DOCUMENT NUMBER: ABMT-EQUIP-001 FRM10

DOCUMENT TITLE:
Optia Apheresis Machine Quality Control Record

DOCUMENT NOTES:

Document Information

Revision: 02
Vault: ABMT-Equipment-rel

Status: Release
Document Type: Equipment

Date Information

Creation Date: 05 May 2015
Release Date: 23 Jun 2017

Effective Date: 23 Jun 2017
Expiration Date:

Control Information

Author: DRAGO001
Owner: DRAGO001

Previous Number: ABMT-EQUIP-001 FRM10
Change Number: ABMT-CCR-109
# ABMT-EQUIP-001 FRM10
## OPTIA APHERESIS MACHINE QUALITY CONTROL RECORD

**Serial #** ____________________________ **Year:** ____________

### 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 |
|------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Alarm Tests | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Date/Initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

<table>
<thead>
<tr>
<th>Weekly Cleaning (refer to page 2)</th>
<th>Week 1</th>
<th>Week 2</th>
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| Date/Initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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<thead>
<tr>
<th>Weekly Review Initial/Date: Week 1</th>
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| Monthly Review: | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

### 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 |
|------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Alarm Tests | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Initials | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| Monthly Review: | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

**P = Pass/Performed**  **F = Fail**  **N = Optia no: in use**
Optia Apheresis Machine Quality Control Record
Instructions For Use

Alarm Tests

Prior to every procedure Optia will perform automatic alarm tests. Record P if the tests are passed and initial in the box under the current date. If the alarm tests fail, repeat the tests and if they fail a second time record F and your initial in the boxes provided under the correct date. Place an Out of Service Form (FRM 6) on the Spectra and arrange for service. (Refer to Troubleshooting Procedure)

Weekly Cleaning

Clean the sensors, the detectors, and the valves on the front panel of Optia weekly. Use a gauze pan damp with water to clean the sensors and detectors. Dry the sensors and detectors immediately after cleaning. Clean the surfaces of the valves using a solution of water and mild detergent and a cotton swab. Record the date the maintenance was completed and initial on the line provided.

Monthly Cleaning

1. Clean the pump housing and pump rotors by removing each pump rotor from the housing by pushing in the rotor and turning it to the left. Pull out the rotor from the housing. Clean the housing and the rotor using a solution of mild detergent and water, and a clean gauze pad. Allow the surfaces to air dry before you replace the rotor.
2. Clean the fluid leak detector with an alcohol pad.
3. Clean the glass covers on the lights in the centrifuge chamber by wiping them with water and a gauze pad. Allow the covers to air dry. Wipe the covers again with water to remove any residue. Dry the covers with a gauze pad.
4. Record the date the cleaning was completed and initial on the line provided.

Weekly and Monthly Review

The Apheresis coordinator or designee will review the Optia Apheresis Machine Quality Control Record monthly and weekly for accuracy and completeness then date and initial in the spaces provided. This form will be filed in the Adult Apheresis Quality Control Book when complete.
Instructions for Completing the Optia Apheresis Machine Quality Control Record

Each COBE Spectra Apheresis machine will have a clipboard with the Quality Control Record attached.

<table>
<thead>
<tr>
<th>Field</th>
<th>Requirements</th>
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</thead>
<tbody>
<tr>
<td>Serial #</td>
<td>Enter the machine serial number, located on the back of the machine.</td>
</tr>
<tr>
<td>Year</td>
<td>Enter the year.</td>
</tr>
<tr>
<td>Month</td>
<td>Record the month at the top of each section.</td>
</tr>
<tr>
<td>Daily alarm tests</td>
<td>Record P for pass, F for fail. Initial that alarms test was performed N = Optia not in use</td>
</tr>
<tr>
<td>Weekly cleaning</td>
<td>Date and initial when weekly cleaning is completed</td>
</tr>
<tr>
<td>Weekly Review</td>
<td>Date and initial weekly when the daily alarm test and weekly cleaning recording is reviewed.</td>
</tr>
<tr>
<td>Monthly cleaning</td>
<td>Date and initial when monthly cleaning is completed.</td>
</tr>
<tr>
<td>Monthly Review</td>
<td>Date and initial when the monthly review of entries is completed.</td>
</tr>
</tbody>
</table>
# Signature Manifest

**Document Number:** ABMT-EQUIP-001 FRM10  
**Revision:** 02  
**Title:** Optia Apheresis Machine Quality Control Record  

*All dates and times are in Eastern Time.*

## ABMT-EQUIP-001 FRM10 Optia Apheresis Machine Quality Control Record

### Author

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
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<tbody>
<tr>
<td>Susan Drago (DRAGO001)</td>
<td></td>
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### Management

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### Medical Director

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### Quality

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<td>John Carpenter (JPC27)</td>
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### Document Release

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<td>Sharon Hartis (SH259)</td>
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<td>Betsy Jordan (BJ42)</td>
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### Review: ABMT-EQUIP-001 FRM10 02

### Review

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## Quick Approval

### Approve Now

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## Quick Approval

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