Guidelines for the Blood Transfusion Services

4.7: Equipment and consumables

http://aws-lon-jpac.targetservers.uk/red-book/chapter-4-premises-and-quality-assurance-at-blood-donor-sessions/4-7-control-of-purchased-material-and-services

4.7: Equipment and consumables

All equipment used for the collection of blood and components must be validated, calibrated, maintained and cleaned, and records kept. Use must be in accordance with the manufacturer's instructions. Faulty, defective, or damaged equipment or consumables must not be used and must be reported and managed through the blood service's quality system.

4.7.1: Specification and inspection of blood bags

Blood must be collected by aseptic techniques using a sterile closed system and a single venepuncture.

The integrity of the system must be checked prior to use looking for signs of damage or defects and/or contamination. Measures must be taken to prevent non-sterile air entering the system.

The containers must be pyrogen-free and sterile, containing sufficient licensed anticoagulant for the quantity and purpose of blood to be collected.

Manufacturers' directions regarding storage, use and expiry dates of packs must be adhered to.

Batch numbers of the blood packs used must be recorded.

The donation number on the pack and associated sample tubes and donor health questonnaires should be checked at the end of the donation that they are identical.

Prior to release from the blood collection session the pack and its associated tubing should be reinspected for defects and its integrity should be checked by applying pressure to the pack to detect any leaks. Any defective pack should be marked for disposal and held separately from intact packs. Details of the defect(s) should be recorded and reported for future analysis and action (see section 5.11).

4.7.2: Specification of apheresis sets

Blood components must be collected by apheresis using sterile, single-use, disposable items that are licensed and CE/UKCA/UKNI marked. The apheresis set for collection of components for direct clinical use must have a preconnected access needle to ensure a sterile pathway, and incorporate a bacterial filter in all fluids that are not connected. (e.g. citrate anticoagulant).

A record must be kept of all lot and/or batch numbers of all the apheresis set components and injectable /infused materials used, in accordance with local quality systems.

4.7.3: Specifications for automated donor apheresis machines (see also section 8.5)

Machines must be correctly installed and commissioned according to each manufacturer's instructions. They must be CE/UKCA/UKNI marked.

The environment and operating area for each machine employed and the power supply available must conform to the manufacturer's recommendations for satisfactory machine performance.

Machines must comply with the relevant aspects of the *Health and Safety at Work Act 1974*[2] and the Good Automated Manufacturing Practice (GAMP) *Guide for Validation of Automated Systems in Pharmaceutical Manufacture*.[3]

Automated apheresis machines must have the following features:

- A manual override system so that the operator can stop the automatic cycle at any time during the procedure.
- A blood flow monitor, to monitor blood flow during blood withdrawal and return. The purpose is to ensure that the selected donor flow rate does not cause collapse of the donor's vein and to monitor the venous pressure during the donor blood return cycle such that if any obstruction to flow occurs the blood pump will automatically reduce speed and/or stop. In either event a visual and audible alarm system should operate.
- An in-line air detector to protect the donor from air embolism. In the event of air entering the extra-corporeal circuit a visible and audible alarm must be activated, the return blood pump must automatically stop and the venous return line must automatically be occluded.
- A blood filter integral with the harness to prevent any aggregates formed during the procedure from being returned to the donor.
- An anticoagulant flow indicator, providing a visible means of monitoring anticoagulant delivery throughout the procedure, and ideally an audible alarm if no anticoagulant is flowing.
- A device for pre-setting the collection volume, monitoring the collection volume during the procedure and automatically ending the procedure. A system with a visual and audible alarm to notify the operator of the completion of the procedure may be provided.
- In the event of a power failure the machine must automatically enter a standby mode once power returns.

Apheresis machines must be serviced in accordance with the manufacturer's instructions.
A planned maintenance scheme should be followed. Machine maintenance and servicing must be documented and be in accordance with the procedures outlined in the appropriate Medicines and Healthcare products Regulatory Agency publications: DB 9801, DB 9801 Supplement 1 and DB 2000(02).[4]

Apheresis machines must be routinely cleaned with a suitable decontaminating agent on a daily basis. A standard procedure for dealing immediately with blood spillage must be in operation.

4.7.4: Anticoagulant

The anticoagulant must be in date, with no evidence of particles or leakage. Any suspect unit must not be used. The batch number must be recorded and any defect reported in accordance with local quality systems.