



# PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Department:** Microbiology

**SOP No.:**

**Title:** Operation, Cleaning, Calibration and Maintenance of Volumetric Air Sampler

**Effective Date:**

**Supersedes:** Nil

**Review Date:**

**Issue Date:**

**Page No.:**

### 1.0 OBJECTIVE

1.1 To lay down the Procedure for Operation, Cleaning, Calibration and Maintenance of Volumetric Air Sampler.

### 2.0 SCOPE

2.1 This procedure is applicable for Volumetric Air Sampler used in the Microbiology section and Production facility.

### 3.0 RESPONSIBILITY

3.1 Microbiologist shall be responsible for performing the air sampling using the air sampler as per the procedure.

3.2 Microbiology section in-charge shall be responsible ensuring compliance of the SOP.

### 4.0 ACCOUNTABILITY

4.1 Head Microbiology

### 5.0 EHS CONSIDERATIONS

5.1 NA.

### 6.0 PROCEDURE

#### 6.1 Instrument Details:

Instrument Name	Instrument ID	Make	Model

#### 6.2 Instrument Description:

6.2.1 The SAS air sampler is divided in to 3 parts:

6.2.1.1 The contact plate chamber containing adjustable holder to accommodate petri plates of different diameters, SS sampler sieve and lid.

6.2.1.2 Lower front panel has an Infrared sensor for Remote control, Back-lit alpha-numeric visual display, “▲” and “▼” buttons, “START” button, “CLEAR” button, “ENTER” button, Rubber gasket and Flashing LED during air sampling.

6.2.1.3 Bottom panel consisting of ON/ OFF switch (black button), battery charger connection, Flashing LED during air sampling, Instrument serial number and CE mark.

#### 6.3 Switching the Sampler ON:

6.3.1 Push the ON / OFF Button (black button on bottom panel) to switch ON the instrument.



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**Note:** The ON/ OFF button must be pushed twice to switch ON the instrument if the automatic switch off timer was operated when last used. Automatic switch Off timer will activate and switch OFF the instrument, if no activity is performed for 4 minutes so as to save battery.

6.3.2 After the initial presentation, the previously selected air sample volume retained in the memory appears on the display as shown below:

START FOR           XXX  
MM/DD/YY — HH:MM

6.3.3 Push the “START” button to start the sampling with the displayed volume of air.

6.3.4 The instrument shall start with flashing red colour LED light on the lower front panel. The display will start counting the volume of air sampled.

6.3.5 Once the set amount of air has been sampled, the instrument will stop with a beep sound and the red LED light will stop flashing.

### 6.4 Adjusting the Volume to be Sampled:

6.4.1 If the sampling volume displayed on the main screen needs to be changed, press the ▼ button once. Following screen will be displayed;

USER MODE  
MM/DD/YY — HH:MM

6.4.2 Press the “ENTER” button, to enter into the user mode. Following screen will be displayed:

S. PROG.           XXXX  
MM/DD/YY — HH:MM

6.4.3 Now press the ▲ or ▼ button to scroll between 7 user-defined sampling volumes i.e. 1000, 750, 650, 550, 450, 350 and 250 Litres.

6.4.4 Once the desired volume has been reached, press the “ENTER” button to confirm.

6.4.5 The display will return to the main screen and the new selected volume will be displayed on the screen. The instrument is now ready to sample the selected volume of air.

6.4.6 Start the sampling by pressing “START” button once.

### 6.5 Setting User-Defined Volume:

6.5.1 Using this feature user can set up to 7 different volumes (from 1 to 1999 litres of air).

6.5.2 Switch ON the instrument by pressing black colored ON/ OFF push button on bottom panel.

6.5.3 The main screen will be displayed. Press the ▼ button twice. Following screen will be displayed.

PROGRAM MODE  
MM/DD/YY — HH:MM



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6.5.4 Press the “ENTER” button, to enter into the Program mode. Following screen will be displayed:

S. PROG.            XXXX  
MM/DD/YY — HH:MM

6.5.5 Now press the ▲ or ▼ button to scroll between 7 user-defined sampling volumes i.e. 1000, 750, 650, 550, 450, 350 and 250 Litres.

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

6.5.7 The display will show the old volume (on the left side) and the new volume (on the right side).

XXXX                    0000  
MM/DD/YY — HH:MM

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

XXXX                    X000  
MM/DD/YY — HH:MM

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

6.5.10 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 seven user-selectable volume.

### 6.6 Setting of Delay time:

6.6.1 Using this feature user can set a delay timer for beginning of the sampling cycle.

6.6.2 Switch ON the instrument by pressing black colored ON/ OFF push button on bottom panel.

The main screen will be displayed. Press the ▼ button thrice. Following screen will be displayed.

DELAY MODE  
MM/DD/YY — HH:MM

6.6.3 Press the “ENTER” button, to enter into the Delay mode. Following screen will be displayed:

DELAY            XX    MIN.  
MM/DD/YY — HH:MM

6.6.4 Now press the ▲ or ▼ button to scroll between 6 settable delay timers. The selectable delay timers are. 01, 02, 03, 05, 10 and 20 minutes.

6.6.5 Once the Delay timer has been selected, press the “ENTER” button to confirm.



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6.6.6 The display will return to the main screen. Press the “START” button to start the sampling with delay timer.

6.6.7 The delay timer will start, indicated by a flashing “Delay” icon on the display as follows:



6.6.8 Once the delay timer has elapsed, the instrument shall start the sampling automatically.

### 6.7 **Sampling of Air:**

6.7.1 Ensure that the Air sampler is fully charged.

6.7.2 Take the Air sampler & the autoclaved sieve to the sampling location.

6.7.3 Press the black colored ON/ OFF button located in the bottom panel to start the instrument.

6.7.4 The screen will show the Volume set for sampling. In case the volume displayed is different than that required, change the Volume by following the procedure defined above.

6.7.5 Place the Air sampler at specified sampling location.

6.7.6 Place the pre-incubated sterile SCDA plate in the plate chamber, lift the plate cover and then place the autoclaved sieve on the air sampler.

6.7.7 Lock the air sieve in place by rotating it in clockwise direction.

6.7.8 Press “START” button to start the air sampler.

6.7.9 After collection of set/feed volume, the air sampler automatically stops. Unlock the sieve by rotating it in anti-clockwise direction. Place the lid back on the plate aseptically and remove the sampled plate from the sampler.

6.7.10 Label the plate with location code, date of sampling and sign.

6.7.11 While performing continuous sampling, disinfect the air sieve with filtered 70% IPA after each sampling and air dry the sieve.

**Note:** While performing continuous sampling, always start sampling from cleaner area and then move on to the lesser clean area.

6.7.12 Perform the air sampling at all the pre-defined approved locations as per respective SOP.

6.7.13 Collect all the plates and bring to microbiology laboratory for incubation.

### 6.8 **Precautions to avoid false positive/negative results:**

6.8.1 Perform the air sampling at workbench level or on a stool.

6.8.2 Do not use oxidizing agents such as hydrogen peroxide or per acetic acid for cleaning of instrument surface.

6.8.3 Avoid spraying liquids into the air sampler.

6.8.4 Do not autoclave or flame the entire tester.

6.8.5 Do not perform any activity over the sampler while it is sampling.

6.8.6 Incubate the petri plates in inverted position to avoid cross contamination.



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### 6.9 Calibration:

- 6.9.1 Calibration of the Air Sampler is to be performed by supplier's service engineer.
- 6.9.2 Frequency: 1 year

### 6.10 Cleaning:

- 6.10.1 Clean the surface of Air Sampler with a lint free cloth soaked in 0.2 $\mu$  filtered 70% IPA before and after every operation.

### 6.11 Maintenance:

- 6.11.1 The instrument should be kept for charging after the completion of sampling using the charger provided with the instrument.
- 6.11.2 In case of any discrepancy, affix the "UNDER MAINTENANCE" label with date and time and inform engineering department for further action.
- 6.11.3 After completion of maintenance work, remove the "UNDER MAINTENANCE" label.

## 7.0 DEFINITIONS AND ABBREVIATIONS

- 7.1 CFU : Colony Forming Unit
- 7.2 LED : Light Emitting Diode
- 7.3 SCDA : Soyabean Casein Digest Agar
- 7.4 SOP : Standard Operating Procedure
- 7.5 QC : Quality Control

## 8.0 REFERENCE

- 8.1 Instruction Manual of instrument.

## 9.0 ANNEXURES

- 9.1 NA

## 10.0 DISTRIBUTION DETAILS

- 10.1 Controlled copy of this SOP shall be distributed to Quality Assurance and Microbiology.

## 11.0 REVISION HISTORY

Supersedes SOP No.	Change Control No.	Reason for revision	Effective date