



ISBT 128 STANDARD

Labeling of Human Milk Banking Products

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1 Introduction

1.1 Purpose

The purpose of this document is to help facilities and software developers design appropriate ISBT 128 labels for human milk banking products

1.2 Scope

This document provides ISBT 128 requirements for information that shall appear on the final label for human milk banking products. This document also provides guidance in the label design following the standards described in the *ISBT 128 Standard Technical Specification*. Because container size for milk products may vary, only a sampling of possible label designs is provided (see section 7).

1.3 Intended Audience

The intended audience of this document is milk banking facility staff (management, information technology, quality, validation, and laboratory), software developers, label/software vendors, nurses, and end-users.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)

1.5 Other Reference

NICE Clinical Guideline 93 – Donor breast milk banks: the operation of donor milk bank services

HMBANA Guidelines for the Establishment and Operation of a Donor Human Milk Bank Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)

Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)




ISBT 128 for Human Milk, An Introduction (IN-031)

1.6 Background

A Specification, ISBT 128, for labeling 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. Around the world, implementation in blood establishments began soon after the standard was issued, with a steady increase in adoption since that time. The model originally developed by the WPADP has demonstrated its suitability by accommodating local and regional changes without requiring substantial structural change.

The Standard has gained widespread acceptance and has been extended beyond blood transfusion to include cellular therapy, tissues, organ, and banked human milk products. There are now more than 4,500 facilities in 77 countries across six continents registered to use ISBT 128, and this number continues to grow. In 2011, a Scottish facility registered with ICCBBA and has since adopted ISBT 128 for banked human milk.

The European Milk Banking Association (EMBA), Human Milk Banking Association of North America (HMBANA), and ICCBBA recognized ISBT 128 as the international coding standard for the bar coding and labeling of human milk products.

International Consensus Statement on the Terminology, Coding and Labeling of Human Milk Donations

The Boards of the European Milk Bank Association, Human Milk Banking Association of North America and ICCBBA, recognizing:

- the rapidly increasing demand for donated human milk as the nutrition of choice where mother's milk is not available;
- the global growth in the numbers of milk banks and the need for common standards of practice;
- the need for globally unique identification of milk donations to support international traceability and biovigilance;
- the benefit of international standardization of terminology, coding and labeling in clinical practice;
- the benefit of bar coding and other electronic messaging systems to ensure accurate and rapid transfer of critical information and to help eliminate manual transcription errors;
- the existing widespread use of the international information standard ISBT 128 in the fields of transfusion and transplantation;
- the successful implementation of an ISBT 128 bar coding and labeling system for human milk by the 'the NHS Greater Glasgow and Clyde (GGC) Milk Bank, Glasgow, UK;
- the need for international management and technical co-operation for the successful maintenance and development of such standards;

support the use of the ISBT 128 international coding standard for the bar coding and labeling of human milk donations.

To achieve this objective the above associations will form an international advisory group to:

- a) develop a standard terminology to describe milk donations;
- b) provide guidance on standard labeling of milk donations;
- c) provide advice and support to milk banks introducing the standard;
- d) advise on the ongoing development of the ISBT 128 standard to support new developments in milk banking.

Milk banks should take note of this initiative and plan for adoption of ISBT 128 coding and labeling of their products once the standard has been published.

For further information on this initiative see <http://www.iccbba.org/subject-area/milk-bank>

2 Data Structures

The data structures that will commonly be used to label milk products include:

- Donation Identification Number (Data Structure 001),
- Product Code (Data Structure 003), and
- Expiration Date and Time (Data Structure 005).

Additional bar codes, such as Collection Date and Time (Data Structure 007) may also be useful.

When multiple data structures are encoded into a single bar code, the ISBT 128 Compound Message data structure (Data Structure 023) shall be used. See *Implementation Guide: Use of Data Matrix Symbols with ISBT 128 (IG-014)* for more information about the use of this data structure.

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

3 Label Size

The size of an ISBT 128 label for human milk will vary depending upon the size of the container and the amount of information that a facility wants to encode using ISBT 128 data structures. Since there is not a standard size container used for milk products, the ISBT 128 Standard does not specify a particular size of label. Additional nationally defined requirements for information on the label may influence the label size.

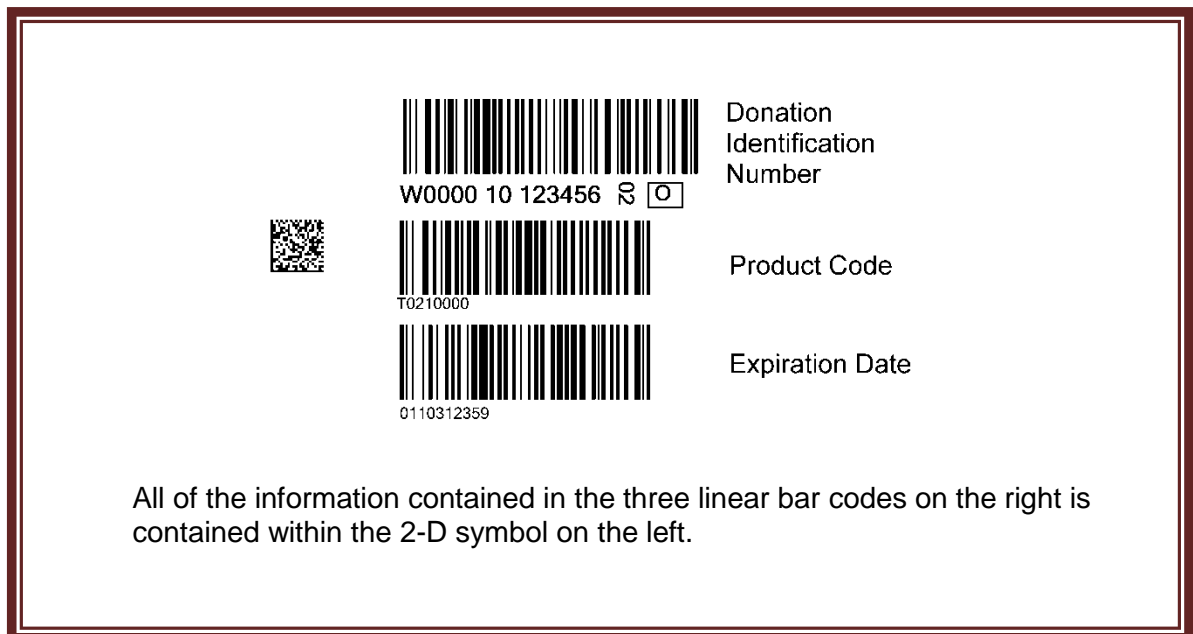
Although label sizes may differ, typical sizes can range from 4.5cm x 4.5cm to 5cm x 7.5cm. Other label sizes are not precluded given that it can be accommodated on the container.

4 Electronically Readable Symbols

Either linear bar codes (Code 128) or two-dimensional (2D) symbols (Data Matrix), or both, may be used to label human milk products; however 2D symbols are recommended where feasible for human milk products. 2D symbols have the advantage of allowing a great deal of information to be encoded into a very small amount of space. See Figure 1. An imaging scanner must be used to read 2D symbols.

Specifications (quality, dimensions, etc.) for the printing of electronically readable symbols may be found in the *ISBT 128 Standard Technical Specification*. Information on the rationale for the selection of Data Matrix, as well as implementation guidance, is found in *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014).

Figure 1 Comparison of 2D and Linear Bar Codes



5 Text

5.1 Data Content Text

In the ISBT 128 Standard, data content text is defined as text appearing immediately beneath a linear bar code that conveys the information content of the bar code. Because linear bar codes are not recommended for human milk products, details are not included here. If linear bar codes are used, please consult the chapter on text found in the *ISBT 128 Standard Technical Specification* or the ICCBBA office (iccbba@iccbba.org).

5.2 Bar Code Text

Bar code text is the interpretation of the data content of the bar code. Bar code text is nationally defined to allow for differences in language, regulatory requirements, and preferences. Where needed, bar code text may appear in multiple languages on a label.

Particular font sizes and types are not specified for bar code text but designers shall ensure clarity of all text and use of larger fonts to emphasize critical information. The font chosen should clearly differentiate between similar characters (e.g., O and 0; l and 1). For Latin alphabets, sans serif fonts should be used. For the purpose of practicality in reading, a minimum font size of 8 is recommended.

5.2.1 Donation Identification Number [001]

Consult the *ISBT 128 Standard Technical Specification* for details about the Donation Identification Number (DIN). The Donation Identification Number shall be printed using a sans serif typeface. A national authority should determine how it should be displayed, for example:

A9999 16 123456

V004316 499999

7004 216 123 456

All 13 characters of the DIN shall be printed.

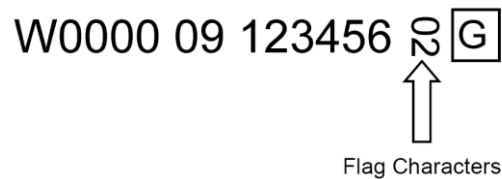
The flag characters “ff” may be used to convey specific information other than the unique identification of the product and shall be distinguished from the Donation Identification Number (see *ISBT 128 Standard Technical Specification* for more details).

When Type 1 or Type 2 flag characters are used 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.

- 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.

Figure 2 Representation of Flag Characters



The keyboard check character shall be printed in a manner that clearly distinguishes it from data content. When printed in association with the eye-readable text of a code, a box shall be drawn around the keyboard entry check character as shown in Figure 2.

5.2.2 Dates

Dates shall be printed in compliance with ISO 8601-2004 extended format (2010-03-17) or in the format day — month — year. If the latter, the day shall be numerical, the month alphabetical, using a three-letter abbreviation. The year shall be a four-digit numerical representation.

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

2011-06-25 15:15
or
25 JUN 2011 15:15

When the default time of 23:59 is encoded, the time does not have to appear as bar code text.

2011-06-25
or
25 JUN 2011

5.2.3 Additional Text

Additional text is defined as text not associated with a bar code. Additional text includes warnings such as “Use within 24 hours of thawing.”

In designing their labels, facilities may add additional text to the label where space permits. The placement of this information is not standardized.

6 Label Design

Since milk products are packaged in a variety of containers with different sizes and shapes, the Standard allows flexibility in designing labels. This document describes label designs that meet the ISBT 128 requirements, but does not preclude other designs that meet the requirements.

National agencies may publish guidelines for labeling that adhere to the ISBT 128 Standard and which take local language and regulatory requirements into consideration.

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 lesser significance to the end-user (physician, nurse, and other hospital personnel).

6.1 Requirements for ISBT 128 Labels

The ISBT 128 label area shall have a white background.

In addition to meeting the requirements of regulatory agencies and applicable standard setting organizations, the minimum information content of the final ISBT 128 area of the label shall be:

- Bar coded Donation Identification Number (DIN) – in milk banking this may also be referred to as the batch number
- Eye readable text of the Donation Identification Number, flag characters when required (rotated 90° clockwise) and the boxed manual check character
- Bar coded Product Code
- Eye readable text of the Product Code (Product Description Code and division code/split number)
- Bar coded expiration date
- Expiration date in text
- Human Milk Pasteurized in text
- Storage temperature in text
- Use within 24 hours of thawing
- For Nutritional Use in text

7 Label Examples

Figure 3 Example Label 4.5cm x 4.5cm

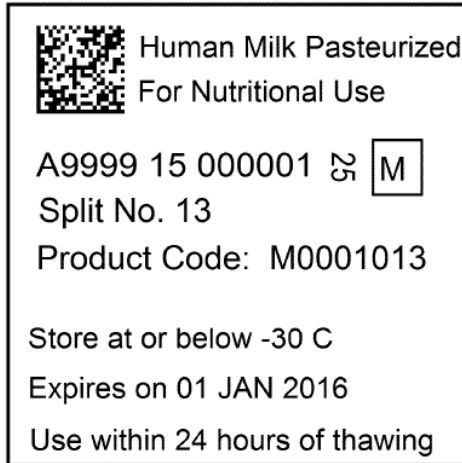


Figure 4 Example Label 5cm x 7.5cm

