



PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: SOP for Operation & Calibration procedure of Air Sampler

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
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1.0 PURPOSE:

1.1 To lay down the procedure for operation and calibration of air Sampler (Make: SAS Super IAQ).

2.0 SCOPE:

2.1 This Standard Operating Procedure is applicable in microbiology section at Quality Control department.

3.0 RESPONSIBILITY:

3.1 Microbiologist / Executive -QC

3.1.1 Responsible for the procedure of operation and calibration of air Sampler.

4.0 ACCOUNTABILITY:

4.1 Head – Quality Control/Designee -Ensure proper control and compliance of the SOP.

5.0 DEFINITIONS:

5.1 NA

6.0 PROCEDURE:

6.1 Operation of air sampler

Push the main switch (black button) to switch on the unit. The main switch (black button) must be pushed twice on the unit if the automatic switch off timer operated when last used. Press “CLEAR” at any time to the initial “START FOR” main screen. The air sampler is provided with eight programmable air volumes (“User Mode”) selectable by the operator. The selection of the volume is made by pressing the “▲” or “▼” buttons when the program is in the relevant sub-menu.



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6.2 Start with the same air volume as the previous sample

- 6.2.1 Switch on the SAS with the black on/off switch, after the initial presentation the main screen will be displayed.

**START FOR XXX
MM/DD/YY – HH:MM**

Push the start button to start a sampling cycle with the displayed volume of air.

**[XX] → XXX
MM/DD/YY – HH:MM**

6.3 “User Mode” Function

- 6.3.1 If the operator wish to use volumes other than the standard volumes, up to 8 additional volumes can be programmed into the unit. The user-selectable volumes can be selected form the user mode, while the selectable volumes can be modified using the program mode function describe in the next paragraph.

Switch on the instrument and wait until the main screen is displayed:

**START FOR XXX
MM/DD/YY – HH:MM**

Press the “▲” or “▼” button to reach the :

**USER MODE
MM/DD/YY – HH:MM**

Press the “ENTER” button, now you can scroll the eight sampling volumes user- defined.

**S.PROG XXXX
MM/DD/YY – HH:MM**

Once the desired sampling volume has been reached press the “ENTER” button to confirm. The instrument is now ready to sample the selected volume of air. Press the “START” Button to begin the sampling cycle:

**START FOR XXXX
MM/DD/YY – HH:MM**



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The total number of available “USER MODE” Programs is eight. The maximum volume of air for each sampling cycle is 1999 liters.

6.4 “Program Mode” Function

6.4.1 Using this procedure, it is possible to memories up to eight different volumes (from 1 to 1999 liters of air). Switch on the instrument and wait until the main screen is displayed:

Press the “▲” or “▼” button to reach the:

**START FOR XXXX
MM/DD/YY – HH:MM**

Press the “ENTER” button, now you can scroll the eight user- selectable sampling volumes.

**PROGRAM MODE
MM/DD/YY – HH:MM**

Once the sampling volume to be modified has been reached, press the “ENTER” button to confirm.

**S.PROG XXXX
MM/DD/YY – HH:MM**

The display will show the old volume and the new volume.

Press the “▲” or “▼” button to select the first digit and press “ENTER” to confirm.

**XXX → 0000
MM/DD/YY – HH:MM**

Press the “▲” or “▼” button to select the second digit and press “ENTER” to confirm.

**XXX → X000
MM/DD/YY – HH:MM**

Repeat the previous step until the last digit, when the last digit is confirmed, the new volume will be memorized and added to the list of eight user- selectable volume. If you want to start a sampling cycle with the new value you have to enter the user mode and select it by using the procedure described in point no. 6.3.

6.5 “Delay Mode” Function



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6.5.1 With this function it is possible to delay the beginning of the sampling cycle. If a delay has been selected, the sampling cycle will begin the selected delay time. Switch on the instrument and wait until the main screen is displayed:

**START FOR XXXX
MM/DD/YY – HH:MM**

Press the “▲” or “▼” button to reach the:

**DELAY MODE
MM/DD/YY – HH:MM**

Press the “ENTER” button, the delay time is displayed:

**DELAY 01 MIN
MM/DD/YY – HH:MM**

6.5.2 Select the desired delay time with the “▲” or “▼” button. The selectable delay values are 1, 2, 3, 5, 10 or 20 minutes. Press “ENTER” button to confirm.

6.5.3 When a delay has been selected, after the “START” button has been pressed, a delay warning message will be displayed.

**** DELAY ****

6.6 “Utility Mode” Function

6.6.1 With this function it is possible to modify all the setting of the air sampler.

6.6.2 The UTILITY MODE is divided into ten sub-menus (Set time; Mode; Set Auto switch; Display Record; Clear Record; Language; Identify; Sampling site.)

6.6.3 Always start from UTILITY MODE to reach one of these SUB-MENU.

6.6.4 Switch on the instrument and wait until the main screen is displayed:

**START FOR XXXX
MM/DD/YY – HH:MM**

Press the “▲” or “▼” button to reach the:

**UTILITY MODE
MM/DD/YY – HH:MM**

Press the “ENTER” button, the first sub-menu is listed:



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■ “Set Time”

From the UTILITY MODE select the “SET TIME” Function. This option is used to program day, month, year and time of the day.

SET TIME
MM/DD/YY – HH:MM

Press ENTER and “▲” or “▼” button to change Month

Press ENTER and “▲” or “▼” button to change Day

Press ENTER and “▲” or “▼” button to change Year

Press ENTER and “▲” or “▼” button to change Hours

Press ENTER and “▲” or “▼” button to change Minutes

■ “Set Auto switch”

To save battery consumption the SAS automatically switches off after 4 minutes. The Set auto switch option is used to enable or disable the automatic switch off.

From the UTILITY MODE select the “SET AUTOSWITCH” function:

SET AUTOSWITCH
MM/DD/YY – HH:MM

Press ENTER and “▲” or “▼” button to change between the two options:

AUTOSWITCH ON
MM/DD/YY – HH:MM

AUTOSWITCH OFF
MM/DD/YY – HH:MM

Select the desired options and press ENTER to confirm and exit. This setting will be lost after the instrument is switched off.

■ “Display Record”

The last 99 samples are memorized in the file “DISPLAY RECORD”. Each sample is identified in chronological order and shows the date, time, operator, site and volume of air sampled. From the UTILITY MODE select the “Display recode” function.

DISPLAY RECORD
MM/DD/YY – HH:MM

Press ENTER to see memorized values:



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**001 MM/DD HH:MM
ID. / SITE VOL. OP**

The following parameter are recorded:

Progressive number; Month and Day; Time; Identification/ Site; Sampling Volume; Option.

If there is no data stored in memory the display will show:

■ “Clear Record”

This option is used to delete all the data memorized in the “DISPLAY RECORD”. Before starting this procedure, please be certain that existing data is not required or that it has been downloaded. From the UTILITY MODE select the “clear record” function.

**CLEAR RECORD
MM/DD/YY – HH:MM**

Press ENTER to delete all the stored data, the display will show the resetting status:

**RESETTING.....
▶▶▶▶**

■ “Language”

The text of the menus may be selected choosing from different languages.

From the UTILITY MODE select the “LANGUAGE” function:

**LANGUAGE
MM/DD/YY – HH:MM**

Press ENTER to list all the available languages:

ENGLISH

Use the “▲” or “▼” button to select the desired language and press ENTER to confirm. There are six available languages:

English, French, Spanish, German, Portuguese and Italian



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■ “Identify”

This option is used to identify the operator. This should be changed if different operator uses the sampler and especially if the data is to be printed.

From the UTILITY MODE select the “IDENTIFY” function.

SAMPLING SITE
MM/DD/YY – HH:MM

Press ENTER to modify the identification code:

IDENTIFY
XXXX

Select the desired character with the “▲” or “▼” button and confirm with ENTER.

Select the next desired characters and confirm them by pressing ENTER.

The selected value is stored in the memory and it will be kept also after the instrument has been switched off.

■ “Sampling Site”

The site identification should be changed for samples taken at different sites especially if the result are to be printed.

From the UTILITY MODE select the “SAMPLING SITE” function.

SAMPLING SITE
MM/DD/YY – HH:MM

Press ENTER to modify the sampling site:

SAMPLING SITE
XXXX

Select the desired character with the “▲” or “▼” button and confirm with ENTER.

Select the next desired characters and confirm them by pressing ENTER.

The selected value is stored in the memory and it will be kept also after the instrument has been switched off.



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6.7 After feeding the required volume of 1000 Ltrs. (1000 Ltrs. equal to 1 cubic meter) start the air sampler on working height for analysis.

6.8 Air sampler disinfection

6.8.1 Body of the Sampler- The plastic body of unit can be wiped with a 70% IPA.

6.7.2 Plate Housing Head- The unit complete with the sampling head can be disinfected using a validated disinfectant.

6.7.3 Cover of Head- The sampling head with its protective plastic lid should be autoclaved at a minimum temperature of 121 °C at least 30 min, following the good sterilization practice. Alternatively, the sampling head can be sanitized by treating the inside and outside surface with a disinfecting 70% IPA or any validated disinfectant wipe.

6.9 Calculation of results

6.9.1 After completion of air sampling remove the perforated lid and close the plate carefully to avoid the contamination.

6.9.2 Incubate the petri plate at 22.5°C ± 2.5°C for 3 days and then at 32.5°C ± 2.5°C for next 2 days.

6.9.3 After incubation, record the counts in the format for Environmental Monitoring Report for Active Air Sampling as per current version of respective SOP as cfu / m³ after applying the J. Maker. Correction Tables as per annexure- I. the probable count (Pr) is then used to calculate the colony forming unit (cfu) per cubic meter of air sampled.

6.9.4 Disinfectant SS cone and SS Feeder Cone with IPA 70 % v/v each time for different location.

6.10 Validation/Calibration

6.10.1 The validation/calibration frequency is yearly and performed the activity by VWR International PBI or an official distributor.

6.10.2 After validation/calibration received the certificate from VWR International PBI or an official distributor and affix the validation/calibration status label as per Annexure-II.

Note: Report any discrepancy observed during operation inform to Quality Control Head and notify the defect to engineering department or Service Engineer of the instrument and affix an Under Maintenance label on the instrument.

7.0 ANNEXURES

7.1 Annexure-I : Positive Hole Conversion Table

7.2 Annexure-II : Validation/Calibration Status Label



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8.0 ABBREVIATIONS

- 8.1 **SOP** : Standard Operating Procedure
8.2 **QC** : Quality Control
8.3 **SS** : Stainless Steel
8.4 **No.** : Number
8.5 **NA** : Not Applicable
8.6 **CC** : Change Control
8.7 **HOD** : Head of Department
8.8 **v/v** : Volume by Volume
8.9 **Min.** : Minute

9.0 REFERENCES

- 9.1 SAS Super IAQ Manual.

10.0 CHANGE HISTORY

Revision no.	Effective date	Change Control Ref. No.	Description of change(s)