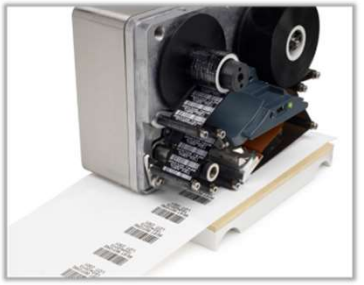
Barcode Verification and LVS-95XX Verifiers

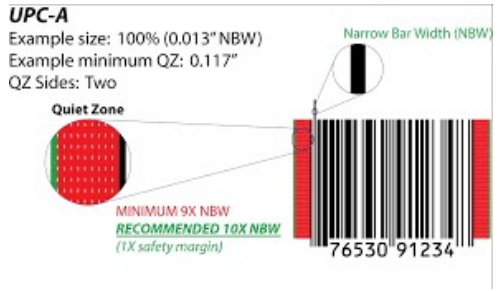
Causes of Barcode and Label Content Defects

- Printer issues such as ribbon wrinkle, end of ribbon life, mismatch of ribbon and label substrate, incorrect heat settings, clogged ink jets, label substrate defects, low resolution, etc.
- Incorrect barcode design including wrong symbology type, mis-scaling, barcode dimensions, poor color contrast, quiet zone violations, incorrect data content, non-conformance to GS1 data structure, missing information



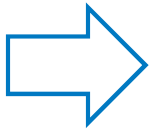
The Global Language of Business

Yellow on White



What Can Go Wrong with Label Print Quality?

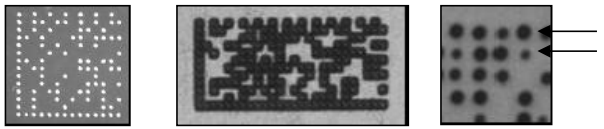
- Ribbon wrinkle
- Mismatch of ribbon and substrate
- Clogged ink jets
- Overspray of ink
- Defective areas in the substrate
- Over or under heated print head
- Something on the label
- Quiet Zone violations
- Incorrect construction of the bar code
- Burned out pixels
- Misaligned print heads
- …

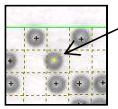


- Lost or misinterpreted information
- Increased labor cost
- High dollar re-labeling costs
- Increased errors
- Product recalls
- Rejected shipments
- User dissatisfaction
- Compliance penalties
- …

Potential Direct Part Mark Quality Problems

- Improper or inconsistent mark dot/cell size
- Improper or inconsistent mark dot/cell location
- Improper overall mark geometry
- Mark or part surface damage
- Very low or inconsistent mark contrast





Barcode Verification

Verification is a method of analyzing a printed code against a published specification (like those of GS1) to determine:

- Whether the barcode is compliant to specifications.
  - Verify **data structure**
- Whether the barcode will be read. ► Inspect **print quality**
- It is a predictor of how well a code will be able to be read throughout its life cycle.

- A ISO 15426 compliant barcode verifier grades barcode print quality and data format to ensure compliance with specifications for:
  - **Print Quality:** ISO/IEC 15415, ISO/IEC 15416
  - **Data Format:** GS1, HIBCC

- Unlike a verifier, A barcode scanner or barcode reader will report the data it sees, but it does not have the ability to tell you that the data in your code is not compliant to your selected standards, or whether it is formatted correctly.

Verification ≠ Validation

Verification : Determining the quality of printing/marking to predict readability

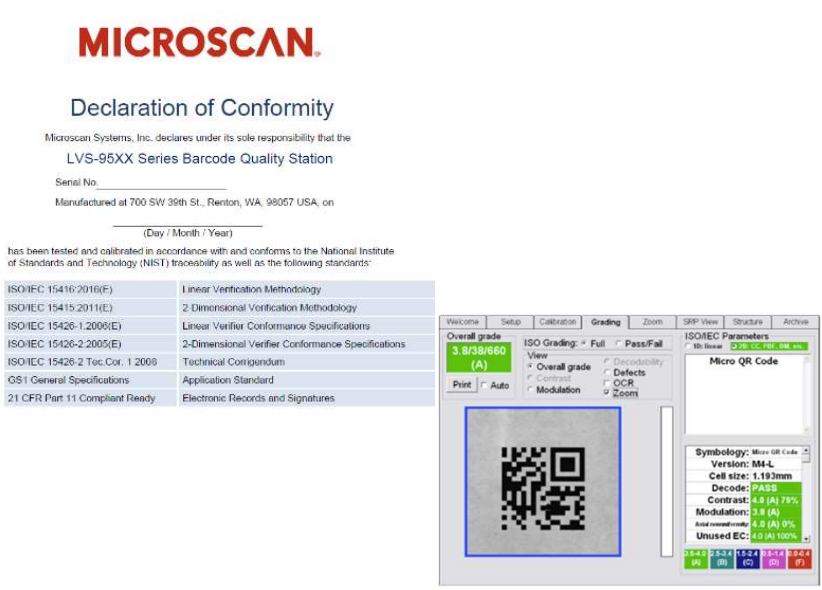
- Checking code quality to an ISO standard to ensure that it can be read by any reader.
- Requires a “precision test instrument” (Verifier) that is certified to conform to a specific ISO standard
- Produces a barcode grading report and typically includes advanced diagnostics tools for printing/marking process troubleshooting.

Validation : Checking the content of the code

- Checking that a code can be read now by a particular reader and confirms that the decoded data output is what was expected
- Confirms that the **data content** and **syntax** are what was expected and/or dictated by standards/specs
- Does not provide a reference point on whether another reader should be able to read the code
- Does not meet requirements for “ISO Grading” found in many specs

Verification vs. Validation

- **Verify:** Check a code's quality to an ISO standard (ISO 15415 or ISO 15416) to ensure that it can be read at any point on the line, by any reader.
  - Requires a "precision test instrument" (verifier) that is certified to conform to a specific ISO standard, ISO 15426
  - Produces a barcode grading report and typically includes advanced diagnostics tools for barcode defect troublleshooting
- **Validate:** Check that a code can be read right now by a particular reader.
  - Doesn't provide a reference point on whether another barcode reader should be able to read the code
  - Does not check whether the barcode size and data structure complies with standards such as GS1
  - Does not meet requirements for "ISO Grading" found in many specs



MICROSCAN

Declaration of Conformity

Microscan Systems, Inc. declares under its sole responsibility that the

LVS-95XX Series Barcode Quality Station

Serial No.

Manufactured at 700 SW 39th St., Renton, WA, 98057 USA, on

(Day / Month / Year)

has been tested and calibrated in accordance with and conforms to the National Institute of Standards and Technology (NIST) traceability as well as the following standards:

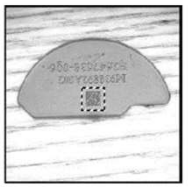
ISO/IEC 15416:2016(E)	Linear Verification Methodology
ISO/IEC 15415:2011(E)	2-Dimensional Verification Methodology
ISO/IEC 15426-1:2006(E)	Linear Verifier Conformance Specifications
ISO/IEC 15426-2:2005(E)	2-Dimensional Verifier Conformance Specifications
ISO/IEC 15426-2 Tec.Cor. 1:2006	Technical Corrigendum
GS1 General Specifications	Application Standard
21 CFR Part 11 Compliant Ready	Electronic Records and Signatures

Omron Microscan Systems, Inc.
LVS-95xx Verification Report

Overall: DPM3.0/07/660/D

Operator signature

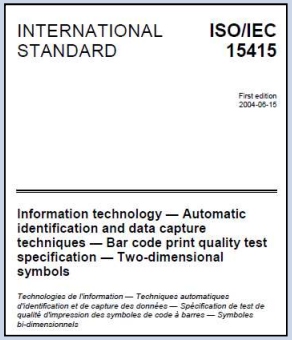
Second signature



2D	
Symbology	Data Matrix
Decoded text	E264758-006,M938892A002
Cell size	8.5 mils
Decode	PASS
Cell contrast	3.2 26%
Cell modulation	3.0
Axial nonuniformity	4.0 1%
Grid nonuniformity	4.0 22%
Unused EC	4.0 100%

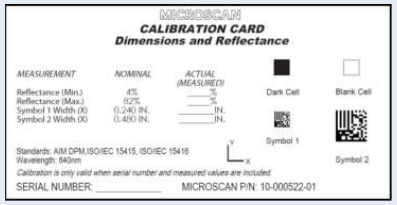
Other information	
Symbol Letter Grade	B
ReportID	136
Operator	admin (LVS Administrator)
Application standard	DPM (ISO/IEC TR29158)
Effective aperture	Reference number 07 (6.69 mil)
Lighting	660/D
Date and time	16-Apr-2018 08:08 local; 16-Apr-2018 15:08 GMT
Time zone	GMT -7
Sector size	0.22° by 0.22°

Applicable Print/Mark Quality Standards

ISO 15416 1D codes	ISO 15415 Printed 2D codes	AIM DPM -1-2006/ ISO 29158 (DPM)
		

Standards specify:

- Lighting wavelength and geometry
- Camera geometry
- Reflectance calibration
- Image processing
- Scan profile(1D) or grid (2D) determination
- Profile or grid analysis steps
- Overall grade determination
- .Reporting scale and report content



Reflectance Calibration Standard

Relevant ISO and GS1 Standards

- ISO 15415 and ISO 15416 / updated every 5 – 10 years
  - The only global standard for barcode quality determination of printed labels. Many other standards refer to ISO 15416/15416 for determining acceptability of a barcode quality. Replaces the ANSI "Letter Grade" convention which was phased out in 1990.
- ISO 15426
  - Defines how a barcode verifier must be tested for accuracy
- ISO/IEC TR 29158
  - The only global standard direct part mark quality determination Replaces the former AIM DPM standard which was phased out in 2011.
- GS1 General Specification / updated annually
  - Detailed specification for both barcode quality, as well as allowable symbology types, barcode sizes, data structure, application identifier code meanings within a barcode. References ISO 15415, 15416, and 29158 for barcode grading methods. Has tables for use in different applications with specific barcode requirements.

FDA UDI /GS1 Requirements for Barcode Verification

Checking of barcode content, format and quality

- Need to deconstruct barcode to confirm correct and correctly formatted data
- Need to check print/mark quality to confirm that codes will be readable

UDI ruling expects that you will follow the issuing agency's rules and guidelines

- All issuing agencies require barcode quality of grade C (numerical grade of 1.5) or better
- In the case of GS1, these are specific. "An unreadable bar code is the same as a missing bar code, which would mean non-compliance"

http://www.gs1.org/docs/barcodes/1D_Barcode_verification_implementation_guideline.pdf

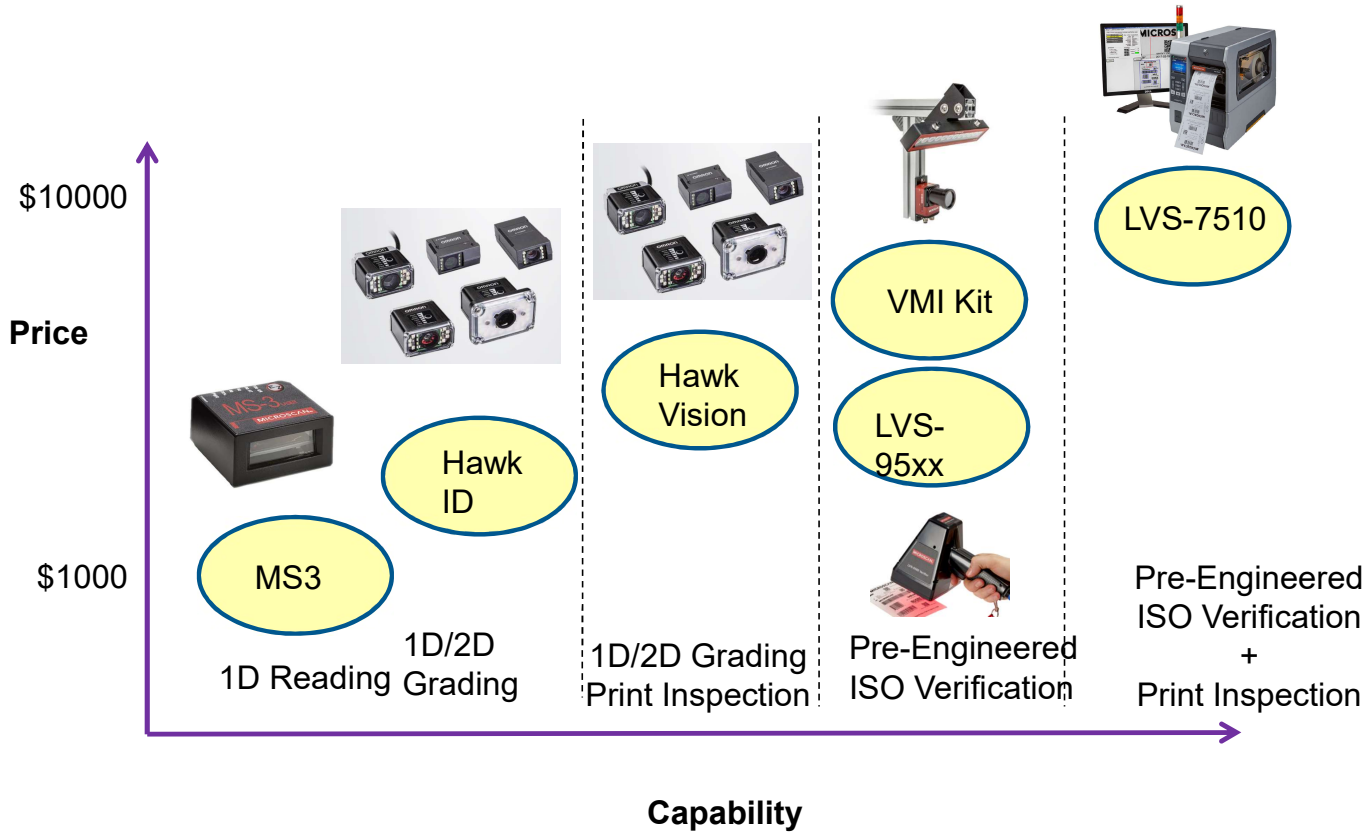
http://www.gs1.org/docs/barcodes//2D_Barcode_Verification_Process_Implementation_Guideline.pdf

Barcodes and UDI

FAQs

- FDA requires UDI info in both AIDC (auto-id) and human readable forms on product label
- Types of acceptable barcodes determined by GTIN issuing agency, e.g. GS1
- Can be either 1D or 2D barcodes, or an RFID tag
- DI must come first in data stream, followed by PI data
- UDI rule requires that whatever PI(s) appear on the device label or package (for whatever reason) must also be included in the UDI.
- UDI should be on every level of packaging, except for the logistics unit.
- For Class 1 devices U.P.C. number will serve as the UDI – which must still be registered in the GUDID with the required data attributes (no PI is required on the label)

Omron Microscan Barcode Inspection Portfolio



Barcode Quality and UDI Compliance

Link between label content, barcode quality, and UDI compliance

- FDA requires quality control of medical device labels by whomever is producing the label and applying it to the product packaging
- GS1 standard requires that barcode meet the GS1 General Specification Table 6
  - Barcode type (e.g GS1 -128, GS1- Data Matrix)
  - Barcode size, height module minimum dimension
  - Minimum print quality per ISO 15416/15416

GS1 General Specifications

5.9.3.6 Symbol specification table 6 - Regulated healthcare non-retail consumer trade items not scanned in general distribution

Figure 5.9.3.6-1. GS1 symbol specification table 6

Symbol(s) specified	X-dimension mm (inches)			Minimum symbol height for given X mm (inches)			Quiet Zone		Minimum quality specification
	Minimum	Target	Maximum	For minimum X-dimension	For target X-dimension	For maximum X-dimension	Left	Right	
GS1-128	0.170 (0.0067")	0.495 (0.0195")	0.495 (0.0195")	12.70 (0.500")	12.70 (0.500")	12.70 (0.500")	10*X*	10*X*	1.5/06/660
GS1 DataMatrix (ECC 200) (*)	0.254 (0.0100")	0.380 (0.0150")	0.990 (0.0390")	Height is determined by X-dimension and data that is encoded			1X on all four sides		1.5/08/660
GS1 DataBar Omni-directional	0.170 (0.0067")	0.200 (0.0080")	0.660 (0.0260")	5.61 (0.221")	6.60 (0.260")	21.78 (0.858")	*Not Applicable*	*Not Applicable*	1.5/06/660
GS1 DataBar Truncated	0.170 (0.0067")	0.200 (0.0080")	0.660 (0.0260")	2.21 (0.087")	2.60 (0.102")	8.58 (0.338")	*Not Applicable*	*Not Applicable*	1.5/06/660
GS1 DataBar Stacked	0.170 (0.0067")	0.200 (0.0080")	0.660 (0.0260")	2.21 (0.087")	2.60 (0.102")	8.58 (0.338")	*Not Applicable*	*Not Applicable*	1.5/06/660
GS1 DataBar Stacked Omni-directional	0.170 (0.0067")	0.200 (0.0080")	0.660 (0.0260")	11.73 (0.462")	13.80 (0.543")	45.54 (1.794")	*Not Applicable*	*Not Applicable*	1.5/06/660
GS1 DataBar Limited	0.170 (0.0067")	0.200 (0.0080")	0.660 (0.0260")	1.70 (0.067")	2.00 (0.079")	6.60 (0.260")	*Not Applicable*	*Not Applicable*	1.5/06/660
GS1 DataBar Expanded	0.170 (0.0067")	0.200 (0.0080")	0.660 (0.0260")	5.78 (0.228")	6.80 (0.268")	22.44 (0.884")	*Not Applicable*	*Not Applicable*	1.5/06/660

Omron Verification Platforms

Fully-integrated off-line & in-line verification solutions that include imaging, precision illumination and software specifically designed for accurate, reliable print/mark quality verification of 1D / 2D codes and Direct Part Marks (DPM) to applicable standards (e.g., ISO / IEC, GS1, HIBC, AIAG, …)

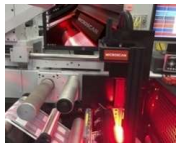
Offline Verification

LVS-9510
Desktop
Code Verifier

LVS-9580
Handheld Code
Verifier

Inline Verification/Inspection

LVS-7510
For Thermal
Transfer Printers



LVS-7000
For Web Press Printing

SC-Based Verification Kits

Large Linear
Verification Kit

Dot Peen
Verification Kit

Identify | **Inspect** | **Verify**

What is ISO and GS1?

- ISO

International Organization for Standardization is a voluntary organization whose members are recognized authorities on standards. The organization promotes Worldwide proprietary, industrial and commercial standards. ISO has 164 national members, out of the 206 total countries in the world.

- GS1

GS1 is a neutral, not-for-profit, international organization that develops and maintains standards for supply and demand chains across 110 countries. GS1 has over a million member companies across the world, executing more than six billion transaction daily using GS1 standards. Works closely with the Life Science and Retail Markets

Relevant ISO and GS1 Standards

- ISO 15415 and ISO 15416 / updated every 5 – 10 years

The only global standard for barcode quality determination of printed labels. Many other standards refer to ISO 15416/15416 for determining acceptability of a barcode quality. Replaces the ANSI “Letter Grade” convention which was phased out in 1990.

- ISO 15426 – Defines how a barcode verifier must be tested for accuracy
- ISO/IEC TR 29158

The only global standard direct part mark quality determination Replaces the former AIM DPM standard which was phased out in 2011.

- GS1 General Specification / updated annually

Detailed specification for both barcode quality, as well as allowable symbology types, barcode sizes, data structure, application identifier code meanings within a barcode. References ISO 15415, 15416, and 29158 for barcode grading methods. Has tables for use in different applications with specific barcode requiremens.

- Other industry specific standards
  - AIAG for automotive labeling
  - MIL-STD-130N and AS-9132 for defense and aerospace (DPM)
  - Many other regional or industry specific data structure standards

2016 Changes to ISO 15416 – Letter Grades De-emphasized

Impact of ISO 15416:2016 Changes to Barcode Grading

Summary:

The changes to ISO 15416:2016 (released December 2016) result in a transition away from the historic letter method of assigning a quality grade. The method of calculating decimal grades for several symbol parameters has also changed, resulting in some cases a higher calculated grade for a given symbol compared with the previous version of ISO 15416.

INTERNATIONAL STANDARD ISO/IEC 15416

Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols

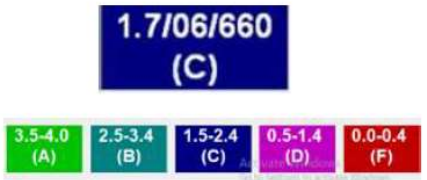
Historical Background for Barcode Grading

- The first published standard for barcode quality was the ANSI X3.182-1990, which built upon previously published barcode guidelines from the UCC (Uniform Code Council). This standard defined print quality guidelines and the foundation concepts such scan reflectance profile, aperture, and lighting wavelength. ISO 15416:2000, in the informative Index E, defined Alphabetic conversions to the numeric grade using A through F letter grading. Letter grades conversion of A through F were assigned to the different numeric parameter grades, and the overall grade, e.g. C = range of 1.5 to 2.4
- A European Norm for barcode quality grading, EN 1635, was published in 1995, followed by ISO/IEC 15416 (1st edition) in 2000. ISO 15416 used concepts from both the ANSI and EN standards and is now viewed as the single global standard which should be used for the grading of 1D printed barcodes (except DPM)
- The concept of alphabetical letter grade conversion for the numeric grading has always been informative (optional) in ISO 15416
- LVS software for many years provided both the numeric grade and the optional Letter grade.

Summary of Changes with ISO 15416:2016

- Computation method for Defects has been modified
- Addition of an interpolation method for scoring of symbol contrast, modulation, and defects. A decimal grade (in steps of 0.1) is now associated with these parameters whereas previously an integer value was used. The purpose of the change was to reduce meaningless grade level fluctuations when small changes in measurements cause a grade to transition between integer grade levels defined in ISO 15416:2000. This new calculation method in some cases will result in a higher averaged score for the above parameters using this interpolation method compared with the method described in ISO 15416:2000.
- The new calculation method also results in a change in the numeric range of what was previously associated with a given alphabetical letter grade.
- The use of Letter grades going forward is being de-emphasized due to the lower precision associated with a letter grade compared with a decimal numeric grade.

Grade reporting v. 4.1.0j (LVS-9510 Example)



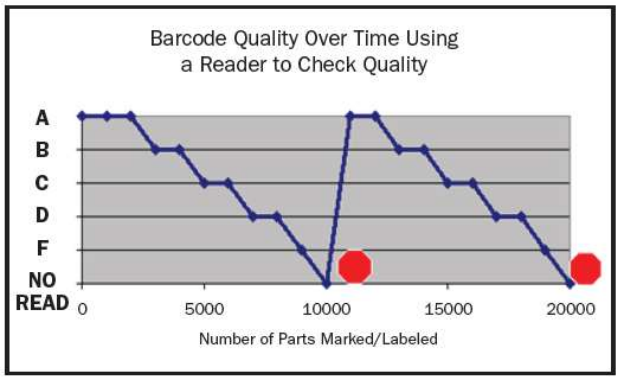
Grade Reporting v 4.3 (LVS-9580 Example)

FAQs

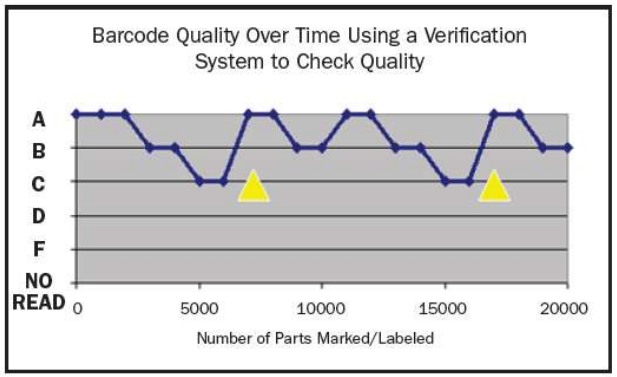
1. **Why are letter grades no longer being reported in version 4.3 of LVS-95xx software?** The letter grade is not used as part of the normative standards of ISO 15416, and the informative table D.1 that has a letter grade reference is not consistent with the 15416:2016 ranges of values for scan reflectance profile values shown in the standards.
2. **Will my barcode grade change when using v. 4.3 compared with earlier versions of LVS-95xx software?** Some barcodes will receive higher scores due to the changes in ISO 15416:2016.
3. **What if a customer has an internal specification that requires use of a letter grade?** A customer can continue to use version 4.1.0j or refer to the ISO 15416 informative table D.1 for a cross reference of letter grade with numeric range. Microscan recommends that customers follow the ISO 15416 normative standard that states the symbol grade shall be reported as a numeric value with decimal.
4. **Does GS1 require a numeric or an letter grade?** GS1 Tables define a 1.5 as the minimum required grade for most applications. A letter grade is not indicated in the GS1 Symbology Specification tables.
5. **How does this change impact 2D symbol grading?** ISO 15415 also defines that symbol grade shall be reported as a numeric value with decimal. For consistency purposes version 4.3 will also no longer report a letter grade for 2D symbols.
6. **Can an existing LVS-95xx be upgraded to v. 4.3 software and use the existing calibration card?** Yes. The formulas used for calculating calibration parameter values such as symbol contrast and modulation have not changed. Only the calculation of the numeric grades associated with the parameter values have changed.

Barcode Verification

- Verification is an objective, precise standardized measurement of the quality of a barcode symbol against a published specification.
- Barcode **reading** shows that a code is readable. Barcode **verification** shows how close a code is to the edge of readability.
- Verification is a predictor of how well a code will be able to be read throughout its life cycle.



Without verification, bad barcodes are not identified until they are unreadable. By the time a bad barcode is identified, several poor-quality barcodes may have already escaped down the line.

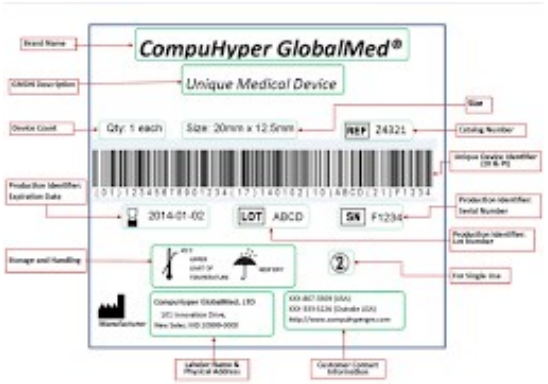


With verification, bad barcodes are prevented from being applied to the product, eliminating the chance for future failures.

Points of Use and Customer Types

When	Customer Type	User Type
During initial label design, typically done with Label Design/Management software such as Bartender, NiceLabel, Loftware, TekLynx, Innovatum, PrisymID, and many others	Manufacturer or Contract Manufacturer	Label Designer Label Compliance
During initial production qualification of a new product	Manufacturer or Contract Manufacturer	Manufacturing Engineer Quality Engineer
Beginning and/or end of a production run	Manufacturer or Contract Manufacturer	Operations
Receipt of outsourced labels	Manufacturer or Contract Manufacturer	Incoming receiving inspection
Receipt of finished goods from supplier	Manufacturer, Wholesaler, Retailer	Incoming receiving inspection
Re-labeling or kitting operation	Manufacturer, Wholesaler	Manufacturer, Wholesaler

Application Photos – Typical Printed Labels



Medical Device Labels

Pharma Packaging Labels

Automotive Parts Shipping Label

Appliance and CPG

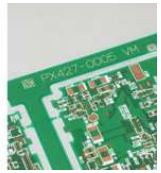
Application Photos – Typical Direct Part Marks

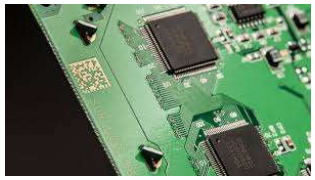
Medical Instruments

Medical Implants

Defense and Aerospace Parts

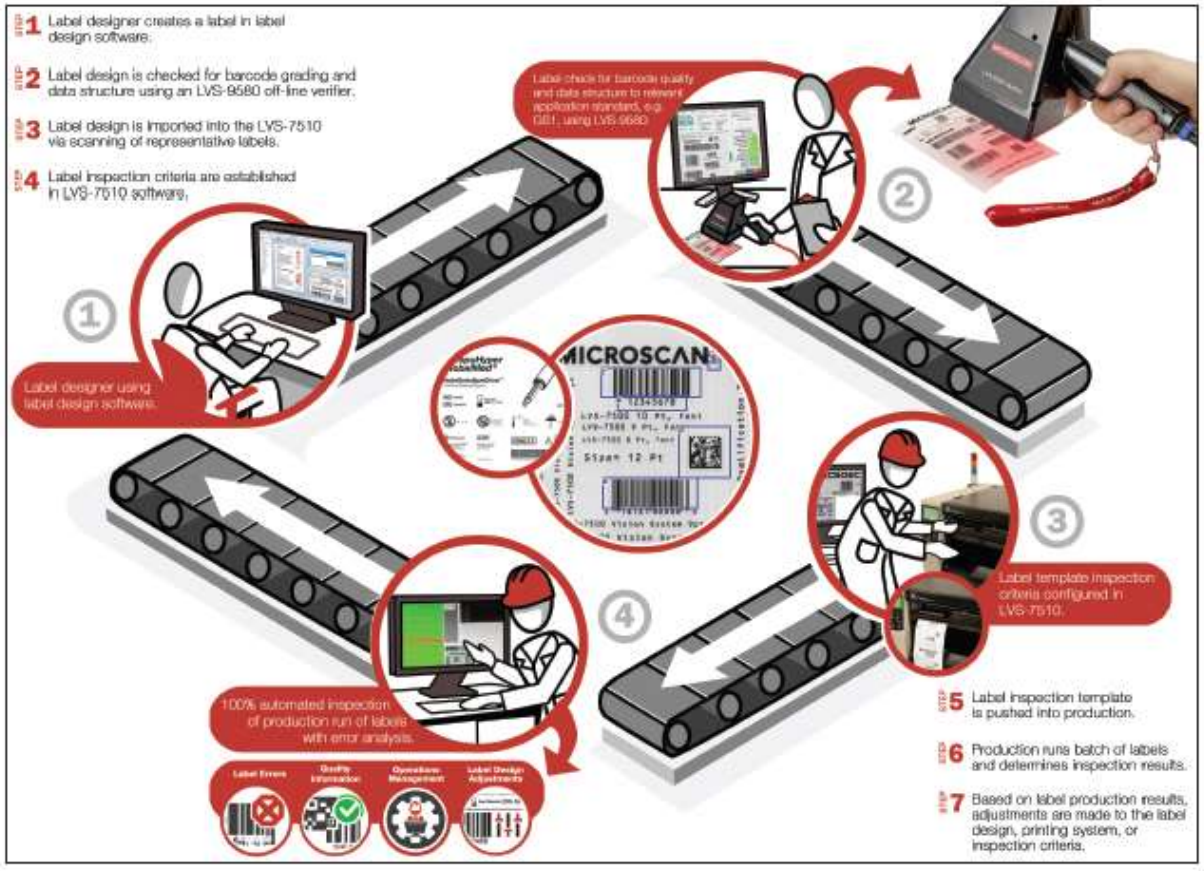
Automotive Parts





Electronic components and PCBs

Verification and Label Inspection Process



In-Line Label Inspection Opportunity

- Trend toward 100% verification to ensure label print quality on all labels, not only a random sample
- Provides automated inspection that integrates with the most popular thermal transfer label printers
- Supplements off-line verification which provides more detailed label inspection to a broad variety of application standards
- Microscan is expanding the LVS-75xx product offering, including established partnerships with leading label printer suppliers such as Zebra, Printronix, and SATO
- Industries to target is not limited to medical devices, but can be any manufacturer where accurate and high print quality is an important objective, or multiple bar codes exist on individual labels
- Anti-counterfeiting detection via label inspection of high value components in industries such as electronics and automotive are also an opportunity

LVS-7510

LVS-7500

In-Line vs. Off-Line Verification Systems

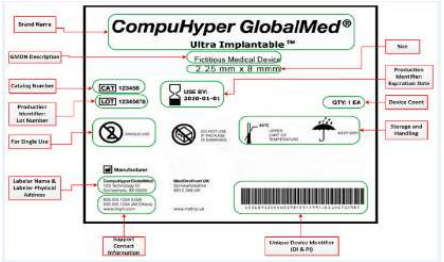
In-Line Verification	Off-Line Verification
100% label inspection, automated process	Used for random sampling, manual process
Requires direct integration with label printing equipment	Sampling interval defined by the labeler, but typically at beginning and end of label production run
Not possible for direct part marking	Off-line verifiers can inspect both labels and direct part marks

- FDA does not mandate how labels should be inspected
- Off-line inspection is an economical and easy way to begin an label verification program
- Combination of off-line and in-line inspection is possible and the recommended approach

Label Verification – FDA UDI (Unique Device ID) Mandate

Challenge:

- Adequately identify medical devices through manufacturing, distribution & use
- Labels include UDI in human & machine-readable form
- 1D/2D codes content & print quality inspection per GS1 & ISO specs

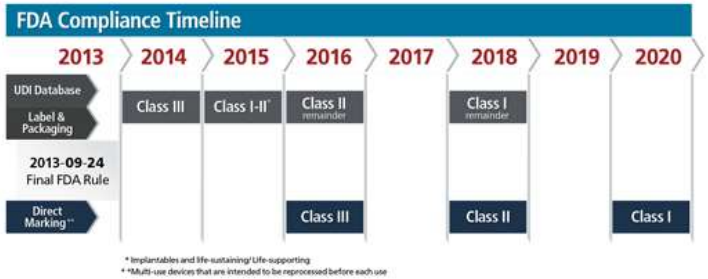


Solution:

- Microscan LVS Verifiers
  - Off-line (95xx line) with IQ/OQ for validated environments, 21 CFR Part 11 ready
  - In-Line (75xx)
  - USP: Off-/In-line consistency

Phased implementation

- (Sept, 2014 - 2020)
- Class II DPM 2018 deadline
- Long tail of smaller MDM companies still not compliant
- Extensions and pushouts by the FDA in early 2017



Direct Part Marking Applications

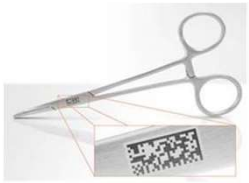


Image courtesy of Foba Laser

Medical Instruments

Image courtesy of Foba Laser

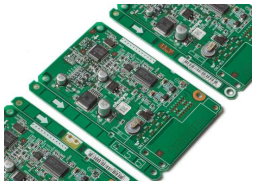
Medical Implants

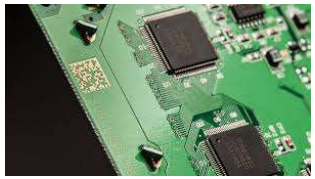
Laser marking technology now allows DataMatrix marks down to a 2 mil cell size to be applied, providing the ability to mark in a very small area of the instrument. GS1 Table 7 allows as small as 3.9 mil cell size (x-dimension).

Defense and Aerospace Parts

Automotive Parts

Image courtesy of Foba Laser and ZF Friedrichshafen





Electronic components and PCBs

Direct Part Marking in Medical Device Applications

- FDA UDI for Class 2 reprocessed (reusable) devices with direct marking is Sept. 24, 2018 deadline (Class III device deadline was Sep. 24, 2016)
- 21 CFR 801.45 requires a “UDI direct marking” on a device subject to UDI labeling, if the device is intended to be used more than once and intended to be reprocessed before each use, such as surgical instruments. In general, UDI direct marking should include both the DI and PI information
- FDA Guidance for UDI when using DPM issued in Nov. 2017
  - Devices already labeled and shipped are exempted for 3 years from deadline date of that class device. For Class 2 devices it means that existing direct marked items already in use are exempt until Sept. 24, 2019. Human readable info is **not** required in addition to the direct part mark.
  - FDA expects that records will indicate whether a device is directly marked and, if so, whether the direct mark DI is the same as or different from the primary DI.

Source: FDA Unique Device Identification: Direct Marking of Devices Guidance for Industry and Food and Drug Administration Staff, Nov. 17, 2017

GS1 Guidance for Marking Technology by Substrate Type

- GS1 provides direct marking guidance in the GS1 DataMatrix Guideline and Table 7 of the GS1 General Specifications
- FDA does not state marking method to use, mark must last the expected service life of the device
- GS1 refers to ISO/IEC TR 29158 as the relevant reference specification for direct part marking
- GS1 DataMatrix and GS1 QR are the only allowed symbologies for direct marking
- GS1 recommends that GTIN and serial number be included in the direct mark.

Table 4-1 Substrate / Marking technology table

Substrate / *Technology*	Paper	Corrugated fibreboard	Glass	Plastic	Metal
Laser Etch	For specific colours or specific finishing	For specific colours or specific finishing	Under certain conditions	If contrast can be achieved or specific finishing	Painted or oxidised
Thermal Transfer (on-demand)	Useful for adhesive labels	No	No	Plastic films	No
YAG/Fibre Laser	Coloured background or specific finishing	No	Yes	Yes	No
Ink Jet (on-demand)	Yes	No	No	No	No
Direct Part Marking	Film transfer	Film Transfer	No	Yes	Yes

Sources: GS1 2018 General Specification and GS1 DataMatrix Guideline, v. 2.5.1, January 2018

GS1 General Specification Table 7 Explanation

Figure 5.5.2.7.7-1. GS1 system symbol specification table 7

Symbol(s) specified	X-dimension mm (inches) Note 1 Note 4			Minimum symbol height for given X mm (inches)	Quiet Zone	Minimum quality specification	
	Minimum	Target	Maximum	For minimum, Target and Maximum X-dimension			
GS1 DataMatrix	0.254 (0.0100″)	0.300 (0.0118″)	0.615 (0.0242″)	Height is determined by X-dimension and data that is encoded	1X on all four sides	1.5/06/660 **Note 3**	For direct marking of items other than medical devices
GS1 QR Code	0.254 (0.0100″)	0.300 (0.0118″)	0.615 (0.0242″)	Height is determined by X-dimension and data that is encoded	4X on all four sides	1.5/06/660 **Note 3**	For direct marking of items other than medical devices
GS1 DataMatrix Ink Based direct part marking	0.254 (0.0100″)	0.300 (0.0118″)	0.615 (0.0242″)	Height is determined by X-dimension and data that is encoded	1X on all four sides	1.5/08/660 **Note 3**	For direct marking of medical devices such as small medical / surgical instruments
GS1 DataMatrix direct part marking - A **Note 2**	0.100 (0.0039″)	0.200 (0.0079″)	0.300 (0.0118″)	Height is determined by X-dimension and data that is encoded	1X on all four sides	DPM1.5/04-12/650/(45Q|30Q|30T|30S|90) **Note 5**	For direct marking of medical devices such as small medical / surgical instruments
GS1 DataMatrix direct part marking - B **Note 2**	0.200 (0.0079″)	0.300 (0.0118″)	0.495 (0.0195″)	Height is determined by X-dimension and data that is encoded	1X on all four sides	DPM1.5/08-20/650/(45Q|30Q|30T|30S|90) **Note 5**	For direct marking of small medical / surgical instruments

Table 7.1

Table 7.2

Table 7.3

Table 7.4

Minimum grade of 1.5 required

Cell size (x-dimension) of 3.9 mil allowed for laser etch marking

There are two basic types of non ink based direct part marks, those with “connected modules” in the “L” shaped finder pattern (GS1 DataMatrix direct part marking – A) created by DPM marking technologies such as laser or chemical etching and those with “non connected modules” in the “L” shaped finder pattern (GS1 DataMatrix direct part marking – B) created by DPM marking technologies such as dot peen

Direct Park Mark vs. Label Verification

- Direct Part Mark grading is “more lenient” than printed label verification to ISO 15415/15416, due to the challenging substrates and marking methods compared to label printing. Therefore the same mark will usually score higher when graded to ISO/IEC TR 29158 compared with ISO 15415/15416
- ISO/IEC TR 29158 allows for, but does not require, different types of lighting such as 30 degree angle and non-660nm red lighting which may provide a higher grade than traditional 45 degree 660nm red lighting used for printed label verification
- Those in the supply chain needing to read direct part marks must invest in a reader that is able to consistently read direct part marks – may require investment in new readers with advanced decoding algorithms for “difficult to read codes”
- The same best practices used for printed barcode design and production should be followed when working with direct part marks
    - Use label design/management software that properly encodes GS1 data structure and GS1 General Specification requirements for barcode size, data contents, and symbology type
    - Pay attention to factors impacting readability such as cell contrast, quiet zones, substrate reflectance, etc.

Use Case –Label Inspection, Pharmaceutical

Challenge:

- Comply with FDA Drug Supply Chain Security Act (DSCSA) which requires a DataMatrix barcode for prescription pharmaceutical tracking / “serialization”
- Verify barcode quality and content on product and case labels per GS1 & ISO specs
- Labels include human & machine-readable information: National Drug Code, serial #, lot #, and expiration date
- 1D/2D codes content & print quality inspection per GS1 & ISO specs
- Additionally, inspection of label contents required to meet 21 CFR Part 211
  - Manual inspection of labels is costly and error prone
- Contract manufacturers and those exporting to U.S. also impacted

Solution:

- Microscan LVS Verifiers
  - Off-line (95xx line) with IQ/OQ for validated environments, 21 CFR Part 11 ready
  - In-Line (75xx)
  - USP: Off-/In-line consistency

Phased implementation

- 2017 for manufacturers
- 2018 for re-packagers

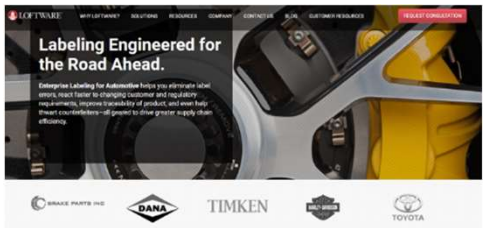
Use Case – Automotive Parts

Challenge:

- Comply with AIAG, VDA, or Odette labeling requirements including barcode grade. Those standards reference use of ISO 15415/15416 grading
  - Avoid supply chain or manufacturing operation disruptions by only receiving parts that can be read by barcode readers in their operations
- Help prevent possibility of counterfeit parts from entering the supply chain
  - Ensure that only parts with valid serial #'s or other unique identifiers are used

Solution:

- Microscan LVS Verifiers
  - Off-line (95xx line) including both label and direct part mark (dpm) applications
  - In-Line (75xx) with inspection of serial #s or other unique identifiers on the labels



Omron Microscan Advantage:

- Offer both inline and offline solutions based on problem to be solved
- Handheld verifier for both printed labels and direct part marks

Use Case – Appliance & Consumer Packaged Goods

Challenge:

- Major retailers issue fines and supplier rating negatively impacted for products received with unreadable or incorrect labels
- Rejected product can lead to shortages and costly returns
- Help prevent possibility of counterfeit parts from entering the supply chain
  - Ensure that only parts with valid serial #'s or other unique identifiers are used

Solution:

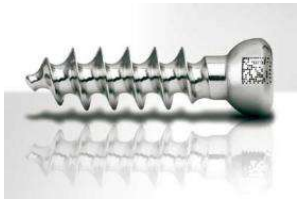
- Primary target customer is manufacturer, secondary is retailer or 3rd party logistics operations
- Microscan LVS Verifiers
  - Off-line (95xx line) including both label and direct part mark (dpm) applications
  - In-Line (75xx) with inspection of serial #s or other unique identifiers on the labels

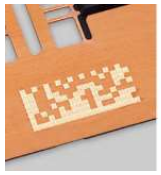
Omron Microscan Advantage:

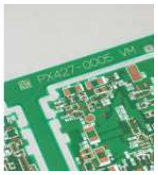
- Offer both inline and offline solutions based on problem to be solved
- 100% in-line inspection avoids potential for gaps and re-work

Direct Part Marking (DPM) Applications

- Medical Device and Implants / Typically laser etch or dot peen
  - FDA UDI for Class 2 reprocessed (reusable) devices with DPM, Sept. 2018
    - GS1 Table 7 defines marking requirements; GS1 DataMatrix or GS1 QR
  - EU Medical Device Regulations (MDR) and UK NHS UDI Compliance
    - Sept 2019 for UK NHS Class 3 DPM devices in UK, 2022 for MDR
  - See Microscan,com/Resources whitepapers for further information
- "Traditional" Markets
  - Automotive
  - Aerospace/Defense
  - Electronics
- Emerging/New; QR DPM for food packaging

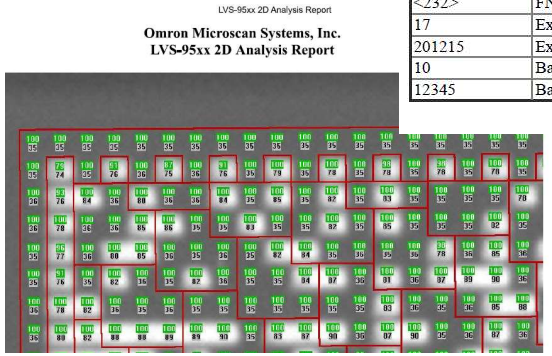






Excerpt of Typical Grading Report

- Use of DPM Application Standard indicated by DPM prefix in reported summary grade
- 2D analysis allows for mark troubleshooting and adjustment of marking conditions
- Data structure analysis shows detail such as GS1 Application Identifier format compliance



2D Structure		
Embedded data	Description	Value
<232>	FNC1	
01	Global Trade Item Number (GTIN)	(01)
00350458251128	Global Trade Item Number (GTIN)	00350458251128
21	Serial Number	(21)
100019021833	Serial Number	100019021833
<232>	FNC1	
17	Expiration Date (YYMMDD)	(17)
201215	Expiration Date (YYMMDD)	201215
10	Batch or Lot Number	(10)
12345	Batch or Lot Number	12345

Omron Microscan Systems, Inc.
LVS-95xx Verification Report

Overall: DPM2.0/08/660/D

Operator signature

Second signature

2D	
Symbology	Data Matrix
Decoded text	0109504000059101105 63GS1@111180330
Cell size	9.4 mils
Decode	PASS
Cell contrast	4.0 54%
Cell modulation	4.0
Axial nonuniformity	4.0 1%
Grid nonuniformity	4.0 22%
Unused EC	4.0 100%
Fixed pattern damage	2.0
L1 (left of L finder)	3.0
L2 (bottom of L finder)	2.0
QZL1 (left quiet zone)	4.0
QZL2 (bottom quiet zone)	4.0
CTR (clock track regularity)	4.0

Other information	
Symbol Letter Grade	C
ReportID	110
Operator	admin (LVS Administrator)
Application standard	DPM (ISO/IEC TR29158)
Effective aperture	Reference number 08 (7.62 mil)
Lighting	660/D
Date and time	06-Apr-2018 09:36 local; 06-Apr-2018 16:36 GMT
Time zone	GMT -7
Sector size	0.26" by 0.24"
Last calibration	30-Aug-2017 07:43 local; 30-Aug-2017 14:43 GMT
Field of view	1.79" (camera is 1536x1536 pixels)
Serial numbers	Unit: 1719018, 9585
Software product and version	LVS-95xx Version 4.4.0.1007

Omron Strengths in Print Quality Inspection

- Currently selling verification products to 90+% of top 25 global medical device and pharma manufacturers
- ISO 15415/15416 barcode verification for most relevant barcode symbologies and application standards (GS1, HIBC, etc.)
  - GS1 U.S. Member and Solution Partner
- Only supplier of integrated into the printer solution that verifies barcode quality and performs print quality inspection to detect all label defects
  - Integrated solutions with Zebra, Printronix
  - External solutions for SATO ,Honeywell, Toshiba, CAB, others
- Global sales and support, both via factory representatives in all regions, as well trained Partner Network in Americas, Europe, APAC
- Engineering team actively working on next generation print quality inspection products