



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Blister Pack Machine (Rotovac- 210V) with Jekson Camera Inspection System

Effective Date:

Supersedes: Nil

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1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Blister Pack machine (Rotovac- 210V) with Jekson Camera Inspection System.

2.0 SCOPE:

This procedure is applicable to the Cleaning and Operation of Blister Pack machine (Rotovac- 210V) with Jekson Camera Inspection System in the Production Area.

3.0 RESPONSIBILITY:

Technical Associate : Operation
Officer/ Executive Production: Supervision
Head Production : SOP Compliance
IPQA : Line Clearance.

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 same potency.

- 5.1.1 Ensure that all the materials of previous batch are removed from the blister-packing cubicle.
- 5.1.2 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP.
- 5.1.3 Record the cleaning start time in equipment usage log sheet as per SOP.
- 5.1.4 Clean the machine with dry lint free cloth and vacuum cleaner/dust extractor.
- 5.1.5 Clean the chute, hopper, vibration plate, and feeding roller and guide track with a dry lint free cloth.
- 5.1.6 Clean the conveyor belt and hatch with a dry lint free duster.
- 5.1.7 Remove the "TO BE CLEANED" label and affix "CLEANED" label to the machine.

5.2 Record the cleaning end time in the equipment usage log sheet as per SOP "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 a week or after maintenance



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- 5.2.1 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP.
- 5.2.2 Ensure that the power supply, chilled water supply and compressed air supply are put off.
- 5.2.3 Clean the machine surface and product deposit area with dry lint free cloth and vacuum cleaner/dust collector.
- 5.2.4 Dismantle the hopper, hopper view glass, hopper lid, feed chute, feeding roller assembly, vibrating plate and guide track and transfer to washing area in virgin poly bag
- 5.2.5 Finally rinse all the cleaned parts with the 20-30 liters of purified water.
- 5.2.6 Dry the cleaned parts with a dry lint free cloth.
- 5.2.7 Wipe the cleaned dismantled parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.
- 5.2.8 Remove the punching tool from the machine and clean with dry lint free cloth.
- 5.2.9 Place a crate below the forming unit and loosen upper bolt.
- 5.2.10 Remove the upper bolt and allow the water from the forming unit to drain and collect the water in a crate and discard it to washing.
- 5.2.11 Dismantle the forming drum and clean it with dry lint free duster.
- 5.2.12 Dismantle the gears of the batch code printing unit and main gears from the machine.
- 5.2.13 Clean them with dry lint free duster and cover with polybag and transfer to the packing spare cabinet.
- 5.2.14 Clean the sealing unit with a brass brush by applying silicon compound.
- 5.2.15 Clean the inner and outer surface of the machine, control panel and utility lines with a dry lint free cloth.
- 5.2.16 Wipe the machine with 70% v/v IPA solution followed by dry mopping with dry lint free cloth.
- 5.2.17 Clean the conveyor belt and hatch with a dry lint free duster.
- 5.2.18 Reassemble the cleaned hopper, chute and hopper lid.
- 5.2.19 Transfer the guide track, feeding chute to the packing spares cabinet.
- 5.2.20 Replace the "TO BE CLEANED" status label by "CLEANED" status label with date and sign of the production officer as per SOP.
- 5.2.21 The cleaned equipment is idle for 72 hours, after this period wipe all the machine and parts with 70% v/v IPA solution before use. Previous "CLEANED" label shall be counter signed by production & QA officer with date as per SOP.
- 5.2.22 Record the cleaning operation time in equipment usage log sheet as per SOP and check the cleaning activity as per Annexure- I.
- 5.2.23 Clean the area as per SOP.



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5.3 Cleaning for Camera:

- 5.3.1 Clean the control panel with dry lint free cloth.
- 5.3.2 Clean the product deposited area on top, bottom, inner and outer surface by dry lint free cloth.

5.4 OPERATING PROCEDURE (Blister Packing Machine)

- 5.4.1 Ensure the area and equipment is clean. Affix 'UNDER PROCESS' label duly filled and signed on the machine and record all the observations in the equipment usage log sheet as per SOP.

5.4.2 Equipment setting

- 5.4.2.1 It consists of two set of reel support, reel fastening screw, reel adjusting screw, one PVC/PVDC foil sensor and one aluminium foil sensor all activities controlled by PLC.

5.4.3 Loading of foil (PVC / PVDC and Aluminium foil)

- 5.4.3.1 Unscrew the reel fastening screws.
- 5.4.3.2 Adjust the back level control screw according to the width of forming foil.
- 5.4.3.3 Load forming material in such a manner that it should unwind in clockwise direction.
- 5.4.3.4 Tighten reel-fastening screw.

5.4.4 Changing of PVC/PVDC foil

- 5.4.4.1 Unscrew the reel fastening screws.
- 5.4.4.2 Mount the foil by reel fastening screw and tight it.
- 5.4.4.3 End edges of wave are joints with edge of mounted roll and wrap them by cello tape.

5.4.5 Procedure for fixing forming die

- 5.4.5.1 Switch OFF the machine, PHR will lift up side.
- 5.4.5.2 Unscrew the centering bolt and fix the forming die on shaft guiding.
- 5.4.5.3 Tighten the forming die with screw in the star knob bolt till the almost reaches the face of the roller.

5.4.6 Procedure for fixing Counter sealing Die

- 5.4.6.1 Switch OFF the machine, PSR will lift up sides.
- 5.4.6.2 Counter sealing die is directly mounted on sealing station shaft
- 5.4.6.3 Clamped / tight with a close tolerance hub.



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5.4.7 **Tablet feeding station:**

5.4.7.1 It consists of hopper, vibrator, tablet level sensing proxy and sweep brush, feeding channel, universal feeder.

5.4.7.2 Speed of all vibrators is controlled independently by the controller provided in operator panel.

5.4.8 **Procedure for fixing of PHR:**

5.4.8.1 Isolate the supply to the machine.

5.4.8.2 Loosen the bracket- clamping screw.

5.4.8.3 Fix the PHR assembly through tightens bracket-clamping screw.

5.4.8.4 Tilt the heater towards BFR and maintain gap 2-4mm (approx).

5.4.8.5 Switch on the machine.

5.4.9 **Procedure for fixing PSR**

5.4.9.1 Isolate the supply to the machine.

5.4.9.2 Loosen the bolt of mounting bracket.

5.4.9.3 Hold pressure sealing roller assembly with right hand under the alignment bracket.

5.4.9.4 Lift the assembly above the CSR and gently introduce the mounting bracket in to the main shaft.

5.4.9.5 Fix the PSR assembly through tightens bracket-clamping screw.

5.4.9.6 Hold the PSR and gently allow lowering on to the CSR after the clamps maintain a gap of 5-7mm approx.

5.4.10 **Embossing tool**

5.4.10.1 It consists of double electric crank, driven motor, servomotor, servomotor driven indexing roller, sucking arms and web guide register roller and punch, Safety sensor. It is situated below perforation station and process done by pneumatically controlled by PLC.

5.4.11 **Operation**

5.4.11.1 After line clearance from QA, put the " UNDER PROCESS" label on the machine.

5.4.11.2 Enter start time of the machine in equipment usage log sheet as per SOP.

5.4.11.3 Switch "ON" the mains from electrical panel.

5.4.11.4 Blister packing of tablet shall be carried out in controlled area Temp = $22^{\circ}\text{C} \pm 3^{\circ}\text{C}$ and RH $50 \pm 5\%$ or as per the BPR of the product.

5.4.11.5 Switch on the heater and adjust thermostat to provide the heating condition predetermined for the particular product as per mention in BPR.



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- 5.4.11.6 Fix printed aluminium foil and PVC/PVDC foil rolls on the machine as per BPR.
- 5.4.11.7 Record the temperature of forming and sealing units in BPR.
- 5.4.11.8 Fill the inkpot into the overprinting kit of the machine with requisite height.
- 5.4.11.9 Affix the approved stereos/metal letters to the stereo drum of the BCP.
- 5.4.11.10 Unit/Embossing unit as per the instructions given in the BPR.
- 5.4.11.11 Check the sealing performance, overprinting/embossing and cutting of strips and adjust if required.
- 5.4.11.12 Affix the specimen of overprinted/embossed matter approved by production Officer and QA Officer to BPR.
- 5.4.11.13 Cross check the containers of the product to be blistered are having 'APPROVED' Status label.
- 5.4.11.14 Cross check the weight of the product and record the total weight of the product on packing BPR.
- 5.4.11.15 Load the product to be blistered in the hopper, cover with lid and start the machine.
- 5.4.11.16 Machine to run the machine through PLC as follows.

5.4.12 Operation of PLC as per following instructions:

5.4.12.1 Switch "ON" the main switch

5.4.12.2 MMI shows

Print	Alarm list	Login
Switch	Recipe	Log out
Product data	PLCI/O	Help

5.4.12.3 Press log in and enter password.

5.4.12.4 Then press switch, MMI shows

- Run mode/JOG Mode
- Vib. (Auto/Manu)
- PSR (ON/OFF)
- Embossing (on/off)
- PRC (ON/OFF)
- NFD (Active/ Bypass)
- Spice Activate
- Guard (Active/ Bypass)
- PHR (ON/OFF)
- Heater Bypass
- PRC-PRO
- NFDS head
- CE (Active/ Bypass)
- Clock Drift Enable

5.4.12.5 Press production data switch for editing of product detail like name /B. No. Mfd. and Exp. then screen display

- Good blister
- Machine run time
- Machine alarm stop
- Rejected blister
- Machine stop time
- Operator name



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- B. No.
- Mfd.date
- Exp.date
- Reset production data

5.4.12.6 Press Recipe for Edit, Save and Load, screen shows

- Current Recipe
- Load Recipe
- Edit and save Recipe
- Delete Recipe
- Display Recipe

5.4.12.7 Press display for setting of parameter like NFD count, No. of track, channels per track, CE error count, rejection enable count.

5.4.12.8 Pack release delay, PRC count etc.

5.4.12.9 Affix 'TO BE CLEANED' label on the machine and record all the observations in the equipment usage log sheet as per SOP.

5.5 OPERATION & SETTING OF CAMERA INSPECTION SYSTEM (JEKSON):

5.5.1 Switch on the main power supply of the machine from the panel and it will take 3 minutes to open the screen.

5.5.2 Then select Blister inspection system in upper right side of the screen and a new screen will be displayed as given below.



5.5.3 This is the main screen displayed whenever user starts the BIS-NXG application. Login using the credentials provided.



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5.5.4 Login:

5.5.4.1 System show 3 types of login levels and they have a specific right assignment.

5.5.4.2 Following tables given below according to user rights:

S.No.	FUNCTION	Meaning of Function	OPERATOR	SUPERVISOR	ADMINSTR- ATOR
1.	Camera Setting	Access the Camera Setting to obtain best image of object.	-----	YES	YES
2.	Machine Rejection Count	No. of blister count required for machine to reject During running	-----	YES	YES
3.	Camera Teaching	For new product, this option will open "TEACHING WIZARD" which gives various option for teaching process to blister format.	-----	YES	YES
4.	Tolerance Setting/Stimulation	For better result User has to simulate the model by selecting the "SIMULATE".	YES	YES	YES
5.	Model Name	Each saved recipe of product given unique name.	-----	YES	YES

5.5.4.3 To start the application, login using a username and password

5.5.4.4 For touch screen monitors, double click on the text boxes to open an on-screen keyboard

5.5.4.5 Then click on the Accept button to start application.

5.5.4.6 The main screen shows the list of existing models stored in the database with their properties and various buttons that can be used to perform different operations.

5.5.4.7 Turn Off: This button allows to shutdown the system.

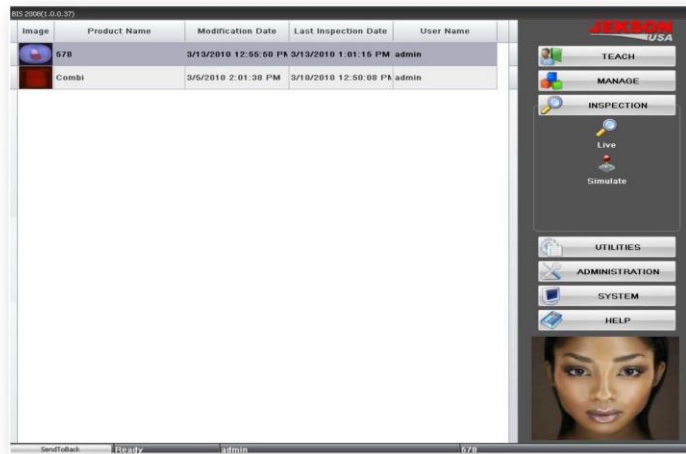


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5.5.4.8 One of the models can be selected to perform operations like “MANAGE” or “INSPECTION”. Other buttons like “TEACH”, “UTILITIES”, etc. perform additional operations. Detailed functionality of each button is explained in below sub-sections.

5.5.5 Teach

5.5.5.1 Use the **TEACH** Group to teach a new model or product.

5.5.5.2 **Teaching Wizard:** Touch Teaching Wizard to start teaching process for the new model.

5.5.6 Manage

5.5.6.1 Model management includes features like rename and delete.

5.5.7 **Rename:** This operation allows renaming the existing model name.

5.5.8 **Delete:** This operation allows deleting the existing model name.

5.5.9 Inspection

5.5.9.1 Use **INSPECTION** group to inspect using existing models stored in the system.

5.5.9.2 **Live:** This operation allows to start inspection for the selected model or newly created model.

5.5.9.3 **Simulate:** This operation allows user to simulate inspection using the selected model or newly created model.

5.5.9.4 **Note:** To perform **Live** or **Simulate** operation, must select one model from the stored list.

5.5.10 Utilities

5.5.10.1 User can use **UTILITIES** group to access various system tools.

5.5.10.2 **Version Info:** This utility allows user to view version information of all supported software and control system used in BIS NXG.

5.5.10.3 **Device Manager:** Device manager utility allows user to open device manager of vision control system.



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5.5.11 System

5.5.11.1 User can Shutdown or Restart the BIS NXG system or can access the desktop using the controls provided in **SYSTEM** group.

5.5.11.2 **Shutdown:** Clicking this button initiates system shutdown process.

Restart: Clicking this button initiates system restart process.

5.5.11.3 **Maintenance:** Clicking this button initiates system desktop access process. To access the desktop user must enter a password and load a data file provided by Jekson USA support team.

5.5.12 Administration

5.5.12.1 User can use **ADMINISTRATION** group to access the system administration tools. Most of the utilities in this group require administrative privilege to use them.

5.5.13 Troubleshoot and Machine Settings.

5.5.13.1 **Camera Setting:** This option allows user to access camera settings to obtain best image of the product.

5.5.13.2 **Change Camera:** This option allows user to set appropriate camera with the application or to change/replace the existing camera (in case of any breakdown).

5.5.13.3 **Help:** User can use **HELP** utility to open various help documents and video tutorials which can assist the user through various operation.

5.5.13.4 **Getting Started:** Clicking this button will open the basic help document to understand the basics of the BIS NXG system.

5.5.13.5 **Operation Manual:** This allows user to access complete operation manual.

5.5.13.6 **Wiring Diagram:** Clicking this button will open wiring diagrams of all IO's.

5.5.13.7 **FAQ:** This will open the list of frequently asked questions. These questions-answers will help operators in basic troubleshooting.

5.5.13.8 **Video Tutorial:** Video Tutorial will give an overview of the system and will assist the user in using different functions of the BIS NXG system.

5.6 TEACHING PROCESS:

5.7 Teaching a Tablet

5.7.1 Grabbing a good Image for teaching a new product

5.7.2 Click on either Grab Once to acquire a single image or Trigger Grab to acquire images continuously when machine is running.

5.7.2.1 Click on **Grab Once** button to take immediate image.

5.7.2.2 Once proper image is acquired, click **Close** button to close current progress and return to main menu.



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5.7.2.3 Click on **Next** button to go to next step of teaching process.

5.7.2.4 Click on **Back** button to go to the previous step.

5.7.3 **Drawing an AOI (area of interest):**

5.7.3.1 Draw an AOI (Area of interest) to specify teaching area.

5.7.3.2 Fine-tune the AOI rectangle using left/right or up/down moving buttons

5.7.3.3 Use this button to move AOI to left/right or up/down

5.7.3.4 Resize the AOI by clicking on the central button. The size will get changed in diagonal direction and user can fine-tune it with left/right or up/down arrows.

5.7.3.5 Click on Previous Image button to view last 10 images.

5.7.3.6 Click on Next Image button to see next image.

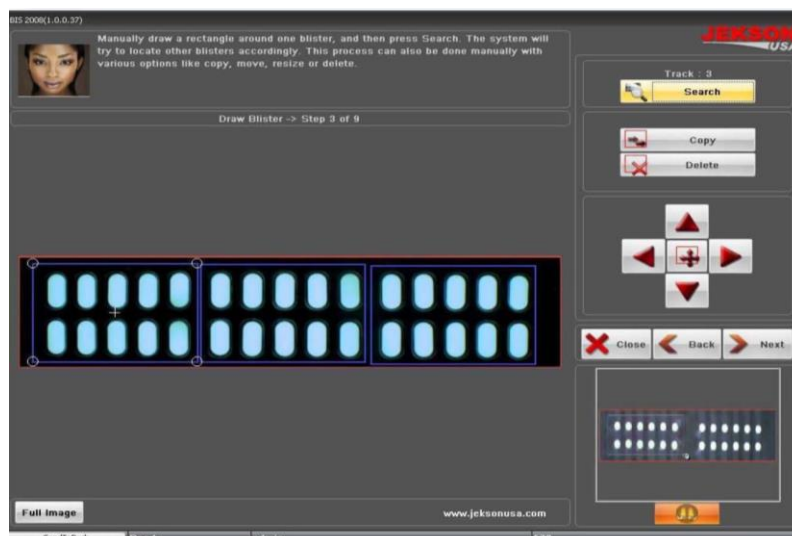
5.7.3.7 Click on Delete button to delete already drawn AOI.

5.7.3.8 After deleting previous AOI, user can draw new AOI.

5.7.3.9 Once AOI is drawn, click on Next to go to next page

5.7.4 **Drawing blisters:**

5.7.4.1 User can draw tracks as per machine mechanism.



5.7.4.2 User should draw only one track and then can use Search” button to find and draw all remaining tracks. Jekson vision application can automatically find all available tracks using one track.

5.7.4.3 Click on **Copy** button to copy any track which can be put on specific blister/track if the application cannot find all the blisters/tracks automatically.



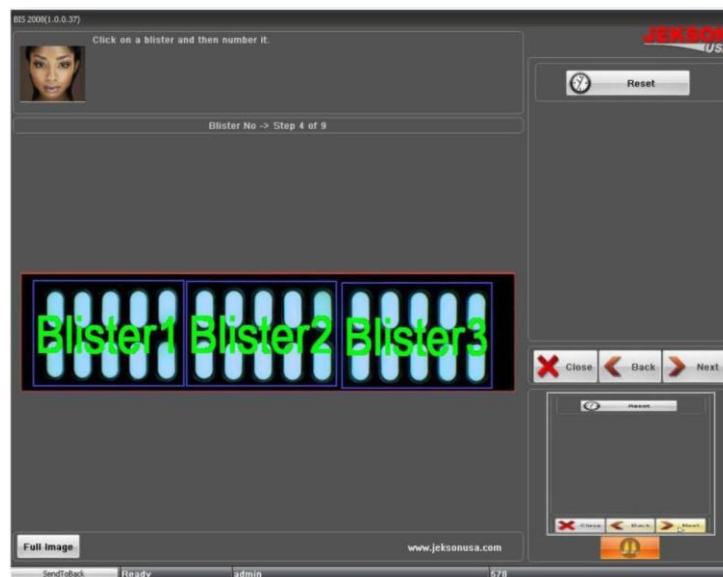
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- 5.7.4.4 Click on **Delete** button if the system draws any blisters in inappropriate area. User should first click on **Delete** button and then should select the blister.
- 5.7.4.5 User can resize the track by clicking on the central button in above image. The size will get changed in diagonal direction and user can fine-tune it with left/right or up/down arrows. The machine will reject the same blister as specified by the vision application, for example – if the vision application rejects blister – 2 then machine will give rejection on track – 2 only.
- 5.7.4.6 To specify blister number user should click on blisters and select one of the numbers from the popup list.



- 5.7.4.7 User can click **Reset** button to reset current blister numbers. Clicking on **Next** button will take the user to the next step of teaching.
- 5.7.5 **Drawing a cavity (pocket):**
- 5.7.5.1 User should draw exact pocket on the cavity to identify the objects. Then click on **Done** button to go to the next page.

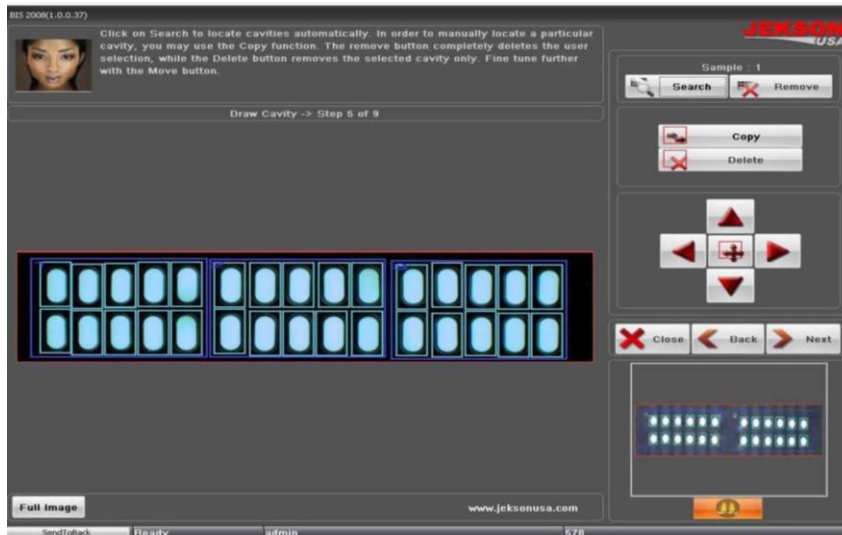


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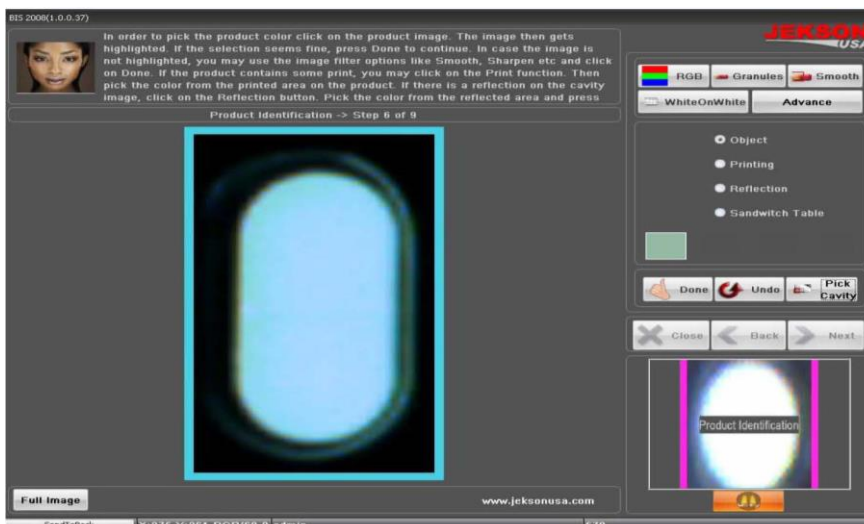
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- 5.7.5.2 User should click on **Search** button to automatically search remaining pockets in all the blisters.
- 5.7.5.3 If application cannot search all the pockets automatically, then user can click on **Copy** button to copy and place it on to actual pocket
- 5.7.5.4 User can use **Delete** button to delete the pockets which do not require.
- 5.7.5.5 User can use the below shown buttons to move the cavity (pocket) to left/right or up/down.
- 5.7.5.6 User can resize the cavity (pocket) by clicking on the central button in above image. The size will get changed in diagonal direction and user can fine-tune it with left/right or up/down arrows.
- 5.7.5.7 User can navigate to next page by clicking on **Next** button.

5.7.6 Product identification:

- 5.7.6.1 To pick the product color user should click on the product in image area.





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- 5.7.6.2 Vision application will automatically decide the threshold value and will grow a region on the product
- 5.7.6.3 If the region grown is proper then user can click on **Done** button to continue to next step.
- 5.7.6.4 If the region is not grown properly then user can apply different image filters as explained below.
- 5.7.6.5 **RGB/HSL:** This option helps user to select proper object when object and back ground color has less contrast (i.e. color difference between object and background is less) or if object has some reflection.
Note: Selecting RGB gives better result often, but if object color and back ground color is in contrast then HSL can give better result.
- 5.7.6.6 **White on White:** This option helps user to select proper object color when both – object and its back ground – are White.
- 5.7.6.7 **Smooth:** This option will be help in selecting better threshold value for the object having distorted shape
- 5.7.6.8 **Granules:** This option is for capsules containing granules.
- 5.7.6.9 **Advance:** Advanced filtering option
Note: Never use **HSL** for White object, it provides better result in **RGB**. Always Select **Smooth** with **HSL** for better results.
- 5.7.6.10 **Teaching Options:** Various teaching options for different products are explained below
- Object:** For object color selection.
 - Printing:** For print color selection. User should use this option after object color selection.
 - Reflection:** For Reflection color selection. User should use this option after object color selection.
 - Sandwich Tablet:** To select second color of the object. This option is useful only for tablets of sandwich type. User should use this option after object color selection.
 - Click on **Done** to move on to next step.
- 5.7.7 **Threshold value selection**
- 5.7.7.1 Click on **Fine-tune** button in case if the region is not grown properly for a specified threshold value.
- 5.7.7.2 User can manually set Threshold value by changing **Threshold Low** or **Threshold High**.
- 5.7.7.3 Click on **Next** button to go to the next step of teaching process.
- 5.7.7.4 Click on **Next** button to go to the next step of teaching process.
- 5.7.7.5 Click on **Next** button to go to the next step of teaching process
- 5.7.7.6 **Sample Selection:** This button allows user to select the particular object (sample) for processing. This operation is mainly used when combi pack Tablets and/or capsules are used.
- 5.8 Teaching a Capsule**



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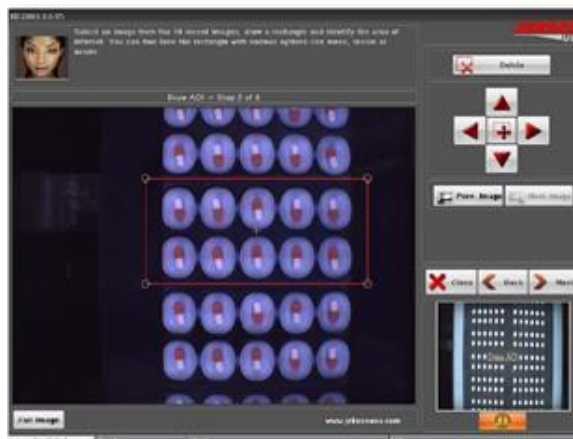
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- 5.8.1 Click on Trigger Grab button to take image while machine is in running mode. Camera will take the image when triggered by input pulse of the machine.
- 5.8.2 Click on Grab Once button to take immediate image



- 5.8.3 **Drawing an AOI**
- 5.8.3.1 User must draw an AOI (Area of interest) to specify teaching area.
- 5.8.3.2 User can fine-tune the AOI rectangle using left/right or up/down moving buttons.



- 5.8.3.3 User can resize the AOI by clicking on the central button in above image. The size will get changed in diagonal direction and user can fine-tune it with left/right or up/down arrows.
- 5.8.3.4 Click on Previous Image button to view last 10 images
- 5.8.3.5 Click on Next Image button to see next image.
- 5.8.3.6 Click on Delete button to delete already drawn AOI.
- 5.8.3.7 After deleting previous AOI, user can draw new AOI.
- 5.8.3.8 Once AOI is drawn, click on Next to go to next page.



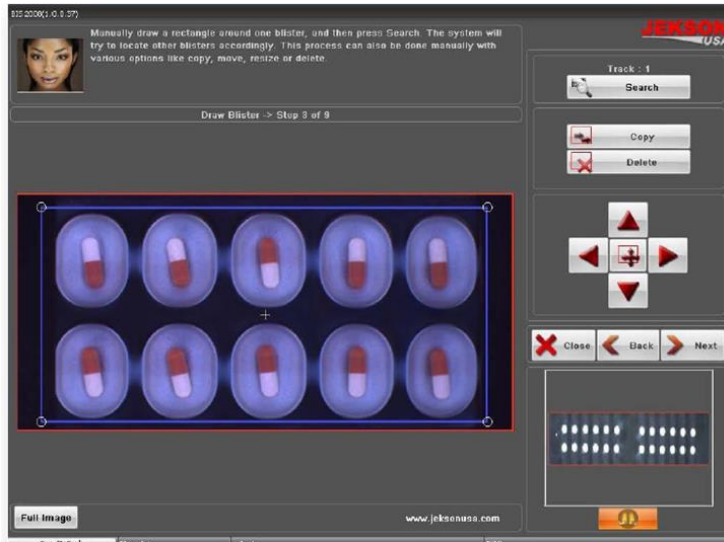
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5.8.4 Drawing blisters



- 5.8.4.1 User can draw tracks as per machine mechanism.
- 5.8.4.2 User should draw only one track and then can use Search” button to find and draw all remaining tracks. Jekson vision application can automatically find all available tracks using one track.
- 5.8.4.3 Click on Copy button to copy any track which can be put on specific blister/track if the application cannot find all the blisters/tracks automatically.
- 5.8.4.4 Click on Delete button if the system draws any blisters in inappropriate area. User should first click on Delete button and then should select the blister.
- 5.8.4.5 User can resize the track by clicking on the central button in above image. The size will get changed in diagonal direction and user can fine-tune it with left/right or up/down arrows.

5.8.5 Setting blister numbers





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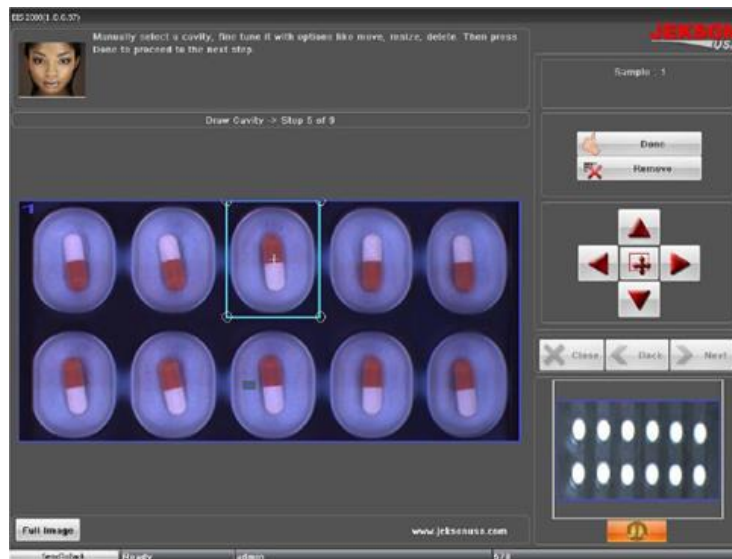
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- 5.8.5.1 On this page, user has to specify blister numbers as per machine requirement (in any order).
- 5.8.5.2 The machine will reject the same blister as specified by the vision application, for example – if the vision application rejects blister – 2 then machine will give rejection on track – 2 only.
- 5.8.5.3 To specify blister number user should click on blisters and select one of the numbers from the popup list.
- 5.8.5.4 User can click Reset button to reset current blister numbers. Clicking on Next button will take the user to the next step of teaching.

5.8.6 Drawing a cavity (pocket)



- 5.8.6.1 User should draw exact pocket on the cavity to identify the objects. Then click on Done button to go to the next page.
- 5.8.6.2 User should click on Search button to automatically search remaining pockets in all the blisters.
- 5.8.6.3 If application cannot search all the pockets automatically, then user can click on Copy button to copy and place it on to actual pocket.
- 5.8.6.4 User can use Delete button to delete the pockets which do not require.
- 5.8.6.5 User can resize the cavity (pocket) by clicking on the central button in above image. The size will get changed in diagonal direction and user can fine-tune it with left/right or up/down arrows.
- 5.8.6.6 User can navigate to next page by clicking on Next button.
- 5.8.6.7 In a blister, some capsules may have inverted orientation (as shown in above image). Jekson vision application automatically detects such capsules and draws the cavities.



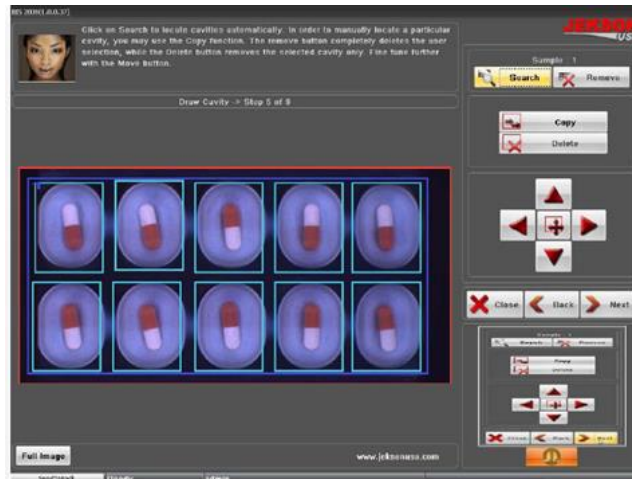
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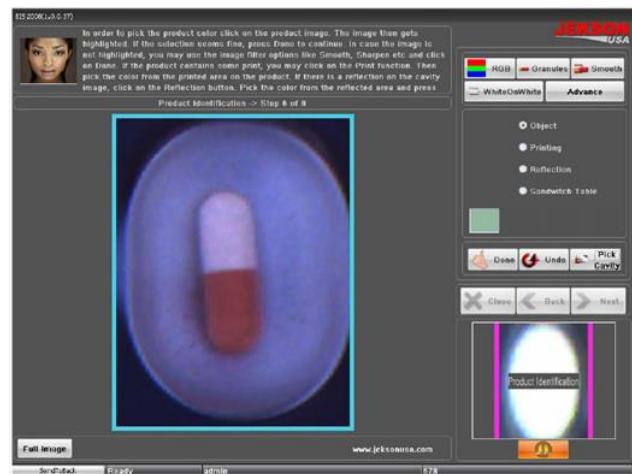
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5.8.6.8 Below image shows the Draw Cavity page with all cavities drawn.



5.8.7 Product identification



- 5.8.7.1 To pick the product color user should click on the product in image area.
- 5.8.7.2 Vision application will automatically decide the threshold value and will grow a region on the product.
- 5.8.7.3 If the region grown is proper then user can click on **Done** button to continue to next step.
- 5.8.7.4 If the region is not grown properly then user can apply different image filters as explained below.
 - a) **RGB/HSL:** This option helps user to select proper object when object and back ground color has less contrast (i.e. color difference between object and background is less) or if object has some reflection. [Note: Selecting RGB gives better result often, but if object color and back ground color is in contrast then HSL can give better result.]
 - b) **White on White:** This option helps user to select proper object color when both – object and its back ground – are White.



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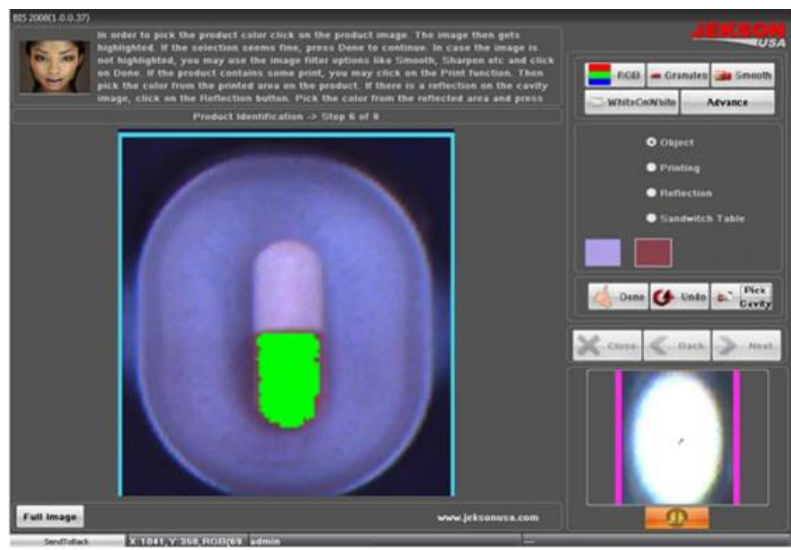
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- c) **Smooth:** This option will help in selecting better threshold value for the object having distorted shape.
- d) **Granules:** This option is for capsules containing granules.
- e) **Advance:** Advanced filtering option.

[**Note:** Never use **HSL** for White object, it provides better result in **RGB**. Always Select **Smooth** with **HSL** for better results.]

Below image shows the product with grown region based on selected threshold value.



- 5.8.7.5 **Teaching Options:** Various teaching options for different products are explained below.
- 5.8.7.6 **Object:** For object color selection.
- 5.8.7.7 **Printing:** For print color selection. User should use this option after object color selection.
- 5.8.7.8 **Reflection:** For Reflection color selection. User should use this option after object color selection.
- 5.8.7.9 **Sandwich Tablet:** To select second color of the object. This option is useful only for tablets of sandwich type. User should use this option after object color selection.
- 5.8.7.10 Click on **Done** to move on to next step.

- 5.8.8 **Threshold value selection**
- 5.8.8.1 Click on **Fine-tune** button in case if the region is not grown properly for a specified threshold value.



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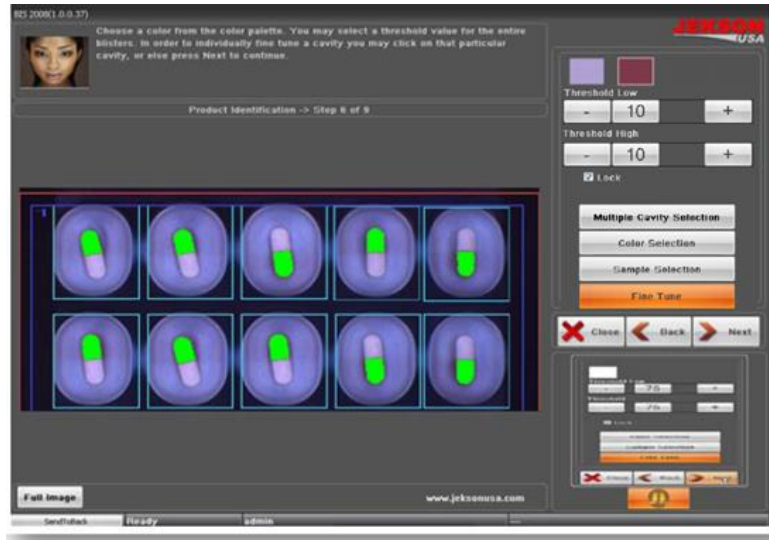
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- 5.8.8.2 User can manually set Threshold value by changing Threshold Low or Threshold High.
- 5.8.8.3 Click on Next button to go to the next step of teaching process.
- 5.8.8.4 Color Selection: This operation allows user to teach multi color object. User should select each object color separately. User should select the other color of the capsule and follow the steps mentioned in Product identification subsection.
- 5.8.8.5 Sample Selection: This button allows user to select the particular object (sample) for processing. This operation is mainly used when combi pack Tablets and/or capsules are used.
- 5.8.8.6 Multiple Cavity Selection: This button allows user to select multiple cavity at once to fine tune that particular cavities.
- 5.8.9 **Teaching an empty cavity**
- 5.8.9.1 User should acquire image of empty cavities using **Grab Once** or **Trigger Grab**.
- 5.8.9.2 After selecting the proper image user should click on **Next** button to go to the next step of teaching.
- 5.8.10 **Tolerance settings/simulation**
- 5.8.10.1 For better inspection results user has to simulate the model by Clicking on Simulate button using which user can verify the acceptance and rejection results.
- 5.8.10.2 After Simulate operation if there is rejection for any pocket or blister having proper product, then user can set appropriate tolerance settings such that the pocket or blister can be accepted by vision system. Detailed explanation is given as Tolerance settings in Settings section.
- 5.8.10.3 User can select the cavity, blister or AOI to apply modified tolerance settings
- 5.8.10.4 Click on Next button to go to the final step of teaching.



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5.8.11 Saving a model

- 5.8.11.1 To save the teaching model user should give unique model name and model description.
- 5.8.11.2 Clicking on **Finish** button will save the model.

5.8.12 Challenge test

- 5.8.12.1 For performing Challenge test, pass one blister each without tablet, broken tablet, and multiple tablets in blister or empty blister.
- 5.8.12.2 Mark the identified blister with marker after the sealing to evaluate the challenge test at rejection chute.
- 5.8.12.3 Ensure that machine rejects the blister
- 5.8.12.4 Carry out the challenge test of the camera at the start of batch or any major stoppage and every 4 hrs.
- 5.8.12.5 Record the details in the BPR or format as apply.

5.9 Precaution

- 5.9.1 **Action at the time of machine stoppage during operation:** At the time of machine stoppage the blister with product under the sealing roller should be cross marked with marker pen and removed manually at conveyor belt and treated as rejected blisters and tablets.

Procedure of marking of blisters: For marking of blisters after stoppage, run the machine and marked the identified blister on the web (at lidding foil side) for proper identification and the same blister shall be collected from the conveyor belt after cutting of blisters at the cutting station.

- 5.9.2 When the machine is stopped during roll change, tea, lunch breaks and shift change over it must be ensured that no tablet/product is retained in blister web.
- 5.9.3 After the machine is restarted, a few empty blisters should run initially to ensure the overprinting details are clear. Empty blister should be removed for the line then packing started.
- 5.9.4 At the end of working shift the product left in hopper or vibratory bowl and channel should be removed, any blister lying on the packing line should also be removed.

6.0 ABBREVIATION (S):

- PVC : Poly vinyl chloride
- v/v : Volume/ Volume
- IPA :Isopropyl alcohol
- MMI : Main machine interference
- PLC : Programmable logical Control



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PIR : Punch index roller
PRC : Print rejection control
NFD : Non Fill Detector

7.0 REFERENCE (S):

SOP: Making entries in equipment usage and cleaning log sheet.
SOP: Cleaning of production area.
SOP: Status Labeling

8.0 ANNEXURE (S):

Annexure – I: Cleaning Checklist of Blister pack machine (ROTOVAC 210V)
Annexure – I: Challenging test for camera operation

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

CLEANING CHECKLIST OF BLISTER PACK MACHINE (ROTOVAC- 210V) WITH JEKSON CAMERA INSPECTION

Name of the Equipment		BLISTER PACK MACHINE (ROTOVAC 210V)	
Equipment I.D. No.		Previous	
Batch No.		Date	
S.No.	Activity	Activity Performed	
1.	Clean the machine surface and product deposit area with dry lint free cloth and vacuum cleaner/dust extractor.		
2.	Dismantle the hopper, hopper view glass, hopper lid, feed chute, feeding roller assembly, vibrating plate and guide track and transfer to washing area in fresh poly bag.		
3.	Flush the dismantled parts with purified water sufficient to remove powder. To remove the adhered particulate scrub the parts with nylon brush using purified water. NOTE: 2% Sodium Lauryl Sulphate (SLS) solution shall be used for scrubbing with nylon brush if API is Efavirenz before final rinsing of equipment/parts.		
4.	Finally rinse all the cleaned parts with the 10-20 liters of purified water.		
5.	Dry the cleaned parts with a dry lint free duster.		
6.	Wipe the cleaned dismantled parts with 70% v/v IPA solution followed by mopping with dry lint free cloth.		
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.	Remove the upper bolt and allow the water from the forming unit to drain and collect the drained water in the crate and discard it in washing area.		
10.	Dismantle the forming drum and clean it with dry lint free cloth.		
11.	Dismantle the gears of the batch code printing unit and main gears from the machine.		
12.	Clean them with dry lint free cloth and cover with polybag and transfer to the packing spare cabinet.		
13.	Wipe the machine surface and guide with 70% v/v IPA solution.		
14.	Clean the conveyor belt and hatch with a dry lint free duster.		
15.	Clean the control panel of camera with dry lint free cloth & clean the product deposited area on top, bottom, inner and outer surface by dry lint free cloth		

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

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date



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ANNEXURE II

CHALLENGING TEST FOR CAMERA OPERATION ON BLISTER PACK MACHINE

BLISTER MACHINE ID.:

PRODUCT NAME:

BATCH No.

DATE	TIME	WITHOUT TABLET/CAPSULE#	WITH BROKEN TABLET#	MULTIPLE TABLETS/CAPSULES #	EMPTY BLISTER#	DONE BY (Prod.)	CHECKED BY (QA)

Write Ok Or Not OK

OK: If camera Reject the defective blister.

Not OK: If Camera accepts the defective blister.

Frequency: Carry out the challenge test of the camera at the start of batch or any stoppage and every 4 hrs.