



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Optia Apheresis Machine Quality Control Record FRM2

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PBMT-EQUIP-001 FRM2

OPTIA APHERESIS MACHINE QUALITY CONTROL RECORD

(Instructions are located on the back)

Spectra Optia Serial #

CE #

Year:

Clinical Engineer (CE) Compliance Due Date:

Clinical Engineer (CE) Compliance Due Date:

MONTH

Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31																												
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MONTH

Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31													
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P = Pass F = Fail N = Not in Use N/A = Not Applicable

PBMT-EQUIP-001 FRM2**OPTIA APHERESIS MACHINE QUALITY CONTROL RECORD****Instructions:**

1. Enter the Spectra Optia Serial Number, Clinical Engineering Number, and Year in space provided.
2. Enter the Clinical Engineer (CE) Compliance Due Date in space provided.
3. Enter the Month(s) in space provided.
4. If the Spectra Optia is not used, place an "N" for Not in Use and N/A if not applicable in the Self-Check box.
5. Prior to Procedure:
 1. Visually inspect machine to ensure cleanliness and within compliance.
 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.
 3. If the Spectra Optia is out of compliance, take the warmer out of service by contacting the Duke CE department either by phone or via work order request. Place a PBMT-EQUIP-001 FRM3 *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.
6. Alarm Test:
 1. Prior to every procedure, Optia will perform automatic alarm tests. Document results on the PBMT-EQUIP-001 FRM2 *Optia Quality Control Record*. Record "P" for PASS if the tests are passed and initial in the box under the current date.
 2. If the Spectra Optia 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 Optia out of service by contacting the Duke CE department either by phone or via work order request. Place an A PBMT-EQUIP-001 FRM3 *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.
7. Cleaning:
 1. **After Each Procedure:** Clean the exterior surfaces, seal safe system, and centrifuge chamber using hospital-approved disinfecting solution. Clean the touch screen, glass cover lights, and AIM system using a dry gauze pad or a soft, lint-free cloth. Allow the surface to air dry.
 2. **Weekly** (performed once a week): Clean the sensors, the detectors, and the valves on the front panel of Optia weekly using hospital-approved disinfectant. Dry the sensors and detectors immediately after cleaning. Record the date the maintenance was completed and initial on the line provided.
 3. **Monthly** (performed once a month): Clean the fluid leak detector, the 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. Allow the surfaces to air dry before you replace the rotor. Clean the glass covers on the lights in the centrifuge chamber by wiping them with a dry gauze pad or a soft, lint-free cloth. Record the date the cleaning was completed and initial on the line provided.
8. Reviews:
 1. The Apheresis lead or designee will review the PBMT-EQUIP-001 FRM2 for accuracy and completeness then date and initial in the space provided.
 2. The Nurse manager will review the data prior to quarterly review then sign and date below.

Manager's Signature: _____ Date: _____

Signature Manifest**Document Number:** PBMT-EQUIP-001 FRM2**Revision:** 03**Title:** Optia Apheresis Machine Quality Control Record FRM2**Effective Date:** 29 Jan 2024

All dates and times are in Eastern Time.

PBMT-EQUIP-001 FRM2 Optia Apheresis Machine Quality Control Record**Author**

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Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		24 Jan 2024, 12:10:36 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
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Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	24 Jan 2024, 03:27:32 PM	Approved