Maintaining a safe environment within the clinical apheresis unit

Lead Organisation: iMATCH

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Author	
Revision	16
Changes from previous Version	• Addition to procedure regarding clearing of machines after procedure and clean tape post procedure • Additional information to oxygen suction • Updated data download frequency for Quality Team and temperature/humidity settings on data loggers.

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1.0 Introduction & Scope

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. This SOP details the steps to achieve this aim.

All stock and equipment should be kept under the storage conditions recommended by the manufacturers and product expiry dates regularly checked (see SOP: APH-152 - Stock and inventory control in the Collection Facility)

For care and maintenance of the Optia machines refer to Optia operators manual. 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 Responsibilities

The Programme Director, Quality Manager, Stem Cell Laboratory Manager and Ward Nursing Leads are responsible for ensuring staff who are required to carry out activities described in this document receive a copy via the Q Pulse document distribution system.

All staff who are required to undertake activities described in this document must read and acknowledge receipt of this document, and where training is required shall not undertake described activities unsupervised until relevant training has been delivered.

All CAU and day unit staff have a responsibility for maintaining a safe and clean environment in the CAU.

3.0 Objectives

The objective of this SOP is to give detail in the maintenance of a safe environment for apheresis in use in the Haematology Programme at The Christie Hospital

4.0 Equipment & Supplies Used in the Procedure

- Electronic Thermometer./ Humidity Monitor

- 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

5.0 Training and Competence

Prior to implementation of any new or revised procedure there shall be a review and if considered appropriate training and competency shall be delivered prior to implementation of the procedure.

6.0 Procedural Statements

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.

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.

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.

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.

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 18°C or if humidity exceeds 75% or falls below 20% (as per the Spectra Optia Apheresis Manual, Terumo and Spectra product recommendations).

A risk assessment has been undertaken and it is considered that the risk of humidity breaching the Optia recommended levels is low as long as the AC unit has been serviced and considered appropriate for use, as such the humidity levels will be assessed weekly when the data logger data is downloaded. If humidity (or temperature) is found to breach the limits a Datix is to be raised and an assessment of the impact upon product quality made.

Data should be downloaded weekly by the quality team and stored on Q-Pulse Quality Management System. The data loggers should be calibrated and revalidated 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.

The logger devices have a visual indicator of limits being breached , below shows all OK while if a breach is noted then the tick will be replaced by an X.

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.

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.

Oxygen, suction and resuscitation equipment will be checked as part of the HTDU environmental monitoring checks. However daily use of oxygen or suction will be replaced after use by the apheresis nurses.

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.

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.

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).

ACDA is stored below 25°C and between 20 – 80% in the agent storage area/treatment room (35-0-72) within the HTDU. Stock will be retained in the agent storage area/treatment room (temperature/humidity controlled and monitored). The apheresis nurses will ensure daily temperature monitoring of the ACDA store area as well as the Apheresis room.

The data logger should be set to record every 10minutes, with an alarm if temperature exceeds 25°C, falls below 18°C or humidity exceeds 75% or falls below 20%. Data should be downloaded weekly by the quality team and stored on Q-Pulse Quality Management System.

	Temperature	**Humidity**	**Permitted Excursions**
ACDA Solution	<25°C	20% - 80%	N/A

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.

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. Machines are cleared as part of the nurses role following procedure
- Visual inspection of machine and environment
- Post procedure - clean machines and apply green clean 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.

Temperature and humidity Limits

Terumo define ambient operating temperatures for the Spectra Optia device as follows.

	Temperature	**Humidity**	**Permitted Excursions**
Spectra Optima	15.5 °C to 27.7 °C	8% to 80%	N/A
Safe Seal system	15.5 °C to 27.7 °C	8% to 80%	N/A
Tubing sets	0 °C to 35 °C	0% to 75%	-29 °C to 0 °C for up to 72 hours 35 °C to 50 °C for up to 6 weeks

7.0 Monitoring Compliance

Compliance to this document will be monitored by a combination of audit where appliable, non-conformance monitoring and Datix incident reporting.

8.0 Dissemination/ Distribution

This document will be distributed to staff members who need visibility of the document via Q Pulse.

9.0 References and Related Forms, Labels, Policies and Procedures

Christie NHS Trust: Health and Safety Policy
SCT/SCL/SOP/OTSCD: Operation of the Terumo TSCDII
APH-31 - Apheresis Room Temperature Log
FORM APH-39 - Machine Cleaning and Stock Control Log - Apheresis
EXT-75 - Optia Apheresis System Operator Manual
APH-161 - Stock and Inventory Control in the Collection Facility
SCL/RISK/PROC - Process Risk Assessment + Environmental Risk Assessment

10.0 Approval Process & Review Process

All new procedures are approved by the Clinical Program Director or approved designate before implementation of the procedure.

Revisions to existing procedures will be approved by the Clinical Director or approved designate prior to implementation.

Procedures will be reviewed every 2 years as a minimum.