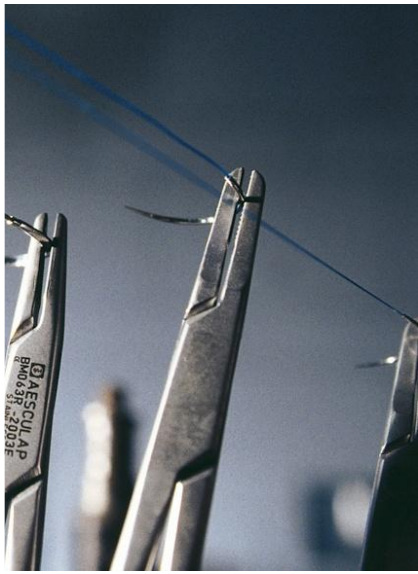




Direct Part Marking

Georg Keller, Aesculap Regulatory Affairs

Amsterdam, October 5th ,2011

B BRAUN
SHARING EXPERTISE

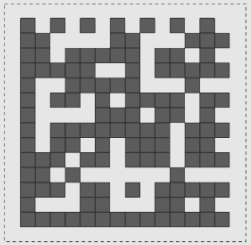
Agenda

- Overview Data Matrix: Structure and Content
- Pro’s and Con’s of the Data Matrix
- Technical Limits and Solutions

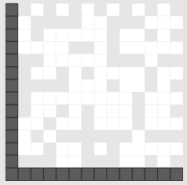
Overview Data Matrix: Structure and Content

A Data Matrix Code consists out of 4 Main Components

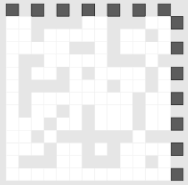
1. Solid Border
2. Broken Border
3. Data Storage
4. Quiet Zone



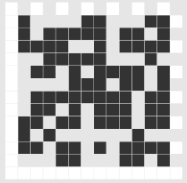
Data Matrix symbol shown complete



Solid Border



Broken Border



Data Storage

Overview Data Matrix: Structure and Content

BC579R-17G9C
AESCULAP Artikelnummer
Individueller Anteil

12 Digits, alpha numeric

current content at AESCULAP:
Article number followed by a dash and a 5-digit individuell part (SerialNumber)

2.5 mm

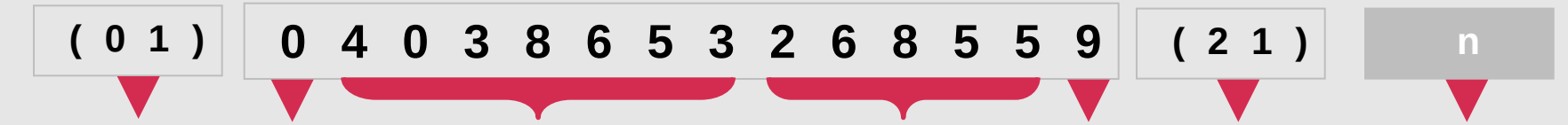
2.5 mm

x-module 0.15 mm

symbol size 16 (row/column)

Overview Data Matrix: Structure and Content

sGTIN:



sGTIN with minimum 25 Digits → Size of Data Matrix is changing

Structure sGTIN
GTIN followed by Serial Number

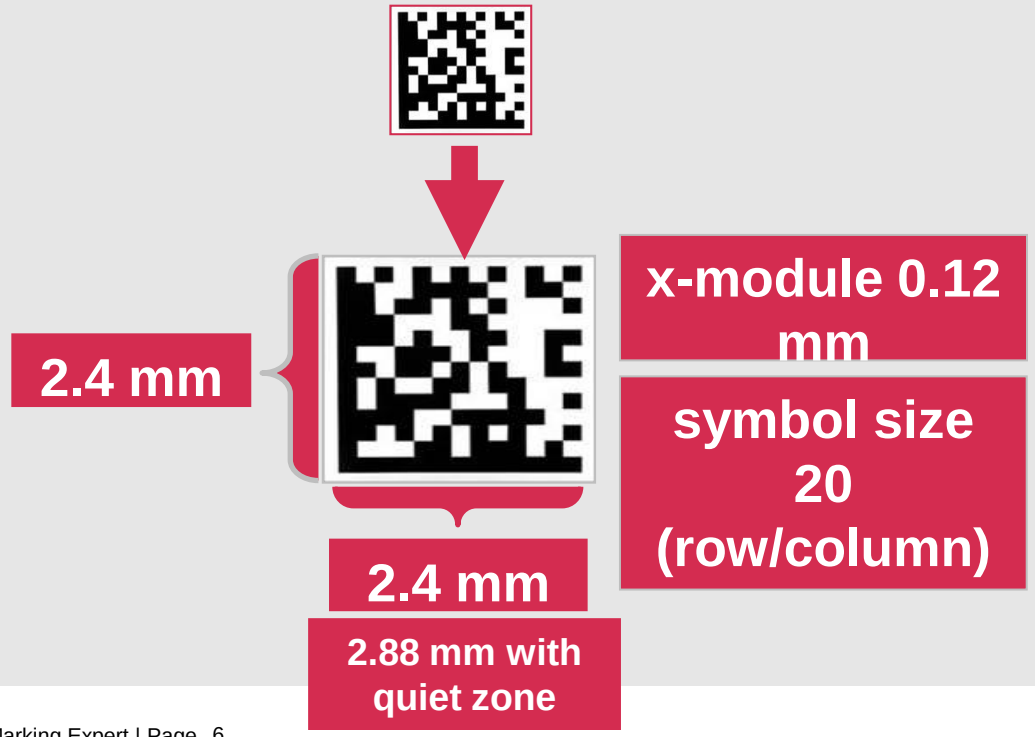
Advantage of sGTIN:
international harmonized System, which guarantees that the Serial Number is only used once worldwide

Overview Data Matrix: Structure and Content

sGTIN

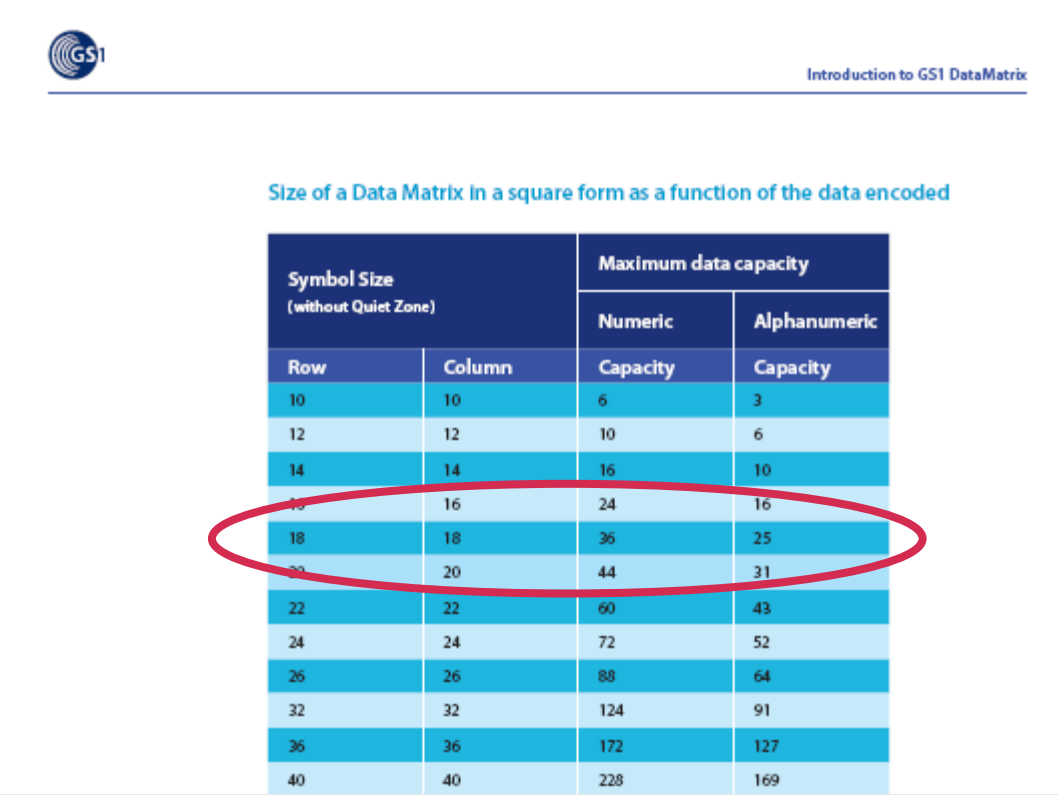
(0 1)	0 4 0 3 8 6 5 3 0 2 0 7 2 0	(2 1)	BH111R-A0001
Application Identifier	Start digit + Manufacturer Code + Article number + Check digit	Application Identifier	Serial number

Goal:



Overview Data Matrix: Structure and Content

Size of the Data Matrix in relation to the Content:



Introduction to GS1 DataMatrix

Size of a Data Matrix in a square form as a function of the data encoded

Symbol Size (without Quiet Zone)		Maximum data capacity	
		Numeric	Alphanumeric
Row	Column	Capacity	Capacity
10	10	6	3
12	12	10	6
14	14	16	10
[illegible]	16	24	16
18	18	36	25
[illegible]	20	44	31
22	22	60	43
24	24	72	52
26	26	88	64
32	32	124	91
36	36	172	127
40	40	228	169

Overview Data Matrix: Structure and Content

XX000R-60001

Human Readable Serial Number!!!

Overview Data Matrix: Structure and Content

Size of the Data Matrix in relation to the module size:

Current Marking:

Module Size 0.15mm → with Code 16*16 Code size 16*0.15mm + 2*10% quiet zone = 2.4mm + 0.48mm = **2.88mm**

Future Marking:

Module Size 0,12mm → with Code 20*20 Code size 20*0.12mm + 2*10% quiet zone = 2.4mm + 0.48mm = **2.88mm**

Pro's and Con's of the Data Matrix

Positive

- existing and used technology
- can be marked without additional costs
- redundant data storage→ still readable if 25% are destroyed
- in comparison to 1D codes very small codes are possible

Negative

- Optical system → sensitive on altering surface and scretches
- the smaller the code better solutions of the camera are required (6 pixel per module)
- requires surface and quiet zone
- gets lost by re-working the surface
- no bulk reading possible

Technical Limits and Solutions

Shelf-Life (Durability)

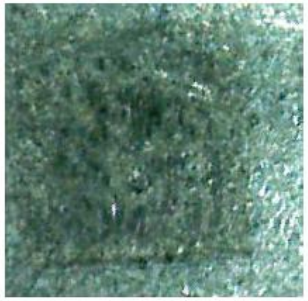
Limits

- fading by chemicals in the re-processing process
- destroyed by scretches
- reduced readability due of wear

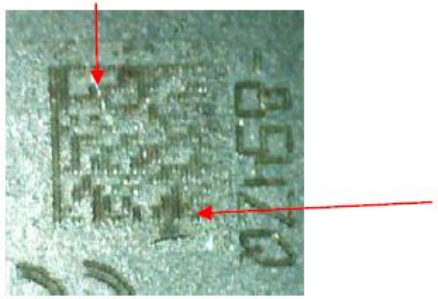
Solutions

- adjusted marking parameters
- proper storage at the end user

- Excessive surface wear



- Scratches

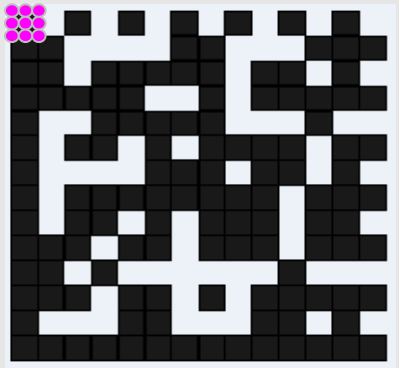


Technical Limits and Solutions

Resolution

Limit

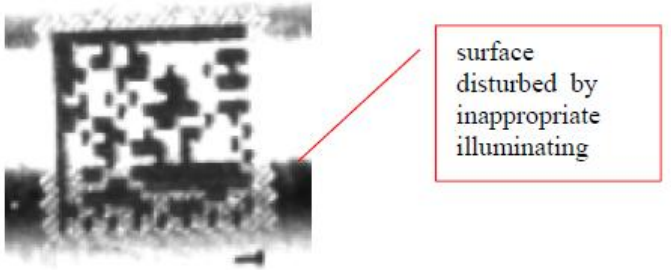
- modules are to small to read and to get translated



Solutions

- minimal module size = 0.12 µm
- use of high definition scanners

Technical Limits and Solutions



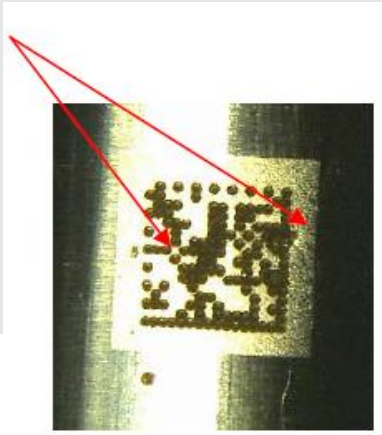
Contrast

Limits

- different contrasts on various surfaces
- with round and none-plane surfaces illumination with different grey areas
- contamination, water spots

Solutions

- background by beam marking
- marking on most possible plane surfaces
- optimizing of illumination
- illumination ‘over-reads‘ surface spots
- with coatings and plastics bright marking on darker surface



Grey areas on surface

Technical Limits and Solutions

Marking Surface Area

Limits

- marking over edges
- alterating marking (out of focus)

Solutions

- optimized Code
- fixed attachements
- use of stable marking processes
- optimized samples for comparison
- depth marker

Technical Limits and Solutions

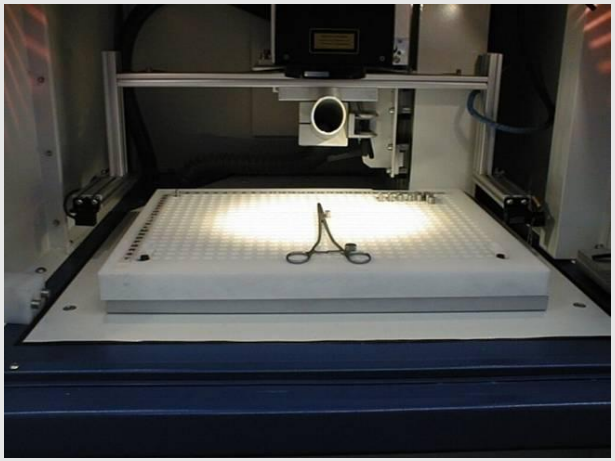
Marking Parameters

Limits

- corrosion
- not visibly marked

Solutions

- optimized parameters for corrosions- resistant coding through validation
- contineously control of equipment
- attachements
- samples for comparison



Technical Limits and Solutions

Scanning process at end users

Limits

- wrong scanners
- wrong handling
- no edequate numbering system

Solutions

- training
- Data Matrix samples for comparison
- automated, validiated software

Quality Management

Summary

Coding machines

Optimized parameters for corrosion-resistant coding through validation.

Every machine is tested in detail before starting up and is adjusted optimally.

Coding material

Use of stadardized instrument steel. Wide ranging incoming controls take place in our material lab.

Coding parameters

Optimized engraving parameters 6-10µm deep.

Coding with defined background.

Coding process

Cyclic scans of the Data Matrix code directly after coding. Visual check of every coding

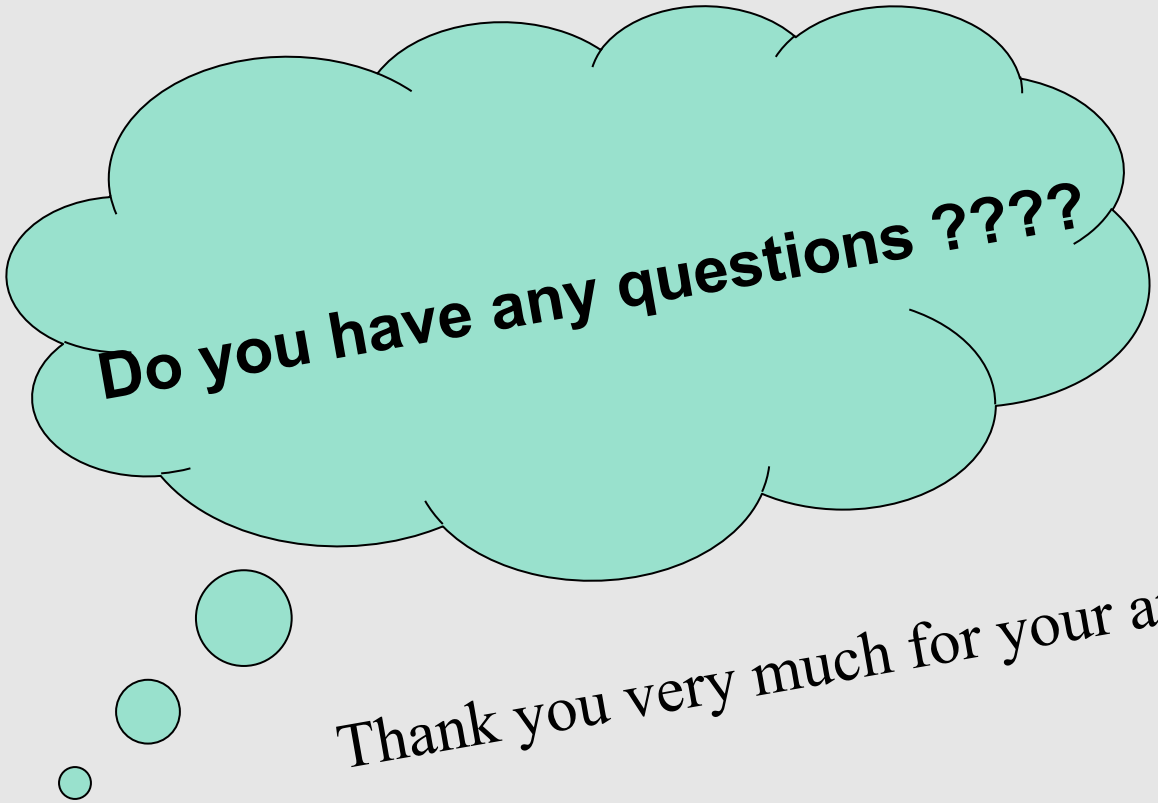
Technical Limits and Solutions

Conclusion

If the Data Matrix is marked on the instrument according to the specifications a long-term function is guaranteed.

Only the deterioration of the surface by scretches can not be influenced

There will be surgical instruments which do not have the space for a direct part marking



Thank you very much for your attention