

Osaka



Japan Association of Medical Equipment Industries

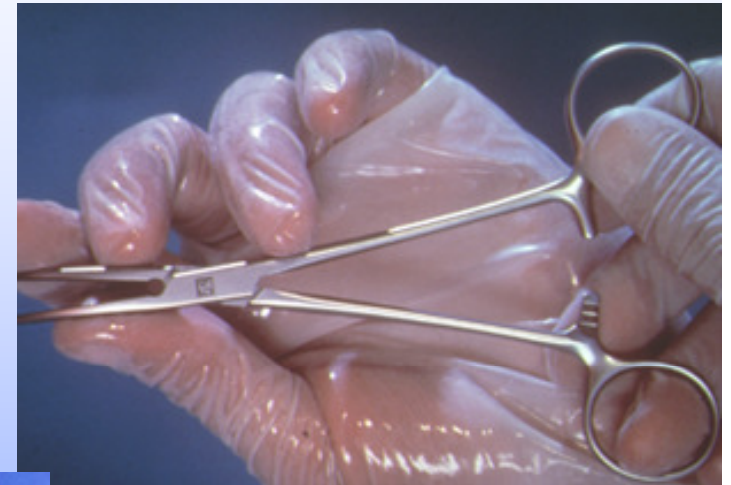
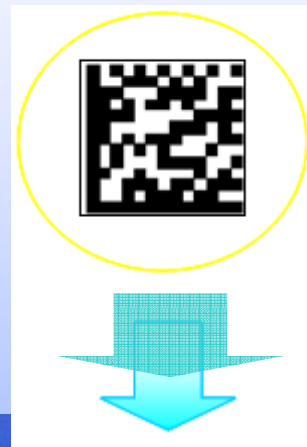


Pilot Test for Durable 2 D Symbol Marking and Reading Technology for Steel Instruments

業界の健全な発展をめざし、
21世紀の医療の進歩を支える

Japan Association of Medical
Equipment Industries (JAMEI)

Why we use the 2 D code on steel instruments ?

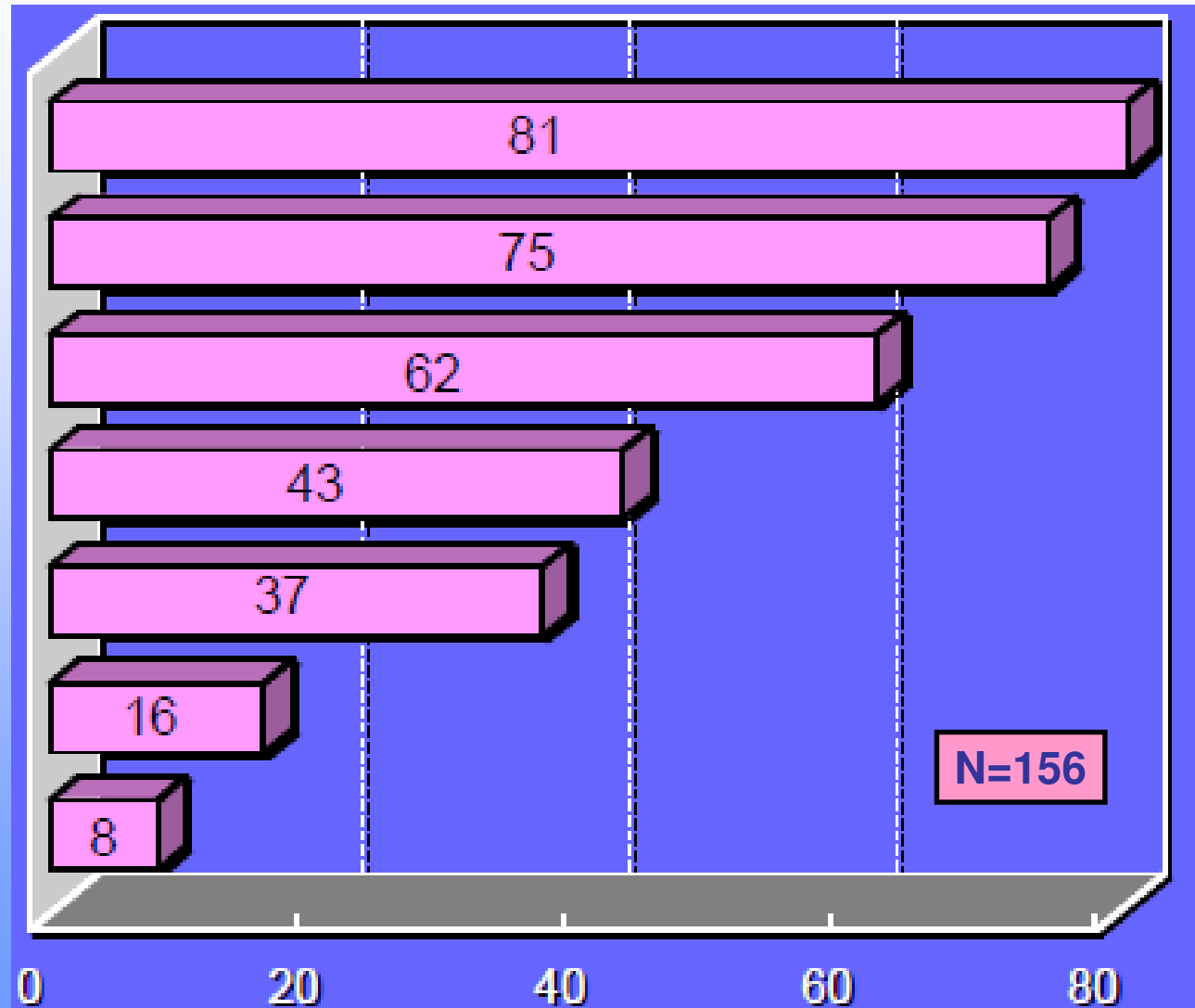


For Patient Safety

- Prevention of VCJD infection
- Recall the product
- Identify defective lots
- Avoidance of non-uniform quality attributable to different levels of operators' skill
- Grasping service life

Hospitals' Expectation for 2D Marking

- Traceability
- VCJD
- Individual Item Management
- Linkage with DB of Attached Documents
- Linkage with DB of Relevant Information
- Management of In-Hospital Information
- Others





Scanner

2-D Direct Part Marking on Steel instruments

Guideline for the indication of two dimensional (2D) symbol on steel instruments

Guideline issued November 2006

Objectives: Patient safety, Traceability/Recall & Asset Management

Metal Apparatus:

Made of stainless, aluminum, copper alloy, titanium, ceramics, etc.

Used for operation, medical treatment, etc.

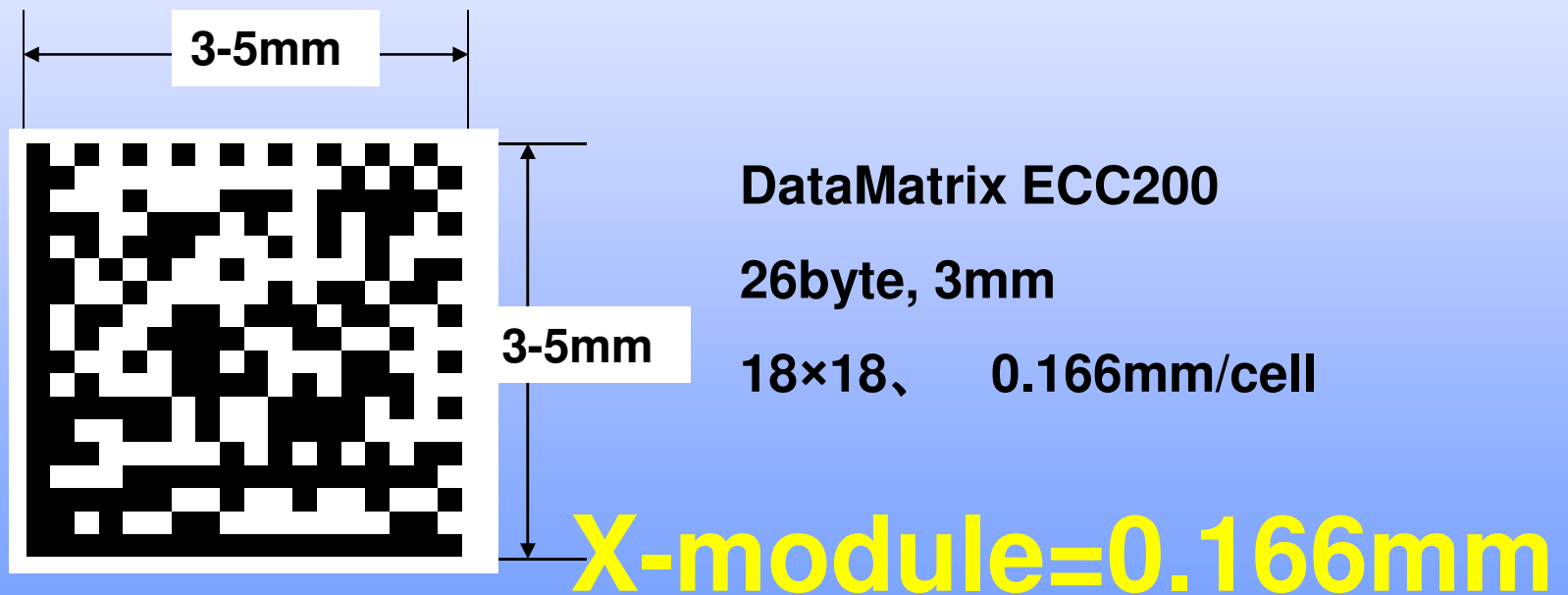
Symbol: **Data Matrix** (ISO/IEC 16023) ECC 200
or **QR Code** (ISO/IEC 18004)

Data : AI (01) 14 digits GTIN
AI (21) 8 digits Serial No.

Two symbols !

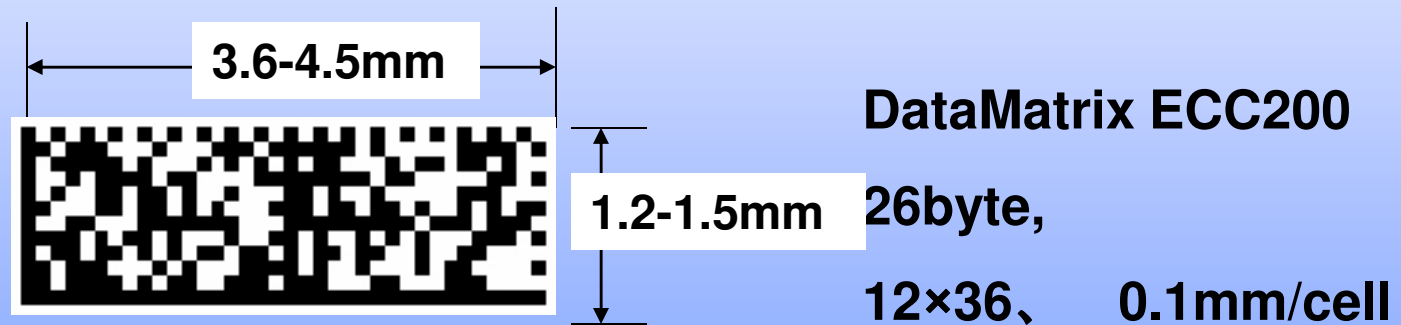
Guideline for the indication of two dimensional (2D) symbol on steel instruments (**DataMatrix**)

(a) 3mm square or larger space can be secured for indication



Guideline for the indication of two dimensional (2D) symbol on steel instruments (**DataMatrix**)

(b) Steel instruments in bar shape on which 3mm square indicator cannot be affixed.



Extra small steel instruments

X-module=0.10mm

Background of the pilot test 1

There are some kind of marking pattern by laser

Which pattern is better

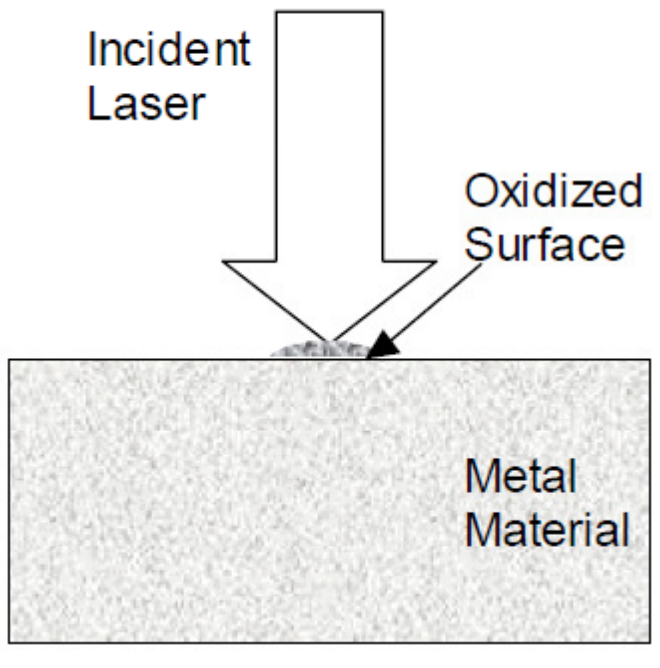
- **White pattern (Melting) ?**
- **Black pattern (Oxidized) ?**

How to marking one cell

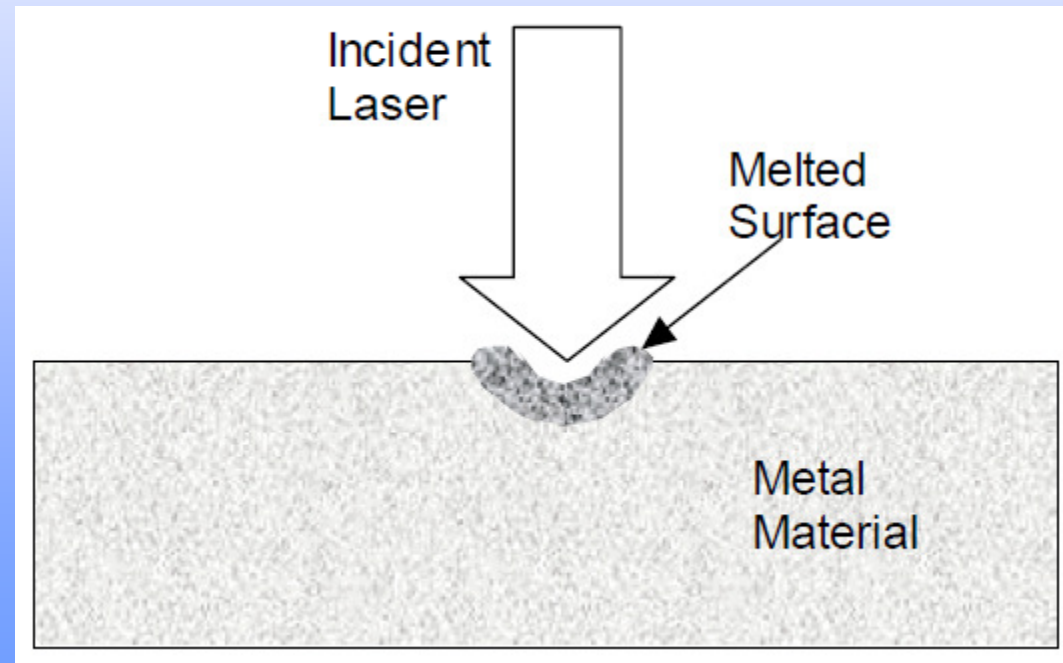
- **Dot pattern**
- **Paint out**

Technical definition

Black pattern (Oxidized)



White pattern (Melting)

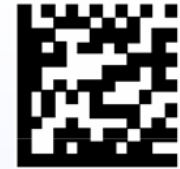


Background of the pilot test 2

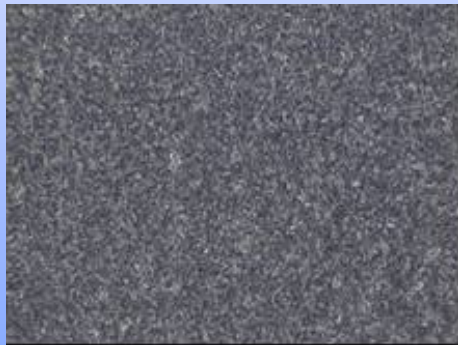
- Is it possible to read 1mm ~ 5mm 2D symbols by a commercially available readout system?
- Is readability of marking on surgical instruments influenced by;
 - **Satin finished surface?**
(**Blast finishing + electrolytic polishing**)
 - **Mirror finished surface?**
 - **Hair-line finished surface?**
- Is there any reading limitation regarding size of 2D symbol?



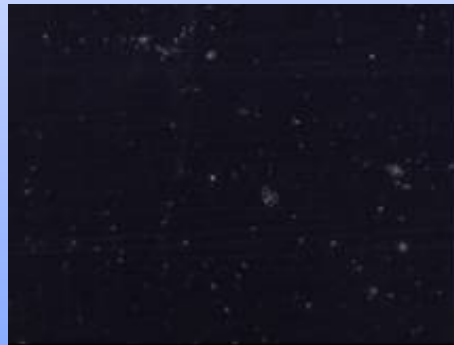
METHODS



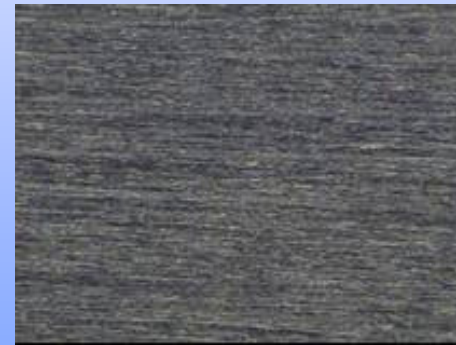
- **Testing material**
 - **SUS / AISI 420 (scissors)**
 - **SUS / AISI 410 (forceps)**
- **Finish of metal surfaces**



Satin finished surface
(Blast finishing +
electrolytic
polishing)



**Mirror finished
surface**



**Hair-line finished
surface**

METHODS



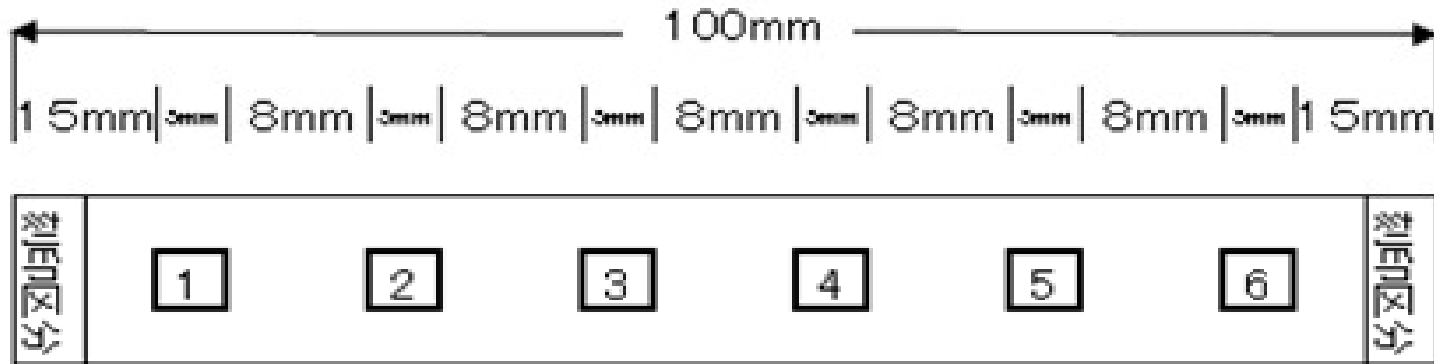
- **Specification of marking**
 - **GTIN + Serial Number : 26 byte**
 - **White pattern Data Matrix**
 - **Black pattern Data Matrix**
 - **1 mm 、 2 mm、 3 mm、 4 mm、 5 mm:**
Square 1.2mm×3.6mm :Rectangle
- **After marking we are ageing test for**
 - **Salt spray test**

Methods of salt spray testing

- ISO 9227, Corrosion tests in artificial atmospheres-Salt spray test (1990)
(JIS Z 2371)



How to make the test material



Testing material

- **SUS/AISI 420 (scissors)**
- **SUS/AISI 410 (forceps)**

Finish for metal surfaces

- **Satin finished surface**
(Blast finishing + electrolytic polishing)
- **Mirror finished surface**
- **Hair-line finished surface**

Specification of marking

- **White pattern Data Matrix**
- **Black pattern Data Matrix**
- **1 mm 、 2 mm、 3 mm、 4 mm、 5 mm: Square**
- **1.2mm×3.6mm :Rectangle**

Laser Marker



SUNX : LP-V
FAYb Laser Marker



MIYACHI :ML-7111A
LD Pumped YVO4

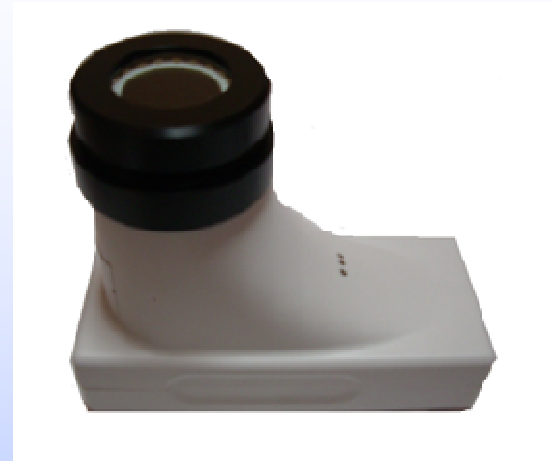


OMRON : MX-SL579A
5W/Single Mode Laser Marker

READER



SYMCO Surgical Eye II



MNEXT HN-06-16-M



DENSO QD25



OMRON V400-F

Validation of 2D symbol marking

- **Equipment : DataMan 100**
- **Spec : based on DPM quality guidelines**
which are published by AIM (Automatic Identification Manufacturers) , authorized by ANSI(American National Standards Institute)

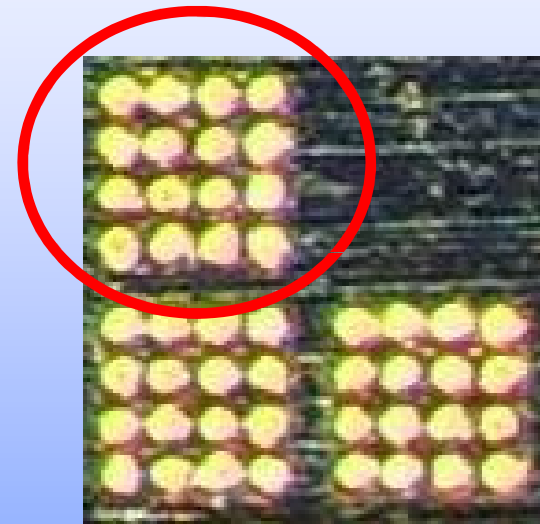
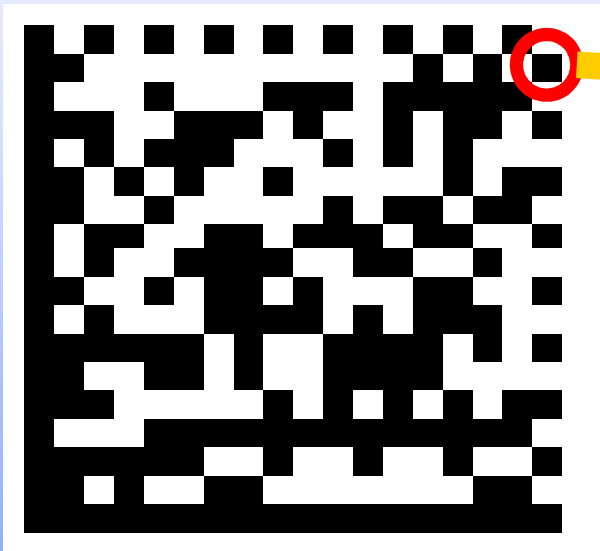
D P M : Direct Part Mark



Code Quality		AIM-DPM	
	Result	Grade	
Symbol Grade			A
Cell Modulation			A
Fixed Pattern Damage			A
Reference Decode			A
Minimum Reflectance	+96.86		A
Cell Contrast	+0.738		A
Axial Non-Uniformity	+0.005		A
Unused Error Correction	+1.000		A
Grid Non-Uniformity	+0.185		A

Marking Methods

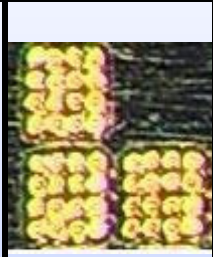
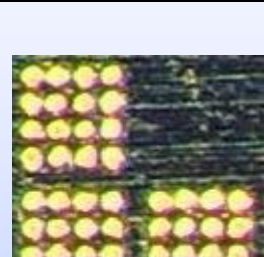
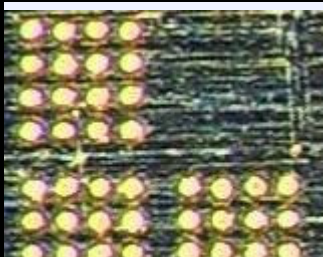

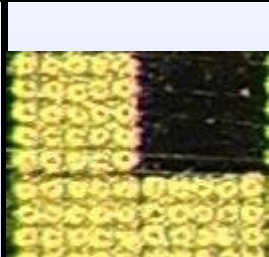
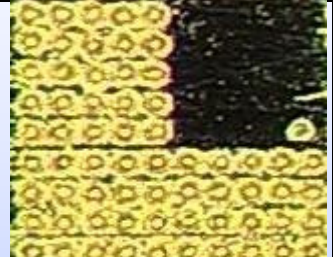
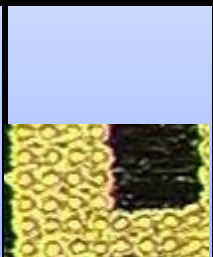
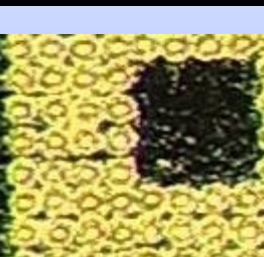
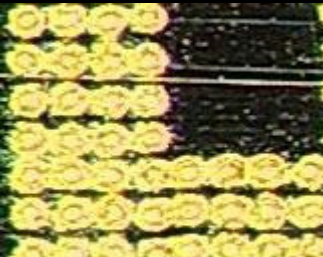

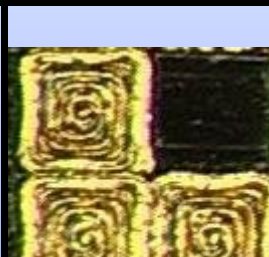
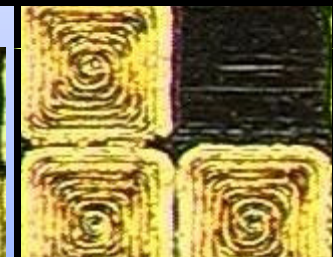
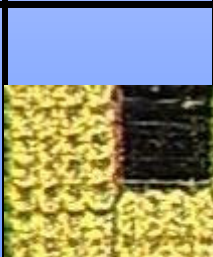
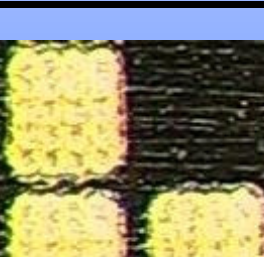
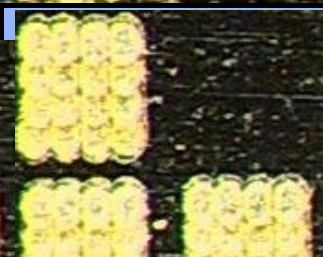

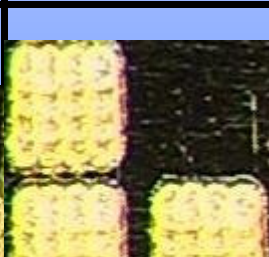
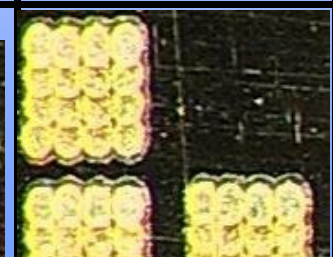
1. Provided protocol by JAMEI



4 × 4 dot makes one sell



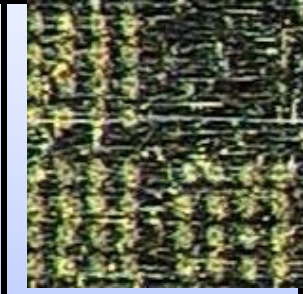
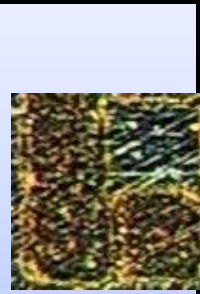
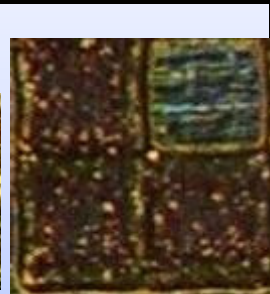
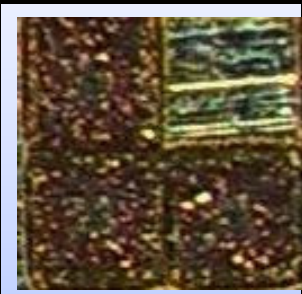

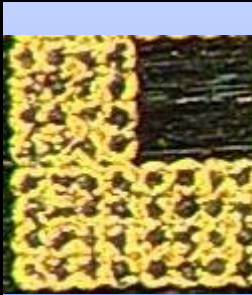
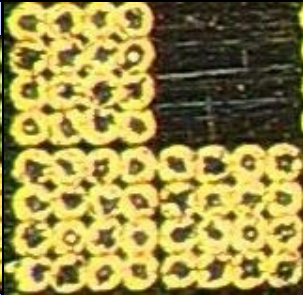


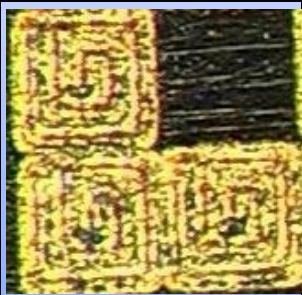

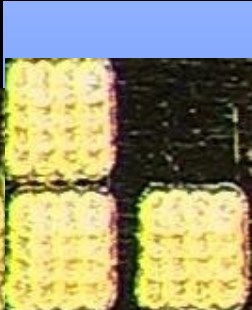
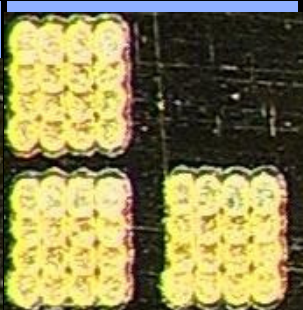
2. Recommended methods by laser marker company

Cell geometry for pattern

	4×4 dot/cell			Company Recommendation		
A						
B						
C						

Cell geometry pattern

Blackor

	4x4 dot/cell			Company Recommendation		
A						
B						
C						

Reading result of white and black pattern

Reader \ Marker		1m m				2m m				3m m				4m m				5m m				1.2×3.6								
		W	X	Y	Z	W	X	Y	Z	W	X	Y	Z	W	X	Y	Z	W	X	Y	Z	W	X	Y	Z					
White	Mirror	A	×	-	×	×	○	○	○	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	×
		C	×	-	×	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
		B	○	-	○	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
	Hair-line	A	×	-	×	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
		C	×	-	×	×	○	○	○	×	○	○	○	×	○	○	○	×	○	○	○	×	○	○	○	×	○	○	○	×
		B	○	-	○	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
	Satin finish	A	×	-	×	×	○	○	○	×	○	○	○	×	○	○	○	○	○	○	○	×	○	○	○	×	○	○	○	×
		C	×	-	×	×	○	○	○	○	○	○	×	○	○	○	○	○	○	○	×	○	×	○	○	×	○	○	○	×
		B	×	-	×	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Black	Mirror	A	×	-	×	×	○	○	○	×	○	○	○	○	○	○	○	×	○	○	○	×	○	○	○	×	○	○	○	×
		C	×	-	×	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
		B	×	-	○	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
	Hair-line	A	×	-	△	×	○	○	○	○	○	○	○	○	○	○	○	×	×	○	○	×	○	○	○	×	○	○	○	×
		C	×	-	×	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	×	×	×	○	×	×	×
		B	×	-	×	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
	Satin finish	A	×	-	○	×	○	○	○	○	○	○	○	○	○	×	△	○	○	×	×	×	○	○	○	△	○	○	△	○
		C	×	-	×	×	○	○	○	×	○	○	○	×	○	○	○	×	○	○	○	×	×	×	○	△	○	○	△	○
		B	○	-	○	×	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○

○ : Perfect to read within 2 second, △ : Some time read, × : Can't read

2D Laser marking for Sample product

Condition of the surface of after salt spray test

White Pattern

Material	Finish	3 mm、4×4、white		Company Recommendation		3 mm、4×4、Black		Company Recommendation	
		×50	×150	×50	×150	×50	×150	×50	×150
SUS420	Mirror								
	Hair-line								
	Satin finished								
SUS410	Mirror								
	Hair-line								
	Satin finished								

Reading test for after salt spray test

				White				Black							
Product	Material	Finish	Marking	4×4 dot/cel		company recommendation		4×4 dot/cel		company recommendation		Read %	Each material	Total	
				BF	AF	BF	AF	BF	AF	BF	AF	AF (%)	AF (%)	AF (%)	
B	SUS AISI 420	Mirror	2541	○	×	○	○	○	×	○	×	25	17	46	
		Hair-line	2542	○	△	○	○	○	×	○	×	25			
		Satin	2543	○	○	○	○	○	×	○	×	50			
	SUS AISI 410	Mirror	1541	○	○	○	○	○	×	○	×	50	58		
		Hair-line	1542	○	○	○	○	○	×	○	×	50			
		Satin	1543	○	○	○	○	○	○	○	×	75			
	Read %				100	87	100	100	100	17	100	0			
	W/B				8 3				8						
					83				8						

Result

- It was possible to perform laser marking the size of **1mm to 5mm** by using the laser marker available on the market based on the JAMEI guidelines.
- All marking sizes except **1mm** could be read by the use of DPM reader - available on the market.
- **Cell with 4×4 dot** in combination with white pattern marking indicates better reading results and showed positive effects for anticorrosion property.
 - ◆ Several black pattern marking showed problems by reading failure after performing the salt spray test which occurred rust.

Discussion

- **Readability of Satin finished surface test materials was some time impossible.**
 - Assumption: Rough surface impedes readability of cell dot which leads to error reading.
- **Confirmed all laser marking equipments were able to mark 1mm 2D symbol with 26Byte.**
- **Individual size 2D symbol allowed reading.**
- **1mm 2D symbol could not be recognized if reading range was set from 1mm to 5mm.**
 - Limitation of optical technology (fixation distance)
 - Difficulty in localization (too small)

Technical guidelines for 2D symbol marking

- Barcode reader should have continuous readability for 2mm to 5mm symbols.
- Symbols should be made by white pattern marking.
- Cells should be made by dot pattern marking.
- DPM quality should be secured over B level on quality guidelines provided by **A I M**

Osaka





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k
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