Zincode Technologies

Why Barcode Verification is a Critical Matter to Industry & Business Performance

www.zincode.net

About Us

Zincode Technologies provides Automatic Identification and Data Collection (AIDC) solutions, Machine Vision Inspection and Printing Inspection Solutions.

Our Mission

To constantly focus on innovating automation solutions to customers providing quality products and services.

ZINCODE

www.zincode.net

GS1 in a Nutshell

Malaysia

Neutral and not-for-profit

User-driven and governed

Global and local

Inclusive and collaborative

GS1 Healthcare Mission:

To lead the healthcare sector to the successful development and implementation of **global standards** by bringing together experts in healthcare to enhance **patient safety** and **supply chain efficiencies**.

1 million

over 1 million companies worldwide use GS1 standards

150 countries

25 industries served across 150 countries

5 billion

Barcodes scanned more than 5 billion times per day globally

112 MOs

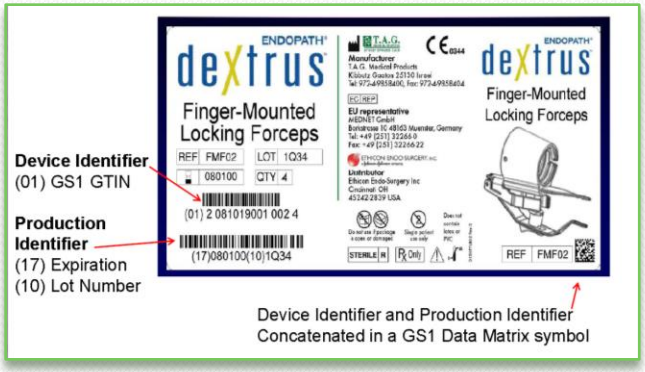
112 Member Organisations around the world

GS1 Malaysia | Strategic Alliance Partner

Jointly help companies transform businesses with the use of GS1 Standards!

Topics

- What is UDI?
  - Why do you care?
- Microscan's Solutions
  - AutoID Basics
  - AutoID and Vision
  - Validation and Verification
- Reading, Verification and Validation with Auto ID and Machine Vision
  - Label Reading
  - Label Quality Check
  - Content Validation of Text and 1D/2D codes
    - *Validation of Code and String Content*
    - *Validation of GS1 Format*
  - Verification of Legibility and Scanability
    - *Standards Based and Custom Verification*
    - *In-Line Verification Example*
    - *OCR and OCV*
  - Solution Examples
  - Artwork/Print Inspection Systems
  - Conclusions



What is FDA UDI?

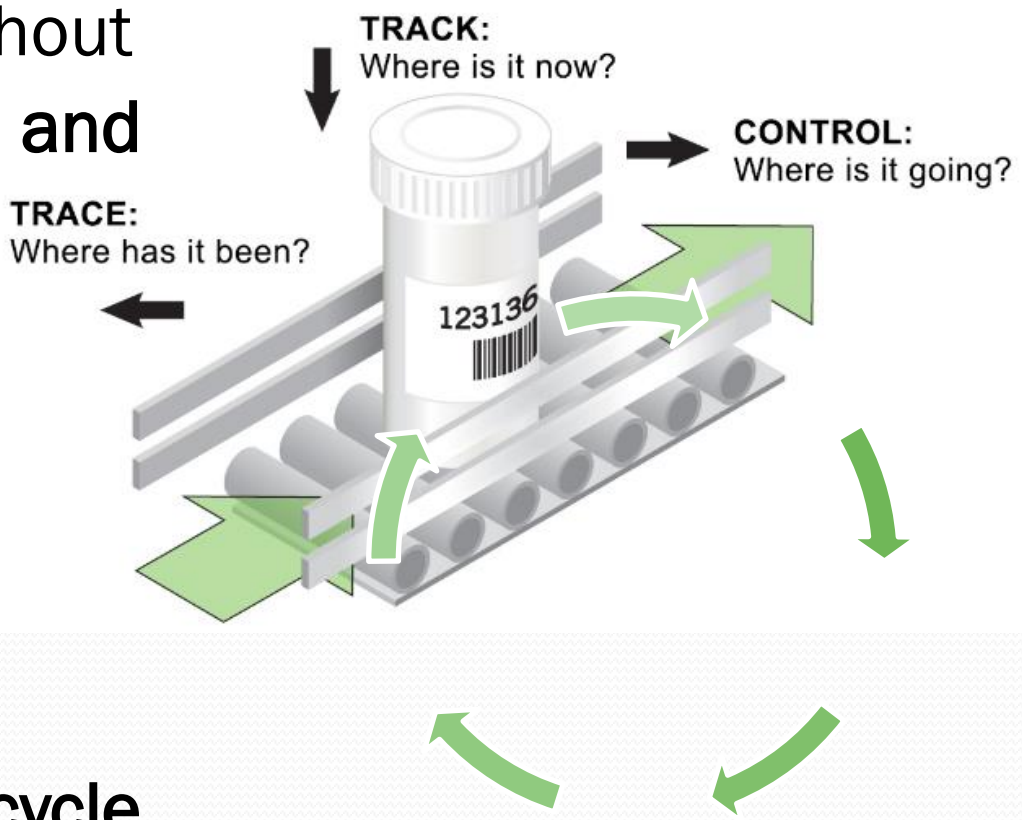
- **Unique Device Identification system, Standard format and content for Medical Device Labeling**
- Allow lookup for identification, recalls, adverse outcomes, medical records
- Dictates a standardized method of coding medical devices with key identifying information.
- Minimum is a **Device Identifier** and **Production Identifier**

(GTIN, Lot/Batch/Prod Date/Serial) in AutoID form for consistency and transparency

- Existing approved organizations such as GS1, HIBCC, ICCBBA
- Data carrier agnostic. Can be 1D, 2D, RFID. Enables traceability of devices throughout manufacture, distribution, and use.

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.**



UDI Implementation

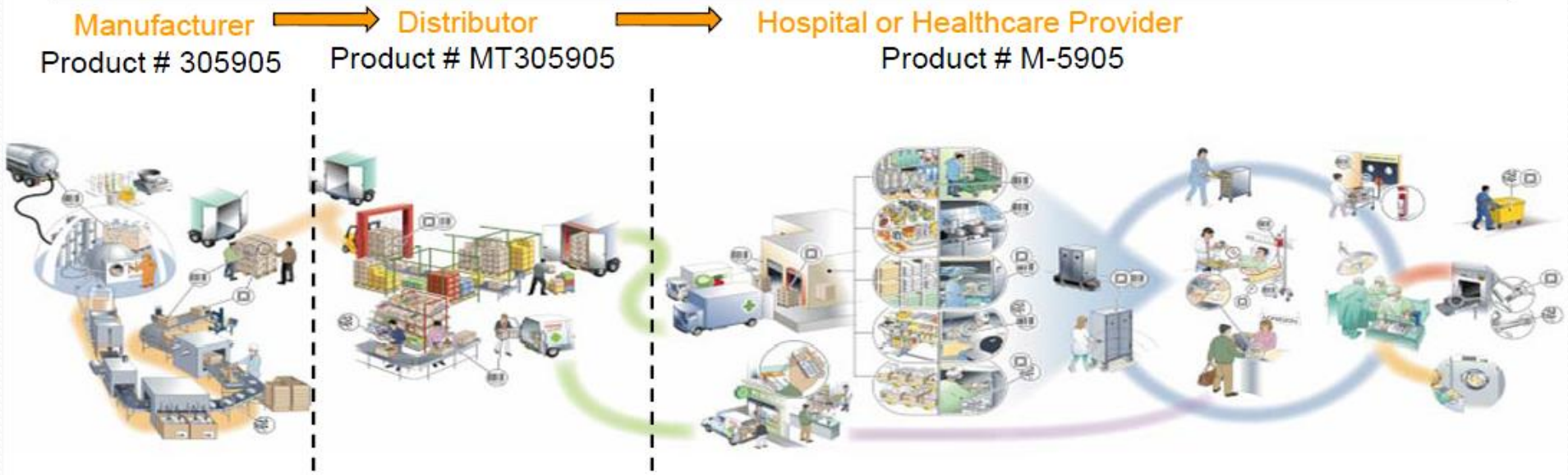
- Medical device labelers, supply chain and users will need to read/validate/verify UDI format labels and marks for Products shipped to USA (FDA Requirements)
- We are ready to support UDI applications for Medical Manufacturing!!

  - **1D/2D Code Reading (IoT Web Based)**
  - **GS1 Code Format Validation**
  - **GS1 Code Content Validation**
  - **1D and 2D Barcode Grading (ISO Standards)**
  - **OCR and OCV**
  - **Human & Machine Readable Cross Verification**
  - **Direct Part Marking on Reusable/Sterilizable Devices**
  - **Point of Use Reading**

Why do we need it?

Current systems allow product re-identification by every stakeholder in the supply chain.

This makes product tracking efforts and recall extremely difficult.



How many names can a Syringe have?

Problem: Distributors and Hospitals Assign Additional Product Numbers

(329461 - 1/2 mL BD Lo-Dose™ U-100 insulin syringe)

Business Name	Item Number Type	Item Number
BD	Mfg Catalog Number	329461
BD	GTIN	00382903294619
BD	GTIN	30382903294610
BD	GTIN	50382903294614
CARDINAL HEALTH	PV Order Number	BF329461
OWENS & MINOR	PV Order Number	0722329461
OWENS & MINOR	PV Order Number	0723329461
AMERICAN MEDICAL DEPOT	Vendor Catalog Number	777127217
AMERICAN MEDICAL DEPOT	Vendor Catalog Number	777127218
GOVERNMENT SCI SOURCE	Vendor Catalog Number	FSC1482679CS
GOVERNMENT SCI SOURCE	Vendor Catalog Number	FSC1482679PK
ALLIANCE JOINT VENTURE	Vendor Catalog Number	888021932
THOMAS SCIENTIFIC	Vendor Catalog Number	8938M25
THOMAS SCIENTIFIC	Vendor Catalog Number	8938M28
VWR INTERNATIONAL	Vendor Catalog Number	BD329461

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

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.

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.

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.

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

What is the required format of a UDI mark?

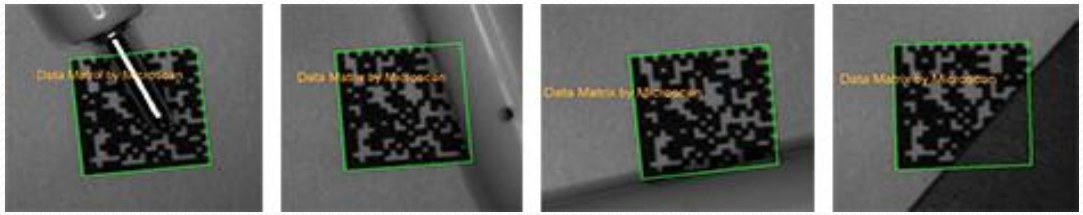
- Unlike UDI on labels and packaging, a permanent UDI mark may be provided in **either**:
  - **Human-readable**: Easily-legible, plain-text format.
  - **Machine-readable**: Able to be interpreted by automatic identification and data capture (AIDC) technology:
    - ✓ Barcode readers
    - ✓ Machine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

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.

Which “data carrier” is recommended for UDI DPM?

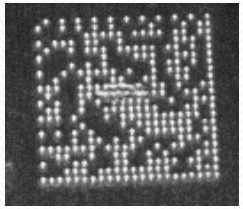
- Choose the best data carrier for your marking method and size of your device.
- Two-dimensional symbols such as Data Matrix are used most commonly for DPM due to:
  - Small size
  - Data capacity
  - Error correction
    - ✓ Read in low contrast
    - ✓ Read in any orientation
    - ✓ Read despite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



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)?

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)

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.

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.

Verification Solutions for Every Category
21 CFR Part 11 Compliance Ready

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.

Analyzing Your Print Quality

- Microscan LVS® Barcode Verifiers are designed streamline and minimize the effort of troubleshooting print quality issues so that you can diagnose issues without advanced tech support, quickly and precisely.

- If defects are present, verifiers will locate and highlight trouble areas on the image, color-coded according to the grade received for meeting a quality parameter.

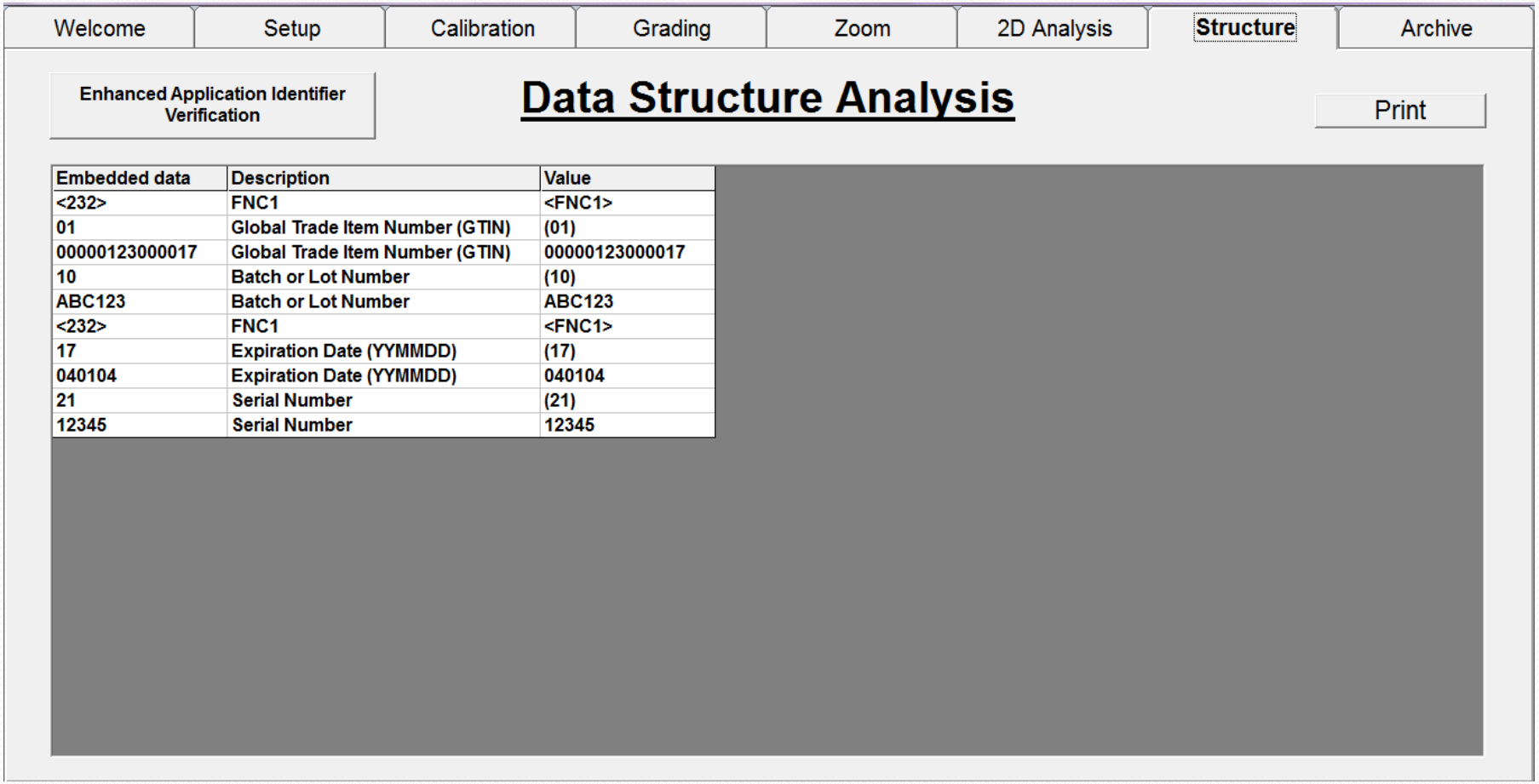
3.5-4.0 (A)	2.5-3.4 (B)	1.5-2.4 (C)	0.5-1.4 (D)	0.0-0.4 (F)

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

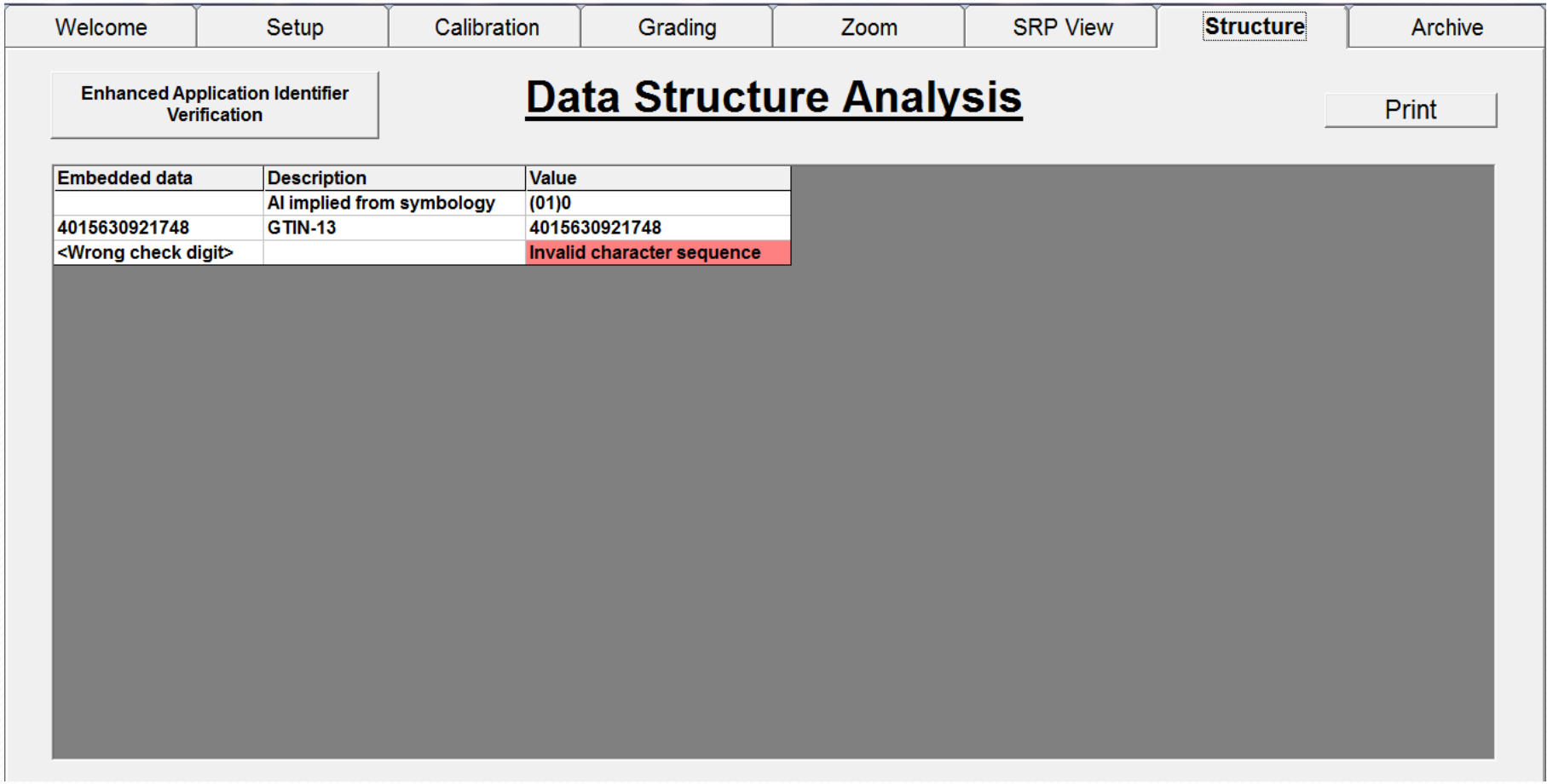
Example: GS1 Data Structure Analysis



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

Error Found in GS1 Data Structure



Microscan LVS-95XX Software Interface
Microscan LVS-95XX Software Interface

Recommended Online Platforms

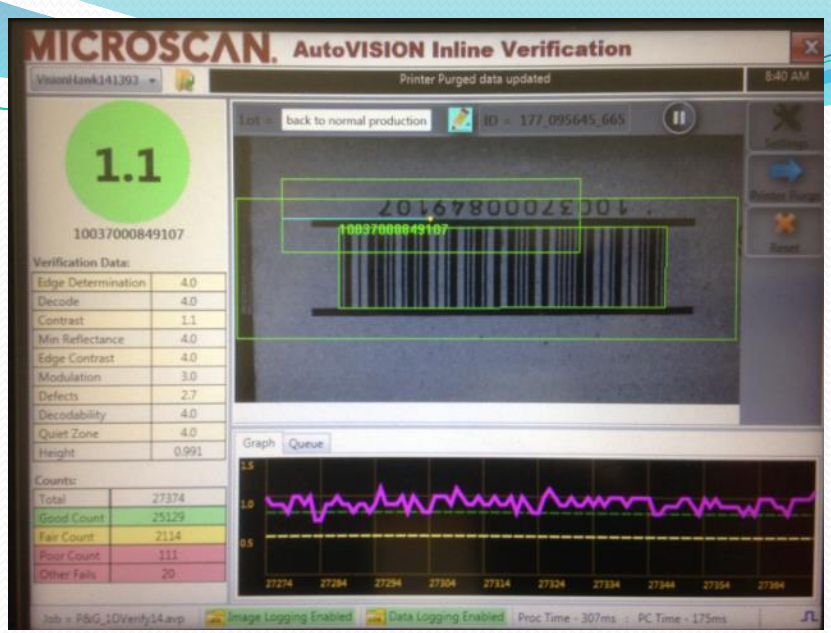
- True verification requires ISO/AIM-compliant light & undistorted image.
  - C-Mount lenses preferred.
  - Perpendicular mounting to avoid perspective distortion.
  - Shield from ambient light.
  - Fixed distance.
  - At least 8 pixels per element.
  - A short (<250µs) exposure time for moving parts/labels.
- Example configurations:

1D/2D Glossy Labels

Dot Peen DPM 2D codes

Package Label Verification/Validation System

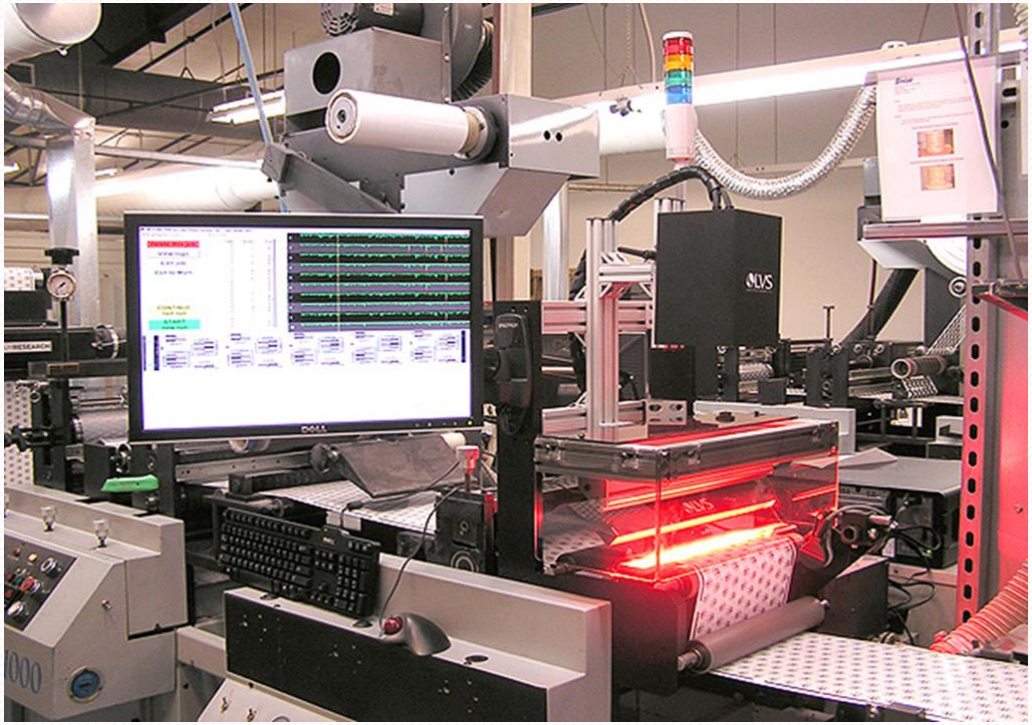
On-Line Verification Implementation

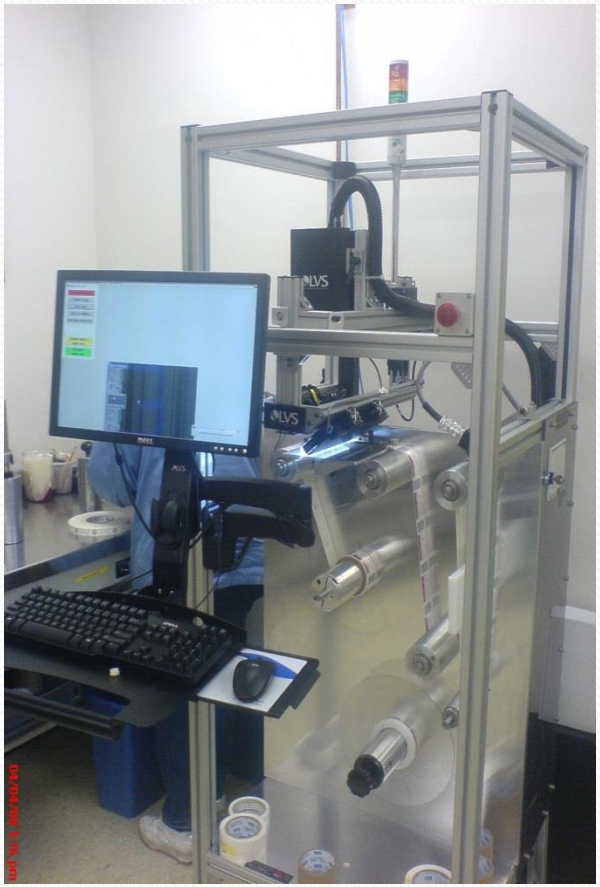


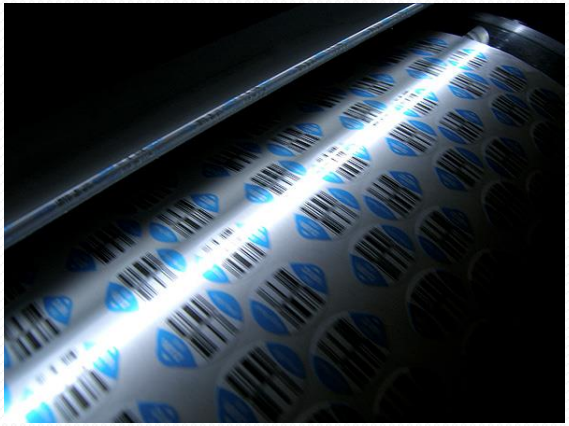
- Not the same as scanning/reading
- Grading (0.0 to 4.0) each code at the point of marking
- Instant feedback on code grade/quality
- Instant warning of low grade/unreadable codes
- Able to observe trends
- Optional logging of grade results and images

Dot Peen DPM 2D codes

Recommended Online Platforms







DPM Verifier for ISO/IEC 29158

- 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)

Thermal Printer Print Inspection Systems

LVS-7510

STEP 1 Label designer creates a label in label design software.

STEP 2 Label design is checked for barcode grading and data structure using an LVS-9580 off-line verifier.

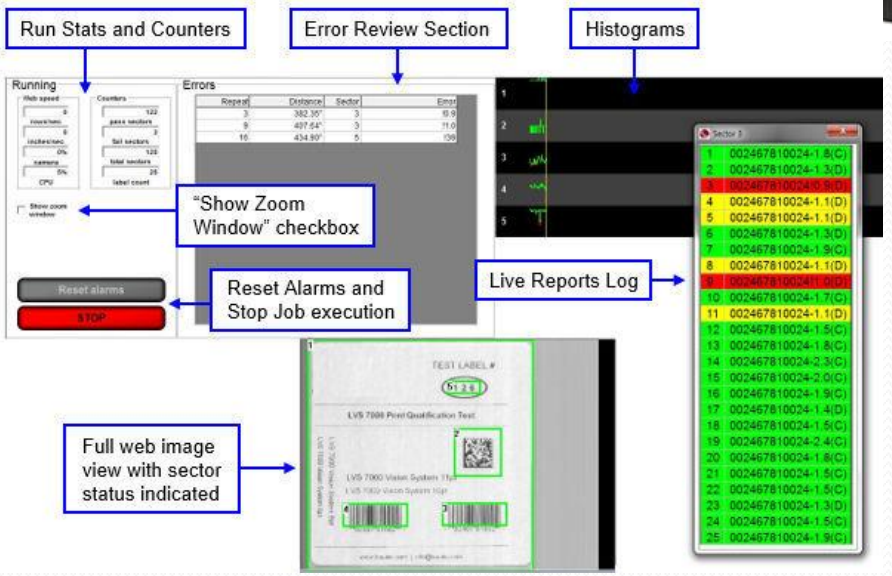
STEP 3 Label design is imported into the LVS-7510 via scanning of representative labels.

STEP 4 Label inspection criteria are established in LVS-7510 software.

STEP 5 Label inspection template is pushed into production.

STEP 6 Production runs batch of labels and determines inspection results.

STEP 7 Based on label production results, adjustments are made to the label design, printing system, or inspection criteria.



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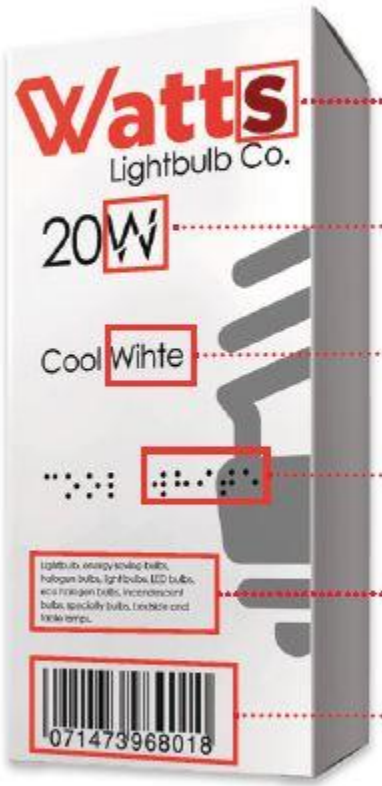
IoT Devices for Data Acquisition

- Get Internet-Friendly Tools
  - Get tools that speak the language of the Internet
  - Choose HTTP devices
  - Choose web user interfaces
  - Choose services or APIs that unite existing systems over web protocols

Microscan MicroHawk ID and MV Smart Cameras

Print Inspection Systems

All-in-One Platform of Inspection Applications



Your entire packaging quality control process, all in one place.

Graphics Inspection
Compare digital artwork files and proofs pixel by pixel for inconsistencies.

Print Inspection
Compare printed labels, cartons, proofs and other packaging material to an approved artwork file to confirm accuracy.

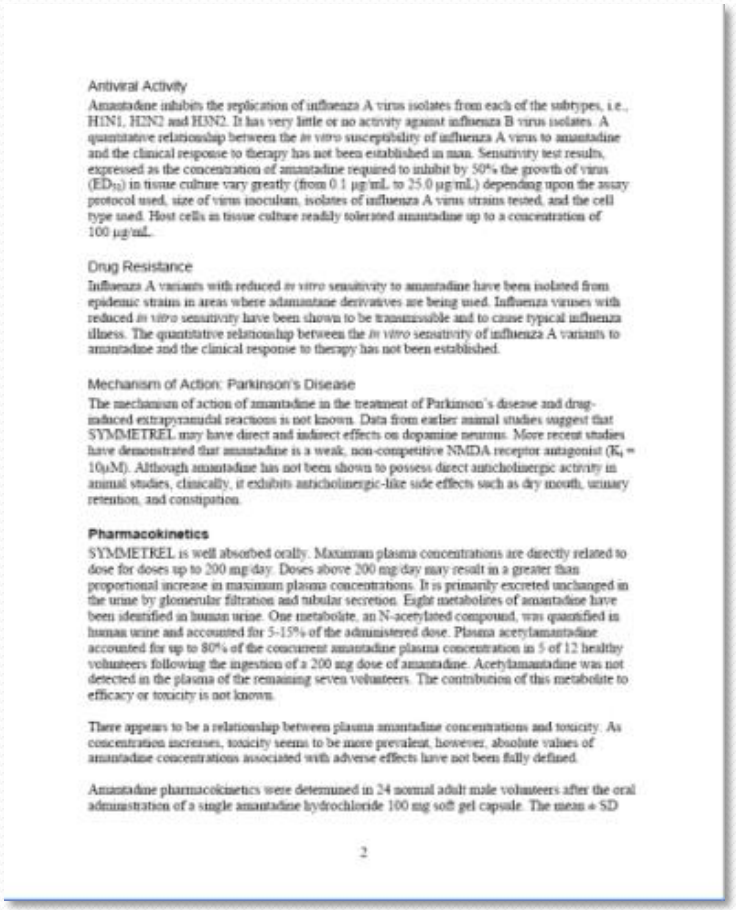
Spelling Inspection
Inspect spelling in any language with a high degree of accuracy.

Braille Inspection
Inspect, translate and verify Braille and find any added or missing dots.

Text Inspection
Compare the copy in a text document to the copy in a PDF file in seconds, regardless of the language.

Barcode Inspection
Verify, decode, and grade barcodes on PDF files, printed packaging and imposition files.

Typesetting Errors



Antiviral Activity

Amantadine inhibits the replication of influenza A virus isolates from each of the subtypes, i.e., H1N1, H2N2 and H3N2. It has very little or no activity against influenza B virus isolates. A quantitative relationship between the *in vitro* susceptibility of influenza A virus to amantadine and the clinical response to therapy has not been established in man. Sensitivity test results, expressed as the concentration of amantadine required to inhibit by 50% the growth of virus (ED_{50}) in tissue culture vary greatly (from 0.1 µg/mL to 25.0 µg/mL) depending upon the assay protocol used, size of virus inoculum, isolates of influenza A virus strains tested, and the cell type used. Host cells in tissue culture readily tolerated amantadine up to a concentration of 100 µg/mL.

Drug Resistance

Influenza A variants with reduced *in vitro* sensitivity to amantadine have been isolated from epidemic strains in areas where adamantane derivatives are being used. Influenza viruses with reduced *in vitro* sensitivity have been shown to be transmissible and to cause typical influenza illness. The quantitative relationship between the *in vitro* sensitivity of influenza A variants to amantadine and the clinical response to therapy has not been established.

Mechanism of Action: Parkinson's Disease

The mechanism of action of amantadine in the treatment of Parkinson's disease and drug-induced extrapyramidal reactions is not known. Data from earlier animal studies suggest that SYMMETREL may have direct and indirect effects on dopamine neurons. More recent studies have demonstrated that amantadine is a weak, non-competitive NMDA receptor antagonist (K_i = 10µM). Although amantadine has not been shown to possess direct anticholinergic activity in animal studies, clinically, it exhibits anticholinergic-like side effects such as dry mouth, urinary retention, and constipation.

Pharmacokinetics

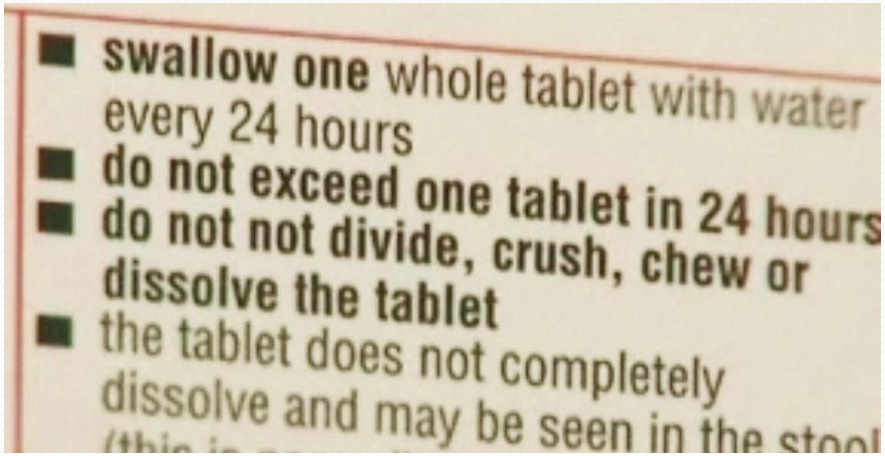
SYMMETREL is well absorbed orally. Maximum plasma concentrations are directly related to dose for doses up to 200 mg/day. Doses above 200 mg/day may result in a greater than proportional increase in maximum plasma concentrations. It is primarily excreted unchanged in the urine by glomerular filtration and tubular secretion. Eight metabolites of amantadine have been identified in human urine. One metabolite, an N-acetylated compound, was quantified in human urine and accounted for 5-15% of the administered dose. Plasma acetylamantadine accounted for up to 80% of the concurrent amantadine plasma concentration in 5 of 12 healthy volunteers following the ingestion of a 200 mg dose of amantadine. Acetylamantadine was not detected in the plasma of the remaining seven volunteers. The contribution of this metabolite to efficacy or toxicity is not known.

There appears to be a relationship between plasma amantadine concentrations and toxicity. As concentration increases, toxicity seems to be more prevalent, however, absolute values of amantadine concentrations associated with adverse effects have not been fully defined.

Amantadine pharmacokinetics were determined in 24 normal adult male volunteers after the oral administration of a single amantadine hydrochloride 100 mg soft gel capsule. The mean ± SD

2

Master Word Document

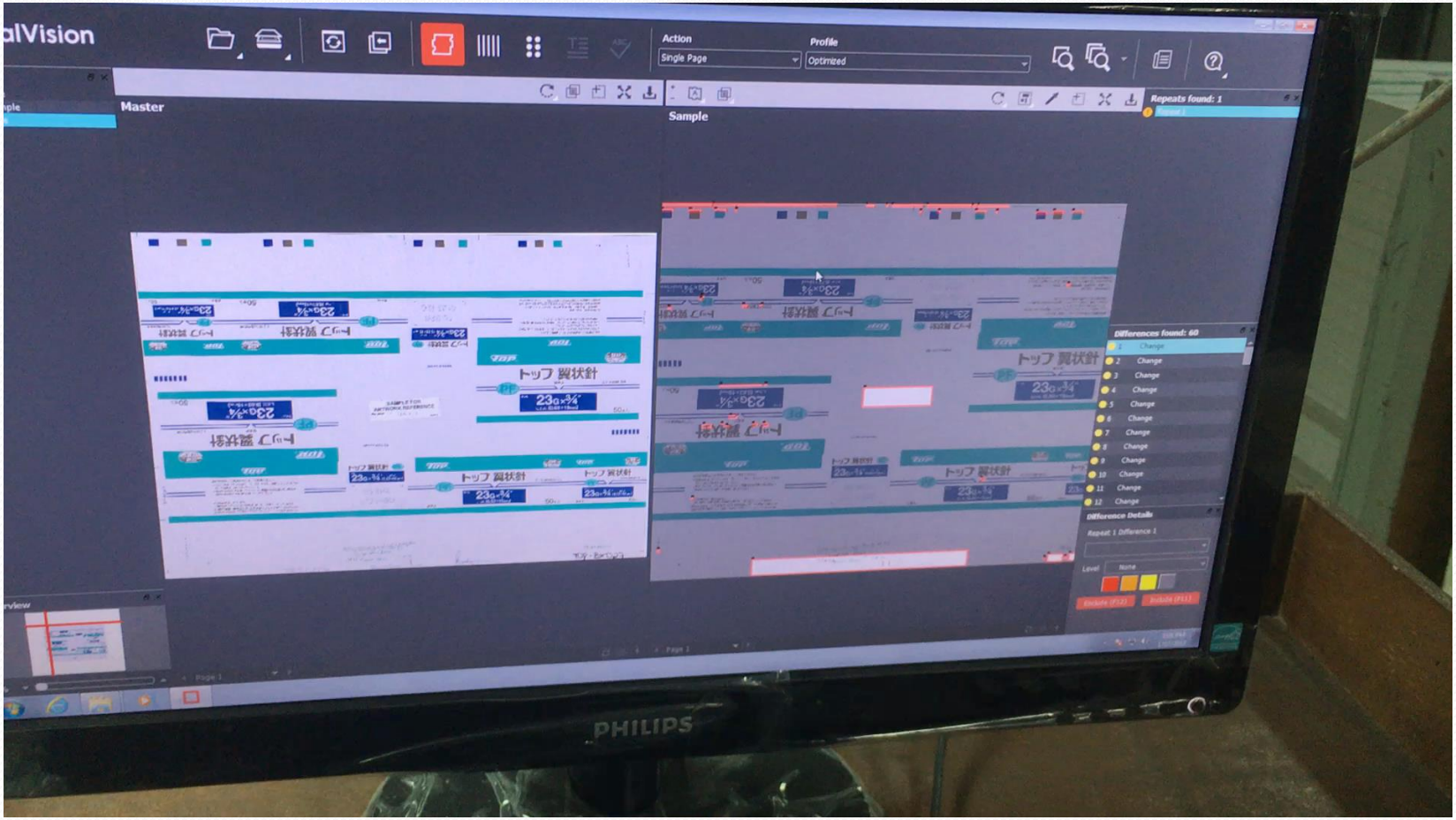


- **swallow one** whole tablet with water every 24 hours
- **do not exceed one tablet in 24 hours**
- **do not not divide, crush, chew or dissolve the tablet**
- the tablet does not completely dissolve and may be seen in the stool

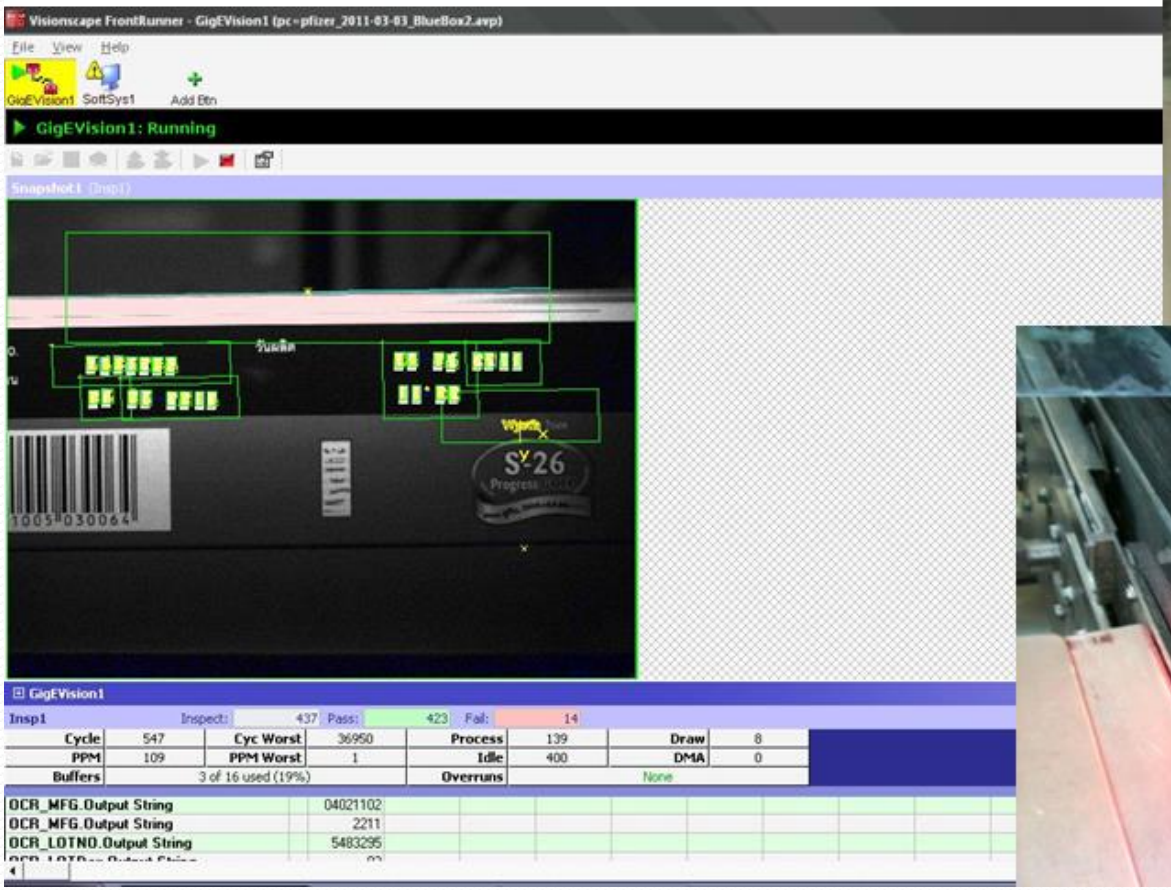
Sample Insert

Printing Differences- COLOR MISMATCH

Automated Artwork Inspection



High Speed OCR Inspection



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High Speed Applications

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Robotic Applications

THANK YOU!!

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