# Specification for Whole Blood Collection Systems including Leucodepletion Filters

**Version Control**

| Revision | Date | Status | Comment |
|---|---|---|---|
| Refer to version 3.7 for previous document history | | | |
| 3.7 | 13/12/11 | FINAL published version. | Version used for original Eurobloodpack collaborative purchasing project/ tender. |
| 4.0 | 15/02/12 | Not published. | Minor changes to label and tube lengths. Changes since version 3.2 issued to the EBA are highlighted in blue text. |
| 4.1 | 24/02/14 | Not published. | Post tender clarifications and removal of EBA copy and design rights from document. Made by Mark Nightingale and Russell Hambleton in January 2013 and updated by Mark Nightingale before release to Eurobloodpack Technical Committee. |
| 4.2 | 25/02/14 | Not published. Eurobloodpack | Technical Committee review of change requests at meeting of 25/02/14. Minor changes to the base label design to avoid covering the eye readable REF/LOT numbers and remove text from white space areas required for barcode integrity. Use of ISBT 128 REF and LOT on outer packaging. |
| 4.3 | 05/08/14 | Not published. | Eurobloodpack Technical Committee review of change requests at meeting of 23/06/14 Removal of EBA design rights. Update of normative references. Clarification of mandatory requirements. Removal of tolerance on anticoagulant contamination of sample pouch and requirement for a donor line break cannula. Change to requirements for needle/guard. Change to provision of instructions for use. Minor editorial changes. |
| 4.4 | 26/03/15 | DRAFT published for consultation purposes. | Eurobloodpack Technical Committee updates at meeting held 04/03/15. Donor line break cannula mandated. Roberts clip colours standardised on the lines to the primary pack and sample pouch. Inclusion of a statement concerning on RFID. Inclusion of requirements for whole blood dry pack. Numerous editorial and numbering changes. |

## Purpose

This document details the technical, design and performance requirements related to Whole Blood Collection Systems including leucodepletion filters.
Grey text provides instructions for Suppliers as to what information MUST be submitted in support of their compliance statement; where no Grey text is detailed and either:

- A response of "Compliant" is chosen, no further information is required; or
- A response of "Non-Compliant" is chosen, information confirming the nature/ extent of the non-compliance MUST be submitted.

## Defined Terms

| Term | Definition |
|---|---|
| "Authority": | means a blood establishment entitled to place orders under the Framework Agreement. |
| "Authority Personnel": | means all persons directly employed by the Authority or an individual authorised to act on behalf of the Authority for a specific purpose. |
| "Blood collection system": | Individual assemblies for the collection of whole blood, complete with any associated filters, ports, transfer tubes and associated transfer packs, tube and needle for collecting blood, needle-stick protection device and pre-donation sampling device. This includes, where appropriate, solutions used within the collection systems. |
| "Framework Agreement": | means the framework agreement entitled "*Primary Blood Collection Systems and Ancillary Processing Systems*" to be entered into by NHS Blood and Transplant and the successful supplier(s). |
| "MUST" or "MUST NOT": | means a mandatory requirement. |
| "Tamper evident": | means 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 Authority personnel that tampering has occurred. Note: The interpretation of this definition in the context of the manufacture of base labels is "*Labels MUST be fabricated so that any attempts made to remove labels will leave visible evidence*". |
| "Supplier": | means the suppliers (including the Supplier) appointed under the Framework Agreement. |
| "SHOULD" or "SHOULD NOT": | means an optional or non-mandatory requirement. |
| "Over-wrap packaging": | means packaging that contains only one article (i.e. a Blood Collection system). |

## Normative References

References to established standards previously published by recognised groups and of particular relevance to this document include:

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

- Council of Europe. Guide to the preparation, use and quality assurance of blood components.
- European Pharmacopoeia (2005). European Directorate for the Quality of Medicines of the Council of Europe (EDQM).
- 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 3826-3:2007: Plastics collapsible containers for human blood and blood components - Part 3: Blood bags with integrated features.
- 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.
- EN ISO 1135-4: 2012: Transfusion equipment for medical use - Part 4: Transfusion sets for single use.
- ISBT 128 Standard Technical Specification. ICCBBA. http://www.iccbba.org/technicalspecification.pdf.
- ISO 11607-1:2006: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems.
- ISO 11607-2:2006: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
- ISO 14971:2007: Medical devices - Application of risk management to medical devices.

The Supplier MUST ensure ongoing compliance with latest versions of established standards when updated.

## Dimensions

Figures 1 to 4 and their accompanying tables of dimensions illustrate the four Blood collection systems, namely:

- Figure 1 - Top and Top (TAT) Blood collection system for whole blood filtration.
- Figure 2 - Bottom and Top (BAT) Blood collection system for red cell concentrates (RCC) filtration.
- Figure 3 - Bottom and Top (BAT) Blood collection system for RCC filtration with integral plasma filter (IPF).
- Figure 4 - Whole blood collection system without anticoagulant.

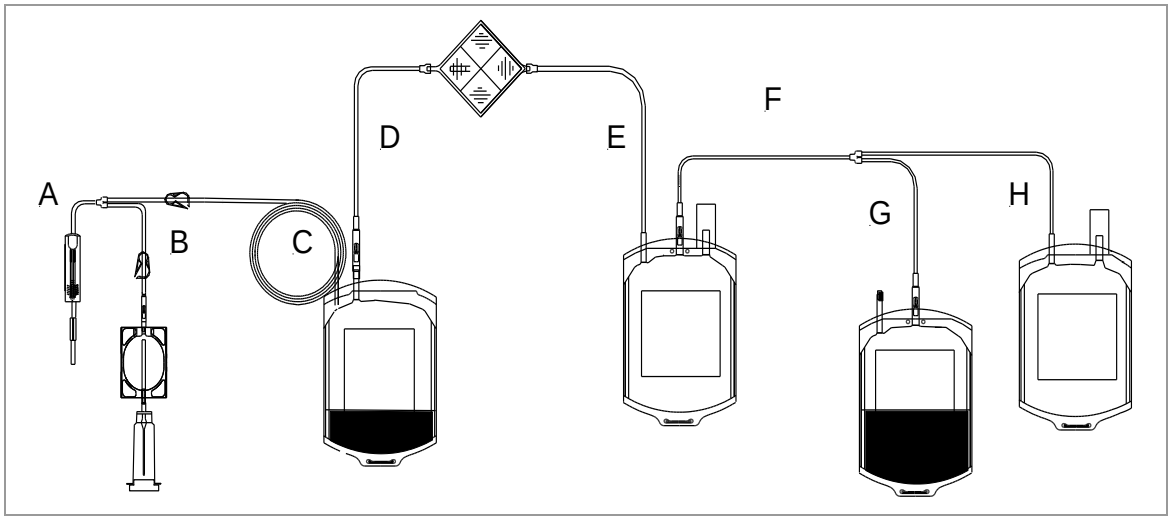
Figures 5 to 16 and their associated table of design characteristics illustrate the sub-components/ integrated features of the Blood collection system assembly, namely:

- Figure 5 - Needle assembly and sample site coupler.
- Figure 6 - Needle and needle guard.
- Figure 7 - Sample site coupler and diversion pouch.
- Figure 8 - Primary collection pack (TAT pack).
- Figure 9 - Red cell storage pack.
- Figure 10 - Optimal additive solution pack.
- Figure 11 - Primary collection pack (BAT pack).
- Figure 12 - Plasma storage pack.
- Figure 13 - Red cell intermediate pack.
- Figure 14 - Primary collection pack (whole blood collection system without anticoagulant).
- Figure 15 - Serum intermediate transfer pack (whole blood collection system without anticoagulant).
- Figure 16 - Serum storage pack (whole blood collection system without anticoagulant).

The Supplier MUST ensure the dimensions (including dimensional tolerances) are achieved post sterilisation.

The diagrams/ figures below are not to scale.

**Figure 1 - Top and Top (TAT) Blood collection system for whole blood filtration**



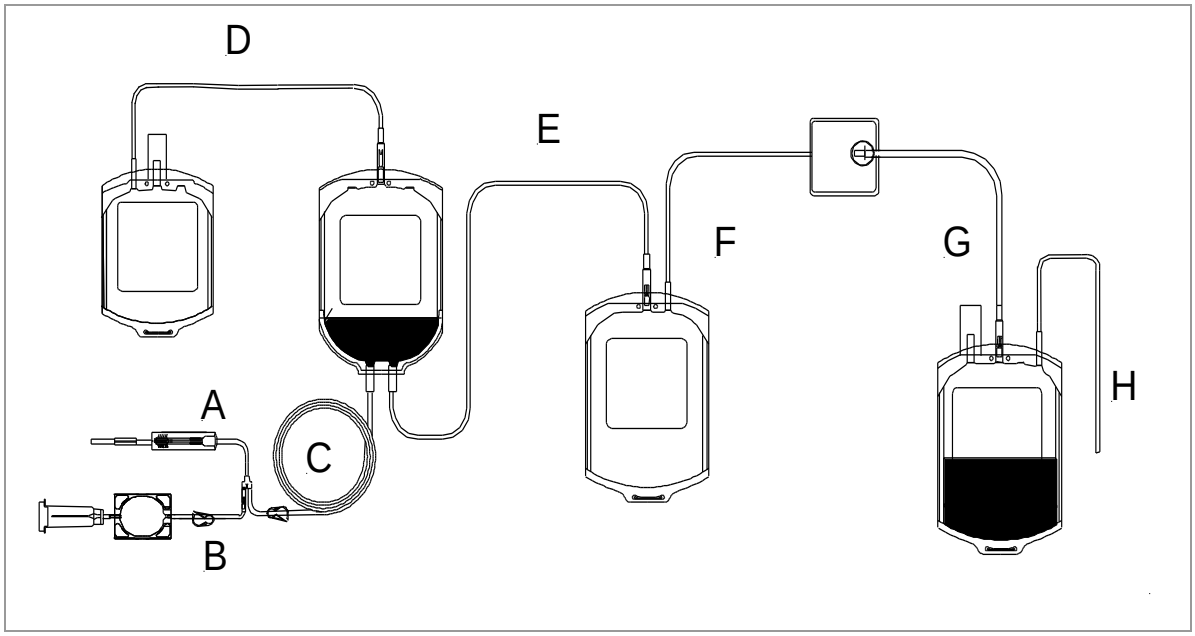

**Dimensions (post sterilisation)**

| Tube | Length | Tolerance (±) |
|---|---|---|
| A + C | 1050 mm | 50 mm |
| A | 320 mm | 50 mm |
| B | 250 mm | 50 mm |
| D | Supplier defined | 0 mm |
| E | Minimum 600 mm | 0 mm |
| D+E | Supplier defined but no greater than 1200 mm | 0 mm |
| F | 450 mm | 50 mm |
| G | 350 mm | 50 mm |
| H | 350 mm | 50 mm |

**Volumes**

| Detail | Specification | Tolerance (±) |
|---|---|---|
| Volume of anticoagulant in primary collection pack | 66.5 ml | 10% |
| Volume of additive solution in SAGM pack or equivalent licensed optimal additive solution (OAS) | 105 ml | 10% |

**Figure 2 - Bottom and Top (BAT) Blood collection system for RCC filtration**




**Dimensions (post sterilisation)**

| Tube | Length | Tolerance (±) |
|---|---|---|
| A + C * | 1050 mm | 50 mm |
| A | 320 mm | 50 mm |
| B | 250 mm | 50 mm |
| D | 450 mm | 50 mm |
| E ** | 450 mm | 50 mm |
| F | Supplier defined | 0 mm |
| G | Minimum 600 mm | 0 mm |
| F + G | Supplier defined but no greater than 1200 mm | 0 mm |
| H | 200 mm | 50 mm |

* Donor line may be top or bottom entry to primary collection pack.

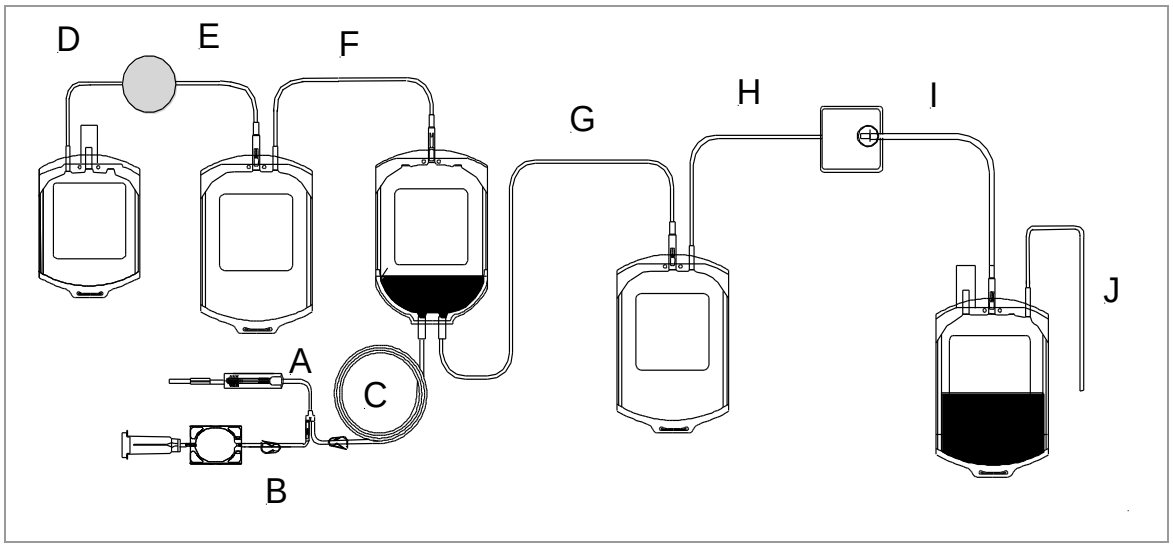
** Wide bore tube – A tube of larger internal diameter than standard tubing within the Blood collection system assembly may be fitted depending on the availability of a suitable sterile tube welding device to join dissimilar tubes. Alternatively, with the written agreement of the Authority, an additional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

**Volumes**

| Detail | Specification | Tolerance (±) |
|---|---|---|
| Volume of anticoagulant in primary collection pack | 66.5 ml | 10% |
| Volume of additive solution in SAGM pack or equivalent licensed OAS | 105 ml | 10% |

**Figure 3 - Bottom and Top (BAT) Blood collection system for RCC filtration with integral plasma filter**

Note: This Blood collection system is similar to Figure 2 with the exception of having a plasma filter and an additional (empty) pack to receive plasma prior to filtration.




**Dimensions (post sterilisation)**

| Tube | Length | Tolerance (±) |
|---|---|---|
| A + C * | 1050 mm | 50 mm |
| A | 320 mm | 50 mm |
| B | 250 mm | 50 mm |
| D | Minimum 200 mm | 0 mm |
| E | Supplier defined | 0 mm |
| D + E | Supplier defined | 0 mm |
| F | 450 mm | 50 mm |
| G ** | 450 mm | 50 mm |
| H | Supplier defined | 0 mm |
| I | Minimum 600 mm | 0 mm |
| H + I | Supplier defined but no greater than 1200 mm | 0 mm |
| J | 200 mm | 50 mm |

* Donor line may be top or bottom entry to primary collection pack.

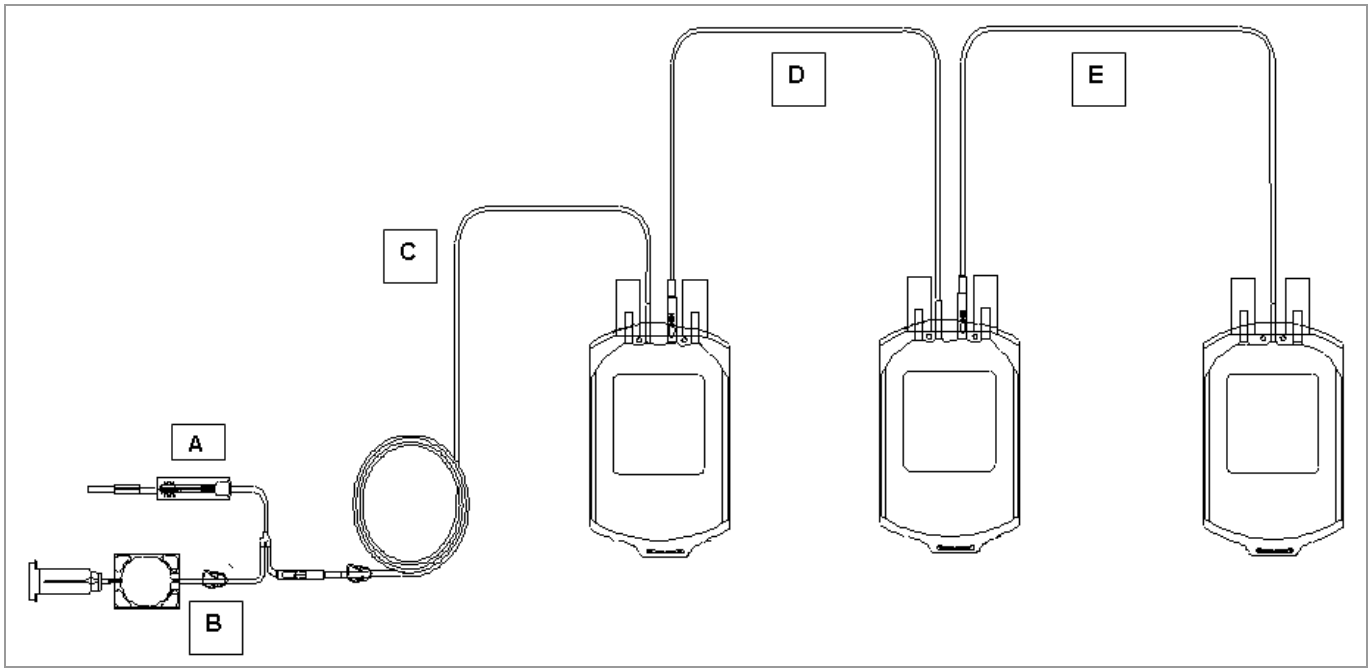
** Wide bore tube – A tube of larger internal diameter than standard tubing within the Blood collection system assembly may be fitted depending on the availability of a suitable sterile tube welding device to join dissimilar tubes. Alternatively, with the written agreement of the Authority, an additional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

**Volumes**

| Detail | Specification | Tolerance (±) |
|---|---|---|
| Volume of anticoagulant in primary collection pack | 66.5 ml | 10% |
| Volume of additive solution in SAGM pack or equivalent licensed OAS | 105 ml | 10% |

**Figure 4 - Whole blood collection system without anticoagulant**

Note: This Blood collection system is a dry system which contains no anticoagulant.




**Dimensions (post sterilisation)**

| Tube | Length | Tolerance (±) |
|---|---|---|
| A + C | 1050 mm | 50 mm |
| A | 320 mm | 50 mm |
| B | 250 mm | 50 mm |
| D | 350 mm | 50 mm |
| E | 350 mm | 50 mm |

**Volumes**

| Detail | Specification | Tolerance (±) |
|---|---|---|
| Volume of anticoagulant in primary collection pack | Not Applicable | Not Applicable |
| Volume of additive solution in SAGM pack or equivalent licensed OAS | Not Applicable | Not Applicable |

**Figure 5 - Needle assembly and sample site coupler**

Note: Applicable to TAT and BAT Blood collection systems (i.e. figures 1 to 4).

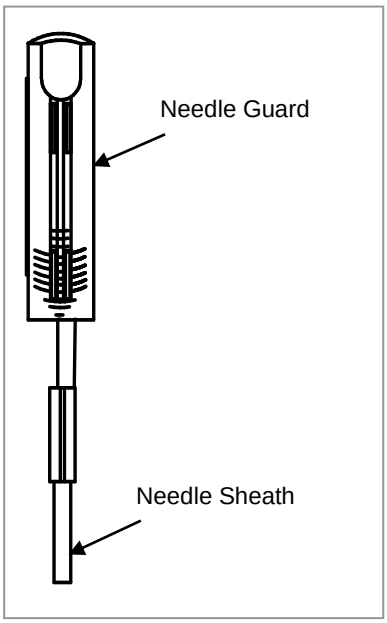
Schematic to be confirmed

**Design characteristics**

| | |
|---|---|
| Break cannula | MUST incorporate a break cannula in the donor line to prevent anticoagulant from the primary collection pack from reaching the sample pouch (see 4.6). |
| Clamp on line to sample site coupler | MUST incorporate a non-re-openable clamp to close the line permanently after diversion of the requisite amount of blood into the sample pouch (see 4.7 and 4.8). |
| Sample diversion pouch | See figure 7. |

**Figure 6 - Needle and needle guard**

Note: Applicable to TAT and BAT Blood collection systems (i.e. figures 1 to 4)

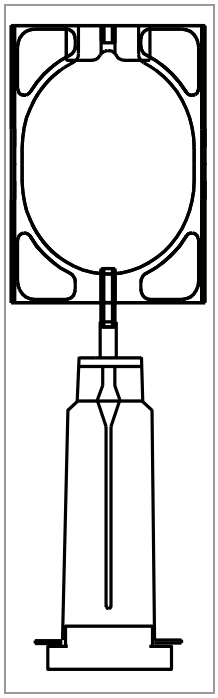



**Design characteristics**

| | |
|---|---|
| Needle sheath | MUST be tamper evident and attached to the needle hub prior to use. |
| Bevel indicator on hub | The needle MUST have a visible or tactile means of indicating the position of the needle bevel (see 7.2). |
| Needle guard | • The needle assembly MUST incorporate a needle guard which can be permanently sleeved over the needle once removed from the venepuncture site and prior to disposal (see 7.4).<br>• The needle guard SHOULD interlock with the sample tube coupler. |
| Interlock indicator | The engagement of the needle guard MUST require minimal force and MUST be signalled to Authority personnel by an audible click or tactile indication (see 7.9). |
| Needle guard action | The design of the needle and needle guard MUST be capable of being withdrawn from the venepuncture site smoothly, in a single step, in the same 'plane', directly into the needle guard (see 7.8). |

**Figure 7 - Sample site coupler and diversion pouch**

Note: Applicable to TAT and BAT Blood collection systems (i.e. figures 1 to 4).



**Design characteristics**

| | |
|---|---|
| Nominal fill volume of diversion pouch | MUST have a nominal fill capacity of 35 ml with a maximum fill volume of 40 ml (see 4.5). |
| Fill line/ graduations on diversion pouch | MUST have a datum line at 30 ml (see 4.5). |
| Protective cap on sample site coupler | MUST be fitted with a safety cap in situ to be removed prior to sample collection and which SHOULD be capable of being refitted following sample collection (see 4.13). |
| Opacity of sample site coupler | MUST be transparent. |
| Length of sample site coupler | The barrel of the sample site coupler MUST extend at least 20 mm beyond the tip of the needle. |
| Use of sample site coupler | MUST allow for the sequential collection of a minimum of four samples, without leakage, when used with standard vacuum sample tubes (e.g. in the range 3 ml (13 x 75 mm) to 10 ml (16 x 100 mm)) (see 4.10). |
| Orientation of system in use | A clear indication of orientation (i.e. angled downwards or upwards), SHOULD be marked on the device but MUST be included in the Instructions for Use (IFU). |

**Figure 8 - Primary collection pack for TAT**

Note: Applicable to TAT Blood collection systems (i.e. figure 1)

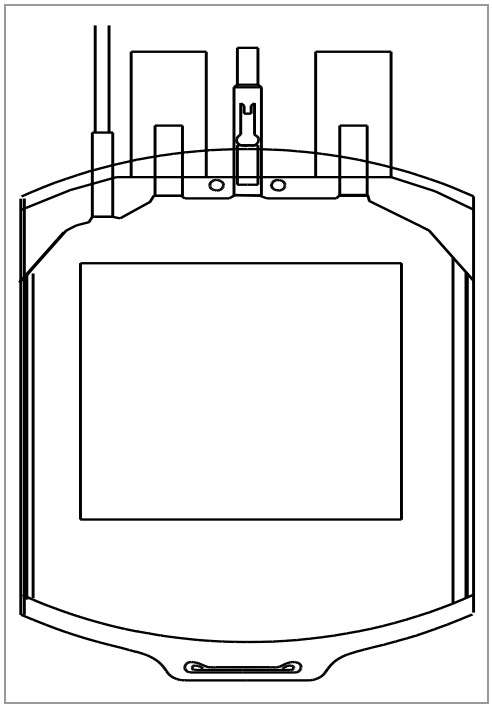
Schematic to be confirmed

**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| Anticoagulant | Citrate Phosphate Dextrose (CPD) based |
| Anticoagulant volume | 66.5 ml |
| Target collection volume (range) | 475 ml (427.5 to 522.5 ml) |
| Spike entry ports | Not Applicable |
| Side slits (eyelets) | Not Applicable |
| Suspension holes (eyelets) | Yes |
| Suspension slit (eyelet) | Yes |
| Base label | Yes |
| Base label text and format | See Appendix 1 |
| Base label text | • Suppliers name and address.<br>• Supplier blood pack reference and batch number.<br>• Symbology for all other details.<br>• Anticoagulant symbol and chemical formulation, written in British English. |

**Figure 9 - Red cell storage pack**

Note: Applicable to TAT Blood collection systems (i.e. figure 1)



**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| Spike entry ports | Two |
| Side slits (eyelets) | Yes (minimum of 2 x 25 to 30 mm in length on the same side) |
| Suspension holes (eyelets) | Yes |
| Suspension slit (eyelet) | Yes |
| Base label required | Yes |
| Base label format | See Appendix 1 |
| Base label text | • Suppliers name and address<br>• Supplier blood pack reference and batch number<br>• Symbology for all other details |

**Figure 10 - Optimal additive solution pack**

Note: Applicable to TAT and BAT Blood collection systems (i.e. figures 1 to 3).

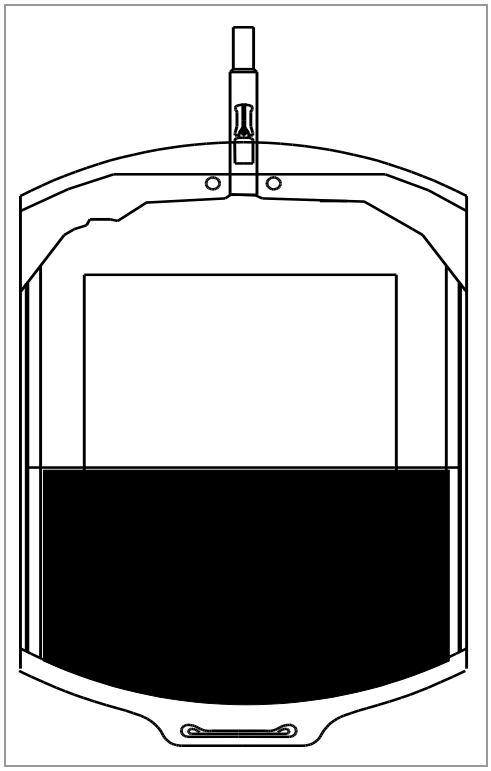


Figure 10a: Top and Top system

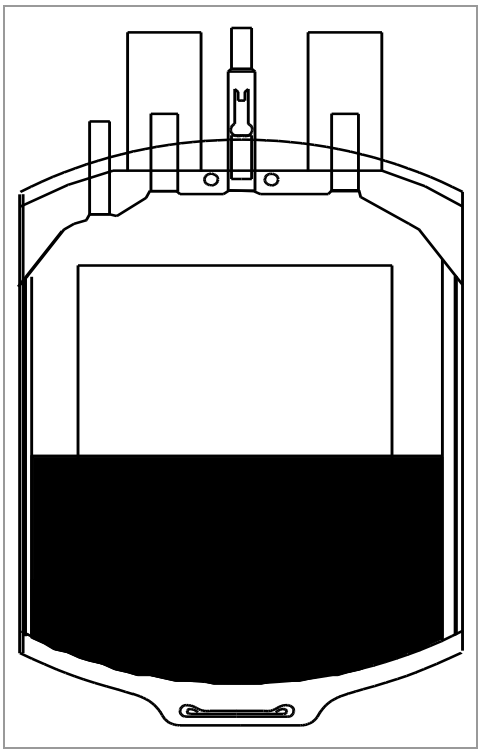


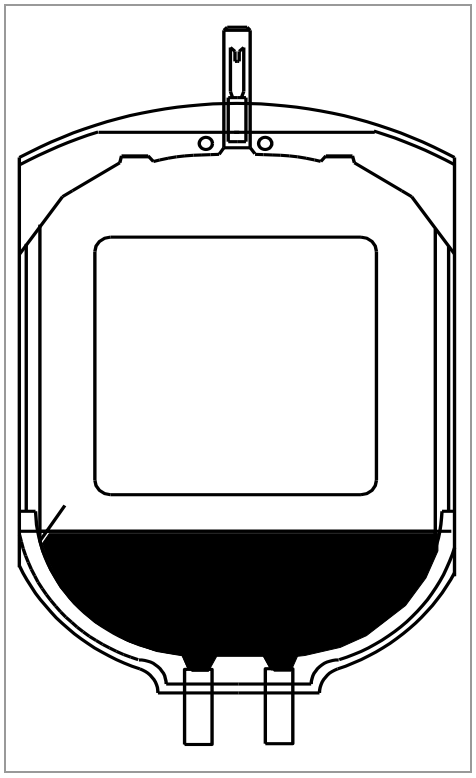
Figure 10b: Bottom and Top system (red cell storage pack)

**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| SAGM/ OAS volume | 105 ml |
| Spike entry ports | 10a - Not Applicable<br>10b - Two |
| Side slits (eyelets) | 10a - Not Applicable<br>10b - Yes (minimum of 2 x 25 to 30 mm in length on the same side) |
| Suspension holes (eyelets) | Yes |
| Suspension slit (eyelet) | Yes |
| Base label required | Yes |
| Base label format | See Appendix 1 |
| Base label text | • Suppliers name and address<br>• Supplier Blood pack reference and batch number<br>• Symbology for all other details<br>• Additive symbol and chemical formulation, written in British English |

**Figure 11 - Primary collection pack for BAT**

Note: Applicable to BAT Blood collection systems (i.e. figures 2 and 3)

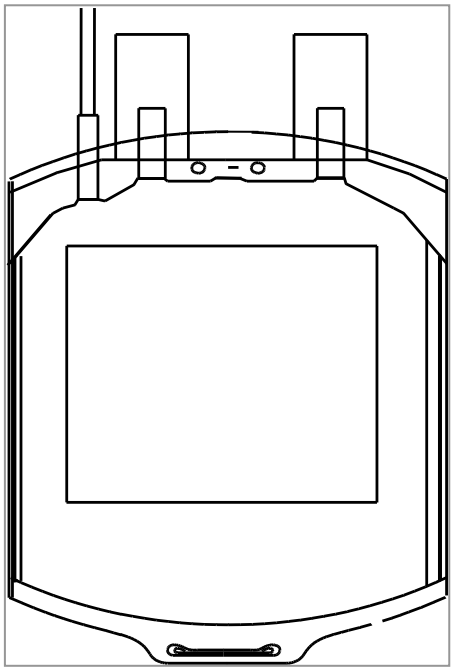


**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| Anticoagulant | CPD |
| Anticoagulant volume | 66.5 ml |
| Target collection volume (range) | 475 ml (427.5 to 522.5 ml) |
| Spike entry ports | Not Applicable |
| Side slits (eyelets) | Not Applicable |
| Suspension holes (eyelets) | Yes |
| Suspension slit (eyelet) | No |
| Base label required | Yes |
| Base label format | See Appendix 1 |
| Base label text | • Suppliers name and address<br>• Supplier Blood pack reference and batch number<br>• Symbology for all other details<br>• Anticoagulant symbol and chemical formulation, written in British English |
| Entry point of donor bleed line | Either top or bottom of pack |

**Figure 12 - Plasma storage pack**

Note: Applicable to TAT and BAT Blood collection systems (i.e. figures 1 to 3).

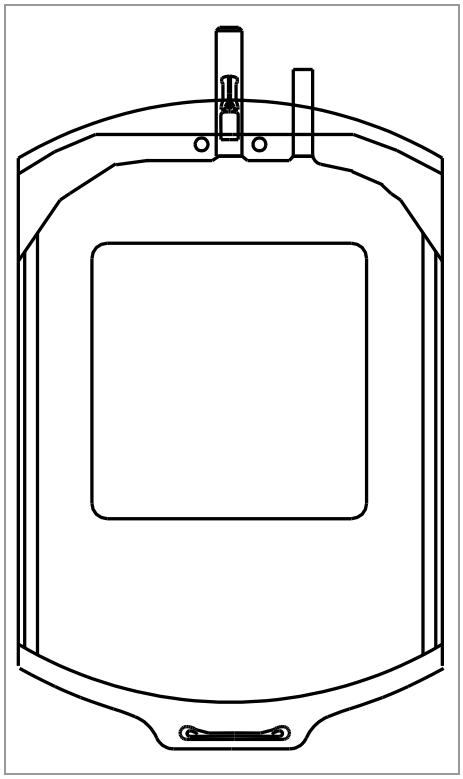


**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| Spike entry ports | Two |
| Side slits (eyelets) | Not Applicable |
| Suspension holes (eyelets) | Yes |
| Suspension slit (eyelet) | Yes |
| Base label required | Yes |
| Base label format | See Appendix 1 |
| Base label text | • Suppliers name and address<br>• Supplier Blood pack reference and batch number<br>• Symbology for all other details |

**Figure 13 - Red cell intermediate pack**

Note: Applicable to BAT Blood collection systems (i.e. figures 2 and 3)

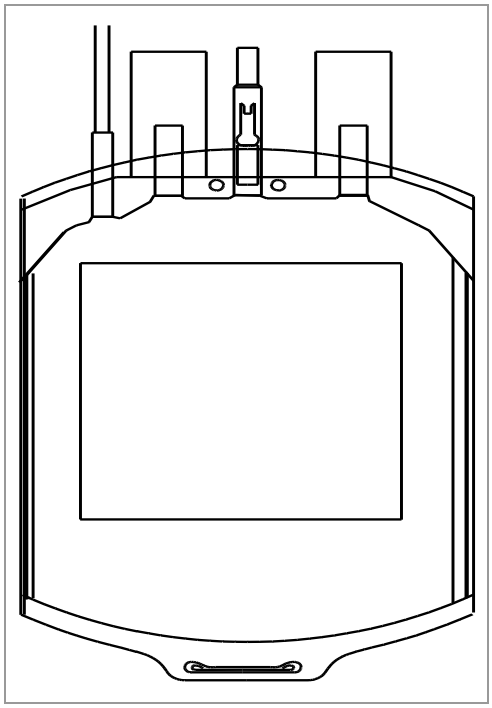


**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| Spike entry ports | Not Applicable |
| Side slits (eyelets) | Not Applicable |
| Suspension holes (eyelets) | Yes |
| Suspension slit (eyelet) | Yes |
| Base label required | Yes |
| Base label format | See Appendix 1 |
| Base label text | • Suppliers name and address<br>• Supplier Blood pack reference and batch number<br>• Symbology for all other details |

**Figure 14 - Primary collection pack for BAT**

Note: Applicable to BAT Blood collection system without anticoagulant (i.e. figure 4); spike entry ports are at Suppliers discretion.

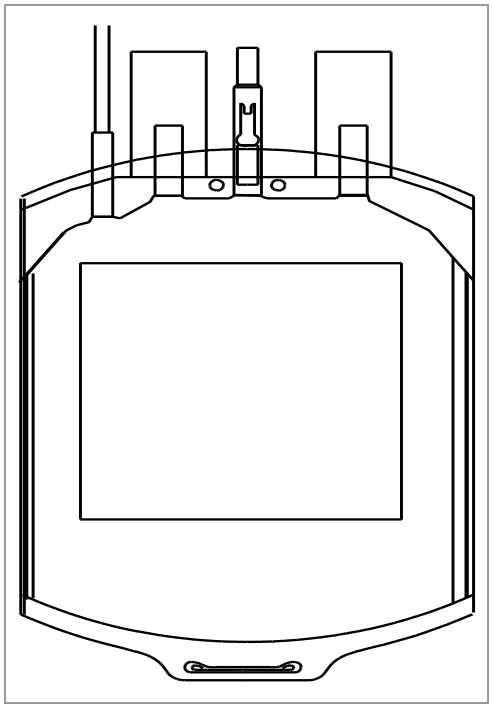


**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| Anticoagulant | Not Applicable |
| Anticoagulant volume | Not Applicable |
| Target collection volume | 475 ml |
| Spike entry ports | Not Applicable (at Suppliers discretion) |
| Side slits (eyelets) | Not Applicable |
| Suspension holes (eyelets) | Yes |
| Suspension slit (eyelet) | Yes |
| Base label | Yes |
| Base label format | See Appendix 1 |
| Base label text | • Suppliers name and address<br>• Supplier Blood pack reference and batch number<br>• Symbology for all other details |

**Figure 15 - Serum intermediate transfer pack**

Note: Applicable to BAT Blood collection system without anticoagulant (i.e. figure 4); spike entry ports are at Suppliers discretion.

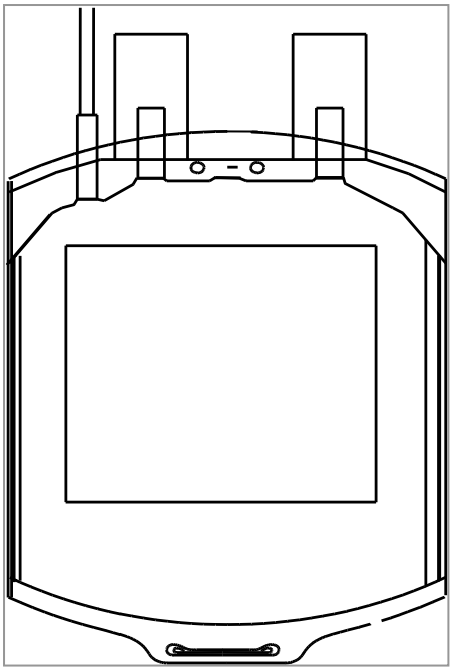


**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| Spike entry ports | Not Applicable (at Suppliers discretion) |
| Side slits (eyelets) | Not Applicable |
| Suspension holes (eyelets) | Yes (must be compatible with extractors on the market) |
| Suspension slit (eyelet) | Yes |
| Base label | Yes |
| Base label format | See Appendix 1 |
| Base label text | • Suppliers name and address<br>• Supplier Blood pack reference and batch number<br>• Symbology for all other details |

**Figure 16 - Serum storage pack**

Note: Applicable to BAT Blood collection system without anticoagulant (i.e. figure 4); spike entry ports are at Suppliers discretion.



**Design characteristics**

| | |
|---|---|
| Nominal pack volume | 600 ml |
| Spike entry ports | Not Applicable (at Suppliers discretion) |
| Side slits (eyelets) | Not Applicable |
| Suspension holes (eyelets) | Yes |
| Suspension slit (eyelet) | Yes |
| Base label required | Yes |
| Base label format | See Appendix 1 |
| Base label text | • Suppliers name and address<br>• Supplier Blood pack reference and batch number<br>• Symbology for all other details |

## Design requirements

### 1. General

1.1. Blood collection systems MUST:
   a. be designed to comply with EN ISO 3826 parts 1 to 3.
   b. be designed for the collection of human blood or blood components.
   c. be CE marked in accordance with the Medical Devices Directive.
   d. have a sterile fluid pathway and be non-pyrogenic.

### 2. Air content

2.1. Blood collection systems MUST be compliant with the normative references ISO 3826-1. and ISO 3826-3.

### 3. Emptying under pressure

3.1. Blood collection systems MUST be compliant with the normative reference ISO 3826-1.

### 4. Pilot samples

4.1. Blood collection systems MUST be compliant with the normative references ISO 3826-1. and ISO 3826-3

4.2. The sampling system 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 Authority personnel to assemble components prior to use.

4.3. The sampling system MUST be linked to the bleed line by a sterile fluid pathway.

4.4. The sampling system MUST allow the pre-donation collection of venous blood samples direct from the vein.

4.5. The sample diversion pouch MUST have a nominal fill capacity of 35 ml with a maximum fill volume of 40 ml of whole blood and incorporate a fill/ graduation datum line at 30 ml.

4.6. The Blood collection system design MUST incorporate a break cannula in the donor line to prevent anticoagulant from the primary collection pack from reaching the sample pouch (see 4.12 and note[1]).

4.7. The design MUST allow controlled filling of the donation and sample tubes as two distinct phases in the collection of the donation. To this effect:
   a. a re-openable clamp MUST be incorporated to control the flow of blood into the primary collection pack.
   b. 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.

4.8. Clamps described in 4.7 MUST be colour coded blue for re-openable and red for non-reopenable.

4.9. The presence and recommended use of the sampling system MUST NOT result in an increased incidence of low volume or clotted donations.

4.10. Sample site couplers MUST be compatible standard vacuum sample tubes (e.g. in the range 3 ml (13 x 75 mm) to 10 ml (16 x 100 mm)).

4.11. When used in conjunction with Authority sample tubes, the sampling system MUST limit haemolysis to < 2g/L of free haemoglobin in supernatant plasma of freshly collected samples, see note).

4.12. Blood diverted for sample tube filling MUST NOT be contaminated with anticoagulant (from the primary collection pack) during the entire shelf life of the pack.

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[1] *Nightingale MJ, Beard M, Bennet J, Hambleton R, Ramskill S, Thomas S. The donor line break cannula - effect on the donation process, blood component quality and transfusion microbiology testing of an important new blood bag safety feature. Transfusion Medicine, 2013, 23, 210-225.*

4.13. The sample site coupler MUST be fitted with a safety cap in situ to be removed prior to sample collection and which SHOULD be capable of being refitted following sample collection.

**5. Rate of collection**

5.1. Blood collection systems MUST be compliant with the normative reference ISO 3826-1.

**6. Collection and transfer tubes**

6.1. Blood collection systems MUST be compliant with the normative reference ISO 3826-1.

6.2. Collection and transfer tube internal/ external diameters and wall thickness MUST allow Authority personnel to make sterile connections using current commercially available equipment (see note[2]).

*The Supplier MUST provide information which accurately states the internal/ external tube diameter and wall thickness of all transfer tubes; this to enable the Authority to assess compatibility with sterile connection devices currently in use.*

6.3. Tubes designated for red cell compatibility testing MUST have a minimum length of 600 mm and have a unique number repeated at 40 mm intervals (tolerance +/- 5 mm) along the entire length (see note[3]).

**7. Blood taking needle**

7.1. Blood collection systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

7.2. The needle MUST have a visible or tactile means of indicating the position of the needle bevel.

7.3. The needle MUST NOT be fitted with a stylet (an opening/ hole in the back of the needle).

7.4. 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.

7.5. The design of the needle and the needle guard assembly MUST NOT significantly interfere with the venepuncture process (e.g. through the needle guard pulling on the donor line whilst inserting the needle or preventing the correct 'lie' of the needle in the donor's vein (see 7.6)).

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

7.7. In operation, the needle assembly MUST be capable of lying flat against the donors arm without affecting the 'lie' of the needle in the vein.

7.8. The design of the needle and guard MUST be capable of being withdrawn from the venepuncture site smoothly, in a single step, in the same 'plane', directly into the needle guard.

7.9. The engagement of the needle guard MUST require minimal force and MUST be signalled to Authority personnel by an audible click or tactile indication.

7.10. The design of the needle assembly MUST prevent bending of the needle during removal of the sheath.

**8. Outlet ports**

8.1. Blood collection systems MUST be compliant with the normative reference ISO 3826-1.

8.2. Outlet ports MUST have a sleeve length of no less than 29 mm.

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[2] *Sterile connection devices currently available from (but may in future not be limited to) Genesis, FreseniusKabi, Haemonetics, Macopharma and TerumoBCT.*

[3] *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*

8.3. 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.

8.4. Outlet ports MUST be compatible with a range of current commercially available CE marked, ISO 1135-4 conforming transfusion set closure piercing devices (spikes), this to ensure that excessive force is not required to insert the spike (see note [4]).

8.5. If the container is provided with a transfer tube to a transfer pack, the transfer port MUST incorporate 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 and MUST NOT lead to increased residual haemolysis of red cell components.

8.6. For manually opened break cannula, it MUST be possible for Authority personnel to open the device with no more than two movements, as detailed and in accordance with the IFU.

*Suppliers MUST provide details of any automated equipment for which the cannula has been designed or is known to be compatible in order to allow 'hands free' opening.*

**9. Suspension (of bag)**

9.1. Blood collection systems MUST be compliant with the normative reference ISO 3826-1.

**10. Integral leucodepletion filters general requirements**

10.1. Blood collection systems MUST be compliant with the normative reference ISO 3826-3.

10.2. When used in accordance with Supplier'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.

10.3. 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; particularly with regard to final Hb content of red cell components.

10.4. The filter batch number MUST be visible on each filter housing.

**11. Integral leucodepletion filters for red cells and whole blood**

11.1. Filters for the leucodepletion of whole blood MUST perform optimally for whole blood with core temperatures in the range 4°C to 30°C (see note[5]).

11.2. Filters for the leucodepletion of red cells MUST perform optimally for components with a core temperature in the range 4°C to 24°C.

11.3. Filtration of whole blood and red cells MUST be completed for >99% of donations within 120 minutes from the time at which the fluid path is open.

**12. Plasma leucocyte depletion filters and plasma bags**

12.1. Filters for the Leucodepletion of plasma products MUST be usable for components with a core temperature in the range 18°C to 24°C.

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 hour) of plasma to -80ºC (see note[6]) and subsequent storage for a period of three years at below -25ºC.

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

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[4] *No more than 35N should be required to insert the spike.*

[5] *Filtration is generally carried out at air temperatures in the range 4ºC to 24ºC. with a 'hold time' that varies from 0 to 26 hours post collection.*

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

13.1. Blood collection systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

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

14.1. Blood collection systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

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

15.1. Blood collection systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

**16. Over-wrap packaging**

16.1. Blood collection systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

16.2. Over-wrap packaging MUST prevent inadvertent damage to the Blood collection system (e.g. bending the donor needle) during its opening by Authority personnel.

**17. Supplier Labels**

17.1. Blood collection systems MUST be compliant with the normative references ISO 3826-1, ISO 3826-2 and ISO 3826-3.

17.2. Base labels MUST conform to the requirements detailed in Appendix 1.

17.3. Base labels MUST NOT be surface damp or otherwise contaminated in such a way that the adhesion of Authority over-stick labels is impaired.

17.4. Base labels MUST be Tamper Evident.

**18. Anticoagulant and Additive Solutions**

18.1. Blood collection systems MUST be compliant with the normative reference ISO 3826-1 and European Pharmacopoeia.

18.2. Anticoagulants MUST be CPD based and approved for a minimum of twenty-eight (28) day storage of red cells in the range 2ºC to 6 ºC.

18.3. Blood collection systems containing an optimal additive solution MUST be approved for red cell storage for a minimum period of forty-two (42) days in the range 2 ºC to 6 ºC.

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**Requirements that could potentially be incorporated into this specification:**

19. **Radio Frequency IDentification (RFID) tags (see note [7])**

19.1. As part of the consultation process Suppliers should outline any plans to apply RFID tags to their blood collection systems and/ or packaging and confirm the standards to which they will conform.

20. **Plasticizers**

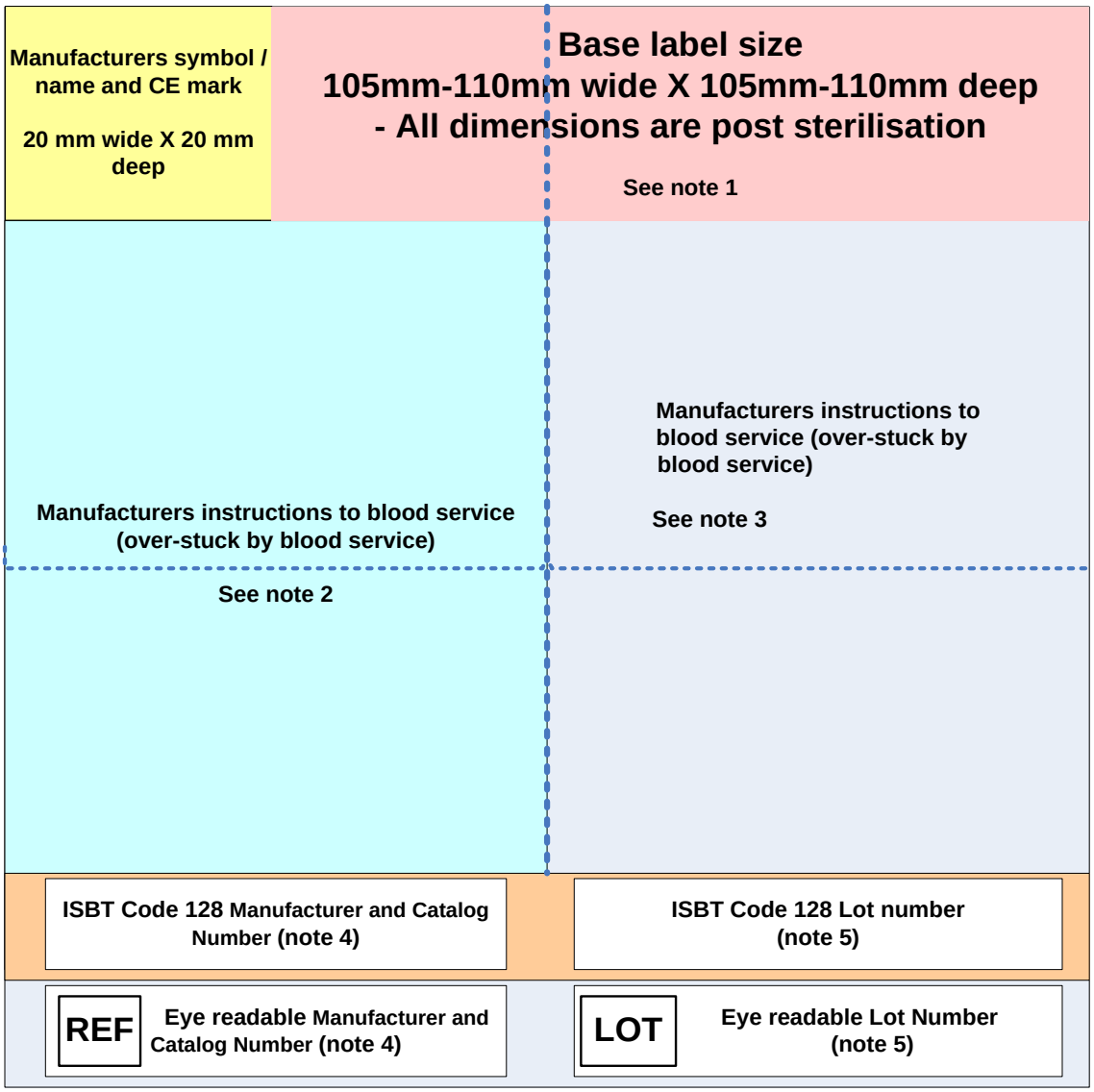
20.1. As part of the consultation process Suppliers should outline any plans they have for use of materials that are free from Di-2-ethylhexlylphtalate (DEHP).

21. **Additive solutions**

21.1. As part of the consultation process Suppliers should outline any plans they have for use of alternatives to current additive solutions.

[7] *Knels Ralf et al. Guidelines for the Use of RFID Technology in Transfusion Medicine.* *http://www.isbtweb.org/fileadmin/user_upload/Wp_on_IT/Guidelines_for_the_Use_of_RFID_technology_April_2010_.pdf*

## Appendix 1 - Base label




Schematic diagram not to scale

**Note 1**

- Symbols or text MUST NOT 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, ISO 3826-2 and EN ISO 15223-1)
    - 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).
    - Latex content (latex free or containing latex).

- The base label MUST have two datum lines as shown (------) splitting the label into four equal area quadrants (to assist Authority personnel 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)
    - Maximum collection volume.
    - The anticoagulant or optimal additive solution name (in British 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 platelets). 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).

**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).