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## **SOP: Maintaining a safe environment within the clinical apheresis unit**

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**STANDARD OPERATING PROCEDURE (SOP)**

**TITLE: MAINTAINING A SAFE ENVIRONMENT WITHIN THE  
CLINICAL APHERESIS UNIT**

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**1.0 INDICATIONS OF PRACTICE**

- 1.1 The Clinical Apheresis Unit (CAU) is used by patients, staff and relatives. It is essential that a clean and safe environment is provided for them in accordance with the trust safety policy.
- 1.2 All stock and equipment should be kept under the storage conditions recommended by the manufacturers and product expiry dates regularly checked (see SOP: FRM/AP/STCK (7.1.1.38) "Stock and inventory control in the Collection Facility")
- 1.3 For care and maintenance of the Optia machines refer to Optia operators manual.
- 1.4 The resuscitation trolley will be located in Haematology and Transplant Day Unit. The HTDU manager is responsible for the maintenance and stocking of this trolley.

**2.0 AUTHORISED PERSONNEL AND RESPONSIBILITIES**

- 2.1 All CAU and day unit staff have a responsibility for maintaining a safe and clean environment in the CAU.
- 2.2 A yearly risk assessment is performed by the Day Unit Manager. CAU specific risks will be highlighted for addition to the document by the lead apheresis nurse.
- 2.3 The lead apheresis nurse will review and maintain a record of all collection staff training records. Compliance with trust mandated essential training for each individual will be recorded on the organisational ESR system and available for review by the lead apheresis nurse. Apheresis nurses have a responsibility for ensuring they are compliant with their own required training.
- 2.4 The apheresis nurses will ensure that the apheresis machine is cleaned according to manufacturer's instructions after use and that the clinical area is left in a tidy state, to allow it to be cleaned by domestic staff as per day unit policy.

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**STANDARD OPERATING PROCEDURE (SOP)**

**TITLE: MAINTAINING A SAFE ENVIRONMENT WITHIN THE  
CLINICAL APHERESIS UNIT**

- Green tape should be applied once clean to mark it as such and a machine cleaning log should be maintained, highlighting the need for machine disinfection.
- 2.5 The apheresis nurses will ensure routine daily temperature monitoring and post procedural monitoring of the CAU room. The data logger should be set to record every 10minutes, with an alarm if temperature exceeds 25°C or falls below 15.5°C or if humidity exceeds 80% or falls below 8% (as per the Spectra Optia Apheresis Manual). Data should be downloaded monthly by the data manager and stored on the transplant shared drive for access by all members of staff. The data loggers should be calibrated or replaced every year. The apheresis nurses also complete the apheresis temperature log (APH-31) pre and post procedure, any deviations in temperature are report to the lead apheresis nurse. The apheresis nurses will ensure the air conditioning is in use and that the apheresis room door remains closed.
- 2.6 The apheresis nurses will ensure that stock levels are checked on a weekly basis to identify stock that is close to its expiry date and dispose of out of date stock.
- 2.7 The apheresis nurses will report any mechanical complications to the lead apheresis nurse and the machine manufacturer, and log these on the mechanical complications records held in the maintenance file.
- 2.8 Oxygen, suction and resuscitation equipment will be checked as part of the HTDU environmental monitoring checks.
- 2.9 The apheresis nurses will inform the Haematology Transplant Day Unit (HTDU) staff when any items are removed from the resuscitation trolley in order that they can be urgently replaced.
- 2.10 CAU staff will report any defective equipment to the apheresis lead or Day Unit Manager for urgent risk assessment and repair. If the CAU has not been cleaned adequately it will be reported to the domestic supervisor.
- 2.11 CAU staff must attend all advanced and essential life support and health & safety training provided by the trust. Medical and nursing staff working on the CAU must be aware of the location and operation of resuscitation equipment (located in the HTDU).
- 2.12 ACDA must be stored below 25°C in the clean utility area of the HTDU. Stock will be retained in the HTDU clean utility (temperature controlled and monitored). The apheresis nurses will ensure daily temperature monitoring of the ACDA store area. The data logger should be set to record every 10minutes, with an alarm if temperature exceeds 25°C or humidity exceeds 80% or falls below 20%. Data should be downloaded monthly by the data manager and stored on the transplant shared drive for access by all members of staff.
- Contingency measures should be followed as per SCL/POL/CONPT Contingency plan for the stem cell lab and collection facility SOP, should temperatures rise above those specified

## STANDARD OPERATING PROCEDURE (SOP)

### TITLE: MAINTAINING A SAFE ENVIRONMENT WITHIN THE CLINICAL APHERESIS UNIT

#### 3.0 PROCEDURE – MONITORING TEMPERATURE AND SAFETY EQUIPMENT

##### 3.1 Materials

- Electronic Thermometer.
- Oxygen flowmeter at each walled oxygen point.
- Oxygen tubing – 1 x nasal cannula and 1 x Hudson mask and connecting tubing.
- Suction flowmeter at each walled suction point.
- Suction bottle, tubing and suction catheters.
- Resuscitation Trolley located on the HTDU
- Apheresis Maintenance file

##### 3.2 Procedure

Prior to any procedure apheresis nurses will check the following:

- Oxygen flowmeter is present and working and oxygen tubing available at each walled oxygen point.
- Suction flowmeter is present and working and suction tubing, bottle and catheters connected at each walled suction point.
- Temperature is recorded in the maintenance file log.
- Unit is cleaned by domestic staff according to daily work schedule.
- Visual inspection of machine and environment
- Post procedure - clean machines and apply green tape.

On a weekly basis, the apheresis coordinators will check that there are sufficient stocks and supplies of disposables, ACDA & reagents within the unit and that they are within the manufacturer's recommended expiry dates.

##### 3.3 Terumo temperature and humidity guidance

Terumo define ambient operating temperatures for the Spectra Optia device. The guidance is as follows:

- Spectra Optia device
  - 15.5 °C to 27.7 °C (60 °F to 82 °F) ambient operating temperature
  - 8% to 80% ambient operating humidity
- Safe seal system
  - 15.5 °C to 27.7 °C (60 °F to 82 °F) ambient operating temperature
  - 8% to 80% ambient operating humidity
- Tubing sets
  - Long term storage range: 0 °C to 35 °C (32 °F to 95 °F)
    - Permitted excursions:
      - -29 °C to 0 °C (-20 °F to 32 °F) for up to 72 hours
      - 35 °C to 50 °C (95 °F to 122 °F) for up to 6 weeks
  - 0% to 75% storage humidity

For full details refer to the Optia apheresis system operator manual on Q-Pulse (DOC405).

**STANDARD OPERATING PROCEDURE (SOP)**

**TITLE: MAINTAINING A SAFE ENVIRONMENT WITHIN THE  
CLINICAL APHERESIS UNIT**

**4.0 FURTHER INFORMATION/EXCEPTIONS**

Optia Operator cleaning and maintenance  
SOP: FRM/AP/STCK (7.1.1.38) "Stock and inventory control in the Collection Facility")

**5.0 REFERENCES**

Christie NHS Trust: Health and Safety Policy  
SCT/SCL/SOP/OTSCD: Operation of the Terumo TSCDII  
SOP APH-31: "Apheresis Room Temperature Log"  
FORM APH-39: "Machine Cleaning and Stock Control Log - Apheresis"  
DOC405 Optia apheresis system operator manual