



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Spectra Optia Apheresis System Continuous Mononuclear Cell (CMNC) Collection Procedure

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SPECTRA OPTIA APHERESIS SYSTEM CONTINUOUS MONONUCLEAR CELL (CMNC) COLLECTION PROCEDURE

1 PURPOSE

- 1.1 To describe the procedure and supplies required for pediatric leukapheresis using the Terumo Spectra Optia Apheresis System (Optia). This procedure is for the collection of Peripheral Blood Progenitor Cells (PBPC), T- Lymphocytes (DLIs) and other mononuclear cells. For information on using the Optia System, refer to the Spectra Optia® Apheresis System Operator's Manual.

2 INTRODUCTION

- 2.1 The collection of PBPC cells by apheresis allows patients to be treated with high dose chemotherapy. Autologous patients will donate following stimulation with chemotherapy and/or colony stimulating factors (CSFs). Other Autologous MNC collections, such as chimeric antigen receptor T cells (CAR-T), may not require chemotherapy and/or CSFs. Allogeneic donors are HLA tested and are stimulated with CSFs prior to donation. Autologous/Allogeneic T-Lymphocytes are collected with or without CSFs being administered.
- 2.2 Peripheral or Central Venous Catheters (CVC) are inserted prior to the pediatric apheresis collection performed in the Children's Health Center (CHC). Apheresis collection are performed in treatment chairs or beds, separated by curtains to prevent improper labeling, mix-ups, contamination or cross-contamination of cellular products. Overhead lighting and adequate ventilation is present and cellular products collected at room temperature. A sink is present in the apheresis collection room for hand hygiene. CHC pharmacy is available to dispense apheresis related medications, if needed. Rapid response team (RRT) is available to respond to emergencies. Emergency equipment is available and in close proximity to the apheresis area.
- 2.3 Apheresis supplies are stored at room temperature in the Adult Blood and Marrow Transplant (ABMT) Clinic Supply Room. No supplies are stored in the pediatric apheresis room at the CHC. Refer to the procedure: PBMT-EQUIP-003 *Pediatric Apheresis Supply Management*. The CHC apheresis room is temperature and humidity monitored during each apheresis collection procedure. Refer to PBMT-COLL-015 *Monitoring Temperature and Humidity* and PBMT-COLL-015 FRM1 *Temperature and Humidity Log* for procedural steps and documentation forms.
- 2.4 The Duke Stem Cell Lab will freeze cells as ordered within 48 hours of collection.
- 2.5 Labeling the cellular product and plasma bag is completed prior to the end of the leukapheresis using a validated indelible pen. Refer to COMM-PAS-003 *Labeling Cellular Therapy Products*. Labels will be double-checked by the attending apheresis physician and/or clinic staff nurse and documented on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*.

- 2.6 During a continuous mononuclear cell (CMNC) procedure, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor of 4.5. The Automated Interface Management (AIM) system adjusts the flow rate of the plasma pump to control the concentration of cells that flow through the collect port, based on the collection preference (CP).
- 2.7 Program the Optia to collect the amount of plasma, if ordered by apheresis attending physician or medical director. Once plasma is collected, the collection of cells begins.
- 2.8 Patient vital signs will be taken and recorded pre- and post-apheresis on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet* or in the EMR.
 - 2.8.1 Vital signs obtained every 15 minutes for first hour and every 30 minutes thereafter throughout procedure by CHC nurse and documented in EMR.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The apheresis nurse is responsible for the collection of PBPCs, DLIs or other mononuclear cell products using the Optia System.
- 3.2 The apheresis nurse, attending apheresis physician and Advanced Practice Providers (APP), and CHC staff nurses are responsible for patient/donor care during apheresis.
- 3.3 Non-tunneled CVC will be removed following the completion of donation by an attending apheresis physician.

4 DEFINITIONS/ACRONYMS

- 4.1 AC Anticoagulant
- 4.2 ACD-A Acid Citrate Dextrose Formula A
- 4.3 APP Advanced Practice Provider
- 4.4 CAR-T Chimeric Antigen Receptor T Cells
- 4.5 CBC Complete Blood Count
- 4.6 CHC Children's Health Center
- 4.7 CMNC Continuous Mononuclear Cell
- 4.8 CMP Complete Metabolic Panel
- 4.9 CP Collection Preference
- 4.10 CPT Collection Preference Tool
- 4.11 CSF Colony Stimulating Factor
- 4.12 DLI Donor Lymphocyte Infusion
- 4.13 ECV Extracorporeal Volume
- 4.14 EMR Electronic Medical Record

4.15	Hct	Hematocrit
4.16	HLA	Human Leukocyte Antigen
4.17	ISBT	International Society for Blood Transfusion
4.18	IV	Intravenous
4.19	mL	Milliliter
4.20	MNC	Mononuclear Cells
4.21	NaCl	Sodium Chloride
4.22	PBMT	Pediatric Blood and Marrow Transplant
4.23	PBPC	Peripheral Blood Progenitor Cells
4.24	PST	Plasma Separator Tube
4.25	PPE	Personal Protective Equipment
4.26	RBC	Red Blood Cells
4.27	SOP	Standard Operating Procedure
4.28	T&S	Type and Screen
4.29	WBC	White Blood Cell
4.30	WBV	Whole Blood Volume

5 MATERIALS

- 5.1 Optia IDL Set
- 5.2 0.9% sodium chloride injection USP 1000 mL bag
- 5.3 ACD-A (Anticoagulant Citrate Dextrose Solution A) 750 mL bag
- 5.4 Triple lumen extension set, if applicable
- 5.5 Alcohol Preps, Gloves, Mask
- 5.6 Heparin flush syringes, as needed
- 5.7 0.9% saline flush syringes, as needed
- 5.8 Blood tubes
 - 5.8.1 Daily lab draw performed by CHC staff prior to collection include:
 - 5.8.1.1 Lavender tube for complete blood count (CBC) with manual differential.
 - 5.8.1.2 Lavender tube for a hematopoietic progenitor cell (HPC) phenotype, if applicable. HPC phenotype with the expression of CD-34 is used for stem cell collection. A HPC phenotype with an expression of CD-3 may be used for CAR-T collections.
 - 5.8.1.3 Light green plasma separator tube (PST) for complete metabolic profile (CMP).

5.8.1.4 Lavender tube for Type & Screen (T&S) drawn on first day of apheresis.

5.8.1.4.1 If T&S sample has been sent to Transfusion Services within forty-eight hours of first day of apheresis an “Apheresis Day #1 T&S Needed” tag should be placed in the bag with the blood sample to prevent the T&S from being cancelled.

5.8.1.5 Research tubes, as ordered.

5.9 Paperwork

- 5.9.1 PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*
- 5.9.2 On-demand printed product base labels, tie tags and tie tag labels
- 5.9.3 International Society for Blood Transfusion (ISBT-128) bar code labels
- 5.9.4 PBMT-COLL-018 *Pediatric Apheresis Checklist*
- 5.9.5 APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire*
- 5.9.6 APBMT-COMM-001 *Donor Selection Evaluation and Management*
- 5.9.7 APBMT-COMM-001 FRM2 *Summary of Donor Eligibility and Infectious Disease Testing*
- 5.9.8 APBMT-COMM-001 FRM3 *Donor Health History Questionnaire*
- 5.9.9 APBMT-COMM-001 JA1 *Medical History Exclusion Criteria*
- 5.9.10 STCL-GEN-009 FRM1 *Cellular Product Chain of Custody FRM1 (if applicable)*
- 5.9.11 STCL-GEN-009 FRM3 *Cellular Product Chain of Custody Form for Products Collected Outside NP*
- 5.9.12 APBMT-COMM-030 FRM1 *Adverse Event Form* (if applicable)
- 5.9.13 APBMT-COLL-001 *Optia Blood Prime Procedure*
- 5.9.14 PBMT-COLL-016 FRM2 *Pediatric Apheresis Order Using Optia*

6 EQUIPMENT

6.1 Optia Apheresis System

7 SAFETY

7.1 Follow all safety related Standard Operating Procedures (SOPs) and wear all required Personal Protective Equipment (PPE) when handling blood and body fluids. PPE includes but is not limited to gloves, surgical mask, face shield or goggles. Hand hygiene performed before and after patient contact and prior to tubing set up. All tubing connections made using aseptic technique.

8 PROCEDURE

8.1 Patient Identification and Assessment

- 8.1.1 Identify the patient by asking the parent/caregiver to state the patient's name and date of birth. Ensure that the name and birthdate on the patient identification wristband match.
- 8.1.2 Patient weight obtained daily by CHC nursing staff.
- 8.1.3 Patient identification labels printed from the electronic medical record and attached to the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet* and APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire*.
- 8.1.4 Complete the APBMT-COMM-001 FRM4 *Interim Donor History Questionnaire*.

8.2 Blood Draw

- 8.2.1 The CHC nursing staff collect blood samples from the CVC per hospital policy.
- 8.2.2 The CHC nursing staff notify the apheresis physician of any abnormal values or findings and document the outcome of the decision regarding acceptability of the patient or donor.
- 8.2.3 The apheresis nurse will review and record the completed blood count (CBC) and hematopoietic progenitor cell that expresses CD-34 in stem cell collections (if applicable) results on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*. Contact the apheresis physician for any abnormal results. Refer to APBMT-COMM-001 *Donor Selection, Evaluation and Management* for collection criteria. As a secondary check, abnormal parameters are listed on PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*.

8.3 Documentation and Labeling

- 8.3.1 Review the PBMT-COLL-016 FRM2 *Pediatric Apheresis Order Using Optia*.
- 8.3.2 Visually inspect each supply and reagent used to collect cellular therapy products for damage or evidence of contamination. Record on PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*. If a supply does not pass visual inspection, refer to PBMT-EQUIP-003 FRM3 *Unacceptable Supply and Corrective Action Log FRM3*.
- 8.3.3 Recorded lot numbers and expiration dates of apheresis related supplies on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*. Record any additional supplies on the spaces provided.
- 8.3.4 Record the current temperature and humidity on the PBMT-COLL-016 FRM 1 *Optia Leukapheresis Run Sheet* and if the temperature is within an acceptable range. Refer to PBMT-COLL-015 *Monitoring Temperature and Humidity* and PBMT-COLL-015 FRM 1 *Temperature and Humidity Log* for details.

- 8.3.5 Record contact phone number for patient/caregiver on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*.
- 8.3.6 Calculate the extracorporeal whole blood volume (WBV) and record on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*. Contact the apheresis physician if the extracorporeal WBV is greater than 15%.

8.4 Selecting the Procedure

NOTE: Procedural steps prompted by the machine in the order shown on the screen. Exact order of other steps in procedure can vary.

- 8.4.1 Confirm attached Optia power cord and plugged into a red power outlet. Turn the power switch ON, located on the upper right side of the system. The system performs a series of self-diagnostic tests to validate the functionality of the hardware and software before beginning the procedure. Once the tests are complete, the enabled buttons appear on screen prompting the start of the procedure.

- 8.4.1.1 Touch **Select Procedure**. The procedure selection screen appears.

- 8.4.1.2 Touch **CMNC Collection**.

- 8.4.1.3 Touch **Confirm**. The system loads the procedure software.

8.5 Loading the Tubing Set

- 8.5.1 Verify installed IDL filler in the centrifuge. The IDL filler has a black square on it.
- 8.5.2 Verify selection of correct tubing set and the expiration date on the package cover.
- 8.5.3 Verify recorded lot numbers and expiration dates of supplies used during collection on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*.
- 8.5.4 Touch **Prepare Tubing Set**. The screen appears instructing preparation of the set.

8.6 Unpacking the Lines and Bags

- 8.6.1 Put the IDL tubing set package on top of the centrifuge cover with the package label upright and facing you, and remove the cover from the package.
- 8.6.2 Take the procedure bags and vent bag out of the package and hang on the intravenous (IV) pole. Hang the bags right to left in this order: Collection bag, Plasma bag and Vent bag.
- 8.6.3 Take out the replace line and put the line over the right side of the front panel between the two sides of the IV pole.
- 8.6.4 Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).

- 8.6.5 Take out the AC line (orange luer connection) and the saline line (green spike) and hang the lines over the left side of the system.
 - 8.6.6 Take out the cassette and the channel, and put them on top of the centrifuge cover.
- 8.7 Snapping the Cassette into the Tray
 - 8.7.1 Take the cassette out of the package and put the bottom of the cassette in the bottom edge of the tray.
 - 8.7.2 Ensure that there is nothing lodged behind the cassette or the tray that could interfere with the loading.
 - 8.7.3 Hold a finger behind the tray to avoid excess pressure, which might cause the cassette to load manually. Press the top corners of the cassette to snap the cassette into the tray.
- 8.8 Loading the Channel in the Centrifuge
 - 8.8.1 Take the channel out of the package and put it on top of the centrifuge cover.
 - 8.8.2 Open the centrifuge door.
 - 8.8.3 Locate the pin on the filler latch. Raise the latch by pushing the pin toward the center of the filler while pulling up the latch.
 - 8.8.4 Turn the centrifuge so that the loading port faces you
 - 8.8.5 Extend the lines between the cassette and the channel and ensure that they are not twisted.
 - 8.8.6 Pull the channel up through the loading port and then through the opening in the center of the filler.
 - 8.8.7 Lower the filler latch and lock it in place.
 - 8.8.8 Position the lower collar holder on the filler latch so that the other lines do not obstruct the inlet line (pink line). Ensure that either the base of the pink line aligns with the space between the two screws or that it is adjacent to the indentation on the filler latch.
 - 8.8.9 Grasp the centrifuge loop below the lower collar and gently pull the collar down until “click” of the locking pin is heard as it pops out and locks the collar in place. Ensure that the notch at the base of the locking pin is visible. The notch with collar locked will be visualized.
 - 8.8.10 Starting with the connector, insert the channel into the groove in the filler, finishing with the inlet port. Run your finger over the groove and completely push down any inserted section of the channel in the groove. The channel must sit flush with the groove.
- 8.9 Loading the Lower and Upper Bearings, and Upper Collar
 - 8.9.1 Insert the narrow part of the lower bearing into the lower bearing holder, and the narrow part of the upper bearing into the upper bearing holder. Ensure that the braided section of the loop is not twisted.

- 8.9.2 Position the upper collar below the upper collar holder and insert the line into the holder. Pull the line up to secure the upper collar in the holder.
- 8.9.3 Spin the centrifuge clockwise to ensure that it rotates freely.
- 8.9.4 Close the centrifuge door.
- 8.9.5 Touch **Load**. The system lowers the cassette. Watch the cassette carefully to ensure that there are no objects or tubing caught under the cassette.

8.10 Testing the Tubing Set

- 8.10.1 Follow the instructions on the screen to perform the following steps:
 - 8.10.1.1 Clamp the line to the diversion bag. Heat seal the line and remove the bag if blood will not be collected using the diversion bag.
 - 8.10.1.2 Heat seal and remove the Replace line, if not used.
 - 8.10.1.3 Close the roller clamps on the inlet saline line and the return saline line.
 - 8.10.1.4 Clamp the line to the sample bulbs on the collection bag
 - 8.10.1.5 Clamp the line above the tubing containing the frangible connector on the accessory line of the collection bag.
 - 8.10.1.6 Touch **Continue**.
 - 8.10.1.7 Follow the instructions on the screens to clamp the inlet and return line.
 - 8.10.1.8 Touch **Continue**.

8.11 Priming the Tubing Set

- 8.11.1 Follow the instructions on the screen to perform the following steps:
 - 8.11.1.1 Aseptically connect the fluid containers.
 - 8.11.1.2 Fill the drip chambers.
 - 8.11.1.3 Insert the AC line in the AC fluid detector.
 - 8.11.1.4 Touch **Start Prime**. The system primes the AC line. After the AC line is primed, the system sounds a tone.
 - 8.11.1.5 Follow the instructions on the screen to open the inlet saline line and the return saline line.
 - 8.11.1.6 Touch **Continue**. The system primes the return line, the inlet line, and the RBC line. Before the system primes the channel, a test verifies correct installed filter. When the prime is complete, the system sounds a tone and the patient data screen appears.

8.12 Entering and Confirming Patient and Procedure Data

8.12.1 Entering patient data

8.12.1.1 Touch the buttons on the screen to enter the following patient information:

8.12.1.1.1 Sex

8.12.1.1.2 Height

8.12.1.1.3 Weight

8.12.1.1.4 Hematocrit (Hct)

8.12.1.2 The Optia system uses sex, height, and weight to calculate the donor/patient's total blood volume (TBV). Record this TBV on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet*.

NOTE: If the patient weighs less than (<) 25 kg (approximately 55 lb.), the system does not calculate a TBV. The TBV must be entered for the patient as calculated by the apheresis physician. Perform a blood prime on the machine if donor/patient weighs 50 kg or less. Refer to APBMT-COLL-001 *Optia Blood Prime Procedure*.

8.12.1.3 The Hct is used in two ways

8.12.1.3.1 To calculate the limits for plasma and collect volumes.

8.12.1.3.2 To calculate the initial plasma pump flow rate before the AIM system starts managing the concentration of cell through the port.

8.12.1.4 Touch **Confirm**. The run values screen appears.

8.12.2 Reviewing and confirming run values

8.12.2.1 Review the run values that appear on the screen and confirm that they are correct. A black border appears around the button of the primary run target. (Whole blood processed, TBV processed, Run Time, Collect volume: Target.)

8.12.2.2 Program the Optia to collect the amount of plasma and product volume ordered by apheresis physician at the start of the run.

8.12.2.3 To collect additional plasma during the run, enter the volume to be collected. A screen for additional plasma collected at start or end of procedure will appear with instructions.

8.12.2.4 To change a value, perform the following steps:

8.12.2.4.1 Touch the button on the screen that corresponds to the value to be changed. The data entry pad appears.

- 8.12.2.4.2 Enter a new value.
- 8.12.2.4.3 If a value is changed, the color of the value on the button changes from white to yellow. Affected values appear with a yellow arrow. As a result, the arrow points up or down to indicate an increase or decrease in the value.
- 8.12.2.4.4 Touch **Confirm**.

8.13 Emptying the Saline Drip Chamber

- 8.13.1 Follow the instructions on the screen to perform the following steps:
 - 8.13.1.1 Empty the saline drip chamber.
 - 8.13.1.2 Rehang the saline container.
 - 8.13.1.3 Touch **Confirm**.

8.14 Priming the Inlet Line and the Return Line

- 8.14.1 Be sure to perform the steps in the order indicated below and on the screen.
 - 8.14.1.1 Prime the inlet line. If using the diversion bag to collect a blood sample, prime the inlet line to the inlet line manifold only. If priming the line to the needle, dilute the sample with saline.
 - 8.14.1.2 Prime the return line and triple extension set (if used).
 - 8.14.1.3 Clamp the inlet line and the return line.
 - 8.14.1.4 Close the inlet saline line.
 - 8.14.1.5 If a diversion bag is not used, clamp and seal the line to the bag, and then remove the bag if not done earlier.
 - 8.14.1.6 Touch **Confirm**. The screen appears instructing connection to the patient.

8.15 Perform Blood Prime, if indicated. Refer to APBMT-COLL-001 *Optia Blood Prime Procedure*.

8.16 Connecting the Patient and Starting the Run

- 8.16.1 Follow the instructions below and on the screen to perform the following steps.
 - 8.16.1.1 If using a CVC or angiocath IV catheter remove the attached needle on the inlet line and discard it in a sharps container. The CHC staff nurse connects the patient lines using aseptic technique and remove the CVC caps and/or IV extension caps to maximize blood flows.
- 8.16.2 CHC staff connect the primed return line to the second port of the CVC or second access.

- 8.16.3 Touch **Start Run**. The system diverts the saline used to prime the tubing set to the saline container (approximately 40mL).

NOTE: If performing a blood prime, the system does not perform the step to divert the saline used to prime the tubing set. A blood prime removes all saline from the set.

- 8.16.4 Double check that the red inlet saline roller clamp is closed.
- 8.16.5 Follow the instructions on the screen to close the return saline line.
- 8.16.6 Touch **Continue**.
- 8.16.7 Follow the instruction on the screen to unclamp the return line.
- 8.16.8 Touch **Continue**.
- 8.16.9 Follow the instructions on the screen to empty the saline drip chamber and rehang the saline container.
- 8.16.10 Touch **Continue**. The system begins drawing the patient's blood into the tubing set, and the main run screen appears.
- 8.16.11 If a blood warmer is used, confirm that the connection of the tubing set to the blood warmer tubing is no higher than 20 inches above the return access to prevent the possibility of air entering the tubing.

8.17 Monitoring the Run

- 8.17.1 Attach the on-demand printed base label to the cellular product bag and plasma bag. Double check all labels for accuracy with a second nurse or the apheresis physician. Refer to *COMM-PAS-003 Labelling Cellular Therapy Products*. Ensure labeling completion before disconnecting the products from the machine at end of procedure.
- 8.17.2 View run information on the main screen. To return to the main screen after viewing a different screen, touch the go back button, or the tab for the current screen.
- 8.17.2.1 To access additional screens, touch the tab for the screen you want to view.
- 8.17.2.2 To access the collection status screen, touch the Collection Status tab. Use this screen to monitor the progress of the run and to adjust the collection preference.
- 8.17.2.3 Increase the inlet flow rate to maximize the collection. Inlet flow rates may range from 10 to 80 mL/min depending on patient height and weight and symptoms of citrate toxicity.
- 8.17.2.4 Monitor and recorded run parameters on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet* every 30 minutes to hourly. Verify that volumes displayed on the screens are consistent with the actual volumes in the fluid containers and in the bags.

- 8.17.2.5 Calcium gluconate IV given as precaution for citrate toxicity, if required. The dosage, rate, and administration notes added by the apheresis physician prior to patient starting the procedure.
- 8.17.3 The collection preference (CP) is a reference number the plasma pump uses to adjust the flow rate, which affects the concentration of cells that flow through the collect port.
 - 8.17.3.1 Place the Collection Preference Tool (CPT) under the collect line to monitor the color of the cells.
 - 8.17.3.2 To change the collection preference to match the color in the collect line with the color on the CPT, use the up/down arrows. The default collection preference is 50. If the CP is not changed, the system targets a CP of 60. If the CP is changed, the system targets a CP that is 10 points higher than the number selected, but is not less than a preference of 20.
 - 8.17.3.3 The collect line color should have an Hct of approximately 3% to 4%. If indicated for type of product, use a lower Hct.
 - 8.17.3.4 To darken the color in the collect line, decrease the CP. This increases the concentration of cells that flow through the collect port.
 - 8.17.3.5 To lighten the color in the collect line increase the CP to decrease the concentration of cells that flow through the collect port.
- 8.17.4 Buffy coat accumulation or a high white blood cell count can be a result of frequent alarms which cause the pumps to stop. To minimize buffy coat accumulation, refer to the Optimizing the Run section of the Spectra Optia Apheresis System Operator's Manual.
 - 8.17.4.1 The connector should be monitored for buffy coat accumulation throughout the run.
 - 8.17.4.2 The collect pump can be increased by increments of 0.1mL/min up to 1.5 until the buffy coat stops accumulating.
 - 8.17.4.3 Lower the CP if the interface is not high enough to allow the system to collect the buffy coat.
- 8.17.5 Managing platelet clumping in the Connector
 - 8.17.5.1 Clumping can affect collection efficiency by interfering with the separation in the connector. The potential for platelet clumping does not always correlate with the patient's platelet count.
 - 8.17.5.2 If visible platelet clumping in the connector, decrease the AC ratio to 8:1 until the clumping disappears and until the system has processed at least 1000 mL of inlet volume.

Adjust the inlet pump to desired rate and instruct the patient to report citrate toxicity symptoms.

- 8.17.5.3 If clumping has resolved, consider increasing the inlet AC ratio to 10:1. Allow the system to process 500 mL to 1000 mL of inlet volume before considering increasing the ratio again. Do not increase the ratio by more than 2.0 for every 500 mL to 1000 mL of inlet volume processed.
- 8.17.5.4 If clumping persists, leave the inlet AC ratio to 8:1 until the clumping disappears or for the remainder of the run. Some clumps may become clots that are difficult to eliminate. Maintaining the 8:1 ratio will help minimize the impact on the collection efficiency.

8.18 Changing the patient data

- 8.18.1 Touch the **Data** menu button. The data tabs appear.
- 8.18.2 Touch the **Patient Data** tab. The patient data screen appears.
- 8.18.3 Adjust the data, as necessary:
- 8.18.4 To adjust the Hct, touch Hct and enter the new hematocrit.
- 8.18.5 Touch **Confirm** to save the change.

8.19 Plasma Collection

8.19.1 Automatic Collection

- 8.19.1.1 Optia configuration allow automatically requested collection of plasma into the plasma bag at the start of the run.
- 8.19.1.2 Additional plasma can be entered by pressing the Plasma Bag plasma button on the Run Values screen

8.19.2 Concurrent plasma

- 8.19.2.1 Concurrent plasma can be collected into the product collection bag with a T-connector on the collection line

8.19.3 Direct Collection Method

- 8.19.3.1 Enter the desired amount of plasma to be collected into the MNC collection bag by pressing the Collect Bag plasma button

8.19.4 Gravity Plasma Transfer Method

- 8.19.4.1 To transfer plasma into the collection bag, manually lower the MNC collection bag so that it is below the plasma bag.
- 8.19.4.2 Press the yellow Start Transfer button to start the gravity drain from the plasma bag into the MNC collection bag

8.19.5 Plasma Transfer

8.19.5.1 Transfer plasma into the collection bag during the run before confirming rinseback. Collection phase plasma transfer unavailable.

8.19.5.1.1 To initiate a transfer, touch End Run menu button and then touch Plasma tab. The instructions for plasma transfer will appear on the screen.

8.19.5.1.2 Place the collection bag lower than the plasma bag and press Start Transfer. The plasma valve will move into the neutral position allowing plasma to flow by gravity from the plasma bag into the collection bag.

8.19.5.1.3 Once the plasma transfer is completed, press Resume Run. If the plasma transfer is done at the end of run, the screen will say End Transfer Patient/Donor.

8.20 Adding Anticoagulant to the Collection Bag if necessary

8.20.1 Clamp the line above the tubing containing the frangible connector on the accessory line of the collection bag.

8.20.2 Completely break the frangible connector by bending the tubing back and forth.

8.20.3 Using aseptic technique, remove the cap from the luer connector below the sterile barrier filter, and attach a syringe containing the desired amount of anticoagulant to the connector.

8.20.4 Unclamp the line above the frangible connector.

8.20.5 Slowly inject the anticoagulant through the sterile barrier filter into the collection bag.

8.20.6 Clamp the line above the frangible connector.

8.20.7 Remove the syringe from the luer connector.

8.20.8 To ensure delivery of all of the anticoagulant in the syringe into the collection bag, perform the following steps:

8.20.8.1 Attach a syringe containing at least 2.3 mL of saline to the luer connector. (The volume of the accessory line and sterile barrier filter is approximately 2.3 mL.)

8.20.8.2 Unclamp the line above the frangible connector.

8.20.8.3 Slowly inject the saline through the sterile barrier filter to flush the anticoagulant in the filter into the collection bag.

8.20.8.4 Clamp the line above the frangible connector.

8.21 Using the Sample Bulbs to Obtain a Product Sample

- 8.21.1 Ensure that the line between the collection bag and the manifold on the sample bulb assembly is clamped.
- 8.21.2 Close the clamp on one of the lines between the manifold and the sample bulb.
- 8.21.3 Thoroughly mix the product in the bag to ensure a representative sample has been obtained.
- 8.21.4 Unclamp the line between the collection bag and the manifold on the sample bulb assembly.
- 8.21.5 Gently squeeze the sample bulb attached to the line.
- 8.21.6 To express any excess sample back into the collection bag, perform the following steps:
 - 8.21.6.1 Invert the sample bulb, and hold it above the fluid level of the collection bag.
 - 8.21.6.2 Gently squeeze the sample bulb to express the excess sample into the bag.
 - 8.21.6.3 To use the residual air in the sample bulb to clear the fluid from the line between the collection bag and the sample bulb, perform the following steps:
 - 8.21.6.4 Hold the sample bulb upright and below the collection bag.
 - 8.21.6.5 Gently squeeze the sample bulb. The residual air in the bulb pushes the product from the line into the collection bag.
 - 8.21.6.6 While maintaining pressure on the sample bulb, close clamped line between the manifold and the sample bulb.
- 8.21.7 Before removing the sample bulb containing the product sample, permanently seal the line between the clamp below the manifold and the sample bulb.
 - 8.21.7.1 Disconnect the sample bulb at the seal on the line.

8.22 Ending the Run before a Run Target is Attained

- 8.22.1 Touch the **End Run** menu button.
 - 8.22.1.1 To discontinue the run and perform rinseback, touch the **Rinseback** tab and follow the instructions in ending the run with rinseback.
 - 8.22.1.2 To discontinue the run and skip rinseback, touch the **Disconnect** tab and follow the instructions in ending the run without rinseback.
 - 8.22.1.3 Touch the button on the screen to proceed with the selection, then touch **Confirm**.

8.23 Ending the Run **after** Run target is Attained

NOTE: If machine was primed with blood prior to connecting the donor/patient, do not perform rinseback.

- 8.23.1 Touch **Rinseback**. The screen appears instructing confirmation of the selection to perform rinseback.
- 8.23.2 Touch Proceed to Rinseback, and then touch **Confirm**.
- 8.23.3 Follow the instructions on the screen to clamp the inlet line.
- 8.23.4 Touch **Continue**. The system tests the pressure in the inlet line.
- 8.23.5 Follow the instructions on the screen to open the inlet saline line, and to clamp and then seal the lines to the plasma and collection bags.
- 8.23.6 Touch **Continue**. The screen appears that shows the status of the rinseback.
- 8.23.7 When rinseback is complete, follow the instructions in section titled “Completing the Procedure.”

8.24 Extending the run

- 8.24.1 Touch the button for the run target to be increased, and use the data entry pad to enter a new value for the target. The run values screen appears.

- 8.24.2 Review the run value and touch Confirm

NOTE: The system will continue the run. The run target screen appears and the system sounds a tone when reaches attained target.

8.25 Ending the run without rinseback

- 8.25.1 Touch the **End Run** menu button.
- 8.25.2 Touch the **Disconnect** tab. The screen appears asking confirmation of the selection to disconnect the patient.
- 8.25.3 Touch Proceed to Disconnect, and then touch **Confirm**.
- 8.25.4 Follow the instructions in section titled “Completing the Procedure.”

8.26 Completing the Procedure

- 8.26.1 Following a six-hour leukapheresis, the platelet count is typically lowered 50%. The attending apheresis physician will obtain a post platelet count at end of procedure, if applicable.
- 8.26.2 Disconnecting the patient. Follow the instructions on the screen to perform the following steps:
 - 8.26.2.1 Close the inlet saline line.
 - 8.26.2.2 Clamp the inlet line and the return line.
 - 8.26.2.3 CHC staff disconnect, replaces caps, and flush the patient’s CVC per Duke Hospital IV Therapy Protocol.

- 8.26.2.4 Seal the AC line, the saline line, and the lines to the bags.
- 8.26.2.5 Touch **Unload**. The system confirms closed saline lines and clamped inlet and return lines. Then it raises the cassette. The procedure summary screen appears.
- 8.27 Reviewing the procedure summary data
 - 8.27.1 Review the data on page 1 of the procedure summary.
 - 8.27.2 Touch **Next Page**.
 - 8.27.3 Review the data on page 2 of the procedure summary.
- 8.28 Removing the Tubing Set
 - 8.28.1 If Rinseback not performed, the channel will be full of fluid when the set is unloaded. After system raises cassette, remove channel by putting the cassette and the bags at a level below the channel, allowing the fluid in the channel to drain into the vent bag.
 - 8.28.1.1 Open the centrifuge door
 - 8.28.1.2 Remove the upper collar holder by grasping the lines above and below the collar, and pulling the lines downward.
 - 8.28.1.3 Remove the upper and lower bearings from the bearing holders.
 - 8.28.1.4 Remove the chamber from the bracket.
 - 8.28.1.5 Gently pull the channel from the filler
 - 8.28.1.6 Push in the locking pin on the centrifuge collar holder and remove the collar from the holder by grasping the tubes above the collar and pulling upward.
 - 8.28.1.7 Push the filler latch pin toward the center of the centrifuge, and raise the filler latch.
 - 8.28.1.8 Fold the channel in half, and pull the channel through the loading port and out of the centrifuge chamber.
 - 8.28.1.9 Lower the filler latch and close the centrifuge door.
 - 8.28.1.10 Remove the lines from the fluid detectors.
 - 8.28.1.11 Remove any bags from the IV pole.
 - 8.28.1.12 Press the latch on the upper right corner of the cassette tray, and lift the cassette from the tray.
 - 8.28.1.13 Discard the tubing set in the Biohazard Trash bins.
- 8.29 Documentation
 - 8.29.1 Record pre and post vital signs on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet* in the spaces provided.
 - 8.29.2 Verify and complete the PBMT-COLL-018 *Pediatric Apheresis Checklist*.

- 8.29.3 Notify the apheresis physician of any untoward side effects or abnormal findings.
- 8.29.4 Record final Run values and end time on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet* in the spaces provided.
- 8.29.5 Record final fluid balance on the PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet* in the spaces provided.
- 8.30 Cleaning of Machine
 - 8.30.1 If a blood spill occurs, inspect the system surface, front panel and centrifuge chamber. Clean the blood with the Duke Hospital approved disinfecting wipe.
 - 8.30.2 Before and after each use clean the system surface and front panel with the Duke Hospital approved disinfecting wipe.
 - 8.30.3 Document cleaning on PBMT-COLL-016 FRM1 *Optia Leukapheresis Run Sheet* and PBMT-EQUIP-001 FRM2 *Optia Apheresis Machine Quality Control Record*.

9 RELATED DOCUMENTS/FORMS

- 9.1 APBMT-COLL-001 Optia Blood Prime Procedure
- 9.2 APBMT-COMM-001 FRM2 Summary of Donor Eligibility and Infectious Disease Testing
- 9.3 APBMT-COMM-001 FRM4 Interim Donor History Questionnaire
- 9.4 APBMT-COMM-001 Donor Selection Evaluation and Management
- 9.5 APBMT-COMM-001 FRM3 Donor Health History Questionnaire
- 9.6 APBMT-COMM-001 JA1 Medical History Exclusion Criteria
- 9.7 APBMT-COMM-030 FRM1 Adverse Event Form
- 9.8 COMM-PAS-003 Labelling Cellular Therapy Products
- 9.9 PBMT-COLL-016 FRM1 Optia Leukapheresis Run Sheet
- 9.10 PBMT-COLL-015 Monitoring Temperature and Humidity
- 9.11 PBMT-COLL-015 FRM1 Temperature and Humidity Log
- 9.12 PBMT-EQUIP-001 FRM2 Optia Apheresis Machine Quality Control Record
- 9.13 STCL-GEN-009 FRM1 Cellular Product Chain of Custody Form
- 9.14 STCL-GEN-009 FRM3 Cellular Product Chain of Custody Form for Products Collected Outside NP FRM3

10 REFERENCES

- 10.1 *Spectra Optia Apheresis System Operator's Manual*. Terumo BCT, Inc. Lakewood, CO. 2015

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	M. Christen	<ul style="list-style-type: none">• Added and removed paperwork to correspond with the merge of the ABMT and PBMT paperwork throughout the document.• Added PBMT-COLL-018 Pediatric Apheresis Checklist• Removed PBMT-COLL-007 Interim Pediatric Donor History Questionnaire.

Signature Manifest

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PBMT-COLL-016 Spectra Optia Apheresis System Continuous Mononuclear Cell (CMNC) Collection Procedure

Author

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