

LVS-7500/7510



LVS-7500 External System
(Goalpost Configuration)



LVS-7510 Integrated System

Validation Procedure Overview

The Validation Procedure Guidelines for the LVS-7500 or LVS-7510 (depending on your system) assist in validating an LVS-7500 or LVS-7510 system. The document provides guidelines to determine if an LVS-7500 or LVS-7510 system meets Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) specifications and fulfills its intended purpose. The document can be modified to fit the client's validation protocol.

Validation Procedure: At a Glance

- 100% print quality inspection for thermal and thermal transfer printers
- Master-to-Label Comparison (Blemish Detection), Barcode Verification and Validation (1D and 2D), OCR, OCV, Field Matching and Number/Data Validation
- Identify Defects; Eliminate Fines and Disputes; Reduce Rework; Control Waste; Avoid Liability
- Ideal for Pharmaceuticals, Medical Devices, Clinical Trials, Contract Packaging, Manufacturing, and Label Converting

For more information on this product, visit www.microscan.com.

Installation Qualification (IQ)

The purpose of IQ is to confirm that the LVS-7500 or LVS-7510 system was installed correctly. A series of questions are provided pertaining to the installation of the system. Specific challenges and tests include:

- **Setup/Configuration:** Component Make, Model, Serial Number, Version
- **Training:** Operator and Administrator training
- **Data:** Parameter settings

Operational Qualification (OQ)

The purpose of OQ is to demonstrate that the LVS-7500 or LVS-7510 system components operate correctly within established limits and tolerances. Specific challenges/tests include:

- Base Functions: System access, navigation, printing, backup
- GxP Functions: Nominal actions, boundaries, errors, and alarms
- System Controls: Security, audit trails, e-records, and e-signatures

Performance Qualifications (PQ)

The purpose of PQ is to demonstrate that the LVS-7500 or LVS-7510 performs as intended. Specific challenges/tests include:

- **Business Scenarios:** End-to-end, full cycle
- **Performance:** Stress, volume, response, reliability
- **Business Integration:** Using approved SOPs, trained users

Items Included with Purchase

- Microsoft Word version of the "LVS-7500 Validation Procedure Guidelines" and "LVS-7510 Validation Procedure Guidelines"
- Microsoft Word version of the "LVS-7500 Operations Manual" or "LVS-7510 Operations Manual"
- Validation file in Adobe PDF format containing 200 labels for challenging the LVS-7500 or LVS-7510 to detect quality defects. The labels have engineered failures dispersed throughout the run. Also included are simple, easy to follow instructions for printing and verifying the roll of validation labels.

LVS-7500 / LVS-7510 VALIDATION PROCEDURE OVERVIEW

IQ, OQ, and PQ Testing

Installation Qualification (IQ)

The purpose of IQ is to confirm that the LVS-7500 or LVS-7510 system was installed correctly. Specific challenges/tests include:

Challenge/Test	Details
Setup/Configuration	Component Make, Model, Serial Number, Version
Standard Operating Procedures (SOPs)	Backup/recovery, security, change control, data architecture
Training	Developers, system users, IT support personnel
Data	Parameter settings, base data files

Performance Qualification (PQ)

The purpose of PQ is to demonstrate that the entire system performs as intended. Specific challenges/tests include:

Challenge/Test	Details
Business Scenarios	End-to-end, full cycle
Performance	Stress, volume, response, reliability
Business Integration	Using approved SOPs, trained users

Operational Qualification (OQ)

The purpose of OQ is to demonstrate that the LVS-7500 or LVS-7510 system components operate correctly within established limits and tolerances. Specific challenges/tests include:

A roll of 200 labels formatted in BarTender software for challenging the LVS-7500 or LVS-7510 to find quality defects. The labels have engineered failures dispersed throughout the run.

In the event that the system detects errors on labels that are designed to “Pass,” an employee can review the errors and decide if the error is acceptable for production use. All results are documented in “Test Results” section.

Challenge/Test	Details
Base Functions	System access, navigation, printing, backup
GxP Functions	Nominal actions, boundaries, errors/alarms
System Controls	Security, audit trails, e-records, e-signatures

Part Numbers

Part Number	Description
98-LVS0092A	LVS-7500 IQ/OQ Validation Procedure Guidelines
98-LVS0092B	LVS-7510 IQ/OQ Validation Procedure Guidelines

QMS CERTIFICATION

www.microscan.com/quality

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Warranty – For current warranty information about this product, please visit www.microscan.com/warranty.



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