TERUMO BLOOD AND CELL TECHNOLOGIES

Therapeutic Plasma Exchange (TPE) Spectra Optia® Apheresis System

Version 12 Procedure Training
(including single-needle option)

TS-OPTI-01918

TRAINING

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
  - WBC reduction for patients with leukocytosis at risk for leukostasis (USA)
- Platelet depletion
- Processing of harvested bone marrow

*Procedure availability varies by country.

Operator’s Manual Information Continued

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

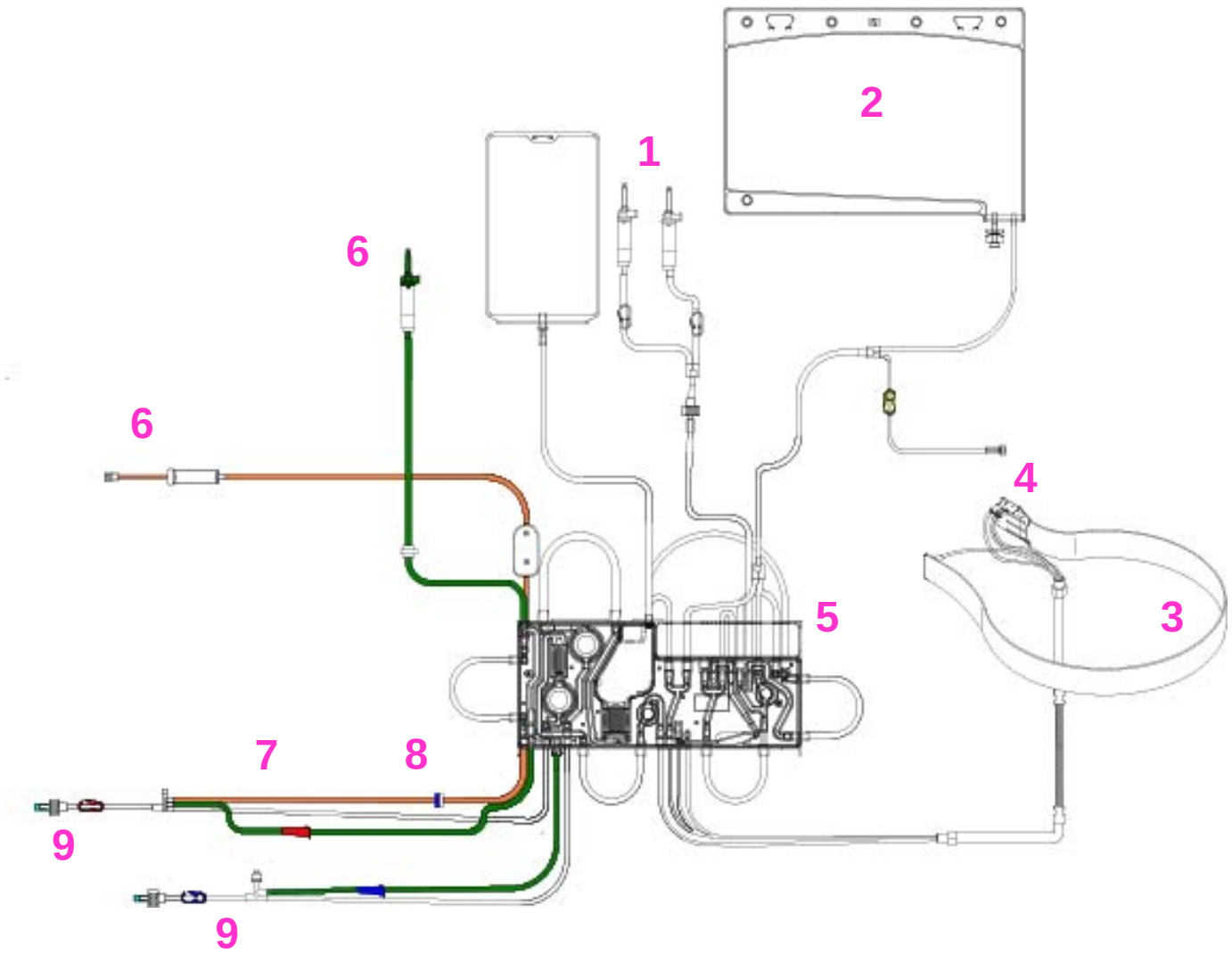
- Introduction
- Preparing to Perform the Procedure
- Monitoring the Run
- Completing the Run
- Making Changes
- Optimization
- Troubleshooting
- Single-Needle Access
- Low-TBV Patients

Introduction

- Exchange Set
- Basic Principles of TPE
- Connector

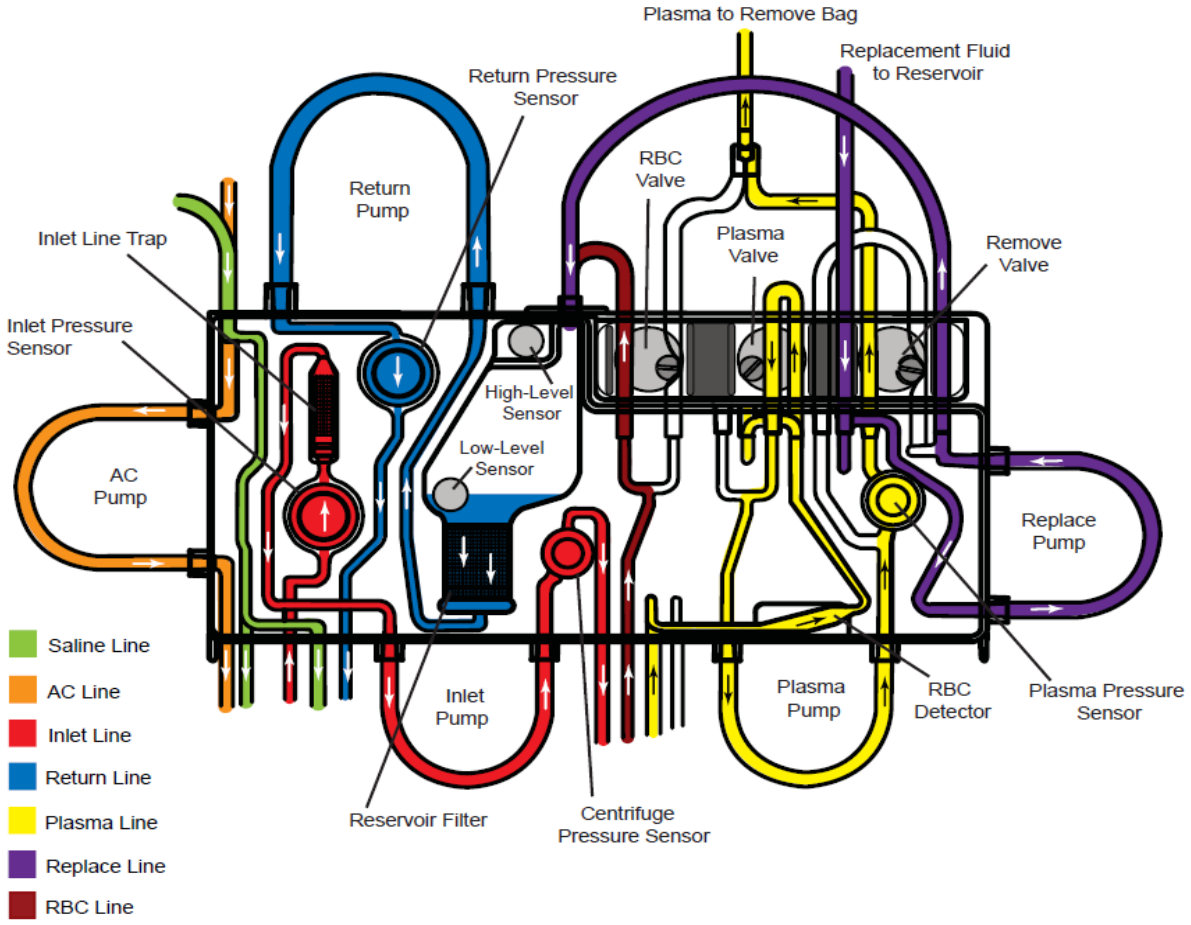
Exchange Set

1. Replace line
2. Remove bag
3. Channel
4. Connector
5. Cassette
6. AC and saline tubing
   - AC Correct Connect luer*
   - Saline spike
   - Sterile barrier filters
7. AC line
8. AC check valve
9. Colored clamps



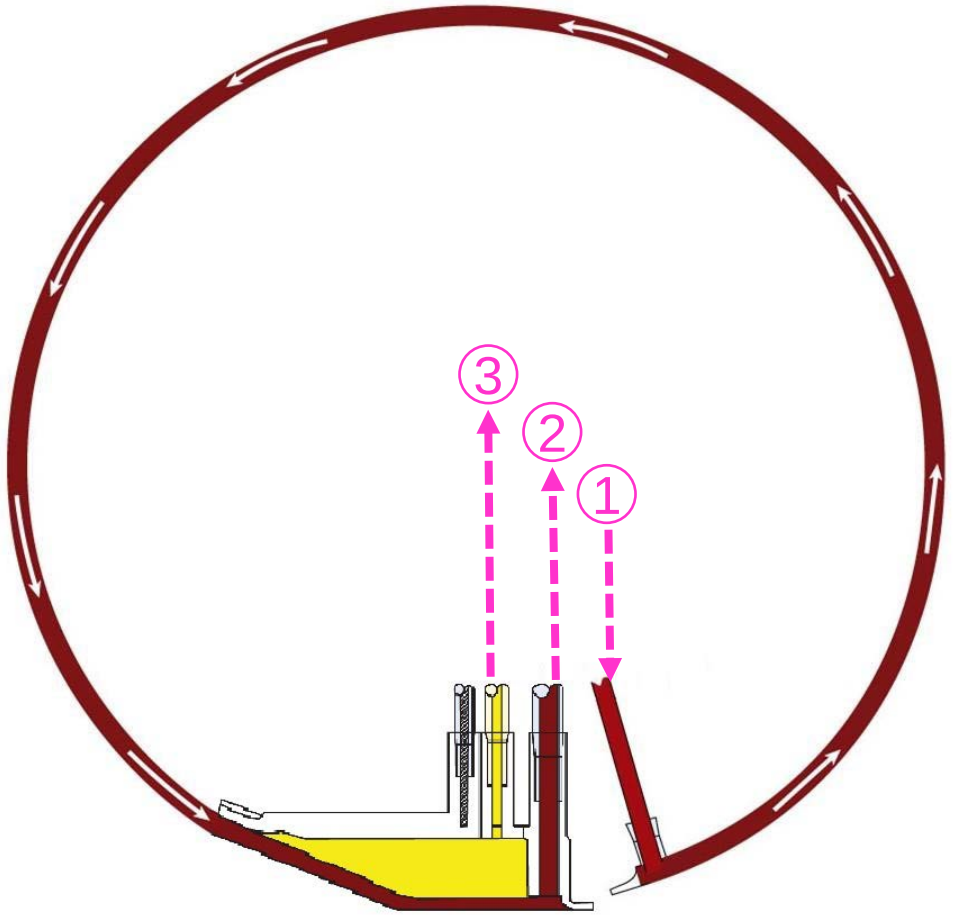
*Correct Connect availability is dependent upon regulatory approval

Basic Principles of TPE



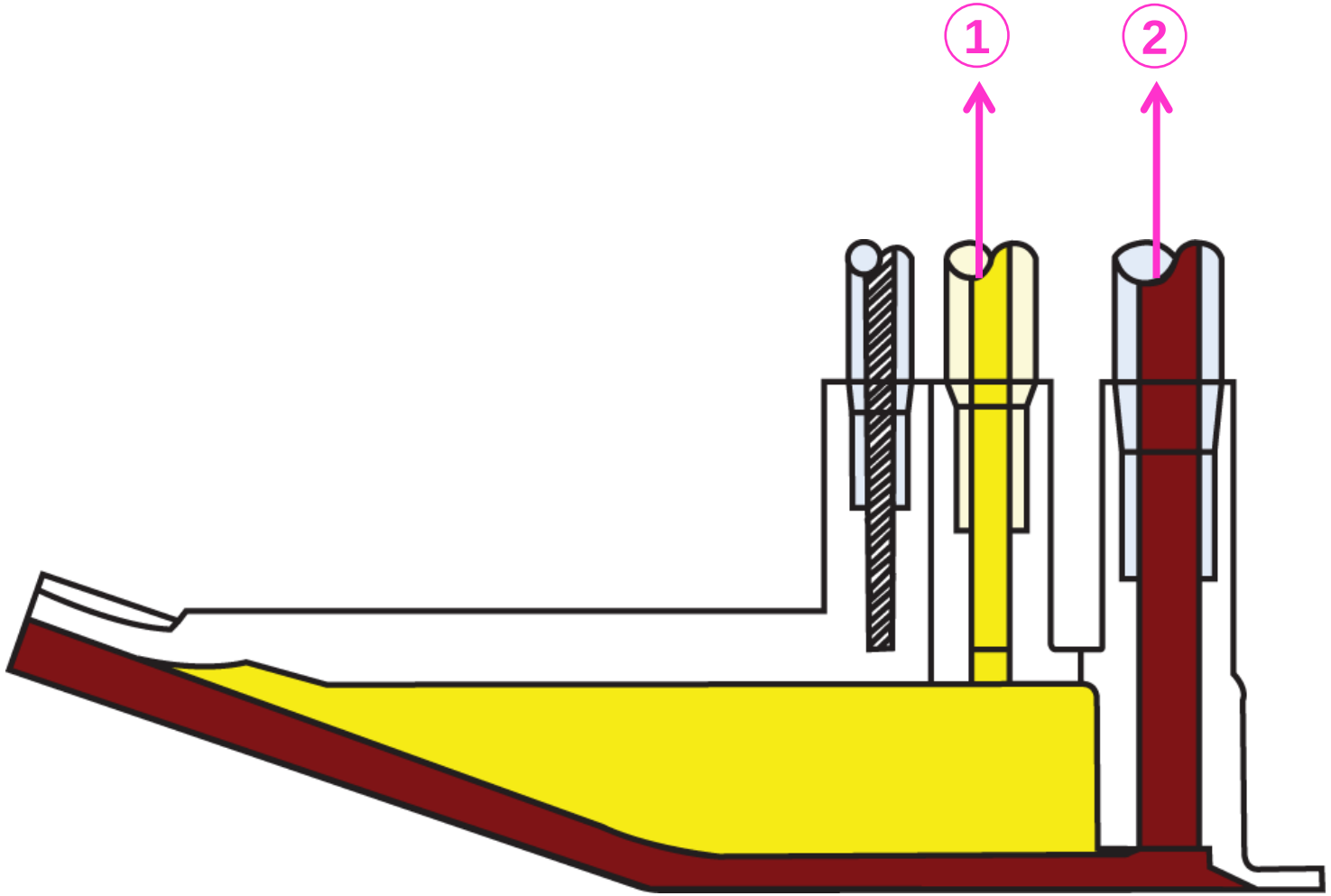
Basic Principles of TPE – Channel

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 remove bag.



Connector

1. Plasma port
2. RBC port



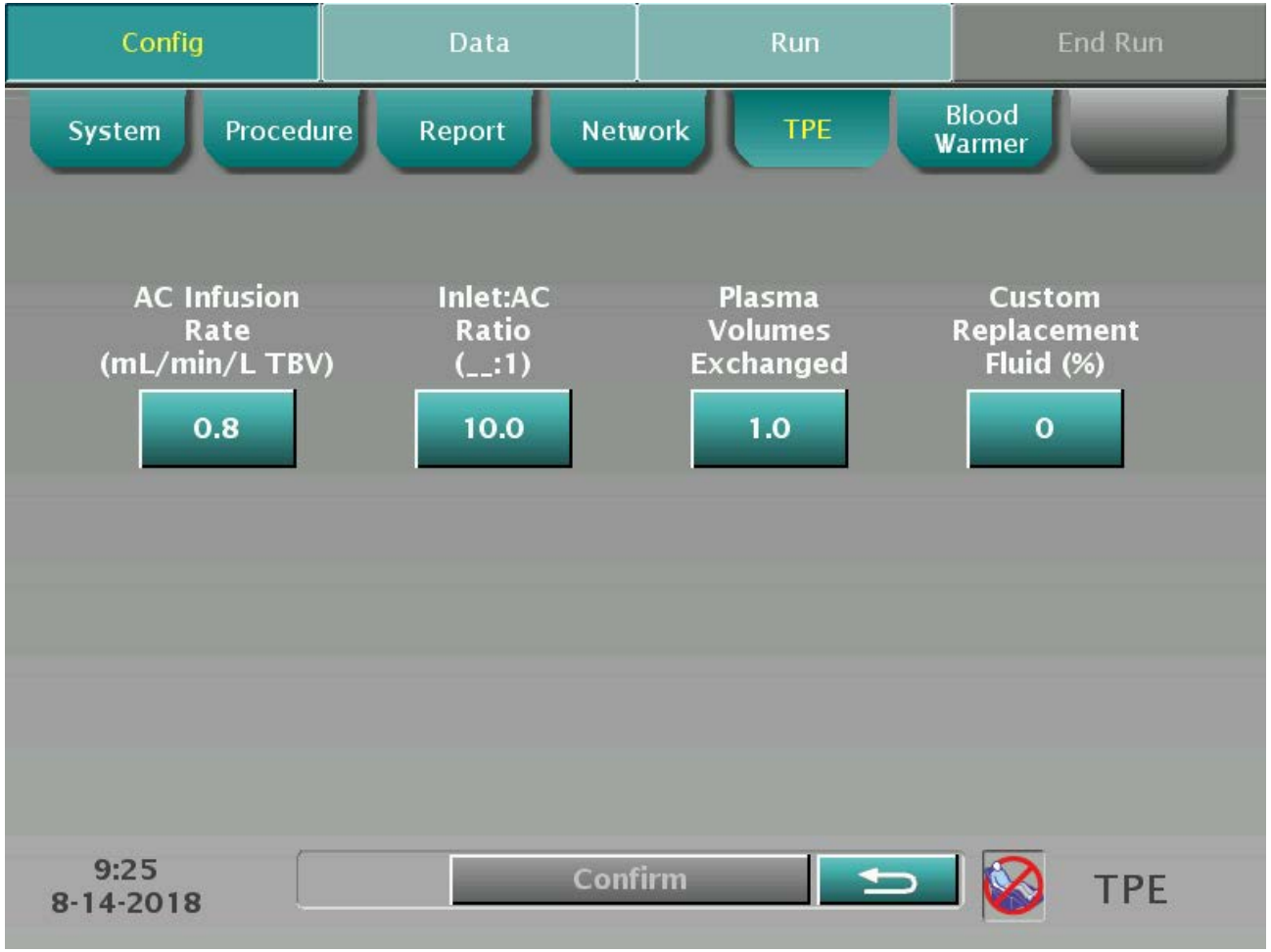
Questions?

Preparing to Perform the Procedure

- Configuration: Medication Infusion Notification
- Configuration – TPE Procedures
- Configuration – Blood Warmer
- Channel Loading
- Single-Needle
- Patient Data
- Fluid Data
  - Replacement Fluid
  - Fluid Balance
- Run Values
- Spiking the Replacement Fluid
- Patient Connection

Configuration: Procedure

Configuration – TPE Procedures

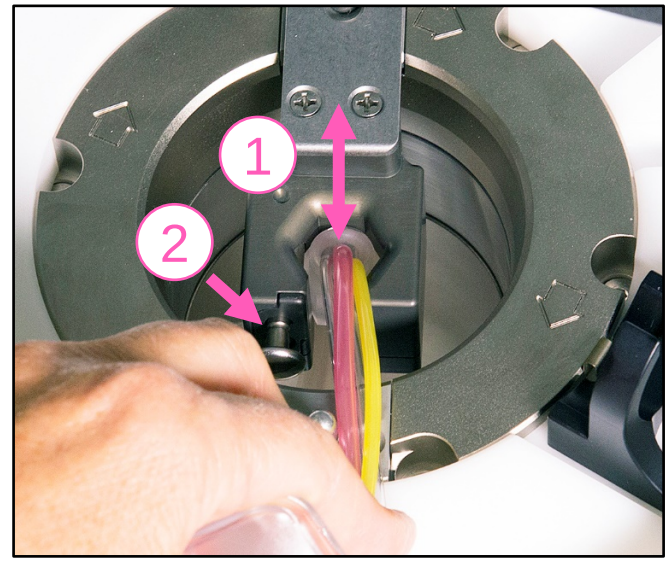


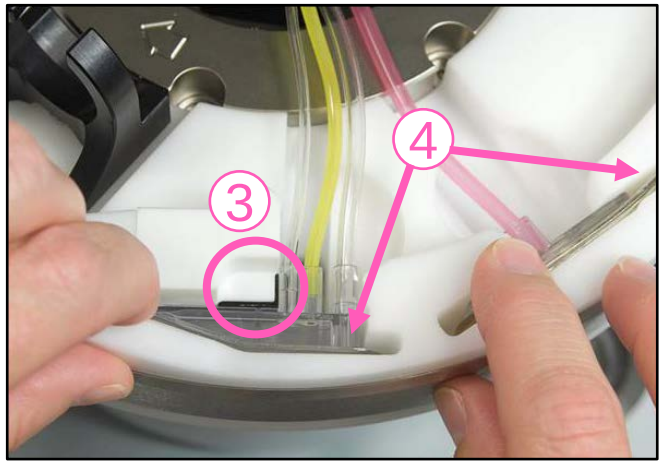
Configuration – Blood Warmer

Channel Loading

Use the standard filler.

1. Centrifuge collar is in the correct position.
2. Notch on the locking pin is visible.
3. Optical reference is visible.
4. Channel sits flush with the groove.



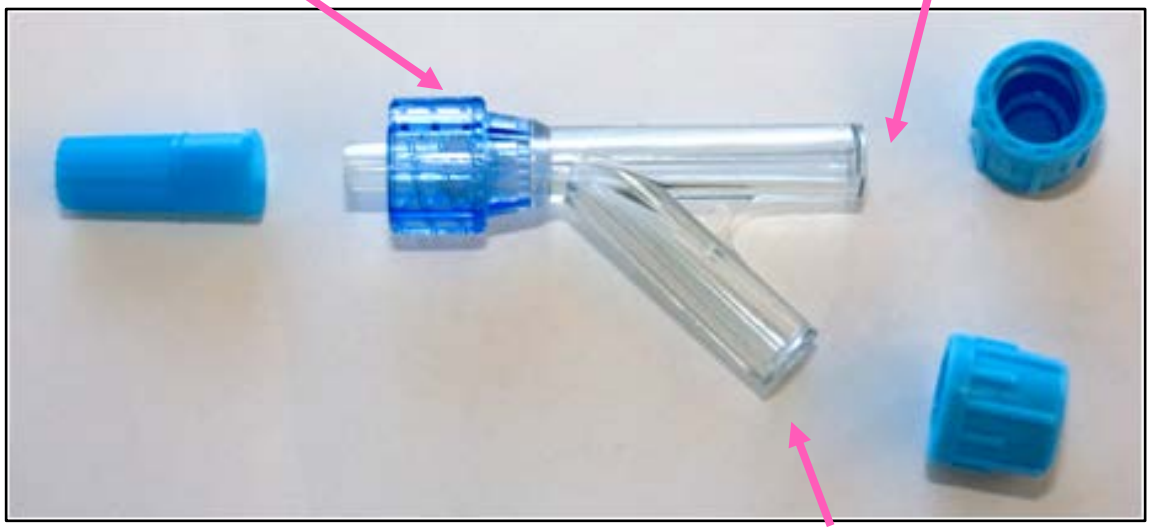


Single-Needle Procedure

Single-Needle Connector

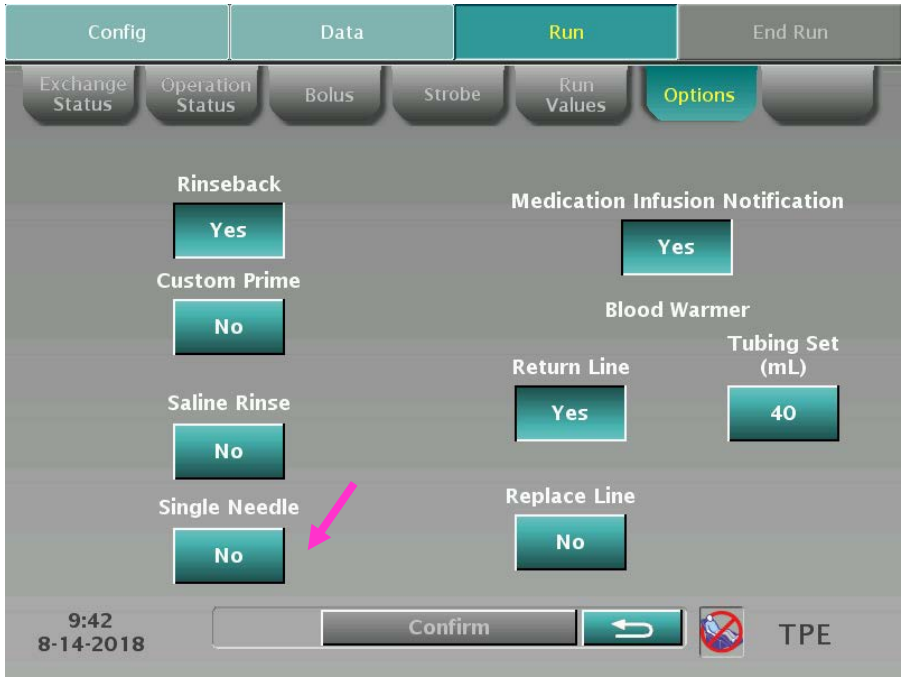
Male luer connection to patient

Female luer connection to inlet line



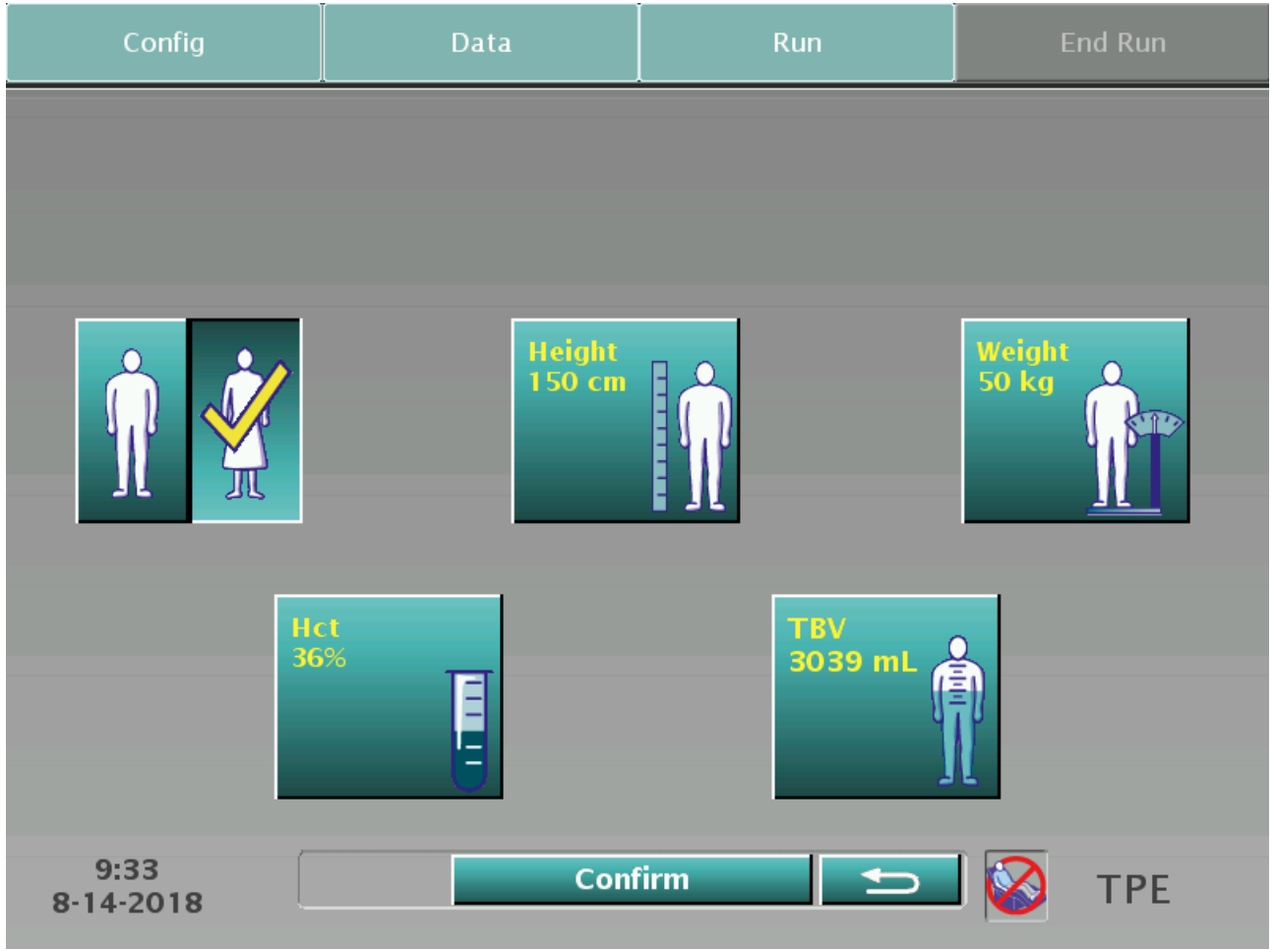
Female luer connection to return line

Converting to Single-Needle Access



Touch **Single Needle** on the options screen and follow the on-screen instructions.

Patient Data



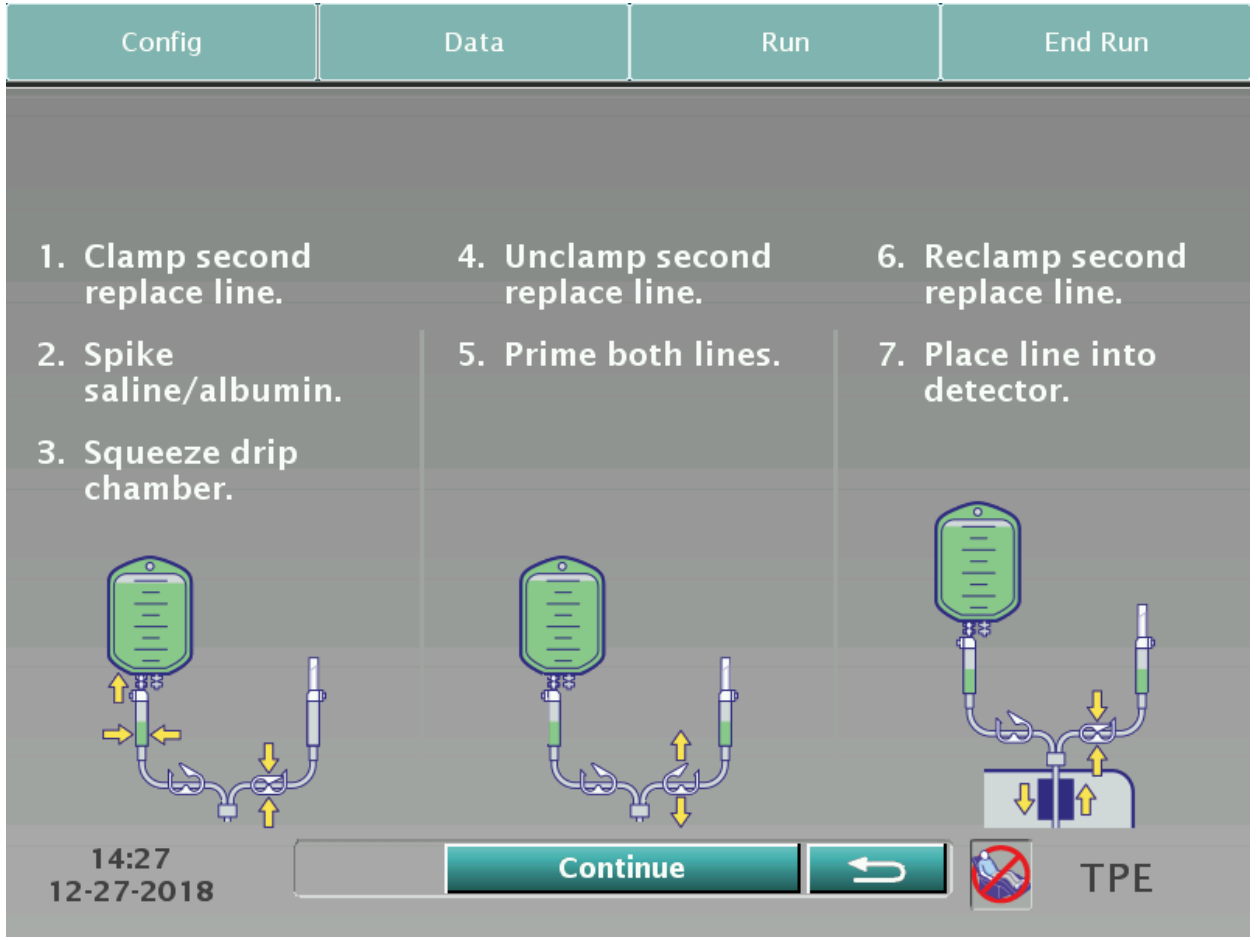
Fluid Data – Replacement Fluid

Run Values

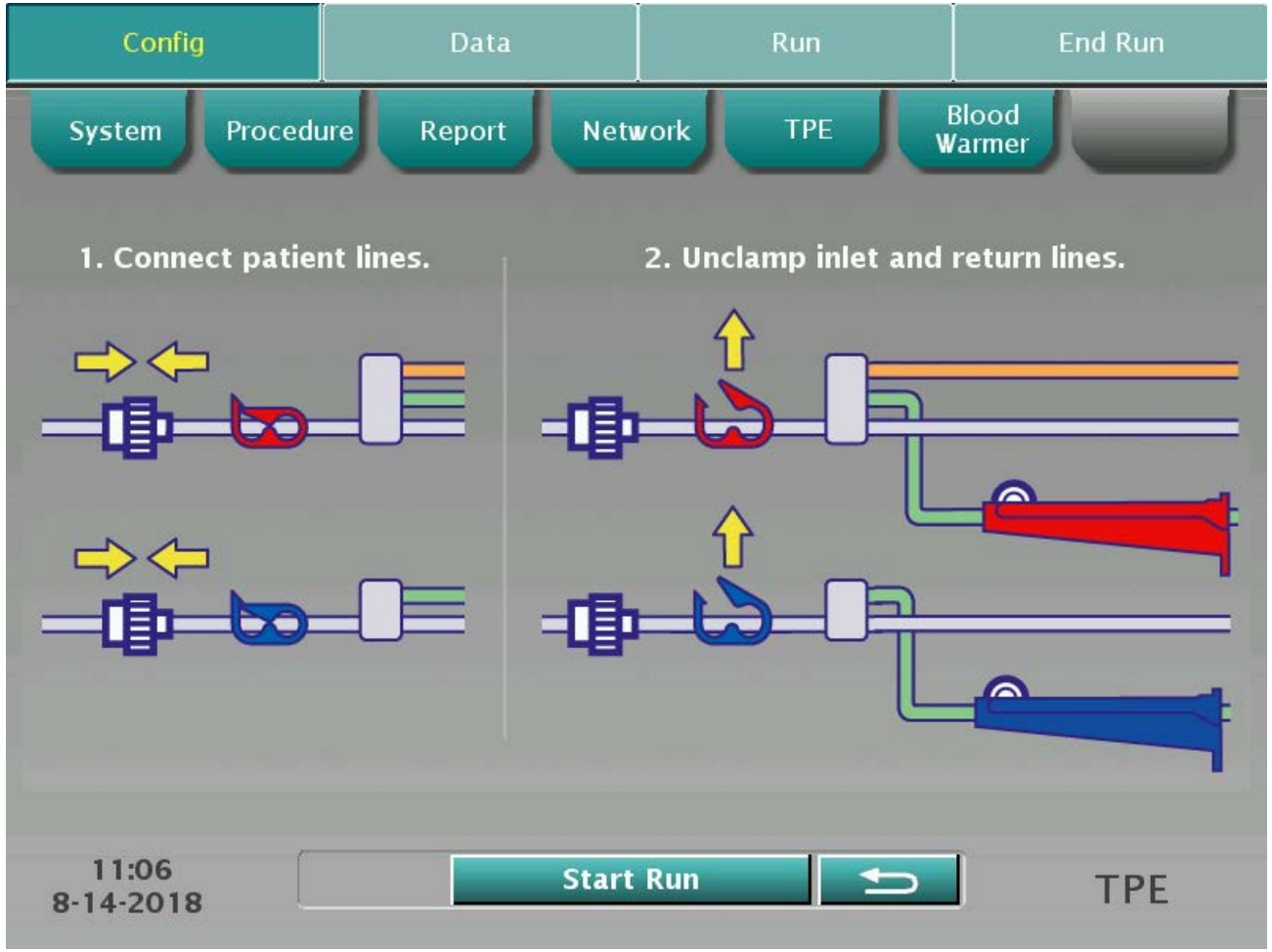

Config
Data
Run
End Run
AC Infusion Rate
1.0
Inlet:AC Ratio (__:1)
10.0
Plasma Removed (mL)
2781
Run Time (min)
47
Plasma Volumes Exchanged
1.0
AC
Inlet
Plasma
Replace
Flow Rate (mL/min)
12.0
120.0
71.4
56.5
Current (mL)
Target (mL)
558
5580
3299
2583
9:47
8-14-2018
Confirm
TPE


Config
Data
Run
End Run
AC Infusion Rate
1.0
Inlet:AC Ratio (__:1)
10.0
Plasma Removed (mL)
2781
Run Time (min)
70
Plasma Volumes Exchanged
1.0
AC
Inlet
Plasma
Replace
Flow Rate (mL/min)
8.0
80.0
47.6
37.7
Current (mL)
Target (mL)
558
5580
3299
2583
9:48
8-14-2018
Confirm
TPE

Spiking the Replacement Fluid



Patient Connection

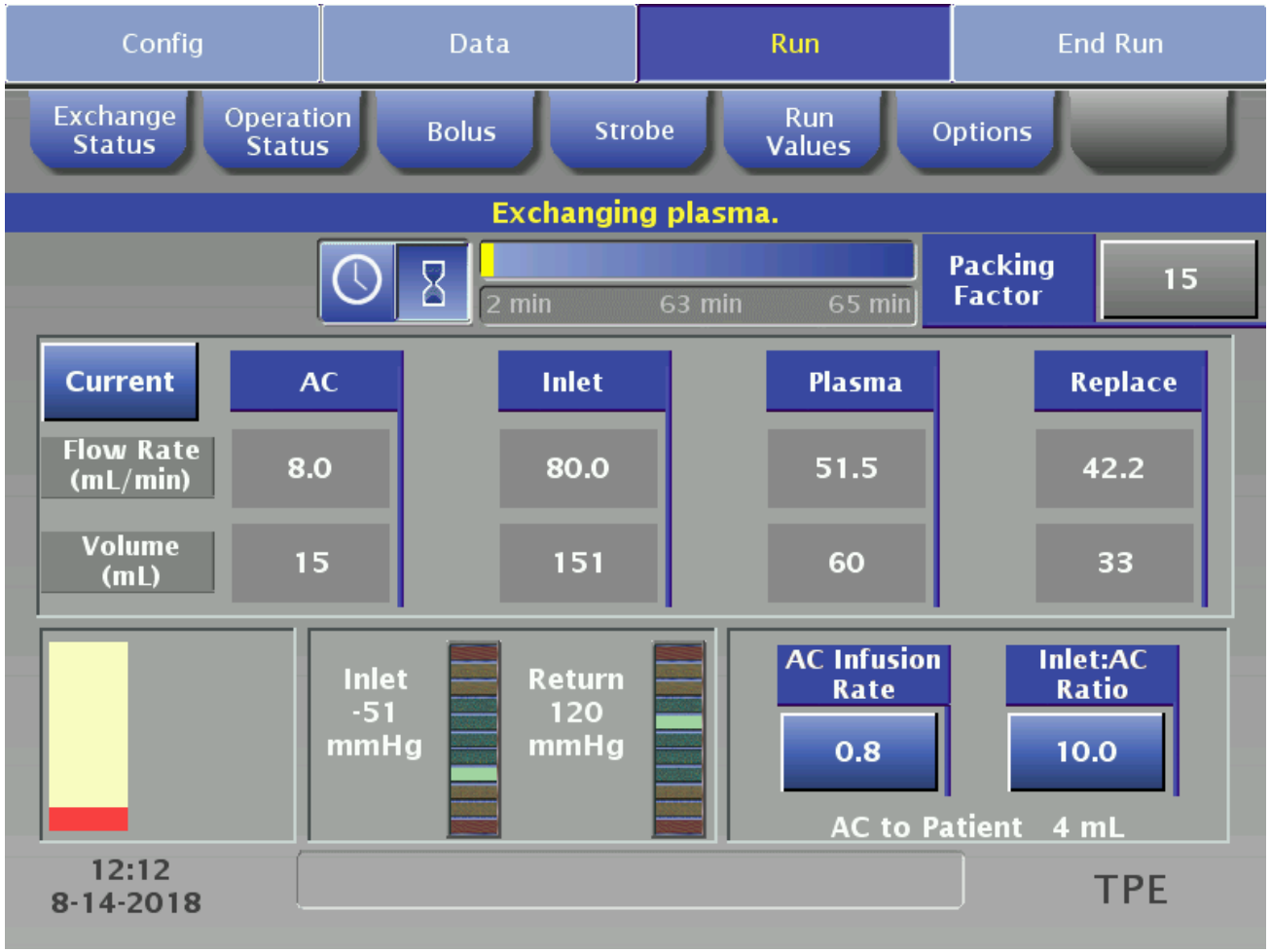


Questions?

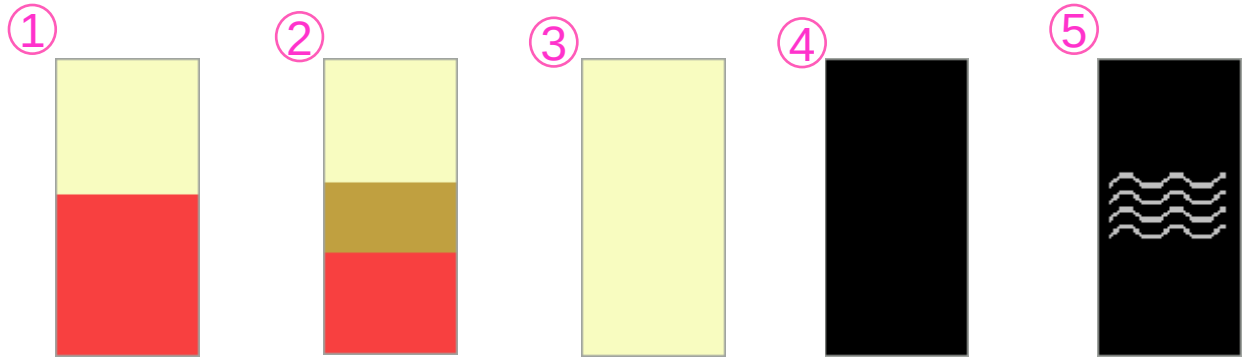
Monitoring the Run

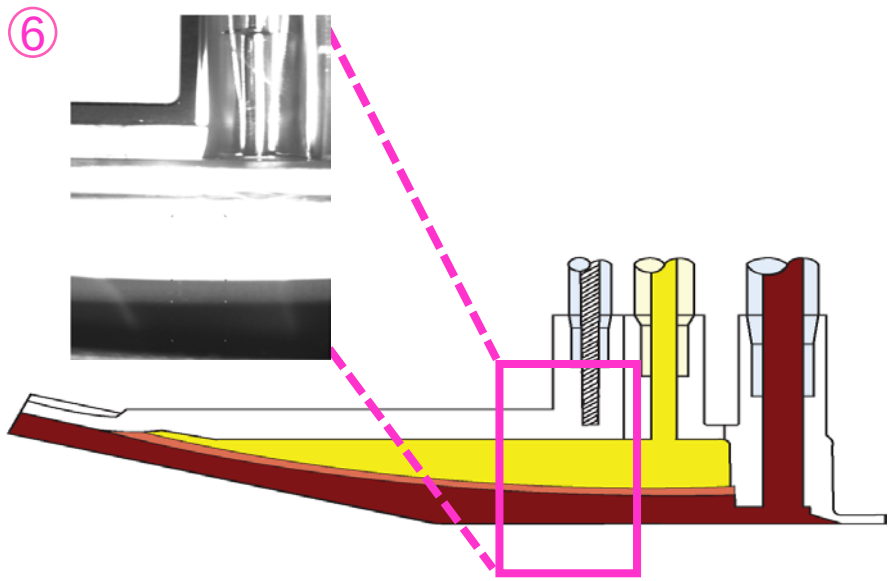
- Main Run
  - AIM Graphic
- Platelet Flush
- View Port

Main Run


Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
Exchanging plasma.
2 min
63 min
65 min
Packing Factor
15
Current
AC
Inlet
Plasma
Replace
Flow Rate (mL/min)
8.0
80.0
51.5
42.2
Volume (mL)
15
151
60
33
Inlet -51 mmHg
Return 120 mmHg
AC Infusion Rate
0.8
Inlet:AC Ratio
10.0
AC to Patient 4 mL
12:12
8-14-2018
TPE

Main Run – AIM Graphic

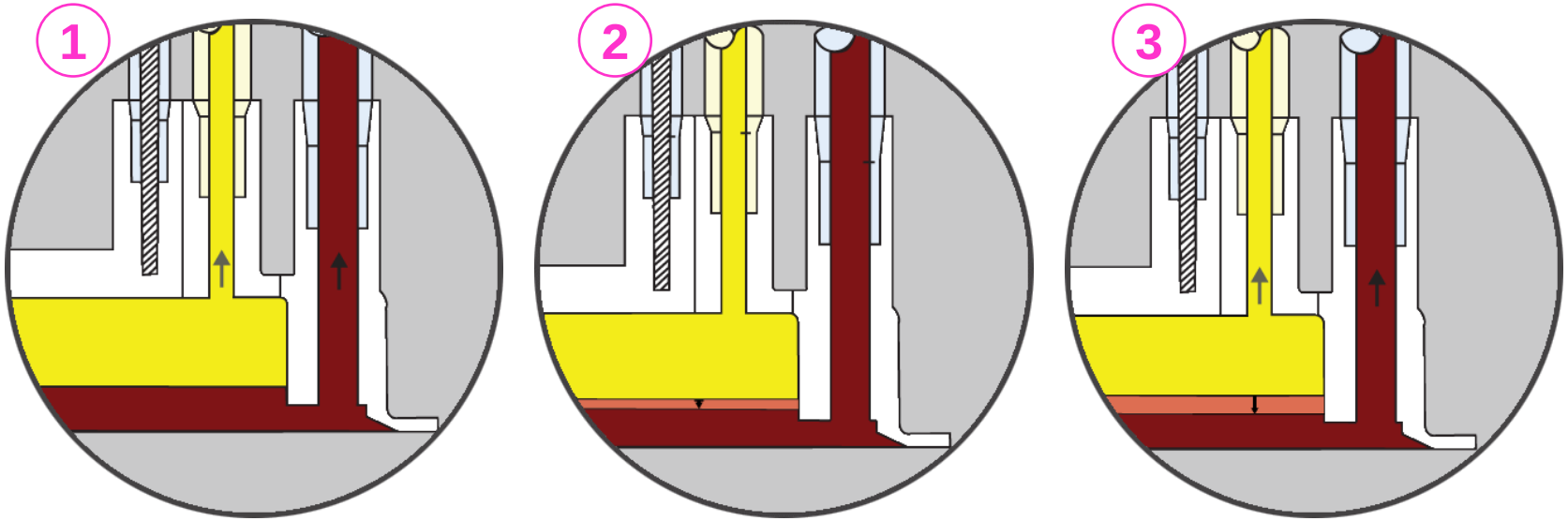




1. Ideal Interface
2. Buffy Coat Accumulation
3. Plasma
4. Black
5. Algorithm Control Icon
6. AIM image

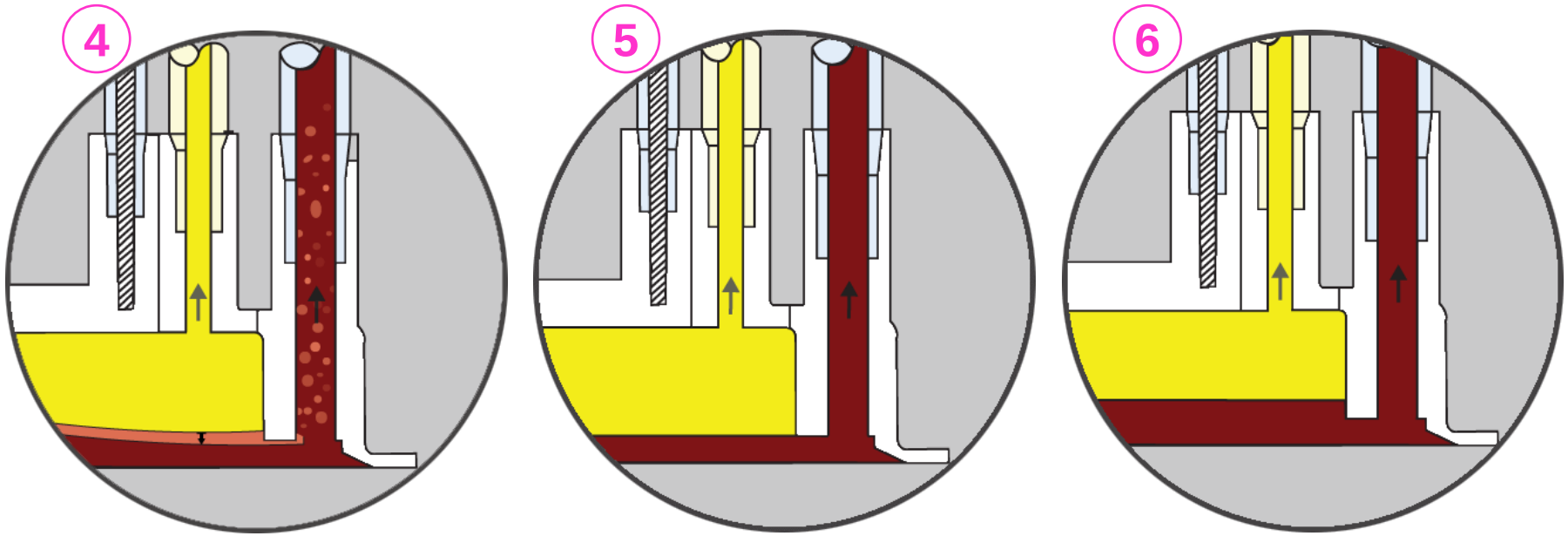
Platelet Flush

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

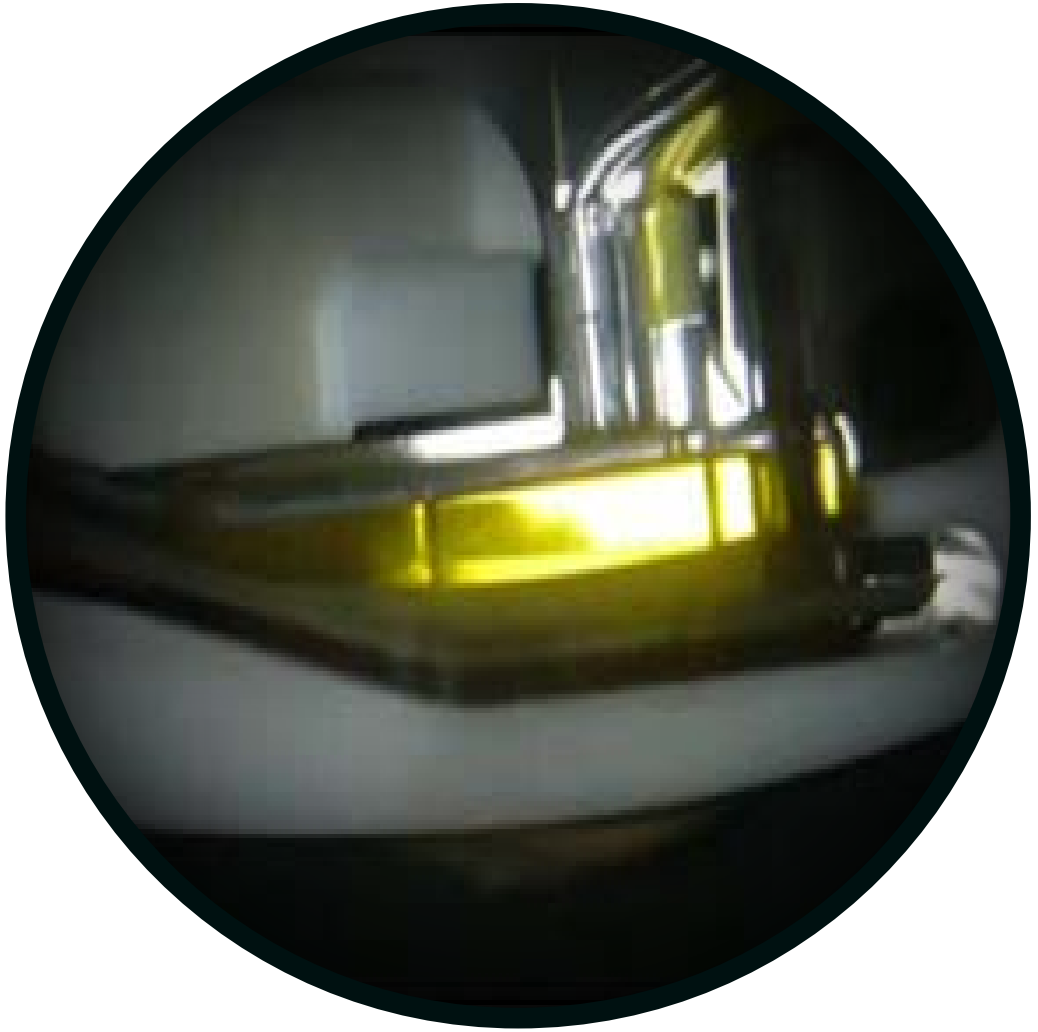


Platelet Flush (Continued)

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 the platelet flush is completed.



View Port



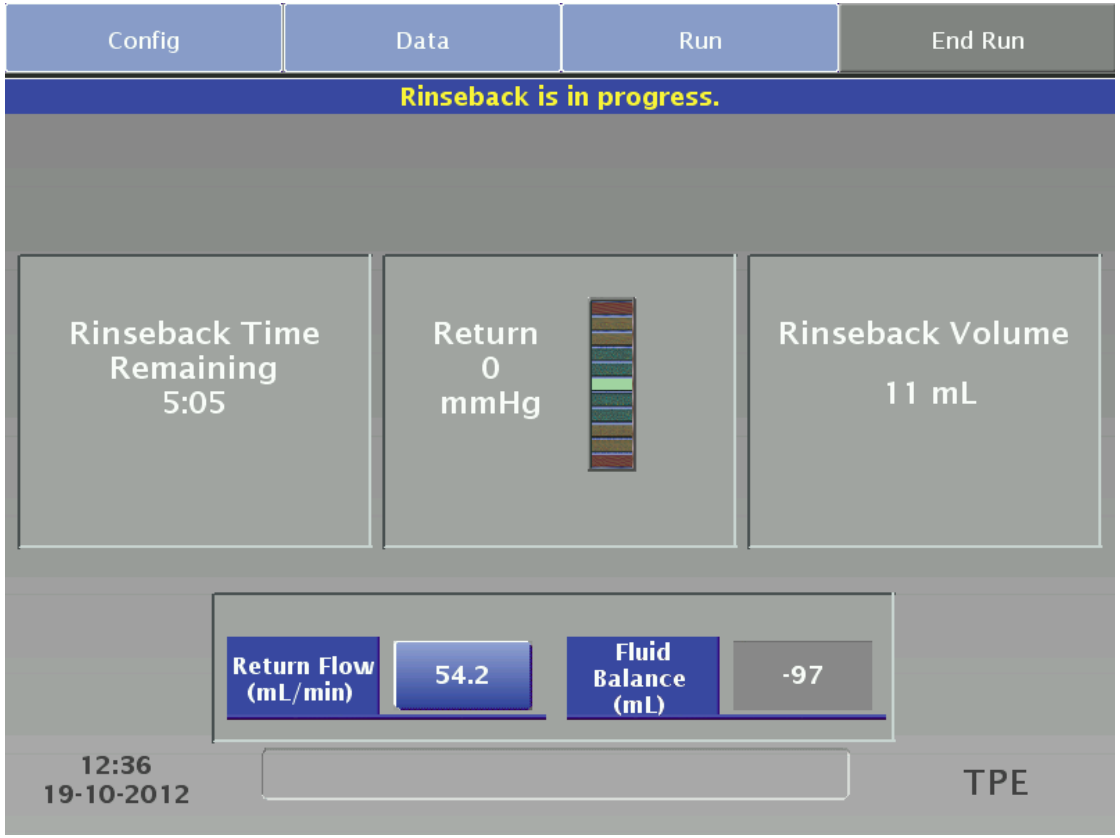
Questions?

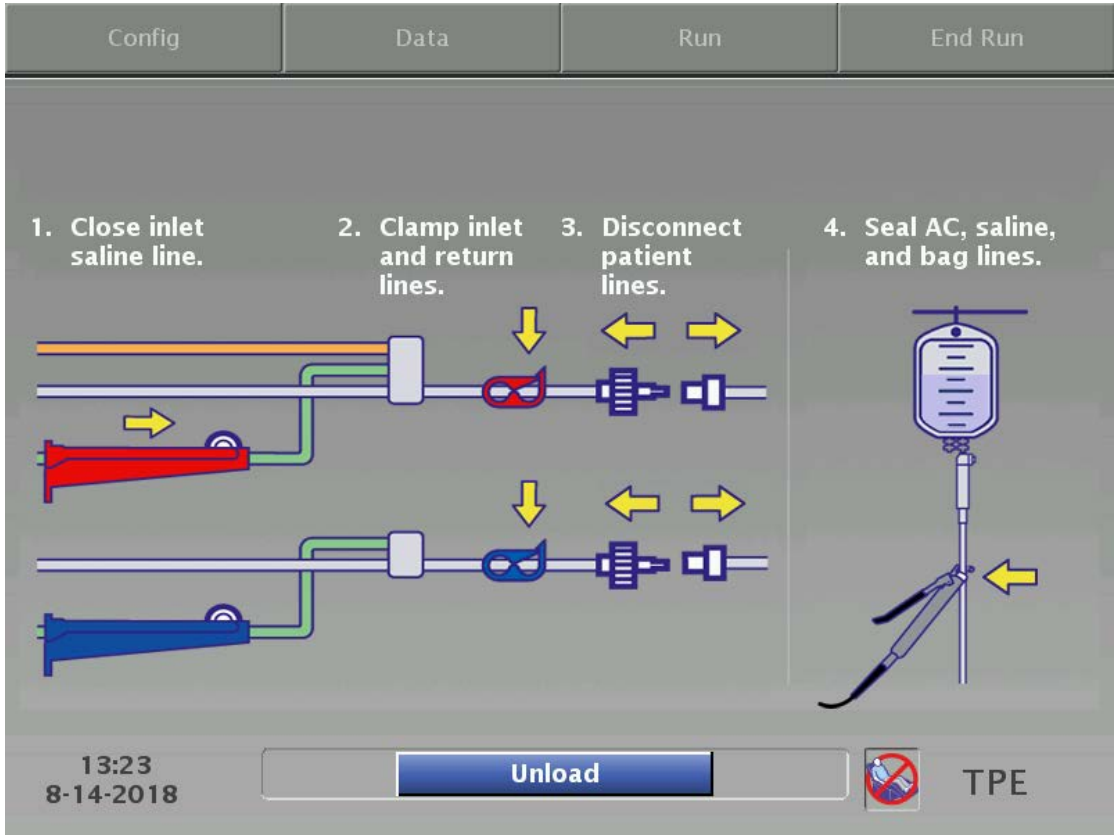
Completing the Run

- Run Targets Attained
- Rinseback and Disconnect
- Procedure Summary

Run Targets Attained

Rinseback and Disconnect





Procedure Summary

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

+371 mL (AC Used)

-2392 mL (Remove Bag)

+1872 mL (Replacement Used)

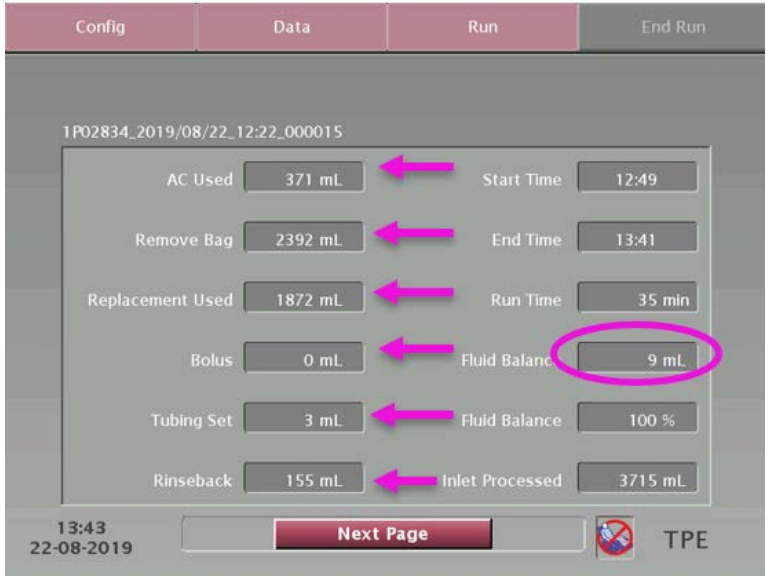
+3 mL (Tubing Set)

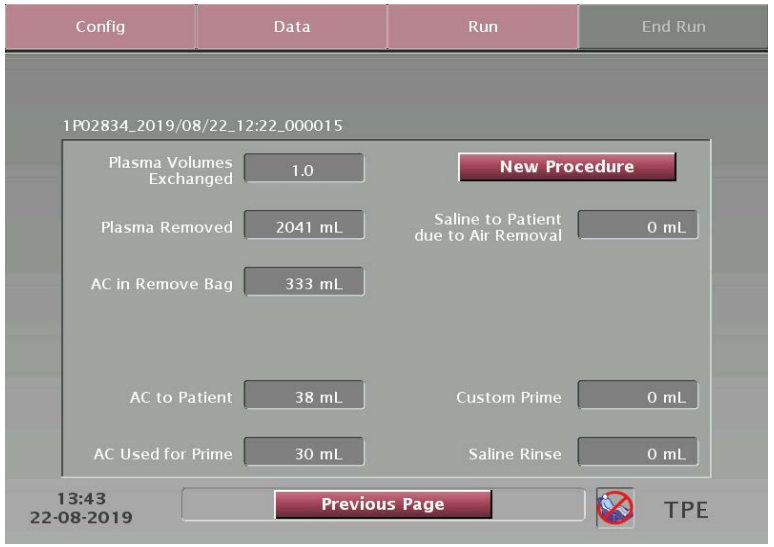
+155 mL (Rinseback)

9 mL (Total)

+0 mL Bolus (if given)

9 mL Patient's fluid balance





Questions?

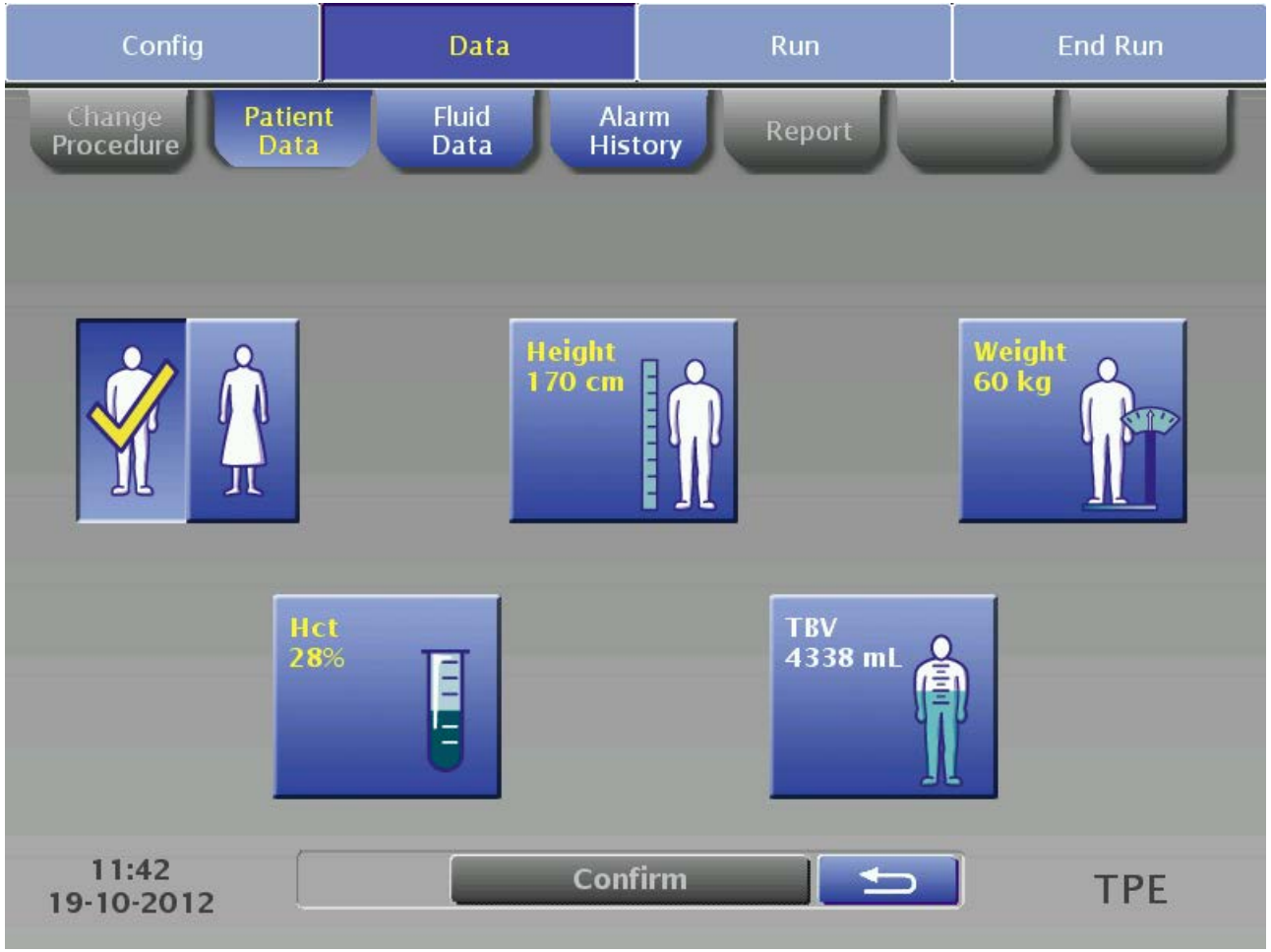
Making Changes

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

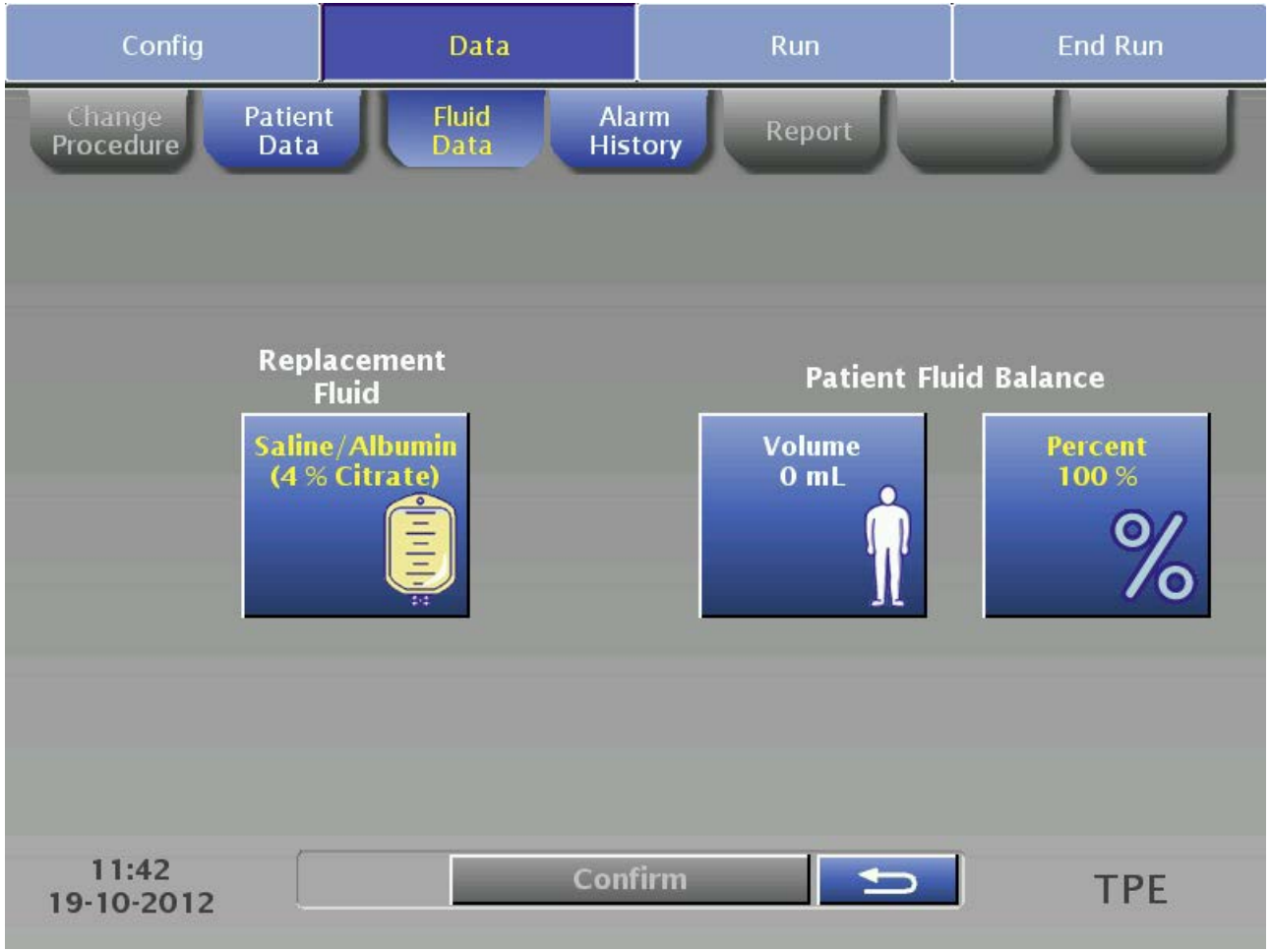
Data Menu

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

Patient Data

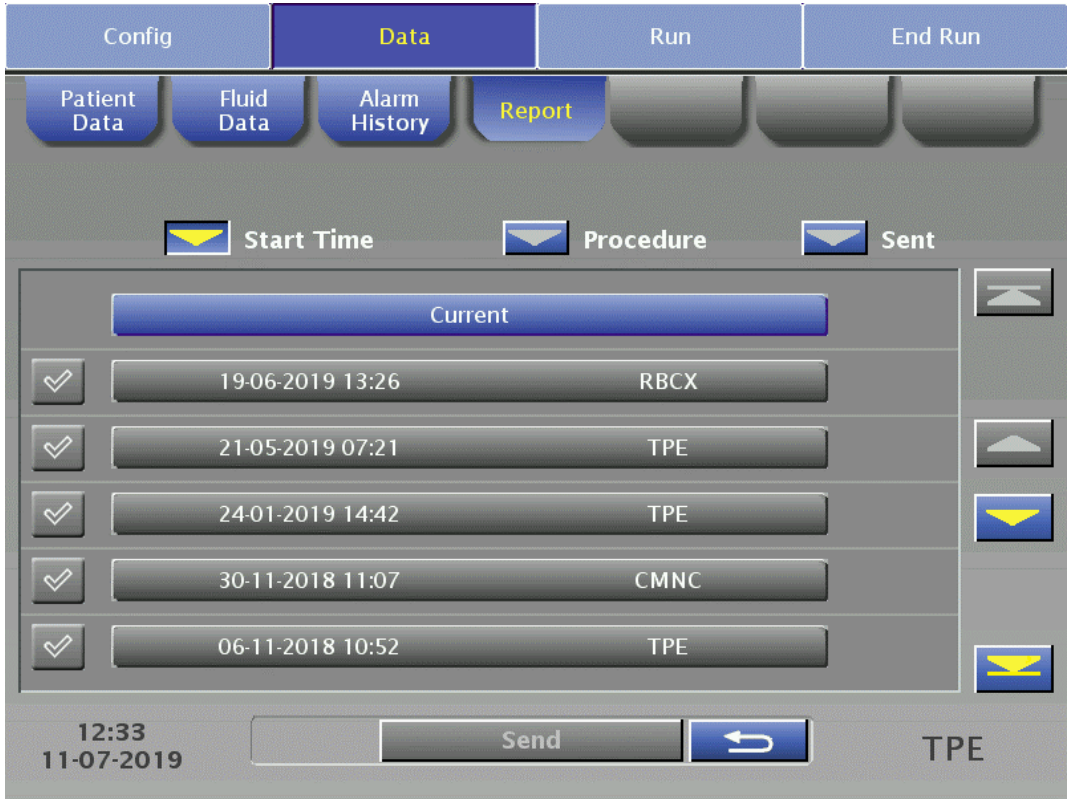


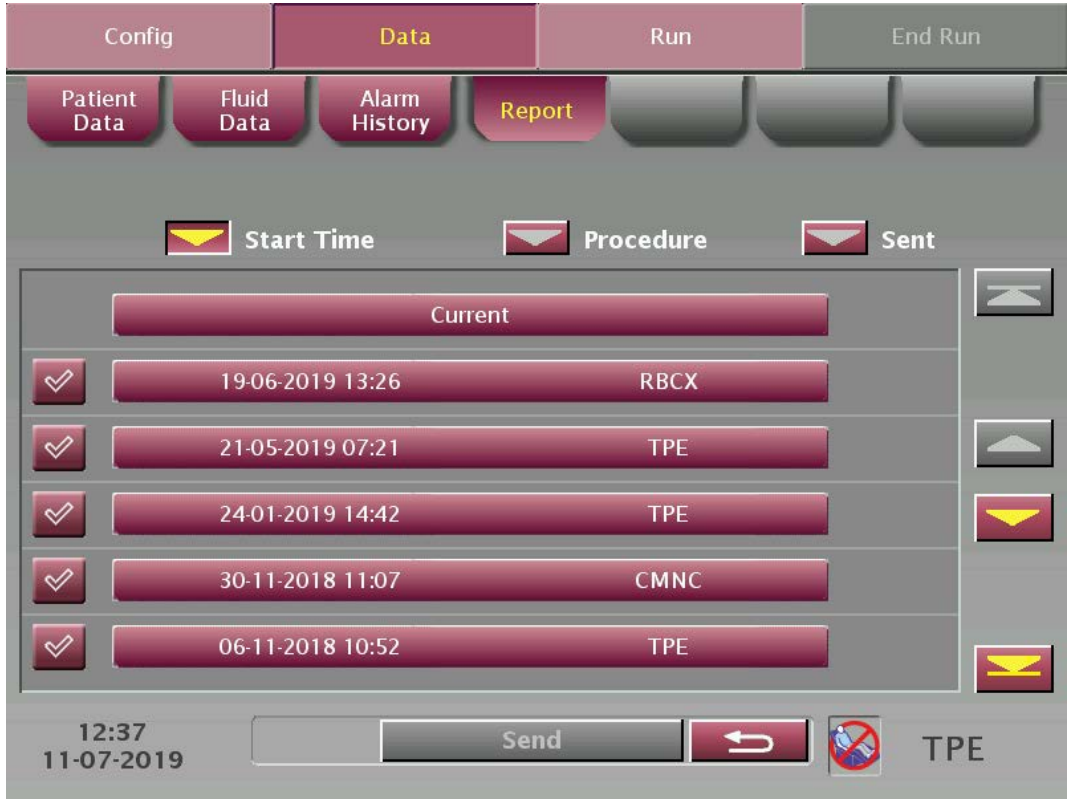
Fluid Data


Config
Data
Run
End Run
Change Procedure
Patient Data
Fluid Data
Alarm History
Report
Replacement Fluid
Saline/Albumin (4 % Citrate)
Patient Fluid Balance
Volume 0 mL
Percent 100 %
11:42
19-10-2012
Confirm
TPE

Alarm History

Report

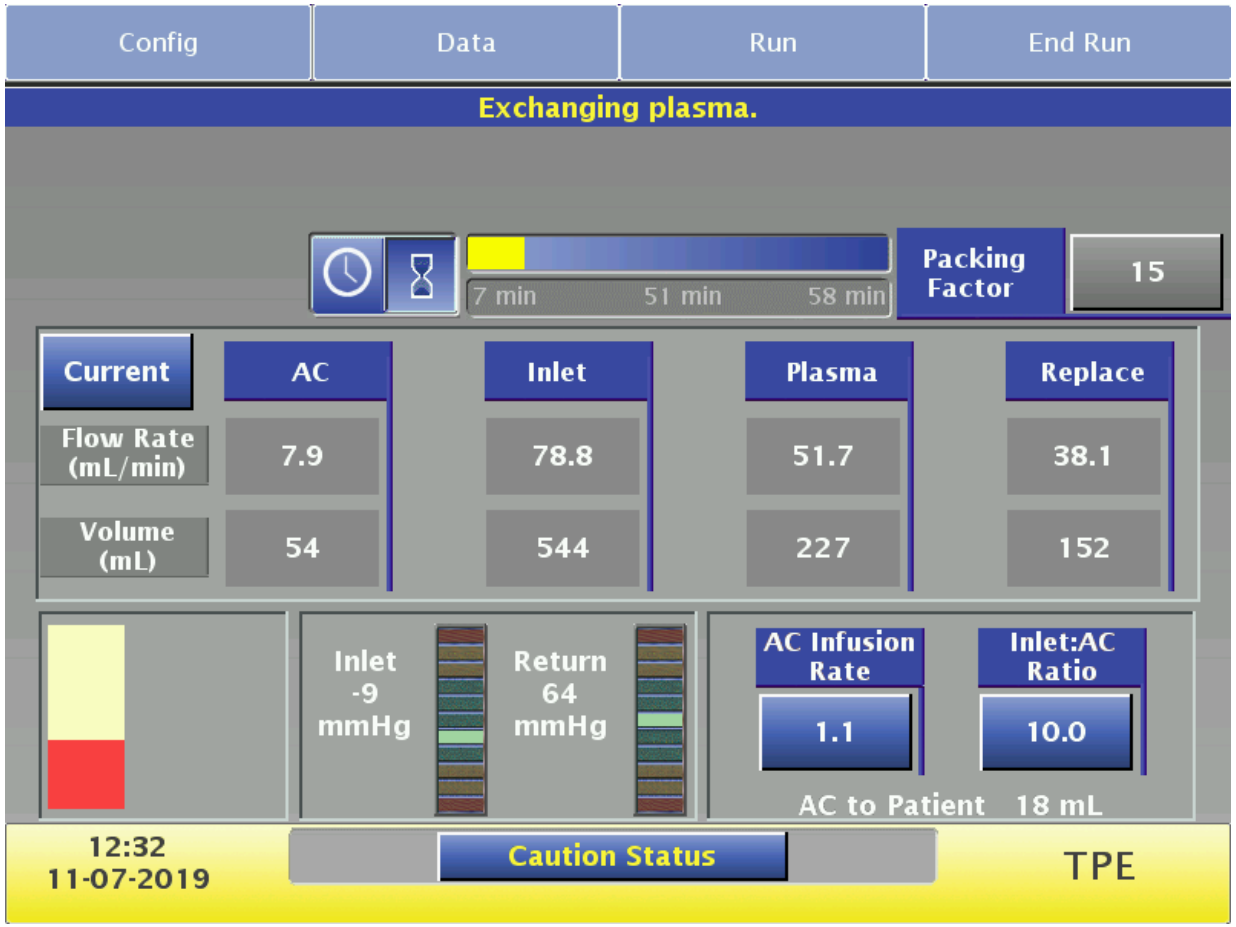

Config
Data
Run
End Run
Patient Data
Fluid Data
Alarm History
Report
Start Time
Procedure
Sent
Current
19-06-2019 13:26 RBCX
21-05-2019 07:21 TPE
24-01-2019 14:42 TPE
30-11-2018 11:07 CMNC
06-11-2018 10:52 TPE
12:33
11-07-2019
Send
TPE

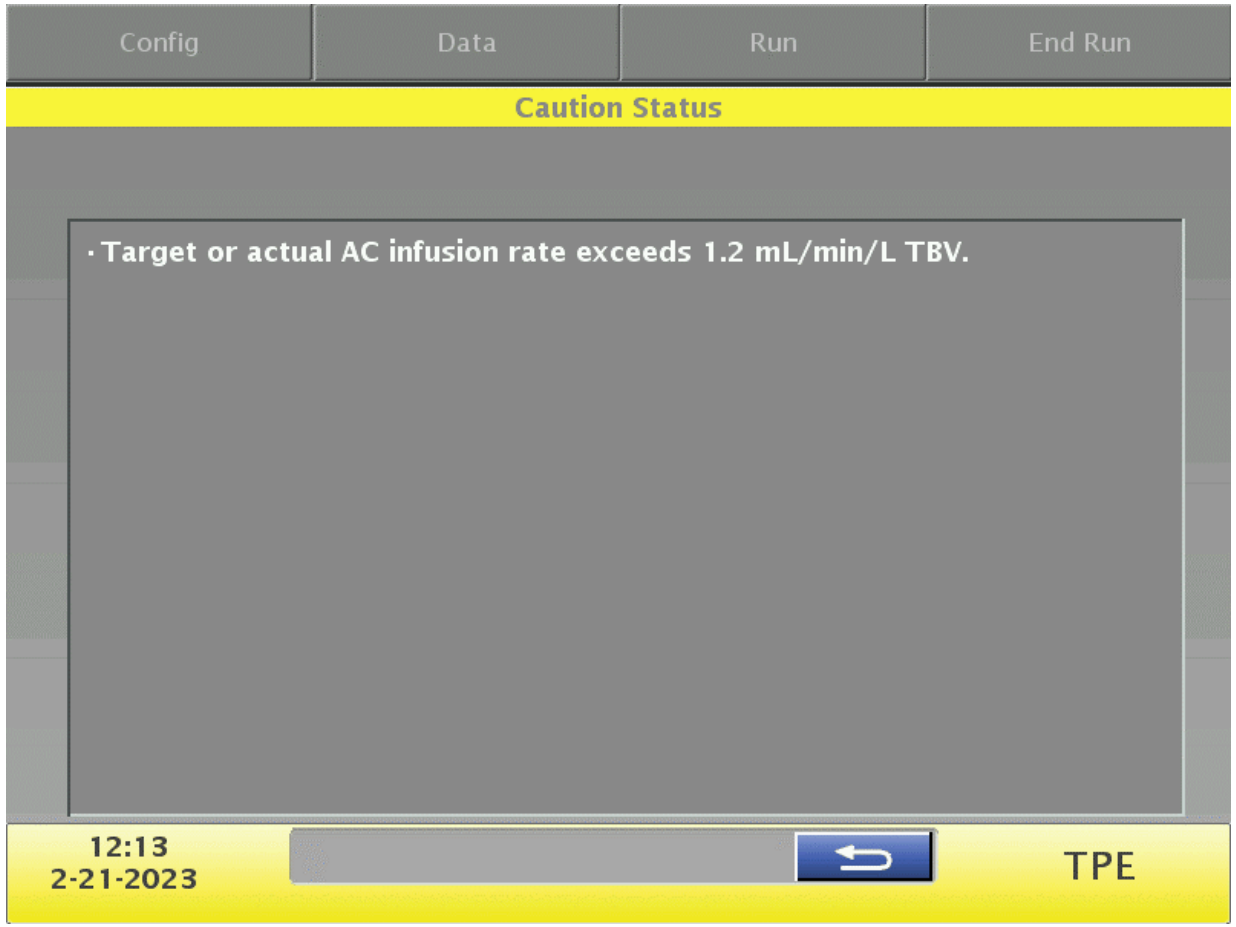

Config
Data
Run
End Run
Patient Data
Fluid Data
Alarm History
Report
Start Time
Procedure
Sent
Current
19-06-2019 13:26 RBCX
21-05-2019 07:21 TPE
24-01-2019 14:42 TPE
30-11-2018 11:07 CMNC
06-11-2018 10:52 TPE
12:37
11-07-2019
Send
TPE

Run Menu

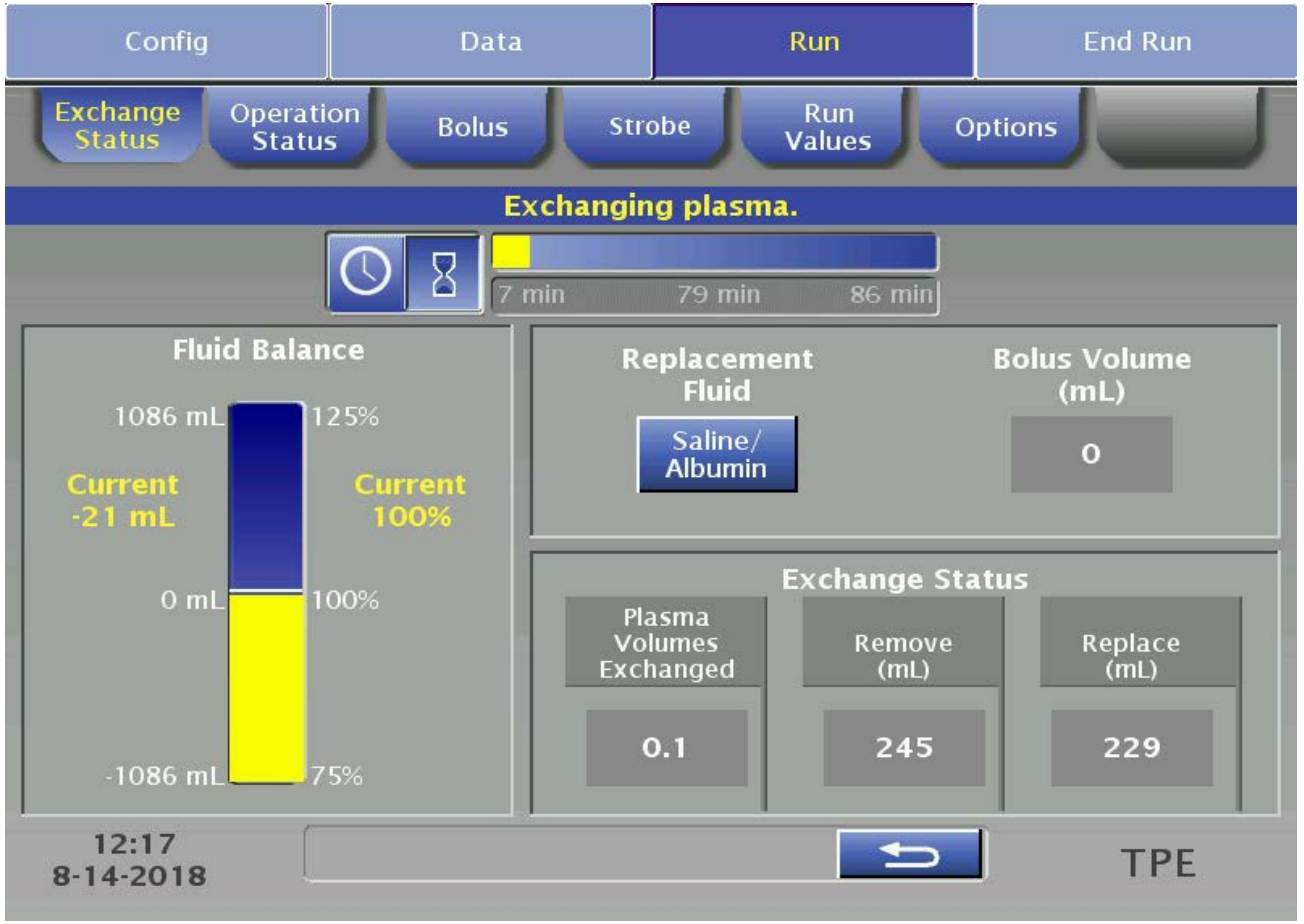
- Main Run – Caution Status
- Exchange Status
- Operation Status
- Bolus
- Strobe
- Run Values
- Options

Main Run – Caution Status

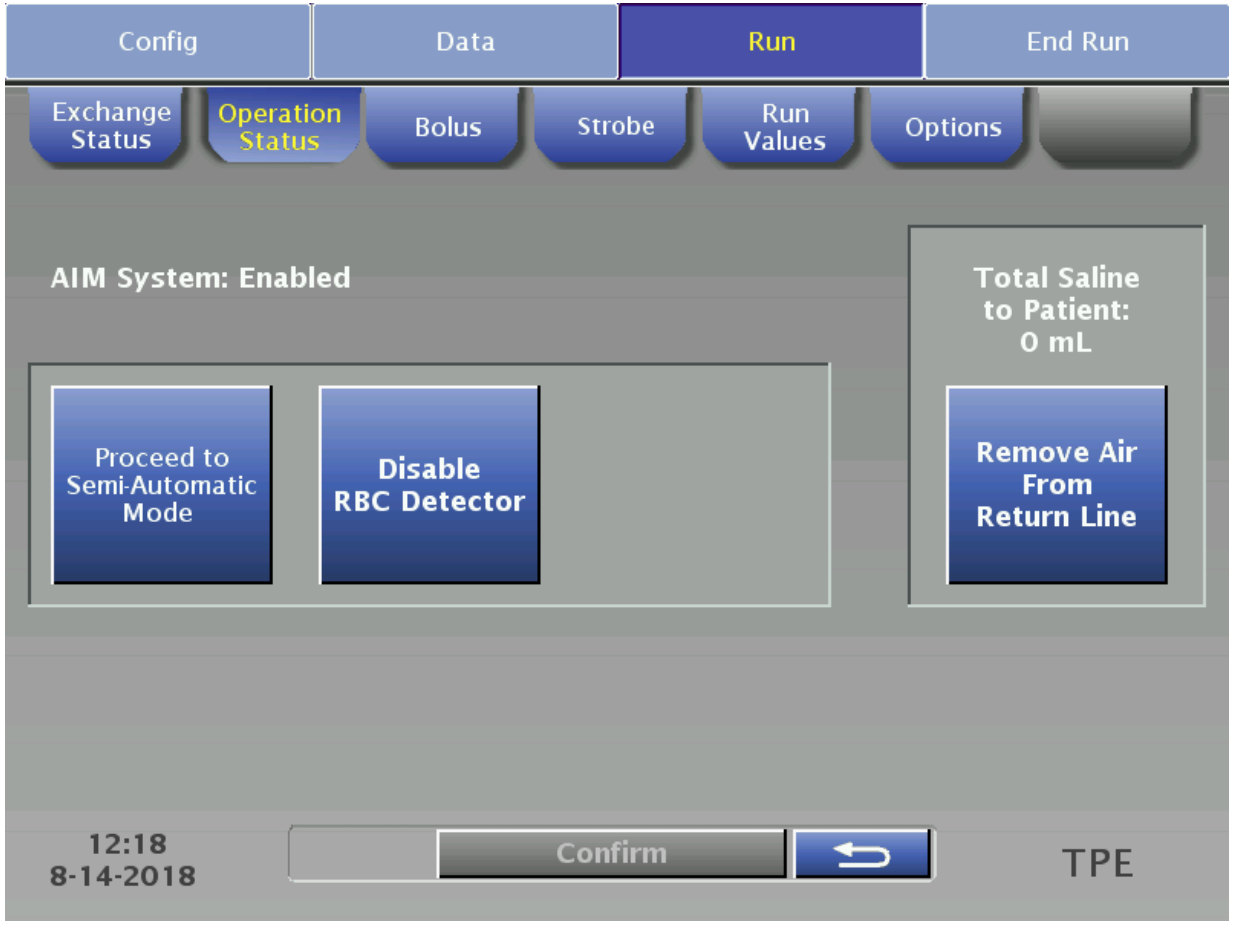




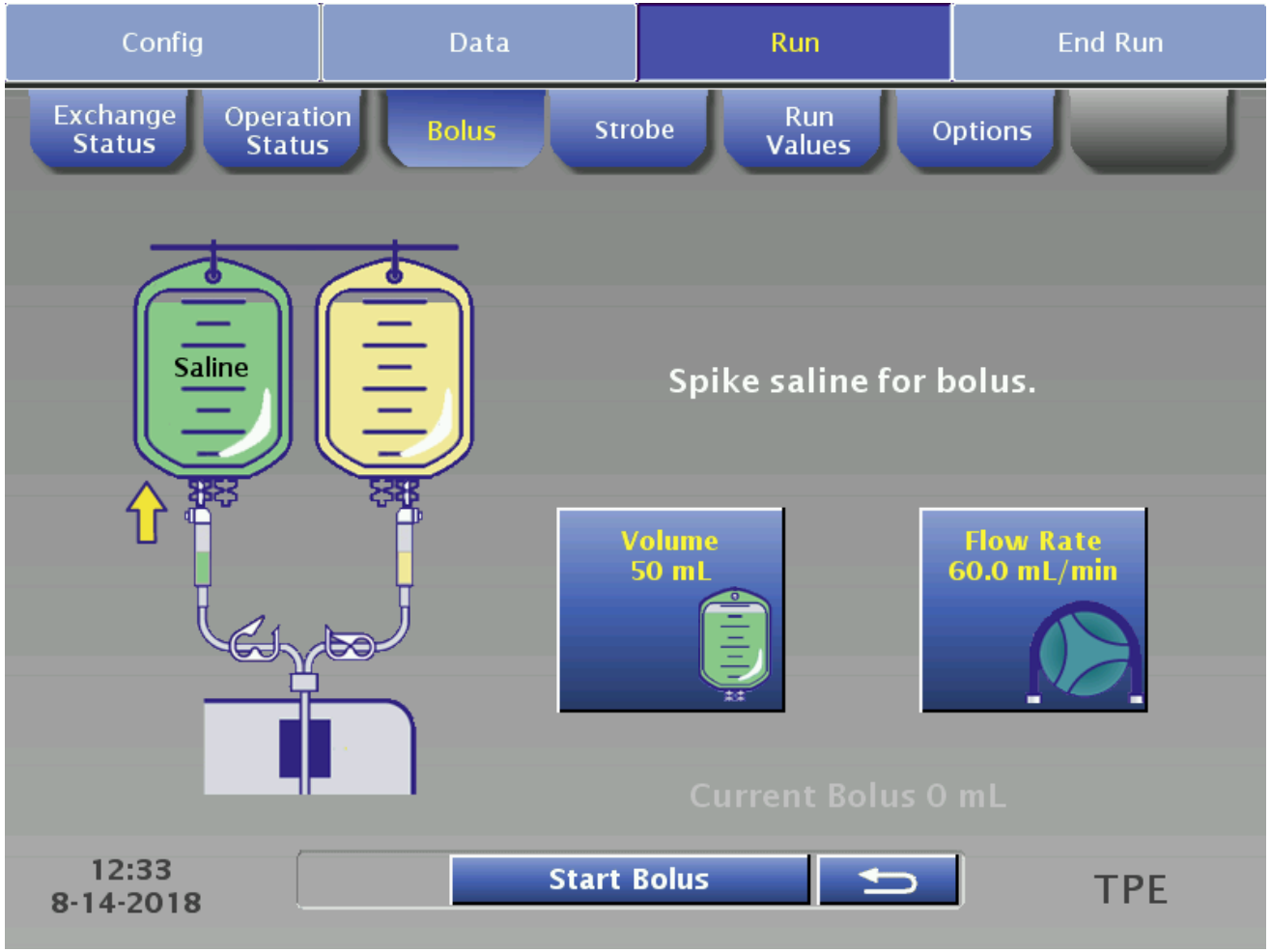
Exchange Status



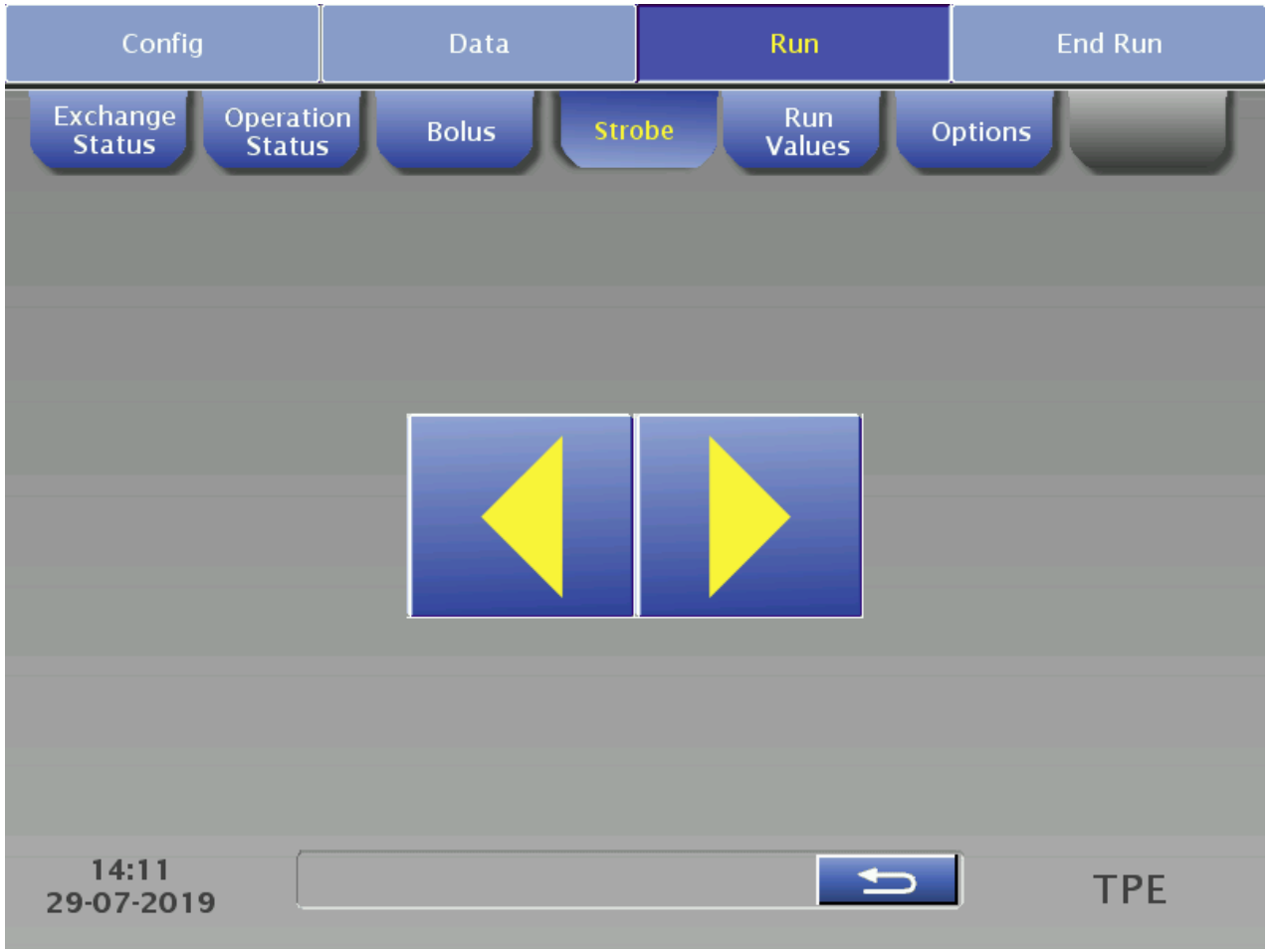
Operation Status



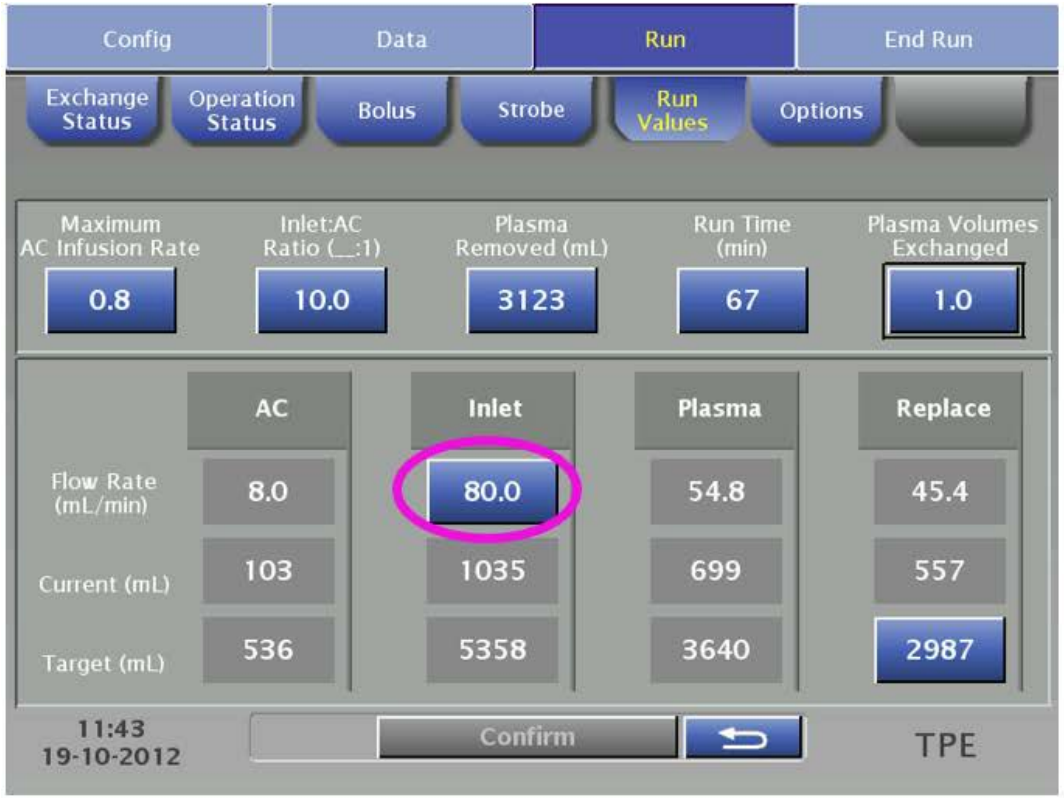
Bolus


Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
Saline
Spike saline for bolus.
Volume 50 mL
Flow Rate 60.0 mL/min
Current Bolus 0 mL
12:33
8-14-2018
Start Bolus
TPE

Strobe

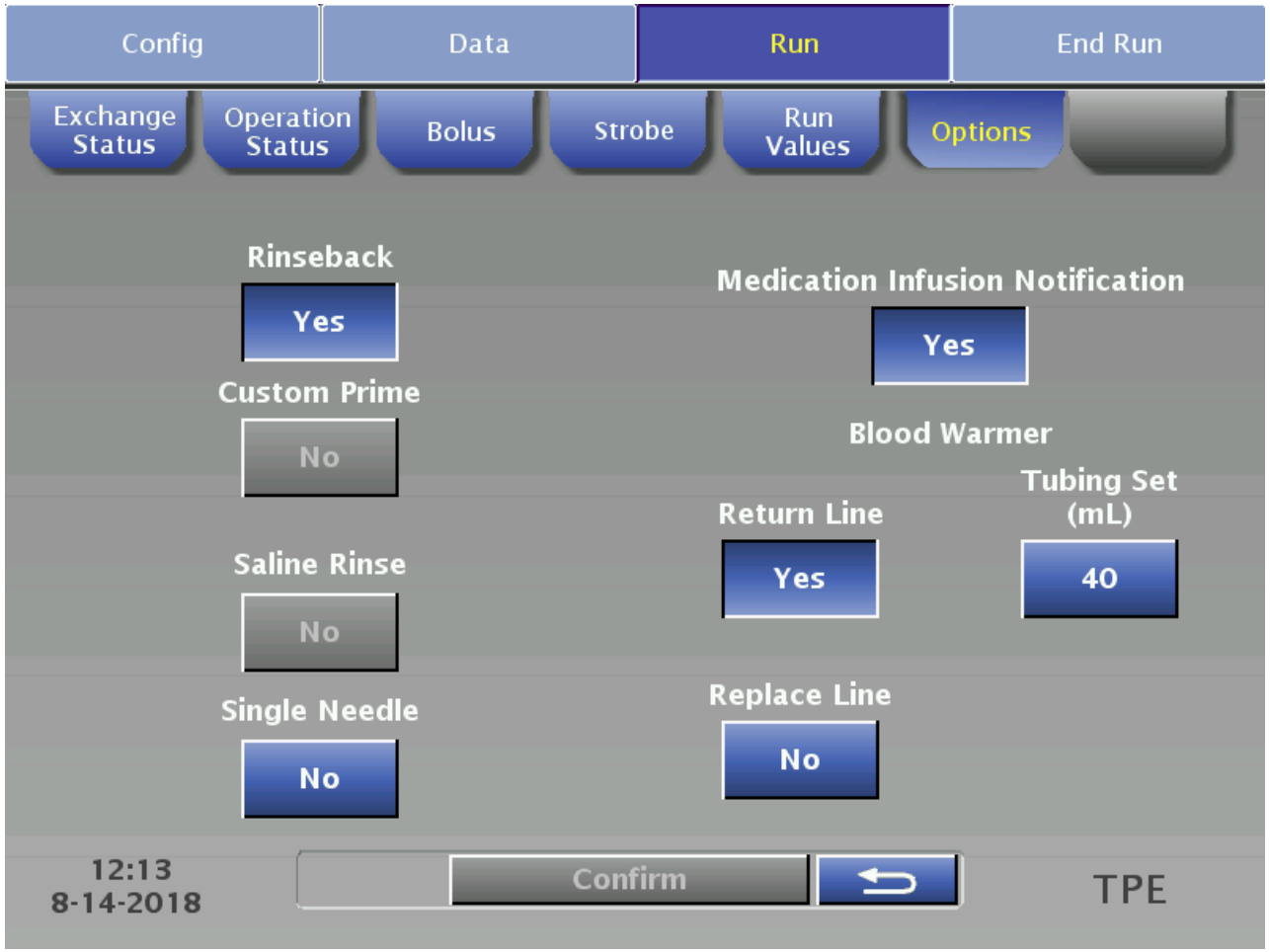

Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
14:11
29-07-2019
TPE

Run Values


Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
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


Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
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

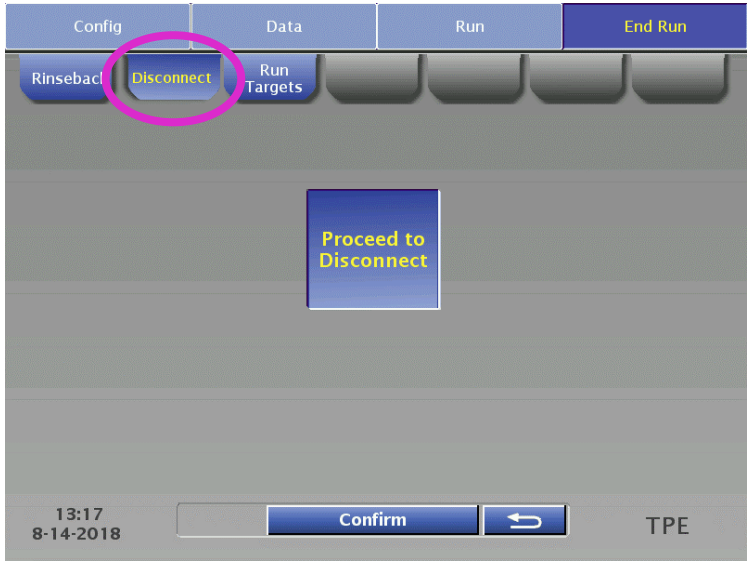
Options


Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
Rinseback
Yes
Custom Prime
No
Saline Rinse
No
Single Needle
No
Medication Infusion Notification
Yes
Blood Warmer
Return Line
Yes
Tubing Set (mL)
40
Replace Line
No
12:13
8-14-2018
Confirm
TPE

End Run Menu

- Rinseback, Disconnect, Run Targets

Rinseback, Disconnect, Run Targets



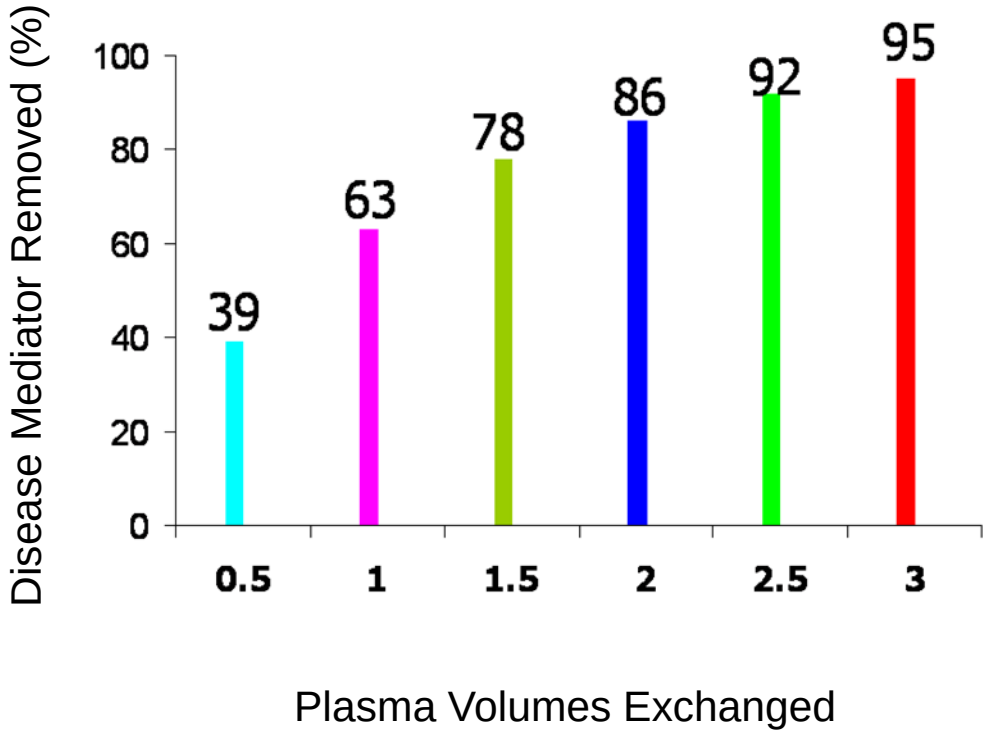
Questions?

Optimization

- Plasma Volumes Exchanged
- Fluid Balance
- AC to Patient

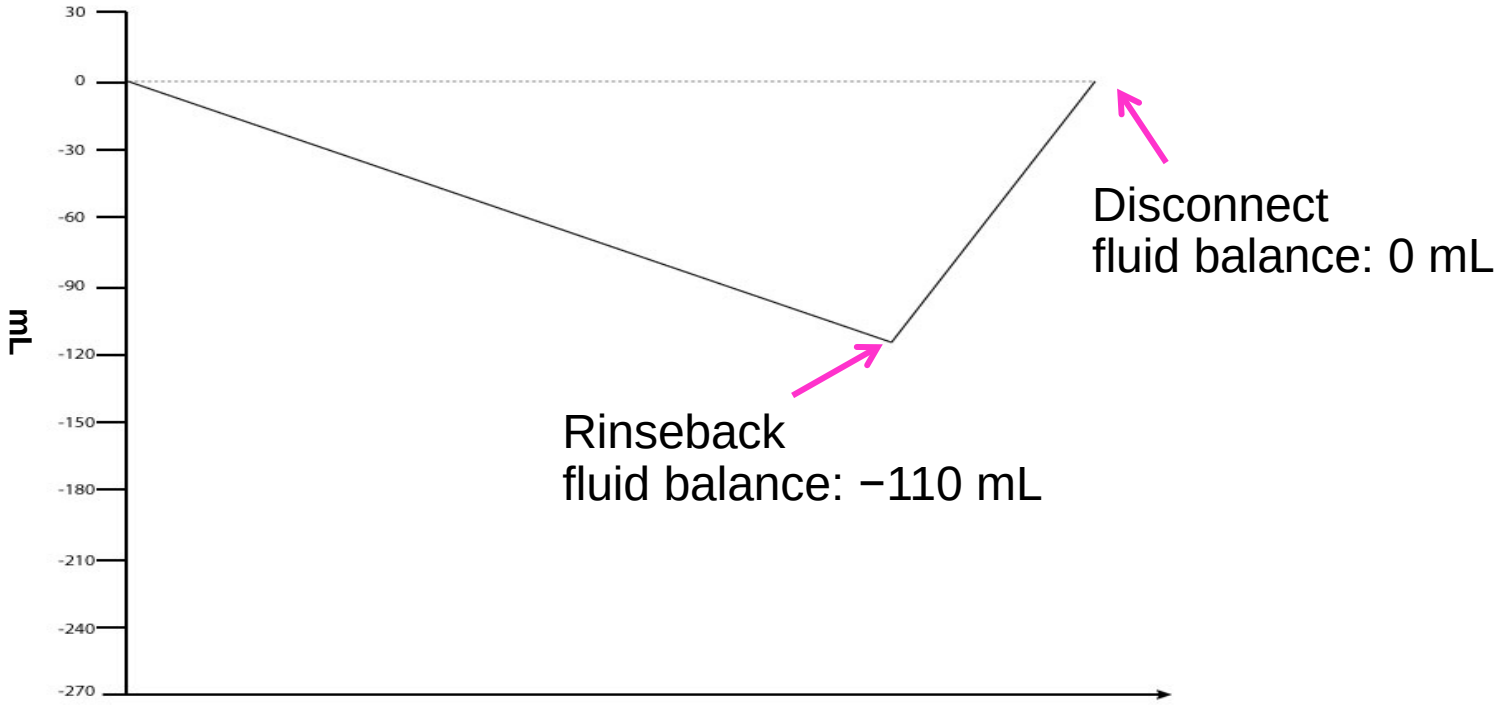
Plasma Volumes Exchanged

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



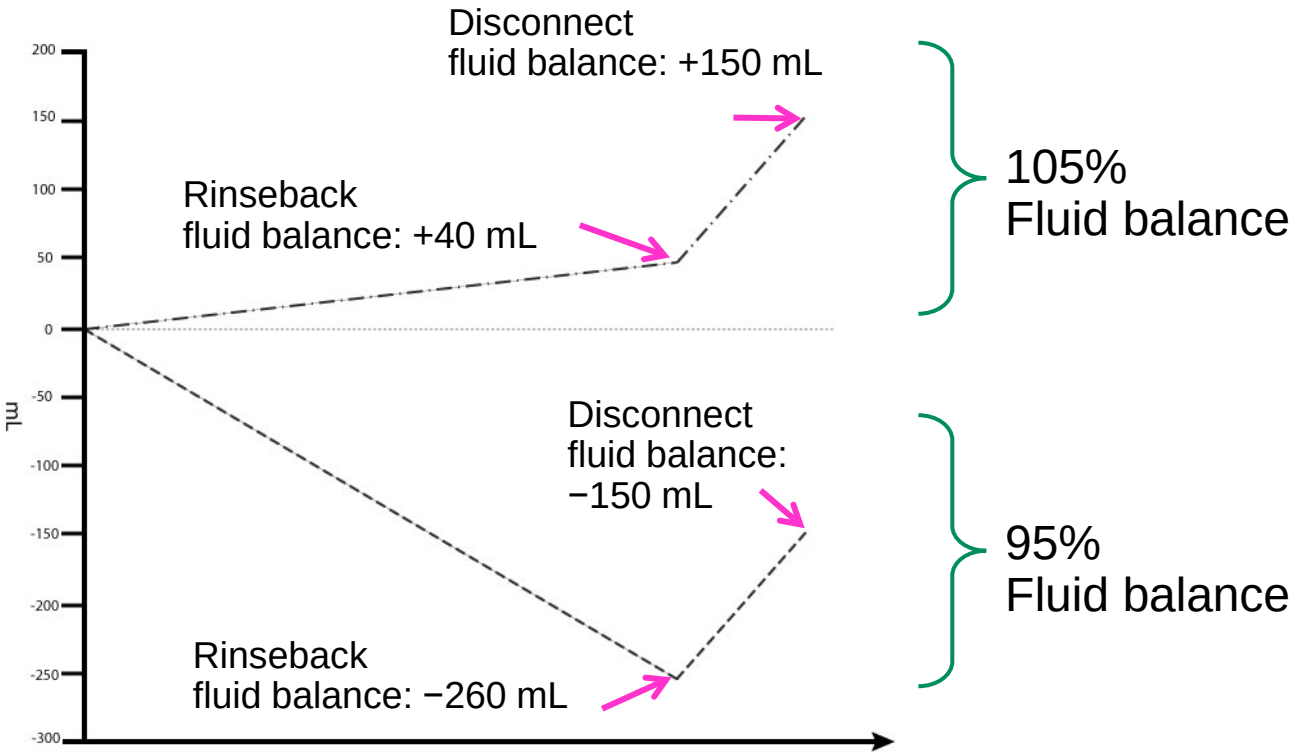
Fluid Balance

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 BCT does not recommend inlet:AC ratios above 15.			

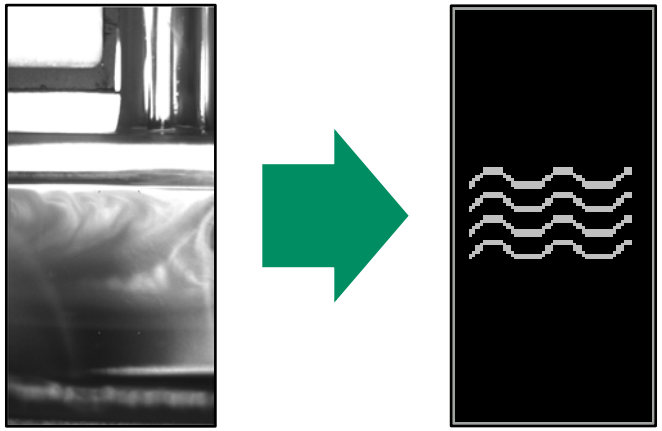
Questions?

Troubleshooting

- Inlet and Return Access Alarms
- Turbulence
- Semi-Automatic Mode
- High Interface
- Hemolysis
- Clumping

Inlet and Return Access Alarms

Turbulence



1. AIM image
2. Algorithm control icon

- Look through the view port to verify if turbulence is present in the connector.

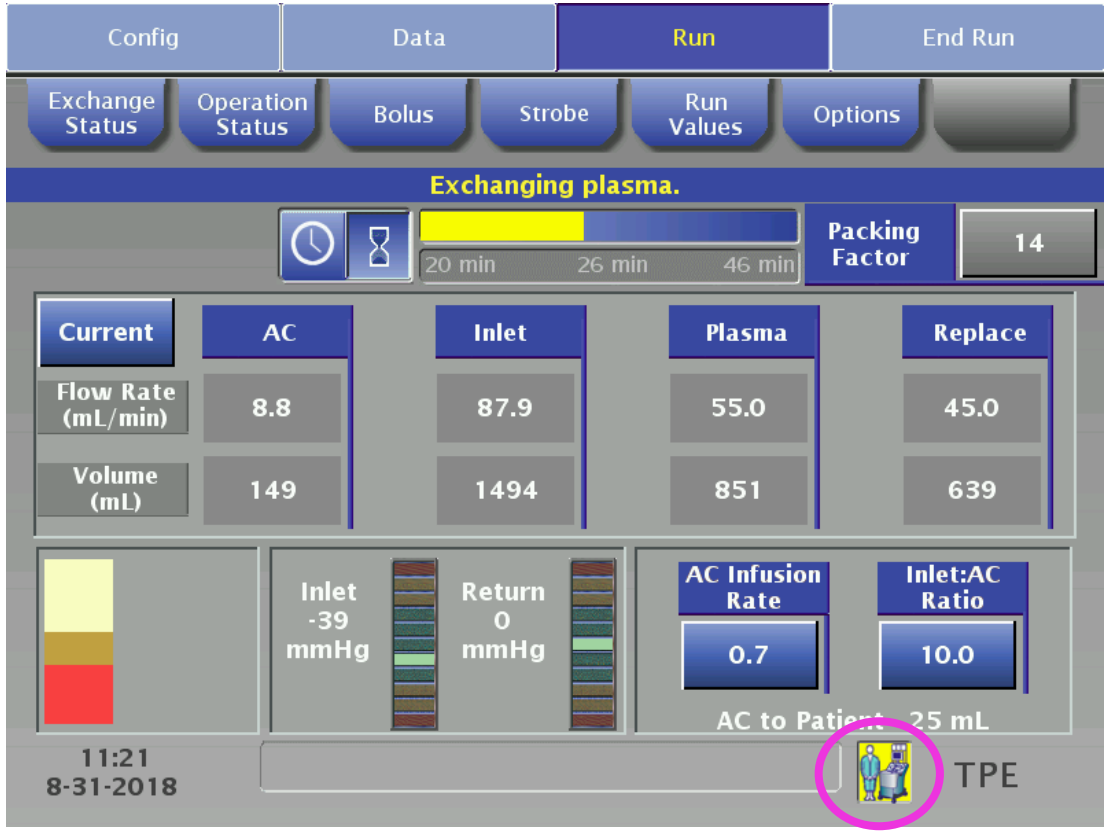
Turbulence may be caused by:

- 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

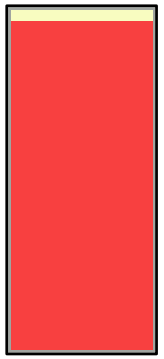
Semi-Automatic Mode

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



High Interface

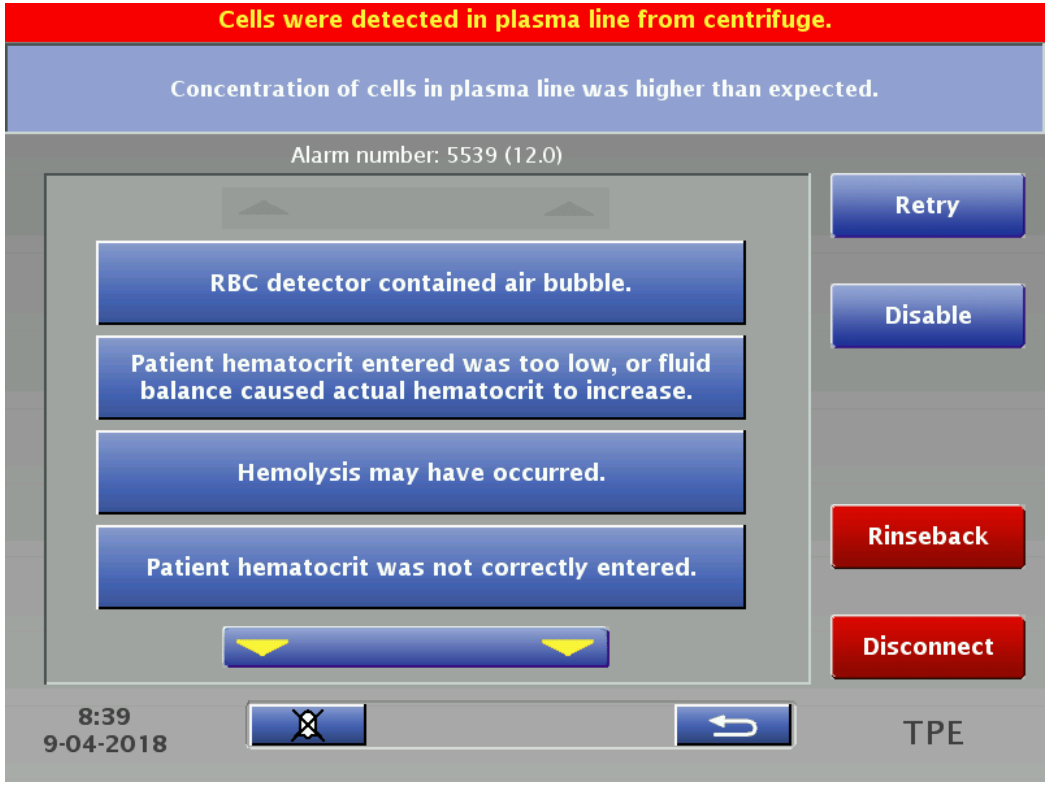
"AIM system detected RBC interface near top of channel"



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

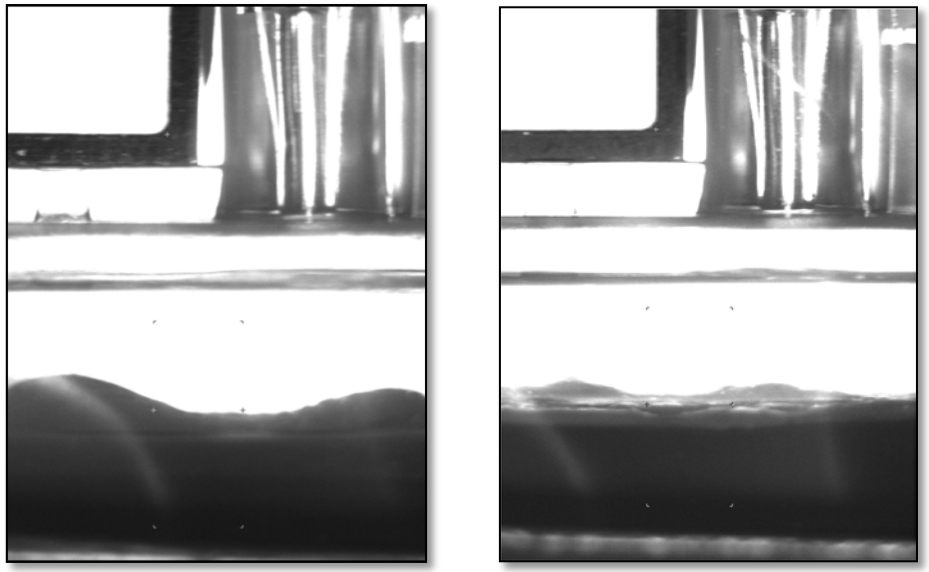
Interface is near the top of the connector and the entered Hct is incorrect.	Lower the interface by increasing the entered Hct by 3% up to 3 times to avoid platelet loss.
Interface is near the top of the connector and the entered Hct is correct.	Touch **Retry** to resume the procedure.

Hemolysis



- Certain patient conditions may cause hemolysis.
- If hemolysis related to the patient's condition is suspected, verify the presence of hemolysis before 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?

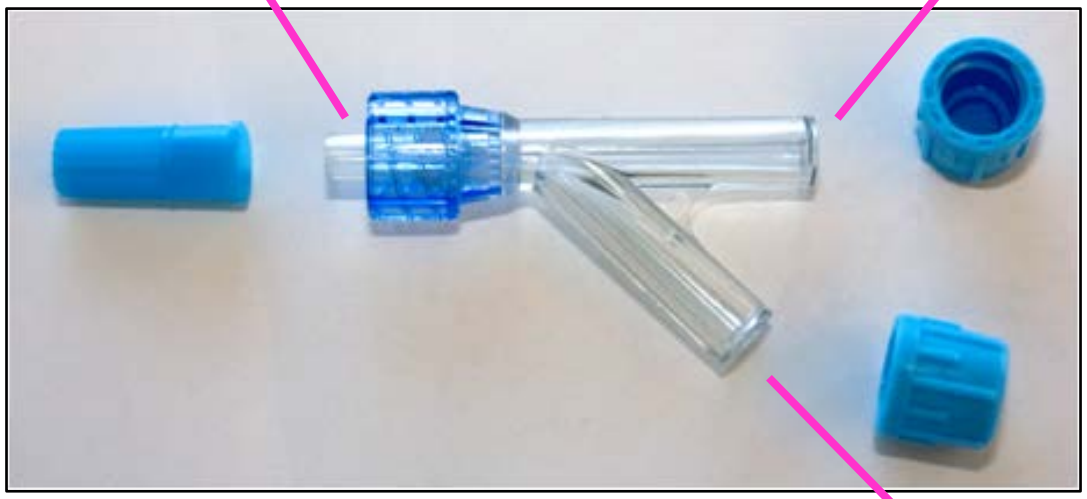
Single-Needle Access

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

Single-Needle Connector

Male luer connection
to patient

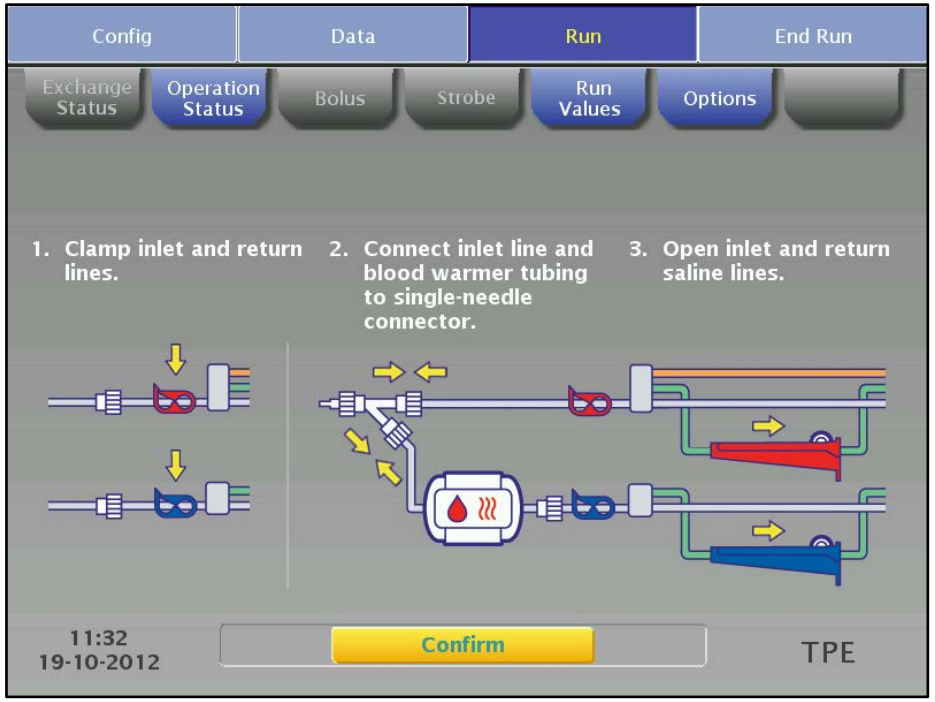
Female luer
connection to inlet line



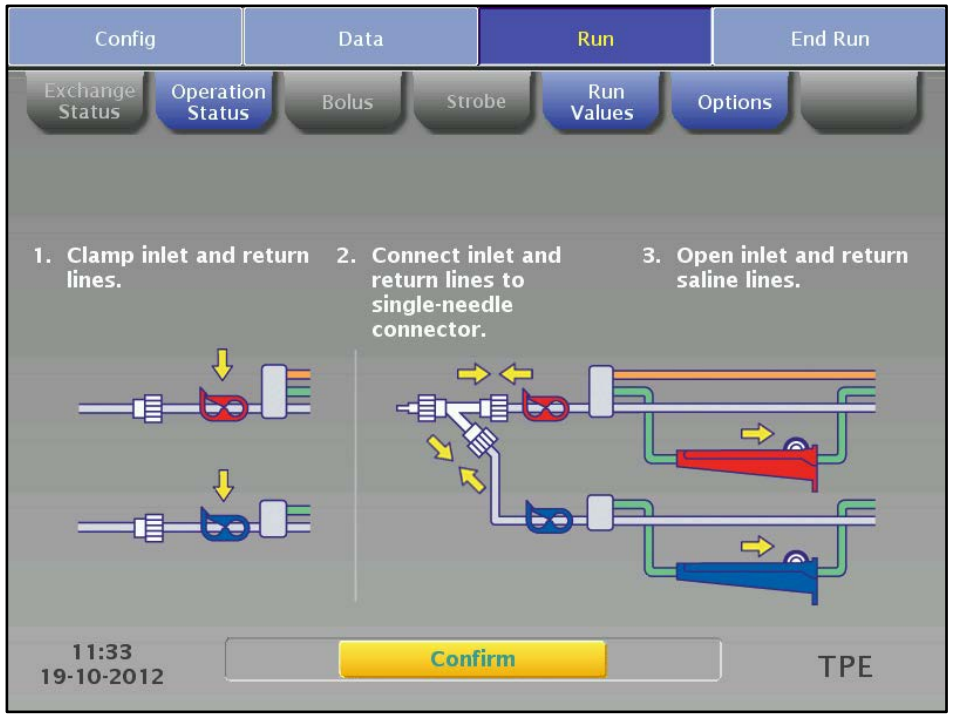
Female luer connection to
return line

Convert to Single-Needle Access

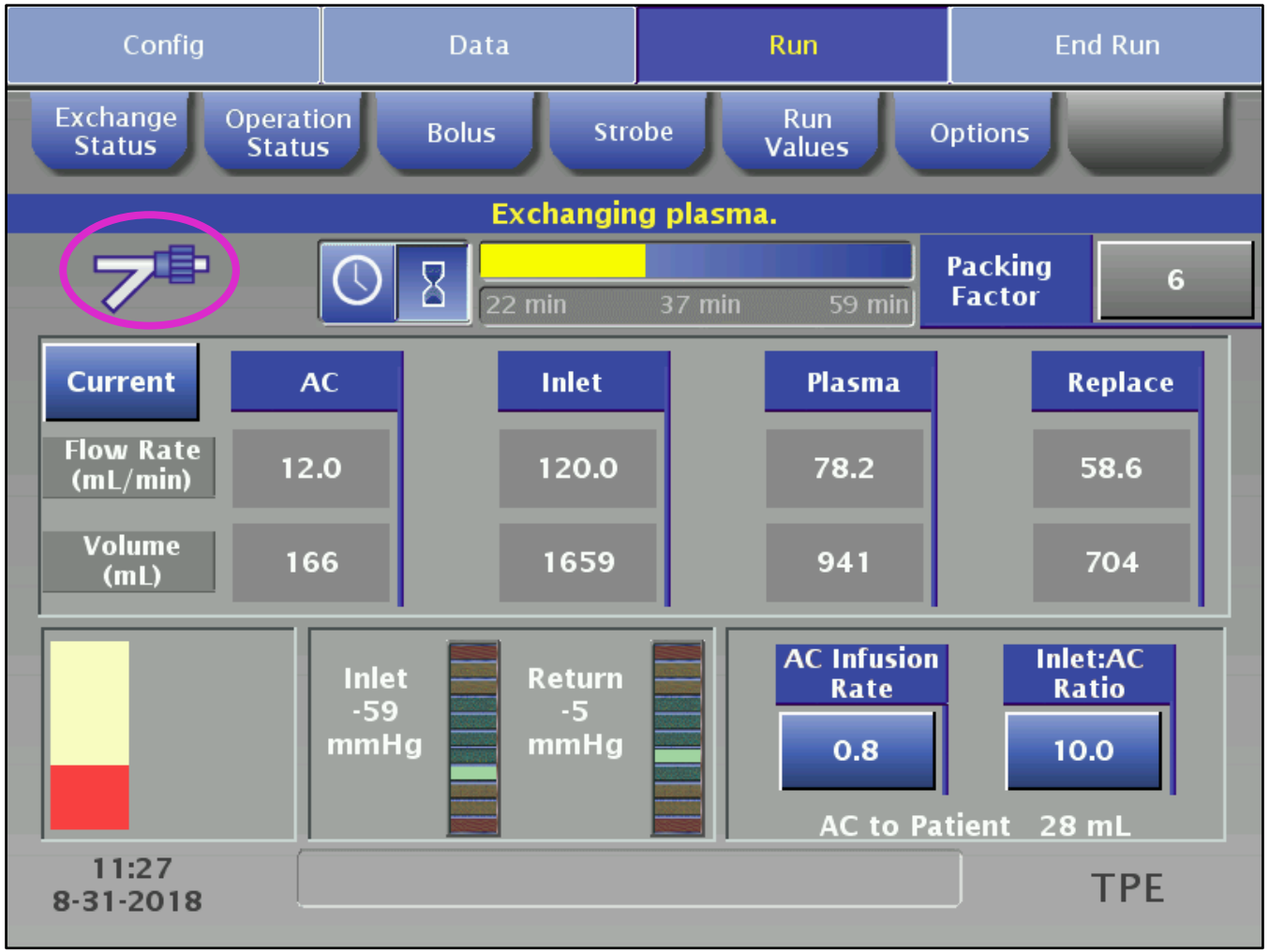
- With a blood warmer on the return line



- Without a blood warmer on the return line

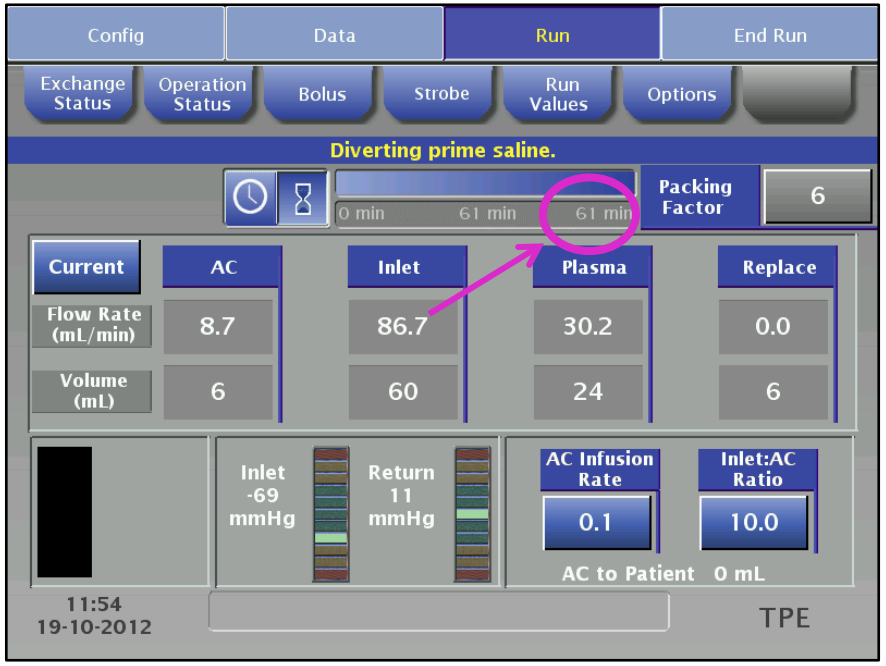


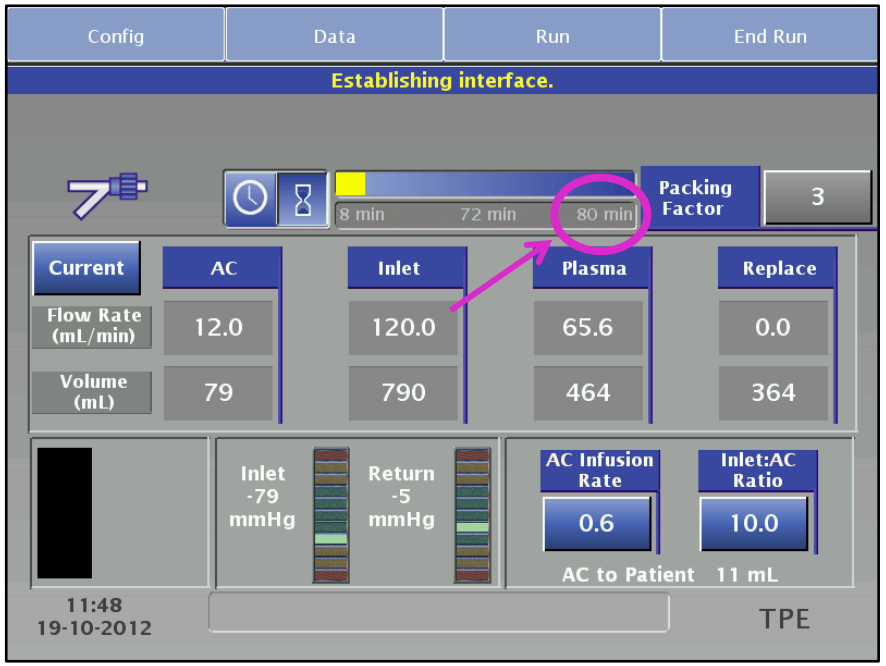
Convert to Single-Needle Access



Optimization

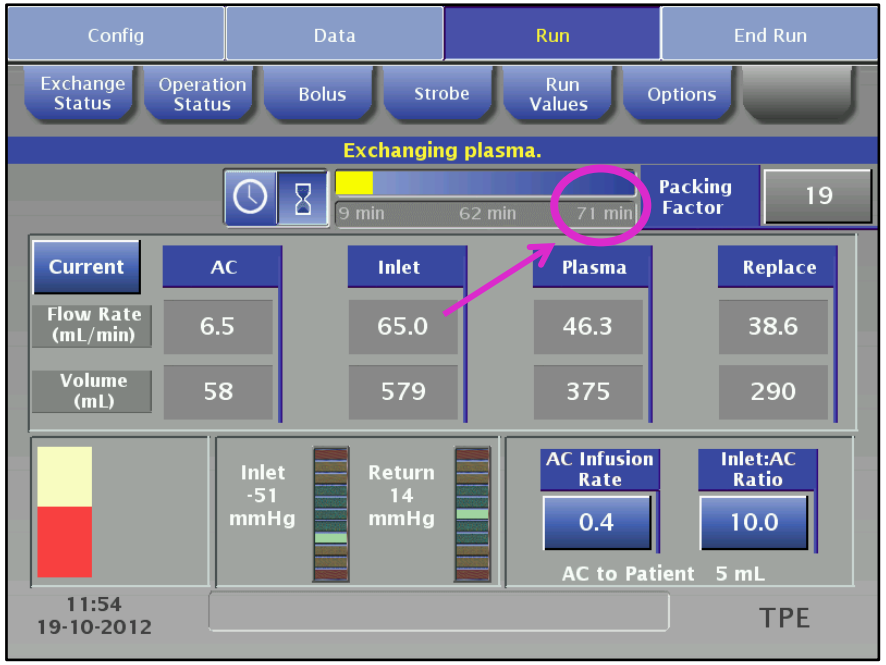
- Inlet pump flow rate is set by the system.
- Procedure continues at a new inlet pump flow rate set by the system.

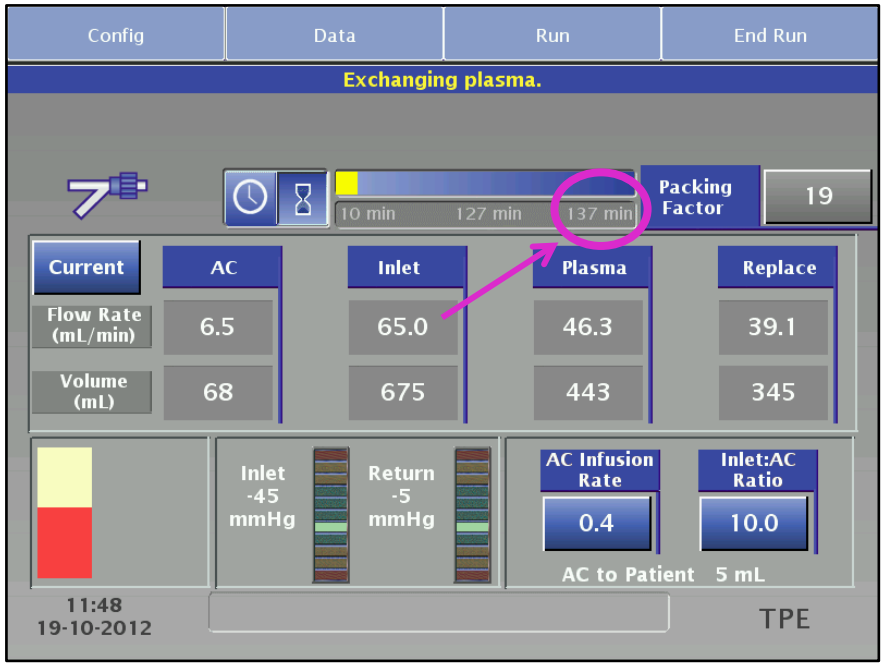




Optimization

- Inlet pump flow rate is set by the operator.
- System will continue the run at the same inlet pump flow rate.





Questions?

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 in or 30 cm
  - Weight: 5 lb or 2 kg
  - TBV: 300 mL
    (The system will not calculate the TBV for weight < 25 kg.)
- Inlet pump flow rate
  - The allowable operator entered minimum inlet pump flow rate is 5 mL/min.
  - System may set up an inlet pump flow rate of less than 5 mL/min and the operator can confirm it.

AC Management

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

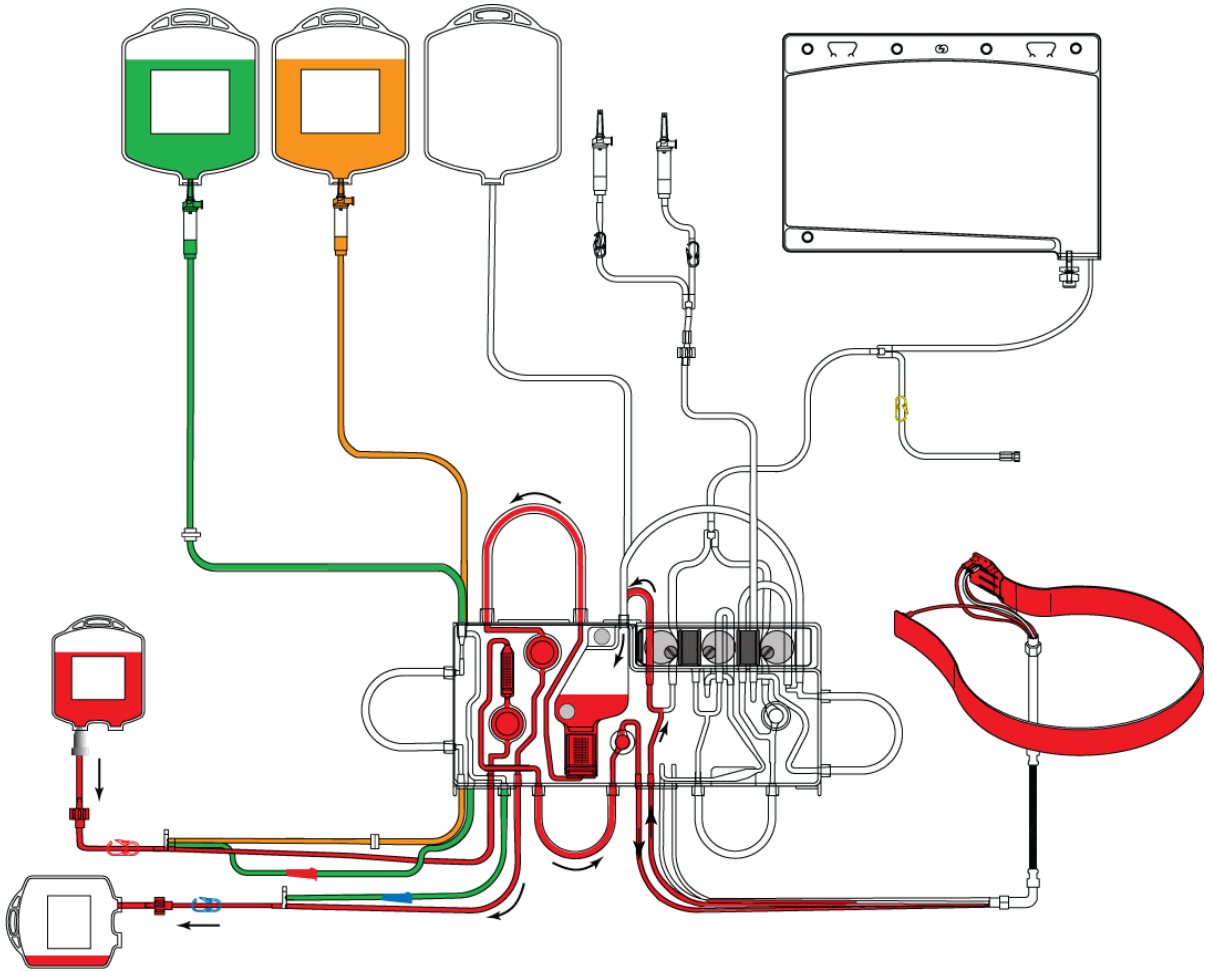
Configured AC infusion rate 0.8 mL/min/L TBV and inlet:AC ratio 10:1				
Patient TBV (mL)	300	400	500	600
Initial inlet pump flow rate	2.7	3.5	4.3	5.2
Increased AC infusion rate	1.5	1.2	1.0	0.9
Inlet pump flow rate	5.0	5.3	5.4	5.8

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

Custom Prime – RBC



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 immediately after custom prime.

Questions?

Thank You

TerumoBCT.com