AIDC Application Standards for Healthcare

GS1 DataMatrix

Chuck Biss – GS1 Global Office

Topics…

- **A General Discussion of GS1 DataMatrix, with a GS1 Healthcare Application Standards Focus**

- Why GS1 DataMatrix in Healthcare
- Data Matrix… The Symbology
  - "GS1 DataMatrix" son of "ISO/IEC Data Matrix"
- Thoughts on Structure & Quality
- Practical Application - Printing / Reading
- Q&A

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Bar Code use in Healthcare

AIDC Application Standards…

- Define which **data** to carry in which **data carrier** for any Healthcare product at all packaging levels

- **Improve patient safety**
  - Reduce medical errors
  - Enable effective product recalls
  - Fight counterfeiting
  - Enable adverse event reporting
  - Increase time for patient care

- **Increase efficiency & save costs**
  - Improve order and invoice process
  - Optimise receiving
  - Reduce inventory & improve shelf management
  - Increase productivity
  - Improve service levels/fill rate
  - Improve benchmarking and management of supply cost
  - Efficiently document treatment in patients' Electronic Health Record

Healthcare specific – data & carrier requirements…

Expiry Date, Lot, and/or Serial Number

Small space

Direct part marking

Additional data & variable data at high production rates

Non-retail channels

And more…

The need to capture the ID key … and beyond…

GS1 Keys prevail… but some users need more detailed information about that specific unit

Data carriers for specific HC needs

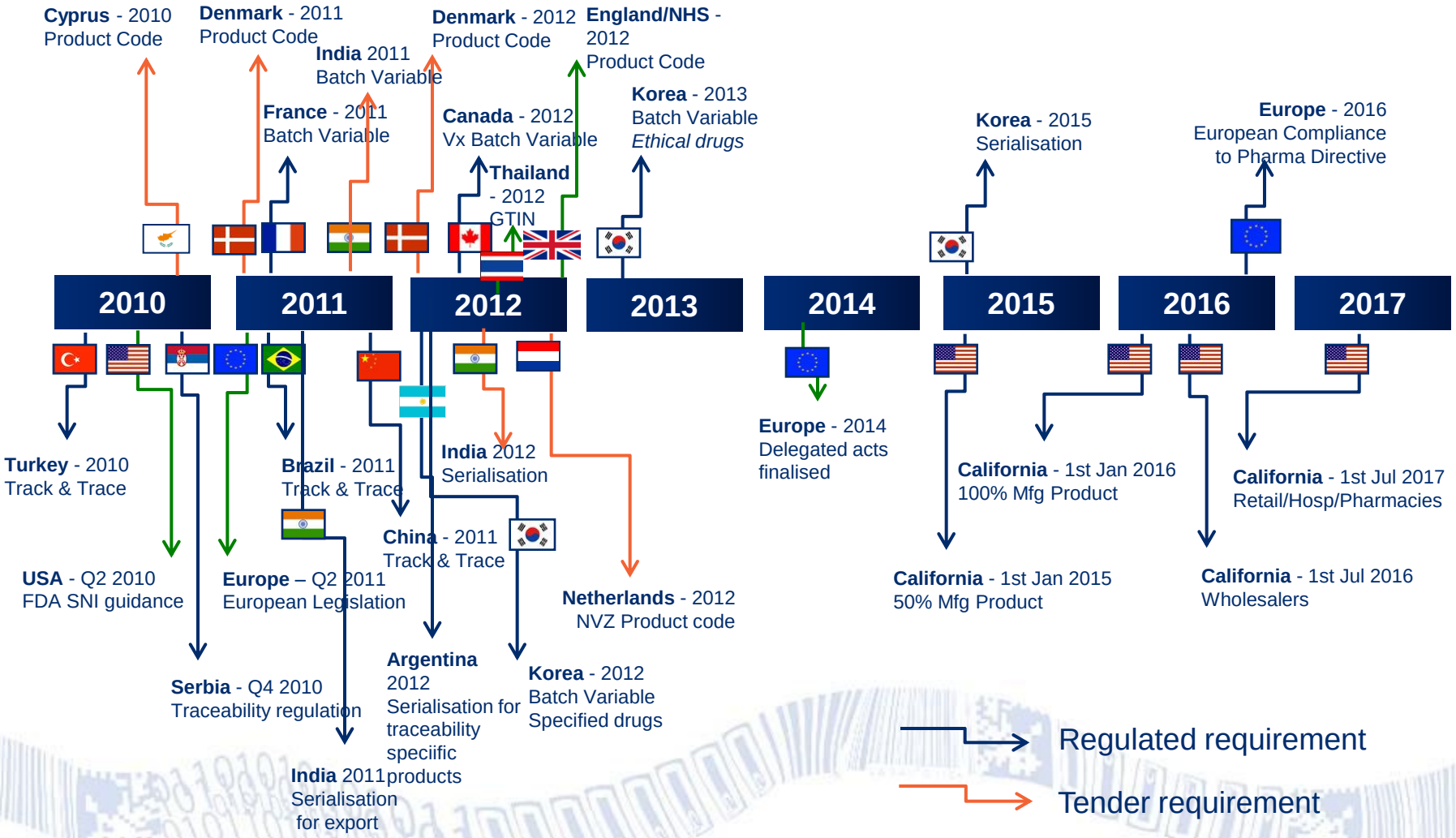
GS1-128 &
GS1 DataBar
Preferred options if:
✓package allows

GS1 DataMatrix
Preferred option if:
✓ Large amount of data in a small space
✓ Variable information at high production rates
✓ Direct part marking

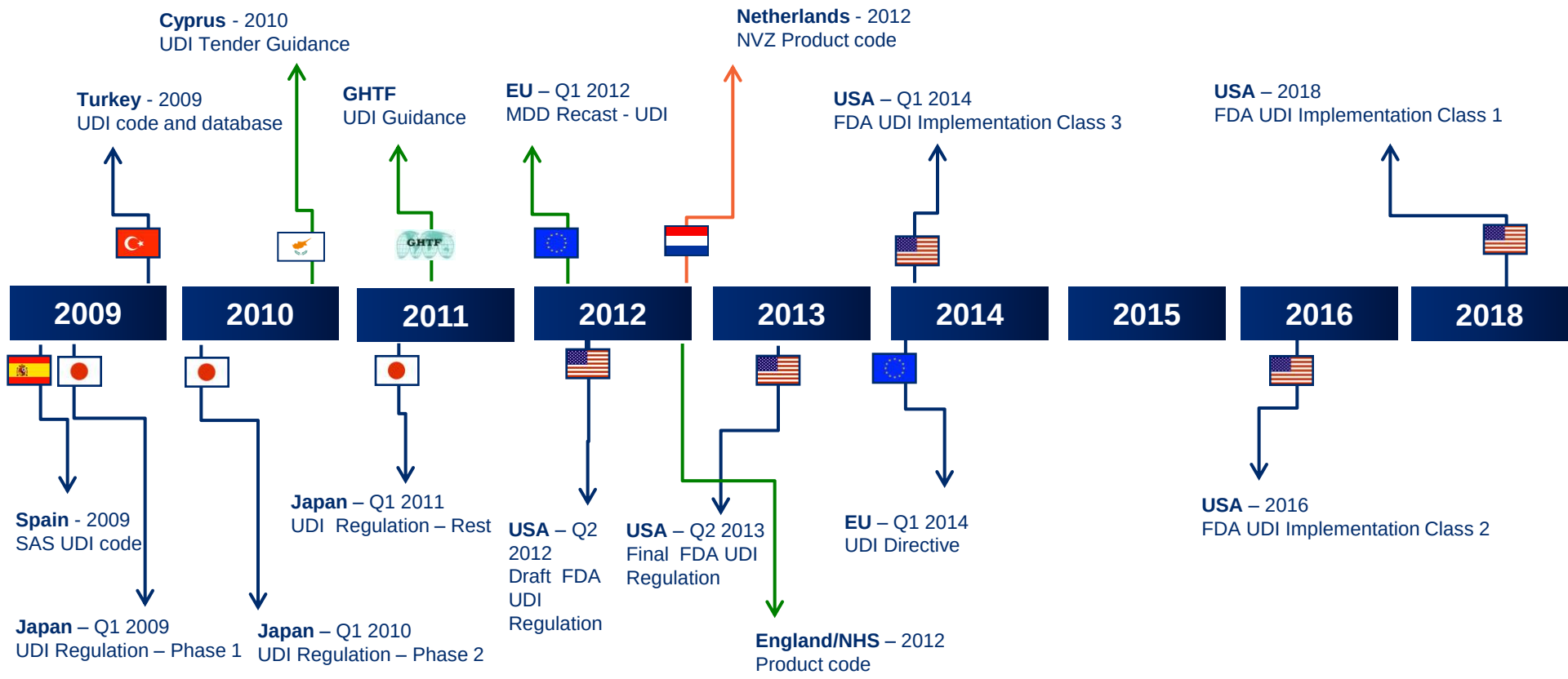
EPC/RFID
Additional option
✓ Non-line of sight
✓ Large amount of data

Pharma

New coding & serialisation requirements



Medical devices
New coding and database requirements



Canada, China, Italy, Korea, UAE, etc.: UDI regulation under development

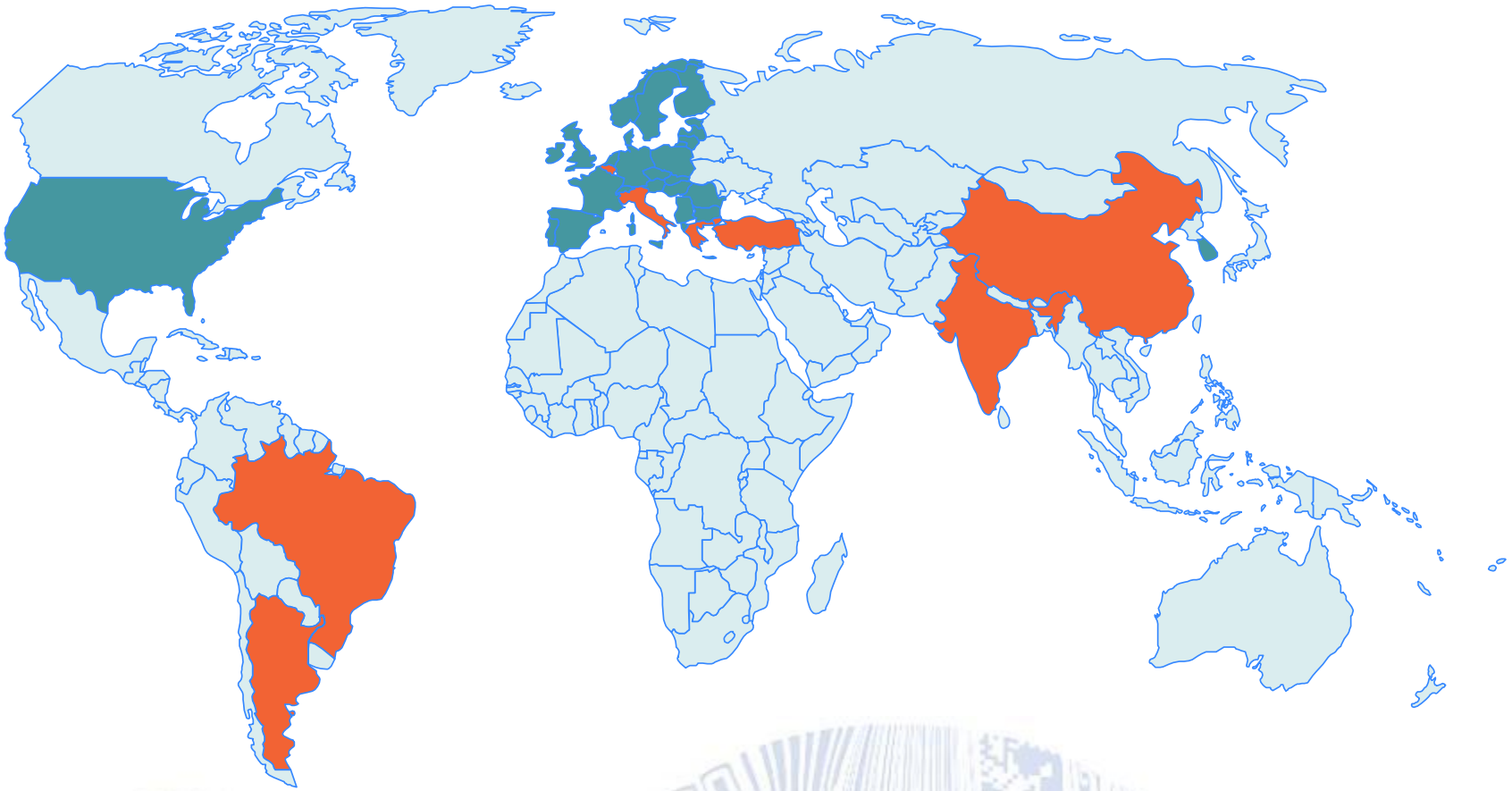
India: UDI requirements pending

Tender requirement

Regulated requirement

Important development

Serialisation of pharmaceuticals



- = country requires serial number
- = country developing requirement for serial number

DataMatrix on pharmaceuticals

Switzerland: SmartLog Pilot

Spain: Pilot

France: AFSSAPS regulation (2011)

Belgium: Pilot project unit dose marking

Austria: Cytostatics

Serbia: Pilot

Turkey: Regulatory requirement (2010)

Korea: pharma regulatory requirement (2012)

Canada: Vaccines

US: Pilot on Vaccines

Brazil: Traceability pilot successfully completed – ANVISA regulation

Argentina: Traceability regulation

India: Tender requirement for October 2011

- = country requires DataMatrix
- = country using DataMatrix in pilots and/or developing requirement for DataMatrix

GS1 Data Carriers for Healthcare… an example…

Product type?	Pharmaceutical
Distribution channel?	Retail POS
Information need?	Minimum
Package level?	Secondary

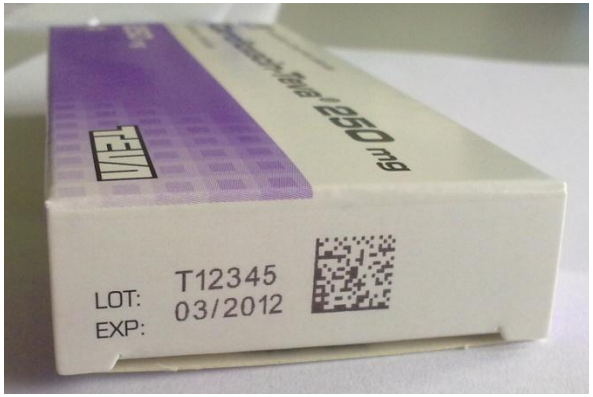
GS1 Data Carriers for Healthcare… an example…

Product type?	Pharmaceutical
Distribution channel?	Non-retail
Information need?	Enhanced
Package level?	Secondary

EAN/UPC

Ideal…

GS1 DataMatrix



GS1 DataBar

IF space allows…

IF space allows…

GS1-128

Composite Component

ITF-14

Topics…

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Data Carriers: Bar Code Symbologies

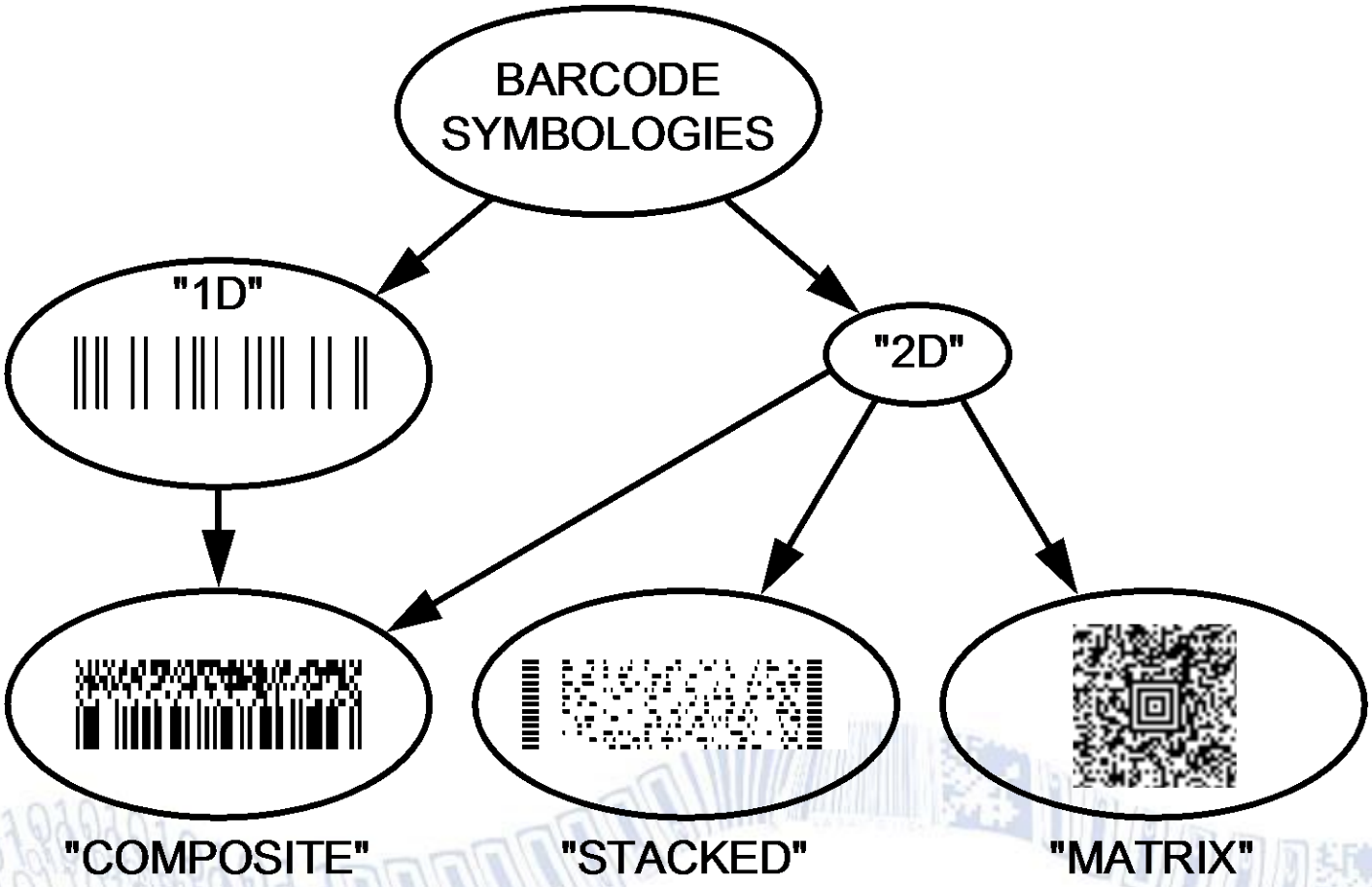
Symbologies…

Bar code symbology “evolution”

1D “Linear” 2D “Multi Row” 2D “Matrix”

Data Carriers: Bar Code Symbologies

Symbologies more simply…



Data Carriers: Bar Code Symbologies

Symbology “categories”…

- 1D Linear
  - The “normal” symbologies we are all familiar with… UPC/EAN, Code 39, Code 128, etc.
- 2D “Multi Row”
  - Also known as “stacked” symbologies, linear or “row” based… Code 16K, Code 49, PDF 417, etc.
- 2D “Matrix”
  - True “two dimensional” codes based on dot or element placements in a matrix… DataMatrix, QR Code, Aztec Code, MaxiCode, etc.

Data Carriers: 2D Bar Code Symbologies

Many to choose from… are they all “the same”…

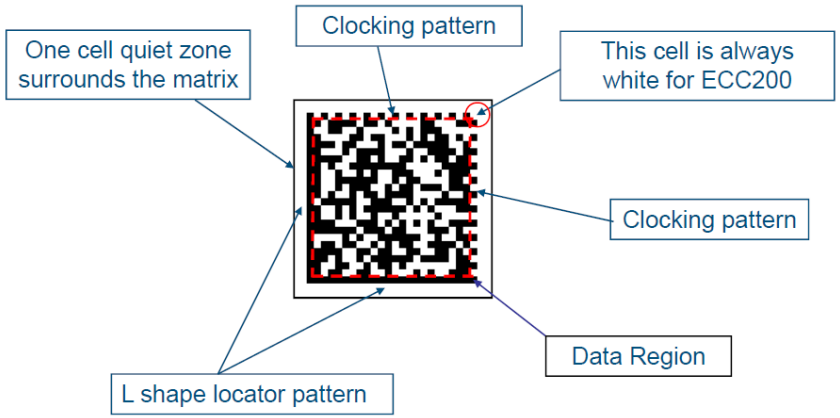
QR Code

MaxiCode

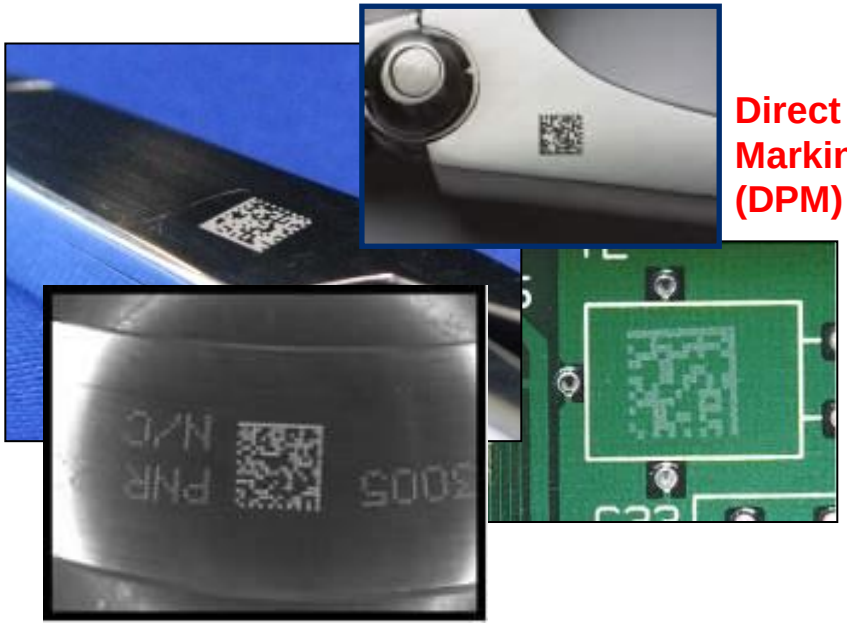
Aztec Code

ISO Data Matrix Symbology

- Established 1989 by International Data Matrix
- Internationally standardized in ISO/IEC 16022
- Scaleable matrix from 9 x 9 to 49 x 49 modules
  (Size Change w/ Data Content… in “block steps”… an example later on)
- Error Detection & Multiple Error Correction Levels
- Multiple encoding formats and macros
- More adaptable to “direct” marking (DPM)
- Primary Applications - Parts marking (Automotive, Semiconductor, Healthcare instruments, Aerospace), Pharmaceutical packaging, Package labeling / addressing



“Some” Data Matrix Applications



Direct Part Marking (DPM)

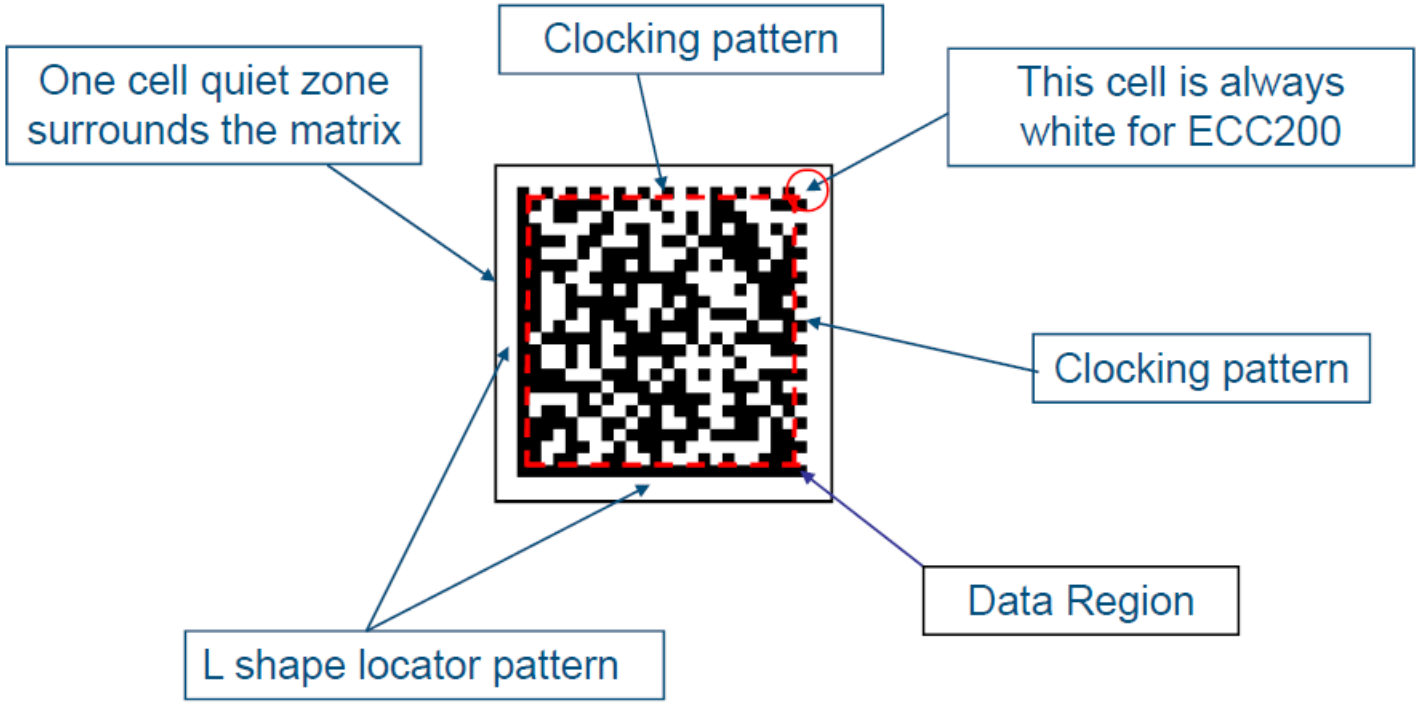
Identification & Document Tracking

Item Package & Label Marking

Packaging Verification

MP/11-177719
Exp.: 30/04/2014

GS1 DataMatrix Symbology



- ISO/IEC 16022 Data Matrix… used as “GS1 DataMatrix”:
  - Special considerations?
    - Similar to the Code 128 / GS1-128 “relationship”, an FNC1 in the first data position signals GS1 formatted data & a **GS1 DataMatrix**
    - Is always “ECC 200” & Alpha-Numeric encodation capable
    - GS1 DataMatrix has a specific ISO/IEC Symbology Identifier

GS1-128…

Size Change w/ Data Content… in “steps”

Symbol 1 - GTIN Only

Symbol 2 - GTIN + AI(17)

Symbol 3 - GTIN + AI(17) + AI(10) of 4 numeric & 6 alpha

Symbol 4 - GTIN + AI(17) + AI(10) of 8 numeric & 12 alpha + AI(21) of 13 numeric & 1 alpha

For EACH extra individual character you add to the data string… the symbol increases in length…

GS1 DataMatrix…

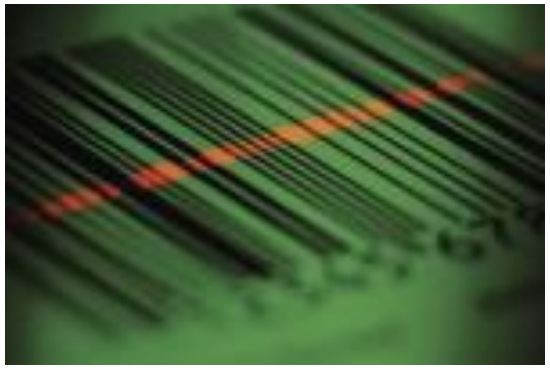
Size Change w/ Data Content… in “block steps”

Symbol 1 - GTIN Only		0.107in x 0/107in (0.011 sq inch)
Symbol 2 - GTIN + AI(17)		0.121in x 0.121in (0.015 sq inch)
Symbol 3 - GTIN + AI(17) + AI(10) of 4 numeric & 6 alpha		0.134in x 0.134in (0.018 sq inch)
Symbol 4 - GTIN + AI(17) + AI(10) of 8 numeric & 12 alpha		0.147in x 0.147in (0.022 sq inch)
Symbol 5 - GTIN + AI(17) + AI(10) of 8 numeric & 12 alpha + AI(21) of 3 numeric		0.468in x 0.468.in (0.219 sq inch)
Symbol 6 - GTIN + AI(17) + AI(10) of 8 numeric & 12 alpha + AI(21) of 13 numeric & 1 alpha		0.507in x 0.507in (0.257 sq inch)
Symbol 7 - GTIN + AI(17) + AI(10) of 8 numeric & 12 alpha + AI(21) of 15 numeric & 2 alpha		0.507in x 0.507in (0.257 sq inch)
Symbol 8 - GTIN + AI(17) + AI(10) of 8 numeric & 12 alpha + AI(21) of 17 numeric & 3 alpha		0.507in x 0.507in (0.257 sq inch)

Scanning 2D Matrix Symbols

Linear Scanners:

- Laser line or linear imager based
- Massive, long-term installed base
- Scans 1D / Linear and some 2D Stacked symbols



Area Image Scanners:

- Camera based
- Growing installed base in industrial, commercial, healthcare
- Scans 1D / Linear, 2D Stacked & 2D Matrix symbols

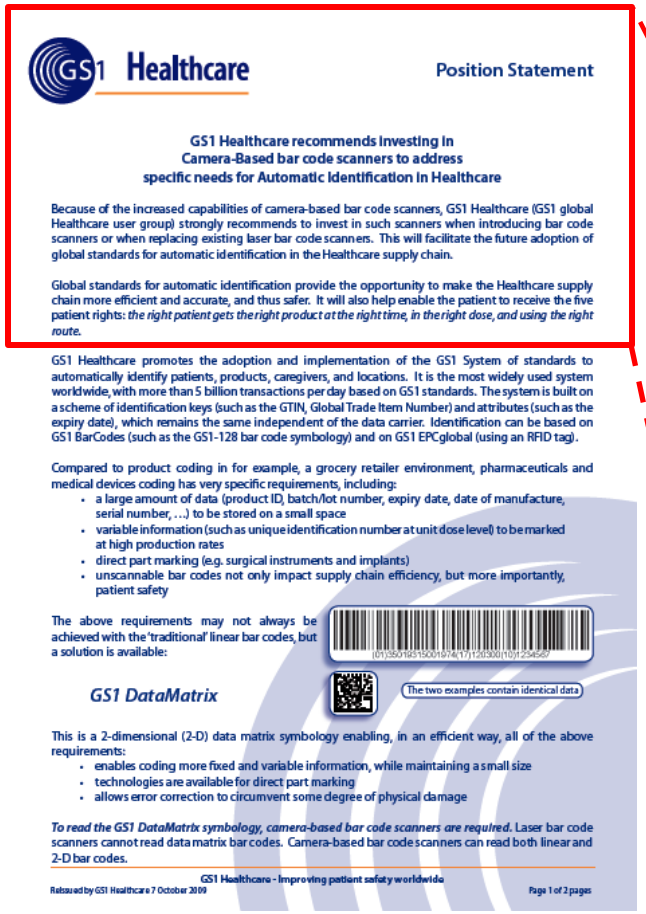
Camera-based bar code scanners are needed in Healthcare AND are a GS1 Healthcare Leadership Team recommendation!!

GS1-128 & GS1 DataBar

GS1 DataMatrix

Position – Camera/Imager Scanners…

(June 2007, Re-issued October 2010)



GS1 Healthcare — Position Statement

GS1 Healthcare recommends investing in Camera-Based bar code scanners to address specific needs for Automatic Identification in Healthcare

Because of the increased capabilities of camera-based bar code scanners, GS1 Healthcare (GS1 global Healthcare user group) strongly recommends to invest in such scanners when introducing bar code scanners or when replacing existing laser bar code scanners. This will facilitate the future adoption of global standards for automatic identification in the Healthcare supply chain.

Global standards for automatic identification provide the opportunity to make the Healthcare supply chain more efficient and accurate, and thus safer. It will also help enable the patient to receive the five patient rights: *the right patient gets the right product at the right time, in the right dose, and using the right route.*

GS1 Healthcare promotes the adoption and implementation of the GS1 System of standards to automatically identify patients, products, caregivers, and locations. It is the most widely used system worldwide, with more than 5 billion transactions per day based on GS1 standards. The system is built on a scheme of identification keys (such as the GTIN, Global Trade Item Number) and attributes (such as the expiry date), which remains the same independent of the data carrier. Identification can be based on GS1 BarCodes (such as the GS1-128 bar code symbology) and on GS1 EPCglobal (using an RFID tag).

Compared to product coding in for example, a grocery retailer environment, pharmaceuticals and medical devices coding has very specific requirements, including:

- a large amount of data (product ID, batch/lot number, expiry date, date of manufacture, serial number, …) to be stored on a small space
- variable information (such as unique identification number at unit dose level) to be marked at high production rates
- direct part marking (e.g. surgical instruments and implants)
- unscannable bar codes not only impact supply chain efficiency, but more importantly, patient safety

The above requirements may not always be achieved with the 'traditional' linear bar codes, but a solution is available:

The two examples contain identical data

GS1 DataMatrix

This is a 2-dimensional (2-D) data matrix symbology enabling, in an efficient way, all of the above requirements:

- enables coding more fixed and variable information, while maintaining a small size
- technologies are available for direct part marking
- allows error correction to circumvent some degree of physical damage

To read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Laser bar code scanners cannot read data matrix bar codes. Camera-based bar code scanners can read both linear and 2-D bar codes.

GS1 Healthcare - Improving patient safety worldwide

Reissued by GS1 Healthcare 7 October 2009 — Page 1 of 2 pages

Preparing members, solutions providers and end users for the future thru global positions…

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Get your copy at:

http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf -or- http://www.gs1.org/healthcare/library

Position – GS1 DataMatrix Adoption…
(December 2011)

GS1 Healthcare Position Paper on GS1 DataMatrix Implementation

GS1 Healthcare Position Statement on GS1 DataMatrix Implementation

To meet the growing demands of increased data needs and facilitate increased patient safety, the healthcare community is in the position to be the leader in GS1 DataMatrix implementation. To demonstrate support of this leadership position, the GS1 Healthcare community has set a goal of 2015 for implementation of GS1 DataMatrix printing on, and scanning of, Regulated Healthcare Trade Items where the current needs are not being met by other GS1 Data Carriers. While not a binding mandate, the community feels strongly in setting a clear direction to further galvanize the industry and encourage action over and above the many active implementations that exist today.

Global standards for automatic identification provide an opportunity to make the healthcare supply chain safer as well as more efficient and accurate. Healthcare regulators and trading partners have realized that a global, standardized identification system from product manufacture to patient treatment is imperative to comply with the increasing need for product traceability around the world.

The GS1 System, globally endorsed by the healthcare community, is the most widely used trade item identification system worldwide with more than 5 billion transactions per day. Built on a foundation of identification keys (such as the Global Trade Item Number or GTIN) and attributes (such as batch/lot numbers, expiry date, etc.) it is uniquely suited to meet the needs of the global healthcare industry.

Pharmaceutical and medical device identification & marking have very specific needs, including:
- Encoding large amounts of variable or dynamic data (lot number, expiration date, serial number, etc.) at high production speeds
- Direct part marking (e.g. marking on surgical instruments, etc.)
- Efficient marking of irregular packaging for many medical products
- Global legal and regulatory requirements that dictate the placement of data in a bar code symbol
- Traceability requirements for both pharmaceuticals and medical devices

Some of these needs are being met, and will continue to be met, through the use of 'traditional' linear bar codes, such as GS1-128 or GS1 DataBar. However, for applications where they are not, GS1 Healthcare has adopted the use of GS1 DataMatrix as the data carrier (bar code symbol) solution.

GS1 DataMatrix is a 2-dimensional (2D) bar code symbology that efficiently meets all of the above needs by:
- **Allowing the encoding and marking** of a greater amount of data within a smaller space
- **Enabling direct part marking** of trade items where labels may not be practical (small medical / surgical instruments)
- **Providing error detection and correction** capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label

As with the implementation of any forward looking technology, there can be challenges that must be recognized. For GS1 DataMatrix, these could include:
- Upgrades to scanner systems: to read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Linear technology based bar code scanners cannot read 2D bar codes, however camera-based bar code scanners can read both linear as well as 2D bar codes and users should be prepared to see both of these types of bar code symbols (see the GS1 Healthcare position statement on 2D camera based scanners)
- Updates to printing systems: to print GS1 DataMatrix, particularly on-line, direct to packaging, within production environments, printing systems may need software / hardware updates or replacement
- Updates to IT infrastructure systems: to ensure that dynamic, variable attribute data (lot/batch, expiry, serial number, etc.) is available for encoding in a "real time" packaging environment as well as ensuring that the underlying systems can support the additional data where this is not already implemented

Recognizing all of these needs, as well as the potential challenges of implementation, GS1 Healthcare and its global members strongly support the implementation of 2D capable scanners and the adoption of GS1 DataMatrix. A global implementation will not be accomplished without time and effort. The use of the GS1 DataMatrix can facilitate increased automation of data capture in any country without creating trade barriers that could otherwise potentially impact patient care and safety.

Where GS1 DataMatrix can enhance or solve data capture issues, we need to begin or expand implementations and ensure that the infrastructure is in place as we move to the use of 2D Symbols (like GS1 DataMatrix) through the investment in 2D capable scanners. To bring awareness to the industry of the need to consider these practical challenges and to move forward as quickly as practical, GS1 Healthcare urges that new investments in printing and scanning systems throughout the global healthcare market include compliancy to GS1 DataMatrix.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is 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.

GS1 Healthcare members include over 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, and to view this paper please visit www.gs1.org/healthcare.

GS1 Healthcare Position Paper on GS1 DataMatrix Implementation - December 2011

Preparing members, solutions providers and end users for the future thru global positions…

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Get your copy at:

http://www.gs1.org/docs/healthcare/GS1_Data_Matrix_Position_Paper.pdf

GS1 DataMatrix Symbology

GS1 DataMatrix
An introduction and technical overview of the most advanced GS1 Application Identifiers compliant symbology

This document facilitates processes by offering detailed information on GS1 DataMatrix and its technical characteristics encoding, printing and reading. It is a repository of reference information that can support the implementation of GS1 DataMatrix in any sector, industry or country.

http://www.gs1.org/services/publications/online/

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Bar Code Symbol Quality is…

…much more than just “optical” print quality and / or using a verifier to determine a grade... there is great benefit in looking at the whole picture of quality and gaining the knowledge and understanding of what these checks, tests and results can tell you... how they can help you… and how they can improve the AIDC system

Awareness and understanding of overall bar code symbol quality, and the complete process to determine and understand it, can have many benefits to the users of bar code driven AIDC systems

Symbol Quality in the GS1 System

GS1 General Specifications

ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

ISO/IEC 15426-2 Information technology -- Automatic identification and data capture techniques -- Bar code verifier conformance specification -- Part 2: Two-dimensional symbols

ISO/IEC 16022 Information technology -- International symbology specification -- Data Matrix

ISO/IEC TR 24720 Information technology -- Automatic identification and data capture techniques -- Guidelines for direct part marking (DPM)

ISO/IEC DTR 29158 Information technology -- Automatic identification and data capture techniques -- Direct Part Mark (DPM) Quality Guideline

Have the right "tools" for the job, starting with proper documentation, education, training…

Linear (1D) & Matrix (2D) Bar Code Symbols

Common Quality Parameters

- Decode / RDA
- X Dimension / Module Size
- Data Structure, Validity
- Human Readable Interpretation
- Symbol Contrast
- Modulation
- Quite Zones, as applicable

1D Only

- Bar Height
- Minimum Reflectance
- Edge Contrast
- Defects
- Decodability

2D Only

- Fixed Pattern Damage
- Axial Nonuniformity
- Grid Nonuniformity
- Unused Error Correction
- Print Growth
- Clock Track Regularity

Quality Parameters

Decode / Reference Decode Algorithm

Is the symbol readable, does it fulfill the rules of the Reference Decode Algorithm, is it a GS1 DataMatrix and is the data in a GS1 format.

- Has the proper structure to be a Data Matrix
- Has a Function One (FNC1) Character in the first data position
- Has data properly structured & encoded according to the GS1 General Specification
  - NOTE: This “data structure” is the same as for GS1-128…just in a different “bar code”!

GS1 DataMatrix Symbology…
…or not… how DO you know?

Symbol decode:

GS1 DataMatrix - (FNC1 & AIs)

]d2 01108576740020171714112010KMB11205201[GS]21CEB630078700

Whether you use a Verifier or go "more manual"… it's all in the data… and the ISO Symbology Identifier!

ISO Symbology ID's are Internationally agreed (ISO/IEC 15424) 3 character codes that scanner/imagers output at the beginning of a data string that tells what bar code symbology has been read. It is in the form

]cm

where:

] - (ASCII 93) the ID flag character
c - code (symbology) character as ISO defined
m - modifier character(s)

Symbol decode:

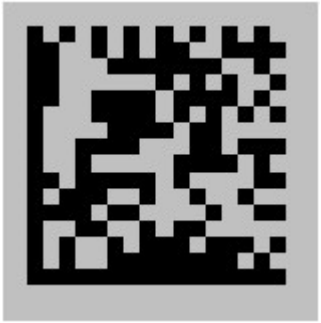
]d1 01108576740020171714112010KMB11205201[GS]21CEB630078700

ISO Data Matrix - (No FNC1)

Quality Parameters

Symbol Contrast

Like with 1D / Linear… the difference between the light and dark parts… a bigger difference is better



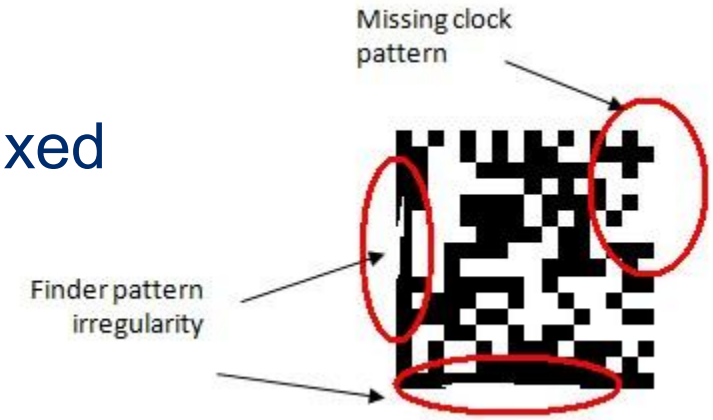
Modulation

Not unlike 1D / Linear… is a measure of the uniformity of reflectance of the dark and light modules

Quality Parameters

Fixed Pattern Damage

A test for damage to any of the “fixed patterns” (finder patterns etc.)



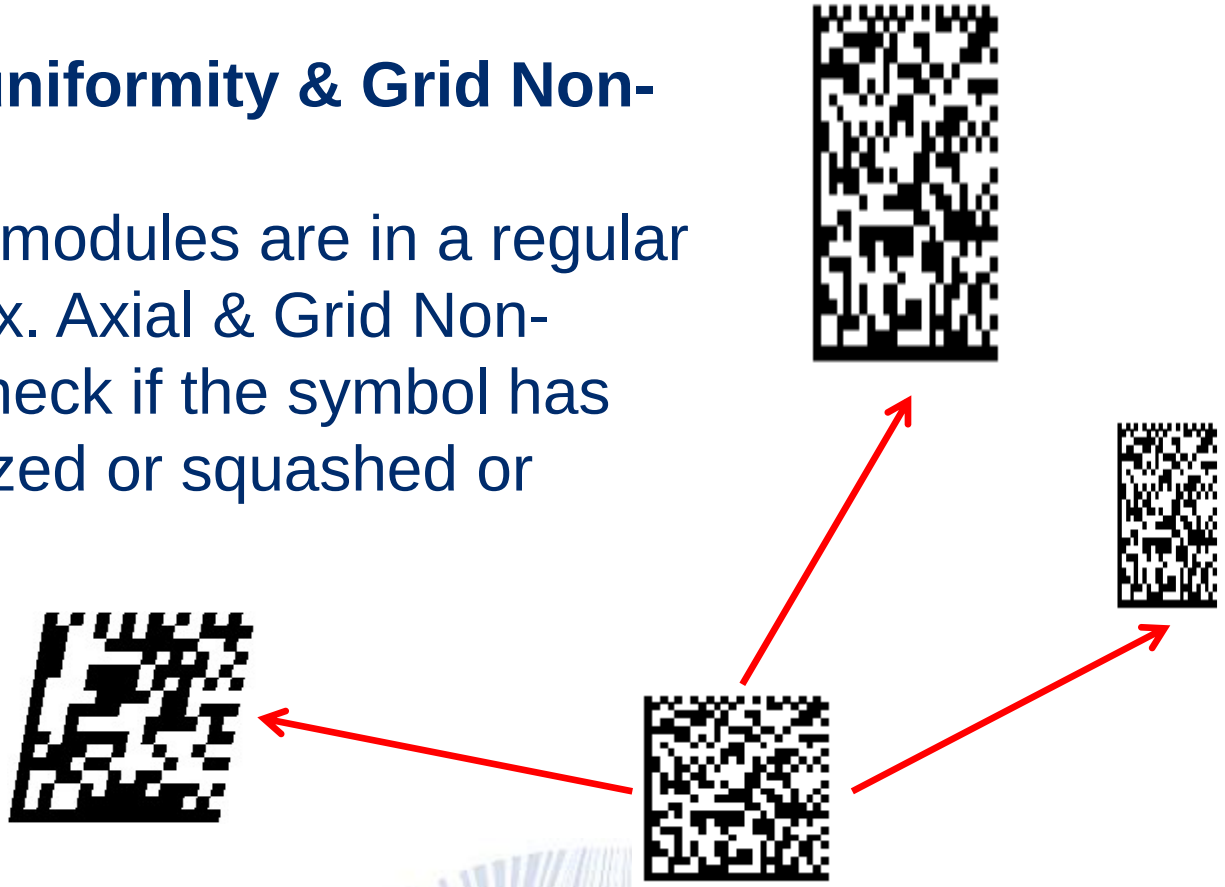
Unused Error Correction

Damage in the Symbol → High Error Correction → Reduced Unused Error Correction Capacity

Quality Parameters

Axial Non-uniformity & Grid Non-uniformity

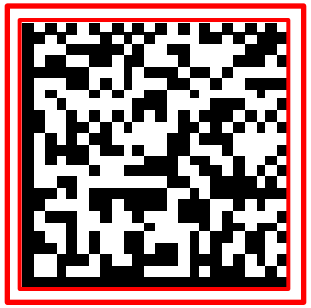
The symbol modules are in a regular grid or matrix. Axial & Grid Non-uniformity check if the symbol has been squeezed or squashed or distorted



Quality Parameters

Print Growth

Have the modules grown or shrunk from normal…



Quiet Zones (aka Light Margins)

Similar to 1D Linear symbols there is a “Quiet Zone” that must be kept clear… but it is on ALL FOUR sides…

Quality Parameters

Bar Code Print Quality Verifiers are available for testing 2D Matrix symbols like GS1 DataMatrix

Check out the AIM Buyer's Guide for a listing of most manufacturers

2D symbol verification…

…just like 1D symbol quality verification is a process where before you use a verifier you should:

- follow common sense, use your eyes, look at the whole picture…
- remember there is more to bar code symbol quality than just getting a “grade” …
- use all the “tools” you have available…
- learn and investigate !

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GS1 DataMatrix Symbology… Implementation questions

Overview – Most early adopters have been hesitant to share details as yet on implementation challenges, this can be for many reasons such avoiding operational comparisons, keeping competitive advantage, protecting an active pilot implementation project, lack of long term cost information, etc. Many times we have been told the more significant costs are in IT infrastructure changes. We are all learning...

Costs - Manufacturing? – When it comes to implementation costs anecdotal estimates have run from $50K to about $500K (or more) USD per manufacturing line for printing / scanning updates (without serial number addition). Many note that with printing software it is critical to ensure automatic inclusion of the leading Function 1 character.

GS1 DataMatrix Symbology… Implementation questions

Productivity? – In all cases we have heard that no one would even attempt to install systems if they were not assured that it would not negatively affect productivity.

Costs – User? – IT infrastructure changes may be the major unknown cost as it is different user to user. Scanner costs will depend on the type & use case need, however single, tethered/corded handheld "gun" type scanner imagers can cost about $250 - $350 USD per unit… from there (depending on quantities, type of unit, features, etc.) the costs can go slightly lower but also can rise into the $1000's USD for some systems. Bar code symbol print quality verifiers can run $2000 USD and up, but are available.

GS1 DataMatrix Symbology… Implementation questions

Printing / Marking:

- Many existing “demand” label printers can print Data Matrix well
- May not be the case for all “in line” printers (validity of inks, needed speeds, etc.)
- DPM brings on a whole new set of challenges
- Beware the missing FNC1

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GS1 DataMatrix

Printing / marking must, of course, be matched to the application use case needs… as with other bar code symbol generation

GS1 DataMatrix Symbology… Implementation questions

Area Image Scanners:

- Camera / area imager based
- Growing installed base in industrial, commercial, healthcare
- Scans 1D / Linear, 2D Stacked & 2D Matrix symbols
- Competitive pricing more apparent

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GS1 DataMatrix

Camera-based bar code scanners are needed in Healthcare AND are a GS1 Healthcare Leadership Team recommendation!!

A Practical need in the Healthcare supply chain #1…

Implementation of GS1 DataMatrix

- To meet the French “CIP” requirements
- Identification of the product with “Lot/Batch” & “Expiry”
- Tests already run to add Serial Number and a country specific NHRN (National Healthcare Reimbursement Number)
- Running at “normal” line speeds - 300 cartons/minute, 45m/min
- Print sizes – 300 DPI, Module size of 345µm, Wolke m600A, Universal Black UB 7482 HP Inkjet cartridge
- Read & verify – On and off-line camera based & verifier systems

Another practical need in the Healthcare supply chain, EFPIA…

EFPIA - Coding Pharmaceutical Products in Europe
Data Matrix – Coding proposal derived from GS1 standards

Manufacturer Product Code (GTIN or NTIN) - 14 digits
Unique Serial Number (randomized) - up to 20 alpha-numeric characters
Expiry Date - 6 digits (YYMMDD)
Batch Number - up to 20 alpha-numeric characters

+ minimum requirements on quality of randomisation

Example:

GTIN: (01) 07046261398572
Batch: (10) TEST5632
Expiry: (17) 130331
S/N: (21) 19067811811

Specifications provided in EFPIA's:
"European Pack Coding Guidelines"

A Practical need in the Healthcare supply chain #2…

Operating Room

Use

Case carts

Stock

Transport

Sterilisation Unit

Preparation

- ✓Cleaning
- ✓Dis-/assembling
- ✓Maintenance
- ✓Substitution
- ✓Set configuration
- ✓Completeness check

Sterilisation

- ✓Creation of ‘Steri Batches‘ (e.g. labels)
- ✓Batch loading and release

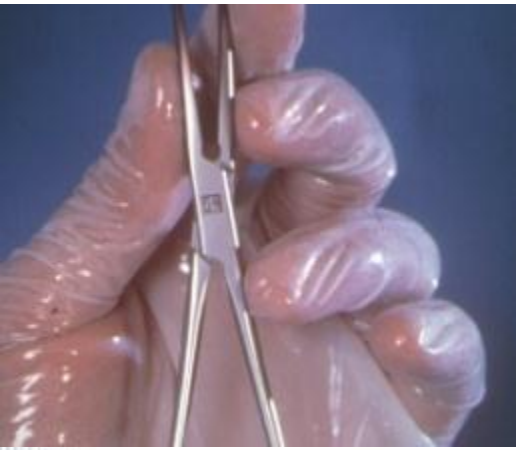
Instruments reprocessing cycle – Micro-logistics

Surgical instruments

- Specific marking needs to manage critical internal logistics processes
- (use, cleaning, (dis)assembly, sterilisation, etc.)

  - must fit on **small space**
  - must be able to carry **sufficient information** (item identifier & serial number) to enable traceability
  - must **remain readable** throughout the intended life span of the item
  - must be **practical** (easily retrievable, etc.)
  - must be **biocompatible**
  - must be **standards-based**

Special cases…
Small instrument marking



- Data carrier: **GS1 DataMatrix**
  - Target useable mark area of 2.5mm x 2.5mm
  - One bar code on a single instrument
  - Though not limited to, laser etching is recommended
  - Mixed marking technologies within the same scanning environment should be avoided (ensures highest reading performance)
- Identification key: **GTIN**
  - GTIN (Global Trade Item Number) – preferred option
    - GTIN-12, -13 or -14 allowed
  - GRAI (Global Returnable Asset Identifier) or GIAI (Global Individual Asset Identifier) – in case of hospital legacy system
- Attribute: **Serial number**
  - AI(21) (Application Identifier) mandatory - Serial number

Small instrument marking
Application

- **Camera-based bar code scanners needed**
- Fixed scanner operation (present the instrument to the scanner to be read) is likely
- Scanner specific for direct part marking will give best performance

Questions?

You can ask now…

…or you can ask later.

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