



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Operation and Cleaning of Rapid Cooling Steam Sterilizer	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Rapid cooling steam sterilizer.

### 2.0 SCOPE:

This SOP is applicable for Operation and cleaning of Rapid cooling steam sterilizer (**Make:** Machine Fabrik) at .....

### 3.0 RESPONSIBILITY:

Officer/Executive – Production

### 4.0 ACCOUNTABILITY:

Head – Production.

### 5.0 DEFINITION:

**5.1 Cleaning-** Cleaning is the process of removing unwanted substances, such as dirt, infectious agents and other impurities, from an object or environment.

### 6.0 PROCEDURE:

**6.1** Before start operating, check the cleaning of the machine.

**6.2** Before starting the machine check the utility services and ensure the availability of the same as per the Table below.

<b>Electricity</b>	<b>Power :</b> 415 V-3 PH-50 Hz AC, 4 Wire Supply <b>Control :</b> 230 V-1 PH-50 Hz Stabilize AC Supply
<b>Pure steam for jacket/chamber (Dry &amp; Saturated )</b>	<b>Pressure:</b> 1.5 – 2.5 kg/cm <sup>2</sup>
<b>Purified Water</b>	<b>Pressure:</b> 1.5 -2.5 kg/cm <sup>2</sup>
<b>Process Air (Fluidization) Oil Free</b>	<b>Pressure:</b> 5- 7 kg/cm <sup>2</sup>
<b>Compressed Air Lubricated (Dry &amp; Saturated)</b>	<b>Pressure:</b> 5 – 7 kg/cm <sup>2</sup>
<b>Soft Water For vacuum System</b>	<b>Pressure:</b> 1.5-2.5 Kg/cm <sup>2</sup>



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6.3 Switch "ON" the main, power supply.



6.4 Switch "ON" the control button of HMI.



6.5 After the HMI ON following display appear.

6.6 Press the main menu.

6.7 Main menu contains following options.

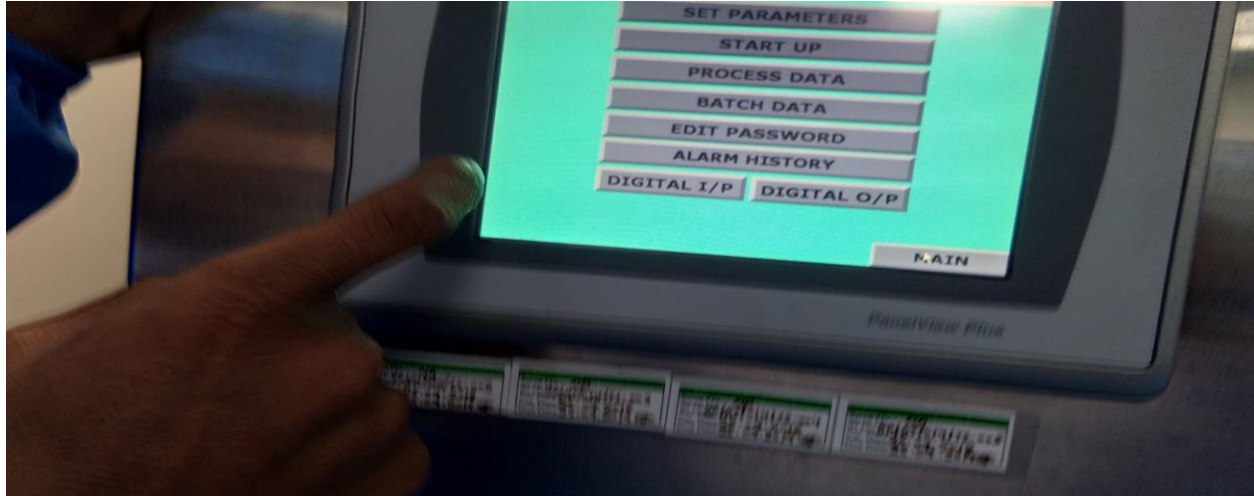


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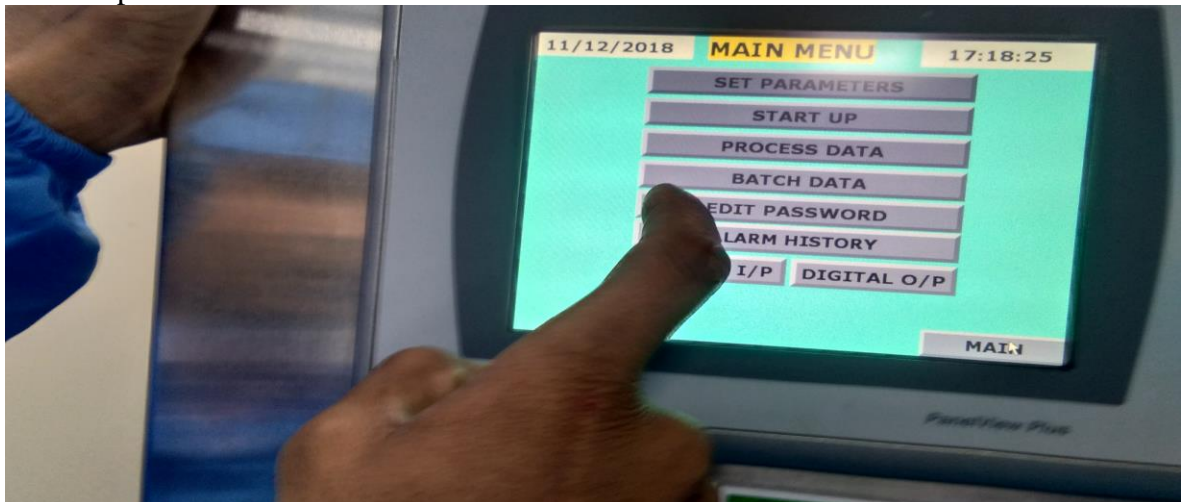
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6.8 Select the edit password on screen.



6.9 Current user display on screen.

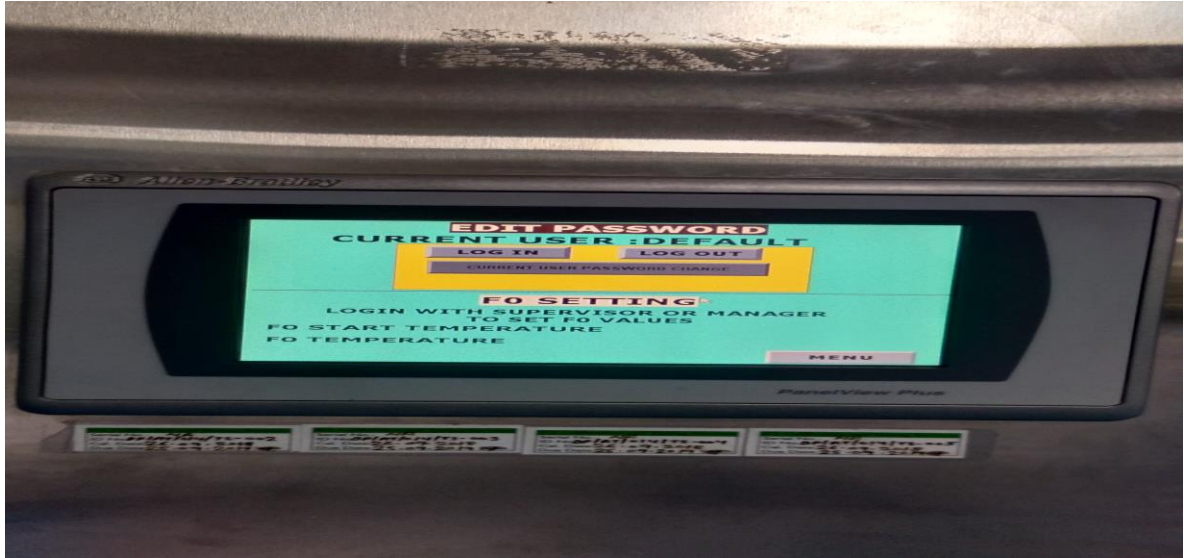


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**6.10** Press login and enter the user name and password.



**6.11** Press main menu

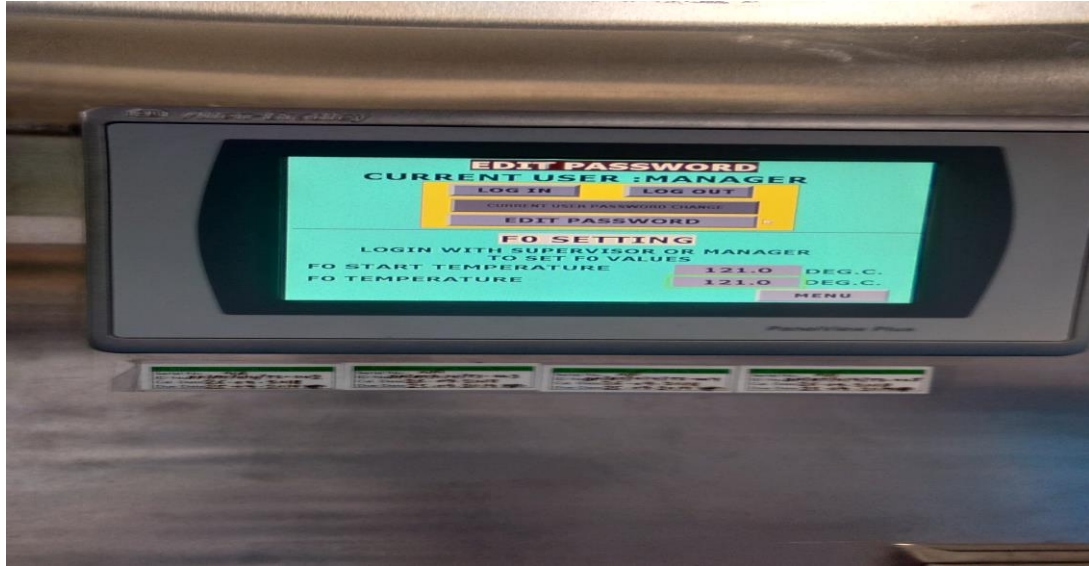


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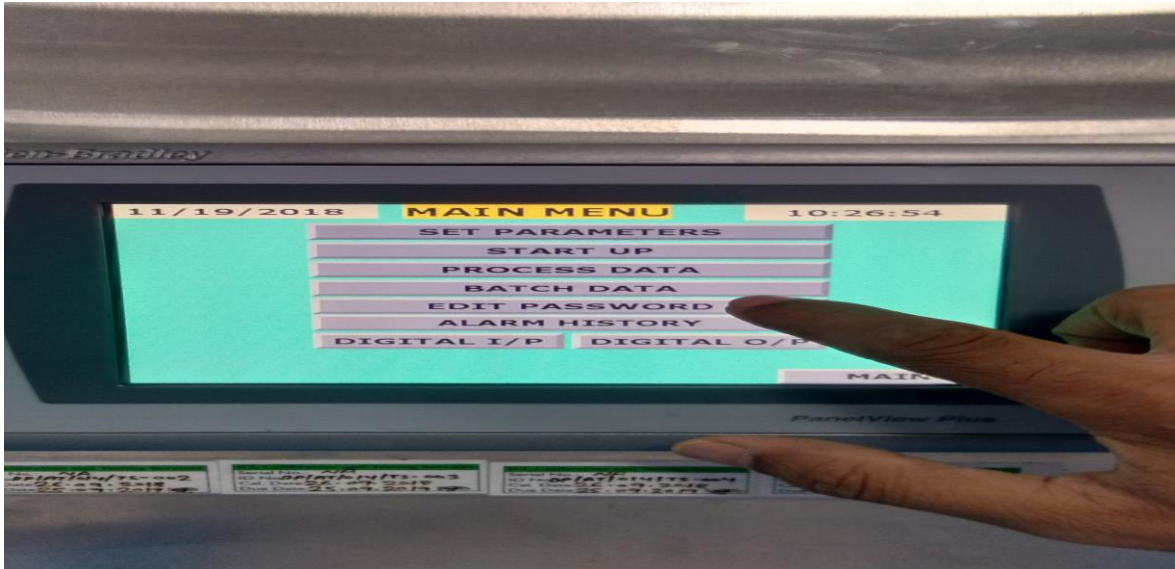
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6.12 Press the button of batch Data.



6.13 Enter the batch data details.

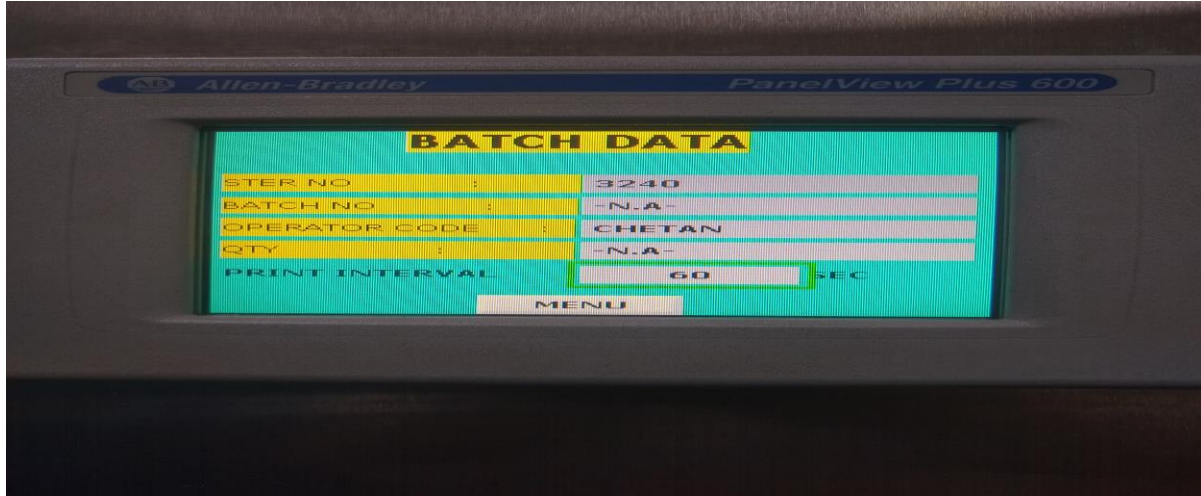


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6.14 Press startup for start respective cycles.



6.15 Press the select button for cycles.

1. VLT
2. Warm-up cycle
3. Standard process
4. Bowie dick test
5. HPHV Process
6. Filter SIP.
7. Ampoule Leak Test.
8. Ampoule Washing.
9. Hot Leak Test.
10. Rapid cooling.



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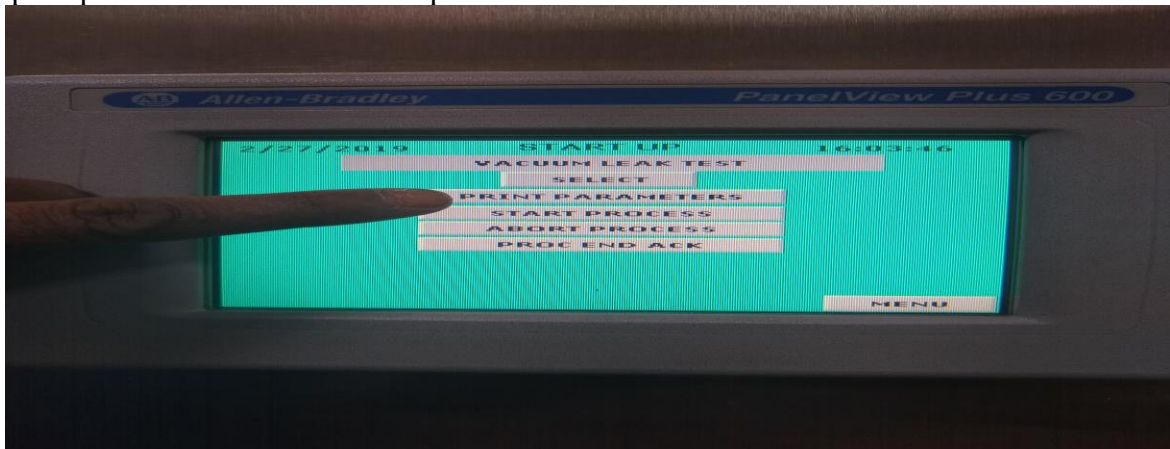
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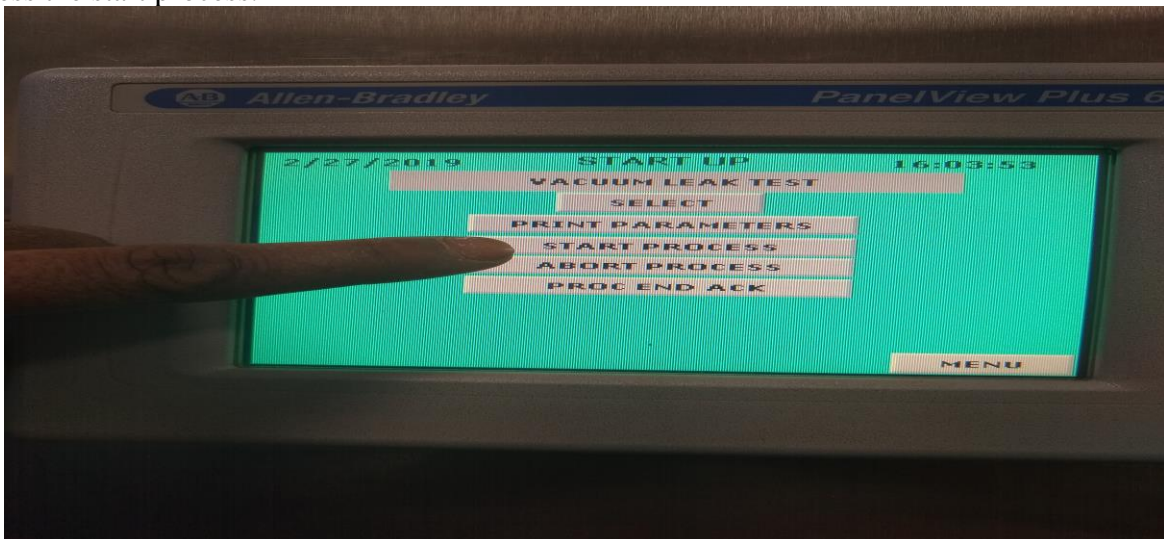
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6.16 Push print parameter to command the print



6.17 Press the start process.





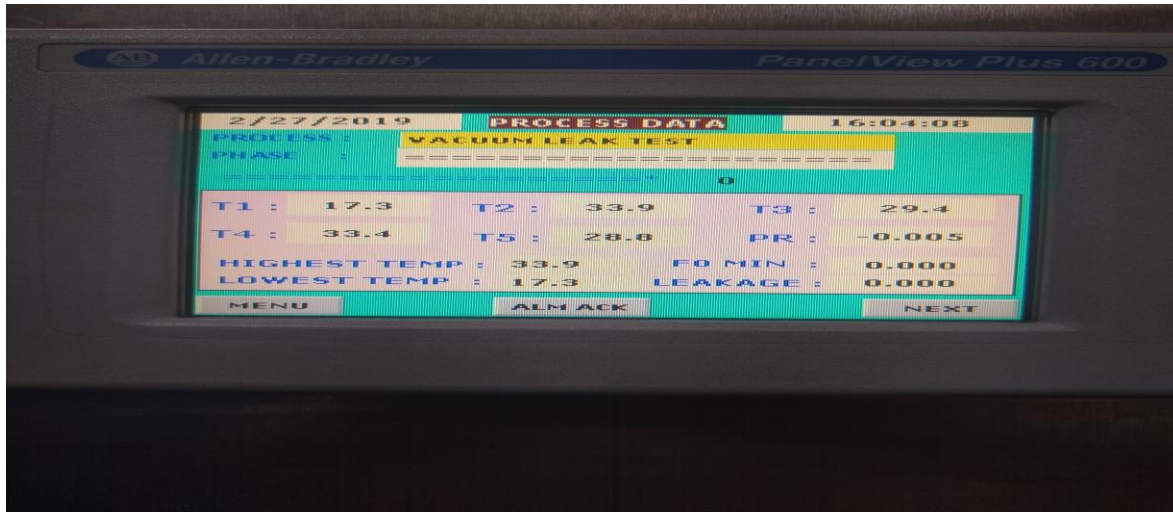
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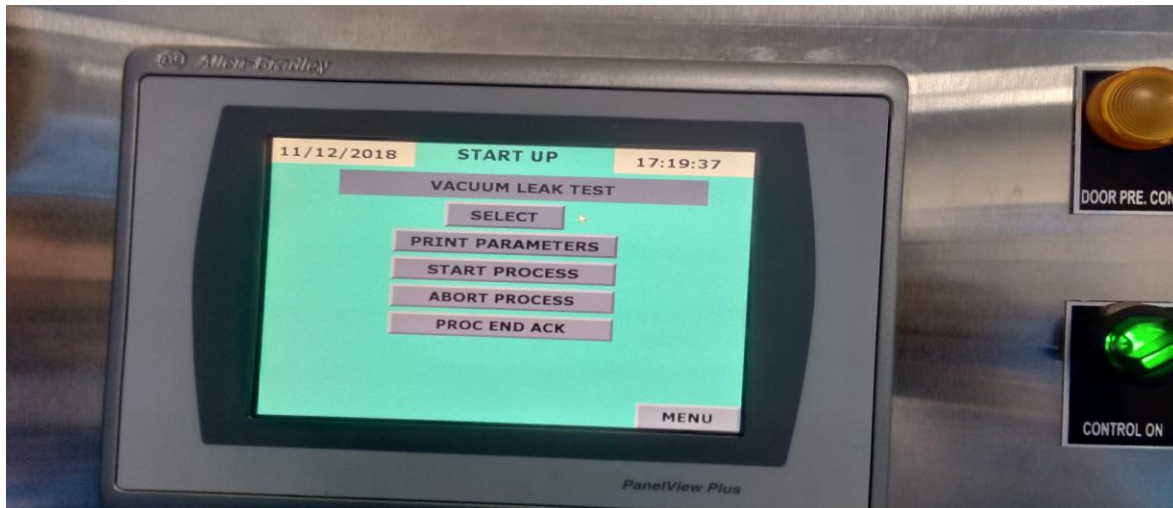
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### 6.18 HMI Display The Process Data.



### 6.19 After completion of cycle process end display on screen



### 6.20 Press process end Ack.



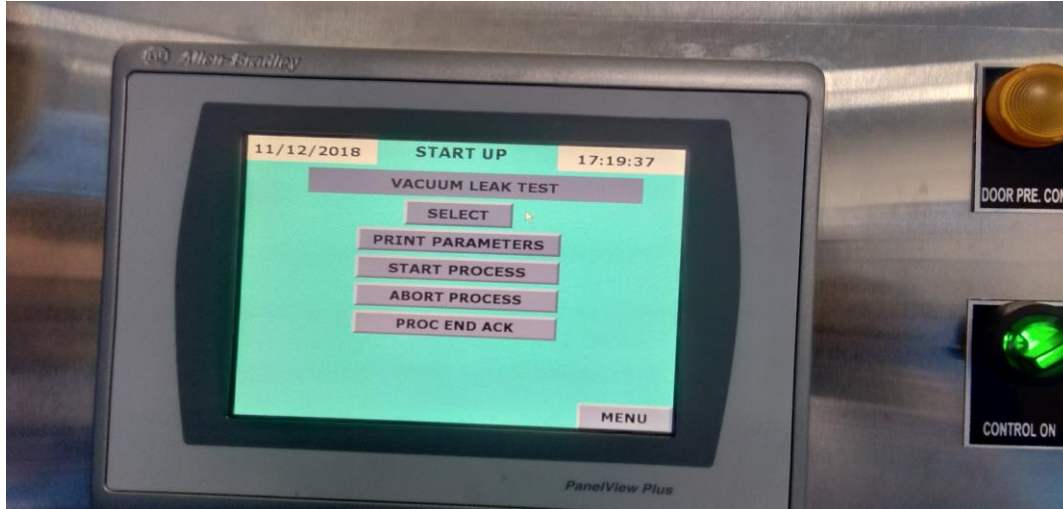


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- 6.21 The selected process will run according to the process parameters saved in the system. If power supply discontinued during run, process will be stopped. After power resume the system will start automatically and the process will resume.
- 6.22 After completion of the cycle the “ALARM” will blink and the buzzer will start.
- 6.23 Manually open the door from sterile side and unload the sterile articles.
- 6.24 Rapid cooling steam sterilizer can also be operated through “Manual Mode” in case of any break down of PLC.
- 6.25 “Manual Mode” operation can be executed by operating all the utility services manually, switch provided on the panel.
- 6.26 For manual mode operation all the pre operation checks are as same as auto mode operation.
- 6.27 During manual mode operation thermograph recorder and temperature display will be functioning but HMI, temperature recorder and printer will not work.
- 6.28 Temperature and pressure at different time interval shall be recoded manually by viewing readings displayed on the temperature display and pressure gauges.
- 6.29 Schematic representation of the device to operate the equipment manually is as under.



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**6.30** In case of acute emergency, press “**EMERGENCY**” button. The cycle will stop where it is. To start the machine again follows the same process stated from point number 6.1 onwards. “**EMERGENCY**” button should be used only in case of high degree of emergency needs such as saving human lives, fire, electrical short circuit, accident etc.

### **6.31 CLEANING OF RAPID COOLING STEAM STERILIZER:**

**6.31.1** Wipe off outside body of the Rapid Cooling Steam sterilizer with mopping pad.

**6.31.2** Wipe off all the pipe connections.

**6.31.3** Take out drain cover screen; Scrub it thoroughly using nylon brush and 0.2% SLS (Sodium Lauryl Sulphate) Solution Wash it with water thoroughly.

**6.31.4** Clean the chamber and door with 0.2% SLS solution using mopping pad, hot water and Nylon Brush. Wash thoroughly with Purified Water followed by final rinse with WFI.

**6.31.5** Wash the trolleys and shelves with 0.2% SLS solution and then with Purified water. Finally rinse it with WFI.

**6.31.6** For Cleaning of Detergent and Silicon reservoir, Remove the detergent and silicone reservoir from the bung processor by removing the TC clamp Scrub it thoroughly using nylon brush and 0.2% SLS Solution and finally rinse it with sufficient quantity of water for injection.

**6.31.7** Record cleaning details in **Rapid Cooling Steam Sterilizer Operation & Cleaning Log Book.**

### **6.32 CLEANING FREQUENCY:**

**6.32.1** After product change over and once in a day in case of equipment not in use.



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**6.32.2** Detergent and silicon reservoir shall be cleaned fortnightly.

**6.33** Record the Operation details of Vacuum Leak Test of Autoclave cum Bung Processor in the **Annexure-I**, Titled “**Rapid Cooling Steam Sterilizer Operation & Cleaning Log Book**”.

**6.34** Record the Operation details of Bowie Dick test in Annexure I.

### 7.0 ABBREVIATIONS:

SOP	Standard Operating Procedure
QA	Quality Assurance
No.	Number
Ltd.	Limited
WFI	Water for Injection
ID No.	Identification Number
Kg	Kilogram
cm	Centimeter
WFI	Water for Injection
SLS	Sodium Lauryl Sulphate
Sec.	Second
Min.	Minutes
°C	Degree Celsius
HPHV	High Pressure High Vacuum
PLC	Programmable Logic Controller

### 8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Rapid cooling Steam sterilizer Operation & Cleaning Log Book	



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### 9.0 DISTRIBUTION:

- Controlled Copy No. 01                      Production Department
- Master Copy                                      Quality Assurance Department

### 10.0 REFERENCE:

In House

### 11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

