DukeMedicine

Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-EQUIP-001

DOCUMENT TITLE:

Quality Control of Equipment

DOCUMENT NOTES:

Document Information

Revision: 14	**Vault:** ABMT-Equipment-rel
Status: Release	**Document Type:** ABMT

Date Information

Creation Date: 12 Feb 2025	**Release Date:** 31 Mar 2025
Effective Date: 31 Mar 2025	**Expiration Date:**

Control Information

Author: KLQ	**Owner:** MC363
Previous Number: ABMT-EQUIP-001 Rev 13	**Change Number:** APBMT-CCR-261

ABMT-EQUIP-001
QUALITY CONTROL OF EQUIPMENT

1 PURPOSE

1.1 To describe the procedure for performing the manufacturer's recommended routine Quality Control for the equipment used in apheresis and photopheresis.

2 INTRODUCTION

2.1 All critical equipment used in apheresis and photopheresis to perform procedures are fully validated and approved for use to ensure equipment is safe. Non-essential equipment used in the procedural area may or may not be validated, however, will either be calibrated or has preventative maintenance (PM) performed. Routine quality control performed on equipment used in procedures ensure that all equipment is maintained at optimum, safe operating levels. The Spectra Optia blood cell separators (Optia) undergo 6-month preventive maintenance, which is performed by a Biomedical Technician in the Duke Clinical Engineering Department (CE). The Therakos Cellex blood cell separator (Cellex) and the Astotherm Plus blood warmers will have preventive maintenance performed every 12 months by CE. All performed PMs have a compliance window of ± 30 days from the scheduled date of maintenance to remain compliant and to be considered in proper working condition.

2.2 Any equipment that has failed any compliance or operational quality control will be labeled with ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form and entered on APBMT-EQUIP-001 FRM1 *Equipment Maintenance & Repair Log*. Any equipment that has failed standard preventative maintenance (PM) performed by CE will be placed "Out of Service" and may require an additional ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke clinical Engineering Out of Service Repair Form. The equipment will not be used until it has been serviced and found to be safe for use by CE or the manufacturer Service Engineering Department. Service documentation and approval for use will be documented on the APBMT-EQUIP-001 FRM1 *Equipment Maintenance & Repair Log*. If a blood cell separator is taken out of service for repair the Apheresis lead or designee will review all cellular collections done since the last service. This review is documented on the APBMT-EQUIP-001 FRM1 *Equipment Maintenance & Repair Log*.

2.3 The equipment used for procedures will be inspected for cleanliness prior to use and cleaned after each patient use with a hospital approved disinfectant. In addition, the equipment compliance will be verified to ensure it is within the maintenance schedule prior to use. The procedural nurse will document the equipment is ready to use on the appropriate quality control form assigned to each machine. In addition, the procedural nurse will document the cleaning of each machine on the appropriate treatment record.

3 SCOPE AND RESPONSIBILITIES

3.1 The apheresis and photopheresis nurse will be responsible for performing all operational quality control documentation. The CE will be responsible for performing the PMs and repairs on all apheresis and photopheresis equipment. Any deviations from the normal found during machine service or routine maintenance will be reported to the Apheresis lead or designee and physician, as needed. The CE will coordinate any equipment service required by the manufacturer.

3.2 In the event of a blood spill involving the centrifuge area, CE will be contacted. The apheresis and photopheresis nurse will be responsible for assisting the CE in cleaning the equipment. If the blood spill does not happen within the centrifuge area, the apheresis and photopheresis nurse will be responsible for cleaning the equipment. The Apheresis lead or designee will be responsible for reviewing all machine service once the instrument is cleared by CE and placed back into operation.

3.3 The Apheresis Program Manager or designee will review cellular therapy from the Optia yields and will arrange equipment service if any unexpected cell yield is suspected to be a result of equipment malfunction. Yields will also be monitored monthly and quarterly to determine if machine service is needed. Cellular therapy product yields are documented in the Apheresis Log Spreadsheet located on the ABMT Shared drive. Monthly and Quarterly reviews are documented in the ABMT Apheresis Quality Report located on the ABMT Shared drive.

3.4 Requests for apheresis or photopheresis machine service can be made online through the Duke Clinical Engineering site. The equipment clinical engineering number (CE #) on each piece of equipment is entered when making an online service request. Duke CE can also be contacted at 681-2525.

4 DEFINITIONS/ACRONYMS

4.1	AIM	Automated Interface Management System
4.2	C	Centigrade
4.3	CE	Duke Clinical Engineering Department
4.4	CE#	Clinical Engineering number
4.5	Cellex	Therakos Cellex Blood Cell Separator
4.6	F	Fail
4.7	LED	Light-emitting diode
4.8	N	Not in Use
4.9	N/A	Not Applicable
4.10	Optia	Spectra Optia Blood Cell Separator
4.11	P	Pass
4.12	PM	Preventative Maintenance
4.13	PPE	Personal Protective Equipment

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 Terumo BCT Spectra Optia Blood Cell Separator

6.2 Astotherm plus Blood Warmer

6.3 Therakos Cellex Blood Cell Separator

7 SAFETY

7.1 Follow all safety-related standard operating procedures and wear all necessary personal protective equipment (PPE), such as gloves, gowns, surgical masks, goggles, and/or face shields when handling potentially hazardous blood and body fluids.

8 PROCEDURE

8.1 Astotherm Plus Blood Warmer

8.1.1 Prior to Procedure

8.1.1.1 Prior to each procedure, the Astotherm Plus blood warmer will be visually inspected for cleanliness and within compliance.

8.1.1.1.1 Visually inspect the machine to ensure that it is clean and free of debride. If equipment appears not clean, wipe equipment thoroughly using hospital-approved disinfectant.

8.1.1.1.2 Visually inspect that the clinical engineering (CE) preventive maintenance (PM) sticker is present and in compliance. If the machine is not within the compliance window, contact the Duke CE department either by phone or via work order request. Place an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Optia. Notify the Apheresis lead or designee for service documentation.

8.1.1.2 Record "**P**" for **PASS** in the **Self-Check** box under the current date to document equipment is clear for use and passed visual inspection using the ABMT-EQUIP-001 FRM8 *Astotherm Quality Control Record.* The record is kept on each Optia blood cell separator with the corresponding blood warmer.

8.1.2 Turn the Astotherm Plus ON by pressing the **ON/OFF** key

8.1.2.1 The orange light-emitting diode (LED) turns off, and the green LED next to the device **ON/OFF** key illuminates and remains steady.

8.1.2.1.1 Note that: When the device is on stand-by mode the LED is orange

8.1.2.2 The alarm status LED flashes red.

8.1.2.3 The **START** key flashes green, the temperature display turns on, and the alarm sounds. Ensure that the alarm (red LED and alarm sound) is activated.

8.1.2.4 Select the temperature using the arrow up/down

8.1.3 Alarm Test

8.1.3.1 To start heating, press the **START** key for approximately one second. The acoustical alarm turns off, and the green LED next to the **START** key becomes steady.

8.1.3.2 The alarm LED will continue to flash until the actual temperature of the device is approximately 4ºC below the selected temperature

8.1.3.3 When the alarm LED goes off record a "**P**" for PASS in the Alarm Test box on the ABMT-EQUIP-001 FRM8 *Astotherm Quality Control Record* and initial in the initial box.

8.1.3.4 If the Astotherm Plus blood warmer test fails, repeat the test and if it fails a second time record "**F**" for **FAIL** and your initial in the boxes provided under the correct date. Take the warmer out of service by contacting the Duke CE department either by phone or via work order request. Place an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Astotherm Plus blood warmer. Notify the Apheresis lead or designee for service documentation.

8.1.4 After Each Procedure Cleaning

8.1.4.1 Regular cleaning and care increase service life and ensures that the specified performance characteristic is always achieved.

8.1.4.2 To clean the surface, wipe equipment thoroughly using hospital-approved disinfectant. Never immerse device completely in fluid or bring into contact with steam.

8.1.5 If the Astotherm Plus blood warmer is not used, place an "**N**" for **Not in Use** and "**N/A**" if **Not Applicable** in the Self-Check box.

8.1.6 Reviews

8.1.6.1 The Apheresis Program Manager or designee will review the ABMT-EQUIP-001 FRM8 *Astotherm Quality Control*

Record monthly for accuracy and completeness then date and initial in the space provided.

8.1.6.2 The Apheresis Program Manager or designee will review the data for final check-off prior to quarterly review then sign and date in the space provided.

8.2 Scale

8.2.1 The scale that is used for whole blood collection and therapeutic phlebotomy will be calibrated before use as described in the ABMT-EQUIP-001 JA1 *Quality Control of Scale*.

8.3 Spectra Optia

8.3.1 Prior to Procedure

8.3.1.1 Prior to each procedure, the Optia will be visually inspected for cleanliness and within compliance.

8.3.1.1.1 Visually inspect the entire machine to ensure that it is clean and free of debride. If equipment appears not clean, wipe equipment thoroughly using hospital-approved disinfectant.

8.3.1.1.2 Visually inspect that the clinical engineering (CE) preventive maintenance (PM) sticker is present and in compliance. If the machine is not within the compliance window, contact the Duke CE department either by phone or via work order request. Place an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Optia. Notify the Apheresis Program Manager or designee for service documentation.

8.3.1.2 Record "**P**" for **PASS** in the **Self-Check** box under the current date to document equipment is clear for use and passed visual inspection using the ABMT-EQUIP-001 FRM10 *Optia Quality Control Record.* The record is kept on each Optia.

8.3.2 Alarm Tests

8.3.2.1 Prior to every procedure, the Optia will perform automatic alarm tests. Document results on the ABMT-EQUIP-001 FRM10 *Optia Quality Control Record.* Record "**P**" for PASS if the tests are passed and initial in the box under the current date.

8.3.2.2 If the alarm tests fail, repeat the tests and if they fail a second time record "**F**" for **FAIL** and your initial in the boxes provided under the correct date. Contact the Duke CE

department either by phone or via work order request. Place an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Optia. Notify the Apheresis Program Manager or designee for service documentation.

8.3.3 After Each Procedure Cleaning

8.3.3.1 At a minimum, clean the exterior surfaces, seal safe system, and centrifuge chamber using hospital-approved disinfecting solution. Avoid damaging the touch screen with fluid. If screen is soiled, clean with hospital-approved disinfecting wipes and dry with gauze pad or clean cloth after exposing it to fluid. Clean the touch screen, glass cover lights, and Automated Interface Management System (AIM) system using a dry gauze pad or a soft, lint-free cloth.

8.3.3.2 The apheresis nurse will document apheresis equipment cleaning by placing an initial on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* in the space labeled "Machine cleaned by".

8.3.4 Weekly Cleaning

8.3.4.1 Clean the sensors, the detectors, and the valves on the front panel of Optia weekly using hospital-approved disinfectant. You may use cotton swabs to clean between crevices. Dry the sensors and detectors immediately after cleaning. Record the date the maintenance was completed and initial on the line provided. Document cleaning on ABMT-EQUIP-001 FRM10 *Optia Quality Control Record.*

8.3.5 Monthly Cleaning

8.3.5.1 At a minimum, clean the fluid leak detector, pump housing, and pump rotors using hospital-approved disinfectant. Remove each pump rotor from the housing by pushing in the rotor and turning it to the left. Use clean dry gauze pad or a soft cloth, as needed. Allow the surfaces to air dry before you replace the rotor.

8.3.5.2 Clean the glass covers on the lights and AIM system in the centrifuge chamber by wiping them a dry gauze pad or soft, lint-free cloth.

8.3.5.3 Record the cleaning on the ABMT-EQUIP-001 FRM10 *Optia Quality Control Record.*

8.3.6 Weekly and Monthly Review

8.3.6.1 The Apheresis Program Manager or designee will review the ABMT-EQUIP-001 FRM10 *Optia Quality Control Record* weekly and monthly for accuracy and completeness then date and initial in the spaces provided.

8.3.6.2 The Apheresis Program Manager or designee will review the data for final check-off prior to quarterly review then sign and date in the space provided.

8.3.7 If the Optia is not used, place an "**N**" for **Not in Use** and "**N/A**" if **Not Applicable** in the Self-Check box.

8.4 Therakos Cellex

8.4.1 Prior to Procedure

8.4.1.1 Prior to each procedure, the Cellex will be visually inspected for cleanliness and within compliance.

8.4.1.1.1 Visually inspect the entire machine to ensure that it is clean and free of debride. If equipment appears not clean, wipe equipment thoroughly using hospital-approved disinfectant.

8.4.1.1.2 Visually inspect that the clinical engineering (CE) preventive maintenance (PM) sticker is present and in compliance. If the machine is not within the compliance window, contact the Duke CE department either by phone or via work order request. Place an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Cellex. Notify the Apheresis Program Manager or designee for service documentation.

8.4.1.2 Record "**P**" for **PASS** in the **Self-Check** box under the current date to document that equipment is clear for use and passed visual inspection using the ABMT-EQUIP-001 FRM11 *Cellex Quality Control Record.* The record is kept on each Cellex. If the machine is not within the compliance window, contact the Duke CE department either by phone or via work order request. Place an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Cellex. Notify the Apheresis Program Manager or designee for service documentation.

8.4.2 Alarm Test

8.4.2.1 Prior to every procedure, Cellex will perform automatic alarm tests. Document results on the ABMT-EQUIP-001 FRM11 *Cellex Quality Control Record.* Record P if the tests are passed and initial in the box under the current date.

8.4.2.2 If the alarm tests fail, repeat the tests and if they fail a second time record "**F**" for **FAIL** and your initial in the boxes provided under the correct date. Contact the Duke CE department either by phone or via work order request. Place

an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Cellex. Notify the Apheresis Program Manager or designee for service documentation.

8.4.3 After Each Procedure Cleaning

8.4.3.1 At a minimum, clean the exterior surfaces, centrifuge chamber door, and centrifuge chamber using a hospital-approved disinfectant. Allow the surfaces to air dry. Avoid damaging the touch screen with fluid. If screen is soiled, clean with hospital-approved disinfecting wipes and dry with gauze pad or clean cloth after exposing it to fluid. Clean the touch screen and bowl optic lens using a dry gauze pad or a soft, lint-free cloth.

8.4.3.2 The photopheresis nurse will document apheresis equipment cleaning by placing an initial on the ABMT-GEN-025 FRM2 *Photopheresis Run Sheet* in the space labeled "Machine cleaned by".

8.4.4 Weekly Cleaning

8.4.4.1 At a minimum, clean the air detectors, hematocrit sensor, and bowl optic lens with a dry gauze pad or soft, lint-free cloth. Document on the ABMT-EQUIP-001 FRM 11 *Cellex Quality Control Record.*

8.4.5 Monthly Cleaning

8.4.5.1 Clean the Air Detectors, pressure sensors, Hematocrit sensor, Bowl Optic Lens, and Leak detector with gauze pad or soft, lint-free cloth. If leak detector is soiled, use the hospital approved disinfecting solution and allow surface to air dry. Document on the ABMT-EQUIP-001 FRM 11 *Cellex Quality Control Record.*

8.4.6 Weekly and Monthly Review

8.4.6.1 The Apheresis Program Manager or designee will review the ABMT-EQUIP-001 FRM11 *Cellex Quality Control Record* weekly and monthly for accuracy and completeness then date and initial in the spaces provided.

8.4.6.2 The Apheresis Program Manager will review the data for final check-off prior to quarterly review then sign and date in the space provided.

8.4.7 If the Cellex is not used, place an "**N**" for **Not in Use** and "**N/A**" if **Not Applicable** in the Self-Check box.

9 RELATED DOCUMENTS/FORMS

9.1 ABMT-COLL-019 FRM1 Optia CMNC Run Sheet

9.2 ABMT-GEN-025 FRM2 Photopheresis Run Sheet

9.3 ABMT-EQUIP-001 FRM8 Astotherm Blood Warmer Quality Control Record

9.4 ABMT-EQUIP-001 FRM6 Out of Service Form

9.5 ABMT-EQUIP-001 JA1 Quality Control of Scale

9.6 APBMT-EQUIP-001 FRM1 Equipment Maintenance & Repair Log

9.7 ABMT-EQUIP-001 FRM10 Optia Quality Control Record

9.8 ABMT-EQUIP-001 FRM11 Cellex Quality Control Record

10 REFERENCES

10.1 Astotherm plus Operating Instructions

10.2 Spectra Optia Apheresis System Operator's Manual, Current edition

10.3 Therakos Cellex Photopheresis System Operator's Manual, Current edition

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
14	K. Beale	- Replaced ABMT-EQUIP-001 FRM9 Equipment Maintenance & Repair Log with APBMT-EUIP-001 FRM1 Equipment Maintenance & Repair Log - Replaced Apheresis Lead with Apheresis Program Manager

Signature Manifest

Document Number: ABMT-EQUIP-001 **Revision:** 14
Title: Quality Control of Equipment
Effective Date: 31 Mar 2025

All dates and times are in Eastern Time.

ABMT-EQUIP-001 Quality Control of Equipment

Author

Name/Signature	Title	Date	Meaning/Reason
Kourtney Beale (KLQ)		13 Feb 2025, 12:05:58 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		28 Feb 2025, 12:58:53 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Stefanie Sarantopoulos (SS595)	Professor of Medicine	04 Mar 2025, 08:45:04 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)	Associate Director, Quality Assurance	11 Mar 2025, 02:53:25 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	13 Mar 2025, 08:53:57 PM	Approved