

ISBT 128 Manufacturer's Data File

Sample ISBT 128 Base Label applied by blood bag manufacturer

Blood bag manufacturer's
catalog number and lot
number bar codes

PLACE DONATION IDENTIFICATION NUMBER HERE	DO NOT TRANSFUSE UNLESS ABO LABEL APPLIED HERE
	ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION, USP
	63 mL Anticoagulant Citrate Phosphate Dextrose Solution USP for collection of 450 mL Whole Blood. Each 63 mL of anticoagulant contains 1.66 g Sodium Citrate (dihydrate) USP, 161 g Dextrose (monohydrate) USP, 1.88 mg Citric Acid (anhydrous) USP and 140 mg Monobasic Sodium Phosphate USP. pH may have been adjusted with Sodium Hydroxide.
	CAUTION: Refer to instructions for use.
	Container Maker, Inc. Somewhere, USA
Bag Intended For WHOLE BLOOD	CPD 500
Cat. # 1234567	Lot 4R12345678
	
1FE1234567	4R12345678

Catalog Number bar code data structure

=)bqqwwwwwww

=) ISBT 128 Data identifier for catalog number

b container identification character that links each bag to the manufacturer's data file (numbers 1-9 are whole blood containers; alphas are used for apheresis; zero and 2-9 are used for transfer packs)

qq container manufacturer's identifier (assigned by ICCBBA)

wwwwwww manufacturer's catalog number
(7 characters padded with "leading zeros")

What is the Manufacturer's Information Data File?

- An electronic file of detailed product information about the set and the individual bags within the set
- A mechanism to transfer information about the set and each bag in the set to the user's computer system
- Information may be used for process control at the blood collection/processing center to indicate the intended storage, contents, etc. for each container

How does it work?

- Bag manufacturers provide data files containing detailed product information for each bag set on their websites (or communicated to blood centers by other electronic means, such as a CD)
- Users download the data files into their data management systems to access set/bag information to assist in process control during component production
- Data files for each set are linked to the ISBT 128 catalog number bar code printed on each bag



Bag manufacturer provides data files to blood centers



Data files are loaded into blood center's data management system



ISBT 128 bar codes are scanned at the time of collection to record the catalog number and lot number of the set



Blood center operator scans the catalog number bar code to access the container information provided in the data file



Blood products are processed and transferred to the appropriate containers

What Information is in the file?

- Information about the set
 - ☐ Number of containers
 - ☐ Intended use of each container
 - ☐ Nominal collection volume for the primary container (optional)
 - ☐ GTIN information
- Information for each individual bag
 - ☐ Type of container (RBC, platelet or plasma)
 - ☐ Volume and type of fluid contained in bag (anticoagulant, additive, etc.)
 - ☐ Nominal volume that each container is designed to hold when filled
 - ☐ Minimum and Maximum volumes
 - ☐ Indication of bags that are downstream from a leukoreduction filter

Structure of data files

- Header line
- Data lines
- Footer line

Header Line

Field	Length	Format	Comment
1	8	Alpha	Fixed text “ICCBAMF” identifies this as an ICCBBA, Inc-specified Manufacturers File format
2	2	Numeric	2 digit number identifies the version of the data file with which message is compliant (version number is found in the Technical Specification)
3	-	-	Available for future use

Data Lines

- Manufacturer
- Catalog number
- Catalog number text
- GS1 Global Trade Item Number
- GS1 GTIN Content (number of items in carton)
- Container number
- Collection volume
- Content (anticoagulant, additive)
- Content volume
- Platelet container
- Plasma container
- Red cell container
- Buffy coat container
- Leukoreduction filter
- Nominal volume
- Minimum Volume
- Maximum Volume
- Comment

Minimum Volume (Optional)

- 4 character (numeric)
- The minimum amount of the product that the container is designed to hold (in mL)

Maximum Volume (Optional)

- 4 character (numeric)
- The maximum amount of product the container is designed to hold (in mL)

Footer

Field	Length	Format	Comment
1	8	Alpha	Fixed text "FILETERM"
2	4	Numeric	The number of data lines in this Manufacturer's Data File (if less than 1000 lines, use leading zeroes)

Description of Data Lines

Manufacturer (required)

- 2 letter code assigned to each manufacturer
- Codes found on Table W1 on www.iccbba.org (under Technical Documentation/Current Versions)

Catalog Number (required)

- 7 character representation of the manufacturer's catalog number for the set
- Alpha or numeric
- Padded with leading zeros for catalog numbers with fewer than 7 characters

Catalog Number Text (required)

- Free format
- Manufacturer's full catalog number as printed in their documentation and used to order the product

GS1 Global Trade Item Number (optional)

- 14 characters (numeric)
- representation of the GS1 Global Trade Item Number

GS1 GTIN Content (optional)

- 3 character (numeric)
- The number of items in the carton

Container Number (required)

- 2 characters (numeric)
- Number of containers in set (when field 2 = #)
or number of containers with specified
container identification (when field 2 =
container identification character)

Collection Volume (optional)

- 3 characters (numeric)
- Nominal collection volume

Content (required)

- Solution contained in each bag
- Anticoagulant and/or additive solution
- Should be defined in ICCBBA Bounded Lists and Definitions document (if not, need to request)
- Default value of “none” applies for empty containers if no contents are specified

ACD-A	Acid Citrate Dextrose, Formula A
ACD-A>AS1	Acid Citrate Dextrose, Formula A – Additive Solution 1
ACD-A>AS3	Acid Citrate Dextrose, Formula A – Additive Solution 3
ACD-A>PASIII	Acid Citrate Dextrose, Formula A – Platelet Additive Solution III
ACD-B	Acid Citrate Dextrose, Formula B
AS1	Additive Solution 1
AS2	Additive Solution 2
AS3	Additive Solution 3
AS5	Additive Solution 5
CPD	Citrate Phosphate Dextrose
CPD>AS1	Citrate Phosphate Dextrose – Additive Solution 1
CPD>AS5	Citrate Phosphate Dextrose – Additive Solution 5
CPD>PASIII	Citrate Phosphate Dextrose – Platelet Additive Solution III

Content Volume (optional)

- Numeric (3)
- Volume of fluid contents

Platelet container (default applies)

- 1 character
- Indicator (Y or N) if this container is suitable for storage of platelets
- Default is N

Plasma Container (default applies)

- 1 character
- Indicator (Y or N) if this container is suitable for storage of plasma
- Default is N

RBC Container (default applies)

- 1 character
- Indicator (Y or N) if the container is suitable for storage of red cells
- Default of N

Buffy Coat Container (default applies)

- 1 character
- Indicator (Y or N) if container is suitable for the storage of buffy coats (liquid phase)
- Default of N

Leukoreduction Filter (default applies)

- 1 character
- Indicates (Y or N) whether the container is downstream of a leukocyte reduction filter
- Default of N

Nominal Volume (optional)

- 4 characters (numeric)
- The volume of final product the container was designed to hold (in mL)

Minimum Volume (Optional)

- 4 characters (numeric)
- The minimum amount of product that the container is designed to hold (in mL)

Maximum Volume (Optional)

- 4 characters (numeric)
- The maximum amount of product the container is designed to hold (in mL)

Comment (optional)

- 200 characters maximum (alpha)
- Field that is available for manufacturers to add comments for internal use; end users are not expected to upload this information

New lines may be added

- Most recent: addition of leukoreduction filter indicator
- Next issue: differentiating bags for variable lengths of platelet storage

Example Data Files

ICCBAMF02

MANUFACTURER

#HG

CATALOGNUMB

#00946FF

CATNUMBTEXT

#946-FF

CONTAINERNUMB

#04

CONTAINERNUMB

A02

CONTAINERNUMB

B01

CONTAINERNUMB

C01

PLTCONTAINER

AY

PMACONTAINER

BY

RBCCONTAINER

CY

NOMINALVOLUME

A1000

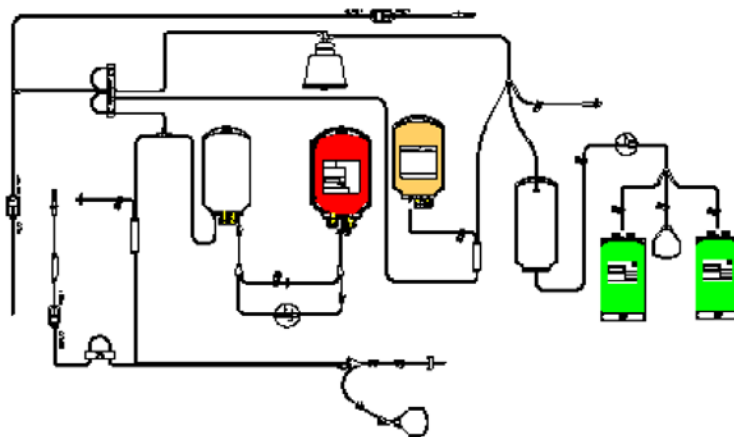
NOMINALVOLUME

B600

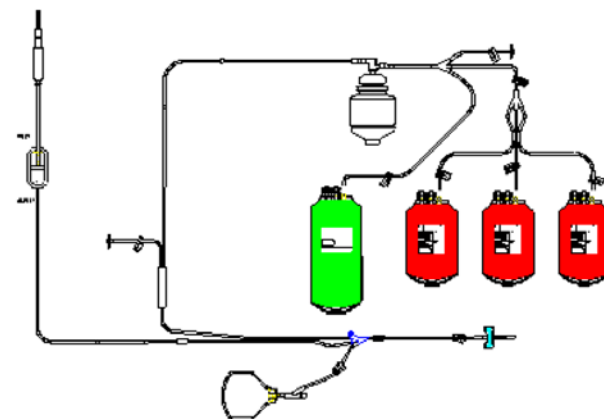
NOMINALVOLUME

C600

FILETERM0013

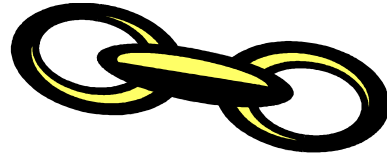


ICCBAMF02
MANUFACTURER #HA
CATALOGNUMB #00623HS
CATNUMBTEXT #623-HS
CONTAINERNUMB #04
CONTAINERNUMB A01
CONTAINERNUMB B03
PMACONTAINER AY
PMACONTAINER BY
NOMINALVOLUME A1000
NOMINALVOLUME B600
FILETERM0010

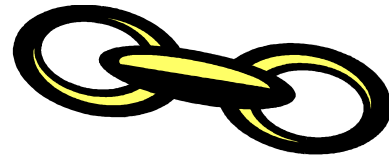


ICCBAMF02	
MANUFACTURER	#BA
CATALOGNUMB	#0XY1234
CATNUMBTXT	#XY-1234
CONTAINERNUMB	#03
CONTAINERNUMB	101
CONTAINERNUMB	201
CONTAINERNUMB	301
COLLECTIONVOL	#450
CONTENT	1CPDA-1
CONTENTVOL	1063
CONTENT	2SAG-M
CONTENTVOL	2100
RBCCONTAINER	1Y
PMACONTAINER	2Y
PLTCONTAINER	3Y
LEUKOREDFILTER	1Y
FILETERM0016	

Set catalog number



Detailed product information



Blood center collection/processing lab