GS1 US
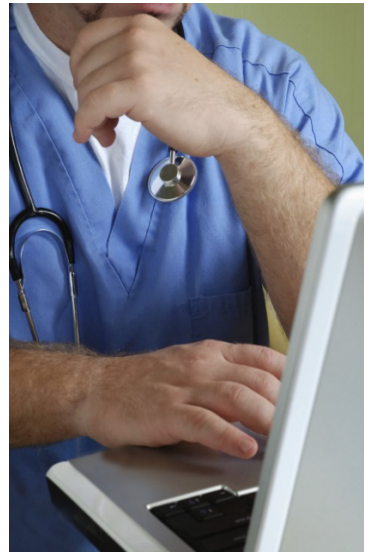
American Academy of Pediatrics & GS1 Healthcare US Guideline for Suppliers

The Application of GS1® DataMatrix Barcodes to Vaccines for Point of Care

Contents

Overview

Using barcode symbols on items down to the dispensed unit has the potential to reduce medication and transcription errors. In 2004, the United States Food & Drug Administration (FDA) issued a regulation for the barcoding of pharmaceutical and biological products. The so-called "barcode rule" required the National Drug Code (NDC) to be barcoded on all pharmaceutical and biological items used in healthcare facilities using a linear barcode.

Use of the linear barcode proved to be an imperfect solution for vaccines. Federal law, specifically the National Childhood Vaccine Injury Act, requires clinicians to record certain pieces of information for each vaccine they administer, including manufacturer, product name, and lot number. Additional pieces of information, including the expiration date, are strongly recommended by the American Academy of Pediatrics (AAP). Encoding a lot number and expiration date in addition to the NDC in a linear barcode was not feasible because the resulting barcode would be too large for vaccine packaging. The end result was that the required information needed to be input via manual data entry, which is an error-prone and inefficient process.

To resolve this problem, a workgroup from the AAP approached the FDA in 2010 to request that the regulation be amended to allow for the use of 2-dimensional (2D) barcodes on vaccines. 2D barcodes can encode large amounts of data in a relatively small space, enabling NDC, expiration date, and lot number to all be encoded into one barcode that is appropriately sized for vaccines. AAP requested this change so that the NDC, expiration date, and lot number could be scanned into a clinician's electronic medical record and used to populate downstream systems such as billing and Immunization Information Systems (IIS), thereby replacing the inefficient and often incorrect manual recording of this information.

The AAP has chosen to work with GS1 to provide the standards around 2D barcoding because of GS1's experience and involvement in healthcare delivery systems. GS1 has developed standards that are followed throughout the world and recognized by many manufacturers. The GS1 DataMatrix is one type of 2D barcoding. It uses the Global Trade Identification Number (GTIN) which integrates the NDC. The remainder of the document will refer to the GS1 DataMatrix and GTIN as the delivery system for 2D barcoding on vaccines.

This guideline is focused on the primary vaccine package. That means that the focus is on the vial or syringe used to administer the vaccine, not any secondary or bulk packaging such as a carton.

This guideline was prepared by GS1 US™ at the request of the AAP to assist the United States healthcare vaccine industry. It provides the current best method for printing and scanning GS1 DataMatrix on vaccine packages for use at point-of-care.

About GS1®

GS1 is a neutral, not-for-profit organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is driven by more than a million companies, who execute more than six billion transactions a day with the GS1 System of Standards. GS1 is truly global, with local Member Organizations in 111 countries, with the Global Office in Brussels, Belgium.

About GS1 US™

GS1 US is the Member Organization of GS1 that serves companies in the United States. As such, it is the national implementation organization of the GS1 System dedicated to the adoption and implementation of standards-based, global supply chain solutions in the United States. GS1 US currently serves over 200,000 U.S. member companies -- 16,000 of which are in healthcare.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers & distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US in the United States.

About GS1 Healthcare US®

GS1 Healthcare US is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of sixty-six local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

About the American Academy of Pediatrics (AAP)

The mission of the American Academy of Pediatrics (AAP) is to attain optimal physical, mental and social health and well-being for all infants, children, adolescents, and young adults. The AAP has approximately 60,000 members in the United States, Canada, Mexico, and many other countries. Members include pediatricians, pediatric medical subspecialists and pediatric surgical specialists. The AAP and its member pediatricians dedicate their efforts and resources to the health, safety and well-being of infants, children, adolescents and young adults. In addition, the AAP supports the professional needs of its members.

Introduction

This application guideline was prepared by GS1 US and the AAP to assist the U.S. healthcare vaccine industry. It is based on the *GS1 General Specification*, and was developed using information obtained from members of the U.S. immunization system, from manufacturers to providers.

Purpose

The purpose of this document is to provide a foundation for the appropriate use of 2D barcodes, specifically the GS1 DataMatrix, on vaccine-related items that are too small for the traditional GS1 linear barcodes containing the same data fields. It outlines the current best method for printing and scanning GS1 DataMatrix encoding GTIN, expiration date, and lot number on vaccine packages for use at point of care. To that end, this guideline covers the following topics:

- Application requirements for GS1 DataMatrix

- Methods for evaluating GS1 DataMatrix readability, scanability and verification

Use of This Guideline

This guideline was written primarily for manufacturers/suppliers, but it can be consulted by the entire healthcare supply chain from the label printer to the healthcare provider. This guideline provides sufficient information and technical detail to implement GS1 DataMatrix technology. The *GS1 General Specification* and clinician guidance available from the AAP should be consulted for additional information.

Scope

The GS1 DataMatrix appearing on the unit-of-use (i.e., primary packaging) for vaccine products is intended for professional prescription use by immunization providers (e.g., physicians, nurses, pharmacists, and other authorized immunizers), not for inventory control in chain drug stores, grocery, retail pharmacies, etc.

- This guideline applies to placement of a GS1 DataMatrix on the unit-of-use (i.e., the primary packaging), which may be a vial, syringe, ampoule or blister pack. It does not apply to secondary packaging or logistics units (e.g., multipacks; cases; pallets; etc.). For example, the guidelines are for use on the individual vial, not the paperboard box of 10 vials.   How manufacturers choose to mark their secondary packaging is based on their individual decisions and any relevant legislation.

- The guidance provided in this document applies to uses of GS1 DataMatrix for inventory control and administration of immunizations. It does not apply to retail point-of-sale applications.

Normative References

This application guideline is based on the *GS1 General Specification*. The specific standards referenced in this guideline are listed below, and the relevant provisions of these standards/specifications are to be considered provisions of this guideline:

- *GS1 General Specification* – Available in the Solutions Center through the GS1 US website at www.gs1us.org/solutionscenter

- *ISO/IEC 16022 Information Technology – International Symbology Specification – DataMatrix*

- *ISO/IEC 15416 Information technology – Automatic identification and data capture techniques – Barcode print quality test specification – Linear symbols*

- *ISO/IEC 15415 Information Technology – Automatic identification and data capture techniques – Barcode print quality test specification – 2D symbols*

- *ISO 1073-2 Alphanumeric character sets for optical recognition – Part 2: Character set OCR-B – Shapes and dimensions of the printed image*

- *AAP Clinician Guidance*

Additional Considerations & Resources

- 2D barcodes require camera-based scanners. Traditional laser barcode scanners cannot read the 2D barcode. As a result, it is important for supply chain partners to communicate prior to implementing 2D barcodes to ensure that the appropriate scanners are in place.

- Prior to purchasing barcode scanning equipment, it is recommended that you consult the Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria and the AAP Clinician Guidance. This document was prepared by GS1 US to assist members of the U.S. healthcare supply chain in evaluating the various barcode scanning equipment options on the market, and selecting the equipment that best fits their needs.

- There are many reasons why a barcode may not scan. Many times it is not the barcode, but the scanner itself. For example, the lens could be dirty or the batteries discharged. GS1 US prepared another document entitled Procedure for Responding to Troublesome Barcodes to help resolve barcode scanning issues. This document offers a simplified process to rectify barcode scanning issues based on the experiences of healthcare users. It is recommended that you download this document as a reference to help you respond if a barcode does not scan.

Overview of the GS1 Standards Used

Global Trade Item Number® (GTIN®)

A Global Trade Item Number® (GTIN®) is the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be sold, delivered or invoiced at any point in the supply chain). GTINs are used to identify individual trade item units (like a box of 15 Brand X tissues), as well as all of their different packaging configurations (like a carton of six boxes of Brand X tissues). GTINs are assigned by the brand owner or manufacturer of the product, and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN has been in use for over forty years in 23 industries globally. This 14-digit number meets the fundamental identification needs of the world's healthcare manufacturers, distributors and suppliers.

GS1 DataMatrix

GS1 DataMatrix is a 2D (two-dimensional) barcode that holds large amounts of data in a relatively small space. These barcodes were developed for items that are too small for the traditional GS1 System linear barcode symbols or that require information in addition to the GTIN (e.g., lot number, expiration date). They are also used for parts that need to be tracked during the manufacturing process. The DataMatrix is used primarily in pharmaceuticals, medical device manufacturing, aerospace, and by the U.S. Department of Defense. In healthcare, DataMatrix is predominantly used for small items, such as vials, ampoules, small bottles, syringes and blister packs. This small symbology is intended for professional prescription use by immunization providers only. It is not intended to be used for inventory control on items that pass through retail point-of-sale (e.g., chain drug stores, grocery, retail, etc.) or for logistics units.

GS1 DataMatrix barcodes may be printed as a square or rectangular symbol made up of independent modules arranged within a perimeter ("L" shaped) finder pattern. They are suitable for nearly all printing processes, including offset, thermal transfer, and direct marking by ink-jet or laser. The barcode, which is read and decoded by a camera-based scanner ("2D imager"), offers readability even with low contrast, and is readable in a 360 degree orientation, which eliminates the need for part orientation prior to reading.

Application Identifiers

GS1 Application Identifiers (AIs) are a finite set of specialized identifiers embedded within numerical string of a barcode to indicate what type of data is represented in each barcode segment. Each AI has a two, three, or four digit numeric prefix that appears in parentheses in the barcode numerical string. For example, the AI for GTIN is it is (01). Thus, when "(01)" appears in the numerical string of a barcode, it means a GTIN follows in the next segment. There are approximately 100 AIs. There is an AI for each GS1 Identification Number. In addition, there are AIs for various types of secondary information to enable supply chain partners to communicate item-specific information wherever the barcode is scanned (e.g., expiration date; lot number; batch number; etc.). GS1 AI's commonly used in healthcare include AI (10) for Lot/Batch Number, AI (17) for Expiration Date, and AI (21) for Serial Number.

Introduction to Identifying Vaccine Products with GTINs

The National Drug Code (NDC) is a <u>regulatory identifier</u> used to identify pharmaceutical products for regulatory purposes. The GTIN is a <u>supply chain identifier</u> used to identify *products* for supply chain purposes. NDCs can be embedded into GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes. In fact, manufacturers of healthcare products have been embedding NDCs in their GTINs for over forty years.

GTIN: Format & Structure

The GTIN is a 14-digit number – a globally unique, standards-based, identification number for trade items. Manufacturers are responsible for generating (*allocating*) GTINs for their products. The GS1 System provides clear, structured data standards and allocation rules that manufacturers follow when allocating GTINs in order to ensure that their GTINs are globally unique and in a consistent format.

Each GTIN is a numerical string comprising four distinct segments. The four segments within a GTIN are:

- **Indicator Digit:** The indicator digit identifies packaging level. The field consists of a numeric value from 1 to 8. (The number "0" can be used as a fill character.)

    > **NOTE:** *Packaging specialists must review the Indicators used on all other packaging levels prior to incorporating a new packaging level for a product. This ensures that there is a unique GTIN on every packaging level, which is <u>imperative</u> to preserve the uniqueness of each GTIN.*

- **GS1 Company Prefix:** A globally unique number assigned to a company/organization by GS1 US to serve as the foundation for generating GS1 identifiers (e.g., GTINs). GS1 *Company Prefixes* are assigned in varying lengths depending on the company/organization's needs.

- **Item Reference:** A number assigned by the holder of the GS1 *Company Prefix* to uniquely identify a trade item. The *Item Reference* varies in length as a function of the *Company Prefix* length. (Refer to the *GS1 General Specifications* and the *GTIN Allocation Rules for the Healthcare Sector* for additional information.)

- **Check Digit:** A one-digit number calculated from the first 13 digits of the GTIN used to ensure data integrity. A check digit calculator can be found at *http://www.gs1us.org/solutions_services/tools/check_digit_calculator*.

Although the length of the GS1 *Company Prefix* and the length of the *Item Reference* vary, they will always be a combined total of 12 digits. Figure 1 below illustrates how the four segments of the GTIN described above are structured in the 14-digits of the GTIN. (Figure 1 uses hypothetical GTIN **00312345678906**.)
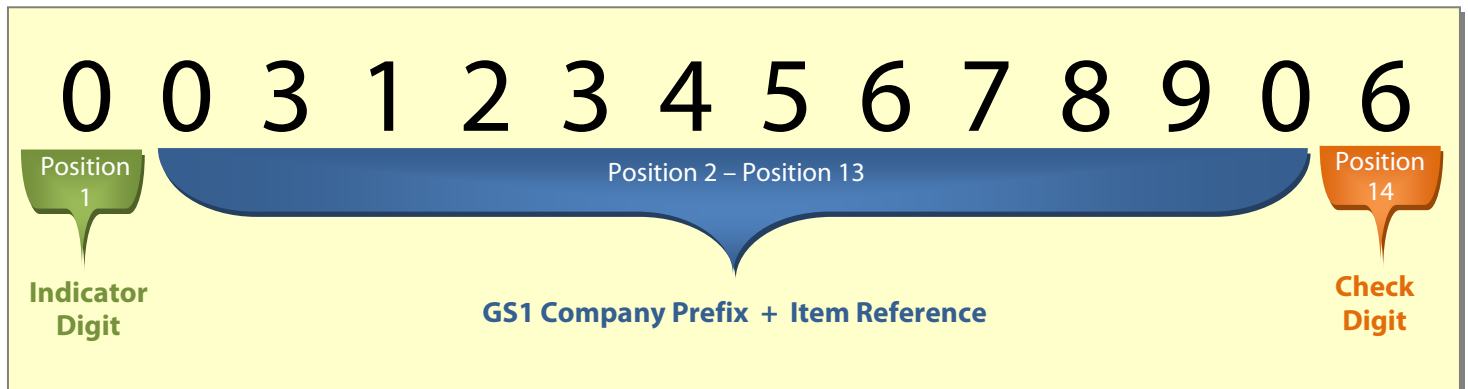

0 0 3 1 2 3 4 5 6 7 8 9 0 6

Position 1 — Indicator Digit

Position 2 – Position 13 — GS1 Company Prefix + Item Reference

Position 14 — Check Digit

Figure 1: Structure of a 14-digit GTIN (based on the hypothetical GTIN "00312345678906")

NDC: Format & Structure

The National Drug Code (NDC) is used to identify pharmaceutical products pursuant to FDA regulations. The NDC is a 10-digit identifier comprising two segments: a *Labeler Code* and a *Product/Package Code*.

- The *Labeler Code* is a variable length identifier assigned by the FDA (and encoded into NDCs) to identify the company. The *Labeler Code* can be either 4- or 5-digits in length.

- The *Product/Package Code* is a variable length identifier assigned by the holder of the *Labeler Code* (and encoded into NDCs) to identify the product. The *Product/Package Code* can be either 5- or 6-digits in length.

Although both segments are variable length, they will always be a combined total of 10 digits.

GTIN with NDC: Format & Structure

Pursuant to GS1 Standards, NDCs can be embedded into GTINs. In order to facilitate the integration of NDCs into GTINs, GS1 US has reserved a placeholder in its *Company Prefix* numbering system that enables *Labeler Codes* to be integrated into the GS1 *Company Prefixes* for pharmaceutical and medical/surgical companies. The GS1 US placeholder is **03**, and the GS1 *Company Prefix* for pharmaceutical and medical/surgical company is simply its *Labeler Code* with an "03" appended in front. For example:

GS1 US Placeholder	**03**
FDA-assigned *Labeler Code*	**61414**
GS1 *Company Prefix*	**0361414**

** **In order to use a *Labeler Code* as a GS1 *Company Prefix*, manufacturers must first contact GS1 US to have a Company Prefix that embeds their *Labeler Code* assigned to the company.**

The four segments within a GTIN were defined in the previous chapter. In GTINs that embed NDCs, the segments are populated as follows:

GS1 Indicator Digit	same
GS1 Company Prefix	**03** + NDC *Labeler Code*
Item Reference	NDC *Product/Package Code*
Check Digit	same

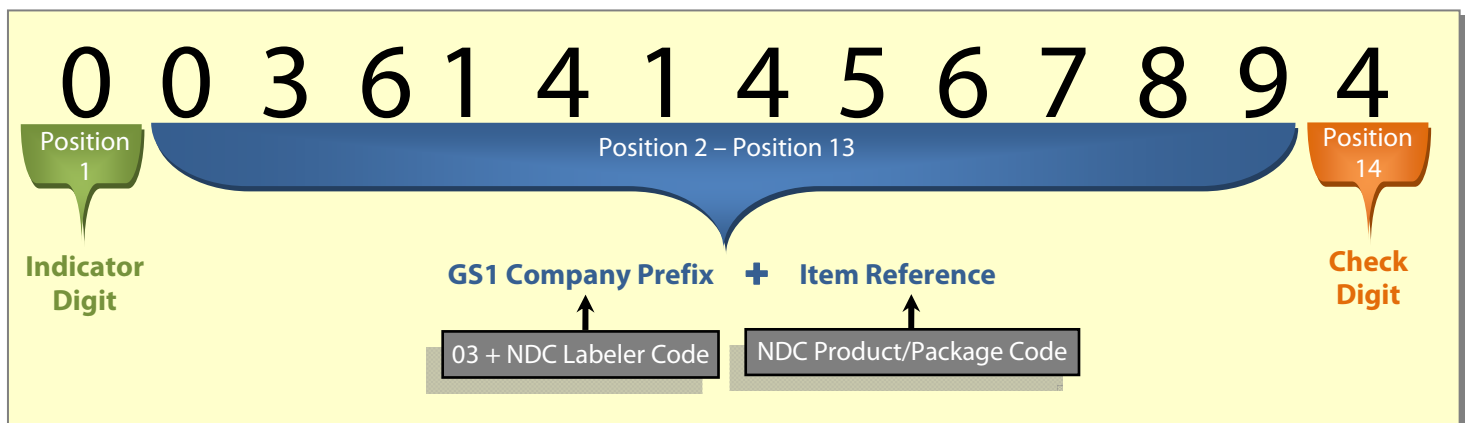Figure 2 below illustrates how the segments are structured in GTINs that embed NDCs.

Figure 2: Segments of a 14-digit GTIN that embeds an NDC (based on the hypothetical GTIN "00361414567894")

Assigning GTINs to Vaccine Unit-of-Use Products

Manufacturers must assign a GTIN that embeds the NDC to any vaccine unit-of-use product to be marked with GS1 DataMatrix.   Because manufacturers of healthcare products have been embedding NDCs in their GTINs for over forty years, many vaccine unit-of-use products may already have GTINs embedding the NDC assigned to them. If that is the case, skip this chapter and continue on to the chapter for Encoding GS1 DataMatrix.

For any vaccine unit-of-use product that does not currently have a GTIN embedding the NDC assigned to it, follow the instructions in this chapter to assign a GTIN that embeds an NDC to any vaccine unit-of-use product to be marked with GS1 DataMatrix.

Creating the 14-digit GTIN Embedding an NDC

Each GTIN is a 14-digit number. Hypothetical GTIN **00301234567896** is shown below with each digit individually numbered:

	0	0	3	0	1	2	3	4	5	6	7	8	9	6
Digit/Position	1	2	3	4	5	6	7	8	9	10	11	12	13	14

Table 1 (below) provides instructions for how to populate each digit in a 14-digit GTIN that embeds an NDC for a vaccine unit-of-use product.

How to Populate Each Digit *(color-coded to coordinate with the GTIN shown above)*	
Position 1	Indicator Digit - enter "0" for vaccine unit-of-use (e.g., vial or syringe)
Position 2 and 3	GS1 US Placeholder - enter "03"
Positions 4 through 13	Enter your NDC Labeler Code as assigned by FDA plus the NDC Product/Package Code for the vaccine created by the pharmaceutical manufacturer
Position 14	Enter the Check Digit**

Table 1: Populating the 14-digit structure of a GTIN for Vaccine Units-of-Use

** GS1 US provides a check digit calculator to automatically calculate check digits for you.   The check digit calculator can be found at http://www.gs1us.org/solutions_services/tools/check_digit_calculator.

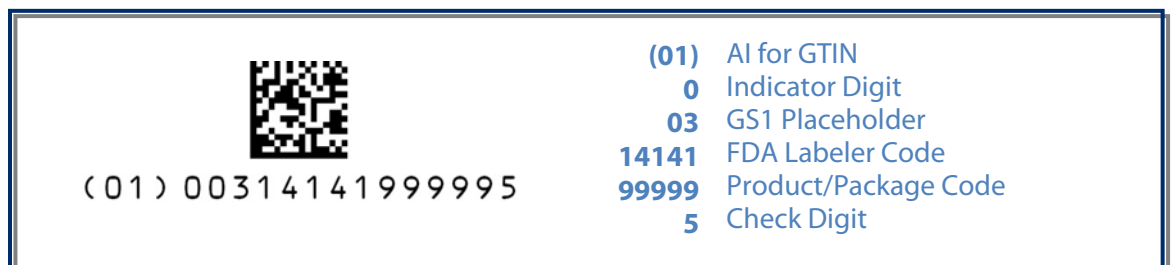|		
(01)	AI for GTIN
0	Indicator Digit
03	GS1 Placeholder
14141	FDA Labeler Code
99999	Product/Package Code
5	Check Digit

(01) 00314141999995

Figure 3: GS1 DataMatrix encoding a GTIN with NDC embedded

Defining Product Master Data

When a manufacturer assigns ("allocates") a GTIN, they define a prescribed set of data about the product to which that GTIN relates. These *product description attributes* define master data that is consistent across all instances of the product (e.g., size; color; brand information; etc.). GS1 standards specify the list of attributes that must be defined for each GTIN, as well as the permissible values. For more information, consult the interactive spreadsheet for [GTIN Attributes for Healthcare](#).)

Storing GTINs

Once the GTIN is allocated and the attributes are defined, the GTIN and its associated attributes are then saved in a database (like a GDSN-certified Data Pool) and shared among supply chain partners. GTIN fields in databases and software applications (other than EPCIS) should always use the following data format:

- 14 digits
- right-justified
- zero-filled to the left
- text field (not numeric)

Encoding GS1 DataMatrix for Vaccine Products

The data elements within a GS1 DataMatrix are demarcated through the use of GS1 Application Identifiers (AIs). Each AI has a two-, three- or four-digit numeric prefix that appears in parentheses to signal a certain type of data in the barcode numerical string. There are approximately 100 AIs, including one AI for each GS1 identifier (e.g., GTIN, GLN, SSCC, etc.) as well as numerous AIs for secondary information. The AI's that are relevant to this guideline are:

AI (01)	GTIN
AI (10)	Batch/Lot Number
AI (17)	Expiration Date

Data Elements to be Encoded for Vaccines

GTIN

- The two-digit AI (01) is used to indicate GTIN.
- A fixed-length field comprising the 14 numeric characters of a GTIN data follows the AI.
- The data syntax for the GTIN component is n2 + n14.
- **EXAMPLE: (01)00312345678906**

(01) 00314141999995

(01)   AI for GTIN
00314141999995   GTIN

Figure 4: GS1 DataMatrix encoding GTIN – no lot number

Batch/Lot Number

A Batch/Lot Number is typically assigned at the point of manufacturer using a production lot number, a shift number, a machine number, a time, or an internal production code. Batch/Lot Number is represented by Application Identifier (10). The data is alphanumeric and the length is variable up to 20 alphanumeric characters.

- The two-digit AI **(10)** is used to indicate *Batch/Lot Number*.
- A variable-length field of up to 20 alphanumeric characters of *Batch/Lot Number* data follows the AI.
- The data syntax for the *Batch/Lot Number* component is n2 + a 20.
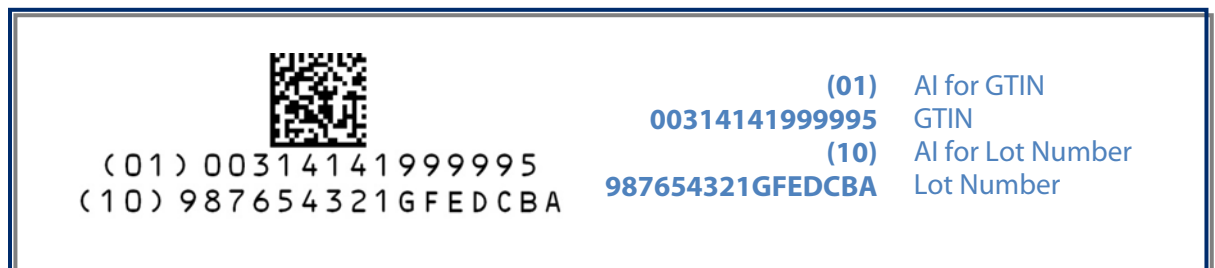- **EXAMPLE: (10)987654321GFEDCBA**

(01) 00314141999995
(10) 987654321GFEDCBA

(01)   AI for GTIN
00314141999995   GTIN
(10)   AI for Lot Number
987654321GFEDCBA   Lot Number

Figure 5: GS1 DataMatrix encoding GTIN and Lot Number

Expiration Date

Expiration Date is often referred to as expiry date or maximum durability date. It indicates the limit of consumption or use of a product (e.g., for pharmaceutical products, it will indicate the possibility of an indirect health risk resulting from the ineffectiveness of the product after the date). *Expiration Date* is represented by Application Identifier **(17)**. The data is numeric and the length is fixed at six numeric characters with the structure **YYMMDD**.

- The two-digit AI **(17)** is used to indicate *Expiration Date*.
- A fixed-length field of six numeric characters representing the *Expiration Date* as **YYMMDD** follows the AI.
    - **YY** = the tens and units of the year (e.g., 2003 = 03).
    - **MM** = the number of the month (e.g., January = 01).
    - **DD** = the number of the day of the relevant month (e.g., second day = 02). Use "00" when day is not needed in the date.
- The data syntax for the *Expiration Date* component is n2 + n6.
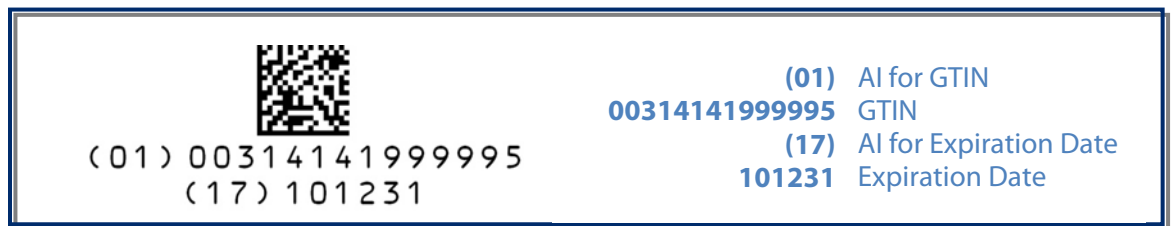- **EXAMPLE: (17)101231**

(01)	AI for GTIN
00314141999995	GTIN
(17)	AI for Expiration Date
101231	Expiration Date

Figure 6: GS1 DataMatrix encoding GTIN and Expiration Date

General Encoding Principles

More than one AI can be carried in one barcode. Table 2 presents some high-level concepts and principles that should be followed when encoding barcodes.

Principle	Example/Illustration	
Each barcode data element has a two- to four-digit AI that defines data type and field size.	GTIN	**AI(01)**
	Batch/Lot Number	**AI(10)**
	Expiration Date	**AI(17)**
When encoding, each data element is preceded by its corresponding AI.	GTIN	**(01)00314141999995**
	Expiration Date	**(17)101231**
	Batch/Lot Number	**(10)987654321GFEDCBA**
Encode the GS1 Identifier first. Encode any optional data (such as bat**ch/lot number, expiration date,** etc.) following the identifier.		
For the most efficient encoding, ensure that fixed-length AI's precede variable-length AI's.		GTIN *fixed* Expiration Date *fixed* Batch/Lot Number *variable* Serial Number *variable*

Table 2: Encoding Principles

Human Readable Interpretation (HRI)

Printing & Expressing Data

- Print the data from top to bottom and left to right.
- Print the GTIN as a single 14-digit number. There are three additional options for how the GTIN may be printed, as shown in Table 3 below. Table 3 uses hypothetical NDC **1414-1000-01** (which converts to GTIN **10314141000012)**:

HRI Options for GTINs with NDCs:	EXAMPLE:
An "N" may precede the number to designate the presence of an NDC number	N 103 1414 1000 01 2
Dashes or spaces may be used to show the NDC separations	N 103 1414-1000 01 2
The AI "01" may precede the GTIN when space allows (if printed, enclose the AI in parenthesis)	N (01) 103 1414 1000 01 2

Table 3: HRI Options for GTINs embedding NDC

- Print the optional attribute data with the preceding AI's enclosed in parenthesis.
- A single AI with accompanying data is displayed on one line and is not broken into two lines.
- Expiration date and lot number may be <u>printed</u> in the most appropriate and understandable format to meet customer needs. It does not have to echo the *data structure* encoded in either the linear or 2D barcode. For example, an expiration date and lot may be <u>written</u> as EXP May 07 Lot 123ABC.
- The order of the data should be the same as encoded in the Composite Component according to the rules in the *GS1 General Specifications*. The parentheses are not part of the data and are not encoded in the barcode symbol, although the AI's are.

Location

- Print the GTIN in human readable form <u>underneath</u> the symbol.
- If there is sufficient space to print the human readable form of the optional attribute data, print it <u>above</u> the symbol in proper sequence of the Application Identifiers (AI's).

Font

- Use a clearly legible font for the human-readable digits, such as OCR-B, as defined in *ISO 1073-2*.
- Reasonable alternative type fonts and character sizes are acceptable provided the interpretation is clearly legible.
- Use a font that is considered suitable and compatible with other printed materials.
- When necessary, ensure the font used is in accordance with applicable government laws and regulations.

Symbol Metrics

- The X-dimension shall be constant throughout a given symbol. The X-dimension should apply to both the width and height of the modules.

- The X-dimension shall be nominally 1.5 times as large as the X-dimension of a like GS1 DataBar linear symbol. The overall dimensions of the GS1 DataMatrix symbol depend upon the data content. (See *ISO/IEC 16022 Information Technology - International Symbology Specification - DataMatrix for* details on calculating the dimensions of a specific GS1 DataMatrix symbol**.)**

- The range of the X-dimensions will be defined by the application specification, having due regard to the availability of equipment for the production and reading of symbols and complying with the general requirements of the application.

Symbol(s) Specified	X-dimension mm (inches)			Minimum Symbol Height for Given X mm (inches)			Quiet Zone		Minimum Quality Specification
	Minimum	Target	Maximum	For Minimum X-dimension	For Target X-dimension	For Maximum X-dimension	Left	Right	
GS1 DataMatrix	0.255 (0.010")	0.380 (0.0150")	0.495 (0.0195")	Height is determined by X-Dimension for Data that is encoded			Symbol must be surrounded by a 1x Quiet Zone		1.5/0***/670

Table 4: Symbol Metrics for GS1 DataMatrix -- X-dimension (module size) and symbol height (Y-dimension)

*** 2D quality Measurement –Refer to section 5.6 of the GS1 General specifications for complete specification. Application X-dimensions will coincide with those of EAN/UPC and GS1 -128.

Placement

Location

For general guidance on placement of barcode labels, refer to the *GS1 General Specifications* (General Placement Principles).

Curved Surfaces

The majority of uses will be on small items with curved surfaces such as vials, ampoules, syringes, and small bottles.

- If a barcode symbol is printed or applied on a curved surface, it is preferable for the bars to be perpendicular to the curvature of the surface of the container, so that a scan line can pass through the symbol on as near a flat plane as possible. This preference may be subject to considerations of space and to the direction of printing, as noted in the previous section.

- If possible, when using flexographic printing, run the bars parallel to the press web direction, or in the *picket fence* orientation. If the bars are required to run perpendicular to the press direction, or in the *ladder* orientation, try to avoid distorting the symbol for the plate roll circumference. This lack of distortion alters the overall width of the symbol, but provides dimensional integrity.

- The text and orientation of the barcode symbol can be read either from the top down or from the bottom up, whichever is consistent with other text, graphics, and print direction on the container. Empirical data demonstrates that it makes no difference one way or the other. This preference for orientation on curved surfaces becomes a mandatory rule on curves with small radii as defined in the following paragraph.

- The angle between the tangent to the center of the curved symbol and the tangent to the extremity of the curved symbol (outer edge of the guard bars for EAN/UPC barcode symbols) must be less than 30 degrees. If this angle is more than 30 degrees, orient the symbol so that the bars are perpendicular to the generating lines of the surface of the item.

Scanning Requirements

The GS1 DataMatrix requires a two-dimensional imaging scanner or vision system to read the symbol. The use of 2D (two-dimensional) array scanners and/or vision systems are specified exclusively for the application and can read GS1 DataMatrix. GS1 DataMatrix is not omni-directionally scannable. Retail style slot scanners, handheld laser scanners, and handheld linear array imagers are not able to read the symbol.

Table 5 reveals the relationship between GS1- DataMatrix print area availability, print density, and scanner readability where:

- The printing area is 0.375 inches (9.525 mm) square or smaller.

- The marking area precludes the application of ink and the symbol must be applied by means of "direct part marking".

Symbology	Print Area Available	Print Density	Scanner Technology Required
GS1 DataMatrix – GTIN + Exp. Date + Lot	≤9.525mm (0.375") square	≥0.010" (mil)	Imaging scanner

Table 5: Marking & Reading (scanning requirements)

Verification

Verification is the technical process by which a barcode symbol is measured to evaluate its conformance with the specification for that symbol. Verification is not intended to be used alone as a method for downstream rejection. GS1 encourages manufacturers and receivers to use the ISO/IEC 15416 methodology as a tool to improve overall scanning performance.

For problems with GS1 System symbols, an ISO-based verifier can be of enormous assistance in diagnosing the problem and providing a standard means of reporting between printing companies and their trading partners. It is also important to note the difference between a scanner and a verifier. A verifier is a measuring tool by which one can make certain determinations concerning the ability of the symbol to carry and deliver data on demand.

- Because traditional verification measurement is typically made in a single scan across the symbol, it is uncertain whether this "snapshot" is truly representative of the symbol's characteristics through the height of the bars.

- The verifier does not check that the Human Readable Interpretation matches the barcode data (and it may be necessary to check that the two correspond particularly where the barcode generating software does not include the Human Readable Interpretation).

Because only a sample of the symbols produced are actually verified, the quality of all the symbols in a production batch cannot be guaranteed beyond the statistical confidence limits associated with the sampling rate used. Even a perfect symbol at the time of production can be damaged or otherwise affected in its passage through the supply chain (for instance, it can be scratched, frozen, or dampened).

Operator error can cause inconsistent results. Operator related factors can only produce a lower grade. The operator's actions cannot cause a higher grade. Therefore, when inconsistent results occur, the higher grade is the true grade of the symbol. Properly train operators and make visual checks to confirm verifier results. For instance, where the barcode is expected to get a good result, but fails the verifier test, recheck the operation of using the verifier. For all GS1 System symbols, the minimum print quality grade should be at least an ISO/ANSI grade of 1.5 (or C). If possible, print GS1 System symbols that are at least a 2.5 (B) grade at the time of printing regardless of size. Table 6 provides a comparison between the ISO method and American National Standards Institute (ANSI) method of grading symbol quality.

ISO/IEC 15416 Grade	Equivalent ANSI X3.182-1990 Grade
3.5 to 4.0	A
2.5 to 3.5	B
1.5 to 2.5	C
0.5 to 1.5	D
Below 0.5	F

Table 6: Comparison of ISO grading scale to ANSI grading scale

Resource Links

- ❖ GS1 General Specification – *available in the* [GS1 US Solutions Center](#)
- ❖ [GS1 Healthcare US Website](#)
- ❖ [GTIN 101 for Healthcare Product Identification webinar](#)
- ❖ [Healthcare Supplier GTIN Quick Start Guide](#)
- ❖ [GS1 US Data Driver®](#)
- ❖ [GTIN Allocation Rules for the Healthcare Sector](#)
- ❖ [Check Digit Calculator](#)
- ❖ [Healthcare Supplier Tool Kit for GS1 Standards](#)
- ❖ [Healthcare Provider Tool Kit for GS1 Standards](#)
- ❖ [2012 GTIN Sunrise webinar](#)
- ❖ [North American Guideline for Application of GS1 Barcodes to Very Small Healthcare Items](#)
- ❖ [Simplified Guide for U.S. Healthcare Barcode Scanner Acquisition Criteria](#)
- ❖ [Procedure for Responding to Troublesome Barcodes](#)
- ❖ [Hospital Checklist for Software System Readiness](#)
- ❖ [EDI Quick Guide for GLN and GTIN](#)

About the GS1 System

The GS1 System is a universally accepted identification and communication system that facilitates efficient global commerce and business communication. This global language of business comprises a standard numbering system and identification carriers to provide global users with the means to uniquely identify items, documents, assets, processes, and physical locations for automatic data capture and electronic data processing.   The GS1 System utilizes a wide variety of integrated data carrier technologies to provide seamless communication throughout the supply chain. In addition, the system includes a series of standard data structures, called Application Identifiers (AI's), which enable companies to encode secondary information about a product on the product itself. In healthcare, AI's are employed for one of the most important logistics tasks: the tracking and tracing of medical products.

The GS1 System enables companies to drive out significant costs from the supply chain. The GS1 System is recognized by businesses worldwide as one of the most important breakthrough technologies in the history of global commerce. Collectively, GS1 and GS1 US have more than one million members in 150 countries worldwide. This global membership spans 25 major industry sectors. GS1 and GS1 US members rely on the integrity of the GS1 System to ensure that items marked with the system identification are globally unique.

GS1 US Glossary

Term	Definition
Application Identifier (AI)	The field of two or more digits at the beginning of an element string that uniquely identifies its format and meaning within the GS1 System.
Barcode	A precise arrangement of parallel lines (bars) and spaces that vary in width to represent data.
Bar Gain/Loss	The increase/decrease in bar dimensions due to effects of the reproduction and printing processes with two-dimensional symbols; bar gain applies to height as well.
Check Digit	A digit calculated from the other digits of an element string, used to check that the data has been correctly composed or correctly keypunched.
Data Carrier	A physical or electronic mechanism that carries data.
Data Structure	The GS1 System data structures defined in the various lengths required for the different identification purposes, which all share a hierarchical composition. Their composition blends the needs of international control with the needs of the user.
Direct Part Marking	Any method of directly marking (as opposed to applying) the part or surface.
Global Trade Item Number® (GTIN®)	The globally unique GS1 System identification number for products and services. A Global Trade Item Number may be 8, 12, 13, or 14 digits in length, represented as GTIN-8, GTIN-12, GTIN-13, and GTIN-14 respectively.
GS1®	GS1, based in Brussels, Belgium, is comprised of global GS1Member Organizations and manages the GS1 System and Global Standards Management Process.
GS1 Company Prefix	A globally unique number assigned to companies by GS1 Member Organizations to create the identification numbers of the GS1 System. It comprises a GS1 Prefix and a Company Number.
GS1 Member Organization	A member of GS1 that is responsible for administering the GS1 System in its country (or assigned area). This task includes, but is not restricted to, ensuring user companies make correct use of the GS1 System, have access to education, training, promotion and implementation support and have access to play an active role in the Global Standards Management Process. GS1 US is the GS1 Member Organization for the United States.
GS1 Prefix	A number with two or more digits, administered by GS1 that is allocated to GS1 Member Organizations or for Restricted Circulation Numbers.
GS1 System	The specifications, standards, and guidelines administered by GS1. GS1, through the Global Standards Management Process, manages the GS1 System to maintain the most implemented supply chain standards in the world.
GS1-128 barcode symbol	A subset of Code 128 that is utilized exclusively for GS1 System element strings. Code 128 symbols have a special start code pattern (consisting of a Start Character in the first symbol character position followed by the Function Code 1 in the second character position) to designate the data that follows will comply with GS1 System standards.
GTIN® Format	The format in which all Global Trade Item Numbers are represented in a 14-digit reference field (key) in computer files to ensure uniqueness of the identification numbers.
Manufacturer's ID	See GS1 Company Prefix.
Manufacturer's Number	See GS1 Company Prefix.
Point-of-Sale (POS)	Refers to a retail checkout where barcode symbols are normally scanned.

Selective Bar Height Reduction	The selective bar height reduction of a barcode the film master or digital barcode file to correct for anticipated bar growth in the imaging or printing process.
Symbol	The combination of symbol characters and features required by a particular symbology, including Quiet Zone, Start and Stop Characters, data characters, and other auxiliary patterns, that together form a complete scannable entity; an instance of a symbology and an element string.
Symbol Character	A group of bars and spaces in a symbol that is decoded as a single unit. It may represent an individual digit, letter, punctuation mark, control indicator, or multiple data characters.
U.P.C. symbol	A barcode symbol that encodes the GTIN-12, Coupon-12, RCN-12, and VMN-12.
"very small healthcare items"	All kinds of very small pharmaceutical and medical products, mainly unit-of-use items and unit dose items, but also very small packages.

Acronyms

2D	Two-dimensional
AAP	American Academy of Pediatrics
AI	Application Identifier
EPC	Electronic Product Code
GTIN®	Global Trade Item Number®
HRI	Human Readable Interpretation
NDC	National Drug Code
NHRIC	National Health Related Item Code
RFID	Radio Frequency Identification
YYMMDD	Expression of year, month, day

Appendix A: Calculating the GTIN Check Digit

GS1 US provides a check digit calculator to automatically calculate check digits for you.   The check digit calculator can be found at http://www.gs1us.org/solutions_services/tools/check_digit_calculator.

Check digits can also be calculated manually. A sample check digit calculation is provided in Table 7 below using hypothetical GTIN **9101454121022**:

Step	Instructions	Demonstration
1	Set up a table with 14 columns, and put the numbers of the GTIN into Positions One through Thirteen. (Position Fourteen will be blank because it is reserved for the Check Digit.)	9 1 0 1 4 5 4 1 2 1 0 2 2 _
2	Add the numbers in Positions One, Three, Five, Seven, Nine, Eleven, and Thirteen.	9 + 0 + 4 + 4 + 2 + 0 + 2 = **21**
3	Multiply the result of Step Two by three.	21 x 3 = **63**
4	Add the numbers in Positions Two, Four, Six, Eight, Ten, and Twelve.	1 + 1 + 5 + 1 + 1 + 2 = **11**
5	Add the results of Step Three and Step Four.	63 + 11 = **74**
6	The Check Digit is the smallest number needed to round the result of Step Five up to a multiple of 10.	Check Digit is **6**
	Completed GTIN with check digit	**9 1 0 1 4 5 4 1 2 1 0 2 2 6**

Table 7: Calculating the Check Digit for the GTIN "9101454121022"

Appendix B: Examples of GS1 DataMatrix Barcodes

(01) 00314141999995

Figure E.1 – Example of GS1 DataMatrix symbol encoded with GTIN.

(01) 00314141999995
        (17) 101231

Figure E.2 – Example of GS1 DataMatrix symbol encoded with GTIN AI (01) and Expiration date AI (17) YYMMDD or December 31, 2010.

(01) 00314141999995
(10) 987654321GFEDCBA

Figure E.3 – Example of GS1 DataMatrix symbol encoded with GTIN AI (01) and Lot Number AI (10).

(01) 0 0314141 99999 5 (17) 101231 (10) 987654321GFEDCBA

Figure E.4 – Example of GS1 DataMatrix symbol encoded with GTIN AI (01), Expiration date AI (17), Lot Number AI (10))

Disclaimer

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IAPMO

In this publication, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.

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