United Kingdom Blood Transfusion Services

Northern Ireland BLOOD TRANSFUSION SERVICE

Welsh Blood Service

NHS Blood and Transplant

Specification for the Future Labelling of Blood Components Prepared in the United Kingdom

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0.2 Document history

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0.3 Normative references and guidelines

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EN ISO 3826-1:2003: Plastics collapsible containers for human blood and blood components Part 1: Conventional containers.

EN ISO 3826-2:2008: Plastics collapsible containers for human blood and blood components Part 2: Graphic symbols for use on labels and instruction leaflets.

EN/ISO 15223-1:2007/ Amendment A1:2008. Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

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

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0.5 Background

In 1998 the Department of Health issued a letter requiring all Trusts to be able to utilise ISBT 128 Donation numbers (DIN) for blood components and by April 2001 all UK Blood Services had implemented the change from dual labelling (ISBT 128 plus Codabar) of the DIN to ISBT 128 alone. The dual labelling of the DIN was introduced as a result of Pulse implementation in NHSBT but the drive to then drop the Codabar DIN was on patient safety grounds to reduce confusion from the dual labelling and duplication of barcodes. While the patient safety aspect of the dual DIN was addressed the issue of component labels containing two separate coding systems for significant safety related data items was not. It was considered acceptable that extension of the use of ISBT 128 to component and other codes would follow at some time in the future as a second phase.

In 2004 THE Joint Professional Advisory Committee (JPAC) endorsed the recommendations in the Standing Advisory Committee Information Technology (SACIT) paper JPAC 04/36 'Recommendations on the further use of ISBT 128 standard in the labelling of blood and blood components' which were:

SACIT recommended the conversion to further compliance of ISBT 128 coding in order to:

- *improve operational flexibility and enhance capability to use blood components within an increasingly complex internal market;*
- *enable movements across national boundaries and allow UK hospitals to receive components from the increasing number of countries that use ISBT128;*
- *help meet the labelling and traceability requirements of the EU Directive;*
- *bring consistency of labelling between blood components, stem cells and tissues in the UK;*
- *allow the transfer of important additional information in barcoded format.*

01/10/17 is the start date for introduction of Transition state labels into supply. From this time Transition state labels can be expected to be found in circulation. The aim is that from 01/02/19 UK hospitals and blood services will be ready to implement the Future State labels. This means that by 01/02/19 all hospital systems must be capable of reading the 2D data matrix.

The SACIT paper further described points of:

- Potential issue for CODABAR codes not being unique and situation of different components having the same code.
- CODABAR specification does not have a built in self-checking mechanism to support validation of the code reading. ISBT128 has 2 built in independent self-checking mechanisms.
- In 2004 CODABAR was already viewed by the NHSIA IT Standards Handbook as "obsolescent technology".
- The need to have a coding system that supports other electronic data transfer systems, for example EDI and enable controlled contingency operating modes.
- Limitations in the CODABAR coding system preventing the coding of significant information e.g. phenotypes, antigens etc.

The paper was tabled at the UK Forum where members agreed to look into this as part of their business planning, and agreed that initial work should proceed on the specifications (taking into account changes imposed by the EU Directive). In 2005 it was later reported in the Forum that the Services did not consider the change as high priority at that time. The subject was brought up again in 2006 when Martin Gorham agreed to take the issue of differences in interpretation of code 128 by different countries to the EBA and also it was noted as part of International Emergency Planning for blood that a common international approach to the use of coding would be beneficial although it does not appear that any action arose from this. In 2006 SACIT set up a project in conjunction with SACBC to try to standardise labelling across the UK, for which there were several drivers:

- EU Directive requirements on labelling were driving some changes (printing of component weight and volume of anticoagulant on the label)
- Some barcodes used in one country may refer to a different component in another
- Different texts appeared on labels from different Blood Establishments (BEs)
- Closer collaboration between UK countries meant movement across borders should be facilitated
- *replace the current frail Excel Spreadsheet based UKBTS system for managing ABC barcodes with a system visible to all UKBTS services and hospitals.*
- *control the allocation of codes solely by SAC.IT/BC and aligned strictly to the ICCBBA database (so no potential misalignment of code use or creating duplicates as currently).*
- *standardise the coding of intermediate blood components allowing potential transfer of part processed components between UK blood services as part of business continuity planning.*

The plan to work towards this was to develop a common UK Portfolio of blood components, assign codes and labels, map back to current components and then convert components to standard specifications with standard labelling. A great deal of work went into this project over the next few years – the current position is that there is much greater standardisation of components (although this is not complete) and a UK Portfolio database of components has been created. This is available with password access (hosted currently by NSS IT), although further relatively minor work is required in order to improve its utility prior to considering rollout to hospital users, with no funding for this currently identified.

In 2008 a further paper from SACIT on considerations for the further implementation of ISBT 128 was presented to the UK Forum. It was recognised that this was a complex issue, and the Forum asked for further information including indications of cost, resource and time required. It was agreed to fund a short-term Project Manager to look into these considerations further. The report from the Project Manager reviewed benefits and risks of each type of coding, described current practices of labelling within the four Services and what changes would be required for BEs and hospitals if ISBT128 were implemented. It estimated some costs, but was not able to assess impact on hospitals, describe full costs or perform a cost-effectiveness analysis of the various options proposed within the resource and timescale available, due to the number of different suppliers involved and the lack of a sufficiently detailed requirement specification.

It was further recognised at this time that there were wider issues with component labelling content and layout and that at some point these issues would have to be

addressed. The working group suggested the introduction of additional ISBT 128 barcodes should be looked at in tandem with a full component label review. The rational being, that while more radical change would incorporate greater project management complexity it would reduce the overall disruption to service and customers of repeated phased change e.g. introduction of additional ISBT128 linear barcodes, move to 2D data matrix barcode, use of QR code, extended phenotyping etc. all of which would require some degree of label redesign.

In order to take the work forward from this point, JPAC hosted a Workshop in 2012 to discuss broader issues around component labelling with SACIT and SACBC members, Blood Service operational staff and hospital users. The agenda included presentations on label design, format and barcoding. Following on from the Workshop Steering and Working Groups were set up. There was great enthusiasm with significant user engagement for taking forward ideas for new label design from the Workshop, which has subsequently been tested in a survey and the results published (Nightingale *et al*, 2013 and 2014).

Also in 2012 the UKBTS contributed to and adopted the Eurobloodpack specification which standardised on the ISBT 128 blood pack manufacturer catalogue and lot numbers. The catalogue number uniquely identifies each bag in the blood pack assembly that provides the opportunity to identify 'in process' products using the ISBT128 coding system without additional labelling.
A further Workshop was held in September 2013 with representatives from all UK Services to discuss the operational issues that may arise from the introduction of a new component label, the potential impact on the Blood Services, and to start to identify where costs may be incurred. A meeting with suppliers of BE systems, hospital laboratory information systems (LIMS) and hospital blooding tracking systems also took place in order to raise the issue of possible change to labelling, including introduction of ISBT128 product code, expiry and extended phenotype codes and discuss the ideas for change and what impact it may have on the suppliers.

The purpose of this paper is to set out for the UK Forum the proposals for change in blood component labelling which have been developed as a result of the work outlined above over recent years, the reasons why these changes should be considered, the options under consideration and outline estimated timescales and costs.

Proposed changes

Changes are proposed to the following aspects of component labelling:

1. Barcodes – complete the move to the ISBT 128 coding system by encoding the donation number, product code (incorporates the move from CODABAR to ISBT Component Codes), expiry date, ABO/Rh D and extended phenotypes into a single ISBT128 2D barcode.
2. Label format – move to full face labels incorporating redesign of the component label to address concerns raised by SHOT, the recent UKBTS hospital labelling survey and best practice guidance from the MHRA.
3. Additional utility by inclusion of QR code to conveniently access component Red Book specifications on the JPAC website

1.0 PURPOSE AND SCOPE

This specification applies to the finished product labelling of therapeutic blood components produced by blood Transfusion Services within the United Kingdom. Other materials that control the appearance of finished product labelling including the blood pack base label, donation number applied to the blood bag at session and demand printed full face label stock have also been specified. The labelling of intermediate products will depend on the IT system in use by each blood service but must be compatible with finished product labelling specified herewith. This specification does not include tissues or cellular and molecular therapy products.

The specification is intended to provide the detailed requirements for materials, print layout and equipment for blood services, hospitals and manufacturers of IT equipment and consumables wishing to implement and/or support the improved blood component labelling within this specification. The specification also outlines validation requirements.

A separate change specification is in progress for changes to the Electronic Delivery Note (EDN file).

2.0 BASIC LABELLING CONCEPT

Existing blood component labelling is a mix of text, ABC Codabar and ISBT128 barcodes. The label format is laid out in ICCBBA quadrant style and lacks a clear separation of critical, clinical and laboratory information. The improved labelling described in this specification seeks to separate and better present these categories of information based on MHRA best practice guidance on the labelling of medicinal products, feedback received from UK hospitals [Nightingale et al 2014] and SHOT and benchmarking against the component labelling of non-UK Countries.

A **‘future state’** label is specified which represents the ultimate goal of this improvement initiative. The future state label standardises on ISBT Code 128 for all bar codes with the exception of a quick response (QR) barcode that will direct users to the UKBTS Guideline specification for each blood component. Apart from the donation number applied to the blood bag at session, all other barcodes (including the component code, expiry date and ABO/Rh D) are condensed into a single ISBT128 2D barcode that also reproduces the donation number and extended phenotypes. The future state label is printed ‘full face’ onto a single 100 x 100 mm demand printed label.

A full face **‘transition’** label is also specified that has basically the same content and layout as the future state but in addition includes the current Codabar barcodes to enable hospitals and blood services to make a phased transition to the future state label.

The extra space made available on the future state and transition label enables additional text concerning DEHP and latex content. All other warning messages are identical to present. Anticoagulant formulation has been removed from the label in line with other EU countries and will be made available to users separately.

3.0 BLOOD PACK / BAG BASE LABEL DIMENSIONS / LAYOUT

3.1 General

This UK Blood Component Labelling Specification has been written to ensure compatibility with blood packs specified within International Standard ISO 3826 parts 1 and 2 and the EBA Eurobloodpack specification. The dimensions and content of the base label applied by manufacturers are as specified below.

3.2 Base label dimensions/ layout

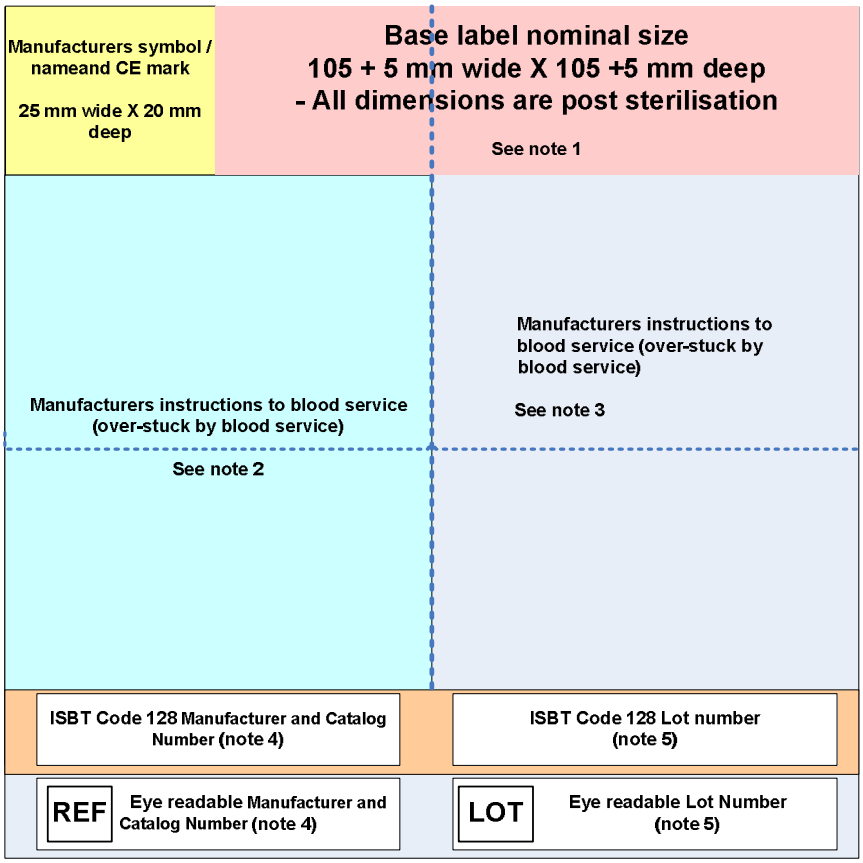

Figure 3.1 – Eurobloodpack base label (schematic diagram not to scale)

Note 1.
No symbols or text is to be placed in this area

Note 2
The following information must be included in this section using symbols taken from recognised medical device standards (ISO 15223-1 and ISO 3826-2)

- Do not reuse this container (single use only)
- Do not vent
- Sterile fluid pathway
- Pyrogen free fluid pathway
- Do not use if there is any visible sign of deterioration
- Contains phthalate (DEHP) – to be applied after March 2010 at the latest.

The base label must have two datum lines as shown (------) splitting the label into four equal area quadrants (to assist blood establishments in aligning over-stick labels).

Note 3.
The following information must be included in this section using symbols taken from recognised medical device standards (ISO 15223-1, ISO 3826-2 and EN 980)

- The maximum volume of the blood/component that is to be collected into the container
- The anticoagulant or additive solution name (in English) its chemical formulation and its volume
- Where a pack is specifically intended for the storage of a particular blood component, the identity of that component e.g. suitable for the storage of platelet. (This requirement must not be applied in general to packs suitable for whole blood and a variety of components)
- The storage temperature range for unused packs
- The expiry date (symbol and text DD/MM/YYYY or MM/YYYY)

Note 4
The format of the ISBT Code 128 Container Manufacturer and Catalogue Number barcode and eye readable number must be exactly as specified in Data Structure 017 of the current version ISBT 128 Standard Technical Specification (see ICCBBA website). The eye readable number must be placed in the final 5mm of space at the bottom of the label.

Note 5.
The format of the Container Lot Number barcode and eye readable number must be exactly as specified in Data Structure 018 of the current version ISBT 128 Standard Technical Specification. (see ICCBBA website). The eye readable number must be placed in the final 5mm of space at the bottom of the label.

Note 6.
During validation the manufacturers barcodes will be assessed using blood establishment's full range of barcode scanning equipment including that linked to integrated computer systems and some blood processing equipment.

4.0 OVER-STICK LABEL PHYSICAL PROPERTIES, MATERIAL / DIMENSIONS

4.1 Label materials

The donation number label and full face label applied to the manufacturer's base label must exhibit the following properties:

- self-adhesive using a non-invasive bio-compatible adhesive (see note)
- tamper-evident (i.e. removal must deface the label)
- smear-resistant
- resistant to water and humidity
- capable of being affixed readily to paper documents, base label material and sample containers (e.g. plastic or glass). Once applied winging ('winging' is defined as the lifting of a label from the surface to which it is applied) must not exceed 2.5 mm as the maximum linear distance of the label not adhering to the surface at any label edge, measured after 24 hrs refrigeration at 4℃.
- capable of withstanding a temperature range of -60℃ to +56℃ after application to the blood pack. This range may be extended by the ordering authority at the time of order.
- capable of being applied without slippage during use where subject to temperature variation, e.g. tubes/packs stored in a vehicle and then used at normal ambient temperature; such equipment being by definition 'damp'
- non-flaking ('flaking' is defined as disintegration of the label or print material potentially affecting readability) regardless of instrumentation used for reading.
- opaque (when applied to a base label or other blood component labelling, the over-stuck text must not be visible).

Note Label adhesives applied either directly to the blood pack or its base label 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).

4.2 Full face label stock dimensions

The dimension of the full face label (with 'cut out' for the donation identification number) and its backing paper are shown in the figure below. All dimensions are in mm.

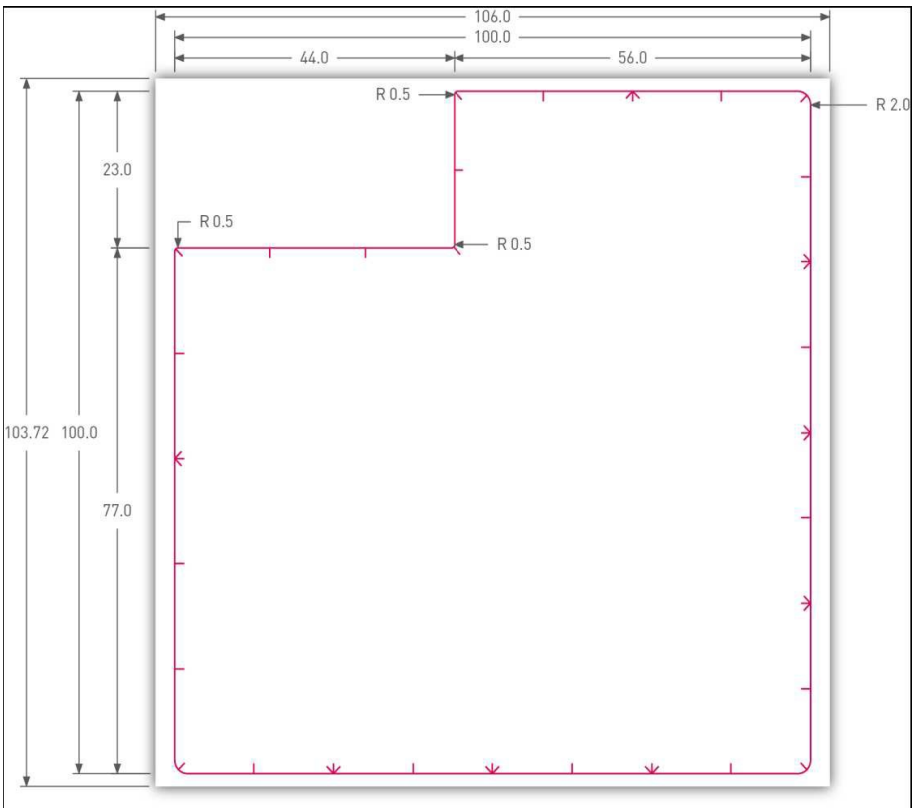

Figure 4.1 – Full face label dimensions (schematic diagram not to scale)

4.3 Donation number label

The ISBT 128 donation identification number (DIN) will continue to be applied to the blood pack at the donor session to provide the unique identification number which cross references blood components and samples taken at the time of donation. The figure below shows the dimensions and layout of the DIN that must be applied to blood bags. The barcode structure for the UKBTS DIN is specified in Chapter 23 of Guidelines for the UKBTS.

Width 42 mm, height 22 mm

Figure 4.2 – DIN dimensions (schematic diagram not to scale)

The precise alignment of the DIN on the base label is vital to avoid wastage of blood components and its top and left hand leading edges must parallel to and within +/- 1 mm of the corresponding top and left hand edges of the base label as shown below.

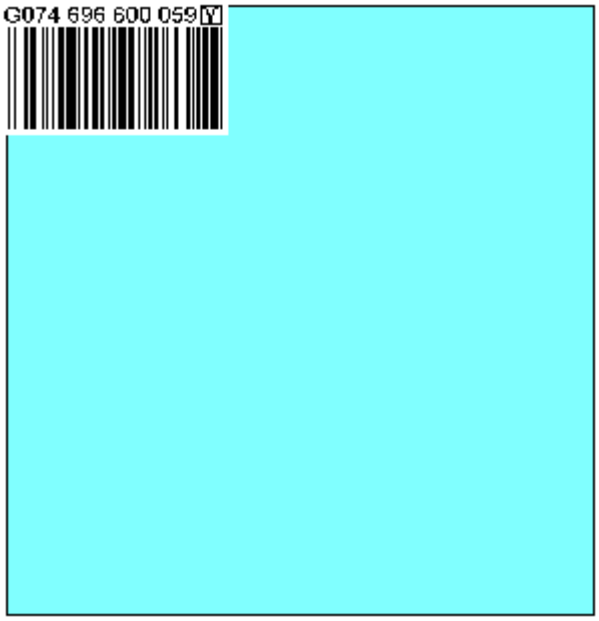

Figure 4.3 – Alignment of DIN on base label (schematic diagram not to scale)

5.0 TRANSITION 'FULL FACE' LABEL LAYOUT / CONTENT

5.1 Transition label layout

The transition label is divided into four zones as shown in Figure 5.1. Zone 1 is for critical information, 2 is for additional clinical information / warnings, 3 is for component selection / laboratory information and 4 is for ABC Codabar barcodes.

The blood bag reference and lot numbers shown below zone 4 are on the blood bag base label and still visible.

The content and format of each zone for each of the main blood component types is specified in the table below.

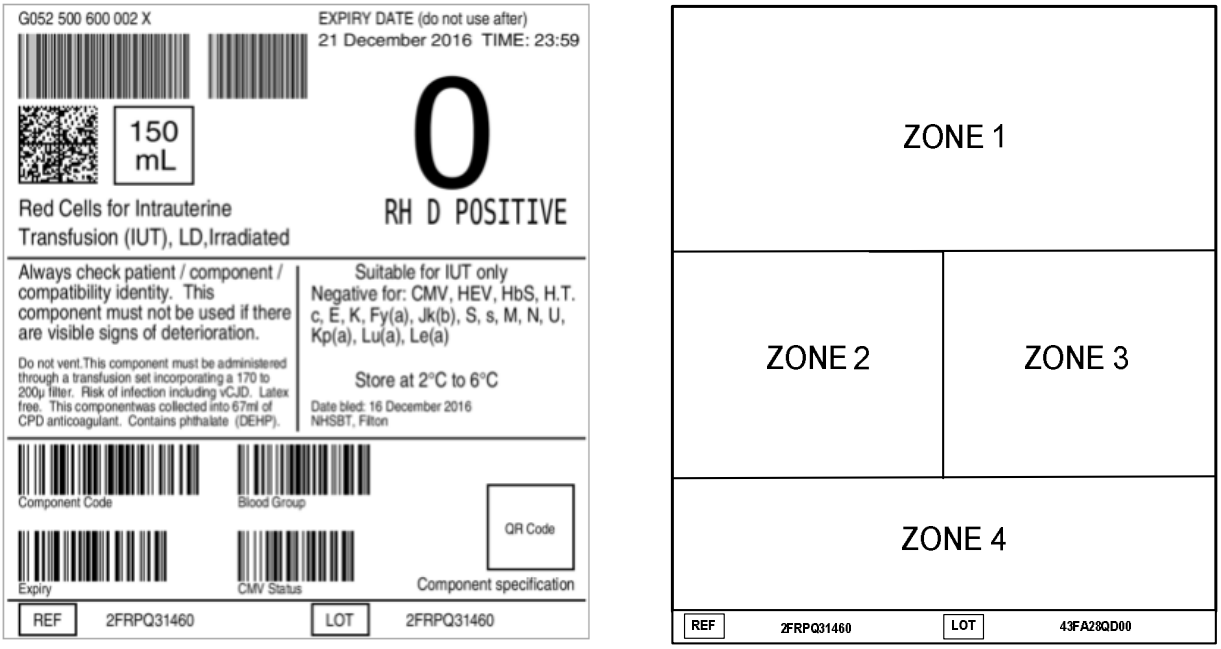

Figure 5.1 – Transition label layout and position of barcodes and text (not to scale)

5.1 Transition label content / format

*Font to be selected to attain equivalence of size (see appendix for zpl code)

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
ZONE 1					
Target font size in Arial	**Variable text is in blue. Characters in bold font are to be reproduced in bold on the label. Content columns are merged when text is common to all component types. Refer to Figure 5.1 for the position of barcodes and text.**				
ISBT 128 DIN barcode / eye readable text - see 4.3	Xnnnnnnnnnnnnn 				
ISBT 128 'short form' DIN barcode - see 4.3					
Expiry date Arial 9	EXPIRY DATE (do not use after) **dd mmm yyyy** TIME: **hh:mm**				
ABO group Arial 90 or current Image file Hollow characters "A,B,AB, O" when RhD negative	A / B / AB /O				
RhD Arial 18 bold Black background "Negative" when Rh D negative	**Rh D Positive / Negative**				

Blood component name - see 7.5 Arial 14	**xxxxxxxxxx**
2D barcode – see 7.0 (13.5x13.5 mm)	
Blood component volume (13.5 x13.5 mm)	**xxx mL**
ZONE 2	
Major clinical warnings / advice Arial 9	**Always check patient /component compatibility /identity.** **This component must not be used if there are visible signs of deterioration.**
Other clinical warnings / advice Arial 7	Do not vent. This component must be administered through a transfusion set incorporating a 170 to 200µ filter. Risk of infection including vCJD. Latex free. This component was collected into 67ml of CPD anticoagulant. Contains phthalate (DEHP).

ZONE 3					
Component suitability (e.g. for IUT only) Arial 10	xxxxxxxx				
Storage temperature Arial 10	**Store at 2°C to 6°C**	**Store at 20°C to 24°C**	**Store at -25°C or below**	**Store at -25°C or below**	
Additional storage instructions Arial 18	N/A	Continuous gentle agitation throughout storage is recommended	Use within 24 hours if held at 4°C or use within 4 hours if held at 20-24°C Date and Time Thawed: ___/___/____ ___ : ___ hrs	Use within 4 hours if held at 20-24°C Date and Time Thawed: ___/___/____ ___ : ___ hrs	
Negative for: Arial 10 Line 1 reserved for CMV, HbS and H.T. when present. Line 2 and 3 reserved for blood group antigens	<line 1> <line 2> <line 3>				
Date bled Arial 7	dd / mmmm / yyyy				
Blood establishment name Arial 7	xxxxxxxx				

Zone 4	
QR barcode and text designation Barcode 12x12mm Text Arial 7	Component specification
Component ABC Codabar barcode and text designation Barcode 23x7mm Text Arial 7	Component code
ABO/Rh D ABC Codabar barcode and text designation Barcode 23x7mm Text Arial 7	Blood Group
Expiry ABC Codabar barcode and text designation Barcode 23x7mm Text Arial 7	Expiry date
CMV negative ABC Codabar barcode and text designation Barcode 23x7mm Text Arial 7	CMV Status

6.0 FUTURE STATE 'FULL FACE' LABEL LAYOUT / CONTENT

6.1 Future state label layout

The future state label is divided into three zones as shown in Figure 6.1. Zone 1 is for critical information, 2 is for additional clinical information / warnings and 3 is for blood component selection / laboratory information.

The blood bag reference and lot numbers shown below zone 3 are on the blood bag base label and still visible.

The content of each zone for each of the main blood component types is specified in the table below.

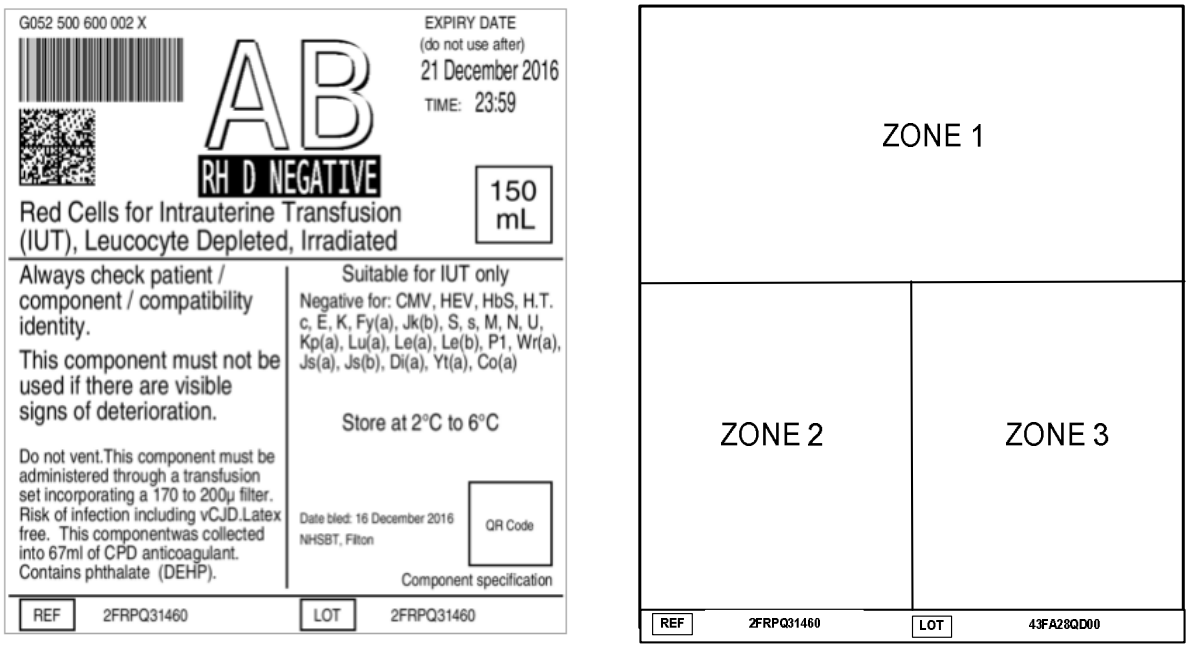

Figure 6.1 – Future state label layout and position of barcodes and text (not to scale)

6.2 Future state label content / format

*Font to be selected to attain equivalence of size (see appendix for zpl code)

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
ZONE 1					
Target font size in Arial	**Variable text is in blue. Characters in bold font are to be reproduced in bold on the label. Content columns are merged when text is common to all component types. Refer to Figure 6.1 for the position of barcodes and text. N.B. Several of the font sizes are increased compared to the transition label.**				
ISBT 128 DIN barcode / eye readable text - see 4.3	Xnnnnnnnnnnnn 				
Expiry date Arial 12	EXPIRY DATE (do not use after) **dd mmm yyyy** TIME: **hh:mm**				
ABO group Arial 90 or current Image file Hollow characters "A,B,AB, O" when RhD negative	A / B / AB /O				
RhD Arial 18 Black background "Negative" when Rh D negative*	**Rh D Positive / Negative**				
Blood component name - see 7.5 Arial 16	**Xxxxxxxxxx**				

2D barcode – see 7.0 (13.5x13.5 mm)					
Blood component volume (13,5x13.5 mm)	**xxx mL**				
ZONE 2					
Major clinical warnings / advice Arial 11	**Always check patient /component compatibility /identity.** **This component must not be used if there are visible signs of deterioration.**				
Other clinical warnings / advice Arial 9	Do not vent. This component must be administered through a transfusion set incorporating a 170 to 200µ filter. Risk of infection including vCJD. Latex free. This component was collected into 67ml of CPD anticoagulant. Contains phthalate (DEHP).				
ZONE 3					
Component suitability (e.g. for IUT only) Arial 11	**Xxxxxxxx**				
Storage temperature Arial 11	**Store at 2°C to 6°C**	**Store at 20°C to 24°C**	**Store at -25°C or below**	**Store at -25°C or below**	
Additional storage instructions Arial 10	N/A	Continuous gentle agitation throughout storage is recommended	Use within 24 hours if held at 4°C or use within 4 hours if held at 20-24°C Date and Time Thawed:	Use within 4 hours if held at 20-24°C Date and Time Thawed: ___/___/____ ___ : ___ hrs	

			___/___/____ ___ : ___ hrs		
Negative for: Arial 10 bold / Line 1 reserved for CMV, HbS and H.T. when present. Line 2 to 5 reserved for blood group antigens	<line 1> <line 2> <line 3> <line 4> <line 5>				
Date bled Arial 7	dd / mmmm / yyyy				
Blood establishment name Arial 7	Xxxxxxxx				
QR barcode and text designation Barcode 12x12mm Text Arial 7	Component specification				

* **Note:** With the implementation of the future state label RhD group text will only be used where it is appropriate to the component type.

7.0 TECHNICAL SPECIFICATION FOR THE 2-D BARCODES IN THE PROPOSED UK TRANSITION AND FUTURE STATE LABELS

7.1 Background

This specification supports the UK proposed new designs for the transition (see 5.0) and future state (see 6.0) labels. The use of two dimensional (2-D) barcodes will convey more blood component information and enable amalgamation of multiple data elements to release space for clearer presentation of the textural information.

2-D symbology is proven for blood, cell, tissue, and organ products by ICCBBA. It is the only adopted international standard to address this challenge. ISBT 128 standard uses states that 'Data Matrix (ECC 200) shall be used as the 2-D symbology for ISBT 128 container labels. The ISO/IEC 16022 Information technology—International symbology specification—Data Matrix shall be followed'.

ECC 200 uses error and erasure recovery that allows the routine reconstruction of the entire encoded data string when the symbol has sustained 30% damage enabling successful translation of creased labels. Data Matrix has an error rate of less than 1 in 10 million characters scanned however, 'readers' need to accurately locate the position of the symbol (printed matrix) in order that reading can occur. The symbol will be square with an even number of rows and columns. Utilisation of the ECC 200 error correction is by the upper right corner module being the same as the background colour. (Binary 0).

ICCBBA have an implementation guide – 'Use of Data Matrix Symbols with ISBT 128'. Currently for blood, the 2-D barcode is only advocated as a supplementary information source, other ISBT 128 linear barcodes are required to attain full observance to the standard. To enable a phased transition to the future state label by UK blood services and hospitals the 2-D barcode will be supplemented by the existing ABC Codabar barcodes for product code, blood group, expiry date and CMV negative status (in addition to the DIN in long and short form ISBT 128).

ISBT 128 2-D barcode is a proven, appropriate extension to the use of the standard by UK services. In theory ICCBBA data structure 023 would accommodate an unassigned message (i.e. made from the other standard data structures but not registered with ICCBBA) but is inappropriate as the standard states that this 'ONLY be used where there is not an appropriate structured message and there is good reason why a structured message should not be created.' A new message has therefore been required to be registered with ICCBBA (see 7.3).

It is important to note that the use of a data structure for data derived from component testing does not compel blood services to do all the tests. There are 'ni' - no information and 'nt' - not tested values.

The 2-D barcode needs to be within a closer proximity to the linear DIN in both the transition and future state labels. ICCBBA has yet to finalise this position in the ICCBBA standard and UKBTS is collaborating to influence the final outcome. There may be potential for minor layout amendments to the UKBTS Specification as ICCBBA developments mature which will be achieved as part of SAC.IT's guidance responsibilities.

7.2 ICCBBA data structures and their appropriate use

The following data structures are relevant to UKBTS component labelling:

1.1. Donation Identification Number [Data Structure 001] – Use, already adopted
1.2. Blood Groups [ABO and RhD] [Data Structure 002] – Use, already adopted for ABO and RhD group information. UK Guidelines currently specifies a limited application of the 'gg' values for this data structure.
1.3. Product Code [Data Structure 003] – Use. Will require a translation table of product codes through the period of transition. (Note that bacterial monitoring is covered under the product code definitions.)
1.4. Expiration Date and Time [Data Structure 005] – Use. Will give greater clarity on expiration of short shelf life components.
1.5. Special Testing: General [Data Structure 010] – Use. Will include the conveyance of; red cell antibodies, IgA deficient, Haemoglobin S status, that product meets additional nationally specified requirements for paediatric use and some immune plasma antibodies (e.g.s. Tetanus, Varicella Zoster).
A further string required that is not currently registered are:
'Low titre anti-T'.
1.6. Special Testing: Red Blood Cell Antigens – General [Data Structure 012] – Use. Will cover the red cell antigenic expressions (be they detected through phenotyping or genotyping) that are important in the provision of matched components. It is considered that this information is relevant to granulocyte, platelet and red cell components and will be included with all components whether or not testing has been carried out for each antigen/allele. This will ensure that the size of the data matrix is consistent when printed on the label.
1.7. Special Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]. There is no clear current benefits for the use of this data structure (blood services provide best matched HLA and HPA components for the hospitals and providing the hospitals with actual type data may provide no direct benefit). Its inclusion for all components again enables the size of the data matrix to be consistent pending a more appropriate structure being identified in future. The HLA coding element does not currently cover the D locus. Experts suggested that if it did, it might prove useful for information on red cells.
1.8. Infectious Markers: [Data Structure 027] –Use will cover CMV antibody status, Hepatitis E Virus and other infectious markers where deemed necessary.

7.3 UK Specifics and example of proposed use of 2-D barcoding

In summary, data structures [001];[002];[003];[005];[010];[012];[014];[027] will be combined in a compound message data structure [023]

The follow is an example of application:

=+08000=G05251352795529=%5100=<E0033000&>2133152359&(N0106=\230000004000000184&{0000000000000000000&"000000000000000000

Here =+08000 identifies this as a compound message of eight data structures using a so called 'undefined message' (NB. Contra to what the name may indicate, this is a compliant use of the ISBT 128 Standard Technical Specification);
=G05251352795529 is the Donation Identification Number Data Structure;

=%5100 is the Blood Groups Data Structure – this unit is O RhD positive;

=<E0033000 is the Product Code Data Structure – this unit is Whole Blood leucocyte depleted (CPD);

&>2133152359 is the Expiration Date and Time Data Structure – this unit expires just before midnight between 11/11/2013 and 12/11/2013.

&(N0106 is the for general special testing – this unit is HbS negative.

=\230000004000000184 is the red blood cell antigen special testing – this unit is R1R1(C-c+E+e-),K-,Fya-Fyb-,CMV-,Vel-

&{000000000000000000 is the platelet HLA and Platelet Specific Antigens special testing – this unit has not been tested for these antigens.

For Special Testing: General [Data Structure 010] – The following codes have been identified as to be or not to be used:

Code	Interpretation	UK use
1aaaa	CMV antibody negative	No
N0000	Default	Yes
N0003	IgA deficient	Yes
N0008	CMV seronegative	No
N0043	IgA deficient; CMV seronegative	No
N0104	Tetanus antibody present	Yes
N0105	Varicella Zoster antibody present	Yes
N0106	Haemoglobin S negative	Yes
N0107	CMV seronegative, Haemoglobin S negative	No
N0116	CMV seronegative, Haemoglobin S positive	No
N0119	CMV seronegative and product meets additional nationally specified requirements for paediatric use	Yes
N0124	No high titre antibody to A and/or B antigens detected	Yes

A request has been made for the following further interpretation which will be included once the request has been confirmed:

Low titre anti-T

&”000001000300000000 is an example of the use of the Infectious Markers data structure where the donation is CMV antibody screen negative and HEV negative.

Ideally, systems should be able to read and interpret any code combination associated with data structures defined in the ICCBBA standards for labelling of blood components, to ensure no compromise of use for ICCBBA compliant imported units.

7.4 Rule set for the commonest mapping to ISBT 128 attributes agreed by UKBTS

1. Use the coding system for anticoagulant or anticoagulant into an additive in core conditions to differentiate components e.g. platelets in PAS.
   (Exception may be imports where multiple types may be too difficult to manage).

2. Do not code component volumes (mL) in core conditions (because these are set values rather than ranges).

3. Do not use the leucocyte residual data (too difficult to prove on every labelled unit)

4. Use ‘Integrity’ (e.g. processed by open or closed system), ‘Irradiated’, ‘Altered (e.g. cryo reduced)’, ‘Treatment’ (e.g. Methylene blue-treated), and ‘Monitoring’ (indicates component status e.g. that a result e.g. bacterial monitoring result is outstanding) where appropriate.

5. Use ‘Content’ (as this is a volume [mL] range) for small volumes not easily discernable through pack divisions.

6. Do not use component ‘Preparation’ information (e.g. Frozen <=120h), ‘Apheresis Container’, ‘Quarantine’, ‘Dosage’ or ‘Donor Exposure’.

8.0 TECHNICAL SPECIFICATION FOR THE QR BARCODES IN THE TRANSITION AND FUTURE STATE LABELS

A QR (quick response) 2-D barcode will be printed on the transition and future state blood component labels as shown in Figures 5.1 and 6.1. When wanded using a Smartphone this will take users to the unique UKBTS blood component specification on the JPAC website for that blood component.

The structure of QR barcodes that code for an internet URL is described in the articles below.
http://www.onbarcode.com/qr_code/#structure
http://jpgraph.net/download/manuals/chunkhtml/ch27.html

The QR barcode derived for each UKBTS Guideline blood component specification is displayed in the table below. There is no intention to transfer any information from the QR code to blood service or hospital IT systems.

G:\008 PT&I\008 Quality\007 QA South

9.0 REQUIREMENTS SPECIFICATION FOR LINEAR AND 2D SCANNERS FOR USE BY UK BLOOD SERVICES AND HOSPITALS

9.1 General

Currently UK blood services and hospitals have mainly standardised on scanners that fulfil the requirements of linear ISBT 128 coding. For blood services this includes the requirement to concatenate 128 codes during blood component label validation.

UK, blood services and their customers will in future need to scan 2D Data Matrix and QR codes following the introduction of improved blood component labelling. Additionally, blood services will need to concatenate the linear donation number barcode with a 2D Data Matrix code to retain the security already specified in the ICCBBA ISBT 128 specification.

Technical requirements are provided (9.2) for scanners capable of reading 2D barcodes and QR barcodes and (9.3) additionally capable of concatenating a linear to a 2D barcode.

9.2 Technical requirements for ISBT 128 2D and QR capable scanners (without concatenation capability)

Requirem-ent reference	Requirement	Current/New Requirement	Essential / Desirable
1	Linear Barcode – 128	Current	Essential
1 a) i)	The 'Temporal/Spatial Constraints' must meet the ICCBBA technical specification (Section 10.1 in version 4.5.0)	Current	Essential
1 a) ii)	The barcodes being read should be decoded from the left barcode to right with the data being passed in the same order.	Current	Essential
1 a) iii)	The alpha characters read should have their case maintained. (i.e. the keyboard caps lock should not change the characters case if used as HID device).	Current	Essential
1 a) iv)	The Linear barcodes must have valid internal Modulus 103 codes when read.	Current	Essential
2	Linear Barcode – Codabar	Current	Essential
2 a)	Must be able to read ABC Codabar	Current	Essential
2 b)	All Codabar codes when read should have their alpha character start and stop codes forced into upper case and the case should not be affected by the selection or de-selection of the CAPs lock or SHIFT keys.	Current	Essential
2 c)	The specification of Codabar barcodes should meet the requirements outlined in the Guidelines to Blood Transfusion version 8	Current	Essential

2 d)	The barcodes being read should be decoded from the left barcode to right with the data being passed in the same order.	Current	Essential
3	2D Barcode - Data Matrix	New	Essential
3 a)	The Data Matrix code requirements should meet the requirements set out in the ICCBBA Technical Specification (See Section 6.2 of Version 4.5.0)	New	Essential
3 b)	The Linear Barcode must have a valid internal modulus 103 checksum included within code or the barcode is invalid.	Current	Essential (for Blood Establishments only)
3 c)	The Data Matrix internal check sums must be valid	New	Essential (for Blood Establishments only)
4	2D Barcode - QR Codes	New	Essential
4 a)	Scanner must be able to read QR codes as established as an ISO (ISO/IEC18004) standard. QR Code specification can, therefore, be purchased from this organization	New	Essential if wishing to display web content on screen.

9.3 Technical requirements for ISBT 128 2D and QR capable scanners with concatenation capability

Requirement reference	Requirement	Current/ New Requirement	Essential /Desirable
1	Linear Barcode – 128	Current	Essential
1 a)	The ISBT 128 barcodes should only concatenate when the following rules are valid:	Current	Essential
1 a) i)	The spatial and temporal constraints must meet the ICCBBA technical specification (Section 10.1 in version 4.5.0)	Current	Essential
1 a) ii)	There should be no lines or any printing between the 2 barcodes being concatenated.	Current	Essential
1 a) iii)	The barcodes being read should be decoded from the left barcode to right with the data being passed in the same order.	Current	Essential
1 a) iv)	The alpha characters read should have their case maintained. (i.e. the keyboard caps lock should not change the characters if used as HID device etc.	Current	Essential
1 a) v)	The Linear barcodes must have valid Modulus 103 codes when read.	Current	Essential

1 b)	The ISBT 128 configuration must accommodate auto discrimination of single and concatenated barcode reads.	Current	Essential
1 c)	If concatenation rules can be programmed in the scanner it must be possible to configure at least 6 concatenation pair rules and allow any ICCBBA data structures to be included in the selection, including Non-ICCBBA Defined Data Structures. (see ICCBBA technical Specification section 2.5 in Version 4.5.0). Scanners programmed with rules must be able to indicate, with different, error messages, what element of the concatenation has failed. (e.g. Differentiate between a wrong label application and a miss scan). Preferably, the control system rather than the scanners will be coded with rules.	Current	Desirable
1 d)	The barcode scanner must be able to only concatenate Data Structure [001] the Non-Defined data structure identified with &a or &b where the 6 digit sequential portion of these 2 barcodes is equal. (see figure 1) Note: - If the Non defined data structure has the data identifier &b then the last digit after the 6 sequential digits should be ignored. (this is a version counter)	Current	Desirable

=G091301***000483***91&a***000482***

=G091301***000482***91&a***000482***

Figure 9.1 – Shows the concatenation is acceptable when the 6 sequential 6 digits in each barcode are equal – ref. requirement 1 d)

Requirement reference	Requirement	Current/New Requirement	Essential /Desirable
2	Linear Barcode - Codabar	Current	Essential
2 a)	Must be able to read ABC Codabar	Current	Essential
2 b)	All Codabar codes when read should have their alpha character start and stop codes forced into upper case	New	Desirable
2 c)	The specification of Codabar barcodes should meet the requirements outlined in the Guidelines to Blood Transfusion version 8	Current	Essential
2 d)	Concatenation can only be achieved when the adjacent alpha start stop codes are equal. I.e. D1234567**D D**510B should concatenate where D1234567**D A**510B should not.	Current	Essential
2 e)	There should be no lines or any printing between the 2 barcodes being concatenated.	Current	Essential
2 f)	The barcodes being read should be decoded from the left barcode to right with the data being passed in the same order.	Current	Essential
2 g)	Scanners must be able to auto discriminate between single and concatenated Codabar reads.	Current	Essential
3	2D Barcode - Data Matrix	New	Essential
3 a)	The Data Matrix code requirements should meet the requirements set out in the ICCBBA Technical Specification (See Section 6.2 of Version 4.5.0)	New	Essential
3 b)	Concatenation of the 2D codes with the linear ISBT 128 code using Data Structure [001] should be possible with the following rules	New	Essential (for Blood Establishments only)
3 b) i)	The position of these codes in relation to each other should be the Linear code above the Data Matrix code. (see figure 2)	New	Essential (for Blood Establishments only)
3 b) ii)	The spatial requirements of the 2 codes in relation to each other should allow for the Data Matrix code to be no more than 13mm below the Linear barcode that it's being concatenated with and be no less than 3 mm from the Linear code.	New	Essential (for Blood Establishments only)
3 b) iii)	The 2D code should be no further left or right in its point of origin in relation to the Linear barcode than ±4mm (see figure 3)	New	Essential (for Blood Establishments only)

Requirement reference	Requirement	Current/New Requirement	Essential /Desirable
3 b) iv)	No lines or text should be incorporated in any label design between the 2 barcodes.	New	Essential (for Blood Establishments only)
3 b) v)	Concatenation will only be possible if the Linear Barcode is ICCBBA Data Structure [001] (i.e. Has data identifier '=' and 15 characters (making 16 in total)) and the Data Matrix contains data including a matching ICCBBA Data Structure [001]. N.B. ICCBBA Data Structure [001] is included in multiple ICCBBA Structured Compound Messages (ref. ICCBBA Table RT017), and may also be included in an unstructured message (message ID 000).	New	Desirable
3 b) vi)	The Linear Barcode must have a valid modulus 103 checksum included within the reading of the Linear barcode	New	Essential (for Blood Establishments only)
3 b) vii)	The Data Matrix internal check sums must be valid	New	Essential (for Blood Establishments only)
3 b) viii)	The Scanner must be able to auto discriminate between single linear 128 , single Data Matrix and a concatenated scan.	New	Essential (for Blood Establishments only)
3 b) ix)	The scanner should allow a small (± 3 º) tolerance of angles between the left hand edges of the linear and 2D barcode line-ups.	New	Essential (for Blood Establishments only)

Figure 9.2 (showing the positional relationship between the linear and 2 D barcodes

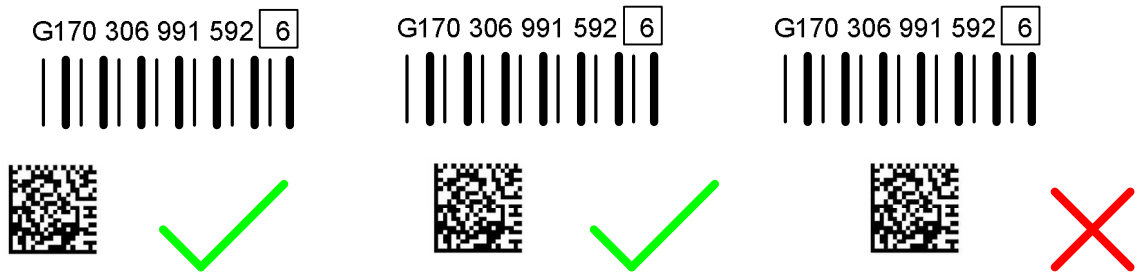

Figure 9.3 (showing valid positions of the barcode pairs)

Requirement reference	Requirement	Current/New Requirement	Essential /Desirable
4	2D Barcode - QR Codes	New	Essential
4 a)	Scanner must be able to read QR codes as established as an ISO (ISO/IEC18004) standard. QR Code specification can, therefore, be purchased from this organisation	New	Essential if wishing to display web content screen.

10.0 Guideline validation protocols for UKBTS use

The following protocols provide guidance on the validation that should be carried out by a UK blood Establishment leading up to the routine introduction of (10.1) new transition full face labels and (10.2) future state full face labels. The protocols are for guidance only and do not replace the routine change control / detailed validation activities of your blood service.

10.1 Transition label

Step	Requirement	Expected outcome	Notes
1	Verify that the base label on all blood packs in use by your service are of the correct size and format.	• Base label dimensions are between width 105 to 110mm, length 105 to 110mm. • When a 100 x 100 mm full face label is applied the eye readable blood pack catalogue number and batch number must be clearly visible at the bottom of the base label.	
2	Test the full face over-stick label stock for its adhesion over the full temperature range to which it will be exposed (typically -40^{o}C, 4^{o}C, 22^{o}C and 37^{o}C)	The full face label: • is tamper evident • does not become detached or 'wing' by more than 2 – 3 mm.	Use the SOP in routine use by your service
3	Verify that full face over-stick material is not translucent and cannot be removed when placed over a previously printed full face label	• Text from the over-stuck label is not visible. • The newly applied full face label is tamper evident.	
4	Sample full face transition labels supplied to blood service's nominated contact.	• Samples received and distributed.	

5.	Verify that your service's integrated blood management IT system and demand printers have been upgraded/configured to print the full face label in Figure 5.1 including the ABC Codabar, 2-D and QR barcodes.	• IT system has been upgraded under change control and validated. • Demand printers are configured and settings verified. • A test sample of each blood component in the current version Red Book (including split components) can be printed and text/layout verified as conforming to the standard at 5.0/Figure 5.1 including extended red cell and platelet phenotypes. • The label print is smear and water resistant when tested to your routine SOP. • The DIN, all ABC Barcodes, the 2-D barcode and QR barcodes of the label test samples are >99% readable on the first attempt and accurately reproduce the intended information.	
6.	Verify that your re-engineered blood component labelling process (including for intermediate components) has been risk assessed, validated and audited 'end to end'.	• Risk assessment complete. • Validation complete • Revised SOPs written and approved. • New process has been audited with a satisfactory outcome/CAPA.	
7.	Hospitals have been informed of the intention and date of change to the transition label and have confirmed their readiness.	• All NHS and private hospitals are aware and have confirmed their readiness.	
8.	Blood stocks management plans (especially for long dated components) leading up to the introduction of the future state label have been drawn up and	• Blood stock management plans in place and approved.	

	approved to avoid stock shortages / excessive outdating		
9.	Change control covers contingency arrangements for transition period	• Risk assessment complete. • Validation complete • Revised SOPs written and approved. • Contingency process(es) has been audited with a satisfactory outcome/CAPA.	

10.2 Future state label (in addition to validation carried out for the transition label)

Step	Requirement	Expected outcome	Notes
1.	Sample full face future state labels supplied to blood service's nominated contact.	• Samples received and distributed.	
2.	Verify that your service's integrated blood management IT system and demand printers have been updated / configured to print the full face label in Figure 6.1 including the 2-D and QR barcodes.	• IT system has been upgraded under change control and validated. • Demand printers are configured and settings verified. • A test sample of each blood component in the current version Red Book (including split components) can be printed and text/layout verified as conforming to the standard at 6.0/Figure 6.1 including extended red cell and platelet phenotypes. • The DIN, 2-D barcode and QR barcodes of the label test samples are >99% readable on the first attempt and accurately reproduce the intended	

		information. • The 2-D barcode can be satisfactorily concatenated with the DIN.	
3.	Verify that your re-engineered blood component labelling process (including for intermediate components) has been risk assessed, validated and audited 'end to end'.	• Risk assessment complete. • Validation complete • Revised SOPs written and approved. • New process has been audited with a satisfactory outcome/CAPA.	
4.	Hospitals have been informed of the intention and date of change to the transition label and have confirmed their readiness.	• All NHS and private hospitals are aware and have confirmed their readiness.	
5.	Blood stocks management plans (especially for long dated components) drawn up at the transition stage have been revised as necessary and circulated / discussed with hospitals.	• Blood stock management plans in place and discussed with hospitals.	
6.	Change control covers contingency arrangements for post transition.	• Risk assessment complete. • Validation complete • Revised SOPs written and approved. • Contingency process(es) has been audited with a satisfactory outcome/CAPA.	

11.0 Guidelines validation protocols for UK hospital use

The following protocols provide guidance on the validation that should be carried out by UK hospitals leading up to the routine introduction of (11.1) new transition full face labels and (11.3) future state full face labels. The protocols are for guidance only and do not replace the routine change control / detailed validation activities of your hospital.

11.1 Transition label

Step	Requirement	Expected outcome	Notes
1	Questionnaires to be issued to hospitals to confirm IT systems in use	• Response from hospitals to allow validation protocols to be formulated. • LIMS systems • Blood tracking systems • Any other possible systems	
2	Hospitals informed of intention of date and change to transition label and specification for barcode scanners issued	• Permit hospitals to survey for any required additional hardware • Risk assessments carried out locally	
3	Samples issued to hospitals	• Tested against existing hardware/scanners • Permit hospitals to purchase any required additional hardware	
4	Hospitals issued with Validation protocols developed (previously) with suppliers and users	• May require supplier workshop to facilitate and identify specific points of interaction within software • SOP’s reviewed and updated • Risk assessments updated	
5	Hospitals have been informed of the intention and date of change to the	• All NHS and private hospitals are aware • Informed of hardware & software	

	transition label and have confirmed their readiness.	requirements • Validation completed • Have confirmed their readiness.	

11.2 Future state label

Essentially same process, but will need suppliers to confirm any changes required to software to facilitate final label have been implemented.

Step	Requirement	Expected outcome	Notes
1	Questionnaires to be issued to hospitals to confirm IT systems in use	• Response from hospitals to allow validation protocols to be formulated. • LIMS systems • Blood tracking systems • Any other possible systems	
2	Hospitals informed of intention of date and change to transition label and specification for barcode scanners issued	• Permit hospitals to survey for any required additional hardware • Risk assessments carried out locally	
3	Samples issued to hospitals	• Tested against existing hardware/scanners • Permit hospitals to purchase any required additional hardware	
4	Hospitals issued with Validation protocols developed (previously) with suppliers and users	• May require supplier workshop to facilitate and identify specific points of interaction within software • SOP’s reviewed and updated	

		• Risk assessments updated	
5	Hospitals have been informed of the intention and date of change to the transition label and have confirmed their readiness.	• All NHS and private hospitals are aware • Informed of hardware & software requirements • Validation completed • Have confirmed their readiness.	