



PHARMA DEVILS
MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Microbiology	SOP No.:
Title: Operation of Dry Heat Sterilizer (DHS)	Effective Date:
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1.0 OBJECTIVE

1.1 To lay down the Procedure for operation of dry heat sterilizer (DHS).

2.0 SCOPE

2.1 This procedure is applicable for Microbiology Laboratory and Quality Control Department.

3.0 RESPONSIBILITY

3.1 Microbiologist/Lab-attendant is responsible for operation of dry heat sterilizer (DHS).

3.2 Lab-attendant is responsible for cleaning of dry heat sterilizer (DHS).

4.0 ACCOUNATABILITY

4.1 Head Microbiology

5.0 EHS CONSIDERATIONS

5.1 Do not open the door when temperature is high.

5.2 While loading the article, make arrangement of material for proper spacing in between articles.

6.0 PROCEDURE

6.1 Equipment Details:

6.1.1 Make: Newtronics

6.1.2 Model No.:

6.1.3 Serial No.:

6.2 Operation of Controller

6.2.1 As main supply is switched on, the controller display will show following window.






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- 6.2.2 Switch “ON” the mains switch of the equipment placed on the control panel of the equipment.
- 6.2.3 The equipment temperature ranges from 50°C – 250°C, so adjust the desired temperature by temperature controller required for dry heat sterilization.
- 6.2.4 To set the temperature use arrow keys.
- 6.2.5 The alarm limits are set to $\pm 5^\circ\text{C}$ deviation than set temperature. If the temperature is deviated more than alarm limit than the lower display of controller will show alarm message as “LOW TEMPERATURE” for low temperature alarm and “HIGH TEMPERATURE” for high temperature alarm.
- 6.2.6 To change any parameters press Scroll key and following parameters can be changed as per table.
- 6.2.7 Press Scroll  button to step through the list of parameters. The mnemonic of the parameter is shown in the lower display. After 5 seconds a scrolling text description of parameter appears.
- 6.2.8 The value of parameter is shown in the upper display.  
- 6.2.9 Press or to adjust this value. If no key is pressed for 30 seconds the controller returns to the HOME display.
- 6.2.10 The following parameters are available.



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Parameter Mnemonic	Scrolling Text and Description	Range
SP1	SET POINT1 Set point1 value (Working set point)	50°C to 280°C
A1.DHI	ALARM 1 SET POINT Set the threshold value at which an alarm occurs. Here it is a deviation high alarm. By default it is set to 5.0°C. When the measured temperature is higher than set point by deviation high alarm; a high temperature alarm will be generated and “ HIGH TEMP ” message will be displayed in the lower display.	50°C to 280°C
A2.DLO	ALARM 2 SET POINT Set the threshold value at which an alarm occurs. Here it is a deviation low alarm. By default it is set to 3.0°C. When the measured temperature is lower than set point by deviation low alarm; a low temperature alarm will be generated and “ LOW TEMP ” message will be displayed in the lower display. Note: This alarm will not be activated on Power ON. It will be activated once the oven has achieved the set temperature and then deviated.	50°C to 280°C
DWELL	SET TIME DURATION – Sets the dwell timing period. It can be adjusted while the timer is running.	00:00 to 99:59 hh : mm
END.T	TIMER END TYPE This determines the behaviour of the timer when it has timed out. This value can be changed while the timer is running.	OFF Control OP goes to zero. Controller Off dwEll Controlling continues at SP1 even after timer is Over SP2 Go to SP2 rES Reset Programmer
T.STAT	TIMER STATUS It is the current status of the timer: Run, Hold, Reset or End. It only appears when a timer is configured.	rES Reset timer run Run /Activate timer hoLd Hold timer End Timed out
WRK.OP	WORKING OUTPUT Is the output from the controller to control temperature.	Read only value 0 to 100%

6.2.11 For advance parameters such as Timer status, timer start threshold, Auto tune, PID values and Home display; go to level 2 with access password. For this refer manual.



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6.3 Printer Interface

6.3.1 The printer interface (PI) collects data from the temperature controller via a serial link. It stores data in its memory as per recording interval. The data can be printed on a dot matrix (DOS base) printer by giving print command.

6.3.2 By pressing SET key the interface will ask for pass code. Enter the default code 0 and press ENT key, the PI will return to default window. On entering correct pass code the PI will show next parameter by pressing SET key. For wrong pass code entry it will ask for pass code.



6.3.3 On entering correct pass code user can access parameters which are displayed in the lower display. To change any parameter press ENT key or press SET key for next parameter.

6.3.4 To print data on printer press ENT key on this display. Data will be printed on printer and following display will be shown. Once the printing is complete it will return to default window.



6.3.5 After printing data to erase memory press ENT key on this page, the memory will be erased and default window will be displayed.



6.4 Loading and Unloading of Samples in DHS

6.4.1 Unlatch the door of the DHS, locate the place to keep/remove the sample and load/unload the samples and close the door.

6.4.2 Make sure that the door is properly latched, otherwise temperature will leak and accuracy will not be maintained.

6.4.3 During sample placement while loading or unloading, the following should be observed:

6.4.4 Sample has to stay in the confined area of tray.

6.4.5 Free space on the side of the trays should not be blocked by the sample.



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- 6.4.6 Air circulation holes should not be blocked.
- 6.4.7 Sensor should not be covered with samples.
- 6.4.8 Affix the chemical indicators on the articles to be sterilized or dehydrogenated.
- 6.5 After attaining the desired temperature, keep the DHS control required holding time 120 min at 170°C for sterilization of glassware and 60 minute at 250°C for Depyrogenation.
- 6.6 After completion of the holding time, reduce the temperature of the DHS to room temperature and allow Dry Heat Sterilizer chamber to cool.
- 6.7 Confirm the chamber cooled to 60°C as needed before opening the door.
- 6.8 After completion of cycle unload the glassware in a clean SS tray for further use.
- 6.9 Close the door.
- 6.10 Record the cycle in Dry Heat Sterilizer usage Record as per abbreviation DHS/YY/XXXX, where DHS=Dry heat sterilization, YY=financial year, XXXX=sequential number i.e. DHS/14/0001.
- 6.11 For load patterns, please refer Annexure II.
- 6.12 For drying purpose of glassware and other article, DHS must be operated at 60°C. There is not any fixed load pattern but make arrangement of material for proper spacing in between articles while loading the articles for drying.
- 6.13 **Cleaning of DHS**
- 6.13.1 Turn OFF the equipment and wait till it attain room temperature (20-25°C) temperature.
- 6.13.2 A routine cleaning of the DHS should be done by swabbing the trays and walls of the equipment with 70% IPA and after purified water.
- 6.14 Calibration of DHS inbuilt temperature sensors will be done annually.

7.0 DEFINITIONS AND ABBREVIATIONS

- 7.1 Dry Heat Sterilization: Method of sterilization that uses heated dry air at a temperature of 160° to 180° C for 90 minutes to 3 hours.
- 7.2 Depyrogenation: Method of removal of pyrogens that uses heated dry air at a temperature of 225° to 250° C for 60 minutes to 2 hours.
- 7.3 SS - Stainless steel



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7.4 IPA – Isopropyl Alcohol

8.0 REFERENCE

8.1 User manual no. 1.1 from Newtronics.

9.0 ANNEXURES

9.1 Annexure I : Dry Heat Sterilizer Usage Record

9.2 Annexure II : Load Patterns of Dry Heat Sterilizer

10.0 DISTRIBUTION DETAILS

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

11.0 REVISION HISTORY

Supersedes SOP No.	Change Control No.	Reason for revision



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ANNEXURE II LOAD PATTERN FOR DRY HEAT STERILIZER

LOAD No. 01: Maximum load pattern for petriplates sterilizing at 170°C for 120 minute hold time.



Load Details:

1. Empty petriplates -300 nos.



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LOAD No. 02: Minimum load pattern for petriplates sterilizing at 170°C for 120 minute hold time.



Load Details:

1. Empty petriplates -135 nos.



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LOAD No. 03: Maximum load pattern for glassware Depyrogenation at 250°C for 60 minute hold time.



Load Details:

1. Test tube 16 mm X 100 mm - 100 nos.
2. Test tube 10 mm X 75 mm - 100 nos.
3. Conical flask 100 ml - 16 nos.



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LOAD No. 04: Minimum load pattern for glassware Depyrogenation at 250°C for 60 minute hold time.



Load Details:

1. Test tube 16 mm X 100 mm- 50 nos.
2. Test tube 10 mm X 75 mm- 50 nos.
3. Conical flask 100 ml- 06 nos.