



STANDARD OPERATING PROCEDURE

Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	1 of 10	

1.0 OBJECTIVE:

To lay down a procedure for external Cleaning and Operation of Blow, Fill & Seal Machine.

2.0 SCOPE:

This SOP is applicable for Cleaning and Operation of Blow, Fill & Seal Machine (Make: **Weiler engineering** Model: **603**) at Production Area of Large Volume Parenteral Line.

3.0 RESPONSIBILITY:

Officer/Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BFS	Blow-Fill & Seal
HEPA	High Efficiency Particulate Air
LAF	Laminar Air Flow
LDPE	Low Density Polyethylene
Ltd.	Limited
M/C	Machine
No.	Number
Pvt	Private
QA	Quality Assurance
QC	Quality Control
Sec	Second
Sign	Signature
SOP	Standard Operating Procedure
WFI	Water for Injection

6.0 PROCEDURE:

6.1 CHECK & PRECAUTION:

6.1.1 Turn on the Chiller from utility (if the same is not running) and open chilled water inlet and outlet valves.

6.1.2 Ensure that chilled water supply is available within 3- 4 kg/cm²at user point.

6.1.3 Open Chilled Water Valve for mold cooling.

6.1.4 Ensure that compress air supply is available within limit of 6- 8 kg/cm².



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	2 of 10

- 6.1.5 Clean the all residues from mold alignment pins and bushings (Main Mold and Seal Molds) and apply film of Petro gel to guide pins / keys.
- 6.1.6 Check the level of Hydraulic oil tank.
- 6.1.7 Turn on the vacuum pump. Checked vacuum pump pressure gauge within limit (450 to 700) mm/hg.
- 6.1.8 Check the filling nozzle diaphragm of each nozzle in **quarterly or when required** & changes the diaphragm if required.
- 6.1.9 Checks the exhaust valve diaphragms in **quarterly or when required** & change the diaphragm if required.

6.2 EXTERNAL CLEANING OF BFS MACHINE:

- 6.2.1 Perform the Machine Cleaning and Sanitization when there is no production activity and whenever required.
- 6.2.2 First of all clean the area which is near to filling zone, after that other part of filling machine.
- 6.2.3 Start cleaning first inner side with Lint free mop with 70% IPA v/v.
- 6.2.4 Clean all outer surfaces with Lint free mop with 70% IPA.

6.3 START OPERATION:

- 6.3.1 Turn on the Main Power switch of the BFS Machine.



- 6.3.2 Main screen display shows than start other activity to machine.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	3 of 10



6.3.3 Turn on the Master Control ON from the Operator Panel.



6.3.4 Put the necessary details like user name and password & login.

6.3.5 Door interlocking system disable for guard open and manual operating system.



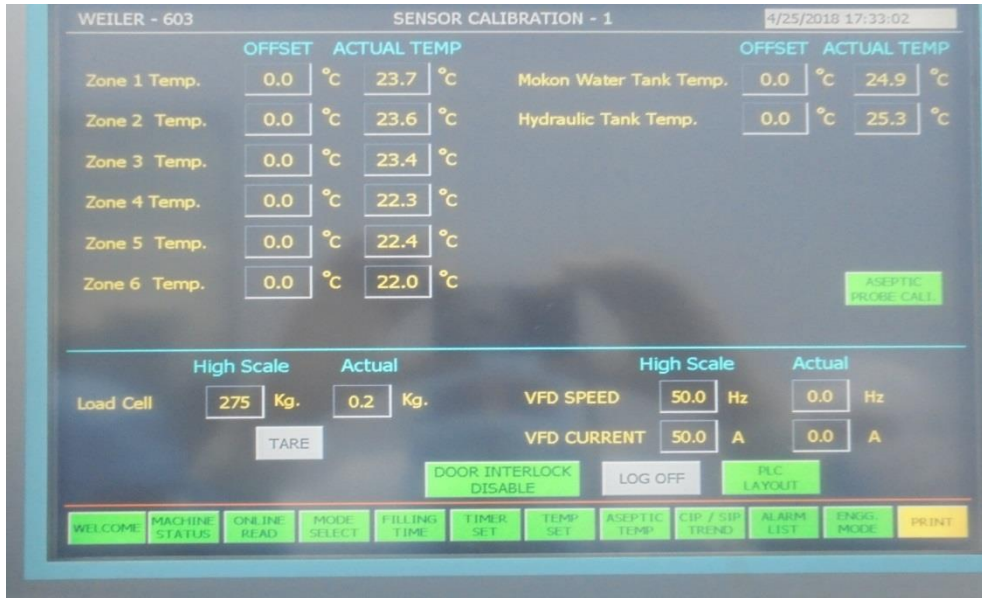
PHARMA DEVILS

PRODUCTION DEPARTMENT

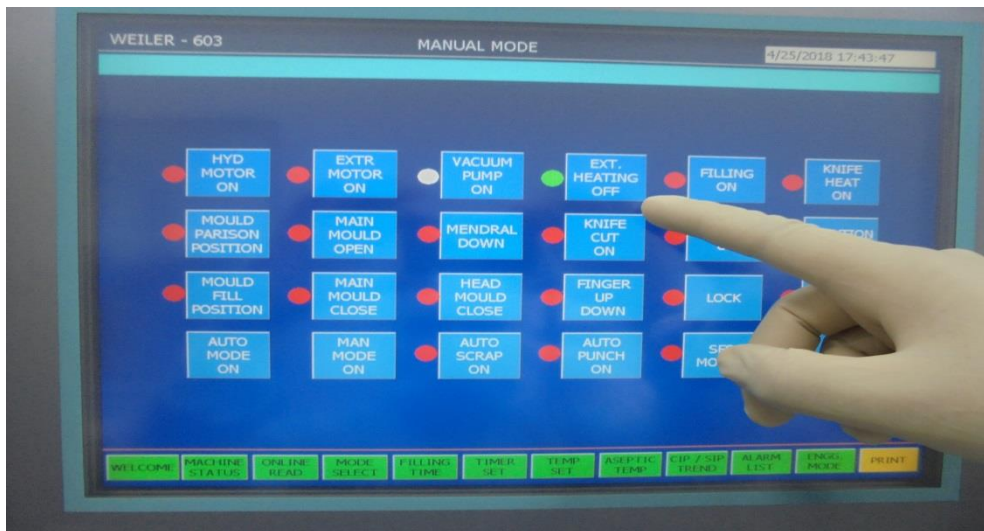
STANDARD OPERATING PROCEDURE

Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	4 of 10



6.3.6 Turn on the Heaters from the Operator Panel & wait till Extruder heat up to Stand by Temperature.



6.3.7 Turn on the Knife heating from the Operator Panel.



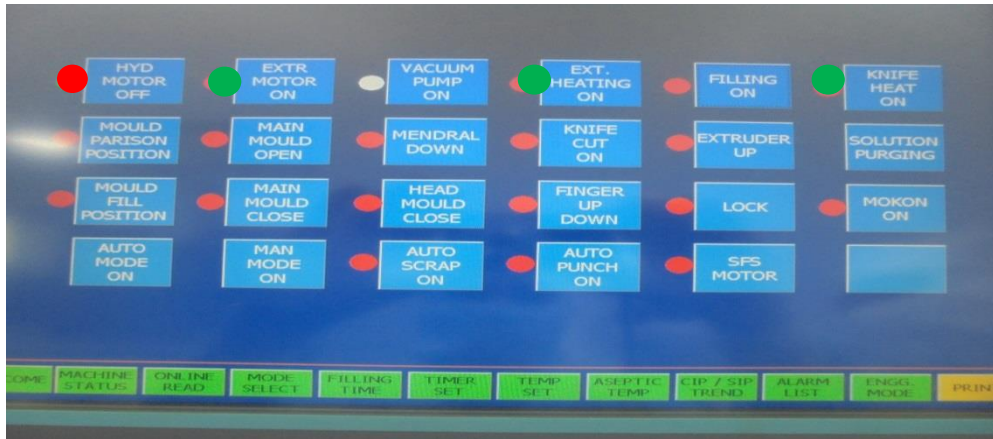
PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

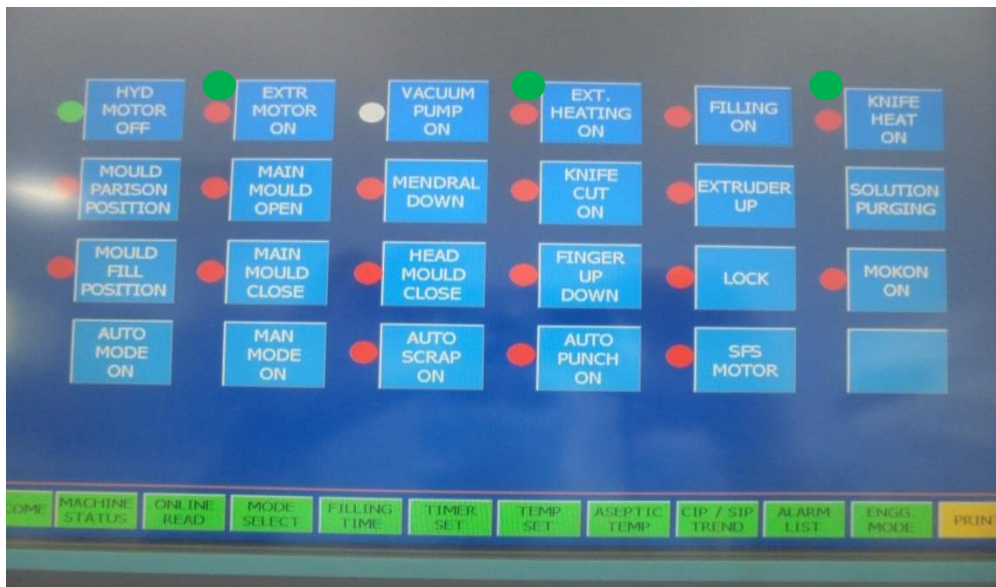
Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	5 of 10



6.3.8 Turn on the Blower for Positive Air Pressure of HEPA in filling area of the machine.

6.3.9 Turn on the Hydraulic Pump from the Operator Panel.



6.3.10 Turn on the Vacuum Pump from electric panel.

6.3.11 Ensure that extruder heating is achieved up to set parameter, and heating temp. is stable.

6.3.12 Switch is on the Auto Mode.



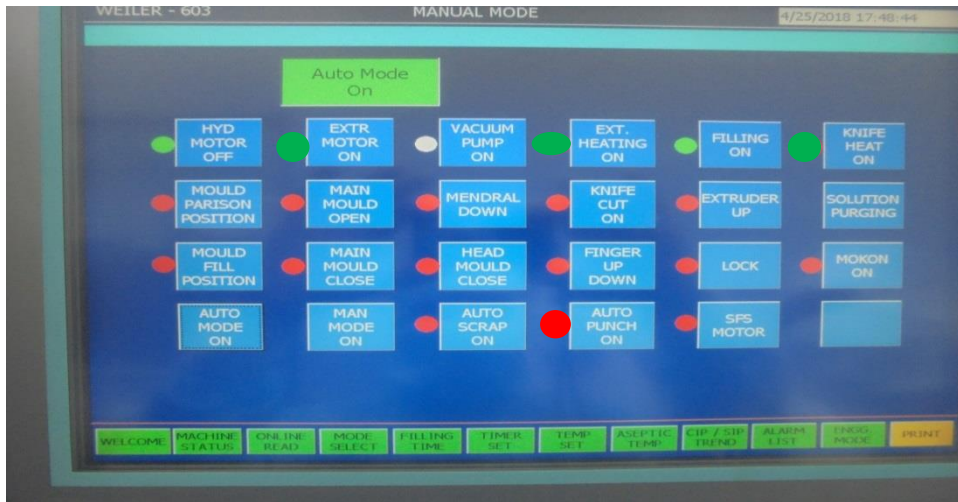
PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	6 of 10



6.3.13 Open the Valve to Transfer Solution from Holding Tank to Buffer Tank of Machine.

6.3.14 Check the Weight of Solution of Buffer Tank at Operator Screen.



6.3.15 Ensure that the extruder heating is within limit, and heating achieved in all sensor. Confirm granule storage tank is filled upto the desired level.

6.3.16 Turn the Extruder ON Button & Knife ON push button from the Operator Panel.

6.3.17 Ensure that granule storage tank is filled with LDPE granule.

6.3.18 Start the Bottle and scrap conveyor belt.



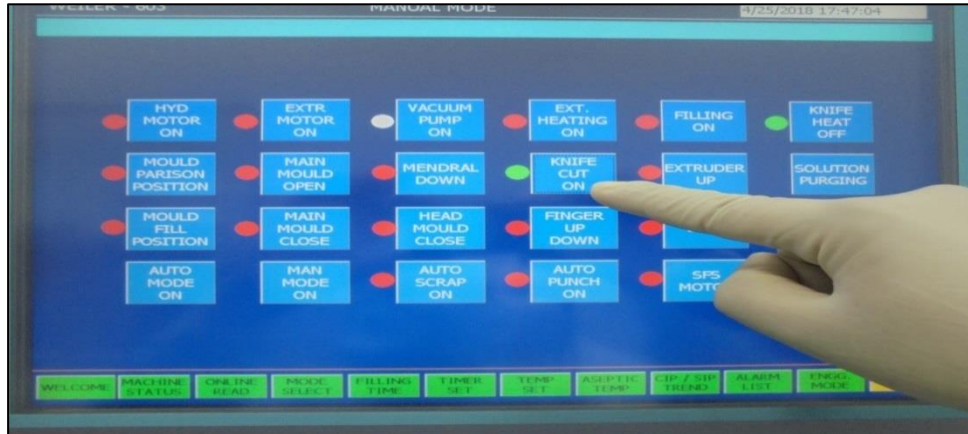
PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	7 of 10



- 6.3.19 After the Parison get straight and equal in length and checked then start the machine by pressing the Cycle Start push Buttons from the Operator Control panel.
- 6.3.20 Check the bottle code embossed on bottle if not proper rectifies the Product code.
- 6.3.21 After the Parison get straight and equal in length and checked then start the machine by pressing the Cycle Start push Buttons from the Operator Control Panel.
- 6.3.22 Visually checks if any extra plastic comes on bottle rectify the problem.
- 6.3.23 Check the empty weight of bottle & if not within limit rectify the Empty Weight of bottles.
- 6.3.24 Push the second cycle start button for filling.



- 6.3.25 Discard initially filled five cycle Bottles, Check for volume with 6th filled cycle & if volume is not within limit adjust the volume & proceed for further filling.

6.4 STOP OPERATION (FOR STOPPING PRODUCTION CYCLE):

- 6.4.1 Press the cycle stops button from the push button panel or machine automatically filling stop at buffer tank level low.
- 6.4.2 Once the cycle gets completed and press the machine stops, Turn the hydraulic off from the push button panel.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	8 of 10	

- 6.4.3 Turn the Extruder off from the Push Button Panel.
- 6.4.4 Turn Off the Vacuum pump from Electric Panel.
- 6.4.5 Turn off the Heaters from the Push Button Control Panel.
- 6.4.6 Turn the hot Knife off from Push Button Control Panel.
- 6.4.7 Clear the Bottles from Mold & Machine area.
- 6.4.8 Turn off all the utilities and conveyor belt.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Monitoring of Filling Nozzle Diaphragm	
Annexure-II	Monitoring of Exhaust Valve Diaphragm	

ENCLOSURES: SOP Training Record.

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: External Cleaning and Operation of Blow, Fill & Seal Machine

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	9 of 10	

ANNEXURE – I MONITORING OF FILLING NOZZLE DIAPHRAGM

Date:

Block:

Frequency:

Nozzle No.	Diaphragm Status OK/Not OK	Diaphragm Replacement Date	Done By Sign & Date	Checked By Sign & Date	Verified By Sign & Date	Remarks
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						

