



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of M Air T Isolator System

SOP No.:		Department:	Microbiology
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 7

1.0 OBJECTIVE:

To lay down procedure for cleaning, calibration and operation of M Air T Isolator System.

2.0 SCOPE:

This SOP is applicable for M Air T Isolator System, Make - Millipore.

3.0 RESPONSIBILITY:

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE:

4.1 Operation

4.1.1 Switching the machine on -

4.1.1.1 Insert the plug of sampler in the main power socket.

4.1.1.2 Start the pump by gently pressing the power switch, provide on the back of pump.

4.1.1.3 On starting following message displays on the screen.

```
M I L L I P O R E M A I R T I S O L
V E R S I O N : x x x x x x
```

```
T E S T
S E N S O R S U P P L Y - > O K
```

```
T E S T
M A I N F R E Q U E N C Y - > O K
```

```
T E S T
R T C C L O C K - > O K
```



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T E S T
T E M P E R A T U R E - > O K

T E S T
F L O W S E N S O R - > O K

4.1.1.4 Pump automatically starts running on auto- test. After five seconds following message displays on the screen.

M I L L I P O R E M A I R T I S O L
A U T O T E S T O K

4.1.1.5 If printer is not attached then an error message for printer connection displays.

4.1.1.6 Connect the printer and press enter button.

4.1.1.7 The last calibration date appears after 5 seconds.

L A S T C A L I B R A T I O N
D A T E : D D M M Y Y

4.1.1.8 After 2 seconds the following message displays on the screen.

V O L U M E S A M P L E D S I N C E
L A S T C A L I B : X X X X X X X X L

R E A D Y D D M M Y Y H R : M N
V O L : X X X X L C Y C L E : X

4.1.2 Operating the machines -

4.1.2.1 After starting the pump, Press the PARAM key.

4.1.2.2 Enter the total volume of the air to be sampled by pressing by using alphanumerical key on control keypad.

4.1.2.3 One key is having 3 or 4 alphabetic and one number.

4.1.2.4 For alphabetic press and hold for few seconds the alphabet will change from first alphabet to second, second alphabet to third, third to fourth, fourth to number and then number to again first alphabet, like that it will keep on rotating.

4.1.2.5 After appearing the required alphabet or number immediately remove the finger from the keypad. For deleting the value use key.





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S A M P L I N G V O L U M E ?
L I T R E S : X X X X

4.1.2.6 Press the ENTER key.

4.1.2.7 Press the ENTER key.

S T A R T D E L A Y ?
M I N : X X X

4.1.2.8 Press the ENTER key.

4.1.2.9 Enter the cycle no.

N U M B E R O F C Y C L E ?
X

4.1.2.10 Press ENTER key.

4.1.2.11 If the number of cycle is more than one then go to step 5 otherwise following display occurs.

E N T E R L O C A T I O N
X X X X X

D E L A Y W I T H I N C Y C L E ?
M I N :

4.1.2.12 Press ENTER key.

4.1.2.13 Enter the operator name.

O P E R A T O R N A M E :
X X X X X X

4.1.2.14 Enter the batch no.

S A M P L I N G L O T N U M B E R
X X X X X X

4.1.2.15 Press the ENTER key.



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4.1.2.16 The main screen re-appears indicating the total sampling time, the total sampling volume and number of sampling cycles.

```
S A M P L I N G   R E M : X X X M I N
V O L : X X X X L           C Y C L E : X
```

4.1.2.17 Press the START button to begin sampling.

4.1.2.18 During sampling the screen shows remaining sampling time, the volume to be sampled and number of cycles as shown below.

```
S A M P L I N G   R E M : 8           M I N
V O L : 1 0 0 0 L           C Y C L E : 1
```

4.1.2.19 When sampling is complete, if the pump is connected to the printer, a print is printed automatically and the screen displays.

```
P R I N T I N G
```

4.1.2.20 If printer is not connected the screen automatically goes to step 5.1.2.11.

4.1.2.21 When sampling is complete screen returns to the main menu.

```
R E A D Y D D M M Y Y   H R : M N
V O L : X X X X X L   C Y C L E
```

4.1.3 Checking the parameters or stopping the pump during sampling -

4.1.3.1 To check the parameters during pump operation press the PARAM key. On pressing the key following display appears.

```
S T A R T   D E L A Y
M I N : X
```

```
L O C A T I O N
X X   X X X X X X
```



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4.1.3.2 To stop a sampling press STOP key.

```
O P E R A T O R   N A M E
X X   X X X X X X X
```

4.1.3.3 Following message display on the screen.

```
S A M P L I N G   A B O R T E D
V O L   S A M P L E D   :   X X X X L
```

4.1.3.4 Alternating with this screen.

```
R E S U M E   >   E N T E R
A B A N D O N   >   S T O P
```

4.1.3.5 Press ENTER to restart sampling.

4.1.3.6 Press STOP to stop sampling and return to the main menu.

4.2 Sampling procedure

4.2.1 Install the sampling head on the tripod.

4.2.2 Connect the M Air T tripod to the pump INLET using the silicone tube.

4.2.3 Connect the opticap filter to the pump OUTLET to avoid any risk of particle contamination.

Note: Install the Opticap with the arrow pointing in the direction of airflow.

4.2.4 Clamp the sieve, cone and reducer (cone set).

4.2.5 Grasp the cassette wings and place it on the sampling head.

4.2.6 Lock the cassette into place.

4.2.7 Remove the cover and place it on a work surface with the inside facing down.

4.2.8 Place the cone set over the cassette and lock it into position.

4.2.9 Insert the Polyurethane tube connection sampling point into the reducer.

4.2.10 Start the sampling by pressing start button on the control keypad.

4.2.11 After sampling loosen and remove the cone set from the analyzer by twisting it counter clockwise.

4.2.12 Loosen and remove the sieve from the sampling head by twisting it counter clockwise.



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4.2.13 Close the plate with cover and remove from the sampling head.

4.2.14 Label the plate as location name, date of sampling and sampled by (initial).

4.2.15 Follow the same procedure for remaining locations.

4.2.16 Bring all the plates to the microbiology lab and incubate the plates at 30 -35°C for 48hrs and followed by 20 -25°C for 72hrs.

4.2.17 Observe the counts and note down results as per SOP.

4.2.18 Note: Ensure all the S.S accessories M Air T isolator including silicone pipe are sterilized.

4.3 Cleaning

Clean the compress air sampler with lint free cloth dipped in approved disinfectant solutions.

4.4 Calibration

Calibration is to be done by supplier at least once in a year.

5.0 SAFETY & PRECAUTIONS:

Before operating check the air pressure.

6.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date
00	First Issue	-----

7.0 REFERENCES:

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8.0 ABBREVIATIONS:

SOP : Standard Operating Procedure

% : Percentage

S. S : Stainless Steel

9.0 ANNEXURES:

Not applicable.