**DOCUMENT NUMBER:** ABMT-EQUIP-001

**DOCUMENT TITLE:**
Quality Control of Equipment

**DOCUMENT NOTES:**

**Document Information**

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**Control Information**

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ABMT-EQUIP-001
QUALITY CONTROL OF EQUIPMENT

1 PURPOSE
1.1 To describe the procedure for performing manufacturer’s recommended routine Quality Control for the equipment used in apheresis.

2 INTRODUCTION
2.1 Routine Quality Control performed on equipment used in apheresis procedures ensures that all equipment is maintained at optimum, safe operating levels. The Terumo BCT Spectra Optia blood cell separators undergo a 6-month preventive maintenance done by a Biomedical Technician in the Duke Clinical Engineering Department or by Gambro/Terumo Technical Services Field Service Engineers. The Therakos Cellex blood cell separator will have preventive maintenance performed every 12 months by Duke Clinical Engineering Department or Therakos Clinical Diagnostics. The Astotherm plus blood warmers will have temperature monitoring done annually by Duke Clinical Engineering.

2.2 Any equipment that has failed routine 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 ABMT-EQUIP-001 FRM9 Equipment Maintenance & Repair Log. The equipment will not be used until it has been serviced and found to be safe for use by Duke Clinical Engineering or the manufacturer Service Engineering Department. Service documentation and approval for use will be documented on the ABMT-EQUIP-001 FRM9 Equipment Maintenance & Repair Log. If a blood cell separator is taken out of service for repair or recalibration the Apheresis coordinator or designee will review all cellular collections done since the last service. This review is documented on the ABMT-EQUIP-001 FRM9 Equipment Maintenance & Repair Log.

2.3 The equipment used for apheresis will be cleaned after each patient use with a hospital approved disinfectant. The apheresis nurse will document apheresis equipment cleaning by placing an initial on the Optia leukapheresis Run Sheet in the space labeled “Machine cleaned by”. Documentation of cleaning the Therakos Cellex will be documented on the Cellex Run Sheet.

3 SCOPE AND RESPONSIBILITIES
3.1 The apheresis nurse will be responsible for performing all routine quality control. The Duke Clinical Engineering Department will be responsible for performing the preventive maintenance and repairs on all apheresis equipment. Any deviations from the normal found during machine service or routine maintenance will be reported to the Apheresis coordinator or designee and physician as needed. Duke Clinical Engineering will coordinate any equipment service required by the manufacturer. The apheresis nurse will be responsible for cleaning the apheresis equipment on a daily routine basis and in the event of a blood spill. Duke Clinical Engineering must be called if the blood spill involves the centrifuge and cleaning.
will require removal of the centrifuge. The Apheresis Coordinator or designee will be responsible for reviewing all machine service to determine if the instrument can be placed back into operation.

3.2 The Apheresis coordinator or designee will review cellular therapy yields daily 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. Monthly and Quarterly reviews are documented in the ABMT Apheresis Quality Report.

3.3 Request for apheresis machine service can be made online through the Duke Clinical Engineering site. The equipment CE # on each piece of equipment is entered when making an online service request. Clinical Engineering can be contacted at 681-2525.

4 DEFINITIONS/ACRONYMS
4.1 LED (Light emitting diode)
4.2 C (Centigrade)
4.3 CE# (Clinical Engineering number)

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 Terumo BCT Spectra Optia
6.2 Astotherm plus Blood Warmer
6.3 Therakos Cellex

7 SAFETY
7.1 Follow all safety-related standard operating procedures and wear all necessary personal protective equipment when handling potentially hazardous blood and body fluids to include but not limited to gloves, scrubs, gowns, surgical masks, goggles, face shields, etc.

8 PROCEDURE
8.1 Daily Astotherm plus Blood Warmer
8.1.1 Turn the Astotherm ON by pressing the ON/OFF key
8.1.1.1 Note that:
8.1.1.1.1 The alarm status LED flashes red.
8.1.1.1.2 The Start key flashes green.
8.1.1.1.3 The temperature display turns on.
8.1.1.1.4 The alarm sounds.
8.1.1.2 If the alarm LED flashes red, the Start key flashes green, the temperature display turns on and the alarm sounds the test is recorded as P passed for test #1. Record the results on the ABMT-EQUIP-001 FRM8 Astotherm Quality Control Record FRM8 kept on each Spectra blood cell separator with the corresponding blood warmer.

8.1.1.3 Select the temperature using the arrow up/down.

8.1.1.4 The alarm LED will continue to flash until the actual temperature of the device is approximately 4°C below the selected temperature.

8.1.1.5 When the alarm LED goes off record a “P” for passed for test #2 on the Blood Warmer Quality Control Record and initial in the initial box.

8.1.1.6 If daily Astotherm Blood Warmer tests are failed take the warmer out of service by placing an ABMT-EQUIP-001 FRM6 Out of Service Form or the Duke Clinical Engineering Out of Service Repair Form on the device. Notify the Apheresis coordinator so that service can be arranged and documented.

8.1.2 Scale

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

8.2 Spectra Optia

8.2.1 Alarm Tests

8.2.1.1 Prior to every procedure Optia will perform automatic alarm tests. Document results on the Optia Quality Control Record. 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 ABMT-EQUIP-001 FRM6 Out of Service Form or the Duke Clinical Engineering Out of Service Repair Form on the Optia and notify the coordinator to arrange for service and documentation.

8.2.2 Weekly Cleaning

8.2.2.1 Clean the sensors, the detectors, and the valves on the front panel of Optia weekly. You may use a gauze pad damp with water to clean the sensors and detectors. Dry the sensors and detectors immediately after cleaning. Clean the surfaces all other services using hospital approved clean wipes. You may use cotton swabs to clean between crevices. Document
cleaning on ABMT-EQUIP-001 FRM10 Optia Quality Control Record.

8.2.3 Monthly Cleaning

8.2.3.1 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 hospital approved cleaning wipes. Use clean gauze pad, as needed. Allow the surfaces to air dry before you replace the rotor.

8.2.3.2 Clean the fluid leak detector with hospital approved wipes and/or an alcohol pad.

8.2.3.3 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.

8.2.4 Record the cleaning on the ABMT-EQUIP-001 FRM10 Optia Quality Control record

9 RELATED DOCUMENTS/FORMS

9.1 ABMT-EQUIP-001 FRM8 Astotherm Blood Warmer Quality Control Record
9.2 ABMT-EQUIP-001 FRM6 Out of Service Form
9.3 ABMT-EQUIP-001 FRM3 Scale Quality Control Record
9.4 ABMT-EQUIP-001 FRM9 Equipment Maintenance & Repair Log
9.5 ABMT-EQUIP-001 FRM10 Optia Quality Control Record

10 REFERENCES

10.1 Astotherm plus Operating Instructions

11 REVISION HISTORY

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<th>Description of Change(s)</th>
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<td>M. Christen</td>
<td>Removed all SpectraTherm information from document Added information about Duke Clinical Engineering Out of Service Repair Form</td>
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ABMT-EQUIP-001 Quality Control of Equipment
ABMT, DUMC
Durham, NC
# Signature Manifest

**Document Number:** ABMT-EQUIP-001  
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All dates and times are in Eastern Time.

## ABMT-EQUIP-001 Quality Control of Equipment

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### Management

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