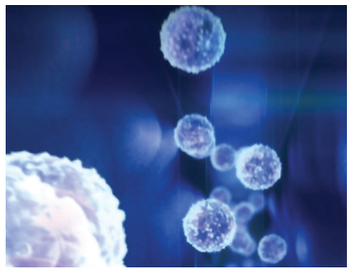


Operator's Manual

THERAKOS™ CELLEX™ Photopheresis System

For Use with Software 5.4

Operator's Manual

THERAKOS™ CELLEX™ Photopheresis System

For Use with Software 5.4

Therakos CellEx™
PHOTOPHERESIS SYSTEM

1470526_Rev03_EN-UK

Therakos CellEx™
PHOTOPHERESIS SYSTEM

1470526_Rev03_EN-UK

2 inch Letter Sized Binder
Cover: 9.75 x 10.75 inches
Spine: 2.67 x 10.75 inches

CE
2797

THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEM

For Use with Software 5.4

1470526_Rev03_ENG-UK

Therakos CellEx™ PHOTOPHERESIS SYSTEM

CE
2797

Mallinckrodt Pharmaceuticals Ireland Ltd
College Business & Technology Park
Cruiserath Road Blanchardstown,
Dublin 15,
Ireland

All additional contact information for Mallinckrodt may be found on the last page of this manual.
Disclaimer: Photographs and schematic diagrams in this operator's manual may vary slightly from the actual products in use. Operators will be informed in writing of any manufacturing variances that result in instructional changes and/or performance changes to the instrument or procedural kit.

CAUTION:
All automatic sensor functions, pump rates, anticoagulant delivery ratios and fluid balance estimates are limited to the accuracies of the component parts listed in ***SECTION 8: SPECIFICATIONS.*** Failure of the instrument to meet these performance specifications may lead to less than optimal buffy coat collections, blood loss due to clotting or leakage, increased risk of infection, hypovolemia or hypervolemia and/or a failed treatment.

Therakos CellEx™
PHOTOPHERESIS SYSTEM

1470526_Rev03_ENG-UK

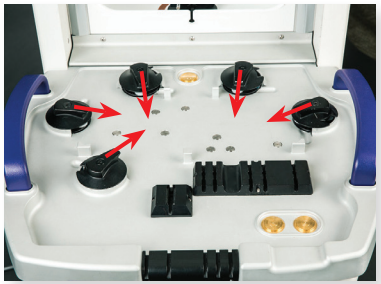
THERAKOS™ CELLEX™ Photopheresis System

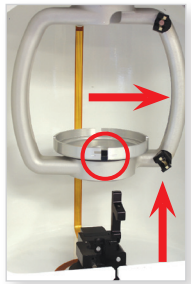
Procedural Kit Installation Guide

For complete instructions, warnings and precautionary information consult the THERAKOS™ CELLEX™ Photopheresis System Operator's Manual.

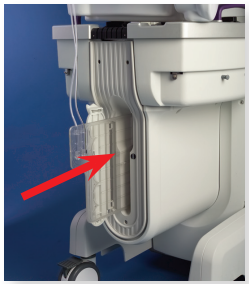
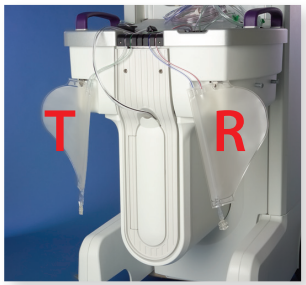
1. Establish "Ready State". Check operator interface for "zeros".

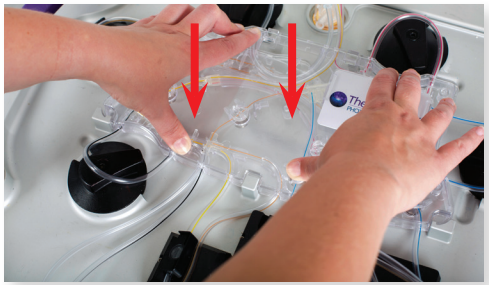




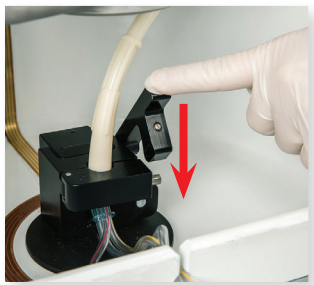



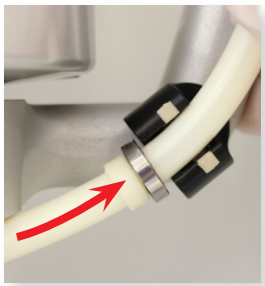
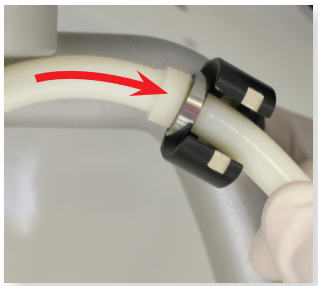
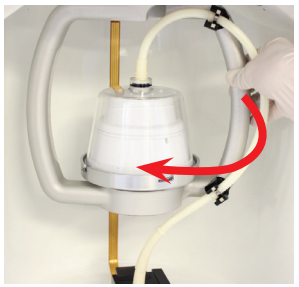
2. Insert photoactivation module, remove kit, hang bags, insert pump tubing organizer.



3. Install drive tube / centrifuge bowl.



THERAKOS™ CELLEX™ Photopheresis System
Procedural Kit Installation Guide

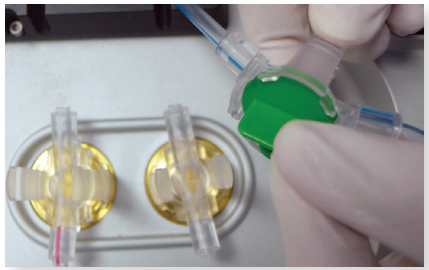
For complete instructions, warnings and precautionary information consult the THERAKOS™ CELLEX™ Photopheresis System Operator's Manual.

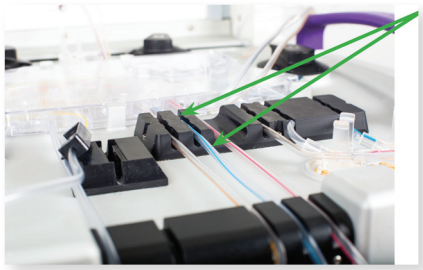
4. Load pump tubing segments.



5.

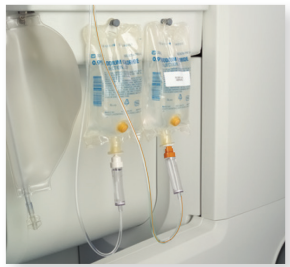
Smart Card


Pressure Domes

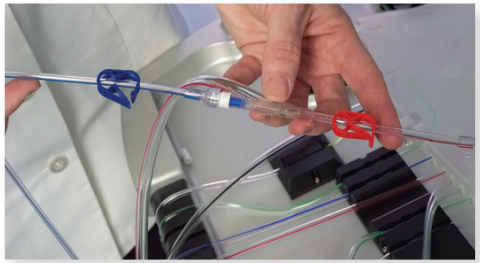

Air Detectors


Hematocrit Cuvette

6.


Spike Fluids


Close Collect Line (RED). Clean needle-free injection port.


Connect Return Line and open (BLUE) clamp.


Hang the Patient Lines on the IV Pole

THERAKOS™ CELLEX™ Photopheresis System
Reference Guide for Estimating ECV and TBV

Extracorporeal Blood Volume (ECV)

CAUTION:

AABB guidelines recommend that the temporary extracorporeal blood volume be less than or equal to 15% of the patient's Total Blood Volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT and SECTION 5: CALCULATING AND SETTING FLUID BALANCE LIMITS*** for additional information on selecting and maintaining Fluid Balance Limits.

A new calculation of Total Blood Volume is necessary prior to each treatment to estimate the safe extracorporeal blood volume that may be allowed for the patient undergoing treatment. These calculations should be performed using the current weight and current hematocrit (the latter drawn after the last photopheresis treatment and within 48 hours prior to the next photopheresis treatment). Certain medical conditions may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume.

Predicting Actual Procedural Kit Extracorporeal Blood Volume

CAUTION:

In some medical conditions, the patient's hematocrit may change from day to day. Use a hematocrit measured within 48 hours prior to photopheresis to estimate the THERAKOS™ CELLEX™ Photopheresis Procedural Kit extracorporeal volume during a treatment.

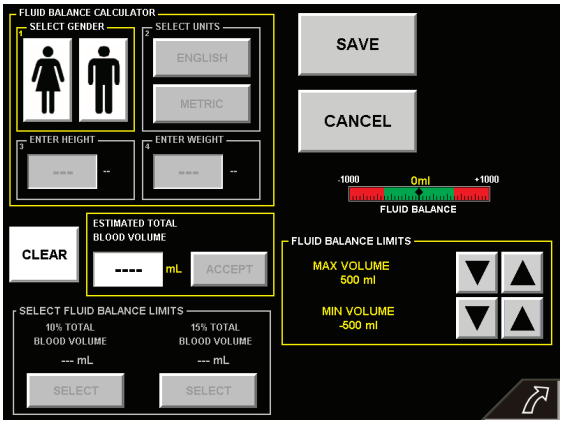
In both DOUBLE NEEDLE and SINGLE NEEDLE modes a minimum amount of whole blood must be processed to prime the Bowl and establish the proper plasma/red blood cell interface. This extracorporeal blood volume increases as the patient's hematocrit decreases (see chart below). A blood prime of the Centrifuge Bowl using crossmatched compatible packed red blood cells may be required if the patient's current weight and hematocrit exceed the safe 10 or 15% extracorporeal blood volume. AABB guidelines recommend that the temporary extracorporeal blood volume be limited to 15% of the patient's estimated total blood volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment. Table 1 estimates the average Procedural Kit ECV for each of the following % hematocrits:

% HCT	Estimated ECV DOUBLE NEEDLE	Estimated SINGLE NEEDLE Mode Extracorporeal Volume (ECV) When Return Bag Threshold Value (RBTV) is Set at (XmL): Return Bag Threshold Value =			
		100	150	200	250
27%	**396**	**441**	491	541	591
28%	**384**	**429**	479	529	579
29%	**372**	**417**	467	517	567
30%	**362**	**407**	457	507	557
31%	**352**	**397**	447	497	547
32%	**343**	**388**	438	488	538
33%	**334**	**379**	429	479	529
34%	**326**	**371**	421	471	521
35%	**319**	**364**	414	464	514
36%	**311**	**356**	406	456	506
37%	**304**	**349**	399	449	499
38%	**298**	**343**	393	443	493
39%	**292**	**337**	387	437	487
40%	**286**	**331**	381	431	481
41%	**280**	**325**	375	425	475
42%	**275**	**320**	370	420	470
43%	**270**	**315**	365	415	465
44%	**265**	**310**	360	410	460

Table 1: Estimated Extracorporeal Volume Relative to % Hematocrit, Access Mode and Return Bag Threshold Value

Estimating the Patient's Total Blood Volume

The THERAKOS™ CELLEX™ Photopheresis System continuously monitors and displays the volume of fluid movement to and from the patient during a THERAKOS™ Photopheresis treatment. These fluids may be blood, anticoagulant, or saline. A negative fluid balance indicates that the patient is undergoing a temporary fluid deficit. A positive fluid balance indicates that the patient has received additional fluids. At completion of a standard treatment the patient will be fluid positive approximately 350 - 450 mL.



Fluid Balance Setup Screen

Integrated TBV Calculator Method:

To assist in establishing appropriate fluid balance alarm limits, the THERAKOS™ CELLEX™ Photopheresis System incorporates an integrated fluid balance calculator that uses the Nadler formula to

estimate the patient's Total Blood Volume. The calculator and fluid balance setup screen will automatically display prior to patient connection and will be available after initiation of the treatment via the setup screen.

The integrated calculator uses the Nadler formula for computing the patients Total Blood Volume using Gender, Weight and Height as Inputs to the equation below.

- (Male) Total Blood Volume in mL = 0.3669 x (height in meters)^3 + 0.03219 x weight in kg + 0.6041
- (Female) Total Blood Volume in mL = 0.3561 x (height in meters)^3 + 0.03308 x weight in kg + 0.1833

Calculator input limits:

- Height 30–244 cm
- Weight 25–227 kg

Please refer to *"Calculating and Setting Fluid Balance Limits" on page 5-10* for specific instructions in using integrated TBV calculator.

CAUTION:

Maximum extracorporeal volume for patients weighting less than 30kg should not exceed 10% of the patient's Total Blood Volume. Patients that do not meet the safe minimal ECV should only be treated using the blood prime procedure. If the treating clinician does not desire to use the blood prime procedure, raising the patient's hematocrit and/or body weight may allow the patient to undergo the standard procedure per Table on ***page 10-3***.

Alternate Method to Compute Total Blood Volume (TBV):

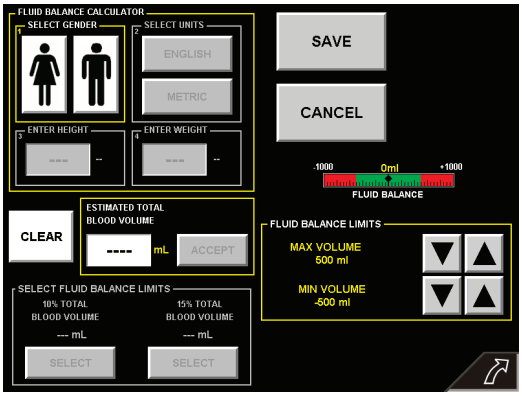
Total Blood Volume (TBV) in milliliters (mL) can be estimated by multiplying the patient's weight in kilograms (kg) by the appropriate body build factor predicting blood volume in mL/kg.

- Compute the estimated TBV by using the body build table below:
- Weight (kg) x Body Build Factor (mL/kg) = TBV (mL)

BODY BUILD	MALE	FEMALE
Adult Muscular	80 mL/kg	75 mL/kg
Adult Normal	75 mL/kg	70 mL/kg
Adult Thin	70 mL/kg	65 mL/kg
Adult Obese	65 mL/kg	60 mL/kg
Adolescent	75–70 mL/kg	75–70 mL/kg
Neonate	100–80 mL/kg	100–80 mL/kg

Table 2: TBV Body Build Factor Table

Once TBV is calculated, you may enter the value into fluid balance setup screen or TBV calculator.



Fluid Balance Setup Screen

1. Press SETUP from a stop or pause screen.
2. Navigate to fluid balance setup screen.
3. Touch white data entry box labeled ESTIMATED TOTAL BLOOD VOLUME. A keyboard will appear.
4. Enter the calculated TBV then press enter button.
5. Press ACCEPT to use this value. The calculator will automatically display calculated fluid balance values for 10% and 15% of the patient's total blood volume.
6. If needed, Press CLEAR to reset the calculator values and return to step 1.
7. Pressing one of the SELECT buttons under the fluid balance (10% or 15%) will set fluid balance alarm limits to the value selected. The selected value will be highlighted.
8. Fluid balance alarm limits may be adjusted up or down in increments of 25 mL using the buttons.
9. Press SAVE to set the fluid balance alarm limits to the new values.

THERAKOS™ CELLEX™ Photopheresis System
Example Flow Sheet

Date:	Treatment No.:	CELLEX™ Serial Number:
Name:	Pt. ID#	Instrument Hours:
Diagnosis:		Lamp Hours:

Draw Date:	WBC:		Lot # Kit:	Exp:
	HCT:		Lot # Saline:	Exp:
	PLT:		Lot # Saline:	Exp:
Other Labs:			Lot # Heparin:	Exp:
			Lot # Methoxsalen:	Exp:
Access:			Lot # Needle:	Exp:
			Lot # Needle:	Exp:

Estimated **TOTAL BLOOD VOLUME (TBV):**	(Wt. in lbs. ÷ 2.2 = Wt. in kg)	x	(Body build factor mL/kg)	=	(TBV mL)	mL
Safe **EXTRACORPOREAL VOLUME (ECV) :**	(TBV x 0.1)		(TBV x 0.15)	mL		
Estimated DOUBLE NEEDLE ECV:		mL	FLUID BALANCE Limits: ±			mL
Estimated SINGLE NEEDLE ECV:		mL	(when Return Bag Threshold =			

PRE-TREATMENT		POST-TREATMENT		
BP:	Resp:	BP:	Resp:	Treatment Start Time:
Pulse:	Temp:	Pulse:	Temp:	Treatment End Time:
Is the patient suitable for treatment?		YES	NO	

WHOLE BLOOD PROCESSED Target:	mL	SINGLE NEEDLE: ☐	DOUBLE NEEDLE: ☐
Collect Rate Limit:	mL/min	A/C Ratio:	
Return Rate Limit	mL/min		

Time	Blood Processed	BP	Pulse	Resp	Collect Rate	Return Rate	A/C mL	Saline mL	Comments	Init

Final Treatment Volume:	x 0.017 = mL Methoxsalen
Injected by:	TIME:
Methoxsalen dose =	mL x 20 mcg/mL = mcg Photoactivation Time:

Fluid Balance =		Heparin:		units/500 mL saline x		A/C mL =		units
Patient advised to wear UV glasses/sunscreen for 24 hours after each ECP treatment?						YES	NO	
Smart Card returned to Mallinckrodt for analysis?						YES	NO	
Initials:	Signature:			Initials:	Signature:			

ECP Operator Notes:

ECP Operator Signature **Date**

Clinician Notes:

Clinician Signature **Date**

Disclaimer: This document has been created as an educational tool for operator's training on THERAKOS™ CELLEX™ Photopheresis System. Mallinckrodt shall not be responsible for any loss or damage arising from the use of or reliance on this information.

THERAKOS™ CELLEX™ Photopheresis System
BLOOD PRIME REFERENCE: DOUBLE NEEDLE Mode

Before You Begin

Abbreviations:

TBV = Total Blood Volume (mL)

ECV = Extracorporeal Volume (mL)

pRBC = packed Red Blood Cells (donor unit)

A/C Ratio = mL of Blood/mL of Anticoagulant

BOS = Bowl Optic Sensor Reading

WBP = Whole Blood Processed (mL)

SN mode = SINGLE NEEDLE mode

DN mode = DOUBLE NEEDLE mode

KVO = Keep Vein Open (anticoagulant or saline drip at 10 mL/hour)

Additional supplies:

a. One donor pRBC unit, minimum volume = 250 mL, minimum hematocrit of 50%. pRBCs should be as fresh as possible (≤ 14 days). Recommend one additional unit available as backup.

b. One blood administration filter set with two-way flow through filter. NOTE: Y-Type filter set allows wetting filter with saline if desired. Care must be taken not to introduce large amounts of extra saline as this may lead to excess dilution of the pRBC unit.

c. One high flow stopcock (with two female luers and one male luer).

- Determine if blood prime is necessary:
  a. Estimate the patient's total blood volume. See ***SECTION 10*** for more information.
  b. Using the patient's hematocrit percent (within 48 hours of treatment) refer to ***"Estimated Extracorporeal Volume" table in SECTION 10*** to estimate the expected ECV during the treatment. Maximum extracorporeal volume for patients weighing less than 30 kg should not exceed 10% of the patient's Total Blood Volume. Patients who do not meet the safe minimal ECV should only be treated using a blood prime procedure.
  c. Also consider the clinical condition of the patient at time of treatment to determine any additional reason for priming the extracorporeal circuit with blood, such as the patient's circulating RBC volume, or a low resting blood pressure, etc.
  d. Document above calculations on flow sheet.
- The patient will be isovolemic during DRAWING/RETURNING when DN mode access is used and the COLLECT and RETURN flow rates are identical. The patient will remain isovolemic during BUFFY COAT if the donor pRBC unit is used to displace the buffy coat and the return flow remains at the blood prime default of 0 mL/min. On average, following the instructions below, the patient will become approximately 170 mL fluid positive once the treated leukocytes are reinfused and rinseback is performed. Confirm that the patient is able to tolerate this positive fluid shift.
- The clinician must establish the patient WBP target and prescribe the appropriate dose of anticoagulant. REMINDER: For patients < 40 kg use 150–250 Units of heparin/kg body weight/500 mL 0.9% Normal saline per treatment. See ***Anticoagulation on page 2-9*** for more information.
- The operator must confirm the proper anticoagulant for the patient before kit installation and PRIME.

- Confirm that a double lumen access is available and that COLLECT and RETURN flow rates of at least 15 mL/min can be achieved.
  - ✓ **Confirm patency of patient's access before continuing.**
- Use aseptic technique when making all connections and disconnections.
- Avoid blood leaks by closing all clamps and verifying the position of the stopcock prior to connecting or disconnecting lines.
- Confirm all lines are void of air before each connection is made.

PRIME:

a. Install the THERAKOS™ CELLEX™ Photopheresis System procedural kit as directed.

b. Press START to begin PRIME.

c. When the Fluid Balance Calculator appears, do not make any changes. Press CANCEL.

Enable Blood Prime:

a. Press SETUP and then press the arrow tab  to access SETUP Page 2.

b. Enable the Blood Prime feature by pressing and holding the 

icon until it changes to 

. Input the appropriate Rinseback Volume.

c. Press SAVE to confirm all changes made to the above parameters.

d. Confirm that the Blood Prime Feature icon 

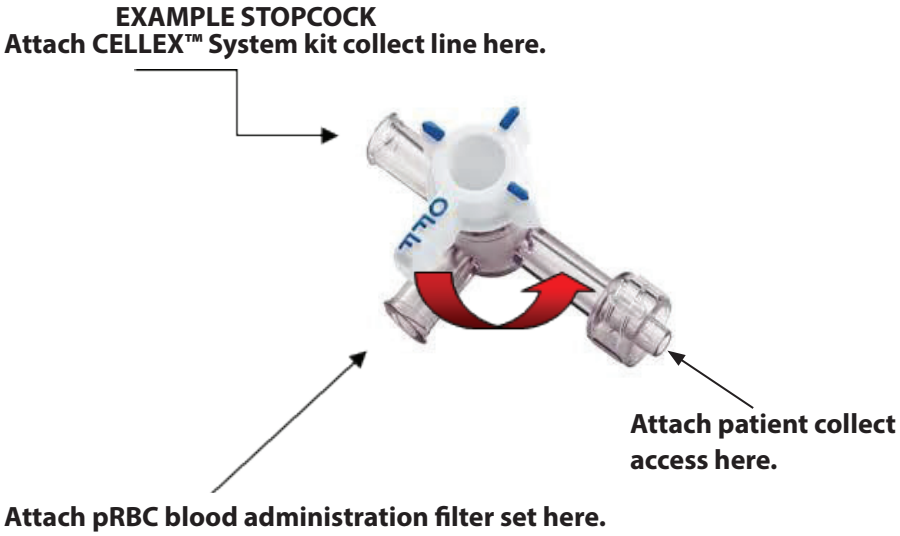
appears at the top of the Main Screen of the Operator Interface.

NOTE:
All parameter settings will be reviewed and reset as needed just prior to connecting the patient.

THERAKOS™ CELLEX™ Photopheresis System
BLOOD PRIME REFERENCE: DOUBLE NEEDLE Mode

PRIME ACCESS:

a. Aseptically add one high flow stopcock to the CELLEX™ System collect line.



b. Open the CELLEX™ System collect line (RED) clamp and open one path of the stopcock. Press PRIME to flush the line and remove remaining air.

c. If necessary, repeat flush by pressing PRIME while rotating stopcock until all air is removed.

d. Close the CELLEX™ System collect line (RED) and return line (BLUE) clamps.

ESTABLISHING ACCESS: (Connecting the donor pRBC unit to the CELLEX™ System)

a. Close all clamps on the blood administration filter set.

b. Aseptically spike the donor pRBC unit with the blood administration filter set.

c. Open the clamps and allow pRBCs to flow to tip of the blood administration filter set. Close the clamps.

d. Keeping the CELLEX™ System collect and return lines configured in SINGLE NEEDLE mode, aseptically attach the blood administration filter set to the stopcock.

e. Rotate the stopcock to be off to the patient's collection port and open to the donor pRBC unit.

f. Open all clamps on the blood transfusion set to allow blood flow from the donor pRBC unit.

g. Open the collect line (RED) and return line (BLUE) clamps of the CELLEX™ System procedural kit.

NOTE:
If you opt to use a Y-Type blood administration set it may be wetted first with saline. Prior to connecting to the CELLEX™ System collect line, clamp the saline and then waste the saline in the filter and tubing as you allow the pRBCs to reach the tip of the blood administration set.

SELECT:

a. **Select and confirm SINGLE NEEDLE on the operator interface.**

b. The screen display schematic shows the return line connected to the collect line and (RED) and (BLUE) clamps open.

COLLECT: (DRAWING/RETURNING from/to donor pRBC unit in SN mode)

a. Press START to begin PURGING AIR. The COLLECT Flow Rate will be limited to 25 mL/min.

b. Continue DRAWING (30 mL/min)/RETURNING (50 mL/min) in SINGLE NEEDLE mode until the plasma/RBC interface is established and the BOS reading reaches 150.

c. If desired, complete additional DRAWING/RETURNING phases to prime the filter in the pump tubing organizer and the return line with donor pRBCs.

d. At the end of a RETURNING phase, press PAUSE. The volume in return bag should be approximately 50 mL.

NOTE:

- PAUSE is only available for 10 minutes.
- If more than 10 minutes elapses the centrifuge will stop.
- Whole blood separation will be lost whenever the centrifuge bowl stops. Repurging and ESTABLISHING SEPARATION will be required before resuming. Before proceeding, decide if repurge is to be done connected to patient in DOUBLE NEEDLE mode or connected to the donor pRBC unit in SINGLE NEEDLE mode.

PAUSED: (Transition from donor pRBC unit to patient)

a. Record all data from the operator interface screen.

b. Change the following SETUP parameters to meet the needs of the patient:

SETUP Page 1

COLLECT Rate Limit 30 mL/min or less

RETURN Rate Limit 30 mL/min or less, and = COLLECT Rate Limit

A/C Ratio = X:1 (Choose ratio appropriate for patient and anticoagulant in use)

REINFUSION Rate Limit = 1–25 mL/min

(Choose rate suitable for patient during fluid gain portion of the treatment)

SETUP Page 2

WBP TARGET = (donor pRBC unit WBP + patient WBP goal)

(Enter value closest to the calculated total)

Blood Prime = ON

Rinseback Volume = 0–999 mL

c. Enter WBP Target number closest to total.

d. Press SAVE. Confirm all entries before proceeding.

e. Reset FLUID BALANCE to zero by pressing and holding the FLUID BALANCE display on the main screen of the operator interface. Confirm by pressing YES. The screen will now show the patients fluid balance.

WARNING:

- Resetting the FLUID BALANCE to zero will tare the displayed fluid balance to 0 mL but will not automatically maintain a FLUID BALANCE of 0 mL. COLLECT and RETURN Flow Rates must still be managed to maintain an appropriate fluid balance.

f. Close the donor pRBC unit clamp. Close the CELLEX™ System collect line (RED) and return line (BLUE) clamps.

g. Connect the patient collect access to the 3-way stopcock on the CELLEX™ System collect line.

h. Confirm the CELLEX™ System return line (BLUE) clamp is closed. Aseptically disconnect the return line from the CELLEX™ System collect line and connect it to the patient's return access.

i. Open the patient's collect and return access clamps. Open the CELLEX™ System collect line (RED) clamp and the CELLEX™ System return line (BLUE) clamp.

j. Rotate the stopcock to be off to the donor pRBC unit and open to the patient.

k. **Confirm that all connections are secure and correct.**

CHANGE Instrument Setting from SINGLE NEEDLE to DOUBLE NEEDLE mode

a. **Press**  **Select and confirm DOUBLE NEEDLE on the operator interface.**

b. Verify on the operator interface that the Return Line is no longer connected to the Collect Line.

COLLECT: (DRAWING/RETURNING from/to Patient in DN mode)

NOTE:

The FLUID BALANCE reading should be zero if reset as directed above.

a. Press START to begin blood collection from the patient. Confirm blood flow from and to the patient. Check all connections for leaks.

b. Carefully monitor the patient at all times.

c. To keep the patient isovolemic, set the Collect Flow Rate equal to the Return Flow Rate. Periodically it may be necessary to adjust either rate independently.

d. Monitor the position of the plasma/RBC interface in the centrifuge bowl and ensure that the RBCs remain near the laser as whole blood is processed.

e. The centrifuge speed increases to 4800 RPM 75 mL prior to the WBP target and pauses for 3 minutes. After collection resumes, the BUFFY COAT phase begins when the BOS is below setup value. When the subtitle line changes to BUFFY COAT press PAUSE.

PAUSE:

a. Record all data from patient collection phase.

b. Open the donor pRBC unit clamp.

c. Rotate the stopcock to be off to the patient and open to the donor pRBC unit.

COLLECT: (BUFFY COAT – DRAWING using donor pRBCs to displace patient's leukocytes)

a. Press START to resume the buffy coat collection.

b. Ensure that the pRBC unit does not deplete during BUFFY COAT. If the pRBC unit begins to deplete before the end of BUFFY COAT, continue with a second (backup) unit of pRBCs or evaluate whether the patient's blood can be used to complete BUFFY COAT.

NOTE:

If there is insufficient volume remaining in the packed red cell bag and if the patient is able to tolerate a temporary fluid deficit you may draw from the patient during BUFFY COAT.

- The whole blood volume required to displace the buffy coat is hematocrit dependent
- The average volume required to displace a buffy coat is 100-150ml
- Low hematocrits may require whole blood volume as high as 280ml to displace the complete buffy coat.

CAUTION:

If drawing from the patient during BUFFY COAT, the operator must increase the return flow rate from 0 mL/min to match the Collect Flow Rate to maintain isovolemic conditions.

c. BUFFY COAT collection will complete automatically, but may also be ended manually by pressing PAUSE, followed by END BUFFY.

d. At the end of BUFFY COAT, the centrifuge will stop and the Centrifuge Bowl will empty.

e. Record all treatment data.

PHOTOACTIVATE

a. When prompted, dispense the appropriate amount of Methoxsalen (20 micrograms / mL) into the treatment bag. Record the amount of Methoxsalen (20 micrograms / mL), UVA time and Return Bag Volume. Close the pop-up window.

b. Open the centrifuge door. Close the pop-up window.

c. Reset the FLUID BALANCE to zero by pressing and holding the FLUID BALANCE display. Confirm when prompted. This reset will now allow you to track the positive fluid gain of the patient.

d. Press  to begin PHOTOACTIVATE.

e. The patient collect access and the donor pRBC unit access may be disconnected. Keep all return access clamps open. The instrument will provide KVO.

f. After PHOTOACTIVATE is complete, the instrument will automatically advance to REINFUSE and the photoactivation module will be emptied and rinsed.

REINFUSE and RETURNING (Rinseback)

a. Reinfusion of the treatment volume will begin automatically using the last user set return rate. The Reinfusion Rate Limit is active at this point.

b. Monitor the patient carefully during REINFUSE and RETURNING.

c. Once all of the treatment volume has been reinfused, the Rinseback Volume will be returned to the patient automatically.

d. An audible cadence will occur when Rinseback is complete. The operator now has the option to:

   a. Repeat the Rinseback using the same volume by pressing START.

   b. Enter SETUP and select a different Rinseback Volume. Save SETUP changes and then press START.

   c. Complete the treatment by pressing  followed by ABORT

NOTE:

- A 20 mL saline bolus may be used as a rinseback to avoid returning any additional RBCs to the patient. Enter SETUP to set saline bolus limit to 20 mL. Then select START SALINE.
- In a non-blood prime procedure, 40 mL of Saline is used as a final rinseback. The Return Line & Filter contain 40 mL of fluid *(See page 10-12)*.

TREATMENT COMPLETE

a. Clamp all lines. Press RELEASE KIT.

b. Disconnect the patient.

c. Record all data.

d. Discard kit (including volume remaining in return bag).

e. Clean instrument and turn power off.

CALCULATIONS:

FLUID BALANCE (FB) = _____ + _____ = _____mL**
(Displayed value on operator interface) (END PT FB)

Definition: END PT FB = difference in fluid balance at the end of patient whole blood collection minus fluid balance value at the start of patient collection. This value represents Δ Patient*.

**Δ Patient = difference in patient fluid balance at end of patient collection from start of patient collection.*

***Use this formula when you reset the FLUID BALANCE display at the start of patient whole blood collection and at the start of REINFUSING.*

Manual FLUID BALANCE (FB) Calculation =

_____ + _____ + _____ = _____ mL****
(Treatment Volume) (Rinseback Volume) (END PT FB)

*****Use this formula if the FLUID BALANCE display was not reset to zero when the patient was connected* and *again before REINFUSE.*

ANTICOAGULANT delivered to patient =

((_____ - _____) + (_____)) / (_____) = _____ mL anticoagulant
(Total WBP) (pRBC prime WBP) Rinseback A/C Ratio

Units of Heparin/mL =

_____ / 500 = _____ Units of Heparin/mL
(Units of Heparin) (mL 0.9% Normal Saline)

Units of Heparin delivered to the patient =

_____ X _____ = _____ Units
(Units of Heparin/mL) (mL Anticoagulant) (Units of Heparin to Patient)

Disclaimer: The steps discussed in this reference guide may not be the complete steps of the procedure. Individual operator experience, as well as patient needs, may require variation in procedure steps. Before using this device, review all relevant labels and package inserts, with particular attention to the indications, warnings and precautions and steps for use of the device.

THERAKOS™ CELLEX™ Photopheresis System

Blood Prime Technique Flow Sheet

Date: _____

Treatment # _____

Name: _____

Pt. ID # _____

Diagnosis: _____

CELLEX™ Serial Number: _____

Remaining Lamp Life: _____

Treatment Start Time: _____

Treatment End Time: _____

Lot # Kit/ID: _____ Exp: _____

Lot # Saline: _____ Exp: _____

Lot # Saline: _____ Exp: _____

Lot # Saline: _____ Exp: _____

Lot # Anticoagulant: _____ Exp: _____

Lot # Methoxsalen: _____ Exp: _____

Type of Access: _____

Checked for patency: ☐

WBC: _____
HCT: _____
PLT: _____

Other Labs:

Prescribed ANTICOAGULANT:
(Dose and delivery rate limit if applicable)

Patient A/C Ratio:

Donor pRBC volume:
(Minimum 250 mL)

Date of Expiration:

pRBC compatibility confirmed:

Estimated:
TOTAL BLOOD VOLUME (TBV): _____ (kg) x _____ (mL/kg) = _____ (mL)

Safe Estimated:
Extracorporeal Volume (ECV) mL: _____ (TBV x 0.10) to _____ (TBV x 0.15)

Estimated DOUBLE NEEDLE ECV: _____ mL Blood prime required? YES ☐ NO ☐

SETUPS:

Patient WHOLE BLOOD PROCESSED GOAL: _____ mL

Rinseback Volume: _____ mL

Time	*Blood Pressure*	*Pulse*	*Respiration*	*Temperature*
Pre-Treatment				
Post-Treatment				

THERAKOS™ CELLEX™ Photopheresis System

Blood Prime Technique Flow Sheet

TIME	TREATMENT PHASE	FLUID BALANCE (mL)	WHOLE BLOOD PROCESSED (mL)	A/C Volume (mL)	Saline Volume (mL)	Collect Rate (mL/min)	Return Rate (mL/min)	Reinfuse Rate (mL/min)	Return Bag Volume (mL)	Comments
	End of COLLECT from donor pRBC unit (SN mode) START of patient		(pRBC WBP) (1)							
	DRAWING/RETURNING from/to patient (pt) (DN mode) pRBC WBP + Pt WBP Goal Pt WBP Target	START PT FB = 0	TARGET		START PT Saline (8)					
		END PT FB (2)	ACTUAL		END PT Saline (9)					
	BUFFY COAT ☐ pRBC ☐ patient	pRBC					0			
		PATIENT (6)								
	PHOTOACTIVATE	Treatment Volume (mL) (4)_____ mL Methoxsalen _____ mL Minutes UVA: _____ min					0			
	REINFUSING (Return of treated buffy coat)									
	End of RETURNING (Rinseback) = TREATMENT COMPLETE Rinseback volume (5)= _____	(3)	Total WBP (7)							

Complete the calculations using the values in the numbered boxes above.

FLUID BALANCE (FB) = _____ (Treatment Volume) (4) + _____ (Rinseback volume) (5) + _____ (Displayed value on operator interface) (3) + _____ (End Pt FB) (2) = _____ **mL***

*Adjust FLUID BALANCE by subtracting BUFFY COAT PATIENT volume if patient is still connected during BUFFY COAT (6)

ANTICOAGULANT delivered to patient = ((_____ (Total WBP)(7) – _____ (pRBC prime WBP)(1)) + (_____ (Rinseback)(5))) / _____ (A/C Ratio) = _mL anticoagulant

Units of Heparin/mL = _____ (Units of Heparin) / 500 (mL 0.9% Normal Saline) = _____ Units of Heparin/mL

Units of Heparin delivered to the patient = _____ (Units of Heparin/mL) X _____ (mL Anticoagulant) = _____ Units (Units of Heparin to Patient)

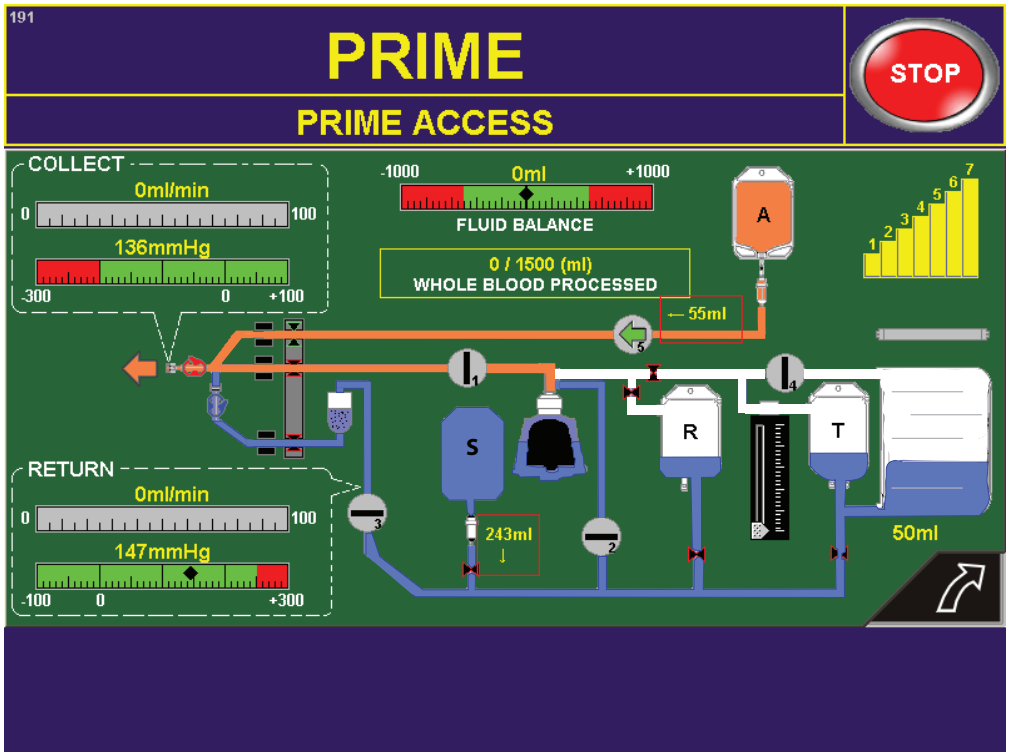
Saline to Pt = Δ Saline = _____ End PT Saline in Tx Bag (9) - _____ Start PT Saline (8) + 50 mL + Prime Saline

THERAKOS™ CELLEX™ Photopheresis System
Flow Guide

The THERAKOS™ CELLEX™ Photopheresis System Flow Guide provides operators information regarding the quantities of fluids (anticoagulant and saline) processed in the instrument during a patient treatment. The Flow Guide will assist the operators in deciding on the proper flow rates to control the delivery of anticoagulant to the patient. In addition, formulas are provided for calculating units of heparin delivered under various treatment scenarios.

FLUIDS USED DURING PRIME

- Approximately 55 mL of anticoagulant
- Approximately 243 mL of saline
- At the end of PRIME, the distribution of these fluids is represented in the screen display below:
  - Anticoagulant (Orange)
  - Saline (Blue)



FLUID DEFINITIONS

Anticoagulant (A/C): Heparin solution prepared from the clinician prescribed dose of heparin added to a 500 mL bag of 0.9% Normal saline. For example, 10,000 Units Heparin/500 mL saline. Concentration A/C = 20 Units of Heparin/mL.

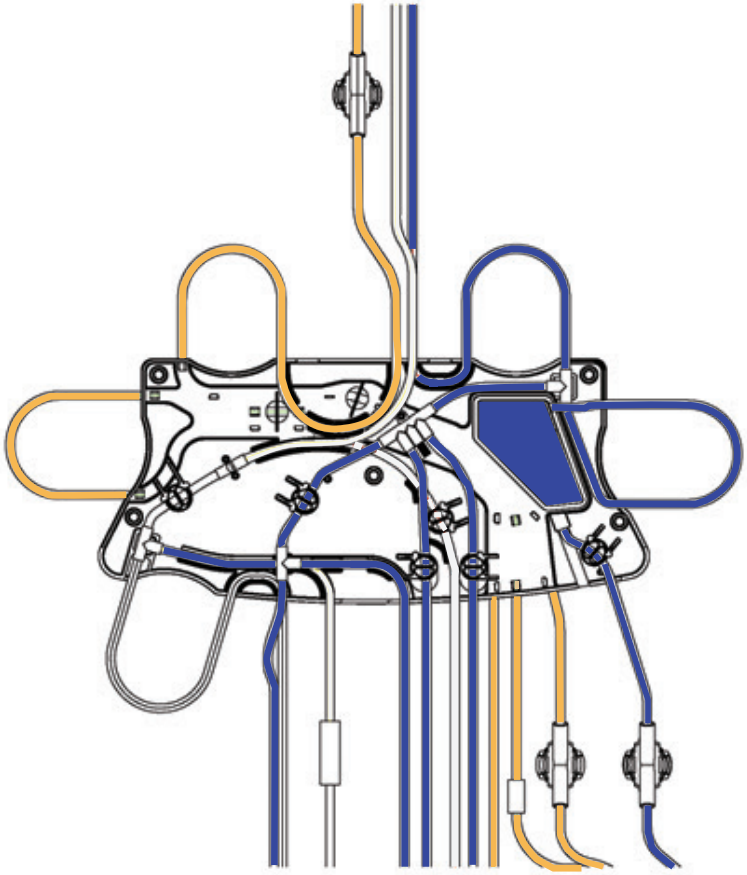
Saline (NS): 0.9% Normal saline.

Refer to *page 8-10 of the THERAKOS CELLEX Photopheresis System Operator's Manual* regarding volume accuracy:

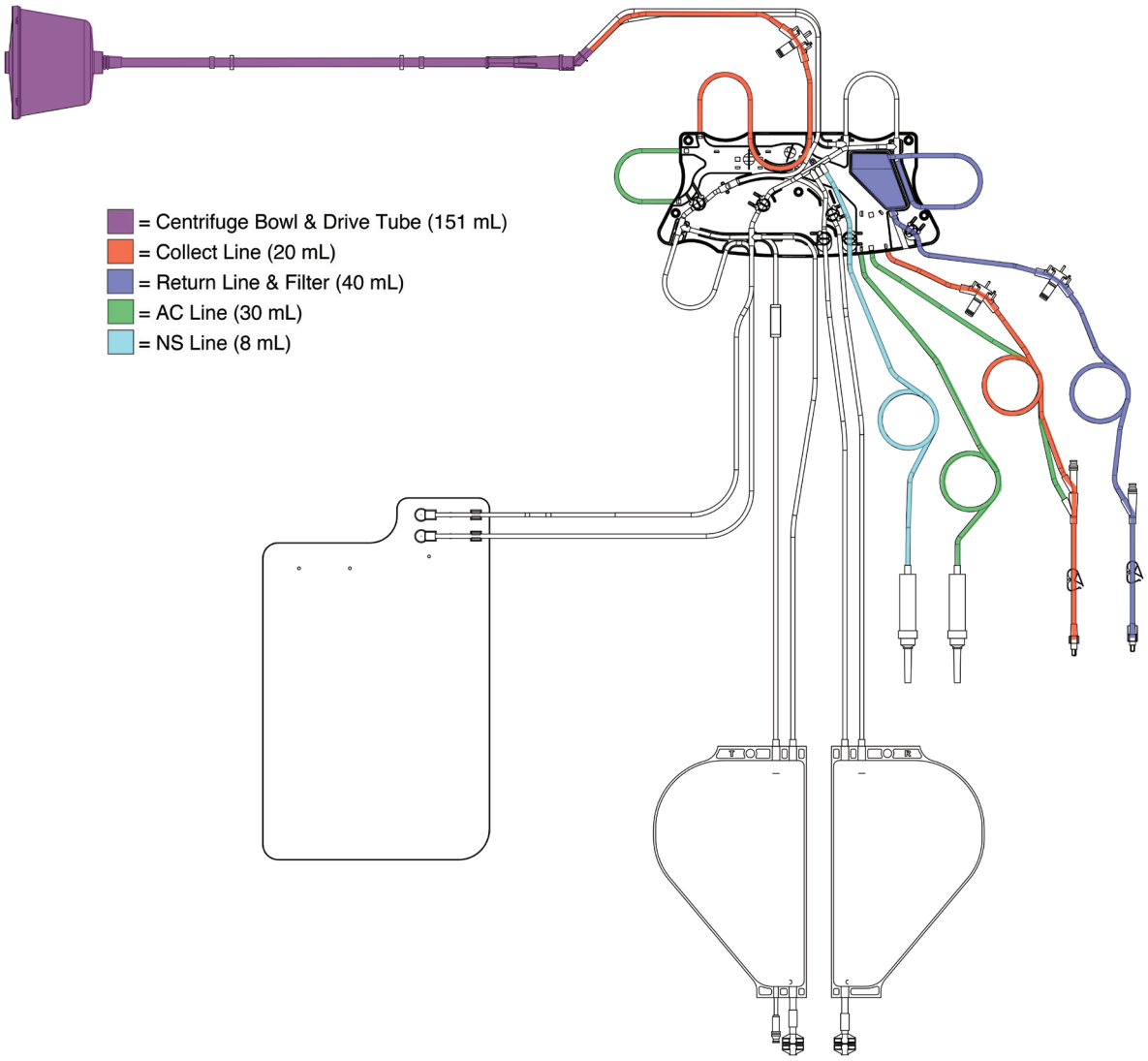
- FLUID BALANCE reading: ± 5% of volume processed or 25 mL (whichever is greater)
- All other volume readings: ± 10% or 25 mL (whichever is greater)

Fluid contents of pump tubing organizer at the end of PRIME

A/C
NS



CELLEX™ System Procedural Kit estimated circuit volume



Estimated total circuit volume during COLLECT (10:1 Anticoagulant Ratio). 10% of toal circuit volume will be comprised of anticoagulant if 10:1 ratio is utilized during COLLECT.

The values presented above represent estimated circuit volume only. Refer to ***page 10-3 in Section 10 of the CELLEX™ System Operator's Manual*** for the estimated average extracorporeal volume whole blood equivalent at various hematocrit values in SINGLE NEEDLE Mode or DOUBLE NEEDLE Mode.

NOTE: Each drip chamber holds approximately 10 mL of fluid that is manually squeezed into the drip chamber and is not counted in the displayed volumes.

DELIVERY OF ANTICOAGULANT AND SALINE DURING A TREATMENT

- Anticoagulant (A/C)
  - Approximately 55 mL A/C during PRIME
  - Approximately 3 mL A/C delivered each time PRIME is pressed
  - A/C is dripped at the default ratio of 10:1 (10 mL whole blood to 1 mL A/C)
  - Anticoagulant is delivered to the collect line at the Keep Vein Open (KVO) rate of 10 mL/hour during PAUSE and STOP.
- Normal Saline (NS)
  - Approximately 243 mL NS during PRIME
  - Default of 5 mL/min during DOUBLE NEEDLE mode PURGING AIR, rate may be increased or decreased by operator
  - Additional NS may be administered during the treatment at the request of the operator
  - 40 mL NS rinse of centrifuge bowl during EMPTYING BOWL
  - 40 mL NS rinse of return line after REINFUSE/RETURNING is complete

STANDARD TREATMENT ANTICOAGULANT DELIVERY CALCULATION

These formulas estimate the amount of anticoagulant (AC) delivered to a patient at the end of a standard treatment.

Step 1: Calculate the Heparin Concentration using
Formula: Units of Heparin/Volume 0.9% Normal Saline (mL)
Example: 10,000 Units of Heparin/500 mL NS = 20 Units of Heparin/mL

Step 2: Calculate the A/C delivered to the patient using
Formula: Displayed A/C – 30 mL*
Example: 239 mL A/C – 30mL = 209 mL A/C delivered to patient

** 30 mL remains in the procedural kit A/C line at end of treatment.*

Step 3: Calculate total Units of Heparin delivered to patient using
Formula: mL A/C to patient x Heparin Concentration
Example: 209 mL A/C to patient x 20 Units of Heparin/mL = 4018 Units of Heparin to patient.

BLOOD PRIME PROCEDURE ANTICOAGULANT DELIVERY CALCULATION

These formulas estimate the amount of anticoagulant (A/C) delivered to a patient at the end of a treatment that follows the Blood Prime Protocol on *pages 10-15 through 10-23 in Section 10 of the CELLEX™ System Operator's Manual.*

ANTICOAGULANT delivered to patient =

((_____ - _____) + (_____)) / _____ = _____mL anticoagulant

(Total WBP) (pRBC prime WBP) (Rinseback) (A/C Ratio)

Units of Heparin/mL =

_____ / 500 = _____ Units of Heparin / mL

(Units of Heparin) (mL 0.9% Normal Saline)

Units of Heparin delivered to the patient =

_____ X _____ = _____ Units of Heparin

(Units of Heparin/mL) (mL Anticoagulant) (Units of Heparin to Patient)

FLUID BALANCE AT THE END OF THE TREATMENT

The estimated volume of all fluids (whole blood, anticoagulant, and saline) removed from and/or returned to the patient during a treatment.

- May be reset during BLOOD PRIME
  - Use the screen display value for standard treatment.
  - Use the screen display value for BLOOD PRIME if reset per instructions on *page 10-15 in Section 10 of the CELLEX™ System Operator's Manual* or in the *Blood Prime Reference Guide*
  - Use the following formula if FLUID BALANCE was not reset as instructed during BLOOD PRIME:

Manual FLUID BALANCE (FB) Calculation =

_____ + _____ + _____ = _____ mL****

(Treatment Volume) (Rinseback Volume) (END PT FB)

*****Use this formula if the FLUID BALANCE display was not reset to zero when the patient was connected* and *again before REINFUSE.*

THERAKOS™ CELLEX™ Photopheresis System

Pump Crank for Manual Blood Return

ENG: Pump Crank for Manual Blood Return

CZE: Klika pumpy pro ruční vrácení krve

DUT: Pomphendel voor handmatige bloedteruggave

DAN: Pumpehåndsving til manuelt blodtilbageløb

FIN: Pumpun kampi veren palautukseen manuaalisesti

FRE-EU: Manivelle à utiliser avec les pompes pour le retour manuel du sang

GER: Pumpenkurbel zur Manuellen Blutrückführung

GRE: Μανιβέλα αντλίας για χειροκίνητη επιστροφή αίματος

HUN: szivattyúkar a vér manuális visszaadásához

ITA: Manovella per pompa per il ritorno sangue manuale

NOR: Pumpehåndtak for manuell retur av blod

POL: Korba pompy do ręcznego zwracania krwi

POR: Manivela de bomba para readministração manual de sangue

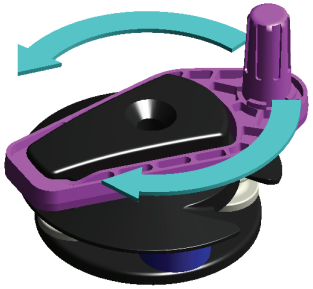
SPA-EU: Manivela de la bomba para el regreso manual de la sangre

SWE: Pumpvev för manuell blodretur

TUR: Manuel Kan Dönüşü İçin Pompa Kolu

1

2



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1470526_Rev03_ML

THERAKOS™ CELLEX™ Photopheresis System

Pump Crank for Manual Blood Return

Table of Contents

1470526_Rev03_EN-UK

SECTION 1: ABOUT THIS MANUAL

Introduction

This manual describes the process of THERAKOS™ Photopheresis and contains information about how to use the THERAKOS™ CELLEX™ Photopheresis System.

NOTE:

- Mallinckrodt provides training for operating the THERAKOS™ CELLEX™ Photopheresis System. Use this manual as a reference after you have been trained.
- Follow the procedures exactly as they are described in this manual. Any deviation or departures from the instructions in this manual are not in accordance with the approved labeling.

How to Obtain Service

Qualified Mallinckrodt service personnel will perform the installation of each THERAKOS™ CELLEX™ instrument. Following installation, each instrument will be inspected to ensure that it is fully operational and set for the proper voltage supply and that the safety alarm systems are tested prior to use.

Mallinckrodt assumes responsibility for the reliability and performance of the THERAKOS™ CELLEX™ Photopheresis System only when installation and service to the system are performed by authorized personnel and only when used in accordance with this THERAKOS™ CELLEX™ Photopheresis System Operator's Manual.

NOTE:

- Only personnel trained in THERAKOS™ CELLEX™ Photopheresis System service procedures should perform maintenance procedures. The THERAKOS™ CELLEX™ Photopheresis System does not contain any components that can be repaired by the user.
- For information about service and repair, call Mallinckrodt at the phone numbers listed on the last page of this manual.

CAUTION:
Follow all operating and maintenance procedures. Failure to do so can result in patient or operator harm.

SECTION 2: WHAT IS PHOTOPHERESIS?

Introduction

Photopheresis or extracorporeal photopheresis (ECP) is a photoimmune therapy where whole blood is removed from the patient, white blood cells are separated from whole blood via apheresis, combined with a photoactive drug and then exposed to ultra violet A (UVA) light. All blood components, including the treated white blood cells are returned to the patient.

THERAKOS™ Photopheresis utilizes the THERAKOS™ CELLEX™ Photopheresis System to combine state-of-the-art cell separation and photoactivation into a single, closed and sterile circuit. The THERAKOS™ CELLEX™ Photopheresis System collects the buffy coat (leukocyte enriched blood) from the patient in a continuous flow process and simultaneously (DOUBLE NEEDLE mode) or intermittently (SINGLE NEEDLE mode) returns the remaining cells to the patient. The buffy coat is passed through the Photoactivation Module where the drug is activated with a precise amount of UVA light determined by the characteristics of the individual patient's buffy coat. After photoactivation, the buffy coat is promptly returned to the patient bloodstream.

Administering THERAKOS™ Photopheresis

Only health care professionals with training in THERAKOS™ Photopheresis should administer this therapy.

When prescribing and administering THERAKOS™ Photopheresis for patients receiving concomitant therapy, exercise caution when changing treatment schedules to avoid increased disease activity that may be caused by abrupt withdrawal of previous therapy.

Consult the 8-methoxypsoralen (Methoxsalen (20 micrograms / mL)) professional leaflet or the oral 8-methoxypsoralen formulation package insert before prescribing or dispensing any medication.

Carefully read and follow all labeling instructions for the anticoagulant in use. If clinically necessary, adjust the dose of anticoagulant prior to priming the instrument. Monitor the patient's platelet count before and after exposure to heparin as recommended by the heparin manufacturer.

AABB guidelines recommend that the temporary extracorporeal blood volume be limited to 15% of the patient's estimated total blood volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment.

Important Safety Information for the THERAKOS™ Photopheresis Procedure

NOTE:
Please refer to the appropriate product labeling for a complete list of warnings and precautions.

Indications

The THERAKOS™ CELLEX™ Photopheresis Systems are indicated for the administration of photopheresis.

Contraindications

THERAKOS™ Photopheresis is contraindicated in patients possessing a specific history of a light sensitive disease.

THERAKOS™ Photopheresis is contraindicated in patients who cannot tolerate extracorporeal volume loss or who have white blood cell counts greater than 25,000 / mm^3 .

THERAKOS™ Photopheresis is contraindicated in patients who have coagulation disorders or who have had previous splenectomy.

Warnings and Precautions

THERAKOS™ Photopheresis treatments should always be performed in locations where standard medical emergency equipment is available. Volume replacement fluids and/or volume expanders should be readily available throughout the procedure.

WARNING:

MR-unsafe! Do not expose the device to a magnetic resonance (MR) environment.

- The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
- Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
- The device may generate artifacts in the MR image.
- The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

Adverse Events

Hypotension may occur during any treatment involving extracorporeal circulation. Closely monitor the patient during the entire treatment for hypotension.

Transient pyretic reactions, 37.7–38.9°C (100–102°F), have been observed in some patients within six to eight hours of reinfusion of the photoactivated leukocyte enriched blood. A temporary increase in erythroderma may accompany the pyretic reaction. Treatment frequency exceeding labeling recommendations may result in anemia. Venous access carries a small risk of infection and pain.

Medications

Important Safety Information for Methoxsalen Used in Conjunction with THERAKOS™ Photopheresis

CAUTION:
Consult the 8-methoxypsoralen (Methoxsalen (20 micrograms / mL)) professional leaflet or the oral 8-methoxypsoralen formulation package insert before prescribing ordispensing any medication.

NOTE:
Carefully read the Methoxsalen (20 micrograms / mL) package insert for side effects prior to dispensing this medication.

Contraindications

Methoxsalen is contraindicated in patients exhibiting idiosyncratic or hypersensitivity reactions to methoxsalen, psoralen compounds, or any of the excipients.

Methoxsalen is contraindicated in patients with co-existing melanoma, basal cell or squamous cell skin carcinoma.

Methoxsalen is contraindicated in sexually active men and women of childbearing potential unless adequate contraception is used during treatment, and during pregnancy and lactation.

Methoxsalen is contraindicated in patients with aphakia because of the significantly increased risk of retinal damage due to the absence of a lens.

Warnings and Precautions

Special care should be exercised in treating patients who are receiving concomitant therapy (either topically or systemically) with known photosensitizing agents.

Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. Because the dose of methoxsalen is about 200 times less than with PUVA therapy and the skin is not exposed to high cumulative doses of UVA light, the risk of developing skin cancer following this therapy may be lower.

Patients should be told emphatically to wear UVA absorbing, wrap-around sunglasses for twenty-four (24) hours after methoxsalen treatment. They should wear these glasses any time they are exposed to direct or indirect sunlight, whether they are outdoors or exposed through a window.

Safety in children has not been established.

First Aid Measures

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical attention.

Skin contact: Wash contaminated areas thoroughly with soap and water. In the case of skin irritation or allergic reactions see a clinician.

Ingestion: If ingested, seek medical attention immediately and show the label.

Inhalation: Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.

Liquid Medication

During a THERAKOS™ Photopheresis procedure, whole blood is withdrawn from the patient and separated by centrifugation to yield a leukocyte enriched blood fraction. Liquid 8-methoxypsoralen (Methoxsalen (20 micrograms / mL)) is injected directly to this leukocyte enriched blood fraction (buffy coat) in the treatment bag. Then the medicated leukocyte enriched blood fraction is exposed to a prescribed amount of UVA light. Remaining red blood cells and plasma are returned to the patient without being treated. Once photoactivation is completed, the treated cells are reinfused to the patient.

Administering Liquid Medication

CAUTION:
READ THE THERAKOS™ UVAR XTS™ or THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEMS' OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.

NOTE:
Carefully read the Methoxsalen (20 micrograms / mL) Important Safety Information for contraindications, side effects, warnings and other information.

Methoxsalen (20 micrograms / mL) is supplied in 10 mL vials. Each vial contains 200 micrograms (mcg) of methoxsalen with a concentration of 20 mcg/mL. There are no preservatives or bacteriostatic agents in the vial, therefore the vial is intended for SINGLE USE ONLY.

Keep Methoxsalen (20 micrograms / mL) stored in the brown glass bottle until use. Do not allow Methoxsalen (20 micrograms / mL) to stand in a syringe or be exposed to UVA light prior to photoactivation.

The instrument calculates the proper dose of Methoxsalen (20 micrograms / mL) using the formula:

TREATMENT VOLUME (mL) multiplied by 0.017 = dose of Methoxsalen (20 micrograms / mL)

Example: TREATMENT VOLUME = 170 mL

170 X 0.017 = 2.8 mL

Dispense the proper dose of Methoxsalen (20 micrograms / mL) into the treatment bag only when you are READY TO PHOTOACTIVATE.

Figure 2-1: READY TO PHOTOACTIVATE

1. Aseptically attach the luer of the syringe directly to the needle-free port of the treatment bag and inject the medication.
2. Rinse the syringe 3 times with a portion of the Treatment Volume to ensure a complete transfer of the medication from the syringe to the treatment bag.



- Measure the medication.
- Remove the needle and attach the syringe luer.
- Dispense the medication and rinse the syringe 3 times.

Figure 2-2: Correct Liquid Medication Administration

CAUTION:

- Do not puncture the needle-free ports with a needle. Damage to these ports will result in leaks.
- Do not remove the treatment bag from the load cell hook. Removal may result in inaccurate FLUID BALANCE readings.

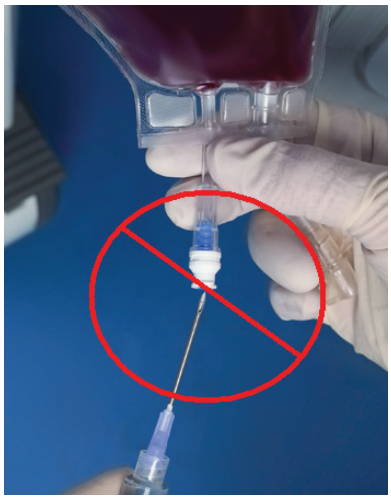


Figure 2-3: Incorrect Liquid Medication Administration

Oral Medication

Oral 8-MOP® must be administered 2 hours prior to the collection of the plasma and buffy coat to allow sufficient time to achieve a minimal blood level of 50 ng/mL at the time of treatment.

CAUTION:

- Follow all medication dosing instructions carefully.
- Advise patient that it is recommended to protect their skin and eyes from sunlight for 24 hours post treatment. Refer to the Methoxsalen (20 micrograms/mL) labeling or the oral 8-methoxypsoralen dosage formulation package insert for more information on protecting the patient from light and for all warnings and precautions.

UVA Light Dose

The THERAKOS™ CELLEX™ Photopheresis System automatically calculates and sets the photoactivation time for the leukocyte enriched blood fraction to be exposed to UVA light. This is based on the remaining lamp life time, percentage of hematocrit of the leukocyte enriched blood fraction, and treatment volume.

WARNING:

- The calculated dose of UVA light energy will not be delivered if the THERAKOS™ CELLEX™ Light Assembly is changed after the calculation of photoactivation MINUTES REMAINING is displayed.
- It is recommended that the full PHOTOACTIVATE time be completed during every treatment. The calculated dose of UVA light energy will not be delivered if PHOTOACTIVATE is ended or aborted before the MINUTES REMAINING is equal to 00:00 (minutes:seconds).

Anticoagulation

The anticoagulant used in the THERAKOS™ CELLEX™ Photopheresis System is a heparinized saline solution. The Units of heparin/500 mL of 0.9% Normal saline may need to be adjusted to the body weight of the patient.

For example:

Patient weight > 40 kg use 10,000–15,000 Units of heparin/500 mL of 0.9% Normal saline

Patient weight < 40 kg use 150–250 Units of heparin per kg body weight/500 mL of 0.9% Normal saline

This concentration is used for priming the system and throughout the patient treatment.

Carefully read and follow all labeling instructions for the anticoagulant in use. Monitor the patient's platelet count before and after exposure to heparin as recommended by the heparin manufacturer.

CAUTION:

- Individual patients may require a heparin dosage that varies from the recommended dose to prevent post-treatment bleeding or clotting during a treatment. The clinician should review the patient's medical condition, medications and platelet count at the time of treatment and use clinical judgment to establish the optimal heparin dosage for each patient.
- Special attention to adequate anticoagulation is advised when treating patients with GvHD, a condition associated with an increased risk of thromboembolic events. Thromboembolic events (including pulmonary embolism and deep vein thrombosis) have been reported with the use of the THERAKOS™ CELLEX™ Photophoresis System in the treatment of GvHD.

If clinically necessary, adjust the dose of heparin prior to priming the instrument and/or by changing the default SETUP parameter setting to alter the A/C ratio. When advised by the clinician, adjust the delivery rate of anticoagulant at any time during the treatment by entering the SETUP screen and changing the Anticoagulant (A/C) Ratio. The default A/C Ratio is 10 mL of whole blood to 1 mL of anticoagulant, or 10:1.

Relevant Fluids

CAUTION:
It is essential for the THERAKOS™ CELLEX™ Photopheresis System to be installed and used in compliance with all center-specific and local regulations / recommendations on the quality of all relevant fluids used during a therapy.

Some examples of relevant fluids are:

- Saline
- Anticoagulant
- Liquid Psoralen
- Optional Fluid Expanders such as Albumin
- Skin Disinfectants

Venous Access

To minimize the risk of infection, Mallinckrodt recommends peripheral venous access. Overall total treatment time is dependant on the performance of the access selected. In SINGLE NEEDLE mode, the access device must be capable of withstanding the negative pressures required to collect whole blood and the positive pressure used to return blood components. In DOUBLE NEEDLE mode, it may be possible to use a large gauge device for DRAWING and a smaller gauge device for RETURNING. Mallinckrodt strongly recommends that more than one type of venous access device be available. Choose the one most suitable for the patient undergoing treatment. The following devices are suitable for venous access during a THERAKOS™ Photopheresis treatment:

Peripheral Venipuncture:

- 16G, 17G Fistula Needles — DRAWING or RETURNING
- 17G, 18G IV Catheter (High durometer angiocatheter) — DRAWING or RETURNING
- 20G IV Catheter (High durometer angiocatheter) — RETURNING

When peripheral venipuncture is not possible, alternative devices such as long-term indwelling catheters, temporary catheters, or subcutaneous ports may be used providing they meet the requirements below. Careful planning to ensure the appropriate device is implanted will prevent failed or shortened therapies due to access failure.

Central Venous Catheters

Any catheter intended to be used with the THERAKOS™ CELLEX™ Photopheresis System must be able to withstand the negative pressure of the peristaltic pressure pumps without collapsing and they must provide a flow rate of at least 15 mL/min. Overall requirements are:

- Minimal internal diameter of 3.0 mm or 9FR. (1 mm = 3 French)
- Maximum length of 36 cm
- High durometer or stiffness of catheter (generally designed for hemodialysis or apheresis procedures to provide high flow output).

Implanted Venous Access Devices

Subcutaneous ports designed specifically for high speed infusions will not provide adequate output for DRAWING. Implant only ports designed for both high-speed input and output.

AV Fistulas or Shunts

The THERAKOS™ CELLEX™ Photopheresis System is capable of both DRAWING from and RETURNING to an AV Fistula or shunt. Carefully follow all center-specific guidelines for accessing and maintaining the graft.

SECTION 3: SYSTEM DESCRIPTION

Introduction

The THERAKOS™ CELLEX™ Photopheresis System offers the option of configuring the THERAKOS™ CELLEX™ Photopheresis Procedural Kit for SINGLE NEEDLE mode or DOUBLE NEEDLE mode use. The DOUBLE NEEDLE mode configuration provides **continuous flow** to and from the patient. As whole blood is drawn from the patient, red blood cells and plasma are simultaneously returned to the patient. SINGLE NEEDLE mode configuration results in **discontinuous flow** to and from the patient. As whole blood is drawn from the patient, red blood cells and plasma are pooled in a reservoir bag and intermittently returned to the patient.

- Both DOUBLE NEEDLE mode and SINGLE NEEDLE mode therapies utilize the custom-designed continuously spinning centrifuge bowl. This centrifuge bowl design, paired with automatic sensitive centrifuge bowl optic monitoring and innovative software-directed pumping mechanisms, allows for a single harvest of the buffy coat. Extending the dwell time of the leukocyte fraction in the centrifuge bowl and harvesting cells only once leads to greater cell collection efficiency and a more consistent buffy coat cut. Overall leukocyte collection time is also reduced.
- Only the THERAKOS™ CELLEX™ Photopheresis Procedural Kit (Order Number CLXECP) should be used with the THERAKOS™ CELLEX™ Photopheresis System. The procedural kit is sterile and single-use. It is pre-connected, latex-free and may be configured for either a single needle or double needle therapy.
- The THERAKOS™ CELLEX™ Photopheresis System is designed for needle-free use and has incorporated needle-free injection access sites in the patient Collect and Return Lines and at the base of the treatment bag.
- Methoxsalen (20 micrograms / mL) may be removed from the vial with the use of a commercially available needle-free vial adapter. If this adapter is not available, withdraw the medication from the bottle using a needle. Discard the needle using center-specific guidelines for disposal of sharp items. Use only the luer of the syringe to inject the Methoxsalen (20 micrograms / mL) into the treatment bag (*See "Figure 2-2: Correct Liquid Medication Administration" on page 2-6* for the correct technique).

CAUTION:

Do not puncture the needle-free ports with a needle. Damage to these ports will result in leaks.

Item 7
Load Cell Hooks

Item 6
Power Failure Battery
Alarm Cover

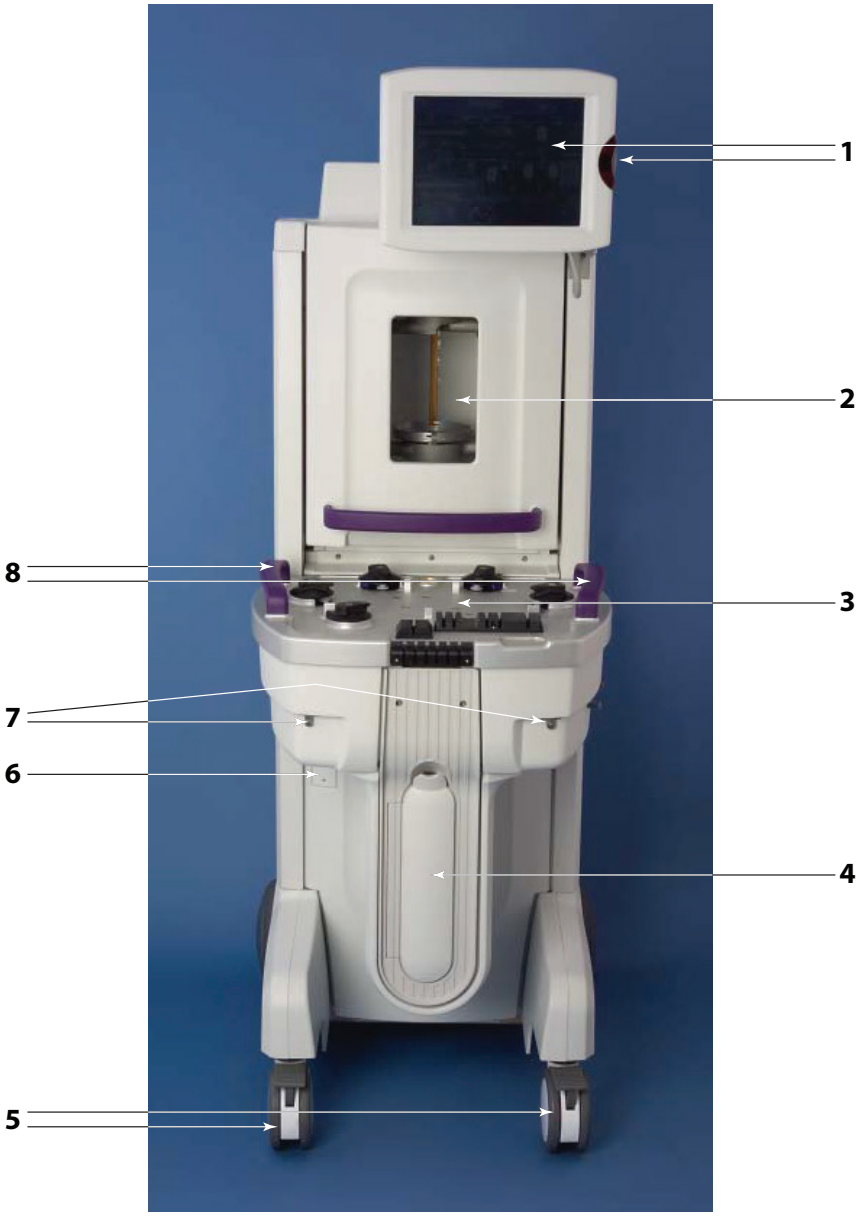


Figure 3-1: THERAKOS™ CELLEX™ Photopheresis System – Front View

1. Operator Interface and Smart Card Port
2. Centrifuge Chamber
3. Pump Deck
4. Photoactivation Chamber
5. Wheel Locks
6. Power Failure Alarm Battery Cover
7. Load Cell Hooks
8. Handles

Figure 3-2: THERAKOS™ CELLEX™ Photopheresis System – Left Side View

1. Operator Interface
2. Pump Deck
3. Front Wheel
4. Rear Wheel
5. Centrifuge Door-Manual Release
6. Rear Handle
7. IV Pole

Figure 3-3: THERAKOS™ CELLEX™ Photopheresis System – Right Side View

1. IV Pole
2. Rear Handle
3. Rear Wheel
4. Front Wheel
5. Saline & Anticoagulant (A/C) Bag Hanging Hooks
6. Centrifuge Chamber Door Handle
7. Power Switch

Figure 3-4: THERAKOS™ CELLEX™ Photopheresis System – Rear View

1. Rear Handle
2. Instrument ID Tag
3. Power Cord Socket
4. Power Cord Wrap Cleats
5. Rear Cooling Vent
6. IV Pole

Description of the THERAKOS™ CELLEX™ Photopheresis System Components

Power Switch

The Instrument must be plugged into an electrical outlet for the ON/OFF power switch to function. A 9 V battery will sound an audible alarm if the power switch is turned on before the Instrument is plugged in.

Figure 3-5a: Power Switch

Figure 3-5b: Power Switch Close-Up

WARNING:
To avoid risk of electric shock, this equipment must only be connected to a supply mains with a protective (earth grounded) receptacle. The use of extension cords is not recommended.

Operator Interface

Figure 3-6: Operator Interface

The operator interface consists of a display monitor with an integrated touch screen. The interface displays the treatment status, treatment data, and any alarm information. You can perform all treatment operations, including PRIME, COLLECT, PHOTOACTIVATE, REINFUSE, and handle all alarms by using the integrated touch screen. Visual and audible alarms are used to alert the user to all special operating conditions. The treatment state number is displayed at the top left of the screen in a faded watermark. This may be useful if technical assistance is required.

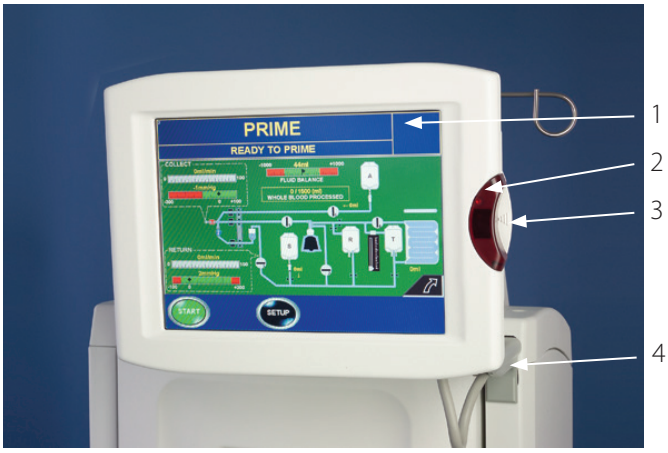


Figure 3-7: Operator Interface in Detail

1. Color LCD Screen/Touch Sensitive Keypad
2. IrDA® Compliant Data Port and USB port (for service troubleshooting only)
3. Smart Card Interface Port
4. Adjustable Display Mount

Treatment data is presented on the user interface in one of two screens.

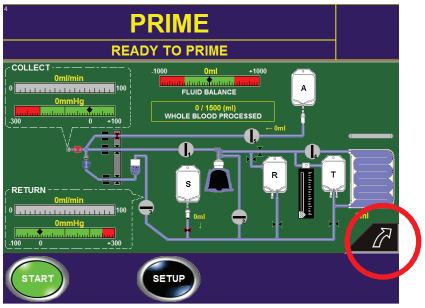


Figure 3-8a: Main Screen of the Operator Interface

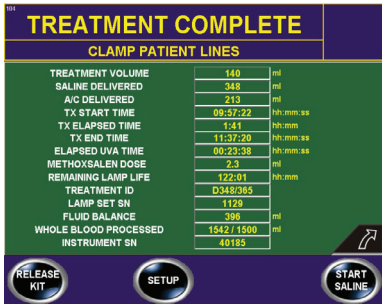


Figure 3-8b: Treatment Summary

The Main Screen of the Operator Interface displays graphical and textual information whereas the other screen only displays textual information. You may switch between these screens by pressing the Next Page Button located in the lower right corner of the screen (***See Figure 3-8a: Main Screen of the Operator Interface***).

A Fluid Balance Calculator is automatically displayed before PRIME ACCESS and is also available through the SETUP screen to assist the operator in estimating the patient's total blood volume and extracorporeal volume limits.

The top center section will display the current phase of the treatment while the subtitle line below will display current status information.

The Priming Status, Photoactivation MINUTES REMAINING, or Hematocrit (HCT) plot are shown in the upper right corner of the middle section of the main screen.

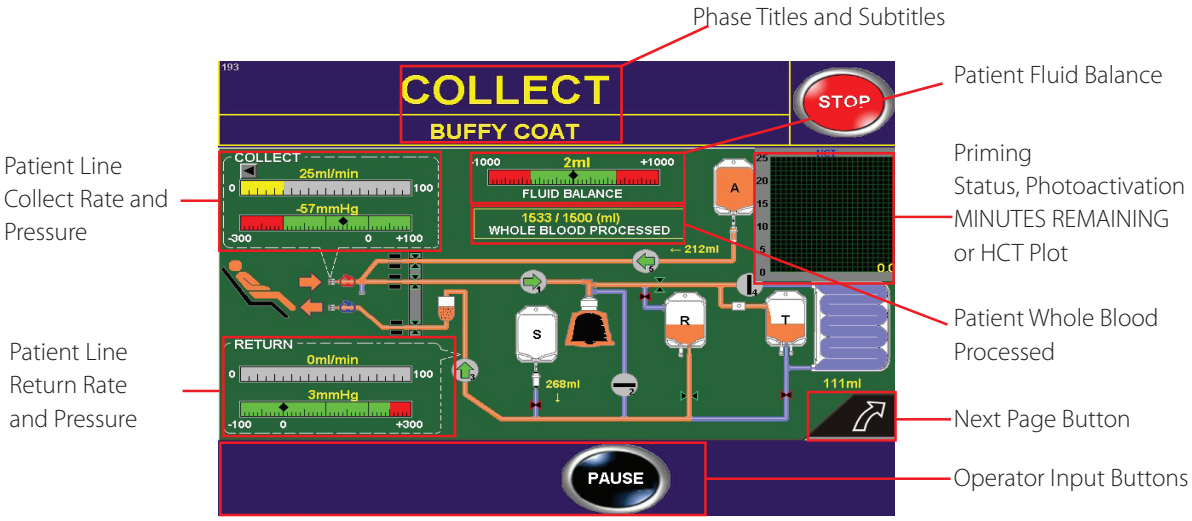


Figure 3-9a: Main Screen Operator Interface Display Detail

Most input is entered using the oval buttons on the bottom of each screen.

The center section of the main screen includes analog bar graphs and numerical indications for COLLECT and RETURN flow rates and line pressures as well as FLUID BALANCE. The screen also displays the current volume of whole blood processed as the treatment proceeds.

The hematocrit of the treatment volume is represented as a bar graph and may be useful if manual intervention is required. The graphic display includes an active schematic representation of the treatment procedural kit and fluid flow paths. Whenever a flow path is active, the path is highlighted in pink. Idle pathways are shown in blue. Pumps (idle, active) and fluid routing valves (closed, open) are also displayed and indicate direction or status real time.

Hematocrit % Plot

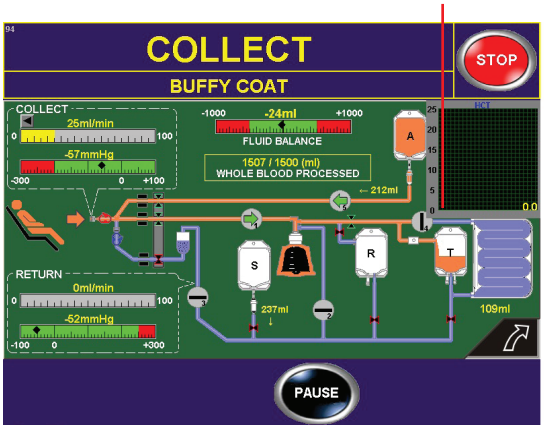


Figure 3-9b: Operator Interface Display Detail

Hematocrit % Bar Graph

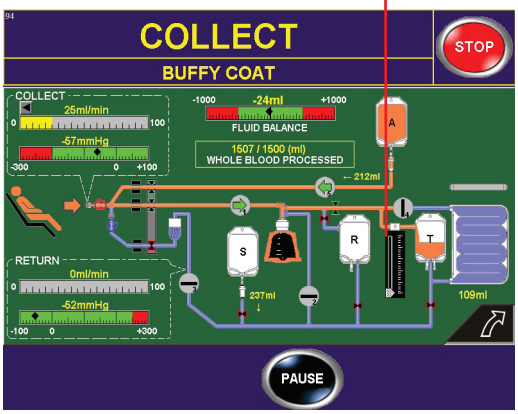


Figure 3-9c: Operator Interface Display Detail

During the BUFFY COAT phase, the Hematocrit % Plot will automatically appear. Tap the Hematocrit % Plot to hide the plot.

The plot displays the slope of the curve as the hematocrit of the buffy coat passing through the cuvette increases.

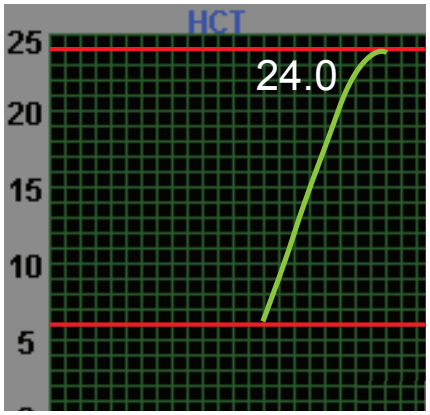


Figure 3-9d: Hematocrit % Plot

NOTE:

- Hematocrit values displayed on the Hematocrit % Bar Graph and Hematocrit % Plot pertain to the hematocrit of the Treatment Volume and not the patient. Sample results obtained via laboratory analyzers may vary. Laboratory analyzers are calibrated to detect only levels within expected clinical low to high ranges.

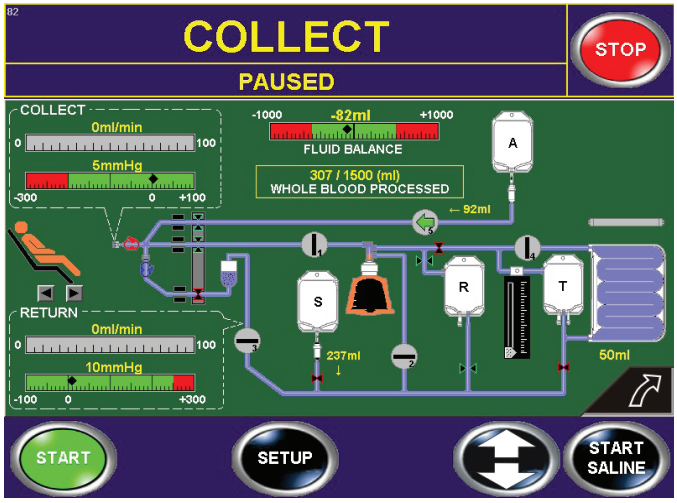


Figure 3-9e: Operator Interface Display Detail

- The treatment is PAUSED. In this state the only active pathway is the Keep Vein Open (KVO) anticoagulant pathway to the patient access.
- The green arrow shows the direction of the (KVO) flow.
- All idle pathways are in blue and their fluid routing valves are closed (RED).
- The START SALINE button is now available.

- In BUFFY COAT, whole blood enters the centrifuge bowl and displaces the buffy coat.
- The routing valve to the return bag is closed (RED) and the routing valve to the treatment bag is open (GREEN).
- Anticoagulant is also active in this phase as shown in pink.
- The Collect Flow Rate is limited to 25 ml/min during BUFFY COAT.
- The Treatment Volume (displayed below the Photoactivation Module) increases.

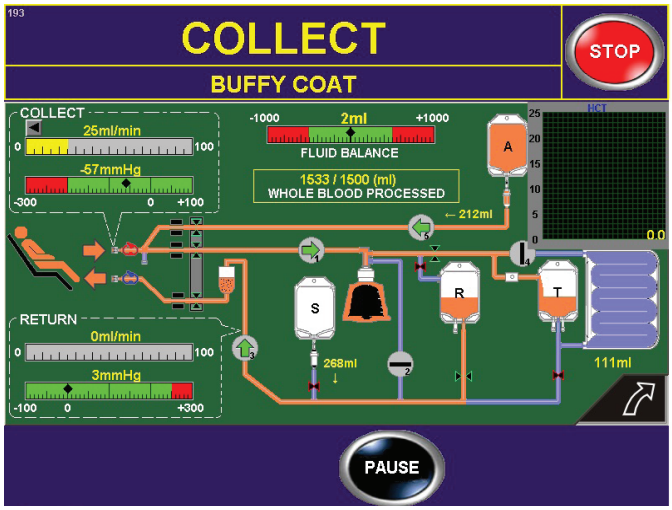
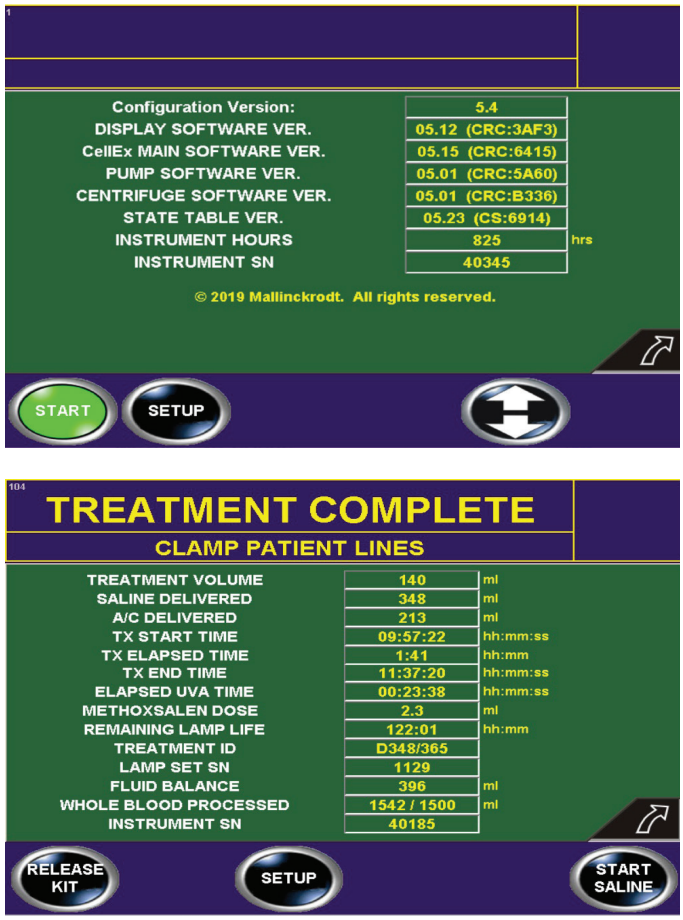


Figure 3-9f: Operator Interface Display Detail



- The System Information screen will display the Instrument Serial Number, Instrument Hours and Software Version Information.
- Treatment Volume = Total Buffy Coat Volume + prime solution.

Figure 3-10: Treatment Summary

THERAKOS™ CELLEX™ Fluid Management System

The THERAKOS™ CELLEX™ Photopheresis System is equipped with a multi microprocessor-controlled Fluid Management System. This system controls all pump and valve functions. It directs fluid routing through the Pump Tubing Organizer and maintains flow rates during all phases of the THERAKOS™ Photopheresis treatment. The Collect and Return Rate Limits are set and controlled by the operator. Collect Line and Return Line pressure is monitored and is a function of the Collect/Return Rate Limit settings and the patient's access. The Collect, Return, and Reinfusion Rate Limits may be changed as needed by entering the SETUP screen. The Collect, Return and Reinfusion Flow Rates may be changed (within the setup limits) directly at the main screen. Pressure limits may also be set by the operator and will stop fluid flow when limits are exceeded. *See "Changing Default SETUP Parameters" on page 5-14*.

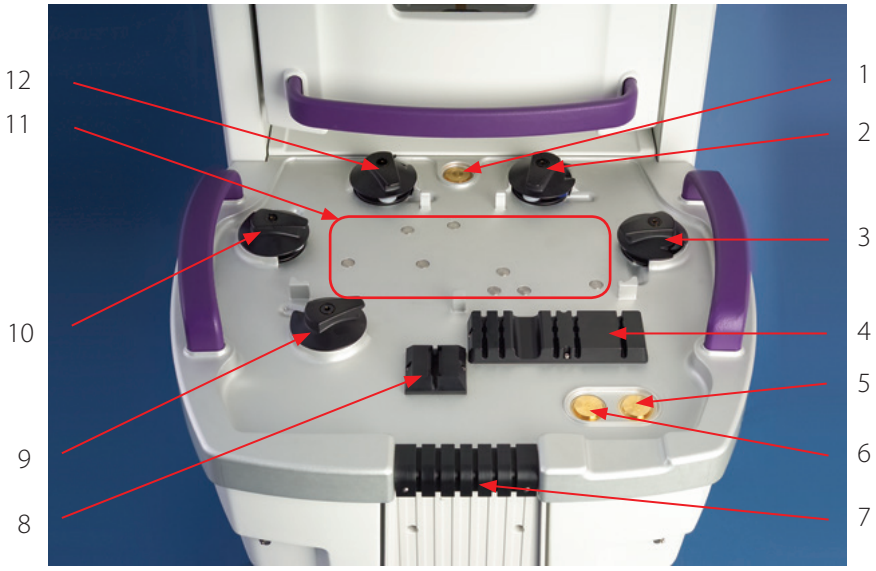


Figure 3-11: THERAKOS™ CELLEX™ Fluid Management System

1. System Pressure Transducer
2. Red Blood Cell Pump (#2)
3. Return Pump (#3)
4. Air Detectors
5. Return Line Pressure Transducer
6. Collect Line Pressure Transducer
7. Tubing Guides
8. Hematocrit Sensor
9. Recirculation Pump (#4)
10. A/C Pump (#5)
11. Fluid Routing Valves
12. Collect Pump (#1)

NOTE:
A number code is assigned to each pump. The pump tubing segments attached to the Pump Tubing Organizer are numbered accordingly.

Fluid Management System and Pump Tubing Organizer

Whole blood, saline, and anticoagulant are all routed through the Pump Tubing Organizer (PTO). Access performance is continually monitored using Pressure Sensors. Any fluids that return to the patient are monitored for air and filtered before leaving the PTO. In some alarm states, all Fluid Routing Valves will be closed to prevent fluid movement within the extracorporeal circuit until the alarm state is cleared.

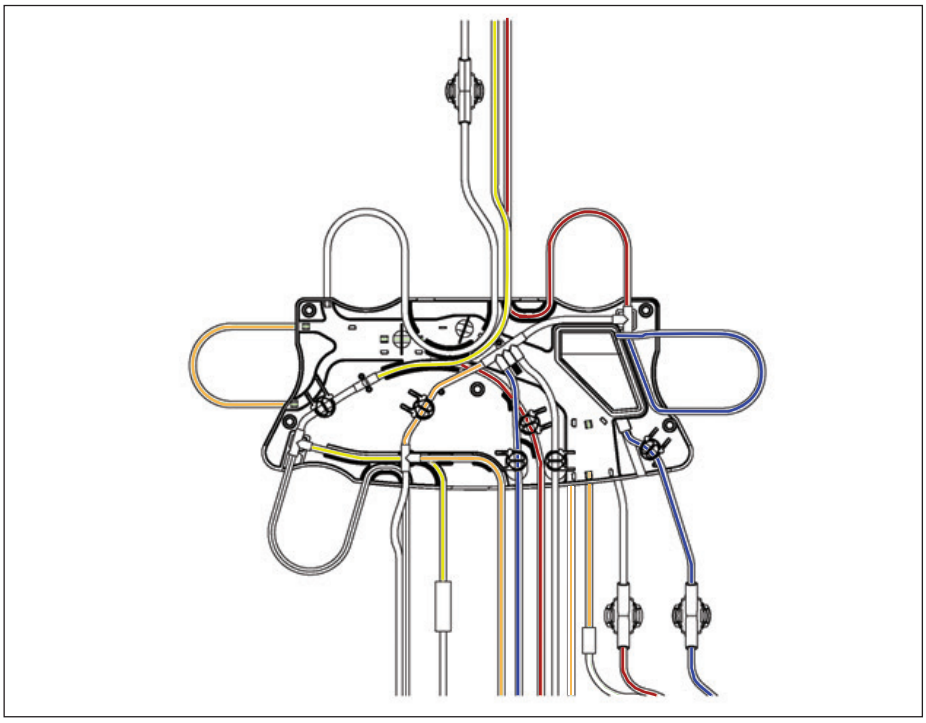


Figure 3-12: Pump Tubing Organizer

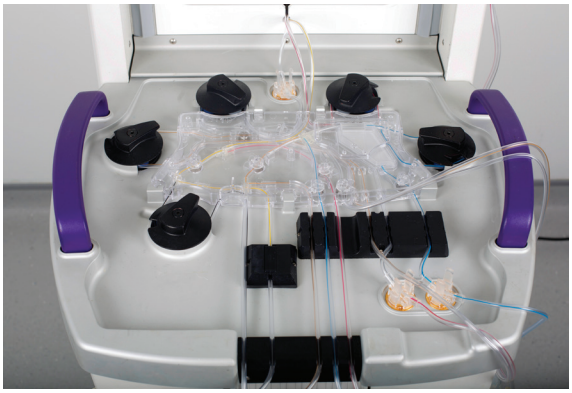


Figure 3-13: Pump Tubing Organizer on Pump Deck

Hematocrit Sensor

The automatic detection of hematocrit is based on a change in light transmittance as the effluent from the centrifuge bowl passes through the hematocrit cuvette seated in the hematocrit sensor housing during BUFFY COAT. (See ***"Figure 3-16: Change in Light Transmittance during BUFFY COAT Phase"***) The Hematocrit Sensor also determines the hematocrit of the Treatment Volume. This value is required to calculate the duration of UVA light exposure or the photoactivation time (displayed in MINUTES REMAINING) during PHOTOACTIVATE.

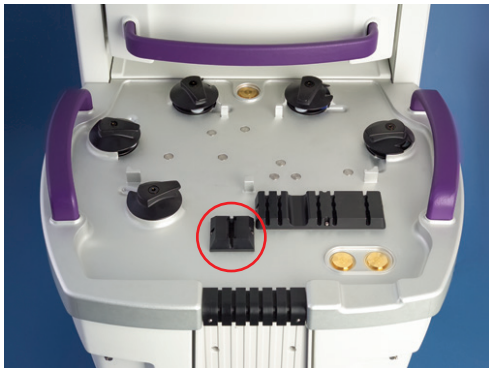


Figure 3-14: Automatic Hematocrit Sensor

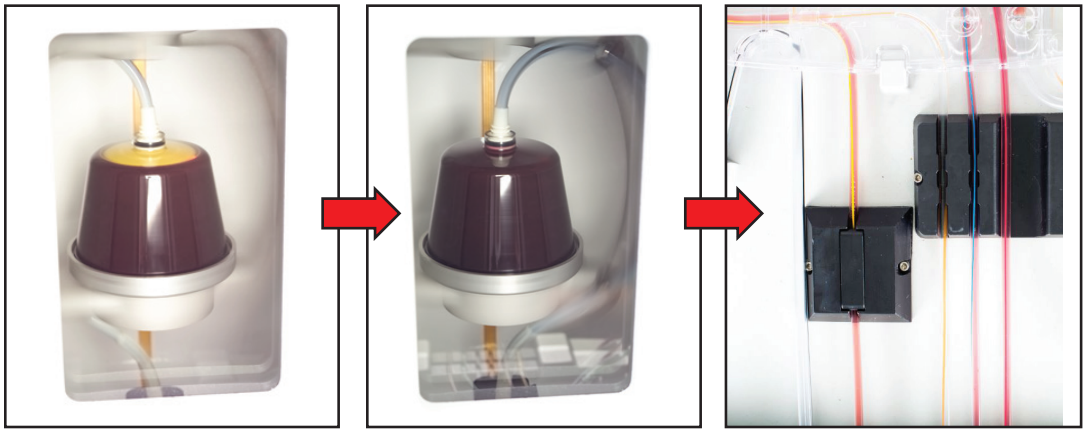
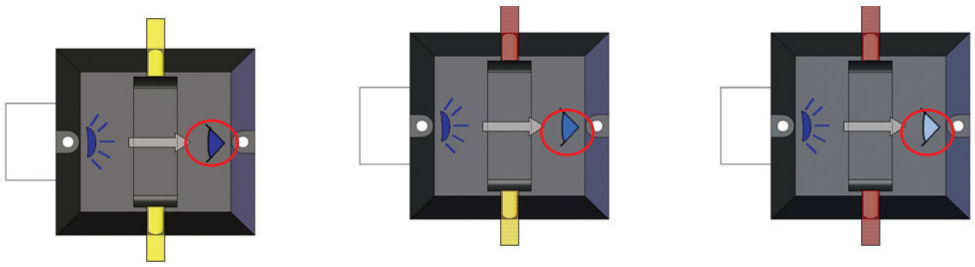


Figure 3-15: Buffy Coat Leaving the Centrifuge Bowl and passing through the Automatic Hematocrit Sensor.

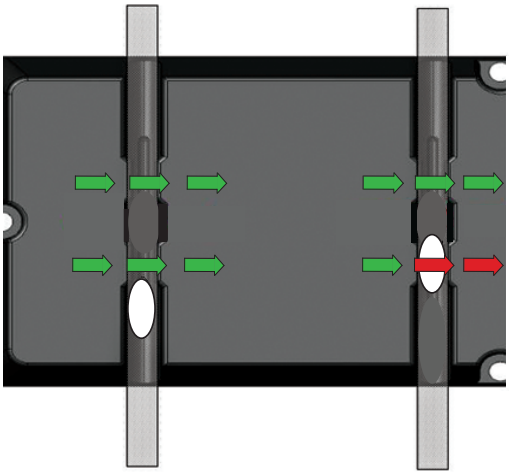


No change Slight Change (↓) Target Change (↓ ↓)

Figure 3-16: Change in Light Transmittance during BUFFY COAT Phase

Air Detectors

Digital ultrasonic pulses are used to detect air bubbles in the patient Collect and Return Lines as well as the Anticoagulant Line. An alarm condition occurs any time air is detected in these lines during a treatment. Additional Air Detectors are used to monitor the level of fluid in the return bag and treatment bag. All Air Detectors are tested as part of the instrument Power-ON self-test.



Ultra sonic pulses pass readily through fluid but are blocked by air.

Figure 3-17: Air Detected by Ultrasonic Pulses

Figure 3-18a: Location of Air Detectors

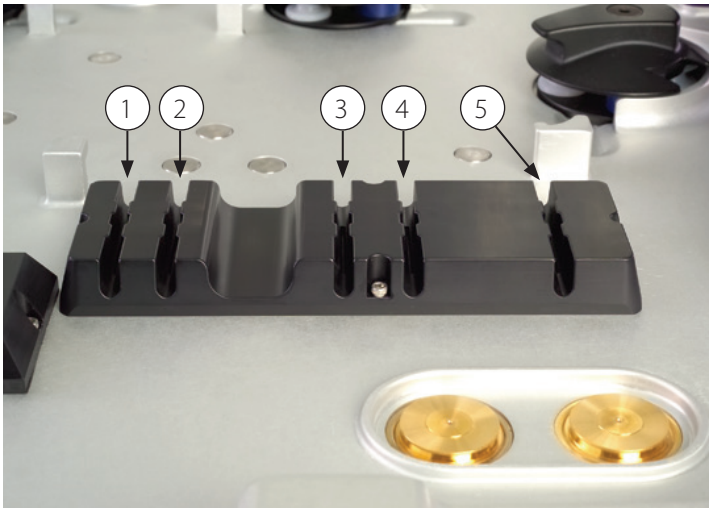


Figure 3-18b: Identification of Air Detectors

1. Treatment Bag Line
2. Return Bag Line
3. Patient A/C Line
4. Patient Collect Line
5. Patient Return Line

Placement of Saline and Anticoagulant Bags

Saline and Anticoagulant Bags hang on the two hooks provided below the pump deck on the lower-right side of the instrument (as you face it) and must be connected to the proper spike port of the procedural kit.

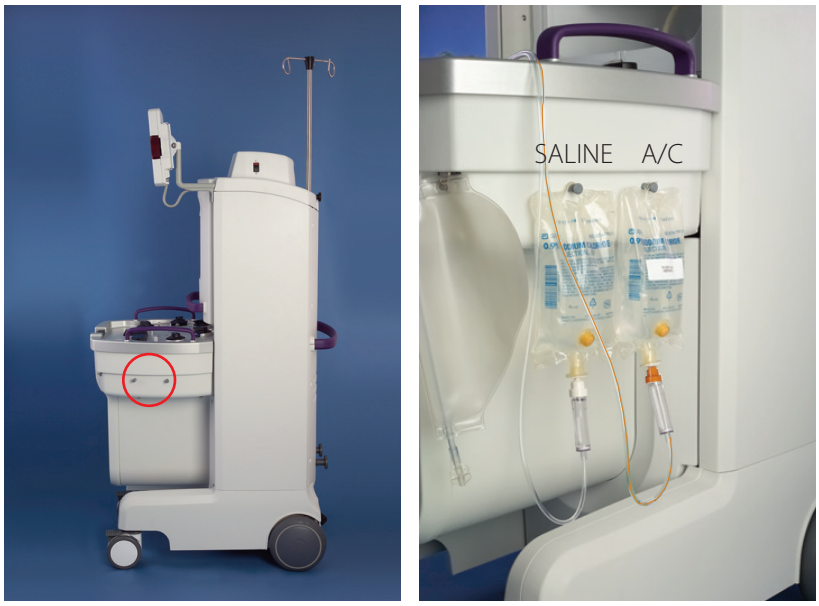


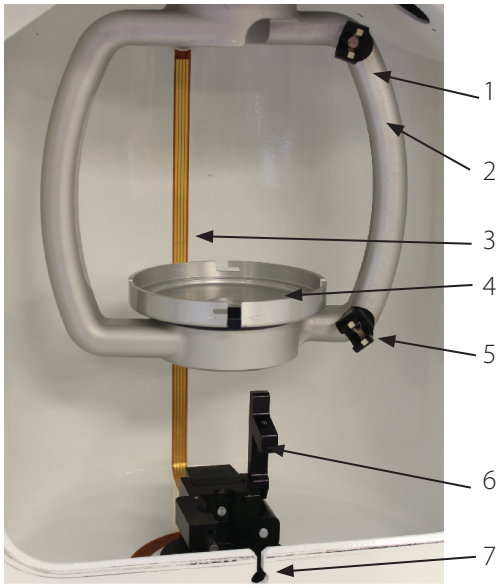
Figure 3-19: Correct Placement of Saline and Anticoagulant (A/C) Bags

CAUTION:

- Correct attachment of the Saline and Anticoagulant Bags to the correct fluid spike is essential. ***(See Figure 3-19: Correct Placement of Saline and Anticoagulant (A/C) Bags)***. Incorrect attachment may lead to clotting in the procedural kit, patient blood loss, and a failed treatment.
- Always confirm the contents, lot number, and expiration date of any solution prior to its use.
- Saline and Anticoagulant Spike Lines do not have slide clamps. Instead, Fluid Routing Valves - activated when the base of the Drive Tube is inserted into the Drive Tube Clamp Assembly and the Drive Tube Latch is closed - prevent gravity flow of fluid from entering the Pump Tubing Organizer prior to PRIME. The presence of the START button indicates these lines are clamped.

Centrifuge Assembly

The centrifuge assembly of the THERAKOS™ CELLEX™ Photopheresis System is located at eye level for easy monitoring.



0. Upper Bearing Retainer
1. Centrifuge Frame
2. Centrifuge Leak Detector
3. Centrifuge Bowl Holder
4. Lower Bearing Retainer
5. Drive Tube Latch
6. Tubing Exit Slot

Figure 3-20a: Centrifuge Assembly

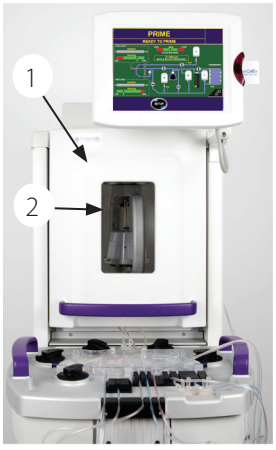


Figure 3-20b: Centrifuge
1. Centrifuge Chamber Door - CLOSED
2. Viewing Window

Figure 3-20c: Centrifuge: Viewing Window

Figure 3-20d: Centrifuge: Bowl Optic Sensor

Bowl Optic Sensor

The Centrifuge Assembly is equipped with a Bowl Optic Sensor that automatically identifies the red blood cell layer. It is used by the system computer to establish the Red Blood Cell Pump speed in an effort to maintain the buffy coat within the spinning centrifuge bowl.
The Bowl Optic Sensor is automatically calibrated to its default setting and checked during PRIME. You can adjust the Bowl Optic setting if necessary. For more information, *See "Changing Default SETUP Parameters" on page 5-14*.

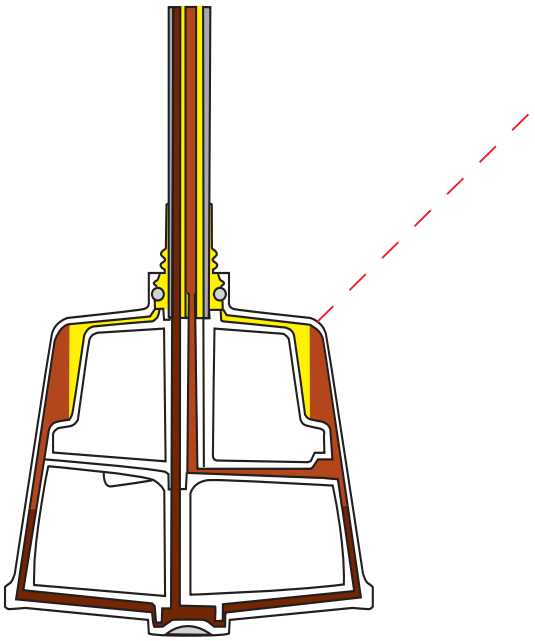


Figure 3-21a: Plasma/Red Blood Cell Interface (Schematic)

Figure 3-21b: Plasma/Red Blood Cell Interface (Actual)

Displaying the Centrifuge Bowl Optic Sensor Value

The main screen display shows a spinning centrifuge highlighted in pink during COLLECT. To display the volume of the bowl in milliliters, tap on the centrifuge bowl icon once. Tap on the centrifuge bowl icon a second time to display the centrifuge bowl optic sensor value.

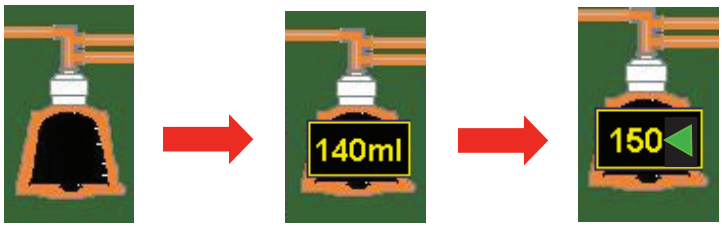


Figure 3-21c: Optic Sensor Value

Using the displayed Centrifuge Bowl Optic Sensor Value

The default BOWL OPTIC THRESHOLD VALUE is 150. The displayed centrifuge bowl optic sensor value has an inverse relationship to the position of the plasma/erythrocyte interface in the centrifuge bowl.

- Constant communication between the bowl optic sensor and the red cell pump (#2) is required to maintain the plasma/erythrocyte interface at the correct position during DRAWING.
- When the interface is directly in line with the level of the red laser beam, the displayed centrifuge bowl optic sensor value is 150.
- When the interface is ***higher*** than the level of the red laser beam, the displayed centrifuge bowl optic sensor value is ***lower*** than 150.
- When the interface is ***lower*** than the red laser beam, the displayed centrifuge bowl optic sensor value is ***higher*** than 150.

NOTE:
For information on changing the BOWL OPTIC THRESHOLD VALUE, *see page 5-25*

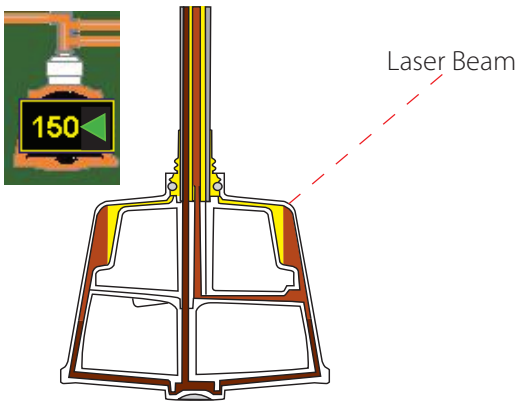


Figure 3-22: Default BOWL OPTIC THRESHOLD VALUE is 150 and interface is established

During COLLECT, after PURGING AIR, the plasma/erythrocyte interface is established. At this time the displayed centrifuge bowl optic sensor value should match the BOWL OPTIC THRESHOLD VALUE. Then, as additional whole blood is processed and the leukocyte fraction expands, the position of the plasma/erythrocyte interface fluctuate

- During DRAWING, when the interface is slightly higher than the level of the red laser beam, the displayed centrifuge bowl optic sensor value is between 150 and 140.
- When the interface is slightly lower than the level of the red laser beam, the displayed centrifuge bowl optic sensor value is between 150 and 160.
- During RETURNING in Single Needle Mode, the centrifuge bowl spins and packs the erythrocytes. The position of the interface becomes even lower in the bowl, so the displayed centrifuge bowl optic sensor value becomes considerably higher than 160.
- During PAUSE in either Double Needle Mode or Single Needle Mode, the interface again packs and becomes lower than the level of the red laser beam. So again, the displayed centrifuge bowl optic sensor value is considerably higher than 160.

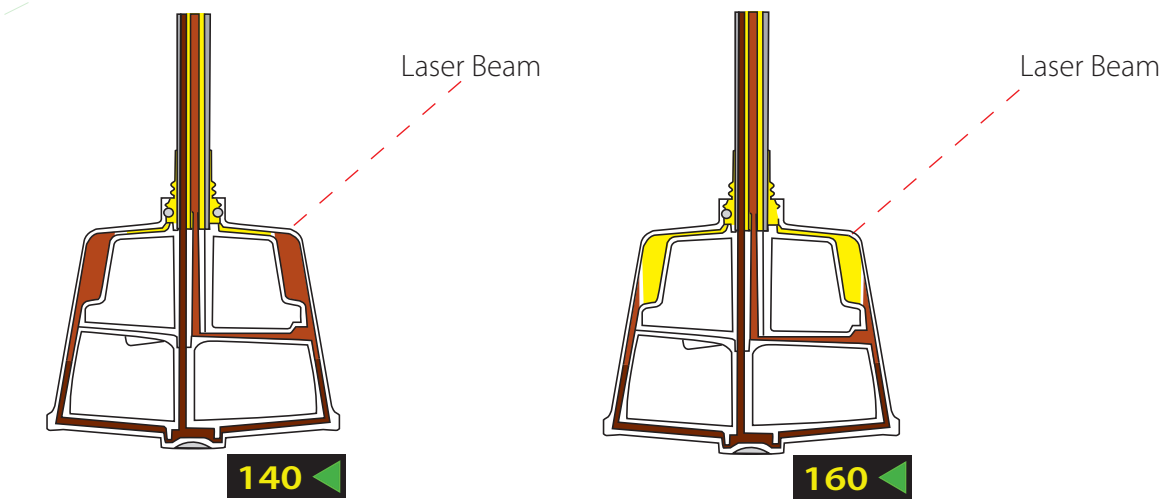
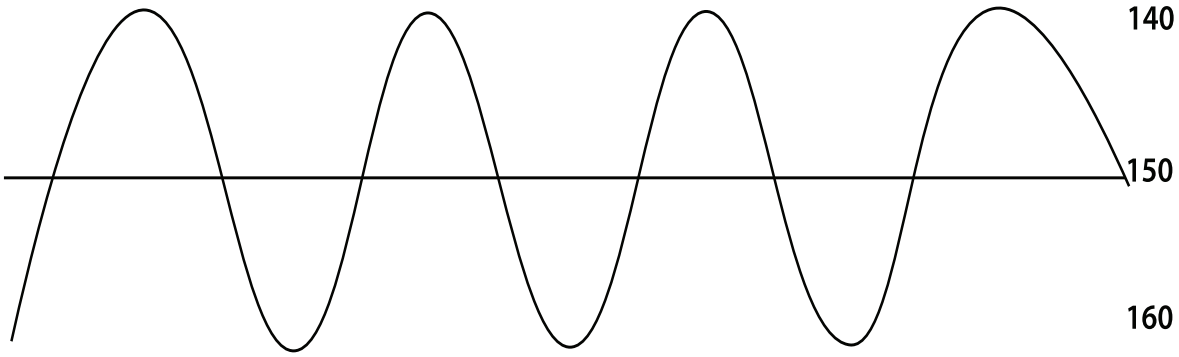


Figure 3-23: During DRAWING, the displayed centrifuge bowl optic sensor value fluctuates between140 and 160.



The graph illustrates the fluctuation of the displayed centrifuge bowl optic sensor value as the plasma/erythrocyte interface is maintained.

NOTE:
During Red Blood Cell Pump Alarms or while processing whole blood with abnormal plasma conditions, displayed bowl optic sensor values may not follow the pattern described above.

WARNING:
The Bowl Optic Sensor contains a laser light source. Do not stare directly into the beam.

CAUTION:
Laser - Use of controls or adjustments or performance of procedures other than those specified in Section 8 may result in hazardous radiation exposure.

Centrifuge Leak Detector

A leak detector located in the centrifuge chamber will stop the centrifuge and sound an alarm if fluid or humidity comes in contact with the sensor due to a centrifuge bowl or drive tube leak.

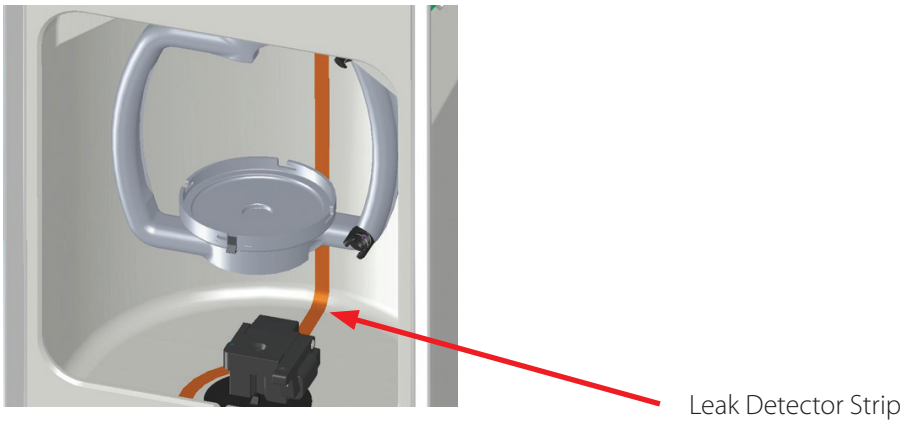


Figure 3-24: Centrifuge Leak Detector

Centrifuge Chamber Door/Manual Release Access

The centrifuge chamber door must be closed before the instrument is primed. An interlocking safety latch will prevent the centrifuge chamber door from opening while the centrifuge is in use. The door will open freely whenever the centrifuge is not in use. If the centrifuge stops due to loss of power during the treatment, you may open the door by manually overriding the safety-interlocking latch (Centrifuge Chamber Door Manual Release). The centrifuge chamber door manual release access is located on the left side of the instrument *(See Figure 3-26)*.

Figure 3-25: Centrifuge Chamber Door: Manual Release Access

Figure 3-26: Centrifuge Chamber Door: CLOSED

Photoactivation Chamber/THERAKOS™ CELLEX™ Light Assembly

The THERAKOS™ CELLEX™ Photopheresis System controls the power source for the THERAKOS™ CELLEX™ Light Assembly. The light assembly is a single assembly incorporating 18 lamps which deliver the optimum UVA light energy for effective photoactivation of the collected leukocytes.

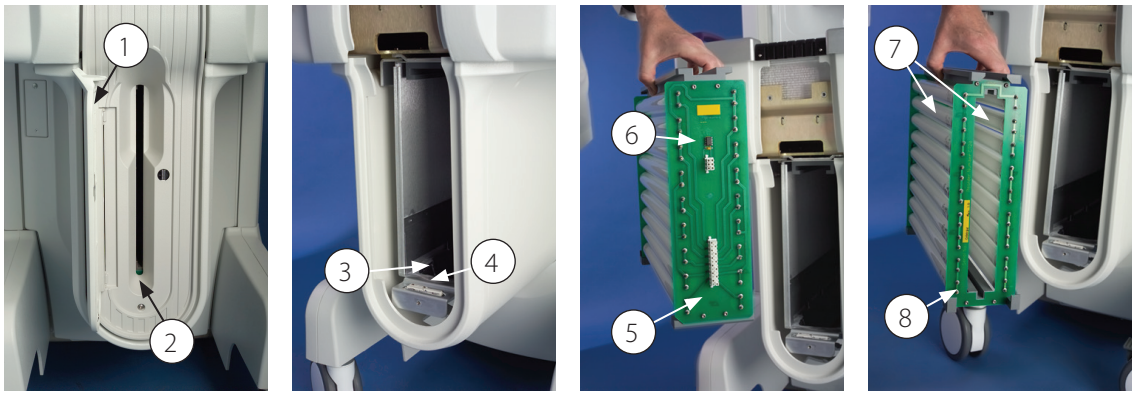


Figure 3-27: Photoactivation Chamber/THERAKOS™ CELLEX™ Light Assembly

1. Photoactivation Chamber Door
2. Receptacle for Photoactivation Module
3. Photoactivation Chamber Leak Detector
4. Photoactivation Chamber Leak Catch Bin
5. THERAKOS™ CELLEX™ Light Assembly Back
6. Lamp Data Chip
7. UVA Lamps
8. THERAKOS™ CELLEX™ Light Assembly Front

The light assembly has a programmed life of 150 photoactivation hours. Lamp life is electronically monitored and displayed by the THERAKOS™ CELLEX™ Photopheresis System. During treatment, the system delivers the full UVA light energy level throughout the entire exposure period. Each light assembly has several reserve hours available to be used if the photoactivation MINUTES REMAINING exceeds remaining hours displayed. When 10 hours of lamp life remain, a pop-up message stating, "Warning! Lamp Life Low" will display on the operator interface, it is recommended that the lights be changed at the end of the current treatment. When the total lamp life has been depleted, an alarm and message will prompt for replacement prior to the next treatment. See ***"Replacing the THERAKOS™ CELLEX™ Light Assembly" on page 7-8*** for complete instructions on how to change the light assembly.

During PHOTOACTIVATE the THERAKOS™ CELLEX™ Photopheresis System continuously pumps and recirculates the leukocyte enriched blood fraction through the Photoactivation Module (at a rate of 100 mL/min) for uniform penetration of UVA light to all collected leukocytes. A leak detector continuously monitors the Photoactivation Chamber for fluid leaks.

WARNING:

- The calculated dose of UVA light energy will not be delivered if the THERAKOS™ CELLEX™ Light Assembly is changed after the calculation of photoactivation MINUTES REMAINING is displayed.
- It is recommended that the full PHOTOACTIVATE time be completed during every treatment. The calculated dose of UVA light energy will not be delivered if PHOTOACTIVATE is stopped for any reason before the photoactivation MINUTES REMAINING is equal to 00:00 (minutes:seconds).

CAUTION:

- Always change an aged THERAKOS™ CELLEX™ Light Assembly prior to starting a treatment.
- Turn the power OFF and unplug the instrument prior to changing the light assembly.
- Never change the light assembly during a treatment if the photoactivation MINUTES REMAINING has already been calculated.
- Do not attempt to modify the THERAKOS™ CELLEX™ Photopheresis System or the THERAKOS™ CELLEX™ Light Assembly in any way.

For more information about replacing the THERAKOS™ CELLEX™ Light Assembly, see *"Replacing the THERAKOS™ CELLEX™ Light Assembly" on page 7-8*.

THERAKOS™ CELLEX™ Photopheresis Procedural Kit

The THERAKOS™ CELLEX™ Photopheresis Procedural Kit is a single-use, latex-free, disposable, closed system with sterile fluid pathways. All components are pre-connected for easy setup. The components are contained in a disposable plastic tray. The tray has an easy-to-remove Tyvek® lid.

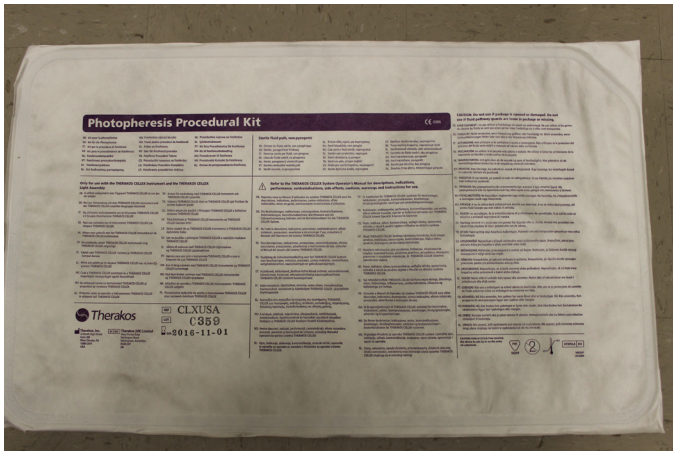


Figure 3-28: THERAKOS™ CELLEX™ Photopheresis Procedural Kit

The THERAKOS™ CELLEX™ Photopheresis Procedural Kit contains the following components:

- Pump Tubing Organizer and Blood Filter
- Photoactivation Module
- Centrifuge Bowl and Drive Tube
- Hematocrit Cuvette
- Treatment Bag
- Return Bag
- Saline and Anticoagulant Spikes
- Patient Collect and Return Lines
- Collect, Return, and System Pressure Domes
- Smart Card

THERAKOS™ CELLEX™ Photopheresis Procedural Kit Storage and Handling

NOTE:

- If the package is opened or items appear damaged, do not use the THERAKOS™ CELLEX™ Photopheresis Procedural Kit. Notify Mallinckrodt of the damage at one of the phone numbers on the back page of this manual and save the damaged item for inspection by Mallinckrodt.
- Do not use a THERAKOS™ CELLEX™ Photopheresis Procedural Kit after its expiration date.
- Do not use the THERAKOS™ CELLEX™ Photopheresis Procedural Kit if any of the protective caps on the patient lines or fluid spikes are missing or off when the kit is opened. Sterility of the kit may be compromised if these caps are removed prior to use.
- Do not allow the packaging tub to become wet.
- Store in a dry place and avoid exposure to vapors of lacquer, paint thinners, and other solvents.
- Avoid exposure to temperatures above 50°C (122°F) and below -20°C (-4°F).
- Make sure that hands and gloves are clean and dry before handling the THERAKOS™ CELLEX™ Photopheresis Procedural Kit to prevent contamination.
- Use special care when handling the Photoactivation Module. Hold the Photoactivation Module by the frosted edges and avoid the fluid pathways.
- The THERAKOS™ CELLEX™ Photopheresis Procedural Kit is intended for Single Use Only! Any attempt to re-use this kit may lead to:
    - A biohazard risk to both patient and operator
    - Risk of infection to the patient
    - Risk of blood incompatibility to the patient

Inspecting the THERAKOS™ CELLEX™ Photopheresis Procedural Kit

Inspect each component of the THERAKOS™ CELLEX™ Photopheresis Procedural Kit at the time of setup. Check tubing for kinks that would obstruct flow. Check plastics, such as the photoactivation module, centrifuge bowl, and pressure domes for any defects. Any defective material should not be used for a patient treatment. Save the defective procedural kit for return to manufacturer. Call Mallinckrodt to report the problem.

WARNING:
Any narrow passages in the procedural kit (such as kinks in the tubing or access devices that are too narrow) may cause hemolysis that will not be detected by the system.

THERAKOS™ CELLEX™ Photopheresis Procedural Kit Components

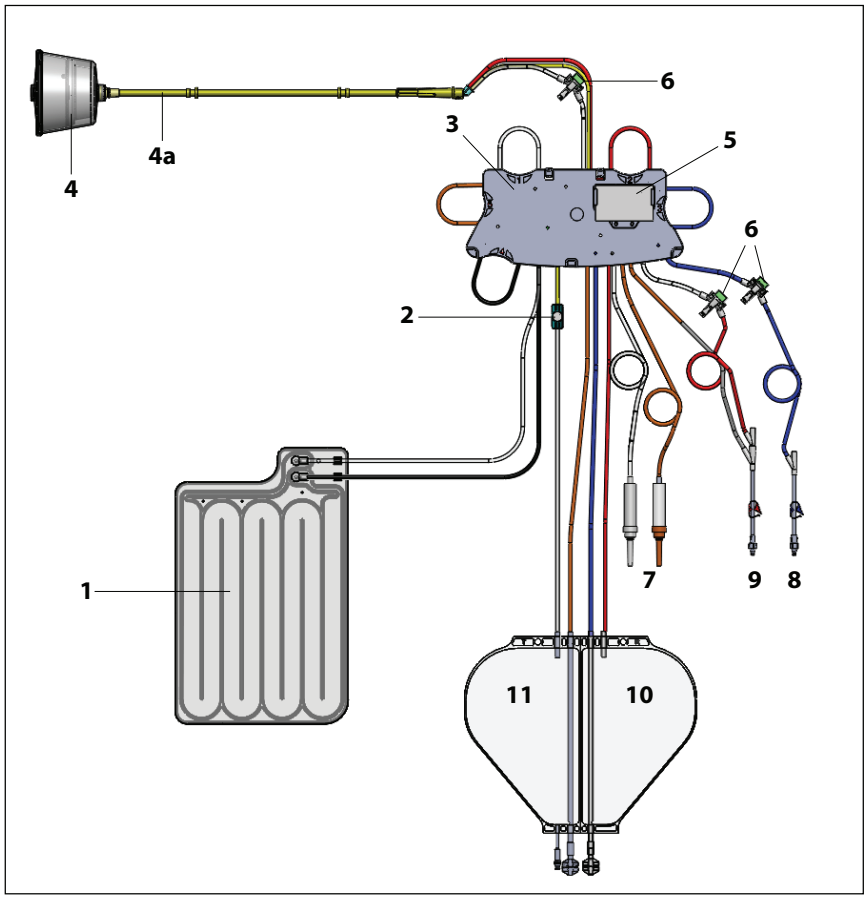


Figure 3-29: THERAKOS™ CELLEX™ Photopheresis Procedural Kit Components

1. Photoactivation Module
2. Hematocrit Cuvette
3. Pump tubing Organizer
4. Centrifuge Bowl

4a. Drive Tube

5. Smart Card
6. Pressure Domes
7. Saline and Anticoagulant Spike Chambers
8. Patient Return Line
9. Patient Collect Line

10. Return Bag
11. Treatment Bag

Photoactivation Module

The Photoactivation Module is a thin, sterile fluid pathway constructed of UVA-transparent acrylic. It is inserted into the slot on the front of the instrument behind the Photoactivation Chamber Door. When installed, it will be situated between the two banks of UVA lamps.

- The buffy coat recirculates through the serpentine pathway of the module during PHOTOACTIVATE.
- The vertical orientation of the Photoactivation Module allows it to be drained without the need of a saline rinse.

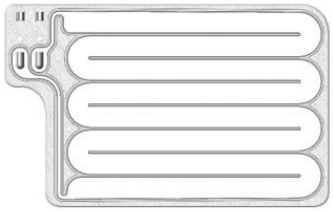


Figure 3-30: Photoactivation Module

CAUTION:
Do not clean the Photoactivation Module. Cleaning agents could leave a film that may adversely affect the transmission of UVA light energy and the photoactivation process.

Centrifuge Bowl

The THERAKOS™ CELLEX™ Photopheresis System incorporates a custom continuous flow centrifuge bowl which is designed to separate the components of anticoagulated whole blood as the blood enters the spinning centrifuge bowl. Separation within the centrifuge bowl is from the lowest density component near the center of the centrifuge bowl to the highest density component near the outer wall (See ***"Figure 3-32: Specific Gravity Chart" on page 3-29***). The order of separation from lowest to highest density is: plasma, platelets, white blood cells, and red blood cells. When the default settings are in use, the entire buffy coat from 1500 mL of Whole Blood Processed will be continuously harvested in the centrifuge bowl. Flow of whole blood to and from the patient may be either continuous (DOUBLE NEEDLE mode) or discontinuous (SINGLE NEEDLE mode).

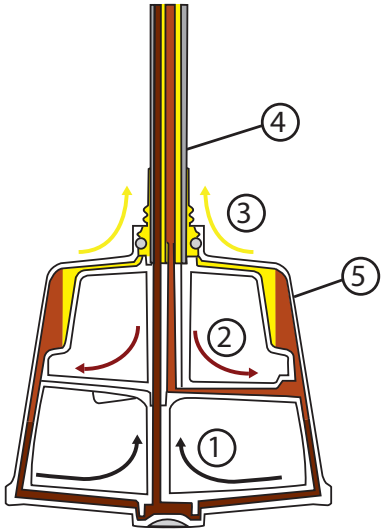


Figure 3-31a: Continuous Flow Centrifuge Bowl

1. Red Blood Cells: OUT
2. Whole Blood: IN
3. Plasma: OUT
4. Drive Tube
5. Continuous Flow Centrifuge Bowl

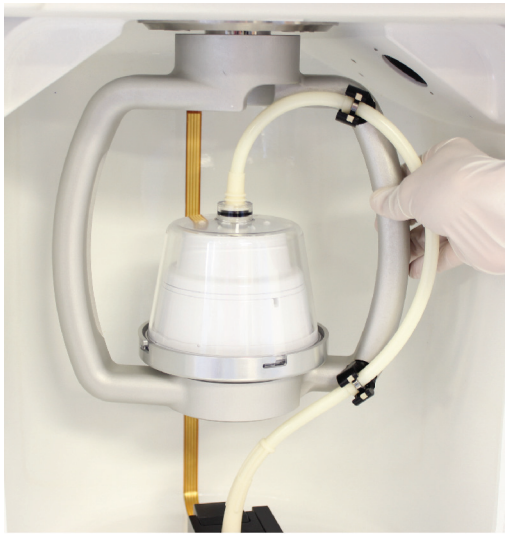


Figure 3-31b: Centrifuge Bowl: Empty

Figure 3-31c: Centrifuge Bowl: Full

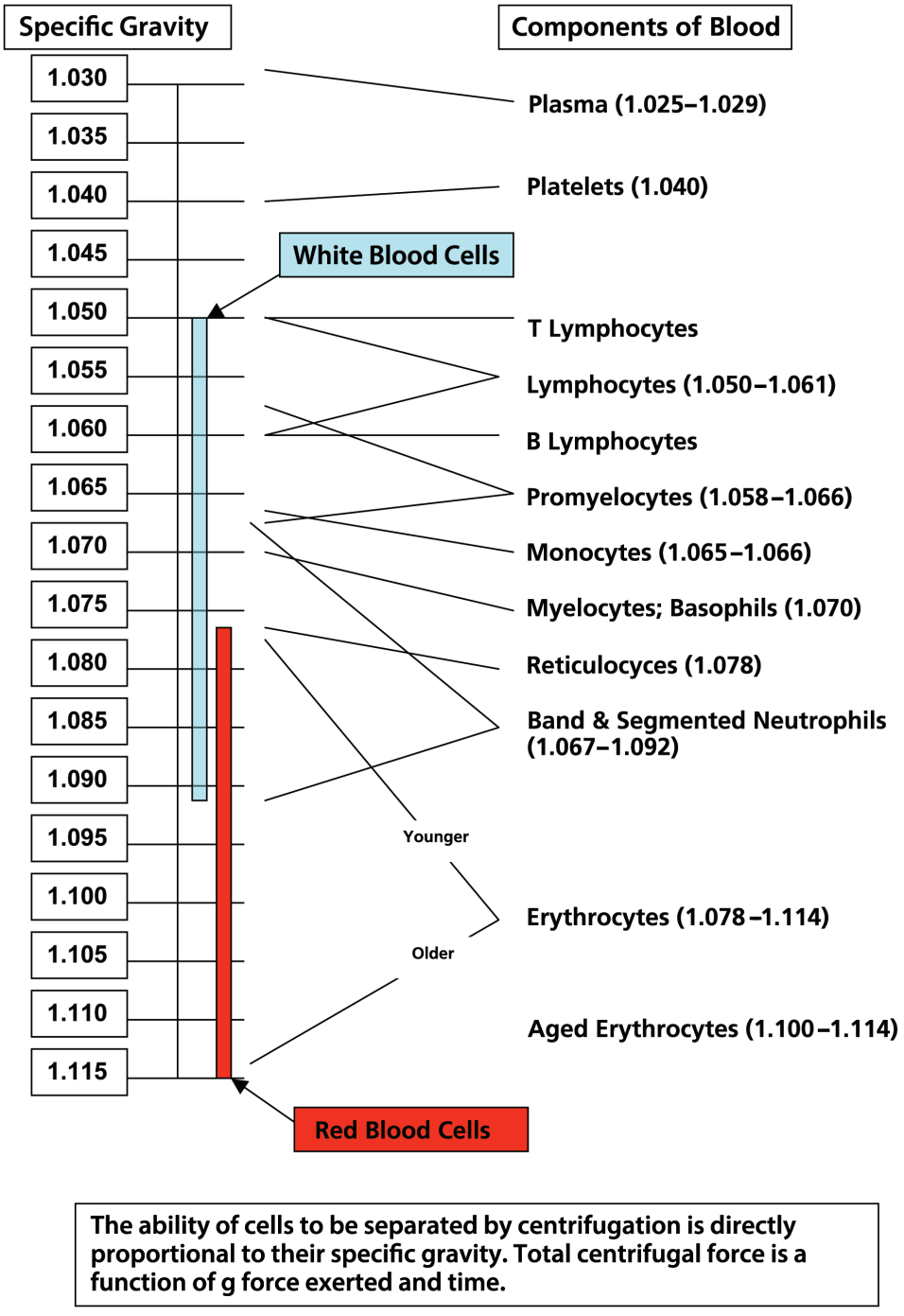


Figure 3-32: Specific Gravity Chart

Pump Tubing Organizer

The Pump Tubing Organizer integrates the fluid tubing segments and routing manifolds to facilitate easier loading of the pump tubing segments and provides the backstop for tubing clamps. The organizer also includes a drip chamber and 200-micron blood filter for fluids returning to the patient. Tubing segments for all five peristaltic pumps are all routed through the Pump Tubing Organizer.

Peristaltic Pumps

Five pumps (identified in Figure 3-34) move fluids by the action of multiple equally spaced rollers, which rotate and compress a flexible tube. See *SECTION 8: SPECIFICATIONS* for pump accuracy and limitation details.

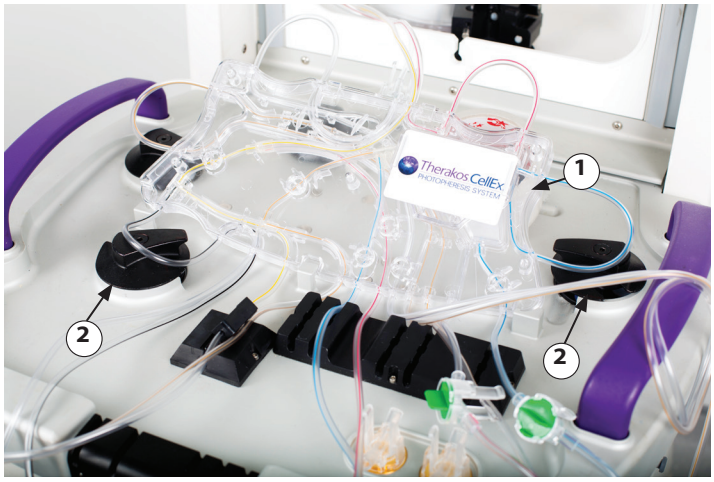
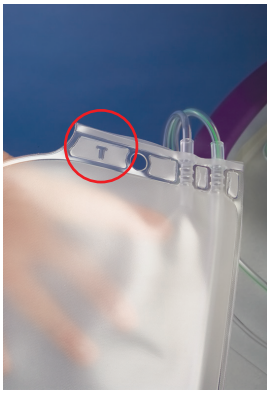
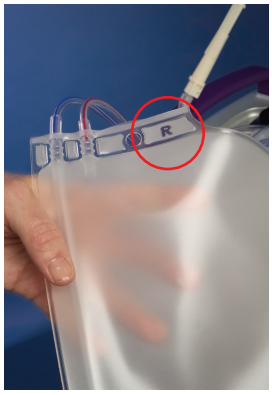


Figure 3-33: Peristaltic Pumps
1. Pump Tubing Organizer
2. Peristaltic Pumps

Treatment Bag/Return Bag

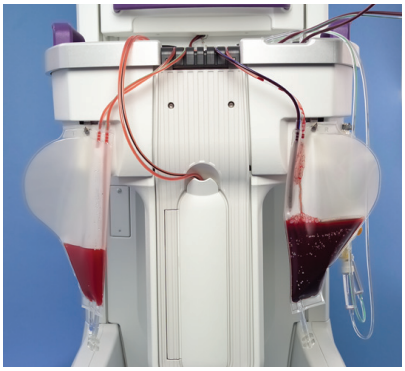
The THERAKOS™ CELLEX™ Photopheresis Procedural Kit includes both Treatment and Return bags that are labeled "T" and "R", respectively.





- The treatment bag contains buffy coat and is a part of the recirculation loop during PHOTOACTIVATE.
- The return bag is used for storage of plasma and/or red blood cells before they are returned to the patient.

Figure 3-34: Treatment Bag and Return Bag Labels



- The treatment bag injection port is used for injecting the prescribed amount of medication prior to photoactivation. It may also be used as a sample site.
- The treatment bag has a spike port that may be used in the event that manual blood return is required.

Figure 3-35: Treatment Bag/Return Bag Placement

Buffy Coat in Treatment Bag (on left)
Red Blood Cells/Plasma in Return Bag (on right)

Figure 3-36a: Treatment Bag: Needle-free Port, Spike Port

Figure 3-36b: Return Bag: Spike Port

Hematocrit Cuvette

The Hematocrit Cuvette provides the disposable viewing window through which the Hematocrit Sensor measures the hematocrit of the leukocyte enriched blood fraction as it leaves the centrifuge bowl and enters the treatment bag. The Hematocrit Sensor determines when buffy coat collection should end. During BUFFY COAT the hematocrit % is constantly measured and displayed by the system. The Hematocrit Sensor also measures the hematocrit % of the product and the THERAKOS™ CELLEX™ Photopheresis System uses this value to calculate the proper photoactivation time.

Avoid putting fingers on the viewing window and be certain the Hematocrit Cuvette is seated properly in the Hematocrit Sensor.

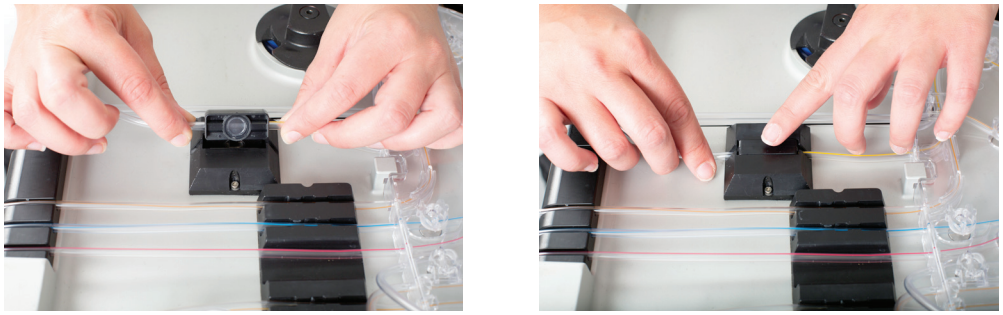


Figure 3-37: Correct: Hematocrit Cuvette Handling and Placement

Tubing Lines

The THERAKOS™ CELLEX™ Photopheresis Procedural Kit contains all tubing necessary to complete a treatment. The tubing includes the following lines:

Patient Collect Line

The Patient Collect Line is used to connect to patient blood access. The Patient Collect Line must be placed into the Collect Air Detector slot and is identified with a (RED) stripe and a (RED) clamp.

Patient Return Line

The Patient Return Line is used to return blood to the patient in DOUBLE NEEDLE mode or is connected to the Patient Collect Line needle-free injection port in SINGLE NEEDLE mode. The Patient Return Line must be placed into the Return Air Detector slot and is identified with a (BLUE) stripe and a (BLUE) clamp.

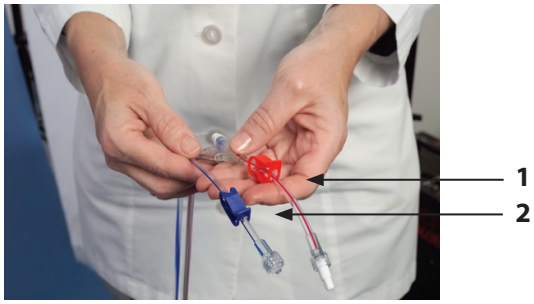


Figure 3-38: Patient Collect and Return Lines

1. Collect Line
2. Return Line

Patient Anticoagulant Line

The Anticoagulant Pump delivers anticoagulant solution to the Patient Collect Line via the Anticoagulant Line during the treatment at a default ratio of 10 mL of blood to 1 mL of anticoagulant or 10:1. The operator may select an alternative rate of delivery for individual patients if directed by the clinician. This line must be placed into the Anticoagulant Air Detector and is identified with an (ORANGE) stripe.

Saline Source Line & Spike Chamber

This Saline Source Line connects the Saline Solution Bag and the Pump Tubing Organizer. It has a (WHITE) spike chamber and clear tubing.

Anticoagulant (A/C) Source Line & Spike Chamber

The A/C Source Line connects the Anticoagulant Solution Bag and the Pump Tubing Organizer. It has an (ORANGE) spike chamber and is identified with an (ORANGE) stripe on the tubing.

Pressure Sensors: Pressure Domes + Pressure Transducers

The THERAKOS™ CELLEX™ Photopheresis System is equipped with three pressure sensors to read the pressures in the centrifuge bowl and the patient collect and return lines. Pressure in these compartments is communicated to the transducers through a membrane on the pressure domes connected to the procedural kit.

A transducer can be damaged when left uncovered. The following procedures contain steps to remind operators to cover the pressure transducers with protective covers and to handle the removal and replacement of covers in a way that prevents damage to the pressure transducers. By using the following procedures, the operator can reduce the likelihood of damage to the pressure transducers during installation, between treatments and when the instrument is not in use.

Keep the pressure transducers on the pump deck covered and protected at all times!

- Use protective pressure dome covers when the instrument is not in use and in between treatments.
- Use procedural kit pressure domes during treatments.
- Never substitute a procedural kit pressure dome for a protective pressure dome cover.

Observe the READY TO PRIME screen display: all pressure readings should be 0 ±10 mmHg before installing the procedural kit:

a. Tap the screen just below the centrifuge bowl icon to view the system pressure sensor reading. All pressure sensors will be re-zeroed when the START button is pressed to begin PRIME.

b. Collect and return pressure readings are displayed in bar graph format.

If any of the pressure readings are not 0 ±10 mmHg before installing the procedural kit, re-cycle the power and answer YES to the prompt to start a new treatment. If the pressure readings do not reset to 0 ±10 mmHg call Mallinckrodt.

Smart Card

Each THERAKOS™ CELLEX™ Photopheresis Procedural Kit is equipped with a custom Smart Card that logs many functions and the data from each treatment for diagnostic use. When the START button is pressed during PRIME, data logging begins. Data logging is maintained when the CELLEX™ is powered down, however, the time of powering down is not captured. In the event of a loss of power, the log is maintained. Each Smart Card has been programmed at the factory with a unique number. You may be asked to return the Smart Card after a treatment should you require service or technical assistance.

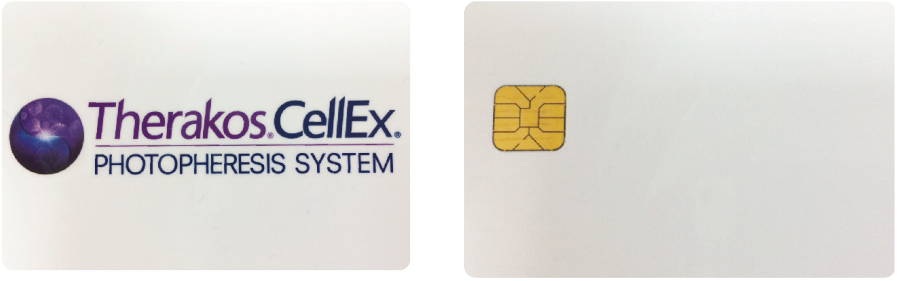


Figure 3-39: Smart Card Front/Back
(Graphics are representative only)

SECTION 4: LOADING THE THERAKOS™ CELLEX™ PHOTOPHERESIS PROCEDURAL KIT

Preparing the Instrument for Procedural Kit Installation

Engaging the Wheel Locks

1. Begin by selecting a clean workspace with proper lighting and access to all necessary supplies. Use institution policy to determine if gloves should be worn during kit installation.
2. Position the instrument within reach of a properly grounded electrical outlet.
3. Ensure that there is no obstruction of airflow on any side of the instrument. Allow a minimum of 50 cm (18 inches) of ventilation space in front and back of the instrument while in use.
4. Engage the Wheel Locks

CAUTION:
Do not operate the instrument in the presence of external radio or electromagnetic disturbances that may interfere with proper performance of the device. This could result in treatment interruptions and the possibility of a failed treatment.

Figure 4-1a: Wheel Locks: OFF

Figure 4-1b: Wheel Locks: ON

Figure 4-1c: Power Switch

Figure 4-1d: Power Switch–Close-up View

Powering On the Instrument

1. Plug the Power Cord into the electrical outlet.
2. Ensure that the protective pressure dome covers are securely attached to the transducers before turning the instrument on.
3. Turn the power ON. The Power Switch is located on the right side of the instrument behind the Operator Interface.

   Once the power is turned ON, the system beeps and performs a self-check. The Operator Interface Screen remains blank for about a minute before the Therakos logo appears.

Warning:
Using a power cord other than the cord specified or supplied with the instrument may result in increased emissions or decreased immunity.

4. Observe the operator interface to ensure that the following values are all approximately zero:

a. Collect pressure

b. Return pressure

c. System pressure (centrifuge bowl), tap below the bowl to display this value

d. Anticoagulant volume

e. Saline volume

f. Return bag volume, tap on the return bag to display this value.

g. Treatment bag volume, tap on the treatment bag to display this value

h. Treatment volume

i. Centrifuge bowl volume, tap on the centrifuge bowl to display this value

j. Whole blood processed volume

k. Fluid balance

If the above values are not approximately zero, re-cycle the power and answer YES to the prompt for a new treatment. If any of these values do not reset to approximately zero, call Mallinckrodt.

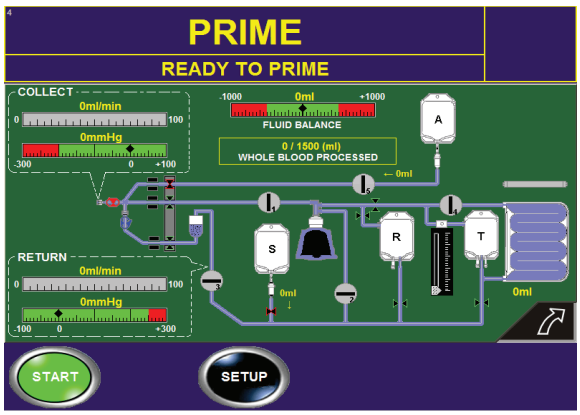


Figure 4-1e: Operator Interface Display Detail

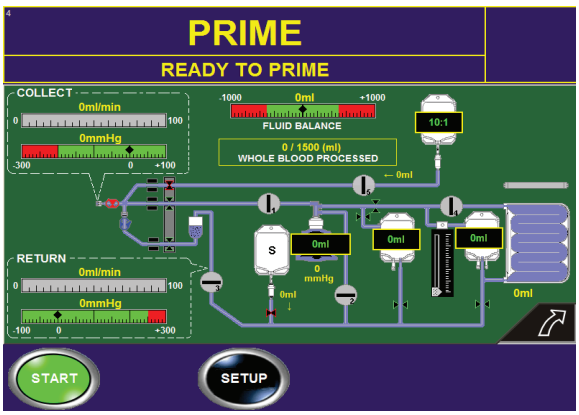


Figure 4-1f: Operator Interface Display Detail with zeroes displayed

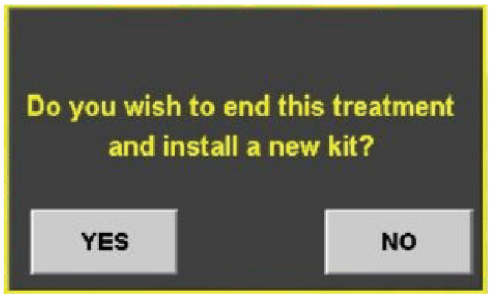


Figure 4-1g: Do you wish to end this treatment and install a new kit?

Opening the Photoactivation Chamber Door

Place your finger in the notch at the top of the door and pull gently. The door is held closed by a magnet.

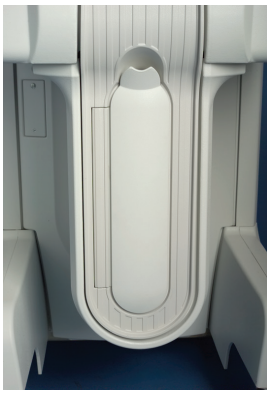


Figure 4-1h: Photoactivation Chamber Door–CLOSED

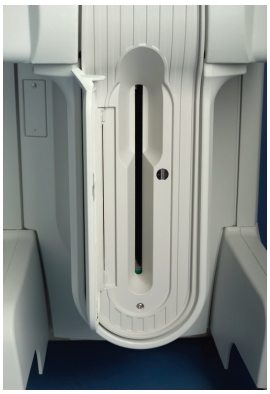


Figure 4-1i: Photoactivation Chamber Door–OPEN

Preparing the Centrifuge Assembly

1. Open the centrifuge chamber door.
2. Position the centrifuge frame so that the two bearing retainers are on the right side as shown.
3. Rotate the centrifuge bowl holder so the retainer clip is facing front.

Figure 4-2a: Centrifuge Chamber Door–CLOSED

Figure 4-2b: Centrifuge Chamber Door–OPEN

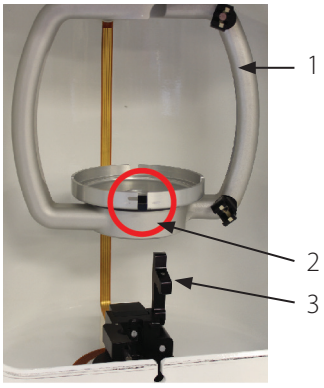


Figure 4-2c: Starting Position of Centrifuge Components

1. Centrifuge Frame
2. Retainer Clip
3. Drive Tube Latch

Preparing the Pump Deck

Turn all Pump Handles so that the tapered (narrow) ends face the center of the Pump Deck.

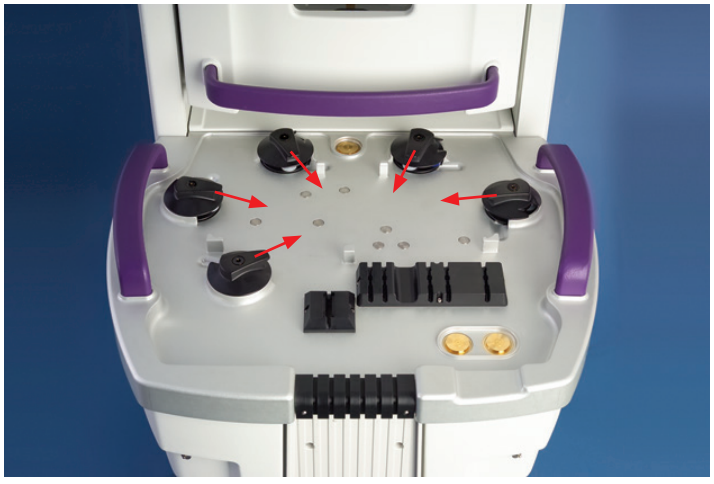


Figure 4-2d: Starting Position of Pump Handles

Installing the THERAKOS™ CELLEX™ Photopheresis Procedural Kit

Opening the Procedural Kit

1. Inspect the procedural kit for any damage to the package that could compromise the sterility of the procedural kit. Do not use a damaged procedural kit or a procedural kit that is expired.

CAUTION:
DO NOT USE the THERAKOS™ CELLEX™ Photopheresis Procedural Kit if:

- the package is already opened or damaged.
- the fluid pathway guards (caps on ends of tubing lines) are loose in packaging or missing.
- the Date of Use is beyond the Expiration Date.

2. Place the procedural kit on the pump deck with the labeling text facing you.
3. Peel back the Tyvek® lid.

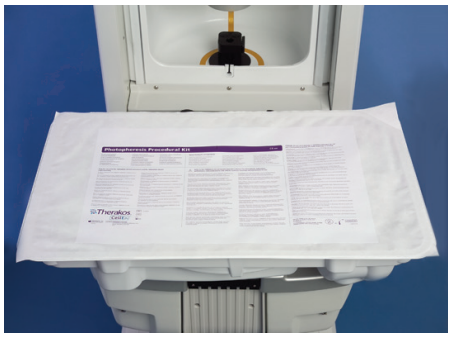


Figure 4-3a: THERAKOS™ CELLEX™ Photopheresis Procedural Kit on Instrument

Figure 4-3b: Peel Back Tyvek® Lid

Removing the Photoactivation Module

1. To release the Photoactivation Module from the protective packing tray, grasp and elevate the top right corner where the tubing lines attach while pushing the back wall of the packing tray away from the plate. Handle the Photoactivation Module by the frosted edges.

2. Discard the protective packing tray.

Figure 4-4a: Removing the Photoactivation Module

Figure 4-4b: Correct handling of Photoactivation Module

Installing the Photoactivation Module

1. Insert the photoactivation module into the photoactivation chamber with the tubing lines at the top.

2. Close the photoactivation chamber door.

3. Confirm that the lines are not pinched.

Figure 4-5a: Inserting the Photoactivation Module

Figure 4-5b: Closing the Photoactivation Chamber Door

Removing the Remaining Procedural Kit Components

1. Loosen the centrifuge bowl from the packing tray.
2. Place the centrifuge bowl into the left side of the centrifuge chamber.
3. Carefully loosen the pump tubing organizer from the packing tray.
4. Remove all remaining procedural kit components and carefully place them on the center of the pump deck surface.
5. Discard the packing tray.

Figure 4-6a: Loosening the Centrifuge Bowl

Figure 4-6b: Removing the Remaining Kit Components

CAUTION:
Do not use the THERAKOS™ CELLEX™ Photopheresis Procedural Kit if any of the protective caps on the patient lines, pressure domes, or fluid spikes are missing or off when the procedural kit is opened. Sterility of the procedural kit may be compromised if these caps are removed prior to use.

Hanging the Treatment and Return Bags

1. The return bag hangs on the right front Load Cell Hook below the Pump Deck and is imprinted with the letter "R".
2. The treatment bag hangs on the left front Load Cell Hook below the Pump Deck. It is imprinted with the letter "T" and contains a needle-free port at the base of the bag.

Figure 4-7a: Treatment Bag

Figure 4-7b: Treatment and Return Bags

Figure 4-7c: Return Bag

WARNING:
Prior to initiating PRIME, ensure the treatment bag and return bag are properly positioned on their respective Load Cell Hooks. Removal of these bags at any time after PRIME is initiated may result in priming alarms and/or inaccurate FLUID BALANCE readings during the treatment.

Installing the Pump Tubing Organizer

1. Set aside the bundled tubing lines.
2. Hold the Pump Tubing Organizer at an angle with all tubing free, and then align mold indents on the front edge of Pump Tubing Organizer with the three tabs protruding from the surface of the Pump Deck.
3. Gently press down on the rear edge of the Pump Tubing Organizer to latch it into place against the rear locking tabs.

Figure 4-8a: Installing the Pump Tubing Organizer

Figure 4-8b: Align Mold Indents

Figure 4-8c: Gently Push Down to Latch

Guidance Instructions For Locating Bearings Against Bearing Stops

1. Please follow the steps below to successfully load a procedural kit with a bearing that is loose or not flush against the bearing stop. ***(See Figure 4-9a).***

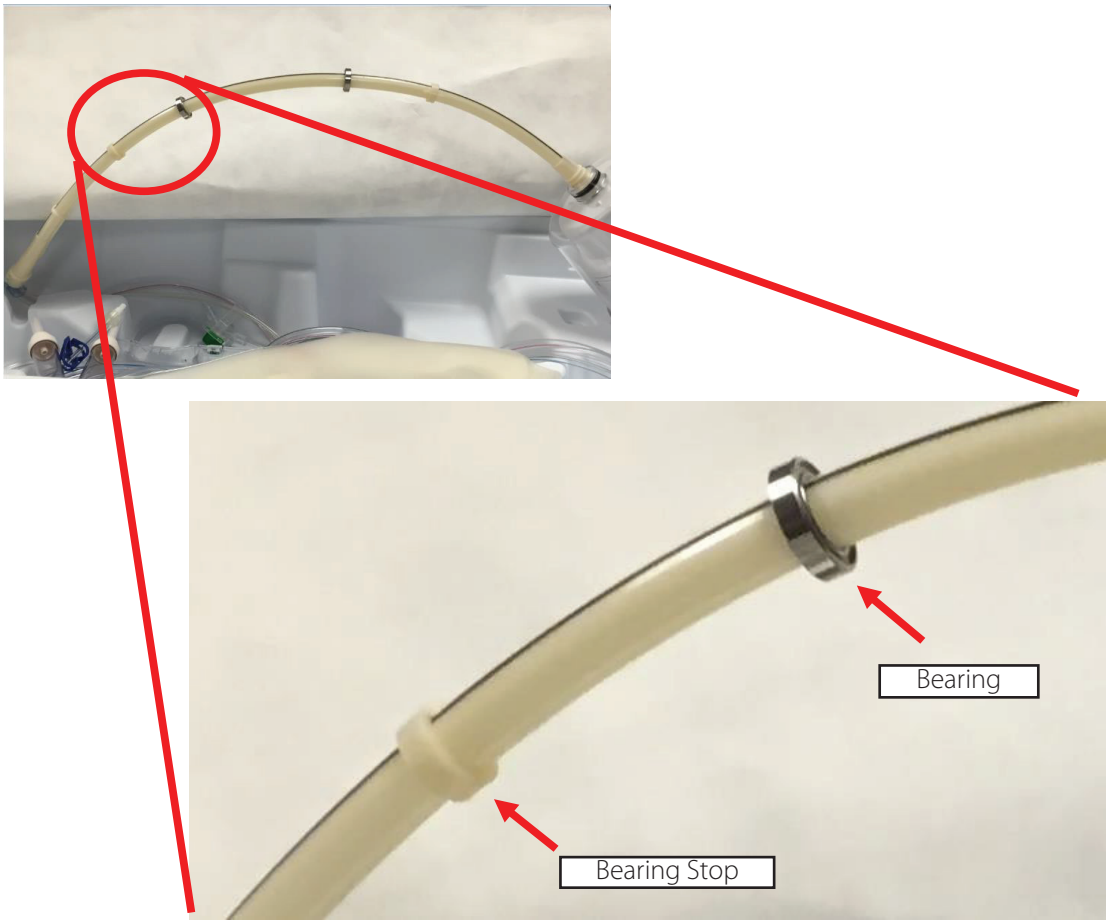


Figure 4-9a: Bearing not fully against Stop

2. To proceed, slide the bearing(s) into position to completely rest against the bearing stop. Use one hand to hold the drive tube and the other to slide the bearing ***(see Figure 4-9b and 4-9c)***.

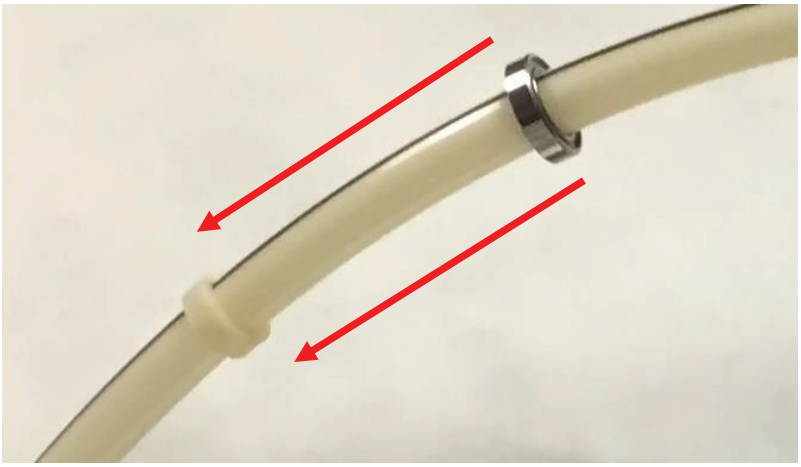


Figure 4-9b Slide the bearing(s) into position

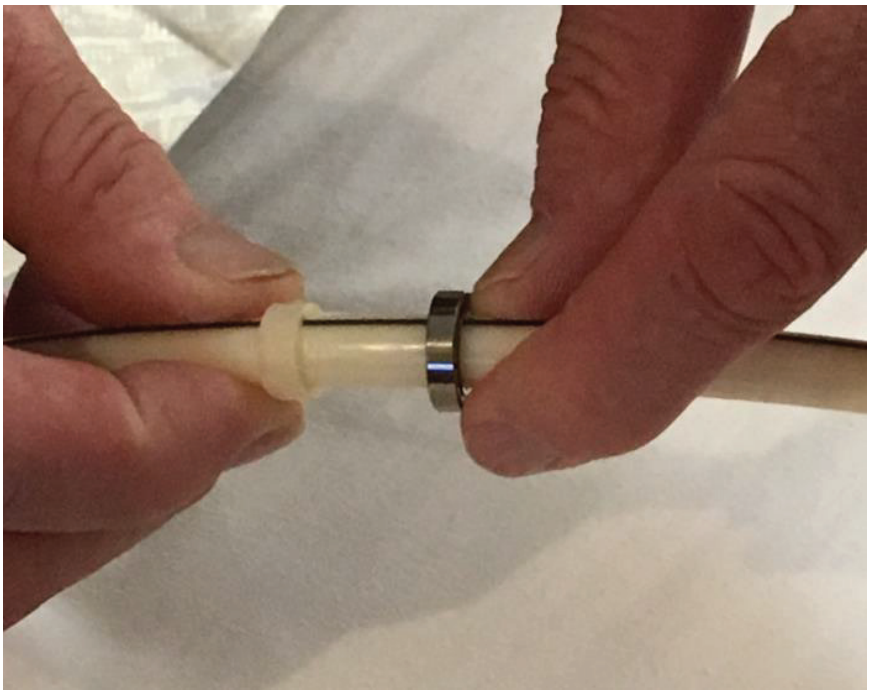


Figure 4-9c Use one hand to hold the drive tube and the other to slide the bearing

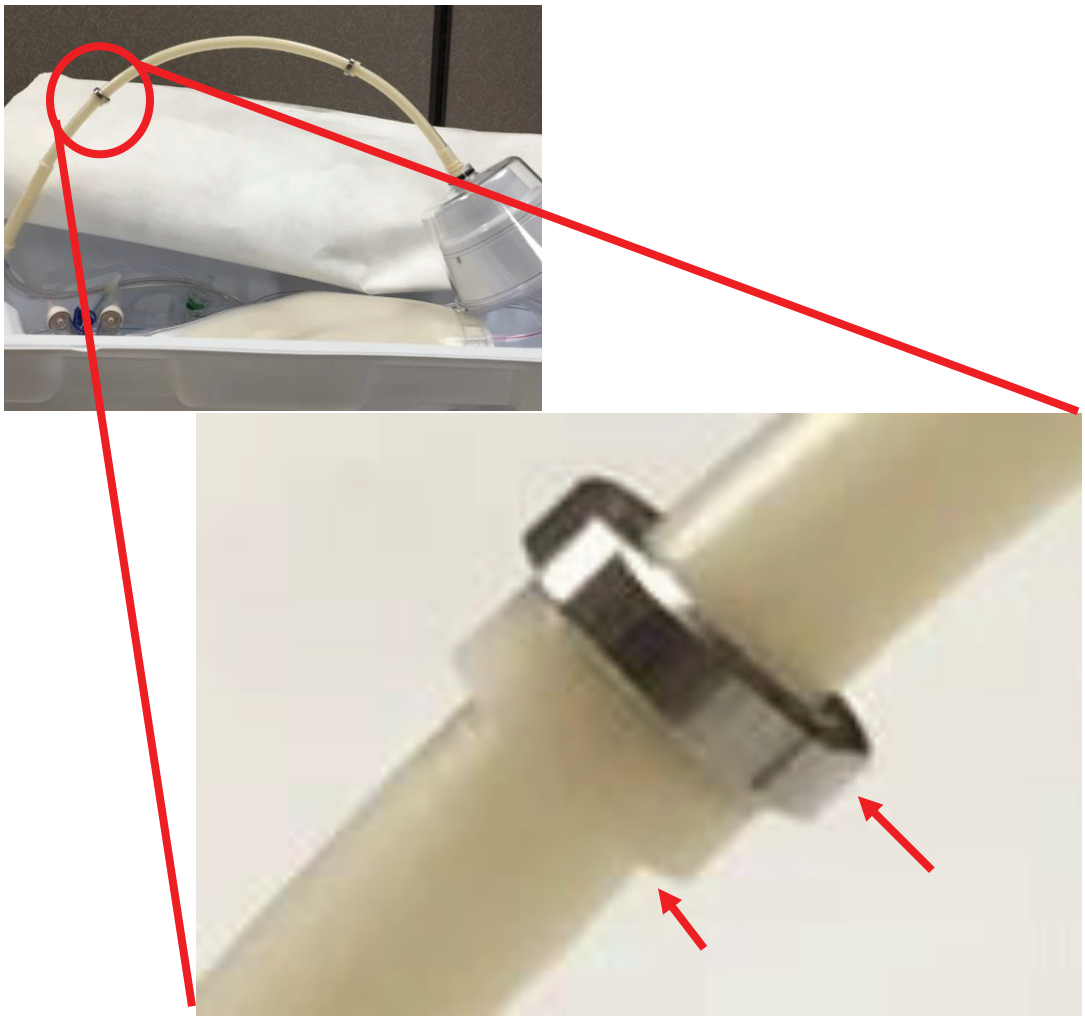
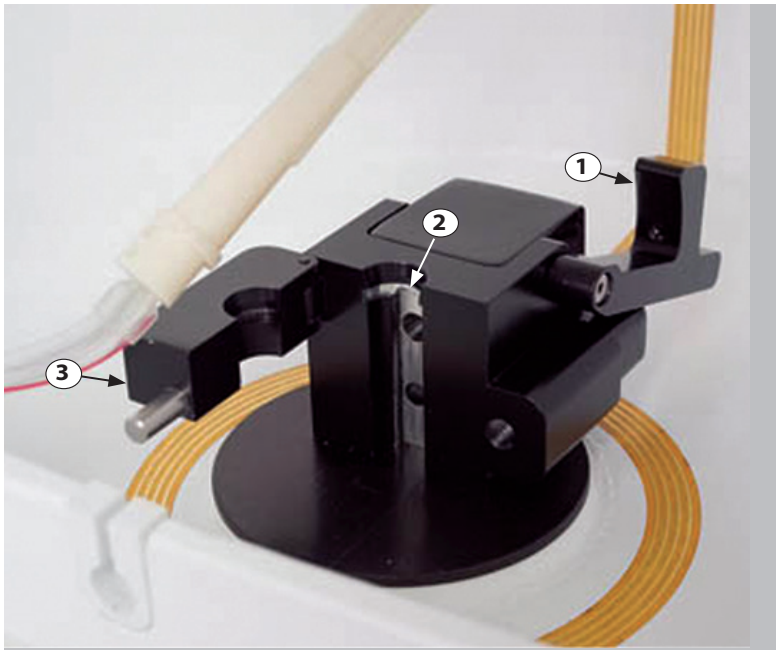


Figure 4-9d Confirm the bearing is completely resting against the bearing stop

3. Proceed to next section Installing the Centrifuge Bowl.

Installing the Centrifuge Bowl

Before proceeding, use Figure 4-10a to identify the parts of the Drive Tube Clamp Assembly.

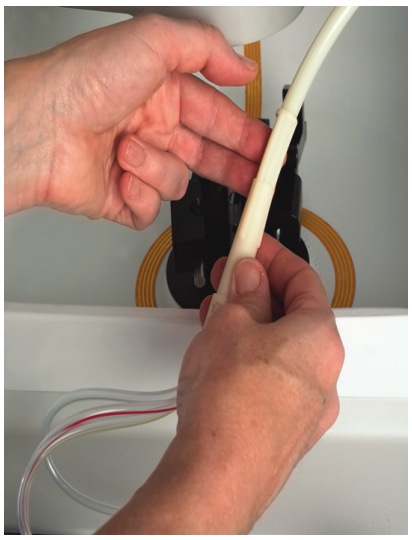


1. Drive Tube Latch
2. Groove for Drive Tube Notch
3. Drive Tube Clamp

Figure 4-10a Drive Tube Clamp Assembly

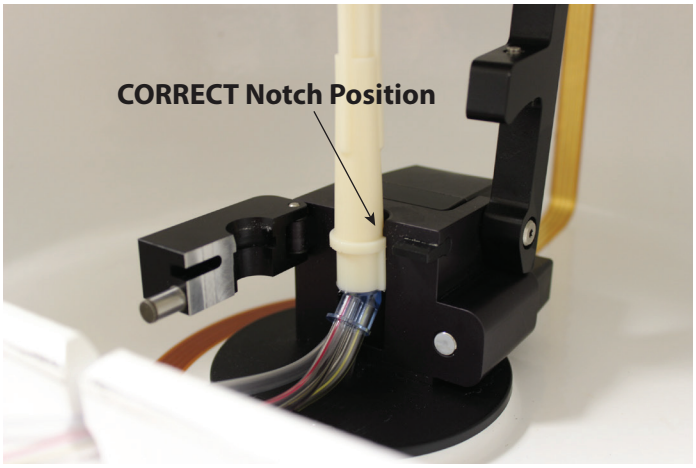
CAUTION:

- Damage to the centrifuge bowl or drive tube could result in further damage to the instrument, loss of treatment, and extracorporeal blood loss.
- During installation, do not excessively bend, kink, or damage the drive tube, bearings, or centrifuge bowl.
- The instrument must be properly maintained to function safely and properly.
- Warranty does not cover damage caused by improper procedural kit loading or improper instrument setup, operation, or maintenance.



1. Confirm that the Centrifuge Frame is positioned with the Bearing Retainers on the right and the Bowl Holder is positioned with the Retainer Clip facing front.
2. Confirm that the tubing from the Pump Tubing Organizer to the Drive Tube is not twisted.
3. Grasp only the reinforced area of the Lower Drive Tube.

Figure 4-10b: Grasping Reinforced Lower Drive Tube



4. Position the Drive Tube so the (BLACK) stripe faces the rear of the Drive Tube Clamp Assembly. The keyed features (notches) of the Drive Tube will mate with the clamp to ensure proper loading.

Figure 4-10c: Keyed Drive Tube and Clamp Assembly

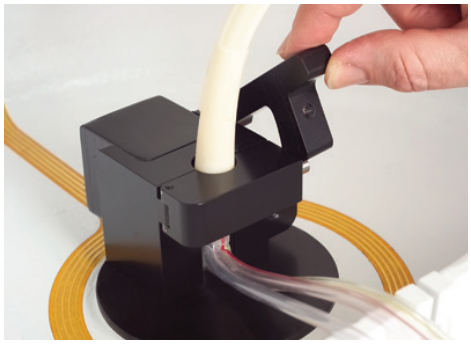


Figure 4-10d: Closing the Drive Tube Latch

5. With the Drive Tube in the correct position, close the Drive Tube Clamp, then the Drive Tube Latch. An audible beep will indicate the activation of two Fluid Routing Valves used to clamp the saline and anticoagulant spike lines. The START button will appear in the bottom left corner of the Main Screen of the Operator Interface when the Drive Tube Latch is properly closed.
6. Load the centrifuge bowl onto the centrifuge bowl holder by grasping the bowl holder as you align the tabs at the bottom of the centrifuge bowl with the slots in the bowl holder.
7. Hold the centrifuge bowl holder firmly as you press the centrifuge bowl downward and rotate it clockwise until all tabs lock into place and you hear an audible "click" from the tab retainer.

Without depressing the engaged retainer clip, verify the tab retainer clip is in the fully locked position by rotating the bowl counterclockwise to challenge the retainer clip ***(see figure 4-10f and 4-10g)***.

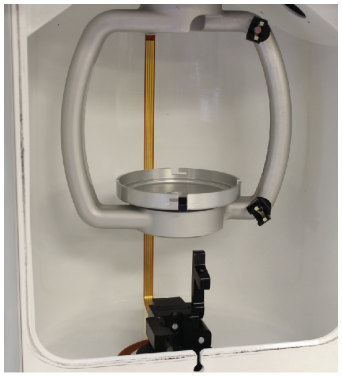


Figure 4-10e: Centrifuge Assembly–Starting Position with Bearing Retainers Facing Front

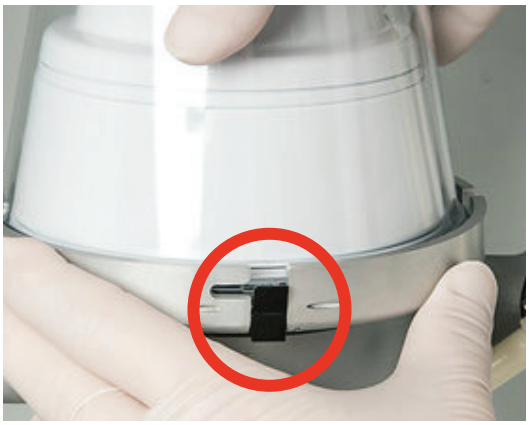


Figure 4-10f: Installing Centrifuge Bowl–Align Centrifuge Bowl Tabs

Figure 4-10g: Installing Bowl–Rotate Bowl Clockwise to Lock Clip and Counterclockwise to Confirm Centrifuge Bowl is Secure

8. Load the Lower Drive Tube Bearing.
    a. Gently bend the drive tube to match the approximate shape of the centrifuge frame.
    b. Move the lower bearing so that it is positioned below the bearing retainer.
    c. Move the lower bearing into the retainer so that it aligns with the indication groove on the front of the retainer.
    d. Gently push the bearing back until you hear the click of the bearing engaging the magnet.
    e. Verify the bearing is seated in alignment with the indication groove on the front of the retainer.

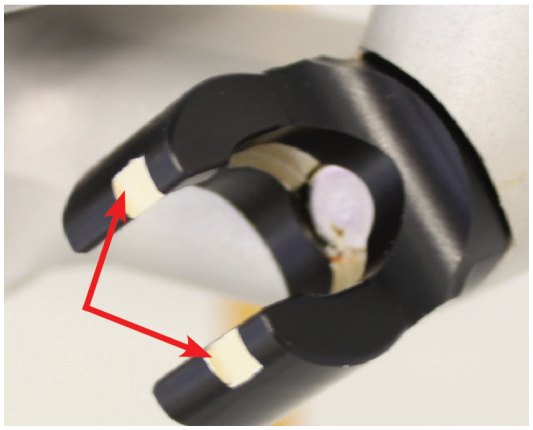


Figure 4-10h: Lower Bearing Retainer with indication groove (see red arrows) on the front of the retainer

Lower Drive Tube Bearing Installed in the Lower Bearing Retainer

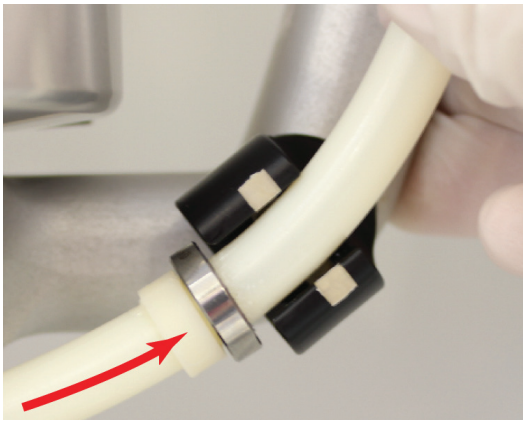


Figure 4-11a: Lower Drive Tube Bearing inserted into the Lower Bearing Retainer

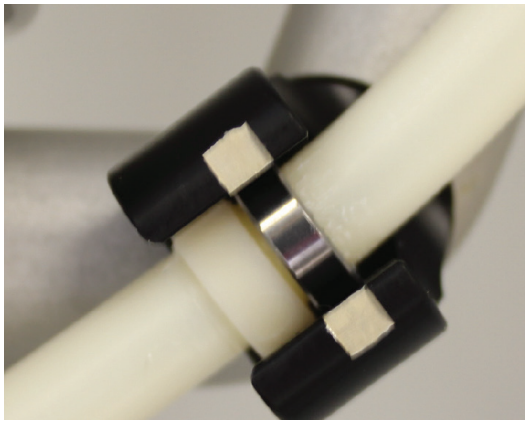
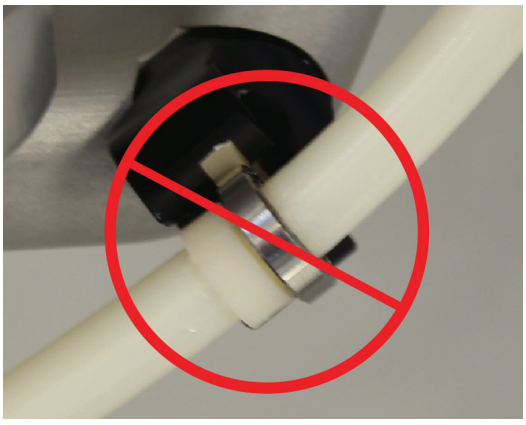


Figure 4-11b: Lower Drive Tube Bearing Installed in the Lower Bearing Retainer



- Bearing not loaded into retainer.
- Bearing and Drive Tube positioned in front of Bearing Retainer.

Figure 4-11c: Incorrect Lower Drive Tube Bearing installation

CAUTION:

- Verify the Lower Drive Tube Bearing is correctly aligned in the Bearing Retainer.
- Verify that the Bearings and Drive Tube are not damaged in any way.
- Verify that the bearing is engaged with the magnet.

9. Load the Upper Drive Tube Bearing.
   a. Move the upper bearing so that it is positioned above the bearing retainer.
   b. Move the upper bearing into the retainer so that it aligns with the indication groove on the front of the retainer.
   c. Gently push the bearing back until you hear the click of the bearing engaging the magnet.
   d. Verify the bearing is seated in alignment with the indication groove on the front of the retainer.

Upper Drive Tube Bearing Installed in the Upper Bearing Retainer

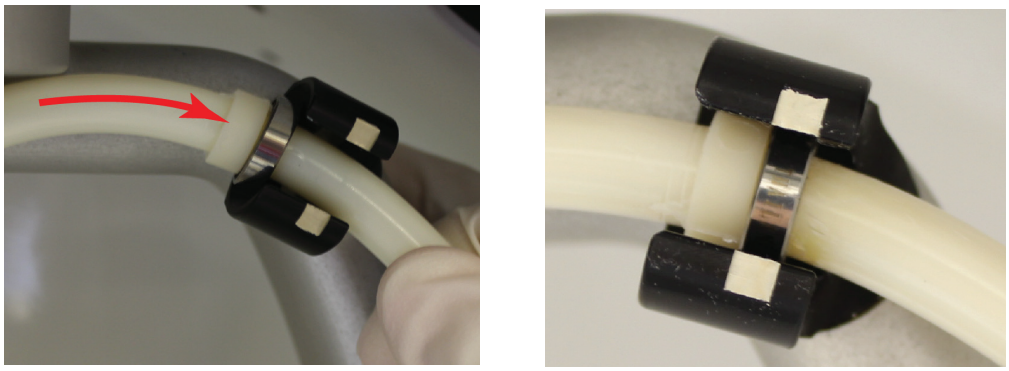


Figure 4-12a: Correct Upper Drive Tube Bearing Installation

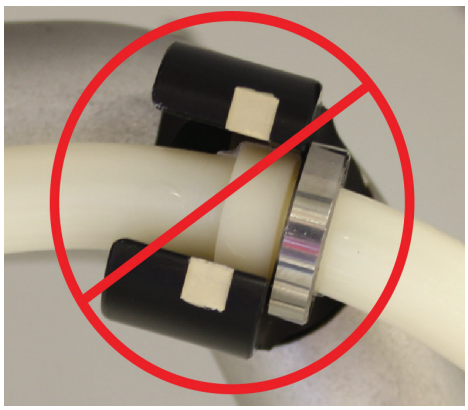


Figure 4-12b: Incorrect Upper Drive Tube Bearing Installation.
- Bearing not aligned with the indication groove.

CAUTION:

- Verify the Upper Drive Tube Bearing is correctly aligned in the Bearing Retainer.
- Verify that the bearings and drive tube are not damaged in any way.
- Verify that the bearing is engaged with the magnet.

10. Carefully insert the centrifuge bowl tubing lines through the tubing exit slot.
11. Insert the centrifuge bowl tubing lines into the tubing guides in front of the drive tube clamp assembly.
12. Spin the centrifuge frame clockwise to confirm proper centrifuge bowl installation.

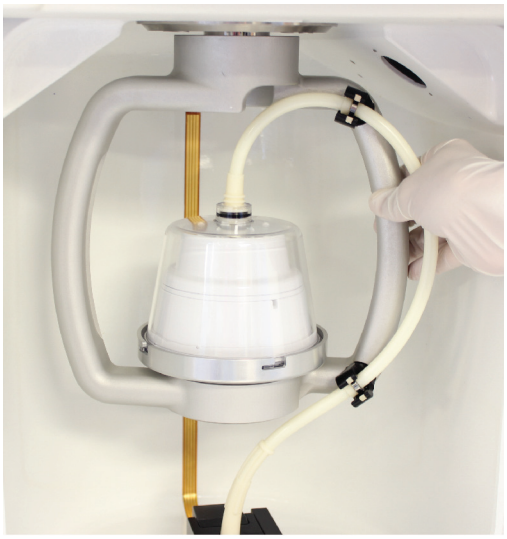


Figure 4-12c: Verifying Proper Bowl Installation

CAUTION:

Do not proceed with procedural kit installation until you confirm:

- ✔ The drive tube latch is closed securely and the START button is visible on the Main Screen of the Operator Interface.
- ✔ The drive tube does not touch the centrifuge frame at any point.
- ✔ The tubing lines exiting the front of the drive tube clamp assembly are in their respective tubing guides and are not pinched in the clamp.
- ✔ All tubing lines pass through the tubing exit slot and are free of kinks or pinch points.
- ✔ The upper and lower bearings are fully seated in the groove of the bearing retainers.
- ✔ The centrifuge bowl and frame spin freely in a clockwise direction.

Manually Loading Each Pump Tubing Segment

i. Rotate each pump head until the tapered edge of each pump handle is facing the Pump Tubing Organizer .

ii. Stretch each Pump Tubing Segment to reach over each Pump Handle.

iii. Rotate the pump handle until slot on the pump head aligns with the recess on the pump deck. Gently push down on the tubing segment into the slot on the pump head and rotate the pump handle counterclockwise until the tubing segment threads into the pump.

iv. Once the pump tubing segment is loaded, turn the pump handle clockwise to ensure the tubing segment is properly loaded and the pump turns freely.

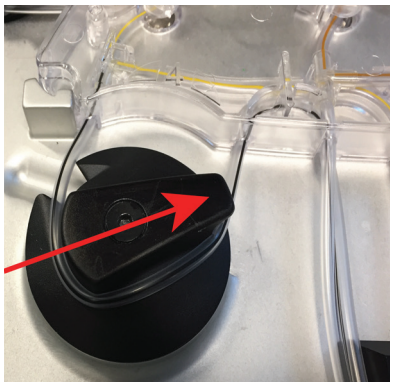


Figure 4-13d: Stretching Pump Tubing Segment

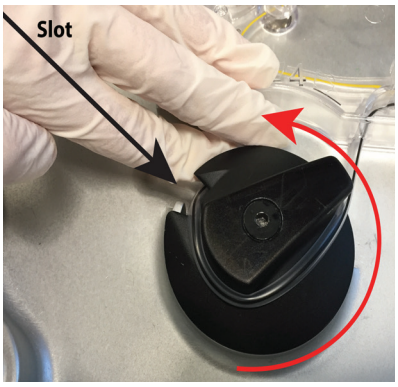


Figure 4-13e: Rotate Pump Handle Counterclockwise

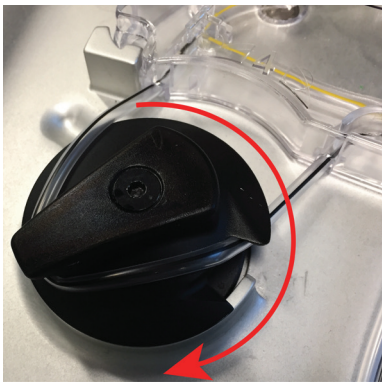


Figure 4-13f: Rotate Pump Handle Clockwise

NOTE:
If you feel the tube binding, rotate the pump slightly in the opposite direction and continue loading.

Installing the Smart Card

1. Remove the Smart Card from the Pump Tubing Organizer.
2. Face the gold connector surface of the Smart Card away from you and insert it into the Smart Card slot as shown.
3. An audible beep will confirm correct insertion.

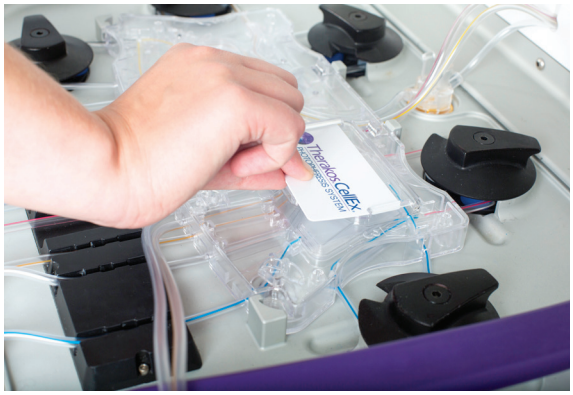


Figure 4-14a: Removing the Smart Card

Figure 4-14b: Correct Smart Card Insertion

Figure 4-14c: Incorrect Smart Card Insertion

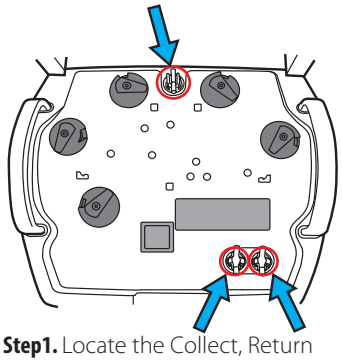
Installing the Three Pressure Domes

CAUTION:

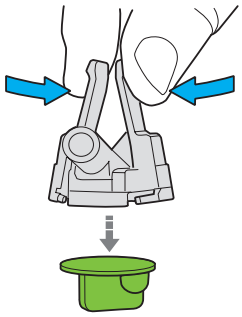
- Handle the pressure domes only by the clips to avoid damage to the internal membrane.
- Partial pressure dome attachment may provide pressure readings, but as pressures increase, the internal membrane may separate from the pressure dome. Fluid leaks may occur resulting in loss of sterility, blood leaks, and possible blood loss to the patient.
- DO NOT REMOVE ANY PRESSURE DOME DURING A TREATMENT.

NOTE:

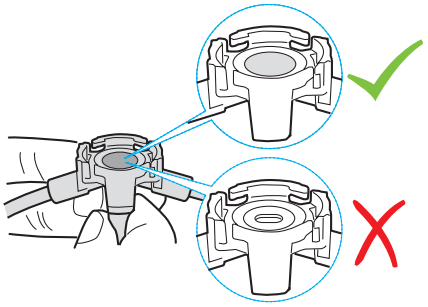
- Do not proceed with kit installation if the green pressure dome protective caps are missing.
- Ensure to **SPREAD TABS** and **VERIFY** pressure dome is secure prior to initiating PRIME sequence. Failure to do so may lead to PRIME TEST failures and longer set up times.



Step1. Locate the Collect, Return and System pressure transducer labels.

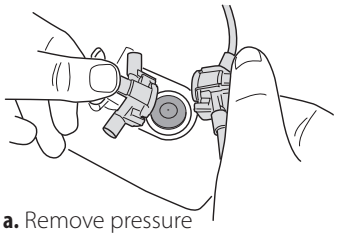


Step 2. Pinch tabs to release green cap.

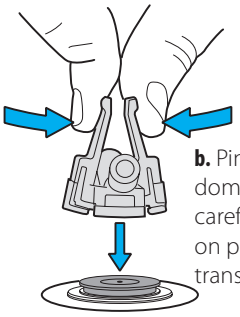


Step 3. Visually confirm that membrane is present and is fully intact.

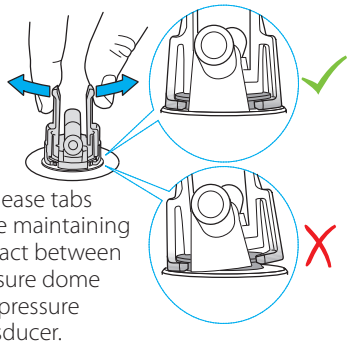
Step 4.



a. Remove pressure dome cover.

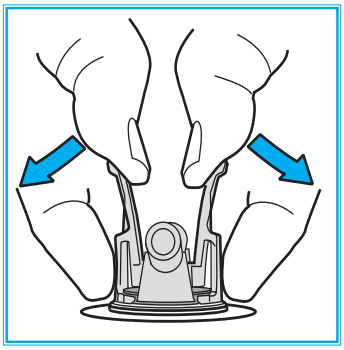


b. Pinch pressure dome tabs and carefully position on pressure transducer.

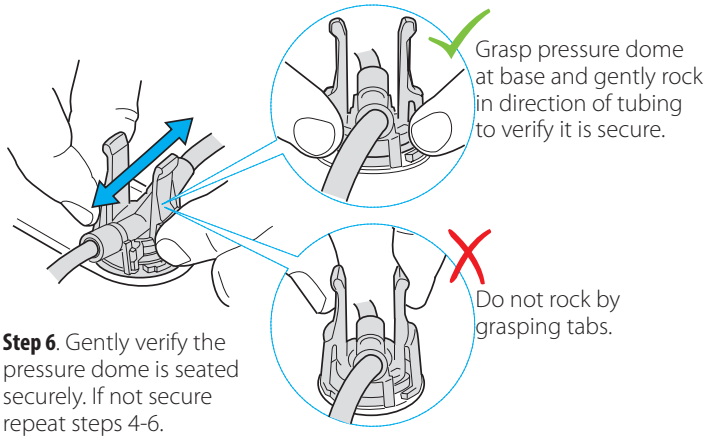


c. Release tabs while maintaining contact between pressure dome and pressure transducer.

Figure 4-15a: Installing the Three Pressure Domes part 1



Step 5. With downward pressure, gently spread tabs to fully engage pressure dome.



Step 6. Gently verify the pressure dome is seated securely. If not secure repeat steps 4-6.

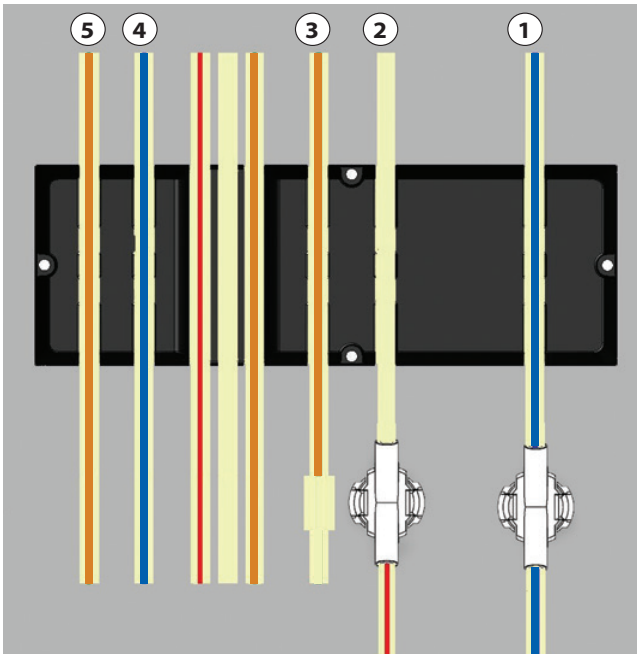
Repeat steps 2–6 for the other two procedural kit pressure domes.

Figure 4-15b: Installing the Three Pressure Domes part 2

Installing the Lines into the Air Detectors

NOTE:
Five lines will be monitored for air during the treatment. During treatment, air will be present at various times in the lines leading to the treatment bag and return bag.

1. Set the bundled fluid spike lines aside. These lines are not monitored for air.
2. Begin at the right side of the Air Detector Block and insert the lines from the Pump Tubing Organizer, making sure the lines touch the bottoms of the channels on both sides, as follows:



1. Patient Return Line (BLUE Striped)
2. Patient Collect Line (Clear segment attached to RED Striped)
3. Patient Anticoagulant Line (ORANGE Striped attached to Clear)
4. Return Bag Line (BLUE Striped)
5. Treatment Bag Line (ORANGE Striped)

Figure 4-16a: Installing Lines into Air Detectors

NOTE:

- The (RED Striped) line to the return bag and the fluid spike lines, shown in Figure 4-16a without numbers, do not need to be monitored for air and are not inserted into the air detectors.
- Missing or improperly installed lines will result in alarms.

Fully Seat the Lines in the Air Detector

To lessen the chance of any Air Detected! alarm, ensure that all lines are properly seated in the air detectors.

Figure 4-16b: Lines Placed incorrectly

Figure 4-16c: Lines placed correctly

Installing the Hematocrit Cuvette

1. Avoid fingerprints on the window of the Hematocrit Cuvette.
2. Verify that the Hematocrit Cuvette is fully seated in the Hematocrit Sensor Housing.

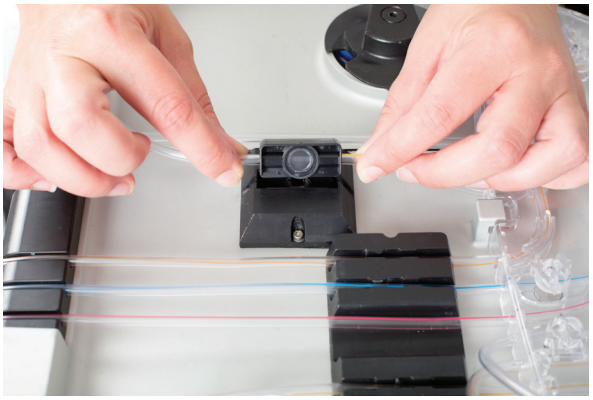


Figure 4-17a: Correct Handling of the Hematocrit Cuvette

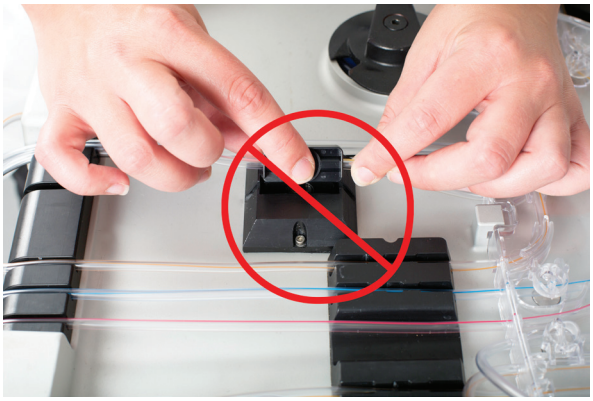


Figure 4-17b: Incorrect Handling of the Hematocrit Cuvette

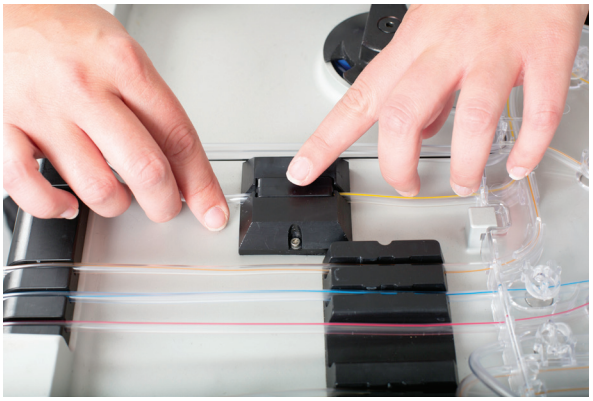


Figure 4-17c: Correct Placement of the Hematocrit Cuvette

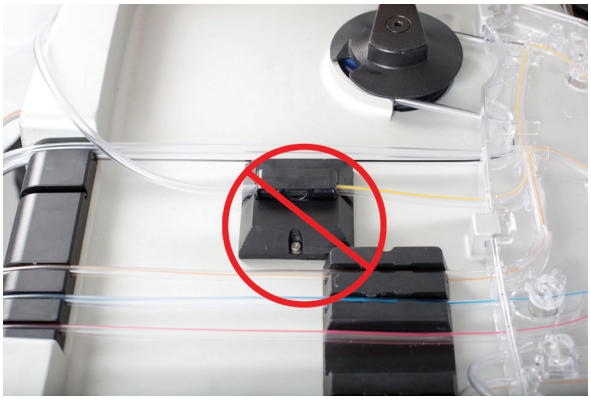


Figure 4-17d: Incorrect Placement of the Hematocrit Cuvette

CAUTION:
Avoid fingerprints on the window of the Hematocrit Cuvette. Natural oils may adversely affect the light transmittance through the lens.

Installing Lines Into the Tubing Guide

Align the treatment bag, the return bag, and the Photoactivation Module tubing lines into the Tubing Guide at the front edge of the Pump Deck.

Preparing and Hanging Saline and Anticoagulant Solutions

CAUTION:

- Correct attachment of the Saline and Anticoagulant Bags to the correct fluid spike is essential. Incorrect attachment may lead to clotting in the procedural kit, patient blood loss and a failed treatment.
- Always confirm the contents, lot number, and expiration date of any solution prior to its use.
- Saline and Anticoagulant Spike Lines do not have slide clamps. Instead, Fluid Routing Valves, activated when the Drive Tube Latch is closed, prevent fluid from entering the Pump Tubing Organizer prior to PRIME.

CAUTION:
Individual patients may require a heparin dosage that varies from the recommended dose to prevent post-treatment bleeding or clotting during a treatment. The clinician should review the patient's medical condition, medications, and platelet count at the time of treatment and use clinical judgment to establish the optimal heparin dosage for each patient.

NOTE:
Confirm the START button is visible on the lower left corner of the main screen operator interface. If START button is not available, refer to section ***4-14 Installing the Centrifuge Bowl for further instructions.***

The Units of heparin/500 mL of 0.9% Normal saline may need to be adjusted to the body weight of the patient. For example:

Patient weight > 40 kg use 10,000–15,000 Units of heparin/500 mL of 0.9% Normal saline

Patient weight < 40 kg use 150–250 Units of heparin per kg body weight/500 mL of 0.9% Normal saline

1. Add X Units of heparin to a 500 mL bag of 0.9% Normal saline and label the bag per your institution's labeling procedures.
2. Undo the packing tapes of the Solution Spike Lines and inspect for kinks.
3. Spike the Anticoagulant Solution with the (ORANGE) spike attached to the Anticoagulant line (ORANGE Striped attached to clear) . Hang the Anticoagulant Bag on the lower right side of the instrument (as you face it) using the back hook.
4. Spike a 500 mL bag of 0.9% Normal saline with the (WHITE) spike attached to the clear line. Hang the Saline Bag on the lower right side of the instrument (as you face it) using the front hook.
5. Squeeze each chamber several times as needed in order to fill each chamber at least halfway with fluid.

Figure 4-18: Placement of Saline and Anticoagulant Bags

Preparing Patient Lines

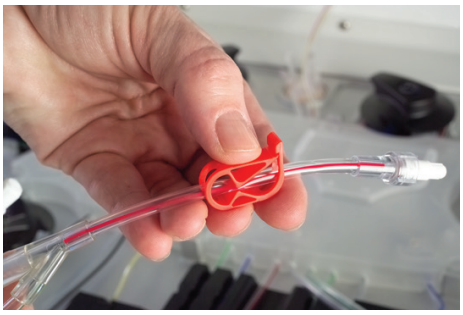


Figure 4-19a: Close Collect Line (RED) Clamp

1. Undo the Patient Line packing tapes. Inspect for kinks.
2. CLOSE Patient Collect Line (RED) Clamp.

Figure 4-19b: Clean Needle-free Port

3. Clean the needle-free injection port of the Patient Collect Line (RED Striped) with an alcohol swab.

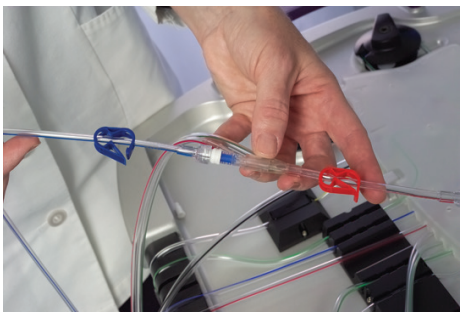


Figure 4-19c: Connect Return Line (BLUE Striped), Open (BLUE) Clamp

4. Remove the cap from the Patient Return Line (BLUE Striped) and aseptically connect it to the needle-free injection port of the Patient Collect Line (RED Striped).
5. Verify that the Patient Return Line (BLUE) Clamp is OPEN.

Figure 4-19d Hang Lines on IV Pole

6. Hang the Patient Lines on the IV Pole during PRIME. Ensure the lines are hanging vertically and are not dangling.

Final Inspection Before Prime

Figure 4-20: Close Centrifuge Chamber Door

1. Visually inspect Pressure Domes and Air Detectors.
2. Check to be sure that the Hematocrit Cuvette is seated in the Hematocrit Sensor.
3. DO NOT rotate the pump heads, but visually inspect all pumps and pump tubing.
4. Inspect Solution Bags for content, Anticoagulant Concentration, and primed Drip Chambers.
5. Verify that the Patient Collect Line (RED) Clamp is CLOSED and Patient Return Line (BLUE) Clamp is OPEN.
6. Check all tubing lines for kinks.
7. Lower the Centrifuge Chamber Door verifying that the Bowl Outlet Tubing is not pinched.

CAUTION:

- Check that the Centrifuge Chamber Door is closed properly. An alarm alerts you if the door is not closed properly or if the Centrifuge Chamber Door Manual Release is in the unlocked position.
- Do not unlatch or attempt to open the Centrifuge Chamber Door while the Centrifuge is in operation.

NOTE:

You are now ready to begin PRIME. Please refer to ***SECTION 5: OPERATING THE THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEM*** to continue.

SECTION 5: OPERATING THE THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEM

Introduction

The THERAKOS™ CELLEX™ Photopheresis System operator should be adequately trained in all procedures described in the instructions for use. Carefully read all warnings, cautions, and instructions before use. Follow all operating and maintenance procedures. Failure to do so can result in patient or operator harm or system damage. See ***SECTION 3: SYSTEM DESCRIPTION*** and ***SECTION 4: LOADING THE THERAKOS™ CELLEX™ PHOTOPHERESIS PROCEDURAL KIT*** for more information.

PRIME

PRIME occurs before connecting the patient.

During PRIME, the system initially performs a series of tests to ensure proper setup of the procedural kit and calibration of sensors as well as proper operation of pumps, lamps and fluid routing valves. All of these tests occur automatically and will generate an alarm message should a problem be found. Refer to ***SECTION 6***: ***CORRECTING ALARMS,*** for alarm troubleshooting.

The system then pumps anticoagulant solution and saline throughout the procedural kit, eventually filling the photoactivation module and the patient collect and return lines fully. The return and treatment bags and the Centrifuge Bowl will only be partially filled during PRIME. Some areas of the procedural kit are simply wetted with anticoagulant solution.

Treatment Phases of THERAKOS™ Photopheresis

The phases of a treatment with the THERAKOS™ CELLEX™ Photopheresis System are COLLECT, PHOTOACTIVATE, and REINFUSE. COLLECT includes PURGING AIR, DRAWING, RETURNING, BUFFY COAT, ELUTRIATION, and EMPTYING BOWL. COLLECT is the phase that concentrates and harvests the leukocyte enriched fraction from whole blood.

COLLECT

In the default COLLECT phase, 1500 mL of whole blood is processed to continuously collect one concentrated buffy coat layer. The bowl optic sensor in the centrifuge chamber detects the plasma/red cell interface and signals the red cell pump (#2) to maintain this interface at the ideal position for optimal cell separation.

PURGING AIR

The patient's volume is used to displace any remaining sterile air contained within the Centrifuge Bowl after PRIME to the Return Bag. PURGING AIR occurs in both SINGLE NEEDLE and DOUBLE NEEDLE mode configuration. For more information, ***See PURGING AIR on page 5-32*** or ***PURGING AIR on 5-49.***

DRAWING/RETURNING (DOUBLE NEEDLE Mode)

The collect pump (#1) draws whole blood from the patient into the Centrifuge Bowl via the Collect Line. Leukocytes concentrate in the spinning Centrifuge Bowl. Red blood cells and plasma are simultaneously returned to the patient via the return line using the return pump (#3). Blood flow from and to the patient is continuous.

DRAWING/RETURNING (SINGLE NEEDLE Mode)

The Collect Pump (#1) draws whole blood from the patient into the Centrifuge Bowl via the Collect/Return Line. Leukocytes concentrate in the spinning Centrifuge Bowl. Red blood cells and plasma are first pooled in the return bag and then intermittently returned to the patient via the Collect/Return line using the Return Pump (#3). Blood flow from and to the patient is discontinuous and extracorporeal volume is higher in SINGLE NEEDLE mode versus DOUBLE NEEDLE Mode *(See "Estimated Extracorporeal Volume Relative to % Hematocrit, Access Mode and Return Bag Threshold Value": Estimated Extracorporeal Volume on page 10-3*).

The Return Bag Threshold Value (mL) determines the frequency of RETURNING as well as the estimated extracorporeal volume required of the patient during SINGLE NEEDLE Mode treatment. ***(See Table 10-1: Estimated Extracorporeal Volume on page 10-3).*** Red blood cells and plasma are pooled in the return bag until the Return Bag Volume Threshold has been reached. When the threshold has been reached, the Collect Pump is stopped and the Collect/Return Line is used to return the red blood cells and plasma. DRAWING will resume once the return bag volume is reduced to about 50 mL.

BUFFY COAT

The collection software algorithm determines the initiation of the BUFFY COAT phase based on the Whole Blood Processed Target. The bowl optic sensor, the collection and control software, and the hematocrit sensor together select the optimal buffy coat and yield the targeted hematocrit of the leukocyte enriched fraction. The THERAKOS™ CELLEX™ Instrument is designed to continuously harvest one concentrated buffy coat using either continuous blood flow or discontinuous blood flow.

EMPTYING BOWL/RECIRCULATING

After the Buffy Coat has been collected, the centrifuge is stopped and the recirculation pump will speed up to thoroughly mix the collected buffy coat. The red blood cells in the Centrifuge Bowl are pumped out of the Centrifuge Bowl into the return bag. The Centrifuge Bowl is rinsed with saline and emptied again into the return bag.

RETURNING/READY TO PHOTOACTIVATE

The volume in the Return Bag will start to return to the patient automatically via the Return Pump (#3). Once the photoactivation time has been calculated, it will be displayed as MINUTES REMAINING on the operator interface. The following factors influence the photoactivation time:

- The total treatment volume (mL)
- The hematocrit of the treatment volume (percent)
- The remaining lamp life (hours)

PHOTOACTIVATE

After adding the required amount of Methoxsalen (20 micrograms/mL), the leukocyte enriched blood fraction in the treatment bag is photoactivated. The fraction is continuously circulated between the photoactivation module and treatment bag via the Recirculation Pump (#4) until the MINUTES REMAINING equal 00:00. At the same time, the volume in the Return Bag continues to be returned to the patient via the Return Pump (#3) until the volume in the Return Bag reaches approximately 50 mL.

REINFUSE

After PHOTOACTIVATE is complete, the leukocyte enriched blood is returned to the patient via the Return Pump (#3). After REINFUSE is complete, the remaining volume in the return bag is returned to the patient via the Return Pump (#3) along with a 40 mL saline flush to the return line to ensure the patient receives the treated cells and residual red cell volume in the return line.

Before You Begin

WARNING:

- To avoid risk of electric shock, this equipment must only be connected to a supply main with a protective (earth grounded) receptacle. The use of extension cords is not recommended.
- DO NOT touch USB port and/or any leak detector while in physical contact with the patient.
- DO NOT position the device where it is difficult to connect or disconnect the device from mains power source.
- The Bowl Optic Sensor contains a laser light source. Do not stare directly into the beam.

CAUTION:

- Review all warnings and cautions summarized in ***Section 9*** of this manual before treating a patient.
- The operator must be present to supervise the treatment at all times. The operator's primary responsibility during the entire treatment is the patient's safety. Carefully monitor the patient for tolerance to the extracorporeal fluid shifts, access performance and potential allergic reactions or potential adverse events.
- Throughout the treatment you should visually monitor the instrument to confirm whole blood separation; the correct position for the plasma/red blood cell interface; unusual conditions such as hemolysis, high bilirubin and/or lipids; and unexpected fluid leaks.
- If hemolysis or unexpected air is observed during a photopheresis treatment, the therapy must be aborted and blood should not be returned to the patient.
- Follow your center specific guidelines for universal precautions whenever exposure to blood is a possibility. Failure to do so may expose you or your patient to harmful blood borne contaminants.
- Follow all operating and maintenance procedures. Failure to do so can result in patient and/or operator harm or system damage.
- Ensure that the room temperature does not exceed 27.5°C (81°F) during the treatment. To avoid excessive heat build-up in the centrifuge chamber, consider keeping the ambient temperature at 25°C (77°F) or less, especially when flow rates are less than 15 mL/min.
- Mallinckrodt does not recommend operating the THERAKOS™ CELLEX™ Photopheresis System ***under the combination of the following***:
  - A room temperature at or greater than 27.5°C (81°F).
  - Centrifuge Bowl RPM greater than 3600 RPM.
  - A collect rate lower than 15 mL/min.

  Under these conditions centrifuge chamber temperature alarms may occur. The decision to operate at or beyond these conditions is the responsibility of the clinician. Mallinckrodt does not recommend operating at lower flow rate than 15 mL/min over an extended period of time.

CAUTION:

- Allow a minimum of 50 cm (18 inches) of ventilation space in front and back of the instrument while in use.
- Do not use the THERAKOS™ CELLEX™ Photopheresis System in the presence of flammable anesthetic gases.
- Do not operate the instrument in the presence of external radio or electromagnetic disturbances that may interfere with proper performance of the device. This could result in treatment interruptions, and the possibility of a failed treatment.
- Do not clean the photoactivation module. Cleaning agents could leave a film that may adversely affect the transmission of UVA light energy and the photoactivation process.
- Complete FINAL INSPECTION BEFORE PRIME before beginning PRIME (Refer to ***page 4-29)***.
- In consultation with the clinician, assess the patient's overall health status immediately before beginning a treatment to determine if the patient is able to tolerate the anticipated fluid shifts during the treatment. Do not proceed if the patient is unstable.
- AABB guidelines recommend that the temporary extracorporeal blood volume be limited to 15% of the patient's estimated total blood volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information on selecting and maintaining Fluid Balance Limits.
- Estimate the patient's total blood volume and calculate 10 or 15% of that volume. Refer to ***"Changing Default SETUP Parameters" on page 5-14*** to determine how to set the ± Fluid Balance Limit before starting COLLECT.
- Optimize venous access. Whenever possible, the COLLECT and RETURN Flow Rates should be greater than 15 mL/min.
- When instructed, establish or disconnect patient access in accordance with your institution's standards of practice for this procedure. Failure to do so may lead to patient harm such as increased risk of infection, trauma to the access site, possible air embolus or post treatment blood loss.
- The used THERAKOS™ CELLEX™ Photopheresis Procedural Kit and any spills should be considered biologically contaminated. When handling the contaminated procedural kit, or cleaning up any blood spills on the instrument, follow your institutions specific policy for biohazard precautions and hazardous waste disposal.
- Advise patients that it is recommended to protect their skin and eyes from sunlight for 24 hours post treatment. Refer to the Methoxsalen (20 micrograms/mL) labeling or the oral 8-methoxypsoralen dosage information package insert for more information on protecting the patient from light and for all medication warnings and precautions.

CAUTION:

- Do not use the THERAKOS™ CELLEX™ Photopheresis System in the presence of flammable anesthetic gases.
- Mallinckrodt recommends that you do not change the THERAKOS™ CELLEX™ Light Assembly during a treatment. Refer to ***page 7-8*** for all warnings, cautions, and instructions when lamp replacement is required.
- Do not attempt to modify the THERAKOS™ CELLEX™ Instrument, THERAKOS™ CELLEX™ Photopheresis Procedural Kit, or THERAKOS™ CELLEX™ Light Assembly in any way.
- Under these conditions centrifuge chamber temperature alarms may occur. The decision to operate at or beyond these conditions is the responsibility of the clinician. Mallinckrodt does not recommend operating at lower flow rate than 15 mL/min over an extended period of time.
- Laser - Use of controls or adjustments or performance of procedures other than those specified in Section 8 may result in hazardous radiation exposure

Sterile Air

All fluid pathways are sterile; therefore, the air contained in these pathways is also sterile. Sterile air is utilised to both empty the centrifuge bowl at the end of BUFFY COAT and empty the photoactiviation module after PHOTOACTIVATE.

Cycling Power OFF/ON: After PRIME/During a Treatment

Numerous internal safety checks are performed during boot-up each time the THERAKOS™ CELLEX™ Instrument is turned on. Cycling the power OFF and then ON at the end of a patient treatment, after the RELEASE KIT button is pressed, allows the instrument to erase the individual patient treatment data and to repeat these safety checks before beginning a new patient treatment.

NOTE:

- The power must be on to properly load a THERAKOS™ CELLEX™ Photopheresis Procedural Kit.
- After a treatment is complete and all data is recorded, you must turn the power OFF and then ON to begin a new treatment. Re-booting the system returns the screen display to READY TO PRIME.
- You may turn OFF the power after PRIME to relocate the instrument. While there is no time limit for power OFF, Mallinckrodt recommends that the pending treatment be initiated within four hours.
- If the power is turned OFF or there is a power failure after PRIME begins, the treatment screen will display the following message when the power is restored: "Do you wish to end this treatment and install a new procedural kit?" (YES) (NO)
  - To end the treatment, indicate YES and confirm your response. The instrument will respond by going to READY TO PRIME.
  - To allow the treatment to resume, indicate NO.
  - If you do not respond to this screen prompt within 30 seconds, the instrument will automatically resume treatment at the place where power was interrupted.

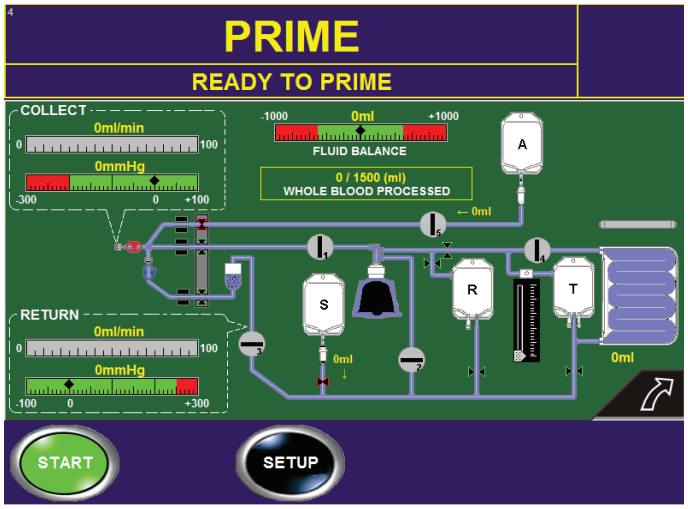
WARNING:

If the power is turned OFF for any reason during COLLECT, the Centrifuge Bowl must be re-purged before treatment resumes. This will result in a partial loss of buffy coat and higher extracorporeal volume. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT*** when re-purging the Centrifuge Bowl before resuming the treatment.

Initiating PRIME

WARNING:

- Prior to initiating PRIME, ensure the Treatment Bag and Return Bag are properly positioned on their respective Load Cells Hooks. Removal of these bags at anytime after PRIME is initiated may result in priming alarms and/or inaccurate FLUID BALANCE readings during a treatment.
- Once PRIME has been completed, the procedure using the primed THERAKOS™ CELLEX™ Photopheresis Procedural Kit must be started within four hours.



Just prior to PRIME, all pathways are illustrated in blue indicating there is no fluid movement within the procedural kit.

Figure 5-1: Initating PRIME

1. Confirm proper procedural kit installation.
2. Press START.

NOTE:

- The system is primed automatically.
- During PRIME, the system initially performs a series of tests to ensure proper setup of the procedural kit and calibration of sensors as well as proper operation of pumps, lamps and fluid routing valves. All of these tests occur automatically and will generate an alarm message should a problem be found. Refer to ***SECTION 6: CORRECTING ALARMS***, for alarm troubleshooting.
- The system then pumps anticoagulant solution and saline throughout the procedural kit, eventually filling the photoactivation module and the patient collect and return lines fully. The return and treatment bags and the Centrifuge Bowl will only be partially filled during PRIME. Some areas of the procedural kit are simply wetted with anticoagulant solution.

3. When prompted, open the centrifuge chamber door and check the drive tube installation.
4. Close the centrifuge chamber door.
5. Inspect entire procedural kit for leaks before proceeding.
6. Press CLOSE.

CAUTION:

To avoid risk of infection and/or potential patient blood loss do not use a THERAKOS™ CELLEX™ Photopheresis Procedural Kit that:

- has been damaged during installation.
- has leaked during PRIME.

Save the defective procedural kit for return to manufacturer. Call Mallinckrodt to report the problem.

Calculating and Setting Fluid Balance Limits

The THERAKOS™ CELLEX™ Photopheresis System continuously monitors and displays the volume of fluid movement to and from the patient during a THERAKOS™ Photopheresis treatment. These fluids may be whole blood, anticoagulant, or saline. A negative fluid balance indicates that the patient is undergoing a temporary fluid deficit. A positive fluid balance indicates that the patient has received additional fluids. At completion of a standard treatment the patient will be fluid positive approximately 350 - 450 mL

To assist in establishing appropriate fluid balance alarm limits, the THERAKOS™ CELLEX™ Photopheresis System incorporates an integral fluid balance calculator that uses the Nadler formula to estimate the patients Total Blood Volume. The calculator and fluid balance setup screen will automatically display prior to patient connection and will be available after initiation of the treatment via the setup screen. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information.

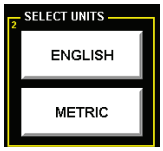
CAUTION:

AABB guidelines recommend that the temporary extracorporeal blood volume be limited to 15% of the patient's estimated total blood volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment. Refer to SECTION ***10: FLUID BALANCE MANAGEMENT*** for additional information on selecting and maintaining Fluid Balance Limits.

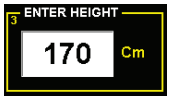
To use the integrated calculator, use the following process:

1. Select the patient's gender.

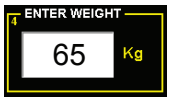
2. Select Units of Measure.



3. Press white box to enter patient's height. A keypad will appear. Enter patient's height into the keypad and press enter.



4. Press white box to enter patient's weight. A keypad will appear. Enter patient's weight into the keypad and press enter.



5. The Estimated Total Blood Volume will be displayed.

   - Press ACCEPT to use this value. The calculator will automatically display calculated fluid balance range values for 10% and 15% of the patient's total blood volume.

Figure 5-2a: Fluid Balance Calculator

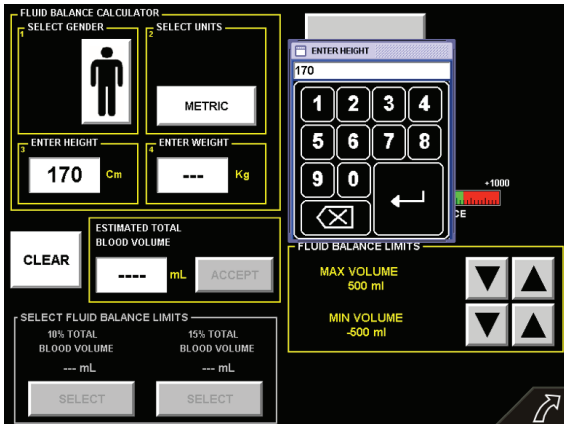
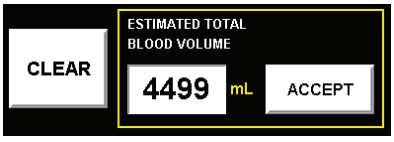


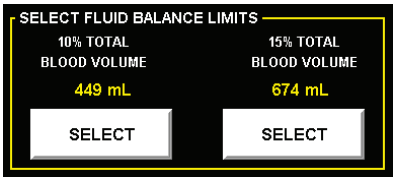
Figure 5-3b: Fluid Balance Calculator

NOTE:
Fluid Balance Calculator may only be used for patients > 25 kg.

   - Press CLEAR to reset the calculator values and return to step 1.



6. Pressing one of the SELECT buttons under the Fluid Balance Limits (10% or 15%) will set fluid balance alarm threshold to the value selected. The selected value will be highlighted.



7. Press SAVE to save the values and set the fluid balance alarm limits to the new values.

NOTE:

- For additional information about selecting and managing the proper fluid balance limits for each patient, please refer to ***SECTION 10: FLUID BALANCE MANAGEMENT.***
- Enter ± 15% of Total Blood Volume as Fluid Balance Limit if patient is stable and able to withstand moderate fluid shifts.
- Enter ± 10% of Total Blood Volume as Fluid Balance Limit if patient's condition warrants minimal fluid shifts.
- Pressing CANCEL at any time will not make changes to the preset values and will exit the calculator screen.
- Fluid balance values may also be set or adjusted via the setup screen at any time throughout the treatment.
- Use of the integrated calculator is not mandatory however is recommended. You may also use an alternate method of computing Total Blood Volume entering appropriate alarm limits manually. Please refer to ***SECTION 10: FLUID BALANCE MANAGEMENT*** for more information.

PRIME ACCESS

To maintain procedural kit sterility, do not remove the vented cap from the patient Collect Line.

1. Remove the Patient Lines from the IV Pole.
2. Ensure that both the Patient Collect Line (RED) Clamp and Patient Return Line (BLUE) Clamp are at the same level as the Pump Deck.

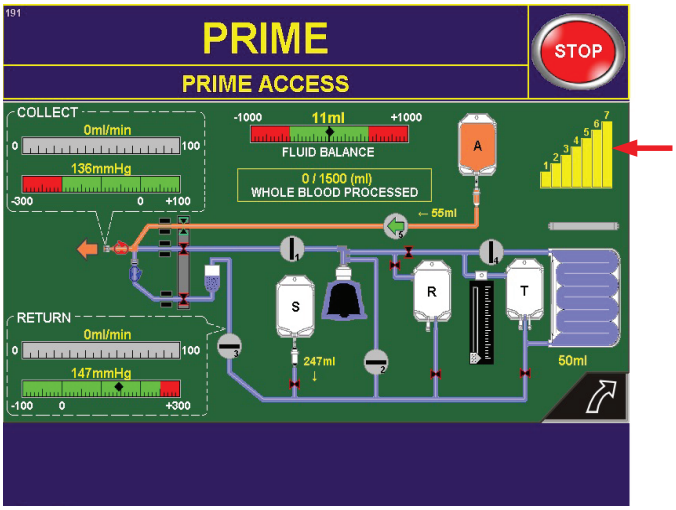
CAUTION:

- Ensure that both the Patient Collect Line (RED) Clamp and Patient Return Line (BLUE) Clamp are at the same level as the Pump Deck (± 45cm) before opening the Patient Collect Line (RED) Clamp and pressing PRIME, ***See Figure 5-3.*** If the Patient Collect Line (RED) Clamp is not at pump deck height during PRIME ACCESS, the pressure in the system will cause pressure alarms and it will not be possible to proceed past PRIME.

3. Open the patient Collect Line (RED) Clamp and press PRIME.
4. Wait for all fluid flow to stop exiting the Collect Line plus an additional 2 seconds - you will hear the instrument beep.
5. Close the Collect Line (RED) Clamp.
6. Check Collect and Return Lines for air. If required to repeat PRIME ACCESS open the Collect Line (RED) Clamp and see steps 7 and 8.

7. If any air remains in the Return Line:
   - Press START SALINE
   - STOP SALINE once the Return Line is completely primed
   - Press PRIME to deliver A/C to the end of the Collect Line
8. If any air remains in the Collect Line, press PRIME.
9. Close the patient Collect Line (RED) clamp. Proceed to changing default SETUP parameters.

Figure 5-3: PRIME ACCESS at the same level as the pump deck (+/- 45 cm)



- All seven stages of PRIME are complete indicated by the seven yellow bars in the upper right hand corner of the screen.
- The mL volume of anticoagulant and saline used to PRIME are displayed.

Figure 5-4: PRIME ACCESS

WARNING:

DO NOT connect patient to the procedural kit lines prior to completing PRIME ACCESS. Pressing PRIME to complete PRIME ACCESS with patient connected will cause air in the line to be delivered to the patient.

Changing Default SETUP Parameters

The THERAKOS™ CELLEX™ Photopheresis System default SETUP parameters and range of available settings are listed in the table below. Individual patients may require a change from these Default Parameters. Use clinical judgment when changing these parameters.

To change a parameter, press SETUP, change the parameter(s) and press SAVE. All parameters will return to the default at the start of a new treatment.

CAUTION:
Ensure settable alarm limits are appropriate for patient conditions.

Setting [Units]	Default Parameter	Range of Settings
COLLECT Limits		
Flow Rate [mL/min]	50	5 to 50 (May be limited in some modes of operation)
Pressure Alarm [mmHg]	-200	-200 to 0
RETURN Limits		
Flow Rate [mL/min]	60	5 to 60
Upper Limit Pressure Alarm [mmHg]	250	0 to 300
Lower Limit Pressure Alarm [mmHg]	-100	-100 to +50
Treatment Settings		
A/C Ratio (mL Blood: mL Anticoagulant)	10:1	8:1, 10:1, 12:1, 14:1, 16:1, 25:1, 30:1, 35:1, 50:1
Saline Bolus [mL]	100	10–100
Centrifuge Bowl Speed [rpm]	3400	3200–4800 (increments of 200)
Reinfusion Rate Limit [mL/min]	60	1–60 (1–5, increments of 1) (5–60, increments of 5)
Whole Blood Processed Target [mL]	1500	500–2000
Fluid Balance Alarm Lower Limit [mL]	-500	-1000 to -50
Fluid Balance Alarm Upper Limit [mL]	500	50–1000
Return Bag Threshold [mL]	100	100–250
A/C Volume Alarm Threshold [mL]	450	200–2000
Saline Volume Alarm Threshold [mL]	450	200–2000
Bowl Optic Threshold Value	150	25–250
Rinseback Volume Limit [mL] (when enabled)	20	0–999

Table 1: Default SETUP Parameter Settings

NOTE:
The THERAKOS CELLEX Photopheresis System default Collect Flow Rate is 30 mL/min and the default Return Flow Rate is 35 mL/min. The Collect and Return Flow Rates are bounded by the Collect and Return Flow Rate Limits respectively and adjusted on the main screen of the Operator Interface, not on the SETUP screen.

Accessing the SETUP Screen

Press SETUP during the treatment to make changes to any parameter setting. SETUP may be accessed by pressing PAUSE (if centrifuge is spinning) or STOP (if centrifuge is stopped):

- Prior to PRIME or PRIME ACCESS
- During COLLECT (DRAWING/BUFFY COAT/RETURNING)
- Prior to or during PHOTOACTIVATE
- During REINFUSE

Changing Limits and Treatment Settings

There are three screens of SETUP parameter settings. Press the arrow tab on the bottom right corner of the screen to access the second and third screens of setup information. Pressing the tab again will return you to the previous screen. Refer to *"Calculating and Setting Fluid Balance Limits" on page 5-10* for more information regarding the third screen of setup information. To adjust the values of the SETUP Screen:

1. Press the ▼▲ to increase or decrease a value or use provided keypad.
2. Press SAVE. This button initiates the changes that you have entered and returns you to the main screen.

   Or
3. Press CANCEL to return to the main screen and to cancel any changes you made.

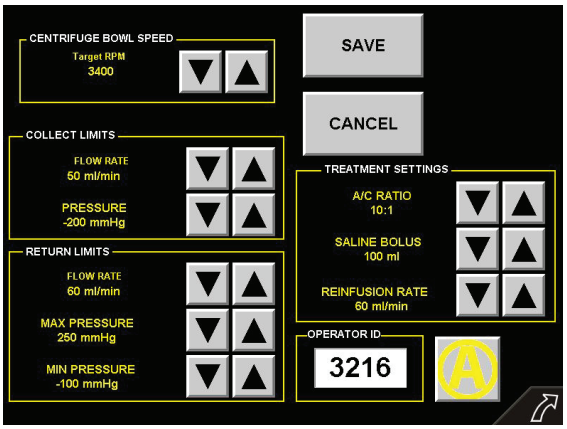


Figure 5-5a: Changing Default SETUP Parameters–SETUP Screen 1

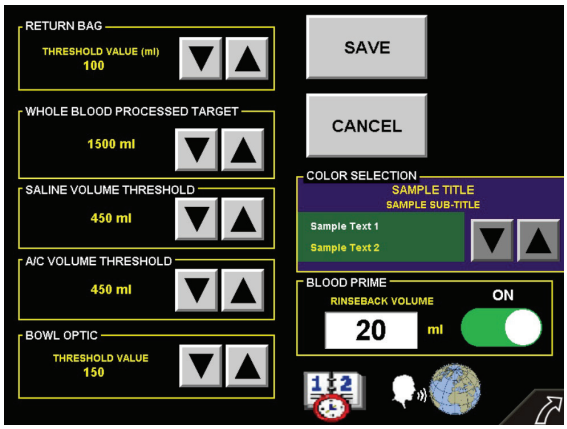


Figure 5-5b: Changing Default SETUP Parameters–SETUP Screen 2

Blood Prime Feature

By default the Blood Prime feature is disabled. (Refer to *SECTION 10: "BLOOD PRIME"*)

To enable the Blood Prime Feature:

1. Enter SETUP Screen Page 2.
2. Press and hold 

until 

appears.
3. Set the required Rinseback Volume by tapping on the white box and using the provided keypad to enter the desired volume.

4. Press SAVE. The Rinseback Volume will appear on the main screen of the operator interface.

To disable the Blood Prime Feature:

1. Enter SETUP Screen Page 2.
2. Press and hold 

until the 

appears.
3. Press SAVE.

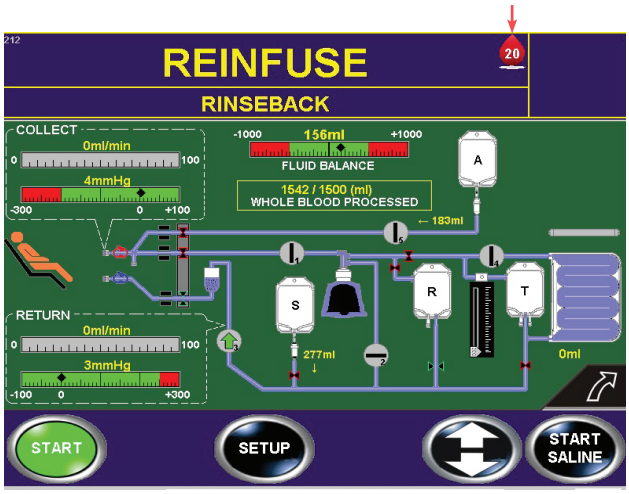


Figure 5-6: When the Blood Prime Feature is enabled an icon appears on screen displaying the Rinseback Volume.

Automatic Flow Control

By default the Automatic Flow Control is enabled and the software will automatically reduce COLLECT and RETURN Flow Rates if the Collect or Return Pressures near their respective pressure alarm limit. Flow rates are reduced to maintain pressure within pressure alarm limits. The following conditions apply to Automatic Flow Control:

- If pressure conditions improve, flow rates will gradually increase back to their target rates.
- If the flow rate is manually adjusted on the main screen of the operator interface during automatic adjustment, the flow rate will be set to the nearest (lower) 5 mL/min set point from the current flow rate. This will become the new target flow rate. It is not possible for the operator to manually raise the flow rate above the adjusted rate applied by the Automatic Flow Control.
- When the Automatic Flow Control reduces flow rates in DOUBLE NEEDLE mode, both COLLECT and RETURN Flow Rates will be reduced to a matched value where applicable. Automatic Flow Control will never increase a flow rate beyond its current target value.
- When the Automatic Flow Control reduces the flow rate in SINGLE NEEDLE mode, only the active flow rate will be reduced. COLLECT and RETURN flow rates are independent of each other.

Automatic Flow Control Disable

The Automatic Flow Control may be disabled. If an operator wishes to disable the Automatic Flow Control they may do so by:

1. Enter SETUP Screen Page 1.
2. Press and hold  until icon changes to  .
3. Press SAVE,  will appear on the Main Screen of the Operator Interface.

To return to the default Automatic Flow Control:

1. Enter SETUP Screen Page 1.
2. Press and hold  until icon changes to  .
3. Press SAVE.

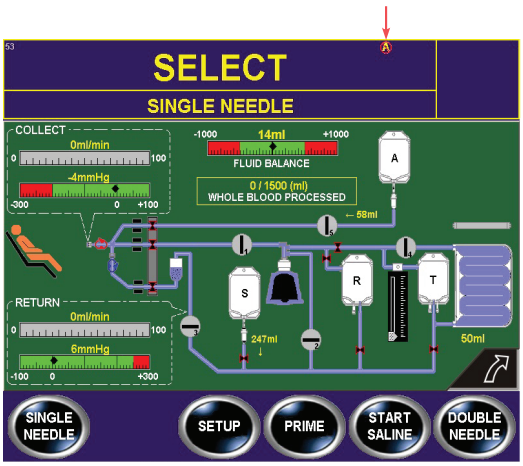


Figure 5-7: When the Automatic Flow Control is disabled an icon appears on screen.

NOTE:

- The operator should always monitor pressures throughout the treatment to remain aware of any automatically adjusted flow rates.
- The operator will not be notified if Automatic Flow Control is automatically adjusting flow rates.
- Disabling this feature may result in increased Collect and Return Pressure Alarms.

Changing the Clock Settings

NOTE:
The SETUP screen will not automatically set for time zone or seasonal time changes and will need to be checked for correct time periodically. (See Below Fig 5-9a)

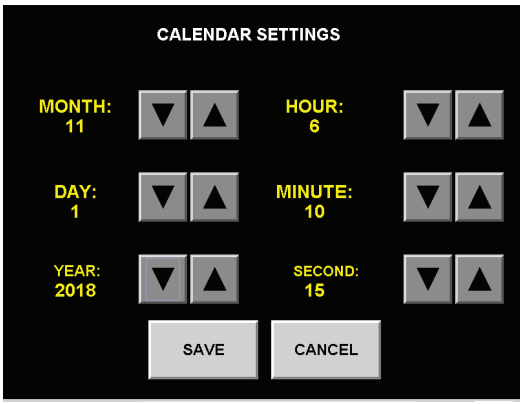


Figure 5-8a: Changing the Date and Time

1. Enter SETUP Screen Page 2 then press .
2. Press to change the time and date of the system.
3. Press SAVE. This button initiates the changes that you have entered and returns you to the previous screen.
   Or
4. Press CANCEL to return to the previous screen and to cancel any changes you made.

Changing the Language Settings

Figure 5-8b: Changing Language Settings

1. Enter SETUP Screen Page 2 then press .
2. Select the language button desired.

Example: ENGLISH

Once you select a language, the text on the screen automatically appears in the selected language.

Operator ID

The operator can enter their unique ID number up to 4 digits. The Operator ID will be saved to the Smart Card. To enter a number select Operator ID on the setup screen

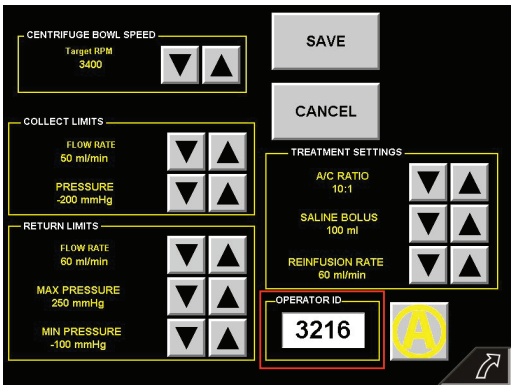


Figure 5-9a: Entering the Operator ID

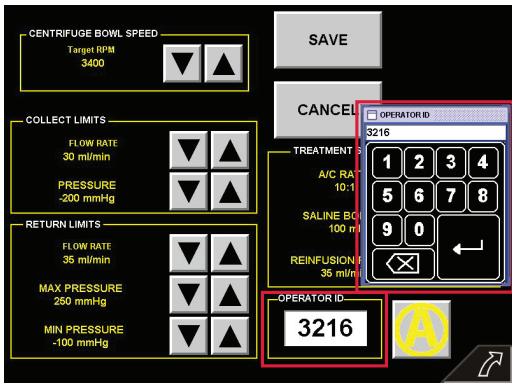


Figure 5-9b: Entering the Operator ID

Centrifuge Bowl Speed

When instructed to turn on, the CENTRIFUGE BOWL SPEED remains constant throughout the COLLECT: DRAWING phase unless changed by the operator. Refer to *"Changing Default SETUP Parameters" on page 5-14* for the default setting and speed range settings. The operator can change the Centrifuge Bowl speed during a treatment via the setup screen. The CENTRIFUGE BOWL SPEED may be increased at any time from the setup screen however can only be adjusted downward when the centrifuge is stopped.

To increase the CENTRIFUGE BOWL SPEED during a treatment

1. Select PAUSE.
2. Select SETUP.
3. Increase the CENTRIFUGE BOWL SPEED to the desired target.
4. Select SAVE.
5. Select START to resume the treatment at the new speed.

To decrease the CENTRIFUGE BOWL SPEED during a treatment.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to *page 5-43* or *5-60* for complete instructions.

1. Select STOP to stop the Centrifuge Bowl. (Plasma/red cell interface will be lost and Centrifuge Bowl must be re-purged resulting in increased ECV).
2. Select SETUP.
3. Decrease the CENTRIFUGE BOWL SPEED to the desired target.
4. Select SAVE.
5. Select START to resume the treatment at the new CENTRIFUGE BOWL SPEED.

NOTE:

During the treatment, tap the Centrifuge Bowl on the screen to display the CENTRIFUGE BOWL SPEED setting.

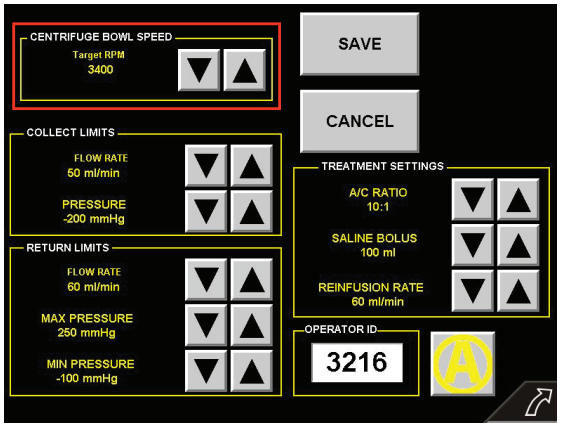


Figure 5-10a: Changing the CENTRIFUGE BOWL SPEED

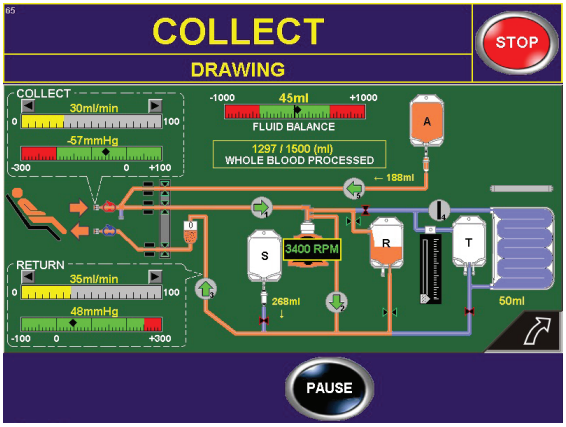


Figure 5-10b: Tap to Display the CENTRIFUGE BOWL SPEED

NOTE:
The software will pause to establish separation following a Centrifuge Bowl speed increase.

Rationale for Changing Default SETUP Parameter Settings

Changing COLLECT, RETURN, and REINFUSE FLOW RATE LIMITS

The instrument gradually reaches a default flow rate of 30 mL/min for the COLLECT Flow Rate and 35 mL/min for the RETURN Flow Rate. You may choose to set lower COLLECT, RETURN and/or REINFUSION rate limits for an individual patient. If so, these limits may be entered and saved via the SETUP screen at any time during the treatment. Medical conditions that warrant lower flow rate limits include, but may not be limited to:

- Cardiac insufficiency
- Pulmonary insufficiency
- Renal insufficiency
- Diabetes
- Hypertension
- Hypotension
- Edema
- Fragile veins
- Low body weights

Disabling the Automatic Flow Control

By default, the software will adjust COLLECT and RETURN rates as necessary if collect or return pressures approach their respective limits.

If an operator does not want the software to automatically adjust flow rates, the Automatic Flow Control may be disabled. Disabling this feature may result in increased Collect and Return Pressure Alarms *(see page 5-17)*.

Changing the CENTRIFUGE BOWL SPEED

Mallinckrodt does not recommend routinely deviating from the default Centrifuge Bowl Speed of 3400 RPM. In the event of an Alarm #51: Centrifuge Chamber Temperature, reducing the Centrifuge Bowl Speed is an optional corrective action *(see page 6-56)*.

Just prior to Buffy Coat Collection, the Centrifuge Bowl speed automatically increases to 4800 RPM.

If the healthcare provider has a preference to perform the entire collection phase at a constant 4800 RPM, the Centrifuge Bowl Speed may be set to 4800 RPM via the SETUP screen.

Changing COLLECT and RETURN Pressure Alarm Settings

The need to control the COLLECT and RETURN pressure will depend on the type of access in use and the condition of the patient's veins if venipuncture is used. Setting the alarm limit to a higher negative value allows for a stronger pull by the roller pumps before reaching an occlusion alarm. Setting the pressure to a lower negative value increases the sensitivity of an occlusion alarm and may be desired when very fragile veins are accessed.

The type of access in use will help to determine if these settings need to be changed. You may need to raise the upper return pressure limit if returning against arterial pressure into an AV Fistula or graft.

CAUTION:
Use clinical judgement when adjusting alarm limits.

Changing the A/C RATIO

The default A/C RATIO is 10:1 (mL of blood: mL of anticoagulant). The standard anticoagulant solution is prepared by adding 10,000–15,000 Units of heparin to 500 mL of 0.9% Normal saline. Patient conditon and institution specific laboratory values may direct clinical judgment and clinician directive, leading to changes in A/C ratio settings. For example:

- Consider using 8:1 if the patient's platelet count is elevated.
- 12:1, 14:1 and 16:1 may be used with lower platelet counts or if the patient is taking maintenance anticoagulant medications.
- 25:1, 30:1, 35:1 or 50:1 may be considered if the patient is on acute systemic anticoagulant medications.

Tap on the A/C bag icon to display the current A/C ratio.

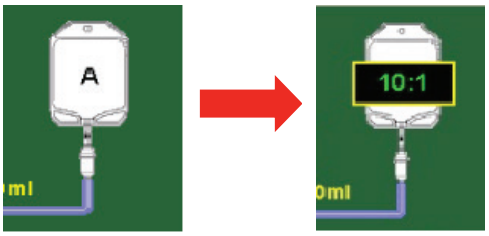


Figure 5-11: A/C ratio

CAUTION:
Individual patients may require a heparin dosage that varies from the recommended dose to prevent post-treatment bleeding or clotting during a treatment. The clinician should review the patient's medical condition, medications and platelet count at the time of treatment and use clinical judgment to establish the optimal heparin dosage for each patient.

Changing the SALINE BOLUS

The default SALINE BOLUS volume is 100 mL. It may be lowered in increments of 10 mL down to 10 mL via the SETUP screen. Alternatively, the operator may request a bolus using the default value of 100 mL and simply press STOP SALINE to interrupt the flow of saline at any point before the full 100 mL is delivered.

Changing the Return Bag Threshold Value (SINGLE NEEDLE Mode Only)

This value determines when the instrument will automatically alternate between DRAWING and RETURNING when operating in SINGLE NEEDLE mode. The default setting is 100 mL. As the volume of plasma and red blood cells pooling in the return bag reaches the threshold value, DRAWING is interrupted and RETURNING begins. An audible beep signals each time the phase changes from DRAWING to RETURNING. Please refer to ***SECTION 10: FLUID BALANCE MANAGEMENT*** for more information. The Centrifuge Bowl will stop spinning when the instrument calculates that the last user set return rate will require greater than 7 minutes to return the contents of the return bag to approximately 50 mL.

Changing the WHOLE BLOOD PROCESSED TARGET

A standard THERAKOS™ Photopheresis therapy will process 1500 mL of whole blood. You may raise this target volume to 2000 mL or lower it to 500 mL.

Reasons to raise the WHOLE BLOOD PROCESSED TARGET:

- Increase the total number of cells collected.
- Process additional volume if the Centrifuge Bowl requires re-purging.

Reasons to lower the WHOLE BLOOD PROCESSED TARGET:

- Poor access or other clinical reasons will not allow full treatment.
- Troubleshooting (Prompted by alarm messages).

Changing the A/C or SALINE VOLUME THRESHOLDS

The default delivery limit value for both A/C and saline are set at 450 mL. This setting is used to warn that the bags are almost empty and will need to be replenished prior to completing the treatment.

Reasons to lower the A/C or SALINE VOLUME THRESHOLDS:

- The patient's condition limits the units of heparin that may be received.
- The patient's condition limits the volume of saline that may be received.
- Reasons to raise the A/C or SALINE VOLUME THRESHOLDS:

- The WHOLE BLOOD PROCESSED TARGET has been increased to 2000 mL.
- THE A/C RATIO has been set to 8:1.

CAUTION:
Do not allow the anticoagulant or saline bags to become empty prior to completing a treatment. Air in the spike lines will interrupt the treatment and prevent successful completion of the therapy. If A/C bag becomes empty during a procedure, the concentration of anticoagulant and instrument settings should be verified to determine if the dose to the patient is accurate and to determine whether it is safe to proceed with a new bag of A/C if needed to continue the treatment.

Changing the BOWL OPTIC THRESHOLD VALUE

The THERAKOS™ CELLEX™ Photopheresis System has an adjustable Bowl Optic Sensor. The BOWL OPTIC THRESHOLD VALUE determines the position of the plasma/red blood cell interface in the spinning Centrifuge Bowl. You may visually recognize that the plasma/red blood cell interface is too low in the Centrifuge Bowl or the instrument may activate the Red Blood Cell Pump Alarm.

a. Correct

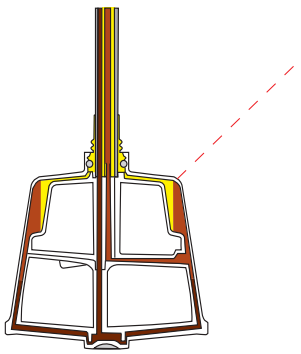


Figure 5-12a: Correct position of plasma/red blood cell interface

b. Too Low

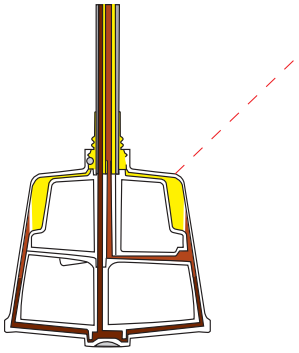


Figure 5-12b: Plasma/red blood cell interface too low

You may need to lower the BOWL OPTIC THRESHOLD VALUE whenever abnormal plasma conditions occur. Reasons to lower the BOWL OPTIC THRESHOLD VALUE:

- The clarity of the plasma is abnormal (instrument mistakes lipids for red blood cells).
- The color of the plasma is abnormal (instrument mistakes dark plasma for red blood cells).

Adjustments to the BOWL OPTIC THRESHOLD VALUE are entered via the SETUP screen.

WARNING:
The Bowl Optic Sensor contains a laser light source. Do not stare directly into the beam.

NOTE:
For more information on displaying and understanding the BOWL OPTIC SENSOR, *see pages 3-18 through 3-20.*

Configuring the THERAKOS™ CELLEX™ Photopheresis Procedural Kit

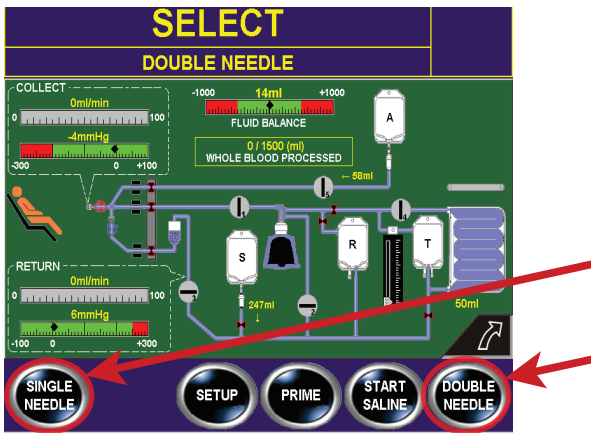
Determine SINGLE NEEDLE or DOUBLE NEEDLE Mode

CAUTION:

- The collect and return lines must be configured to match the access mode selected. Failure to do so may lead to clotting at one access site, treatment interruption, recirculation and a possible failed treatment.

NOTE:

- The same procedural kit is used for either a SINGLE NEEDLE mode or DOUBLE NEEDLE mode treatment. To ensure that the established access matches the software mode instruction, you should first establish your access sites by connecting the patient lines and then select SINGLE NEEDLE or DOUBLE NEEDLE on the operator interface screen.
- The mode of access may be changed anytime during the treatment.



After you select SINGLE NEEDLE or DOUBLE NEEDLE, a pop-up message will display the access mode selected and the screen schematic will be set to match the mode selected.

SINGLE NEEDLE

DOUBLE NEEDLE

Figure 5-13: Select SINGLE NEEDLE Mode or DOUBLE NEEDLE Mode

Change between SINGLE NEEDLE and DOUBLE NEEDLE Mode

CAUTION:

Selecting 

during the COLLECT phase to change access mode will stop the centrifuge bowl and cell separation will be lost.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

The mode of access can be changed anytime during treatment

1. Press PAUSE during COLLECT or press STOP if the PAUSE button is not available
2. Establish the new patient access configuration, refer to ***page 5-28*** or ***5-30*** for instruction
3. Press  , then select the desired access mode (only the mode not currently being used is available).
4. Select YES or NO in the confirmation message that appears
   - Pressing YES changes the access mode and the Main Screen of the Operator interface appears
   - Pressing NO returns you to the previous screen without changing access mode. Press  again to return to the Main Screen of the Operator Interface
5. Verify that the screen display shows the desired configuration.
6. Confirm that the collect and return line configuration matches the access mode selected and press START to resume treatment.

CAUTION:

The Collect and Return Lines must be configured to match the access mode selected. Failure to do so may lead to clotting at one access site, treatment interruption, recirculation and a possible failed treatment.

NOTE:

- The same procedural kit is used for either a SINGLE NEEDLE mode or DOUBLE NEEDLE mode treatment. To ensure that the established access matches the software mode instruction, you should first establish your access sites by connecting the patient lines and then select SINGLE NEEDLE or DOUBLE NEEDLE on the operator interface screen.
- The mode of access may be changed anytime during the treatment.

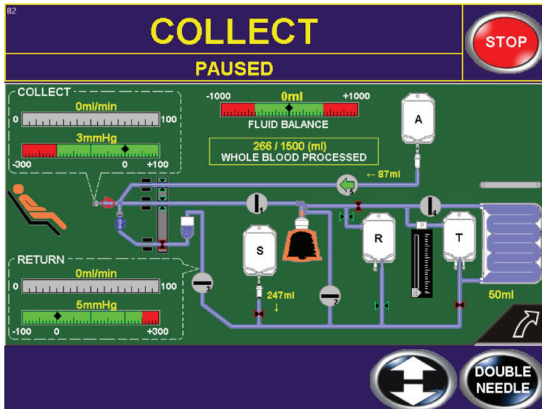


Figure 5-14a: Changing from SINGLE NEEDLE mode to DOUBLE NEEDLE mode

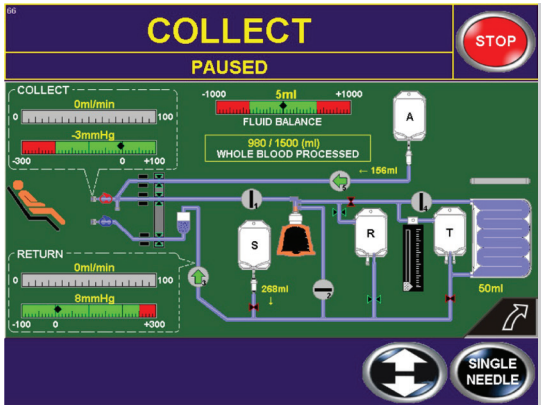


Figure 5-14b: Changing from DOUBLE NEEDLE mode to SINGLE NEEDLE mode

Configuring Collect And Return Lines For SINGLE NEEDLE Mode

NOTE:
PRIME and PRIME ACCESS are already configured for SINGLE NEEDLE mode.

1. Following PRIME ACCESS, confirm that the male luer of the return line (BLUE striped) is connected to the collect line (RED striped) needle-free injection port.

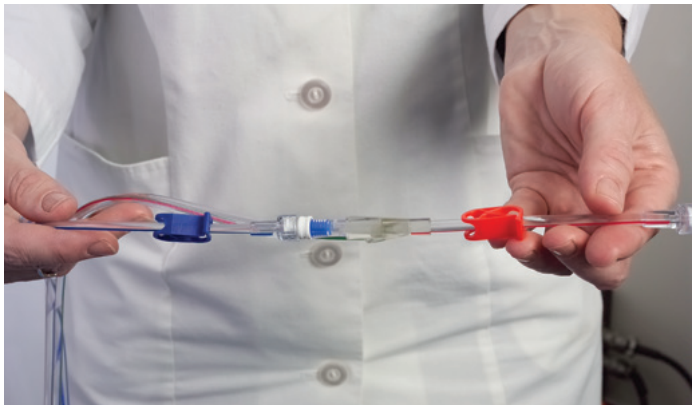


Figure 5-15a: SINGLE NEEDLE Mode Line Configuration

2. Attach the patient collect/return line to the patient's access site.
3. Select SINGLE NEEDLE button and confirm.
4. Verify that the screen display shows SINGLE NEEDLE configuration.

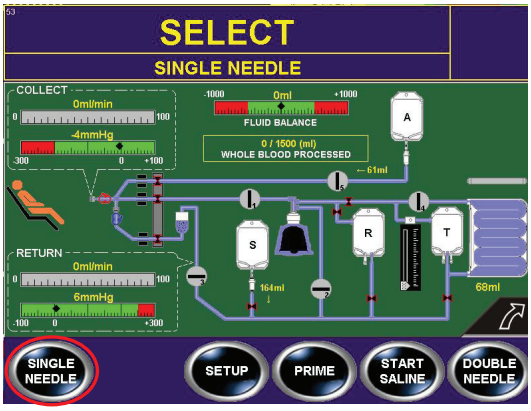


Figure 5-15b: SELECT SINGLE NEEDLE

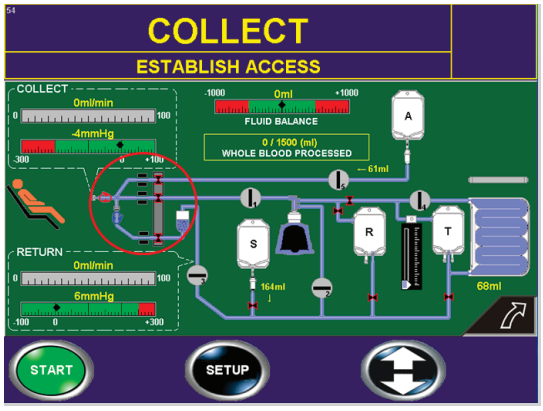


Figure 5-15c: Confirm Screen Display: SINGLE NEEDLE

5. Follow operating instructions in *"Single Needle Mode Treatment Procedure" on page 5-31* to continue.

Configuring Collect and Return Lines for DOUBLE NEEDLE Mode

1. Following PRIME ACCESS close the return line (BLUE) clamp.
2. Remove return line (BLUE Striped) from the patient collect line (RED striped) needle-free access port and connect to patient's return access site.
3. Connect the collect line (RED striped) to the patient's collect access site.

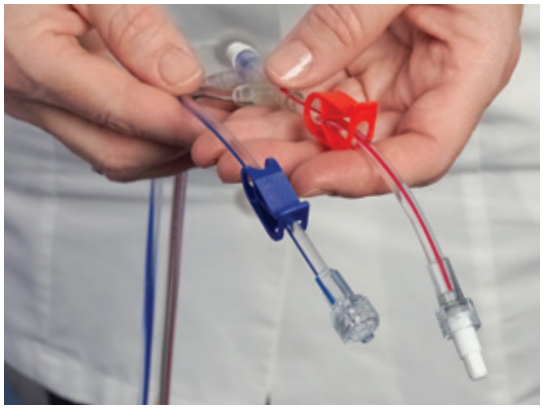


Figure 5-16a: DOUBLE NEEDLE Mode Line Configuration

4. Select DOUBLE NEEDLE on the display screen and confirm.
5. Verify that the screen display has changed to DOUBLE NEEDLE.

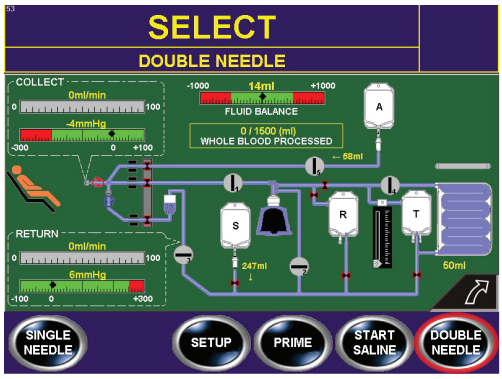


Figure 5-16b: SELECT DOUBLE NEEDLE

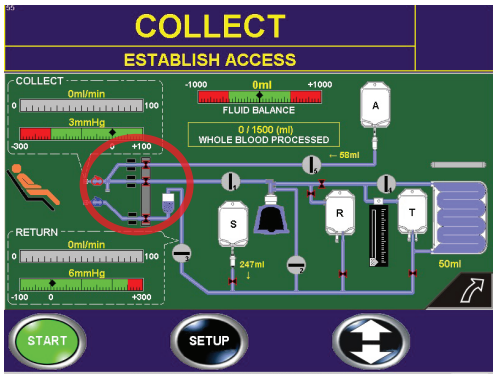


Figure 5-16c: Confirm Screen Display: DOUBLE NEEDLE

6. Follow operating instructions in *"Double Needle Mode Treatment Procedure" on page 5-48* to continue.

Single Needle Mode Treatment Procedure

WARNING:

- Prior to initiating PRIME, ensure the Treatment Bag and Return Bag are properly positioned on their respective Load Cells Hooks. Removal of these bags at anytime after PRIME is initiated may result in priming alarms and/or inaccurate FLUID BALANCE readings during a treatment.
- Once PRIME has been completed, the procedure using the primed THERAKOS™ CELLEX™ Photopheresis Procedural Kit must be started within four hours.

CAUTION:

The Collect and Return Lines must be configured to match the access mode selected. Failure to do so may lead to clotting at one access site, treatment interruption, recirculation and a possible failed treatment.

ESTABLISH ACCESS

- Subtitle display line alternates between ESTABLISH ACCESS and READY TO COLLECT.
- Only one access line is connected to the patient access site for both collect and return.

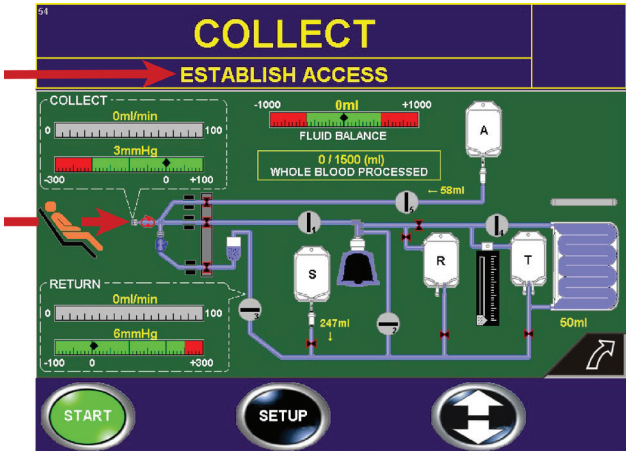
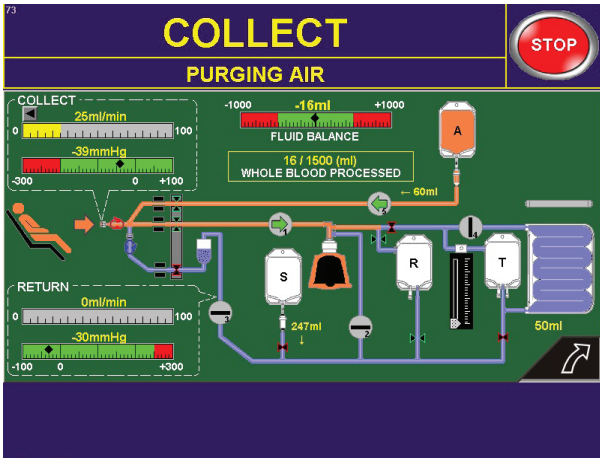


Figure 5-17a: ESTABLISH ACCESS (SINGLE NEEDLE Mode)

1. Verify the patient's access configuration correlates with the treatment mode selected and verify the following clamps are OPEN:
   - Patient access clamp
   - Collect Line (RED) clamp
   - Return Line (BLUE) clamp
2. Press START.
   - The START button is always located in the lower left corner of the main screen of the operator interface

PURGING AIR

- Whole blood is drawn from the patient at the default rate of 25 mL/min if access allows.
- Anticoagulant is added at the preset delivery ratio to the speed of the collect pump.
- Anticoagulated blood fills the Centrifuge Bowl and the lines to the return bag.
- The Centrifuge Bowl speed will vary during PURGING AIR and does not spin at the full speed until it is filled.



- Active pathways are illustrated in pink.
- Inactive pathways are blue.

Figure 5-17b: PURGING AIR (SINGLE NEEDLE Mode)

Figure 5-17c: PURGING AIR

NOTE:

- Pressing the COLLECT Increase or COLLECT Decrease rate arrows on the Main Screen of the operator interface will change the flow rate within the COLLECT Flow Rate Limit Range.
- The RETURN Flow Rate may also be adjusted from the main screen of the operator interface within the RETURN Flow Rate Limit Range.
- You may change the COLLECT or RETURN Flow Rate Limit Ranges by entering a new value via the SETUP screen. Refer to ***Changing Default SETUP Parameters on page 5-14*** for more information.
- If the operator changes the COLLECT Flow Rate during PURGING AIR, the software will keep the adjusted COLLECT Flow Rate following PURGING AIR. The RETURN Flow Rate will default at 35 mL/min, or the last user set rate.

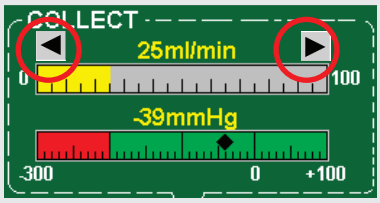


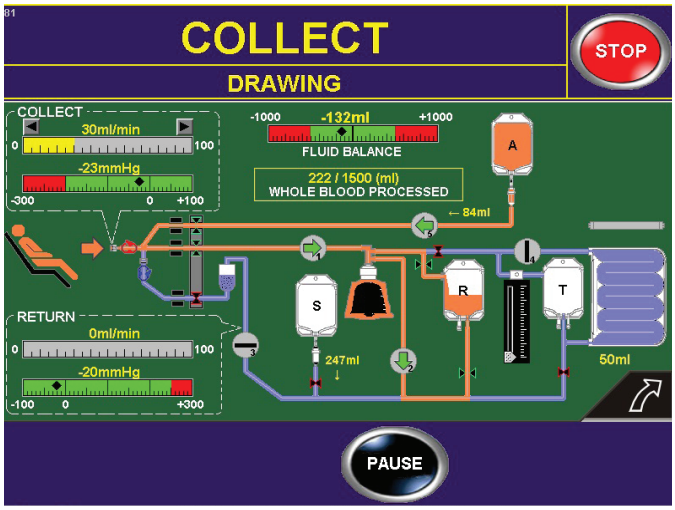
Figure 5-17d: COLLECT Flow Rate and Pressure Display

DRAWING

In SINGLE NEEDLE Mode DRAWING and RETURNING alternate automatically as whole blood is processed. You should monitor the patient throughout the treatment.

WARNING:

- The COLLECT Rate Limit Range is 5–50 mL/min. DRAWING will automatically use a flow rate of 30 mL/min if access allows. Careful fluid balance management may require a slower COLLECT Flow Rate. Please refer to ***Changing Default SETUP Parameters on page 5-14*** and ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information.
- Vascular access or clinical condition may require a COLLECT, RETURN and/or REINFUSION rate to be less than the default.



The screen display will show changes in:

- FLUID BALANCE
- WHOLE BLOOD PROCESSED
- COLLECT flow rate and pressure
- RETURN flow rate and pressure
- ANTICOAGULANT DELIVERED
- SALINE DELIVERED
- TREATMENT VOLUME

Figure 5-18: DRAWING (SINGLE NEEDLE Mode)

- Blood is drawn from the patient and pumped into the Centrifuge Bowl. Anticoagulant is delivered to the collect line at a preset ratio to the speed of the collect pump.
- Red blood cell volume within the Centrifuge Bowl will be maintained at the bowl optic sensor line. The buffy coat layer will form just inside the red blood cell line. Excess red blood cells, plasma and processed anticoagulant will exit the Centrifuge Bowl and are pooled in the return bag. DRAWING will continue until the RETURN BAG THRESHOLD VALUE is reached.
- DRAWING will be temporarily interrupted to return plasma and red blood cells to the patient and then resume until BUFFY COAT collection begins.

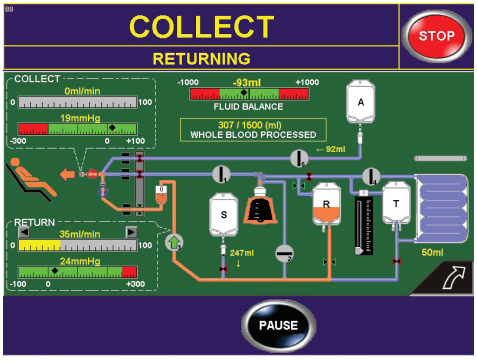
RETURNING

Once the volume in the return bag reaches a preset threshold, DRAWING will be temporarily interupted and the Return Pump will pump the red blood cells, plasma, and processed anticoagulant from the return bag to the patient via the Return Line.

- The centrifuge will continue to spin if the calculated time to return the contents of the return bag to approximately 50 mL is less than 7 minutes. The calculation is based on the last set return rate and the volume required to reduce the contents of the return bag to approximately 50 mL.
- An audible beep signals when blood flow changes between DRAWING to RETURNING.

WARNING:

- The operator may change the return bag threshold setting at any time during the treatment via the SETUP screen. In SINGLE NEEDLE Mode, this setting determines how often the instrument alternates between DRAWING and RETURNING and also determines the patient's extracorporeal blood volume during COLLECT.
- The RETURN Rate Limit Range is 5–60 mL/min. RETURNING will automatically use a flow rate of 35 mL/min if access allows. Careful fluid balance management may require a slower RETURN Flow Rate. Please refer to ***Changing Default SETUP Parameters on pg 5-14*** and ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information.
- Vascular access or clinical condition may require a COLLECT, RETURN and/or REINFUSION rate to be less than the default.
- To limit heat generation in single needle mode, the Centrifuge Bowl will stop spinning if greater than 7 minutes will be required to return the contents of the return bag to approximately 50 mL.



- The pathway from the A/C Bag is idle and illustrated in blue during RETURNING.
- RETURNING begins automatically each time the Return Bag Threshold is reached and continues until the volume in the return bag is approximately 50 mL.

Figure 5-19 RETURNING (SINGLE NEEDLE Mode)

NOTE:
The DRAWING and RETURNING phases immediately before BUFFY COAT may be shortened to ensure that ECV is minimized at the onset of BUFFY COAT.

BUFFY COAT

The following steps describe the sequence of events during a typical buffy coat collection:

- At 75 mL prior to reaching the WHOLE BLOOD PROCESSED TARGET (WBP - 75mL), the Centrifuge Bowl will begin to spin at 4800 RPM.

NOTE:

When lowering WHOLE BLOOD PROCESSED TARGET to start early BUFFY COAT collection, the Centrifuge Bowl will begin to spin at 4800 RPM immediately upon pressing START, unless already spinning at 4800 RPM.

- After the centrifuge speed increases, a three minute ESTABLISHING SEPARATION pause will occur. Following ESTABLISHING SEPARATION, collection will resume and BUFFY COAT will begin once the bowl optic sensor value drops below the Bowl Optic Threshold or at 75mL past the WHOLE BLOOD PROCESSED TARGET (WBP + 75 mL)
- Accumulating red blood cells in the centrifuge bowl will push the buffy coat out the top of the bowl. The effluent from the centrifuge bowl will be directed to the treatment bag via the hematocrit sensor. Initially, the effluent is plasma, followed by leukocytes and then red blood cells.
- After 10 mL of effluent has been directed toward the treatment bag, the hematocrit sensor will take a reading. This reading is known as the plasma offset (maximum of 5%) and will help compensate for abnormal plasma conditions.
- When the hematocrit sensor detects a hematocrit of 5% plus the plasma offset reading, a two minute ESTABLISHING SEPARATION pause will occur to allow for a second separation at the top of the Centrifuge Bowl.
- After the ESTABLISHING SEPARATION pause, ELUTRIATING will begin. Fluid from the return bag is used to push additional cells from the centrifuge bowl. A maximum volume of 20 mL is used during ELUTRIATING.
- BUFFY COAT collection will end automatically when the hematocrit sensor reads 24%. If a 24% hematocrit is not reached during ELUTRIATING, an additional 10mL may be collected from the patient before BUFFY COAT ends automatically.
- If necessary, operator can manually end BUFFY COAT by selecting the PAUSE button, then selecting the END BUFFY button and confirm the selection.

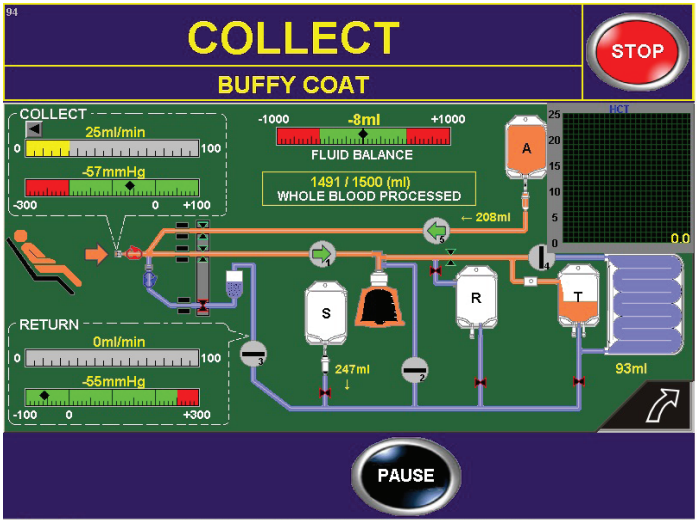


Figure 5-20: BUFFY COAT (SINGLE NEEDLE Mode)

EMPTYING BOWL/RECIRCULATING

Following the BUFFY COAT phase, the Centrifuge is stopped and its contents are emptied into the Return Bag. The Recirculation Pump will speed up to mix the collected buffy coat. After the Centrifuge Bowl is emptied, it is rinsed with saline and partially emptied again into the Return Bag.

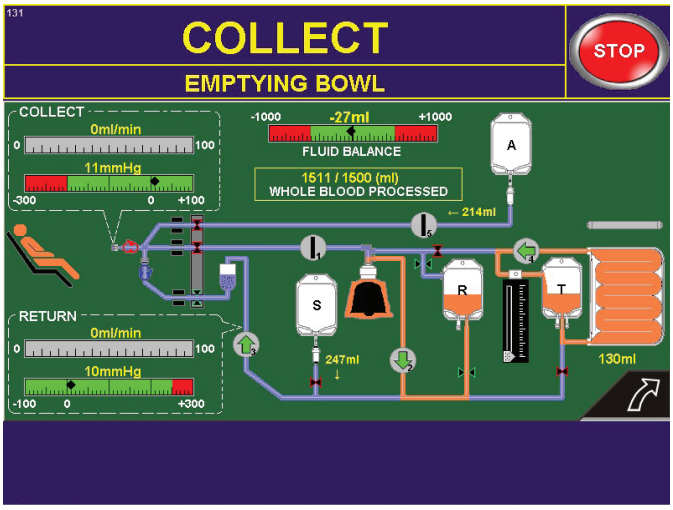


Figure 5-21 EMPTYING BOWL/RECIRCULATING (SINGLE NEEDLE Mode)

- EMPTYING BOWL occurs after BUFFY COAT.
- A small volume of saline rinse will remain in the Centrifuge Bowl to flush the treated cells out of the line after REINFUSE.

RETURNING/READY TO PHOTOACTIVATE

NOTE:
Disregard Steps 1 and 2 and proceed to Step 3 if oral 8-methoxypsoralen has already been administered.

1. The instrument calculates and displays the proper dose of Methoxsalen (20 micrograms/mL) using the formula: TREATMENT VOLUME (mL) multiplied by 0.017 = dose of Methoxsalen (20 micrograms/mL)
   Example:

   TREATMENT VOLUME = 170 mL

   170 X 0.017 = 2.8 mL

2. Dispense the proper dose of Methoxsalen (20 micrograms/mL) into the treatment bag when you are READY TO PHOTOACTIVATE and rinse the syringe three times.

   a. Measure medication.

   b. Remove needle and attach syringe luer.

   c. Dispense medication and rinse syringe 3 times.

   d. Record dose of medication and time administered.

3. Press  to begin PHOTOACTIVATE.
4. Open the door of the centrifuge chamber to allow cooling to begin. At this point, the centrifuge is no longer in use and the door is not locked.

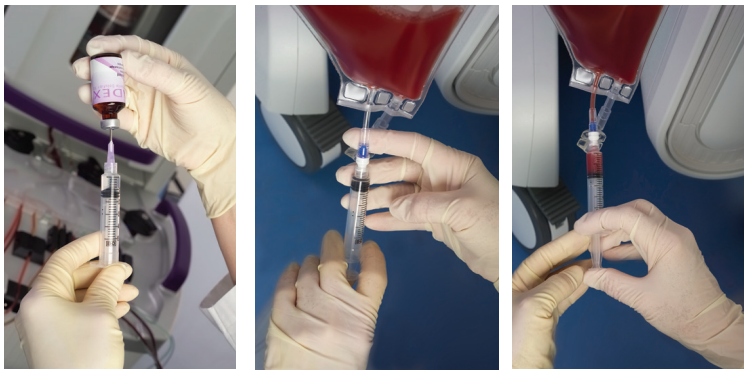
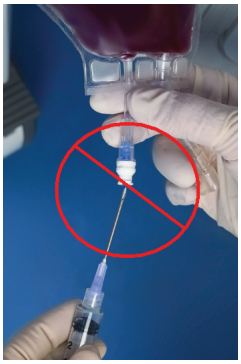


Figure 5-22a: Correct Liquid Medication Administration

CAUTION:
Do not remove the Treatment Bag from the Load Cell Hook. Removal may result in inaccurate FLUID BALANCE readings.



CAUTION:
Do not puncture any needle-free port with a needle. Damage to these ports will result in leaks.

Figure 5-22b: Incorrect Liquid Medication Administration

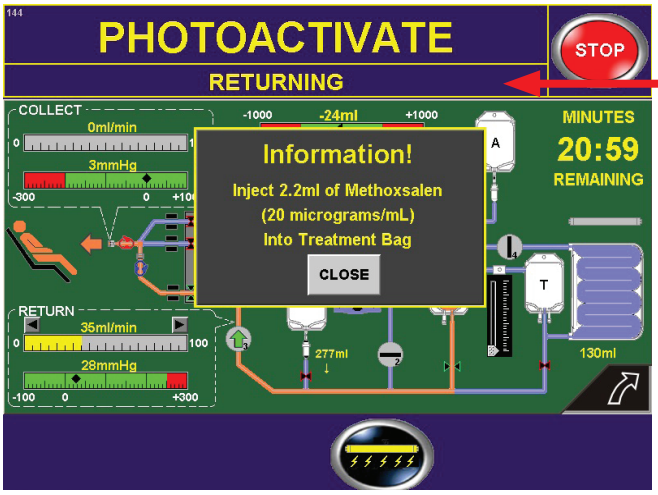


Figure 5-23a: RETURNING/READY TO PHOTOACTIVATE (SINGLE NEEDLE Mode), Methoxsalen (20 micrograms/mL) pop-up

- The instrument will calculate the amount of Methoxsalen (20 micrograms/mL) to be injected.
- The subtitle line will alternate between RETURNING and READY TO PHOTOACTIVATE.
- RETURNING will begin automatically as soon as the Centrifuge Bowl is emptied and rinsed.
- The photoactivation time in MINUTES REMAINING will be displayed.
- A pop-up message to open the centrifuge chamber door will be displayed.

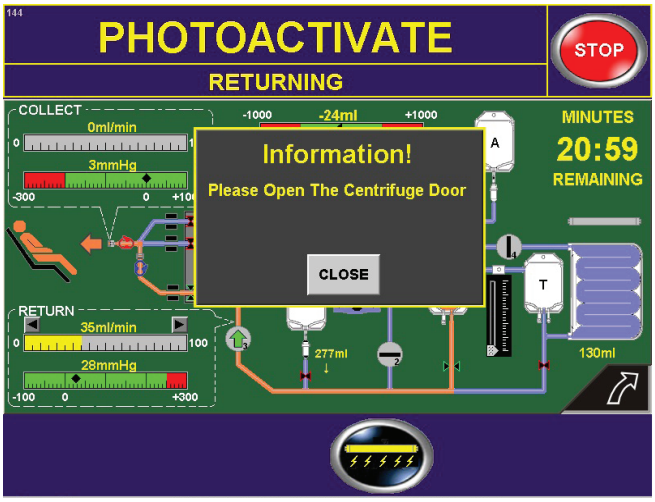
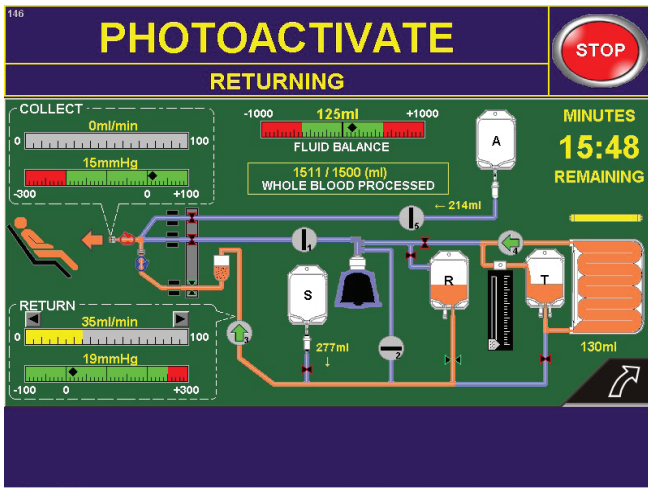


Figure 5-23b: RETURNING/READY TO PHOTOACTIVATE (SINGLE NEEDLE Mode), Centrifuge door pop-up

PHOTOACTIVATE

Once Methoxsalen (20 micrograms/mL) has been injected into the treatment bag and  has been pressed, the buffy coat will be circulated through the Photoactivation Module for the calculated photoactivation time.



- The Return pathway and Recirculation Loop are both active at the same time, illustrated in pink.
- If the return bag volume reaches 50 mL before the minutes remaining equal zero, KVO will be delivered from the return bag to the return line.

Figure 5-24: PHOTOACTIVATE (SINGLE NEEDLE Mode)

NOTE:

If either PHOTOACTIVATE or RETURN are interrupted for any reason, press START to resume RETURNING and press  to resume PHOTOACTIVATE.

WARNING:

- The calculated dose of UVA light energy will not be delivered if the THERAKOS™ CELLEX™ Light Assembly is changed after the calculation of photoactivation MINUTES REMAINING is displayed.
- It is recommended that the full PHOTOACTIVATE time be completed during every treatment. The calculated dose of UVA light energy will not be delivered if PHOTOACTIVATE is ended or aborted before the MINUTES REMAINING is equal to 00:00 (minutes:seconds).

REINFUSE

WARNING:

- The system automatically returns the treated cells to the patient following PHOTOACTIVATE. Therefore, it is recommended that the patient not be disconnected from the system at any time during the treatment.
- The REINFUSION Rate Limit Range is 1–60 mL/min. REINFUSING will automatically use the last user set RETURN rate if access allows (default RETURN rate is 35mL/min) or the REINFUSION Rate Limit, whichever the lowest. Careful fluid balance management may require a slower REINFUSION RATE. Please refer to ***Changing Default SETUP Parameters on page 5-14*** and ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information.
- Vascular access or clinical condition may require a COLLECT, RETURN and/or REINFUSION rate to be less than the default.

After PHOTOACTIVATE is complete, the treated cells are automatically reinfused to the patient. After the treatment bag is emptied, the remaining fluid in the return bag is also returned to the patient.

The REINFUSION RATE may be adjusted within the REINFUSION RATE LIMIT range by using the RETURN increase or decrease arrows on the main screen of the operator interface.

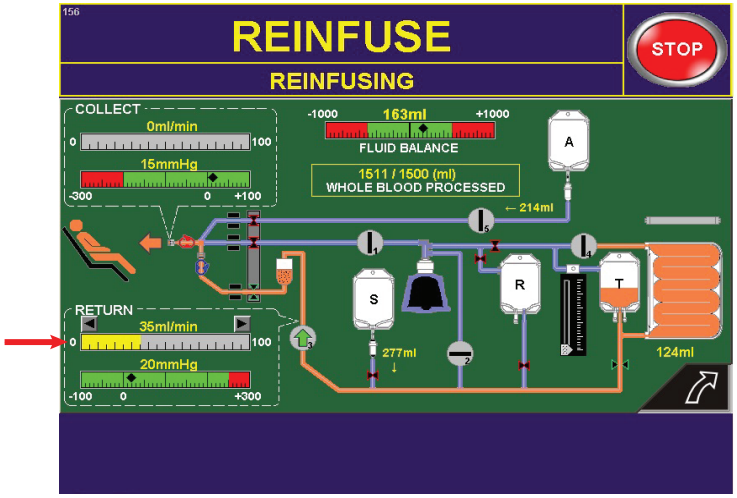


Figure 5-25: REINFUSE (SINGLE NEEDLE Mode)

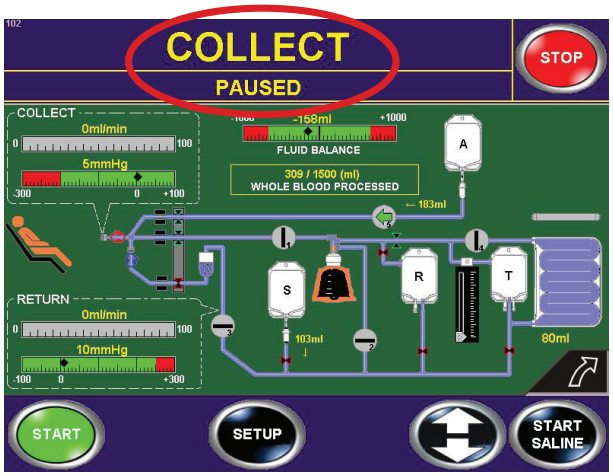
PAUSED

CAUTION:

Maximum PAUSE time is 10 minutes. After being paused for 8 minutes, an audible beep signals and a Pop-Up Message declares that the centrifuge will stop in 2 minutes.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** for complete instructions.



- When the system is PAUSED, Keep Vein Open (KVO) is delivered.
- The SETUP screen may be accessed in the PAUSED mode.
- Additional Treatment options are accessed by pressing  .
- Refer to *"Interrupting a Treatment" on page 5-64* for more information.
- The spinning Centrifuge Bowl is shown in pink.

Figure 5-26: PAUSED (SINGLE NEEDLE Mode)

NOTE:

- The Keep Vein Open (KVO) rate of anticoagulant, anticoagulated plasma, or saline is 10 mL/hour. KVO is utilized during PAUSE, STOP or PHOTOACTIVATE.
- In SINGLE NEEDLE mode, KVO dispensed to the Collect Line comes from the anticoagulant bag. KVO dispensed during PHOTOACTIVATE comes from the return bag.

1. Press 

if you need to temporarily stop blood flow or pumping activity. Pressing the PAUSE button keeps the Centrifuge spinning and the blood components separated.
2. SETUP, START SALINE, or additional treatment option buttons may be selected while PAUSED.
3. To resume, press START.
4. If a delay of greater than 10 minutes is required, select STOP.
    - After 10 minutes, PAUSE Timeout will automatically stop the Centrifuge Bowl.

PROCEED IMMEDIATELY TO BUFFY COAT/PHOTOACTIVATE/REINFUSE

Occasionally, poor access or other clinical concerns may not allow processing 1500 mL of whole blood. In order to proceed immediately to BUFFY COAT, you must process at least 500 mL and the plasma/red blood cell interface must be established.

1. PAUSE. Do not press STOP.
2. Enter SETUP screen.
3. Lower WHOLE BLOOD PROCESSED TARGET as much as possible.
4. Press SAVE.
5. Press START to resume treatment and follow instructions beginning with *"BUFFY COAT" on page 5-36* to complete the treatment.

NOTE:

Lowering the WHOLE BLOOD PROCESSED TARGET as far as possible will automatically direct the system to proceed immediately to ESTABLISHING SEPARATION and then to BUFFY COAT. As soon as BUFFY COAT phase is complete, the instrument will proceed to the EMPTYING BOWL/RECIRCULATING. At this point, it is not possible to continue COLLECT or to change the WHOLE BLOOD PROCESSED TARGET. However, the volume in the treatment bag will be photoactivated and REINFUSED to the patient.

STOPPED

The 

button is always located in the right side upper portion of the screen away from all other buttons. The plasma/red blood cell interface will be lost whenever STOP is activated. Upon selecting START to resume collection, the Centrifuge Bowl must be re-purged and the interface will be re-established before additional whole blood volume is processed.

While the treatment is STOPPED, the Smart Card may be removed from the instrument without receiving an alarm. The Smart Card must be reinserted before resuming the treatment.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information before resuming the treatment.

NOTE:

Use 

to:

- **STOP** the Centrifuge immediately!
- **PAUSE** for more than 10 minutes.
- **STOP** and END TREATMENT.
- **STOP** and ABORT TREATMENT.

Instrument Automatically *stops* for:

- Alarm #4: Centrifuge Chamber Door
- Alarm #7: Blood leak? (Centrifuge Chamber)
- Alarm #18: System Pressure
- Alarm #33: PAUSE Timeout
- Alarm #47: Drive Tube Alarm
- Technical Alarm
- Power Failure

RESULTS:

- Lose plasma/red blood cell interface
- Re-purge of Centrifuge Bowl required resulting in higher ECV (approximately 65 mL)
- Displacement of leukocytes already in the centrifuge bowl

To compensate for the displacement of leukocytes, the Whole Blood Processed Target may be increased (via the SETUP screen) prior to pressing START to resume COLLECT.

TREATMENT COMPLETE

The Treatment Complete screen appears when all blood has been returned to the patient.

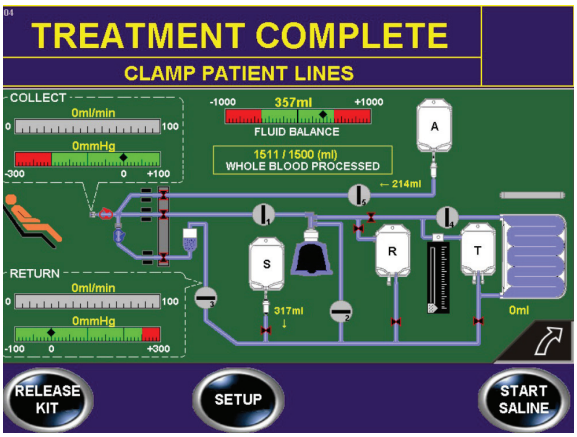


Figure 5-27: TREATMENT COMPLETE (SINGLE NEEDLE mode)

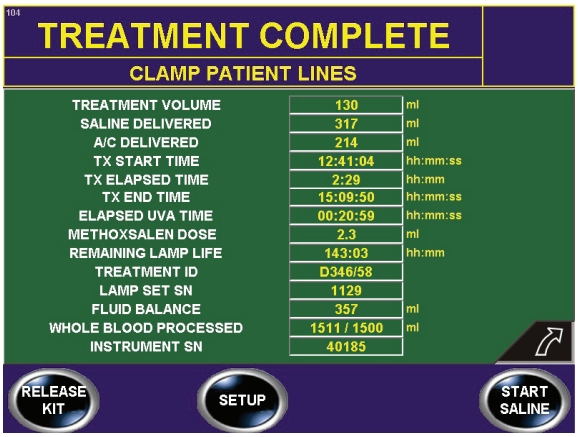


Figure 5-28: Record Treatment Data

CAUTION:

The used THERAKOS™ CELLEX™ Photopheresis Procedural Kit and any spills should be considered biologically contaminated. When handling the contaminated procedural kit, or cleaning up any blood spills on the instrument, follow your institutions specific policy for biohazard precautions and hazardous waste disposal.

1. Clamp the patient's access line, Collect Line, and Return Line.
2. Press RELEASE KIT to release all valves and allow the procedural kit to be removed. DO NOT PRESS 'RELEASE KIT' UNTIL ALL PATIENT LINES HAVE BEEN CLAMPED. Failure to clamp patient lines may result in fluid movement between the patient and kit.
3. Disconnect the patient.
    a. Use your institution's standards to provide proper care of the access site.
    b. If venous access or a subcutaneous port was used, apply a pressure dressing.
    c. Use caution to ensure that the patient's fluid shifts have stabilized before allowing the patient to stand and ambulate.
    d. Communicate all center-specific discharge instructions to the patient including but not limited to:
        - 24-hour increased sun sensitivity to eyes and skin
        - Possible slight elevation in temperature
        - Possible urticaria
        - Possible hypertension
        - Risk of bleeding post treatment

CAUTION:
To release all internal pressure before removing the kit, always remove all Pump Tubing Segments before removing any Pressure Domes.

4. Remove each Pump Tubing Segment by placing a finger beneath the Pump Tubing Segment at the groove in the pump deck near each pump head. Slightly lift the pump tubing segment and gently rotate the Pump counterclockwise until the pump tubing segment is fully unloaded ***(See Figure 5-29a).***

5. For each pressure sensor:

   a. Release the procedural kit pressure dome by pinching the tabs together while pulling upward.

   b. Immediately install a protective pressure dome cover onto the pressure transducer.

CAUTION:
Do not leave the transducers uncovered at any time!

6. Remove all lines from the Air Detectors.

7. Remove the Hematocrit Cuvette from the Hematocrit Sensor.

8. Remove the Pump Tubing Organizer by pulling backward on both Release Clips and lifting the Organizer upward ***(See Figure 5-29b).***

Figure 5-29a: Removing the Pump Tubing Segment

Figure 5-29b: Removing the Pump Tubing Organizer

9. Remove the Centrifuge Bowl.
    a. Open the Drive Tube Latch.
    b. Release the top bearing by pulling toward you, then up and out.
    c. Release the bottom bearing by pulling toward you, then down and out.
    d. Depress release tab while rotating the Centrifuge Bowl counterclockwise to release it.

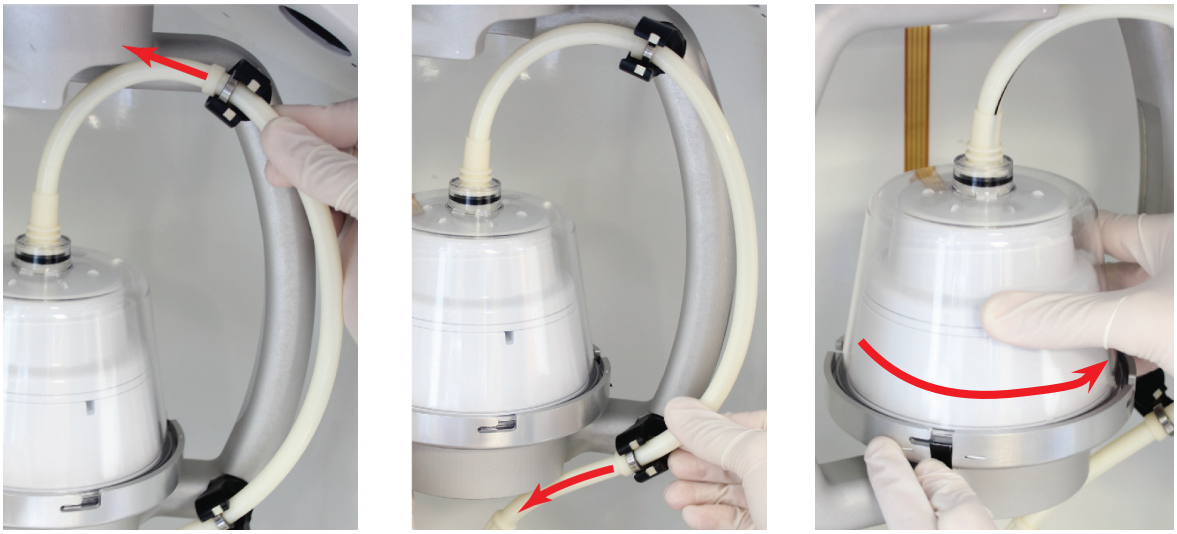


Figure 5-30: Removing the Centrifuge Bowl

10. Remove the remaining procedural kit components and fluid bags.
11. Discard the used procedural kit using biohazard precautions.

NOTE:

- Record Treatment Data as required by your institution. Data will be erased when the power is turned OFF.
- The power must be cycled OFF and then ON before beginning another treatment.

12. Turn the power OFF.
13. Clean the instrument using the instructions in SECTION 7: MAINTAINING THE THERAKOS CELLEX PHOTOPHERESIS SYSTEM and your institution's biohazardous cleaning policy prior to storing or next use.
14. If this is the last treatment of the day, clean the inside of the Centrifuge Chamber to remove bearing grease and gently clean the Bowl Optic Sensor. Refer to ***SECTION 7: MAINTAINING THE THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEM*** for complete instructions.
15. Close the centrifuge door.

DOUBLE NEEDLE Mode Treatment Procedure

WARNING:

- Prior to initiating PRIME, ensure the Treatment Bag and Return Bag are properly positioned on their respective Load Cells Hooks. Removal of these bags at anytime after PRIME is initiated may result in priming alarms and/or inaccurate FLUID BALANCE readings during a treatment.
- Once PRIME has been completed, the procedure using the primed THERAKOS™ CELLEX™ Photopheresis Procedural Kit must be started within four hours.

CAUTION:

The Collect and Return Lines must be configured to match the access mode selected. Failure to do so may lead to clotting at one access site, treatment interruption, recirculation and a possible failed treatment.

ESTABLISH ACCESS

Subtitle display line alternates between ESTABLISH ACCESS and READY TO COLLECT.

Two separate patient access sites must be established. One for the Collect Line and one for Return Line.

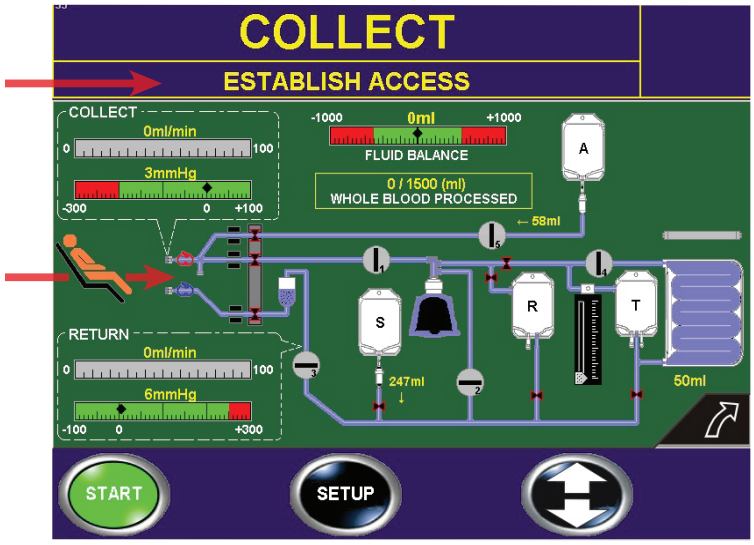


Figure 5-31: ESTABLISH Access (DOUBLE NEEDLE Mode)

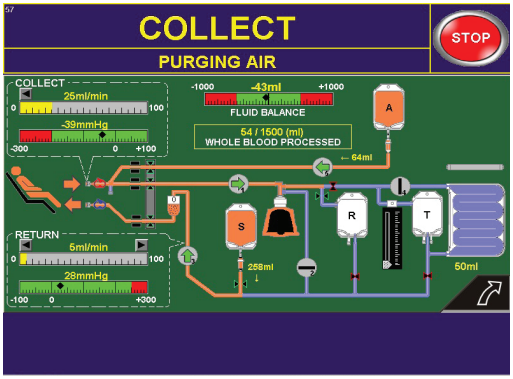
1. Verify the patient's access configuration correlates with the treatment mode selected and verify the following clamps are open:
   - Patient's Collect Access Clamp
   - Patient's Return Access Clamp
   - Collect Line (RED) Clamp
   - Return Line (BLUE) Clamp

2. Press START.

    - The START button is always located in the lower left corner of the main screen of the operator interface.

PURGING AIR

- Whole blood is drawn from the patient at the default rate of 25 mL/min if access allows.
- Anticoagulant is added at the preset delivery ratio to the speed of the Collect Pump.
- Anticoagulated blood fills the Centrifuge Bowl and the lines to the return bag.
- The Centrifuge Bowl speed will vary during PURGING AIR and does not spin at the full speed until it is filled.
- DOUBLE NEEDLE mode is designed to be a continuous flow system to manage fluid balance. During PURGING AIR, saline is returned to the patient at the default Return Rate of 5 mL/min.



- A minimal fluid deficit will develop during PURGING AIR.
- Active pathways are illustrated in pink.
- Inactive pathways are shown in blue.

Figure 5-32: PURGING AIR (DOUBLE NEEDLE Mode)

Figure 5-33: PURGING AIR

NOTE:

- Pressing the COLLECT Increase or COLLECT Decrease rate arrows on the main screen of the operator interface will change the flow rate within the COLLECT Flow Rate Limit Range.
- The RETURN Flow Rate may also be adjusted from the main screen of the operator interface within the RETURN Flow Rate Limit Range.
- You may change the COLLECT or RETURN Flow Rate Limit Ranges by entering a new value via the SETUP screen. Refer to *Changing Default SETUP Parameters on page 5-14* for more information.
- If the operator changes the COLLECT Flow Rate during PURGING AIR, the software will keep the adjusted COLLECT Flow Rate following PURGING AIR and the RETURN Flow Rate will be 5 mL/min faster than the COLLECT Flow Rate after PURGING AIR. However, if Automatic Flow Control is enabled and activated, the COLLECT and RETURN Flow Rates will be equal.

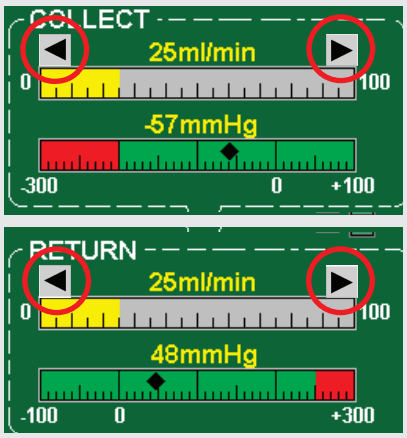


Figure 5-34: COLLECT and RETURN Flow Rates and Pressure Displays

DRAWING/RETURNING

In DOUBLE NEEDLE mode, DRAWING and RETURNING occur simultaneously in continuous flow as whole blood is processed. You should monitor the patient throughout the treatment.

WARNING:

- The COLLECT Rate Limit Range is 5–50 mL/min. DRAWING will automatically use a flow rate of 30 mL/min if access allows. The RETURN Rate Limit Range is 5–60 mL/min. RETURNING will automatically use a flow rate of 35 mL/min if access allows.
- Careful fluid management may require adjustments on these flow rates. Refer to *"Changing Default SETUP Parameters" on page 5-14* and *SECTION 10: FLUID BALANCE MANAGEMENT* for additional information.
- Vascular access or clinical condition may require a COLLECT, RETURN and/or REINFUSION rate to be less than the default.

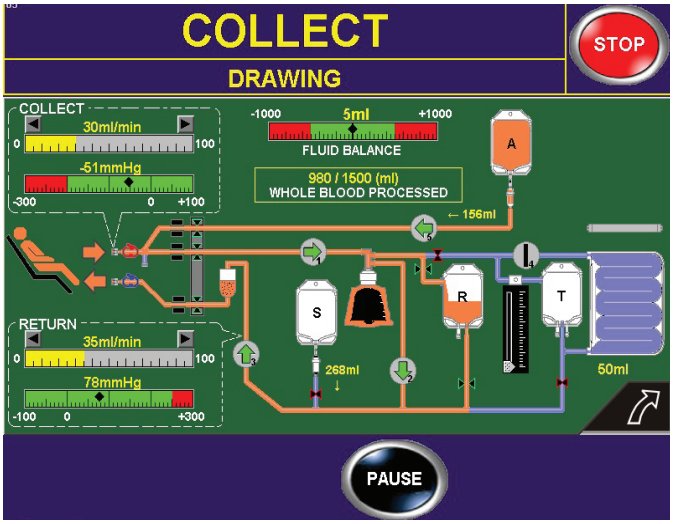


Figure 5-35: DRAWING/RETURNING (DOUBLE NEEDLE Mode)

The screen display will show changes in:

- FLUID BALANCE
- WHOLE BLOOD PROCESSED
- COLLECT Flow Rate and Pressure
- RETURN Flow Rate and Pressure
- ANTICOAGULANT DELIVERED
- SALINE DELIVERED
- TREATMENT VOLUME

- Blood is drawn from the patient and pumped into the Centrifuge Bowl. Anticoagulant is delivered to the Collect Line at the preset ratio to the speed of the Collect Pump.
- Red blood cell volume within the Centrifuge Bowl will be maintained at the Bowl Optic Sensor Line. The buffy coat layer will form just inside the red blood cells line. Excess red blood cells, plasma and processed anticoagulant will exit the Centrifuge Bowl.
- The Return Pump will return the red blood cells, plasma and processed anticoagulant to the patient via the Return Line. DRAWING/RETURNING will continue until BUFFY COAT collection begins.

BUFFY COAT

The following steps describe the sequence of events during a typical buffy coat collection:

- At 75 mL prior to reaching the WHOLE BLOOD PROCESSED TARGET (WBP - 75mL), the Centrifuge Bowl will begin to spin at 4800 RPM.

NOTE:

When lowering WHOLE BLOOD PROCESSED TARGET to start early BUFFY COAT collection, the Centrifuge Bowl will begin to spin at 4800 RPM immediately upon pressing START, unless already spinning at 4800 RPM.

- After the centrifuge speed increases, a three minute ESTABLISHING SEPARATION pause will occur. Following ESTABLISHING SEPARATION, collection will resume and BUFFY COAT will begin once the bowl optic sensor value drops below the Bowl Optic Threshold or at 75mL past the WHOLE BLOOD PROCESSED TARGET (WBP + 75 mL).
- Accumulating red blood cells in the centrifuge bowl will push the buffy coat out the top of the bowl. The effluent from the centrifuge bowl will be directed to the treatment bag via the hematocrit sensor. Initially, the effluent is plasma, followed by leukocytes and then red blood cells.
- After 10 mL of effluent has been directed toward the treatment bag, the hematocrit sensor will take a reading. This reading is known as the plasma offset (maximum of 5%) and will help compensate for abnormal plasma conditions.
- When the hematocrit sensor detects a hematocrit of 5% plus the plasma offset reading, a two minute ESTABLISHING SEPARATION pause will occur to allow for a second separation at the top of the Centrifuge Bowl
- After the ESTABLISHING SEPARATION pause, ELUTRIATING will begin. Fluid from the return bag is used to push additional cells from the centrifuge bowl. A maximum volume of 20 mL is used during ELUTRIATING.
- BUFFY COAT collection will end automatically when the hematocrit sensor reads 24%. If a 24% hematocrit is not reached during ELUTRIATING, an additional 10mL may be collected from the patient before BUFFY COAT ends automatically.
- If necessary, operator can manually end BUFFY COAT by selecting the PAUSE button, then selecting the END BUFFY button and confirm the selection.

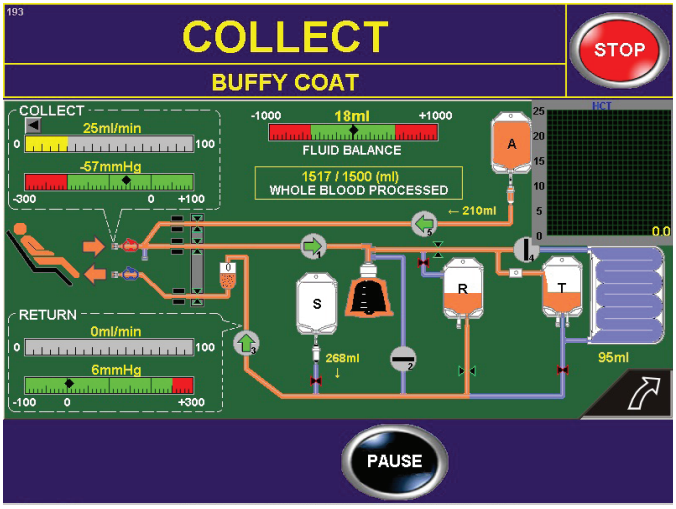


Figure 5-36: BUFFY COAT (DOUBLE NEEDLE Mode)

EMPTYING BOWL/RECIRCULATING

Following the BUFFY COAT phase, the Centrifuge is stopped and its contents are emptied into the return bag. The Recirculation Pump will speed up to mix the collected buffy coat. After the Centrifuge Bowl is emptied, it is rinsed with saline and partially emptied again into the return bag.

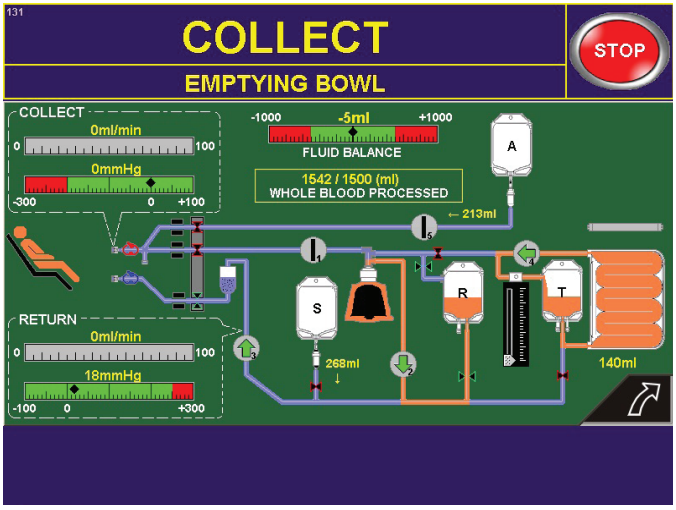


Figure 5-37: EMPTYING BOWL/RECIRCULATING (DOUBLE NEEDLE Mode)

- EMPTYING BOWL occurs after BUFFY COAT.
- A small volume of saline rinse will remain in the Centrifuge Bowl to flush the treated cells out of the line after REINFUSE.

RETURNING/READY TO PHOTOACTIVATE

NOTE:
Disregard Steps 1 and 2 and proceed to Step 3 if oral 8-methoxypsoralen has already been administered.

1. The instrument calculates and displays the proper dose of Methoxsalen (20 micrograms/mL) using the formula: TREATMENT VOLUME (mL) multiplied by 0.017 = dose of Methoxsalen (20 micrograms/mL). Example:

   TREATMENT VOLUME = 170 mL

   170 X 0.017 = 2.89 = 2.8 mL

2. Dispense the proper dose of Methoxsalen (20 micrograms/mL) into the treatment bag when you are READY TO PHOTOACTIVATE and rinse the syringe three times.
   a. Measure medication.
   b. Remove needle and attach syringe luer.
   c. Dispense medication and rinse syringe 3 times
   d. Record dose of medication and time of administration.
3. Press  to begin PHOTOACTIVATE.
4. When prompted by the pop-up message, open the door of the centrifuge chamber to allow cooling to begin. At this point, the centrifuge is no longer in use and the door is not locked.

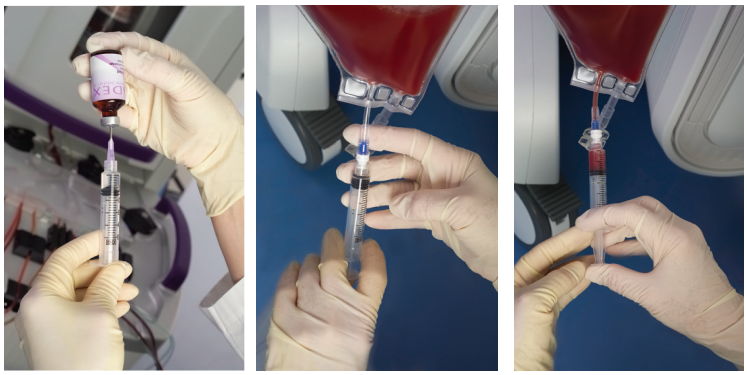
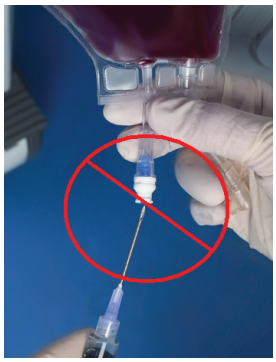


Figure 5-38a: Correct Liquid Medication Administration

CAUTION:
Do not remove the Treatment Bag from the Load Cell Hook. Removal may result in inaccurate FLUID BALANCE readings.



CAUTION:
Do not puncture any needle-free port with a needle. Damage to these ports will result in leaks.

Figure 5-38b: Incorrect Liquid Medication Administration

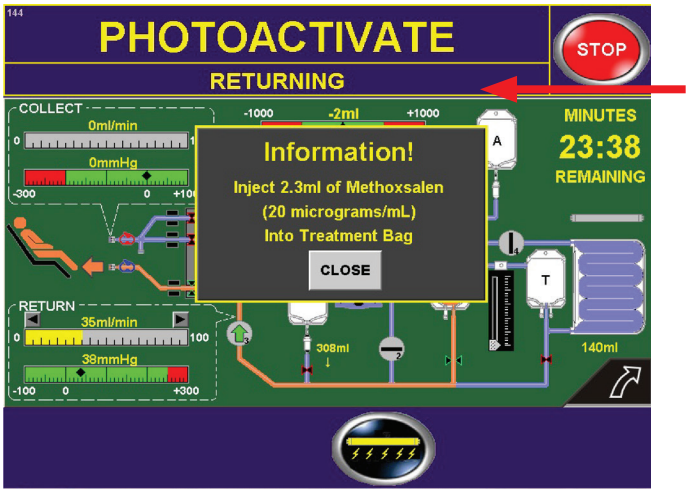


Figure 5-39a: RETURNING/READY TO PHOTOACTIVATE (DOUBLE NEEDLE Mode), Methoxsalen (20 micrograms/mL) pop-up

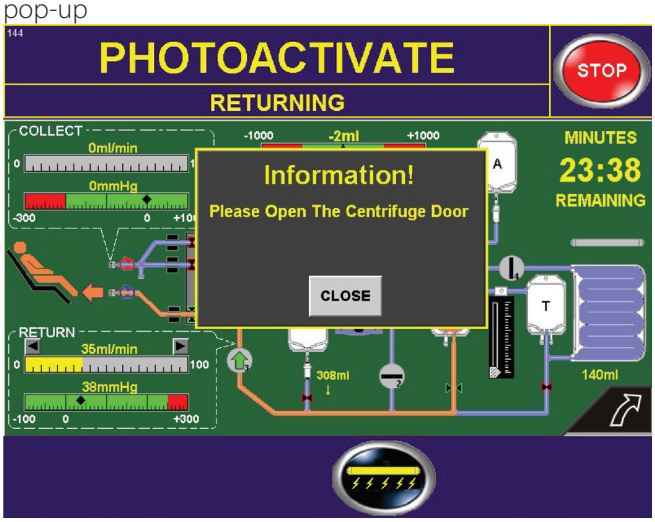


Figure 5-39b: RETURNING/READY TO PHOTOACTIVATE (DOUBLE NEEDLE Mode) Centrifuge door pop-up

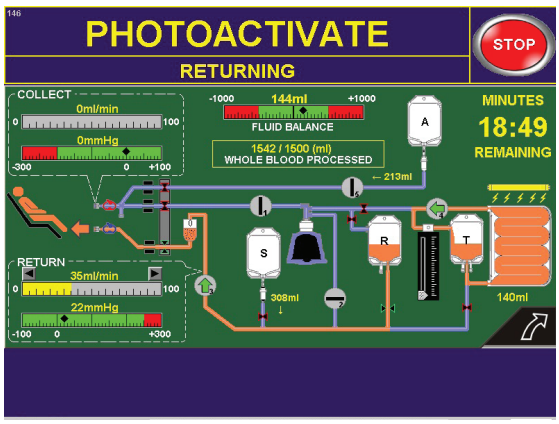
- The instrument will calculate the amount of Methoxsalen (20 micrograms/mL) to be injected.
- The operator may initiate PHOTOACTIVATE by pressing while RETURNING is in progress.
- The subtitle line will alternate between RETURNING and READY TO PHOTOACTIVATE.
- RETURNING will begin automatically as soon as the Centrifuge Bowl is emptied and rinsed.
- The photoactivation time in MINUTES REMAINING will be displayed.
- A pop up message to open the centrifuge chamber door will be displayed.

WARNING:

- After BUFFY COAT, the patient Collect Line will no longer be used for collecting blood, and the instrument will not deliver KVO fluid to maintain the Collect Line access. To prevent stagnant blood in the Collect Line, use your institution's standards to provide proper care of the access site (e.g. flush the line or disconnect the patient).

PHOTOACTIVATE

Once Methoxsalen (20 micrograms/mL) has been injected into the treatment bag and  has been pressed, the buffy coat will be circulated through the Photoactivation Module for the calculated photoactivation time.



- The Return pathway and Recirculation Loop are both active at the same time, illustrated in pink.
- If the return bag volume reaches 50 mL before the minutes remaining equal zero, KVO will be delivered from the return bag to the return line.

Figure 5-40: PHOTOACTIVATE (DOUBLE NEEDLE Mode)

NOTE:

If either PHOTOACTIVATE or RETURN are interrupted for any reason, press START to resume RETURNING and press  to resume PHOTOACTIVATE.

WARNING:

- The calculated dose of UVA light energy will not be delivered if the THERAKOS™ CELLEX™ Light Assembly is changed after the calculation of photoactivation MINUTES REMAINING is displayed.
- It is recommended that the full PHOTOACTIVATE time be completed during every treatment. The calculated dose of UVA light energy will not be delivered if PHOTOACTIVATE is ended or aborted before the MINUTES REMAINING is equal to 00:00 (minutes:seconds).

REINFUSE

WARNING:

- The system automatically returns the treated cells to the patient following PHOTOACTIVATE. Therefore, it is recommended that the patient not be disconnected from the system at any time during the treatment.
- The REINFUSION Rate Limit Range is 1–60 mL/min. REINFUSING will automatically use the last user set RETURN rate if access allows (default RETURN rate is 35mL/min) or the REINFUSION Rate Limit, whichever the lowest. Careful fluid balance management may require a slower REINFUSION RATE. Please refer to ***Changing Default SETUP Parameters on page 5-14*** and ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information.
- Vascular access or clinical condition may require a COLLECT, RETURN and/or REINFUSION rate to be less than the default.

After PHOTOACTIVATE is complete, the treated cells are automatically reinfused to the patient. After the treatment bag is emptied, the remaining fluid in the return bag is also returned to the patient.

The Reinfusion Rate may be adjusted within the Reinfusion Rate Limit range by using the RETURN increase or decrease arrows on the main display screen.

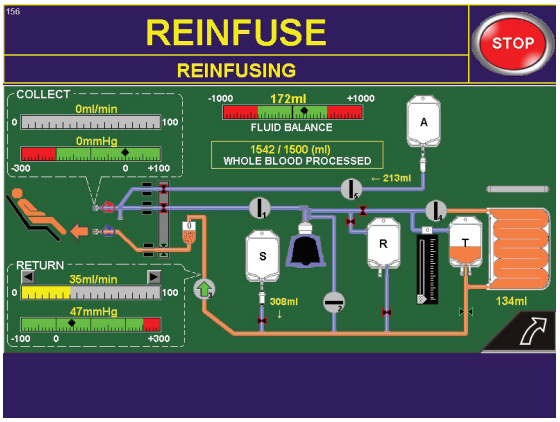


Figure 5-41: REINFUSE (DOUBLE NEEDLE Mode)

PAUSED

CAUTION:

Maximum PAUSE time is 10 minutes. After being paused for 8 minutes, an audible beep signals and a Pop-Up Message declares that the centrifuge will stop in 2 minutes.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-60*** for complete instructions.

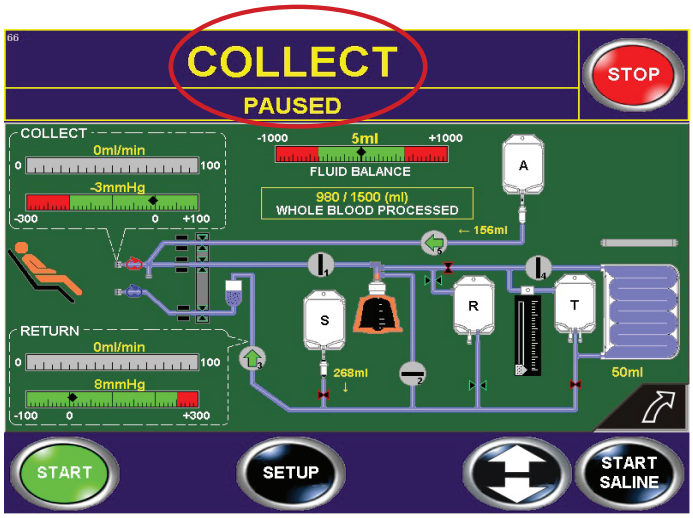


Figure 5-42: PAUSED (DOUBLE NEEDLE Mode)

- When the system is PAUSED, Keep Vein Open (KVO) is delivered.
- The SETUP screen may be accessed in the PAUSED mode.
- Additional Treatment options are accessed by pressing .
- Refer to ***"Interrupting a Treatment" on page 5-65*** for more information.
- The spinning Centrifuge Bowl is shown in pink

NOTE:

The Keep Vein Open (KVO) rate of anticoagulant, anticoagulated plasma, or saline is 10 mL/hour. KVO is utilized during PAUSE, STOP or PHOTOACTIVATE.

In DOUBLE NEEDLE mode, KVO dispensed to the COLLECT line comes from the anticoagulant bag. KVO dispensed to the return line comes from the patient's heparinized plasma pooled in the return bag. KVO dispensed during PHOTOACTIVATE comes from the return bag.

1. Press PAUSE if you need to temporarily stop blood flow or pumping activity. Pressing the PAUSE button keeps the Centrifuge spinning and the blood components separated.
2. Select SETUP, START SALINE, or additional treatment option buttons while PAUSED.
3. To resume, press START.
4. If a delay of greater than 10 minutes is required, select STOP.
   - After 10 minutes, PAUSE Timeout will automatically stop the Centrifuge Bowl.

PROCEED IMMEDIATELY TO BUFFY COAT/PHOTOACTIVATE/REINFUSE

Occasionally, poor access or other clinical concerns may not allow processing 1500 mL of whole blood. For you to proceed immediately to BUFFY COAT, you must process at least 500 mL and the plasma/red blood cell interface must be established.

NOTE:
When access issues occur in DOUBLE NEEDLE Mode to avoid lowering the WHOLE BLOOD PROCESSED Target it may be possible to change to SINGLE NEEDLE mode, following the instructions on ***page 5-28***, and continue treatment.

1. PAUSE. Do not press STOP.
2. Enter the SETUP screen.
3. Lower the WHOLE BLOOD PROCESSED TARGET as much as possible.

NOTE:
Lowering the Whole Blood Processed Target as far as possible will direct the system to proceed immediately to ESTABLISHING SEPARATION and then to BUFFY COAT. As soon as BUFFY COAT phase is complete, the instrument will proceed to the EMPTYING BOWL/ RECIRCULATING. At this point, it is not possible to continue COLLECT or to change the WHOLE BLOOD PROCESSED TARGET. However, the volume in the treatment bag will be photoactivated and REINFUSED to the patient.

4. Press SAVE.
5. Press START to resume treatment and follow the instructions beginning with BUFFY COAT (Double Needle mode) in ***page 5-48*** to complete the treatment.

STOPPED

The 

button is always located in the right side upper portion of the screen away from all other buttons. The plasma/red blood cell interface will be lost whenever STOP is activated. Upon selecting START to resume collection, the Centrifuge Bowl must be re-purged and the interface must be re-established before additional whole blood volume is processed.

While the treatment is STOPPED, the Smart Card may be removed from the instrument without receiving an alarm. The Smart Card must be reinserted before resuming the treatment.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information before resuming the treatment.

NOTE:

Use 

to:

- **STOP** the Centrifuge immediately!
- **PAUSE** for more than 10 minutes.
- **STOP** and END TREATMENT.
- **STOP** and ABORT TREATMENT.

Instrument Automatically *stops* for:

- Alarm #4: Centrifuge Chamber Door
- Alarm #7: Blood leak? (Centrifuge Chamber)
- Alarm #18: System Pressure
- Alarm #33: PAUSE Timeout
- Alarm #47: Drive Tube Alarm
- Technical Alarm
- Power Failure

RESULTS:

- Lose plasma/red blood cell interface
- Re-purge of Centrifuge Bowl required resulting in higher ECV (approximately 65 mL)
- Displacement of leukocytes already in the centrifuge bowl

To compensate for the displacement of leukocytes, the Whole Blood Processed Target may be increased (via the SETUP screen) prior to pressing START to resume COLLECT.

TREATMENT COMPLETE

The Treatment Complete screen appears when all treated cells have been returned to the patient.

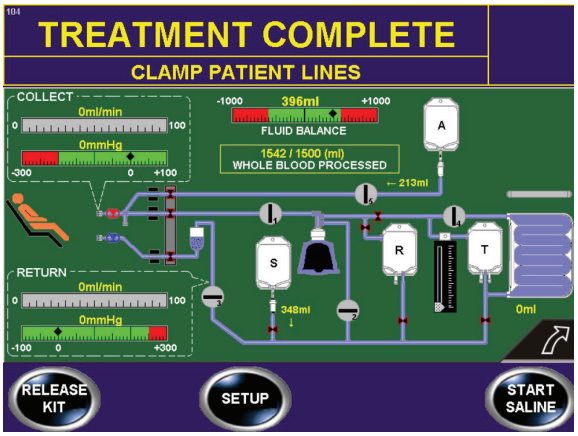


Figure 5-43: TREATMENT COMPLETE (DOUBLE NEEDLE Mode)

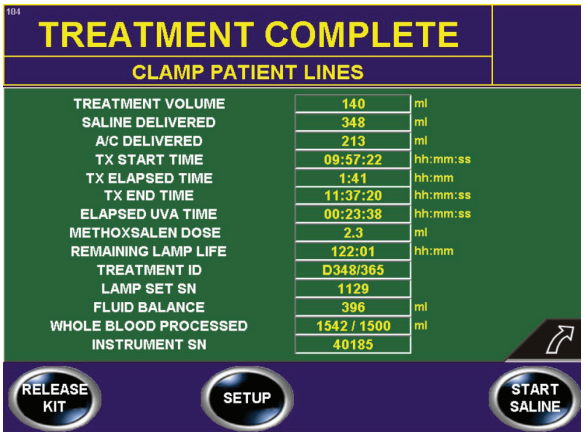


Figure 5-44: Record Treatment Data

CAUTION:

The used THERAKOS™ CELLEX™ Photopheresis Procedural Kit and any spills should be considered biologically contaminated. When handling the contaminated procedural kit, or cleaning up any blood spills on the instrument, follow your institutions specific policy for biohazard precautions and hazardous waste disposal.

1. Clamp the patient's access lines, Collect Line, and Return Line.
2. Press RELEASE KIT to release all valves and allow the procedural kit to be removed. DO NOT PRESS 'RELEASE KIT' UNTIL ALL PATIENT LINES HAVE BEEN CLAMPED. Failure to clamp patient lines may result in fluid movement between the patient and kit.
3. Disconnect the patient.
    a. Use your institution's standards to provide proper care of the access site.
    b. If venous access or a subcutaneous port was used, apply a pressure dressing.
    c. Use caution to ensure that the patient's fluid shifts have stabilized before allowing the patient to stand and ambulate.
    d. Communicate all center-specific discharge instructions to the patient including, but not limited to:
        - 24-hour increased sun sensitivity to eyes and skin
        - Possible slight elevation in temperature
        - Possible urticaria
        - Possible hypertension
        - Risk of bleeding post treatment

CAUTION:
To release all internal pressure before removing the kit, always remove all Pump Tubing Segments before removing any Pressure Domes.

4. Remove each Pump Tubing Segment by placing a finger beneath the Pump Tubing Segment at the groove in the pump deck near each pump head. Slightly lift the pump tubing segment and gently rotate the Pump counterclockwise until the pump tubing segment is fully unloaded ***(see figure 5-45)***.
5. For each pressure sensor:

   a. Release the procedural kit pressure dome by pinching the tabs together while pulling upward.

   b. Immediately install a protective pressure dome cover onto the pressure transducer.

CAUTION:
Do not leave the transducers uncovered at any time!

6. Remove all lines from the Air Detectors.
7. Remove the Hematocrit Cuvette from the Hematocrit Sensor.
8. Remove the Pump Tubing Organizer by pulling backward on both Release Clips and lifting the Organizer upward ***(See figure 5-46).***

Figure 5-45: Removing the Pump Tubing Segment

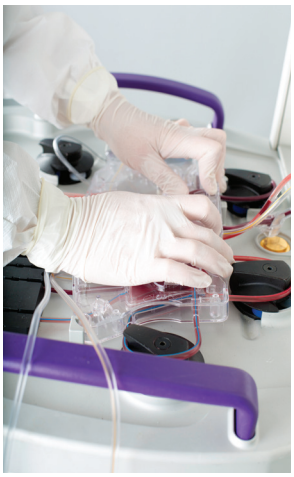


Figure 5-46: Removing the Pump Tubing Organizer

9. Remove the Centrifuge Bowl.
    a. Open the Drive Tube Latch.
    b. Release the top bearing by pulling toward you, then up and out.
    c. Release the bottom bearing by pulling toward you, then down and out.
    d. Depress release tab while rotating the Centrifuge Bowl counterclockwise to release it.

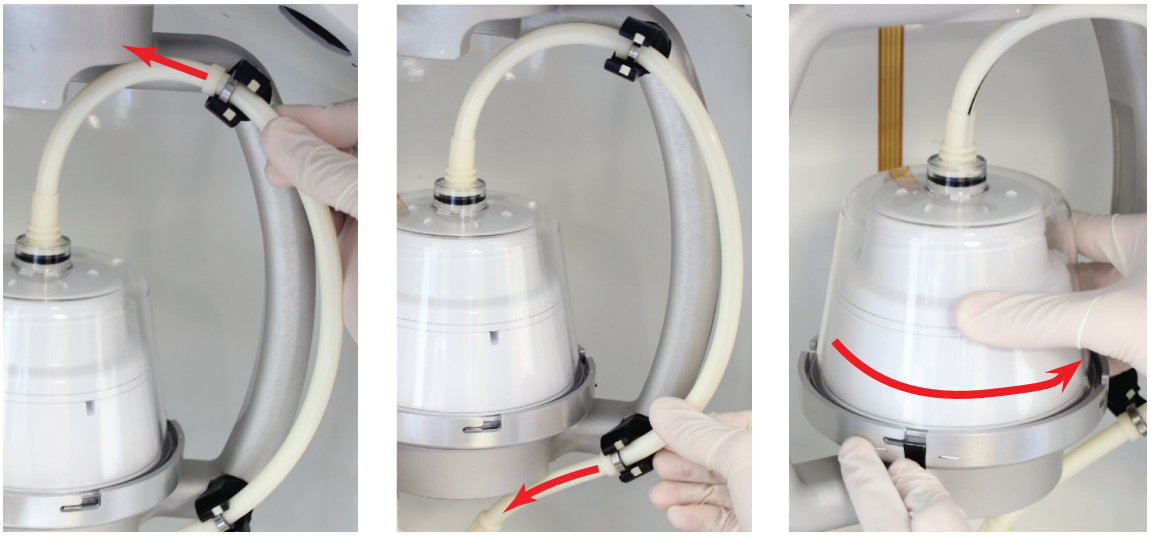


Figure 5-47: Removing the Centrifuge Bowl

10. Remove remaining procedural kit components and fluid bags.
11. Discard the used procedural kit using biohazard precautions.

NOTE:

- Record Treatment Data as required by your institution. Data will be erased when the power is turned OFF.
- The power must be cycled OFF and ON before beginning another treatment.

12. Turn the power OFF.
13. Clean the instrument using the instructions in ***SECTION 7: MAINTAINING THE THERAKOS CELLEX PHOTOPHERESIS SYSTEM*** and your institution's biohazardous cleaning policy prior to storing or next use.
14. If this is the last treatment of the day, clean the inside of the Centrifuge Chamber to remove bearing grease and gently clean the Bowl Optic Sensor. Refer to ***SECTION 7: MAINTAINING THE THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEM*** for complete instructions.
15. Close the centrifuge door.

Interrupting a Treatment

To temporarily interrupt a treatment and then resume use the PAUSE button. PAUSE allows the operator the following options:

- Up to 10 minutes time to adjust or flush the patient's access site
- Time to deliver a saline bolus
- Time to enter the SETUP screen to modify any Treatment Parameter Setting

For complete instructions on how to use the PAUSE button refer to *"PAUSED" on page 5-41* or *"PAUSED" on page 5-58*.

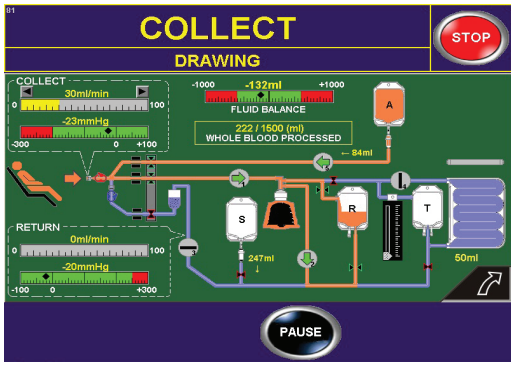
If you need to interrupt the treatment for longer than 10 minutes or if you intend to stop COLLECT to change the course of the treatment, then pressing STOP in any phase of the treatment enables you to choose from the following options:

- END TREATMENT
- ABORT TREATMENT

For complete instructions on how to use the STOP button refer to *"STOPPED" on page 5-43* or *"STOPPED" on page 5-60*.

Use PAUSE **to:**

- Flush access
- Give saline bolus
- Go to SETUP
- Go to BUFFY COAT



Use STOP **to:**

- END TREATMENT
- ABORT TREATMENT
- Go to SETUP, when PAUSE is not available

Figure 5-48: Deciding when to PAUSE or STOP

CAUTION:

- END TREATMENT and ABORT TREATMENT are both selections that will not allow the operator to proceed to PHOTOACTIVATE. Selection and confirmation of these selections will result in immediate termination of the treatment.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

Delivering a Saline Bolus

CAUTION:

Selecting 

during the COLLECT phase to deliver a saline bolus will stop the centrifuge bowl and cell separation will be lost.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

If the patient requires fluids during the procedure, you may administer a saline bolus during the COLLECT or PHOTOACTIVATE phases.

1. Press PAUSE during COLLECT or press STOP if the PAUSE button is not available.
2. Press START SALINE. A confirmation message appears.
3. Select YES or NO.
   - Pressing the YES button automatically begins the delivery of the preset volume of saline. After the saline is delivered, the main screen appears.
   - Pressing the NO button returns you to the main screen without delivering saline.

   To stop the saline bolus before the entire bolus volume has been delivered, press **STOP SALINE**.
4. When the bolus is complete press START to resume treatment.

NOTE:

- The default Saline Bolus volume is 100 mL. Enter the SETUP menu to increase or decrease this setting as required.
- To stop the saline bolus before the entire bolus volume has been delivered, press STOP SALINE.
- If a saline bolus is interrupted by an alarm, clear the alarm state and select START SALINE again.

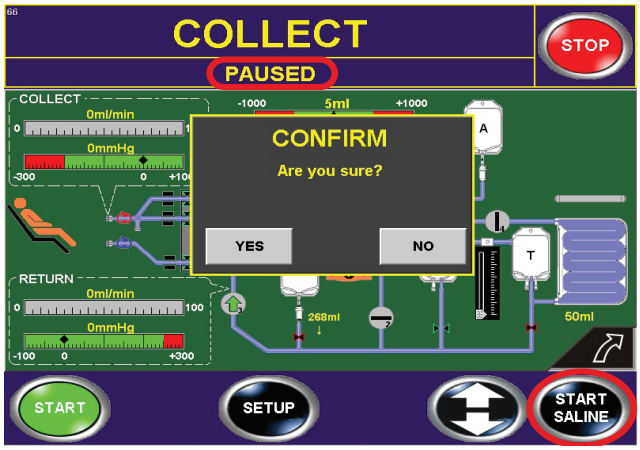


Figure 5-49: Delivering a Saline Bolus

END TREATMENT

CAUTION:

END TREATMENT and ABORT TREATMENT are both selections that will not allow the operator to proceed to PHOTOACTIVATE. Selection and confirmation of these selections will result in immediate termination of the treatment.

If for any reason you want to interrupt the treatment, stop collection and **have the instrument return all blood to the patient immediately:**

1. Press STOP.
2. Press  .
3. Press END TX. The button selected will flash and the screen will display a prompt to confirm.
4. Confirm by pressing the END TX button in the display box. Press CANCEL if you do not want to END TREATMENT.

Refer to *"TREATMENT COMPLETE" on page 5-45* or *"TREATMENT COMPLETE" on page 5-61* for instructions on how to complete the treatment.

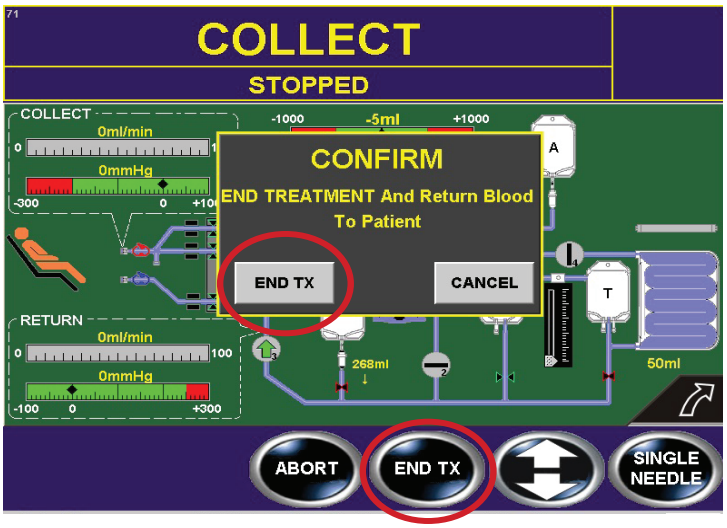


Figure 5-50: END TREATMENT

ABORT TREATMENT

If for any reason you want to interrupt the treatment, stop all functions and **not have the instrument return any blood to the patient:**

1. Press STOP.
2. Press  .
3. Press ABORT. The button selected will flash and the screen will display a prompt to confirm.
4. Confirm by pressing the ABORT button in the display box. Press CANCEL if you do not want to ABORT TREATMENT.

Refer to *"TREATMENT COMPLETE" on page 5-45* or *"TREATMENT COMPLETE" on page 5-61* for instructions on how to complete the treatment.

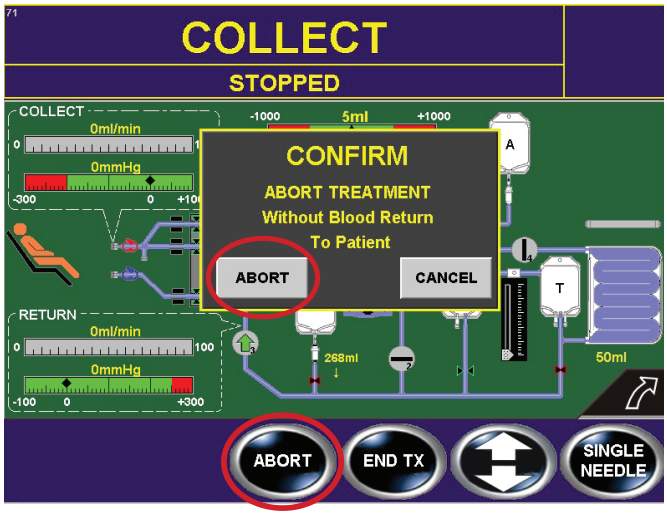


Figure 5-51: ABORT TREATMENT

NOTE:

Reasons to ABORT TREATMENT:

- Clotting in the procedural kit.
- Possible blood contamination due to a leak.
- Possible allergic reaction.
- Prevent return of packed red blood cells if blood prime has been used.
- Any other condition where return of the blood is not desired.

Manual Blood Return

In the event of an instrument malfunction, prolonged power failure, or procedural kit failure, it may be necessary to manually return blood from the procedural kit to the patient. Two sets of instructions are available. Follow Manual Return (With Power ON) if you are able to activate the RELEASE KIT button. Follow Manual Return (With Power OFF) if you are unable to activate the RELEASE KIT button.

CAUTION:

- Before you begin Manual Blood Return, consult the treating clinician to determine if there is any reason that the blood in the procedural kit should not be returned to the patient.
- In the event of a brief power failure during treatment when Buffy Coat has reached the photoactivation module and a Manual Blood Return is not required, turn the power switch OFF, open the door to the Photoactivation Chamber and pull the Photoactivation Module out half way. When power is restored, put the Photoactivation Module back in position, close the Photoactivation Chamber Door and turn the power ON. In the event of a prolonged power failure, follow instructions for Manual Blood Return (With Power OFF and/or No Access to RELEASE KIT Button) below.
- To release all internal pressure before removing the kit, always remove all Pump Tubing Segments before removing any Pressure Domes.

MANUAL BLOOD RETURN		
Supplies Required	(with Power ON)	(with Power OFF)
	Access to RELEASE KIT button	No access to RELEASE KIT button
Filtered Blood Administration Set	1	1
Slide Clamps or Hemostats	4	9
Flat head Screwdriver	N/A	1
Small Allen Key	N/A	1
Pump Crank Handles	1 (optional)	1 (Optional)

Table 2: Manual Blood Return

Manual Blood Return (With Power ON and Access to RELEASE KIT Button)

1. Clamp all patient line clamps.
2. Use a Slide Clamp or Hemostat to clamp the Anticoagulant and Saline Lines.
3. Press  .
4. Press ABORT and Confirm.
5. Press the RELEASE KIT Button. If you are unable to release the kit, proceed to MANUAL BLOOD RETURN (With Power OFF and No Access to RELEASE KIT Button) (***See page 5-73).***
6. Keep the Power ON
7. If there is buffy coat in the Photoactivation Module, drain the Photoactivation Module. If buffy coat is not present in the Photoactivation Module, proceed to step 7d.
   a. Drain the Photoactivation Module.
   b. Open door of the Photoactivation Chamber and slide Photoactivation Module out half way.
   c. Manually rotate the Recirculation Pump (#4) counterclockwise until all the buffy coat in the Photoactivation Module is transferred to the treatment bag.
   d. Clamp the lines of the Photoactivation Module close to the Pump Tubing Organizer.

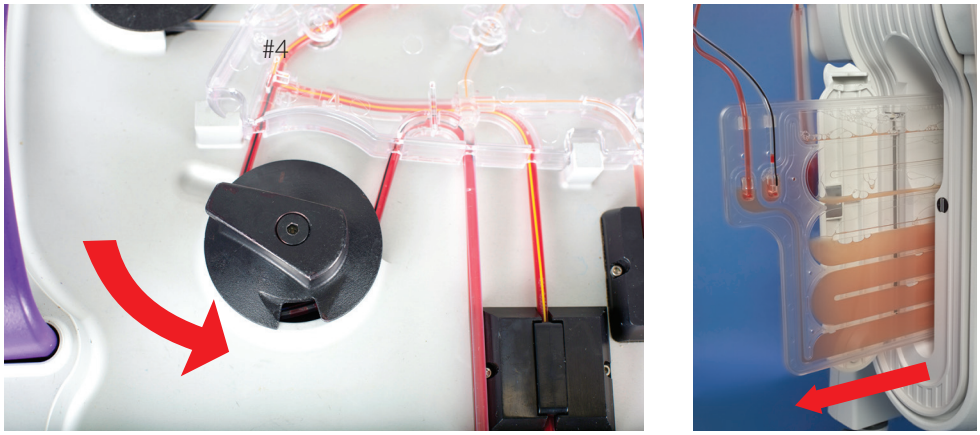


Figure 5-54: Manually Draining the Photoactivation Module

8. If blood is present in the Centrifuge Bowl, proceed to step 8a. If Blood is not present in the Centrifuge bowl, proceed to step 8c.
   a. Drain the centrifuge bowl.
   b. Manually rotate the Red Blood Cell Pump (#2) clockwise to empty the contents of the Centrifuge Bowl. The blood will flow to the treatment bag and/or to the return bag.
   c. Clamp all three lines that exit from the Centrifuge Bowl.

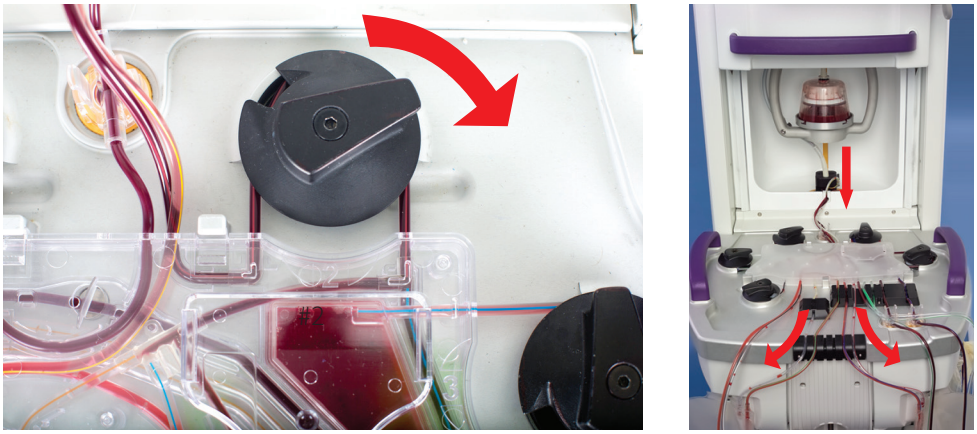


Figure 5-55: Manually Draining the Centrifuge Bowl

9. Drain the return bag.

    a. Raise and invert the return bag to allow the contents to drain into the treatment bag. All blood should now be in the treatment bag.

    b. If needed, rotate the Recirculation Pump (#4) counterclockwise to initiate blood flow.

    c. Use a Slide Clamp or Hemostat to clamp both lines of the treatment bag.

Figure 5-56: Manually Draining the Return Bag

10. Prepare the treatment bag for reinfusion to the patient.

    a. Remove the remaining portion of the procedural kit from the instrument.

    b. Spike the treatment bag with a blood transfusion filter and prime the filter.

CAUTION:
Do not manually return any blood products without proper filtration. Refer to your institution's blood transfusion guidelines.

11. Manually return blood from treatment bag to patient.
    a. Hang the treatment bag on an IV pole.
    b. Connect the filtered blood administration line to the patient's access.
    c. Return blood through the filter and to the patient using center specific guidelines for autologous blood products for rate and method of reinfusion.
    d. Discard the procedural kit using biohazard precautions when Manual Return is complete.
    e. Record all treatment data from the instrument and turn the power OFF.

NOTE:

- Data will be erased when the power is turned OFF.
- Power must be cycled OFF and then ON before beginning a new treatment.
- Call Mallinckrodt if instrument service is required.

Figure 5-57a: (Step 10) Prepare the treatment bag for reinfusion to the patient.

Figure 5-57b: (Step 11)Manually return blood from treatment bag to patient.

Manual Blood Return (With Power OFF and/or No Access to RELEASE KIT Button)

NOTE:

Due to an instrument malfunction or prolonged power failure the operator is not able to access the ABORT Treatment button or RELEASE KIT button. Consequently, the Fluid Routing Valves are all in the raised position and will block the flow of fluids as you attempt to drain the procedural kit.

Call Mallinckrodt at any of the numbers on the last page of this manual to report the problem and to obtain guidance as you proceed.

1. Clamp all patient lines.
2. Clamp the Anticoagulant and Saline lines.
3. If possible, open the Centrifuge Chamber Door and then turn the power OFF.
4. If necessary, manually release the Centrifuge Chamber Door.
    a. Turn power OFF.
    b. Insert a flat head screwdriver into the Centrifuge Chamber Door Manual Release and turn the latchkey one half turn clockwise.
    c. Raise the Centrifuge Chamber Door.
    d. Return the latchkey to its original position by turning it one half turn counterclockwise.

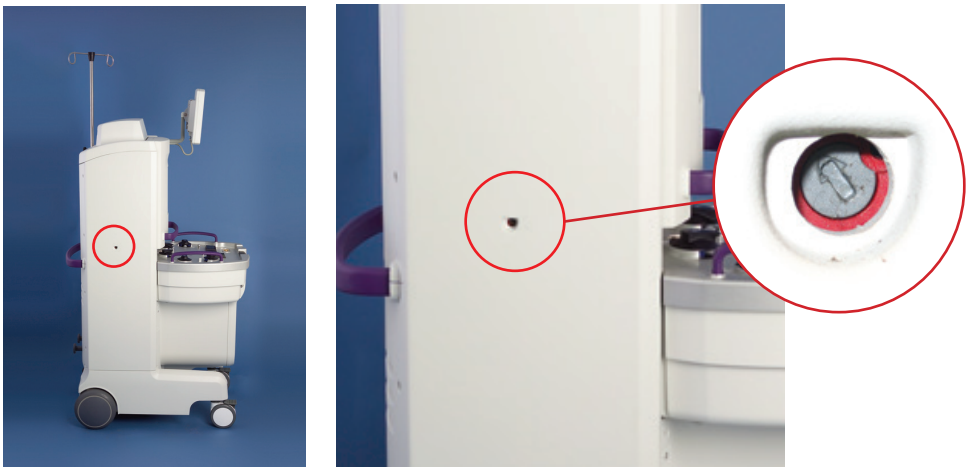


Figure 5-59: Centrifuge Chamber Door Manual Release Access

5. If there is buffy coat in the Photoactivation Module, proceed to step 5a. If buffy coat is not present in the Photoactivation Module, proceed to step 5d.
    a. Drain the Photoactivation Module.
    b. Open door of the Photoactivation Chamber and slide Photoactivation Module out half way

c. Manually rotate the Recirculation Pump (#4) counterclockwise until all the buffy coat in the Photoactivation Module is transferred to the treatment bag.

d. Clamp the lines of the Photoactivation Module close to the Pump Tubing Organizer.

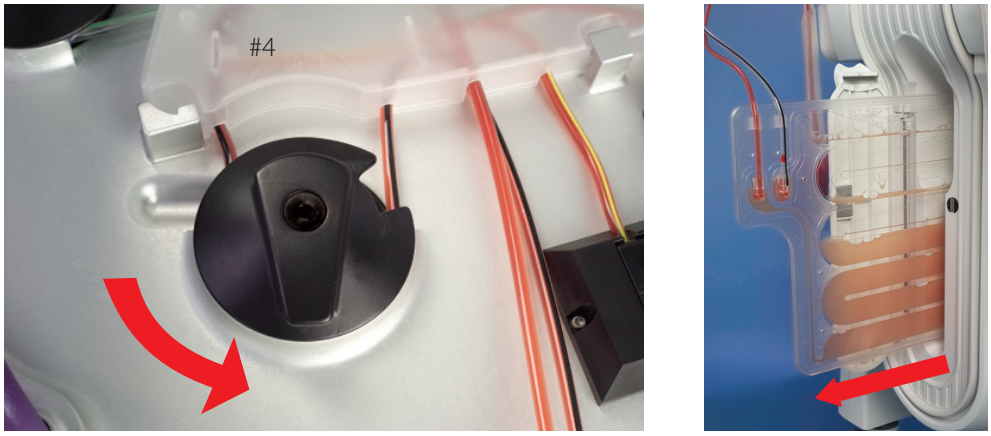
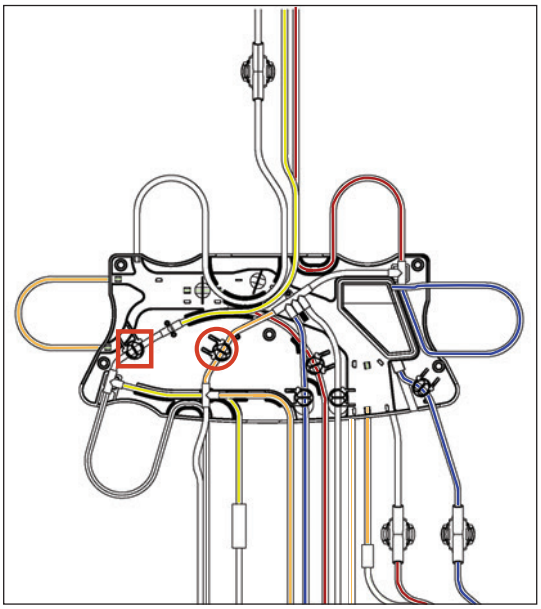


Figure 5-60 Manually Draining the Photoactivation Module

6. If blood is present in the Centrifuge Bowl, proceed to step 6a. If Blood is not present in the Centrifuge bowl, proceed to step 6d.

a. Drain the Centrifuge Bowl

b. Use ***extreme care*** to avoid puncturing the tubing line as you insert the Fluid Routing Valve Release Tool (small Allen Key) by gently moving tubing to the side before pushing the fluid routing valve down. Depress and hold the valve down (indicated by the circle in Figure 5-61) to open the pathway for blood to flow from the Centrifuge Bowl to the treatment bag. Locate this valve by following the ORANGE Striped line of the treatment bag back to the bottom of the Pump Tubing Organizer.



Circle = Fluid Routing Valve depressed during Manual Return

Square = Fluid Routing Valve depressed if venting required during Manual Return

Figure 5-61 Pump Tubing Organizer Schematic

c. Keeping the valve depressed, manually rotate the Red Blood Cell Pump (#2) clockwise until the Centrifuge Bowl is completely empty. If the Centrifuge Bowl does not readily drain, additional venting can be provided by depressing the Fluid Routing Valve indicated by the red square box in Figure 5-61. Call Mallinckrodt for assistance.

d. Clamp the lines of the Photoactivation Module close to the Pump Tubing Organizer.

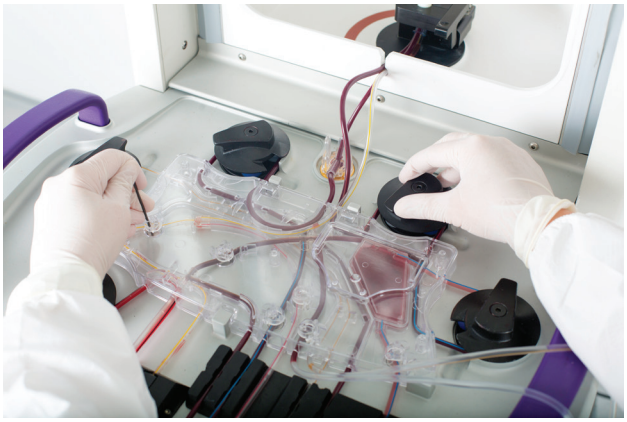


Figure 5-62: Manually Draining the Centrifuge Bowl by turning the RBC Pump clockwise and depressing fluid routing valve with small Allen Key (With Power OFF and/or No Access to RELEASE KIT Button)

CAUTION:

Do not puncture tubing line!

7. Remove the Pump Tubing Organizer.

a. Remove all Pump Tubing Segments and Pressure Domes.

b. Pull tabs and lift to remove Pump Tubing Organizer.

Figure 5-63a: Removing the Pump Tubing Segments

Figure 5-63b: Removing the Pump Tubing Organizer

8. Drain the return bag.
   a. Raise and invert the return bag to allow the contents to drain into the treatment bag. All blood should now be in the treatment bag. Clamp both lines of the return bag.
   b. Clamp both lines of the treatment bag.

Figure 5-64: Draining the Return Bag

9. Prepare the treatment bag for reinfusion to the patient.
   a. Remove the remaining portion of the procedural kit from the instrument.
   b. Spike the treatment bag with a blood transfusion filter and prime the filter.

CAUTION:
Do not manually return any blood products without proper filtration. Refer to your institution's guidelines for blood transfusions.

10. Manually return blood from treatment bag to patient.
    a. Hang the treatment bag on an IV pole.
    b. Connect the filtered blood administration line to the patient's access.
    c. Return blood through the filter and to the patient using center specific guidelines for autologous blood products for rate and method of reinfusion.
    d. Discard the procedural kit using biohazard precautions when Manual Return is complete.
    e. Record all treatment data from the instrument and turn the power OFF.

NOTE:
- Power must be cycled OFF and ON before beginning a new treatment.
- Data will be erased when the power is turned OFF.
- Call Mallinckrodt if instrument service is required.

SECTION 6: CORRECTING ALARMS

Introduction

Whenever an alarm condition occurs, the THERAKOS™ CELLEX™ Photopheresis System sounds an audible alarm and displays a message on the screen. The probable cause of the alarm and recommended action are displayed on the operator interface screen.

CAUTION:

General guidelines suggest that blood removed from the body should not be extracorporeal for longer than four hours. Use clinical judgment to determine the length of delay each patient may be able to tolerate. In case of clotting in the procedural kit, treatment should be aborted.

NOTE:

- Alarm system functionality is verified by an automatic pre-use check (single beep) at Power ON.
- The 9 V battery is driving the alarm whenever there is a power failure.
- The power failure alarm will not display a message. Only an audible alarm is sounded.
- Airflow in the photoactivation chamber is not monitored during a power outage. Verify that the door to the Photoactivation Chamber is open and the Photoactivation Module is halfway out to prevent the product from overheating.
- In the event that power is not restored, the patient's blood may be manually reinfused as described in *SECTION 5: MANUAL BLOOD RETURN WITH POWER OFF AND/OR NO ACCESS TO RELEASE KIT BUTTON.*

NOTE:

For certain alarms that may occur during PRIME, the same cause can trigger two different alarms depending on whether the instrument was able to automatically release internal pressure built up during testing or not. If the internal pressure could not be released (Alarms #22 - 28), the operator must manually unload all pump tubing segments from the pumps.

Alarm Types:

The THERAKOS™ CELLEX™ Photopheresis System incorporates three types of alarm signals: LOW Priority, MEDIUM Priority (Operator Correctable) and MEDIUM Priority (Technical). There are no HIGH Priority alarms. The table below defines and provides the visual and audible characteristics of each type.

	LOW Priority Alarm	MEDIUM Priority Alarm	HIGH Priority Alarm
Definition	**Operator Correctable** Alarm indicating that operator awareness is required. Priority was assigned through risk analysis.	**Operator Correctable** Alarm indicating that prompt operator response is required. Priority was assigned through risk analysis. **Technical Alarm** A coded alarm message indicating a technical problem that may be resolved by rebooting the instrument, but most often requires technical support and/or service to be resolved.	Not applicable
Visual	Constant, Blue (Cyan)	Flashing Yellow to Grey	Not applicable
Audible	2 pulses 16 seconds apart	3 pulses 7.5 seconds apart	Not applicable

Alarm Prioritization:

The THERAKOS™ CELLEX™ Photopheresis System utilizes an intelligent alarm system. Priority for each alarm condition during PRIME and during TREATMENT has been assigned through risk analysis and is defined in the table on ***page 6-3***. Prioritization for multiple concurrent alarms is as follows:

- ☐ MEDIUM (Operator Correctable) alarms take priority over LOW alarms
- ☐ The following MEDIUM (Operator Correctable) alarms take priority over all other MEDIUM (Operator Correctable) and LOW alarms
  - ☐ Alarm #4: Centrifuge Chamber Door
  - ☐ Alarm # 7: Blood leak? (Centrifuge Chamber)
  - ☐ Alarm # 18: System Pressure
  - ☐ Alarm #33: PAUSE Timeout
  - ☐ Alarm #47: Drive Tube Alarm
- ☐ MEDIUM (Technical Alarms) take priority over MEDIUM (Operator Correctable) and LOW alarms

CAUTION:
Use clinical judgment when responding to alarms on multiple CELLEX devices

Alarm	Priority during PRIME	Priority during TREATMENT
Alarm # 2: Temperature!!	LOW	MEDIUM
Alarm # 3: Light Assembly Failure!	LOW	LOW
Alarm # 4: Centrifuge Chamber Door!!	LOW	MEDIUM
Alarm # 5: Lamp Life Expired!	LOW	LOW
Alarm # 6: Smart Card Failure!	LOW	LOW
Alarm # 7: Blood leak? (Centrifuge Chamber)!!	LOW	MEDIUM
Alarm # 8: Blood Leak? (Photoactivation Chamber)!!	LOW	MEDIUM
Alarm # 10: Buffy Volume Exceeded!!	LOW	MEDIUM
Alarm # 11: Fluid Routing Valve Failure!!	LOW	MEDIUM
Alarm # 12: Kit Used!	LOW	LOW
Alarm # 13: Photoactivation Chamber Door!	LOW	LOW
Alarm # 14: A/C VOLUME THRESHOLD Limit!!	LOW	MEDIUM
Alarm # 15: SALINE VOLUME THRESHOLD Limit!!	LOW	MEDIUM
Alarm # 16: Collect Pressure!!	LOW	MEDIUM
Alarm # 17: Return Pressure!!	LOW	MEDIUM
Alarm # 18: System Pressure!!	LOW	MEDIUM
Alarm # 19: FLUID BALANCE Limit!!	LOW	MEDIUM
Alarm # 20: Low Airflow!	LOW	LOW
Alarm # 21: Air Detector Test Failure!	LOW	LOW
Alarm # 22: Collect Pressure Limit - Unload Tubings!	LOW	LOW
Alarm # 23: Return Pressure Limit - Unload Tubings!	LOW	LOW
Alarm # 24: System Pressure Limit - Unload Tubings!	LOW	LOW
Alarm # 25: Return Pressure Error - Unload Tubings!	LOW	LOW
Alarm # 26: Collect Pressure Error - Unload Tubings!	LOW	LOW
Alarm # 27: System Pressure Error - Unload Tubings!	LOW	LOW
Alarm # 28: PRIME 4!	LOW	LOW
Alarm # 29: PRIME 5!	LOW	LOW
Alarm # 30: PRIME 6!	LOW	LOW
Alarm # 31: PRIME 7!	LOW	LOW
Alarm # 32: PRIME 8!	LOW	LOW
Alarm # 33: PAUSE Timeout!!	LOW	MEDIUM
Alarm # 40: Is the Anticoagulant Bag empty?!!	LOW	MEDIUM
Alarm # 41: Is the Saline Bag empty?!	LOW	LOW
Alarm # 42: PRIME 9!	LOW	LOW
Alarm # 43: PRIME 10!	LOW	LOW
Alarm # 44: PRIME 11!	LOW	LOW
Alarm # 45: Red Blood Cell Pump Alarm!	LOW	LOW
Alarm # 47: Drive Tube Alarm!!	LOW	MEDIUM
Alarm # 48: Treatment Bag - Air Detected!!	LOW	MEDIUM
Alarm # 49: Return Bag - Air Detected!!	LOW	MEDIUM
Alarm # 50: PRIME 12!	LOW	LOW
Alarm # 51: Centrifuge Chamber Temperature Alarm!!	LOW	MEDIUM
Alarm # 52: Collect Line Air Detected!!	LOW	MEDIUM
Alarm # 53: Return Line Air Detected!!	LOW	MEDIUM
Alarm # 54: Anticoagulant Line Air Detected!!	LOW	MEDIUM
Alarm # 55: Collect Pump (#1) Error!!	LOW	MEDIUM
Alarm # 56: Red Cell Pump (#2) Error!!	LOW	MEDIUM
Alarm # 57: Return Pump (#3) Error!!	LOW	MEDIUM
Alarm # 58: Recirculation Pump (#4) Error!!	LOW	MEDIUM
Alarm # 59: A/C Pump (#5) Error!!	LOW	MEDIUM
Alarm #60: Residual Pressure Detected in Kit!	LOW	LOW
Alarm #62: Collect Pressure Limit!	LOW	LOW
Alarm #63: Return Pressure Limit!	LOW	LOW
Alarm #65: Return Pressure Error!	LOW	LOW
Alarm #66: Collect Pressure Error!	LOW	LOW
Alarm #67: System Pressure Error!	LOW	LOW

Alarm: Power Failure During Treatment

In the event of a power failure:

1. Turn the power switch to the OFF position to silence the alarm.
2. Check the power cord at the wall outlet and at the back of the instrument. If re-securing the power cord resolves the power failure, turn the power ON. See NOTE and WARNING below.
3. If the power failure is not related to the power cord, open the Photoactivation Chamber Door and pull the Photoactivation Module out halfway.
4. When the power is restored, the treatment may be continued.
5. Reinstall the Photoactivation Module.
6. Close the Photoactivation Chamber Door.
7. Turn the power switch to the ON position. See NOTE and WARNING below.
8. Select START to release pressure and purge air in Centrifuge Bowl.
9. Select START again to resume treatment.

NOTE:

After powering ON, a pop-up message will appear asking "Do you wish to end this treatment and install a new kit?"

- Selecting YES will terminate the existing treatment process and initiate a new treatment at the READY TO PRIME screen. All parameters will be returned to default settings.
- Selecting NO will maintain all treatment settings and return the treatment to the step that was interrupted when power was lost.
- If a selection is not made within 30 seconds, NO will be automatically selected.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

Figure 6-1: Do you wish to end this treatment and install a new kit?

Technical Alarm Messages

Technical Alarms are not generally operator correctable alarms.

1. Note the alarm code number.
2. Turn OFF the power.
3. Turn the power back ON.
4. Call Mallinckrodt at one of the phone numbers listed in the Operator manual if the alarm continues.
5. If the alarm clears, complete the treatment. Call Mallinckrodt at one of the phone numbers listed in the Operator manual to report the Technical Alarm number.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

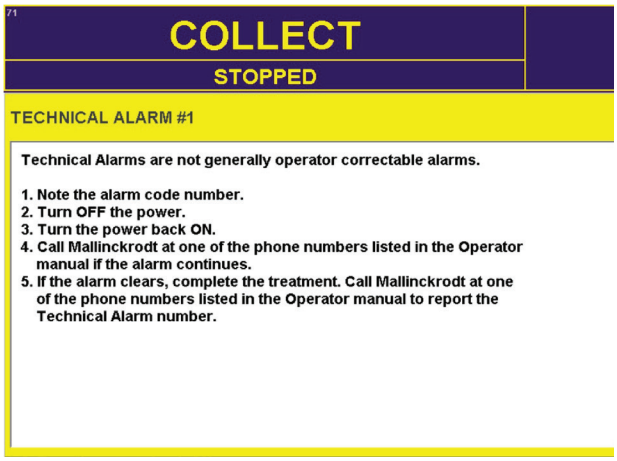


Figure 6-2: Example Technical Alarm

Correcting Alarms - Process Overview

The following steps outline the general procedure for correcting an alarm. Instructions for correcting specific alarms are provided later in the chapter.

1. Press MUTE to silence the alarm for a maximum of 60 seconds.
2. Resolve the problem according to the instructions posted on the screen and this section of the Operator's Manual.
3. Press RESET.
4. Press START to continue the treatment.

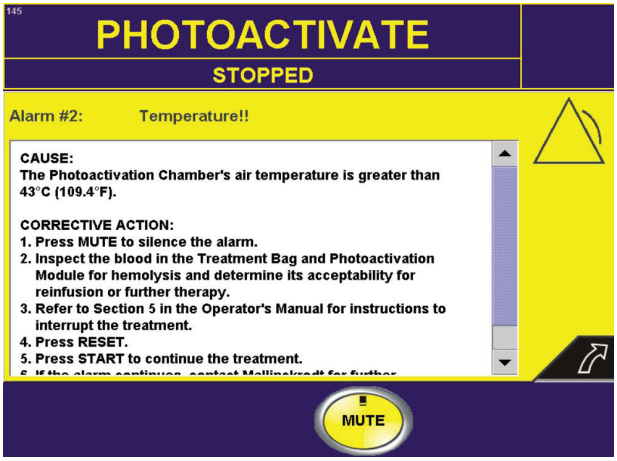


Figure 6-3: Example Medium Priority Alarm Screen - Alarming

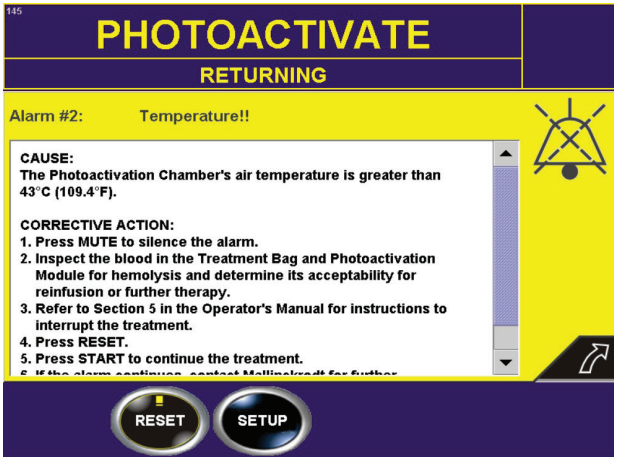


Figure 6-4: Example Medium Priority Alarm Screen - Audio Paused

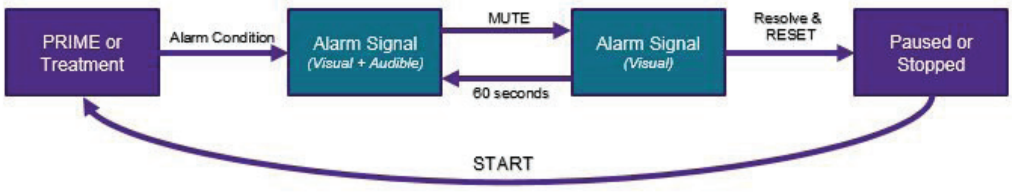


Figure 6-5: Correcting Alarms Process

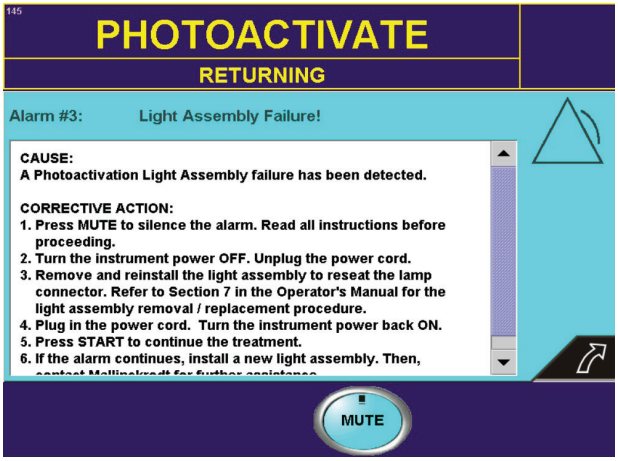


Figure 6-6: Example Low Priority Alarm Screen - Alarming

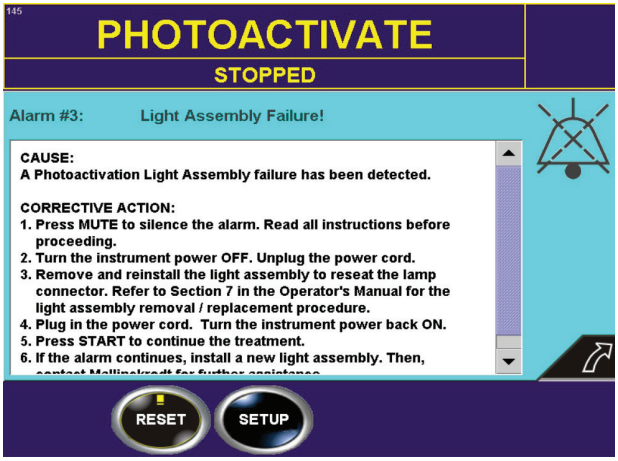


Figure 6-7: Example Low Priority Alarm Screen - Audio Paused

NOTE:

Be sure to read the screen and resolve the alarm before pressing RESET. Pressing the RESET button will clear the alarm text message from the operator interface.

Symbols:

	Indicates an alarm condition. While this symbol is displayed, the system is presenting an audible alarm signal.
	Indicates an alarm condition is in the audio paused state (MUTE button has been pressed) until an additional 60 seconds has elapsed or the RESET button has been pressed.

Alarm Messages

The following section lists alarms, pop-up messages, and alerts, along with the recommended actions.

Alarm #2: Temperature!!

CAUSE:

The Photoactivation Chamber's air temperature is greater than 43°C (109.4°F).

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Inspect the blood in the Treatment Bag and Photoactivation Module for hemolysis and determine its acceptability for reinfusion or further therapy.
3. Refer to Section 5 in the Operator's Manual for instructions to interrupt the treatment.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

If the alarm does not clear and you are unable to select END TX or ABORT and unable to activate the RELEASE KIT button, refer to ***SECTION 5: MANUAL BLOOD RETURN (WITH POWER OFF AND NO ACCESS TO RELEASE KIT BUTTON)*** for instructions on how to manually return blood to the patient. Confirm that the blood is acceptable for reinfusion before you proceed.

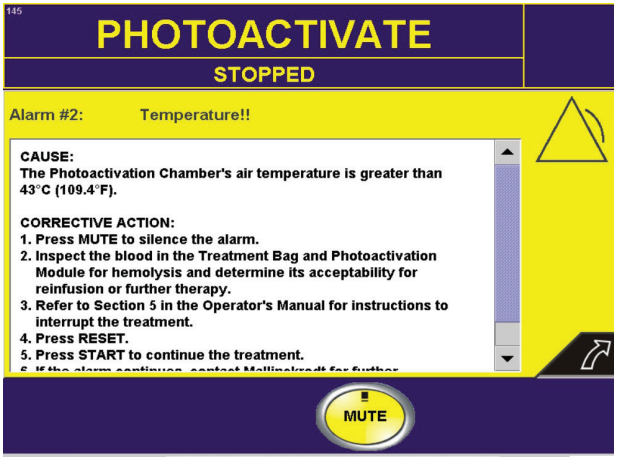


Figure 6-8: Alarm #2: Temperature!! Alarming

Alarm #3: Light Assembly Failure!

CAUSE:

A Photoactivation Light Assembly failure has been detected.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm. Read all instructions before proceeding.
2. Turn the instrument power OFF. Unplug the power cord.
3. Remove and reinstall the light assembly to reseat the lamp connector. Refer to Section 7 in the Operator's Manual for the light assembly removal/replacement procedure.
4. Plug in the power cord. Turn the instrument power back ON.
5. Press START to continue the treatment.
6. If the alarm continues, install a new light assembly. Contact Mallinckrodt for further assistance.

WARNING:

- The calculated dose of UVA light energy will not be delivered if the THERAKOS™ CELLEX™ Light Assembly is changed after the calculation of photoactivation MINUTES REMAINING is displayed.
- It is recommended that the full PHOTOACTIVATE time be completed during every treatment. The calculated dose of UVA light energy will not be delivered if PHOTOACTIVATE is stopped for any reason before the photoactivation MINUTES REMAINING is equal to 00:00 (minutes:seconds).

CAUTION:

- Always change an aged THERAKOS™ CELLEX™ Light Assembly prior to starting a treatment.
- Turn the power OFF and unplug the instrument prior to changing the Light Assembly.
- Never change the THERAKOS™ CELLEX™ Light Assembly during a treatment if the photoactivation MINUTES REMAINING has already been calculated.
- Do not attempt to modify the THERAKOS™ CELLEX™ Photopheresis System or the THERAKOS™ CELLEX™ Light Assembly in any way.

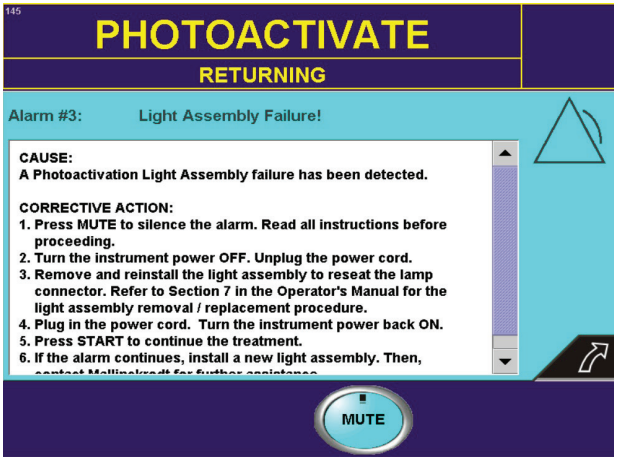


Figure 6-9: Alarm #3 Light Assembly Failure! Alarming

Alarm #4: Centrifuge Chamber Door!!

CAUSE:

The Centrifuge Chamber Door is open.

The Centrifuge Chamber Door Manual Release is not in the correct position.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Close the Centrifuge Chamber Door and/or confirm correct position.
3. Press RESET.
4. Press START to continue.
5. If the alarm continues, contact Mallinckrodt for further assistance.

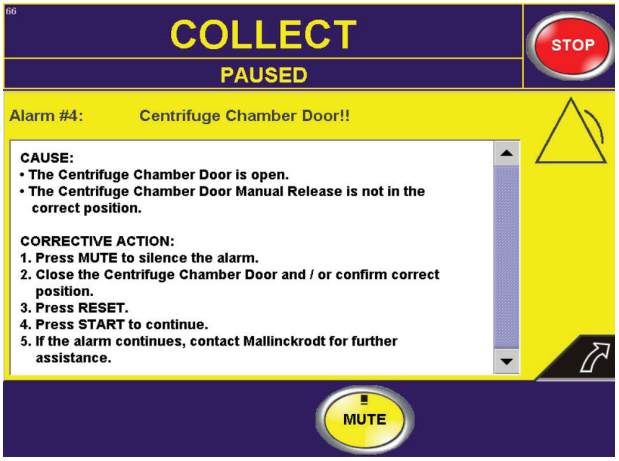


Figure 6-10: Alarm #4: Centrifuge Chamber Door!! Alarming

Alarm #5: Lamp Life Expired!

CAUSE:

The Photoactivation Light Assembly lamp life expired.

CORRECTIVE ACTION:

1. Turn the instrument power OFF. Unplug the power cord.
2. Replace the Photoactivation Light Assembly. Refer to Section 7 in the Operator's Manual for the light assembly removal/replacement procedure.
3. Plug in the power cord. Turn the instrument power back ON.
4. If the alarm continues, contact Mallinckrodt for further assistance.

WARNING:

- The calculated dose of UVA light energy will not be delivered if the THERAKOS™ CELLEX™ Light Assembly is changed after the calculation of photoactivation MINUTES REMAINING is displayed.
- It is recommended that the full PHOTOACTIVATE time be completed during every treatment. The calculated dose of UVA light energy will not be delivered if PHOTOACTIVATE is stopped for any reason before the photoactivation MINUTES REMAINING is equal to 00:00 (minutes:seconds).

CAUTION:

- Always change an aged THERAKOS™ CELLEX™ Light Assembly prior to starting a treatment.
- Turn the power OFF and unplug the instrument prior to changing the Light Assembly.
- Never change the THERAKOS™ CELLEX™ Light Assembly during a treatment if the photoactivation MINUTES REMAINING has already been calculated.
- Do not attempt to modify the THERAKOS™ CELLEX™ Photopheresis System or the THERAKOS™ CELLEX™ Light Assembly in any way.

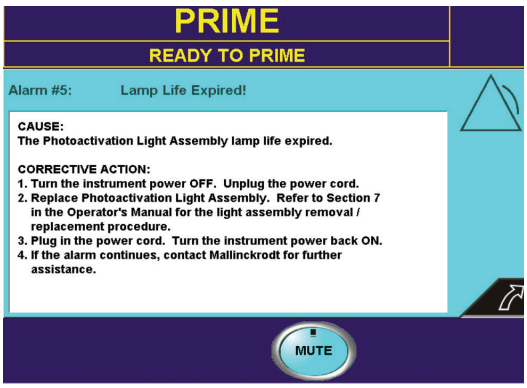


Figure 6-11: Alarm #5 Lamp Life Expired! Alarming

Alarm #6: Smart Card Failure!

CAUSE:

The Smart Card is not installed or is installed incorrectly.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove the Smart Card.
3. Hold the Smart Card so that the gold connector faces away from you and insert it into the Smart Card Holder.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

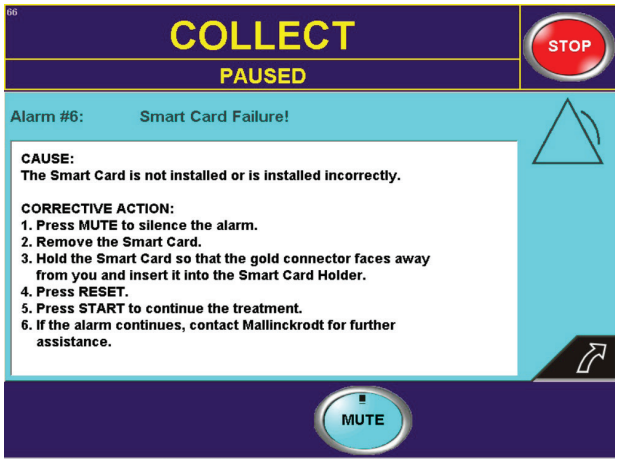


Figure 6-12: Alarm #6: Smart Card Failure! Alarming

Alarm #7: Blood Leak? (Centrifuge Chamber)!!

CAUSE:

The Centrifuge Fluid Leak Detector has detected a potential fluid leak.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Open centrifuge door and inspect bowl, drive tube and chamber.
3. If a leak is confirmed, ABORT TREATMENT. Due to possible contamination, blood product in the Procedural Kit should not be returned to the patient.
4. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- A leak in the Centrifuge Bowl should be detected during PRIME. Pressing the ABORT TREATMENT option will allow you to dislodge the THERAKOS™ CELLEX™ Photopheresis Procedural Kit and clear the memory so that a new treatment may be started.
- Save the defective procedural kit for return to manufacturer. Call Mallinckrodt to report the problem.
- A false positive alarm may be caused by failure to routinely clean the inside of the Centrifuge Chamber to remove bearing grease. Refer to *SECTION 7: MAINTAINING THE THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEM* for more information.

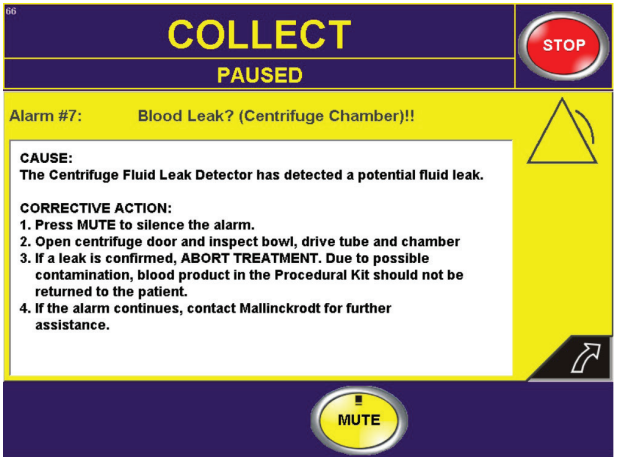


Figure 6-13: Alarm#7: Blood Leak? (Centrifuge Chamber)!! Alarming

Alarm #8: Blood Leak? (Photoactivation Chamber)!!

CAUSE:

The Photoactivation Chamber Fluid Leak Detector has detected a fluid leak.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. If a leak is confirmed, ABORT TREATMENT. Due to possible contamination, blood product in the Procedural Kit should not be returned to the patient.
3. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

A leak in the Photoactivation Module should be detected during PRIME. Pressing the Abort Treatment option will allow you to dislodge the THERAKOS™ CELLEX™ Photopheresis Procedural Kit and clear the memory so that a new treatment may be started.

Save the defective procedural kit for return to manufacturer. Call Mallinckrodt to report the problem.

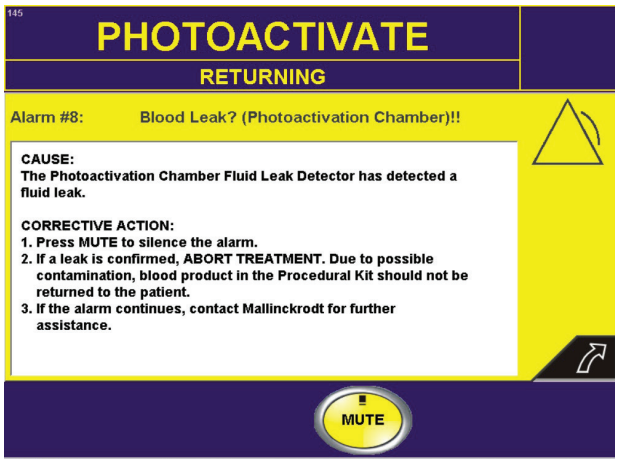


Figure 6-14: Alarm #8: Blood Leak? (Photoactivation Chamber)!! Alarming

Alarm #10: Buffy Volume Exceeded!!

CAUSE:

The Hematocrit Sensor Cuvette is not installed.

The Buffy Coat Volume has exceeded the volume limit.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Verify that the Hematocrit Sensor Cuvette is fully seated into its housing.
3. Press RESET.
4. Press START to continue the treatment. Additional buffy coat will be collected
5. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- The initial alarm will occur when 180 mL Buffy Volume has been collected. The displayed Treatment Volume includes 50 mL prime solution for a total of 230 mL Treatment Volume.
- When this alarm is reset, the alarm limit is adjusted upwards by 25 mL to a maximum Buffy Volume of 280 mL, which corresponds to a displayed Treatment Volume of 330 mL (280 mL Buffy Volume + 50 mL prime solution).

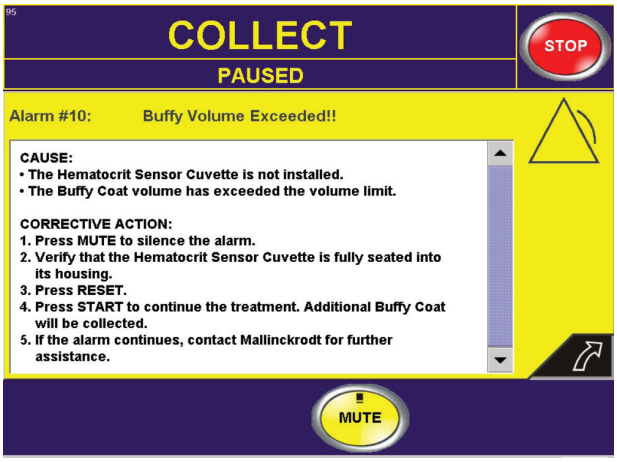


Figure 6-15: Alarm #10: Buffy Volume Exceeded!! Alarming

Alarm #11: Fluid Routing Valve Failure!!

CAUSE:

The Fluid Routing Valves beneath the Pump Tubing Organizer are not in the correct position.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Verify that the Pump Tubing Organizer is properly loaded.
3. Press RESET.
4. Press START to continue the treatment.
5. If the alarm continues, contact Mallinckrodt for further assistance.

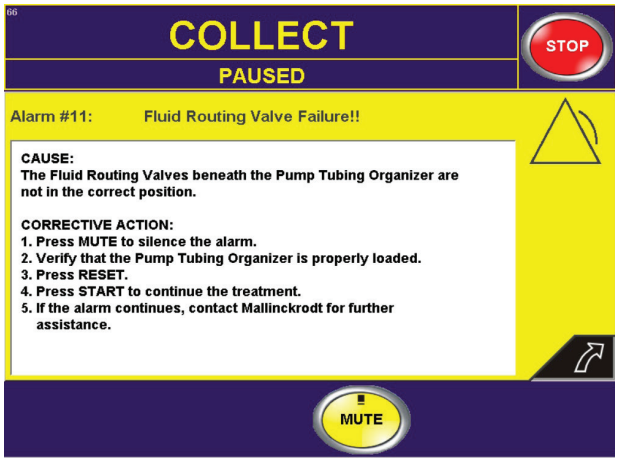


Figure 6-16: Alarm #11: Fluid Routing Valve Failure!! Alarming

Alarm #12: Kit Used!

CAUSE:

The Procedural Kit or Smart Card has been already used.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove the used Procedural Kit and/or Smart Card.
3. Install a new Procedural Kit and/or Smart Card.
4. Press RESET.
5. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- Check to see that the Smart Card from the previous treatment has been removed.
- Each new THERAKOS™ CELLEX™ Photopheresis Procedural Kit has a Smart Card attached to the Pump Tubing Organizer.

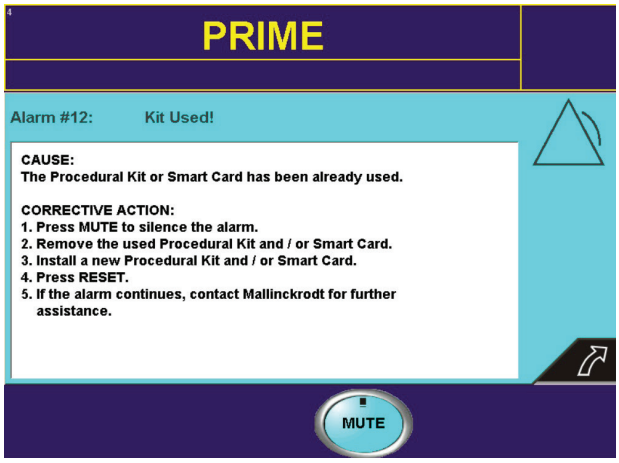


Figure 6-17: Alarm #12: Kit Used! Alarming

Alarm #13: Photoactivation Chamber Door!

CAUSE:

The Photoactivation Chamber Door is open.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Close the Photoactivation Chamber Door.
3. Press RESET.
4. Press START to continue.
5. If the alarm continues, contact Mallinckrodt for further assistance.

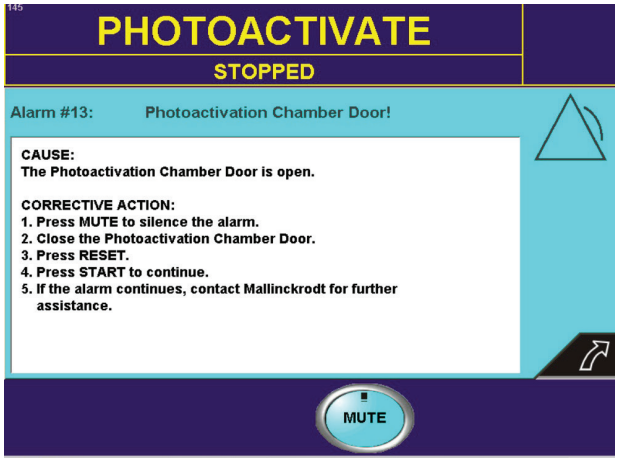


Figure 6-18: Alarm #13: Photoactivation Chamber Door! Alarming

Alarm #14: A/C VOLUME THRESHOLD Limit!!

CAUSE:

The Anticoagulant (A/C) Volume has reached its default or preset Volume Threshold limit.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Exercise clinical judgment to verify that the patient can tolerate further anticipated delivery of anticoagulant if treatment continues.
3. If the patient can tolerate additional anticoagulant, enter the SETUP screen to increase the A/C VOLUME THRESHOLD limit.
4. Press RESET.
5. Press START to continue.
6. If the patient is unable to tolerate additional anticoagulant, enter the SETUP screen and lower the Whole Blood Processed Target to allow for earlier photoactivation of the product already processed.
7. Press RESET.
8. Press START to continue.
9. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- Approximately 10 additional milliliters of anticoagulant solution will be delivered during BUFFY COAT and PHOTOACTIVATE. At completion of a standard treatment the patient will be fluid positive approximately 350 - 450 mL.
- Operator should verify that the volume used from the A/C bag is approximately equal to the volume displayed on the operator interface.

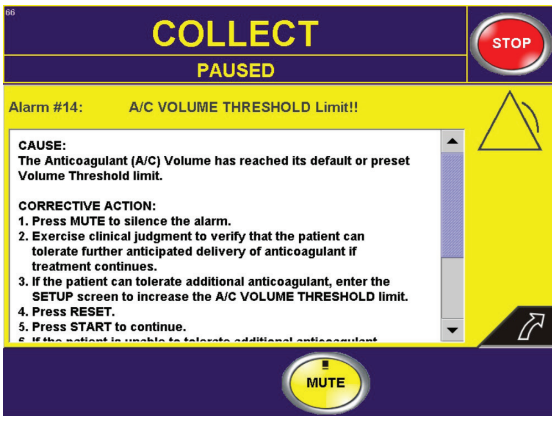


Figure 6-19: Alarm #14: A/C VOLUME THRESHOLD Limit!! Alarming

Alarm #15: SALINE VOLUME THRESHOLD Limit!!

CAUSE:

The Saline Volume has reached its default or preset Volume Threshold limit.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Use clinical judgment to determine if the patient can tolerate the additional fluids delivered if the treatment continues.
3. Enter the SETUP screen to increase the Saline Volume Threshold limit.
4. To minimize additional fluids given, lower the Whole Blood Processed Target to allow you to immediately proceed to BUFFY COAT collection and photoactivation.
5. Press RESET.
6. Press START to continue.
7. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- The default Saline Delivery Limit is 450 mL.
- If the default limit was reached, add a new bag of saline before proceeding.
- Do not allow the Saline Bag to empty completely. It may be difficult to re-prime the line, and the treatment may be interrupted unnecessarily.
- Operator should verify that the volume used from the saline bag is approximately equal to the volume displayed on the operator interface.

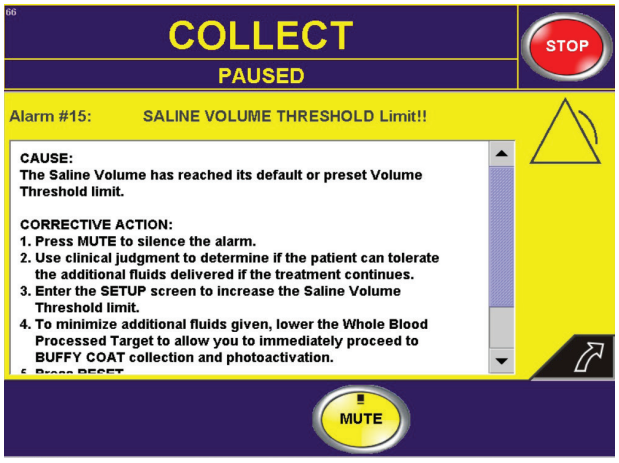


Figure 6-20: Alarm #15: SALINE VOLUME THRESHOLD Limit!! Alarming

Alarm #16: Collect Pressure!!

CAUSE:

The Collect Line pressure has exceeded the preset limit.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. DO NOT remove the Collect Line Pressure Dome.
3. Check the Collect Line for occlusions, pinch points, or closed clamps.
4. Verify that the patient's venous access line is acceptable for the flow rate selected.
5. Select a slower COLLECT Rate Limit, if required.
6. Press RESET.
7. Press START to continue the treatment.
8. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- The default COLLECT Rate Limit is 50 mL/min. The instrument will automatically collect at a flow rate of 30 mL/min if access allows. You may raise or lower the actual flow rate within the range of the limit from the main display screen any time collection is in progress.
- To lower the COLLECT Rate Limit, enter the SETUP screen.

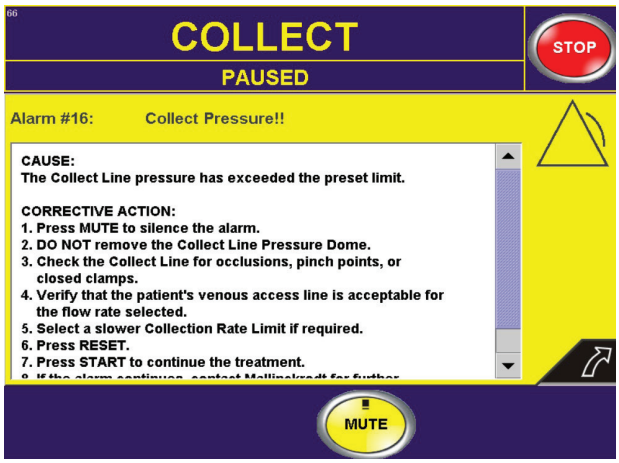


Figure 6-21: Alarm #16: Collect Pressure!! Alarming

Alarm #17: Return Pressure!!

CAUSE:

The Return Line pressure exceeded the preset limit.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. DO NOT remove the Return Line Pressure Dome.
3. Check the Return Line for occlusions, pinch points, or closed clamps.
4. Verify that the patient RETURN access is acceptable for the flow rate selected.
5. Select a slower RETURN Flow Rate Limit, if required.
6. Press RESET.
7. Press START to continue the treatment.
8. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- The default Return Rate Limit is 60 mL/min. The instrument will automatically return at a flow rate of 35 mL/min if access allows. You may raise or lower the actual flow rate within the range of the limit from the main display screen any time collection is in progress.
- To lower the RETURN Rate Limit, enter the SETUP screen.

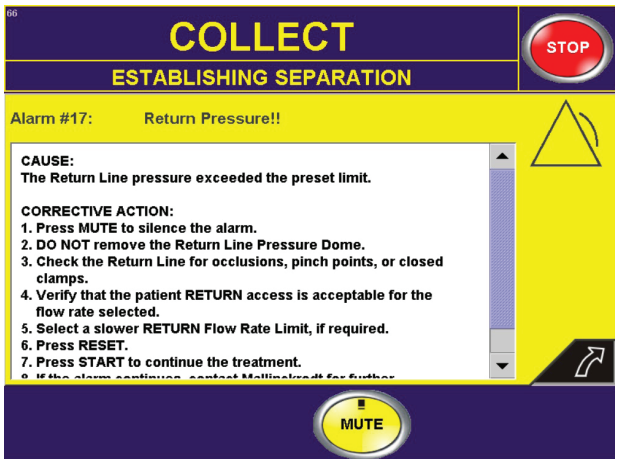


Figure 6-22: Alarm #17: Return Pressure!! Alarming

Alarm #18: System Pressure!!

CAUSE:

The system pressure is outside specified limits.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. DO NOT remove the System Pressure Dome.
3. Press RESET.
4. Press START to continue the treatment.
5. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

Possible Causes of System Pressure Alarms,

- Air trapped in the centrifuge bowl during PURGING AIR.
- Air added to the centrifuge bowl after PURGING AIR.
- Platelet aggregates (Consider changing A/C ratio).
- Increased viscosity of the product exiting the centrifuge bowl during BUFFY COAT.

If System pressure alarm occurs during BUFFY COAT, Re-purging the centrifuge bowl will expel any remaining buffy coat to the return bag. If the majority of white blood cells are in the treatment bag, do not press START! Instead: Select End Buffy Button. To proceed to photoactivation press  .

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

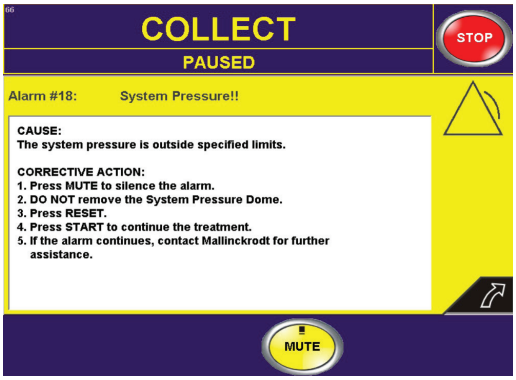


Figure 6-23: Alarm #18: System Pressure!! Alarming

Alarm #19: FLUID BALANCE Limit!!

CAUSE:

The FLUID BALANCE has exceeded the preset or default limits.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Verify that the patient can tolerate further anticipated shifts in fluid balance during the remainder of the treatment.
3. Exercise clinical judgment and deliver a saline bolus if the patient needs additional fluids.
4. Continue to monitor the patient closely.
5. If required, enter SETUP and adjust the fluid balance limits.
6. Press RESET.
7. Press START to continue the treatment.
8. If the alarm continues, contact Mallinckrodt for further assistance.

CAUTION:

- AABB guidelines recommend that the temporary extracorporeal blood volume be limited to 15% of the patient's estimated total blood volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT and SECTION 5: CALCULATING AND SETTING FLUID BALANCE LIMITS*** for additional information on selecting and maintaining Fluid Balance Limits.

NOTE:

- FLUID BALANCE is the tool that allows the operator to track the fluid shifts in and out of the patient during a treatment. When the fluid balance is negative the patient has fluid deficit approximating the amount displayed on the screen. A positive fluid balance indicates that the patient has received additional fluids such as anticoagulant and/or saline. At completion of a standard treatment the patient will be fluid positive approximately 350 - 450 mL.
- The default Fluid Balance Alarm Limits are set at -500 mL and +500 mL.
- Verify that the Collect and Return Rates or the Return Bag Threshold are appropriate to maintain Fluid Balance in Double Needle Mode or Single Needle Mode, respectively.

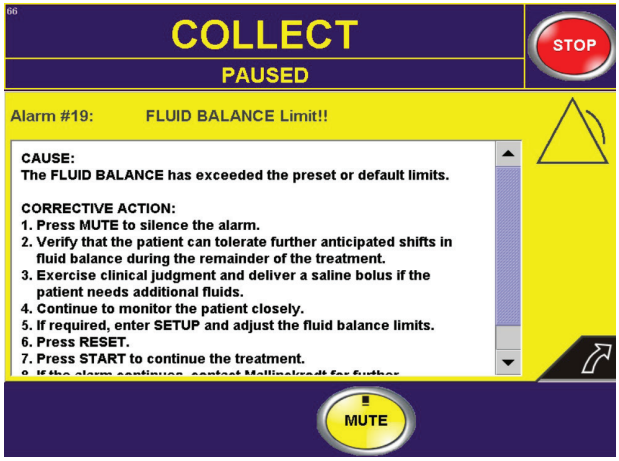


Figure 6-24: Alarm #19: FLUID BALANCE Limit!! Alarming

Alarm #20: Low Airflow!

CAUSE:

The system has detected low airflow in the Photoactivation Chamber.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove any obstructions from the rear of the instrument that would impede air exhaust.
3. Press RESET.
4. Press START to continue the treatment.
5. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- Press START to resume RETURNING and press  to resume PHOTOACTIVATE.

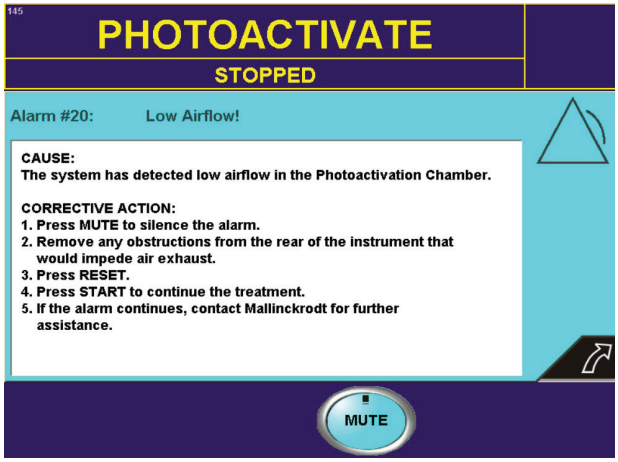


Figure 6-25: Alarm #20: Low Airflow! Alarming

Alarm #21: Air Detector Test Failure!

CAUSE:

Air was not detected in the air detector lines at the beginning of a new treatment.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Verify that there is a new kit installed.
3. Press RESET.
4. Press START to resume PRIME.
5. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:
• At the start of a new treatment the instrument expects to see air (no fluid in the lines).

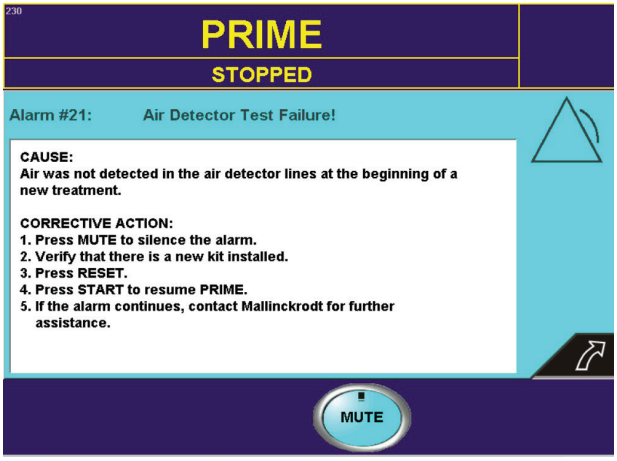


Figure 6-26: Alarm #21: Air Detector Test Failure! Alarming

Alarm #22: Collect Pressure Limit - Unload Tubings!

CAUSE:

The Collect Line Pressure Sensor has failed to reach its preset limit.

The instrument was unable to automatically release internal pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Unload all Pump Tubing Segments from the Pumps.
3. Ensure the Collect Line Pressure Dome is correctly installed.
4. Reload all Pump Tubing Segments.
5. Press RESET.
6. Press START to resume PRIME.
7. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:
The Alarm #22: Collect Pressure Limit - Unload Tubings! is triggered by the same cause as Alarm #62: Collect Pressure Limit!. In Alarm #22: Collect Pressure Limit - Unload Tubings!, the instrument was unable to automatically release the internal pressure built up during testing, therefore it is NECESSARY to manually unload pump tubing segments. Failure to release internal kit pressure during alarm resolution, by unloading and reloading all pump tubing segments, before pressing START (to resume PRIME), may lead to subsequent alarms.

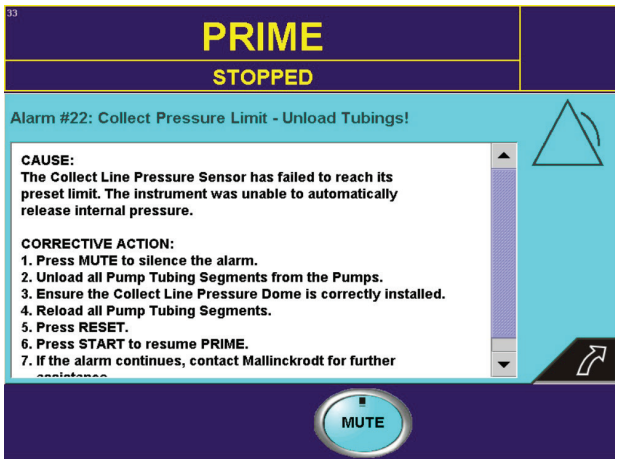


Figure 6-27: Alarm #22: Collect Pressure Limit - Unload Tubings! Alarming

Alarm #23: Return Pressure Limit - Unload Tubings!

CAUSE:

The Return Line Pressure Sensor has failed to reach its preset limit.

The instrument was unable to automatically release internal pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Unload all Pump Tubing Segments from the Pumps.
3. Ensure the Return Line Pressure Dome is correctly installed.
4. Reload all Pump Tubing Segments.
5. Press RESET.
6. Press START to resume PRIME.
7. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

The Alarm #23: Return Pressure Limit - Unload Tubings! is triggered by the same cause as Alarm #63: Return Pressure Limit!. In Alarm #23: Return Pressure Limit - Unload Tubings!, the instrument was unable to automatically release the internal pressure built up during testing, therefore it is NECESSARY to manually unload pump tubing segments. Failure to release internal kit pressure during alarm resolution, by unloading and reloading all pump tubing segments, before pressing START (to resume PRIME), may lead to subsequent alarms.

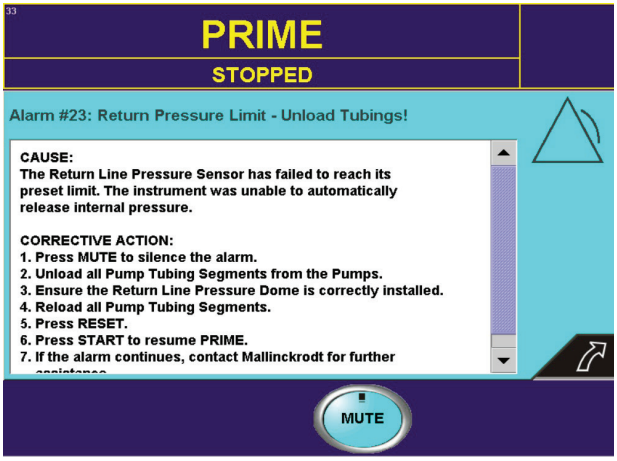


Figure 6-28: Alarm# 23: Return Pressure Limit - Unload Tubings! Alarming

Alarm #24: System Pressure Limit - Unload Tubings!

CAUSE:

The System Pressure Sensor has failed to reach its preset limit.

The instrument was unable to automatically release internal pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Unload all Pump Tubing Segments from the Pumps.
3. Ensure the System Pressure Dome is correctly installed.
4. Reload all Pump Tubing Segments.
5. Press RESET.
6. Press START to resume PRIME.
7. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

In Alarm #24: System Pressure Limit - Unload Tubings!, the instrument was unable to automatically release the internal pressure built up during testing, therefore it is NECESSARY to manually unload pump tubing segments. Failure to release internal kit pressure during alarm resolution, by unloading and reloading all pump tubing segments, before pressing START (to resume PRIME), may lead to subsequent alarms.

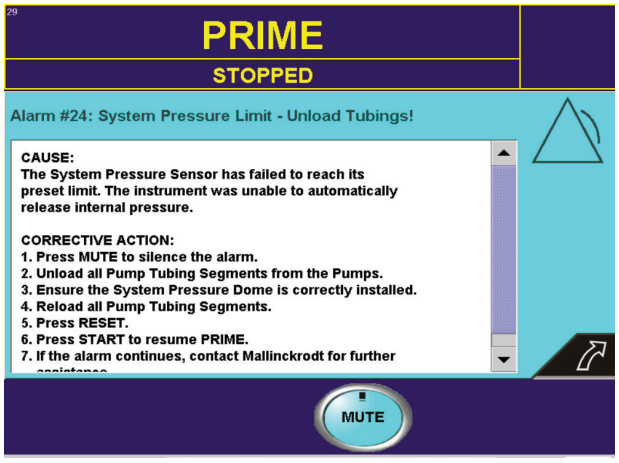


Figure 6-29: Alarm #24: System Pressure Limit - Unload Tubings! Alarming

Alarm #25: Return Pressure Error - Unload Tubings!

CAUSE:

The Return Line Pressure Sensor could not detect negative pressure.

The instrument was unable to automatically release internal pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Unload all Pump Tubing Segments from the Pumps.
3. Ensure the Return Line Pressure Dome and the Collect Line Pressure Dome are correctly installed.
4. Connect the Return Line to the Collect Line at the needle-free injection port.
5. Close the Collect Line (Red) Clamp.
6. Open the Return Line (Blue) Clamp.
7. Reload all Pump Tubing Segments.
8. Verify that all lines are free of kinks and obstructions.
9. Press RESET.
10. Press START to resume PRIME.
11. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- The Alarm #25: Return Pressure Error - Unload Tubings! is triggered by the same cause as Alarm #65: Return Pressure Error!. In Alarm #25: Return Pressure Error - Unload Tubings!, the instrument was unable to automatically release the internal pressure built up during testing, therefore it is NECESSARY to manually unload pump tubing segments. Failure to release internal kit pressure during alarm resolution, by unloading and reloading all pump tubing segments, before pressing START (to resume PRIME), may lead to subsequent alarms.
- To ensure the indicated Pressure Dome is correctly installed, inspect placement on the Pressure Transducer. If proper installation cannot be confirmed, remove and reinstall Pressure Dome.
- For Corrective Actions 4-6 above, confirm that the Procedural Kit is configured as specified. If not, take the steps specified in each Corrective Action to configure the Procedural Kit correctly.

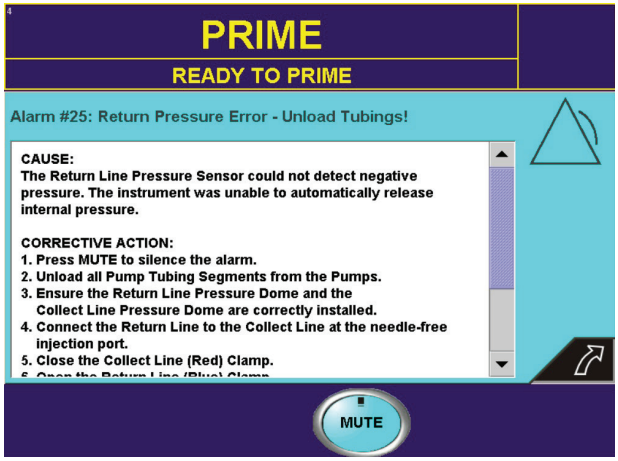


Figure 6-30: Alarm #25: Return Pressure Error - Unload Tubings!

Alarm #26: Collect Pressure Error - Unload Tubings!

CAUSE:

The Collect Line Pressure Sensor could not detect negative pressure.

The instrument was unable to automatically release internal pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Unload all Pump Tubing Segments from the Pumps.
3. Ensure the Collect Line Pressure Dome is correctly installed.
4. Connect the Return Line to the Collect Line at the needle-free injection port.
5. Close the Collect Line (Red) Clamp.
6. Open the Return Line (Blue) Clamp.
7. Reload all Pump Tubing Segments.
8. Verify that all lines are free of kinks and obstructions.
9. Press RESET.
10. Press START to resume PRIME.
11. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- The Alarm #26: Collect Pressure Error - Unload Tubings! is triggered by the same cause as Alarm #66: Collect Pressure Error!. In Alarm #26: Collect Pressure Error - Unload Tubings!, the instrument was unable to automatically release the internal pressure built up during testing, therefore it is NECESSARY to manually unload pump tubing segments. Failure to release internal kit pressure during alarm resolution, by unloading and reloading all pump tubing segments, before pressing START (to resume PRIME), may lead to subsequent alarms.
- To ensure the indicated Pressure Dome is correctly installed, inspect placement on the Pressure Transducer. If proper installation cannot be confirmed, remove and reinstall Pressure Dome.
- For Corrective Actions 4-6 above, confirm that the Procedural Kit is configured as specified. If not, take the steps specified in each Corrective Action to configure the Procedural Kit correctly.

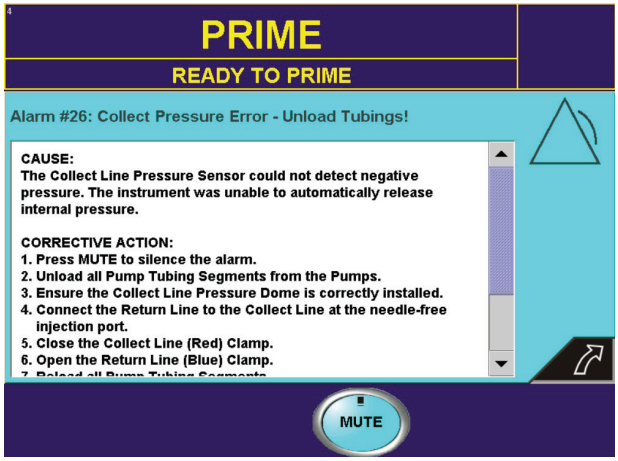


Figure 6-31: Alarm #26: Collect Pressure Error - Unload Tubings!

Alarm #27: System Pressure Error - Unload Tubings!

CAUSE:

The System Pressure Sensor could not detect negative pressure.

The instrument was unable to automatically release internal pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Unload all Pump Tubing Segments from the Pumps.
3. Ensure the System Pressure Dome is correctly installed.
4. Connect the Return Line to the Collect Line at the needle-free injection port.
5. Close the Collect Line (Red) Clamp.
6. Open the Return Line (Blue) Clamp.
7. Reload all Pump Tubing Segments.
8. Verify that all lines are free of kinks and obstructions.
9. Press RESET.
10. Press START to resume PRIME.
11. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- The Alarm #27: System Pressure Error - Unload Tubings! is triggered by the same cause as Alarm #67: System Pressure Error!. In Alarm #27: System Pressure Error - Unload Tubings!, the instrument was unable to automatically release the internal pressure built up during testing, therefore it is NECESSARY to manually unload pump tubing segments. Failure to release internal kit pressure during alarm resolution, by unloading and reloading all pump tubing segments, before pressing START (to resume PRIME), may lead to subsequent alarms.
- To ensure the indicated Pressure Dome is correctly installed, inspect placement on the Pressure Transducer. If proper installation cannot be confirmed, remove and reinstall Pressure Dome.
- For Corrective Actions 4-6 above, confirm that the Procedural Kit is configured as specified. If not, take the steps specified in each Corrective Action to configure the Procedural Kit correctly.

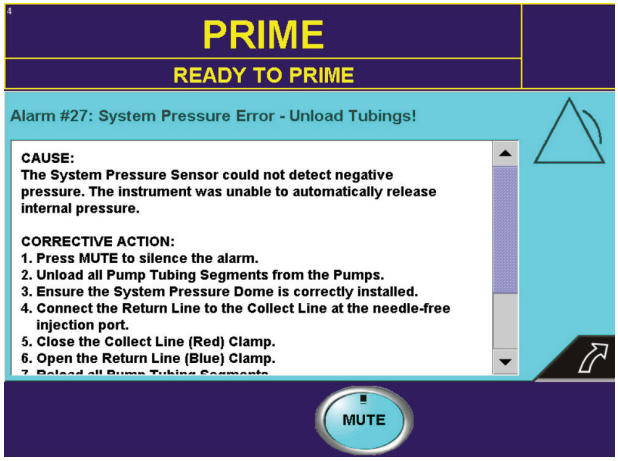


Figure 6-32: Alarm #27: System Pressure Error - Unload Tubings!

Alarm #28: PRIME 4!

CAUSE:

The System Pressure Dome is not installed properly.

The Pump Tubing Segment is not installed properly.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Unload all Pump Tubing Segments from the Pumps.
3. Check the installation of the System Pressure Dome.
4. Connect the Return Line to the Collect Line at the needle-free injection port.
5. Close the Collect Line (Red) Clamp.
6. Open the Return Line (Blue) Clamp.
7. Reload all Pump Tubing Segments.
8. Verify that all lines are free of kinks and obstructions.
9. Press RESET.
10. Press START to resume PRIME.
11. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- Failure to release internal kit pressure during alarm resolution, by unloading and reloading all pump tubing segments, before pressing START (to resume PRIME), may lead to subsequent alarms.
- To check the position of the indicated Pressure Dome, inspect placement on the Pressure Transducer. If proper installation cannot be confirmed, remove and reinstall Pressure Dome.
- For Corrective Actions 4-6 above, confirm that the Procedural Kit is configured as specified. If not, take the steps specified in each Corrective Action to configure the Procedural Kit correctly.

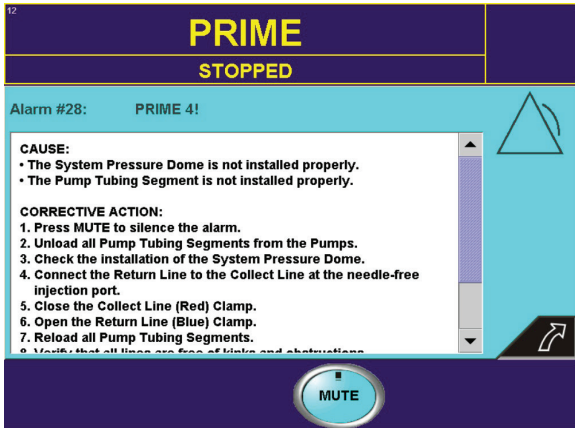


Figure 6-33: Alarm #28: PRIME 4! Alarming

Alarm #29: PRIME 5!

CAUSE:

The Centrifuge Bowl Lines are obstructed or are pinched in the door.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Open Centrifuge door and inspect tubing for kinks and obstructions.
3. Close Centrifuge door.
4. Verify that all lines are free of kinks and obstructions.
5. Press RESET.
6. Press START to resume PRIME.
7. If the alarm continues, contact Mallinckrodt for further assistance.

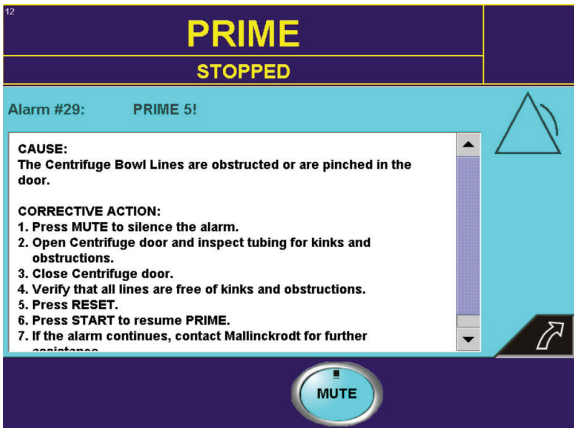


Figure 6-34: Alarm #29: PRIME 5! Alarming

Alarm #30: PRIME 6!

CAUSE:

The Centrifuge Bowl Lines are obstructed or are pinched in the door.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Open Centrifuge door and inspect tubing for kinks and obstructions.
3. Close Centrifuge door.
4. Verify that all lines are free of kinks and obstructions.
5. Press RESET.
6. Press START to resume PRIME.
7. If the alarm continues, contact Mallinckrodt for further assistance.

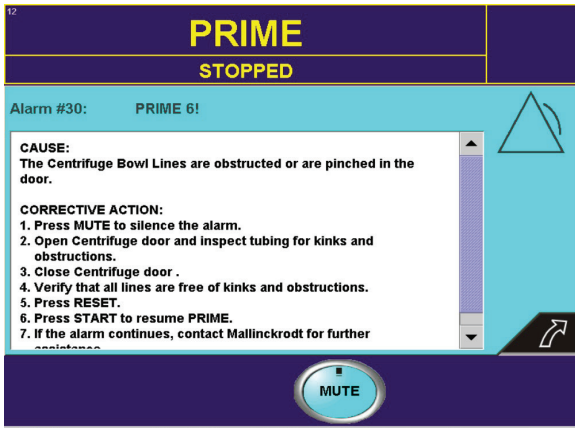


Figure 6-35: Alarm #30: PRIME 6! Alarming

Alarm #31: PRIME 7!

CAUSE:

The Bowl Optic Lens needs to be cleaned.

The Centrifuge Bowl is not installed properly.

The Hematocrit Sensor optical path is obstructed or needs to be cleaned.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Clean the Bowl Optic Lens.
3. Verify that the Centrifuge Bowl is installed properly.
4. Clean the Hematocrit Sensor optical path. Reseat the Hematocrit Cuvette.
5. Verify that all lines are free of kinks and obstructions.
6. Press RESET.
7. Press START to resume PRIME.
8. If the alarm continues, contact Mallinckrodt for further assistance.

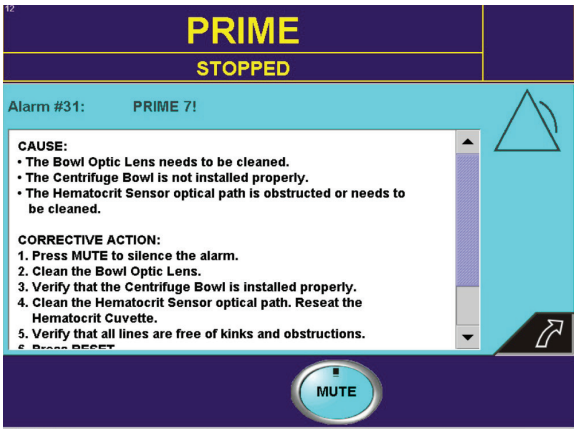


Figure 6-36: Alarm #31: PRIME 7! Alarming

Alarm #32: PRIME 8!

CAUSE:

The Collect Line is not installed properly into the Air Detector.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Reinstall the Collect Line into the Air Detector.
3. Press RESET.
4. Press START to continue.
5. If the alarm continues, contact Mallinckrodt for further assistance.

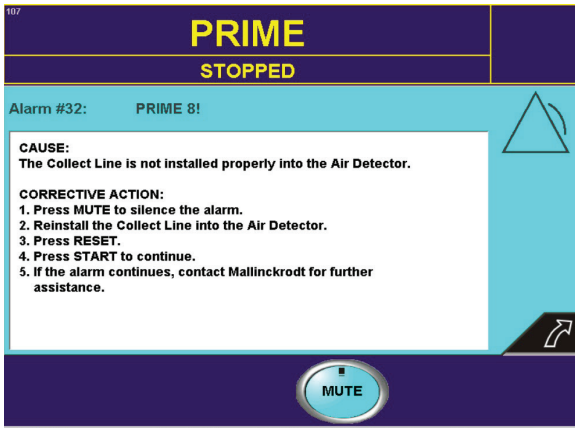


Figure 6-37: Alarm #32: PRIME 8! Alarming

Alarm #33: PAUSE Timeout!!

CAUSE:

The system PAUSED with the Centrifuge spinning for longer than 10 minutes.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Press RESET.
3. Press START to continue.
4. The system will re-prime the Centrifuge Bowl and then re-establish separation of the plasma/red blood cell interface before resuming operation.
5. If the alarm continues, contact Mallinckrodt for further assistance.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to *page 5-43* or *5-60* for complete instructions.

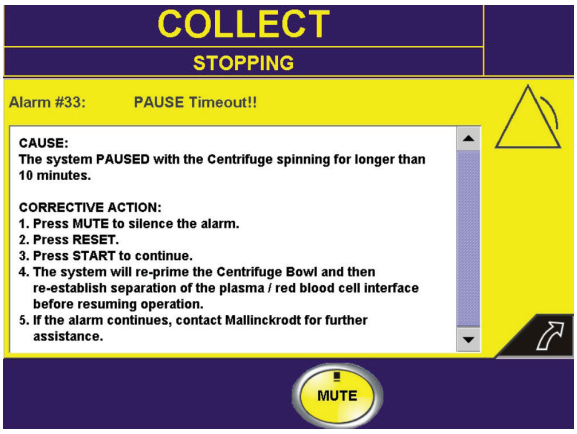


Figure 6-38: Alarm #33: PAUSE Timeout!! Alarming

Alarm #40: Is the Anticoagulant Bag Empty?!

CAUSE:

Anticoagulant delivery has not been detected during PRIME.

Prior to starting PRIME, the anticoagulant drip chamber was not primed.

The Anticoagulant Line is not installed properly into the Air Detector.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Verify that the anticoagulant is properly connected to the anticoagulant spike port.
3. Reinstall the Anticoagulant Line into the Air Detector.
4. Press RESET.
5. Press START to continue.
6. If the alarm continues, contact Mallinckrodt for further assistance.

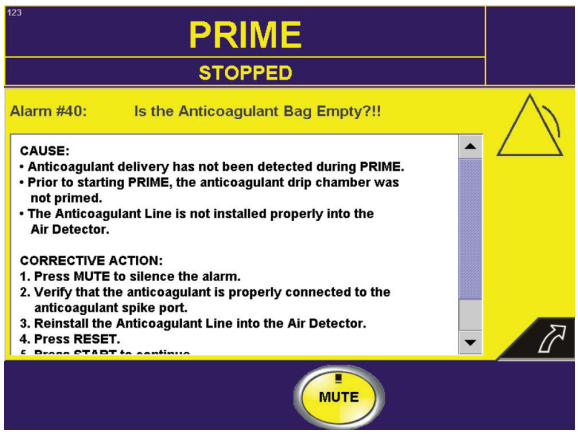


Figure 6-39: Alarm #40: Is the Anticoagulant Bag Empty?! Alarming

Alarm #41: Is the Saline Bag Empty?!

CAUSE:

The Saline delivery has not been detected during PRIME.

Prior to starting PRIME, the saline drip chamber was not primed.

The Patient Return Line is not installed properly into the Air Detector.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Verify that the saline is properly connected to the saline spike port.
3. Reinstall the Patient Return Line into the Air Detector.
4. Press RESET.
5. Press START to continue.
6. If the alarm continues, contact Mallinckrodt for further assistance.

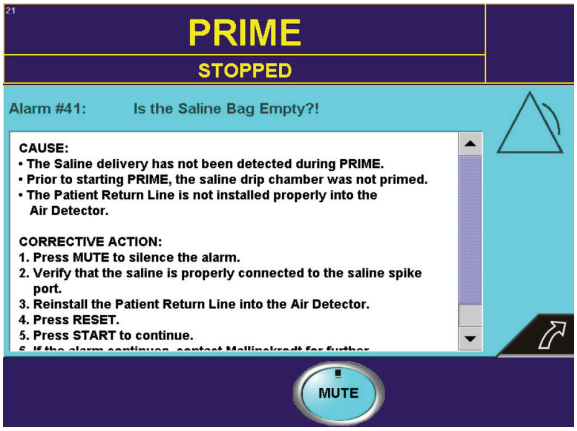


Figure 6-40: Alarm #41: Is the Saline Bag Empty?! Alarming

Alarm #42: PRIME 9!

CAUSE:

The Treatment Bag is not installed properly.

The Treatment Bag is hung on the wrong side.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Reinstall the Treatment Bag on the LEFT front load cell hook.
3. Press RESET.
4. Press START to continue.
5. If the alarm continues, contact Mallinckrodt for further assistance.

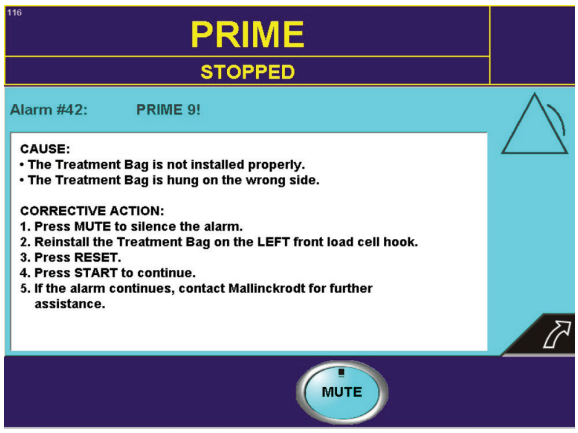


Figure 6-41: Alarm #42: PRIME 9! Alarming

Alarm #43: PRIME 10!

CAUSE:

The Return and Treatment Bags are not installed properly.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Reinstall the Return Bag on the RIGHT front load cell hook.
3. Reinstall the Treatment Bag on the LEFT front load cell hook.
4. Press RESET.
5. Press START to continue.
6. If the alarm continues, contact Mallinckrodt for further assistance.

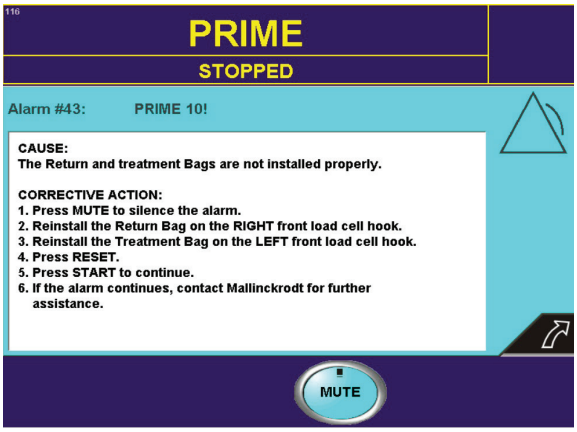


Figure 6-42: Alarm #43: PRIME 10! Alarming

Alarm #44: PRIME 11!

CAUSE:

An occlusion in the Photoactivation Module, Treatment Bag, or tubing.

Leakage in the Photoactivation Module, Treatment Bag, or tubing.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Check the Photoactivation Module, tubing, and bags to determine the possible source of occlusion or leakage.
3. Press RESET.
4. Press START to continue.
5. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- All THERAKOS™ CELLEX™ Photopheresis Procedural Kits are leak tested prior to sterilization. If a leak is detected during PRIME, do not attempt to re-prime the procedural kit.
- Save the defective procedural kit for return to manufacturer. Call Mallinckrodt to report the problem.

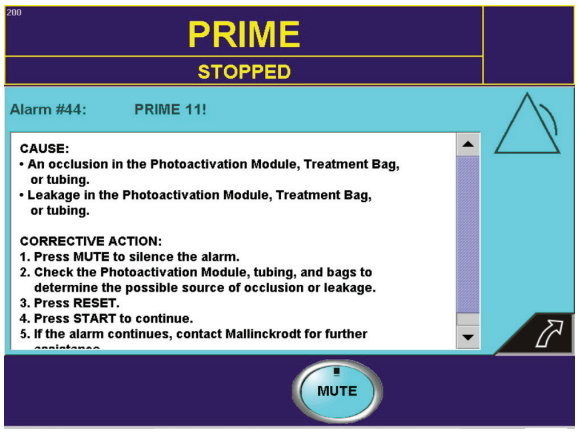


Figure 6-43: Alarm #44: PRIME 11! Alarming

Alarm #45: Red Blood Cell Pump Alarm!

CAUSE:

The Red Blood Cell Pump is not maintaining the position of the plasma/red blood cell interface correctly.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Check the Centrifuge Bowl to determine the position of the plasma/red blood cell interface.

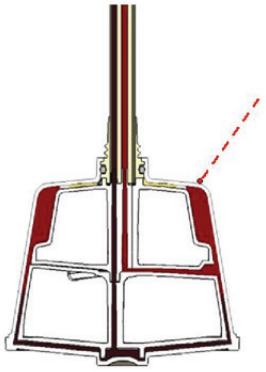


Figure 6-44: Interface Too High
Or

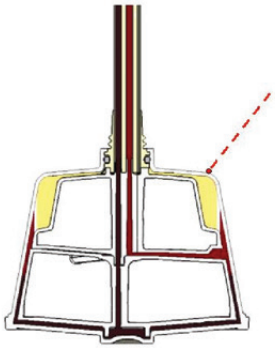


Figure 6-45: Interface Too Low

If the interface is too low:

a) Press SETUP.

b) Lower (decrease) the Bowl Optic Threshold Value by 10.

c) Press SAVE.

d) Press START.

e) Allow the system time to adjust. The interface should rise in the bowl to meet the laser.

f) If subsequent alarm occurs check the position of the plasma/red blood cell interface and if necessary, repeat steps a through e.

g) If the alarm continues, contact Mallinckrodt for further assistance.

If the interface is too high:

a) Press RESET.

b) Press STOP.

c) Press START to allow the system to purge the Centrifuge Bowl and reestablish the plasma/red blood cell interface.

3. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

After any centrifuge stop, the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl.

- To compensate, the Whole Blood Processed Target may be increased (via the SETUP screen) prior to pressing START to resume COLLECT.
- Instead of Stopping, consider proceeding immediately to BUFFY COAT to reduce risk of losing leukocytes collected to this point. (Refer to ***page 5-43*** or ***5-59*** for instruction)

The decision to STOP or to proceed immediately to BUFFY COAT requires clinical judgement based upon factors such as adequate patient access, current Whole Blood Processed Volume and patient condition.

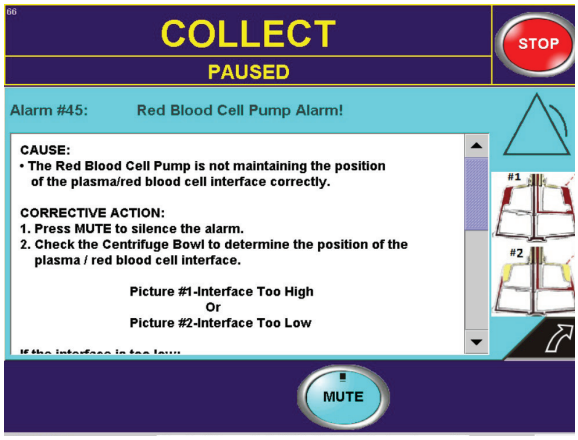


Figure 6-46: Alarm #45: Red Blood Cell Pump Alarm! Alarming

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

Alarm #47: Drive Tube Alarm!!

CAUSE:

The Drive Tube is not installed correctly into the Drive Tube Clamp.

The Drive Tube Latch is not closed properly.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Open the Centrifuge Chamber Door.
3. Reinstall the Centrifuge Bowl and the Drive Tube. Close the Drive Tube Latch.
4. Close the Centrifuge Chamber Door.
5. Press RESET.
6. Press START to continue the treatment.
7. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

Refer to ***SECTION 4: LOADING THE THERAKOS™ CELLEX™ PHOTOPHERESIS PROCEDURAL KIT*** for complete instructions on installing the Centrifuge Bowl.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

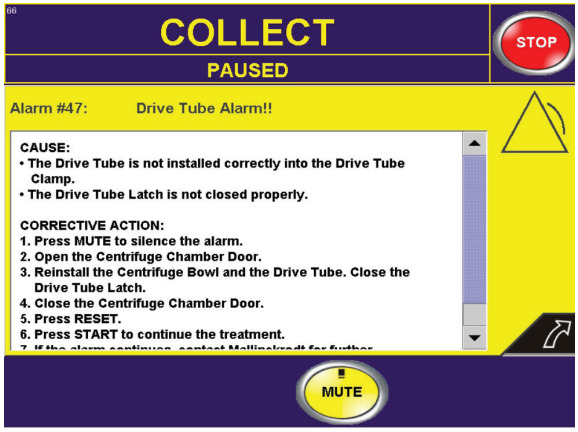


Figure 6-47: Alarm #47: Drive Tube Alarm!! Alarming

Alarm #48: Treatment Bag - Air Detected!!

CAUSE:

Air has been detected in the Treatment Bag Line.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Reinstall the Treatment Bag Line into the Air Detector.
3. Press RESET
4. Press START.
5. If the alarm continues, contact Mallinckrodt for assistance.

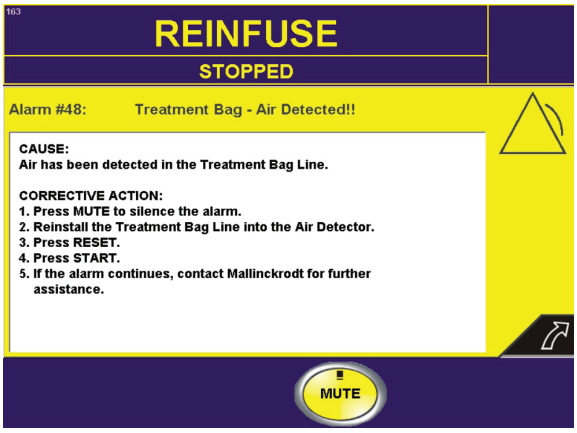


Figure 6-48: Alarm #48: Treatment Bag - Air Detected!! Alarming

Alarm #49: Return Bag - Air Detected!!

CAUSE:

Air has been detected in the Return Bag Line.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Reinstall the Return Bag Line into the Air Detector.
3. Press RESET.
4. Press START to continue.
5. If the alarm continues, contact Mallinckrodt for assistance.

NOTE:

Upon clearing the alarm and restarting return, approximately 1-2 mL will be advanced toward the pump tubing organizer before reactivating the Return Bag Air Detector.

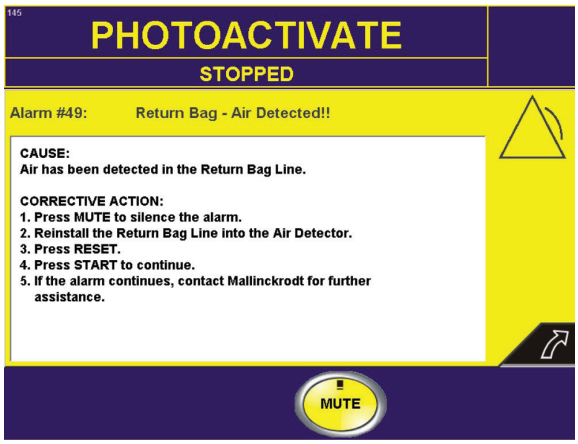


Figure 6-49: Alarm #49: Return Bag - Air Detected!! Alarming

Alarm #50: PRIME 12!

CAUSE:

The Return Line is not installed properly in the Air Detector.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Reinstall the Return Line into the Air Detector.
3. Press RESET.
4. Press START to continue.
5. If the alarm continues, contact Mallinckrodt for assistance.

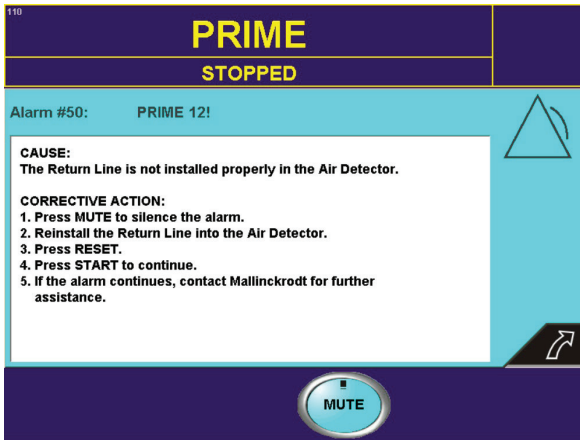


Figure 6-50: Alarm #50: PRIME 12! Alarming

Alarm #51: Centrifuge Chamber Temperature Alarm!!

CAUSE:

The temperature of the Centrifuge Chamber is over the preset threshold.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Consider inspecting the blood in the Return Bag and Centrifuge Bowl for hemolysis.
3. Before continuing treatment consider taking at least one of the following actions:
   a. Lower the room temperature.
   b. Reduce the centrifuge speed.
   c. Increase the flow rate.
   d. Lower the Whole Blood Processed in order to proceed to Buffy Coat Collect.
4. Press RESET.
5. Press START.
6. If the alarm continues, contact Mallinckrodt for further assistance.

WARNING:

Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to *page 5-43* or *5-60* for complete instructions.

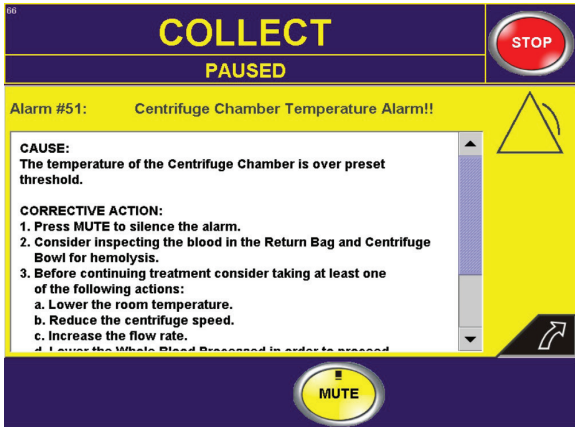


Figure 6-51: Alarm #51: Centrifuge Chamber Temperature Alarm!! Alarming

Alarm #52: Collect Line Air Detected!!

CAUSE:

Air has been detected in the Collect Line.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove air from the Collect Line.
3. Check the connections to determine the possible source of air.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- A small aliquot of air at the onset of COLLECT will be purged out of the Centrifuge Bowl as it is initially filled.
- Upon clearing the alarm and restarting collection, approximately 1-2 mL will be moved by the collect pump toward the centrifuge bowl before reactivating the collect line air detector.

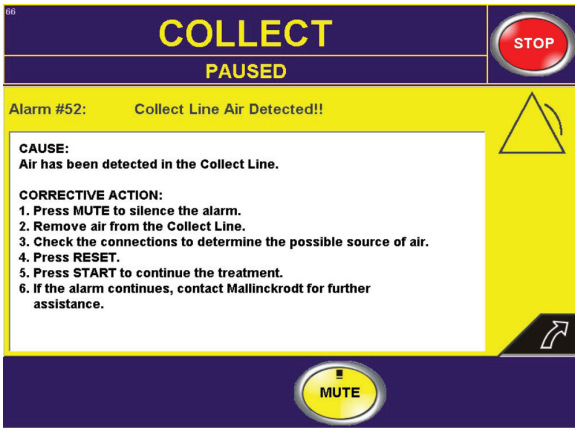


Figure 6-52: Alarm #52: Collect Line Air Detected!! Alarming

Alarm #53: Return Line Air Detected!!

CAUSE:

Air has been detected in the Return Line.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove air from the Return Line.
3. Check the connections to determine the possible source of air.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

NOTE:

- First disconnect your patient and then use a saline bolus to flush any air detected in the patient Return Line. Do not continue RETURNING until the source of the air has been documented and removed.

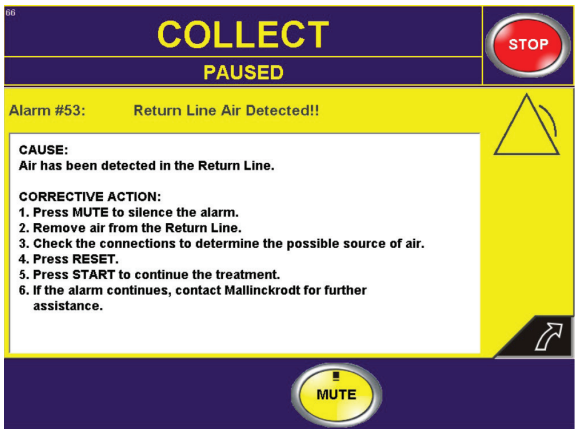


Figure 6-53: Alarm #53: Return Line Air Detected!! Alarming

Alarm #54: Anticoagulant Line Air Detected!!

CAUSE:

Air has been detected in the Anticoagulant Line.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove air from the Anticoagulant Line.
3. Check the connections to determine the possible source of air.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

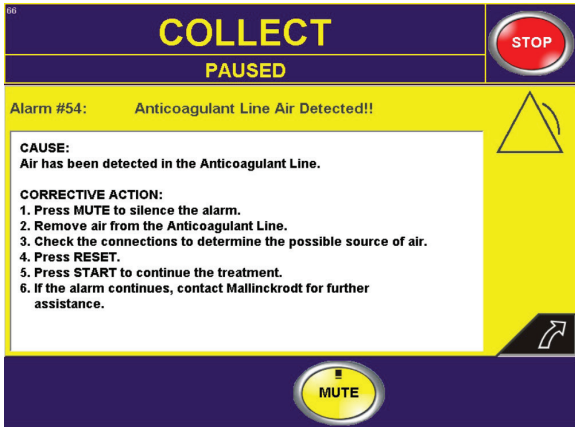


Figure 6-54: Alarm #54: Anticoagulant Line Air Detected!! Alarming

Alarm #55: Collect Pump (#1) Error!!

CAUSE:

The Collect Pump (#1) is rotating too slowly or the head is jammed.

The Collect Pump (#1) is rotating too fast.

The Collect Pump (#1) sensor has detected multiple pump rotations while the pump is OFF.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove the obstruction from the Collect Pump (#1) head or stop manual movement of the pump.
3. Inspect Collect Pump (#1) tubing segment for possible damage.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

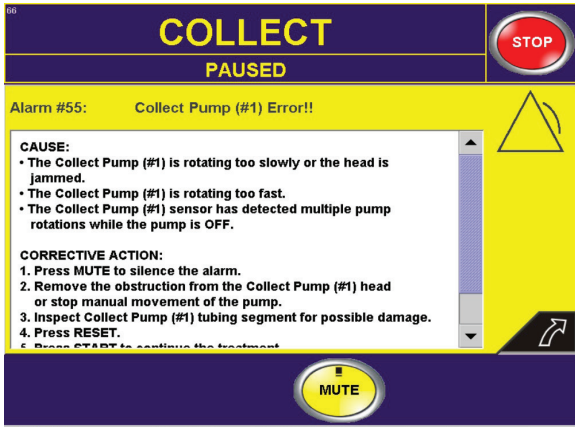


Figure 6-55: Alarm #55: Collect Pump (#1) Error!! Alarming

Alarm #56: Red Cell Pump (#2) Error!!

CAUSE:

The Red Cell Pump (#2) is rotating too slowly or the head is jammed.

The Red Cell Pump (#2) is rotating too fast.

The Red Cell Pump (#2) sensor has detected multiple pump rotations while the pump is OFF.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove the obstruction from the Red Cell Pump (#2) head or stop manual movement of the pump.
3. Inspect Red Cell Pump (#2) tubing segment for possible damage.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

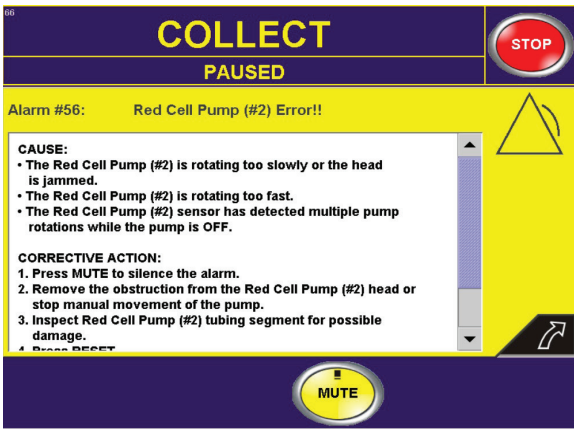


Figure 6-56: Alarm #56: Red Cell Pump (#2) Error!! Alarming

Alarm #57: Return Pump (#3) Error!!

CAUSE:

The Return Pump (#3) is rotating too slowly or the head is jammed.

The Return Pump (#3) is rotating too fast.

The Return Pump (#3) sensor has detected multiple pump rotations while the pump is OFF.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove the obstruction from the Return Pump (#3) head or stop manual movement of the pump.
3. Inspect Return Pump (#3) tubing segment for possible damage.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

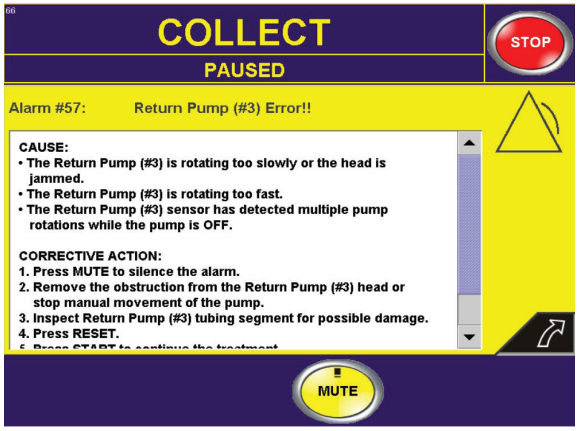


Figure 6-57: Alarm #57: Return Pump (#3) Error!! Alarming

Alarm #58: Recirculation Pump (#4) Error!!

CAUSE:

The Recirculation Pump (#4) is rotating too slowly or the head is jammed.

The Recirculation Pump (#4) is rotating too fast.

The Recirculation Pump (#4) sensor has detected multiple pump rotations while the pump is OFF.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove the obstruction from the Recirculation Pump (#4) head or stop manual movement of the pump.
3. Inspect Recirculation Pump (#4) tubing segment for possible damage.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

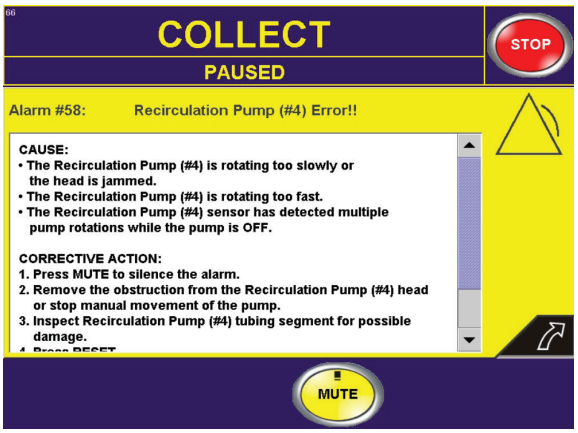


Figure 6-58: Alarm #58: Recirculation Pump (#4) Error!! Alarming

Alarm #59: A/C Pump (#5) Error!!

CAUSE:

- The A/C Pump (#5) is rotating too slowly or the head is jammed.
- The A/C Pump (#5) is rotating too fast.
- The A/C Pump (#5) sensor has detected multiple pump rotations while the pump is OFF.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Remove the obstruction from the A/C Pump (#5) head or stop manual movement of the pump.
3. Inspect A/C Pump (#5) tubing segment for possible damage.
4. Press RESET.
5. Press START to continue the treatment.
6. If the alarm continues, contact Mallinckrodt for further assistance.

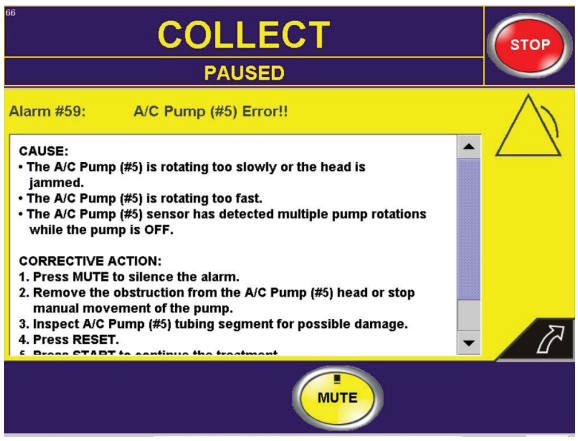


Figure 6-59: Alarm #59: A/C Pump (#5) Error!! Alarming

Alarm #60: Residual Pressure Detected in Kit!

CAUSE:

An unexpected internal pressure has been detected in the kit.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Verify the Collect Line (RED) Clamp is at pump deck height.
3. Open the Collect Line (RED) Clamp.
4. Press RESET
5. Press PRIME and wait for all fluid flow to stop exiting the collect line plus an additional 2 seconds-you will hear the instrument beep.
6. Close the Collect Line (RED) Clamp.
7. If the alarm continues, contact Mallinckrodt for further assistance.

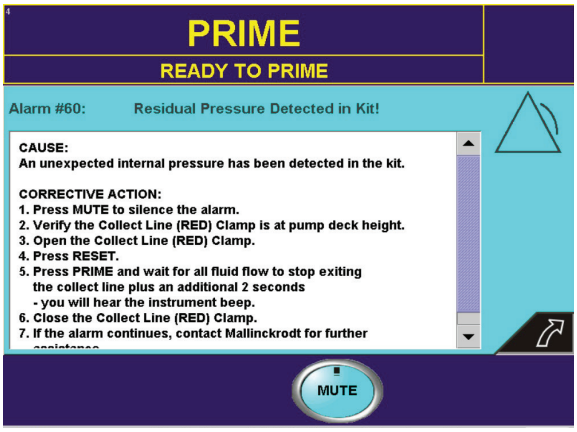


Figure 6-60: Alarm #60: Residual Pressure Detected in Kit!

NOTE:
The Alarm #60: Residual Pressure Detected in Kit! is triggered when the Collect Line pressure is beyond +/- 40 mmHg at the end of PRIME ACCESS. The height of the Collect Line (Red) clamp will influence the line pressure. Please refer to ***page 5-12*** for complete instructions.

Alarm #62: Collect Pressure Limit!

CAUSE:

The Collect Line Pressure Sensor has failed to reach its preset limit.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Ensure the Collect Line Pressure Dome is correctly installed.
3. Press RESET.
4. Press START to resume PRIME.
5. If the alarm continues, contact Mallinckrodt for further assistance.

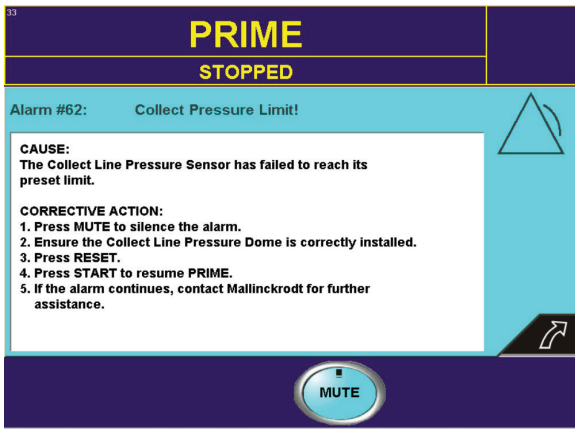


Figure 6-61: Alarm #62: Collect Pressure Limit!

NOTE:
The Alarm #62: Collect Pressure Limit! is triggered by the same cause as Alarm #22: Collect Pressure Limit - Unload Tubings!. In Alarm #62: Collect Pressure Limit! the instrument has been able to automatically release the internal pressure built up during testing, therefore it is NOT necessary to manually unload pump tubing segments.

Alarm #63: Return Pressure Limit!

CAUSE:

The Return Line Pressure Sensor has failed to reach its preset limit.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Ensure the Return Line Pressure Dome is correctly installed.
3. Press RESET.
4. Press START to resume PRIME.
5. If the alarm continues, contact Mallinckrodt for further assistance.

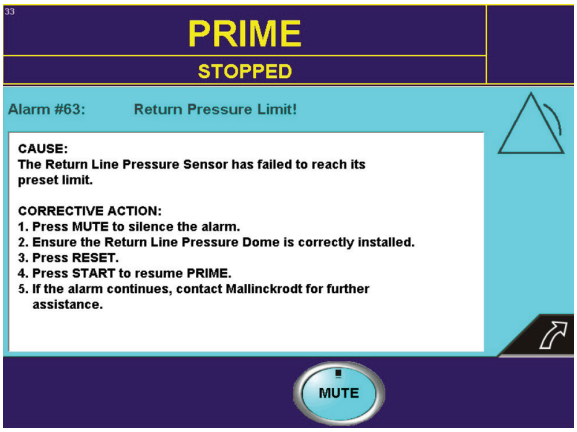


Figure 6-62: Alarm #63: Return Pressure Limit!

NOTE:
The Alarm #63: Return Pressure Limit! is triggered by the same cause as Alarm #23: Return Pressure Limit - Unload Tubings!. In Alarm #63: Return Pressure Limit! the instrument has been able to automatically release the internal pressure built up during testing, therefore it is NOT necessary to manually unload pump tubing segments.

Alarm #65: Return Pressure Error!

CAUSE:

The Return Line Pressure Sensor could not detect negative pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Ensure the Return Line Pressure Dome is correctly installed.
3. Connect the Return Line to the Collect Line at the needle-free injection port.
4. Close the Collect Line (Red) Clamp.
5. Open the Return Line (Blue) Clamp.
6. Verify that all lines are free of kinks and obstructions.
7. Press RESET.
8. Press START to resume PRIME.
9. If the alarm continues, contact Mallinckrodt for further assistance.

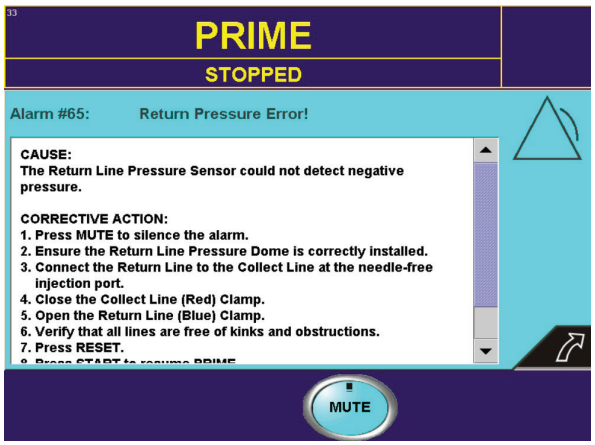


Figure 6-63: Alarm #65: Return Pressure Error!

NOTE:

- The Alarm #65: Return Pressure Error! is triggered by the same cause as Alarm #25: Return Pressure Error - Unload Tubings!. In Alarm #65: Return Pressure Error! the instrument has been able to automatically release the internal pressure built up during testing, therefore it is NOT necessary to manually unload pump tubing segments.
- To ensure the indicated Pressure Dome is correctly installed, inspect placement on the Pressure Transducer. If proper installation cannot be confirmed, remove and reinstall Pressure Dome.
- For Corrective Actions 3-5 above, confirm that the Procedural Kit is configured as specified. If not, take the steps specified in each Corrective Action to configure the Procedural Kit correctly.

Alarm #66: Collect Pressure Error!

CAUSE:

The Collect Line Pressure Sensor could not detect negative pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Ensure the Collect Line Pressure Dome is correctly installed.
3. Connect the Return Line to the Collect Line at the needle-free injection port.
4. Close the Collect Line (Red) Clamp.
5. Open the Return Line (Blue) Clamp.
6. Verify that all lines are free of kinks and obstructions.
7. Press RESET.
8. Press START to resume PRIME.
9. If the alarm continues, contact Mallinckrodt for further assistance.

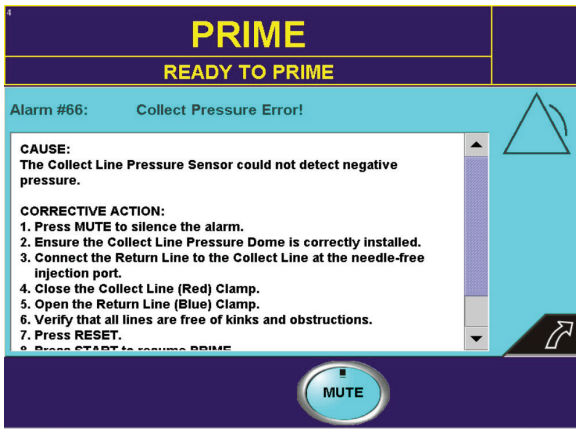


Figure 6-64: Alarm #66: Collect Pressure Error!

NOTE:

- The Alarm #66: Collect Pressure Error! is triggered by the same cause as Alarm #26: Collect Pressure Error - Unload Tubings!. In Alarm #66: Collect Pressure Error! the instrument has been able to automatically release the internal pressure built up during testing, therefore it is NOT necessary to manually unload pump tubing segments.
- To ensure the indicated Pressure Dome is correctly installed, inspect placement on the Pressure Transducer. If proper installation cannot be confirmed, remove and reinstall Pressure Dome.
- For Corrective Actions 3-5 above, confirm that the Procedural Kit is configured as specified. If not, take the steps specified in each Corrective Action to configure the Procedural Kit correctly

Alarm #67: System Pressure Error!

CAUSE:

The System Pressure Sensor could not detect negative pressure.

CORRECTIVE ACTION:

1. Press MUTE to silence the alarm.
2. Ensure the System Pressure Dome is correctly installed.
3. Connect the Return Line to the Collect Line at the needle-free injection port.
4. Close the Collect Line (Red) Clamp.
5. Open the Return Line (Blue) Clamp.
6. Verify that all lines are free of kinks and obstructions.
7. Press RESET.
8. Press START to resume PRIME.
9. If the alarm continues, contact Mallinckrodt for further assistance.

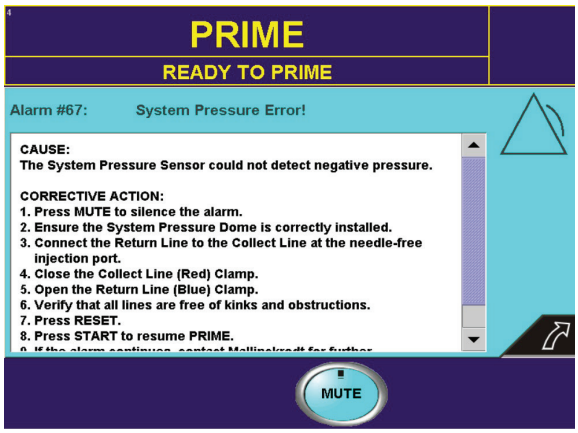


Figure 6-65: Alarm #67: System Pressure Error!

NOTE:

- The Alarm #67: System Pressure Error! is triggered by the same cause as Alarm #27: System Pressure Error - Unload Tubings!. In Alarm #67: System Pressure Error! the instrument has been able to automatically release the internal pressure built up during testing, therefore it is NOT necessary to manually unload pump tubing segments.
- To ensure the indicated Pressure Dome is correctly installed, inspect placement on the Pressure Transducer. If proper installation cannot be confirmed, remove and reinstall Pressure Dome.
- For Corrective Actions 3-5 above, confirm that the Procedural Kit is configured as specified. If not, take the steps specified in each Corrective Action to configure the Procedural Kit correctly.

Information Signals (Pop-ups and Icons)

Warning! 9 V battery is low CLOSE	The 9 V battery voltage is below an acceptable value and should be replaced. Operator must acknowledge message by pressing CLOSE button.
	**BATTERY ICON:** The 9 V battery voltage is below an acceptable value and should be replaced.
Information! New Treatment SETUP Entered	The system has stored the new treatment settings.
Information! New Date & Time Entered	The system has stored the new date and time settings.
Information! Water Treatment	The Smart Card inserted has been coded as a training card. This procedure should be reserved only for training!
Warning! Lamp Output Reduced CLOSE	The system has detected a failure of some of the UVA lamps during the treatment. At least 2/3 of the lamps must work or a Lamp Failure Alarm will be generated. This message indicates that the energy delivered to the cells may be reduced by up to 1/3. The Lamps should be replaced prior to the next treatment. Operator must acknowledge message by pressing CLOSE button.
Warning! Please Set Clock CLOSE	This message indicates that the current clock setting is invalid and should be reset. Operator must acknowledge message by pressing CLOSE button.
Warning! Lamp Life Low CLOSE	The Lamp Life Remaining is below 10 hours. Please reorder a new lamp and install it as soon as possible. Operator must acknowledge message by pressing CLOSE button.
Do you wish to end this treatment and install a new kit? YES NO	Allows the user to initiate a new treatment regardless of whether the last treatment was completed. If the user selects YES a confirmation message will appear. Confirming this message will terminate the existing treatment process and initiate a new treatment at the READY TO PRIME screen. This message is displayed for 30 seconds upon power up. If a selection is not made within 30 seconds, NO will automatically be selected.
Warning! Smart Card is Full CLOSE	The Smart Card event log is full. This message indicates that event logging is no longer possible.
CANCEL Do you want to Save the Changes you Made? YES NO	User has selected CANCEL after making changes while in setup mode. This message asks to confirm the loss of these changes.
Information! Single Needle Configuration	User has selected 1-needle configuration.

	**AUTOMATIC FLOW CONTROL DISABLED ICON:** The operator has disabled the Automatic Flow Control.
	**BLOOD PRIME FEATURE ENABLED ICON:** The operator has enabled the Blood Prime Feature. The value displayed within the icon is the operator set Rinseback Volume.
Information! **Double Needle Configuration**	User has selected 2-needle configuration.
CONFIRM **Are you sure?** **YES NO**	This message is displayed whenever a button confirmation from the user is required.
Warning! **Centrifuge Will Stop in 2 Minutes**	This message is displayed when the system has been paused for 8 minutes and is accompanied by an audible beep. Press START to resume, or select STOP before 10 minutes expires to avoid generating a PAUSE Timeout Alarm.
CONFIRM **ABORT TREATMENT** **Without Blood Return To Patient** **ABORT CANCEL**	Confirm message for ABORT button. Pressing the ABORT button will end the treatment without returning the patient's blood. Press CANCEL to return to the previous screen.
CONFIRM **END TREATMENT** **And Return Blood To Patient** **END TX CANCEL**	Confirm message for END TX button. Pressing END TX will end the treatment and return the patient's blood. Press CANCEL to return to previous screen.
Communication **Watchdog Time-out!**	This message indicates that there is no communication between the display and the main controller.
Information! **Inject X.X mL of Methoxsalen (20 micrograms/mL) into Treatment Bag** **CLOSE**	This message displays the calculated dose of Methoxsalen (20 micrograms/mL). The operator must select CLOSE to continue.

	**TEMPERATURE ICON:** Ensure that the room temperature does not exceed 27.5°C (81°F) during the treatment. A flashing Temperature Icon will appear in the title line of the Operator Interface for one of the following reasons: 1) "Alarm #51: Centrifuge Chamber Temperature Alarm !" will occur if the centrifuge temperature reaches 43°C (109.4°F). After this alarm, once the treatment is resumed the temperature icon will appear and flash until the centrifuge chamber temperature is reduced below the threshold. In addition, an intermittent audio beep will sound. After action is taken to reduce temperature it may take several minutes for the system to respond and the temperature icon to disappear. If the centrifuge chamber temperature continues to rise the alarm will re-occur every additional 2°C above the initial threshold. 2) Ambient air is used to cool the Photoactivation Chamber during PHOTOACTIVATE. "Alarm #2: TEMPERATURE" occurs when the temperature sensor in the Photoactivation Chamber reaches 43°C (109.4°F). Before reaching alarm conditions, a flashing temperature icon will appear. In addition, an intermittent audio beep will sound. The appearance of the temperature icon indicates that the Photoactivation Chamber temperature has increased to 39°C (102.2°F). When the temperature icon appears take measures to lower the room temperature to prevent reaching temperature alarm conditions during PHOTOACTIVATE.
Information! **Open Centrifuge Chamber Door.** **Check the Drive Tube Installation.** **Inspect entire kit for leaks.** **CLOSE**	This message indicates that the operator should inspect the drive tube installation before proceeding. The operator should confirm that the drive tube bearings are secure in the bearing retainers and that the kit has no leaks.
Information! **Please Open The Centrifuge Door.** **CLOSE**	This message indicates that the operator should open the Centrifuge Chamber Door.
Set Fluid Balance to zero	The user confirms the setting of patient fluid balance to zero.

The THERAKOS™ CELLEX™ Photopheresis System incorporates additional non-alarm visual and/or audible signals to keep the operator informed throughout the prime and treatment process. The visual and audible presentation of all Information Signals are provided in the table below.

Information Signal	Visual	Audible
• Information! New Treatment SETUP Entered • Information! New Date & Time Entered • Communication Watchdog Time-out! • Warning! Lamp Output Reduced • Information! Single Needle Configuration • Information! Double Needle Configuration • Information! Please Open the Centrifuge Chamber Door. Check the Drive Tube Installation. Inspect entire kit for leaks. • Warning! Smart Card is Full • Do you wish to end this treatment and install a new kit? • Information! Inject X.X mL Methoxsalen (XX micrograms/mL) into Treatment Bag • CONFIRM Are you sure? • CANCEL Do you want to Save the Changes you Made? • CONFIRM ABORT TREATMENT Without Blood Return To Patient • CONFIRM END TREATMENT And Return Blood To Patient • CONFIRM Set Fluid Balance to 0? • Information! Please Open The Centrifuge Door	Pop-up	None
• Warning! 9V Battery is Low • Information! Water Treatment • Warning! Lamp Life Low • Warning! Please Set Clock • CONFIRM Set Fluid Balance to 0? • Warning! Centrifuge Will Stop in 2 Minutes	Pop-up	1 beep, does not repeat
• Battery icon • Temperature icon	Icon	1 beep, repeats every 60 seconds while condition present
• Automatic Flow Control Disabled Icon • Blood Prime Feature Enabled Icon	Icon	None

Information Signal	Visual	Audible
• Treatment Aborted. Clamp Access Lines • Treatment Completed. Clamp Access Lines	None	1 beep, repeats every 16 seconds
• Smart Card inserted properly • Drive Tube Latch Opened • Drive Tube Latch Closed • Prime is Complete, Ready to Prime Access • Prime Access Complete • Double Needle Mode Selected before Treatment Start • Double Needle Begin Drawing/Returning • Double Needle Begin Collecting Buffy Coat • Single Needle Mode Selected before Treatment Start • Single Needle Begin Drawing • Single Needle Return Bag Volume Threshold Met, Begin Return • Single Needle Begin Collecting Buffy Coat • Ready to Photoactivate • Start of Reinfusion from Treatment Bag • Switch from Reinfusion of Treatment Bag to Reinfusion of Return Bag when Blood Prime Feature is not Enabled • Switch from Reinfusion of Treatment Bag to Reinfusion of Rinseback Volume when Blood Prime Feature is Enabled • Blood Prime Feature Rinseback Complete	None	1 beep, does not repeat

SECTION 7: MAINTAINING THE THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEM

General maintenance procedures described below are to be performed only by fully trained personnel. Call Mallinckrodt once a year to schedule complete Preventative Maintenance servicing. Please refer to the last page of this manual for phone numbers.

WARNING:

Electric Shock Hazard. Turn OFF and unplug the THERAKOS™ CELLEX™ Photopheresis System before servicing. Never perform maintenance on the THERAKOS™ CELLEX™ Photopheresis System during a treatment.

CAUTION:

Do not allow cleaning solutions to come into contact with any of the automatic sensors. Gently clean all sensors with warm water only.

NOTE:

To retain valid warranty coverage, Preventative Maintenance Service on the instrument (for example: the Hematocrit Sensor, Load Cells, Centrifuge Bowl Optic Sensor (Laser) and Power Supply) must be performed only by Mallinckrodt trained personnel.

Recommended Cleaning and Maintenance Schedule

Mallinckrodt recommends that you keep a schedule of maintenance and cleaning for your THERAKOS™ CELLEX™ Photopheresis System.

Procedure	After Each Use	As Needed	Weekly	Quarterly	Annually
Cleaning					
System Exterior	•	•			
Photoactivation Chamber Door		•			
Centrifuge Chamber	Daily		•		
Air Detectors		•		•	
Pressure Sensors		•		•	
Hematocrit Sensor		•		•	
Bowl Optic Lens	Daily	•		•	
Leak Detector (Centrifuge) (with White Vinegar)		•		•	
Mallinckrodt Service					•

Table 1: Cleaning and Maintenance Schedule

Cleaning

Supplies

The following supplies are needed for cleaning:

- Mild soap and water solution
- Warm water
- Lint-free cloths for cleaning and drying
- Cotton swabs
- Center approved biohazard wipes
- White vinegar
- 1:10 dilution of household bleach or a disinfectant wipe suitable for blood decontamination approved for use by your institution's Infection Control Plan
- Isopropyl Alcohol

NOTE:

Household bleach is a 5% solution of sodium hypochlorite. A 1:10 dilution equals 1 part bleach added to 9 parts water.

CAUTION:

- Do not allow cleaning solutions to come in contact with the air detectors.
- For optimal performance, the Bowl Optic Sensor Lens must be clean and clear. A dirty or clouded lens on the Bowl Optic Sensor could interfere with its proper function.

Air Detectors

1. Gently wash the pathways of the detector with warm water and a moist cotton swab or a lint-free cloth.
2. Dry thoroughly.
3. Clean the outside of the detector with a mild soap and water solution. A 1:10 bleach solution or an approved disinfectant wipe may be used if necessary.

Bowl Optic Lens

1. Use a cotton swab dipped in isopropyl alcohol to clean the Bowl Optic Sensor lens, followed by a clean, lint free cloth moistened with water.
2. Dry the lens with a clean, lint-free cloth and make sure the surface of the Bowl Optic Sensor lens is clean and streak free.

Centrifuge Leak Detector

1. As needed, or quarterly, dampen a non-abrasive towel with white vinegar and gently clean the Centrifuge Leak Detector.
2. Air dry before using.

Centrifuge Chamber

CAUTION:
Do not allow corrosive/abrasive solutions to come in contact with the Bowl Optic Lens.

Daily, to prevent the build up of bearing grease that may lead to a false positive Alarm: Leak Detected (Centrifuge), clean the inside wall of the Centrifuge Chamber.

1. Turn the Power Switch ON. Open the Centrifuge Chamber Door.
2. Turn the Power Switch OFF and disconnect the power cord from the wall outlet.
3. Spray cleaning solution against the wall of the Centrifuge Chamber avoiding the Bowl Optic Lens. Or, use a center approved biohazard wipe. Wipe the inside chamber including the Leak Detector and viewing window. Use a clear water moisten non-abrasive towel to rinse the Leak Detector and viewing window. Allow Leak Detector to dry overnight.
4. Inspect the Bowl Optic Lens. If necessary, carefully wipe the Bowl Optic Lens.

External Instrument

Clean the THERAKOS™ CELLEX™ Photopheresis System after each treatment and as needed with warm soapy water and a clean damp cloth. A 1:10 bleach solution or an approved disinfectant wipe may be used to disinfect the instrument when needed.

CAUTION:

- The used THERAKOS™ CELLEX™ Photopheresis Procedural Kit and any spills should be considered biologically contaminated. When handling the contaminated procedural kit, or cleaning up any blood spills on the instrument, follow your institutions specific policy for biohazard precautions and hazardous waste disposal.

Hematocrit Sensor

CAUTION:
Do not allow corrosive/abrasive solutions to come in contact with the Hematocrit Sensor.

1. Gently wash the pathways of the sensor with warm water and a moist cotton swab or a lint-free cloth.
2. Dry thoroughly .
3. Clean the outside of the sensor with a mild soap and water solution. A 1:10 bleach solution or an approved disinfectant wipe may be used if necessary.

Pressure Transducers

CAUTION:
Never poke or puncture the center pinhole opening of any pressure transducer.

1. Gently wash only the surface of all pressure transducers with warm water and a moist lint-free cloth. *See Figure 3-5b: Power Switch Close-Up on page 3-6* for the location of the Collect, Return, and System Pressure Transducers.
2. Dry thoroughly.

Operator Interface

1. Clean the Operator Interface screen as needed using a mild soap and warm water solution on a dampened lint-free cloth. Avoid large amounts of water.
2. Dry with a lint-free cloth.

NOTE:

- Avoid glass cleaning agents. These products tend to smear the screen and decrease visual clarity.
- Disinfect with a 1:10 bleach solution or an approved disinfectant wipe only if a blood splash has occurred. Allow disinfectant to dry and then re-wash the screen with clear water to remove any residue. Dry with a lint-free cloth.

Cleaning a Fluid Spill in the Centrifuge Chamber

CAUTION:
When cleaning the Centrifuge Chamber, ensure that the cleaning solution does not come in contact with the Bowl Optic Lens. If this should occur, rinse the lens with clear water and dry it so that the lens does not cloud.

1. Turn the Power ON. Open the Centrifuge Chamber Door.
2. Turn the Power OFF and disconnect the power cord from the wall outlet.
3. Wipe away as much blood as possible with gauze pads.
4. Spray cleaning solution against the wall of the Centrifuge Chamber avoiding the Bowl Optic Lens. Wipe the chamber. Follow with a clear water rinse.
5. Wash inside the Centrifuge Chamber Door with a cloth moistened with cleaning solution.
6. Wash the Centrifuge Frame with a cloth moistened with cleaning solution.
7. Dry all surfaces with a lint-free cloth.

Detachable Parts and Accessories

Accessories

See the last page of this manual for part numbers.

Power Cord

Should the Power Cord be lost or damaged please refer to the last page of this manual for a list of replacement part numbers and call Mallinckrodt to report the suspected cause of damage.

Disposal of the Instrument and Its Components

In the event that the THERAKOS™ CELLEX™ Photopheresis System or its components including batteries require disposal, please contact the Mallinckrodt Service Manager for instructions. Refer to phone numbers listed on the last page of this manual.

Power Failure Alarm Battery

The power failure alarm battery is continuously monitored when the system is powered ON. A Low Battery information signal is displayed at power ON if the battery voltage is too low. During treatment, a flashing battery icon and an alarm chirp will be displayed/heard if the voltage is too low.

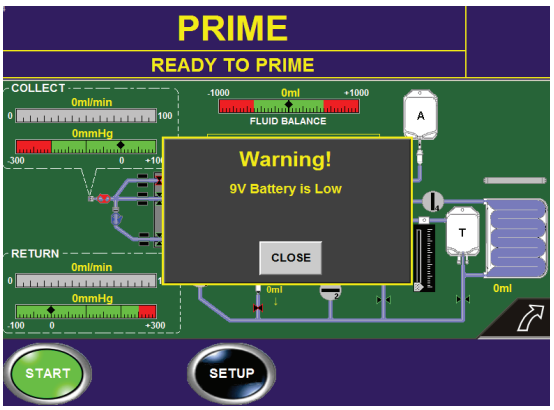


Figure 7-1a: 9 V Battery Low Warning

Figure 7-1b: Changing the 9 V DC Battery

Battery Change

NOTE:

- Only trained personnel should replace the 9 V DC Battery.
  - The battery is located on the front lower left of the instrument as you face it, behind a small door.
  - Replace annually or as needed.
- Remove battery if instrument is idle for three months or longer; replace prior to use.

1. Turn power OFF before changing the battery.
2. Using a flat head screwdriver, turn the battery cover screw. The bottom screw does not need to be unscrewed to access the battery.
3. Rotate the battery cover to the side to replace the battery. Use only a 9V DC battery.

Replacing the THERAKOS™ CELLEX™ Light Assembly

The light assembly is packaged as a single set of 18 lamps. The light assembly is designed for 150 hours of use. The THERAKOS™ CELLEX™ Photopheresis System automatically records the number of hours of use. The remaining lamp life is displayed throughout the treatment on the Treatment Summary text screen.

It is recommended that the THERAKOS™ CELLEX™ Light Assembly be replaced when the hours remaining are less than or equal to 10. Keep the old lamp in case a new lamp set fails.

Figure 7-2a: Light Assembly Back

Figure 7-2b: Light Assembly Front

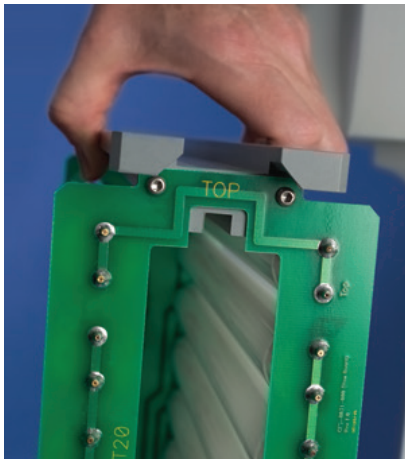


Figure 7-2c: Light Assembly Front: Close-up

WARNING:

- The calculated dose of UVA light energy will not be delivered if the light assembly is changed after the calculation of photoactivation MINUTES REMAINING is displayed.
- It is recommended that the full PHOTOACTIVATE time be completed during every treatment. The calculated dose of UVA light energy will not be delivered if PHOTOACTIVATE is stopped for any reason before the photoactivation MINUTES REMAINING is equal to 00.00 (minutes : seconds).

CAUTION:

- Always change an aged THERAKOS™ CELLEX™ Light Assembly prior to starting a treatment.
- Turn the power OFF and unplug the instrument prior to changing the THERAKOS™ CELLEX™ Light Assembly.
- Never change the THERAKOS™ CELLEX™ Light Assembly during a treatment if the photoactivation MINUTES REMAINING has already been calculated.
- Do not attempt to modify the THERAKOS™ CELLEX™ Photopheresis System or the THERAKOS™ CELLEX™ Light Assembly in any way.
- Changing the THERAKOS™ CELLEX™ Light Assembly with the power ON is UNSAFE and WILL NOT reset the number of lamp hours remaining to 150 hours.

1. Turn the power OFF and unplug the instrument.
2. Using the flat head screwdriver provided (or a slotted screwdriver) loosen the three screws sufficiently from the Photoactivation Chamber Cover Assembly and then remove the cover.

NOTE:

- There are 3 screws on the the Photoactivation Module Door assembly.
- Two screws are above the door.
- One screw is behind the door.
- Turn each screw left to loosen and right to tighten.

3. Using two hands, pull the light assembly out without touching the bulbs.
4. Install the new assembly by aligning the lamp set channel with the slot on the instrument and pushing the lamp set all the way into the instrument by the grey handles (without touching the bulbs).
5. Replace the cover and reinstall the three cover screws.
6. Plug power cord back in and turn instrument power ON.

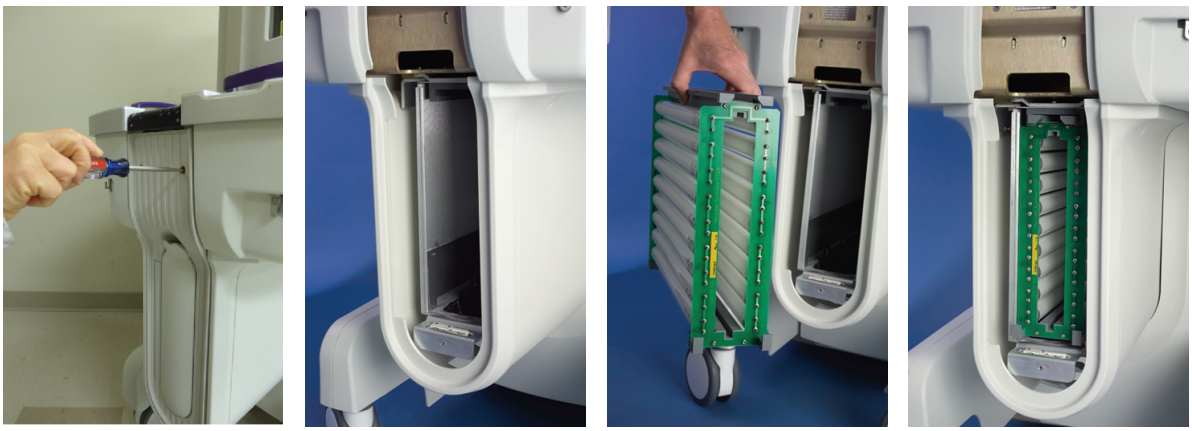


Figure 7-3: Changing the THERAKOS™ CELLEX™ Light Assembly

SECTION 8: SPECIFICATIONS

Caution

CAUTION:

Moving the CELLEX™ System instrument: The CELLEX™ System unit may tip forward if pushed from the rear when encountering an obstruction (door threshold, cable, elevator gap) of 10 mm vertical height or more. Use the rear handle to PULL the unit across the obstruction, or use a 10° or less ramped threshold cover to allow the unit to ride over the obstruction.

Instrument Specifications

CENTRIFUGE	Motor Brushless DC, with hall effect feedback Control System Closed loop with continuous speed/safety monitor Safety Interlock Mechanical/electrical door latch interlock Humidity/Fluid Leak Detector to detect fluid on the sensor surface Accuracy—Greater than 0.5 mL of blood in contact with sensor. Speed Frame: 0–2400 Revolutions per Minute; +5%/-10% during speed transition; +/-2% when at constant speed Centrifuge Bowl: 0-4800 Revolutions per Minute; +5%/-10% during speed transition; +/-2% when at constant speed
DEGREE OF PROTECTION AGAINST INGRESS OF WATER AND OTHER FLUIDS	Classification IPX0

Section 8: SPECIFICATIONS

ELECTRICAL

Nominal Voltages:

100, 115, 230, 240 VAC (± 10% respectively).

Input voltage greater than 264 VAC will damage the device.

Installation technician will set the proper voltage.

Frequency:

50/60 Hz

Current:

7, 6.3, 3.9, 3.8 Amps respectively

Maximum Power Input:

700 VA

Fuses:

Replacing fuses should only be performed by trained personnel. Always replace blown fuses with the correct size and international certification stamp.

Fuse ID	Rating	Circuit	Location
F1 and F2	T6.3A, 250V*	Main Power	Power Entry Module
F1 and F2	T10AH, 250V*	Main Power	Power Entry Module
F1	T3.5A, 250V	+5, +12, -12VDC	Power Supply
F1	T3.5A, 250V	+24VDC	Power Supply
F3	T1A, 250V	System Fans	CELLEX™ Fuse PCB
F4	T5A, 250V	Lamps	CELLEX™ Fuse PCB
F5	T5A, 250V	Centrifuge & Air Pump	CELLEX™ Fuse PCB

*See Data Plate Label on back of instrument.

Electromagnetic Emissions		
The THERAKOS™ CELLEX™ Photopheresis System is intended for use in the electromagnetic environment specified below. The customer or the user of the THERAKOS™ CELLEX™ Photopheresis System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment—guidance**
RF emissions CISPR 11	Group 1	The THERAKOS™ CELLEX™ Photopheresis System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The THERAKOS™ CELLEX™ Photopheresis System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity			
The THERAKOS™ CELLEX™ Photopheresis System is intended for use in the electromagnetic environment specified below. The customer or user of the THERAKOS™ CELLEX™ Photopheresis System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 2,4,6,& 8 kV contact ±2, 4, 8 & 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines ± 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Ut (100% dip in Ut) for 0,5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	0% Ut (100% dip in Ut) for 0,5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the THERAKOS™ CELLEX™ Photopheresis System requires continued operation during power interruptions, it is recommended that the THERAKOS™ CELLEX™ Photopheresis System be powered from an uninterruptible power supply or a battery.
	70% Ut (30% dip in Ut) for 25 cycles	70% Ut (30% dip in Ut) for 25 cycles	
	0% Ut (100% dip in Ut) for 1 cycle	0% Ut (100% dip in Ut) for 1 cycle	
	0% Ut (100% drop in Ut) for 5 sec	0% Ut (100% drop in Ut) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration—electromagnetic immunity			
The THERAKOS™ CELLEX™ Photopheresis System is intended for use in the electromagnetic environment specified below. The customer or the user of the THERAKOS™ CELLEX™ Photopheresis System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms outside industrial, scientific and medical (ISM) and amateur radio bands. 6 Vrms in ISM and amateur radio bands 150 kHz–80 MHz 10 V/m 80 MHz–2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz	6Vrms 150 kHz to 80 MHz 10 V/m 80 MHz–2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the THERAKOS™ CELLEX™ Photopheresis System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz–800 MHz $d = 2.3\sqrt{P}$ 800 MHz–2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment—guidance
	28 V/m, 18 Hz PM 930 MHz	28 V/m, 18 Hz PM 930 MHz	
	28V/m, 217 Hz PM1720 MHz	28V/m, 217 Hz PM1720 MHz	
	28 V/m, 217 Hz PM 1845 MHz	28 V/m, 217 Hz PM 1845 MHz	
	28 V/m, 217 Hz PM 1970 MHz	28 V/m, 217 Hz PM 1970 MHz	
	27 V/m, 217 Hz PM 2450 MHz	27 V/m, 217 Hz PM 2450 MHz	
	9V/m, 217 Hz PM 5240 MHz	9V/m, 217 Hz PM 5240 MHz	
	9 V/m, 217 Hz PM 5500 MHz	9 V/m, 217 Hz PM 5500 MHz	
	9 V/m, 217 Hz PM 5785 MHz	9 V/m, 217 Hz PM 5785 MHz	

Recommended separation distances between portable and mobile RF communications equipment and the THERAKOS™ CELLEX™ Photopheresis System

The THERAKOS™ CELLEX™ Photopheresis System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the THERAKOS™ CELLEX™ Photopheresis System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the THERAKOS™ CELLEX™ Photopheresis System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz–80 MHz $d = 1.2\sqrt{P}$	80 MHz–800 MHz $d = 1.2\sqrt{P}$	800 MHz–2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

List of Essential Performance Functions	Software Check and Alarms/Technical Errors
Pressure sensing of blood collection and return lines	Alarm#16: Collect Pressure!! Alarm #17: Return Pressure!!
Air sensors for bubbles in patient tubing	Alarm #52: Collect Line Air Detected!! Alarm #53: Return Line Air Detected!! Alarm #54: Anticoagulant Line Air Detected!! Technical Alarm #3
Blood flow	Alarm #55: Collect Pump (#1) Error!! Alarm #56: Red Cell Pump (#2) Error!! Alarm #57: Return Pump (#3) Error!! Alarm #58: Recirculation Pump (#4) Error!! Alarm #59: A/CPump (#5) Error!! Technical Alarm #17 Technical Alarm #33 Technical Alarm #34 Technical Alarm #35
Net Fluid Removal	Alarm #19: FLUID BALANCE Limit!!
Max Blood Temperature	Alarm #2: Temperature!! Alarm #51: Centrifuge Chamber Temperature Alarm!! Technical Alarm #19 Technical Alarm #140 Technical Alarm #141 Technical Alarm #142 Technical Alarm #144

FLOW RATES AND TREATMENT SETTINGS	Collect and Return Pumps Collect Pump: 5–50 mL/min (adjustable in 5 mL/min increments) Return Pump: 5–60 mL/min (adjustable in 5 mL/min increments) Return Bag Threshold 100 mL–250 mL Saline Volume Threshold 200 mL–2000 mL (adjustable in 50 mL increments) A/C Volume Threshold 200 mL–2000 mL (adjustable in 50 mL increments) Whole Blood Processed 500 mL–2000 mL (adjustable in 50 mL increments) Fluid Balance Limits -1000 mL–1000 mL (adjustable in 50 mL increments) Reinfusion Rate 1–60 mL/min (1–5 mL, adjustable in increments of 1; 5–60 mL/min, adjustable in increments of 5) Saline Bolus 10 mL–100 mL (adjustable in 10 mL increments) A/C Ratio 8:1, 10:1, 12:1, 14:1, 16:1, 25:1, 30:1, 35:1, 50:1

GENERAL OPERATING CONDITIONS

Operating Temperature:

15°C–27.5°C (59°F to 81°F)

Operating Humidity:

10%–75% RH, non-condensing

BTU/Hour:

2390

Operating Atmosphere/Altitude Pressure:

525 mmHg to 795 mmHg

Time Measurements	Range
Start Time	00:00–23:59
Elapsed Time	00:00–23:59
Elapsed UVA Time	2–99 minutes
Remaining Lamp Life	0–150 hours

Volume Measurements	Range
Fluid Balance	-1000–1000 mL
Whole Blood Processed	0–2000 mL
Treatment Volume	0–1000 mL
Buffy Coat Volume	0–1000 mL
Saline Delivered	0–2000 mL
Anticoagulant Delivered	0–2000 mL

PHYSICAL INSTRUMENT	
	Dimensions (Height x Width x Depth): 163 cm x 58.4 cm x 79 cm (64 in x 23 in x 31 in) Working Height: 84 cm (33 in) height from floor to pump deck surface Shipping Height: 147.3 cm (58 in) with monitor and IV pole down IV Pole Height: 142 cm (56 in) retracted 183 cm (72 in) extended Weight: 166 kg (366 lb) Shipping Weight: 266 kg (568 lb); instrument plus shipping crate Shipping Container Dimensions (Height x Width x Length): 173 cm (68 in) x 81.3 cm (32 in) x 117 cm (46 in) Recommended Operating Space: 50 cm (18 in) clearing on all sides Required Floor Space: 4614 cm^2 (713 in^2) Power Cord Length: 3.05 m (10 ft) Display Adjustment: Tilt up: 3° Tilt down: 5° Rotate: 0°–90° with 0° being the normal operating position; 90° used during transport to enable better visibility Finish: All exposed plastic surfaces are coated with a polyurethane enamel finish: purple, gray, or white. All metal surfaces have either a clear or black anodized finish. Mobility: Front Wheels: 2 swivel and lock casters Rear Wheels: 2 large non-swivel/non-locking wheels

PUMPS	
	Type Peristaltic type tubing with pressure sensor monitor on patient and centrifuge lines Stepper motor drive with 3 channel rotary encoder Control System Closed loop continuous monitor of speed/direction Pump Pressure Greater than 500 mmHg At < 40 PSI: Flow Rate Accuracy ± 10% Range: 0 to 100 mL/min Volume Accuracy Fluid Balance Reading — ± 5% of volume processed or 25 mL (whichever is greater) All Other Volume Readings — ± 10% or 25 mL (whichever is greater)

Pump Task	Monitoring Frequency	Monitoring Condition
Interrupt/loss communication between main controller and pump controller.	Every 200 msec	Pump ON or OFF
Pump is spinning faster than its command speed.	Every 50 msec	Pump ON
Pump is spinning lower than its command speed.	Every 50 msec	Pump ON
Pump is spinning in opposite direction from command direction.	Every 50 msec	Pump ON
Pump is running when is it not commanded to run.	Pump is rotated > 5 mL manually	Pump OFF
Any other medium or low priority alarm puts all pumps in stop or KVO mode.	Continual	Pumps ON or OFF

SAFETY/EMC	CE Marking per EC Declaration of Conformity to MDD 93/42EEC Annex II; June 14, 1993 for Class IIb products Electromagnetic Compatibility IEC60601-1-2, with radiated and conducted emissions per CISPR 11, Class A Limits, Group 1 Functional Safety For THERAKOS™ CELLEX™ Systems with serial number 54001 or above: IEC60601-1:2005, 3rd Edition ANSI/AAMI ES60601-1:2005 Relevant clauses IEC60601-1-8 (Alarms) For THERAKOS™ CELLEX™ Systems with a serial number below 54001: IEC60601-1:1988, EN60601-1:1990 , 2nd Edition IEC60601-2-16:1998 (Haemodialysis)—Relevant clauses

SYSTEM SENSORS

Audible Alarms

There are no adjustable audible alarms.

The sound pressure level of audible alarms is 64–77 dB at 1 meter, which is at least 6 dB above the system generated background noise.

Air Detection

Type

5 channel pulsed digital ultrasonic

Sensitivity and Alarm Set Point

Intact air bubble

125 microliters at all flow rates

Test Interval

Two seconds

Sensitivity During Testing: 375 microliters

Pump Tubing Organizer Includes

Internal air trap provided by drip/blood filter

Greater than 12 cc

Leak Detection

0.5 mL droplet onto detection strip for both Centrifuge and Photoactivation Chamber

SYSTEM SENSORS (continued)

Bowl Optic Sensor

Type

Laser red (670 nm), Class I

Sensing Range

1% < HCT < 90%

Pressure

Pressure sensor range = -600 to 700 mmHg

Hematocrit (HCT)

LED and Photodiode Assembly,

Sensing Range

0.4% < HCT < 25.5%

Accuracy

± 0.2%

Temperature

Type

- *Photoactivation Chamber*

  Dual digital silicon type non-blood contact chamber air temperature exit measurement

- *Centrifuge Chamber*

  Dual Surface Mount Thermistor Sensors

Range

- *Photoactivation Chamber*

  15°C–45°C (59°F–113°F)

- *Centrifuge Chamber*

  -80°C–120°C (-110°F–250°F)

Accuracy

- *Photoactivation Chamber*

  ± 1°C (± 1.8°F)

- *Centrifuge Chamber*

  ± 1°C (± 1.8°F)

Safety Interlock

- *Photoactivation Chamber*

  Both temperature sensors must be within 3°C (5.4°F) of each other

- *Centrifuge Chamber*

  Both temperature sensors must be within 3°C (5.4°F) of each other

System reacts to all alarms within 250 msec.

TRANSPORTATION

Do:

- Lock front casters while in use
- Transport in an upright position
- Use caution when moving up and down inclined surfaces or across thresholds
- Push or pull the instrument via the rear handle or the pump deck handles.
- Pull the instrument when passing across thresholds with a height of 10 mm or higher
- Call Customer Care for additional information

Do Not:

- Lay instrument on its side
- Lift off the ground via rear and pump deck handles
- For hospital to hospital transport, to prevent against instrument slippage, do not store the instrument on an inclined surface greater than 5˚ with the pump deck facing the incline ***(See Figure 8-1 below).*** For all other orientations, do not store the instrument on an incline greater than 10˚.

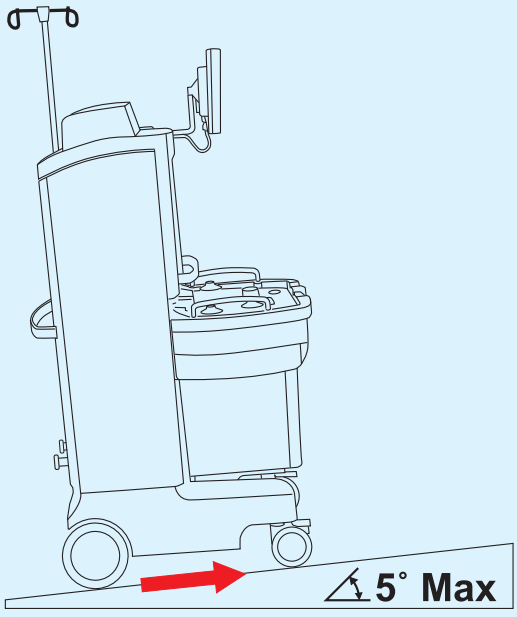


Figure 8-4: Max incline for transport in this orientation

TRANSPORTATION (continued)	**Do Not (Continued):** • Operate on an inclined surface • Push or pull on any of the plastic covers • Push or pull the instrument by the load cell covers • Stand, push, or pull on the wheel covers • Push or pull the instrument by the monitor • Push the instrument when
TRANSPORT AND STORAGE CONDITIONS	Storage Temperature: 0°C–57°C (32°F–135°F) Storage Humidity: 10%–95% RH, non-condensing Atmospheric Pressure Range: 525 mmHg to 795 mmHg
FLIUD ROUTING VALVES	Type Normally closed, spring actuated Pneumatically retracted Occluding Pressure Greater than 350 mmHg after priming Operation All closed if Technical Alarm detected or power off

SECTION 9: WARNINGS AND CAUTIONS

CAUTION:
Review all warnings and cautions summarized in this section before treating a patient!

WARNING:

- MR-unsafe! Do not expose the device to a magnetic resonance (MR) environment.
    - The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
    - Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
    - The device may generate artifacts in the MR image.
    - The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.
- The calculated dose of UVA light energy will not be delivered if the THERAKOS™ CELLEX™ Light Assembly is changed after the calculation of photoactivation MINUTES REMAINING is displayed.
- It is recommended that the full PHOTOACTIVATE time be completed during every treatment. The calculated dose of UVA light energy will not be delivered if PHOTOACTIVATE is ended or aborted before the MINUTES REMAINING is equal to 00.00 (minutes:seconds).
- To avoid risk of electric shock, this equipment must only be connected to a supply main with a protective (earth grounded) receptacle. The use of extension cords is not recommended.
- The Bowl Optic Sensor contains a laser light source. Do not stare directly into the beam.
- Hypotension may occur during any treatment involving extracorporeal circulation. Closely monitor the patient during the entire treatment for any signs of hypotension.
- Prior to initiating PRIME, ensure the treatment bag and return bag are properly positioned on their respective Load Cell Hooks. Removal of these bags at any time after PRIME is initiated may result in priming alarms and/or inaccurate FLUID BALANCE readings during the treatment.
- The REINFUSION Rate Limit Range is 1–60 mL/min. REINFUSING will automatically use the last user set RETURN rate if access allows (default RETURN rate is 35mL/min) or the REINFUSION Rate Limit, whichever the lowest. Careful fluid balance management may require a slower REINFUSION RATE. Please refer to *"Changing Default SETUP Parameters" on page 5-14* and *SECTION 10: FLUID BALANCE MANAGEMENT* for additional information.

Section 9: WARNINGS AND CAUTIONS

WARNING:

- Venipuncture access may require a RETURN Flow Rate of less than the default.
- The default setting for the Return Bag Threshold is 100 mL. You may change this setting at any time during the treatment via the SETUP screen. In SINGLE NEEDLE Mode, this setting determines how often the instrument alternates between DRAWING and RETURNING and also determines the patient's extracorporeal blood volume during COLLECT. Please refer to ***SECTION 5: CHANGING DEFAULT SETUP PARAMETERS*** and ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information.
- The system automatically returns the treated cells to the patient following PHOTOACTIVATE. Therefore, it is recommended that the patient should not be disconnected from the system at any time during the treatment.
- Electric Shock Hazard. Turn OFF and unplug the THERAKOS™ CELLEX™ Photopheresis System before servicing. Never perform maintenance on the THERAKOS™ CELLEX™ Photopheresis System during a treatment.
- If the power is turned off for any reason during COLLECT the Centrifuge Bowl must be re-purged before treatment resumes. This will result in higher extracorporeal volume. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT*** when re-purging the Centrifuge Bowl before resuming the treatment.
- Using a power cord other than the cord specified or supplied with the instrument may result in increased emissions or decreased immunity.
- Use of this equipment the (THERAKOS™ CELLEX™ Photopheresis System) adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Vascular access or clinical condition may require a COLLECT, RETURN and/or REINFUSION rate to be less than the default.
- Any narrow passages in the procedural kit (such as kinks in the tubing or access devices that are too narrow) may cause hemolysis that will not be detected by the system.
- After BUFFY COAT, the patient Collect Line will no longer be used for collecting blood, and the instrument will not deliver KVO fluid to maintain the Collect Line access. To prevent stagnant blood in the Collect Line, use your institution's standards to provide proper care of the access site (e.g. flush the line or disconnect the patient).
- Resetting the FLUID BALANCE to zero will tare the displayed fluid balance to 0 mL but will not automatically maintain a FLUID BALANCE of 0 mL. COLLECT and RETURN Flow Rates must still be managed to maintain an appropriate fluid balance.
- DO NOT connect patient to the procedural kit lines prior to completing PRIME ACCESS. Pressing PRIME to complete PRIME ACCESS with patient connected will cause air in the line to be delivered to the patient.

WARNING:

- Upon resuming collection after any centrifuge stop the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.
- DO NOT touch USB port and/or any leak detector while in physical contact with the patient.
- DO NOT position the device where it is difficult to connect or disconnect the device from mains power source.
- The COLLECT Rate Limit Range is 5–50 mL/min. DRAWING will automatically use a flow rate of 30 mL/min if access allows. Careful fluid balance management may require a slower COLLECT Flow Rate. Please refer to ***"Changing Default SETUP Parameters" on page 5-14*** and ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information.
- The RETURN Rate Limit Range is 5–60 mL/min. RETURNING will automatically use a flow rate of 35 mL/min if access allows. Careful fluid balance management may require a slower RETURN Flow Rate. Please refer to ***"Changing Default SETUP Parameters" on page 5-14*** and ***SECTION 10: FLUID BALANCE MANAGEMENT*** for additional information.
- Once PRIME has been completed, the procedure using the primed THERAKOS™ CELLEX™ Photopheresis Procedural Kit must be started within four hours.
- The operator may change the return bag threshold setting at any time during the treatment via the SETUP screen. In SINGLE NEEDLE Mode, this setting determines how often the instrument alternates between DRAWING and RETURNING and also determines the patient's extracorporeal blood volume during COLLECT.
- To limit heat generation in single needle mode, the Centrifuge Bowl will stop spinning if greater than 7 minutes will be required to return the contents of the return bag to approximately 50 mL.

CAUTION:

- AABB guidelines recommend that the temporary extracorporeal blood volume be limited to 15% of the patient's estimated total blood volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT and SECTION 5: CALCULATING AND SETTING FLUID BALANCE LIMITS*** for additional information on selecting and maintaining Fluid Balance Limits.
- Correct attachment of the Saline and Anticoagulant Bags to the correct fluid spike is essential. ***(See Figure 3-19: Correct Placement of Saline and Anticoagulant (A/C) Bags).*** Incorrect attachment may lead to clotting in the procedural kit, patient blood loss and a failed treatment.
- Individual patients may require a heparin dosage that varies from the recommended dose to prevent post-treatment bleeding or clotting during a treatment. The clinician should review the patient's medical condition, medications and platelet count at the time of treatment and use clinical judgment to establish the optimal heparin dosage for each patient.
- When instructed, establish or disconnect patient access utilizing your institution's standards of practice for this procedure. Failure to do so may lead to patient harm such as increased risk of infection, trauma to the access site, possible air embolus or post treatment blood loss.
- Do not allow the anticoagulant or saline bags to become empty prior to completing a treatment. Air entering the spike lines will interrupt the treatment and may prevent successful completion of the therapy. If A/C bag becomes empty during a procedure, the concentration of anticoagulant and instrument settings should be verified to determine if the dose to the patient is accurate and to determine whether it is safe to proceed with a new bag of A/C if needed to continue the treatment.
- Do not remove the treatment bag from the Load Cell Hook. Removal may result in inaccurate FLUID BALANCE readings.
- Always confirm the contents, lot number and expiration date of any solution prior to its use.
- During installation, do not excessively bend, kink or damage the Drive Tube, Bearings, or Centrifuge Bowl.
- Instrument must be properly maintained to function safely and properly.
- The warranty does not cover damage caused by improper loading, setup, operation, or improper maintenance.

CAUTION:

- Do Not Proceed (with the THERAKOS™ CELLEX™ Photopheresis Procedural Kit Installation) until you confirm:
  - ✓ The drive tube latch is closed securely and the START button is visible on the Main Screen of the Operator Interface.
  - ✓ The Drive Tube does not touch the Centrifuge Frame at any point.
  - ✓ The tubing lines exiting the front of the Drive Tube Clamp Assembly are in their respective tubing guides and are not pinched in the clamp.
  - ✓ All tubing lines pass through the Tubing Exit Slot and are free of kinks or pinch points.
  - ✓ The Upper and Lower Bearings are fully seated in the bearing retainers.
  - ✓ The Centrifuge Bowl and Frame spin freely in a clockwise direction.
- Verify the lower drive tube bearing is correctly aligned in the bearing retainer.
- Verify that the Bearings and Drive Tube are not damaged in any way.
- Verify that the bearing is engaged with the magnet.
- Verify the upper drive tube bearing is correctly aligned in the bearing retainer.
- Handle the Pressure Domes only by clips to avoid damage to the internal membrane.
- Partial pressure dome attachment may provide pressure readings, but as pressures increase, the internal membrane may separate from the pressure dome. Fluid leaks may occur resulting in loss of sterility, blood leaks, and possible blood loss to the patient.
- DO NOT REMOVE ANY PRESSURE DOME DURING A TREATMENT.
- Avoid fingerprints on the window of the Hematocrit Cuvette. Natural oils may adversely affect the light transmittance through the lens.
- Use clinical judgement when adjusting alarm limits.
- Check that the Centrifuge Chamber Door is closed properly. An alarm alerts you if the door is not closed properly or if the Centrifuge Chamber Door Manual Release is in the unlocked position.
- Do not unlatch or attempt to open the Centrifuge Chamber Door while the Centrifuge is in operation.
- It is essential for the THERAKOS™ CELLEX™ Photopheresis System to be installed and used in compliance with all center specific and local regulations/recommendations on the quality of all relevant fluids used during a therapy.

CAUTION:

- To avoid risk of infection and/or potential patient blood loss do not use a THERAKOS™ CELLEX™ Photopheresis Procedural Kit that:
  - Has been damaged during installation.
  - Has leaked during PRIME.

  Save the defective procedural kit for return to manufacturer. Call Mallinckrodt to report the problem.
- The Collect and Return Lines must be configured to match the access mode selected. Failure to do so may lead to clotting at one access site, treatment interruption and a possible failed treatment.
- Ensure settable alarm limits are appropriate for patient conditions.
- Maximum PAUSE time is 10 minutes. After being paused for 8 minutes, an audible beep signals and a Pop-Up Message declares that the centrifuge will stop in 2 minutes.
- In the event of a brief power failure during treatment that does not require Manual Blood Return, turn the power switch OFF, open the door to the Photoactivation Chamber and pull the Photoactivation Module out half way. When power is restored, put the Photoactivation Module back in position, close the Photoactivation Chamber Door and turn the power ON. If the power failure is prolonged, follow instructions for Manual Blood Return (With Power OFF and/or No Access to RELEASE KIT Button).
- Do not manually return any blood products without proper filtration. Refer to your institution's guidelines for blood transfusions.
- Do not allow cleaning solution to come into contact with any of the automatic sensors. Gently clean all sensors with warm water only.
- Never poke or puncture the center pinhole opening of any pressure transducer.
- Do not leave the transducers uncovered at any time!
- Do not puncture tubing line!
- The used THERAKOS™ CELLEX™ Photopheresis Procedural Kit and any spills should be considered biologically contaminated. When handling the contaminated procedural kit, or cleaning up any blood spills on the instrument, follow your institutions specific policy for biohazard precautions and hazardous waste disposal.
- END TREATMENT and ABORT TREATMENT are both selections that will not allow you to proceed to PHOTOACTIVATE. Selection and confirmation of these selections will result in immediate termination of the treatment.
- Selecting 

during the COLLECT phase to deliver a saline bolus will stop the centrifuge bowl and cell separation will be lost.

CAUTION:

- Before you begin Manual Blood Return consult the clinician in charge to determine if there is any reason that the blood in the procedural kit should not be returned to the patient.
- For optimal performance, the Bowl Optic Sensor Lens must be clean and clear. A dirty or clouded lens on the Bowl Optic Sensor could interfere with its proper function.
- When cleaning the Centrifuge Chamber, ensure that the cleaning solution does not come in contact with the Bowl Optic Lens. If this should occur, rinse the lens with clear water and dry it so that the lens does not cloud.
- An IrDA™ Port is located on the user interface. Only authorized and approved devices should be used or connected to this port.
- All automatic sensor functions, pump rates, anticoagulant delivery ratios and fluid balance estimates are limited to the accuracies of the component parts listed in *SECTION 8: SPECIFICATIONS*. Failure of the instrument to meet these performance specifications may lead to less than optimal buffy coat collections, blood loss due to clotting or leakage, increased risk of infection, hypovolemia or hypervolemia and/or a failed treatment.
- If priming alarms occur, do not remove the pressure domes until after you remove the pump tubing segments. Check the screen display to confirm that all pressure has been released from the sensors.
- Always change an aged THERAKOS™ CELLEX™ Light Assembly prior to starting a treatment.
- Turn the power OFF and unplug the instrument prior to changing the THERAKOS™ CELLEX™ Light Assembly.
- Never change the THERAKOS™ CELLEX™ Light Assembly during a treatment if the photoactivation MINUTES REMAINING has already been calculated.
- Do not attempt to modify the THERAKOS™ CELLEX™ Instrument, Procedural Kit or Light Assembly in any way.
- Changing the THERAKOS™ CELLEX™ Light Assembly with the power ON is UNSAFE and WILL NOT reset the number of Lamp Hours Remaining to 150 hours.
- Do not clean the Photoactivation Module. Cleaning agents could leave a film that may adversely affect the transmission of UVA light energy and the photoactivation process.
- Special attention to adequate anticoagulation is advised when treating patients with GvHD, a condition associated with an increased risk of thromboembolic events. Thromboembolic events (including pulmonary embolism and deep vein thrombosis) have been reported with the use of the THERAKOS™ CELLEX™ Photophoresis System in the treatment of GvHD.

CAUTION:

- DO NOT USE the THERAKOS™ CELLEX™ Photopheresis Procedural Kit if:
  - the package is already opened or damaged.
  - the fluid pathway guards (caps on ends of tubing lines) are loose in packaging or missing.
  - the Date of Use is beyond the Expiration Date.
- Damage to the Centrifuge Bowl or Drive Tube could result in further damage to the instrument, loss of treatment and extracorporeal blood loss.
- READ THE THERAKOS™ UVAR XTS™ or THERAKOS™ CELLEX™ PHOTOPHERESIS SYSTEMS 'OPERATOR'S MANUAL PRIOR TO PRESCRIBING OR DISPENSING THIS MEDICATION.
- Do not remove the treatment bag from the load cell hook. Removal may result in inaccurate FLUID BALANCE readings.
- Follow all medication dosing instructions carefully.
- Advise patients that it is recommended to protect their skin and eyes from sunlight for 24 hours post treatment. Refer to the Methoxsalen (20 micrograms/mL) labeling or the oral 8-methoxypsoralen dosage formulation package insert for more information on protecting the patient from light and for all warnings and precautions.
- Do not puncture the needle-free ports with a needle. Damage to these ports will result in leaks.
- Saline and Anticoagulant Spike Lines do not have slide clamps. Instead, Fluid Routing Valves, activated when the base of the Drive Tube is inserted into the Drive Tube Latch Assembly and the Drive Tube Latch is closed, prevent fluid from entering the Pump Tubing Organizer prior to PRIME.
- If drawing from the patient during BUFFY COAT, the operator must increase the return flow rate from 0 mL/min to match the Collect Fow Rate to maintain isovolemic conditions.
- Do not use the THERAKOS™ CELLEX™ Photopheresis Procedural Kit if any of the protective caps on the patient lines, pressure domes, or fluid spikes are missing or off when the procedural kit is opened. Sterility of the procedural kit may be compromised if these caps are removed prior to use.
- The integrity of pressure monitoring will be compromised if the Pressure Domes are removed after PRIME. Damaged or misplaced pressure domes may leave lines unmonitored which could lead to undetected trauma at the patient access site, Centrifuge Bowl breakage with subsequent blood loss, and a failed treatment.
- Ensure that both the Patient Collect Line (RED) Clamp and Patient Return Line (BLUE) Clamp are at the same level as the Pump Deck (± 45cm) before opening the Patient Collect Line (RED) Clamp and pressing PRIME. ***See Figure 5-4.***

CAUTION:

- The operator must be present to supervise the treatment at all times. The operator's primary responsibility during the entire treatment is the patient's safety. Carefully monitor the patient for tolerance to the extracorporeal fluid shifts, access performance and potential allergic reactions or potential adverse events.
- Throughout the treatment you should visually monitor the instrument to confirm whole blood separation; the correct position for the plasma/red blood cell interface; unusual conditions such as hemolysis, high bilirubin and/or lipids; and unexpected fluid leaks.
- If hemolysis or unexpected air is observed during a photopheresis treatment, the therapy must be aborted and blood should not be returned to the patient.
- Follow your center specific guidelines for universal precautions whenever exposure to blood is a possibility. Failure to do so may expose you or your patient to harmful blood borne contaminants.
- Follow all operating and maintenance procedures. Failure to do so can result in patient and/or operator harm or system damage.
- Ensure that the room temperature does not exceed 27.5°C (81°F) during the treatment. To avoid excessive heat build-up in the centrifuge chamber, consider keeping the ambient temperature at 25°C (77°F) or less, especially when flow rates are less than 15 mL/min.
- Mallinckrodt does not recommend operating the THERAKOS™ CELLEX™ Photopheresis System under the combination of the following:
  - A room temperature at or greater than 27.5°C (81°F).
  - Centrifuge Bowl RPM greater than 3600 RPM.
  - A collect rate lower than 15 mL/min.

  Under these conditions centrifuge chamber temperature alarms may occur. The decision to operate at or beyond these conditions is the responsibility of the clinician. Mallinckrodt does not recommend operating at lower flow rate than 15 mL/min over an extended period of time.
- Allow a minimum of 50 cm (18 inches) of ventilation space in front and back of the instrument while in use.
- Do not use the THERAKOS™ CELLEX™ Photopheresis System in the presence of flammable anesthetic gases.
- Do not operate the instrument in the presence of external radio or electromagnetic disturbances that may interfere with proper performance of the device. This could result in treatment interruptions, and the possibility of a failed treatment.
- Complete FINAL INSPECTION BEFORE PRIME before beginning PRIME (Refer to *page 4-29)*.

CAUTION:

- In consultation with the clinician, assess the patient's overall health status immediately before beginning a treatment to determine if the patient is able to tolerate the anticipated fluid shifts during the treatment. Do not proceed if the patient is unstable.
- Estimate the patient's total blood volume and calculate 10 or 15% of that volume. Refer to ***"Changing Default SETUP Parameters" on page 5-14*** to determine how to set the ± Fluid Balance Limit before starting COLLECT.
- Optimize venous access. Whenever possible, the COLLECT and RETURN Flow Rates should be greater than 15 mL/min.
- Mallinckrodt recommends that you do not change the THERAKOS™ CELLEX™ Light Assembly during a treatment. Refer to ***Replacing the THERAKOS™ CELLEX™ Light Assembly on page 7-8*** for all warnings, cautions, and instructions when lamp replacement is required.
- Do not attempt to modify the THERAKOS™ CELLEX™ Instrument, THERAKOS™ CELLEX™ Photopheresis Procedural Kit, or THERAKOS™ CELLEX™ Light Assembly in any way.
- General guidelines suggest that blood removed from the body should not be extracorporeal for longer than four hours. Use clinical judgment to determine the length of delay each patient may be able to tolerate. In case of clotting in the procedural kit, treatment should be aborted.
- Do not allow corrosive/abrasive solutions to come in contact with the Bowl Optic Lens.
- Do not allow corrosive/abrasive solutions to come in contact with the Hematocrit Sensor.
- To release all internal pressure before removing the kit, always remove all Pump Tubing Segments before removing any Pressure Domes.
- Do not allow cleaning solutions to come in contact with the air detectors.
- Moving the CELLEX™ System instrument: The CELLEX™ System unit may tip forward if pushed from the rear when encountering an obstruction (door threshold, cable, elevator gap) of 10 mm vertical height or more. Use the rear handle to PULL the unit across the obstruction, or use a 10° or less ramped threshold cover to allow the unit to ride over the obstruction.
- In some medical conditions, the patient's hematocrit may change from day to day. Use a hematocrit measured within 48 hours prior to photopheresis to estimate the THERAKOS™ CELLEX™ Photopheresis Procedural Kit extracorporeal volume during a treatment.

CAUTION:

- Maximum extracorporeal volume for patients weighting less than 30kg should not exceed 10% of the patient's Total Blood Volume. Patients that do not meet the safe minimal ECV should only be treated using the blood prime procedure. If the treating clinician does not desire to use the blood prime procedure, raising the patient's hematocrit and/or body weight may allow the patient to undergo the standard procedure per Table on ***page 10-3***.
- If necessary, deliver a saline bolus to the patient prior to resuming treatment to prevent hypovolemia.
- Patients who may not be able to tolerate the fluid changes associated with extracorporeal photopheresis should be monitored carefully. Procedures, such as renal dialysis, which might cause significant fluid changes (and expose the patient to additional anticoagulation) should not be performed on the same day as extracorporeal photopheresis.
- Laser - Use of controls or adjustments or performance of procedures other than those specified in Section 8 may result in hazardous radiation exposure.
- Selecting 

during the COLLECT phase to change access mode will stop the centrifuge bowl and cell separation will be lost.
- Ensure that both the Patient Collect Line (RED) Clamp and Patient Return Line (BLUE) Clamp are at the same level as the Pump Deck (± 45cm) before opening the Patient Collect Line (RED) Clamp and pressing PRIME, See Figure 5-3. If the Patient Collect Line (RED) Clamp is not at pump deck height during PRIME ACCESS, the pressure in the system will cause pressure alarms and it will not be possible to proceed past PRIME.
- Use clinical judgment when responding to alarms on multiple CELLEX devices.

SECTION 10: FLUID BALANCE MANAGEMENT

Introduction

Fluid Balance Management of any patient undergoing a therapeutic photopheresis treatment is critically important. Key factors to estimate and control are:

a. Total Blood Volume and anticipated Extracorporeal Blood Volume (ECV)

b. Rate of Fluid Shifts

c. Negative and Positive Fluid Balance during and immediately post treatment

d. Delivery Rate and Concentration of Anticoagulant

At the time of treatment, the operator and clinician must know the patient's health history, age and current condition to predict how well he/she will tolerate fluid shifts during the procedure. In addition, the patient's sex, body build, current hematocrit, height and weight may be required to perform the calculations necessary to manage fluid balance safely.

The THERAKOS™ CELLEX™ Photopheresis System incorporates numerous software features to assist in maintaining proper fluid balance during a treatment. The following variables are displayed in real time as the treatment proceeds:

1. FLUID BALANCE
2. WHOLE BLOOD PROCESSED
3. SALINE DELIVERED (to procedural kit)
4. ANTICOAGULANT DELIVERED (to procedural kit)
5. COLLECT AND RETURN FLOW RATES

NOTE:

- Instructions on how to alter the above variables will vary depending on whether the instrument is run in DOUBLE NEEDLE mode (Continuous flow) or SINGLE NEEDLE mode (Discontinuous flow).

Extracorporeal Blood Volume (ECV)

CAUTION:

AABB guidelines recommend that the temporary extracorporeal blood volume be less than or equal to 15% of the patient's Total Blood Volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment. Refer to ***SECTION 10: FLUID BALANCE MANAGEMENT and SECTION 5: CALCULATING AND SETTING FLUID BALANCE LIMITS*** for additional information on selecting and maintaining Fluid Balance Limits.

A new calculation of Total Blood Volume is necessary prior to each treatment to estimate the safe extracorporeal blood volume that may be allowed for the patient undergoing treatment. These calculations should be performed using the current weight and current hematocrit (the latter drawn after the last photopheresis treatment and within 48 hours prior to the next photopheresis treatment). Certain medical conditions may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume.

Predicting Actual Procedural Kit Extracorporeal Blood Volume

CAUTION:

In some medical conditions, the patient's hematocrit may change from day to day. Use a hematocrit measured within 48 hours prior to photopheresis to estimate the THERAKOS™ CELLEX™ Photopheresis Procedural Kit extracorporeal volume during a treatment.

In both DOUBLE NEEDLE and SINGLE NEEDLE modes a minimum amount of whole blood must be processed to prime the Bowl and establish the proper plasma/red blood cell interface. This extracorporeal blood volume increases as the patient's hematocrit decreases (see chart below). A blood prime of the Centrifuge Bowl using crossmatched compatible packed red blood cells may be required if the patient's current weight and hematocrit exceed the safe 10 or 15% extracorporeal blood volume.

% HCT	Estimated ECV DOUBLE NEEDLE	Estimated SINGLE NEEDLE Mode Extracorporeal Volume (ECV) When Return Bag Threshold Value (RBTV) is Set at (XmL): Return Bag Threshold Value =			
		100	150	200	250
27%	**396**	**441**	491	541	591
28%	**384**	**429**	479	529	579
29%	**372**	**417**	467	517	567
30%	**362**	**407**	457	507	557
31%	**352**	**397**	447	497	547
32%	**343**	**388**	438	488	538
33%	**334**	**379**	429	479	529
34%	**326**	**371**	421	471	521
35%	**319**	**364**	414	464	514
36%	**311**	**356**	406	456	506
37%	**304**	**349**	399	449	499
38%	**298**	**343**	393	443	493
39%	**292**	**337**	387	437	487
40%	**286**	**331**	381	431	481
41%	**280**	**325**	375	425	475
42%	**275**	**320**	370	420	470
43%	**270**	**315**	365	415	465
44%	**265**	**310**	360	410	460

Table 1: Estimated Extracorporeal Volume Relative to % Hematocrit, Access Mode and Return Bag Threshold Value

Estimating the Patient's Total Blood Volume

The THERAKOS™ CELLEX™ Photopheresis System continuously monitors and displays the volume of fluid movement to and from the patient during a THERAKOS™ Photopheresis treatment. These fluids may be blood, anticoagulant, or saline. A negative fluid balance indicates that the patient is undergoing a temporary fluid deficit. A positive fluid balance indicates that the patient has received additional fluids. At completion of a standard treatment the patient will be fluid positive approximately 350 - 450 mL.

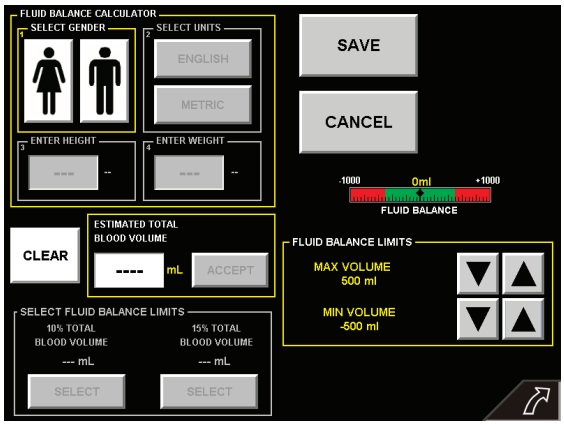


Figure 10-1: Fluid Balance Setup Screen

Integrated TBV Calculator Method:

To assist in establishing appropriate fluid balance alarm limits, the THERAKOS™ CELLEX™ Photopheresis System incorporates an integrated fluid balance calculator that uses the Nadler formula to estimate the patient's Total Blood Volume. The calculator and fluid balance setup screen will automatically display prior to patient connection and will be available after initiation of the treatment via the setup screen.

The integrated calculator uses the Nadler formula for computing the patients Total Blood Volume using Gender, Weight and Height as Inputs to the equation below.

- (Male) Total Blood Volume in mL = 0.3669 x (height in meters)^3 + 0.03219 x weight in kg + 0.6041
- (Female) Total Blood Volume in mL = 0.3561 x (height in meters)^3 + 0.03308 x weight in kg + 0.1833

Calculator input limits:

- Height 30–244 cm
- Weight 25–227 kg

Please refer to ***Calculating and Setting Fluid Balance Limits on pg 5-10*** for specific instructions in using integrated TBV calculator.

CAUTION:

Maximum extracorporeal volume for patients weighting less than 30kg should not exceed 10% of the patient's Total Blood Volume. Patients that do not meet the safe minimal ECV should only be treated using the blood prime procedure. If the treating clinician does not desire to use the blood prime procedure, raising the patient's hematocrit and/or body weight may allow the patient to undergo the standard procedure per Table on ***page 10-3.***

Alternate Method to Compute Total Blood Volume (TBV):

Total Blood Volume (TBV) in milliliters (mL) can be estimated by multiplying the patient's weight in kilograms (kg) by the appropriate body build factor predicting blood volume in mL/kg.

- Compute the estimated TBV by using the body build table below:
- Weight (kg) x Body Build Factor (mL/kg) = TBV (mL)

BODY BUILD	MALE	FEMALE
Adult Muscular	80 mL/kg	75 mL/kg
Adult Normal	75 mL/kg	70 mL/kg
Adult Thin	70 mL/kg	65 mL/kg
Adult Obese	65 mL/kg	60 mL/kg
Adolescent	75–70 mL/kg	75–70 mL/kg
Neonate	100–80 mL/kg	100–80 mL/kg

Table 2: TBV Body Build Factor Table

Once TBV is calculated, you may enter the value into fluid balance setup screen or TBV calculator.

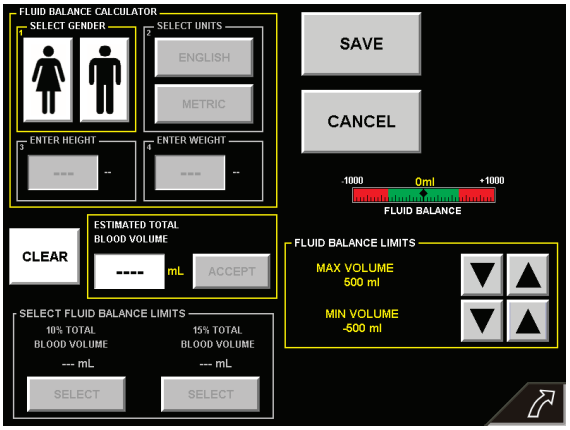


Figure 10-2: Fluid Balance Setup Screen

1. Press SETUP from a stop or pause screen.
2. Navigate to fluid balance setup screen
3. Touch white data entry box labeled ESTIMATED TOTAL BLOOD VOLUME. A keyboard will appear.
4. Enter the calculated TBV then press enter button.
5. Press ACCEPT to use this value. The calculator will automatically display calculated fluid balance values for 10% and 15% of the patient's total blood volume.
6. If needed, Press CLEAR to reset the calculator values and return to step 1.
7. Pressing one of the SELECT buttons under the fluid balance (10% or 15%) will set fluid balance alarm limits to the value selected. The selected value will be highlighted.
8. Fluid balance alarm limits may be adjusted up or down in increments of 25 mL using the buttons.

9. Press SAVE to set the fluid balance alarm limits to the new values.

Example Calculations of TBV and Safe ECV:

Patient: Adult female, thin body build, weight = 44.5 kg

Estimated Total Blood Volume:

(44.5) x (65 mL/kg) = 2892 mL TBV

Estimated Safe Extracorporeal Blood Volume:

10% of TBV = (2892 x 0.1) = 289 mL

15% of TBV = (2892 x 0.15) = 434 mL

CAUTION:

- AABB guidelines recommend that the temporary extracorporeal blood volume be limited to 15% of the patient's estimated total blood volume. The patient's clinical condition at the time of THERAKOS™ Photopheresis may warrant an extracorporeal blood volume of less than 15% of Total Blood Volume to maintain haemodynamic stability. Complete assessment of the patient prior to every treatment is necessary to determine the appropriate extracorporeal blood volume and fluid balance during each treatment.

NOTE:

- In DOUBLE NEEDLE mode, the temporary fluid deficit that is generated as the patient's blood fills the Centrifuge Bowl may be reduced or eliminated by simultaneously returning saline to the patient until the Return Line fills with plasma and red blood cells.
- ECV ≠ FLUID BALANCE. A patient may lose a significant ECV but still be in an isovolemic condition due to simultaneous fluid replacement.

Rate of Fluid Shifts

The COLLECT, RETURN, and REINFUSION rates are set to default rates and are user adjustable (see *"Changing Default SETUP Parameters" on page 5-14*. Factors that determine the most appropriate speed of DRAWING whole blood, RETURNING plasma and red blood cells, and REINFUSING treated white blood cells are the following:

Weight: Low body weight patients will require slower flow rates to allow time for the physiological adjustments necessary to adapt to the fluid shifts of the procedure.

Medical Condition at time of treatment: Any condition that includes pulmonary, cardiac or renal insufficiencies will require moderate to slow flow rates. Careful monitoring of the patient's vital signs during the procedure will guide you in selecting the most appropriate flow rates.

Access: Vascular access may require flow rates less than default settings. Carefully monitor the Collect Line Pressure display and the Return Line Pressure display and lower the flow rates as needed to maintain stable line pressures and to avoid Collect and/or Return Pressure alarms.

Fluid Balance: In DOUBLE NEEDLE mode (Continuous flow) COLLECT and RETURN flow rates may be adjusted independently to achieve the desired positive or negative fluid balance for a given patient during a treatment. Flow rates do not influence fluid balance in SINGLE NEEDLE mode.

Fluid Balance Management

DOUBLE NEEDLE Mode

Careful Fluid Balance Management is the combination of knowing and controlling extracorporeal volume, the rate of fluid shifts and any fluid deficits or fluid positive states that occur during the photopheresis procedure and/or immediately post treatment. At completion of a standard treatment the patient will be fluid positive approximately 350 - 450 mL. Appropriate medical follow up and intervention must be given to any patient whose medical condition at the time of treatment warrants assistance in eliminating these extra fluids.

In DOUBLE NEEDLE mode (Continuous Flow), simultaneous flow of approximately equal amounts of fluids to and from the patient can create a state of isovolemia. These fluids will be various volumes of whole blood, plasma, red blood cells, saline and anticoagulant. You may adjust COLLECT and RETURN flow rates to manage overall fluid balance.

WARNING:

- DOUBLE NEEDLE mode is required when:
  - Isovolemic FLUID BALANCE is required.
  - Minimum fluid deficit is required.
  - Minimum ECV is allowed.
  - BLOOD PRIME is required.
- SINGLE NEEDLE mode is a discontinuous flow process, even though the harvesting of white blood cells in the Centrifuge Bowl is continuous. It is not possible to maintain isovolemic conditions in SINGLE NEEDLE mode. The patient must be able to tolerate the predicted procedural kit extracorporeal volume without simultaneous fluid replacement.

SINGLE NEEDLE Mode

Once PURGING AIR is completed in SINGLE NEEDLE mode the Return Bag Threshold Volume will determine how often the instrument alternates between DRAWING and RETURNING. The default setting is 100 mL. The range is 100–250 mL. Each time the threshold volume is reached an audio beep will sound, DRAWING will be interrupted and RETURNING will resume until the volume in the return bag is approximately 50 mL.

Helpful Fluid Balance Management Screen Displays

Screen displays that are helpful for fluid balance management in both DOUBLE NEEDLE mode and SINGLE NEEDLE mode are:

COLLECT and RETURN Rates and Pressures

FLUID BALANCE

RETURN BAG VOLUME (Tap on screen icon to see mL volume displayed)

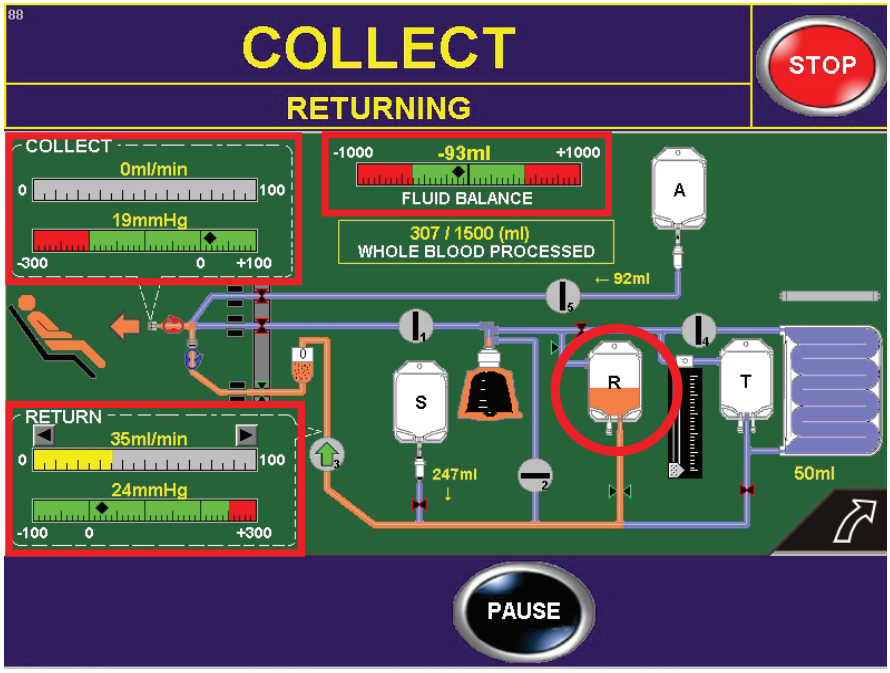


Figure 10-3: Helpful Fluid Balance Management Screen Displays

NOTE:

- The FLUID BALANCE displayed shows the difference between fluid taken from and fluid returned to the patient. The value displayed is accurate to ± 5% of volume processed or 25 mL, whichever is greater. The accuracy of this value is also dependent on the correct placement of the Return bag during setup and Prime. Once a treatment is started, the treatment and return bags should never be removed from the load cell hook until the treatment is complete.
- FLUID BALANCE does not represent red blood cell loss. Refer to the charts in this section for estimates of extracorporeal volume at a given hematocrit.

Fluid Balance Management When Re-purging the Bowl

CAUTION:

- Re-purging the Centrifuge Bowl with whole blood during a treatment will result in a higher (approximately 65 mL) extracorporeal blood volume than anticipated.
- If necessary, deliver a saline bolus to the patient prior to resuming treatment to prevent hypovolemia.

The following events will lead to the automatic stopping of the centrifuge bowl.

- Alarm #7: Blood Leak? (Centrifuge Bowl)
- Alarm #18: System Pressure alarm
- Alarm #33: Pause Timeout Alarm
- Alarm #47: Drive Tube Alarm
- Power Interruption
- Technical Alarms
- Single Needle Mode return time calculated over 7 minutes *"Changing the Return Bag Threshold Value (Single Needle Mode Only)" on page 5-24.*

In all of these events, you must determine the root cause of the problem and resolve it and then, if possible, resume the treatment. Any time the Centrifuge Bowl is stopped, it must be re-purged and the plasma/red blood cell interface reestablished.

WARNING:

- Upon resuming collection after any centrifuge stop, the Centrifuge Bowl will need to be re-purged, causing displacement of leukocytes already in the Centrifuge Bowl and will result in a higher extracorporeal volume than anticipated. Please refer to ***page 5-43*** or ***5-60*** for complete instructions.

Flow Guide

The THERAKOS™ CELLEX™ Photopheresis System Flow Guide provides operators information regarding the quantities of fluids (anticoagulant and saline) processed in the instrument during a patient treatment. The Flow Guide will assist the operators in deciding on the proper flow rates to control the delivery of anticoagulant to the patient. In addition, formulas are provided for calculating units of heparin delivered under various treatment scenarios.

Fluids Used During PRIME

- Approximately 55 mL of anticoagulant
- Approximately 243 mL of saline
- At the end of PRIME, the distribution of these fluids is represented in the screen display below:
  - Anticoagulant (Orange)
  - Saline (Blue)

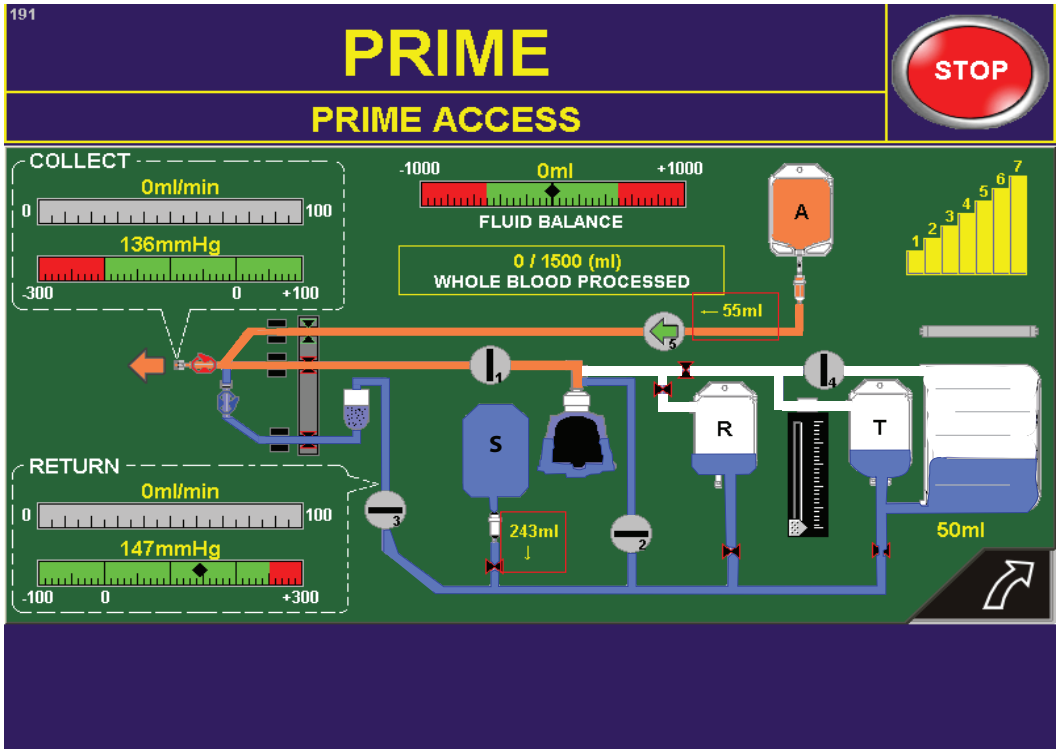


Figure 10-4: Distribution of Anticoagulant and Saline in the procedural kit at the End of PRIME.

- At the end of prime, there is 50 mL of Saline between the treatment bag and photoactivation module.

Fluid Definitions

Anticoagulant (A/C): Heparin solution prepared from the clinician prescribed dose of heparin added to a 500 mL bag of 0.9% Normal saline. For example, when 10,000 Units of Heparin is added to 500 mL saline, the concentration A/C. Concentration A/C = 20 Units of Heparin/mL.

Saline (NS): 0.9% Normal saline.

Refer to pg 8-10 of the THERAKOS™ CELLEX™ Photopheresis System Operator's Manual regarding volume accuracy:

FLUID BALANCE reading: ± 5% of volume processed or 25 mL (whichever is greater)

All other volume readings: ± 10% or 25 mL (whichever is greater)

Fluid contents of pump tubing organizer at the end of PRIME

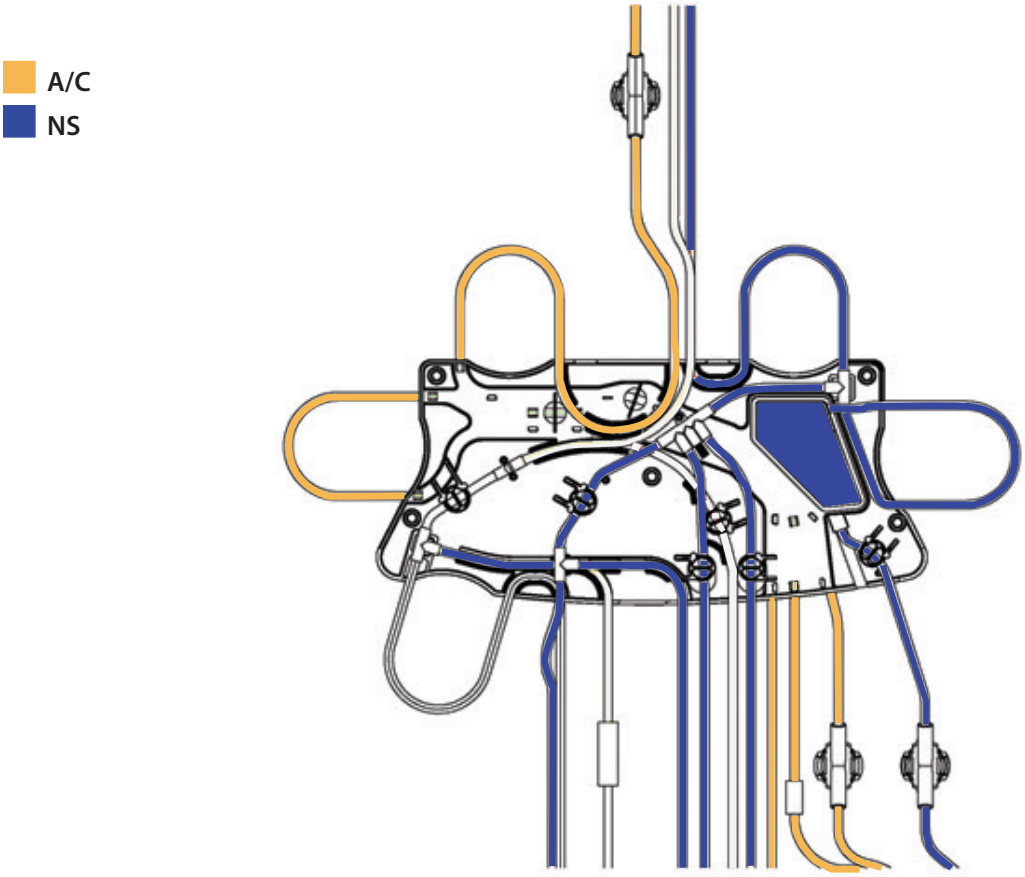


Figure 10-5: Fluid Contents of Pump Tubing Organizer at the End of PRIME.

CELLEX™ System Procedural Kit estimated circuit volume

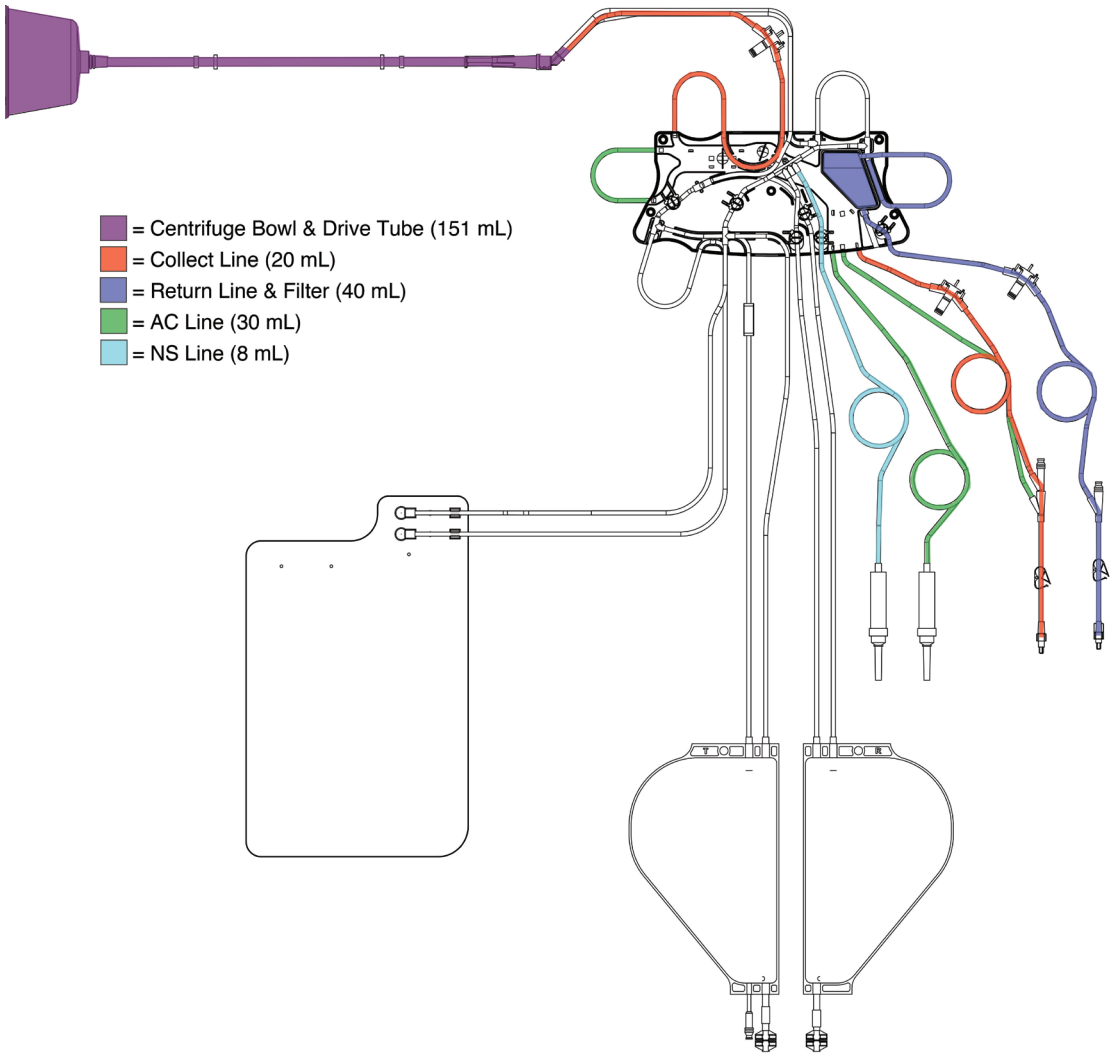


Figure 10-6: Estimated total circuit volume during COLLECT (10:1 Anticoagulant Ratio).
10% of total circuit volume will be comprised of anticoagulant if 10:1 ratio is utilized during COLLECT.

The values presented above represent estimated circuit volume only. Refer to ***page 10-3*** for the estimated average extracorporeal volume whole blood equivalent at various hematocrit values in SINGLE NEEDLE Mode or DOUBLE NEEDLE Mode.

NOTE: Each drip chamber holds approximately 10 mL of fluid that is manually squeezed into the drip chamber and is not counted in the displayed volumes.

Delivery of Anticoagulant and Saline during a Treatment

- **Anticoagulant (A/C)**
  - Approximately 55 mL A/C during PRIME.
  - Approximately 3 mL A/C delivered each time PRIME is pressed during prime access.
  - A/C is dripped at the default ratio of 10:1 (10 mL whole blood to 1 mL A/C).
  - Anticoagulant is delivered to the Collect Line at the Keep Vein Open (KVO) rate of 10 mL/hour. during PAUSE and STOP.
  - The volume of A/C displayed on the operator interface includes all volume delivered to the kit from the A/C bag, including 30 mL retained in the A/C tubing line.
- **Normal Saline (NS)**
  - A total of approximately 243 mL NS during PRIME and 11 mL NS is delivered during PRIME ACCESS.
  - A default Return rate of 5 mL/min will be delivered during DOUBLE NEEDLE mode PURGING AIR. Rate may be increased or decreased by operator.
  - Additional NS may be administered during the treatment at the request of the operator.
  - 40 mL NS rinse of centrifuge bowl during EMPTYING BOWL.
  - 40 mL NS rinse of Return Line after REINFUSE/RETURNING is complete.

RESET FLUID BALANCE TO ZERO

The operator can reset the fluid balance to zero at any time during the course of a treatment if desired.

1. Press and hold on the center of the FLUID BALANCE display for 2 seconds.

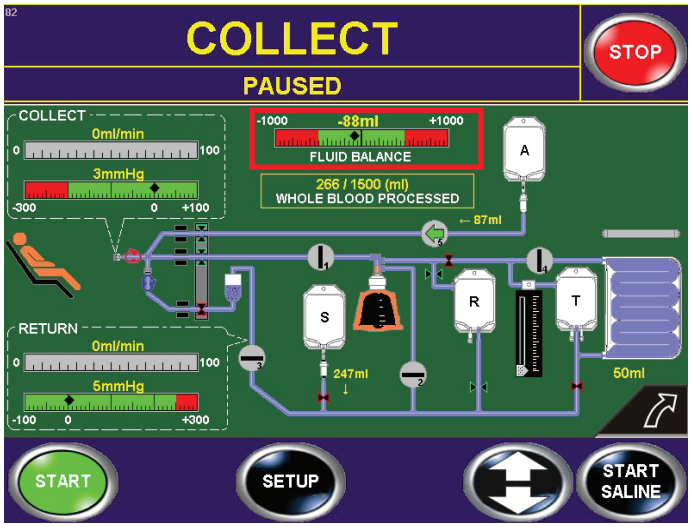


Figure 10-7: Resetting the Fluid Balance to Zero

2. A pop-up window will appear asking to confirm setting fluid balance to ZERO

3. Select YES to confirm and to set fluid balance to ZERO. Select NO to CANCEL.

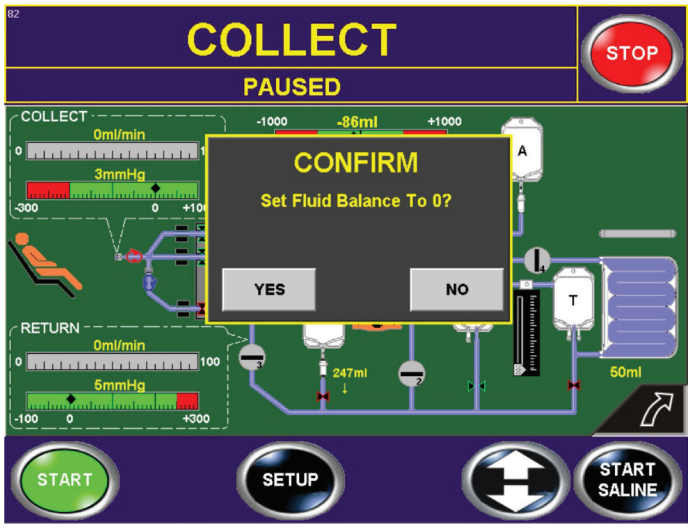


Figure 10-8: Confirming Reset of the Fluid Balance to Zero

WARNING:

- Resetting the FLUID BALANCE to zero will tare the displayed fluid balance to 0 mL but will not automatically maintain a FLUID BALANCE of 0 mL. COLLECT and RETURN Flow Rates must still be managed to maintain an appropriate fluid balance.

Blood Prime

Some medical conditions require not only maintaining intravascular fluid volumes during a procedure, but also, carefully controlling the circulating red blood cell volume. If in preparation for a treatment, calculations show that the estimated extracorporeal blood volume exceeds 10 or 15% of the patient's Total Blood Volume (TBV) or the resulting circulating red blood cell volume will become too low due to fluid replacement it will be necessary to prime the procedural kit with packed red blood cells. In these patients careful attention to both negative and positive fluid balance is mandatory.

CAUTION:

- Maximum extracorporeal volume for patients weighing less than 30kg should not exceed 10% of the patient's Total Blood Volume. Patients that do not meet the safe minimal ECV should only be treated using the blood prime procedure. If the treating clinician does not desire to use the blood prime procedure, raising the patient's hematocrit and/or body weight may allow the patient to undergo the standard procedure per table on ***page 10-3.***

Blood Prime SETUP Parameter (SETUP Screen 2)

By default, the Blood Prime SETUP parameter is disabled (OFF). When enabled (ON) the following features will be activated:

1. At the onset of BUFFY COAT, the return flow rate will automatically be reduced to zero and the return access will be maintained with KVO. The operator is able to manually increase the return flow rate using the arrows on the Main Screen of the Operator Interface.
2. During PHOTOACTIVATE, no return bag contents will be returned to the patient.
3. Reinfusion of the treatment volume will begin automatically using the last user set return rate. The Reinfusion Rate Limit is active at this point.
4. Once all of the treatment volume has been reinfused, the Rinseback Volume will be returned to the patient automatically.
5. An audible cadence will occur when Rinseback is complete. The operator now has the option to:
    a. Repeat the Rinseback using the same volume
    b. Enter SETUP and select a different Rinseback Volume
    c. Complete the treatment by pressing  followed by ABORT

Before You Begin

Abbreviations:

TBV = Total Blood Volume (mL)

ECV = Extracorporeal Volume (mL)

pRBC = packed Red Blood Cells (donor unit)

A/C Ratio = mL of Blood/mL of Anticoagulant

BOS = Bowl Optic Sensor Reading

WBP = Whole Blood Processed (mL)

SN mode = SINGLE NEEDLE mode

DN mode = DOUBLE NEEDLE mode

KVO = Keep Vein Open (anticoagulant or saline drip at 10 mL/hour)

Additional supplies:

a. One donor pRBC unit, minimum volume = 250 mL, minimum hematocrit of 50%. pRBCs should be as fresh as possible (≤ 14 days). Recommend one additional unit available as backup.

b. One blood administration filter set with two-way flow through filter. NOTE: Y-Type filter set allows wetting filter with saline if desired. Care must be taken not to introduce large amounts of extra saline as this may lead to excess dilution of the pRBC unit.

c. One high flow stopcock (with two female luers and one male luer).

- Determine if blood prime is necessary:
  a. Estimate the patient's total blood volume. See ***page 10-4*** for more information.
  b. Using the patient's hematocrit percent (within 48 hours of treatment) refer to ***page 10-3*** to estimate the expected ECV during the treatment. Maximum extracorporeal volume for patients weighing less than 30 kg should not exceed 10% of the patient's Total Blood Volume. Patients who do not meet the safe minimal ECV should only be treated using a blood prime procedure.
  c. Also consider the clinical condition of the patient at time of treatment to determine any additional reason for priming the extracorporeal circuit with blood, such as the patient's circulating RBC volume, or a low resting blood pressure, etc.
  d. Document above calculations on flow sheet.
- The patient will be isovolemic during DRAWING/RETURNING when DN mode access is used and the COLLECT and RETURN flow rates are identical. The patient will remain isovolemic during BUFFY COAT if the donor pRBC unit is used to displace the buffy coat and the return flow remains at the blood prime default of 0 mL/min. On average, following the instructions below, the patient will become approximately 170 mL fluid positive once the treated leukocytes are reinfused and rinseback is performed. Confirm that the patient is able to tolerate this positive fluid shift.
- The clinician must establish the patient WBP target and prescribe the appropriate dose of anticoagulant. REMINDER: For patients < 40 kg use 150–250 Units of heparin/kg body weight/500 mL 0.9% Normal saline per treatment. See ***"Anticoagulation" on page 2-8*** for more information.
- The operator must confirm the proper anticoagulant for the patient before kit installation and PRIME.

- Confirm that a double lumen access is available and that COLLECT and RETURN flow rates of at least 15 mL/min can be achieved.
  - ✓ **Confirm patency of patient's access before continuing.**
- Use aseptic technique when making all connections and disconnections.
- Avoid blood leaks by closing all clamps and verifying the position of the stopcock prior to connecting or disconnecting lines.
- Confirm all lines are void of air before each connection is made.

PRIME:

a. Install the THERAKOS™ CELLEX™ Photopheresis System procedural kit as directed.

b. Press START to begin PRIME.

c. When the Fluid Balance Calculator appears, do not make any changes. Press CANCEL.

Enable Blood Prime:

a. Press SETUP and then press the arrow tab  to access SETUP Page 2.

b. Enable the Blood Prime feature by pressing and holding the 

icon until it changes to 

. Input the appropriate Rinseback Volume.

c. Press SAVE to confirm all changes made to the above parameters.

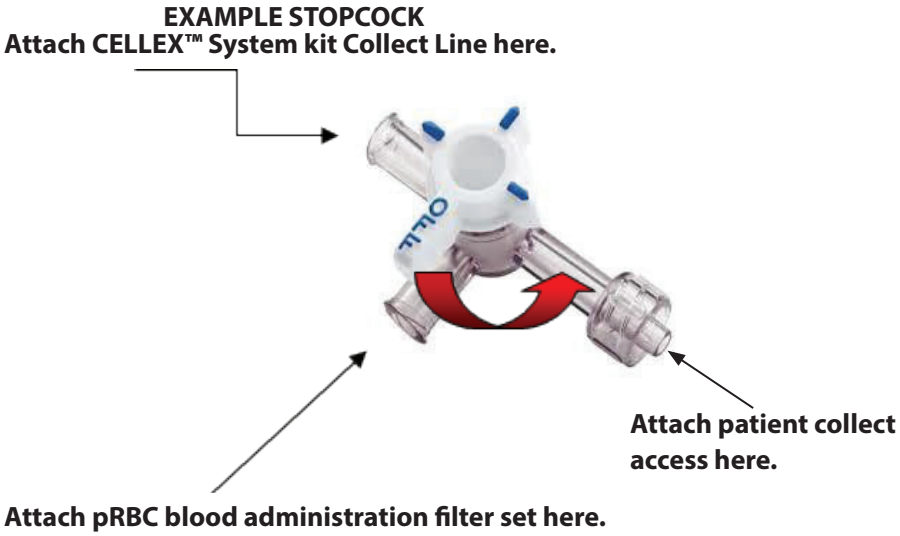
d. Confirm that the Blood Prime Feature icon 

appears at the top of the Main Screen of the Operator Interface.

NOTE:
All parameter settings will be reviewed and reset as needed just prior to connecting the patient.

PRIME ACCESS:

a. Aseptically add one high flow stopcock to the CELLEX™ System Collect Line.



b. Open the CELLEX™ System Collect Line (RED) clamp and open one path of the stopcock. Press PRIME to flush the line and remove remaining air.

c. If necessary, repeat flush by pressing PRIME while rotating stopcock until all air is removed.

d. Close the CELLEX™ System Collect Line (RED) and Return Line (BLUE) clamps.

ESTABLISHING ACCESS: (Connecting the donor pRBC unit to the CELLEX™ System)

a. Close all clamps on the blood administration filter set.

b. Aseptically spike the donor pRBC unit with the blood administration filter set.

c. Open the clamps and allow pRBCs to flow to tip of the blood administration filter set. Close the clamps.

d. Keeping the CELLEX™ System Collect and Return Lines configured in SINGLE NEEDLE mode, aseptically attach the blood administration filter set to the stopcock.

e. Rotate the stopcock to be off to the patient's collection port and open to the donor pRBC unit.

f. Open all clamps on the blood transfusion set to allow blood flow from the donor pRBC unit.

g. Open the Collect Line (RED) and Return Line (BLUE) clamps of the CELLEX™ System procedural kit.

NOTE:
If you opt to use a Y-Type blood administration set it may be wetted first with saline. Prior to connecting to the CELLEX™ System Collect Line, clamp the saline and then waste the saline in the filter and tubing as you allow the pRBCs to reach the tip of the blood administration set.

SELECT:

a. **Select and confirm SINGLE NEEDLE on the operator interface.**

b. The screen display schematic shows the Return Line connected to the Collect Line and (RED) and (BLUE) clamps open.

COLLECT: (DRAWING/RETURNING from/to donor pRBC unit in SN mode)

a. Press START to begin PURGING AIR. The COLLECT Flow Rate will be limited to 25 mL/min.

b. Continue DRAWING (30 mL/min)/RETURNING (50 mL/min) in SINGLE NEEDLE mode until the plasma/RBC interface is established and the BOS reading reaches 150.

c. If desired, complete additional DRAWING/RETURNING phases to prime the filter in the pump tubing organizer and the Return Line with donor pRBCs.

d. At the end of a RETURNING phase, press PAUSE. The volume in return bag should be approximately 50 mL.

NOTE:

- PAUSE is only available for 10 minutes.
- If more than 10 minutes elapses the centrifuge will stop.
- Whole blood separation will be lost whenever the centrifuge bowl stops. Repurging and ESTABLISHING SEPARATION will be required before resuming. Before proceeding, decide if repurge is to be done connected to patient in DOUBLE NEEDLE mode or connected to the donor pRBC unit in SINGLE NEEDLE mode.

PAUSED: (Transition from donor pRBC unit to patient)

a. Record all data from the operator interface screen.

b. Change the following SETUP parameters to meet the needs of the patient:

SETUP Page 1

COLLECT Rate Limit 30 mL/min or less

RETURN Rate Limit 30 mL/min or less, and = COLLECT Rate Limit

A/C Ratio = X:1 (Choose ratio appropriate for patient and anticoagulant in use)

REINFUSION Rate Limit = 1–25 mL/min

(Choose rate suitable for patient during fluid gain portion of the treatment)

SETUP Page 2

WBP TARGET = (donor pRBC unit WBP + patient WBP goal)

(Enter value closest to the calculated total)

Blood Prime = ON

Rinseback Volume = 0–999 mL

c. Enter WBP Target number closest to total.

d. Press SAVE. Confirm all entries before proceeding.

e. Reset FLUID BALANCE to zero by pressing and holding the FLUID BALANCE display on the main screen of the operator interface. Confirm by pressing YES. The screen will now show the patients fluid balance.

WARNING:

- Resetting the Fluid Balance to zero will tare the displayed fluid balance to 0 mL but will not automatically maintain a Fluid Balance of 0 mL. COLLECT and RETURN Flow Rates must still be managed to maintain an appropriate fluid balance.

f. Close the donor pRBC unit clamp. Close the CELLEX™ System Collect Line (RED) and Return Line (BLUE) clamps.

g. Connect the patient collect access to the 3-way stopcock on the CELLEX™ System Collect Line.

h. Confirm the CELLEX™ System Return Line (BLUE) clamp is closed. Aseptically disconnect the Return Line from the CELLEX™ System Collect Line and connect it to the patient's return access.

i. Open the patient's collect and return access clamps. Open the CELLEX™ System Collect Line (RED) clamp and the CELLEX™ System Return Line (BLUE) clamp.

j. Rotate the stopcock to be off to the donor pRBC unit and open to the patient.

k. **Confirm that all connections are secure and correct.**

CHANGE Instrument Setting from SINGLE NEEDLE to DOUBLE NEEDLE mode

a. **Press**  **Select and confirm DOUBLE NEEDLE on the operator interface.**

b. Verify on the operator interface that the Return Line is no longer connected to the Collect Line.

COLLECT: (DRAWING/RETURNING from/to Patient in DN mode)

NOTE:

The FLUID BALANCE reading should be zero if reset as directed above.

a. Press START to begin blood collection from the patient. Confirm blood flow from and to the patient. Check all connections for leaks.

b. Carefully monitor the patient at all times.

c. To keep the patient isovolemic, set the Collect Flow Rate equal to the Return Flow Rate. Periodically it may be necessary to adjust either rate independently.

d. Monitor the position of the plasma/RBC interface in the centrifuge bowl and ensure that the RBCs remain near the laser as whole blood is processed.

e. The centrifuge speed increases to 4800 RPM 75 mL prior to the WBP target and pauses for 3 minutes. After collection resumes, the BUFFY COAT phase begins when the BOS is below setup value. When the subtitle line changes to BUFFY COAT press PAUSE.

PAUSE:

a. Record all data from patient collection phase.

b. Open the donor pRBC unit clamp.

c. Rotate the stopcock to be off to the patient and open to the donor pRBC unit.

COLLECT: (BUFFY COAT – DRAWING using donor pRBCs to displace patient's leukocytes)

a. Press START to resume the buffy coat collection.

b. Ensure that the pRBC unit does not deplete during BUFFY COAT. If the pRBC unit begins to deplete before the end of BUFFY COAT, continue with a second (backup) unit of pRBCs or evaluate whether the patient's blood can be used to complete BUFFY COAT.

NOTE:

If there is insufficient volume remaining in the packed red cell bag and if the patient is able to tolerate a temporary fluid deficit you may draw from the patient during BUFFY COAT.

- The whole blood volume required to displace the buffy coat is hematocrit dependent
- The average volume required to displace a buffy coat is 100-150ml
- Low hematocrits may require whole blood volume as high as 280ml to displace the complete buffy coat.

CAUTION:

If drawing from the patient during BUFFY COAT, the operator must increase the return flow rate from 0 mL/min to match the Collect Flow Rate to maintain isovolemic conditions.

c. BUFFY COAT collection will complete automatically, but may also be ended manually by pressing PAUSE, followed by END BUFFY.

d. At the end of BUFFY COAT, the centrifuge will stop and the Centrifuge Bowl will empty.

e. Record all treatment data.

PHOTOACTIVATE

a. When prompted, dispense the appropriate amount of Methoxsalen (20 micrograms / mL) into the treatment bag. Record the amount of Methoxsalen (20 micrograms / mL), UVA time and Return Bag Volume. Close the pop-up window.

b. Open the centrifuge door. Close the pop-up window.

c. Reset the FLUID BALANCE to zero by pressing and holding the FLUID BALANCE display. Confirm when prompted. This reset will now allow you to track the positive fluid gain of the patient.

d. Press  to begin PHOTOACTIVATE.

e. The patient collect access and the donor pRBC unit access may be disconnected. Keep all return access clamps open. The instrument will provide KVO.

f. After PHOTOACTIVATE is complete, the instrument will automatically advance to REINFUSE and the photoactivation module will be emptied and rinsed.

REINFUSE and RETURNING (Rinseback)

a. Reinfusion of the treatment volume will begin automatically using the last user set return rate. The Reinfusion Rate Limit is active at this point.

b. Monitor the patient carefully during REINFUSE and RETURNING.

c. Once all of the treatment volume has been reinfused, the Rinseback Volume will be returned to the patient automatically.

d. An audible cadence will occur when Rinseback is complete. The operator now has the option to:

   a. Repeat the Rinseback using the same volume by pressing START.

   b. Enter SETUP and select a different Rinseback Volume. Save SETUP changes and then press START.

   c. Complete the treatment by pressing  followed by ABORT

NOTE:

- A 20 mL saline bolus may be used as a rinseback to avoid returning any additional RBCs to the patient. Enter SETUP to set saline bolus limit to 20 mL. Then select START SALINE.
- In a non-blood prime procedure, 40 mL of Saline is used as a final rinseback. The Return Line & Filter contain 40 mL of fluid *(See page 10-12)*.

TREATMENT COMPLETE

a. Clamp all lines. Press RELEASE KIT.

b. Disconnect the patient.

c. Record all data.

d. Discard kit (including volume remaining in return bag).

e. Clean instrument and turn power off.

CALCULATIONS:

FLUID BALANCE (FB) = _____ + _____ = _____mL**
(Displayed value on operator interface) (END PT FB)

Definition: END PT FB = difference in fluid balance at the end of patient whole blood collection minus fluid balance value at the start of patient collection. This value represents Δ Patient*.

**Δ Patient = difference in patient fluid balance at end of patient collection from start of patient collection.*

***Use this formula when you reset the FLUID BALANCE display at the start of patient whole blood collection and at the start of REINFUSING.*

Manual FLUID BALANCE (FB) Calculation =

_____ + _____ + _____ = _____ mL***
(Treatment Volume) (Rinseback Volume) (END PT FB)

****Use this formula if the FLUID BALANCE display was not reset to zero when the patient was connected* and *again before REINFUSE.*

ANTICOAGULANT delivered to patient =

((_____ - _____) + (_____)) / (_____) = _____ mL anticoagulant
(Total WBP) (pRBC prime WBP) Rinseback A/C Ratio

Units of Heparin/mL =

_____ / 500 = _____ Units of Heparin/mL
(Units of Heparin) (mL 0.9% Normal Saline)

Units of Heparin delivered to the patient =

(Units of Heparin/mL)	X	(mL Anticoagulant)	=	(Units of Heparin to Patient)	Units

SECTION 11: GLOSSARY AND SYMBOLS

8-methoxypsoralen (8-MOP®): A light-sensitive medication that is biologically inert until it is activated by specific wavelengths of UVA energy.

Abnormal plasma: Plasma is visually examined for color. Normal plasma should be clear or pale yellow in color. The pale yellow color is due to the presence of carotenes which are yellow pigments found in a variety of plant materials, including some seeds. Some abnormal plasma conditions may warrant an adjustment of the Bowl Optic Sensor, such as:

- Dark yellow colored plasma is icteric plasma. In mammals, icterus or jaundice is due to increased amounts of bilirubin pigments in plasma as a result of liver disease.
- White or milky colored plasma is lipemic, which is due to the presence of fat. Lipemic plasma is most commonly seen if blood is drawn shortly after a meal high in fat. Sometimes the plasma will always appear mildly lipemic. Medication, liver or pancreatic disorders can cause lipemia.
- Pink color in the plasma is due to hemolysis, which is the breaking apart of RBC's and the subsequent release of red hemoglobin molecules into the plasma. Hemolysis is most commonly caused by improper handling of blood, such as forcibly expelling blood through the needle, over-centrifugation or mechanical trauma from the peristaltic pumps. If hemolysis is observed during a photopheresis treatment the therapy must be aborted and blood should not be returned to the patient.

Abnormal Red Blood Cell Morphology: Any variation from normal in size, shape or color of erythrocytes as indicated in high or low values of red blood cell indicies such as MCV, MCHC, MCH or RDW in a complete blood cell count laboratory analysis.

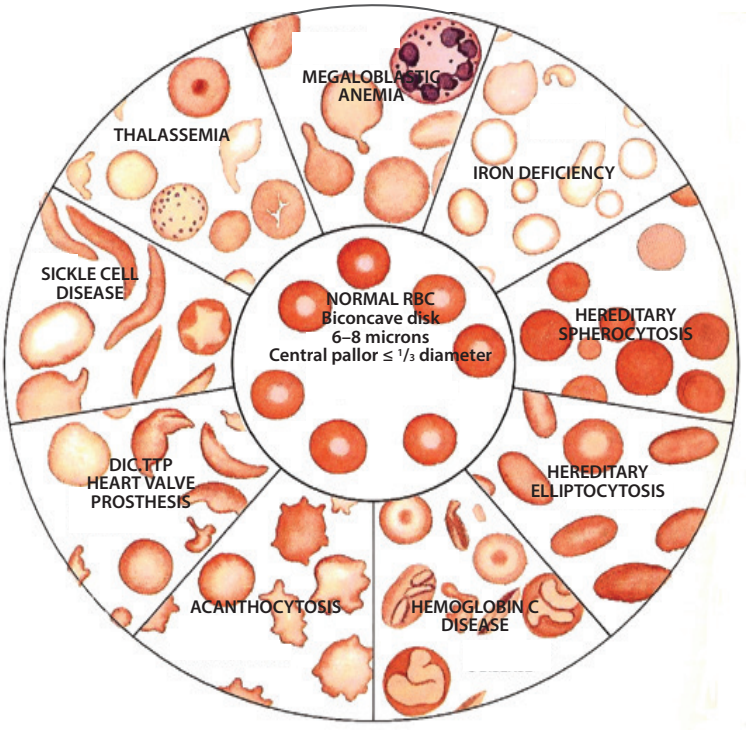


Figure 11-1: Normal and Abnormal Red Blood Cell Morphology

Abort Treatment: Interruption of a photopheresis treatment that results in termination of the treatment without any further fluid return to the patient.

A/C Ratio: The relationship of peristaltic pump flow rates between anticoagulant delivery and whole blood as it is drawn into the instrument.

Air Detector: An ultrasonic pulse sensor that detects air bubbles in patient COLLECT and RETURN, anticoagulant, treatment bag and return bag lines. The air detector may also be referred to as the air sensor.

Anemia: A condition characterized by abnormally low levels of healthy red blood cells or hemoglobin (the component of red blood cells that delivers oxygen to tissues throughout the body).

Anticoagulant Line, Spike and Drip Chamber:

- Line: Tubing line that delivers anticoagulant solution during the procedure.
- Spike: Sharp hollow adapter used to access to the port of the anticoagulant solution bag.
- Drip Chamber: Hollow cylinder with inlet and outlet to monitor anticoagulant fluid levels.

Automatic Flow Control: Software algorithm that automatically adjusts COLLECT and RETURN flow rates when collect or return pressures approach their respective limits.

Bearing: A structural part that supports, guides, and reduces the friction of motion between fixed and moving machine parts.

Blood Prime Feature: A treatment setting available via the SETUP screen. When turned ON, the RETURN flow rate is automatically adjusted to zero during BUFFY COAT and PHOTOACTIVATE and following reinfusion of the Treatment Volume, only the Rinseback Volume is reinfused from the Return Bag.

Bowl Optic Sensor: Red laser sensor located in the Centrifuge Chamber, used to detect and maintain the position of the plasma/red blood cell interface in the spinning Centrifuge Bowl.

Buffy Coat: A leukocyte enriched blood fraction containing plasma, leukocytes and erythrocytes.

BUFFY COAT: A THERAKOS™ Photopheresis phase in which the leukocyte enriched blood fraction is displaced from the Centrifuge Bowl by the addition of more whole blood and routed to the treatment bag.

CAUTION: Use careful forethought to minimize risk of mistakes that may lead to a failed treatment or cause physical harm to the patient or photopheresis operator.

Centrifuge: Machine used to separate blood components by their density using centrifugal force.

Centrifuge Assembly: Includes the following component parts: 1) Centrifuge Frame 2) Upper and Lower Bearing Retainers 3) Fluid Leak Detector 4) Centrifuge Bowl Holder 5) Drive Tube Clamp Assembly and 6) Tubing Guide and Tubing Exit Slot.

Centrifuge Bowl: Sterile, disposable chamber used in the Centrifuge to hold the blood.

Centrifuge Bowl Holder: Free spinning platform used to hold the Centrifuge Bowl.

Centrifuge Bowl Drive Tube: A triple lumen tube that provides whole blood entry and simultaneous plasma and red blood cell exit from the spinning Centrifuge Bowl. Because the tube is secured to the spinning Centrifuge Frame and attached to the free rotational Centrifuge Bowl it is responsible for driving the rotation of the Centrifuge Bowl.

Centrifuge Bowl Speed: A user-selectable speed

Centrifuge Chamber Door Manual Release Access: Rotational latchkey that allows manual opening of a locked Centrifuge Chamber Door in the event of an instrument malfunction or power outage. A flat head screwdriver is required to turn the latchkey.

Clamp Release Tool: a Tool required to disengage a Fluid Routing Valve in the event of a power failure or instrument malfunction. Used in Manual Blood Return w/o Power or Access to the RELEASE KIT Button.

COLLECT: Phase of operation used to harvest the leukocyte enriched fraction of the processed whole blood. Includes as sub-phases: DRAWING, RETURNING, BUFFY COAT and EMPTYING BOWL. Designed to be accomplished with only one cycle.

Default Parameter(s): A particular setting(s) or value for a variable that is assigned automatically by an operating system and remains in effect unless canceled or overridden by the operator.

DOUBLE NEEDLE Mode: Software program written to manage the continuous flow process of drawing and simultaneously returning fluids to and from the patient during a photopheresis therapy.

DRAWING: Sub-phase of COLLECT where whole blood is drawn from the patient using the negative pressure of the collect pump (pump #1). The whole blood is routed to the Centrifuge, plasma is expressed from the top of the Centrifuge Bowl and red blood cells are removed from the bottom of the Centrifuge Bowl allowing the leukocyte fraction to expand within the Centrifuge Bowl. The DRAWING phase continues until the Whole Blood Processed target is reached, at which time the software advances to BUFFY COAT.

Drive Tube Clamp Assembly: Groove, latch and clamp that secures the base of the Centrifuge Bowl Drive Tube and routes the three internal tubing lines to the Pump Tubing Organizer.

ELUTRIATING: "To wash out". Plasma is used "to wash out" additional leukocytes from the packed red blood cells layer in the Centrifuge Bowl during BUFFY COAT. This sub-phase is automatic.

EMPTYING BOWL: The sub-phase that follows BUFFY COAT, used to transfer the packed red blood cells from the Centrifuge Bowl to the return bag, just prior to PHOTOACTIVATE.

END TREATMENT: Treatment interruption that results in stopping the therapy and returning all blood and fluids to the patient immediately. Cells may not have been photoactivated.

Erythrocyte: Red Blood Cell.

Erythroderma: Abnormal redness of the skin. A phase of exfoliative dermatitis.

Establishing Separation: Is a PAUSE state where the cenrifuge bowl is spinning and the Red Cell/Plasma interface is re-established following a centrifuge bowl speed change, a bowl re-purge or during BUFFY COAT. Establishing Separation will be 2-3 minutes depending on phase of treatment

Filtered Blood Administration Set: A commercially available sterile tubing system that includes a 200-micron filter suitable for blood transfusion, a spike port adapter and luer connection.

FLUID BALANCE: Operator Interface screen display that estimates the fluid volumes taken from and given to the patient during a treatment. Fluids included in the estimation are whole blood, saline and anticoagulant. Pump Head rotation as well as Load Cell data are combined to estimate volumes.

Fluid Balance Calculator: Integrated calculator that uses patient gender, height and weight to estimate Total Blood Volume using the Nadler Formula

Fluid Leak Detector: A sensor located on the wall and floor of the Centrifuge Chamber and floor of the Photoactivation Chamber that detects blood or fluid leaks and alerts the operator with an alarm when unexpected fluid or humidity is present.

Fluid Routing Valves: Mechanical devices controlled by the instrument software to direct the flow of fluid through the tubing lines of the Pump Tubing Organizer.

Hematocrit Cuvette: A cuvette located on the treatment bag collect line. It works in conjunction with the Hematocrit Sensor to determine the hematocrit of the blood and buffy coat.

Hematocrit Sensor: Sensor that detects the hematocrit of the blood as it enters the treatment bag and detects the hematocrit of the buffy coat (or Final Treatment Volume) to help determine the duration of UVA exposure necessary for photoactivation.

Hemostats: A clamp like instrument used to compress a blood vessel in order to reduce or arrest the flow of blood during surgery. Used to clamp Procedural Kit tubing lines during the Manual Blood Return process.

Heparin: A complex organic acid found especially in lung and liver tissue, which has a mucopolysaccharide as its active constituent, prevents platelet agglutination and blood clotting, and is used in the form of its sodium salt in the treatment of thrombosis.

Information Signal: A non-alarm visual and/or audible signal which provides the operator with information.

Instrument ID Tag: Label found on the back of the THERAKOS™ CELLEX™ Photopheresis System that contains the Model Number, Serial Number, Date of Manufacture, voltage, weight and fuse information. Cautions to: order by clinician only, use hospital grade receptacles, check grounding periodically, risk of explosion if used in the presence of anesthesia.

Isovolemic Conditions: A condition during a photopheresis procedure where the fluid balance remains constant. An isovolemic condition can only be maintained when the collect and return rates are equal during double needle mode.

KVO: Keep Vein Open. An automatic flow of anticoagulant solution to the COLLECT Line or heparinized plasma to the RETURN line that begins any time the instrument is PAUSED or STOPPED during a treatment. The KVO flow rate is 10 mL/hour and is independent of the A/C ratio.

Lamp Failure: Automatic detection of a single lamp malfunction or of light emission below an acceptable treatment intensity.

Lamp Life Remaining: Hours of lamp usage available on the installed light assembly that remain within the therapeutic light intensity required.

Leukocyte: White blood cell.

Light Assembly: Collection of lamps, validated and quality controlled for even distribution, energy decay and performance, used to deliver the UVA energy during PHOTOACTIVATE.

Line Configuration: The position of the connections of the Patient COLLECT and RETURN Lines to the patient access sites and to each other in either SINGLE NEEDLE or DOUBLE NEEDLE modes of operation.

Load Cell Hook: An electronic device (transducer) that is used to convert a force into an electrical signal. Used to estimate the volume of fluid in the treatment bag and return bag during a photopheresis treatment.

LOW Priority Alarm: Alarm indicating that operator awareness is required. Priority was assigned through risk analysis

Nadler Formula: Formula used in integrated Fluid Balance Calculator to estimate Total Blood Volume

Manual Blood Return: A process that aseptically drains all blood and fluids from the Procedural Kit and allows return to the patient through a filtered blood administration kit. It is used only in the event of an instrument malfunction or prolonged power outage.

MEDIUM Priority Alarm: Alarm indicating that prompt operator response is required. Priority was assigned through risk analysis.

Methoxsalen (20 micrograms/mL): Sterile liquid formulation of 8-methoxypsoralen (8-MOP®).

MUTE: An operator-initiated command to silence an audible alarm signal.

NOTE: A comment, explanation or tip to aid in memory or successful execution of the photopheresis therapy.

Operator ID: An optional one to four digit field in SETUP which allows an operator to input a unique numerical identifier

Operator Interface: Instrument display monitor with integrated touch screen.

Operator Interface Display Detail:

Main screen provides visual and numeric tracking of treatment progress.

Text Screen: Summarizes the treatment

Patient Lines: Tubing lines that are used to collect whole blood from and return blood components, anticoagulant and/or saline to the patient.

PAUSE: A brief (limited to 10 minutes) intentional interruption of the treatment.

Peristaltic Pump: A device for moving fluids by the action of multiple, equally spaced rollers, which rotate and compress a flexible tube.

Phases: Titled steps of the THERAKOS™ Photopheresis therapy include Prime, Select, Collect, Photoactivate, Reinfuse, and Treatment Complete.

Photoactivation Chamber: Instrument compartment that houses the THERAKOS™ CELLEX™ Light Assembly and the Photoactivation Module.

Photoactivation Module: A molded, validated and quality-controlled for UVA-transparency and sterility, acrylic module containing sterile fluid serpentine pathways through which the buffy coat is exposed to the UVA light. Module may also be referred to as "plate".

PHOTOACTIVATE: The THERAKOS™ Photopheresis phase in which the buffy coat is exposed to an automatically calculated, controlled dose of UVA energy and an operator-injected specific dose of medication, both of which have been validated with post-treatment cell viability testing.

Photopheresis: THERAKOS™ Photopheresis is a leukopheresis-based, immunomodulatory therapy that integrates the use of a medical device, one sterile disposable procedural kit and a psoralen medication. All components are regulated and quality controlled to be used as a complete closed system providing ultimate safety of the patient and maximum efficacy to the patient.

Pop-up Message: Informational or confirmatory statements that appear on the main screen of the Operator Interface Display at various times throughout the treatment and require acknowledgement by the operator to clear. Reference to the standard IEC 60601-1-8 the pop-up message is classified as an information signal

Power Cord Wrap Cleats: Projecting arms on which the power cord can be wound and secured.

Pressure Sensors (Domes and Transducers): Instrument components that detect a fluid pressure and produce an electrical signal related to the pressure. Also known as electrical pressure transducers. Used to monitor procedural kit line pressures and the internal pressure of the spinning Centrifuge Bowl.

PRIME: Prime is a phase of the procedure, prior to patient connection, where the system performs a series of tests to ensure proper operation of the instrument components and functionality of the procedural kit while priming the kit with fluids. Once initiated, PRIME occurs automatically and generates alarm messages should a problem be detected.

Procedural Kit: (Part #: CLXECP) A custom made, regulated, patented, sterile, single use only, disposable tubing set made specifically to aseptically contain the patient's whole blood while undergoing a THERAKOS™ Photopheresis therapy.

Pump Deck: Working surface of the THERAKOS™ CELLEX™ Photopheresis System that supports the Pump Tubing Organizer and contains the Fluid Routing Valves, Hematocrit Sensor, Air Detectors and Tubing Guides.

Pump Tubing Organizer: A cassette designed to integrate all of the peristaltic pump tubing for easy loading and fluid management during the treatment.

Pump Tubing Organizer Mold Indents: Fabricated notches that allow proper alignment and installation of the Pump Tubing Organizer on the Pump Deck.

Pump Tubing Segment: The length of procedural kit tubing that wraps around each peristaltic pump to provide fluid movement.

Purging Air: Sub-phase of COLLECT where the patient's volume is used to displace any remaining sterile air contained within the Centrifuge Bowl after PRIME to the Return Bag. PURGING AIR occurs in both SINGLE NEEDLE and DOUBLE NEEDLE mode configuration.

Recirculation: A condition where volume exiting the return line mixes with volume entering the collect line which can result in dilution of the whole blood entering the extracorporeal circuit.

Reinfusing: Phase following Photoactivation during which all Treatment and Return Bag contents are infused to the patient

RESET: An operator-initiated command to return instrument to the ready state required to resume a treatment following an alarm interruption.

Retainer clip: A device designed to restrain. Used to secure the Centrifuge Bowl to the Centrifuge Bowl Holder.

Return Bag: Disposable procedural kit bag used to pool the untreated blood components to be returned to the patient.

RETURNING: The THERAKOS™ Photopheresis phase that routes all blood components, excluding the leukocyte enriched fraction, back to the patient using the return pump (pump #3).

Rinseback: Reinfusion of a set volume of Return Bag contents following reinfusion of Treatment Bag contents

Rinseback Volume: A user-selectable volume that dictates how much of the Return Bag is reinfused following reinfusion of the Treatment Bag when the Blood Prime Feature is enabled

Saline: A 0.9% Normal salt solution that is isotonic with blood.

Saline Bolus: Direct infusion of 100 mL (default volume) of 0.9% Normal saline.

Saline Line, Spike and Drip Chamber:

Line: Tubing line that delivers 0.9% Normal saline solution during the procedure.

Spike: Sharp hollow adapter used to access the port of the saline solution bag.

Drip Chamber: Hollow cylinder with inlet and outlet to monitor saline fluid levels.

SINGLE NEEDLE Mode: Software programs designed to manage the discontinuous flow process of intermittently drawing, pooling and then returning fluids to and from the patient during a photopheresis therapy using a single access device.

Specific Gravity (SG): A unitless value quantifying the density of a substance compared to water. The density of water, which is one kilogram per liter (at 4 degrees C), is assigned a SG of 1.000. If a substance is denser than water, it will have a SG greater than 1.000; if it is less dense than water, its SG will be a value less than 1.000 (but greater than zero).

Smart Card: An integral part of the disposable procedural kit. Data pertaining to the instrument function and the patient treatment is recorded on the Smart Card as the START button is pressed to initiate PRIME.

Smart Card Port: Receptacle in the Operator Interface Screen into which the Smart Card is placed.

Sterility: As it pertains to the procedural kit refers to the microenvironment made free of infectious agents by exposure to ethylene oxide. "Sterilized with Ethylene Oxide" labeling requires meeting all testing requirements for no viable organisms, endotoxins, biocompatibility and residual levels of ethylene oxide following sterilization and required quarantine time prior to shipping.

STOP: Halts the spinning of the Centrifuge as well as all other functions until directed to resume. The instrument activates KVO maintenance of the COLLECT and RETURN Lines while stopped. Cell separation is lost and the plasma/red blood cells interface must be re-established before the treatment may be resumed. A partial loss of the concentrated leukocyte enriched blood fraction may occur.

Technical Alarm: A coded alarm message indicating a technical problem that may be resolved by re-booting the instrument, but most often requires technical support and/or service to be resolved.

Treatment Bag: Disposable procedural kit bag which contains the buffy coat and is part of the recirculation loop during PHOTOACTIVATE.

Treatment Volume: The total volume of buffy coat plus prime solution that will undergo photoactivation. The number is displayed on the TREATMENT SUMMARY screen and directly below the Photoactivation Module icon on the main display screen. This volume is used to determine the proper dose of 8-methoxypsoralen and the proper dose of UVA irradiation.

Tubing Guides: Tracks designed to organize and stabilize tubing of the procedural kit during a treatment. Tracks are found at the base of the centrifuge chamber to stabilize the three tubing lines from the centrifuge drive tube to the pump tubing organizer and also at the front of the pump deck to stabilize patient lines, treatment bag line, return bag line and anticoagulant line.

Tyvek® Lid: Tyvek is a brand of spunbonded olefin, a synthetic material made of high-density polyethylene fibers; the name is a registered trademark of the DuPont Company. Water vapor and ethylene oxide can pass through Tyvek, but not liquid water.

UVA: Ultra Violet-A radiation.

WARNING: Advice to beware of impending danger that may lead to a failed treatment or cause physical harm to the patient or photopheresis operator.

Wetted: A form of priming that uses anticoagulant solution to prepare various components of the Procedural Kit prior to performing a treatment.

Wheel Locks: Clamps that prevent movement of the instrument wheels when engaged.

Whole Blood Processed Target: The desired amount of whole blood to be drawn from the patient during a photopheresis treatment and centrifuged to extract the leukocyte enriched fraction. The default setting is 1500 mL. The possible target range is 500–2000 mL.

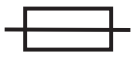
Symbols Key

Symbol	Symbol Title	Description	Standard Title and Designation Number	Reference Number
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.4.4
	Authorized representative in the European community	Indicates the Authorized Representative in the European Community.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.1.2
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.4.3
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.1.3
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.1.1
	Use by Date	Indicates the date after which the medical device is not to be used.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.1.4
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.1.7

Symbol	Symbol Title	Description	Standard Title and Designation Number	Reference Number
LOT	Lot Number / Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.1.5
REF	Reorder Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.1.6
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.3.7
	Contents Fragile	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.3.1
	For Single Use Only (Do Not Reuse)	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.4.2
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.2.6
STERILE EO	Sterilized by Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.2.3
	Sterile Fluid Path Sterilized by Ethylene Oxide	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.2.9

Symbol	Symbol Title	Description	Standard Title and Designation Number	Reference Number
	Non-Pyrogenic	Indicates a medical device that is non-pyrogenic.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.6.3
	Contains Phthalate DEHP	Indicates a medical device contains Bis(2-ethylhexyl) phthalate (DEHP).	BS EN 15986 / Medical Device Directive 93/42/ EEC as amended by Directive 2007/47/EC. IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	2725
	Contains Mercury	Indicates product contains Mercury. The states of Connecticut, Louisiana, Maine, Massachusetts, Minnesota, New York, Rhode Island, Vermont, and Washington (lamps only) prohibit the sale of mercury-added products unless they have a label indicating that the product contains mercury and information concerning proper disposal.	NEMA – National Electrical Manufacturers Association.	N/A
	Biological Risks	Indicates that there are potential biological risks associated with the medical device.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.4.1
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.2.8

Symbol	Symbol Title	Description	Standard Title and Designation Number	Reference Number
	WEEE Waste of Electrical and Electronic Equipment. Do Not Dispose of Instrument without following local directives as prescribed by CENELEC stand EN50419, dated December 7, 2004	Indicates that when end-user wishes to discard this product is must be sent to separate collection facilities for recovery and recycling in the EU.	BS EN 50419: 2006 Marking of Electrical Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	N/A
	UV Light Symbol Warning: Do Not Operate With Cover Removed!	To warn of optical radiation (UV radiation).	ISO 7010 - If necessary, a supplementary sign shall be used to give further information about the kind of optical radiation (e.g. UV, visible radiation, IR). IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	ISO 7010-W027
	Class 1 Laser Product. Do Not Stare Into Beam.	To warn of a laser beam.	EN ISO 7010. IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	ISO 7010-W004
	Dangerous Voltage	To indicate hazards arising from dangerous voltages.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	5036
	Type B applied part	On medical equipment. To identify a type B applied part complying with IEC 60601-1. Note - B = Body.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	5840
	Do Not Push, in accordance with Section 8: Instrument Specifications-Transportation	To prohibit pushing against an object.	IEC/TR 60878, Graphical symbols for electrical equipment in medical practice.	ISO 7010-P017
	Refer to instruction manual/booklet	To signify that the instruction manual/ booklet must be read.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	ISO 7010-M002

Symbol	Symbol Title	Description	Standard Title and Designation Number	Reference Number
	"On" (power)	To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	5007
	"Off" (power)	To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	5008
	IEC 6F22/6LR61 Nine Volt Battery	Indicates a 9V battery type as defined in IEC 60086-2 Category 6.	Battery Directive IEC 60086-2 Category 6 (2006/66/EC).	Page 41
	Lead Free	Indicates that an electronic assembly or sub-assembly within the medical device is "Pb-free". It conforms to EU RoHS requirements. Specific applications may require the maximum concentration of Pb (lead) to be < 0.1%, by weight.	IPC/JEDEC J-STD-609A-2010.	Figure 4-2
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	ISO & ANSI/AAMI/ ISO 15223-1 Medical devices – Symbols to be used with medical device labels – General requirements.	5.3.4
	Fuse	To identify fuse boxes or their location.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	5016
	Conformité Européene (European Conformity)	CE Marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation, in practice by many of the so-called Product Directives.	Directive 93/42/EEC.	N/A

Symbol	Symbol Title	Description	Standard Title and Designation Number	Reference Number
	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	IEC/TR 60878 Graphical symbols for electrical equipment in medical practice.	5140
	Female Patient Gender	Indicates Female gender of patient	Not applicable – internationally recognised symbol	7001
	Male Patient Gender	Indicates Male gender of patient	Not applicable – internationally recognised symbol	7001
	Alarm, general	To indicate an alarm on a control equipment.	IEC TR 60878:2015 Graphical symbols for electrical equipment in medical practice	5307
	AUDIO PAUSED	To identify the control for AUDIO PAUSED or to indicate that an auditory ALARM SYSTEM is in the AUDIO PAUSED state. See IEC 60601-1-8: 2006/AMD1:2012.	IEC TR 60878:2015 Graphical symbols for electrical equipment in medical practice	5576-2
	MR Unsafe	Indicates medical device that is known to pose hazards in all MRI environments.	ASTM F2503-13	N/A

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Limited Warranty

Mallinckrodt warrants its photopheresis equipment to conform to the specifications contained herein and in literature relating to the equipment and against defects in the workmanship or material under normal use and service for a period of one (1) year from the date of start-up. The sole obligation of Mallinckrodt under this warranty is to repair or replace, at its option, defective components sold under this warranty. Replacement components may be new or refurbished at the discretion of Mallinckrodt.

Mallinckrodt personnel perform equipment start-up (including installation and training). The warranty activation date will be that date indicated on the installation/warranty verification form.

This warranty does not apply to electrical fuses, light bulbs, filters, or other consumable items. Mallinckrodt will not warrant any parts found to be defective due to shipping damage, misuse, use of unauthorized parts, or lack of maintenance as specified within the THERAKOS™ CELLEX™ Photopheresis System Operator's Manual.

This warranty extends to the original purchaser of the equipment from Mallinckrodt and is not transferred upon re-sale.

Buyer's sole remedy for the breach of the Mallinckrodt warranty obligation shall be limited to the cost of the equipment and in no event include consequential damages or liability for personal injury or property damages. The foregoing warranty is in lieu of all other warranties, expressed or implied, and no other warranties exist including, without limitation, any warranty of merchantability or fitness for a particular purpose.

If a defect develops with your photopheresis equipment, contact Mallinckrodt to be advised as to the disposition of the defective part.

Questions relating to the warranty should be directed to:
National Service Manager

Mallinckrodt Pharmaceuticals Ireland Limited,
College Business & Technology Park,
Cruiserath Road, Blanchardstown,
Dublin 15, Ireland

All general inquiries should be directed to:

Distributed in North America by:

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Telephone: +1 877-566-9466

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Telephone: +44 (0) 1784 636 700

For Technical Support, Spare Parts and Return Good Authorization:

In US and Canada:

Toll Free: +1 877-865-6850

Available for most countries in Europe and the Middle East:

Toll-Free Numbers and Email:

00800 THERAKOS (00800 843 725 67) ecphelp@therakos.com
Within Germany: 0800 181 1715 **Within UK:** 0808 238 6011
Within France: +33 18 288 0867 **Within Italy:** 800 149 844

For enquiries relating to product orders, deliveries or invoicing contact:

Toll Numbers and Emails: International and National

French: Phone: (+33) 186260833, (+33) 0805082214, Fax: (+33) 1 80206913
Email: customerservice.emea.fr@mnk.com

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Email: customerservice.emea.it@mnk.com

English: Phone: (+44) 1784614060, (+44) 8000698136, Fax: (+44) 2037441022
Email: customerservice.emea.en@mnk.com

To place an order, please send a PO to the relevant email address above

THERAKOS™ CELLEX™ Power Cord:

Continental Europe Power Cord / IEC 320 10A	CON-9000-007
U.K. and Ireland Power Cord / IEC 320 10A	CON-9000-009
Italy Power Cord / IEC 320 10A	CON-9000-013
North America Power Cord / IEC 320 10A	CON-9000-006

To Reorder Disposable Products:

In USA and Canada:

Telephone: +1 855-422-9115 (#2)
Fax: +1 302-353-4191
e-mail: therakos@ups.com

In Europe:

To place an order, Refer to Toll Numbers and Emails: International and National (Above)

ITEM	ORDER CODE
THERAKOS™ CELLEX™ Instrument	CELLEX
THERAKOS™ CELLEX™ Photopheresis Procedural Kit	CLXUSA (Shipped 3 per case) USA / Canada
THERAKOS™ CELLEX™ Photopheresis Procedural Kit	CLXECP (Shipped 3 Per case) EMEA
THERAKOS™ CELLEX™ Light Assembly	CLXLGT