

UDI Verification and Process Control Metrics

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COGNEX

Market Drivers

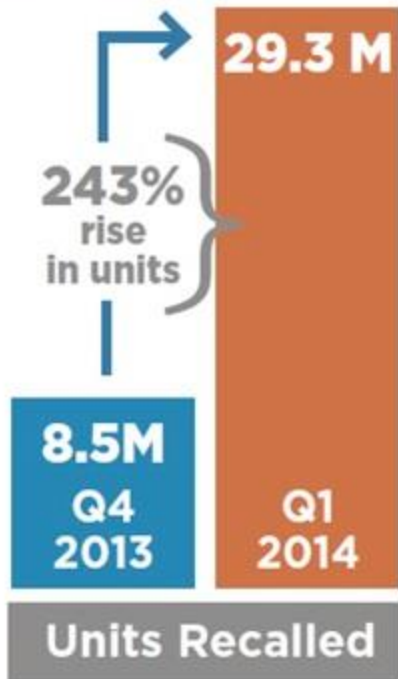
- **Business Needs & Industry Regulations**

Products

- **Vision & ID Overview**
- **Verification Application Solutions**

Q&A

Medical Device Recalls



were nationwide, a continued trend of over 70% nationwide recalls over the past year.



ENSURING

Patient Safety

COMPLYING

With Regulations

PROTECTING

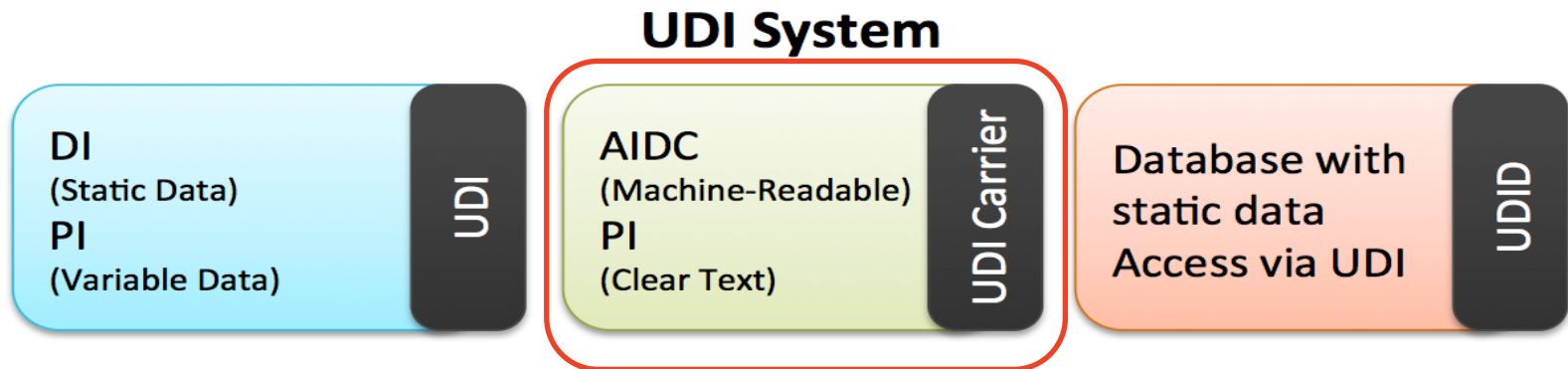
Brand Reputation

TRACING

Through Supply Chain

3 Core Components

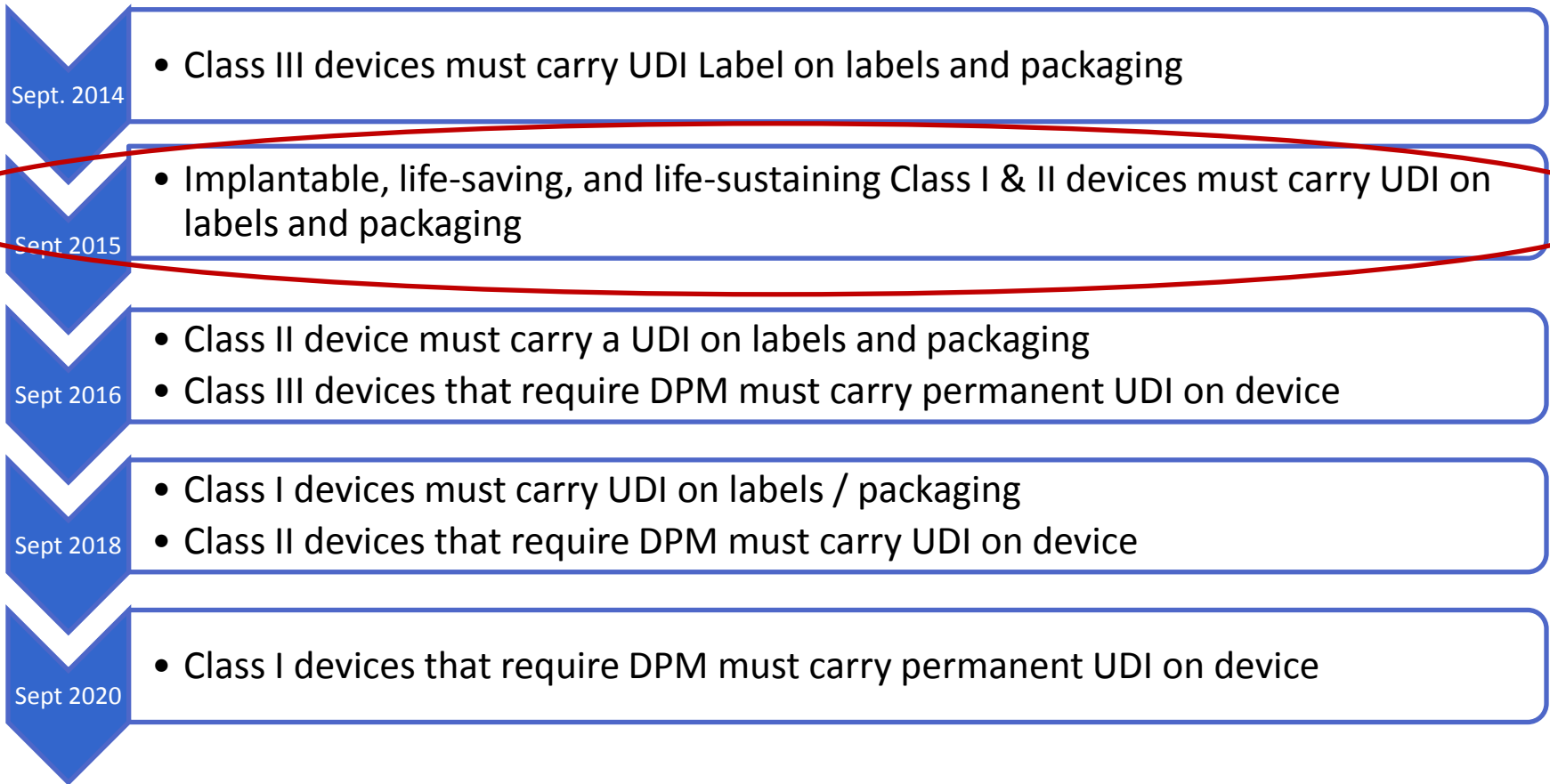
- The actual unique identifier
- The carrier label with human readable and machine readable formats
- The global Database



DI = Device Identifier
PI Product Identifier

AIDC = Automatic Identification and Data Capture
HRI = Human Readable Interpretation

UDI Implementation Timeline

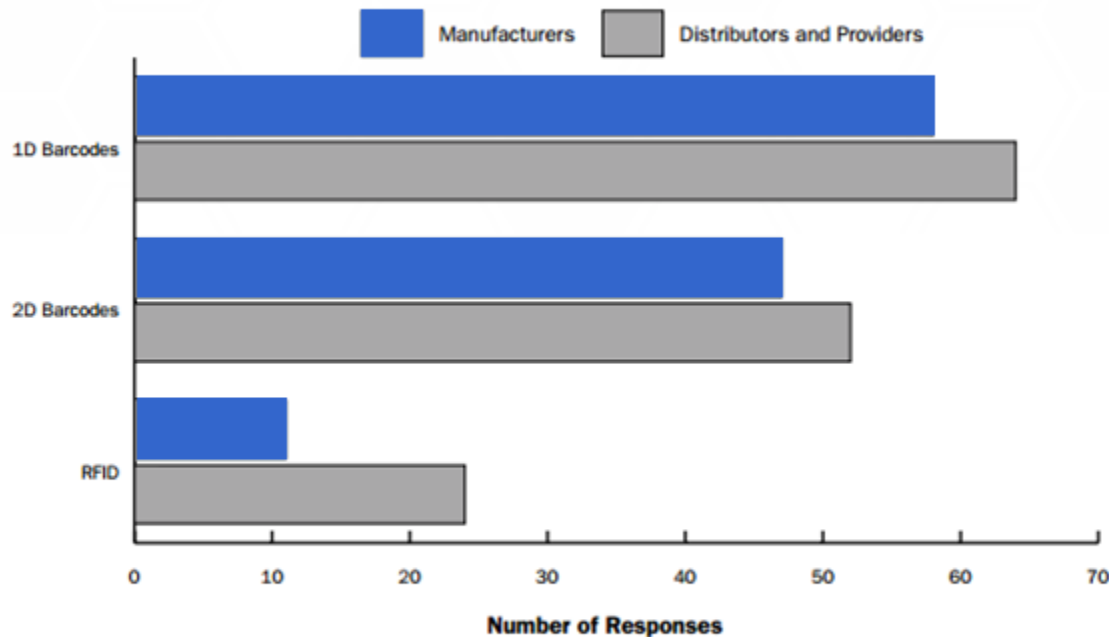


The time to implement has arrived

1-D Code Requirements

Most manufacturers prefer 2-D codes, but continue to rely on 1-D because of supply chain considerations

Figure 17: Survey Responses: What AIDC technology is your organization able to read?



Organization Type	1D Barcodes	2D Barcodes	RFID
Manufacturers	58%	47%	11%
Distributors and Providers	64%	52%	24%

Why 1-D Codes?

- Established infrastructure
- Widely accepted

Why 2-D Codes?

- Small form factor / data density
- Data redundancy / error correction

Data Matrix vs. Code 128

- Data Matrix – Better density, better data redundancy
- Code 128 – Allows alpha numeric characters

Let's add up the information:

GTIN + LOT + EXP + S/N

14 + 7 + 6 + 13 = 40 characters!

Code 128 barcode



0001234567999512ja28a12/20141234567890181

Datamatrix barcode

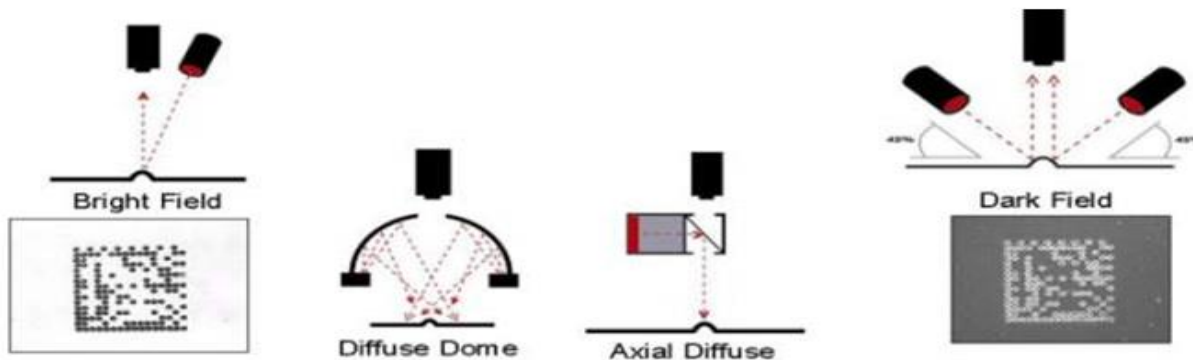


How do we make sure our barcode mark is good?

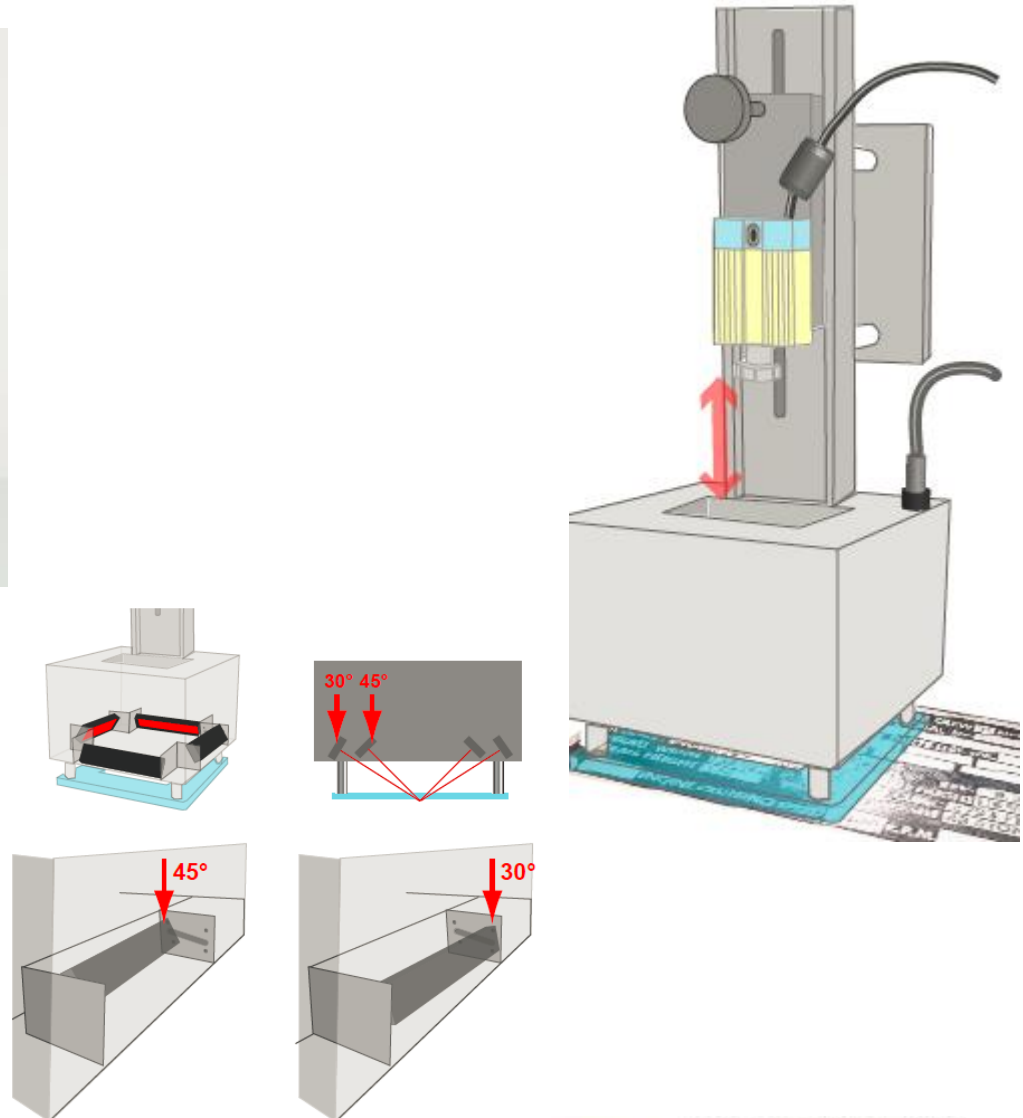
We could follow ISO standards

- ISO 15415 – grade of printed 2D codes
- ISO 15416 – grade of printed 1D codes
- ISO 29158 – grade of DPM/print codes (updated)

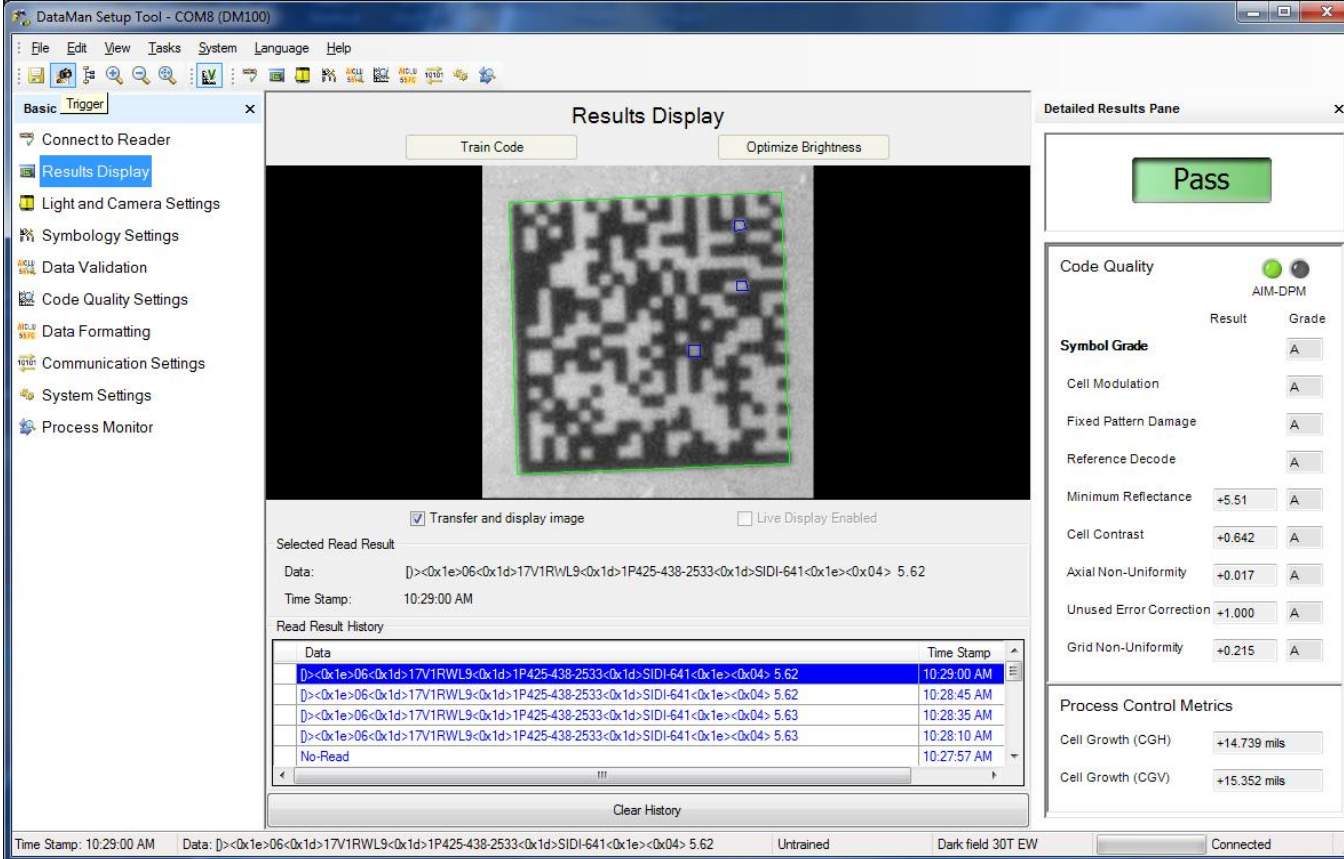
Standards call for “OFFLINE” grading, fixed lighting



DataMan Verifier Systems



DataMan Verification

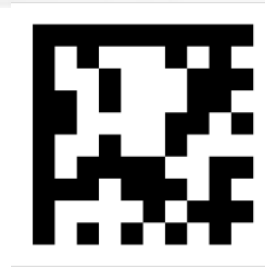
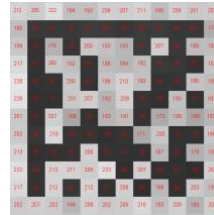


The screenshot displays the DataMan Setup Tool interface. The main window is titled "DataMan Setup Tool - COM8 (DM100)". The interface is divided into several sections:

- Left Panel (Basic Trigger):** Contains a list of settings including Connect to Reader, Results Display (selected), Light and Camera Settings, Symbology Settings, Data Validation, Code Quality Settings, Data Formatting, Communication Settings, System Settings, and Process Monitor.
- Results Display:** Shows a QR code scan with a green bounding box. Above the image are buttons for "Train Code" and "Optimize Brightness". Below the image are checkboxes for "Transfer and display image" (checked) and "Live Display Enabled".
- Selected Read Result:** Displays the current scan data: "Data:]><0x1e>06<0x1d>17V1RWL9<0x1d>1P425-438-2533<0x1d>SIDI-641<0x1e><0x04> 5.62" and "Time Stamp: 10:29:00 AM".
- Read Result History:** A table showing previous scan results.
- Detailed Results Pane:** Shows a large green "Pass" button and various quality metrics.
- Bottom Status Bar:** Displays "Time Stamp: 10:29:00 AM", "Data:]><0x1e>06<0x1d>17V1RWL9<0x1d>1P425-438-2533<0x1d>SIDI-641<0x1e><0x04> 5.62", "Untrained", "Dark field 30T EW", and "Connected".

Data	Time Stamp
]><0x1e>06<0x1d>17V1RWL9<0x1d>1P425-438-2533<0x1d>SIDI-641<0x1e><0x04> 5.62	10:29:00 AM
]><0x1e>06<0x1d>17V1RWL9<0x1d>1P425-438-2533<0x1d>SIDI-641<0x1e><0x04> 5.62	10:28:45 AM
]><0x1e>06<0x1d>17V1RWL9<0x1d>1P425-438-2533<0x1d>SIDI-641<0x1e><0x04> 5.63	10:28:35 AM
]><0x1e>06<0x1d>17V1RWL9<0x1d>1P425-438-2533<0x1d>SIDI-641<0x1e><0x04> 5.63	10:28:10 AM
No-Read	10:27:57 AM

Metric	Value
Code Quality	AIM-DPM
Symbol Grade	A
Cell Modulation	A
Fixed Pattern Damage	A
Reference Decode	A
Minimum Reflectance	+5.51 A
Cell Contrast	+0.642 A
Axial Non-Uniformity	+0.017 A
Unused Error Correction	+1.000 A
Grid Non-Uniformity	+0.215 A
Cell Growth (CGH)	+14.739 mils
Cell Growth (CGV)	+15.352 mils



AIM DPM Metrics

- **Decodability** – pass / fail on decode
- **Cell Contrast** – difference in the means
- **Cell Modulation** – greyscale analysis of data region. Grid centers that approach GT will lower CM score
- **Fixed Pattern Damage** – greyscale analysis of finder + QZ. Grid centers that approach GT will lower CM

AIM DPM Metrics

- **Grid Non-Uniformity** – qualifies the module placement by comparing to a nominal evenly spaced grid
- **Axial Non-Uniformity** – Describes grid squareness
- **Unused Error Correction** – Binary analysis of bit errors
- **Minimum Reflectance** – Ensure a minimum reflectance level
- **Final Grade** – Equal to lowest individual metric score

DataMan Verification

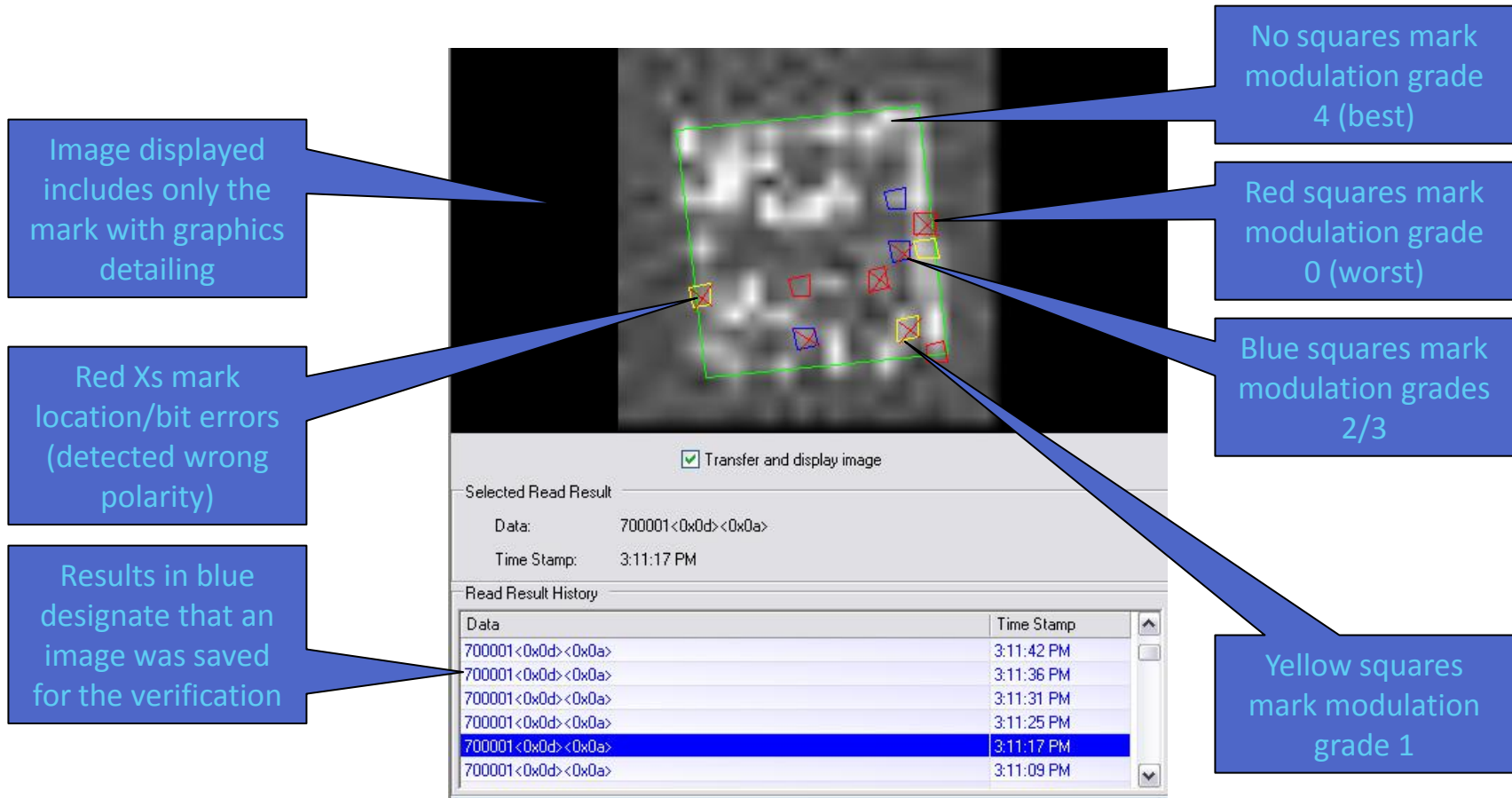


Image displayed includes only the mark with graphics detailing

Red Xs mark location/bit errors (detected wrong polarity)

Results in blue designate that an image was saved for the verification

No squares mark modulation grade 4 (best)

Red squares mark modulation grade 0 (worst)

Blue squares mark modulation grades 2/3

Yellow squares mark modulation grade 1

Transfer and display image

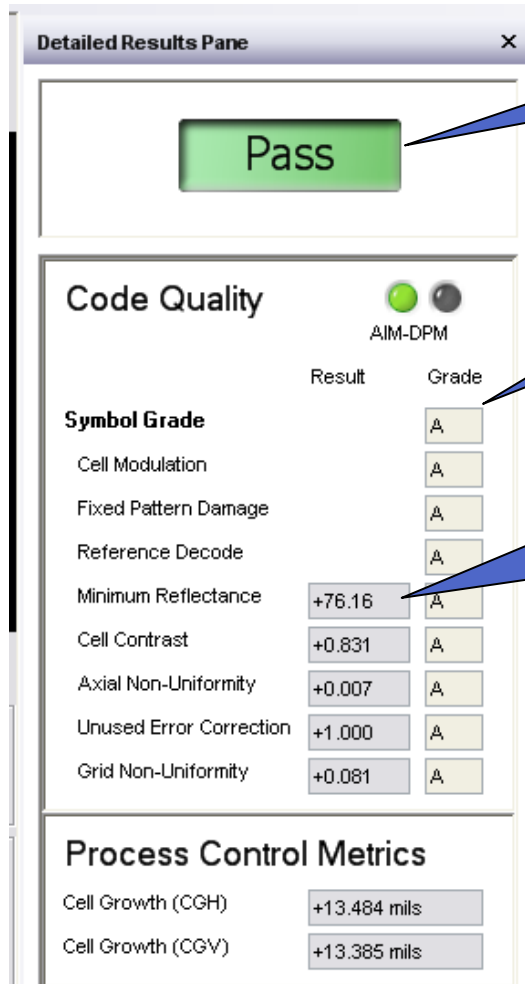
Selected Read Result

Data: 700001<0x0d><0x0a>

Time Stamp: 3:11:17 PM


Read Result History

Data	Time Stamp
700001<0x0d><0x0a>	3:11:42 PM
700001<0x0d><0x0a>	3:11:36 PM
700001<0x0d><0x0a>	3:11:31 PM
700001<0x0d><0x0a>	3:11:25 PM
700001<0x0d><0x0a>	3:11:17 PM
700001<0x0d><0x0a>	3:11:09 PM



Detailed Results Pane [X]

Pass

Code Quality 

AIM-DPM

	Result	Grade
Symbol Grade		A
Cell Modulation		A
Fixed Pattern Damage		A
Reference Decode		A
Minimum Reflectance	+76.16	A
Cell Contrast	+0.831	A
Axial Non-Uniformity	+0.007	A
Unused Error Correction	+1.000	A
Grid Non-Uniformity	+0.081	A

Process Control Metrics

Cell Growth (CGH)	+13.484 mils
Cell Growth (CGV)	+13.385 mils

Final verification result

Individual grades

Individual metrics returned for the mark in current verification

DataMan Verification

Decoded images

Save in: C:\Documents and Settings\mperez

Prefix filename with

Report Storage

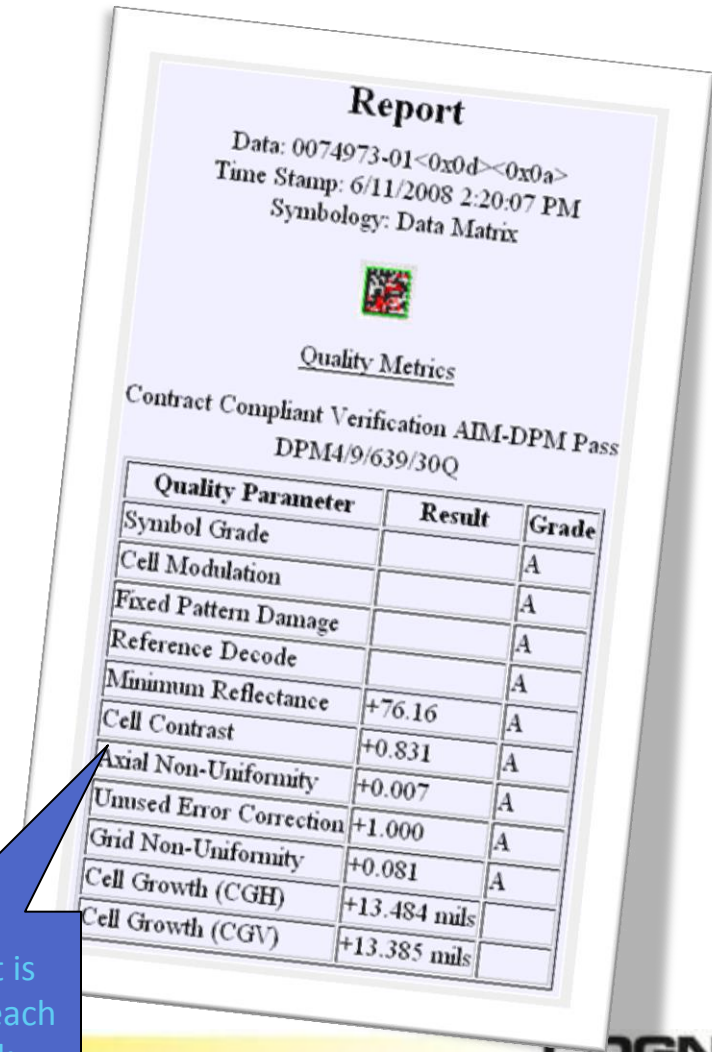
Save in: C:\Documents and Settings\mperez

Filename Structure: Include timestamp

Prefix filename with

Disable overlay graphics in report

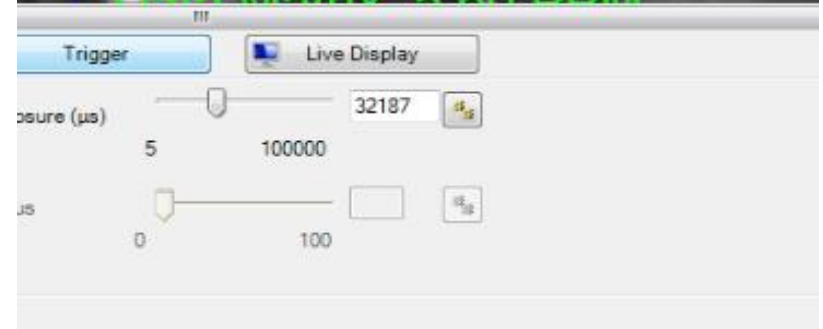
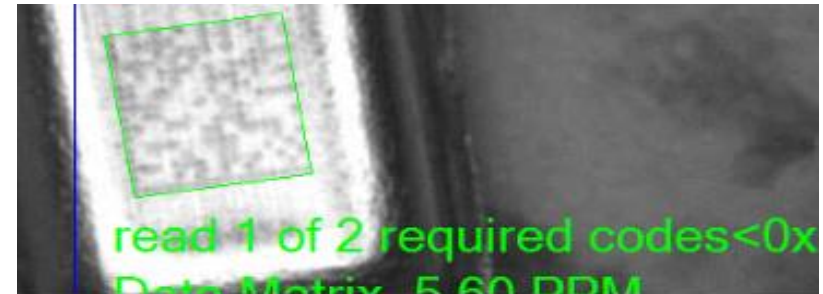
Allows verification reports to be automatically generated



Unique report is generated for each verified mark

Still want to grade but “ONLINE”?

Use process metrics to give feed back on when code is degrading



fixedPatternDamage = F (0.00) gridNonUniformity = A (0.232)

fixedPatternDamage = F (0.00) gridNonUniformity = A (0.222)

by = A (0.232) <0x0d><0x0a>

= A (0.222) <0x0d><0x0a>

Serialization on a Typical Packaging Line

Off-Line Data Matrix Quality Verification



GTIN 00012345679995
LOT 10JA28A
EXP 12/2012
S/N 1234567890180

Read Carton Code
Grade Code
Verify Printed Text



Read Codes in Bundle



Read Bundle Code



Read Case Code



Read Pallet Code



Print Carton Code
And Human Readable Data



Print Bundle Code



Print Case Code



Print Pallet Code



COGNEX

DATAMAN

Handheld Readers



Fixed Mount Readers



Verifiers



Rugged, lightweight design with liquid lens variable focus

DATAMAN

Handheld Readers



Fixed Mount Readers



Verifiers



Small size and ultra high performance

DATAMAN

Handheld Readers



Fixed Mount Readers



Verifiers



Handheld and Fixed Mount verifiers designed to ensure every code meets manufacturer's and industry standards

In-Sight Track & Trace – UDI Solution



COGNEX

In-Sight® Track & Trace

Off-the-shelf “Job File” for In-Sight Vision Systems

- No programming required
- Easy to use
- Step-by-step setup

Optimized for Serialization Applications

- Uses industry standards (e.g. GS1)
- IPsec to prevent data theft

Simplifies Validation Procedures

- User access control
- Parameter change & event logging
- FS/DS & IQ/OQ Templates



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Customer Success Stories

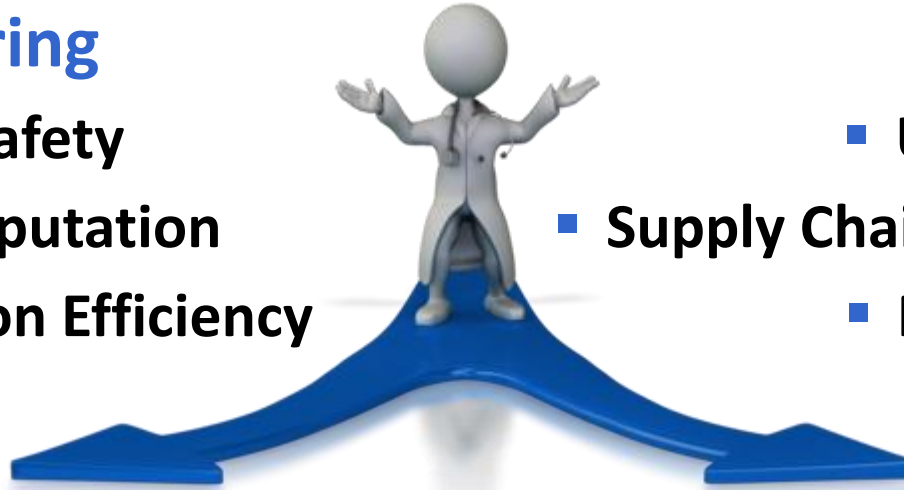


Manufacturing

- Patient Safety
- Brand Reputation
- Production Efficiency

Traceability

- UDI Compliance
- Supply Chain Management
- Recall Efficiency



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Questions and Answers



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