



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Blister packing machine (BQS).

2.0 SCOPE:

This procedure is applicable for Cleaning and Operation of Blister packing machine (BQS).

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation
Production : Officer / Executive / Assistant Manager
Head Production: To ensure execution & compliance.

4.0 PROCEDURE:

4.1 TYPE A CLEANING

Change over from one batch to next batch of the same product, same potency and of similar product with ascending potency provided the color is same.

- 4.1.1 Ensure that all the materials of previous batch are removed from the blister packing cubicle.
- 4.1.2 Replace the 'UNDER PROCESS' status label by 'TO BE CLEANED' status label then 'UNDER CLEANING' while starting the cleaning procedure.
- 4.1.3 Clean the machine, hopper and bowl with dry lint free cloth.
- 4.1.4 Clean the feeding channel, tablet supporting drum, guide track, sealing unit and forming unit with dry lint free Cloth.
- 4.1.5 Clean the sealing unit with Copper wire brush.
- 4.1.6 Clean the guide track and all supporting parts with dry lint free Cloth.
- 4.1.7 Clean the punching tools with dry lint free Cloth.
- 4.1.8 Clean the stereo roller (after stereo removal), supporting shafts with thinner followed by cleaning with dry lint free cloth.
- 4.1.9 Clean the punching tools with dry lint free cloth. clean the trim and pack reject delivery chute, conveyor belt with dry lint free cloth.
- 4.1.10 Clean the control panel, machine body, base, acrylic guards and other non-contact parts with dry lint free Cloth.
- 4.1.11 Record the cleaning activity in equipment usage log as per SOP.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.1.12 Maintain the cleaning checklist as per Annexure - I.

4.2 TYPE B CLEANING

This is a cleaning procedure for Changeover of product with different actives / color / descending potency or after maintenance of contact parts.

- 4.2.1 Replace the 'UNDER PROCESS' status label by 'TO BE CLEANED' status label then 'UNDER CLEANING' while starting the cleaning procedure.
- 4.2.2 Dismantle the hopper, hopper lid, Linear and rotary vibrator, feeding channel assembly (including Tablet supporting drum), vibrating plate and guide track.
- 4.2.3 Clean the dismantled parts hopper, hopper lid, vibrating plate, and feed channel with dry lint free cloth and transfer to washing area in poly bag. Scrub the dismantled parts with a nylon scrubber using purified water. Finally rinse all the cleaned parts with the sufficient amount of purified water.
- 4.2.4 Dry the cleaned parts with a dry lint free cloth.
- 4.2.5 Wipe the dismantled parts with lint free cloth dipped in 70% v/v IPA solution.
- 4.2.6 Remove the perforation tool, indexing roller and punching tool from the machine and clean with dry lint free cloth.
- 4.2.7 Clean the sealing unit with a cooper wire brush followed by dry lint free cloth.
- 4.2.8 Clean the forming, sealing and cooling plate with wet lint free cloth followed by dry lint free cloth, cover with polybag and transfer to the packing change part room.
- 4.2.9 Clean the stereo roller, supporting shafts with thinner followed by dry lint free Cloth.
- 4.2.10 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.
- 4.2.11 Wipe the machine with 70% v/v IPA solution.
- 4.2.12 Reassemble the cleaned hopper, channel and hopper lid.
- 4.2.13 Transfer the guide track; feeding channel, sealing and forming plate to the packing change part room.
- 4.2.14 Replace the 'UNDER CLEANING' status label by "CLEANED" status label with date and sign of the production officer as per SOP.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.2.15 Record the Cleaning Activity 'time' in equipment usage log sheet and clean the area as per SOP.

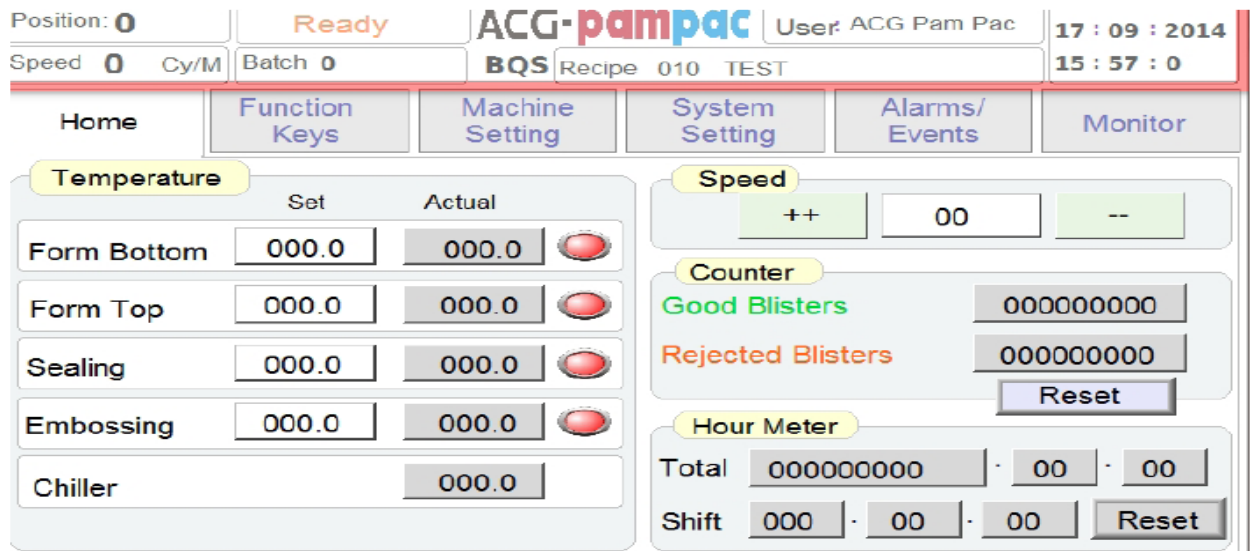
4.2.16 Maintain the cleaning checklist as per Annexure II.

4.3 MMI Setting:

4.3.1 Switch 'ON' the power supply of machine. The below Screen will display-



4.3.2 Press Log In Button. Following screen will be displayed



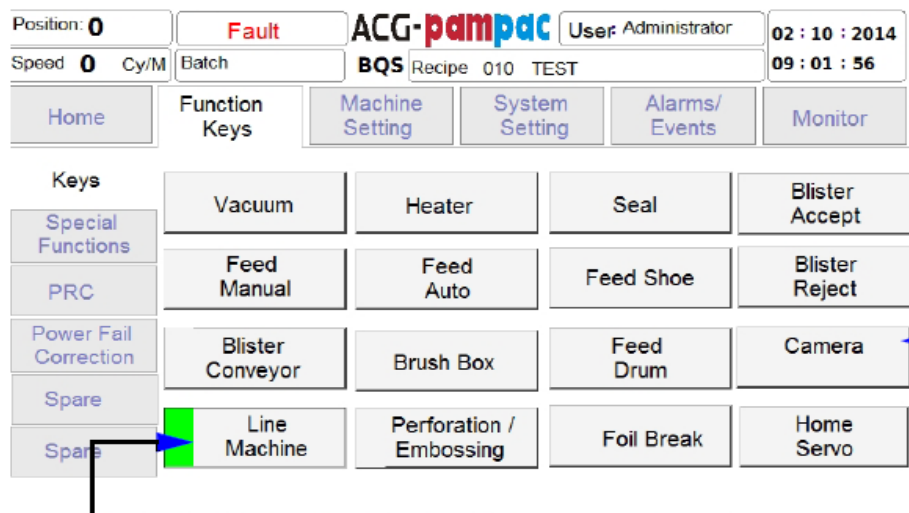
4.3.3 The system will show forming (lower and top) and sealing heater temperature (Set & Actual).



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.3.4 The display showing speed of the machine in cycles / min and Position of machine (0-999 in one cycle).
- 4.3.5 Enter the values for temperature and other by pressing on the respected icon on the screen, a keypad will appear, enter the value and press ENTER key to save.
- 4.3.6 After pressing of Function key the below screen will be displayed-



- 4.3.7 All inputs which are 'ON' are indicated with Green signal, Red signal indicates the input is 'OFF'.
- 4.3.8 On pressing the 'Special function key' in the Main screen, the below will be displayed. Here user can monitor various data / PLC inputs and outputs for operation and information purpose.
- 4.3.9 In special function, various key / parameters can be selected such as Alu-Alu, unseal, chiller supply, joint rejection, print rejection, pinhole rejection. Etc. as per requirement.

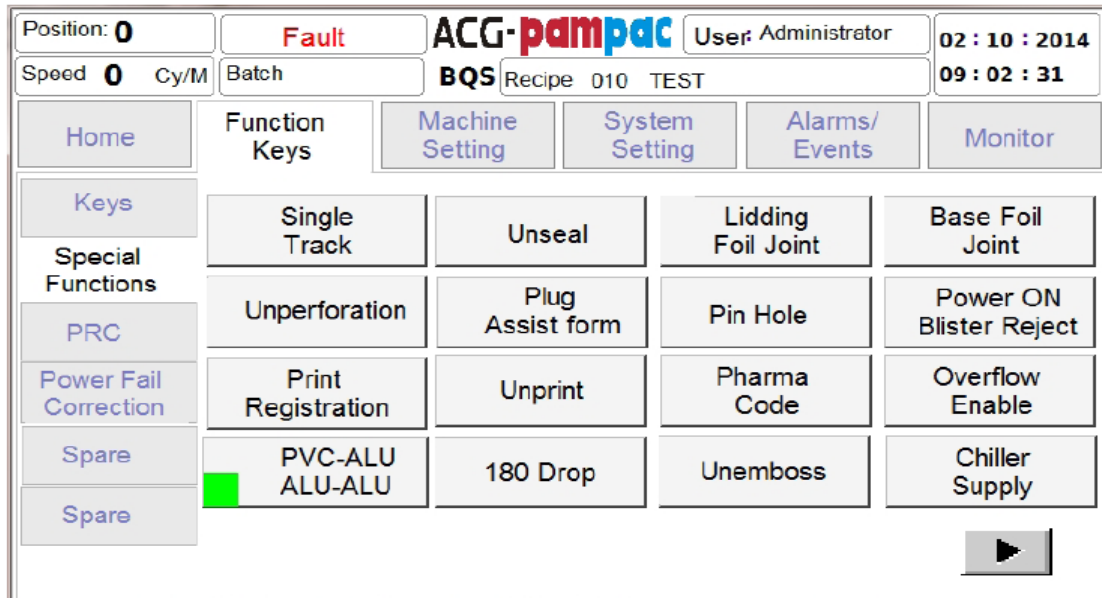


PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

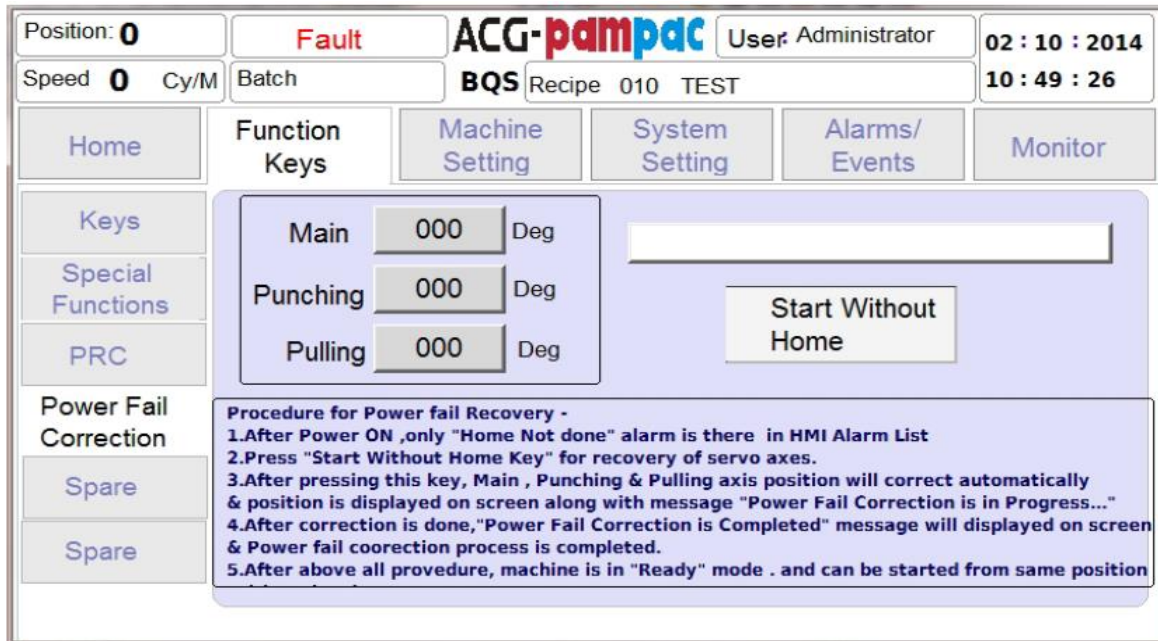


- 4.3.10 'PRC key' in the Main screen is used for basic correction ,PRC correction, Advance (current draw of length of format part in mm)
- 4.3.11 **Power fail correction :** This key in the Main screen is applicable for power fail recovery , press power fail correction and another screen will open which will show "Start without home key" then press this key for recovery of servo axes or to perform correction after power fail as per below screen -



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



- 4.3.12 **Machine setting** :It contains the key for Basic cams, Cyclic cams, User cam, Universal cams, Timers, Recipe, and Manual mode which shall be used as per requirement.
- 4.3.13 **Timers**: This key in the Main screen is applicable for setting of time for different Parameters such as machine off time for unseal, un print, un emboss, conveyor off delay timer, lidding and base foil joint timer etc.
- 4.3.14 **Recipe**: It contains different parameter as per below screen:-



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

Position: 0		ACG-pampac	User: Administrator	02 : 10 : 2014	
Speed 0 Cy/M	Batch	BQS	Recipe 010 TEST	11 : 34 : 20	
Home	Function Keys	Machine Setting	System Setting	Alarms/ Events	Monitor
Basic Cams	Advance (Draw Of Length)		000.00	000.00	
Cyclic Cams	Number of Punch Cycle		00	00	
User Cam	Number of Blister on Feeding Drum		00	00	
Univesal Cams	Number of Blister on Printing Roller		00	00	
Timers	Number Of Tracks		0	0	
Recipe	NFD Offset Count		0	000	
Manual Mode					▶

Position: 0		ACG-pampac	User: Administrator	02 : 10 : 2014	
Speed 0 Cy/M	Batch	BQS	Recipe 010 TEST	12 : 51 : 49	
Home	Function Keys	Machine Setting	System Setting	Alarms/ Events	Monitor
Basic Cams	Base Foil Joint Reject Offset		000	000	
Cyclic Cams	Base Foil Offset For Feeding Stop		000	000	
User Cam	Pin Hole Offset (Rejection)		000	000	
Univesal Cams	Pin Hole Offset For Feed Drum Stop		00	00	
Timers	Unemboss Offset Count		000	000	
Recipe	Pharma Code Reject Offset		000	000	
Manual Mode	◀				▶

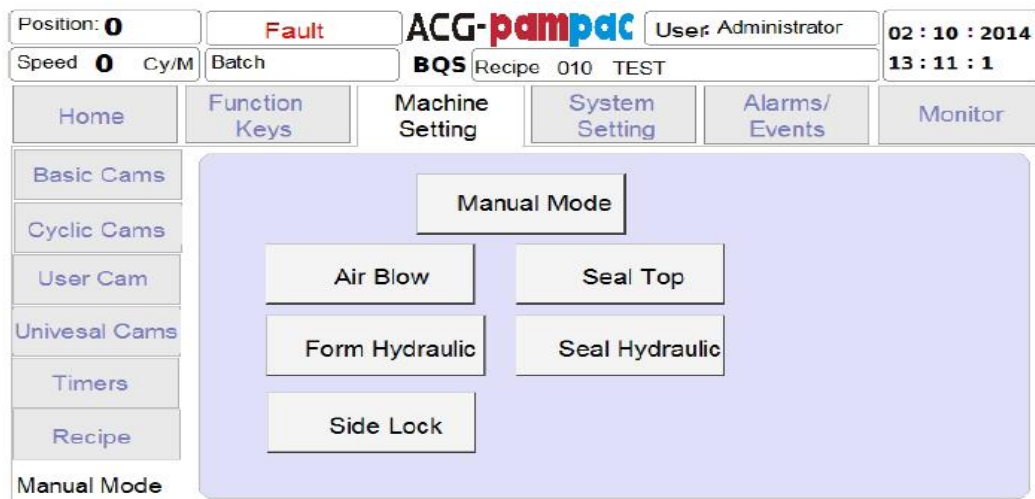
Position: 0		ACG-pampac	User: Administrator	02 : 10 : 2014	
Speed 0 Cy/M	Batch	BQS	Recipe 010 TEST	12 : 56 : 49	
Home	Function Keys	Machine Setting	System Setting	Alarms/ Events	Monitor
Basic Cams	Pinhole Shuttlefeed Offset		000	000	
Cyclic Cams	Pinhole Feedshoe Offset		000	000	
User Cam	Forming Bottom Set Temperature		000.0		
Univesal Cams	Forming Top Set Temperature		000.0		
Timers	Sealing Set Temperature		000.0		
Recipe	▶ 010 : TEST ▶		▶	Load Recipe	
Manual Mode	◀				



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

4.3.15 **Manual Mode:** Manual mode is recommended during change over and trouble shooting. It contains different parameter as per below screen:-



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

4.4.1 Once it is set various change part parameters like Advance (draw of length) and number of punching cycles. User can press RECIPE key to calculate all other parameters.

4.4.2 RECIPE helps to give nearby values for each parameter and 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.

4.4.3 Similarly for other offsets user need to correct as per loop set between pulling and punching station.

4.4.4 Once all parameters are set and functionally tested we can store the data for change part under recipe Press ENTER key to save. Recipe will store data.

4.4.5 If user wants to recall the recipe by putting the number and giving LOAD command all parameters related to that recipe will be loaded.

4.5 OPERATION:

4.5.1 After line clearance from QA, put the “UNDER PROCESS” label on the machine as per SOP before starting of the operation.

4.5.2 Switch “ON” the mains from electrical panel.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.5.3 Ensure the presence of sufficient water in the water cooler tank.
- 4.5.4 Open the valves of the chilled water and compressed air supply of machine.
- 4.5.5 Transfer all the primary packing material in the blister cubicle
- 4.5.6 Transfer all the approved containers to the primary packing cubicle.
- 4.5.7 Switch on the heater and adjust thermostat to provide the heating condition predetermined for the particular product as mentioned in BPR.
- 4.5.8 Record the temperature of forming and sealing units in BPR.
- 4.5.9 Fix printed Aluminium Foil and PVC/PVDC/ALU foil rolls on the machine as per BPR.
- 4.5.10 Apply ink on the inking roller and BCP, add appropriate amount of blister aid for good printing.
- 4.5.11 Affix the approved stereotypes to the stereo drum of the BCP unit as per the instructions given in the BPR.
- 4.5.12 Check the sealing performance, overprinting and cutting of blister. Adjust if required.
- 4.5.13 Affix the specimen of overprinted matter on foil approved by production Officer & QA officer to BPR.
- 4.5.14 Cross checks the weight of individual container from the BMR.
- 4.5.15 charge the tablets into the hopper with a SS basket serially container wise and Perform the leak test as per SOP.
- 4.5.16 Operate the machine as per BPR.
- 4.5.17 Enter the start time and end time of the operation in equipment usage log book as per SOP.
- 4.5.18 Affix 'TO BE CLEANED' label on the machine after completion of activity.

4.6 Precaution:

- 4.6.1 Wear PPE during machine cleaning and operation.
- 4.6.2 Any tablet that would have come in contact with the sealing plate shall be removed and discarded.
- 4.6.3 When the machine is stopped during tea and lunch breaks, it must be ensured that no tablet is retained in feed chute.
- 4.6.4 After the machine is restarted, a few empty blisters shall run initially to ensure the overprinting details are clear and empty blister shall be removed for the line.



STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Procedure for Cleaning and Operation of Blister packing machine (BQS)

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

4.6.5 At the end of working shift, the product left in hopper or vibratory bowl and channel shall be removed, any blister lying on the packing line should also be removed.

5.0 ANNEXURE (S):

Annexure I : Type 'A' Cleaning checklist for blister pack machine (BQS).

Annexure II : Type 'B' Cleaning checklist for blister pack machine (BQS).

6.0 REFERENCE (S):

SOP: Procedure for are line Clearance.

SOP: Status Labeling in Production dept.

SOP: Operation and cleaning and operation of leak test apparatus

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) /DEFINITION (S):

PLC : Programmable logical control.

MMI : Man machine interference.

NFD : Non Filled Detector.

BQS : Blistering Quickly through Servo.

QA : Quality Assurance

BPR : Batch Packing Record

PPE : Personal Protective Equipment.

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---