PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Quality Control of Apheresis Instruments

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PBMT-EQUIP-001
QUALITY CONTROL OF APHERESIS INSTRUMENTS

1 PURPOSE

1.1 To describe the procedure for performing manufacturer's recommended routine Quality Control (QC) for the equipment used in pediatric apheresis located in Children's Health Center (CHC) or other designated location.

2 INTRODUCTION

2.1 All critical equipment used in apheresis 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 QC is performed on equipment used in apheresis procedures ensures that equipment is maintained to ensure optimal, safe operating levels. The Spectra Optia blood cell separator (Optia) will undergo a 6-month preventive maintenance (PM) schedule performed by a Biomedical Technician in the Duke Clinical Engineering Department (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 the PBMT-EQUIP-001 FRM 3 *Out of Service Form* or the Duke Clinical Out of Service Repair Form and entered on the APBMT-EQUIP-001 FRM1*Equipment Maintenance and Repair Log.* Any equipment that has failed standard PM performed by CE will be placed "Out of Service" and may require an additional PBMT-EQUIP-001 FRM3 *Out of Service Form* or the Duke Clinical Out of Service Repair Form. The equipment will not be used until it has been serviced and found to be safe for use by the CE or the manufacturer Service Engineering Department. Service documentation and approval for use will be documented on the APBMT-EQUIP-001 FRM1 *Equipment Maintenance and Repair Log*. If the Optia is taken out of service for repair the Apheresis Program Manager or designee will review all cellular collection data since last service. This review is documented on the APBMT-EQUIP-001 FRM1*Equipment Maintenance and 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 nurse will be responsible for performing all routine quality control documentation. The CE will be responsible for performing the PM and repairs of the Optia. Any deviations from the normal found during machine service or routine maintenance will be reported to the Apheresis Program Manager 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 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 nurse will be responsible for cleaning the equipment. The Apheresis Program Manager 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 Spectra 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 quarterly to determine if machine service is needed. Cellular therapy product yields are documented in the Apheresis Log Spreadsheet located on the PBMT Shared drive.

3.4 Request for apheresis machine service can be made online through the Duke Clinical Engineering site. The equipment Clinical Engineer number (CE#) is entered when making an online request. Duke CE department can be contacted at 681-2525.

4 DEFINITIONS/ACRONYMS

4.1	AIM	Automated Interface Management System
4.2	CE	Duke Clinical Engineering Department
4.3	CE#	Clinical Engineering number
4.4	CHC	Children’s Health Center
4.5	F	Fail
4.6	N	Not in Use
4.7	N/A	Not Applicable
4.8	Optia	Spectra Optia Blood Cell Separator
4.9	P	Pass
4.10	PM	Preventive Maintenance

4.11 PPE Personal Protective Equipment

4.12 QC Quality Control

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 Terumo BCT Spectra Optia Blood Cell Separator

7 SAFETY

7.1 Follow all safety-related standard operating procedure and wear all necessary personal protective equipment (PPE) when handling potentially hazardous blood and body fluids to include, but not limited to, gloves, barrier gowns, goggles, surgical mask, and/or face shields.

8 PROCEDURE

8.1 Spectra Optia

8.1.1 Prior to Procedure

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

8.1.1.1.1 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.

8.1.1.1.2 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 PBMT-EQUIP-001 FRM3 *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.

8.1.1.2 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 APBMT-EQUIP-001 FRM2 *Optia Apheresis Machine Quality Control Record.* The record is kept in the PBMT file within the Blood Cancer Center. The form is brought to the CHC for each collection.

8.1.2 Alarm Tests

8.1.2.1 Prior to every procedure, Optia will perform an automatic alarm test. Document results on PBMT-EQUIP-001 FRM2 *Optia Apheresis Machine Quality Control Record.* Record "**P**" for PASS if the tests are passed and initial in the box under the current date.

8.1.2.2 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. Place a PBMT-EQUIP-001 FRM3 *Out of Service Repair Form* or the Duke CE Out of Service Repair Form on the Optia and notify the Apheresis Program Manager or designee to arrange for service documentation.

8.1.3 After Each Procedure Cleaning

8.1.3.1 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 AIM system using a dry gauze pad or a soft, lint-free cloth.

8.1.3.2 The apheresis nurse will document apheresis equipment cleaning by placing an initial on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet* in the space labeled "Machine cleaned by".

8.1.4 Weekly Cleaning

8.1.4.1 Clean the sensors, the detectors, and the valves on the front panel of Optia at least bi-monthly 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 PBMT-EQUIP-001 FRM2 *Optia Apheresis Machine Quality Control Record.*

8.1.4.2 Weekly cleaning **MUST** be performed a minimum of two times monthly. If weekly cleaning has not been completed, the Apheresis Program Manager or designee will assign cleaning for the following week. Document not applicable (N/A) on the weekly cleanings and reviews for the weeks the machine is not cleaned.

8.1.5 Monthly Cleaning

8.1.5.1 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.

8.1.5.2 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.

8.1.5.3 Record the cleaning on the PBMT-EQUIP-001 FRM2 *Optia Apheresis Machine Quality Control Record.*

8.1.6 Weekly and Monthly Review

8.1.6.1 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.

8.1.6.2 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.

8.1.7 If the Spectra Optia machine 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 PBMT-COLL-016 FRM1 Optia Leukapheresis Run Sheet

9.2 PBMT-EQUIP-001 FRM2 Optia Apheresis Machine Quality Control Record

9.3 PBMT-EQUIP-001 FRM3 Out of Service Form

9.4 APBMT-EQUIP-001 FRM1 Equipment Maintenance and Repair Log

10 REFERENCES

10.1 Spectra Optia Apheresis System Operator's Manual, Current Edition

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	Kourtney Beale	-_Updated Apheresis Lead to Apheresis Program Manager throughout document -Updated Nurse Manager to Apheresis Program Manager -Updated PBMT-EQUIP 001 FRM4 Equipment Maintenance and Repair Log to APBMT-EQUIP-001 FRM1 Equipment Maintenance and Repair Log

Signature Manifest

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