Cleaning and Operation of Alu-Alu Blister Pack Machine

1.0 **OBJECTIVE**

To lay down a procedure for cleaning and Operation of Blister Packing Machine (BQS).

2.0 **SCOPE**

This procedure is applicable to the cleaning and Operation of Blister Packing Machine (BQS) in production area.

3.0 **RESPONSIBILITY**

Technical Associate : Cleaning and Operation
Officer and Executive : Supervision
IPQA Person : Verification
Head Production : SOP compliance

4.0 **DEFINITION (S)**

NA

5.0 **PROCEDURE**

5.1 **TYPE A CLEANING**

Change over from one batch to next batch of the same product and potency.

5.1.1 Ensure that all the materials of previous batch are removed from the blister packing cubicle.

5.1.2 Remove 'UNDER PROCESS' label and affix 'TO BE CLEANED' label on the machine with date and sign of the production officer.

5.1.3 Clean the machine, hopper, hopper lid, feeding sector and linear vibrator and rotary vibrator with dry lint free cloth and then by vacuum cleaner.

5.1.4 Clean the operator panel of pin hole detector unit with dry lint free cloth.

5.1.5 Clean the feeding channel, tablet supporting drum, guide track, cooling plate and forming plate and guide piece with dry lint free Cloth.

5.1.6 Clean the pressure-sealing roller with brass brush using silicone compound.

5.1.7 Clean the guide rollers and all supporting rollers with dry lint free Cloth.

5.1.8 Clean the punching tools with dry lint free cloth.

5.1.9 Clean the stereo roller (after stereo removal), supporting shafts with thinner followed by cleaning with dry lint free cloth.

5.1.10 Clean the punching tools with dry lint free cloth. clean the trim delivery chute, pack reject and chute conveyor belt with dry lint free cloth.

5.1.11 Clean the control panel, machine body, base, acrylic guards and other non-contact parts with dry lint free Cloth.

5.1.12 Record the cleaning activity in equipment usage log as per SOP.

5.2 **TYPE B CLEANING**

This is a cleaning procedure for Change over of product with different actives / color / descending potency/ascending potency/and if same product processed for more then one week or after maintenance of contact parts.

5.2.1 Replaced the 'UNDER PROCESS' status label by 'TO BE CLEANED' status label with date and sign of the production officer.

5.2.2 Dismantle the hopper, hopper lid, Linear and rotary vibrator, feed channel assembly (including Tablet supporting drum), vibrating plate and guide track.

5.2.3 Clean the machine and area with vacuum cleaner.

5.2.4 Clean the dismantled parts hopper, hopper lid, vibrating plate, and feed channel with dry lint free cloth and transfer to washing area in virgin poly bag.

5.2.5 Scrub the above dismantled parts with a nylon scrubber using purified water.

52.6 Finally rinse all the cleaned parts with the 20-30 liters of purified water.

5.2.7 Wipe the dismantled parts with lint free cloth dipped in 70% v/v IPA solution.

5.2.8 Cover all the change parts with poly bag and transfer to the packing spare cabinet.

5.2.9 Remove the perforation tool, induction roller and punching tool from the machine and clean with dry lint free cloth.

5.2.10 Clean the forming, cooling plate with wet lint free cloth followed by dry lint free cloth.

5.2.11 Clean the sealing unit with a brass brush by applying silicon compound followed by dry lint free cloth.

5.2.12 Clean the stereo roller (after stereo removal), supporting shafts with thinner followed by cleaning with dry lint free cloth.

5.2.13 Clean the operator panel of pin hole detector unit with dry lint free cloth.

5.2.14 Clean the inner and outer surface of the machine, control panel and utility lines with wet lint free cloth followed by dry lint free cloth.

5.2.15 Wipe the machine with 70% v/v IPA solution.

5.2.16 Reassemble the cleaned hopper and hopper lid.

5.2.17 Transfer the guide track, sealing and forming plate, cooling plate to the packing change part room.

5.2.18 Replace the 'TO BE CLEANED' status label by ''CLEANED'' status label with date and sign of the production officer.

5.2.19 If the machine remains idle for more than72 hours after cleaning, then replace the ''CLEANED' status label with ''TO BE CLEANED'' status label with date and sign of the production officer.

5.2.20 Clean the machine with dry lint free cloth followed by wiping with 70% v/v IPA solution before using the machine and affix previous ‘‘CLEANED’’ status label with further sign of production officer and IPQA officer.

5.2.21 Record the Cleaning Activity in equipment usage log sheet.

5.2.22 Clean the area as per SOP.

5.3 **FREQUENCY:**

5.3.1 Shift end cleaning to be done at the end of shift if same batch is to be continued for next day.

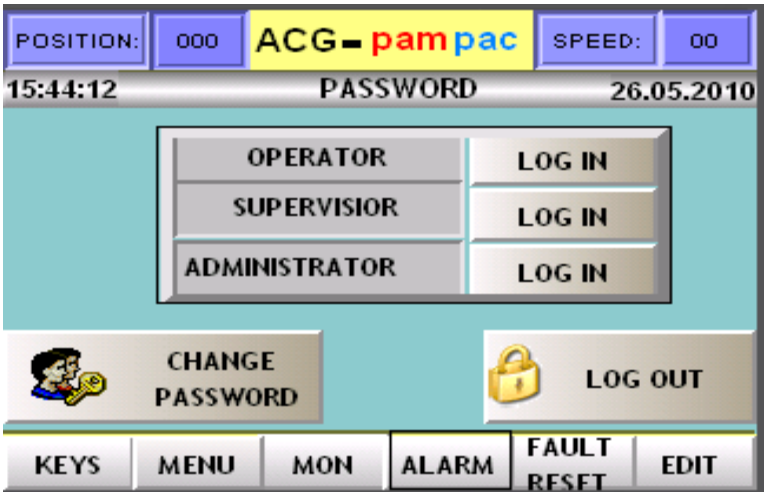
5.3.2 In case the activity is planned for 24 hours, no shift end cleaning to be done.

5.3.3 Shift end cleaning includes closing the in process product in closed condition, wiping of machine parts with dry lint free duster, and sanitization of area.

5.4 **OPERATION:**

5.4.1 Switch on the machine the following screen is displayed. It takes few seconds to establish communication between the MMI & PLC.

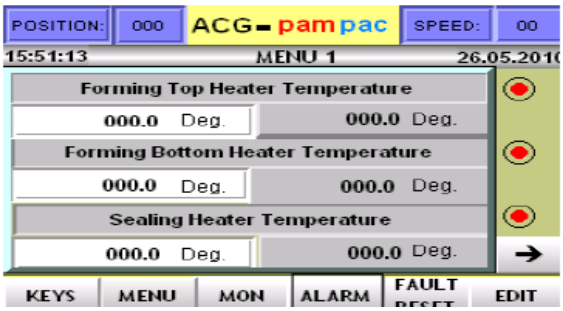
5.4.2 Press Log In Button. Following screen will be displayed:

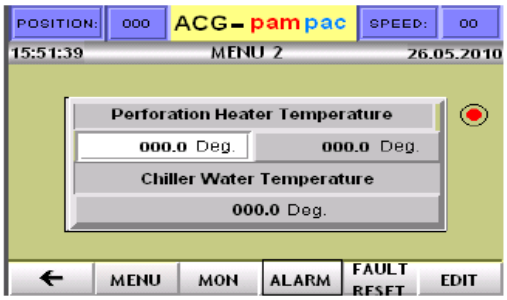


5.4.3 Based on the security level, three 'USER' level are given with their access rights assignment as given below.

Type of Function		Rights To Access (Yes/No)		
		Operator (Level-I)	Supervisor (Level-II)	Administrator (Level-III)
1.	Recipe Formulation	No	Yes	Yes
2.	Manual Mode Operation	Yes	Yes	Yes
3.	Change Password	No	No	Yes

5.4.4 Enter password to the above screen and press 'MON' the following screen will displayed :





5.4.5 The system is showing forming and sealing heater temperature (Set & Actual).

5.4.6 The status 'Red' colour of the above-mentioned heaters is indicated the heater is 'OFF' while 'Green' means the heater is 'ON'

5.4.7 Chiller temperature also shall be displayed on 'PLC' as in above screen.

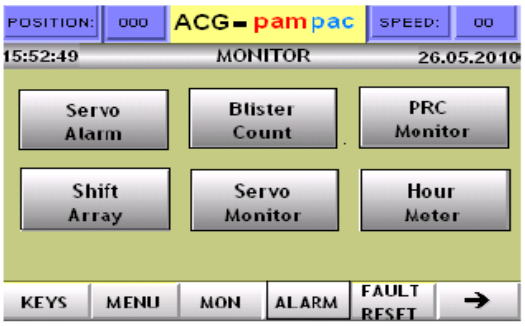
5.4.8 Speed of the machine in cycles / min also shall be displayed on screen.

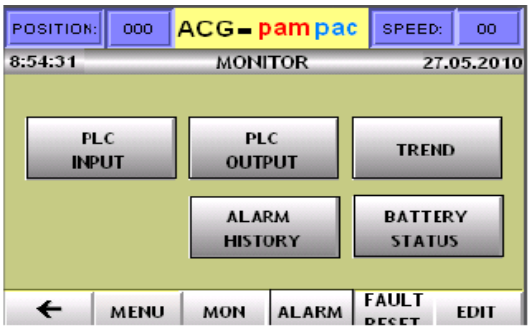
5.4.9 Machine stop position displayed as (0-999 in one cycle)

5.4.10 To enter the values for temperature in the above screen or to enter any other values in any screens follow the below mentioned procedure:

5.4.10.1 Select the option in screen where the value has to be entered. A keypad will appear as below, enter the required values and press the Enter key.

5.4.11 On pressing the 'MON' key in the Main screen the following screen is displayed. Here you can monitor various data /PLC inputs and outputs for troubleshooting purpose or for information.





5.4.12 For trouble shooting go to Alarm servo, In this screen, User will check the Minor Error, Major Error, Servo Error & Real to Virtual Switch Error.

5.4.13 On pressing the 'BLIST COUNT' key in the Data Monitor screen, the following SCREEN IS DISPLAYED. From here we can check total no blisters produced rejected and good.

5.4.14 On pressing the 'HOUR METER' key in the Data Monitor screen, the following screen Displays. The above screen displays the Total Hours.

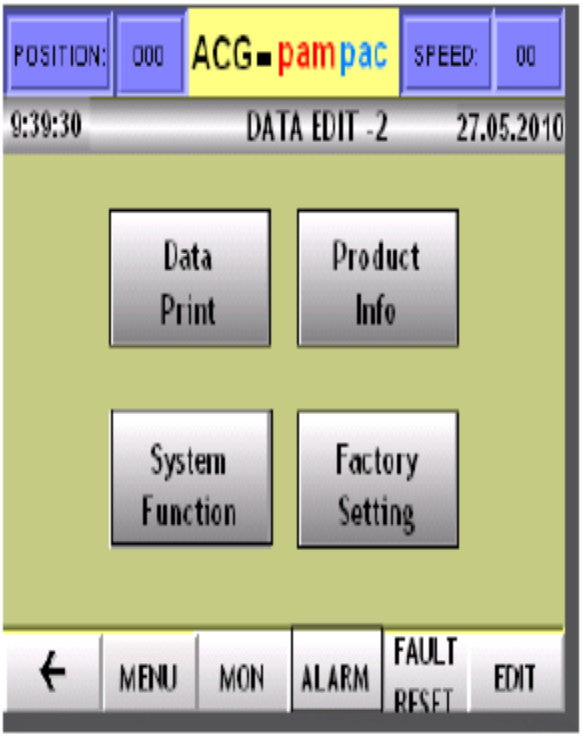
5.4.15 MACHINE RUN TIME:
To reset the same , press the 'RESET' key. Hold the key for few seconds to RESET the time.

5.4.16 On pressing the 'PLC INPUT' key in the Data Monitor screen, we can see various inputs to PLC. All inputs which are 'ON' are indicated with Green signal, Red signal indicates the input is 'OFF'.

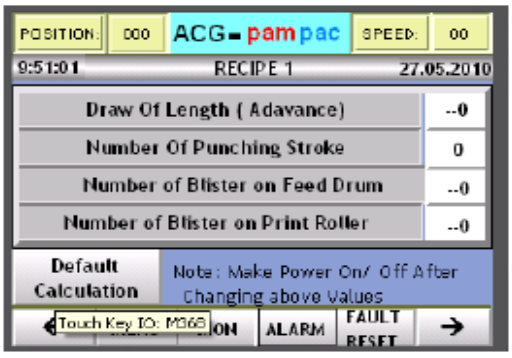
5.4.17 On pressing the 'PLC OUT PUT' key in the Data Monitor screen, we can see various outputs of PLC. All outputs which are 'ON' are indicated with Green signal, Red signal indicates the output is 'OFF'.

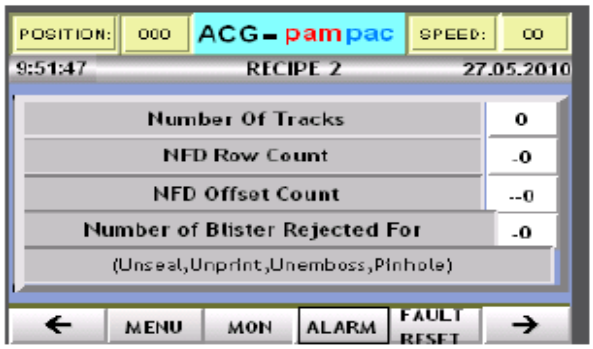
5.4.18 On pressing the 'TREND' key in the Data Monitor screen, we can check trend of various temperatures (actual and set) vs. time.

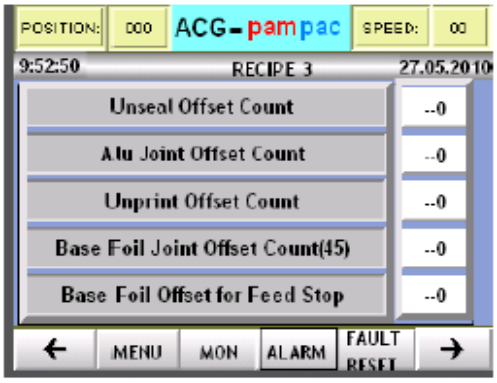
5.4.19 On pressing the 'EDIT' key in the Main screen the following screen is displayed :



5.4.20 Go to change over for EDIT product data values. In this screen all change part related parameter are entered.







5.4.21 After changing value in this screen switch off the main power supply and restart for entering this value permanently in the system.

5.4.22 In this screen enter value for NFD Inspection System if applicable.

5.5 **RECIPE UPLOAD**:

5.5.1 User can Save/Load up to 20 Recipe using above screen. User can save all change part parameter in one recipe.

5.5.3 AUTO CALC helps you to give nearby values for each parameter. You need to correct other 2 parameters like no of blisters on feeding drum and printing drum as per actual. In few cases it may not match.

5.5.4 Similarly for other OFFSETS we need to correct as per loop set between pulling and punching station.

5.5.5 Pin Hole Offset (Rejection)

5.3.5.1 Enter the number of packs between the pin hole device and punching tool-1.

5.5.6 Once all parameters are ‘SET’ and functionally tested we can store the data for change part under recipe. We can give name and no to store the recipe.

5.5.7 Enter required name and ensure that no is also assigned to it. Press SAVE button. Recipe will store data.

5.5.8 If you want to recall the recipe by putting the number and giving LOAD command all parameters related to that recipe will be loaded.

NOTE :

Manual mode is recommended during change over and trouble shooting.

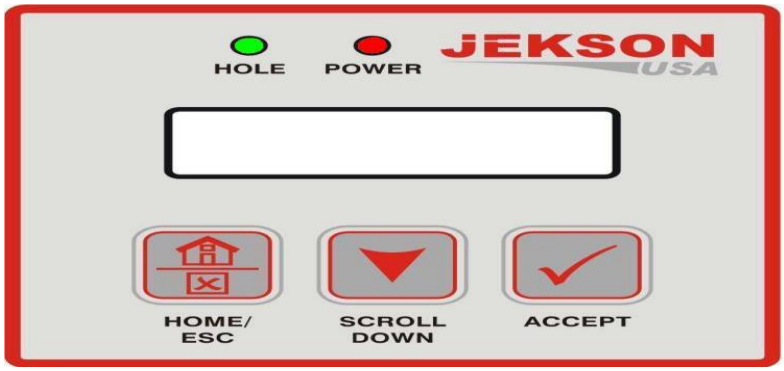
In special function various functions can be selected such as Alu-Alu, camera, NFD, Pharma code, joint rejection, print rejection, pinhole rejection. etc. we can choose the desired function as per requirement.

5.6 **PIN HOLE DETECTOR**

5.6.1 Pin hole detector is used for detection of pin holes, fissures and pores which may occur on aluminum blister Packs during their cold-forming or lamination process and usually impossible to be seen by human eyes.

5.6.2 LCD screen is provided on front panel of system along with keypad for viewing counter verification and various system statuses.

5.6.3 **Key pad of pin hole detector**



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	**STATUS LED** Indicates a hole has been detected
	**STATUS LED** Indicates device is powered ON
	**HOME/ESC KEY** Leads one out of the current screen to previous screen
	**SCROLL DOWN KEY** Scroll through options on the screen
	**ACCEPT KEY** Key confirms changes made
 	Simultaneously pressing Scroll Down & Accept keys resets RATOR.

5.6.4 **Operation**

5.6.4.1 Place a good foil in between illumination and detector unit. The foil must cover the sensor over the entire length by adjusting the web guides and pin hole device properly.

5.6.4.2 If 'green led' remain 'switch off' this indicate that good foil web located properly in between the device.

5.6.4.3 Ensure that pin hole rejection count value shall always be 001.

5.6.4.4 **Hole size setting**

5.6.4.4.1 Press the 'accept key' continuously then press 'home key'.

5.6.4.4.2 Now bring the cursor at 'hole size' option in 'LCD display' by 'scroll down key' given on operator panel.

5.6.4.4.3 Set the hole size as 50 microns with the help of 'scroll down key'.

5.6.4.4.4 Then press the 'accept' button.

5.6.4.5 **Re-setting of pin hole device**

5.6.4.5.1 After shift end if batch continue to pack in morning shift, reset the pin hole device by pressing 'accept key' simultaneously with 'scroll down key'.

5.6.4.6 **Total rejection counter reset**

5.6.4.6.1 Press the 'accept key' simultaneously with the 'home key'.

5.6.4.6.2 Than bring the cursor at 'count reset' by 'scrolling down key'.

5.6.4.6.3 Press the 'accept button.

5.6.4.6.4 The pin hole device shall be reset with the message of 'resetting counter'.

5.6.4.6.5 The foil is guided between the transmitter and the receiver of detection unit. The foil is illuminated by infrared light while being transmitted. Highly sensitive sensor element registers if the infrared light beam penetrates a crack.

5.7 **Challenge test for Pin Hole Detector**

5.7.1 Run the machine and ensure that the 'hole status' (green LED) must turn 'off'.
This confirms that the normal web has transferred in between the pin hole device.

5.7.1 Stop the machine and pierce or punch a hole (0.3-1.0 mm in diameter) in formed web by a fine needle.

5.7.2 Marked the punctured area of foil with ink marker.

5.7.3 Run the machine.

5.7.4 The Hole status (green LED) must turn 'on'. This confirms that the pin hole in the marked web was detected.

5.7.5 The challenge test pass if marked blister rejected and fall into rejection box.

Frequency: At the start , end and after every 4 hours of the operation.

5.8 **Setting For Web Loop Sensor**

5.8.1 Both the loop sensor set as such a way that machine stop if web length increase or decrease for one blister pack and PLC gives message as 'Indexing Slip'

5.9 **Precautions**

5.9.1 Never run the machine empty.

5.9.3 Before starting the inspection, all the components of the detection unit must have reached operating temperature. The detection unit must therefore be switched 'on' at least ½ hour prior starting the inspection.

6.0 **ABBREVIATION (S):**

QA : Quality Assurance

SOP : Standard Operating Procedure

v/v : Volume/Volume

PPE : Personal Protective Equipment.

BQS : Blistering Quickly through Servo.

MON: Monitor screen.

7.0 **RERERENCE (S):**

7.1 SOP Making entries in equipment usage and cleaning log sheet.

7.2 SOP Cleaning of production area.

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8.0 **ANNEXURE (S):**

8.1 Annexure – I : Cleaning checklist of Blister Packing Machine (BQS)

Annexure – II : Challenge test for pin hole detector.

9.0 **DISTRIBUTION:**

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

9.2 **Controlled copy (S)** **:** Production department, Quality Assurance

9.3 **Reference copy** **:** Production Department.

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ANNEXURE I

CLEANING CHECKLIST OF BLISTER PACK MACHINE (ALU-ALU)

Name of the Equipment		**BLISTER PACK MACHINE (ALU-ALU)**	
Equipment I.D. No.		**Previous product**	
Batch No.		**Date**	

S.No.	Activity	Activity Performed
1	Dismantle the hopper, hopper lid, feed channel, assembly, vibrating plate and guide track. Put all the dismantled parts in a virgin poly bag and affixed ‘‘TO BE CLEANED” label and transfer the poly bag to washing area for cleaning.	
2	Scrub the dismantled parts with a nylon scrubber using purified water.	
3	Finally rinse the cleaned parts with 10-20 liters of purified water.	
4	Dry the cleaned parts with a dry lint free cloth.	
5	Keep all the dried parts on a cleaned stainless steel pallet and cover it with a virgin polythene bag with a status label as “CLEANED” with date and signature of the production officer and transfer them to respective packing cubicle.	
6	Wipe the dismantled parts with 70% v/v IPA solution.	
7	Remove the punching tool from the machine and clean with dry lint free cloth.	
8	Place a crate below the forming unit and loosen upper bolt.	
9	Clean them with dry lint free duster and cover with polybag and transfer to the packing spare cabinet.	
10	Clean the sealing unit with a brass brush by applying silicon compound.	
11	Clean the inner and outer surface of the machine, control panel and utility lines with a dry duster.	
12	Wipe the machine with 70% v/v IPA solution.	

Checked By (Prod.)
Sign/date

Verified By (QA)
Sign/date

Note : Put ‘√’ mark if activity performed and put ‘X ‘ if activity not performed.

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ANNEXURE II

CHALLENGE TEST FOR PIN HOLE DETECTOR ON ALU/ALU MACHINE

FREQUENCY:AT START, END AND AFTER EVERY 4 HOUR OF THE OPERATION.

PRODUCT NAME: **BATCH No.:**

S.No.	DATE	TIME	OBSERVATIONS * MARKED BLISTER	CHECKED BY (Production)	Verified By (IPQA)	REMARKS

*MARKED STRIPS: Mark ‘OK’ in observation if rejected and mark ‘NOT OK’ if not rejected.