IMPLEMENTATION GUIDE

Manufacturer's Catalog Number and Lot Number (Items Other Than Containers)

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Table of Contents

1 Introduction 5
1.1 Purpose 5
1.2 Scope 5
1.3 Intended Audience 5
1.4 Normative Reference 5
1.5 Other Reference 5
1.6 Background 5
2 Examples of Use 7
3 Data Structures 8
3.1 Manufacturer and Catalog Number: Items Other Than Containers [Data Structure 021] 8
3.2 Lot Number: Items Other Than Containers [Data Structure 022] 8
4 Compound Messages 10

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance for the use of the Manufacturer and Catalog Number: Items Other Than Containers [Data Structure 021] and the Lot Number: Items Other Than Containers [Data Structure 022].

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification*. It provides background information and examples of the use of the Manufacturer and Catalog Number: Items Other Than Containers [Data Structure 021] and the Lot Number: Items Other Than Containers [Data Structure 022].

1.3 Intended Audience

This guidance document is intended for staff (management, laboratory, quality, and information technology) of facilities using ISBT 128, software developers, and manufacturers of labels for MPHO.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

1.5 Other Reference

ICCBBA Website (www.iccbba.org)

1.6 Background

Authorities in many countries demand that facilities collecting, processing, distributing or issuing blood or blood components must keep track of blood containers used. For this purpose ISBT 128 has two data structures for capturing the necessary information:

- Container Manufacturer and Catalog Number [Data Structure 017]
- Container Lot Number [Data Structure 018]

Facilities collecting, processing, distributing or issuing blood, blood components, tissues, or human progenitor cells may also wish to keep track of other items that have the potential to influence the quality of their products.

The reasons for this may be:

- Process control of critical points or procedures
- Documentation
- Demand from authorities

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To facilitate capture of data on items other than containers, the following two data structures were created:

- Manufacturer and Catalog Number: Items Other Than Containers [Data Structure 021]
- Lot Number: Items Other Than Containers [Data Structure 022]

By incorporating these data structures onto their products, using either barcodes or newer technologies such as radio frequency identification tags (RFID), suppliers provide their customers with a simple and rapid way of accurately capturing key information about their products.

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2 Examples of Use

If captured, data structures 021 and 022 (the two data structures for items other than containers) may prove valuable in many different situations. For example:

- Documentation for all items and fluids involved in a complicated procedure such as leukapheresis can be captured easily and stored in a computer system.
- Documentation for all items and fluids used in the processing of a product. For example, a piece of bone can be captured in a two-dimensional bar code or a radio frequency tag (RFID) that is attached to the product. Alternatively, it can be sent as an electronic message to the end user.
- A problem discovered in quality control can be traced back to a specific lot of leukocyte depletion filters and blood components processed with this lot can easily be withdrawn.
- A message from a vendor of wafers for sterile docking mentioning a problem with a particular lot number can result in a swift withdrawal of involved products.

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3 Data Structures

3.1 Manufacturer and Catalog Number: Items Other Than Containers [Data Structure 021]

Purpose: Data Structure 021 shall specify the manufacturer and the catalog number of an item used in collection or processing other than the container (set)

Structure: =-NNOOOOOOOO

Element	Length	Type
=	1	data identifier, first character
-	1	data identifier, second character
NN	2	alphanumeric {A–Z; 0–9}
OOOOOOOO	8	alphanumeric {A–Z; a–z; 0–9}

The ten (10)-character data content string, **NNOOOOOOOO** shall be encoded and interpreted as follows:

NN shall specify the identity of the item manufacturer and is encoded and interpreted from Table W1, [RT016] – Manufacturer Identifier Codes (this table is maintained on the ICCBBA website: https://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/reference-tables).

OOOOOOOO shall specify the manufacturer's catalog number. This shall be interpreted from information provided by the manufacturer. If the catalog number is less than eight (8) characters, it shall be padded with zeroes at the beginning of the string (i.e., the catalog number 27QzE would be transmitted as 00027QzE).

3.2 Lot Number: Items Other Than Containers [Data Structure 022]

Purpose: Data Structure 022 shall specify the manufacturer's lot number for an item used in collection or processing other than a container (set).

Structure: &-PPPPPPPPPP

Element	Length	Type
&	1	data identifier, first character
-	1	data identifier, second character
PPPPPPPPPP	10	alphanumeric {A–Z; a–z; 0–9}

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The ten (10)-character data content string, **PPPPPPPPPP**, shall encode the manufacturer's lot number. If the lot number is less than ten (10) characters, it shall be padded with zeroes at the beginning of the string (i.e., the lot number 1234rZ would be transmitted as 00001234rZ).

Because lot numbers can be padded with zeroes, ideally they should not begin with a 0 (zero). If the lot number begins with 0 (zero), the manufacturer shall have a mechanism to ensure correct identification of the lot number when a problem is reported and the lot number is indicated without the leading 0 (zero).

This data structure shall be used in conjunction with Data Structure 021.

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4 Compound Messages

Where more items and containers are involved in the processing of a product, it is possible to forward (by two dimensional bar codes or RFID) or send (by electronic messages) the information about manufacturers, catalog numbers and lot numbers together with other information such as the donation identification number and the product code in one single message. This is done by using the Compound Message [Data Structure 023].

Compound messages are created by combining ISBT 128 data structures into a sequential string. The Compound Message [Data Structure 023], which identifies the data string as an ISBT 128 compound message, is placed at the start of the message, and provides a lookup reference to the appropriate compound message structure (i.e., Data Structure 023 followed by other ISBT 128 data structures [as depicted below]).

Compound message structures can be either ICCBBA-specified or undefined. ICCBBA-specified compound message structures are published and maintained on the ICCBBA website which are available to licensed ISBT 128 users/vendors.

Use of the ISBT 128 compound message ensures that information is presented in an internationally standard format, thus allowing the message to be read and interpreted by an ISBT 128 compliant system that is compatible with compound messages.

For further information on the Compound Message [Data Structure 023], see the *ISBT 128 Standard Technical Specification* (ST-001).

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