

This is an electronic version of a booklet available from ICCBBA, Inc. To obtain the booklet please contact to ICCBBA, Inc office.

An Introduction to *ISBT 128*

2nd edition, 2002

Revised by

Paul Ashford

Chairman

Middle East and Europe Technical Advisory Group

ICCBBA, Inc

This document may be distributed freely provided that the copyright statement remains an integral part of the document or any quoted portion.

Copyright Notice

It may also be translated, without written permission, provided that the translation indicates that it is a translation from an ICCBBA, Inc copyrighted document and that ICCBBA, Inc is not responsible for the accuracy of the translation.

Those wishing to implement *ISBT 128* must register with ICCBBA, Inc and pay the annual license fee.

The English language version of the *ISBT 128 Application Specification* is the only official version. Unless licensed by ICCBBA, Inc, implementation of *ISBT 128*, or the use of a translation of all or part of the English language version of the *ISBT 128 Application Specification* is a violation of copyright and can be punished under international law.

An Introduction to *ISBT 128*

Preface

A great deal of important information is presented on the label of a blood, hematopoietic progenitor (stem) cells or tissue product. The information varies from country to country according to licensing regulations, language differences and local practice but, in all cases, it is essential that it is recorded accurately, transferred correctly, and that critical items such as the blood groups, expiration date and product description are clearly understood by medical personnel transfusing or transplanting the product. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

In today's world of multinational disaster relief programs, military operations, and international databases of patients and donors, blood, stem cells or tissue collected in one country may be used in another. In such situations the criteria identified above still have to be met.

Increasingly, facilities dealing with the collection and transfusion/transplantation of blood, stem cells and tissue operate sophisticated computer systems to enhance safety and efficiency. Transfer of information between such facilities by electronic means ensures accuracy, but can only be effectively achieved in a global context by use of internationally agreed standards for both the information and its delivery mechanism.

ISBT 128 provides such an international standard. It specifies:

- a donation numbering system that ensures globally unique identification;
- the information to be transferred, using internationally agreed reference tables;

An Introduction to *ISBT 128*

- an international product reference database;
- the data structures in which this information is placed;
- a bar coding system for transfer of the information on the product label;
- a standard layout for the product label;
- a standard reference for use in electronic messaging.

The standard, originally accepted by the ISBT Council in 1994, has gained widespread acceptance and is now endorsed by the American Association of Blood Banks, European Plasma Fractionators Association, European Blood Alliance and the US Food and Drug Administration. By the end of 2001, facilities in 28 countries across five continents were registered to use *ISBT128*, and this number continues to grow.

An Introduction to *ISBT 128*

ISBT 128 provides for unique identification of any donation worldwide. It does this by using a 13 character identifier built up from three elements, the first identifying the collection facility, the second the year, and the third a sequence number for the donation. For example:

G151700600001⁹

4

where:

G1517 identifies the collection facility (in this case Welsh Blood Service, Wales, United Kingdom);
00 identifies the collection year as 2000;
600001 is the sequence number of the donation assigned by the collection facility.

The two digits printed vertically allow individual bar codes in a number set to be discretely identified hence providing an option to add process control into the collection process.

An additional character is enclosed in a box at the end of the identifier. This is a checksum character used when a number is entered into a computer system through the keyboard to verify the accuracy of the keyboard entry.

Collection facility codes are assigned by ICCBBA, Inc, who maintain a database of all registered facilities on their Website.

***Unique
Donation
Identification***

An Introduction to *ISBT 128*

In addition to the donation identifier, many other pieces of important information need to be provided with a blood, stem cells or tissue donation. *ISBT128* provides data structures for the following:

Data Structures for Critical Information

ABO and Rh(D) Blood Groups;

Product Description (see next section);

Type of Donation (Volunteer, Directed, Autologous, *etc*);

Expiration Date and Time;

Red Cell Phenotyping Information;

HLA Typing Information;

Collection Container Catalog and Lot Number;

as well as a number of other data structures covering such areas as donor and staff member identification.

An Introduction to *ISBT 128*

Product Description Databases

ISBT 128 provides a comprehensive and highly flexible system for assigning product codes. New codes are built by specifying a combination of a component class, a modifier, core conditions, and a range of attributes. A unique combination of these values is assigned a product code number that becomes incorporated into the *ISBT 128* product description database table, ensuring that the product will be accurately identified in any country in the world that is using *ISBT 128*.

Examples taken from the database tables follow:

Component Class: Red Blood Cells
Modifier: None
Core Conditions: anticoagulant CPDA-1; original
volume 450 mL; storage
conditions refrigerated
Attribute: Irradiated

has product code E0206.

Component Class: HPC, Cord
Modifier: Cryopreserved
Core Conditions: DMSO; volume not specified;
storage conditions <-120 C
Attributes: Open
6% HES/5% DMSO

has product code S0017.

Component Class: Cancellous Bone Peg
Modifier: Freeze Dried
Attributes: Irradiated
Single

has product code T0055.

Note: Core Conditions are not used in coding tissues.

An Introduction to *ISBT 128*

In addition to specifying the requirements for the electronic coding of information, *ISBT 128* provides a standard labeling format that ensures a consistent layout of product labels with the bar codes, and critical eye readable information such as blood groups, product description and expiration date, appearing in fixed positions on the label. This reduces the risk of confusion when product from multiple sources is being used.

Product Labeling

An *ISBT 128* label is illustrated on the next page.

An Introduction to *ISBT 128*

An *ISBT 128* Label

1  W1234 02 1234564 	 5100	2
Accurate Blood Center Anywhere, Worldwide		 Rh(D) Positive
<small>Properly Identify Intended Recipient See Circular of Information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents.</small>		
Rx only VOLUNTEER DONOR		
3  E0291V00	 0022062359	4 Expiration Date
RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED		JULY 31 2002
From 450 mL CPD Whole Blood		Special Testing bar code goes here

1 Donation Identification Number	2 ABO/Rh(D) Blood Groups
3 Product Code	4 Expiration Date and Time

*Boxes around bar codes indicate actual size of
bar codes; there are no boxes on the actual label*

An Introduction to *ISBT 128*

The data structures specified in *ISBT 128* are simply the formal definitions of how information is to be identified and electronically presented. These definitions allow software developers to provide the interfaces necessary to output and input messages containing *ISBT 128* data structures. When used in bar coding, each data structure commences with specified data identifier characters. These ensure that there can be no ambiguity arising from a user scanning the wrong bar code on a label.

The data structures also provide a standard reference that allows transfusion and transplantation information to be encoded within electronic messages such as HL7.

ISBT 128 Data Structures

An Introduction to *ISBT 128*

Bar coding in blood transfusion has traditionally been based on the *ABC Codabar* standard. This symbology, which is restricted to coding only numbers and a few additional symbols, has been superseded by newer systems that allow coding of a greater range of characters, provide enhanced security, and have a higher density. *ISBT 128* uses Code 128, a well established symbology. Code 128 permits over 100 different characters to be encoded, provides greater security by including internal integrity checking, and is designed to support increased data density thus allowing more information to be encoded in a shorter bar code.

The *ISBT 128* standard specifies how Code 128 bar codes are used in product labeling to transmit information encoded in *ISBT 128* data structures.

The Bar Coding System

An Introduction to *ISBT 128*

ICCBBA, Inc has the responsibility for the management, development and distribution of the *ISBT 128 Application Specification* and databases. It maintains a permanent office to manage the registration of facilities, updating of reference tables and databases, and development of additional functionality. It supports two technical advisory groups made up of experts from both the transfusion/transplantation community and relevant manufacturers.

Blood/tissue collection facilities, and manufacturers of equipment or software that uses *ISBT 128*, are required to register with ICCBBA, Inc and pay a registration and an annual license fee. Registered organizations obtain access to all ICCBBA, Inc documents and databases.

For further information on *ISBT 128* visit the ICCBBA, Inc Website at <http://www.iccbba.com>.

***The Role of
ICCBBA, Inc***

The current members of the Editorial Board are:

Paul Ashford

Chairman, Middle East and Europe Technical Advisory
Group

Suzanne Butch

Chairman, The Americas Technical Advisory Group

Pat Distler

Vice-Chairman, The Americas Technical Advisory
Group

Jørgen Georgsen

Former Chairman, European Technical Advisory Group

Patti Larson

Former Chairman, North American Technical Advisory
Group

ICCBBA, Inc
publications are
edited by the
Executive
Director

Edwin Steane

assisted by an
Editorial Board