Specification for Ancillary Blood Processing Systems

Compatible with primary components manufactured from whole blood collection systems that meet the requirements of the Eurobloodpack specification

Version Control

Revision	Date	Status	Comment
1.0	26/03/15	DRAFT	Published for consultation purposes.

Purpose

This document details the technical, design and performance requirements related to Ancillary blood processing systems.
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.
"Ancillary blood processing system"	Individual assemblies which are suitable for use in the preparation of blood components as a result of secondary manufacturing techniques. Such assemblies are used in conjunction with components that have been produced as a result of initial separation from the primary whole blood collection system, and where the primary whole blood collection system has met the requirements of the 'Eurobloodpack' specification. This also includes associated filters, ports, transfer tubes and transfer packs.
"Framework Agreement":	means the framework agreement entitled "*Whole 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. an Ancillary blood processing 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 13 and their accompanying tables of dimensions and their associated table of design characteristics illustrate the requirements for ancillary blood processing systems, namely:

- Figure 1 - Quadruple transfer system for the storage of platelets for neonatal use.
- Figure 2 - Quadruple transfer system for the storage of frozen plasma for neonatal use.
- Figure 3 - Quadruple transfer system for the storage of red cells for neonatal use.
- Figure 4 - Sextuplet transfer system for the storage of red cells for neonatal use.
- Figure 5 - Single transfer pack for the handling of waste material or storage of plasma components.
- Figure 6 - Cryoprecipitate pooling system.
- Figure 7 - Single plasma filter system.
- Figure 8 - Double plasma filter system.
- Figure 9 - Platelet storage system with inline filter.
- Figure 10 - Platelet storage system with inline filter and integral sampling device.
- Figure 11 - Platelet storage system.
- Figure 12 - Platelet pooling filter system.
- Figure 13 - Platelet pooling filter system with integral sampling device.

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

A schematic of each final storage pack (for figures 1 to 13) is provided overleaf. Note this schematic is not to scale.

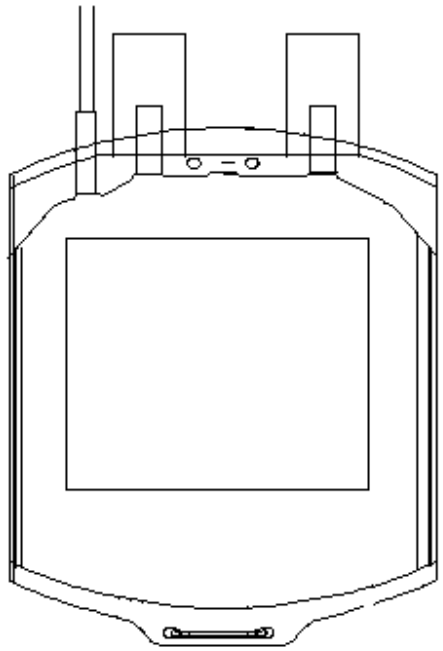

Figure 1 - Quadruple transfer system for the storage of platelets for neonatal use

This Ancillary blood processing system MUST be suitable for use in the production/ preparation and storage of four equal sub-aliquots of platelet components from the corresponding leucodepleted start material, that are suitable for neonatal use.

Design characteristics

Pack volume	Suitable to maintain platelets in sufficient suspending media, in order to meet the requirements for platelet content during storage and pH at end of shelf life, as defined in the current versions of associated guidelines (e.g. BSQR, Guidelines for the Blood Transfusion Services in the United Kingdom).
Spike entry ports	Two per pack
Side slits (eyelets)	Not Applicable
Tubing	From entry point to y-connector(s) and from y-connectors to transfer packs this MUST be a minimum 300mm to permit sterile connection to other compatible pack tubing.
Clamps on tubing	SHOULD have re-openable clamps on the tubing leading into each pack.
Suspension holes (eyelets)	Two per pack (MUST be compatible with extractors on the market)
Suspension slit (eyelet)	Yes, on each pack
Base label	Yes, on each pack
Base label format	See Appendix 1
Base label text	• Suppliers name and address • Supplier Blood pack reference and batch number ▪ Symbology for all other details
Pack materials	▪ Free from Di-2-ethylhexlylphtalate (DEHP)

Figure 2 - Quadruple transfer system for the storage of frozen plasma for neonatal use

This Ancillary blood processing system MUST be suitable for use in the production/ preparation and storage of four equal sub-aliquots of frozen plasma components from the corresponding leucodepleted start material, that are suitable for neonatal use.

Design characteristics

Minimum pack volume	400 ml
Spike entry ports	Two per pack
Side slits (eyelets)	Not Applicable
Tubing	From entry point to y-connector(s) and from y-connectors to transfer packs this MUST be a minimum 300mm to permit sterile connection to other compatible pack tubing.
Clamps on tubing	SHOULD have re-openable clamps on the tubing leading into each pack.
Suspension holes (eyelets)	Two per pack (MUST be compatible with extractors on the market)
Suspension slit (eyelet)	Yes, on each pack
Base label	Yes, on each pack
Base label format	See Appendix 1
Base label text	• Suppliers name and address • Supplier Blood pack reference and batch number ▪ Symbology for all other details

Figure 3 - Quadruple transfer system for the storage of red cells for neonatal use

This Ancillary blood processing system MUST be suitable for use in the production/ preparation and storage of four equal sub-aliquots of red cell components from the corresponding leucodepleted start material, that are suitable for neonatal use.

Design characteristics

Minimum pack volume	400 ml
Spike entry ports	Two per pack
Side slits (eyelets)	Not Applicable
Tubing	From entry point to y-connector(s) and from y-connectors to transfer packs, this MUST be a minimum 300mm to permit sterile connection to other compatible pack tubing.
Clamps on tubing	SHOULD have re-openable clamps on the tubing leading into each pack.
Suspension holes (eyelets)	Two per pack (MUST be compatible with extractors on the market)
Suspension slit (eyelet)	Yes, on each pack
Base label	Yes, on each pack
Base label format	See Appendix 1
Base label text	• Suppliers name and address • Supplier Blood pack reference and batch number

	▪ Symbology for all other details

Figure 4 - Sextuplet transfer system for the storage of red cells for neonatal use

This Ancillary blood processing system MUST be suitable for use in the production/ preparation and storage of six equal sub-aliquots of red cell components from the corresponding leucodepleted start material, that are suitable for neonatal use.

Design characteristics

Minimum pack volume	400 ml
Spike entry ports	Two per pack
Side slits (eyelets)	Not Applicable
Tubing	From entry point to y-connector(s) and from y-connectors to transfer packs this MUST be a minimum 300mm to permit sterile connection to other compatible pack tubing.
Clamps on tubing	SHOULD have re-openable clamps on the tubing leading into each pack.
Suspension holes (eyelets)	Two per pack (MUST be compatible with extractors on the market)
Suspension slit (eyelet)	Yes, on each pack
Base label	Yes, on each pack
Base label format	See Appendix 1
Base label text	• Suppliers name and address • Supplier Blood pack reference and batch number ▪ Symbology for all other details

Figure 5 - Single transfer pack for the handling of waste material or storage of plasma components

This Ancillary blood processing system MUST be suitable for use during secondary manufacturing processes. Examples of such application include, but are not limited to:

- Storage and removal of waste material during secondary manufacturing/ resuspension/ washing procedures.
- Secondary manufacture and storage of plasma components.

Design characteristics

Minimum pack volume	400 ml
Spike entry ports	Two
Side slits (eyelets)	Not Applicable
Tubing	MUST be a minimum 400mm to permit handling and sterile connection to other compatible pack tubing.
Clamps on tubing	SHOULD have re-openable clamps on the tubing leading into the pack.
Suspension holes (eyelets)	Two (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

	• Supplier Blood pack reference and batch number ▪ Symbology for all other details

Figure 6 - Cryoprecipitate pooling system

This Ancillary blood processing system MUST be suitable for use in the production/ preparation and storage of pooled cryoprecipitate from starting materials of at least six leucodepleted single cryoprecipitate.

Design characteristics

Minimum pack volume	400 ml
Spike entry ports	Two
Side slits (eyelets)	Not Applicable
Tubing	MUST be a minimum 200mm on each lead (on all six leads) to permit sterile connection to other compatible pack tubing.
Clamps on tubing	Not Applicable
Suspension holes (eyelets)	Two (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 • Supplier Blood pack reference and batch number ▪ Symbology for all other details

Figure 7- Single plasma filter system

This Ancillary blood processing system MUST be suitable for use in the production/ preparation and storage of a single leucodepleted plasma component from non-leucodepleted start material.

Design characteristics

Minimum pack volume	400 ml
Spike entry ports	Two
Side slits (eyelets)	Not Applicable
Tubing (pre-filter)	Dependent upon the Supplier's instructions for use, but SHOULD be a minimum 200mm to permit sterile connection to other compatible pack tubing.
Tubing (post-filter)	MUST be a minimum 300mm to permit sterile connection to other compatible pack tubing.
Clamps on tubing	Not Applicable
Suspension holes (eyelets)	Two (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 • Supplier Blood pack reference and batch number

	▪ Symbology for all other details

Figure 8- Double plasma filter system

This Ancillary blood processing system MUST be suitable for use in the production/ preparation of a leucodepleted plasma component from non-leucodepleted start material, and facilitate the further production/ preparation and storage of derived components, for example cryoprecipitate and cryoprecipitate-poor plasma.

Design characteristics

Minimum pack volume	400 ml
Spike entry ports	Two per pack
Side slits (eyelets)	Not Applicable
Tubing (pre-filter)	Dependent upon the Supplier's instructions for use, but SHOULD be a minimum 200mm to permit sterile connection to other compatible pack tubing.
Tubing (post-filter)	MUST be a minimum 300mm to permit sterile connection to other compatible pack tubing.
Clamps on tubing	Not Applicable
Suspension holes (eyelets)	Two per pack (MUST be compatible with extractors on the market)
Suspension slit (eyelet)	Yes, on each pack
Base label	Yes, on each pack
Base label format	See Appendix 1
Base label text	• Suppliers name and address • Supplier Blood pack reference and batch number ▪ Symbology for all other details

Figure 9 - Platelet storage system with in-line filter

This Ancillary blood processing system MUST:

a. contain an integral leucocyte depletion filter.
b. be suitable for use in the production/ preparation and storage of a pooled leucodepleted platelet component in plasma or an additive solution mixture, from starting material of non-leucodepleted pooled platelet component in plasma or additive solution.
c. contain a sampling pouch with a minimum 20ml capacity and maximum 40ml capacity (with a datum line at 30ml), which permits the removal of air and the collection of samples of the final component without the requirement for attachment of further tubing, and which MUST be detachable from the pack by means of heat sealing.

Design characteristics

Pack volume	Suitable to maintain platelets in sufficient suspending media, in order to meet the requirements for platelet content during storage and pH at end of shelf life, as defined in the current versions of associated guidelines (e.g. BSQR, Guidelines for the Blood Transfusion Services in the United Kingdom).
Spike entry ports	Two
Side slits (eyelets)	Not Applicable
Tubing (pre-filter)	Dependant upon the Supplier's instructions for use, but SHOULD be a minimum 320mm to permit handling and sterile connection to other compatible pack tubing.

Tubing (post-final y-connector, to final storage pack)	MUST be a minimum 350mm to permit sterile connection of final storage pack to other compatible pack tubing, in support of a number of additional activities.
Clamps on tubing	Yes, on air/sample pouch to permit controlled sampling.
Suspension holes (eyelets)	Two (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 • Supplier Blood pack reference and batch number ▪ Symbology for all other details
Pack materials	▪ Free from DEHP

Figure 10 - Platelet storage system with in-line filter and integral sampling device

This Ancillary blood processing system MUST:

a. contain an integral leucocyte depletion filter.
b. be suitable for use in the production/ preparation and storage of a pooled leucodepleted platelet component in plasma or an additive solution mixture, from starting material of non-leucodepleted pooled platelet component in plasma or additive solution.
c. contain a sampling pouch with a minimum 20ml capacity and maximum 40ml capacity (with a datum line at 30ml), which permits the removal of air and the collection of samples of the final component without the requirement for attachment of further tubing, and which MUST be detachable from the pack by means of heat sealing.
d. This system MUST also contain an integral sampling assembly comprising a needle which permits the aseptic collection of a sample directly into another vessel (e.g. sample bottle or culture bottle).

Schematic of the sampling device attached to the final storage pack is provided below:

Schematic to be confirmed

Design characteristics

Pack volume	Suitable to maintain platelets in sufficient suspending media, in order to meet the requirements for platelet content during storage and pH at end of shelf life, as defined in the current versions of associated guidelines (e.g. BSQR, Guidelines for the Blood Transfusion Services in the United Kingdom)
Spike entry ports	Two
Side slits (eyelets)	Not Applicable
Tubing (pre-filter)	Dependant upon the Supplier's instructions for use, but SHOULD be a minimum 320mm to permit handling and sterile connection to other compatible pack tubing.
Tubing (post final y-connector, to final storage bag)	MUST be a minimum 350mm to permit sterile connection of final storage pack to other compatible pack tubing, in support of a number of additional activities.
Clamps on tubing	Yes, on air/sample pouch to permit controlled sampling.
Suspension holes (eyelets)	Two (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 • Supplier Blood pack reference and batch number ▪ Symbology for all other details
Pack materials	▪ Free from DEHP

Figure 11 – Platelet storage System

This Ancillary blood processing system MUST be suitable for use in the production/ preparation and storage of an adult therapeutic dose of platelets in plasma or an additive solution mixture.

Design characteristics

Minimum pack volume	1300ml
Spike entry ports	Two
Side slits (eyelets)	Not Applicable
Tubing	MUST be a minimum 250mm to permit sterile connection of final storage pack to other compatible pack tubing, in support of a number of additional activities.
Clamps on tubing	If an additional sample pouch is present, a clamp MUST be added in order to permit controlled sampling.
Suspension holes (eyelets)	Two (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 • Supplier Blood pack reference and batch number ▪ Symbology for all other details
Pack materials	▪ Free from DEHP

Figure 12 - Platelet pooling filter system

This Ancillary blood processing system MUST:
a. contain an integral leucocyte depletion filter.
b. be suitable for use in the production/ preparation and storage of a pooled leucodepleted platelet component in plasma or an additive solution mixture, from starting material of non-leucodepleted buffy coats and plasma or additive solution.

This system MUST comprise the following in order of arrangement:
a. Tubing leads that permit the attachment of six buffy coats in plasma or additive solution, which then feed into a single pooling pack which is suitable for centrifugation.
b. A break cannula that leads from the pooling pack to the leucodepletion filter.
c. A y-connector beyond the leucodepletion filter that provides the capability to divert material to:
    i. a sampling pouch; and
    ii. the final storage pack

d. A sampling pouch with a minimum 20ml capacity and maximum 40ml capacity (with a datum line at 30ml), which permits the removal of air and the collection of samples of the final component without the requirement for attachment of further tubing, and which MUST be detachable from the pack system by means of heat sealing.
e. A final storage pack.

Design characteristics

Pack volume	Suitable to maintain platelets in sufficient suspending media, in order to meet the requirements for platelet content during storage and pH at end of shelf life, as defined in the current versions of associated guidelines (e.g. BSQR, Guidelines for the Blood Transfusion Services in the United Kingdom)
Spike entry ports	Two
Side slits (eyelets)	Not Applicable
Tubing (pre-filter)	Dependant upon the Supplier's instructions for use, but SHOULD have a minimum 400mm to permit handling and sterile connection to other compatible pack tubing.
Tubing (post-filter and final y-connector, to final storage pack.)	MUST be a minimum 400mm to permit sterile connection of final storage pack to other compatible pack tubing, in support of a number of additional activities.
Tubing (post-filter and final y-connector, to sampling device)	MUST be a minimum 300ml to permit operational use.
Clamps on tubing	Yes, on air/sample pouch to permit controlled sampling.
Suspension holes (eyelets)	Two (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 • Supplier Blood pack reference and batch number ▪ Symbology for all other details
Pack materials	▪ Free from DEHP

Figure 13 - Platelet pooling filter system with integral sampling device

This Ancillary blood processing system MUST:
a. contain an integral leucocyte depletion filter.
b. be suitable for use in the production/ preparation and storage of a pooled leucodepleted platelet component in plasma or an additive solution mixture, from starting material of non-leucodepleted buffy coats and plasma or additive solution.
c. include an integral sampling assembly comprising a needle which permits the aseptic collection of a sample directly into another vessel (e.g. sample bottle or culture bottle).

This system MUST comprise the following in order of arrangement:
a. Tubing leads that permit the attachment of six buffy coats in plasma or additive solution, which then feed into a single pooling pack which is suitable for centrifugation.
b. A break cannula that leads from the pooling pack to the leucodepletion filter.
c. A y-connector beyond the leucodepletion filter that provides the capability to divert material to:
    i. a sampling pouch and
    ii. the final storage pack

d. A sampling pouch with a minimum 20ml capacity and maximum 40ml capacity (with a datum line at 30ml), which permits the removal of air and the collection of samples of the final component without the requirement for attachment of further tubing, and which MUST be detachable from the pack by means of heat sealing.
e. A final storage pack.

Schematic of the sampling device attached to the final storage pack is provided below:

Schematic to be confirmed

Design characteristics

Pack volume	Suitable to maintain platelets in sufficient suspending media, in order to meet the requirements for platelet content during storage and pH at end of shelf life, as defined in the current versions of associated guidelines (e.g. BSQR, Guidelines for the Blood Transfusion Services in the United Kingdom).
Spike entry ports	Two
Side slits (eyelets)	Not Applicable
Tubing (pre-filter)	Dependant upon the Supplier's instructions for use, but SHOULD have a minimum 400mm to permit handling and sterile connection to other compatible pack tubing.
Tubing (post-filter and final y-connector, to final storage pack.)	MUST be a minimum 350mm to permit sterile connection of final storage pack to other compatible pack tubing, in support of a number of additional activities.
Tubing (post-filter and final y-connector, to sampling device)	MUST be a minimum 300ml to permit operational use.
Clamps on tubing	Yes, on air/sample pouch to permit controlled sampling.
Suspension holes (eyelets)	Two (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 • Supplier Blood pack reference and batch number ▪ Symbology for all other details
Pack materials	▪ Free from DEHP

Design requirements

1. General

1.1. Ancillary blood processing 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.

1.2. Ancillary blood processing systems MUST be suitable for attachment to the start material by the use of approved sterile connection procedure.

1.3. Ancillary blood processing systems will be used in conjunction with components that have been produced as a result of initial separation from the primary collection pack, and where the Whole blood collection system has met the requirements of the normative references.

1.4. In addition to physical compatibility with the tubing of Whole blood collection systems that meet the normative references, there MUST be the required specified tubing length on Ancillary blood processing systems in order to permit attachment to other tubing via sterile connection techniques.

1.5. Where used for production and/ or storage of manufactured components, the quality of the Ancillary blood processing system MUST ensure that the integrity and fitness for use of the component(s) are maintained throughout their corresponding shelf life as follows;

- Frozen components, the components will be fit for use for at least three (3) years from the date of collection.
- Platelet components, the components will be fit for use for at least seven (7) days from the date of collection.
- Red cell components in CPD, the components will be fit for use for at least twenty-eight (28) days from the date of collection.
- Red cell components in optimal additive solution, the components will be fit for use for at least forty-two (42) days from the date of collection.

2. Air content

2.1. Ancillary blood processing systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

3. Emptying under pressure

3.1. Ancillary blood processing systems MUST be compliant with the normative reference ISO 3826-1.

4. Pilot samples

4.1. Ancillary blood processing systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

4.2. Where applicable the sampling system MUST incorporate a sample diversion pouch and sample site coupler for the aseptic collection of blood samples during the manufacturing process. These items shall be an integral part of the Ancillary blood processing system, obviating the need for Authority personnel to assemble components prior to use.

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

4.4. The sampling system MUST allow the collection of samples direct from the component.

4.5. The design MUST incorporate a re-openable clamp on the line from the sample pouch in order to allow controlled filling of sample devices

4.6. Clamps described in 4.5 MUST be colour coded blue for re-openable.

5. Transfer tubes

5.1. Ancillary blood processing systems MUST be compliant with the normative reference ISO 3826-1.

5.2. Transfer tube internal and external diameters and wall thickness MUST allow Authority personnel to make sterile connections using current commercially available equipment (see note1).

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. Outlet ports

6.1. Ancillary blood processing systems MUST be compliant with the normative reference ISO 3826-1.

6.2. Outlet ports MUST have a sleeve length of not less than 29 mm.

6.3. 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.

6.4. 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 note2).

7. Suspension (of bag)

7.1. Ancillary blood processing systems MUST be compliant with the normative reference ISO 3826-1.

8. Integral leucodepletion filters general

8.1. Ancillary blood processing systems MUST be compliant with the normative reference ISO 3826-3.

8.2. When used in accordance with the 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.

8.3. 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.

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

9. Plasma leucocyte depletion filters and plasma bags

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

9.2. 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 3) and subsequent storage for a period of three years at below -25ºC,

9.3. The plasma filter MUST also comply with the requirements in Figures 7 and 8 above.

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[1] Sterile connection devices currently available from (but may in future not be limited to) instruments currently available from Genesis, Fresenius Kabi, Haemonetics, Macopharma and TerumoBCT.

[2] No more than 35N SHOULD be required to insert the spike.

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

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

10.1. Ancillary blood processing systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

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

11.1. Ancillary blood processing systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

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

12.1. Ancillary blood processing systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3.

13. Over-wrap packaging

13.1. Ancillary blood processing systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3

13.2. Over-wrap packaging MUST prevent inadvertent damage to the Ancillary blood processing system (e.g. bending the sample needle) during its opening by Authority personnel.

14. **Supplier Labels**

14.1. Ancillary blood processing systems MUST be compliant with the normative references ISO 3826-1 and ISO 3826-3

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

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

14.4. Base labels MUST be Tamper Evident.

Requirements that could potentially be incorporated into this specification:

15. Radio Frequency IDentification (RFID) tags (see note 4)

15.1. 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.

16. Plasticizers

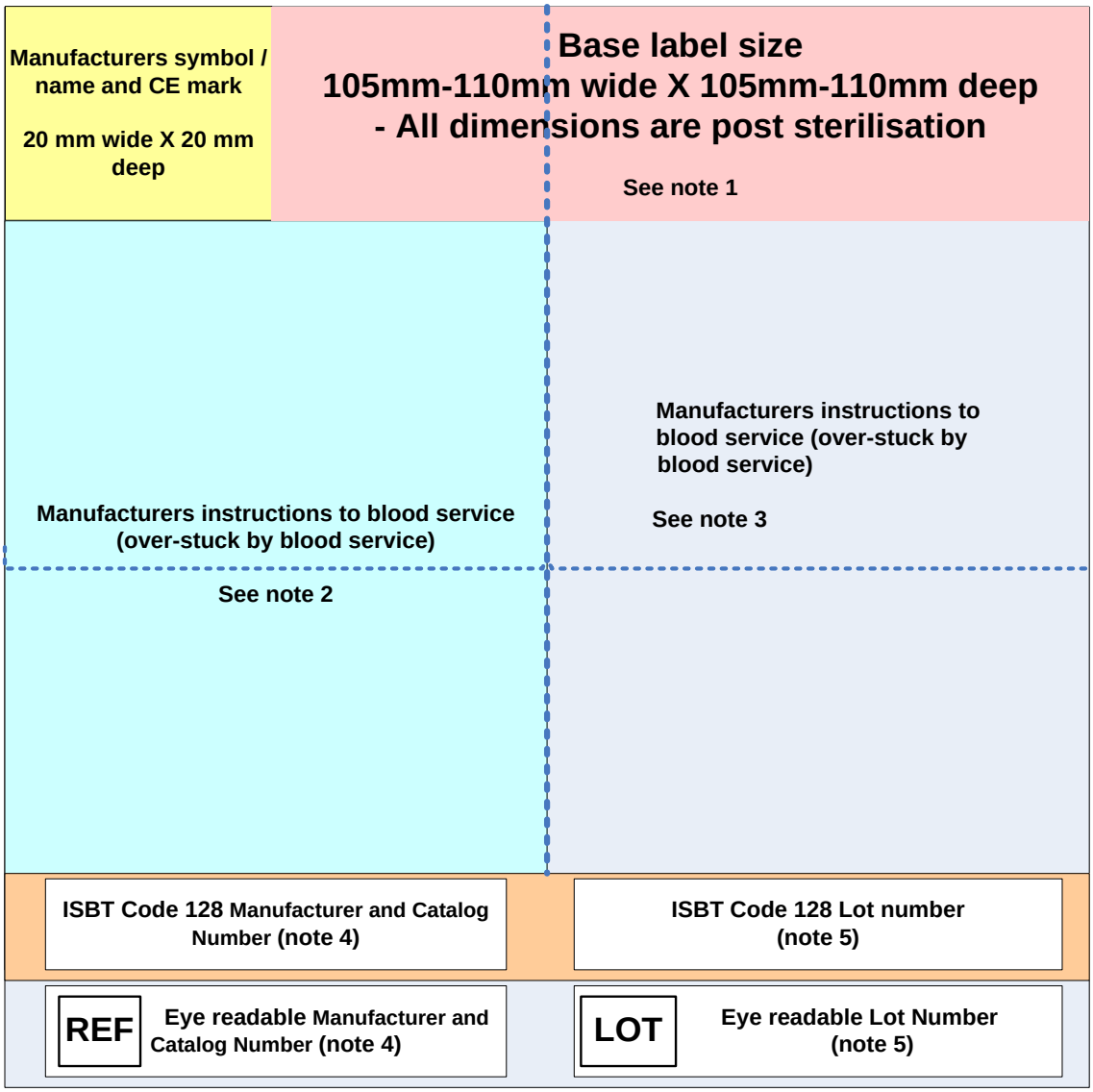
16.1. As part of the consultation process Suppliers should outline any plans they have for use of materials that are free from Di-2-ethylhexlylphtalate (DEHP).

17. Additive solutions

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

[4] *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.
    - 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 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 Catalog 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).