



Date of publication: 10 th February 2009	Implementation: For clarification
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Change Notification UK National Blood Services No. 5 - 2009

To clarify label dimensions and requirements to assess label glue in the Red Book (Chapters 25 and 28)

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 7th Edition 2005

This update provides revised wording to align label dimension requirements with recent changes in standards and also clarifies the requirements for testing of label glue (*JPAC 08-77*).

Please delete:

Chapter 25 – Specification for the uniform labelling of blood and blood components

Page 279 **24.1.4 Referenced documents**

1. ISBT 128 Standard Technical Specification (Version 2.0.0 June 2003).

Page 294 **25.5. Component labels**

25.5.2 Label dimensions

- a) 55 mm x 55mm
- b) 55 mm x 35mm

Chapter 28 - Specifications for blood pack base labels

Page 327 **28.1 Specification**

- | | |
|-----------------------|--|
| Para 1, 2nd sentence | Labels should, be within the specified dimensions (+/-5%). |
| 2nd main bullet point | <ul style="list-style-type: none"> • on all packs the words ISO 3826-1 (2003) |

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Page 328 1st para (below Fig 28.1) The following text must be printed in area 3 (subsequently covered when the Blood Transfusion Service applies a component label).

Legend for Fig 28.2

Figure 28.2 Base label layout: dimensions in millimetres

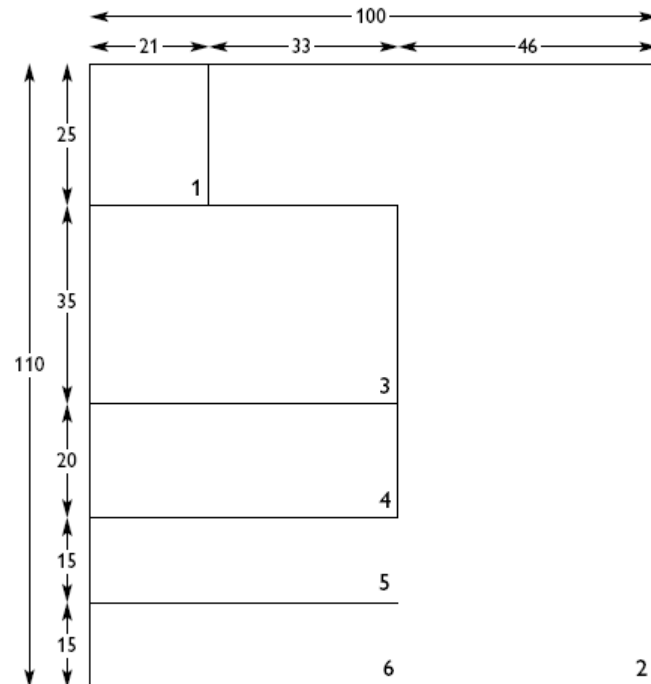


Figure 28.2 Base label layout: dimensions in millimeters”

Replace with:

Chapter 25 – Specification for the uniform labelling of blood and blood components

Page 279 **25.1.4 Referenced documents**

1. ISBT 128 Standard Technical Specification (Version 3.3.0 May 2008).

Page 294 **25.5 Component labels**

25.5.2 Label dimensions

- a) 55 mm +/- 1mm wide x 55mm +/-3 mm deep
(range 54 – 56 mm wide x 52 – 56 mm deep)
- b) 55 mm +/- 1mm wide x 35mm +/- 1mm deep
(range 54 – 56 mm wide x 34 - 36 mm deep)

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Chapter 28 - Specifications for blood pack base labels

Page 327 28.1 Specification

Para 1, 2nd sentence Labels should, after sterilisation, be within the dimensions specified in Table 28.1.

Para 3 - addition following the 3rd sentence. Label adhesives must be tested and approved by manufacturers in accordance with applicable current versions of the ISO 10993 series of standards: Biological evaluation of medical devices (biocompatibility standards).

2nd main bullet point • on all packs the 'CE' mark and registration number.

Page 328 1st para (below Fig 28.1) The following text must be printed in area 3 (subsequently covered when the Blood Transfusion Service applies a component label). Alternatively the information may be conveyed using approved medical device symbols (published in current versions of ISO 3826-2, ISO 15223-1 and EN980).

Legend for Fig 28.2 **Figure 28.2** Base label layout for 400 to 600 ml bags: dimensions in millimetres

Add to this page **Table 28.1** - Blood bag base label dimensions (width x depth)

100 ml bag	60 x 85 +/- 5 mm
250 ml bag	90 x 85 +/- 5 mm
400 ml bag	105 x 105 +/- 5 mm
500 ml bag	105 x 105 +/- 5 mm
600 ml bag	105 x 105 +/- 5 mm

(extract from ISO 3826-1)

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