Intro to UDI Barcode Verification

June 30, 2016
Speakers

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Outline

1. UDI Rule & Barcode Overview
2. Barcode Verification
3. Controlling Barcode Quality
4. Q&A Session
UDI & Barcode Overview
What is UDI?

• Final Ruling – Effective September 24, 2013

• Medical devices to bear a unique device identifier (UDI) in both human and machine readable forms
  • Direct Part Marking (DPM)
  • AIDC Technology (Barcodes, Magnetic Stripes, RFID, Symbols)

• Standardized date formatting
  • YYYY-MM-DD

• Submission to FDA’s Global Unique Device Identification Database (GUDID)
FDA Accredited Issuing Agencies

- GS1
- HIBCC
- ICCBBA

Approved, infrequently used for Medical Device Labeling
AIDC Technology Symbols

Automatic Identification and Data Capture
Most Common Types of Barcodes

*Used in the Medical Device Industry*

**Linear (1D) Barcodes**

![Linear Barcode Example](image)

**2 Dimensional (2D) Barcodes**

![2D Barcode Example](image)
Section 2

Barcode Verification
What is Barcode Verification?

Controlled process which assesses the quality of the machine-readable element of a printed linear (1D) or a block (2D) barcode.

Measures 2 Features

1. Formatting
   - Pass/Fail Test

2. Readability
   - Typical Scanning Equipment
   - Graded on scale of 0.0 to 4.0
Scanning vs. Verification

**Scanning**

- Only reads data from barcode
- Only ensures scanned barcode has some region on it that is readable, by the specific scanner used
Scanning vs. Verification

Verification

• Method that assesses the format and quality of barcode
• Decodes, measures and verifies formatting of barcode
• Indicates faulty/deficient attributes so adjustments and/or corrective actions may be applied
Why Verify?

- Regulatory Compliance
- Ensure barcodes are readable
  - Handling
  - Storage
  - Distribution
  - Point of Use
Equipment for Verification

Verifier

- Validated and calibrated system
- Uses vision system
- Conforms to ISO/EIC 15426-1 (1D) and 15426-2 (2D)
Composition of a UDI Symbol

- Device Identifier
- Production Identifier
- Other Machine Codes
Composition of a UDI Symbol

Device Identifier, a code that signifies:

- Version or model of the device
- Labeler of the device
- Package quantity (unit of sale, multi-pack, etc.)
Composition of a UDI Symbol

**Production Identifier:**
- Conditional, variable
- Identifies the following IF included on the device label
  - Lot/Batch Number
  - Serial Number
  - Expiration Date
  - Manufacture Date
Composition of a UDI Symbol

Other Machine Codes:

- Quiet Zones
- Start/Stop Characters
- FNC1 Character(s)
- Machine Check Characters
- Code Change Signals

(01)10123456789125(17)000101(10)00000DDDYYzxx
Analysis of Barcode Structures

Message Structure = PASS

Data Structure Analysis

<table>
<thead>
<tr>
<th>Embedded data</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;StartC&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;FNC1&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>01</td>
<td>Global Trade Item Number (GTIN)</td>
<td>(01)</td>
</tr>
<tr>
<td>00123456912434</td>
<td>Global Trade Item Number (GTIN)</td>
<td>00123456912434</td>
</tr>
<tr>
<td>17</td>
<td>Expiration Date (YYMMDD)</td>
<td>(17)</td>
</tr>
<tr>
<td>161121</td>
<td>Expiration Date (YYMMDD)</td>
<td>161121</td>
</tr>
<tr>
<td>&lt;Code B&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Batch or Lot Number</td>
<td>(10)</td>
</tr>
<tr>
<td>1234</td>
<td>Batch or Lot Number</td>
<td>1234</td>
</tr>
<tr>
<td>&lt;Check 63&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;Stop&gt;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GS1 UDI Example

(01)00123456912434(17)161121(10)1234
Barcode Print Quality

1. Inspection band (normally 80% of average bar height).
2. 10% of average bar height above inspection band.
3. 10% of average bar height above average bar bottom edge.
4. Light margins or quiet zones.
5. Scanning lines
6. Average bar bottom edge
Barcode Print Quality

A Linear Symbol and its Scan Reflectance Profile
Barcode Print Quality

- Attributes for Linear Barcodes (ISO/IEC 15416)
  - Decode
  - Minimum Reflectance
  - Symbol Contrast
  - Minimum Edge Contrast
  - Modulation
  - Defects
  - Decodability

- Additional attributes for 2D Barcodes (ISO/IEC 15415)
Attributes: Decode

- ISO/IEC 15416 definition: “Determination of the information encoded in a barcode symbol”
- Ability of the barcode to be translated into data characters
- Pass – Fail
Attributes:

Minimum Reflectance ($R_{\text{min}}$)

- Lowest reflectance value in the scan reflectance profile
- $<$ Half of max reflectance to pass
- Pass – Fail
Attributes:

Symbol Contrast (SC)

• Difference between min and max reflectance
  \[ SC = R_{\text{max}} - R_{\text{min}} \]

• Graded 0 – 4

*Blackest possible bars printed on the whitest possible surface would have 100% contrast*
Attributes:

Minimum Edge Contrast ($E_{C_{\text{min}}}$)

- Difference between reflectance of a bar and that of the adjacent space (background)

- Pass – Fail
Attributes: Modulation

- Ratio of the min Edge Contrast ($EC_{\text{min}}$) to Symbol Contrast (SC)
- Graded 0 – 4
Attributes: Defects

- Irregularities within the symbol
  - Voids – light areas within the bars
  - Spots – dark area in the spaces

- Ratio of max element reflectance non-uniformity to symbol contrast

- Graded 0 – 4
Attributes: Decodability

- Measurement of how close the printed symbol is to a theoretically perfect symbol
- Graded 0 – 4
Attributes:
Additional for 2D Barcodes

- Axial Non-Uniformity
- Grid Non-Uniformity
- Unused Error Correction
- Fixed Pattern Damage
Additional 2D Attributes: Axial Non-Uniformity

• Amount of deviation along the X or Y axis of a symbol

• Graded 0 – 4
Additional 2D Attributes:

**Grid Non-Uniformity**

- Amount of deviation of grid intersection
- Graded 0 – 4
Additional 2D Attributes: Unused Error Correction

- Remaining error correction available
- Graded 0 – 4
Additional 2D Attributes:

**Fixed Pattern Damage**

- Damage to the quiet zone, finder pattern or clock pattern
- Graded 0 – 4
Expression of Overall Symbol Grade

- **G / A / W**
  - G = overall measured grade (typically numeric value)
  - A = aperture size reference of the verifier (in mils)
  - W = wavelength of light (in nm) of the verifier

- Average of the results of 10 scans

- Numeric or alphabetic

<table>
<thead>
<tr>
<th>Alphabetic</th>
<th>Numeric Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>3.5 – 4.0</td>
</tr>
<tr>
<td>B</td>
<td>2.5 – 3.5</td>
</tr>
<tr>
<td>C</td>
<td>1.5 – 2.5</td>
</tr>
<tr>
<td>D</td>
<td>0.5 – 1.5</td>
</tr>
<tr>
<td>F</td>
<td>0.0 – 0.5</td>
</tr>
</tbody>
</table>
Analysis of Print Quality

Overall grade: 4.0/06/660 (A)

ISO/IEC Parameters:
- Symbology: GS1-128
- Xdim: 10.0 mils
- Edge determ: PASS
- Min Reflect: PASS
- Minimum EC: PASS
- Decode: PASS 169
- Quiet zone: PASS
- Contrast: 4.0 (A) 91%
- Modulation: 4.0 (A) 81%
- Decodability: 4.0 (A) 71%
- Defects: 4.0 (A) 6%
- Blemish: 4.0 (A) 0%

For best results, place the barcode as close to the center of the image as possible.
Analysis of Print Quality

Overall grade: 2.2/06/660 (C)

ISO Grading: Full Pass/Fail
- View: Overall grade, Contrast, Modulation
- Decodability, Defects, OCR, Zoom

ISO/IEC Parameters
- Symbology: GS1-128
- Xdim: 10.0 mils
- Edge determ: PASS
- Min Reflect: PASS
- Minimum EC: PASS
- Decoder: PASS 161
- Quiet zone: PASS
- Contrast: 4.0 (A) 98%
- Modulation: 2.8 (B) 63%
- Decodability: 3.3 (B) 60%
- Defects: 4.0 (A) 7%
- Blemish: 3.1 (B) 23%

WARNING: Non ISO blemish errors reduced the overall grade by 23%
Analysis of Print Quality

Overall grade
0.0/06/660 (F)

ISO/IEC Parameters
Symbology: GS1-128
Xdim: 10.0 mils
Edge determination: 19% ERROR
Min Reflect: PASS
Min Elastic: PASS
Decode: FAIL
Quiet Zone: PASS
Contrast: 4.0 (A) 98%
Modulation: 2.6 (B) 61%
Decodability: 3.2 (B) 58%
Defects: 1.9 (C) 23%
Blemish: 3.8 (A) 4%

WARNING: Wrong check digit detected
WARNING: Edge determination failures reduced the overall grade by 19%
WARNING: Non ISO blemish errors reduced the overall grade by 4%
Common Specifications & Quality Requirements

HIBCC

• Minimum Grade of C (1.5/06/660)

GS1

• Varies by application
• Common for single-use prescription medical devices
  • GS1-128: Minimum Grade of C (1.5/06/660)
  • GS1 DataMatrix: Minimum Grade of C (1.5/08/660)
Controlling Barcode Quality
Factors Affecting Barcode Quality

- Bright White Label Stock
- Dark Black Printing
- White Space Allowed Around Barcode
- Barcode Lines Parallel To Printer Feed

Example Shown Is A Linear Barcode, Which Is Larger Than An Equivalent 2-D Barcode
QTS Controls on Barcode Grading

- Validated & Calibrated Verification Equipment
- Engineering Label Design
  - Correct formatting of messages
  - Minimum readability grade exceeded
  - Sample labels verified
- Production Label Printing
  - Verification of first & last labels of print job
  - Comparing grades to customer specifications
Q&A Session
Thank You!

A better approach. A better solution.
References

• FDA Website (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification)
• GS1 Website (www.GS1.org)
• Health Industry Business Community Council (HIBCC) Website (www.HIBCC.org)
• International Council for the Commonality in Blood Banking Automation (ICCBBA) Website (www.iccbba.org)
• ISO/IEC 15415:2011 – Information Technology – Automatic identification and data capture techniques - Bar code symbol print quality test specification – Two-dimensional symbols
• ISO/IEC 15416:2000 – Information Technology – Automatic identification and data capture techniques - Bar code print quality test specification – Linear symbols
• 21 CFR 801 – Labeling – Medical Device
• 21 CFR 830 – Unique Device Identification
• Image credits: Pixabay and Vecteezy