



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Sticker Labeling Machine	Effective Date:
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1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Sticker Labeling Machine ID.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Sticker Labeling Machine in Production Area of Dry Powder injection Line

3.0 RESPONSIBILITY:

Officer/Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 DEFINITIONS:

Not Applicable

6.0 PROCEDURE:

6.1 Operation:

- 6.1.1** Take the area clearance from QA personnel.
- 6.1.2** Bring the dispensed labels in the area.
- 6.1.3** Connect the power supply and switch “ON” the mains.
- 6.1.4** Run the machine for at least 2 minutes.
- 6.1.5** Load the label roll in label box.
- 6.1.6** Adjust peel off the paper about 5 to 10 mm from the scraper blade by rotating the pinch roller manually.
- 6.1.7** Adjust the Label Sensor’s point mark between two labels gap.
- 6.1.8** After adjusting the Sensor’s point between two labels gap, press Auto Set button given on the Sensor & wait for three seconds.



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- 6.1.9** The green light given on the Sensor's will start blinking., move the Label forward on reverse and adjust the Label Sensor's point mark on the label and press Auto Set button again and light will stop blinking.
- 6.1.10** Follow the same procedure to get the best performance of the machine every time while changing the Label roll or changeover the size.
- 6.1.11** Adjust the guide Rails according to container size such as, the container should move freely on to the conveyor.
- 6.1.12** Put the container in between the Separator and its back guide and apply the Pressure by 5mm on container and tighten the same.
- 6.1.13** Place the container between Pressing Belt and Massage Plate.
- 6.1.14** Place another container nearly at the end of Pressing Belt and Massage Plate.
- 6.1.15** Press massage Plate against container in such a way that the container is under slight pressure. Re-tighten the Knob.
- 6.1.16** Keep one container in between Pressing belt and Massage Plate at the starting edge i.e. just after the dispensed label & adjust the product sensor accordingly until the LED will glow. Retighten the product sensor Knob firmly.
- 6.1.17** Put some containers on conveyor and checks the sticking of labels there on.
- 6.1.18** Adjust the product sensor forward or reverse if any crease of labels after pasting is observed.
- 6.1.19** To change the label application height on the container, move the hand wheel given below the top plate clock-wise & anti clock-wise for up/down.
- 6.1.20** Re- tightens the bolt of hand wheel.
- 6.1.21** Enter the user details and password to open the system.
- 6.1.22** To set the printing details open the massage.
- 6.1.23** Type and set Batch No., Mfg. Date, EXP. Date, in the system from the BPR and MRP from MRP file.
- 6.1.24** After setting the printing details check details with BPR after zooming it.
- 6.1.25** Perform Challenge test of sensors before start of operation and after any break-down of machine.



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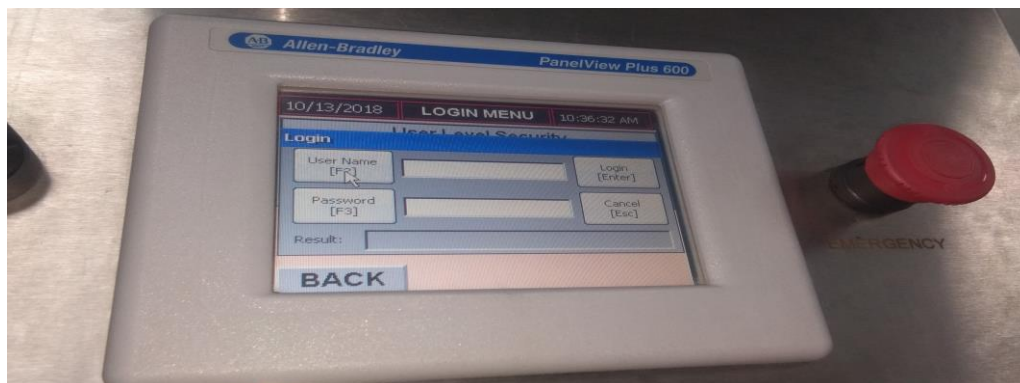
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6.1.26 Record the details of sensors challenge test in **Annexure-I**

6.1.27 Load the message & give print command. On main of the HMI and find the display as under:



6.1.28 Following display on screen for User login and Password.



6.1.29 Press F2 and enter the user name, Press F3 and enter the Pass word. Now Press the login, on following display:

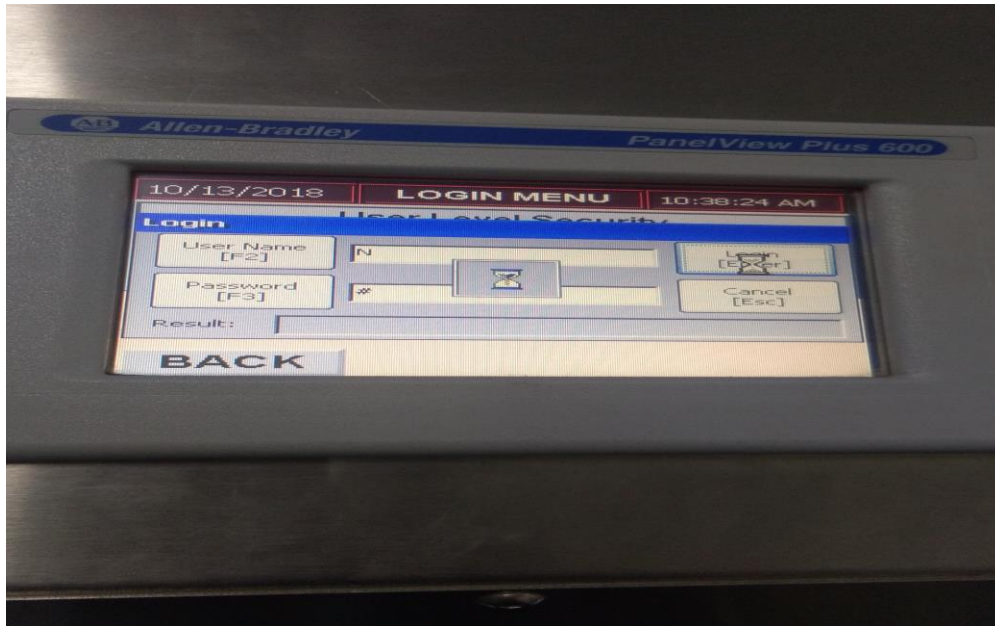


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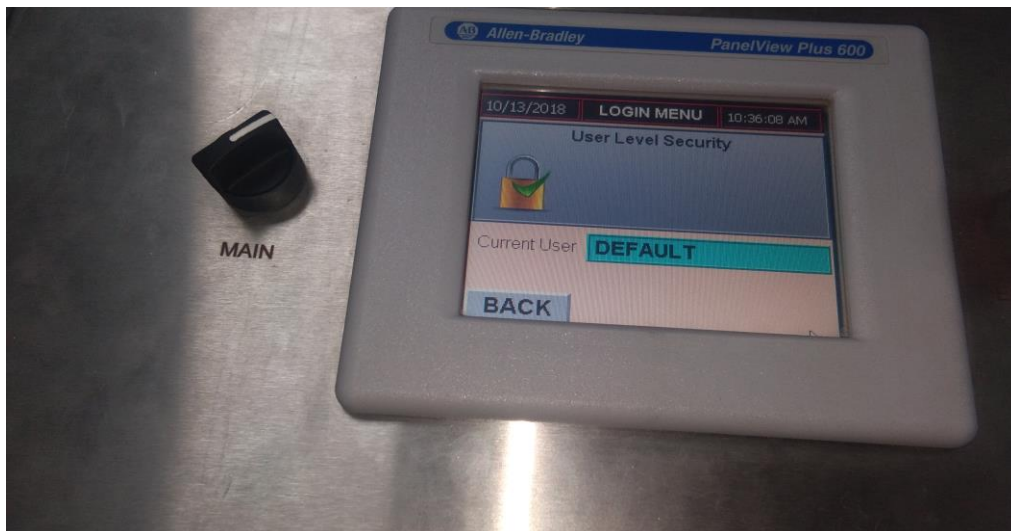
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6.1.30 HMI show following display, Press current user.



6.1.31 Now following display show on screen:

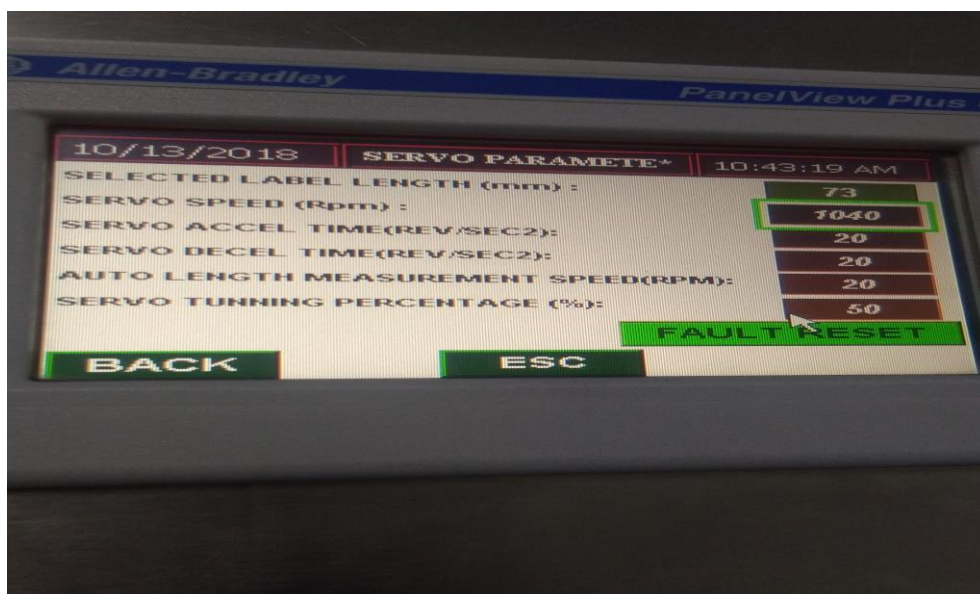


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6.1.32 Fill the required details on display as under:

6.1.33 Now select the Auto mode for machine running on following display:



6.1.34 Start the machine and get first two prints on the label in order to get QA approval.

6.1.35 During labeling Operation of Vials visual inspector continuously verify the Vials coding.

6.1.36 Without coding Vials identified by visual inspector shall be kept in rejection box for relabeling.

6.1.37 The visual inspector shall be rotated after every two hours.

6.1.38 Record the details of verification of coded vials in **Annexure-II**.

6.1.39 During labeling operation following display should be continued on screen.



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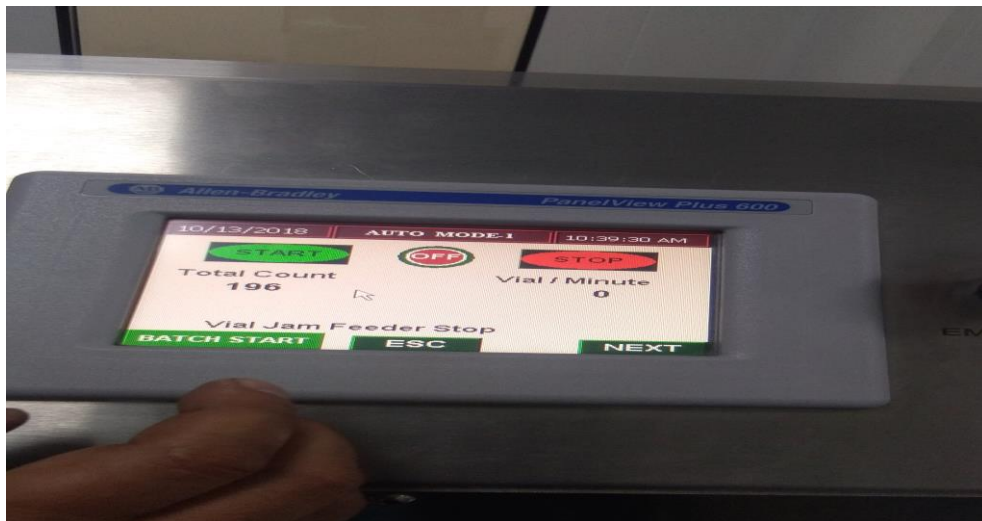
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6.1.40 De label the all improper labeled rejected vials, manually and do re label.

6.1.41 After completion of labeling operation stop the machine by pressing STOP option on following display:



6.2 CLEANING:

- 6.2.1 Switch "OFF" the electric supply of the machine.
- 6.2.2 Remove guard and pressing belt.
- 6.2.3 Clean the machine and its parts with 70% IPA solution.
- 6.2.4 Clean the machine body with 70% IPA solution.
- 6.2.5 Clean the surrounding area of the machine with dust collector / vacuum cleaner.
- 6.2.6 Fix the guard and pressing belt at its specified place.
- 6.2.7 If machine is not used within 24 hrs, re-clean it before its operation.



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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		



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ANNEXURE-I

	PRODUCTION
	SENSOR CHALLENGE TEST RECORD

Frequency: Before Start of Operation and After Machine Break-Down

Date	Product Name	Batch No.	Sensor Details	Status (Ok/Not Ok)	Done By Sign & Date	Checked By Sign & Date	Verified By Sign & Date	Remarks
			Coding Sensor					
			Label Sensor					
			Product Sensor					
			Feeder Jam Sensor					

