The Global Language of Business

ASK THE EXPERTS
GS1 DataMatrix & HRI

Some Basics…

GS1 Healthcare Conference – Berlin

5 April 2017

Introduction… Me…

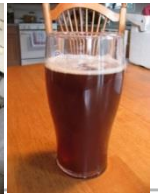
Company/Organisation

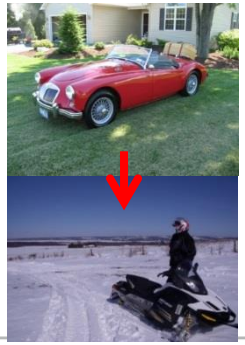
GS1 Global Office – Senior Director, AIDC Healthcare

Relevant experience / knowledge

- 40+ years in the AIDC industry in the areas of scanning technologies, bar code print quality verification equipment & processes, printing techniques (35 years combined with PSC / Hand Held Products / Honeywell Scanning & Mobility)
- 35+ years in National & International AIDC Standards Development (Past Chairman of ISO/IEC JTC 1 Sub-Committee 31 on AIDC)
- Education - Bachelor of Science (BS) from Rochester Institute of Technology (Rochester NY USA) in Photographic Science & Engineering
- IP – Various patents in the area of Bar Code Print Quality

&





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Ask the Experts – Topics…

A General Discussion of GS1 DataMatrix & HRI, with a GS1 Healthcare Application Standards Focus

- Why GS1 DataMatrix in Healthcare
- Data Matrix… The Symbology
  - "GS1 DataMatrix" or "ISO/IEC Data Matrix"
- Thoughts on Structure & Quality
- Practical Application - Printing / Reading
- Human Readable Interpretation - HRI
- Audience Q & A

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GS1 DataMatrix

Some Data Carrier Basics

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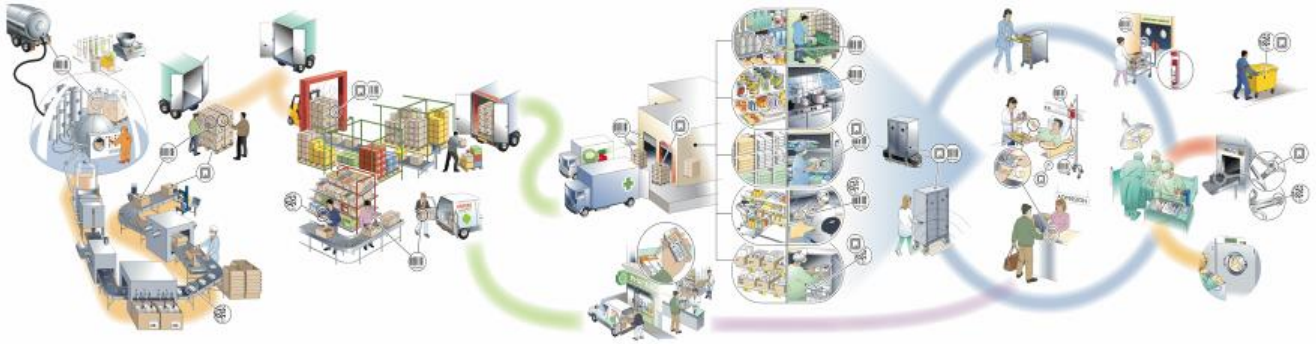
Healthcare – A need for “Unique” ID…

“Traceability is the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration” …generally using documented & recorded ”unique” identification.



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Healthcare – A need for "Unique" ID…

AIDC – Unique Product Identification

The goal is unambiguous identification of a specific product. From an AIDC standpoint this identification would have two (2) parts:

- The **Product Identifier** – Meant to be the identification of the "generic" product – GS1 **GTIN** enables this.
- The **Product Attribute** – Meant to be whatever "control" numbers or data a manufacturer uses in their process – GS1 **Application Identifiers** (**AI's** such as lot/batch number, serial number, expiry, in any combination with a GTIN) enable this aspect.

GTIN + AI(s) = Unique Product ID

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Healthcare – Data / Data Carrier needs…

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…

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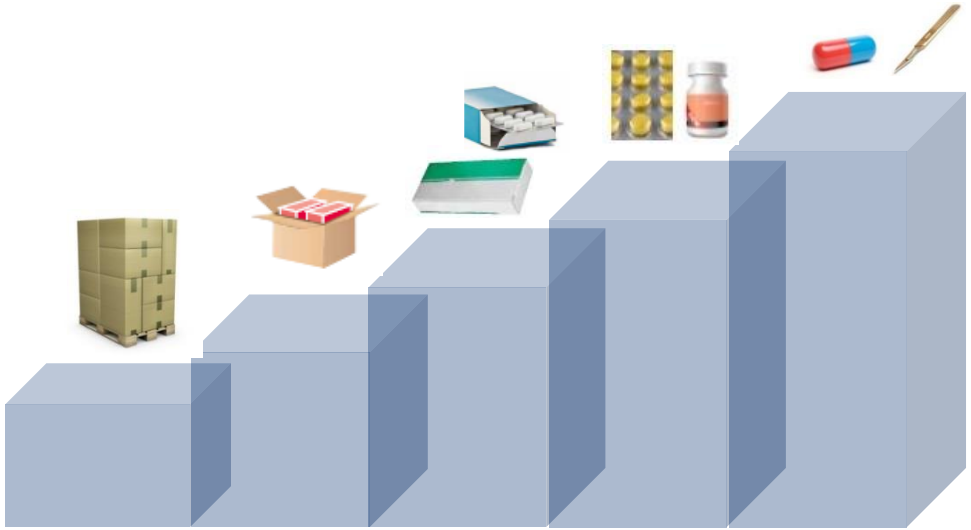
Healthcare – Data / Data Carrier needs…



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.

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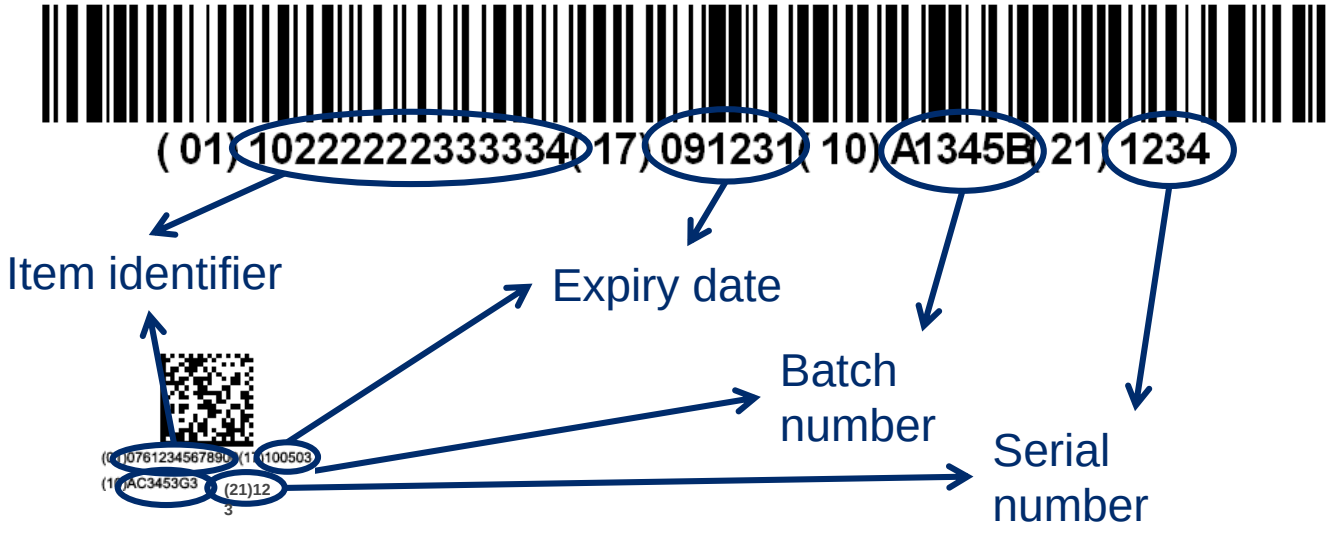
Healthcare – Data need beyond GTIN…

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



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Healthcare – GS1 DataMatrix global…


Argentina


Jordan


India


Algeria


T…


…orea


Saudi Arabia


Brazil


El…


USA

GTIN – Global Trade Item Number

Plus attributes

- Lot number
- Expiry date
- Serial number (2016)

In a GS1 DataMatrix

Changes often… shown here for illustration of adoption emphasis / need…
!! NOT FOR CIRCULATION or DUPLICATION !!
GS1 Global Healthcare Members have direct access to updated information

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Healthcare – GS1 Data Carrier choices…

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

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Ask the Experts – Topics…

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Data Carriers – Some history…

Bar code symbology “evolution”…
or “revolution”…

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

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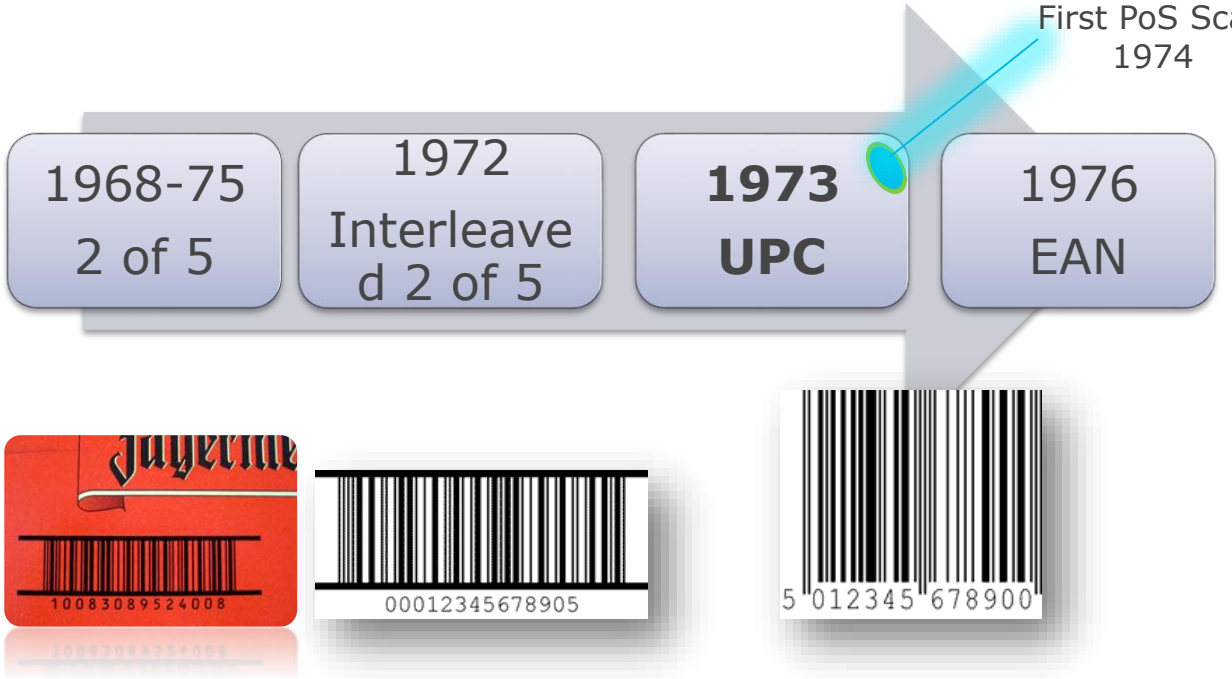
Data Carriers – Some history…



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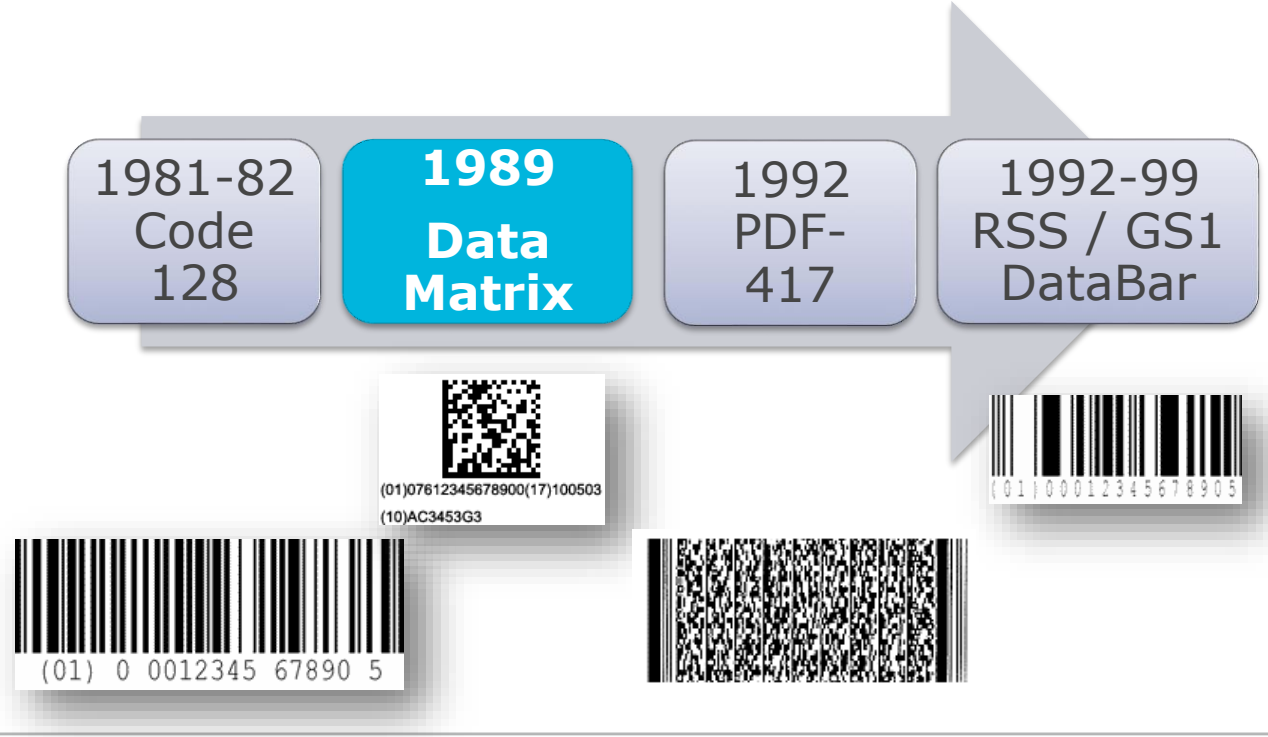
Data Carriers – Some history…



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Data Carriers – 2D/Matrix technology…

- Mature Technology
- Weak Vertical and Horizontal Redundancy
- “Strong” Finder Patterns
- Omnidirectional Design for Scanning
- Inherent Robust Error Detection and Error Correction
- Complex Algorithms
- Data Compaction Modes
- Structured Append
- Extended Channel Interpretation (ECI)
- Image Reverse and Color Reverse

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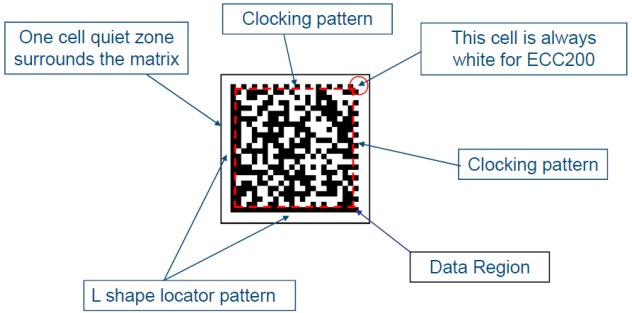
Data Carriers – 2D/Matrix technology…

- General Components of a 2D Symbol
  - Finder Patterns
    - Robustness & Weakness
  - Data Region(s)
    - Balanced by amount of Error Detection & Correction
  - Error Correction Region(s)
    - Balanced by amount of Error Detection & Correction



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Data Carriers – 2D/Matrix symbologies…

Many to choose from… are they all "the same"…

Data Matrix

QR Code

MaxiCode

Aztec Code

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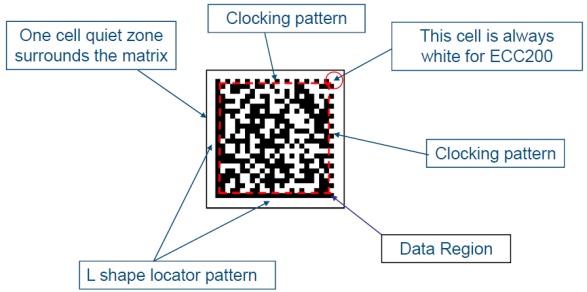
Data Carriers – ISO/IEC Data Matrix…

- 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"…)
- Error Detection & Multiple Error Correction Levels
- Multiple encoding formats and macros
- More adaptable to "direct" marking (DPM)
- Primary Applications - Parts marking (Aerospace, Automotive, Semiconductor, Medical instruments), Pharmaceutical packaging, Documents



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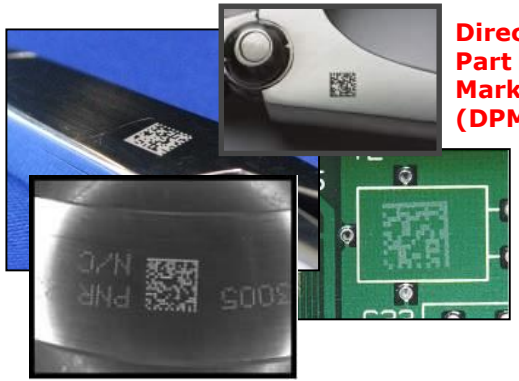
Data Carriers – ISO/IEC Data Matrix…



Direct Part Marking (DPM)

Identification & Document Tracking

Item Package & Label Marking

Packaging Verification

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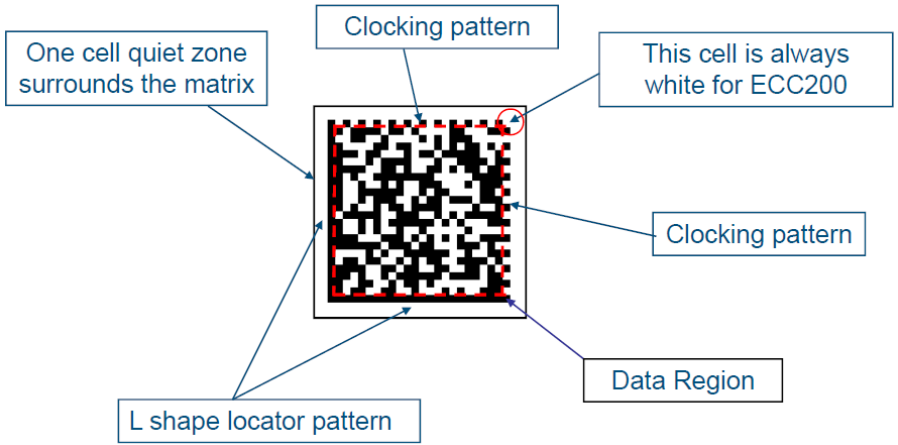
Data Carriers – GS1 DataMatrix…



- ISO/IEC 16022 Data Matrix… as "GS1 DataMatrix":
  - 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

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Data Carriers – 2D/Matrix size change…

GS1 DataMatrix… Size Change w/ Data Content… in “blocks”

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 - Symbol 4 + AI(21) of 3 numeric	0.468in x 0.468.in (0.219 sq inch)
Symbol 6 - Symbol 4 + AI(21) of 13 numeric & 1 alpha	0.507in x 0.507in (0.257 sq inch)
Symbol 7 - Symbol 4 + AI(21) of 15 numeric & 2 alpha	0.507in x 0.507in (0.257 sq inch)
Symbol 8 - Symbol 4 + AI(21) of 17 numeric & 3 alpha	0.507in x 0.507in (0.257 sq inch)

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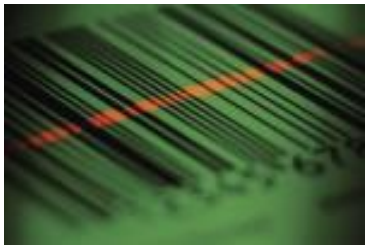
Data Carriers – 2D/Matrix scanning…

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 all sectors
- Scans 1D/Linear, 2D/Stacked & 2D/Matrix symbols

Camera-based bar code scanners… needed in Healthcare & GS1 Healthcare Leadership Team recommended!!

GS1-128 & GS1 DataBar

GS1 DataMatrix

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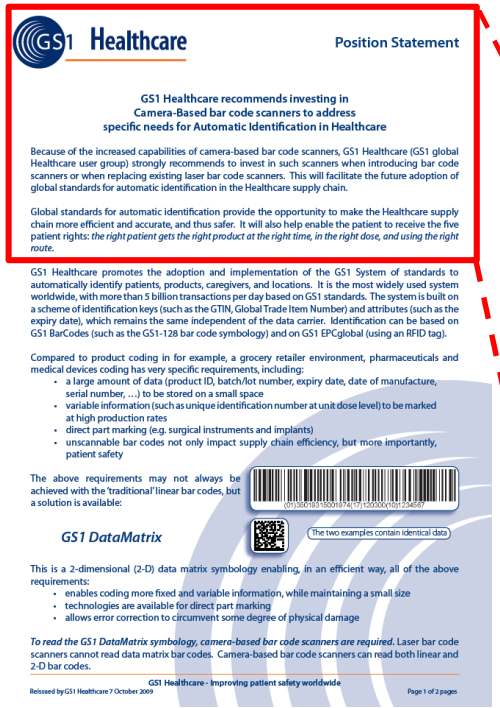
Position – 2D Imager/Camera scanners…



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:

(01)38019315001974(17)120300(10)1234567

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…

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Get your copy at:

http://www.gs1.org/docs/healthcare/GS1_HUG_ps_Camera_Based_Scanners.pdf

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Position – GS1 DataMatrix adoption…


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

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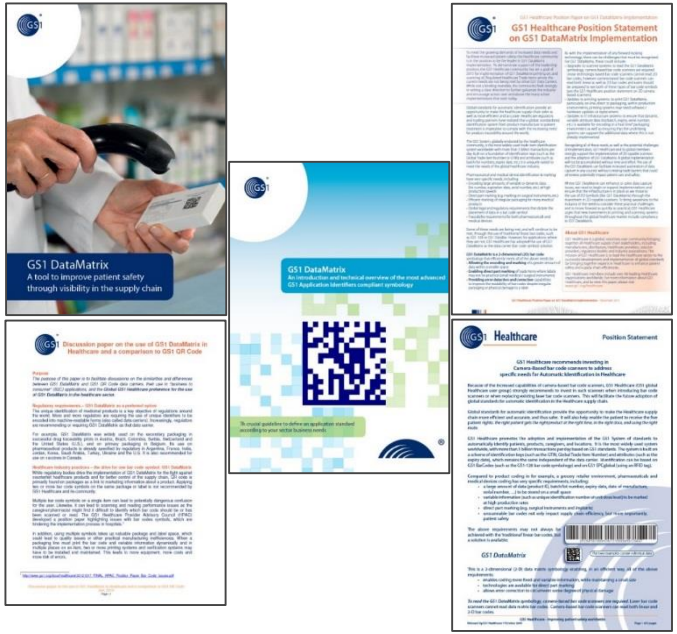
GS1 DataMatrix & unique product ID…

GS1 DataMatrix

(01)00012345678905

As we see more AIDC marking on small Pharmaceutical and Medical Device products (and/or on their packaging) we will see more GS1 DataMatrix due to its ability to efficiently and securely carry more data in smaller areas, and also due to its promotion for use by the GS1 Healthcare global members. Becoming familiar with the available support materials is advised...



CHECK OUT: http://www.gs1.org/healthcare/library
http://www.gs1.org/docs/barcodes/GS1_DataMatrix_Introduction_and_technical_overview.pdf

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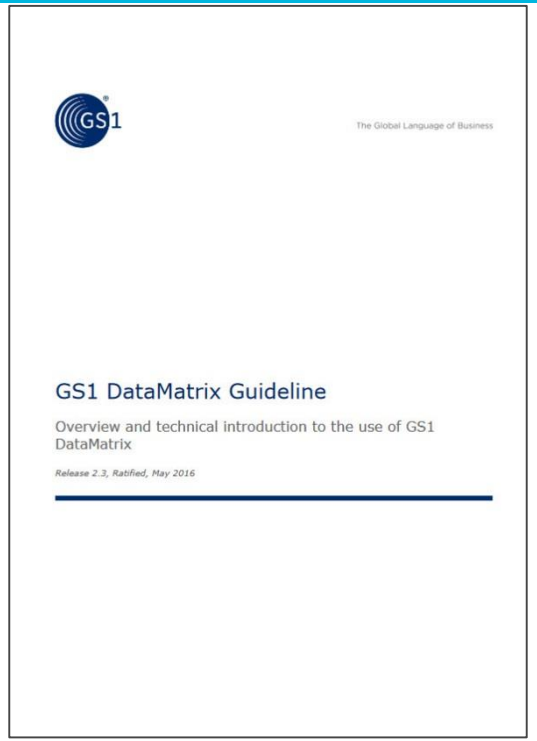
GS1 DataMatrix – technical help…

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/docs/barcodes/GS1_DataMatrix_Guideline.pdf

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GS1 DataMatrix versus GS1 QR Code…

Data Matrix

QR Code

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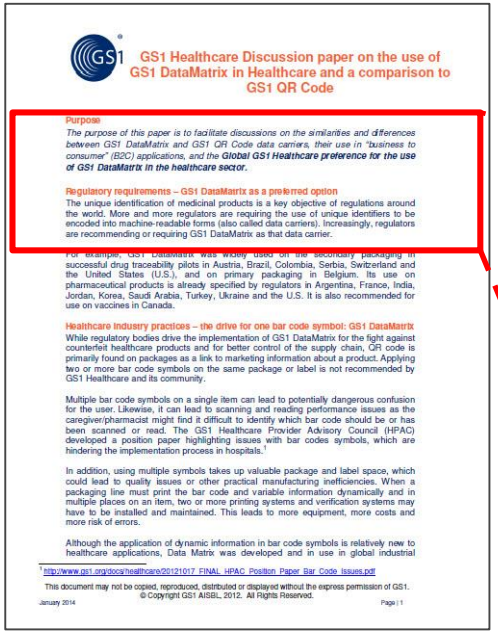
Position – DataMatrix or QR Code…



GS1 Healthcare Discussion paper on the use of GS1 DataMatrix in Healthcare and a comparison to GS1 QR Code

Purpose

The purpose of this paper is to facilitate discussions on the similarities and differences between GS1 DataMatrix and GS1 QR Code data carriers, their use in "business to consumer" (B2C) applications, and the ***Global GS1 Healthcare preference for the use of GS1 DataMatrix in the healthcare sector.***

Regulatory requirements – GS1 DataMatrix as a preferred option

The unique identification of medicinal products is a key objective of regulations around the world. More and more regulators are requiring the use of unique identifiers to be encoded into machine-readable forms (also called data carriers). Increasingly, regulators are recommending or requiring GS1 DataMatrix as that data carrier.

For example, GS1 DataMatrix was widely used on the secondary packaging in successful drug traceability pilots in Austria, Brazil, Colombia, Serbia, Switzerland and the United States (U.S.), and on primary packaging in Belgium. Its use on pharmaceutical products is already specified by regulators in Argentina, France, India, Jordan, Korea, Saudi Arabia, Turkey, Ukraine and the U.S. It is also recommended for use on vaccines in Canada.

Healthcare industry practices – the drive for one bar code symbol: GS1 DataMatrix

While regulatory bodies drive the implementation of GS1 DataMatrix for the fight against counterfeit healthcare products and for better control of the supply chain, QR code is primarily found on packages as a link to marketing information about a product. Applying two or more bar code symbols on the same package or label is not recommended by GS1 Healthcare and its community.

Multiple bar code symbols on a single item can lead to potentially dangerous confusion for the user. Likewise, it can lead to scanning and reading performance issues as the caregiver/pharmacist might find it difficult to identify which bar code should be or has been scanned or read. The GS1 Healthcare Provider Advisory Council (HPAC) developed a position paper highlighting issues with bar codes symbols, which are hindering the implementation process in hospitals.[1]

In addition, using multiple symbols takes up valuable package and label space, which could lead to quality issues or other practical manufacturing inefficiencies. When a packaging line must print the bar code and variable information dynamically and in multiple places on an item, two or more printing systems and verification systems may have to be installed and maintained. This leads to more equipment, more costs and more risk of errors.

Although the application of dynamic information in bar code symbols is relatively new to healthcare applications, Data Matrix was developed and in use in global industrial

[1] http://www.gs1.org/docs/healthcare/20121017_FINAL_HPAC_Position_Paper_Bar_Code_Issues.pdf

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Reinforcing the GS1 Global Healthcare direction for **ONE** 2D Matrix data carrier… **GS1 DataMatrix**…

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Get your copy at:

http://www.gs1.org/sites/default/files/docs/healthcare/GS1%20QR%20DM%20discussion%20paper_20140113_FINAL.pdf

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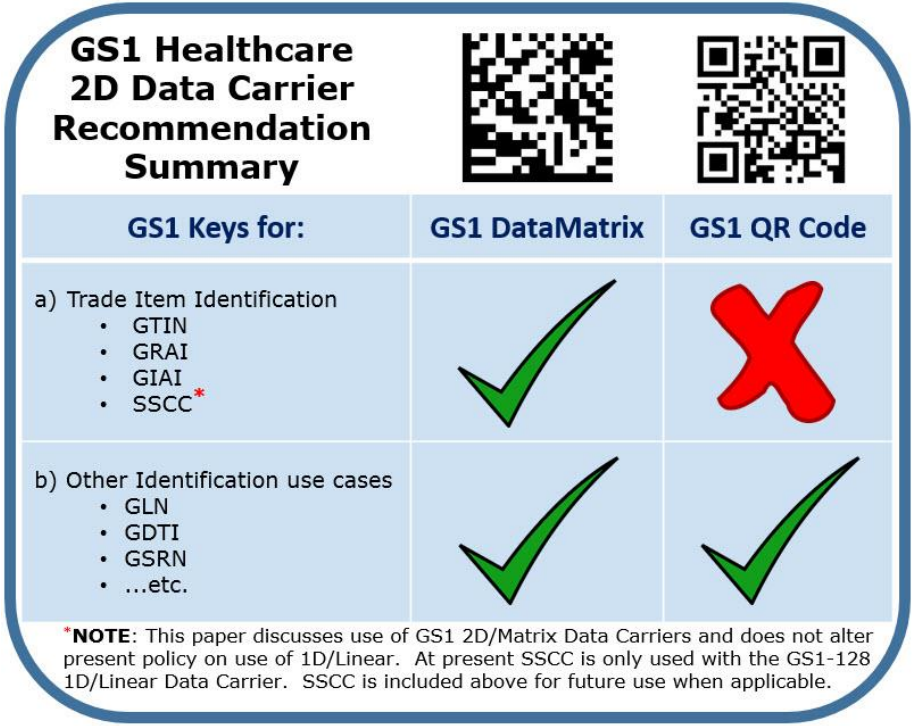
GS1 DataMatrix versus GS1 QR Code…



GS1 Healthcare 2D Data Carrier Recommendation Summary

GS1 Keys for:	GS1 DataMatrix	GS1 QR Code
a) Trade Item Identification • GTIN • GRAI • GIAI • SSCC*	✓	✗
b) Other Identification use cases • GLN • GDTI • GSRN • …etc.	✓	✓

*__NOTE__: This paper discusses use of GS1 2D/Matrix Data Carriers and does not alter present policy on use of 1D/Linear. At present SSCC is only used with the GS1-128 1D/Linear Data Carrier. SSCC is included above for future use when applicable.

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Ask the Experts – 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" or "ISO/IEC Data Matrix"
- **Thoughts on Structure & Quality**
- Practical Application - Printing / Reading
- Human Readable Interpretation - HRI
- Audience Q & A

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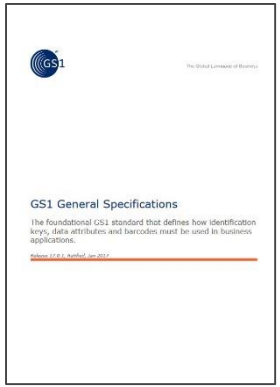
GS1 system – Bar code symbol quality…



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 TR 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…

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Symbol quality - 1D/Linear vs. 2D/Matrix…

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

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Symbol quality – Reference decode…

GS1 DataMatrix… or not… how do you know?

Symbol decode:

GS1 DataMatrix - (FNC1 & AIs)

]d2011085767400201717141120 10KMB11205201[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:

]d1011085767400201717141120 10KMB11205201[GS]21CEB630078700

ISO Data Matrix - (No FNC1)

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Symbol quality – There is help…

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

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

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GS1 DataMatrix – Implementation…

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.

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GS1 DataMatrix – Implementation…

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 $100 - $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 very available.

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GS1 DataMatrix – Implementation…

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

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

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

GS1 DataMatrix

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GS1 DataMatrix – Implementation…

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

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

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

GS1 DataMatrix

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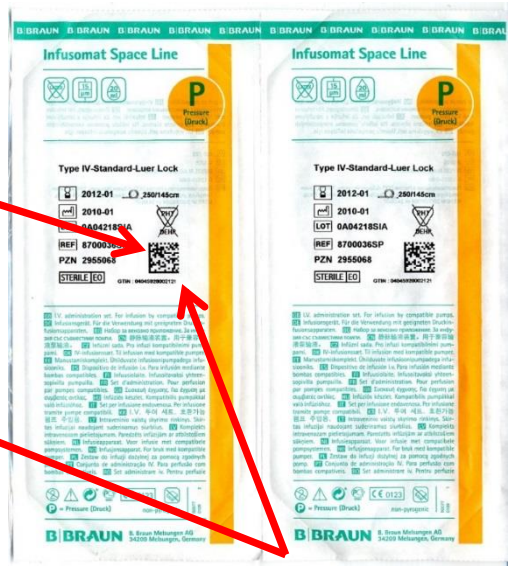
GS1 DataMatrix – Unique product ID…

For pharmaceutical & medical device…

GTIN (static data)



AI's (variable attribute data)

…in <u>one</u> bar code symbol (GS1 Data Carrier)

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GS1 DataMatrix – Implementation test…

- 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 Reimburse 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

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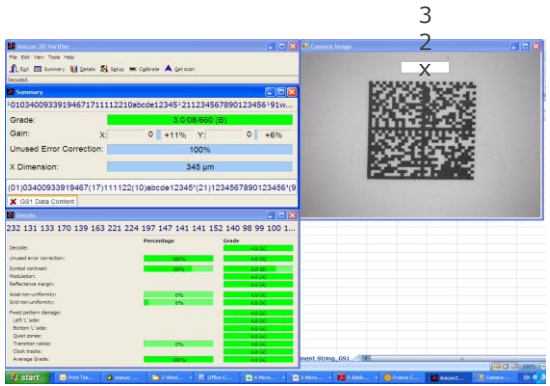
GS1 DataMatrix – Implementation test…

- Tests have also been run to add Serial Number, a country specific NHRN (National Healthcare Reimbursement Number) and a URL
- Run at "normal" line speed - 300 cartons/minute, 45m/min
- Again print sizes – 300 DPI, Module size of 345µm, Wolke m600A, Universal Black UB 7482 HP Inkjet cartridge
- Data: 74 Alphanumeric characters (GTIN, Expiry, Lot/Batch, Serial, NHRN, URL)
- Symbol Size: 32x32 matrix, physical size of 11x11mm
- 94% of run achieved an ISO/IEC 15415 Grade of "B" - 3.0/08/660 (with the remainder a "C" grade)



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GS1 DataMatrix – Implementation test…

DMX through the camera of the verifier

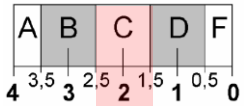
Technical challenges

Limited space means → small carriers + high data density

- e.g. DMX size : 6x6 - 10x10 mm
- Production/packaging line speed
- Packaging materials
- Printing technology
- Inks

Quality challenges

- Quality verification (ISO)
- Translucent paper
- Impact on contrast



ISO required = C (1.5 – 2.5)

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GS1 DataMatrix – Implementation test…

- Only 2D DataMatrix possible at present
  - Consistent reading… min. area of 3x3mm needed
- Size of surgical instruments extremely limited
  - Not all can be encoded (size, material, etc.)
- Implants (!?!?)
  - Size, corrosion, bio-compatibility, warranty issues, etc.
  - High-quality DPM technology required (laser, dot peen, etc.)






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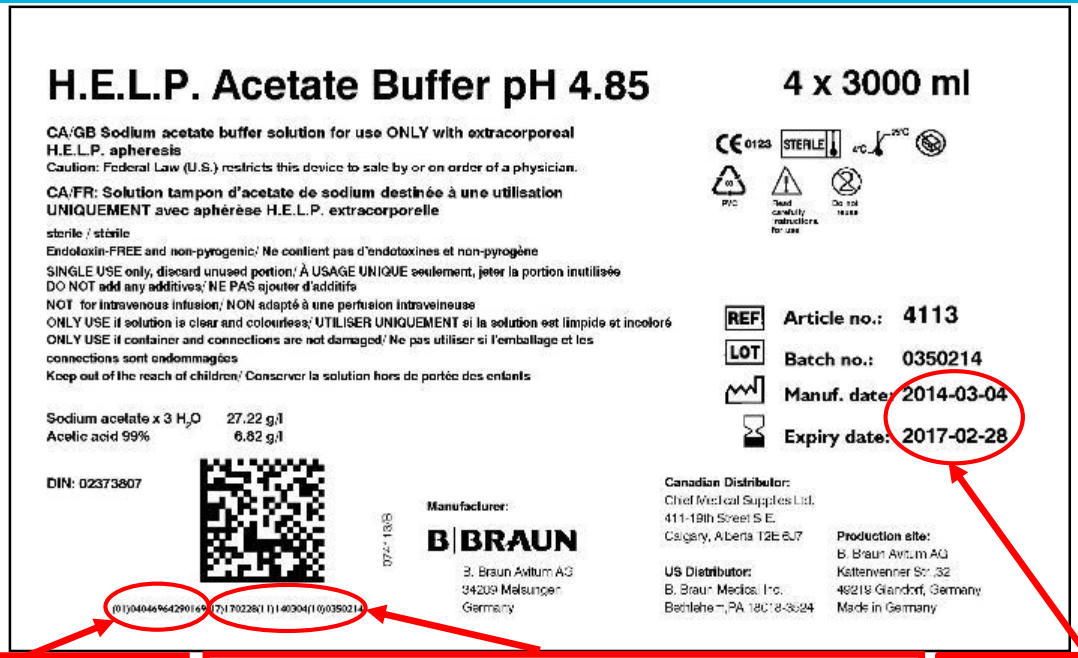
GS1 DataMatrix - UDI label – B.Braun…



Device Identifier (DI)
"Static" portion
GTIN (product identifier)

Production Identifier (PI)
"Dynamic" portion
Application Identifiers (e.g. serial, lot number & expiry date)

US FDA UDI required
ISO 8601 date format

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The Global Language of Business

Human Readable Interpretation - HRI

Recent General Specifications Changes

What is HRI ?

Human Readable Interpretation

- HRI show a human exactly what's in a barcode
- It's there in case the barcode does not read
- Some HRI rules are **specific to Healthcare** and these have been updated

Whether a GS1 AIDC Data Carrier encodes a GS1 identification Key, GS1 Key Attributes, or a combination of both, the HRI should be placed below the barcode and grouped together wherever physically possible while maintaining the HRI legibility and minimum barcode height.

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HRI… GS1 base definitions…

Human Readable Interpretation (HRI)

- "Characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The Human Readable Interpretation is a one-to-one illustration of the encoded data. However Start, Stop, shift and function characters, as well as the Symbol Check Character, are not shown in the human readable interpretation."

Non-HRI Text

- "Characters such as letters and numbers that can be read by persons and may or may not be encoded in GS1 AIDC data carriers and are not confined to a structure and format based on GS1 standards (e.g., a date code expressed in a national format that could be used to encode a date field in a GS1 AIDC data carrier, brand owner name, consumer declarations)."

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HRI… more simply…

Human Readable Interpretation (HRI)

- …the information below or beside a barcode or tag which is encoded in the barcode or tag and represents the same characters as carried in the barcode or tag…

Non-HRI Text

- …all other text on package, label or item…

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HRI… in pictures…

Non-HRI Text

Characters (i.e. letters, numbers, graphic symbols) which can be interpreted by people and may or may not be encoded in GS1 AIDC data carriers (i.e. not confined to a structure & format based on GS1's standards).

Controlled by Regulators & Manufacturers!

HRI (Human Readable Interpretation)

Characters (i.e. letters and numbers) which can be read by people and are encoded in GS1 AIDC data carriers, confined to GS1's standard structure and format. HRI is a one-to-one illustration of the encoded data. Note that Start, Stop, Shift & Function characters, and any Symbol Check Characters, are not shown in the HRI.

The US FDA requires labelers to follow the rules of their UDI Issuing Agency… this is part of GS1's Scope & Standards!

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HRI… in the GS1 General Specifications…

GS1 has always had HRI Rules and Recommendations…

- 4.14. Human Readable Interpretation (HRI) Rules
  - 4.14.1. Healthcare Human Readable Interpretation Rules
- HRI is noted individually in many other sections of the Gen Specs.

The “basic guidance” within is pretty clear…

- The GS1 System requires printing both the GS1 AIDC data carrier and the HRI that represents all the information encoded within that GS1 AIDC data carrier.
- HRI shall appear except in rare circumstances for specific applications where there are extreme space constraints
- …rules are intended for global use. Exceptions may occur only when local regulatory or legal requirements mandate otherwise

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HRI… in the GS1 General Specifications…

…as are the base format recommendations…

Figure 4.14.1-1. Preferred HRI Format Examples

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HRI Situation

- Regulators require data such as GTIN, Batch, Expiry & serial number to be held in a DataMatrix
- Brand owners may want to hold additional information in the same data carrier e.g. URL
- This data is identified differently with the data carrier than in human readable formats e.g.
  - Expiry date format is 141120 in the data carrier and may be displayed as 20 Nov 2014 in the human readable format
  - The data elements in a data carrier are identified using application identifiers (17 = expiry) whilst human readable format may identify expiry using a prefix of Exp
- Different users of the pack will need to access the data through different means
  - e.g. A patient will need to read the expiry date in human readable format whilst a wholesaler may scan the GS1 DataMatrix to access/ capture the expiry date
- There are existing regulations which constrain how content appears on the product packaging

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Why have the HRI rules been updated

- In retail the barcode usually only contains the GTIN
- This makes adding the HRI simple

- Healthcare is now a lot more complex
- Regulators are driving a more data into the barcodes on products

(01) 09504000059101
(21) 12345678p901
(713) 1312345678913
(17) 141120
(10) 1234567p

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Lack of space and technical constraints

- It was not always possible to meet all stakeholders requirements using the pervious HRI standards, especially on smaller packs
- Factors like on line printing, language and local regulations all created issues

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So we needed a **Healthcare** solution

- A way of incorporating the HRI and non-HRI text onto a product where regulations, space and technical constraints prevented the application of both

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How deviation for Healthcare works . . .

If a deviation from the preferred format is required that results in HRI not being printed, then **a combination of HRI and Non-HRI Text may be used**. When doing so, the following rules apply:

- If the data represented in the Non-HRI Text is exactly as in the HRI, then the appropriate AI shall be printed along with the data title.
- If data represented in the Non-HRI Text does not match the HRI, then only a data title may be used. The AI shall not be printed.
- The selection of data titles may be determined by the manufacturer based on regulatory, local language requirements, relevant standards (e.g. ISO/IEC 15223) or appropriate abbreviations.

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Simple example 1

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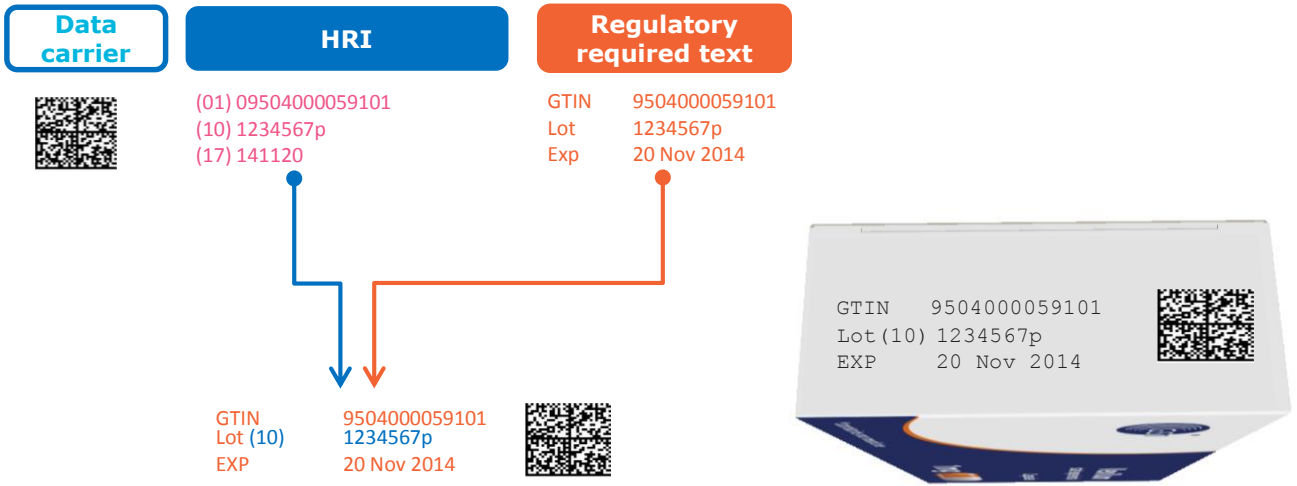
Simple example 2



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Complex example

Data carrier

HRI

(01) 09504000059101
(21) 12345678p901
(713) 1312345678913
(17) 141120
(10) 1234567p
(8200) http://www.gs1.org/demo/

Regulatory required text

GTIN 09504000059101
SN 12345678p901
Reg No 1312345678913
Exp 20 Nov 2014
Lot 1234567p

Commercial required text

Scan for online product information or go to:
http://www.gs1.org/demo/09504000059101

GTIN (01) 09504000059101
Reg No (713) 1312345678913
SN (21) 12345678p901
Lot (10) 1234567p
EXP 20 Nov 2014

Scan for online product information or go to:
http://www.gs1.org/demo/09504000059101

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HRI… in the GS1 General Specifications…

…remembering of course…

- …when "…printing both the GS1 AIDC data carrier and the associated HRI may not be possible due to many factors such as the intended use of the item, available space for marking, etc. deviation from the HRI format should be minimised and consider impacts to downstream trading partners and users."

For more details your attention is directed to the GS1 General Specifications.

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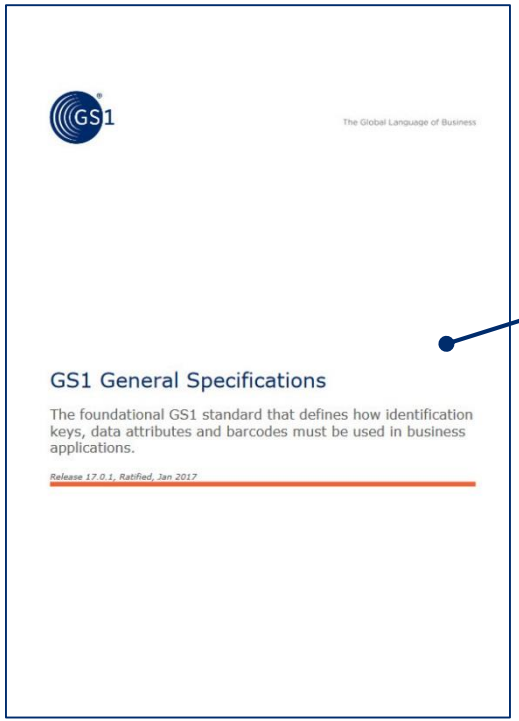
Where can I find this information ?



Version 17

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Why is this important

- The new Healthcare HRI rules allow us to work in a common way across many markets
- Promoting these standards will help prevent the proliferation of national requirements which drive complexity

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And now… audience questions…

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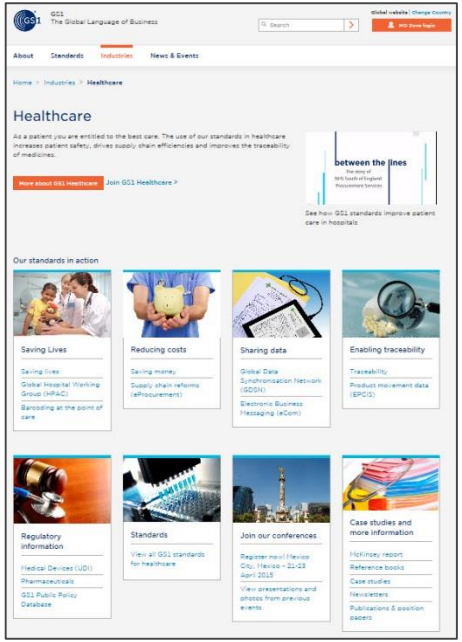
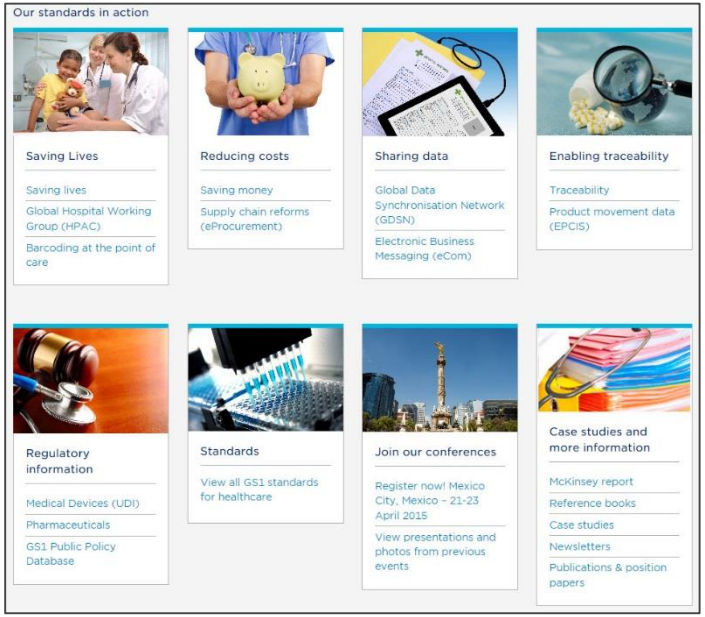
GS1 DataMatrix & Healthcare…

Find information & support at GS1 Global Healthcare on the web…





Check out: http://www.gs1.org/healthcare

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AIDC in Healthcare

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