



IMPLEMENTATION GUIDE

Use of Data Matrix Symbols with ISBT 128

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1 Introduction

1.1 Purpose

The purpose of this document is to assist users and software developers to implement Data Matrix two-dimensional (2-D) symbology for delivery of ISBT 128 data structures for blood, cellular therapy, and tissue labeling as well as for patient wristbands. Labeling includes affixed, attached, and accompanying labeling.

1.2 Scope

This document provides background information and examples of the use of Data Matrix with ISBT 128 data structures. It provides supplementary information only and is therefore intended to be used in conjunction with the *ISBT 128 Standard Technical Specification*.

1.3 Intended Audience

This document is intended for staff (management, laboratory, quality, and information technology) of facilities using ISBT 128, software developers, and manufacturers of labels for blood, cellular therapy, and tissue products.

1.4 Normative References

ISBT 128 Standard Technical Specification

ISO/IEC 16022:2006(E): Information technology—International symbology specification—Data Matrix

ISO/IEC 15415:2204 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

Knels R, Davis R, Ashford P, et al: Guidelines for the use of RFID technology in transfusion medicine. *Vox Sang* 2010; 98(s2):1-24.

1.5 Other References

Palmer, RC. The bar code book. Victoria: Trafford Publishing, 2007.

Technical Bulletin 10: Valid and Invalid Bar Codes for Use in ISBT 128 Validations, 2009.

1.6 Background

Code 128 symbology for linear bar codes was selected as the delivery mechanism for ISBT 128 in 1989 because it offered a variety of desirable features including: it was alphanumeric; it was widely supported; and it provided high density, flexibility, and high

data security. As the use of ISBT 128 expanded to patient wristbands, tissues, and cellular therapy products, and as the amount of information to be conveyed increased, it became necessary to evaluate delivery mechanisms that allowed more information to be encoded in a smaller space. Both two-dimensional (2-D) symbols and Radio Frequency Identification (RFID) tags offered this capacity.

Information about the use of RFID is out of the scope of this document. Further information may be found in:

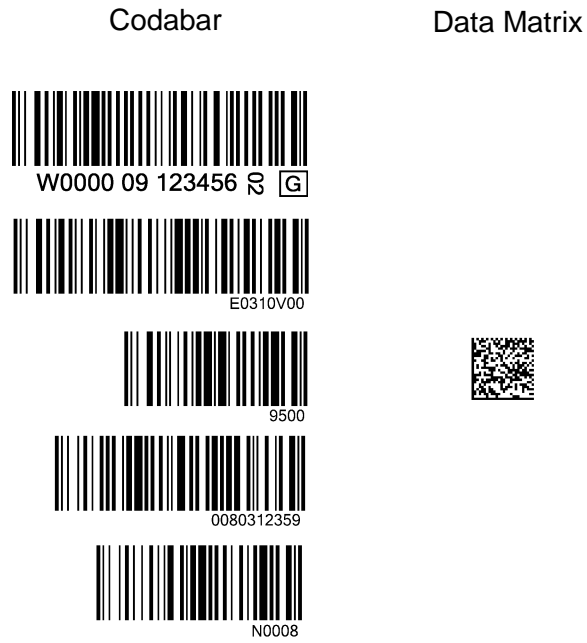
Knels R, Davis R, Ashford P, et al: Guidelines for the use of RFID technology in transfusion medicine. *Vox Sang* 2010; 98(s2):1-24.

There are a number of 2-D symbologies available. Requirements for the selection of a 2-D symbology for ISBT 128 included:

- It had to be capable of encoding up to 150 characters.
- It had to support the full set of characters supported by Code 128 (full US ASCII character set).
- The symbol had to fit on a space of 13 mm x 13 mm. (It was accepted that 2D bar codes may not meet the requirements of small containers with even less space.)
- Reed-Solomon error-checking (or equivalent) mechanism had to be supported.
- Reading technology (scanners) had to be:
 - Cost-effective
 - Commonly available
 - Available as both handheld devices and fixed devices (found on automated testing equipment)
 - Able to read both the selected 2-D bar code and Code 128
- It could be printed using commonly available printers.
- The labels had to be readable on a variety of “challenging” surfaces:
 - Curved surfaces, such as a cylindrical vial 13 mm in diameter
 - Irregular surfaces (e.g., frozen product bag)
 - Wet or frosty surfaces (e.g., frozen product bag)

After a careful analysis, Data Matrix (ECC 200) was chosen as the required 2-D symbol for ISBT 128 label applications for blood, tissue, or cellular therapy. It is also recommended for non-label applications. Data Matrix was selected because it best met the criteria listed, especially the criterion of density. A 10 mm square Data Matrix symbol can encode as much information as five linear bar codes (see Figure 1, Page 8).

Figure 1 Comparison of the Size of Data Matrix and Code 128 Symbols



2 Use of Data Matrix with ISBT 128

2.1 Specifications for the Use of Data Matrix with ISBT 128

2.1.1 General Requirements

Data Matrix (ECC 200) shall be used as the 2-D symbology for ISBT 128 labels. The ISO/IEC 16022 Information technology—International symbology specification—Data Matrix shall be followed.

For applications of ISBT 128 other than labels Data Matrix is recommended.

2.1.2 Symbol Quality

As described in ISO/IEC 15415, print quality shall be 1.5/6/670 where 1.5 is the overall quality, 6 is the measuring aperture reference number (corresponding to a 0.15 mm diameter aperture) and 670 is the peak response wave length in nanometers. A 1.5 corresponds to a C grade in ANSI standard X3.182 – 1990.

2.1.3 Symbol Dimensions

X dimension: As large an X dimension as practical should be used, with a minimum nominal X dimension of 0.25 mm and a maximum nominal X dimension of 1 mm.

Finder pattern: The width of the finder pattern shall equal X.

Alignment pattern: The width of the alignment pattern shall equal 2X.

Quiet zone: The minimum quiet zone is equal to X on all four sides. For applications with moderate to excessive reflected noise in close proximity to the symbol, a quiet zone of 2X to 4X is recommended.

2.2 Scanners

Data Matrix symbols must be read using an imaging scanner. These scanners create an image of the symbol and then decode the message from the image. While all imaging scanners can also read linear bar codes, the reverse is not true. That is, not all scanners that can read linear bar codes can read 2-D bar codes. Therefore, facilities may have to invest in new scanners in order to read Data Matrix symbols.

2.3 Encoding Information

Because Data Matrix allows up to 2335 alphanumeric characters or 3116 numeric characters to be encoded, information from multiple data structures can be encoded into a single symbol. This is accomplished through the use of the Compound Message Data Structure [023]. Details for use of this structure may be found in the *ISBT 128 Standard Technical Specification*. Its structure is:

=+aabb

Where:

=+ is the data identifier

aa is the number of ISBT 128 data structures that follow;

bbb is either:

- a three digit number referencing an entry in an ICCBBA maintained table that defines the content of this structured compound message (see *ISBT 128 Standard Technical Specification*).
- all zeros – indicating this is an undefined message, i.e. only the number of data structures is identified, but not what each one is;

Messages shall be constructed by combining ISBT 128 data structures sequentially with no intervening characters. Any ICCBBA-defined data structure (but not nationally or locally defined data structures) may be included.

ICCBBA structured compound messages are defined in Table W2, Structured Compound Messages (RT017) found on the ICCBBA Website. Requests for additional entries should be submitted to the ICCBBA office (tech.director@iccbba.org).

Unstructured messages should ONLY be used where there is not an appropriate structured message and there is good reason why a structured message should not be created. Unstructured messages should be used when a message structure is needed only temporarily (will only be used once or a few times). If there is any uncertainty whether a structured message should be created, the user should contact the ICCBBA office.

For example:

A compound message using defined structured message 003 from Table RT017 [Donation Identification Number [001], Blood Group [002], Product Code [003], and Expiration Date and Time [005]] would look like:

=+04003=A99990612345600=%5100=<E0001000&>0060252359

where

=+04003 identifies this as a compound message of four data structures using the format defined for structured message type 003 (from Table RT017)

= A99990612345600 is the donation identification number data structure

=%5100 is the blood group code data structure

=<E0001000 is the product code data structure

&>0060252359 is the expiration date and time data structure

An example of an undefined message is:

=+03000= A99990612345600=%5100&(N0001

where

=+03000 identifies this as an undefined message structure containing three ISBT 128 data structures. The three following data structures have to be parsed and identified on the basis of their data identifiers.

In this case the three data structures encoded are Donation Identification Number [001], Blood Group Code [002], and Special Testing (general) [010].

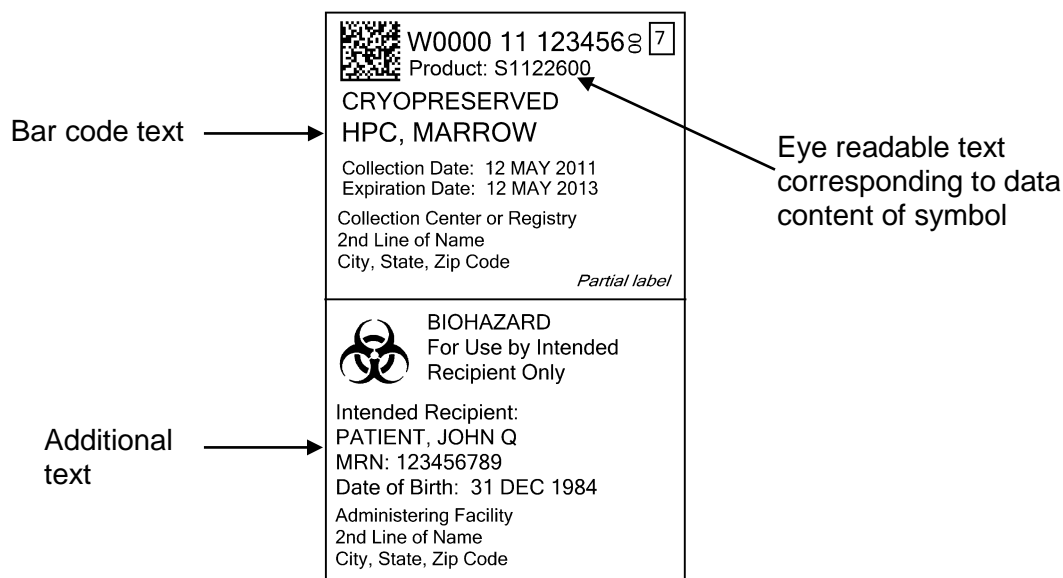
2.4 Affixed Labels

2.4.1 Text Terminology

There are three types of text for ISBT 128 labels:

- Eye readable text: The eye-readable representation of the data characters in a bar code printed left justified immediately below the bar code. Eye readable text is used routinely with linear bar codes. For two-dimensional symbols, eye readable text is generally only present for the Donation Identification Number and Product Code.
- Bar code text: The interpretation of the data content of the bar code.
- Additional text: All other information on the label that is not associated with a bar code.

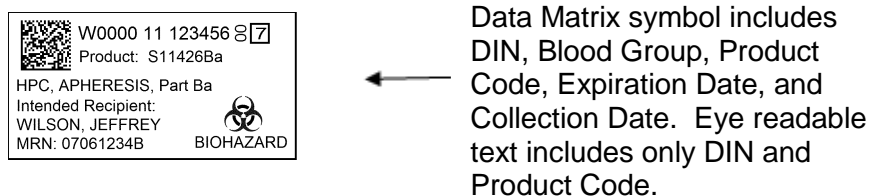
Figure 2 Text Terminology



2.4.2 Eye Readable Text

Because there is so much information in such a small symbol, it is not possible to include corresponding eye readable text beneath each symbol as is required for linear bar codes. Further, it is not practical to manually enter the amount of information encoded in a compound message. To support traceability, the Donation Identification Number and Product Code (both the product description code and the division/pack codes) shall be present in eye-readable text.

Figure 3 2-D Symbol with Minimum Data Content



2.4.3 Bar Code Text

There may be insufficient space on the affixed label for all the associated bar code text to be displayed. In this case, some text may appear on attached or accompanying documentation provided that adequate controls are in place to ensure correct matching of this documentation to the labeled unit and that local regulations permit this.

2.4.4 Small Label Examples

Data Matrix symbols are ideal when small labels must be used because the product container is small; there is a great deal of information that must be carried on the label; or the symbol is to be used on a patient wristband.

Figure 4 "Fold Over" Cellular Therapy Vertical Label

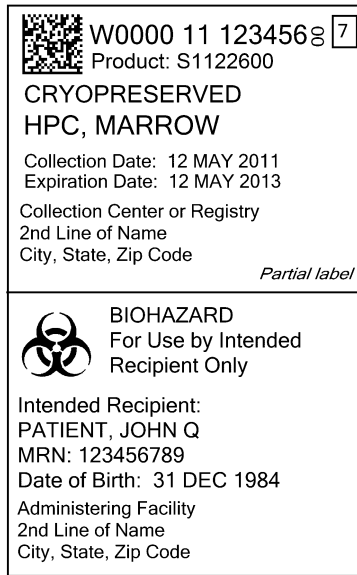


Figure 5 "Fold Over" Cellular Therapy Horizontal Label

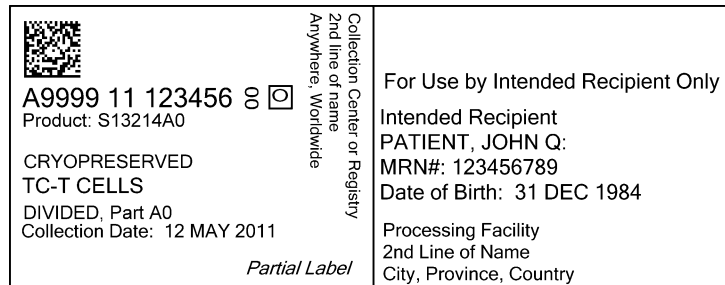


Figure 6 Tissue Product Label



2.4.5 100 mm x 100 mm Affixed Labels

Users may find it more efficient to scan a single 2-D bar code rather than multiple linear bar codes. For this reason, an additional 2-D bar code may be placed on a 100 mm x 100 mm ISBT 128 label.

The 2-D symbol is placed in the lower right quadrant of the label (see Figure 7). At a minimum, the 2-D symbol shall contain the same information as the required linear bar codes.

The same information that is encoded in additional (optional) linear bar codes present on the product label should also be included in the 2-D bar code. Appropriate control mechanisms shall be in place to ensure all the information on the label (linear bar codes, 2-D bar codes and text) is the same.

For blood products, linear bar codes must still be present on the label (see Figure 7). Cellular Therapy and tissue facilities may use either linear or 2-D symbols or both.

Figure 7 100 mm x 100 mm Blood Label

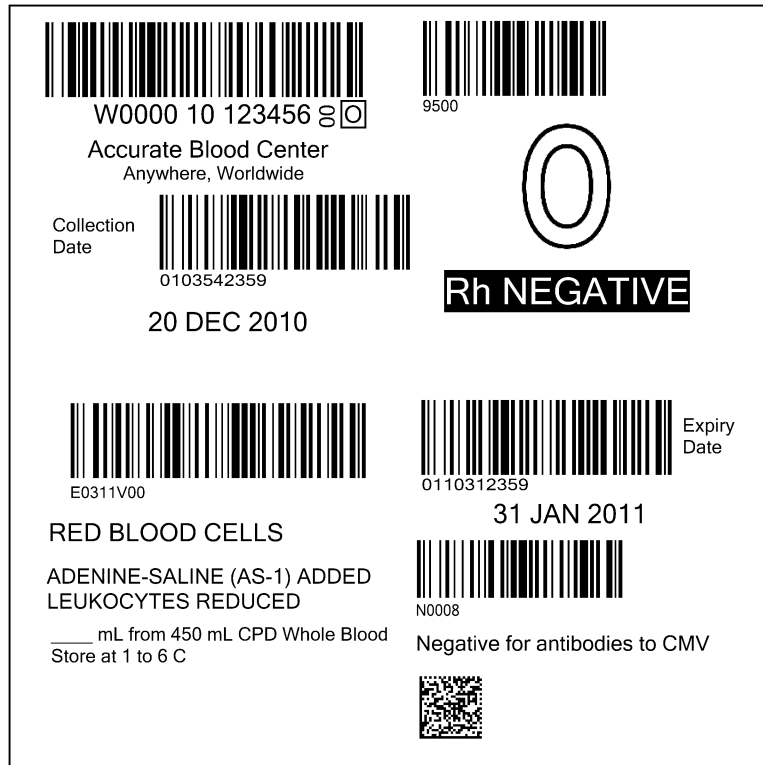
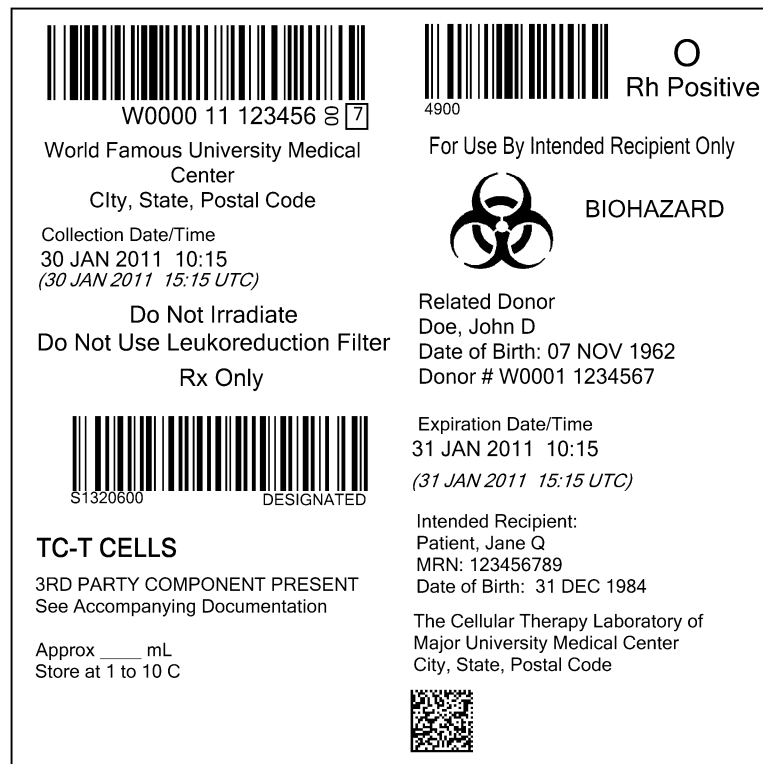


Figure 8 100 mm x 100 mm Cellular Therapy Product Label



2.5 Attached or Accompanying Labeling

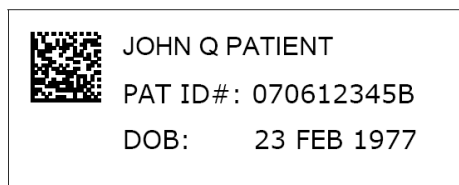
Some ISBT 128 data structures, such as the Infectious Marker Data Structure [027], are not intended to be used on affixed product labels. Additionally, some product containers are too small to include all the information needed to ensure patient safety. Data Matrix symbols can be used to encode such information into a machine readable format on the accompanying or attached documents. This can be done most simply by printing a label on a standard label printer and affixing it to the document(s). Alternatively, software can be created to print forms with the appropriate 2-D symbols.

Mechanisms must be in place to ensure such labeling is attached to the correct product. It is strongly recommended that the DIN be included in all messages.

2.6 Patient Wristbands

Data Matrix symbols are particularly useful on patient wristbands where curvature creates a problem for reading linear bar codes. ISBT 128 has data structures for Patient ID [025] and Patient Date of Birth [024] which are intended for use on patient wristbands. *Technical Bulletin 8, Specification for ISBT 128 Data Structures to Support the Secure Bedside Matching of Patient and Transfusion/Transplant Product Identification* describes how ISBT 128 data structures can be used to increase patient safety.

Figure 9 Patient Wristband



3 Example Messages and Symbols

ICCBBA provides sample symbols for use in validation in *Technical Bulletin 10 Valid and Invalid Bar Codes for use in ISBT 128 Validations*, which may be found on the ICCBBA Website (www.iccbba.org).

3.1 Example 1

The Data Structures desired in a compound message are:

- Donation Identification Number [001]
- Blood Group [002]
- Product Code [003]
- Expiration Date and Time [005]
- Special Testing: Red Cell Antigen – General [012]

Per Table W2 Data Structure 023 Structured Compound Messages [RT017] on the ICCBBA Website this is a standard compound message: 010.

Table 1 Excerpt from RT017

010	05	001;002;003;005;012	Donation Identification Number [001]; Blood Group [002];Product Code [003]; Expiration Date and Time [005];Special Testing: Red Cell Antigen – General [012]
-----	----	---------------------	--

The message desired is:

Data Structure	Information to transfer	Data Identifier and Code
Donation Identification Number	W00001012345621	=W00001012345621
Blood Group	A, Rh Positive	=%6200
Product Code	RED BLOOD CELLS CP2D>AS3/500mL/refg from a volunteer blood donor, undivided.	=<E0366V00
Expiration Date and Time	31 JAN 2010, 23:59	&>0100312359
Special Testing: Red Cell Antigen General	C+, c-, E-, e+	=\699999999999999999

A compound message with this data would be:

Data Characters	Meaning of Data Characters
=+	Data identifier
05	There are five data structures in the message
010	This is standard message 010 from Table RT017
=W00001012345621	Data identifier and data content for DIN
=%6200	A, Rh Positive
=<E0366V00	E0336V00
&>0100312359	31 JAN 2010, 23:59
=\6999999999999999999	C+, c-, E-, e+

The data string would therefore be:

=+05010=W00001012345621=%6200=<E0366V00&>0100312359=\6999999999999999999

The Data Matrix symbol would be:



This symbol, created with an X dimension of approximately 0.3 mm, is 8 mm square.

3.2 Example 2

The Data Structures desired in the compound message are:

- Donation Identification Number [001]
- Blood Group [002]
- Product Code [003]
- Expiration Date and Time [005]
- Special Testing: General [010]

Per Table W2 Data Structure 023 Structured Compound Messages [RT017] on the ICCBBA Website, this is a standard compound message: 009.

Table 2 Excerpt from RT017

009	05	001;002;003;005;010	Donation Identification Number [001];Blood Group [002];Product Code [003];Expiration Date and Time [005];Special Testing General [010]
-----	----	---------------------	--

The message desired is:

Data Structure	Information to transfer	Data Identifier and Code
Donation Identification Number	W0000 10 123356 00	=W00001012335600
Blood Group	A, Rh Negative	=%0600
Product Code	Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<1log6 from a volunteer blood donor, undivided.	=< E3929V00
Expiration Date	12 JAN 2010, 23:59	&>0100122359
Special Testing: General	CMV Seronegative	&(N0008

A compound message with this data would be:

Data Characters	Meaning of Data Characters
=+	Data identifier
05	There are five data structures in the message
009	This is standard message 010 from Table RT017
=W00001012335600	Data identifier and data content for DIN
=%0600	A, Rh Negative
=< E3929V00	E3929V00
&>0100122359	12 JAN 2010, 23:59
&(N0008	CMV seronegative

The data string would therefore be:

=+05009=W00001012335600=%0600=< E3929V00&>0100122359&(N0008

The Data Matrix symbol would be:




This symbol, created with an X dimension of approximately 0.3 mm, is 8 mm square.

3.3 Additional Examples of Data Matrix Symbols

Compound Message 001: Donation Identification Number [001];Product Code [003]

Data Structure	Information to transfer	Data Identifier and Code
Donation Identification Number	W00001022335624	=W00001022335624
Product Code	Apheresis FRESH FROZEN PLASMA ACD-A/XX/<-25C from a volunteer blood donor, undivided.	=< E3893V00


Data String: =+02001=W00001022335624=<E3893V00

Symbol: 

Compound Message 002: Donation Identification Number [001];Blood Group [002]

Data Structure	Information to transfer	Data Identifier and Code
Donation Identification Number	W00001031335600	=W00001031335600
Blood Group	B, Rh Negative	=%1700

Data String: =+02002=W00001031335600=%1700

Symbol: 

Compound Message 003: Donation Identification Number [001];Blood Group [002];Product Code [003];Expiration Date and Time [005]

Data Structure	Information to transfer	Data Identifier and Code
Donation Identification Number	W00001072335600	=W00001072335600
Blood Group	AB, Rh Negative	=%2800
Product Code	RED BLOOD CELLS CPD>AS5/450mL/refg, Volunteer donor, undivided	=<E0385V00
Expiration Date and time	03 JUL 2010, 23:59	&>0101842359

Data String: =+04003=W00001072335600=%2800=<E0385V00&>0101842359

Symbol:



Compound Message 004: Donation Identification Number [001];Product Code [003];Expiration Date and Time [005]

Data Structure	Information to transfer	Data Identifier and Code
Donation Identification Number	W00001072335700	=W00001072335700
Product Code	RED BLOOD CELLS CPD>AS5/450mL/refg, Volunteer donor, undivided	=<E0385V00
Expiration Date	08 JUL 2010, 23:59	&>0101892359

Data String: =+03004=W00001072335700=<E0385V00&>0101892359


Symbol:



Compound Message 006: Patient Birth Date Bar Code Data Structure [024]; Patient Hospital ID Number Data Structure [025]

Data Structure	Information to transfer	Data Identifier and Code
Patient Date of Birth	03 JAN 1943 taken from the patient wristband	=#0119430103
Patient Hospital ID Number	AB12345691	nAB12345691


Data String: =+02006=#0119430103nAB12345691

Symbol: 

Undefined Message (000): Donation Identification Number [001];Production Date and Time [009]

Data Structure	Information to transfer	Data Identifier and Code
Donation Identification Number	W00001072335900	=W00001072335900
Production date and time	1 April 2010 15:15	&}0100911515

Data String: =+02000=W00001072335900&}0100911515

Symbol: 

Additional examples of 2-D labels which may be used for validation are found in Technical Bulletin 10: Valid and Invalid Bar Codes for Use in ISBT 128 Validations, 2009. This document may be found on the ICCBBA Website.

4 Notes for Software Developers

Software should be written to ensure that the full data string matches the information provided in the compound message data structure and Table RT017. Additionally when the source of the information is identified using Table RT018 [Data Structures 024 and 025], the software should confirm that there is consistency (i.e., both data structures identify the same source).

Once verification is complete, the data string can be parsed into its individual data structure elements and handled in the same way as the corresponding linear bar code entry. In this way software can operate independently of the input format and products labeled with linear and 2-D codes can be handled simultaneously.

Each data structure in the string should be verified individually in the same way that their linear counterparts are verified.