

IMPLEMENTATION GUIDE

A Validation Tool for ISBT 128 Data Structures

Version 1.3.0

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Table of Contents

1	Intro	duction	6
	1.1	Purpose	6
	1.2	Scope	6
	1.3	Intended Audience	7
	1.4	Normative Reference	7
	1.5	Other References	7
	1.6	Background	8
	1.7	Changes in this Version	8
2	ISB	Г 128 Data Structures	10
	2.1	Data Identifiers	10
	2.1.	1 The Role of Data Identifiers in ISBT 128 Bar Codes	11
3	Тур	es of Data Structure Messages	12
	3.1	Donation Identification Number [Data Structure 001]	
	3.1.	1 Valid Messages – Data Structure 001	14
	3.1.	2 Non-Compliant Messages – Structural	19
	3.1.	3 Non-Compliant Messages – Invalid Data	21
	3.1.	Non-Compliant Messages – Contextual Inconsistency	21
	3.2	Blood Groups [ABO and RhD] [Data Structure 002]	22
	3.2.	1 Valid Messages – Data Structure 002:	23
	3.2.	2 Non-Compliant Messages – Structural	26
	3.2.	3 Non-Compliant Messages – Invalid Data	28
	3.3	Product Code [Data Structure 003]	
	3.3.	1 Valid Messages – Data Structure 003	30
	3.3.	2 Non-Compliant Messages – Structural	37
	3.3.	3 Non-Compliant Messages – Invalid Data:	38
	3.3.	Non-Compliant Messages – Contextual Inconsistency:	39
	3.4	Expiration Date and Time [Data Structure 005]	40
	3.4.	1 Valid Messages – Data Structure 005	41
	3.4.	2 Non-Compliant Messages – Structural	42
	3.5	Special Testing: General [Data Structure 010]	44
	3.5.	1 Valid Messages – Data Structure 010	45
	3.5.	2 Non-Compliant Messages – Structural	46
	3.6	Special Testing: Red Blood Cell Antigens – General [Data Structure 012]	48
	3.6.	1 Valid Messages – Data Structure 012:	49
	3.6.	2 Non-Compliant Messages – Structural	50

3.0	6.3	Non-Compliant Messages – Contextual Inconsistency	51
3.7	Spe	ecial Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]	53
3.	7.1	Valid Messages – Data Structure 014:	54
3.	7.2	Non-Compliant Messages – Structural	56
3.	7.3	Non-Compliant Messages – Invalid Data	57
3.	7.4	Non-Compliant Messages – Contextual Inconsistency	59
3.8	Cor	npound Message [Data Structure 023]	60
3.8	8.1	Valid Messages – Data Structure 023	61
3.8	8.2	Non-Compliant Messages – Structural	63
3.8	8.3	Non-Compliant Messages – Contextual Inconsistency	64
3.9	Cha	ain of Identity Identifier [Data Structure 040]	66
3.9	9.1	Valid Messages – Data Structure 040	66
3.9	9.2	Non-Compliant Messages – Invalid Data	67

Figures

Figure 1: Data Structure	10
Figure 2: DIN Data Elements	14
Figure 3: Product Code Data Elements	30
Figure 4: Excerpt of Special Testing: General [RT029]	44

Tables

Table 1: Data Structure 001 Coding Values	13
Table 2: Data Structure 002 Coding Values	22
Table 3: Data Structure 003 Coding Values	29
Table 4: Data Structure 005 Coding Values	40
Table 5: Data Structure 010 Coding Values	44
Table 6: Data Structure 012 Coding Values	48
Table 7: Data Structure 014 Coding Values	53
Table 8: Data Structure 023 Coding Values	60

1 Introduction

1.1 Purpose

This guidance document is intended to provide users with assistance in evaluating the capabilities of their ISBT 128 bar code reading software and to provide input to their validation process.

This document provides a means to help make users aware of how their system responds to a given data structure and focuses on one data structure per section. The following types of information (when applicable) are included in each section:

- An overview of the data structure and its coding values table, consistent with the *ISBT 128 Standard Technical Specification* (ST-001)
- Features and/or elements unique to the data structure
- Reference to other ICCBBA publications that may be pertinent to the data structure
- Scannable bar codes encoded with either valid or non-compliant messages
- General considerations pertinent to the data structure

This guidance should be used in conjunction with the current version of the <u>ISBT 128</u> <u>Standard Technical Specification</u> (ST-001), and the intended audience should already be familiar with the specifications of the Standard and have a comprehensive understanding of ISBT 128 data structures.

The purpose of this document is to provide a mechanism to validate software reading bar coded labels. Regulatory and compliance staff, as well as software developers, may find this guidance document helpful when developing certain validation test plans.

1.2 Scope

This version of IG-043 provides ISBT 128 linear bar code examples [Code 128] using the following data structures:

- Donation Identification Number [Data Structure 001]
- Blood Groups [ABO and RhD] [Data Structure 002]
- Product Code [Data Structure 003]
- Expiration Date and Time [Data Structure 005]
- Special Testing: General [Data Structure 010]
- Special Testing: Red Blood Cell Antigens General [Data Structure 012]
- Special Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]

2-D symbols [Data Matrix] will be provided for the Compound Message [Data Structure 023] examples.

The example bar codes are encoded with either valid or non-compliant ISBT 128 messages. The types of non-compliant messages pertain to structural non-compliance, invalid data, and/or contextual inconsistency—some of these types of non-compliant messages do not apply to certain data structures. While these bar codes are intended for validation purposes, users and developers should not rely solely on this guidance

document when validating software (or when developing such software). This document is intended to be used as a validation tool, not a compliance checklist.

Note: The bar codes provided in this document are not intended for code density comparison. Users are advised to reference the ISBT 128 Standard Technical Specification (ST-001) for information/requirements pertaining to symbol print quality and symbol dimensions.

In addition to the ISBT 128 Standard Technical Specification (ST-001), this document is supplemented with other ICCBBA publications that provide greater detail and additional information on various aspects pertaining to the implementation of ISBT 128. For additional bar code examples, see Implementation Guide: ISBT 128 Bar Codes: Valid and Invalid Examples (IG-013).

1.3 Intended Audience

The intended audience for this document is as follows:

- Users of ISBT 128 (e.g., staff of facilities utilizing, or planning to utilize, the ISBT • 128 Standard).
- ICCBBA-licensed vendors (e.g., software developers, label vendors, etc.).
- Other interested parties (e.g., regulators, auditors, etc.). •

Users are encouraged to provide feedback on this document by sending an email to IG043.Comments@isbt128.org.

1.4 Normative Reference

ICCBBA:

[www.isbt128.org]

ISBT 128 Standard Technical Specification (ST-001)

American National Standards Institute (ANSI):

[webstore.ansi.org]

ANSI MH10.8.2:2010, Data Identifier and Application Identifier Standard (18 May 2010)

International Standards Organization (ISO): [https://www.iso.org/store.html]

ISO/IEC 7064:2003 Information technology — Security techniques — Check character systems

1.5 **Other References**

The following guidelines¹ are maintained on the ICCBBA website

¹ The publication titles are current as of the date on the front cover of this document—while the title for a publication may change, the assigned tracking designation (e.g. IG-999) would remain the same. It is the

- Implementation Guide: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution (<u>IG-010</u>)
- Implementation Guide: ISBT 128 Bar Codes: Valid and Invalid Examples (<u>IG-013</u>)
- Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)
- Implementation Guide: Use of Product Code [Data Structure 003] Blood (IG-021)
- Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (<u>IG-033</u>)
- Implementation Guide: ISBT 128 Facility Identification Number (<u>IG-034</u>)

1.6 Background

ISBT 128 is the global standard for the terminology, identification, coding, and labeling of medical products of human origin (MPHO). ISBT 128 Data Structures are internationally agreed entities for encoding information relevant to MPHO and define the technical characteristics necessary for the interpretation of the information.

As a global standard used in disparate health care systems, software systems that support ISBT 128 may vary in terms of the degree of compliance with the Standard. For example, a system could have a high level of ISBT 128 compliance which allows it to interpret many data structures for more than one product category; while, on the other hand, a system could have a low level of compliance which may only allow it to interpret a few data structures for a given product category.

Users and software developers should have a firm understanding of their system's degree of ISBT 128 compliance and, if applicable, should be aware of the implications associated with the limitations of the system.

1.7 Changes in this Version

The following table indicates the major changes between version 1.2.0 and version 1.3.0. Actual changes or additions to requirements of the ISBT 128 Standard are in **bold print**; changes to formatting or organization, or additional guidance, are in regular print. If changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

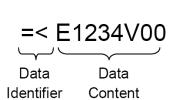
responsibility of the registered and licensed establishments (or other parties alike) to ensure that they have the most recent version of all ICCBBA publications by regularly consulting the listing maintained on the ICCBBA website.

	Version 1.2.0 Chapter, Section, Table or Figure	Version 1.3.0 Chapter, Section, Table or Figure	Change	Rationale
1.	Section 3.8	Section 3.8	Added additional 2-D example containing the Chain of Identity Identifier	To provide visual assistance and clarification.
2.		Section 3.9	Added a new section for Valid and Non-Compliant Linear label examples of the Chain of Identity Identifier.	To provide visual assistance and clarification.

2 ISBT 128 Data Structures

ISBT 128 Data Structures define the technical characteristics necessary for the interpretation of the information and are composed of two elements: the *data identifier* and the *data content*. Data structures specify the context and structure and, when applicable, provide the associations to the appropriate reference tables for conversion of codes to meaningful information.

Figure 1: Data Structure



- The *data identifier* determines the length and the allowable coding values (and the sequence of these values) for the data content.
- The *data content* is made up of data characters that provide the information to be conveyed.²

2.1 Data Identifiers

The *data identifier* is a two- or three-character code² that serves to identify the data structure. Its use is required when the context of the data structure presentation makes it necessary to also indicate the nature of the information being conveyed—for example, bar codes.

- <u>First Character</u>: ISBT 128 data identifiers begin with either the equals sign ("=") [ASCII character code 61] or the ampersand ("&") [ASCII character code 38]. These identifiers have been reserved by ANSI (ANSI MH10.8.2:2010) as ISBT 128 data identifiers to distinguish ISBT 128 data structures from all others.
- <u>Second Character</u>: The second character of an ISBT 128 data identifier is a nonalphanumeric ASCII character. However, there are some exceptions:
 - The data identifier for the DIN² (where the second character can be any of the alphanumeric characters 1–9, A–N, P–Z [but not a–z]).
 - The data identifier for data structures not defined by ICCBBA (refer to Chapter 2 of the ISBT 128 Standard Technical Specification [ST-001] for more information).
- <u>Third Character</u>: The third character of an ISBT 128 data identifier can be alphanumeric.

(**Note:** The first two characters of a three-character data identifier will never be a two-character data identifier on their own. For example, since the data identifier for the MPHO Lot Number [Data Structure 035] is ***&,1***, ***&,*** does not [and will not] represent any two-character data identifier.)

² The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content.

See **Table RT003** of the *ISBT 128 Standard Technical Specification* (ST-001) for a list of ISBT 128 data identifiers with their corresponding data structures.

2.1.1 The Role of Data Identifiers in ISBT 128 Bar Codes

In bar codes, the data identifier is required for ensuring the correct interpretation of the encoded message. Therefore, in order to accurately interpret information from an ISBT 128 bar code, it is crucial that application software carry out the following steps before interpreting the data values (the data content):

- Analyze the data identifier to ensure that the bar code entered is of the correct type.
- Verify that the length and format of the data content match that defined for the corresponding data structure.

If a system fails to identify the framework and syntax of the encoded message prior to analyzing the data values themselves, the system could misinterpret the bar coded message [i.e. the system could confuse the data values with those of another data structure]. This could lead to incorrect assignment of critical information.

The following example illustrates this.

An ISBT 128 Blood Groups [ABO and RhD] [Data Structure 002] bar code for an A, RhD Positive unit reads as:

=%6200

where "=%" are the data identifier characters indicating that this is a Blood Groups [ABO and RhD] data structure, and "6200" are the data values for A, RhD Positive with no information encoded concerning C, c, E, e, K or Miltenberger phenotypes.

A Special Testing: Red Blood Cell Antigens – General [Data Structure 012] bar code on a Group O, RhD negative unit reads as:

=\620000000000000000000

If the data identifier characters are ignored by the application software, entry of this second bar code in response to a blood groups prompt could cause the system to incorrectly assign a blood group for the unit as A, RhD Positive.

3 Types of Data Structure Messages

This validation tool includes the following types of bar coded data structure messages:

- <u>Valid message</u>: Includes a valid ISBT 128 data identifier and a data string that complies with the format, syntax, and application of the data structure associated with the data identifier.
- <u>Non-compliant messages</u>: This document includes examples for the following types of non-compliance:
 - **Structural:** Syntax-related errors such as the use of unallowable coding values or the incorrect data content length, as defined by the specifications for the data structure—for instance, the data structure does not meet the syntactic requirements specified in the allowable coding values table provided for each data structure.
 - Invalid data: The data content is structurally compliant but has values not defined within the standard. Invalid data occurs where the valid data values are specified within the *ISBT 128 Standard Technical Specification* (ST-001) in a bounded list (e.g., the Blood Groups [ABO and RhD] table [RT005] for Data Structure 002). Any value outside this list is non-compliant with the standard.

(**Note:** Because the Facility Identification Number [FIN] Database and ISBT 128 Product Description Code [PDC] Database are not part of a bounded list, unallocated FINs and unassigned PDCs are considered valid messages.)

 Contextual inconsistency: The data structure is structurally compliant and each element contains valid data, but there is an inconsistency between the elements. For example, a Donation Identification Number [Data Structure 001] with Type 3 flags, where the value of the Type 3 flag is not consistent with the checksum.

The types of data content permutations (the selection of coding values) presented in this document can be used for performing high-level (rudimentary verification) and low-level tests (specific verification) on software for reading bar coded labels. The examples in this document are limited to data content with a propensity of making a significant impact on a validation outcome.

Additional scannable bar codes—both linear (Code 128) and 2-D (Data Matrix)—can be found in the "Implementation Guide: ISBT 128 Bar Codes: Valid and Invalid Examples" guidance document (IG-013).

3.1 Donation Identification Number [Data Structure 001]

Purpose: Data Structure 001 shall specify:

- a thirteen (13)-character Donation Identification Number (DIN) that is a unique identification of:
 - a donation event [collection or recovery]
 - a product pool
 - for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product
 - a zygote/embryo formed through ART

AND

• flag character values.

Structure: = *appppyynnnnnff*

Element	Length	Туре
=	1	data identifier, first character
α	1	data identifier, second character alphanumeric {A–N; P–Z; 1–9}
рррр	4	First two characters alphanumeric {A–N, P–Z, 0–9}; second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future (e.g., if α = A and pppp = BC12, the α pppp will be ABC12)
уу	yy 2 numeric {0–9}	
nnnnnn 6 numeric {		numeric {0–9}
ff 2 alpha		alphanumeric {0–9}, {A–H, J–N, P, R–Y}

Table 1: Data Structure 001 Coding Values

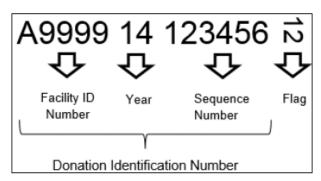
For more information on Data Structure 001, see **section 2.4.1** of the *ISBT 128 Standard Technical Specification* (ST-001).

Considerations for Data Structure 001:

- It is the only data structure in which the second character of the data identifier is part of the data content.
- It comprises two fundamental elements, the Donation Identification Number (thirteen characters) and the flag characters (two characters).
 - The Donation Identification Number (DIN) comprises the following elements:

- A five-character Facility Identification Number (FIN)
- A two-digit year code
- A six-digit sequence number
- The flag characters should be interpreted independently of the thirteencharacter DIN as they are a separate data item. The ISBT 128 Standard defines three modes of use for flag characters, and it may be important to understand which of these the computer system supports.

Figure 2: DIN Data Elements



Additional References:

- Implementation Guide: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution (IG-010)
- Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)
- Implementation Guide: ISBT 128 Facility Identification Number (IG-034)

3.1.1 Valid Messages – Data Structure 001

 Examples 1.1 through 1.5: Data content string begins with an uppercase alpha character. Default flag characters used [no additional meaning]. 							
Example 1.1	Example 1.1 Data Identifier Data Content Check Character Elements						
	=	W00001642817500	1	DIN (αppppyynnnnn): W000016428175 Flag Characters (ff): 00			
Complete message encoded in bar code: =W00001642817500							

Example 1.2	Data Identifier	Data Conte	ent	Check Character	Elements				
	=	A9999160000	6500	A	DIN (αppppyynnnnn): A999916000065				
					Flag Characters (ff): 00				
Complete message encoded in bar code: =A99991600006500									
Example 1.3	Data Identifier	Data Conte	ent	Check Character	Elements				
	=	W1256071234	15600	к	DIN (αppppyynnnnn): W125607123456				
Complete message encode	d in bar cod	e:			Flag Characters (ff): 00				
=W12560712345600		~ .							
	Data			Check					
Example 1.4	Identifier	Data Conte	ent	Character	Elements				
	=	C00030600145800		N	DIN(αppppyynnnnn): C000306001458				
					Flag Characters (ff): 00				
Complete message encode =C00030600145800	d in bar cod	e:							
	r	I		ſ					
Example 1.5	Data Identifier	Data Conte	ent	Check Character	Elements				
	=	P00020601906300		х	DIN(αppppyynnnnn): P000206019063				
	l <u></u> .				Flag Characters (ff): 00				
Complete message encode = P00020601906300	a in bar cod	e:							
	Consideration	no for From	oo 4 4 4	through 4.5					
Element of DIN Data Struct	uro	ons for Exampl	es 1.1						
(=αppppyynnnnnff)	Cla	arification		Considerations					
FIN (αρρρρ)		st character of		Facility identifiers within a country may have the same first character, but other characters					
				are used in different countries. There will be					
	{A-N; F	P–Z; 1–9}.		situations where systems need to limit					
		acceptable donation numbers to th specific FIN or range of FINs, and							
			be oth	ner situations v	where accepting the full				
			where		Ns is appropriate (e.g., eds to be able to accept				

Examples 1.6 & 1.7:								
 Data content string comprises only numeric characters. Default flag characters used [no additional meaning]. 								
Example 1.6	Data Identifier	Data Conte		Check Character	Elements			
	=	90001161234	5600	E	DIN (αppppyynnnnn): 9000116123456			
					Flag Characters (ff): 00			
Complete message encode =900011612345600	d in bar coo	le:			•			
=900011612345600								
Example 1.7	Data Identifier	Data Conte	nt	Check Character	Elements			
	=	= 50321165932		Q	DIN (αppppyynnnnn): 5032116593212			
					Flag Characters (ff): 00			
Complete message encode =503211659321200	d in bar coo	le:						
	Consider	ations for Even	nlaa 4	C and 1 7				
Element of DIN Data Struct (=αρρρργγηηηηηf)	uro	onsiderations for Examp Clarification		Considerations				
FIN (αpppp) Year code (yy) Serial number (nnnnnn) Flags (ff)	"Data S Coding a DIN string o	cated in the Structure 001 – g Values" table, data content can be made ill numeric ters.		the Considera hrough 1.5 (á	ations section for Examples above).			

Example 1.8:								
 First three characters of the data content string are uppercase alpha characters. Default flag characters used [no additional meaning]. 								
Example 1.8 Data Data Content Check Elements								
	=	WWW001612345600	6	DIN (αppppyynnnnn): WWW0016123456				
Complete message encoded in bar code: Flag Characters (ff): 00 =WWW001612345600 =WWW001612345600								

Considerations for Example 1.8								
Element of DIN Data Structure (=αppppyynnnnnnff)	Clarification	Considerations						
FIN (αpppp)	 The first character of the FIN may be any character in the set {A-N; P-Z; 1-9}. The second and third character of the FIN may be any character in the set {A-N; P-Z; 0-9}. The fourth and fifth character of the FIN may be numeric {0-9}. 	With regard to "pppp" of "apppp", current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future.						

Example 1.9

- Data content string begins with an uppercase alpha character.
- Type 1 flag characters used [two-character code used for process control and defined by ICCBBA].

Example 1.9	Data Identifier	Data Content	Check Character	Elements		
	=	W00001612345601	x	DIN (αppppyynnnnn): W000016123456		
	d in har cod	0.		Flag Characters (ff): 01		
Complete message encoded in bar code:						

=W00001612345601

Example 1.10

- Data content string begins with an uppercase alpha character.
- Type 2 flag characters used [two-character code used for process control, but locally defined].

Example 1.10	Data Identifier	Data Content	Check Character	Elements
	=	W00001698765425	U	DIN (αppppyynnnnn): W000016987654
				Flag Characters (ff): 25
Complete message encoded in bar code:				

=W00001698765425

Example 1.11

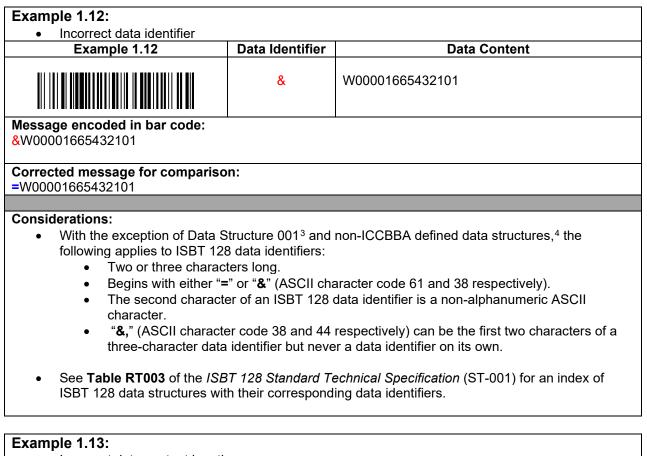
- Data content string begins with an uppercase alpha character.
- Type 3 flag characters used [a weighted ISO/IEC 7064 modulo 37-2 check character on the entire thirteen-character DIN].

Example 1.11	Data Identifier	Data Content	Check Character	Elements
	=	W00001600000172	С	DIN (αppppyynnnnn): W000016000001
				Flag Characters (ff): 72

=W00001600000172						
Considerations for Examples 1.9–1.11						
Element of DIN Data Structure (=αppppyynnnnnff)	Clarification	Considerations				
Flag Characters (ff)	Flag characters should be interpreted independently of the DIN as they are a separate data item.	 ISBT 128 defines three modes of use for flag characters (see Section 2.4.1 of ST-001 for details), and it may be important to understand which of these a computer system supports. System rules may impose control on which flag characters are accepted in specific situations in order to provide process control. However, where products are imported from external organizations (e.g., blood testing facilities), their use of flag characters may differ and thus may be more appropriate for importing software to allow other valid flag characters. Hospital blood bank systems users—who may receive blood from more than one source—may also wish to be able to accept all valid flag values. 				

Complete message encoded in bar code: =W00001600000172

3.1.2 Non-Compliant Messages – Structural



Example 1.13	Data Identifier	Data Content	
	=	W000016428175	
Message encoded in bar code: =W000016428175			
Corrected message for compariso =W00001642817500	n:		

³ The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content; therefore, the second character of its data identifier can be: A–N, P–Z, or 1–9.

⁴ See Section 2.5 of the "ISBT 128 Standard Technical Specification" document (ST-001) for details on non-ICCBBA defined data structures.

Considerations for Example 1.13:

- In this example, flag characters are missing from the encoded data content.
 - Even though the use of flag characters is optional, ISBT 128 requires the data content string of the DIN data structure to be 15 characters long.
 - When flag characters are not used, the value of the flags [the 14th and 15th position of Data Structure 001] shall be "00".
- The keyboard entry check character is calculated from the 13-character DIN only (i.e. excluding the flag characters).

Example 1.14:

Incorrect data content length. •

	W0000164281750000			
Message encoded in bar code: =W0000164281750000				
Corrected message for comparison: =W00001642817500				
	s 15 alı			

A valid DIN data content string comprises 15 alphanumeric characters.

Example 1.15:

Unallowable coding values used in the 3rd and 4th position of the DIN data content string (FIN element).

Example 1.15	Data Identifier	Data Content
	=	W0OA01642817500
Message encoded in bar code:		

=W0OA01642817500

Corrected message for comparison: =W00401642817500

Considerations:

- The allowable coding values for the first five characters of the DIN (i.e. the FIN portion of the DIN) are as follows:
 - The first three characters may be any character in the set {A-N; P-Z; 1-9}. •
 - The fourth and fifth character may be numeric $\{0-9\}$. •
- Although current usage is numeric for the second through fifth position of the DIN (i.e., the last four characters of the FIN), alpha characters may be introduced into the second and third position of the DIN in the future-for example, a FIN could be WAB01.

3.1.3 Non-Compliant Messages – Invalid Data

Example 1.16	6 Data Identifier Data Content				
= W000016428175AA					
Message encoded in bar code: =W000016428175AA					
Corrected message for comparison: =W00001642817512					
Considerations:					
 While "AA" is structurally compliant, Table RT004 (a bounded list) specifies that flags outside the range of 00 through 96 are reserved for future assignment. Therefore, "AA" is considered invalid until it is defined by ISBT 128. 					

3.1.4 Non-Compliant Messages – Contextual Inconsistency

Example 1.17:					
 Value of type 3 flags is not of 	onsistent with the	checksum.			
Example 1.17	Data Identifier Data Content				
= W00001600000171					
Message encoded in bar code: =W00001600000171					
Corrected message for comparison: =W00001600000172					
Considerations:					
 Flag values 60 through 96 are reserved for indicating the ISO/IEC 7064 modulo 37-2 check character on the Donation Identification Number—the value is assigned as 60 plus the modulo 37-2 checksum. Appendix A of the <i>ISBT 128 Technical Specification</i> (ST-001) demonstrates how to calculate the checksum character for a DIN. 					

3.2 Blood Groups [ABO and RhD] [Data Structure 002]

Purpose: Data Structure 002 EITHER

- Shall indicate the blood groups [ABO and RhD] of a product and
- May convey information regarding C, c, E, e, K, or Miltenberger phenotypes and/or
- May include information defining the type of collection

OR

• Shall convey special messages such as the status of a collection, restrictions on use, or processing instructions.

Structure: =%ggre

Element	Length	Туре
=	1	data identifier, first character
%	1	data identifier, second character
gg	2	alphanumeric {A–Z; a–z; 0–9}
r	1	alphanumeric {A–Z; 0–9}
е	1	alphanumeric {A–Z; 0–9}

Table 2: Data Structure 002 Coding Values

For more information on Data Structure 002, see **section 2.4.2** of the *ISBT 128 Standard Technical Specification* (ST-001).

Considerations for Data Structure 002:

- A value of 0 (zero) in the third position of the data content [the "r" portion of "ggre"] indicates that the Data Structure 002 message does not contain information about Rh and Kell or Miltenberger phenotypes.
- The fourth position of the data content [the "e" portion of "ggre"] is reserved for future use and should be set to 0 (zero).

3.2.1 Valid Messages – Data Structure 002:

 Examples 2.1 through 2.7: The following data content can be int Including Optional Type of Collection <i>Technical Specification</i> (ST-001). These examples provide a sinformation pertaining to the 	Information" table [RT005] fo	
Example 2.1:	Data Identifier	Data Content
	=%	9500
Complete message encoded in bar code: =%9500		
Example 2.2:	Data Identifier	Data Content
	=%	G600
Complete message encoded in bar code: =%G600		
Example 2.3:	Data Identifier	Data Content
	=%	0600
Complete message encoded in bar code: =%0600		
Example 2.4:	Data Identifier	Data Content
	=%	A000
Complete message encoded in bar code: =%A000		

Example 2.5:	Data Identifier	Data Content
	=%	F000
Complete message encoded in bar code: =%F000		
Example 2.6:	Data Identifier	Data Content
	=%	G000
Complete message encoded in bar code: =%G000		
Example 2.7:	Data Identifier	Data Content
	=%	O600
Complete message encoded in bar code: =%O600		

Examples 2.8 & 2.9:

- The following data content can be interpreted by reference to the "Blood Groups [ABO and RhD], Including Optional Type of Collection Information" table [RT005] found in the *ISBT 128 Standard Technical Specification* (ST-001).
 - These examples provide both blood group and type of collection related information.

Example 2.8:	Data Identifier	Data Content
	=%	9700
Complete message encoded in bar code: =%9700		

Example 2.9:	Data Identifier	Data Content
	=%	4700
Complete message encoded in bar code: =%4700		

 Example 2.10: The following data content can be int Messages" table [RT006] found in th 		
Example 2.10	Data Identifier	Data Content
	=%	Mr00
Complete message encoded in bar code: =%Mr00		

Collection Information" table	<i>fication</i> (ST-001): od Groups [ABO and RhD], Ind	cluding Optional Type of
Example 2.11:	Data Identifier	Data Content
	=%	51E0
Complete message encoded in bar code: =%51E0		
Example 2.12:	Data Identifier	Data Content
	=%	58L0
Complete message encoded in bar code: =%58L0	I	

3.2.2 Non-Compliant Messages – Structural

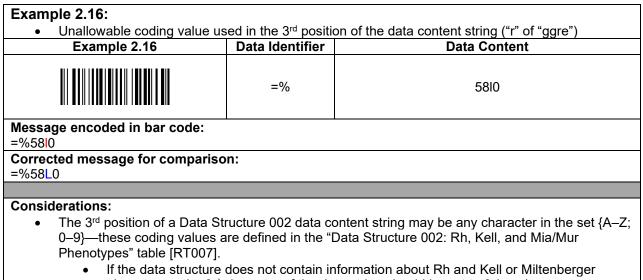
Example 2.13:		
 Incorrect data identifier 		
Example 2.13	Data Identifier	Data Content
	=?	9500
Message encoded in bar code: =?9500		
Corrected message for compariso =%9500	n:	
following applies to ISBT 128 Two or three charact Begins with either "= The second character character. "&," (ASCII character	3 data identifiers: ters long. " or "&" (ASCII cha er of an ISBT 128 d er code 38 and 44	non-ICCBBA defined data structures, ⁶ the aracter code 61 and 38 respectively). data identifier is a non-alphanumeric ASCII respectively) can be the first two characters of a ar a data identifier on its own.
 See Table RT003 of the ISB ISBT 128 data structures wit 		echnical Specification (ST-001) for an index of ing data identifiers.

r

⁵ The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content; therefore, the second character of its data identifier can be: A–N, P–Z, or 1–9.

⁶ See Section 2.5 of the ISBT 128 Standard Technical Specification (ST-001) for details on non-ICCBBA defined data structures.

Example 2.15	Data Identifier	Data Content
	=%	95000
lessage encoded in bar code: %9500 <mark>0</mark>		
corrected message for compar %9500	ison:	



phenotypes, the 3rd character of the data string should be set to 0 (zero).

3.2.3 Non-Compliant Messages – Invalid Data

Example 2.17	Example 2.17 Data Identifier Data Content					
	=%	F200				
Message encoded in bar code: =%F200						
Corrected message for compar =%A200	rison:					
O a se a la la se a la se a se						
• While "F2" is structurally		in the "Blood Groups [ABO and RhD], ble [RT005] (a bounded list).				
Including Optional Type o						
While "F2" is structurally Including Optional Type of Example 2.18:	of Collection Information" ta					
While "F2" is structurally Including Optional Type of Example 2.18:	of Collection Information" ta	ble [RT005] (a bounded list).				

Message encoded in bar code:

=%950<mark>A</mark>

Corrected message for comparison:

=%9500

Considerations:

• While the letter A is an allowable coding value, the 4th data character position of Data Structure 002 ("e" of "ggre") has been reserved for future use—the value of "e" shall always be set to 0 (zero).

3.3 Product Code [Data Structure 003]

Purpose: Data Structure 003 shall:

- Identify a product intended for human use
- Optionally encode information about the type of collection
- Encode whether or not the product has been divided

Structure: =<αooootds

Element	Length	Туре
=	1	data identifier, first character
<	1	data identifier, second character
α	1	alphabetic {A–Z}
0000	4	alphanumeric {A–Z; 0–9}
t	1	alphanumeric {A–Z; a–z; 0–9} (depends on value of α)*
d	1	alphanumeric {A–Z; 0–9}, (depends on value of α)*
s	1	alphanumeric {a–z; 0–9} (depends on value of α)*

Table 3: Data Structure 003 Coding Values

*See **Section 2.4.3** of the ISBT 128 Standard Technical Specification (ST-001) for additional information.

Considerations for Data Structure 003:

- "αοοοο" is the Product Description Code, a 5-character alphanumeric string from the ICCBBA-maintained ISBT 128 Product Description Code Database or the Clinical Trials PDC Database which can be found on the <u>ICCBBA website</u>. E is the first character for blood products [for information on additional product types see section 2.4.3 of ST-001]. The following interpretation of t and ds applies where α is E.
 - "t" shall specify the type of collection (e.g., autologous, directed) and shall be encoded and interpreted according to Table RT008 of the *ISBT 128 Standard Technical Specification* (ST-001).
 - "ds" shall specify information as to whether the unit has been divided. If the unit has not been divided, "ds" shall be set to the default value of 00 (zero, zero).

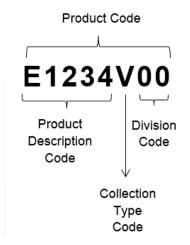


Figure 3: Product Code Data Elements

Additional References:

• Implementation Guide: Use of Product Code [Data Structure 003] - Blood (IG-021)

3.3.1 Valid Messages – Data Structure 003

Note: Bar code examples for other product categories will be added to future versions of this document (IG-043).

 Example 3.1: Blood: The Product Code data content includes a Product Description Code (alpha character followed by four numeric characters), the default collection code (alpha character), and the default division code (numeric characters). 			
Example 3.1 Data Data Content Elements			
	=<	E0150V00	Product Description Code (αοοοο) : E0150 Type of Collection Code (t) : V Division Code (ds) : 00
Complete message encoded in bar code: = <e0150v00< th=""></e0150v00<>			

Example 3.2: The data content includes a retired Product Description Code.			
Example 3.2	Data Identifier	Data Content	Elements
	=<	E0131V00	Product Description Code (αοοοο) : E0131 Type of Collection Code (t) : V Division Code (ds) : 00
Complete message encoded in bar code: = <e0131v00< td=""></e0131v00<>			

	Considerations for Example 3.2
Element of Product Code Data Structure (=<αooootds)	Considerations
PDC (αpppp)	Over time, codes may become inappropriate, redundant, or errors may be discovered. As a result, a mechanism exists to discontinue future use of these codes. However, because products may exist in inventories across the world, the codes must be retained in the database for backward compatibility. The "RETIREDATE" column of the Product Description Codes table of the ISBT 128 Product Description Code Database (ISBT 128 PDC Database) indicates the date on which ICCBBA recommended the codes no longer be used for new products. Software should be written to recognize these codes but not assign them to newly created products. It is understood that facilities must be given time to retire codes after ICCBBA has made its recommendation.
	Updated versions of the ISBT 128 PDC Database are released ten times per year (\approx on a monthly basis) on the ICCBBA website. Users are advised to visit the website periodically or to sign up for the <u>ICCBBA newsletter</u> to receive notifications regarding ISBT 128 related updates (e.g., updates to databases, publications, etc.).

Example 3.3: Blood: Use of the Division C 7 th and 8 th position of respectively.			e alpha character and numeric character
Example 3.3	Data Identifier	Data Content	Elements
	=<	E2756VA0	Product Description Code (αοοοο) :E2756Type of Collection Code (t) : VDivision Code (ds) : A0
Complete message encode = <e2756va0< td=""><td>d in bar cod</td><td>e:</td><td></td></e2756va0<>	d in bar cod	e:	

 Example 3.4: Blood: Use of the Division Code—second-level divisions. 7th and 8th position of the Product Code is an uppercase alpha character and lowercase alpha character respectively. 			
Example 3.4	Data Identifier	Data Content	Elements
	=<	E0624VBa	Product Description Code (αοοοο) :E0624Type of Collection Code (t) : VDivision Code (ds) : Ba
Complete message encode = <e0624vba< th=""><th>ed in bar cod</th><th>e:</th><th></th></e0624vba<>	ed in bar cod	e:	
Element of Product Code	Consider	rations for Examples	s 3.3 & 3.4
Data Structure (=<αooootds)	Considerations		
Division Code (ds)	If the Product Description Code begins with E , F , X0 , H , S , or P then ds shall specify information as to whether the unit has been divided. Division Codes apply to units made by the division of a single container of a product into two or more parts that are identical—at the time of division— <i>except</i> for volume. Such units have the same Donation Identification Number and may have the same first six data characters of the eight-digit Product Code. The purpose of the seventh and eighth data characters is to provide a mechanism to distinguish each part (division) uniquely for tracking purposes. Note: In the case where the Product Description Code begins with H, S, or P, if the Product Divisions [Data Structure 032] is used, ds shall be set to 99. Software shall require that when a 99 appears in positions 7 and 8 of the Product Code [Data Structure 003], the Product Divisions Data Structure shall be scanned and recorded.		

Example 3.5:

Blood:

- Use of the collection type code (non-default value; uppercase alpha character). Use of a high-value division code (first-level division). •
- •

Example 3.5	Data Identifier	Data Content	Elements
	=<	E0023ST0	Product Description Code (αοοοο) : E0023 Type of Collection Code (t) : S Division Code (ds) : T0
Complete message encoded in bar code: = <e0023st0< th=""></e0023st0<>			

Example 3.6:					
Blood:	• ··· / ··· /				
Use of the collection	Use of the collection type code (numeric character).				
Example 3.6	Data Identifier	Data Content	Elements		
			Product Description Code (αοοοο) : E0098		
	=<	E0098200	Type of Collection Code (t) : 2		
			Division Code (ds) : 00		
Complete message encode = <e0098200< th=""><th>d in bar cod</th><th>e:</th><th></th></e0098200<>	d in bar cod	e:			
Example 3.7: Blood: • Use of the collection	type code (la	wercase alpha charad	cter)		
Example 3.7	Data Identifier	Data Content	Elements		
			Product Description Code (αοοοο) : E0112		
	=<	E0112r00	Type of Collection Code (t) : r		
			Division Code (ds) : 00		
Complete message encode = <e0112r00< td=""><td colspan="4">Complete message encoded in bar code:</td></e0112r00<>	Complete message encoded in bar code:				
		·· · · ·			
Element of Product Code	Conside	rations for Example	s 3.5–3.7		
Data Structure (=<αooootds)	Considerations				
Collection Type Code (t)	If the Product Description Code begins with E , F , X0 , H , S , or P then t (the Collection Type Code [sometimes referred to as the Donation Type Code]) shall specify the type of collection and shall be encoded and interpreted by reference to Table RT008 of the <i>ISBT 128 Standard Technical Specification</i> (ST-001).				
	Collection, processing, and transfusion services often find it useful to be able to distinguish collection types such as "autologous" and "directed" through the Product Code.				
	The use of certain collection type codes may vary from country to country. An accrediting agency (or national authority) may regulate the use of certain collection/donation types. For instance, the US FDA does not allow the use of 0 (zero)—defined as "not specified"—as the collection type code for blood components				

 Example 3.8: Use of an unassigned Product Description Code that begins with two alpha characters. 				
Example 3.8	Data Identifier	Data Content	Elements	
	=<	EA001V00	Product Description Code (αοοοο):EA001Type of Collection Code (t): VDivision Code (ds): 00	
Complete message encoded in bar code: = <ea001v00< td=""></ea001v00<>				
 Example 3.9: Use of a local code: α value of "A" followed by numeric characters. 				
Example 3.9	Data Identifier	Data Content	Elements	
	=<	A0005000	Product Description Code (αοοοο):A0005Type of Collection Code (t): n/a*	
			Division Code (ds): n/a*	

Complete message encoded in bar code: =<A0005000

Example 3.10:

• Use of a national code: α value of "B" followed by an alpha character.

Example 3.10	Data Identifier	Data Content	Elements	
	=<	BA001000	Product Description Code (αοοοο):BA001Type of Collection Code (t): n/a*	
			Division Code (ds): n/a*	
Complete message encoded in bar code: = <ba001000< th=""></ba001000<>				
 Example 3.11: Use of a local code with allowable coding values for "tds". 				
Example 3.11	Data Identifier	Data Content	Elements	
	=<	B23413A0	Product Description Code (αοοοο): B2341 "tds": defined in conjunction with B2341	
Complete message encoded in bar code: = <b23413a0< td=""></b23413a0<>				

Considerations for Example 3.9, 3.10, and 3.11			
Element of Product Code Data Structure (=<αooootds)	Considerations		
Product Description Code (αοοοο)	The block of Product Description Codes (PDCs) beginning with the alpha characters A-D (A0000–D9999 and AAAAA–DZZZZ) shall be reserved for use as nationally-defined or facility-defined Product Description Codes.		
	Note: Certain coding sequences are designated for assignment by a national authority. For example, a code with α equaling A–C followed by one or more alpha characters (e.g., A0ZA3, BA001, CRUA5, etc.) is reserved for national assignment. See section 2.4.3 of the <i>ISBT 128 Standard Technical Specification</i> (ST-001) for information on reserved codes.		
	Local codes should ONLY be used where there is not an appropriate international code and there is good reason why an international code should not be allocated. For example, local/facility codes should be used when a product is only produced in one or a very small number of facilities. If there is any uncertainty whether the code assigned to a product should be an international code versus a nationally- or locally/facility-defined code, the user should contact the ICCBBA office (support@isbt128.org).		
	Where such codes are used, the facility shall ensure that definitions are provided for use within their service region and that products bearing such codes are not transferred outside their normal distribution network. Care shall be taken in interpreting the product description from a local/facility code as this will be specific to the supplier. Software systems reading a national or local/facility code should ensure that they interpret the code taking into account the source country/facility.		
	In all cases, the product definition for nationally defined or facility/locally defined codes shall be retained permanently for traceability purposes. Once assigned, codes shall not be reassigned.		
"tds"	*"tds" is not defined for nationally or facility defined PDCs (i.e., PDCs beginning with A–D). If "tds" is set to something other than 000, it shall be defined in conjunction with the nationally- or locally/facility-defined code assignment.		

Example 3.12: Blood: • Use of an unassigne	d Product De	scription Code that be	gins with three alpha characters.
Example 3.12	Data Identifier	Data Content	Elements
	=<	EAA00V00	Product Description Code (αοοοο): EAA00 Type of Collection Code (t): V Division Code (ds): 00
Complete message encoded in bar code: = <eaa00v00< td=""></eaa00v00<>			

 Example 3.13: Cellular Therapy: Use of the collection type code (numeric character) for Cellular Therapy product. 				
Use of the collection	type code (n	umeric character) for (Cellular Therapy product.	
Example 3.13	Data Identifier	Data Content	Elements	
			Product Description Code (αοοοο): S1224	
	=<	S1224100	Type of Collection Code (t): 1	
			Division Code (ds): 00	
Complete message encode = <s1224100< td=""><td>a in bar cod</td><td>le:</td><td></td></s1224100<>	a in bar cod	le:		
01221100				
Example 3.14:				
Tissue:				
			acks of the product. If multiple	
		hall be set to 000 (thre k sequence. (Undivide	•	
	•	K Sequence. (Onama		
Example 3.14	Data Identifier	Data Content	Elements	
			Product Description Code (αοοοο):	
	=<	T1234000	T1234	
		11234000	Division Pack (tds) : 000	
Complete message encoded in bar code: = <t1234000< td=""></t1234000<>				
Example 3.15:				
Ocular Tissue:				
			acks of the product. If multiple	
 divisions/packs do not exist, tds shall be set to 000 (three zeroes) Use of the three-digit division pack sequence. (Divided) 				
	Data			
Example 3.15	Identifier	Data Content	Elements	
			Product Description Code (αοοοο): V0005	
	=<	V0005002	Division Pack (tds) : 002	
Complete message encoded in bar code:				
= <v005002< td=""></v005002<>				

Non-Compliant Messages – Structural 3.3.2

Example 3.16:					
 Incorrect data identifier 					
Example 3.16	Data Identifier	Data Content			
=? E0150∨00					
Message encoded in bar code: =?E0150V00					
Corrected message for comparison: = <e0150v00< th=""><td></td><td></td></e0150v00<>					
 Considerations: With the exception of Data Structure 001⁷ and non-ICCBBA defined data structures,⁸ the following applies to ISBT 128 data identifiers: Two or three characters long. Begins with either "=" or "&" (ASCII character code 61 and 38 respectively). The second character of an ISBT 128 data identifier is a non-alphanumeric ASCII character. "&," (ASCII character code 38 and 44 respectively) can be the first two characters of a three-character data identifier but never a data identifier on its own. 					
• See Table RT003 of the <i>ISBT 128 S</i> ISBT 128 data structures with their c					

Example 3.17	Data Identifier	Data Content
	=<	E2756
Message encoded in bar code: = <e2756< td=""><td></td><td></td></e2756<>		

⁷ The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content; therefore, the second character of its data identifier can be: A–N, P–Z, or 1–9. ⁸ See Section 2.5 of the ISBT 128 Standard Technical Specification (ST-001) for details on non-ICCBBA

defined data structures.

Example 3.18	Data Identifier	Data Content		
	=<	E0624V000		
Message encoded in bar code: = <e0624v00<mark>0</e0624v00<mark>	1 1			
= <e0624v000 Corrected message for comparison: =<e0624v00< td=""></e0624v00<></e0624v000 				

Example 3.19:					
Blood:					
 Unallowable coding value used in the 8th position of the data content string ("s" of "αooootds") 					
Example 3.19 Data Identifier Data Content					
Example 3.19	Data identinei	Data Content			
	=<	E2121VBA			
	- 1	LZIZIVDA			
Message encoded in bar code:					
= <e2121vba< td=""><td></td><td></td></e2121vba<>					
Corrected message for comparise	on:				
= <e2121vba< td=""><td></td><td></td></e2121vba<>					
Considerations:					
The 8 th position of a Data S	tructure 003 data co	ontent string may be any character in the set {a-z;			
•		show only one of any one dotter in the set (a-z,			
0-9}.					

3.3.3 Non-Compliant Messages – Invalid Data:

Example 3.20:

- Blood:
 - Use of an undefined coding value in the 6th position of the data content string ("t" of "αooootds").

Example 3.20	Data Identifier	Data Content
	=<	E2121Z00
Message encoded in bar code: = <e2121z00< th=""><th></th><th></th></e2121z00<>		
Corrected message for compariso = <e2121v00< th=""><th>on:</th><th></th></e2121v00<>	on:	

Considerations:

 While "Z" is a structurally compliant coding value, it does not exist in the "Type of Collection in 6th Position of Product Code" table [RT008] (a bounded list).

3.3.4 Non-Compliant Messages – Contextual Inconsistency:

Example 3.21	Data Identifier	Data Content
	=<	E2528V99
Message encoded in bar code: = <e2528v99< td=""><td></td><td></td></e2528v99<>		
Corrected message for comparis = <e2528vz0< td=""><td>on:</td><td></td></e2528vz0<>	on:	

3.4 Expiration Date and Time [Data Structure 005]

Purpose: Data Structure 005 shall indicate the date and time of when the product expires.

Structure: &>cyyjjjhhmm

Element	Length	Туре
&	1	data identifier, first character
>	1	data identifier, second character
с	1	numeric {0–9}
уу	2	numeric {0–9}
jjj	3	numeric {0–9}
hh	2	numeric {0–9}
mm	2	numeric {0–9}

Table 4: Data Structure 005 Coding Values

For more information on Data Structure 005, see **section 2.4.5** of the *ISBT 128 Standard Technical Specification* (ST-001).

Considerations for Data Structure 005:

- "jjj" (of "cyyjjjhhmm") shall specify the *ordinal (Julian) date* on which the product expires.
- A day shall be defined as beginning at midnight (00:00) and ending at 23:59. When a time is not specified, the default of "2359" shall be encoded in the data structure.

3.4.1 Valid Messages – Data Structure 005

Example 4.1:		
Use of a leap year.		
 Use of the default value for time. 		
Example 4.1:	Data Identifier	Data Content
	&>	0163662359
Complete message encoded in bar code:		
&>0163662359		
 Example 4.2: Use of a non-leap year. Use of a specified time. 		
Example 4.2:	Data Identifier	Data Content
	&>	0172221230
Complete message encoded in bar code: &>0172221230		
 Example 4.3: Use of a non-leap year. Use of a specified time. 		
Example 4.3:	Data Identifier	Data Content
	&>	0180790001
Complete message encoded in bar code: &>0180790001		

3.4.2 Non-Compliant Messages – Structural

			1	
Example 4.4	Da	ta Identifier	Data Content	
&? 0160602359				
Message encoded in bar code: ?0160602359 Corrected message for comparison):			
>0160602359	Considera			
character.	data identifiers: ers long. or "&" (ASCII cha r of an ISBT 128 d	racter code 61 and lata identifier is a r respectively) can b	d 38 respectively). non-alphanumeric ASCII ne the first two characters of a	
 See Table RT003 of the ISB7 ISBT 128 data structures with 				
Example 4.5:				
Incorrect data content length.				
Example 4.5	Data Identifier		Data Content	

&>

Corrected message for comparison:

Message encoded in bar code:

&>016158

&>0161582359

016158

⁹ The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content; therefore, the second character of its data identifier can be: A–N, P–Z, or 1–9.

¹⁰ See Section 2.5 of the ISBT 128 Standard Technical Specification (ST-001) for details on non-ICCBBA defined data structures.

		Example 4.6 Data Identifian Data Contant					
Example 4.6	Data Identifier	Data Content					
&> 01725723590							
Message encoded in bar code: &>0172572359 <mark>0</mark>							
Corrected message for comparison: &>0172572359							
Considerations: • The Data Structure 005 da	ta content must be te	n characters long.					
Example 4.7:		n characters long. position of the data content string.					
The Data Structure 005 da Example 4.7:							
 The Data Structure 005 da Example 4.7: Unallowable coding value 	used in the 1 st and 8 ^t	position of the data content string.					

Considerations:

• The Data Structure 005 data content must be comprised of numeric characters only.

3.5 Special Testing: General [Data Structure 010]

Purpose: Data Structure 010 shall indicate special characteristics of a product such as whether it has been phenotyped, the presence of antibodies, CMV antibody status, Hemoglobin S status, etc.

Structure: &(zzzz

Element	Length	Туре
&	1	data identifier, first character
(1	data identifier, second character
ZZZZZ	5	alphanumeric {A–Z; 0–9}

Table 5: Data Structure 010 Coding Values

Considerations for Data Structure 010:

 The five (5)-character data content string, zzzzz, shall be encoded and interpreted by reference to the ICCBBA-maintained Special Testing General database which can be found on the ICCBBA website: <u>https://isbt128.org/mdatabases-ref-tables</u>.*

*See **section 5.2** of the ISBT 128 Standard Technical Specification (*ST-001*) for additional information on the Special Testing General database [*RT029*].

• To serve as an example, the following is an entry from the Special Testing General database:

Figure 4: Excerpt of Special Testing: General [RT029]

	Codes				
NCODE	INTERPRETATION	RETIREDATE	DEFINITION		
N0008	CMV seronegative				

3.5.1 Valid Messages – Data Structure 010

Examples 5.1 through 5.4:

• The following data content can be interpreted by reference to the "Special Testing: General" table [RT029] found on the <u>ICCBBA website.</u>

Example 5.1:	Data Identifier	Data Content
	&(N0000
Complete message encoded in bar code: &(N0000		
Example 5.2:	Data Identifier	Data Content
	&(N0008
Complete message encoded in bar code: &(N0008		
Example 5.3:	Data Identifier	Data Content
Example 5.3:	Data Identifier &(Data Content N0026
Complete message encoded in bar code:		
Complete message encoded in bar code: &(N0026	&(N0026

3.5.2 Non-Compliant Messages – Structural

	Data Identifier	Data Content
	&?	N0008
Message encoded in bar code &?N0008		
Corrected message for compa &(N0008	arison:	
	aracters long. er "=" or "&" (ASCII character o aracter of an ISBT 128 data ide	code 61 and 38 respectively). ntifier is a non-alphanumeric ASCII ively) can be the first two characters of a

Example 5.6	Data Identifier	Data Content	
	&(N009	
Message encoded in bar code: &(N009_			
Corrected message for comparison: &(N0009			
Example 5.7:			
Incorrect data content leng	th.		

¹¹ The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content; therefore, the second character of its data identifier can be: A–N, P–Z, or 1–9.

¹² See Section 2.5 of the ISBT 128 Standard Technical Specification (ST-001) for details on non-ICCBBA defined data structures.

Example 5.7	Data Identifier	Data Content
	&(N00008
Message encoded in bar code: &(N00008	1 1	
Corrected message for compariso & (N0008	on:	
Considerations: • The Data Structure 010 data	a content must be five	e characters long.

Example 5.8	Data Identifier	Data Content
	&(No009
Message encoded in bar code: &(N <mark>o</mark> 009	1	
Corrected message for comparise &(N0009	on:	

47

3.6 Special Testing: Red Blood Cell Antigens – General [Data Structure 012]

Purpose: Data Structure 012 shall provide information regarding red blood cell phenotypes,* CMV antibody, IgA, Parvovirus B19, Hemoglobin S, and/or a nationally specified characteristic of the product.

*Phenotype: The observable expression of the genes inherited by a person that reflects the biological activity of the genes. In ISBT 128 coding of test results, the term phenotype includes predicted phenotypes based on genotyping where there is evidence in the literature to support such a prediction.

Structure: =\aaaaaaaaaaaaaaaaii

Element	Length	Туре
=	1	data identifier, first character
١	1	data identifier, second character
aaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaaa	16	numeric {0–9}
ii	2	numeric {0–9}

Table 6: Data Structure 012 Coding Values

For more information on Data Structure 012, see **section 2.4.12** of the *ISBT 128 Standard Technical Specification* (ST-001).

Considerations for Data Structure 012:

- The eighteen (18)-character data content string, **aaaaaaaaaaaaaaaaaaaii**, shall be encoded and interpreted by reference to the following tables in the *ISBT 128 Standard Technical Specification* (ST-001):
- "Special Testing: Red Blood Cell Antigens General, Positions 1 through 9" [RT009]—this includes the coding values for positions 10 through 16 as well.**

Common Rh antigens may be encoded together as a phenotype (Rh column 1 [for position 1 of the data content]) or as individual Rh antigens (C,c,E,e, columns 14–16 [for positions 14–16 of the data content]). If Rh antigens are encoded individually using positions 14, 15, and/or 16, then the value of column one shall be set to 9 (no information). Conversely, if the phenotype is present in column 1, then the values of the C,c,E,e antigens shall all be set to 9, ni (no information). For examples, see **section 9.1 of the ISBT 128 Standard Technical Specification (ST-001).

 "Special Testing: Red Blood Cell Antigens — General, Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested for and Found Negative" [RT011].*** ***If there are Red Blood Cell antigens test results that cannot be encoded using RT009 or RT011, positions 17 and 18 of the data content string may be set to 00 [interpreted as "information elsewhere" in RT011]. Alternatively, red cell antigens not found on these tables may be encoded using the Red Cell Antigens with Test History [Data Structure 030].

3.6.1 Valid Messages – Data Structure 012:

 Examples 6.1 through 6.3: The following data content can be inf ISBT 128 Standard Technical Specification 		09 and RT011 found in the
Example 6.1:	Data Identifier	Data Content
	=/	979999999999924799
Complete message encoded in bar code: =\9799999999999924799		
Example 6.2:	Data Identifier	Data Content
	=/	67999999999999999996
Complete message encoded in bar code: =\6799999999999999999		
	l .	
Example 6.3:	Data Identifier	Data Content
	=/	88000008700000100
Complete message encoded in bar code: =\880000008700000100		

3.6.2 Non-Compliant Messages – Structural

Example 6.4	Data Identifier	Data Content
	=?	979999999999924799
Message encoded in bar code: =?9799999999999924799	1	
Corrected message for comparison: =\97999999999999924799		
5	lentifiers:	d 38 respectively).

Example 6.5	Data Identifier	Data Content
	=\	9799999999999247
Message encoded in bar code: =\97999999999999247		1
Corrected message for comparison: =\9799999999999924799		
Example 6.6:		

¹³ The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content; therefore, the second character of its data identifier can be: A–N, P–Z, or 1–9.

¹⁴ See Section 2.5 of the ISBT 128 Standard Technical Specification (ST-001) for details on non-ICCBBA defined data structures.

Example 6.6	Data Identifier	Data Content
	=\	9799999999999247999
Message encoded in bar code: =\97999999999999247999		
Corrected message for comparison: =\9799999999999924799		
 Considerations: The data content string of Data Struct 	ture 012 is eighteen charac	ters long.

Example 6.7	Data Identifier	Data Content
	=\	B799999999999924799
Message encoded in bar code: =\B7999999999999924799		
Corrected message for comparison: =\97999999999999924799		

3.6.3 Non-Compliant Messages – Contextual Inconsistency

Example 6.8	Data Identifier	Data Content
	=\	679999999999924799
Message encoded in bar code: =\ <mark>6</mark> 799999999999992 <mark>47</mark> 99		
Corrected messages for comparison: =\9799999999999924799		

 Example 6.9: The same antigen results are encoded twice, and the results are conflicting. 		
Example 6.9	Data Identifier	Data Content
	=\	679999999999914799
Message encoded in bar code: =\67999999999999914799		
Corrected messages for comparison: =\97999999999999924799		
=\67999999999999999999999999999999999999		
 If Rh antigens are encoded individ of column one [first position of the Conversely, if the phenotype is pre- string], then the values of the C,c,l The decoded "corrected messages interpretation: C+c-E-e+, K+k-, no 	data content string] shal esent in column one [first E,e antigens shall all be s s for comparison" (above	l be set to 9 (no information). position of the data content set to 9, ni (no information).

3.7 Special Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]

Purpose: Data Structure 014 shall provide information regarding HLA and HPA phenotypes, CMV antibody, IgA status, and anti-A and -B for platelet products. If genomic typing is used, only the first two digits of the type shall be encoded.

Structure: &{AAAABBBBBCCCCCCCDE

Element	Length	Туре
&	1	data identifier, first character
{	1	data identifier, second character
AAAA	4	numeric {0–9}
BBBB	4	numeric {0–9}
000000000000000000000000000000000000000	8	numeric {0–9}
D	1	numeric {0–9}
E	1	numeric {0–9}

Table 7: Data Structure 014 Coding Values

For more information on Data Structure 014, see **section 2.4.14** of the *ISBT 128 Standard Technical Specification* (ST-001).

Considerations for Data Structure 014:

- The eighteen (18)-character data content string, **AAAABBBBCCCCCCCDE**, shall be encoded and interpreted by reference to the following tables in the *ISBT 128 Standard Technical Specification* (ST-001):
 - For AAAA and BBBB of the data content string, the coding values from the "Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 1 through 8" table [RT013] will be used to specify HLA-A antigens and HLA-B antigens respectively.*

*Two AA values shall be encoded first in ascending order. This would then be followed by two BB values in ascending order. For examples, see section 9.2 of the ISBT 128 Standard Technical Specification (*ST*-001).

 For CCCCCCC of the data content string, the coding values from the "Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 9 through 16" table [RT014] will be used to specify platelet-specific antigens, IgA antigen and CMV antibody status.

- \circ **D** of the data content string is reserved for future use and should be encoded with a 0 (zero) at the current time.
- For E of the data content string, the coding values from the "Special Testing: Platelet HLA and Platelet Specific Antigens, Position 18" table [RT044] will be used to specify information about high titered antibodies to A and B antigens.

3.7.1 Valid Messages – Data Structure 014:

	13, RT014, and RT044 found in
Data Identifier	Data Content
&{	0299079999999999900
Data Identifier	Data Content
&{	0202070799999999900
Data Identifier	Data Content
&{	0224082799999999900
	Data Identifier &{ Data Identifier &{ Data Identifier &{

Example 7.4:	Data Identifier	Data Content
	&{	999999993999999900
Complete message encoded in bar code: &{999999999399999900		
Example 7.5:	Data Identifier	Data Content
	&{	9999999999999999400
Complete message encoded in bar code: &{99999999999999999400		
Example 7.6:	Data Identifier	Data Content
Example 7.6:	Data Identifier &{	Data Content 029907999999999901
Complete message encoded in bar code:		
Complete message encoded in bar code: &{029907999999999901	&{	0299079999999999901

3.7.2 Non-Compliant Messages – Structural

	Data Identifier	Data Content
	&?	0299079999999999900
essage encoded in bar code: 2029907999999999900	1	
orrected message for comparison: 029907999999999900		
 The second character of an character. "&," (ASCII character code) 	(ASCII character code 61 ar ISBT 128 data identifier is a 38 and 44 respectively) can l er but never a data identifier	non-alphanumeric ASCII be the first two characters of a on its own. <i>tion</i> (ST-001) for an index of

Example 7.9	Data Identifier	Data Content
	&{	0224082799999999
Message encoded in bar code: &{02240827999999999		
Corrected message for comparison: &{022408279999999900		

¹⁵ The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content; therefore, the second character of its data identifier can be: A–N, P–Z, or 1–9.

¹⁶ See Section 2.5 of the ISBT 128 Standard Technical Specification (ST-001) for details on non-ICCBBA defined data structures.

Example 7.10	Data Identifier	Data Content
	&{	9999999999999999994000
Message encoded in bar code: &{999999999999999994000		
Corrected message for comparison:		
&{999999999999999400		

Example 7.11	Data Identifier	Data Content
	&{	0299O799999999990L
Message encoded in bar code: &{0299 <mark>0</mark> 7999999999990L		
Corrected message for comparison: &{0299079999999999901		

3.7.3 Non-Compliant Messages – Invalid Data

Example 7.12:

• Use of undefined coding value in 3rd and 4th character of the data content string (undefined value of AA).

Example 7.12	Data Identifier	Data Content
	&{	0204079999999999900
Message encoded in bar code: &{02 <mark>04</mark> 07999999999900		
Corrected message for comparison: &{029907999999999900		

Considerations:

• While "04" is structurally compliant, it does not exist in the "Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 1 through 8" table [RT013] (a bounded list).

Example 7.13:

• Use of unapproved coding value in the undefined position of the data content string.

Example 7.13	Data Identifier	Data Content
	&{	0202070799999999990
Message encoded in bar code:		
&{0202070799999999 <mark>9</mark> 0		
Corrected message for comparison:		

&{0202070799999999900

Considerations:

• While "9" is an allowable coding value, the 17th position of the Data Structure 014 data content ("D" of "AAAABBBBCCCCCCCDE") has been reserved for future use. The value of "D" shall be set to 0 (zero).

Example 7.14:

• Use of a coding value reserved for future assignment.

Example 7.14	Data Identifier	Data Content
	&{	0224082799999999903
Message encoded in bar code: &{022408279999999903		
Corrected message for comparison: &{022408279999999900		
Considerations:		

• While "3" is structurally compliant, Table RT044 (a bounded list) specifies that values "2" through "8" are reserved for future assignment.

3.7.4 Non-Compliant Messages – Contextual Inconsistency

Example 7.15	Data Identifier	Data Content
	&{	240227089999999900
Message encoded in bar code: &{ <mark>24022708</mark> 9999999900		
Corrected message for comparison: &{ <mark>02240827</mark> 9999999900		
 Considerations: While "24" and "02" are allowable codi listed in ascending order. While "27" and "08" are allowable codi listed in ascending order. 	U	•

3.8 Compound Message [Data Structure 023]

Purpose: Data Structure 023 shall allow multiple data structures to be combined into a single data string to facilitate use of newer technology delivery systems.

Structure: =+aabbb

Element	Length	Туре
=	1	data identifier, first character
+	1	data identifier, second character
аа	2	numeric {0–9}
bbb	3	numeric {0–9}

Table 8: Data Structure 023 Coding Values

For more information on Data Structure 023, including the rules for constructing compound messages, see **section 2.4.23** of the *ISBT 128 Standard Technical Specification* (ST-001).

Considerations for Data Structure 023:

- The five (5)-character data content string, **aabbb**, shall be encoded and interpreted as follows:
 - o **aa** shall specify the number of ISBT 128 data structures that follow;
 - **bbb** shall be either:
 - all zeroes indicating this is an undefined message, i.e., only the number of data structures is identified, but not what each one is or the order in which they occur
 - a three-digit number referencing the ICCBBA-Specified Compound Messages table [RT017] found on the ICCBBA website: <u>https://www.isbt128.org/p-databases-ref-tables</u>

Note: Because of the complexity created by multiple product categories and the many codes that would result from permutations of order of data structures, ICCBBA now encourages the use of undefined messages.

• Reading software should be able to interpret both unspecified sequence and specified sequence compound messages. The software should always verify the integrity of the data string, including checking that the correct number of data structures appears and, when specified sequence messages are used, that the sequence of data structures is correct. Data should only be interpreted if the integrity of the relevant data structures has been confirmed.

Additional References:

• Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)

3.8.1 Valid Messages – Data Structure 023

Example 8.1:	Data Identifier	Data Content		
	=+	03000=W00001712345600= <e0150v00&*0170612359< td=""></e0150v00&*0170612359<>		
Complete message encoded in bar code: =+03000=W00001712345600= <e0150v00&*0170612359< td=""></e0150v00&*0170612359<>				
Example 8.2:	Data Identifier	Data Content		
	=+	03000=W00001712345600=%5100= <e3046v00< td=""></e3046v00<>		
	encoded in bar c 12345600=%5100=			
Example 8.3:	Data Identifier	Data Content		
	=+	05000=A99991700007800=%9500&>0172002359= <e0311v00 =\9799999999999924799</e0311v00 		
Complete message	encoded in bar c 00007800=%9500&	ode: >0172002359= <e0311v00=\979999999999924799< td=""></e0311v00=\979999999999924799<>		
=+05000=A9999170				
=+05000=A9999170				
=+05000=A999917(Example 8.4:	Data Identifier	Data Content		
	Data Identifier =+	Data Content 05000=A99991700000501=%5100= <e2756va0&>0171552359 &(N0008</e2756va0&>		

	 Examples 8.5 and 8.6: The following are examples of ICCBBA-specified compound messages. 				
Example 8.5:	Data Identifier	Data Content			
	=+	04003=A99991756321300=%9500= <e2121v00&>0172221230</e2121v00&>			
	Complete message encoded in bar code: =+04003=A99991756321300=%9500= <e2121v00&>0172221230</e2121v00&>				
Example 8.6:	Data Identifier	Data Content			
	=+	05009=A99991700000501=%5100= <e2756va0&>0171552359 &(N0008</e2756va0&>			
Complete message =+05009=A99991700		ode: <e2756va0&>0171552359&(N0008</e2756va0&>			
Example 8.7:	Example 8.7: Data Identifier Data Content				
	=+ 04000=A99962312345600=<\$1303100&>0231501216&/CHA99 9922123456				
Complete message encoded in bar code: =+04000=A99962312345600= <s1303100&>0231501216&/CHA999922123456</s1303100&>					
		und Messages table [RT017] (found on the <u>ICCBBA website</u>) ata structures for a given ICCBBA-specified compound message.			
Note: Because of the complexity created by multiple product categories and the many codes that would result from permutations of order of data structures, ICCBBA now encourages the use of undefined messages.					

3.8.2 Non-Compliant Messages – Structural

Example 8.8	Data Identifier	Data Content	
=? 04000=A99991756321300=%9500= <e2121v00&>017222123</e2121v00&>			
Message encoded =?04000=A9999175		<e2121v00&>0172221230</e2121v00&>	
Corrected message	e for comparison		
		-E0404)/008> 0470004000	
		<e2121v00&>0172221230</e2121v00&>	
=+04000=A9999175		<e2121v00&>0172221230</e2121v00&>	
=+04000=A9999175 Considerations: • With the exc	56321300=%9500= ception of Data Stru	icture 001 ¹⁷ and non-ICCBBA defined data structures, ¹⁸ the	
=+04000=A9999175 Considerations: • With the exc following ap	56321300=%9500= ception of Data Stru pplies to ISBT 128 d	icture 001 ¹⁷ and non-ICCBBA defined data structures, ¹⁸ the ata identifiers:	
-+04000=A9999175 Considerations: • With the exc following ap • Two	56321300=%9500= ception of Data Stru pplies to ISBT 128 d o or three character	icture 001 ¹⁷ and non-ICCBBA defined data structures, ¹⁸ the ata identifiers: s long.	
=+04000=A9999175 Considerations: • With the exc following ap • Two • Beg	56321300=%9500= ception of Data Stru pplies to ISBT 128 d o or three character gins with either "=" o	icture 001 ¹⁷ and non-ICCBBA defined data structures, ¹⁸ the ata identifiers: s long. or "&" (ASCII character code 61 and 38 respectively).	
=+04000=A9999175 Considerations: • With the exc following ap • Two • Beg • The	ception of Data Stru pplies to ISBT 128 d o or three character gins with either "=" o e second character o	icture 001 ¹⁷ and non-ICCBBA defined data structures, ¹⁸ the ata identifiers: s long.	
=+04000=A9999175 Considerations: • With the exc following ap • Two • Beg • The cha	ception of Data Stru pplies to ISBT 128 d o or three character gins with either "=" o e second character o racter.	icture 001 ¹⁷ and non-ICCBBA defined data structures, ¹⁸ the ata identifiers: s long. or "&" (ASCII character code 61 and 38 respectively).	

=+ 0300=W00001712345600= <e0150v00&*0170612359< td=""> Message encoded in bar code: =+0300_=W00001712345600=<e0150v00&*0170612359< td=""> Corrected message for comparison: =+03000=W00001712345600=<e0150v00&*0170612359< td=""></e0150v00&*0170612359<></e0150v00&*0170612359<></e0150v00&*0170612359<>	Message encoded in t	=+	0300=W00001712345600= <e0150v00&*0170612359< th=""></e0150v00&*0170612359<>				
=+0300_=W00001712345600= <e0150v00&*0170612359 Corrected message for comparison:</e0150v00&*0170612359 	Message encoded in b		=+ 0300=W00001712345600= <e0150v00&*0170612359< td=""></e0150v00&*0170612359<>				
Corrected message for comparison:	•						
=+03000=W00001712345600= <e0150v00&*0170612359< td=""><td colspan="4"></td></e0150v00&*0170612359<>							
	=+03000=W00001712345600= <e0150v00&*0170612359< td=""></e0150v00&*0170612359<>						
	Example 8.10:Incorrect data data data	content length					

¹⁷ The Donation Identification Number (DIN) [Data Structure 001] is the only ISBT 128 Data Structure in which the second character of the data identifier is part of the data content; therefore, the second character of its data identifier can be: A–N, P–Z, or 1–9.

¹⁸ See Section 2.5 of the ISBT 128 Standard Technical Specification (ST-001) for details on non-ICCBBA defined data structures.

Example 8.10	Data Identifier Data Content		
	=+	050000=A99991700000500=%5100= <e2756va0&>017155235 9&(N0008</e2756va0&>	
Message encoded in =+050000=A9999170		= <e2756va0&>0171552359&(N0008</e2756va0&>	
Corrected message for comparison:			
		<e2756va0&>0171552359&(N0008</e2756va0&>	
Considerations:			
 The Data Structure 023 data content must be five characters long. 			

Example 8.11	Data Identifier Data Content			
=+ o5000=A99991700007800=%9500&>0172002359= <e0311v00 =\97999999999999924799</e0311v00 				
Message encoded in bar code:				
=+05000=A9999170	0007800=%9500&	>0172002359= <e0311v00=\979999999999924799< td=""></e0311v00=\979999999999924799<>		
Corrected message	e for comparison:			
=+05000=A99991700007800=%9500&>0172002359= <e0311v00=\97999999999999924799< td=""></e0311v00=\97999999999999924799<>				
		>0172002359= <e0311v00=\979999999999924799< td=""></e0311v00=\979999999999924799<>		

3.8.3 Non-Compliant Messages – Contextual Inconsistency

Example 8.12:

• The data structures of the ICCBBA-specified compound message are out of sequence.

Example 8.12	8.12 Data Identifier Data Content			
=+ 04003=A99991756321300= <e2121v00&>0172221230=%9500</e2121v00&>				
Message encoded i =+04003=A9999175		/00&>0172221230=%9500		
Corrected message =+04003=A9999175		<e2121v00&>0172221230</e2121v00&>		
=+04003=A9999175 Considerations:	6321300=%9500=	<e2121v00&>0172221230</e2121v00&>		
For ICCBBA	•	nd messages, the order of the data structures shall be that showr ound Messages table [RT017] for the reference number selected		

Examples 8.13 and 8.14:

• The number of data structures that follow the Compound Message [Data Structure 023] in the data string is inconsistent with the number of data structures specified in the Compound Message [Data Structure 023].

Example 8.13	Data Identifier	Data Content		
=+ 04000=A99991742565600=%5100= <e3046v00< td=""></e3046v00<>				
Message encoded in bar code: =+04000=A99991742565600=%5100= <e3046v00< td=""></e3046v00<>				
Corrected message for comparison: =+03000=A99991742565600=%5100= <e3046v00< td=""></e3046v00<>				
Example 8.14 Data Identifier Data Content				
	=+	03000=A99971756321300=%9500= <e2121v00&>0172221230</e2121v00&>		
Message encoded in bar code: =+03000=A99971756321300=%9500= <e2121v00&>0172221230</e2121v00&>				
Corrected message for comparison: =+04000=A99971756321300=%9500= <e2121v00&>0172221230</e2121v00&>				
 Considerations: The first two characters of the Compound Message [Data Structure 023] data content shall specify the number of ISBT 128 data structures that follow. 				

3.9 Chain of Identity Identifier [Data Structure 040]

Purpose: Data Structure 040 shall specify an ISBT 128 Col Identifier.

Structure: &/CHappppyynnnnn

Element	Length	Туре
&/	2	data identifiers
CH	2	literal "CH"
α	1	Alphanumeric {A-N; P-Z; 1-9}
рррр	4	First two characters alphanumeric {A–N; P–Z; 0–9}; second two characters numeric {0–9}. pppp 4 Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future (e.g., if α = A and pppp = BC12, the α pppp will be ABC12).
уу	2	numeric {0-9}
nnnnn	6	Alphanumeric {A-Z; 0-9}

For more information on Data Structure 040 see, **section 2.4.40** of the ISBT 128 Standard Technical Specification (ST-001).

Considerations for Data Structure 040:

- The fixed characters "CH" within the string are used to visually distinguish the Col from the DIN.
- The five-character Facility Identification Number identifies the Issuing Organization
- The two-digit year indicator is the nominal year of issue
- The six-character alphanumeric sequence number is assigned by the Issuing Organization

Additional References:

• ISBT 128 Standard Chain of Identity (Col) Identifier (ST-028)

3.9.1 Valid Messages – Data Structure 040

Example 9.1Use of upper-case alphanumeric characteristic	Example 9.1 Use of upper-case alphanumeric characters in the sequence number portion.				
Example 9.1	Data Identifier	Data Content			
	&/	CHA999923ABC999			
Complete message encoded in bar code: &/CHA999923ABC999					

Example 9.2 Use of numeric characters in the sequence number portion.				
Example 9.2	Data Identifier	Data Content		
	&/	&/CHA999923123456		
Complete message encoded in bar code: &/CHA999923123456				
Example 9.3 Use of all upper-case characters in the 	ne sequence number portion.			
Example 9.3	Data Identifier	Data Content		
	&/	CHA999923ABCXYZ		
Complete message encoded in bar code: &/CHA999923ABCXYZ		L		

3.9.2 Non-Compliant Messages – Invalid Data

Example 9.4	Data Identifier	Data Content
	&/	CHA999923abc123
Message encoded in bar code: A/CHA999923abc123		I
Corrected message for comparison: &/CHA999923ABC123		

case alpha characters are not allowed.

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