Pre-Execution Approvals

Document information, authorship, and approvals			
Author signs to confirm technical content			
Prepared by:	Job title:	Signature:	Date:
Technical representative signs to confirm document complies with quality management system			
Authorised by:	Job title:	Signature:	Date:

Post-Execution Approvals

Document information, authorship, and approvals			
Author signs to confirm technical content			
Prepared by:	Job title:	Signature:	Date:
Technical representative signs to confirm document complies with quality management system			
Authorised by:	Job title:	Signature:	Date:

Introduction

This document outlines the Operational Qualification (OQ) testing required to ensure that the Epson CW-C4000U label printer, together with BarTender Enterprise labelling software, operates correctly installed across its full functional range and satisfies user requirements for printing labels that are applied directly to a medical device. This protocol follows successful completion and approval of the Installation Qualification (IQ) and forms part of the overall equipment/software validation package required prior to the printer being released for Medical Use.

The CW-C4000U is an industrial 4-colour inkjet label printer. BarTender Enterprise is the label design and print-management software used to generate and send label print jobs to the printer.



Asset ID:
Location:
Manufacturer: Epson
Model: CW-C4000U
Serial Number:

Brief System Description

The CW-C4000U printer is a serial inkjet, dot-matrix label printer used to print variable and fixed label data (including text, barcodes, and 2D symbols such as Data Matrix for compliance) directly onto roll or fanfold label stock. The printer connects to a host computer via wired LAN or USB 2.0 and is driven by the Windows printer driver in combination with BarTender Enterprise software, which manages label templates, data sources, and print job submission.

Key sub-systems/components of the printer include: the print head and four individual ink cartridges (cyan, magenta, yellow, and black — gloss or matte), the auto cutter, the maintenance box (waste ink absorber), the operation panel/touchscreen, and the paper feed and ejection mechanisms.

Scope

This protocol covers the Operational Qualification of the CW-C4000U label printer and the associated BarTender Enterprise software, as used at the manufacturer's site. It challenges the operating ranges and functions of the system – including print speed/quality settings, media handling methods, operational panel/touchscreen functions, connectivity and BarTender software functiosn – to confirm the system operates as intended across its specified range. Print quality, barcode grading and label content verification under worst case/production conditions are covered under the separate Performance Qualification (PQ) protocol.

This protocol shall be reviewed and authorised by the stated personnel in the approval box prior to execution. The OQ execution shall be reviewed and approved prior to summary write-up. Upon completion of the OQ, a final review will be performed and signed off.

For the remainder of this document, the Epson CW-C4000U label printer will be referred to as 'the printer'.

Objectives

This protocol covers the validation of the printers hardware and software (BarTender Enterprise) operation to complete the Operational Qualification (OQ). This OQ will validate that the printer and software have been correctly and completely installed in accordance with the manufacturer's (Epson) specifications and user requirements.

Pre-requisites

- The IQ has been completed, reviewed and approved.
- The printer has been installed, powered and connected (with available WiFi) to a host PC with BarTender Enterprise installed and licensed.
- A representative range of media (die-cut label, continuous, gap-detect and black-mark stock, as applicable) is available for testing..
- The printer's Technical Reference Guide (TRG), User's guide, and BarTender Enterprise documentation are available for reference.

Report

Upon completion of the OQ protocol, the findings must be summarised in a Validation Summary Report. The following must be reported within the summary:

- Any corrective actions identified during the execution of this protocol have been deemed not to impact on the OQ and have been completed and approved.
- Any non-conformances identified during the execution of the protocol have been investigated and deemed not to impact on the validation status.

- Any deviations to the protocol, specification or requirements have been investigated and evaluated, and deemed not to have an impact on the validation status.
- Supporting Data/Documentation is referenced for traceability. Where documented evidence is to remain with the Validation package, this is adequately labelled/identifiable, as well as signed and dated by the person responsible.

Responsibilities

- This protocol shall be approved by a Manufacturer representative.
- The Validation Provider shall execute this qualification protocol, noting any deviations from the protocol.

Index of OQ – CW-C4000U Label Printer

OQ section	Test Name	TRG Chapters
1	Connectivity (USB / LAN (Ethernet) / Wi-Fi)	Connectors; Status Sheet; Network Connection Check (p.21, p.33–35, p.50–63)
2	Operational Panel / Touchscreen Functions	Product Overview; Operational Panel Settings (p.22 – 24, p229-240)
3	Maintenance Functions	Nozzle Check Settings; Cleaning the Printer (p.215 p.273–282)
4	Media Handling & Detection (Continuous Roll)	Loading Roll Paper; Media Settings (p.66–92, p.229–230, p.270)
5	BarTender Enterprise Software	Printer Driver for Windows; Printing Barcodes/2D Symbols (p.83–129)
6	Print Speed & Print Quality Modes & Functional Label QC	Media Settings – Print Quality; Auto Nozzle Check(p.25–30, p.87–89)
7	Cutter & Print Stop Modes	Settings for Paper Handling After Print; Cleaning Auto Cutter (p.89, p.276)
8	PrinterSetting Utility, Driver Configuration & Print Data Management	How to start, p.189 (also Restrictions on using the printer driver, p.166)
9	Print Position Adjustment & Calibration	Position Adjustment / Start Adjustment, p.194 (also Print

		Head Alignment, p.207–212)
10	Colour Correction & Spot Colour Settings	Colour Correction, p.250 – p.264 Spot Colour Settings, p244-249
11	System Administration & Security	Restricting Operation of the Operation Panel — Lock Setting, p.271
12	Optimisation of settings	p.25 - 30
—	Appendices (Deviation Log, Attachments Log)	—

PERSONNEL

Record below all personnel involved in the execution of this protocol:

Company	Name	Job Title	Signature	Initials

Index of IQ	Test Name
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
IOPQ	Installation, Operational and Performance Qualification (Combined Protocol)
SOP	Standard Operating Procedure

DOCUMENT REFERENCE

1.1 Internal

Document Ref.	Title
	Label Printing and Control (parent SOP)
	User Guide for Epson printer
	Installation Qualification (IQ)

1.2 External Regulatory References & Guidelines

Document Ref.	Title
21 CFR Part 11	Electronic Records; Electronic Signatures
21 CFR 820.30 / 820.70	Design Controls / Production and Process Controls
21 CFR 801.20 / UDI Rule	Unique Device Identification requirements
ISO 13485:2016	Medical devices — Quality management systems
BS EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISPE GAMP5®	A risk-based approach to compliant GxP regulated computerised systems
None	CW-C4000U Technical Reference Guide (Epson, M00143402 Rev. C)

TEST EQUIPMENT

	Test Equipment	Test Equipment purpose	Serial Number
1	Stopwatch/Timer	Verify Print Speed	
2	Calibrated Ruler/Callipers	Verify print position, cut position, label dimensions	
3	Media Rolls	Media Handling Tests	
4	2D Barcode Scanner	Affirms barcode legibility	
5	Host PC with BarTender Enterprise Software	Tests Software	

Test 1 Connectivity (USB / LAN (Ethernet) / Wi-Fi)

Objective	To verify that the printer connects and communicates reliably with the host computer via USB, LAN/Ethernet and WiFi, and that the printer's connectivity functions operate correctly.
Method	Connect the printer via each interface in turn (USB/WiFi/LAN) and confirm driver communication and print capability. Print the status sheet and the network connection check report from the operation panel. Simulate a connection loss (e.g. disconnect the WiFi) during idle and printing a job to assess detection and recovery. Enable EPSON Status monitor and confirm error reporting.
Acceptance Criteria	The printer is detected and addressable by the host computer via each connectivity method tested; Status Sheet and Network Connection Check reports print correctly and accurately reflect the printer's actual configuration and connection status; the printer correctly detects and reports connection loss and recovers automatically on reconnection without requiring a printer restart; EPSON Status Monitor correctly displays paper type/ink level pop-ups at print start and error windows on fault conditions.
Reference Guide references	Connectors; Status Sheet; Network Connection Check (p.21, p.33–35, p.50–63)

Test No.	Requirement	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
1.1	Following driver installation, connect the rinter to the computer via USB. Confirm Windows detects the printer and print a test label *(TRG p.51)*	a) Windows detects the printer as soon as the USB cable is connected A test label prints successfully over USB			
1.2	LAN/Ethernet connectivity. Connect the printer to the site network via LAN; confirm/assign an IP address; print a test label from the host PC. *(TRG p.51)*	**a)** The printer gets a valid IP address on the network. **b)** The host PC can "see" and print to the printer over the network. **c)** A test label prints successfully over LAN. •			

Test No.	Requirement	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
1.3	Wi-Fi connectivity. Connect the printer to the site wireless network (if a Wireless LAN Unit is fitted); confirm signal status; print a test label. *(TRG p.34)*	**a)** The printer connects to the Wi-Fi network with a good signal (check the status sheet). **b)** A test label prints successfully over Wi-Fi.			
1.4	Print Status Sheet. [Menu] > [General Settings] > [Network Settings] > [Network Status] > [Print Status Sheet]. *(TRG p.33)*	**a)** The status sheet prints successfully. **b)** The firmware version and settings shown on it match the printer's actual, real configuration.			
1.5	Print Network Connection Check report. [Menu]>[General Settings]>[Network Settings]>[Connection Check] *(TRG p.35)*	a) The report prints successfully b) Every connected interface shows a PASS/OK result – no errors.			

Test No.	Requirement	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
1.6	Connection loss / recovery. Disconnect the LAN cable (or disable Wi-Fi) while the printer is idle, then reconnect; repeat during an active print job. *(TRG p.293)*	a) The printer notices the connection has dropped and shows this on the panel or in the driver. b) The printer reconnects by itself once the cable/Wi-Fi is restored — no power cycle needed. c) If a print job was interrupted, no half-printed or corrupted label comes out.			
1.7	EPSON Status. Enable via Driver Utilities > Driver Preferences Start a print job and observe the pop-up; induce a fault (e.g. open cover) and observe the error window. *(TRG p.160)*	a) A pop-up shows paper type and ink levels when a print job starts. b) An error window appears clearly when a fault happens (e.g. cover open) and clears once fixed.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 2) Operational Panel / Touchscreen Functions

Objective	To verify that the printer's touchscreen operation panel is fully functional, responsive and correctly displays and applies all general and display-related settings, and that access restriction (Lock setting) functions as intended
Method	Power on the printer and systematically navigate through the Home Screen and all General Settings menus via the touchscreen. Apply eah available setting/valu (brightness, sound, language, date/time, background colour, keyboard layout, sleep timer, control panel button enable/disable) and visually confirm the change is reflected correctly. Induce a recoverable error condition to confirm eorror messaging
Acceptance Criteria	- The touchscreen responds correctly when buttons and menu options are selected. - All menu screens open and function as expected - Changes made to settings are saved correctly - Saved settings remain after leaving and returning to the menu - Error messages are displayed when a fault occurs and disappear after the issue is resolved - Locked settings cannot be accessed by unauthorised users - Authorised users can unock and access protected settings successfully.
Reference Guide references	Product Overview; Operational Panel Settings (p.22 – 24, p229-240)

Test	Requirement	Acceptance Criteria	Actual Result (Screenshot where necessary or	Pass/Fail	Performed By / Date

No.			enter values)	(P/F)	
2.1	**Home screen dsplay. Power on the printer. Observe the home screen**	a) Home screen displays correctly: b) media/in/status icons, c) maintenance box status, d) paper settings (type, detection method, width, length) as described in TRG "Home Screen" Reference Page number Manual			
2.2	**Menu Navigation. Press [Menu] and navigate through General Settings, Printer Settings, Media Settings and Maintenance menus**	a) All menu items are accessible, b) touch-responsive and navigate/return correctly without lag or unresponsive zones			
Test	**Requirement**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or**	**Pass/Fail**	**Performed By / Date**

No.			enter values)	(P/F)	
2.3	**LCD Brightness. [Menu] > [General Settings] > [Basic Settings] > [LCD Brightness]. Set to each value 1-5**	Screen brightness changes accordingly at each of the 5 levels. Setting is retained after leaving the menu			
2.4	**Sound Settings. [Menu] > [General Settings] > [Basic Settings] > [Sound]. Set to Off, Low, Medium, High, Max**	Audible feedback volume changes correctly for each setting, including off (silent).			
2.5	**Language settings. [Menu] > [General Settings] > [Language]. Change to an alternative language (e.g. French) and back to English.**	a) Screen text updates to selected language throughout the menu system reverts correctly.			
Test No.	**Requirement**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail**	**Performed By / Date**

2.6	**Date/Time Settings. [Menu] > [General Settings] >[Date/Time Settings]. Set date, time, daylight saving and time difference**	Values are accepted within range and retained; date/time displayed/used correctly (e.g. on print history)			
2.7	**Background colour. [Menu] > [General Settings] >[Background colour]. Set to Grey, Black, White**	Screen background updates correctly for each option.			
2.8	**Keyboard Layout. [Menu] > [General Settings] > [Keyboard]. Set to QWERTY**	On-screen keyboard layout changes correctly to match selection			
2.9	**Sleep Mode. [Menu] > [General Settings] >[Sleep]. Set Sleep Timer to a short interval (e.g. 1 minute) and leave printer idle**	Printer enters sleep mode after the set interval; wakes correctly on touch/print job			
Test No.	**Requirement**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail**	**Performed By / Date**

2.10	**Control panel button settings. [Menu] > [General Settings] >[Control panel Button Settings]. Disable then re-enable Cut, Cancel and Feed buttons in turn.**	When disabled, associated physical/on-screen button is inactive; when enabled, functions normally.			
2.11	**Error notice display. Induce a recoverable error (e.g., open cover, remove media).**	Error message/icon displays clearly on screen with appropriate guidance; clears once resolved.			
2.12	**Lock Setting function. [Menu] > System Administration > Lock Setting. Apply General/Printer/Media Settings lock levels per TRG "Restricting Operation of the Operation Panel".**	Locked menu items are greyed out/inaccessible per the lock level applied; unlocked items remain accessible.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 3) Maintenance Functions

Objective	To verify that the printer's built-in maintenance functions (nozzle check, print head cleaning, auto-cleaning schedule) and the manufacturer's manual cleaning procedures operate correctly and can be performed safely per the TRG.
Method	Print the nozzle check pattern and evaluate it; configure Nozzle Check Settings; execute manual print head cleaning; perform manual cleaning of the exterior (including alcohol disinfection procedure if used at this site), platen, auto cutter, and interior paper path per the TRG step-by-step procedures; confirm the printer's automatic capping/storage behaviour for extended non-use.
Acceptance Criteria	**a)** The nozzle check pattern prints fully and clearly. **b)** Nozzle Check Settings apply and stay saved. **c)** Manual cleaning keeps or improves print quality. **d)** Every cleaning step is done exactly as the TRG describes, with no damage to the printer. **e)** The print head is capped automatically when the printer is powered off correctly.
Reference Guide references	Nozzle Check Settings; Cleaning the Printer (p.215 p.273–282)

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date

3.1	Print the nozzle check pattern from the operation panel and visually inspect it. *(TRG p.32)*	**a)** The pattern prints in full — all lines present. **b)** No gaps in the lines (a gap means a clogged nozzle).			
3.2	Configure Nozzle Check Settings: Trigger to Head Maintenance threshold, Additional auto nozzle check during printing (on/off and interval), Cleaning after self-check. *(TRG p.215)*	**a)** Each setting is accepted and saved. **b)** During a print run, the printer behaves exactly as configured.			
3.3	Manual print head cleaning. Execute via the operation panel or PrinterSetting utility, then reprint the nozzle check pattern. *(TRG p.215)*	**a)** Cleaning finishes with no errors. **b)** The nozzle check pattern is the same or better quality afterwards.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
3.4	Exterior cleaning	**a)** Only a dry or slightly			

	(dry/damp cloth). Disconnect power and wipe the exterior with a dry or slightly damp cloth, per the TRG procedure. *(TRG p.273)*	damp cloth is used — no alcohol, benzine, thinner, or similar solvents. **b)** No damage to the plastic or rubber parts.			
3.5	Exterior cleaning with alcohol disinfection (if used at this site). Follow the verified procedure: rubbing alcohol (ethanol 70–80 vol% or isopropyl ~70 vol%), uncoloured microfibre cloth, vinyl gloves; avoid connectors, labels, operation panel window, and AC adapter. *(TRG p.273)*	**a)** Done no more than 3 times per day. **b)** Only the correct alcohol strength and cloth type are used. **c)** Connectors, labels, screen window, and AC adapter are avoided. **d)** No damage, discolouration, or cracking afterwards.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
3.6	Platen cleaning. Remove	**a)** The shutters are not			

	paper and clean the platen using non-woven fabric/cotton swabs (no water or alcohol), taking care not to move the shutters or damage the four sensors. *(TRG p.274)*	knocked out of position. **b)** None of the 4 sensors are damaged. **c)** No ink marks appear on the next prints.			
3.7	Interior cleaning (paper fed from inside). Remove adhesive from the roller and paper guides using a cloth moistened with alcohol (recommended ≤80 vol% ethanol), per the TRG procedure. *(TRG p.277)*	**a)** Only the correct type of cloth/alcohol is used. **b)** No alcohol gets inside the printer housing. **c)** Print quality is the same or better afterwards.			
3.8	Power off the printer using the (power) button after ink is charged, and confirm automatic print head capping. *(TRG p.283)*	**a)** The print head is automatically capped when the printer is switched off using the (power) button.			

		b) Confirm site SOP says to always use the (power) button to shut down — never the wall switch or breaker.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 4 Media Handling & Detection (Continuous Roll)

Objective	To verify the printer correctly loads, feeds and prints on continuous roll paper across its supported operating parameters, and that media source/detection settings function as intended.
Method	Load the roll into the printer as per the TRG procedure. Configure Media Source = Internal roll and Media Detection = No Detection (appropriate for continuous stock without gaps or black marks). Test width/length parameter entry against the specified valid range. Adjust the platen shutters to the loaded roll width. Remove and reload paper mid-operation. Run the sensor calibration routine.
Acceptance Criteria	A) Paper loads and feeds into the printer with no jamming or folding B) Media Source and Media Detection settings apply and stay saved C) Width/Length entries within the allowed range are accepted D) Shutters can be adjusted to stop the paper skewing/folding E) Removing/loading paper is correctly picked up as a paper-out condition F) Sensor calibration finishes with no errors
Reference Guide references	Loading Roll Paper; Media Settings (p.66–92, p.229–230, p.270)

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date

4.1	Load continuous roll paper into the printer *(TRG p.66)*	a) Paper loads with no jamming or skewing b) The home screen media icon updates to show paper is loaded			
4.2	Set Media Source = [Internal Roll] in the printer driver/PrinterSetting; confirm the setting is applied and reflected onto the operational panel. *(TRG p.90)*	a) The setting is accepted b) The panel and driver both show the same correct setting			
4.3	Set Media Detection = [No detection], appropriate for continuous paper without gaps or black marks; print a multi label batch. *(TRG p.90)*	a) The printer prints continuously with no gap/black-mark detection. b) No false paper-position errors occur			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**

4.4	Enter media width at the specified boundary values (minimum 25.4mm and maximum 108mm for continuous paper) in Layout settings *(TRG p.229)*	a) Values between 25.4-108mm are accepted b) Values outside that range are rejected or capped			
4.5	Enter media Length at the specified boundary values (minimum 8.0mm and maximum 406.4mm). *(TRG p.229)*	a) Values between 8.0-406.4mm are accepted. b) Values outside that range are rejected or capped.			
4.6	Adjust the platen shutters to match the loaded roll width. *(TRG p.77)*	a) The shutters can be set to match the roll width b) Printed labels line up correctly with no skew.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**

4.7	Remove the paper mid-job and reload it, observing printer behaviour *(TRG p.79)*	**a)** The printer detects the paper is missing and shows an error/notice **b)** The printer resumes correctly (or the job restarts, as designed) once the paper is reloaded.			
4.8	Media Size Notice. Set to [ON] and [OFF] in turn and send print data that does not match the configured media size. *(TRG p.230)*	**a)** With the setting On: the printer warns about a media size mismatch **b)** With the setting Off: no warning appears.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**

4.9	Sensor calibration. [Menu] > [Maintenance] > [Calibration] > run [Simple Media Detect] *(TRG p.270)*	**a)** Calibration completes with no errors. **b)** Paper detection is as reliable afterwards			
4.10	Applicability review — Processing Paper to Avoid Unprinted Labels ('Printing from the 1st Label' / 'Printing on the Last Label'). Confirm whether this function applies to the media/detection mode configured at this site. *(TRG p.266)*	**a)** N/A for this site — the TRG says this feature only applies to Black Mark or Gap-detect media. **b)** This site uses continuous roll with No detection (Test 4.3), so it does not apply. **c)** Re-check this if the site ever changes media/detection mode.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
4.11	Applicability review —	**a)** N/A for this site —			

	Detecting Differences in Paper Size Using Label Command. Confirm whether this function is used at this site. *(TRG p.270)*	this feature is only for raw label-command users. **b)** This site prints through BarTender Enterprise and the Windows driver, not raw label commands.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 5 BarTender Enterprise Software

Objective	To validate that the BarTender Enterprise Software correctly works with the C4000U printer, to design, generate and print labels containing the data types used (e.g. QR code or Data Matrix), and that the key print management functions operate as expected. *(Version No. BarTender 12.0.1)*

Method	Within BarTender Enterprise, confirm the printer is recognised as an installed output device using the correct driver. Create/open a labe template containing text, a Data matrix (UDI) symbol and a QR code. Print single-label and batch print jobs, including a batch with an incrementing serialised data field. Test job cancellation mid-batch. Confrim template storage/retrieval and high speed batch label printing.
Acceptance Criteria	a) Software correctly talks to the printer through the installed driver b) Printed Data Matrix and QR code symbols scan and decode correctly c) Serial data prints correctly and increments properly across a batch d) Batch jobs finish with no duplicated labels – count matches BarTender's queue. e) Cancelling mid-batch stops the printer cleanly with no half-printed label and the label doesn't get stuck f) Templates save and load correctly from the template library
Reference Guide references	Printer Driver for Windows; Printing Barcodes/2D Symbols (p.83–129)

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
5.1	Confirm BarTender Enterprise recognises	**a)** The printer appears in BarTender's printer			

	the CW-C4000U as an installed output device with the correct driver selected. *(TRG p.83)*	list with the correct model/driver. **b)** BarTender-specific settings (e.g. Favorite Settings) can be opened from within BarTender.			
5.2	Using a test label template contining a Data Matrix (UDI) symbol, print and scan the symbol with a 2D barcode scanner. *(TRG p.110)*	**a)** The data matrix prints in the correct position and size **b)** It scans successfully and decodes the correct data			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
5.3	Create a test label template containing a QR code, print and scan	**a)** The QR code prints in the correct position and size			

	the symbol. *(TRG p.110)*	**b)** It scans successfully and decodes the correct data			
5.4	Confirm the completed batch label count matches the BarTender print queue/job	The number of physical labels printed matches the quantity submitted in BarTender exactly.			
5.5	Cancel a batch print job from BarTender mid-run *(TRG p.84)*	**a)** The printer clearly stops **b)** No label comes out half-printed/corrupted **c)** The label doesn't get left/lodged in the print queue			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
5.6	High speed batch label printing. Print a batch of 20 with the function	Function on: Printing speed increases with no decrease in label			

	enabled and then disabled. Compare the output.	quality			
5.	Save a label template to and retrieve from the BarTender's software library/location.	**a)** The template saves successfully **b)** The template reloads correctly with all fields and print settings intact.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 6 – Cutter & Print Stop Modes

Objective	To verify that the auto cutter and each 'Settings for Paper Handling After Print' mode function correctly and safely, and that the cutter's safety guards and cleaning procedure operate as specified.

Method	For each Settings for paper handling after print option, print a multi-label batch and observe/measure the resulting behaviour using callipers/calibrated rule. Verify the auto-cutter guard/finger-trap protection and cover-lift interlock. Perform the cuter cleanin procedure and confirm cut quality is restored.
Acceptance Criteria	**a)** Every paper-handling mode does as expected (cut/no-cut, correct stop position) **b)** The auto-cutter guard and cover-lift interlock both work correctly **c)** Cleaning restores a clean, complete cut. d) The measured cut position is within ±10.8 mm of the target.
Reference Guide references	Settings for Paper Handling After Print; Cleaning Auto Cutter (p.89, p.276)

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
6.1	Cut (after printing last label). Print a batch of 20 labels with this	**a)** The printer cuts automatically after the last label.			

	setting selected.	**b)** The cut is complete and clean (straight edge).			
6.2	Cut (at specified label). Configure to cut at a specified label interval within a batch and print.	**a)** The printer cuts at the exact interval configured. **b)** The resulting strips are the correct size.			
6.3	Do not cut (stop at the peel position). Print a label with this setting selected. *(TRG p.89)*	**a)** The printer stops at the peel position without cutting. **b)** The label is correctly positioned to be peeled by hand.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
6.4	Do not cut (stop at cut position) – initial/default setting. Prit a label with this setting selected. *(TRG p.89)*	The printer stops at the cut position without cutting (this is the factory			

		default).			
6.5	Do not cut (stop at the print end position). Print a label with this setting selected. *(TRG p.89)*	The printer stops at the print end position without cutting.			
6.6	Auto cutter guard/cover-lift interlock. Lift the auto-cutter unit from the installation surface and attempt to close the cover.	Lifting the unit locks the cover so it cannot close.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
6.7	Cutter cleaning. Simulate adhesive build-up (or use a cutter that has been in service) and perform the TRG cutter cleaning procedure.	**a)** After cleaning, the cut is clean and complete again **b)** No fraying or partial cuts.			

	(TRG p.276)				
6.8	Cut position measurement. See cut position adjustment to several values across its range and measure the actual cut position with calibrated callipers. *(TRG p.230)*	**a)** The measured cut position matches the setting within ±10.8 mm. **b)** The result stays consistent across the whole batch.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 7 - PrinterSetting Utility, Driver Configuration & Print Data Management

Objective	To verify that the functions of the Epson PrinterSetting utility operate correctly, and that the printer's documented restrictiosn and print behaviour are correctly applied for the stated configuration.
Method	Start the printersetting per the TRG procedure.Work through the following configuration screens: Layout settings, Print results adjustment, store data in the printer, Printer settings/Preferences, Operating Time settings, Advanced settings/Favorite settings, Initialise printer, Printer information, Settings save and restore. For each configuration, apply and verify the representative settings.

Acceptance Criteria	**a)** Every PrinterSetting function applies, saves and shows correctly on the printer or in a print. **b)** Stored data (images, templates, fonts) registers successfully and works **c)** Factory reset returns the printer to defaults and clears registered data, as documented. **d)** Settings save/restore produces a working backup file that correctly restores the saved setup.
Reference Guide references	How to start, p.189 (also Restrictions on using the printer driver, p.166)

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
7.1	Layout settings. In [PrinterSetting] > [Edit Layout…], create a user-defined Media Layout with a: name, media, form, width, length and gap; Press Save	**a)** The new layout saves successfully **b)** It appears in [Defined media layout] and can be selected for printing.			

	(TRG p.192)				
7.2	Print results adjustment – Ink profile. Adjust the print density in darker/lighter. Print a test label and repeat the QC check. *(TRG p.196)*	**a)** Print density visibly changes to match the adjustment **b)** The label passes the QC check **i)** Print is accurate **ii)** The print is legible **iii)** The print doesn't erase or smudge			
7.3	Adjust the ratio between black and composite, print a test label ad inspect for adhesion/smudging (ink may adhere to fingers if ratio is increased). *(TRG p.196)*	**a)** The setting is accepted and the density changes as expected. **b)** No amudging beyond what the TRG documents for higher ratios.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
7.4	Bar width adjustment. Adjust the value and print a test barcode. *(TRG p.196)*	Bar width visibly changes and the barcode still scans			
7.5	Register a background image. Prepare a PNG file	The image registers successfully and can be used			

	at the appropriate resolution and register it: [Store data in the printer] > [Image] > [Store…) *(TRG p.197)*	as a background via Printersetting/Panel.			
7.6	Register a template, a font (.ttf/tte) and a character code table via [Store data in the printer]. (*TRG p.197)*	**a)** Each item registers with no errors **b)** Each item appears correctly in the printer's stored-data list.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
7.7	Printer settings — Preferences. Configure Power on action and Paper replacement action; power-cycle the printer	**a)** The printer does the configured action on power-on. **b)** The printer does the configured action on paper			

	and replace paper to confirm the configured behaviour occurs. *(TRG p.206)*	replacement.			
7.8	Operating Time Settings. Configure power saving transition time, media hold fan stop time, and data standby time to non-default test values; confirm each behaviour occurs at the configured interval. *(TRG p.214)*	**a)** Power saving mode starts at the set time **b)** The media hold fan stops at the set time. **c)** Data standby times out at the set time			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
7.9	Favourite Settings. Register a set of favourite settings for a representative label configuration, then apply it via [Select the Favourite	**a)** The favourite settings set saves successfully with the name you set. **b)** Applying it correctly changes the printer to match			

	Setting]. *(TRG p.221)*	those stored settings.			
7.10	Initilise printer – Factory reset. Execute [Factory Reset] and confirm settings return to default. *(TRG p.224)*	**a)** All settings return to factory default **b)** All registered images and setting files are deleted			
7.11	Settings save and restore. Save the current (validated, production-ready) printer configuration to a backup file; then restore from that file and confirm the configuration matches. *(TRG p.227)*	**a)** Saving settings produces a usable backup file. **b)** Restoring from that file correctly brings back the saved configuration. **c)** After this test, confirm the printer is back in its validated production setup, with Bidirectional Printing = On			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
7.12	Confirm [Print spooled document first] is disabled in the Windows printer driver's advanced/print-processor settings, so that	**a)** The setting is switched off, as required. **b)** A sequence of test print jobs comes out in the order they were sent.			

	multiple print jobs (e.g. from BarTender) print in submission time order. *(TRG p.166)*				

Acceptance criteria met | | **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 8 – Print Position Adjustment and Calibration

Objective	To verify that print start position, cut position and orunt head akignment adjustments function correctly and produce measureable, repeatble corrections across their calibration ranges.
Method	Using the PrinterSetting utility Position Adjustment screen, adjust Vertical, Horizontal, Paper Tip and cut Position settings within their specified ranges and measure the resulting runt position using a calibrated ruler/callipers. Run the media feed adjustment (both 'Do not print adjustment sheet' and 'Print adjustment sheet' methods) and the Bi-directional Print Adjustment using printed test patterns. Note: the shortest production label in current use (the 3.81 cm Label Type 2 label) is shorter than the minimum paper length needed to print the built-in Media Feed Adjustment (≥6.67 cm, Test 9.6) and Bi-directional Printing Adjustment (≥9.95 cm, Test 9.7) patterns; run those two steps on a longer continuous roll of the same media/ink combination, not on Label Type 2 stock. The 3.81 cm Label Type 2 roll does not meet this minimum — use a longer roll of the same media/ink for this step.
Acceptance Criteria	**a)** Each adjustment produces a real, repeatable change to print/cut position, within its tolerance. **b)** Media Feed Adjustment removes or reduces visible banding/streaking. **c)** Bi-directional Printing Adjustment removes or reduces visible skew/blur. **d)** All adjustments stay applied after they're set.
Reference Guide references	Position Adjustment / Start Adjustment, p.194 (also Print Head Alignment, p.207–212)

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
8.1	Vertical print start position adjustment. Set to boundary and mid-range values (-10.9 to +10.9 mm) via PrinterSetting > Position Adjustment and print a test label; measure the resulting vertical offset. *(TRG p.194)*	The measured vertical position moves in line with the value entered, within tolerance.			
8.2	Horizontal print start position adjustment. Set to boundary and mid-range values (-1.5 to +1.5 mm) and print a test label; measure the resulting horizontal offset. *(TRG p.194)*	The measured horizontal position moves in line with the value entered, within tolerance.			
8.3	Paper Tip Position adjustment (continuous paper). Adjust the print start position from the leading edge of continuous paper (0.0–3.0 mm) and print a test label. *(TRG p.194)*	The print start position (from the paper's leading edge) moves in line with the value entered, within tolerance.			

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
8.4	Cut position adjustment via PrinterSetting Position Adjustment. Set to several values and measure with calibrated callipers. *(TRG p.194)*	The measured cut position matches the value entered, within tolerance			
8.5	Media Feed Adjustment — 'Do not print adjustment sheet' method. Print sample data showing banding/streaking, then follow the TRG adjustment procedure using the on-screen +/– selection. *(TRG p.208)*	After the adjustment, a reprint shows less (or no) banding compared to before.			
8.6	Media Feed Adjustment — 'Print adjustment sheet' method. Load paper ≥66.7 mm length and print the preset adjustment pattern; select the pattern with least gap/overlap and apply. *(TRG p.209)*	**a)** The adjustment sheet prints correctly. **b)** After applying the best pattern, a reprint shows less (or no) banding.			

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
8.7	Sensor calibration cross-check. Confirm the Simple Media Detect / Media Detect calibration performed remains applied and effective after the print head alignment adjustments above. *(TRG p.270)*	**a)** Paper detection still works reliably after the position/alignment changes above.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 9 – Print Position Adjustment and Calibration

Objective	To verify that the printer's colour correction methods produce consistent, expected colour output, and that Spot Colour Settings (if used at this site, e.g. for brand/PMS colour matching on labels) correctly substitute a specified colour without affecting unrelated print content.
Method	For each colour correction method relevant to this site's print pipeline, set the printer driver's [Color Correction Mode] accordingly (Setting on the printer = Vivid colors; Setting using OS = ICM; Setting using an application = No composite) and print an identical colour reference/test label under each; compare visually. If Spot Color Settings are used at this site, create a spot colour setting file per the TRG procedure and print with it applied, confirming the specified original colour converts to the target colour and other colours are unaffected. Confirm the documented combination rule between Color Correction and Spot Color Settings.
Acceptance Criteria	**a)** Each colour correction method gives the expected, repeatable colour result on the reference label. **b)** If Spot Color Settings are used: the specified colour converts correctly, and nothing else on the label changes colour. **c)** The driver correctly blocks Spot Color Settings from being combined with ICM or None (only allowed with Epson vivid/preferred colour).
Reference Guide references	Colour Correction, p.250 – p.264 Spot Colour Settings, p244-249

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
9.1	Color Correction — Setting on the printer. Set [Color Correction Mode] = [Vivid colors] in the driver and print a colour reference/test label. *(TRG p.252)*	**a)** The label prints using the printer's own colour engine. **b)** The colours match the expected/reference appearance.			
9.2	Color Correction — Setting using OS. Set [Color Correction Mode] = [ICM] and print the same reference label. *(TRG p.254)*	**a)** The label prints using Windows' ICM colour engine. **b)** The colours match the expected appearance and are repeatable.			
9.3	Color Correction — Setting using an application / No composite (if used at this site, e.g. colour managed within BarTender or the label design). If not used, mark N/A. *(TRG p.265)*	**a)** If used: the label prints with the driver applying no extra correction, matching the expected appearance. **b)** If not used at this site: mark N/A.			

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
9.4	Create a Spot Color Setting file. Determine original and target RGB values for a colour used on-label (e.g. a brand/PMS-matched colour); create the setting file via PrinterSetting > Store data in the printer > Spot color table, per the TRG procedure. If spot colour matching is not used at this site, mark N/A and record justification. *(TRG p.244)*	**a)** If used: the file is created successfully with the correct RGB values and a valid name. **b)** If not used at this site: mark N/A.			
9.5	Print using the Spot Color Setting file. Select the file in the driver's [Spot Color Settings] and print a label containing the original colour. *(TRG p.249)*	**a)** The original colour converts to the target colour on the label. **b)** No other colours or content on the label are affected.			

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
9.6	Combination rule check. Attempt to apply Spot Color Settings with Color Correction set to [ICM] or [None]. *(TRG p.250)*	**a)** The driver either blocks this combination, or spot colour replacement simply does not apply — matching the TRG's documented rule.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 10 System Administration and Security

Objective	To verify that administrative access control (Lock Setting function and administrator password) correctly restricts unauthorised configuration changes on the printer, consistent with GxP access-control expectations.
Method	Set the administrator password; enable Lock Setting at each level (General Settings, Printer Settings, Media Settings); attempt to access locked settings without the password; confirm password entry grants access; change the administrator password; perform the documented password reset procedure.

Acceptance Criteria	**a)** The admin password can be set and changed correctly. **b)** Each Lock Setting level correctly blocks access until the correct password is entered. **c)** The password reset procedure works as documented and needs someone physically at the printer panel — it cannot be done remotely. **d)** The default password (the serial number) is changed to a site-controlled one at go-live, per SOP.
Reference Guide references	Restricting Operation of the Operation Panel — Lock Setting, p.271

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
10.1	Set the initial administrator password. Note the TRG default is the product serial number (visible on the status sheet); confirm the password is changed from this default per site SOP.	**a)** The admin password is set successfully. **b)** The default (serial number) password is changed to a site-controlled value, per SOP.			

	(TRG p.271)				
10.2	Enable Lock Setting = On for General Settings. [Menu] > [General Settings] > [System Administration] > [Security Settings] > [Admin Settings] > [Lock Setting] > On. *(TRG p.271)*	**a)** General Settings become locked. **b)** This also automatically locks General Settings itself and cannot be separately turned off while Lock Setting is On (this is expected TRG behaviour).			
10.3	Enable Lock Setting for Printer Settings. *(TRG p.271)*	**a)** Printer Settings menu items are greyed out and cannot be opened without the admin password.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
10.4	Enable Lock Setting for Media Settings. *(TRG p.271)*	**a)** Media Settings menu items are greyed out and cannot be opened without the admin password.			
10.5	Attempt to change a locked setting without entering the administrator password.	**a)** Access is blocked and the printer asks for the admin password.			

	(TRG p.271)				
10.6	Enter the correct administrator password when prompted for a locked setting. *(TRG p.271)*	**a)** Access is granted and the change goes through successfully.			
10.7	Change the administrator password. [Menu] > [General Settings] > [System Administration] > [Security Settings] > [Admin Settings] > [Admin Password] > [Change]. *(TRG p.272)*	**a)** The new password is accepted. **b)** The old password no longer works; the new one is required going forward.			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
10.8	Reset the administrator password using the documented recovery procedure (Home button, then hold Back + Cancel simultaneously, confirm, enter the unlock code, set new password). *(TRG p.272)*	**a)** The reset procedure completes successfully. **b)** It requires someone physically at the printer panel — this is a deliberate security control. **c)** A new password can be set			

		right after the reset.			
10.9	Confirm the printer's serial number (as used for the default password) matches the asset record held in the IQ documentation. *(TRG p.271)*	**a)** The serial number in this document matches the one shown on the printer's status sheet.			

Acceptance criteria met | | **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Section 11 – Optimisation of settings

Objective	Verify that print speed and print quality mode settings can be selected and configured
Method	Print batches of labels using templates containing an incrementing variable data field, covering each label type in use (e.g. Label Type 1, Label Type 2, Label Type 3 — see individual test scripts for batch sizes and specific templates).

Acceptance Criteria	a) Variable data values increment correctly and match the expected sequence for each batch. b) No values are skipped, duplicated, or corrupted across any batch or label type. c) All labels within each batch scan/verify successfully.

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)

11.1	Print a batch of 10 labels using a template with an incrementing variable data field for each of the 4 different label types (Label Type 1, Label Type 2, Label Type 3).	**a)** Every label shows the correct, correctly-incremented value **b)** No values are skipped or duplicated across the batch **c)** Every label scans successfully		

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Test 12 - Print Speed & Print Quality Modes & Functional Label QC

Objective	To verify that all the print quality/speed modes supported by the printer produce printed output that passes a functional label QC check (legible, correctly registered and scannable) at every setting. Additionally, the expected speed/resolution trade-off across modes is observed and that related print-speed functions (bidirectional printing, auto nzzle check, periodic auto cleaning) operate correctly. This part of the OQ establishes functional pass/fail performance at each print speed/quality setting. The barcode grading and quality stress-testing of the same settings under worst-case conditions are assessed separately in the PQ protocol. **(See Appendix A for the different labels and the speeds at which they were tested).** – QC check includes: Print Accuracy, Legibility and indelibility.
Method	Using the printer driver [General Tab] > [Media Settings] > [Print Quality], select each print quality setting applicable to the media coating type in use and print a test label (containing a UDI Matrix or QR code) at each setting, timing each print job with a stopwatch. Immediately following each print, perform a functional QC check: 1) Visually inspect the label against the QC check. 2) Scan the UDI or QR code with the Barcode scanner to confirm a successful scan. Repeat the print and QC check with bidirectional printing enable and disabled. Configure and observe the Auto Nozzle Check System and Periodic Auto Cleaning during a print run. Print the test label at the smallest of the three label sizes (5.08 x 3.81cm Label Type 2) which is to be used as the worst case size for legibility and scan margin. Then repeat the functional label QC check at normal mode on the largest label size (10.16 x 10.16 cm Label Type 3 label) as a confirmation check.
Acceptance Criteria	**a)** Every print quality mode prints with no errors and passes the functional label QC check **b)** Speed/resolution differences match expectations. Max speed is fastest/lowest resolution, Quality/Max quality is slowest slowest/highest resolution **c)** Bidirectional printing is measurably faster with no drop in QC pass rate **d)** Auto Nozzle check and periodic auto cleaning both run automatically as configured, without interrupting print jobs.

Reference Guide references	Media Settings – Print Quality; Auto Nozzle Check(p.25–30, p.87–89)

Test No.	Requirement / Test Set-up	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
Complete the following tests in Appendix B					
12.1	**Mode: Max Speed mode (300 x 600 dpi).** Select [Max Speed] in printer driver Media Settings, print a test label, and record print time using a stopwatch. *(TRG p.87)*	**a)** The label prints with no errors (no mechanical issues). **b)** This is the fastest print time of all the modes tested.			
12.2	**Mode: Max speed mode** – UDI or QR Code check. Inspect and scan the label printed	**a)** Print is accurate **b)** The print is legible **c)** The print doesn't erase or smudge			
12.3	**Mode : Speed mode (600 x 600 dpi)**. Select [Speed] in printer driver Media Settings, print a test label, and record print	The label prints with no errors. (no mechanical issues).			

	time using a stopwatch. *(TRG p.87)*				
12.4	**Mode : Speed mode** – UDI or QR Code check Inspect and scan the label printed	**a)** Print is accurate **b)** The print is legible **c)** The print doesn't erase or smudge			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
12.5	**Mode : Normal mode (600 x 600 dpi**). Select [Normal] in printer driver Media Settings, print a test label, and record print time using a stopwatch. *(TRG p.87)*	The label prints with no errors. (no mechanical issues).			
12.6	**Mode : Normal mode** – UDI or QR Code check. Inspect and scan the label printed	**a)** Print is accurate **b)** The print is legible **c)** The print doesn't erase or smudge			
12.7	**Mode : Quality mode (600 x 1200 dpi**). Select [Quality] in printer driver Media Settings, print a	The label prints with no errors. (no mechanical issues).			

	test label, and record print time using a stopwatch. *(TRG p.88)*				
12.8	**Mode : Quality mode** – – UDI or QR Code check.Inspect and scan the label printed	**a)** Print is accurate **b)** The print is legible **c)** The print doesn't erase or smudge			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
12.9	**Mode: Max Quality mode (1200 x 1200 dpi**). Select [Max Quality] in printer driver Media Settings, print a test label, and record print time using a stopwatch. This is for glossy media only *(TRG p.88)*	**a)** If tested: the label prints with no errors at the highest resolution. (no mechanical issues). **b)** If not tested (site uses plain continuous roll only): mark N/A			

12.10	**Mode: Max Quality mode** – – UDI or QR Code check. Inspect and scan the label printed *(TRG p.88)*	**a)** Print is accurate **b)** The print is legible **c)** The print doesn't erase or smudge			
Test No.	**Requirement / Test Set-up**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**
12.11	Bidirectional printing. Print a test label with bidirectional printing disabled, then enabled (Driver Utilities > Advanced > Bidirectional Printing) Compare the print time and QC check on each label. *(TRG p.89)*	**a)** Enabling bidirectional printing is measurably faster **b)** Both labels (on and off) pass the QC check: i)Print is accurate **ii)** The print is legible **iii)** The print doesn't erase or smudge.			
12.12	Auto nozzle check	The nozzle check runs automatically			

	system. Configure auto nozzle check per site requirements and print a batch of labels. Observe whether the system triggers automatically. *(TRG p.25)*	at its configured trigger with no operator input.			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

APPENDICES

Appendix A)

Label Description	Max Quality	Quality	Normal	Speed	Max Speed
Label Type 1	10	10	10	10	10
Label Type 2	10	10	10	10	10
Label Type 3	10	10	10	10	10
Total Labels	**150 Labels**				

a) Print is accurate

b) The print is legible

c) The print doesn't erase or smudge.

Appendix B) Test Sheets

	Quality

Label No.	Print is accurate – Pass (P), Fail (F)	The print is legible Pass (P), Fail (F)	The print doesn't erase or smudge. Pass (P), Fail (F)
Label 1			
Label 2			
Label 3			
Label 4			
Label 5			
Label 6			
Label 7			
Label 8			
Label 9			
Label 10			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

Appendix B) Test Sheets

	Normality		
Label No.	Print is accurate – Pass (P), Fail (F)	The print is legible Pass (P), Fail (F)	The print doesn't erase or smudge. Pass (P), Fail (F)

Label 1			
Label 2			
Label 3			
Label 4			
Label 5			
Label 6			
Label 7			
Label 8			
Label 9			
Label 10			

Acceptance criteria met ☐ **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

	Speed		
Label No.	**Print is accurate – Pass (P), Fail (F)**	**The print is legible Pass (P), Fail (F)**	**The print doesn't erase or smudge. Pass (P), Fail (F)**
Label 1			
Label 2			
Label 3			
Label 4			
Label 5			
Label 6			
Label 7			
Label 8			
Label 9			
Label 10			

Acceptance criteria met | | **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____
Verified By	Sign: _____	Date: _____

	Max

Label No.	Print is accurate – Pass (P), Fail (F)	The print is legible Pass (P), Fail (F)	The print doesn't erase or smudge. Pass (P), Fail (F)
Label 1			
Label 2			
Label 3			
Label 4			
Label 5			
Label 6			
Label 7			
Label 8			
Label 9			
Label 10			

Acceptance criteria met | | **YES / NO** – If **NO**, record deviation number in comments box

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____

Verified By	Sign: _____	Date: _____

REVISION HISTORY

Version	Date	Author	Change