



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and operation Of Induction cap sealer(Electronic Devices; Model: SIGMA III TC)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for cleaning and operation of induction cap sealer (Electronic Devices).

2.0 SCOPE:

This SOP is applicable for cleaning and operation of induction cap sealer (Electronic Devices). in production.

3.0 RESPONSIBILITY:

Technical Associate : For cleaning and operation of machine.

Officer / Executive Production : For checking.

Head Production : SOP Compliance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Cleaning

Carry out the following procedure for batch to batch or product to product changeover.

5.1.1 Disconnect the machine by switch "OFF" the power supply.

5.1.2 Clean the all the height adjustment gauge, bottle guide with wet mop followed by dry mop.

5.1.3 Clean all the sticky material from induction plate, head, platform and outer body Surface with wet mop followed by dry mop.

5.1.4 For cleaning refer to the points given in "LINE CLEARANCE CHECKLIST "

5.1.5 Affix "CLEANED" label on the machine as per SOP.

5.1.6 Record the details of cleaning of induction cap sealer in equipment usage log sheet as per SOP.

5.2 Machine 'SET UP'

5.2.1 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 anticlockwise direction.

5.2.2 Setting of "BOTTLE UNDER INDUCTION PLATE"

For better induction, bottle shall be exposed to maximum electromagnetic field generated under induction plate. To achieve this platform is given with circle having variable diameter and bottle with different diameter can be set into given circle.



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5.2.3 Setting of "GAP BETWEEN BOTTLE AND INDUCTION PLATE"

The GAP adjusted between plate and bottle is 3-6 mm.

5.3 OPERATION

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

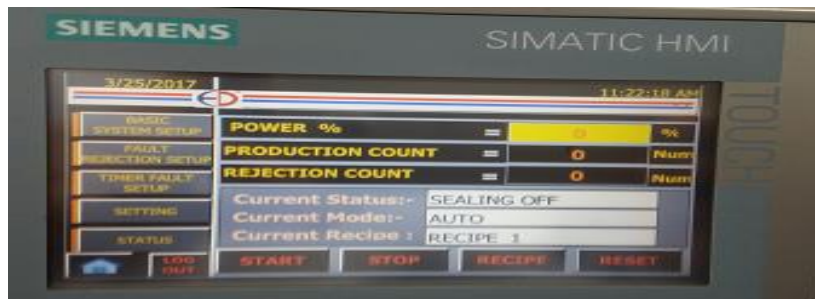
5.3.2 Press "start" Next screen will display as follow:



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

S.No.	Type of Functions	User Rights Assignment(Y/N)		
		Operator	Supervisor	Admin
1.	To "ON" and "OFF"	Y	Y	Y
2.	To prepare Recipe	N	Y	Y
3.	Create User ID & Login password	N	N	Y

5.3.6 Screen will display as following:





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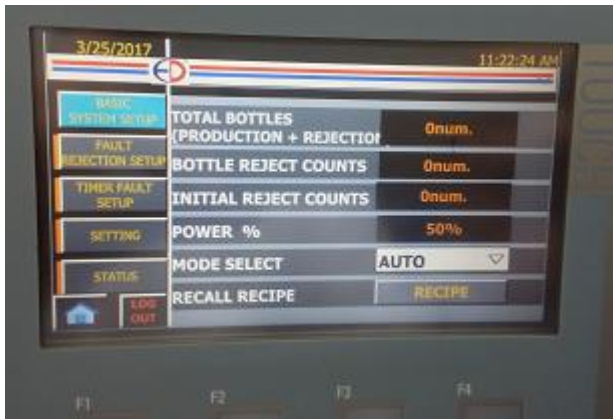
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5.3.7 Following are the details :

- A) Power % :Displays % of power
- B) Production count : Count of the bottles (if applicable).
- C) Rejection count : No. of Rejected bottles (if applicable).
- 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.

5.3.8 Press “basic system setup” screen will display as follow:



Details are :

- a)Total bottles: Display the total production count (if applicable).
- b) Bottle reject count: Display rejected bottle count (if applicable).
- c)Initial reject count: Display bottles to be rejected initially when machine is started (if applicable).
- d)Power %: Display power %
- e)Mode: Display mode of running the machine there are two modes AUTO and MANNUAL.
- f)Recall Recipe :To load previous recipe.

5.3.9 Press fault rejection setup to set following parameters, and screen will display as follow (if applicable):



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Details are :

- Rejection ON timer: Time taken to activate rejection system to reject the bottle.
- Rejection extends time: Time taken to activate rejection system in ON condition.

5.3.10 Press “Timer fault setup” and screen will display as follow (if applicable):



Details are :

- Jam Timer: It will stop the conveyor system in case bottle gets jammed in front of sensor.
- Power save time: Machine will go into power saving mode.
- Excess fault: For excess bottles.
- Consecutive fault: Will display alarm if consecutively bottles are rejected.
- Batch set: set total number of bottles to be sealed for the particular batch.



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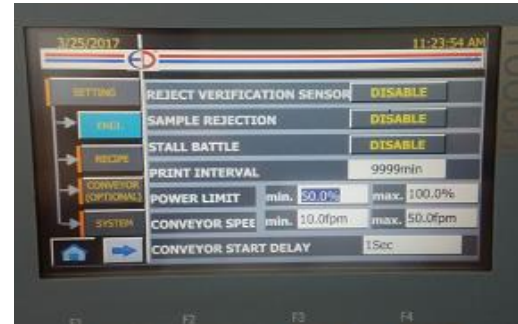
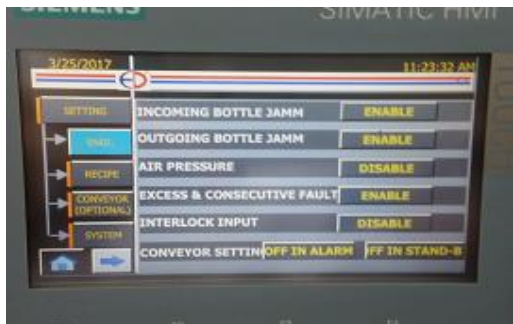
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5.3.11 Press “setting” screen will display as follow:



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

5.3.12 Press “system” screen will display as follow(if applicable):

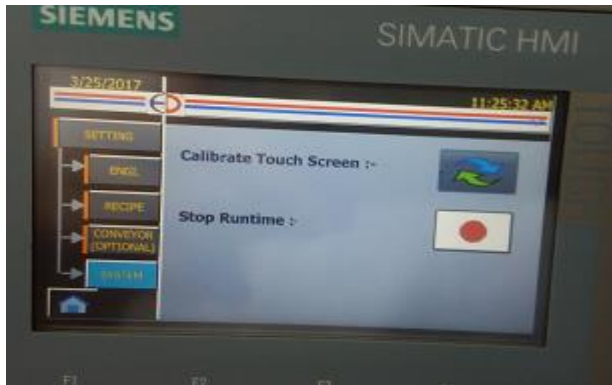


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Note : this screen is for auto calibration of the induction sealing machine (non functional at the user end)

5.4 ED-vantage system sensors setup (if applicable):

5.4.1 Setting for 'No foil Sensor' with bottle present sensor :

- 5.4.1.1 Place bottle with foil cap under the 'NO foil sensor'. Adjust the 'NO foil sensor' so that it is in center of the bottle.
- 5.4.1.2 Adjust the height of the 'NO foil sensor' so that the small red 'LED' on the sensor glows. The distance between the 'no foil sensor' and the cap shall around 3 mm to 4 mm.
- 5.4.1.3 Adjust the position of 'bottle present sensor' that when a bottle without foil pass under the 'no foil sensor' it rejected by ejector system and fall into rejection box.

5.4.2 Setting of 'fallen bottle sensor':

- 5.4.2.1 Place a bottle on conveyor belt.
- 5.4.2.2 Set a ray light emitted by sensor on bottle neck.
- 5.4.2.3 Now pass a fallen bottled on conveyor belt.
- 5.4.2.4 Fallen bottle must be rejected by pusher and fall into rejection box.

5.4.3 Setting of cross cap:

- 5.4.3.1 Take a bottle with normally tight closure on it.
- 5.4.3.2 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.
- 5.4.3.3 When a cross capped bottle pass through the sensor it reject the bottle and fall into rejection box.

5.4.4 Setting of burn seal sensor :

- 5.4.4.1 IR Sensor height adjusted according to the height of bottle.
- 5.4.4.2 Switch on the main power supply.
- 5.4.4.3 Press the push button twice then red indicator will glow and yellow indicator will blink.



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5.4.4.4 Now seal the bottle by setting the induction power as per limit given in BPR and check for normal seal of bottle and place it at an angle of 90⁰(perpendicular) below the IR sensor.

5.4.4.5 Than teach the sensor by pressing the push button (present either on sensor or another present near the power supply) for single time.

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

5.5.3 **Challenge test for 'cross cap sensor' :**

5.5.3.1 Take a marked bottle with cross cap and pass it through the 'cross cap sensor'.

5.5.3.2 It must be rejected by pusher system.

5.5.3.3 Record the observation in Annexure-I.

5.5.4 **Challenge test for 'fallen bottle sensor' :**

5.5.4.1 When fallen bottle pass through the conveyor it must be rejected by pusher system.

5.5.4.2 Record the observation in Annexure-I.

5.5.4.3 Send the marked rejected bottles for destruction.

5.5.4.4 Record the challenge test as per attached annexure-I.

NOTE: The challenge test shall be performed at every start up, after four hours and at the end of process.(if applicable).

7.0 **REFERENCE (S):**

SOP No.: Status labeling

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

Format No.: For cleaning refer to the points given.

8.0 **ANNEXURE (S):**

Annexure I

9.0 **DISTRIBUTION:**

Master Copy : Quality Assurance

Controlled copy (S) : Production department, Quality Assurance

Reference Copy (S): Production department



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ANNEXURE I

CHALLENGE TEST FOR BURN SEAL/ FALLING BOTTLE/ NO FOIL/ CROSS CAP

INDUCTION SEALER ID No:

FREQUENCY: AT EVERY START UP, AFTER EVERY FOUR HOURS AND AT END OF OPERATION

PRODUCT NAME:					BATCH No.:		
DATE	TIME	# NO FOIL	# CROSS CAP	FALLEN BOTTLE (SENSOR-III) #	# BURNT SEAL	CHECKED BY PRODUCTION	VERIFIED BY QA

Mark 'OK' in observation if bottle 'rejected' & Mark 'not ok' in observation if bottle not rejected.