



IMPLEMENTATION GUIDE

MPHO Unique Identifier

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance on creating and using the MPHO Unique Identifier in compliance with the ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier.

1.2 Scope

This document provides guidance on creating an MPHO Unique Identifier from the traceability data elements carried on an ISBT 128 labeled product.

This document is a supplement to the

- ISBT 128 Standard Technical Specification (ST-001)
- ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier (ST-026)
- ISBT 128 Standard for XML (ST-020)

1.3 Intended Audience

The intended audience of this document is developers of systems creating and receiving information on MPHO products labeled with ISBT 128. It is of particular relevance to developers intending to send information in electronic messages or enter information on infusion/implantation of MPHO products into an electronic health record. The MPHO Unique Identifier should be used as the identifier element for the HL7 FHIR BiologicallyDerivedProduct resource.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier (ST-026)

ISBT 128 Standard for XML (ST-020)

Use of ISBT 128 in Electronic Messaging (IG-044)

1.5 Other Reference

ICCBBA Website (www.isbt128.org)

1.6 Background

There are four data elements that together uniquely identify an individual MPHO product. At a minimum, a Donation Identification Number and Product Description Code must be provided. If a final product has been divided, then the division identifier is also required. The processing facility identification number may also be present on product labeling and where this is provided it may also be required to ensure unique identification.

The MPHO Unique Identifier has been developed in order to standardize and simplify this traceability information across multiple areas of MPHO activity with differing labeling requirements. This identifier combines the four traceability data elements in a single string that has a consistent structure across all MPHO types.

The MPHO Unique Identifier provides an ideal way to uniquely identify MPHO product instances in electronic messages, and to capture critical traceability information in electronic health records.

The rules provided in ST-026 must be carefully followed to ensure the consistent presentation of the MPHO Unique Identifier. This guidance provides examples to help users understand the way they should construct an MPHO Unique Identifier.

2 MPHO Unique Identifier Structure

2.1 Data elements to be included in the MPHO Unique Identifier

The MPHO Unique Identifier data element (<https://www.isbt128.org/uri/MPHOUniqueIdentifier>) is constructed from the following four ISBT 128 data elements:

- Processing Facility Identification Number (FIN(P)) – <https://www.isbt128.org/uri/ProcessorFIN>
- Product Description Code (PDC) – <https://www.isbt128.org/uri/ProductDescriptionCode>
- Donation Identification Number (DIN) – <https://www.isbt128.org/uri/DonationIdentificationNumber>
- Divisions Identifier (DIV) – <https://www.isbt128.org/uri/DivisionIdentifier>

2.2 Construction Rules

- These data elements are concatenated into a single string in the order listed. Thus, for a product with:
 - FIN(P) = W9999
 - PDC = E1234
 - DIN = W000018123456
 - DIV = Ab0000

The MPHO Unique Identifier data element will be:

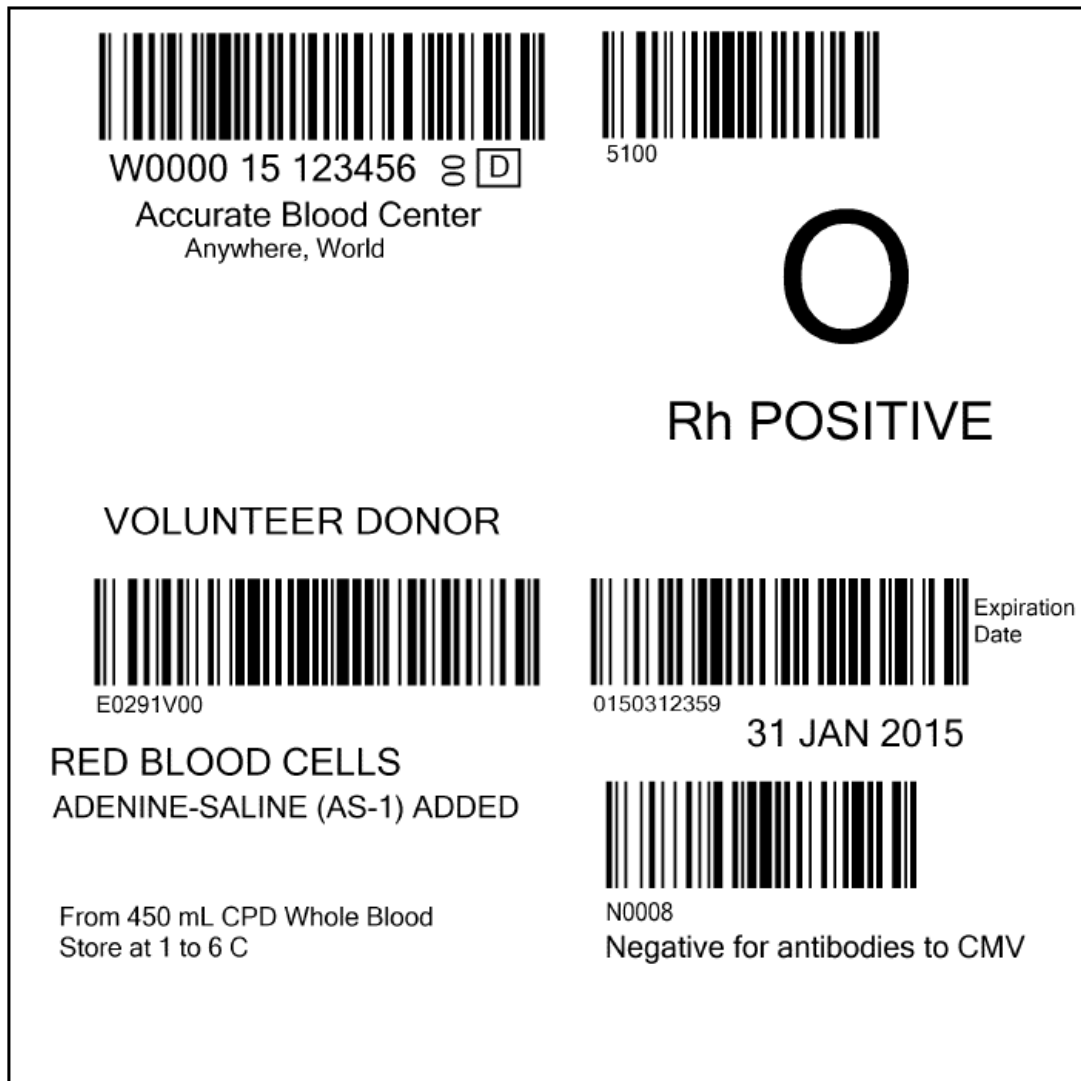
- W9999E1234W000018123456Ab0000
- For traceability purposes it is essential that the information in the MPHO Unique Identifier matches the information held in ISBT 128 data structures on the product label.
- FIN(P) shall only be included in the MPHO Unique Identifier if it appears in bar coded form on the product label in either DS-033 or DS-034. If neither of these data structures is present on the product label then the FIN(P) shall be set to all zeros.
- The Division Identifier is a fixed length six-character string. There are specific rules for populating this field with division information from DS-003.
- For products labeled with DS-003 where the division code is in the two-character position referenced as 'ds' in ST-001 the two-character division code shall be padded with TRAILING zeros.
- For products labeled with DS-003 where the division code is in the three-character position referenced as 'tds' in ST-001 the three-character division code shall be padded with LEADING zeros.

3 Examples

The MPHO can be constructed from any ISBT 128 labeled MPHO. The following examples demonstrate how the MPHO Unique Identifier can be generated from various labels.

3.1 Blood

Figure 1 Blood

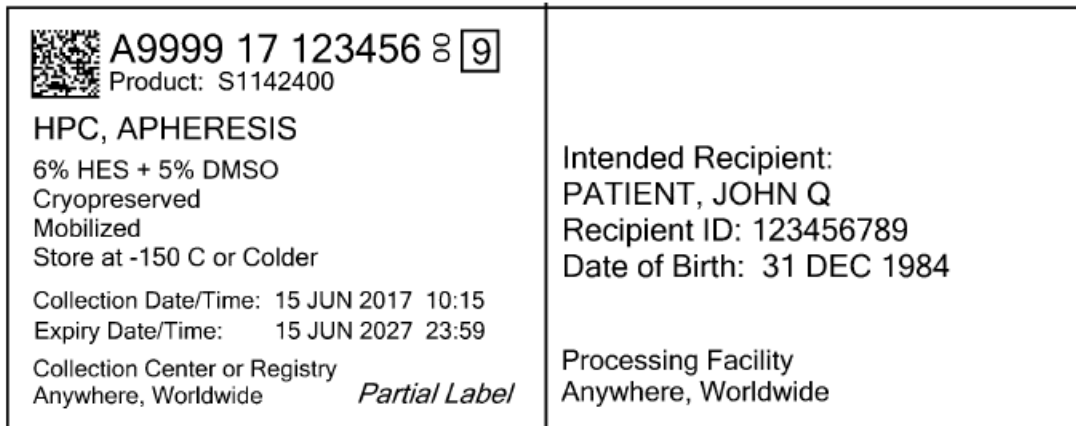


- FIN(P) – 00000 (not present on label)
- PDC – E0291
- DIN – W000015123456
- DIV – 000000 (00 padded with TRAILING zeros)

MPHO Unique Identifier – 00000E0291W000015123456000000

3.2 Cell Therapy

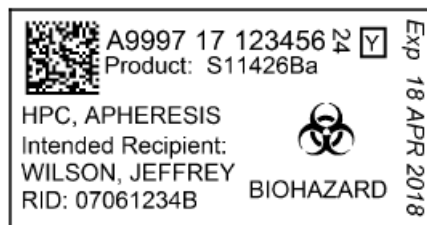
Figure 2 Cell Therapy Partial Label



- FIN(P) – 00000 (present in text on label, but not encoded)
- PDC – S1142
- DIN – A999917123456
- DIV – 000000 (00 padded with TRAILING zeros)

MPHO Unique Identifier - 00000S1142A999917123456000000

Figure 3 Cell Therapy Cryo Vial Label

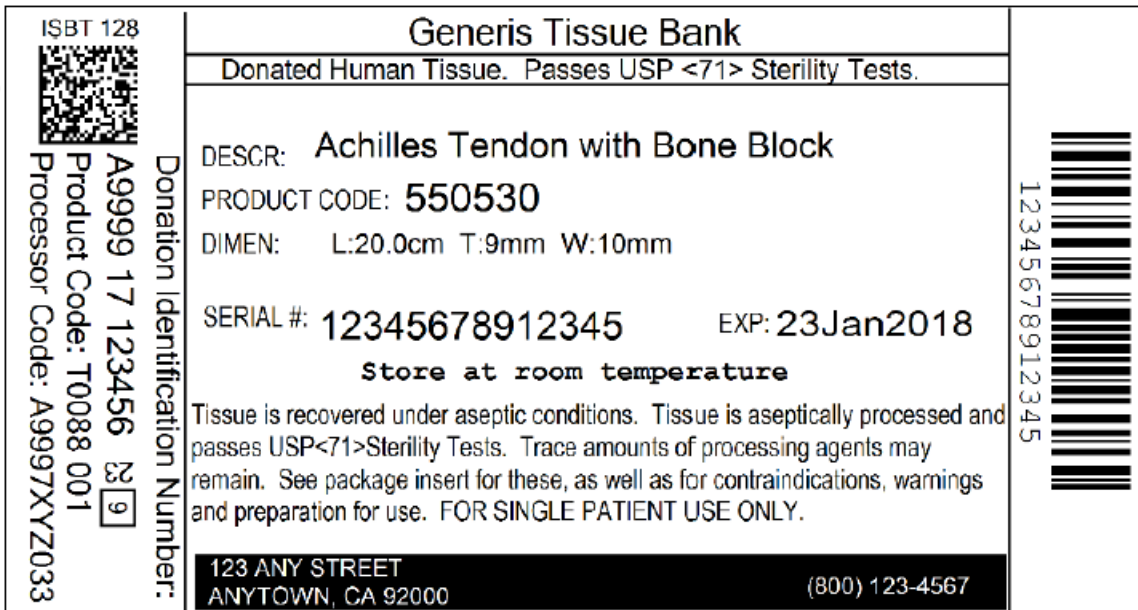


- FIN(P) – 00000 (not present on label)
- PDC – S1142
- DIN – A999717123456
- DIV – Ba0000 (Ba padded with TRAILING zeros)

MPHO Unique Identifier - 00000S1142A999717123456Ba0000

3.3 Tissues

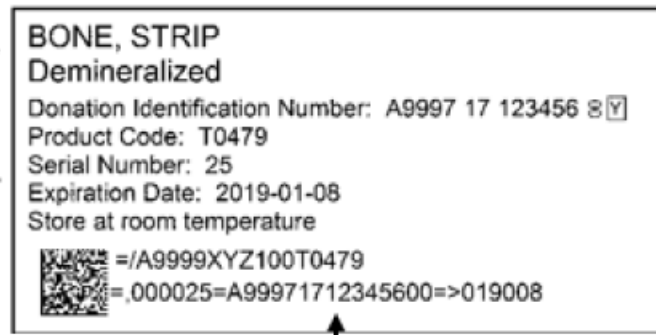
Figure 4 Large Vial Label



- FIN(P) – A9997
- PDC – T0088
- DIN – A999917123456
- DIV – 000001 (001 padded with LEADING zeros)

MPHO Unique Identifier – A9997T0088A999917123456000001

Figure 5 Tissue with UDI



- FIN(P) – A9999
- PDC – T0479
- DIN – A999717123456
- DIV – 000025

MPHO Unique Identifier – A9999T0479A999717123456000025