Item Name: Design Specifications for Whole Blood Collection Systems Including Leucodepletion Filters (from European blood alliance)

I- Specifications:

The basic standards for conformance are the ISO Standards and European Directives.
Manufacturers will be required to provide with a minimum documentation set that comprises a detailed specification of the product offered and recommended instructions for use
This Technical Specification must be retained by Suppliers as a controlled document to ensure that any proposed changes to their product can be identified and notified to the Customer in advance of making the change.

Closed system for the collection and pre-storage leukoreduction of one unit of whole blood and the subsequent storage of the red blood cell and plasma components. It should be a high Efficiency Filter that reduces the levels of leukocytes and microaggregates from a single unit of whole blood.

1. General Requirements:

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 Council of Europe guide to the preparation, use and quality assurance of blood components.

1.1. 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.

1.2. Filtration capacity: one unit of whole blood.

1.3. Filtration efficiency: White cell residuals consistently averaging less than 1x106

2. DESIGN

2.1. Needle and needle guard

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..
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.

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

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

2.1.3. 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

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

2.1.5. 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.

2.1.6. 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.

2.1.7. 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 signaled to the operator by an audible click or tactile indication.

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

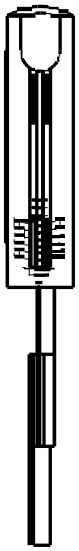

Fig 1: Needle and needleguard

2.2. Sample Coupler and Diversion Pouch

2.2.1. 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.

2.2.2. 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.

2.2.3. The design must incorporate an appropriately positioned integral break cannula.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.

2.2.4. 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.

2.2.5. Closure devices on the lines to the sample pouch and to the primary collection pack should be color coded.

2.2.6. Sample site couplers must be compatible with the dimensions of vacuum sample tubes

2.2.7. 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.

2.2.8. 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 .

2.2.9. 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.

Nominal fill volume of diversion pouch	Must have a nominal fill capacity of 35 ml with a maximum fill volume of 40ml.
Protective cap on sample coupler	Must be present and fitted in place by manufacturer
Opacity of sample coupler	Transparent
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 3 samples, without leakage, when used with standard evacuated blood collection tubes.

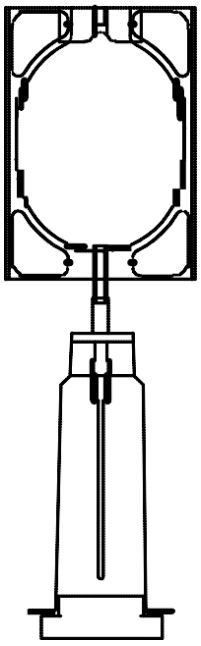

Fig 2: Sample coupler and diversion pouch

2.3. Primary collection pack

Nominal pack volume	600 ml
Anticoagulant	CPD based (63 ml)
Target collection volume (range)	450 ml (405 - 495 ml)
Base label text	□□Manufacturers name and address □□Blood bag reference and batch number

2.4. Red cell storage pack

Nominal pack volume	500-600 ml
Spike entry ports	Two
Base label text	□□Manufacturers name and address □□Blood bag reference and batch number □□

2.5. Optimal Additive Pack

Nominal pack volume	500-600 ml
SAG-M / OAS volume	100-105 ml
Spike entry ports	Variable
Base label required	Yes
Base label text	□□Manufacturers name and address □□Blood bag reference and batch number □□

2.6. Plasma Storage Pack

Nominal pack volume	600 ml
Spike entry ports	Two
Base label required	Yes
Base label text	□□Manufacturers name and address □□Blood bag reference and batch number

2.7. Collection and transfer tubes

2.7.1. Collection and transfer tube internal and external diameters and wall thickness must enable to make sterile connections.

2.7.2. To enable blood banks 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.

2.7.3. 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

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.

3. LABELLING(including general label on plastic container)

3.1. 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.

3.2. Boxes shall carry Lot / Batch number in eye readable and internationally accepted barcode format. Note. ISBT 128 is acceptable.

3.3. The following information must be included in this section using symbols taken from recognized 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)

4. ANTICOAGULANT AND ADDITIVE SOLUTIONS

4.1. Anticoagulants will be CPD based and must be approved for a minimum of 21 day storage of red cells at 2 – 6 ^{o}C.

4.2. 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°C

5. INSTRUCTIONS FOR USE

5.1. 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.

5.2. 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

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

5.4. The expiration dates, delivery conditions, duration of the contract, minimum and maximum quantities to be purchased should be included in the contract between hospital and suppliers

NB: The supplier commits to put all efforts towards reducing or stopping the use of di-ethylhexyl phthalate (DEHP).

II- Training:

III- Documents to be delivered:

IV- Accessories required:

V – Transport, installation, and setup

Prepared by:…… **Approved by:……**