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: Global UDI Founder	Signature:	Date:
Reviewed by:	the Manufacturer		

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: Global UDI Founder	Signature:	Date:
Reviewed by:	the Manufacturer		

Introduction

This document outlines the Installation Qualification (IQ) testing required to ensure that the Epson CW-C4000U label printer, together with BarTender Enterprise labelling software, has been correctly installed, configured, and is fit for its intended use: printing labels that are applied directly to a medical device. This protocol forms part of the overall software and equipment validation package required prior to the printer and software 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 UDI 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 Installation Qualification of the CW-C4000U label printer and the associated BarTender Enterprise software installation, as used at the manufacturer's site. The scope is limited to installation-level testing (equipment identification, facility/utility checks, safety, software installation, and documentation) to confirm the system is fit for use. Operational and Performance Qualification (OQ/PQ) of label print quality, barcode verification, and label content accuracy are covered under separate protocols.

This protocol shall be reviewed and authorised by the stated personnel in the approval box prior to execution. The IQ execution shall be reviewed and approved prior to summary write-up. Upon completion of the IQ, 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) installation to complete the Installation Qualification (IQ). This IQ will validate that the printer and software have been correctly and completely installed in accordance with the manufacturer’s (Epson) specifications.

Pre-requisites

- The printer has been unpacked and all protective/transite materials removed.
- A dedicated, suitably rated power outlet (in accordance with the manufacturers rating) is available at the installation location
- A host computer with available Wi-Fi has the available BarTender Enterprise licensed and ready for installation
- The printer’s Technical Reference Guide (TRG), User’s guide, and BarTender Enterprise documentation are available for reference.

Report

Upon completion of the IQ protocol the findings must be summarised in a Combined IOPQ 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 IQ 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 Global UDI and a Manufacturer representative.
- the Manufacturer shall execute this qualification protocol, noting any deviations from the protocol.

Index of IQ – CW-C4000U Label Printer

IQ section	Test Name
1	Equipment / Component Identification
2	Mechanical, electrical and Facility Checks
3	Critical Components and Consumables
4	Maintenance and Calibration
5	Software Installation & Connectivity (Printer Driver + BarTender Enterprise)
6	Documentation Review
7	Health, Safety & Environmental Checklist

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

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	Data logger	Used in combination with humidity and temperature sensors to check the installation environment	
2	Humidity sensor	Measure relative humidity at the installation location	
3	Temperature sensor	Measure room temperature at the installation location	
4	Multimeter	Voltage/output check of the printer's power supply	
5	Sound Level Meter	Measure ambient noise level at the installation location, for comparison against the printers rated noise output (58dB)	

Test 1) Equipment / Component Identification

Objective	To record and confirm the identity, location, and included components of the printer as installed.
Method	Record all asset and component details in the tables below by physical inspection of the printer against the packing list in the Technical Reference Guide.
Acceptance Criteria	All details are recorded, and all listed components/accessories are present and undamaged.

Asset Details

Field	Details
Asset ID / Equipment Number	
Location	
Manufacturer	**Seiko Epson Corporation**
Model	**CW-C4000U**

Field	Details
Serial Number	
Firmware Version	
Black Ink Type Selected (Gloss / Matte)	**Gloss**

Included Components / Accessories Check (per Technical Reference Guide, 'Unpacking')

#	Unit Description	Present (Y/N)	Undamaged (Y/N)	Performed By / Date
1	Printer main unit (CW-C4000U Series)			
2	Ink cartridges — C, M, Y, and BK or MK (for initial ink charging)			
3	Roll paper (for initial operation check)			
4	AC adapter (AC ADAPTER, K1, Model: M248B)			
5	Power cable			
6	USB cable			
7	Printed manual(s) / Start Here guide			
8	Paper tray (OT-PT40), if supplied			

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

Comments / reference to attachments (if applicable)

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

Test 2) Mechanical, Electrical & Facility Checks

Objective	To confirm that the printer has been installed with the correct services, on a suitable surface, and in an appropriate location for operation.
Method	Verify the installation location and electrical supply against the manufacturer's requirements, using a multimeter to check the AC adapter output where applicable.
Acceptance Criteria	Services must be available and meet the acceptance criteria specified: Power supply: Dedicated AC adapter (AC ADAPTER, K1, Model: M248B) — rated output 42V DC, 1.38A; average operating consumption approx. 28.2W. Weight: approx. 13 kg — installation surface must be level, stable, and able to support this weight. Dimensions (approx.): Height 285mm x Width 310mm x Depth 283mm.

Requirement	Acceptance Criteria	Actual Result	Performed By / Date
Installation surface	Level, stable, sufficient strength to support ~13 kg; area larger than the printer's footprint		
Power outlet	Dedicated, grounded power outlet within reach of the supplied power cable, located so the plug can be disconnected quickly in an emergency		
AC adapter output voltage (multimeter	42V DC nominal		

Requirement	Acceptance Criteria	Actual Result	Performed By / Date
check)			
AC adapter output current rating	1.38A		
Clearance for paper loading, consumable replacement, and daily cleaning	Sufficient open space on all sides; no obstruction to covers or paper path		
Only the specified AC adapter and power cable are used	Dedicated AC adapter (K1, M248B) and supplied power cable only — not used with any other device		

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) Critical Components and Consumables

Objective	To record the critical consumable components fitted to the printer and confirm they are correct for the installed model.
Method	Physically inspect the fitted ink cartridges and maintenance box; cross-reference the model/part numbers against the Technical Reference Guide 'Consumables Specifications'.
Acceptance Criteria	Fitted ink cartridges and maintenance box match the part numbers specified for the installed CW-C4000U model variant, and are within their expiration date.

Ink Cartridge Part Numbers by Model Variant (for reference)

Printer Model	Ink Cartridge Part Numbers (BK / MK / C / M / Y)
CW-C4000u	SJIC41P-BK, SJIC41P-MK, SJIC41P-C, SJIC41P-M, SJIC41P-Y

Fitted Components — Report

Critical Component	Part No. Fitted	Expiry / Best-before	Correct for Model? (Y/N)	Performed By / Date
Black ink cartridge (Gloss or Matte)				
Cyan ink cartridge				
Magenta ink cartridge				
Yellow ink cartridge				
Maintenance box (SJMB4000)				

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

Comments / reference to attachments (drawing numbers etc)

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

Test 4) Maintenance and Calibration

Objective	To ensure the printer's maintenance requirements are understood, scheduled, and that critical components are added to the maintenance system.
Method	Confirm the maintenance procedure and frequency for each item below is documented and, where applicable, that the item has been added to the site's maintenance/calibration system. Append print-outs of the maintenance system record if available.
Acceptance Criteria	All applicable components have a documented maintenance procedure and frequency, and are recorded in the maintenance system where required.

Component / Task	Method & Frequency	Added to Maintenance System (Y/N)	Performed By / Date
Exterior cleaning	Wipe with a dry or slightly damp cloth. **Do not** use alcohol, benzine, thinner, trichloroethylene, or ketone-based solvents (except for verified alcohol disinfection procedure, max 3x/day).		
Platen cleaning	Clean with non-woven fabric / cotton swabs when ink adheres to the platen or holes become blocked. Do not use water or alcohol.		
Auto cutter cleaning	Clean the fixed blade when adhesive build-up prevents a clean cut.		
Print head cleaning / nozzle check	Run nozzle check pattern and print-head cleaning via the operation panel or PrinterSetting utility if print quality degrades or after long idle periods. Auto Nozzle Check System / Periodic Auto Cleaning can be configured.		
Ink cartridge replacement	Replace when prompted by the printer / IC chip low-ink detection.		
Maintenance box replacement	Replace when prompted by the printer (waste ink capacity reached).		

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

Comments / reference to attachments (drawing numbers etc)

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

Test 5) Software Installation & Connectivity

Objective	To document the printer driver and BarTender Enterprise software versions installed, and confirm the printer is correctly connected and addressable from the host computer.
Method	On the designated host computer: ● Install the Windows printer driver for the CW-C4000U (via Install Navi or manual installation). ● Connect the printer to the host computer/network via USB or LAN as specified for the site. ● Install BarTender Enterprise and confirm licensing/activation. ● Configure BarTender Enterprise to communicate with the printer (select/confirm the correct printer driver as the output device). ● Perform a self-test print directly from the printer, and a test label print from BarTender Enterprise.
Acceptance Criteria	The printer driver installs successfully and the correct model/version is displayed. BarTender Enterprise installs successfully, is correctly licensed, and recognises the printer as an available output device. A self-test print and a BarTender-driven test label both print successfully and legibly.

Test	Check	Result	Performed By / Date
A	Windows printer driver installed — record version		
B	Connection method used (USB / LAN) — record details (e.g. IP address, port, cable ID)		
C	BarTender Enterprise installed — record version		
D	BarTender Enterprise license/activation confirmed		
E	Printer selected/recognised correctly within BarTender		

Test	Check	Result	Performed By / Date
	Enterprise as the output device		
F	Self-test print from printer operation panel — successful and legible		
G	Test label printed from BarTender Enterprise — successful and legible		

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

Comments / reference to attachments (drawing numbers etc)

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

Test 6) Documentation Review

Objective	Manuals and technical documentation verification.
Method	List all applicable SOPs, manuals, and label specifications, and verify they are filed, under control, and available for reference.
Acceptance Criteria	All applicable SOPs, manuals, and label specifications are filed and under control.

Title	Document #	Location	Present / Under Control (Y/N)	Performed By / Date
Label Printing and Control SOP	SOP-037			
Printer User Guide				
CW-C4000 Series Technical Reference Guide	NA			
CW-C4000 Series User's Guide	NA			
BarTender Enterprise user documentation	NA			

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

Comments / reference to attachments (drawing numbers etc)

Completed By	Sign: _____	Date: _____

Verified By	Sign: _____	Date: _____

Test 7) Health, Safety & Environmental Checklist

Test	Check	Method / Acceptance Criteria
1	Guards check	Confirm the auto-cutter guard/finger-trap protection is intact and functional. The cover lock mechanism must stop the cover closing if the printer unit is lifted from the installation surface; ensure the printer is installed on a level surface.
2	Caution labels present	Confirm caution labels (auto-cutter blade warning, finger-trap warning) affixed to the printer are present, legible, and undamaged.
3	Safety certification	Append any supplier safety certification/declaration of conformity that deems the equipment fit and safe for use.

Protocol — Environmental Checklist

Test	Check	Method / Acceptance Criteria
1	Surface	Printer placed on a solid, level surface of sufficient size/strength to hold it (approx. 13 kg).
2	Humidity	Relative humidity 20–80% RH, no condensation (printing conditions) — confirm with a datalogger and digital humidity sensor.
3	Temperature	Temperature 5–35°C (printing conditions); 15–35°C for barcode printing — confirm with a datalogger and digital temperature sensor.
4	Elevation	0–3000 m — confirm installation site elevation is within range.
5	Ventilation / clearance	Sufficient open space around the printer on all sides for ventilation, cooling, and access to components/connectors. No padding or cushioning behind the printer that could restrict airflow.
6	Noise	For information: approx. 58 dB under Epson evaluation conditions — confirm installation location is suitable for this noise level.

Report

Test	Check	Result	Performed By / Date
H&S-1	Guards check		
H&S-2	Caution labels present		
H&S-3	Safety certification appended		
ENV-1	Surface		
ENV-2	Humidity (measured)		
ENV-3	Temperature (measured)		
ENV-4	Elevation		
ENV-5	Ventilation / clearance		
ENV-6	Noise		

Acceptance criteria met ☐ **YES / NO** – If **NO**, record Concession 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