

Proposed change to Red Book label specification

Key to changes: **New text** ~~Deleted text~~ Unchanged text **Note (not for publication)**

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

Page 279

245.1.4 Referenced documents (correction of an existing error)

1. ISBT 128 Standard Technical Specification (~~Ver 2.0.0 June 2003~~ **Version 3.3.0 May 2008**).

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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)

Chapter 28 - Specifications for blood pack base labels

28.1 Specification

Page 327, para 1, 2nd sentence.

"Labels should, after sterilisation, be within the ~~specified~~ dimensions ~~specified in Table 28.1 (+/-5%)~~". (to allow for label shrinkage)

Page 327, 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)". (toxicity, haemolysis etc)

Page 327, 2nd main bullet point

?? "on all packs the ~~words ISO 3826-1(2003)~~ 'CE' mark and registration number.

(Conformity assessment against ISO 3826-1 is not yet an EU accepted route to the registration of blood packs as medical devices. It will become so later this year when 3826-1 is listed in OJEU as a 'harmonised standard').

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).~~

(Manufacturers are already using these internationally recognized symbols)

Page 328, legend for Fig 28.2

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

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

(New table, extract from ISO 3826-1)