

**DukeMedicine****Division of Cellular Therapy****DOCUMENT NUMBER:** ABMT-EQUIP-001 FRM10**DOCUMENT TITLE:**

Optia Apheresis Machine Quality Control Record

**DOCUMENT NOTES:****Document Information****Revision:** 03**Vault:** ABMT-Equipment-rel**Status:** Release**Document Type:** ABMT**Date Information****Creation Date:** 23 Jan 2024**Release Date:** 29 Jan 2024**Effective Date:** 29 Jan 2024**Expiration Date:****Control Information****Author:** MC363**Owner:** MC363**Previous Number:** ABMT-EQUIP-001 FRM10 Re **Change Number:** ABMT-CCR-337

ABMT-EQUIP-001 FRM10  
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
Self-checks																															
Alarm Tests																															
Initials																															

Weekly Cleaning:		Week 1		Week 2		Week 3		Week 4		Week 5
Date/Initials:										

Weekly Review:		Week 1		Week 2		Week 3		Week 4		Week 5
Date/Initials:										

Monthly Cleaning:	
Date/Initials:	

Monthly Review:	
Date/Initials:	

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.

P = Pass F = Fail N = Not in Use N/A = Not Applicable

## ABMT-EQUIP-001 FRM10 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 Compliance Due Date in space provided
3. Enter the Month in space provided.
4. 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 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.
5. Alarm Test:
  1. Prior to every procedure, 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.
  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 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.
6. 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.
7. Reviews:
  1. The Apheresis lead or designee will review the ABMT-EQUIP-001 FRM10 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' Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Signature Manifest****Document Number:** ABMT-EQUIP-001 FRM10**Revision:** 03**Title:** Optia Apheresis Machine Quality Control Record**Effective Date:** 29 Jan 2024

All dates and times are in Eastern Time.

**ABMT-EQUIP-001 FRM10 Optia Apheresis Machine Quality Control Record****Author**

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		23 Jan 2024, 06:36:34 PM	Approved

**Management**

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		24 Jan 2024, 03:01:54 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		24 Jan 2024, 03:45:11 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)	Associate Director, Quality Assurance	24 Jan 2024, 04:02:47 PM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	24 Jan 2024, 04:52:59 PM	Approved