



Barcode quality considerations for
packaging requiring serialisation or UDI



Agenda Topics

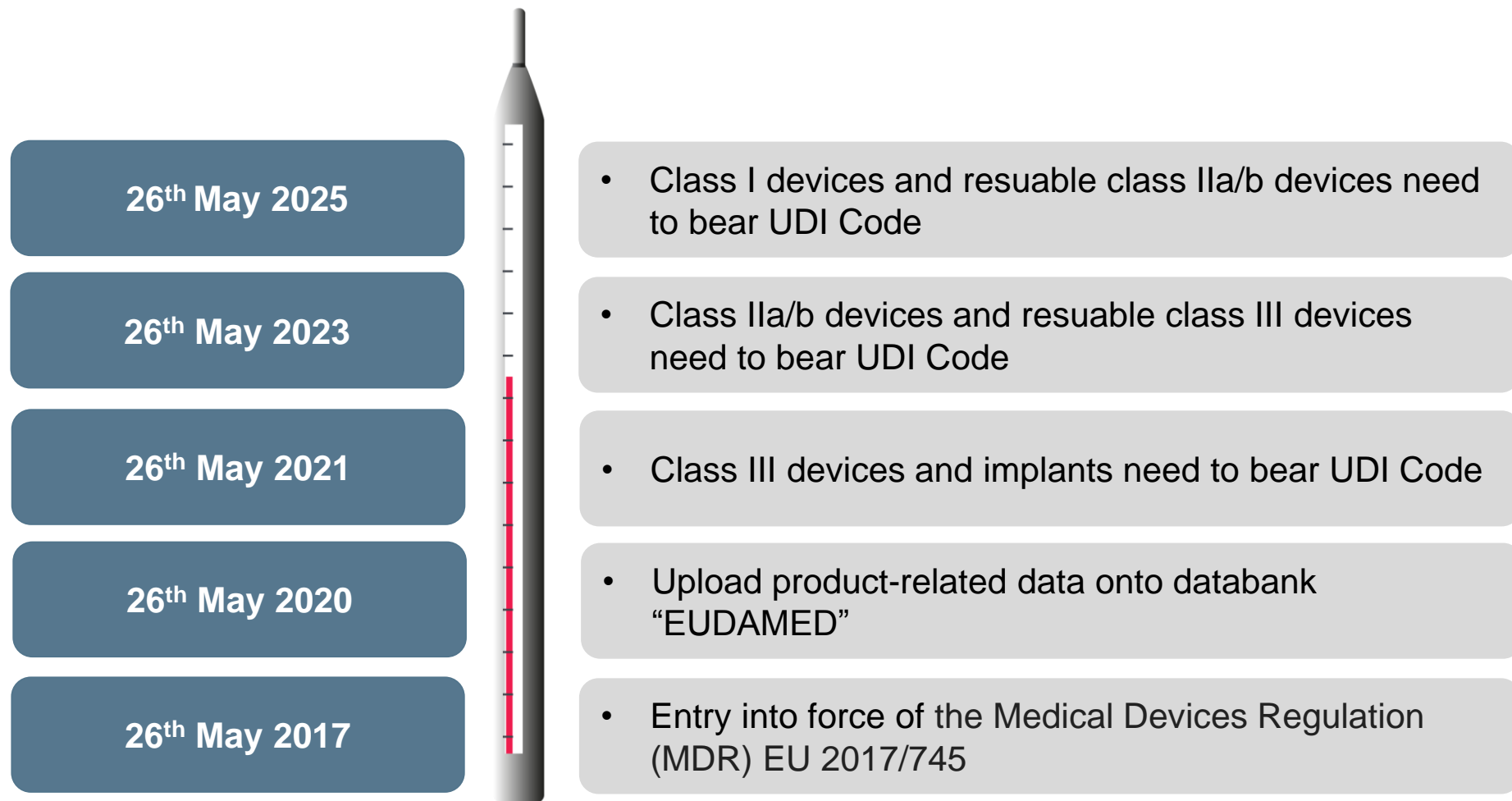
1. Medical Device Regulation (MDR) in Europe

2. Key influences on barcode quality

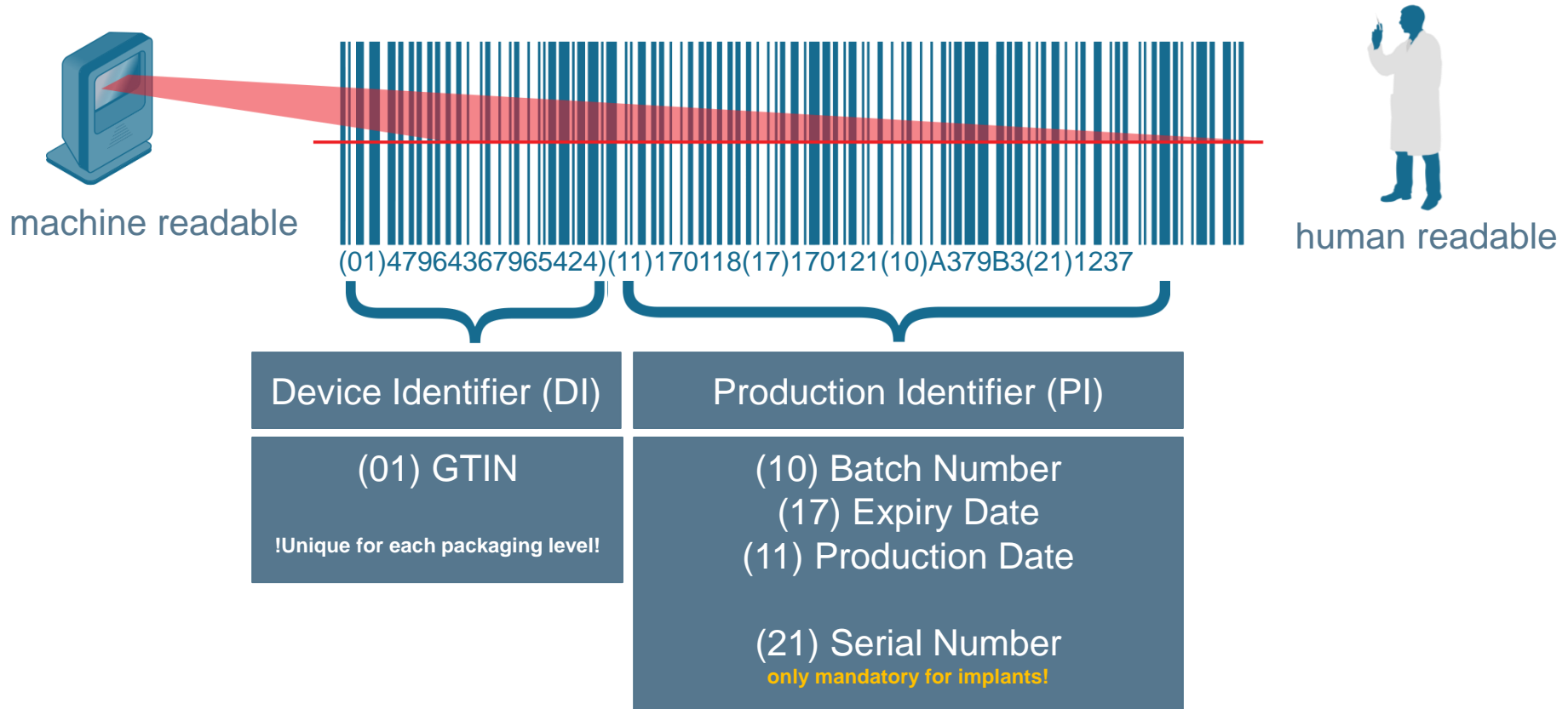
3. ISO 15415 – Parameters measured, causes & optimization

4. Testing quality – How do you ensure and test the quality of codes?

Timeline Medical Device Regulation (MDR)



Details UDI



Where to place UDI?

- ✓ „UDIs shall be placed on the label of the device and on all higher packaging levels”
- ✓ If limited space, then Human Readable Text is optional and to be placed on next packaging level
- ✓ Should always include barcode (linear or 2D), RFID is optional
- ✓ Issuing agencies: GS1, HIBCC, ICCBAA
- ✓ Should be obvious which barcode to scan

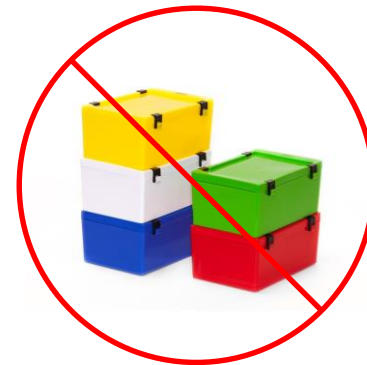
Exceptions



Medical disposables that are individually packed, need to bear an **UDI code on the next packaging level**



If the UDI carrier is scannable through the device's packaging, **an UDI code on the packaging is not required.**

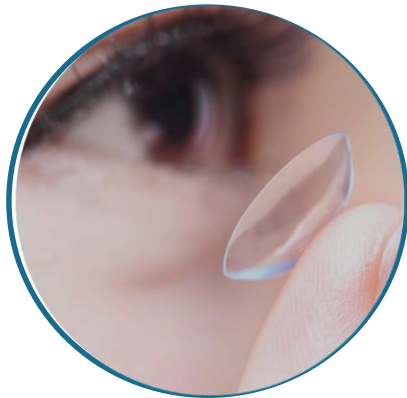


No UDI on
Shipping containers

Exceptions for reusable devices




Reusable devices need to bear the UDI directly on the device



If it restricts the functionality or safety of the reusable device, the **UDI code can be placed on the next packaging level**



If the reusable device is too small to be coded, the **UDI code can be placed on the next packaging level**

A female scientist with dark hair, wearing a white lab coat and clear safety goggles, is focused on her work in a laboratory. She is holding a black tube that leads into a large Erlenmeyer flask. A metal funnel is positioned over the neck of the flask. The background shows shelves with various white bottles and other laboratory equipment. The lighting is warm and focused on the scientist.

What is the formula
for applying a
high-quality barcode?

Key influences on barcode quality



Printing technology



Ink quality



Printing parameters



Carton quality



Production Environment

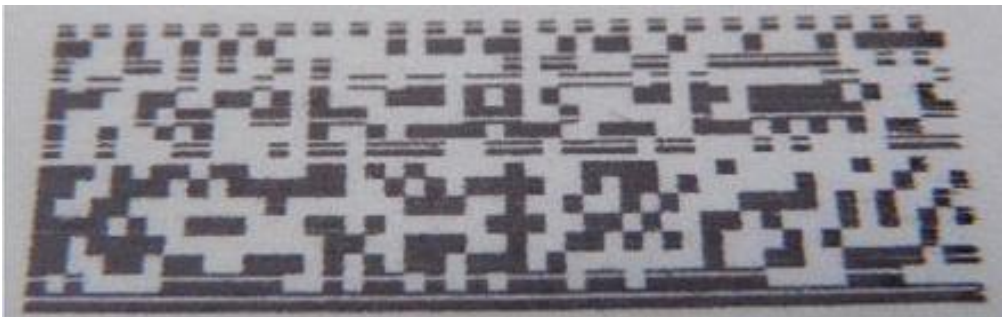


Line integration



Example – Thermal Inkjet Printing

- Defective or blocked nozzle
 - Dust
 - Air in the cartridge
 - Electro static build up
- Dirty contact pads of the ink cartridge



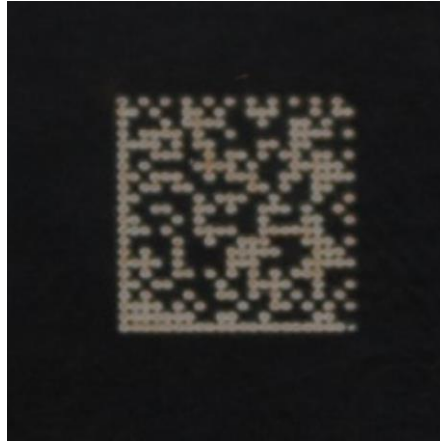
A non electrostatic and dust free environment is key for superior code quality

Example – Laser marking

Optimum wavelength for code superiority




9,3 μ m
wavelength



10,6 μ m
wavelength

- Same carton quality
- Same laser type
- Same laser power

Low contrast =
Poor camera readability

A black and white photograph of a man in a white lab coat and hairnet, focused on a laptop. He is in a laboratory or cleanroom environment, with various equipment and materials visible in the background. The image is used as a background for a text overlay.

ISO/IEC 15415/15416
Parameters measured,
causes & optimization

Quality of UDI according to MDR

4.11. The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device.

Medical Device Regulation (EU) 2017/745, Annex VI – Part C

- Very basic and general info
- What is readable?
- How to test ?
- What does this mean in Praxis?

EU FMD – Quality Requirements



Packaging requirements

- ✓ Manufacturers shall print the barcode on the packaging on a smooth, uniform, low-reflecting surface



Readability requirements

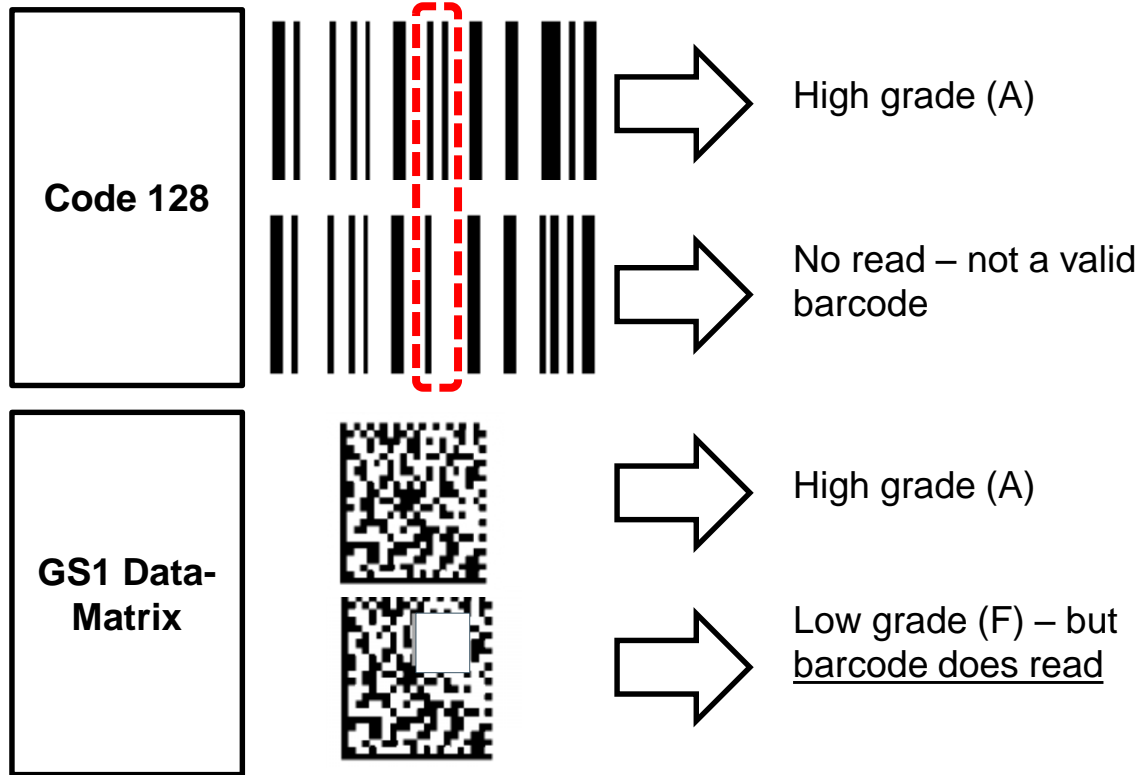
- ✓ Readability of the Data Matrix throughout the supply chain until at least one year after the expiry date of the pack or five years after the pack has been released for sale
- ✓ Ensure that the structure and printing quality of the two-dimensional barcode allow for high-speed reading and minimization of reading errors.
- ✓ A quality of printing rated at least 1.5 in accordance with ISO/IEC 15415:2011

Why preference for Datamatrix

- Compact size
- High data carrying capacity
- More robust than 1D codes
- Embedded error correction / redundancy
- Very common in pharma
- Can be read with low cost optical imagers



Other Datamatrix Advantages



can be critical when printing on uneven surfaces

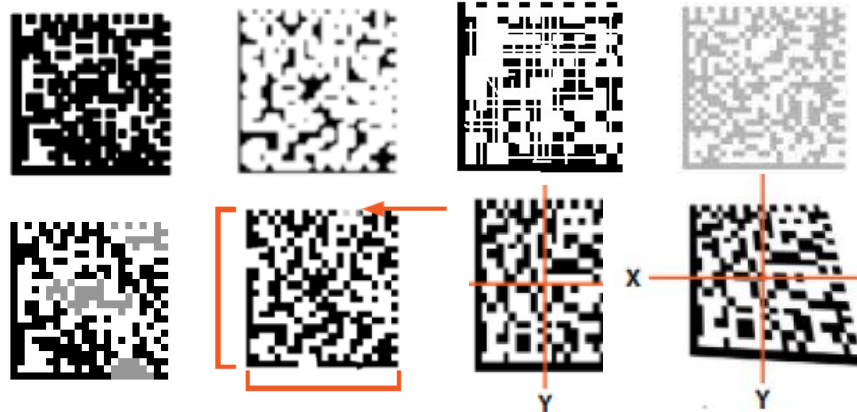
ISO/IEC 15415 Parameters

ISO/IEC 15415 standard identifies methods to evaluate, measure and grade the quality of 2D and stacked symbols.

2D-Code quality grading is based on 7 Parameters:


Is the code readable? Does it correspond to the required data structure?
Defined in ISO/IEC16022.

1. Print Growth or Print Loss
2. Unused Error Correction
3. Symbol Contrast
4. Modulation
5. Fixed Pattern Damage
6. Axial Non-Uniformity
7. Grid Non-Uniformity




ISO/IEC 15415 Basic Principles

- The measurement must always be carried out at standstill, processes in the run do not meet the ISO requirements
- The OVERALL grade is the lowest grade achieved, 4 being the best and 0 the worst
- The verifier process should be fully compliant and in accordance with standard ISO/IEC15426-2



ISO/IEC-Grade	ANSI-Grade	Multiple <u>measurements</u>	<u>Result</u>
4	A	3,5 - 4,0	<u>Very good</u>
3	B	2,5 - 3,49	<u>Good</u>
2	C	1,5 - 2,49	Medium
1	D	0,5 - 1,49	<u>Acceptable</u>
0	F	< 0,5	Bad



Causes for low grade results

Parameter

Decode Unused Error Correction
(01)09501101020917(17)190508(10)ABCD1234(21)10
FNC101095011010209171719050810ABCD1234FNC12110

Possible causes for low results

- Barcode software tool creation issues
- Wrong selection of barcode format by designer
- Non complying to GS1 standards for structure of barcode
- Quiet zone violations
- Malfunctioning of verifier

Fixed Pattern Damage



- Blocked or defective nozzle
- Defective printhead, pads, pins
- Damage to material
- Particles in material

Causes for low grade results

Parameter

Symbol contrast



Possible causes for low results

- Material background is too dark versus barcode printed
- Glossy material causing reflection
- Ink color gives not enough contrast
- Too low DPI used, not enough ink used
- Incorrect illumination angle

Modulation

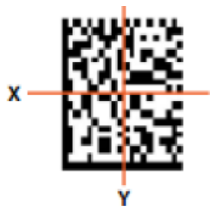


- Ink Absorption of the material
- Dot size
- Blocked nozzles
- Incorrect marking distance

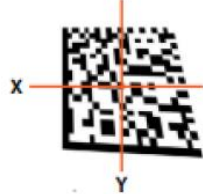
Causes for low grade results

Parameter

Axial non-uniformity



Grid non-uniformity



Print growth



Print loss

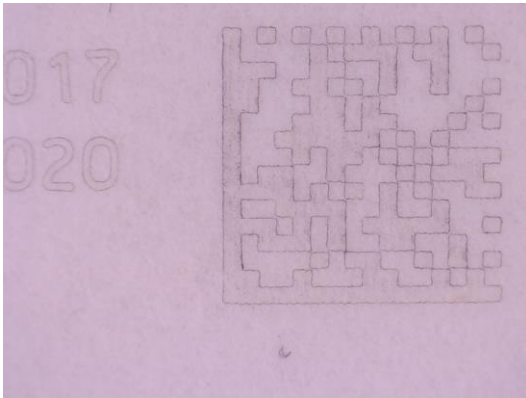


Possible causes for grade results

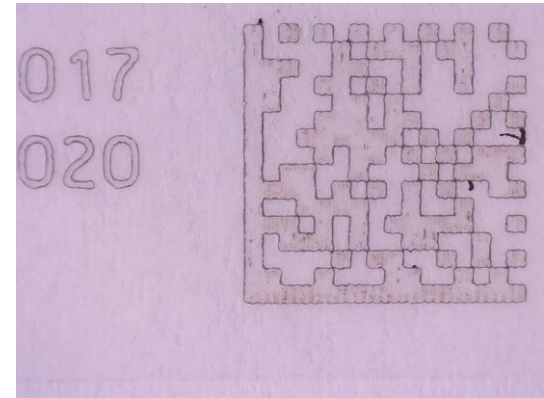
- Varying line speed
 - Printing software error
 - Vibration
 - Varying distance between material and printhead
 - Poor integration of printing technology
-
- Ink Absorption of the material
 - Dot size
 - Blocked nozzles
 - Incorrect marking distance

Example – Laser marking

Same parameters used
for both carton qualities,
different result



- Videojet VJ3640
- 60W CO2 laser
- Wavelength of 9,3μm
- Lens of f=150 mm
- Lenshead type SHC100C



Certain carton types
generate more dust

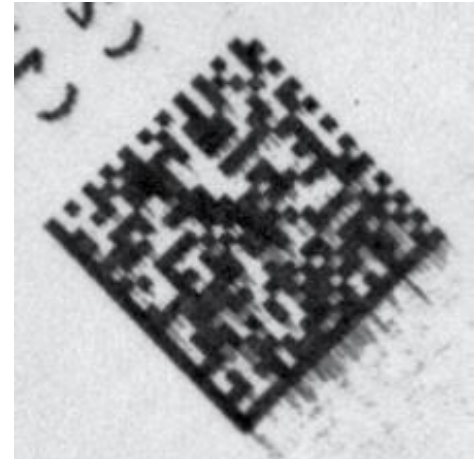
Example – Thermal Inkjet Printing



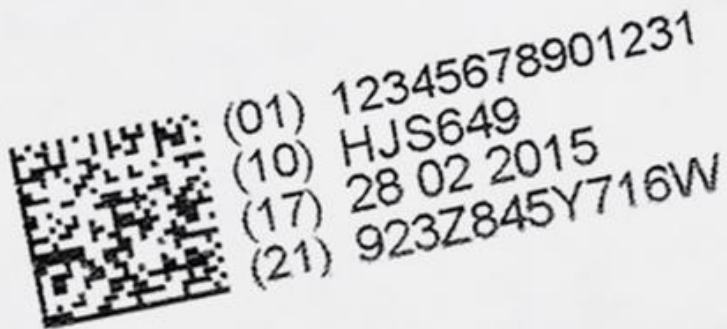
Possible causes or combinations of

- Carton quality
- Ink quality
- Environment
- Line integration
- Settings

Combination of causes
could be resulting in
poor barcode quality



How to ensure that durable, high-quality codes are applied?



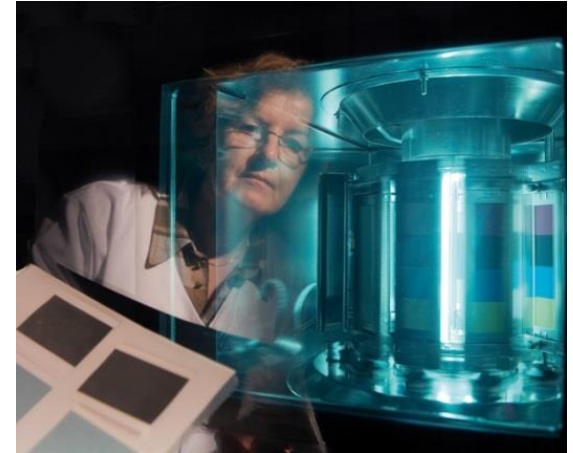
Testing your code

Help customers to

- achieve code superiority
- be compliant with code readability requirements
- avoid recalls derived from poor code quality

Provide a service to find optimum combination of

- coding technology
- parameter settings
- ink quality
- carton quality



+



=



Which tests can be performed?



Thermal Inkjet



Laser Marking



Thermal Transfer
Overprinter



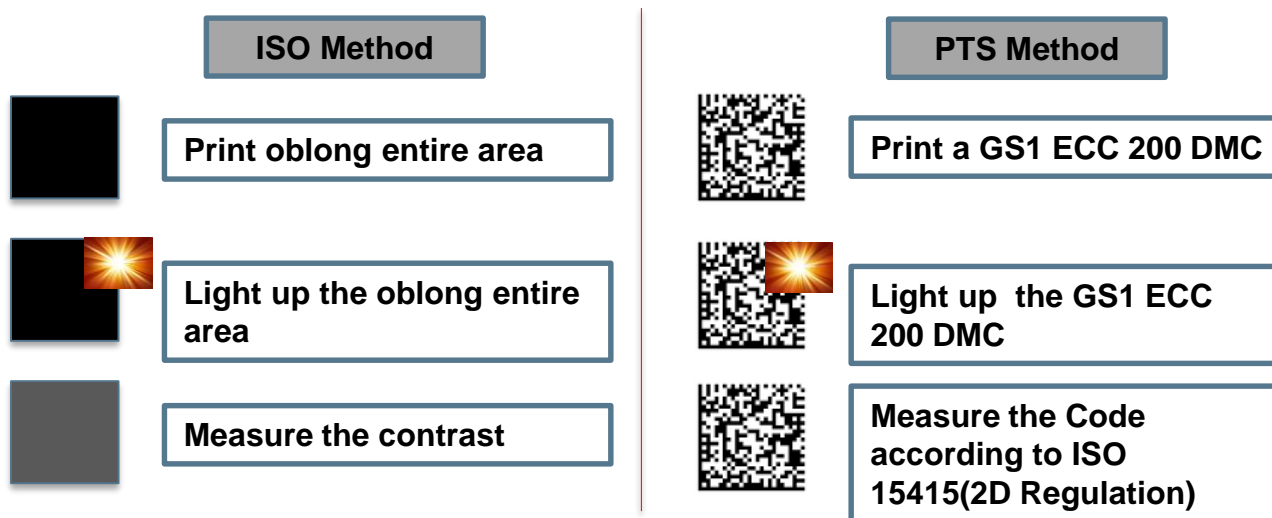
Continuous
Inkjet

- Lightfastness (DIN-EN ISO 105 – Bo2)
- Water Resistance according to ISO 18935
- Abrasion (200 strokes), Rub resistance
- Drying time according to PTS-DF 103/2011
- Code Quality according to ISO/IEC 15415 & ISO/IEC 15416

Amended measuring method for light fastness test

Main difference before...

- Original ISO Standards were developed in the seventies for the Graphic Industry
- Comparison to the Wool Scale Range
- Black entire areas are printed



Relevant findings on dry time and wipe resistance

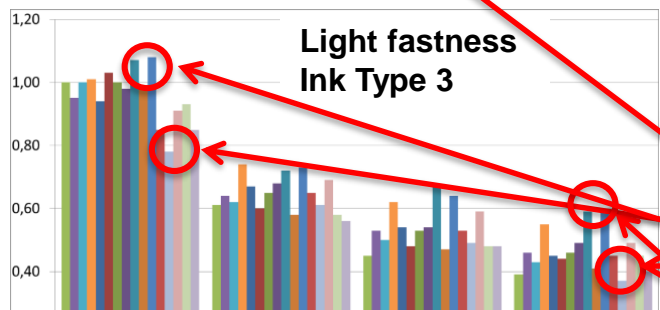
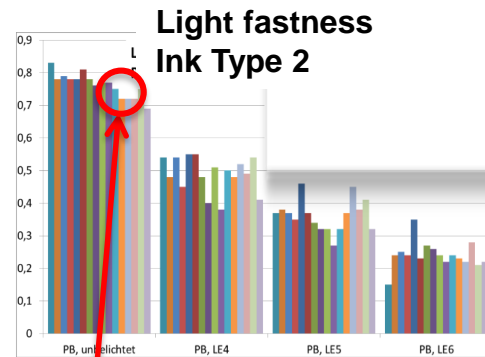
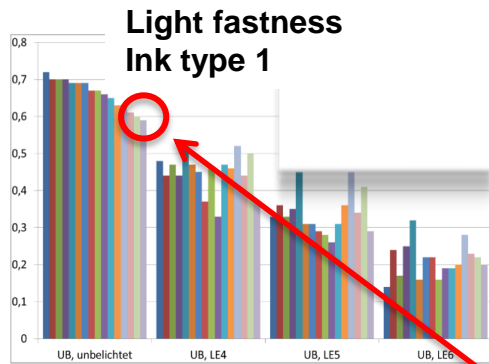
300 dpi with ink Universal Black WLK667482 (UB)												
No.	w/o wipe-test			wt after 0.3 sec			wt after 0.5 sec			wt after 0.7 sec		
	grading/contrast			grading/contrast			grading/contrast			grading/contrast		
1	3,0	B	0,651	3,0	B	0,631	3,0	B	0,651	-	-	-
2	3,0	B	0,659	3,0	B	0,639	3,0	B	0,647	-	-	-
3	3,0	B	0,667	0,0	F	0,604	0,0	F	0,627	0,0	F	0,647
4	3,0	B	0,678	0,0	F	0,667	3,0*	B	0,678	3,0	B	0,667
5	3,0	B	0,639	3,0	B	0,631	3,0	B	0,635	-	-	-
6	3,0	B	0,639	1,0	D	0,635	3,0*	B	0,643	3,0	B	0,639
7	3,0	B	0,647	3,0*	B	0,678	3,0	B	0,647	-	-	-
8	3,0	B	0,655	2,0	C	0,643	3,0	B	0,651	-	-	-
9	3,0	B	0,651	0,0	F	0,616	1,0	D	0,631	3,0	B	0,635

300 dpi with ink Premium Black WLK660068 (PB)												
No.	w/o wipe-test			wt after 0.3 sec			wt after 0.5 sec			wt after 0.7 sec		
	grading/contrast			grading/contrast			grading/contrast			grading/contrast		
1	4,0	A	0,737	4,0	A	0,725	4,0	A	0,733	-	-	-
2	4,0	A	0,745	2,0	C	0,741	3,0	B	0,741	3,0	B	0,757
3	4,0	A	0,757	0,0	F	0,698	0,0	F	0,733	0,0	F	0,749
4	4,0	A	0,761	0,0	F	0,753	0,0	F	0,749	3,0	B	0,765
5	4,0	A	0,729	3,0	B	0,722	4,0	A	0,718	-	-	-
6	4,0	A	0,722	0,0	F	0,722	3,0	B	0,722	3,0	B	0,725
7	4,0	A	0,733	1,0	D	0,733	3,0	B	0,741	4,0	A	0,753
8	4,0	A	0,741	2,0	C	0,737	4,0	A	0,737	-	-	-
9	4,0	A	0,733	0,0	F	0,702	1,0	D	0,729	3,0	B	0,725

- Without wipe test all carton qualities tested passed grading test.
- Varying results including wipe test
- Higher pigmented ink gives better grading results

Relevant findings on light fastness

Light fastness (DIN EN ISO 105-B02)



Contrast-range:

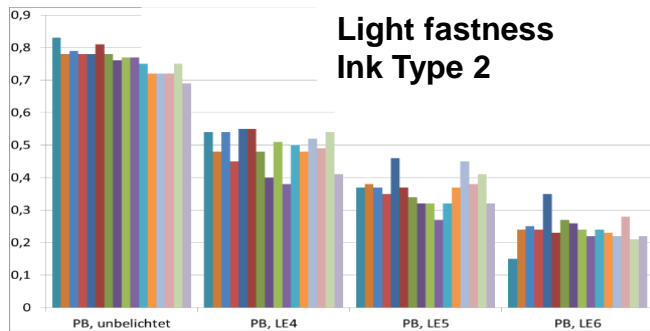
0.59-1.07 (based on ink)

0.78-1.07 (based on paper)

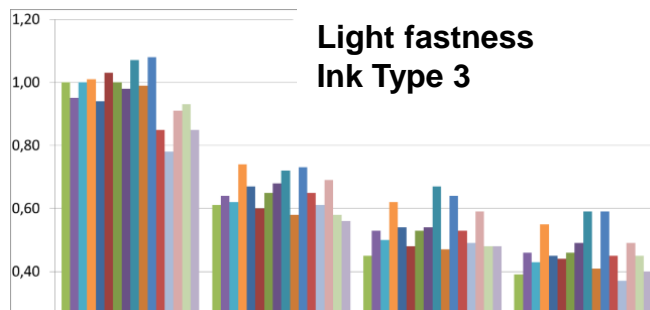
0.38-0,59 (Light Exposure level 6/LE6)

Relevant findings on light fastness

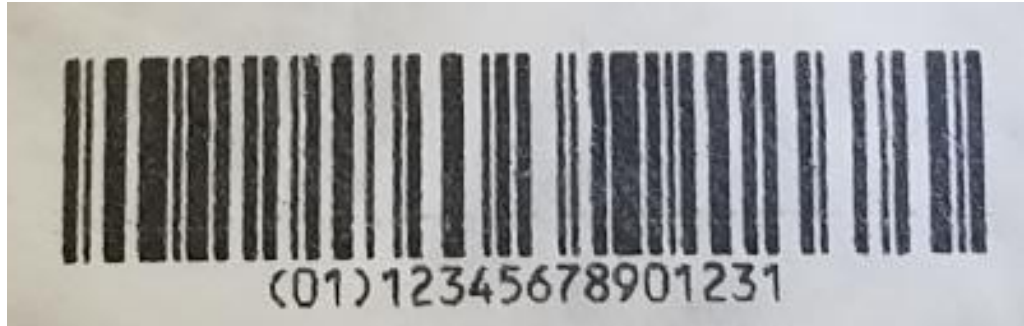
Light fastness (DIN EN ISO 105-B02)



- Higher pigmented ink enables better Contrast results
- Paper quality is highly relevant for Contrast result
- Best combination of Paper & Ink is key „to ensure readability of coding over the required time“



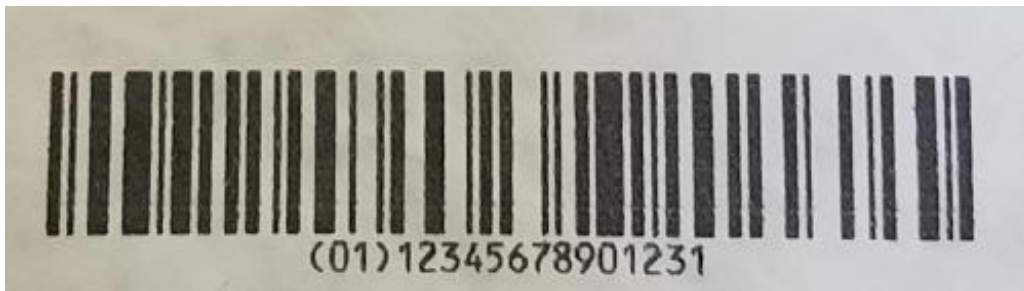
Example – Thermal Inkjet marking



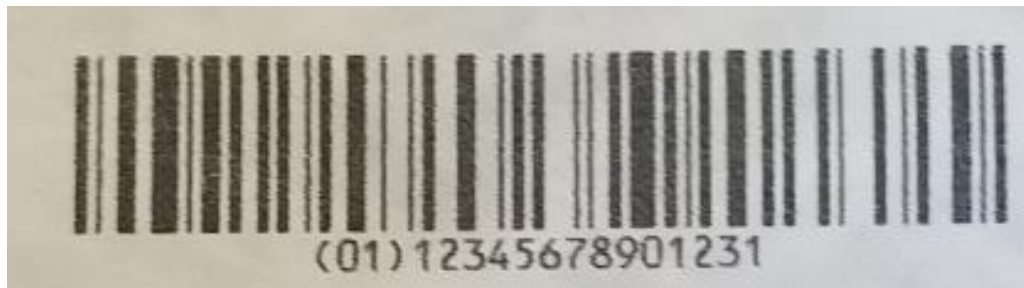
Same ink

Same Tyvek material

Playing with varying DPI resolution



Porous material
creates higher risk for
ink to bleed



Example – Laser marking



Same parameters used for both carton qualities, different result

- Videojet VJ3640
- 60W CO2 laser
- Wavelength of 9,3 μ m
- Lens of f=150 mm
- Lenshead type SHC100C



Carton type impacts
barcode quality

Wrap up

VIDEOJ



Videojet Pharma Line App

- Easy access to helpful resources
 - case studies
 - white papers
 - specification sheets and
 - application videos
- Find you nearest Videojet contact
 - no matter where you are



Thank you for your interest!

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