Operator's Manual MAS-100[™]

Professional Microbial Air Monitoring System for the Microbiological Testing of Air



MAS-100[™] is a registered trade mark of MBV AG, Switzerland from Firmware Version 5.0x

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1 Introduction

There is increasing need for effective air sampling in all areas where airborne micro-organisms may contaminate or otherwise affect industrial products and processes. Monitoring is especially important in:

- the pharmaceutical industry
- the food industry
- hospitals
- the cosmetics industry
- the environment

Today a number of monitoring methods are available, most of which are based on the impaction principle. During development of the MAS-100[™], all the shortcomings of existing sampling systems were eliminated, and their best aspects retained, leading to the creation of a user-friendly, dependable and precise air sampler for standard Petri dishes.

The MAS-100[™] aspirates 100 liters of air per minute, allowing up to 2000 liters to be sampled per cycle. This performance enables sampling to be carried out according to the strict conditions of monitoring in sterile and "clean" areas (see point 1 in chapter 19).

The impaction velocity (speed at which airborne micro-organisms hit the surface of the agar) is approximately 11 meters per second, corresponding to stage 5 of the Andersen Sampler (see point 3 in chapter 19). This velocity guarantees that all particles > 1 μ m are collected. Comparisons with other methods of air sampling (see point 2 in chapter 19) have not revealed any significant differences in the numbers of micro-organisms collected.

Note:

The MAS-100^{TM} corresponds to International Standard ISO 14698-1:2003(E)¹

2 Basic principle

The MAS-100[™] is a high-performance instrument that is based on the principle of the Andersen air sampler (see point 3 in chapter 19), which aspirates air through a perforated plate. The resultant airflow is directed onto a standard agar poured plate. After the collection cycle, the Petri dish is incubated and the colonies are counted. The MAS-100[™] operates with a high-performance suction device, and the aspirated volume is continuously monitored. The system measures the inflow of air and regulates the aspirated volume to a constant value of 100 liters per minute. The MAS-100[™] automatically regulates this volume if there are external factors preventing a steady flow of air, or if overfilled Petri dishes are blocking or impeding flow. For measurement in pharmaceutical industry the recommended sampling volume – according to international guidelines – should be 1000 liters.

¹ ISO 14698-1:2003(E) Cleanrooms and associated controlled environments - Biocontamination control Part1: general principles and methodes; chapter 3.1.13; 5.3;

3 Most important advantages of the MAS-100[™]

- *new:* individual activation of calibration reminder
- *new:* Adapter-Kit for RODAC-Plates
- new: Validated Firmware MAS-100 V5.0X by Novatek for "Environmental Monitoring" software
- **new:** SQS-Cycle (see point 5 in chapter 19) may be selected. If this cycle is activated, the desired volume may be split up to 20 sequences over a period of total 24 hours
- Uses standard 90-100mm Petri dishes
- Data communication for error-free results and automatic record-keeping
- Manual and/or template mode
- Build in anemometer for automatic volume compensation: Differences in Petri dish fills cannot affect airflow
- Indication of low airflow
- Real time clock and calendar
- Compact and easy to use
- Easy to calibrate
- Adjustable for different Petri dish sizes
- 100/240V, 50-60kHz power unit, or battery operation
- According to international Guidelines: Isokinetic measurement, 0.45 m/sec, 100 liters / minute
- Sampling volume adjustable from 1 2000 liters

3.1 First time use of MAS-100[™]

If the MAS-100[™] is used for the first time or after a calibration the "calibration reminder" has to be set. (see 4.2 and 20.6)

3.2 New: SQS- Sequential air sampling⁵

A newly developed control system (Software V 5.0x) allows a measurement with the MAS-100[™] over a prolonged time with a single agar plate. Hereby, without any microbial loss, up to 20 air samples can be accumulated on the same Petri dish over a period of several hours. The main advantage of this method is that the risk of secondary contamination by the operators during the exchange of plates is reduced to a minimum. This is of very great importance for ambient air monitoring in sterile zones. In addition, by collecting sequential samples over a prolonged period of time the randomization is improved and thus a more reliable result obtained. Moreover, instead of several 90mm standard Petri dishes, only one dish has to be evaluated, thus reducing the expenditure on equipment and labour.

⁵ SQS-Sequential air sampling; Validation of the microbial count in the air using the MAS-100; Swiss Pharama 26 (2004) No.11,9-11

General functions 4

4.1 Overview

MAS100 V5.XX

The MAS-100[™] has built-in dialog software. To accept a parameter or command, answer the question "Modify?" by pressing the "yes" or "no" button. The program works its way automatically through all the required parameters. Once you have set the aspirated volume and delay, the program goes to the "Start ?" prompt. When you press "yes", the MAS-100[™] starts to sample the pre-set volume of air, and a green light indicates that the instrument is operating. The sampled volume and time remaining are continuously displayed. Once the pre-set volume has been sampled, the red "stop" LED lights.

Press "yes" to switch on the MAS-100[™] for the first time. The firmware

4.2 First time use of MAS-100[™] = Activation of calibration reminder

S/N: XXXXX	version is shown on the display. The calibration reminder has to be set by the first user. (see 20.6)
Set calibration reminder Y/N	If you select "no" the instrument will go off immediately. If you select "yes" next window will be displayed.
Set reminder to 12 month Y/N	The reminder is set by the manufacturer to 12 month. If you would like to change , push "no" as many times until you get the time for recalibration between 1 and 12 month. If you select 0, the calibration reminder is deactivated. Push "yes" to accept the displayed value.
Are you sure to set xx month Y/N	If you select "no" the instrument will go off immediately. If you push "yes" the selected time for recalibration starts to count down. The last two month will be displayed as 60 days. After this the menu will proceed as written in (4.3).
Calibration valid: XX month	The time until next calibration is shown . The last 2 month will be displayed in days.
4.3 Switching ON a	nd OFF the MAS-100™
MAS100 V5.XX S/N: XXXXX	Press "yes" to switch on the MAS-100 [™] The firmware version V5.XX and the serial number of the instrument is shown on the display. (see 20.2)
Calibration valid: XX months	After a few seconds the display will indicate the remaining time until next calibration.
XXXXX litres left to aspirate	Again a few seconds after the display will show the total amount of liters which can be sampled with the battery charge.
Volume:XXXX Y/N?	The last used volume is displayed. Accept by pushing "yes". If you push "no" next step is displayed.
Select other	With "yes" you can select other volumes. Accept a volume with "no" the

dd.mm.yy hh:mm Start? (Y/N)

With "yes" start the sampling. With "no" the menu starts with the last used volume.

If no further manipulations are made on the Instrument and no run is started, the instrument will switch off automatically after 5 minutes.

Exception:	With the calibration reminder being activated and the calibration deadline reached, the display first shows "Calibration time expired" and then "Please recalibrate unit". If you press "yes" or "no", you will see the date on which the MAS-100 [™] was last calibrated. The program then moves to the next prompt.
Note:	The MAS-100 ^{$^{\text{TM}}$} is permanently on if connected to the battery charger.
Note:	After a collection cycle the instrument will display the last volume collected. It will shut off after 30 minutes unless you press "yes" or "no", to activate the 5-minute automatic shut off.

4.4 Calibration reminder



A calibration reminder is displayed once the calibration expiry date has been reached. The calibration reminder is set from the manufacturer to 12 month. The last two month will be displayed as 60 days. The reminder may be set from 0 up to 12 month. 0 month means deactivation of calibration reminder.

Last calibration Volume:XXXX Y/N?

If yes or no is pushed the last calibration date is displayed.

Note:

To program the calibration reminder see Mode 5 (see 4.2 and 13.2).

4.5 Selectabel Mode 3

In parameter Mode 3 it is possible to select between "manual mode", "template mode" or "selectable mode" (see 20.4)

- The "manual mode" is selected if no PC is connected to the MAS-100 [™]
- The "selectable mode" is selected if only a few data are stored and transferred to the PC
- The "template mode" is used if all information is transferred from and to the PC

4.6 Last volume used

After the MAS-100 is started always the last volume or SQS-cycle used will be displayed and may be used again without changing any parameters.

4.7 Select other volumes

Volume:XXXX Y/N?

If the volume is displayed and "no" is pressed the MAS-100[™] changes to the volume selection menu. If you accept with "yes" the start menu is displayed.

Select other volumes Y/N ?

The MAS-100[™] has 5 pre-set sampling volumes: 50, 100, 250, 500 and 1000 liters. These can be found in parameter Mode 5 under "Change volumes?" Each of these volumes can be modified between 0 and 2000 liters. Setting a volume to 0 will blank it from the display in the main menu. Each volume can be re-activated and be displayed again. Accept a displayed volume by pressing "no".

4.8 Delay function

Delay:	0:00
Modify	? (Y/N)

If the delay function is activated in Parameter Mode 4, the display shows "Change delay? (Y/N)". By choosing "yes" you may set a start delay between 1 and 60 minutes. This function makes sense if the room in which the sampling takes place has to be left during the sampling process.

4.9 User menu

User X	
change user? Y/N	

If the user menu is activated it is possible to choose between 10 user names. The user names may be programmed with the MAS-100 C&C software (see 10.2)

4.10 Start sampling

dd.mm.yy hh:mm Start? (Y/N)	To start sampling, press "yes". If a delayed start has been programmed, the sampling cycle only starts when the delay time has elapsed.
Volume [I]: XXXX Time: h.mm	During the run the display shows the sampled volume and counts down the time until the total sampling volume is reached.

4.11 Adjusting Petri dish

Before using the MAS-100 for the fist time you will need to adjust the blue Petri dish support. Lift off the perforated lid and place a Petri dish on the dish support. Use a 3 mm Allen key to adjust the three blue jaws until the Petri dish is securely supported and there is no play. Check that the Petri dish is properly supported by turning the sampling head to the horizontal position. The Petri dish support is now adjusted. The procedure need only be repeated at most if you change Petri dish manufacturer.

Note: Do not over-tighten the blue jaws. If you do, the Petri dish may break and shed plastic debris in the aspiration unit and block the motor.

4.12 Adjusting RODAC plates

New : The MAS-100 may be used with commercially available contact plates. The use of a special Adapter No. 1.09214.0001 and Sampling head NO. 1.09213.0001 is necessary.



- Take the allen key and exchange the 3 existing blue jaws by removing the allen screw and replace with the 3 new blue jaws.
- Place the positioning template and mark the centre (see picture) with a marker pen.
- Remove the positioning template and put the Adapter ring as shown in the picture bellow.

• Put now your contact plate in the adaptor and tighten the 3 allen screws. The marked point should be in the centre of the contact plate as shown in the picture.

Note:

Tighten the blue jaws and make sure that the stainless steel adapter holds firmly .

5 Perform a "Manual" air sampling

5.1 Switch the MAS-100[™] "ON" for manual sampling

To work in manual mode you just push the yes button to switch on the MAS-100^{™.}

Note: The MAS-100^{$^{\text{TM}}$} must be in the manual mode. If it is in the selectable or in the template mode change to manual mode (see 4.5 and 6).

- Place the MAS-100[™] on a firm support.
- Open the perforated lid (with attached dust cover) by rotating counter clock wise.
- Place a closed standard Petri dish² filled with agar on top of the dish support.
- Take the lid off the Petri dish.
- Close the MAS-100 perforated lid.
- The sampling head can be adjusted to any angle from horizontal to vertical airflow direction.
- Program the MAS-100 as follows

MAS100 V5.XX S/N: XXXXX	Press "yes" to switch on the MAS-100 [™] The firmware version V5.XX and the serial number of the instrument is shown on the display.
Calibration valid XX months	After a few seconds the display will indicate the remaining time until next calibration.
Exception:	With the calibration reminder being activated and the calibration deadline reached, the display first shows "Calibration time expired" and then "Please recalibrate unit". If you press "yes" or "no", you will see the date on which the MAS-100 [™] was last calibrated. The program then moves to the next prompt.
XXXXX litres left to aspirate	Again a few seconds after the display will show the total amount of liters which can be sampled with the current battery capacity.
Volume:XXXX Y/N?	The last used volume is displayed. Accept by pushing "yes". If you push "no" next step is displayed.
Select other volumes Y/N? _	With "yes" you can select other volumes. Accept a volume with "no" the menu changes into the start menu.
User X change user ? Y/N	If the user menu is activated (see 8.16) it is possible to change the user with "yes" and accept it wit "no".
Delay: mm:ss Modify? Y/N	Modify "Delay" with "yes" and accept with pressing "no". If "Delay" is not active, the start menu will be displayed.
dd.mm.yy hh:mm Start? (Y/N)	Date and time are displayed. To start the sampling press "yes". To change some of the parameters press "no" and change the desired parameters. If no further manipulations are made on the instrument and no run is started, the instrument will shut down automatically after 5 minutes.

² Petri dish or if the contact plate adapter is used contact plate.



5.2 Sampling interrupted; failed

failed!	
repeat test!	

If "failed repeat test" is displayed the test was interrupted by pressing "no" during sampling.

Air flow blocked

If the air flow was blocked and the MAS-100 could not get 100 liter/min "air flow blocked" will be displayed and the red LED is blinking. Quit with "yes" or "no"

Note:

Make sure that the dust cover was removed before start was pushed, and there is not to much agar in the Petri dish which could block the wholes on the sampling head.

- Open the sampling head, cover the Petri dish with the lid and remove the Petri dish from the dish support.
- The Petri dish is now ready for incubation.

5.3 Switching off the MAS-100[™]

Volume [l]: XXXX Time: 0:00 After sampling, the red (stop) LED will light up and the total volume collected will be displayed. In this position the MAS-100TM will automatically shut down after 30 minutes. In all other menu positions the MAS-100TM switches off automatically after 5 minutes.

Note:

After a collection cycle the instrument will display the last volume collected. Press "yes" or "no" to activate the 5-minute automatic shut-down.

5.4 Interrupting a test

failed! repeat test! If the "no" button was pressed during sampling, the instrument will display "failed! repeat test!". Repeat the test by using a new Petri dish filled with media. Note: If the MAS-100[™] was activated in the "template mode", the interrupted test will not be registered by the software, unless the total volume has been collected without interruption.

5.5 Airflow blocked

failed! repeat test! If the built-in sensor does not attain 100 liters of air per minute, the message "failed! repeat test!" and "Air flow blocked" appears on the display and the red LED flashes. Sampling is stopped. Remove the Petri dish and start a new test. Press "yes" or "no" to cancel the error message. Repeat the test.

```
Air flow blocked
```

Note:

If the air flow was blocked and the MAS-100 could not get 100 liter/min air flow blocked will be displayed and the red LED is blinking. Quit with "yes" or "no"

Make sure that the dust cover was removed before start was pushed, there is not to much agar in the Petri dish which could block the wholes on the sampling head.

6 Perform air sampling in "Template mode"

6.1 Switch the MAS-100[™] "ON" for template sampling

To work with templates the calibration MAS100 C&C software is needed. It is possible to download the software from internet: <u>www.mbv.ch</u>. A special communication cable between PC and MAS-100^T is provided by the local distributor. More details are given in the Software manual.

Note: The MAS-100 must be in the selectable or in the template mode (see 4.5 and 6)

- Place the MAS-100[™] on a firm support.
- Open the perforated lid (with attached dust cover) by rotating counter clock wise.
- Place a closed standard Petri dish filled with agar on top of the dish support.
- Take the lid off the Petri dish.
- Close the MAS-100[™] perforated lid.
- The sampling head can be adjusted to any angle from horizontal to vertical airflow direction.
- Program the MAS-100[™] as follows



Location Device	Each template may contain up to 10 sampling places defined with Location and Device. Push "no" to choose the position you would like to take the sample. If the position has already been measured and the rum was not interrupted the position is hidden and appears only after having transferred the data to a PC or if the values have been erased in the MAS-100 (see Clear protocol data 8.1)		
Example:	1. Location name = Fill_Line 123_A, Device = Position 123_A 2. Location name = Fill_Line 123_B, Device = Position 123_B		
Delay: mm:ss Modify? Y/N	If delay menu is activated modify "Delay" with "yes" and accept with pressing "no". If "Delay" is not active, the start menu will be displayed.		
User X change user ? Y/N	If the user menu is activated (see 8.16) it is possible to change the user with "yes" and accept it with "no".		
Delay: mm:ss Modify? Y/N	The "Delay" may be accepted by pressing yes and changed by pressing "no". If "Delay" is not active, the start menu will be displayed.		
dd.mm.yy hh:mm Start? (Y/N)	Date and time are displayed. To start the sampling press "yes". To change some of the parameters press "no" and change the desired parameters. If no further manipulations are made on the instrument and no run is started, the instrument will shut down automatically after 5 minutes.		
Note:	The MAS-100 ^{m} is permanently on if connected to the battery charger.		
Volume [I]: XXXX Time: h.mm	During the sampling the aspirated volume and the remaining sampling time are displayed.		
passed test completed	After the sampling cycle, the message "passed test completed" indicates that the total volume has been sampled without any disturbances and the test is valid.		
Note:	After a sampling run the last used volume is displayed. Push "yes" or "no" to shut off the MAS-100 after 5 minutes.		
Volume [I]: XXXX Time: 0:00	Nach dem Sammelvorgang wird das total gesammelte Volumen angezeigt und die verbleibende Zeit ist 0:00 und die rote (stop) LED leuchtet auf.		
6.2 Interrupted sampling			
failed! repeat test!	If "failed repeat test" is displayed the test was interrupted by pressing "no" during sampling.		
Air flow blocked	If the air flow was blocked and the MAS-100 could not get 100 liter/min air flow blocked will be displayed and the red LED is blinking. Quit with "yes" or		

- Open the sampling head, cover the Petri dish with the lid and remove the Petri dish from support.
- The Petri dish is now ready for incubation.

"no"

7 Perform air sampling in "Selectable-Mode"

Selectable mode is used if the user wants both, to work with individual samples and with preset values in the "Template mode". In this mode the display asks before each sampling run, whether sampling is to be performed manually or at a location designated by the template. In "Template mode", the user is prompted to select the protocol and location before sampling is started.

8 Instrument settings "Parameter Mode 4"

Volume XXXX Y/N?	Pressing "yes" and "no" simultaneously for about 5 seconds after you activated the MAS-100 or in any other menu position, will take you to the instrument settings "Parameter Mode 4". This mode allows to erase data in the memory if the "template mode" was used. It is also possible to connect a printer. All other user-specific data such as date, time, volume, start delay etc. can be set.
Note:	If the MAS-100 is working in the Protected mode (see 13.1) the access without the MAS-100 C&C Software, is only possible to the following menu points:

- Print protocol
- Battery discharge
- Anemometer mode

8.1 Clear protocol data

Clear protocol data? (Y/N)

Press "yes" to erase protocol data. If you are in the selectable mode you can choose between erasing the manual or the template data. With the function "Clear all prot." It is possible to erase all data collected in the PC mode. With the function "Modify? (Y/N) an individual protocol may be selected and the data erased. During this process the red and green LED's are flashing and a message "Clear data in progress" is displayed. Erasing all the protocol data together may take up to 2 minutes.

8.2 Connecting a Printer



The output is configured for a portable thermo printer*

(model on picture: CUSTOM s'print[®])

A connection cable is available from your supplier.

(* ask MAS-100 [™] supplier for other printer models)

8.3 Print protocol



Protocol 1..10 Modify ? (Y/N) It is possible to connect a printer directly to the MAS-100[™]. The output is configured for a portable thermo printer (model CUSTOM s'print[®]) A connection cable is available from your supplier.

You can choose one of the protocol or print all protocols.



Example of a calibration parameter printout :

8		17:23,01
Calibration parameters MISIC S/N:66499 K3 = 62 K4 = 10182 mV K5 = 0 Ramp = 1 K9 = 3 K4 = 2 Flow = 100 L/min. Volume = 1000 L Delay = 0 m. Cal. rem. = 12 mL Last calibration: 2.9.05	Online print: after 10 smp. Standard volumes: - 1: 11 litres - 2: 0 litres - 3: 0 litres - 4: 500 litres - 5: 1000 litres Delay menu: inactive Operation mode: manual mode SQS mode: off SQS time: Protected mode: off	Forn printed on: 06.09.05 Signature:

8.4 Back to main menu



With "yes" you return to the Start-Menu with "no" you continue in the instrument settings-menu.

8.5 Set time and date



Push "no" to proceed. Push "yes" to choose date format.

8.6 Selecting date format (EU or US) and changing time and date

Date:EURModify? (Y/N)The first item in the Parameter menu is the "Date mode". With "yes" you can
switch between US and European date format. By pressing "no" you accept
the displayed format.

Time S. Then the time is displayed. Pressing "no" places a cursor underneath the first digit. Press "no" until the required number is displayed. When you press "yes", the cursor moves on to the next digit. Continue until you have set the correct time.

Date dd.mm.vv

hh.mm.ss.

Now the date is displayed. The cursor moves to the first digit. Pressing "no" changes the numerical value and "yes" places the cursor below the next digit. You return to the start of the "Set time and date" menu. Clicking "no" takes you to the next prompt. (Please note that US format is: mm-dd-yy, EUR format is: dd.mm.yy)

8.7 Battery discharge?



Batt. discharge:

XXXXX litres

For battery maintenance it is possible to discharge the battery by pressing "yes". Push "no" to proceed to next position.

For battery maintenance it is possible to discharge the battery by pressing "yes". The batteries will discharge while the display shows a decreasing number of liters and the run and stop LED are blinking. If you push "no" during discharge the process of discharge will be interrupted.

Note:

The discharge process may last several hours depending on the actual battery charge. Do recharge the MAS-100[™] after discharge for at least 3 hours.

8.8 Anemometer mode



This mode is used to check the anemometer function. After a start up phase.., the anemometer goes to 100 L/min.

Anemometer mode Please wait..x



If the anemometer has a problem Anemometer error is displayed.

Displays the measured liters.

8.9 Change volumes



Each of the 5 pre-set volumes (standard volumes 50, 100, 250, 500, 1000 liters) may be customized. A value between 0 and 2000 liters can be specified.

Volume 1 = 50 Modify? (Y/N) Press "yes" to increment the displayed value by 1. By holding down "yes" you can scroll quickly to the required value. Pressing "no" takes you to the next volume. Setting a volume to 0 will delete it from the screen. For example, you could display just two volumes by setting the other three to 0. They are activated again as soon as you assign them a value between 1 and 2000. Continue through the volumes until you get to the "change volumes?" display. Quit with "no" to go to next menu step.

8.10 Delay menu (Change / Activate / Deactivate)

Change delay? (Y/N) The MAS-100[™] has a start menu that enables you, if you wish, to set a delay time between 1 and 60 minutes before the start of a sampling cycle . The last used delay time will be displayed. By pressing "yes", you can set a delay time between 0 and 60 minutes. If you enter 0 as delay time, no delay is activated. The MAS-100[™] starts as soon as you press "yes" at the "Start?" prompt.

If you never use the delay function, you can suppress the "Delay?" prompt by deactivating the delay in this menu (to exit the program answer "no" to "deactivate delay menu?"). You can reactivate the delay at any time (to exit the program answer "no" to "activate delay menu?").

8.11 Select operation mode



Select manual or Template mode? Use this menu to define how to work with the MAS-100TM. There are 3 options, as briefly described below.

8.12 Manual mode



Use Manual mode when you do not wish to establish a PC connection. For example, when your work does not follow a regular pattern and/or there is no PC available, it is recommended to work in manual mode.

8.13 Selectable mode



Selectable mode is used when only sometimes data are sent to the PC and flexibility in the use of the MAS-100[™] must be guaranteed. In this mode the display asks before each sampling run whether sampling is to be performed manually or at a location designated by the PC. In PC mode the user is prompted to select the report and location before sampling is started.

8.14 Template mode



The MAS-100^m is equipped for data communication. A software is available as freeware on (<u>www.mbv.ch</u>).

Note:

A communication cable to transfer data between MAS-100^{$^{\text{M}}$} and the PC, which comes with user instructions for the MAS-100^{$^{\text{M}}$} software, is available separately from your MAS-100 distributor.

8.15 Select SQS mode



activated Modify? (Y/N) The default names are User 1 etc. To define proper user names you need the C&C communication and calibration Software. (see 10.2)

8.17 Back to main menu



With "yes" the MAS-100[™] will go to the start menu. With "no" the MAS-100 starts from first menu point of the selected Mode.

9 Sampling head

9.1 Adjustment of Petri dish

Before using the MAS-100[™] the first time you will need to adjust the blue Petri dish support. Take off the perforated lid and place a Petri dish on the dish support. Use a 3 mm Allen key (supplied) to adjust the three blue jaws symmetrical, until the Petri dish is securely supported and it is fixed in place. Check that the Petri dish is properly supported by turning the sampling head to the horizontal position. The Petri dish support is now adjusted. This procedure has not to be repeated unless you change the Petri-dish manufacturer.

Note: Do not over-tighten the blue jaws. The Petri dish may break and plastic parts could block the unit.

9.2 Sampling head 400 x 0,7

The MAS-100[™] runs with 100 liters/min. The calculated impaction speed is approx. 11 m/sec with the sampling head with 400 holes with a diameter of 0,7mm.

Note: Be sure to use 400 x 0.7 mm Feller conversion table(see 20.1)

9.3 Sterilization of sampling head

The sampling head may be sterilized at 121°C for 20 minutes.

10 Software for MAS-100[™]

10.1 Validated Software for MAS-100[™]

The MAS-100[™] may be connected to a validated LIMS Software from the Canadian Company Novatek. With this Software it is possible to exchange data between the MAS-100[™] and a computer. More information you will find over: <u>http://www.ntint.com/prod-envmon.shtml</u>

10.2 Software download new MAS-100[™] C&C

The MAS-100[™] C&C Software is a terminal software which enables the user to communicate with the MAS-100[™] in an easy way. The user gets all information about the settings in the MAS-100[™] but is not authorized to change any calibration parameters. Please find the software on the internet <u>www.mbv.ch</u>, button "Software". Choose MAS-100[™] C&C Software Version 2.7x or higher. The software will be installed automatically on your PC.

Note:

To communicate between MAS-100^{$^{\text{TM}}$} and a PC you need a special communication cable. The cable is part of the MAS-100 C&C communication kit.

11 Interpreting results

First the total microbial count is corrected based on the statistical correction table according to Feller⁴ (see Appendix 20.1), then it is converted to contaminant particles per cubic meter. The correction table is based on the presumption that, as the number of organisms being impinged on a given plate during sampling rises, the chance that several organisms will enter the same hole in the perforated lid is also increasing.

Pr = N [1/N + 1/N-1+ 1/N-2.....1/N-r+1]

- Pr = Probable statistical total
- N = Number of holes in the perforated lid (400)
- r = Number of colony-forming units counted on standard Petri dish

For each colony count "r" the table gives a statistically corrected total count "Pr".

For easy application of this formula, please refer to the table (see Appendix 20.1)

(A table of statistical corrections according to Feller for the MAS-100[™] in a plastified cover is provided separately with each sampler).

Note: The MAS-100^{$^{\text{TM}}$} software corrects the results according to Feller and automatically converts them to CFU/m³.

12 Charging the MAS-100[™]

12.1 Battery charging

Connect the battery charger on the handle. "Battery charging" appears on the display and the red light is on. A complete recharging cycle takes about 3.5 hours. With a fully charged battery, the instrument has a sampling capacity of approximately 7.0 hours. .(value for new batteries)

12.2 Battery discharge

See description in chapter 8.7

12.3 Battery status display



left to aspirate

If the battery capacity decreases the MAS-100[™] will display the total amount of litres which can still be sampled without recharging the batteries. The Low battery display appears from a total sampling volume below 10'000 litres. Press yes to see the total amount of volume which is possible to sample. If you press "no" the MAS-100[™] will start the sampling. Recharge the batteries as soon as possible (see chapter 12.1).

Note:

Use only the MAS-100^{$^{\text{TM}}$} battery charger to recharge the NiMH battery. The charging circuitry of the MAS-100^{$^{\text{TM}}$} prevents overcharging of the battery.

12.4 Battery replacement

If the batteries have to be changed, loosen the bottom screw and replace the batteries with an original battery pack from the manufacturer. We advise that this is done by a service engineer who has been instructed by the supplier.

Note: After changing the battery pack recharge the MAS-100^{TT} for at least 3.5 hours.

13 Calibration

The MAS-100[™] is calibrated in the factory for a mass flow of 100 liters/min. Detailed information are provided in the calibration certificate which is delivered with each instrument.

Note: Only authorized person may exchange any mechanical parts in the instrument or change any of the software settings in the "service" menu.

13.1 Protected mode

If you use the MAS-100 C&C software it is possible to block the calibration value and/or all settings in the "Parameter Mode 4" see point "Protected mode " in the Instruction-manual of the software.

Note: To communicate between MAS-100[™] and a PC you need a special communication cable. The cable is part of the MAS-100C&C communication kit.

13.2 Calibration reminder

The MAS- 100^{TM} has an integrated calibration reminder. It can be set between 0 and 12 months. If 0 month is selected the calibration reminder is deactivated. If 6 months is set, the reminder will add 6 months to the actual date in the MAS- 100^{TM} . If after 6 months the instrument is turned on, the display will show the following message:

Calibration time expired! Please recalibrate unit.

When pressing down the "yes" or "no" button, the display will show the date of the last calibration. After releasing the button the menu proceeds to the start line.

Each time the MAS-100[™] is turned on, this message will be displayed until the instrument is recalibrated and the reminder is set to the corresponding value.

14 Technical specifications

General:

- Flow rate: 100 Liters
- Standard sampling volumes:
- Freely definable sampling volumes:

Sampling head :

- Diameter:
- Weight:
- Material:
- Autoclavable:

MAS-100TM with handle

- Height:
- Width incl. handle:
- Weight:
- Case for storage
- Material:

Additional information:

- Tripod screw:
- Battery pack:
- Motor:
- Battery charger input:
- Charger output:
- Display:
- Lifetime RTC Battery:
- Driving motor:
- Processor:
- CE approval:

14.1 Environemental conditions

Altitude: Temperature: Maximum relative humidity:

Mains supply-voltage:

Transient over-voltage:

100 liters / min. $\pm 2.5\%$ 50, 100, 250, 500, 1000 liter 1 to 2000 liters ,volumes individually selectable between 0 and 2000 liters.

110 mm 190 g Anodized aluminum 20 minutes at 121°C

260 mm 180 mm 2.2 kg plastic Anodized aluminum

For use with normal camera tripod 9 cells NiMH, 10.8 V 6 V 100-240 Volt, 47-63 Hz 24 V DC, 1.5 A, 36 W Alphanumeric liquid crystal display, 32 characters Approx. 10 years PWM frequency for driving motor Type : 80C552 EN 55022 Class B, EN 61000-4-2, ENV 50140, ENV 50204, EN 61000-4-4, ENV 50141



Up to 2000 m or above if specified by manufacturer 0 to 40°C 80 percent for temperatures up to 31°C, decreasing linearly to 50 percent relative humidity at 40°C; Fluctuations must not exceed ± 10 percent of the nominal voltage; other supply voltage: fluctuations as stated by the manufacturer Acc. to INSTALLATION CATEGORIES (OVERVOLTAGE CATEGORIES) I,II, and III and normal category is II;POLLUTION DEGREE 1 or 2 in accordance with IEC 664

Technical modification possible without prior notice.

15 Components check list

The MAS-100[™] is delivered in an plastic case containing the following:

1 MAS-100^{$^{\text{TM}}$}, complete system with sampling head (400 x 0.7)

- 1 battery charger
- 1 allen key 3 mm (for centering the Petri dish)
- 1 mains cable
- 1 plastified "Table of statistical corrections according to Feller"
- 1 calibration certificate
- 1 calibration certificate for DA-100
- 1 MAS-100 Operator's Manual CD

16 Care and maintenance

The MAS-100^{$^{\text{TM}}$} should be periodically calibrated (see 13).

The sampling head is autoclavable (20min/121°C). When the MAS-100[™] is moved to a sterile or "clean" area, we suggest to wipe it with a suitable disinfectant. Between sampling cycles, the lid may also be cleaned with disinfectant. Make sure that the holes in the perforated lid are not clogged.

17 Warranty

With the purchase of the MAS-100[™] you will receive a 1-year warranty against any failure resulting from malfunction of electrical and electronic components (see invoice date).

The MAS-100[™] is a laboratory instrument and should only be used by qualified personnel.

Note: The MAS-100[™] is calibrated and a screw in the sampling head is sealed. If the seal is removed by a unauthorized person the warranty will decay.

18 Accessories and spare parts

Accessories:

Calibration unit DA-100	1.09228
PC-cable / C&C Software package	1.09226
Quick adapter (for tripod)	1.09223
Tube adapter	1.09224
Lightweight Shoulder bag, blue	1.09126
MAS-100 [™] plastic case	1.09225

Spare parts:

Perforated lid (400x0.7)	1.09088
Dustcover	1.09084
Mains power supply unit	1.09085
Battery pack NiMH	1.09229
Perforated lid (400x0.7) for "contact" plates	1.09213
Adapter for "contact" plates	1.09214

19 References

- [1] The Rules Governing Medicinal Products In The European Community Vol. IV: Guide to Good Manufacturing practice for medicinal products, 1992
- [2] MAS-100, Qualification of air sampler systems: The MAS-100 Meier R. und Zingre H., (Swiss Pharma 1-2/00)
- [3] New Sampler for the Collection, Sizing, and Enumeration of Viable Airborne Particles, A. Andersen, U.S. Army Chemical Corps Proving Groung, Dugway, Utha., 1958
- [4] Feller, W. An introduction to the probability theory and its application, p. 175. John Wiley and sons, Inc., New York, 1950
- [5] SQS-Sequential air sampling; Validation of the microbial count in the air using the MAS-100; Swiss Pharama 26 (2004) No.11,9-11

20 Appendix

- 20.1 Table of statistical corrections according to Feller for SH 400 x 0.7mm
- 20.2 Firmware Flow Diagram MAS-100TM: Manual Mode 1
- 20.3 Firmware Flow Diagram MAS-100[™]: Template Mode 2
- 20.4 Firmware Flow Diagram MAS-100TM: Selectable Mode 3
- 20.5 Firmware Flow Diagram MAS-100[™]: Parameters Mode 4
- 20.6 Firmware Flow Diagram MAS-100TM: Calibration reminder Mode 5
- 20.7 CE Conformity declaration

20.1 Table of statistical corrections according to Feller for SH 400 x 0.7mm

r = Number of colony forming units counted on standard Petri dish Pr = Probable statistical total

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39 41 39 101 139 171 169 233 239 303 209 511 339 749 505 1420 40 42 90 102 140 172 190 257 240 366 290 515 340 756 390 1456 41 43 91 103 141 174 191 259 241 368 291 519 341 763 391 1496 42 44 92 104 142 175 192 261 242 371 292 522 342 769 392 1541 43 45 93 106 143 177 193 263 243 373 293 526 343 776 393 1591 44 47 94 107 144 178 194 265 244 376 294 530 344 783 394 1648 45 48 95 108 145 <	30	40	80	101	130	103	100	255	230	262	200	511	330	743	380	1420
41 43 91 103 141 174 191 259 241 368 291 519 341 763 391 1496 42 44 92 104 142 175 192 261 242 371 292 522 342 769 392 1541 43 45 93 106 143 177 193 263 243 373 293 526 343 776 393 1591 44 47 94 107 144 178 194 265 244 376 294 530 344 783 394 1648 45 48 95 108 145 180 195 267 245 378 295 534 345 791 395 1715 46 49 96 110 146 181 196 269 246 381 296 537 346 798 396 1795 47 50 97 111 147 <	40	41	09	101	1/10	172	109	257	239	366	209	515	340	749	300	1420
41 43 31 103 141 174 131 233 241 306 231 513 341 703 331 1433 42 44 92 104 142 175 192 261 242 371 292 522 342 769 392 1541 43 45 93 106 143 177 193 263 243 373 293 526 343 776 393 1591 44 47 94 107 144 178 194 265 244 376 294 530 344 783 394 1648 45 48 95 108 145 180 195 267 245 378 295 534 345 791 395 1715 46 49 96 110 146 181 196 269 246 381 296 537 346 798 396 1795 47 50 97 111 147 <	40	42	01	102	1/1	174	101	250	240	368	200	510	3/1	763	301	1406
42 44 45 93 106 143 177 193 263 243 373 293 526 343 776 393 1591 44 47 94 107 144 178 194 265 244 376 294 530 344 783 394 1648 45 48 95 108 145 180 195 267 245 378 295 534 345 791 395 1715 46 49 96 110 146 181 196 269 246 381 296 537 346 798 396 1795 47 50 97 111 147 183 197 271 247 384 297 541 347 805 397 1895 48 51 98 112 148 185 198 273 248 386 298 545 348 813 398 2028 49 52 99 114 <t< td=""><td>42</td><td>44</td><td>92</td><td>104</td><td>142</td><td>175</td><td>102</td><td>261</td><td>242</td><td>371</td><td>201</td><td>522</td><td>342</td><td>769</td><td>302</td><td>1541</td></t<>	42	44	92	104	142	175	102	261	242	371	201	522	342	769	302	1541
44 47 94 107 144 178 194 265 244 376 294 530 344 783 394 1648 45 48 95 108 145 180 195 267 245 378 295 534 344 783 394 1648 45 48 95 108 145 180 195 267 245 378 295 534 345 791 395 1715 46 49 96 110 146 181 196 269 246 381 296 537 346 798 396 1795 47 50 97 111 147 183 197 271 247 384 297 541 347 805 397 1895 48 51 98 112 148 185 198 273 248 386 298 545 348 813 398 2028 49 52 99 114 149 <	43	45	92	104	143	177	102	263	243	373	202	526	343	776	303	1591
45 48 95 108 145 180 195 267 245 378 295 534 345 791 395 1715 46 49 96 110 146 181 196 269 246 381 296 537 346 798 396 1795 47 50 97 111 147 183 197 271 247 384 296 537 346 798 396 1795 47 50 97 111 147 183 197 271 247 384 297 541 347 805 397 1895 48 51 98 112 148 185 198 273 248 386 298 545 348 813 398 2028 49 52 99 114 149 186 199 275 249 389 299 549 349 820 399 2238 50 52 99 114 149 <	44	47	94	107	144	178	194	265	240	376	294	530	344	783	394	1648
46 49 96 110 146 181 196 269 246 381 296 537 346 798 396 1795 47 50 97 111 147 183 197 271 247 384 296 537 346 798 396 1795 47 50 97 111 147 183 197 271 247 384 297 541 347 805 397 1895 48 51 98 112 148 185 198 273 248 386 298 545 348 813 398 2028 49 52 99 114 149 186 199 275 249 389 299 549 349 820 399 2238 49 52 99 114 149 186 199 275 249 389 299 549 349	45	48	95	108	145	180	195	267	245	378	295	534	345	791	395	1715
47 50 97 111 147 183 197 271 247 384 297 541 347 805 397 1895 48 51 98 112 148 185 198 273 248 386 298 545 348 813 398 2028 49 52 99 114 149 186 199 275 249 389 299 549 349 820 3999 2228 50 52 199 114 149 186 199 275 249 389 299 549 349 820 399 2288	46	49	96	110	146	181	196	269	246	381	296	537	346	798	396	1795
48 51 98 112 148 185 198 273 248 386 298 545 348 813 398 2028 49 52 99 114 149 186 199 275 249 389 299 549 349 820 399 2228 50 52 100 115 148 188 199 275 249 389 299 549 349 820 399 2228	47	50	97	111	147	183	197	271	247	384	297	541	347	805	397	1895
49 52 99 114 149 186 199 275 249 389 299 549 349 820 399 2228 50 52 100 145 146 199 275 249 389 299 549 349 820 399 2228	48	51	98	112	148	185	198	273	248	386	298	545	348	813	398	2028
50 52 100 115 150 100 200 277 250 201 200 552 250 000 100 200	49	52	99	114	149	186	199	275	249	389	299	549	349	820	399	2228
	50	53	100	115	150	188	200	277	250	391	300	553	350	828	400	2628

20.2 Firmware Flow Diagram MAS-100[™]: Manual Mode 1





20.3 Firmware Flow Diagram MAS-100[™]: Template Mode 2



20.4 Firmware Flow Diagram MAS-100[™]: Selectable Mode 3



20.5 Firmware Flow Diagram MAS-100[™]: Parameters Mode 4



Continue: Firmware Flow Diagram MAS-100[™]: Parameters Mode 4

MAS100_Mode4_01.vsd

20.6 Firmware Flow Diagram MAS-100[™]: Calibration reminder Mode 5



MAS100_Mode5_01_Cal_Rem.vsd

CE Konformitätserklärung						
🛛 🝆 CE Con	formity Declaration					
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Das bezeichnete Gerät entspricht der einschlägigen grundlegenden Anforderungen der aufgeführten EG-Richtlinien und Normen. Bei Änderungen am Gerät verliert diese Erklärung ihre Gültigkeit.						
The device named below fulfills the relevant fundamental requirements of the EC directives and standards listed. In the case of unauthorized modification to the device, this declaration becomes invalid.						
Gerätebezeichnung Gerätetyp	MAS-100 [™] Mikrobiologischer Luftkeimsammler					
Device name: Device type	MAS-100 [™] Microbiological Air Sampler					
EMV: EG-Richtlinien/Normen Relevant directives/standards:	EN 55022 Class B, EN 61000-4-2, ENV 50140, ENV 50204, EN 61000-4-4, ENV 50141					
MBV AG						
L. Le pe H. Zingre Director	A. Barmettler Director					
Staefa, 4. Februar 2003						