

Version 12.0 Software Updates

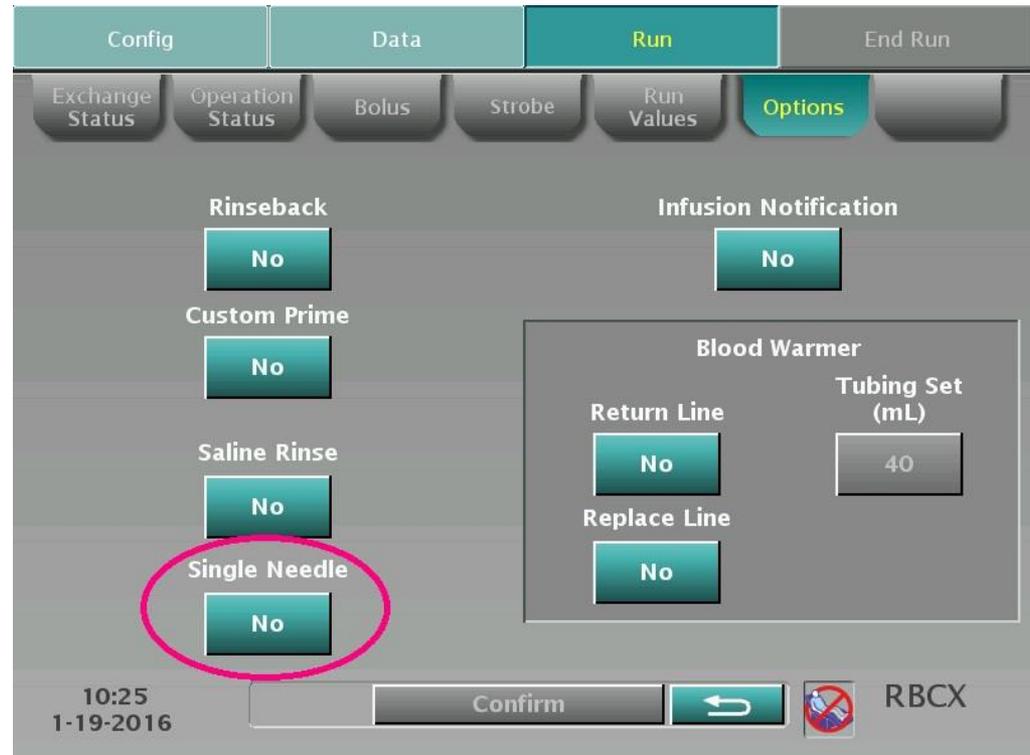
Spectra Optia® Apheresis System
February 2019

RBCX Single-Needle (SN) Option

RBCX

Single-needle (SN) option

- SN is an option for the RBCX procedure.
- SN may be selected at the start of the run or during the run.
- Once SN is confirmed during the run, there is no ability to go back to the dual-needle option.



RBCX

SN adapter

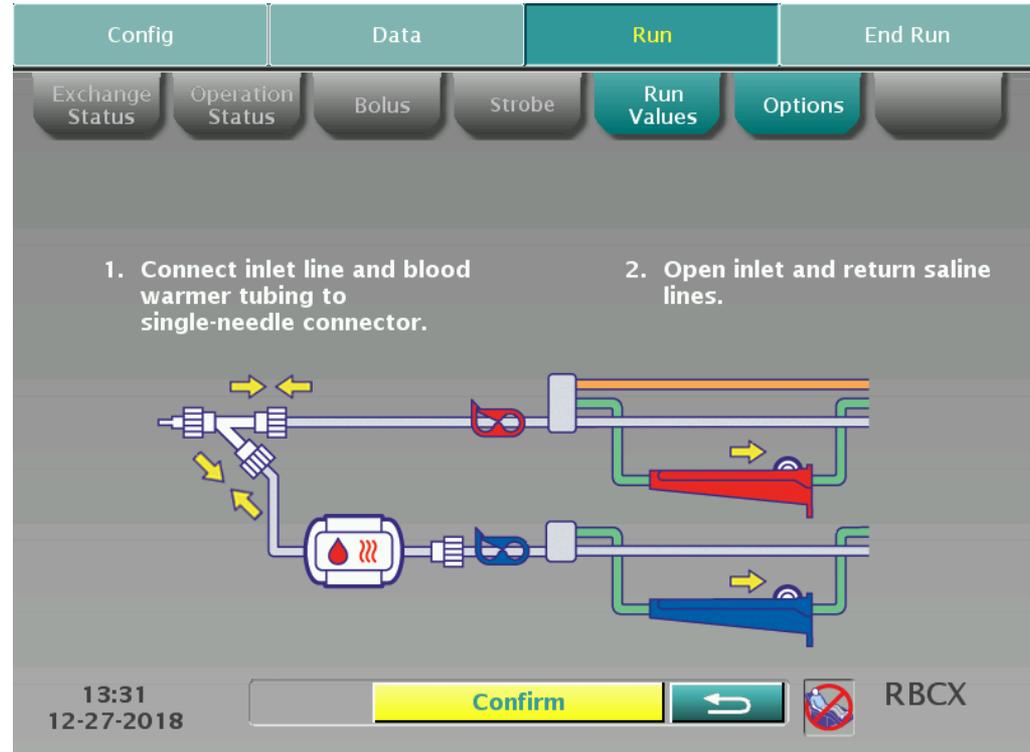
- The SN adapter is required for the conversion from dual-needle to SN.
- The SN adapter must be purchased separately: catalog number 11220.



RBCX SN Option

Screen prompts for line connection

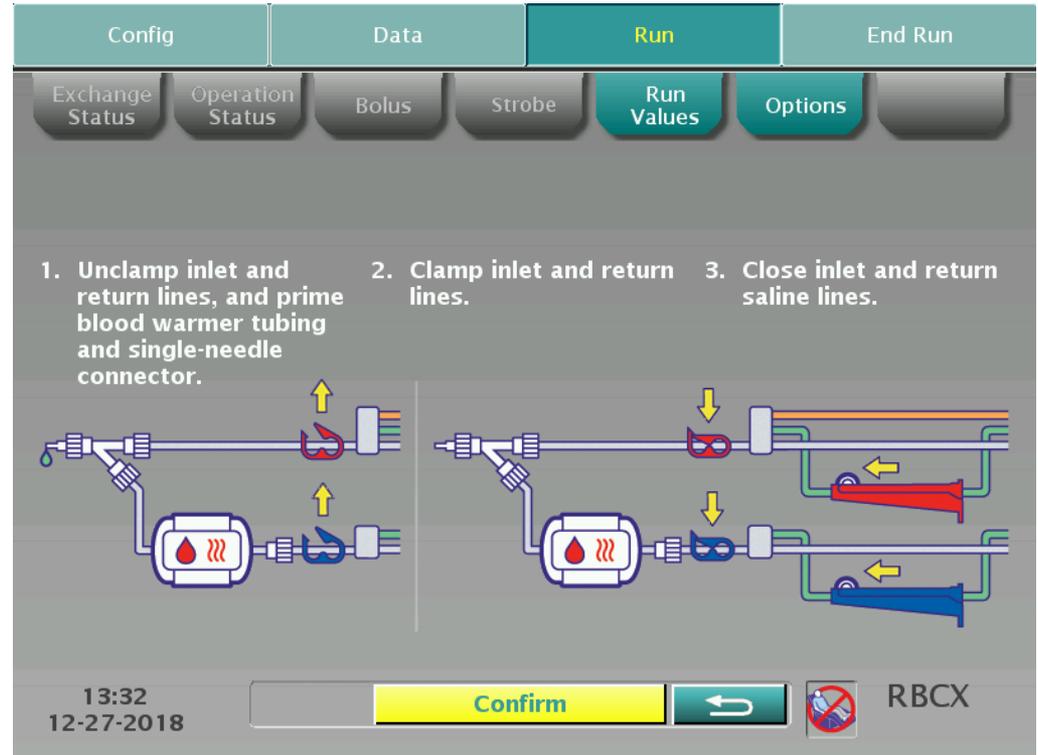
- This screen shows prompts for connecting the inlet and return lines to the SN adapter.
- The blood warmer has been enabled.



RBCX SN Option

Screen prompts for line connection

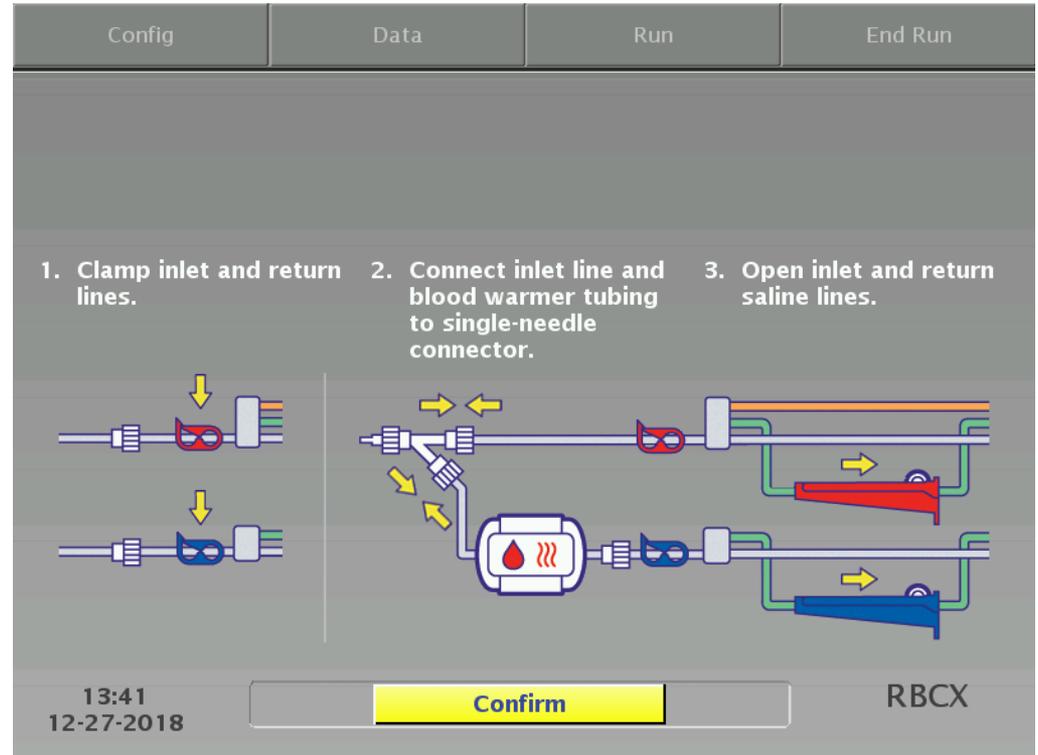
- This screen shows prompts to prime the tubing and the SN adapter.



RBCX SN Option

Screen prompts for line connection

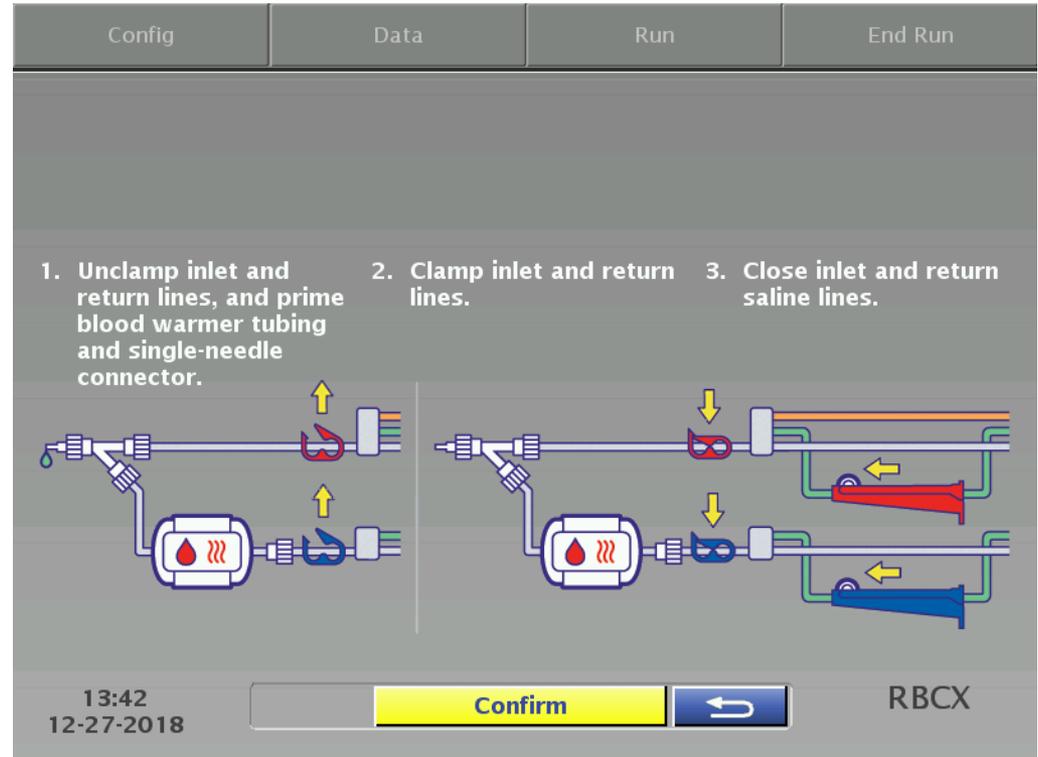
- This screen shows prompts to connect the inlet and return lines to the SN adapter if the procedure is converted to SN after the procedure has been started.



RBCX SN Option

Screen prompts for line connection

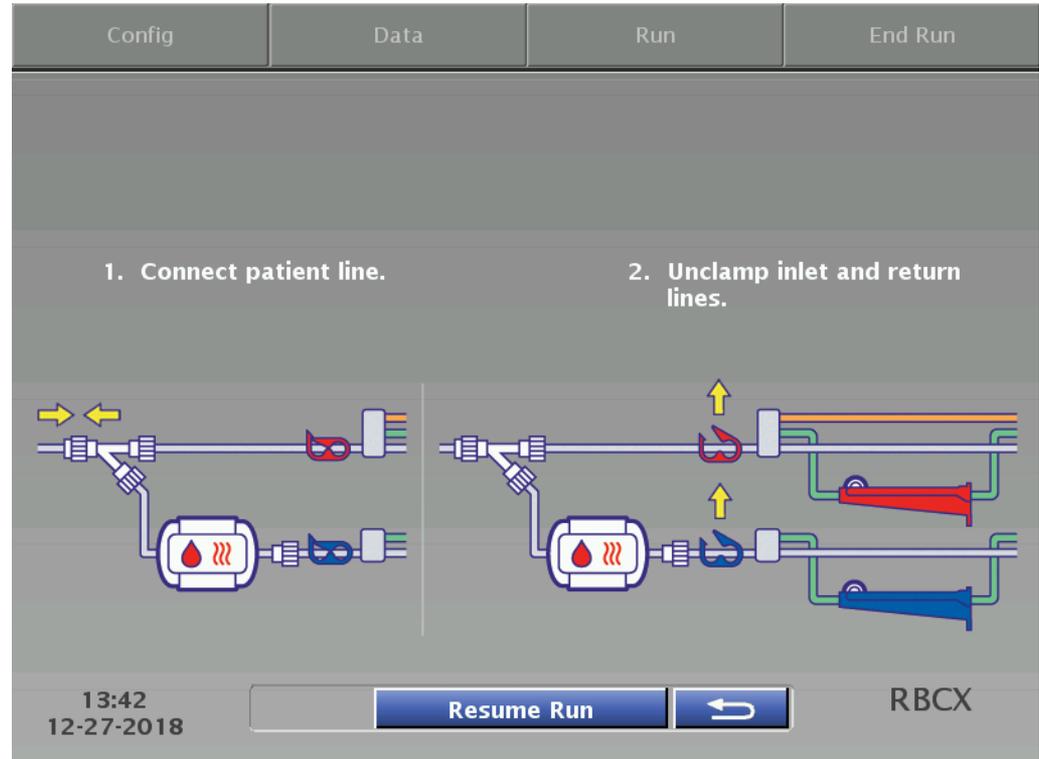
- This screen shows prompts to prime the SN adapter and inlet/return lines if the SN option is selected after the procedure has been started.



RBCX SN Option

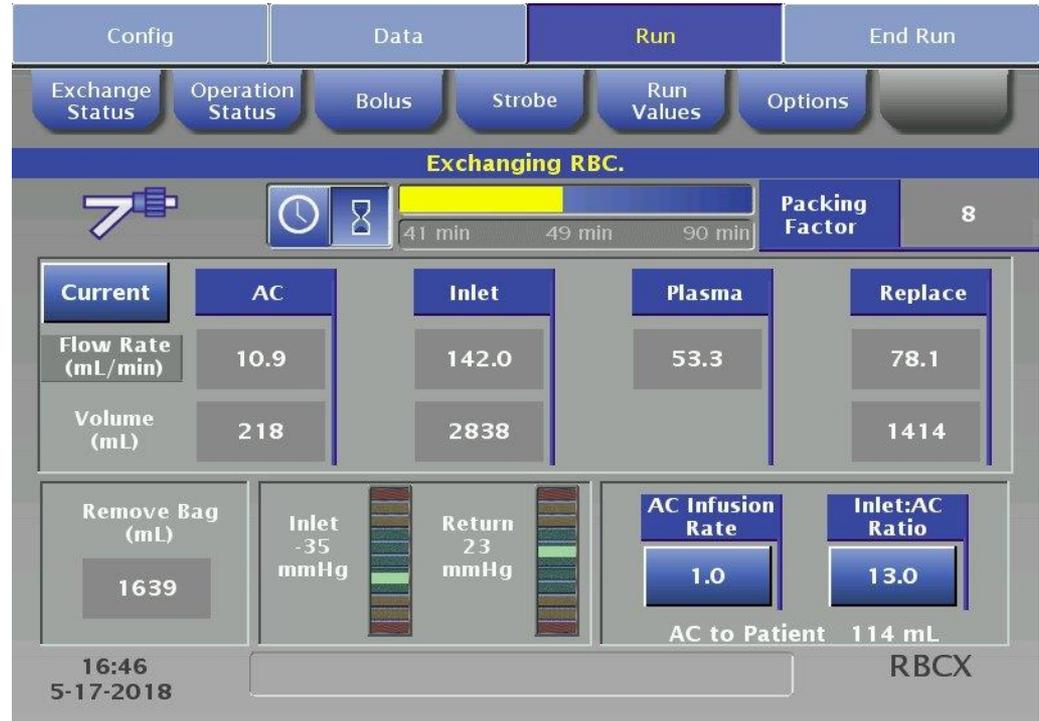
Screen prompts for line connection

- This screen shows prompts to connect the SN adapter to the patient line and resume the run after converting to SN.



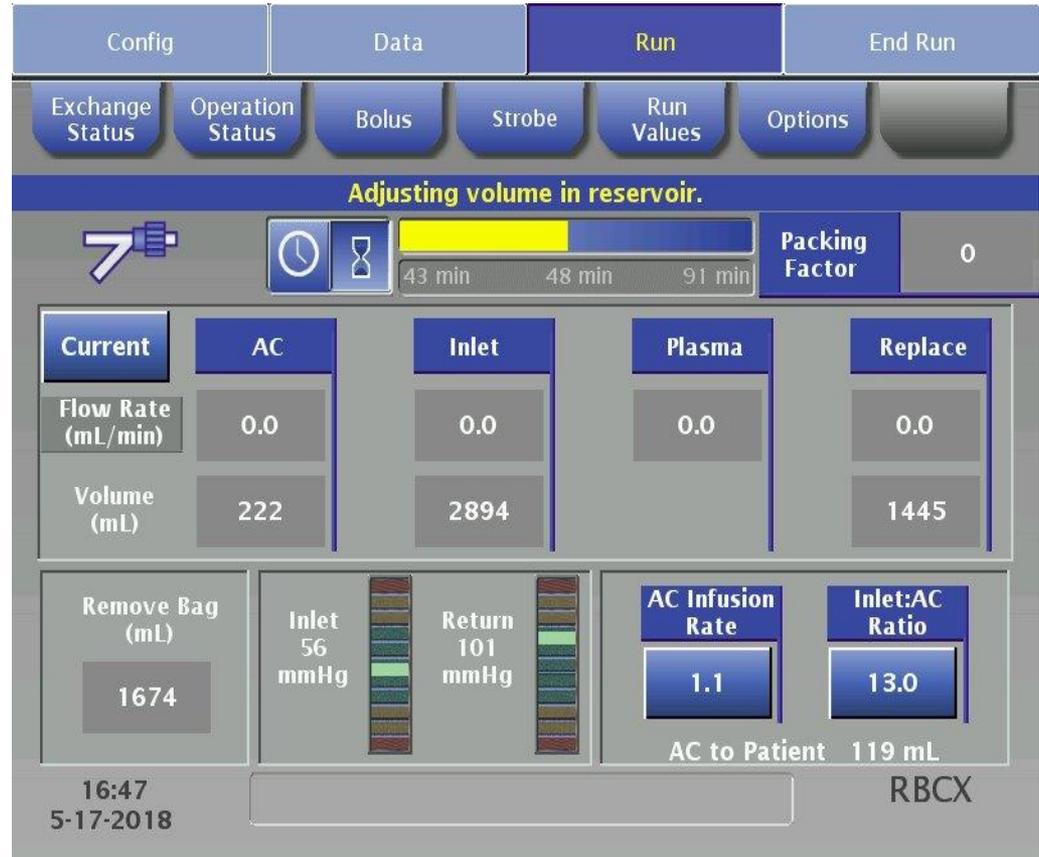
RBCX SN Option

- When SN is selected, the system cycles between drawing from the patient and returning to the patient.



RBCX SN Option

- During the **return cycle** of a SN procedure, the contents of the reservoir are returned to the patient.
- The flow rates of the pumps displayed on the main run screen will go to zero.



RBCX HCT Entry Limits

RBCX

Hct entry limits

Depletion/Exchange:

Minimum Hct that can be entered on the data entry screen is 10%.

The screenshot displays the 'Data' tab of the RBCX interface. A teal banner at the top reads 'Enter minimum hematocrit for patient (%)'. A numeric keypad is overlaid on the screen, showing the digit '0' in a yellow box. The keypad includes buttons for digits 0-9, a 'C' (clear) button, and an 'Enter' button. A range indicator '[10 ... 26]' is visible next to the keypad. The background interface shows various fields: 'AC Infusion Rate' (0.8), 'Minimum Hct (%)', 'Run Time (min)', 'FCR (%)', 'Replaced (mL): Exchange', 'Plasma', and 'Replace'. At the bottom, there is a 'Confirm' button, a back arrow, a 'No' icon, and the text 'RBCX'. The time and date '14:48 12-18-2018' are displayed in the bottom left corner.

RBCX

Hct entry limits

Exchange and Depletion/Exchange:
Operator is warned if the replacement fluid Hct entered is less than 50%.

The screenshot displays the RBCX interface with a warning message. At the top, there are four tabs: "Config", "Data", "Run", and "End Run". Below the tabs, a red banner reads "Check replacement fluid hematocrit entered." The main message in yellow text says "Check Replacement Fluid Hematocrit" followed by "Replacement fluid hematocrit entered is lower than 50%." Below this, it says "Do one of the following:" and lists two options: "If the hematocrit entered was not correct, touch the go back button." with a "Go Back" button (a blue square with a white arrow pointing left), and "If the hematocrit entered was correct, re-enter the hematocrit." with an "Hct (%)" button (a blue square with white text). At the bottom left, the time is "14:40" and the date is "12-18-2018". In the center bottom is a "Confirm" button. At the bottom right is a "No Blood" icon (a red circle with a white slash over a blue and red blood drop icon) and the text "RBCX".

RBCX

Hct entry limits

Exchange:

Target Hct may be either a minimum of 20% or the patient's starting Hct.

RBCX Caution Status

RBCX

Caution status

Exchange:

If the entered **target Hct** is less than 70% or greater than 130% of the patient Hct, a Caution status alert appears.

Example: Patient Hct = 28%

$$28 \times 70\% = 19.6\% \text{ and } 28 \times 130\% = 36.4\%$$

In this example, if the operator enters a target Hct below 20% or above 36%, the system enters Caution status.

RBCX

Hct entry verification

- When the operator enters a target Hct outside of the recommended range, this screen prompts for verification.

Config Data Run End Run

Check target hematocrit entered.

Check Target Hematocrit
Recommended range: 20% - 36%

Do one of the following:

- If the hematocrit entered was not correct, touch the go back button. 
- If the hematocrit entered was correct, re-enter the hematocrit. 

14:41
12-18-2018

Confirm  RBCX

RBCX

Hct entry verification

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 (%)			
0.8	13.0	1719	60	43			
Minimum Hct (%)	27	Target Hct (%)	37	Replaced (mL): Exchange	1703		
Target Flow Rate (mL/min)	AC	Inlet	Plasma	Replace			
	2.9	38.1	11.2	24.4			
Target Volume (mL)	180	2344		1703			
13:06 12-27-2018		Confirm			RBCX		

RBCX

Caution status

Depletion/Exchange:

If the entered **minimum Hct** is lower than 70% of the patient's Hct, a Caution status alert appears.

Example: Patient Hct = 28%

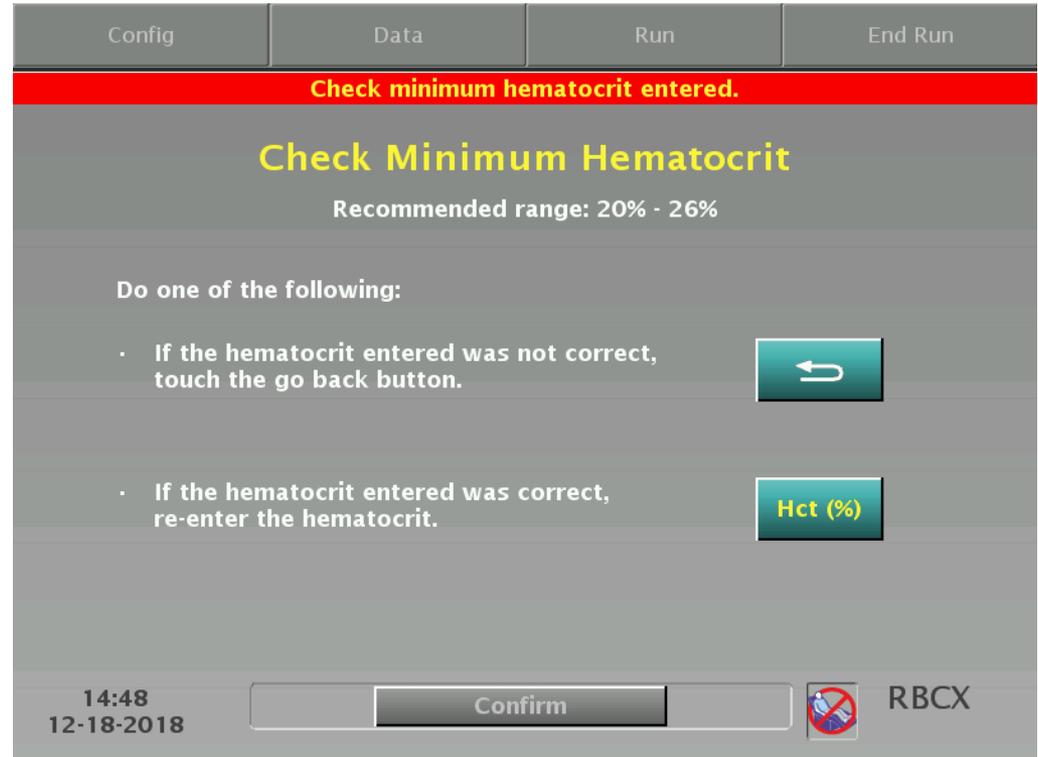
$$28 \times 70\% = 19.6\%$$

In this example, if the operator enters a minimum Hct below 20%, a Caution status alert appears.

RBCX

Hct entry verification

- When the operator enters a minimum Hct outside of the recommended range, this screen prompts for verification.





Medication Infusion Notification All Protocols

Medication Infusion Notification

If the medication infusion notification option is selected and a medication is infused at the patient's return access, the system notifies the operator to consider pausing and starting the infusion when the Spectra Optia pumps pause or resume.

Medication Infusion Notification

Configuration

- You can access the medication infusion notification feature on the configuration screen.
 - If **Yes** is selected, this feature will be active for all procedures.
 - If **No** is selected, this feature is not active and the notification screens will not be displayed.

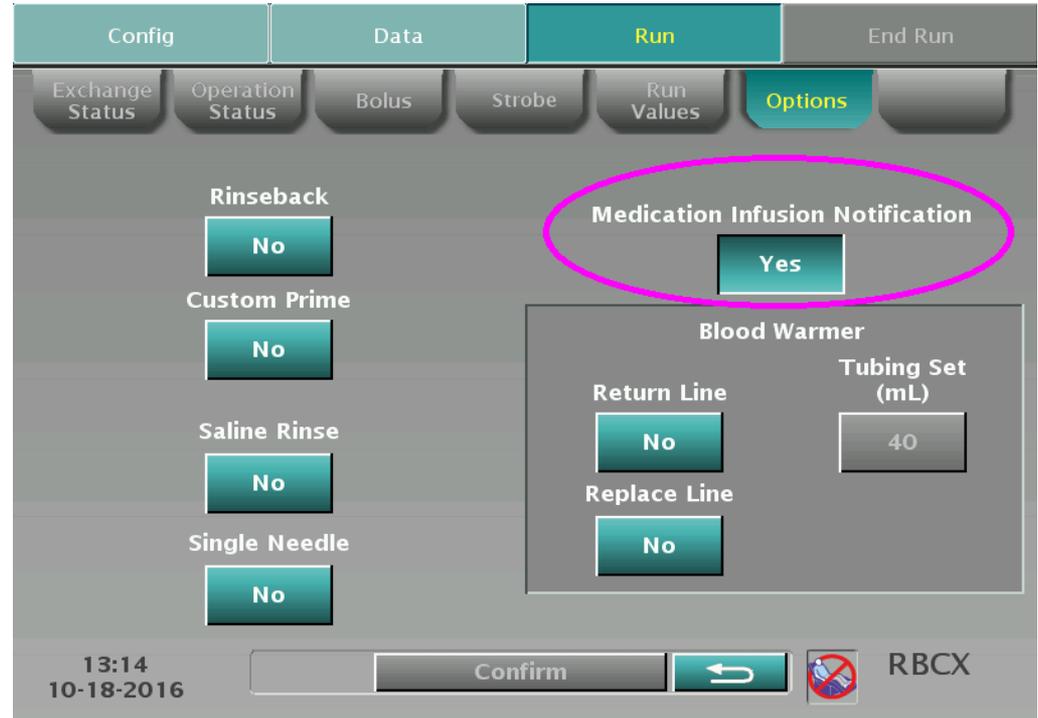
The screenshot displays the configuration screen for Medication Infusion Notification. The screen is divided into several sections:

- Top Navigation:** Config (highlighted), Data, Run, End Run.
- Sub-Menu:** System, Procedure (highlighted), Report, Network.
- Configuration Options:**
 - Height Units:** cm
 - Weight Units:** kg
 - Medication Infusion Notification:** Yes
 - Custom Prime Recommendation (% TBV):** 10
 - Pressure Alarm Limit (mmHg):** Inlet: -250, Return: 400
 - AC Container:** Notification: Yes, Volume (mL): 750
- Bottom Bar:** 14:14, 12-18-2018, Confirm button, back arrow, and a red prohibition sign over a person icon.

Medication Infusion Notification

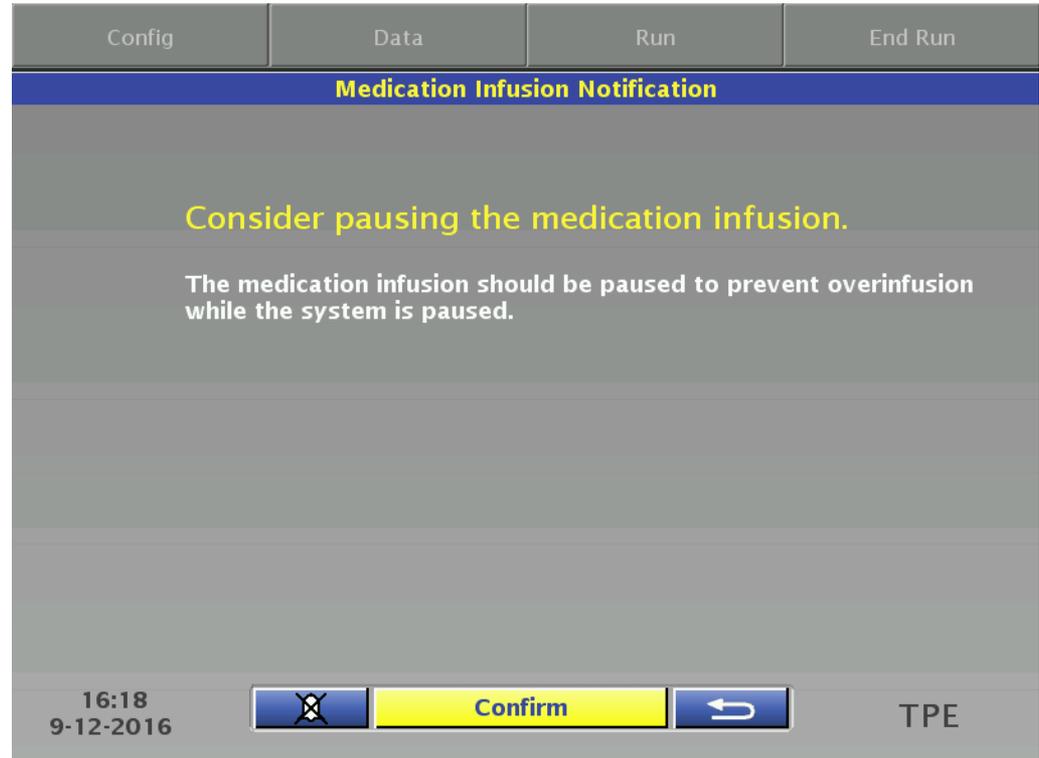
Options tab

- Medication infusion notification can also be enabled/disabled from the Run menu, Options tab.
- If **Yes** is displayed, the medication infusion notification is active only for the current procedure.



Medication Infusion Notification

- If the medication infusion notification is enabled, when the return pump is paused for 2 minutes, a screen appears to notify the operator to consider pausing the medication infusion.



Medication Infusion Notification

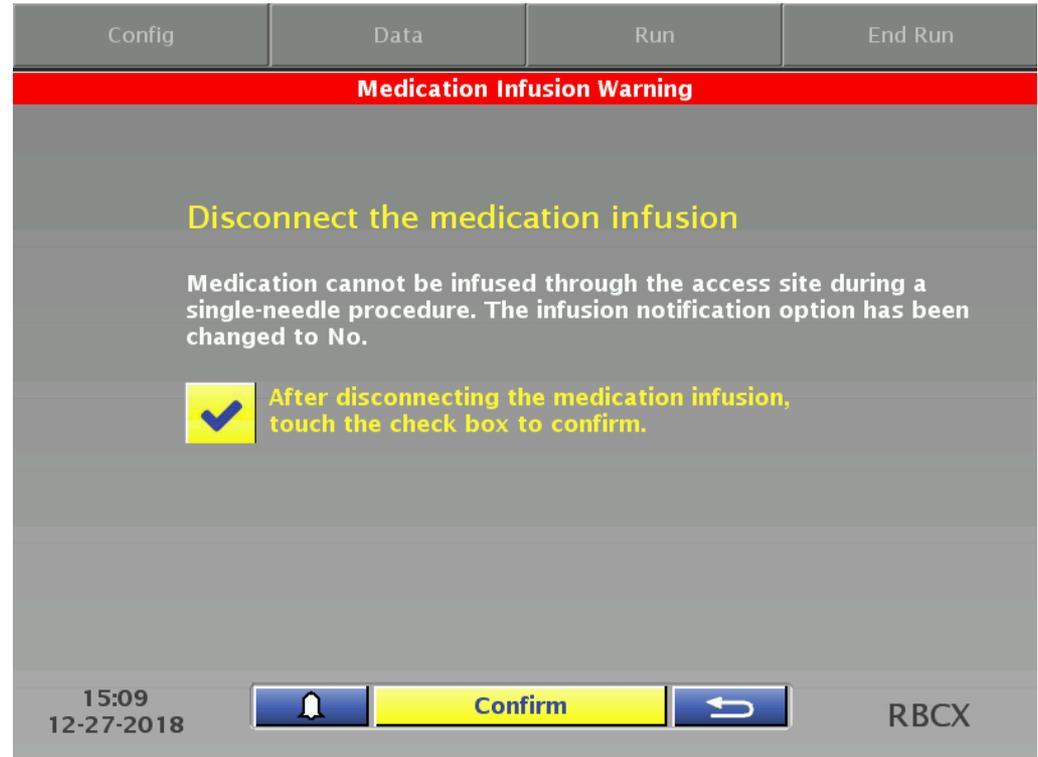
- If the medication infusion notification is enabled, when the return pump resumes, a screen appears to notify the operator to consider restarting the medication infusion.



Medication Infusion Notification

SN option

- If SN is selected for TPE or RBCX, the medication infusion notification option is disabled.



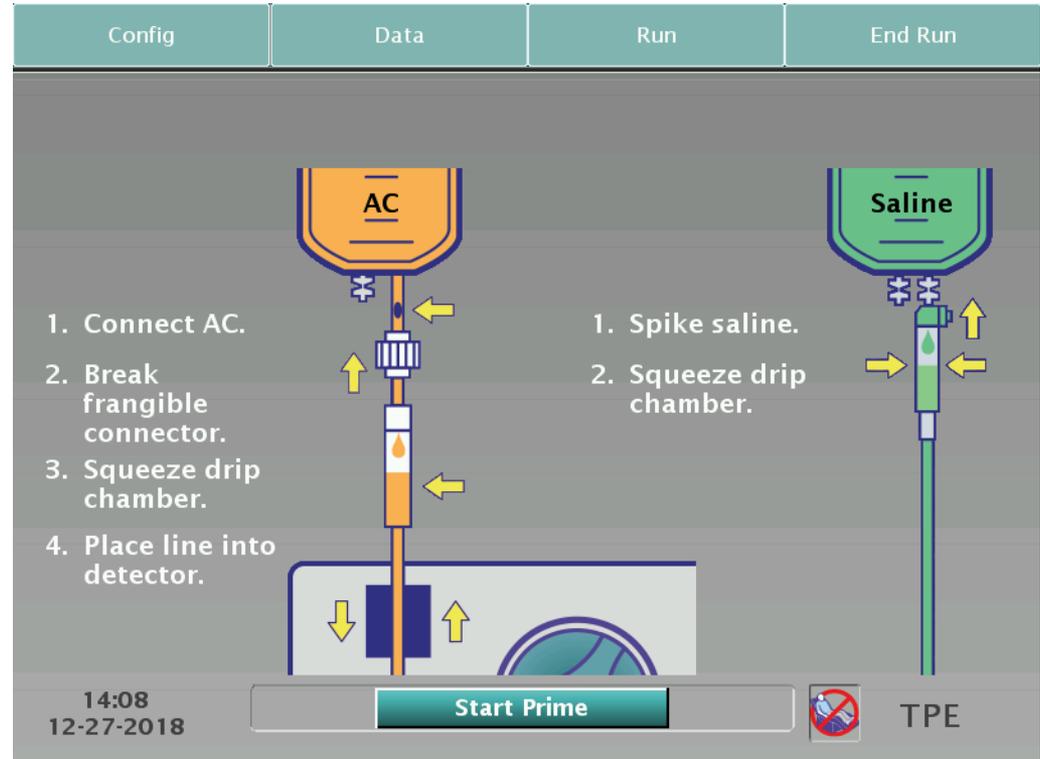
Correct Connect

Correct Connect

ACD-A

- Instead of a spike, the Correct Connect ACD-A bag has a unique luer connection.

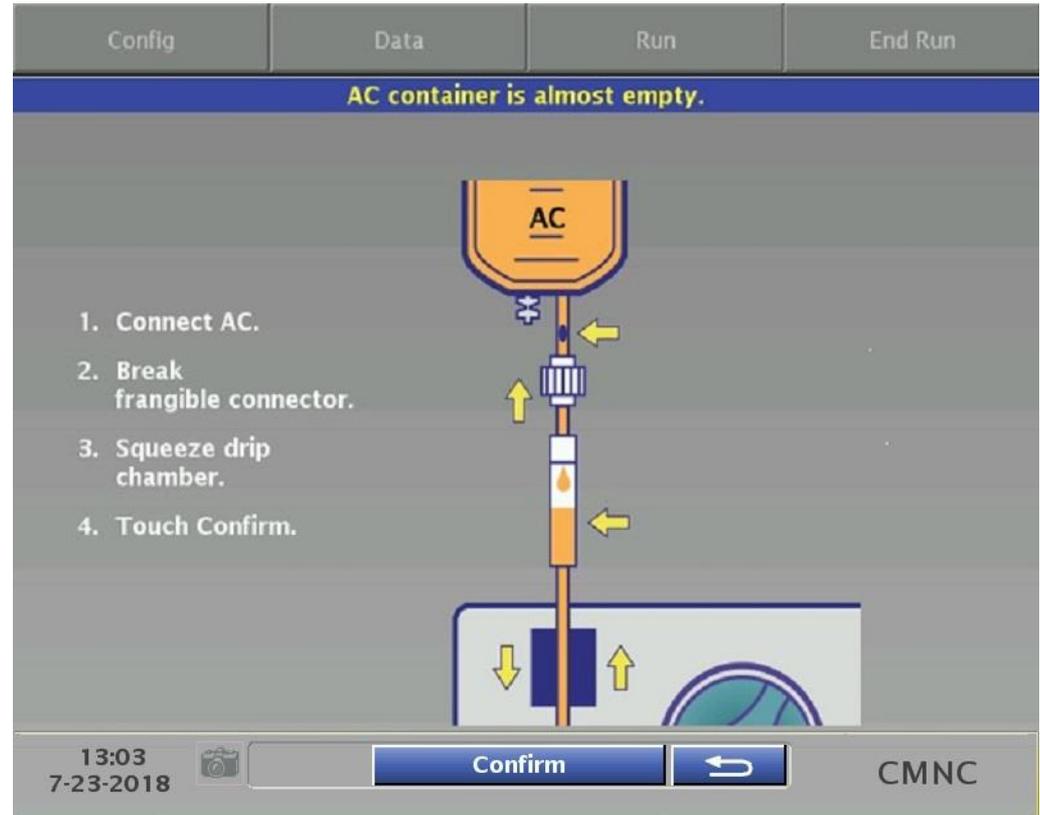
 The ACD-A bag line has a frangible connector that must be thoroughly broken after connecting the luers.



Correct Connect

ACD-A

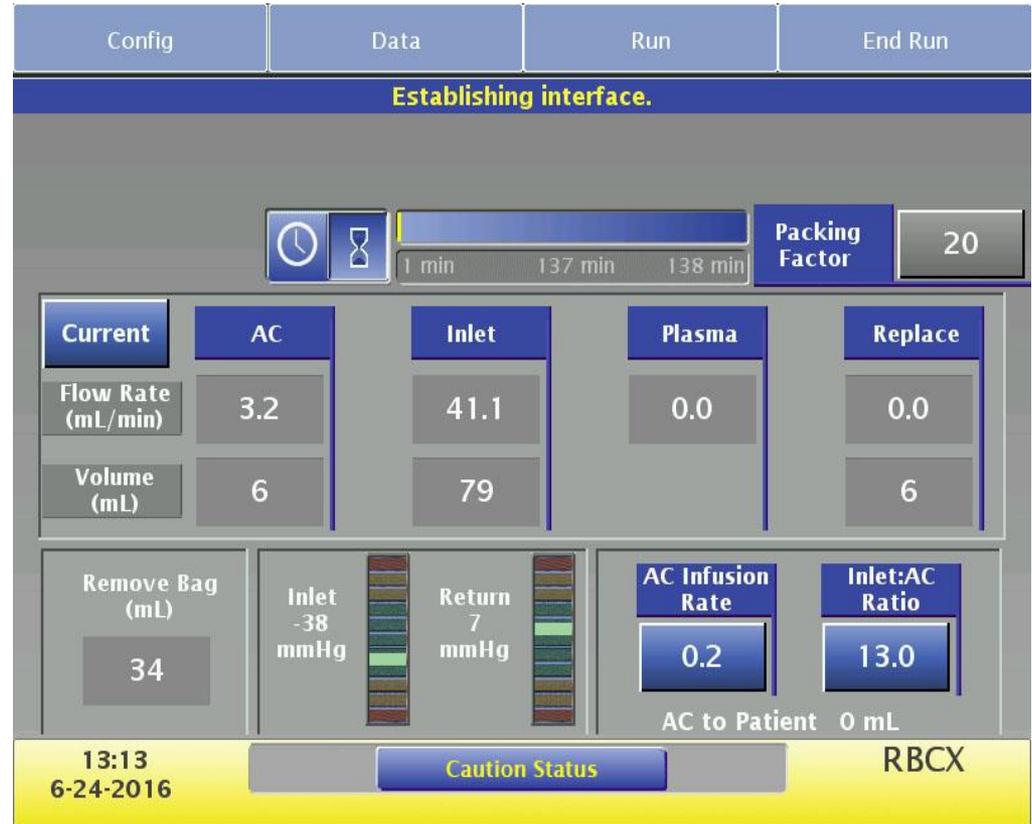
- If the AC container notification is enabled, a screen prompts the operator to break the frangible connector on additional ACD-A bags.



Caution Status
All Protocols

Caution Status

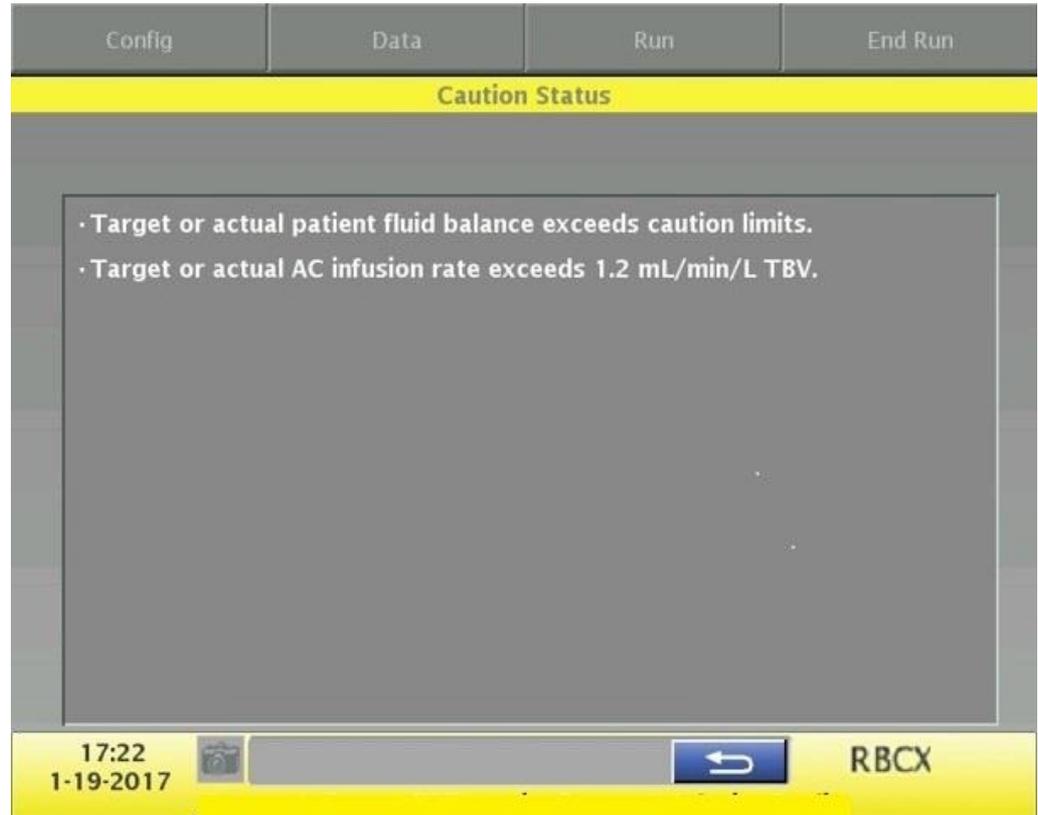
- Caution Status alerts the operator that the system is operating outside of certain established limits.
- When the system is operating in Caution Status, a yellow line appears on the bottom of the screen.



Caution Status

List

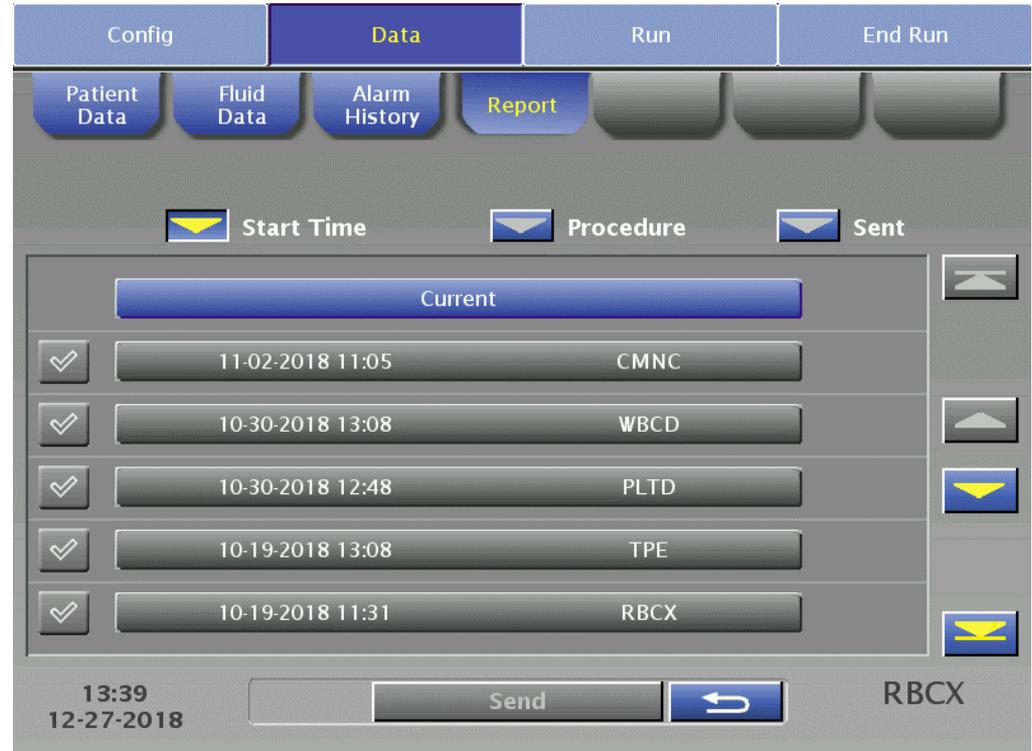
- When the operator touches the **Caution Status** button on the main run screen, a list of causes for the Caution Status is displayed.



**Miscellaneous
All Protocols**

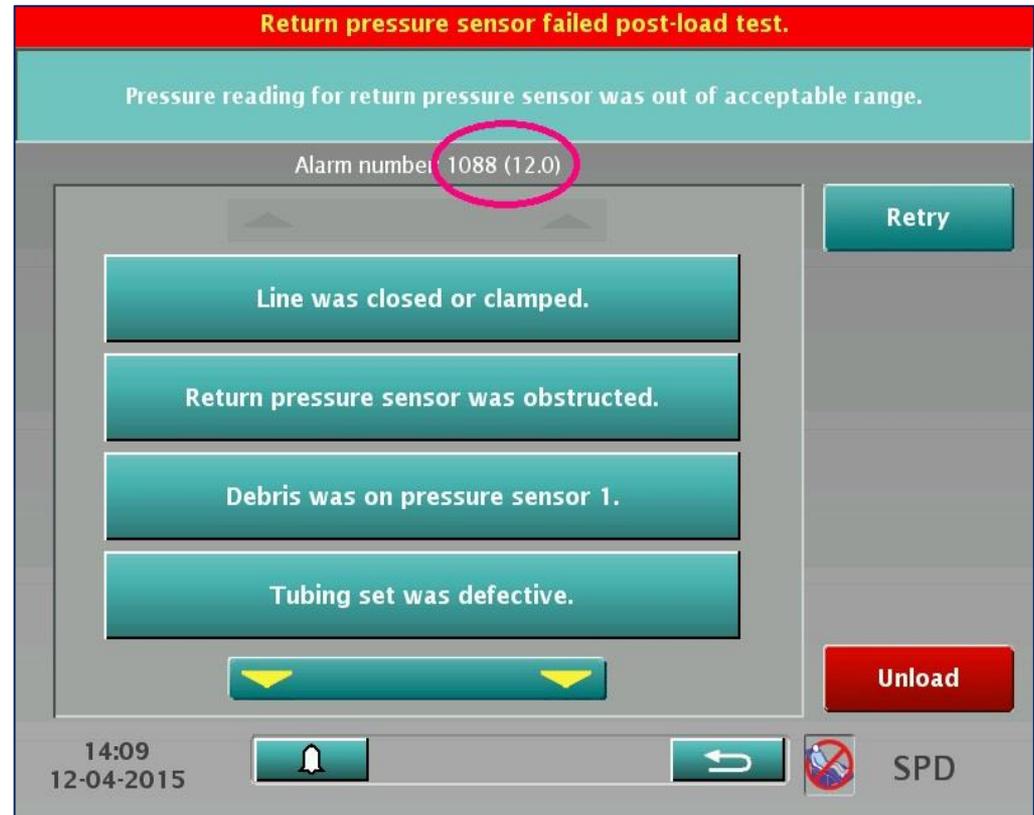
Reports

- The user can view the current procedure report during the run.



Alarm Number

- Alarm screens have been updated to include an alarm number that is associated with an alarm name.
- The current system software version is displayed in parenthesis next to the alarm number.



Alarm

CMNC, BMP, PLTD, WBCD

“Cells were not collected” message

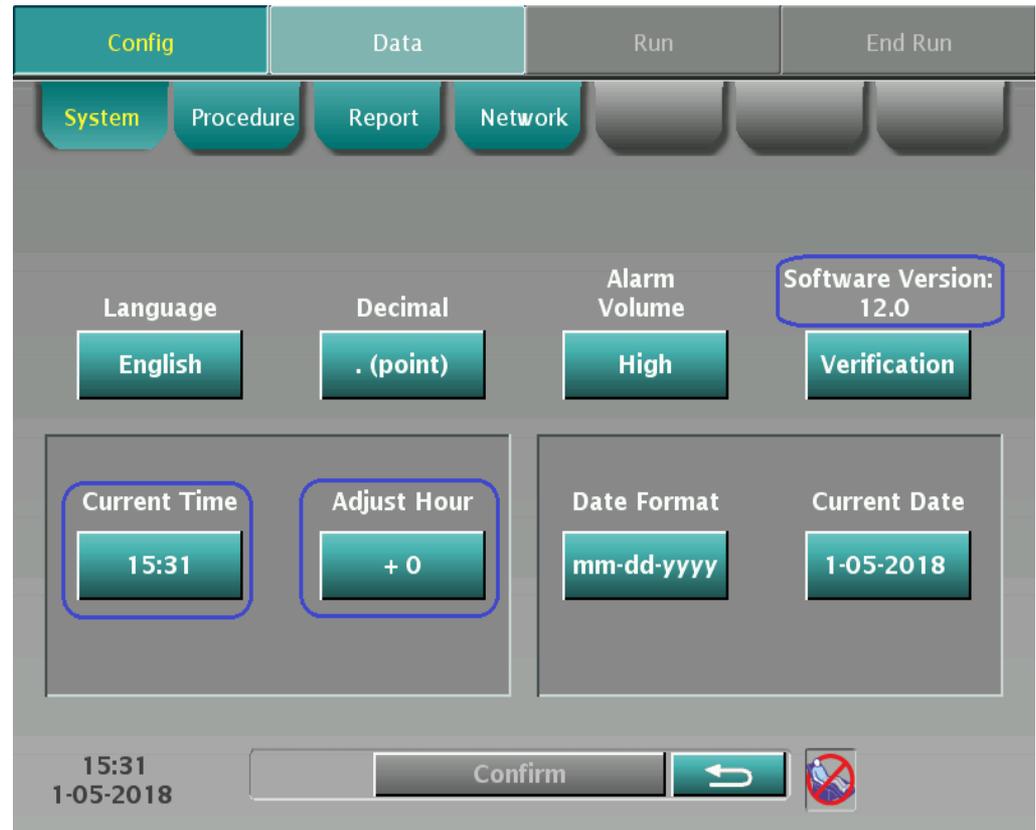
- If the operator has set the collect valve to “Return to Patient,” the “cells were not collected” alarm is displayed after approximately 5 minutes to warn the operator that no cells are being collected. **When the alarm is displayed, the pumps no longer pause.**
- If the alarm is ignored for an additional 5 minutes, a new alarm is displayed, and the pumps pause.



System Configuration Updates All Protocols

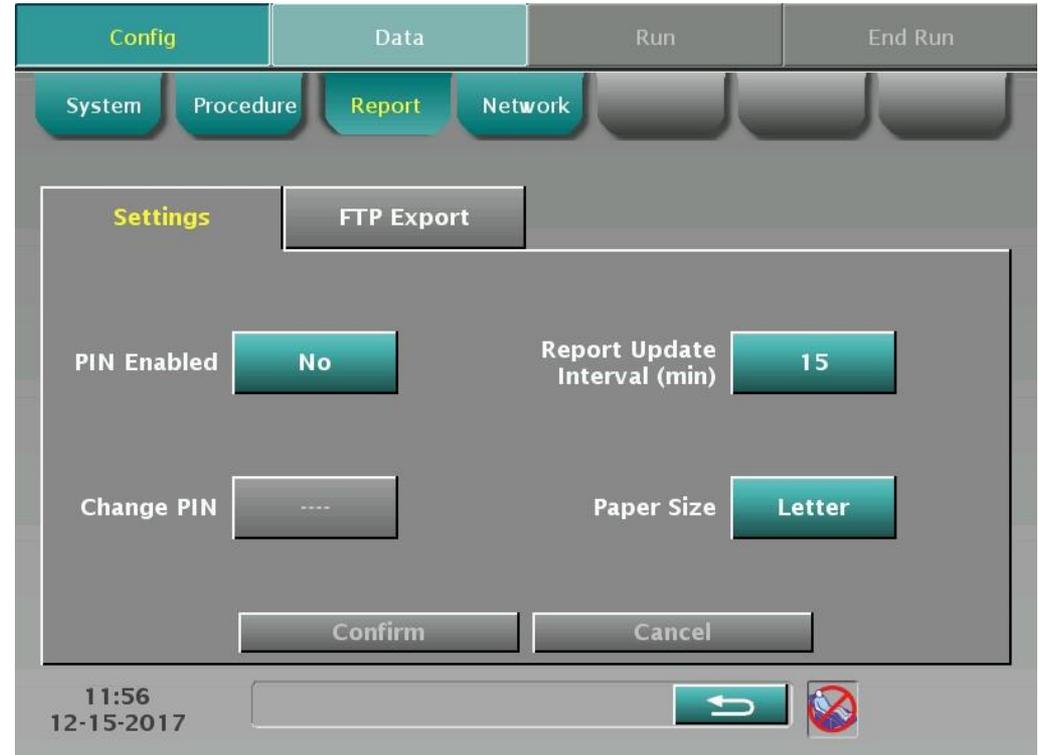
Software Version and Current Time

- The software version is displayed on the configuration screen.
- Current time is displayed only in a 24-hour format.
- Current time can be changed easily for daylight saving time.



Historical Report Access

- This option requires a PIN to view the procedure reports.
- To access this feature, enable the setting and enter the PIN on the Config menu, Report tab, Settings section.



Data Export

- Historical procedure reports can be configured to be exported as a PDF file via FTP server.
- Note: The system no longer allows the report to be exported to a printer.

The screenshot shows a software interface for configuring data export. At the top, there are four tabs: 'Config' (highlighted in yellow), 'Data', 'Run', and 'End Run'. Below these are sub-tabs: 'System', 'Procedure', 'Report' (highlighted in yellow), and 'Network'. The main content area is titled 'Settings' and 'FTP Export'. It contains several controls: an 'Automatic' section with a 'No' button; a 'Connection' section with a 'Test' button; a 'PDF' checkbox which is checked; and three input fields for 'IP Address' (172.21.199.254), 'Port' (23), and 'Password'. At the bottom of the settings area are 'Confirm' and 'Cancel' buttons. The bottom status bar shows the time '11:56' and date '12-15-2017', along with a back arrow button and a red prohibition sign icon.

Data Export

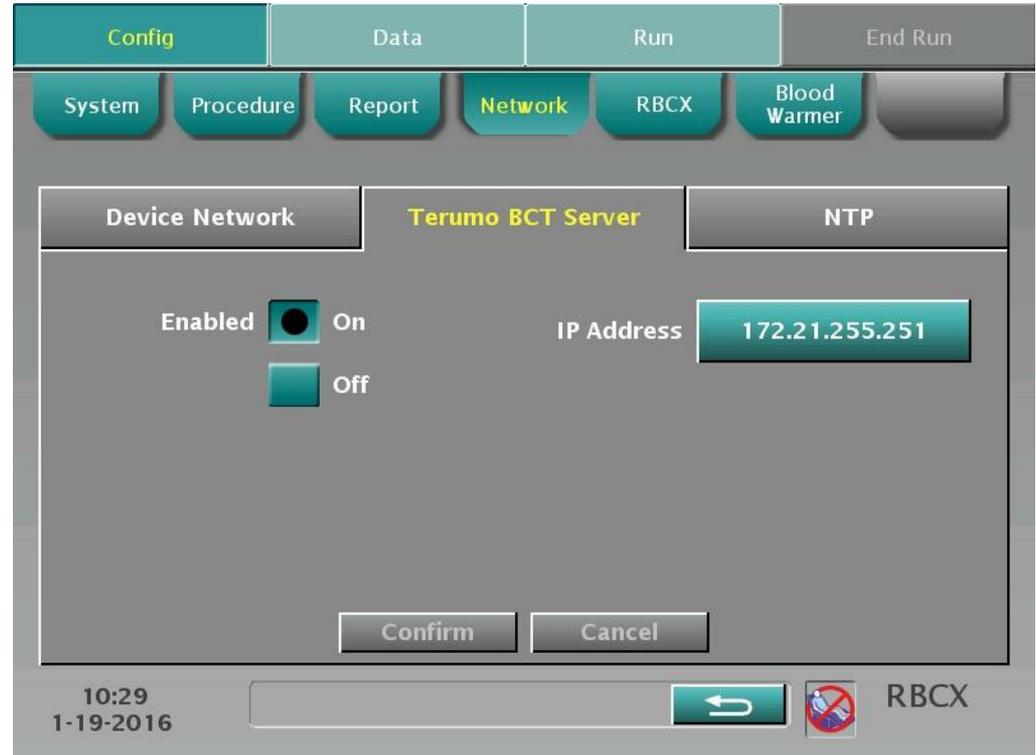
- This screen allows for the operator to configure the IP address of the device.

The screenshot displays the 'Network' configuration screen for a Terumo RBCX device. The interface is organized into several sections:

- Top Navigation:** A horizontal bar with tabs for 'Config' (highlighted), 'Data', 'Run', and 'End Run'.
- Function Buttons:** A row of buttons including 'System', 'Procedure', 'Report', 'Network' (highlighted), 'RBCX', and 'Blood Warmer'.
- Device Network Section:** A central panel with a title 'Device Network' and sub-sections for 'Terumo BCT Server' and 'NTP'.
 - DHCP:** A radio button interface with 'Off' selected (indicated by a black dot) and 'On' as an alternative option.
 - IP Address:** A text field containing '172.21.179.33'.
 - Subnet Mask:** A text field containing '255.255.0.0'.
 - Default Gateway Address:** A text field containing '172.21.255.251'.
- Action Buttons:** 'Confirm' and 'Cancel' buttons located at the bottom of the configuration panel.
- Footer:** A status bar showing the time '10:28' and date '1-19-2016', a back arrow button, a 'No Network' icon, and the label 'RBCX'.

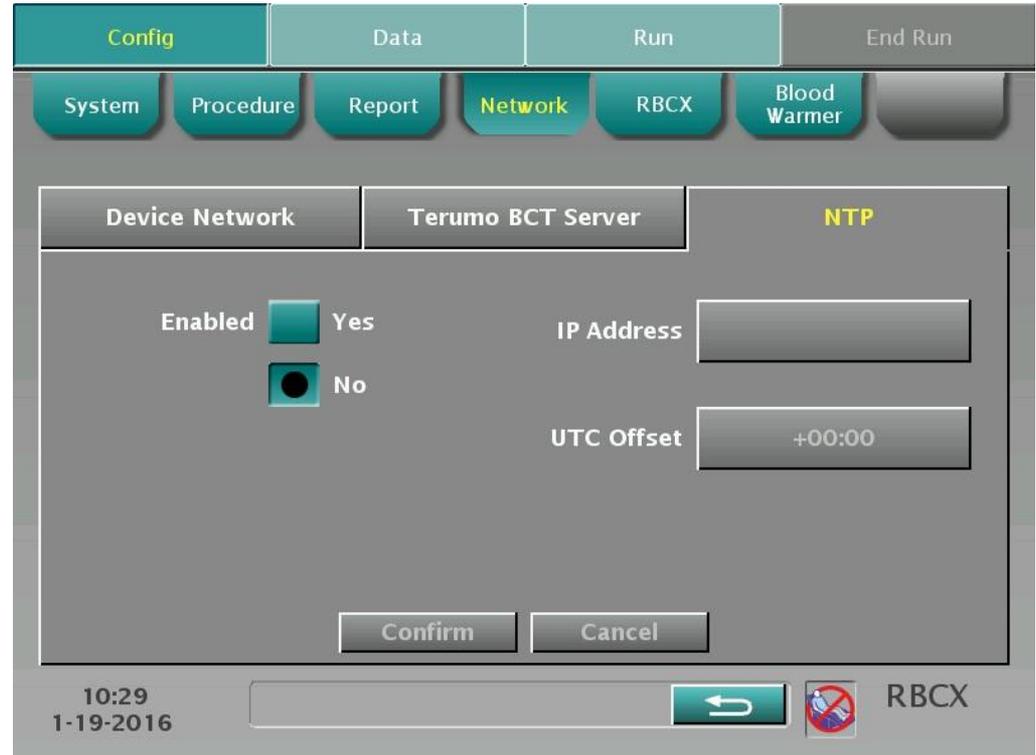
Network Connection

- This screen allows for a connection to a Terumo Blood and Cell Technologies server.
- Example: Cadence® Data Collection System server.



Network Connection

- This screen allows for a connection to a time synchronization server.



QUESTIONS?





We Touch a Patient's Life Every Second of Every Day

*Delaney Stafford, patient
Acute Lymphoblastic Leukemia*

 **TERUMO** BLOOD AND CELL
TECHNOLOGIES