



## Division of Cellular Therapy

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Extracorporeal Photopheresis using the Therakos Cellex System

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## **ABMT-GEN-025**

# **EXTRACORPOREAL PHOTOPHERESIS USING THE THERAKOS CELLEX SYSTEM**

## **1 PURPOSE**

- 1.1 To describe the procedure and supplies required for performing extracorporeal photopheresis (ECP) using the Therakos CELLEX System.

## **2 INTRODUCTION**

- 2.1 ECP is a photoimmune therapy for the treatment of cutaneous T-cell lymphoma (CTCL) in dermatology patients, graft vs. host disease (GVHD) in blood and marrow transplant (BMT) patients, and solid organ rejection in patients that underwent heart or lung transplants. ECP may also be used for the treatment of bronchiolitis obliterans (BOS) without transplant. The goal of ECP is to alter the T-cell population to not attack the host.
- 2.2 During the procedure, the white blood cells (WBC), which contain lymphocytes, are separated from whole blood via apheresis. The WBC product is combined with a photoactive drug (8-methoxypsoralen, also referred to as Methoxsalen or Uvadex), and exposed to ultra violet-A (UVA) light. Methoxsalen attaches to the T-lymphocyte cells, causes photosensitivity, altering the DNA and causing apoptosis of the treated cells. A small number of lymphocytes (<10%) are collected each procedure in the WBC product. All blood components, including the treated WBC's, are returned to the patient. This is a closed circuit procedure; the treatment Bag is never disconnected from the system. The procedure can be performed as either a continuous flow therapy (double needle mode) or a cyclic flow therapy (single needle mode).
- 2.3 Patients considered for photopheresis therapy are referred from the Adult Blood and Marrow Transplant (ABMT) daily, return or GVH clinic, Dermatology clinic (CTCL, Sezary Syndrome), Cardiology/Pulmonary Transplant Medicine clinic (solid organ transplant of heart/lung) or Autoimmune clinic.
- 2.4 Each patient is evaluated by their referring physician/designee prior to the initiation of the procedure. This evaluation consists of, but is not limited to, the patient being able to maintain the required photopheresis schedule: 2 days/week, for 24 treatments and maintain adequate intravenous (IV) access. Long term peripheral intravenous (PIV) or central venous line (CVC) access is required for adequate ECP treatment. A physician/designee will obtain informed consent, and complete the physician order for ECP. Both the signed consent and the signed physician order should be given to the apheresis nurse to keep in the patient's ECP chart for reference. The physician order for ECP will include the frequency of lab tests.
- 2.5 For GVHD patients, the referring physician/designee in the ABMT group will complete at photopheresis start note consisting of patient's diagnosis and GVHD grade, including what organs are involved. The indication, timing of the procedure, proposed regimen, and additional labs needed to monitor the patient's

clinic course and maintain patient safety will be placed into infusion therapy plan for photopheresis to promote safe administration of ECP.

- 2.6 For CTCL and/or solid organ rejection patients, the referring physician will discuss patient goals with the designated ABMT physician. The ABMT physician will complete the photopheresis start note. The referring physician will be given feedback during the treatment regimen of any potential issues that may arise. The designated ABMT physician will document all start, progress, and stop ECP notes.
- 2.7 Maintenance therapy is discussed by the referring physician after evaluating the success/benefit of the initial treatment period. A photopheresis progress note will document the continuation or holding of the treatment.
- 2.8 At completion of ECP therapy, a photopheresis summary note will be completed by the referring physician.
- 2.9 The daily physician will see the patient during each treatment and complete a procedure note. The procedure note will consist of patient's diagnosis, GVHD grade, reason for the treatment, and patient's status. CVC and PIV status and potential side effects discussed and documented.

### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 The ABMT apheresis nurse is responsible for the photopheresis procedure using the CELLEX system.
- 3.2 The ABMT daily physician, physician extenders, and apheresis nurse are responsible for patient care during photopheresis.
- 3.3 The referring physician and/or the designated ABMT physician is responsible for completing the photopheresis notes.

### **4 DEFINITIONS/ACRONYMS**

- 4.1 AABB: American Association of Blood Banks
- 4.2 ABMT: Adult Blood and Marrow Transplant
- 4.3 ACD-A: Acid Citrate Dextrose Formula A
- 4.4 BMT: Blood and Marrow Transplant
- 4.5 CBC: Complete Blood Count
- 4.6 Cm: Centimeter
- 4.7 CTCL: Cutaneous T-Cell Lymphoma
- 4.8 CVC: Central venous catheter
- 4.9 DNA: Deoxyribonucleic Acid
- 4.10 ECP: Extracorporeal Photopheresis
- 4.11 ECV: Extracorporeal Volume
- 4.12 EMR: Electronic Medical Record

- 4.13 FR: French
- 4.14 g: Gauge
- 4.15 GVHD: Graft vs. Host Disease
- 4.16 HCT: Hematocrit
- 4.17 IV: Intravenous
- 4.18 kg: Kilogram
- 4.19 LCD: Liquid crystal display
- 4.20 mL: Milliliter
- 4.21 PIV: Peripheral Intravenous
- 4.22 SOP: Standard Operating Procedures
- 4.23 PPE: Personal Protective Equipment
- 4.24 TBV: Total Blood Volume
- 4.25 UVA: Ultra Violet-A
- 4.26 WBC: White Blood Cell

## 5 MATERIALS

- 5.1 THERAKOS® CELLEX disposable Photopheresis Procedural kit
- 5.2 Acid Citrate Dextrose Formula-A (ACD-A) solution
  - 5.2.1 Available in 250ml, 500 mL, 750 mL, or 1000 mL bags
- 5.3 Normal Saline 0.9% Sodium Chloride (NS) solution
  - 5.3.1 Available in 500 mL bags
- 5.4 Venipuncture Supplies:
  - 5.4.1 See ABMT-COLL-011 *Venipuncture Procedure*
- 5.5 Central Venous (CVC) Access Supplies:
  - 5.5.1 CVC access device
  - 5.5.2 Dressing change kit
  - 5.5.3 IV extension
  - 5.5.4 Sterile 0.9% Sodium Chloride 10 mL syringe
- 5.6 Heparin flush syringes, as needed
- 5.7 0.9 Sodium Chloride 10 mL syringes, as needed
- 5.8 Blood Collection Tubes
  - 5.8.1 Blood tube (Lavender) for CBC collection on day 1
  - 5.8.2 Other blood tubes if other labs ordered
  - 5.8.3 10 mL syringes for lab draw

5.8.4 Transfer device

5.9 Paperwork:

5.9.1 Patient armband

5.9.2 Blood specimen label if lab(s) ordered

5.9.3 ABMT-GEN-025 FRM1 Physician Photopheresis Note (in downtime)

5.9.4 ABMT-GEN-025 FRM2 Photopheresis Run Sheet

5.9.5 ABMT-GEN-025 FRM3 Physician Order Sheet Extracorporeal Photopheresis-ECP

## 6 EQUIPMENT

6.1 THERAKOS® CELLEX Extracorporeal Photopheresis System

## 7 SAFETY

7.1 Follow all safety related standard operating procedures (SOP) and wear all necessary personal protective equipment (PPE) when handling potentially hazardous blood and body fluids. PPE includes but is not limited to gloves and surgical mask. Hand hygiene will be performed before and after patient contact and prior to tubing set up. All tubing connections will be made using aseptic technique.

## 8 PROCEDURE

8.1 Prior to initiating the first ECP procedure, confirm that the consent for ECP has been signed, and the ABMT-GEN-025 FRM3 *Physician Order Sheet Extracorporeal Photopheresis-ECP* has been signed and is in the patient's ECP chart and/or EMR.

8.2 Prior to each procedure, a patient assessment is performed. This assessment includes, but is not limited to:

8.2.1 Assessment of vital signs.

8.2.2 Assessment of any change in health history since last procedure.

8.2.3 Assessment of any new symptoms of pain, fever, cough, shortness of breath, central venous access redness or drainage.

8.2.4 Medication reconciliation.

8.2.5 Any negative alteration in assessment, vital signs, symptoms, will be reported to the patient's attending physician/coordinator for evaluation.

8.3 A complete blood count (CBC) is performed on the first day of treatment session (unless it has been completed within the last 24 hours). The CBC results are used for calculating the patient's safe extracorporeal volume (ECV). The patient's attending physician/coordinator may request additional weekly labs to be drawn.

8.4 Calculating the patient's fluid balance limit is required with each treatment. The AABBs' guidelines set a maximum ECV to be less than or equal to 15% of the patient's total blood volume (TBV). Refer to Section 10: Fluid Balance

Management in the Therakos Operators Manual for the Table listing Body Build Factors (ml/kg). There are also laminated reference tables for the body build factors, estimated patient TBV, safe minimal and maximum ECV and estimated ECV based on the hematocrit (HCT) for single needle and double needle procedure modes, located in the Therakos Operators Manual. All of this information is recorded on the ABMT-GEN-025 FRM2 *Photopheresis Run Sheet*.

- 8.4.1 Obtain HCT from CBC.
- 8.4.2 Obtain weight in kilograms (kg).
- 8.4.3 Obtain body build factor from reference table.
- 8.4.4 Using the following formula, calculate the patient's TBV:
- 8.4.5  $\text{Weight in kg} \times \text{body build factor} = \text{TBV}$ .
- 8.4.6 To determine the minimum safe ECV, multiply the TBV by 10%.
- 8.4.7 To determine the maximum safe ECV, multiply the TBV by 15%.
- 8.4.8 To determine reserve volume, subtract CELLEX ECV from 15%TBV.
- 8.4.9 CELLEX estimated ECV relative to % HCT, access mode, and return bag threshold should not exceed the patient's maximum safe ECV, unless if approved by provider.
- 8.5 Record all the required information on the ABMT-GEN-025 FRM2 *Photopheresis Run Sheet*.
- 8.6 Notify referring physician and/or daily physician if vital signs, lab results, or % ECV are out of parameters. Refer to ABMT-GEN-025 FRM2 *Photopheresis Run Sheet*.
- 8.7 Positioning and Turning on the Machine:
  - 8.7.1 Position machine beside the chair/bed where patient will be located.
  - 8.7.2 Ensure there is no obstruction of airflow on any side of the machine.
  - 8.7.3 Machine must be plugged into a red electrical outlet.
  - 8.7.4 Lock wheels.
  - 8.7.5 Turn instrument on using the black power switch on the top right side of the instrument.
  - 8.7.6 The instrument will beep and perform a self-check. The color LCD touch sensitive screen will remain blank for 30 seconds before the THERAKOS® logo appears. At the end of this set up, the operator interface screen is displayed. The initial screen is titled **PRIME**.
- 8.8 Prepare instrument for loading kit.
  - 8.8.1 Open the photoactivation chamber door by gently pulling door open by notch at the top.
  - 8.8.2 Open the centrifuge chamber door.
  - 8.8.3 Position the centrifuge frame so the two bearing holders are on the right side.

- 8.8.4 Rotate the centrifuge bowl holder so the retainer clip is facing front.
- 8.8.5 Open the drive tube latch and clamp.
- 8.8.6 Position all pump handles so the narrow ends face the center of the pump deck.
- 8.8.7 Zero out the return bag, treatment bag, and centrifuge on touch screen.
- 8.9 Install the THERAKOS CELLEX photopheresis procedural kit. These steps do not have to be performed in the exact order as they are listed.
  - 8.9.1 Inspect the procedural kit for damage.
  - 8.9.2 Record the lot number, kit number, and expiration date of the kit on the ABMT-GEN-025 FRM2 *Photopheresis Run Sheet* in labeled spaces.
  - 8.9.3 Place the kit on the pump deck of the instrument with the labeling text facing you.
  - 8.9.4 Peel the cover off and discard.
  - 8.9.5 Remove the photoactivation module from the protective tray. Handle the module by placing fingers on the outer rim.
  - 8.9.6 Insert the photoactivation module into the photoactivation chamber with the tubing lines at the top, and close the photoactivation chamber door. Confirm that the lines are not pinched by the door at the top.
  - 8.9.7 Remove centrifuge bowl from package and place into left side of the centrifuge chamber.
  - 8.9.8 Remove the pump tubing organizer and remaining components from the package and place them on the pump deck surface. Discard the packing kit.
  - 8.9.9 Inspect the kit for secure protective caps on the patient lines and fluid spikes. Sterility will be compromised if any caps are dislodged prior to use.
  - 8.9.10 Hang the return bag (imprinted with the letter “R” at the top) on the right front Load Cell Hook below the Pump Deck. The tubing should be on the left side.
  - 8.9.11 Hang the Treatment Bag (imprinted with the letter “T” at the top) on the left front load cell hook below the pump deck. The tubing should be on the right side.
  - 8.9.12 The treatment and return bags must be hung properly on the load cell hooks, free of any impingement from other kit components, and not removed at any time during or after **PRIME**. This will ensure accurate Fluid Balance reading during the treatment, and avoid priming alarms.
  - 8.9.13 Remove bundled tubing lines from the pump tubing organizer. Hold the organizer at an angle and align the three indents on the front with the three tabs on the surface of the pump deck, push into place. Press down on the rear edge of the pump tubing organizer to latch it into place against the two rear locking tabs.

- 8.9.14 Insert the reinforced lower drive tube with the black stripe facing the rear into the groove on the drive tube clamp assembly. The keyed notches of the drive tube will mate with the clamp assembly. This can be tricky. Adjustment of the drive tube may be necessary to ensure proper loading.
- 8.9.15 Close the drive tube clamp around the drive tube in the assembly.
- 8.9.16 Close the drive tube latch over the clamp. An audible beep will sound when latch is closed properly. The instrument cannot prime if the lower drive tube is not properly seated and latched in the drive tube assembly.
- 8.9.17 Load the centrifuge bowl into the centrifuge bowl holder, aligning the tabs at the bottom of the bowl with the slots in the holder.
- 8.9.18 Rotate the bowl clockwise until the black retainer clip locks into place.
- 8.9.19 Load the lower drive tube bearing into the lower bearing retainer clip, aligning the notches, until it clicks into place. Close the latch.
- 8.9.20 Load the upper drive tube bearing into the upper bearing retainer clip, aligning the notches, until it clicks into place. Close the latch.
- 8.9.21 Verify that each tube bearing is correctly seated in the bearing retainer clip and the latches are closed.
- 8.9.22 Insert centrifuge bowl tubing lines through the tubing exit slot.
- 8.9.23 Insert centrifuge bowl tubing lines into the tubing guides in front of the drive tube clamp.
- 8.9.24 Spin the centrifuge frame clockwise to confirm proper bowl installation.
- 8.9.25 Manually load each pump tubing segment onto the pump handle by stretching the tubing over the handle. Turn the handle counter-clockwise to catch the tubing in the cutout and load it onto the pump. Rotate the handle counter-clockwise twice and clockwise once to confirm the tubing is loaded and the pump handle turns freely.
- 8.9.26 Remove the smart card from the pump tubing organizer. Insert the card into the smart card slot located to the right of the operator screen. The gold connector surface should be facing away from you. An audible beep will confirm correct insertion.
- 8.9.27 Remove the protective pressure domes from the transducers.
- 8.9.28 Install the three pressure domes onto the three pressure transducers. Pinch the dome clip, remove the protective cover, seat the dome on the transducer and release the clip. Gently rock the dome back and forth to verify it is seated securely.
- 8.9.29 Handle the pressure dome only by the clip. Touching the membrane may cause damage. Do not remove the pressure domes after **PRIME**. Improper pressure dome attachment may cause membrane damage, resulting in loss of sterility, fluid leaks, blood leaks, blood loss to the patient and a failed treatment.



- 8.9.30 Set the bundled fluid spike lines aside. Install the tubing lines from the pump tubing organizer into the air detector block as follows, starting on the right side:
  - 8.9.30.1 Patient Return Line (Blue stripe)
  - 8.9.30.2 Patient Collect Line (Red stripe)
  - 8.9.30.3 Patient ACD-A Line (Orange stripe)
  - 8.9.30.4 Return Bag Line (Blue stripe)
  - 8.9.30.5 Treatment Bag Line (Orange stripe)
- 8.9.31 The red striped line to the return Bag and the fluid spike lines do not need to be monitored for air, and are not inserted into air detectors.
- 8.9.32 Missing or improperly installed lines will result in priming alarms.
- 8.9.33 Install the hematocrit cuvette into the hematocrit sensor housing.
- 8.9.34 Avoid touching the hematocrit cuvette on the sides. Finger oils may affect the light transmission through the lens.
- 8.9.35 Align the treatment bag, return bag, and the photoactivation module tubing lines into the tubing guide at the front edge of the pump deck.
- 8.9.36 Remove the packing tape from the solution spike lines and inspect tubing for kinks.
- 8.9.37 Inspect the NS solution, and the ACD-A solution for damage, discoloration and leakage.
- 8.9.38 Record the lot numbers and expiration dates of each solution bag on the ABMT-GEN-025 FRM2 *Photopheresis Run Sheet* in labeled spaces.
- 8.9.39 Spike the ACD-A with the orange striped line. Hang the ACD-A bag on the lower right side of the instrument, on the back hook.
- 8.9.40 Spike the NS solution with the clear line. Hang the NS bag on the lower right side of the instrument, on the front hook.
- 8.9.41 Squeeze and mid-fill both drip chambers.
- 8.9.42 Correct placement of the NS and ACD-A bags is essential. Incorrect placement can result in clotting in the kit, patient blood loss, and a failed treatment.
- 8.9.43 Remove the packing tape from the patient Lines. Inspect tubing for kinks.
- 8.9.44 Close the red clamp on the patient collect line (Red stripe).
- 8.9.45 Clean the needleless injection port on the patient collect line with an alcohol pad.
- 8.9.46 Remove the cap from the patient return line (Blue stripe), and aseptically connect it to the needleless port of the patient collect line.
- 8.9.47 Verify the blue clamp on the patient return line is open.

- 8.9.48 Place the patient lines aside in patient area.
- 8.9.49 Final Inspection before **PRIME**:
  - 8.9.49.1 Close the centrifuge chamber door, making sure the bowl outlet tubing is not pinched under the door.
  - 8.9.49.2 Visually inspect pressure domes and air detectors.
  - 8.9.49.3 Check that the hematocrit cuvette is seated in the hematocrit sensor. Visually inspect all pumps and tubing.
  - 8.9.49.4 Inspect solution bags for content, correct placement and primed drip chambers.
  - 8.9.49.5 Verify that the patient collect line (Red) Clamp is closed and the patient return line (Blue) clamp is open.
  - 8.9.49.6 Check all tubing lines for kinks.
- 8.10 Initiate **PRIME** by pressing **START** at the lower left of the operator interface screen. The instrument will automatically prime.
- 8.11 At the completion of the automatic prime, a screen titled **PRIME/PRIME ACCESS** will appear.
- 8.12 You will be prompted to open the centrifuge chamber door and check the drive tube installation below the centrifuge bowl for leaks. Close the centrifuge chamber door. Press **CLOSE** on the prompt.
- 8.13 Holding the end of the Patient Lines over a waste basket, open the patient access line (Red) clamp and press **START**. An automatic 4mL of ACD-A solution will be delivered through the end of the line (**Press Prime two times, if required**).
- 8.14 Close the patient access line (Red) clamp.
- 8.15 Establish patient access. Overall treatment time is dependent on the performance of the access.
  - 8.15.1 Peripheral access: Must be able to accommodate negative pressure for draw, flowing at >25 mL/min, and positive pressure for return.
    - 8.15.1.1 18g IV angio-catheter for draw and return
    - 8.15.1.2 18 or 20g IV angio-catheter for return may be used.
    - 8.15.1.3 16g or 17g fistula needle for draw and return
  - 8.15.2 Central Venous Access: Must be able to withstand negative pressure without collapsing, and provide a flow rate >25 mL/min.
    - 8.15.2.1 Acceptable types of accesses include:
      - Apheresis Catheter
      - Implanted Ports
    - 8.21.2.3 Apheresis catheter should have a minimal internal diameter of 9 French (FR) and maximum length of 36 cm.

- 8.21.2.4 Implanted ports designed for both high speed input and output are acceptable. Appropriate access needles will be required for these subcutaneous ports.
- 8.16 Following prime Access and establishing patient access, select either **Single or Double Needle Mode**. The mode of access may be changed anytime during the treatment.
- 8.17 It is recommended that single needle mode settings be entered prior to starting double needle mode procedures in the event that the procedure is changed to single needle mid-procedure.
  - 8.17.1 Single Needle Mode:
    - 8.17.1.1 Confirm that the return line (Blue) remains connected to the patient access or collect line (Red) needle-free port.
    - 8.17.1.2 Connect the collect line to the patient's access site.
    - 8.17.1.3 Select single needle mode by pressing **Single Needle** at the lower left of the operator interface screen.
    - 8.17.1.4 Verify the screen display shows single needle configuration.
    - 8.17.1.5 Change the **Return Limits Minimum Pressure** to -100. This change allows the return line pressure to be less sensitive during draw.
      - 8.17.1.5.1 Press **SETUP** at the lower middle of the screen.
      - 8.17.1.5.2 There are two pages of **SETUP** parameter settings. Press the arrow at the bottom right of the screen to access the second page. Press again to return to the first page.
      - 8.17.1.5.3 Find the return limits min pressure settings, press the up and down arrows to adjust the default setting.
      - 8.17.1.5.4 Press **SAVE** to save change and return you to previous screen.
  - 8.17.1.6 Change the Return Bag Threshold to 100mL:
    - 8.17.1.6.1 Press **SETUP** at the lower middle of the screen.
    - 8.17.1.6.2 There are two pages of **SETUP** parameter settings. Press the arrow at the bottom right of the Screen to access the second page. Press again to return to the first page.
    - 8.17.1.6.3 Find the return bag setting, press the up and down arrows to adjust the default setting.
    - 8.17.1.6.4 Press **SAVE** to save change and return you to previous screen.

- 8.17.1.7 Press **Start** at the lower left of the screen.
- 8.17.1.8 Single Needle Mode will draw whole blood from the patient into the centrifuge bowl. The bowl will spin and concentrate leukocytes. Red blood cells and plasma are pooled into the return bag and then intermittently returned to the patient. The return bag threshold value (mL) determines the frequency of **RETURNING** as well as the ECV. The blood flow from and to the patient is discontinuous, and results in higher ECV's than in double needle mode. The whole blood processed target is 1500mL.

#### 8.17.2 Double Needle Mode:

- 8.17.2.1 Close the blue clamp on the return line (Blue).
- 8.17.2.2 Remove the return line (Blue) from the collect line (Red) and connect to patient's return access site.
- 8.17.2.3 Connect the collect line (Red) to the patient's access site.
- 8.17.2.4 Select double needle mode by pressing **Double Needle** at the lower left of the operator interface screen.
- 8.17.2.5 Verify the screen display shows double needle configuration.
- 8.17.2.6 Change the return limits minimum pressure to -100. This change allows the return line pressure to be less sensitive during draw.
  - 8.17.2.6.1 Press **SETUP** at the lower middle of the screen.
  - 8.17.2.6.2 There are two pages of **SETUP** parameter settings. Press the arrow at the bottom right of the screen to access the second page. Press again to return to the first page.
  - 8.17.2.6.3 Find the return limits min pressure settings, press the up and down arrows to adjust the default setting.
  - 8.17.2.6.4 Press **SAVE** to save change and return you to previous screen.
- 8.17.2.7 Change the Return Bag Threshold to 100mL:
  - 8.17.2.7.1 Press **SETUP** at the lower middle of the Screen.
  - 8.17.2.7.2 There are two pages of setup parameter settings. Press the arrow at the bottom right of the screen to access the second page. Press again to return to the first page.

- 8.17.2.7.3 Find the return bag setting, press the up and down arrows to adjust the default setting.
- 8.17.2.7.4 Press **SAVE** to save change and return you to previous screen.
- 8.17.2.8 Press **Start** at the lower left of the screen.
- 8.17.2.9 Double needle mode is a continuous flow mode. Whole blood will be drawn from the patient into the centrifuge bowl. The bowl will spin and concentrate leukocytes. The excess red cells, plasma, and processed ACD-A will be returned to the patient through the Return Line. The whole blood processed target is 1500mL.
- 8.18 After initiating the procedure, begin monitoring the patient collect and return line flow rates and pressure. Default collect and return flow rates are set at 50mL/min. A collect flow rate higher than 50mL/min may result in decreased cell collection efficiency. In both double needle mode and single needle mode, lower collect rate to 25mL/min during **Purging Air Phase** of treatment. In double needle mode, lower the return rate to 10mL/min during **Purging Air Phase** of treatment. A collect/return flow rate of 40-45mL/min is ideal. Collect and return rates may vary from 25-50 mL/min depending on patient situation. To adjust the flow rates, press the arrows above the collect and return flow rate graphs on the screen. In double needle mode, the collect and return flow rates can be different, but the return flow rate needs to be 5mL/min higher than the collect, if tolerated.
- 8.19 Monitoring throughout the procedure requires assessing the patient for symptoms of fluid imbalance, citrate toxicity from the ACD-A, access/return site patency, monitoring for lipemic plasma, clotting in the system, and addressing all alarm conditions. Whenever an alarm condition occurs, the instrument will sound an audible alarm and display the probable cause of the alarm and recommended action on the screen. Refer to the Section 6: Correcting Alarms in the Therakos Operators Manual for additional help in resolving alarm conditions. If additional support is required, call Therakos Technical Support at 1-877-566-9466.
  - 8.19.1 If patient develops citrate toxicity, give ordered Calcium products as needed. \*Remember that IV Calcium **CANNOT** be given while the photoactivated product is being returned and/or using single needle mode.
- 8.20 Once the whole blood processed target of 1500mL has been reached, the **BUFFY COAT** cycle will begin. During **BUFFY COAT**, the cells are concentrated in the centrifuge bowl, and diverted to the treatment bag. Elutriation occurs during this cycle. The **BUFFY COAT** collection is complete when the HCT sensor detects a HCT of 24% leaving the centrifuge bowl and entering the treatment bag. The **BUFFY COAT** collection needs to be monitored to verify HCT is correct while entering the HCT Sensor.
- 8.21 At the completion of **BUFFY COAT**, the content of the centrifuge is emptied into the return bag and returned to the patient. There will be 50mL left in the return bag that will be reinfused after the treated cells are reinfused to ensure all the treated cells are returned to the patient.

- 8.22 If double needle mode is being used, the collect line access can now be discontinued since there will not be any more withdrawal from the patient. Be sure to close the clamp, disconnect the collect line and cover the end with a sterile cap.
- 8.23 After the instrument finishes **RECIRCULATION**, or mixing, of the **BUFFY COAT**, the calculated dose of UVADEX to be injected into the Treatment Bag will be displayed on the screen. The formula used to calculate the UVADEX dose is:  
$$\text{Treatment Volume (mL)} \times 0.017 = \text{UVADEX dose (mL)}$$
- 8.24 The treatment volume will be displayed below the photoactivation module diagram on the screen.
- 8.25 Draw up the proper dose of UVADEX from the vial provided from pharmacy using a syringe and needle. Remove the needle and attach syringe to the luer lock needle-free port at the bottom of the treatment bag and inject the medication into the bag. Rinse the syringe three times by withdrawing from the bag and re-injecting. Do not remove the treatment bag from the load cell hook or inaccurate fluid balance readings may result.
- 8.26 Press the **Photoactivation symbol** on the screen to initiate photoactivation. Once photoactivation has begun, you may open centrifuge door to allow unit to cool down.
- 8.27 The photoactivation time will be displayed in the upper right of the screen, below the **STOP** symbol.
- 8.28 If **PHOTOACTIVATE** is interrupted for any reason, press the **Photoactivation symbol** on the screen to resume.
- 8.29 If the **RETURN** is interrupted for any reason, press **START** on the screen to resume.
- 8.30 After photoactivation is complete, the treated cells are automatically reinfused to the patient. After the treatment bag is emptied, the remaining fluid in the return bag (50mL) is also returned to the patient, ensuring all the treated cells are returned to the patient. \*Remember that IV Calcium **CANNOT** be given while the photoactivated product is being returned.
- 8.31 The treatment complete screen appears when the return bag fluid has been returned to the patient.
- 8.32 Record the final values on the ABMT-GEN-025 FRM2 *Photopheresis Run Sheet*.
- 8.33 Clamp the patient's return line and access line if it has not already been disconnected and release the kit.
- 8.34 Disconnect the patient.
- 8.35 Provide care to the access sites per Duke Policy. PIV's may be flushed and secured and left in for the procedure the next day, or removed and new PIV's started for the next procedure. Flush CVC per Duke Hospital policy.
- 8.36 Monitor the patient's vital signs. Do not allow them to stand and ambulate prior to evaluating stabilization of their fluid shifts.

- 8.37 Reinforce discharge instructions to the patient:
- 8.37.1 Wear sunglasses and sunscreen for 24 hours due to increased sun sensitivity to eyes and skin
  - 8.37.2 Possible slight elevation in temperature
  - 8.37.3 Possible urticaria
  - 8.37.4 Possible hypertension
  - 8.37.5 Risk of bleeding post procedure
- 8.38 Removing the kit post procedure (These steps do not have to be performed in the exact order as they are listed).
- 8.38.1 Press **RELEASE KIT** at the lower left of the screen, if not already completed. All valves will be released so the kit can be removed from the instrument. **DO NOT PRESS 'RELEASE KIT' UNTIL ALL PATIENT LINES HAVE BEEN CLAMPED** as blood may flow back into the kit.
  - 8.38.2 Pinch the pressure dome tabs together and pull upward to release pressure domes.
  - 8.38.3 Return the protective pressure domes for the transducers.
  - 8.38.4 Remove each pump tubing segment by placing a finger beneath the pump tubing and gently rotating the pump counter-clockwise 1-2 turns.
  - 8.38.5 Remove all lines from the air detectors.
  - 8.38.6 Remove the pump tubing organizer by pulling backward on both the release clips and lifting the organizer upward.
  - 8.38.7 Open the centrifuge chamber door, if not already opened (See 8.3.1).
  - 8.38.8 Open the drive tube latch.
  - 8.38.9 Release the top and bottom drive tube bearings.
  - 8.38.10 Remove the centrifuge bowl by gently pushing down the black lock clip on the bowl holder and rotating the bowl counter clockwise. Lift upward to remove the bowl.
  - 8.38.11 Remove the remaining procedural kit components and fluid bags.
  - 8.38.12 Discard the used procedural kit in a biohazard waste receptacle.
  - 8.38.13 Clean and disinfect the instrument with a hospital approved solution to prevent cross contamination. Clean the inside of the centrifuge chamber and inside of centrifuge chamber door to remove bearing grease deposited during the procedure.
  - 8.38.14 Close the centrifuge door.
  - 8.38.15 Turn the instrument power off.
  - 8.38.16 Please refer to the THERAKOS Operators Manual for more information about the THERAKOS instrument, set up, kit installation, troubleshooting, alarm resolution, fluid balance and technical bulletins.

**9 RELATED DOCUMENTS/FORMS**

- 9.1 ABMT-GEN-025 FRM2 Photopheresis Run Sheet
- 9.2 ABMT-GEN-025 FRM1 Physician Photopheresis Note
- 9.3 ABMT-GEN-025 FRM3 Physician Order Sheet for Photopheresis (ECP)

**10 REFERENCES**

- 10.1 THERAKOS® Cellex® Photopheresis System Operators Manual- current edition
- 10.2 AABB Technical Manual, current edition

**11 REVISION HISTORY**

<b>Revision No.</b>	<b>Author</b>	<b>Description of Change(s)</b>
09	Kourtney Beale	<ul style="list-style-type: none"> <li>• Updated section 5.2.1 to include 250ml ACD-A bags available for use</li> </ul>



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