

Red Blood Cell Exchange (V12 RBCX) Rx Only 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
 - 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 RBCX procedures using the Spectra Optia system:

- Discuss the principles of the procedure.
- Enter and discuss the data needed to run the procedure.
- Discuss how the data you entered affects the procedure and run targets.
- Understand the effect of the replacement fluid types.
- View and change data on the run values screen.
- Make changes to data on the data, run, and end run menu screens.
- Troubleshoot issues that may arise.
- Describe using the single-needle option with RBCX procedures.
- Understand the issues related to pediatric/low total blood volume (TBV) patients.

Presentation Overview

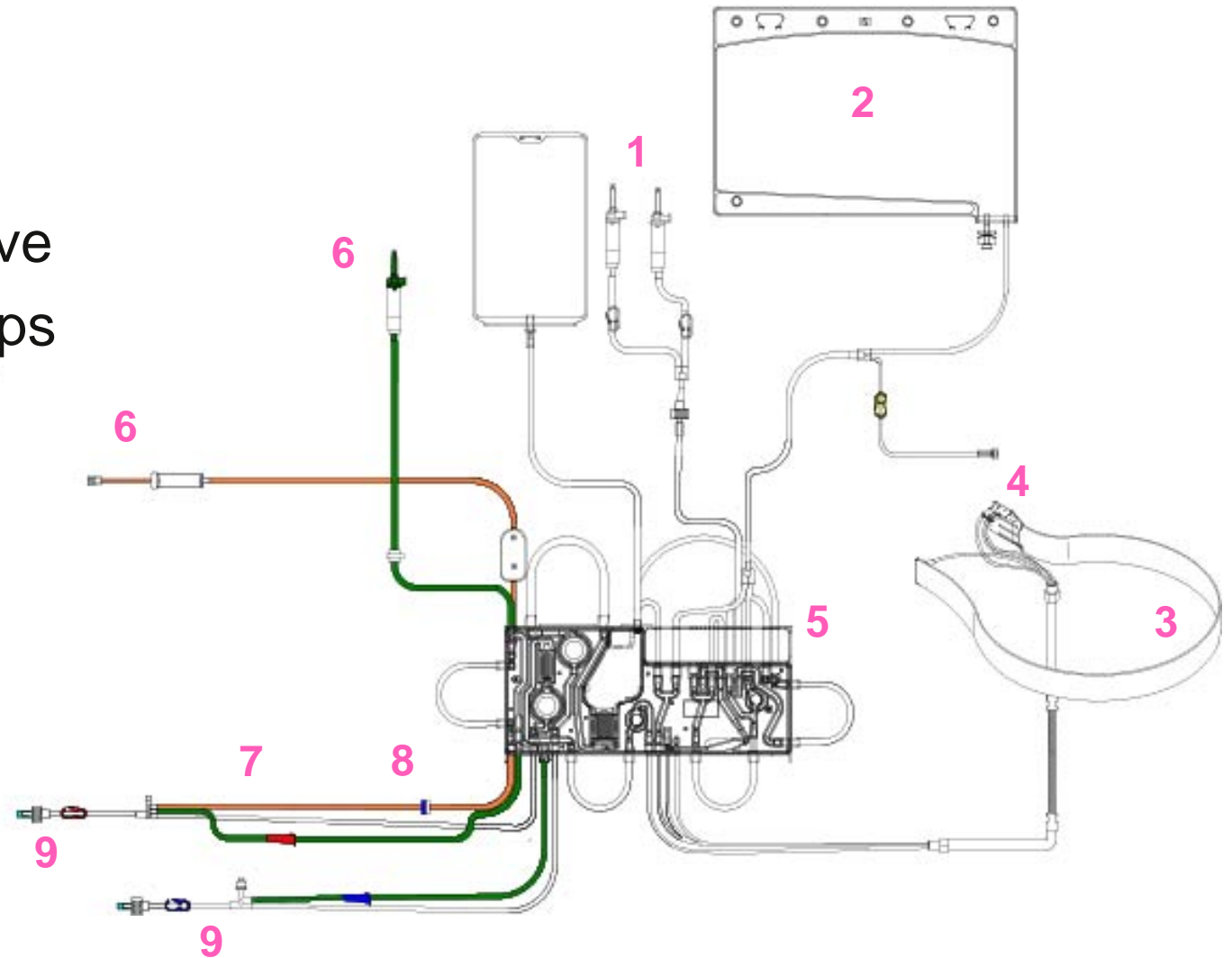
- Introduction
- Preparing to Perform the Procedure
- Exchange
- Depletion
- Depletion/Exchange
- Making Changes
- Optimization
- Troubleshooting
- Single-Needle
- Pediatric/Low-TBV Patients

Introduction

- Exchange Set
- Basic Principles of RBCX
 - Flow Path
 - Channel
- Connector
- Single-Needle Procedure

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

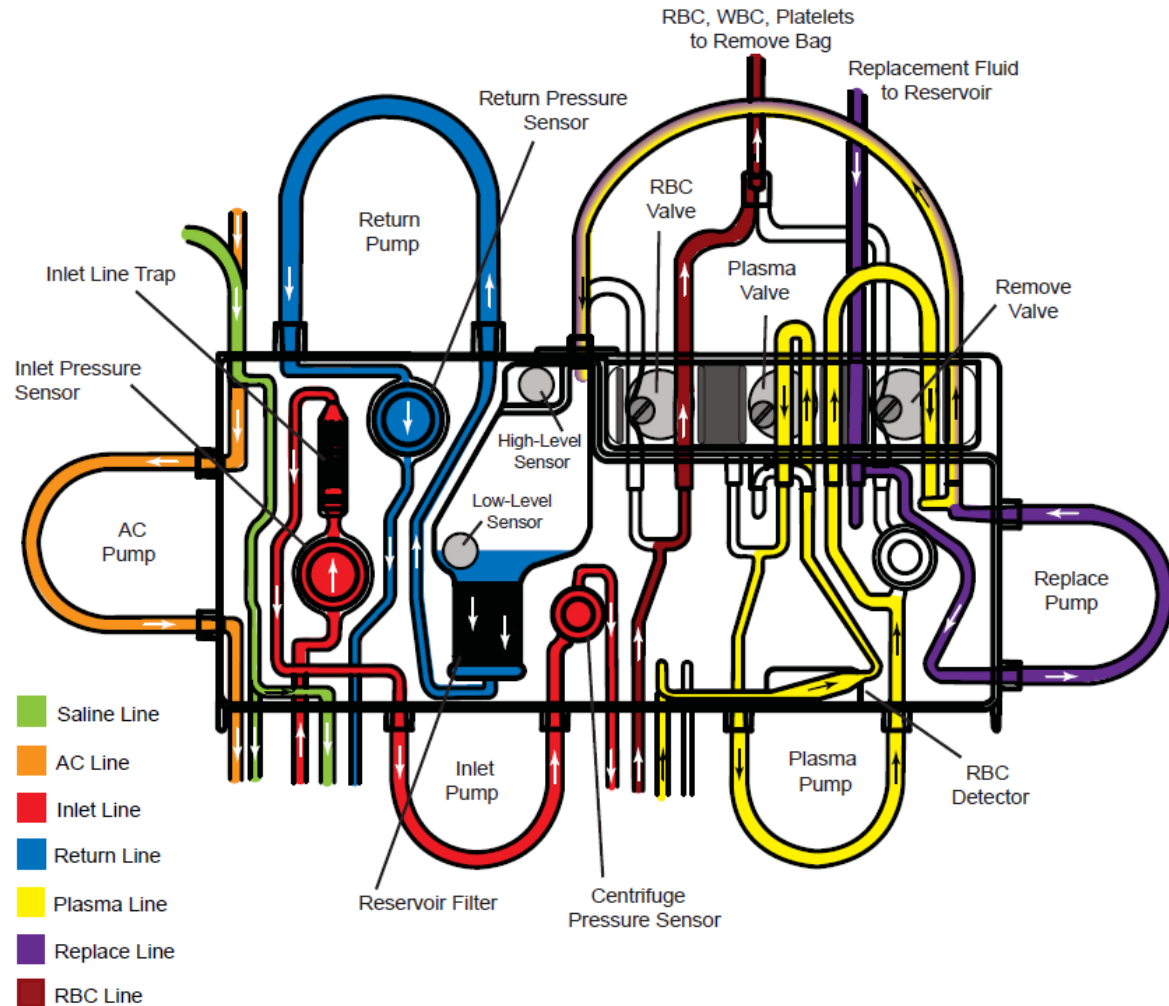


*Correct Connect availability is dependent upon regulatory approval

Basic Principles of RBCX

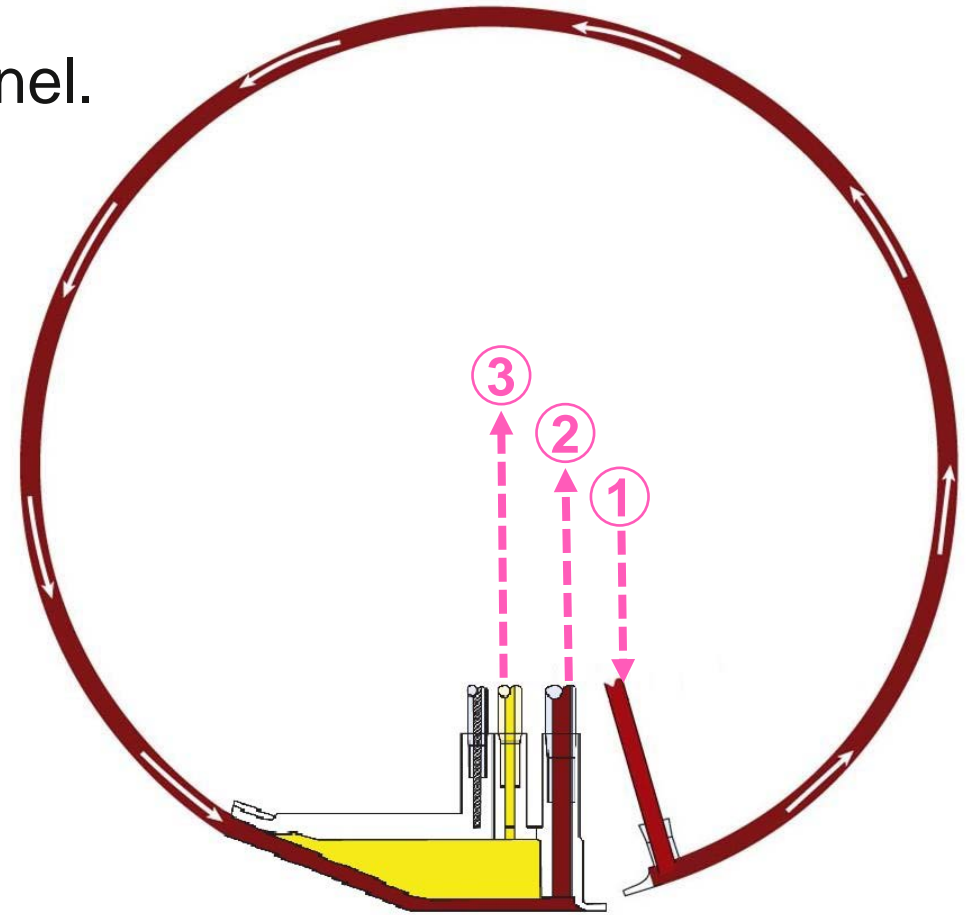
- Indications for RBCX
- Procedure goals:
 - Remove defective or excessive red blood cells (RBC)
 - Infuse replacement fluid
 - Change patient's hematocrit (Hct) (increase or decrease)
 - Maintain fluid balance
- Replacement fluids

Basic Principles of RBCX – Flow Path



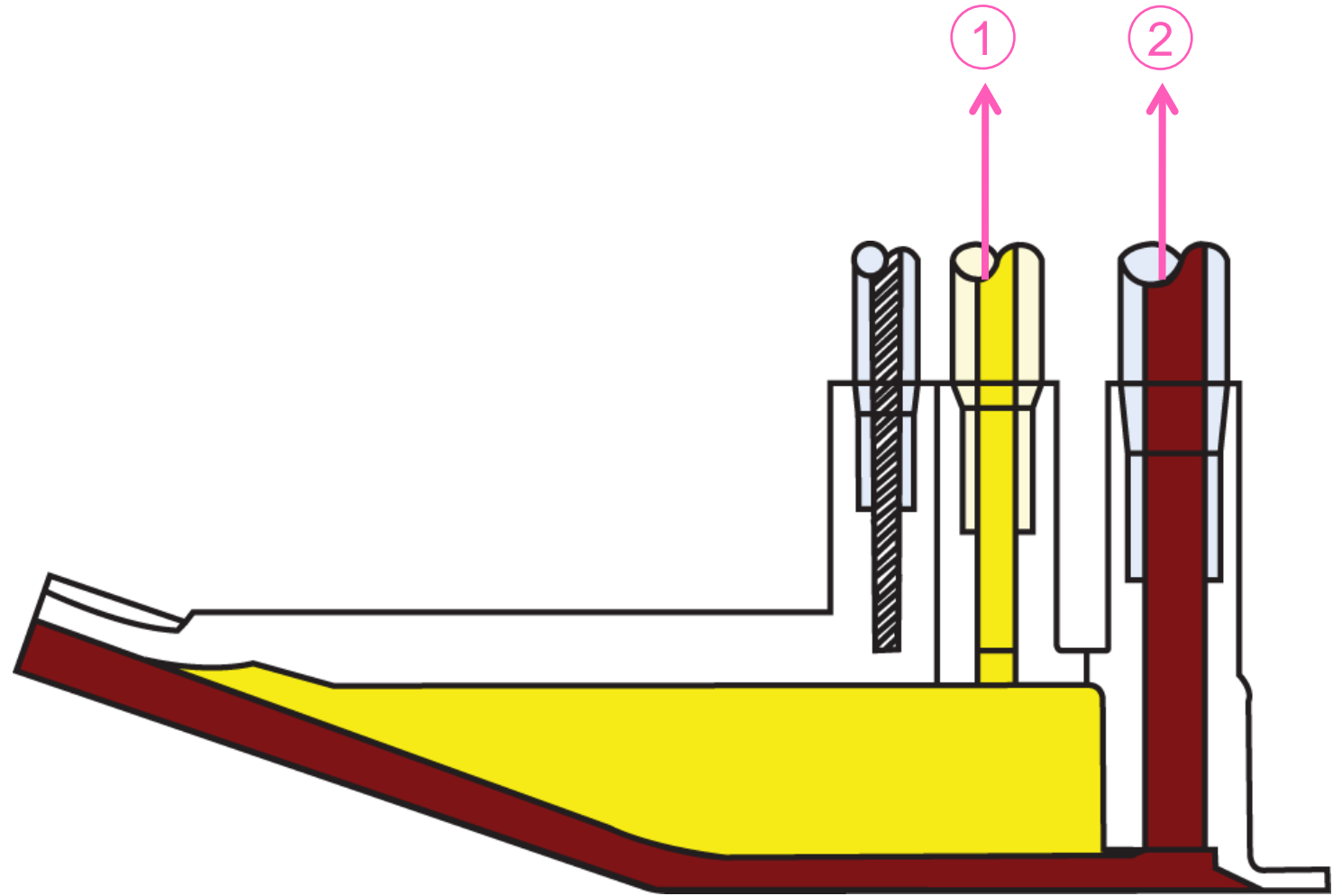
Basic Principles of RBCX – Channel

1. Anticoagulated whole blood enters the channel.
2. Red blood cells (RBC) flow to the remove bag.
3. Plasma is pumped to mix with the replacement fluid.



Connector

1. Plasma port
2. RBC port



Questions?



Preparing to Perform the Procedure

- Configuration: Medication Infusion Notification
- Configuration – RBCX Procedures
- Configuration – Blood Warmer
- Channel Loading
- Single-Needle Procedures
- Patient Data
- Exchange Type
- Fluid Data
 - Replacement Fluid
 - Fluid Balance

Configuration: Procedure

Config		Data	Run	End Run
System	Procedure	Report	Network	
Height Units	Weight Units	Medication Infusion Notification	Custom Prime Recommendation (% TBV)	
cm	kg	Yes	10	
Pressure Alarm Limit (mmHg)		AC Container		
Inlet	Return	Notification	Volume (mL)	
-250	400	Yes	750	
14:14 12-18-2018		Confirm	←	

Configuration – RBCX Procedures

Config		Data	Run	End Run	
System	Procedure	Report	Network	RBCX	Blood Warmer
AC Infusion Rate (mL/min/L TBV)					
0.8					
Inlet:AC Ratio (__:1)		Custom Replacement Fluid (%)			
13.0		0			
15:21 3-20-2018					
Confirm					
					
 RBCX					

Configuration – Blood Warmer

Config Data Run End Run

System Procedure Report Network RBCX **Blood Warmer**



Blood Warmer

Return Line
Yes

Tubing Set (mL)
40

Replace Line
No

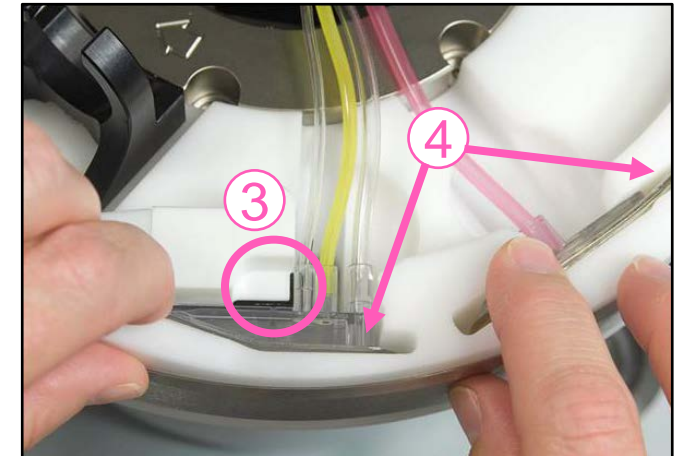
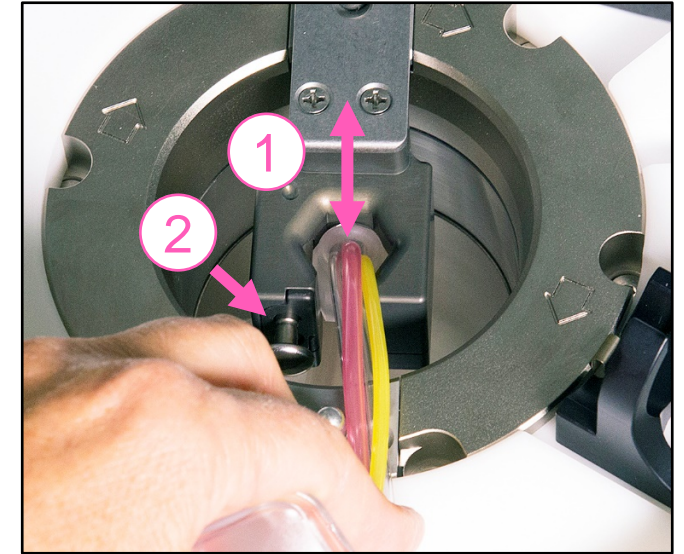
15:21
3-20-2018

Confirm   RBCX

Channel Loading (very important)

Use the standard filler.

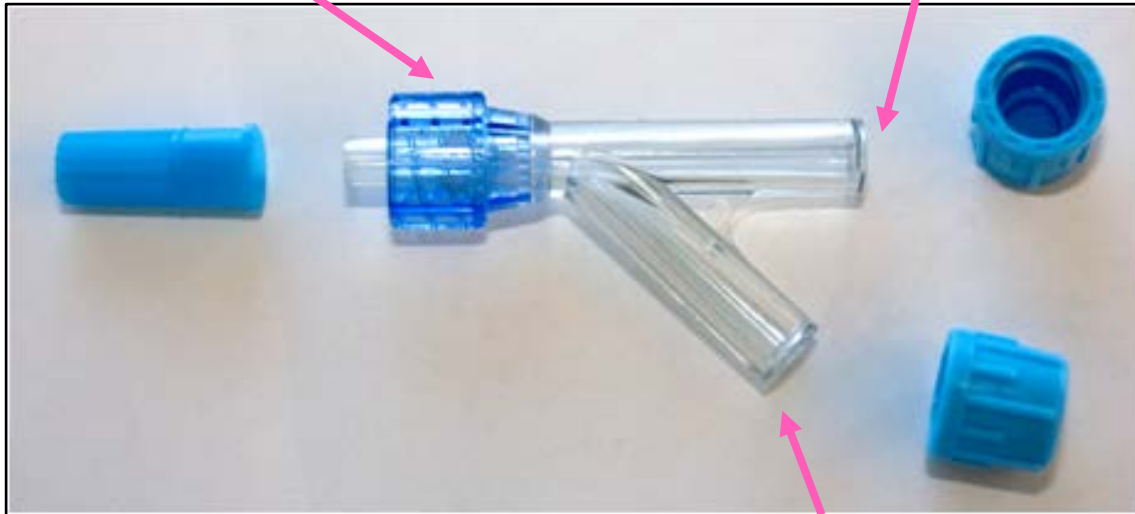
1. Centrifuge collar is in the correct position.
2. Notch on the locking pin is visible.
3. Optical reference is visible.
4. Channel sits flush with the groove.



Single-Needle Procedure

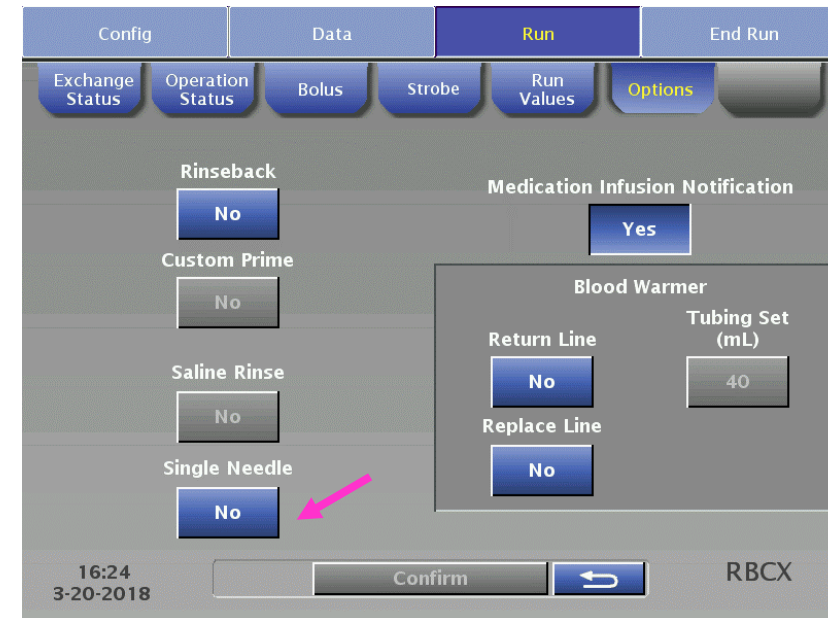
Male luer connection
to patient

Female luer connection
to inlet line



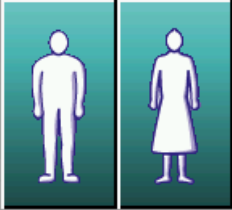




Female luer connection to return line

■ Converting to Single-Needle Access



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

Patient Data

Config	Data	Run	End Run
<div><div></div><div><div>Height (cm)</div></div><div><div>Weight (kg)</div></div></div> <div><div>Hct (%)</div></div> <div><div>TBV (mL)</div></div>			

15:22
3-20-2018





Confirm





RBCX

Exchange Type

Config	Data	Run	End Run
<div>Exchange Type</div> <div>Exchange</div> <div><div>Depletion</div><div>Fluid Type</div><div></div></div> <div><div>Exchange</div><div>Hct 57% (8% citrate)</div><div></div></div> <div><div>Fluid Balance</div><div>Volume 0 mL</div><div></div></div> <div><div>Percent 100%</div><div></div></div>			

16:05
3-20-2018

Confirm





RBCX

Exchange
Depletion/Exchange
Depletion

Fluid Data

- Replacement fluids
- Fluid balance

The screenshot shows the 'Data' tab of a medical device interface. At the top are four tabs: 'Config', 'Data', 'Run', and 'End Run'. The main display area is titled 'Exchange Type' and shows a large button labeled 'Depletion/Exchange'. Below this, there are three columns of settings: 'Depletion' with a button for 'Saline/Albumin (4% citrate)', 'Exchange' with a button for 'Hct 60% (8% citrate)', and 'Fluid Balance' with two buttons: 'Volume 0 mL' and 'Percent 100%'. At the bottom left, the time '11:08' and date '1-12-2010' are displayed. In the bottom center is a 'Confirm' button. To the right of 'Confirm' are a back arrow button, a red 'X' icon, and the text 'RBCX'.

A modal window is shown, containing three buttons stacked vertically: 'Plasma', 'Saline/Albumin', and 'Custom'. A pink dashed arrow points from the 'Saline/Albumin (4% citrate)' button in the 'Depletion' section of the main screen to the 'Saline/Albumin' button in this modal.

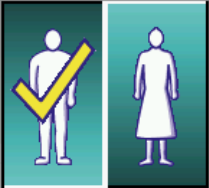






Questions?

Exchange

- Data Entry
- Run Values
- Calculate FCR
- Enter FCR
- FCR: System-Calculated
- Spike Replacement Fluid
- Main Run
- Exchange Status
- Run Targets Attained and Disconnect
- Procedure Summary

Data Entry

Patient Data

Config	Data	Run	End Run
<div><div></div><div><div>Height 180 cm</div></div><div><div>Weight 80 kg</div></div></div> <div><div><div>Hct 27%</div></div><div><div>TBV 5319 mL</div></div></div> <div><div>16:05 3-20-2018</div><div>Confirm</div><div></div><div></div><div>RBCX</div></div>			

Fluid Data

Config	Data	Run	End Run
<div>Exchange Type</div> <div>Exchange</div> <div><div>Depletion</div><div>Fluid Type</div></div> <div>Exchange</div> <div>Hct 57% (8% citrate)</div> 			

Fluid Balance

Volume
0 mLPercent
100%

16:05
3-20-2018

Confirm





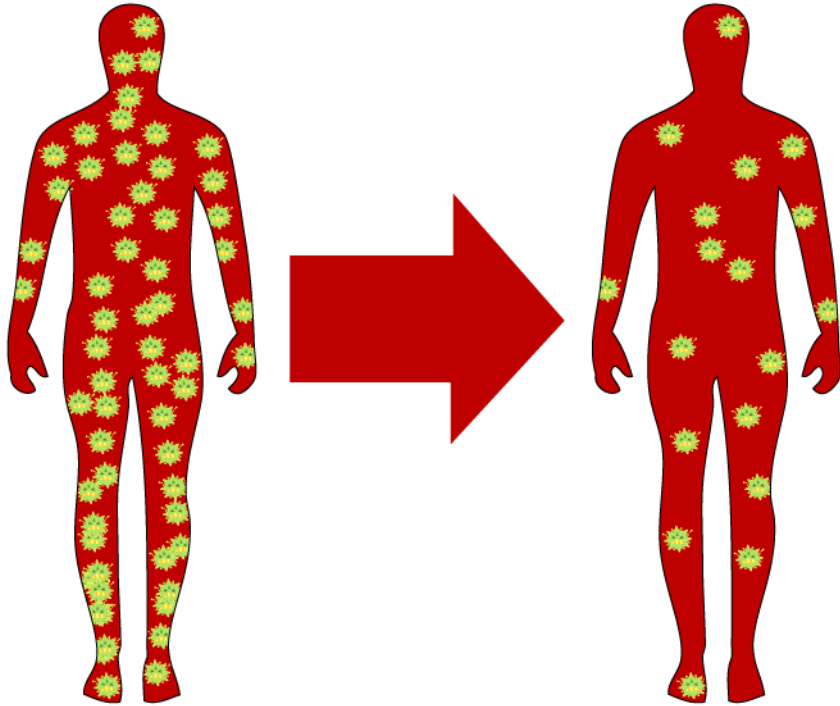
RBCX

Run Values

Config		Data		Run		End Run	
AC Infusion Rate	Inlet:AC Ratio (___:1)	Blood Removed (mL)	Run Time (min)	FCR (%)			
0.8	13.0						
Minimum Hct (%)		Target Hct (%)	Replaced (mL): Exchange				
Target Flow Rate (mL/min)	AC	Inlet	Plasma	Replace			
Target Volume (mL)							
16:06 3-20-2018	Confirm		←	RBCX			

Config		Data		Run		End Run	
AC Infusion Rate	Inlet:AC Ratio (___:1)	Blood Removed (mL)	Run Time (min)	FCR (%)			
0.8	13.0	3494	119	30			
Minimum Hct (%)	27	Target Hct (%)	Replaced (mL): Exchange	3291			
		32					
Target Flow Rate (mL/min)	AC	Inlet	Plasma	Replace			
	3.9	50.4	21.4	25.3			
Target Volume (mL)	462	6004		3291			
16:07 3-20-2018	Confirm		←	RBCX			

Calculate FCR



Starting Defective RBC
(Pre)

60%

Target Defective RBC
(Post)

18%

$$\frac{\text{Post \%}}{\text{Pre \%}} = \text{Target FCR}$$

$$\frac{18\%}{60\%} = 30\% \text{ Target FCR}$$

Enter FCR

The screenshot shows the 'Data' tab of the Terumo Exchange device interface. A pink circle highlights the instruction 'Enter target FCR for patient (%)'. The interface displays various parameters and a numeric keypad for input.

AC Infusion Rate	Inlet:AC Ratio (___:1)	Blood Removed (mL)	Run Time (min)	FCR (%)
0.8	13.0		30	

Below the main display, there are sections for 'Minimum Hct (%)', 'Target Hct (%)', 'AC', 'Inlet', 'Target Flow Rate (mL/min)', 'Target Volume (mL)', 'Replace', and 'RBCX'. A numeric keypad is overlaid on the screen, showing the value 30 in the FCR field.

16:07
3-20-2018

FCR: System-Calculated

1. Enter the starting defective RBC (%).
2. Enter the target defective RBC (%).

Config Data Run End Run

Enter starting defective RBC for patient (%).

AC Infusion Rate: 0.8 Inlet:AC Ratio (___:1): 13.0 Blood Removed (mL): 349 Run Time (min): 60 FCR (%):

Minimum Hct (%): 27 Target Hct (%): 3291

Target Flow Rate (mL/min): 3.9 AC: 50.4 Inlet: 6004

Target Volume (mL): 462

16:08 3-20-2018

Conf

Replace: 25.3 3291

RBCX

Config Data Run End Run

Enter target defective RBC for patient (%).

AC Infusion Rate: 0.8 Inlet:AC Ratio (___:1): 13.0 Blood Removed (mL): 349 Run Time (min): 18 FCR (%):

Minimum Hct (%): 27 Target Hct (%): 3291

Target Flow Rate (mL/min): 3.9 AC: 50.4 Inlet: 6004

Target Volume (mL): 462

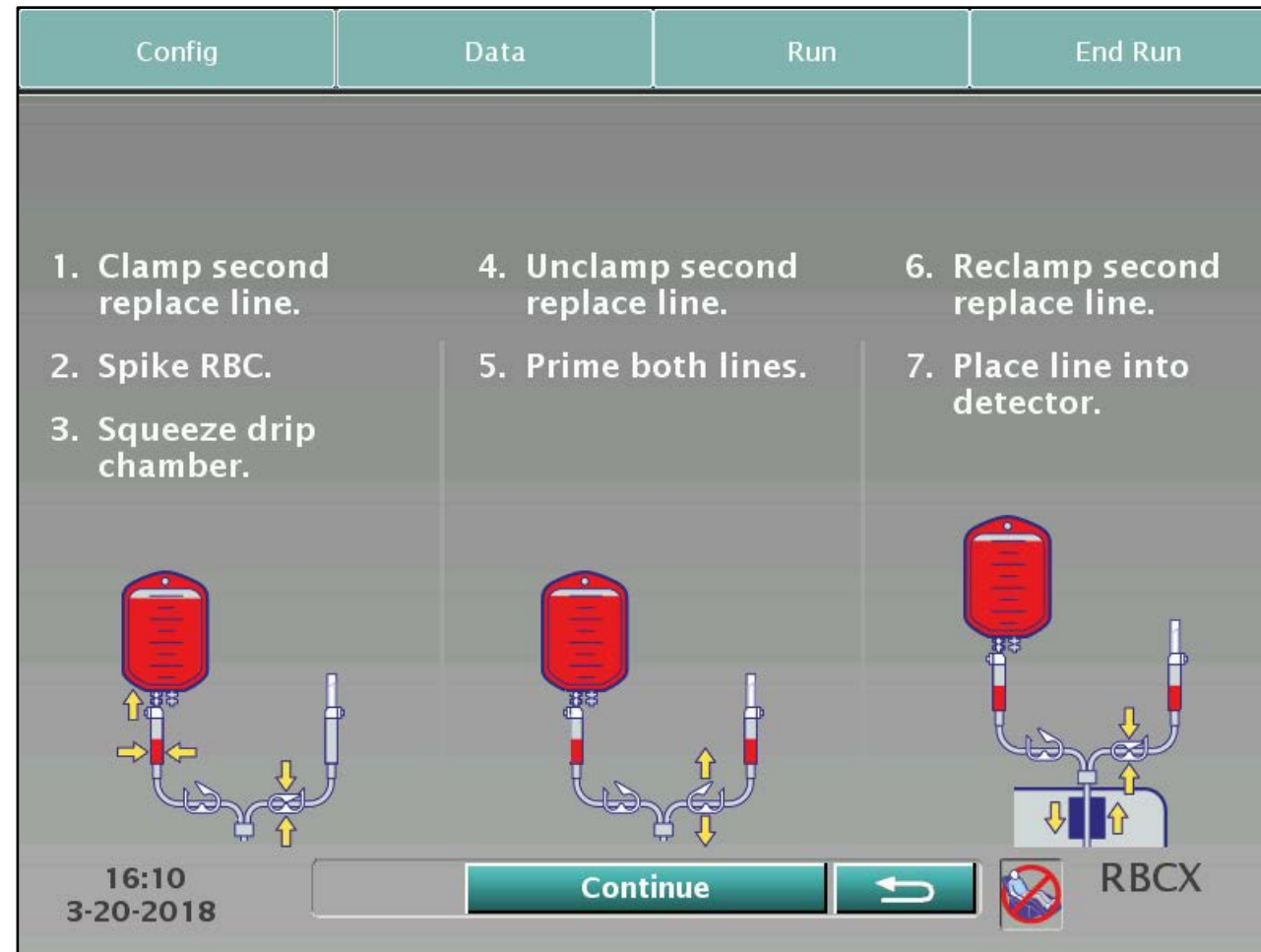
16:08 3-20-2018

Conf

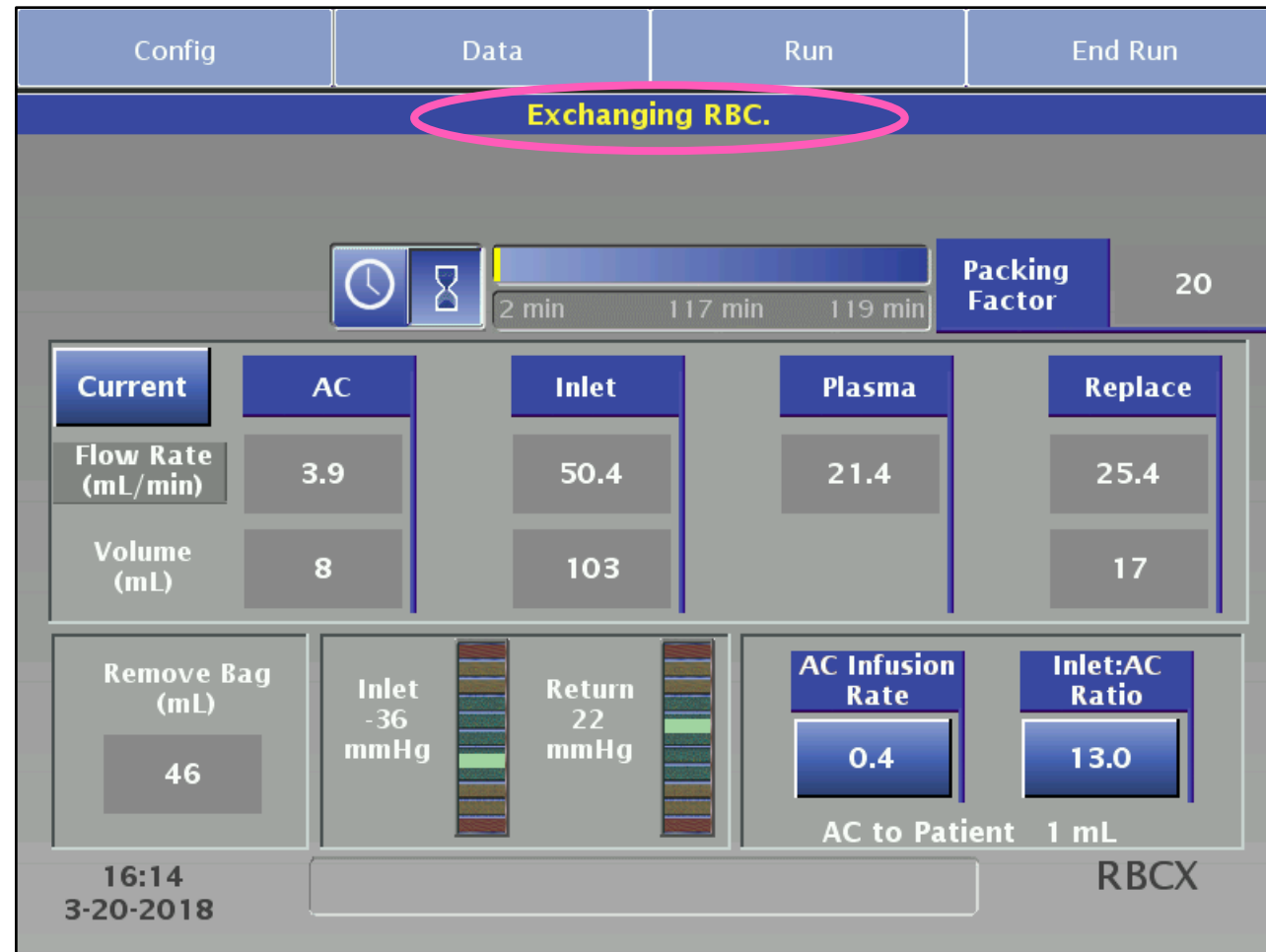
Replace: 25.3 3291

RBCX

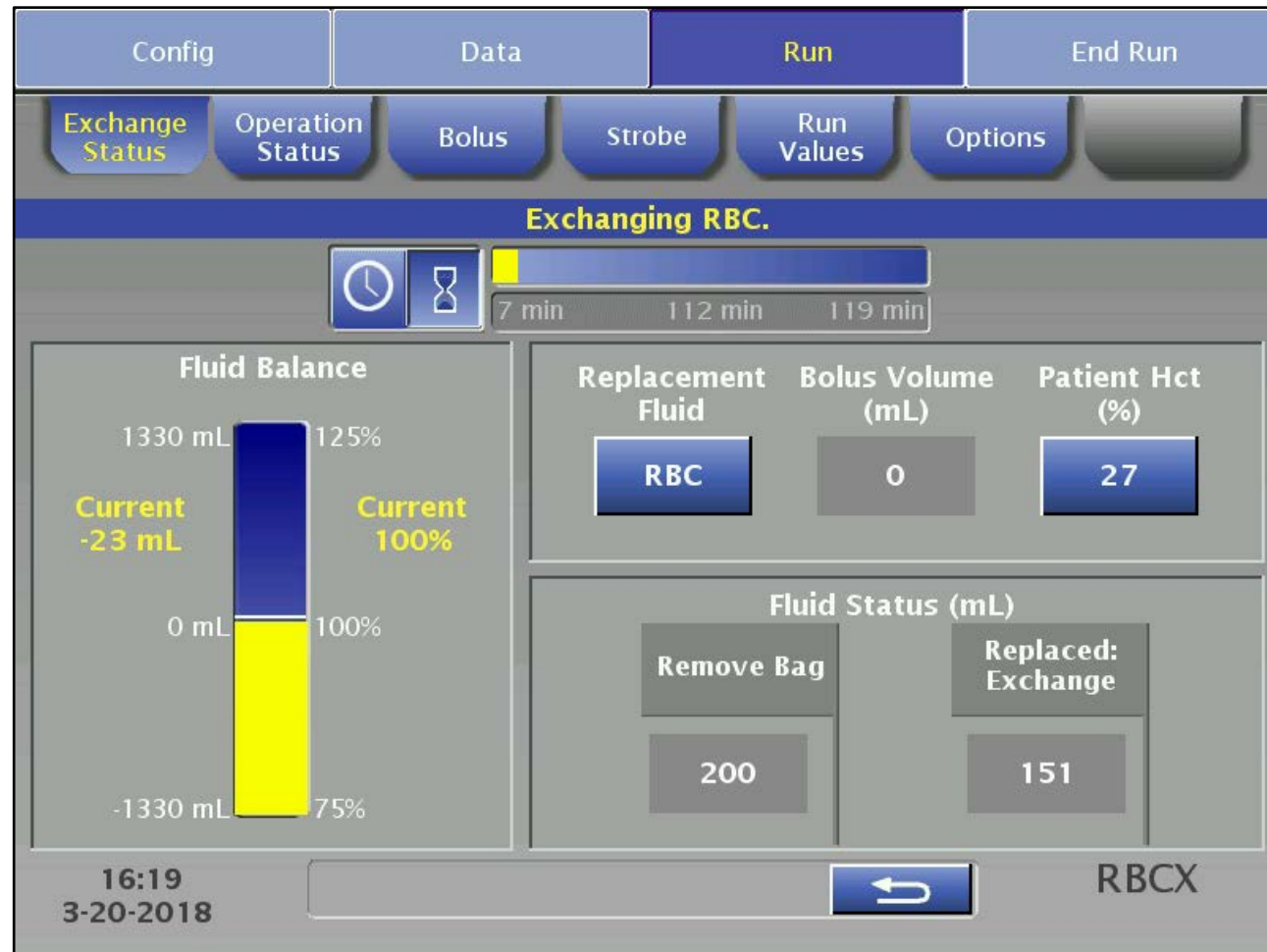
Spike Replacement Fluid



Main Run

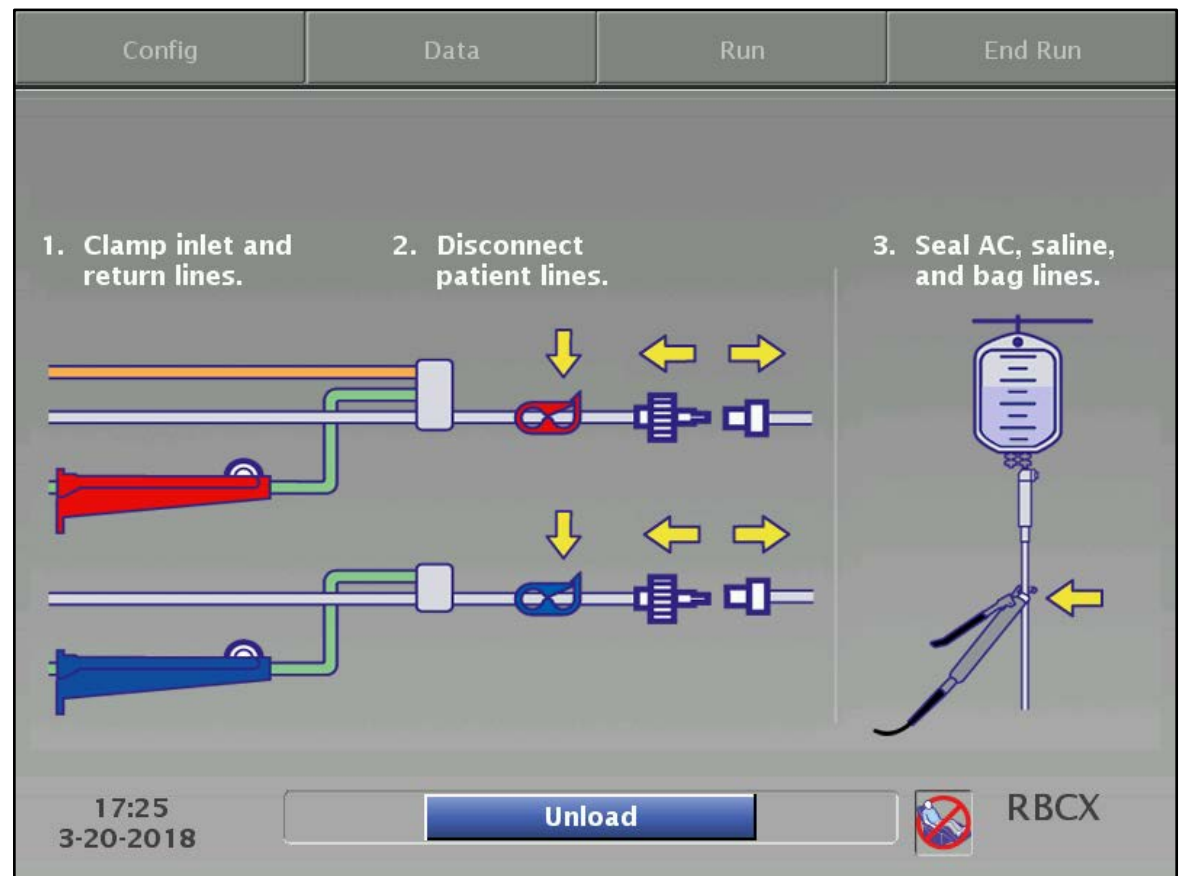


Exchange Status



Run Targets Attained and Disconnect

Config	Data	Run	End Run
Rinseback	Disconnect	Run Targets	
Run targets attained.			
	Target	Current	
Target Hct (%)	32	32	
Run Time (min)	66	66	
FCR (%)	29	29	
Replaced (mL): Exchange	3350	3350	
17:25 3-20-2018	Disconnect		RBCX



Procedure Summary

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

- +469 mL (AC Used)
- 3818 mL (Remove Bag)
- +3350 mL (Replacement Fluid)
- 3 mL (Tubing Set)
- +0 mL (Rinseback)
- 2 mL (Total)
- +0 mL Bolus (if given)
- 2 mL Patient's Fluid Balance

Config	Data	Run	End Run
Rinseback	Disconnect	Run Targets	
AC Used	469 mL	Start Time	16:12
Remove Bag	3818 mL	End Time	17:25
Replacement Used	3350 mL	Run Time	66 min
Bolus	0 mL	Fluid Balance	-2 mL
Tubing Set	-3 mL	Fluid Balance	100 %
Rinseback	0 mL	Inlet Processed	6104 mL
17:26 3-20-2018		Next Page	RBCX

Config	Data	Run	End Run
Rinseback	Disconnect	Run Targets	
FCR	29 %	New Procedure	
Target Hct	32 %	Saline to Patient due to Air Removal	0 mL
Blood Removed	3568 mL	Replaced: Exchange	3350 mL
AC in Remove Bag	229 mL	Custom Prime	0 mL
AC to Patient	235 mL	Saline Rinse	0 mL
AC Used for Prime	21 mL		
17:26 3-20-2018		Previous Page	RBCX

Questions?

Depletion

- Data
 - Patient Data
 - Fluid Data
- Run Values
- Spike Replacement Fluid
- Main Run
- Exchange Status
- Run Targets Attained
- Procedure Summary

Data

Patient Data

Config	Data	Run	End Run
<div><div></div><div>Height 178 cm</div><div>Weight 82 kg</div><div>Hct 60%</div><div>TBV 5313 mL</div></div>			
<div>17:47 3-20-2018</div> <div><div>Confirm</div><div>←</div><div></div><div>RBCX</div></div>			

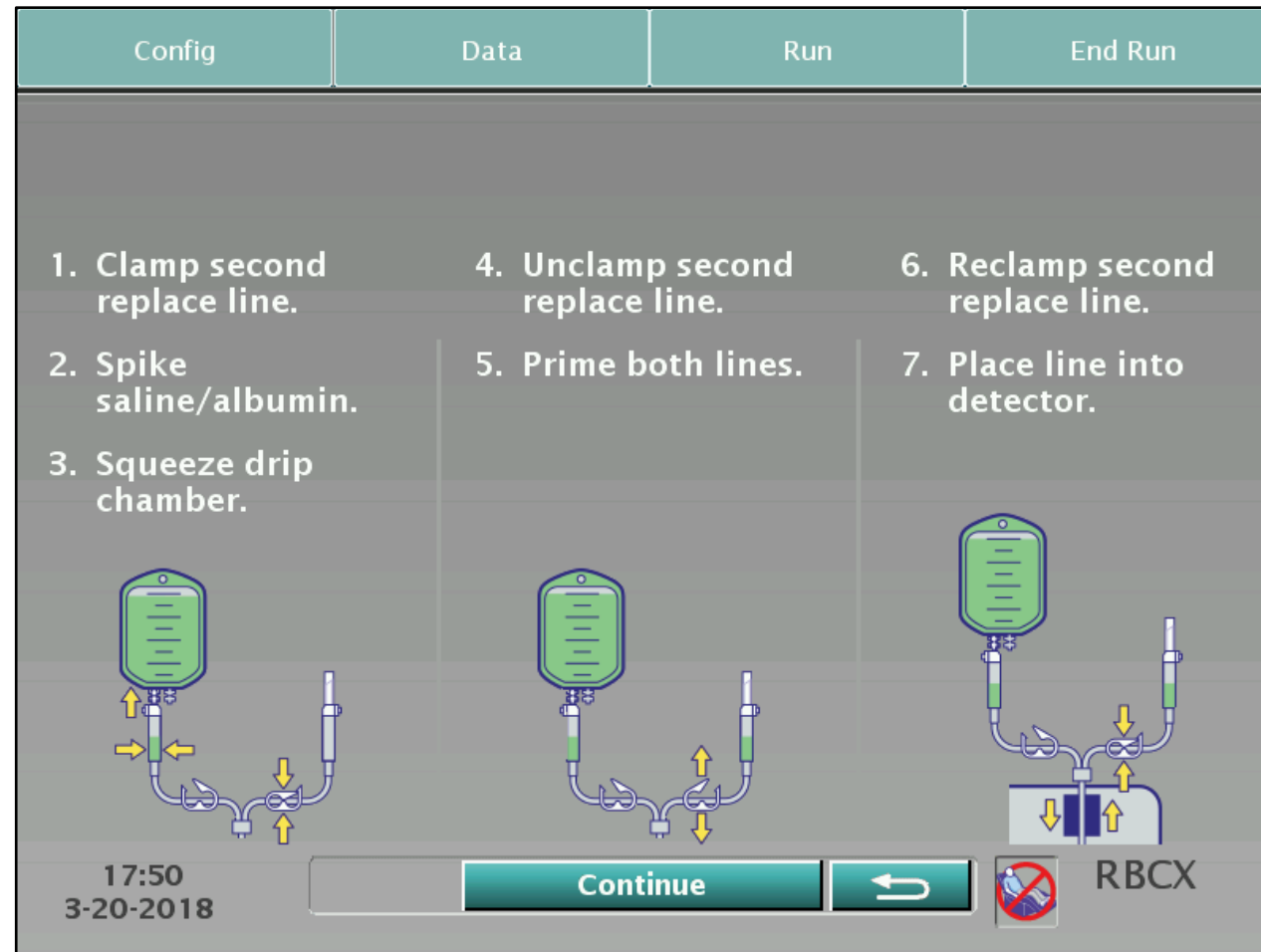
Fluid Data

Config	Data	Run	End Run
<div>Exchange Type Depletion</div>			
<div><div>Depletion Saline/Albumin (4% citrate)</div><div>Exchange Fluid Hct (%)</div><div>Fluid Balance Volume 0 mL</div><div>Percent 100%</div></div>			
<div>17:48 3-20-2018</div> <div><div>Confirm</div><div>←</div><div></div><div>RBCX</div></div>			

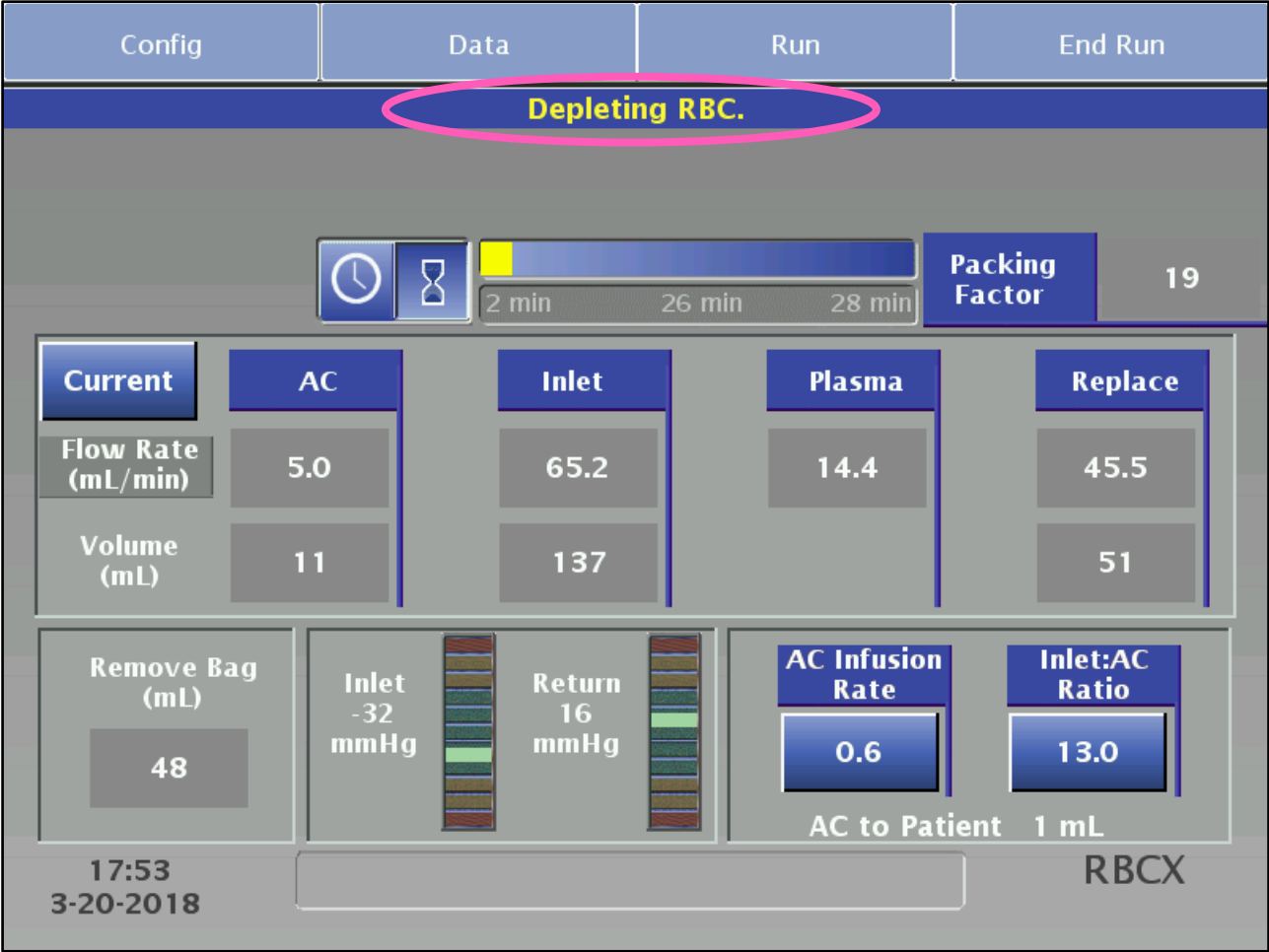
Run Values

Config		Data		Run		End Run	
AC Infusion Rate		Inlet:AC Ratio (__:1)		Blood Removed (mL)		Run Time (min)	
0.8		13.0					
Minimum Hct (%)		Target Hct (%)		Replaced (mL): Depletion			
Target Flow Rate (mL/min)		AC		Inlet		Plasma	
Target Volume (mL)						Replace	
17:48 3-20-2018		Confirm		←		RBCX	

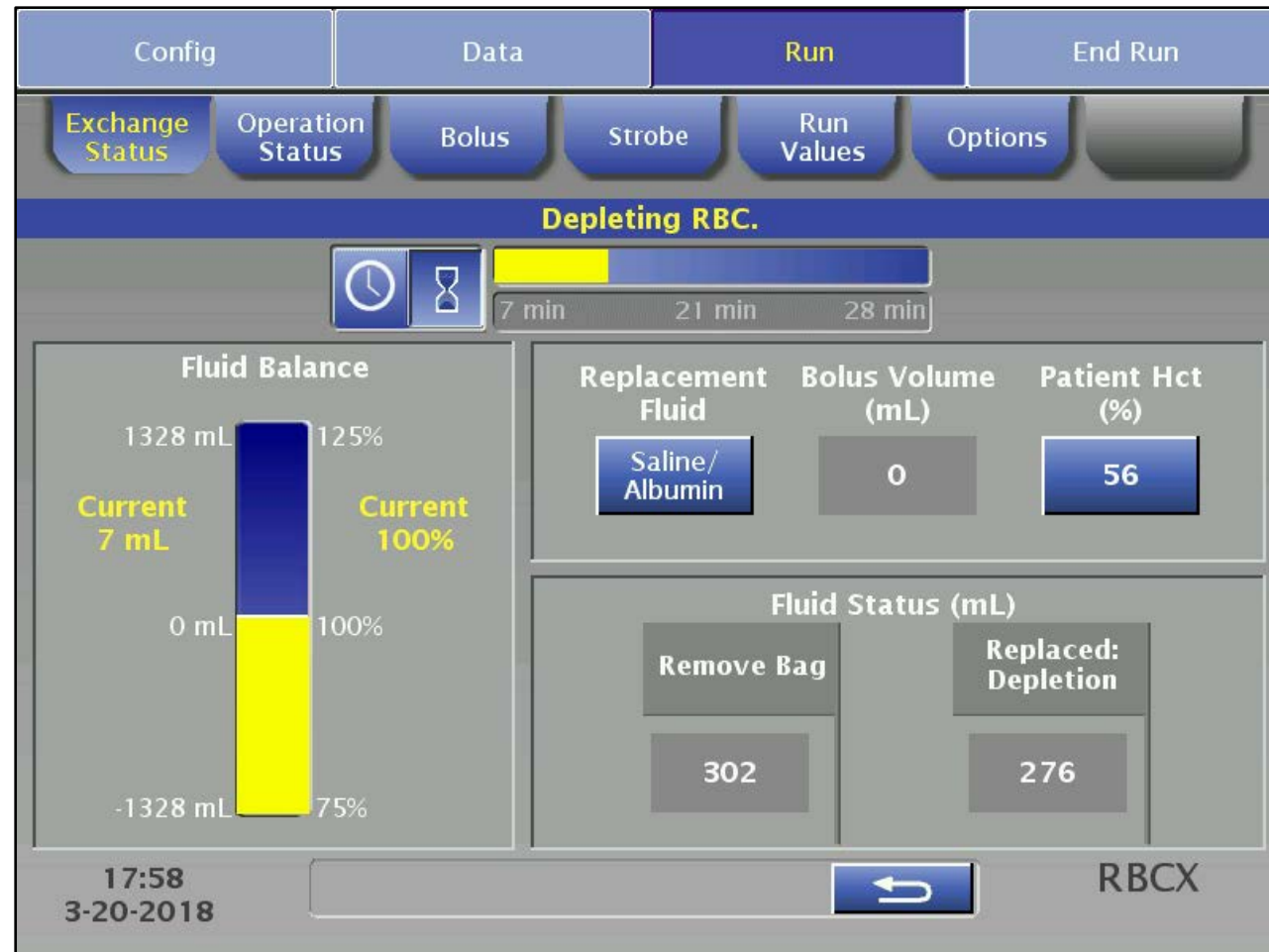
Spike Replacement Fluid



Main Run



Exchange Status



Run Targets Attained

	Config	Data	Run	End Run
Run targets attained.				
	Target		Current	
Target Hct (%)	45		45	
Run Time (min)	22		22	
18:14 3-20-2018		Disconnect		RBCX

Procedure Summary

1.

Config	Data	Run	End Run
<div>AC Used <input type="text" value="131 mL"/></div>			
<div>Start Time <input type="text" value="17:50"/></div>			
<div>Remove Bag <input type="text" value="1149 mL"/></div>			
<div>End Time <input type="text" value="18:15"/></div>			
<div>Replacement Used <input type="text" value="1021 mL"/></div>			
<div>Run Time <input type="text" value="22 min"/></div>			
<div>Bolus <input type="text" value="0 mL"/></div>			
<div>Fluid Balance <input type="text" value="-2 mL"/></div>			
<div>Tubing Set <input type="text" value="-6 mL"/></div>			
<div>Fluid Balance <input type="text" value="100 %"/></div>			
<div>Rinseback <input type="text" value="0 mL"/></div>			
<div>Inlet Processed <input type="text" value="1708 mL"/></div>			
<div>18:17 3-20-2018</div>			
<div><input type="button" value="Next Page"/></div>			
<div> RBCX</div>			

2.

Config	Data	Run	End Run
<div>FCR <input type="text" value="100 %"/></div>			
<div><input type="button" value="New Procedure"/></div>			
<div>Target Hct <input type="text" value="45 %"/></div>			
<div>Saline to Patient due to Air Removal <input type="text" value="0 mL"/></div>			
<div>Blood Removed <input type="text" value="1091 mL"/></div>			
<div>AC in Remove Bag <input type="text" value="55 mL"/></div>			
<div>Replaced: Depletion <input type="text" value="1021 mL"/></div>			
<div>AC to Patient <input type="text" value="70 mL"/></div>			
<div>Custom Prime <input type="text" value="0 mL"/></div>			
<div>AC Used for Prime <input type="text" value="21 mL"/></div>			
<div>Saline Rinse <input type="text" value="0 mL"/></div>			
<div>18:17 3-20-2018</div>			
<div><input type="button" value="Previous Page"/></div>			
<div> RBCX</div>			




Questions?

Depletion/Exchange



- Data
 - Patient Data
 - Fluid Data
- Run Values
- Considerations for Depletion/Exchange
- Spike Replacement Fluid
- Main Run
- Exchange Status
- Run Targets Attained
- Procedure Summary

Data

Patient Data

Config	Data	Run	End Run
<div><div></div><div>Height 160 cm</div><div>Weight 50 kg</div><div>Hct 28%</div><div>TBV 3716 mL</div></div>			
<div>11:07 1-12-2018</div> <div><div>Confirm</div><div></div><div></div><div>RBCX</div></div>			

Fluid Data

Config	Data	Run	End Run
<div>Exchange Type Depletion/Exchange</div>			
<div><div>Depletion Saline/Albumin (4% citrate)</div><div>Exchange Hct 60% (8% citrate)</div><div>Fluid Balance Volume 0 mL</div><div>Percent 100%</div></div>			
<div>11:08 1-12-2018</div> <div><div>Confirm</div><div></div><div></div><div>RBCX</div></div>			

Run Values

Config		Data		Run		End Run	
AC Infusion Rate	Inlet:AC Ratio (___:1)	Blood Removed (mL)	Run Time (min)	FCR (%)			
0.8	13.0						
Minimum Hct (%)	Target Hct (%)	Replaced (mL): Depletion	Replaced (mL): Exchange				
Target Flow Rate (mL/min)	AC	Inlet	Plasma	Replace			
Target Volume (mL)							
11:09 1-12-2018		Confirm		←		RBCX	

Config		Data		Run		End Run	
AC Infusion Rate	Inlet:AC Ratio (___:1)	Blood Removed (mL)	Run Time (min)	FCR (%)			
0.8	13.0	2371	(19) 117	30			
Minimum Hct (%)	Target Hct (%)	Replaced (mL): Depletion	Replaced (mL): Exchange				
23	32	190	2032				
Target Flow Rate (mL/min)	AC	Inlet	Plasma	Replace			
	3.0	38.5	24.5	11.1			
Target Volume (mL)	335	4355		2222			
11:10 1-12-2018		Confirm		←		RBCX	

Considerations for Depletion/Exchange

■ Lower FCR

- Same volume of blood is used
- Lower FCR is attained

■ Less RBC

- Same FCR is targeted
- 1 unit less RBC is needed

Patient: 5 L TBV, Hct 26%, fluid balance 100%

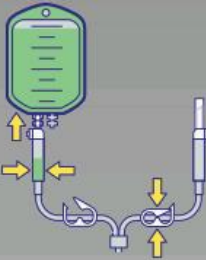
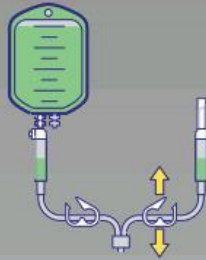

	FCR	
	Exchange	Depletion/ Exchange
Min Hct (%)	26	22
Target Hct (%)	32	32
Target FCR (%)	33	30
Replace vol (mL)	2921	2921

Patient: 5 L TBV, Hct 26%, fluid balance 100%

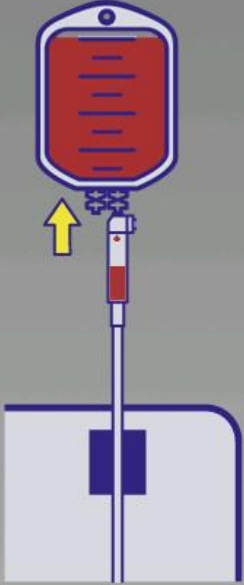

	RBC	
	Exchange	Depletion/ Exchange
Min Hct (%)	26	22
Target Hct (%)	32	32
Target FCR (%)	30	30
Replace vol (mL)	3148	2921

Spike Replacement Fluid

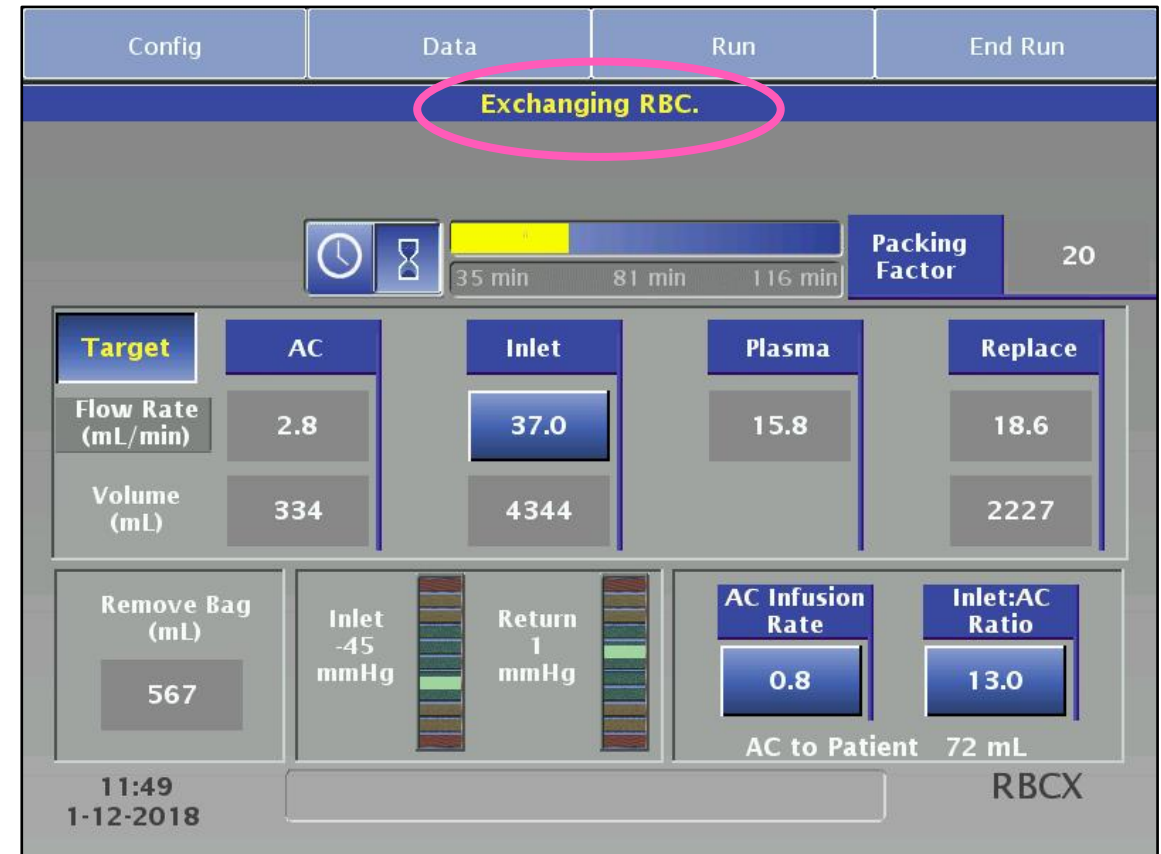
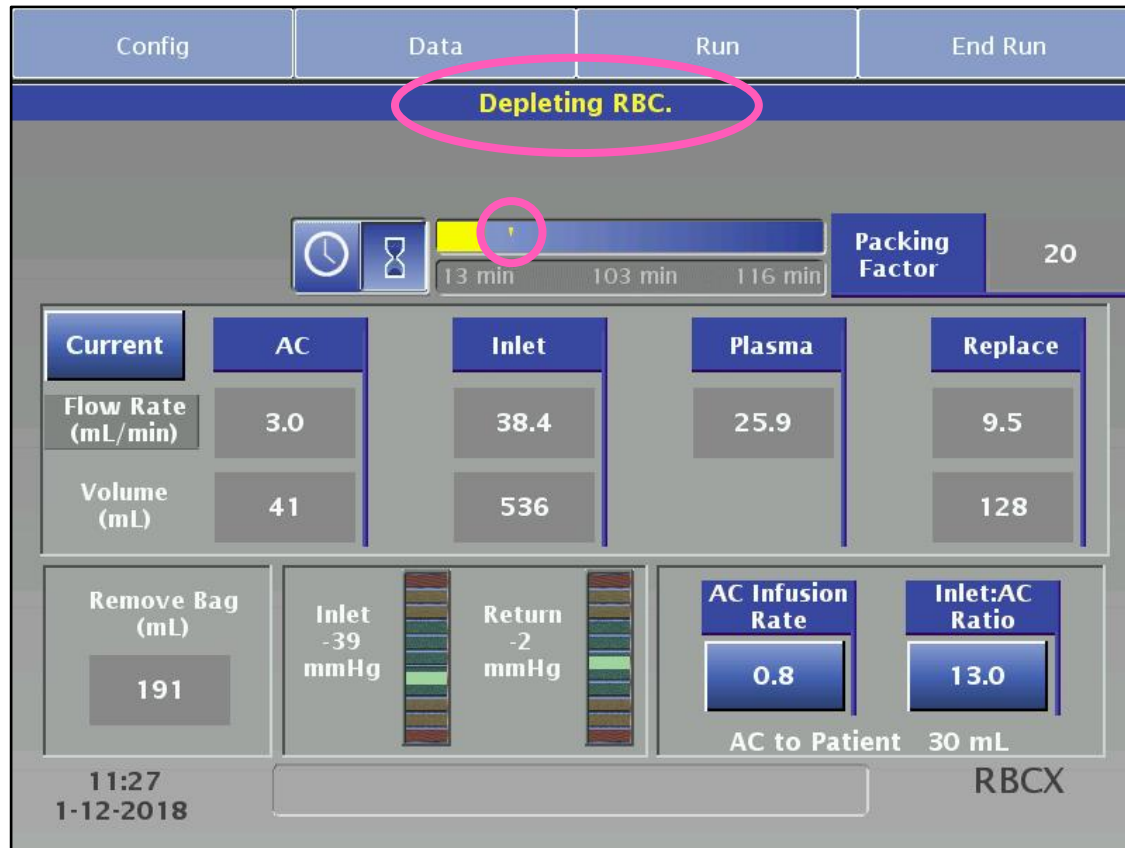
Depletion Phase

Config	Data	Run	End Run
Exchange Status	Operation Status	Bolus	Strobe
Run Values		Options	
1. Clamp second replace line. 2. Spike saline/albumin. 3. Squeeze drip chamber.		4. Unclamp second replace line. 5. Prime both lines. 6. Reclamp second replace line. 7. Place line into detector.	
			
11:12 1-12-2018		Continue	
		 RBCX	

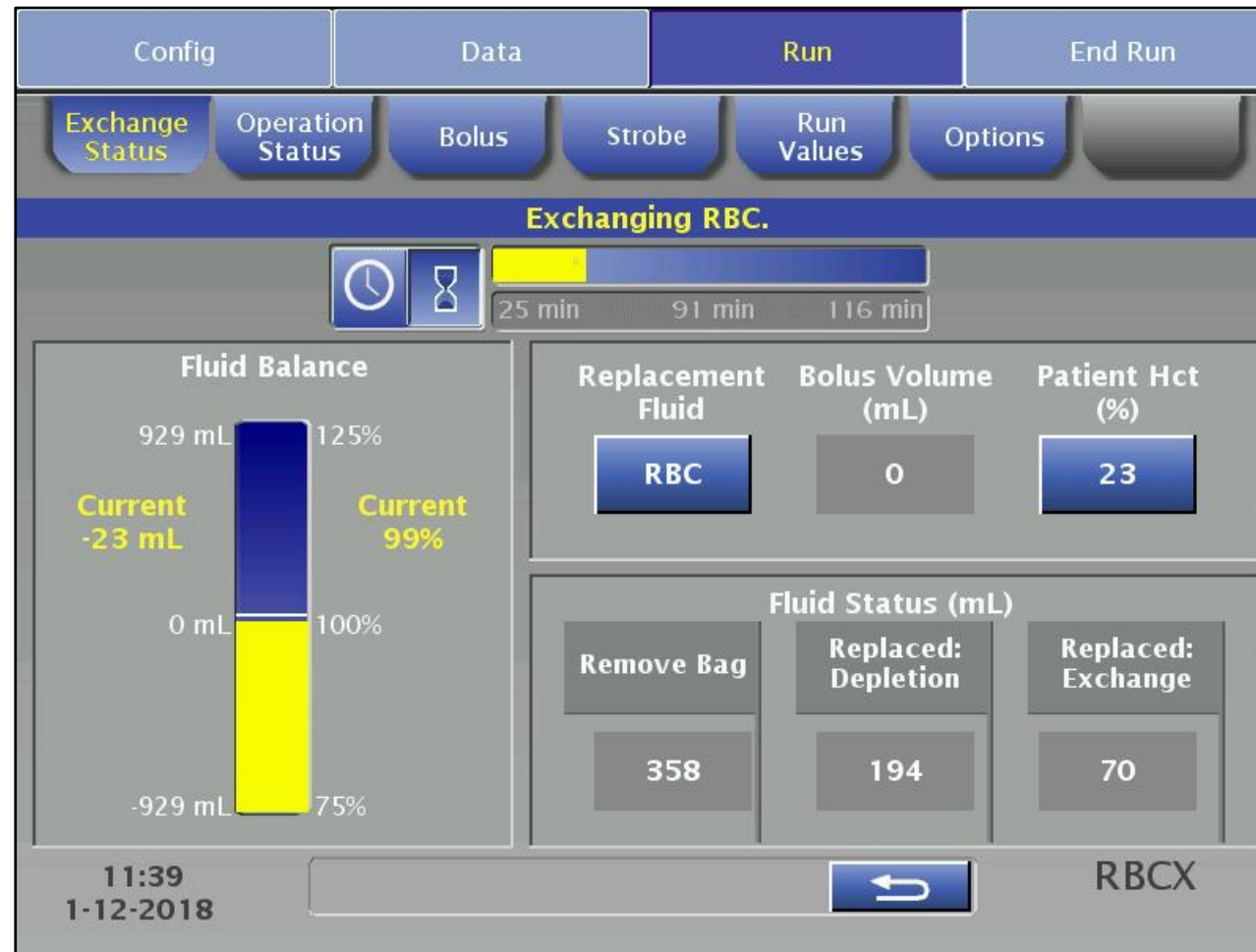
Exchange Phase

Config	Data	Run	End Run
			
Spike replacement fluid for exchange.			
11:34 1-12-2018		Confirm	
		 RBCX	

Main Run



Exchange Status



Run Targets Attained

	Config	Data	Run	End Run
Run targets attained.				
		Target	Current	
Target Hct (%)		32	32	
Run Time (min)		94	94	
FCR (%)		30	30	
Replaced (mL): Exchange		2032	2032	
12:48 1-12-2018		Disconnect		RBCX

Procedure Summary

1.

Config	Data	Run	End Run
AC Used	333 mL	Start Time	11:13
Remove Bag	2557 mL	End Time	12:48
Replacement Used	2226 mL	Run Time	94 min
Bolus	0 mL	Fluid Balance	-1 mL
Tubing Set	-3 mL	Fluid Balance	100 %
Rinseback	0 mL	Inlet Processed	4332 mL

12:49
1-12-2018

[Next Page](#)


 RBCX

2.

Config	Data	Run	End Run
FCR	30 %	New Procedure	
Target Hct	32 %	Saline to Patient due to Air Removal	0 mL
Blood Removed	2383 mL	Replaced: Depletion	194 mL
AC in Remove Bag	153 mL	Replaced: Exchange	2032 mL
AC to Patient	175 mL	Custom Prime	0 mL
AC Used for Prime	21 mL	Saline Rinse	0 mL

12:49
1-12-2018

[Previous Page](#)

 RBCX

Questions?

Making Changes

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

Data Menu

- Patient Data
- Fluid Data
- Alarm History
- Report

Patient Data

The screenshot shows a medical device interface with a top navigation bar containing four tabs: "Config", "Data", "Run", and "End Run". The "Data" tab is selected and highlighted in blue. Below this bar is a sub-menu with five buttons: "Patient Data", "Fluid Data", "Alarm History", "Report", and three unlabeled buttons. The "Patient Data" button is selected and highlighted in blue. The main display area shows five data fields arranged in a grid:

- Top left: A button with a male and female icon and a checkmark.
- Top middle: A button labeled "Height 5 ft 8 in" with a male icon and a height scale.
- Top right: A button labeled "Weight 170 lb" with a male icon and a scale.
- Bottom left: A button labeled "Hct 27%" with a test tube icon.
- Bottom right: A button labeled "TBV 4977 mL" with a male icon.

At the bottom of the screen, there is a status bar with the following elements from left to right:

- Time and date: "9:53 1-12-2018".
- A "Confirm" button.
- A blue button with a white left-pointing arrow.
- The text "RBCX".

Fluid Data

Config

Data

Run

End Run

Patient Data

Fluid Data

Alarm History

Report

Exchange Type

Exchange

Depletion

Exchange

Fluid Balance

Fluid Type

Hct 57%
(8% citrate)

Volume
0 mL

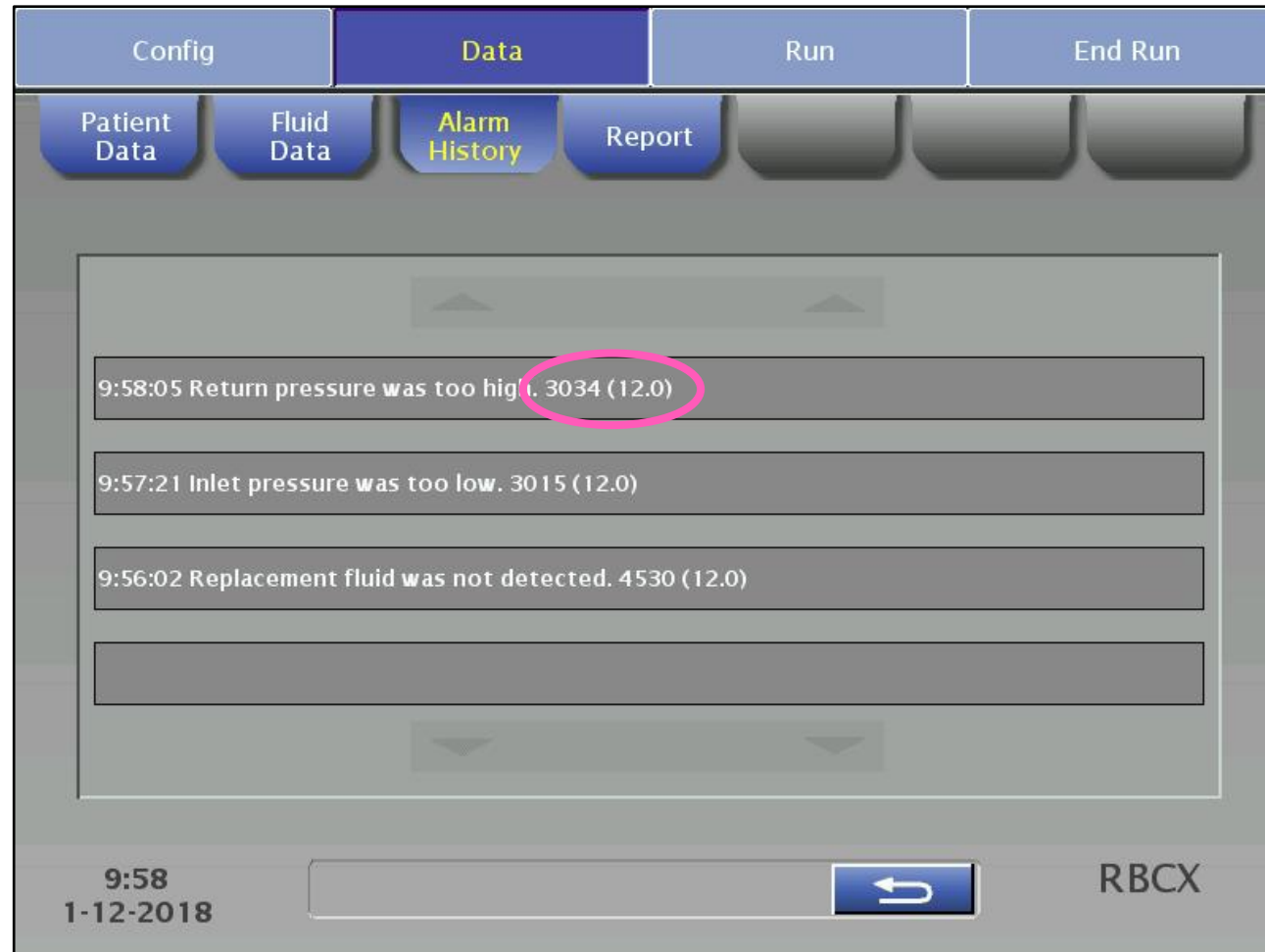
Percent
100%

9:53
1-12-2018

Confirm

RBCX

Alarm History



Report

Config

Data

Run

End Run

Patient Data

Fluid Data

Alarm History

Report

Start Time

Procedure

Sent

Current

✓

12-22-2017 11:19

TPE

✓

12-22-2017 09:48

TPE

✓

12-01-2017 12:15

TPE

✓

12-01-2017 09:32

TPE

✓

12-01-2017 08:41

TPE

9:54
1-12-2018

Send

RBCX

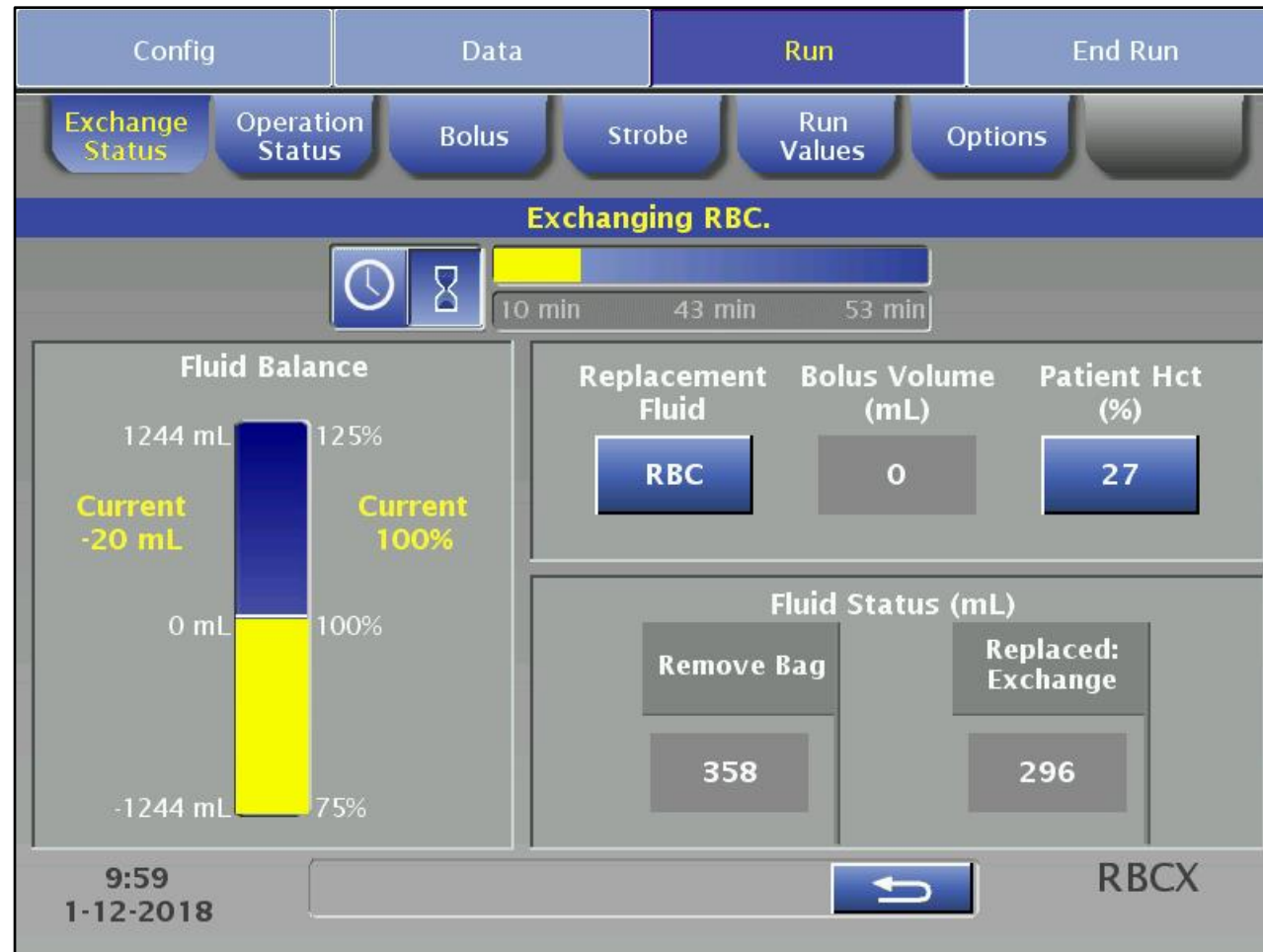
Run Menu

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

Main Run – Caution Status

Config		Data		Run		End Run	
Exchange Status	Operation Status	Bolus	Strobe	Run Values	Options		
Exchanging RBC.							
<div> <div></div> <div>28 min</div> <div>17 min</div> <div>45 min</div> </div>				Packing Factor		16	
Current	AC	Inlet	Plasma	Replace			
Flow Rate (mL/min)	6.0	78.1	22.4	50.3			
Volume (mL)	117	1517		884			
Remove Bag (mL)	Inlet -45 mmHg		Return 43 mmHg	AC Infusion Rate	Inlet:AC Ratio		
1010				0.9	13.0		
				AC to Patient 48 mL			
10:16 1-12-2018		Caution Status		RBCX			

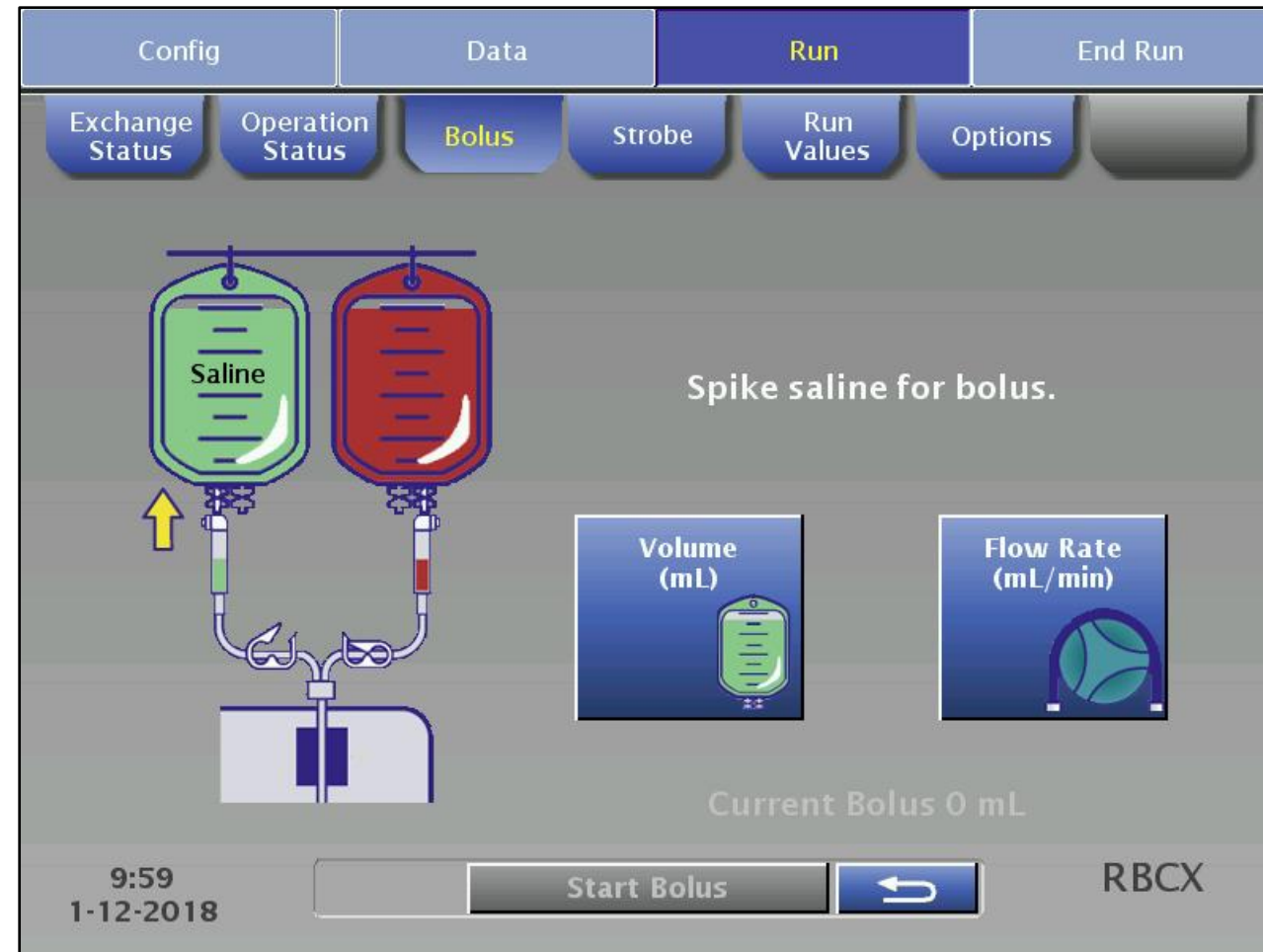
Exchange Status



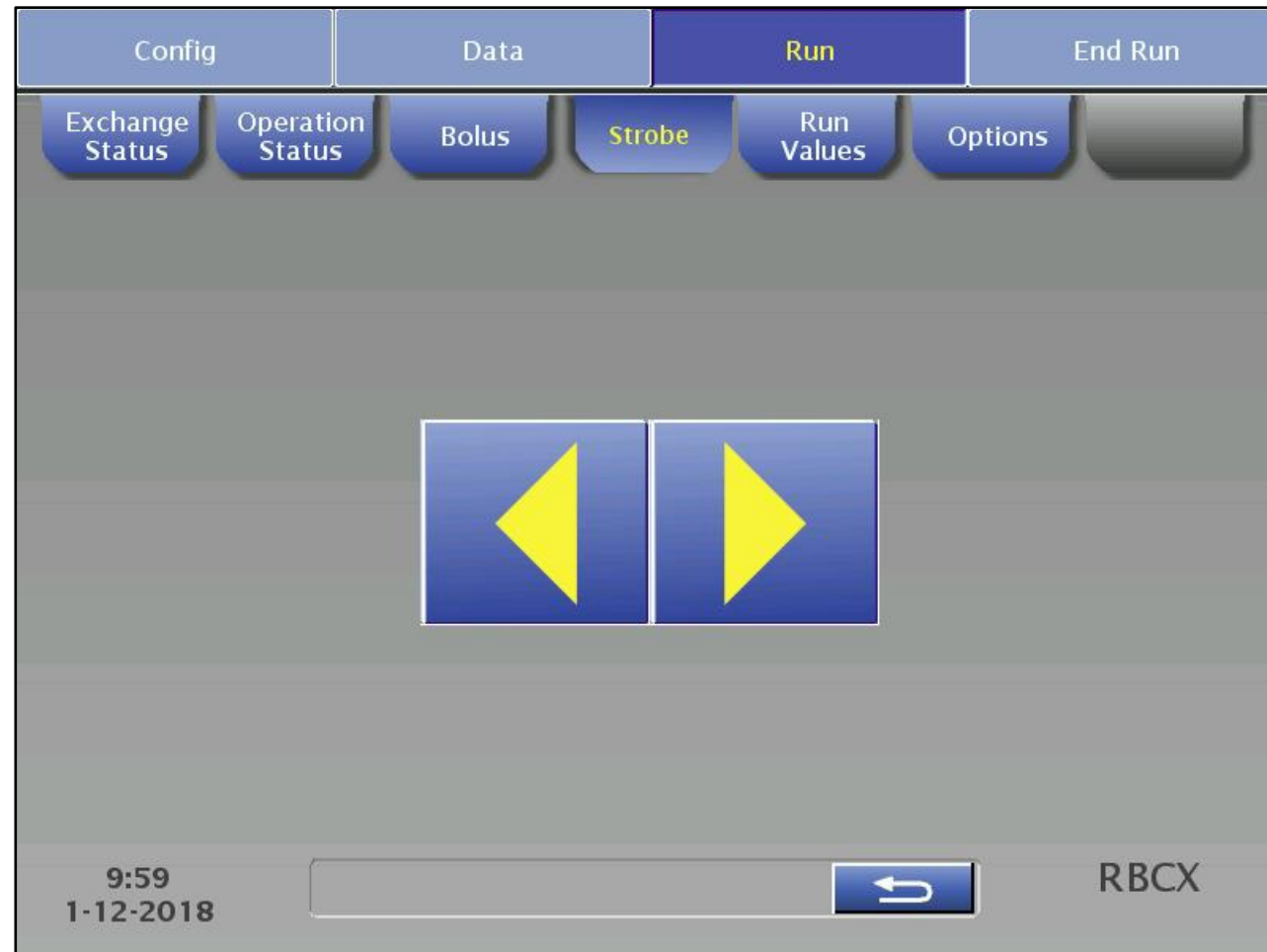
Operation Status

The screenshot displays the 'Operation Status' screen of a medical device. At the top, there are four main tabs: 'Config', 'Data', 'Run' (highlighted in yellow), and 'End Run'. Below these, a row of sub-tabs includes 'Exchange Status', 'Operation Status' (highlighted in yellow), 'Bolus', 'Strobe', 'Run Values', and 'Options'. The main display area shows 'AIM System: Enabled' on the left. In the center, there is a large blue button labeled 'Disable RBC Detector'. On the right, a box displays 'Total Saline to Patient: 0 mL' above another blue button labeled 'Remove Air From Return Line'. At the bottom left, the time '9:59' and date '1-12-2018' are shown. In the bottom center, there is a 'Confirm' button and a blue button with a white arrow pointing left. At the bottom right, the text 'RBCX' is displayed.

Bolus



Strobe



Run Values

Config		Data		Run		End Run	
Exchange Status	Operation Status	Bolus	Strobe	Run Values	Options		
AC Infusion Rate	Inlet:AC Ratio (___:1)	Blood Removed (mL)	Run Time (min)	FCR (%)			
0.9	13.0	1845	52	50			
Minimum Hct (%)	27	Target Hct (%)	32	Replaced (mL): Exchange	1779		
Target Flow Rate (mL/min)	AC	Inlet	Plasma	Replace			
	4.2	54.1	15.3	35.1			
Target Volume (mL)	218	2840		1779			
10:18 1-12-2018		Confirm		RBCX			

Config		Data		Run		End Run	
Exchange Status	Operation Status	Bolus	Strobe	Run Values	Options		
AC Infusion Rate	Inlet:AC Ratio (___:1)	Blood Removed (mL)	Run Time (min)	FCR (%)			
1.1	13.0	1845	49 ↓	50			
Minimum Hct (%)	27	Target Hct (%)	32	Replaced (mL): Exchange	1779		
Target Flow Rate (mL/min)	AC	Inlet	Plasma	Replace			
	5.1	66.1 ↑	18.3 ↑	43.3 ↑			
Target Volume (mL)	218	2839		1779			
10:20 1-12-2018		Confirm		RBCX			

Options

The screenshot displays the 'Options' screen within a medical device interface. At the top, there are four tabs: 'Config', 'Data', 'Run' (highlighted in blue), and 'End Run'. Below these tabs is a row of buttons: 'Exchange Status', 'Operation Status', 'Bolus', 'Strobe', 'Run Values', 'Options' (highlighted in blue), and a greyed-out button. The main area contains several settings:

- Rinseback**: A blue button labeled 'No'.
- Custom Prime**: A grey button labeled 'No'.
- Saline Rinse**: A grey button labeled 'No'.
- Single Needle**: A blue button labeled 'No'.
- Medication Infusion Notification**: A blue button labeled 'Yes'.
- Blood Warmer**: A section containing:
 - Return Line**: A blue button labeled 'No'.
 - Replace Line**: A blue button labeled 'No'.
 - Tubing Set (mL)**: A grey button labeled '40'.

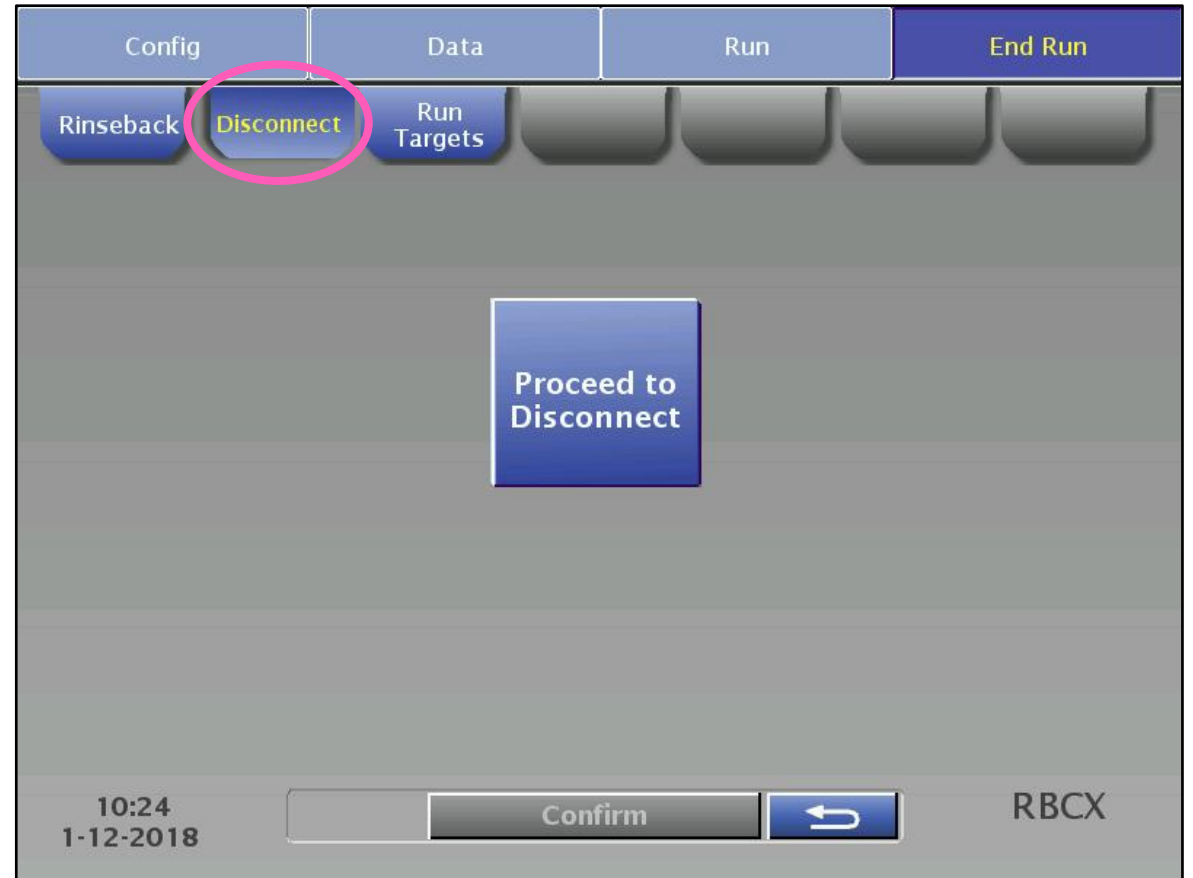
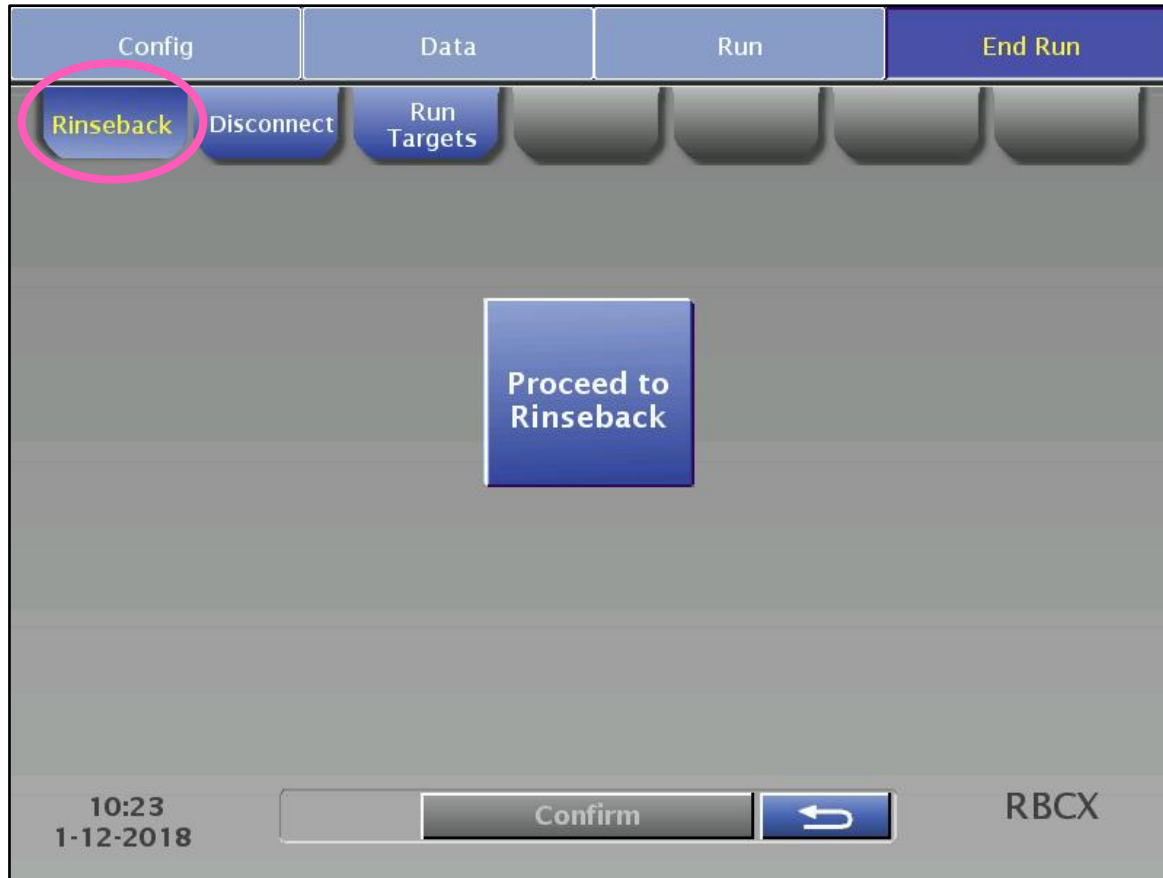
At the bottom, the status bar shows the time '10:21', the date '1-12-2018', a 'Confirm' button, a back arrow button, and the text 'RBCX'.

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

End Run Menu

- Rinseback, Disconnect
- Run Targets

Rinseback, Disconnect



Run Targets

Config

Data

Run

End Run

Rinseback

Disconnect

Run Targets

	Target	Current
Target Hct (%)	32	30
Run Time (min)	52	35
FCR (%)	50	63
Replaced (mL): Exchange	1779	1147

10:24
1-12-2018

↩

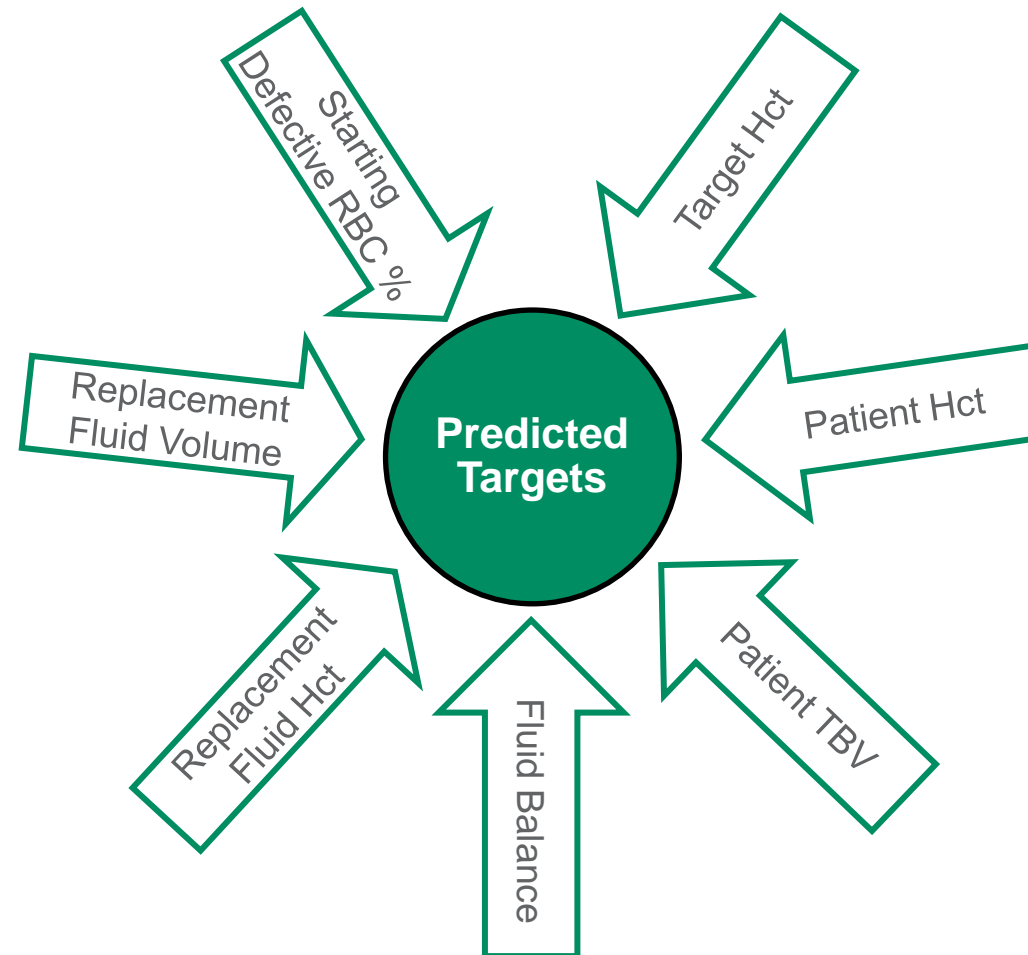
RBCX

Questions?

Optimization

- Targets Not Achieved
- Helpful Hints

Targets Not Achieved



Targets Not Achieved (continued)

Incorrect Replacement Fluid Hct

Incorrect Patient Hct

Too high or too low post-procedure patient Hct or FCR

Example:	Entered	Actual
Patient Hct	27%	27%
Replacement Hct	27%	57%
Target Hct	27%	37%

Helpful Hints

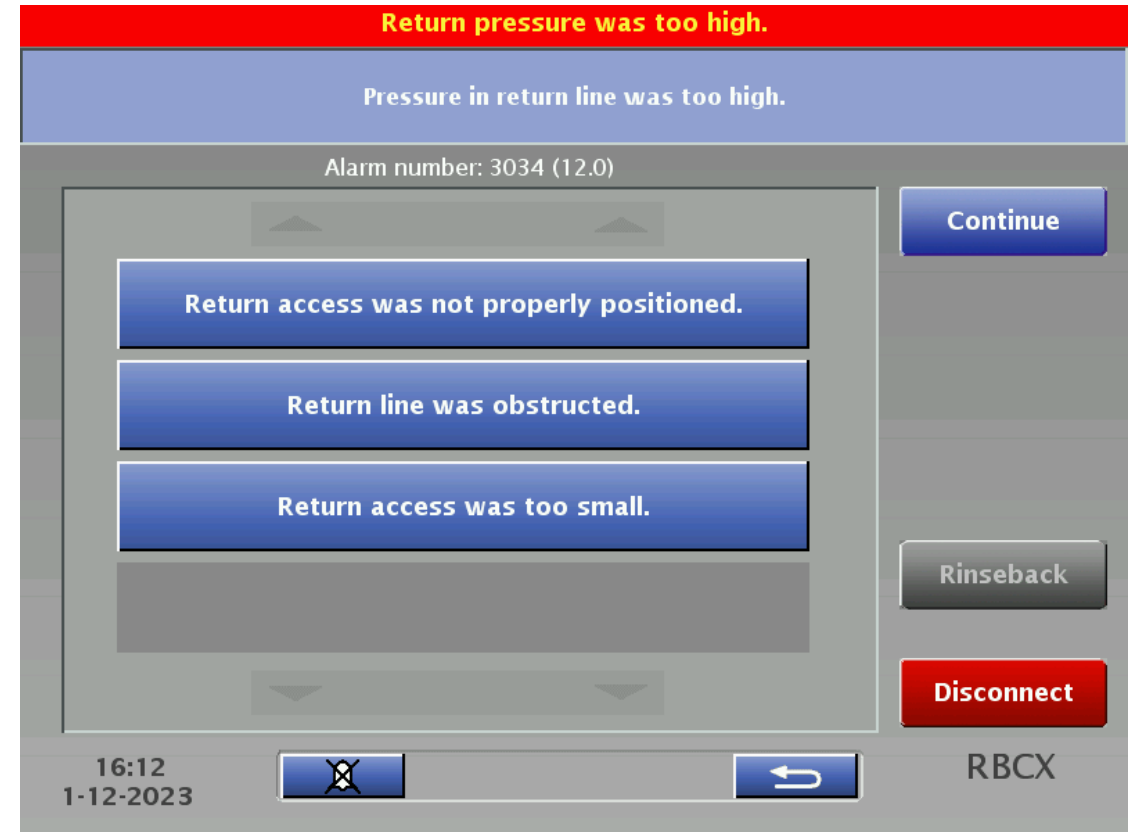
- No rinseback should be performed.
- Enter accurate patient Hct. This is essential!
- Know the Hct and volume of each unit of replacement RBC.
- Certain additive solutions cause an inaccurate spun Hct of the RBC unit.
- For sickle cell patients, screen the replacement RBC units for sickle cell trait.
- The patient's platelet count will decrease depending on the number of TBVs processed.

Questions?

Troubleshooting

- Inlet and Return Access Alarms
- Unattainable Procedure
- High Interface
- Updating the Patient's Hct – Pause

Inlet and Return Access Alarms



Unattainable Procedure

Current run targets could not be attained with run value entered.

Alarm number: 4548 (12.0)




Some acceptable values appear below.

Target Hct (%)	Replaced (mL): Exchange (FCR%)	
	Minimum	Maximum
33	1400 (65%)	9800 (5%)
35	2000 (55%)	9800 (5%)
37	3000 (42%)	9800 (6%)
39	4200 (30%)	9800 (6%)

Do one of the following:

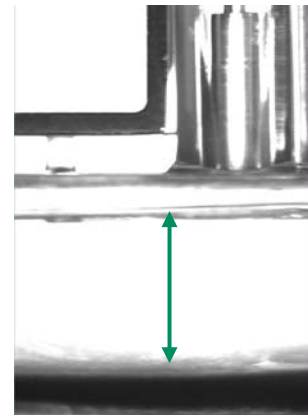
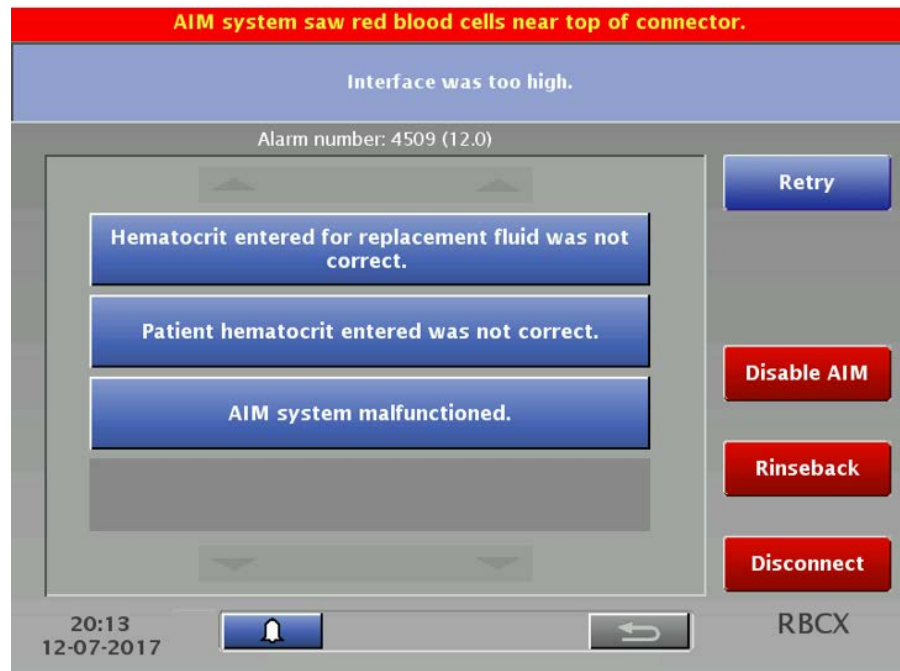
- Change a value by touching the go back button and navigating to the appropriate screen.
- If no acceptable values appear above, reconsider the values entered on the patient data and fluid data screens.

18:41
3-20-2018

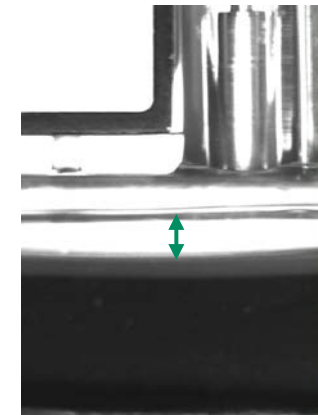
   RBCX

High Interface

1. Look through the viewport.
2. Check the patient's current Hct.
3. Check the replacement fluid Hct.

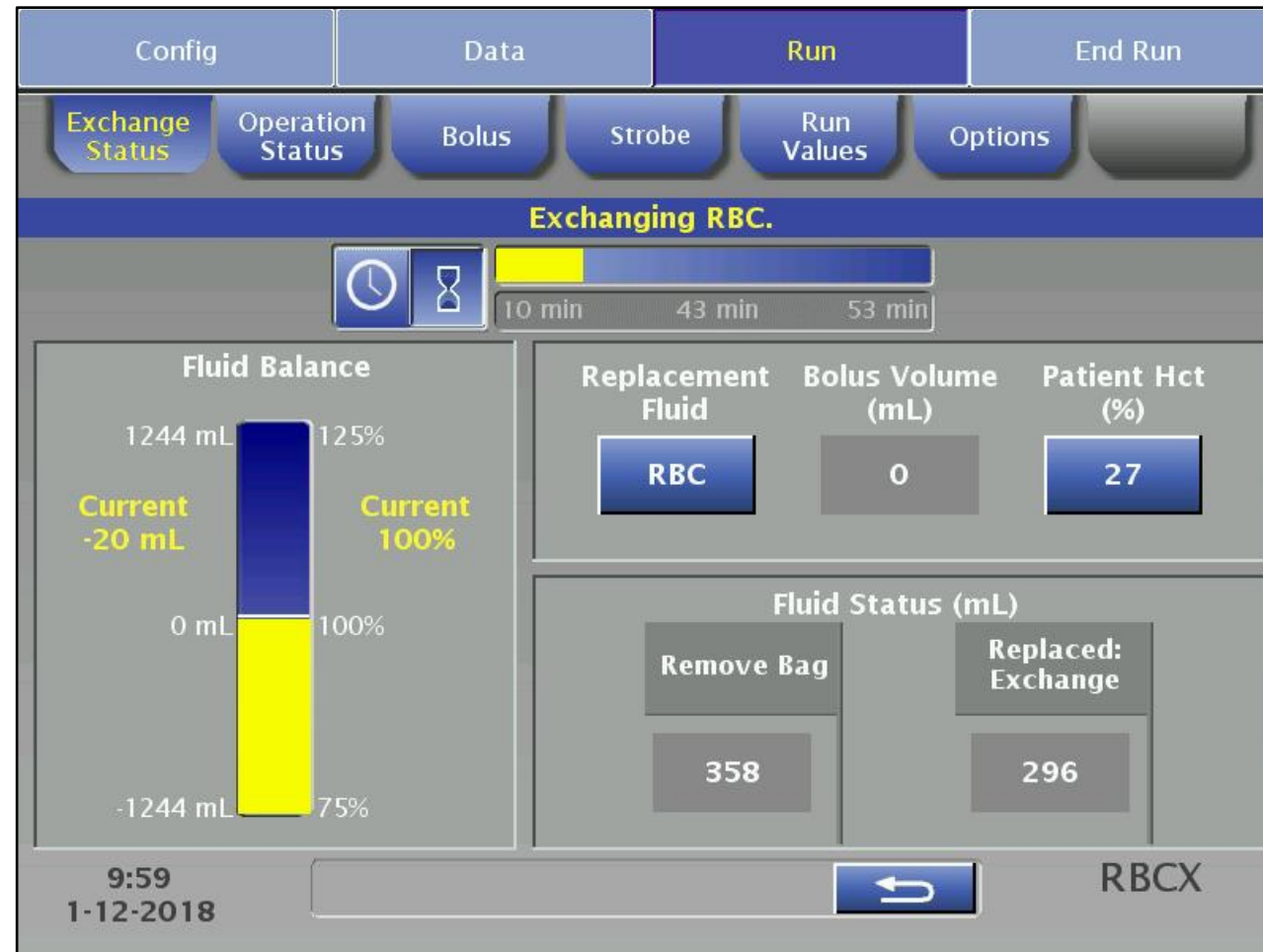


Typical RBCX
Interface



High RBCX
Interface

Updating the Patient's Hct – Pause



Questions?

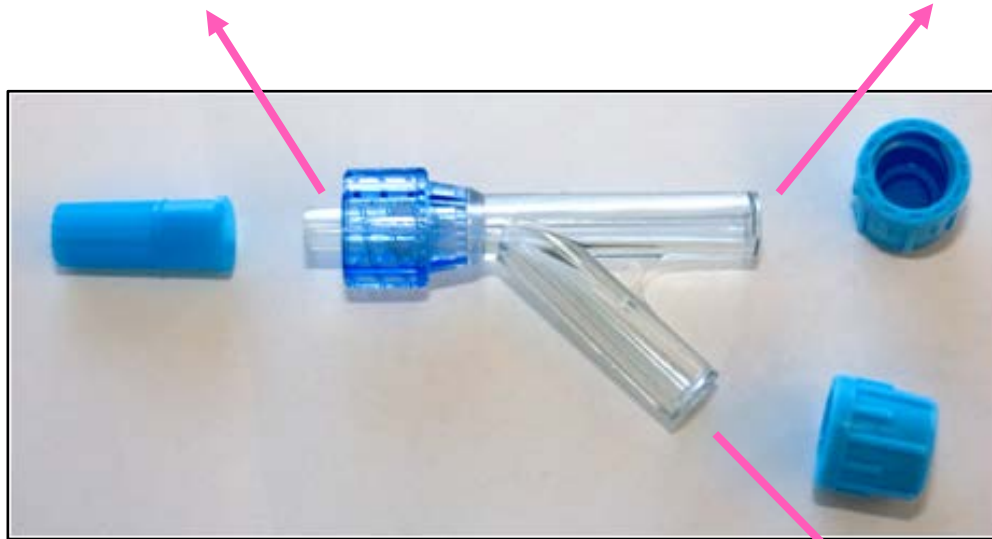
Single-Needle Procedures

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

Single-Needle Connector

Male luer connection to patient

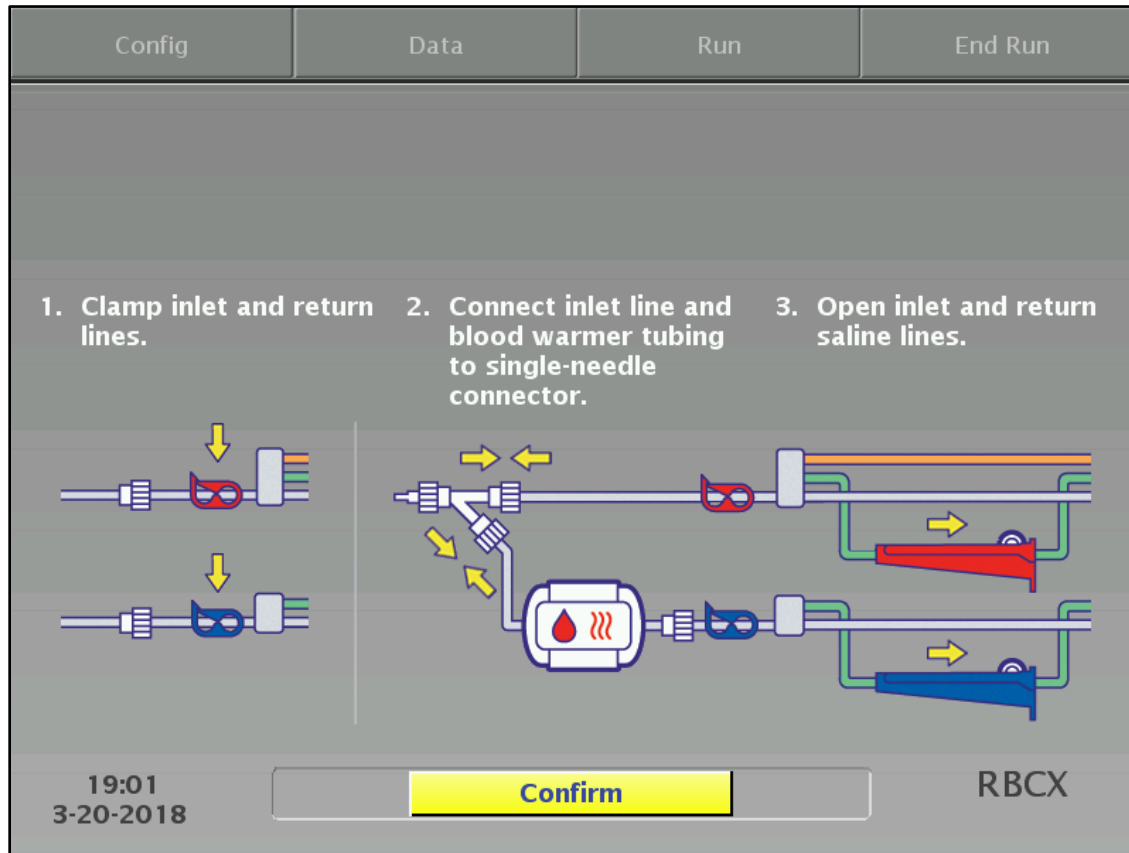
Female luer connection to inlet line



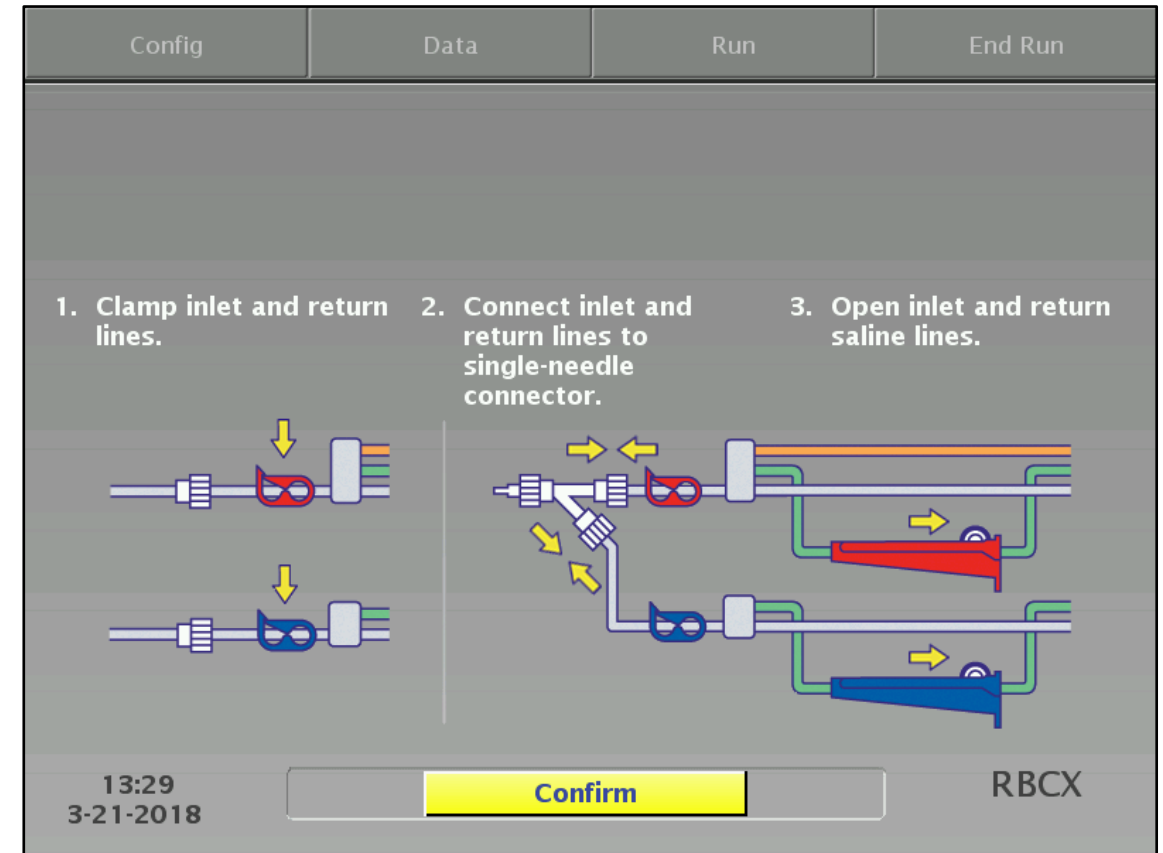
Female luer connection to return line

Convert to Single Needle

With blood warmer on return line

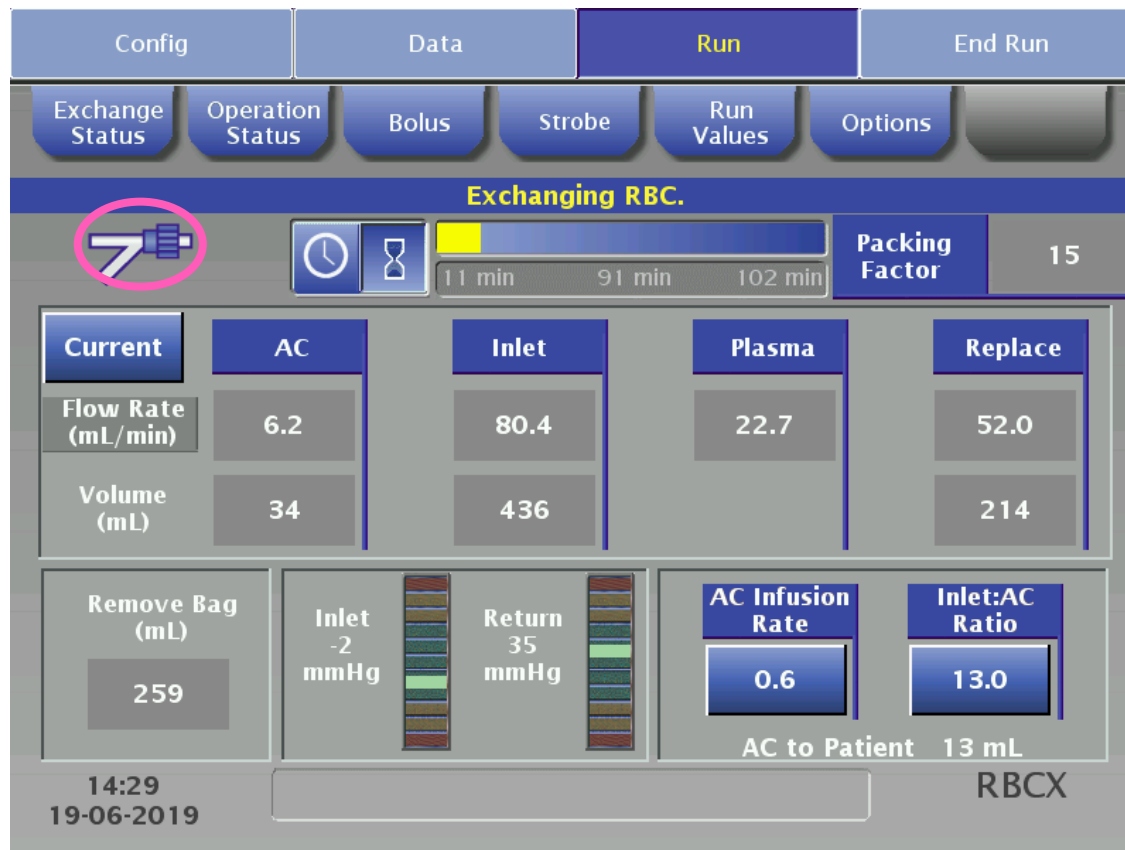


Without blood warmer on return line

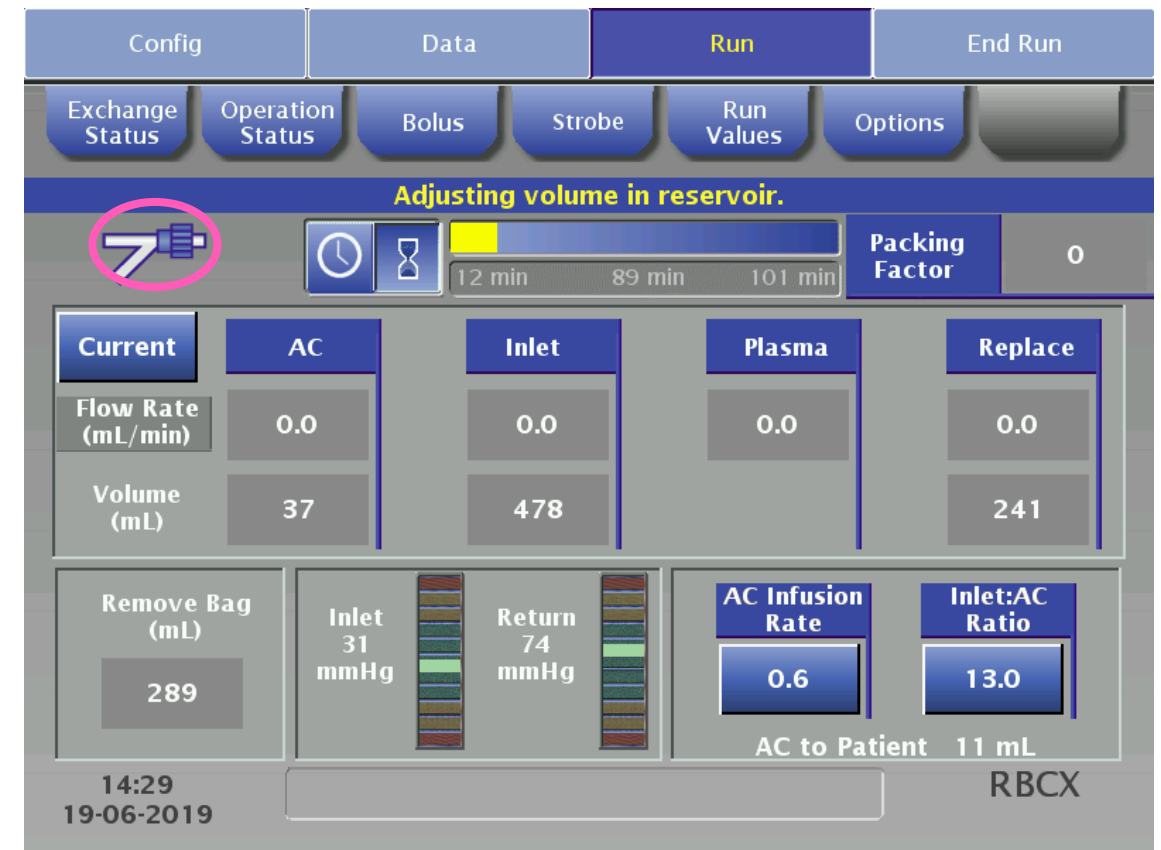


Convert to Single-Needle Access

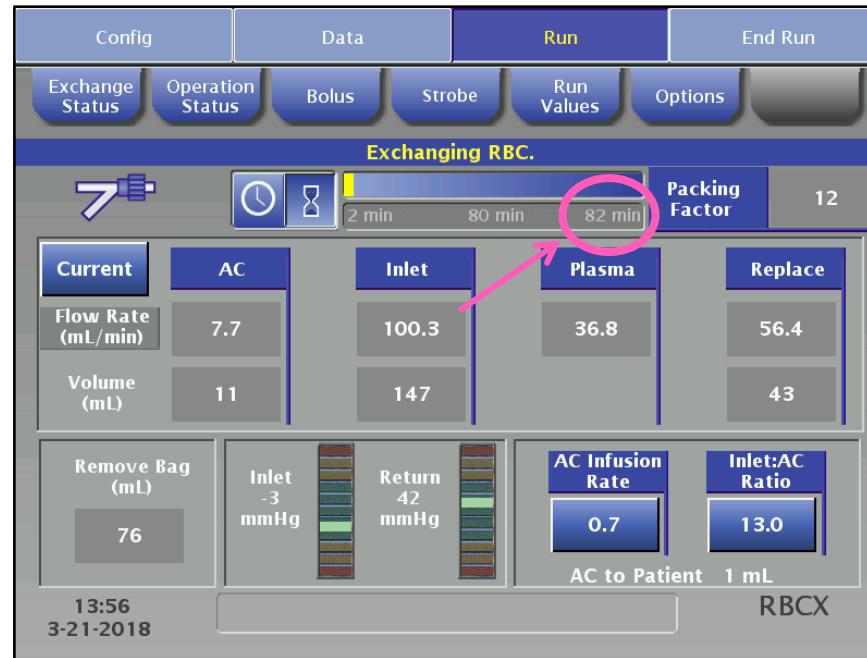
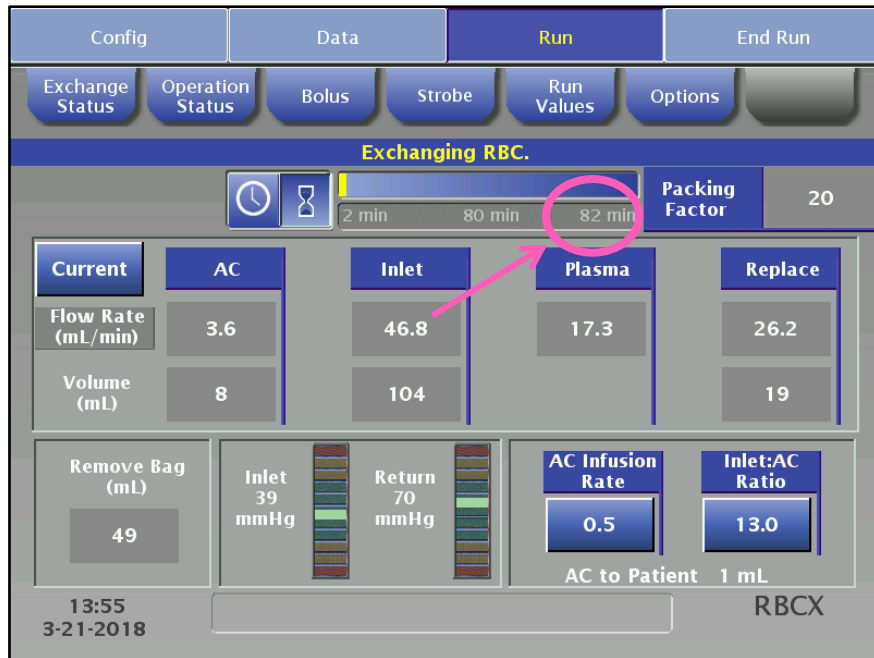
Draw Cycle



Return Cycle

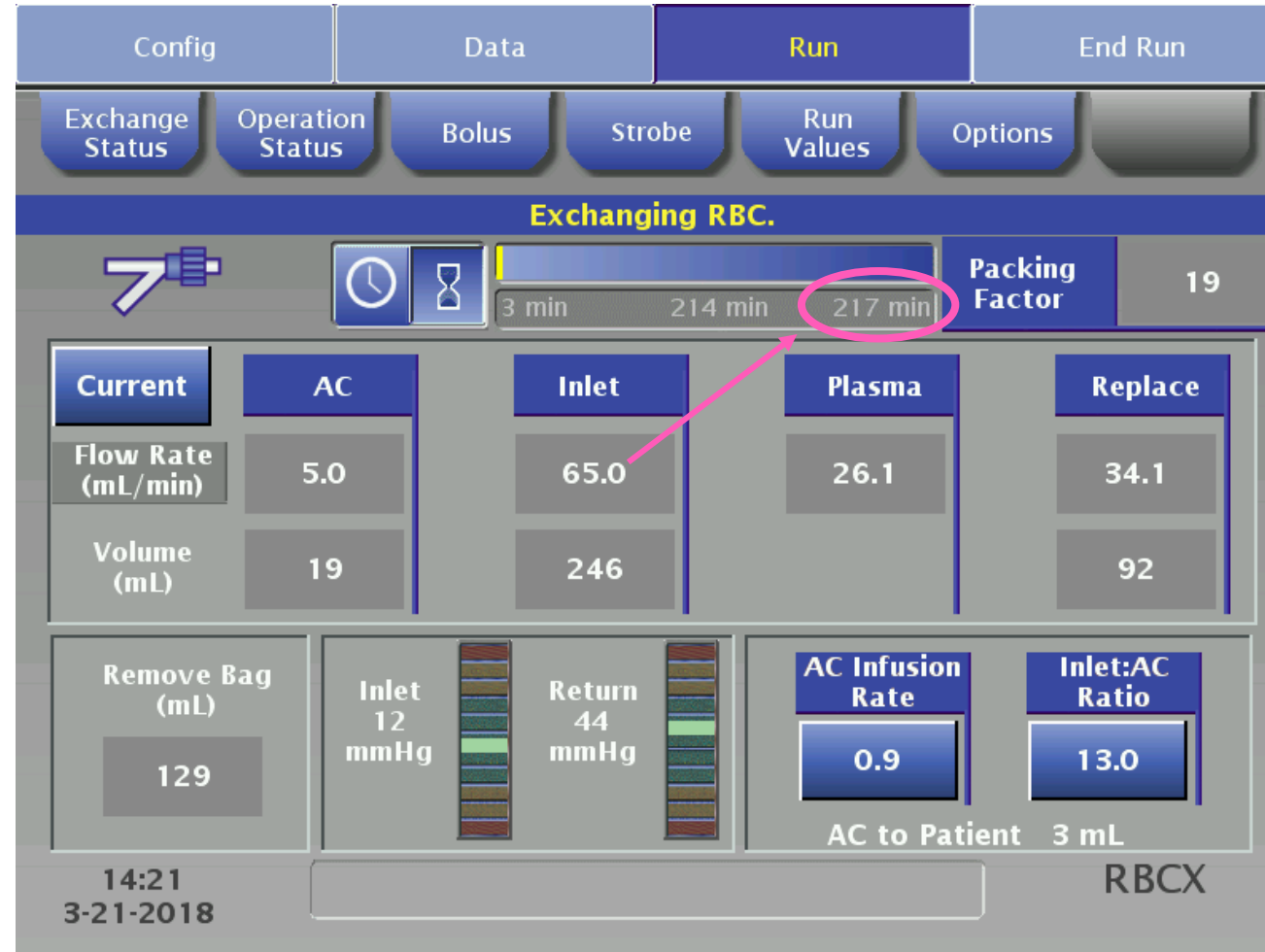


Optimization



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

Optimization



Questions?

Pediatric/Low-TBV Patients

- Minimum Data Entry Limits
- AC Management
- Fluid Balance
- Custom Prime
- Custom Prime – Albumin or RBC
- Custom Prime – RBC Hct 60%

Minimum Data Entry Limits

- Patient data

- Height: 12 inches 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.
- The system may set up an inlet pump flow rate of less than 5 mL/min and the operator can confirm it.

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

Config	Data	Run	End Run
Enter data for custom prime.			
<div><div>RBC</div><div>Plasma</div><div>Albumin</div></div>			
RBC Unit Hct (%)	Maximum Inlet Flow Rate (mL/min)	Volume (mL)	
0	100	300	
11:20 5-12-2013	Confirm		 RBCX

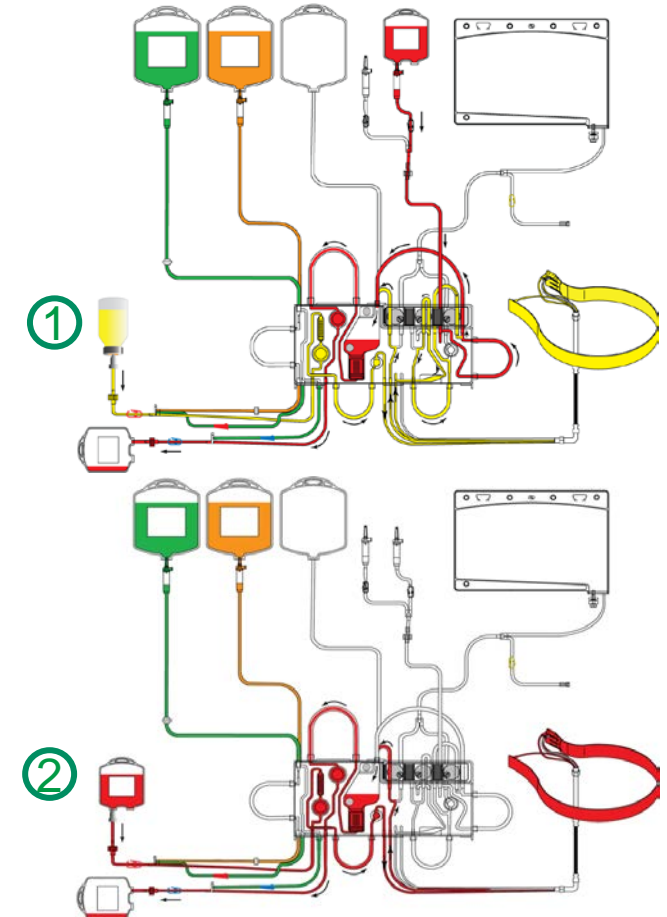
Custom Prime – Albumin or RBC

1. Albumin

- No extra RBC are required.
- Hct in the return line is the same as the patient Hct at the start of the procedure.

2. RBC

- Extra RBC are required.
- Hct in the return line is the same as the RBC Hct at the start of the procedure.
- RBC in the channel are sent to the patient at the start of the procedure.



Questions?

Thank You

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