TERUMO BLOOD AND CELL TECHNOLOGIES

Red Blood Cell Exchange (V12 RBCX) Rx Only Procedure Training

(Including single-needle option)

Spectra Optia® Apheresis System

TS-OPTI-00799

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 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

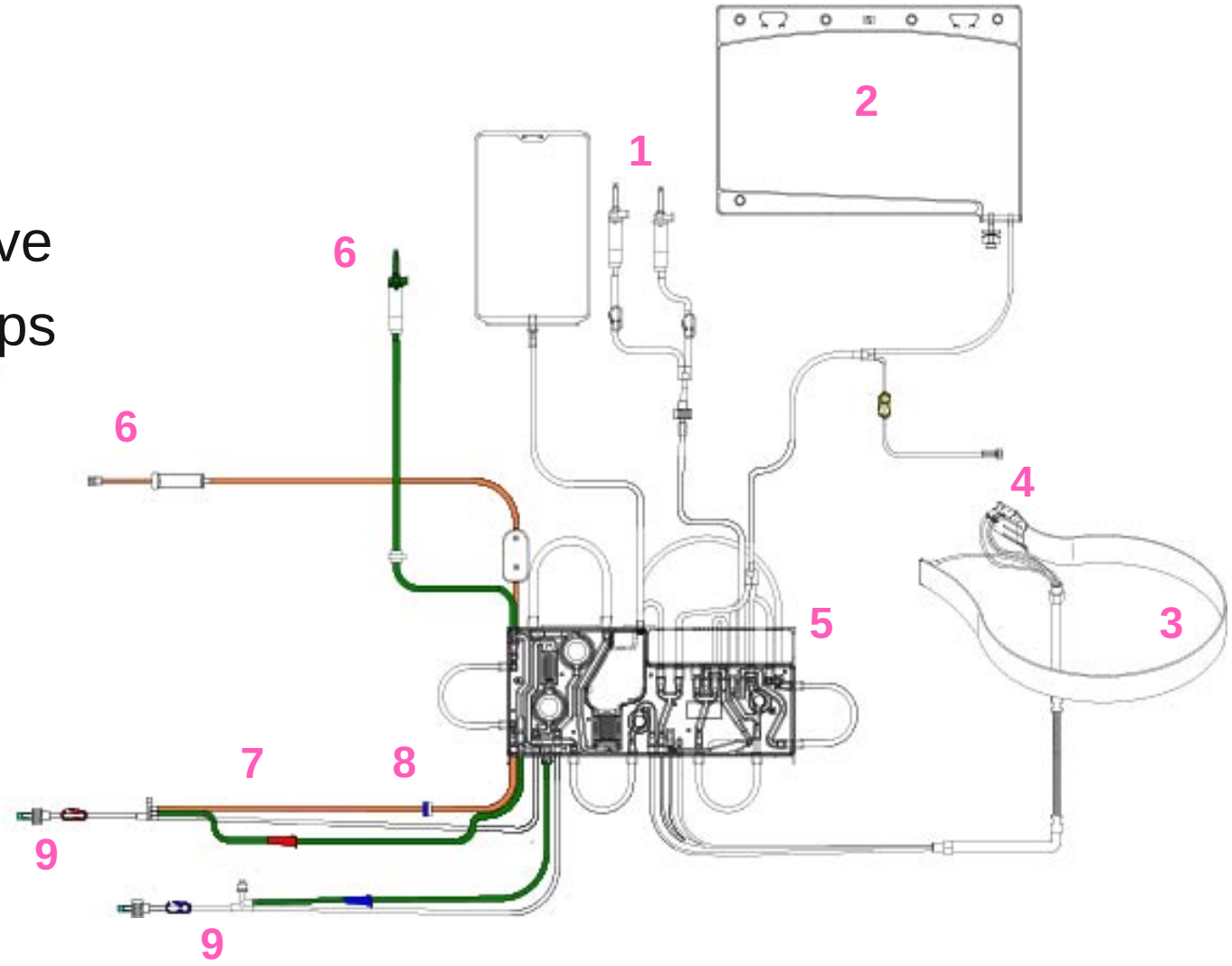
- Introduction
- Preparing to Perform the Procedure
- Exchange
- Depletion
- Depletion/Exchange
- Making Changes
- Optimization
- Troubleshooting
- Single-Needle
- Pediatric/Low-TBV Patients

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

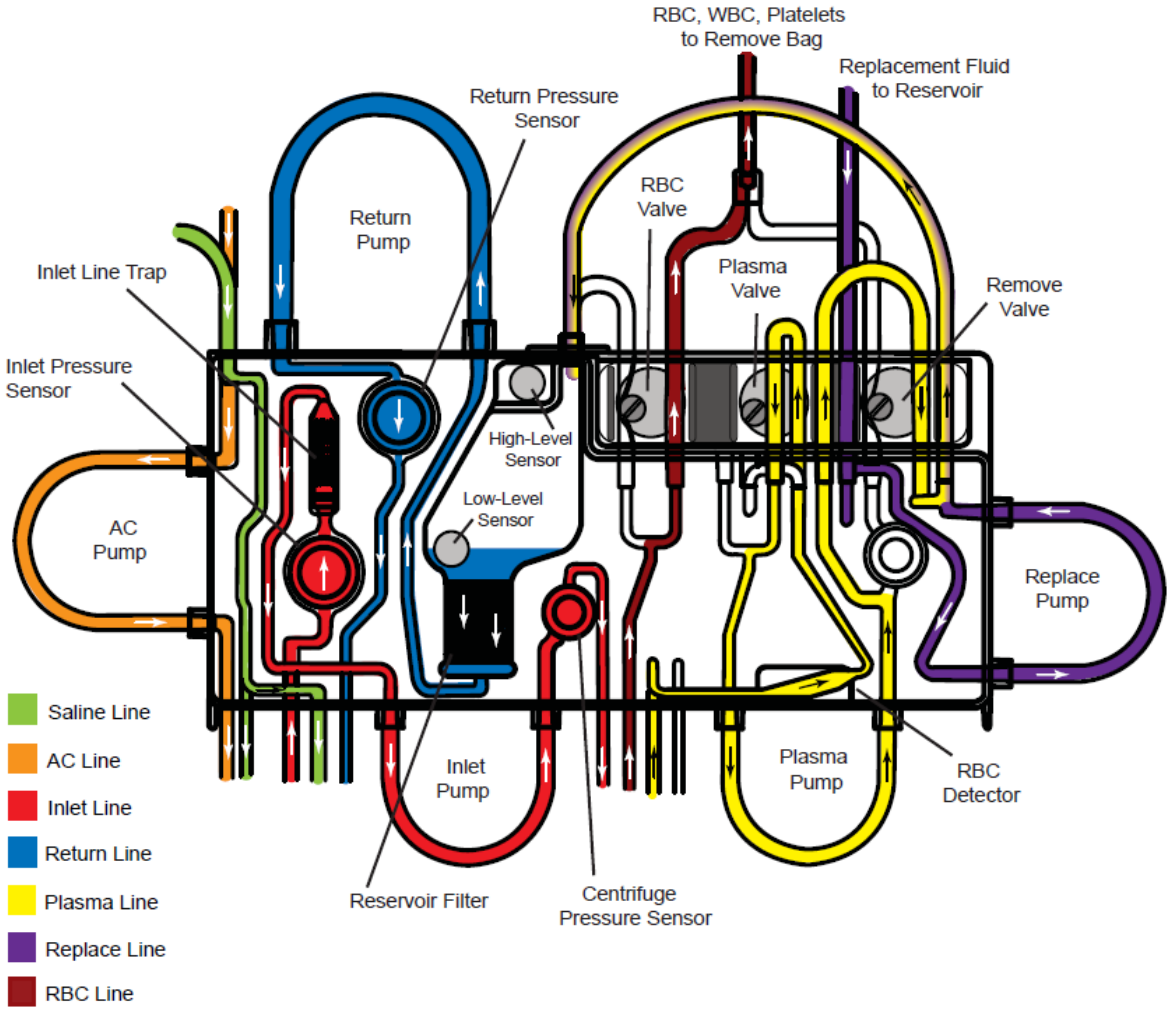


*Correct Connect availability is dependent upon regulatory approval

Basic Principles of RBCX

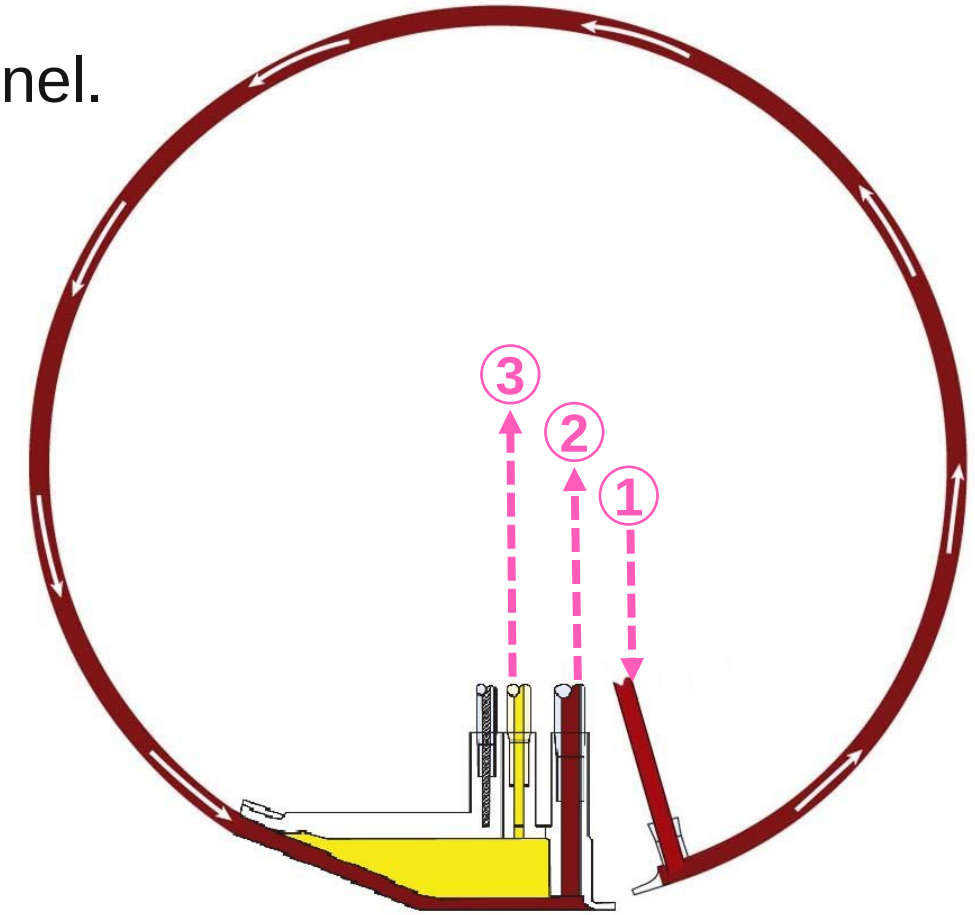
- Indications for RBCX
- Procedure goals:
  - Remove defective or excessive red blood cells (RBC)
  - Infuse replacement fluid
  - Change patient’s hematocrit (Hct) (increase or decrease)
  - Maintain fluid balance
- Replacement fluids

Basic Principles of RBCX – Flow Path



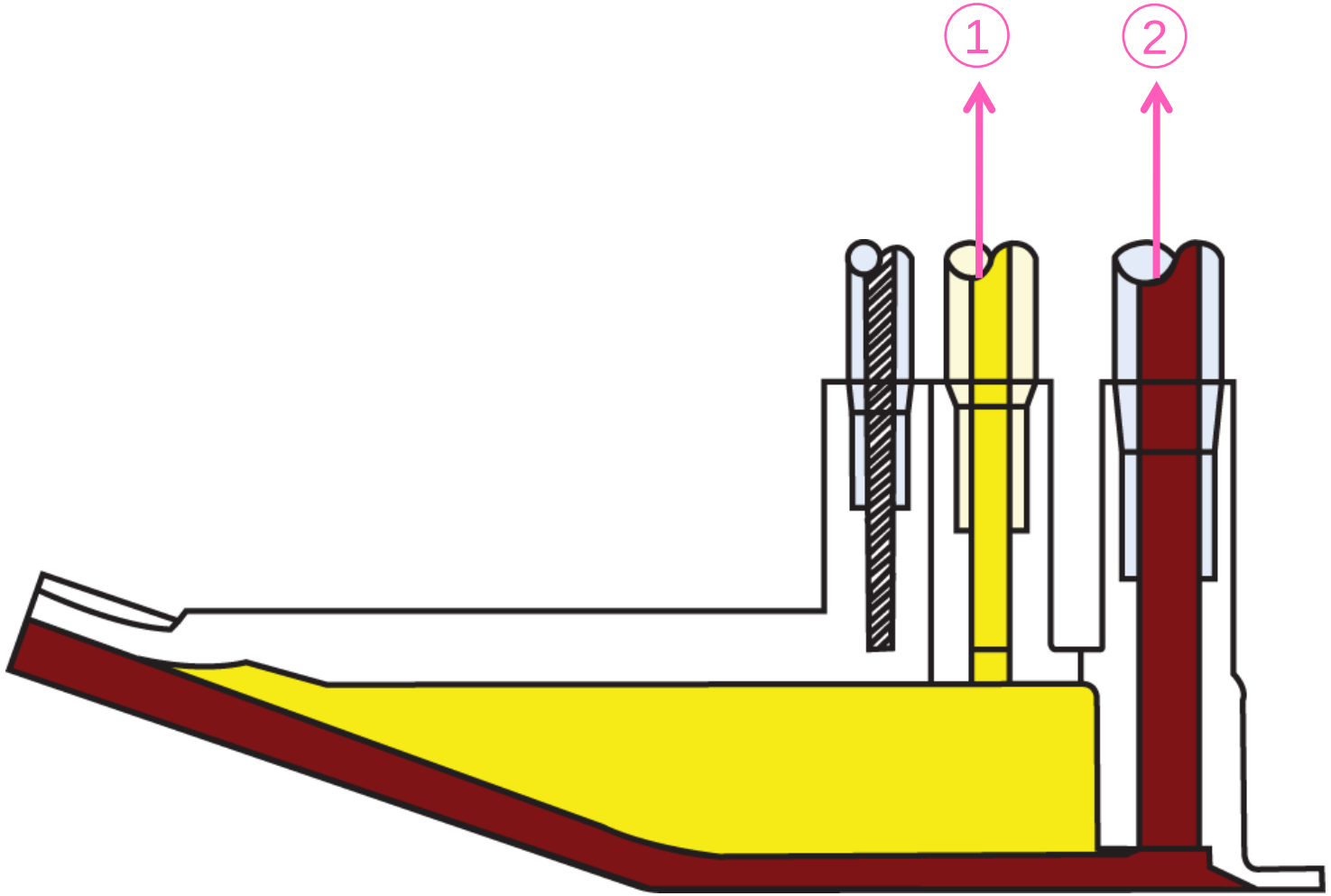
Basic Principles of RBCX – Channel

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

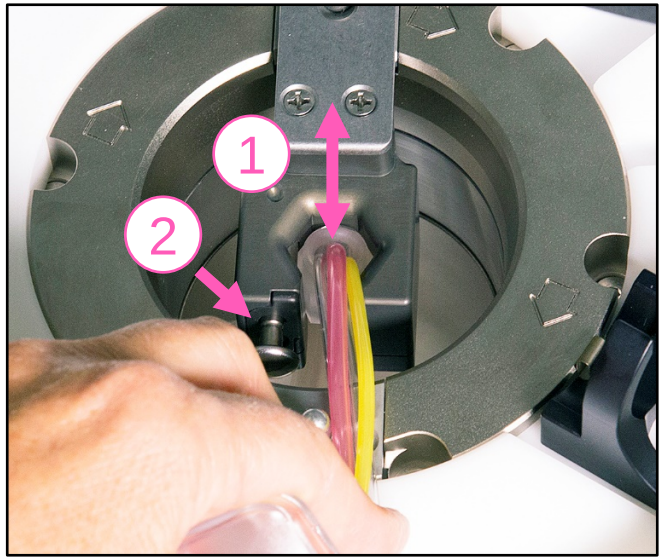
Configuration – RBCX Procedures

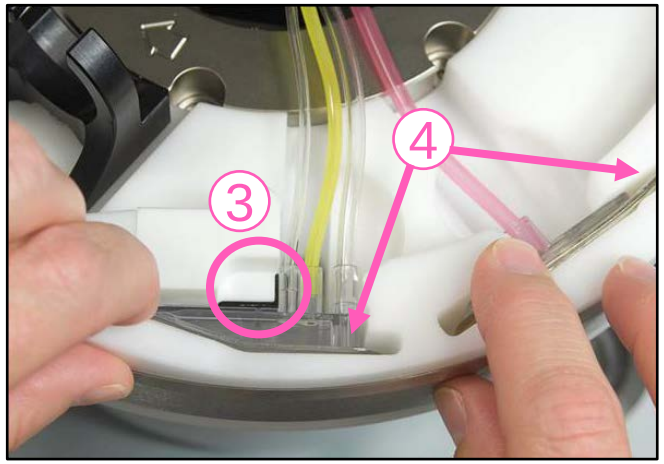
Configuration – Blood Warmer

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.

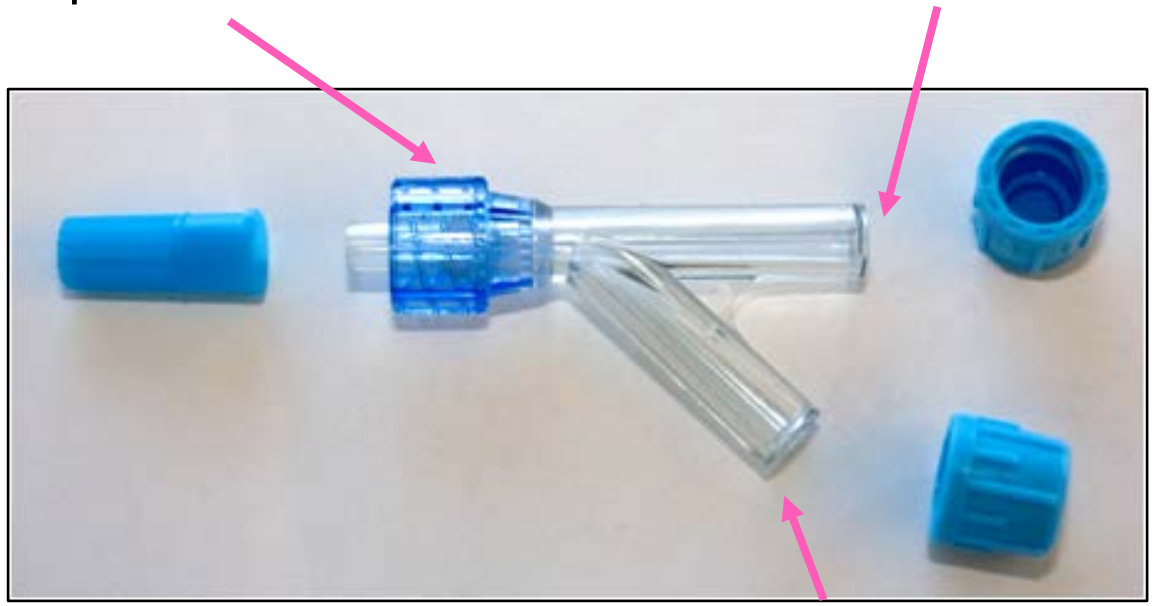




Single-Needle Procedure

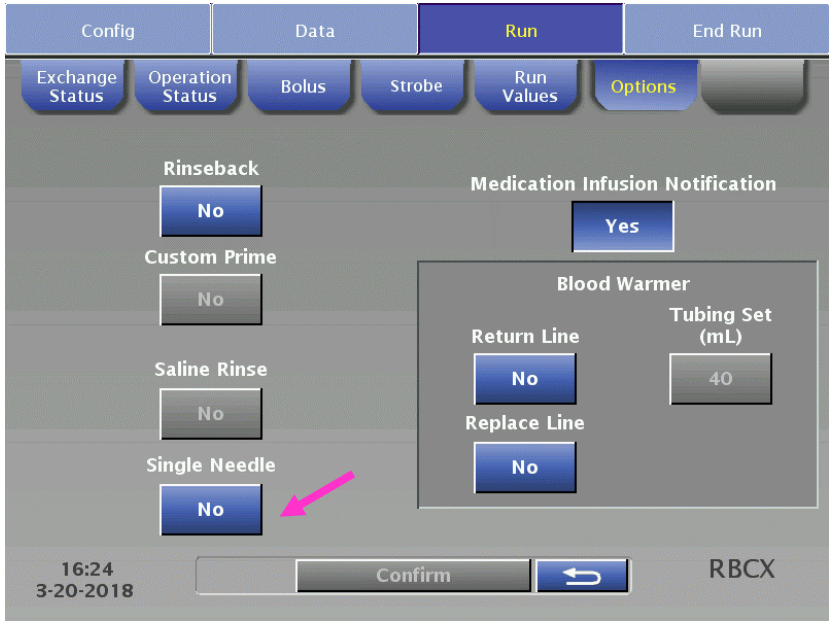
Male luer connection to patient

Female luer connection to inlet line



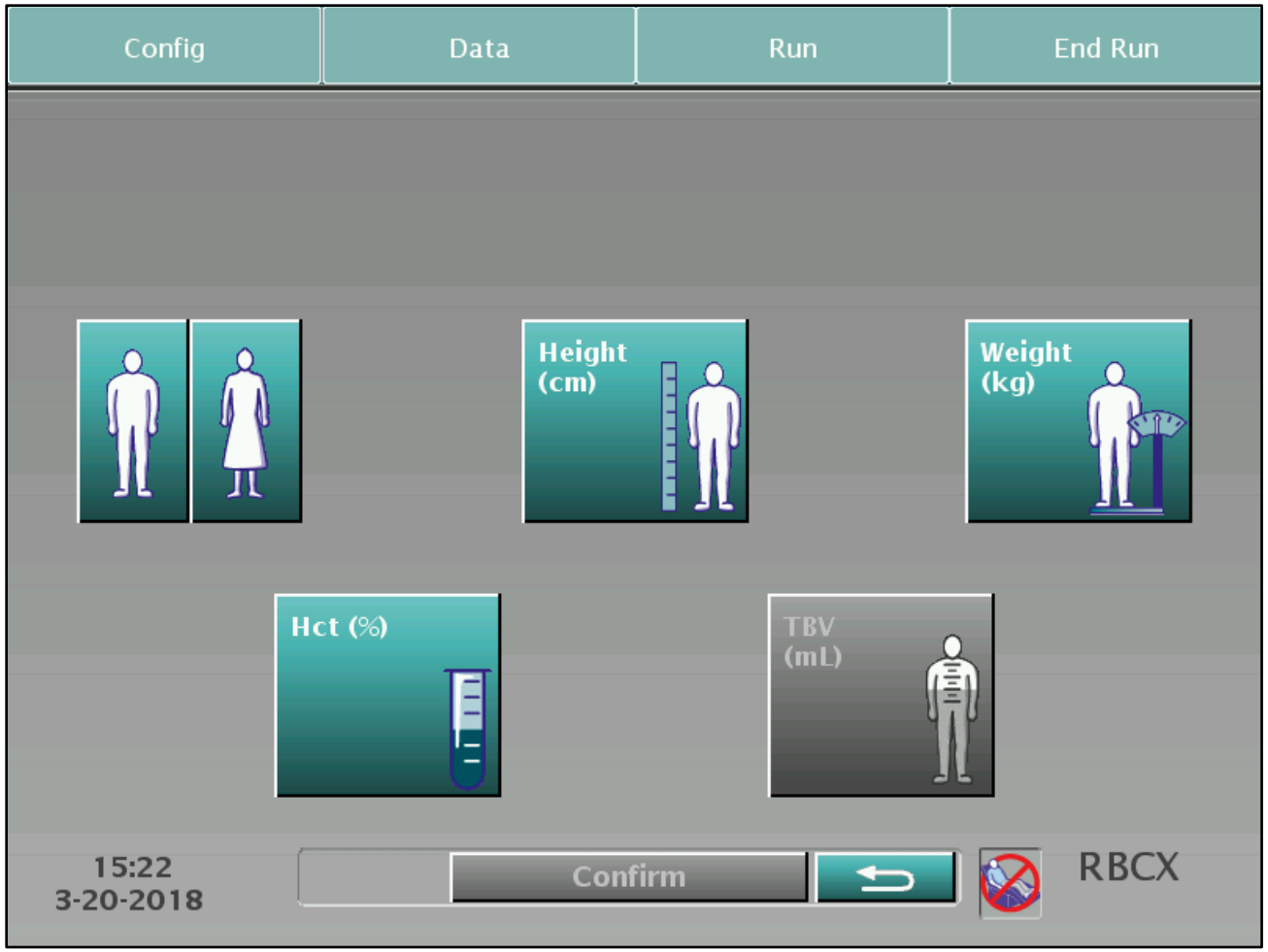
Female luer connection to return line

- Converting to Single-Needle Access

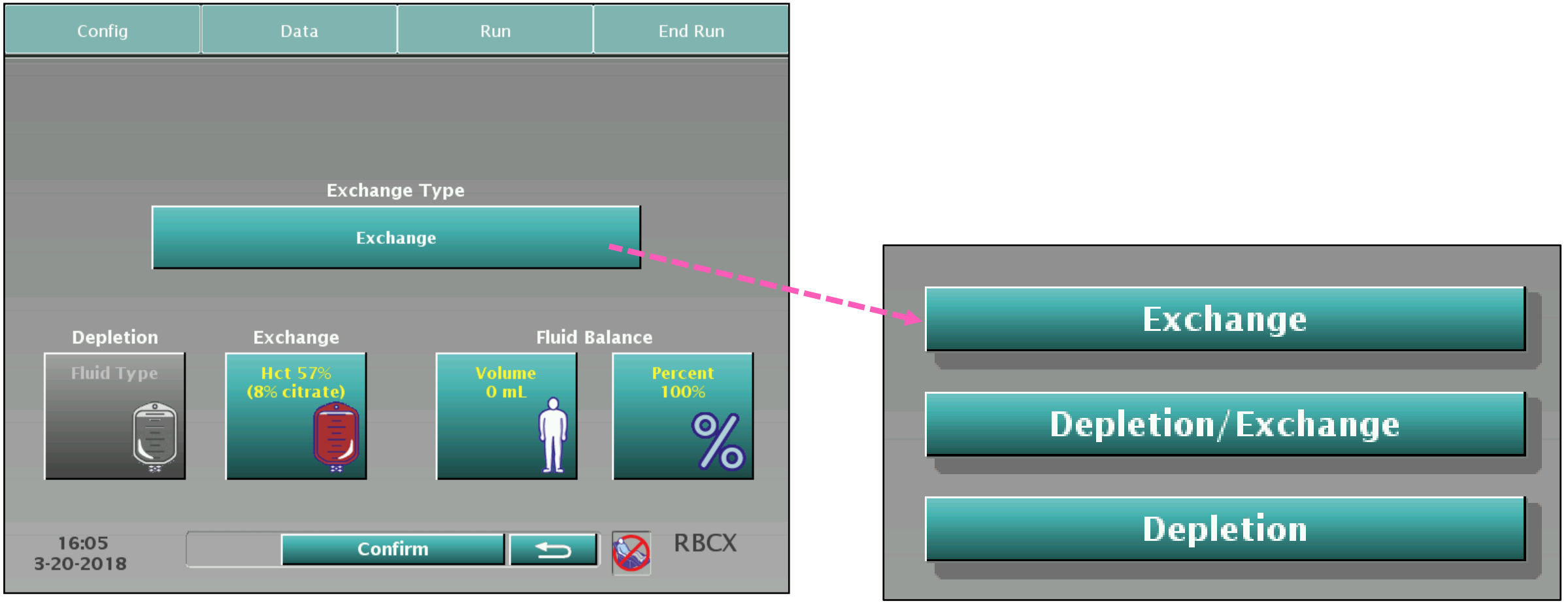


Touch **Single Needle** on the Options screen and follow the on-screen instructions.

Patient Data

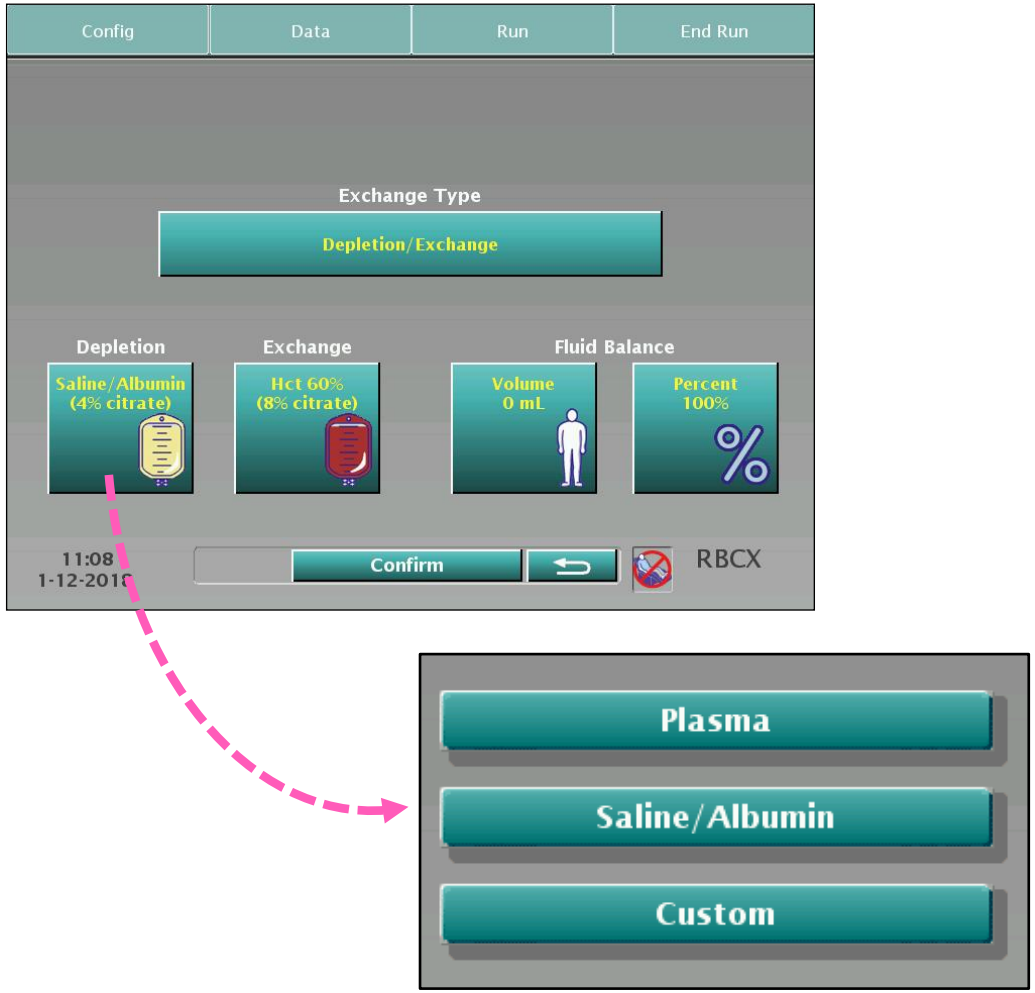


Exchange Type



Fluid Data

- Replacement fluids
- Fluid balance



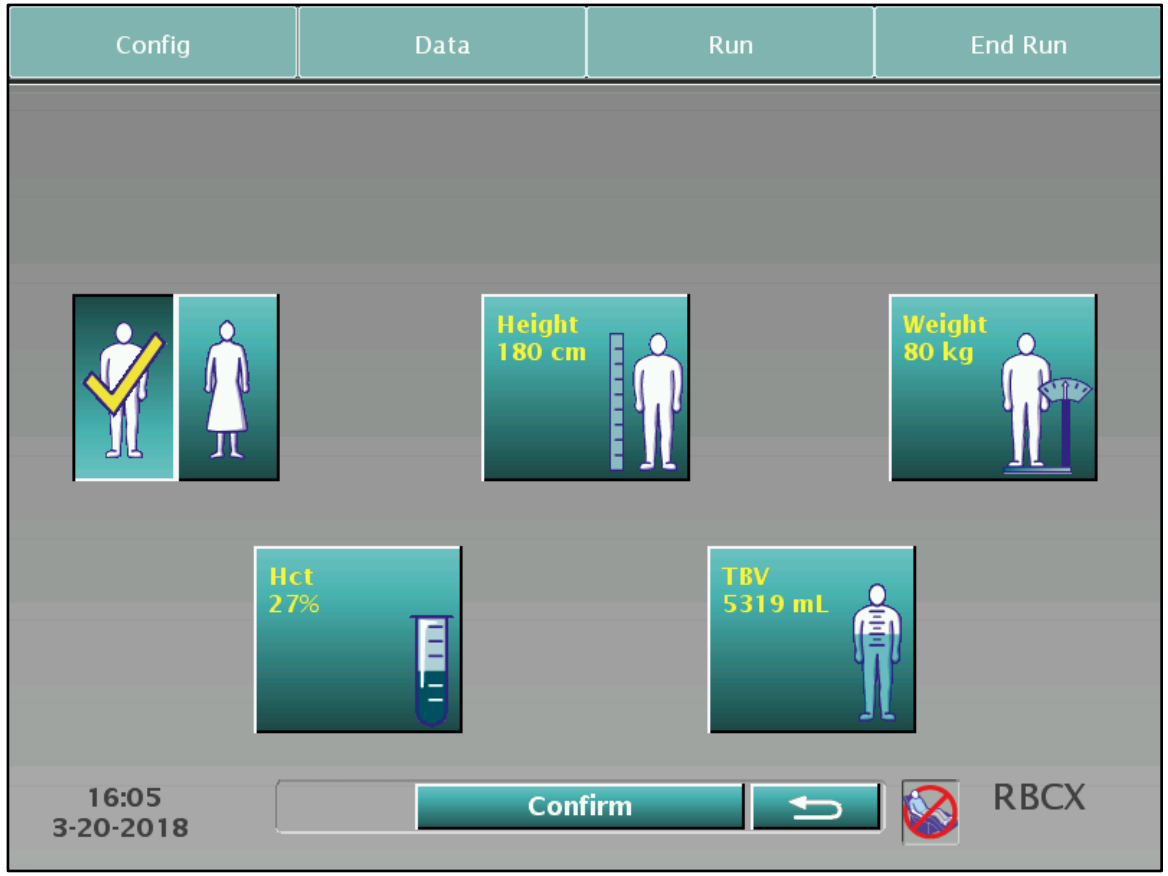
Questions?

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

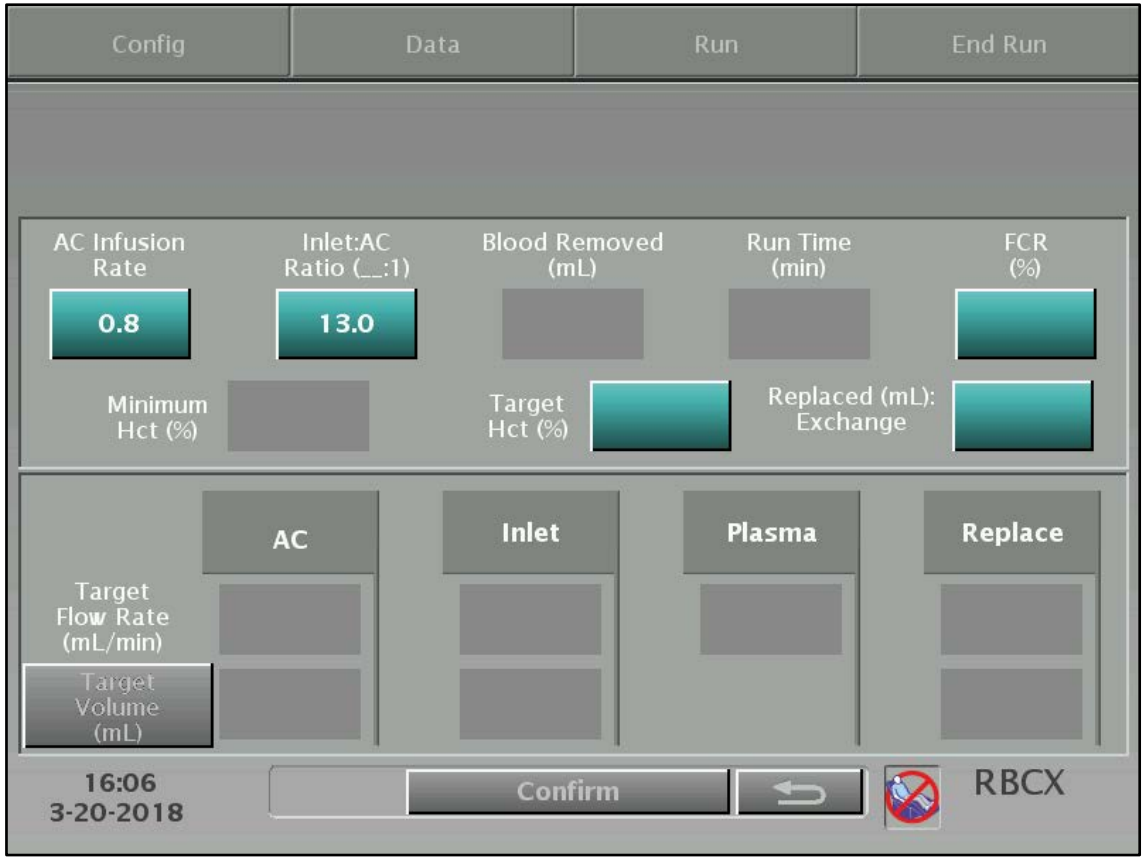
Data Entry

Patient Data



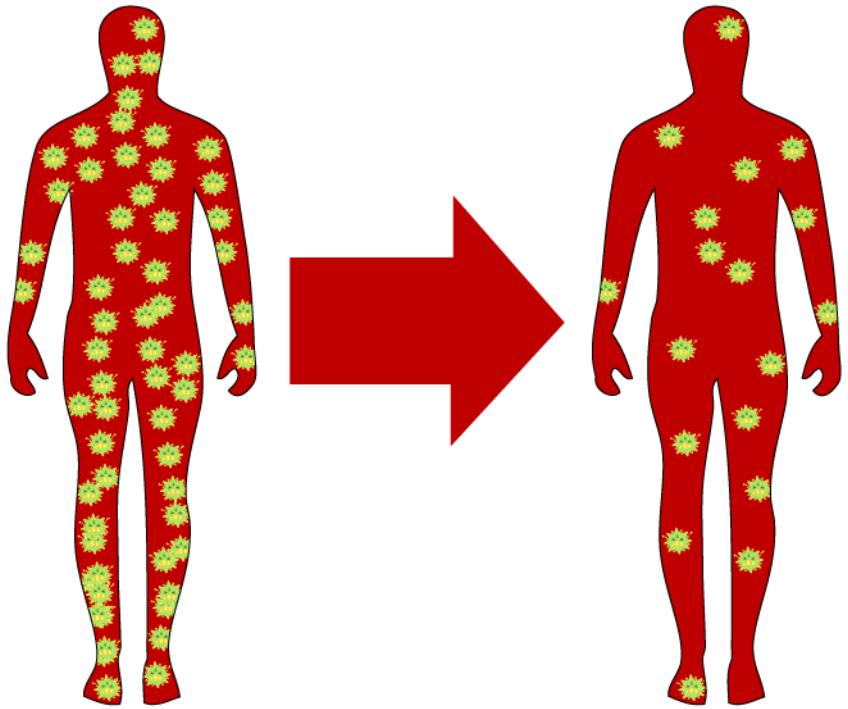
Fluid Data

Run Values


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


Config
Data
Run
End Run
AC Infusion Rate
0.8
Inlet:AC Ratio (__:1)
13.0
Blood Removed (mL)
3494
Run Time (min)
119
FCR (%)
30
Minimum Hct (%)
27
Target Hct (%)
32
Replaced (mL): Exchange
3291
AC
Inlet
Plasma
Replace
Target Flow Rate (mL/min)
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%

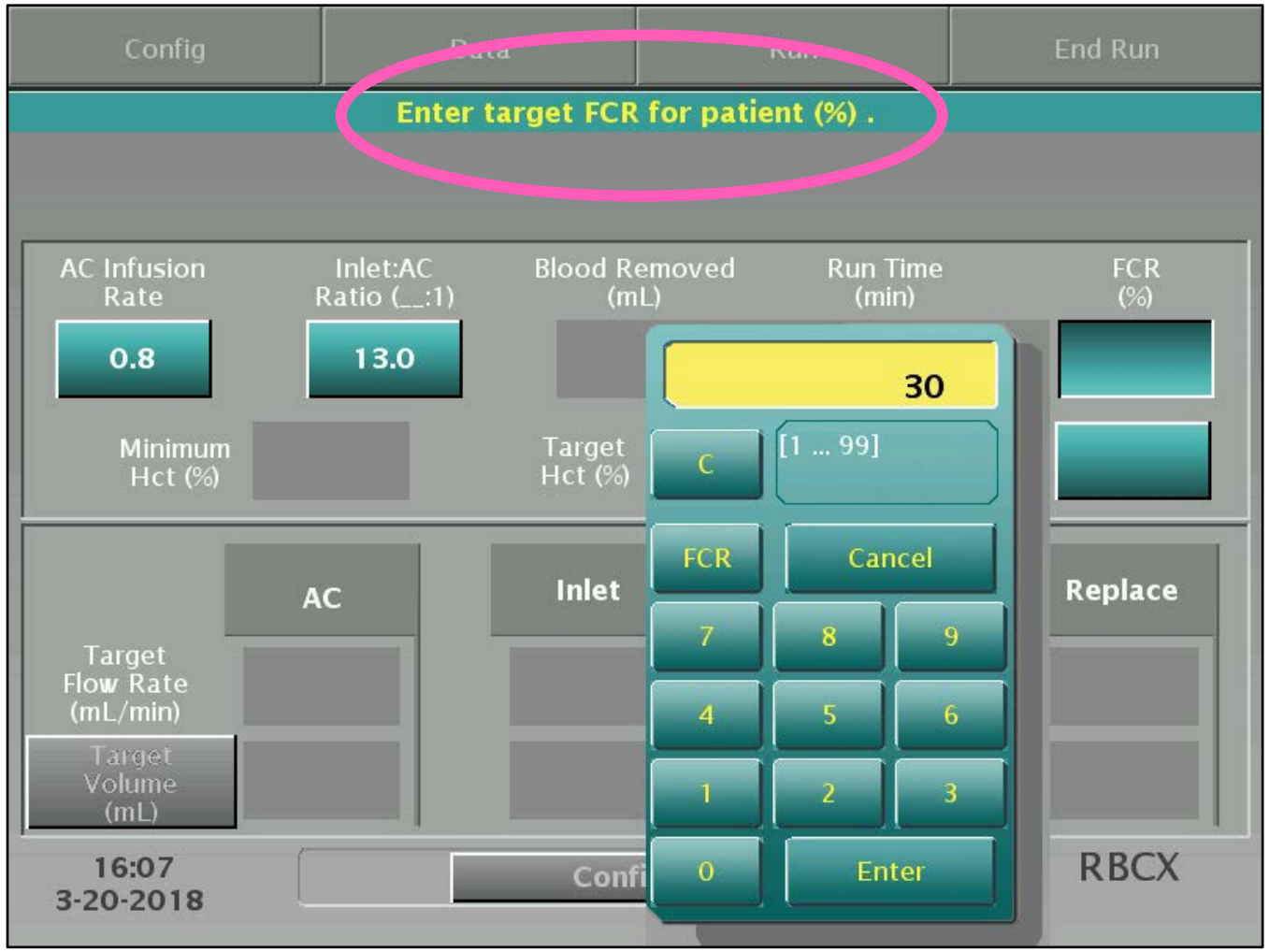
Target Defective RBC (Post)

18%

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

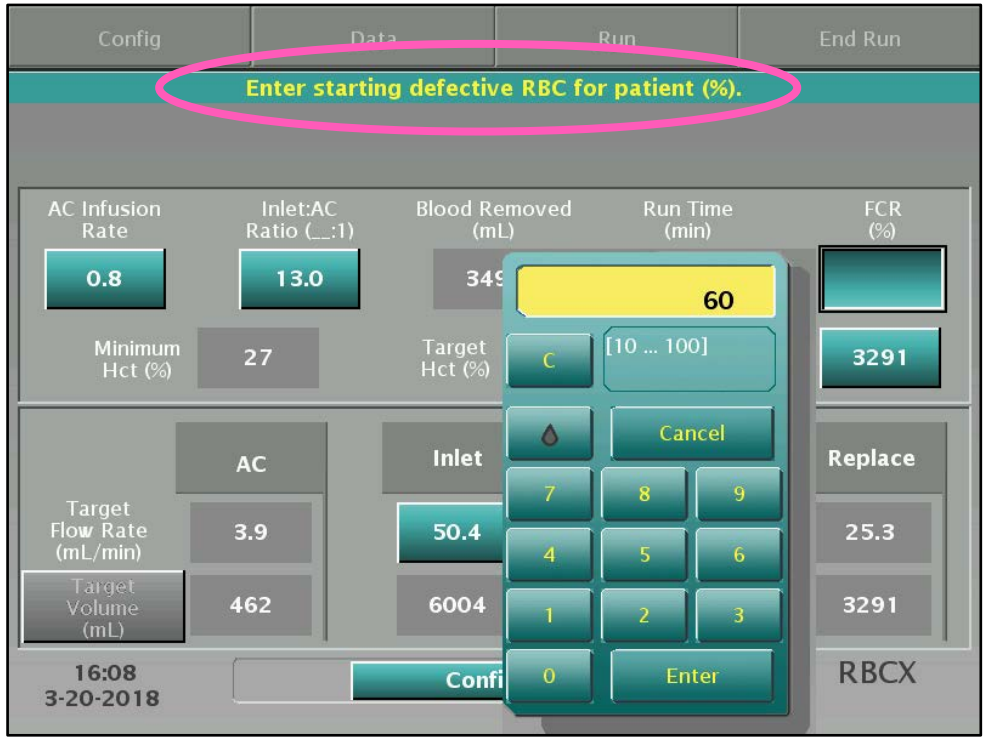
$$\frac{18\%}{60\%} = \frac{30\%}{\text{Target FCR}}$$

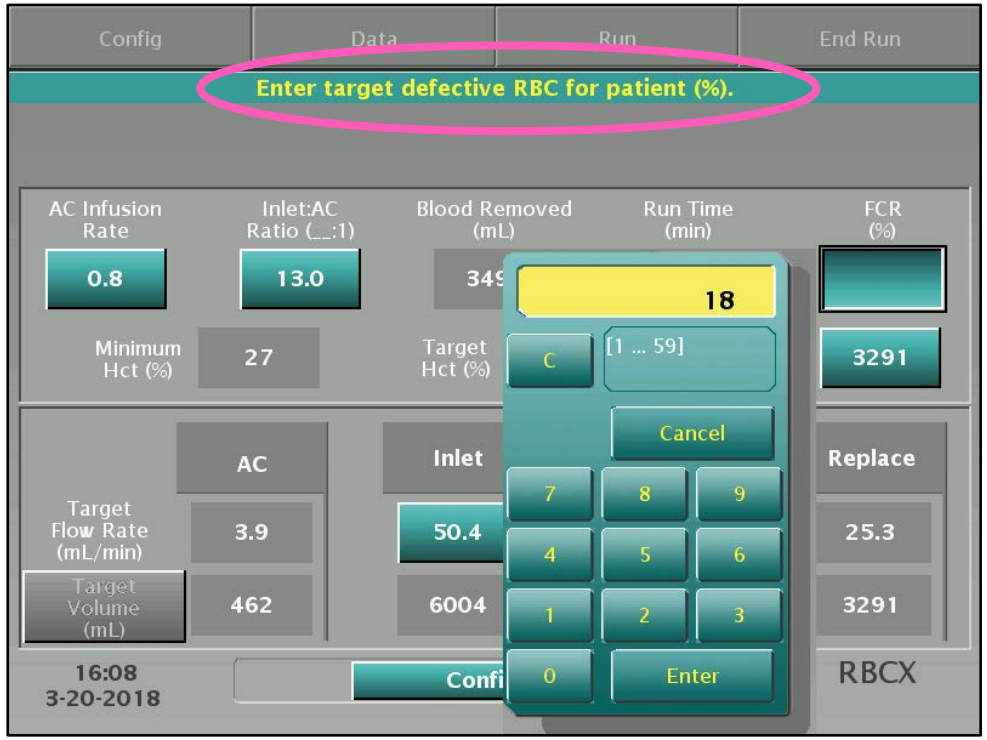
Enter FCR


Config
End Run
Enter target FCR for patient (%) .
AC Infusion Rate
0.8
Inlet:AC Ratio (__:1)
13.0
Blood Removed (mL)
Run Time (min)
FCR (%)
Minimum Hct (%)
Target Hct (%)
30
C
[1 ... 99]
FCR
Cancel
7
8
9
4
5
6
1
2
3
0
Enter
AC
Inlet
Replace
Target Flow Rate (mL/min)
Target Volume (mL)
16:07
3-20-2018
RBCX

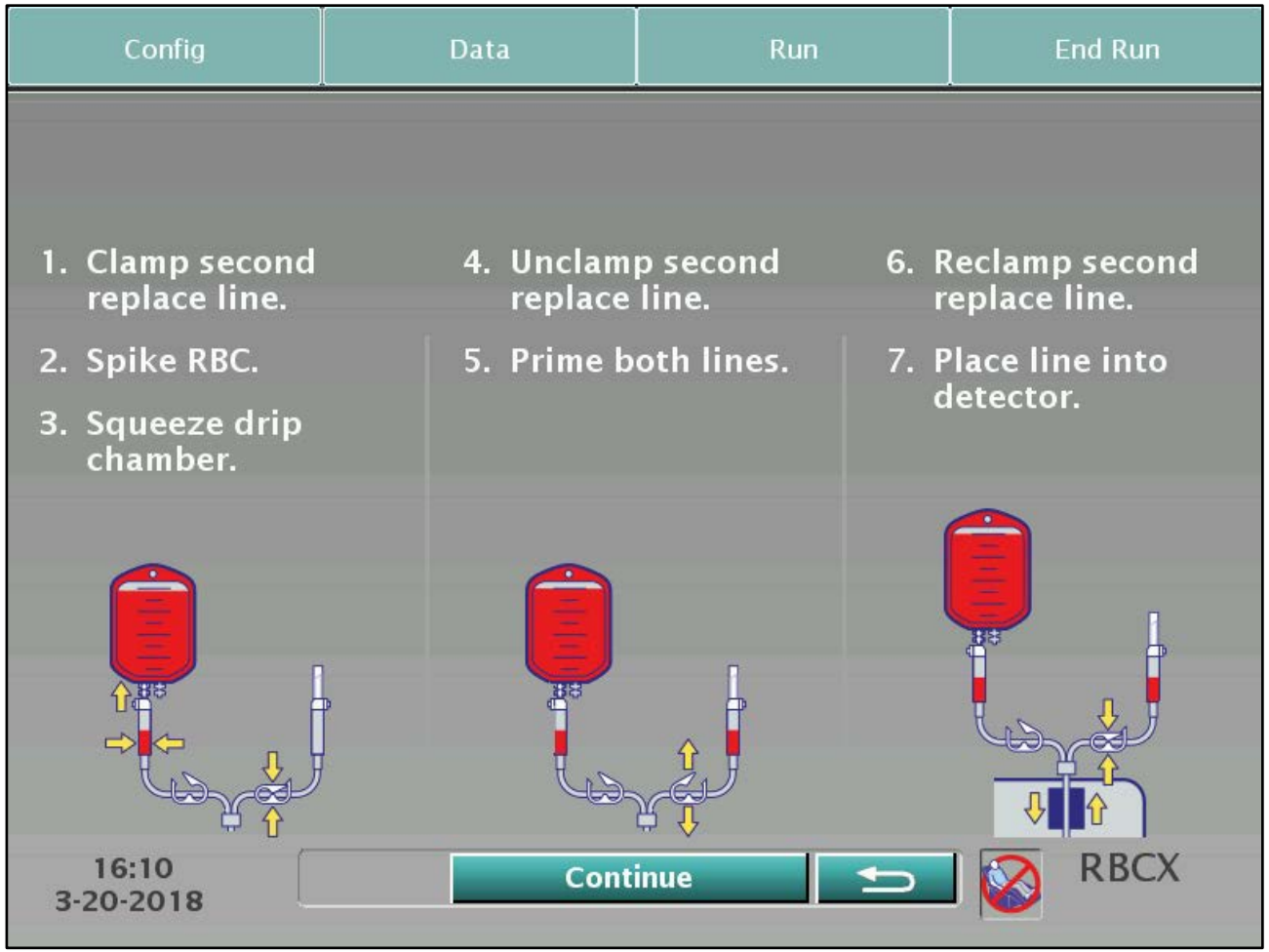
FCR: System-Calculated

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

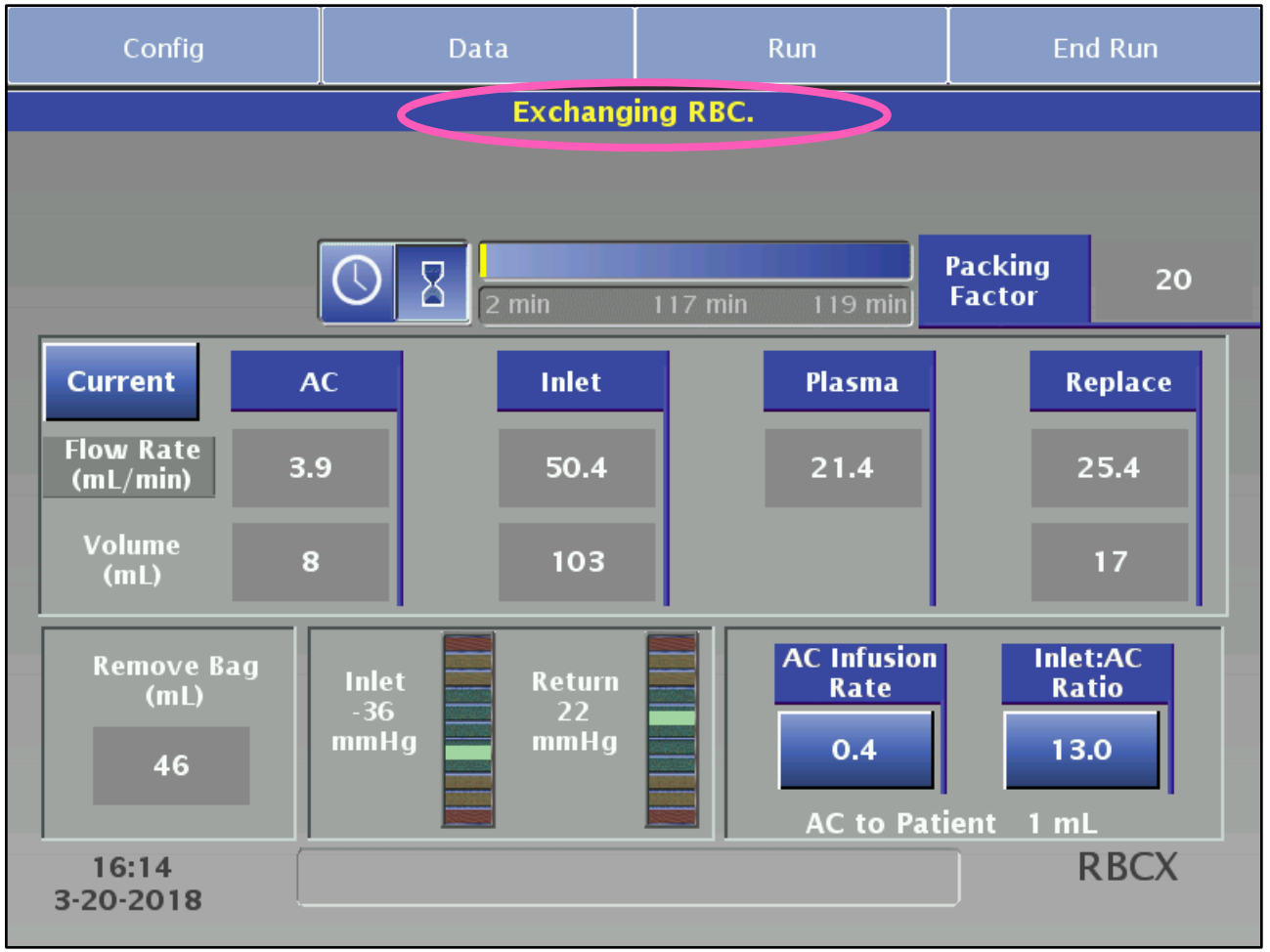




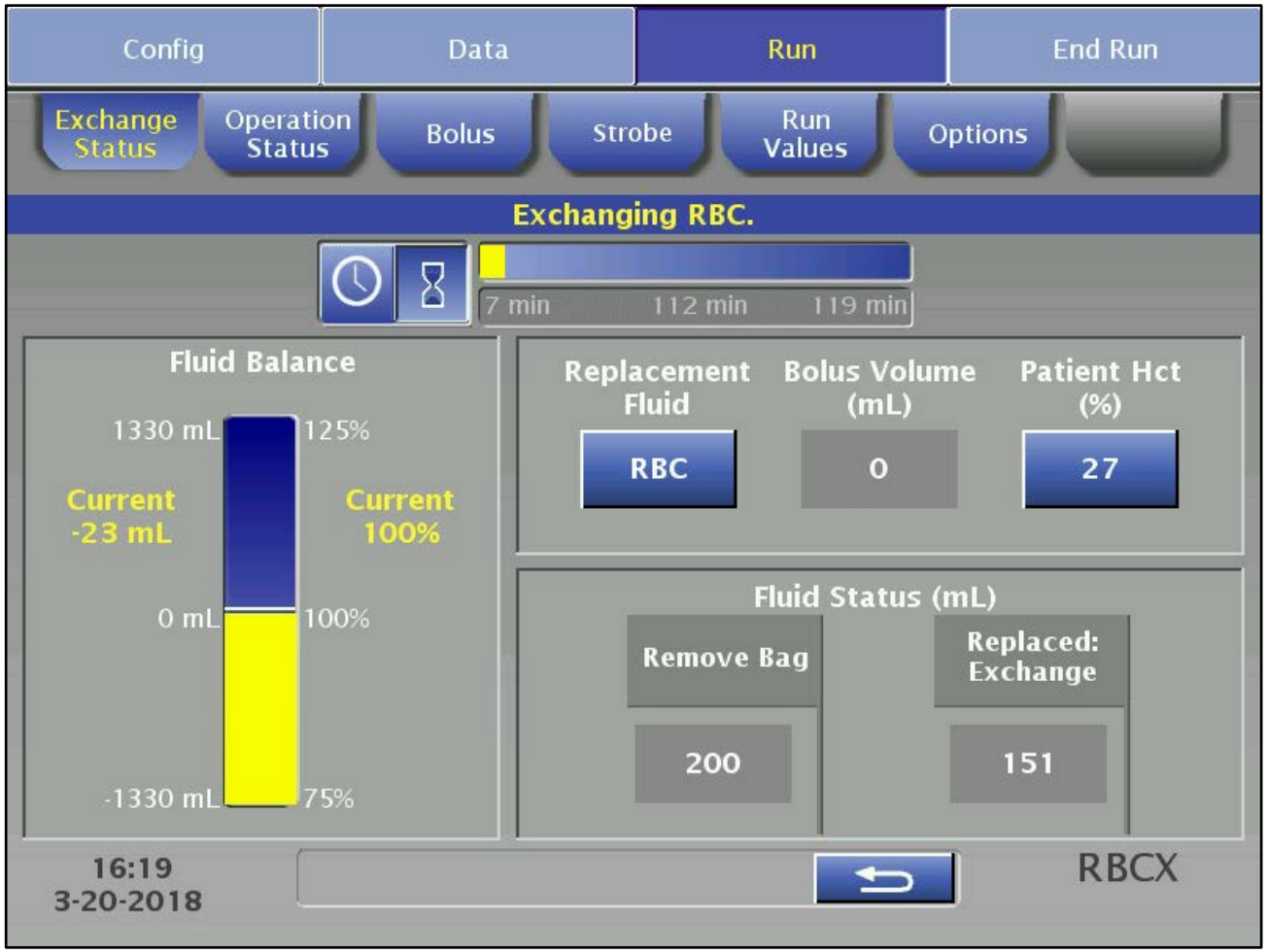
Spike Replacement Fluid



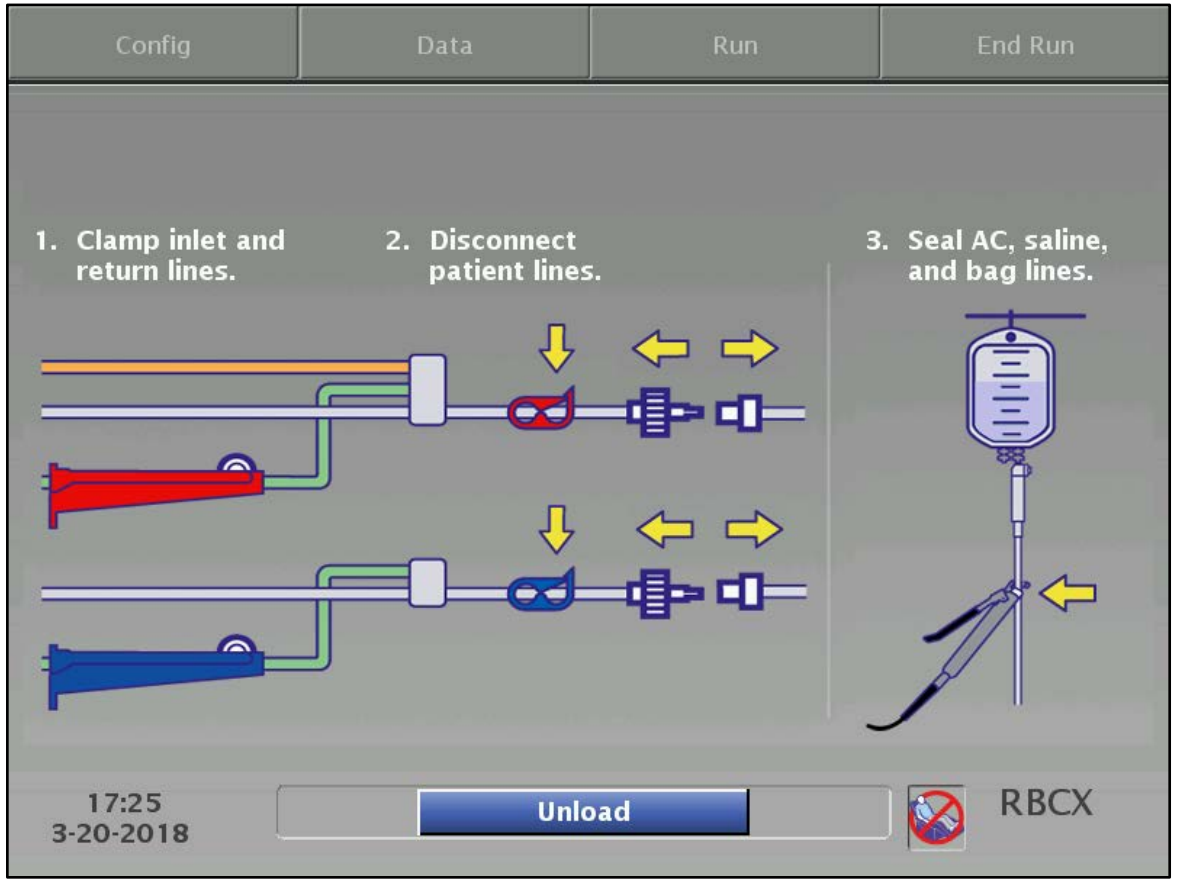
Main Run


Config
Data
Run
End Run
Exchanging RBC.
2 min
117 min
119 min
Packing Factor
20
Current
AC
Inlet
Plasma
Replace
Flow Rate (mL/min)
3.9
50.4
21.4
25.4
Volume (mL)
8
103
17
Remove Bag (mL)
46
Inlet -36 mmHg
Return 22 mmHg
AC Infusion Rate
0.4
Inlet:AC Ratio
13.0
AC to Patient 1 mL
16:14
3-20-2018
RBCX

Exchange Status



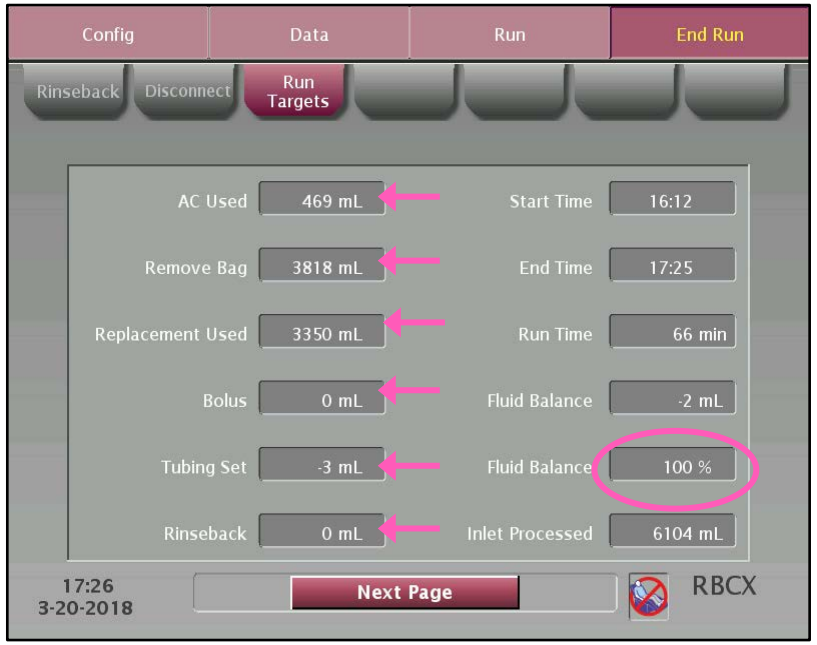
Run Targets Attained and Disconnect



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



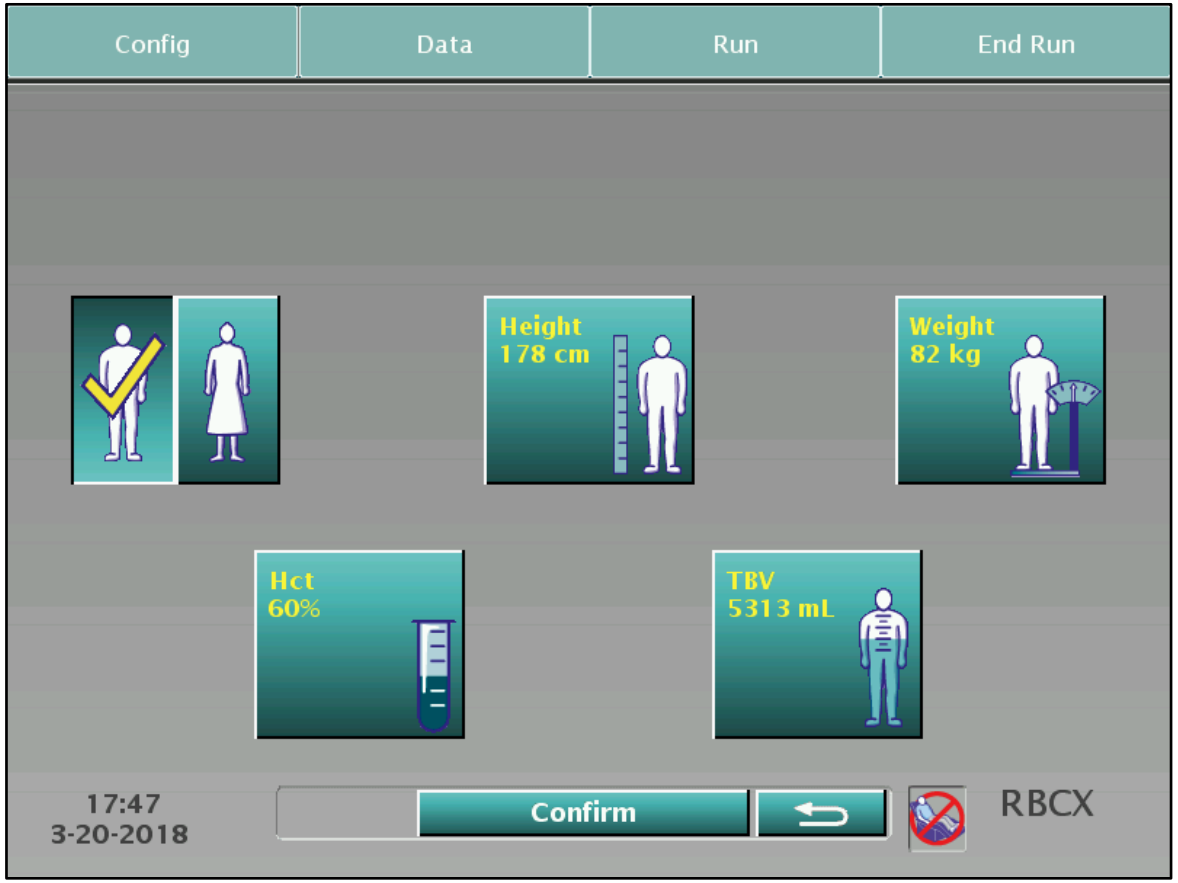
Questions?

Depletion

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

Data

Patient Data

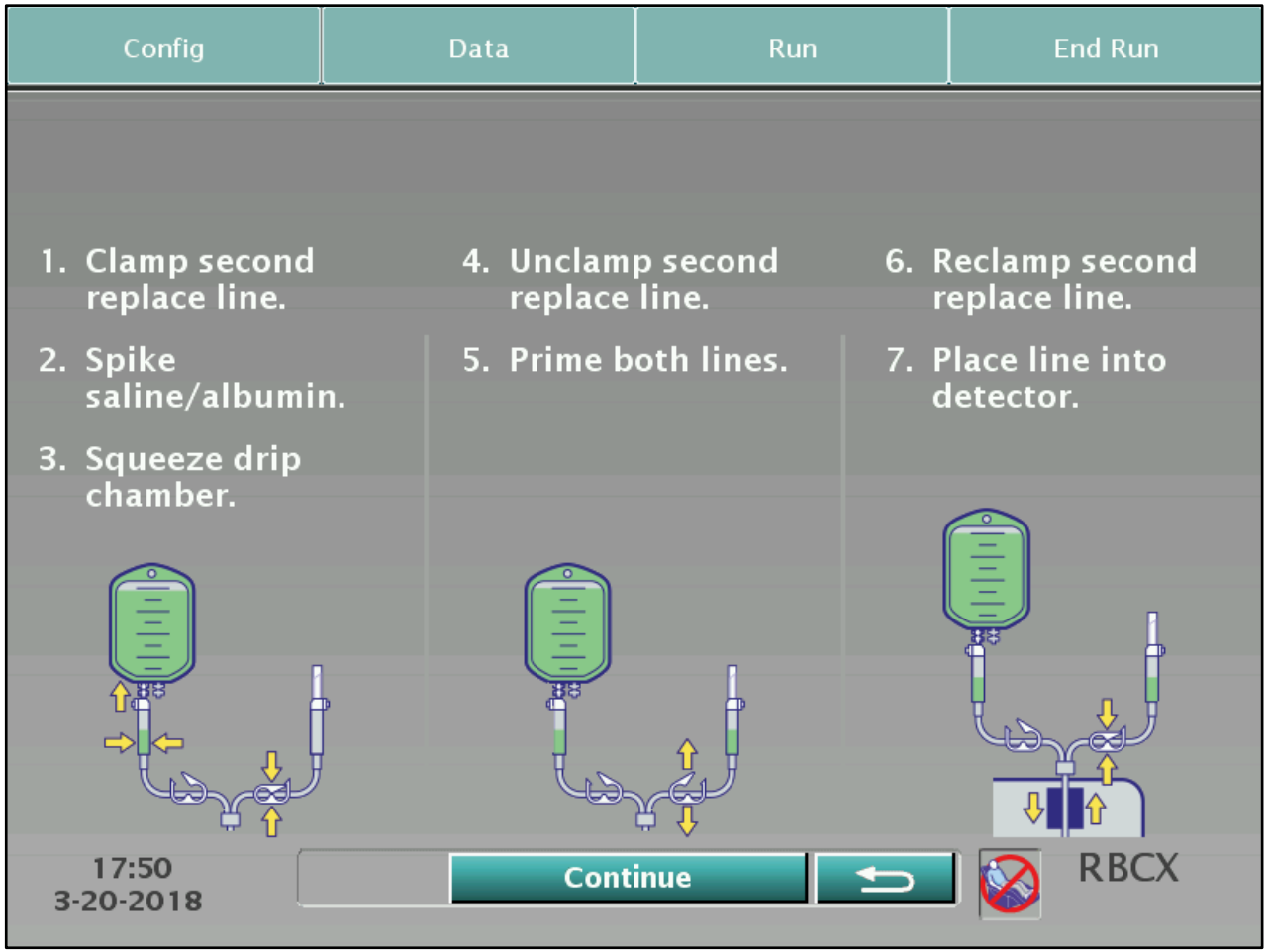


Fluid Data

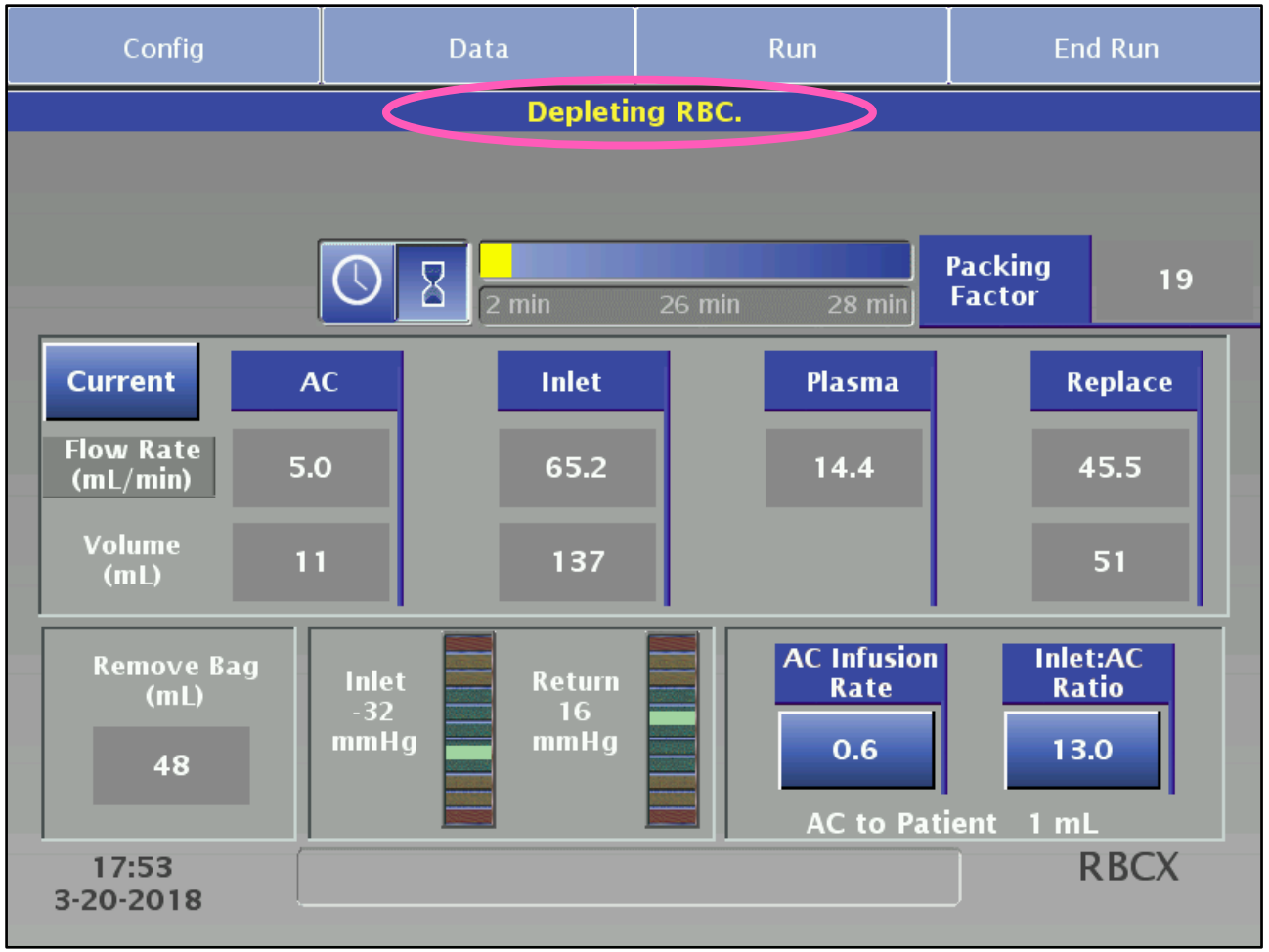
Run Values


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

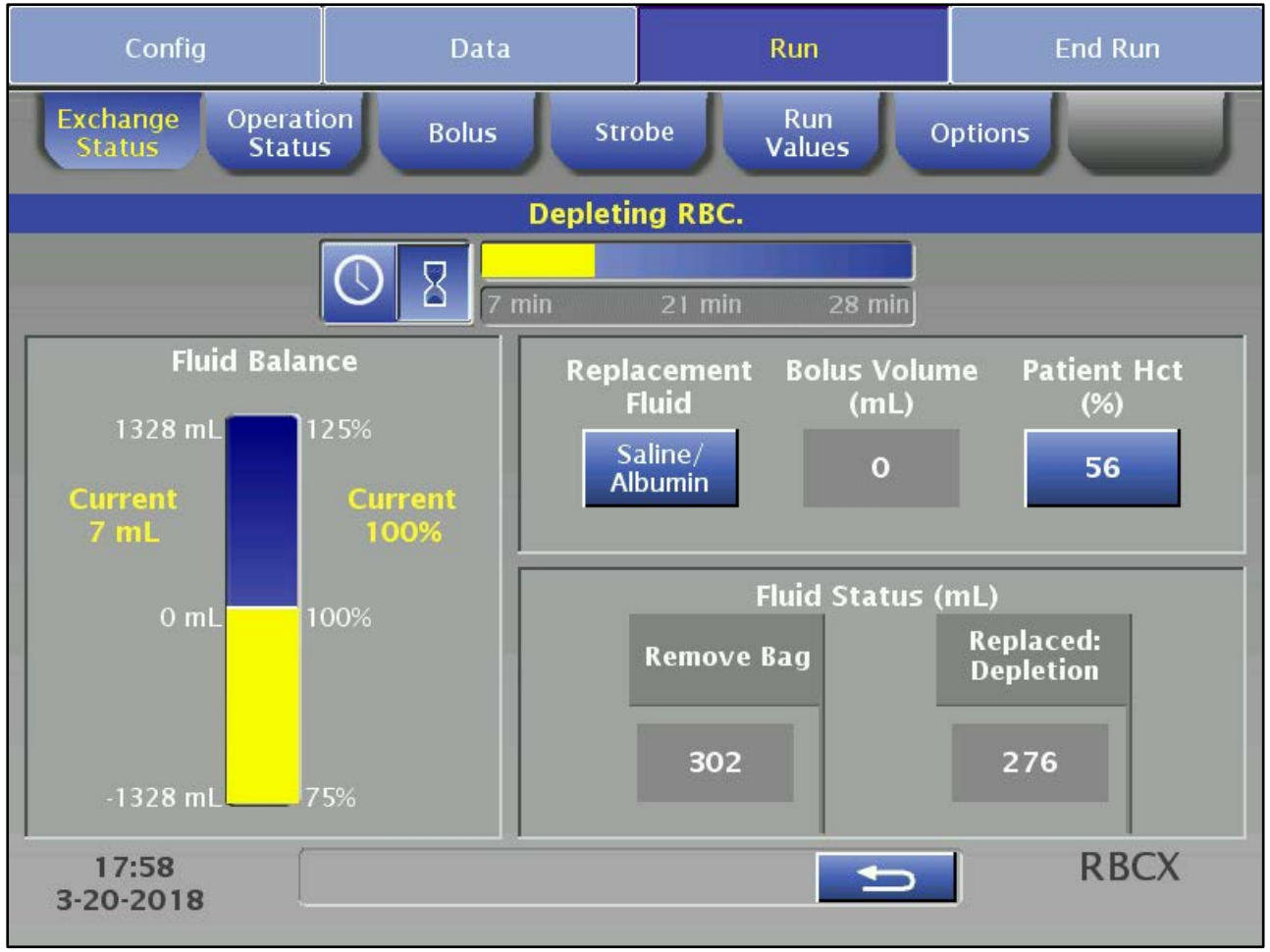
Spike Replacement Fluid



Main Run


Config
Data
Run
End Run
Depleting RBC.
2 min
26 min
28 min
Packing Factor
19
Current
AC
Inlet
Plasma
Replace
Flow Rate (mL/min)
5.0
65.2
14.4
45.5
Volume (mL)
11
137
51
Remove Bag (mL)
48
Inlet -32 mmHg
Return 16 mmHg
AC Infusion Rate
0.6
Inlet:AC Ratio
13.0
AC to Patient 1 mL
17:53
3-20-2018
RBCX

Exchange Status



Run Targets Attained

Procedure Summary

1.

2.

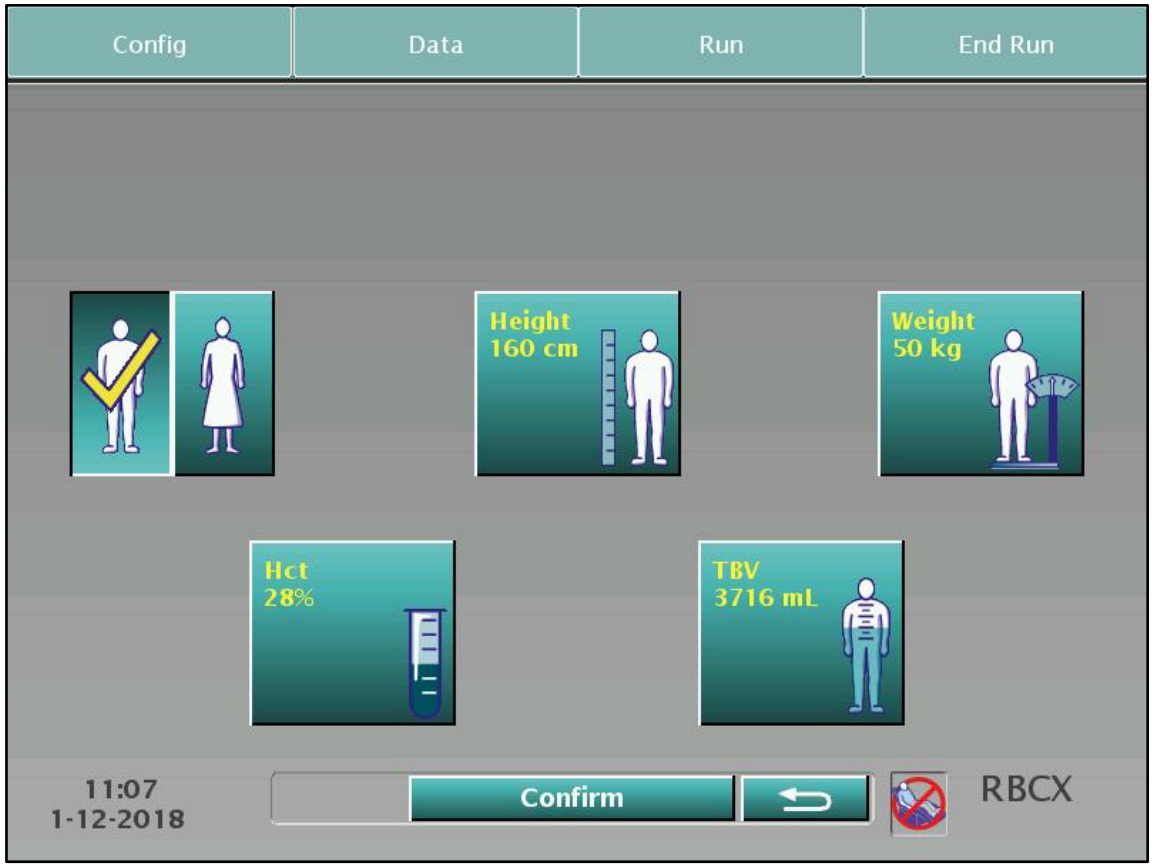
Questions?

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

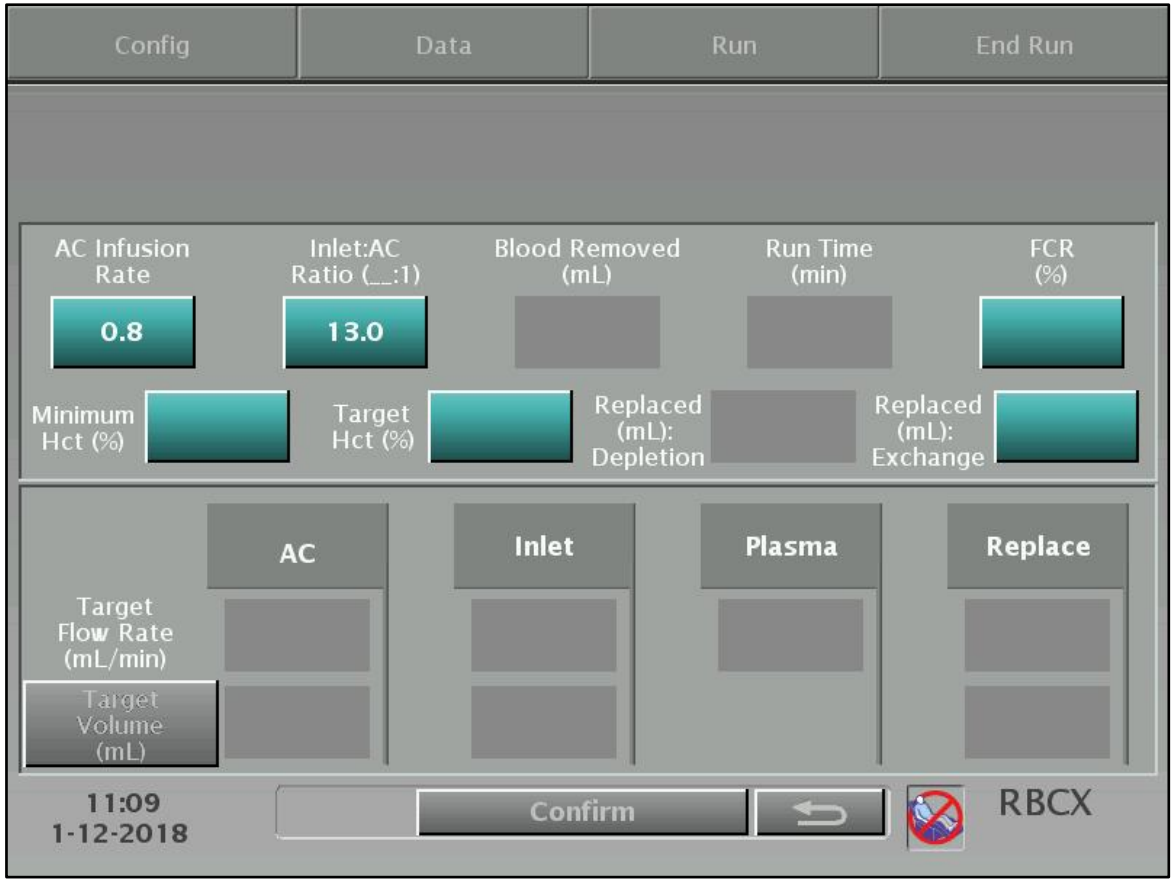
Data

Patient Data



Fluid Data

Run Values


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


Config
Data
Run
End Run
AC Infusion Rate
0.8
Inlet:AC Ratio (__:1)
13.0
Blood Removed (mL)
2371
Run Time (min)
(19)
117
FCR (%)
30
Minimum Hct (%)
23
Target Hct (%)
32
Replaced (mL): Depletion
190
Replaced (mL): Exchange
2032
AC
Inlet
Plasma
Replace
Target Flow Rate (mL/min)
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

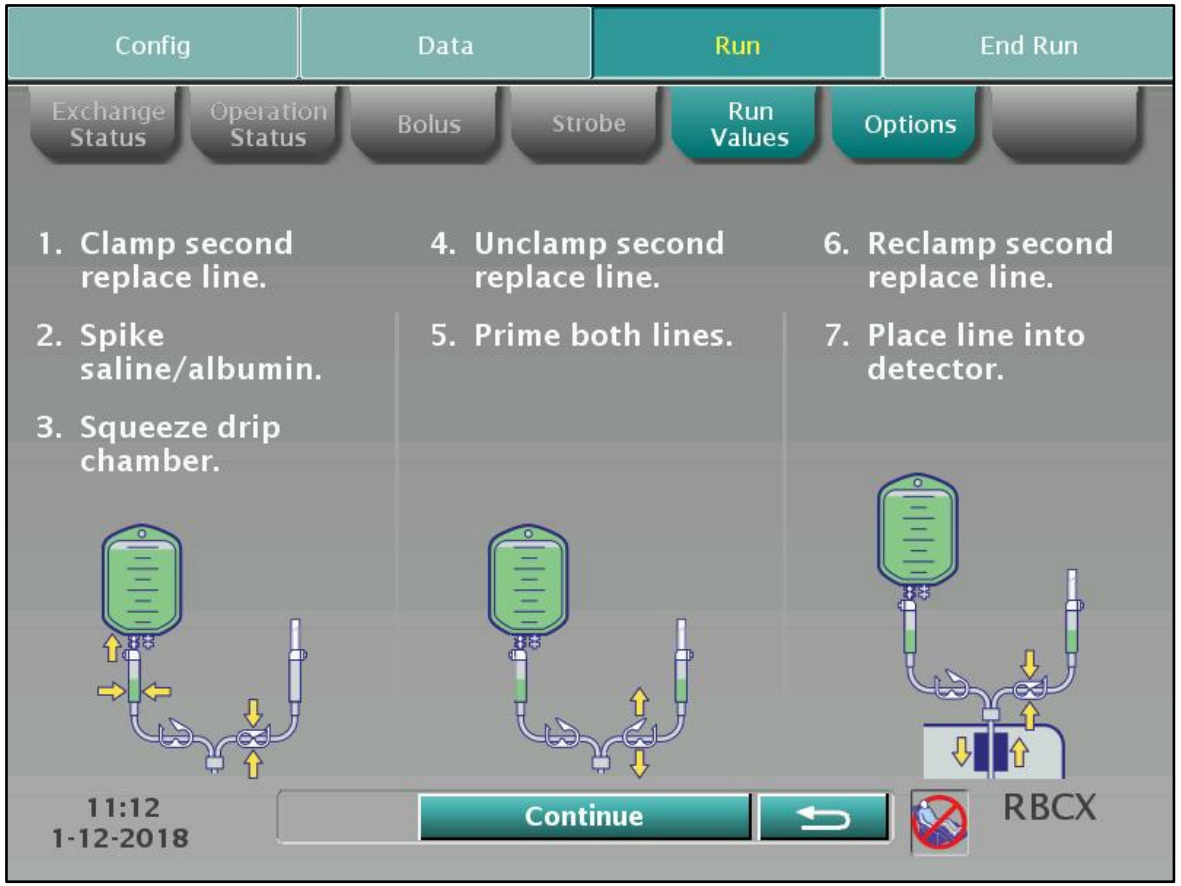
- Less RBC
  - Same FCR is targeted
  - 1 unit less RBC is needed

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

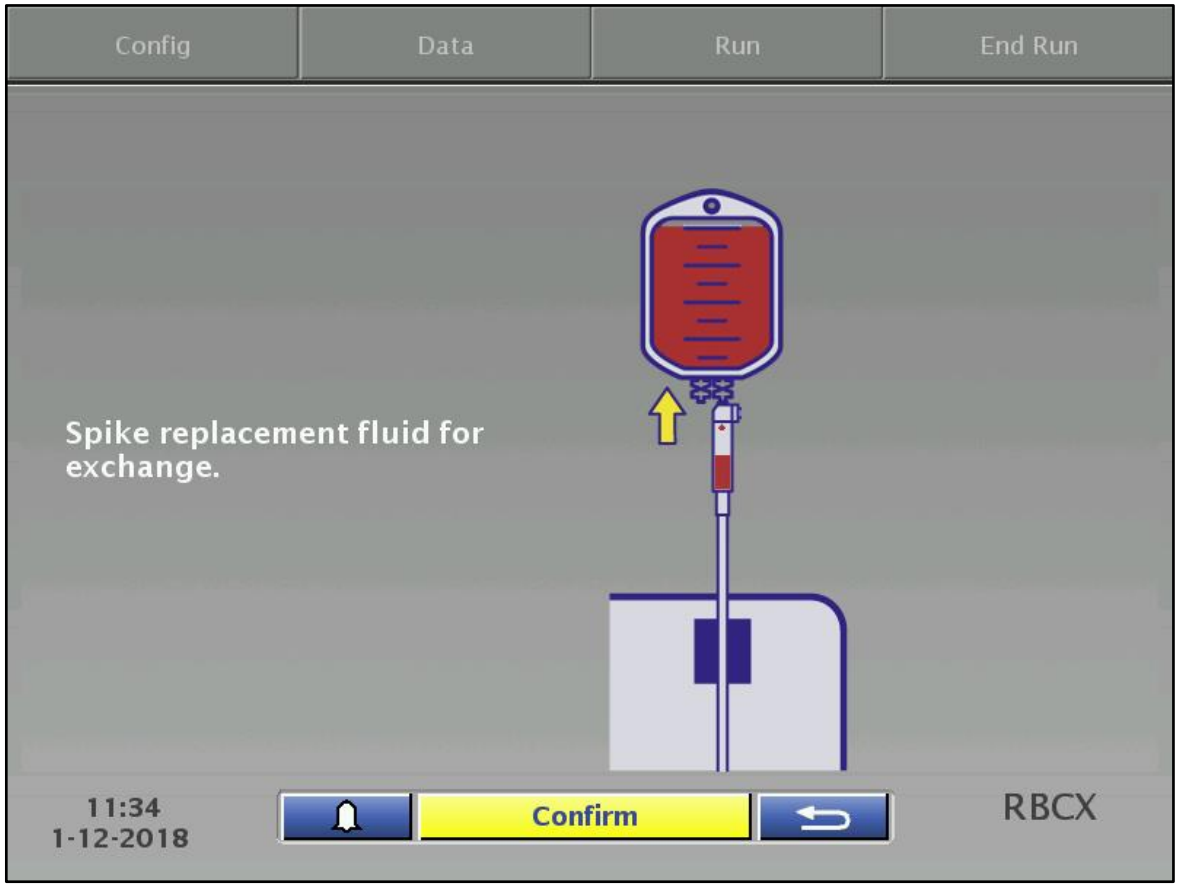
Patient: 5 L TBV, Hct 26%, fluid balance 100%		
	RBC	
	Exchange	Depletion/ Exchange
Min Hct (%)	26	22
Target Hct (%)	32	32
Target FCR (%)	30	30
Replace vol (mL)	3148	2921

Spike Replacement Fluid

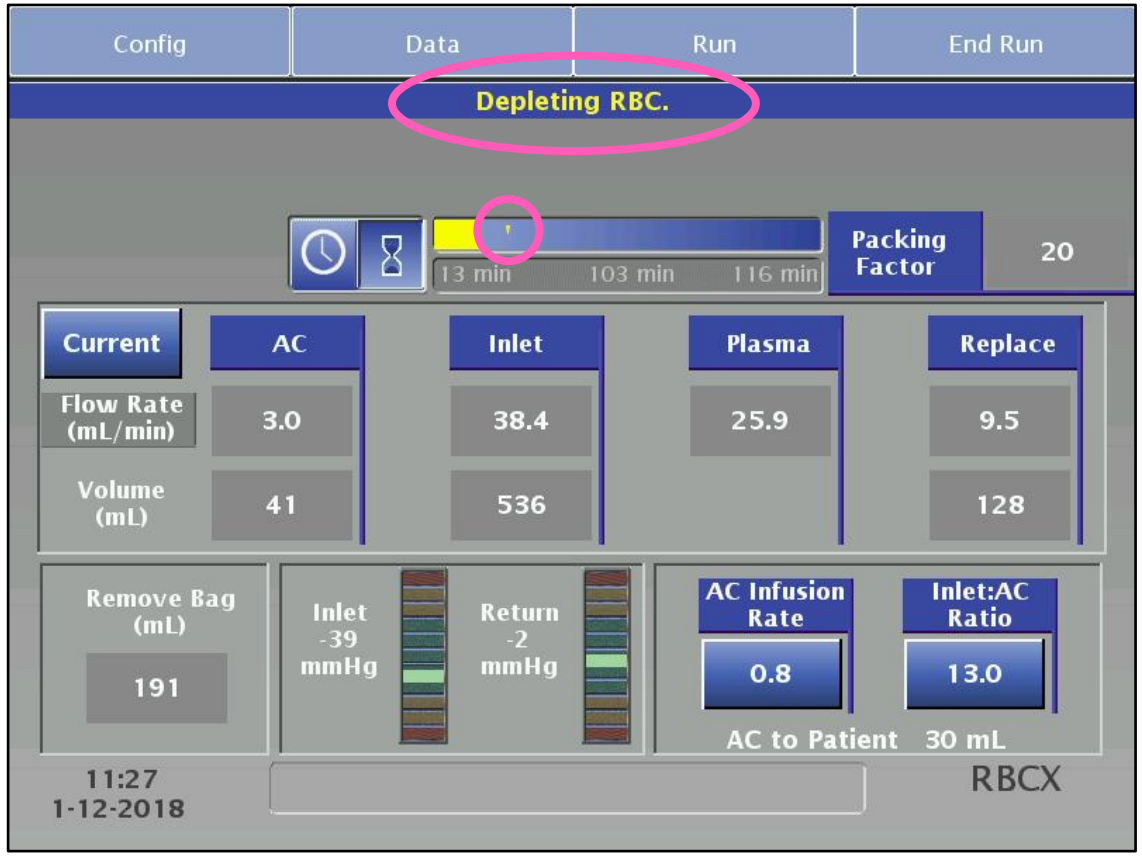
Depletion Phase

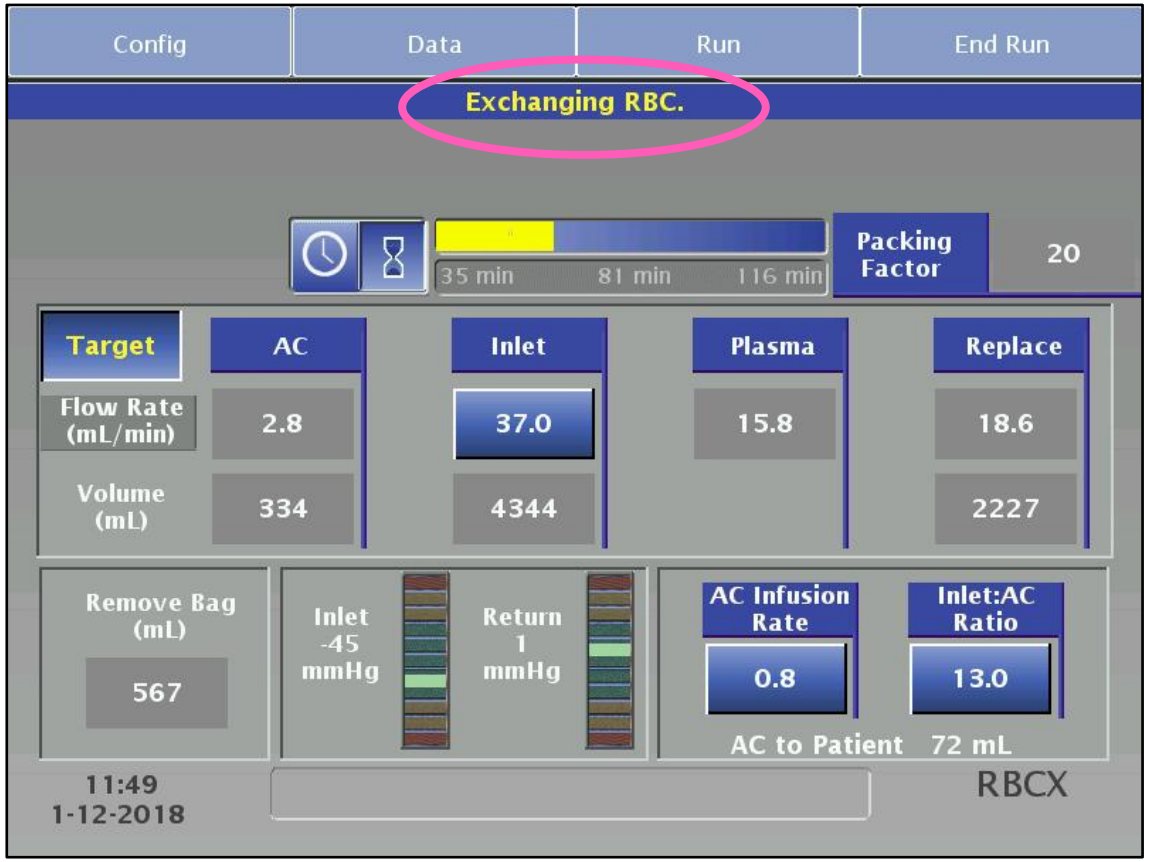


Exchange Phase

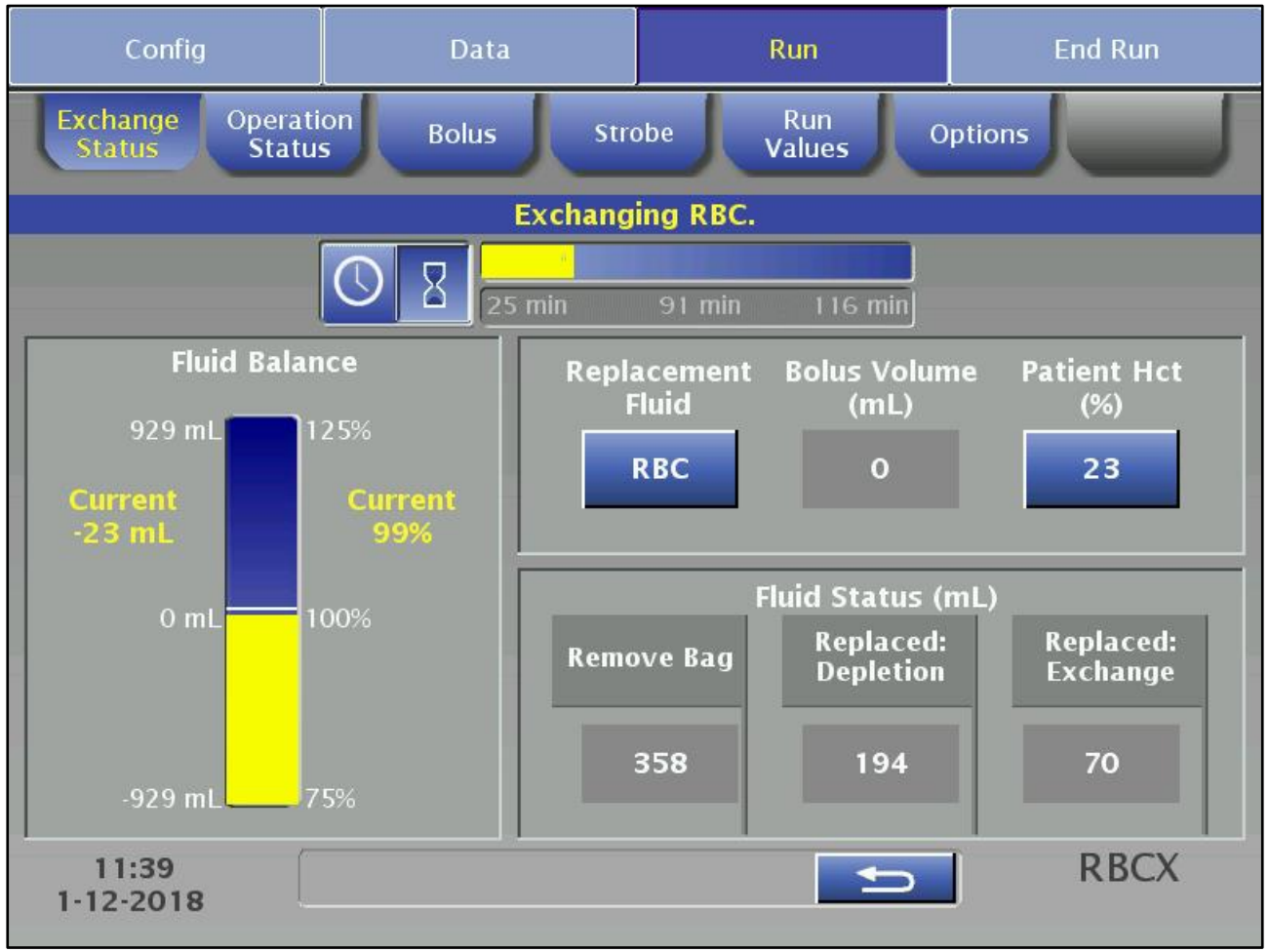


Main Run


Config
Data
Run
End Run
Depleting RBC.
13 min
103 min
116 min
Packing Factor
20
Current
AC
Inlet
Plasma
Replace
Flow Rate (mL/min)
3.0
38.4
25.9
9.5
Volume (mL)
41
536
128
Remove Bag (mL)
191
Inlet -39 mmHg
Return -2 mmHg
AC Infusion Rate
0.8
Inlet:AC Ratio
13.0
AC to Patient 30 mL
11:27
1-12-2018
RBCX


Config
Data
Run
End Run
Exchanging RBC.
35 min
81 min
116 min
Packing Factor
20
Target
AC
Inlet
Plasma
Replace
Flow Rate (mL/min)
2.8
37.0
15.8
18.6
Volume (mL)
334
4344
2227
Remove Bag (mL)
567
Inlet -45 mmHg
Return 1 mmHg
AC Infusion Rate
0.8
Inlet:AC Ratio
13.0
AC to Patient 72 mL
11:49
1-12-2018
RBCX

Exchange Status

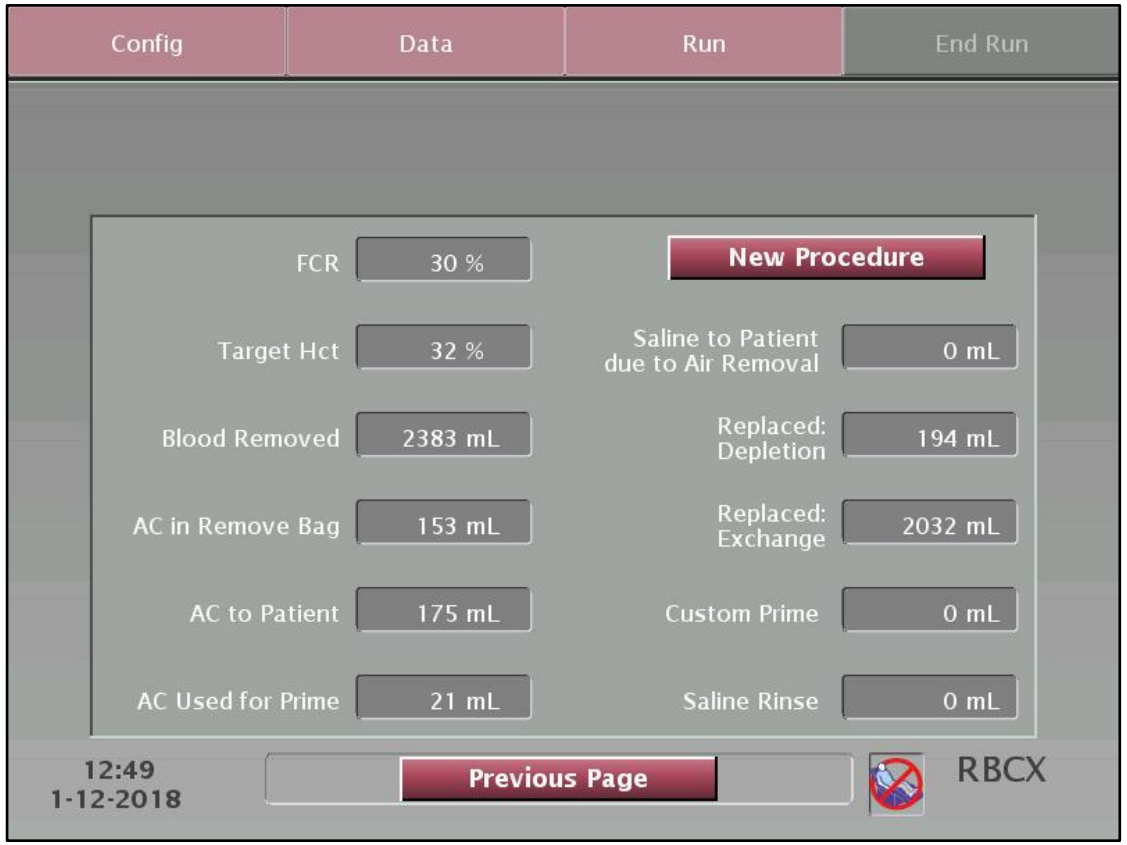


Run Targets Attained

Procedure Summary

1.

2.



Questions?

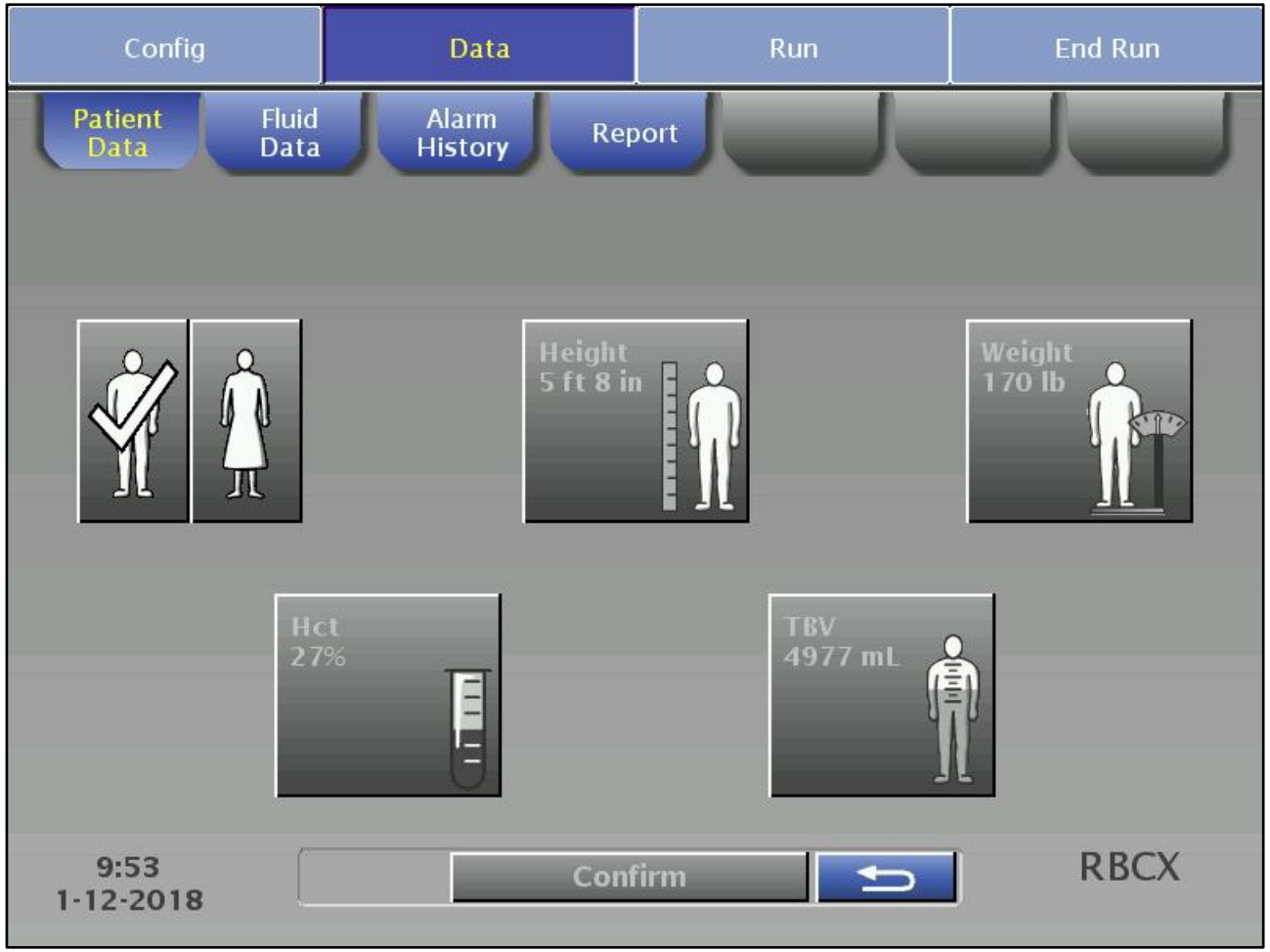
Making Changes

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

Data Menu

- Patient Data
- Fluid Data
- Alarm History
- Report

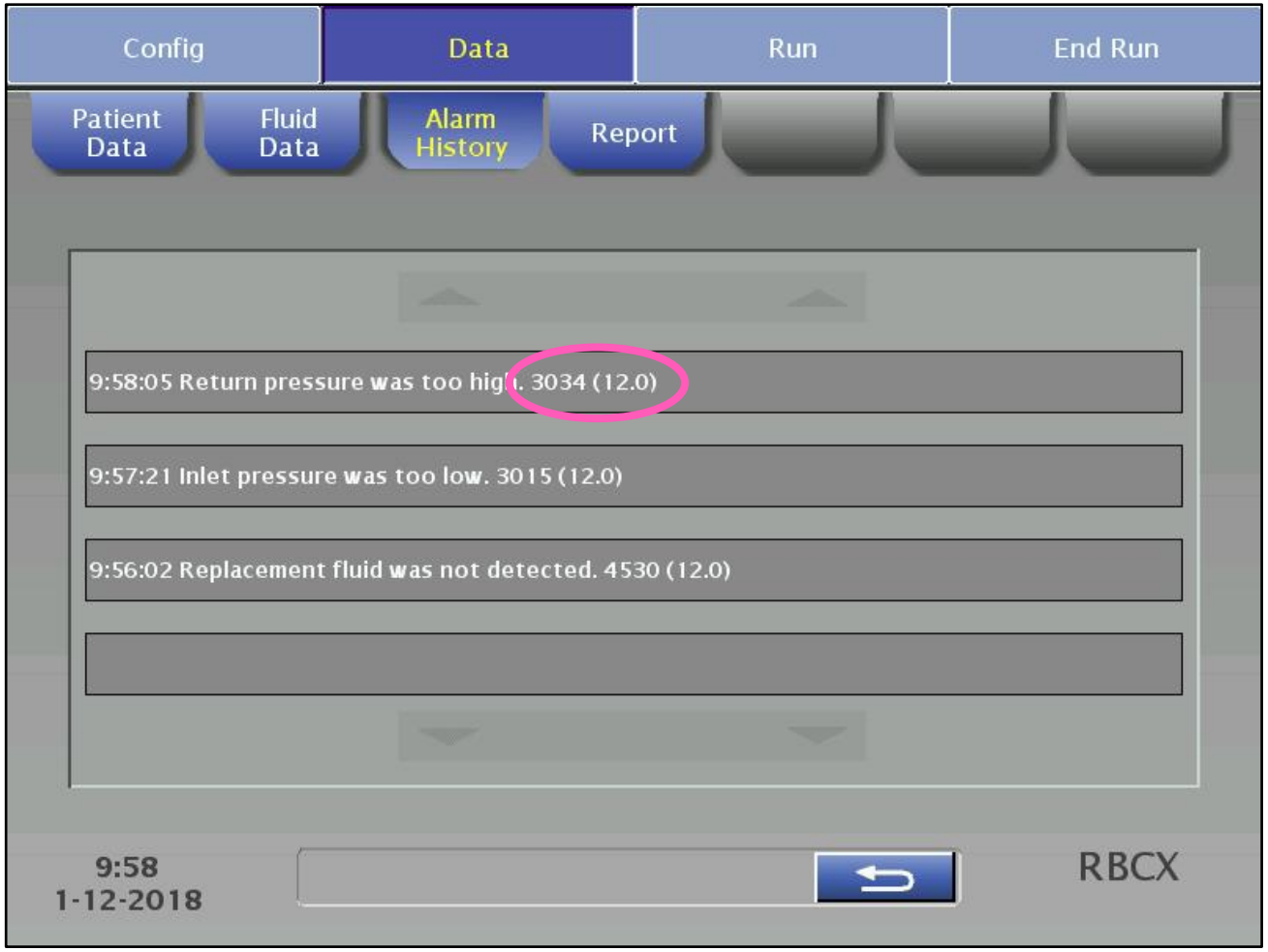
Patient Data



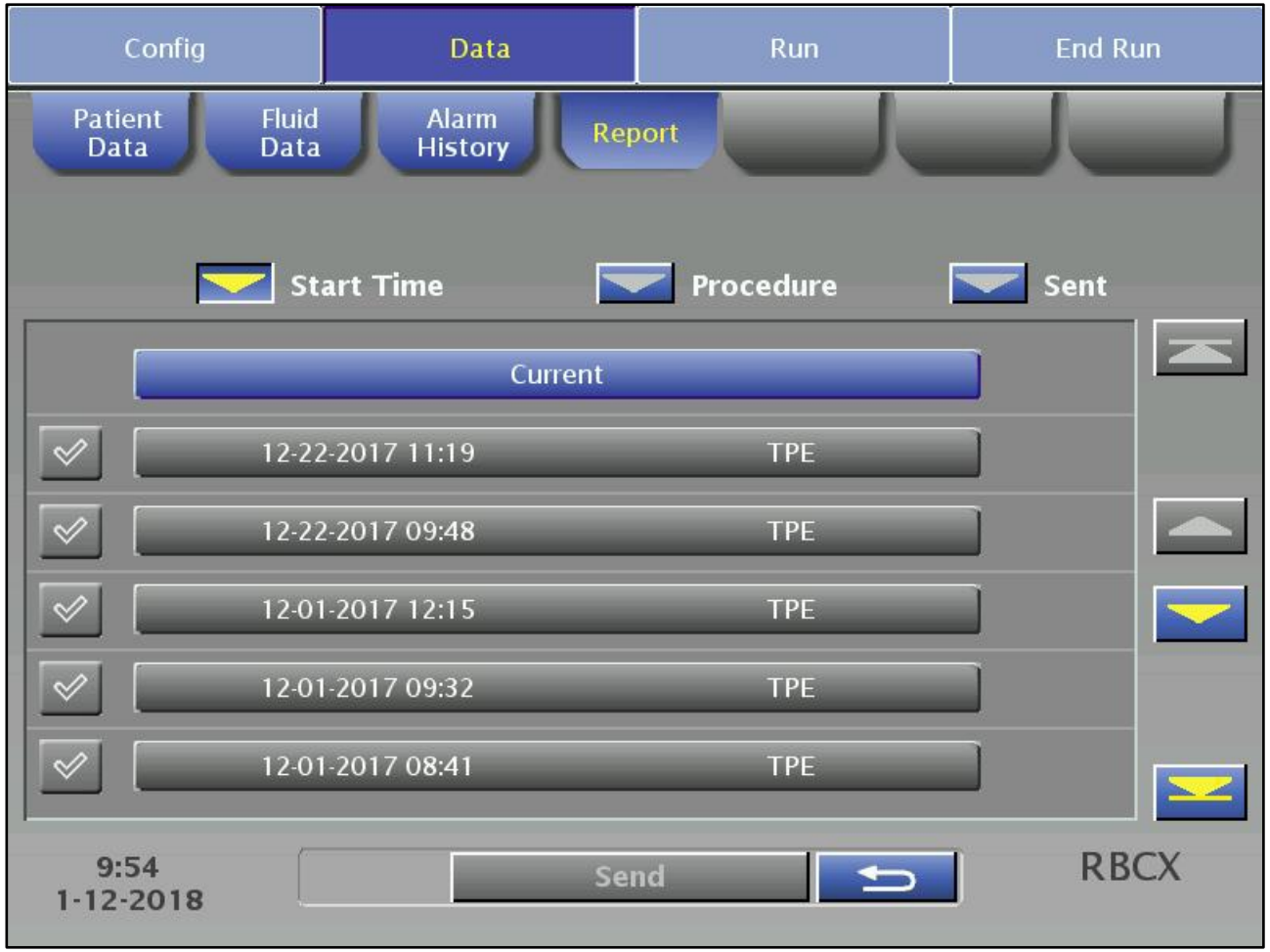
Fluid Data


Config
Data
Run
End Run
Patient Data
Fluid Data
Alarm History
Report
Exchange Type
Exchange
Depletion
Fluid Type
Exchange
Hct 57%
(8% citrate)
Fluid Balance
Volume
0 mL
Percent
100%
9:53
1-12-2018
Confirm
RBCX

Alarm History



Report

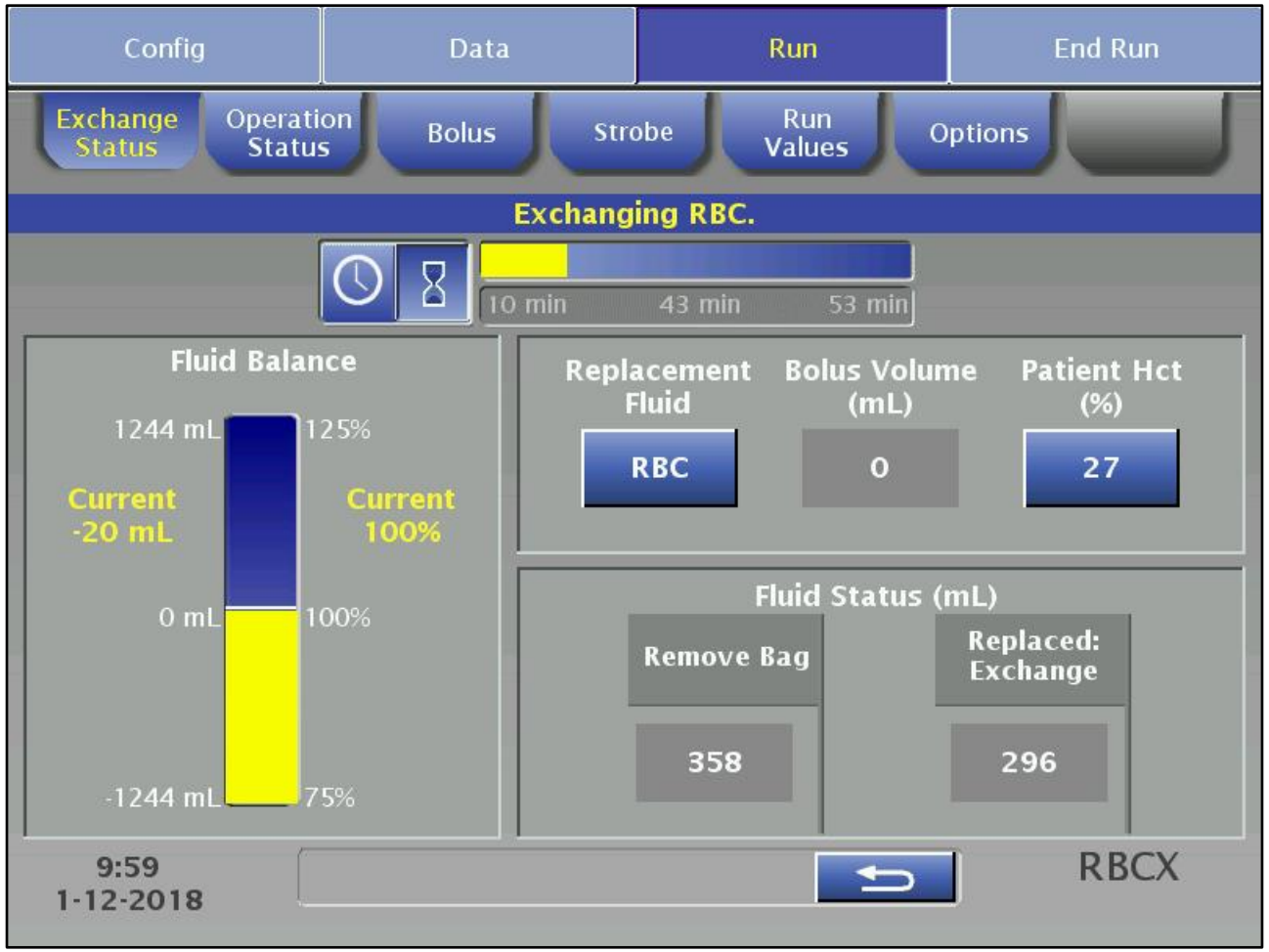

Config
Data
Run
End Run
Patient Data
Fluid Data
Alarm History
Report
Start Time
Procedure
Sent
Current
12-22-2017 11:19 TPE
12-22-2017 09:48 TPE
12-01-2017 12:15 TPE
12-01-2017 09:32 TPE
12-01-2017 08:41 TPE
9:54
1-12-2018
Send
RBCX

Run Menu

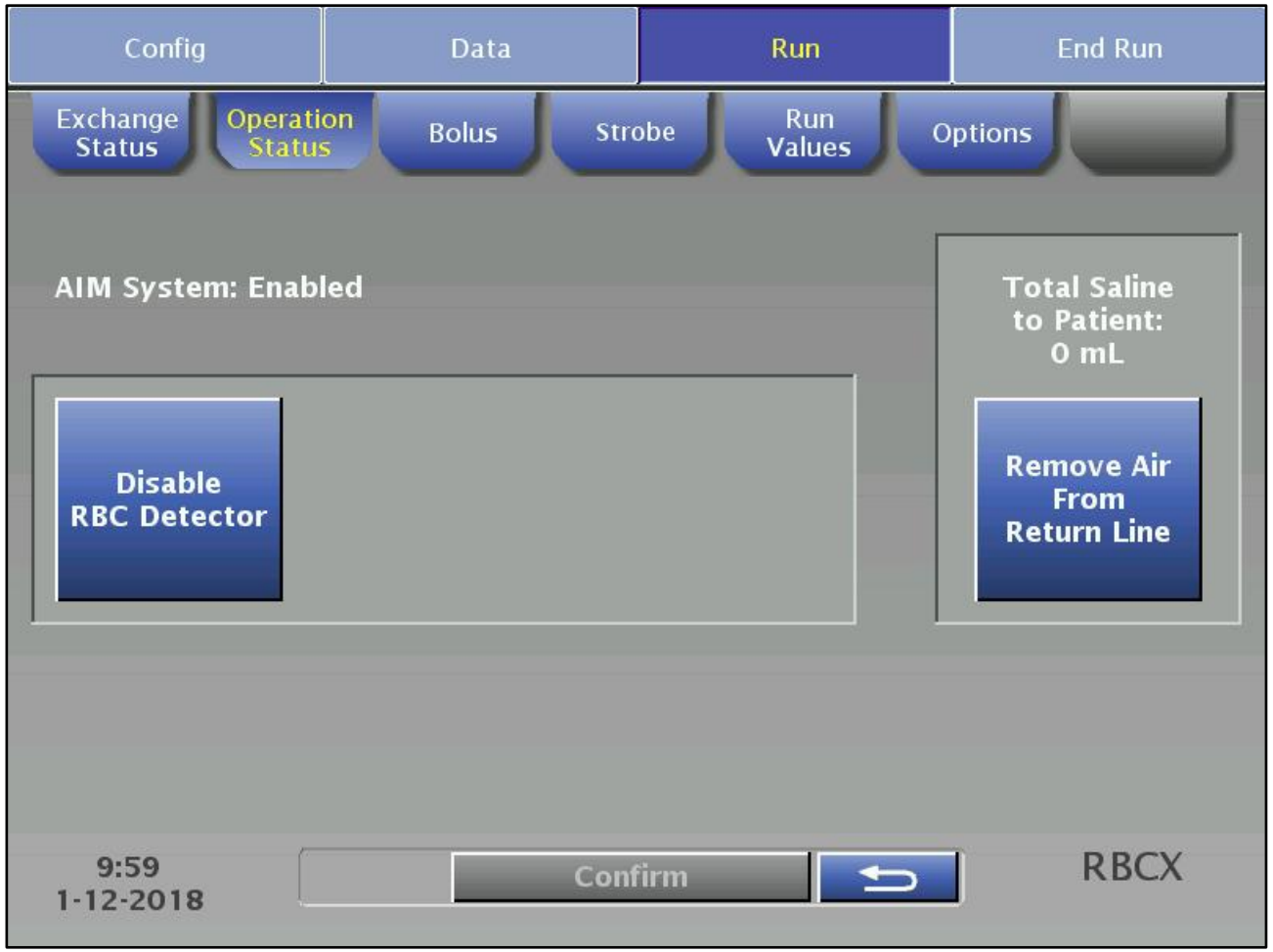
- Main Run – Caution Status
- Exchange Status
- Operation Status
- Bolus
- Strobe
- Run Values
- Options

Main Run – Caution Status

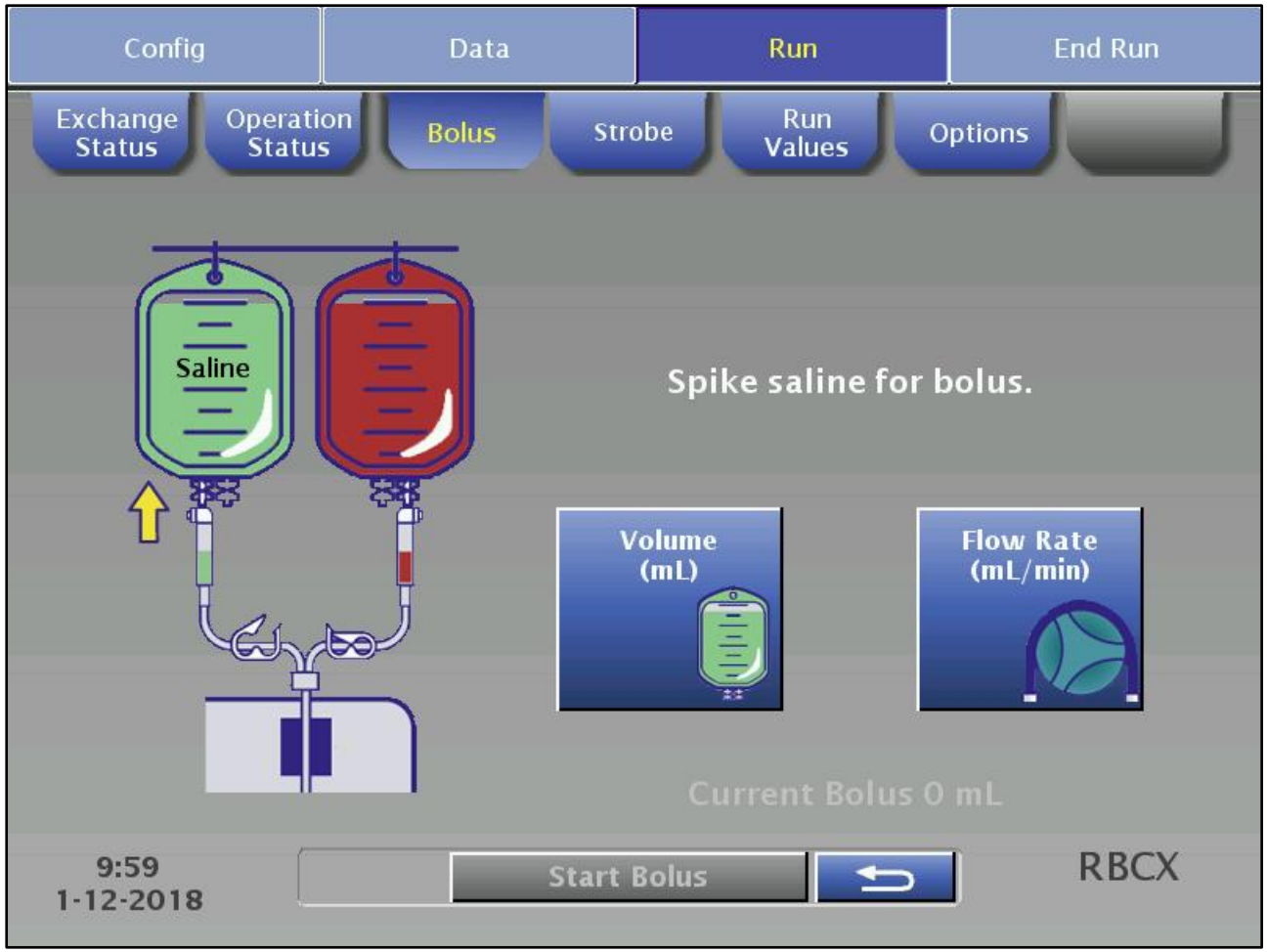
Exchange Status



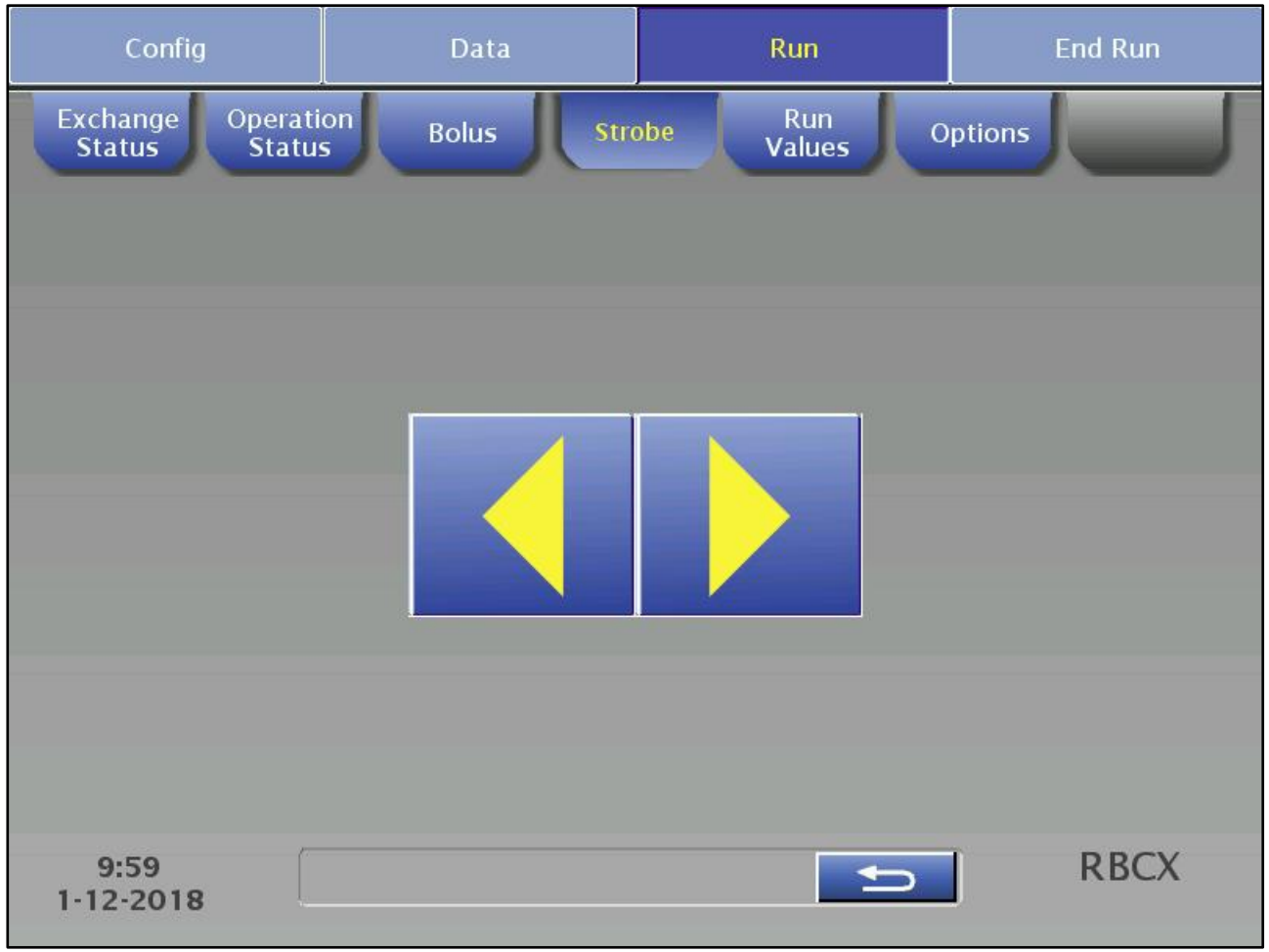
Operation Status



Bolus


Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
Saline
Spike saline for bolus.
Volume (mL)
Flow Rate (mL/min)
Current Bolus 0 mL
9:59
1-12-2018
Start Bolus
RBCX

Strobe

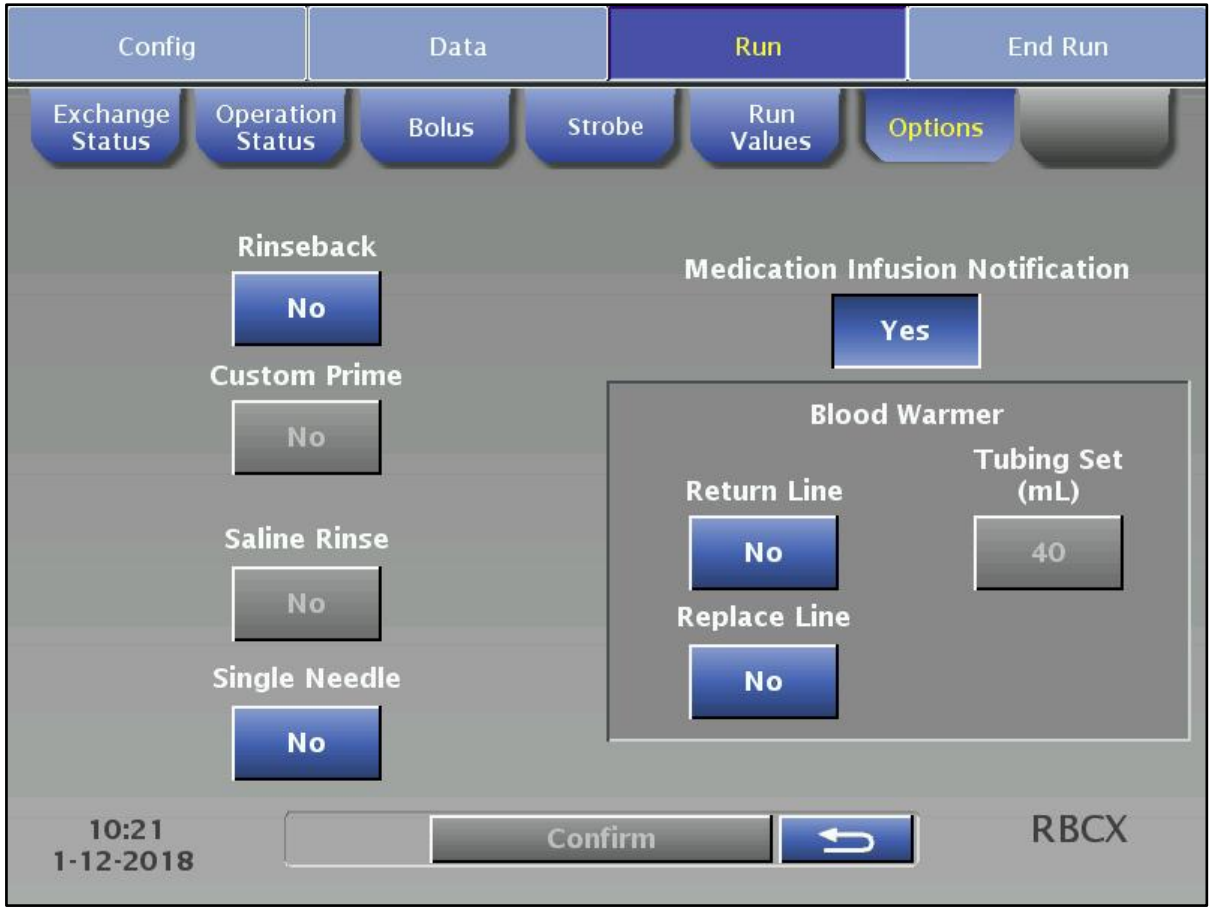

Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
9:59
1-12-2018
RBCX

Run Values


Config
Data
Run
End Run
Exchange Status
Operation Status
Bolus
Strobe
Run Values
Options
AC Infusion Rate
0.9
Inlet:AC Ratio (__:1)
13.0
Blood Removed (mL)
1845
Run Time (min)
52
FCR (%)
50
Minimum Hct (%)
27
Target Hct (%)
32
Replaced (mL): Exchange
1779
AC
Inlet
Plasma
Replace
Target Flow Rate (mL/min)
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
1.1
Inlet:AC Ratio (__:1)
13.0
Blood Removed (mL)
1845
Run Time (min)
49
FCR (%)
50
Minimum Hct (%)
27
Target Hct (%)
32
Replaced (mL): Exchange
1779
AC
Inlet
Plasma
Replace
Target Flow Rate (mL/min)
5.1
66.1
18.3
43.3
Target Volume (mL)
218
2839
1779
10:20
1-12-2018
Confirm
RBCX

Options

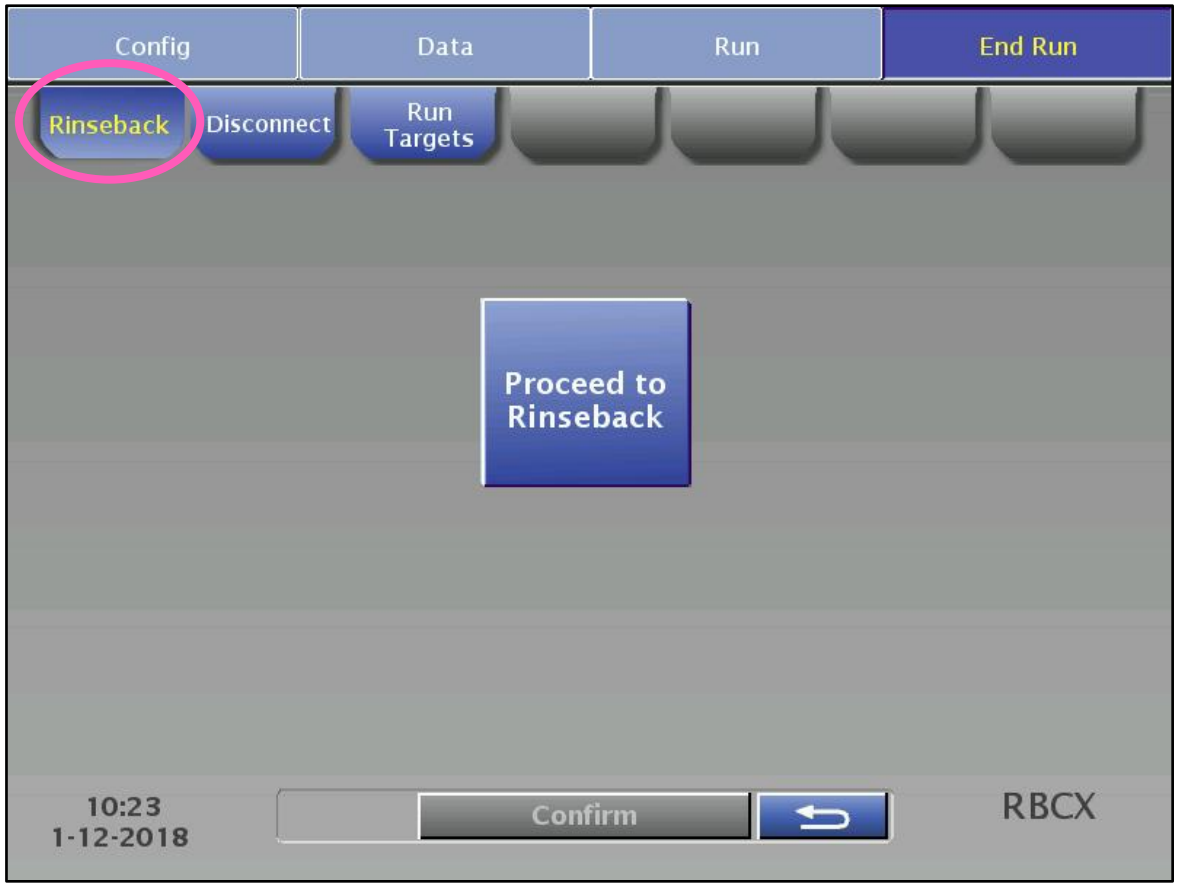


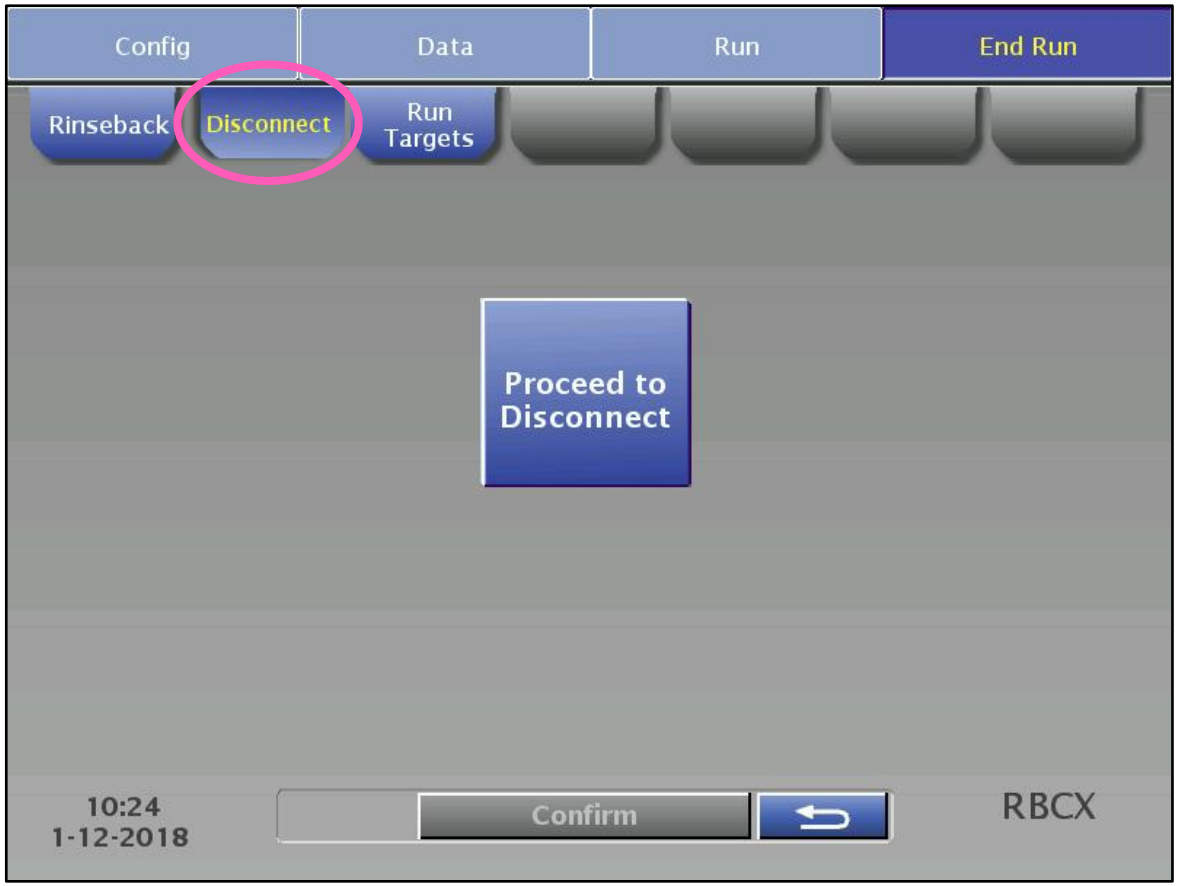
***Note**: Not all options are commercially available in all world areas.*

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.

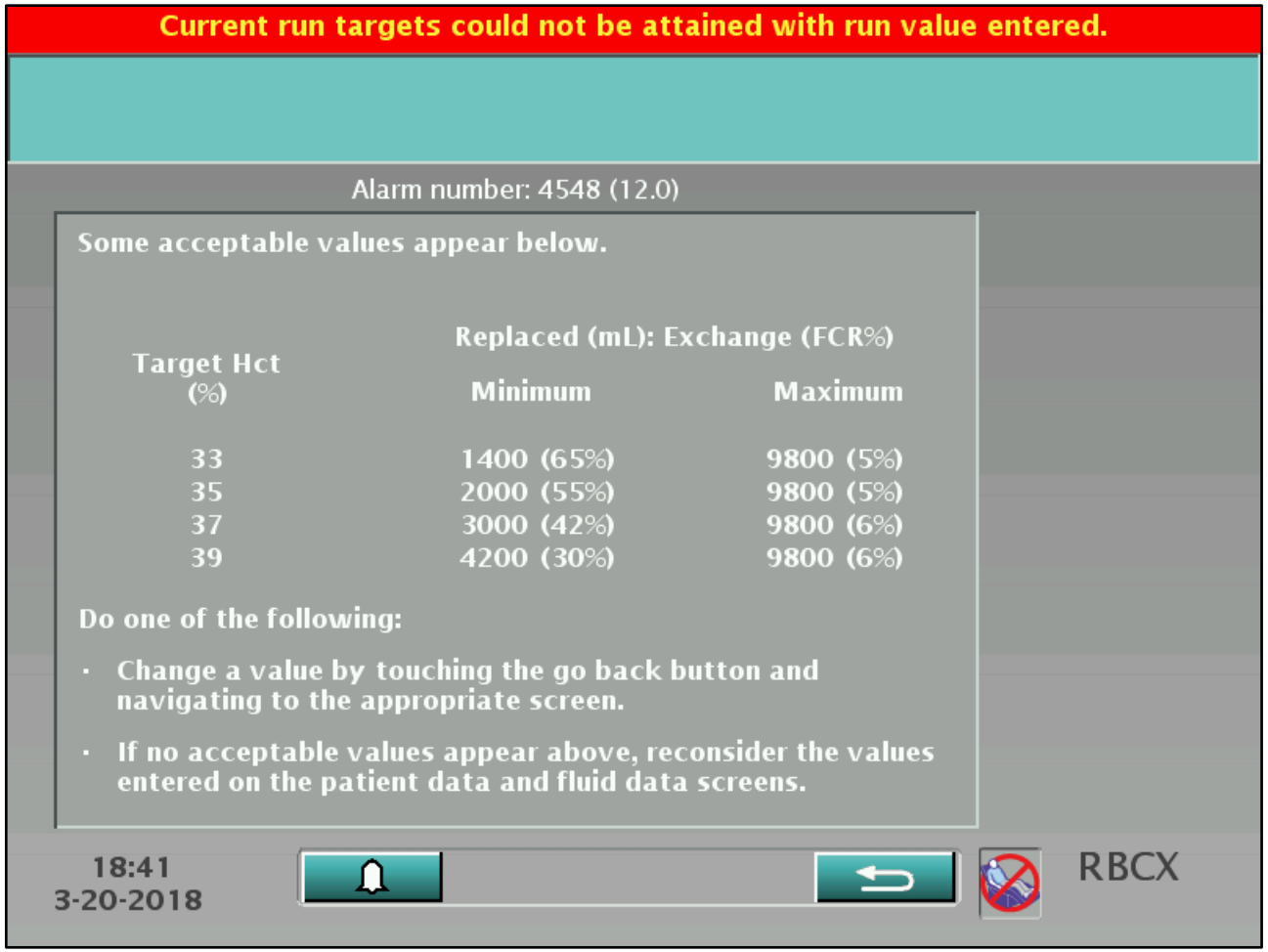
Questions?

Troubleshooting

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

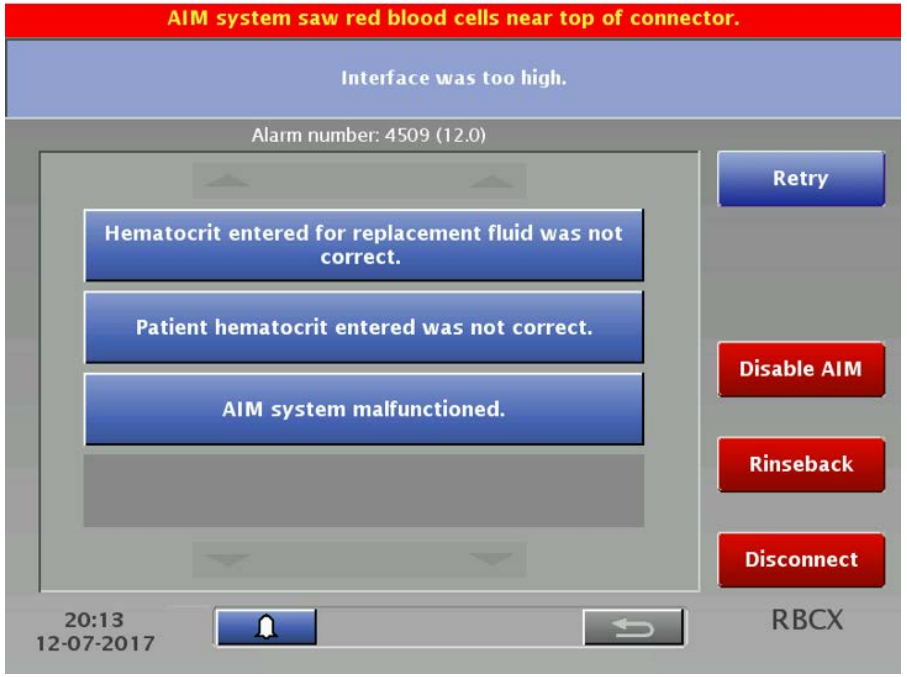
Inlet and Return Access Alarms

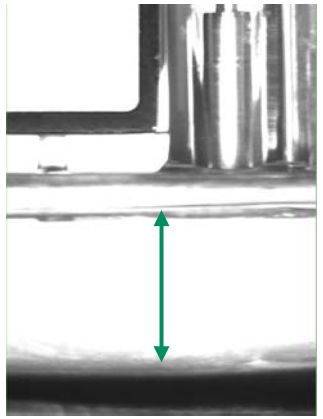
Unattainable Procedure



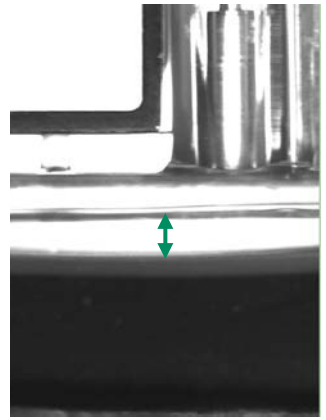
High Interface

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



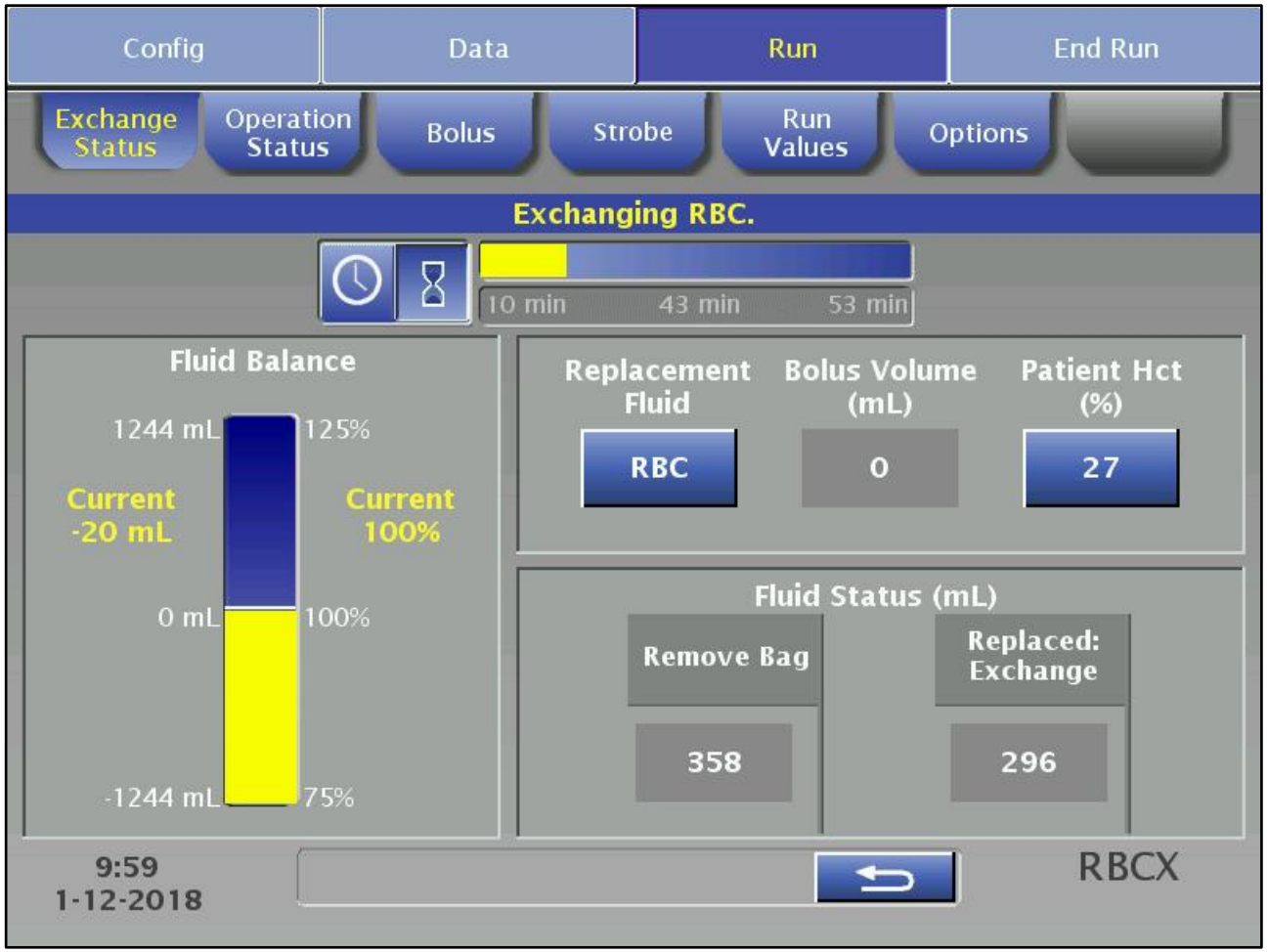


Typical RBCX Interface



High RBCX Interface

Updating the Patient's Hct – Pause



Questions?

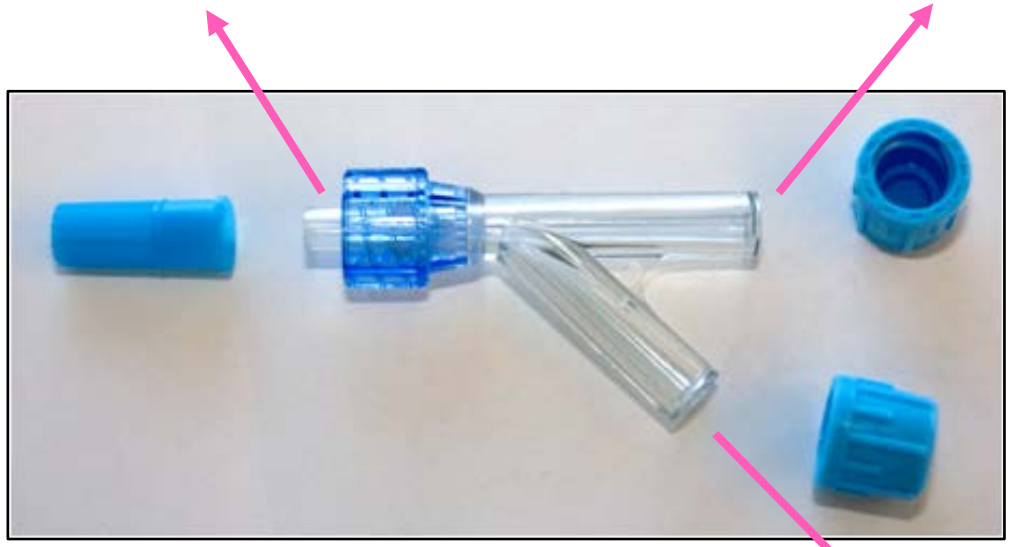
Single-Needle Procedures

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

Single-Needle Connector

Male luer connection to patient

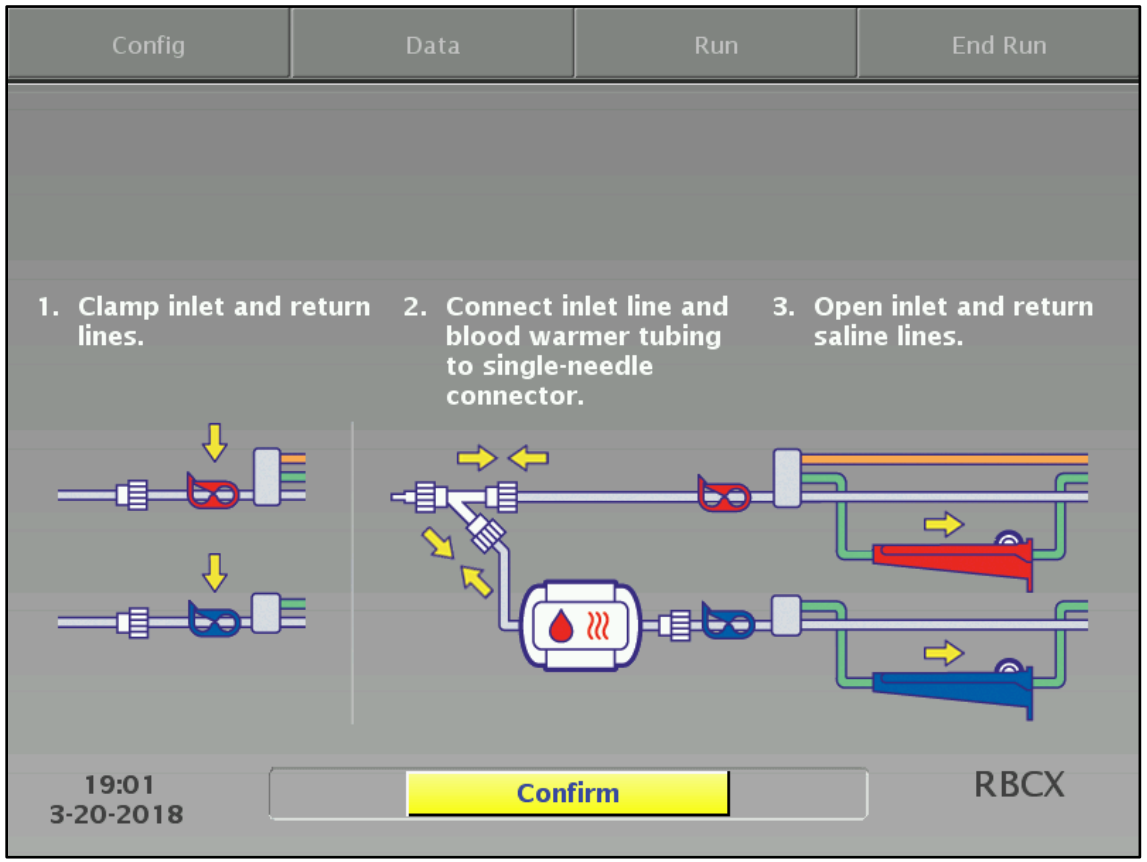
Female luer connection to inlet line



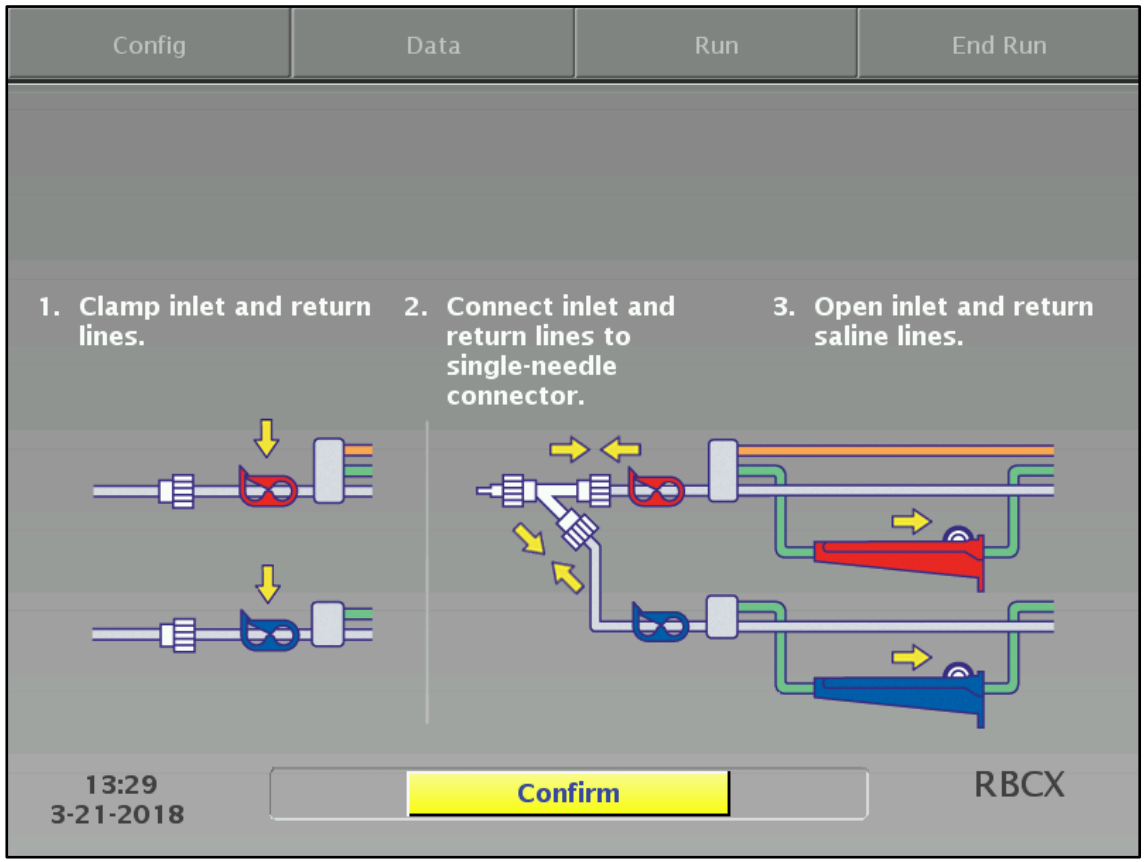
Female luer connection to return line

Convert to Single Needle

With blood warmer on return line

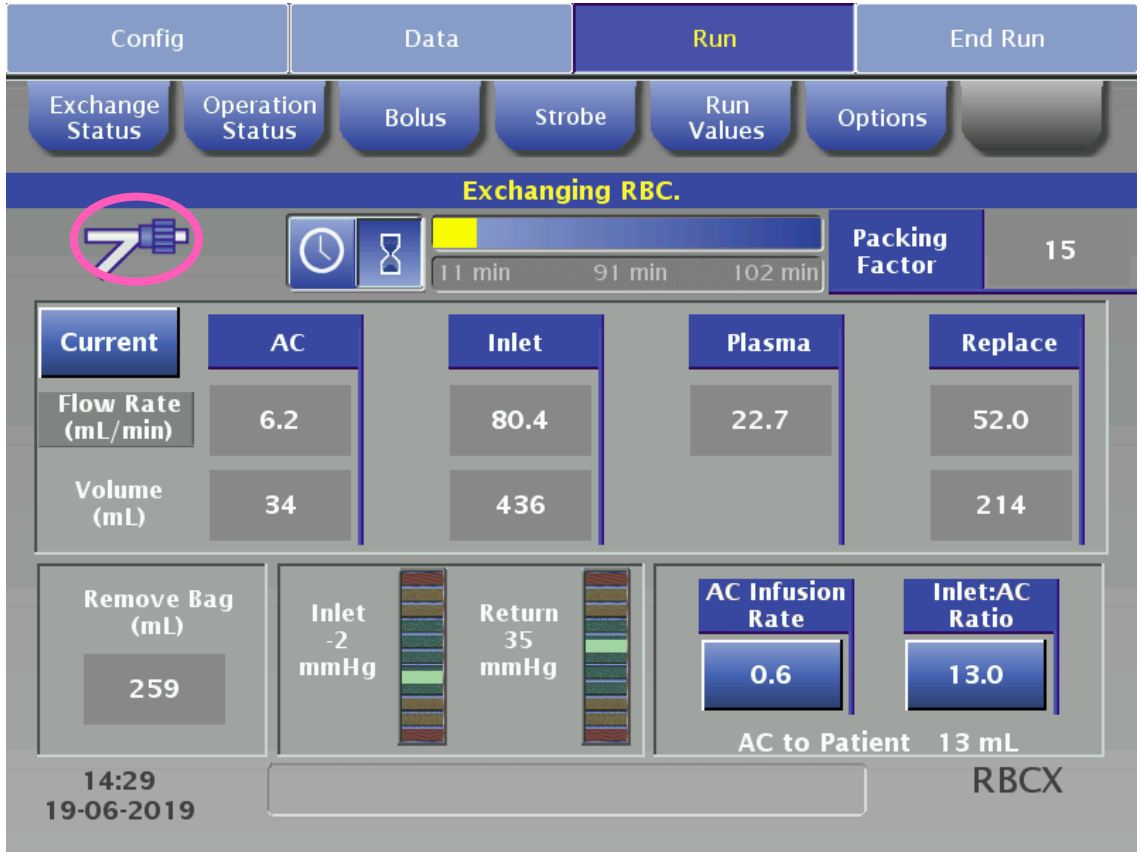


Without blood warmer on return line

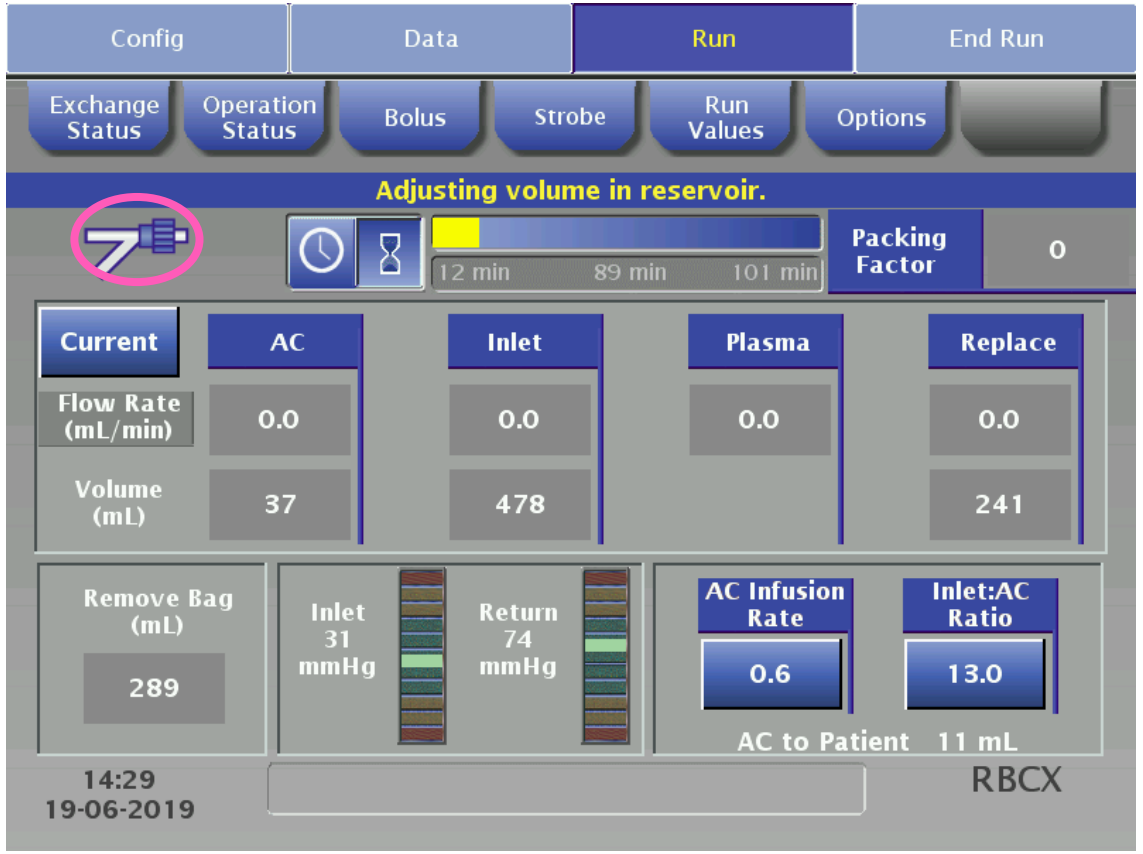


Convert to Single-Needle Access

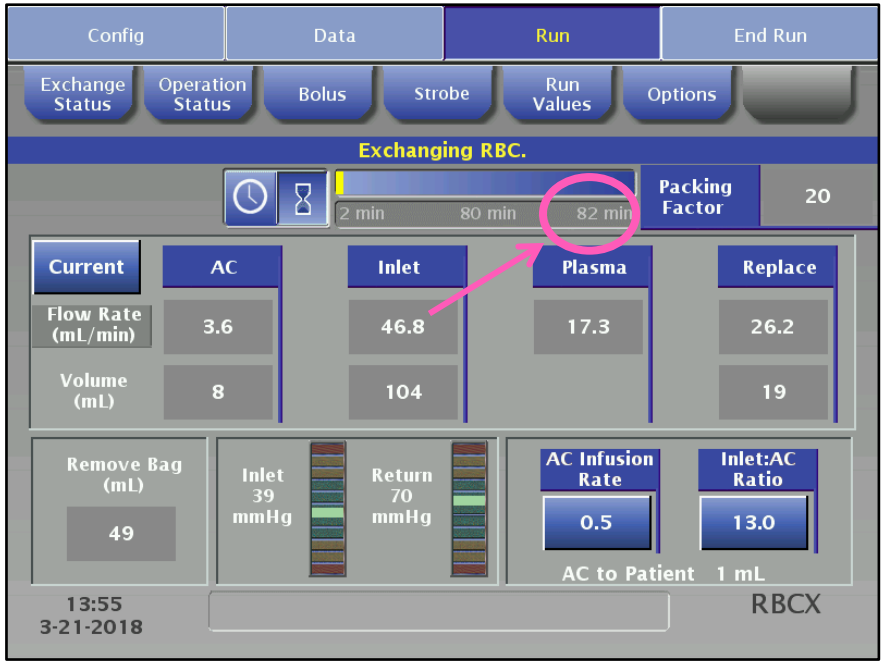
Draw Cycle

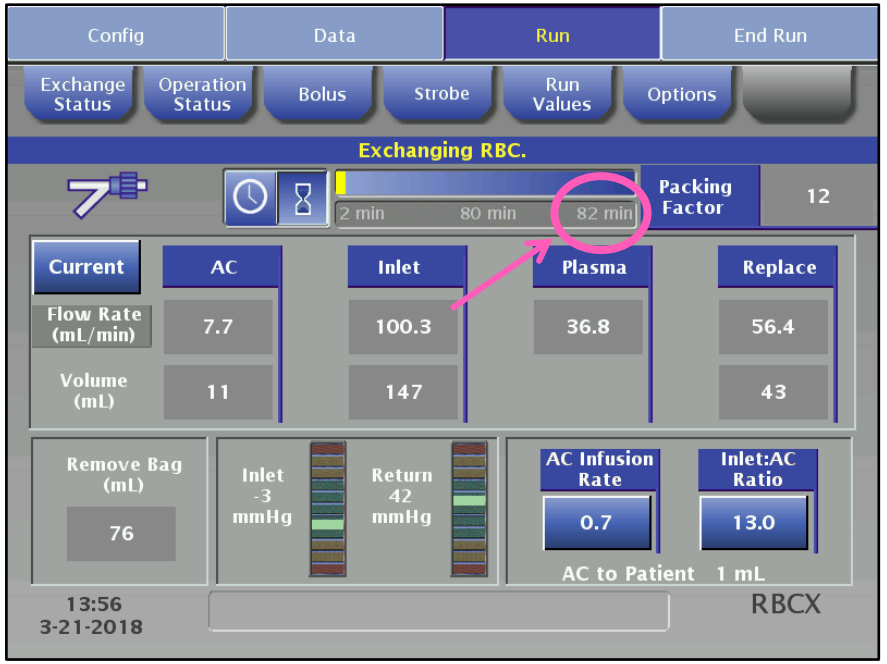


Return Cycle



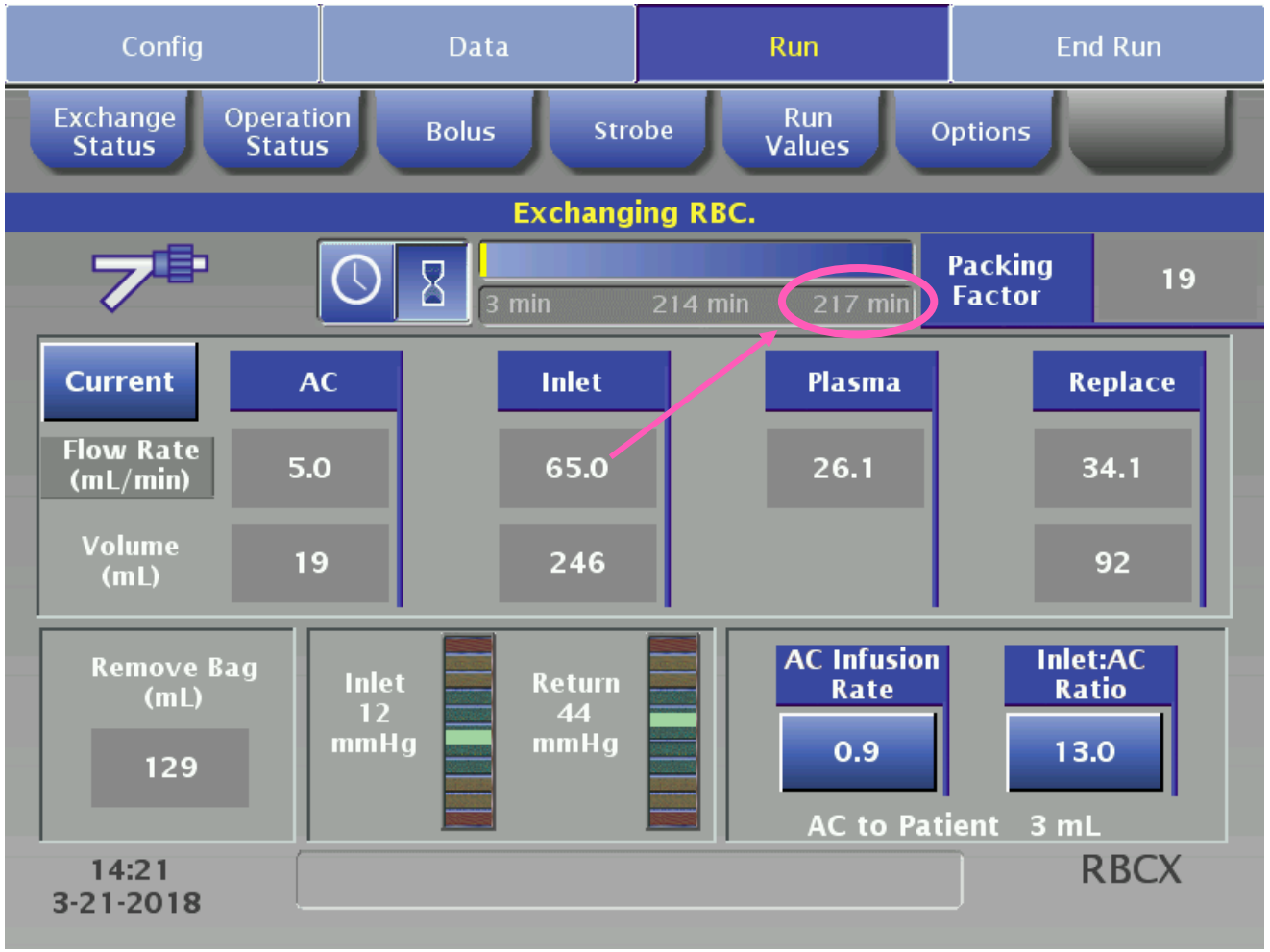
Optimization





- 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

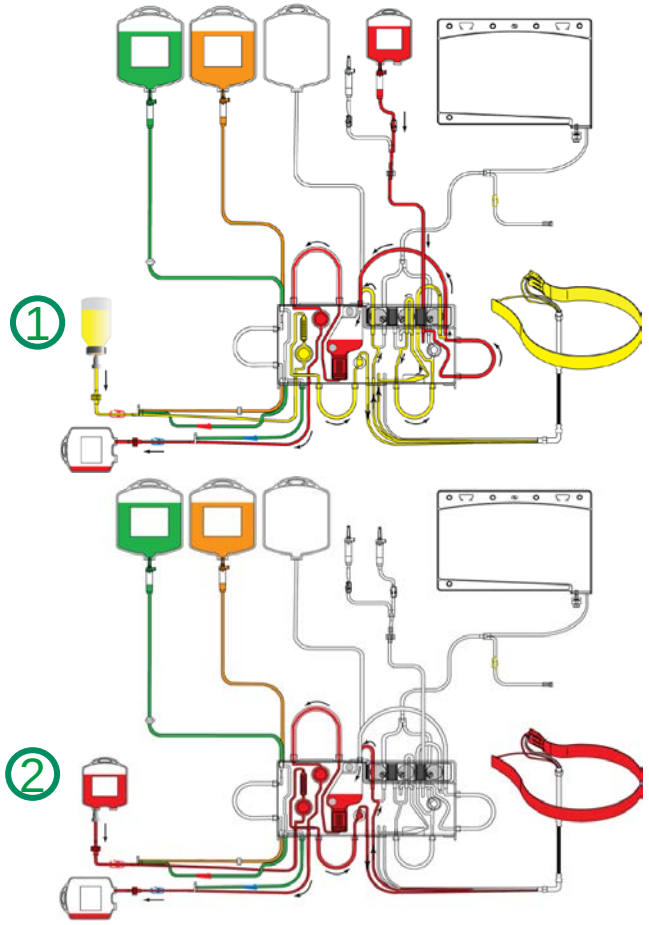
- Target fluid balance
  - Patient tolerance of the procedure
- Blood warmer
  - Patient comfort
- Custom prime
  - Improved tolerance of the volume of the extracorporeal circuit

Custom Prime

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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