Warranty Disclaimer and Limitation of Liability

ICCBBA provides no representation or warranty that the Licensee’s use of ISBT 128 is suitable for any particular purpose and the selection, use, efficiency and suitability of ISBT 128 is the sole responsibility of the Licensee.

ICCBBA’s liability is limited to that specified in the ICCBBA License Agreement which is available on the ICCBBA website. Under no circumstances shall ICCBBA’s liability to licensee or any third party under any theory or cause of action exceed the current annual license fee payable by the licensee to ICCBBA hereunder, and ICCBBA will in no circumstances be liable for any direct or indirect damages whatsoever, including without limitation special, incidental, consequential, or punitive damages or damages for loss of data, business or goodwill or any other consequential losses of any nature arising from the use of ISBT 128 or the marks.

Copyright Notice

Copyright 2004-2016. ISBT 128 is not in the public domain and is protected by law. Implementation of ISBT 128 requires the end-user to register with ICCBBA and to pay an annual license fee. License fees are established by the ICCBBA Board of Directors to cover the expenses of maintaining and extending ISBT 128, and making available current versions of the documents and database tables that are needed to implement this Standard.

This Standard is intended for the use of those implementing ISBT 128, regulatory agencies, and software developers and other manufacturers that support end-users.

Although it is made available to anyone wishing to obtain a copy, national “Guidelines” describing its use in a particular country may be an additional source of information for the end-user. If such “Guidelines” exist, they must be consulted because there are options in ISBT 128, and country-specific information pertaining to the particular use of such options will only be found in such “Guidelines.”

Any use of this Guideline, or the accompanying database tables, by other than registered organizations, or facilities that have obtained their computer software from a registered and licensed developer, is strictly forbidden. Copying any portion of the Standard, or of any accompanying database table, either in electronic or other format, without express written permission from ICCBBA is strictly forbidden. Posting of any portion of the Standard, or of any accompanying database table, to any online service by anyone other than ICCBBA is strictly forbidden.

There are no guarantees or warranties attached to this Standard other than that ICCBBA, Inc agrees to furnish registered and licensed end-users with the most up-to-date information available. Successful implementation of this Standard, and use of any accompanying database table(s), depend(s) upon the correct incorporation of the rules and table contents into the software used by or provided to the registered and licensed facility. ICCBBA, Inc makes no other warranties of any kind, whether expressed or implied, including any implied warranty of merchantability or fitness for any particular purpose. Further information can be found at www.iccbba.org.
Editor
Briana Rice
Information Standards Specialist II, ICCBBA

Standards Committee

John Armitage, Prof., BSc, PhD United Kingdom
Paul Ashford, MSc. CEng. CSci. ICCBBA
Wayne Bolton, B.App.Sc., M.App.Sc Australia
Suzanne Butch, MA, MT(ASCP)SBB United States of America
Erwin Cabana, BA ICCBBA
Pat Distler, MS, MT(ASCP)SBB ICCBBA
Jørgen Georgsen, MD Denmark
Suzy Grabowski, BA, BB(ASCP)SBB United States of America
Mario Muon, MD Portugal
Stefan Poniatowski, BSc, MIBMS Australia
Leigh Sims Poston, BS, MT(ASCP) United States of America
Ineke Slaper-Cortenbach, PhD The Netherlands
Zbigniew Szczepiorkowski, MD, PhD United States of America
Izabela Uhrynowska-Tyszkiewicz, MD, PhD Poland
# Table of Contents

1  Introduction .................................................................................................................. 5

1.1 Purpose ...................................................................................................................... 5

1.2 Scope ......................................................................................................................... 5

1.3 Intended Audience .................................................................................................... 5

1.4 Normative References .............................................................................................. 5

1.5 Other References ....................................................................................................... 5

1.6 Background ................................................................................................................ 5

1.7 Changes in this Version ............................................................................................ 6

2  Data Structures ............................................................................................................ 7

3  Electronically Readable Symbols .................................................................................. 8

4  Labeling Considerations ............................................................................................... 9

4.1 National Labeling Guidelines .................................................................................. 9

4.2 General Principles .................................................................................................... 9

4.3 Printing of Bar Codes ............................................................................................... 9

4.4 Base Label Bar Code Placement ............................................................................... 9

4.4.1 Standard Base Label Bar Code Placement ......................................................... 9

4.4.2 Small Base Label Bar Code Placement .............................................................. 10

4.5 Final Label Bar Code Placement ............................................................................ 13

4.5.1 100 mm by 100 mm Final Label ....................................................................... 13

4.5.2 Small Final Label ............................................................................................... 16

5  Text .............................................................................................................................. 17

5.1 Definitions .................................................................................................................. 17

5.2 Data Content Text for Linear Bar Codes ................................................................ 17

5.2.1 Donation Identification Number [Data Structure 001] ........................................ 18

5.2.2 Container Manufacturer/Catalog Number [017] and Container Lot Number [018] 19

5.2.3 All Other Bar Codes ......................................................................................... 19

5.2.4 Keyboard Entry Check Character K .................................................................. 19

5.3 Bar Code Text ............................................................................................................ 22

5.3.1 Facility .................................................................................................................. 22

5.3.2 Blood Groups [ABO and RhD] [Data Structure 002] ......................................... 23

5.3.3 Product Descriptions [Data Structure 003] ....................................................... 24

5.3.4 Dates [Data Structures 004, 005, 006, 007, 008, 009, 024] ............................ 24

5.3.5 Month-Year [Data Structure 026] .................................................................... 25

5.3.6 Special Testing, Red Blood Cell Antigens [Data Structures 011, 012, and 013] ... 25

5.3.7 Donor Identification Number [Data Structure 019] ........................................... 25

5.4 Additional Text ......................................................................................................... 26

6  Label Examples ........................................................................................................... 27

7  International Label Examples ...................................................................................... 32

8  Glossary ....................................................................................................................... 34
Tables

Table 1  Positioning Bar Codes on the Base Labels [RT020] ............................. 10
Table 2  Positioning Bar Codes on 50 mm by 75 mm Containers [RT021] .................. 12
Table 3  Final Label Quadrants and Bar Codes [RT022] .................................. 14
Table 4  Required Positioning of Bar Codes on Final Labels [RT023] ...................... 14
Table 5  Recommended Positioning of Bar Codes on Final Labels [RT024] ............... 14
Table 6  Keyboard Entry Check Character Requirements for ISBT 128 Data Structures Utilizing Code 128 [RT002] .......................................................... 21

Figures

Figure 1  Comparison of 2-D and Linear Bar Codes ........................................ 8
Figure 2  Placement and Nominal Size of Bar Codes on Base Label .................. 10
Figure 3  Placement and Nominal Size of Bar Codes on a 50 mm by 75 mm Base Label ... 12
Figure 4  Placement and Nominal Size of Bar Codes on Final Label .................. 15
Figure 5  Text Terminology Used in ISBT 128 ............................................... 17
Figure 6  Upper Left Quadrant Facility Bar Code Text ..................................... 22
Figure 7  Upper Right Quadrant for Designated or Directed Donation ............. 23
Figure 8  Upper Right Quadrant for Autologous Donation .............................. 23
Figure 9  Upper Right Quadrant for “Non-Specified” Donation ...................... 24
Figure 10  Optional Differentiation of RhD Negative Units ............................... 24
Figure 11  Relative Text Size of Class, Modifier, and Attributes ...................... 24
Figure 12  Standard Base Label ................................................................. 27
Figure 13  Small Base Label ........................................................................ 28
Figure 14  Final Label Showing Manufacturer’s Data Content Information ....... 29
Figure 15  Final Label with Optional Collection Date .................................. 30
Figure 16  Final Label with 2-D Bar Code ..................................................... 30
Figure 17  Platelet Apheresis Label ............................................................... 31
Figure 18  Denmark (Danish) ........................................................................ 32
Figure 19  Canada (French/English) .............................................................. 32
Figure 20  Finland (Finnish) .......................................................................... 33
Figure 21  Portugal (Portuguese) ................................................................. 33
1 Introduction

1.1 Purpose

This document is intended to help facilities, label vendors, and software developers design appropriate ISBT 128 labels for blood products.

1.2 Scope

This document provides guidance in the design of labels for blood products following the Standards described in the ISBT 128 Standard Technical Specification.

This document addresses affixed labels in the ISBT 128 format. It does not address the design of attached labels or accompanying documents.

1.3 Intended Audience

The intended audience of this document is staff at facilities of blood collection and processing centers and transfusion services (management, information technology, quality, validation, and laboratory), auditors, software developers, and label vendors.

1.4 Normative References

*ISBT 128 Standard Technical Specification (ST-001)*

*ISO 8601-2004 Data elements and interchange formats — Information interchange — Representation of dates and times*

1.5 Other References

**ICCBBA:**
ICCBBA publications are maintained on the ICCBBA Website. It is the responsibility of registered and licensed establishments to ensure that they have the most recent version of all ICCBBA publications by regularly consulting the listing maintained on the ICCBBA Website. A subscription email notification system is available on the ICCBBA Website. The following listing is current as of the date on the front cover of this document.

**Standards Documents**

*ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-003)*

**Implementation Guides**

*Use of Product Code [Data Structure 003], Blood (IG-021)*

*Use of Red Cell Antigens with Test History [Data Structure 030] (IG-027)*

1.6 Background

A specification for the use of ISBT 128 for the labeling of blood products was developed by the International Society of Blood Transfusion Working Party on Automation and Data Processing (WPADP) [now called the Working Party on Information Technology] and
published by ICCBBA in 1995. Countries around the world are in various stages of implementation, and the model originally developed by the WPADP has demonstrated its suitability by accommodating regional changes without substantial structural change.

International standardization of labeling is a key element of ISBT 128. Standardized bar codes allow blood products to be shipped internationally with clear, unambiguous labeling and can be used to overcome language barriers.

1.7 Changes in this Version

The following table indicates the major changes between Version 1.0.0 and Version 1.1.0. 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. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

<table>
<thead>
<tr>
<th>Version Control: Version 1.0.0 vs. Version 1.1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Chapter, Section, Table, or Figure</strong></td>
</tr>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
<tr>
<td>5.</td>
</tr>
<tr>
<td>6.</td>
</tr>
</tbody>
</table>
2 Data Structures

The data structures that will commonly be used for affixed labels on blood products include:

• 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]
• Collection Date [Data Structure 006] or Collection Date and Time [Data Structure 007]
• Production Date [Data Structure 008] or Production Date and Time [Data Structure 009]
• Special Testing: General [Data Structure 010]
• Special Testing: Red Cell Antigens [Data Structure 012]
• Special Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]
• Dimensions [Data Structure 029]
• Red Cell Antigens with Test History [Data Structure 030]

Detailed information for all data structures is found in the *ISBT 128 Standard Technical Specification*. 
3 Electronically Readable Symbols

Linear bar codes (Code 128) shall be used to label blood products. Two-dimensional (2-D) symbols (Data Matrix) may be used in addition to linear bar codes on blood labels to improve efficiency. 2-D symbols have the advantage of allowing a great deal of information to be encoded into a very small amount of space (see Figure 1) and allowing a single scan to convey a great deal of information. They have the disadvantage of requiring a more modern type of scanner, an imaging scanner, to read them. Imaging scanners may not be widely available in hospitals at the current time and therefore 2-D symbols shall not be used as the sole means of encoding machine readable information on a blood product label. However, this is anticipated to change in the future as the implementation of 2-D labels increases.

Figure 1 Comparison of 2-D and Linear Bar Codes


- The use of passive HF (13.56 MHz)
- That the user follow ISO 18000-3, tag standard and the ISO 15961 and ISO 15962 data encoding rules.
- That ISBT 128 data structures be used within the message.

Additional guidance will be provided as this technology develops.
4 Labeling Considerations

4.1 National Labeling Guidelines

National bodies may publish guidelines for labeling which adhere to the ISBT 128 Standard, as well as the rules set forth in this document. ICCBBA maintains on its Website examples of such national documents. For assistance in creating such national guidelines, or to share a national guideline on the ICCBBA Website, contact the ICCBBA office (tech.manager@iccbba.org).

4.2 General Principles

Two general label types are specified in ISBT 128:

- Base label - the label applied by the manufacturer of the container.
- Final label - the label placed on a product container by the processing facility.

Note: Facilities may also apply intermediate or in-process labels.

The following general principles apply to label design:

- Primary considerations in label design shall include improving the safety of the product and the efficiency of processing/administering. If these two considerations conflict, safety shall take precedence over efficiency.

- Critical information on the container shall dominate the label via position and prominence and shall take precedence over information that is of little importance to the end-user (clinician, nurse, laboratory staff, and other hospital personnel).

- The use of color (for example, for ABO) is neither prohibited nor encouraged.

4.3 Printing of Bar Codes

Specifications (quality, dimensions, etc.) for the printing of electronically-readable symbols may be found in the ISBT 128 Standard Technical Specification.

4.4 Base Label Bar Code Placement

4.4.1 Standard Base Label Bar Code Placement

Where the container is of sufficient size, it shall carry a 100 ± 2 mm by 106 ± 2 mm base label.

The base label should carry the two manufacturer’s information bar codes: the Container Manufacturer and Catalog Number [017] bar code in the lower left quadrant and the Manufacturer’s Lot Number [018] bar code in the lower right quadrant. The recommended position for these bar codes on 100 ± 2 mm by 106 ± 2 mm label is indicated in Table 1, page 10.
Table 1 Positioning Bar Codes on the Base Labels [RT020]

<table>
<thead>
<tr>
<th>Bar Code</th>
<th>Vertical Alignment</th>
<th>Horizontal Alignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container Manufacturer and Catalog Number [017]</td>
<td>9 mm ± 2mm from bottom of label*</td>
<td>Bar code right edge should be at 4 mm ± 2mm from right edge of Left Quadrant*</td>
</tr>
<tr>
<td>Container Lot Number [018]</td>
<td>9 mm ± 2mm from bottom of label*</td>
<td>Bar code left edge should be at 4 mm ± 2mm from left edge of Right Quadrant*</td>
</tr>
</tbody>
</table>

* Concatenation distances must also be maintained

Figure 2 Placement and Nominal Size of Bar Codes on Base Label

Required Bar Codes
1 – Container Manufacturer and Catalog Number
2 – Container Lot Number

Gray lines are for reference only and should not be printed on the label

4.4.2 Small Base Label Bar Code Placement

The size of some containers does not allow a 100 ± 2 mm by 106 ± 2 mm base label. In designing smaller labels the principles outlined in this chapter should be applied to the extent possible.
An alternative label design may be used if the container will accommodate a 50 mm x 75 mm label. The Container Manufacturer and Catalog Number [017] bar code shall be printed vertically in the upper half of the label and the Manufacturer’s Lot Number [018] shall be printed vertically in the lower half of the label. The recommended position for these bar codes is indicated in Table 2, and is illustrated in Figure 3, page 12. This places the bar codes in an ideal position for concatenation.

In order to accommodate the smaller size of the 50 mm x 75 mm label, and allow for concatenation of the bar codes, an X dimension as small as 0.17 mm may be used.

The bar code height may also be reduced to equal or greater than 15% of the bar code length (e.g., reduced to approximately 7 mm if the bar code is approximately 43 mm) in order to accommodate required text. Refer to ISBT 128 Standard Technical Specification (ST-001) for the standard bar code height.
Table 2  Positioning Bar Codes on 50 mm by 75 mm Containers [RT021]

<table>
<thead>
<tr>
<th>Bar Code</th>
<th>From vertical center of label</th>
<th>From left side of label</th>
</tr>
</thead>
<tbody>
<tr>
<td>Container manufacturer and catalog number</td>
<td>The right edge of the bar code is 4 mm ± 2mm above the vertical center of the label*</td>
<td>Lower edge of the bar code is 6 mm ± 2mm from the left side of the label*</td>
</tr>
<tr>
<td>Lot number</td>
<td>The left edge of the bar code is 4 mm ± 2mm below the vertical center of the label*</td>
<td>The lower edge of the bar code is 6 mm ± 2mm from the left side of the label*</td>
</tr>
</tbody>
</table>

* Concatenation distances must also be maintained

Figure 3  Placement and Nominal Size of Bar Codes on a 50 mm by 75 mm Base Label

1 – Container Manufacturer and Catalog Number
2 – Container Lot Number
4.5 Final Label Bar Code Placement

4.5.1 100 mm by 100 mm Final Label

The default size of the final label is 100 (+/-2) mm by 100 (+/-2) mm. The final label may be applied as a single 100 mm x 100 mm label or may be built up with smaller labels applied at different stages during the process.

The final label design shall be based upon the concept of four equal 50 (+/-1) mm by 50 (+/-1) mm quadrants. The bar codes shall be placed in these quadrants as shown in Table 3, page 14.

Linear bar codes for Data Structures 001, 002, 003 and 005 shall be present and positioned as described in Table 4, page 14. These requirements place the bar codes in an ideal position for concatenation. No vertical lines may appear between pairs of bar codes that are meant to be concatenated.

Linear bar codes for other Data Structures found on the final label, and the Data Matrix symbol, are optional and if used should be positioned as described on Table 5, page 14.

When present, the Data Matrix symbol shall include the four data structures (DIN, Product Code, ABO/RhD, and Expiration Date and Time) required for linear bar codes. Additional ISBT 128 data structures (excluding nationally defined structures) may also be included.

Figure 4, page 15, shows final label printed according to these tables.
Table 3 Final Label Quadrants and Bar Codes [RT022]

<table>
<thead>
<tr>
<th>Quadrant</th>
<th>Data Structure [Reference number]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper Left</td>
<td>Donation Identification Number (required) [001]</td>
</tr>
<tr>
<td></td>
<td>Collection Date and Time (optional) [006, 007] or Production Date and Time (optional) [008, 009]</td>
</tr>
<tr>
<td>Lower Left</td>
<td>Product Code (required) [003]</td>
</tr>
<tr>
<td></td>
<td>Dimensions (optional) [029]</td>
</tr>
<tr>
<td>Upper Right</td>
<td>ABO/RhD Blood Group (required) [002]</td>
</tr>
<tr>
<td>Lower Right</td>
<td>Expiration Date and Time (required) [005]</td>
</tr>
<tr>
<td></td>
<td>Special Testing (optional) [010,011,012,013,014,015,016]</td>
</tr>
</tbody>
</table>

Table 4 Required Positioning of Bar Codes on Final Labels [RT023]

<table>
<thead>
<tr>
<th>Bar Code</th>
<th>Vertical Alignment</th>
<th>Horizontal Alignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation Identification Number</td>
<td>3 mm ± 2mm from top of Upper Left Quadrant*</td>
<td>Bar code right edge should be 4 mm ± 2mm from right edge of Upper Left Quadrant*</td>
</tr>
<tr>
<td>Number [001]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Code [003]</td>
<td>3 mm ± 2mm from top of Lower Left Quadrant*</td>
<td>Bar code right edge should be 4 mm ± 2mm from right edge of Lower Left Quadrant*</td>
</tr>
<tr>
<td>ABO/RhD Blood Groups [002]</td>
<td>3 mm ± 2mm from top of Upper Right Quadrant*</td>
<td>Bar code left edge should be 4 mm ± 2mm from left edge of Upper Right Quadrant*</td>
</tr>
<tr>
<td>Expiration Date (and Time) [005]</td>
<td>3 mm ± 2mm from top of Lower Right Quadrant*</td>
<td>Bar code left edge should be 4 mm ± 2mm from left edge of Lower Right Quadrant*</td>
</tr>
<tr>
<td>Special Testing [one of several alternative data structures]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dimensions [029]</td>
<td>20 mm ± 2mm from top of Lower Right Quadrant*</td>
<td>Bar code right edge should be at 4 mm ± 2mm from right edge of Lower Right Quadrant*</td>
</tr>
<tr>
<td>Data Matrix symbol (for transition labels)</td>
<td>As close to the bottom of the label as practical*</td>
<td>Bar code right edge should be at 4 mm ± 2mm from right edge of Lower Left Quadrant*</td>
</tr>
</tbody>
</table>

* Concatenation distances must also be maintained.

Table 5 Recommended Positioning of Bar Codes on Final Labels [RT024]

While these barcodes shall be placed in the quadrants indicated, their exact placement within the quadrant is not mandated.

<table>
<thead>
<tr>
<th>Bar Code</th>
<th>Vertical Alignment</th>
<th>Horizontal Alignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection Date (and Time) [006, 007] or Production Date (and Time) [008, 009]</td>
<td>20 mm ± 2mm from top of Upper Left Quadrant*</td>
<td>Bar code right edge should be at 4 mm ± 2mm from right edge of Upper Left Quadrant*</td>
</tr>
<tr>
<td>Special Testing [one of several alternative data structures]</td>
<td>20 mm ± 2mm from top of Lower Right Quadrant*</td>
<td>Bar code left edge should be at 4 mm ± 2mm from left edge of Lower Right Quadrant*</td>
</tr>
<tr>
<td>Dimensions [029]</td>
<td>As close to the bottom of the label as practical*</td>
<td>Bar code right edge should be at 4 mm ± 2mm from right edge of Lower Left Quadrant*</td>
</tr>
<tr>
<td>Data Matrix symbol (for transition labels)</td>
<td>Nationally defined</td>
<td>Nationally defined</td>
</tr>
</tbody>
</table>

* Concatenation distances must also be maintained.
Figure 4 Placement and Nominal Size of Bar Codes on Final Label

Required Bar Codes
1 – Donation Identification Number
2 – ABO/RhD
3 – Product Code
4 – Expiration Date and Time

Optional Bar Codes and Symbols
5 – Special Testing
6 – Collection (or Production) Date or Date and Time
7 – Dimensions
8 – Data Matrix symbol
To assist in label design, if more than one linear bar code is to be placed in a quadrant, e.g., Expiration Date and Special Testing, some adjustment of the absolute position of bar codes other than those for Data Structures 001, 002, 003, and 005 is permissible. Additionally, depending on the amount of text that is required, it may be necessary to reduce bar code height in accordance with bar code height requirements described in the ISBT 128 Standard Technical Specification.

A library of example labels from different countries is posted on the ICCBBA Website. (See Tech Library, Sample Bar Codes and Labels.)

4.5.2 Small Final Label

Some containers for distribution within a facility may require a smaller final label. In designing such labels the principles outlined in this chapter should be applied to the extent possible.

If the design includes use of linear bar codes with an X dimension of less than 0.25 mm, care should be taken to ensure that all scanners that will be used to read the label are able to do so.

At a minimum:
1) Every ISBT 128-labeled product shall carry an electronically readable Donation Identification Number and Product Code.
2) Every ISBT 128-labeled product shall carry a text Donation Identification Number and Product Code.
3) If linear bar codes are used and the affixed label is too small to carry both bar codes, then the DIN bar code shall appear on the affixed label, along with text DIN and Product Code. The DIN and Product Code bar codes shall also be carried together on an attached label or on accompanying documentation (Note: For traceability, both the ISBT 128 DIN and the full Product Code, which includes the Product Description Code and the Division Code, are required on the affixed label.)

When using small affixed labels, additional required information shall appear on an attached or accompanying labeling meeting national requirements.
5 Text

5.1 Definitions

There are three types of text for ISBT 128 labels:

- Data content text: The eye-readable representation of the data characters in a linear bar code. For linear bar codes, it is printed left justified immediately below the bar code, unless otherwise specified.

- 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 5 Text Terminology Used in ISBT 128

5.2 Data Content Text for Linear Bar Codes

Linear Symbols: Every Code 128 (linear) bar code on a container label shall be accompanied by data content text. Bar code data identifiers shall not appear in the data content text. Except for the DIN, data content text shall appear immediately below, but not touching, the bar code; commence in line with the leftmost bar of the bar code (left justified) and be represented in a typeface that differentiates characters from numbers with a maximum height of 2 mm.
2-D Symbols: While data content text generally is not associated with Data Matrix (2-D) symbols, the DIN and Product Code shall appear in data content text when Data Matrix symbols are used. This is necessary to ensure adequate traceability since a product is uniquely identified based on the DIN and the Product Code. It is therefore essential that this information be available to the receiving facility in a human-readable format. For blood, where linear bar codes for DIN, Product Code, ABO/RhD, and expiration date/time are required, data content text will appear beneath the linear bar codes. However, for other information that may be encoded in the 2-D bar code that is not in linear bar codes (e.g., Red Cell Antigens with Test History or Dimensions), data content text may appear in attached or accompanying documentation.

5.2.1 Donation Identification Number [Data Structure 001]

The data content text for a Donation Identification Number is unique in that it is the sole means of presenting the data content of the bar code, i.e., it serves the dual role of data content text and bar code text. As bar code text, it shall be printed using a typeface that differentiates characters from numbers. A national authority should determine the grouping of characters in the DIN presentation, for example:

```
V4043 12 499999
B404 212 123 456
```

All data characters shall be printed. (The DIN is the only data structure for which the second data identifier character is also a data character).

The flag characters “ff” may be used to convey specific information other than the unique identification of the product and shall be distinguished from the Donation Identification Number (see ISBT 128 Standard Technical Specification and Technical Bulletin 7: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution (IG-010) for information about the use of flag characters). When Type 1 or Type 2 flag characters are used (see ISBT 128 Standard Technical Specification) they shall be printed as either:

- Numeric Presentation: The two-digit values of flags “ff” shall be printed rotated 90° clockwise to make them visually different from the Donation Identification Number.

```
A9999 12 123456
```

- Non-numeric Presentation: A graphical icon or other representation of the value of “ff”, e.g., for flag “07” printing an icon showing a small test tube.

```
A9999 12 123456
```
5.2.2 Container Manufacturer/Catalog Number [017] and Container Lot Number [018]

When these bar codes are printed on the 100 ± 2 mm by 106 ± 2 mm base label, data content text shall be printed in typeface that differentiates characters from numbers in the 6 mm segment of the base label that will remain visible after the application of the final label. The height of this text shall not exceed 3 mm. It shall be centered vertically within the segment (Figure 12, page 27) and commence in line with the leftmost bar of the bar code.

When these bar codes are printed on smaller base labels, the data content text for these two bar codes shall be printed left justified immediately below the bar code. The data content text should remain visible after the base label is over-labeled with the final label. See Figure 13, page 28.

5.2.3 All Other Bar Codes

Data content text shall appear immediately below, but not touching, the bar code; commence in line with the leftmost bar of the bar code and be represented in a typeface that differentiates characters from numbers with a maximum height of 2 mm (see Figure 5, page 17).

5.2.4 Keyboard Entry Check Character K

A keyboard entry check character K shall be used when data content text appears in conjunction with the following data structures in order to verify correct manual entry of the data content:

- Donation Identification Number [001]
- Donor Identification Number [019]
- Infectious Marker [027]

If data content text is included with the following data structures, a keyboard entry check character K shall be used.

- Special Testing: Red Blood Cell Antigens [011] [Retired]
- Special Testing: Red Blood Cell Antigens — General [012]
- Special Testing: Platelet HLA and Platelet-Specific Antigens [014]
- Special Testing: HLA-A and –B Alleles [015] [Retired]
- Special Testing: HLA-DRB1 Alleles [016] [Retired]

Note: While some of these data structures have been retired, they are still being used in some countries. Therefore, the data structures are still included in the requirement to use the check character.

In the case of Donation Identification Number [Data Structure 001], the calculation shall be based on the Donation Identification Number only, i.e., excluding the flag characters.

For other bar codes, the keyboard entry character may be used (see Table 6, page 21). Because the ISO/IEC 7064 modulo 37-2 checksum method does not...
allow for lower case alpha characters, it shall not be used in data structures that have lower case alpha characters.

\( \mathbf{K} \) is not part of the data content string but is calculated from it using the ISO/IEC 7064 modulo 37-2 checksum method. \( \mathbf{K} \) is a character in the range \{A-Z, 0-9, *\} determined from the modulo 37 remainder of the weighted sum of the data content string. Information about this calculation and an example of the calculation for the 13-character string \texttt{appppyynnnnn} of the Donation Identification Number may be found in the ISBT 128 Standard Technical Specification.

Wherever the keyboard check character is printed, it shall be clearly distinguished from data content. When printed in association with the data content text of a code, a box shall be printed around the keyboard entry check character.

For example, a Red Cell phenotype would be printed:

\[
\text{959789997599924799 D}
\]

It shall be printed in a typeface that clearly distinguishes alphabetic and numeric characters; e.g., there shall be no confusion between 1 (one) and I (capital letter I), or between 0 (zero) and O (capital letter O).
### Table 6: Keyboard Entry Check Character Requirements for ISBT 128 Data Structures Utilizing Code 128 [RT002]

<table>
<thead>
<tr>
<th>Number</th>
<th>Data Structure Name</th>
<th>Modulo 37-2 Keyboard Entry Check Character [K]</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>Donation Identification Number</td>
<td>Required</td>
</tr>
<tr>
<td>002</td>
<td>Blood Groups [ABO and RhD]</td>
<td>Not applicable</td>
</tr>
<tr>
<td>003</td>
<td>Product Code</td>
<td>Not applicable</td>
</tr>
<tr>
<td>004</td>
<td>Expiration Date</td>
<td>Optional</td>
</tr>
<tr>
<td>005</td>
<td>Expiration Date and Time</td>
<td>Optional</td>
</tr>
<tr>
<td>006</td>
<td>Collection Date</td>
<td>Optional</td>
</tr>
<tr>
<td>007</td>
<td>Collection Date and Time</td>
<td>Optional</td>
</tr>
<tr>
<td>008</td>
<td>Production Date</td>
<td>Optional</td>
</tr>
<tr>
<td>009</td>
<td>Production Date and Time</td>
<td>Optional</td>
</tr>
<tr>
<td>010</td>
<td>Special Testing: General</td>
<td>Optional</td>
</tr>
<tr>
<td>011</td>
<td>Special Testing: Red Blood Cell Antigens (RETIRED)</td>
<td>Required</td>
</tr>
<tr>
<td>012</td>
<td>Special Testing: Red Blood Cell Antigens — General</td>
<td>Required if data content text is printed</td>
</tr>
<tr>
<td>013</td>
<td>Special Testing: Red Blood Cell Antigens — Finnish</td>
<td>Required if data content text is printed</td>
</tr>
<tr>
<td>014</td>
<td>Special Testing: Platelet HLA and Platelet-Specific Antigens</td>
<td>Required if data content text is printed</td>
</tr>
<tr>
<td>015</td>
<td>Special Testing: HLA-A and –B Alleles (RETIRED)</td>
<td>Required if data content text is printed</td>
</tr>
<tr>
<td>016</td>
<td>Special Testing: HLA-DRB1 Alleles (RETIRED)</td>
<td>Required if data content text is printed</td>
</tr>
<tr>
<td>017</td>
<td>Container Manufacturer and Catalog Number</td>
<td>Not applicable</td>
</tr>
<tr>
<td>018</td>
<td>Container Lot Number</td>
<td>Not applicable</td>
</tr>
<tr>
<td>019</td>
<td>Donor Identification Number</td>
<td>Required</td>
</tr>
<tr>
<td>020</td>
<td>Staff Member Identification Number</td>
<td>Optional</td>
</tr>
<tr>
<td>021</td>
<td>Manufacturer and Catalog Number: Items Other Than Containers</td>
<td>Not applicable</td>
</tr>
<tr>
<td>022</td>
<td>Lot Number: Items Other Than Containers</td>
<td>Not applicable</td>
</tr>
<tr>
<td>023</td>
<td>Compound Message</td>
<td>Not applicable</td>
</tr>
<tr>
<td>024</td>
<td>Patient Date of Birth</td>
<td>Optional</td>
</tr>
<tr>
<td>025</td>
<td>Patient Hospital Identification Number</td>
<td>Not applicable</td>
</tr>
<tr>
<td>026</td>
<td>Expiration Month and Year</td>
<td>Optional</td>
</tr>
<tr>
<td>027</td>
<td>Infectious Markers</td>
<td>Required</td>
</tr>
<tr>
<td>028</td>
<td>Product Consignment</td>
<td>Optional</td>
</tr>
<tr>
<td>029</td>
<td>Dimensions</td>
<td>Optional</td>
</tr>
</tbody>
</table>
### Number  Data Structure Name  Modulo 37-2  
<table>
<thead>
<tr>
<th>Number</th>
<th>Data Structure Name</th>
<th>Keyboard Entry</th>
<th>Check Character [K]</th>
</tr>
</thead>
<tbody>
<tr>
<td>030</td>
<td>Red Cell Antigens with Test History</td>
<td></td>
<td>Not applicable</td>
</tr>
<tr>
<td>031</td>
<td>Flexible Date and Time</td>
<td></td>
<td>Optional</td>
</tr>
<tr>
<td>032</td>
<td>Product Divisions</td>
<td></td>
<td>Optional</td>
</tr>
<tr>
<td>033</td>
<td>Processing Facility Information Code</td>
<td></td>
<td>Optional</td>
</tr>
<tr>
<td>034</td>
<td>Processor Product Identification Code</td>
<td></td>
<td>Optional</td>
</tr>
<tr>
<td>035</td>
<td>MPHO Lot Number</td>
<td></td>
<td>Optional</td>
</tr>
<tr>
<td>036</td>
<td>MPHO Supplemental Identification Number</td>
<td></td>
<td>Optional</td>
</tr>
<tr>
<td>037</td>
<td>Global Registry Identifier for Donors</td>
<td></td>
<td>Required</td>
</tr>
<tr>
<td>038</td>
<td>Single European Code (SEC)</td>
<td></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### 5.3 Bar Code Text

Bar code text is the interpretation of the data content text (the data content of the bar code) in terminology meaningful to the user (see Figure 5, page 17). Bar code text is nationally defined to allow for differences in language, regulatory requirements, and preferences.

Particular font sizes and types are not specified for bar code text but designers shall ensure clarity of all text and use larger fonts to emphasize critical information. The font chosen should clearly differentiate between similar characters (e.g., O and 0; I and 1).

Bar code text corresponding to information content of electronically readable information shall appear on the label. If this is not possible (e.g., on a small syringe label or information corresponding to the Red Cell Antigen with Test History data structure), appropriate regulations and requirements of standard setting organizations should be consulted to determine what information shall appear on the affixed label and what information may be on an attached label or accompanying documentation.

#### 5.3.1 Facility

The name and the address of the facility that corresponds to the Facility Identification Number (FIN) may appear beneath the data content text for the DIN.

**Figure 6 Upper Left Quadrant Facility Bar Code Text**
5.3.2 Blood Groups [ABO and RhD] [Data Structure 002]

ABO status may be printed black on white if RhD positive, and outline black on white if RhD negative, but this is not required.

RhD status for the Blood Groups [ABO and RhD] bar code text may be printed black on white if RhD positive; white on black if RhD negative, but this is not required.

Figure 7 Upper Right Quadrant for Designated or Directed Donation

Figure 8 Upper Right Quadrant for Autologous Donation
Figure 9 Upper Right Quadrant for “Non-Specified” Donation

Figure 10 Optional Differentiation of RhD Negative Units

5.3.3 Product Descriptions [Data Structure 003]

Where space permits, the Class, Modifier, and Attributes (except default Attribute variables) text shall be printed on the label. See Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions for default attribute variables.

Product description bar code text should be printed with the Modifier proportionally smaller than the Class name and Attribute(s) text should be proportionately smaller than Modifier text.

Figure 11 Relative Text Size of Class, Modifier, and Attributes

5.3.4 Dates [Data Structures 004, 005, 006, 007, 008, 009, 024]

Dates shall be printed in compliance with ISO 8601-2004 extended format or in the format day — month — year. In the latter case, the day shall be numerical,
the month alphabetical, using a three-letter abbreviation. The year shall be a four-digit numerical representation.

Expiration Date:

2017-03-17
OR
17 MAR 2017

*Note:* Abbreviations for month shall comply with relevant national standards where applicable.

Times shall be printed based on a twenty-four hour clock with a colon placed between the hours and minutes.

Time:
15:15

5.3.5 Month-Year [Data Structure 026]

The date shall be printed in compliance with ISO 8601-2004 extended format or in the format month — year. In the latter case, the month alphabetical expression shall use a three-letter abbreviation. The year shall be a four-digit numerical representation.

2017-03
OR
MAR 2017

*Note:* Abbreviations for month shall comply with relevant national standards where applicable.

5.3.6 Special Testing, Red Blood Cell Antigens [Data Structures 011, 012, and 013]

*Note:* Data Structure 011 has been retired.

National guidelines should be consulted for specific information regarding the printing of this bar code text. As an example, rather than the complete red blood cell phenotype associated with Data Structure 012, the bar code text may read:

Phenotype provided in accompanying documentation.

or some similar phrase. Alternatively, the antigen profile relevant to the recipient may be emphasized with the notation that the remainder of the interpretation of the bar code is presented elsewhere.

5.3.7 Donor Identification Number [Data Structure 019]

The Facility Identification Number comprises the first five characters of the 21-character Donor Identification Number.
The next 16 characters are defined by the facility. When the facility-defined portion of Donor Identification Number is less than 16 digits, it shall be padded with zeros at the beginning of the actual number. If desired, software developers may routinely strip off padding and present the actual number when printing the number or displaying the number on a screen.

For example:

In Denmark, a possible data content string would be: 000000 080656 1665, a ten (10)-digit number with six (6) leading zeroes as padding. This number might display on a screen as 080656 1665.

In France, it might be: 0 1 56 05 18 033 087 78, a fifteen (15)-digit number with a single (1) leading zero as padding. This number might display on the screen as 1 56 05 18 033 087 78.

5.4 Additional Text

Additional text is defined as text not associated with a bar code. Additional text includes warnings (e.g., “This product may transmit infectious agents”) and information such as Volunteer Donor or a platelet count on a platelet apheresis product.

The placement of this information is not standardized internationally, but may be standardized nationally. Users should review national documents for additional information.

If not nationally defined, facilities may add additional text to the label where space permits and there is need.

Particular font sizes and types are not specified for additional text but designers shall ensure clarity of all text and use larger fonts to emphasize critical information.
6 Label Examples

Figure 12 represents the minimum amount of ISBT 128 information that shall appear on the base label. Manufacturers may include additional information such as:

- icons
- user friendly catalog numbers and lot numbers
- the intended use of the bag in text (e.g., For Platelet Storage)
- appropriate warnings (e.g., Not Suitable for Storage of Red Blood Cells or the number of days a platelet product can be stored within the container)

Figure 12 Standard Base Label
Figure 13 represents the minimum amount of ISBT 128 information that shall appear on a small base label. Manufacturers may include additional information such as:

- icons
- user friendly catalog numbers and lot numbers
- the intended use of the bag in text (e.g., For Platelet Storage)
- appropriate warnings (e.g., Not Suitable for Storage of Red Blood Cells or the number of days a platelet product can be stored within the container)
Figure 14  Final Label Showing Manufacturer’s Data Content Information

<table>
<thead>
<tr>
<th>Barcode</th>
<th>Data Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>W0000 15 123456</td>
<td>Accurate Blood Center Anywhere, World</td>
</tr>
<tr>
<td>E0291V00</td>
<td>VOLUNTEER DONOR</td>
</tr>
<tr>
<td>0150312359</td>
<td>Expiration Date 31 JAN 2015</td>
</tr>
<tr>
<td>N0008</td>
<td>Negative for antibodies to CMV</td>
</tr>
<tr>
<td>1FE1234567</td>
<td>RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED</td>
</tr>
<tr>
<td>4R12345678</td>
<td>From 450 mL CPD Whole Blood Store at 1 to 6 °C</td>
</tr>
</tbody>
</table>

Rh POSITIVE
Note: The exact location of a 2-D symbol, when it is the only symbol on a label, is currently under consideration. A proposal has been approved that will locate the symbol on the upper half of the label. When a 2-D symbol containing information for multiple data structures is present with linear bar codes, it is considered a “transition label”. Transition labels allow facilities time to develop the software capacity to read and interpret 2-D symbols. In this case, the location of the 2-D symbol may be nationally-defined. In discussions of Technical Advisory Groups, the suggestion has been made to place such a 2-D symbol as close as possible to its eventual location. Transition labels are not standardized and facilities may select a different location.

Figure 17 Platelet Apheresis Label
7 International Label Examples

This section contains example labels adapted from sample labels provided by users.

Figure 18 Denmark (Danish)

Figure 19 Canada (French/English)
Figure 20  Finland (Finnish)

Figure 21  Portugal (Portuguese)
# 8 Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Content</td>
<td>The characters in a data structure that encode the desired message (a Product Code, for example).</td>
</tr>
<tr>
<td>Data Identifier</td>
<td>The first two characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined. (The Donation Identification Number is an exception to this rule. The second character of the data identifier can never be dropped because it is also part of the data content. See ISBT 128 Standard Technical Specification.)</td>
</tr>
<tr>
<td>Data Structure</td>
<td>Defined format for information transfer within ISBT 128. The data structure defines the data identifiers, the data content, and the means to encode specific information within the data content. It specifies the context and structure and provides the links to the appropriate reference tables for conversion of codes to meaningful information. Information content comprising the data identifier and data content. When a data structure is represented as a bar code, the term data structure does not include the symbology-specific and always present start and stop codes, the modulo 103 check character, or any specified control characters.</td>
</tr>
<tr>
<td>Label</td>
<td>An independent entity that may carry one or more bar codes and also provides eye-readable information about the product.</td>
</tr>
<tr>
<td>Affixed Label</td>
<td>A label that adheres in physical contact with the product container.</td>
</tr>
<tr>
<td>Attached Label</td>
<td>A label that is fastened securely to the product container by means of a tie tag or comparable alternative.</td>
</tr>
<tr>
<td>Accompanying Documentation</td>
<td>Documentation containing product information that is together with the product, or is available to the appropriate individual(s) electronically, but is not affixed or attached to the product.</td>
</tr>
<tr>
<td>Base Label</td>
<td>The label placed on a container by a manufacturer. It carries the manufacturer’s identity, the catalog number of the container (or container set), and the lot number of the container (or container set) encoded as ISBT 128 data structures.</td>
</tr>
<tr>
<td>Final Label</td>
<td>Labeling as it appears on a product ready for release to another entity or for administration to a recipient. (A different entity in this context means an institution with different ownership/leadership than the facility that labeled the product.)</td>
</tr>
</tbody>
</table>
## Terminology Used in Donation Coding

Donation Identification Number + Flag Characters + Check Character

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donation Identification Number (DIN)</td>
<td>A thirteen-character code that identifies products from a single donation event. This identifier allows each donation event to be uniquely identified globally for a period of 100 years. The DIN comprises three elements: the Facility Identification Number (FIN), DIN year code, and DIN sequence number.</td>
</tr>
<tr>
<td>Facility Identification Number (FIN)</td>
<td>A five-character alphanumeric code assigned to facilities licensed to use ISBT 128 by ICCBBA. The code provides a globally unique identifier that is an essential element of a Donation Identification Number.</td>
</tr>
<tr>
<td>DIN Year Code</td>
<td>A two-character numeric code assigned by the facility that is used to ensure uniqueness of a Donation Identification Number for a period of 100 years.</td>
</tr>
<tr>
<td>DIN Sequence Number</td>
<td>A six-character numeric code assigned by a facility as part of the Donation Identification Number to ensure unique identification of each donation event.</td>
</tr>
<tr>
<td>Flag Character</td>
<td>A two-character code that is an element of the Donation Identification Number Data Structure. Flag characters can be used to identify the specific instance of a DIN label (e.g. identify a primary collection bag, a sample tube, or a donation record) and may be used to facilitate process control. They are not part of the unique 13-character Donation Identification Number (DIN) of the product.</td>
</tr>
<tr>
<td>Check Character</td>
<td>A character used to ensure the accuracy of the data in a data structure when such data is entered manually via a keyboard. The value is calculated by applying an algorithm to the appropriate data (see ISBT 128 Standard Technical Specification for details). The check character is most often used in association with the Donation Identification Number but may be used with some other ISBT 128 data structures. It is not part of the unique 13-character Donation Identification Number (DIN) of the product.</td>
</tr>
</tbody>
</table>
## Terminology Used in Product Coding

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Code</strong></td>
<td>An eight-character ISBT 128 code that comprises the Product Description Code, a Donation Type Code, and a Division Code. This code makes each product from a collection unique. This is the Data Content for the Product Code Data Structure.</td>
</tr>
<tr>
<td><strong>Product Description Code</strong></td>
<td>A five-character alphanumeric code assigned to each unique product type listed in the ISBT 128 database.</td>
</tr>
<tr>
<td><strong>Donation Type Code</strong></td>
<td>A one-character alphanumeric code indicating the type of donation (e.g., autologous, directed, or designated).</td>
</tr>
<tr>
<td><strong>Division Code</strong></td>
<td>A two-character code that uniquely identifies multiple products with the same Product Description Code and Donation Identification Number.</td>
</tr>
</tbody>
</table>

### Text

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data content text (previously called eye-readable text)</strong></td>
<td>The eye-readable representation of the data characters in a linear bar code. For linear bar codes, it is printed left justified immediately below the bar code, unless otherwise specified.</td>
</tr>
<tr>
<td><strong>Bar code text</strong></td>
<td>The interpretation of the data content of the bar code.</td>
</tr>
<tr>
<td><strong>Additional text</strong></td>
<td>All other information on the label that is not associated with a bar code.</td>
</tr>
</tbody>
</table>
Illustration of the Terms Data Content Text, Bar Code Text, and Additional Text

- **Data content text (previously called eye readable text)**
- **Bar code text**
- **Additional text**

**ACCURATE BLOOD CENTER**
Anywhere, Worldwide

**VOLUNTEER DONOR**

**RED BLOOD CELLS**
ADENINE-SALINE (AS-1) ADDED
LEUKOCYTES REDUCED

From 500 mL CPD Whole Blood
Store at 1 to 6°C