**STANDARD OPERATING PROCEDURE**

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**Vernacular SOP:** No

**1.0     OBJECTIVE:**

1.1      To lay down a procedure for Cleaning & Operation of Pack i 2 Camera System.

**2.0     SCOPE:**

2.1      This procedure is applicable for Cleaning and Operation of Pack i 2 Camera System in production department.

**3.0     RESPONSIBILITY:**

3.1      Technical Associate         : For cleaning & operation of PACK i2 Camera System

3.2      Officer and Executive       : Production department: Setting of camera

3.3      Head Production             : Compliance of SOP

3.4      IPQA Person/ Executive     : Verification.

**4.0     DEFINITION (S):**

4.1      NA.

**5.0     PROCEDURE:**

5.1      **CLEANING:**

5.1.1    Ensure that all the materials of previous batch are removed from the Packing line.

5.1.2    Remove ''EQUIPMENT STATUS'' label and affix "UNDER CLEANING/TO BE CLEANED'' label on the machine with date and sign of the production officer.

5.1.3    Switch ''OFF'' the utility supply before cleaning.

5.1.4    Clean the control panel with clean and dry lint frees cloth.

5.1.5    Clean the top and outer surface of machine with the dry lint free cloth.

5.1.6    Clean the rejection box provided in machine with lint free cloth.

5.1.7    Replace the "UNDER CLEANING/TO BE CLEANED" status label by "CLEANED" status label on the machine with date and sign of the production officer.

5.1.8    Clean the area as per SOP, "Cleaning of Production Area".

5.2      **OPERATING PROCEDURE:**

5.2.1    Switch 'ON' the mains, switch on ''UPS'' wait for 5 sec., Switch 'ON' console unit by pressing 'Red' switch on the right-side wall of the console unit.

5.2.2    Pack i2 screen will be displayed and asking for login names and password. Three level 'user' with their rights assignment are given as:

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| S.No. | Type of Functions | User Rights Assignment (Y/N) | | |
|---|---|---|---|---|
| | | **Operator** | **Supervisor** | **Manager** |
| 1. | To create new 'user' & 'password' | N | N | Y |
| 2. | To prepare Recipe | N | Y | Y |
| 3. | To set the eject count | N | Y | Y |

5.2.3 On selecting correct user name & password followed by 'OK', system will display. 'DO YOU WANT TO SET THE CAMERA'? Press 'NO'. Then system will go in learn mode. Then pass the bottle, image will be displayed on screen by adjusting label gap sensor image position (horizontal can be adjusted).

5.2.4 To start fresh job it will display learn mode as waiting for label.

5.2.5 Then screen will display "PLEASE SET IMAGE & PRESS OK BUTTON" If image is OK then press OK. (Rotate image by clicking on rotate button to set angle (0°, 90°, 180°, 270°) if image displayed is seen rotated. And then press OK).

5.2.6 The screen will display "please give area for reference'. Then give AREA (AOI) & PRESS "OK" BUTTON.

5.3 **SETTING OF CAMERA 1:**

5.3.1 **PHARMACODE SETTING:**

5.3.1.1 In options window click on Pharmacode option, green indicator of Pharmacode will glow. Pop up window will be displayed.

5.3.1.2 If you know Pharmacode value directly feed it or else to find value click on bar indicator. Choose thin and thick bar as seen in image so that same combination of bar is produced. It will give Pharmacode value in value indicator. Click direction arrow, value will change. Select appropriate direction and click ok and press 'CLOSE' to return main screen.

5.3.1.3 Give 'ROI' on Pharmacode. In right side, in preview window image of Pharmacode will be displayed. This bar should be always vertical, if it is horizontal use rotate button and set it vertical by giving proper angle. Pharmacode value is displayed in left bottom.

5.3.1.4 Rotate image by clicking on rotate button to set angle (0°, 90°, 180°, 270°) as per requirement.

5.3.1.5 Press Test Button to check the Pharmacode value if Pharmavalue is wrong then it shows "Pharmavalue is hard to analyze''. Please give proper 'ROI' or Press Direction Button or set Mini value. If Pharma value is scanned successfully. Then it shows "Pharmavalue" is scanned successfully." Press 'OK' button to exit Pharma setting.

5.3.2 **PRESENT1 SETTING (OVER PRINTING):**

5.3.2.1 Click on option Present1. Select portion to be inspected as ROI.

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5.3.2.2   It stores given ROI in memory in form of image considering as idle image and every image captured further will be compared with this 'idle image'.

5.3.2.3   If it is same as idle image (Within set tolerance) it will be passed.

5.3.2.4   Rotate image by clicking on rotate button to set angle (0°, 90°, 180°, 270°) as per requirement.

5.3.2.5   To check over print select 'Present1'. Click On Present1 and then give ROI for overprint area & select 'test' button then it gives message " Present1 created successfully!!! Lines found". The image will be displayed in preview window.

5.3.2.6   If CAM2 not applicable then go for 'start' option to run machine.

5.3.2.7   It will give message 'CAM2 not set' then select 'OK' from the window.


5.3.3   **ENTERING JOB NAME:**

5.3.3.1   Click on text box 'JOB NAME'. Keypad will appear.

5.3.3.2   Enter job name with the help of keypad. If job name already exits system will ask for re-entering the job name.

5.3.3.3   After click 'OK' keypad will appear again. Enter new job name ad press 'ok' to return main menu.


5.3.4   **LOAD FROM PREVIOUS JOB:**

5.3.4.1   This option will be selected after each roll change to avoid the rejection count error during machine running.

5.3.4.2   If you want to load from previous job click on 'LOAD' button.

5.3.4.3   Once you load from previous job you can directly start machine running. Click load button and give job name and click 'OK' button to return main screen.

5.3.4.4   Press start button to run the job.

5.3.5   **SETTING OF MACHINE STOP / EJECTION CONTROL SYSTEM:**

5.3.5.1   **FOR MACHINE EJECTION CONTROL SYSTEM:**

5.3.5.1.1   At bulk pack-I line, in camera inspection system at sticker labeling machine the 'machine stop' option is disabled hence only 'ejection control system' shall be selected.

5.3.5.1.2   Select ''setting'' option from the bottom right side of window and 'job setting' window will be displayed as:

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```
                          JOB SETTING
    ┌──────────┐    JOB NAME
    │          │
    └──────────┘

   O  MACHINE STOP #                        CAM 1
   O  EJECTION CONTROL  $               Lab/Product count


                               ϴ      ┌──────────┐
                                      │          │
                                      └──────────┘

      AUDIT  TRIAL         LOAD                OK
```

**# : Selected for bulk-III ;   $ : Selected for bulk-I**

5.3.5.1.3   Select the 'ejection control' option from the above window and enter the numeric value in given field against the ''lab/product count' 'This numeric value is rejection count of camera and is depend on the number of labels exist between camera and 'product sensor'.

5.3.5.1.4   For faulty bottle two pusher systems working at rejection point:

(1) Pusher system for rejection of 'Pharmacode' and 'overprinting detail'.

(2) Pusher system for rejection of 'no label bottle'.

5.3.5.1.5   Now press ''OK'' to return main menu.

5.3.5.2   **FOR MACHINE STOP CONTROL SYSTEM:**

5.3.5.2.1   At bulk pack-III line, in camera inspection system at sticker labeling machine the 'ejection control system' option is disabled hence only 'machine stop control system' shall be selected.

5.3.5.2.2   Select the 'machine stop option' from the screen under point no. 5.3.5.1.2.

5.3.5.2.3   Enter number of labels between camera and Label gap sensor in the field given against ''lab/product count'' as in screen 5.3.5.1.2.

5.3.5.2.4   When faulty bottle comes machine will stop and it gives a beep signal with message 'faulty bottle found, Do YOU WANT TO CONTINUE'.

5.3.5.2.5   Then operator identifies the faulty bottle and put into rejection box.

5.3.5.2.6   Then select the 'enter' option from the window and machine will be further continue to run automatically.

5.3.6   **TOLERANCE:**

5.3.6.1   To set tolerance value for PRESENT1.

5.3.6.2   Click on tolerance button. Slider window will appear. Containing different sliders through which we can adjust tolerance level in %. (Default value is 65% in PRESENT2)

5.4   **SETTING OF CAMERA2:**

5.4.1   Select the 'CAM2' Tab. Pass bottle on conveyor. Check camera, flashes, trigger position, and avoid glossy reflection. Adjust proper light, no wrinkle or sag on leaflet.

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5.4.2    Set the Image according to standard described for the 1st camera, and press 'OK' button.

5.4.3    **PHARMACODE SETTING (CAMERA2):**

5.4.3.1    Set the individual operations as per the given below.

5.4.3.2    This option is for the inspection for Pharmacode data. If you select Pharmacode, pop will appear enter the Pharma code value.

5.4.3.3    If you know PHARMA code value, you can directly feed it. For this click on 'VALUE' Window, the keyboard appears.

5.4.3.4    Then feed the known Pharmacode value in digits & click 'OK' button at right left bottom of keyboard.

5.4.3.5    If you don't know the value, to find the value of PHARMA code, click on 'BAR'. Then Choose thin & thick bar as seen in your image so the same combination of bar is produce in blank window.

5.4.3.6    Click on OK button & then CLOSE button. Now you can see the value of Pharmacode in Value Indicator.

5.4.3.7    Click the direction arrow, value will change. Select the appropriate direction & click 'OK', & press 'CLOSE' and return to main screen now.

5.4.3.8    Give ROI on Pharmacode. The Pharmacode in area selected should be always horizontal. If it is vertical, then use rotate button & set it horizontal by giving proper angle it is either (90,180,270,360).

5.4.3.9    Automatically program will start to find and verify the value. Change the 'DIRECTION' and 'MINI' if value not read properly.

5.4.3.10    Press 'OK'. Value of Pharmacode is displayed in left bottom.

5.4.4    **JOB LOAD: (CAMERA2):**

5.4.4.1    Click on the 'Job Load' button.

5.4.4.2    A drop-down box will appear, click on the right button of this box.

5.4.4.3    List of all previously saved parameters will appear.

5.4.4.4    Select desired job name out of this.

5.4.4.5    Corresponding parameters of this particular job will be loaded.

5.4.4.6    Press 'start' to continue to run job.

5.4.4.7    Select ''lock'' option from upper right side of window and following.

5.5    **MACHINE EJECTION CONTROL SETTING:**

5.5.1    Same as in CAM1 control actions are provided in CAM2 also.

5.5.2    You can eject the faulty bottle (Machine stop is selected by Default).

5.5.3    Click on round button you can see ECS if ejection mode is selected, or MCS if Machine stop mode is selected.

5.6    **TOLERANCE:**

5.6.1    To set tolerance value (for PRESENT) click on tolerance button.

5.6.2    Slider window will appear.

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5.7        **STOP**

5.7.1      To stop the system enter STOP button. One pop up will ask whether to stop or pause the system.

5.7.2      If we want to halt machine for lesser time we can select for the option (It will save our time of resetting the job).

5.7.3      While breaks we should have to pause the machine and can restart after resuming.

5.8        **EXIT**

5.8.1      If you want to exit entire system press 'EXIT' button.

5.8.2      If you want to start new job press ''START' button or press 'EXIT' button

5.8.3      System will shut down if you press exit button.

5.9        **Camera Challenge Test For CAM 1:**

5.9.1      **Challenge Test for Pharmacode reader:**

5.9.1.1    Place defaced printed labels (by placing one or more line parallel and diagonally to Pharmacode) in line.

5.9.1.2    Challenge test will be pass if camera detect the bottle with defaced labels and   rejection mechanism reject the faulty bottle individually If machine ejection control system is selected (Refer to point no 5.3.5.1) or machine will stop with beep signal if 'machine stop' option selected for rejection (Refer to point no 5.3.5.2.).

5.9.1.3    Record the observation in Annexure - I.

5.9.1.4    **Frequency:** Perform the challenge test at start, after every four hours, after any breakdown and at end of operation.

5.9.2      **Challenge Test for overprinting detail:**

5.9.2.1    Stop the overprinting.

5.9.2.2    Challenge test will pass if camera detect the bottle with misprinting and rejection mechanism reject the faulty bottle individually If machine 'ejection control' system is selected (Refer to point no. 5.3.5.1) or machine will stop with beep signal if 'machine stop' option selected for rejection (Refer to point no. 5.3.5.2.).

5.9.2.3    Further restart the overprinting.

5.9.2.4    Record the observation in Annexure-I.

5.9.2.5    Check the coding detail on first two labeled container to ensure that overprinting detail is further 'OK'.

5.9.2.6    **Frequency:** Perform the challenge test at start, after every four hours, after any breakdown and at end of operation.

5.9.3      **Challenge Test For 'No label Bottle' sensor:**

5.9.3.1    Place 'no label container' on conveyor belt before 'no label sensor'.

5.9.3.2    Challenge test will pass if sensor detect the 'no label bottle' and rejection mechanism reject the faulty bottle individually If machine ejection control system is selected (Refer to point no. 5.3.5.1) or machine will stop with beep signal if 'machine stop' option selected for rejection (Refer to point no. 5.3.5.2.).

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5.9.3.3    Record the observation in Annexure-I.

5.9.3.4    **Frequency:** Perform the challenge test at start, after every four hours, after any breakdown and at end of operation.

5.10        **Camera Challenge Test for CAM 2:**

5.10.1      **Challenge Test for Pharmacode reader:**

5.10.2      Take a bottle with good leaflet placed on its closure top.

5.10.3      Deface the leaflet by placing one or more line parallel or diagonally to Pharmacode.

5.10.3.1    Now pass bottle with defaced leaflet through the CAM2.

5.10.3.2    Challenge test pass if defaced leaflet with bottle rejected by ejector control system at camera (CAM2).

5.10.3.3    Record the observation in Annexure-I.

5.10.3.4    **Frequency:** Perform the challenge test at start, after every four hours, after any breakdown and at end of operation.

5.11        **Operating procedure for camera in liquid oral**

5.12        Take line clearance from Q.A for Packing before operating.

5.13        Switch 'ON' the camera through the Red button on the panel of the camera system and then push the red button of the camera monitor.

5.14        Set the label roll on the machine as per SOP, "Cleaning and operation of sticker labeling machine with condot printer.

5.15        Double click the Insight explorer on the desktop.

5.16        Select: is………… shown on Insight network. Select User name from   Log ON/OFF. Select User:

                  USERS: ADMIN - For internal setting of camera system.

                   SUPERVISOR - For setting of batch details.

                   OPERATOR - To run the camera system.

5.17        Select User Supervisor type password (as per SOP). Select Reset on the window of the ……….. Pvt. Ltd. The counts should be zero.

5.18        Take the image of the label on the screen by passing the label through the camera. Go OFFLINE through window for setting.

5.19        Select SETTING on the window of the Propix Technologies Pvt. Ltd. Only INSPECTION and OCR FONT options are active and then select Inspection on Wizard Menu, the screen will show:

5.20        Select manual string by clicking on it, and then select line 1,2,3,4 as per requirement of batch that is printed on label.

5.21        Write detail which is required on line 1 (details which is printed on label) by selecting cursor below the manual string and the select Line 1 (In orange color). Screen will show:

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5.22    Take the red Color line (X & Y axis line) with the help of cursor to the details of Line 1 on monitor and adjust it to the center of the details as shown in image.

5.23    Double click on image, the inspection window will open.

5.24    Similarly write the batch detail on Line No. 2, 3, 4 as per requirement below the manual string and adjust the red line of (X & Y axis line) on the image show on the monitor.

5.25    After setting of all the line as per batch requirement, select Menu.

5.26    Select OCR FONT and then select CLEAR FONT the screen will show:

5.27    Write detail of Line1 on space provided above TRAIN FONT, then select FONT ROI, screen will show:

5.28    By using cursor take the red line to the image (detail of Line 1) which is shown on monitor and adjust the red line of (X & Y axis line) to the Center of image.

5.29    Double click on image by using cursor. Select TRAIN FONT. Then write

5.30    By using cursor take the red line to the image (detail of Line 2) which is shown on monitor and adjust the red line of (X & Y axis line) on the image show on the monitor. Double click on image by using cursor. Select TRAIN FONT. Then write details of line 3 on space provided, then FONT ROI. By using cursor take the red line to the image (detail of Line 3) which is shown on monitor and adjust the red line of (X & Y axis line) on the image show on the window. Double click on image by using cursor. Select TRAIN FONT.

5.31    Then write details of line 4 on space provided, then FONT ROI. By using cursor take the red line to the image (detail of Line 4) which is shown on monitor and adjust the red line of (X & Y axis line) on the image show on the monitor. Double click on image by using cursor. Select TRAIN FONT.

5.32    Similarly as per batch requirement do the process of step 6.19 to 6.21

5.33    After selecting TRAIN FONT, select OK the screen will show:

5.34    **Camera setting for Pharmacode:**

5.34.1    Select SETTING on the window of the Propix Technologies Pvt. Ltd. Select Inspection on Wizard Menu, the screen will show:

5.34.2    Select 1D and then double click on 'SET ROI'. Take the red Color line (X & Y axis line) with the help of cursor to the Pharmacode on monitor and adjust it to the center of the Pharmacode. Double click on it. Select 1D Verify on Inspection window write the Pharmacode value on the space provided from the respective batch record.

5.34.3    Select 1D Data and then select 'OK'. If Pharmacode value is wrong then it Shows "PHARMACODE error''. Please give proper 'ROI' or check for correct value entered for Pharmacode. If Pharma value is scanned successfully. Then it shows "Pharmavalue" is scanned successfully. Select 'OK' to exit.

5.35    Select file on window, then select save job. The message is save.

5.36    Go ONLINE through cursor on window and select 'Yes'. As per screen:

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5.37    Select 'System' on Monitor. As shown on screen. The screen shows Log ON/OFF

5.38    Select USER "Operator" type password and then select Logon to run the system by operator.

5.39    **Challenge Test for overprinting detail on sticker label:**

5.39.1    Push the red button on TCU unit on sticker labeling machine once and check the image of overprinting on screen; coding should not be done. The labeling machine should stop with beep sound.

5.39.2    Further press the red button given on TCU unit on sticker labeling machine. Reset the machine with the help of Green push button provided on machine, the machine will start, remove the un coded labeled bottle and kept in rejection box and mention the quantity of un coded labeled bottle in BPR.

5.39.3    Challenge test will pass if camera detects the bottle with misprinting and Machine will stop.

5.39.4    Check the coding detail on first 2-3 labeled bottles to ensure that overprinting detail is further 'OK'.

5.39.5     **Frequency:** Perform the challenge test at start, after every four hours, after any breakdown and at end of operation.

5.40    **Challenge Test for Pharmacode reader:**

5.40.1    Place deface printed label (by placing one or more line parallel and diagonally to Pharmacode) in line.

5.40.2    Challenge test will be passing if camera detects the bottle with defaced labels and the machine will stop. Record the observation in Annexure - II.

5.40.3    **Frequency:** Perform the challenge test at start, after every four hours, after any breakdown and at end of operation.

5.41    **Challenge test for rejection system of sticker labeling machine**

5.41.1    Obstruct the compressed air supply by removing air supply port or folding of supply pipe. Ensure conveyor stop automatically when drop in the compressed air pressure.

5.41.2    If conveyor not stopped then inform to engineering for rectification until unless stopped the activity. Record the observation in Annexure - I.

5.41.3    **Frequency:** Perform the challenge test at start, after every four hours, after any breakdown and at end of operation.

5.42    After completion of batch select 'System' on monitor and select Log on/off and then select user 'SUPERVISOR' type Password, then select OK. Go to SETTING on Propix Technologies then INSPECTION. Select Manual string and all the line which is selected for batch and then delete the details from all line. Delete the Pharmacode value (if applicable) and then select 'OK' to exit.

5.43    Close the window and shut down the camera and do the process of cleaning as per SOP.

**6.0    ABBREVIATION (S):**

6.1    SOP         :        Standard Operating Procedure

6.2    AOI         :        Area of Interest

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6.3     ROI    :     Region of Interest

6.4     UPS    :     Uninterrupted Power Supply

**7.0     REFERENCE (S):**

7.1     SOP: Cleaning of production area.

7.2     SOP: Password protection in PLC System

7.3     SOP: Cleaning and operation of sticker labeling machine with condot printer.

**8.0     ANNEXURE (S):**

| Annexure no. | Tittle of Annexure | Format no. | Mode of Execution |
|---|---|---|---|
| Annexure I | Pack i 2 Camera Challenge Test Record | | Log Book |
| Annexure II | Challenge Test for Pack I2 Camera Inspection System on Sticker Labeling Machine | | Log Book |

**9.0     DISTRIBUTION:**

9.1     Master Copy     : Quality Assurance

9.2     Controlled copy (S) : Production department (02), Quality Assurance (01)

9.3     Reference copy (S) : Production department (01)

**10.0     REVISION HISTORY:**

| S.No. | Version No. | Change Control No. | Reason (s) for Revision | Details of Revision | Effective Date |
|---|---|---|---|---|---|
| 1. | 00 | NA | New SOP | New SOP | |

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### ANNEXURE I

### CHALLENGE TEST FOR PACK I2 CAMERA INSPECTION SYSTEM

| DATE | TIME | CAMERA CHALLENGE TEST | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | **PRODUCT NAME** | | | | **AREA** | | |
| | | **BATCH No.** | | | | **EQIPMENT ID** | | |
| | | **FREQUENCY:** PERFORM CHALLENGE TEST AT START, AFTER EVERY FOUR HOURS, AFTER ANY BREAKDOWN AND AT END OF OPERATION | | | | | | |
| | | *For no labeled container | *For overprinting Detail | *For Pharmacode Reader (Camera 1) | *For Pharmacode Reader (Camera 2) | $ For Rejection system of sticker labeling machine | Checked By (Prod.) | Verified By (IPQA) |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

$*$Record 'ok' if faulty bottle rejected/machine stop by camera system and record 'not ok' if faulty bottle not rejected/machine not stop by camera system.

$ Record "ok" when obstruct the compressed air supply and conveyor stop automatically. If not then put "NOT OK" and stop the activity until unless problem rectified.

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**ANNEXURE II**

**CHALLENGE TEST FOR PACKI2 CAMERA INSPECTION SYSTEM ON STICKER LABELING MACHINE**

| DATE | TIME | CAMERA CHALLENGE TEST FOR PHARMACODE READER | | | |
|---|---|---|---|---|---|
| | | **PRODUCT** | | **AREA** | |
| | | **BATCH No.** | | **EQUIPMENT ID** | |
| | | **FREQUENCY: PERFORM CHALLENGE TEST AT START, AFTER EVERY FOUR HOURS, AFTER ANY BREAKDOWN AND AT END OF OPERATION** | | | |
| | | *For Pharmacode Reader | No. of bottles rejected during challenge test | Checked By (Prod.) | Verified By (IPQA) |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**INSTRUCTION:**

1. Place defaced printed labels (by placing one or more line parallel and diagonally to Pharmacode) in line.
2. Challenge test will be passing if camera detects the bottle with defaced labels and machine will stop.

**\* Record 'ok' if faulty bottle rejected/machine stop by camera system and record 'not ok' if faulty bottle not rejected/machine not stop by camera system.**