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Direct Marking for UDI Compliance

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Direct Marking for UDI Compliance

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A Certified GS1 Standards Professional, Barbie LaBine has provided training to global medical device manufacturers on UDI compliance and UDI code and label verification for the past two years. LaBine comes to Microscan from the industry-leading barcode verification systems manufacturer Label Vision Systems, Inc., (acquired by Microscan in August 2015), and now offers a range of training on LVS® brand barcode verification and other Microscan technology and applications.

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FDA UDI Has Arrived…

- What is UDI?
  - Unique Device Identification system.
  - Dictates a standardized method of coding **medical devices** with key identifying information.
  - Medical devices sold in the United States must be logged in a **Global Unique Device Identification Database (GUDID)** for consistency and transparency.
  - Enables **traceability** of devices throughout manufacture, distribution, and use.

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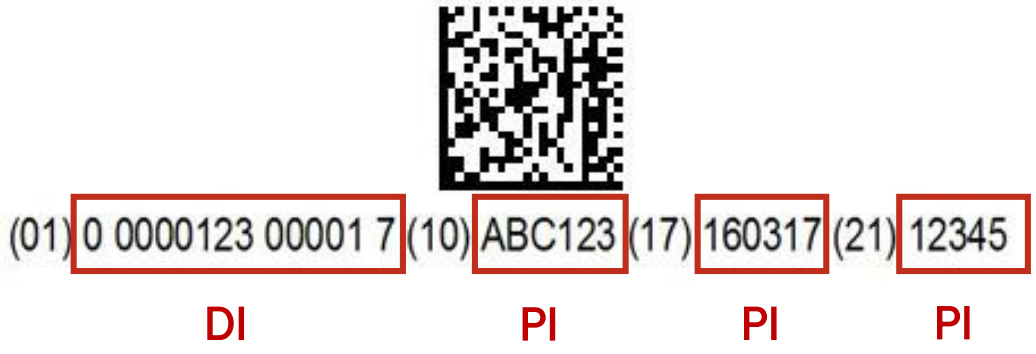
What are the parts of a UDI?

A UDI code consists of two parts:

- **Device Identifier (DI)** – a mandatory, fixed portion that identifies the labeler and the specific version or model of a device.

- **Production Identifier (PI)** – a conditional, variable portion of a UDI.



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Device Identifiers (DI)

Must be issued by an FDA-accredited **issuing agency**:

- GS1
- Health Industry Business Communications Council (HIBCC)
- ICCBBA or ISBT 128

You must submit every unique DI to the GUDID for documentation and compliance!

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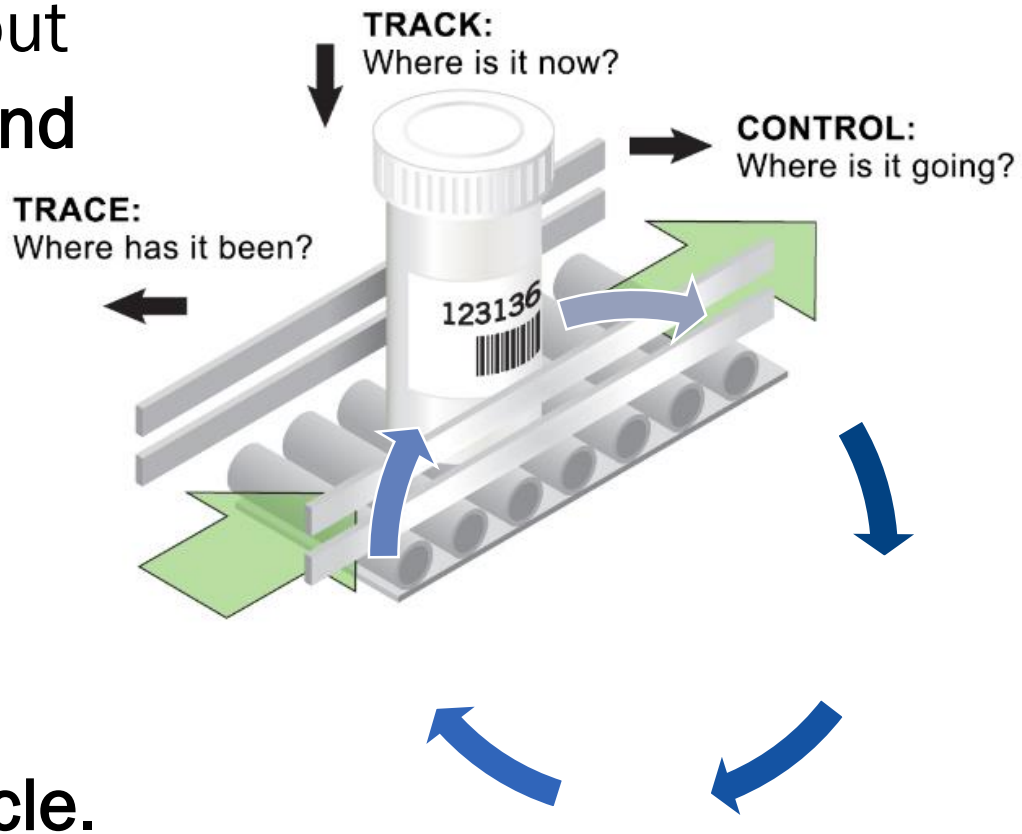
How long does a device need to bear a UDI?

- UDI must enable identification of medical devices throughout **manufacture, distribution, and use…**
  - Regardless of:
    - ✓ Handling
    - ✓ Reprocessing
    - ✓ Reuse
- UDI protects consumers throughout the **device lifecycle.**



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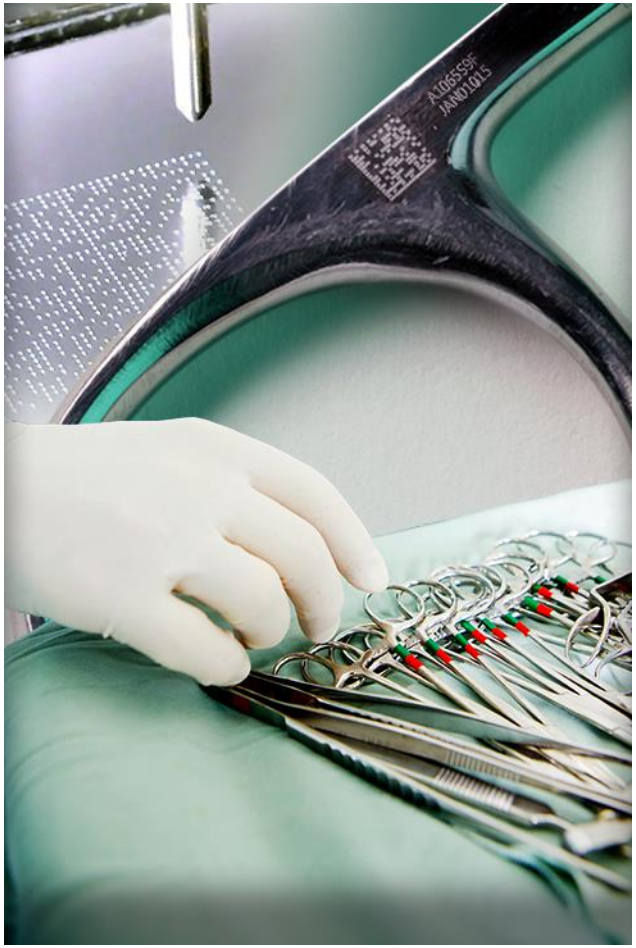
UDI: Not Just for Your Packaging Anymore…

- Packaging and labeling may not stand the test of time…
- According to the FDA:

  *"A device that must bear a unique device identifier (UDI) on its label must also bear a **permanent marking** providing the UDI **on the device itself** if the device is intended to be used more than once and intended to be reprocessed before each use."*
  --- 21 CFR 801.45

- **Permanent UDI marks** ensure device information is always available, even when labels and packaging aren't.



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Why do I need a permanent mark when there is already a UDI on my label?

- UDI is the only method of effectively **tracing** a device to know:
  - Where the device came from
  - Where the device is now
  - Where the device will be applied

- UDI ensures **adverse events** (like product recalls) can be addressed quickly with minimal risk to the consumer.

Remember: A direct part mark is typically the only identifier of your device after it is taken out of the package.

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What are the deadlines to implement permanent UDI?

For permanent UDI marks, GUDID data must be submitted to FDA with UDI permanently affixed to the device by:

September 24…

- 2015 – Implantable, Life-Supporting, and Life-Sustaining Devices
- **2016 – Class III Devices**
- 2018 – Class II Devices
- 2020 – Class I and All Other Devices

For complete FDA UDI Compliance Dates, visit:
www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm

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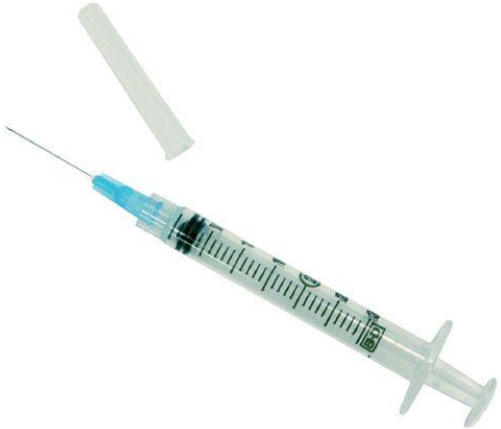
How do I know the class of my device?

Class I

Low-risk devices requiring little regulatory control, like dental floss and gauze bandages.

Class II



Higher-risk devices like syringes, requiring regulatory controls to ensure safety and effectiveness.

Class III

Highest-risk devices, approved by FDA before release, like replacement heart valves and other implantable devices.

Visit the FDA's classification database to look up your device:
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm

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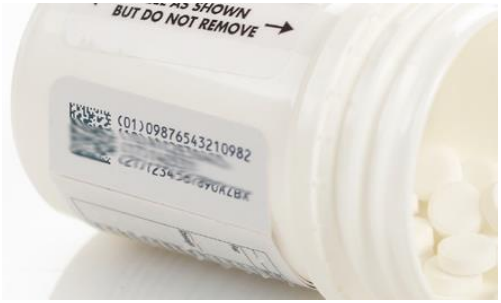
What is “permanent” or “direct” marking?

- **Direct part marking (DPM)** is a process of abrading a code directly onto a device surface.
- Unlike labels, DPM codes are not easily:
  - Discarded
  - Obscured
  - Wiped off
  - Degraded
- Ensures the availability of encoded information **throughout device lifecycle.**

Not Permanent: Inkjet Code on Label
Easily Smudged



Permanent: Laser-etched Code
Withstands Wear

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What is “reprocessing”?

- Any process used to render a medical device fit for subsequent use.
- Used to remove blood, tissue, biological debris, and other contaminants.
- Generally intended for devices that have repeated use on or by more than a single patient.

Note: Devices used only once before disposal, or used multiple times by the **same** patient, do **not** require permanent UDI marks.

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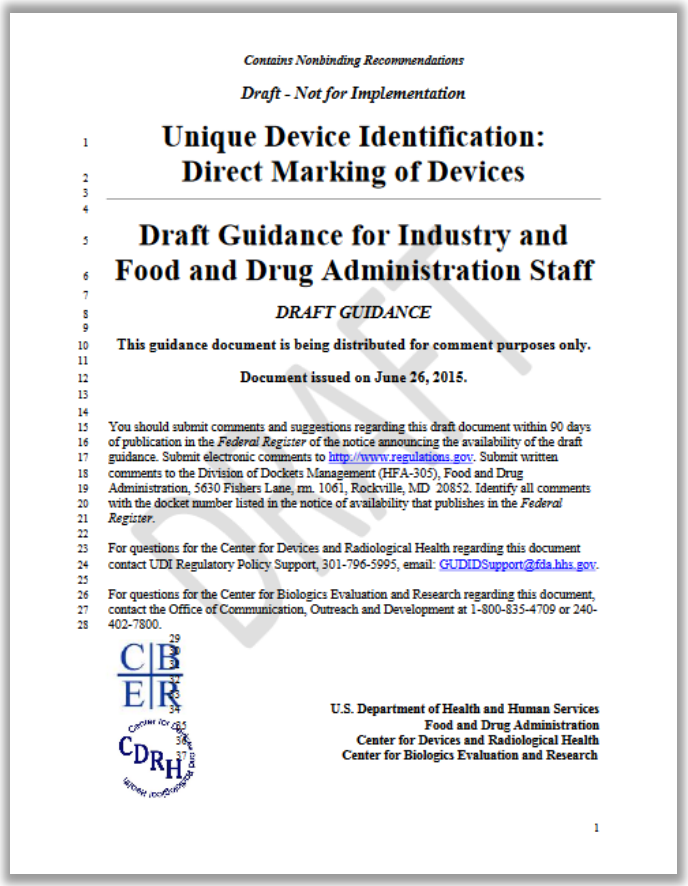
What are the FDA requirements for permanent marks?

- FDA has not finalized a regulation for permanent UDI…
  - We know what data is required to be encoded in a UDI mark.
  - But we don't know exactly how a UDI should be marked, read, and verified in every situation.
- However, FDA has supplied **draft guidance** for direct marking:

  www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM452262.pdf



Contains Nonbinding Recommendations

Draft - Not for Implementation

Unique Device Identification: Direct Marking of Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on June 26, 2015.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions for the Center for Devices and Radiological Health regarding this document contact UDI Regulatory Policy Support, 301-796-5995, email: GUDIDSupport@fda.hhs.gov.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

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DRAFT

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What part of the UDI must be marked on a device?

- Like UDI on labels and packaging, a permanent UDI mark must contain all information required by the FDA:
  - **Device Identifier (DI)** – A mandatory, fixed portion that identifies the labeler and the specific version or model of a device.
    - ✓ The Device Identifier must be issued by an FDA-accredited issuing agency and submitted to the GUDID.
  - **Production Identifier (PI)** – A conditional, variable portion of a UDI.
    - ✓ Production Identifiers do not need to be issued or submitted and are not required to be encoded in direct part marks on Class I devices.

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What is the required format of a UDI mark?

- Unlike UDI on labels and packaging, a permanent UDI mark may be provided in **either**:
  - **Human-readable**: Easily-legible, plain-text format.
  - **Machine-readable**: Able to be interpreted by automatic identification and data capture (AIDC) technology:
    - ✓ Barcode readers
    - ✓ Machine vision systems
    - ✓ RFID equipment

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Does the UDI marked on my device need to be the same as the UDI on my label?

- NO
- You can choose to use the same UDI, or create a new UDI to distinguish your “packaged” device from your “unpackaged” device.

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What if I choose to mark a new UDI on my device?

- You must be issued a new DI from your issuing agency.
  - Request a new DI for your marked UDI
  - Submit your new DI to the GUDID
  - *Each unique DI issued for a device **must** be submitted to the GUDID for FDA UDI documentation and compliance!*

- **Primary DI:** The DI issued for your label or packaging.

- **Direct-mark DI (DM-DI):** The DI issued for your direct mark.

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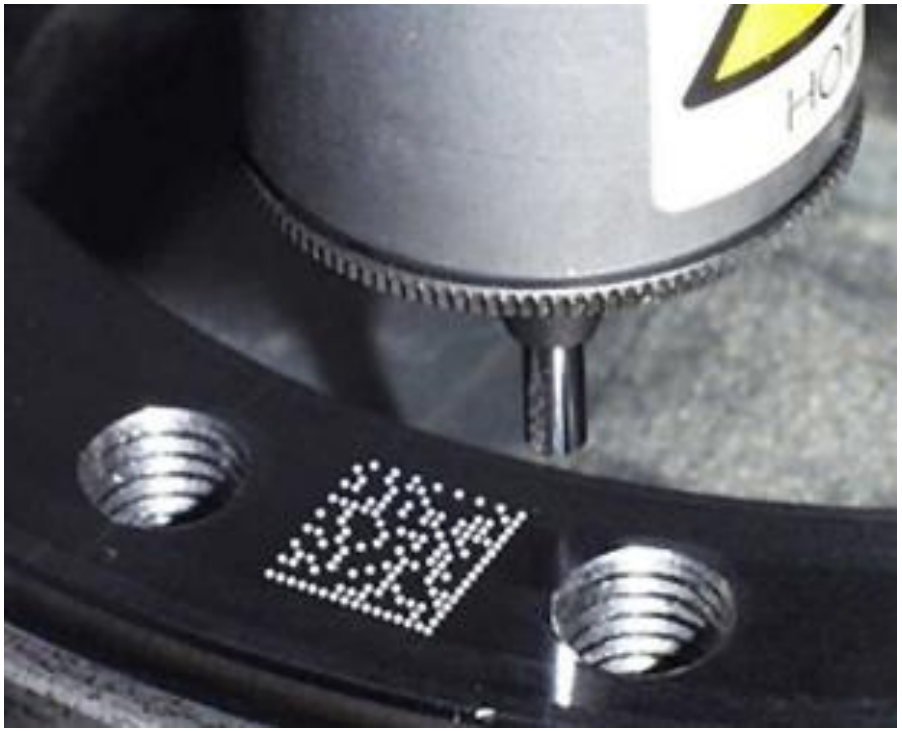
If the UDI on my label changes, does the permanent UDI mark need to be replaced?

- NO
- Once a device has been marked with a UDI code and the code has been verified to be in compliance with UDI direct marking requirements, there is no FDA mandate to replace the UDI mark.



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Best Practices for UDI Marking

- FDA requirements have not been finalized
- But UDI marking deadlines are on the horizon…
- Best practices for UDI marking:

1. Choose the best marking method for your device.

2. Choose a data carrier that suits your marking method and size of your device.

3. Choose a process for verifying UDI mark accuracy and quality, based on currently-accepted quality parameters.

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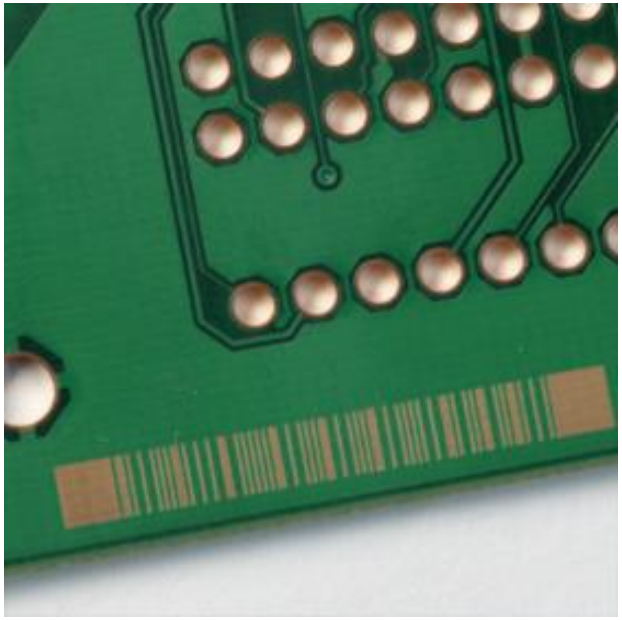
How should I apply a direct part mark?

- A direct part mark is made by altering a device surface to expose a pattern in a different **reflectance** or **color**.

- There are a variety of permanent direct part marking methods.
  - Most common methods:
    - ✓ Laser etch
    - ✓ Electrochemical etch
    - ✓ Dot peen



Laser etching reveals this linear barcode by removing the green surface of a PCB and exposing the copper sub-layer.

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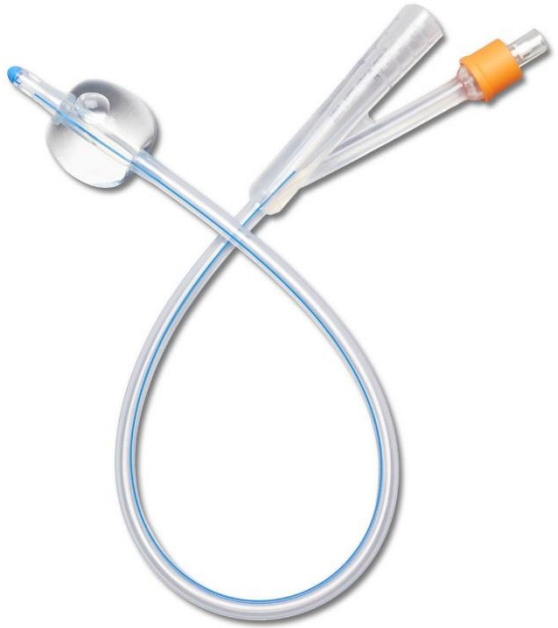
Which marking method should I choose?

- Choose the best marking method for your device, based on:
  - **Function:** Non-intrusive marking methods should be used for balloons, catheters, or high-pressure and high-stress systems.
    - ✓ Etching may be best in these cases.



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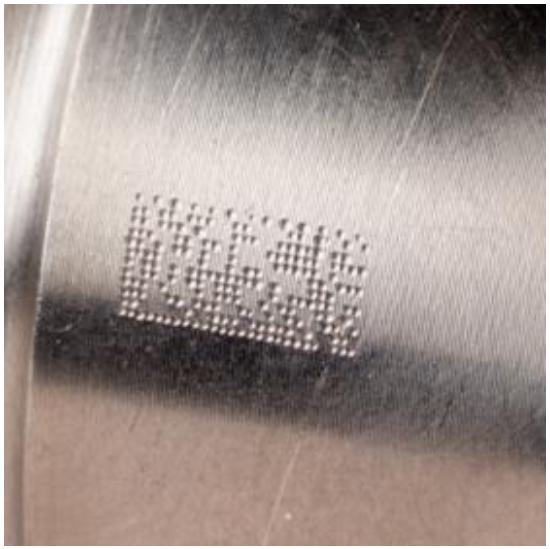
Which marking method should I choose?

- Choose the best marking method for your device, based on:
  - **Geometry**: It is more difficult to mark a curved surface than a flat surface.
    - ✓ Laser may be best in these cases.



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Which marking method should I choose?

- Choose the best marking method for your device, based on:
  - **Device size:** Small devices require small marks. In most cases, when a 2D symbol (like QR Code or Data Matrix) is used, the size of the device is irrelevant (codes can be reduced to below 1/4 inch square).
    - ✓ If device size dictates symbol type, choose the best marking method for the symbol.

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Which marking method should I choose?

- Choose the best marking method for your device, based on:
  - **Application environment / lifespan:**
    A mark must last as long as the device is used, withstanding the same environmental conditions.
    - ✓ Dot peen is the most hardy marking method.

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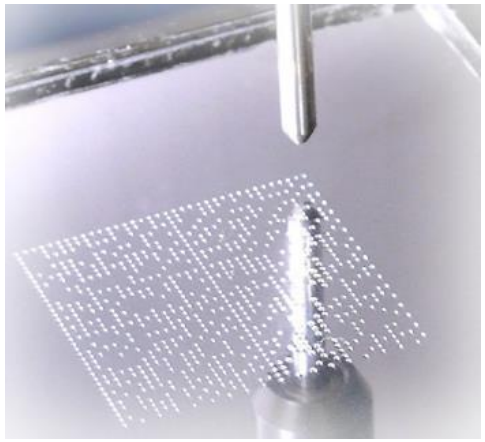
Which marking method should I choose?

- Choose the best marking method for your device, based on:
  - **Surface Glossiness**: Highly-polished metal surfaces are highly-reflective causing glare that can “blind” the reader or verifier.
    - ✓Glossy surfaces should be lightly textured to reduce glare prior to marking. Texture should extend 1 symbol-width beyond the marked area.



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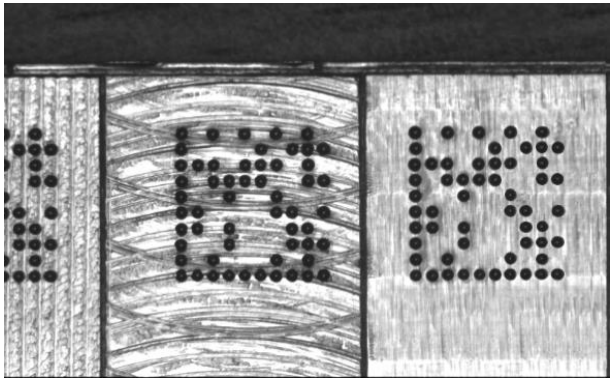
Which marking method should I choose?

- Choose the best marking method for your device, based on:
  - **Surface Roughness**: Surface roughness should be limited to 8 micro-inches for dot peen marking.
    - ✓Laser systems are ideal for rougher surfaces because they first burn a "quiet zone" (smooth, blank area on the surface of the device where the symbol will be marked).



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Which marking method should I choose?

- Choose the best marking method for your device, based on:
  - **Surface Thickness**: Surface thickness must be taken into account to prevent deformation or excessive weakening of the device.
    - ✓The marking depth should not exceed 1/10 the thickness of the device to avoid compromising the safety of the device.

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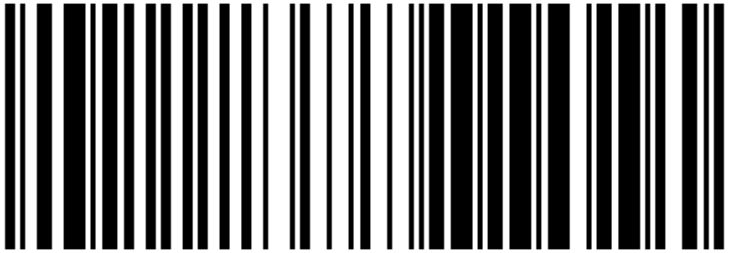
Which “data carrier” is recommended for UDI DPM?

- A “data carrier” is a symbol that encodes UDI information.

Data Matrix



Code 128

Databar Stacked, Omni-directional

Code 128 CC/A

UPC-A

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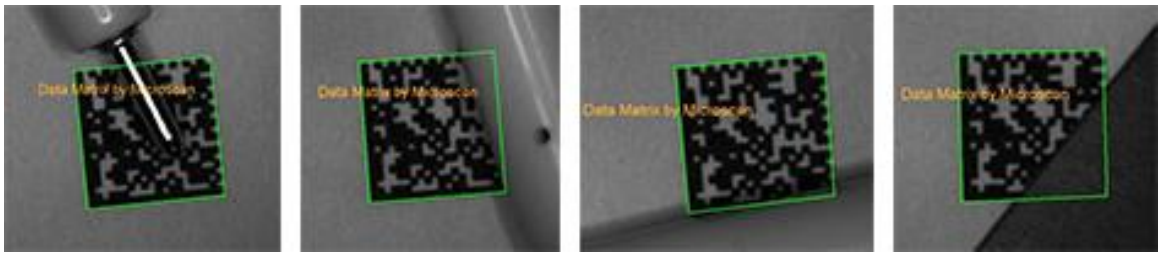
Which “data carrier” is recommended for UDI DPM?

- Choose the best data carrier for your marking method and size of your device.
- Two-dimensional symbols such as Data Matrix are used most commonly for DPM due to:
  - Small size
  - Data capacity
  - Error correction
    - ✓ Read in low contrast
    - ✓ Read in any orientation
    - ✓ Read despite up to 20% obstruction
  - Ability to be produced by a variety of marking methods



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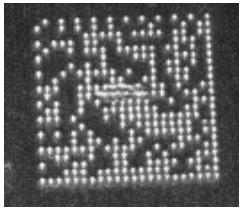
How do I make sure my mark is UDI compliant?

- There are many devices and possible marking methods…
- Subtle inconsistencies may render a UDI unreadable.
  - A UDI mark must be **readable** and **decipherable** throughout the device lifecycle in order to remain compliant!

- **Verify Readability**
  Long-term readability requires **verification** of symbol **quality**.



Is the mark high-quality?

- **Validate Decipherability**
  Decipherability requires **validation** of the **accuracy** of the encoded information in the symbol.

(01) 0 0000123 00001 7 (10) ABC123 (17) 040104 (21) 12345

Does the symbol have correct data in the correct format (data structure)?

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Can I use a barcode reader to check UDI compliance?

- NO
- Barcode readers and scanners **cannot** be used to verify or validate a symbol. Barcode readers only:
  - Recognize the barcode symbology (UPC, Data Matrix, QR Code, etc.)
  - Extract the content of the symbol (decode it)
  - Transmit data to a connected device (communicate what it decoded)

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Can I use a barcode reader to check UDI compliance?

Barcode readers do not assess the **accuracy** of encoded data or the **quality** of the symbol to ensure long-term readability across various decoding equipment.

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Readability Does Not Equal Quality

READ

Barcode readers designed for advanced decoding may be able to read a low-quality symbol. But not everyone has an advanced reader.

VERIFY

Barcode verifiers measure physical properties of a symbol against quality parameters to ensure that symbols can be read by any decoding equipment.

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Validating UDI Data Accuracy

- **Validation** is the process of checking that the proper data has been encoded within a barcode.
  - Is data in the correct format?
  - Is it compliant with issuing agency specifications?
    - ✓GS1
    - ✓HIBCC
    - ✓ICCBBA
- Barcode Verification Systems can check if the encoded data is structured according to standard requirements.

(01) 0 0000123 00001 7 (10) ABC123 (17) 040104 (21) 12345

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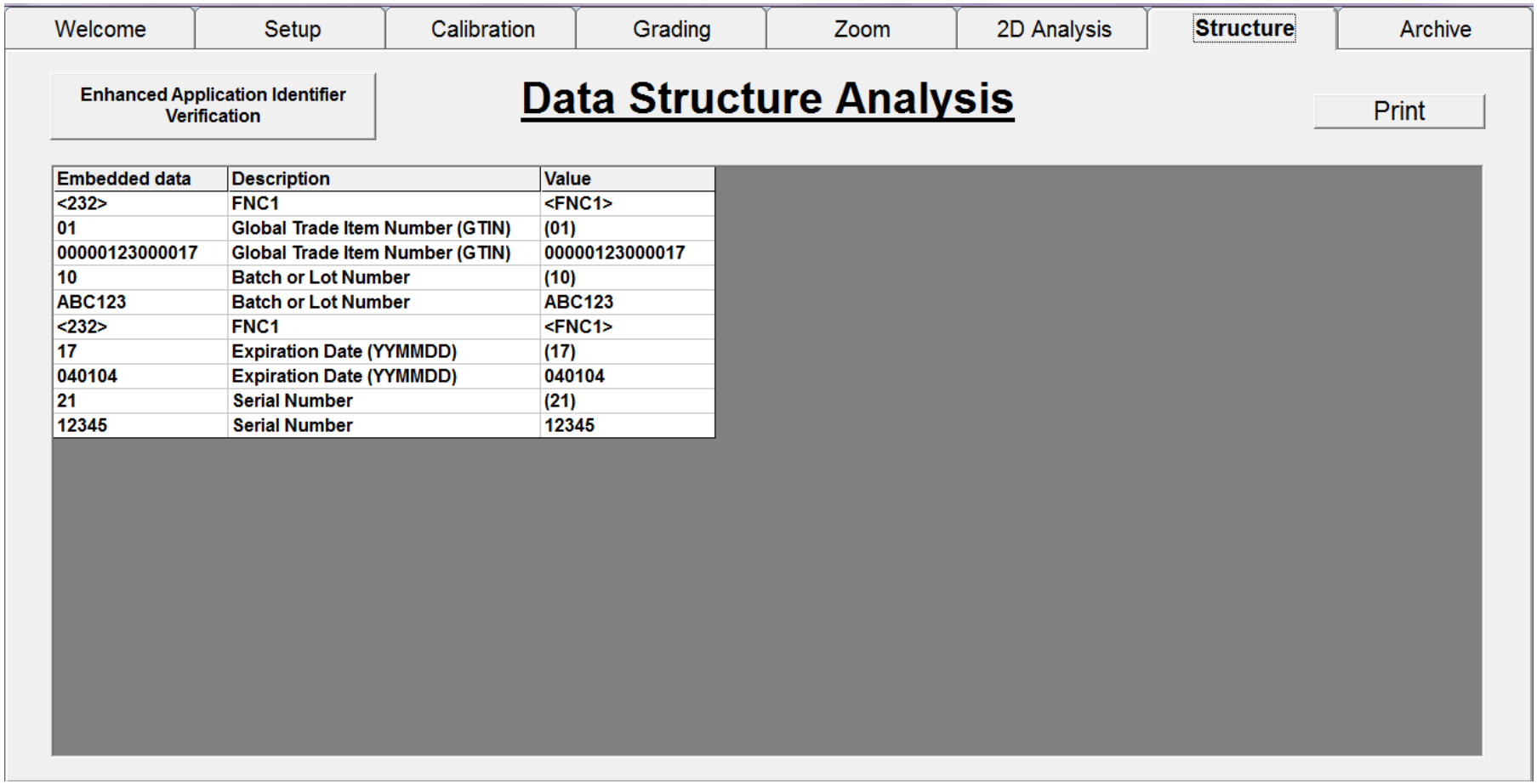
Example: GS1 Data Structure Analysis



Embedded data	Description	Value
<232>	FNC1	<FNC1>
01	Global Trade Item Number (GTIN)	(01)
00000123000017	Global Trade Item Number (GTIN)	00000123000017
10	Batch or Lot Number	(10)
ABC123	Batch or Lot Number	ABC123
<232>	FNC1	<FNC1>
17	Expiration Date (YYMMDD)	(17)
040104	Expiration Date (YYMMDD)	040104
21	Serial Number	(21)
12345	Serial Number	12345

Microscan LVS-95XX Software Interface

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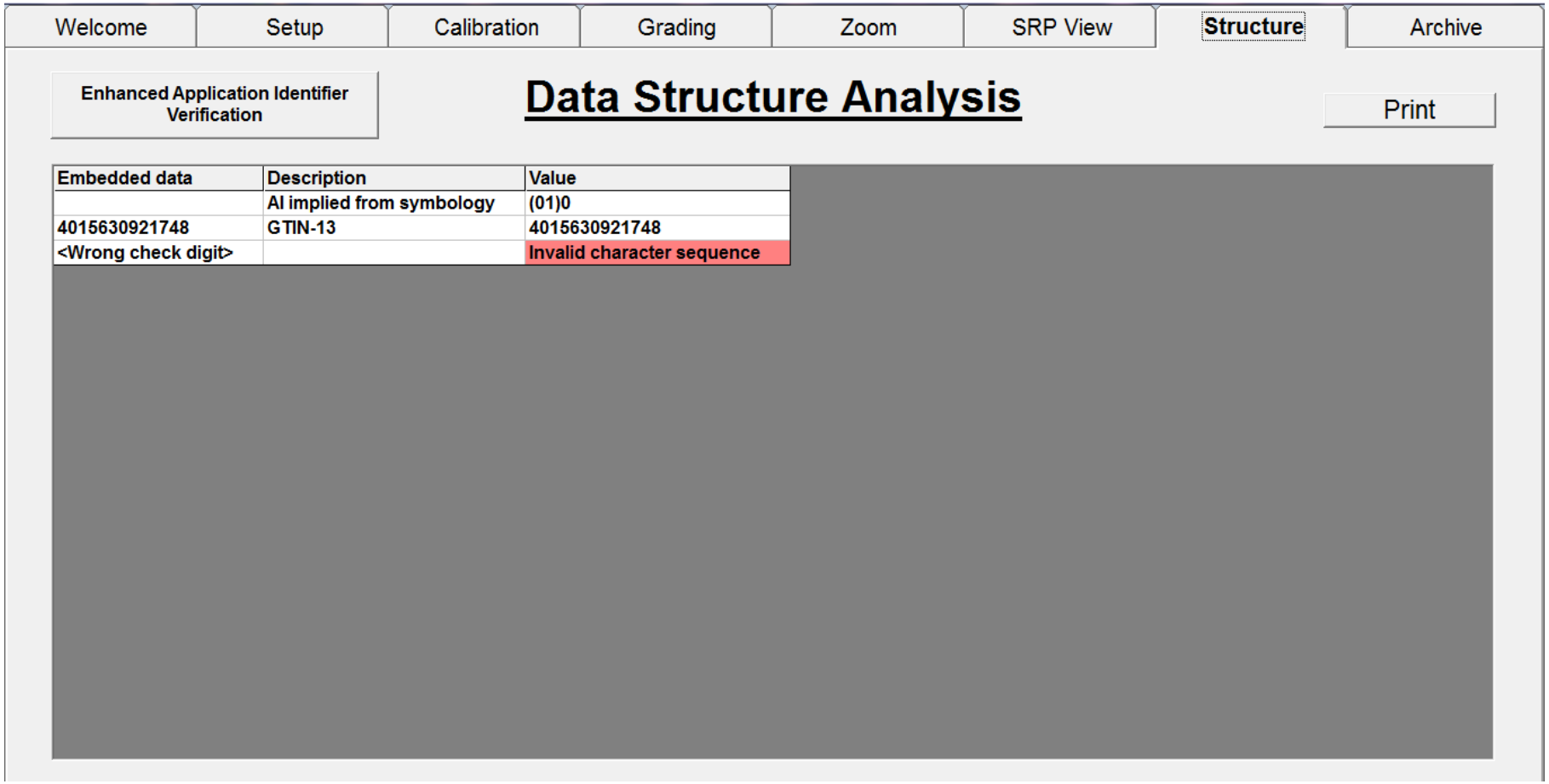
Error Found in GS1 Data Structure



Microscan LVS-95XX Software Interface

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How can you catch a GS1 data structure error?

- Visually: NO
  - You can't tell by looking at a symbol that it contains an error, since you can't visually extract encoded data from a symbol.
- Barcode Reader: NO
  - A barcode reader just tells you what data it finds in the symbol without making a determination about data accuracy.
- Barcode Verifier: YES
  - A barcode verifier uses issuing agency specifications to validate that the data in a symbol is accurate and properly-formatted according to the specifications.

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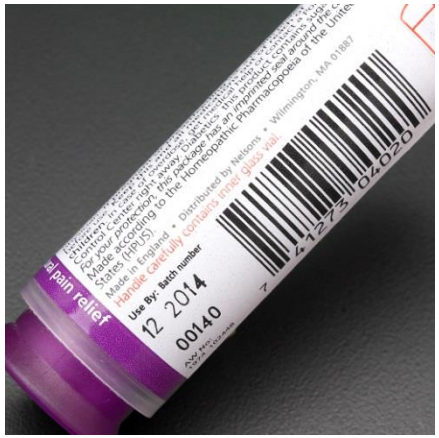
Verifying UDI Mark Quality

- Verification is the evaluation of **physical properties** of a mark against **accepted barcode quality standards.**
  - ISO (International Standards Organization) provides standard parameters for grading the quality of:

Printed Linear (1D) Barcodes
Standard: **ISO/IEC 15416**



Printed 2D Symbols
Standard: **ISO/IEC 15415**

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What about direct part marks?

- The appearance of direct part marks varies more than printed marks due to:
  - Marking method
  - Surface reflectiveness
  - Surface color
  - Surface texture
  - Surface curvature

- Each combination of marking method and surface features produces unique reflections of **light.**
- Reflections can cause poor contrast and make marks hard for readers and verifiers to “see” against the device surface.

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What makes DPM reading and verification so difficult?

- Example: Taking a photo through a window.
  - If your camera has the flash on, what does your photo look like?
  - If there is a light on behind you causing glare on the window, at what angle can you take the photo to alleviate the glare?

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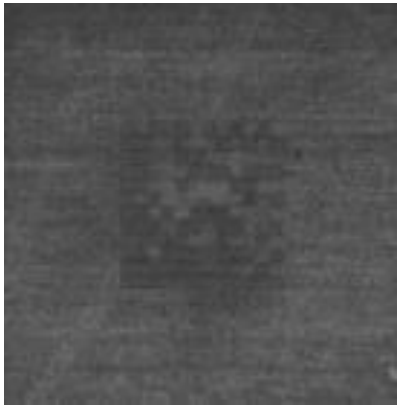
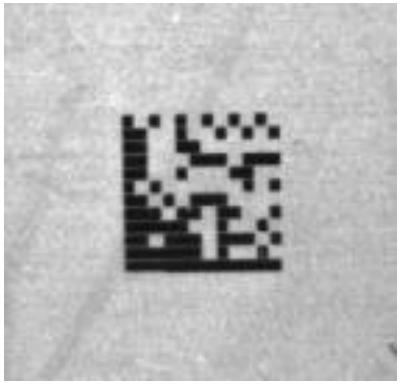
What makes DPM reading and verification so difficult?

- The same goes for reading and verifying marks on various surfaces.
- By positioning a verifier at a slightly different angle, or applying different geometries of lighting, the mark appears in different clarity to the verifier. Reflected light either:
  1. Obscures the mark's features from the verifier; or
  2. Emphasizes the details of the mark in high contrast.



Ambient Lighting



Appropriate Lighting Geometry

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Example: Specular Reflection

Like taking a photo through a window with your flash on, specular reflections of light bouncing back from the surface of a device can “blind” the verifier.

Can you spot the Data Matrix symbol on this reflective part?

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Why is UDI mark quality so important?

The FDA UDI rule relies on 100% traceability to ensure actions can be taken based on device types, origins, and statuses.

Traceability is an unbroken record of a device lifecycle, from creation to consumption.

To ensure traceability, it is critical that your device complies with standard UDI requirements.

You must verify that data on your device can be interpreted and transmitted accurately as devices move through the supply chain.

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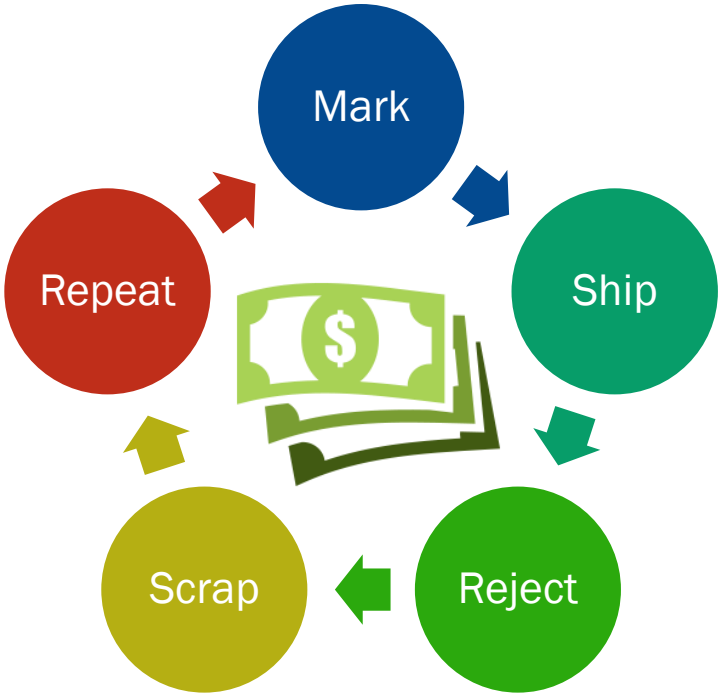
The Importance of DPM Verification – Cost of Errors

- Direct part marks are applied **permanently** to the surface of a device.
- If an error is made in the data and it is not identified prior to marking, it is not just a matter of relabeling with DPM.
- Errors in permanent marks mean:
  - Large rework projects
  - Lengthy manufacturing downtime
  - Scrapped materials



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The Importance of DPM Verification – Cost of Errors

- Beyond operational costs, noncompliance may result in:
  - Fees
  - Seizures
  - Injunction
  - Civil or criminal penalties
- Verification provides both cost-savings and peace of mind that all UDI marks are **quality-made** and **comply** with the specifications of your issuing agency.

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How do you verify the quality of a direct part mark?

- FDA guidance is working to define the best method to cover the range of variable DPM factors:
  - Marking methods
  - Device types
  - Reading and verifying environments
- Barcode quality standards and verification parameters will depend on what the FDA decides
- Until then, ISO has provided a Technical Report outlining suggested barcode verification parameters for DPM symbols:

ISO/IEC TR 29158

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ISO/IEC TR 29158

- A **Technical Report** (not quite a standard)
- Poised to be **the** verification standard for UDI permanent marks and DPM codes.
- Based on standards for verifying printed codes:
  - Linear Barcodes (ISO/IEC 15416)
  - 2D Symbols (ISO/IEC 15415)
- But ISO/IEC TR 29158 has specific requirements for **lighting.**

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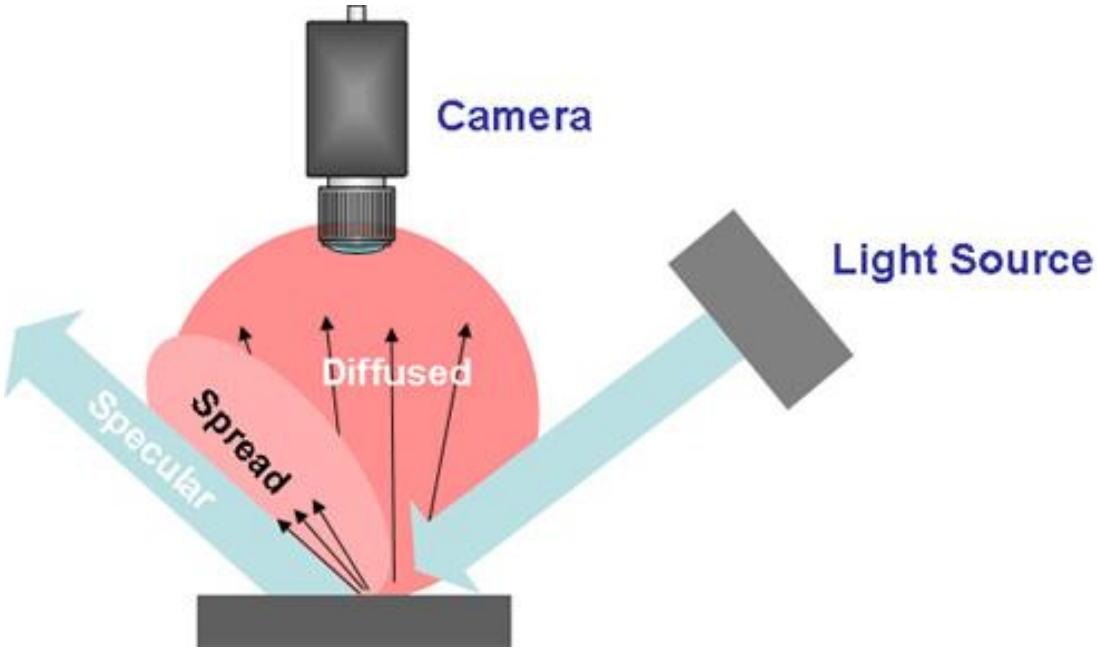
ISO/IEC TR 29158 Lighting Requirements

- ISO/IEC TR 29158 assigns all symbols to one of three categories:
  - Category 0
  - Category 1
  - Category 2
- A symbol's category is determined by the **lighting environment** required to properly illuminate it.



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ISO/IEC TR 29158 Lighting Requirements

- A typical light range is 635-660 nm, recommended by the TR 29158 guidelines for three lighting environments:

  - ✓ **Diffuse on-axis illumination (DOAL®):** Uses a diffuse light source to illuminate the symbol perpendicular to the device surface.

  - ✓ **Diffuse off-axis illumination (Dome):** Uses light from an array of LEDs diffusely reflected from the inside of a dome to provide even illumination from all directions.

  - ✓ **Directional illumination:** Uses a light source oriented at a low angle (approximately 30 degrees) to the symbol surface.

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ISO/IEC TR 29158 Lighting Requirements

- In barcode verification, lighting environments are coded to indicate the kind of lighting that is provided by a particular barcode verifier:

Verifier Lighting Settings	Lighting Environment
90	Diffuse on-axis illumination: Perpendicular (90-degree) on-axis or bright field lighting
D	Diffuse off-axis illumination: Dome lighting
45Q	Directional illumination: Low angle (45-degrees), four-direction lighting
30Q	Directional illumination: Low angle (30-degrees), four-direction lighting
30T	Directional illumination: Low angle (30-degrees), two-direction lighting
30S	Directional illumination: Low angle (30-degrees), one-direction lighting

# = degree of the lighting angle
D = Diffuse
Q = Quadrant (four-direction lighting)
T = Twin (two-direction lighting)
S = Single (one-direction lighting)

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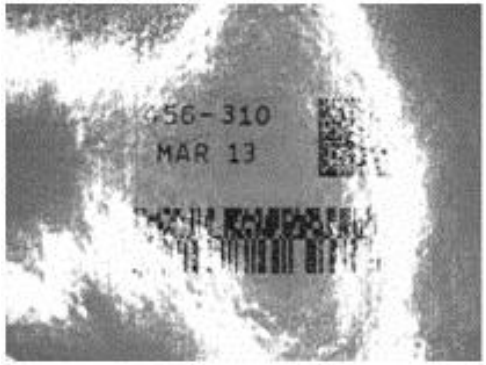
Category 0 Symbols

Lighting Environment: Directional (45Q)

- This symbol category requires a lighting environment **45Q**, which is available in Microscan's LVS® Barcode Verifiers.
- 45Q lighting is required in the ISO/IEC 15415 and 15416 specifications for printed **2D symbols and linear barcodes**.
- Commonly applied in a printed label environment where **DPM codes are not encountered.**



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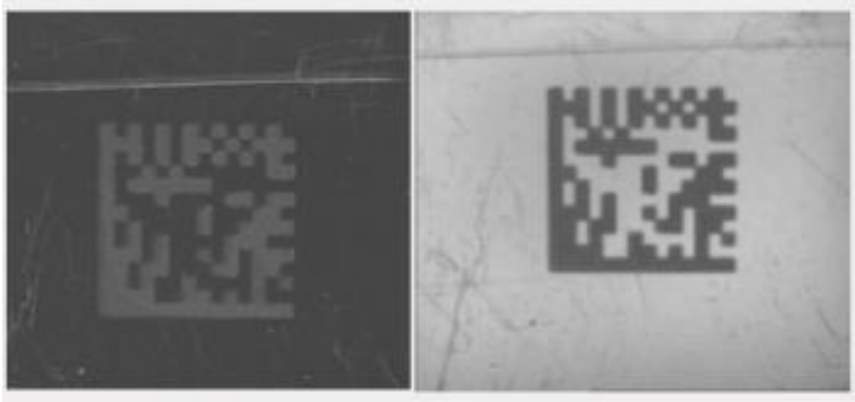
Lighting Environment: Directional (30Q or 90)

- This symbol category requires a lighting environment with light aimed at the device at an angle of **30 (+/- 3) degrees** from the surface of the symbol, cast from **four sides**, or **90 degrees** from the surface.
- The lighting method should illuminate the symbol **uniformly.**
- Commonly applied with **easily-readable DPM.**



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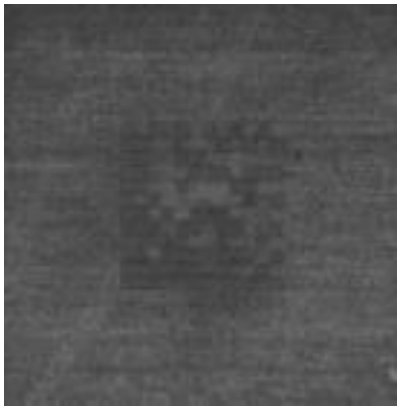
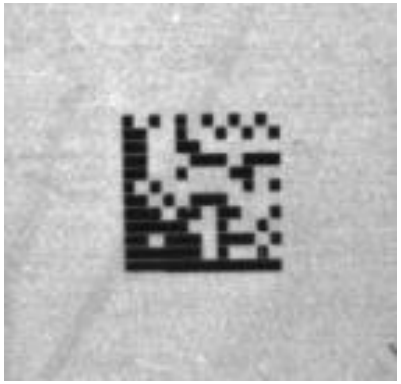
Category 2 Symbols

Lighting Environment: Directional (30Q, 30T, D, or 90)

- This symbol category requires a very **specialized lighting environment** based on the object's surface.
- Commonly applied to **DPM codes on curved surfaces, surfaces with very low contrast, or on highly-textured surfaces**.
- Symbols of this category are intended to be read in specialized environments.





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Do I need to know my UDI symbol category?

- It is helpful to know your symbol's category to determine the best solution for verifying your mark quality.
- Future-proof your UDI marking processes by selecting a verification system that:
  - Employs **ISO/IEC TR 29158** DPM quality parameters
  - Has the appropriate **lighting geometry** for your symbol category
  - Offers **data structure analysis** to check the encoded data of your UDI against issuing agency specifications (GS1, HIBCC)

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Verification Solutions for Every Category

Microscan offers **verification solutions** for all symbol categories, featuring lighting geometries designed in line with **ISO/IEC** barcode grading requirements. Our verification software is programmed for barcode data structure analysis based on issuing agency specifications from **GS1 and HIBCC**, so errors never go undetected.

Our verification experts offer **personal training** to assist in the setup of UDI verification systems specifically for your application to make sure your codes stay up to code.

Remember to establish a verification plan for UDI – Get expert help at www.microscan.com.

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Direct Marking for UDI Compliance

GS1 Standards Professional
(8018) 08622830000002850

Barbie LaBine

Microscan Training Coordinator

A Certified GS1 Standards Professional, Barbie LaBine has provided training to global medical device manufacturers on UDI compliance and UDI code and label verification for the past two years. LaBine comes to Microscan from the industry-leading barcode verification systems manufacturer Label Vision Systems, Inc., (acquired by Microscan in August 2015), and now offers a range of training on LVS® brand barcode verification and other Microscan technology and applications.

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Thank You!

Any Questions?

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