

LVS-95XX



LVS-95XX Series IQ/OQ Overview

The “LVS-95XX Series Installation Qualification (IQ) and Operational Qualification (OQ) Guideline” assists in validating an LVS-95XX Series system. The document provides guidelines to determine if an LVS-95XX Series system meets IQ and OQ specifications and fulfills its intended purpose. The document can be modified to fit the specifications of the client’s validation protocol.

LVS-95XX Series: At a Glance

- Offline verification of bar codes to ISO/IEC standards.
- Inspects all nine of the ISO (ANSI) parameters, plus added features of determining blemishes, opacity, and human readable validation.
- Verifies 1D & 2D codes and reports all parameters as specified in the applicable symbology specification.

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

Installation Qualification (IQ)

The purpose of IQ is to confirm that the LVS-95XX system was installed correctly. A series of questions are provided pertaining to the installation of the system. In addition, a Calibrated Conformance Standard Test Card for GS1 Symbols accompanies an LVS-95XX system purchase. The Test Card reports on several certified parameters. The system must demonstrate its ability to stay within +/- 5 percentage points of the parameters listed on the Test Card. The IQ section provides a chart to document and verify each Test Card parameter.

- Linear codes (1D):**
ISO/IEC 15426-1:2000(E)
- Two-dimensional codes (2D):**
ISO/IEC 15426-2:2004(E)

To pass the OQ test, each test label supplied with the package is graded twice. The First Test Overall Grade and Second Test Overall Grade must measure within +/- 0.3 of each other’s grade point average. The labels to be tested can be taken from the “LVS-95XX Series IQ and OQ Validation Guidelines,” supplied by the client, or a combination of both. The labels must have at least a 1.4 grade point average.

Operational Qualification (OQ)

The purpose of OQ is to demonstrate that LVS-95XX system components operate correctly within established limits and tolerances. OQ sections include:

Operational Status: This section provides a series of questions about the system’s operational status.

Testing: This section is designed to certify that the system is working according to factory specifications and according to the following test methods:

Continued on back

LVS-95XX: Available Symbologies



LVS-95XX SPECIFICATIONS AND OPTIONS

Support Documentation:

This section verifies that supporting documentation is supplied with the system. Sample documents include the “LVS-95XX Series Operations Manual,” Pre-ventive Maintenance Schedule, and Certificate of Training Documentation.

Electronic Records and Signatures:

This section provides a list of questions associated with the criteria of using Electronic Records and Electronic Signatures with the LVS-95XX system; this pertains to FDA regulations required under 21 CFR Part 11.

Training Documentation:

This section provides a place for training instructors to document operational training session information pertaining to the calibration process; calibration test card replacement process; setup screen functions; system verification methods; printing and archiving reports; and software upgrades.

Items Included with Purchase

Microsoft® Word version of the “LVS-95XX Series IQ and OQ Guidelines”

Microsoft® Word version of the “LVS-95XX Series Operations Manual”

One set of twenty five (25) challenge barcode labels (1D and 2D barcodes) for testing (see example images)



Example 1D (Code 39) Bar Code



Example 2D (Data Matrix) Bar Code



Example 2D (Data Matrix) Bar Code

SAFETY CERTIFICATIONS DESIGNED FOR

FCC, CE, UL (Pending)

ROHS COMPLIANT

QMS CERTIFICATION

www.microscan.com/quality

©2016 Microscan Systems, Inc. ML052A-EN-0416

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



MICROSCAN®

www.microscan.com