



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Blister-Pack Inspection System (Make: Jekson)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 **OBJECTIVE:**

To lay down a procedure for cleaning and operation of Blister pack inspection system.

2.0 **SCOPE:**

This procedure is applicable for cleaning and operation of blister pack inspection system installed in blister packing machine in production department.

3.0 **RESPONSIBILITY:**

3.1 **Technical Associate- Production Department**

3.1.1 To operate and clean the blister pack inspection system as per procedure mentioned.

3.2 **Officer and Executive – Production Department**

3.2.1 To check and ensure the operation & cleaning of the blister pack inspection system as per procedure.

Head – Production Department

3.3 To ensure the compliance of SOP.

3.3.2 To ensure the training of concerned personal.

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

5.1.2 Switch “OFF” all the main electricity supply before cleaning.

5.1.3 Clean the control panel with clean and dry lint free cloth.

5.1.4 Clean the top and outer surface of blister pack inspection system with the dry lint free cloth.

5.1.5 Affix status Label “CLEANED” status label on the machine with date and sign of the production officer.

5.1.6 Record the cleaning activity in equipment usage log of machine as per SOP.

5.2 **TYPE B CLEANING:**



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

- 5.2.1 Remove “UNDER PROCESS “label and affix “TO BE CLEANED “label on the machine with date and sign of the production officer.
- 5.2.2 Switch OFF all the utility supply before cleaning.
- 5.2.3 Clean the control panel with clean and dry lint free cloth.
- 5.2.4 Clean the top and outer surface of panel with the dry lint free cloth. Followed by moping with 70 % w/w IPA solution and dry with dry lint free cloth.
- 5.2.5 Affix status Label “CLEANED” status label on the machine with date and sign of the production officer.
- 5.3 **OPERATION**
 - 5.3.1 Switch on the main power supply of the machine from the panel and it will take 3 minutes to open the screen.
 - 5.3.2 Then select **Blister inspection system** in the screen and a new screen will be displayed as given below.





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Or as



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

5.3.3.1 **Login:**

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

5.3.3.3 Following tables given below according to user rights.

S.N.o	FUNCTION	Meaning of Function	OPERATOR	SUPERVISOR	ADMINSTR-ATOR
1	Camera Setting	Access the Camera Setting To Obtained 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 stimulate the model by selecting the "STIMULATE".	-----	YES	YES
5	Model Name	Each saved recipe of product given unique name.	YES	YES	YES
6	Date and Time	For Date and time setting	-----	-----	YES
7	User Profile	For addition and deletion of user	-----	-----	YES

5.3.3.4 To start the application, login using a username and password.

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



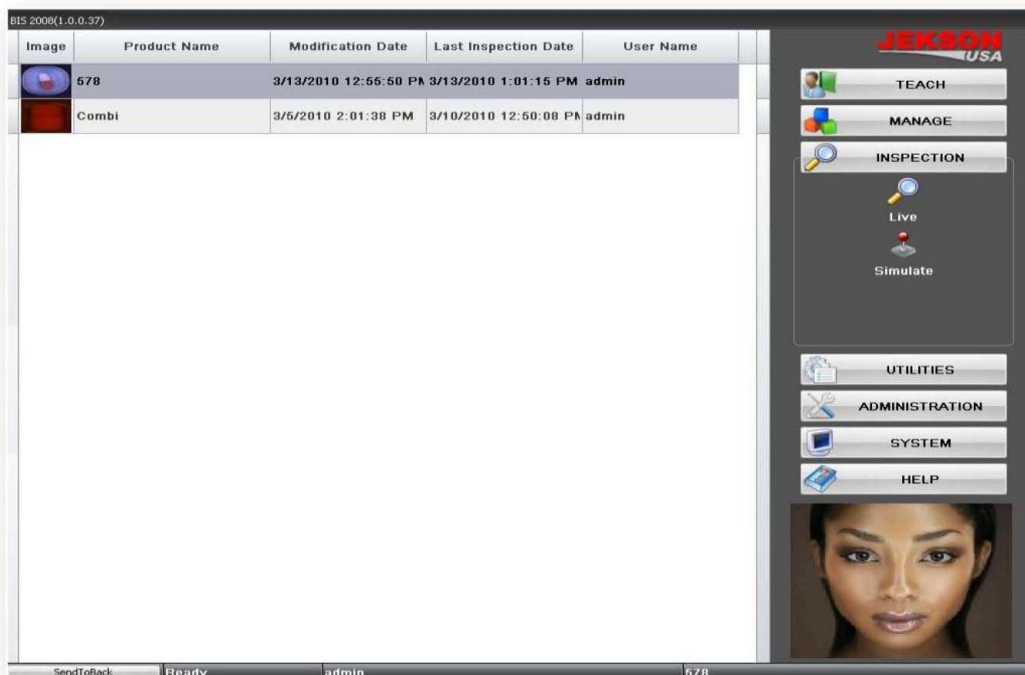
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- 5.3.3.6 Then click on the **Accept** button to start application.
- 5.3.3.7 **Turn Off:** This button allows to shutdown the system.
- 5.3.3.8 **Main screen** displayed after successful user authentication and IO selection.
- 5.3.3.9 The main screen shows the list of existing models stored in the database with their properties and various buttons that can be used to perform different operations



- 5.3.3.10 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.
- 5.3.3.11 **Jackie** :-provides audio assistance in teaching and inspection wizard
- 5.3.4 **Teach**
- 5.3.4.1 Use the **TEACH** Group to teach a new model or product.
- 5.3.4.2 **Teaching Wizard:** Touch Teaching Wizard to start teaching process for the new model.
- 5.3.5 **Manage**
- Model management includes features like rename and delete
- 5.3.5.1 **Rename:** This operation allows renaming the existing model name.
- 5.3.5.2 **Delete:** This operation allows deleting the existing model name.



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5.3.5.3 **Access Rights:** This operation allows user to assign rights on selected models

5.3.6 Inspection

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

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

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

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

5.3.7 Utilities

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

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

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

5.3.7.3 **Language/Themes:** This utility allows user to change the language and appearance of BIS NXG application.

5.3.7.4 **Image Viewer:** Image viewer utility allows user to save required images on the hard disk of the computer

5.3.7.5 **Company Details:** Company name display in this option.

5.3.8 System

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

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

Restart: Clicking this button initiates system restart process.

5.3.8.1 Maintenance or Exit option (One option applicable for individual system)

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.

Exit : To Exit form the system.

5.3.9 Administration

User can use **ADMINISTRATION** group to access the system administration tools.

Most of the utilities in this group require administrative privilege to use them.

5.3.9.1 **Troubleshoot and Machine Settings.**

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



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- 5.3.9.3 **Change Camera:** This option allows user to set appropriate camera with the application or to change/replace the existing camera
- 5.3.9.4 **IO Config :** This option allows user to set configuration parameters for I/O interfaces. As each I/O associated with the application requires different set of parameters, these parameter settings are important for proper machine operation.
- 5.3.9.5 **Troubleshoot:** This option allows user to troubleshoot IO operations like Input scanning (primary and secondary), all available outputs, illumination unit, etc.
- 5.3.9.6 **Machine Setting:** This allows user to set different properties of the machine settings. These settings are applicable to individual model; hence they are required to be set individually for each model.
- 5.3.9.7 **Activation Delay:** Specifying delay in generating output is called Activation Delay. This option allows user to set the activation delay for application.
- 5.3.9.8 **Reports:** This option allows user to generate audit trails and production summary reports. User must have administrative privileges to perform these operations.
- 5.3.9.9 **Product Recovery:** This allows user to modify product recovery settings which can recover good products from partially filled blisters using Product Recovery System.
- 5.3.9.10 **Some more screen are also incorporated in other camera as-**
- 5.3.9.10.1 **Configuration:** This allows user to set different machine specific options.
- 5.3.9.10.2 **Charts:** This option allows user to generate machine up time and production summary charts. User must have administrative privileges to perform these operations.
- 5.3.9.10.3 **21 CFR:** This option allows user to open utility for security policies based on 21 CFR part 11. However, administrative privilege is required to access 21 CFR security policy (For more details refer the 21 CFR section).
- 5.3.10 **Help :** User can use **HELP** utility to open various help documents and video tutorials which can assist the user through various operations (Note: In some camera only Video Tutorial is available) -
- 5.3.10.1 **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.
- 5.3.10.2 **Op. Manual:** This allows user to access complete operation manual.
- 5.3.10.3 **Wiring Diagram:** Clicking this button will open wiring diagrams of all IOs.
- 5.3.10.4 **FAQ:** This will open the list of frequently asked questions. These questions-answers will help operators in basic troubleshooting.



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

5.4 TEACHING PROCESS

5.4.1 Select **TEACH** group to teach a new product. This will open **Teaching Wizard** which will give various options during teaching process.

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

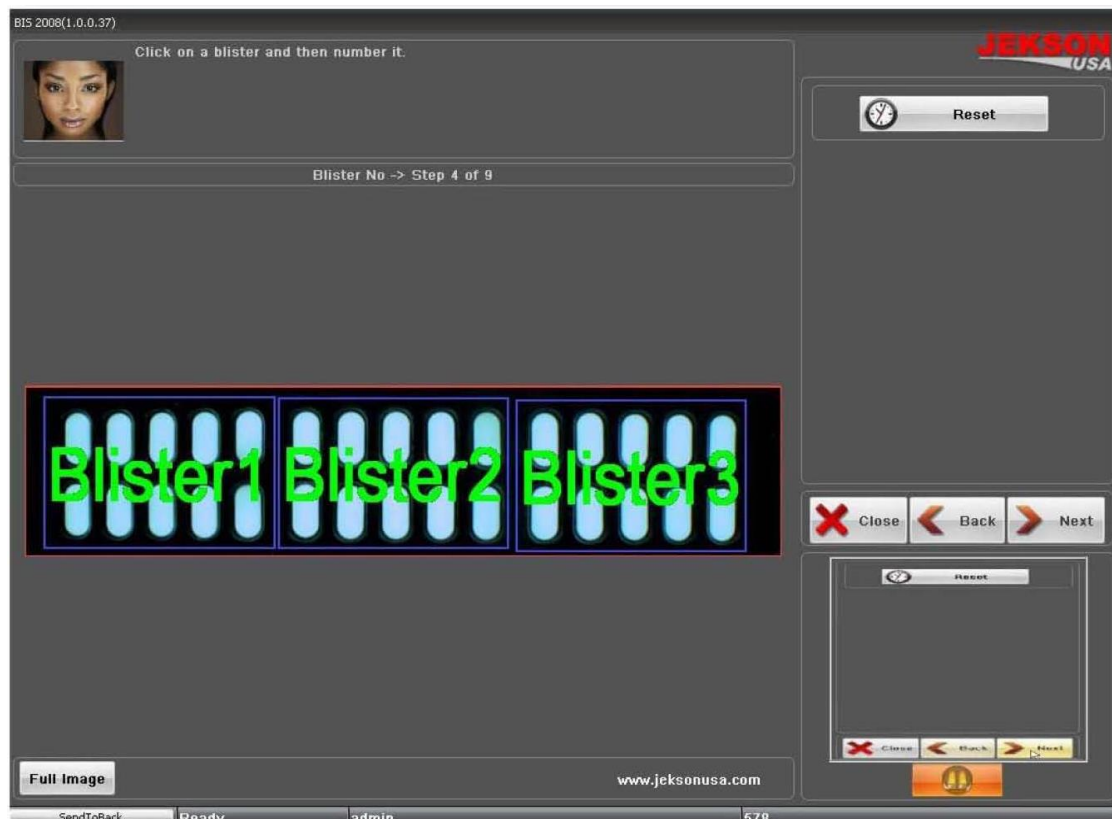
5.4.3 Click on the **Next** button to go to the next step of teaching.

5.4.4 Draw an **AOI (Area of Interest)** to cover all required blisters & Click on **Next** button.

5.4.5 Draw a **Track** for a specific blister.

5.4.6 Click on **Search** button to auto find all the Tracks (blisters) available in the AOI. User can also copy any track manually by clicking **Copy** button and can specify the blister area. User can also delete any track manually by clicking **Delete** button. Once done, **Next** button will take the user to the next step.

5.4.7 Number each blister for their identification and click on **Next**.



5.4.8 Draw a **cavity** and then click on **Done** button.



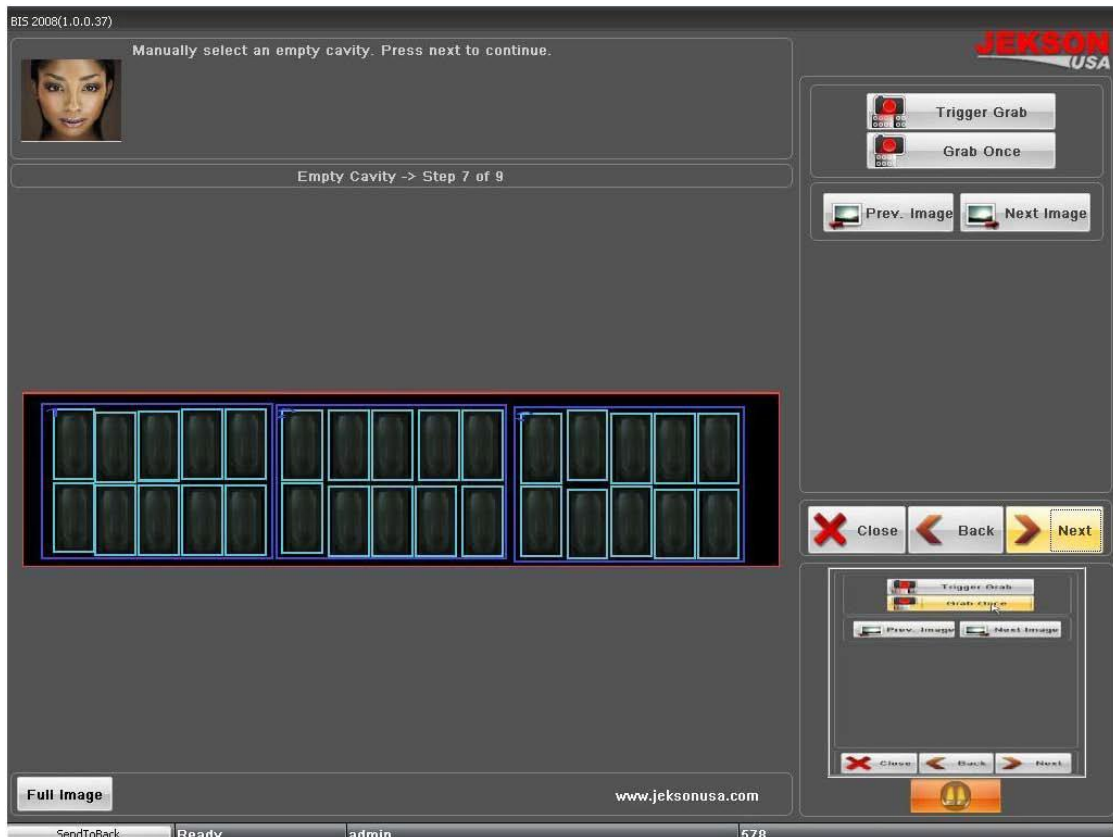
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- 5.4.9 Click on **Search** button to auto find all the cavities. User can also copy any cavity manually using **Copy** button and can specify its area. User can also delete any cavity using **Delete** button. Click **Next** to go to the next step.
- 5.4.10 Pick the color of the product for product identification and then click on **Done**
- 5.4.11 Set Threshold value by **Threshold Low** or **Threshold High** property values so that the identified product area will be as close to the actual area. Then click on **Next**.
- 5.4.12 Teaching an empty cavity screen appears as



Acquire image of empty cavities using **Grab Once** or **Trigger Grab**.
After selecting the proper image click on **Next** button to go to the next step of teaching.



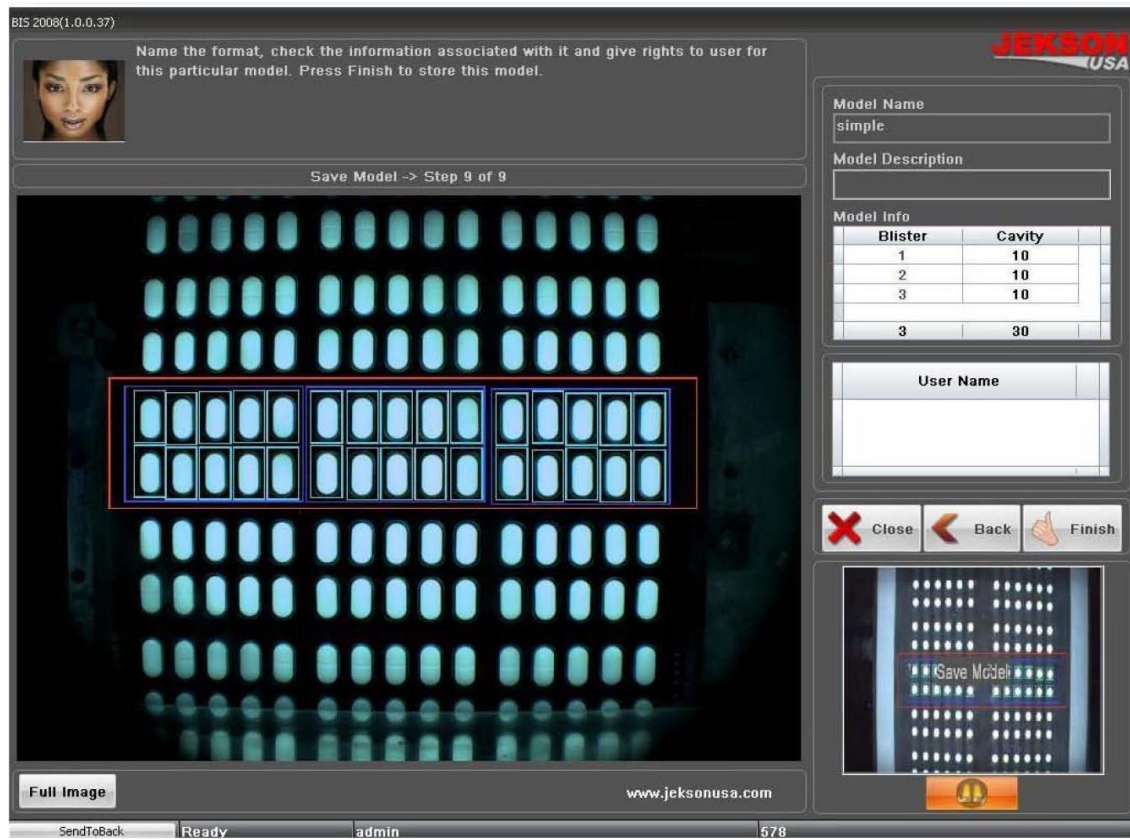
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5.4.13 Click on **Simulate** button to test the product. User can change relevant properties for maximum product acceptance if required.



5.4.14 **Next** button will take the user to the next stage where the model can be saved by specifying a **Model Name** and **Model Description**.

5.4.15 Click on **Finish** button to save the model.

5.5 Teaching a Tablet

5.5.1 Grabbing a good Image for teaching a new product

5.5.1.1 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

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

5.5.1.3 Correct Radial Distortion

Check **Correct Radial Distortion** to correct Lens Barrel Distortion of the image.

5.5.1.4 Select the appropriate **Lens** and **Distance** from the dropdown box and click **Save**.

5.5.1.5 Correct Intensity Distortion

Check **Correct Intensity Distortion** to apply uniform illumination over the entire image.



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- 5.5.1.6 If intensity distortion needs to be corrected, then take white paper image and click **Set Selected Image** to set that image for extraction of intensity distortion
- 5.5.1.7 Once proper image is acquired, click **Close** button to close current progress and return to main menu.
- 5.5.1.8 Click on **Next** button to go to next step of teaching process.
- 5.5.1.9 Click on **Back** button to go to the previous step.
- 5.5.2 **Drawing an AOI (area of interest)**
- 5.5.2.1 Draw an AOI (Area of interest) to specify teaching area.
- 5.5.2.2 Fine-tune the AOI rectangle using left/right or up/down moving buttons
- 5.5.2.3 Use this button to move AOI to left/right or up/down
- 5.5.2.4 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.
- 5.5.2.5 Click on **Previous Image** button to view last 10 images.
- 5.5.2.6 Click on **Next Image** button to see next image.
- 5.5.2.7 Click on **Delete** button to delete already drawn AOI.
- 5.5.2.8 After deleting previous AOI, user can draw new AOI.
- 5.5.2.9 Once AOI is drawn, click on **Next** to go to next page.



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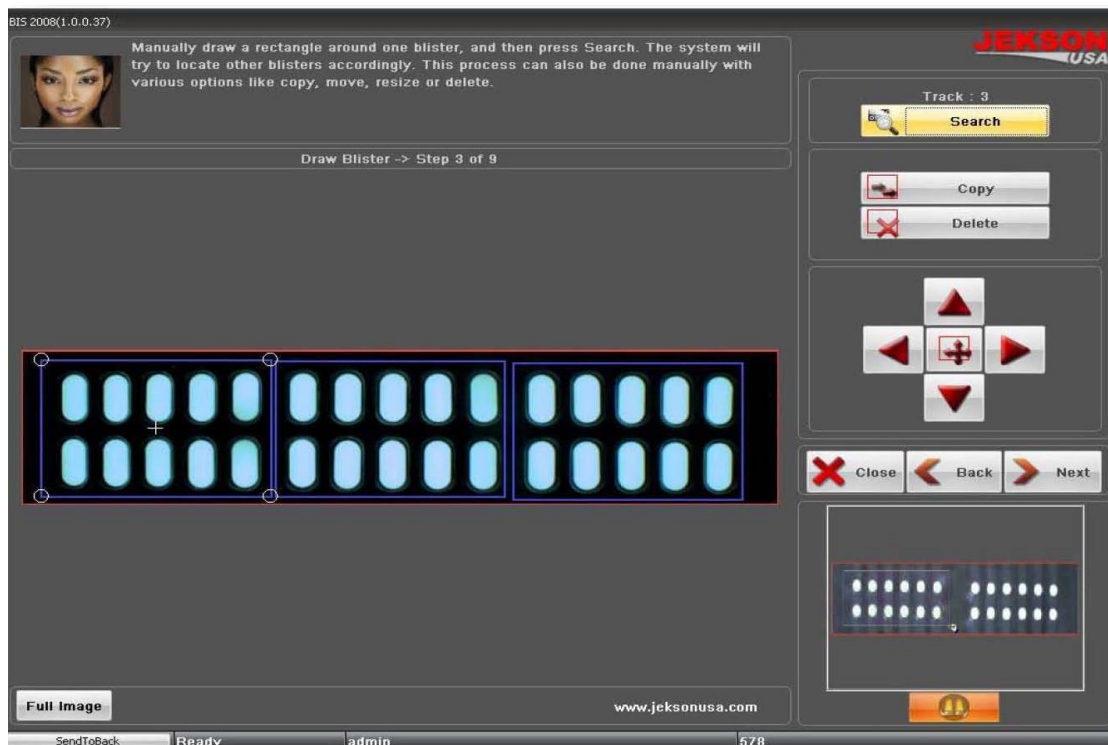
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5.5.3 Drawing blisters

5.5.3.1 User can draw tracks as per machine mechanism.



5.5.3.2 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.

5.5.3.3 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.

5.5.3.4 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.

5.5.3.5 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.

5.5.3.6 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.

5.5.3.7 To specify blister number user should click on blisters and select one of the numbers from the popup list.

5.5.3.8 User can click **Reset** button to reset current blister numbers. Clicking on **Next** button will take the user to the next step of teaching.



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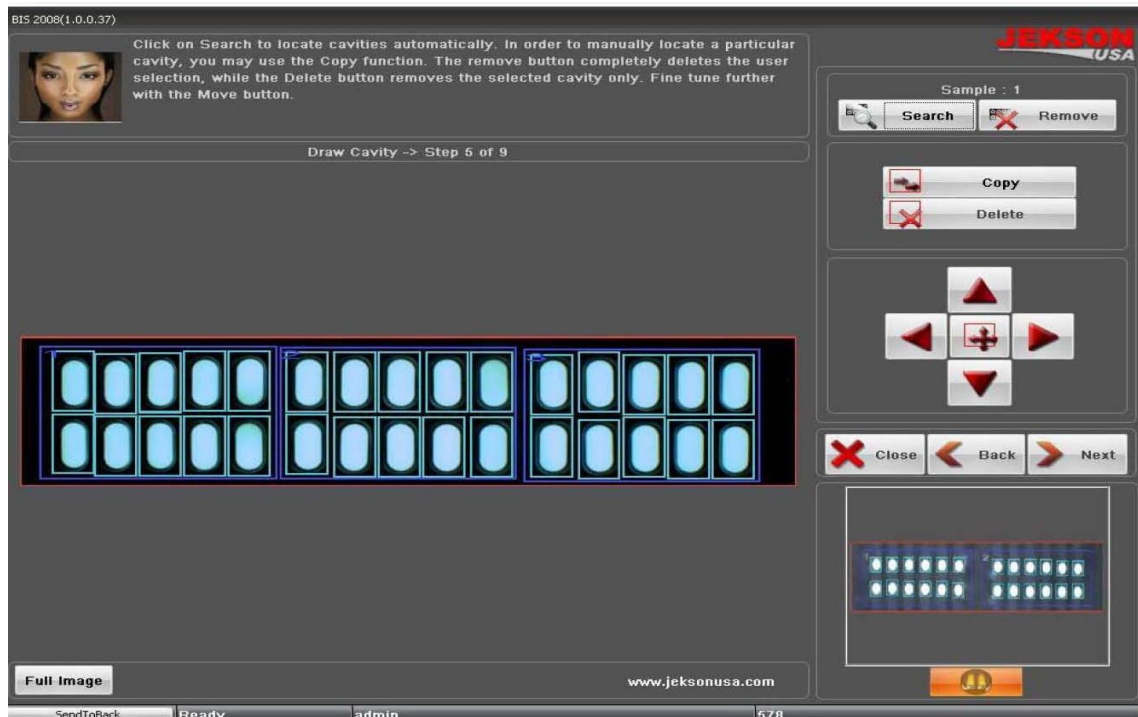
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5.5.4 Drawing a cavity (pocket)

5.5.4.1 User should draw exact pocket on the cavity to identify the objects. Then click on **Done** button to go to the next page



5.5.4.2 User should click on **Search** button to automatically search remaining pockets in all the blisters.

5.5.4.3 If application cannot search all the pockets automatically, then user can click on **Copy** button to copy and place it on to actual pocket

5.5.4.4 User can use **Delete** button to delete the pockets which do not require.

5.5.4.5 User can use the below shown buttons to move the cavity (pocket) to left/right or up/down.

5.5.4.6 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.

5.5.4.7 User can navigate to next page by clicking on **Next** button.

5.5.5 Product identification



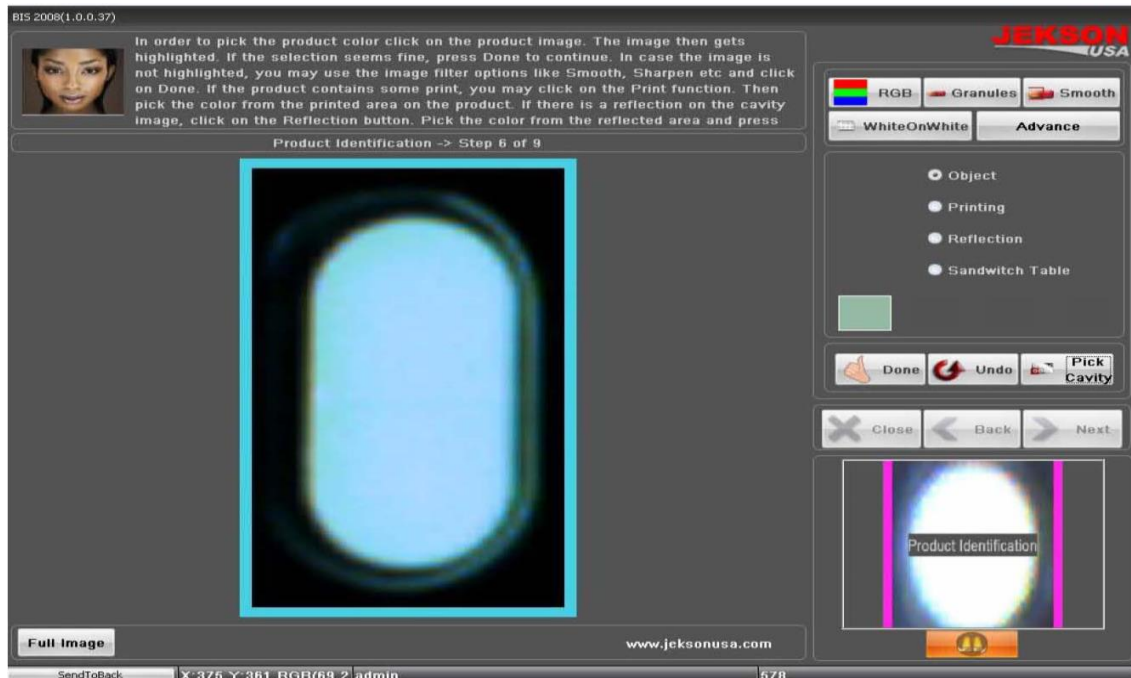
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5.5.5.1 To pick the product color user should click on the product in image area.



5.5.5.2 Vision application will automatically decide the threshold value and will grow a region on the product

5.5.5.3 If the region grown is proper then user can click on **Done** button to continue to next step.

5.5.5.4 If the region is not grown properly then user can apply different image filters as explained below.

5.5.5.5 **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. This option is used for capsule having different body and cap color and bi-layered tablet.

5.5.5.6 **White On White:** This option helps user to select proper object color when object are white and foil are white/ Opaque PVC or PVDC.

5.5.5.7 **Smooth:** This option will be help in selecting better threshold value for the object having distorted shape

5.5.5.8 **Granules:** This option is for capsules containing granules.

5.5.5.9 **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.]



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- 5.5.5.10 **Teaching Options:** Various teaching options for different products are explained below
Object: For object color selection.
- 5.5.5.10.1 **Printing:** For print color selection. User should use this option after object color selection for tablets with printing matter on it.
- 5.5.5.10.2 **Reflection:** For Reflection color selection. User should use this option after object color selection.
- 5.5.5.10.3 **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.
- 5.5.5.11 Click on **Done** to move on to next step.
- 5.5.6 **Threshold value selection**
- 5.5.6.1 Click on **Fine-tune** button in case if the region is not grown properly for a specified threshold value.
- 5.5.6.2 User can manually set Threshold value by changing **Threshold Low** or **Threshold High**.
- 5.5.6.3 Click on Next three times button to go to the next step of teaching process.
- 5.5.6.4 **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.
- 5.5.7 **Teaching an empty cavity**
- 5.5.7.1 User should acquire image of empty cavities using **Grab Once** or **Trigger Grab**.
- 5.5.7.2 After selecting the proper image user should click on **Next** button to go to the next step of teaching.
- 5.5.8 **Tolerance settings/simulation**
- 5.5.8.1 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.
- 5.5.8.2 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.
- 5.5.8.3 User can select the cavity, blister or AOI to apply modified tolerance settings
- 5.5.8.4 Click on **Next** button to go to the final step of teaching.
- 5.5.9 **Saving a model**
- 5.5.9.1 To save the teaching model user should give unique model name and model description.
- 5.5.9.2 Clicking on **Finish** button will save the model.
- 5.6 **Rejection count Setting**
- 5.6.1 **In Machine PLC (Applicable for EP 3015PDA)**
- 5.6.1 Select 'parameter' from 'home' position given in machine PLC then go into 'rejection' option.



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5.6.2 Put rejection count into option given in screen 'Non filling detect to punch'

5.6.2 **In Machine PLC (Applicable for BQS machine)**

5.6.2.1 Select 'edit' option from home screen then select 'changeover' and then next option.

5.6.2.2 Enter blister rejection count in option 'NFD offset count'.

5.6.3 **In camera PLC (Applicable for PG Ecostar machine)**

5.6.3.1 Select 'administration' from 'home' screen given in machine PLC then go into 'machine setting' option.
Enter blister rejection count in option 'queue count' and then select save option.

5.7 **Challenge test**

5.7.1 For performing challenge test, pass one blister each empty tablet, broken tablet in blister.

5.7.2 Mark the blister for identification after the sealing to evaluate the challenge test at rejection chute.

5.7.2 Ensure that machine rejects the blister.

5.7.3 Carry out the challenge test of camera at the start, after every four hour and at end of operation or after any breakdown.

5.7.4 Record the details in the BPR or format as apply.

6.0 **ABBREVIATION (S):**

PVC : Poly vinyl chloride

v/v : Volume/ Volume

IPA : Isopropyl alcohol

MMI : Main machine interference

PLC : Programmable logical Control

PIR : Punch index roller

PRC : Print rejection control

NFD : Non Fill Detector

7.0 **REFERENCES (S):**

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

SOP No. : Cleaning of production area.

8.0 **ANNEXURE (S):**

Annexure – I: Challenge test for camera operation (Jekson Vision) on blister machine



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9.0 DISTRIBUTION

- 9.1 Master copy : Quality assurance
- 9.2 Controlled copy (S) : Production General Block, Quality assurance
- 9.3 Reference copy (S) : Production General Block



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Annexure I

CHALLENGING TEST FOR CAMERA OPERATION (JEKSON VISION) ON BLISTER PACK MACHINE

BLISTER MACHINE ID.:

FREQUENCY: At Start, After Every Four Hour and at end of Operation or any Break Down

PRODUCT NAME:

BATCH No.

DATE	TIME	WITHOUT TABLET/ CAPSULE#	WITH BROKEN / OPEN TABLET/ CAPSULE #	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.