

2D BARCODING ON PRIMARY LEVEL

A feasibility Study

Project Description :

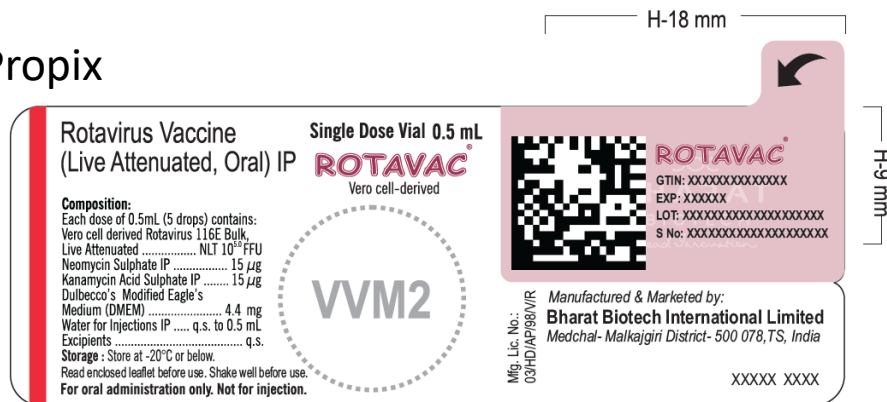
DCVMN (Developing Countries Vaccine Manufacturers Network) in consultation with M/s Bharat Biotech was working out on feasibility of extending the solution of 2 D barcoding to primary level. Bharat Biotech team discussed the matter on 15th March 2022, for possible extension of solution of 2D barcoding technology to Primary packaging level. After due delegece, the project being awarded to M/S Propix technologies Pvt. Ltd. Pune India, for giving consultancy for supporting the project including, Labels artwork modification and Designing a solution architecture for implementation of Track and Trace technology up to the primary packaging level.

Activity Description	Scope	Process Owner
Gap analysis of equipment and software/Hardware requirements understanding for implementation of 2D bar coding at Primary Packaging Level	Propix BBIL	Nirav Trivedi BBIL
Integration part for New software requirement for extending any existing barcoding equipment up to primary packaging level with documentation and qualification	Propix BBIL	Nirav Trivedi BBIL
Guidance & Support for Software and Hardware Requirements / Modifications.	Propix	Nirav Trivedi Ashwin Kapadnis
Assistance for integration, qualifications of Equipment and Modification requirements for Artwork of Labels and Cartons.	Propix BBIL	Ashwin Kapadnis Nirav Trivedi Ajay Bapat BBIL
Consultation for GS1 registration (Not Applicable incase already registered with GS1)	Propix	Ajay Bapat Nirav Trivedi
Assistance for Documentation and SOP preparation for BBIL	Propix	Nirav Trivedi Documentation Team
Sample Collection for Trials and to understand modification requirements for Primary Packaging Level	Propix BBIL	Nirav Trivedi Ajay Bapat BBIL
Sample Study & feasibility to include 2D barcode on primary packaging level. BBIL to provide details of all Primary packaging material used (Vials are considered as Primary Packaging Level, Syringes or Ampules are not considered due to Space constraint)	Propix BBIL	Nirav Trivedi Ajay Bapat BBIL
Samples/Layouts preparation with 2D Barcode on Primary Packaging Level	Propix	Ajay Bapat
Samples to be sent to Bharat Biotech for approval	Propix	Nirav Trivedi Ajay Bapat

Activity Description	Scope	Process Owner
Internal study (Gap analysis) of Modification required for Software and Hardware in Existing Machines	Propix	Ashwin Kapadnis Nirav Trivedi Documentation Team
Visit to Bharat Biotech plant to understand line level feasibility and integration of software	Propix	Nirav Trivedi Ajay Bapat
Layout Preparation of Hardware / Software	Propix	Nirav Trivedi Design Team Development Team
Submission of Techno - Commercial details to BBIL for Approval	Propix	Ashwin Kapadnis Nirav Trivedi
Extended Support for Documentation and Trials post installation	Propix	Nirav Trivedi Project Team

Sr. No	Description
1	Discussion on Artwork Modification for below Products (discussed in detail with a focus on space creation on labels) 1. Typbar TCV 0.5ml Vial and PFS Labels 2. Rotovac 0.5ml ug Vial Label 3. BioPolio 1ml Vial Label
2	Finalization of Minimum readable 2D Code size considering space constraint on Vial labels i.e., 8 x 8mm
3	Reducing font size to create more space to cater 2D code on label (There is no specific guidelines available thus can be minimized up to minimum reading level).
4	Removing Unwanted text matter from artwork like Address Lines and product details etc..
5	Removing red colored warning box, as It is for export purpose and warning box is not required
6	Modification in Label Size If possible
7	As suggested by BBIL team, decided to go for a trial run/ feasibility work on Rotovac 0.5 ml vial label

Draft proposed by Propix



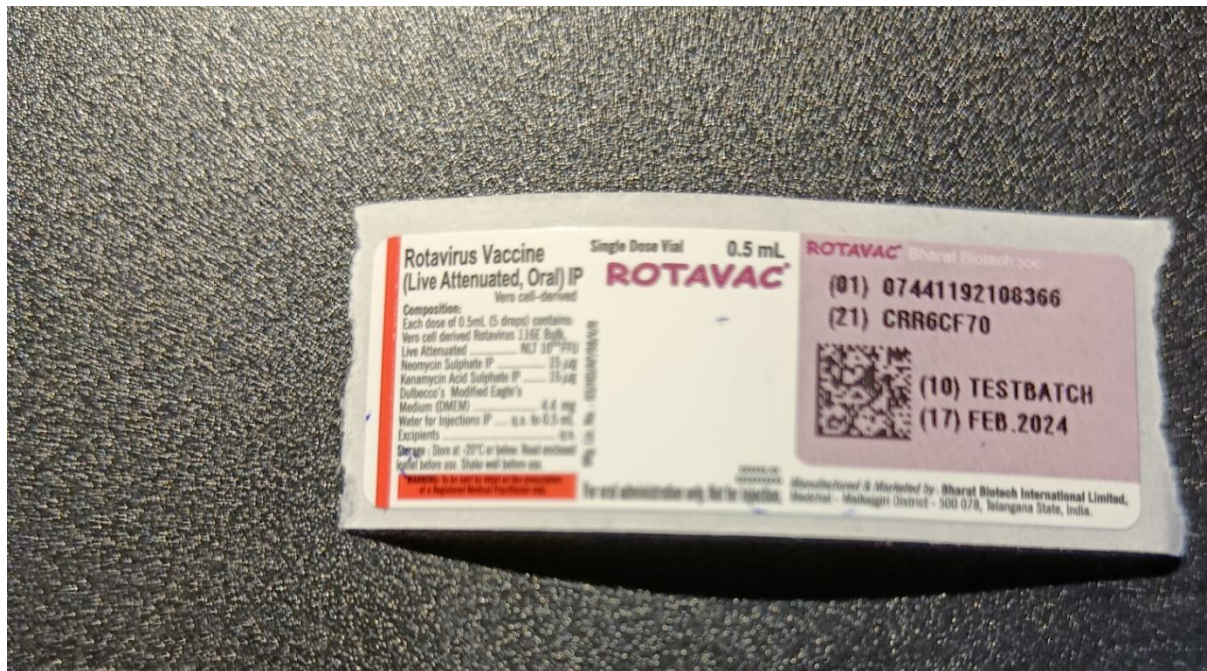
Vial Label Size: W-50mm x H-18mm print on PP White

Sr. No	Description
1	Font Size is reduced
2	Red Warning Box is Removed. Hindi text for product name removed
3	Instruction Line along with Warning Box is removed
4	Manufacturing License Text orientation is changed
5	Bharat Biotech Logo is in Back Side of 2D Code which is to be removed
6	BBIL is to send label roll with suggested Artwork for Trials with Actual Vials
7	While actual printing of sample roll the pink color shown here in draft to be made white so as to have max contrast for 2D code printing.
8	VVM2 size and place can not be touched.

Sr. No	Description
1	L2 i.e., Secondary Packaging level Software Modification required considering aggregation between Primary and Secondary objects, as suggested by BBIL team
2	L3 i.e., Server Level Software Modification required for Addon of Primary packaging level into the Track and Trace Process
3	Modification in Line Level hardware Setup
4	Vial Label batch Coding / 2D Coding Inspection system along with rejection system shall be added into the process
5	360° Inspection System for Vials and Accumulator Mechanism to be assessed with Mechanism to Enhance Packing process to be added within Existing Setup
6	Divertor for Outer Carton filling and Shipper Level generation system shall be added into the process.
7	General Drawing Layout shall be sent to BBIL for approval suggesting above changes.

- The samples of proposed labels, 2 ml vials and plain laminated cartons were received at Propix Technologies Pune from Bharat Biotech on 29th Sep 2022 for trials
- The label samples received as one roll, with overprinting zone of 20 x 12 mm created for trials.
- However, the pink zone of OPZ needs to be made in white when we go for commercial.
- The cartons received are laminated cartons, whereas the actual product will be non-laminated.
- Following trials were undertaken and the evident samples are enclosed for ready reference

Sample of label with 6 x 6 mm barcode



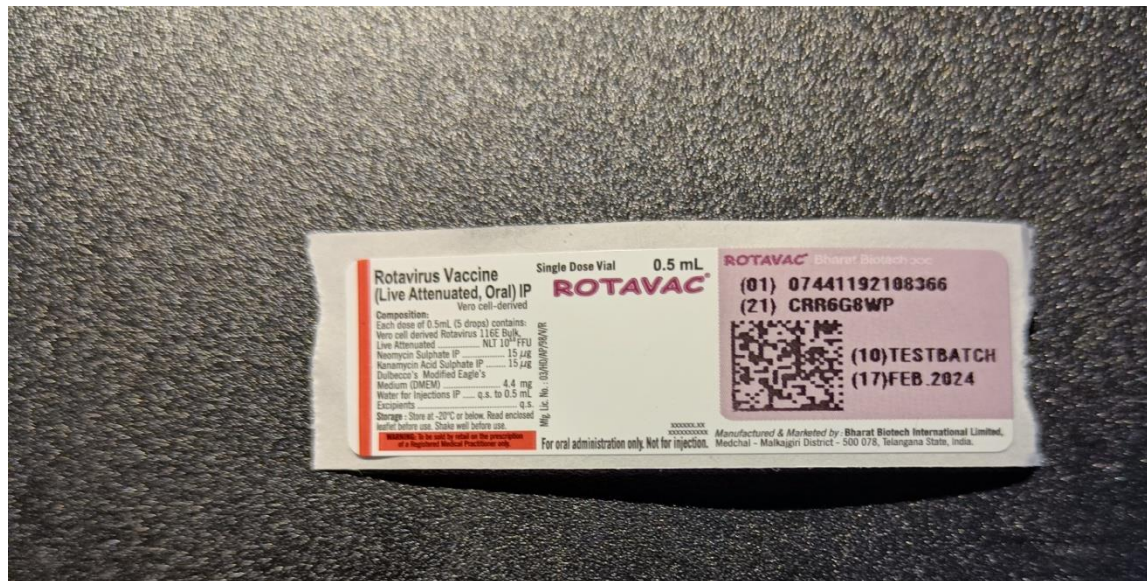
Picture of new labeled vial



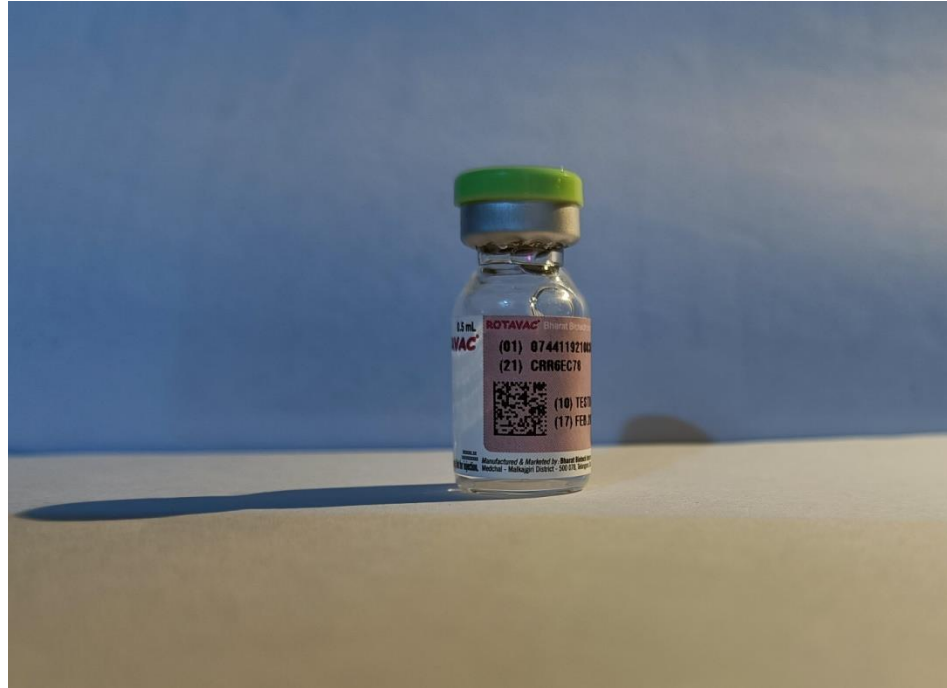
Copy of screenshot that the barcode is read successfully



Sample of label with 8 x 8 mm barcode



Picture of new labeled vial

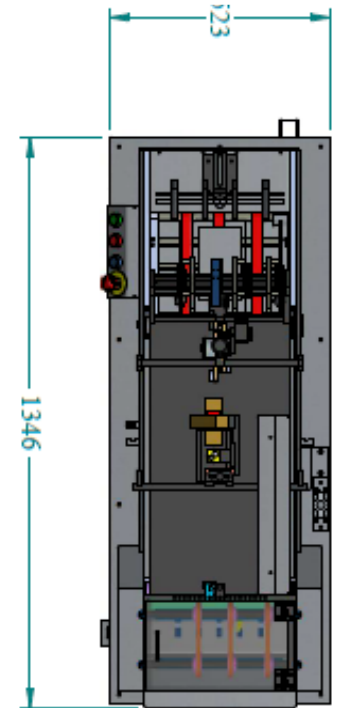
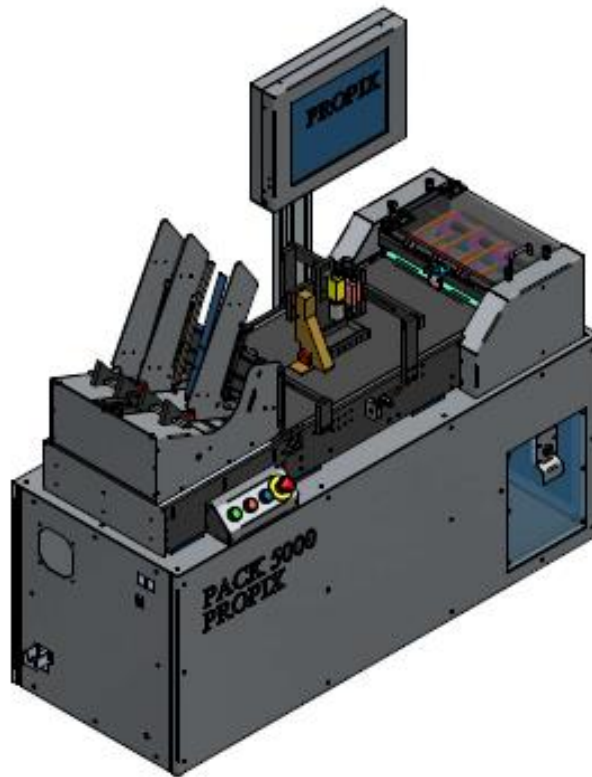
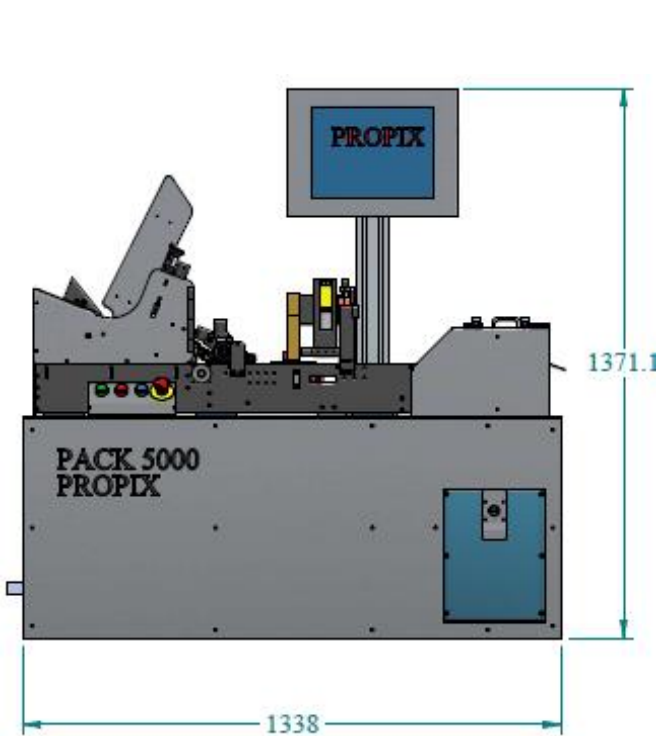


Copy of screenshot that the barcode is read successfully



- Though the trial is taken on label for 2 options, 6 x 6 mm and 8 x 8 mm 2D barcode printing, Propix recommends :
 1. To have a 2D barcode of 8 x 8 mm looking at the label size and complexities involved in artwork modifications.
 2. The recommended size of 8 x 8 mm can easily be printed and scanned on camera system
 3. For aggregation purpose we recommend to install a fixed camera and an operator will have to show one labelled vial and carton already printed and pair them by software for aggregation.

REQUIREMENTS (Option – 1 Manual Operation)
Station 1 - Offline Carton Printing Station

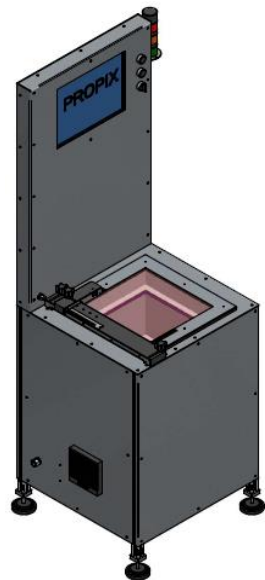
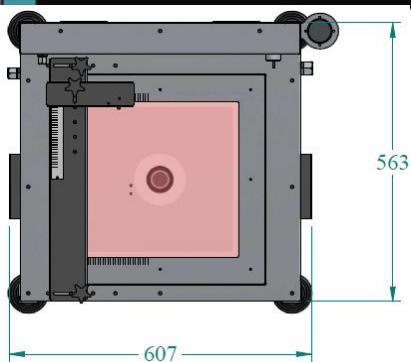


Offline Carton Printing Station with Carton Stacker and Rejection System

Sr. No	Description	QTY	Price (INR)	Price(USD)
1	PACK5000 SYSTEM: Flat Carton Conveying system with top motorized belt to hold carton from top side a) Integrated Flat carton destalking unit for various size carton b) Keyless operation for printer & camera and carton top belt guide assembly. c) Required Mounting Fixtures for Vision Controller, Camera & Printer d) In built rejection system with rejection bin e) Safety door sensors, Rejection verification sensor, rejection bin full sensor. Flat Carton Size (Min-Max mm) Length: 110 – 250 mm Width: 60 - 175mm	1	3141000.00	42000\$
2	Main Application Software Lic: PACKi Track & Trace Software license with printer communication, Camera communication, I/O (Conveyer Control) Communication, 2D Code inspection as ISO15415 Standard, Database Management, 21CFR Part 11 Compliance, User friendly User interface, Rework functionality, challenge test functionality, product sampling functionality, Single Application for Label application and Track n Trace functionality.	1		
3	Printer: HP cartridge based TIJ Printer, max resolution 600 DPI, Suitable for printing on Un-varnished area, Single printing head (12 MM print height)	1		
4	Inspection device: Insight HR series Cognex Smart camera with Lens and while LED based high-definition illumination	1		
5	Vision Controller: Intel Chipset High Speed Controller, above 2.2GHz intel i7 processor, 8GM RAM, 120GB SSD Storage device, 17 Inch HMI / LCD Touch Screen, ethernet switch, Windows 10 Operating system	1		
6	I/O Controller: Various Sensor, Cognex Cable set, Propix Cable Set for rejection & Electronic Hardware with Power supply, rejection	1		
7	Documentation & Validation including DQ, IQ, OQ, SOP and Operational Manual ONLY IN ENGLISH	1		
8	Installation & Training	1		

REQUIREMENTS

Station 2 - Vial to Carton Aggregation Station



Offline Vial and Carton 2D Code scanning Station with Bottom Camera

Sr. No	Description	QTY	Price (INR)	Price (USD)
1	Inspection Device 2D Code Scanning Camera system to Read 2D code on labels and Cartons	1	1017000.00	13600\$
2	Main Application Software Lic: PACKi Track & Trace Software license with printer communication, Camera communication, I/O (Conveyer Control) Communication, 2D Code inspection as ISO15415 Standard, Database Management, 21CFR Part 11 Compliance, User friendly User interface, Rework functionality, challenge test functionality, product sampling functionality, Single Application for Label application and Track n Trace functionality.	1		
3	Vision Controller: Intel Chipset High Speed Controller, above 2.2GHz intel i7 processor, 8GM RAM, 120GB SSD Storage device, 17 Inch HMI / LCD Touch Screen, ethernet switch, Windows 10 Operating system	1		
4	I/O Controller: Various Sensor, Cognex Cable set, Propix Cable Set for rejection & Electronic Hardware with Power supply, rejection	1		
5	Documentation & Validation including DQ, IQ, OQ, SOP and Operational Manual ONLY IN ENGLISH	1		
6	Installation & Training	1		

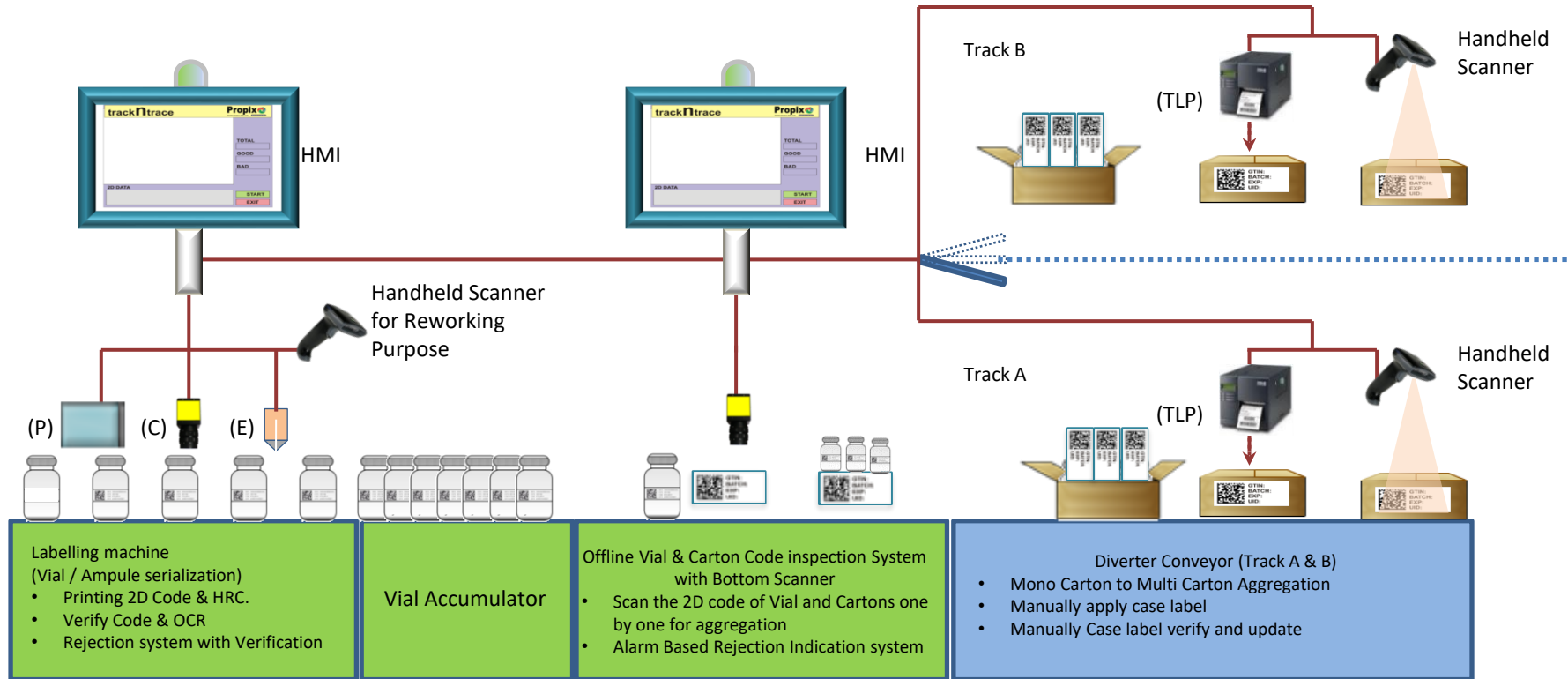
Accumulator along with Diverter and Multi Carton Print & Scan & Shipper Station

Sr. No	Description	QTY	Price (INR)	Price (USD)
1	500mm Accumulator with Drive	1	1701000.00	22700\$
2	Diverter with Traffic Management System Approx. 1000mm	1		
3	Thermal Label printer for Multi Carton Label Printing for Diverter Side A & B	2		
4	Handheld scanner for Multi Carton Label scanning for Diverter Side A & B	2		
5	Standard PC with 15" Touch Screen	1		
6	Application Software Lic.	1		
7	Documentation & Validation including DQ, IQ, OQ, SOP and Operational Manual ONLY IN ENGLISH	1		
8	Installation & Training	1		

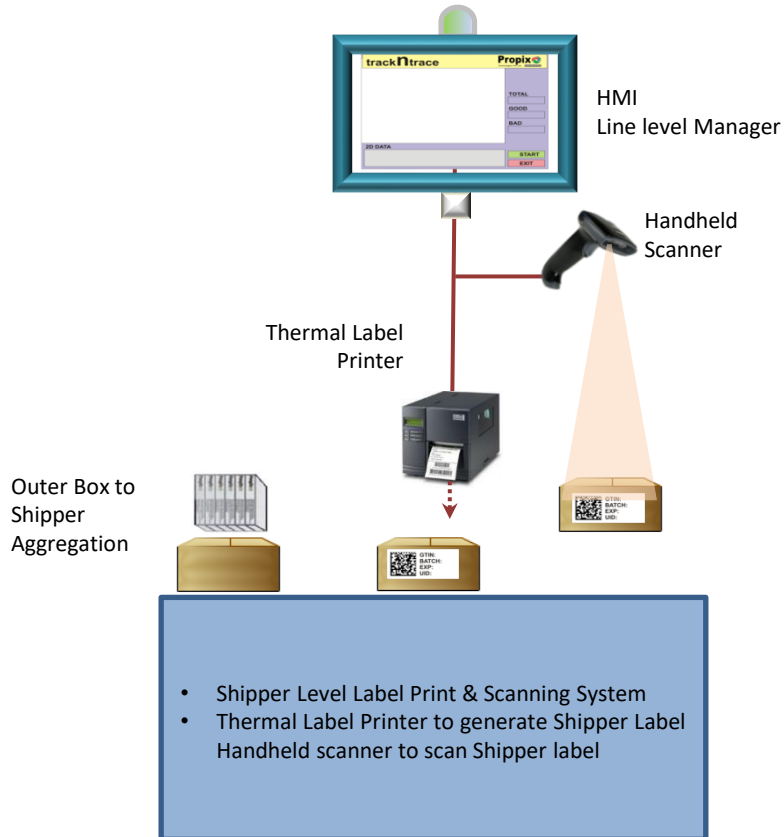
Shipper Level Label Print & Scanning

Sr. No	Description	QTY	Price (INR)	Price (USD)
1	Thermal Label printer for Shipper Label Printing	1	819000.00	11000\$
2	Handheld scanner for Shipper Label scanning	1		
3	Standard PC with 15" Touch Screen	1		
4	Application Software Lic.	1		
5	Documentation & Validation including DQ, IQ, OQ, SOP and Operational Manual ONLY IN ENGLISH	1		
6	Installation & Training			

Proposed Line Layout



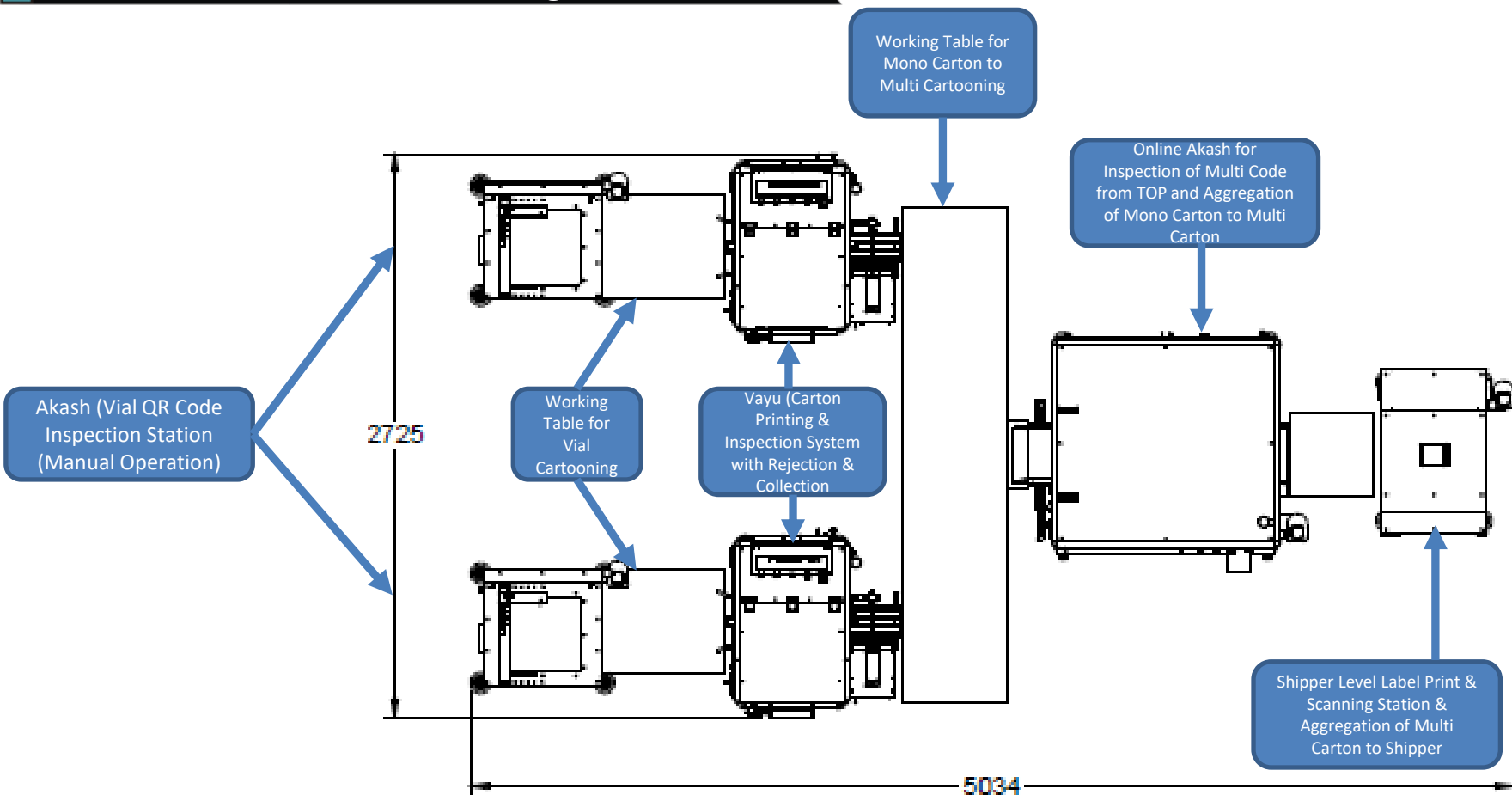
Line Layout (Shipper)



1. Offline Carton Printing Station will be installed Separately for Pre-Printing cartons. System will be integrated with Track and Trace server and data will be generated on server.
2. A Camera and TIJ (Thermal Ink Jet Printer) will be installed on the labelling machine along with Encoder Based Rejection Mechanism and Collection Box, for Printing of 2D code along with Batch details in Human Readable format.
3. Vial Accumulator will be aligned along with Labelling machine to accumulate vials to ensure vial labelling at its optimum rated speed.
4. After Accumulator there will be a Offline system installed with Bottom 2D Code scanner. User will scan 2D Code printer on Vial and Mono Carton one by one to establish aggregation between Vial and Carton.
5. Diverter will be placed along with each Vial / Mono Carton inspection station. User will have to convey Scanned Mono Carton on Diver A & B Respectively for manual operation of Multi Carton filling. Multi carton Label will be automatically generated once required quantity of Mono cartons are scanned.
6. User will have to paste Multi Carton Label manually and scan 2D code manually using handheld scanner integrated with system, after scanning user will put scanned multi carton in shipper.
7. A shipper label will be automatically generated, and user has to scan shipper label manually to complete the aggregation process.

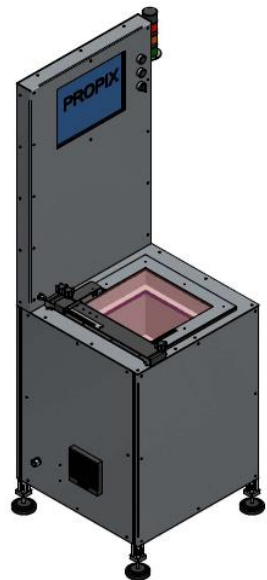
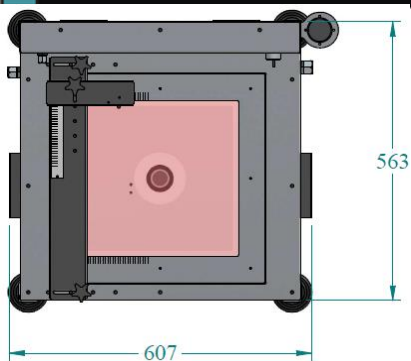
REQUIREMENTS (Option – 2 Semi Automatic)

Station 1 - Offline Carton Printing Station



REQUIREMENTS

Station 1 - Offline Vial QR Code inspection

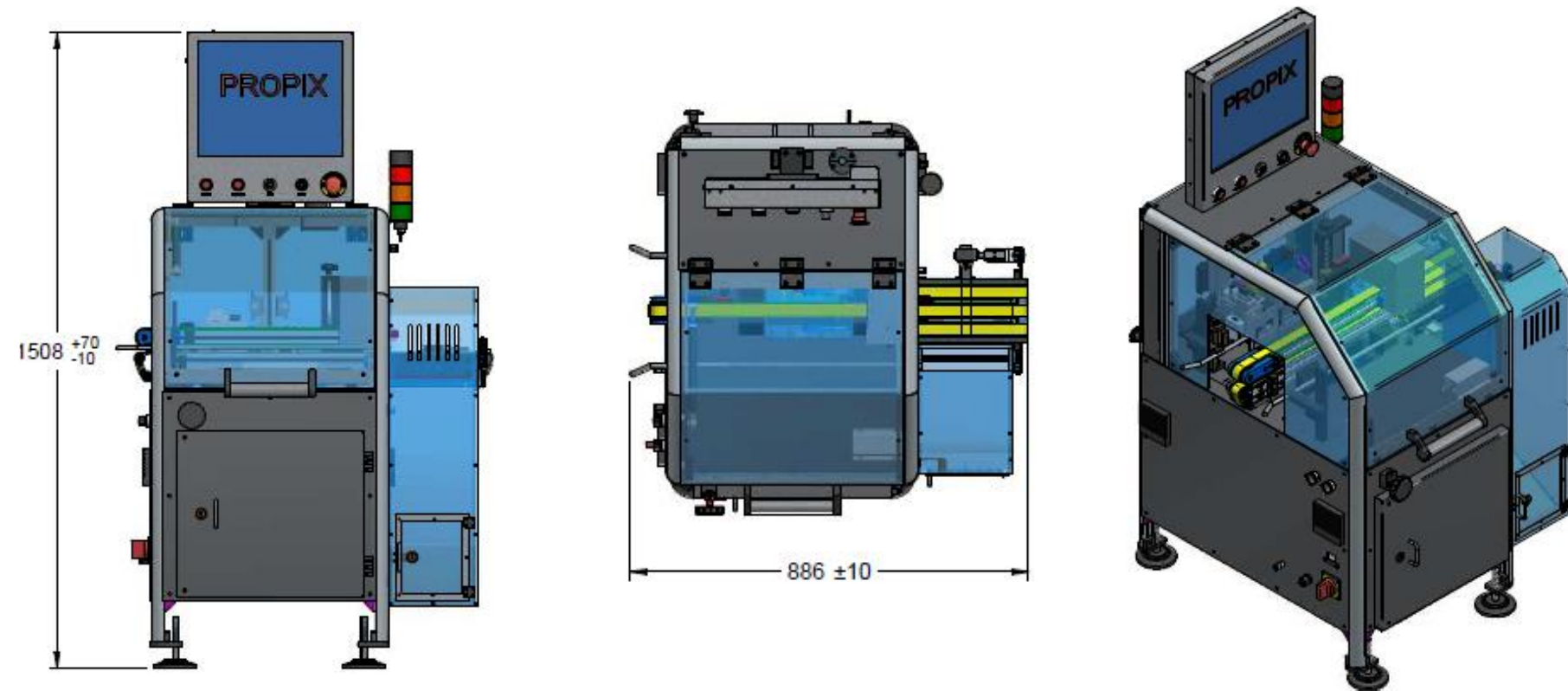


Offline Vial and Carton 2D Code scanning Station with Bottom Camera

Sr. No	Description	QTY	Price (INR)	Price (USD)
1	Inspection Device 2D Code Scanning Camera system to Read 2D code on labels and Cartons	2	2250000.00	29400\$
2	Main Application Software Lic: PACKi Track & Trace Software license with printer communication, Camera communication, I/O (Conveyer Control) Communication, 2D Code inspection as ISO15415 Standard, Database Management, 21CFR Part 11 Compliance, User friendly User interface, Rework functionality, challenge test functionality, product sampling functionality, Single Application for Label application and Track n Trace functionality.	2		
3	Vision Controller: Intel Chipset High Speed Controller, above 2.2GHz intel i7 processor, 8GM RAM, 120GB SSD Storage device, 17 Inch HMI / LCD Touch Screen, ethernet switch, Windows 10 Operating system	2		
4	I/O Controller: Various Sensor, Cognex Cable set, Propix Cable Set for rejection & Electronic Hardware with Power supply, rejection	2		
5	Working Table	2		
6	Documentation & Validation including DQ, IQ, OQ, SOP and Operational Manual ONLY IN ENGLISH	2		
7	Installation & Training	2		

REQUIREMENTS

Station 2 - Vayu (Carton Printing & Rejection)

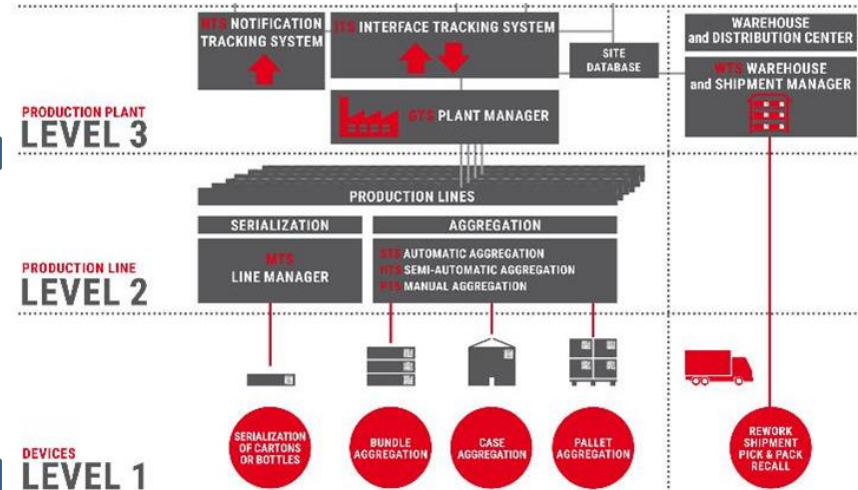
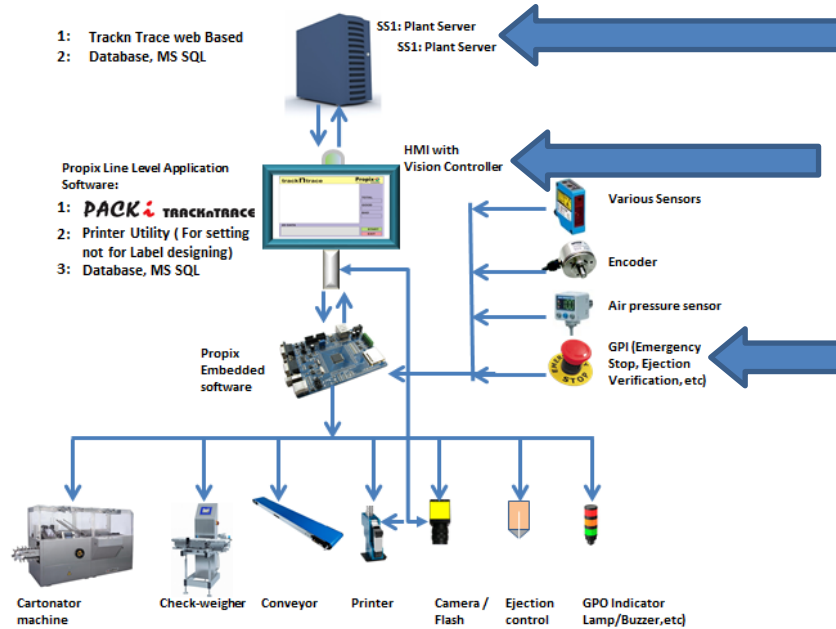


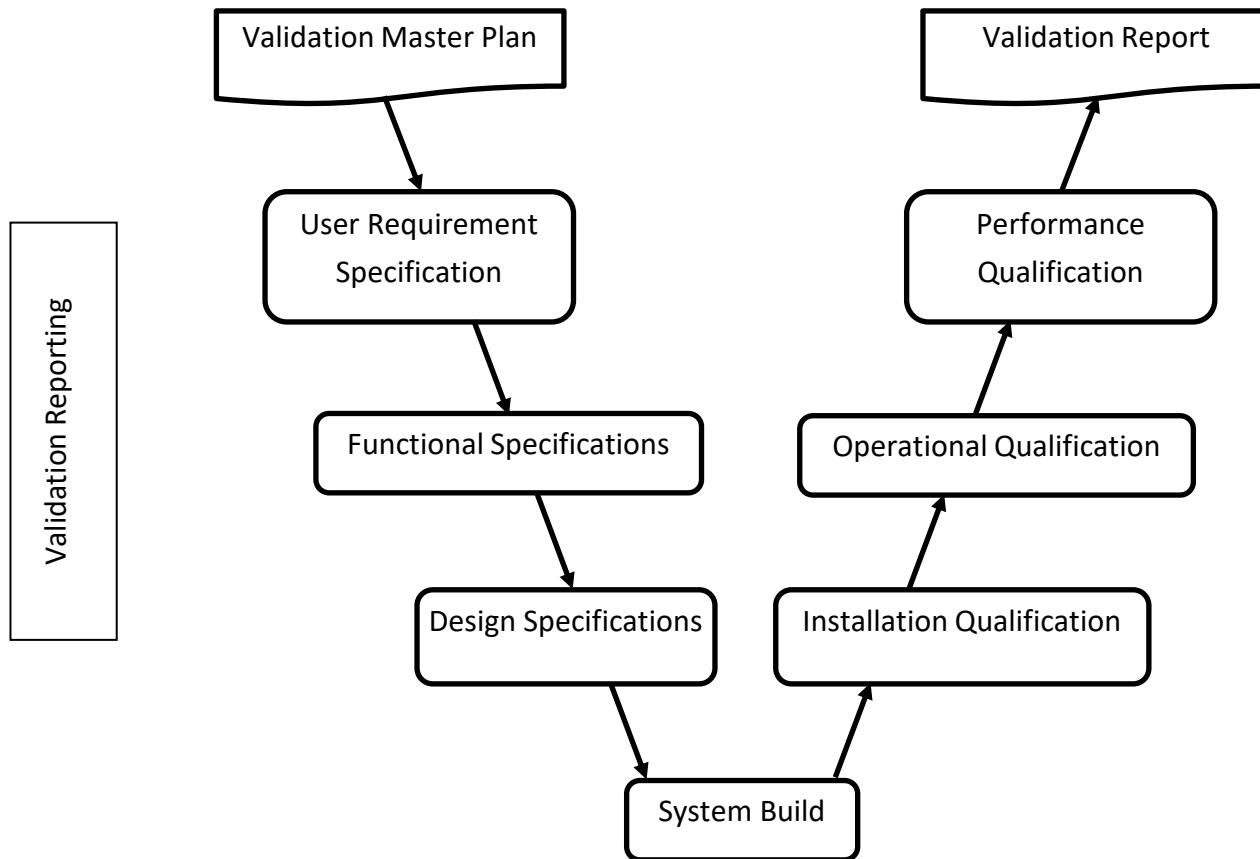
Carton Printing Station with Printing, Inspection and Rejection System

Sr. No	Description	QTY	Price (INR)	Price(USD)
1	VAYU: Carton Conveying system with top motorized belt to hold carton from top side a) Keyless operation for printer & camera and carton top belt guide assembly. b) Required Mounting Fixtures for Vision Controller, Camera & Printer c) In built rejection system with rejection bin d) Safety door sensors, Rejection verification sensor, rejection bin full sensor.	2	5040000.00	67200\$
2	Main Application Software Lic: PACKi Track & Trace Software license with printer communication, Camera communication, I/O (Conveyer Control) Communication, 2D Code inspection as ISO15415 Standard, Database Management, 21CFR Part 11 Compliance, User friendly User interface, Rework functionality, challenge test functionality, product sampling functionality, Single Application for Label application and Track n Trace functionality.	2		
3	Printer: HP cartridge based TIJ Printer, max resolution 600 DPI, Suitable for printing on Un-varnished area, Single printing head (12 MM print height)	2		
4	Inspection device: Insight HR series Cognex Smart camera with Lens and while LED based high-definition illumination	2		
5	Vision Controller: Intel Chipset High Speed Controller, above 2.2GHz intel i7 processor, 8GM RAM, 120GB SSD Storage device, 17 Inch HMI / LCD Touch Screen, ethernet switch, Windows 10 Operating system	2		
6	I/O Controller: Various Sensor, Cognex Cable set, Propix Cable Set for rejection & Electronic Hardware with Power supply, rejection	2		
7	Documentation & Validation including DQ, IQ, OQ, SOP and Operational Manual ONLY IN ENGLISH	2		
8	Installation & Training	2		

Offline Vial and Carton 2D Code scanning Station with Bottom Camera

Sr. No	Description	QTY	Price (INR)	Price (USD)
1	Inspection Device 2D Code Scanning Camera system to Read 2D code on Cartons	1	3970000.00	53000\$
2	Inspection Device Multi 2D Code Scanning Camera system to Read 2D code on Mono Cartons from TOP			
3	Main Application Software Lic: PACKi Track & Trace Software license with printer communication, Camera communication, I/O (Conveyer Control) Communication, 2D Code inspection as ISO15415 Standard, Database Management, 21CFR Part 11 Compliance, User friendly User interface, Rework functionality, challenge test functionality, product sampling functionality, Single Application for Label application and Track n Trace functionality.	1		
4	Vision Controller: Intel Chipset High Speed Controller, above 2.2GHz intel i7 processor, 8GM RAM, 120GB SSD Storage device, 17 Inch HMI / LCD Touch Screen, ethernet switch, Windows 10 Operating system	1		
5	Carton Conveying system with top motorized belt to hold carton from top side a) Keyless operation for printer & camera and carton top belt guide assembly. b) Required Mounting Fixtures for Vision Controller, Camera & Printer c) In built rejection system with rejection bin d) Safety door sensors, Rejection verification sensor, rejection bin full sensor.	1		
6	I/O Controller: Various Sensor, Cognex Cable set, Propix Cable Set for rejection & Electronic Hardware with Power supply, rejection	1		
7	Printer: HP cartridge based TIJ Printer, max resolution 600 DPI, Suitable for printing on Un-varnished area, Single printing head (12 MM print height)	1		
8	Working Table	1		
9	Documentation & Validation including DQ, IQ, OQ, SOP and Operational Manual ONLY IN ENGLISH	1		
10	Installation & Training	1		





Qualification activity documents		Additional Documents as per requirements:
Validation Master Plan	Performance Qualification (PQ)	Non-Disclosure Agreement (NDA)
21 CFR Part 11 Assessment	IQ/OQ/PQ Reports	Service Level Agreement (SLA)
Risk Assessment Protocol (RAP)	Requirement Traceability Matrix (RTM)	Point of Contacts as per project
User Requirement Specifications (URS)	Validation Summary Report	User role authorization matrix
Functional Specifications (FS)	Standard Operating Procedure's (SOP's) 1. SOP for Database Backup 2. SOP for Operator 3. SOP for Administrator 4. SOP for change over mounting assembly 5. SOP for perform challenge test 6. SOP for creating user or changing password	Network Qualification (NQ)
Configuration Specifications (CS)		Statement of Work (SOW)
Design Specification (DS)		Master Service Agreement (MSA)
Factory Acceptance Test (FAT)		System Overview Document (SOD)
Installation Qualification (IQ)		System Design Document (SDD)
Operational Qualification (OQ)		Software Development Life Cycle
User Acceptance Test (UAT)	Operational Manual	
	Hardware Certificates	

- Primary level which is the innermost packaging level is without 2D barcode in most of the cases. This might give a way for counterfeiting companies to replace a product in market.
- With a 2D barcode on primary level will help the manufacturers to defend entry of spurious products entering market.
- Having aggregation with secondary level will have end to end traceability even at the dispensing level
- Although, this is a very difficult task to create a space on labels of smaller vials, ampoules, PFS or even on Al foil, the serialization up to primary packing level will be helpful for manufacturers to save the brand and may not loose the market share to counterfeiters.

- As per initial trials and observations, process flow is added in presentation. Actual SOP can be prepared after modifications in the software as per architecture requirements and hardware designs at implementation stage
- The solution Offered is as per initial trials and with available samples and primary requirements, there will be more enhancements in solution during actual site implementation.
- Application and server will comply with current regulatory requirements as per DGFT standards. Over a period of the time, system can be upgraded as per new guidelines and regulatory requirements.
- Training is a part of project execution and same will be imparted during project implementation. Propix shall provide complete documentation package with Operational Manual, Design Qualification, Installation Qualification, SOP and CSV.



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THANK YOU