



# PHARMA DEVILS

## MICROBIOLOGY DEPARTMENT

### STANDARD OPERATING PROCEDURE

**Title:** Operation of Milliflex Water filtration Unit

<b>SOP No.:</b>		<b>Department:</b>	Microbiology
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
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#### 1.0 PURPOSE

To lay down the procedure for operation of Milliflex Water Filtration unit.

#### 2.0 SCOPE

It is applicable to Microbiology Lab.

Equipment ID No.

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Make  
Millipore

Model  
Milliflex PLUS

#### 3.0 RESPONSIBILITY

Microbiology personnel

#### 4.0 PROCEDURE

##### 4.1.1 Pre operational checks

4.1.1.1 Check the calibration status of the instrument

4.1.1.2 Check the status of the sanitization cycle.

4.1.1.3 Check the status of the monthly calibration.

4.1.1.4 Ensure the head, funnel and SS grid are autoclaved.

4.1.1.5 Check the cleaning of the instrument.

4.1.1.6 Use sterile filter membrane only.

4.1.1.7 Ensure the printer is attached properly.

##### 4.2 Operation of milliflex

4.2.1 Install the pump head. Switch on the pump by pressing the On/Off button on the key pad the display shows

MILLIFLEX PLUS SERIAL NO. 1676
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4.2.2 Set the date with arrow key by Up and Down

DATE
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4.2.3 After setting the date, set time with arrow key by Up and Down

TIME

4.2.4 Manual will appear on the screen

MANUAL

4.2.5 Press OK, tare will appear.

TARE

4.2.6 Select the sampling option with the help of arrow key

4.2.7 Enabling data export.

4.2.7.1 In the main menu, use the down arrow to scroll down to export data, press OK, the display shows

START

4.2.7.2 Press OK, display will show

OPERATOR

4.2.7.3 Press up or down keys the display will show

ABCDEFGHIJKL  
MNOPQRSTUVWXYZ  
Z0123456789

4.2.7.4 Enter the name by pressing the up or down arrow to highlight a character, and then press OK to select it .The selected character is displayed.

4.2.7.5 Press the up and down arrow to highlight a character selection screen again



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4.2.7.6 Repeat this process for each character. The characters selected so far are displayed when OK is pressed. To delete the last character entered, press C

4.2.7.7 After entering operator press OK, display will show

CASSETTE

4.2.7.8 Press OK, display will show

LOT NO.

4.2.7.9 Enter the media lot No. as described in point No. 4.7.1 to 4.7.6

Increment start  
1

4.2.7.10 Enter the date and time, using the up and down arrows, press OK to confirm the completed entry, in each case. The display show.

Begin  
Press start

4.2.10.11 Press START. The settings just entered will be printed

### 4.3 Set up for manual sampling

4.3.1 In main menu, use the up or down arrows to select sampling and press OK. The display shows.

MANUAL

4.3.2 Press OK. The display shows:

VOLUME OFF

4.3.3 Select the ON option by arrow key



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VOLUME  
ON

4.3.4 Press OK. The display shows

MILLIFLEX 100

4.3.5 Select the milliflex 250 funnel, press the down arrow, the display shows

MILLIFLEX 250

4.3.6 Press OK, the display shows:

DENSITY (g/ml)  
1.00

4.3.7 Use the up or down arrows to select the density of the liquid to be tested. Press OK the display shows.

MANUAL  
MIL 250/1.00

#### 4.4 Set up for auto sampling

4.4.1 In main menu, use the up or down arrows to select sampling and press OK. The display shows.

MANUAL

4.4.2 Press the down arrow the once. The display shows

AUTO SAMPLING

4.4.3 Press OK. The display shows the name of the last auto sampling program selected

4.4.4 Use the up or down arrows to move through the list of programs to the required program. Press OK. The display shows



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SELECT

4.4.5 To proceed with the selected program, press OK. The display shows the main program screen for the selected program. For example

MF X 100  
MIL 100 / 100  
ML

4.5 Use sterile forceps to place the sterile membrane filter on the pump head. Firmly press the sterile funnel onto the pump head.

**Note:** Make sure that the base of the funnel is touch with the top of the pump head filter support.

4.6 Pour sample into the funnel, slowly to achieve the required volume

4.7 In Manual mode, if Volume 'ON' has been selected, the display will show the volume filled.

4.8 In Auto Sampling mode, the buzzer will sound when the required volume has been reached.

4.9 When the required volume has been reached, stop pouring.

4.10 In Manual mode, press START to start the pump.

4.11 In Auto Sampling mode, filtration starts automatically.

4.12 In Manual mode, operate the pump until the sample has been filtered, then press START to dry out the pump head. Wait for the pump to stop.

4.13 In Auto Sampling mode, when the sample has been filtered, the pump switches automatically to drying. Wait for the pump to stop.

4.14 Remove the funnel from the pump head and remove the membrane with the sterile forceps.

4.15 Place the sterile membrane filter on the pre incubated R<sub>2</sub>A agar plates. Ensure that there is no air trap inside the filter paper

4.16 Incubates the plates as required.

4.17 Before taking next sample wipe with the head with sporocidal agent and change the SS grid.



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#### 4.18 Calibration

4.18.1 Enter the configuration menu as described in the configuration section. Press the down arrow until the display shows validation.

4.18.2 Press OK. The display shows

WEIGHT  
CALIBRATION

4.18.3 Press OK. The display shows

ENTER CODE OR  
PRESS C

4.18.4 Enter the security code (press start three times) and then press OK

4.18.5 When the security code has been entered, the display shows

CALIBRATION  
DATE  
DD MM YY

4.18.6 Press the UP or down arrows to enter the calibration date, and then press OK the display shows

REMOVE HEAD  
PRESS START

4.18.7 Remove the pump head and press START, the display shows

MEASURING . . .  
PLEASE WAIT . . .

4.18.8 After a few seconds the display shows

PUT HEAD  
PRESS START

4.18.9 Reinstall the pump head and press START the display shows,



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PUT 50 G  
PRESS START 0, 0

4.18.10 Place the 50 g calibration weight on the pump head and press start

4.18.11 The pump calibrates with the 50 g weight . Next the display prompts the user for the 100 g weight and then for the 200 g weight. Follow the prompts as they are displayed. After calibration with the three weights, the display shows,

SAVE CALIBRATION:  
OK  
CANCEL: C

4.18.12 To proceed, and confirm the calibration, press OK. The displays,

VERIFICATION  
PRESS OK

4.18.13 Follow the prompts displayed to verify the new calibration. After each weight measurement, the display shows the measured value. Press START to confirm the displayed value and proceed to the next step.

4.18.14 When the verification procedure is completed, The display shows

PRINT PRESS START  
CONTINUE: OK

4.18.15 Press START, the printer prints the calibration data while the display shows

PRINTING

4.18.16 When printing has finished, the display returns to

WEIGHT  
CALIBRATION

**Frequency of calibration: Monthly**



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#### 4.19 Sanitizing

4.19.1 Sanitize the pump interior, using the automated procedure described in the Sanitization section. Sanitizing agents: Disinfectant available for the day of use.

4.19.2 At the main program screen press OK to enter the main menu the display shows.

TARE

4.19.3 Press the down arrow until the display shows

SANITIZING

4.19.4 Press OK the display shows.

PUT EXPANDABLE  
PRESS START

4.19.5 Place the sterile membrane filter and a milliflex funnel, on the pump head and press START. The display shows

4.19.6 FILL 100 ML OF AGENT  
PRESS START

4.19.7 Fill the funnel with 100 ml of sanitizing agent and press START. The display shows

SANITIZING

4.19.8 The pump pulls through 50 ml of agent, pause for ten minutes, and then pulls through the remaining 50 ml A bar graph at the bottom of the display shows the progress of the operation.

4.19.9 After the pump has emptied the funnel, its runs a drying cycle and then display shows

FILL 4 X 100 ML OF  
WATER, PRESS START

4.19.10 Fill the funnel with 100 ml of sterile water and press START. The display shows



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RINSING

4.19.11 The pump empties the funnel and runs a drying cycle then the display shows

FILL 100 ML OF WATER  
PRESS START

4.19.12 Fill the funnel with 100 ml of sterile water and press START. The rinsing cycle is performed as before. Then the display prompts for the funnel to be filled again, for each rinse, for a total of four rinses when the fourth rinse has been completed, the display shows

SANITIZING FINISHED  
PRESS START

4.19.13 Press START, remove the funnel and discard it, the display shows

SANITIZING

4.19.14 Press C to go back to the main program screen

#### 4.20 **Frequency of sanitization: Weekly Cleaning**

4.20.1 Clean the exterior of pump with a lint free mop with 70 % filtered v/v isopropyl alcohol.

**Frequency: Before and after every use.**

#### 4.21 **Tare procedure**

Note: The tare procedure adjusts the measurement system in the pump for the weight of the installed pump head. The tare procedure shall be performed whenever the pump head is changed, and whenever the display does not show 'O', with an empty funnel on the head.

4.21.1 When the display shows tare, press OK. The displays show

REMOVE EXPANDABLE  
PRESS START

4.21.2 Remove anything on the pump head and press START. The display shows



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MEASURING . . .  
PLEASE WAIT . . .

4.21.3 After a few seconds, the display returns to the main program screen for the previously selected program.

4.22 Autoclave the pump head, SS grit before first use.

#### 5.0 ABBREVIATIONS AND DEFINITIONS

SOP	Standard Operating Procedure
QCM	Quality Control Microbiology
QAD	Quality Assurance Department
Rev.	Revision
No.	Number
G	Gram
ML	Milli litre
%	Percentage

#### 6.0 REFERENCE DOCUMENTS

Operation and Cleaning of Steam Sterilizer

#### 7.0 ANNEXURE / ATTACHMENTS

Annexure I : Form I- Calibration of milliflex water filtration unit by weight verification

Annexure II : Form II- Milliflex water filtration unit usage log book.

Annexure III : Form III - Sanitization record of Milliflex.



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#### 8.0 REVISION LOG

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00		