IMPLEMENTATION GUIDE

Use of the Manufacturers Data File

Version 1.2.1

December 2016

Tracking Number ICCBBA IG-015

Published by:
ICCBBA
PO Box 11309, San Bernardino, CA 92423 USA

Warranty Disclaimer and Limitation of Liability

ICCBBA provides no representation or warranty that the Licensee's use of ISBT 128 is suitable for any particular purpose and the selection, use, efficiency and suitability of ISBT 128 is the sole responsibility of the Licensee.

ICCBBA's liability is limited to that specified in the ICCBBA License Agreement which is available on the ICCBBA website. Under no circumstances shall ICCBBA's liability to licensee or any third party under any theory or cause of action exceed the current annual license fee payable by the licensee to ICCBBA hereunder, and ICCBBA will in no circumstances be liable for any direct or indirect damages whatsoever, including without limitation special, incidental, consequential, or punitive damages or damages for loss of data, business or goodwill or any other consequential losses of any nature arising from the use of ISBT 128 or the marks.

Copyright Notice

Editor

Pat Distler, MS, MT(ASCP)SBB
Technical Expert, ICCBBA

Standards Committee

Table of Contents

Tables

Figures

1 Introduction

1.1 Purpose

The purpose of this document is to provide implementation guidance on the use of the Manufacturers Data File. Specifications pertaining to the Manufacturers Data File are contained in the *ISBT 128 Standard Technical Specification* (ST-001) and this information must be read for a complete understanding of the subject.

Illustrations provided in the document are formatted to provide clarity rather than as copy/paste examples for software development.

1.2 Scope

This document provides background information and examples of the use of the ISBT 128 Manufacturers Data File. It provides supplementary information only and is therefore intended to be used in conjunction with the *ISBT 128 Standard Technical Specification* (ST-001)

1.3 Intended Audience

This document is primarily intended as guidance for laboratory supervisors. It describes the benefits of using the Manufacturers Data File. Some information may also be useful to container manufacturers and software developers.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)
ISBT 128 Standard, Standard Terminology for Medical Products of Human Origin (ST-002)

1.5 Background

A data file is a computer file containing information that is used by a computer system as input. It does not contain programming information or information defining the structure of an application.

For biological products, data files can be useful when the amount of information that needs to be conveyed about a product is greater than that which can be printed on a label. The information in the data file can be connected to the product through a key that is printed on the product label.

ISBT 128 offers the ability to create a data file for blood containers. This file allows information specific to a blood collection set that is needed for process control to be entered into a blood processing facility's computer system electronically improving the security of information transfer. For example, information such as the anticoagulant, additives, presence of leukocyte reduction filter, volume limits of the container, etc., is too great to fit on the base label printed on a blood container. However, by using the information contained within the Container Manufacturer and Catalog Number Data Structure [017] as a key, the container may be linked to a data file that contains this

detailed information. The manufacturer of the container set maintains the data file and makes it available to its customers in an electronic format that can be downloaded into the customers' computer system. With appropriate software, the customers can then use the downloaded data for process control when manufacturing blood products.

1.6 New in this Version

The following table indicates the major changes between Version 1.2.0 and Version 1.2.1. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print.

When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

	Version 1.2.0 Chapter, Section, Table, or Figure	Version 1.2.1 Chapter, Section, Table, or Figure	Change	Rationale
1.	Throughout	Throughout	Removed leading zeroes from examples of data files.	Leading zeroes are not required.

2 ISBT 128 Manufacturers Data File

2.1 Structure

The data file structure specifies the field definitions and formats together with default values and lookup table references. Beginning with Version 05 of the Manufacturers Data File, the message structure may be in either an XML message or an ASCII text file using comma separated values (CSV). Manufacturers are responsible for providing their own data files for each catalog number of containers they produce.

The specifics of how the message should be formatted (field lengths; numeric, alphanumeric, or free format; default values if any; whether a line is optional, etc.) are defined in the *ISBT 128 Standard Technical Specification* (ST-001), Tables RT031, RT032, RT033, and RT034. For convenience, these tables are reproduced below (Table 1 through Table 4), but the *ISBT 128 Standard Technical Specification* (ST-001) should be consulted for the latest version of the tables.

The structure of a manufacturer data file comprises a header line (described in Table 1), a variable number of data lines (described in Table 2), and a footer line (described in Table 3). The footer line is for use with a CSV file; it is not used in an XML message since this type of file has its own terminator.

Table 4 lists the data lines that may appear in a Manufacturers Data File.

Table 1 Header Line [RT031]

Field	Length	Format	Comment
1	8	Alpha (8)	Fixed text “ICCBBAMF” identifies this as an ICCBBA-specified Manufacturers File format
2	2	Numeric (2)	Two (2)-digit version number identifies the version of the data structure with which this message is compliant (currently all messages are 07, i.e., this version of the data file)

Table 2 Data Lines [RT032]

Field	Length	Format	Comment
1	max 20	Alphanumeric (max 20)	ICCBBA-defined Data Label (see Table 4)
2	1	Alphanumeric or "#" (1)	Set to # for information relevant to the whole set, or the container identification character from the Container Manufacturer and Catalog Number Data Structure [017] for information specific to all containers with this identification character in the set. Numeric and upper case alpha characters shall be used to identify individual containers within the set. 1 shall be reserved for the primary collection container of a whole blood collection set.
3	variable	Alphanumeric (var)	Data content (see below). Data shall not contain the comma character as this is the field delimiter. Other non-alphanumeric characters used as default delimiters in HL7 messages should also be avoided (|^~\&)

Table 3 Footer Line [RT033]

Field	Length	Format	Comment
1	8	Alpha (8)	Fixed text "FILETERM"
2	Variable	Numeric	Count of number of data lines in file

Table 4 ICCBBA-Assigned Data Labels and Content (Version 07) [RT034]

Data Label	Content	Format (max length)	Required*	Default Value	Application
MANUFACTURER	Identity of the container set manufacturer (uses the ICCBBA identification letters assigned in the Manufacturer Identifier Codes, see RT016)	Alpha (2)	M	N/A	Set
CATALOGNUMB	Manufacturer's catalog number (seven data characters as read from Container Manufacturer and Catalog Number Data Structure)	Alpha-numeric (7)	M	N/A	Set
CATNUMBTEXT	Manufacturer's catalog number as printed in documentation	free format	M	N/A	Set
GS1GTIN	The GS1 Global Trade Item Number	Numeric (14)	O	N/A	Set
GS1GTINCONTENT	The number of items in the carton	Numeric (3)	O	N/A	Set
CONTAINERNUMB	Number of containers in set (when field 2 = #) or number of containers with specified container identification character (when field 2 = container identification character).	Numeric (2)	M	N/A	Set
COLLECTIONVOL	The nominal collection volume for whole blood donations (in mL)	Numeric (3)	O	N/A	Set
CONTENT	The fluid content of the container as supplied (anticoagulant, additive, etc.)	Select from ICCBBA lookup table‡	D	NONE	Container

Data Label	Content	Format (max length)	Required*	Default Value	Application
CONTENTVOL	The volume of the fluid described in the CONTENT field (in mL)	Numeric (3)	O	N/A	Container
PLTCONTAINER	Indicator if this is a container suitable for the storage of platelets (liquid phase)	Y or N	D†	N	Container
PMACONTAINER	Indicator if this is a container suitable for the storage of plasma (liquid or frozen)	Y or N	D†	N	Container
RBCCONTAINER	Indicator if this is a container suitable for the storage of red cells (liquid phase)	Y or N	D†	N	Container
BFYCONTAINER	Indicator if this is a container suitable for the storage of buffy coat (liquid phase)	Y or N	D†	N	Container
PROCONLY CONTAINER	Indicator that this is a container suitable for in-process product only (not designed for storage of final product)	Y or N	D†	N	Container
LEUKREDFILTER	Indicates whether the container is downstream of a leukocyte reduction filter	Y or N	D†	N	Container
NOMINALVOLUME	The volume of final product that the container is designed to hold (in mL)	Numeric (4)	O	N/A	Container
MINVOL	The minimum amount of product that the container is designed to hold (in mL)	Numeric (4)	O	N/A	Container
MAXVOL	The maximum amount of liquid product the container is designed to hold (in mL)	Numeric (4)	O	N/A	Container

Data Label	Content	Format (max length)	Required*	Default Value	Application
MAXFRZVOL	The maximum amount of frozen product the container is designed to hold (in mL)	Numeric (4)	O	N/A	Container
SOLN1	A solution (e.g., additive solution or pathogen inactivation solution) that is integrally attached to the set but not contained within a container designed to store blood components	Alpha-numeric (7)	O	N/A	Set
SOLN1VOL	The volume (in mL) of Solution 1	Numeric (4)	O	N/A	Set
COMMENT	Field that is available for manufacturers to add comments; end-users are not expected to upload this information	Alpha (200)	O	N/A	Both

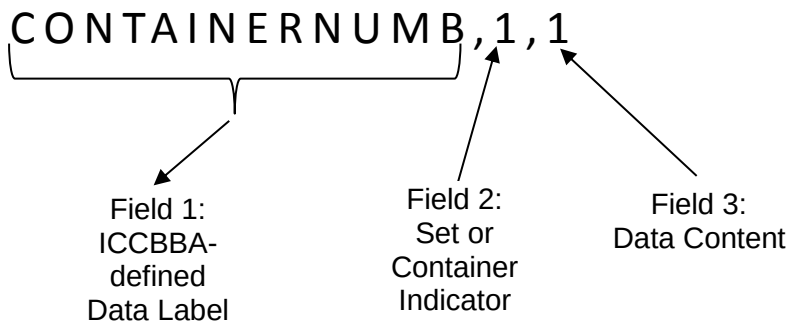
N/A = not applicable; Y = yes; N = no
M = mandatory; O = optional (included at manufacturer's discretion); D = default value applies if the data line is not present
† At least one of the PLTCONTAINER, PMACONTAINER, RBCCONTAINER, BFYCONTAINER, or PROCONLYCONTAINER fields shall be set to Y for each container type
‡ This table can be found in the definitions for Core Conditions in the ICCBBA document *ISBT 128 Standard Terminology for Medical Products of Human Origin s* in the Tech Library area of the ICCBBA Website.

2.2 Information Contained in the Manufacturers Data File

The Manufacturers Data File provides information useful for process control when making blood products. This information, and how it may be used, is described in Table 5, which reflects version 07 of the Manufacturers Data File specification. For the most current version, consult the *ISBT 128 Standard Technical Specification* (ST-001)

Table 5 includes a column entitled Example Data Line. Each data line has three fields. In a Comma Separated File (CSV) the fields are separated by commas.

Figure 1 Example Data Line



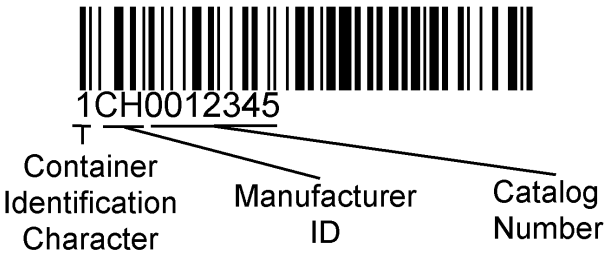
1. The first field is the unique name of the data line (variable length with a maximum of 20 characters, assigned by ICCBBA).

2. The second field is a single character indicating whether the information is about the entire set or a specific subset of containers within the set as follows:

   - When the character is a # symbol, it indicates the information in that data line pertains to the entire container set.
   - When the character is a number or upper case letter (e.g., 1, 2, 3 or A, B, C), it indicates that data line pertains to specific containers within the set. The number or upper case letter corresponds to the container identification character (see Figure 2, Page 14) of the Manufacturer and Catalog Number Data Structure [017] and the information applies to all containers in the set bearing this identifier.

3. The third field is the data content, which is the information being provided (alphanumeric, variable length).

Figure 2 Manufacturer and Catalog Number Bar Code Data Structure [017] from Base Label



Another example of a data line is:

MANUFACTURER,#,XZ

In this example,

- MANUFACTURER is the name of data line (first field)
- # is the character indicating the information applies to the entire set (second field)
- XZ is the abbreviation for the manufacturer of the container set (third field). The key to the manufacturer's code is found on W-1 Manufacturers ID Codes [RT 016] found on the ICCBBA Website.

Data lines within the data file may:

- Be mandatory: Information for this line must be specified in each data file;
- Be optional: The line may be omitted from the data file; or
- Have a default value: A default value will apply if the data line does not appear in the file.

The "Required" column on Table 4 [RT034] beginning on Page 10, specifies whether each line is mandatory, optional, or has a default value. If a default value exists, it is defined in the table.

Table 5 Data Lines in the Manufacturers Data File

Data Line (Data Label in Manufacturers Data File)	Information Provided	Example Data Line	Why This Information Is Needed
Manufacturer (MANUFACTURER)	This is an ICCBBA-assigned identifier that indicates the manufacturer of the container set	MANUFACTURER,#,YZ	It is possible that two manufacturers could use the same catalog number. Therefore, this is necessary to connect the catalog number of the container to information from the correct manufacturer.
Catalog Number (CATALOGNUMB)	Manufacturer's catalog number (seven data characters as read from Container Manufacturer and Catalog Number Data Structure)	CATALOGNUMB,#,0XY1234	The catalog number and the manufacturer's name uniquely identify a container set. This unique identification allows the user to download the correct data file.
Catalog Number Text (CATNUMBTEXT)	Manufacturer's catalog number as printed in documentation	CATNUMBTXT,#,XY-1234	This line provides information about how the number appears in human friendly text on the label.
GS1 Trade Item Number (GS1GTIN)	The GS1 Global Trade Item Number (GTIN)	GS1GTIN,#,32005000004004	This information allows the GS1 Global Trade Item Number (GTIN) printed on the shipping carton to be associated with the ISBT 128 Catalog Number printed on the containers. This allows electronic communication between a warehouse system, which would typically use the GTIN, and a blood bank application, which would typically use the ISBT 128 Catalog Number, to track the containers. *Note: Similar to ISBT 128, GS1 is a coding system. It is the most widely used supply chain coding system in the world. Manufacturers often use GS1 coding for their shipping cartons.*
Number of items in carton (GS1GTINCONTENT)	The number of items in the carton (from GS1GTIN)	GS1GTINCONTENT,#, 24	To set up automatic re-order, it is necessary to know how many items are in the shipping container (minimum purchasing quantity).

Data Line (Data Label in Manufacturers Data File)	Information Provided	Example Data Line	Why This Information Is Needed
Container Number (CONTAINERNUMB)	There will be multiple Container Number lines in each data file. These lines indicate one of two things:		
	1. When the character in the second field is #, this line indicates the number of containers within the set. For example: #,5 means there are four containers in the collection set.	CONTAINERNUMB**,#**,5	1. This information indicates the number of containers in the set that are suitable for storage of blood components. In order to account for all products that are made from a blood donation, you must know how many component storage containers were in the set. That is, was the set a single, double, triple, or quadruple container set?
	2. When the character in the second field is a number or upper case letter, it indicates a specific container type within the set. The characters in the third field indicate how many containers of that type are present. Example 1: The character in the second field of this line is 1, indicating the primary collection container. A 1 in the third field indicates there is only one container of this type in the set. Example 2: The character in the second field of this line is 2 indicating it is the second type of container present. A 2 in the third field indicates there are two identical containers of this type within the set.	CONTAINERNUMB,1,1 CONTAINERNUMB,2,2 CONTAINERNUMB,3,1 CONTAINERNUMB,4,1	2. For process control, there is a need to differentiate the red cell container from the platelet container, etc. Not only is appropriate use of each container different, but each will have different characteristics (e.g., one will have an anticoagulant present and another will not). In order to describe each container type differently, it is essential to assign identifiers.

Data Line (Data Label in Manufacturers Data File)	Information Provided	Example Data Line	Why This Information Is Needed
Collection Volume (COLLECTIONVOL)	This value indicates (in mL) the collection volume ("nominal collection volume") the set was designed to hold (e.g., whole blood containers are designed to collect a given amount of blood, usually 450 mL or 500 mL).	COLLECTIONVOL,#,450	Many regulatory agencies require that the final blood product labels include the nominal collection volume.
Content (CONTENT)	The fluid content of the container as supplied (anticoagulant, additive, etc.)	CONTENT,1,CPDA-1	The anticoagulant and additive affect the allowable storage period of the product. Also, many regulatory agencies require the anticoagulant and/or additive appear on the final blood product label.
Volume of Content (CONTENTVOL)	The volume of the fluid described in the CONTENT field (in mL)	CONTENTVOL,1,63	Many regulatory agencies require the final blood product label include the volume of the anticoagulant and/or additive.
Platelet Container (PLTCONTAINER)	A yes/no field to indicate if this container is suitable for the storage of platelets (liquid phase).	PLTCONTAINER,3,Y	Allows facilities to set up controls to ensure only appropriate products are stored in the container.
Plasma Container (PMACONTAINER)	A yes/no field to indicate if this container is suitable for the storage of plasma (liquid or frozen)	PMACONTAINER,2,Y	Allows facilities to set up controls to ensure only appropriate products are stored in the container.
Red Cell Container (RBCCONTAINER)	A yes/no field to indicate if this container is suitable for the storage of red cells (liquid phase)	RBCCONTAINER,1,Y	Allows facilities to set up controls to ensure only appropriate products are stored in the container.
Buffy Coat Container (BFYCONTAINER)	A yes/no field to indicate if this container is suitable for the storage of buffy coat (liquid phase)	BFYCONTAINER,3,Y	Allows facilities to set up controls to ensure only appropriate products are stored in the container.
Processing Only Container (PROCONLY CONTAINER)	A yes/no field to indicate if this container is intended for short term holding of products during processing	PROCONLY CONTAINER,3,Y	Allows facilities to set up controls to ensure products are stored in the container only temporarily during processing.
Leukocyte Reduction Filter (LEUKREDFILTER)	A yes/no field to indicate whether the container is downstream of a leukocyte reduction filter	LEUKREDFILTER,2,Y	Allows facilities to set up controls to indicate if the product in the container should routinely be labeled as leukocyte reduced.

Data Line (Data Label in Manufacturers Data File)	Information Provided	Example Data Line	Why This Information Is Needed
Nominal Volume Capacity of Container (NOMINALVOLUME)	The volume of final product that the container is designed to hold (in mL)	NOMINALVOL,A,600	This information is needed to determine if there is too much or too little product is stored in the container. While Minimum and Maximum Volume Capacity lines replace it to a large extent, it is retained for backward compatibility.
Minimum Volume Capacity (MINVOL)	The minimum amount of product that the container is designed to hold (in mL)	MINVOL,A,200	This allows facilities to set up controls to recognize and appropriately react to situations in which too little product is stored in the container.
Maximum Volume Capacity (MAXVOL)	The maximum amount of product the container is designed to hold (in mL)	MAXVOL,A,600	This allows facilities to set up controls to recognize and appropriately react to situations in which too much product is stored in the container.
MAXFRZVOL	The maximum amount of frozen product the container is designed to hold (in mL)	MAXFRZVOL,A,400	This allows facilities to set up controls to recognize and appropriately react to situations in which too much product is in the container for frozen storage.
Solution 1 (SOLN1)	A solution (e.g., additive solution or pathogen inactivation solution) that is integrally attached to the set but not contained within a container designed to store blood components.	SOLN1,#,AS1	This information is needed to determine the appropriate labeling of the blood component(s).
Solution 1 Volume (SOLN1VOL)	Value indicates the volume of solution (in mL) described in the SOLN1 line.	SOLN1VOL,#,100	Many regulatory agencies require the final blood product label include the volume of the additive and/or other solutions.
Comment (COMMENT)	Field that is available for manufacturers to add comments; end-users are not expected to upload this information		This is a free-style comment field intended for use by the manufacturer. It is not intended to be used by the blood center or hospital.

2.3 Illustration of a Data File

Figure 3 is an illustration Manufacturers Data File. Not all possible data lines shown in Table 4 [RT034] are present. Data lines may be missing for two reasons:

1. The data line is optional (as indicated in the “Required” column of Table 4) and not pertinent to the container set. In Figure 3, data lines that were omitted because they are optional and not pertinent are: Nominal Volume, Minimum Volume, Maximum Volume, Solution 1, and Solution 1 Volume.

2. A default value (as indicated in the “Default Value” column of Table 4) exists. If the default value applies to the container, including the data line is optional and the default value will be assumed Table 7, Page 21, provides the values that are assumed because they are default values.

Figure 3 Illustration of a Data File

```
ICCBBAMF07
MANUFACTURER,#,YZ
CATALOGNUMB,#,0XY1234
CATNUMBTXT,#,XY-1234
GS1GTIN,#,32005000004004
GS1GTINCONTENT,#,24
CONTAINERNUMB,#,4
CONTAINERNUMB,1,1
CONTAINERNUMB,2,2
CONTAINERNUMB,3,1
CONTAINERNUMB,4,1
COLLECTIONVOL,#,450
CONTENT,1,CPDA-1
CONTENTVOL,1,63
PLTCONTAINER,3,Y
PMACONTAINER,2,Y
RBCCONTAINER,1,Y
RBCCONTAINER,2,Y
RBCCONTAINER,4,Y
LEUKREDFILTER,2,Y
LEUKREDFILTER,3,Y
LEUKREDFILTER,4,Y
FILETERM,21
```


Table 6 Interpretation of Figure 3

Line	Values of Fields 2 and 3	Interpretation
ICCBBAMF07		This is a header. It communicates that this is an ICCBBA-defined Manufacturers Data File, version 7.
MANUFACTURER	#,YZ	The # indicates the information is about the set; YZ is the abbreviation for the manufacturer of the kit and is interpreted according to Table W1 (RT016) on the ICCBBA Website.
CATALOGNUMB	#,0XY1234	The # indicates the information is about the set; the catalog number is 0XY1234. Because the line must have 7 characters, a leading zero has been added to the 6-character catalog number.
CATNUMBTXT	#,XY-1234	The # indicates the information is about the set; the user friendly text version of the catalog number that appears on the container and perhaps in the company catalog is XY-1234.
GS1GTIN	#,32005000004004	The # indicates the information is about the set; the GS1 Global Trade Identification Number that appears on the shipping carton is 32005000004004.
GS1GTINCONTENT	#,24	The # indicates the information is about the set; there are 24 sets in the shipping container.
CONTAINERNUMB	#,5	The # indicates the information is about the set; within the collection set there are 5 containers suitable for storage of blood components.
CONTAINERNUMB	1,1	This information is about container 1; there is one such container within the set.
CONTAINERNUMB	2,2	This information is about container 2; there are two such identical containers within the set.
CONTAINERNUMB	3,1	This information is about container 3; there is one such container within the set.
CONTAINERNUMB	4,1	This information is about container 4; there is one such container within the set.
COLLECTIONVOL	#,450	The # indicates the information is about the set; it is intended to collect 450 mL of whole blood. This value applies to the set (rather than just the primary collection bag) because regulatory agencies may require this information to appear on the labels of various blood components produced from the collection.
CONTENT	1,CPDA-1	In container 1, there is CPDA-1 anticoagulant.

Line	Values of Fields 2 and 3	Interpretation
CONTENTVOL	1,63	In container 1, there is 63 mL of anticoagulant.
PLTCONTAINER	3,Y	Container 3 is suitable for the storage of platelets.
PMACONTAINER	2,Y	Both Container 2 bags are also suitable for the storage of plasma.
RBCCONTAINER	1,Y	Container 1 is suitable for the storage of red cells or whole blood.
RBCCONTAINER	2,Y	Both container 2 bags are suitable for the storage of red cells or whole blood.
RBCCONTAINER	4,Y	Container 4 is suitable for the storage of red cells or whole blood.
LEUKREDFILTER	2,Y	Both Container 2 bags are downstream from a leukocyte reduction filter.
LEUKREDFILTER	3,Y	Container 3 is downstream from a leukocyte reduction filter.
LEUKREDFILTER	4,Y	Container 4 is downstream from a leukocyte reduction filter.
FILETERM	21	This is a footer. It indicates that this is the end of the file and there were 21 data lines included in the file.

Table 7 Interpretation of Default Values in Figure 3

Data Line	Value	Interpretation
CONTENT	2 None	There is no fluid content in Container 2
CONTENT	3 None	There is no fluid content in Container 3
CONTENT	4 None	There is no fluid content in Container 4
PLTCONTAINER	1N	Container 1 is not suitable for the storage of platelets
PLTCONTAINER	2N	Container 2 is not suitable for the storage of platelets
PLTCONTAINER	4N	Container 4 is not suitable for the storage of platelets
PMACONTAINER	1N	Container 1 is not suitable for the storage of plasma
PMACONTAINER	3N	Container 3 is not suitable for the storage of plasma
PMACONTAINER	4N	Container 4 is not suitable for the storage of plasma
RBCCONTAINER	3N	Container 3 is not suitable for the storage of red cells
BUFFY COAT CONTAINER	1N	Container 1 is not suitable for the storage of buffy coat (liquid phase)
BUFFY COAT CONTAINER	2N	Container 2 is not suitable for the storage of buffy coat (liquid phase)
BUFFY COAT CONTAINER	3N	Container 3 is not suitable for the storage of buffy coat (liquid phase)
BUFFY COAT CONTAINER	4N	Container 4 is not suitable for the storage of buffy coat (liquid phase)
PROCONLY CONTANER	1N	Container 1 is not a processing-only container
PROCONLY CONTANER	2N	Container 1 is not a processing-only container

PROCONLY CONTANER	3N	Container 1 is not a processing-only container
PROCONLY CONTANER	4N	Container 1 is not a processing-only container
LEUKOCYTE REDUCTION FILTER	1N	Container 1 is not downstream from a leukocyte reduction filter.

In this example, the manufacturer has identified two identical containers by indicating there are two “copies” of Container 2. It is also acceptable for the manufacturer to indicate each of these identical containers separately. In this case, the data file would define characteristics of each container separately. The Container Number lines would then appear as:

```
CONTAINERNUMB,#,5
CONTAINERNUMB,1,1
CONTAINERNUMB,2,1
CONTAINERNUMB,3,1
CONTAINERNUMB,4,1
CONTAINERNUMB,5,1
```

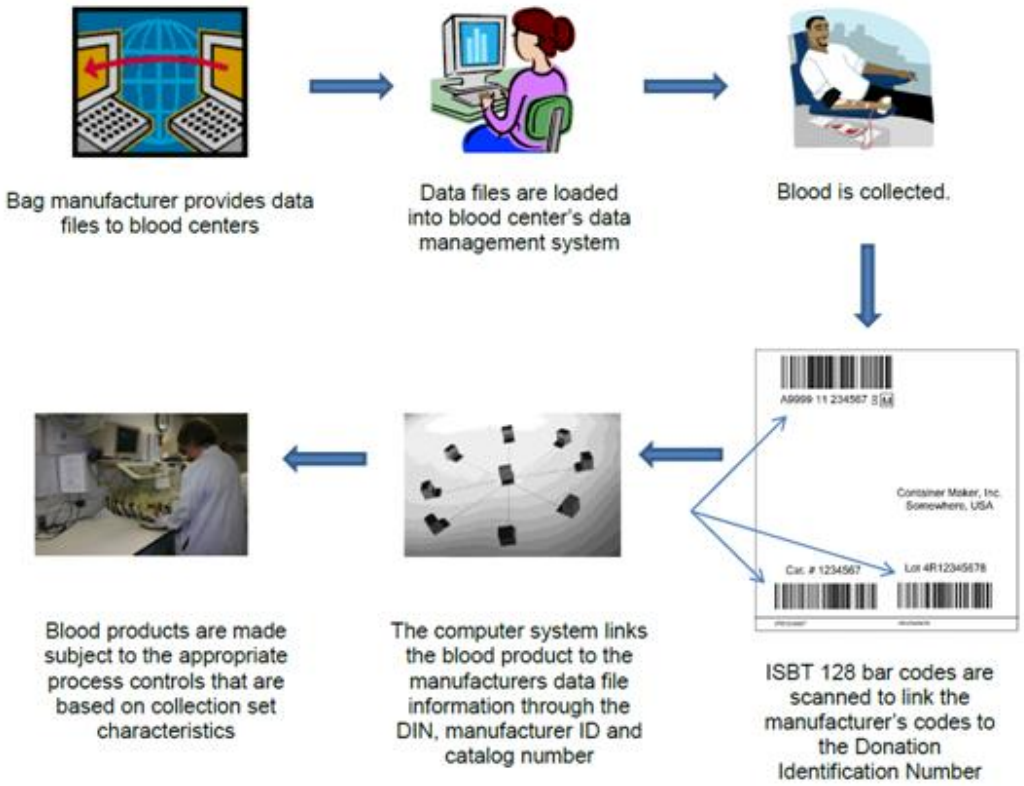

2.4 How the Manufacturers Data File May Be Used

Using the manufacturer's data file depends on the manufacturer of the containers selected providing an electronic data file. This may be provided on their Website, on a CD received with the product, or by other electronic means. Users should contact suppliers to determine if a data file is available and, if so, in what format.

Next, computer software must be designed to allow downloading of the data file and using the information contained within it for process control. Users should contact their software vendor for information on the availability of this functionality.

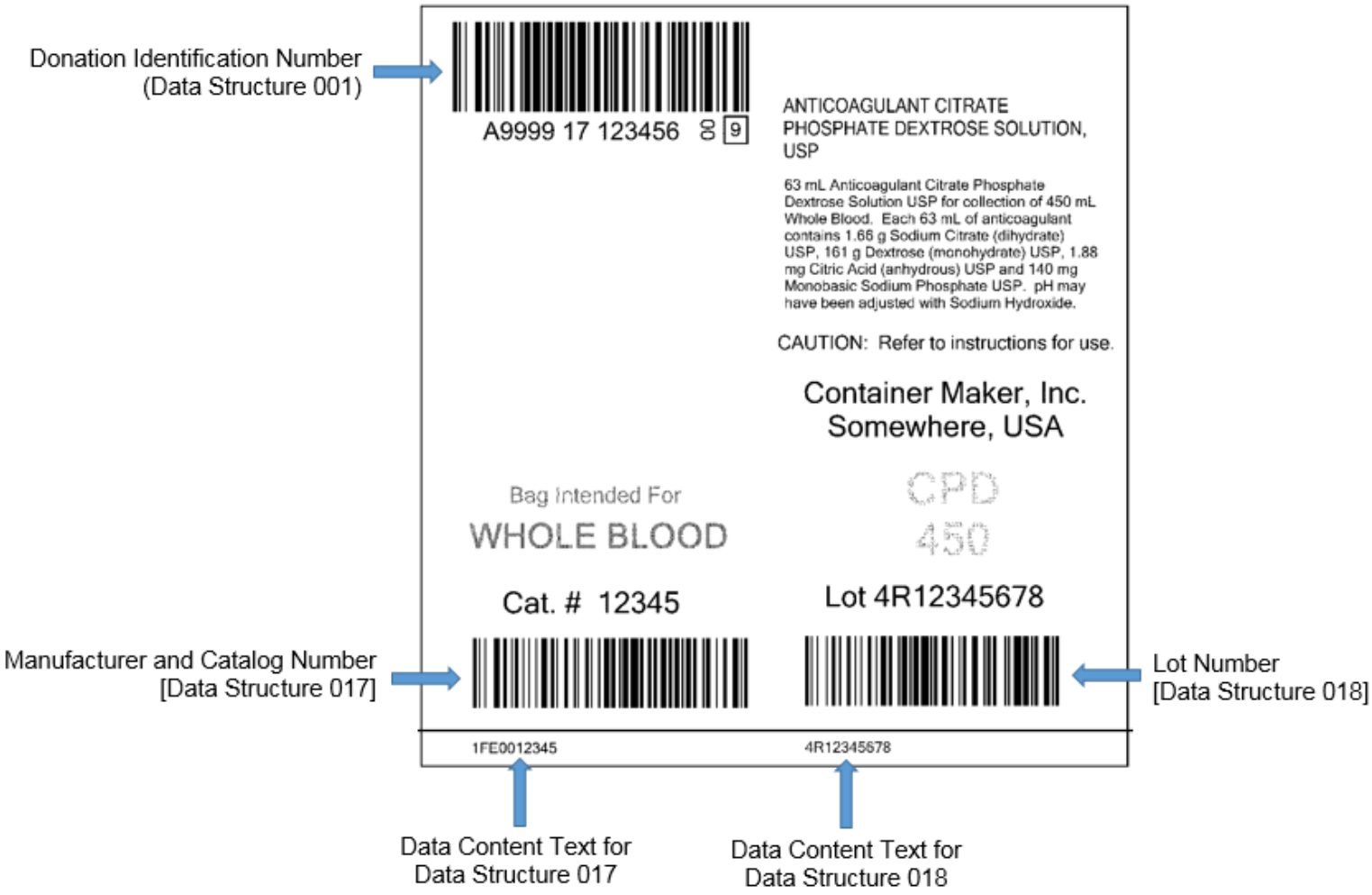
Once the file is available, and software supports its use, the Manufacturers Data File may be used. See Figure 4. At any time—when products are selected, ordered, or received from the container manufacturer for the first time--the catalog number for the product(s) should be identified and entered into the computer system. Using the catalog number information, the corresponding Manufactures Data File should be retrieved from the manufacturer and downloaded into the computer system. Generally, this only needs to occur once for each catalog number.

Figure 4 System for Use of Manufacturers Data File



When the collection sets with this catalog number are used, the Donation Identification Number Data Structure [001] and the Container Manufacturer and Catalog Number Data Structure [017] bar codes from the base label of the primary container can be scanned into the computer system. Manufacturers will have different information on containers, and the exact layout of the container may vary. However, in general the ISBT 128 Container Manufacturer and Catalog Number bar code will appear near the bottom of the container as shown in Figure 5.

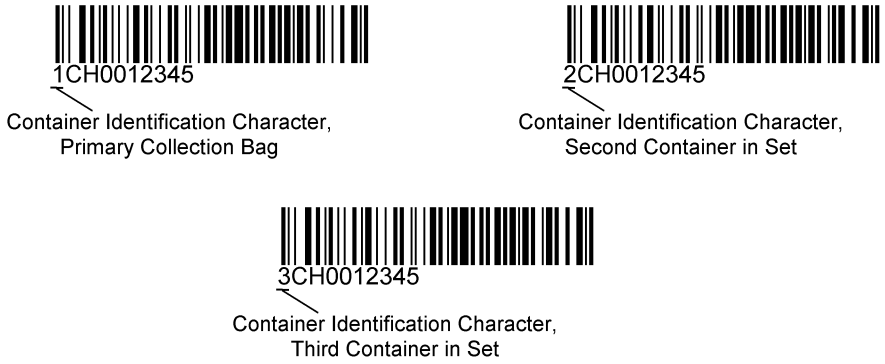
Figure 5 Base Label on Blood Container after Application of Donation Identification Number



Once this information is scanned into the computer system, the information from the data file can be linked to the Donation Identification Number for use in process control. The user should then scan the second manufacturer's bar code which is the lot number of the container set. Alternatively, both of the manufacturer's bar codes may be read together in a concatenated scan.

The Container Manufacturer and Catalog Number and Container Lot Number bar codes appear on each container within the set. The Container Manufacturer and Catalog Number Data Structure [017] includes as its first character the identifier (number or upper case letter) of the container as described in the Manufacturers Data File. See Figure 6.

Figure 6 Bar Codes from Base Labels on Primary and Satellite Containers



This allows the computer system to associate the characteristics described in the data file for the individual container to the container and its contents. Therefore, as components are made from whole blood, the laboratory can scan the various bar codes (DIN, Product Code, and Container Manufacturer and Catalog Number) on each container and associate the container with its contents as the products are produced. During this production phase when contents are being linked with the container information, the product label cannot cover the manufacturer's bar codes. Therefore the scans that associate the container with its contents must be done immediately before the Product Code label is applied or the product label used during this production phase must be placed so that it does not cover the manufacturer's bar code.

Over time, ICCBBA may add lines of information to the Manufacturers Data File standard and increment the version number of the Manufacturers Data File. Manufacturers may update their data files to support the additional information. When this happens, manufacturers should notify their customers so that the new data files may be downloaded.

2.5 Process Control Applications

Blood collectors and processors would use this data file to provide process controls such as:

- Ensuring correct labels are applied to products (e.g., anticoagulant and/or additive, nominal collection volume, reduction of leukocytes)
- Ensuring products stored in a container not designed for the purpose are not released (e.g., red cells stored in a platelet container could not be released)
- Ensuring containers that are over-filled or under-filled according to manufacturer's directions are not released

3 Information for Manufacturers of Blood Containers and Software Vendors

3.1 Structure of the Data File

The structure of the Manufacturers Data File is described in 2.1. Additional lines of information may be added as needed and should be requested from the ICCBBA office. New versions of the Manufacturers Data File will be given a new version number and published in the next version of the *ISBT 128 Standard Technical Specification* (ST-001) Every effort will be made to ensure new versions are backward compatible. Because multiple versions of the Manufacturers Data File will exist at any given time, it is critical to ensure version numbers are included in every file.

3.2 Specific Issues for Container Manufacturers

3.2.1 Containers intended for collection only

Containers that are suitable for the collection of whole blood, but are not intended for longer-term storage of blood components, should have the RBCCONTAINER set to “Y”.

3.2.2 Containers suitable for storage of more than one type of product

One or more of the fields PLTCONTAINER, PMACONTAINER, RBCCONTAINER and BFYCONTAINER may be set to “Y” to indicate suitability for more than one type of product. For platelets, the dating may be affected by the container in which the product is stored. The Manufacturers Data File does not address dating, so it would be appropriate to set the PLTCONTAINER field to “Y” if the container is suitable for storage of platelets regardless of the dating that may result. Control of dating should be addressed by the user (see 3.3.2).

3.3 Specific Issues for Software Vendors

3.3.1 Process control capabilities

Software should be written to take advantage of the process control opportunities afforded by the Manufacturers Data File described in Section 2 of this document.

3.3.2 Configurability

Users, under carefully controlled conditions, may need the ability to override a parameter in the Manufacturers Data File. For example, some container sets will have two types of containers that are suitable for storage of platelets. Within the Manufacturers Data File, both will be indicated as suitable for storage of platelets (PLTCONTAINER set to “Y”). However, the manufacturer may have performed studies to show that platelets may be stored in one type of container for up to three days and in the other type of container for up to five days. The user may elect to make platelets only in the container that allows five-day storage. In this situation, the user may want to disallow release of platelets made in the three-day storage container.

Another user may choose to make platelets in either container. For this reason, product dating should be configurable based on the container number. In the above example, the users should be allowed to configure different dating for platelets (e.g., three or five days) based on the manufacturer's specifications for each container.

4 Example Files

4.1 CSV Files

An example text data file for a whole blood collection set:

```
ICCBBAMF,07
MANUFACTURER,#,YZ
CATALOGNUMB,#,0XY1234
CATNUMBTXT,#,XY-1234
GS1GTIN,#,32005000004004
GS1GTINCONTENT,#,24
CONTAINERNUMB,#,3
CONTAINERNUMB,1,1
CONTAINERNUMB,2,1
CONTAINERNUMB,3,1
COLLECTIONVOL,#,450
CONTENT,1,CPDA-1
CONTENTVOL,1,63
CONTENT,2,SAG-M
CONTENTVOL,2,100
PLTCONTAINER,2,Y
PLTCONTAINER,3,Y
PMACONTAINER,2,Y
RBCCONTAINER,1,Y
LEUKREDFILTER,1,Y
FILETERM,19
```

This data file describes a fictional set from Manufacturer YZ with a catalog number of XY-1234, a GTIN 32005000004004, with 24 items within the carton, for the collection of 450 mL of blood. It comprises 3 containers, one with each of the container identification characters 1, 2, and 3.

The primary container contains 63 mL CPDA-1 anticoagulant and is suitable for red cell storage but not plasma or platelet storage; container 2 contains 100 mL SAG-M additive, is suitable for plasma or platelet storage and is not suitable for red cell storage; container 3 has no content (*i.e.*, is empty) and is suitable for platelet storage.

A leukocyte reduction filter is present in the set. Only the red cell bag is downstream of the filter.

Second example of a text file for a whole blood collection set

```
ICCBBAMF,07
MANUFACTURER,#,YZ
CATALOGNUMB,#,0XY1235
CATNUMBTXT,#,XY-1235
GS1GTIN,#,32005000004005
GS1GTINCONTENT,#,24
CONTAINERNUMB,#,2
CONTAINERNUMB,1,1
CONTAINERNUMB,2,1
COLLECTIONVOL,#,450
CONTENT,1,CPD
CONTENTVOL,1,63
PMACONTAINER,2,Y
RBCCONTAINER,1,Y
LEUKREDFILTER,1,Y
SOLN1,#,AS-1
SOLN1VOL,#,100
FILETERM,16
```

This data file describes a fictional set from Manufacturer YZ with a catalog number of XY-1235, a GTIN 32005000004005, with 24 items within the carton, for the collection of 450 mL of blood. It comprises 2 containers, one with each of the container identification characters 1 and 2.

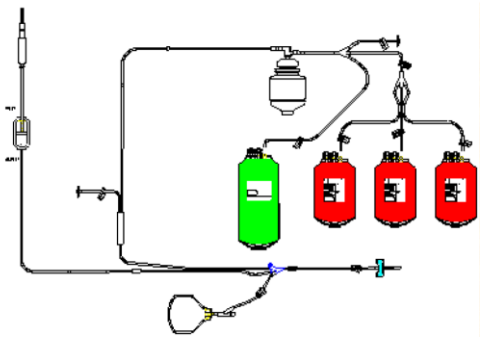
The primary container contains 63 mL CPD anticoagulant and is suitable for red cell storage but not plasma or platelet storage; container 2 is suitable for plasma storage and is not suitable for red cell or platelet storage.

A leukocyte reduction filter is present in the set. Only the red cell bag is downstream of the filter.

There is a container that is not suitable for blood component storage with 100 mL of AS-1 additive solution.

Example of a text file for an apheresis set:

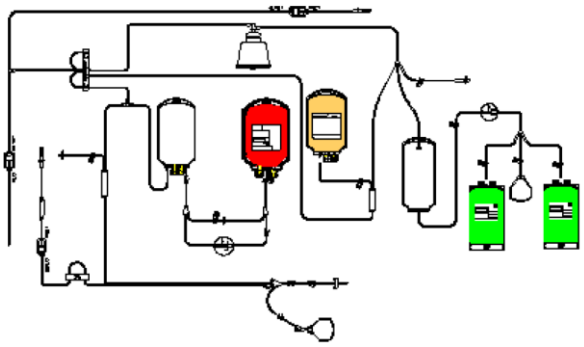
ICCBBAMF,07
MANUFACTURER, #,YZ
CATALOGNUMB,#,00623HS
CATNUMBTEXT,#,623-HS
GS1GTIN,#,32005000005003
GS1GTINCONTENT,#,2
CONTAINERNUMB, #,4
CONTAINERNUMB,A,1
CONTAINERNUMB,B,3
PMACONTAINER,A,Y
PMACONTAINER,B,Y
MAXVOL,A,1000
MAXVOL,B,600
FILETERM,12



This describes a fictional apheresis set made by Manufacturer YZ with a catalog number of 623-HS, a GTIN 32005000005003, with 2 items within the carton comprising four containers: one empty container, maximum volume 1000 mL suitable for plasma storage; three empty containers, maximum volume 600 mL, suitable for plasma storage.

Second example of a text file for an apheresis set example:

ICCBBAMF,07
MANUFACTURER,#,YX
CATALOGNUMB,#,00946FF
CATNUMBTEXT,#,946-FF
CONTAINERNUMB,#,4
CONTAINERNUMB,A,2
CONTAINERNUMB,B,1
CONTAINERNUMB,C,1
PLTCONTAINER,A,Y
PMACONTAINER,B,Y
RBCCONTAINER,C,Y
MAXVOL,A,1000
MAXVOL,B,600
MAXVOL,C,600
FILETERM,13



This describes a fictional apheresis set made by fictional manufacturer YX with a catalog number of 946-FF comprising four containers: two empty containers, maximum volume 1000 mL suitable for platelet storage; one empty container, maximum volume 600 mL, suitable for plasma storage; one empty container, maximum volume 600 mL, suitable for red cell storage.

4.2 XML File

The Manufacturers Data File may also be in an XML format.
An example file is:

```
<?xml version="1.0" encoding="UTF-8" standalone="no"?> <!DOCTYPE
ICCBBA_Manufacturer_Data_File SYSTEM
"http://www.iccbba.org/ICCBBA_Manufacturer_Data_File.dtd">
<ICCBBA_Manufacturer_Data_File>
 <Version>07
 </Version>
 <Data_line>
  <Data_label>MANUFACTURER</Data_label>
  <Pack-set_identifier>#</Pack-set_identifier>
  <Value>YZ</Value>
 </Data_line>
 <Data_line>
  <Data_label>CATALOGNUMB</Data_label>
  <Pack-set_identifier>#</Pack-set_identifier>
  <Value>00623HS</Value>
 </Data_line>
 <Data_line>
  <Data_label>CATNUMBTEXT</Data_label>
  <Pack-set_identifier>#</Pack-set_identifier>
  <Value>623-HS</Value>
 </Data_line>
 <Data_line>
  <Data_label>GS1GTIN</Data_label>
  <Pack-set_identifier>#</Pack-set_identifier>
  <Value>32005000005003</Value>
 </Data_line>
 <Data_line>
  <Data_label>GS1GTINCONTENT</Data_label>
  <Pack-set_identifier>#</Pack-set_identifier>
  <Value>2</Value>
 </Data_line>
 <Data_line>
  <Data_label>CONTAINERNUMB</Data_label>
  <Pack-set_identifier>#</Pack-set_identifier>
  <Value>4</Value>
 </Data_line>
 <Data_line>
  <Data_label>CONTAINERNUMB</Data_label>
  <Pack-set_identifier>A</Pack-set_identifier>
  <Value>1</Value>
 </Data_line>
 <Data_line>
  <Data_label>CONTAINERNUMB</Data_label>
  <Pack-set_identifier>B</Pack-set_identifier>
  <Value>3</Value>
 </Data_line>
 <Data_line>
```



```
 <Data_label>PMACONTAINER</Data_label>
 <Pack-set_identifier>A</Pack-set_identifier>
 <Value>Y</Value>
</Data_line>
<Data_line>
 <Data_label>PMACONTAINER</Data_label>
 <Pack-set_identifier>B</Pack-set_identifier>
 <Value>Y</Value>
</Data_line>
<Data_line>
 <Data_label>MAXVOL</Data_label>
 <Pack-set_identifier>A</Pack-set_identifier>
 <Value>1000</Value>
</Data_line>
<Data_line>
 <Data_label>MAXVOL</Data_label>
 <Pack-set_identifier>B</Pack-set_identifier>
 <Value>600</Value>
</Data_line>
</ICCBBA_Manufacturer_Data_File>
```

The DTD file for checking the validity of an XML file is located on the ICCBBA Website at http://iccbba.org/tech-library/manufacturers-data-file

The file looks like:

```
<!ELEMENT ICCBBA_Manufacturer_Data_File (Version, Data_line+)>
<!ELEMENT Version (#PCDATA)> <!ELEMENT Data_line (Data_label, Pack-set_identifier, Value)> <!ELEMENT Data_label (#PCDATA)> <!ELEMENT Pack-set_identifier (#PCDATA)> <!ELEMENT Value (#PCDATA)>
```

This DTD file indicates that each file is to contain exactly one version element and one or more data_line elements. Each data_line element contains exactly one of each element: Data_label, Pack-set_identifier, and Value.

