



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Procedure for Cleaning and Operation of New DGFT Packi Track N Trace System with Conveyor Belt and Camera Inspection System	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
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### 1.0 OBJECTIVE:

- 1.1 To lay down a procedure for operation and cleaning of new DGFT Packi Track n Trace system with conveyor belt and camera inspection system.

### 2.0 SCOPE:

- 2.1 This procedure is applicable to cleaning and operation of new DGFT Track n trace system with conveyor belt and camera inspection system for overprinting detail on carton in production area.

### 3.0 RESPONSIBILITY:

- 3.1 Officer / Executive Production: Generation of DGFT bar code through ERP.  
3.2 Officer / Executive IPQA: Review and checking DGFT bar code through ERP.  
3.3 Head, Production and Head, Quality Assurance: Compliance to procedure.

### 4.0 DEFINITION (S):

- 4.1 Nil

### 5.0 PROCEDURE:

#### 5.1 CLEANING :

- 5.1.1 Ensure that the main power supply is switched "OFF".  
5.1.2 Remove "UNDER PROCESS" label and affix "TO BE CLEANED" label on the machine with signature of production and IPQA officer.  
5.1.3 Remove all the previous packing material, rejected carton and its pieces present on the conveyor belt and dispose it as per SOP.  
5.1.4 Clean the conveyor belt, rollers, carton guides, utility cables, camera lens and its body and computer of the machine with a clean dry lint free duster.  
5.1.5 Clean the printing head by using tissue paper.  
5.1.6 Clean the outer surface of machine with dry lint free cloth.  
5.1.7 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the production officer.  
5.1.8 Record the cleaning start time in the Equipment usage log sheet as per SOP.

#### 5.2 Operation



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- 5.2.1 Switch "ON" the main from electric panel and turn "ON" the knob given for conveyor belt and PC.
- 5.2.2 Press the red button given on console unit at right side of monitor and monitor will turn "ON".
- 5.2.3 Double click the "ERP icon" (Base e12) and put ERP login and user name and password, go to Manufacturing, production and then work order , open w. order option refresh the w.order home screen select the particular B.no as shown in screen:
- 5.2.4 Right click the selected transaction and go to "Request for condot Label" as shown in screen:



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5.2.5            Condot Label screen will be displayed, Select the secondary packing option for secondary packing and press the “GO” button as shown as below screen.

5.2.6            The details of the product will appear, check Batch No, Mfd. Date, Exp. Mfg.Lic.No., MRP and No. of labels etc.as shown in screen.



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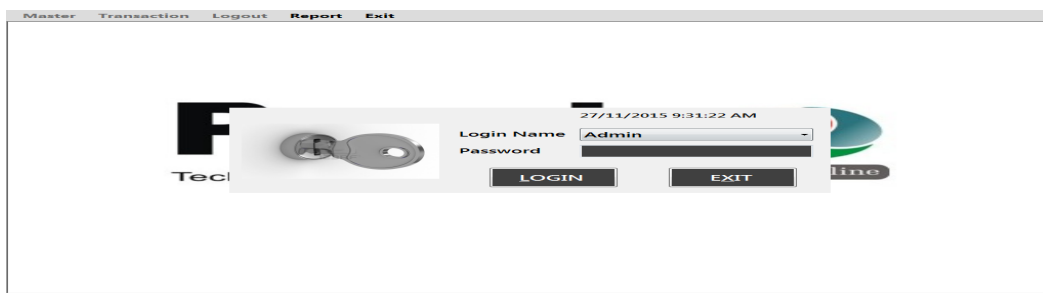
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5.2.7 Press the “Request NOS” and “Request Done Successfully” will appear on following screen.

5.3 **To Login Packi Track n Trace system :**

5.3.1 Click on “Label Print” Icon from desktop. The screen will display as below:



Select proper Login Name and enter the correct password for respective user then click on ‘**Login**’ button. The three “USERS” given with their different rights assignments as below given:



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5.3.2

S.no.	Type of Functions	User Rights Assignment(Y/N)		
		Operator	Supervisor	Administrator (Production Head)
1.	To create new 'user' & 'pass word'	N	N	Y
2.	Open Report	Y	Y	Y
3.	Finish Batch	Y	Y	Y

5.4 How to create New User:

5.4.1 A new window is open which is a multiple document interfaces for user which will display below



screen.

5.4.2 Click on Master to create new user and label:



5.4.3 On clicking "User Create" window will be displayed as:



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5.4.4 Select a 'role assign' from window to provide rights assignment for different user by selecting 'masters', 'batch finished' or 'report'. Fill all the details of new user and click on 'save' button. On click of 'Find' button you get all the details of the registered user & their roles:

5.4.5 How to Set Label Master To Give Job Name:

5.4.5.1 On clicking 'Label Master' Menu (As per window of 5.4.2):

5.4.5.2 You have to enter unique Label Name i.e. 'JOB' name. When you click on 'ADD' button then Label Name is saved in database. Label name is unique.

5.5 How to Set Transaction:



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5.5.1

Master Transaction Logout Report Exit

ProductName [ ] GTIN No [ ]  
Batch No. [ ]  MFG Date [ ]  
Select Label [ ] EXP Date [ ]  
Batch Quantity [ ] Select Date Format [ ]

Printed Count 0 / 0

START STOP BATCH FINISHED EXIT

Login Name : ADMIN Date : 27/11/2015 09:45:37

5.5.2 These details which shown above are coming from ERP given request. At first time for batch serial number gets generated with respect to this message is shown above.

5.5.3 Label Names are automatically displayed in 'Select label', as 'job name' these Label Names are already saved in database from 'Label Master' form. Select all the details & click on "Start" button for printing operation.

5.6 How to start and Stop the Batch:

5.6.1 On clicking "Start" button the Software is ready for printing and the print count is started incrementing

Master Transaction Logout Report Exit

ProductName DUMMY GTIN No 18901463041960  
Batch No. TEST  MFG Date 01/11/2015  
Select Label MacLabel EXP Date 01/10/2017  
Batch Quantity 100 Select Date Format [ ]

Print Count 4

START STOP BATCH FINISHED EXIT

Login Name : ADMIN Date : 27/11/2015 09:46:46

5.6.2 On clicking 'Stop' button the running batch is stopped and a message window is shown for confirmation:

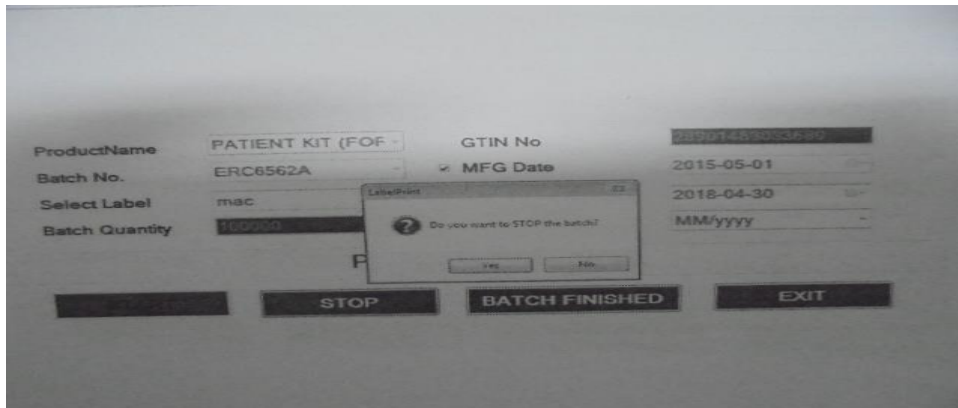


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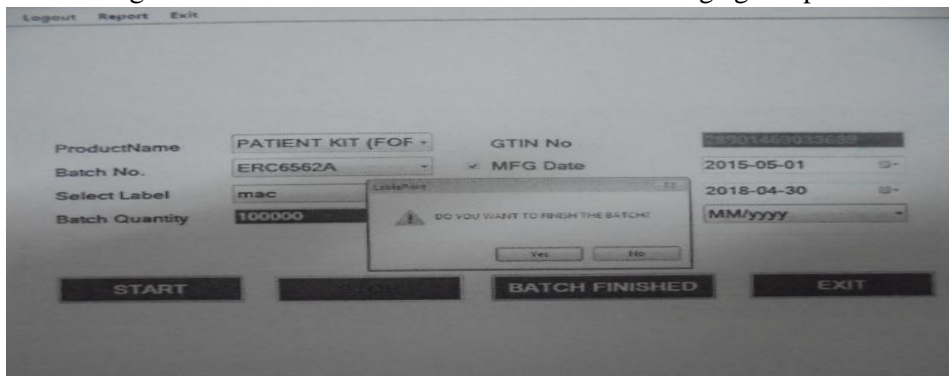
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5.6.3 How to finish the batch:-

On clicking “**Batch Finished**” button confirmation message gets open to finish running batch.



5.6.4 On clicking “**yes**” button you can finish the running batch and by click of **EXIT** button respective transaction form gets closed.

5.7 How to See Reports:

5.7.1 On clicking the ‘report menu’ a new window displayed as below and select the desired ‘job name’ from pop up help a window will displayed:



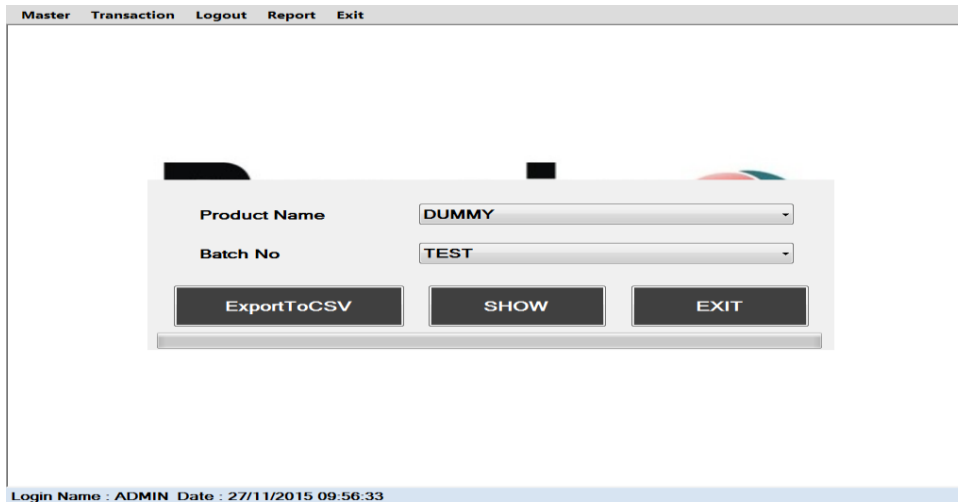


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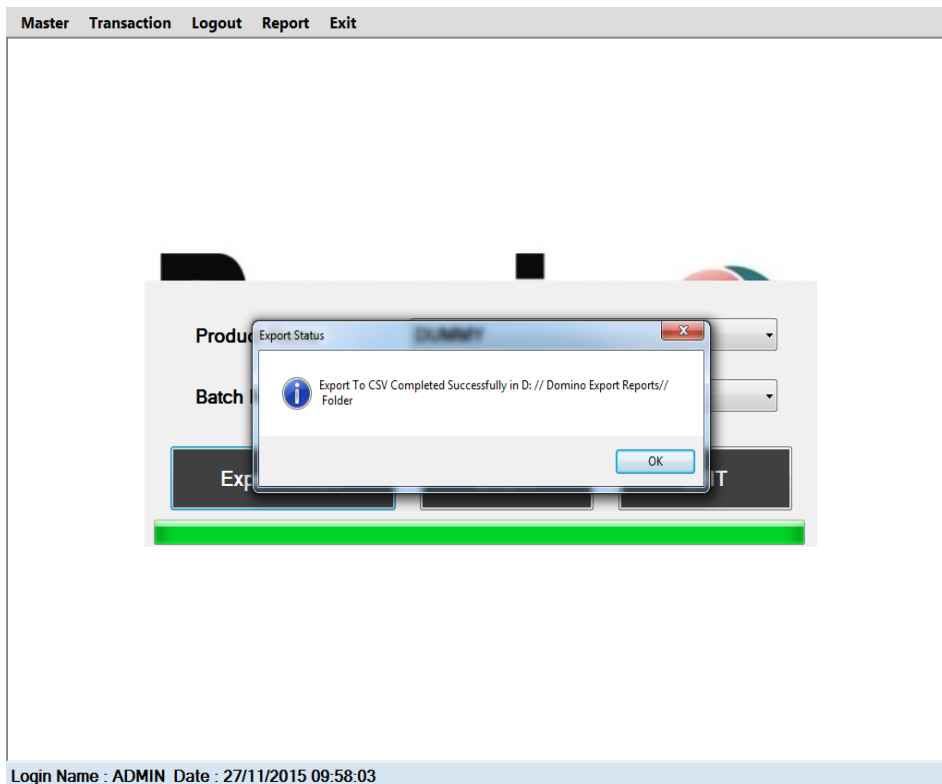
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5.7.2 When clicking 'ExportToCSV' button then Automatic CSV report created for selected product-batch pair on **D** drive in 'Domino Export Reports' Folder.



5.7.3 On clicking 'Show' button Report will be as shown:



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Report For Display Batchwise Serial Numbers

Product Name :- DUMMY  
Batch Quantity :- 100.00      Lot Number:- TEST  
Good Count :- 4.00      MFG Date :- 01/11/2015  
Login Name:- Admin      EXP Date:- 01/10/2017

Serial Nos.	Serial Nos.
-------------	-------------

Current Page No.: 1      Total Page No.: 1      Zoom Factor: 100%

Export to Excel      Close

### 5.7.4 How to “Logout” from the Application:

By selecting ‘Logout’ menu from upper side of window you can successfully logout from application & a login window is shown. If you click on ‘EXIT’ button of login form, software/Application gets closed.



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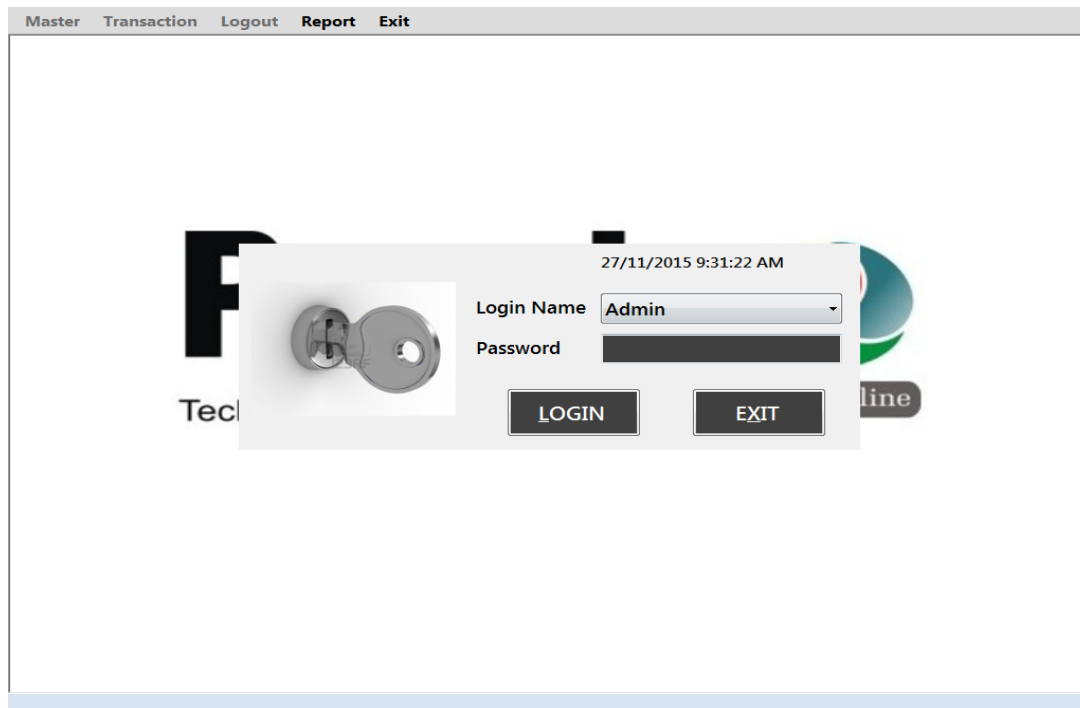
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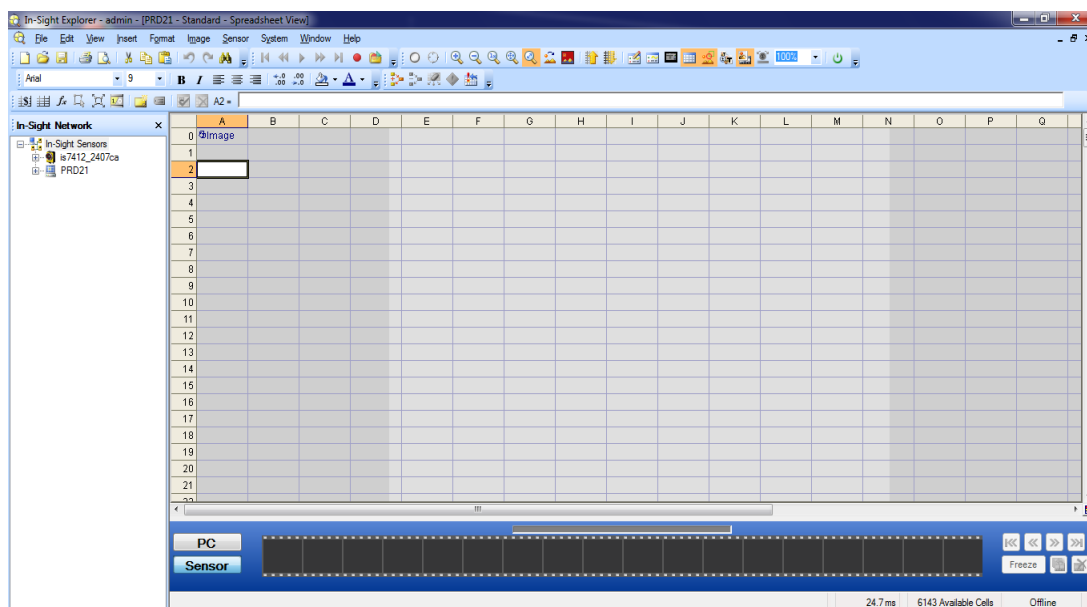
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### 5.8 CAMERA SETTING

5.8.1 Double click on the “In-Sight Explorer 4.8.0” icon on the desktop. This will open the In-Sight Explorer software.



5.8.2 Then double Click on the camera (is7412\_2407ca) after that following window will be displayed. Enter



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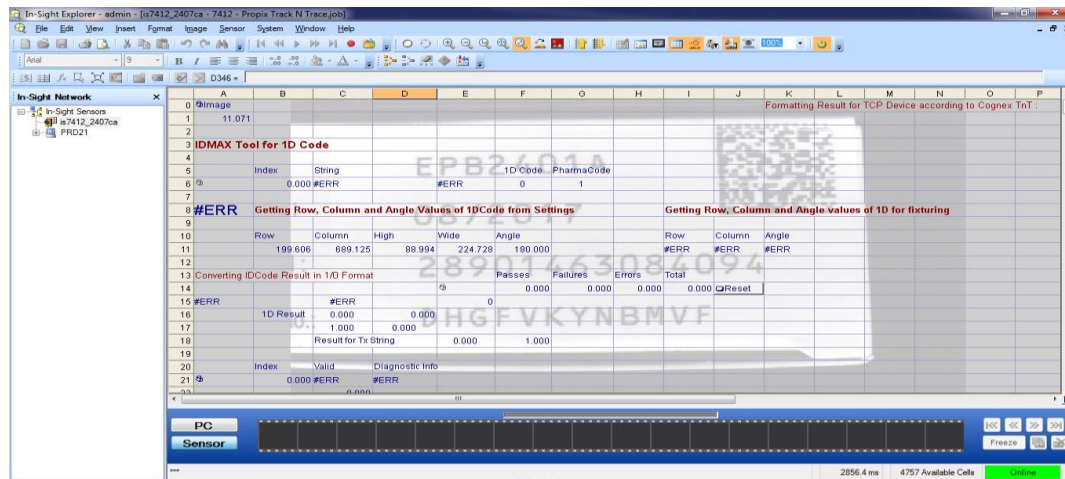
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the 'user name and password', click on 'LOG ON'.

S.no.	Type of Functions	User Rights Assignment(Y/N)		
		Operator	Supervisor	Administrator (Production Head)
01	To create new 'user' & 'password'	N	N	Y
02	Start / stop camera	Y	Y	Y
03	Setting of camera	N	Y	Y

and three different user have different right assignments as below given:

5.8.3 After selecting 'log on' displayed as below. Click on 'custom view' button(on the top) as highlighted above on below display:



5.8.4 Pass one object to take image after that display will shows below screen:





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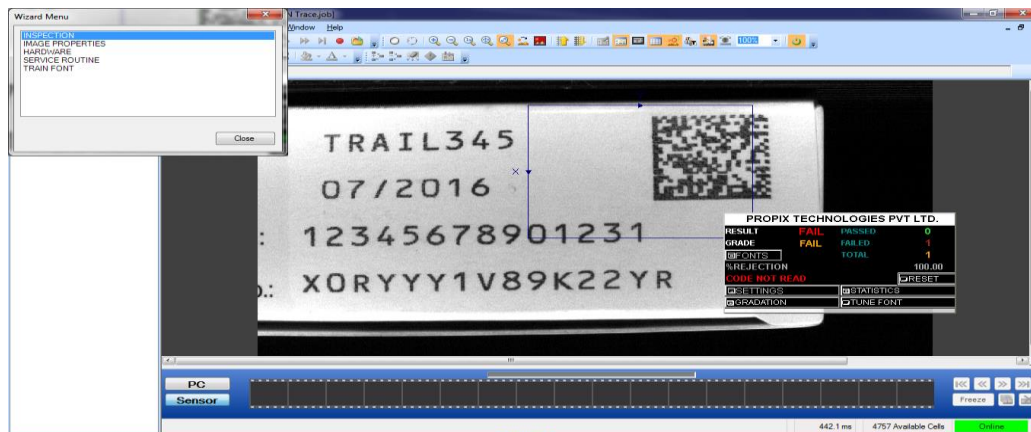
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- 5.8.5 Then select the 'setting' button present on the small screen of the propix technologies pvt. Ltd. for setting of inspection mode and click on the 'inspection' button.

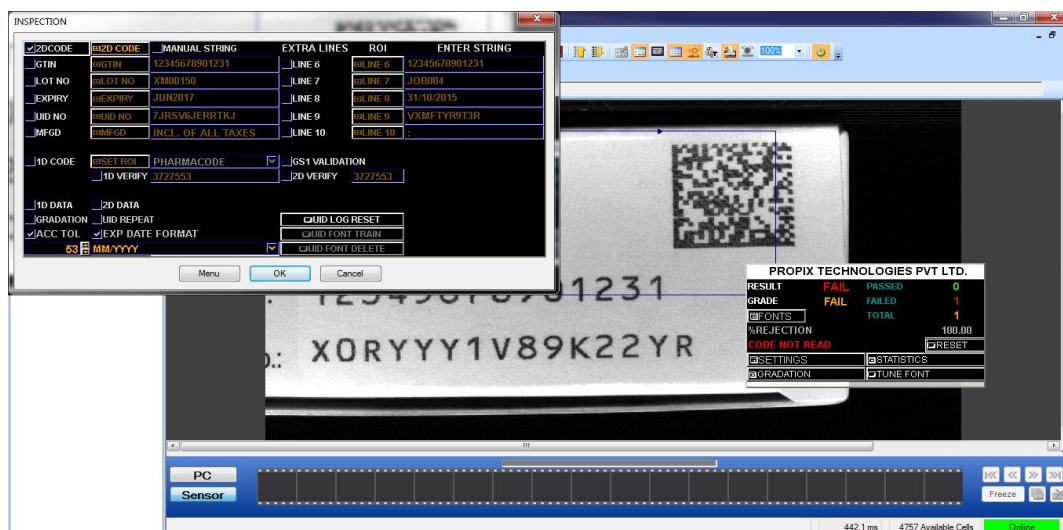


- 5.8.6 And then set 'ROI' of the required filled like as '2DCODE / GTIN / LOT NO / EXPIRY /MFGD / LINE / etc' as per requirements.

- 5.8.7 Click on the 'LINE' button to set the Region of Interest for the 'OCR' line that is to be inspected.

- 5.8.8 Enter the actual characters that will be printed on the Carton/Inner for that particular line into the adjacent text box to the 'LINE' button.

- 5.8.9 Repeat this procedure for all the 'OCR' lines that are to be inspected by enabling the lines by clicking on respective checkboxes.



- 5.8.10 For individual 'ROI' setting draw 'ROI' in as per the below image.



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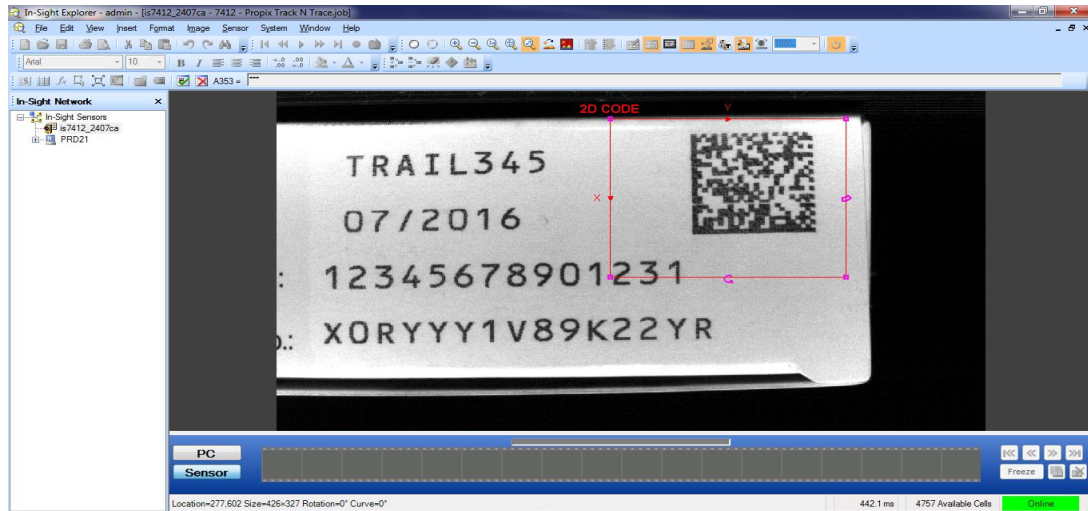
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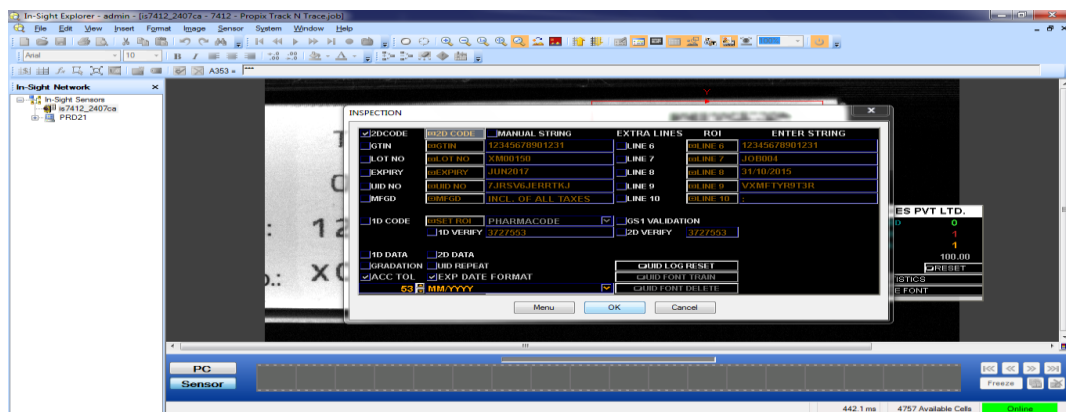
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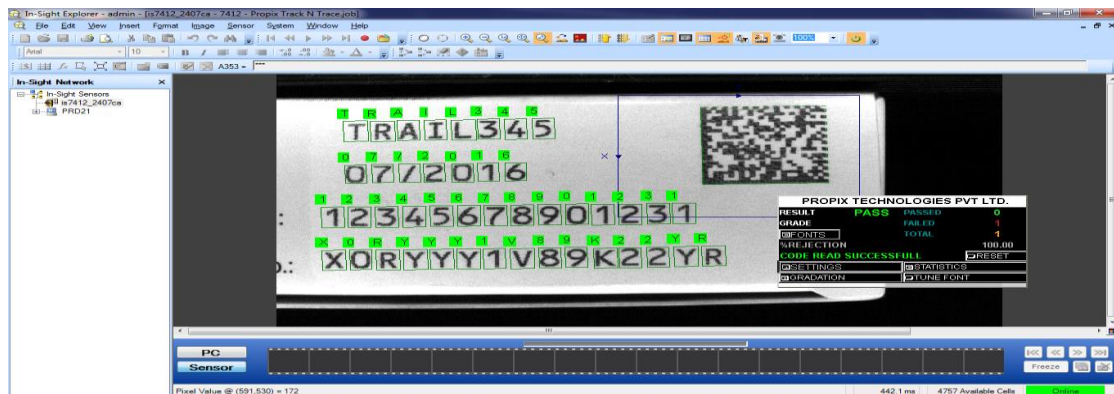
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5.8.11 After setting all required character 'ROI' press ok button on the screen as per below image.



5.8.12 After that do a 'TUNE FONT' by pressing tune font on the screen as per below image for train the font automatically.







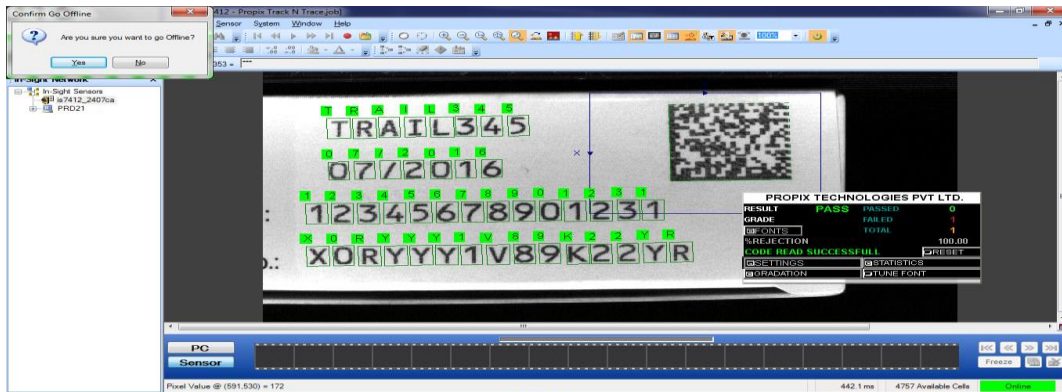
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5.8.13 After all required setting of 'OCR' to start the inspection activity press 'start' (online) / stop (offline) icon on the screen as per the below image.



5.8.14 For exit stop the inspection and close the window.

5.8.15 A typical GTIN number would look like 8901463057985 which is of 13 digits where in :  
8901463 07 digits Stands for Company Prefix Number & in GTIN terms is also reflected as GS1. This doesn't change.

XXXXX 5 digits Stands for FG Code (Last 5 Digit from FG Code). This will change as per product

X 1 last digit Stands for Check Digit (Auto Generated by System)

Just for example, suppose if the FG code is FG005798, then the Base GTIN will be 8901463 05798 5

For the **Primary** level packaging the GTIN number will be start from no. 0, for example (0 8901463 05798 5)

For the **Secondary** level packaging the GTIN number will be start from no. 1, for example (1 8901463 05798 5)

For the **Tertiary** level packaging the GTIN number will be start from no. 5, for example (5 8901463 05798 5)

5.8.16 After completion of setting take the print and check the visibility of the print Scan and verify the 2D Barcode by using portable barcode scanner (Take the approval of carton from the concern production officer and Q.A. officer)

5.8.17 DGFT system generates serial no. which is unique identification no. which varies according to respective software.



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### 5.9 Camera Challenge test:

#### 5.9.1 CHALLENGE TEST FOR GOOD CARTON:

5.9.1.1 After approval of overprinting detail pass the overprinted good carton through the machine.

5.9.1.2 It must be pass.

5.9.1.3 Record the observation in Annexure-I.

#### 5.9.2 CHALLENGE TEST FOR 2D CODE:

5.9.2.1 Mark extra lines or deface the 2D CODE by making big dot in center of 2D code with marker.

5.9.2.2 Now pass the carton through camera.

5.9.2.3 It must be rejected.

5.9.2.4 Record the observation in Annexure-I.

#### 5.9.3 CHALLENGE TEST FOR CARTON WITHOUT 2D CODE (Applicable For Overprinting Detail Only):

5.9.3.1 Deface the overprinting detail with marker by overlapping the last digit of B.no. and pass it through camera.

5.9.3.2 It must be rejected.

5.9.3.4 Record the observation in Annexure-I.

#### 5.9.4 CHALLENGE TEST FOR CARTON WITH PHARMA CODE:

5.9.4.1 Mark extra line by marker in the pharmacode.

5.9.4.2 Now pass the carton through camera.

5.9.4.3 It must be rejected.

5.9.4.4 Record the observation in Annexure-I.

#### 5.9.5 CHALLENGE TEST FOR DOUBLE CARTON:

5.9.5.1 Pass the double carton together through the DGFT bar code system with camera inspection system.

5.9.5.2 Both carton must be rejected by rejection system and must be fall into collection box.

5.9.5.3 Record the observation in Annexure-I

Note: Cartons (excluding cartons used for good carton challenge) used for the challenge test shall be marked.

**Frequency:** At the start, after every two hours and at the end of operation.

### 6.0 ABBREVIATION (S):

6.1 SOP: Standard Operating Procedure.





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6.2 DGFT : Directorate General of Foreign Trade.

6.3 GTIN : Global Trade Identification Number.

6.4 CPU: Central Processing Unit.

6.5 UPS: Uninterrupted power supply.

6.6 OCR : Optical character recognition.

### 7.0 REFERENCE (S):

7.1 SOP : Disposal of excess printed material.

### 8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Challenge test for camera inspectio system of DGFT bar code for overprinting detail on carton.		Format

### 9.0 DISTRIBUTION

9.1 **Master copy** : Quality Assurance

9.2 **Controlled copy (s):** Production General Block (01), Quality Assurance (01)

9.3 **Reference copy (s) :** Production General Block (05)

### 10.0 REVISION HISTORY:

S. No.	Version No.	Change Control No.	Reason (S) For Revision	Details Of Revision	Effective Date



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### ANNEXURE I

#### Procedure for cleaning and operation of DGFT Packi Track n Trace system with conveyor belt and camera inspection system

FREQUENCY: At start, after every two hours and at end of operation.									
No. of good cartons taken 02 Nos.					No. of bad carton taken 01 No.				
DATE	TIME	CHALLENGE TEST FOR				RESULT OK/NOT OK	CHECKED BY (Production)	VERIFIED BY(IPQA)	
		* GOOD CART ON	# CARTON WITH 2D CODE	# CARTON WITH OVERPRINTING DETAIL(where 2D BAR CODE not applicable)	# CARTON WITH PHARMACODE				¥ DOUBLE CARTON

\* Mark "OK" in observation if pass and mark "NOT OK" if rejected.

# Mark "OK" in observation if rejected and mark "NOT OK" if pass & ¥ Mark "OK" in observation if both cartons rejected and mark "NOT OK" if one or both carton passed.