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# Introduction to the ISBT 128 Labelling Standard for Blood Components

## Hospital IT Perspective

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## What is ISBT 128?

"An international standard for the transfer of information associated with tissue transplantation, cellular therapy and blood transfusion.

It provides for a globally unique donation numbering system, internationally standardized product definitions and standard data structures for bar coding and electronic data interchange."

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## ISBT 128 Technology Standard

- Much more than a new label layout
- Provides standard information and layout for blood component labels
- Defines data structure for information appearing on labels
- Defines data identifiers for bar codes used in blood component labelling & data transfer
- Defines technical details for the bar code
- Technical Specifications document available on ICCBBA website

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# ISBT 128
# Implementation

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# ISBT 128 Implementation

- Canadian Blood Services plans to implement ISBT 128 by May 2009
- Will require changes to Canadian Blood Services blood management system (PROGESA)
- Many hospitals may also be required to update their systems
- Will require changes to SOPs, forms and labels
- Implementation timelines announced April 9, 2008 to allow hospitals adequate notice for successful implementation

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# ISBT 128 Data Structures and Identifiers

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# ISBT 128 Data Structures

- Data structures define the way information is presented in ISBT 128.
- Data structure can be incorporated into many information delivery systems e.g. bar codes, electronic messages, RFID tags
- Donation Number and Product Code are just two of many ISBT 128 data structures
- When ISBT 128 data structure appears in bar code format the data characters are printed in eye readable format immediately beneath the bar code

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# ISBT 128 Data Structures

- The data structures and identifiers for the ISBT 128 Donation Number, Product Codes and Blood Groups are summarized in this presentation
- Refer to the current version of the *ISBT 128 Standard Technical Specification* at ICCBBA.org for a complete description of all the ISBT 128 data structures.

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# Data Identifiers

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## ISBT 128 Data Identifiers

- Data identifiers define the type of information the bar code contains (e.g. Product Code, ABO/Rh Blood Group)
- Each bar code on a blood product will begin with 2 data identifier characters (except Donation Number)
- The first character will always be "=" or "&". By international agreement, these characters specify an ISBT 128 data structure
- Reduces error since data cannot be entered into an incorrect field

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## Data Identifiers for Major Bar Codes

| | |
|---|---|
| = | Donation Number |
| =% | Blood Group (ABO/Rh) |
| =< | Product Code |
| =* | Collection Date |
| => | Expiration Date |
| &> | Expiration Date & Time |
| =\ | Special Testing: Red Cell Antigen |
| &( | Special Testing: General |

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# Donation Number

## ISBT 128 Data Structure 001

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# Donation Number Data Structure

## =appppyynnnnnnff

| | |
|---|---|
| = | Data identifier |
| a | Country Code |
| pppp | Facility Code |
| yy | Year of Collection |
| nnnnnn | Serial Number |
| ff | Flag Character (NOT part of Donation Number |

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# ISBT 128 Donation Number

C0500  07  123456  21  Q

- 13 Digit Donation Number
  - Facility identification code (global)
  - Year indicator (won't repeat for 100 years)
  - Sequential number (999,999/facility/year)
- Additional elements – not part of DN
  - Flag characters
  - Manual entry check character

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# ISBT 128 Donation Number

- Donation Number data structure provides unique identification of donation world wide for 100 years.
- Comprised of 13 data characters.
- Included in the data structure are 2 flag characters and a Keyboard Entry Check Character. These are **NOT** part of the Donation Number

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# Donation Number – Flag Characters

- Flag characters are NOT part of the Donation Number
- Are used for process control
- Will NOT be the same on component label as on label applied at collection or what is printed on packing slips
- Are encoded in the bar code and printed on labels and reports

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# Keyboard Entry Check Character

- Keyboard entry into computer system should be strongly discouraged.
- When keyboard entry is necessary, computer software should be designed to recognize manual entry and require entry of Check Character for verification of data entered.
- Check character required for manual entry of long numbers (e.g., donation number and red cell antigen testing)
- Not in the bar code because it's meant to check KEYBOARD entry
- May want to record in manually written records

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# ISBT 128 Product Codes and Definitions

## ISBT 128 Data Structure 003

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# ISBT 128 Product Codes & Definitions

8 digit product code data structure includes donation type and allows for definition of additional information

- 5 digit product code which defines
    - Core conditions – e.g. anticoagulant, volume, storage conditions
    - Component Class - e.g. Red Blood Cells, Platelets
    - Modifiers – e.g. washed, thawed
    - Attributes – e.g. irradiated, residual white count, low platelet count
- 3 digits define donation type and divisions/splits

Product Code Database maintained by ICCBBA. All products distributed nationally/internationally must have a standard ISBT 128 product code.

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# Product Code Data Structure

## =<αooootds

| αooooo | product code |
|--------|--------------|
| t | donation type (e.g. Volunteer, Directed) |
| d | divisions A0, B0, |
| s | second level divisions Ba, Bb, Bc |

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# Product Code Structure

## 1st Character

- Indicates Type of Donation
  - E & F:  Blood
  - S:  HPC (Stem cells)
  - T:  Tissue
  - A-D reserved for internal or national use; not defined internationally

E0150V00

# Product Code Structure

## 2nd Through 5th Characters

- Identifies product
- Sequentially assigned--unstructured

E0150V00

RED BLOOD CELLS/CPD/from 450 mL whole blood/refrig

# Type of Donation

## 6th Character

- Sixth character identifies donation type

E0150(V)00

V = Volunteer Donor

1= Autologous Use Only

2= Directed Use Only

X= Autologous Biohazard

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# Divisions/Splits

E0150V(00)    (Original  product)

RED BLOOD CELLS/CPD/from 450 mL whole blood/refrig

E0150V(A0)   (Divided from original –e.g. pediatric)

RED BLOOD CELLS/CPD/from 450 mL whole blood/refrig/Divided  (closed system)

E0150V(Aa)(Divided from first level division (e.g. syringe)

RED BLOOD CELLS/CPD/from 450 mL whole blood/refrig/Divided  (closed system)

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## Product Codes – Codabar vs ISBT 128

- No one to one relationship between Codabar & ISBT 128. Example - CPD Whole Blood:

| Codabar Product Code | 00150 |
|---|---|

| ISBT 128 Product Codes include: | |
|---|---|
| Whole Blood \|CPD/450mL/refg | E0009 |
| Whole Blood \|CPD/450mL/refg/Open | E0013 |
| Whole Blood \|CPD/500mL/refg | E0023 |
| Whole Blood \|CPD/500mL/refg/Open | E0027 |

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## Example of ISBT 128 Product Code

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

    ISBT PRODUCT CODE = E0206

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# ISBT 128 Blood Groups

## ISBT 128 Data Structure 002

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## Blood Groups

- Indicates the blood groups (ABO and Rh) or a product
- *Optionally,* may display information indicating
  - Donation type (e.g. Autologous, Directed)
  - Status of donation or collection (e.g. Biohazard, Research Use)
- *Optionally,* may encode information for C, c, E, e, K or Miltenberger phenotypes

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# Blood Groups Data Structure

## =%ggre

=%     Data identifier

gg     ABO & Rh blood group and type of donation or collection information

r      Optional.  If used provides Rh, Kell phenotype

e      Reserved for future use.  Value always set to 0 (zero)

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# ISBT 128
# Standard Label

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# ISBT 128 Standard Label

- ISBT 128 blood product label is divided into four quadrants
- Regardless of site of collection globally, the bar codes should be placed in same relative positions on product label
- The ISBT 128 Standard defines the placement of the following bar codes:
  - Donation Identification Number
  - ABO/Rh Blood Group
  - Product Code
  - Collection Date
  - Special Testing
- The Canadian Blood Services label design is not finalized and the label will not be exactly as shown in the following diagrams

# Standard ISBT 128 End Label Format

**Unique Donation Number & Static Text**

- 13 digit unique Donation Number (plus flag & manual check characters)
- Blood centre name, address, licence number
- Static legal text

**Product Code & Description**

- Includes donation type (e.g. autologous, directed)
- Includes divisions (e.g. for pediatric use)
- Includes modifier and attribute information (e.g. washed, irradiated)



C0000 07 123456 Q
Blood Agency Name
Blood Agency Address
Establishment License no

Volunter Donor information, Transmissible Disease risk
statement and reference to Circular of Information.

5100

**0**
**Rh POSITIVE**

E0361V00

**RED BLOOD CELLS**
LEUKOCYTES REDUCED
Adenine-Saline (AS-3)Added

From 450 mL CP2D Whole Blood
Store at 1 – 6° C

0073492359
15 Dec 2007 23:59

Expiration Date

6399999993999999199 M   CMV –

C+ c– E– e+ K– Jka –

# Standard ISBT 128 End Label Format



**Blood Group**
- More prominent
- May indicate intended use
- May indicate Rh, Kell phenotypes

**Expiry Date**
- Time also shown if other than midnight

**Special Testing/ Characteristics (Optional)**
- Red Cell Phenotype
- CMV status
- Special information, e.g. antibodies present
- In eye readable and, optionally, bar code format

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# Extended ISBT 128 Label

- Canadian Blood Services plans to use an extended ISBT 128 label for a transition period to allow hospital systems time to become ISBT 128 compliant
- Duration of transition period has not yet been determined
- Extended portion of label has critical information (Donation Number, Product Code, Blood Group, Facility Code, Expiration) in Codabar format
- Similar format to that implemented by Héma-Québec (refer to CL #2007-24)

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# ISBT 128 Impact on Hospitals

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## Impact on Hospitals

Things to consider:
- – Project planning and communication
- – Work instruction and form revision
- – Training of Transfusion Service and Clinical Staff
  - • Anyone who handles blood components need training to the changes to the label
- – Software preparation & validation
  - • Version upgrade may be required
- – Hardware requirements – bar code scanners, printers
- – Impact on other systems
  - • Medical Records, report generating systems
- – Registration with ICCBBA
  - • Information available at www.iccbba.org

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# Communication is Key!

- Communication is key to a successful ISBT 128 Implementation
- Anyone who handles blood components or enters/ records donation information is potentially impacted
  - Lab staff
  - Systems administrators
  - Logistics staff
  - Nursing staff
  - Physicians
  - Patient records office
  - Hospital education office
  - Senior management
  - Outside agencies

# Canadian Blood Services Communications Tools

- Customer Letters
  - CL #2008-06 issued to provide Canadian Blood Services planned implementation date
  - Additional letters will be issued when significant events are planned

- Consultation with Hospital Liaison Specialists
- Presentations

# Canadian Blood Services Communications Tools

- Internet
  - Information and links to be posted on transfusionmedicine.ca
  - Sample Implementation Readiness Checklist
  - Information Powerpoint presentations
  - Timelines
  - Sample labels
  - Feedback tool for questions – isbt128@blood.ca
  - Database of frequently asked questions

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# Canadian Blood Services Implementation Support

Support will be provided including:
  - Adequate and timely information and updates on implementation timelines/plans
  - Detailed information on label configuration
  - Sample labels
  - Product codes
  - Facility codes
  - Other information required for successful implementation

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**For more information on ISBT 128 implementation at Canadian Blood Services:**
www.transfusionmedicine.ca

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