PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Cleaning and Operation of Induction Cap Sealer Machine	**Effective Date:**
Supersedes: Nil	**Review Date:**
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Induction Cap Sealer Machine.

2.0 SCOPE:

2.1 This SOP is applicable for Cleaning and Operation of Induction Cap Sealer Machine in production.

3.0 RESPONSIBILITY:

3.1 Technical Associate : Operation and cleaning

3.2 Officer and Executive : Verification for cleaning and operation

3.3 Officer and Executive IPQA: Line clearance and SOP Compliance

3.4 Head Production : SOP Compliance

4.0 DEFINITION (S):

4.1 Done By- The activity performed by the Person

4.2 Verified By- Evidence that establish or confirm the accuracy or truth of activity

5.0 PROCEDURE:

5.1 **Cleaning procedure for batch to batch or product to product changeover.**

5.1.1 Ensure that all the materials of previous batch are removed.

5.2 Remove “EQUIPMENT STATUS” label and affix ‘UNDER CLEANING’ label on the machine with date and sign of the production officer.

5.2.1 Switch ‘‘OFF’’ the electric supply before start the cleaning activity of machine.

5.2.2 Clean the operator panel, cooling vents, sealing coil and all the outer surface of machine with dry lint free cloth.

5.2.3 If any sticky material available on sealing coil, rejection swipe arm and conveyor belt wipe with lint free cloth moisten with 70% v/v IPA solution.

5.2.4 Replace the ‘UNDER CLEANING’ status label by “CLEANED” status label on the machine with date and sign of the production officer.

5.2.5 Record the cleaning activity in equipment usage log as per SOP (“Making entries in equipment usage and cleaning log sheet”).

5.2.6 If machine is ideal for more than 72 hrs. Then clean the machine with lint free cloth dipped in 70% v/v IPA solution.

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5.2.7 **General Machine ''SET UP''**

5.2.8 **Setting of "INDUCTION SEALELER HEAD''**

Height of induction sealing head is adjusted by its vertical movement upon the given slide by rotating given knob in clockwise or anti clockwise direction. Check for paralleled sealing head with respect to the conveyor by placing two bottles at each end of induction sealer head. Adjust the height of sealing head as per bottle size and maintain gap between bottle tip and induction sealer head as per BPR.

5.2.9 **Setting of ''BOTTLE UNDER INDUCTION PLATE''**

For better induction, bottle shall be exposed to maximum electromagnetic field generated under induction plate. The bottle must travel in straight line and middle region of the induction head. Speed of conveyor belt shall be set as per BPR.

5.2.10 **Setting of ED-vantage system sensors**

5.2.11 **Setting for No foil Sensor:**

5.2.11.1 Place a properly tighten bottle with cap (with foil) under the 'No foil sensor'.

5.2.11.2 Adjust the 'No foil sensor' so that it is in center of the bottle.

5.2.11.3 Adjust the height of the 'No foil sensor' so that the LED indicator on the sensor glows.

5.2.11.4 Adjust the position of 'bottle present sensor' that when a bottle without foil pass under the 'no foil sensor' it to be reject by the rejection system and fall into rejection box.

5.2.12 **Setting of Fallen bottle sensor:**

5.2.12.1 Place a bottle on conveyor belt.

5.2.12.2 Set a ray light emitted by sensor on bottle neck.

5.2.12.3 Now pass a fallen bottled on conveyor belt.

5.2.12.4 Fallen bottle must be rejected by pusher and fall into rejection box.

5.2.13 **Setting of Cross cap Sensor:**

5.2.13.1 Take a bottle with properly tight closure on it.

5.2.13.2 Place bottle on conveyor belt and set the 'cross cap sensor' that it emit the ray of light just above the upper surface of closure.

5.2.13.3 When a cross capped bottle pass through the sensor it rejected by rejection system and it fall into rejection box.

5.2.14 **Setting of Burn seal sensor:**

5.2.14.1 Set the height of thermo Sensor according to the height of bottle.

5.2.14.2 Press the push reset button twice then red indicator will glow and yellow indicator will blink.

5.2.14.3 Now seal the bottle by setting the induction power as per limit given in BPR and check for normal seal of bottle and pass the sealed bottle again below the sealing coil and stop the conveyor belt and place the bottle below the IR sensor.

5.2.14.4 Then teach the sensor by pressing the push reset button for single time.

5.2.14.5 So green indicator will glow which indicates that machine is ready to work.

5.3 **Settings and operation of Induction sealer machine (Make: SIGMA JR)**

5.4 **Setting of ''SEALING TIME''**

It can be set by given (▲) increment or (▼) decrement push button on PLC. Sealing time limit shall be 2-3 sec.

5.5 **OPERATION**

5.5.1 Connect the machine to power. Switch "ON" the induction cap sealer machine.

5.5.2 After few time GREEN indicator will confirm that "Induction Is Ready"

5.5.3 Adjust the bottle into circle given on platform and set bottle guide surrounding circumference of circle.

5.5.4 Push the button OR press the paddle to start sealing "ON".

5.5.5 While sealing is going on for specified time a RED indictor will remain ''ON'' and time set on PLC will start to decrease till zero and when sealing completed indicator gets ''OFF''

5.6 Machine set up and operation of induction sealing machine (Electronic devices)

5.6.1 Switches and their functionality

5.6.2 **Start switch**: This switch is used to start the heating process. When HEATING is ON, power percentage and current reading shall be indicated on the LCD SCREEN. If the induction cap sealer is in FAULT MODE, the co-responding FAULT MESSAGE shall be displayed on the LCD SCREEN and heating will not be turned on even if this button is pressed.

5.6.3 **Stop switch:** This switch is used to stop the heating process when heating is on. As HEATING is turned OFF the power percentage and current reading will be indicated as "0" on the LCD SCREEN. If the induction cap sealer is in FAULT MODE, the Corresponding FAULT MESSAGE will be displayed on the LCD SCREEN.

5.6.4 **Reset switch:** This switch used to reset any critical fault alarm after it has been attended to. When pressed, the LCD SCREEN shall display a reset message return back to the VIEW STATISTICS SCREEN, if the critical fault does not persist. If there is no critical fault then pressing this button has no effect on the operation of the machine.

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5.6.5 **Menu switch:** This switch is used to appear through different main menus of the system. When this switch is pressed LCD SCREEN shall show the next MAIN MENU. After the last MAIN MENU if the switch is pressed it will wrap around to the first MAIN MENU**.**

5.6.6 **Sub Menu Switch:** This is used to navigate through different sub-menus of each main menu. When this switch pressed the LCD SCREEN shall show the next SUB MENU of the current MAIN MENU. After the last SUB-MENU of the current MAIN MENU, if this switch is pressed it will wrap around to the first SUB-MENU.

5.6.7 **Increment Switch:** This switch is used to increment the value of various parameters.

5.6.8 **Decrement Switch:** This switch is used to decrement the value of various parameters.

5.6.9 **Mains on LED:** This is a green led used to indicate the presence of supply to the control card. When SIGMA-III is turned on, this LED will glow.

ELECTRONICS DEVICES				
MAINS	MENU	LED SCREEN	INC	START
RESET	SUB MENU		DEC	STOP

5.6.10 Make sure the bottle lip (seal point on bottle) is free of burrs, product, seams, etc.

5.6.11 Make sure caps are properly tightened and seal are in contact with lip of the bottle.

5.6.12 **Operation of induction sealing machine (Make: Enercon)**

5.6.13 Main switch panel displays as following:-

Electronic devices			
READY		**TEMPARATURE**	
RUN	**OUT PUT (%)**	**FAULT**	
REMOTE		**AUTO**	
AUTO / **MANUAL**	**LOCAL** / **REMOTE**	**START**	**STOP**

5.6.14 **Switches and their functionality**

5.6.15 **Start switch:** This switch is used to start the heating process. When HEATING is ON, power percentage and current reading shall be indicated on the LCD SCREEN. If the induction cap sealer is in FAULT MODE, the co-responding FAULT indicator will glow.

5.6.16 **Stop switch:** This switch is used or stopping the heating process and when heating is 'ON'. As heating is turned 'OFF' the induction power percentage reading will blink on the 'LCD screen'.

5.6.17 **Increment Switch:** This switch is used to increment the value of various parameters.

5.6.18 **Decrement Switch**: This switch is used to decrement the value of various parameters.

5.6.19 **Following are the details of control display lamps and fault display lamps**:-

1.0 Control display lamps

a) Ready – Green, breaker energized – power applied.
b) Remote – amber, remote start mode selected.
c) Auto- amber, auto mode selected.

2.0 Fault display lamps

a) Temperature – red, temperature fault.
b) Fault- red, power supply failure.
c) Front panel push button
d) Start: Start power supply locally
e) Stop: Stops power supply locally resets fault.
f) Up: For adjusting output level up.
g) Down: For adjusting output level down.
h) Local/remote: For selecting local o remote mode.
i) Auto/manual: For selecting auto or manual mode.

5.6.20 Set the gap, power and speed of conveyor as per BPR.

5.6.21 For setting of ED-vantage system sensors (no foil, fallen bottle, cross cap, burn seal) follow point number 5.2.8 to 5.2.11.

5.6.22 After completion of sealing activity press the stop button from operator panel to stop the operation.

5.6.23 Turn off the power switch from operator panel which will cut off the electric power of the machine.

5.6.24 Now turn off the main Power switch of main.

5.7 **Operation of induction cap sealer Electronic devices (Model: SIGMA III TC)**

5.7.1 Connect the machine to power. Switch "ON" the induction cap sealer machine.

5.7.2 Machine will display as following :-

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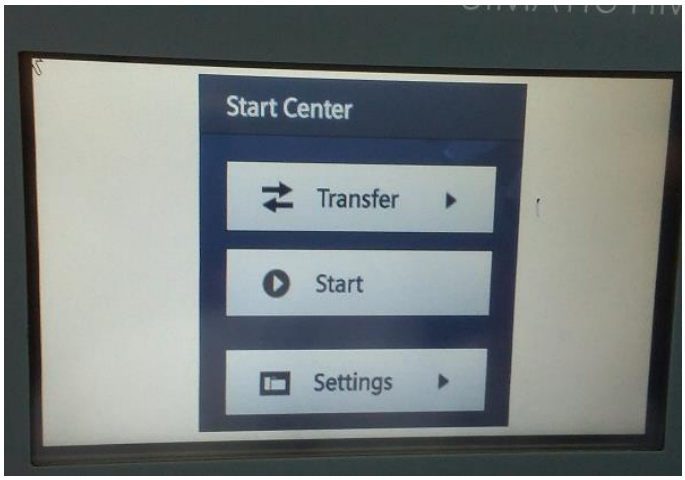
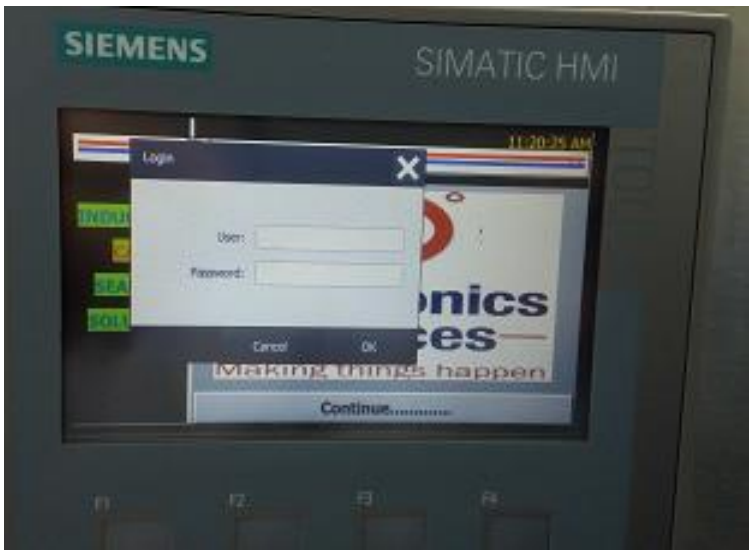
5.7.3 Press “start” Next screen will display as follow:-



5.7.4 Press “continue” screen will display as follow :-



5.7.5 Enter the password. Following are the access granted to different level :

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S.No.	Type of Functions	User Rights Assignment (Y/N)		
		Operator	Supervisor	Manager
1.	To "ON" and "OFF"	Y	Y	Y
2.	To prepare Recipe	N	Y	Y
3.	All access	N	Y	Y

5.7.6 Screen will display as following:

5.7.7 Following are the details :

A) Power %: Displays % of power

B) Production count: Cont of the bottles

C) Rejection count: No. of Rejected bottles

D) Current status: Display sealing off / on

E) Current Mode: Displays in which mode machine is running (AUTO/MANNUAL).

F) Current recipe: Displays current recipe at which machine is running)

G) START: To start the machine.

H) STOP: To stop the machine.

I) RECIPE: To select recipe

J) RESET: To rest the count.

5.7.8 Press "basic system setup" screen will display as follow:

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Details are:

a) Total bottles: Display the total production count.

b) Bottle reject count: Display rejected bottle count.

c) Initial reject count: Display bottles to be rejected initially when machine is started.

d) Power % : Display power %

e) Mode: Display mode of running the machine there are two modes AUTO and MANUAL.

f) Recall Recipe: To load previous recipe.

5.7.9 Press fault rejection setup to set following parameters, and screen will display as follow :

Details are:

a) Rejection ON timer: Time taken to activate rejection system to reject the bottle.

b) Rejection extends time: Time taken to activate rejection system in ON condition.

5.7.10 Press “Timer fault setup” and screen will display as follow :

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Details are:

a) Jam Timer: It will stop the conveyor system in case bottle gets jammed in front of sensor.

b) Power save time: Machine will go into power saving mode.

c) Excess fault: For excess bottles.

d) Consecutive fault: Will display alarm if consecutively bottles are rejected.

e) Batch set: set total number of bottles to be sealed for the particular batch.

5.7.11 Press “setting” screen will display as follow:

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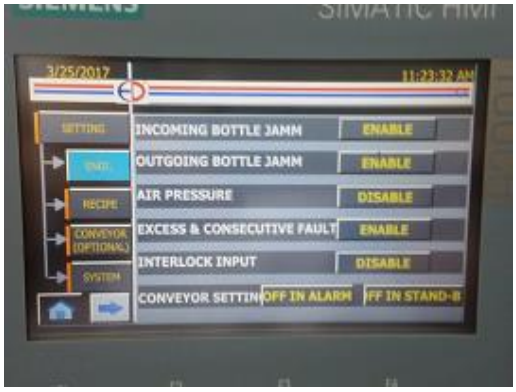

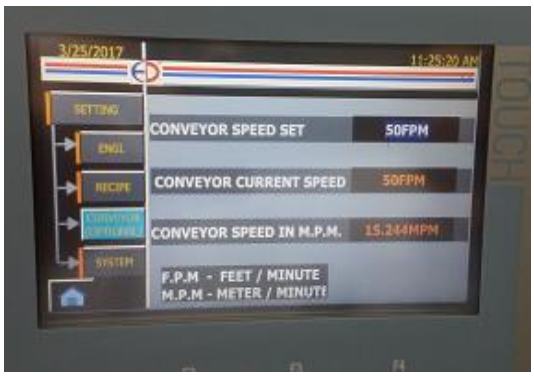

NOTE: Press against the different parameters or given icons to change the values, values can be changed with the help of keyboard displayed.

5.7.12 Press “system” screen will display as follow:

Note: this screen is for auto calibration of the induction sealing machine

(Nonfunctional at the user end)

Note: All bottles used for setting of machine should be segregated and destroy after completion of activity.

5.8 **Challenge test for cross cap sensor:**

5.8.1 Take a capped bottle having cross cap and pass it through the ‘cross cap sensor’.

5.8.2 It must be rejected.

5.8.3 Record the observation in Annexure-I (Challenge test for Induction Cap Sealer Machine).

5.9 **Challenge test for fallen bottle sensor:**

5.9.1 Pass a fallen bottle on conveyor belt through the fallen bottle sensor.

5.9.2 It must be rejected.

5.9.3 Record the observation in Annexure-I (Challenge test for Induction Cap Sealer Machine).

5.10 **Challenge test for without foil sensor:**

5.10.1 Affix a cap (i.e. without foil) on bottle.

5.10.2 Place the bottle on conveyor belt before without foil sensor.

5.10.3 It must be rejected.

5.10.4 Record the observation in Annexure-I (Challenge test for Induction Cap Sealer Machine).

5.11 **Challenge test for burn seal sensor:**

5.11.1 Take a properly capped bottle (without product) and pass it under the induction sealer two to three times.

Note: During execution of validation batch burn seal challenge test to be done with product and in other than validation batch burn seal challenge test to be done with polyester coil (without product).

5.11.2 It must be rejected.

5.11.3 Record the observation in Annexure-I (Challenge test for Induction Cap Sealer Machine).

Note:

1. The challenge test shall be performed at every start up, after four hours and at the end of process.
2. For identification purpose of challenge test bottles/ containers, use challenge test sticker labels.
3. Conduct leak test before start of packing activity.

6.0 ABBREVIATION (S):

6.1 SOP - Standard Operating Procedure

6.2 HMI - Human Machine Interface

6.3 IPA – Isopropyl alcohol

6.4 V/V- Volume by Volume

6.5 SPD – Speed

6.6 ORT BLT SPD – Orientating Belt Speed

7.0 RERERENCE (S):

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7.1 SOP No.: Status labeling

7.2 SOP No. : Making entries in equipment usage and cleaning log sheet.

8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Challenge test for Induction Cap Sealer Machine.	…….	Controlled Copy

9.0 DISTRIBUTION:

9.1 **Master Copy** **:** Quality Assurance.

9.2 **Controlled Copy (S) :** Production Department (02), Quality Assurance (01)

9.3 **Reference Copy (S) :** Production Department (03)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date

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ANNEXURE I

CHALLENGE TEST FOR INDUCTION CAP SEALER MACHINE							
FREQUENCY: AT EVERY START UP, AFTER EVERY FOUR HOURS AND AT END OF OPERATION							
PRODUCT NAME:				**BATCH NO.:**			
DATE	**TIME**	**Sensor**				**Done By**	**Verified by**
		# Cross Cap	**# Fallen Bottle**	**# Without Foil**	**# Burnt Seal**		

Mark ‘OK’ in observation if bottle ‘rejected’ & Mark ‘not ok’ in observation if bottle not rejected.