MBV

AIR. NOTHING ELSE.

MAS-100 NT®

Microbiological Air Sampler

USER MANUAL



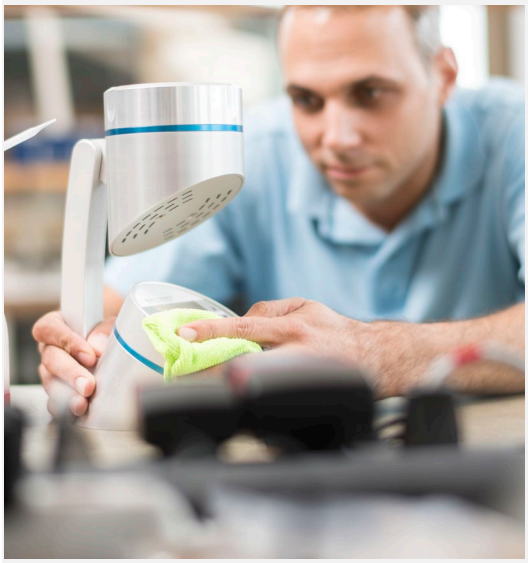
The life science business of Merck KGaA, Darmstadt, Germany
operates as MilliporeSigma in the US and Canada.

Millipore®

THANK YOU VERY MUCH!

Dear customer

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



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

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

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

MANUFACTURER

MBV AG
Industriestrasse 9
CH-8712 Stäfa
Switzerland

DISTRIBUTION PARTNER

Merck KGaA
Frankfurter Straße 250
D-64239 Darmstadt
Germany



Note

Up-to-date product information – such as Service Information Letters (SIL) – are available in the Customer Center area of the MBV AG website www.mbv.ch.

There, important product after-sales information about changes, issues, instructions and news is provided to customers.

DOCUMENT HISTORY

Version	Released	History
22.0	26.02.2021	– Chapter 2.2 Working principle: picture corrected

21.0	06.10.2020	– Extensive rework of document:
		  – MAS-100 Regulus introduced
		  – Filter and filter kit introduced
		  – Improved chapter structure for better understanding
		  – Adapted to new CI/CD of MBV AG and Merck
		  – Consolidated and/or removed redundant information (e.g. Feller correction tables…etc)
		  – Improved overall picture quality
		  – Document renamed
		  – Safety Data Sheet and Quickstart Guide included in the USB Stick MBV Information Sheet introduced
		  – Introduced new tripod
		  – Alarm 92 and 94 better described
		  – Autoclaving Temperature to ≤180°C updated
		– Chapter 4.4: Red reference lines corrected
		– Chapter 6.4.2: Corrected minimum SQS fraction to 40 ℓ
		– Chapter 7: Warnings descriptions added
		– Chapter 8: New autoclaving parameters.
		– Chapter 10.2. changed from GWF to MBV.

20.0	11.06.2018	– Page 2: Introduced new «Customer Center» on MBV AG website and removed «RSS feed» – Chapter 3.2: Added «Safety Data Sheet» – Added chapter 4.6 (PC Software installation) – MBV AG logo changed
19.0	08.08.2017	– Chapter 2.3: Added languages Portuguese and Italian.
18.0	05.04.2017	– Corrected pictures in chapter 3.2
17.0	05.04.2017	– Adaptations to new firmware version – Chapter 9.2.2: Added dry-decontamination – Various typo and format corrections
16.0	20.12.2016	– Harmonized the wording of chapter 1.1.2 to be consistent throughout all MBV AG user manuals. – Harmonized chapter structure to be consistent throughout all MBV AG user manuals. – Added chapter 1.2.4 («Dual-Use» statement). – Various typo corrections.
15.0	19.04.2016	– New template used – Total rework of document structure – CE certificate removed
14.0	21.05.2013	– New template used – Updated CE Certificate – Changed order of revision history – Corrected Printer Configuration

13.0	30.07.2012	– Corrected EG -> EU GMP – Grammatical and structural corrections
12.0	26.01.2012	– Renamed File – Integrated Revision History in User Manual – Removed HACCP Compliant (FDA 21CFR part 11)
11.0	01.06.2011	– Warranty adapted
10.0	19.04.2011	– Total rework of the SOP and new structure of the manual – Chapter 6.5: SQS example adapted – ON/OFF redundancies optimized – Converted document format from .doc to .docx – Footnotes lower page chapter – Chapter 21: Updated CE-Certificate date – Chapter 13.1: Alarm IDs with cause and solution – Address MBV AG corrected (Industriestrasse 9) – Chapter 20: New Warranty from «AGB» of MT – Chapter 17: GWF according to EN 45004 / IEC 17025 – Chapter 16.2: Max rel. hum. Non-condensing – Chapter 3: Firmware Update reworked – ™replaced by ®
10_110308	04.04.2011	– Sub-version 110308 – Chapter 1 Formatting headings adapted Warranty seal inserted – Chapter 5/8/16 Recharge time adapted to 3.5 h Running time adapted to 5.5 h Aspiration adapted to 33'000 liters – Chapter 17.1 Temperature from -20°C changed to 0°C – Chapter 16/21 New standard for EMC test inserted – Chapter 5/5.1/9.13 Languages Spanish, Polish, Czech, Italian and Portuguese inserted – Chapter 9.14 Contrast adjustable from 0 - 14
9.0	04.08.2010	– Sub-version 100804 – Chapter 10 inserted (Printing)
8.0	20.03.2009	– Sub-version 090920 – Introduction particle counter and results
7.0	05.12.2008	– Sub-version 081205 – Removed Warning notice for batteries – General 20 min / 121°C – Alignment German Manual
6.0	28.10.2008	– Unpacking instructions removed from Version 5
5.0	20.09.2008	– Battery dis/connect procedure because of Li-ion cells added – Unpacking Instructions inserted.

		– Some wording changes
4.0	30.07.2008	– Charging inserted – Tripod inserted
3.0	29.07.2008	– CE/EMV pages removed and replaced by CE-Conformity Certificate – New Menu item template data in main menu: deletion of protocol data or complete templates possible
2.0	09.07.2008	– 2 Version: EMV test-numbers corrected to EMV Report 7E033-2 – CE/EMV 3 pages from EMV Report 7E033-2 integrated to Manual – Integration of Revision history in Manual – Correction on Technical specification page
1.0	02.05.2008	– Original Version

TRADEMARKS

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

External
The vibrant M, Millipore, and Sigma-Aldrich are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. Detailed information on trademarks is available via publicly accessible resources.
Opticap® 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.
Safari® is a registered trademark of Apple Inc. in the U.S. and other countries.
Firefox® is a registered trademark of the Mozilla Corporation in the U.S. and other countries..
Chrome™ is a trademark of Google Inc. in the U.S. and other countries.
Growth DirectTM is a trademark of Rapid Micro Biosystems Inc. in the U.S. and other countries.

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

Copyright © 2020 MBV AG. All rights reserved.

This document may not be reproduced, in whole or in part, in any form or by any means electronic or mechanical (including photocopying, recording, or any other process), without the written permission of MBV AG, Switzerland.

Information contained in this document may be subject to change without notice.

ABBREVIATIONS

The microbiological air sampler MAS-100 NT is designated hereafter as «Instrument».

The PC Software MAS-100 NT/NT Ex Portable Air Sampler - C&C communication and calibration) is designated hereafter as «PC Software».

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

APPLICABILITY

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

Component	Version
Hardware	≥V8.0
Firmware	≥V1.7.18
PC Software	≥V1.6.31 SP1



Note

For older software and firmware versions please consult previous versions of this user manual.

RELATED USER MANUALS

The following user manuals provide additional essential information:

Document	Scope
Anemometer User Manual	Describes the adjustment and calibration procedures
Software Manual MAS-100 NT&NT Ex	Describes the functions of the PC Software

TABLE OF CONTENTS

MANUFACTURER		2
DISTRIBUTION PARTNER		2
DOCUMENT HISTORY		3
TRADEMARKS		6
ABBREVIATIONS		7
APPLICABILITY		7
RELATED USER MANUALS		7
1.	**GENERAL INFORMATION**	**11**
1.1.	Safety information	11
1.1.1.	Severity levels	11
1.1.2.	Specific safety information for the instrument	11
1.2.	General Provisions	14
1.2.1.	Personnel qualification	14
1.2.2.	Intended product use	14
1.2.3.	Operating conditions	14
1.2.4.	«Dual-Use» statement	14
1.3.	Warranty	14
1.3.1.	General	14
1.3.2.	Quality statement	14
1.3.3.	Contact	14
1.3.4.	Exclusion clauses	15
1.4.	Product labeling	16
2.	**INSTRUMENT DESCRIPTION**	**17**
2.1.	Application	17
2.2.	Working principle	18
2.3.	Main features	19
2.3.1.	Perforated lid	20
2.3.2.	Change of the HEPA filter	21
2.3.3.	SQS – Sequential air sampling	22
2.3.4.	Communication	23
2.3.5.	Validation and classification	23
3.	**HARDWARE DESCRIPTION**	**24**
3.1.	Parts designation	24
3.2.	Scope of delivery	25

3.3. Optional accessories 27

4. GETTING STARTED 28
4.1. Adjusting a Petri dish 28
4.2. Adjusting a contact plate 28
4.3. Battery charging 29
4.4. Firmware update tool 30
4.5. PC Software installation 30
4.6. Using the tripod 30

5. OPERATION 31
5.1. User interface 31
5.2. Startup the instrument 32
5.2.1. Startup 32
5.2.2. Intro screens 32
5.3. Activation of the calibration reminder 33
5.4. Home screen 34
5.5. Start sampling 35
5.6. Operating and sampling modes 36
5.7. Shutdown the instrument 37

6. SETTINGS AND CONFIGURATION 38
6.1. Protected mode 38
6.2. Menu structure 38
6.3. Operating mode selection 39
6.3.1. Mode selection 39
6.3.2. Template handling 39
6.3.3. Template data 40
6.4. Process settings (sampling mode) 41
6.4.1. Std mode (Standard) 42
6.4.2. SQS mode (Sequential) 42
6.5. Preset standard volumes 43
6.6. Delay 43
6.7. User selection 44
6.8. Print instrument settings 44
6.9. Sample log 46
6.10. Alarm log 47
6.11. Config device 48
6.11.1. Time/Date 48
6.11.2. Language 48

6.11.3. Contrast 49
6.11.4. Device info 49
6.12. System info 50
6.13. Printer configuration 51
6.13.1. Functionalities 51
6.13.2. Set printer settings 52
6.13.3. Other printers 53
6.13.4. Online printing activation via HMI 53
6.13.5. Online printing activation via PC Software 53

7. ALARMS AND WARNINGS 54
7.1. Alarms 54
7.2. Warnings 55

8. CARE AND MAINTENANCE 57
8.1. General 57
8.2. Cleaning and decontamination 57
8.2.1. Perforated lid and dust cover 57
8.2.2. Exterior 58
8.2.3. Interior 59

9. INTERPRETATION OF RESULTS 60

10. ADJUSTMENT AND/OR CALIBRATION OF THE INSTRUMENT 61
10.1. General 61
10.2. Factory calibration certificates 61
10.3. Calibration periodicity 61

11. REGULATORY INFORMATION 62
11.1. Substances subject to Chinese RoHS 62
11.2. IATA (air transportation) 62

12. TECHNICAL SPECIFICATIONS 63

ANNEX A – PHYSICAL SAMPLING EFFICIENCY 65
Annex A.1 - d_{50} value 65
Annex A.2 ISO 14698 validation statement 66

ANNEX B – ISO 14644-1 CLEANLINESS STATEMENT 68

1. GENERAL INFORMATION

This chapter provides information of general interest regarding the instrument.

1.1. SAFETY INFORMATION



IT IS IMPORTANT TO READ THESE INSTRUCTIONS BEFORE USING THIS INSTRUMENT.
Please read the safety data sheet and the instrument-specific safety information in this manual carefully before using the instrument and/or any accessory supplied with this product.
Keep this notice and all other manuals on the USB flash drive for future reference.

1.1.1. SEVERITY LEVELS

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

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

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

1.1.2. SPECIFIC SAFETY INFORMATION FOR THE INSTRUMENT



Hazard of injury
The sampling head can be tilted.
Fingers can get trapped whilst lowering the sampling head.



Hazard of falling instrument
When using the optional tripod, follow the safety instructions included in the tripods' user manual.



Hazard of explosion and/or fire
Do not enter explosion hazard areas with this instrument.



Hazard of damage to the instrument

Read the instructions in this user manual carefully before any usage of the instrument and pay attention to all warnings.

Keep this manual in a designated place, accessible for all users for future reference.

Ensure that all personnel have read and understood the content of this manual.



Risk of warranty loss

Every instrument is secured with an anti-tamper seal.

Disassembling the instrument will break the seal and render the warranty void.



Hazard of damage to the instrument

The instrument is not IP-protected.

Do not spill liquids into the electric/electronic connections or through the sampling head.



Hazard of damage to the instrument

All of the cleaning/disinfection solution must be removed/wiped dry properly prior use.

Never dry the instrument by turning on the blower.



Hazard of damage to the instrument

The instrument must remain shut down during the whole vaporized hydrogen peroxide decontamination process.



Hazard of damage to the instrument

Ensure that the red dot of the charging plug matches the black dot of the handle.



Hazard of damage to the instrument or wrong air sampling results

Variations from lid to lid can result in flow variations when using one lid for adjustment and another one for sampling. It is strongly recommended to use the same lid for adjustment and sampling.



Hazard of damage to the instrument

Do not over-tighten the blue clamps. Otherwise the Petri dish may break and shed debris in the aspiration unit and damage the blower fan.



Hazard of wrong air sampling results

An adequate handling of the Petri dish and/or the instrument is essential.

Always follow good cleanroom practices to ensure that the Petri dish and sampling head do not get contaminated.



Hazard of wrong air sampling results

Although possible, is is not recommended to use preset volumes smaller than 40 L in STD mode.



Hazard of wrong sampling results

Do not use an uncalibrated instrument. It is recommended to adjust and calibrate the instrument in a periodicity of 12 months.

Hazard of wrong air sampling results

The manufacturer declines any responsibility for misuse of the PC Software and for entering wrong results.

It is the sole responsibility of the user to fill-in the correct values.

This system was not developed to meet the technical requirements from 21 CFR part 11 and international regulations regarding GxP regulated records.

If data is needed generated by this system in a GxP regulated environment, ensure to maintain paper recording in accordance with GxP procedures.

Hazard of cross contamination

The FDA considers the separation of penicillin production from other drug products for human use as a GMP requirement (21 CFR 211.46(d)), therefore MBV AG recommends taking any precaution for installing and handling the MAS system accordingly.

Update of PC Software 1.6.31 SP1

PC Software V1.6.31 contains type errors in the French and Spanish language translations.

Operators of V1.6.31 may find on the USB memory stick or on the MBV AG homepage patch MAS100_NT_AirSampler_ver_1.6.31_UpdateSP1.exe to correct this.

IMPORTANT:

The patch must be installed after installation of the PC Software.

1.2. GENERAL PROVISIONS

1.2.1. PERSONNEL QUALIFICATION

The instrument is a precision device for industrial and laboratory use. Its use should be restricted to trained, qualified and authorized personnel.

1.2.2. INTENDED PRODUCT USE

The instrument is intended solely for the collection of air samples at ambient pressure onto a microbiological culture medium to monitor the microbiological air quality in contamination-controlled areas, such as cleanrooms, operating theatres, flow hoods or general environmental monitoring etc.

1.2.3. OPERATING CONDITIONS

The instrument must be calibrated and operated in similar environmental conditions. Please consult the operating conditions in chapter 12.

1.2.4. «DUAL-USE» STATEMENT

The instrument is designed solely for civilian purposes. It is excluded in the scope of the European «Dual-Use» regulation EC 428/2009.

1.3. WARRANTY

1.3.1. GENERAL

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

For products listed in this publication purchased via Merck KGaA the applicable warranty terms may be found at: www.millipore.com/terms (within the «Terms and Conditions of Sale» applicable to your purchase transaction).

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

1.3.2. QUALITY STATEMENT

The instrument has been designed and manufactured to the highest quality levels as described in our ISO 9001 processes.

MBV AG guarantees the instruments performance to specifications for a period of 24 months (starting from shipping date) and for spare and replacement parts for a period of 3 months after repair or service.

1.3.3. CONTACT

In case of warranty claim please contact your instrument supplier:

MBV AG	Worldwide	www.mbv.ch/service
Merck KGaA	USA	Call 1-800-MILLIPORE (1-800-645-5476)
	Rest of the world	www.millipore.com/techservice

1.3.4. EXCLUSION CLAUSES

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

- The instrument shall only be serviced or repaired by qualified, trained and authorized technicians.
- The instrument shall only be serviced or repaired as described in the MBV AG service manual.
- The instrument shall only be serviced or repaired using original MBV AG spare parts.
- The instrument shall only be operated according to the defined intended use.
- The instrument shall only be operated and updated with original firmware from MBV AG.
- The instrument shall not be modified physically in any way.



Hazard of damage to the instrument

There are no user-serviceable parts inside the instrument.

Do not perform any intervention inside the instrument.

Only trained, qualified and authorized technicians can perform repair and maintenance activities.



Risk of warranty loss

Every instrument is secured with an anti-tamper seal.

Disassembling the instrument will break the seal and render the warranty void.

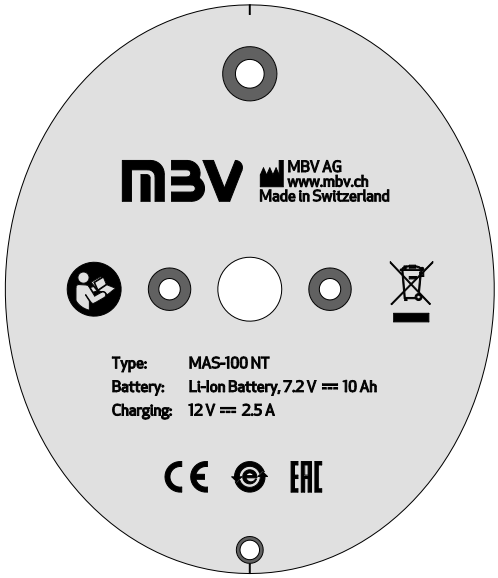
1.4. PRODUCT LABELING

The label on the bottom plate of the instrument identifies the instrument and its manufacturer.

The information on the label includes:

- Manufacturer's name
- Instrument type
- Battery capacity
- DC supply data
- Regulatory information

A unique serial number is printed on the handle of the instrument.



SIGNIFICANCE OF THE SYMBOLS ON THE LABEL

CE	With the CE symbol the manufacturer declares conformity with the relevant directives of the European Union as stated in the Declaration of Conformity which can be found on the USB memory stick delivered with the instrument.
EAC	With the EAC symbol the manufacturer declares conformity with the relevant directives of the Eurasian Trade Union as stated in the Declaration of Conformity which can be found on the USB memory stick delivered with the instrument.
	This symbol indicates that this electronic information product does not contain any toxic or hazardous substances or elements above the maximum concentration value established by the Chinese standard SJ/T11363-2006 as stated in chapter 11.1, and can be recycled after being discarded and should not be casually discarded.
	Read the instructions before using the instrument.
	With this symbol the manufacturer declares conformity with the WEEE directive as described in the Declaration of Conformity which can be found on the USB memory stick delivered with 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.

2. INSTRUMENT DESCRIPTION

2.1. APPLICATION

Microorganisms in the air represent a potential contamination risk for raw materials, semi-finished or end products or pose a threat to human or animal health. Based on a risk assessment or stipulated by application-specific guidelines the air in cleanrooms, associated controlled environments or other critical areas must be analyzed for the presence of airborne microbial contamination.

Further information on the use of active microbial air samplers in different environments can be found in this non-exhaustive list of norms and guidelines:

- ISO 14698 1:2003: Cleanrooms and associated controlled environments - Bio-contamination control – Part 1: General principles and methods.
- ISO 14698 2:2003: Cleanrooms & associated controlled environments – Bio-contamination control - Part 2: Evaluation and interpretation of bio-contamination data.
- EN 17141:2020: Cleanrooms and associated controlled environments — Biocontamination control.
- United States Pharmacopeia (USP) <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.
- European Commission EudraLex "The Rules Governing Medicinal Products in the European Union" Volume 4, EU Guidelines for Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Annex 1 - Manufacture of Sterile Medicinal Products, 25Nov08.
- VDI 6022 Blatt 1:2018-01: Ventilation and indoor-air quality - Hygiene requirements for ventilation and air-conditioning systems and units (VDI Ventilation Code of Practice)

The instrument is intended solely for the collection of air samples at ambient pressure onto a microbiological culture medium to monitor the microbiological air quality in controlled areas, such as cleanrooms, operating theatres, flow hoods or general environmental monitoring, etc.

2.2. WORKING PRINCIPLE

The instrument is an active microbiological air sampler, using the impaction principle[(1)]. A predefined volume of air is aspirated through the small orifices of the sampling head. The air is accelerated and microorganism-carrying particles impact on an appropriate microbiological culture medium in a Petri dish. The impaction speed is optimized for maximum sampling [2]efficiency.

The instrument is equipped with a high-performance blower. An air mass flow sensor continuously monitors the aspirated air flow and compensates for the effects of pressure and temperature. Based on the air flow measurements a controller adjusts the blower to assure a constant flow of 100 SLPM.



In the standard configuration the instrument has a d_{50} value of 1.1 µm, (see Annex A – Physical sampling efficiency).

Up to five different defaults sampling volumes can be predefined by the user according to international guidelines, for samplings in the pharmaceutical industry the recommended sampling volume is 1'000 L.

The Petri dish is removed after the sampling process and incubated according to the specific growth parameters of the expected microorganisms. During the incubation, the microorganisms captured on the surface of the culture medium will grow and form colonies. These colony-forming units (CFU) are counted and the microbiological load of the analyzed air is expressed in CFU/m^3 of air.

All settings and parameters of the instrument can be programmed via the PC Software.

(1) New Sampler for the Collection, Sizing, and Enumeration of Viable Airborne Particles, A. Andersen, U.S. Army Chemical Corps Proving Groung, Dugway, Utah, 1958

[2]Stewart S.L. et al. Effect of impact stress on microbial recovery on agar surfaces. Appl. Environ. Microbiol. 1995, (Apr) pp. 1232–1239

2.3. MAIN FEATURES

- Compliant with ISO 14698-1,ISO 14698-2, and EN 17141
- Compliant with ISO 14644-1, Class 5 cleanrooms and GMP Grade A environment
- Developed according to GAMP 5
- Same working principle as the proven MAS-100 Air Sampler[3]
- High collection rate of airborne contaminants (d_{50}=1.1 µm)
- Integrated mass flow sensor with temperature and air pressure compensation
- Open system for standard Petri dishes, adjustable for different Petri dish sizes
- Adapter kits for contact and other specialty plates (optional)
- Backwards compatible with perforated lids of first generation MAS-100 air samplers
  - Standard perforated lid with 300 holes / Ø 0.6 mm (Short: 300 × 0.6), d_{50}=1.1 µm
  - Classical perforated lid with 400 holes / Ø 0.7 mm (Short: 400 × 0.7), d_{50}=1.6 µm
- Real-time clock and calendar
- Display illuminated with easy navigation, simple cleaning and disinfection properties
- Multi-lingual: English, French, German, Spanish, Polish, Czech, Portuguese and Italian.
- Sequential air sampling with SQS mode possible (sampling volume split up in up to 50 sequences over a period of 24 hours)
- Indication of low air flow
- Extensive data logging functionalities
- Electronic connectivity (RS-232, USB)
- Automatic, operator-independent calibration procedure and automatic printing of calibration certificate (to PDF file)
- Lock function to prevent unintended changes of sampling parameters
- Sampling start delay to prevent influence of operator-generated air turbulence
- Calibration reminder and out-of-calibration interval locking option
- Fully validated system (hardware, software, firmware, consumables)

(3) MAS-100, Qualification of air sampler systems: The MAS-100, Meier R. und Zingre H., (Swiss Pharma 1-2/00) https://www.mbv.ch/media/microbialairsamplerqualificationmas100_1.pdf

2.3.1. PERFORATED LID

The sampling head is designed to accommodate one standard 90mm Petri dish.

The instrument is delivered with one perforated lid. Additional lids are available as accessories. Lids can be exchanged between instruments.

The instrument's standard sampling head configuration includes a perforated lid with 300 holes of 0.6 mm in diameter.

The 400 × 0.7 perforated lid is mainly used in older products of the MAS-100 product family and is available as an optional accessory.

Specialty lids and adapters are available as accessories. These include lids for 55mm contact plates, glass plates or plates for the Growth Direct™ plates from Rapid Micro Biosystems.

Hazard Hazard of damage to the instrument or wrong air sampling results

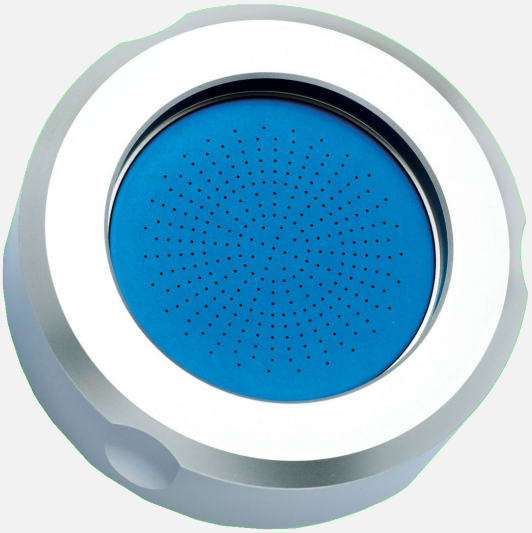
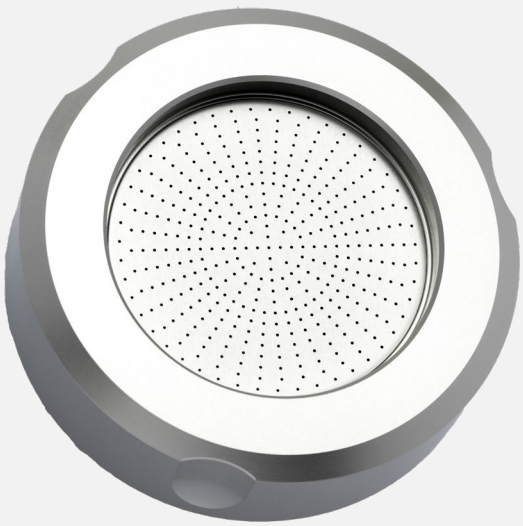
The bottom surface of the lid is the sealing surface towards the base. Avoid scratches or dents on the sealing surface.

Hazard of damage to the instrument or wrong air sampling results

Variations from lid to lid can result in flow variations when using one lid for adjustment and another one for sampling. It is strongly recommended to use the same lid for adjustment and sampling.

Note

The 400 × 0.7 perforated lid has a smaller collection efficiency compared to the 300 × 0.6 perforated lid. (see Annex A.1 - d_{50} value)

300 × 0.6 Standard product Impaction speed <19.6 m/s	400 × 0.7 Legacy product, optional Impaction speed <11.0 m/s
	

2.3.2. CHANGE OF THE HEPA FILTER

Attention

The HEPA filter may pose a biological or chemical hazard. Wear protective clothing and gear. Exchange it using the appropriate safety precaution. Safely dispose of the used HEPA filter.

Loosen the four screws on the exhaust plate with the Slotted screwdriver size 3 and detach it from the head of the Instrument	
Remove the old filter and replace with a replacement filter. Handle the filter carefully and make sure not to damage the replacement filter	
Mount the exhaust plate with the 4 screws. Tighten the screws firmly and make sure that there is no gap between the filter adapter and the exhaust plate	

2.3.3. SQS – SEQUENTIAL AIR SAMPLING

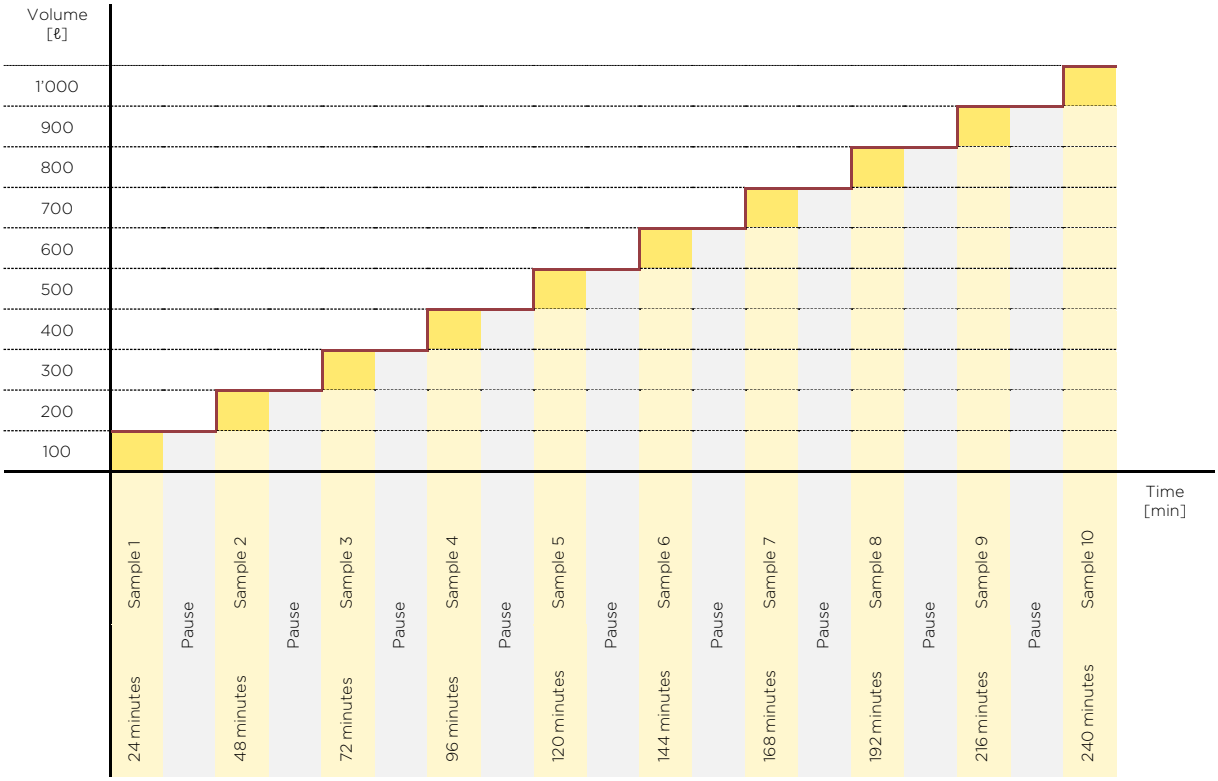
The instrument allows sampling over a prolonged time with a single Petri dish. Hereby, the total sampling volume can be split into up to fractions over a period of several hours.

The main advantage of this method is the risk of operator-induced contamination during the exchange of plates is reduced to a minimum.

This is very important for ambient air monitoring in clean controlled environments. In addition, by collecting sequential samples over a prolonged period the randomization is improved and thus a more reliable result over time is obtained.

Moreover, instead of several 90 mm standard Petri dishes, only one dish must be evaluated, thus reducing the expenditure on equipment and labor.

EXAMPLE



A more detailed explanation with actual sampling data can be found in:

SQS-Sequential air sampling. Validation of the microbial count in the air using the MAS-100. Ewald *et al.* (Swiss Pharma 26 (2004) No. 11, 9-11

mbv.ch/media/sqssamplingwithmas100nt.pdf

2.3.4. COMMUNICATION

The instrument features a comprehensive connectivity: USB interface, RS-232 to other systems (PC, printers, MBV AG digitals anemometers).

All functions can be programmed via the HMI on the instrument or by means of the PC Software delivered with each instrument.

This manual describes the programming via the HMI (display and buttons).



Note

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



Note

For additional information about how to use the PC Software please refer to the Software Manual MAS-100 NT&NT Ex.

The PC Software is a validated communication and calibration software. It is delivered together with the instrument.

A specific calibration menu with the option of fully automatic calibration (adjustment of flow sensor, calibration of the instrument and printing calibration certificate) is available.

The software features an alarm and sample log file, which stores 100 events of each type. The logs can be printed or exported to an Excel® sheet.

2.3.5. VALIDATION AND CLASSIFICATION

The instrument has been developed according to GAMP 5.

3. HARDWARE DESCRIPTION

Hazard of injury
The sampling head can be tilted.
Fingers can get trapped whilst lowering the sampling head.

3.1. PARTS DESIGNATION

The figures blow show the main components of the instrument as well as the location of the connection sockets.

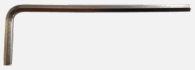


3.2. SCOPE OF DELIVERY

Unpack the instrument carefully and verify whether all items listed below are present in the portable case. If ordered, please check the accessories too.

Contact your local representative immediately if items are missing or show signs of defect.

Description	Article No.		Picture
	Merck KGaA	MBV AG	
Portable case MAS-100 NT	1194980001	06.9048.01	
MAS-100 NT	1.09191.0001	06.6200.01	
Or MAS-100 NT with HEPA filter, 300x0.6mm	1.17274.0001	06.5020.01	
OR MAS-100 NT with HEPA filter 400x0.7mm	N/A	06.5021.01	

Documents - Calibration certificate - Feller correction table - MBV Information Sheet	N/A N/A N/A	N/A 06.6051.02 99.0047.01	
USB memory stick	N/A	03.3120.01	
Allen key No. 3	N/A	06.6053.01	
Perforated lid 300 × 0.6mm	1.09195.0001	06.6020.01	
Dust cover	1.09084.0001	06.6022.01	
USB cable 1.5 m	1.19453.0001	06.7901.01	
Battery charger 12V/2.5A with DC plug	1.19133.0001	06.8023.01	
US/JPN plug adapter	1.19478.0001	06.8024.01	
EU plug adapter	1.19479.0001	06.8025.01	
GB plug adapter	1.19480.0001	06.8026.01	
AUS plug adapter	1.19481.0001	06.8027.01	

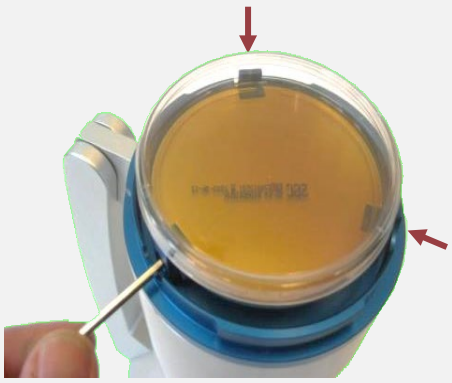
3.3. OPTIONAL ACCESSORIES

Description	Article No.		Picture
	Merck KGaA	MBV AG	
Perforated lid 400 × 0.7mm	1.09088.0001	06.6021.01	
Tripod for portable instruments of the MAS-100 product family	N/A	06.6054.03	
Quick change adapter for tripod	1.09223.0001	06.6055.02	
Digital anemometer MAS-100 Regulus	1.19153.0001	01.2000.01	
Perfor. lid alu 400 × 0.7mm for contact plate	1.09213.0001	06.7120.01	
Adapter for contact plates	1.09214.0001	06.7124.01	
Perforated lid alu 400 × 0.7mm for contact plate incl. adapter	N/A	06.7121.01	
Set filter bracket compl. w/HEPA filter H13 Ø74mm	1.17276.0001	06.5000.01	
HEPA filter H13 Ø74mm	1.17278.0001	06.6068.01	

4. GETTING STARTED

4.1. ADJUSTING A PETRI DISH

Before using the instrument for the first time, the Petri dish support may need to be adjusted. To adjust the Petri dish support, proceed as follows:



PROCEDURE

1) Lift off the perforated lid and place a Petri dish on the dish support.
2) Use the 3 mm Allen key to adjust the three blue clamps until the Petri dish is securely supported and there is no clearance (see picture).
3) Ensure that the Petri dish is properly supported by turning the sampling head to the horizontal position.
4) The procedure only needs to be repeated if a Petri dish of different dimensions is used.

Hazard of damage to the instrument

Do not over-tighten the blue clamps. Otherwise the Petri dish may break and shed debris in the aspiration unit and damage the blower fan.

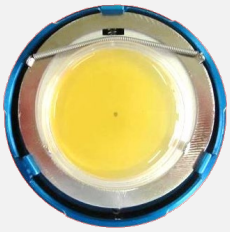
4.2. ADJUSTING A CONTACT PLATE

The instrument can be used with commercially available contact plates. Therefore, a special adapter and sampling head is necessary (see chapter 3.3).



PROCEDURE

5) Use the Allen key to exchange the three existing blue clamps by removing the screws and replacing with the three new blue clamps.



6) Place the adapter ring into the sampling head as shown in the figure
7) Put the contact plate in the adapter and tighten the three Allen screws. The marked point should be in the center of the contact plate as shown in the figure.

Note

Tighten the blue clamps and ensure, that the stainless-steel adapter is firmly held.

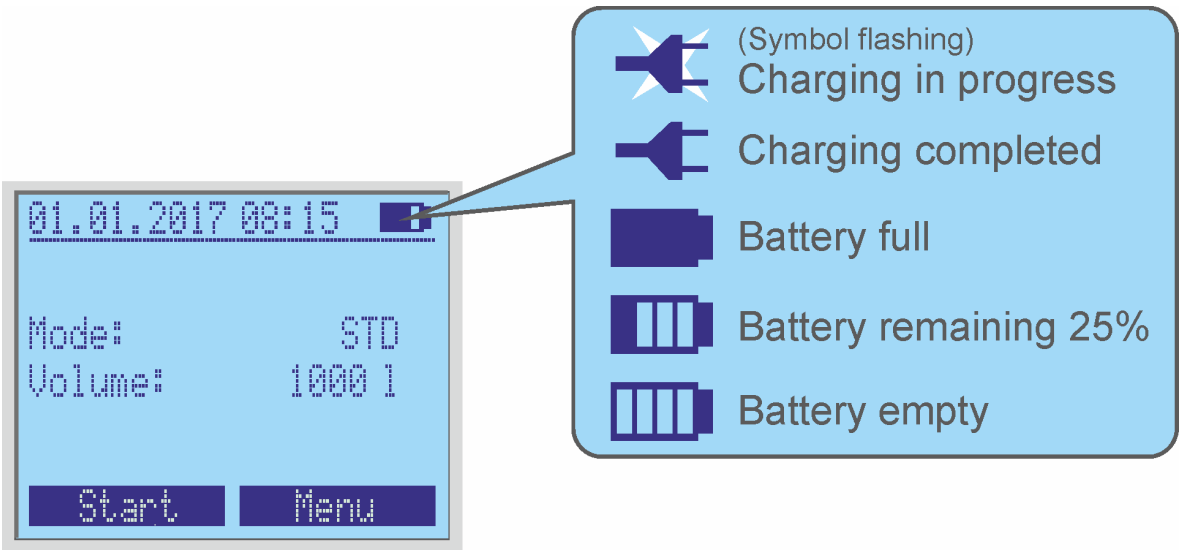
4.3. BATTERY CHARGING

The instrument is powered by a rechargeable Litium-Ion battery pack.

Note
The battery needs to be charged prior first-time use.

Note
For more battery-related data please refer to chapter 12.

The charge status of the battery is indicated with the battery symbol on the top right side of the on the screen. While connected to the mains, the battery symbol changes to the mains plug symbol.





PROCEDURE

1) Aside of the 2D code, a power jack is available designed for use with MBV's current DC plug battery charger.

Multiport socket:

1) Align the red dot of the charging plug with the black dot of the handle.
2) Insert the charging plug.

Hazard of damage to the instrument
Ensure that the red dot of the charging plug matches the black dot of the handle.

4.4. FIRMWARE UPDATE TOOL

Use the Firmware Update Tool to update the instruments firmware. This special software is delivered on the USB memory stick and is also available for download on www.mbv.ch.

4.5. PC SOFTWARE INSTALLATION



Note

The installation and operation of the PC Software is described in the Software Manual MAS-100 NT&NT Ex..



Update of PC Software 1.6.31 SP1

PC Software V1.6.31 contains type errors in the French and Spanish language translations.

Operators of V1.6.31 may find on the USB memory stick or on the MBV AG homepage patch MAS100_NT_AirSampler_ver_1.6.31_UpdateSP1.exe to correct this.

IMPORTANT:

The patch must be installed after installation of the PC Software.

4.6. USING THE TRIPOD

The instrument is prepared to be installed on an optional tripod.



Hazard of falling instrument

When using the optional tripod, follow the safety instructions in the tripods' user manual.



Note

A quick-change adapter for an easy tripod connection is available as an optional accessory. Please consult chapter 3.3.

5. OPERATION

Note

Prior to operating the instrument, please study the general safety information (see chapter 1.1) and the user interface (see chapter 5.1).

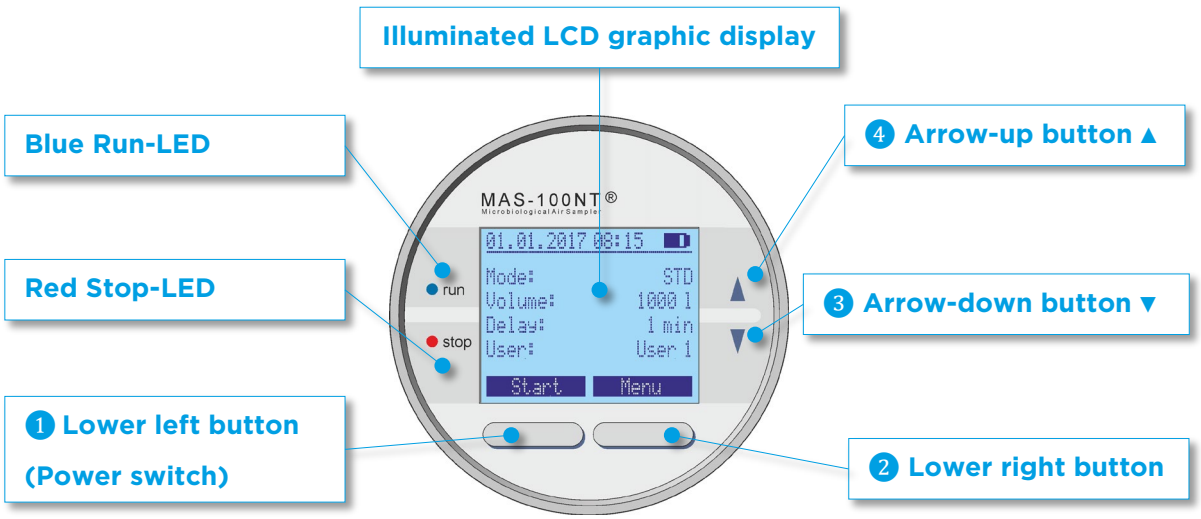
Note

If the instrument is used for the first time or after a calibration, the «Calibration reminder» needs to be activated (see chapter 5.3).

5.1. USER INTERFACE

The instrument features a built-in multilingual dialogue software. To navigate through the graphic interface, follow the indications on the screen.

There are four buttons available. Buttons 1 and 2 are located underneath the screen and are used for accepting or rejecting a suggested action. Buttons 3 and 4 on the right side of the screen serve as arrow buttons (▲/▼) and are used to navigate up and down a menu or to set values.



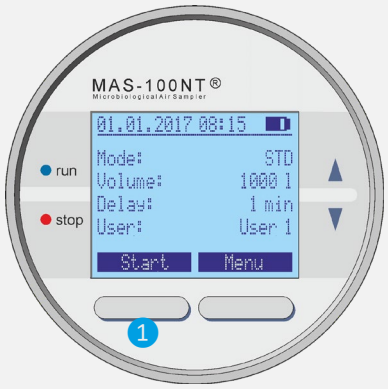
The red Stop-LED indicates that a sampling was stopped, e.g. after an alarm occurred.

The blue Run-LED indicates with continuous light that the instrument is ready for starting a sampling. It flashes during a sampling or indicates waiting times (e.g. defined delays or pauses between cycles in SQS mode).

When the instrument is switched off, the blue Run-LED indicates with flashing that the battery is being charged or, when permanently on, that the charging is completed.

5.2. STARTUP THE INSTRUMENT

5.2.1. STARTUP



PROCEDURE

1) Press the lower left button 1 until the blue LED lights up.
2) The instrument starts up.

5.2.2. INTRO SCREENS

After starting up the instrument, a sequence of screens will appear.



FIRST SCREEN

The first screen shows the instrument's name.

After a few seconds it will automatically switch to the second screen.



SECOND SCREEN

The second screen shows basic instrument information.

- Individual name of the instrument.
- Location of instrument, e.g. «Laboratory X»(4).
- Serial number.
- Currently set perforated lid (300 × 0.6 or 400 × 0.7)(4)
- Time remaining (months) until the next due calibration.

After about five seconds the display changes to the Main menu.

Press OK will change without delay to the Home screen.

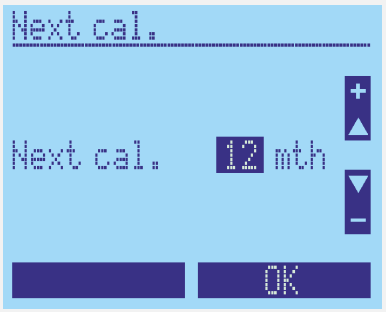
Note

Both intro screens can be deactivated (see chapter 6.11.4).

(4) These settings can be modified by the user with the PC Software.

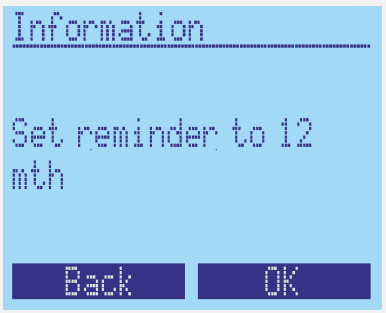
5.3. ACTIVATION OF THE CALIBRATION REMINDER

The instrument has a built-in calibration reminder. After the instrument has been calibrated, it will ask the operator to activate the calibration reminder right after the first startup.



PROCEDURE

1) Start the instrument.
2) The calibration reminder screen appears.
3) Choose with the ▲/▼ buttons a value from 1 to 12 months (the calibration reminder can be disabled by setting the value 0 months)
4) Press OK to accept.



5) Press OK to confirm, or
6) Press Back to return to the start screen.

After activation, fill in the calibration certificate the date on which the instrument was first used and the date for recalibration.

Note

It is mandatory to select a time (number of months) and accept it by pressing OK in order to initialize the instrument. Otherwise, a sampling cannot be started.

Note

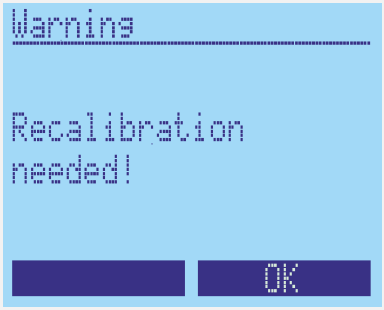
MBV AG suggests setting the calibration reminder to 12 months.

Note

Adjustment and calibration must only be performed by either qualified and authorized personnel or an authorized service center.

For an optimal result, MBV AG suggests using the anemometer.

MESSAGE «RECALIBRATION NEEDED»



If the calibration reminder is activated and recalibration is due the instrument will display a warning before each run: Recalibration needed!.

By default, the instrument can still be operated. Recalibration should be performed as soon as possible.

BLOCK SAMPLING UPON CALIBRATION EXPIRY

If the calibration reminder is activated and the Block measurement if calibration validity expired checkbox in the PC Software is activated, it is not possible to start a sampling.

The alarm Recalibration needed! will be displayed on the instrument. In this case, it is mandatory to calibrate the instrument before continuing.

Note

Please refer to the Software Manual MAS-100 NT/NT Ex for further details.

5.4. HOME SCREEN



The Home screen diplays the following information:

- Top row: Date, time and the battery/charge state.
- Current sampling mode.
- Current sampling volume.
- Delay after pressing Start (if activated)
- User (if activated)

Note

If the Delay function (see chapter 6.6) is deactivated, the Delay will not be displayed.

Note

If the User selection function (see chapter 6.7) is deactivated, the user name will not be displayed.

5.5. START SAMPLING



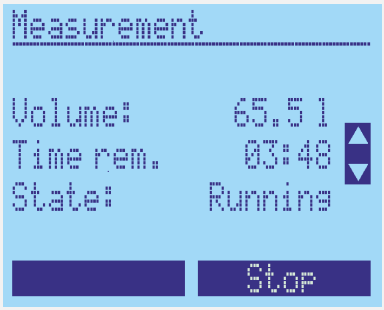
PROCEDURE

1) Press Start to initiate a sampling, or
2) Press Menu to check the process settings or access further functions.



If the User selection is activated, a user may be chosen:

3) Toggle to the desired user with the ▲/▼ buttons.
4) Press Start to start the sampling, or
5) Press Back to return to the Home screen.



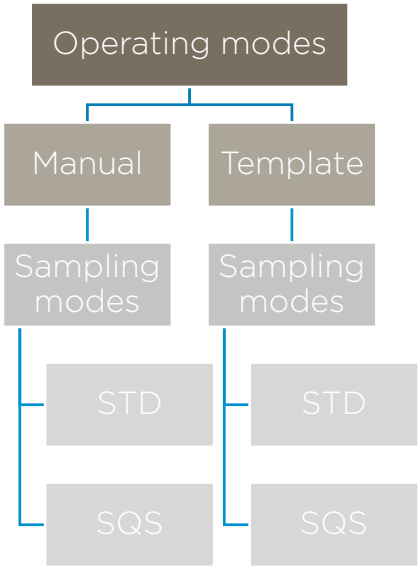
6) During the sampling process, the instrument will display this information:
   - Currently sampled volume.
   - Remaining sampling time.
   - Operating state.

The operating states mean:

Running	A sampling is in progress.
Waiting	A delay is active or the instrument pauses between two SQS cycles.
Passed	The current sampling has been completed.

5.6. OPERATING AND SAMPLING MODES

The diagram shows the different modes in which the air samples can be taken.



OPERATING MODES

Manual mode: The instrument runs one single sampling.

Template mode: The instrument runs a predefined sequence of samplings according to a sampling plan which is defined in a template.

Up to ten templates can be programmed in the PC Software and downloaded to the instrument by means of the USB cable. Please refer to the Software Manual MAS-100 NT&NT Ex for further details.

SAMPLING MODES

STD / Standard mode: Samples the selected volume within one sampling process.

SQS / Sequential mode: Splits the selected volume into fractions over a selected time.



Note

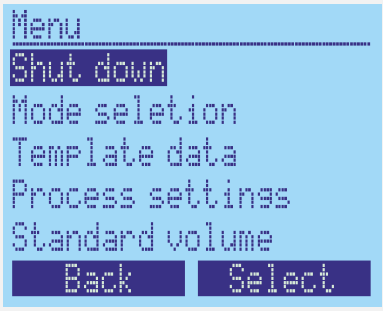
It is not recommended to work with SQS mode in the template mode.

5.7. SHUTDOWN THE INSTRUMENT



PROCEDURE

1) Return to the Home screen. (if not already there).
2) Press Menu.



3) Toggle with the ▲/▼ buttons to Shut down.
4) Press Select.



5) Press OK for the question Shut down device?



Note

If no sampling is running and interactions via HMI have ceased, the instrument will shut down automatically after five minutes of inactivity.

6. SETTINGS AND CONFIGURATION

6.1. PROTECTED MODE

The instrument can be locked via the PC Software to block manual interventions on the instrument. By doing so, starting and stopping a sampling will be the only accessible functions on the instrument.

Note
Please refer to the Software Manual MAS-100 NT/NT Ex for further details.

6.2. MENU STRUCTURE



PROCEDURE

1) Press Menu on the Home screen to access the Main menu.



2) Choose a menu item with the ▲/▼ buttons:

- Shut down, see chapter 5.7
- Mode selection, see chapter 6.3 (Operating mode)
- Template data, see chapter 6.3.3
- Process settings, see chapter 6.4 (Sampling mode)
- Standard volume, see chapter 6.4.1



- Delay, see chapter 6.6.
- User selection, see chapter 6.7.
- Print settings, see chapter 6.8.
- Sample log, see chapter 6.9.
- Alarm log, see chapter 6.10.



- Config device, see chapter 6.11.
- System info, see chapter 6.12.

3) Press Select to enter the desired menu, or
4) Press Back to return to the previous screen.

6.3. OPERATING MODE SELECTION

Note

Templates can only be generated using the PC Software.

Please refer to the Software Manual MAS-100 NT&NT Ex for further details.

6.3.1. MODE SELECTION



PROCEDURE

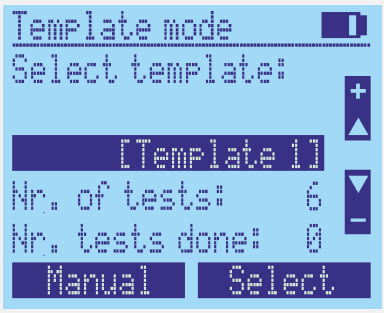
5) Go to the Main menu.
6) Press Mode selection.
7) Choose Manual or Template.

Note

The instrument will display the message There are no templates saved! if no templates are present on the instrument.

6.3.2. TEMPLATE HANDLING

With the PC Software, the operator can create templates for the download to the instrument. Up to ten templates or a total of 100 locations /sampling points can be stored on the instrument.



PROCEDURE

1) Choose Template in the menu Mode selection.
2) Select a template with the ▲/▼ buttons.
3) Press Select to confirm.

As shown in this example, [Template 1] can be changed or renamed in the PC Software.

The instrument displays the number of tests defined in the corresponding template and, if appropriate, the number of tests already done.



4) Select the location/sampling point for the next sample with the ▲/▼ buttons.
5) Press Select to confirm.

The user can select the Location and Sampling point, all these names can be changed or renamed in the PC Software.



6) Press Start to perform a sampling on the instrument.



After sampling, the values can be uploaded to the PC where the values are used to create an automatic report.

7) Press Back to return to the Home screen.

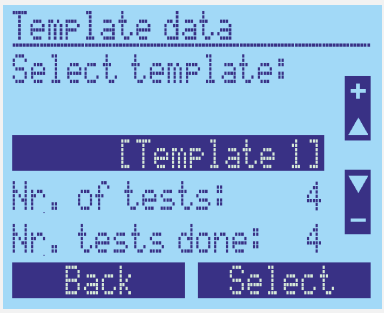
8) Press Delete... to remove the data or the complete template from the instrument. See chapter 6.3.3.

Note

For further information, refer to the Software Manual MAS-100 NT&NT Ex.

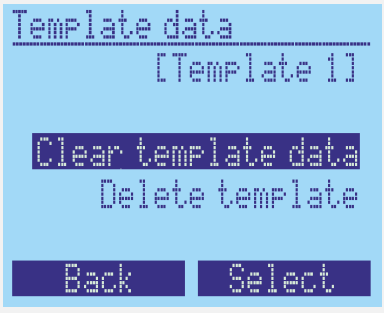
6.3.3. TEMPLATE DATA

This function allows to clear the data collected in a template and re-use the same template again. It can also be used to erase the entire template.

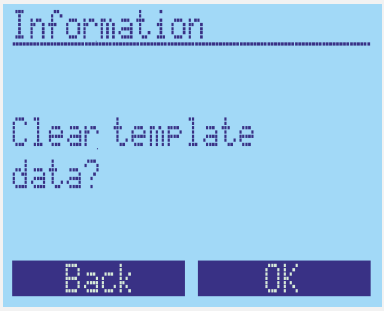


PROCEDURE

1) Go to the Main menu.
2) Press Template data.
3) Choose the template with the ▲/▼ buttons.
4) Confirm with Select.



5) Decide whether to delete the entire template or to clear only the data collected in the selected template:
   Select Clear template data to clear the collected data.
   or
   Select Delete template to delete the template.



To ensure that no important data is deleted by accident, the instrument asks for verification to clear the template data.

6) Accept with OK or press Back twice to return to the Main menu.



To ensure that no important data is deleted by accident, the instrument asks for verification to clear the template itself.

7) Accept with OK or press Back twice to return to the Main menu.



Note

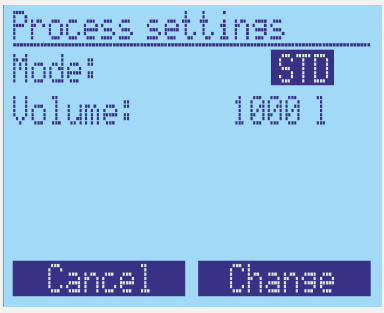
Templates or data contained therein, can only be deleted if the Protected mode is deactivated via the PC Software.

6.4. PROCESS SETTINGS (SAMPLING MODE)



PROCEDURE

1) Go to the Main menu.
2) Press Process settings.
3) Choose the template with the ▲/▼ buttons.
4) Confirm with Select.

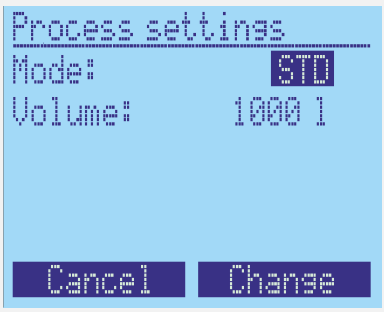


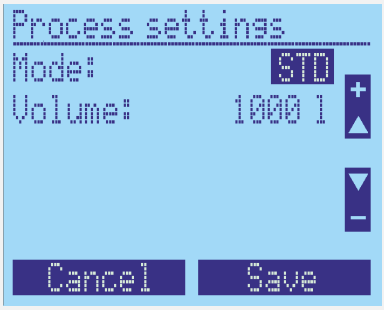
The Process settings menu shows in the first line what sampling mode is currently activated.

The following lines display the parameters associated with the chosen sampling mode.

The shown example shows an instrument in STD mode with a sampling volume of 1000 ℓ.

6.4.1. STD MODE (STANDARD)





PROCEDURE

1) Press Change and select STD with the ▲/▼ buttons.
2) Press Save to confirm.
3) Select Volume with the ▲/▼ buttons.
4) Press Change and select one of the predefined standard volumes (see chapter 6.5) with the ▲/▼ buttons.
5) Press Save and twice Back to return to the Home screen.

6.4.2. SQS MODE (SEQUENTIAL)

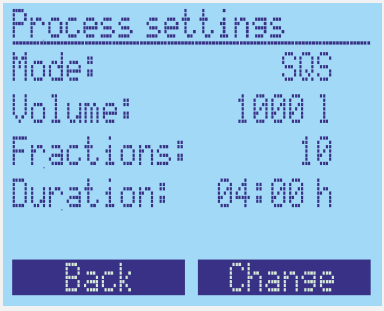


PROCEDURE

1) Press Change and select SQS with the ▲/▼ buttons.
2) Press Save to confirm.
3) Toggle to the desired parameter (Volume, Fractions or Duration) and press Change to modifify it:

   Volume: 40 - 2'000 ℓ (Predefined, see chapter 6.5)
   Fractions: 2 - 50
   Duration: Max. 23:59 h

4) Press Save after each parameter has been changed or press Cancel to abort.
5) Press Back twice to return to the Home screen.



The Home screen now shows that the SQS mode is selected with 10 fractions and a total of 1'000 ℓ (100 ℓ per fraction). It further shows, that the samples are taken over the time of 4 hours.

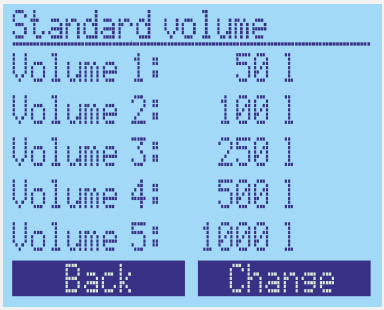


Note

The SQS mode will not accept preset volumes smaller than 40 ℓ. The instrument will display the warning Volume is set too low! upon starting a sampling.

6.5. PRESET STANDARD VOLUMES

- The instrument has 5 slots for storing preset standard volumes.
- These preset volumes serve as parameters of the STD and SQS sampling mode.
- Each slot contains a value between 0 and 2'000 ℓ.
- An unused slot can be omitted for easier handling. To do so, enter the value of 0 ℓ in the slot to be omitted.
- A maximum of 4 slots can be omitted.



PROCEDURE

1) Enter the menu item Standard volume.
2) Choose with the ▲/▼ buttons the slot to modify.
3) Set the volume with the ▲/▼ buttons.
4) Press Save.
5) Press Back if finished, or
6) Toggle with the ▲/▼ buttons to the next slot to modify and proceed with step 3.

Hazard of wrong air sampling results

Although possible, is not recommended to use preset volumes smaller than 40 L in STD mode.

6.6. DELAY

- The Delay function allows to postpone the actual sampling start by a predetermined time after having pressed Start.
- This function allows the operator to walk away from the instrument prior starting the sampling process, thus reducing the risk of cross-contamination by the operator.



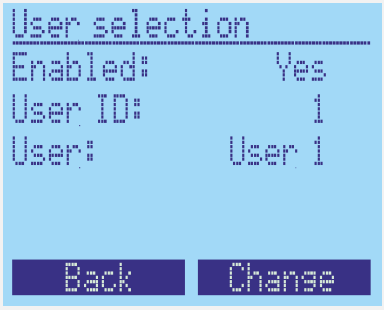
PROCEDURE

1) Enter the menu item Delay.
2) Toggle with the ▲/▼ buttons to the parameter to modify
3) Press Change.
   Delay: On / Off
   Time: 1 – 120 min
4) Press Save to store the value
5) Press Back if finished, or
6) Toggle with the ▲/▼ buttons to the next parameter to modify and proceed with step 3.

6.7. USER SELECTION

- The instrument can handle up to 10 predefined users (ID1 to ID10)
- The users are created in the PC Software
- Renaming the users is only possible in the PC Software
- If User selection is disabled, the user selection will not appear after the start.
- If this option is enabled, the instrument will prompt you to choose a user after pressing the Start button, before it is possible to start a sampling.

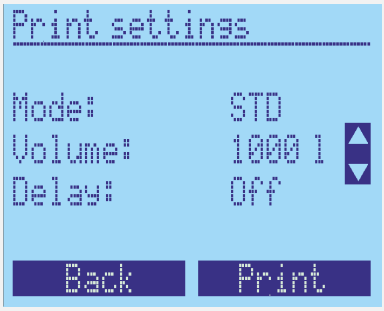
To activate this feature and to choose the active user proceed as follows:



PROCEDURE

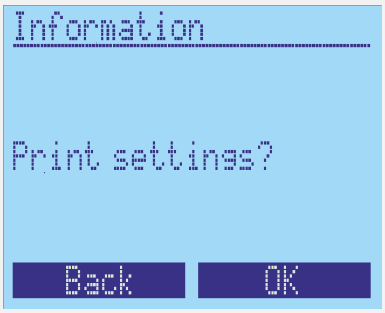
1) Enter the menu item User selection.
2) Toggle with the ▲/▼ buttons to the parameter to modify
3) Press Change.
   Enabled: Yes / No
   User ID: 1 – 10
   User: User name defined by PC Sofware
4) Press Save to store the value.
5) Press Back if finished, or
6) Toggle with the ▲/▼ buttons to the next parameter to modify and proceed with step 3.

6.8. PRINT INSTRUMENT SETTINGS



PROCEDURE

1) Enter the menu item Print settings.
   The current process settings are show on two pages. Toggle with the ▲/▼ buttons between these pages.
2) Press Print to print out the process settings

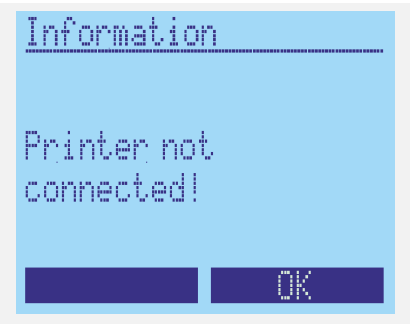


3) The instrument asks for confirmation.
4) Press OK to print, or
5) Press Back to return to the Main menu.



Note

For more information about the printing configuration, please consult chapter 6.13.



The message Printer not connected! will be displayed, if a printer is not connected to the instrument

Press OK to return to the previous screen.

PRINTOUT EXAMPLE

```
MAS-100 NT / NT Ex, S/N: 103526
Process settings
Date:          11/21/2016
--------------------------------
Mode:          STD
Volume:        1000 l
Delay:         On
Time:          5 min
User selection:On
User:          User 10
Dep.:          Location Dep.
Name:          Head Name

Signature: ____________________________
```

6.9. SAMPLE LOG

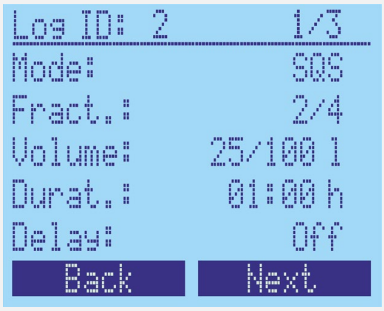
- Up to 100 sample log entries are logged in the system. Each can be reviewed individually.
- After 100 entries the first one will be overwritten. Only the last 100 entries can be accessed.
- The Log ID number will not reset to 1 after reaching 100 entries. It will continue counting even if the sample log is cleared (the number of possible entries is more than 10'000'000)

To access the sample logs, proceed as follows:



PROCEDURE

1) Enter the menu item Sample log.
2) Toggle with the ▲/▼ buttons to the desired Log ID.
3) Press Show to access this log, or
4) Press Back to return to the Main menu.



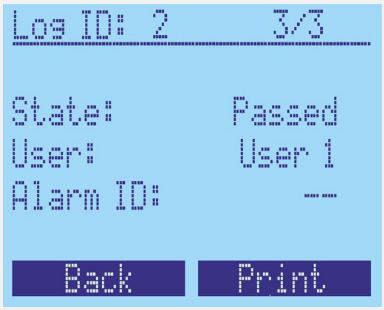
The sample log information extends over 3 pages. The first page 1/3 shows the chosen sampling mode an its settings.

5) Press Next to access page 2/3, or
6) Toggle with the ▲/▼ buttons to an adjacent entry, or
7) Press Back to return to the sample log selection menu.



Page 2/3 shows the samples start and end date & time

8) Press Next to access page 3/3, or
9) Toggle with the ▲/▼ buttons to an adjacent entry, or
10) Press Back to return to page 1/3.



Page 3/3 shows the sampling state, the user and the corresponding Alarm ID (if there is any).

If a printer is connected and the printing function is enabled, it is possible to make a printout of the currently selected sample log entry.

11) Press Print to make a printout, or
12) Toggle with the ▲/▼ buttons to an adjacent entry, or
13) Press Back to return to page 2/3.

6.10. ALARM LOG

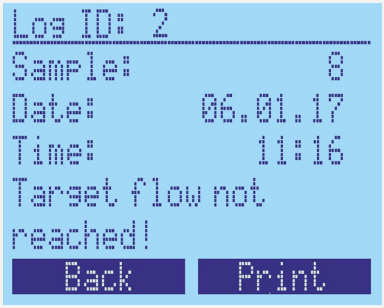
- Up to 100 alarm log entries are logged in the system. Each can be reviewed individually.
- After 100 entries the first one will be overwritten. Only the last 100 entries can be accessed.
- The Log ID number will not reset to 1 after reaching 100 entries. It will continue counting even if the alarm log is cleared (the number of possible entries is more than 10'000'000)
- For detailed information about the alarm ID's refer to chapter 7.1.

To access the alarm logs, proceed as follows:



PROCEDURE

1) Enter the menu item Alarm log.
2) Toggle with the ▲/▼ buttons to the desired Log ID.
3) Press Show to access this log, or
4) Press Back to return to the Main menu.



An alarm log entry contains the following information:

- Sample ID when alarm occured
- Date of alarm
- Time of alarm
- Alarm description

If a printer is connected and the printing function is enabled, it is possible to make a printout of the currently selected alarm log entry.

5) Press Print to make a printout, or
6) Press Back to return to the log selection.

6.11. CONFIG DEVICE



PROCEDURE

1) Enter the menu item Config device.
   The menu contains the following sub-items:
   - Time/Date
   - Language
   - Contrast
   - Device info
2) Choose the desired sub item with the ▲/▼ buttons.
3) Press Select.

6.11.1. TIME/DATE



Appearance of the date formats:

- EUR: dd.mm.yyyy hh:mm
- JPN: yyyy.mm.dd hh:mm
- USA: mm/dd/yyyy hh:mm am/pm

Settings for summer time:

- Summer On: Daylight saving time (summer time)
- Summer Off: Standard time

PROCEDURE

1) Select the desired sub-item with the ▲/▼ buttons.
2) Press Change and adjust the value with the ▲/▼ buttons.
3) Press Save to confirm.

6.11.2. LANGUAGE



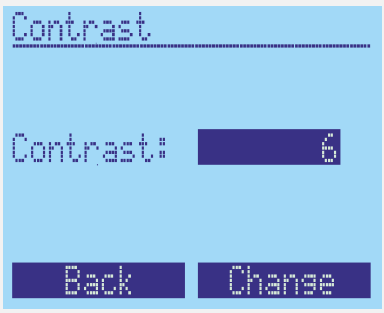
Eight languages can be selected:

- English
- French
- German
- Spanish
- Polish
- Czech
- Portuguese
- Italian

PROCEDURE

1) Press Change and select the desired language with the ▲/▼ buttons.
2) The instrument changes the language immediately after pressing Save.

6.11.3. CONTRAST



The contrast value of the display can be adjusted in a range from 0 to 14.

PROCEDURE

1) Press Change and select the desired contrast value.
2) Press Save to confirm.

6.11.4. DEVICE INFO



The Device info menu displays the following parameters:

❶ Instrument type
❷ Name — Individual name of the instrument[5]
❸ Dep. — Location, e.g. «Laboratory X»[5]
❹ Perf. lid — Currently set lid (300 × 0.6 or 400 × 0.7)
❺ Skip intro — Flag which defines how intro screens work.

Parameter ❶ cannot be modified.

Parameters ❷ and ❸ can only be modified in the PC Software.

Parameters ❹ and ❺ can be modified directly on the instrument. To do so, proceed as follows:



PROCEDURE

1) Select Perf. lid with the ▲/▼ buttons.
2) Press Change and select the dimension of the used perforated lid with the ▲/▼ buttons.
3) Press Save to confirm.
4) Select Skip intro with the ▲/▼ buttons.
5) Press Change and select the code for the behavior during start-up with the ▲/▼ buttons.

1 = First intro screen skipped
2 = First and second intro screens skipped
0 = Both intro screens will appear

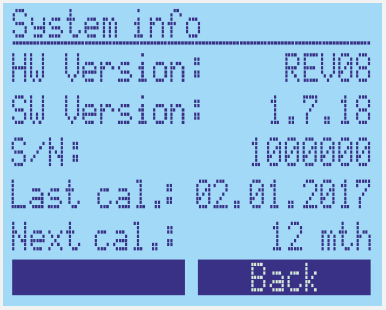


Note

The intro screens are the first screens displayed after switching on the instument.

(5) These settings can be modified by the user with the PC Software.

6.12. SYSTEM INFO



PROCEDURE

1) Enter the menu item System info.

   The System info screen shows

   - Hardware version
   - Software version
   - Serial number
   - Date of last calibration
   - Time to next calibration

   If the calibration validity is set to zero, the Last calibration and Next calibration date are not displayed.

2) Select Back to quit.

6.13. PRINTER CONFIGURATION

6.13.1. FUNCTIONALITIES

The instrument is capable of printing directly via RS-232 port. The system can output:

Summary	Automatically after each sampling
Instrument settings	Manually, see chapter 6.8
Sample logs	Manually, see chapter 6.9
Alarm logs	Manually, see chapter 6.10

PRINTOUT EXAMPLES WITH EPSON TM-U220

```
MAS-100 NT / NT Ex, S/N: 103526
Protocol Nr.:      1
Manual mode
----------------------------------------

User:           User 3
Department:     Location 1
Name:           Head 1

Start date:     11/11/2016
Start time:     09:31 AM
End date:       11/11/2016
End time:       09:32 AM

Mode:           STD
Volume:         86 of 1000 l

Delay:          Off

Meas. status:   Stopped
Alarm ID:       104

Signature: ____________________________
```

```
MAS-100 NT / NT Ex, S/N: 103526
Protocol Nr.:      5
Template mode
----------------------------------------

Template:       Tests 1
Location:       Place 2
Sampl. point:   Point 2

User:           User 5
Department:     Location 1
Name:           Head 1

Start date:     11/11/2016
Start time:     11:54 AM
End date:       11/11/2016
End time:       11:54 AM

Mode:           SQS
Volume:         100 l
Fractions:      2
Duration:       00:01  h

Delay:          Off

Meas. status:   Passed

Signature: ____________________________
```

6.13.2. SET PRINTER SETTINGS

If the printers are bought from MBV AG directly, the printers are preconfigured. To check or set the printer's configuration, follow the steps below:

PROCEDURE

1) Disconnect the power cord of the printer.
2) Remove the cover at the bottom of the printer to gain access to the DIP switches to adjust the printing parameters.
3) Adjust with a small flat head screw driver the two DIP switch banks according to the following 2 tables
4) Reassemble the cover
5) Reconnect the power cord
6) Keep pressing the line feed key while switching on the printer, it will print the printer settings
7) Once everything is set correctly, connect the serial cable from the air sampler.

SETTINGS FOR PRINTER EPSON TM-U220D

Dip SW1 (upper bank)								
	1	2	3	4	5	6	7	8
ON			X		X	X		
OFF	X	X		X			X	X

Dip SW2 (lower bank)								
	1	2	3	4	5	6	7	8
ON								
OFF	X	X	X	X	X	X	X	X

SETTINGS FOR PRINTER SAMSUNG BIXOLON 275AG

Dip SW1 (upper bank)								
	1	2	3	4	5	6	7	8
ON			O		O			
OFF	X	X		X		X	X	X

Dip SW2 (lower bank)								
	1	2	3	4	5	6	7	8
ON			X		X	X		
OFF	X	X		X			X	X

X	Mandatory
O	Optional

6.13.3. OTHER PRINTERS

Although not supported by MBV AG, other printers might work. Adjust the communication settings to:

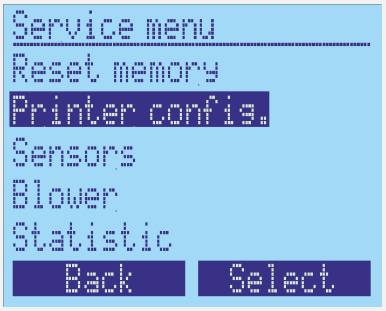
- 9'600 Baud
- 8 data bits
- Parity even
- 1 Stop bit
- Handshake XON / XOFF

If an emulator / interpreter setting can be selected, choose Epson.

6.13.4. ONLINE PRINTING ACTIVATION VIA HMI

The instrument needs to be enabled for online printing.

This procedure must be performed only once and can be configured via the instruments service menu or via the PC Software.



PROCEDURE

1) Startup the instrument
2) Wait until the Home screen appears.
3) Press simultaneously the ▲/▼ buttons and keep them pushed for a few seconds to enter the Service menu.
4) Choose Printer config. with the ▲/▼ buttons.
5) Press Select.



6) Select Printer with the ▲/▼ buttons.
7) Press Change.
8) Choose the printer TM-U220 with the ▲/▼ buttons.
9) Press Save to confirm.
10) On Onl. print press Change and set to On with the ▲/▼ buttons.
11) Press Save to confirm.
12) Press Back twice to quit the service menu.
13) Connect the printer with the instrument.

6.13.5. ONLINE PRINTING ACTIVATION VIA PC SOFTWARE



Note

The instrument may also be enabled for online printing via the PC Software.
Please refer to the Software Manual MAS-100 NT/NT Ex for further details.

7. ALARMS AND WARNINGS

7.1. ALARMS

- The table below lists all alarms provided by the instrument.
- All alarms are announced with an acoustic sound from the instrument and displayed on the screen.
- Once an alarm occurs, the instrument is locked in an alarm state.
- All alarms are logged in the alarm log file of the instrument (consult chapter 6.10).
- Quit the alarm state by pressing the OK button on the instrument.

Alarm ID	Description	Possible Cause	Possible Solution
9[6]	Calibration soon required	– This warning is displayed if the calibration validity is less than 30days and alarm 92 has occurred during the warning was displayed	– Calibrate device
36[6]	Recalibration required	– This warning is displayed if the calibration validity has expired and alarm 92 has occurred during the warning was displayed	– Calibrate device
91	Blower does not start!	– Hardware fault	– Unit needs service
92	Min. flow not reached!	– If the instrument cannot collect at least 15L, this alarm is triggered. This applies if the fan does not start or if the dust cover is still attached during the measurement.	– Clean perforated lid – Remove dust cover
94	Target flow not reached!	– Occurs when the measured volume and the target volume differ by more than 5%. This monitoring only becomes active after the 15L threshold of alarm 92 (about 10 seconds after the start of the measurement).	– Clean perforated lid – Remove dust cover
97	Temperature too high!	– Hardware fault	– Unit needs service
98	Measurement interrupted!	– Battery capacity too low – Hardware fault	– Recharge Battery – Unit needs service
99	Sample duration set too low!	– Sample duration in SQS mode too short for the selected volume	– Increase sample duration or decrease volume
100	Invalid calibration/ not activated!	– Device was not calibrated, or calibration is invalid – Calibration data lost	– Calibrate device
101[7]	Recalibration needed!	– Calibration expired	– Calibrate device

(6) Marked warning ID can overwrite the Alarm 92 entry in the sample log.

(7) This alarm is only displayed if the setting Block measurements if calibration validity expired is activated in the PC Software.

102	Volume is set too low!	– The selected volume is too low: 0 ℓ in STD mode or <40 ℓ per fraction in SQS mode.	– Increase the selected volume or decrease the number of fractions in the SQS mode
103	Sensor supply out of tol.!	– Hardware fault	– Unit needs service
104	Measurement stopped!	– Stop button pressed during sampling	– Do not abort sampling
107	Battery nearly discharged!	– Device was used too long without recharging battery	– Recharge battery immediately

7.2. WARNINGS

- The table below lists all warnings and failures provided by the instrument.
- Warnings are displayed on the screen (without the ID number).
- Quit the warning state by pressing the OK button on the instrument.
- None of the warnings are logged in the alarm log file of the instrument.

Warning ID	Description	Possible Cause	Possible Solution
1	Printer not ready, busy	– The printer is busy.	– Wait until printer is ready. – Retry printing.
2	Printer not connected	– The printer is not connected / configured.	– Configure a printer and enable «online» printing function.
3	Clear Sample log?	– Selected to clear the sample log (all entries in it) .	– Confirm with OK or abort by pressing Back.
4	Clear Alarm log?	– Selected to clear the sample log (all entries in it) .	– Confirm with OK or abort by pressing Back.
5	Reset Statistics?	– Selected to clear the statistics data.	– Confirm with OK or abort by pressing Back.
6	Clear all logged data (Sample, Alarm log and statistics)?	– Selected to clear all logged data (all alarm and sample log entries and the statistics) .	– Confirm with OK or abort by pressing Back.
7	Load factory defaults?	– Selected to load factory defaults.	– Confirm with OK or abort by pressing Back.
9[8]	Calibration soon required	– This warning is displayed if the calibration validity is less than 30 days.	– Confirm with OK. – Calibrate device.
10	Volume has been changed	– Is displayed if the currently selected standard volume was changed.	– Confirm with OK.
11	Print adjustment data?	– Is displayed if the function Print adj. data was selected.	– Confirm with OK or abort by pressing Back.
12	Print settings?	– Is displayed if the function Print settings was selected.	– Confirm with OK or abort by pressing Back.
13	Shut down device?	– Is displayed if the function Shut down was selected.	– Confirm with OK or abort by pressing Back.
14	Calibration reminder	– Is displayed after device startup if the calibration reminder has not yet been activated.	– Set calibration reminder.

(8) Marked warning ID can overwrite the Alarm 92 entry in the Sample log.

15	No calibration reminder active	– Is displayed shortly after calibration validity is disabled (set to 0) .	– Calibrate device and set a calibration validity duration.
16	Clear template data?	– Is displayed if the function to clear the template data is selected.	– Confirm with OK or abort by pressing Back.
17	Clear template?	– Is displayed if the function to clear the template is selected.	– Confirm with OK or abort by pressing Back.
18	Set serial number?	– Is displayed if the function to set the serial number is selected	– Enter the device's serial number
19	Activate calibration validity immediately?	– Is displayed after the calibration was executed successfully	–
31	Default value loaded	– Factory defaults were loaded – RTC not properly inserted	– Check RTC for proper insertion – Further diagnosis necessary
32	Mainboard temperature too high	– The temperature of the Mainboard is higher than 60 °C and leads to Alarm 97	– If device stalls, remove battery pack and send to your local service center
35	Offset High flow Sensor out of tolerance	– The Flow sensor value at zero flow is out of tolerance	– Unit needs service
36[9]	Recalibration required	– This warning is displayed if the calibration validity has expired	– Calibrate device
38	All standard volumes are 0	– All standard volumes were set to zero	– At least one standard volume must not be set to zero
39[10]	Battery nearly discharged	– Battery capacity is very low and leads to Alarm 107	– Recharge battery
61[11]	Error during writing data to NVRAM.	– RTC not fully inserted.	– Unit needs service.
62[11]	Invalid checksum in NVRAM	– RTC not fully inserted^.	– Unit needs service.

(9) Marked warning ID can overwrite the Alarm 92 entry in the Sample log.

(10) MAS-100 NT: Possible to run a 1'000 ℓ sample 1-2 times. MAS-100 NT Ex: Recharge battery immediately, a measurement cycle cannot be guaranteed.

(11) In the Communication Manual MAS-100 NT/NT Ex this warning is categorized as «Technical failure».

8. CARE AND MAINTENANCE

8.1. GENERAL

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

- Follow the general safety information (chapter 1.1)
- Always follow the cleaning and decontamination procedures (chapter 8.2)
- The instrument must be calibrated periodically (chapter 10.3).
- Always cover the perforated lid with the dust cover when the instrument is not in use.

8.2. CLEANING AND DECONTAMINATION

8.2.1. PERFORATED LID AND DUST COVER

Remove these components from the instrument. The available cleaning /decontamination options are:

Cleaning/disinfection solution

Use a commercial product or a 70-90 % ethanol/water solution (or isopropanol/water).

Spray the solution directly on the parts, wipe with a sterile towel or spray the towel and then wipe.

Autoclaving

Autoclave, either dry or applying steam. Keep the following process parameters within these limits:

Temperature:	≤ 180 °C
Duration:	< 60 min

Ultrasonic bath

Use an ultrasonic bath with a 70-90 % ethanol/water solution (or isopropanol/water). Ensure that the perforated lids do not collide in the ultrasonic bath.

Vaporized hydrogen peroxide

Use vaporized hydrogen peroxide with a concentration of up to 840 ppm.



Hazard of damage to the instrument

All of the cleaning/disinfection solution must be removed/wiped dry properly prior use.

Never dry the components by turning on the blower.



Note

In case of dirt blocking the holes of the perforated lid, use the ultrasonic bath.

If this does not suffice, pinch the dirt carefully out of the holes with a thin needle and redo the ultrasonic bath.



Note

The blue anodized parts may experience a (harmless) decolorization after applying vaporized hydrogen peroxide.

8.2.2. EXTERIOR

The available cleaning /decontamination options are:

Cleaning/disinfection solution

Use a commercial product or a 70-90 % ethanol/water solution (or isopropanol/water).

Spray the solution directly on the instruments exterior, then wipe with a sterile towel or spray the towel, then wipe.

Vaporized hydrogen peroxide

Use vaporized hydrogen peroxide with a concentration of up to 840 ppm.

The perforated lid and dust cover must be unmounted during the process.



Hazard of dangerous voltage

The instrument must be disconnected from the power supply prior cleaning.



Hazard of damage to the instrument

The instrument is not IP-protected.

Do not spill liquids into the electric/electronic connections or through the sampling head.



Hazard of damage to the instrument

All of the cleaning/disinfection solution must be removed/wiped dry properly prior use.

Never dry the components by turning on the blower.



Hazard of damage to the instrument

The instrument must remain shut down during the whole vaporized hydrogen peroxide decontamination process.



Note

The blue anodized parts may experience a (harmless) decolorization after applying vaporized hydrogen peroxide.

8.2.3. INTERIOR

PROCEDURE

1) Put the instrument in a laminar flow cabinet.
2) Use a cleaning/disinfection solution of 70-90 % ethanol/water (or isopropanol/water) in a spray bottle.
3) Run the instrument in the laminar flow cabinet for a minimum of 2 cycles at 1'000 L each.
4) At the start of each cycle, spray two short strokes of cleaning/disinfection solution in front of the sampling head with the perforated lid installed.
5) Dry the instruments exterior with a sterile towel.
6) Put the instrument in a sterile plastic bag until it is used or for transportation of the instrument to the sterile area.

9. INTERPRETATION OF RESULTS

The sampling results are typically interpreted by counting the colony forming units (CFU) on the incubated Petri dish. The discrete number of holes in the sampling head leads to the effect that as the number of CFU's per sample rises, the chance that several CFU's will enter the same hole in the perforated lid will also increase. When this happens the two grow so close together on the Petri dish that they cannot be distinguished from each other. Due to this effect, the number of counted CFU and the number of actual CFU are not identical. Feller's positive hole correction tables consider this effect and correct the CFU with the following formula:

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

Where:

r = Counted CFU

N = Number of lid holes

Pr = Corrected value for CFU

Therefore, the interpretation of sampling results is done by following these 3 steps:

1) Count all CFU on the incubated Petri dish.

   Correct the count based on Feller's statistical correction table.

   Convert to CFU/m^3.



Note

Feller correction tables are delivered with the instrument and can also be found on the USB memory stick delivered with the instrument.



Note

The statistical distortion comes into force the higher the counted CFU is. Below a certain number of CFU the correction is negligible:

For 300 × 0.6 mm sampling head: 18 CFU

For 400 × 0.7 mm sampling head: 21 CFU

10. ADJUSTMENT AND/OR CALIBRATION OF THE INSTRUMENT

10.1. GENERAL

Adjustment = Adjust a device to a standard

Calibration = Compare a device to a standard



Note

Detailed proceedings of adjustment and calibration are described in the Anemometer User Manual and the Software Manual MAS-100 NT/NT Ex .



Note

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

10.2. FACTORY CALIBRATION CERTIFICATES

The instrument is factory calibrated by a digital anemometer. The airflow of the anemometer itself is calibrated by the MBV calibration laboratory, which has been accredited by the Swiss Accreditation Service SAS according to ISO 17025:2017.

MBV AG
Industriestrasse 9
CH-8712 Stäfa

Certificate Number	16115-20190709161559	Order Number	11364

10.3. CALIBRATION PERIODICITY

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



Hazard of wrong sampling results

Do not use an uncalibrated instrument. It is recommended to adjust and calibrate the instrument in a periodicity of 12 months.

11. REGULATORY INFORMATION

11.1. SUBSTANCES SUBJECT TO CHINESE ROHS

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

The table below lists the instruments' hazardous substances and their concentration in milligrams per instrument.

部件名称 Component name	有害物质或元素 Hazardous substances or elements					
	铅 Pb	汞 Hg	镉 Cd	六价铬 Cr(VI)	多溴联苯 PBB	多溴联苯醚 PBDE
PCB's	o	o	o	o	o	o
Blower	o	o	o	o	o	o
Litium-Ion Battery	o	o	o	o	o	o
Timekeeper	o	o	o	o	o	o

O: 表示该有毒有害物质在该部件所有均质材料中的含量均在SJ/T11363-2006 标准规定的限量要求以下
X: 表示该有毒有害物质至少在该部件的某一均质材料中的含量超出SJ/T11363-2006 标准规定的限量要求
(企业可在此处，根据实际情况对上表中打“X”的技术原因进行进一步说明。)

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

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

11.2. IATA (AIR TRANSPORTATION)



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.

EXAMPLE



12. TECHNICAL SPECIFICATIONS

General	
Flow rate	Default: 100 SLPM ± 2.5 %
Standard sampling volumes	Out-of-specification limit selectable from 2.5 up to 25 %
Freely definable sampling volumes	50, 100, 250, 500, 1'000 ℓ

Sampling head	
Material	Anodized aluminum
Dimensions (D × H)	Ø 109 × 32 mm
Weight	190 g
Lid geometry	300 × Ø 0.6 mm, or 400 × Ø 0.7 mm
Sampling efficiency	d_{50} value 1.1 µm at 100 SLPM
Autoclaving (wet or dry)	Temperature: ≤ 180 °C Duration: < 60 min
Petri dish	For standard Petri dishes and contact plates

Body		
Material	Anodized aluminum	
Dimensions (H × W × L)	270 × 109 × 170 mm	(with handle)
Weight	2.37 kg	(with perforated lid)

Power supply	
Input external power supply	100 - 240 V AC, 50 - 60 Hz, 700 mA - 350 mA
Mains supply voltage	Fluctuations must not exceed ± 10 % of the nominal voltage
Transient overvoltage	Overvoltage category: Category II Pollution degree: 2
Input instrument	12 V DC, 2.5 A
Battery pack	6-cell Litium-Ion, 7.4 V DC, 6.9 Ah
Full recharging time	Approx. 3.5 h
Total running time	Approx. 5.5 h
RTC battery	3 V Lithium
Lifetime RTC battery	Approx. 10 years

Envoronmental conditions	
Altitude	Up to 2'000 m above sea level
Temperature	Storage: -10 to +50 °C Operation: 5 to +40 °C
Maximum relative humidity	Max. 80 % RH for temperatures up to 31 °C, decreasing linearly to 50 % relative humidity at 40 °C; non-condensing
EMC, ESD	Equipment class A, industrial environment

Miscellaneous	
Total aspiration volume	Approx. 33'000 ℓ
Blower motor	EC motor 6 V, 12 W
Particle generation	ISO 14644-1, Class 5
Display	Alphanumeric graphic display
Controller	Microprocessor
Flow regulation	Mass flow sensor
Tripod screw thread	⅜" UNC (and ¼" UNC insert), for use with standard camera tripod
Transport case	Plastic



Note

Operation of the instrument at altitudes significantly higher than sea level may cause a reduced blower lifetime.

ANNEX A – PHYSICAL SAMPLING EFFICIENCY

ANNEX A.1 - D_{50} VALUE

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

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

The physical sampling efficiency is the same whether the particles consist of single microorganisms, particles carrying microorganisms, or are nonviable (inert) particles. The physical sampling efficiency is based on the physical characteristics of the sampling device such as air flow, orifice shape, and orifice size.

Detailed information how to calculate the d_{50} value may be found the publications [(12)] [(13)].

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

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

Where:

40 = Constant factor for air viscosity

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

U = Impact velocity [m/s]

The lower the d_{50} value is, the better the physical sampling efficiency. In the MAS-100 product family the d_{50} value is governed by the sampling head configuration:

Sampling head	d_{50} [µm]
300 × 0.6	1.1
400 × 0.7	1.6

(12) Willeke K, Baron PA, eds. Aerosol Measurement: Principles, Techniques and Applications. New York: Van Nostrand Reinhold, 1993

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

ANNEX A.2 ISO 14698 VALIDATION STATEMENT

Note

The instruments MAS-100 NT and MAS-100 NT Ex share an exactly identical mechanical layout in all components affecting the air flow path.

Therefore, all data, results and conclusions shown hereafter – which were gathered with a MAS-100 NT – are applicable to the MAS-100 NT Ex as well, without any kind of restrictions

The MAS-100 NT system was tested by an independent air monitoring expert public laboratory, following ISO 14698-1:2003, Annex B guideline.

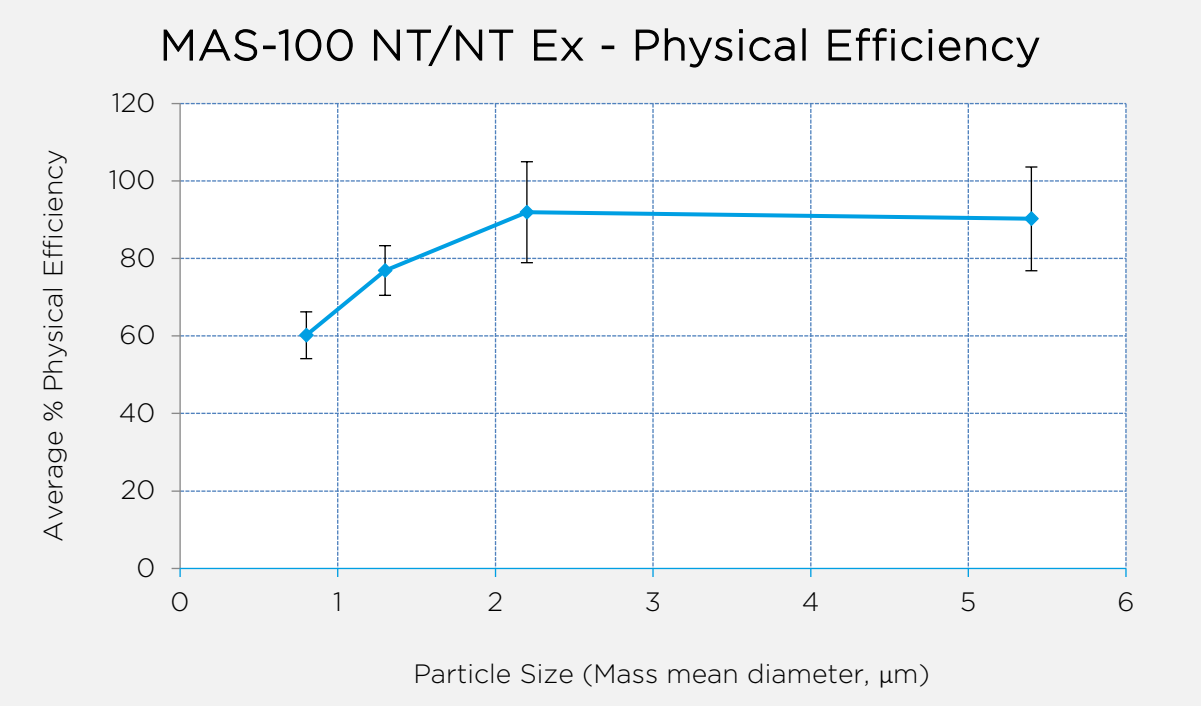
The study was conducted using the 300 × 0.6 mm holes perforated lids, with a MAS-100 NT system calibrated at 100 ±2.5L/min. The study was conducted using Heipha TSA + LTHTh ICRplus 30 mℓ media plates on the MAS-100 NT system and the reference systems.

The study consisted in physical efficiency testing and biological efficiency testing.

PHYSICAL EFFICIENCY RESULTS

The physical efficiency of the MAS-100 NT air sampler for collecting small bacteria-laden particles of various sizes was compared with membrane filter samplers using the techniques described in ISO 14698-1:2003, Annex B. The results showed that the MAS-100 NT sampler was ca. 60.2-76.9% efficient for collecting particles containing bacterial spores in the 1-micron size, in comparison with the membrane filter samplers, rising to 90.2 % in the range of 5-6-micron size.

The experimental results indicate a 50 % cut-off, also referred as d_{50} value, of below 1 µm, making the sampler suitable for use within a clean room environment.



MAS-100 NT / NT Ex - Physical Efficiency

Average physical efficiency in % per mass mean diameter particle size in µm.
Error bars represent standard deviation.

BIOLOGICAL EFFICIENCY RESULTS

The biological efficiency of a sampler is a measure of how effectively it can collect microorganisms on an agar plate in such a way the microorganism will subsequently form a colony. As suggested in the ISO 14698-1:2003, the common human derived environment contaminant «Staphylococcus epidermidis» was used as an indicator of biological efficiency. In the study performed, the biological efficiency of the MAS-100 NT sampler was compared to that of the reference Casella slit sampler.
The biological efficiency measured of the MAS-100 NT was found to be on average 82.6 % (number of repeats = 20) that of the Casella sampler, indicating the sampler is effective at sampling bacteria-laden particles, without loss of viability.

ANNEX B – ISO 14644-1 CLEANLINESS STATEMENT

The instrument has been designed and validated for a very low particle generation rate and is compliant with the requirements of ISO 14644-1, Class 5.

Operators committed to the highest degree of cleanliness are advised to prevent impurity traces inside the instrument (due to packaging, storage, transport… etc.), by flushing the instrument during 24 hours prior commissioning and/or cleanliness qualification.

To flush the instrument, please proceed as follows:

1.	Install the instrument in an environment with controlled clean air (flow cabinet, isolator… etc.)
2	Remove the dust cover.
3	Connect the instrument to the power supply.
4	Startup the instrument.
5	Confirm with OK.
6	Press simultaneously the ▲ / ▼ keys and keep them pushed for a few seconds.
7	The instrument is now in the Service menu.
8	Toggle to the Blower option and push Select.
9	The instrument is now in the Blower menu.
10	Press Change.
11	Toggle with the ▲ / ▼ keys to select a blower PWM of 50 %.
12	Confirm at 50 % by pressing Save.
13	Keep the blower running for 24 hours. Keep the instrument connected to the power supply while the blower is running.
14	Stop the blower after the 24-hour flush run. The instrument will change to the Service menu
15	Press Back again. The instrument will change to the Main menu.
16	Switch off the instrument or Proceed with the cleanliness qualification measurements according to the operator's specifications. Keep the instrument in a clean environment until the validation is finished to avoid re-contamination.

ANNEX C – GLOSSARY

Term	Meaning
AC	Alternating Current
ATEX	European directive for equipment in explosive environments
AUS	AUStralia
CE	European certification mark
CFR	Code of Federal Regulations (USA)
CFU	Colony Forming Units
CI/CD	Corporate Identitity/Corporate Design
DC	Direct Current
DIP	Dual In-line Package (switch type)
EAC	Eurasian conformity mark
EC	Electronic Commutated (electric motor)
EMC	ElectroMagnetic Compatibility
EN	European standard
ESD	Electrostatic-Sensitive Device
EU / EG / EUR	European Union / Europäische Gemeinschaft / EURopean
FDA	Food and Drug Administration (USA)
FRS	Functional Requirement Specification
GAMP	Good Automated Manufacturing Practice,
GB	Great Britain
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points
HMI	Human Machine Interface
HW	HardWare
IATA	International Air Transport Association
ID	IDentification number
IEC	International Electrotechnical Commission
IP	International Protection marking
ISO	International Organization for Standardization (standards)
LED	Light-Emitting Diode
NVRAM	Non-Volatile Random Access Memory
PC	Personal Computer
PCB	Printed Circuit Board
RoHS	Restriction of Hazardous Substances (directive)

RSS	Rich Site Summary
RTC	Real Time Clock
SIL	Service Information Letter (MBV AG)
SJ	Chinese standard for electronic equipment
SLPM	Standard Liters Per Minute
SW	SoftWare
SQS	Sequential sampling mode
STD	Standard sampling mode
S/N	Serial Number
UNC	Unified thread standard (standard, USA and Canada)
URS	User Requirements Specification
US / USA	United States of America
USB	Universal Serial Bus
XOFF	Transmitt code «ON»
XON	Transmit code «OFF»
WEEE	Waste Electrical and Electronic Equipment (European directive)

The vibrant M, [Mark[1], Mark[2] and Mark[3]], and Sigma-Aldrich are trademarks of Merck KGaA, Darmstadt, Germany or its affiliates. All other trademarks are the property of their respective owners. Detailed information on trademarks is available via publicly accessible resources.
© 2018 Merck KGaA, Darmstadt, Germany and/or its affiliates. All Rights Reserved.

www.sigmaaldrich.com