

# Concepts of Anticoagulant (AC) Management

Using the Spectra Optia® Apheresis System

# Concepts of AC Management

- Terumo Blood and Cell Technologies recommends using the anticoagulant acid citrate dextrose formula A (ACD-A) with the Spectra Optia system
- Citrate in ACD-A is the primary molecule responsible for anticoagulation in the extracorporeal circuit

# Concepts of Anticoagulant (AC) Management

The Spectra Optia system uses specific AC management principles to:

- Control the rate of anticoagulant (AC) infusion to the patient
- Maintain adequate anticoagulation in the extracorporeal circuit

The three AC management concepts are:

- AC infusion rate
- AC pump flow rate
- Inlet:AC ratio

# AC Infusion Rate

- Rate at which anticoagulant is infused to the patient in mL per minute per liter of total blood volume (mL/min/L TBV)

# AC Infusion Rate – Patient Data

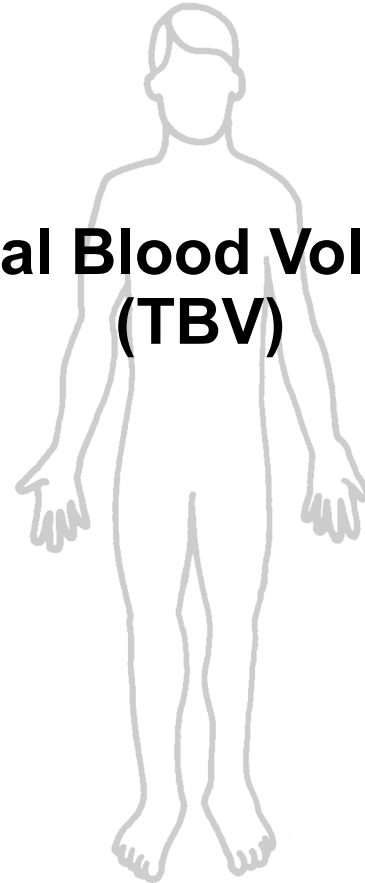
Entering accurate patient data allows a safe and efficient procedure by ensuring:

- AC is infused at a rate that is appropriate for each individual patient
- Pump flow rates and endpoints are appropriate for the procedure being performed

# AC Infusion Rate – Total Blood Volume

- Sex
- Height
- Weight

**Total Blood Volume  
(TBV)**



The Spectra Optia system uses the patient's TBV to calculate pump flow rates and other run values.

# AC Infusion Rate – Total Blood Volume

The screenshot displays a medical device interface with a top navigation bar containing four tabs: "Config", "Data", "Run", and "End Run". The "Config" tab is currently selected. Below the navigation bar, there are five data cards arranged in two rows. The first row contains three cards: a patient selection card with a checkmark, a height card showing "Height 150 cm", and a weight card showing "Weight 50 kg". The second row contains two cards: a hemoglobin card showing "Hct 36%" and a total blood volume card showing "TBV 3039 mL". At the bottom of the screen, there is a status bar with the time "9:33" and date "8-14-2018" on the left, a "Confirm" button in the center, a back arrow button to its right, a red prohibition sign on the far right, and the text "TPE" next to it.

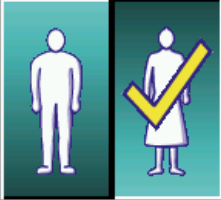
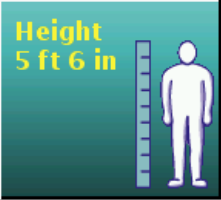

# AC Infusion Rate – Total Blood Volume



- Please note the Spectra Optia TBV calculation is not accurate for patients weighing less than 25 kg (approx. 55 lb) or who have certain conditions
- The operator must enter an appropriate TBV as directed by a physician or their facility's standard operating procedure





# AC Infusion Rate – Total Blood Volume

Config      Data      Run      End Run

13:29  
25-11-2019

Confirm             TPE

# AC Infusion Rate – Total Blood Volume

For patients weighing less than 25 kg, the operator must enter an appropriate TBV.

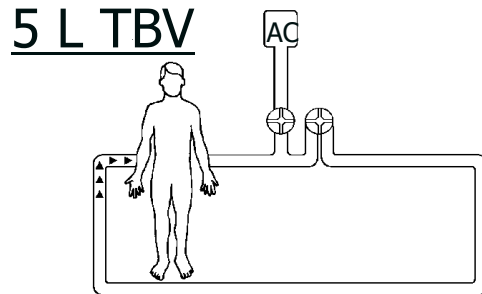
The screenshot shows the 'Data' tab of the AC Infusion Rate interface. A red banner at the top reads "Check height and weight entries for errors." Below this, a message states: "The system cannot use the height and weight that were entered to calculate the patient's TBV. Check the values and units for errors." The interface displays "Height entered (cm): 30" and "Weight entered (kg): 20". Two instructions are provided: "If the data is not correct, touch the go back button to return to the patient data screen and enter the correct data." and "If the data is correct, you must calculate, enter, and confirm the appropriate TBV for the patient." At the bottom, there are input fields for "Enter TBV (mL):" and "Re-enter TBV (mL) to confirm:", both containing the value "0". A "Confirm" button, a back arrow, and a "TPE" icon are visible at the bottom right. The timestamp "13:27 25-11-2019" is in the bottom left.

The screenshot shows the 'Data' tab of the AC Infusion Rate interface after successful data entry. It features four icons: a checkmark and a female figure, a height icon showing "Height 30 cm", a weight icon showing "Weight 20 kg", and a hematology icon showing "Hct 35%". A TBV icon shows "TBV 1260 mL" with a small and a large human figure. At the bottom, a "Confirm" button, a back arrow, and a "TPE" icon are visible. The timestamp "13:28 25-11-2019" is in the bottom left.

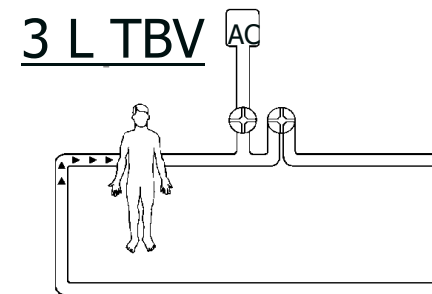
# AC Infusion Rate

The Spectra Optia system calculates an individualized “AC or citrate dose” for each patient:

AC infusion rate (AC or citrate dose rate) × Patient’s TBV = AC infused to patient per minute (AC dose)



$0.8 \text{ mL/min/L TBV} \times 5 \text{ L TBV}$   
↳ 4.0 mL/min of AC infused  
to the patient (AC dose)



$0.8 \text{ mL/min/L TBV} \times 3 \text{ L TBV}$   
↳ 2.4 mL/min of AC infused  
to the patient (AC dose)

# AC Infusion Rate – Definitions

- **Target**  
System-imposed value based on individual patient data and limits imposed by the system.
- **Maximum**  
Operator-defined limit. The system will not exceed this value unless the operator makes changes. It is displayed on the run values screen.
- **Current**  
Displayed AC infusion rate, which is an average and may fluctuate. It is displayed on the main run screen.


# Maximum AC Infusion Rate – Configuration

The screenshot displays a configuration menu for a medical device. The top navigation bar includes 'Config', 'Data', 'Run', and 'End Run'. Below this, a secondary menu has 'System', 'Procedure', 'Report', 'Network', 'TPE', and 'Blood Warmer'. The 'TPE' option is highlighted in yellow. The main configuration area is divided into four columns:

AC Infusion Rate (mL/min/L TBV)	Inlet:AC Ratio (__:1)	Plasma Volumes Exchanged	Custom Replacement Fluid (%)
0.8	10.0	1.0	0

At the bottom left, the time and date are shown as 13:20 and 25-11-2019. The bottom right features a 'Confirm' button, a back arrow, a red prohibition sign over a person icon, and the text 'TPE'.

# Maximum AC Infusion Rate – Run Values Screen

Config	Data	Run	End Run	
AC Infusion Rate	Inlet:AC Ratio (__:1)	Plasma Removed (mL)	Run Time (min)	Plasma Volumes Exchanged
0.8	10.0	2328	51	1.0
	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	10.0	100.1	55.1	42.4
Current (mL)				
Target (mL)	511	5112	2794	2125
13:31 25-11-2019	Confirm	←		TPE

# Maximum AC Infusion Rate – Inlet Flow Rate

The screenshot displays the 'Run' tab of a medical device interface. The 'Run Values' section shows the following data:

AC Infusion Rate	Inlet:AC Ratio (__:1)	Plasma Removed (mL)	Run Time (min)	Plasma Volumes Exchanged
1.0	10.0	2328	43	1.0

Below this, a detailed flow rate table is shown:

	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	12.0	120.0	66.0	50.8
Current (mL)				
Target (mL)	511	5112	2794	2125

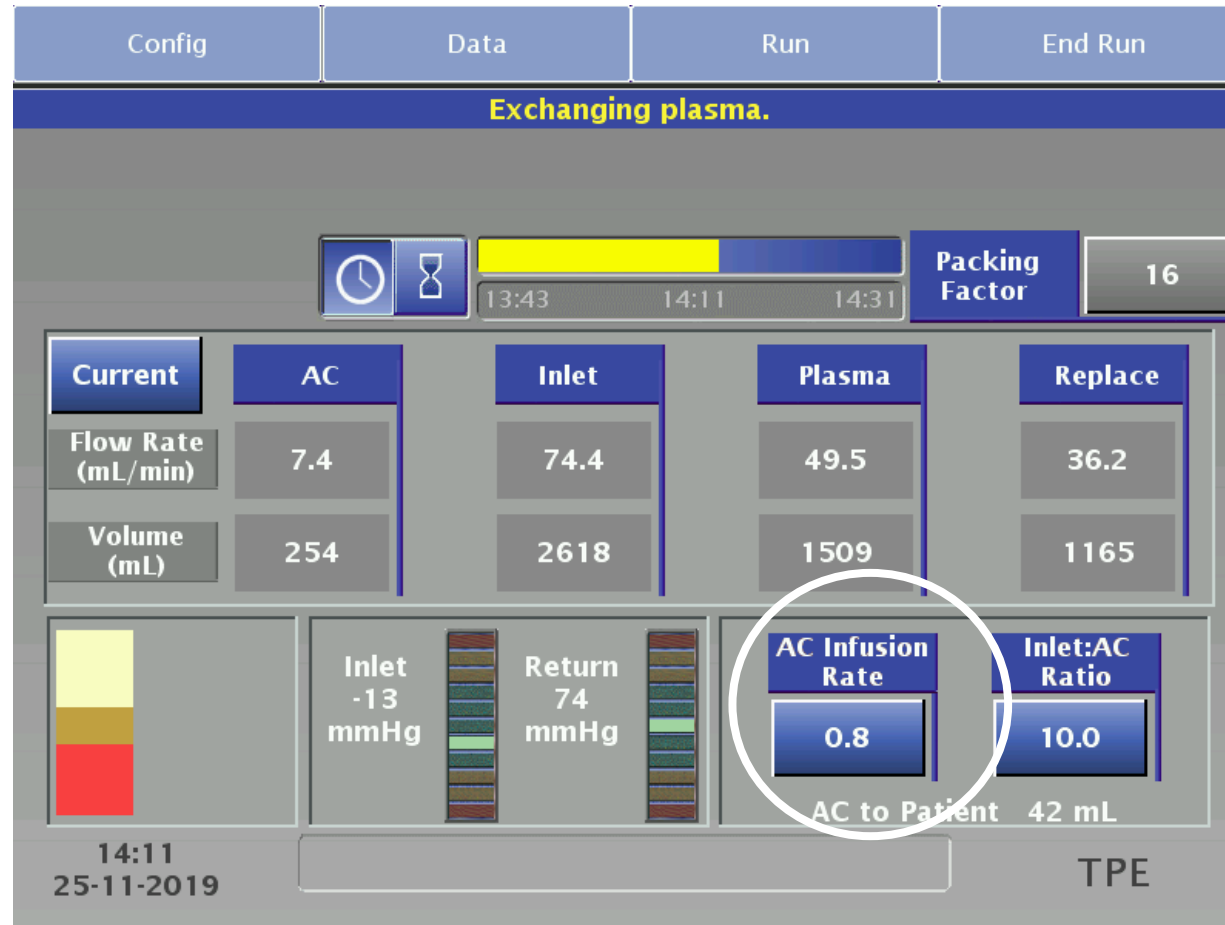
The 'Inlet' flow rate of 120.0 mL/min is circled in white. At the bottom, the time is 10:46 on 25-11-2019, and there is a 'Confirm' button, a back arrow, a 'TPE' indicator with a red prohibition sign, and a 'Confirm' button.

# Maximum AC Infusion Rate

The screenshot displays the 'Data' tab of a medical device interface. At the top, a blue banner reads 'Enter maximum AC infusion rate (mL/min/L TBV)'. A numeric keypad is centered on the screen, with the value '0.8' entered in a yellow box. The keypad includes buttons for digits 0-9, a decimal point, a 'Cancel' button, and an 'Enter' button. The background interface shows several data fields: 'Current AC' with a range of [0.2 ... 1.2] and [1.3 ... 2.5], 'Flow Rate (mL/min)' at 6.0, 'Volume (mL)' at 242, 'Packing Factor' at 20, 'Plasma' at 36.9, 'Replace' at 27.7, 'AC Infusion Rate' (empty), 'Inlet:AC Ratio' at 10.0, and 'AC to Patient' at 41 mL. A status bar at the bottom left shows the time '14:09' and date '25-11-2019', and the bottom right shows 'TPE'. A vertical bar on the left side of the screen is divided into yellow, brown, and red sections.



# Current AC Infusion Rate



# AC Infusion Rate – Maximum Limits

- Recommended maximum AC infusion rate is **1.2 mL/min/L TBV**
- Can be increased above 1.2 mL/min/L TBV in caution status within a range of **1.3 to 2.5 mL/min/L TBV**

# AC Infusion Rate – Making Changes

Config | Data | Run | End Run

**Exchanging plasma.**

13:43 | 13:55 | 14:28 | Packing Factor 10

Current	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	12.0	120.0	77.5	67.7
Volume (mL)	104	1036	583	440

Inlet -58 mmHg | Return 38 mmHg

**AC Infusion Rate** 0.8 | **Inlet:AC Ratio** 10.0

AC to Patient 16 mL

13:55 25-11-2019 | TPE

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

Exchange Status | Operation Status | Bolus | Strobe | **Run Values** | Options

AC Infusion Rate	Inlet:AC Ratio ( _:1)	Plasma Removed (mL)	Run Time (min)	Plasma Volumes Exchanged
<b>1.3</b>	10.0	2638	50 ↓	1.0

	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	12.0 ↑	<b>120.0 ↑</b>	66.9 ↑	52.1 ↑
Current (mL)	127	1266	707	534
Target (mL)	554	5536	3087	<b>2388</b>

13:58 25-11-2019 | Confirm | TPE

# AC Infusion Rate – Making Changes

The screenshot shows a medical device interface with a navigation bar at the top containing four tabs: "Config", "Data", "Run", and "End Run". Below the navigation bar, a blue banner displays the error message: "AC infusion rate entered exceeded recommended maximum rate." The main display area contains the following text: "The AC infusion rate of 1.3 mL/min/L TBV exceeds the recommended maximum rate of 1.2mL/min/L TBV. Do one of the following:" followed by two bullet points: "· To restore the previous AC infusion rate and resume the procedure, touch the go back button." and "· To use the entered AC infusion rate, touch Confirm. The procedure will resume in Caution status. Monitor the patient for citrate toxicity during the procedure." At the bottom of the screen, there is a status bar with the time "13:57" and date "25-11-2019" on the left, a "Confirm" button and a back arrow button in the center, and the text "TPE" on the right.

# AC Infusion Rate – Caution Status

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

Patient Data | Fluid Data | Alarm History | Report

**Exchanging plasma.**

13:43 | 14:05 | 14:21 | Packing Factor: 10

Current	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	9.9	118.5	70.3	56.0
Volume (mL)	211	2181	1241	963

Inlet: -40 mmHg | Return: 100 mmHg

AC Infusion Rate: 1.3 | Inlet:AC Ratio: 12.0

AC to Patient: 37 mL

14:05 25-11-2019 | **Caution Status** | TPE

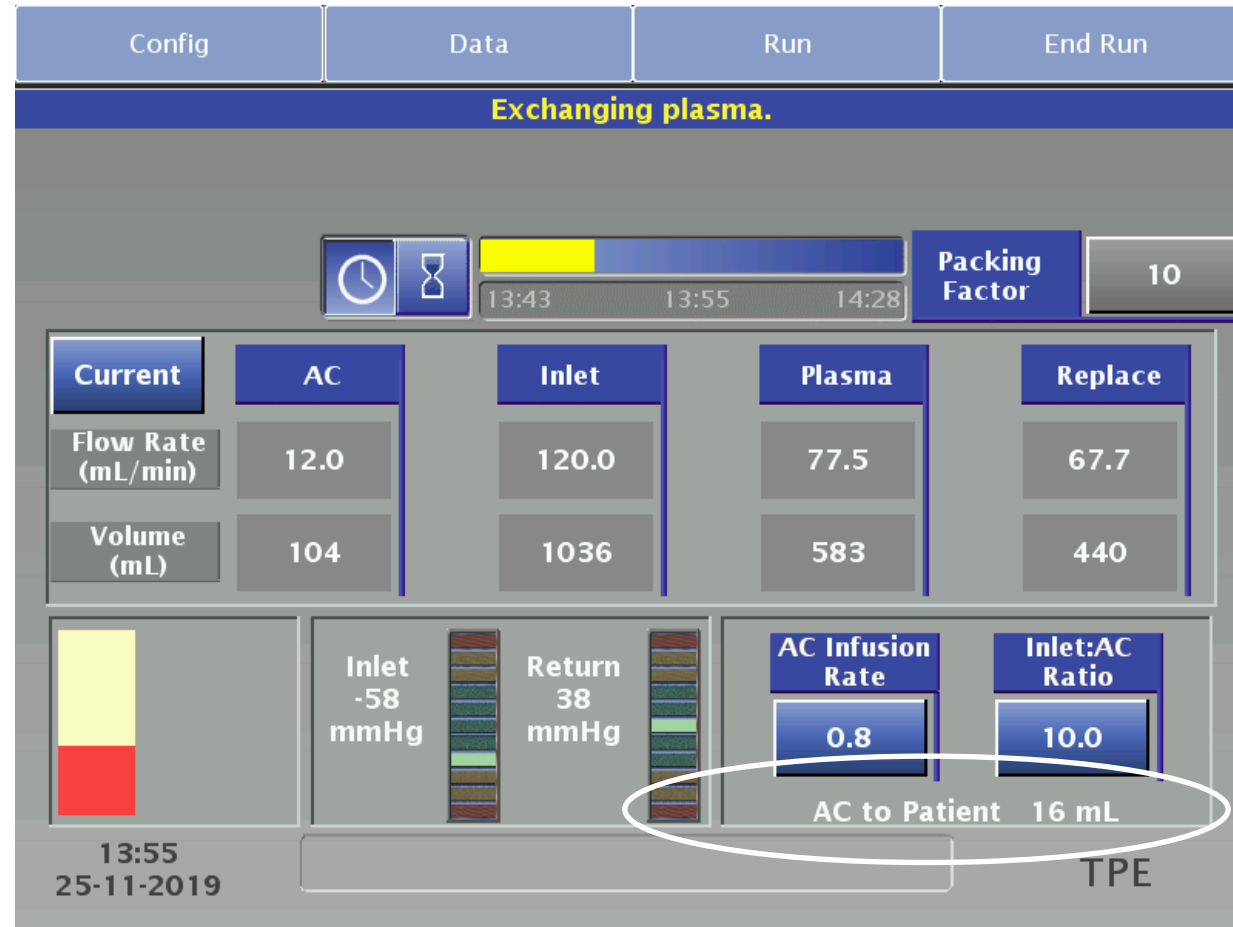
Config | Data | Run | End Run

**Caution Status**

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

14:06 25-11-2019 | | TPE

# AC to Patient

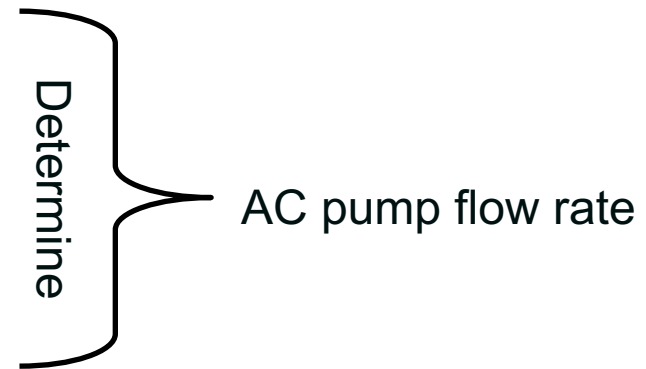


# AC Pump Flow Rate

- Rate at which AC is added to the extracorporeal circuit by the AC pump
- Determined by adding the volume of AC being infused to the patient from the AC bag to the volume of AC being removed to the remove bag

mL of AC infused to the patient from the AC bag

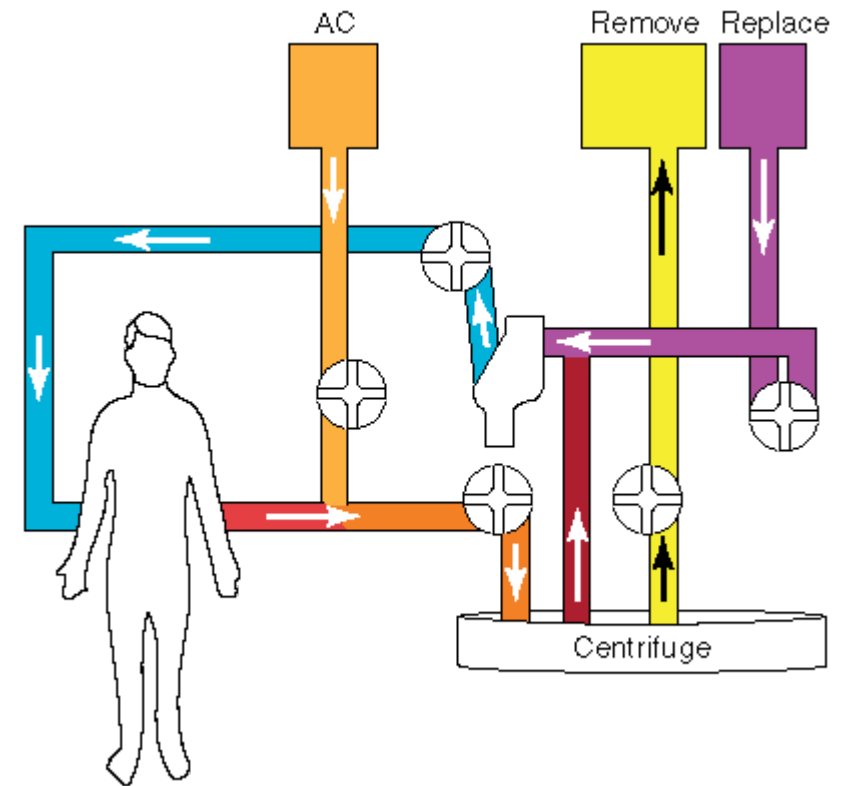
mL of AC removed to the remove bag



# AC Pump Flow Rate – Therapeutic Plasma Exchange

For TPE procedures:

1. Volume of AC added to the extracorporeal circuit from:
  - ACD-A bag
  - Replacement fluid
2. Minus the volume of AC removed to:
  - Remove bag
3. Equals the volume of AC delivered to:
  - Patient





# Fluid Data Screen

Config | Data | Run | End Run

Select replacement fluid.

Replacement Fluid



Plasma

Saline/Albumin

Custom

13:30  
25-11-2019

Confirm



TPE

Config | Data | Run | End Run

Replacement Fluid

Saline/Albumin (4% Citrate)



Patient Fluid Balance

Volume 0 mL



Percent 100 %



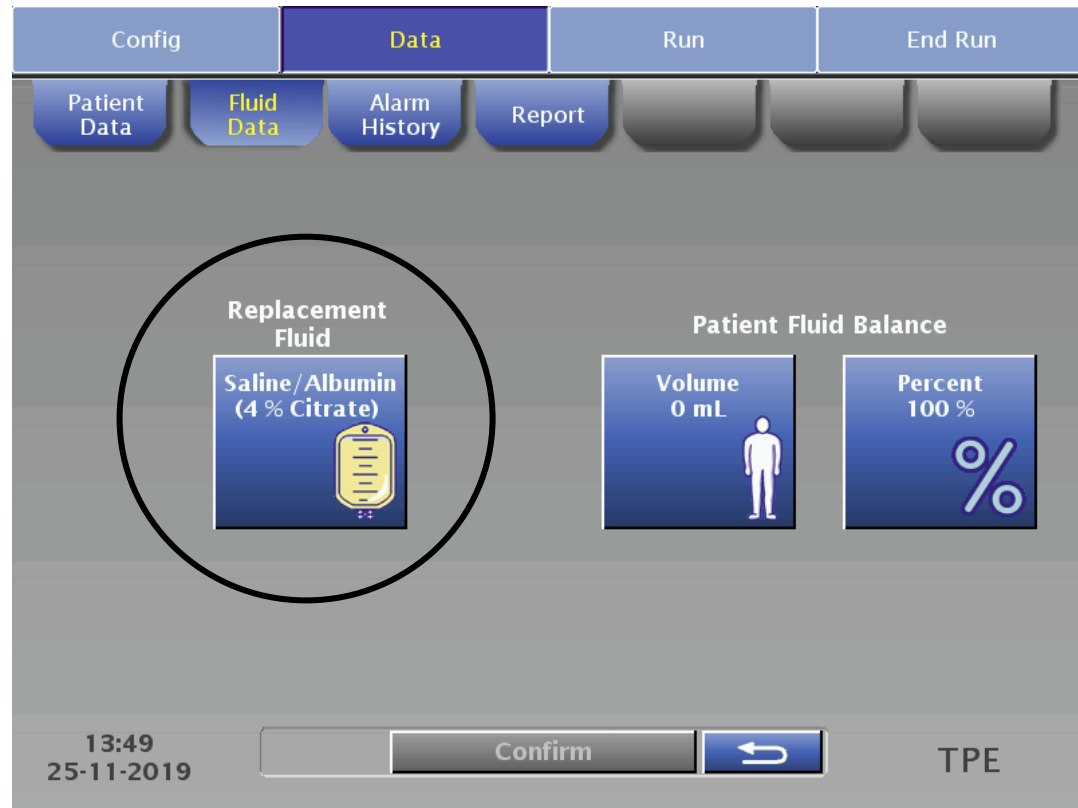
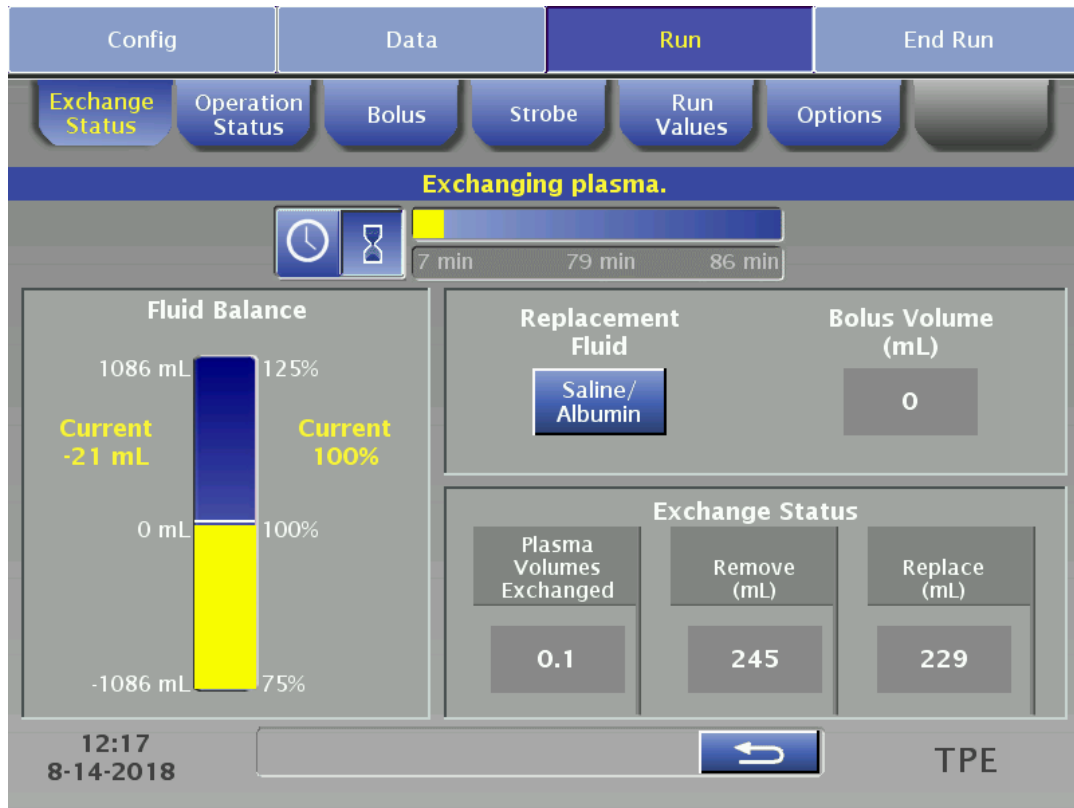
13:30  
25-11-2019

Confirm



TPE

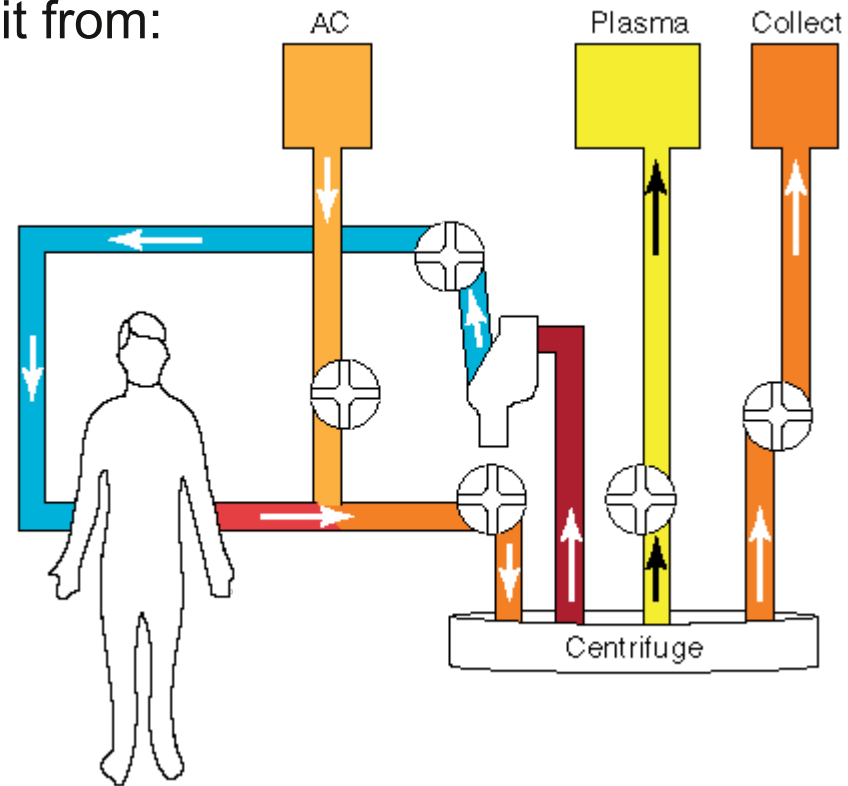
# Fluid Data Screen



# AC Pump Flow Rate – Collection Procedures

For MNC procedures with concurrent plasma collection:

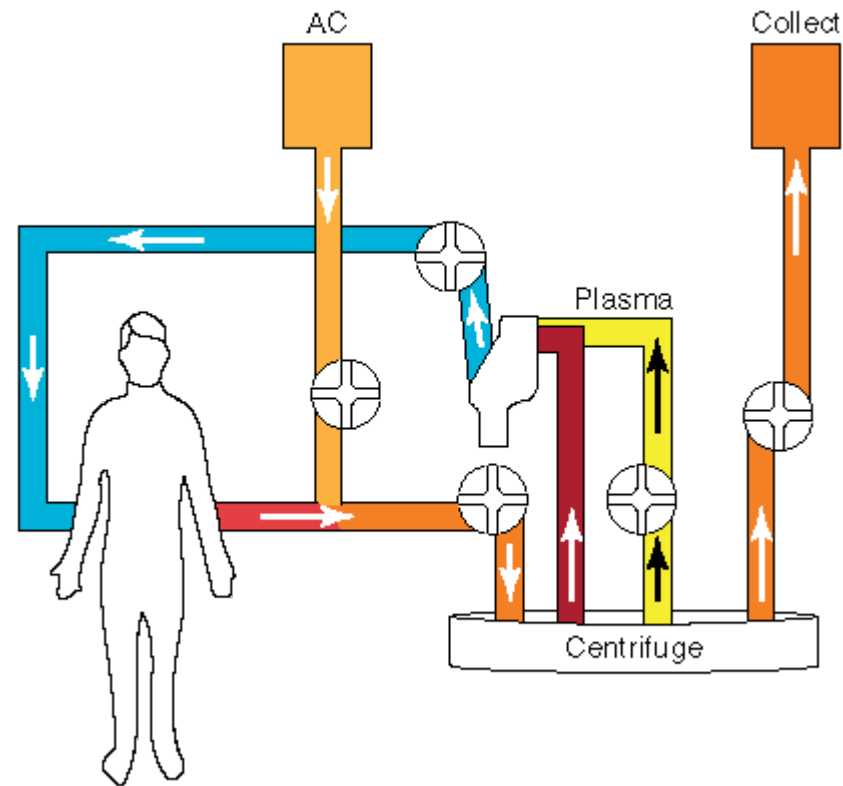
1. Volume of AC added to the extracorporeal circuit from:
  - ACD-A bag
2. Minus the volume of AC removed to:
  - Collect and/or plasma bags
3. Equals the volume of AC delivered to:
  - Patient



# AC Pump Flow Rate – Collection Procedures

For MNC procedures without plasma collection:

1. AC added to the extracorporeal circuit from:
  - ACD-A bag
2. Minus the AC removed to:
  - Collect bag
3. Equals the AC delivered to:
  - Patient

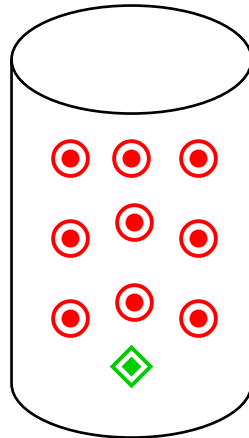


# Inlet:AC Ratio

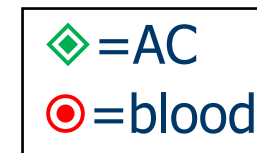
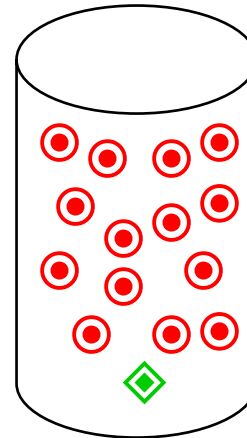
- The proportion of whole blood to AC in the extracorporeal circuit determines the concentration of AC in the extracorporeal circuit and the degree to which blood in the system is anticoagulated

# Inlet:AC Ratio

Ratio=10



Ratio=15



① If you ↑ the Inlet:AC ratio, more whole blood is added to the same amount of citrate. There is a ↓ in the concentration of AC in the circuit, which ↓ the anticoagulation effect.

# Inlet:AC Ratio Configuration

You can configure the Inlet:AC ratio for all procedures by accessing the appropriate configuration screen.



# Inlet:AC Ratio

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

Exchange Status | Operation Status | Bolus | Strobe | **Run Values** | Options

AC Infusion Rate	Inlet:AC Ratio (_:1)	Plasma Removed (mL)	Run Time (min)	Plasma Volumes Exchanged
0.8	10.0	2040	50	1.0

	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	6.0	60.0	37.6	29.1
Current (mL)	239	2471	1418	1095
Target (mL)	394	4014	2384	1844

14:09 25-11-2019 | Confirm | TPE

Config | Data | Run | End Run

**Exchanging plasma.**

13:43 | 14:10 | 14:34 | Packing Factor 20

Current	AC	Inlet	Plasma	Replace
Flow Rate (mL/min)	6.0	60.0	37.6	29.0
Volume (mL)	248	2557	1471	1136

Inlet -16 mmHg | Return 61 mmHg | AC Infusion Rate 0.6 | **Inlet:AC Ratio 10.0**

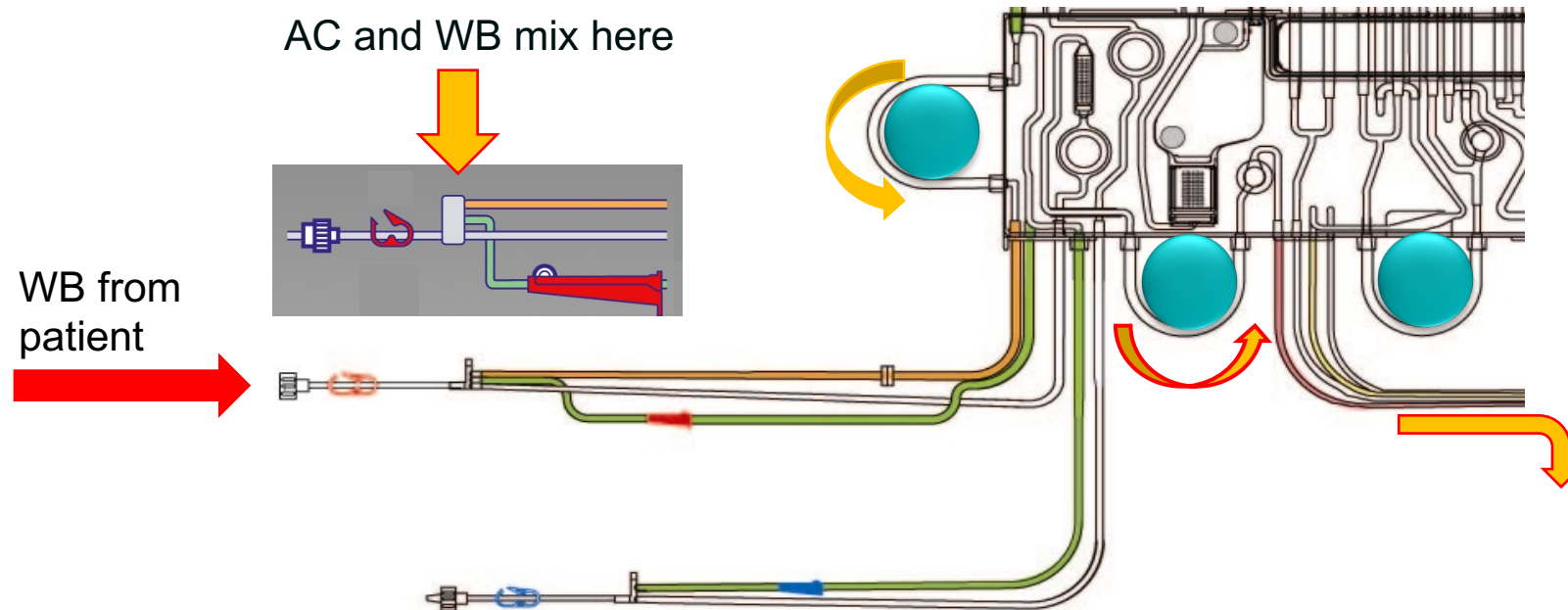
AC to Patient 42 mL

14:10 25-11-2019 | TPE

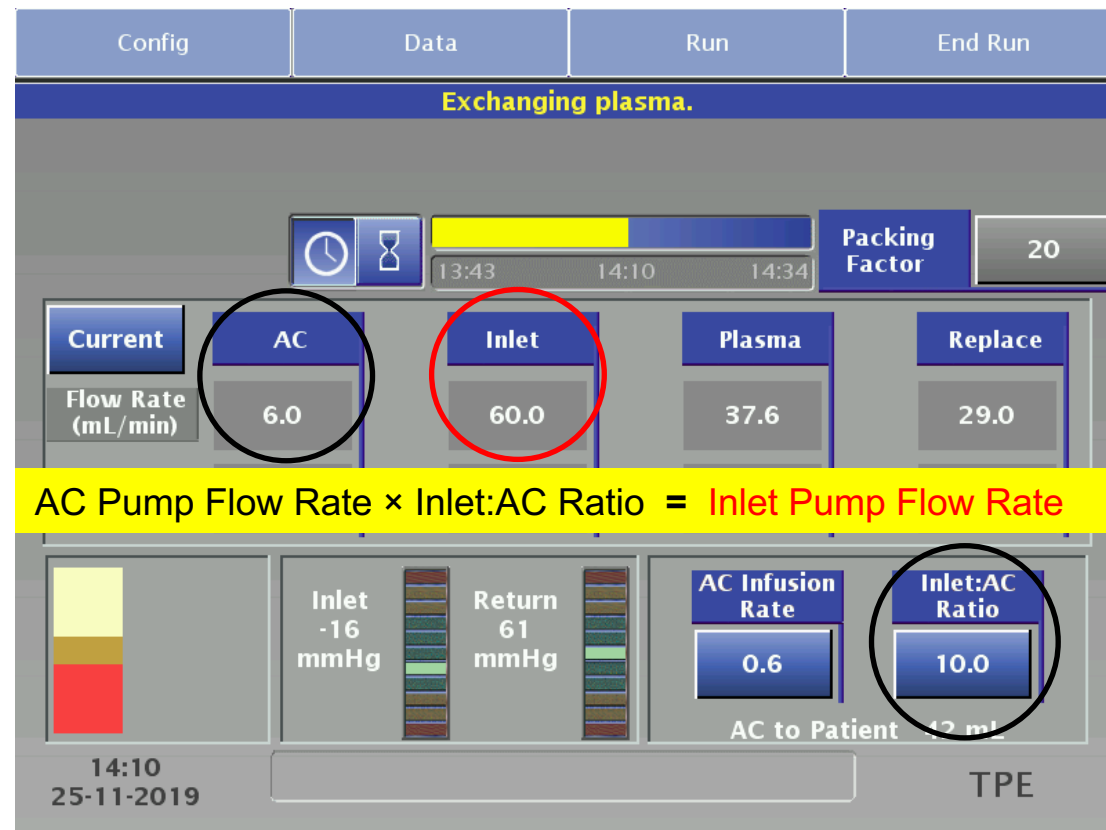


# Inlet Pump Flow Rate

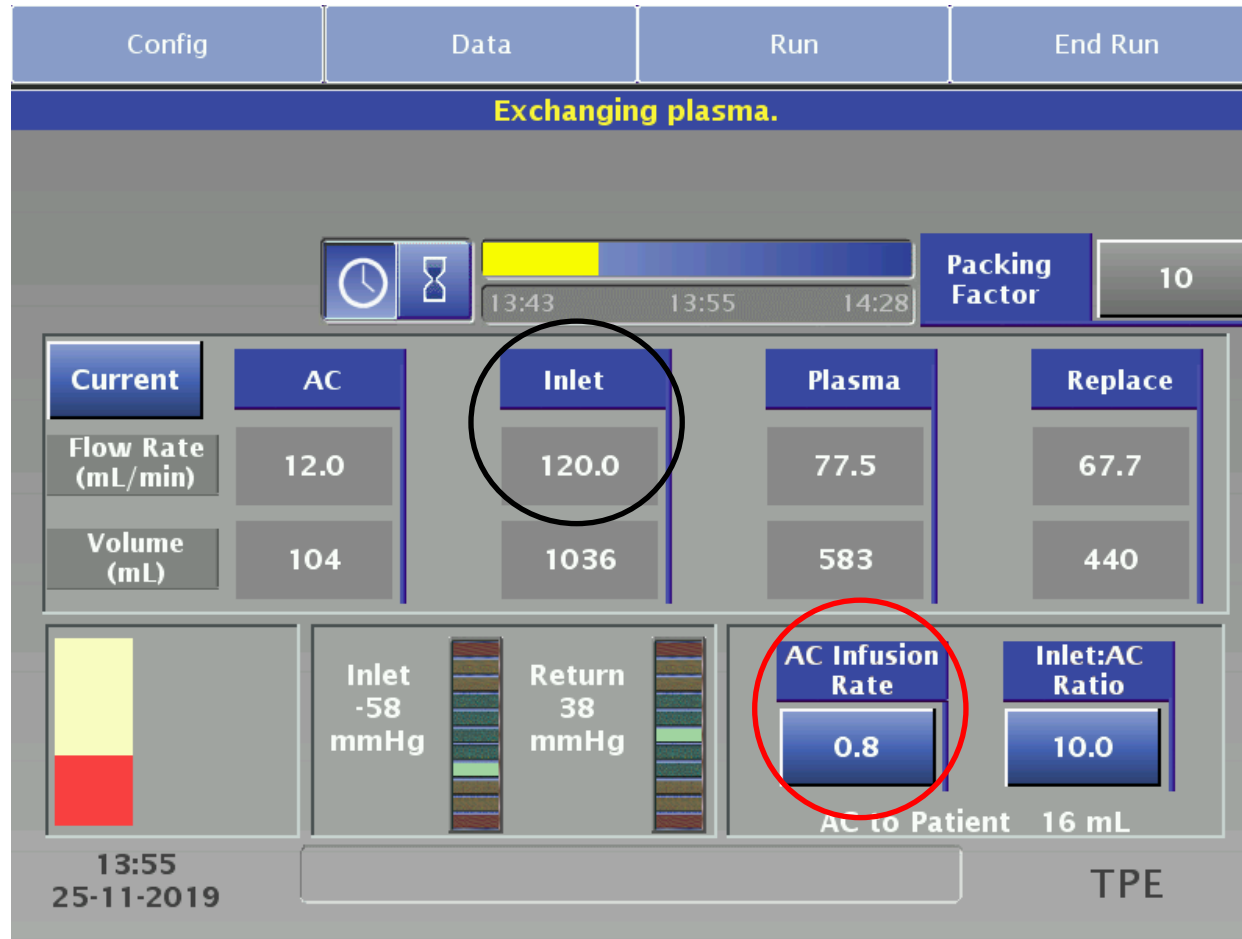
The rate at which anticoagulated whole blood (WB) is drawn into the system by the inlet pump



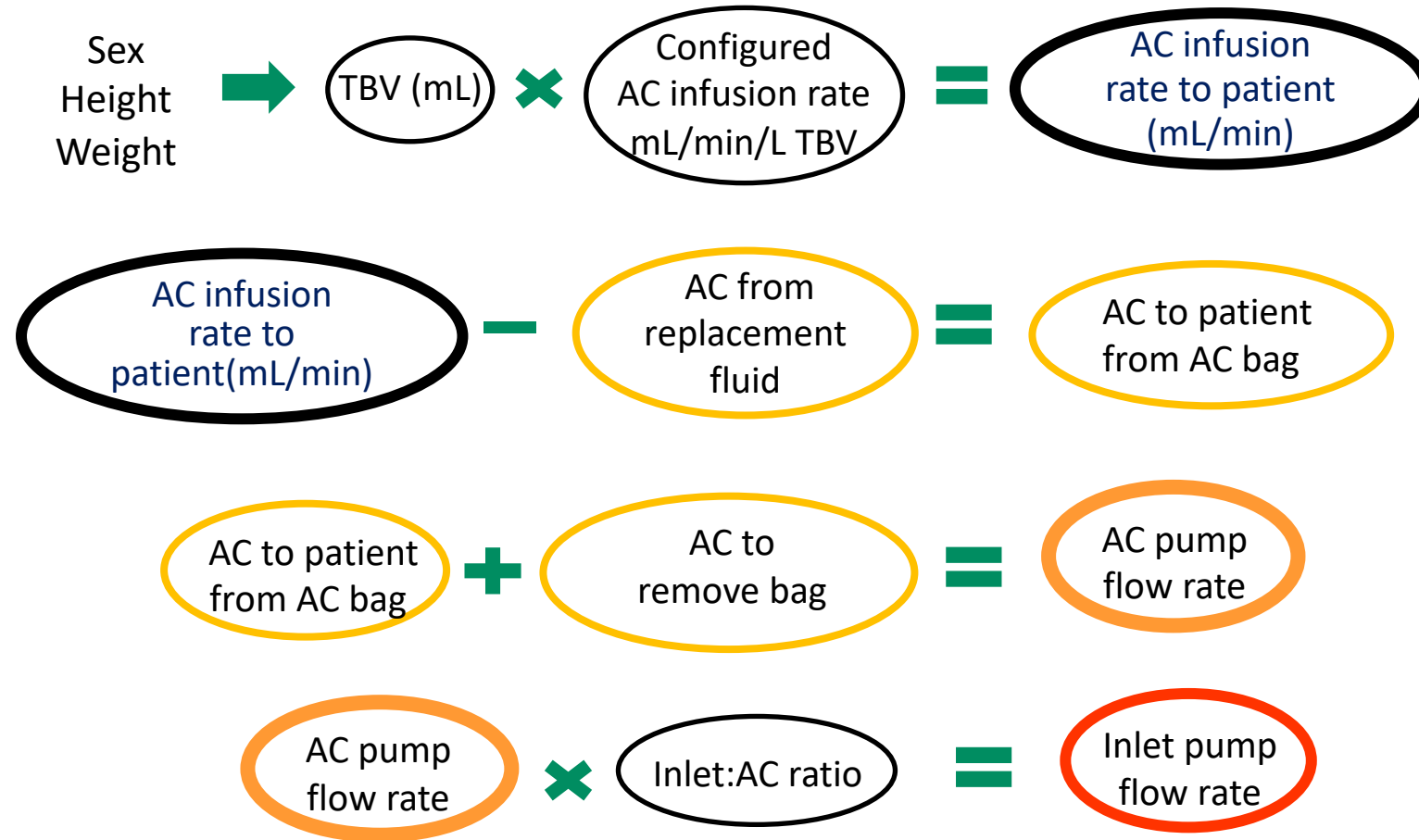
# Inlet Pump Flow Rate



# Inlet Pump Flow Rate



# Summary: AC Management Concepts



# Consequences of Changing the AC Infusion Rate



AC infusion rate



AC infusion rate



Inlet flow rate



Inlet flow rate



Procedure time



Procedure time



Inlet:AC ratio



Inlet:AC ratio











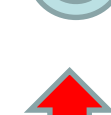

Citrate reaction



Citrate reaction

**Note:** If the recommended maximum AC infusion rate limit of 1.2 mL/min/L TBV is exceeded, the system operates in caution status.

# Consequences of Changing the Inlet Flow Rate

 Inlet flow rate	 Inlet flow rate
 AC infusion rate	 AC Infusion rate
 Procedure time	 Procedure time
 Inlet:AC ratio	 Inlet:AC ratio
 Citrate reaction	 Citrate reaction

**Note:** The recommended maximum AC infusion rate limit of 1.2 mL/min/LTBV cannot be exceeded by increasing the inlet flow rate.

# Consequences of Changing the Inlet:AC Ratio



Inlet:AC ratio



Inlet:AC ratio



Inlet flow rate



Inlet flow rate



Procedure time



Procedure time



AC infusion rate



AC infusion rate



Anticoagulation



Anticoagulation

**Note:** Inadequate anticoagulation can cause platelet activation and aggregation, formation of micro-aggregates and clotting of the system.

# Questions?

[TerumoBCT.com](http://TerumoBCT.com)

