

Continuous Mononuclear Cell Collection (Version 12 CMNC) Procedure 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‡
- Platelet depletion
- Processing of harvested bone marrow

*Procedure availability varies by country.

‡White blood cell reduction for patients with leukocytosis at risk for leukostasis (Intended Use in the U.S.)

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 CMNC 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 data on the run values screen
- Make changes to data on the data, run, and end run menu screens
- Optimize the run for the desired procedure outcomes
- Troubleshoot issues that may arise



Presentation Overview

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

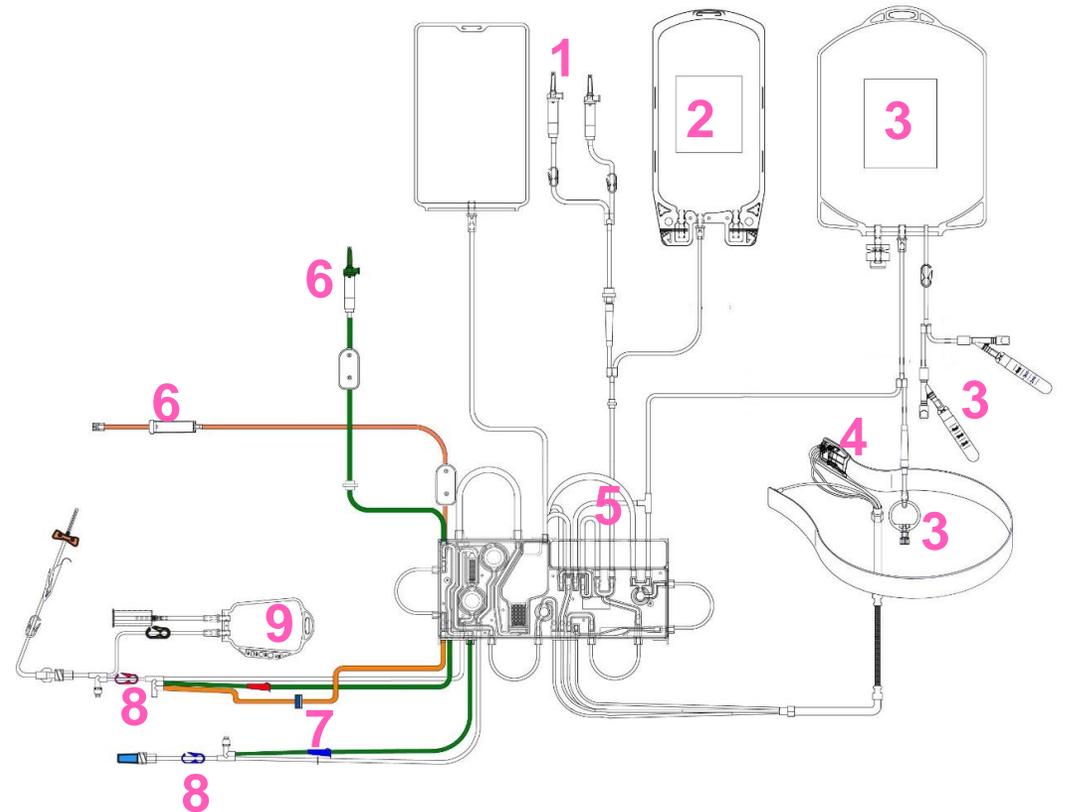


Introduction

- IDL Set
- Basic Principles of CMNC Collection
- Cell Separation: Channel
- Cell Separation: Connector
- AIM System Control of Collection
- Collection Preference (CP)

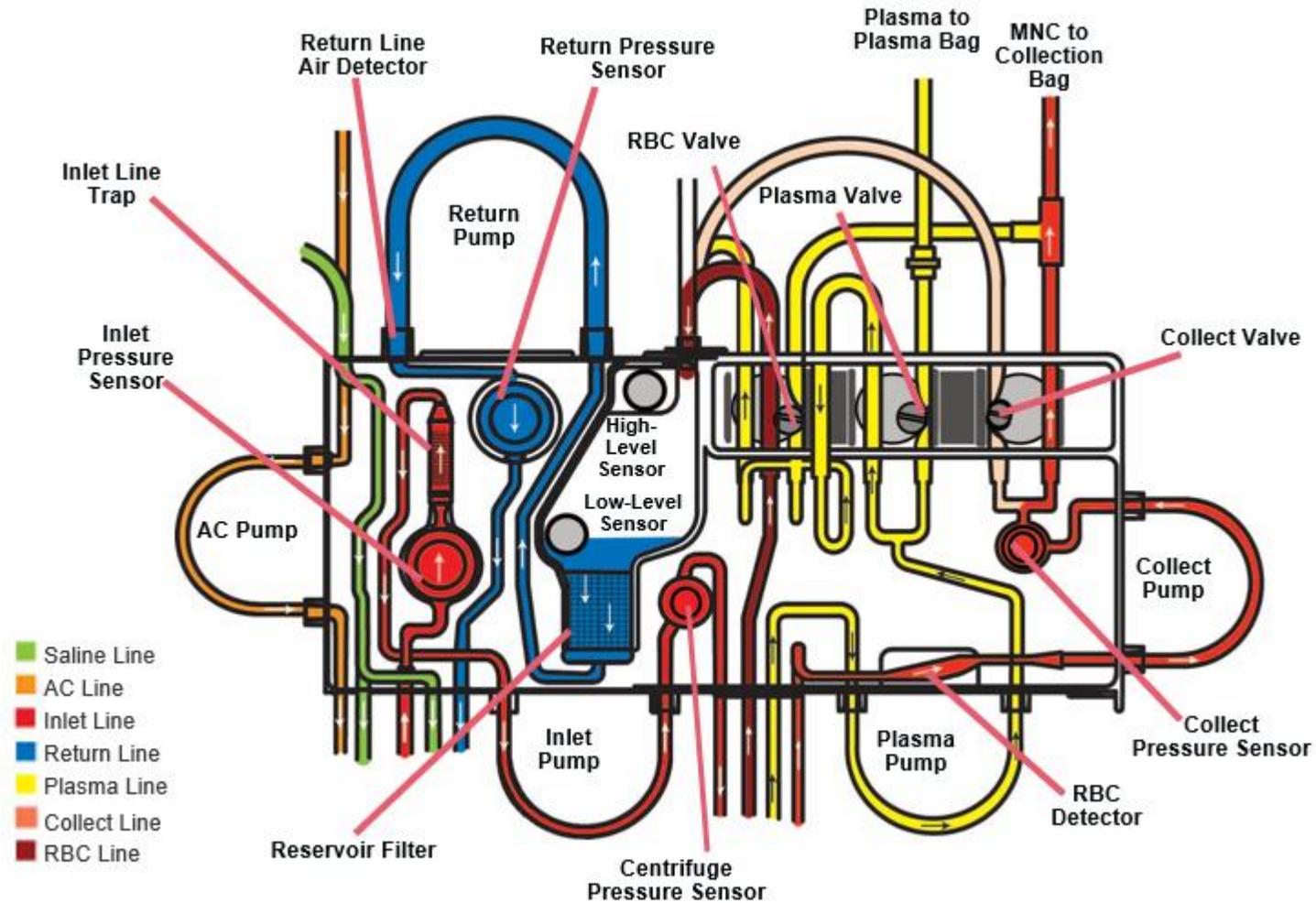
IDL Set

1. Replace line
 - Frangible connector
2. Plasma bag
3. Collection bag
 - Spike port
 - Sample bulbs
 - Sterile barrier filter
4. Connector
5. Cassette
6. AC and saline tubing
 - AC Correct Connect* luer
 - Saline spike
 - Sterile barrier filters
7. AC check valve
8. Colored clamps
9. Diversion bag

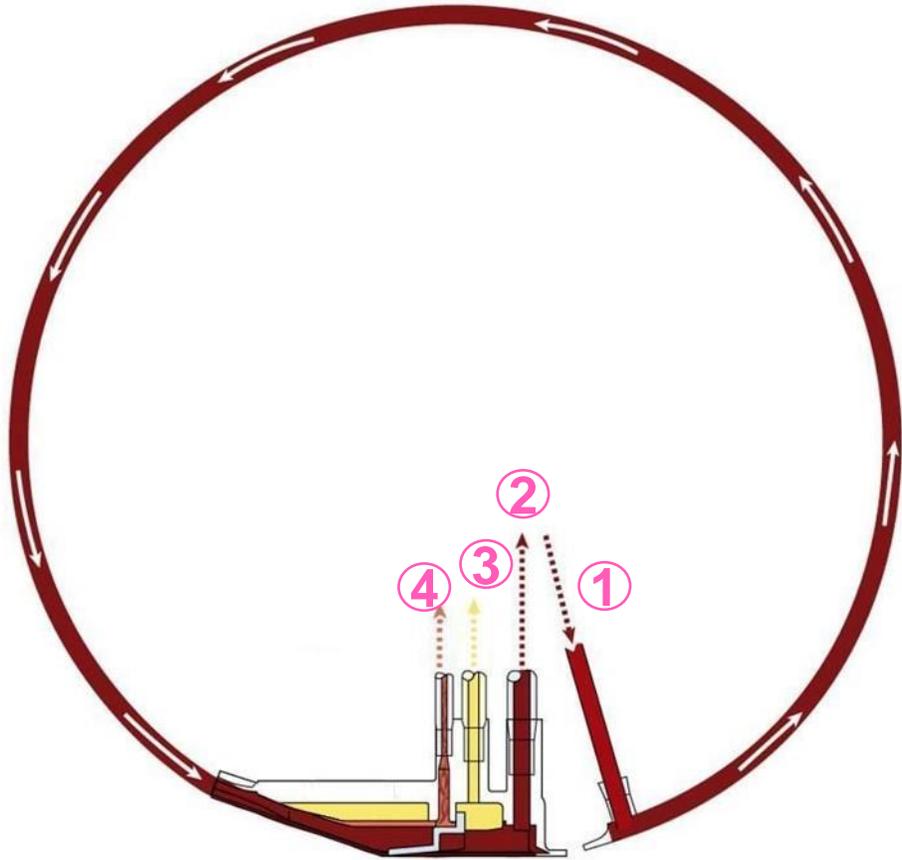


*Correct Connect IDL Set availability is dependent upon regulatory approval

Basic Principles of CMNC Collection



Cell Separation: Channel



1. Whole blood enters the channel.
2. Red blood cells (RBC) flow passively to the reservoir.
3. Plasma is pumped into the reservoir, or it is collected.
4. Cells are continuously pumped into the collection bag.

Cell Separation: Connector

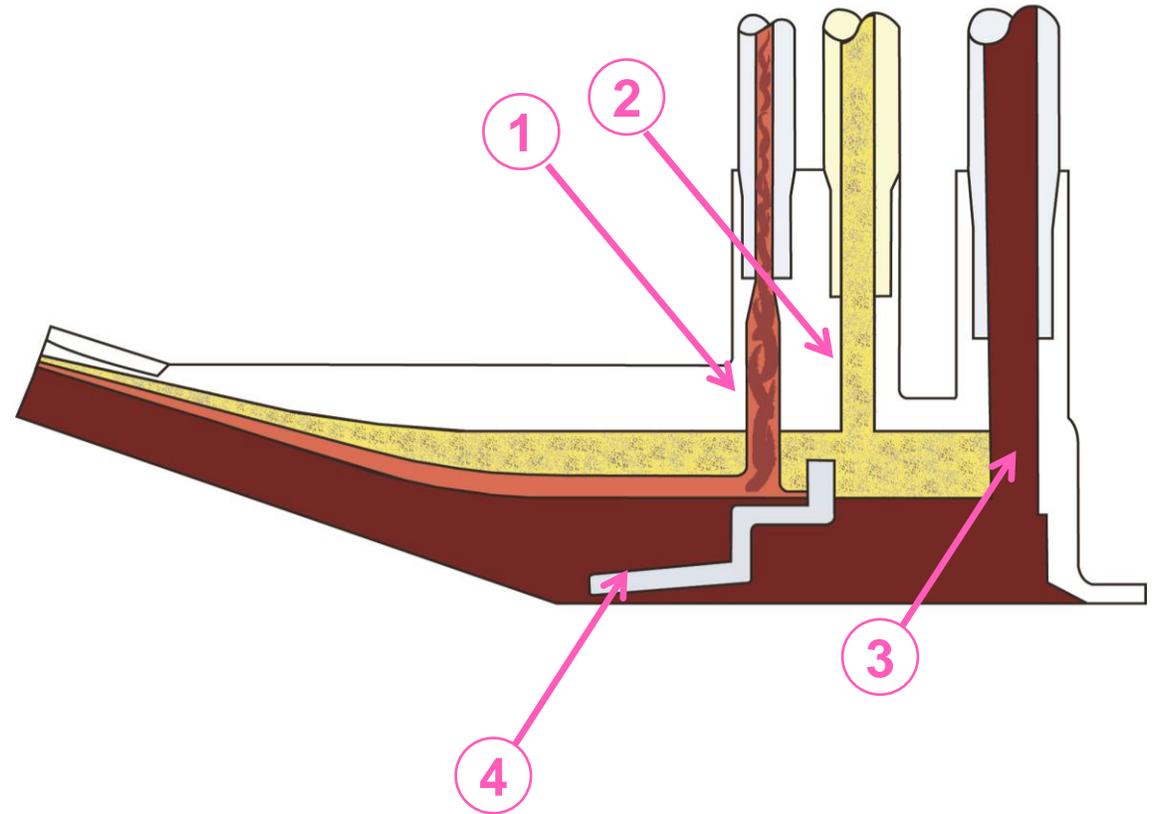
Centrifugal force separates the blood in the connector into layers based on the **specific gravity** of the cells:

Platelets: 1.04 to 1.08

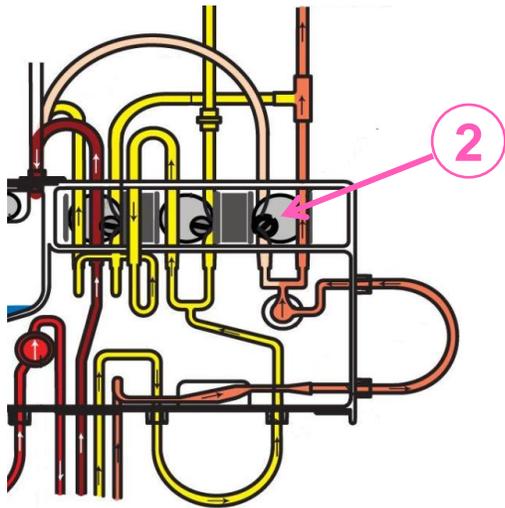
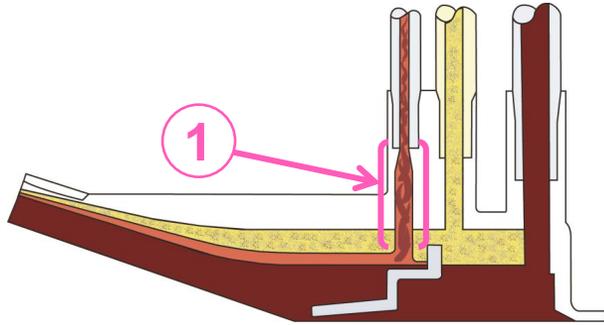
MNC: 1.06 to 1.09

RBC: 1.08 to 1.11

1. Collect port
2. Plasma port
3. RBC port
4. Skimmer dam



AIM System Control of Collection

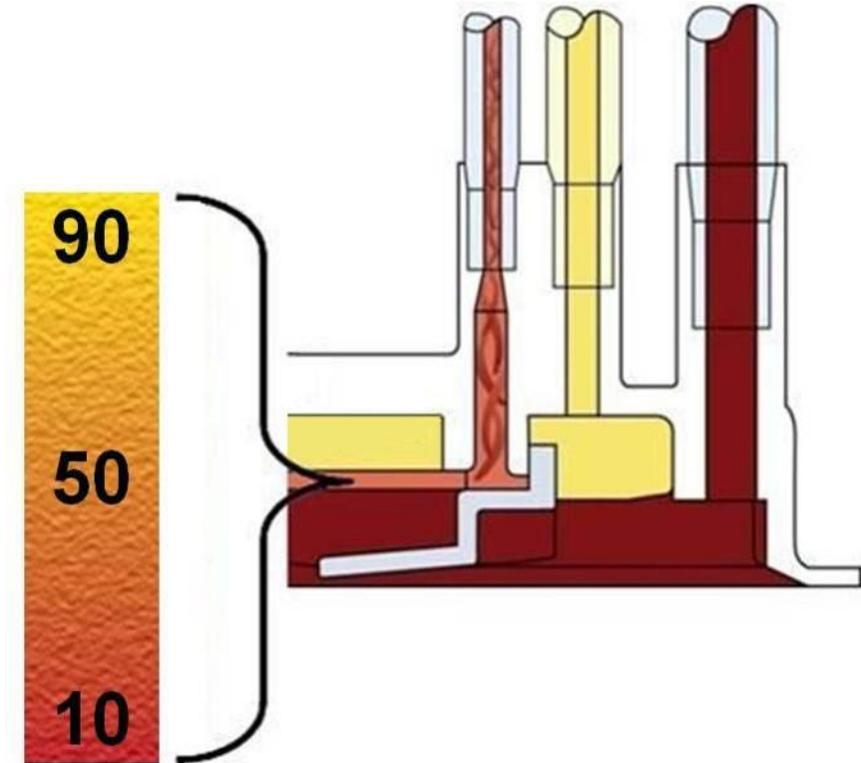


1. The AIM system controls the concentration of cells in the collect port (collection preference).
2. When cells are detected in the collect port the collect valve moves to the collect position.
 - The cells are continuously collected into the collection bag.

Questions?

Collection Preference (CP)

- The AIM system controls the concentration of cells (collection preference) flowing through the collect port by adjusting the plasma pump flow rate.
- The CP will always default to 50.



Preparing to Perform the Procedure

- Configuration: Medication Infusion Notification
- Configuration: CMNC
- Configuration: Blood Warmer and AC
- Channel Loading
- Patient Data
- Run Values
- Patient Connection

Configuration: Procedure

The screenshot displays a configuration menu for a medical device. At the top, there are four main tabs: 'Config' (highlighted in yellow), 'Data', 'Run', and 'End Run'. Below these are sub-tabs: 'System', 'Procedure' (highlighted in yellow), 'Report', and 'Network'. The main configuration area is divided into several sections:

- Height Units:** A button labeled 'cm'.
- Weight Units:** A button labeled 'kg'.
- Medication Infusion Notification:** A button labeled 'Yes'.
- Custom Prime Recommendation (% TBV):** A button labeled '10'.
- Pressure Alarm Limit (mmHg):** A sub-section with two buttons: 'Inlet' labeled '-250' and 'Return' labeled '400'.
- AC Container:** A sub-section with two buttons: 'Notification' labeled 'Yes' and 'Volume (mL)' labeled '750'.

At the bottom left, the time '14:14' and date '12-18-2018' are displayed. At the bottom center, there is a 'Confirm' button and a back arrow button. At the bottom right, there is a red prohibition sign over a person icon.

Configuration: CMNC

The screenshot displays the configuration interface for the CMNC procedure. It features a top navigation bar with 'Config', 'Data', 'Run', and 'End Run' tabs. Below this is a secondary menu with 'System', 'Procedure', 'Report', 'CMNC', 'Blood Warmer', and 'AC' buttons. The main area is divided into two primary sections: 'Run Target' and 'Plasma Collection'. The 'Run Target' section includes three input fields: 'Whole Blood Processed (mL)', 'Run Time (min)', and 'TBV Processed' (set to 2.0). The 'Plasma Collection' section includes two input fields: 'Plasma Bag (mL)' and 'Collection Bag (mL)', both set to 0. To the right of these fields are two checkboxes: 'Beginning of Run' (checked) and 'End Of Run' (unchecked). At the bottom of the screen, there is a 'Confirm' button, a back arrow button, a 'CMNC' label with a no-bleed icon, and a timestamp '17:27 15-01-2014'.

Configuration: Blood Warmer and AC

Config Data Run End Run

System Procedure Report CMNC **Blood Warmer** AC

Blood Warmer

Return Line: No

Tubing Set (mL): 40

17:28 15-01-2014 Confirm [Back Arrow] CMNC

Config Data Run End Run

System Procedure Report CMNC Blood Warmer **AC**

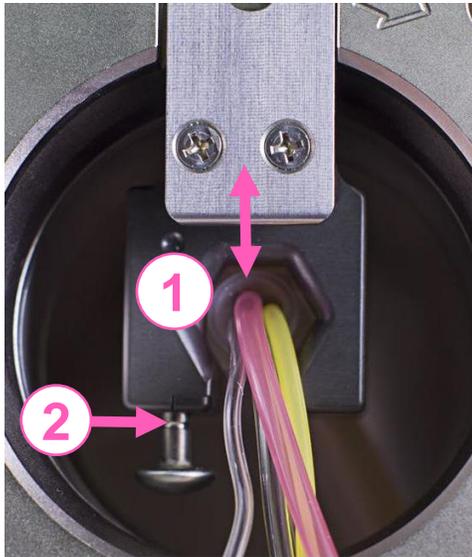
AC Infusion Rate (mL/min/L TBV): 0.8

Inlet:AC Ratio (..:1): 12.0

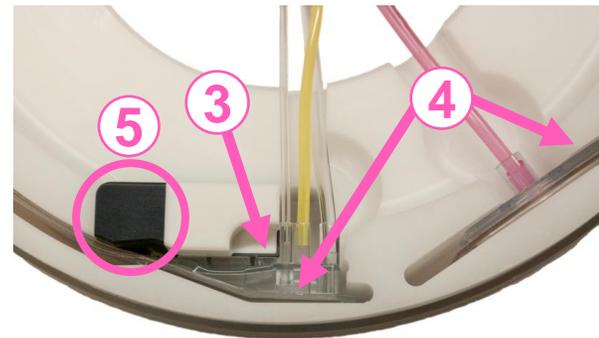
17:28 15-01-2014 Confirm [Back Arrow] CMNC

Channel Loading

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



3. Optical reference is visible.
4. Connector and channel sit flush in the filler.
5. Section of IDL filler has a black square.



Patient Data

Config Data Run End Run

✓ Height 178 cm Weight 80 kg TBV 5248 mL

Hct 28%

18:07
15-01-2014

Confirm ↩ CMNC

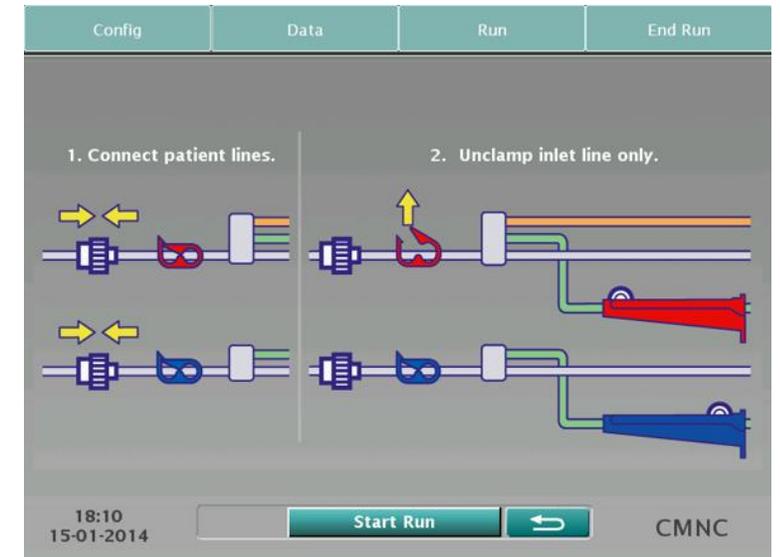
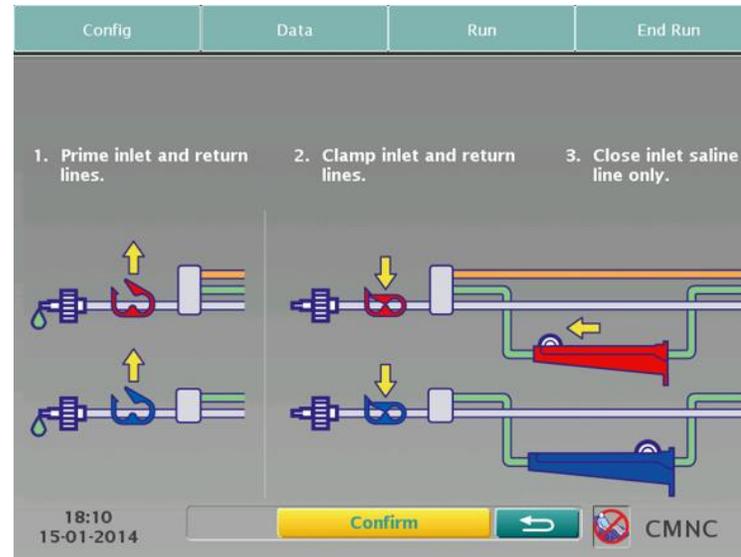
Run Values

Config		Data		Run		End Run	
AC Infusion Rate	Inlet:AC Ratio (.:1)	Whole Blood Processed (mL)	Run Time (min)	TBV Processed			
0.8	12.0	10496	226	2.0			
	AC	Inlet	Plasma	Collect	Plasma in Collection Bag		
Flow Rate (mL/min)	4.2	50.7	30.2	1.0			
Current (mL)							
Target (mL)	954	11450	0	225	0		
18:07 15-01-2014	Confirm				CMNC		

Patient Connection

Important!

- Unclamp, clamp and close the lines as instructed on the screens.
- Leave the return saline line open at the start of the run to divert the prime saline.

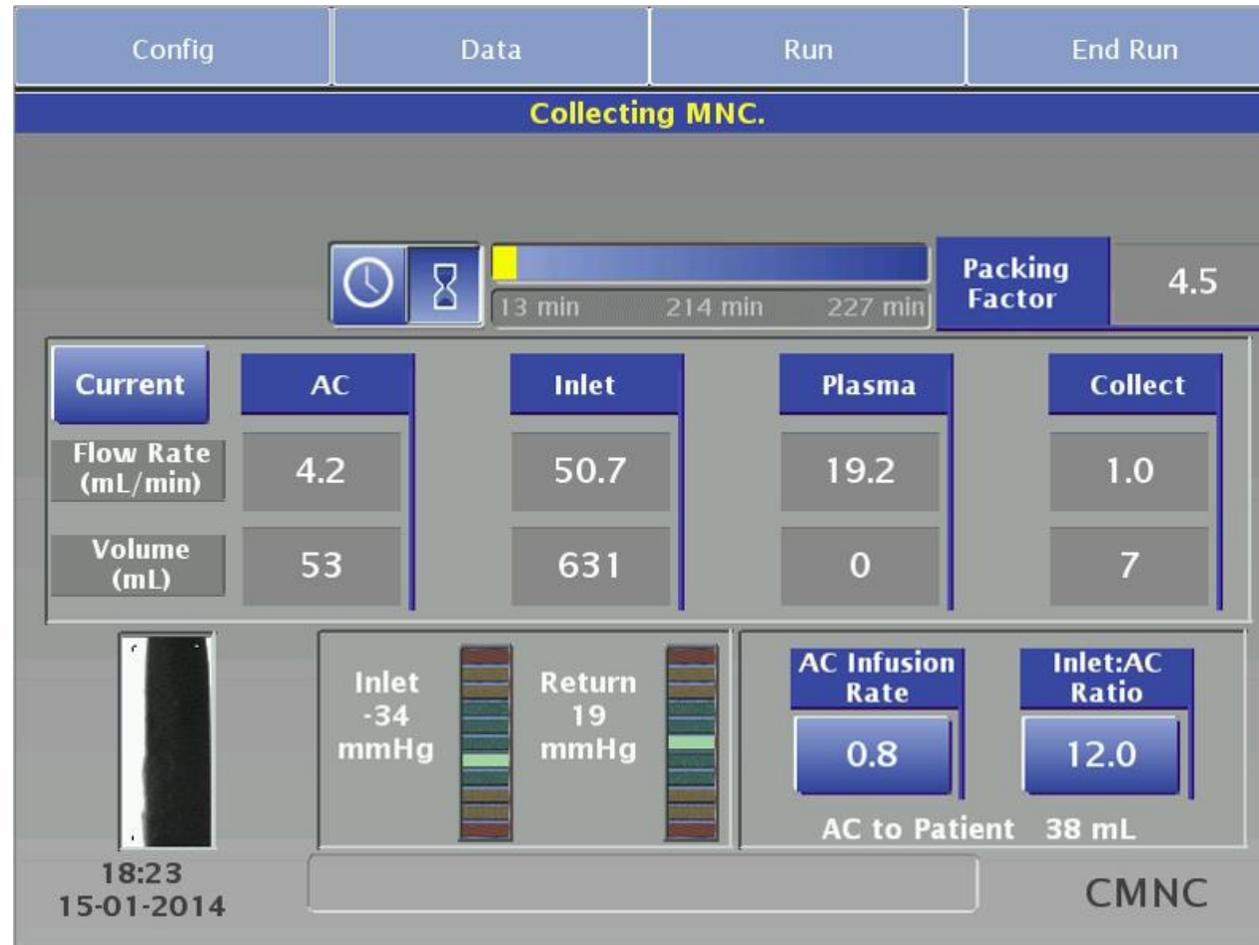


Questions?

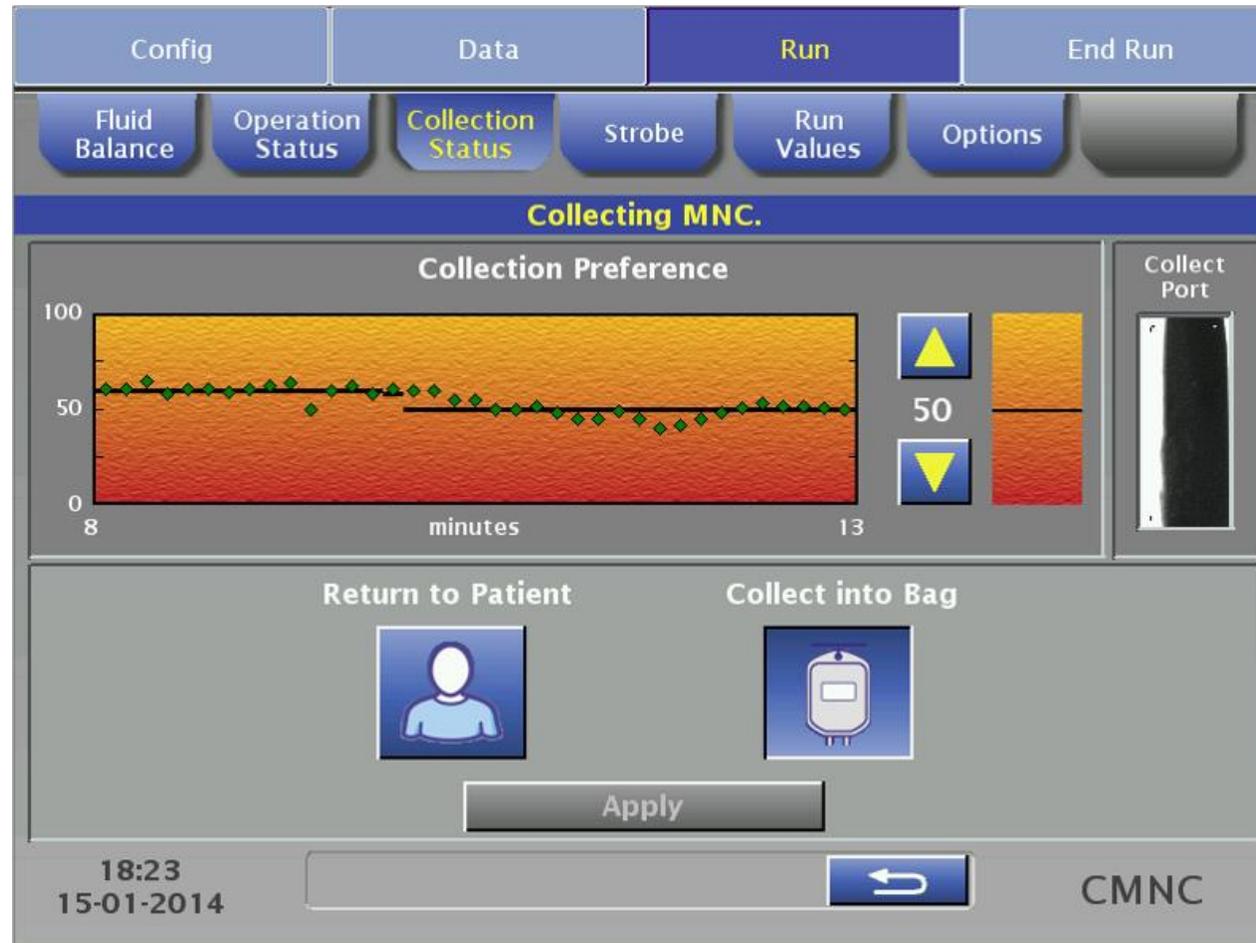
Monitoring the Run

- Main Run
- Collection Status
- Connector
- Collect Line from the Centrifuge
- Caution Status

Main Run



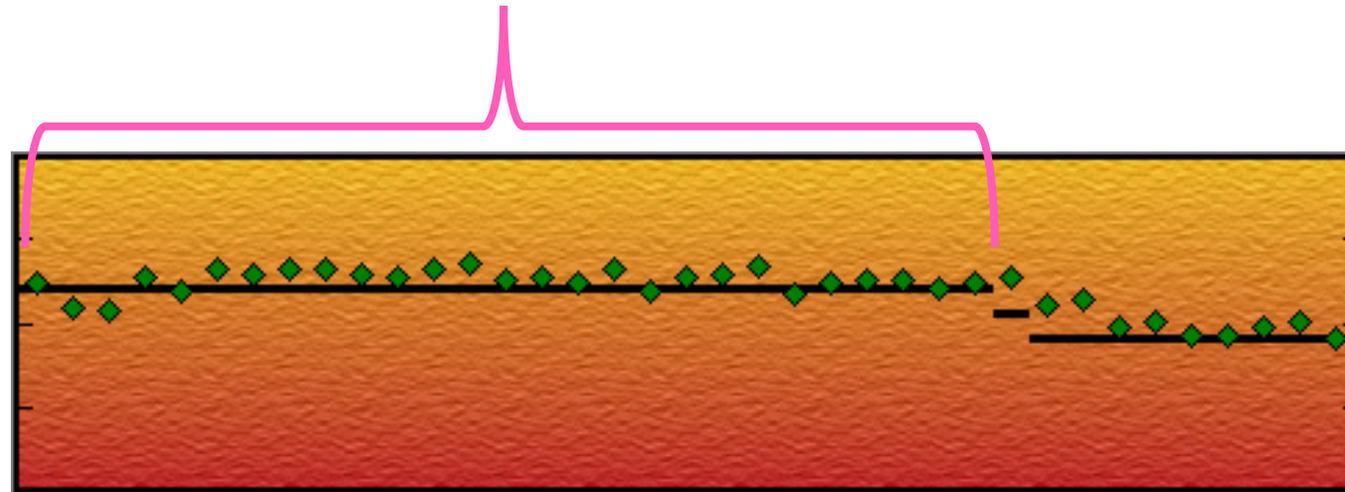
Collection Status



Collection Status (continued)

CP trend graph

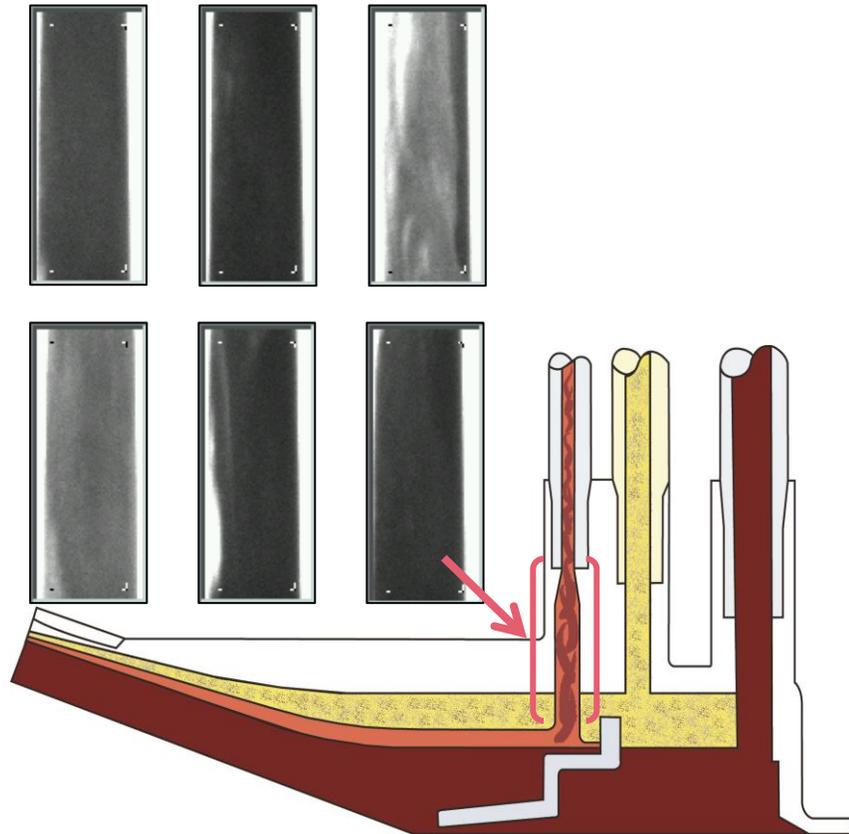
Establishing the interface



— Targeted CP

◆◆◆◆ Concentration of cells at the collect port

Collection Status (continued)



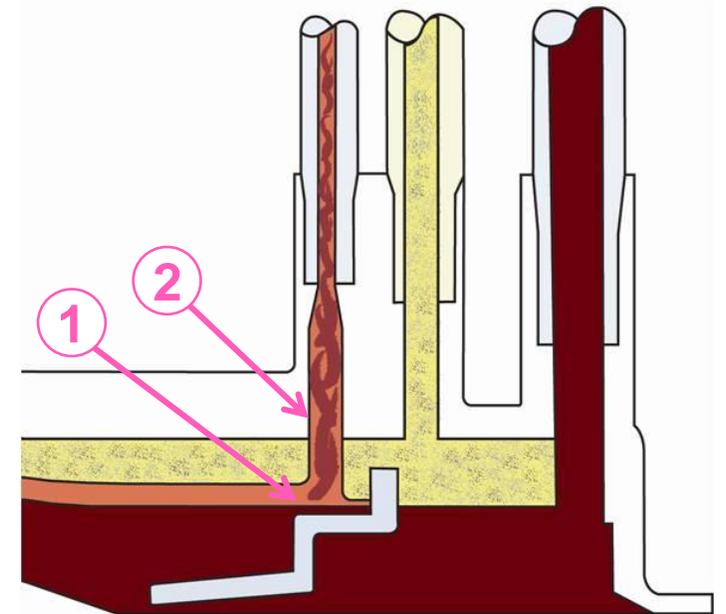
Collect port image:

- The AIM system captures images of the collect port.
- The images show the variation of the concentration of cells in the collect port.

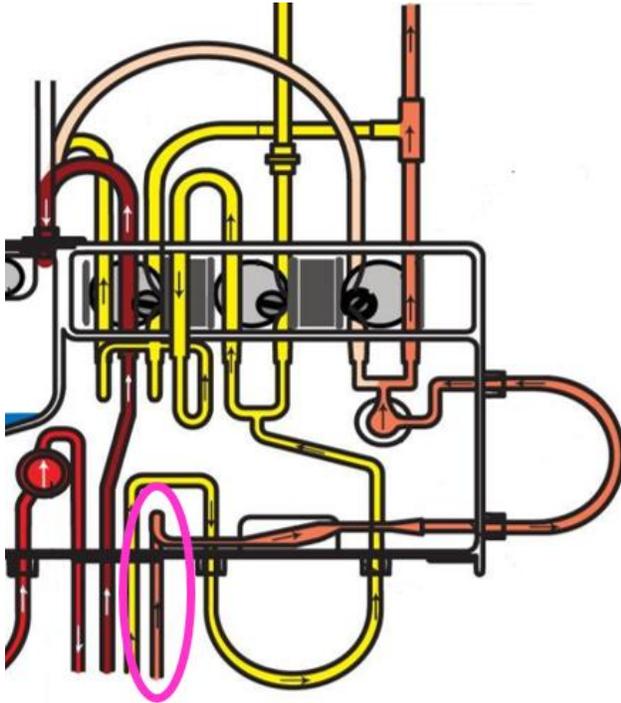
Connector

Monitor the separation of cells in the connector and the concentration of cells in the collect port.

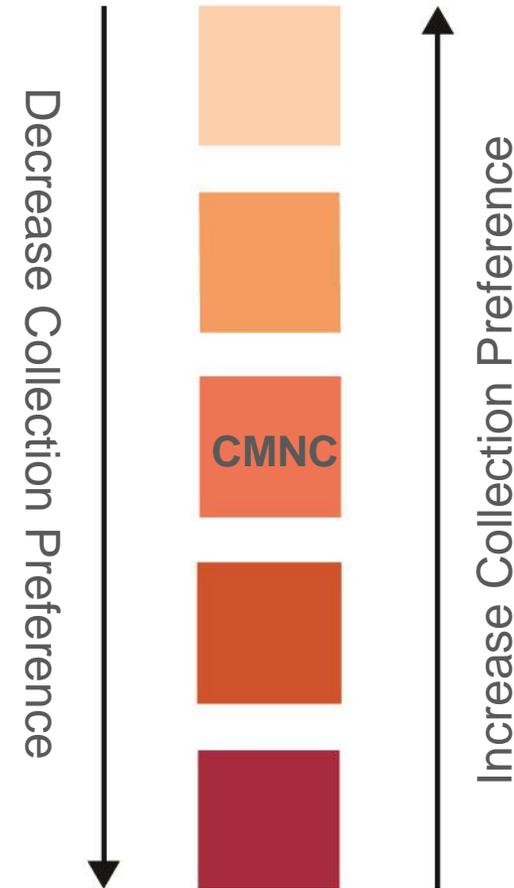
1. The interface should be positioned at the collect port.
2. The cellular concentration in the collect port should be monitored to maintain an appropriate Hct in the collect line.



Collect Line From the Centrifuge



Monitor the color in the collect line below the cassette.



Caution Status

Config | Data | **Run** | End Run

Fluid Balance | Operation Status | Collection Status | Strobe | Run Values | Options

Establishing initial interface.

2 min | 35 min | 37 min | Packing Factor 1.2

Current	AC	Inlet	Plasma	Collect
Flow Rate (mL/min)	1.4	56.4	4.0	0.0
Volume (mL)	2	100	0	0

Inlet 33 mmHg | Return 55 mmHg | AC Infusion Rate 0.1 | Inlet:AC Ratio 40.0

AC to Patient 0 mL

11:50 6-24-2019 | **Caution Status** | CMNC

Config | Data | **Run** | End Run

Caution Status

· Target or actual AC infusion rate exceeds 1.2 mL/min/L TBV.

17:22 1-19-2017 | **Caution Status** | CMNC

Questions?



Completing the Run

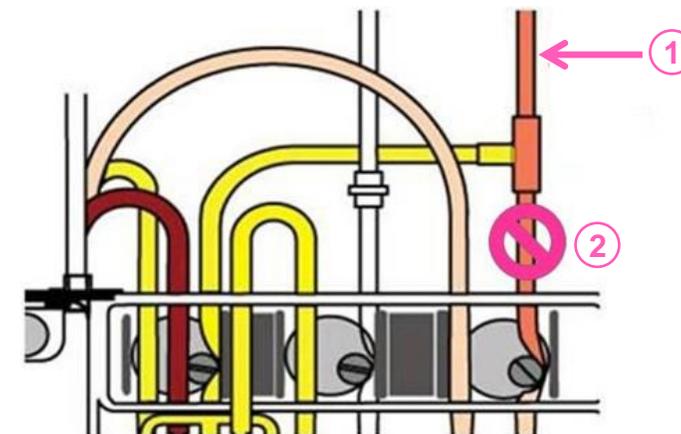
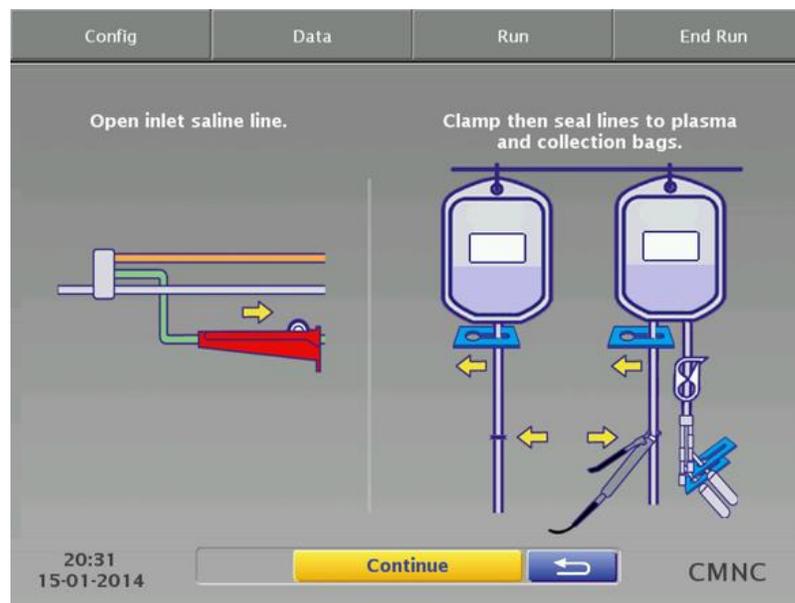
- Run Targets Attained
- Sealing the Product Bags
- Rinseback and Disconnect
- Procedure Summary

Run Targets Attained

Config	Data	Run	End Run
Run targets attained.			
	Target	Current	
Plasma Bag (mL)	100	100	Collection Bag
		AC 9 mL	Target
			Current
			Plasma (mL)
			0
			0
Run Time (min)	138	138	Collect (mL)
			128
			128
Whole Blood Processed (mL)	10496	10495	Total (mL)
			128
			128
TBV Processed	2.0	2.0	AC 12 mL
20:30 15-01-2014	Rinseback		CMNC

Sealing the Product Bags

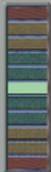
1. Seal the collect line above the T-shaped connector to the plasma line.
2. If you seal the collect line below the connector, the cells in the collection bag could flow back into the tubing set when the system raises the cassette.



Rinseback and Disconnect

Config | Data | Run | End Run

Rinseback is in progress.

Rinseback Time Remaining 9:00	Return 26 mmHg 	Rinseback Volume 62 mL
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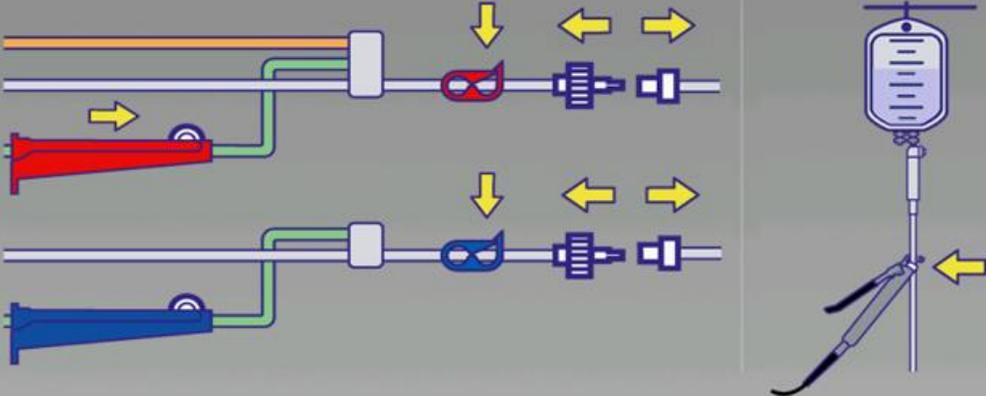
Return Flow (mL/min)	87.0	Fluid Balance (mL)	561
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20:31
15-01-2014

CMNC

Config | Data | Run | End Run

1. Close inlet saline line.
2. Clamp inlet and return lines.
3. Disconnect patient lines.
4. Seal AC, saline, and bag lines.



20:36
15-01-2014

Unload

CMNC

Procedure Summary

Config	Data	Run	End Run
AC Used	799 mL	Start Time	18:10
Plasma Bag	100 mL	End Time	20:36
Collection Bag	128 mL	Run Time	138 min
Saline Diverted	49 mL	Fluid Balance	734 mL
Tubing Set	-22 mL	Fluid Balance	114 %
Rinseback	234 mL	Whole Blood Processed	10497 mL

20:37
15-01-2014

Next Page

CMNC

Config	Data	Run	End Run
TBV Processed	2.0	New Procedure	
AC in Plasma Bag	9 mL	Saline to Patient due to Air Removal	0 mL
AC in Collection Bag	12 mL	Plasma in Collection Bag	0 mL
		Collect	128 mL
AC to Patient	781 mL	Custom Prime	0 mL
AC Used for Prime	25 mL	Saline Rinse	0 mL

20:37
15-01-2014

Previous Page

CMNC

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

+799 mL (AC Used)
 -100 mL (Plasma Bag)
 -128 mL (Collection Bag)
 -49 mL (Saline Diverted)
 -22 mL (Tubing Set)
 +234 mL (Rinseback)
734 mL (Total)

Questions?



Making Changes

- Data Menu
- Run Menu
- End Run Menu

Data Menu

- Patient Data
- Alarm History
- Report

Patient Data

The screenshot shows a medical device interface with a top navigation bar containing 'Config', 'Data', 'Run', and 'End Run'. Below this is a secondary menu with 'Patient Data', 'Alarm History', and 'Report'. The main display area shows four data points: a gender selection screen with a male icon and a checkmark, 'Height 178 cm' with a height scale icon, 'Weight 80 kg' with a scale icon, and 'TBV 5248 mL' with a human torso icon. Below these is a 'Hct 28%' screen with a test tube icon. At the bottom, there is a timestamp '18:36 15-01-2014', a 'Confirm' button, a back arrow button, and the text 'CMNC'.

Alarm History

The screenshot shows a medical device interface with a top navigation bar containing 'Config', 'Data', 'Run', and 'End Run'. Below this is a secondary bar with 'Patient Data', 'Alarm History', and 'Report'. The 'Alarm History' section is active, displaying a list of four alarm events in a scrollable area. At the bottom, the current time and date are shown as '18:36 15-01-2014', along with a return button and the text 'CMNC'.

Time	Alarm Description
18:17:03	Return pressure was too high.
18:12:03	Inlet pressure was too low.
18:10:03	Inlet pressure was too low.
17:50:03	AC was not detected.

Report

Config | **Data** | Run | End Run

Patient Data | Alarm History | **Report**

Start Time | Procedure | Sent

	Start Time	Procedure	Sent
	Current		
✓	06-19-2019 13:59	WBCD	→
✓	06-19-2019 12:30	RBCX	→
✓	06-18-2019 08:31	MNC	→
✓	03-20-2019 14:05	MNC	
✓	03-20-2019 12:16	TPE	

13:39
12-27-2018

Send [Refresh] [No Access] CMNC

Config | **Data** | Run | End Run

Patient Data | Fluid Data | Alarm History | **Report**

Start Time | Procedure | Sent

	Start Time	Procedure	Sent
	Current		
✓	11-02-2018 11:05	CMNC	
✓	10-30-2018 13:08	WBCD	
✓	10-30-2018 12:48	PLTD	
✓	10-19-2018 13:08	TPE	
✓	10-19-2018 11:31	RBCX	

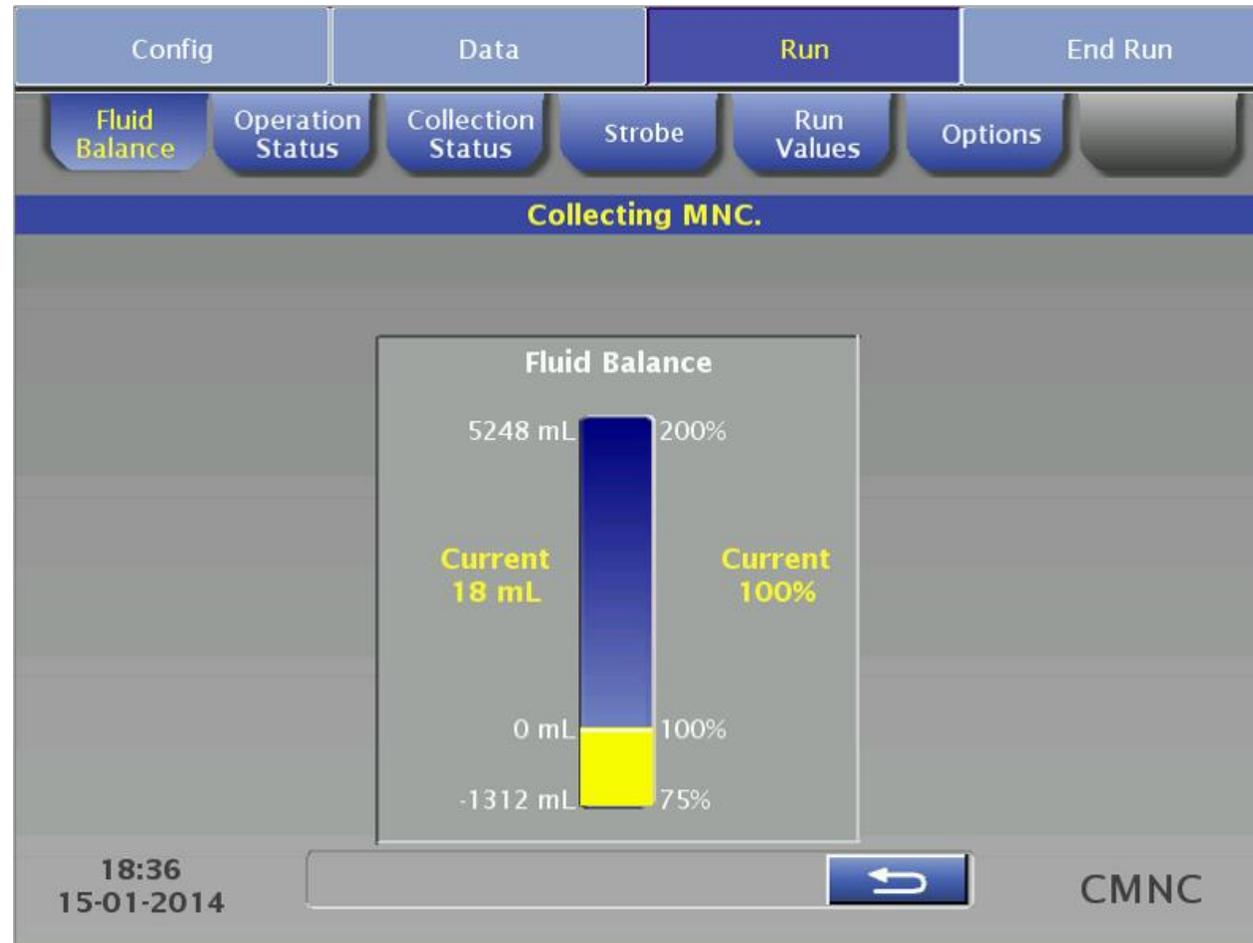
13:39
12-27-2018

Send [Refresh] CMNC

Run Menu

- Fluid Balance
- Operation Status
- Collection Status
- Strobe
- Run Values
- Options

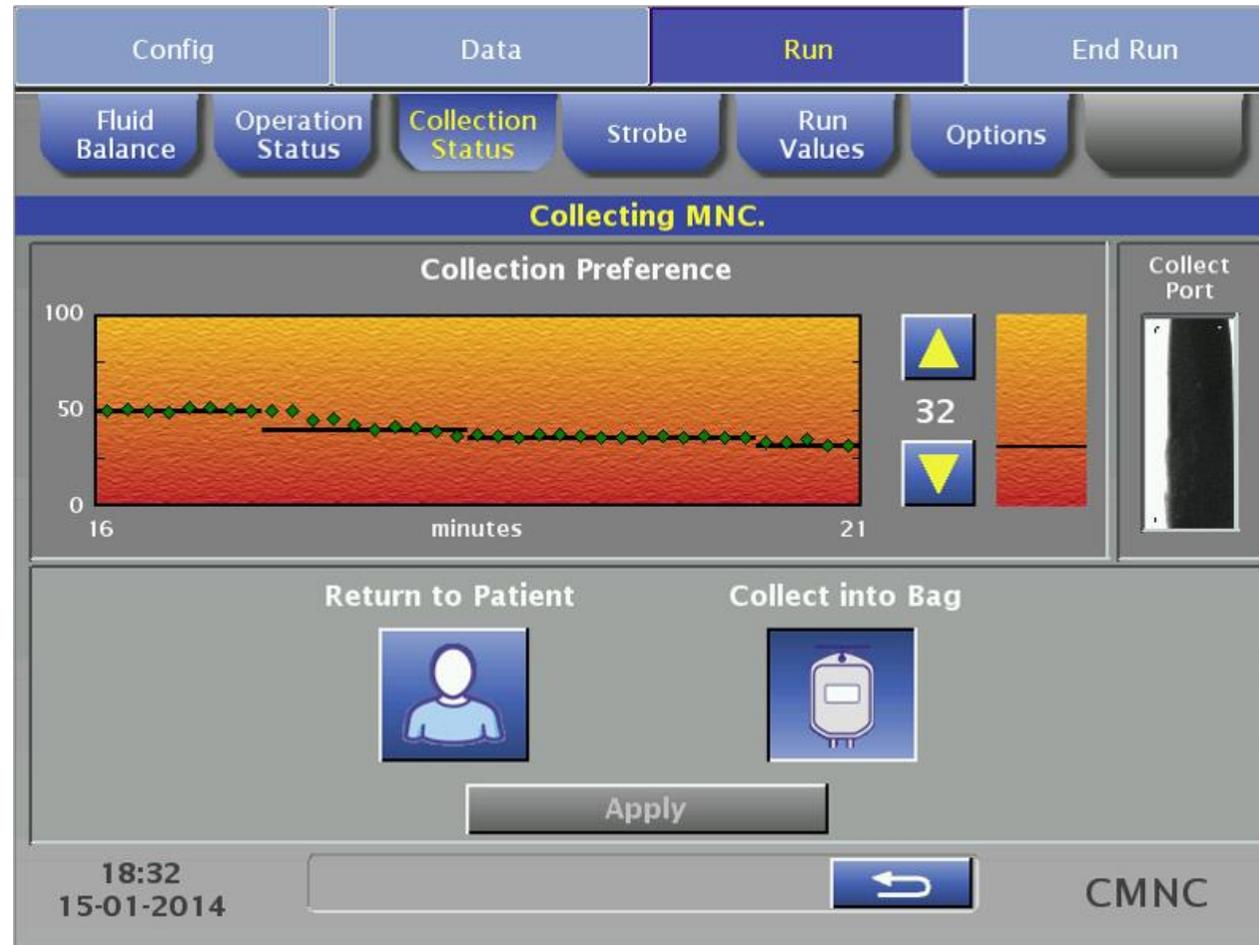
Fluid Balance



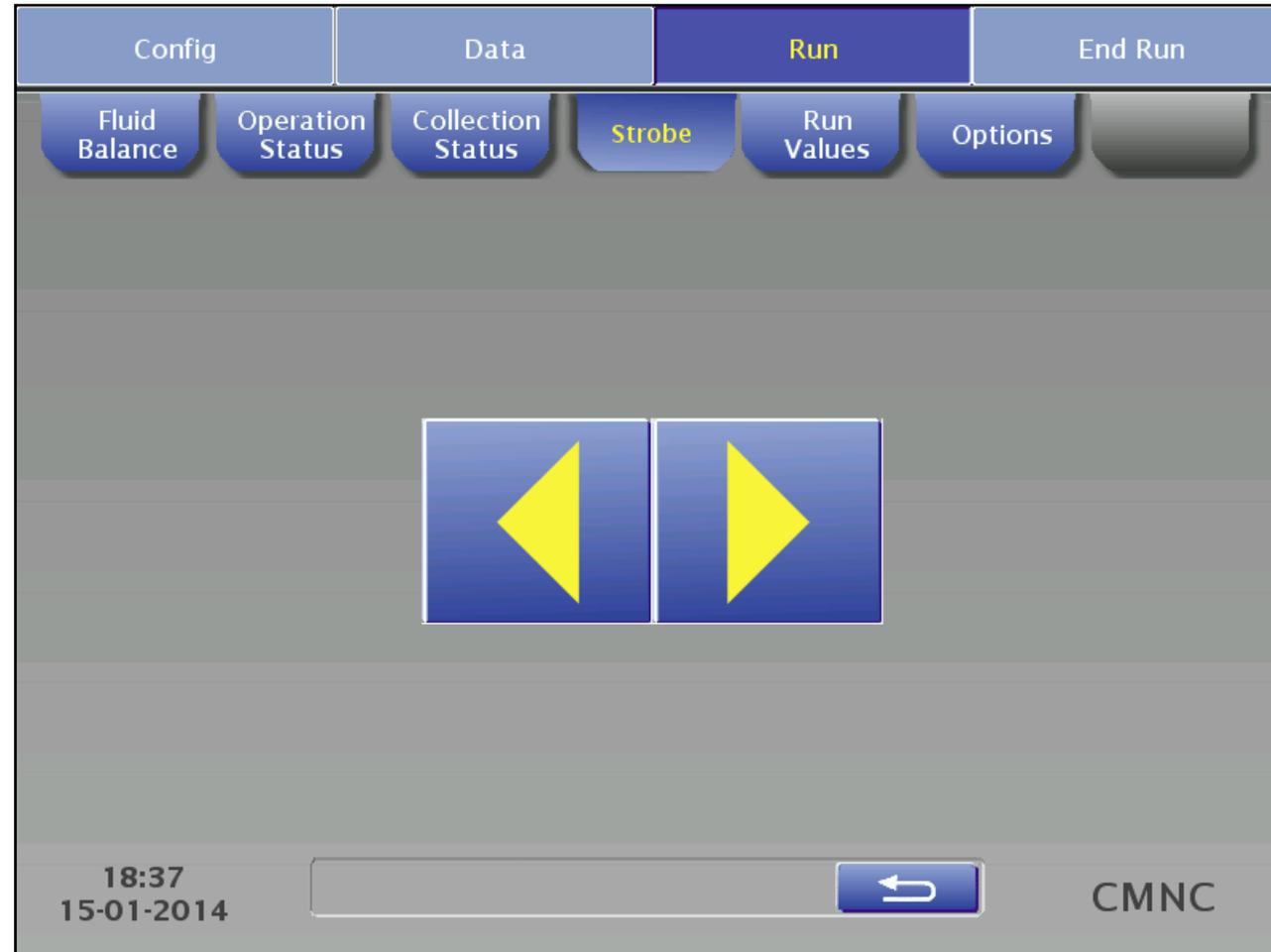
Operation Status

The screenshot displays the 'Run' menu of a medical device. At the top, there are four main menu items: 'Config', 'Data', 'Run' (highlighted in yellow), and 'End Run'. Below these are several sub-menu items: 'Fluid Balance', 'Operation Status' (highlighted in yellow), 'Collection Status', 'Strobe', 'Run Values', and 'Options'. The main display area is divided into two sections. The left section shows 'AIM System: Enabled' and a button labeled 'Proceed to Semi-Automatic Mode'. The right section shows 'Total Saline to Patient: 0 mL' and a button labeled 'Remove Air From Return Line'. At the bottom of the screen, there is a status bar containing the time '18:37', the date '15-01-2014', a 'Confirm' button, a back arrow button, and the text 'CMNC'.

Collection Status



Strobe



Run Values

Config		Data		Run		End Run	
Fluid Balance	Operation Status	Collection Status	Strobe	Run Values	Options		
AC Infusion Rate	Inlet:AC Ratio (.:1)	Whole Blood Processed (mL)	Run Time (min)	TBV Processed			
0.8	12.0	10496	239	2.0			
	AC	Inlet	Plasma	Collect	Plasma in Collection Bag		
Flow Rate (mL/min)	4.2	50.7	30.2	1.0			
Current (mL)	108	1301	0	21	0		
Target (mL)	1007	12081	0	233	0		
18:37 15-01-2014	Confirm		←		CMNC		

Config		Data		Run		End Run	
Fluid Balance	Operation Status	Collection Status	Strobe	Run Values	Options		
AC Infusion Rate	Inlet:AC Ratio (.:1)	Whole Blood Processed (mL)	Run Time (min)	TBV Processed			
1.2	12.0	10496	166 ↑	2.0			
	AC	Inlet	Plasma	Collect	Plasma in Collection Bag		
Flow Rate (mL/min)	6.3	75.4	45.4	1.0			
Current (mL)	110	1322	0	21	0		
Target (mL)	1064	12772	100	169 ↓	0		
18:37 15-01-2014	Confirm		←		CMNC		

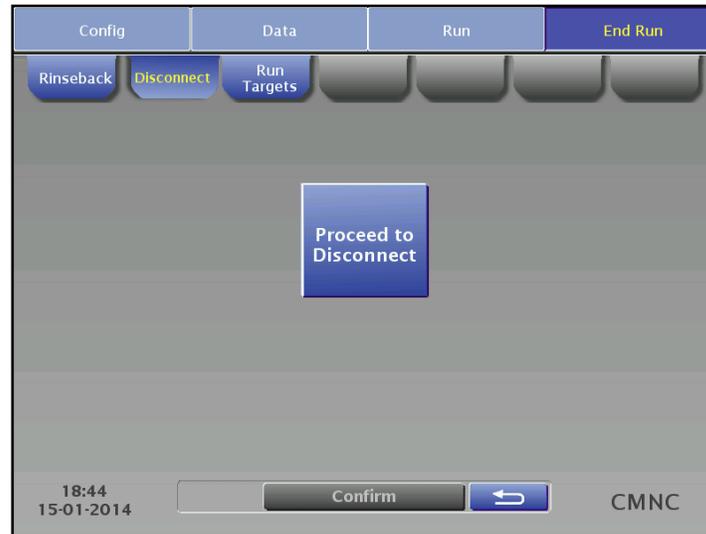
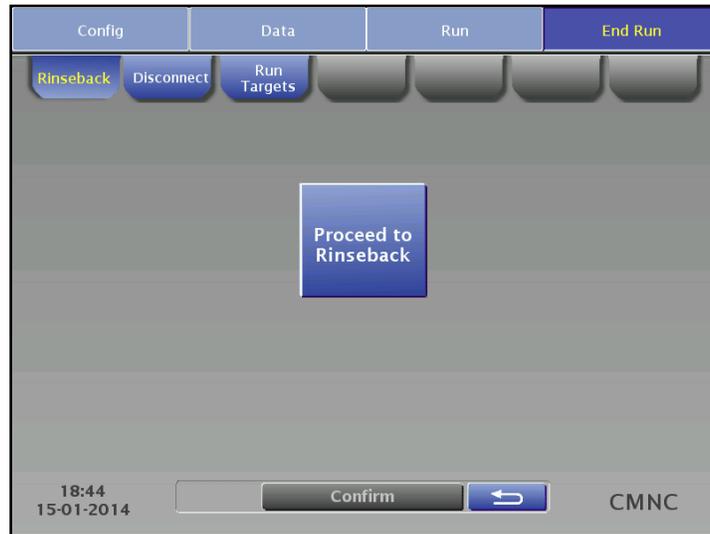
Options

Config		Data		Run		End Run	
Fluid Balance	Operation Status	Collection Status	Strobe	Run Values	Options		
Rinseback		Blood Warmer		Tubing Set (mL)			
<input type="button" value="Yes"/>		Return Line		<input type="text" value="40"/>			
Custom Prime		<input type="button" value="No"/>					
Medication Infusion Notification		Plasma Collection					
<input type="button" value="No"/>		<input type="checkbox"/> Now					
Saline Rinse		<input checked="" type="checkbox"/> End Of Run					
<input type="button" value="No"/>							
15:20 6-24-2019		<input type="button" value="Confirm"/>		<input type="button" value="↩"/>		CMNC	

End Run Menu

- Rinseback
- Disconnect
- Run Targets

Rinseback, Disconnect, Run Targets



Questions?

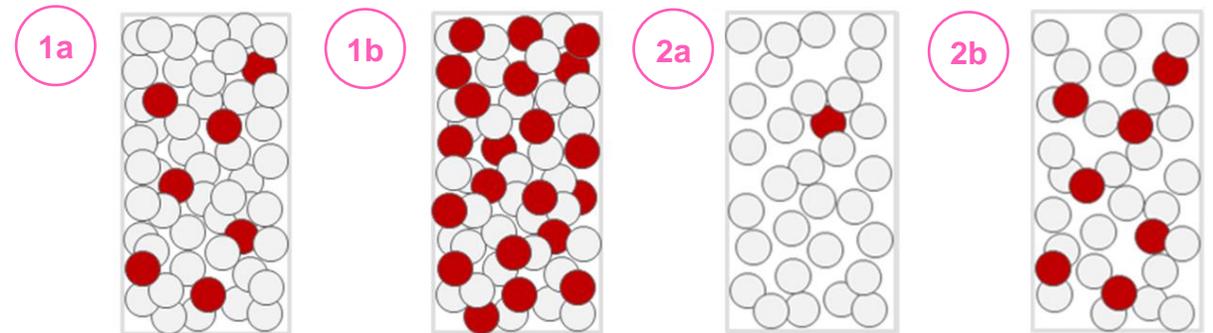
Optimization

- Collection Preference
- Optimizing the Collection Preference
- Product Purity Versus Yield
- Inlet Pump Flow Rate
- Setting the Run Target
- Collecting Plasma
- Decreasing the Run Time

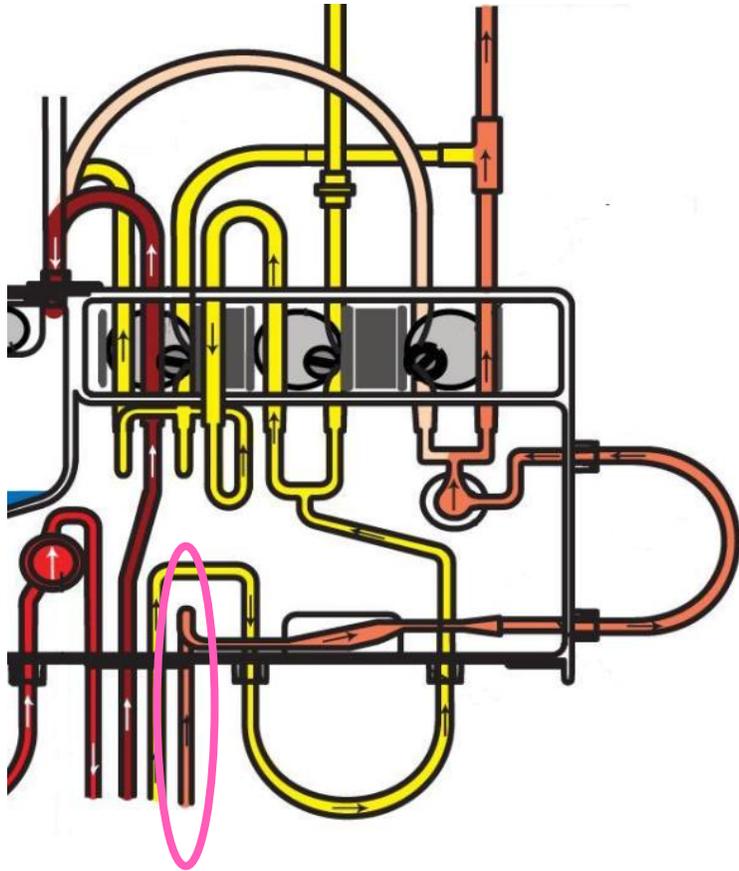
Collection Preference

CP controls the concentration of cells flowing through the collect port.

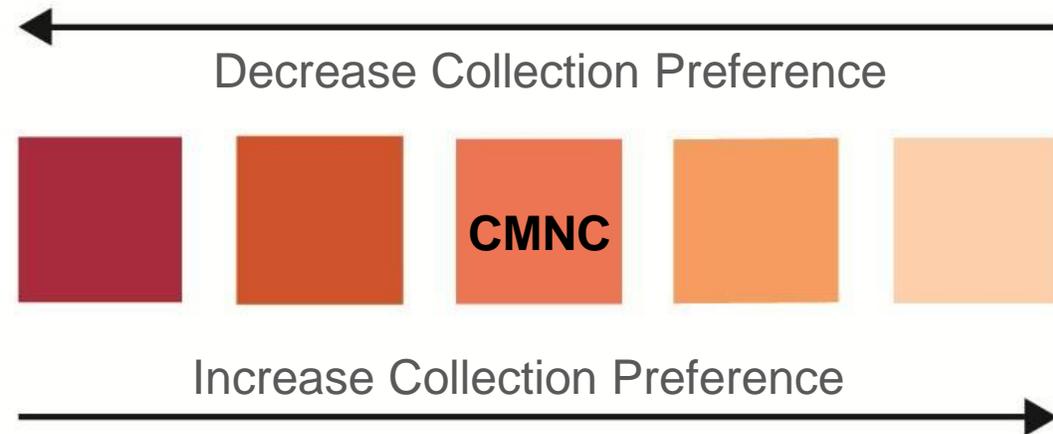
1. Low CP (less light can pass through):
high concentration of cells
 - a. Patient with high MNC
 - b. Patient with low MNC
2. High CP (more light can pass through):
low concentration of cells
 - a. Patient with high MNC
 - b. Patient with low MNC



Optimizing the Collection Preference



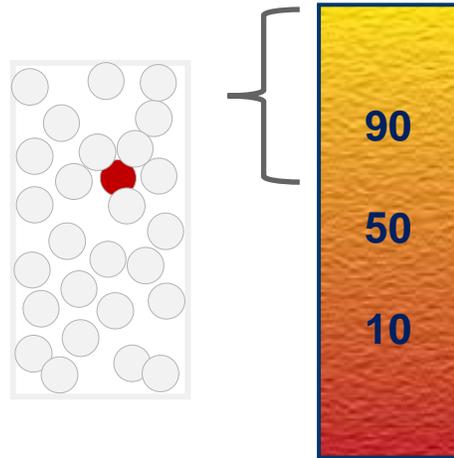
- Periodically monitor the color in the collect line below the cassette.
- Change the CP to maintain the optimal color.



Product Purity Versus Yield

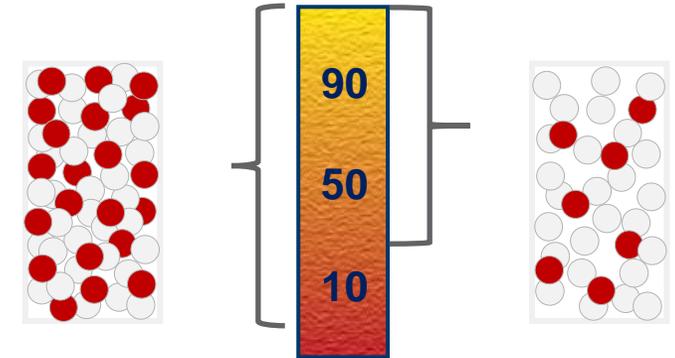
Purity

- Start with a CP ≥ 50
- Example:
 - ABO-mismatch donor
 - Extracorporeal photochemotherapy



Yield

- Start with a CP ≤ 50
- Example:
 - Patients with low MNC counts or non-mobilized donors
 - Donor lymphocyte infusion (donor cell counts are also low or normal)



Inlet Pump Flow Rate

Maintaining a steady inlet flow rate allows for a more stable interface position and optimal collection of cells.

- Minimizes the occurrence of pressure alarms.
- Optimizes establishment of the interface and separation of the buffy coat.

Setting the Run Target

Config		Data		Run		End Run	
Fluid Balance	Operation Status	Collection Status	Strobe	Run Values	Options		
AC Infusion Rate	Inlet:AC Ratio (:1)	Whole Blood Processed (mL)	Run Time (min)	TBV Processed			
0.8	12.0	10496	239	2.0			
	AC	Inlet	Plasma	Collect	Plasma in Collection Bag		
Flow Rate (mL/min)	4.2	50.7	30.2	1.0			
Current (mL)	108	1301	0	21	0		
Target (mL)	1007	12081	0	233	0		
18:37 15-01-2014	Confirm		←		CMNC		

Primary Targets:

- Whole Blood Processed
- Run Time
- TBV Processed
- Collect Volume

Secondary Target:

- Plasma Collection

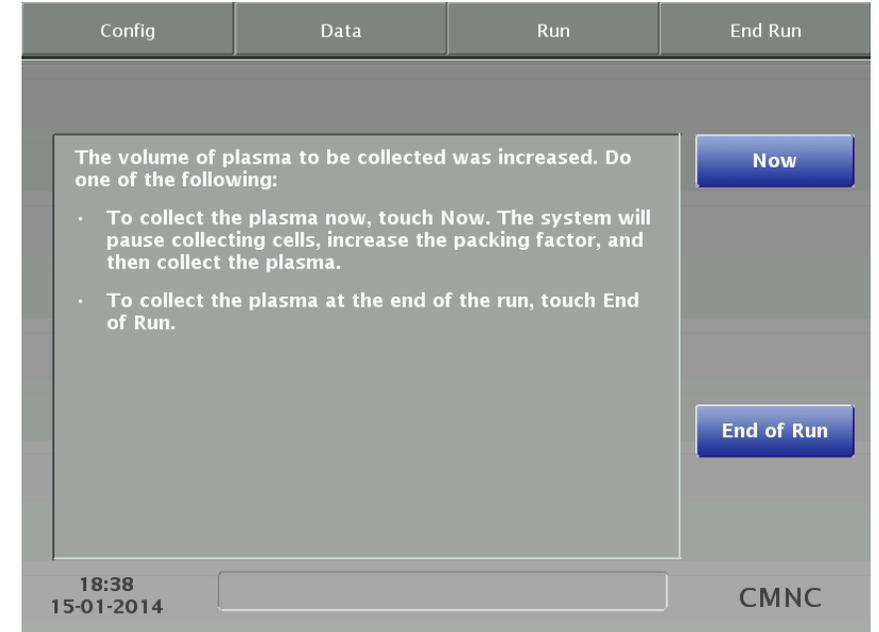
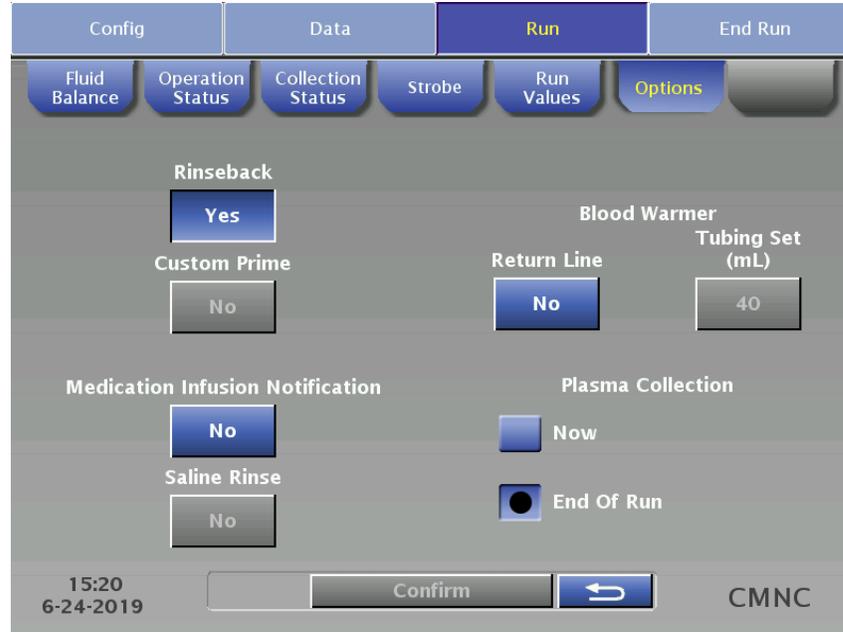
Collecting Plasma

Plasma is collected at a high packing factor. Once plasma collection has been initiated:

- The collect pump stops and the centrifuge speed increases.
- If necessary, the inlet flow rate decreases to 60 mL/min.
- Plasma pump decreases to lower the interface.
- Plasma pump increases.
- Plasma valve moves to collect position.

Collecting Plasma

- Beginning of Run
- End of Run
- Now



Decreasing the Run Time

- Increase the inlet flow rate.
 - This increases the AC infusion rate.
- Increase the AC infusion rate.
 - This increases the inlet flow rate.
- Increase the inlet: AC ratio.
 - This decreases anticoagulation in the extracorporeal circuit and therefore, increases the potential for clumping.
 - This increases the inlet pump flow rate without increasing the AC infusion rate.
- Decrease the target run time.

Questions?

Troubleshooting

- Alarm Screen
- Inlet and Return Access Alarms
- Accumulation of a Buffy Coat
- Contents in Collect Line Look Too Light
- Contents in Collect Line Look Too Dark
- Clumping in the Collect Port

Alarm Screen

Inlet pressure was too low.

Pressure in inlet line was too low.

Alarm number: 2001 (12.0)

Inlet access was not properly positioned.

Inlet line was obstructed.

Inlet pump flow rate was too high for size of inlet access.

Continue

Rinseback

Unload

14:23
10-17-2019

CMNC

Inlet and Return Access Alarms

Inlet pressure was too low.

Pressure in inlet line was too low.

Alarm number: 2502 (12.0)

Continue

Inlet access was not properly positioned.

Inlet line was obstructed.

Inlet pump flow rate was too high for size of inlet access.

Rinseback

Disconnect

15:49
2-23-2023

CMNC

Return pressure was too high.

Pressure in return line was too high.

Alarm number: 2503 (12.0)

Continue

Return access was not properly positioned.

Return line was obstructed.

Return pump flow rate was too high for size of return access.

Rinseback

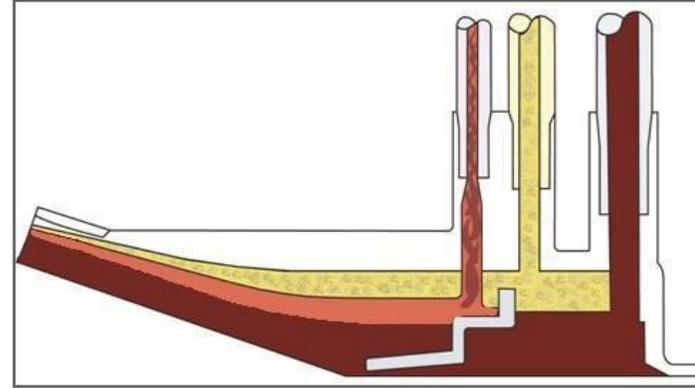
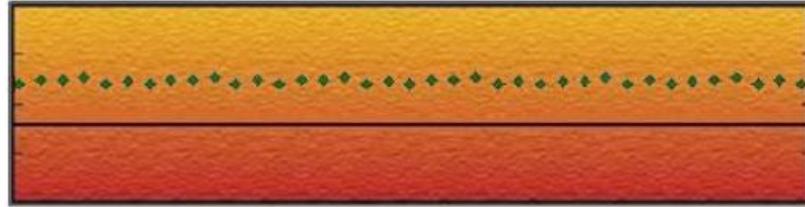
Disconnect

19:53
12-07-2017

Opt_alarm_MNCI_AlarmCode(2503)

CMNC

Accumulation of a Buffy Coat

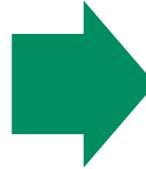


Collect pump flow rate is too slow.



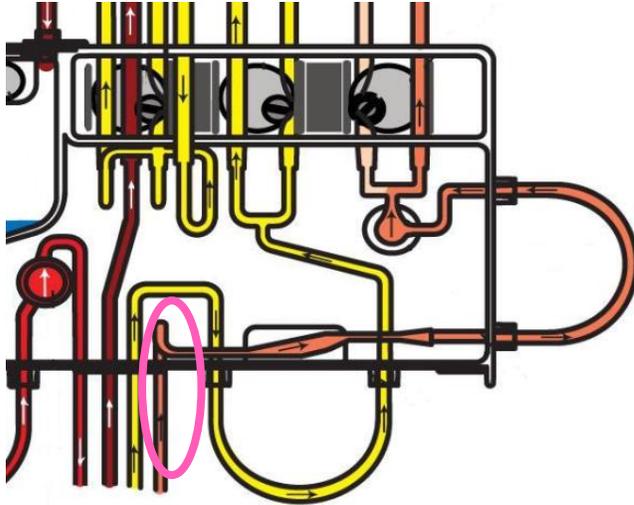
Increase the collect pump flow rate.

CP is too high.



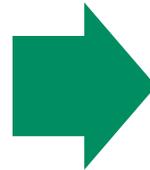
Decrease the CP.

Contents in Collect Line Look Too Light



Contents of the collect line look too light during the run.

CP is too high.



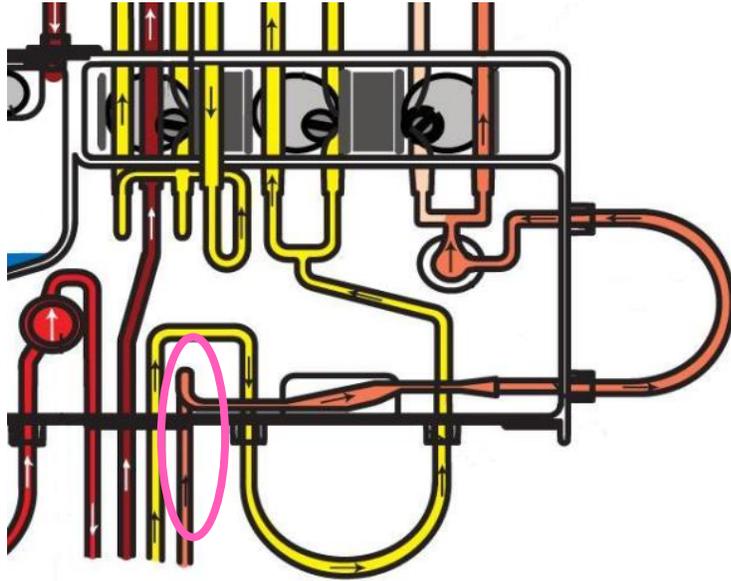
Decrease the CP to darken the contents.

Collect pump flow rate is too slow.



Reset collect pump flow rate to the default value.

Contents in Collect Line Look Too Dark



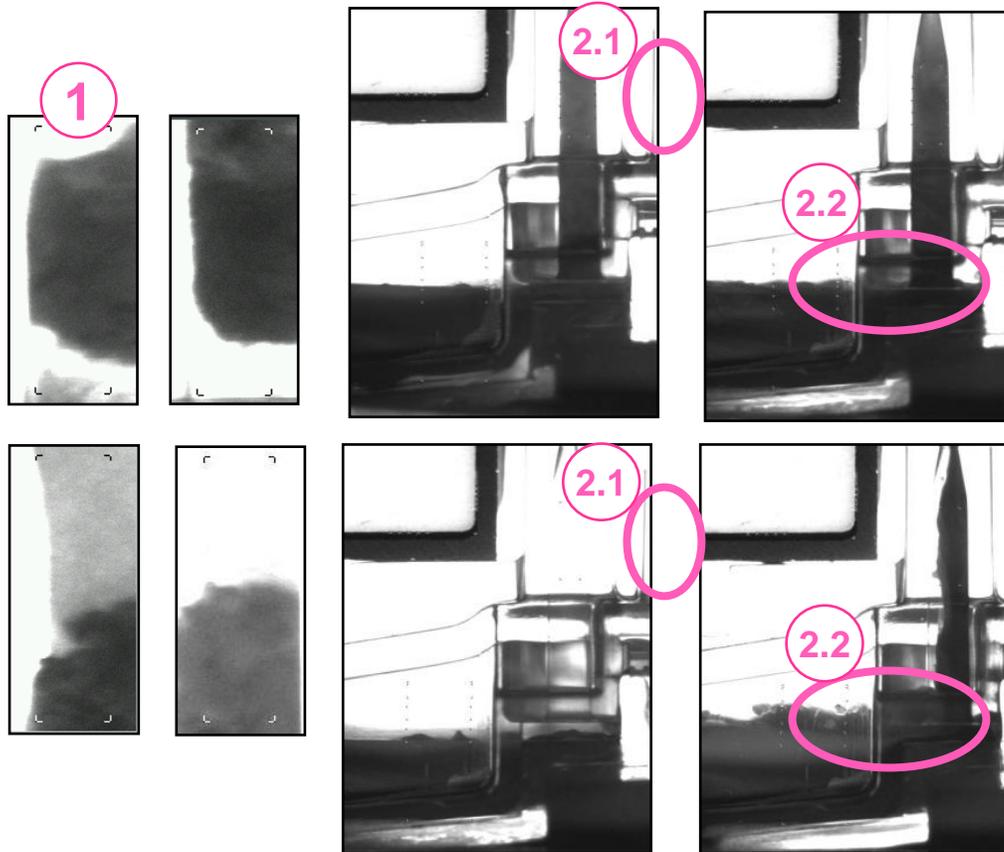
Contents of the collect line look too dark.

CP is low.



Increase the CP.

Clumping in the Collect Port



1. Collect port image alternates between dark and light.

2. Viewport
 (2.1) Collect port
 (2.2) Interface

Inadequate anticoagulation.



Decrease inlet:AC ratio to 8:1.ase the CP.

Low TBV Patients

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

Minimum Data Entry Limits

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

AC Management

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

Pt TBV	500	600	700	800	900	1000
Initial inlet pump flow rate	5.4	6.3	7.4	8.4	9.5	10.5
Configured AC infusion rate 0.8 mL/min/L TBV						
If you Increase AC infusion rate	1.8	1.5	1.3	1.1	1.0	1.2
Inlet pump flow rate	10.5	10.5	10.7	10.3	10.5	14.0
Configured inlet:AC ratio 12:1						
If you Increase Inlet:AC ratio	23:1	19:1	17:1	15:1	13:1	15:1
Inlet pump flow rate	10.1	10.0	10.4	10.5	10.3	13.2

Fluid Balance

- Managing fluid in and fluid out
 - Volume of AC to the patient versus volume collected
 - Collect pump flow rate
- Blood warmer
 - Patient comfort
- Custom prime
 - Improved tolerance of the volume of the extracorporeal circuit

Custom Prime – RBC

Config Data Run End Run

Consider performing a custom prime using RBC.

Patient data:
 TBV: 680 mL
 Hct: 28%

Patient volumes in tubing set:
 TBV: 297 mL (44%)
 RBC: 124 mL (65%)

Patient hematocrit if custom prime is not performed: 10%

Do one of the following:

- To accept a custom prime, touch Yes. The system will not perform rinseback.
- To decline a custom prime, touch No.

Yes

No

18:08
15-01-2014

 CMNC

Config Data Run End Run

Enter data for custom prime.

RBC

Plasma

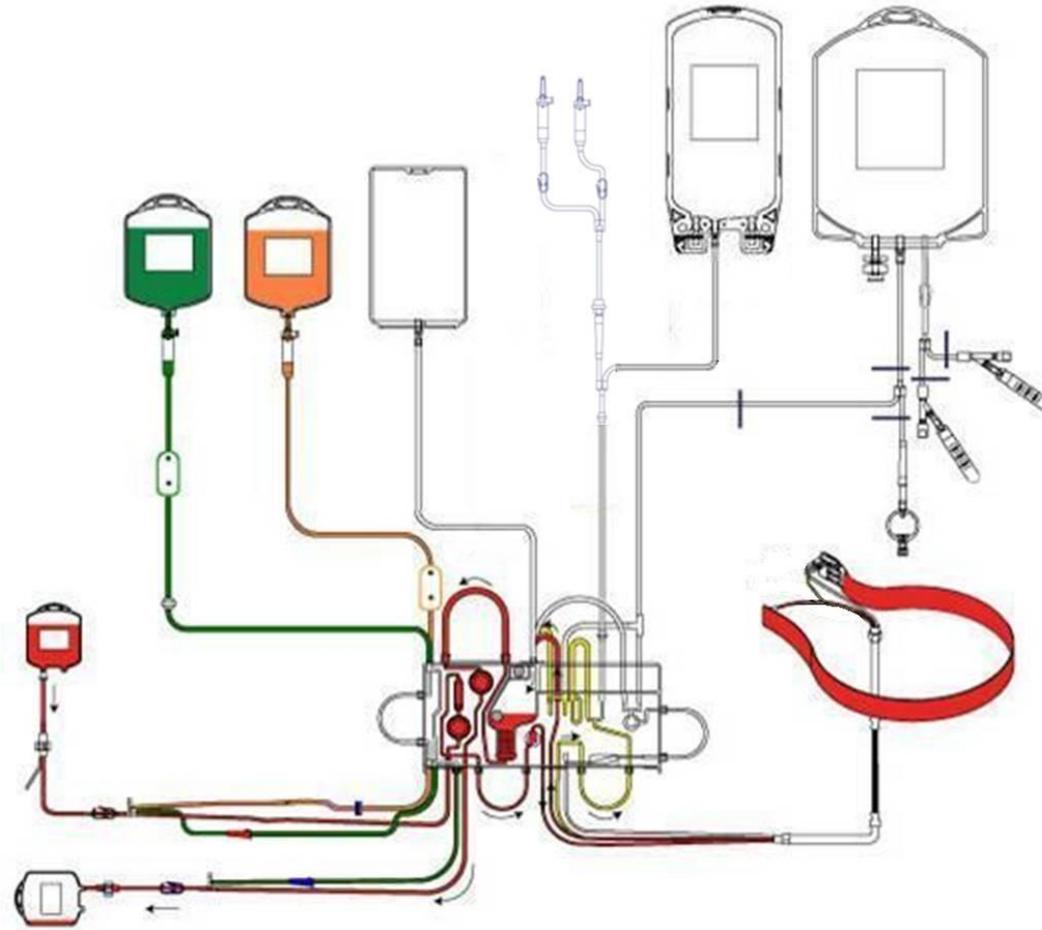
Albumin

RBC Unit Hct (%)	Maximum Inlet Flow Rate (mL/min)	Volume (mL)
60	70	300

18:09
15-01-2014

Confirm   CMNC

Custom Prime – RBC



Custom Prime – RBC (60% Hct)

This table indicates the calculated estimate of the change in the patient’s Hct immediately after the custom prime RBC have been delivered to the patient. This is not an indication of the patient’s post procedure Hct since it cannot predict the patient’s hemodynamic response to the procedure.

Patient		300 mL RBC	No blood prime	340 mL RBC	No blood prime
		No blood warmer		40 mL blood warmer	
TBV	Hct (%)	Change in patient Hct (%)			
300 mL	25	+11	-22	+13	-22
	30	+10	-26	+12	-26
	35	+9	-27	+10	-28
	40	+8	-28	+9	-29
600 mL	25	+6	-14	+8	-14
	30	+5	-14	+7	-15
	35	+5	-15	+6	-16
	40	+4	-15	+5	-17
1000 mL	25	+4	-9	+5	-9
	30	+3	-9	+4	-10
	35	+3	-9	+4	-10
	40	+3	-10	+3	-11
1500 mL	25	+3	-6	+3	-6
	30	+2	-6	+3	-7
	35	+2	-6	+3	-7
	40	+2	-7	+2	-7

Questions?

Thank You

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