



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Cleaning, Calibration and Operation of Equinox System

SOP No.:		Department:	Microbiology
		Effective Date:	
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1.0 OBJECTIVE:

To lay down procedure for cleaning, calibration and operation of Equinox system.

2.0 SCOPE:

This SOP is applicable for Equinox system, Make - Millipore in microbiology laboratory.

3.0 RESPONSIBILITY:

Prepared by - Executive Microbiology

Checked by - Assistant Manager Microbiology / QC

Approved by - Head QA, QC

4.0 PROCEDURE:

4.1 Operating and Assembling Instructions

- 4.1.1 Connect the accessories (pump head, bottle holder, power box, drain tray and foot switch) to the pump.
- 4.1.2 Switch on the main power supply.
- 4.1.3 Press the 'Power' key for On/Off on the power box.
- 4.1.4 Press 'On/Off' button on the pump.
- 4.1.5 The start up screen appears and pump head opens.
- 4.1.6 After equipment initialization, the initial "Testing Mode" screen displays.
- 4.1.7 Select 'Manual/Automatic' testing mode by turning the knob on the pump.
- 4.1.8 Press the knob to confirm the selection of the mode.

4.2 Installation of Steritest Canister for Testing

- 4.2.1 Install the cover on the drain tray.
- 4.2.2 Remove the canister from its package and place the two canisters in the drain tray.
- 4.2.3 Install the tubing in the pump head by pulling the tubing and engage it fully in the cover.



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4.2.4 Check that the two tubing hoses are positioned both side of the bosses on the right and kept sides of the cover.

4.2.5 Side the tubing from left to right and right to left, to ensure that it is correctly positioned.

4.2.6 Close the pump head by pressing Open/Close button on the right side of the pump.

4.3 Operating the Pump in the Manual mode for Testing

4.3.1 In testing mode screen, turn the knob to highlight “Manual” and press the knob to confirm.

4.3.2 The manual mode screen is displayed.

4.3.3 Turn the knob to change the pump rotation speed, turn clock wise to increase speed and anti clock wise to reduce the speed. (Rotation speed can be change while the pump is running).

4.3.4 Close the pump head with the help of Open/Close button start the rotation of the pump by pressing the knob or using foot switch.

4.3.5 Press and hold the knob till a buzzer rings and the word “Timer” blinks on the display.

4.3.6 Release the knob and turn it to program the timer value. Confirm by briefly pressing the knob. The “Timer” stops blinking and the value set is memorized.

4.3.7 Press the knob to start the pump, the pump will stop automatically after the programmed timer value elapsed.

4.3.8 Note: Timer setting value cannot be changed while pump is running.

4.4 Operating the Pump in the Automatic Mode for Testing

4.4.1 In testing mode screen, turn the knob to highlight “Automatic” and press the knob to confirm.

4.4.2 The Automatic mode screen displays the following information.

4.4.3 Title of the selected test procedure, name of the current step with comments, pump rotation speed timer setting, high pressure alert message and pump head status.

NOTE: Before using the pump in Automatic mode, the testing procedure must be configure on a computer and then transfer this configuration to the pump.

4.4.4 Select the test procedure applicable for the product tested by turning the knob, and then confirm by pressing the knob.

4.4.5 The Automatic mode screen for the first step of the selected test procedure is displayed.

4.4.6 Press the knob (or the foot switch) to start the pump, the pump speed and the timer (if activated) are pre set.

4.4.7 When the pump head is rotating in the timer mode, the timer value is blinking.



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4.4.8 Pressing “Next/Back” button moves on to the next step in the testing procedure.

4.4.9 At the end of the last step of selected testing procedure is completed hold “Next/Back” button to return the list of testing procedures present in the Equinox pump.

4.5 Setting Parameters by Using MENU Option

4.5.1 Access the configuration menu by turning the knob to highlight the “Menu” option and pressing the knob to select.

4.5.2 The configuration menu displays, turn the knobs to scroll through the functions on the menu the following configurations are available in the menu.

4.5.3 PRESSURE CONTROL -

4.5.3.1 This function allows running the pump at optimal speed to save testing time with out risk of over pressure.

4.5.3.2 When pressure control is enable, the soft aware adjust pump speed to keep pressure in the Steritest unit with in acceptable range.

4.5.3.3 This function can be enable or disabled independently in both manual and automatic mode. When pressure control function is enabled the pressure-controlled indicator is displayed on the screen.

4.5.4 FOOT SWITCH -

4.5.4.1 On the configuration menu highlight “Foot Switch” function and select by pressing the knob.

4.5.4.2 The foot switch screen will displays with two modes 1) pulse: pump runs when you press the foot switch and stops when you raise your foot 2) two - way mode: pressing foot switch with your foot start the pump and again pressing stops the pump.

4.5.4.3 Confirm your selection by pressing the knob.

4.5.5 DATE /TIME -

4.5.5.1 On the configuration menu highlight “Date & Time” function and select by pressing the knob, the date and time screen displays turn the knob to select date, time and year.

4.5.5.2 Confirm the set parameter by pressing the knob.

4.5.6 NET WORK COMMUNICATON -

4.5.6.1 On the configuration menu highlight “Net Work” function and select by pressing the knob.

4.5.6.2 The network screen displays the values shown are default values and are not be to be changed.

4.5.6.3 The default values are for IP address as 192.168.0.1, sub net mask as 255.255.0.0 and the default gate way is 0.0.0.0.



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4.5.7 SYSTEM INFORMATION -

4.5.7.1 On the configuration menu highlight “Information” functions and select by pressing the knob, the ‘information’ screen displays the following information.

4.5.7.2 Steritest equinox pump serial number as Y82, Steritest equinox software version as v2.1, and date of last SOP modified or updated from the computer.

4.6 Installation and operation of Steritest equinox software

4.6.1 To install the soft ware insert the CD ROM provided with the equinox pump with soft ware version 2.1 SP1.

4.6.2 Double click the CD ROM set up.exe file to start installing the soft ware.

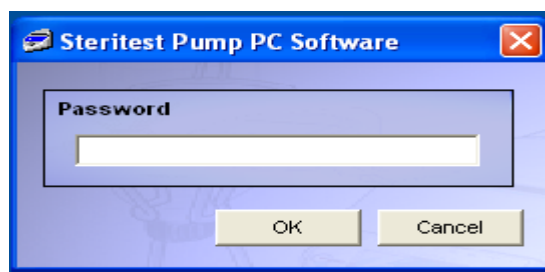
4.6.3 The install shield will configure the system and select the folder for installation of soft ware as it default directory. After selection of the folder the wizard is ready for installation. By pressing the “install” button on the screen completes the installation the soft ware. The installation is completed by pressing “finish” button in the wizard screen.

4.6.4 The Steritest system icon is displayed on the desktop.



Steritest Pump PC Software.lnk

4.6.5 Double click the Steritest pump PC icon display will show.



4.6.6 The access to the soft ware enter the default password is “Millipore”. And click OK button to enter the soft ware.

4.6.7 The main screen of the soft ware is displayed.

4.6.8 Configuration of Steritest equinox pump to the computer where the soft ware is installed.

4.6.9 Connect the computer to the power supply with RJ45 cross over cable supplied with the pump.

4.6.10 Select the network configuration by click on “my Net work places” icon and select “properties” in it.



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4.6.11 Open “local area connection” and click on “properties” button, choose “internet protocol (TCP/IP)” and click the “properties” button.

4.6.12 Define the PC IP address as 192.168..... and sub net mask as click on OK button.

4.6.13 After specifying PC network characteristic, click on the “close” button.

4.6.14 Restart the computer, so that the changes will effect.

4.7 SOP preparation

4.7.1 An SOP is characterized by its title, a comment and set of handling steps.

4.7.2 A handling step is characterized by its positioned in the SOP, its type (dilution, dissolution, prewetting, filtration, rinsing, media transfer, others), a pump speed (from 1 to 150) and a timer settings (0.5 to 999 seconds).

4.7.3 Note: a Maximum of 50 SOP’s can be stored in Steritest equinox pump.

4.7.4 Creation of new SOP.

4.7.5 To add a new SOP select “New SOP” command in the main screen of “SOP”.

4.7.6 The following window is displayed.

The screenshot shows a software window titled 'SOP'. It has a light blue background. At the top, there is a blue header bar with the text 'SOP' in white. Below the header, there are two text input fields. The first is labeled 'Title :' and the second is labeled 'Comment :'. At the bottom of the window, there are two buttons: 'Next >>' and 'Cancel'.

4.7.7 Enter the title and comment of the new SOP, entry of title is mandatory, while comment is optional. Title 12 characters and comment 40 characters with out any symbols.

4.7.8 Click “next” button on the screen to confirm entry.

4.7.9 The “handling step” window is displayed to add the first step to the new SOP.



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HANDLING STEP

Step : 1

Type : [dropdown]

Speed : [input]

Timer : 0

Comment : [input]

OK Cancel

- 4.7.10 Select step 1 and “type” as pre-wetting with speed 35 and timer off and comments as required for the step.
- 4.7.11 Select step 2 and “type” as filtration with speed 40 and timer 2 seconds and comments as required for the step. This step is very important as it is used for transferring products from the vials to the canister. This step shall be repeated for 20 or 40 times depending upon the product volume.
- 4.7.12 Select step 3 and “type” as rinsing with speed 50 and timer off and comments as required for the step. Use 3 * 100 rinse fluid A/D/K as per the requirement.
- 4.7.13 Select step 4 and “type” as media addition with speed 25 and timer off and comments as required for the step. Use 100ml of Fluid thioglycollate medium into one canister.
- 4.7.14 Note: While media transfer close one of the canister tubes with the help of clamp provided with out fail.
- 4.7.15 The canisters are closed from below with the help of yellow plugs provided prior to media addition.
- 4.7.16 Select step 5 and “type” as media addition with speed 50 and timer off and comments as required for the step. Use 100ml of Soyabean casein digest medium into another canister.
- 4.7.17 Note: After completion of the test the tubing’s are cut with sterile scissors after clamping near the canister body.
- 4.7.18 After clamping & cutting the canisters are ready for incubation.
- 4.7.19 After completion of the above 5 steps to the list of Work file in the computer, This SOP is now ready for transferring to the equinox pump.
- 4.7.20 During the transfer of the SOP to the Equinox pump the pump is in off mode and the power box where the cable is connected is on.



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4.7.21 Select “Connect...” command in the main screen of “Steritest” menu.

4.7.22 Click “OK” to initialize the connection of the computer to the pump.

4.7.23 Select the “Synchronization” command in the main screen of the menu.

4.7.24 Click on “yes” to accept the synchronization. A message “Successful transfer” appears.

4.7.25 Click “OK” to close the transfer of SOP.

4.7.26 All the SOP’s in the “work file” column are transferred to the Steritest equinox pump.

4.7.27 The SOP appears in green color in the work file of the compute and also in the SOP list of the pump screen in automatic mode.

4.7.28 After completion of filtration incubate the Soyabean casein digest medium canister at 30-35 ° C and Fluid thioglycollate medium canister at 20-25 ° C for 14 days.

4.8 Cleaning

4.8.1 Clean the outer surface of equinox system with the help of lint free cloth dipped in 70 % IPA or any other disinfectant solution.

4.8.2 Autoclave the drain tubing before use.

4.8.3 Autoclave the autoclavable parts of the equinox system.

5.0 SAFETY & PRECAUTIONS:

5.1 Incase of not using instrument, switch off the instrument and switch of the main power supply.

5.2 Before transferring SOP from computer to pump always switch off the pump.

6.0 REVISION HISTORY:

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

7.0 REFERENCES

Not applicable.



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8.0 ABBREVIATIONS:

SOP	:	Standard Operating Procedure
IPA	:	Iso Propyl Alcohol
°C	:	Degree Centigrade
%	:	Percentage
CD	:	Compact Disc

9.0 ANNEXURES:

Not applicable.