

MAS-100 ISO NT

Microbiological Air Sampler

USER MANUAL



AIR. NOTHING ELSE.

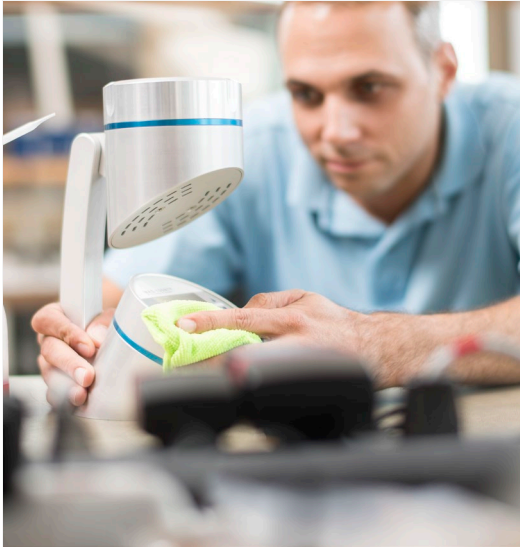


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Dear customer

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.

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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 and [MICROBIAL AIR SAMPLER MAS-100 Iso NT \(mbv.ch\)](http://www.mbv.ch/en/expert-center/downloads/mas-100-iso-nt/) (<https://www.mbv.ch/en/expert-center/downloads/mas-100-iso-nt/>).

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

DOCUMENT HISTORY

Revision	Date	History
26.0	2024-03-21	- Chapter 1.1 Safety information updated - Chapter 3.2 Optional accessories updated USB Memory Stick removed and Global Safety Data Sheet included - Footer: Document name and Version included - Wrong atex chapter removed
25.0	15.08.2022	- Chapter 5.4.3 RUNNING A DECONTAMINATION; Hazard of ineffective decontamination of the sampling head added. - Chapter 7. Alarm IDs and description; Alarm ID 95 updated - CICD & Trademarks updated
24.0	06.08.2020	- Alarm 92 and 94 better described - CICD & Trademarks updated - Include 03.3120.01 USB Memory Stick new MBV CICD - Document renamed - New design introduced - Factory calibration certificate changed from GWV to MBV
23.0	15.03.2017	- Page 2: Introduced new «Customer Center» on MBV AG website and removed RSS feed - Chapter 1.4: Removed mention of product CD - Chapter 14: Re-formulated Tri-Clamp size - Included new MBV AG logo - Minor typo and format corrections.
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14.0	27.07.2011	- Registered symbol corrected - Grammatical corrections - Endnotes converted into footer - Remote switch as option
13.0	07.02.2011	Chapter calibration of MAS-100 Iso NT transferred and referred to DA-100 NT user manual
12.0	1.01.2008	- New packing list inserted - Chapter 1.3 inserted - Schematics updated with valve numbers - Chapter 12 «Create Test Protocol» included
11.0	26.01.2008	Correction of different windows for SW version 2.1

TRADEMARKS

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ABBREVIATIONS

The microbiological air samplers **MAS-100 Iso NT** is designated hereafter as «Instrument».

The Software **MAS-100 Iso NT/MH Air Sampler - C&C** (communication and calibration) is designated hereafter as «PC Software».

APPLICABILITY

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

Component	Version
Main PCB MAS-100 Iso NT	≥ V6
Firmware MAS-100 Iso NT	≥ V2.8.5
Software MAS-100 Iso NT/MH Air Sampler - C&C	≥ V3.1.14



Note

The PC Software works for these instruments:

- MAS-100 Iso MH
- MAS-100 Iso NT (Standard and RABS)



Note

The instrument will communicate its type and firmware version to the PC Software.

The PC Software will interact with the instrument accordingly.

RELATED USER MANUALS

The following user manuals provide additional essential information:

Document designation	Document scope
Installation Manual MAS-100 Iso NT en	Describes the installation options. Contains technical information and the installation checklist.
Software Manual MAS-100 Iso NT&MH en	Describes the PC Software functions
Communication Manual MAS-100 Iso NT&MH en	Describes the communication protocol used to communicate with the instrument via all available interfaces, e.g. Ethernet, Profibus and RS-232
Anemometer User Manual	Describes the adjustment and calibration procedures
Pressure Test Manual MAS-100 Iso NT&MH en	Describes how to operate the pressure test kit

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1. GENERAL INFORMATION

This chapter provides information of general interest regarding the instrument.

1.1. SAFETY INFORMATION



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

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

1.1.1. SEVERITY LEVELS

Warning

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

Attention

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

Note

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

1.1.2. SPECIFIC SAFETY INFORMATION FOR THE INSTRUMENT



Hazard of dangerous voltage inside the power supply.

Do not open the power supply.

Always keep the areas of electric parts dry (e.g. USB plugs).



Hazard of explosion and/or fire.

The instrument contains a Lithium-Ion battery which might catch fire if damaged.



Hazard of injury and/or damage to the instrument.

Make sure that the equipment does not drop on the floor.

Always ensure secure hold and stability.



Hazard of explosion and/or fire.

The instrument is not explosion protected; never use it in explosion hazard areas.

	Hazard of serious injury and/or death. The used decontamination gas may be toxic, corrosive, flammable or explosive. Ensure the safety according to the safety data sheet of the used decontamination gas.
	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.
	Hazard of damage to the instrument. Do not spill liquids into the electric/electronic connections or through the sampling heads.
	Hazard of damage to the instrument. Do not perform any intervention inside the instrument. Only trained, qualified and authorized technicians are allowed to perform repair and maintenance activities.
	Hazard of damage to the instrument. The system power cord must always be easily accessible. Pull the plug rather than the cord to disconnect the system from any electrical outlet. Keep the power cord off the passage; make sure it is not pinched at the plug, electrical outlets, and the point from which it is connected to the system.
	Hazard of damage to the instrument. The piping downstream of the decontamination outlet must be unblocked and free of obstructions. Otherwise, an excessive backpressure could build up and release decontamination fluid into the instrument.
	Hazard of damage to the instrument and/or wrong air sampling results. The instrument is a precision device for industrial and laboratory use. The instrument shall only be operated by trained, qualified and authorized personnel as stated in chapter 1.2.1.
	Hazard of damage to the instrument and/or wrong air sampling results. Any application other than the intended use is not covered by warranty. For additional information, please consult chapter 1.2.2 and chapter 1.3.
	Hazard of wrong air sampling results. Using the instrument with the «Easy-Clean» base requires additional considerations during adjustment and calibration: Always perform calibrations and adjustments with the MAS-100 Family Calibration Disk with 85mm diameter or a Petri dish inside the sampling head.

	Hazard of wrong air sampling results. An adequate handling of the Petri dish and of the instrument are essential. Always follow good cleanroom practices to make sure that the Petri dish and sampling head do not get contaminated.
	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 21CFR part 11 and international regulations regarding GxP regulated records. If data generated by this system in a GxP regulated environment is needed, 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 (21CFR211.46(d)), therefore we recommend that you take any precaution for installing and handling your instrument accordingly.
	Hazard of damage to the instrument and/or wrong results Ensure that the instrument does not drop on the floor. Any exposure of the instrument to conditions outside the specified limits and approved uses in the user manual may result in invisible damage and deviations of the instrument. Therefore, after such an incident, an instrument must be checked for correct functioning by trained personnel or an MBV certified service centre. Any application other than the intended use is not covered by warranty.

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, isolators, operating theatres, flow hoods, 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 MAS-100 Iso NT is an instrument designed solely for civilian purposes and 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 isn't working as described in the user manuals.

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

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

1.3.2. QUALITY STATEMENT

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

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

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

1.3.3. CONTACT

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

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

1.3.4. EXCLUSION CLAUSES

The warranty covers exclusively material and manufacturing defects which occurred during the above described periods of time. The warranty does not cover the natural wear and tear of parts or any damage caused by improper handling, negligence, or non-observance of the user manuals or 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 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.

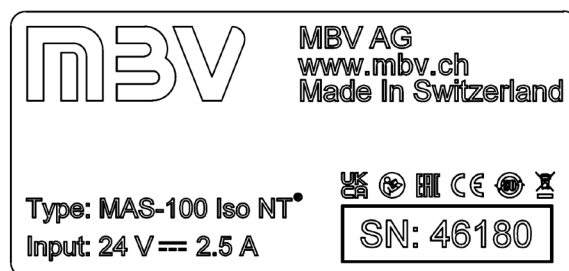
	Hazard of damage to the instrument There are no user-serviceable parts inside the instrument. Do not perform any intervention inside the instrument. Only trained, qualified and authorized technicians can perform repair and maintenance activities.
	Risk of warranty loss Every instrument is secured with an anti-tamper seal. Disassembling the instrument will break the seal and render the warranty void.

1.4. PRODUCT LABELING

The label on the electrical connection side of the instrument identifies the instrument and its manufacturer.

The information on the label includes:

- Manufacturer's name
- Instrument type
- Serial number (SN)
- DC supply data.



1.4.1. SIGNIFICANCE OF THE PICTOGRAMS

	Indicates the serial number of the instrument
	Identifies the manufacturer of the instrument
	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 MBV AG Website MICROBIAL AIR SAMPLER MAS-100 Iso NT (mbv.ch)
	With the UK Conformity Assessed (UKCA) marking the manufacturer declares conformity with the relevant directives of Great Britain as stated on the «Declaration of Conformity» which can be found on the MBV AG website MICROBIAL AIR SAMPLER MAS-100 Iso NT (mbv.ch)
	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 MBV AG Website MICROBIAL AIR SAMPLER MAS-100 Iso NT (mbv.ch)
	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 11.2, and can be recycled after being discarded and should not be casually discarded.
	Read the instructions before using the instrument.
	With this symbol the manufacturer declares conformity with the WEEE directive as described in the Declaration of Conformity which can be found on the MBV AG Website MICROBIAL AIR SAMPLER MAS-100 Iso NT (mbv.ch) . It should not be disposed of as household waste at the end of its life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this instrument from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources. Users should either send the instrument back to the supplier or dispose it locally in accordance with the applicable local waste legislations.
	Indicates the date of manufacture

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 — Bio-contamination 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 a microbiological air sampler for isolators and cleanrooms (standard version). A special version for RABS systems (Restricted Access Barrier Systems) is also available.

2.2. GENERAL DESCRIPTION

The instrument is an active microbiological air sampler, working on the impaction principle ⁽⁴⁾. By this principle, a predefined volume of air passes through the small holes of the sampling head. The air is accelerated to a speed of up to 19.6 m/s and the microorganism's impact on an appropriate microbiological culture medium filled in a Petri dish without suffering significant harm. The instrument has an industry leading collection rate and a very low d_{50} value of 1.1 μm (see Annex A – Physical sampling efficiency). The mass flow rate is sensor-controlled and kept automatically within narrow margins. Up to five different default sampling volumes can be predefined by the user.

The Petri dish is removed after the sampling process and incubated afterwards 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/m³ of air.

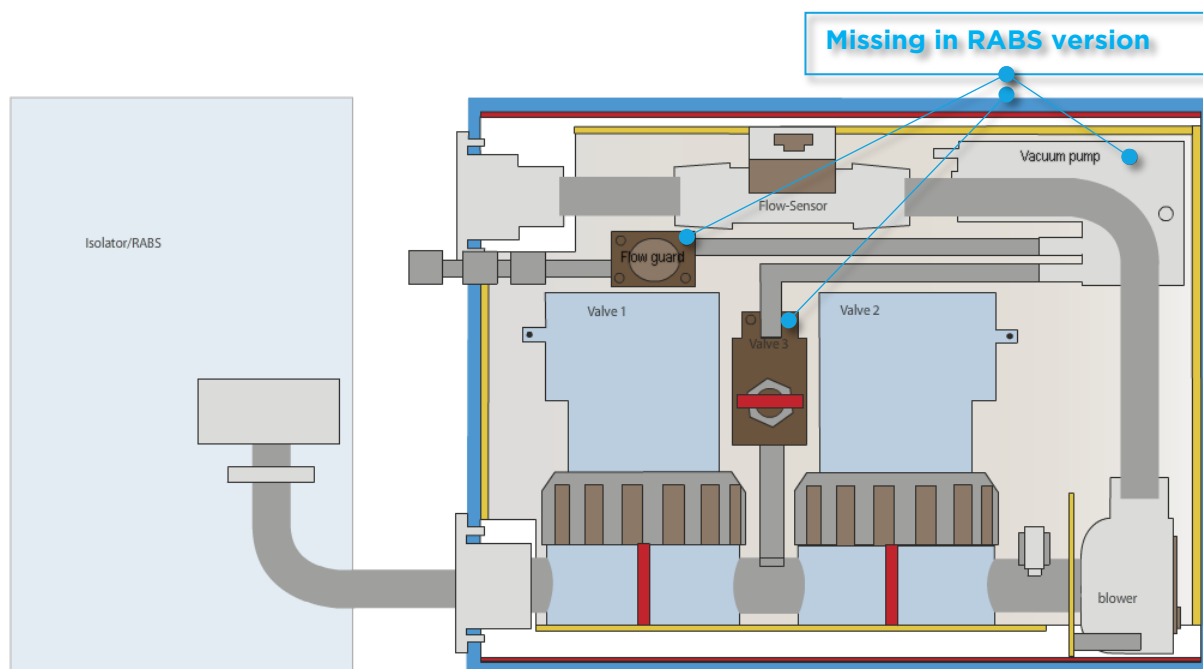
Since in cleanrooms and isolators every attempt is made to exclude items, such as electronic devices, fans, moving parts etc., the instrument is designed in such a way that only the static sampling heads are present in the critical area. All electronic and mechanical moving components are located outside the critical zone, encapsulated in a tight container. An integrated twin-valve airlock system prevents the ingress of air in the event of a pressure drop in the instrument assembly. The instrument is connected on-site to the piping by standard stainless-steel Tri-Clamp fitting components.

The instrument can be fully integrated in the on-site decontamination procedures. The components inside the clean zone (sampling head and pipes) can be decontaminated by flushing them with the decontamination gas. An integrated flow-controlled pump ensures a thorough decontamination of the instrument.

The “all-in-one” concept combines all electronic, mechanical and safety parts in one instrument. Service and calibration of the instrument are straight forward. All settings and parameters of the instrument are programmed via the PC Software which can be found on the MBV AG Website [MICROBIAL AIR SAMPLER MAS-100 Iso NT \(mbv.ch\)](http://mbv.ch).

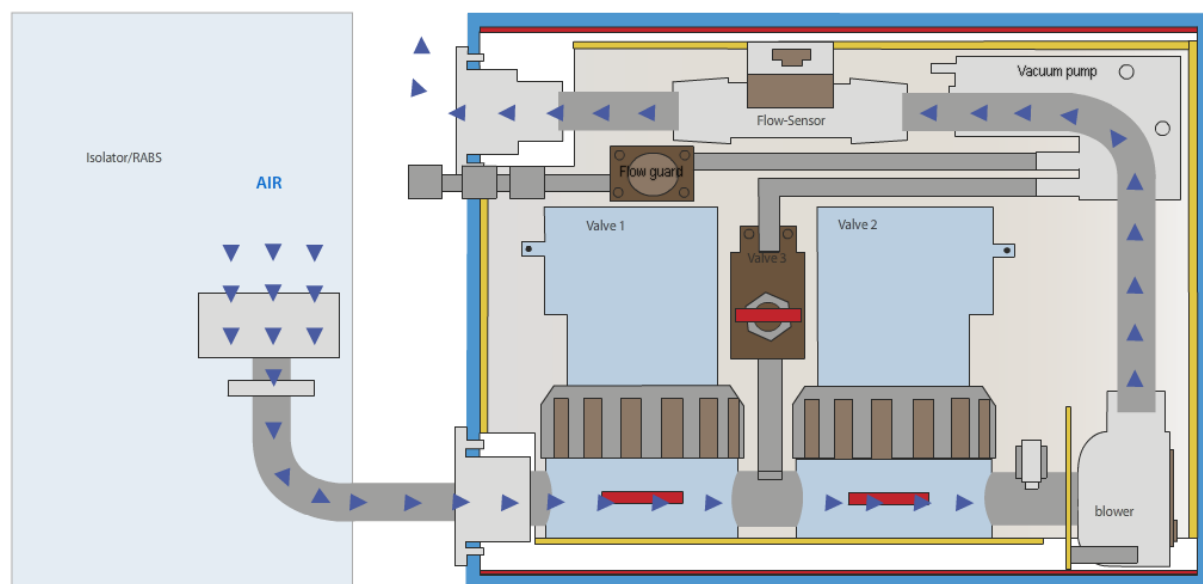
2.3. WORKING PRINCIPLE

2.3.1. VALVE POSITIONS OF INSTRUMENT AT REST



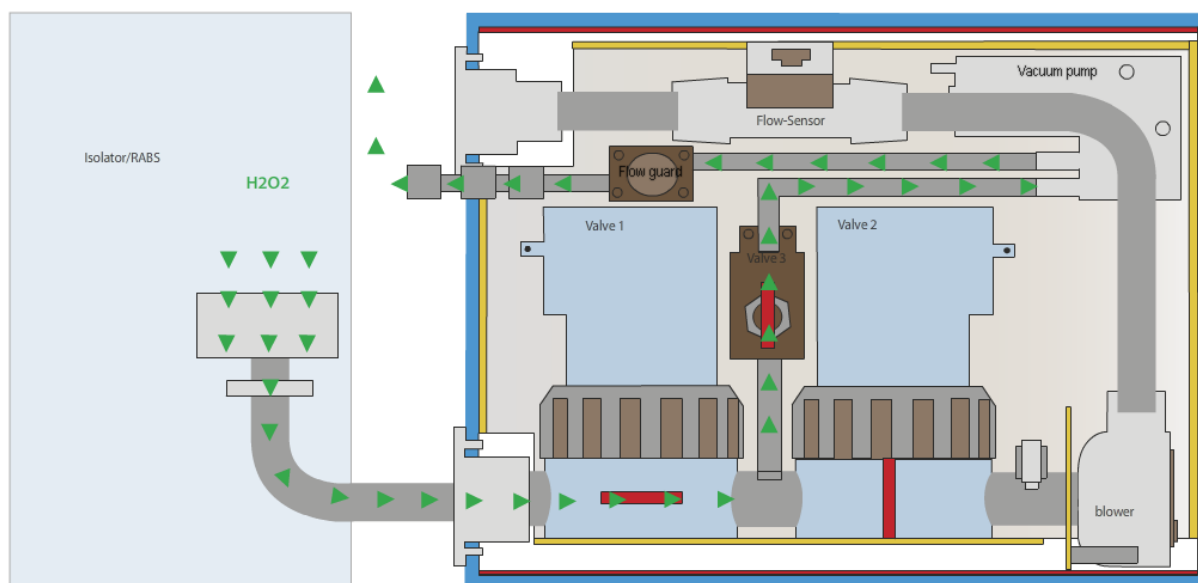
Both main valve 1 + valve 2 closed, decontamination valve 3 closed.

2.3.2. AIR FLOW DURING SAMPLING



Both main valves 1 and valve 2 are open during sampling, decontamination valve 3 is closed.

2.3.3. GAS FLOW DURING DECONTAMINATION



First main valve 1 and decontamination valve 3 are open, second main valve 2 is closed, during decontamination.

2.4. MAIN FEATURES

- High collection rate of airborne contaminants by the impaction principle ($d_{50}=1.1\ \mu\text{m}$)
- Open system for standard Petri dishes
- Compact dimensions
- Easy installation
- Twin-valve airlock isolation system
- Flexible use of different sampling heads and dish bases
 - Standard or Easy clean base
 - With edge protection
 - Stainless steel or anodized aluminum heads
 - Perforated lid with 300 holes / diameter 0.6 mm (short: 300×0.6)
 - Perforated lid with 400 holes / diameter 0.7 mm (short: 400×0.7)
- Multiple sampling options
 - Standard sampling (STD)
 - Sequential sampling (SQS)
- State of the art electronic connectivity (see chapter 2.7)
- Extensive data logging functionalities
- Remote switch
- IP54 protection level (optional)
- Easy automated calibration with an MBV digital anemometers
- Electronic flow control during sampling and decontamination cycle
- Fully validated system (hardware, software, firmware and consumables)
- Developed according to GAMP 4
- Compliant with ISO 14698-1 and ISO 14698-2.



Note

Customized instruments without decontamination cycle components (RABS) are available on request.

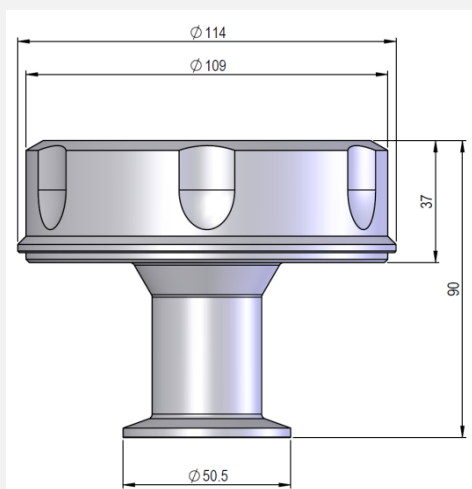
2.4.1. ALL-IN-ONE UNIT

The instrument is an all-in-one unit consisting of an air aspiration device, a special circuit with independent pump and flow control for the decontamination cycle and a command and communication board. The twin-valve security system ensures the outside-to-inside protection of the isolator and vice-versa. An integrated mass flow sensor guarantees a highly accurate mass flow.

2.5. SAMPLING HEADS

The instrument is an open system which allows accommodating standard Petri dishes.

2.5.1. MAX. OUTER DIMENSIONS



The displayed dimensions are applicable for standard sampling heads with edge protection.

Tri-Clamp connection

Outer diameter: 50.5 mm

Inner diameter: 21.7 mm

2.5.2. BASE

Standard base



- For Petri dishes from Ø90-100 mm base
- Spring-loaded petri dish clamps (adjustable)
- Horizontal or vertical mounting
- Gas decontamination
- Autoclavable

Easy clean base



- For Petri dishes from Ø90-100 mm base
- Passive Petri dish support (no moving parts)
- Horizontal mounting only
- Gas decontamination or by wiping with a cloth
- Autoclavable

2.5.3. 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.



Note

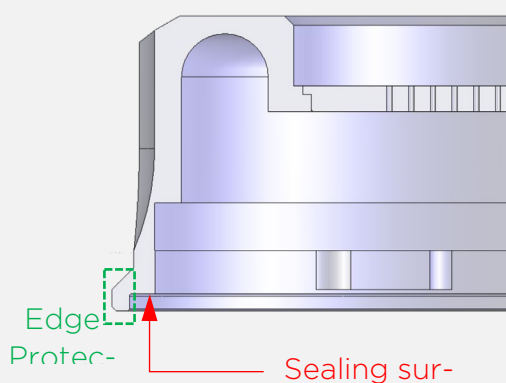
The 400×0.7 perforated lid has a smaller collection efficiency compared to the 300×0.6 perforated lid. (see Annex A – Physical sampling efficiency)



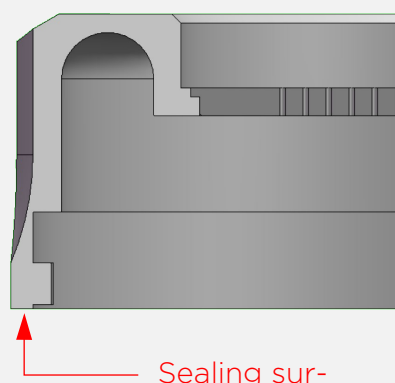
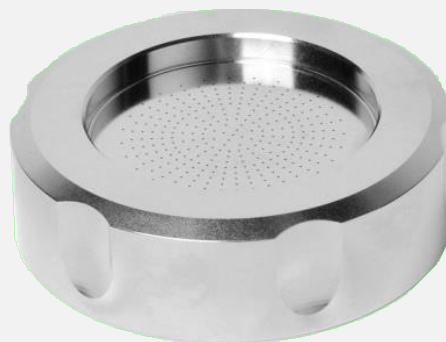
Hazard of damage to the instrument.

Since the sealing surface is exposed, it is prone to get damaged if the lid is not handled with care (e.g. by incautious handling when autoclaving).

**Perforated lid with edge protection
(Standard)**



Perforated lid with free edge (Legacy product)



Materials

Standard: Stainless steel EN 1.4435 (X2CrNiMo18-14-3) According to BN2 (electro polished pharmaceutical quality)

Optional: Anodized aluminum EN AW-6060

2.5.4. DUST COVER

Whenever the instrument is not in use, it is recommended to cover the sampling head with the optional stainless-steel cover.



2.6. SAMPLING MODES

2.6.1. OPERATION AND SAMPLING MODES

This chapter gives basic information about the operating and sampling modes of the instrument and related safety aspects.

2.6.2. STANDARD SAMPLING MODE (STD)

Standard mode sampling means that a previously selected volume of air is aspirated for one sampling process.

2.6.3. SQS - SEQUENTIAL AIR SAMPLING

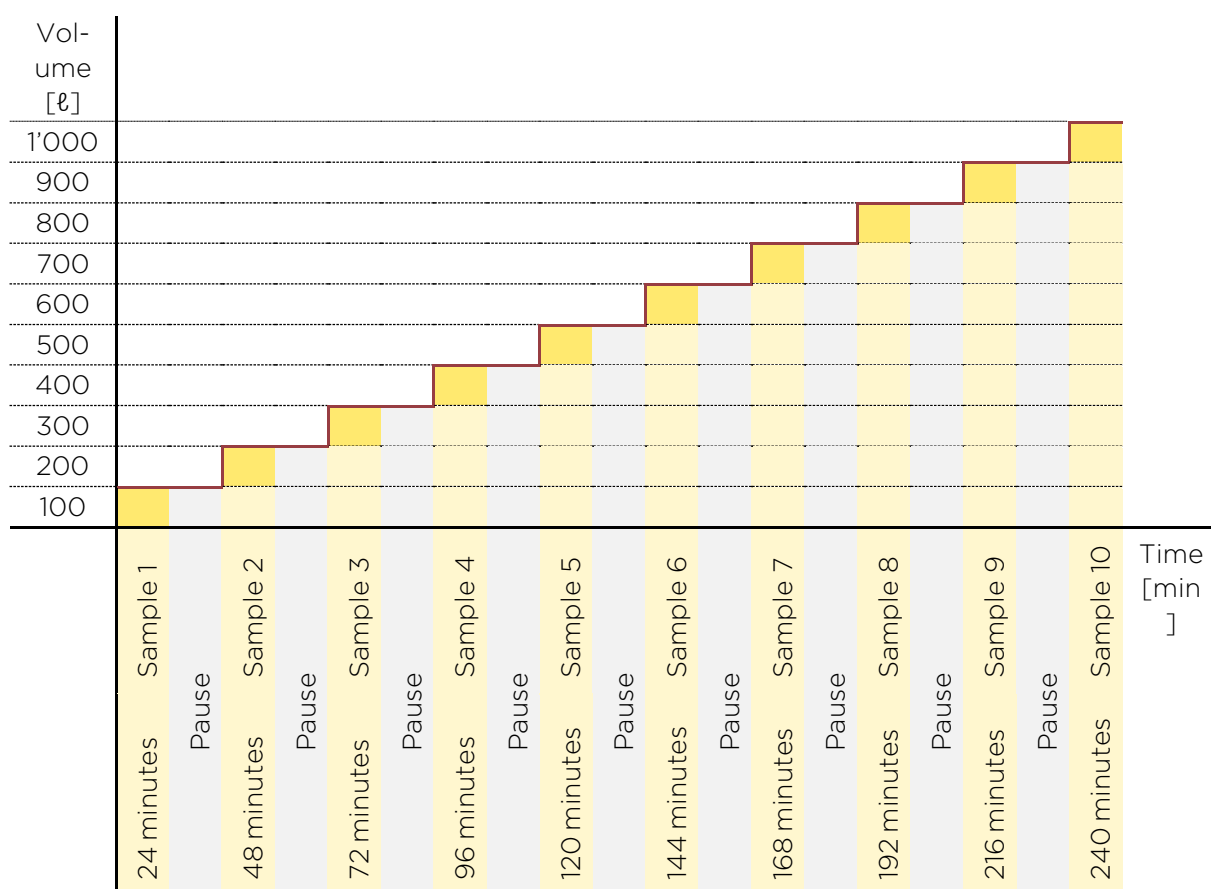
The instrument allows sampling over a prolonged time with a single Petri dish. Hereby, the total sampling volume can be split into up to fractions over a period of several hours.

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



2.7. COMMUNICATION

The communication to higher-level control systems is possible through these electronic communication interfaces:

- RS-232
- USB
- SPS
- 9 digital IN/OUT
- Ethernet (optional)
- Profibus (optional).

2.7.1. PC SOFTWARE

The instrument can be operated and programmed via the PC Software or the user interface on the instrument.

The main features of the PC Software are:

- Delivered together with the instrument
- Works on standard PC's under Windows systems
- Up to nine instruments at a time can be connected to one PC
- Allows calibration with a digital anemometer
- All measurements and calibrations with an anemometer can be exported to a PDF files
- Keeps track of the last 100 sample and the last 100 alarm log records
- All records can be easily printed or exported to an Excel file.



Note

MBV AG strongly recommends programming the instrument via the PC Software.

Please consult the [Software Manual MAS-100 Iso NT/MH](#) for detailed information about all the functionalities and options.



Note

It is mandatory to use the delivered PC Software for the settings of the instrument for calibration and during IQ/OQ

The electronic log records are informational only. The instrument has the capacity to record electronically a maximum of 100 event logs. Additional event logs will obscure the previously recorded electronic records which do not allow to use these electronic records to support GxP operations, as they do not meet requirements of 21CFR11.10(e). All records can be printed systematically by using the recommended printer and printing option. See [chapter 4.3](#) for printers compatible with the instrument. To keep track of records supporting GxP processes, direct printing of each log record it is recommended to ensure the integrity of primary data. Each printed report has a unique incremental number, allowing identifying a missing report

2.8. VALIDATION AND CLASSIFICATION

The instrument has been developed according to GAMP4 and is validated thereupon, covering the following development activities:

3. HARDWARE DESCRIPTION



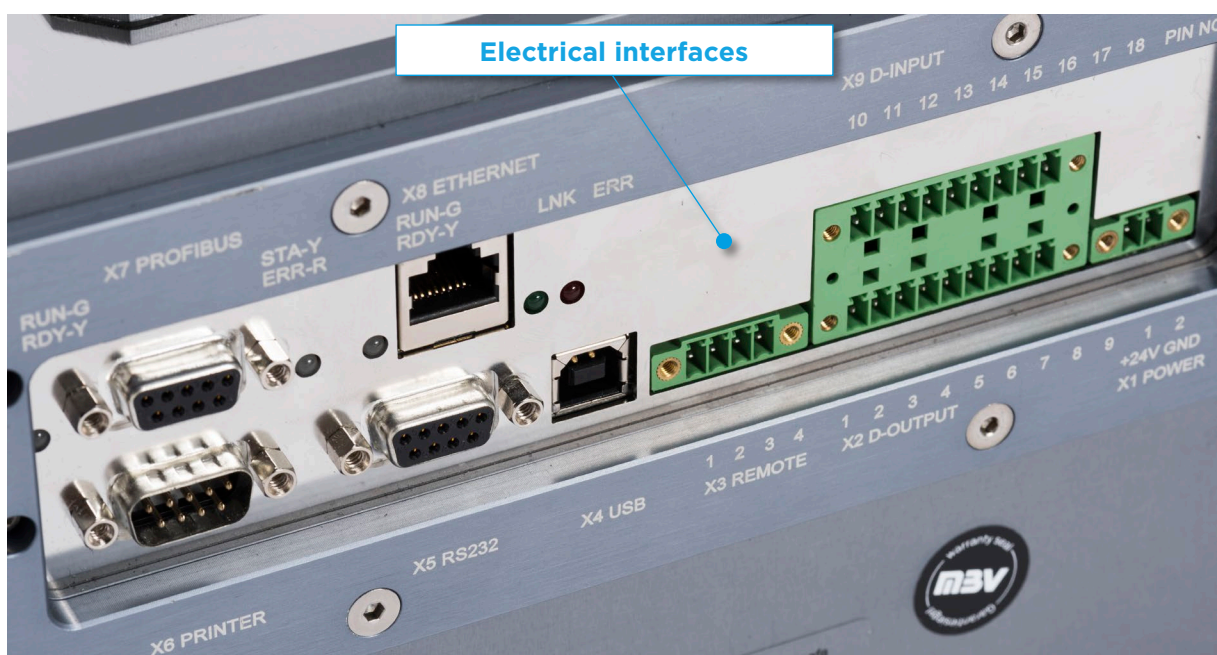
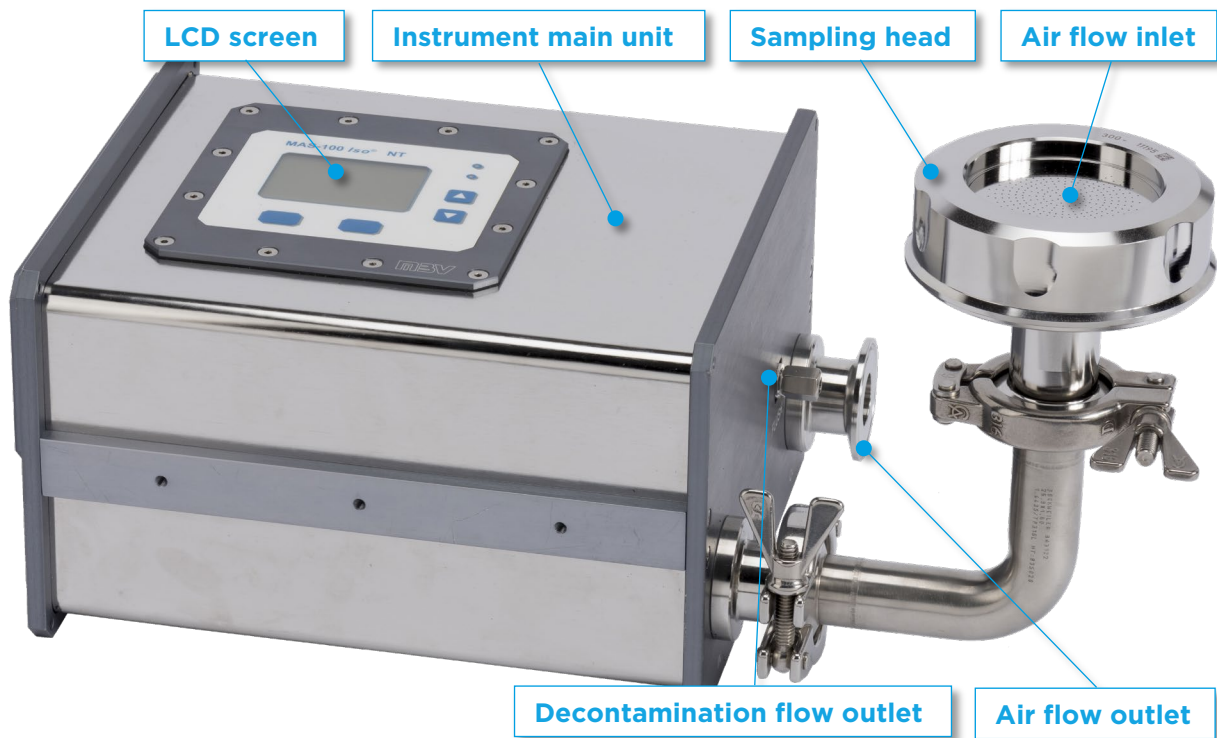
Hazard of injury

The sampling head can be tilted.

Fingers can get trapped whilst lowering the sampling head.

3.1. PARTS DESIGNATION

This chapter describes the mechanic layout of the instrument. All dimensions are in mm if not indicated otherwise.



3.2.

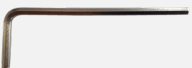
The instrument is a built-to-order product which is customized to specific customer needs. Any configuration is defined by these component parameters:

- Base type
- Sampling head type
- Gaskets
- Optional communication modules.
- Optional IP54 protection

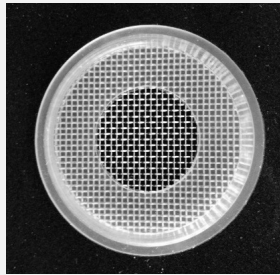
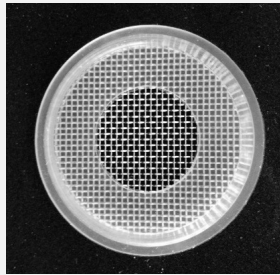
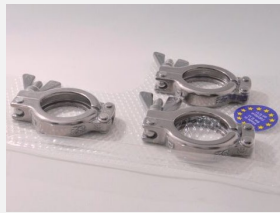
The local representative of our distribution partner will gladly help you to find the optimal configuration. The following list gives an overview of all available components:

Description	Article No.		Picture
	Merck KGaA	MBV AG	
MAS-100 Iso NT instrument	Depends on configuration	Depends on configuration	Depends on configuration
Documents - Calibration certificate - MBV Information Sheet - Global Safety Data Sheet - Installation checklist	N/A	N/A	

3.3. OPTIONAL ACCESSORIES

Description	Article No.		Picture
	Merck KGaA	MBV AG	
Allen key No. 3	N/A	New: 101.06.6053.01 Previous: 06.6053.01	
Standard base for sampling head, stainless steel, with one silicon gasket	NA	New: 108.070 Previous: 04.4113.01	
Standard base for sampling head, stainless steel, with one silicon gasket and one Tri-Clamp	1.09328.0001	New: 108.070.1 Previous: 04.5023.01	

Easy clean base for sampling head, stainless steel, with one silicon screen gasket	NA	New: 101.523 Previous: 04.4114.01	
Easy clean base for sampling head, stainless steel, with one silicon screen gasket and one Tri-Clamp	1.17091.0001	New: 108.075.1 Previous: 04.5024.01	
Perforated lid, stainless steel, 300-hole with edge protection	1.09189.0001	New: 101.292 Previous: 04.4953.01	
Perforated lid, stainless steel, 400-hole with edge protection	1.09222.0001	New: 101.293 Previous: 04.4954.01	
IP54 Kit	1.17159.0001	New: 108.499 Previous: 04.4118.01	
Power supply 24 Volt / 65 W for Iso NT (including cord EU, UK, USA, JPN)	1.17182.0001	New: 130.2156 Previous: 04.4182.04	

Silicon gasket one piece	NA	New: 108.541 Previous: 04.4915.02	
Silicon gasket five pieces	1.17084.0001	New: 108.541.1 Previous: 04.5020.01	
Silicon screen gasket for easy clean base	NA	New: 108.542 Previous: 04.4916.01	
Silicon screen gasket for easy clean base, five pieces	1.17099.0001	New: 108.542.1 Previous: 04.5021.01	
Tri-Clamp, clamp only, one piece	NA	New: 101.984 Previous: 04.4910.01	
Tri-Clamp, clamp only, three pieces	1.09440.0001	New: 101.984.1 Previous: 04.5022.01	
Dust cover, stainless steel	1.09644.0001	New: 101.513 Previous: 04.4115.01	
Ethernet Module including 2 jumpers	1.09789.0001	New: 130.0440 Previous: 04.4181.02	
Profibus Module including 2 jumpers	1.17097.0001	New: 130.0441 Previous: 04.4180.01	

Pressure test kit	1.17085.0001	New: 04.4900.02 Previous: 04.4900.01	
RS-232 extension cable 10 m for calibration	1.17098.0001	New: 130.0797 Previous: 01.1040.01	
Remote cable	1.17181.0001	New: 108.599 Previous: 04.4119.01	
Perforated lid 400 × 0.7	1.09128.0001	New: 101.200 Previous: 06.6021.01	
Digital anemometer MAS-100 Regulus	1.19153.0001	New: 130.3035 Previous: 01.2000.01	
Perfor. lid alu 400 × 0.7 for contact plate	1.19447.0001	New: 101.230 Previous: 06.7120.01	
Adapter for contact plates	1.19449.0001	New: 130.1870 Previous: 06.7124.01	
Perforated lid 400 × 0.7 incl. adapter	N/A	New: 130.1868 Previous: 06.7121.01	

4. GETTING STARTED

4.1. INSTALATION

**Note**

Please consult the [Installation Manual MAS-100 Iso NT](#) for detailed information about the installation options of the instrument.

**Note**

Once the instrument is connected to the power supply it will automatically be turned on.

Although its' use is not common in isolator applications, the sampling heads for the MAS-100 product family are optionally available in anodized aluminum. Please consult our official local distribution partner.

4.2. PERIPHERAL DEVICES

4.2.1. REMOTE SWITCH

The remote switch consists of a cable with a two-colour LED switch, a connector with cable-relief housing, a label to mark the terminals and a manual. The remote switch allows to

- Start & stop a standard sampling
- Start & stop an SQS sampling
- Quit an alarm

The remote switch can display the instruments' status via the LED:

- The green LED is on ⇒ Unit is ready for sampling.
- The green LED is flashing ⇒ Sampling is running
- The red LED is on ⇒ Error detected. Press the red LED to turn the alarm off.

For purchase information please refer to chapter 3.2

4.3. PRINTER

Two commercially available printers (Epson TM U220 and Samsung Bixolon Type SRP 275) are pre-programmed and may be selected. The printers will be factory preconfigured to display special characters like à, é, è, ä, ö, ü, etc.

**Note**

The printer is preconfigured when ordered from MBV AG directly and will be ready to use.

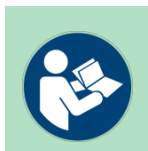
4.4. PROTECTION FILTER

Specific on-site conditions may require preventing toxic particles from escaping the isolator via the instrument. For such purposes, it is possible to fit a high-throughput filter under the sampling head.



Hazard of wrong air sampling results.

To compensate the additional pneumatic loss generated by the filter, any adjustment or calibration must be done with the filter connected.



Note

A possible choice can be the filters of the Millipore Aervent Opticap XL product family. The user is advised to assess whether the used filter allows an acceptable flow rate for the given pneumatic layout.

4.5. PRESSURE TEST

A pressure test must be carried out after installation and prior to every calibration. This is to ensure that there is a tight connection between the aspiration unit and the valve unit including the piping to the sampling head and to verify the integrity of the valves in the valve and aspiration units.

For purchase information please refer to chapter 3.2



Note

Please read the [Pressure Test Manual MAS-100 Iso NT](#) delivered with the kit.

5. OPERATION



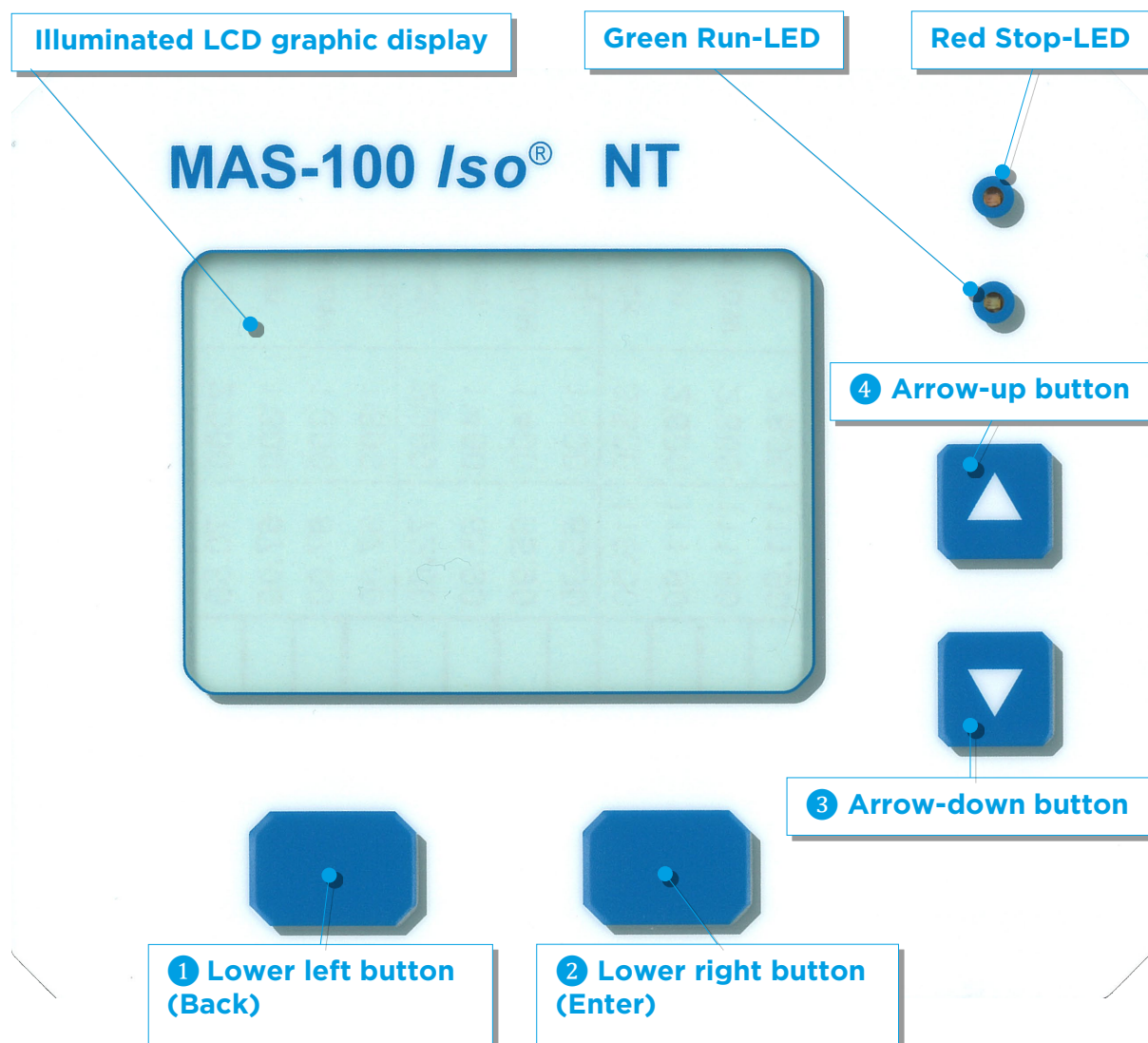
Note

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

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 green **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).

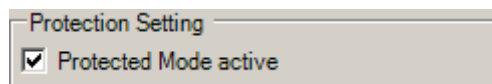
When the instrument is switched off, the blue **Run-LED** indicates with flashing that the battery is being charged or, when permanently on, that the charging is completed.

5.2. PROTECTION

With the PC Software, it is possible to block manual interventions on the HMI. A key symbol is displayed on the instruments' LCD screen to indicate that the hardware system is locked. Only starting and stopping of measurements and decontamination are accessible.

To activate the protection, proceed as follows:

- Start PC Software
- Go to menu «Process and device settings»
- Enable «Protected mode active»
- Press button «Save to device».



5.3. ADDRESS SETTING

If several instruments are operated in parallel, address numbers from «A1» to «C3» must be allocated to each unit. Each instrument address must be set once via the HMI in the menu «Config Device» ⇒ «Device Info».

For further details, please refer to [chapter 6.1.3.4](#).



Note

Setting the address cannot be done with the PC Software.

5.4. DECONTAMINATION CYCLE

5.4.1. DEFINITION

During the decontamination cycle of an isolator the internal pump aspirates the decontamination gas.



Note

The RABS version has no decontamination path.

5.4.2. THRESHOLD FOR FLOW GUARD

Prior starting a decontamination cycle, the parameter «Threshold for flow guard» must be set. This is best done after the installation of the instrument, during IQ/OQ. This setting can be performed directly via HMI or via the PC Software (recommended).



Note

For setting the decontamination parameter «Threshold for flow guard» proceed as described in the [Installation Manual MAS-100 Iso NT, chapter « 2.3 Decontamination cycle verification»](#).

5.4.3. RUNNING A DECONTAMINATION

The actual decontamination cycle can either be triggered directly by the operator via the PC Software or it can be delegated to a higher-level system via the electronic communication interfaces.



Note

Remove the lid during the decontamination process to allow an undisturbed flow through the instrument.

All components which can be regularly disassembled (perforated lid, dust cover) shall be decontaminated separately from the instrument according to a procedure which considers the components' material characteristics:

- Stainless steel: Expose fully to the decontamination gas, or autoclave at 121°C for 20 min.
- Aluminum: Autoclave at 121°C for 20 min.
Alternatively, the sampling head can be dry decontaminated at 180°C during 60 min.



Hazard of damage to the instrument due to corrosion.

Never expose aluminum components to the decontamination gas. Aluminum components shall only be decontaminated by autoclaving.



Hazard of damage to the instrument due to corrosion.

Do not use the internal blower to dry the sampling head.



Hazard of ineffective decontamination of the sampling head. Remove the dust cover and the perforated lid during the decontamination process to allow an undisturbed access of the sterilant to all exposed parts of the instrument. If the perforated lid and/or dust cover was not removed before the decontamination cycle:

- the bayonet lock (Lid & base) is not effectively decontaminated.
- the decontamination air flow is reduced due to partial closure of the inlet.
- Possible incomplete decontamination of the flow path from the inlet to the MAS-100 Iso NT.

6. SETTINGS AND CONFIGURATION

6.1. INSTRUMENT SETUP MENU

Menu	Menu
Prozess Settings Standard Volume Delay Data User Selection Print Settings	Probe Log Alarm Log Config Device System Info
▲▼	▲▼
Back Select	Back Select

Press «Menu» on the start menu.

All menus are explained in the following chapters.

6.1.1. PROCESS SETTINGS

Process Settings	Process Settings
Mode: STD Volume: 1000l	Mode: SQS Volume: 1000l Fractions: 10 Duration: 04:00h
Back Change	Back Change

- Choose «STD» (see [chapter 6.2.1](#)) or «SQS» mode (see [chapter 6.2.3](#))
- Move with the «Arrow» keys
- Press «Change» to choose option.

6.1.1.1. Standard volumes

Standard Volume
Volume 1: 50l Volume 2: 100l Volume 3: 250l Volume 4: 500l Volume 5: 1000l
Back Change

Five volumes are pre-set and can be changed between 0 and 2'000 liters.

If zero liter is selected, the volume will not be displayed anymore.



Note

If only one volume (e.g. 1'000 liters) shall be displayed, then put the other volumes to zero.

Hence now only 1000 liters will be visible.

6.1.1.2. Delay data

Delay Data Delay: Off Time: 1 min Back Change	A delay time for the measurement start between 1 and 120 minutes can be selected once the option «Delay» is set to «On». If no delayed measurement start is desired, the option «Delay» shall be set to «Off».
---	--

6.1.1.3. User selection

User Selection Enable: On User ID: 1 User User 1 Back Change	Up to ten different users are selectable («User 1», «User 2» ... «User 10»). User names can be renamed with the PC Software. If the «Enable» option is «Off» the user selection won't appear after the start. If the «Enable» option is «On» will cause that after pressing the start button a user needs to be chosen before it is possible to start a sampling process.
--	---

6.1.1.4. Print settings

Information Print settings? Back OK	Information Printer not Connected! OK	Choose «Print settings» and select «OK». If no printer is connected a corresponding message will be displayed on the screen. Press «OK» to quit.
--	---	---

6.1.1.5. Probe (sample) log

Log Selection Nr of entries: 30 + Log ID: 30 ▲ Select Log ID to show ▼ Back Show	Up to 100 samples are logged in the system. Each sample can be reviewed individually. After 100 samples the first one will be overwritten. Therefore, the user has only access to the latest 100 samples. The sample log may be printed once a printer is connected: 1. Select the number of entries to be printed and then press «Show» 2. Scroll through the windows 3. Press «Print» for a hard copy.
--	---

Probe Log ID:31 1/3 Mode: STD Volume: 0/1000l Delay Off Back Next	Probe Log ID:31 2/3 Start D. : 02.03.07 Start T. : 11:06 End D. : 02.03.07 End T. : 11:06 Back Next	Probe Log ID:31 3/3 State: failed User: User 1 Alarm ID: Back Print
--	---	---

6.1.2. ALARM LOG

Log Selection Nr of entries: 30 + Log ID: 30 ▲ Select Log ID to ▼ show - Back Show	Alarm Log ID:31 Date: 02.03.07 Time 11:06 Alarm ID: 100 Invalid Calibration! Back 	Up to 100 alarms are logged in the system. Each alarm can be re-viewed individually. After 100 alarms the first one will be overwritten. Therefore, the user has only access to the latest 100 alarms. (see chapter 7)
--	--	---

6.1.3. CONFIG. DEVICE

Config Device Time/Date Language Contrast Device Info Back Select	The following parameters can be selected and defined in this menu: ▪ «Time / Date» ▪ «Language» ▪ «Contrast» ▪ «Device Info»
--	--

6.1.3.1. Time and date

Time/Date Time: 15:39 Date: 02.03.2007 Format: EUR Summer: On Back Change	▪ Set «Time» to adjust the time with the arrows ▪ Set «Date» to adjust the date with the arrows ▪ Set «Format» to choose date formats between «EUR/JPN/USA» ▪ Set «Summer» to «ON» to activate summer time.
---	--

6.1.3.2. Language

Language Language: English BackChange	Select «Language» to set the language of the menus. Three languages are pre-programmed. The user may select between «English», «German» and «French».
---	--

6.1.3.3. Contrast

Contrast Contrast: 0 BackChange	Select «Contrast» to modify the visibility of the LCD screen. The selectable values range from «0» to «10».
---	---

6.1.3.4. Device info

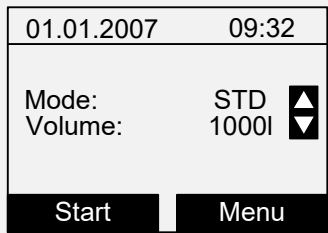
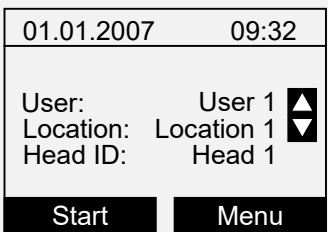
Device Info Name: MAS-100 Iso NT Model: Std / RABS Location: Location 1 Head ID: Head 1 Pos: A1 BackChange	The options «Location» and «Head ID» can only be re-named with the PC Software. Address setting - Press «Change» and select «Pos» - Insert the position with the + or – key - The unit will then display on the LCD screen the corresponding addresses in a grid of «A» to «C» and «1» to «3» <table border="1"><tr><td>A1</td><td>A2</td><td>A3</td></tr><tr><td>B1</td><td>B2</td><td>B3</td></tr><tr><td>C1</td><td>C2</td><td>C3</td></tr></table> - Press «Change» and 3× «Back» to return to the «Main» menu	A1	A2	A3	B1	B2	B3	C1	C2	C3
A1	A2	A3								
B1	B2	B3								
C1	C2	C3								

6.1.4. SYSTEM INFO

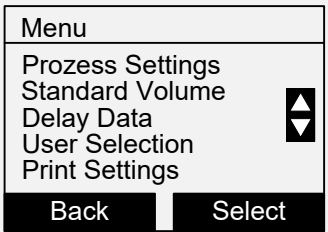
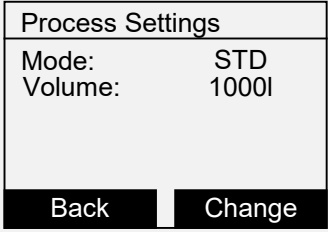
Standard Volume HW Version: REV02 SW Version: 0.9 Serial Num: 40 Last Calib: 01.01.07 Validity: 4 month Back	This menu displays relevant information about the instrument. Press «Back» to quit.
--	---

6.2. OPERATION AND SAMPLING MODES

6.2.1. START SAMPLING IN STD MODE

	Press «Start» to start sampling. Press «Arrow» keys up or down to get additional information.
	The screen will switch back to the first screen after three seconds. If the «User Selection» is deactivated the user will not be displayed. For more information about the user deactivation see chapter 6.1.1.3.

6.2.2. CHANGE SAMPLING VOLUME IN STD MODE

	▪ Press «Menu» in the main menu ▪ Select «Process Settings» ▪ Press «Select» to activate next screen.
	▪ Scroll down to «Volume» with the «Arrow» keys ▪ Press «Change» ▪ Select the desired volume with the «Arrows» keys ▪ Press «Change» ▪ Press twice «Back» to return to the «Main» menu.

6.2.3. START SAMPLING IN SQS MODE

The SQS Sequential Sampling splits the selected volume into fractions during the selected sampling time.



Note

Please refer to [chapter 2.6.3](#) for more detailed information about the SQS sampling process.

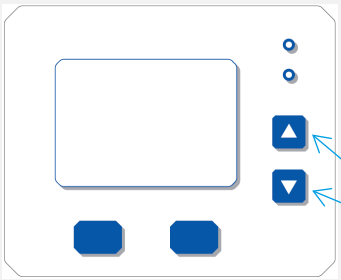
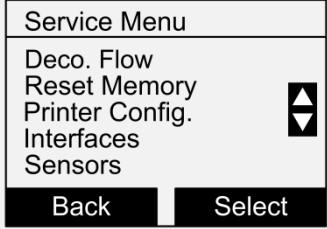
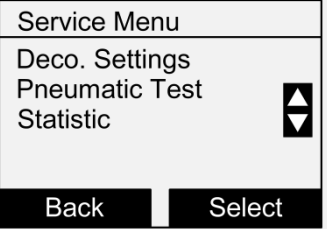
<table><tr><th colspan="2">Process Settings</th></tr><tr><td>Mode:</td><td>SQS</td></tr><tr><td>Volume:</td><td>1000l</td></tr><tr><td>Fractions:</td><td>10</td></tr><tr><td>Duration:</td><td>04:00h</td></tr><tr><td colspan="2"> BackChange </td></tr></table>	Process Settings		Mode:	SQS	Volume:	1000l	Fractions:	10	Duration:	04:00h	BackChange		▪ Press «Menu» in the main menu ▪ Select «Process Settings ▪ Press «Change» and select «SQS» with the «Arrow» keys ▪ Press «Save» to store new value. ▪ Press «Change» and select next parameter ▪ Change it to the desired requirements ▫ «Volume» 0 to 2'000 liters ▫ «Fractions» 2 to 50 ▫ «Duration» up to 23:59 hours
Process Settings													
Mode:	SQS												
Volume:	1000l												
Fractions:	10												
Duration:	04:00h												
BackChange													
<table><tr><td colspan="2">01.01.2007 09:32</td></tr><tr><td>Mode:</td><td>SQS(10) ▲▼</td></tr><tr><td>Volume:</td><td>1000l</td></tr><tr><td>Duration:</td><td>04:00h</td></tr><tr><td colspan="2"> StartMenu </td></tr></table>	01.01.2007 09:32		Mode:	SQS(10) ▲▼	Volume:	1000l	Duration:	04:00h	StartMenu		The screen shows that the «SQS » mode is selected with «10» fractions of a total of «1'000» liters (100 liters per fraction) and the samples are taken over the time of «4» hours beginning from start time. The sampling process may be stopped at any time by pressing «Abort».		
01.01.2007 09:32													
Mode:	SQS(10) ▲▼												
Volume:	1000l												
Duration:	04:00h												
StartMenu													

6.3. SERVICE MENU

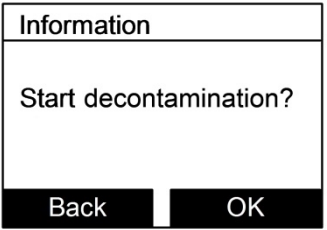
The «Service» menu is an advanced tool for service technicians to control all functions of the instrument and gather additional status information.

The «Service» menu can be accessed either via the PC Software or directly via the HMI on the instrument.

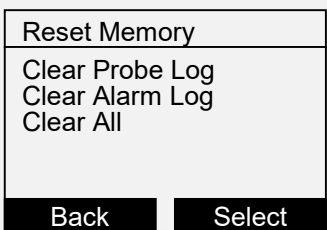
6.3.1. GENERAL

	To enter the «Service» menu via the instruments HMI press and hold both «Arrow» keys for about two seconds. The screen will show the menu as mentioned below. «Arrow» Keys
	

6.3.2. DECONTAMINATION FLOW

	Select «Start decontamination» to start a manual decontamination process by pressing «OK».
---	---

6.3.3. RESET MEMORY

	Select the log which should be cleared («Probe log» or «Alarm log») or Select «Clear All» for clearing both logs simultaneously. Press «Select» and «OK».
---	---

6.3.4. PRINTER CONFIGURATION

<table border="1"><tr><td colspan="2">Printer Config.</td></tr><tr><td>Onl. Printer:</td><td>Off</td></tr><tr><td>Printer:</td><td>None</td></tr><tr><td>Back</td><td>Change</td></tr></table>	Printer Config.		Onl. Printer:	Off	Printer:	None	Back	Change	This menu allows managing a connected printer. ▪ Select «Onl. Printer» and set «On/Off» to respectively activate or deactivate the printer If this option is on a printout will be generated after every measurement. ▪ Select «Printer» to choose between the preconfigured printers. Press «Back» to return to the main menu.
Printer Config.									
Onl. Printer:	Off								
Printer:	None								
Back	Change								

6.3.5. INTERFACES

<table border="1"><tr><td colspan="2">Interfaces</td></tr><tr><td>RS232 PLC</td><td></td></tr><tr><td>Profibus</td><td></td></tr><tr><td>Ethernet</td><td></td></tr><tr><td>Fieldbus Info</td><td></td></tr><tr><td>Back</td><td>Select</td></tr></table>	Interfaces		RS232 PLC		Profibus		Ethernet		Fieldbus Info		Back	Select	This menu allows setting the electronic communication interface to be used. Some interfaces are optional and will therefore only work when installed. Press «Back» to return to the main menu.
Interfaces													
RS232 PLC													
Profibus													
Ethernet													
Fieldbus Info													
Back	Select												



Note

For more detailed information, consult the [Communication Manual MAS-100 Iso NT/MH](#).

6.3.6. SENSORS

<table border="1"><tr><td colspan="2">Sensors 1/2</td></tr><tr><td>Flow:</td><td>0.0 l/min</td></tr><tr><td>Fl. Flow:</td><td>Off</td></tr><tr><td>Temp.:</td><td>0.0 Deg.C</td></tr><tr><td>Humidity:</td><td>0%</td></tr><tr><td>Amb. Pr.:</td><td>961mbar</td></tr><tr><td>Back</td><td>Next</td></tr></table>	Sensors 1/2		Flow:	0.0 l/min	Fl. Flow:	Off	Temp.:	0.0 Deg.C	Humidity:	0%	Amb. Pr.:	961mbar	Back	Next	<table border="1"><tr><td colspan="2">Sensors 2/2</td></tr><tr><td>Dev. T.:</td><td>33.8 Deg.C</td></tr><tr><td>24V Sup.:</td><td>23.47V</td></tr><tr><td>10V Sup.:</td><td>9.97V</td></tr><tr><td>Back</td><td>Exit</td></tr></table>	Sensors 2/2		Dev. T.:	33.8 Deg.C	24V Sup.:	23.47V	10V Sup.:	9.97V	Back	Exit	Press «Select». The two screens are displayed for information on different sensors and values. This screen is for information only. Press «Back» to return to the main menu.
Sensors 1/2																										
Flow:	0.0 l/min																									
Fl. Flow:	Off																									
Temp.:	0.0 Deg.C																									
Humidity:	0%																									
Amb. Pr.:	961mbar																									
Back	Next																									
Sensors 2/2																										
Dev. T.:	33.8 Deg.C																									
24V Sup.:	23.47V																									
10V Sup.:	9.97V																									
Back	Exit																									

6.3.7. DECONTAMINATION SETTINGS

Sterilis. Settings	
Enable:	On
Pump Power:	78%
Dig. Flowg.:	Off
Fl. Thresh:	2520mV
Back Change	

This menu allows to set the decontamination parameters:

- «Enable» Enables or disable the vacuum pump.
- «Pump power» Sets the % PWM of the pump (typically 50%)
- «Dig. Flowg.» This parameter normally set to Off
- «Fl. Thresh» This parameter defines the alarm limit value for the flow guard signal.

The values are pre-set when using the automatic decontamination cycle.



Note

Do not activate parameter «Dig. Flowg.», unless instructed explicitly by MBV AG.

6.3.8. PNEUMATIC TEST

Pneumatic Test	
Valve 1:	Closed
Valve 2:	Closed
Valve 3:	Closed
Blower:	Off
Pump:	Off
Back Change	

This menu allows to manually set selected components «On/Off».

This function is especially useful for service, troubleshooting and IQ/OQ.

6.3.9. STATISTIC

Statistic 1/2	
Device:	45h
Blower:	4 min
Pump:	0 min
Back Next	

The statistics menu is split in two tabs. The first tab shows the total individual working hours of key components:

- «Device » (instrument)
- «Blower»
- «Pump» (decontamination vacuum pump).

Statistic 2/2	
Valve 1:	27 cyc
Valve 2:	25 cyc
Valve 3:	5 cyc
Back Exit	

The second tab shows the total individual switching cycles of the three valves.

7. ALARM ID'S AND DESCRIPTION

In the event of the instrument not working properly, the system will automatically trigger an alarm and emit a high-pitched acoustic signal. The alarm event is stored in the alarm log of the instrument, which the user can visualize with the PC software. The user has several options to stop the alarm sound:

- a. By pressing the «Quit alarm» button on the instrument
- b. Via PC software, press «Acknowledge alarm»
- c. Via the digital inputs
- d. Via the remote switch connection



Note

For commissioning and testing purposes it is possible to provoke harmless alarms.

Please consult the [Installation Manual MAS-100 Iso NT](#) for the proceedings

Alarm ID	Description	Possible cause	Possible solution
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, if the dust cover is still attached during the measurement or if the valve 1 remains closed.	Clean perforated lid Remove dust cover
93	Valves do not close!	Hardware fault	Unit needs service
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
95	Decontamination flow too low!	Decontamination flow clogged Dust cover not removed	Check decontamination tubing for clogging Remove dust cover & Lid
96	Valves do not close! (deco. valve)	Hardware fault	Unit needs service
97	Temperature too high!	Hardware fault	Unit needs service

98	Measurement/decontamination interrupted!	Power supply too low/high Hardware fault	Check power supply (replace) Unit needs service
99	Sample duration too low!	Sample duration in SQ mode too short for the selected volume	Increase sample duration or decrease volume
100	Invalid calibration or calibration not activated!	Device was not calibrated/calibration is invalid/cal. validity is not activated Calibration data lost	Calibrate instrument Set calibration validity
101	Recalibration needed!	Calibration due date expired	Calibrate instrument
102	Target volume is 0!	The selected volume is too low (0 in Standard mode or < 20 liters in SQS mode)	Increase the selected volume or decrease the number of fractions in the SQS mode
103	Flow sensor defect!	Hardware fault	Unit needs service
104	Measurement stopped!	Stop button pressed during measurement	Do not abort measurement
105	24Volt supply too low!	Power supply too low Hardware fault	Check power supply (replace) Unit needs service
106	24 Volt supply too high!	Power supply too high Hardware fault	Check power supply (replace) Unit needs service

8. CARE AND MAINTENANCE

The instrument should be calibrated periodically (at least once a year).

Dirt may be removed from the exterior of the instrument by wiping with a clean cloth moistened with a mixture of 60-80% alcohol/deionized water or with one of the commonly used disinfectants.

	Electrical hazard. The instrument shall be disconnected from the power supply prior cleaning.
	Electrical hazard. Avoid spilling liquid into the electric/electronic connections.
	Hazard wrong air sampling results. Ensure that the holes in the perforated lid are not obstructed.
	Hazard of damage to the instrument due to corrosion. Do not use the internal blower to dry the sampling head.

9. INTERPRETATION OF RESULTS

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

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

Where:

r = positive holes (counted CFU)

N = Number of lid holes

Pr = Corrected value for CFU

Therefore, a proper interpretation of sampling results is done by following these three steps:

1. Count all CFU on the incubated Petri dish
2. Correct the count based on Feller's statistical correction table
3. Convert to CFU/m³.



Note

Feller correction tables can be found on the MBV AG website [MICRO-BIAL AIR SAMPLER MAS-100 Iso NT \(mbv.ch\)](https://www.mbv.ch/MICRO-BIAL-AIR-SAMPLER-MAS-100-Iso-NT)



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

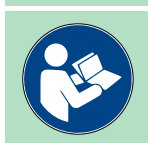
Adjustment = Adjust a device to a standard

Calibration = Compare a device to a standard



Note

Detailed proceedings of adjustment and calibration are described in the [Anemometer User Manual](#).



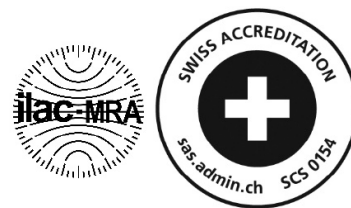
Note

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
Lithium-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 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 labelling rules in case your instrument should travel by air.

EXAMPLE



12. TECHNICAL SPECIFICATIONS

General	
Flow rate	100 standard liter/min $\pm 2.5\%$
Standard sampling volumes	50, 100, 250, 500, 1'000 liters
Freely definable sampling volumes	1 to 2'000 liters, volumes are individually selectable between 0 and 2'000 liters. Volume 0 is not displayed
Sampling head	
Material	Stainless steel EN 1.4435 (X2CrNiMo18-14-3), according to BN2 (electro polished pharmaceutical quality)
Dimensions	$\varnothing 10.9 \times 9.0$ cm
Weight	~1.5 kg
Lid geometry	300 holes, $\varnothing 0.6$ mm
Sampling efficiency	d_{50} value $1.1 \mu\text{m}$ @ 100 SLPM (confirmed acc. ISO 14698)
Autoclaving	20 min @ $+121^\circ\text{C}$
Petri dish	For standard Petri dishes and contact plates
Connector	Tri-Clamp, $\varnothing 50.5$
Hardware	
Height- with mounting plate and valve unit	16.0 cm
Length - with mounting plate and valve unit	28.3 cm
Width - with mounting plate and valve unit	23.0 cm
Weight	7.5 kg
Case	Side walls: Anodized aluminum Body: Electro polished stainless steel
Power supply	
Input external power supply	110-240 V AC, 0.7-1.5 A / 47-63 Hz
Input instrument	24 V DC $\pm 5\%$, Max. limits: 2.7 A and 65 W.
Additional information	
User interface screen	Alphanumeric LCD graphic screen
Lifetime RTC battery	~10 years

Flow valve	2/2 - way NC, 24 V DC
Flow regulation	Mass flowmeter
Environmental conditions	
Altitude	Up to 2'000 m above sea level
Temperature	Storage: -10°C to +50°C Operation: +10°C to +40°C
Maximum relative humidity	80% for temperatures up to +31°C, decreasing linearly to 50% at +40°C, non-condensing
EMC, ESD	Group 1, Class B (Industrial environment)
Mains supply voltage	Fluctuations must not exceed ±5% of the nominal voltage
Transient overvoltage	Overvoltage category: Category II Pollution Degree: 2

ANNEX A – PHYSICAL SAMPLING EFFICIENCY

ANNEX A.1 - D₅₀ 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 impact nozzle or the filter.

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

Detailed information how to calculate the d₅₀ value may be found in the publications [\(1\)](#) [\(2\)](#).

An approximation for calculating the d₅₀ value in µm is given by the following formula:

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

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 d₅₀ value is, the better the sampling efficiency. In the MAS-100 product family the d₅₀ value is governed by the sampling head configuration:

Sampling head	d ₅₀ [µm]
300 × 0.6	1.1
400 × 0.7	1.6

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

(2) 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 STATEMEN

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

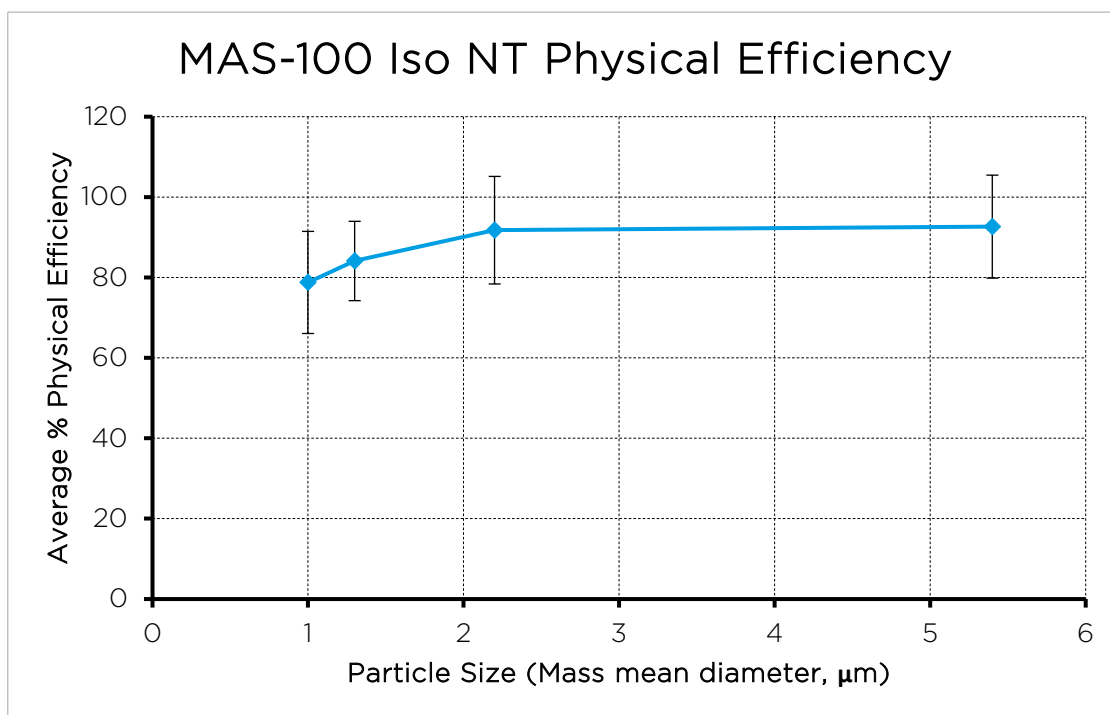
The study was conducted using the 300×0.6 mm holes perforated lids, with a MAS 100 Iso NT system calibrated at 100±2.5 liter/min. The study was conducted using Heipha TSA + LTHTh - ICRplus 30 mL media plates on the MAS 100 Iso NT system and the reference systems.

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

PHYSICAL EFFICIENCY RESULTS

The physical efficiency of the MAS 100 Iso 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 Iso NT sampler was ca. 78.8-84.1% efficient for collecting particles containing bacterial spores in the 1 micron size, in comparison with the membrane filter samplers, rising to 92.6% in the range of 5-6-micron size.

The experimental results indicate a 50% cut-off, also referred as d50 value, of below 1 µm, making the sampler suitable for use within a clean room environment.



MAS-100 Iso NT 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 micro-organisms on an agar plate in such a way the micro-organism 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 Iso NT sampler was compared to that of the reference Casella slit sampler.

The biological efficiency measured of the MAS-100 Iso NT was found to be on average 78.1% (number of repeats = 10) that of the Casella sampler, indicating the sampler is effective at sampling bacteria-laden particles, without loss of viability.

ANNEX B REFERENCES

- (1) The Rules Governing Medicinal Products in the European Union, Volume 4 - EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary use
- (2) ISO 14698-1, Cleanrooms and associated controlled environments - Bio-contamination control – Part 1: General principles and methods
- (3) ISO 14698-2, Cleanrooms & associated controlled environments – Bio-contamination control - Part 2: Evaluation and interpretation of bio-contamination data
- (4) Qualification of air sampler system: The MAS-100, M. Meier and H. Zingre, Swiss Pharma 12/2000
- (5) Willeke K, Baron PA, eds. Aerosol Measurement: Principles, Techniques and Applications. New York: Van Nostrand Reinhold, 1993
- (6) 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 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 Identity/Corporate Design
DC	Direct Current
DIP	Dual In-line Package (switch type)
EAC	Eurasian conformity mark
EC	Electronic Commutated (electric motor)
EMC	Electro Magnetic 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)



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