



# AIDC Application Standards for Healthcare

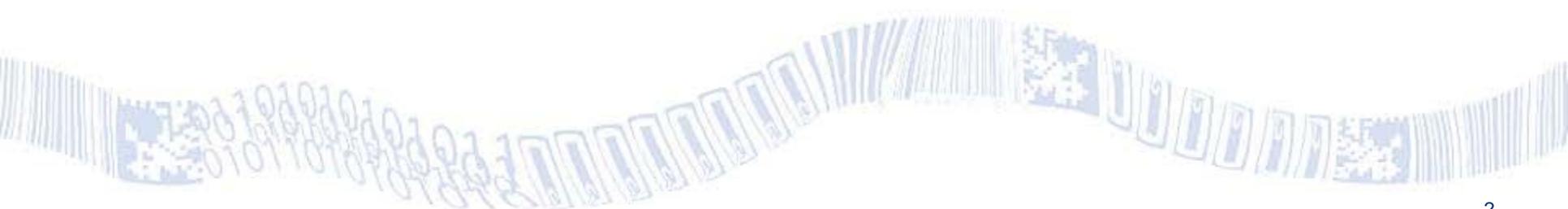
## GS1 DataMatrix

Chuck Biss – GS1 Global Office



## 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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# Healthcare Bar Code use in Healthcare



# There are 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...**

# There are Healthcare-specific marking requirements...



**Bar Code Label**

**Bar code on a label  
LABEL on the item**



**Direct Marked Parts**

**Bar code  
DIRECTLY ON THE ITEM**

# GS1 General Specification was changed...



**Revised!!**

GS1 General Specifications

Version 10

Issue 1, Jan-2010

The modifications resulting from the Healthcare AIDC Work Group, that describe how GS1 BarCodes and Identification Keys should be used for the Healthcare sector, are commonly referred to as the “*AIDC Application Standards for Healthcare*”, and are implemented within the Gen Spec.

These changes have “touched” many areas of the document...



# **GS1 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

# GS1 Healthcare Trade Items & Channels...

Pharma / Vaccine / Nutritional



Medical devices



Retail

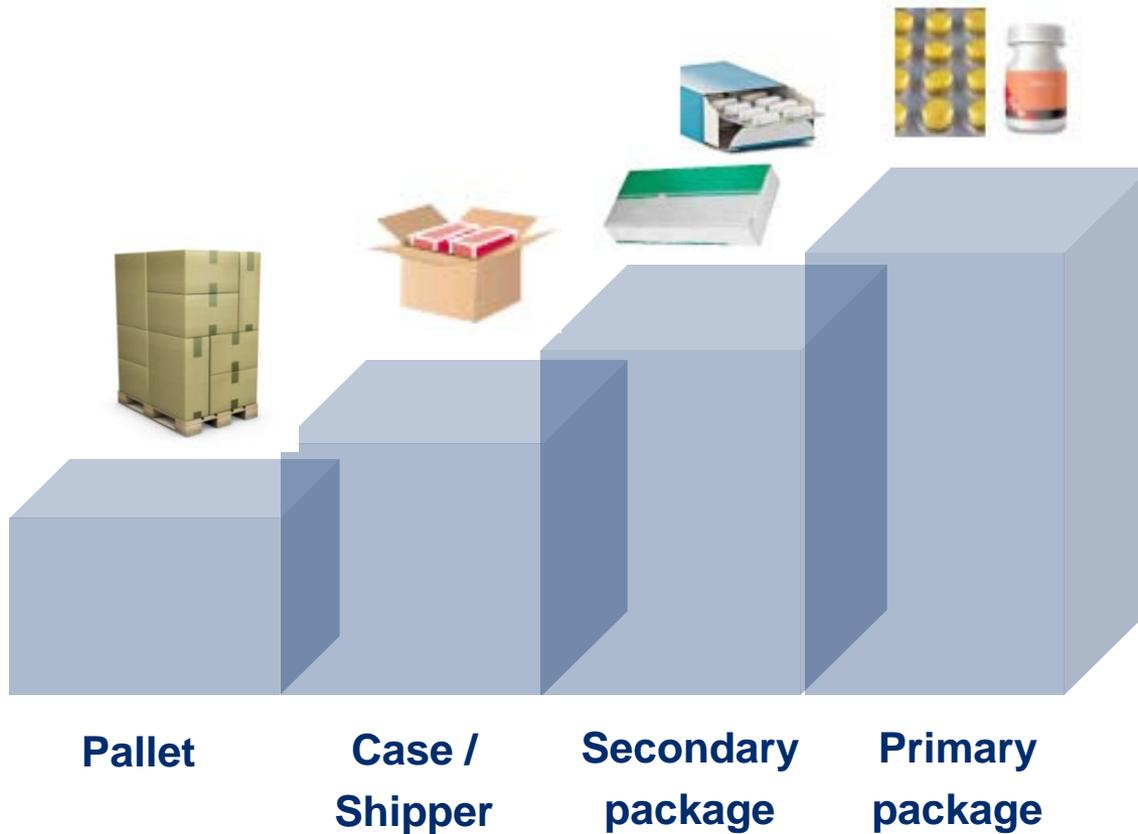


Non-retail





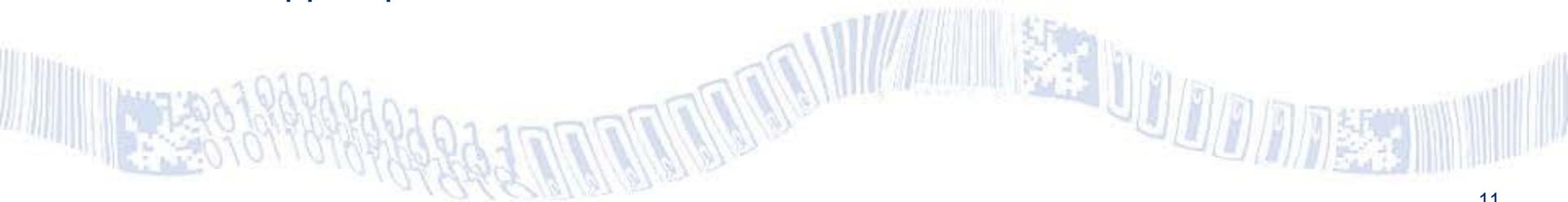
# Healthcare Packaging levels...



**Note:** Images shown are for illustration example only, refer to local regulations and/or the latest version of the GS1 General Specification for more detail.

## A framework to define level of AIDC marking (data carriers and encoded data)

- *By product type*
  - Pharmaceuticals and medical devices
  - Low to high risk products
- *By distribution channel*
  - Retail or non-retail
- *By packaging level* (NEW GLOSSARY TERMS)
  - Direct part marking, primary package, secondary package, case-shipper, pallet



# The need to capture the ID key ... and beyond...

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



(01) 1022222333334 (17) 091231 (10) A1345B (21) 1234

Item identifier

Expiry date

Batch number

Serial number



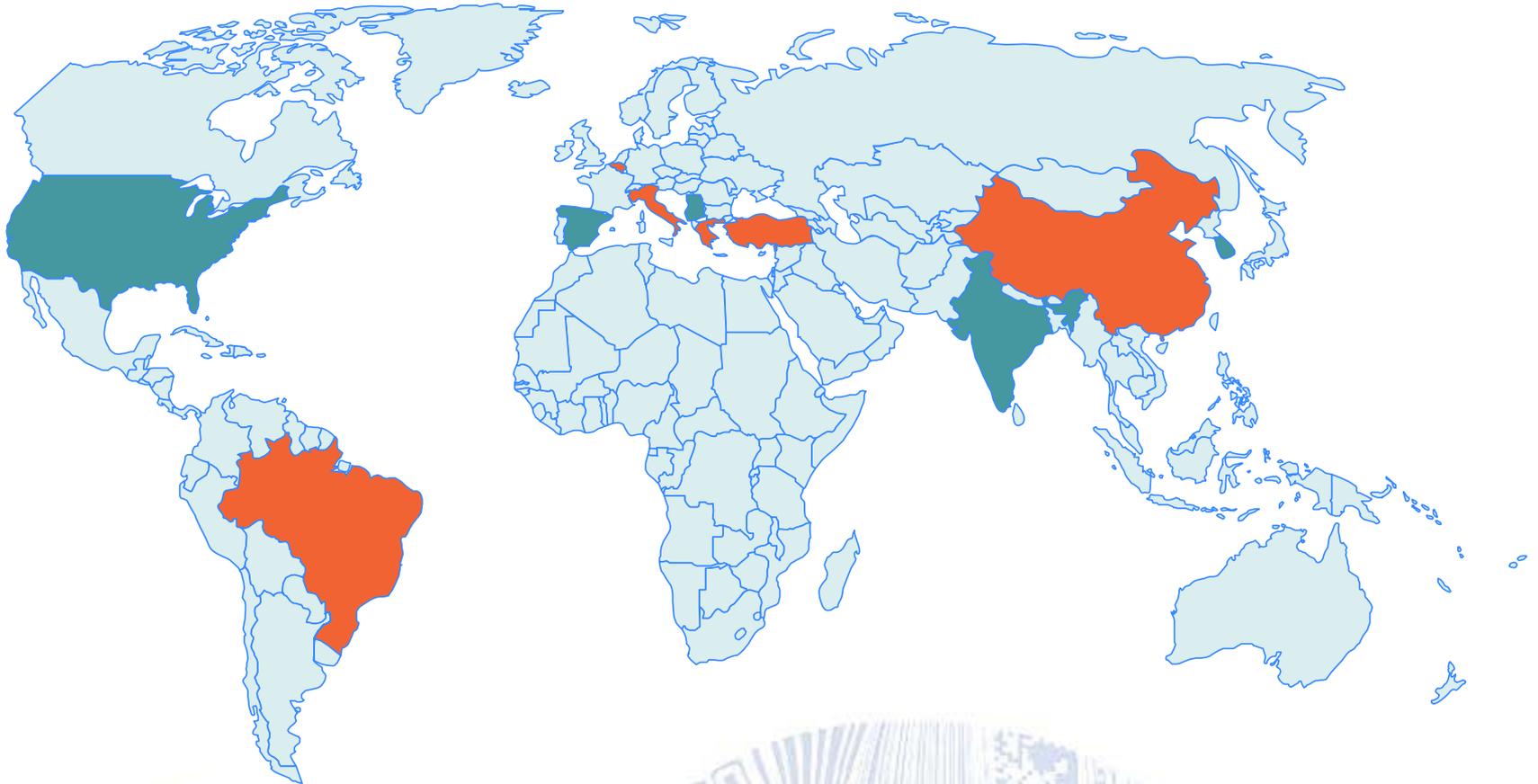
## **GS1 General Specifications includes complete list of 100+ GS1 Application Identifiers**

### **Application Identifiers for Healthcare Use**

00	SSCC (Serial Shipping Container Code)
01	GTIN (Global Trade Item Number)
10	Lot / Batch
17	Expiry Date
21	Serial Number
7003	Expiry Date + Time
7004	Active Potency
8003	GRAI (Global Returnable Assets Identifier)
8004	GIAI (Global Individual Assets Identifier)



# Healthcare Serialisation of pharmaceuticals...



= country requires serial number

= country developing requirement for serial number



# Healthcare DataMatrix on pharmaceuticals...

**Switzerland:**  
SmartLog Pilot

**Spain:** Pilot

**France:**  
AFSSAPS regulation (2011)

**Belgium:**  
Pilot project unit dose marking

**Austria:**  
Cytostatics

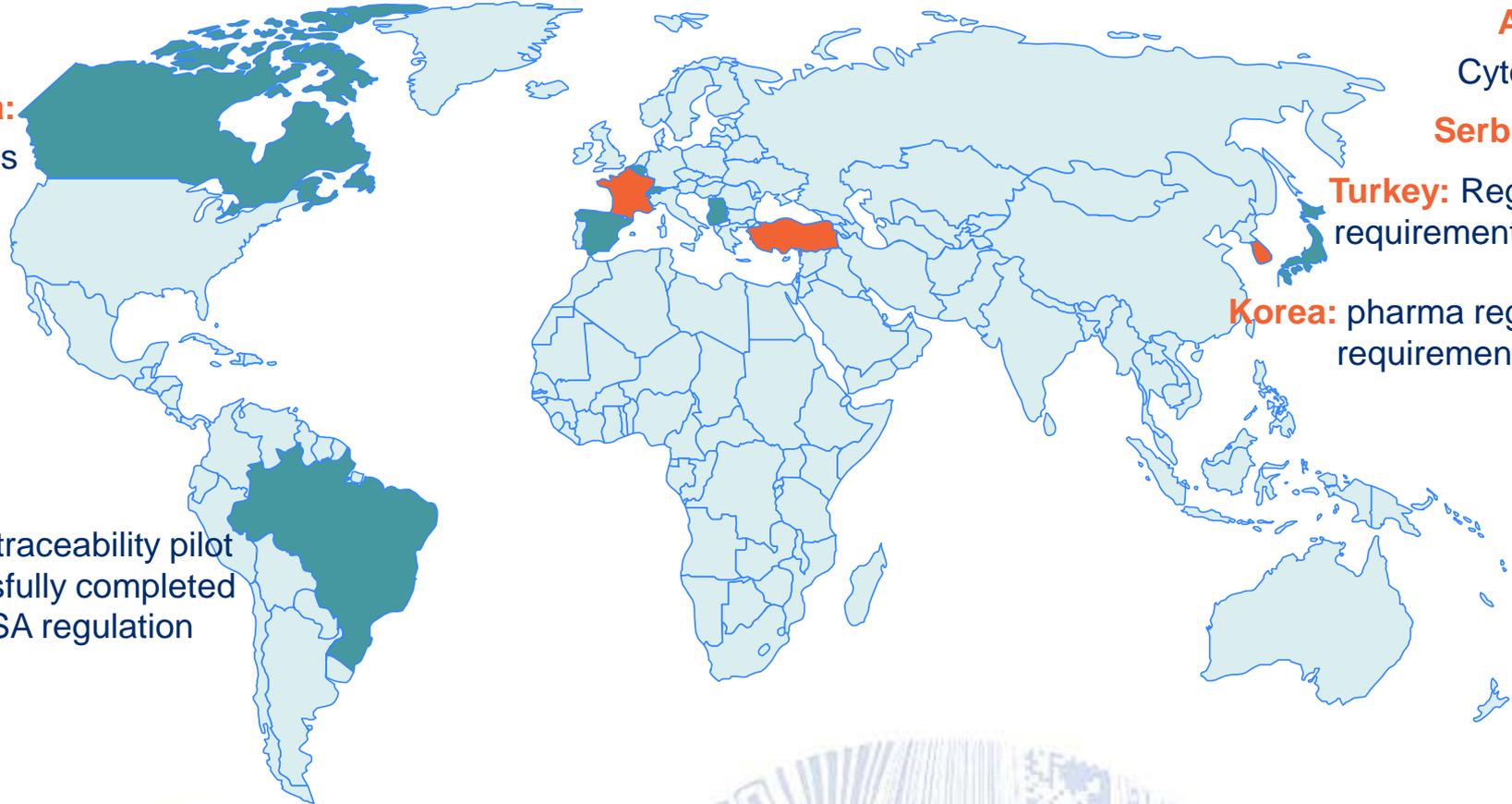
**Serbia:** Pilot

**Turkey:** Regulatory requirement (2010)

**Korea:** pharma regulatory requirement (2011)

**Canada:**  
Vaccines

**Brazil:** traceability pilot successfully completed – ANVISA regulation



= country requires DataMatrix

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



(01) 0 0012345 67890 5



**GS1-128 &  
GS1 DataBar**

**Preferred options** if:

- ✓ package allows



(01)07612345678900(17)100503  
(10)AC3453G3

**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



# GS1 Data Carriers for Healthcare... an example...

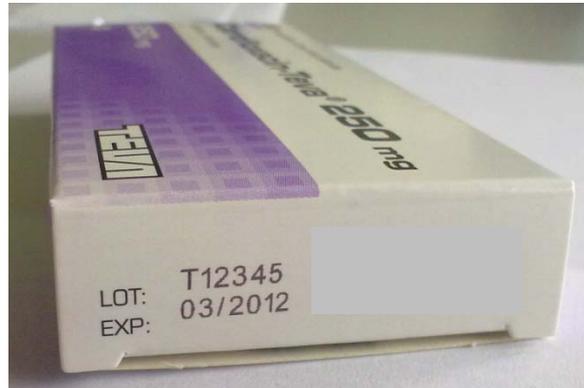
Product type?	Pharmaceutical
Distribution channel?	Non-retail
Information need?	Enhanced
Package level?	Secondary



**EAN/UPC**



**Composite Component**



**GS1-128**



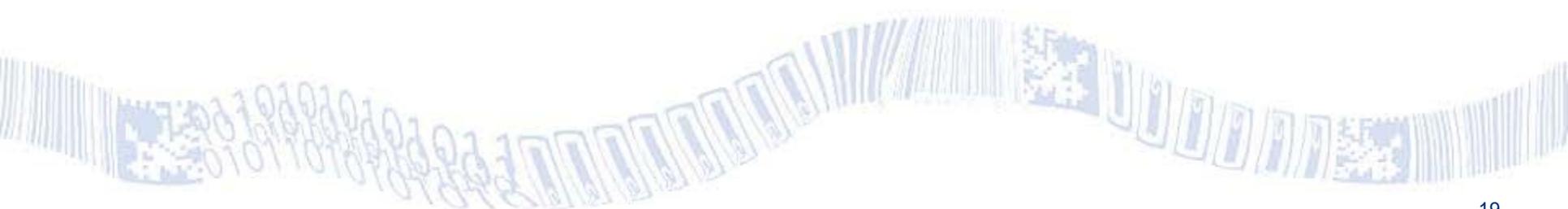
**ITF-14**



# GS1 Healthcare 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"**
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# Data Carriers: Bar Code Symbologies

## Bar code symbology “evolution”



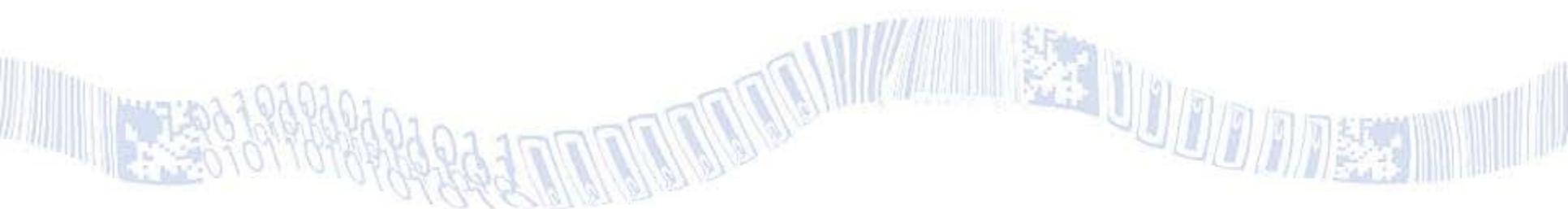
1D “Linear”



2D “Multi Row”



2D “Matrix”





# 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.

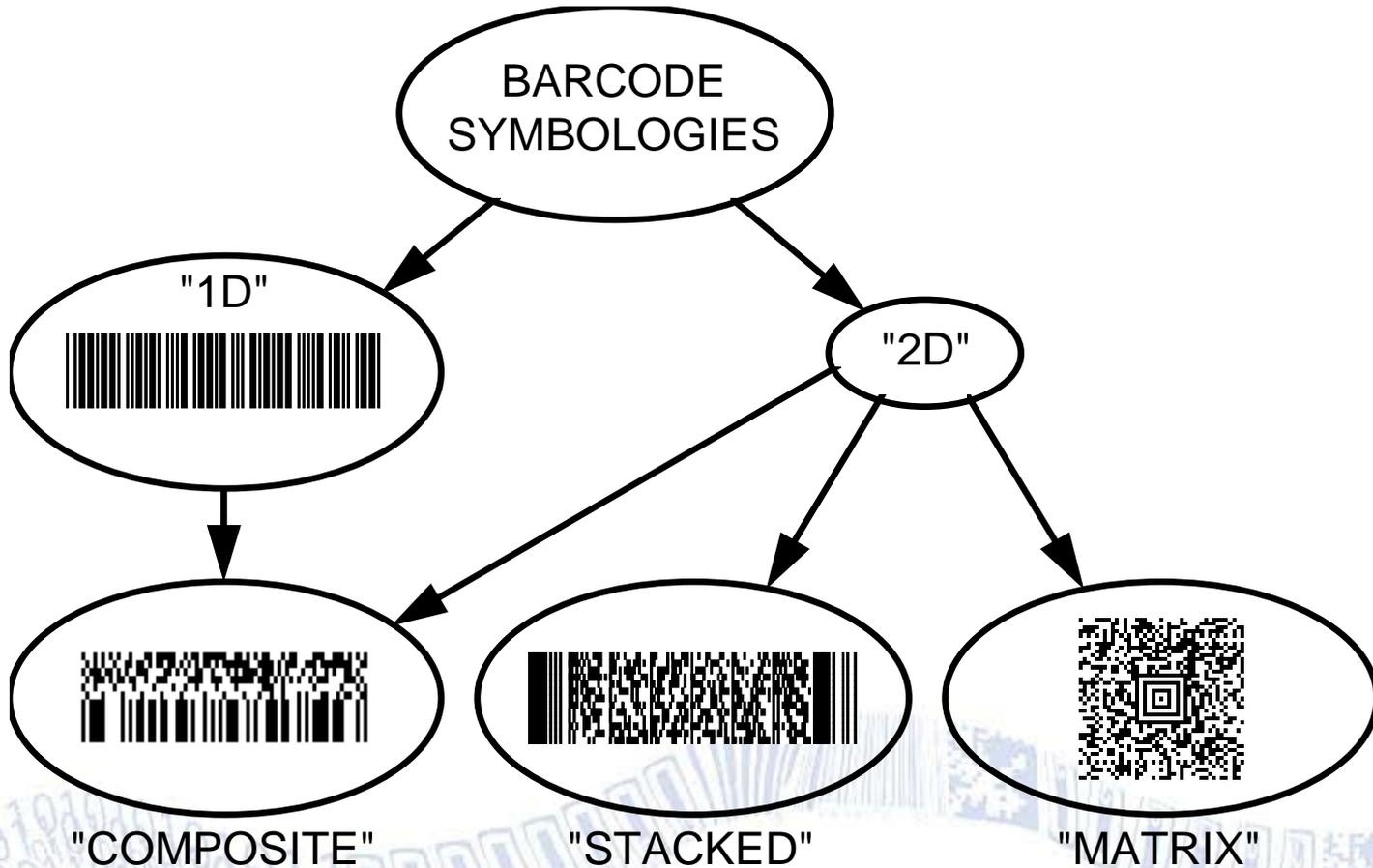
## 2D “Matrix”

- True “two dimensional” codes based on dot or element placements in a matrix... DataMatrix, QR Code, MaxiCode, etc.



# Data Carriers: Bar Code Symbologies

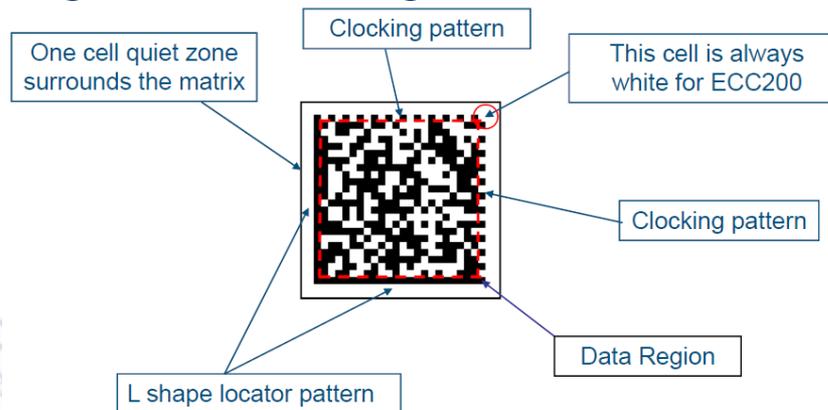
Symbologies more simply...





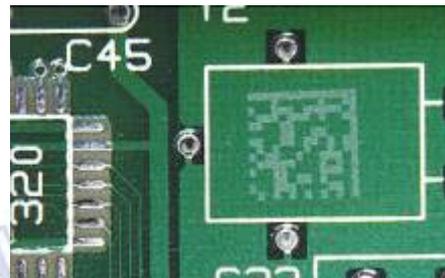
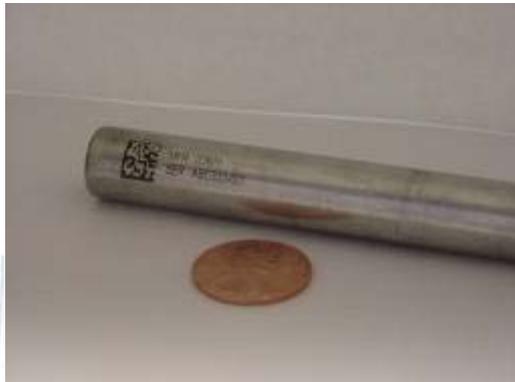
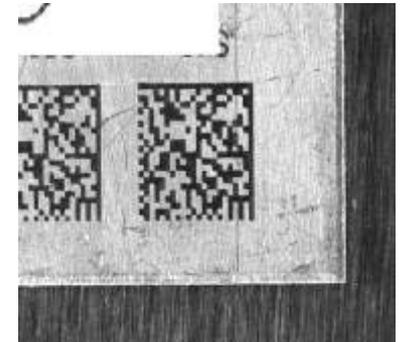
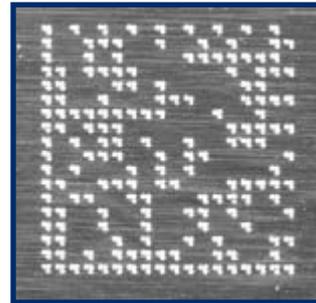
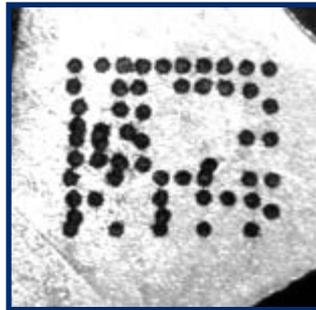
# Healthcare ISO Data Matrix Symbology

- Established 1989 by International Data Matrix
- Internationally standardized in ISO/IEC 16022
- Scalable 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





# Healthcare Data Matrix Applications

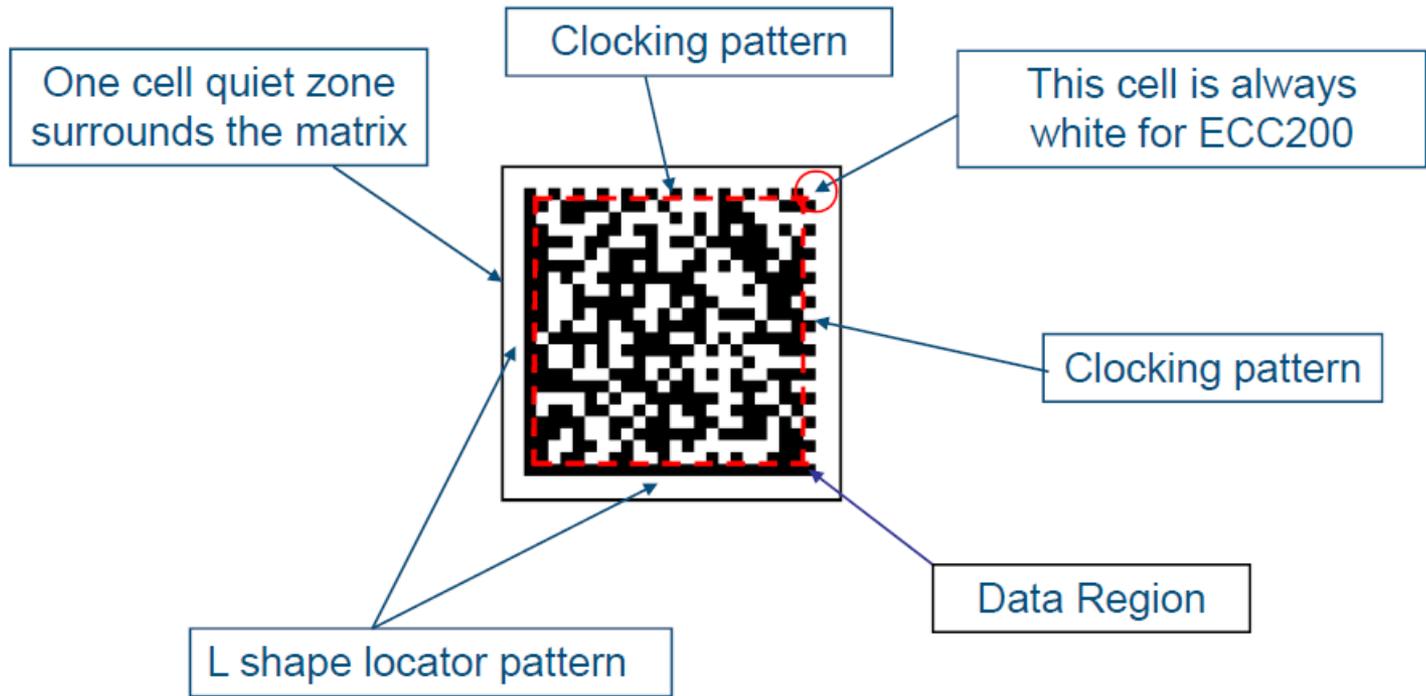


MFR A1234





# Healthcare 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

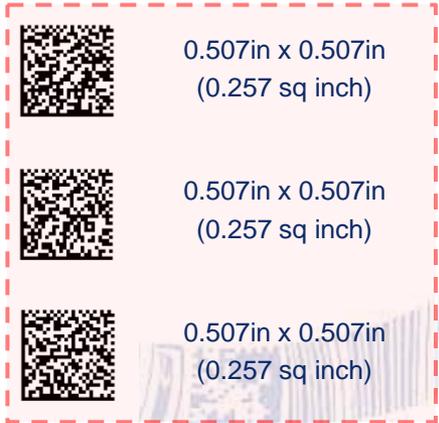


For **EACH** extra individual character you add to the data string... the symbol increases in length...

# GS1 DataMatrix...

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

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

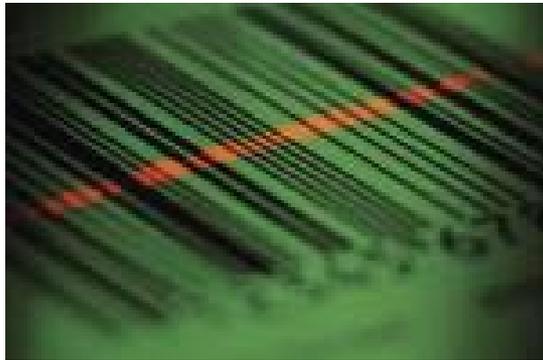




# Healthcare Scanning 2D Matrix Symbols

## 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!!**



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11MAR2007

**GS1-128 & GS1 DataBar**

**GS1 DataMatrix**

# Position - Camera-Based scanners

(June 2007)



**Position Statement**

**GS1 HUG 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, the GS1 HUG™ (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.*

Preparing members, solutions providers and end users for the future...



**Position Statement**

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GS1 HUG 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 marking (e.g. surgical instruments and implants)
  - unscannable bar codes do 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:



**GS1 DataMatrix**



The two examples contain identical data

- 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.

Get your copy at:

[http://www.gs1.org/docs/healthcare/GS1\\_HUG\\_ps\\_Camera\\_Based\\_Scanners.pdf](http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf)



Healthcare

# 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/>



## GS1 DataMatrix

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

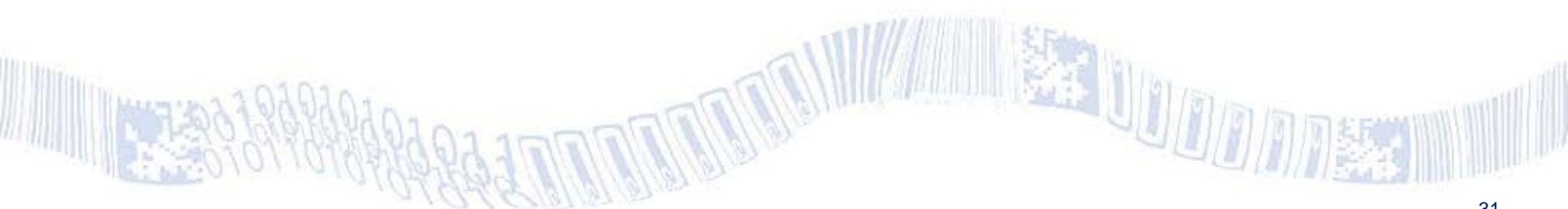


The crucial guideline to define an application standard according to your sector business needs



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# Healthcare 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
- Quiet 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

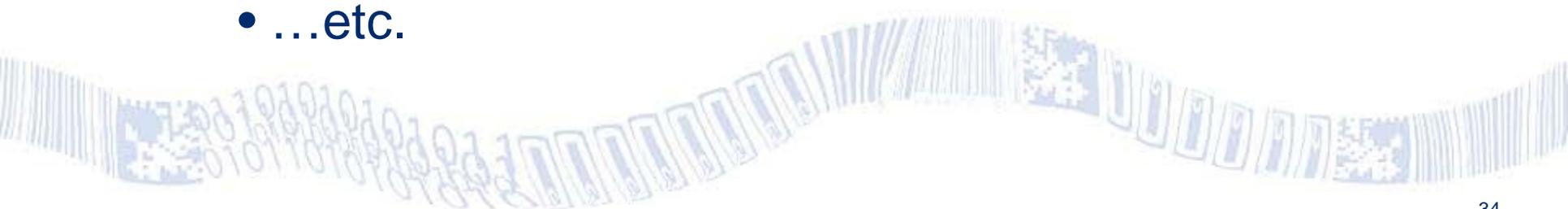


# Healthcare Quality Parameters

## 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
- ...etc.





# Healthcare 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

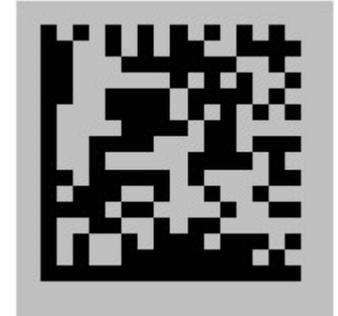
→ ISO Data Matrix - (No FNC1)



# Healthcare Quality Parameters

## Symbol Contrast

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



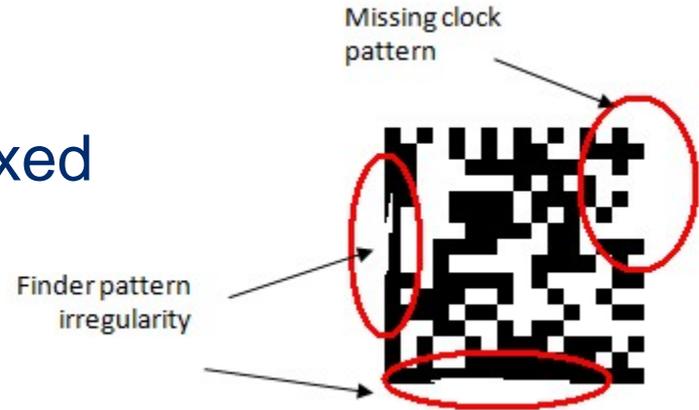
## Modulation

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



### Fixed Pattern Damage

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



### Unused Error Correction

Damage in the Symbol

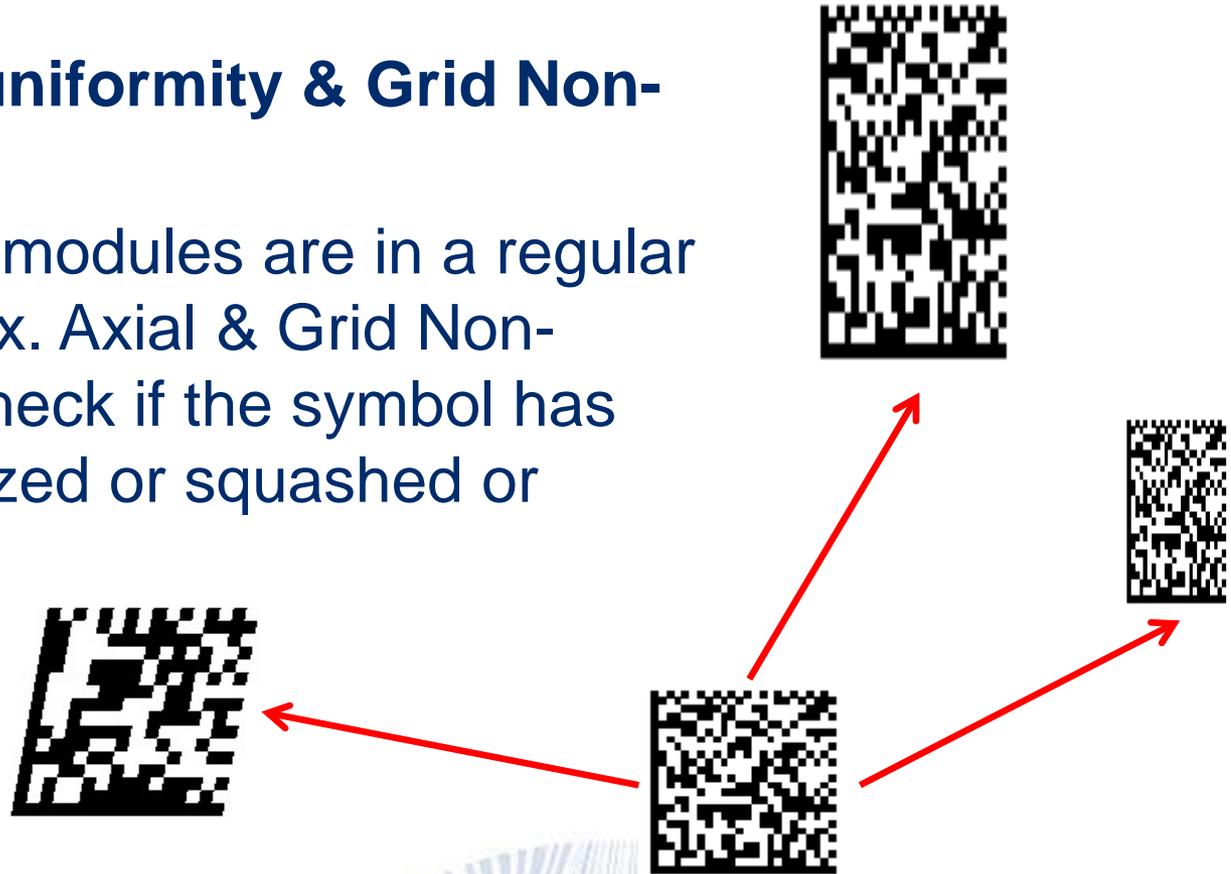
High Error Correction

Reduced Unused Error Correction Capacity



## 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





# Healthcare Quality Parameters

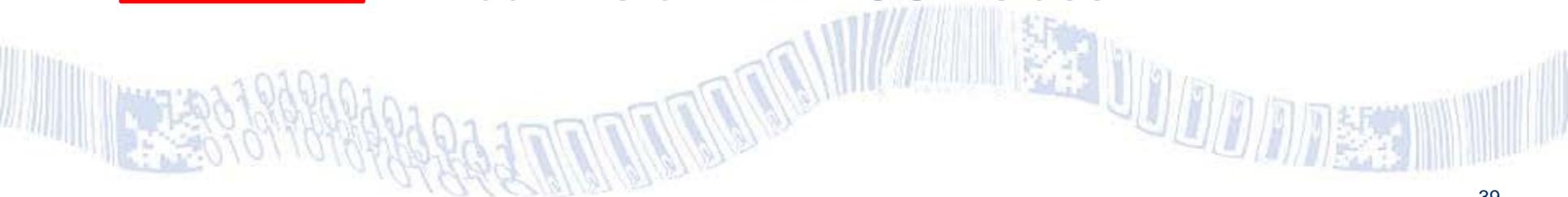
## Print Growth

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...



# Healthcare **Quality Parameters**

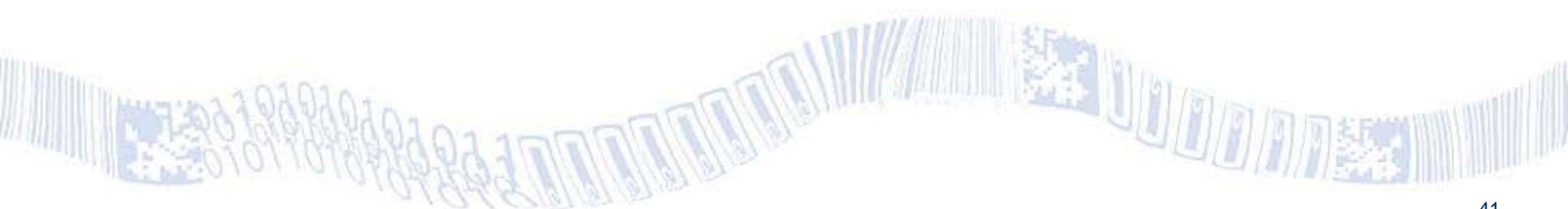
**Bar Code Print Quality Verifiers are available for testing 2D Matrix symbols like GS1 DataMatrix**



Check out the [AIM Buyer's Guide](#) for a listing of most manufacturers

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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 as 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 \$200K 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 \$300 - \$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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(10)AC3453G3

**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



(01)07612345678900(17)100503

(10)AC3453G3

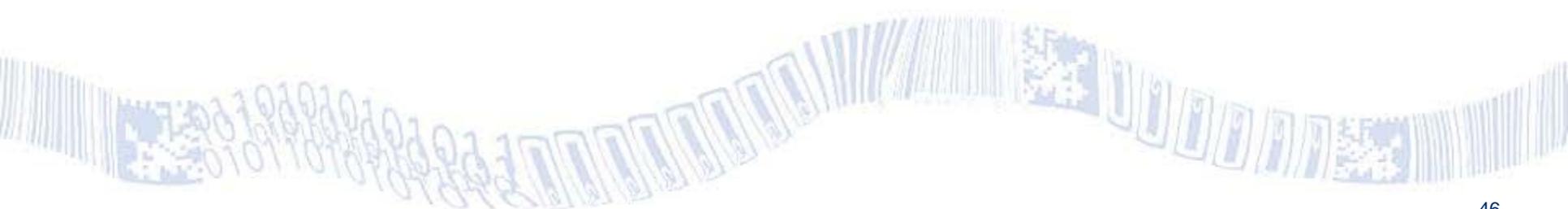
## GS1 DataMatrix

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

# Addressing a specific need in the Healthcare supply chain...



Ratified GS1 Standards for  
**direct part marking**  
**of small surgical instruments**  
to ensure their traceability in the  
instruments reprocessing cycle



# Traceability of small surgical instruments

## 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



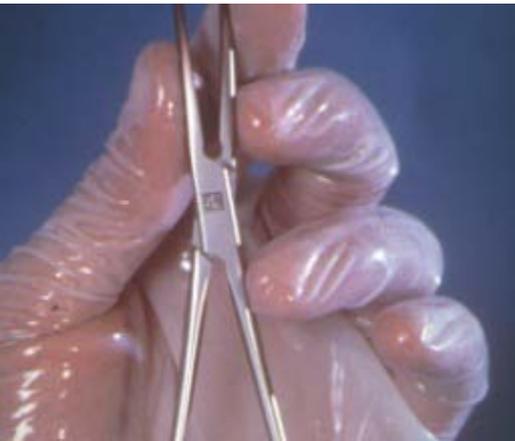
- Specific marking needs to manage critical internal logistics processes (use, cleaning, (dis)assembly, sterilisation, etc.)
  - must fit on **small space**
  - must be able to carry **sufficient information** (item identifier & serial number) to enable traceability
  - must **remain readable** throughout 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

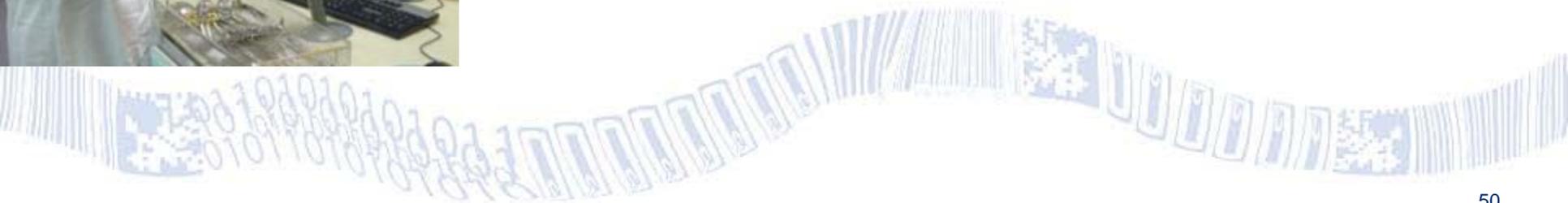


# Small instrument marking Application

## 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



 **Healthcare Questions?**

You can ask now...



...or you can ask later.



# Contact Details

Chuck Biss - GS1 Global Office

**T** + 1 (315) 252-5941

**M** +1 (315) 480-2034

**E** [chuck.biss@gs1.org](mailto:chuck.biss@gs1.org)

