

“Putting Patient Safety First with ISBT 128 Compliance”



APPLICATION WHITE PAPER



Copyrights

©ZIH Corp. All product names and numbers are Zebra trademarks, and Zebra and the Zebra head graphic are registered trademarks of ZIH Corp. All rights reserved. All other trademarks are the property of their respective owners.

Executive Summary:

The multinational distribution of blood products, tissues and stem cells has transformed the nature of the technology needed in blood banking. More complex information and improved electronic means for data transfer and data integrity are at the core of our current need to adopt and implement ISBT 128. The new standard will help eliminate both unacceptable deaths and errors during the collection and transfusion of blood and blood products.

As the U.S. healthcare industry is rapidly expanding the use of Information Technology (IT) to improve patient outcomes, the blood banking community has adopted the use of ISBT 128 bar coding. ISBT 128 is an international information standard for identifying, labeling and processing human blood, tissue, organs and cellular products.

Blood banking pioneered the use of bar coding in healthcare in the 1970s with the use of the CODABAR symbology. Now years of effort by the International Council for Commonality in Blood Banking Automation (ICCBBA) have culminated in the publication of the U.S. Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128 (see www.iccbba.org). The implementation of ISBT128 is supported by the FDA and will be required for accreditation by the AABB after April 30, 2008.

Regulatory Components:

The worldwide ISBT128 standard has now been accepted for use by the FDA, Center for Biologics Evaluation and Research (CBER). The amended 21 CFR 606.121(c) (13) requires the use of “machine-readable” symbols as of April 2006.

The AABB has reaffirmed its commitment to enhancing patient safety by mandating the use of ISBT 128 (see: Oct 12, 2005 AABB Bulletin #05-12) for continued accreditation. Blood Collection Centers and Transfusion Services must adhere to the AABB timeline:

- Nov 1, 2006: a written plan for ISBT 128 implementation must be in place;
- May 1, 2008: ISBT 128 must be fully implemented.

In the U.S., 46% of all donated blood is collected by the American Red Cross (ARC). They have stated: “In accordance with the timeline, the ARC is planning to implement ISBT 128 bar code labeling concurrently with the deployment of a new manufacturing system called BioArch.”

Advantages of ISBT 128:

1. Complies with all FDA drug regulations and AABB mandates
2. Provides unique Donor Identification Number (DIN) worldwide for 99 years with no duplication; includes country code and year of collection
3. Requires a self-checking bar code, which contains more usable data, manual check digit and assured traceability
4. Enables improved process control and data exchange
5. Facilitates point-of-care transfusion verification of blood units with patient
6. Reduces misread errors, risk and liability
7. Formalizes a product code structure maintained globally by the ICCBBA
8. Supports international exchange of blood, tissues and stem cells
9. Provides for concatenation... scanning of two adjacent bar codes as a single message; e.g. DIN and ABO; Product Code and Expiration
10. Specifies data structures that allow for future use of 2-D codes and RFID

Getting Started with ISBT 128 Standards and Registration

The global ISBT 128 initiative to provide a standard for identification labeling of human blood, tissue and organ products was developed over the past 12 years by and is being managed by the ICCBBA.

As a first step, all facilities intending to use ISBT 128 to comply with FDA and AABB requirements must register and pay their registration fees to the ICCBBA. Blood or Cellular Therapy organizations that assign Donation Identification Numbers (DIN) and tissue facilities that do the same will be issued unique worldwide Facility Identification Numbers (FIN) when their registration fee is paid (see registration and licensing area at www.iccbba.com).

ICCBBA operations are funded entirely from licensing fees collected from ALL facilities using ISBT 128, including vendors like Zebra® and Digi-Trax who provide hardware, software and/or label media that adhere to ISBT128 standards.

By registering, you will be entitled, with your password, to view all pertinent documents, including the U.S. Standard, all databases, validation tools, product code description look-up, and more. The AABB “Implementation Plan” is available from the AABB (\$20. for both members and non-members at www.aabb.org). You may order stock #043005, revised: June 2004, this includes both a timeline and Gantt chart.

More information and resources are available in the Implementation Plan or at Digi-Trax (www.digi-trax.com) salient data, test labels, webcast demonstrations of on-demand printing capabilities and much more material related to ISBT 128 label printing, software, hardware, supplies and support can be provided. In addition, we suggest you consult these additional resources:

- The Blood Bank Talk Forum: www.bloodbanktalk.com
- FAQ for bar code labeling: www.fda.gov/cber/index.html
- The AABB: www.aabb.org
- The ICCBBA: www.iccbba.com
- Guidance for Industry: <http://www.fda.gov/cber/gdlns/unilabblld.pdf>

The ISBT 128 Label Layout:

ISBT 128 changes the Base Label size from 4" x 3" to 4" x 4" with four 2" x 2" quadrants or combinations for convenient on-demand labeling. The manufacturers' bag labels will be 4" x 4 1/4" to accommodate viewing of their ID and Lot Number (e.g. see www.BaxterTransfusionTherapies.com).

Illustrated below: the various label configurations available for ISBT128

Donor Identification Number (DIN)
Includes Country/
Center ID, Collection
Year, Serial Number,
Flag Digits & Manual
Check Character

**Single (2" x 2")
ABO quadrant**
80 ABO types, plus
Donation ID types

**Combination (2" x 4")
with Expiration Date &
Time plus CMV testing**

**Full Face Label (4" x 4")
with cut out to view
original DIN per
FDA requirement**

**Facility/Product
label (2" x 3.23")**

**Combination (4" x 2")
for all Product Codes
with corresponding
Expiration Dates,**

The diagram shows several examples of these labels. A small label shows a barcode with 'W1234 06 123456' and a '1' in a box. A 2x2 quadrant label shows 'AB' and 'Rh NEGATIVE'. A 2x4 label shows 'AB' and 'Rh POSITIVE' with a barcode and 'Expiration Date' '16 DEC 2005 23:59'. A full face label for 'VOLUNTEER DONOR' has a cutout showing the DIN 'E20316AB'. A full face label for 'THAWED APHERESIS PLASMA' has a cutout showing the DIN 'E20316AB'. A 4x2 label shows 'THAWED APHERESIS PLASMA' and 'Expiration Date' '16 DEC 2005 23:59'.

Computerized?...Some things you need!

Make certain that you contact your Blood Bank Laboratory Information System (LIS) vendor to ensure they have incorporated the reading and use of ISBT 128. Ask if they offer a method of printing all required labels and if their system operation will require bar code concatenation (reading 2 bar codes as a single data element; e.g. DIN and ABO or Product Code and Exp. Date). If this is the case, you will need to procure a specialized bar code scanner. Also, test your scanners' ability to read ISBT 128 and any analyzers that utilize bar code identification. Digi-Trax can provide you with ISBT 128 label samples for this purpose.

For printing ISBT 128 labels on-demand you need to secure 300 dots per inch (dpi) resolution thermal transfer printers. To print durable high density DIN tube labels and the best overall image quality for all ISBT 128 labels consistent with the standards. Thermal transfer is the ideal technology. Determine with your IT department the locations where you'll be printing and whether you will be using an Ethernet network or a workstation with serial connection.

Label supplies need to be carefully chosen with proper adhesives to meet FDA requirements (CFR21, Sec. 175.105), regardless of whether they are preprinted or blanks for on-demand printing. Both the label stock and print ribbon need to withstand the rigors of the blood banking process (freezing, water bath, bleach disinfecting and abrasion).

On-demand printing vs. popular pre-print labels:

The ISBT 128 standard provides for many more label products, including splits, divisions and irradiated products. There are now almost 4000 products in the U.S. database and 80 possible ABOs. If your blood bank software or bedside system requires concatenation of the product and expiration date, then you will most certainly need to print the variable bar code data for the expiration dates with on-demand printing.

If your organization only receives, doesn't collect blood, and/or uses just a very few products, then you can consider the use of pre-printed labels. If you need to print on-demand, it's important that the on-demand printing software technology seamlessly interfaces to leading U.S. Blood Bank LIS systems. Also, it is important to note that complete PC stand-alone ISBT 128 print systems are available as a primary imaging method with multi-level password protection capable of generating a full compliment of look-back audit trail reports. These systems can also serve as a back-up during system maintenance times for this "mission critical" labeling in your blood bank.

Blood Collection and On-Demand Printing:

The new Donor Identification Number (DIN) is a non-repeating global system designed to uniquely identify each donation for 99 years. It contains a World Code and Center ID, Year of Collection and 6-digit sequential number. There are process control flag characters (90° rotated) plus a manual check-sum digit.



The ISBT 128 DIN will now be about 30% larger and more expensive than a comparable CODABAR DIN. Consider on-demand printing of DIN labels with software developed using current Good Manufacturing Practice (cGMP) to safely provide cost effective, high quality DIN labels. On-demand printing has the potential feature of generating complete and accurate label audit trail reports.

The Digi-Trax/Zebra Value Proposition:

Digi-Trax/Zebra successfully pioneered the use of on-demand printing in 1990 for FDA acceptable CODABAR ABO Rh/Exp. dating at collection centers. Today we are consulting members to the AABB's ISBT 128 Task Force that developed the new standards.

Digi-Trax's Hema Trax™ on-demand ISBT 128 printing system, an all-inclusive interfaced solution that includes specialized Zebra 300dpi Z4Mplus™ BB printers, is available from every major U.S. Blood Bank LIS company. Additionally, Digi-Trax's easy-to-use Hema Trax stand-alone PC product can serve as a back-up or, for smaller transfusion services, as the primary ISBT 128 labeling system.

Complete your total ISBT 128 solution with Digi-Trax synthetic labels and matched thermal transfer ribbon, which meets the FDA adhesive requirement. Our label media withstand the rigors of blood banking: freezing, water bath, bleach disinfecting, solvents and repeated abrasion. Combine this with the Digi-Trax total hardware maintenance and Lifecycle Software Support (LSS) for simplified ISBT 128 compliance labeling, improved patient safety, and enhanced efficiencies.

Summary:

It has been a significant challenge bringing blood quality improvements vis-à-vis automation and global standardization to the blood banking community. Now with the support of the FDA, AABB and many U.S. software vendors and blood centers, ISBT 128 is becoming a reality.

Our current health care culture is focused on improved patient safety and outcomes. This has brought about a major paradigm shift in the blood banking community with the move from CODABAR to ISBT128. Now accuracy and efficiency co-exist with computer-directed printing of ISBT128 compliant labels from Digi-Trax/Zebra.

For More Information:

Contact Digi-Trax Corporation, 650 Heathrow Drive, Lincolnshire, IL 60069-4205
Phone: 800-356-6126
Fax: 847-465-9055
Email: info@digitrax.com
Website: www.digitrax.com