

The Global Language of Business

GS1 AIDC Standards in Healthcare Standards Detail & Application



GS1: global system of standards



3LN Global Location Numb	er GTIN Global	Trade Item Number	SSCC Serial Shipping Container C	ode GRAI Global Returnat	ole Asset Identifier GIAI Gla	obal Individual Asset Ider	ntifier GSRN Glob	al Service Relation Number
GLN GTIN	GTIN SSCC	GRAI GTIN SSCC	GIAI GLN	GIAI SS	ICC GLN	GIAI GTI SSC	IN GTIN	GLN GSRN
Aanufacturer Item	Case	Pallet T	ansport Distributor	Transport Pa	illet Distribution Centre	Transport Cas	se Item	Retailer Healthcare
Capture: GS1 St	andards fo	or Barcodes	& EPC/RFID					Provider Caregiver Operator
	651-128		TE-14 GS1 Data	Bar GS1 DataMatr	ix GS1 OR Code	GS1 Composite	EPC HE Gen 2	EDC LINE Gen 2
(00) 3 9501101 021037	9501100 00000100	19 19				Barcode part Holike Li		
Share: GS1 Stan	dards for I	Data Exchan	ge					
Master Data Global D	ata Synchroni	sation Network (GDSN) Transactional D	ata eCom (EDI) Ev	vent Data EPC Informa	ation Services (EPCI	IS)	
←				Interoperability				



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AIDC in Healthcare

The Basics



Automatic Identification & Data Capture (AIDC)



"Automatic Identification and Data Capture (AIDC) refers to the methods of **automatically identifying** objects, **collecting data** about them, and **entering that data** directly into computer systems (i.e., without human involvement)."

Wikipedia, 2009





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AIDC vs manual data entry...



1 keystroke (input) error in every 300 to 500 keystrokes

versus

- 1 error in 350 Thousand (350,000) on the low end (linear symbology) ...to...
- …1 error in 10.5 Million (10,500,000) on the high end (2D/Matrix symbologies)





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GS1 standards framework...



Part of the traceability "building blocks"...





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AIDC for Healthcare - the Vision...



EVERY item has ONE set of key identification data carried in ONE data carrier able to be scanned by EVERYONE at every key process step...



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<u>Scope</u> - All healthcare products...



Pharma / Vaccine / Nutritional



Retail



Medical devices



Non-retail





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<u>Scope</u> – ID at all packaging levels...





Note 1: * There is no globally standardized definition of "tertiary package"...

Note 2: Images shown are for illustration only, refer to local regulations and/or the latest version of the GS1 General Specifications for more detail.



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<u>Scope</u> - Data & Data Carriers...







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<u>Scope</u> - All for a secure supply chain...







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Identification "Keys"



Foundation of the GS1 System...



...the GS1 Identification Keys

Provides access to information held in computer files – Information about company/location, package, product, price, shipment, assets etc.





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GS1 Identification Keys...





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GS1 Identification Keys...

- GTIN (Global Trade Item Number) Products*
- GLN (Global Location Number) Locations
- SSCC (Serial Shipping Container Code) Logistics
- GSRN (Global Service Relation Number) Providers of Care
- GSRN (Global Service Relation Number) Subject of Care/Patient**
- SRIN (Service Relation Instance Number) Instance of care
- GDTI (Global Document Type Identifier) Documents/Forms
- GIAI (Global Individual Asset Identifier) Assets***
- GRAI (Global Returnable Asset Identifier) Assets***

* Additional attribute data can be added to this identifier within AIDC to enable serialisation, batch control, expiry date management. Recognised and mandated in many countries globally as method for identifying pharmaceuticals, medical devices & many other products

** Must be used with primary patient identifier GSRN to provide context of patient where instance applies

*** Choice of which Asset identifier is determined by requirements and systems capability to track & capture events/data related to assets. Serialised GTIN also able to be used for some asset types such as instruments where available



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Identification & visibility via our global system of standards...an example







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GTIN – Global Trade Item Number



GTIN – Global Trade Item Number...



Used on any item upon which there is a need to retrieve pre-defined information that may be priced, ordered, or invoiced at any point in any supply chain.



The base for unique item identification... GTIN is an <u>umbrella term</u> for all GS1 "trade item" identification numbers. A Global Trade Item Number may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure.



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	N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ GTIN - 8	C ₈
	$N_1 N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11}$ GTIN - 12	C ₁₂
	$N_1 N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12}$ GTIN - 13	C ₁₃
N ₁	$N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12} N_{13}$ GTIN - 14	C ₁₄

- A GTIN is used to identify any item upon which there is a need to retrieve pre-defined information that may be priced, ordered, or invoiced at any point in any supply chain.
- GTIN is an umbrella term for all GS1 "trade item" identification numbers.
- A GTIN may use the GTIN-8, GTIN-12, GTIN-13, or GTIN-14 numbering structure.



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The <u>GTIN-14 Data Structure</u> is used for grouping of items. For GTIN-14 the Indicator Digit (the "N₁") has a value of 1 to 8 and allows for the identification of eight packaging levels. The 9 has a special application for Variable Measure. The Indicators have no inherent meaning and do not have to be used in sequential order, and some may not be used at all. The holder of the Company Prefix determines their use. <u>By definition</u>... if it has 14-digits and starts with a "0" it is not a GTIN-14... it is instead a GTIN-8, -12, or -13 in a 14-digit format with a "Filler" digit "0".



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0	0 0 0 0 0 N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ GTIN – 8 as a 14 digit number	C ₈
0	0 N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ GTIN – 12 as a 14 digit number	C ₁₂
0	N ₁ N ₂ N ₃ N ₄ N ₅ N ₆ N ₇ N ₈ N ₉ N ₁₀ N ₁₁ N ₁₂ GTIN – 13 as a 14 digit number	C ₁₃
N ₁	$N_2 N_3 N_4 N_5 N_6 N_7 N_8 N_9 N_{10} N_{11} N_{12} N_{13}$ GTIN – 14 as a GTIN-14	C ₁₄

It is important to note that <u>ANY GTIN</u> can be encoded within the most common GS1 Data Carriers that are used for product identification within Healthcare (GS1-128 and GS1 DataMatrix). When encoded within GS1-128 and GS1 DataMatrix GTIN-8, -12 and -13 have leading Zeros added to create a 14-digit number for encodation purposes. Again <u>by definition</u>... if the encoded 14-digits starts with a "0" it is not a GTIN-14... it is instead a GTIN-8, -12, or -13 in a 14-digit format with leading zeros ("0").



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...both are valid uses, are unique GTINs and are valid barcode symbols for use dependent upon how a brand owner wishes to identify their products & groupings.

The same applies for encoding a GTIN in GS1-128!!



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GS1 Healthcare GTIN Allocation Rules...





GTIN assignment in Healthcare

- A guide to GS1 ID Key assignment... the GS1 GTIN Allocation Rules presented in Healthcare related terms with Healthcare specific examples – Available online at: <u>http://www.gs1.org/docs/gsmp/healthcare/</u> <u>GS1 Healthcare GTIN Allocation Rules.pdf</u>
- Translated in many other languages
- Work group is launched to review and update



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GTIN uniqueness...



For every different variant of a trade item a unique GTIN should be allocated sequentially*



*Do not insert internal numbers (e.g. style or item numbers) within the GTIN. The GTIN is just a number in a sequential reference database, just like a driver's license number



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The brand owner allocates the GTIN...



For example, a product is contract manufactured in Pakistan for brand owner: **123ABC Medical Devices**. The brand owner is required to allocate the GTIN and provide it to the Pakistani manufacturer.

If the product is **imported**, the importer should use the GTIN allocated by the brand owner (even though this organisation is abroad).







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GTIN allocation rules in brief...







Brand owners (the manufacturer) allocate GTIN's

based on standardised allocation rules, for example:

- 1 GTIN = 1 product
- 1 product = 1 GTIN
- Different GTIN for each packaging level
 - Example Change GTIN when pack of 20
 becomes pack of 25
- Add language, same GTIN
- Change language, new GTIN
- Country of manufacturing changes... GTIN does not need to change when manufactured to the same specifications
- Never re-allocate a GTIN to another product !



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Example: Additional Language

Healthcare GTIN Allocation Rules

Type of Change to Trade Item

Add an additional language on the packaging





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Example: Healthcare Kits







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Example: Sterile packaging







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GTIN Hierarchy – Pharmaceuticals...



Example of Typical Pharmaceutical Hierarchy Levels





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A **one to one** relationship - trade items and GTINs





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GTIN allocation fundamentals



1-pack, multiple identifiers including 3 GTINs 9088882431984 / PZN-2006490 / 5012712003083 / 7046260081383 54105-2 Vnr 00 81 38 ViaSpan Bristol-Myers Squibb AB E istol-Myers Squibb GmbH Bristol-Myers Squit Bristol-Myers Squibb GesmbH Bristol- wers Soubb Pharmaceuticals Ltd. Box 15200 apporobogen 6-8 Representative: Columbusgasse 4 SE-16715 Bromma -80809 München Athens, Greece A-1101 Wien s. County Dublin, Ireland ¹⁷MS = Mol Hydroxyethylgruppen per Mol w seerffeier Glucose-Einheiten ¹ beutsche Pateri-Nummer 3.888.936. Die Osmolaigt der Lösung berkigt in etwa 320 möbenko mit einer Natrumkonzentration von 23 mEg.1 und einer Kallumkonzentration von 125 mEg.1 Lösung zur Herstellung der hypothermischen Bei er UW Aufbewahrungslösung zur Pertusion und Aufbewahrung von Ögensen. Nicht zur diekken jinklich oder 14. Influsion gegingen. Versichter Hoher Kallumgehäft - Gefahr eines Herzstillstan es. Die Lösung darf nicht vernender werden, wenn sin enticht kan, faktios bei lichtit gelie pertuit ist dem PALL Biel-Transbasions-filter (Nr. SO405) verwendet werden. Nich zu onstellt aufgehäft in dem FALL Biel-Transbasions-mässen verworder werden. Bei 42 - v31 augern Nicht einferem. Im Organabehältne aufbewahren. Entfernen Sie die außere imbilitige grat zu der Amwendung. 2016 - 124203 Zu d. 46.54576.000 - 2017. Zu d. 46.54576.000 - 2014. (is or y to be used to prepare Belz r UW Cold Storage Solution) 1 litre solution for organ preservation Box of 6 bags of 1 litre Organkonservierung ilösung Karton mit 6 Beuteln à 11 Lösung Zusammensetzunc : 11 Lösung zur Orga konservierung enthält: -arzneillich wirksar te Bestandteile Poly(0-2-hydroxyet //Jstärke 50.0 g/l 0.40 - 0.50 MS¹ (/P ntafraktion¹) Lactobionsäure-de a-Lacton 35.83 g/l (105 mmol/l) tactobionsäure-de a-Lacton 35.83 g/l (105 mmol/l) Kaliumhydroxid-Lö ung 56% 14.5 g/l (27 mmol/l) Natriumhydroxid-Lö ung 56% 1.3679 g/l (27 mmol/l) Adenosin 1.34 g/l (5 mmol/l) Menuring 0.136 g/l (1 mmol/l) Composition: - a tive ingredients Poly (0-2-hydroxyethy Po v (0-2-hydroxyethyl starch) 0, 0 - 0.50 MS¹¹ (Pentafraction*) Li ctobionic Acid (as Lactone) Potassium Hydroxide 56% 50.0 35.83 14.5 3.679 1.34 0.13 odium Hydroxide 40% Z.Nr.: 1-24389 AT Zul.-Nr. 51675.00.00 Ch.-B.: Potassium Dihydrogen D3G03 7100 Kaliumdihydroger shosphat 3,4 g/l (25 mmol/l) Magnesiumsulfat |eptahydrat 1,23 g/l 5 mmol/l Glutathion 0,922 g/l 3 mmol/l - sonstige Besta ditelle Natriumfydroxid , Ssung 20% (zur pH-Einstellung) Satzsäure-Ssung 14 6% (zur pH-Einstellung) Wasser für injek onszwecke 3.4 91 1.23 91 17.13 01 0.922 9/i Phosphate Magnesium Sulphate x 7H₂O Rafiinose x 5H₂O Glutathione Batch-No .: Verwendbar bis: 9 JUL 2004 - other ingredients Expliny date: Sodium Hydroxide 20% (crit adjuster) Hydrochloric Acid 14.6% (pH adjuster) Water for injection to 1000 ml ¹MSix moles hytroxyell y groups per moles anhydroglucose units ² German Patent-Number 3.483 936. The solution has in approximate comolality of 320 mosmol/kg, sodium final concentrieffen of 29 ndSir, for asium concentration of 125 mdSir. Not to be used for direct injection or Lw. Initiation. Attention: High Potassium concentration. Danger of a could be errers. Do not up, he solution, II is in and clear colourises to alignity tellow, or if povince particulate matrix, procipitate, or contamination is evident in the solution. The solution are the visual of the PALL Blood Transbasion Filer (No. 50005). Any unused pathema the notation must be discarded. Store product at 2 - 9 °CI Do not freeze. Store in response to the solution of the discarded. Store product at 2 - 9 °CI Do not freeze. Store in the considered and the response of alimentate profer busine. Reg. on: PA2751, 10 °C - 10 °CH, MTN, 32315 DK, MTY, 17 °S 6. MTR: 16418 FIN, MA No. 26866 EL CO-10 °C N, MTN, 32315 DK, MTY, 17 °S 6. MTR: 16418 FIN, MA No. 26866 EL Verschreibungs, flichtig! Arzneimittel für fünder unzugänglich aufbewahren! Wichtig: Vor der Anwendung kombinierte Prescription only medicine Keep out of the reach of children. Important, Please read carefully Gebrauchs- une Fachinformation beachten! the package insert prior to use Deutschland iteland. Sinavia Vint 00 81 38 7 046260 081383 9 088882 431984 PZN -2006490 VIASPAN opplasting til organkonser-verinssvæske Box of 6 bags of 1 litre Rezept- und apothekenpflichtig Fachinformation beachten.

An example of an INCORRECT method...



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SSCC – Serial Shipping Container Code



Serial Shipping Container Code (SSCC)...

- The SSCC is the GS1 identification key used to identify logistics units. This key is comprised of an extension digit, the GS1 Company Prefix, serial reference, and check digit.
- It provides a link between the physical logistic unit and information pertaining to the logistic unit that is communicated between trading partners using Electronic Data Interchange (EDI).
- The SSCC is assigned for the life time of the logistic unit and is a mandatory element of the GS1 Logistic Label.

GS1	SSCC (Serial Shipping Container Code)								
Application Identifier	Extension digit	GS1 Company Prefix Serial reference	Check digit						
0 0	N1	N2 N3 N4 N5 N6 N7 N8 N9 N10 N11 N12 N13 N14 N15 N16 N17	N ₁₈						



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SSCC: Key Identifier - track & trace logistic items in the supply chain



Supplier Transporter Distributor Transporter Customer





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Benefits of SSCC: Shipping & Receiving...



Measurable improvements in speed and accuracy

- More precise and timely information about incoming shipments
- Reduction of time-consuming and error-prone manual intervention
- Reduction of incorrect shipments

Traceability at all levels along the entire supply chain



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Who allocates the SSCC...



It is the **physical builder or brand owner of the logistic unit** that is responsible for the allocation of the SSCC :

- manufacturer
- wholesaler
- logistic provider
- retailer





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So... do I use GTIN and/or SSCC...



First Question - Is it a "Trade Item" or "Logistic Unit"?

- Trade items: Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced or ordered or invoiced at any point in the supply chain
 - Identify and mark with a <u>GTIN / GTIN+</u>
- Logistic units: An item of any composition established for transport and/or storage which needs to be managed though the supply chain
 - Identify and mark with at least an SSCC
 - IF also a Trade Item it can <u>also have</u> GTIN / GTIN+



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So... do I use GTIN and/or SSCC...





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So... do I use GTIN and/or SSCC...





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GLN – Global Location Number



What is a GLN?

The **Global Location Number** is designed to improve the efficiency of communication with trading partners and add value to the trading partners involved, as well as to consumers.

GLNs can be used to identify a:

- Legal entity
- Function
- Physical location
- Digital location





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Global Location Number (GLN)...



- GLNs used when there is a need to retrieve pre-defined information to improve the efficiency of communication with the supply-chain.
- GLNs are a prerequisite for GS1 EDI and to access information from the Global Data Synchronisation Network.
- The GLN is constructed as follows from the same company prefix as the products... AI(414) Identification of a physical location is shown:

GS1 Application Identifier	GS1 Company Prefix							Location reference					Check digit
4 1 4	N ₁	N_2	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃

• NOTE: There are different AI's based upon the GLN use... AI (410) Ship to - Deliver to GLN, AI(411) Bill to - Invoice to GLN, AI(412) Purchased from GLN, AI(413) Ship for - Deliver for - Forward to GLN, AI(414) Identification of a physical location, AI(415) Invoicing party GLN, AI(416) Production or service location GLN, etc.



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Using GLNs for locations...







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GLN example (Hospital): Company Prefix = 0012345







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Application Identifiers



GS1 Application Identifiers (AIs)...



In addition to the GS1 "Keys" a GS1 Application Identifier (AI) is an element string that carriers dynamic or "production identification" data that... in conjunction with the GS1 ID "Key"... provides more granular information about the items identified at the point of data acquisition (scanning).



(01) 09504000059118 17) 141120 10) 7654321D 21) 10987654d321



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A need to capture the GTIN & more...





A GS1 Application Identifier (AI) is an element string that carriers <u>dynamic or</u> <u>"production</u> <u>identification"</u> data that... in conjunction with the GS1 "Key"... they provide <u>more</u> <u>granular information</u> about the items identified <u>at the point</u> <u>of data acquisition</u> (scanning).



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GS1 Application Identifiers (AIs)...



The GS1 Gen Specs include <u>100+ "AI's"</u> for various use cases & sectors

..however <u>relying on Master Data as well as limiting & staging</u> the Application Identifiers <u>commonly used</u> in Healthcare helps:

- ...to reduce implementation complexity
- ...maximize use of existing systems
- ...potentially minimize cost implications

01	GTIN (Global Trade Item Number) – 14 digit numeric
10	Batch / Lot – up to 20 characters, alphanumeric
17	Expiry Date – 6 digit numeric, YYMMDD format
21	Serial Number – up to 20 characters, alphanumeric

Note 1 – Other than certain efficiency recommendations within the GS1 General Specifications, the order of AI's is not significant and should not be mandated.

Note 2 – GTIN and serial number makes a product truly unique – serial numbers can be repeated with other GTIN's. Randomisation is today state of the art although not part of GS1 Gen Specs.



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Why standardize on as few as possible...



- The barcode grows larger when too much information is included...
- With local variances costs increase beyond those already necessary for changing packaging lines...
- Increased complexity for manufacturers in managing "mult-market" or special packaging...
- When local rules are not aligned with rest of the world, it becomes an additional burden for any exporting and well as importing manufacturer...



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Scanning & Processing GS1 Data Structures...







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Packaging Levels & Hierarchies



Different pack levels... definitions...





<u>Healthcare primary packaging</u> - The first level of packaging for the product marked with an AIDC data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be the packaging in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system, May consist of a single item or group of items for a single therapy such as a kit. For packaging configurations that include a retail consumer trade item, primary packaging is a packaging level below the retail consumer trade item.

<u>Healthcare secondary packaging</u> - A level of packaging marked with an AIDC carrier that may contain one or more primary packages or a group of primary packages containing a single item.

Notes:

The above are GS1 General Specifications definitions.
 "Primary packaging" is usually also the "unit of use".
 As shown here "Tertiary" refers to "Trade Items" only and not "Logistic Units". (See the GS1 General Specifications for more detail.)



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Ideally - ID and data carriers at all 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.



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Packaging definitions...



Single unit

Single item of medicine/medical device **without any package**, for example the single tablet from a blister or bottle, the syringe as such.





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Packaging definitions...



Single unit package – this is NOT unit dose

A healthcare primary package that contains one discrete pharmaceutical dosage form i.e. a tablet in blister pack, a certain volume of a liquid **in the immediate package** for a medical device like a syringe. A number of single units may be attached to each other, but are easy to separate through a perforation.





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Packaging definitions...

Single unit package... continued

Marking goods at this level is becoming critical for those operating in the hospital environment. In the Healthcare industry, this smaller unit, will be scanned at the POC (C=care)





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Primary packaging identification... ... in support of point of care...

- Provides good practice recommendations to • enable enhanced medication administration processes in care settings such as in hospitals, nursing homes, or at patient's home for chronic diseases.
- Being adopted by stakeholder organisations that recognise how important it is to support efforts for enhanced safety in the medication process by sharing a joint vision to make this a reality.
- It stresses a recognition of the importance of focusing on the same vision, identification and labelling of primary packages in such a way that scanning at the point of care is enabled.





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Position paper on the identification of the primary package level of drugs

This position paper provides good practice recommendations that enable enhanced medication administration processes in care settings such as in hospitals, nursing homes, or at patient's home for chronic diseases. It is adopted by stakeholder organisations that recognise how important it is to support efforts for enhanced safety in the medication process by sharing a joint vision to make this a reality.

Positioning the problem Medication errors are recognised as an important failure point in care processes. Studies have been conducted to measure such errors and their impact on patients, as well as to measure the benefits of processes that are supported by electronic means (e.g. prescription, dispensation, administration). It is recognised that medication administration at the point of care is significantly means security if it is unconcluding the second processes. more accurate if it is supported by scanning a medicinal product's barcode, matching this with the patient's identification, the physician's computerised order entry and other process factors such as time and route of administration. Identification of primary packages such as vials, pre-filled syringes or solid forms in blister cavity is an important prerequisite for successful point of care verification and registration in electronic health records. Several stakeholders¹ or regulators² already require manufacturers to identify primary packages with barcodes. Hospital implementation can be observed in various places², but their number is limited since a critical mass of source barcoded primary packages has not been reached in many regions. As healthcare providers see this critical importance, many hospitals today are re-labelling all medications to enable scanning at the point of care. This is a time and cost intensive process that ideally should not take place at the hospital, but at the source of manufacturing, where the right equipment, control and expertise

Purpose of this position paper

By supporting this position paper, the supporting organisations noted wish to stress the importance of enabling safer processes at the point of care. This can be done with appropriate identification of primary packages, thus avoiding errors due to "sound-alike" or "look-alike" medicinal product packages.

¹ E.g. Amgros, in Denmark ² E.g. US FDA ³ E.g. Belgium, Netherlands, Portugal, Brazil, USA, Spain, Switzerland, Argentina, Singapore



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Primary packaging identification... ... in support of point of care...

&

Endorsed by:



- Defines hospital pharmacists' demand for barcoding
- Hospitals to invest in IT solutions to make bedside scanning reality
- Supports suppliers investment decisions
- Helps suppliers counter disruptive demandes from customers, such as proprietary barcoding.





efpia

















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AIDC in Healthcare

Data carriers



GS1 AIDC Data Carriers...



GS1's ISO compliant machine-readable **Data Carriers** for use with the product (via packaging, label or DPM... <u>Direct Part Marking</u>) containing the Product ID – 1D / Linear & 2D / Matrix bar code symbols, RFID.



NOTE: Though "any" approved machine-readable Data Carrier is applicable... GS1 Healthcare members have agreed to focus at this time on the **use of bar code technology** before considering other data carriers...



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Data carrier features...



Barcodes	RFID				
✓ Affordable and easy	✓ Non-line of sight				
implementations	✓ Range				
✓ Pervasive technology	✓ Bulk read - Speed				
✓ Extensive standardization	✓ Zero Human Involvement Operations				
✓ Proven applications / ROI's	✓ Durability				
✓ Adaptability / flexibility	✓ Read/Write				
✓ Expandable data capacity	 Visibility into the movement of 				
\checkmark Visibility into the movement of	physical objects in the supply chain at				
physical objects in the supply chain	new levels				
Automation					

Automation Integration of physical and digital worlds



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RFID vs. Barcode...

RFID is like a barcode

- Both are data carriers (data is encoded like our GS1 Keys)
- Both use the electro-magnetic spectrum
 - Barcodes use light (red)
 - RFID use Radio Frequency
- Both use a transmitter and receiver
- Both the barcode and RFID reflect back modulated energy

• RFID is different from barcodes

- RFID does not need a line of sight
- RFID is automatic (no human intervention)
- RFID can both read and write data
- RFID can have embedded sensors
- RFID systems can seemingly identify hundreds of tags at once



NOTE: Though "any" approved machine-readable Data Carrier is applicable... GS1 Healthcare members have agreed to focus at this time on the <u>use of bar code technology</u> before considering other data carriers...



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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



GS 1

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Healthcare - Specific marking needs...





Barcode on a LABEL on the item or on the item PACKAGING

Direct Marked Parts barcode directly ON the item



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GS1 Data Carriers...

...barcode symbologies...







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GS1 Data Carriers...

...supporting attributes...







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GS1 Data Carriers... ...chosen to support item serialization... (01)000123 5(21)12345678 **GS1** DataBar 0 0123456 12 **GS1-128** EAN/UPC (01)00012345678905 GS1 **DataMatrix** 12345678305 **ITF-14 GS1** Composite GS **NOTE:** In Healthcare GS1 QR Code is not **OR** Code Component endorsed for Trade Item related marking.



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GS1 Data Carriers for serialisation...





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Item identification: Serialization



GTIN plus Serial Number (a.k.a. **Serialized GTIN** or **SGTIN**) is a contextdependent feature of the GTIN that is used to identify a specific instance of a product or service identified by a GTIN. It is semantically equivalent to the "concatenation" of Application Identifier (AI) 01, GTIN, and AI 21, Serial Number:

e.g. (01)09312345000005(21)01B2C3

Though the addition of a serial number to the encoded data for a Secondary package in the pharmaceutical sector is becoming more common it is at present a "future goal" for the Primary package level.



The Global Language of Business
GS1 Data Carriers...

...regulatory needs...





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Unique product ID in the GS1 system



...GS1 barcode Data Carriers <u>seen in</u>...



All data carriers are for illustration only, not to scale and not in proportional size to one another. Refer to the GS1 General Specifications for detailed & up-to-date GS1 System information. Requirements may vary by geography - please refer to regional regulations.



The Global Language of Business

Unique product ID in the GS1 system



...GS1 barcode Data Carriers <u>seen at</u>...











All data carriers are for illustration only, not to scale and not in proportional size to one another. Refer to the GS1 General Specifications for detailed & up-to-date GS1 System information. Requirements may vary by geography - please refer to regional regulations.



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Barcode/Scanner Selection in Healthcare... Know your "scanning environment"







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"Mechanics" of reading barcodes...



- A barcode is a "data carrier" that has the GS1 ID number encoded within as a key to the information about a product
- The GS1 data carrier is a **graphical representation** of the GS1 ID key used to **automatically capture** data and access information and data through a database in a computer system
- **NOTE THAT** camera-based bar code scanners are needed in Healthcare for 2D Data Carriers such as GS1 DataMatrix AND are a GS1 Healthcare Leadership Team recommendation!!



The Global Language of Business

Mobile phones...





Cameron	Bell ¹ , BEng; Julien Guerinet ¹ , BEng; Katherine M Atkinson ¹² , BSc; Kumanan Wilson ¹² , MD, MSc, FRCP(C)
Otawa Ho	pital Research Institute, Climical Epidemiology Program, Ottawa, ON, Canada
³ Karelinde	Institutet, Department of Public Health Sciences, Stockholm, Sweden
³ University	of Otrawa, Departments of Medicine, Epidemiology and Community Medicine, Otrawa, ON, Canada
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Done 16	111 708 5555 ant 17021
Fax: 1.611	741 5492
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Abstra Backgrou of care. H systems. 3 product-sp Objective to examin mobile ph	cd and "two-dimensional (2D) bisereding his the presented in exhance documentation of two rates measurements in the priori where, this is constrained his measurements applyed with dedicated baseds scattered and compatible mean defined detects may present a const-deficient admension to already 2D socials via bisection and improve stocial which detects have bayerable in corpore priority defined and the DE social via bisection and improve stocial via bisection and present a const-deficient defined and the DE social via bisection. We single the detection predmanance, and present limitations of scattaining 2D baseden on social vision wing 4 different mes.
Abstra Backgrow of care. H systems. 3 product-sp Objective to examin mobile ph Methods: on the scn conditions	cd and "two-dimensional (12) here oblig her the presented in whiten 6 documentation of two rates seconserve in the prior where, this is constrained by the constraints applyed with dedicated bacode scatases and compatible secon- diabile detects may present a const-deficient admention to leaves 20 voccine to the interdes and improve stocase which detects are the present a constraints of the spectral detection and improve stocases which detects are the present and compared by spectral detections and 20 models. We suggest the detection of the present and present and improve stocases with invalid 4 differences A sample such as assuming any sense of metalized for Audited and 50 spectral growthms. The improve of 4 vanchines A sample such as assuming approve and sense that and the spectral detection of a vanchine.

Bell et al

JOURNAL OF MEDICAL INTERNET RESEARC

(J Med Internet Res 2016;18(6):e143) doi:10.2196/jmir 559

Use of smartphones for scanning is increasing as their performance... and that of any associated apps... also increases...

Results: Of the 1832 successful scans performed in this evaluation, zero produced incorrect data. Five-millimeter barcodwere the slowest to scan, although only by 0.5 seconds on average. Barcodes with up to 50% fading had a 100% success ratbut success rate deteriorated beyond 60% fading. Curved barcodes took longer to scan compared with flat, but success ratleterioration was only observed at a vial diameter of 10 mm. Light conditions did not affect success rate or scan time betwee 500 lux and 20 lux. Conditions below 20 lux impeded the device's ability to scan successfully. Variability in scan time w: bbserved across devices in all trials performed. Journal of Medical Internet Research, vol.18,2016



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AIDC in Healthcare

Data Carriers - GS1 DataMatrix





Data Carriers...

Different "bar code symbologies" are like different languages...



...lots and lots of languages!!



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Data Carriers...

...bar code symbologies...



...they each have their own graphical way of portraying human understandable information for automatic input...





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Data carriers for Healthcare needs...





Note – If 1D/Linear data carriers as in successful use today there is "usually" no significant reason for immediate change to 2D/Matrix data carriers... as seen in UDI applications



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Healthcare - Data carriers...



(01) 0 0012345 67890 5	/	(01)07612345678900(17)100503 (10)AC3453G3	
GS1-128		GS1 DataMatrix	EPC/RFID
Preferred option if:		Preferred option if:	Additional option
✓ Package allows (size)		 ✓ Larger amounts of data in a small space 	✓ Non-line of sight
✓ Moderate amount of data		 ✓ Variable information at high production rates 	\checkmark Large amount of data
		V Direct Part Marking	



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1D vs. 2D sizes... GS1-128... Size Change w/ Data Content... in "steps"

Symbol 1 - GTIN Only



<u>Symbol 2</u> - 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 <u>EACH</u> extra individual character you add to the data string... the symbol increases in length...



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1D vs. 2D sizes... GS1 DataMatrix...

Size Change w/ Data Content... in "steps"





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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 – 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 – GS1 DataMatrix...





- ISO/IEC 16022 Data Matrix... as "GS1 DataMatrix":
 - Similar to the Code 128 / GS1-128 "relationship", <u>an FNC1 in</u> the first data position signals GS1 formatted data & a GS1 <u>DataMatrix</u>
 - Is always "ECC 200" & Alpha-Numeric encodation capable
 - GS1 DataMatrix has a specific ISO/IEC Symbology Identifier



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Data Carriers – ISO/IEC Data Matrix...



...well proven applications





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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

Stack



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 AND are GS1 Healthcare Leadership Team recommended!!





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Position – 2D Imager/Camera scanners...







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Position – GS1 DataMatrix adoption...







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Data Carriers... ISO/IEC & GS1 Data Matrix Summary



- Symbology established 1989 by International Data Matrix
- Internationally standardized in ISO/IEC 16022
- Scaleable matrix size 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
- Adaptable to "direct" marking (DPM)
- Primary Applications Parts direct marking (Multiple industries), Pharmaceutical packaging, Documents
- GS1 DataMatrix... a GS1 version of ISO/IEC Data Matrix:
 - Similar to the Code 128 / GS1-128 "relationship", <u>an FNC1 in the first</u> <u>data position signals GS1 formatted</u> <u>data & a GS1 DataMatrix</u>
 - GS1 DataMatrix has a specific ISO/IEC Symbology Identifier assigned





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GS1 DataMatrix & unique product ID...





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: <u>http://www.gs1.org/healthcare/library</u> <u>http://www.gs1.org/docs/barcodes/GS1 DataMatrix Introduction and technical overview.pdf</u>



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GS1 DataMatrix versus GS1 QR Code...





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Position – DataMatrix or QR Code...





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...







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GS1 Data Structure...

...the ISO/IEC Symbology ID unlocks the semantics...



- Does the data encodation fulfill the rules of the appropriate Reference Decode Algorithm, is it a "GS1" data carrier and is the data in a GS1 format?
 - Has the proper structure to be a valid data carrier approved by GS1
 - EAN/UPC,
 - Where mandated has a Function One (FNC1) Character in the first data position
 - Has data elements properly structured & encoded according to the GS1 General Specifications



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GS1 Data Structure...

...the ISO/IEC Symbology ID unlocks the semantics...

Example: GS1 DataMatrix... or not... how do you know?







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GS1 Data Structure...

...the ISO/IEC Symbology ID unlocks the semantics...





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Latest technology developments

Ulrike

Application Identifier (8009) with Sensor **Descriptor Attribute 01** (Sensor AI (8009) <u>01</u>), is the result of an exclusive collaboration between GS1 and AIM, launched in October 2017, to partner GS1's **Application Identifier** data encodation rules with sensor technical specifications developed by AIM. This allows reading and interpretation of the sensor and barcode using a single scan.

One**Scan**™

Compliant GS1 Barcode with Temperature Sensor



A brand new standard

Temperature Intelligence[™] Solutions



Product Monitoring with Dynamic GS1 Compliant Barcodes

An additional dynamic dimension, through incorporation of temperature sensors, to enhance the value of barcodes for patient safety and anti-counterfeiting



Step 2: Barcode Scanning

Inact

Expirat Produc GTIN: Batch

Serial I





Scanning barcodes yields					
static and dynamic					
information including GTIN,					
Expiry Date, Serial Number,					
Temperature Exposure,					
Authenticity, etc.					

ivated Poli	o Vaccine	Inactivated Polio Vaccine Tests Failed		
Tests Pas	ssed			
r Category:	VVM7	Monitor Category:	VVM7	
ning Life:	80%	Remaining Life:	0%	
ion Date:	2019-12-31	Expiration Date: 2	019-12-31	
t Authenticity	г. 🗸 ок	Product Authenticity:	🗸 ок	
1012	3451234512	GTIN: 1012345	1234512	
Number:	16R00150	Batch Number: 1	6R00150	
lumber:	1234	Serial Number: 1	234	
√ OneSe	can™	🗶 OneSca	n™	
Tomot	lime	Temptime		

Close collaboration between GS1 and AIM to develop *standards (Application Identifiers)* for temperature sensors



Continuous Product Monitoring with OneScan[™] From Manufacture to End Use

- **Serialized** barcodes on individual saleable units provide enabling technology for global identification and tracking regulations
- Merges unit serialization and *temperature-monitoring/assurance* in a single scan
- Technology adaptable for *anti-counterfeiting* and *authentication* applications
- Facilitates *inventory management* and product flow
- GS1 compliant 2D barcode provides *portable database* at point of use
- Significantly enhances product integrity, patient safety, supply security and temperature compliance from *point of manufacture to point of use*





End-to-end unique identifier and unique temperature monitor



Patient Caregive

altheau



Dynamic Barcodes Allow Unit Level Data Connection





Temptime: A World Leader In Time-Temperature Monitoring

- Pioneers in the development, design, and manufacture of time-temperature indicators ("TTI")
- Sole approved supplier of vaccine vial monitors ("VVM") to global manufacturers of vaccines distributed through the United Nations Children's Fund ("UNICEF") and the World Health Organization ("WHO") – More than 600 Million devices used per year

"Sometimes it's the simple ideas that make all the difference. Making it super easy for a rural health worker to know whether a vial of vaccine is still effective by scaling up the VVMs has saved hundreds of thousands of lives."





Bill Gates - February 21st, 2017

• Continuously innovating cost effective monitoring solutions for environmentally sensitive products to ensure supply chain integrity, protect patients and benefit communities globally





GS1 2D Data Matrix with Incorporated Time Temperature Indicator (TTI)

• **Time temperature indicator** – gradual, irreversible color change from light to dark develops with cumulative time and temperature exposure




GS1 2D Data Matrix with incorporated Threshold Sensor

Threshold Indicator – rapid, irreversible color change when peak ٠







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Human Readable Information

So what is HRI ?

Human Readable Interpretation

- HRI show a human <u>exactly what's</u> <u>in a barcode</u>
- It's there in case the barcode does not read
- Some HRI rules are specific to Healthcare and these have been recently 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 standardized 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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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...







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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 <u>requires printing both</u> the GS1 AIDC data carrier and the HRI that represents all the information encoded within that GS1 AIDC data carrier.
- HRI <u>shall</u> 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...



Figure 4.14.1-1. Preferred HRI Format Examples





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Human Readable Interpretation (HRI)...



The Healthcare HRI rules enable label designers to minimise space requirements by merging HRI and non-HRI text. This enables the manufacturer to display product safety information such as the lot and expiry date, without the need to display it both as HRI and in a standard label structure.



The above figure illustrates one application of this approach, combining data labels (e.g. GTIN, SN, and batch/lot) with application identifier labels [(01), (21), (10)]



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The Global Language of Business

AIDC in Healthcare

Barcode symbol quality - Verification



Barcode symbol quality – Verification...







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Barcode quality... where it begins...



- Each manufacturer should make sure that GTINs are correctly allocated and recorded for all their products.
- Staff responsible for artwork should be made aware of the minimum requirements for barcode quality and work with their packaging printers.
- Packaging printers need to know about barcode verification and how to use verifiers properly.
- Specialised solution providers can help, they can be found via your local GS1 member organisation



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Barcode quality... in the GS1 system...





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Barcode quality... key points...







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Barcode quality... in conclusion...



...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 barcode driven AIDC systems



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Use the Ten Steps to Implementation

- Step 1: Get a GS1 Company Prefix
- Step 2: Assign GTINs to your products •
- Step 3: Select a Bar Code printing Method •
- Step 4: Select a "Primary" Scanning Environment ٠
- Step 5: Select a Bar Code Symbology •
- Step 6: Pick a Bar Code Size
- Step 7: Format the Bar Code Text •
- Step 8: Pick a Bar Code Colour
- Step 9: Pick the Bar Code Placement
- Step 10: Ensure you have a Bar Code Quality Plan

https://www.gs1.org/standards/barcodes/10-steps-to-barcode-your-product/english



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So... where can I find more information ?







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So... where can I find more information ?



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



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



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And now... Audience Q&A...







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