

---

# Maintaining a safe environment within the clinical apheresis unit

---

Lead Organisation: iMATCH

Author: The Christie NHS Foundation Trust

Version Number: 16.0

Finalisation Date: 09/24

## End user rights:

This document is shared with permission for re-use to distribute, remix, adapt, and build upon the material in any medium or format for non-commercial purposes only, so long as the attributions listed below are given.

**Attributions:** The Christie NHS Foundation Trust

This document is made available under a Creative Commons Attribution-NonCommercial 4.0 International License as described here: <https://creativecommons.org/licenses/by-nc/4.0/>

The information, materials and any opinions contained in this document are provided for general information and educational purposes only, are not intended to constitute legal, medical or other professional advice and should not be relied on or treated as a substitute for specific advice relevant to particular circumstances. Although we make all reasonable efforts to ensure the information is up to date, we make no representations, warranties or guarantees in that regard. In no event shall the creator(s) be liable for any direct, indirect, special, consequential or other claims, losses or damages that are related to the use or reliance whatsoever in the content of the document or any part thereof, except to the extent that such liability cannot be excluded by law. We do not seek to exclude or limit in any way our liability to the user for personal injury or death caused as a result of our negligence or seek to exclude or limit our liability for fraud or fraudulent misrepresentation by us.

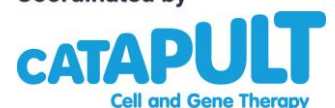
We reserve the right to make changes and improvements to any information contained within this document, at any time and without notice. Where this document contains hyperlinks to other websites operated by parties not connected to us, such hyperlinks are provided for your reference only. We do not control such websites and are not responsible for their contents.

The inclusion of hyperlinks from this document or the website to such websites does not imply any endorsement of the material on such websites or any association with their operators. We accept no responsibility of any nature whatsoever for linked web sites or any information contained in them.

Funded by



Coordinated by





## Maintaining a Safe Environment within the Clinical Apheresis Unit

Author	
Revision	16
Changes from previous Version	<ul style="list-style-type: none"> <li>• Addition to procedure regarding clearing of machines after procedure and clean tape post procedure</li> <li>• Additional information to oxygen suction</li> <li>• Updated data download frequency for Quality Team and temperature/humidity settings on data loggers.</li> </ul>
<b>Table of Contents</b>  <b>1.0 Introduction &amp; Scope.....4</b> <b>2.0 Responsibilities .....4</b> <b>3.0 Objectives.....4</b> <b>4.0 Equipment &amp; Supplies Used in the Procedure .....4</b> <b>5.0 Training and Competence .....5</b> <b>6.0 Procedural Statements .....5</b> <b>7.0 Monitoring Compliance .....9</b> <b>8.0 Dissemination/ Distribution.....9</b>	

**PRINTED COPIES MAY NOT BE THE MOST CURRENT VERSION OF THIS DOCUMENT. ALWAYS REFER TO Q PULSE FOR THE MOST UP TO DATE VERSION**

Document Name: Maintaining a Safe Environment Within the Clinical Apheresis Unit		Version: 16.0
Index Number: APH-154		Author:
Effective Date: September 2024	Review Date: See Q Pulse	Page: 2 of 9



<b>9.0 References and Related Forms, Labels, Policies and Procedures .....</b>	<b>9</b>
<b>10.0 Approval Process &amp; Review Process .....</b>	<b>9</b>

**PRINTED COPIES MAY NOT BE THE MOST CURRENT VERSION OF THIS DOCUMENT. ALWAYS REFER TO Q PULSE FOR THE MOST UP TO DATE VERSION**

Document Name: Maintaining a Safe Environment Within the Clinical Apheresis Unit

Version: 16.0

Index Number: APH-154

Author:

Effective Date: September 2024

Review Date: See Q Pulse

Page: **3** of **9**



## 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

**PRINTED COPIES MAY NOT BE THE MOST CURRENT VERSION OF THIS DOCUMENT. ALWAYS REFER TO Q PULSE FOR THE MOST UP TO DATE VERSION**

Document Name: Maintaining a Safe Environment Within the Clinical Apheresis Unit

Version: 16.0

Index Number: APH-154

Author:

Effective Date: September 2024

Review Date: See Q Pulse

Page: 4 of 9



- 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).

**PRINTED COPIES MAY NOT BE THE MOST CURRENT VERSION OF THIS DOCUMENT. ALWAYS REFER TO Q PULSE FOR THE MOST UP TO DATE VERSION**

Document Name: Maintaining a Safe Environment Within the Clinical Apheresis Unit		Version: 16.0
Index Number: APH-154		Author:
Effective Date: September 2024	Review Date: See Q Pulse	Page: 5 of 9



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.

**PRINTED COPIES MAY NOT BE THE MOST CURRENT VERSION OF THIS DOCUMENT. ALWAYS REFER TO Q PULSE FOR THE MOST UP TO DATE VERSION**

Document Name: Maintaining a Safe Environment Within the Clinical Apheresis Unit	Version: 16.0
Index Number: APH-154	Author:
Effective Date: September 2024	Review Date: See Q Pulse
	Page: 6 of 9



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.

**PRINTED COPIES MAY NOT BE THE MOST CURRENT VERSION OF THIS DOCUMENT. ALWAYS REFER TO Q PULSE FOR THE MOST UP TO DATE VERSION**

Document Name: Maintaining a Safe Environment Within the Clinical Apheresis Unit      Version: 16.0

Index Number: APH-154      Author:

Effective Date: September 2024      Review Date: See Q Pulse      Page: 7 of 9



**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

**PRINTED COPIES MAY NOT BE THE MOST CURRENT VERSION OF THIS DOCUMENT. ALWAYS REFER TO Q PULSE FOR THE MOST UP TO DATE VERSION**

Document Name: Maintaining a Safe Environment Within the Clinical Apheresis Unit	Version: 16.0
--	---------------

Index Number: APH-154	Author:
-----------------------	---------

Effective Date: September 2024	Review Date: See Q Pulse	Page: 8 of 9
--------------------------------	--------------------------	--------------



## 7.0 Monitoring Compliance

Compliance to this document will be monitored by a combination of audit where applicable, 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.

**PRINTED COPIES MAY NOT BE THE MOST CURRENT VERSION OF THIS DOCUMENT.  
ALWAYS REFER TO Q PULSE FOR THE MOST UP TO DATE VERSION**

Document Name: Maintaining a Safe Environment Within the Clinical Apheresis Unit

Version: 16.0

Index Number: APH-154

Author:

Effective Date: September 2024

Review Date: See Q Pulse

Page: 9 of 9