

Guidelines for the Blood Transfusion Services

Chapter 26: Specification for blood pack base labels

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Chapter 26: Specification for blood pack base labels

26.1: Introduction

This chapter defines the requirements of the UK Blood Transfusion Services for the layout and information content of the blood pack base label affixed to the blood pack by the pack manufacturer.

This specification applies to the base labels provided on all blood component packs either within a blood pack or apheresis assembly or 'stand-alone' (in this context, a blood component is a component as described in Chapter 7). In addition to these labelling requirements, all blood packs must satisfy the validation criteria of Chapter 8.

The base label must be able to accommodate the donation identification number, blood group and blood component overstick labels defined in Chapter 23.

References to linear dimensions in this document are in millimetres.

26.2: Specification

The layout of the blood pack base label is shown in Figure 26.1 and is divided into three areas. Area numbers on the diagram are for reference purposes only and must not be reproduced on the label. Where volumes are to be specified on the base label they must be given in millilitres. Anticoagulant and additive formulations must be in English.

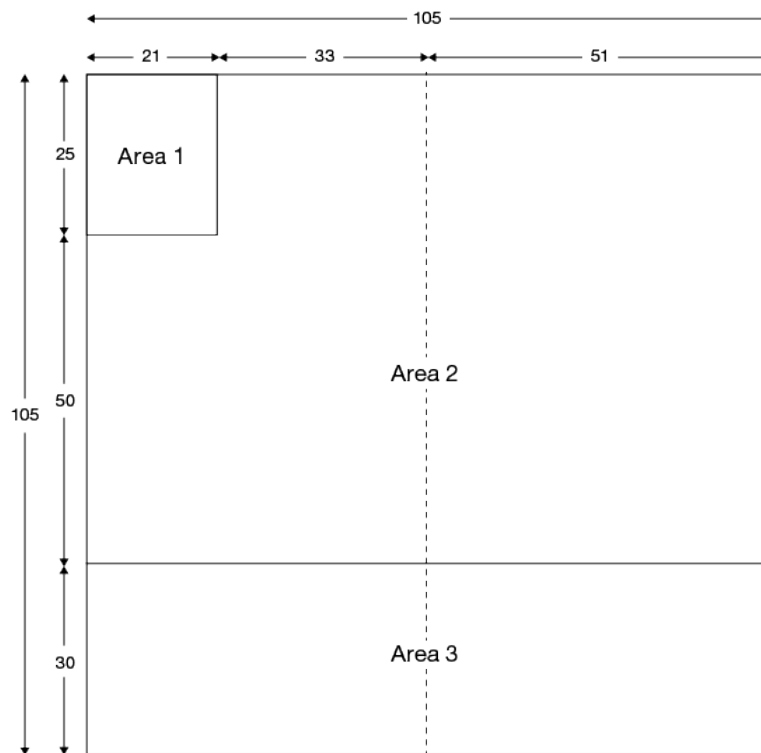


Figure 26.1 Base label layout: dimensions in millimetres for 400 mL to 600 mL pack

The manufacturer's logo may be printed in a colour of their choice. All other printing must be black on white. Labels, adhesive and ink must comply with the requirements of the current version of the International Organization for Standardization Standard ISO 3826-1, Plastics collapsible containers for human blood and blood components – Part 1: Conventional containers.

Area 1 is provided for the manufacturer to print their logo, name and address.

Area 2 is provided for the manufacturer for the following information concerning the medical device. (Note: this area is typically covered after application of Blood Transfusion Service overstick labelling.)

- On all packs the words or approved medical device symbol(s) shown in Figure 26.2:
 - Do not re-use this container
 - Do not vent
 - Contains phthalate e.g. DEHP (if applicable)
 - Sterile
 - Pyrogen free fluid pathway
 - Do not use if damaged/deteriorated
 - Expiry date (see note below)
 - Refer to instructions for use
- On all packs the 'CE' mark and the registration number.
- On primary blood collection packs, the formulation and volume of anticoagulant.
- On additive packs, the formulation and volume of the additive solution.
- The nominal volume of blood/component that is to be collected into the container. (Instructions for use should also give the volume range.)

- Where a pack is specifically intended for the storage of a particular component, the identity of that component, e.g. 'Suitable for the storage of platelets', must be labelled. Alternatively this information can be provided by symbols in the current version of ISO 3826-2 Plastics collapsible containers for human blood and blood components – Part 2: Graphic symbols for use on labels and instruction leaflets.
- Manufacturers should, where appropriate, indicate that the blood pack including its sub-components are latex free. The symbol in Figure 26.2 may be used.

Note: The expiry date may be expressed as: 'Do not use after DD/MM/YY' where DD is the day number, MM the month number and YY the year. For clarity, the expiry date will be midnight (23:59 hours) on the date shown. It is permissible to use only MM/YY; in this instance the expiry date will be midnight on the last day of the month/year shown.

The expiry date may alternatively be provided by the manufacturer on the immediate overwrap in which case the following statement must be applied to the base label: 'Use within x days of opening the immediate overwrap', where x is the number of days validated by the manufacturer.

Labelling of the blood pack overwrap and packaging must comply with the current versions of ISO 3826-1 and the EU Medical Devices Directive.

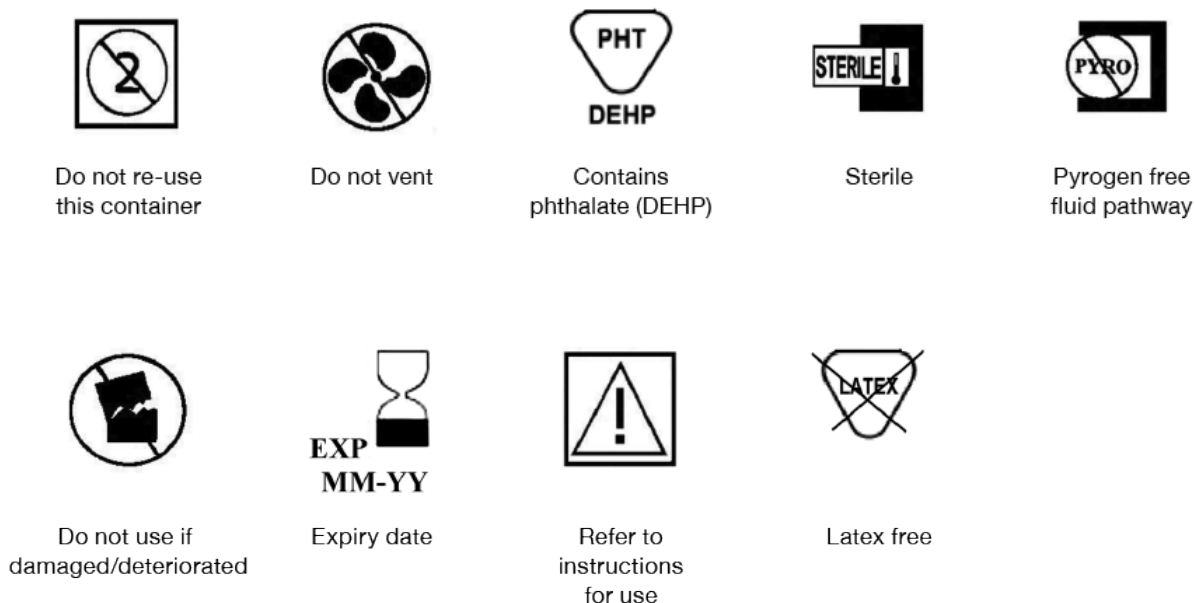


Figure 26.2 Symbols used on blood packs and on critical consumables (ISO 3826-2, ISO 15223-1 and EN 980)

Area 3 is provided for the manufacturer's pack type (list/catalogue) and pack batch or lot number. This information must be printed in both eye-readable and barcoded formats. The UK Blood Transfusion Services are currently in transition from ABC Codabar to ISBT 128 for the provision of this information. Details of both conventions are provided below. The manufacturer's pack type and lot number must remain visible in eye-readable format after application of overstick labels.

Labels must, after sterilisation, conform to the dimensions specified in Table 26.1.

Labelling of the blood pack overwrap and packaging must comply with the current versions of ISO 3826-1 and EU Medical Devices Directive.

Label adhesives applied directly to the plastic film of a blood bag must be tested and approved by manufacturers in accordance with the relevant current versions from the ISO 10993 biocompatibility series of standards (or equivalent national standards). The risk of the adhesive coming into contact with blood or blood components should be established by 'extractables' testing (ISO 10993 – Parts 1, 17 and 18). If testing reveals an unacceptable level of migration, biocompatibility testing should be extended to interaction with blood (ISO 10993 – Part 4) and toxicological testing (ISO 10993 – Parts 3 and 5).

- ISO 10993-1:2009 Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
- ISO 10993-3:2003 Biological evaluation of medical devices. Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2002/Amd 1:2006 Biological evaluation of medical devices. Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity
- ISO 10993-17:2002 Biological evaluation of medical devices. Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2005 Biological evaluation of medical devices. Part 18: Chemical characterisation of materials.

Table 26.1 Blood bag base label dimensions (width × depth)

100 mL bag	60 × 85 ±5 mm*
250 mL bag	90 × 85 ±5 mm*
400 mL bag	105 × 105 ±5 mm
500 mL bag	105 × 105 ±5 mm
600 mL bag	105 × 105 ±5 mm
* The layout of base labels applied to smaller packs must be controlled within the purchasing specification. Barcode positions are indicated in the ISBT 128 (ICCBBA) product labelling section.	

26.3: Manufacturers' blood pack catalogue and lot numbers

Below we describe two data structures for encoding the manufacturer's blood pack catalogue and lot numbers. The structures are fundamentally different but both coding systems use two data structures. For

Codabar the manufacturer's code is with the lot number and the catalogue number/pack type is a separate code. For ISBT 128 the catalogue number/pack type is with the manufacturer's code and the lot number is a separate code. For ISBT both the catalogue and lot number are required to uniquely identify a batch of blood bags.

26.3.1: ABC Codabar manufacturer's blood pack catalogue and lot numbers

Currently Blood Services request Codabar barcoded information on each pack. Two classes of data are recorded, namely:

Catalogue number (pack type)

This label defines the type of pack, e.g. whole blood, platelet etc. The code is defined as follows:

c p p p p p k 7 b

Where:

c	is the start code
p p p p p p	is the manufacturer's list/catalogue number
k	is the modulus 11 check digit
7b	is the stop code.

Batch/lot number

This number describes the batch/lot number for each individual pack. The format is:

b 1 X X D D D D D D C 6 b

Where:

b1	is the start code
XX	is the manufacturer's code (see Table 26.2)
DDDDDDDD	is the batch/lot number
C	is a modulus 11 check digit based on XXDDDDDDDD
6b	is the stop code.

Table 26.2 Manufacturers' Codabar codes

Manufacturer	Code	Manufacturer	Code
Baxter Healthcare	01	ASAHI Medical GmbH	10
TUTA Laboratories	02	Gambro BTC – UK	11
Biotest UK	03	Kawasumi Laboratories Inc	12

Haemonetics	04	Charter Medical	13
NPBI FRESENIUS	05	Baxter Healthcare – La Chatre	14
Terumo	06	Baxter Healthcare – Haina	15
Gambro BTC – US	07	Baxter Healthcare – Mountain Home	16
Maco Pharma	08	Cerus Europe BV	17
PALL	09	Fenwal – La Chatre	18

Note: Not all entries are in current use but are retained for use in look-back situations.

26.3.2: ISBT 128 manufacturers' blood pack catalogue and lot numbers

To achieve ISBT 128 compliance the UK Blood Transfusion Services will adopt the ISBT 128 convention for manufacturers' blood pack catalogue and lot numbers. Details are provided in the current version of ISBT 128 Standard Technical Specification, Data Structures 017 and 018, which is available on ICCBBA's website (www.iccbba.org).