Coding Technology and Serialization: It’s more than just a printer

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Overview

- The most important element of serialization is data management, or data transfer.

- In today's presentation we are going to review other areas of serialization that are commonly overlooked, and the role coding technology plays.
Times Have Changed

The good old days?

Not for much longer!
What is Serialization?

- **Carton Serialization**: Each saleable unit is assigned a unique identifier.
- **Case Serialization**: Units packed into cases. Each case is assigned a unique identifier, and each unit (child) is associated with the case (parent).
- **Pallet Serialization**: Cases packed onto pallets. Each pallet is assigned a unique identifier, and each case (child) is associated with the pallet (parent).
Global Pharma Serialization Mandates

Example of current Legislation driving Serialization

The Drug Supply Chain Security Act (DCSCA) mandates that manufacturers begin serializing all drug products at the saleable unit and case level for the US market starting November 2017.
Serialization...not just for Pharma!

“Every automobile sold in the U.S. bears a unique serial number that enables the car’s seller and buyer to track the vehicle’s history, authenticate ownership, and manage safety recalls. Today’s food consumers have similar interests in transparency about the products they buy and the ability of the food producer to take responsibility for the product across the entire value chain.”

“The food industry is also seeking ways to meet the interest of today’s consumer in much greater transparency and connectivity with those who are producing and marketing their food. Companies need to cater to the next generation of consumers—Gen Z—who are “born digital,” and to target and share information with consumers in real time in order to build consumer confidence and nurture brand loyalty.”

- Food Quality & Safety, Thomas Körmendi

Key Considerations.
What impacts Serialization Efforts?
Operating Cost Considerations

Importance often neglected: “It’s just a printer”
Holistic Approach Needed

Any system is only as good as its worst part!
Coding Considerations

1. Decoding and Verifying
   a) Which standard is valid for my application?
   b) Which vision systems/cameras are used?
   c) When and where does the final decoding take place?

2. Substrate Material
   a) Is the material inkjet / laser-friendly?
   b) How big is the impact if the packaging material is changed

3. Product Handling
   a) Where do I code / static or on-the-fly application?
   b) Which impact do machine vibrations have on the code quality?
Decoding and Verifying
Standards

Serialization

• Folded boxes
• Syringe & vial labels

UDI Track & Trace

Direct parts marking:
e.g. pens, inhaler cartridges, blisters, medical devices
Reading and Grading
• Grades the data matrix code in 6 different categories
• Lowest grade in any of the six categories determines the overall grading

Modulation and fixed pattern damage are the two main causes for failure

Requested by most customers

Requested by the FMD (at the point of disposal)
DIN-ISO 15415

Grading Parameters

Possible Reason for Failure

- **Marking contrast (Symbol contrast)**
  Measures the difference in reflectance between the light areas and dark areas on the marking. Reflectance is the level of reflection of light on a given surface.

- **Damage to the boundary and quiet zone (Fixed pattern damage)**
  Measures the damage to the external marking boundary and to the quiet zone.

- **Inhomogeneity (Modulation)**
  Measures the variation in reflectance or in the size of the light and dark modules.

- Substrate material (composition / color)
- Ink issues

- Product handling issues
- Machine vibrations
- Substrate material
Grading Parameters

- **Axial non-uniformity**
  Measures the deviation of the marking following one of the main axes (x or y).

- **Grid non-uniformity**
  Measures the most significant trapezoidal deviation with respect to the axes of the theoretical grid.

- **Evaluation of available Reed-Solomon calculation headers**
  (Unused error correction)
  Measures the unused error correction level.

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**Possible Reason for Failure**

- Encoder settings
- Distance print head - substrate
- Print head twisted/tilted with respect to the substrate
Cardboard Type 1

Cell size: 15.1 mils
Decode: PASS
Contrast: 4.0 (A) 82%
Modulation: 4.0 (A)
Axial nonuniformity: 3.5 (A) 6%
Grid nonuniformity: 4.0 (A) 0%
Unused EC: 4.0 (A) 100%
Fixed pattern damage: 4.0 (A)
Cardboard Type 2
Substrate Material
The Basics: Laser Wavelengths

• CO₂ laser coding is a thermal effect
  – Energy must be absorbed
  – Temperature achieved
  – Contrast created

• In order to achieve optimal laser coding, we must evaluate the characteristics of both the laser AND the material being marked

• The challenge is that not all substrates are created equal.
  – Understand the different materials
  – Match them with our different lasers “Wavelength Matching”

• CO₂ wavelength can significantly affect energy absorption
  – 9.3 micron
  – 10.2 micron
  – 10.6 micron

• If laser power can be provided at the wavelength which the material absorbs well, then good marking is possible
Thermal Process

Temperature = Absorption \times Power

- Contrast
- Concentration

Absorption
- Is determined by the Material Characteristics

Power
- Optical Efficiency
- Determined by Laser Power

High power concentration and low absorption results in poor code quality (or contrast)

Little power concentration and high absorption results in good code quality (or contrast)
Scientific Sampling Process

All materials are not created equally. Next we must understand the unique absorption characteristics of your materials, something we refer to as “wavelength matching”. To do this, we use analytical tools for a more scientific approach versus the more historical trial & error process.

- Characterization of substrates
- Determination the most effective laser wavelength
- Quick identification of any substrate variations that could adversely affect coding performance
- More effective specifications for substrate suppliers
Substrate Composition

• Summarize substrate composition

• Understanding the composition is important, including the composition of the coatings

• Laser friendly materials and non-laser friendly materials
Substrate Composition Study

- Domino has produced a “comprehensive” test document of all common carton boards on the market, available upon request.

This study outlines the specification of laser friendly carton materials... however, 80% of all commonly used Pharma cardboard materials contain too little of a key ingredient.
Influence of the Substrate Color

<table>
<thead>
<tr>
<th>What we see</th>
<th>What the (DIN-ISO 15415 compliant) camera sees</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>B100</strong></td>
<td><img src="image1" alt="Black Image" /></td>
</tr>
<tr>
<td><strong>C100</strong></td>
<td><img src="image2" alt="Blue Image" /></td>
</tr>
<tr>
<td><strong>M100</strong></td>
<td><img src="image3" alt="Red Image" /></td>
</tr>
</tbody>
</table>
Coding with ink requires the same scientific approach:

- Photochemical stability (light fastness test)
- Bonding of the ink to the substrate
- Drying time
Ink Drying Time

Typical distance between printer and camera: 300 - 500 mm

Line speed 60 m/min → max. 300 ms – 500 ms drying time

Drying time depends on ink AND substrate
### Material Qualification Report
**Thermal Inkjet ink BK652 on pharma cartons**

<table>
<thead>
<tr>
<th>Manufacturer:</th>
<th>Carton Type:</th>
<th>Tested Date:</th>
<th>2D Grade</th>
<th>LVS Report</th>
<th>1D 36.9mm Grade</th>
<th>LVS Report</th>
<th>1D 45mm Grade</th>
<th>LVS Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stora Enso</td>
<td>Tambrite</td>
<td>03/02/2016</td>
<td>Grade A – 4.0</td>
<td>✓</td>
<td>Grade A – 3.9</td>
<td>✓</td>
<td>Grade A – 4.0</td>
<td>✓</td>
</tr>
</tbody>
</table>

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### Lightfastness Testing

<table>
<thead>
<tr>
<th>Sample Reference</th>
<th>Test</th>
<th>2D Code Reading – after Xenon light exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Un tested</td>
<td>Readability after 80 hours exposure to Xenon light (³ Blue Wool 3, equals 2 years with proper mounting and display)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>73%</td>
</tr>
<tr>
<td>BK652</td>
<td>Symbol Contrast</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Code Legibility</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Decode</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>Unused Error Correction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sample Print</td>
<td></td>
</tr>
</tbody>
</table>

Product Handling
Product Handling Issues

Typical DMC:

24 x 24 modules

9.12 mm x 9.12 mm

Cell size = 15 mil (0.38 mm)

Displacement of module in the range of 100 µm can cause bad gradings (modulation / fixed pattern damage)
Typical Coding Positions

Inside the cartoner

Mark-to-mark distance 120 – 150 mm
Line speed up to 60 m/min
Product rate up to 500 ppm

Stand-alone coding stations

Mark-to-mark distance 100 – 200 mm
Line speed up to 100 m/min
Product rate up to 500 ppm
Product Handling Issues

Two conveyor belts

Synchronization necessary for smooth movement

Distance between the two conveyors too small → Jerking movement  
→ Grid pattern gets broken

Distance between the two conveyors too big → Box slips / encoder can’t compensate for that  
→ DMC can look „torn“
Machine Vibrations/ Product Handling Issues

- Grid pattern is broken
- Modules are split
- Windows flag like appearance
- Shift of modules to neighboring grid positions
Domino Study About Machine Vibrations

- Frequency of the vibration
- Amplitude of the vibration
- Distance of the vibration source to the point of coding

50 cm distance

5 cm distance
The closer the source of the vibration to the point of coding the bigger the influence on coding quality.

Vibrations in Y-direction (90° to the product movement) have a stronger influence on the code quality of DMCs.

Vibrations in X-direction (inline with the product movement) have a stronger influence on the code quality of 1D barcodes.

Moderate vibrations in Z-direction don’t have a significant influence on the code quality of machine readable codes.

In general the variation of the frequency seems to have a bigger impact on the code quality than the variation of the power (amplitude) of the hits.
And what this means for Serialization…
A reminder…

“Any system is only as good as its worst part”
Further Reading

- We have a large selection of white papers, further best practice documents, technical documents, videos, etc… please just let us know what you need.
Thank you!

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