

Therapeutic Plasma Exchange (TPE) Procedure Training (Including Single Needle Option)

Spectra Optia[®] Apheresis System

Operator's Manual Information

Spectra Optia Apheresis System

Intended Use

The Spectra Optia Apheresis System, a blood component separator, may be used to perform the following therapeutic apheresis, cell collection, and cell processing procedures*:

- Therapeutic plasma exchange
- Therapeutic plasma exchange with a secondary plasma device
- Red blood cell exchange, depletion, and depletion/exchange
- Mononuclear cell collection from the peripheral blood
- Granulocyte collection from the peripheral blood
- White blood cell depletion
- Platelet depletion
- Processing of harvested bone marrow

*Procedure availability varies by country.

Contraindications for Use

- Leukocytapheresis is contraindicated in AML FAB M3 (APL) because of the accompanying disseminated intravascular coagulation. (Vahdat L, et al., "Early mortality and the retinoic acid syndrome in acute promyelocytic leukemia: impact of leukocytosis, low-dose chemotherapy, PMN/RAR-alpha isoform and CD13 expression in patients treated with all-trans retinoic acid." *Blood* 1994; 84: 3843-3849. Daver, et al., "Clinical characteristics and outcomes in patients with acute promyelocytic leukaemia and hyperleucocytosis." *British Journal of Haematology* 2015, 168, 646-653.)
- Other contraindications for the use of the Spectra Optia system are limited to those associated with the infusion of solutions and replacement fluids as required by the apheresis procedure, and those associated with all types of automated apheresis systems.

Possible Adverse Events of Apheresis Procedures Include:

- Anxiety, headache, light-headedness, digital and/or facial paresthesia, fever, chills, hematoma, hyperventilation, nausea and vomiting, syncope (fainting), urticaria, hypotension, allergic reactions, infection, hemolysis, thrombosis in patient and device, hypocalcemia, hypokalemia, thrombocytopenia, hypoalbuminemia, anemia, coagulopathy, fatigue, hypomagnesemia, hypogammaglobulinemia, adverse tissue reaction, device failure/disposable failure, air embolism, blood loss/anemia, electrical shock hazard, fluid imbalance, inadequate separation of blood components.

Reactions to Blood Products Transfused During Procedures

- Reactions to transfused blood products can include fever, circulatory overload, shock, allergic reactions, alloimmunization, transfusion-related acute lung injury (TRALI), and graft-versus-host disease (GVHD), as well as transmission of infectious diseases and bacteria. (Sources: *Circular of Information for the Use of Human Blood and Blood Components*, AABB, et al, ed., April, 2006; *Guide to the preparation, use and quality assurance of blood components*, 10th Edition, Council of Europe Publishing; Toy P et al., "Transfusion-Related Acute Lung Injury: Incidence and Risk Factors." *Blood*, 2012; 119: 1757-1767.)

Restricted to Prescription Use Only:

- Operators must be familiar with the system's operating instructions.
- Procedures must be performed by qualified medical personnel.

Learning Objectives

After completing this training you will be able to do the following regarding a TPE procedure using the Spectra Optia system:

- Discuss the principles of the procedure.
- Enter and discuss the data needed to perform the procedure.
- Discuss how the data you entered affects the procedure and the run targets.
- View and change the data on the run values screen.
- Make changes to the data on the Data, Run, and End Run menu screens.
- Optimize the run to achieve the desired procedure outcomes.
- Troubleshoot issues that may arise.
- Describe using the single-needle option with a TPE procedure.
- Understand the issues related to pediatrics/low total blood volume (TBV) patients.

Presentation Overview

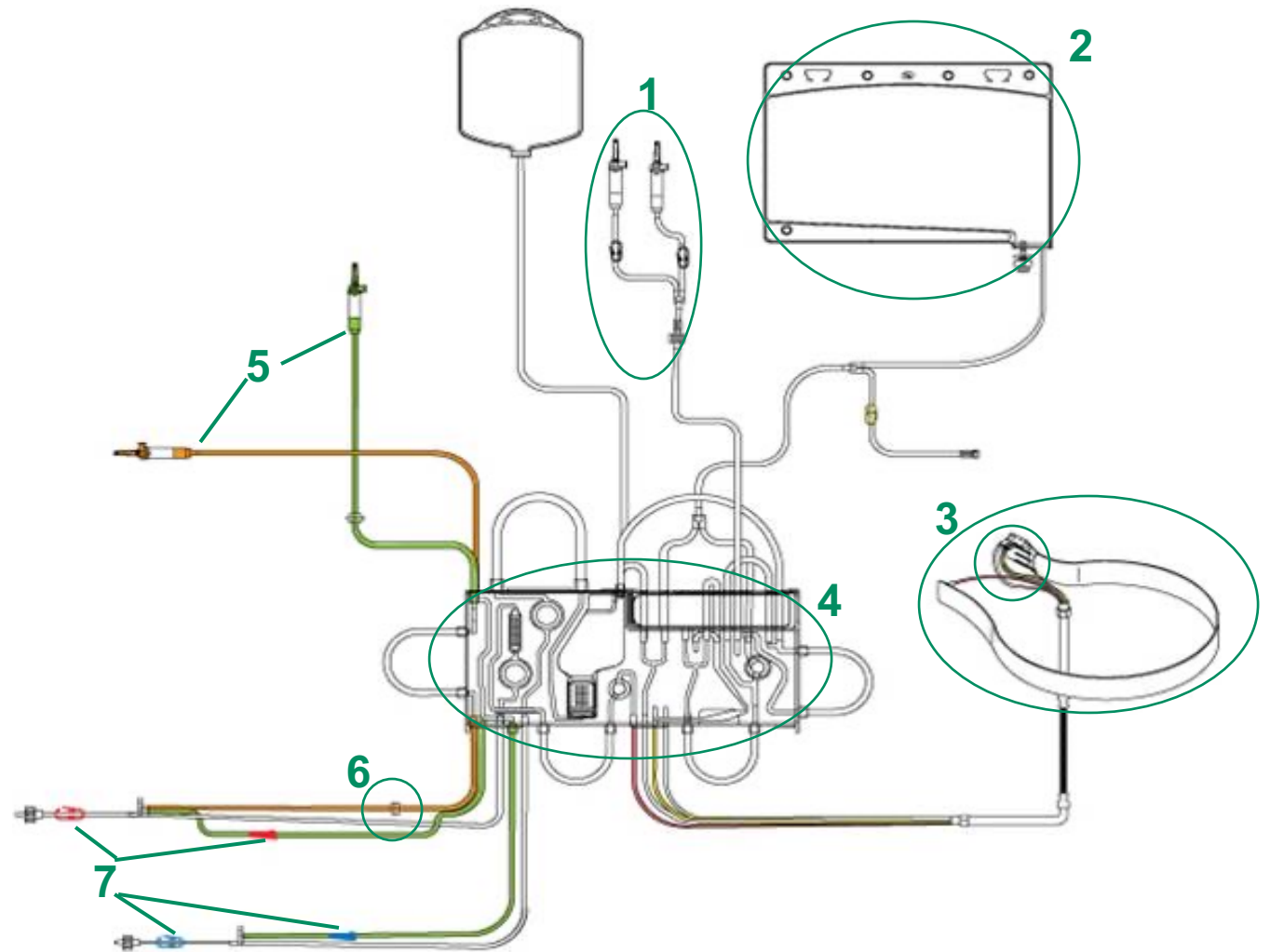
- Introduction
- Preparing to Perform the Procedure
- Monitoring the Run
- Completing the Run
- Making Changes
- Troubleshooting
- Single-Needle
- Pediatric/Low TBV Patients

Introduction

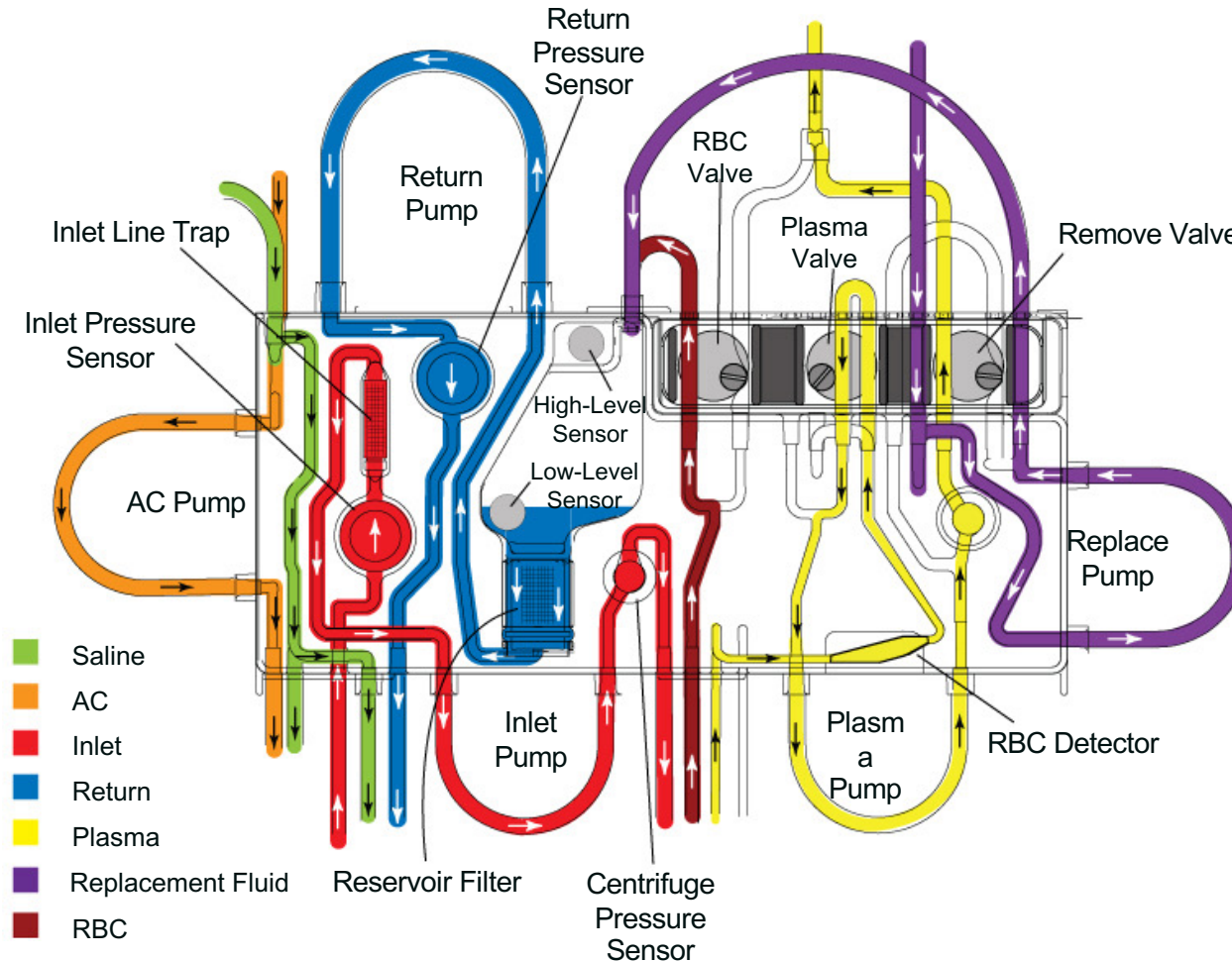
- Exchange Set
- Basic Principles of TPE
- Connector

Exchange Set

1. Replace Line
2. Remove Bag
3. Channel
 - Connector
4. Cassette
5. Colored Spikes and Tubing
6. AC Check Valve
7. Colored Clamps



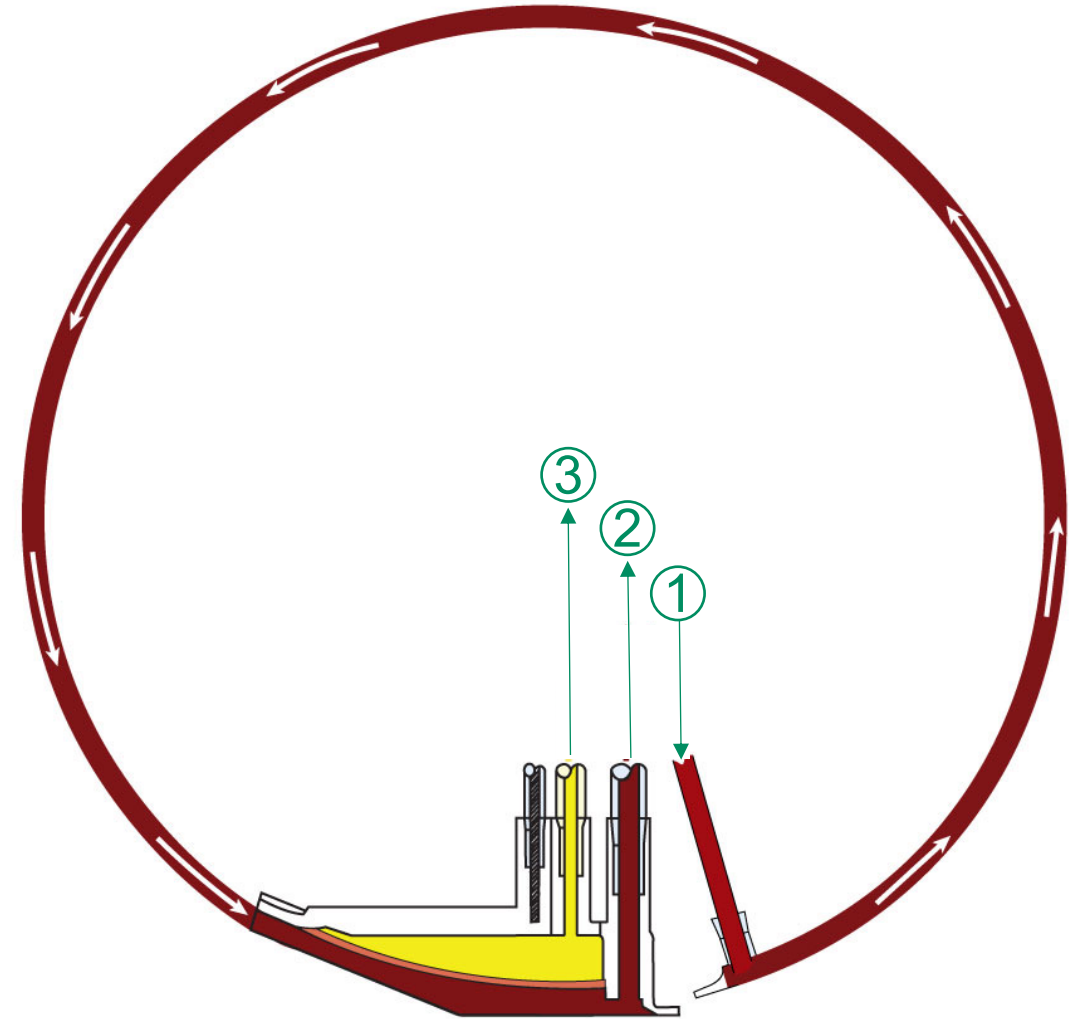
Basic Principles of TPE



Click for interactive version
(requires Flash Player)

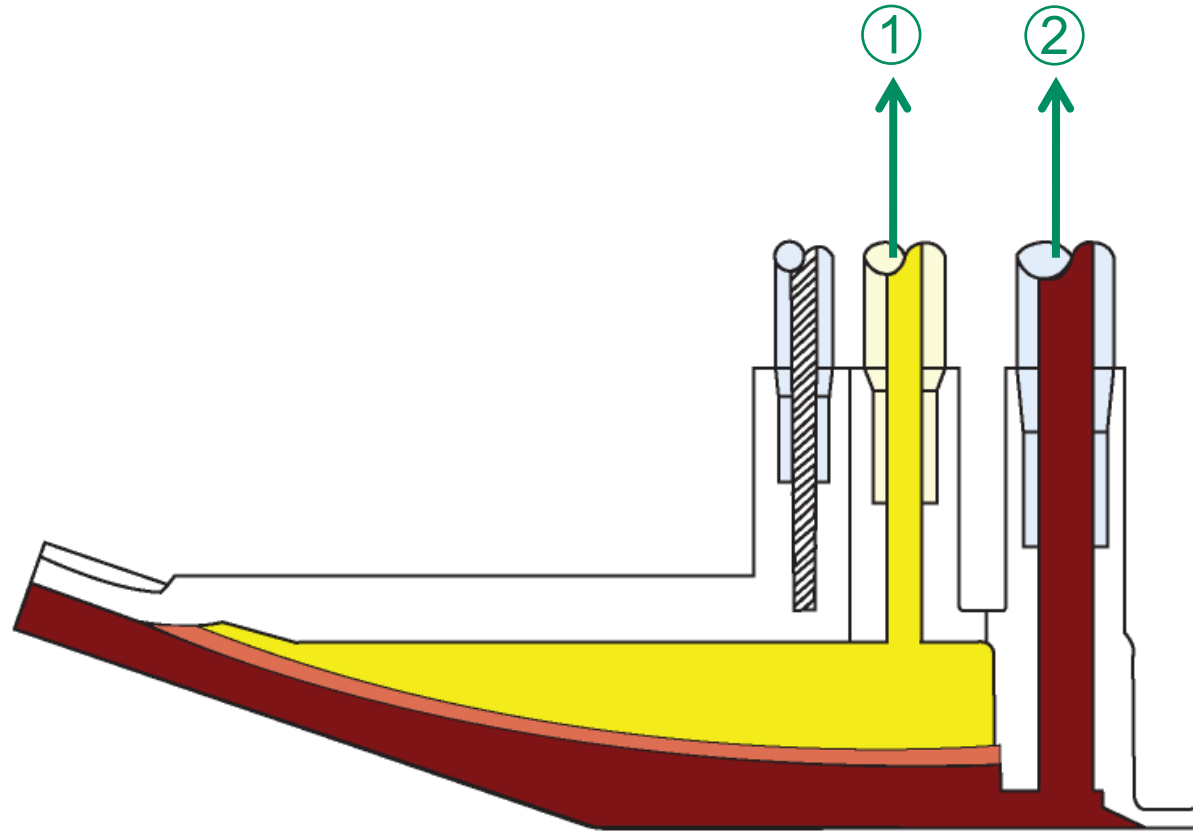
Basic Principles of TPE – Channel

1. Anticoagulated whole blood enters the channel.
2. Red blood cells (RBC) flow to the reservoir.
3. Plasma is pumped to the reservoir or to the plasma bag.



Connector

- 1. Plasma Port
- 2. RBC Port



Questions?



Preparing to Perform the Procedure

- Configuration – TPE Procedures
- Configuration – Blood Warmer
- Channel Loading
- Patient Data
- Fluid Data
 - Replacement Fluid
 - Fluid Balance
- Run Values
- Spiking the Replacement Fluid
- Patient Connection

Configuration – TPE Procedures

The screenshot displays the configuration interface for TPE procedures. It features a top navigation bar with 'Config', 'Data', 'Run', and 'End Run' tabs. Below this is a secondary menu with 'System', 'Report', 'TPE', and 'Blood Warmer' options. The main configuration area is divided into several sections, each with a parameter name and a corresponding value in a teal button:

- Maximum AC Infusion Rate (mL/min/L TBV):** 0.8
- Inlet:AC Ratio (__:1):** 10.0
- Pressure Alarm Limit (mmHg):** Inlet: -250, Return: 400
- Custom Prime Recommendation (% TBV):** 10
- Custom Replacement Fluid (%):** 0
- Plasma Volumes Exchanged:** 1.0
- Fluid Balance Limit (% TBV):** 10

At the bottom, there is a timestamp '11:23 19-10-2012', a 'Confirm' button, a back arrow, a 'no touch' icon, and the text 'TPE'.

Configuration – Blood Warmer

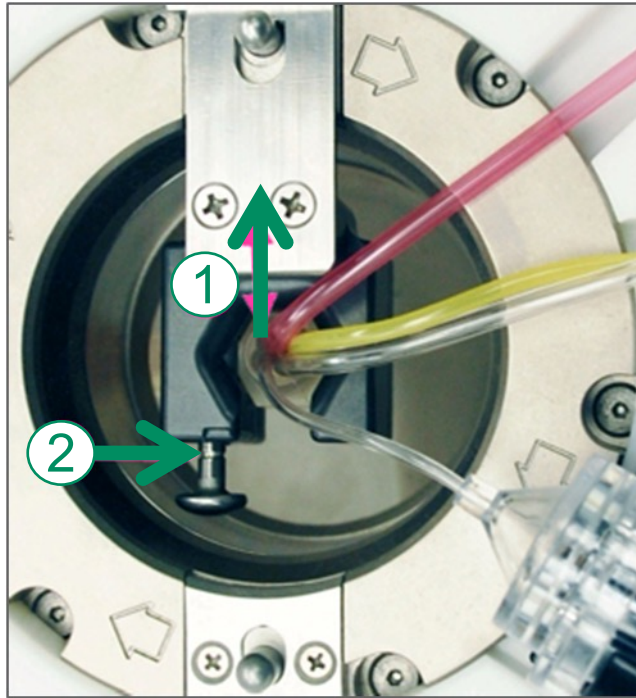


Channel Loading (very important)

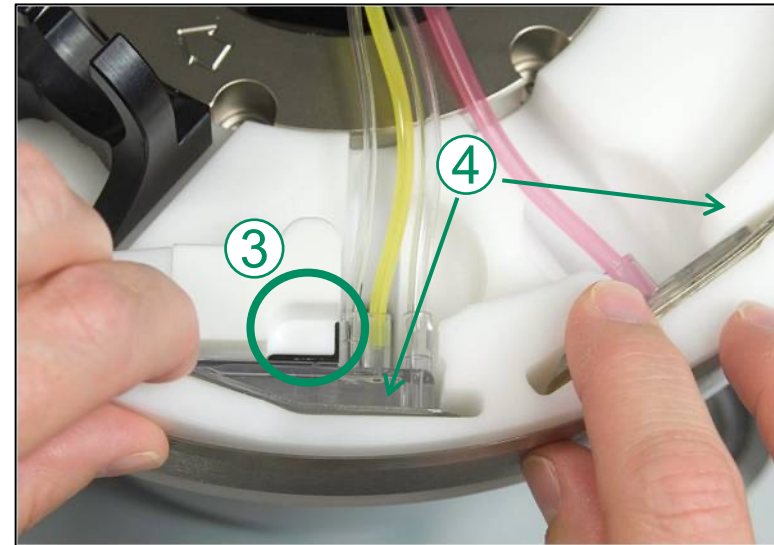
Use standard filler

Preparing to Perform the Procedure

1. Centrifuge collar is in the correct position.
2. Notch on locking pin is visible.



3. Optical reference is visible.
4. Channel sits flush with the groove.

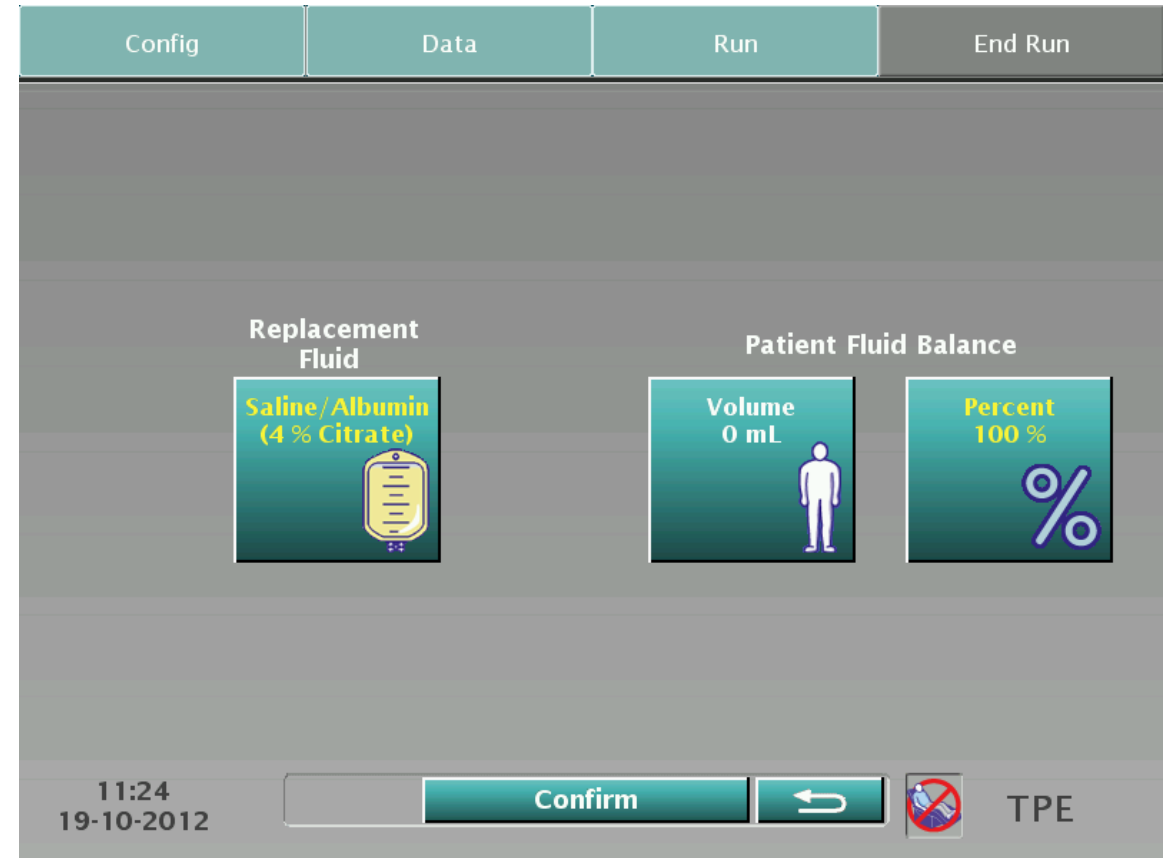


Patient Data

Preparing to Perform the Procedure

The screenshot displays the 'Data' screen of the Spectra Optia TPE interface. At the top, there are four tabs: 'Config', 'Data', 'Run', and 'End Run'. The 'Data' tab is active. The main area contains five data entry cards: 1. A card with a male and female icon and a large yellow checkmark. 2. A 'Height' card showing '170 cm' with a height scale icon. 3. A 'Weight' card showing '60 kg' with a scale icon. 4. An 'Hct' card showing '28%' with a test tube icon. 5. A 'TBV' card showing '4338 mL' with a human torso icon. At the bottom, there is a timestamp '11:23 19-10-2012', a 'Confirm' button, a back arrow button, a red prohibition sign over a person icon, and the text 'TPE'.

Fluid Data – Replacement Fluid



Run Values

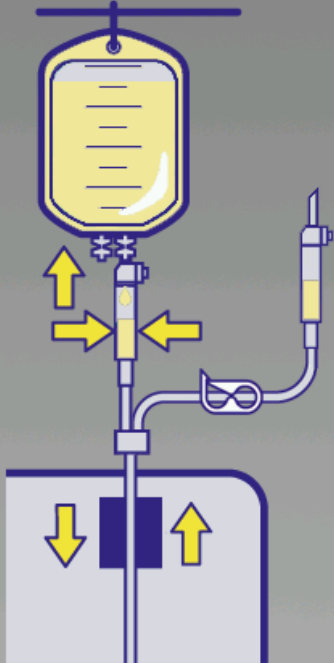
Config	Data	Run	End Run	
Maximum AC Infusion Rate	Inlet:AC Ratio (__:1)	Plasma Removed (mL)	Run Time (min)	Plasma Volumes Exchanged
0.8	10.0	3123	48	1.0
	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	11.2	111.5	76.4	63.3
Current (mL)				
Target (mL)	536	5358	3640	2987
11:24 19-10-2012	Confirm		←	⊘ TPE

Config	Data	Run	End Run	
Maximum AC Infusion Rate	Inlet:AC Ratio (__:1)	Plasma Removed (mL)	Run Time (min)	Plasma Volumes Exchanged
0.8	10.0	3123	67 ↑	1.0
	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	8.0 ↓	80.0 ↓	54.8 ↓	45.4 ↓
Current (mL)				
Target (mL)	536	5358	3640	2987
11:24 19-10-2012	Confirm		←	⊘ TPE

Spiking the Replacement Fluid

Config Data Run End Run

1. Spike saline/albumin.
2. Squeeze drip chamber.
3. Unclamp second replace line.
4. Prime both lines.
5. Reclamp second replace line.
6. Place line into detector.

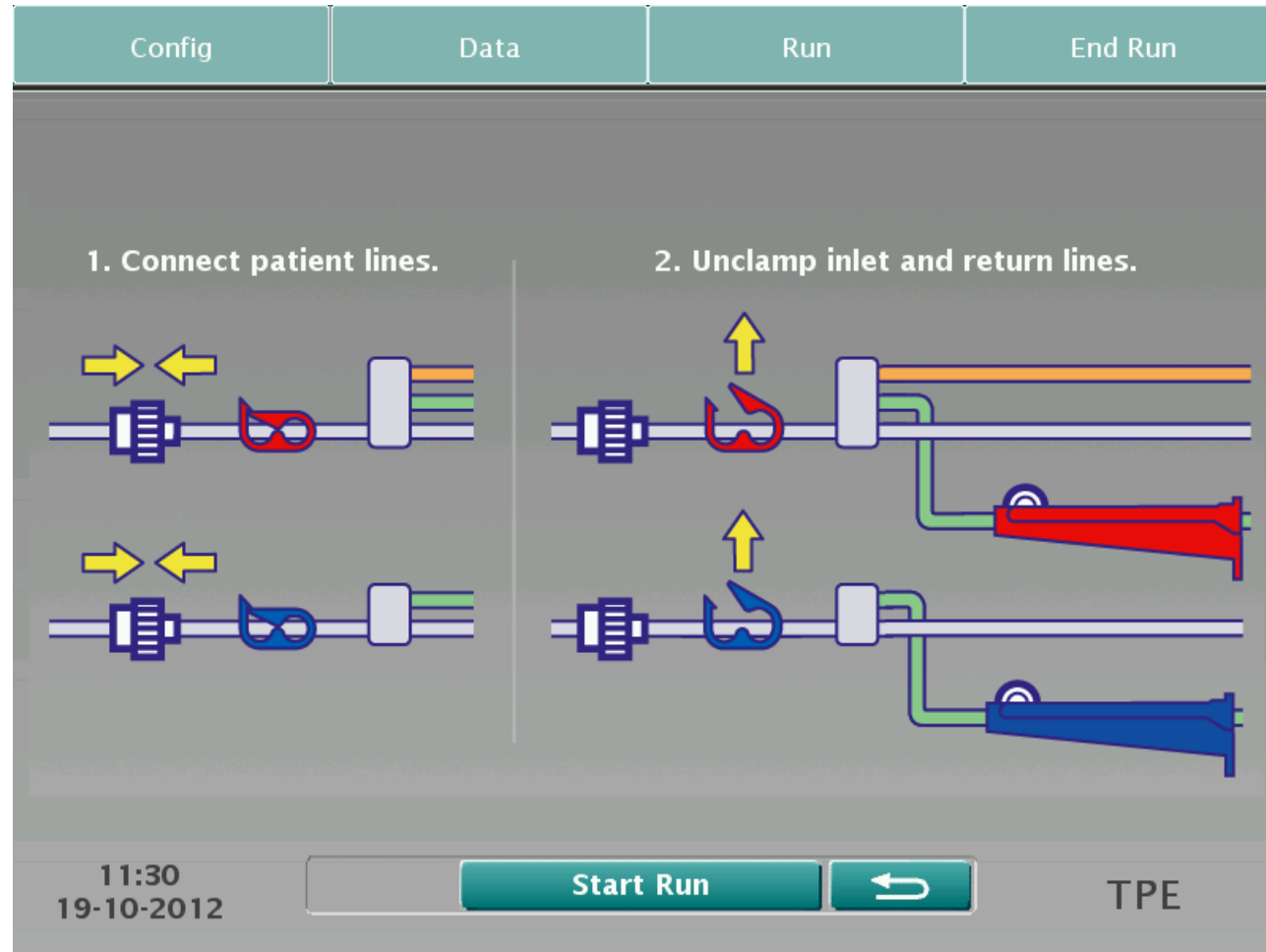


11:25
19-10-2012

Continue

TPE

Patient Connection



Questions?



Monitoring the Run

- Main Run
 - AIM Graphic
- Platelet Flush
- View Port

Main Run

Current	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	6.2	62.0	39.3	25.0
Volume (mL)	11	107	37	9

Inlet Pressure	Return Pressure	AC Infusion Rate	Inlet:AC Ratio
-49 mmHg	11 mmHg	0.8	10.0

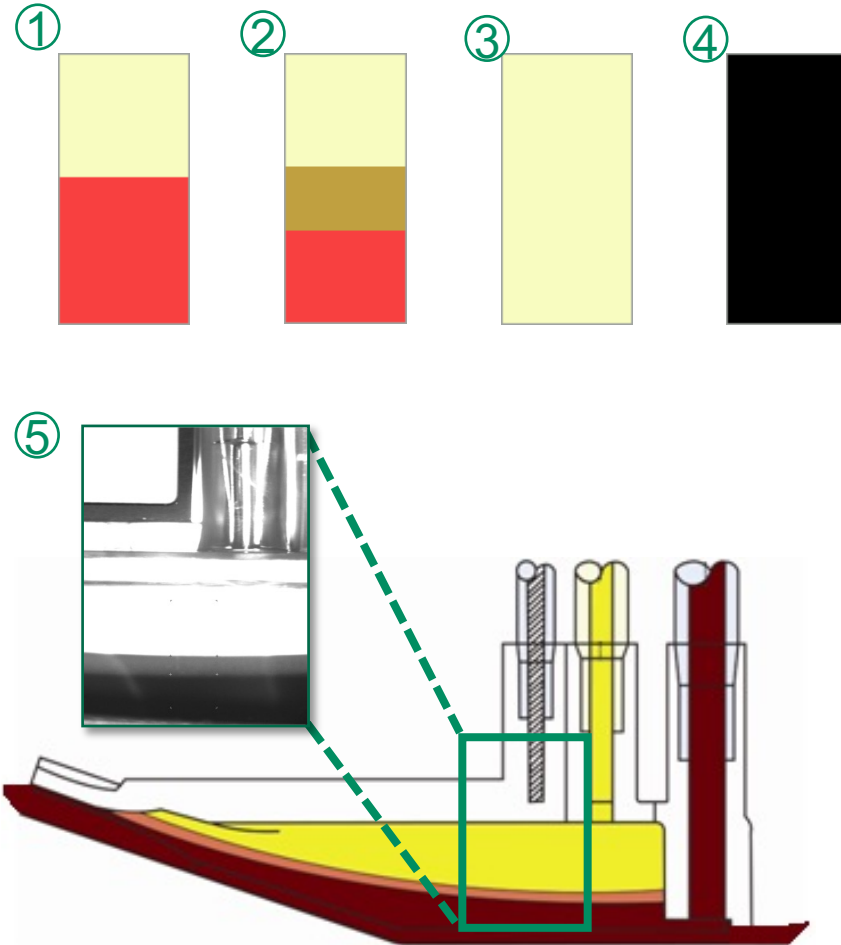
AC to Patient 3 mL

11:32
19-10-2012

TPE

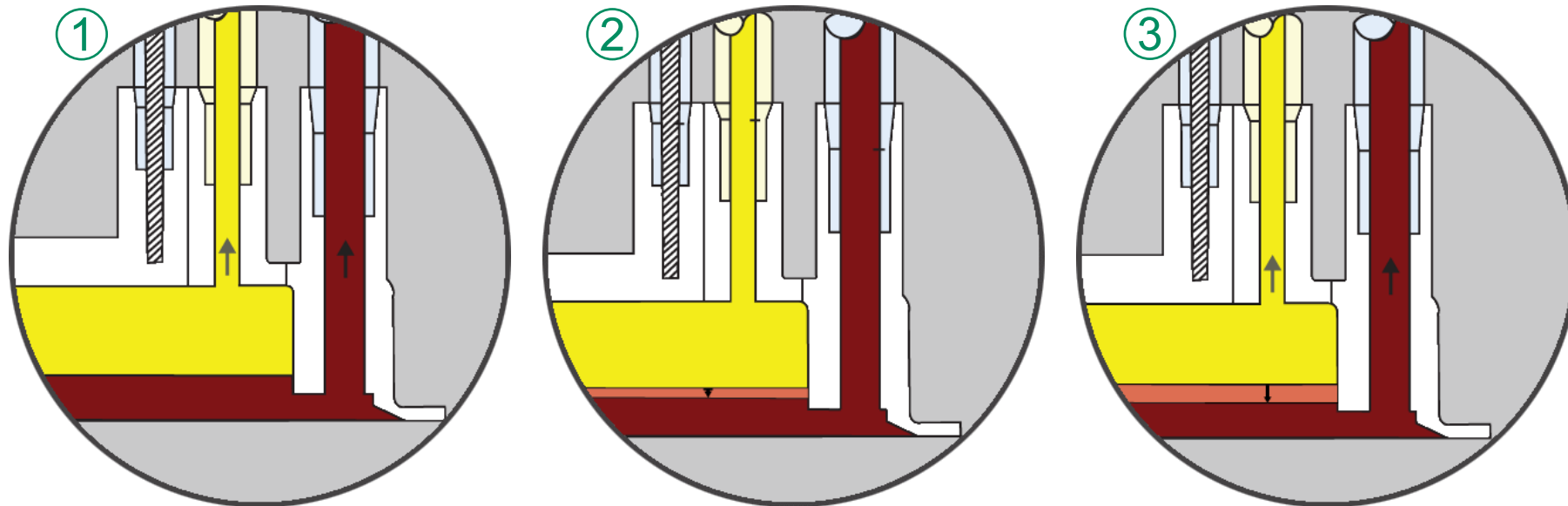
Main Run

1. Ideal Interface
2. Buffy Coat Accumulation
3. Plasma
4. Black
5. AIM image



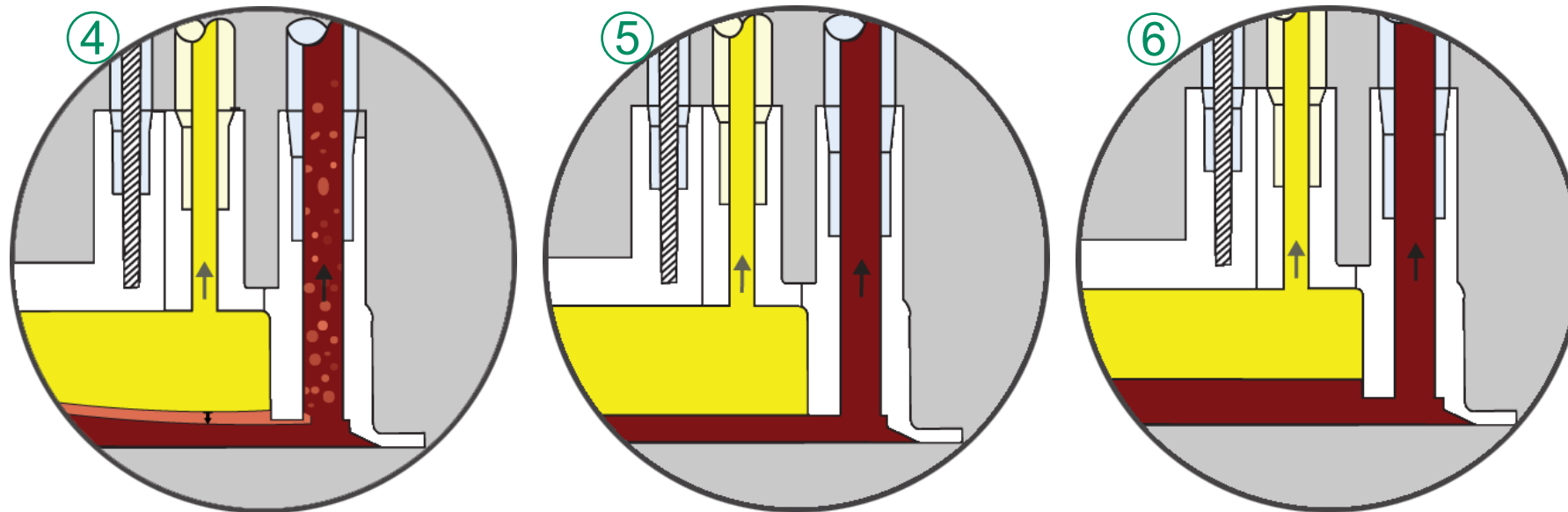
Platelet Flush

1. AIM system establishes the interface.
2. AIM system continuously monitors the interface position.
3. Buffy coat accumulates.



Platelet Flush (Continued)

4. System changes the pump flow rates to lower the position of the interface.
5. Buffy coat is returned to the patient.
6. Interface position is returned to normal after platelet flush is completed.



View Port



Questions?



Completing the Run

- Run Targets Attained
- Rinseback and Disconnect
- Procedure Summary

Run Targets Attained

	Config	Data	Run	End Run
Run targets attained.				
		Target	Current	
Volumes Exchanged		1.0	1.0	
Run Time (min)		67	67	
Plasma Removed (mL)		3123	3123	
Replacement Fluid Used (mL)		2987	2987	
12:36 19-10-2012	Rinseback			TPE

Rinseback and Disconnect

The screenshot shows the 'Run' tab of the Spectra Optia TPE interface. A blue banner at the top indicates 'Rinseback is in progress.' The main display area is divided into three sections: 'Rinseback Time Remaining' showing 5:05, 'Return' showing 0 mmHg with a vertical bar chart, and 'Rinseback Volume' showing 11 mL. Below these, a data panel shows 'Return Flow (mL/min)' at 54.2 and 'Fluid Balance (mL)' at -97. The bottom status bar displays the time 12:36, date 19-10-2012, and the device name TPE.

The screenshot shows the 'Run' tab of the Spectra Optia TPE interface during the 'Unload' step. A diagram illustrates the four steps for disconnecting the circuit: 1. Close inlet saline line, 2. Clamp inlet and return lines, 3. Disconnect patient lines, and 4. Seal AC, saline, and bag lines. The diagram shows the circuit components, including the inlet saline line, inlet and return lines, patient lines, and the AC, saline, and bag lines. A 'Unload' button is visible in the bottom right. The bottom status bar displays the time 12:41, date 19-10-2012, and the device name TPE.

Procedure Summary

Config	Data	Run	End Run
AC Used	533 mL	Start Time	11:30
Remove Bag	3620 mL	End Time	12:39
Replacement Used	2987 mL	Run Time	69 min
Bolus	0 mL	Fluid Balance	0 mL
Tubing Set	-3 mL	Fluid Balance	100 %
Rinseback	121 mL	Inlet Processed	5234 mL

12:43 19-10-2012 Next Page TPE

Config	Data	Run	End Run
Plasma Volumes Exchanged	1.0	New Procedure	
Plasma Removed	3123 mL		
AC in Remove Bag	480 mL		
AC to Patient	31 mL	Custom Prime	0 mL
AC Used for Prime	21 mL	Saline Rinse	0 mL

12:43 19-10-2012 Previous Page TPE

To calculate the patient's fluid balance, use the values on the procedure summary screen:

- +533 mL
- 3620 mL
- +2987 mL
- 3 mL
- +121 mL
- 0 mL
- +0 mL Bolus (if given)
- 0 mL Patient's Fluid Balance

Questions?



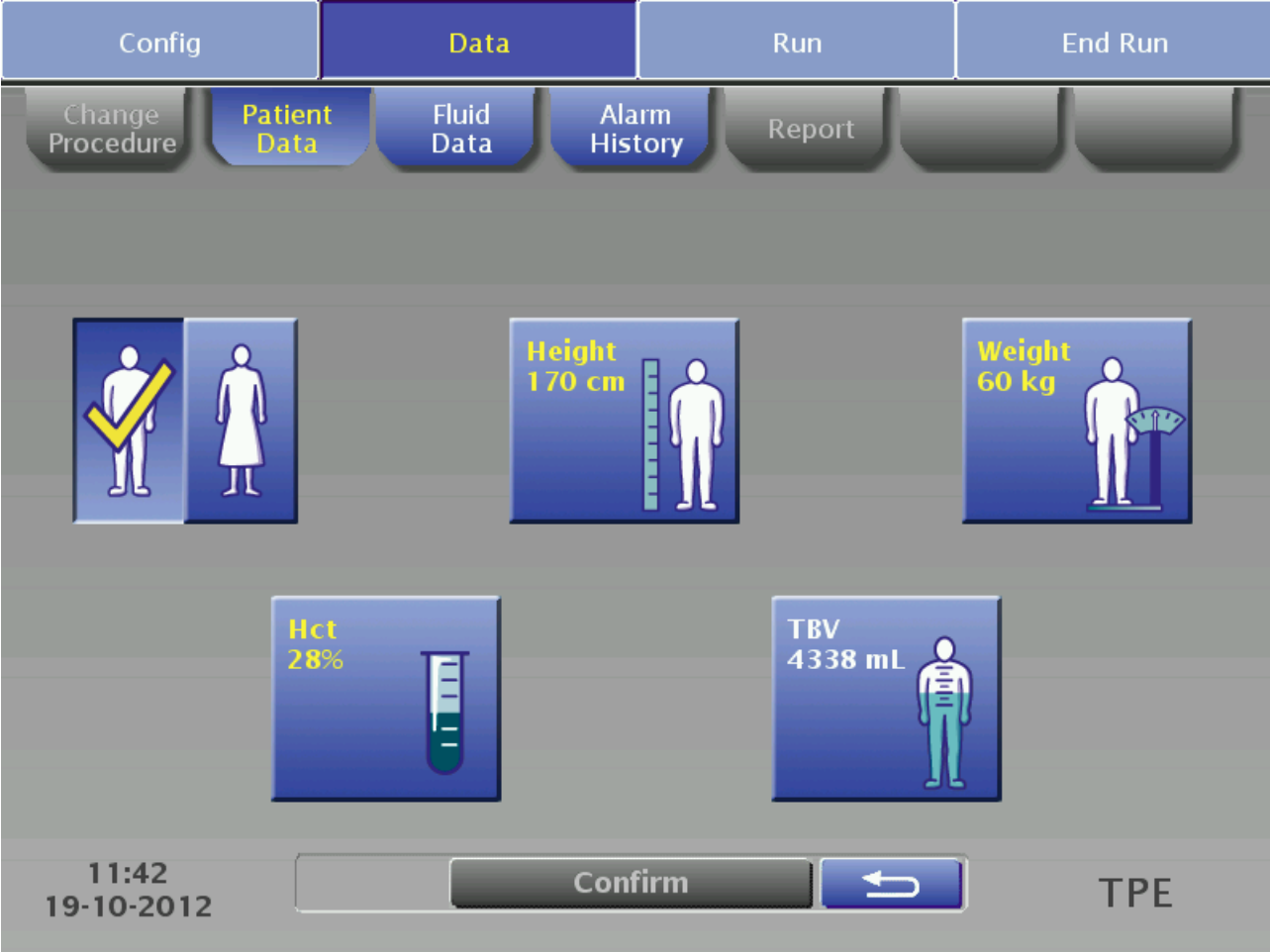
Making Changes

- Configuration Menu
- Data Menu
- Run Menu
- End Run Menu

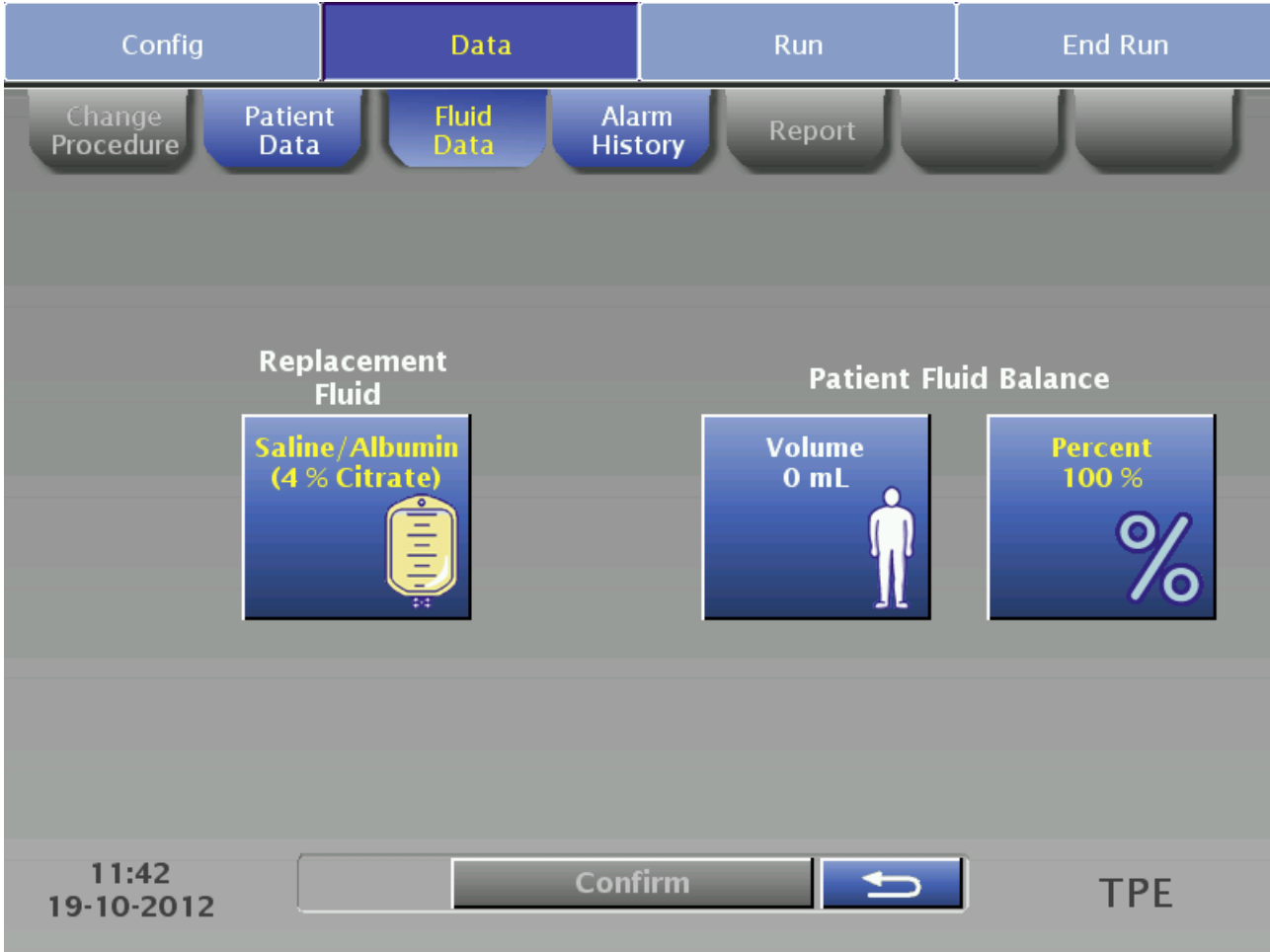
Data Menu

- Change Procedure
- Patient Data
- Fluid Data
- Alarm History
- Report

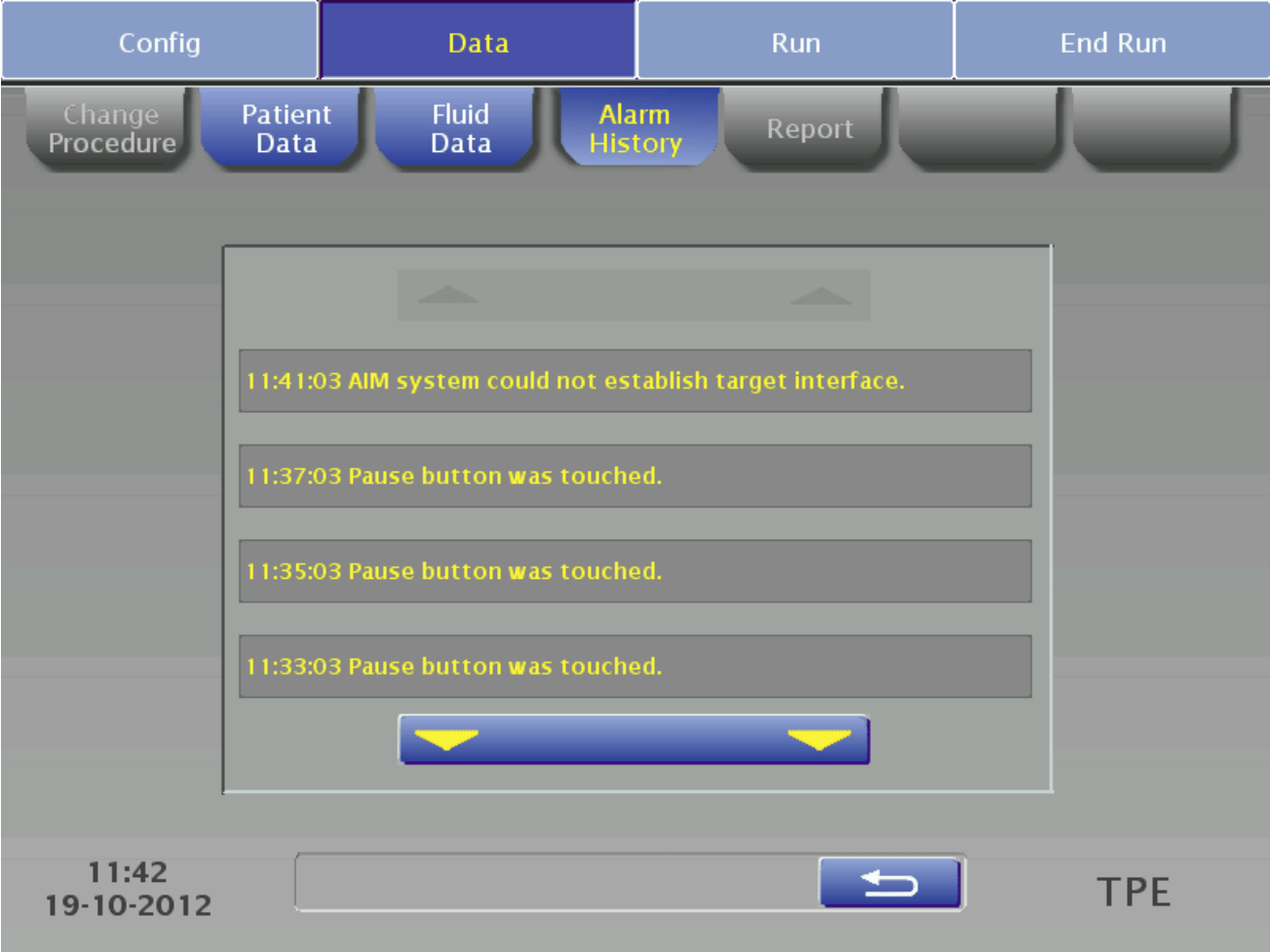
Patient Data



Fluid Data



Alarm History



Report



Run Menu

- Exchange Status
- Operation Status
- Bolus
- Strobe
- Run Values
- Options

Exchange Status

Config Data **Run** End Run

Exchange Status Operation Status Bolus Strobe Run Values Options

Exchanging plasma.

12 min 70 min 82 min

Fluid Balance

1085 mL 125%
Current -41 mL **Current 99%**
0 mL 100%
-1085 mL 75%

Replacement Fluid
Saline/Albumin

Bolus Volume (mL)
0

Exchange Status

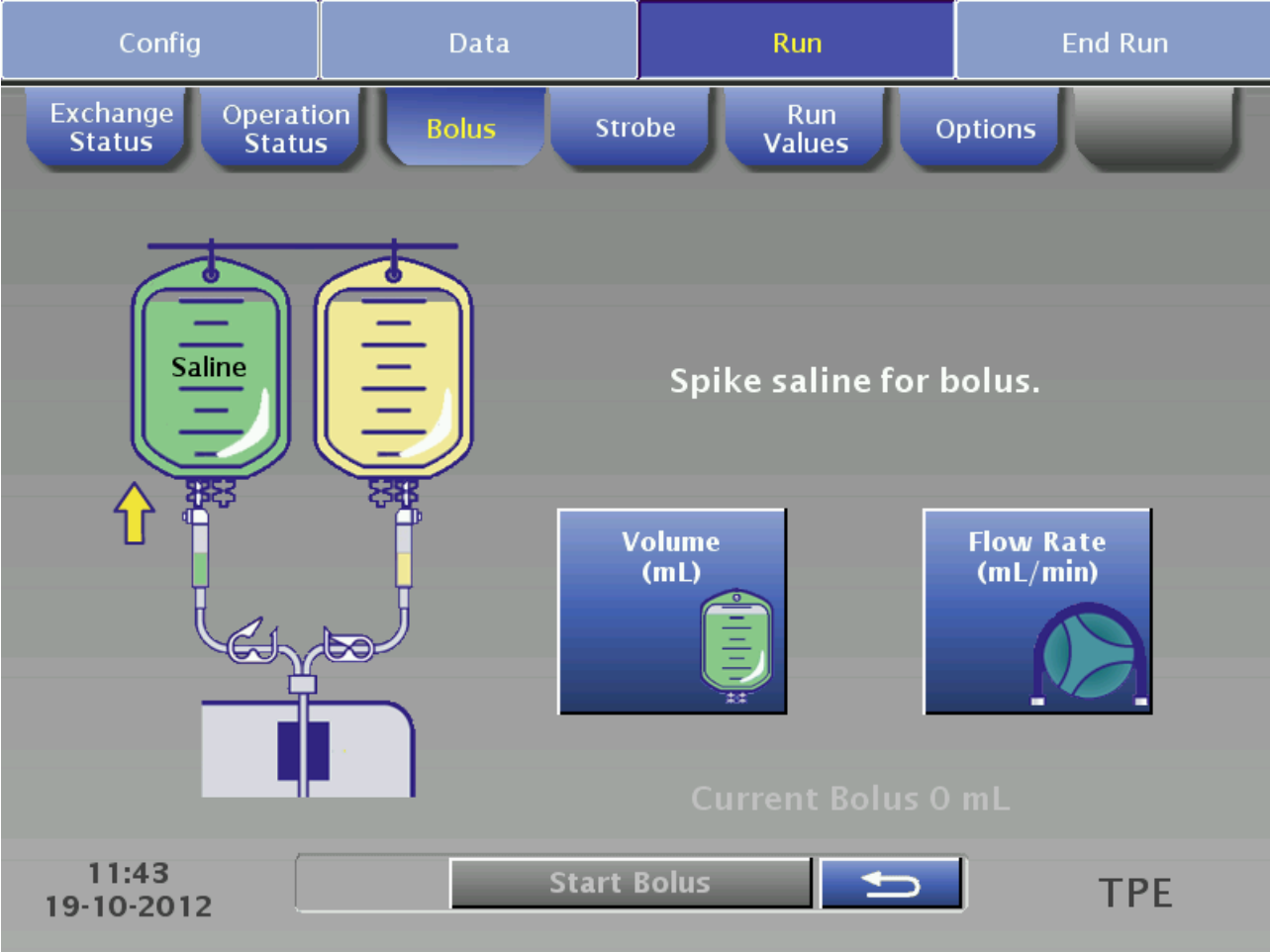
Plasma Volumes Exchanged: 0.2
Remove (mL): 549
Replace (mL): 521

11:42 19-10-2012 TPE

Operation Status



Bolus



Strobe



Run Values

Maximum AC Infusion Rate	Inlet:AC Ratio (__:1)	Plasma Removed (mL)	Run Time (min)	Plasma Volumes Exchanged
0.8	10.0	3123	67	1.0

	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	8.0	80.0	54.8	45.4
Current (mL)	103	1035	699	557
Target (mL)	536	5358	3640	2987

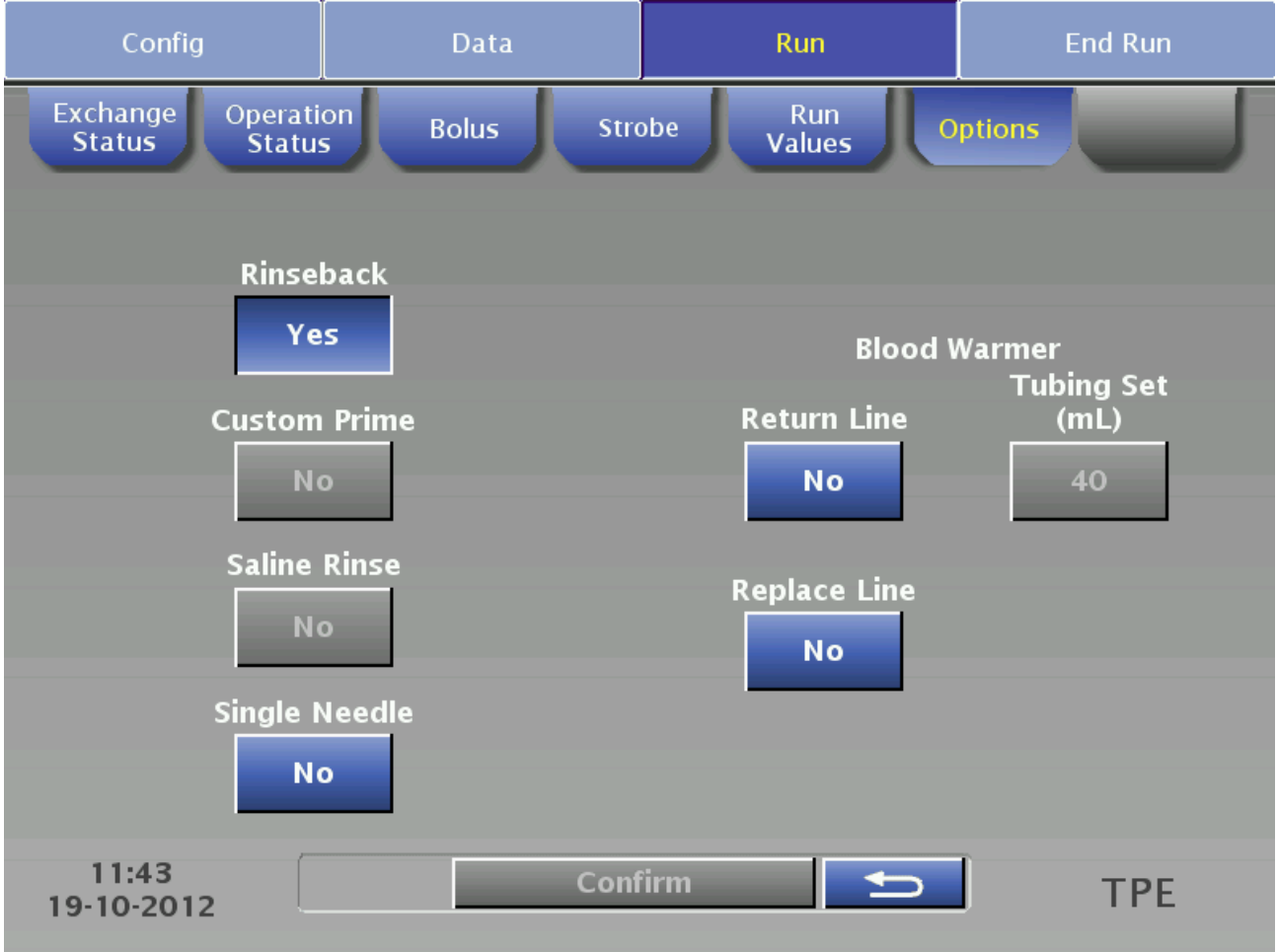
11:43 19-10-2012 Confirm TPE

Maximum AC Infusion Rate	Inlet:AC Ratio (__:1)	Plasma Removed (mL)	Run Time (min)	Plasma Volumes Exchanged
1.0	10.0	3123	48 ↓	1.0

	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	12.0 ↑	120.0 ↑	82.2 ↑	68.3 ↑
Current (mL)	114	1141	774	620
Target (mL)	536	5358	3640	2987

11:43 19-10-2012 Confirm TPE

Options



Note: Not all options are commercially available in all world areas.

End Run Menu

- Rinseback, Disconnect, Run Targets

Rinseback, Disconnect, Run Targets

The image displays three sequential screenshots of the Spectra Optia TPE End Run menu. Each screenshot shows a top navigation bar with 'Config', 'Data', 'Run', and 'End Run' tabs. The 'End Run' tab is active in all three. Below the navigation bar are buttons for 'Rinseback', 'Disconnect', and 'Run Targets'. The first screenshot shows the 'Rinseback' button circled in white, with a 'Proceed to Rinseback' button in the center. The second screenshot shows the 'Disconnect' button circled in white, with a 'Proceed to Disconnect' button in the center. The third screenshot shows the 'Run Targets' button circled in white, with a table of target and current values.

	Target	Current
Volumes Exchanged	1.0	0.2
Run Time (min)	67	15
Plasma Removed (mL)	3123	692
Replacement Fluid Used (mL)	2987	658

Questions?

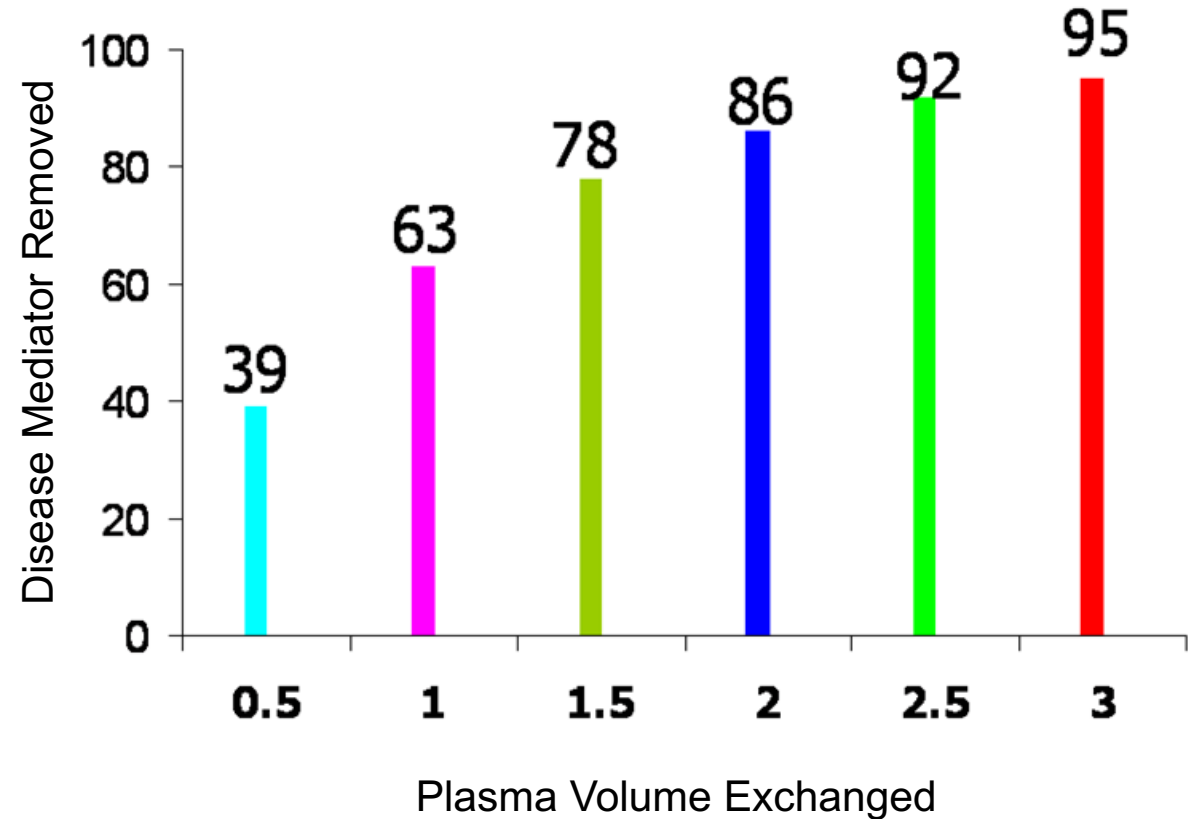


Optimization

- Plasma Volumes Exchanged
- Fluid Balance
- AC to Patient

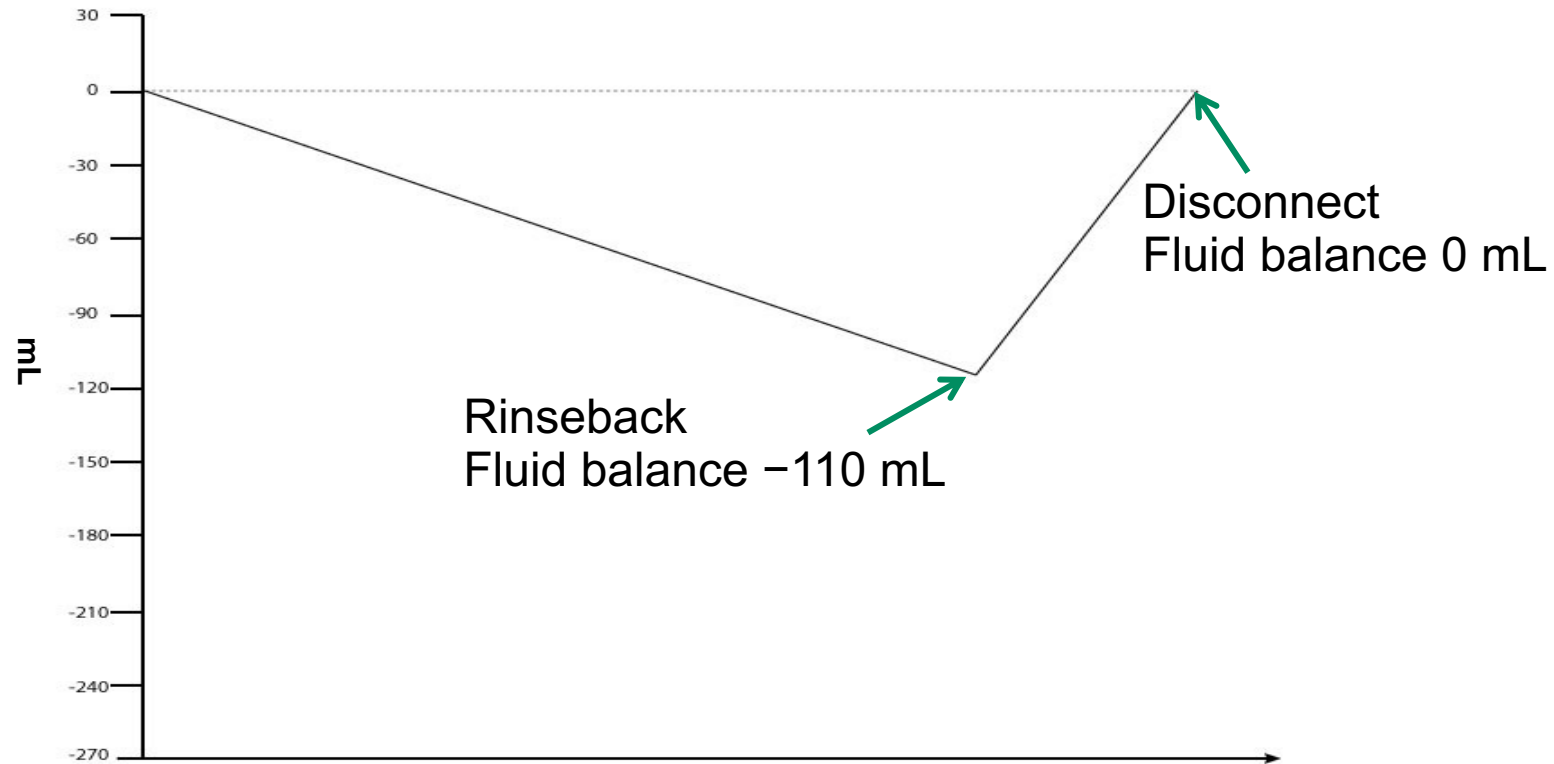
Plasma Volumes Exchanged

The number of plasma volumes exchanged determines the amount of disease mediator removed.



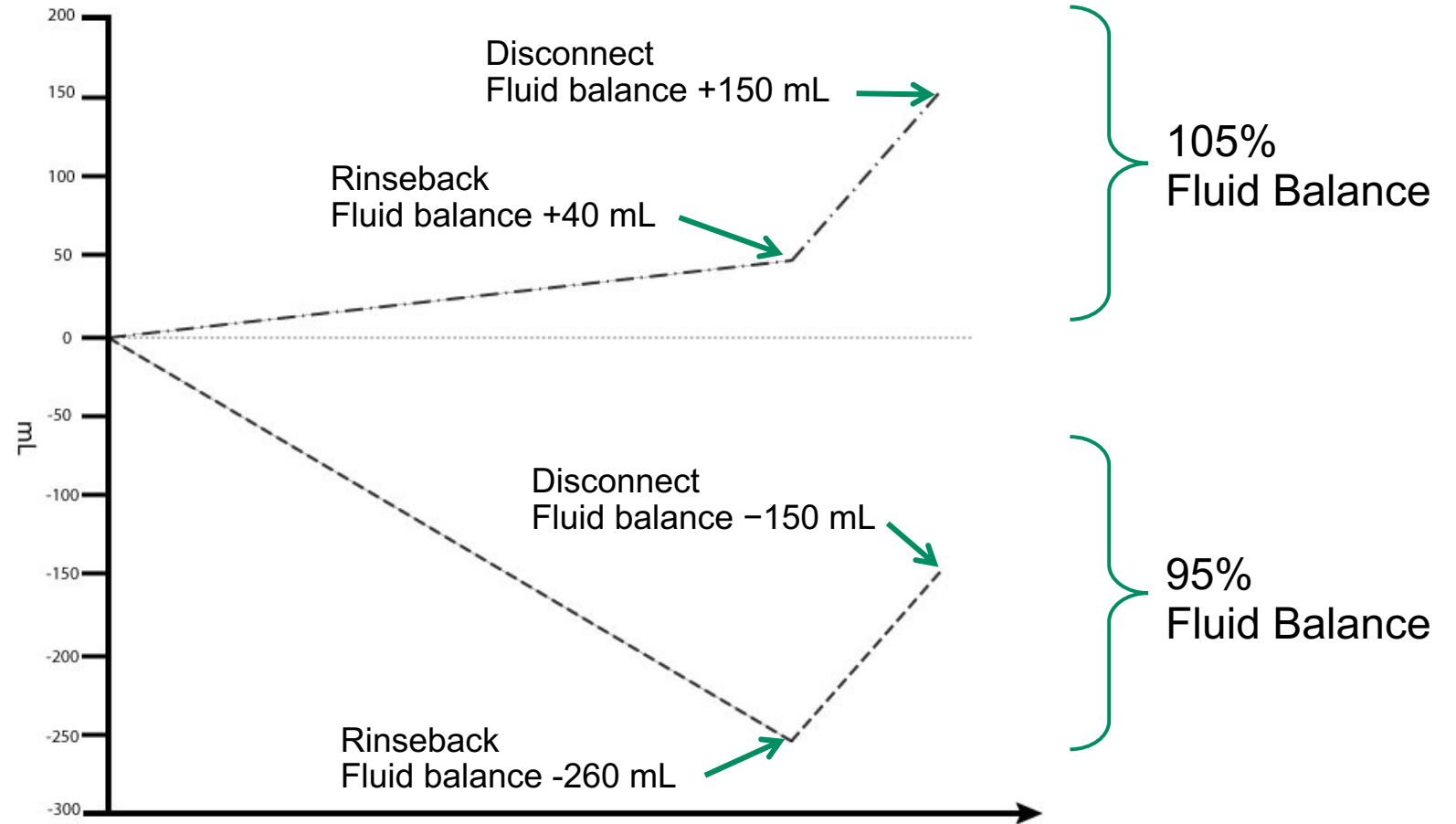
Fluid Balance

Patient TBV 3000 mL, Target Fluid Balance 100%



Fluid Balance

Patient TBV 3000 mL



AC to Patient

1.0 Plasma Volumes Exchanged, AC Infusion Rate 0.8 mL/Min/L TBV

TBV 1000 mL, 28% Hct

Inlet:AC Ratio	10:1	15:1	20:1
AC Used	120 mL	77 mL	57 mL
AC to Patient	39 mL	36 mL	34 mL

TBV 3000 mL, 28% Hct

Inlet:AC Ratio	10:1	15:1	20:1
AC Used	359 mL	232 mL	171 mL
AC to Patient	115 mL	107 mL	102 mL

TBV 5000 mL, 28% Hct

Inlet:AC Ratio	10:1	15:1	20:1
AC Used	599 mL	387 mL	285 mL
AC to Patient	191 mL	178 mL	171 mL

Note: Terumo Blood and Cell Technologies does not recommend inlet:AC ratios above 15.

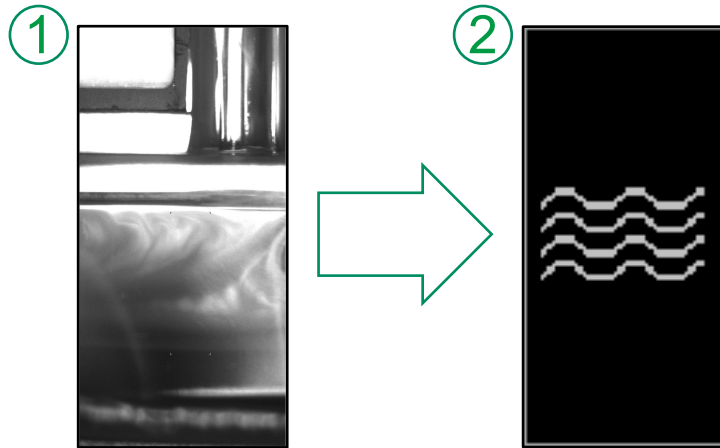
Questions?



Troubleshooting

- Turbulence
- Semi-Automatic Mode
- High Interface
- Hemolysis
- Clumping

Turbulence

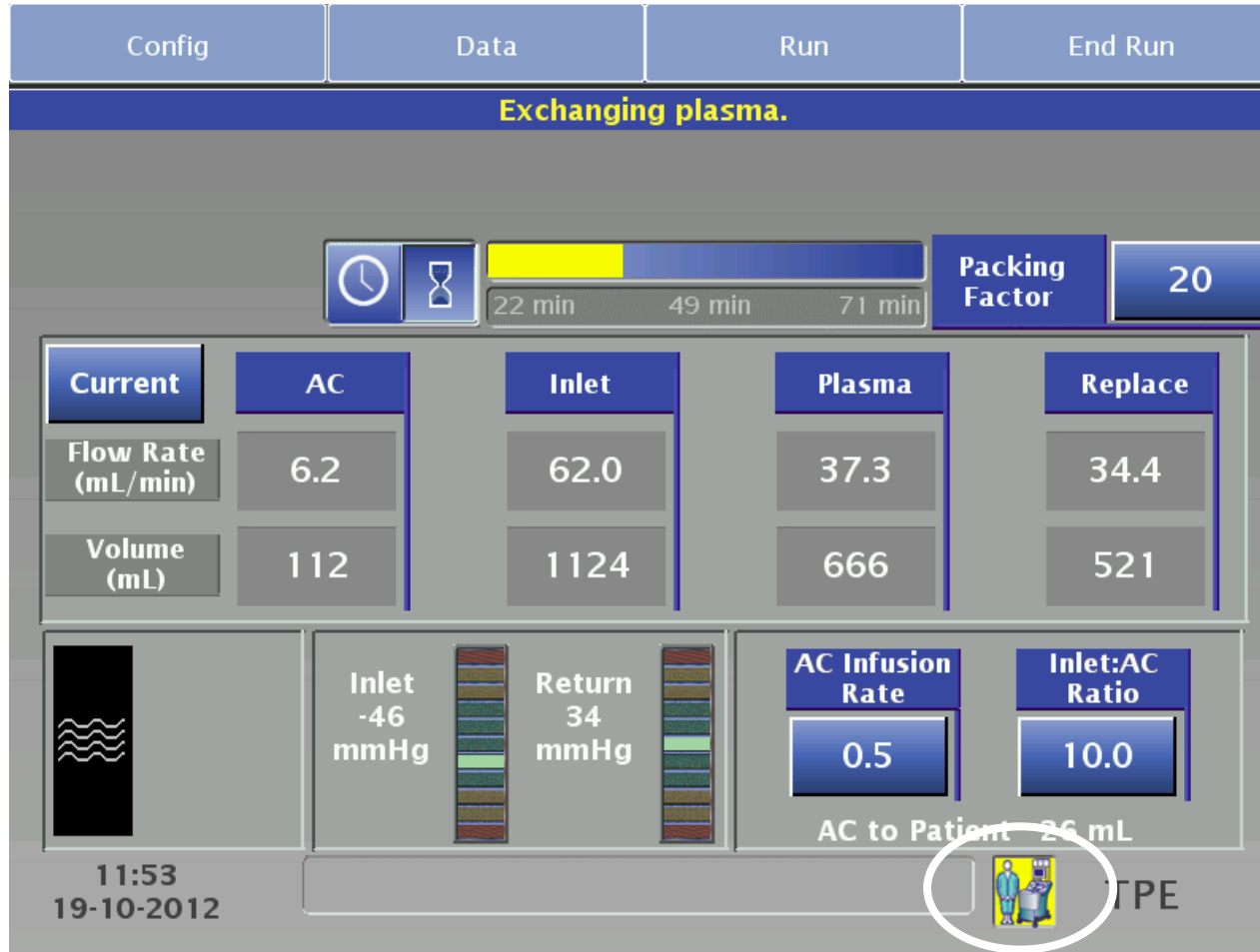


1. AIM Image
2. Algorithm Control Icon
 - Look through the view port to verify if turbulence is present in the connector.

Turbulence may be caused by:
High inlet pump flow rate
Low packing factor
Platelet swirling
Hyperviscosity/Mild Lipemia

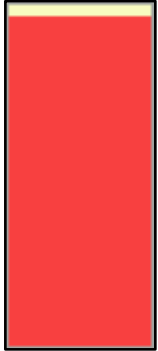
Decrease the inlet pump flow rate to increase the packing factor
Do nothing
Enter Semi-Automatic mode

Semi-Automatic Mode



- Semi-Automatic mode icon appears on the screen
- AIM system no longer controls the interface position

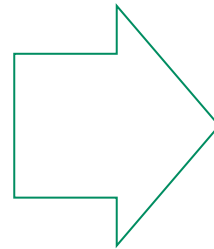
High Interface



“AIM system detected RBC interface near top of channel”

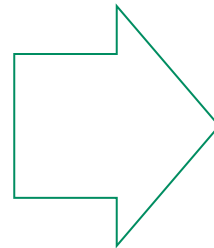
- Look through the view port to verify the position of the interface and verify entered Hct.

Interface is near the top of the connector and entered Hct is incorrect



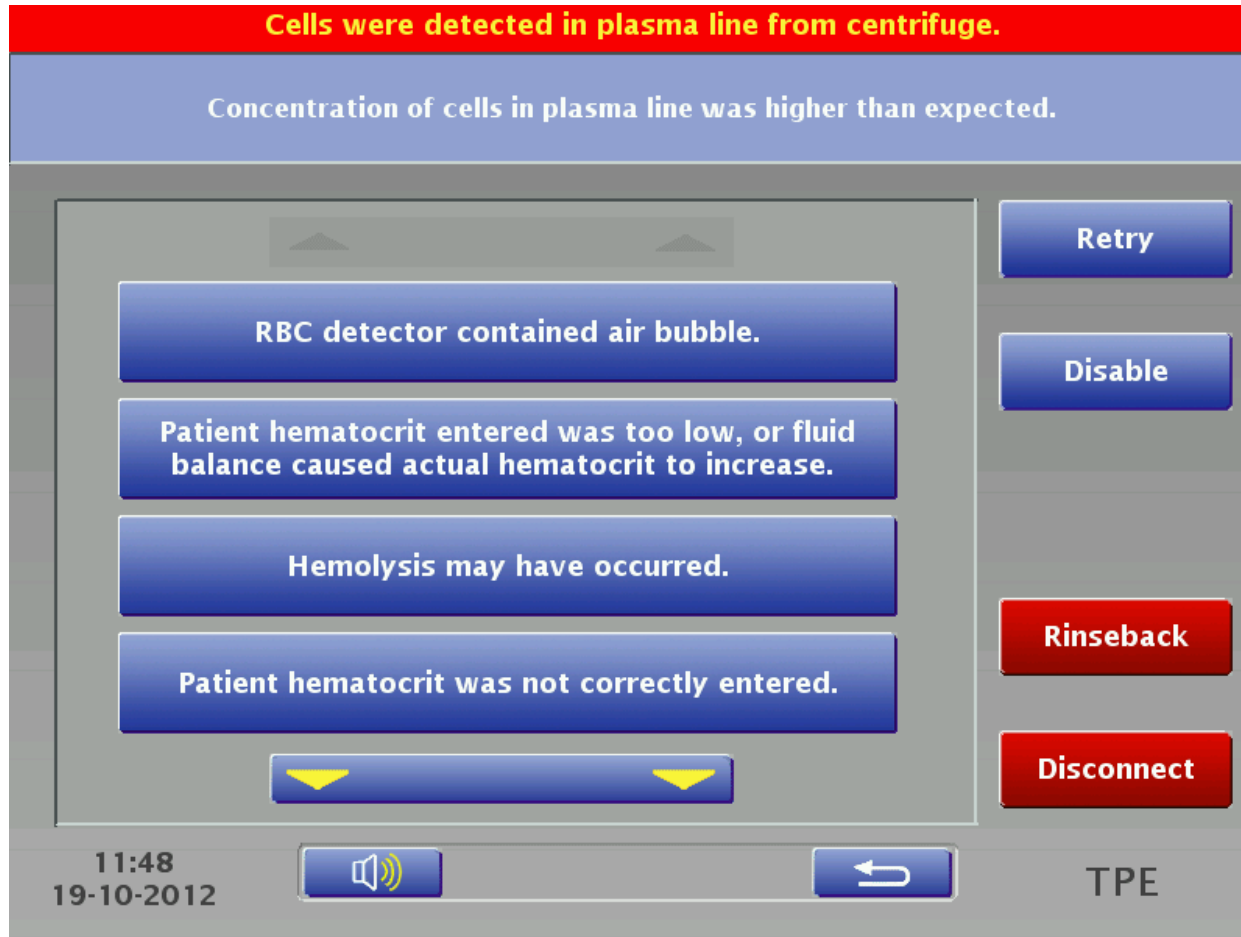
Lower the interface by increasing the entered Hct by 3% up to 3 times to avoid platelet loss

Interface is near the top of the connector and entered Hct is correct



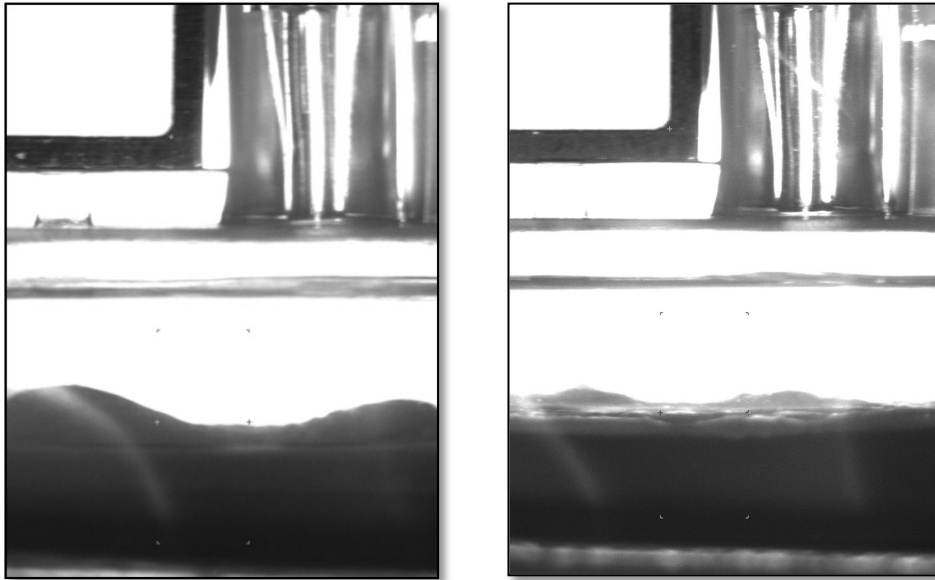
Touch Retry to resume the procedure

Hemolysis



- Certain patient conditions may cause hemolysis
- If hemolysis related to the patient's condition is suspected, verify presence of hemolysis prior to disabling the RBC detector

Clumping



If clumping is suspected:

- Decrease the inlet:AC ratio to 8:1
- Process 100 mL of inlet volume
- Verify clumping has resolved
- Consider increasing the inlet:AC ratio to 10:1

Questions?



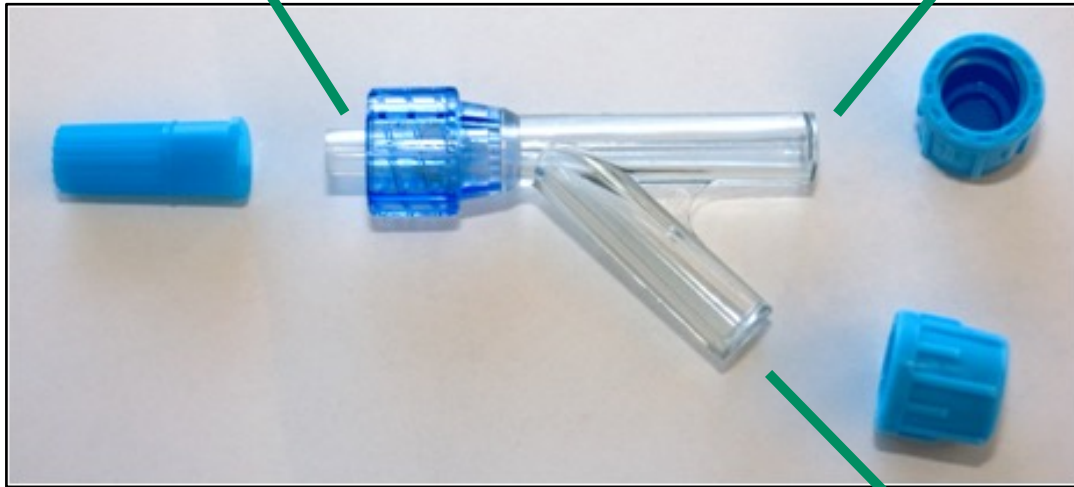
Single Needle

- Single-Needle Connector
- Convert Access to Single-Needle
- Optimization

Single-Needle Connector

Male luer connection to patient

Female luer connection to inlet line



Female luer connection to return line

Convert to Single Needle

With blood warmer on return line

Config	Data	Run	End Run
Exchange Status	Operation Status	Bolus	Strobe
Run Values	Options		
<p>1. Clamp inlet and return lines.</p> <p>2. Connect inlet line and blood warmer tubing to single-needle connector.</p> <p>3. Open inlet and return saline lines.</p>			
11:32 19-10-2012	Confirm		TPE

Without blood warmer on return line

Config	Data	Run	End Run
Exchange Status	Operation Status	Bolus	Strobe
Run Values	Options		
<p>1. Clamp inlet and return lines.</p> <p>2. Connect inlet and return lines to single-needle connector.</p> <p>3. Open inlet and return saline lines.</p>			
11:33 19-10-2012	Confirm		TPE

Convert to Single Needle

Exchanging plasma.

10 min 164 min 174 min

Packing Factor 19

	Current	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)		6.5	65.0	36.9	29.2
Volume (mL)		71	716	392	284

Inlet -61 mmHg Return -7 mmHg

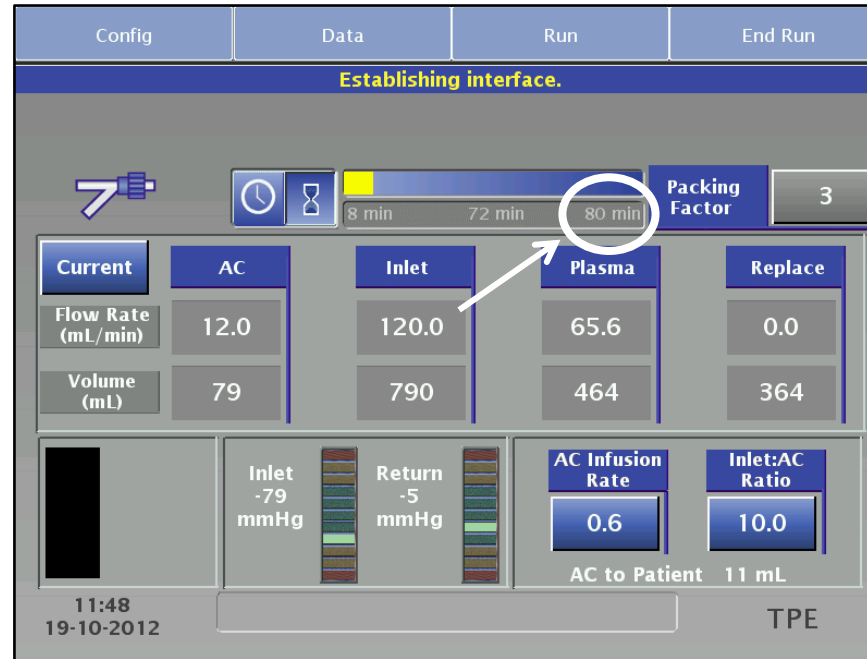
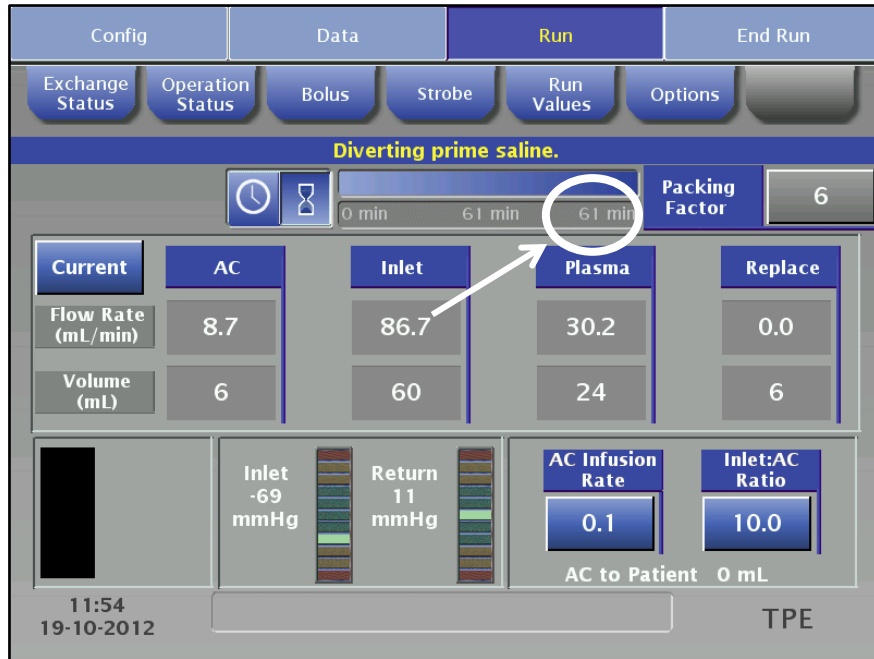
AC Infusion Rate: 0.6 Inlet:AC Ratio: 10.0

AC to Patient 15 mL

11:35
19-10-2012

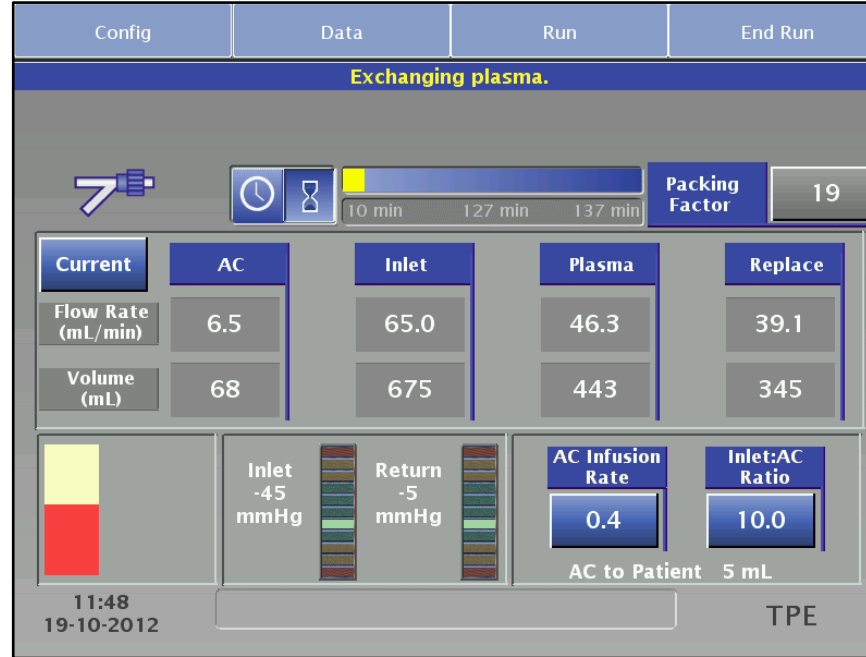
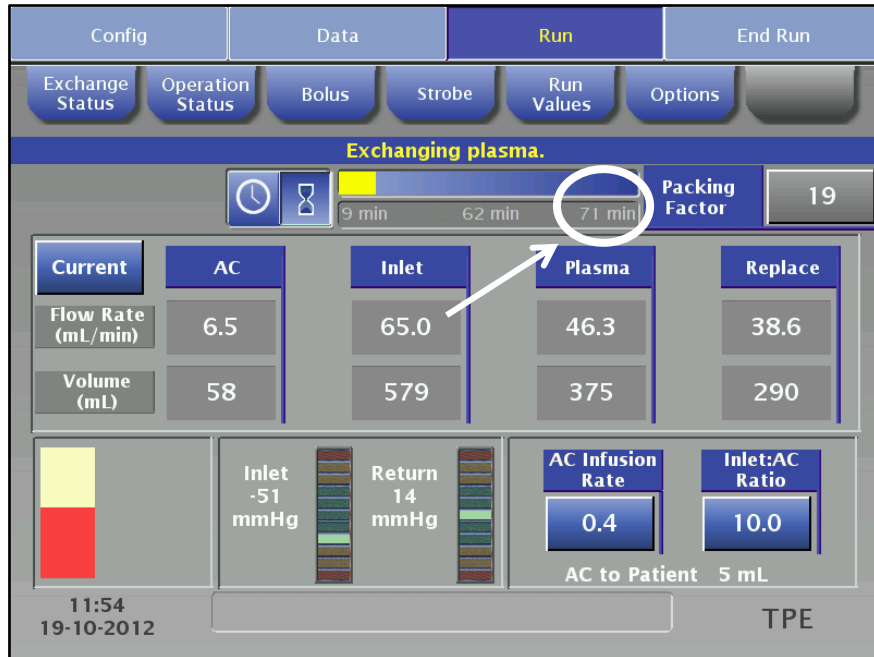
TPE

Optimization



- Inlet pump flow rate set by the system
- The procedure continues at a new inlet pump flow rate set by the system

Optimization



- Inlet pump flow rate set by the operator
- The system will continue the run at same inlet pump flow rate

Questions?



Pediatrics/Low TBV Patients

- Minimum Data Entry Limits
- AC Management
- Fluid Balance
- Custom Prime – RBC
- Custom Prime – RBC (60%)

Minimum Data Entry Limits

- Patient data
 - Height: 12 inches or 30 cm
 - Weight: 5 lbs or 2 kg
 - TBV: 300 mL
(The system will not calculate the TBV for weight < 25 kg)
- Inlet pump flow rate
 - 5 mL/min

AC Management

- AC infusion rate
 - The AC infusion rate may need to be increased to achieve an inlet pump flow rate ≥ 5 mL/min.
- Inlet: AC ratio
 - The inlet:AC ratio needs to be kept at a value that maintains proper anticoagulation.

Configured AC infusion rate 0.8 mL/min/L TBV and inlet:AC ratio 10:1				
Patient TBV	300	400	500	600
Initial Inlet pump flow rate	2.7	3.5	4.3	5.2
Increased AC infusion rate	1.5	1.2	1.0	0.9
Inlet pump flow rate	5.0	5.3	5.4	5.8

Fluid Balance

- Target fluid balance
 - Patient tolerance of the procedure
- Blood warmer
 - Patient comfort
- Custom prime
 - Improved tolerance of the volume of the extracorporeal circuit

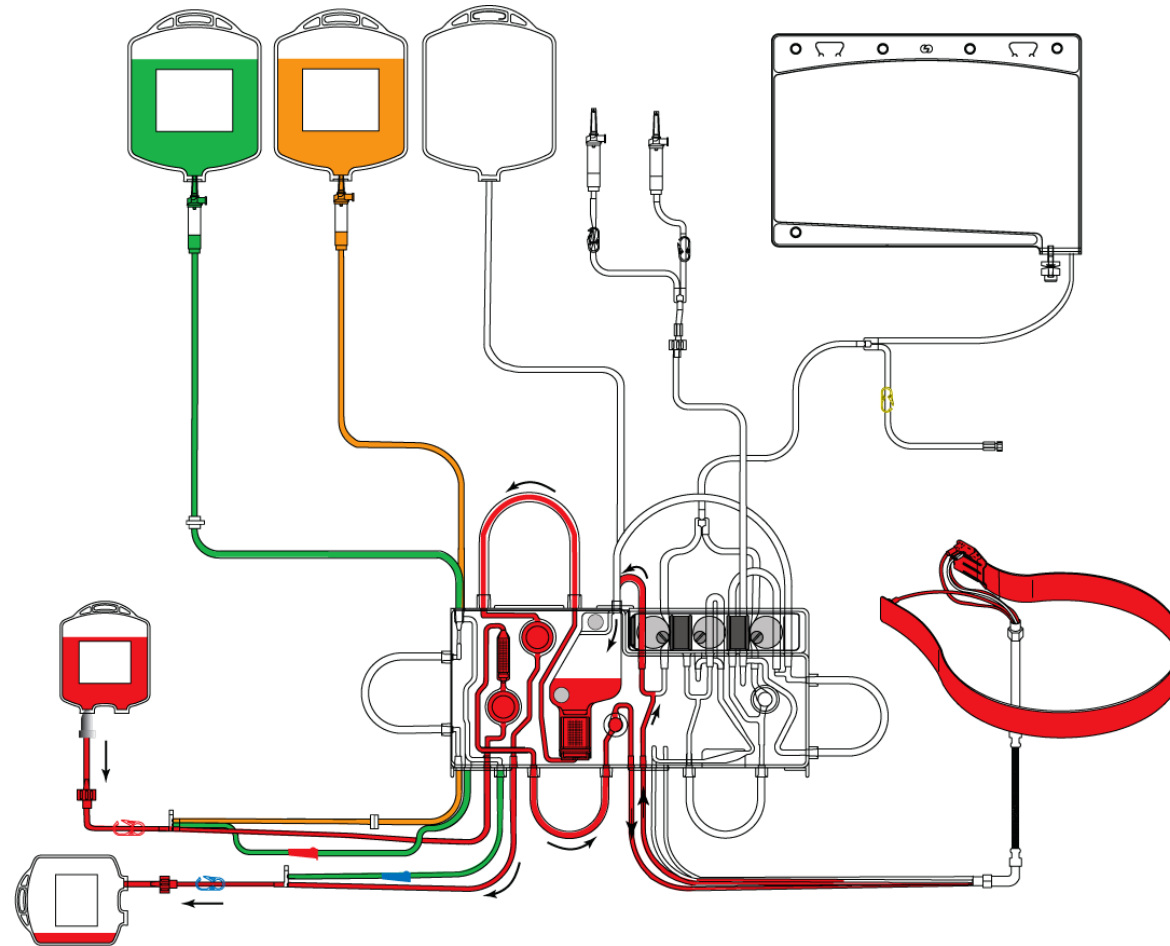
Custom Prime – RBC

Pediatrics/Low TBV Patients

Config	Data	Run	End Run
Enter data for custom prime.			
<div style="border: 1px solid gray; padding: 10px; margin: 10px auto; width: 80%;"><p style="text-align: center; margin: 5px 0;">RBC</p><p style="text-align: center; margin: 5px 0;">Plasma</p><p style="text-align: center; margin: 5px 0;">Albumin</p></div>			
RBC Unit Hct (%)	Maximum Inlet Flow Rate (mL/min)	Volume (mL)	
55	100	230	
11:24 19-10-2012	Confirm		 TPE

Custom Prime – RBC

Pediatrics/Low TBV Patients



Custom Prime – RBC (60%)

Patient		200 mL RBC	No blood prime	240 mL RBC	No blood prime
		No blood warmer		40 mL blood warmer	
TBV	Hct (%)	Change in patient Hct (%)			
300 mL	25	+5	-13	+8	-14
	30	+4	-14	+7	-16
	35	+3	-15	+6	-17
	40	+2	-16	+4	-18
600 mL	25	+3	-7	+5	-8
	30	+2	-8	+4	-9
	35	+2	-8	+3	-10
	40	+1	-9	+2	-11
1000 mL	25	+2	-5	+3	-5
	30	+2	-5	+2	-6
	35	+1	-5	+2	-6
	40	+1	-6	+2	-7

Note: The table indicates the approximate change in the patient’s Hct after custom prime.

Questions?

