FINAL

Design Specification for Standardised Whole Blood Collection Systems Including Leucodepletion Filters

Eurobloodpack ™

Prepared by the Blood Pack Systems Standardisation Committee (BPSC)
On behalf of the EBA

Version 3.2, February 2010

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0.0 FOREWORD

Within the European Union (EU) there are several different practices in place for the collection of whole blood. As a result, over the years some services have developed individualised whole blood collection pack systems to meet their perceived individual needs. In reviewing these needs it has been identified that the potential exists for blood collection systems to be harmonised to the extent that only three basic systems are required for general blood collection and processing. The designs presented allow blood services to continue to collect according to their current practices but will offer the potential for further standardisation of such practices at a later date. Additional considerations have been to further reduce the risk of pack defects during manufacture and use and to minimise the impact on manufactures and their existing designs.

The key issues considered in drawing up and reaching a consensus on this specification are as follows: Accommodation of the current range of acceptable donation volumes (usable 405 – 525 ml, target 450 – 500 ml); corresponding optimal additive solution (OAS) fill volumes; format and numbering of the compatibility line; collection needle and sample site coupler design, tubing dimensions, access ports, leucodepletion filter performance and product labelling.

This Technical Specification covers those aspects of blood collection systems that the BPSC felt necessary to define and control in addition to those specified in applicable International Standards

Other related issues discussed as part of harmonisation included change control, validation and centralised reporting of faults. These were agreed to be beyond the scope of this document and will be addressed separately.

0.1 DOCUMENT HISTORY

Revision	Date	Status	Comment
1.0	26/09/07	Committee draft	
1.1	26/09/07	Committee draft	
1.2	17/12/07	Committee draft	
2.0	08/02/08	Committee draft	
2.1	15/02/08	Committee draft	Reviewed at BPSC meeting 10th April 2008
2.2	23/05/08	Draft fro EBA comment	
2.3	27/04/09	Draft for EBA/supplier comment	
2.4	29/04/09	Draft for supplier comment	Reviewed at supplier liaison meeting 21/07/09
2.5.1	22/07/09	Draft for BPSC/supplier comment	Incorporating suppliers comments from 21/07/09
2.5.2i	29/09/09	Draft for information prior to EBA BPSC / Supplier liaison webinar on 02/010/09	Incorporating comments and EBA BPSC responses.
2.5.2	29/09/09	Draft for review during EBA BPSC Supplier liaison webinar on 02/010/09	Incorporating unresolved issues and proposals to complete this document.
2.6	06/10/09	Draft agreed during EBA BPSC Supplier liaison webinar on 02/10/09	Manufacturers may jointly provide single examples of alternative (more generic) figures to replace those in this version and will be incorporated into final draft 3.0 if received by MN before 31/10/09.
3.0	29/10/09	Final draft	Issued to EBA and BPSC.
3.1	02/02/10	Final	Incorporating advice from Ian Hardie, SNBTS
3.2	02/02/10	Final	Incorporating further advice from Ian Hardie, SNBTS on addition of Eurobloodpack ™ to title page.

1.0 PURPOSE AND SCOPE

This document defines the technical specifications for blood collection systems with integrated features that have been standardised and agreed by BPSC. The BPSC has where possible harmonised its requirements for blood packs. This is to facilitate the standardisation of blood collection and blood component production processes in line with the EU Blood Safety Directive and to facilitate the transfer of blood packs between participating Member States (henceforth referred to as the 'Customer'.

This specification includes only those features of blood pack systems that the BPSC requires to standardise and control with tighter or additional specifications than are currently included within the ISO 3826 series of standards.

This contract specification is intended to ensure as far as possible:

1.1 That the quality of the blood and blood components is maintained,

1.2 That the containers for blood and blood components are suitable for use with administration sets which comply with ISO 1135 - 4.

1.3 That the intended contents of the containers can be efficiently and safely collected, identified, stored, separated and infused.

1.4 That the blood collection systems should be capable of producing relevant leucodepleted blood components identified in the EU Blood Safety Directive.

It should be noted that compliance with this specification will be reviewed as part of the acceptance criteria for products offered under tender.

The basic standards for conformance are the ISO Standards and European Directives listed in Section 2.

Blood collection systems are referred to by generic specifications which are not designed to be specific to any one Supplier. Each Supplier is responsible for ensuring that their own implementation of the generic specification meets the requirements of the Customer.

Manufacturers will be required to provide the Customer with a minimum documentation set (in the language of each participating Member State) that comprises a detailed specification of the product offered including drawings (with dimensions) and recommended instructions for use

Manufacturers will also be required to provide the Customer with a data set to support product conformity to the EU Blood Safety Directive to support any claims made for this product.

This Technical Specification must be retained by Suppliers as a controlled document to ensure that any proposed changes to their product(s) can be identified and notified to the Customer in advance of making the change.

2.0 NORMATIVE REFERENCES

Standards of particular relevance to this document include:

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

2.2 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.

2.3 EN ISO 3826-3:2006: Plastics collapsible containers for human blood and blood components Part 3: Blood bags with integrated features.

2.4 EN ISO 980: (2008) Graphical symbols for use in the labelling of medical devices.

2.5 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

2.6 EN ISO 1135 – 4: 2004: Transfusion equipment for medical use - Part 4: Transfusion sets for single use.

2.7 Commission of European Communities. Directive 2002/98/EC of The European Parliament and Council of 27th January 2003 and daughter directives. Setting standards of safety and quality for collecting, processing, testing, storage and distribution of human blood and blood components.

2.8 Commission of European Communities. Directive 93/42/EEC of The European Parliament and Council of 14th June 1993. Medical devices.

2.9 European Pharmacopoeia (2005). European Directorate for the Quality of Medicines of the Council of Europe (EDQM).

2.10 Council of Europe. Guide to the preparation, use and quality assurance of blood components - 14th edition (2008)

2.11 ISBT 128 Standard Technical Specification. ICCBBA. Version 3.5.1, January 2009. http://www.iccbba.org/technicalspecification.pdf.

2.12 ISO 11607-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

2.13 ISO 11607-2:2006 Packaging for terminally sterilized medical devices -Part 2: Validation requirements for forming, sealing and assembly processes

2.14 ISO 14971:2007 Medical devices - Application of risk management to medical devices

3.0 TERMS, DEFINITIONS AND ABBREVIATIONS

Blood collection system. Individual assemblies for the collection of whole blood, complete with any associated filters, ports, transfer tubes and associated transfer packs and where applicable, tube and needle for collecting blood, needle-stick protection device and pre-donation sampling device..

Container. The primary blood collecting pack or pack attached to an apheresis harness where appropriate.

IFU: Instructions for use

OAS: Optimal additive solution

Shelf life. The period between the date of sterilisation of the container and the date after which the container should not be used for the collection of blood.

Tamper evident: A package [or device] which has an indication or barrier to entry or opening which if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred.

4.0 DIMENSIONS AND DESIGNATIONS

4.1 Dimensions.

Figures 1 to 3 and their accompanying tables of dimensions illustrate the three blood bag systems, namely:

- Figure 1 – Standard Top and Top Collection System for whole blood filtration
- Figure 2 – Standard Bottom and Top System for RCC filtration
- Figure 3 – Bottom and Top System for RCC filtration with Integral Plasma Filter

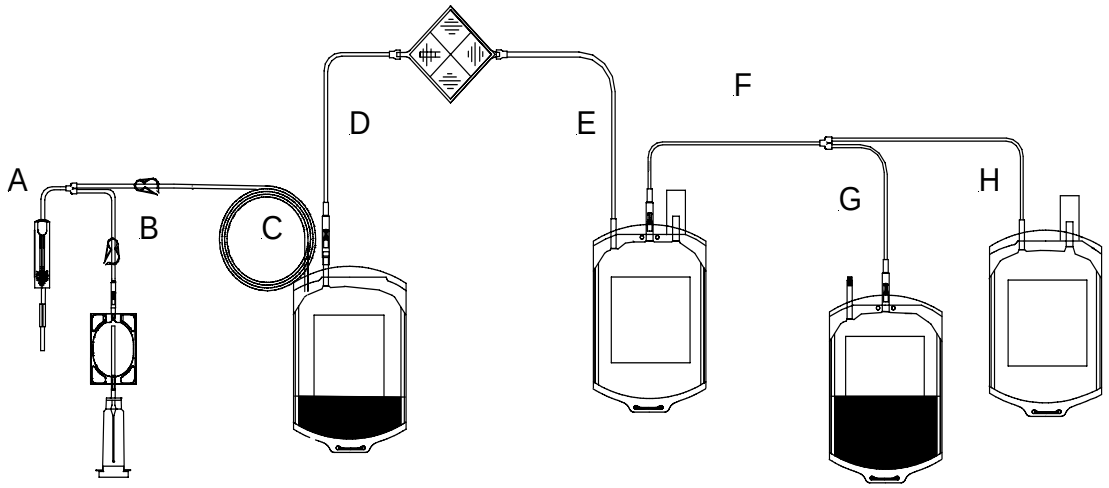
Dimensions are provided with tolerances which should be met by the supplier or an explanation provided if product with an alternative dimension(s) are to be offered.

Dimensions and/or tolerances that do not fall within the specification may only be modified by written mutual agreement between the supplier and the Customer.

Figures 4 to 12 and their associated table of design characteristics illustrate the sub-components/integrated features of the blood pack assembly, namely:

- Figure 4 - Needle Assembly and Sample Site Coupler
- Figure 5 - Needle and needle guard
- Figure 6 - Sample Coupler and Diversion Pouch
- Figure 7 - Primary Collection Pack
- Figure 8 - Red cell storage packs
- Figure 9 - Optimal Additive Pack
- Figure 10 - Primary collection pack
- Figure 11 - Plasma Storage Pack
- Figure 12 - Red Cell Intermediate Pack

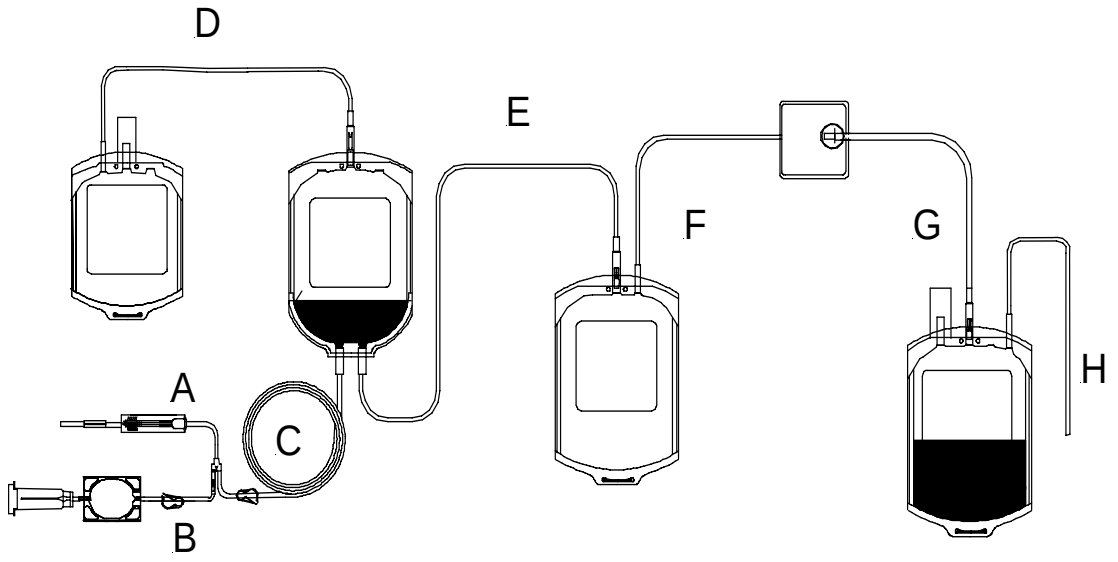
Figure 1 - Standard Top and Top Collection System for whole blood filtration



Dimensions (post sterilisation)		
Tube	***Length mm***	***Tolerance (±) mm***
A + C	1000	100
A	300	50
B	220	50
D	D + E = manufacturer defined	-
E	E = minimum 500	-
F	450	50
G	350	50
H	350	50

Volumes		
Detail	Specification	Tolerance (±)
Volume of anticoagulant in primary pack	66.5 ml	10%
Volume of additive in SAG-M pack or equivalent licensed OAS	105 ml	10%

Figure 2 -Standard Bottom and Top System for RCC filtration



N.B. Donor line may enter the top of the primary bag

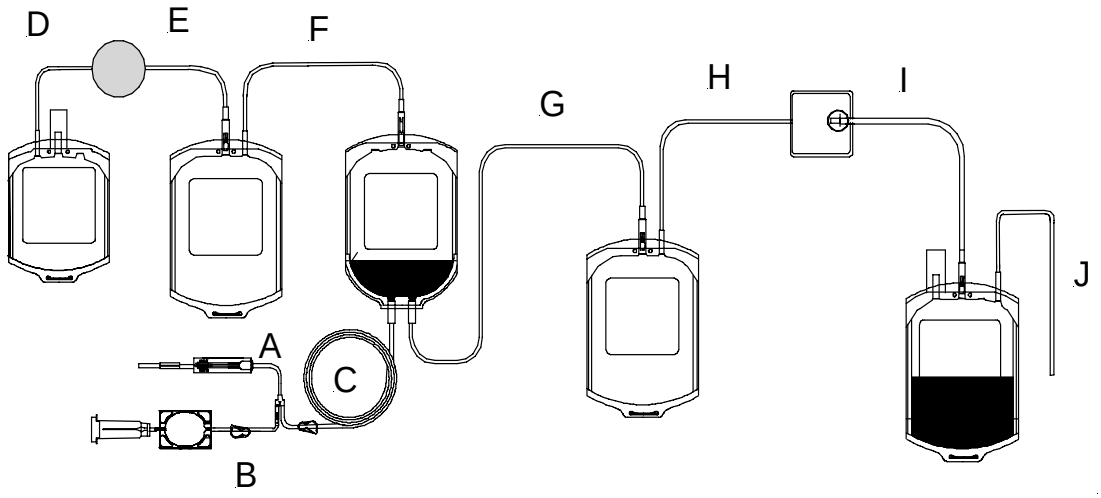
Dimensions (post sterilisation)		
Tube	***Length mm***	***Tolerance (±) mm***
A + C Donor line may be top or bottom entry to primary bag	1000	100
A	300	50
B	220	50
D	450	50
E*	450	50
F	F + G = manufacturer defined G = minimum 500	-
G		-
H	200	50

* Wide bore tube – A tube of larger internal diameter than standard tubing within the pack assembly may be fitted depending on the availability of a suitable sterile tube welding device to join dissimilar tubes. Alternatively, with the written agreement of the Customer, an additional short line (‘pigtail’) may be provided on the primary bag adjacent to tube (E) for the purposes of sterile connection.

Volumes		
Detail	Specification	Tolerance (±)
Volume of anticoagulant in primary pack	66.5 ml	10%
Volume of additive in SAG-M pack or equivalent licensed OAS	105 ml	10%

Figure 3 - Bottom and Top System for RCC filtration with Integral Plasma Filter

N.B. This pack system is similar to the Standard Bottom and Top System with the exception of having a plasma filter and an additional (empty) bag to receive plasma prior to filtration.



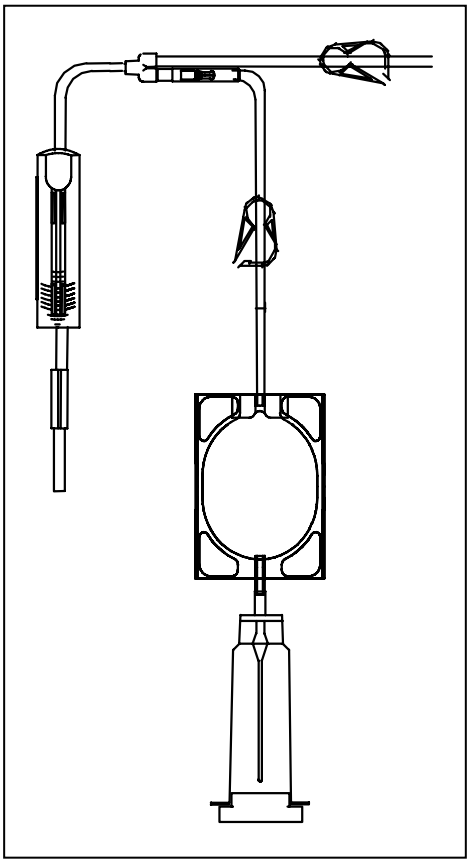
N.B. Donor line may enter the top of the primary bag

Dimensions (post sterilisation)		
Tube	***Length mm***	***Tolerance (±) mm***
A + C Donor line may be top or bottom entry to primary bag	1000	100
A	300	50
B	220	50
D	D = minimum 200 D + E = manufacturer defined	-
E		-
F	450	50
G*	450	50
H	H + I = manufacturer defined I = minimum 500	-
I		-
J	200	50

* Wide bore tube – A tube of larger internal diameter than standard tubing within the pack assembly may be fitted depending on the availability of a suitable sterile tube welding device to join dissimilar tubes. Alternatively, with the written agreement of the Customer, an additional short line (‘pigtail’) may be provided on the primary bag adjacent to tube (G) for the purposes of sterile connection.

Volumes		
Detail	Specification	Tolerance (±)
Volume of anticoagulant in primary pack	66.5 ml	10%
Volume of additive in SAG-M pack or equivalent licensed OAS	105 ml	10%

Figure 4 -Needle Assembly and Sample Site Coupler General Design
(applicable to TAT and BAT systems)

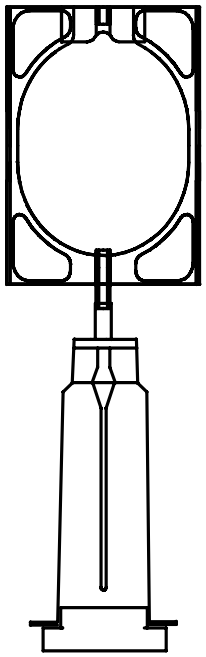


Design characteristics	
Break Cannula	Placed as defined in 5.5.4 in order to prevent seepage of anticoagulant toward the sample pouch
Clamp on line to Sample Coupler	Non accidentally re-openable after first closure
Sample diversion pouch	See figure 6

Figure 5 - Needle and needle guard
(applicable to TAT and BAT systems)

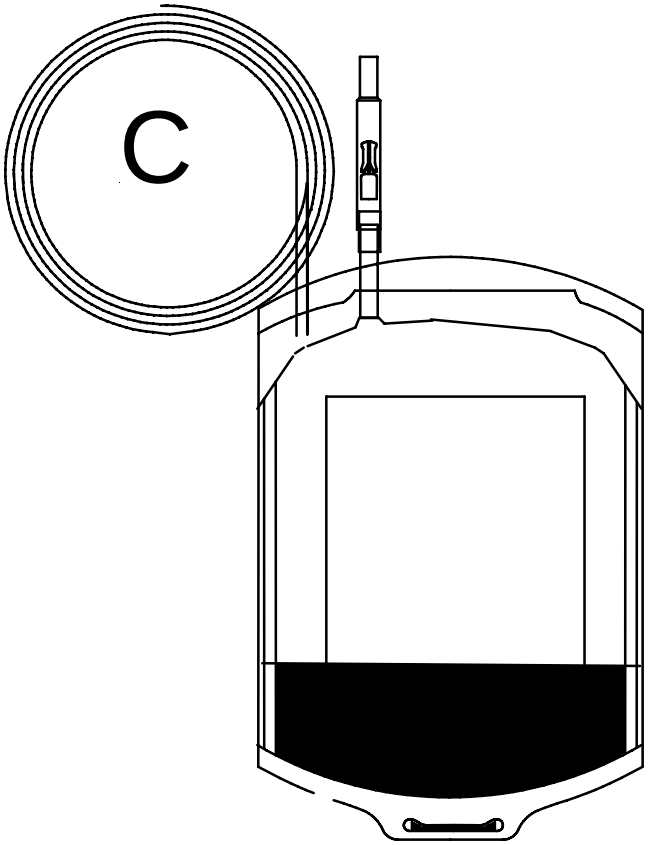
Design characteristics	
Needle sheath (cover)	Present and tamper evident attachment to the needle hub prior to use.
Bevel indicator on hub	Present and detectable visually or by touch
Needle guard	Present and interlocking with needle. The needle must lock efficiently into the protector after removing the needle sheath. The needle assembly should not be capable of locking into the protector before the needle cover is removed.. The needle guard may also be capable of interlocking with the sample tube coupler
Interlock indicator	Sensory indicator when locking occurs e.g. a ‘click’ that may be felt or heard
Needle guard action	Capable of single step withdrawal of needle from vein and directly into needle guard.

Figure 6 - Sample Coupler and Diversion Pouch
(applicable to TAT and BAT systems)



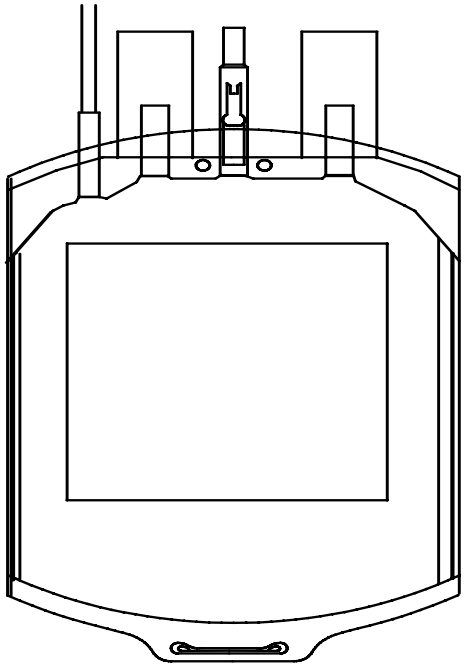
Design characteristics	
Nominal fill volume of diversion pouch	Must have a nominal fill capacity (see note) of 35 ml with a maximum fill volume of 40ml. **Note**: Maximum fill volume can be assessed using the simulated blood donation apparatus in ISO 3826-I Annex B, Test B.2.
Fill line / graduations on diversion pouch	Not essential
Protective cap on sample coupler	Must be present and fitted in place by manufacturer
Opacity of sample coupler	Transparent
Tint of sample coupler	Not essential
Length of sample coupler	The barrel of the sample site coupler must extend at least 20 mm beyond the tip of the needle..
Use of sample coupler	Suitable for the sequential collection of a minimum of four samples, without leakage, when used with standard evacuated blood collection tubes. Tubes are in the range 3 ml (13 x 75 mm) to 10 ml (16 X 100 mm)
Orientation of system in use	Must have within the IFU a clear indication of orientation (i.e. angled downwards or upwards), preferably also marked on the device.

Figure 7 - Primary Collection Pack for Top and Top



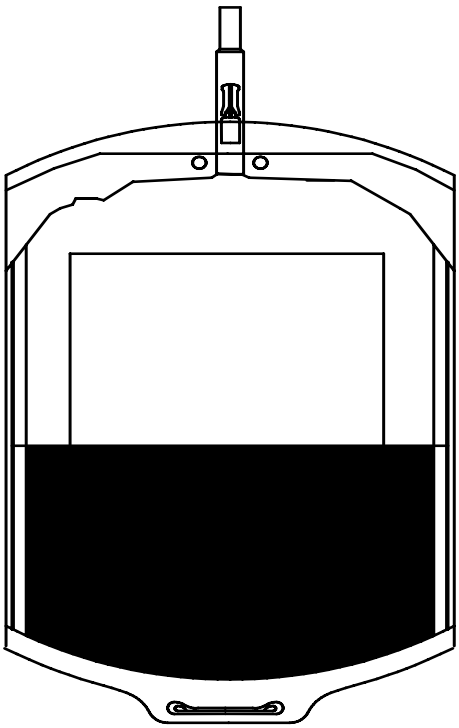
Design characteristics	
Nominal pack volume	600 ml
Anticoagulant	CPD based
Anticoagulant volume	66.5 ml
Target collection volume (range)	475 ml (427.5 - 522.5 ml)
Spike entry ports	None
Side slits (eyelets)	Not essential
Suspension holes (eyelets)	Yes (must be compatible with extractors on the market)
Suspension slit (eyelet)	Yes
Base label	Yes
Base label format	See Appendix
Base label text	▪ Manufacturers name and address ▪ Blood bag reference and batch number ▪ Symbology for all other details Anticoagulant symbol and chemical formulation in English

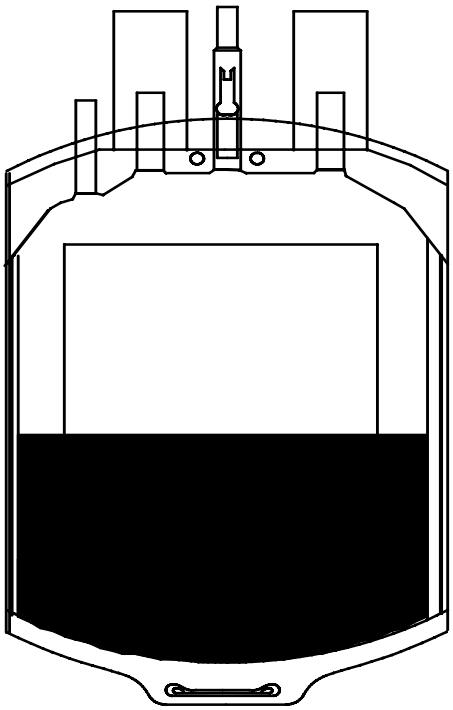
Figure 8- Red cell storage pack (for Top and Top)



Design characteristics	
Nominal pack volume	600 ml
Spike entry ports	Two
Side slits (eyelets)	Yes (minimum of 2 X 25 – 30 mm in length)
Suspension holes (eyelets)	Yes (must be compatible with extractors on the market)
Suspension slit (eyelet)	Yes
Base label required	Yes
Base label format	See Appendix
Base label text	▪ Manufacturers name and address ▪ Blood bag reference and batch number ▪ Symbology for all other details

Figure 9 -Optimal Additive Pack



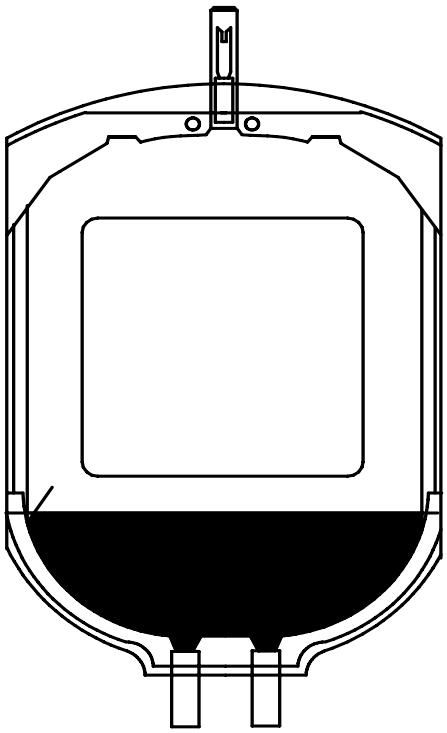


9a – For Top and Top system

9b - For Bottom and Top system (red cell storage pack)

Design characteristics	
Nominal pack volume	600 ml
SAG-M / OAS volume	105 ml
Spike entry ports	9a – None. 9b – Two
Side slits (eyelets)	9a – No 9b – Yes (minimum of 2 X 25 – 30 mm in length)
Suspension holes (eyelets)	Yes (must be compatible with extractors on the market)
Suspension slit (eyelet)	Yes
Base label required	Yes
Base label format	See Appendix
Base label text	▪ Manufacturers name and address ▪ Blood bag reference and batch number ▪ Symbology for all other details Additive symbol and chemical formulation in English

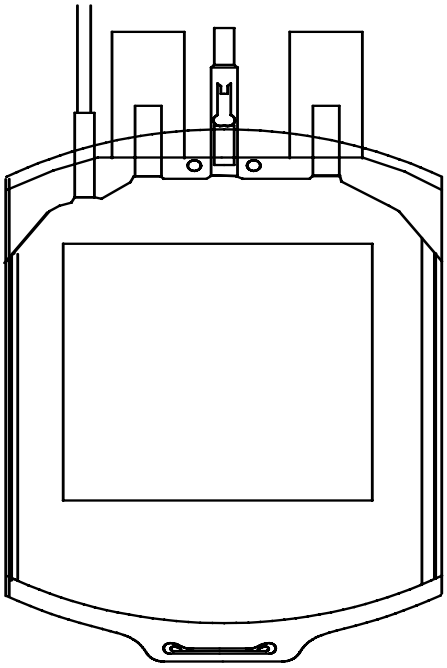
Figure 10 - Primary collection pack for BAT blood pack



N.B. Donor line may enter the top of the bag

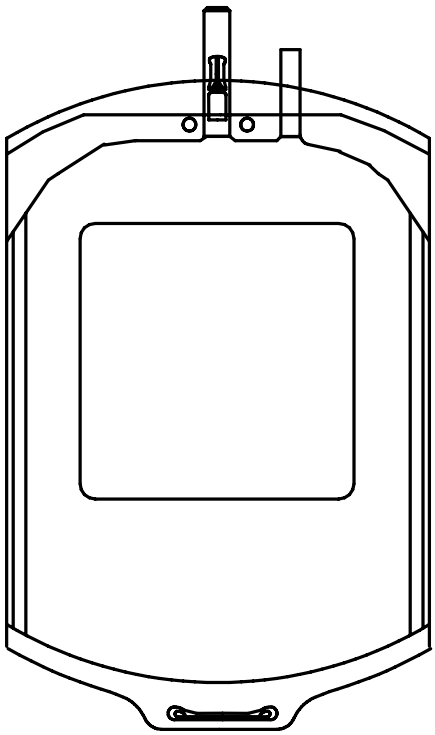
Design characteristics	
Nominal pack volume	600 ml
Anticoagulant	CPD
Anticoagulant volume	66.5 ml
Target collection volume (range)	475 ml (427.5 - 522.5 ml)
Spike entry ports	None
Side slits (eyelets)	Not essential
Suspension holes (eyelets)	Yes (must be compatible with extractors on the market)
Suspension slit (eyelet)	No
Base label required	Yes
Base label format	See Appendix
Base label text	▪ Manufacturers name and address ▪ Blood bag reference and batch number ▪ Symbology for all other details Anticoagulant symbol and chemical formulation in English
Top or bottom entry of donor bleed line	Either

Figure 11 - Plasma Storage Pack



Design characteristics	
Nominal pack volume	600 ml
Spike entry ports	Two
Side slits (eyelets)	Not essential
Suspension holes (eyelets)	Yes (must be compatible with extractors on the market)
Suspension slit (eyelet)	Yes
Base label required	Yes
Base label format	See Appendix
Base label text	▪ Manufacturers name and address ▪ Blood bag reference and batch number ▪ Symbology for all other details

Figure 12 - Red Cell Intermediate Pack for BAT



Design characteristics	
Nominal pack volume	600 ml
Spike entry ports	None
Side slits (eyelets)	Not essential
Suspension holes (eyelets)	Yes
Suspension slit (eyelet)	Yes
Base label required	Yes
Base label format	See Appendix
Base label text	▪ Manufacturers name and address ▪ Blood bag reference and batch number ▪ Symbology for all other details

5.0 DESIGN

5.1 General

In addition to ISO 3826-1 and 3:

Blood collection systems must be designed to comply with EN/ISO 3826 parts 1 – 3 and be CE marked in accordance with the requirements of the Medical Devices Directive.

All blood collection systems will be designed for the collection of human blood or blood components and will be sterile fluid path and non-pyrogenic.

5.2 Air content

Refer to ISO 3826-1 and ISO 3826-3.

5.3 Emptying under pressure

Refer to ISO 3826-1

5.4 Pilot samples

In addition to ISO 3826-1 and 3:

5.4.1 Sampling systems must incorporate a sample diversion pouch and sample site coupler for the aseptic collection of blood samples during the donation process. These items shall be an integral part of the blood collection system, obviating the need for collection staff to assemble components prior to use. The sampling system must be linked to the bleed line by a sterile fluid pathway.

5.4.2 Blood collection systems with integral sampling systems must be packaged as 'sterile fluid path' within an over-wrap bag in such a manner as to prevent damage to any component of the pack assembly.

5.4.3 The sampling system, must allow the pre-donation collection of venous blood samples direct from the vein. The sample diversion pouch must be suitable for the collection of 35 ml of whole blood.

5.4.4 The design must incorporate an appropriately positioned (see note) integral break cannula. A re-openable clamp must be incorporated to control the flow of blood into the primary blood bag. The sample line must incorporate a non-re-openable clamp to close the line permanently after diversion of the requisite amount of blood into the sample pouch.

Note. EU blood establishment policy varies with respect to the position of the break cannula and that some countries do not currently permit the use of a break cannula on the donor line (see also 5.4.10).

5.4.5 The design must incorporate a temporary closure device on the line to the primary collection pack in order to allow control of the filling of donation and sample tubes as two distinct phases in the collection of the donation.

5.4.6 Closure devices on the lines to the sample pouch and to the primary collection pack should be colour coded (see note).

Note: Manufacturers are jointly discussing standard colour coding.

5.4.7 The presence and recommended use of the sampling system must not result in an increased incidence of low volume or clotted donations.

5.4.8 Sample site couplers must be compatible with the dimensions of vacuum sample tubes specified in Figure 6.

5.4.9 When used in conjunction with Customer sample tubes, the sampling system must not result in visible haemolysis (< 2g/L of free haemoglobin in supernatant plasma of freshly collected samples, see note).

Note. A visual colour comparator will be used for this assessment during validation and can be made available to suppliers upon request.

5.4.10 Blood diverted for sample tube filling must not be contaminated with anticoagulant (from the primary pack) to a concentration that prevents clotting in a non-anticoagulated sample i.e. not greater than 1 ml of anticoagulant may gain entry to the sample pouch (see note).

Note. Manufacturers must state how they intend to prevent the ingress of anticoagulant into the sample pouch. This is to enable blood establishment to confirm compatibility with their blood collection processes and ensure during validation that there is no adverse impact on the rate of collection, donor adverse events (bruising) or the quality of the donation.

5.4.11 The sample site coupler must be fitted with a safety cap *in situ* to be removed prior to sample collection and which may be refitted following sample collection. An acceptable alternative will be a needle and needle guard assembly which can be fitted into the sample site coupler to provide a closed system against needle-stick injury.

5.5 Rate of collection

Refer to ISO 3826-1

5.6 Collection and transfer tubes

In addition to ISO 3826-1:

5.6.1 Collection and transfer tube internal and external diameters and wall thickness must enable Customers to make sterile connections using the equipment commonly used in blood centres (see note)

Note. Sterile tube welding devices typically include (but may in future not limited to) instruments currently available from Fresenius, Haemonetics and Terumo.

5.6.2 To enable Customers to make an assessment of compatibility with processing equipment (including sterile tube welders), Suppliers must provide information accurately stating the internal and external tube diameter and wall thickness of all transfer tubes.

5.6.3 Tubes designated for red cell compatibility testing should be a minimum of 500 mm and have a unique number repeated at 40 +/- 5 mm intervals along the entire length (see note).

Note. The unique number repeat interval is to accommodate a range of current automated practices in preparing cross-match line segments (70 and 80 mm length) and will ensure that each segment has at least one readable number per segment. Any alternative proposals from Suppliers for configuration of the cross match lines will be assessed for suitability in consultation with hospitals provided for by the blood establishment.

5.7 Blood taking needle

In addition to ISO 3826-I and 3.

5.7.1 There must be a visible or tactile means of indicating the position of the needle bevel

5.7.2 The needle shall not be fitted with a stylet (an opening/hole in the back of the needle.

5.7.3 Design of the donor line and integral needle must incorporate a needle guard which can be permanently sleeved over the needle once removed from the venepuncture site and prior to disposal

5.7.4 The design of the needle and the needle guard assembly must not significantly interfere with the venepuncture process

5.7.5 On completion of venepuncture and during the collection episode, the needle must be capable of being fixed in position and unable to rotate except when manual adjustment is required.

5.7.6 In operation, the needle assembly should be designed to be capable of laying flat against the arm without affecting the ‘lie’ of the needle in the vein.

5.7.7 The design of the needle and guard must be such that it is capable of being withdrawn from the venepuncture site smoothly, in a single step, directly into the needle guard. Engagement of the guard should require minimal force and should preferably be signalled to the operator by an audible click or tactile indication.

5.7.8 The donor needle sheath should be rigid and designed to prevent bending of the needle during removal.

5.8 Outlet ports

In addition to ISO 3826-1:

5.8.1 Outlet ports (see Figures above) will have a sleeve length of not less than 29 mm.

5.8.2 A siliconised administration set spike conforming to ISO 1135-4 nominal dimensions must not become detached when a static tensile force of 15N is applied for 15 seconds along the longitudinal axis of the plane of the administration set.

5.8.3 The blood pack port must show compatibility with a range of CE marked, ISO 1135-4 conforming transfusion set closure piercing devices (spikes) in use within Customer hospitals. This must ensure that excessive force is not required to insert the spike (see note).

Note. As a guideline no more than 35N should be required to insert the spike. This will be assessed during tender evaluation.

5.8.4 If the container is provided with a transfer tube to a transfer pack, the transfer port shall be provided with a device that first acts as a seal and when broken permits the free uninterrupted flow of blood components in either direction. This device must be simple and easy to use in routine processing and must not lead to increased residual haemolysis of red cell components. For a manually opened break cannula, it must be possible to open the device with no more than two movements in accordance with the IFU.

5.9 Suspension (of bag)

Refer to ISO 3826-1

5.10 Integral leucodepletion filters general

In addition to ISO 3826-3:

5.10.1 When used in accordance with the manufacturer's instructions, filters must reduce the leucocyte content of the final product in accordance with the current EU Blood Safety Directive and CoE guide to the preparation, use and quality assurance of blood components.

5.10.2 Following filtration, blood components must comply with the EU Blood Safety Directive and EDQM (CoE) guide to the preparation, use and quality assurance of blood components. This is particularly important with regard to final Hb content of red cell components.

5.10.3 If filters require any special form of packing prior to centrifugation, this must be clearly identified to the user along with any recommended filter holders/supports.

5.10.4 In order for the Customer to manage batch acceptance more easily, it is required that a batch of blood collection systems should contain no more than one batch of filters (see note). When this is not practical, the Supplier may alternatively provide filter traceability by ensuring that the filter batch number is visible on each filter housing.

Note. It is acceptable however for one batch of filters to be used over several batches of blood collection systems.

5.10.5 Suppliers must state how they define a batch of filters.

5.11 Integral leucodepletion filters for red cells and whole blood

5.11.1 Filters for the leucodepletion of whole blood must be usable with blood of core temperatures in the range 4°C - 30°C (see note).

Note. Filtration is generally carried out at air temperatures in the range 4^{o}C to 24^{o}C. with a 'hold time' that varies from nil to 26 hours post collection.

5.11.2 Filters for the leucodepletion of red cells must be usable with components of core temperature 4°C as a minimum requirement. Where a red cell filter is also recommended for use at ambient temperatures, the filter must be usable with components of core temperature in the range 4°C - 24°C

5.11.3 Filtration of whole blood and red cells must be completed for >95% of donations within 120 minutes from the time at which the cannula preventing the flow of blood into the filter is opened.

5.12 Plasma leucocyte depletion filters and plasma bags

5.12.1 Filters for the Leucodepletion of plasma products must be usable with components of core temperature in the range 4°C - 24°C.

5.12.2 Where a plasma filter is supplied with a receiving pack for the leucodepleted product, the receiving pack must be suitable for the rapid freezing (< 1 hr) of plasma to -80ºC (see note) and subsequent storage for a period of three years at -25ºC and must also comply with the requirements of figure 11.

Note. Some blood establishments freeze in the vapour phase of liquid nitrogen (-140ºC) and may therefore impose more stringent standards.

6 REQUIREMENTS

6.1 General

Refer to ISO 3826 – 1 and 3

6.2 Physical requirements including sterilisation, transparency, coloration, thermal stability, water vapour transmission, resistance to leakage and particulate contamination.

Refer to ISO 3826 – 1 and 3

6.3 Chemical requirements including the raw container or sheeting and test fluid.

Refer to ISO 3826 – 1 and 3

6.4 Biological requirements including general, impermeability for micro-organisms and compatibility.

Refer to ISO 3826 – I and 3

7.0 PACKAGING

Refer to ISO 3826 – I and 3

8.0 LABELLING including general, label on plastic container, label on over package, label on shipping box and label requirements

Refer to ISO 3826 – 1, 2 and 3

In addition:

8.1 Blood collection systems shall be provided in bulk container boxes. These boxes must be of a size that is suitable for safe lifting by one person and must comply with the EC Directive on Manual Handling: Council Directive of 29th May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (fourth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (90/269/EEC). The number of boxes which can be safely stacked is to be shown on the bulk container boxes.

8.2 Boxes shall carry Lot / Batch number in eye readable and internationally accepted barcode format (see note).

Note. ISBT 128 or ABC codebar are acceptable.

8.3 Boxes will be consigned on pallets and packaged in such a way as to minimise damage in transit. Pallet size will be indicated in the contract/tender

8.4 Where possible, packaging should contain recycled material and should where possible, be recyclable

8.5 Refer to Appendix 1 for schematic diagram of a proposed 'interim' base label layout whilst blood establishments make the transition to reading/storing ISBT Code 128 barcodes for container manufacturer/catalogue number and lot number. **N.B.** Other base designs are permissible pending Code 128 standardisation.

9.0 ANTICOAGULANT AND ADDITIVE SOLUTIONS

Refer to ISO 3826 – 1 and European Pharmacopoeia

9.1 Anticoagulants will be CPD based and must be approved for a minimum of 28-day storage of red cells at 2 – 6^{o}C.

9.2 Collection system configurations containing an optimal additive solution must be approved for red cell storage for a minimum period of 42 days at 2 – 6^{o}C.

10.0 INSTRUCTIONS FOR USE

10.1 Detailed directions for use of blood collection systems must be included with each box of blood collection systems either as information on the label affixed to the over-package or provided on a separate sheet. Instructions for all integrated features such as needle guards and sample site couplers must also be included. Instructions must be available in all EU languages. Alternatively a copy of the IFU for each product code may be provided with each consignment provided that the IFU are made more widely available by publishing under version control on the internet.

10.2 Instructions for leucodepletion must also be supplied and include the following information:

- Recommended hold period and temperature prior to filtration.
- Acceptable filtration temperature range.
- Recommended filtration (gravity) height or pressure

10.3 Instructions for use must carry information concerning the latex (and its derivatives) content of the product in relation to risk of allergic and anaphylactic responses in the patients.

10.4 Instructions for use must be version controlled and changes notified by an appropriate means.

Appendix 1. Base label.

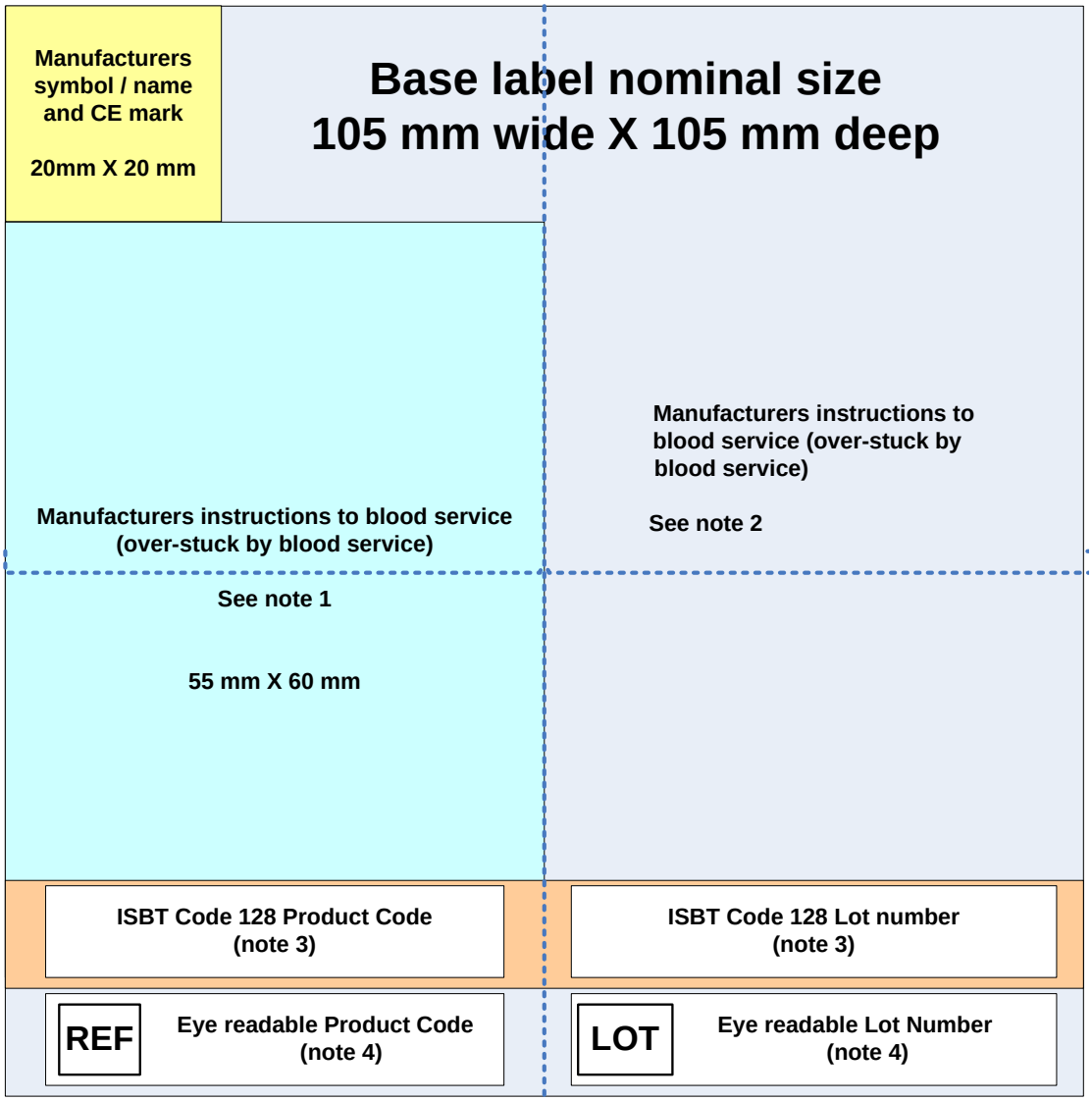


Figure 1 – (Schematic diagram not to scale)

Note 1.

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 anticoagulant or additive solution chemical formulation and its volume
- 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.

In addition, the formulation of the anticoagulant or additive solution must be stated in English.

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 2.

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
- 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)

Note 3

The ISBT Code 128 Lot and Product Code barcode format must be exactly as specified in the current version ISBT 128 Standard Technical Specification.
http://iccbba.org/tech_currentversions.html

Note 4.

The Lot and Product Code eye readable numbers must be exactly as specified in the current version ISBT 128 Standard Technical Specification. http://iccbba.org/tech_currentversions.html

Note 5.

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.

Note 6.

Some EBA members are unable to utilise ISBT 128 Product reference and lot numbers and will specify their requirements for barcoding this information separately.

