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 Performance Qualification (PQ) testing required to ensure that the Epson CW-C4000U label printer, together with BarTender Enterprise labelling software, consistently and reliably produces conforming labels under actual production and worst-case conditions, using the fixed, optimised operating settings confirmed during Operational Qualification (OQ).

This protocol follows successful completion and approval of the Installation Qualification (IQ) and Operational Qualification (OQ) forms the final stage 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 Performance Qualification of the CW-C4000U label printer and the associated BarTender Enterprise software, as used at the manufacturer's site. It challenges print quality, barcode/2D scan-verification, and label content accuracy under production-representative and orst-case conditions across repeated consecutive runs, to confirm the system operates consistently and reliably prior to release for routine production use.

This protocol shall be reviewed and authorised by the stated personnel in the approval box prior to execution. The PQ execution shall be reviewed and approved prior to summary write-up. Upon completion of the PQ, 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) operating under the fixed, optimised settings, consistently produce labels that meet print quality, barcode legibility and content accuracy requirements under real product and worst-case conditions to complete the Performance Qualification (PQ).

Pre-requisites

- The IQ & OQ has been completed, reviewed and approved.
- The optimised print settings identified in OQ have been confirmed, documented and are available to be applied and locked for this PQ.
- The printer has been installed, powered and connected to a host PC with BarTender Enterprise installed and licensed
- Production-representative media (used for routine manufacture) is available in sufficient quantity for three consecutive full runs
- The printer’s Technical Reference Guide (TRG, User’s guide and BarTender Enterprise documentation are available for reference.

Report

Upon completion of the PQ 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 PQ 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 PQ – CW-C4000U Label Printer

PQ section	Test Name	TRG Chapters
1	QC Check -- Print Quality & Label Content Verification -- Production Run (all 3 label types) Functional QC Check -- Barcode / 2D Symbol (Data Matrix / UDI) Scan-Verification (all 3 label types)	Media Settings -- Print Quality (TRG p.87-89); BarTender template/label content (BarTender Enterprise documentation) Printing Barcodes / 2D Symbols (TRG p.98-116); 21 CFR 801.20 UDI Rule
2	Functional QC Check -- Label Adhesion & Application Verification (all 3 label types)	Label/media manufacturer specification;
3	QC Check -- Label Reconciliation & Traceability (all 3 label types)	N/A -- procedural/UDI traceability control
--	Appendices A – Test Sheets (Deviation Log, Reconciliation Log, Attachments Log)	--

PERSONNEL

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

Company	Name	Job Title	Signature	Initials

Index of PQ	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)
	Operational Qualification (OQ)

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
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 - QC Check -- Print Quality & Label Content Verification -- Production Run (all 3 label types)

Objective	To verify that, using the fixes settings confirmed as optimal in OQ section 12, the printer and BarTender Enterprise software consistently produce labels with acceptable print quality and 100% correct content when printing production-representative batches and are readable from the scanner, for each of the four label types individually at the settings recorded below from OQ.
Method	Without adjusting any print quality, speed, position or colour setting from the confirmed optimum, print a production-representative batch of each label tupe in turn, using the approved, BarTender template for that label type, populated with representative variable data. Visually inspect every label for print quality defects (smudges, missing dots, incorrect colour). Reconcile printed label content against the master data record for all labels in the batch. Complete a QC check as per the acceptance criteria.
Parameter Settings	**Record Parameter Settings here from OQ:**
Acceptance Criteria	**a)** All labels of the label type are free from visible print quality defects (banding, streaking, smearing, missing print, incorrect colour) throughout the batch. **b)** 100% of printed label content (text, QR codes, dates, serial data) matches the master/source data record exactly for that label type. **c)** No degradation in print quality is observed between the first and last label of the batch **d)** All barcodes on the label type scan successfully on first attempt. **e)** Decoded data from each scan matches the intended encoded value for that label.

	f) No scan failures or mis-reads are observed across the batch for that label type

Test No.	Requirement	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
1.1	**Label type: Label Type 1** Print 3 production-representative batches of 20 using the OQ-confirmed optimised settings and complete the QC check including: Scan/verify every barcode/2D symbol across the fully batch of the Label Type 1 Label	**See acceptance criteria above**			
1.2	**Label type: Label for Label Type 2**	**See acceptance criteria above**			

	Print 3 production-representative batches of 20 using the OQ-confirmed optimised settings and complete the QC check. including: Scan/verify every barcode/2D symbol across the fully batch of the Label Type 1 Label				
1.3	**Label type: Label for Label Type 3** Print 3 production-representative batches of 20 using the OQ-confirmed optimised settings and complete the QC check. including: Scan/verify every barcode/2D symbol across the fully batch of the Label Type 1 Label	**See acceptance criteria 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 2 – Functional QC check: Label adhesion and Application verification

Objective	To verify that when printed under the OQ-optimised settings, each label type adheres correctly to its intended device and remains functionally attached under normal handling, for each of the 3 label types
Method	Take a representative sample of printed labels for the label type from the Test 1 batch. Apply each sampled label to a representative device following the Work Instruction. Inspect immediately for correct placement, full contact and absence of air bubbles/lifting edges. Re-inspect after X period to confirm the label remains fully adhered with no edge lift or curling.
Acceptance Criteria	**a)** 100% of the sampled labels for the label type apply cleanly, with full contact and no bubbling or misalignment of application **b)** No edge lift or curling is observed at the post-application inspection interval **c)** Printed content remains legible and scannable after application

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

No.		Criteria	enter values)	(P/F)	
2.1	**Label type: Label Type 1.** Apply a representative sample of printed Label Type 1 labels to the intended substrate/test surface and verify adhesion at application and after the dwell period.	**See acceptance criteria above**			
2.2	**Label type: Label for Label Type 2.** Apply a representative sample of printed Label Type 1 labels to the intended substrate/test surface and verify adhesion at application and after the dwell period.	**See acceptance criteria above**			
Test No.	**Requirement**	**Acceptance Criteria**	**Actual Result (Screenshot where necessary or enter values)**	**Pass/Fail (P/F)**	**Performed By / Date**

2.3	**Label type: Label for Label Type 3.** Apply a representative sample of printed Label Type 1 labels to the intended substrate/test surface and verify adhesion at application and after the dwell period.	**See acceptance criteria 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 3 –QC check: Label reconciliation and Traceability

Objective	To confirm 100% reconciliation of labels printed against labels required for each production run in this PQ, supporting UDI traceability and preventing over-run, under-run, or unaccounted labels, for each label type.
Method	For each run performed, and for each label type, record the expected batch quantity, the actual quantity of labels printed (including any rejected/voided labels), and reconcile the two. Record disposition (e.g. destroyed, retained as evidence) of any reject/voided labels in accordance with .
Acceptance Criteria	a) Printed label quantity matches the expected batch quantity for every run and label type, once reject/voided labels are accounted for. b) All reject/voided labels are individually recorded, with disposition evidenced. c) No unaccounted or 'loose' labels remain at the end of any run, for any label type.

Test No.	Requirement	Acceptance Criteria	Actual Result (Screenshot where necessary or enter values)	Pass/Fail (P/F)	Performed By / Date
3.1	**Label type: Label Type 1** Complete the label reconciliation record for the Label Type 1 label	**See acceptance criteria above**			

	across all runs performed in Tests 1				
3.2	**Label type: Label Type 2** Complete the label reconciliation record for the Label Type 2 label across all runs performed in Tests 1	**See acceptance criteria above**			
3.3	**Label type: Label Type 3** Complete the label reconciliation record for the Label Type 3 label across all runs performed in Tests 1	**See acceptance criteria 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: _____

REVISION HISTORY

Version	Date	Author	Change

Appendix A) Test Sheets 3 Batches

Batch One)

Label Type 1	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)	Scan Successful (P/F)	Label Reconciliation Successful (P/F)
Label 1					
Label 2					
Label 3					
Label 4					
Label 5					
Label 6					
Label 7					
Label 8					
Label 9					
Label 10					
Label 11					
Label 12					
Label 13					
Label 14					
Label 15					
Label 16					
Label 17					
Label 18					
Label 19					
Label 20					

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 _____

Label for Label Type 2	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)	Scan Successful (P/F)	Label Reconciliation Successful (P/F)
Label 1					
Label 2					
Label 3					
Label 4					
Label 5					
Label 6					
Label 7					
Label 8					
Label 9					
Label 10					
Label 11					
Label 12					
Label 13					
Label 14					
Label 15					
Label 16					
Label 17					
Label 18					
Label 19					
Label 20					

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 _____

Label for Label Type 3	**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)**	**Scan Successful (P/F)**	**Label Reconciliation Successful (P/F)**
Label 1					
Label 2					
Label 3					
Label 4					
Label 5					
Label 6					
Label 7					
Label 8					
Label 9					
Label 10					
Label 11					
Label 12					
Label 13					
Label 14					
Label 15					
Label 16					
Label 17					
Label 18					
Label 19					
Label 20					

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 _____

Batch Two)

Label Type 1	**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)**	**Scan Successful (P/F)**	**Label Reconciliation Successful (P/F)**
Label 1					
Label 2					
Label 3					
Label 4					
Label 5					
Label 6					
Label 7					
Label 8					
Label 9					
Label 10					
Label 11					
Label 12					
Label 13					
Label 14					
Label 15					
Label 16					
Label 17					
Label 18					
Label 19					
Label 20					

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 _____

Label for Label Type 2	**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)**	**Scan Successful (P/F)**	**Label Reconciliation Successful (P/F)**
Label 1					
Label 2					
Label 3					
Label 4					
Label 5					
Label 6					
Label 7					
Label 8					
Label 9					
Label 10					
Label 11					
Label 12					
Label 13					
Label 14					
Label 15					
Label 16					
Label 17					
Label 18					
Label 19					
Label 20					

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 _____

Label for Label Type 3	**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)**	**Scan Successful (P/F)**	**Label Reconciliation Successful (P/F)**
Label 1					
Label 2					
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Label 19					
Label 20					

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 _____

Batch Three)

Label Type 1	**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)**	**Scan Successful (P/F)**	**Label Reconciliation Successful (P/F)**
Label 1					
Label 2					
Label 3					
Label 4					
Label 5					
Label 6					
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Label 11					
Label 12					
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Label 15					
Label 16					
Label 17					
Label 18					
Label 19					
Label 20					

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 _____

Label for Label Type 2	**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)**	**Scan Successful (P/F)**	**Label Reconciliation Successful (P/F)**
Label 1					
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Label 19					
Label 20					

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 _____

Label for Label Type 3	**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)**	**Scan Successful (P/F)**	**Label Reconciliation Successful (P/F)**
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