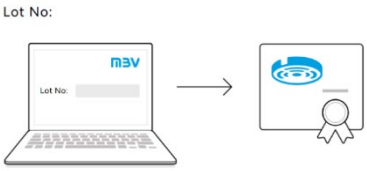
Mount the filter

- Place the new filter into the filter carrier and the filter carrier in your hand

  NOTE: the filter does not have a preferred direction (i.e. any side can face up/down)
- Secure the instrument with the other hand.
- Lift the filter carrier back into the instrument head, ensuring correct orientation for the filter carrier to match the bayonet lock.

  NOTE: The filter carrier can be inserted in one position/rotation only (poka yoke). Once the filter carrier is locked in place, the section without ventilation holes is facing the handle (instrument back side).With the upper hand on the lid, secure the instrument.
- Apply a gentle upward pressure until you feel a firm resistance.
- Rotate the lower hand counterclockwise until the end position of the bayonet lock is

reached.



Filter traceability

Every filter packaging contains a sticker with the filter lot number. At https://certificate.mbv.ch/ the filter lot number can be entered and the corresponding filter certificate downloaded.

NOTE: Make sure you remember the batch number of the filter. It is recommended to stick its sticker to the Quick Start Guide contained in the transport case or log the filter lot number matching the instrument elsewhere.

7.2.2. BATTERY REPLACEMENT

A new instrument comes with a battery already installed. Exchange the battery only if you have noticed a considerable deterioration in capacity and the battery does not offer you sufficient sampling cycles anymore (see chapter 8.3.2). The battery can be exchanged by a user without breaking the warranty seal.

	**Hazard of explosion and/or fire** Use the instrument only with the original battery delivered with the instrument or available as an accessory.
	**Risk of instrument damage** When removing the battery, fully locking the clip on the battery connector before releasing the connector from the instrument. Mismanipulation may damage the battery wires/connector and/or the electronic board in the instrument.
	**Propper disposal of used battery** Do dispose of the used battery properly, according to local regulations. Do not dispose the battery with normal waste.
	**Observe the indiquated torque** Tightening the foot screws with too much force might lead to damage on the display unit.

Follow these steps to exchange the instrument battery:

- Turn off the instrument, place a lid onto the instrument and turn the instrument upside down.
- Lift the carrier for the WiFi dongle out of the base plate (see chapter 3.1).
- Carefully remove the 3 feet using a 7mm spanner or hexagonal socket key. Lift off the base plate. Lift the old battery out of the battery compartment with one hand and use the other hand to firmly push down the locking clip on the connector to release it from the instrument before gently pulling out the connector.

  NOTE: Do not pull on the battery cable. Ensure that the connector has fully unlocked before pulling out the connector to prevent damage to the instrument.

- Connect the new battery to the instrument, ensuring the connector locks in firmly.
- Place the new battery in the battery compartment and arrange the battery wires beside the battery, within the battery compartment.

  NOTE: Ensure the wires are not below or on top of the battery, as they may get compressed after mounting back the base plate.

- Place the base plate back into place, replace and gently tighten the three feet.
  NOTE: For tightening the feet use a maximum torque of 0.25Nm. Rather than using a normal spanner it is recommended to use a torque wrench with controlled maximum torque of 0.25Nm.
- Place back the carrier for the WiFi dongle following chapter 3.1.

NOTE: While no battery is connected to the instrument, the date/time will be maintained for >12 hours. If the instrument is without battery for longer, the instrument date/time may have to be set again (see chapter 5.5.6).

7.2.3. SERVICE CONTACT

There are two main service contacts available:

- Send the instrument to the manufacturer:

  MBV AG Service
  Industriestrasse 9
  CH-8712
  Stäfa Switzerland
  service@mbv.ch / https://www.mbv.ch/servicecenters

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

7.2.4. PREPARE INSTRUMENT FOR EXTERNAL SERVICE

To prepare the instrument for maintenance/service, the System Administrator is advised to:

- Ensure the proper **decontamination** of the instrument

Hazard of microbiological or toxic contamination

When using the instrument in connection with potentially harmful substances, follow all relevant regulations to prevent personal injury.

Before sending an instrument to service or anywhere outside of your jurisdiction, ensure necessary decontamination.

- In case a user management is setup on the instrument (see chapter 5.9.6): User Administrator to **export the Local User List** (see chapter 5.10.5) to maintain an up-to-date backup.
- **Export the Instrument Settings** (see chapter 5.5.21) to maintain an up-to-date backup.
- **Export the audit trail** (see chapter 5.7.2) to prevent possible data loss in case the main board gets damaged during transport or needs to be replaced during maintenance/repair.
- As long as there is no memory warning/lock (see chapter 8.2.1) do NOT delete the audit trail, as warning/error/technical events logged are needed by the Service Engineer to efficiently analyze and diagnose potential problems with the instrument.

  Only if the instrument shows a memory warning or memory lock, delete the audit trail (see chapter 5.7.3) to ensure there is enough memory for service to use and investigate the instrument.

  NOTE: In case of insufficient memory, service might be prevented from performing necessary operations, as the Service Engineer role does not have access to the CLEAR AUDIT TRAIL.
- Use the provided transport case and overpack the transport case for shipping to avoid damaging of the instrument and accessories (see chapter 4.2).
- Ensure appropriate labeling of the shipment

Hazard of explosion and/or fire

The instrument contains a Lithium-Ion battery which is regulated for air transportation. Please respect IATA rules in case your instrument should travel by air.

When receiving back the instrument from maintenance/service the System Administrator is advised to:

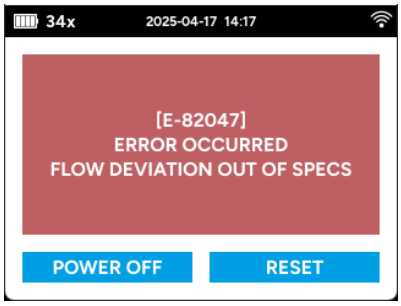
- Break the calibration seal (see chapter 6.1) and check the as-left calibration certificates (see chapter 6.4.1).
- Export (see chapter 5.7.2) and delete (see chapter 5.7.3) the audit trail.
- Review and approve/reject setting changes done by the Service Engineer (see chapter 5.6).
- If the Base PCB was replaced during service, restore the Instrument Settings (see chapter 5.5.21) and Local User List (see chapter 5.10.6).
- Ensure local date/time are correct and adjust if necessary (see chapter 5.5.6).

8. ERRORS AND WARNINGS

Errors and warnings are identified through their unique identifiers (ID). This chapter provides relevant information related to the cause and possible resolution of these errors/warnings.

NOTE: Strings that are associated with these unique IDs (as displayed on Local User Interface and in the audit trail) are by themselves not unique and may change in future versions of the software, to allow correcting unclear or misleading wording or providing more helpful messages to the user.

8.1. ERRORS



Errors events [E-XXXXX] are displayed on the local user interface (red screen) and logged in the audit trail of the instrument.

The user has the option to reinitialize the instrument (RESET), or the user may confirm to power-off the instrument.

Please consult below table for trouble shooting.

ERROR ID	MESSAGE, DESCRIPTION, TROUBLESHOOTING
E-10382	**The private user group key is missing.** Instrument has experienced critical internal data corruption and needs to be repaired by service.
E-11245	**Insufficient battery charge for operation.** Triggered if battery charge is insufficient at start of calibration. Charge battery and try again.
E-11385	**Battery temperature out of bounds.** Triggered if battery temperature is out of predefined limits. Let the instrument cool down and make sure you are working inside the instrument's temperature specifications. If the problem persists, the battery must be replaced.
E-11471	**Battery not present.** Triggered if battery controller does not see the battery. Shut the instrument down and make sure the battery is inserted and connected. If the problem persists, the battery must be replaced.
E-35104	**Unable to save to USB storage.** Triggers if storage is write-protected or has a format different from FAT32 or current demand exceeds the limits. For trouble-shooting refer to chapters 8.3.4.
E-35958	**Settings archive has invalid signature.** Occurs, if the signature of an uploaded file (settings file and user list are protected with such signature.
E-74340	**Communication with reference device failed.** Occurs, if the connection to the reference anemometer is interrupted. Check cable connection.
E-74426	**Anemometer response timed out.**

ERROR ID	MESSAGE, DESCRIPTION, TROUBLESHOOTING
	Triggered if anemometer is disconnected during initialization (approx. 2 sec after connecting). Once attached, keep the anemometer connected.
E-74782	**Communication with head timed out.** The head did not return an answer in time.
E-74957	**Calibration aborted due to error.** Triggered if one of the following actions fails: start/stop calibration, communication with anemometer, measure flow/ambient pressure/temperature/humidity. Ensure that anemometer is securely connected and running.
E-75923	**Calibration aborted due to flow adjustment failure.** Triggered if adjustment of flow rate fails or if calculated RPM values are invalid. Make sure to select an appropriate target flow for your lid, mount the lid and the reference properly, avoid drafts or obstruction of airflow.
E-82047	**Error occurred in head.** Triggered by one of several failures. A corresponding exception text is displayed on the local user interface and logged as parameter in the audit trail. For description, refer to chapter 8.1.1
E-82923	**Communication with head failed.** Triggered if either: – Failed to get measurement from head – Invalid head operation mode – Could not get time from head or from server – Could not set certificate Ensure that head and base are securely connected.

8.1.1. HEAD ERROR DETAILS

LOCAL USER INTERFACE	AUDIT TRAIL PARAMETER	DESCRIPTION
Sanity check of ambient temperature failed	kSanityCheckOfAmbientTemperatureFailed	The exception is triggered during head start-up, if the measured temperature is far outside the specifications. This usually indicates a defective sensor.
Sanity check of ambient pressure failed	kSanityCheckOfAmbientPressureFailed	The exception is triggered during head start-up, if the measured pressure is far outside the specifications. This indicates a defective sensor.
Sanity check of diff pressure 1 failed Sanity check of diff pressure 2 failed	kSanityCheckOfDiffPressure1Failed kSanityCheckOfDiffPressure2Failed	The exception is triggered during head start-up, if the differential pressure is far outside the specifications. This indicates a defective sensor.
Sanity check of humidity failed	kSanityCheckOfHumidityFailed	The exception is triggered during head start-up, if the measured humidity is invalid. This indicates a defective sensor.
Sanity check of temperature consistency failed	kSanityCheckOfTemperatureConsistencyFailed	The exception is triggered during head start-up, if the difference between two of the three temperature sensors is way outside the specifications. This indicates a defective sensor or abnormal, transient conditions, e.g. bringing the instrument from a cold/hot environment and starting it up without acclimatization time.
Diff pressure drop out of specs	kDiffPressureDropOutOfSpecs	The exception is triggered during a sampling, if the difference between the two differential pressure sensors is > 500 Pa. This indicates a defective sensor.
Ambient pressure out of specs	kAmbientPressureOutOfSpecs	The exception is triggered during a sampling, if the measured pressure is outside the specification. Make sure to meet operating conditions. Sampling accuracy can be affected.
Flow deviation out of specs	kFlowDeviationOutOfSpecs	The exception is triggered during a sampling, if the deviation of the measured mass flows of the two sensors is out of specification. This indicates abnormal sensor drift.
Humidity out of specs	kHumidityOutOfSpecs	The exception is triggered during a sampling, if the measured relative humidity is outside the specification. Make sure to meet operating conditions. Sampling accuracy can be affected.

LOCAL USER INTERFACE	AUDIT TRAIL PARAMETER	Description
Blower speed feedback	kBlowerSpeedFeedback	The exception is triggered during a sampling, if the blower speed limit is reached before the target flow is reached, e.g. if the dust cover is mounted.
Blower startup failure	kBlowerStartupFailure	The exception is triggered at blower start, if the impeller cannot rotate, e.g. the impeller is jammed by an object, or the motor control is defective.
Blower overvoltage Blower undervoltage	kBlowerOverVoltage kBlowerUnderVoltage	The exception is triggered during blower operation, if the motor control circuit detects a too high or too low voltage for proper operation. If the problem persists, the motor control is defective.
Blower overheat	kBlowerOverHeat	The exception is triggered during blower operation, if the motor control circuit detects too high motor temperatures. If the problem persists, the air path, impeller, motor and control circuit must be checked.
Flow sensor1 not responding Flow sensor2 not responding	kFlowSensor1NotResponding kFlowSensor2NotResponding	The exception is triggered during head start-up, if one of the two differential pressure sensors does not send any values. This indicates a defect of the head PCB.
Ambient sensor not responding	kAmbientSensorNotResponding	The exception is triggered during head start-up, if the ambient sensor does not send any value. This indicates a defect of the head PCB.

8.2. WARNINGS

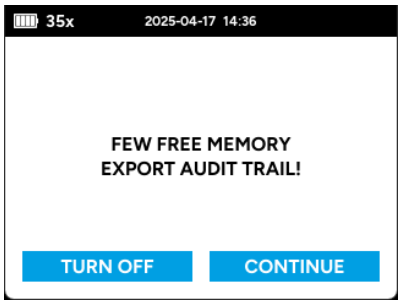
Warning events [W-XXXXX] are logged in the audit trail of the instrument. Only the warnings listed in chapters 8.2.1 to 8.2.5 are additionally shown on the local user interface. The following table provides information to the different warning IDs.

WARNING ID	MESSAGE, DESCRIPTION, TROUBLESHOOTING
W-10024	**Opening a login session is not allowed.** Log-in on browser-based user interface is not allowed during sampling and calibration processes. Touch the Home button to go to the menu screen before log-in.
W-10106	**The password status is undefined.** Restart the instrument and try again.
W-10143	**User data from foreign user group.** Importing a user list from a foreign user group is not allowed. Join existing user group (see chapters 5.9.6) before importing (see chapters 5.10.6).
W-10185	**User Administrator is not logged in.** User Administrator tasks are only allowed if logged-in with User Administrator role. Hard refresh the page (Ctrl+F5 on most browsers) to see current log-in status (see chapters 5.2).
W-10254	**User key data could not be read correctly or might be corrupted.** Applies to Service Engineer only. Restart the instrument and try again. Make sure the unaltered key file is used.
W-10257	**The ID of the login session is invalid.** Possible cause: login was performed from a different browser session. Hard refresh the page (Ctrl+F5 on most browsers) to see current log-in status (see chapters 5.2). Logout and log-in as User Administrator again.
W-10284	**Username is empty.** Make sure every user gets a unique username.
W-10288	**Wrong password was entered.** If the Password is lost, the User Administrator has to set a new password (see chapters 5.10.4).
W-10310	**User key is not valid for this instrument type.** Applies to Service Engineer only. Use the appropriate key file for this instrument.
W-10316	UserManager_ExpiredSETokenDetected **Service engineer with expired training tried to login.** A new Service Engineer key file must be issued by MBV.
W-10355	**The new password is the same as the old password.** The new Password set has to be different than last used password
W-10381	**The user's first name is empty.** This warning is triggered, if loaded user has not set first name
W-10401	**This user already exists.** Every username must be unique within a user group.
W-10427	**This user is not allowed to perform this action.** Hard refresh the page (Ctrl+F5 on most browsers) to see current log-in status. Log-in with the appropriate role for the action.

WARNING ID	MESSAGE, DESCRIPTION, TROUBLESHOOTING
W-10432	**Password has expired.** Renew password.
W-10521	**User data is invalid.** Fill in all fields for a new user.
W-10533	**The password violates the constraints.** The entered password violates the configured password constrains and/or the blacklist of common passwords, if active (see chapter 5.5.8).
W-10588	**This user is already logged out.** Hard refresh the page (Ctrl+F5 on most browsers) to see current log-in status.
W-10591	**This user is blocked.** Contact the User Administrator to re-activate the user.
W-10644	**This user is already logged in.** Hard refresh the page (Ctrl+F5 on most browsers) to see current log-in status.
W-10670	**Setting a new password is not allowed.** Make sure to set a password according to the password rules (see chapters 5.5.8).
W-10692	**This user is archived.** The User Administrator can re-activate a user.
W-10696	**Action is not allowed.** The selected action is not allowed in the current user management mode or with Active Directory.
W-10792	**The user's last name is empty.** Make sure every user's last name is filled in.
W-10817	**User key of foreign user group tried to login.** Applies to Service Engineer only: Use a key file of the correct user group.
W-10824	**Wrong user management mode.** The selected action is not available in the current user management mode or with Active Directory.
W-10903	**Operators have to login on instrument.** Only Administrators have access via browser-based user interface.
W-10904	**Administrators have to login in browser.** Only Operators have access via local user interface.
W-10918	**Login is not allowed in the current state of the instrument.** On the local user interface, navigate to the menu screen for log-in.
W-10940	**User could not be found.** Check spelling of the user and whether the user is on the current user list of the instrument.
W-11671	**Unable to start charging.** Due to an internal exception the charging could not start. Disconnect charger, restart the instrument and connect charger again.

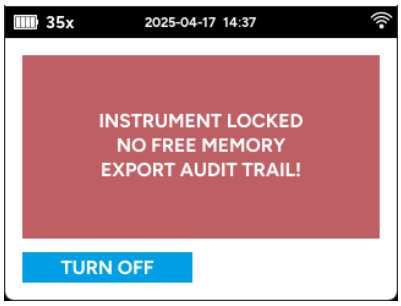
WARNING ID	MESSAGE, DESCRIPTION, TROUBLESHOOTING
W-11681	**Unable to stop charging.** Due to an internal exception the charging could not stop. Restart instrument. Disconnect charger, restart the instrument and connect charger again, wait until charging starts, then disconnect charger.
W-28195	**Time zone could not be changed.** Internal exception. Restart instrument and set time zone again.
W-28409	**Instrument time could not be changed.** Internal exception. Restart instrument and set time again.
W-28758	**Failed to unlock access to update page.** Internal exception. Restart instrument and try update again.
W-28885	**Instrument time could not be changed.** Internal exception. Restart instrument and set time again.
W-35271	**Data export to memory stick failed.** USB dump failed because archiver is already running. Restart instrument. Do click 'Export' only once and await the download to be completed. If you are using USB memory-stick, try a different stick or refer to troubleshooting in chapter 8.3.4.
W-46053	**Instrument lost the time because battery was empty too long.** See chapter 8.2.2
W-46148	**The instrument is running out of memory.** See chapter 8.2.1
W-46694	**The instrument has no memory left.** See chapter 8.2.1
W-62531	**Communication with Network Time Protocol server failed.** Make sure the instrument has network access over WiFi and your network has access to an NTP-server. In case of Timer calibration ensure the entered NPT server address is valid
W-82018	**Lid not detected** The lid in use does not seem to be consistent with the type of lid selected during sampling selection (see chapter 4.5.4). See chapter 8.2.3 for troubleshooting.
W-82019	**Filter not detected** The exhaust filter could not be detected during sampling (see chapter 4.5.4). See chapter 8.2.5 for troubleshooting.
W-82048	**Base received a warning from the head** Please refer to string logged in the audit trail as 'Parameter': • k**LidNotDetected** see chapter 8.2.3 • k**FilterNotDetected** see chapter 8.2.5 The corresponding warning is as well be included in the AT entry of the sampling (see W-82018, W-82019)

8.2.1. MEMORY WARNING



A memory warning is issued on the local user interface when the audit trail reaches 75'000 entries or when less than 1'000'000 bytes are left.

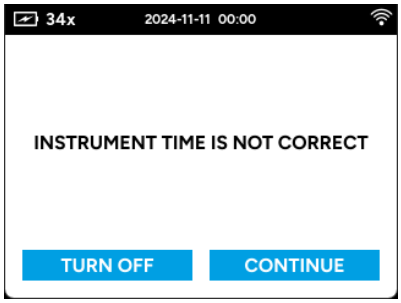
The user is advised to export the audit trail (see chapter 5.7.2) at this point and delete the audit trail from the instrument (see chapter 5.7.3).



An instrument lock message is issued on the local user interface when the audit trail reaches 100'000 entries or when less than 500'000 bytes are left.

At this point the operation of the instrument is blocked until the audit trail is deleted from the instrument (see chapter 5.7.3).

8.2.2. CLOCK WARNING



When the instrument date/time is lost, the instrument will show a warning message on the local user interface of the instrument during start-up.

The System Administrator may set the instrument time (see chapter 5.5.6).

If the user acknowledges this warning without adjusting the time, the instrument will work correctly but all time stamps in the audit trail will not be correct. It is not recommended to operate the instrument without correct date and time.

8.2.3. LID CHECK

The lid check is described under sampling screen in in chapter 4.5.4.
It is sensitive to any changes in the resistance of the air flow path.

- The lid check is performed throughout the sampling (i.e. not only at the start of the sampling)
- Ensure correct lid is used: Lid type in sample setting must match lid marking (see chapter 2.6). E.g. Lid type 'A' in sampling setting matches the first character 'A' of the lid marking.
- Inspect the lid for clogged holes in the sieve.
- Ensure nothing is blocking the air exhaust from the head.
  NOTE: a blocked filter will lead to a lid check warning, not a filter warning.
- Perform leak test (see chapter 4.5.5) to ensure the lid is sealing tightly.
- Check may be affected by accessories used in the air flow (e.g. if sampling with Tube and Tube Adapter, see chapter 4.4.4). Remove all accessories from the air flow and repeat the sampling with the perforated lid only. No warning should show in this configuration.

- If using accessories in the airflow (or alterations in the airflow path): perform an as-left calibration with adjustment (see chapter 4.5.5) with that specific configuration (i.e. including that accessory).
- If you perform your sampling under conditions that do trigger the Lid Check warning, but you have verified your setup as correct, you may decide to ignore the Lid Check warning (Lid Check warning cannot be disabled).

8.2.4. FILTER CHECK

The filter check is described under sampling screen in chapter 4.5.4. It is sensitive to the dynamic changes of pressure in front of the filter during sampling.

- The filter check is performed throughout the sampling (i.e. not only at the start of the sampling)
- **NOTE**: The check detects a missing filter or severe alterations in the filter integrity. It cannot ensure the integrity of the filter nor the filter performance of the instrument.
- Ensure the filter is present and properly mounted (see chapter 7.2.1). No warning should show up in this situation.
- **NOTE**: a blocked filter will lead to a lid check warning (see chapter 8.2.3), not a filter warning.
- **NOTE**: the filter check might be triggered by sudden pressure changes in the environment, e.g. strong thunder, door fast-closing to an enclosed room.
- If you perform your sampling under conditions that do trigger the Filter Check warning, but you have verified your setup as correct, you may decide to ignore the Filter Check warning (Filter Check warning cannot be disabled).

8.3. FURTHER TROUBLESHOOTING

Before consulting the troubleshooting, please check the corresponding section of this user manual, to ensure you understand the expected behavior and have read the relevant information and notes.

Check if any warnings and errors have been logged in the audit trail (see chapter 5.7, use the appropriate filters). If so, check first the corresponding error ID in chapter 8.1 or warning ID in chapter 8.2. Further check the audit tail for technical log entries (use appropriate filters) for information that may be helpful to understand a certain behavior and possibly narrow down a problem.

Further, it may be helpful to perform a service file download (see chapter 5.9.3) to save a snapshot of the instrument state. The download consists of a series of text files which may help you or your service representative to diagnose the observed behavior.

If the problem persists, get in touch with your local service contact (see chapter 7.2.3).

8.3.1. LEAK TEST

See chapter 4.5.5 for purpose and performing of the leak test. Follow these steps if the result of the leak test is 'INVESTIGATE LEAK':

1. Perform a visual inspection of the sealing surfaces on the perforated lid and the instrument. Ensure there are no obvious dents or scratches.
2. Perform the leak test with a second lid. If passing with the second lid, that second lid and the instrument are okay. Put the first lid aside.

3. If leak test of the second lid results in ‘investigate leak’, perform an as-found flow calibration with both lids. If both as-found calibrations are okay, the first lid, the second lid and the instrument are okay. Otherwise contact the service department (see chapter 7.2.3).

8.3.2. BATTERY CHARGING

The instrument contains a Li-ion battery pack with an internal safety-board; Nominal voltage: 7.38; Total capacity: 9.6Ah, 70Wh.

Typical time to fully recharge the battery is 3.5 hours when using the recommended power supply which is available as an accessory.

If the battery is not charging, it is charging slowly or the charger does not seem to work properly:

- NOTE: While the charger stays connected, the battery management will stop charging at 100% and will only resume charging once the charge state falls below 85% threshold. This feature enhances battery lifetime by preventing continuous ‘trickle charge’.
- Ensure you are using the original battery delivered with the instrument or available as an accessory (see chapter 2.7).
- Ensure you use a proper cable. Use a cable compliant to USB type C 2.0 or higher. We recommend to use the USB type C cable delivered together with the instrument and available as an accessory.
  USB type A to USB type C cables for charging from a USB type A port are not supported. Current drawn from an USB type A port (e.g. power supply or notebook port) will be limited to 0.5A (to protect USB type A ports on certain notebooks from overloading) which may support instrument operation but not be sufficient for battery charging.
- Avoid connecting and disconnecting a power supply in short sequence, as this may cause the instrument SW to hang and the instrument will need a hard reset (see chapter 4.5.1).
- Ensure you are using a compliant power supply with USB Power Delivery and the specification given in chapter 9.1). Third party charging modes are not supported. We recommend using the power delivery power supply available as an accessory (see chapter 2.7).
- Actual charging times depend on the type of charger used. Using a power supply with more than 36W will not result in faster charging as the charge current of the battery is limited by the instrument. If available, MAS-100 Sirius charges in 20V mode.
- If connecting any other Power Delivery power supply to the instrument in off state, the instrument may wake up, but charging may be slow (not using the full power). If so, wait until the instrument has booted, disconnect and reconnect the power supply in order to reset the communication between power supply and instrument.
- If the battery is charging but not anymore reaching 100% charge state, the most likely cause is an imbalanced battery. Replace the battery.
- If the battery loads to 100% but reaches less than 40 sampling cycles, the battery seems to have aged (it is normal for rechargeable batteries to lose capacity over time and repeated charging discharging cycles). Replace the battery if the number of sampling cycles reached is no longer meeting the requirements of your operation.

8.3.3. USB-C CONNECTION TO PC

For issues with battery charging, please refer to chapter 8.3.2.

- Ensure you use a cable compliant to USB standard. We recommend using the USB type C cable delivered together with the instrument and available as an accessory. For communication only (but not for charging) you may use a compliant USB type A to USB type C cable.
- Ensure the cable is intact.
- Avoid connecting and disconnecting to a PC's USB-A port (USB legacy) in short sequence, in particular while the instrument is in stand-by or about to go to stand-by or wake-up from stand-by, as this may cause the instrument SW to hang and the instrument will need a hard reset (see chapter 4.5.1).
- Ensure the PC supports data transfer rates according to USB 2.0 (the data rate used by the instrument).
- Once a compliant cable connects the instrument to the PC, ensure the Instrument Information screen (see chapter 4.5.5) shows the IP address for USB as 192.168.254.1 . If the IP address is not displayed, the communication between the instrument and the PC has not been established correctly. You may try another port of the PC, another cable and/or another PC.
- If the connection is established, but connection via the browser-based user interface is not possible
  - Check the local user interface of the instrument. If there is any ongoing activity (e.g. sampling) wait for the activity to be completed or abort it. Click the Home button (see chapter 4.5.1) to get to the menu screen.
  - Check the information bar on top of the local user interface. If the name of a user is indicated, logout that user by entering standby mode, wait until standby mode has been entered, then touch the Home button (see chapter 4.5.1) to wake-up the instrument. The username should now have disappeared from the information bar.

  It should now be possible to access the browser-based user interface. In case of loading issues please hard refresh the browser page (Ctrl+F5 on most browsers).

8.3.4. USB-C CONNECTION TO DEVICES

The USB-C port supports USB on-the-go (OTG) for connecting e.g. barcode reader (see chapter 3.4), memory stick (see chapter 5.9.3) and digital anemometer (see chapter 6.2).

- Preferably, connect the OTG-device to the instrument only once the instrument has completed start-up. If Instrument is startup with an OTG-device connected to the USB-C port and goes to stand-by in that configuration, wake-up from stand-by is delayed by several seconds (but it will correctly wake-up).
- If the OTG-device has a USB type A connector, use a USB type A to type C adapter to connect it to the USB type C port of the instrument. Always remove the adapter together with the OTG-device. I.e. do not leave such adapter connected to the instrument without an OTG-device attached, as this will lead to the following behavior: when the instrument is switched off with a USB-A-to-C adapter connected (without a device attached), the instrument will start up again and again until the adapter is disconnected.
- While most simple USB type A to USB type C adapters work without problems, some adapters featuring additional ports like DisplayPort/HDMI etc. would require drivers the instrument doesn't have. In rare cases, connecting such an

adapter to the instrument, may require a reboot of the instrument for its USB-C port to again work.

- Ensure the USB cable is intact.
- The instrument can supply a connected OTG-device with up to 7.5W (1.5 A at 5V). Ensure your OTG device consumes less power or has its own power source (e.g. integrated battery or own power supply).
- If connecting a USB memory stick for service file download (see chapter 5.9.3), ensure it is formatted for the FAT32 file system. Format your memory stick for FAT32 or use a memory stick that is correctly formatted.
- When using the Regulus Bridge (see chapter 5.9.4), the cable needs to be disconnected/reconnected with for every flow/lid combination for the instrument to (re-)recognize the anemometer.

8.3.5. WIFI CONNECTION TO NETWORK

- Ensure a supported dongle is mounted. We recommend using the WiFi Dongle available as an accessory (see chapter 2.7). Other dongles may not be supported due to lack of appropriate driver on the instrument. It is not possible for the end-user to install additional drivers.
- Ensure the dongle is correctly mounted (see chapter 3.1).
- Verify the configuration of the wireless access in the Instrument Settings (see chapter 5.5.7) is correctly configured (correct SSID and password) for your wireless network.
  Temporarily (as a way of troubleshooting) you may configure Instrument Settings for an alternative network, e.g. a hotspot which you setup on a mobile phone. If the connection to an alternative network works, a compatible dongle is correctly mounted and the problem lays in the connection/configuration to the regular network. You may want to seek support from your IT-department.
- Verify that the Instrument Information screen (see chapter 4.5.5) shows an IP address for WiFi. If the IP address is not displayed, the WiFi connection has not been established.
- Ensure the PC, from which you want to connect to the instrument is located in the same network (which may not be the case if, following the above step, you temporarily configured the instrument to connect to an alternative wireless network).
- After starting up the instrument as well as after configuring the WiFi, wait until the IP address is showing in the Instrument information screen. It will take another 30 sec before a connection to the browser can be established.
- The WiFi icon on the local user interface (see chapter 4.5.24.5.5) is only displayed if the signal from the network is strong enough to ensure a reliable connection. If the IP address is being displayed in the Instrument information screen but the WiFi icon is not, a network connection has been established but the signal is weak and may not allow a reliable communication. Move the instrument close to a wireless network transmitter, to ensure sufficient signal strength.

8.3.6. LOGIN

- Operator and System Administrator having problems to login, are advised to contact their User Administrator. The User Administrator may modify the user (see chapter 5.10.4) to unblock (in case the user is blocked intentionally by the User Administrator or automatically after three failed login attempts) or (in case of forgotten/lost password) set a new password.

- User Administrators having problems to login are advised to contact a fellow User Administrator to unblock their user or set a new password (see chapter 5.10.44.5.5) or use extra credentials that have been locked in a safe (see chapter 5.10.1).
- In case no User Administrator is able to login (e.g. after a change of password or three failed login attempts), a System Administrator may try to reestablish the User Administrator access:
  1. System Administrator to disable User synchronization (see chapter 5.5.10)
  2. System Administrator to export the Instrument Settings (see chapter 5.5.21) to maintain an up-to-date backup
  3. System Administrator to re-setup user management by joining an existing user group (see option 3 in chapter 5.9.6), using the most recently exported user list.
  4. User Administrator trying to login with the password valid at the time the user list was exported.
     If login is successful:
     a) User Administrator to create at least one new User Administrator (see chapter 5.10.2)
     b) User Administrator to change own password (see chapter 5.11)
     c) User Administrator to export latest user list (see chapter 5.10.5) as a new backup.
     d) System Administrator to re-enable user synchronization (see chapter 5.5.10) if it previously was enabled.

     If login was not successful:
     a) System Administrator will need to re-setup user management by creating a new user group (see option 2 in chapter 5.9.6) losing all previously user information.
     b) System Administrator to import the Instrument Settings (see chapter 5.5.21) that were exported as part of the earlier step.
     c) User Administrator to recreate all users (see chapter 5.10.2)
     d) User Administrator to export the user list (see chapter 5.10.5) as a new backup.
     e) System Administrator to re-setup user management by joining an existing user group (see option 3 in chapter 5.9.6) **on all other instruments** that belonged to the same user group, using the user list just exported under the step before.
- In case no User Administrator nor System Administrator is able to login, contact your service organization for a Service Engineer to remove user management (see option 1 in chapter 5.9.6) **on all instruments** belonging to the user group, before the System Administrator can re-setup a new user group from scratch (see chapter 5.9.6).

8.3.7. USER LIST SYNCHRONIZATION BETWEEN INSTRUMENTS

If automatic user lists do not correctly synchronize between instruments (as mentioned in chapter 5.10.7 and described in chapter 5.5.10):

- Ensure all concerned instruments are in the same user group: compare user group in the Instrument Information (see chapter 5.4) on the browser-based user interface (note that in the instrument information on the local user interface the

information is truncated).
To change an instrument from one user group to another user re-setup its user management by joining an existing user group (see option 3 in chapter 5.9.6).

- System Administrator to ensure all concerned instruments are configured to the same network, by comparing their WiFi settings (see chapter 5.5.7)
- Ensure all concerned instruments do have access to the common network (see chapter 8.3.5).
- User Administrator to create some new user on one instrument and observe if it is being replicated to all other instruments of the user group. Depending on the number of instruments in the user group, it may take several seconds to several minutes for new user information to be replicated across the whole user group.

8.4. SOFTWARE FREEZE

- If the application software of the instrument has frozen, disconnect all accessories from the instrument and force a shutdown of the air sampler (touch the HW button on the air sample for >6.4 seconds (see chapter 4.5.1) and switch on the instrument again. Wait for the instrument to start-up completely before connecting accessories to its USB port.

9. TECHNICAL SPECIFICATIONS

9.1. MECHANICAL AND ELECTRICAL

	SPECIFICATION
Material	Body and perforated lid: 316L stainless steel **NOTE:** Minor imperfections such as small scratches, dents, marks, discolorations, spots, shadows, irregularities in the weld lines or similar appearances are not considered defects. Display cover: glass Improved sanitization
Impact protection rating	IK 08 Covering instrument including display glass.
Instrument dimensions (H x W X L)	277x147x160mm (includes lid for 90mm agar plate, lid handle positioned to the front of the instrument) Ensures stable and robust instrument stand
Weight (with perforated lid)	2.6 kg Reflects the choice of stainless steel as material
Perforated lid dimensions (H x W X L)	64x160x117 mm (including handle)
Lid closing mechanism	Magnetic without polymer seal Easier handling with less force required
Battery	MBV type H2B661.4, rechargeable Li-Ion battery, 7.4Vdc, 9.6Ah
Power Supply Unit	The charger needs to fulfil following specification: – Input: 100-240Vac, 50-60 Hz, overvoltage category II, double insulation or reinforced insulation to mains – Output: USB type C, Power Delivery (USB-PD) 5/15/20Vdc, min 10W, 36W recommended for optimized charging time
Packaging Material	Transport case shell: PP with recycling content Transport case inlay: PE foam, partially recycled Outer box: cardboard

9.2. OPERATING CONDITIONS

	SPECIFICATION
Temperature	0-40°C
Humidity	Max. 80 % RH for temperatures up to 31 °C, decreasing linearly to 50 % relative humidity at 40°C; non-condensing
Altitude	0-3'000 m above sea level. Flow rates >100 SLPM cannot be achieved above 1'500 m under all environmental conditions.

9.3. OPERATION

	SPECIFICATION
Configuration	Browser-based user interface (no internet needed)
Full recharging time	Approx. 3.5 h
Battery running time	min. 40 sampling cycles of 1000L @100 SLPM (applies for a new battery at low altitude
Leak test	The instrument offers a leak test to test the sealing of the lid onto the instrument
Instrument self-check	Warning during sampling if -wrong lid -exhaust filter missing
Airflow and tolerance	100 up to 200 SLPM ± 2.5%
Sampling volumes	Manual configuration between 50 and 4000 SL
Sampling modes	Single volume or SQS mode (interval sampling)
Physical sampling efficiency	Nominal d50 value of 1.1 µm (acc. ISO 14698/ EN 17141) at 100 SLPM
Agar plate compatibility	-90mm -55mm -Growth Direct® cassettes No adapter required
Exhaust filter	ISO 35H (HEPA H13)
Available accessories	-Tripod and quick-change adapter -Perforated lids for 100/200 SLPM flow rates and 55mm agar/Growth Direct® cassettes -Blind lid (instrument protection during lid autoclaving) -Wireless dongle for WiFi features

9.4. SAMPLING DATA MANAGEMENT

	SPECIFICATION
Data storage	Tamper proof audit trail (tamper proof within instrument and tamper evident outside instrument)
Capacity of data storage	Approx. 7'300 sampling entries
Data export	-via browser-based user interface using USB-C cable or WiFi -Sampling result QR code on instrument display -Application programmable interface (API) e.g. for LIMS/EM integration

9.5. REGULATORY COMPLIANCE

	SPECIFICATION
Accurate and reliable sampling results according to ISO 14698/ EN 17141 and EU GMP Annex 1	Two redundant mass flow sensors to detect deviations between sensor values caused by drift/malfunction of one sensor to prevent instrument operation out of specification
Physical and biological sampling efficiency according to ISO 14698/ EN 17141	Validation of physical and biological sampling efficiency on-going (100 and 200 SLPM)
Electromagnetic compatibility	EMC (CISPR 11) Group 1, Class A (Industrial and domestic location)
Maximum noise peak emission according to ISO 14644-16 and OSHA	<56 dBA (200 SLPM)
Traceable air flow according to ISO 17025 or NIST	via MAS-100 Regulus anemometer
Traceable timer calibration according to ISO 17025 or NIST	Automated timer calibration
Data Integrity and ALCOA+	-Sampling environment (location, agar, lid) can be scanned with barcode scanner connected to Sirius -tamper proof audit trail within the instrument and tamper evident outside the instrument -Sampling notes on local user interface for documentation of sampling errors -Error proof data transfer using result QR code or API interface
FDA 21 CFR part 11	Supports a 21 CFR Part 11 compliant workflow with: -tamper proof audit trail within the instrument and tamper evident outside the instrument -local 21 CFR part 11 compliant user management or connection to existing active directory (among other features)
Particle emission according to ISO 14644/EU GMP Annex 1	Suitable for operation in cleanroom class 5 according to ISO 14644 (GMP grade A)
Airflow turbulence according to ISO 14644/EU GMP Annex 1	Due to its vertical air outlet the instrument creates minimal disturbances when placed in an unidirectional air flow setting (CFD and smoke study)

APPENDIX A – FELLER CORRECTION TABLE

Positive hole conversion table according to Feller, 1950 for the different perforated lid types of the instrument:

LID A (300X0.6)

r = Number of colony forming units counted on nutrient plate **Pr** = Probable statistical total

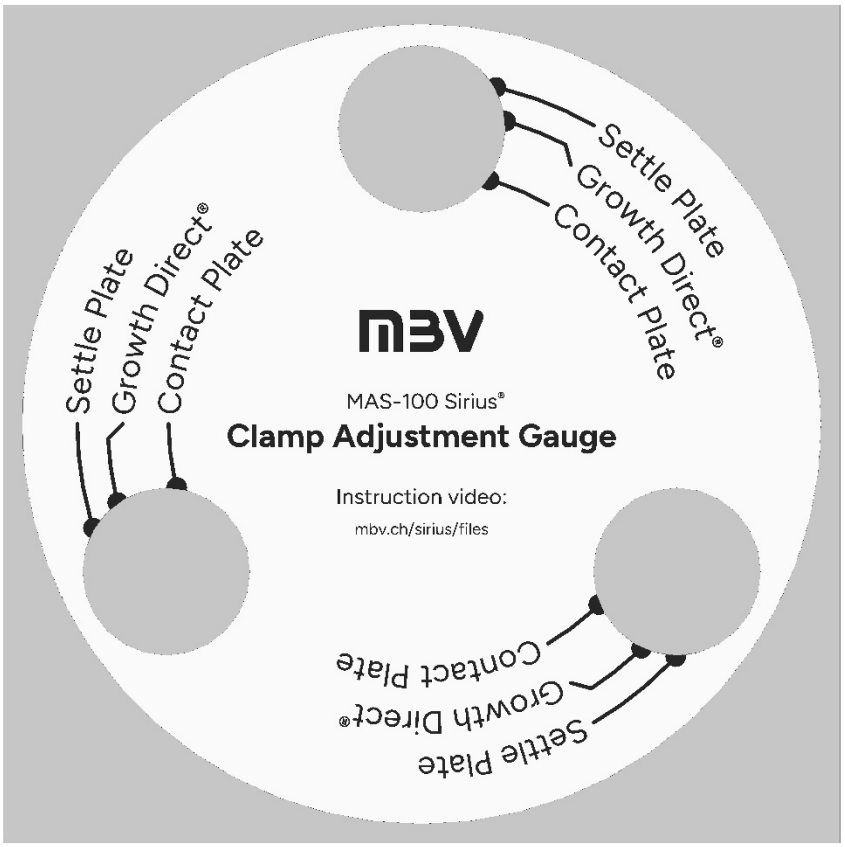
r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr
1	**1**	51	**56**	101	**123**	151	**209**	201	**332**	251	**541**
2	**2**	52	**57**	102	**124**	152	**211**	202	**335**	252	**547**
3	**3**	53	**58**	103	**126**	153	**213**	203	**338**	253	**553**
4	**4**	54	**59**	104	**127**	154	**216**	204	**341**	254	**560**
5	**5**	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**

LID B (400X0.7)

r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr	r	Pr
1	1	51	54	101	116	151	189	201	279	251	394	301	557	351	836
2	2	52	56	102	118	152	191	202	281	252	397	302	561	352	844
3	3	53	57	103	119	153	193	203	283	253	400	303	565	353	853
4	4	54	58	104	120	154	194	204	285	254	402	304	569	354	861
5	5	55	59	105	122	155	196	205	287	255	405	305	573	355	870
6	6	56	60	106	123	156	197	206	289	256	408	306	578	356	879
7	7	57	61	107	124	157	199	207	291	257	411	307	582	357	888
8	8	58	63	108	126	158	201	208	293	258	413	308	586	358	897
9	9	59	64	109	127	159	202	209	295	259	416	309	591	359	907
10	10	60	65	110	128	160	204	210	297	260	419	310	595	360	917
11	11	61	66	111	130	161	206	211	299	261	422	311	599	361	927
12	12	62	67	112	131	162	207	212	301	262	425	312	604	362	937
13	13	63	68	113	133	163	209	213	304	263	428	313	608	363	947
14	14	64	70	114	134	164	211	214	306	264	431	314	613	364	958
15	15	65	71	115	135	165	212	215	308	265	433	315	618	365	969
16	16	66	72	116	137	166	214	216	310	266	436	316	622	366	981
17	17	67	73	117	138	167	216	217	312	267	439	317	627	367	992
18	18	68	74	118	140	168	218	218	314	268	442	318	632	368	1005
19	19	69	76	119	141	169	219	219	317	269	445	319	637	369	1017
20	20	70	77	120	142	170	221	220	319	270	449	320	642	370	1030
21	22	71	78	121	144	171	223	221	321	271	452	321	647	371	1043
22	23	72	79	122	145	172	224	222	323	272	455	322	652	372	1057
23	24	73	80	123	147	173	226	223	325	273	458	323	657	373	1071
24	25	74	82	124	148	174	228	224	328	274	461	324	662	374	1086
25	26	75	83	125	150	175	230	225	330	275	464	325	667	375	1102
26	27	76	84	126	151	176	232	226	332	276	467	326	673	376	1118
27	28	77	85	127	153	177	233	227	335	277	471	327	678	377	1134
28	29	78	87	128	154	178	235	228	337	278	474	328	684	378	1152
29	30	79	88	129	156	179	237	229	339	279	477	329	689	379	1170
30	31	80	89	130	157	180	239	230	342	280	480	330	695	380	1189
31	32	81	90	131	158	181	241	231	344	281	484	331	701	381	1209
32	33	82	92	132	160	182	242	232	346	282	487	332	706	382	1230
33	34	83	93	133	161	183	244	233	349	283	491	333	712	383	1252
34	35	84	94	134	163	184	246	234	351	284	494	334	718	384	1276
35	37	85	95	135	164	185	248	235	353	285	497	335	724	385	1301
36	38	86	97	136	166	186	250	236	356	286	501	336	730	386	1327
37	39	87	98	137	167	187	252	237	358	287	504	337	737	387	1356
38	40	88	99	138	169	188	254	238	361	288	508	338	743	388	1387
39	41	89	101	139	171	189	255	239	363	289	511	339	749	389	1420
40	42	90	102	140	172	190	257	240	366	290	515	340	756	390	1456
41	43	91	103	141	174	191	259	241	368	291	519	341	763	391	1496
42	44	92	104	142	175	192	261	242	371	292	522	342	769	392	1541
43	45	93	106	143	177	193	263	243	373	293	526	343	776	393	1591
44	47	94	107	144	178	194	265	244	376	294	530	344	783	394	1648
45	48	95	108	145	180	195	267	245	378	295	534	345	791	395	1715
46	49	96	110	146	181	196	269	246	381	296	537	346	798	396	1795
47	50	97	111	147	183	197	271	247	384	297	541	347	805	397	1895
48	51	98	112	148	185	198	273	248	386	298	545	348	813	398	2028
49	52	99	114	149	186	199	275	249	389	299	549	349	820	399	2228
50	53	100	115	150	188	200	277	250	391	300	553	350	828	400	2628

APPENDIX B – CLAMP ADJUSTMENT GAUGE

An clamp adjustment guide is part of the scope of delivery (see chapter 2.5 and 3.2). For additional clamp adjustment guides, this page may be printed on A4 page size and cut out.



APPENDIX C – GLOSSARY

TERM	MEANING
AD	Active Directory
ATEX	European directive for equipment in explosive environments
BCR	Barcode Reader
BUI	Browser-based User Interface
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)
GAMP	Good Automated Manufacturing Practice,
GMP	Good Manufacturing Practice
IATA	International Air Transport Association
ID	IDentification number
IEC	International Electrotechnical Commission
IP	Ingress Protection
IP	Internet Protocol
ISO	International Organization for Standardization (standards)
LED	Light-Emitting Diode
LIMS	Laboratory Information Management System
LUI	Local User Interface (instrument screen)
MES	Manufacturinng Execution System
NL	Normal Liters
NL/min	Normal Liters per minute
NTP	Network Time Protocol
OP	'Operator' user role
PD	Power Delivery (part of USB standard)
PIN	Personal Identification Number
QR (code)	Quick Response code (2D barcode)
RoHS	Restriction of Hazardous Substances (directive)
RPM	Revolutions Per Minute
SA	'System Administrator' user role
SE	'Service Engineer' user role
SL	Standard Liters
SLPM	Standard Liters Per Minute
SIL	Service Information Letter (MBV AG)
SJ	Chinese standard for electronic equipment
S/N	Serial Number

TERM	MEANING
SOP	Standard Operating Procedure
SQS	Sequential Sampling Mode
UA	'User Administrator' user role
URS	User Requirements Specification
USA	United States of America
USB	Universal Serial Bus
WEEE	Waste Electrical and Electronic Equipment (European directive)

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LitCode: VM_UG14696EN V1 Date: 07/2025