

Offline Track and Trace System

INSTALLATION AND OPERATIONAL QUALIFICATION
ITX - INTEGRATED SOLUTIONS

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INSTALLATION AND OPERATIONAL QUALIFICATION (IOQ) PROTOCOL		Document #	<i>IOQ-ALLMED--</i>
		Revision	<i>01</i>
System	<i>Online Track and Trace System</i>	Date:	Jul 26th , 2019
Process:	<i>Full System Qualification and Validation</i>		
Location:	ALLMED HQ		

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Protocol Approval

This Protocol for the Installation Qualification (IQ) and Operational Qualification (OQ) protocol has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

PREPARED BY: Ibrahim Elwy (itX) DATE: _____
Site System Engineer

REVIEWED BY: _____ DATE: _____
 -

REVIEWED BY: _____ DATE: _____
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REVIEWED BY: _____ DATE: _____

REVIEWED BY: _____ DATE: _____
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APPROVED BY: _____ DATE: _____
 -

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REVISION HISTORY

Revision	Date	Description
01	JUL 20 th , 2019	Original release of protocol.

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Installation Qualification

Purpose:

Installation qualification is prepared to (have documented evidence that) the track and trace machine S.N: _____ is installed as complied with appropriate standards and regulations through analyzing critical specification factors.

Scope

This document is aimed to document all installation qualification (IQ) and operational qualification (OQ) activities for the 'Online Track and Trace System', installed in: _____.

Test Items:

- Safety
- Mechanical Installation
- Electrical Installation
- Utility
- Drawings
- Parts check
- Documentation

System Description

The 'Online Track and Trace System' is a stand-alone system for printing GS1 Data-matrix and human readable code, according to GS1 standards for pharmaceutical track and trace.

The system comprises of a conveyor for transporting Flat cartons from Feeder Magazine , a means for spacing cartons for precise printing and camera-based verification, means for printing, a camera and lighting system for verifying the printed code, a pneumatic rejection system, and a means for reject verification.

The operator interacts with the machine via 12" touch screen monitor& and is able to control all machine operations via strict user access level control, and is supervised with an online audit trail system.

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Steps

- Installation Qualification Tests Procedure:-

1- Safety

- **Purpose:**

To ensure the machine installation status in terms of safety and Operation to prevent the accident of operator and product damage in Advance.

- **Method:**

Be familiar with the attached safety instruction

- **Test Result**

No.	Item	Pass	Fail
1	Before Power ON, check all earthing connections are connected to chassis.		
2	With main circuit breaker off and machine connected to Mains Supply, check that machine chassis is connected to Mains earth.		
3	Power-ON, ensure no abnormal noise is observed		
4	Check AC/DC potential difference between machine chassis and another grounded surface (Should be 0V)		
5	Check that Safety Labels are properly attached		
6	Check that the machine provided Emergency Stop Push button		

Test Result	Pass <input type="checkbox"/>	Fail <input type="checkbox"/>
Note:		
Prepared by : Ibrahim Elwy (itX) Sign: Date:	Reviewed by : Sign: Date:	

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2- Mechanical Installation

- **Purpose:**

To ensure the machine installation is safety

- **Method:**

Check the Machine in Visual, and if required

Test Result

No.	Item	Pass	Fail
1	Check that the Machine is installed on a flat floor		
2	Check that there are no sharp edges or corners		
3	Check that there should be enough space for maintenance (Electric Panel, Mechanical Components)		
4	Check that belt/chain tension is adjustable		
5	Check that the feeder can be changed over Quickly		

Test Result	Pass <input type="checkbox"/>	Fail <input type="checkbox"/>
Note:		
Prepared by : Ibrahim Elwy (itX)		Reviewed by :
Sign:		Sign:
Date:		Date:

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3- Electrical Installation

Purpose:

To ensure that installed electrical components are suitable for main Power condition, main power is connected properly, and Connections for each part are properly installed.

Method:

- 1- Check electrical installation status as following
 - Check that approved components are properly installed
 - Check that is any damage or defect of components
 - Check the electrical wiring whether it is complied with electrical diagram.
 - Check that installed equipment's are suitable plant power condition
- 2- Check the following conditions before main power is plugged in
 - Check the protection status about circuit separation
 - Check the connection of each part

3.1Test Result

3.1.1 Electrical Installation: -

No.	Item	Pass	Fail
1	Check that electrical components are installed properly		
2	Check that there is any damage or defect on the installed equipment		
3	Check that there is any part mismatched with electrical diagram		
4	Check that all the wires are tagged with the right tag number as the wiring diagram		
5	Check that all components are suitable for electric power condition supplied		

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3.1.2 Sensor Check: -

No.	Item	Specification	Pass	Fail
1	Carton Presence Sensor (Trigger Sensor)	arca		
2	Reject Verification Sensor	Autonics		

3.1.3 Electrical Component: -

No.	Item	Specification	Pass	Fail
1	12V – 10A DC Power Supply	SDR-120-12		
2	24V – 10 A Power Supply	NDR-240-24		
3	Reject Solenoid SSR	OMCH JGX-2525DD		
4	Printer Controller	Zenjet Silver Sn()		
5	Real-time Controller	ITX RTC-V2.0		
6	Lighting Controller	OMCH JGX-2525DD		
7	Industrial PC	IPC		
8	Touch screen	12 inch NI USA		

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4- Imaging System

- **Purpose:**

To ensure the imaging system and its components are installed as designed

- **Method:**

Visually check the availability and interconnection of imaging components.

Test Result

No.	Item	Pass	Fail
1	Check camera Presence of Basler Ace Camera SN() with it's main assembly (Lens, Antipolarization).		
2	Check availability and fixation of lighting component		
3	Check polarization sheet is installed over lighting component		
4	Check availability and connection of lighting controller (electric panel)		
5	Check camera ethernet connection (CAT6 Cable)		

Test Result	Pass <input type="checkbox"/>	Fail <input type="checkbox"/>
Note:		
Prepared by : Ibrahim Elwy (itX)		Reviewed by :
Sign:		Sign:
Date:		Date:

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5- Utility:

- **Purpose:**

To ensure that Utility Condition for Machine running is provided Properly as per Utility conditions approved.

- **Method:**

1. Check the Space of production area.
2. Check the Utility Condition whether those are complied with following conditions

Test Result:

No.	Item		Pass	Fail
1	Voltage Check	~ 225.6 V AC		
2	Earthing Check			
3	Compressed air Check	Bar		
4	Room Temperature Check	°C		
5	Room Humidity Check	%		

Test Result	Pass <input type="checkbox"/>	Fail <input type="checkbox"/>
Note:		
Prepared by : Ibrahim Elwy (itX) Sign: Date:	Reviewed by : Sign: Date:	

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6-Manuals and Technical Documentation

The following manuals and datasheets are verified to reflect the as-built system:

Major Component	Document ID	Soft/Hard Copy	Verified / Date
Basler Camera	AW00089320000 ace GigE Users Manual	Soft	
Lights Datasheet	VL-B05015W SepcSheet	Soft	
Lights Drawings	VL-B05015.pdf	Soft	
Lens Drawings	VS-1614H.pdf		
Lens Specifications + Drawings	VS-1614H.pdf	Soft	
Ethernet Switch User Manual	DS_EKI-2525 2528 EN20160518163536.pdf	Soft	
Touch Screen Monitor	374647b.pdf	Soft	
Control Panel Schematic	SCH_PHC-160827-0100.pdf	Soft	
Beagle Bone Black Industrial	BBB_SCH.pdfBBB_SRM.pdf	Soft	
itX I/O Signal Conditioner Drawing	Schematic.pdf	Soft	
24V Power Supply	NDR-480-SPEC.PDF	Soft	
12V Power Supply	SDR-120-spec.pdf	Soft	

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Track and Trace Machine Installation Qualification Report Approval

Final conclusion:

The following signature shows the full agreement with the current protocol for installation qualification, including the verification and tests (Safety, Mechanical Installation, Electrical Installation, Utility, Spare parts, Parts check and Drawings) as well as their acceptance criteria and performance. Hereby certifying that all tests have been completed and approved, thus authorizing to proceed to operate the machine.

Prepared By:

Reviewed BY:

Name

position

signature

Approved by:

Name

position

signature

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II- Operational Qualification

1. Purpose:

The purpose of the operation qualification is to research and document that track and trace machine is operated and functioned complying with appropriate standards and regulations through analyzing critical parameters of specification.

2. Scope:

- Operation qualification is consisted of various test items which verifies the system components are properly functional.
- If there is any process or failed test item not-accepted during OQ procedure, it should be re-tested until the result is accepted with the allowable error.

- Test Items:

- Rejection Control
- Safety Control
- Operation Control
- Touch screen Control

Roles and responsibilities

Roles	Responsibility	Description
Authorized by	ITX Team	Prepare OQ protocol by means of analyzing of track and trace machine features and risks
Approved by	Quality/validation department	Approval OQ protocol
Executed by	ITX team	Execution of OQ procedure based on IQ protocol approved check whether the result complies to acceptance criteria
Approved by	Quality/validation department	Approval of OQ report

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Systems and Software Features

a- Operational Control

URS ID	Test ID	Test Description	Test Case ID	Test Case Name	Pass/Fail	Verified/Date
	TS.01	Start Machine		Connect Machine to Mains Supply	P / F	
				Wait for operating system to boot and start main application		
				Success Criterion: Main Conveyor operates		
	TS.02	Stop Machine		While main conveyor is in operation; press the red (Stop) button on the control panel	P / F	
				Success Criterion: Main conveyor stops		

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B- Rejection Control

URS ID	Test ID	Test Description	Test Case ID	Test Case Name	Pass/Fail	Verified/Date
	TS.03	Reject Control		Pre-print in the GS1 DM location	P / F	
				Enter carton into machine with batch started		
				Success Criterion: System rejects on GS1 Matrix		
				Repeat the above for line 1		
				Repeat the above for line 2		
				Repeat the above for line 3		
				Repeat the above for line 4		

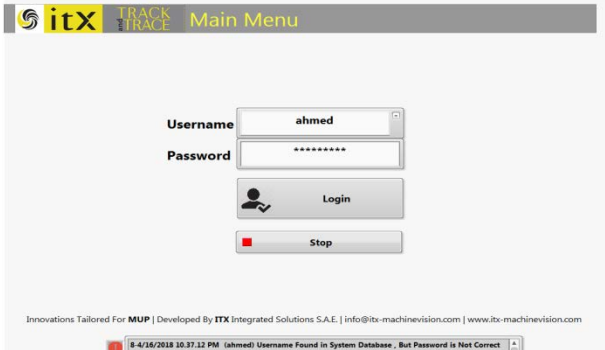


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b- Safety Control


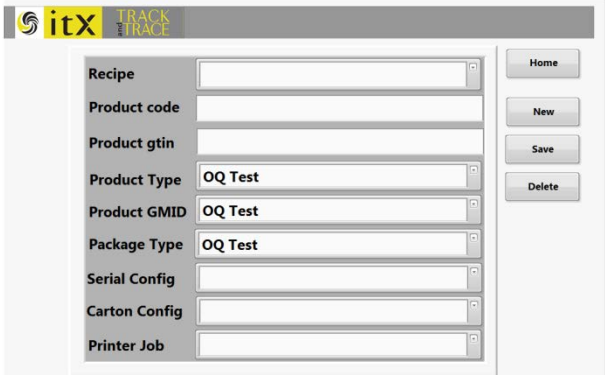
URS ID	Test ID	Test Description	Test Case ID	Test Case Name	Pass / Fail	Verified/ Date
	TS.04	Safety Stop Button		Operate main conveyor	P / F	
				Press Emergency Stop		
				Success Criterion: Machine stops, and motors (conveyor and infeed) are de-energized		

c- Touch Screen Control

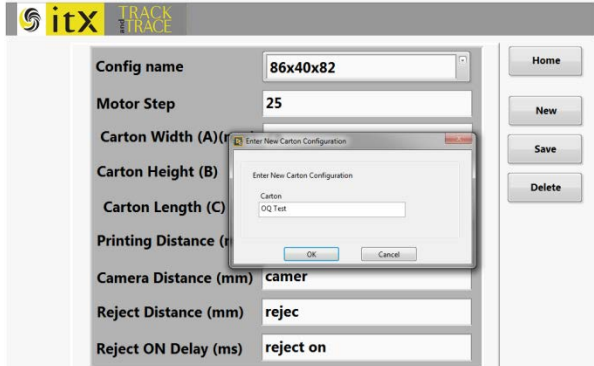
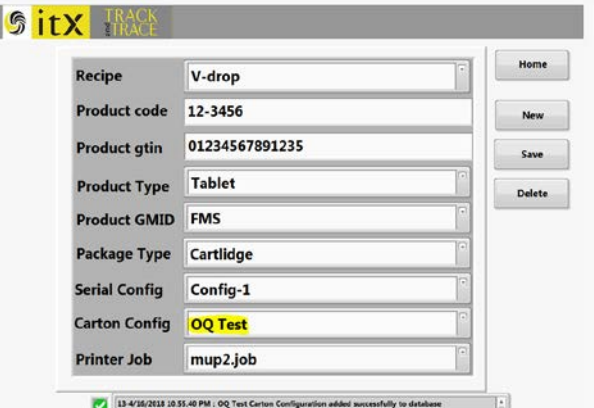
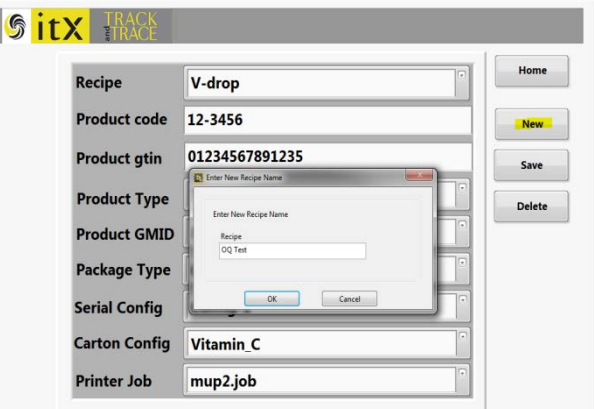
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URS ID	Test ID	Test Description	Test Case ID	Test Case Name	Pass/Fail	Verified/Date
	TS.05	Test User Login/Logout (User Security)		Login with Random user name/password	P / F	
				Define New User with specified responsibilities		
				Login using the defined user name with wrong password		
				Success Criteria: Login fails		
				Login using the defined user name with correct password	P / F	
				Success Criteria: Login successful		
	TS.6	Enable/Disable user		Login with Existing User Name and password	P / F	
				Disable the User Login and Save the data		
				Login with the disabled User name/password		
				Success Criteria: Login fails		
				Enable that user again		
				Login with the same user name/password		

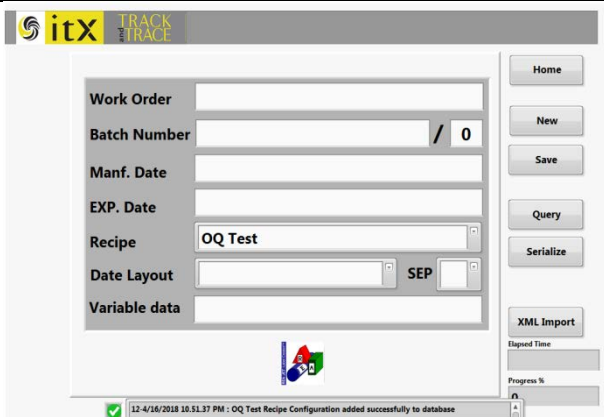
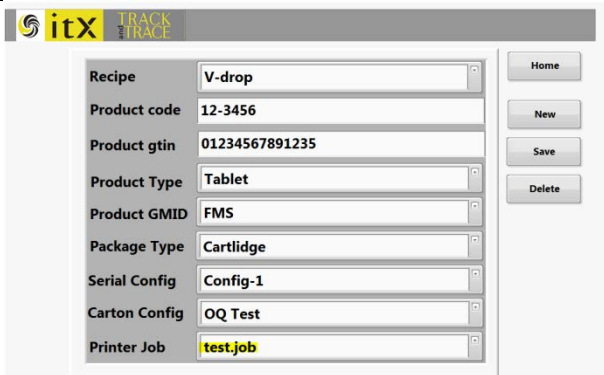
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				Success Criteria: Login successful	P / F	
	TS.7	Add / Retrieve a Product Type		Login as a supervisor	P / F	
				Goto Work Order Management Module		
				Click on Product Types		
				Add a new 'Product Type'		
				Add a new 'GMID'		
				Add a new 'Package Type'		
				Go back to 'Work Order Management' Main Page		
				Click on 'Recipe Configuration'	P / F	
				Success Criteria: Ensure that the created 'Product Type', 'GMID', and 'Package Type' are available in drop-down list.		
	TS.8	Establish / Retrieve a 'Carton Configuration'		Login as a supervisor	P / F	
				Go to 'Work Order Management' Main Page		
				Click on 'Carton Configuration'		
				Select an existing configuration		
				Edit features as specific to current carton		
				Press 'New' to create the new configuration		

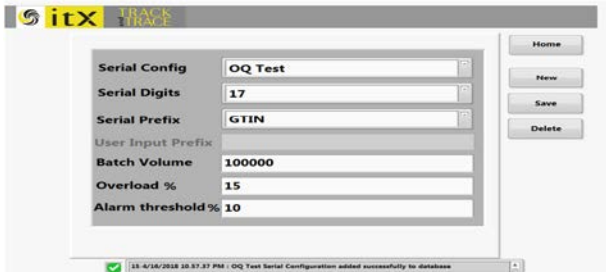
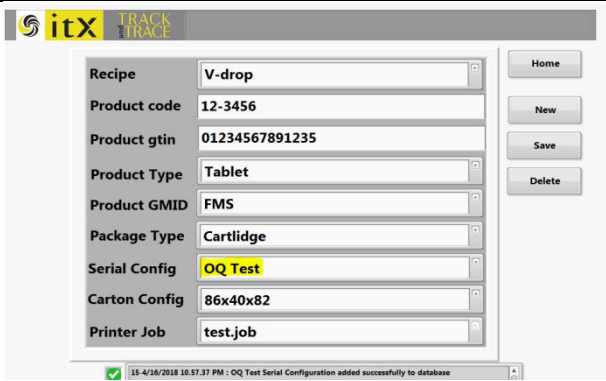
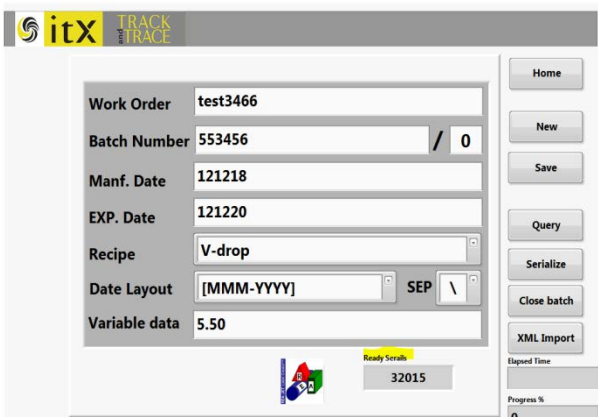
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			Go back to 'Work Order Management' main page		
			Click on 'recipe management' '		
			Success Criteria: Ensure that the new carton configuration is available in drop-down list.		
			Success Criteria: Ensure that the new configuration's parameters are saved correctly to the new configuration (Carton Configuration Page)	P / F	
TS.9	Establish/Retrieve a 'Recipe'		Go to 'Work Order Management' Main Page		
			Click on 'Carton Configuration'		
			Select an existing recipe		
			Edit features as specific to the current Recipe		
			Press 'New' to create a new recipe		
			Go back to 'Work Order Management' main page		

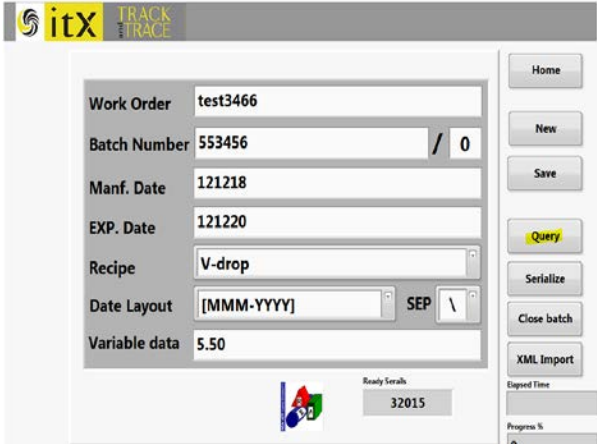
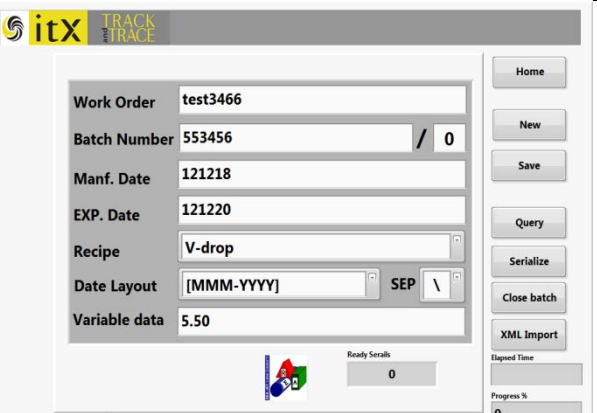

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			Click on 'Create Work Order'	P / F	
			Success Criteria : Ensure that the new carton configuration is available in drop-down list. Success Criteria: Ensure that the new configuration's parameters are saved correctly to the new configuration (Recipe configuration page)		
TS.10	System shows all layout configurations		Ensure that the new configuration's parameters are saved correctly to the new configuration (Carton Configuration Page)	P / F	
			Establish a new layout via REA JET layout editor and save in designated location Success Criteria: Check that layout is available in drop down menu and is linkable to carton configuration		
TS.11	Establish / Retrieve a 'Serial Configuration'		Go to 'Work Order Management' Main Page		
			Click on 'Serial Configuration'		
			Select an existing serial configuration		
			Edit features as specific to the current serial configuration		

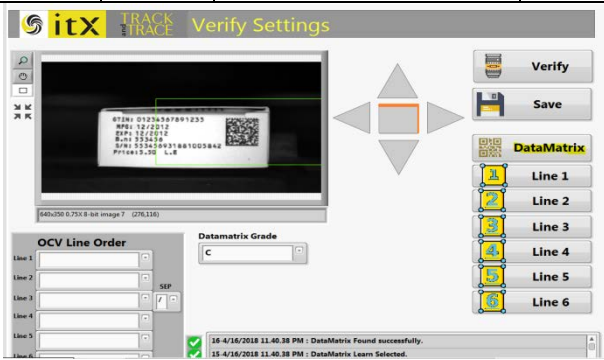
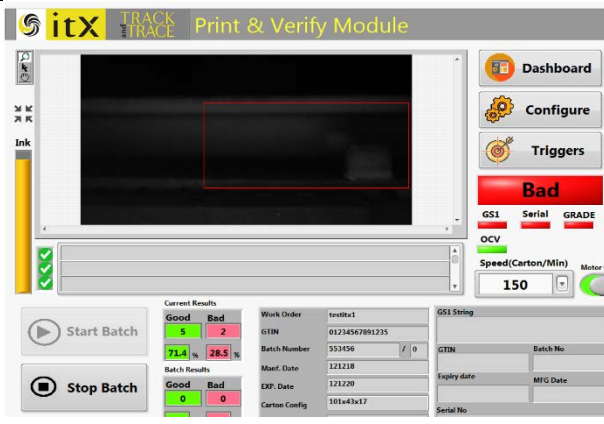
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			Press 'New' to create a new configuration.	P / F	
			Go back to 'Work Order Management' main page		
			Click on 'Recipe'	P / F	
			Success Criteria: Ensure that the new carton configuration is available in drop-down list.		
			Success Criteria: Ensure that the new configuration's parameters are saved correctly to the new configuration (serial configuration page)	P / F	
TS.12	Establish/Retrieve a work order		Login as a supervisor	P / F	
			Go to 'Work Order Management' page		
			Press Query to ensure no work orders are open. If a work order exists, retrieve it then close it.		
			Edit all features as specific to current work order.		
			Press Serialize, and wait for operation completion		
			Success Criteria: Check serials by pressing query	P / F	
			Success Criteria: To retrieve the current work order, open 'Work Order' page, and press query, then enter work order name into the designated field to retrieve its information.	P / F	

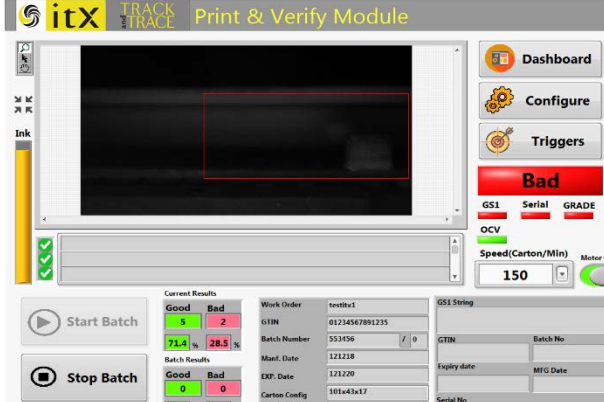
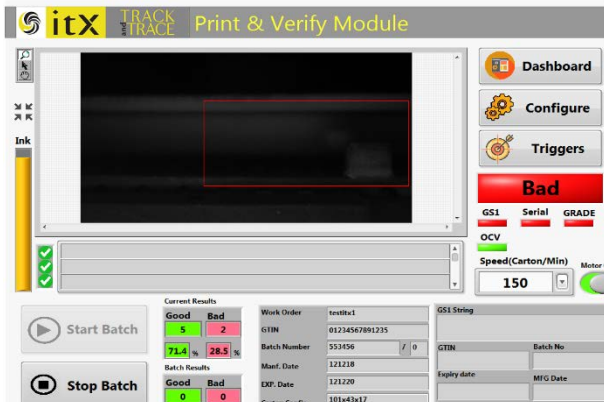
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TS.13	Serialize using itX Engine		Enter a desired batch signature	P / F
		Check number of serials in batch (ensure it is zero)		
		Put 100 in the batch volume field		
		Check number of serials		
TS.14	Load Open Batch		Log in as an operator OR supervisor	P / F
		Select 'Print and Verify Module'		
		Press 'Start Batch'		
		Success Criteria: Ensure that batch information is coherent with open workorder info		
		Success Criteria: Print one carton and ensure layout and printed data	P / F	

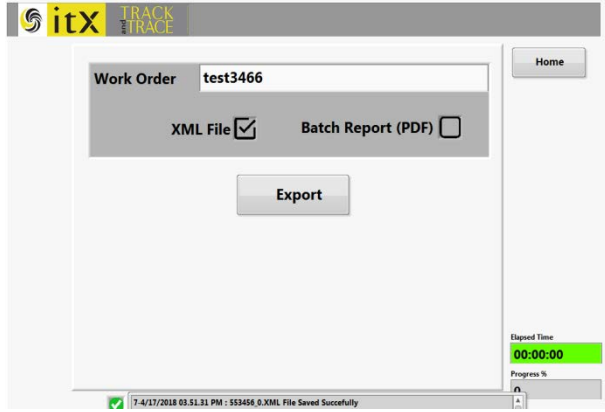
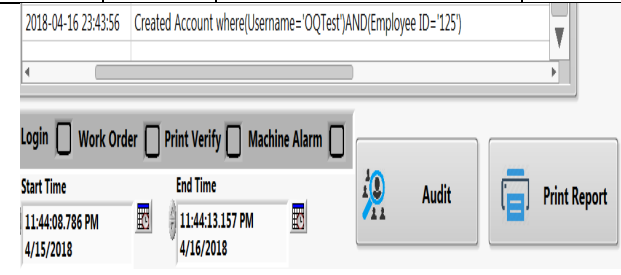
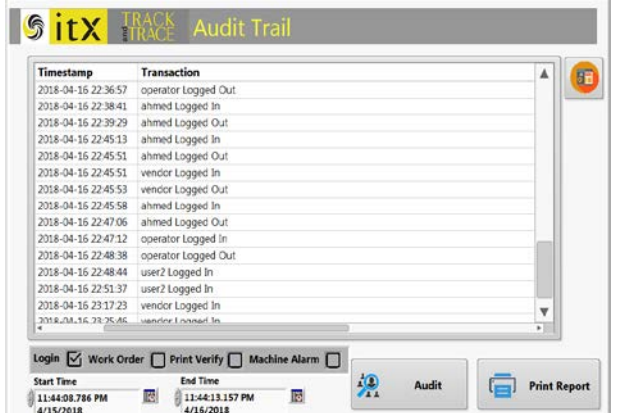
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				are coherent with workorder info		
				Success Criteria: Print another carton to ensure random serialization reflects on carton print	P / F	
	TS.15	Set GS1 Code Location		Go to 'Verify Config' page	P / F	
				Using the rectangular ROI button, select area of GS1 code		
				Press 'Set GS1 Location' Button		
				Press 'Save'		
				Back to 'Verify' page, and print one carton		
				Success Criteria: GS1 code is read and verified		
	TS.16	Set Camera Trigger Location	TS.28.03	Goto 'Triggers' page	P / F	
				Change camera trigger location, and observe effect		
				Success Criterion: Camera field of view changes		
	TS.17	Set Reject Location		Goto 'Triggers page		
				Change printer trigger location, and observe effect		

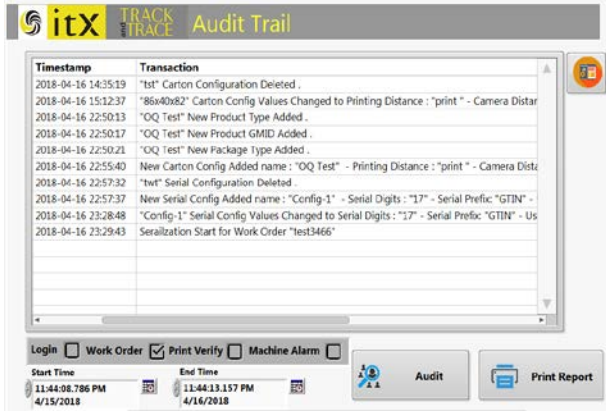
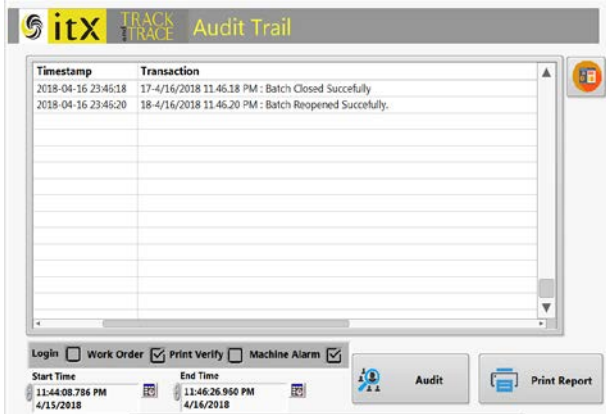
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			Success Criterion: Reject location changes	P / F	
TS.18	End Batch		Press 'Stop Batch'		
			Success Criterion: Printer stops printing	P / F	
TS.19	Generate .xml Report for a desired batch		Go to 'Serialize Page'		

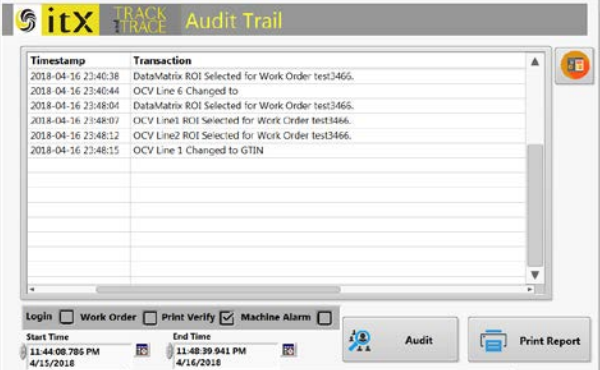
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			Load desired batch		
			Press 'Generate Reconciliation Report' button		
			Open .xml report for desired batch from save location		
	TS.20	Audit Trail module responds to changes in 'User Access Management' Module	Add a user using the UAM module	P / F	
			Success Criterion: Check reflection in audit trail module		
URS#36	TS.25	Audit Trail module logs operational transaction	Success Criterion: Open audit trail module, and check for the following:		P / F
			Login/ Logout events		
	TS.21		Serialization events	P / F	

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	TS.22			Open/Close Batch events	P / F
					
	TS.23			Start/End Batch events	P / F
				Change in printer layout	P / F

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	Change in GS1/OCV ROI's	P / F	

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Exception Handling :

URS ID	Test ID	Test Case Name	Test Case ID	Test Case Description	Pass/Fail	Verified/Date
URS#7	TS.24	Sampling		Get 2 Accepted Cartons	P / F	
				Goto Exception Handling		
				Enter Appropriate Credentials		
				Scan 1 st Carton of the 3 Cartons		
				Change it's status from accepted to Sample		
				Success Criterion : System should Convert carton status from accepted to Sample		
URS#7	TS.25	Destroying		Scan 2 nd Carton	P / F	
				Change it's status from accepted to Destroy		
				Success Criterion: System should Convert carton status from accepted to Destroyed		
URS#7	TS.26	Verifying		Get any Rejected Carton from the reject bin	P / F	
				Scan the carton		
				Check that the carton is already rejected		
				Change it's status to verify		
				Success Criterion : System should Convert carton status from Rejected to verified		
URS#7	TS.27	Check on database for the serials		From database choose the opened work-order check for the 3 serials and check their status		
				Success Criterion 1: TS.01 serial No. is Sample	P / F	
				Success Criterion 2: TS.02 serial No. is Sample	P / F	
				Success Criterion 3: TS.03 serial No. is Sample	P / F	

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Test Result	Pass <input type="checkbox"/>	Fail <input type="checkbox"/>
Note:		
Prepared by: Ibrahim Elwy (itX) Sign: Date:		Reviewed by: Sign: Date:

10 Minutes Run

Run line with print and verify module ON for **10 minutes OR 3,000** cartons (whichever comes first), and realize the following success criteria:

- 1- No missing prints
- 2- No truncated messages
- 3- For random samples, barcode scanner test passes.

Test Result	Pass <input type="checkbox"/>	Fail <input type="checkbox"/>
Note:		
Prepared by: Ibrahim Elwy (itX) Sign: Date:		Reviewed by: Sign: Date:

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Track and Trace Machine Operation Qualification Report Approval

Final conclusion:

The following signature shows the full agreement with the current protocol for Operation qualification, including the verification and tests (Safety, Operation Control, Touch screen Control, Rejection Control, and Machine Run) as well as their acceptance criteria and performance. Hereby certifying that all tests have been completed and approved, thus authorizing to proceed to operate the machine.

Prepared By:

Name

position

signature

Reviewed BY:

Name

position

signature

Approved by:

Name

position

signature