



Blood Bag Identification Using ISBT 128 and GS1

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PO Box 11309, San Bernardino, CA 92423-1309 USA

Authors

Paul Ashford, MSc. CEng. CSci.
Executive Director, ICCBBA

Pat Distler, MS, MT(ASCP)SBB
USA

Jørgen Georgsen, MD
Medical Director, Funen Transfusion Service

Christian Hay, Master of Law
Senior Consultant, GS1 Global Office

Ulrike Kreysa
Group Manager Healthcare, GS1 Global Office

Christine Larson
Principal Engineer, Fenwal Inc.

Karen Peterson-Doyle
Sr. Director, Global Labeling, Pall Corporation

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1 Introduction

This document is intended to provide guidance to blood bag manufacturers, their customers, and software developers on the bar coding of blood bags and their shipping containers. It deals with the relationship between information held in the GS1 carton codes and the ISBT 128 blood container label codes, and recommends ways to simplify the mapping between this information.

The main business driver for achieving this mapping is to allow blood collection facilities to scan the GS1 carton codes on receipt into stores in order to increment stock levels, and then decrement stock by the scanning of the ISBT 128 codes on the individual sets at the time of use.

The two critical pieces of information required to achieve this mapping are:

- the product identification, represented in the GTIN (AI [01]) in GS1 and the Container Manufacturer and Catalog Number (Data Structure [017]) in ISBT 128
- the lot number, represented in the Batch or Lot Number (AI [10]) in GS1 and the Container Lot Number (Data Structure [018]) in ISBT 128

2 GS1 Structures

The following sections contain extracts of the GS1 General Specifications, Release 17.0.1, Jan 2017 (<http://www.gs1.org/>). The GS1 General Specifications should be referenced for additional information or clarification.

2.1 Global Trade Item Number (GTIN): AI (01)

Purpose: Identification key for the carton, pointing to product information which the manufacturer populates either by Electronic Data Interchange (EDI) message PRODAT or by Data Synchronization Network (GDSN), or by other means defined bilaterally.

2.2 Trade Item Groupings of Identical Trade Items

For a trade item grouping that is a predefined grouping of identical trade items, the manufacturer or supplier has the option of either assigning a unique GTIN-13 or GTIN-12 to each trade item grouping or assigning a unique GTIN-14. These 14-digit GTINs incorporate the GTIN (less its check digit) of the trade item contained in each grouping.

- The GTIN-12 is the 12-digit GS1 Identification Key composed of a U.P.C. Company Prefix, Item Reference, and Check Digit used to identify trade items.
- The GTIN-13 is the 13-digit GS1 Identification Key composed of a GS1 Company Prefix, Item Reference, and Check Digit used to identify trade items.
- The GTIN-14 is the 14-digit GS1 Identification Key composed of an Indicator digit (1-9), GS1 Company Prefix, Item Reference, and Check Digit used to identify trade items.

Structure:

GTIN-14 data structures														
Global Trade Item Number (GTIN)														
	Indicator	GTIN of contained trade items (without check digit)											Check digit	
GTIN-8 based	N ₁	0	0	0	0	0	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄
GTIN-12 based	N ₁	0	N ₃	N ₄	N ₅	N ₆	N ₇	N ₈	N ₉	N ₁₀	N ₁₁	N ₁₂	N ₁₃	N ₁₄
GTIN-13 based	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	N ₁₄

The Indicator is a digit with a value of 1 to 8. It is assigned as required by the company that constructs the identification number. It can provide up to eight separate GTIN-14s to identify trade item groupings. The 12-, or 13-digit GTIN of the trade items contained must always be the one of the relevant levels of packaging contained, usually the lowest level. If the brand owner considers the carton as the lowest level of packaging, it has to be identified with a GTIN-13 or a GTIN-12 (this means that the indicator is a digit with a value of 0).

2.3 Batch or Lot Number: AI (10)

Purpose: Indicates that the GS1 Application Identifier data field contains a batch or lot number. The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item to which the Element String is applied. The data may refer to the trade item itself or to items contained. The data is alphanumeric and may include all characters contained in ISO/IEC 646.

Format of the Element String	
Application Identifier	Batch or Lot Number
1 0	X_1 ————— variable length ————— X_{20}

The Element String represents an attribute of a trade item; therefore the lot number should not be processed on its own, but together with the GTIN of the trade item to which it relates.

2.4 Expiration Date: AI (17)

Purpose: Indicates that the GS1 Application Identifier data fields contain an expiration date. The expiration date is the date that determines the limit of consumption or use of a product. The structure is:

- Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory
- Month: the number of the month (e.g., January = 01), which is mandatory
- Day: the number of the day of the relevant month (e.g., second day = 02); if it is not necessary to specify the day, the field must be filled with two zeros

Format of the Element String			
Application Identifier	Expiration Date		
	Year	Month	Day
1 7	$N_1 N_2$	$N_3 N_4$	$N_5 N_6$

The Element String represents an attribute of a trade item; therefore the expiration date should not be processed on its own, but together with the GTIN of the trade item to which it relates.

2.5 Data Encoded in the GS1 Label

The data carrier to be usually used on the carton is the GS1-128. This data carrier can encode the GTIN and its attributes in one or eventually two lines. The following example helps understand the processing of data which is captured:



(01)03123451234569(17)000201(10)X245

- GS1-128 is recognised by the initial character FNC1 (see ISO/IEC 15417 and 15424).
- The Application Identifiers (AI) are encoded without brackets in the GS1-128. Application Identifiers are defined in the *GS1 General Specifications*.
- AI (01): The Application Identifier (01) indicates that the GS1 Application Identifier data field contains a GTIN.
- AI (17): The Application Identifier (17) indicates that the GS1 Application Identifier data fields contain an expiration date.
- AI (10): The Application Identifier (10) indicates that the GS1 Application Identifier data field contains a batch or lot number.
- Sequence of AIs starts usually with (01); it is up the user to continue with (10) or (17). The label is shorter if the variable length (10) is placed at the end of the barcode.

3 ISBT 128 Structures

The following are extracts from the ISBT 128 Technical Specification (ST-001), version 5.7.0, dated January 2017. The ISBT 128 Technical Specification should be referenced for additional information or clarification.

3.1 Container Manufacturer and Catalog Number [Data Structure 017]

Purpose: To specify the manufacturer and catalog number of the container set and the identifying character(s) of the individual container(s) in the set.

Structure: =)bqqwwwwwww

Element	Length	Type
=	1	data identifier, first character
)	1	data identifier, second character
b	1	alphanumeric {A–Z; a–z, 0–9}
qq	2	alphanumeric {A–Z; 0–9}
wwwwwww	7	alphanumeric {A–Z; a–z; 0–9}*

*When used as a unique device identifier (UDI) for medical devices, only upper case alphas may be used in compliance with ISO/IEC 15459-4.

The ten (10)-character data content string, **bqqwwwwwww** is encoded and interpreted as follows:

- b** specifies the container identification character in a container or transfer set. The value of b is set as follows:
- The character “1” shall be reserved for the primary collection container.
 - Other numbers and upper case alpha characters may be used as container manufacturers choose.
 - For an entire set of integrally attached containers, the character “y” shall be used. This code may appear on a set wrapper or individual container.
 - For cartons containing blood collection containers, the character “z” shall be used. This code may appear on a packaging carton containing many sets of a given type.
 - Remaining lower case alphas are reserved for future use.

Note: This proposal does not change ICCBBA’s recommendation to use GS1 identifiers on a carton. It merely allows an additional ISBT 128 identifier to appear on cartons for those facilities unable to use the GS1 identifier in their blood bank computer systems.

- qq** specifies the identity of the container set manufacturer and is encoded and interpreted from Table W1, [RT016] – Manufacturer Identifier Codes. Table W1 can be found on the [ICCBBA website](#).
- wwwwwww** specifies the manufacturer's catalog number. This shall be interpreted from information provided by the manufacturer. If the catalog number is less than seven (7) characters, it shall be padded with zeroes at the beginning of the string (i.e., the catalog number 27QzE would be transmitted as 0027QzE).

Used in conjunction with the Manufacturers Data file (see the *ISBT 128 Standard Technical Specification* [ST-001] and the *Implementation Guide: Use of the Manufacturers Data File* [IG-015]), this data structure can be a powerful tool for process control. With use of appropriate software and downloading of the data file, much information about the container set can be determined automatically. This information includes the number of bags in the set, the anticoagulant/preservative, the intended nominal collection volume, etc.

3.2 Container Lot Number [Data Structure 018]

Purpose: To specify the manufacturer's lot number for the container set.

Structure: &)xxxxxxxxx

Element	Length	Type
&	1	data identifier, first character
)	1	data identifier, second character
xxxxxxxxx	10	alphanumeric {A–Z; a–z; 0–9}*

*When used as a unique device identifier (UDI) for medical devices, only upper case alphas may be used in compliance with ISO/IEC 15459-4.

The ten (10)-character data content string, **xxxxxxxxx**, shall encode the manufacturer's lot number. If the lot number is less than ten (10) characters, it shall be padded with zeroes at the beginning of the string (i.e., the lot number 1234rZ would be transmitted as 00001234rZ).

Because lot numbers can be padded with zeroes, ideally they should not begin with a 0 (zero). If the lot number begins with 0 (zero), the manufacturer shall have a mechanism to ensure correct identification of the lot number when a problem is reported and the lot number is indicated without the leading 0 (zero).

This data structure shall be used in conjunction with Data Structure 017.

4 Mapping Between Structures

4.1 Product Identification

The GTIN used on the outer carton will be unique to the specific item (catalog number) contained in the carton. The number will not change between lots, but will change if there is any change in specification of the item or if the number of items in the carton changes. The ISBT 128 (Data Structure 017) will not change between lots, but will change if there is any change in specification of the item. This data structure does not change if the number of items in the carton changes.

As the GTIN and Data Structure 017 do not have any structural similarities, manufacturers should provide a means for their customers to create the necessary one to one mapping on receipt of product. The information should be provided either by including the GTIN within the ISBT 128 Manufacturers Data File or by providing both identifiers in an electronic readable format on the dispatch documentation.

The ISBT 128 Manufacturers Data File has been modified to include new data labels for this purpose: GS1GTIN holds the GTIN of the carton, and GS1GTINCONTENT holds the number of collection sets in the carton specified by the GTIN.

Customer systems should maintain a lookup table containing the 1-1 mapping between these two identifiers.

4.2 Lot Numbers

The Lot Number should be incorporated into both GS1 [AI (10)] and ISBT 128 (Data Structure 018). Because the GS1 structure supports variable length, the lot number can be included directly. In ISBT 128 the field is a fixed length of 10 characters so the Lot Number should be padded with leading zeros.

It must be borne in mind that the actual Lot Number itself may commence with a leading zero and this can lead to some confusion in comparing the information in the two structures. The following algorithms will ensure accurate mapping:

GS1 to ISBT 128

Take Lot Number from GS1
Add leading zeros until length is 10
Compare with ISBT 128 Lot Number

ISBT 128 to GS1

Take Lot Number from ISBT 128
Remove leading zeros until length is same as GS1 Lot Number
Compare with GS1 Lot Number.