TERUMO BLOOD AND CELL TECHNOLOGIES

Concepts of Anticoagulant (AC) Management

Using the Spectra Optia® Apheresis System

TS-OPTI-01105

TRAINING

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

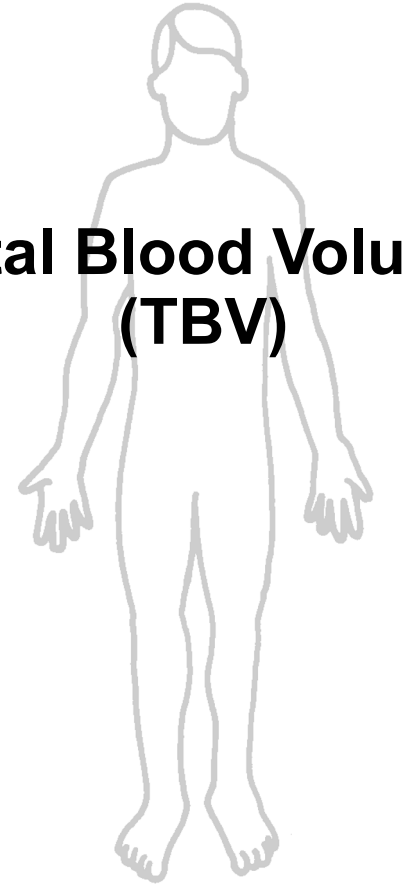
Entering accurate patient data allows a safe and efficient procedure by ensuring:

- 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

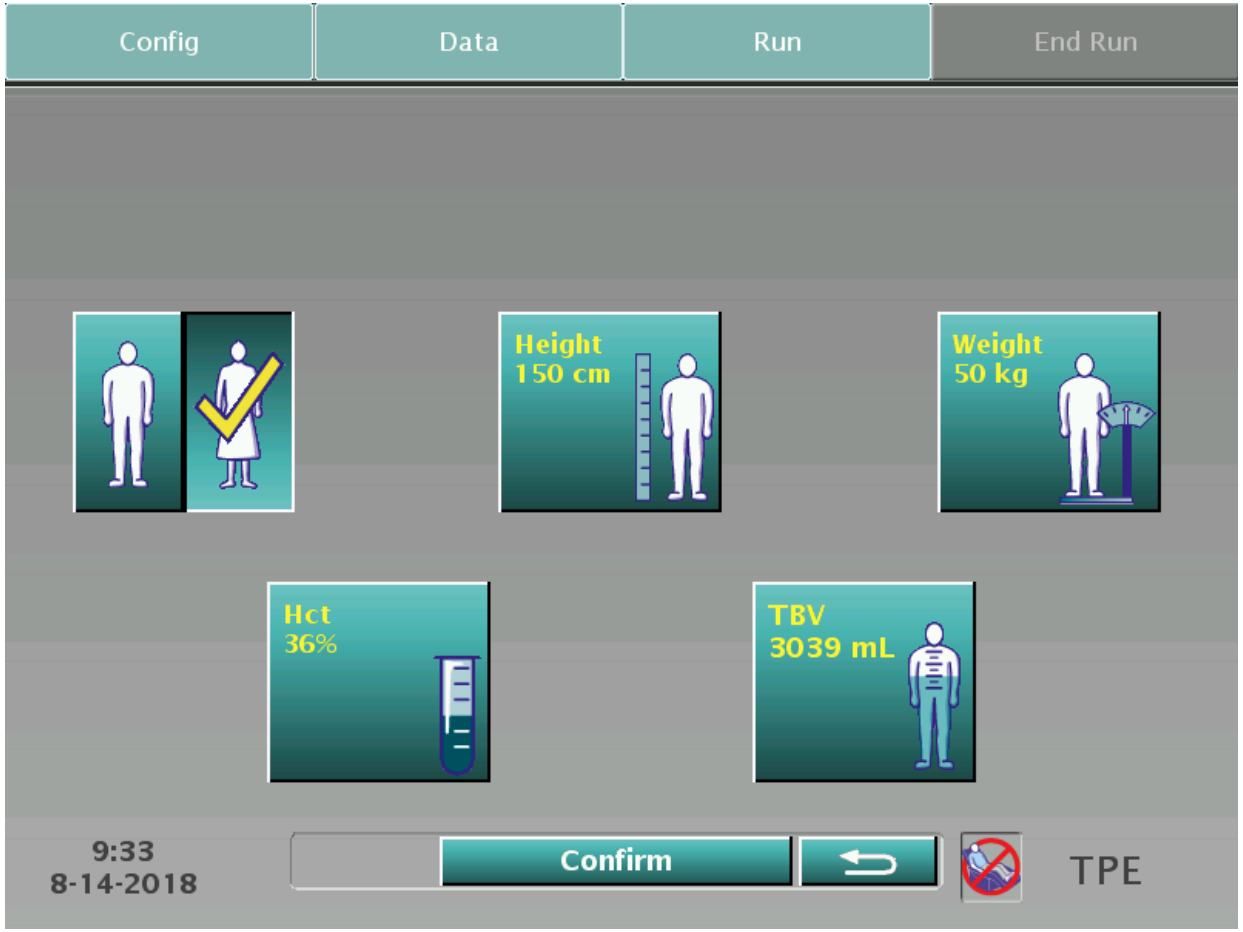
- Sex
- Height
- Weight

Total Blood Volume (TBV)



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

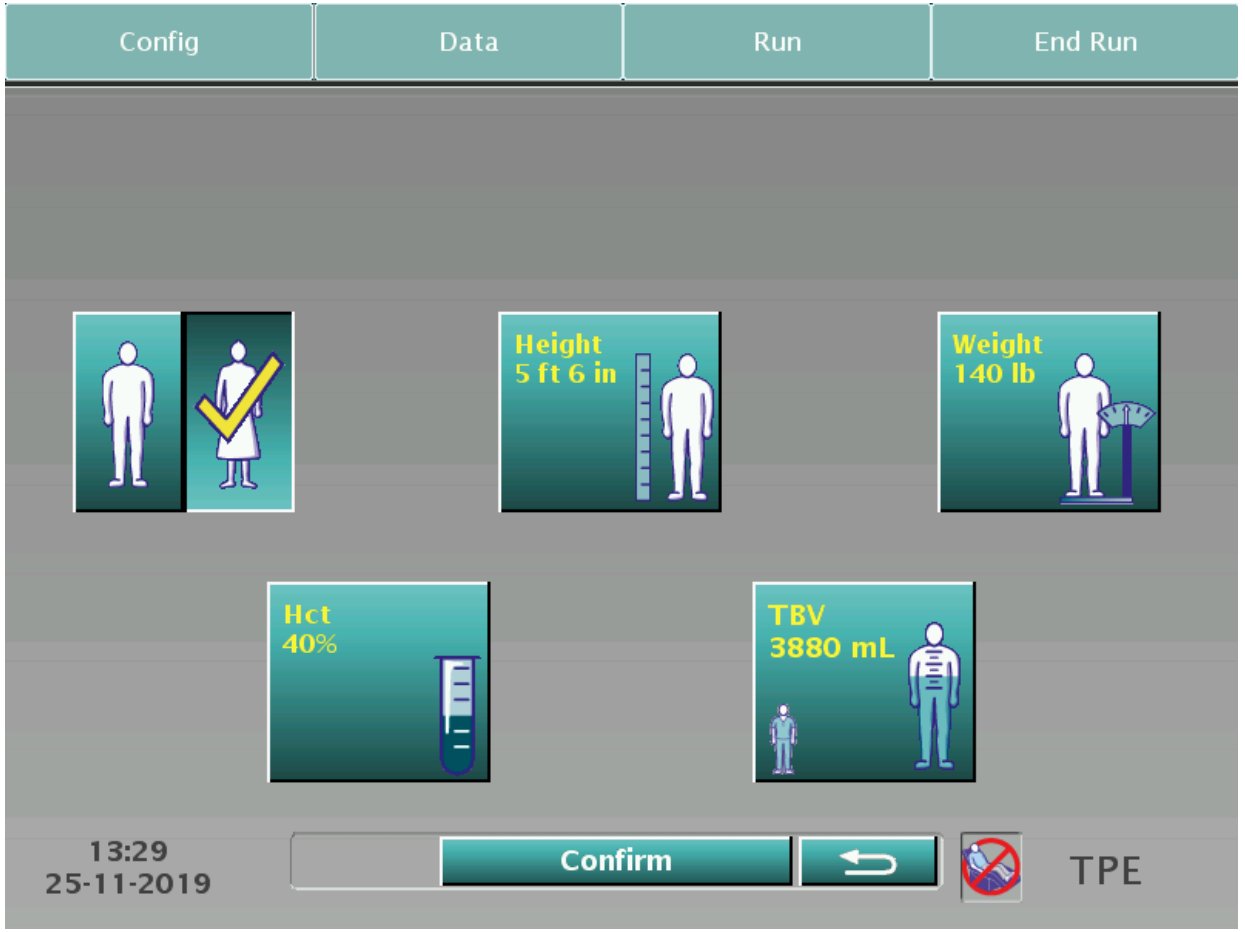
AC Infusion Rate – Total Blood Volume



AC Infusion Rate – Total Blood Volume

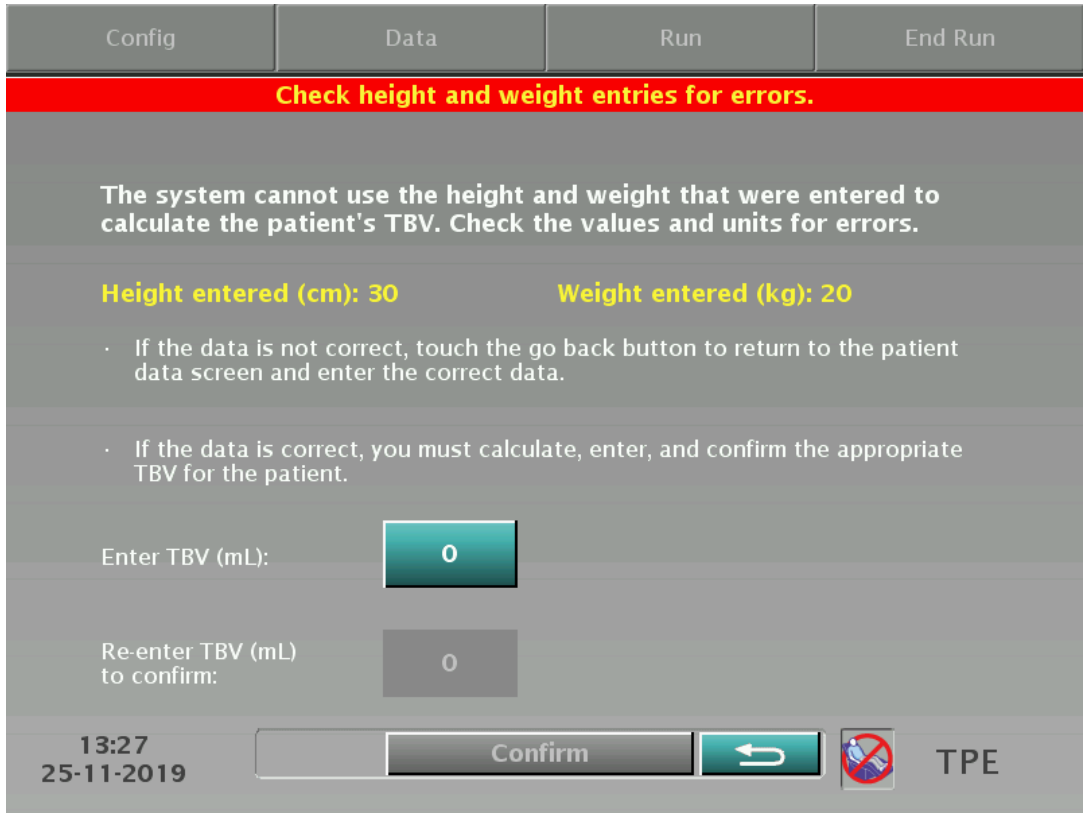
- Please note the Spectra Optia TBV calculation is not accurate for patients weighing less than 25 kg (approx. 55 lb) or who have certain conditions
  - The operator must enter an appropriate TBV as directed by a physician or their facility's standard operating procedure

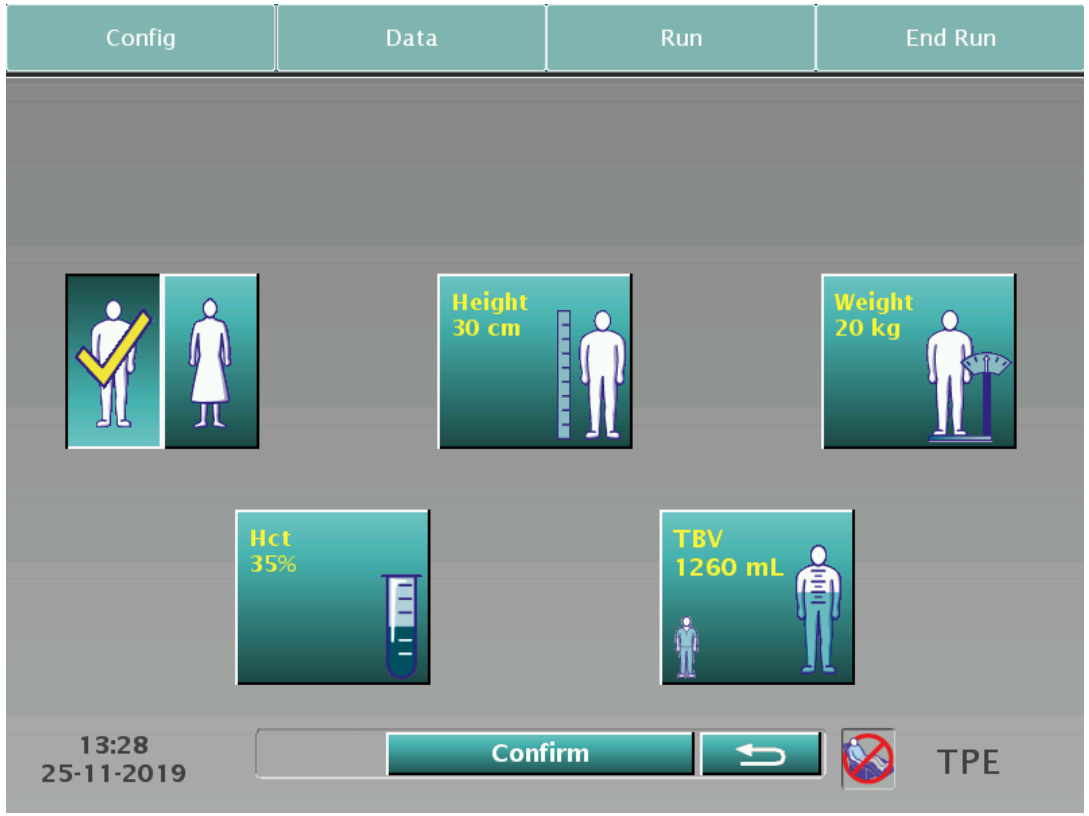
AC Infusion Rate – Total Blood Volume



AC Infusion Rate – Total Blood Volume

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



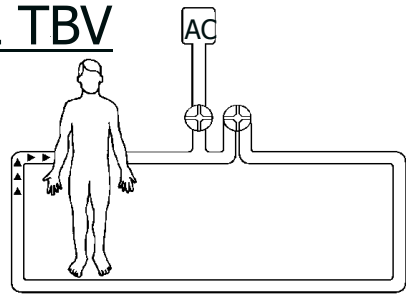


AC Infusion Rate

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

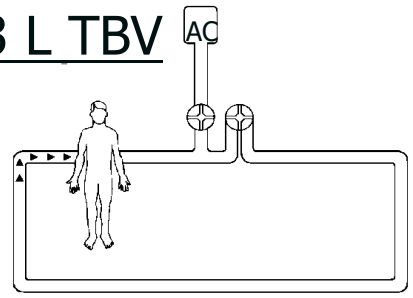
AC infusion rate (AC or citrate dose rate) × Patient’s TBV = AC infused to patient per minute (AC dose)

5 L TBV



0.8 mL/min/L TBV × 5 L TBV
↳ 4.0 mL/min of AC infused to the patient (AC dose)

3 L TBV

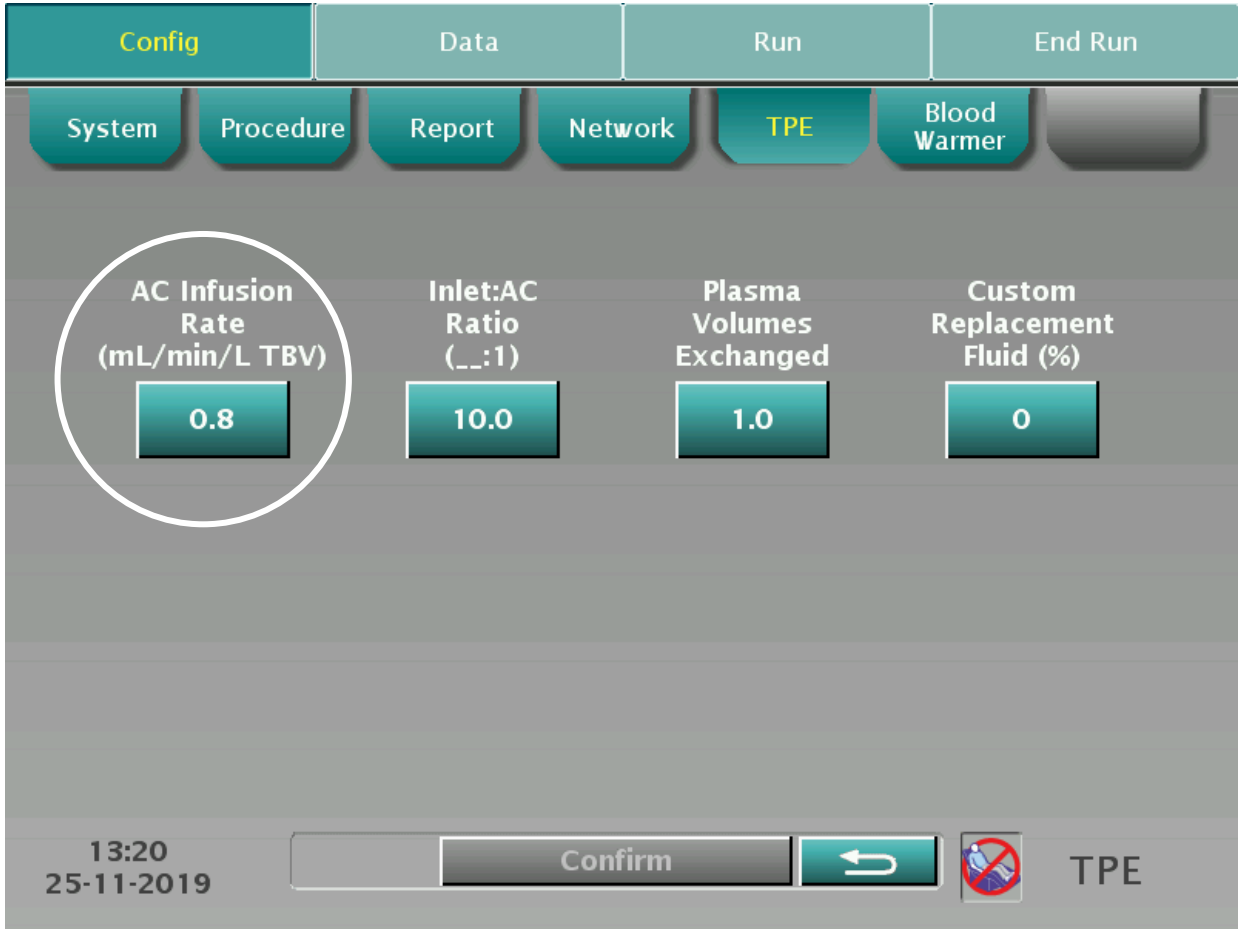


0.8 mL/min/L TBV × 3 L TBV
↳ 2.4 mL/min of AC infused to the patient (AC dose)

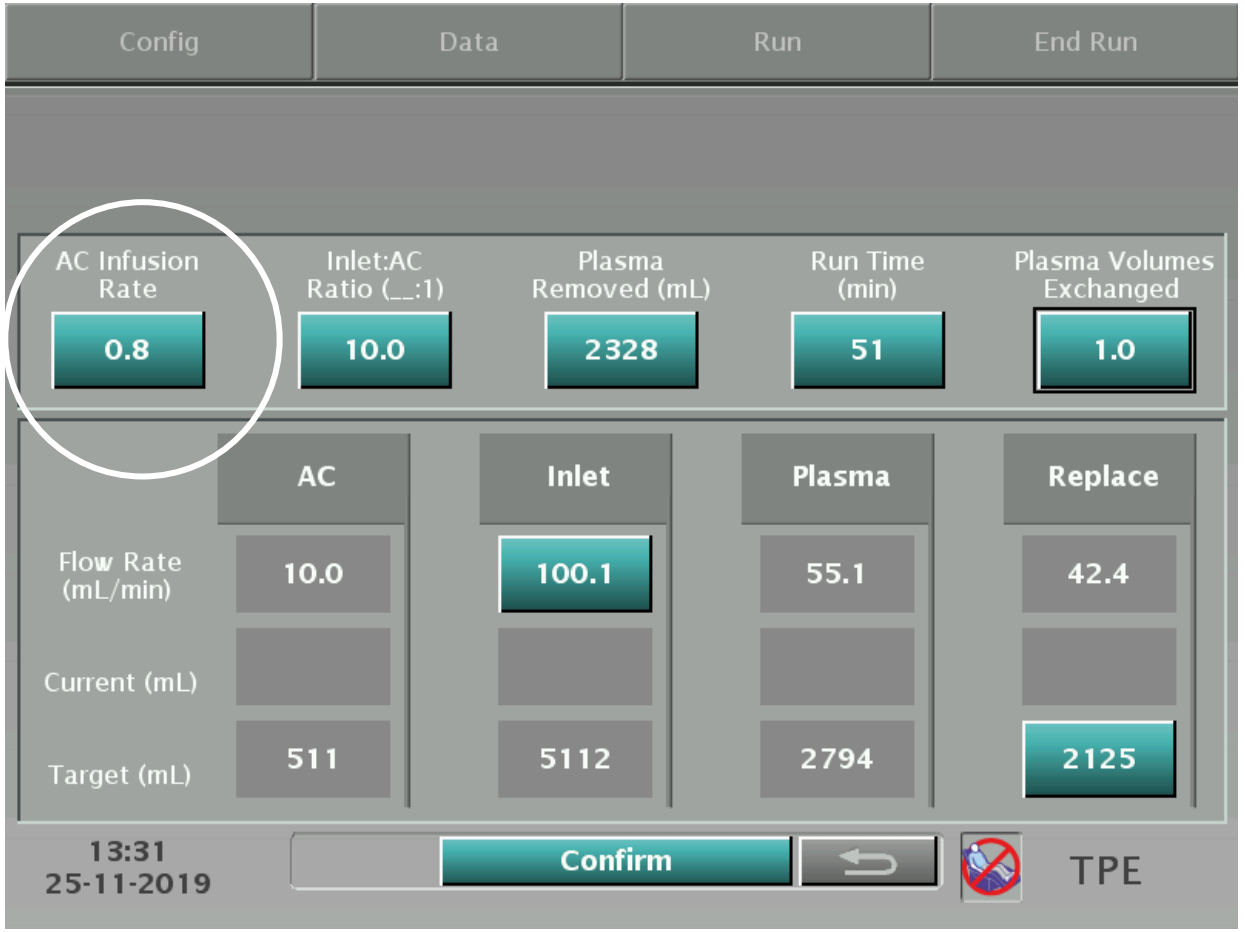
AC Infusion Rate – Definitions

- 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

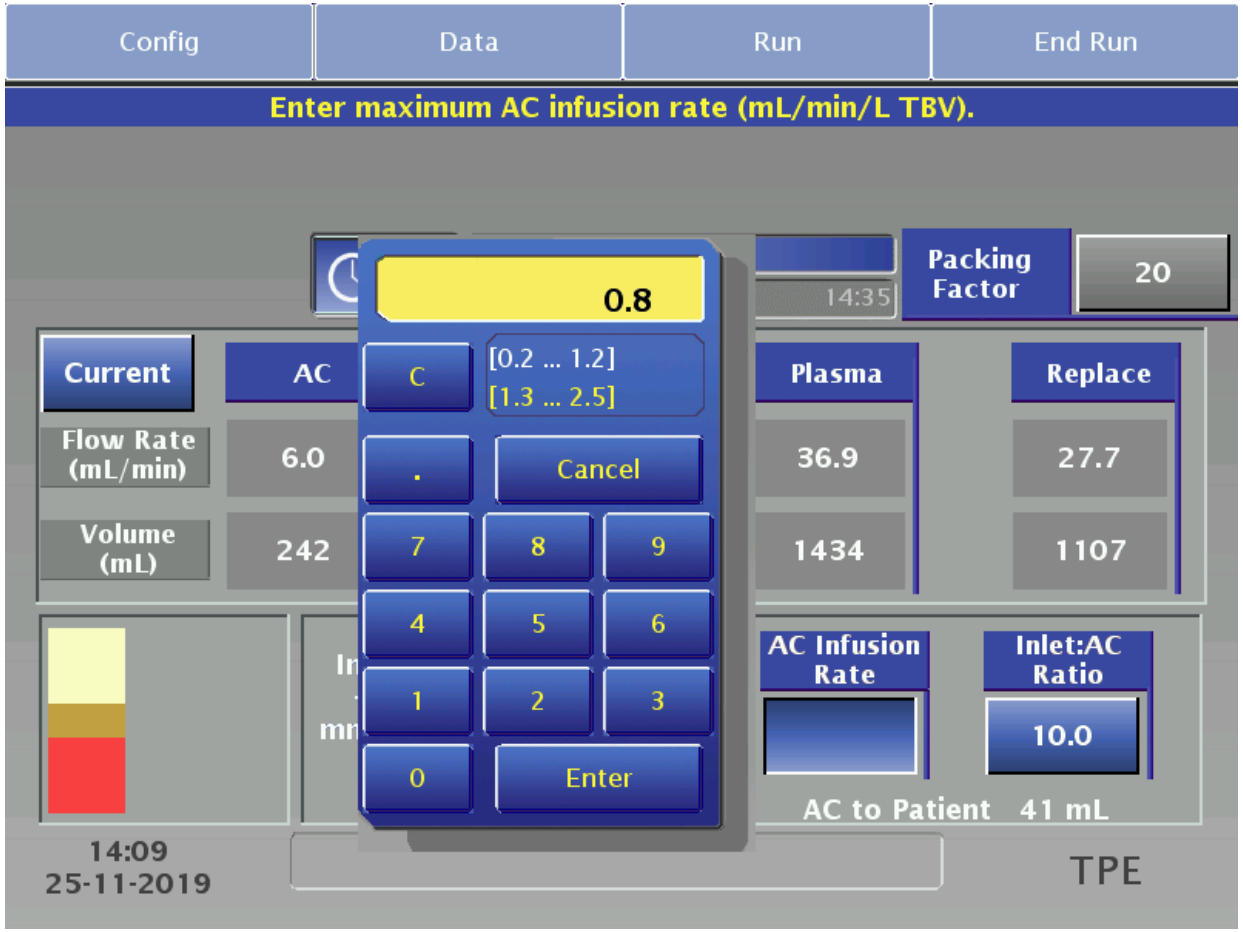


Maximum AC Infusion Rate – Run Values Screen

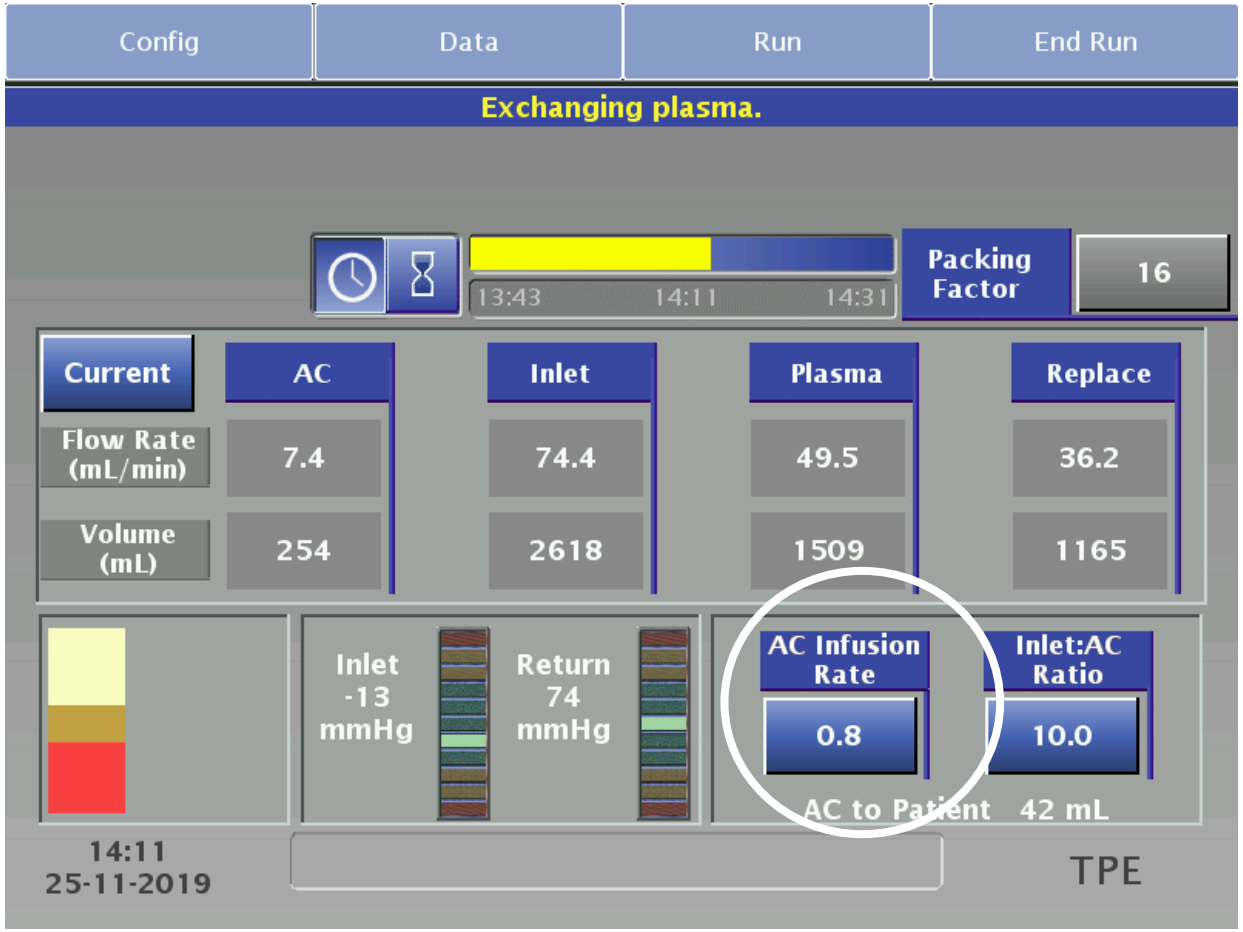


Maximum AC Infusion Rate – Inlet Flow Rate

Maximum AC Infusion Rate



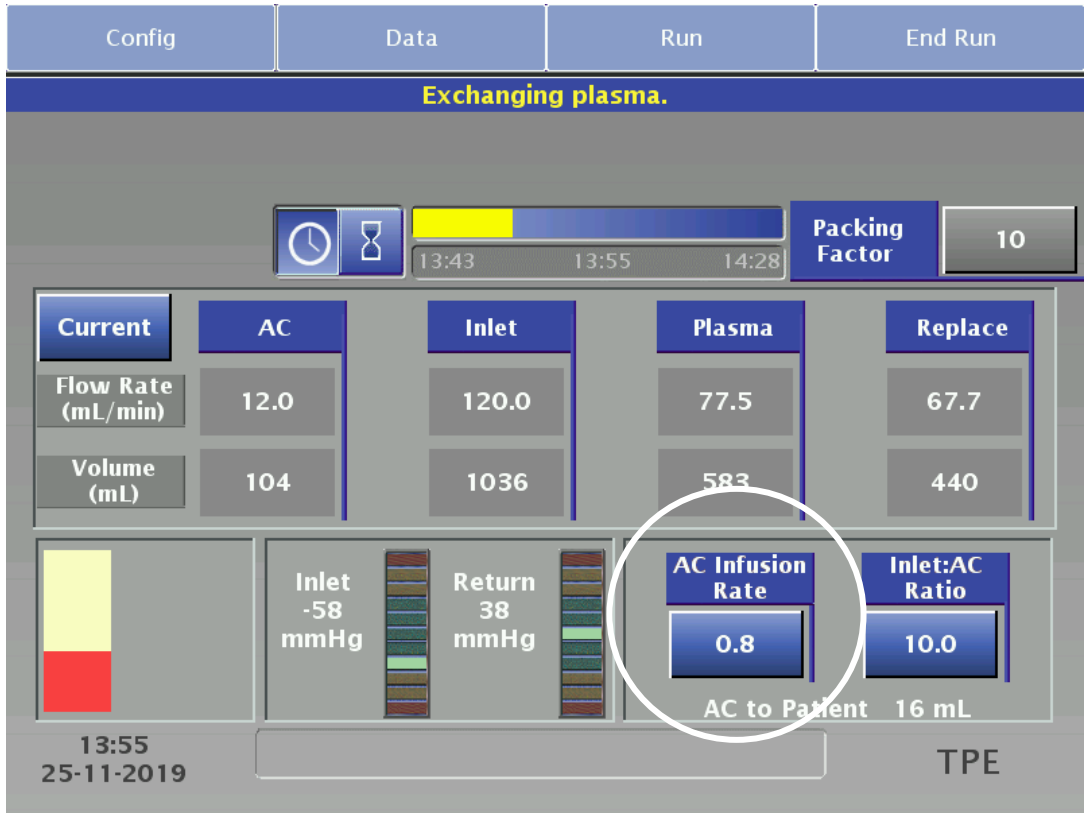
Current AC Infusion Rate

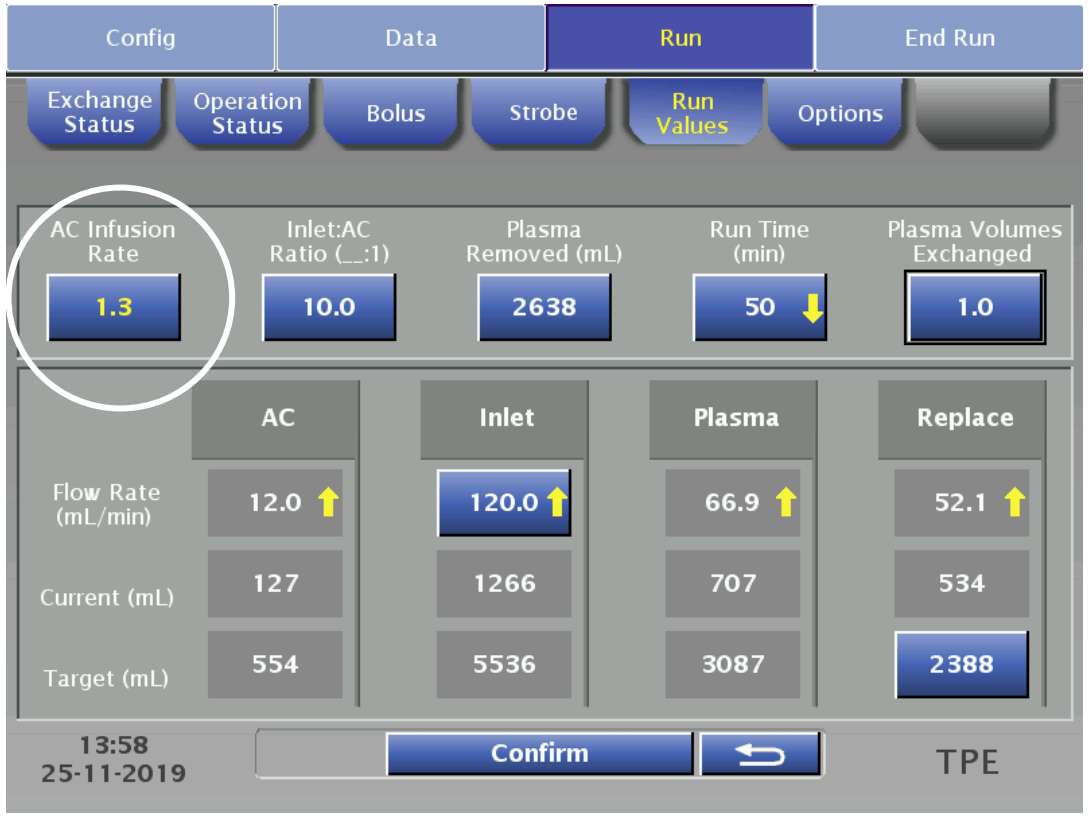


AC Infusion Rate – Maximum Limits

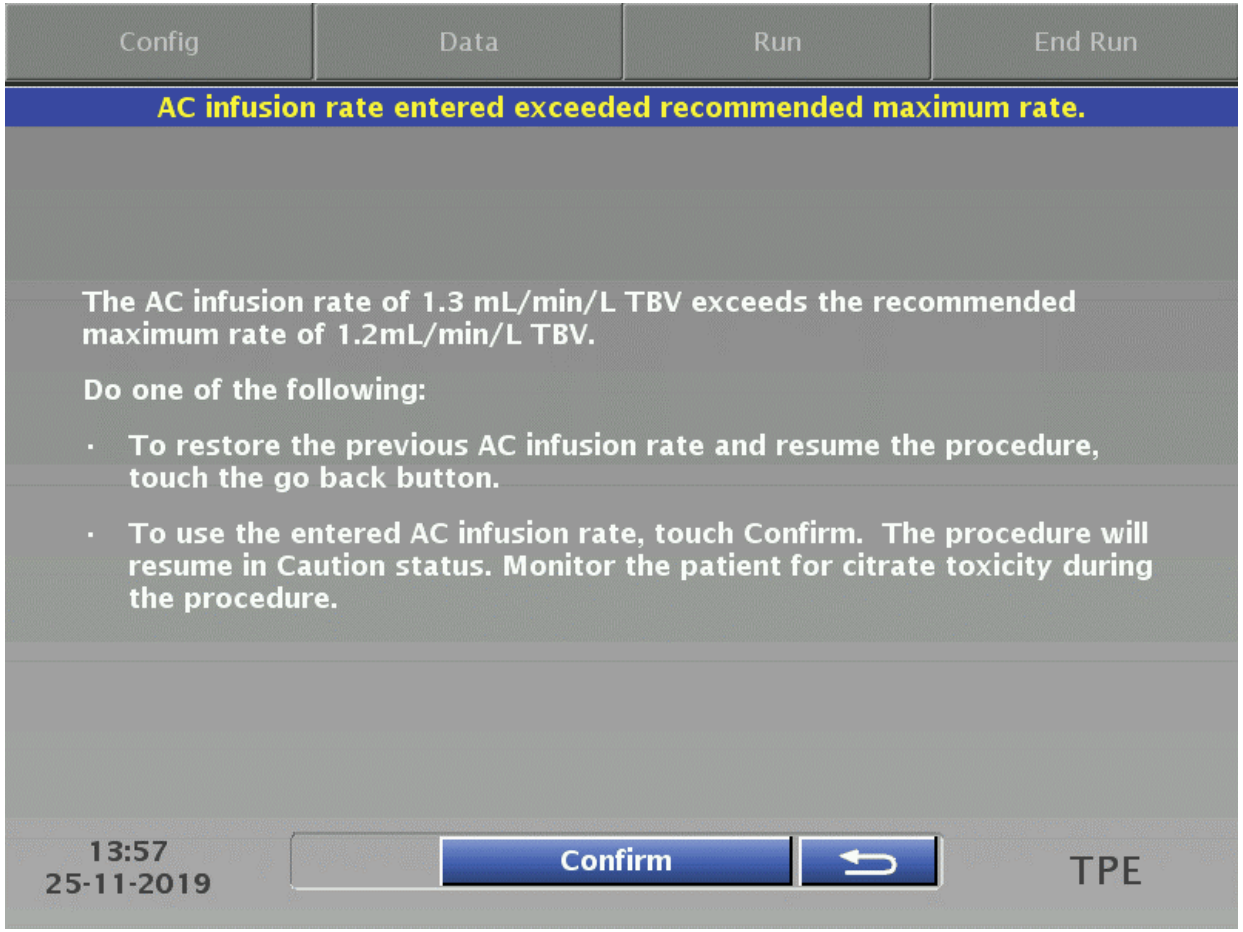
- Recommended maximum AC infusion rate is **1.2** mL/min/L TBV
- Can be increased above 1.2 mL/min/L TBV in caution status within a range of **1.3** to **2.5** mL/min/L TBV

AC Infusion Rate – Making Changes

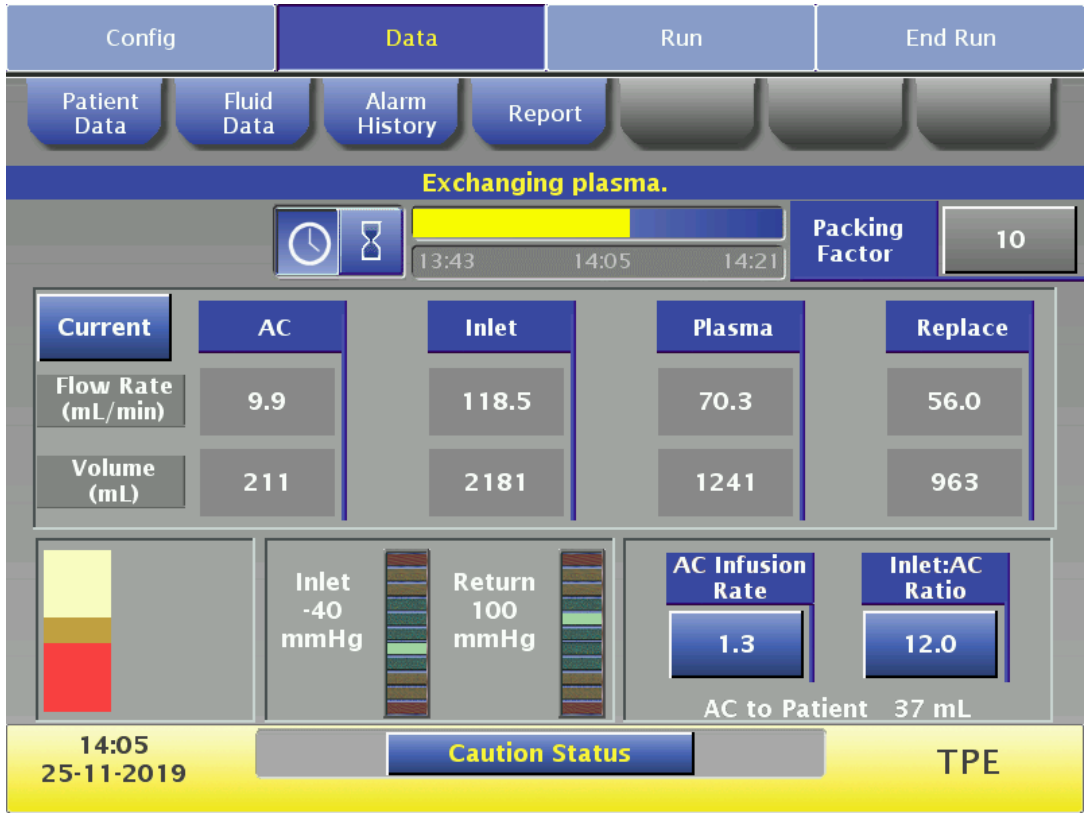


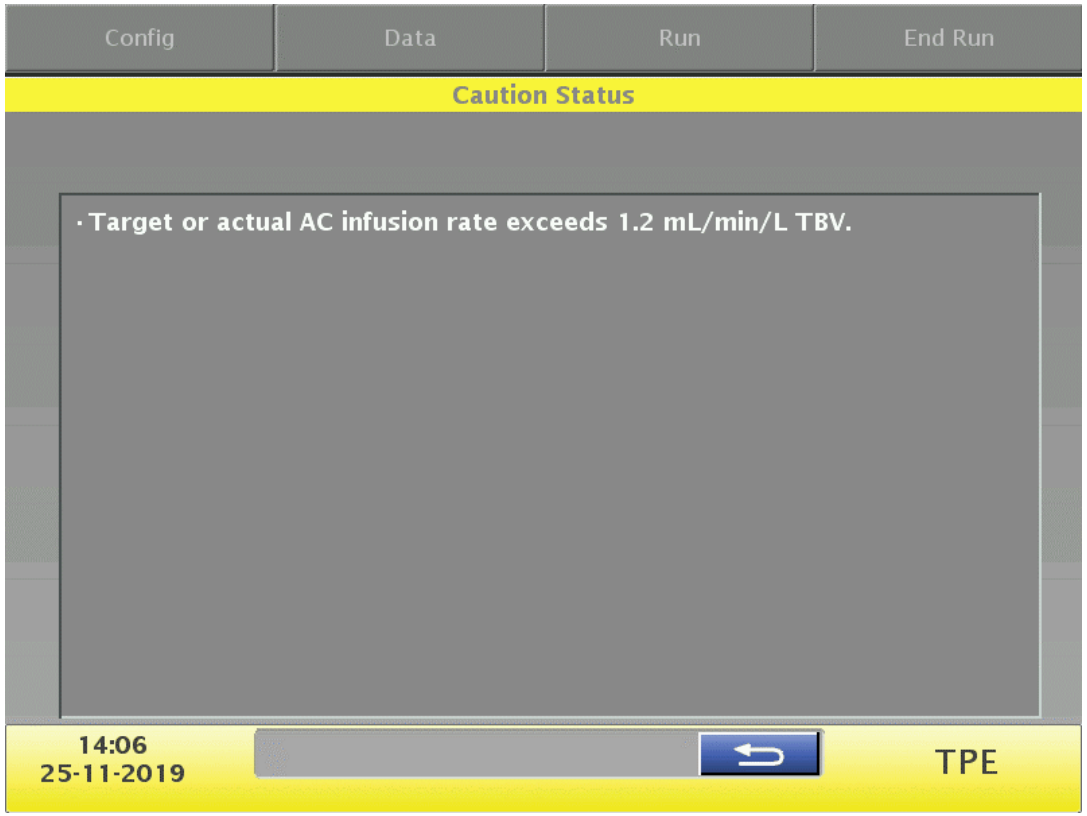


AC Infusion Rate – Making Changes

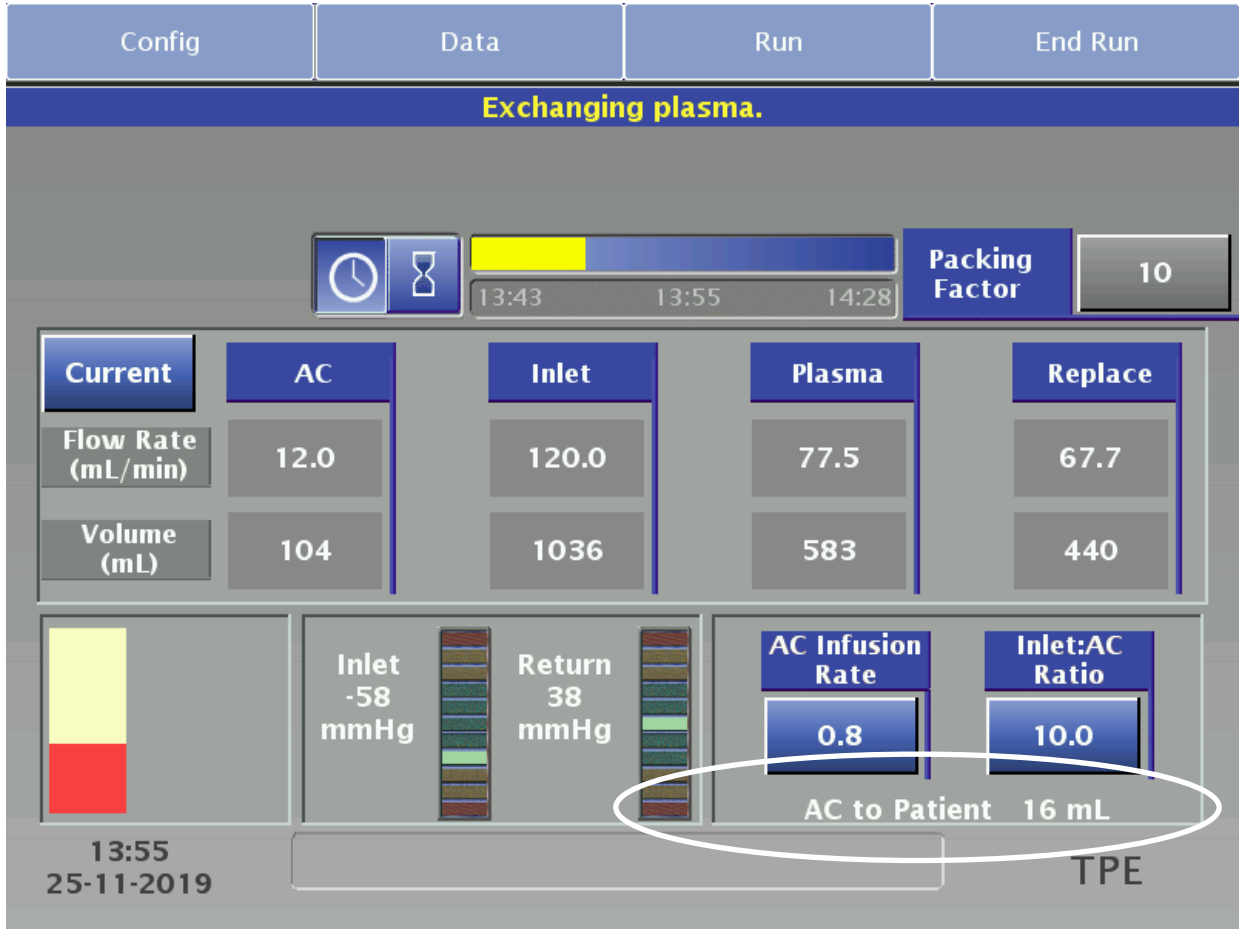


AC Infusion Rate – Caution Status





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

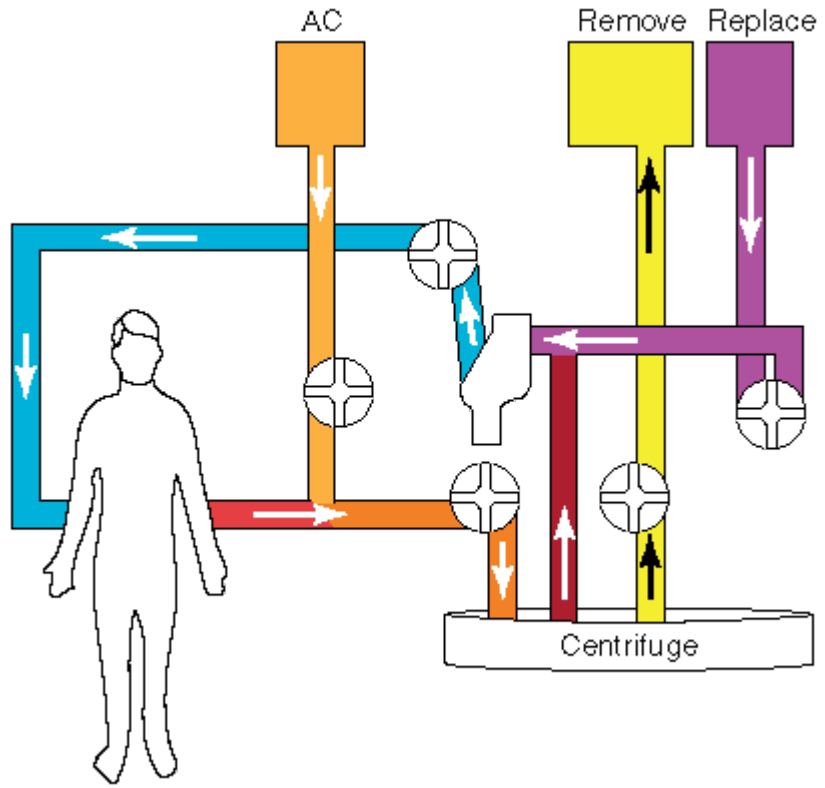
mL of AC removed to the remove bag

Determine → AC pump flow rate

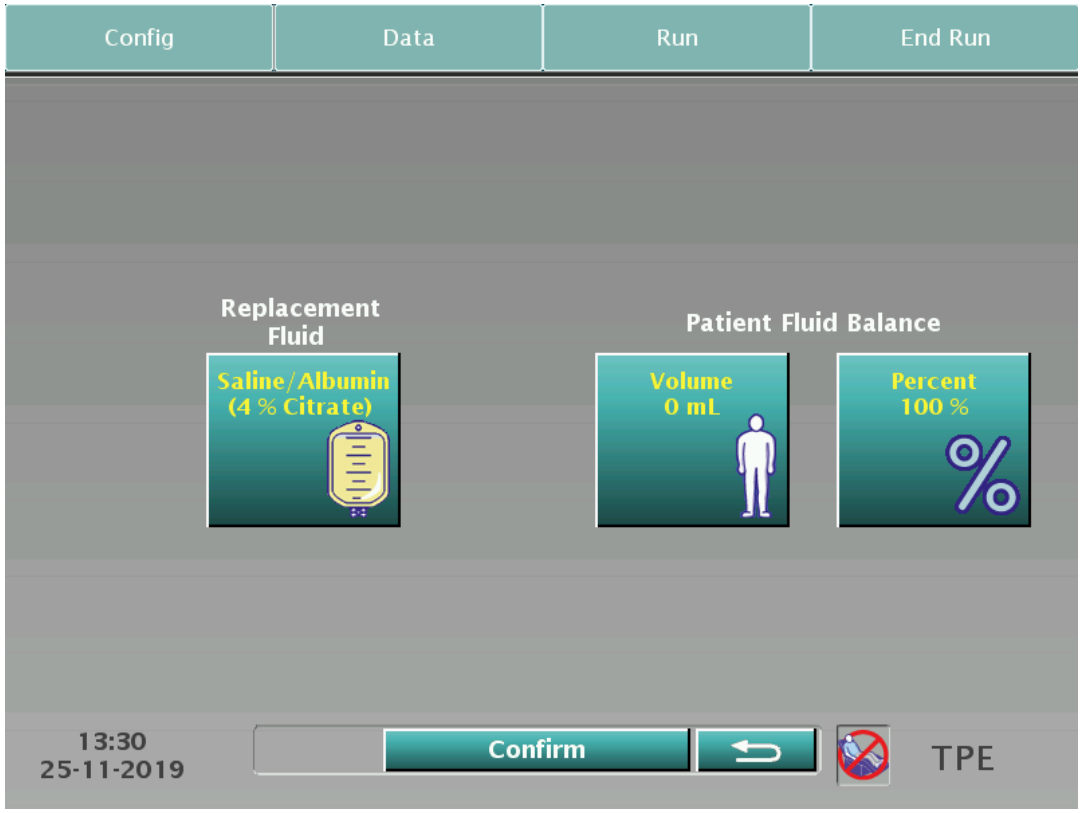
AC Pump Flow Rate – Therapeutic Plasma Exchange

For TPE procedures:

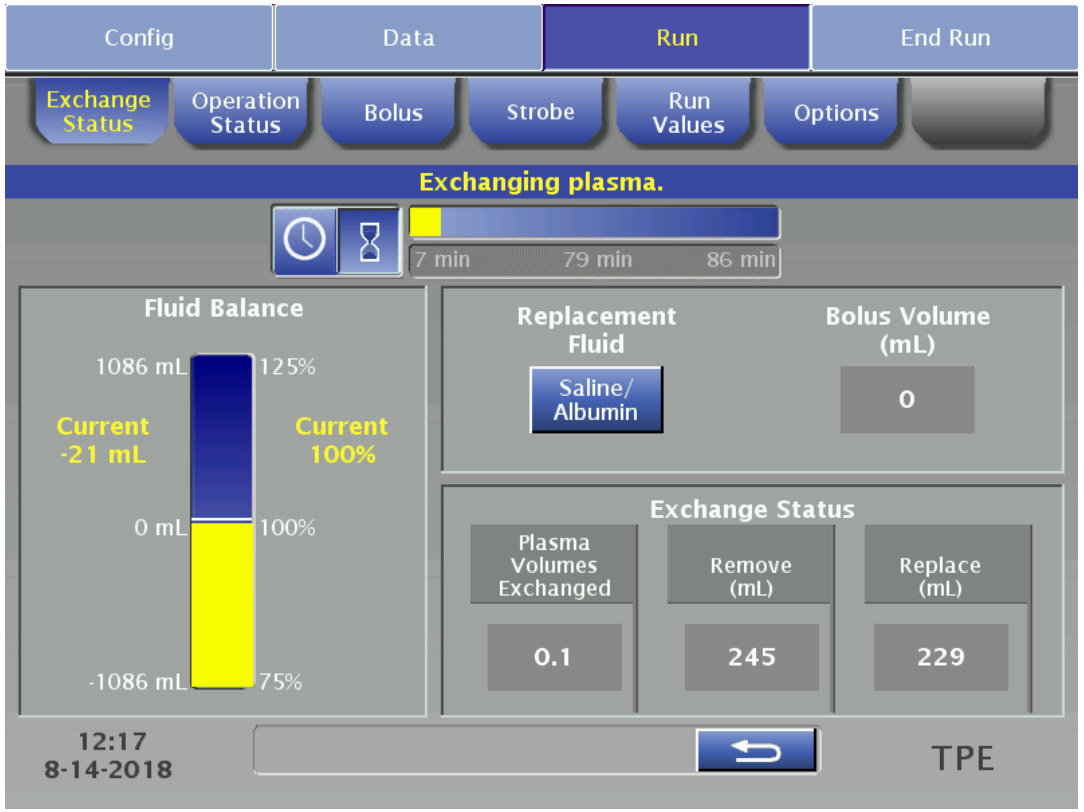
1. Volume of AC added to the extracorporeal circuit from:
    - ACD-A bag
    - Replacement fluid
2. Minus the volume of AC removed to:
    - Remove bag
3. Equals the volume of AC delivered to:
    - Patient

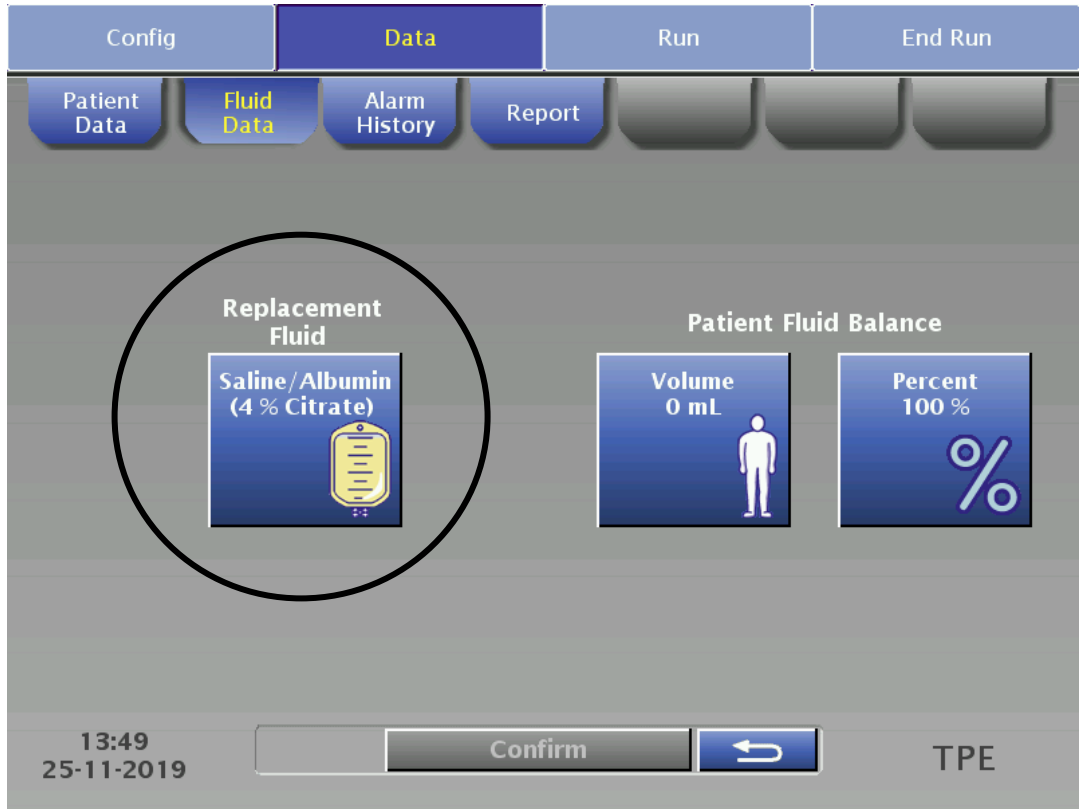


Fluid Data Screen



Fluid Data Screen

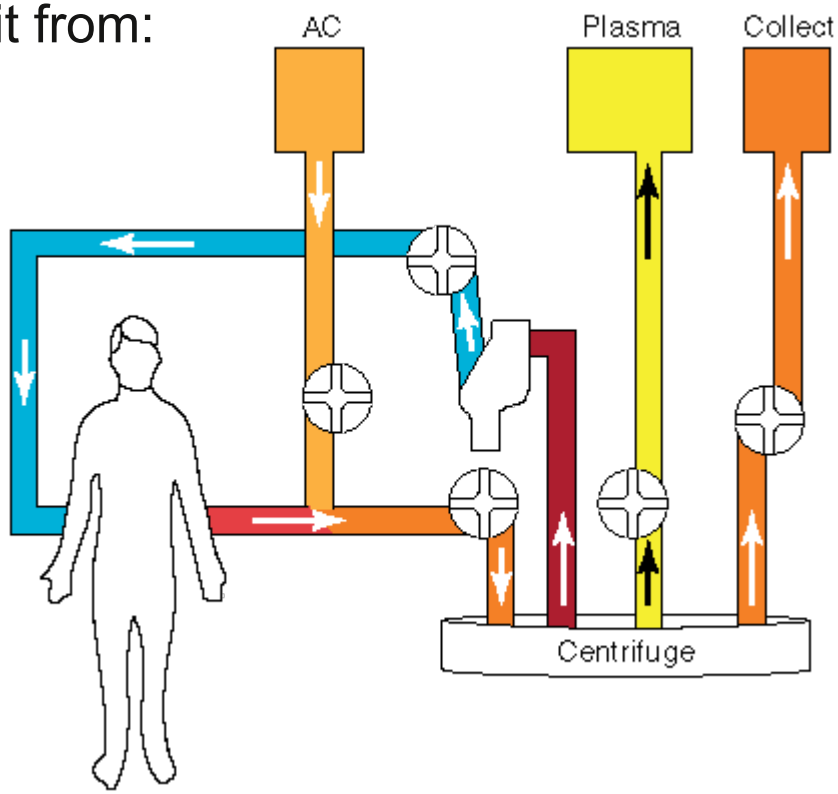




AC Pump Flow Rate – Collection Procedures

For MNC procedures with concurrent plasma collection:

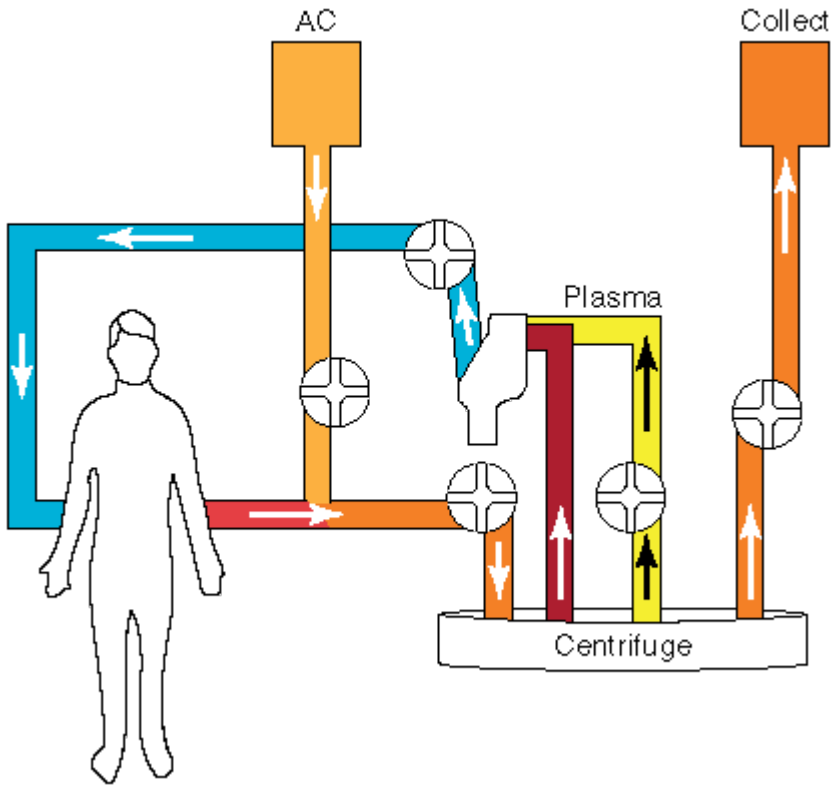
1. Volume of AC added to the extracorporeal circuit from:
   - ACD-A bag
2. Minus the volume of AC removed to:
   - Collect and/or plasma bags
3. Equals the volume of AC delivered to:
   - Patient



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

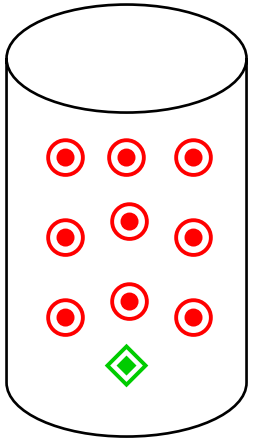


Inlet:AC Ratio

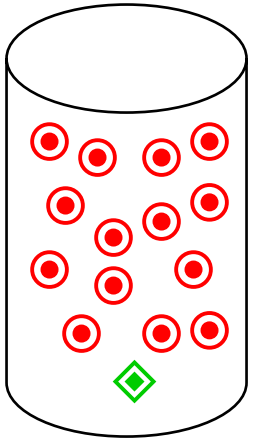
- The proportion of whole blood to AC in the extracorporeal circuit determines the concentration of AC in the extracorporeal circuit and the degree to which blood in the system is anticoagulated

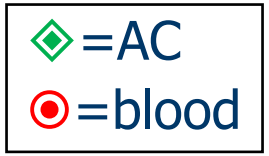
Inlet:AC Ratio

Ratio=10



Ratio=15

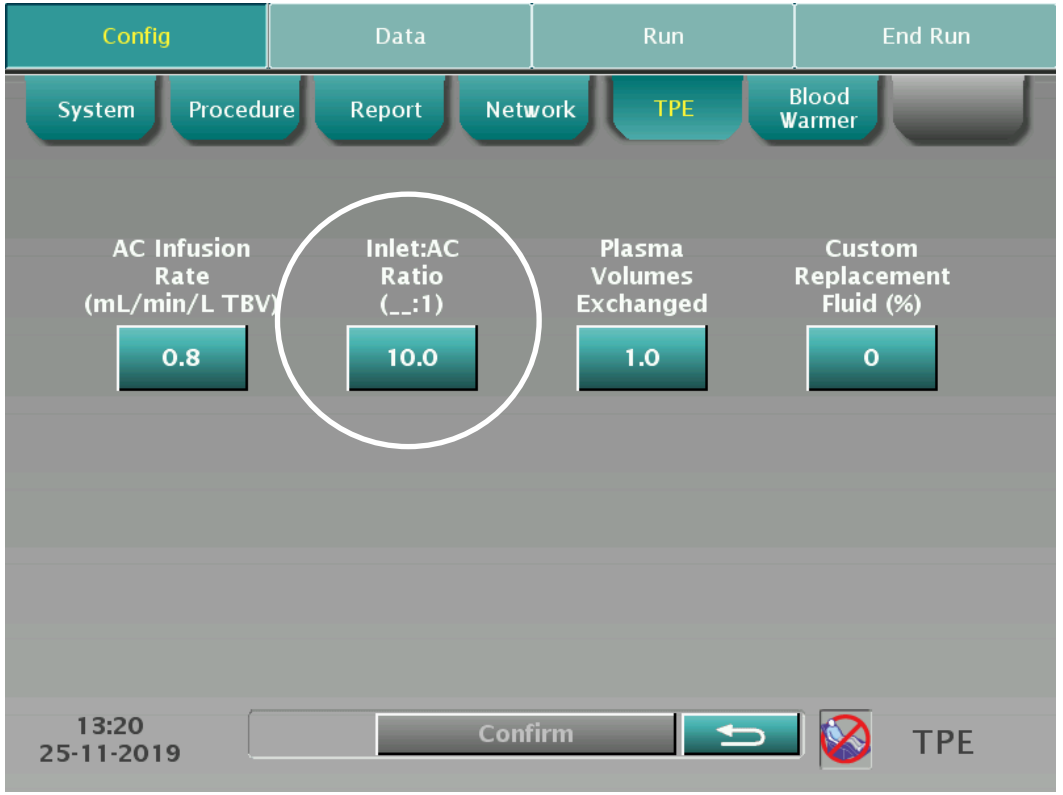




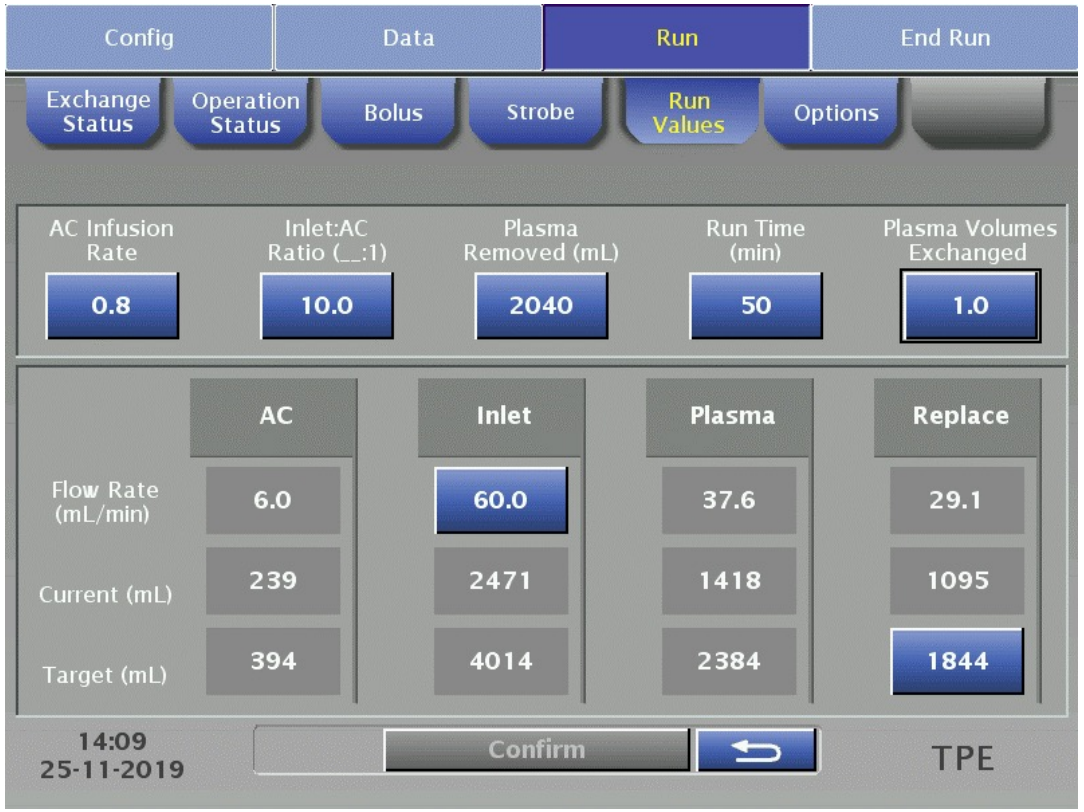
ⓘ If you ↑ the Inlet:AC ratio, more whole blood is added to the same amount of citrate. There is a ↓ in the concentration of AC in the circuit, which ↓ the anticoagulation effect.

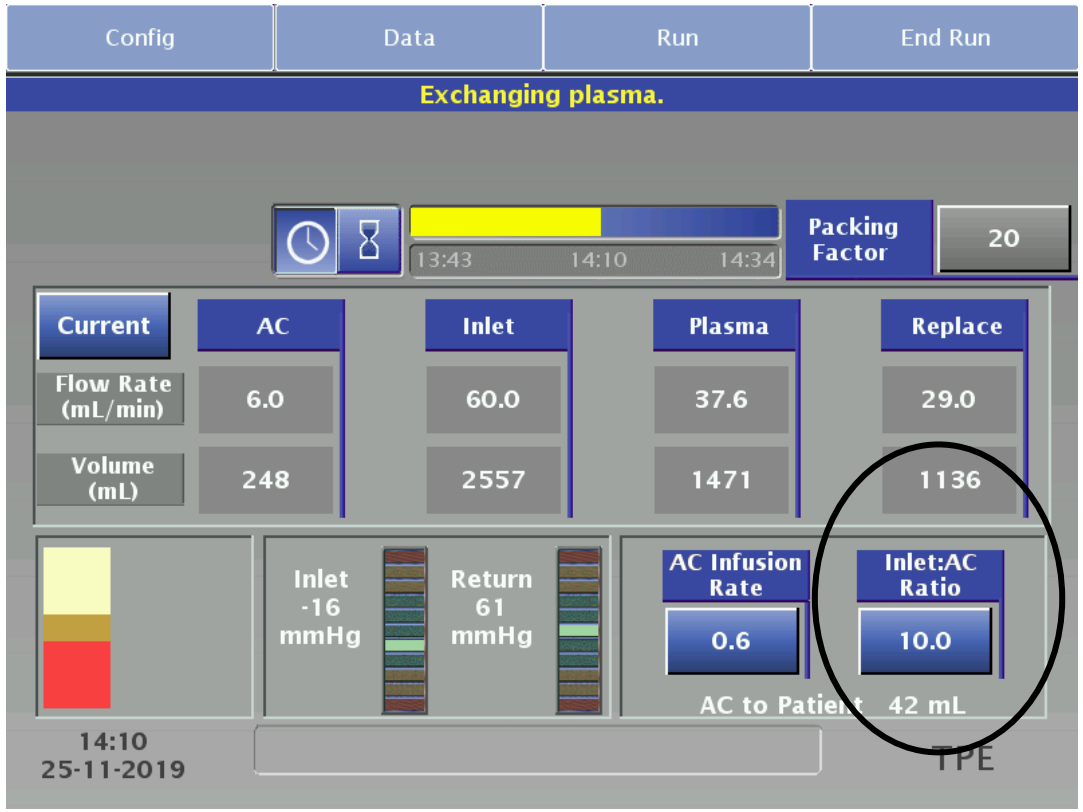
Inlet:AC Ratio Configuration

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



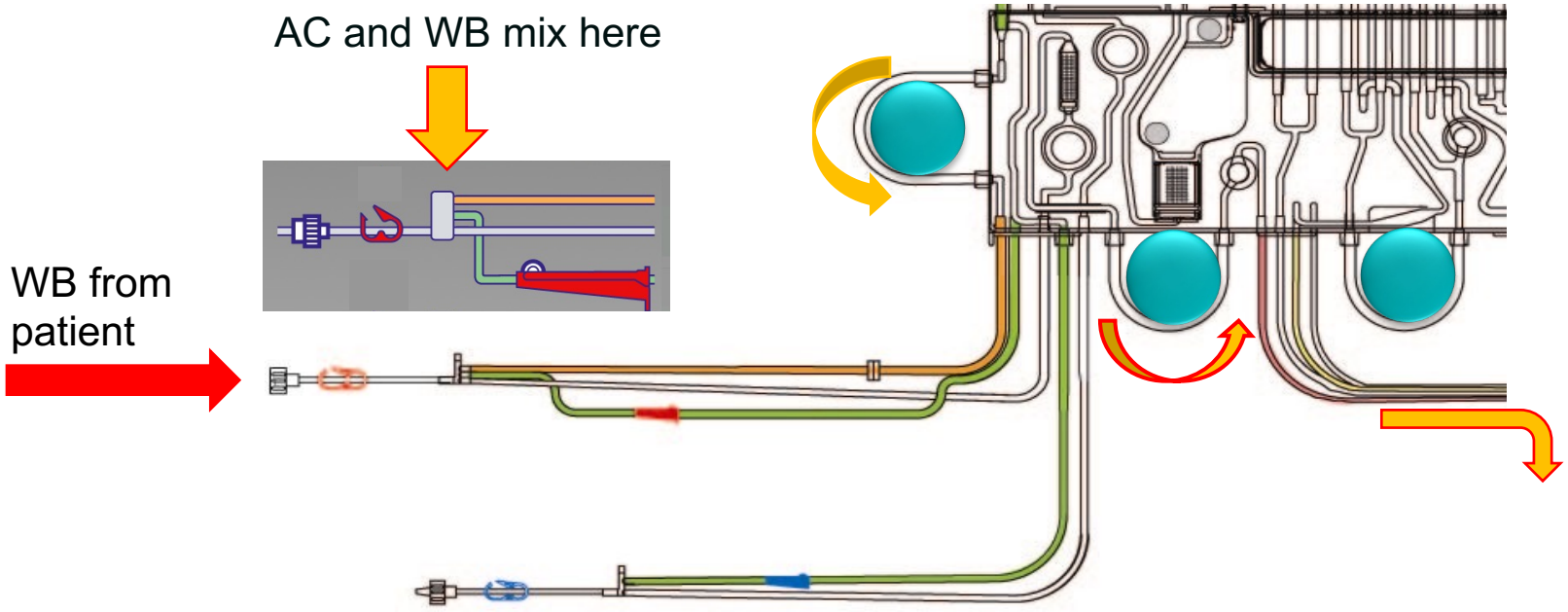
Inlet:AC Ratio



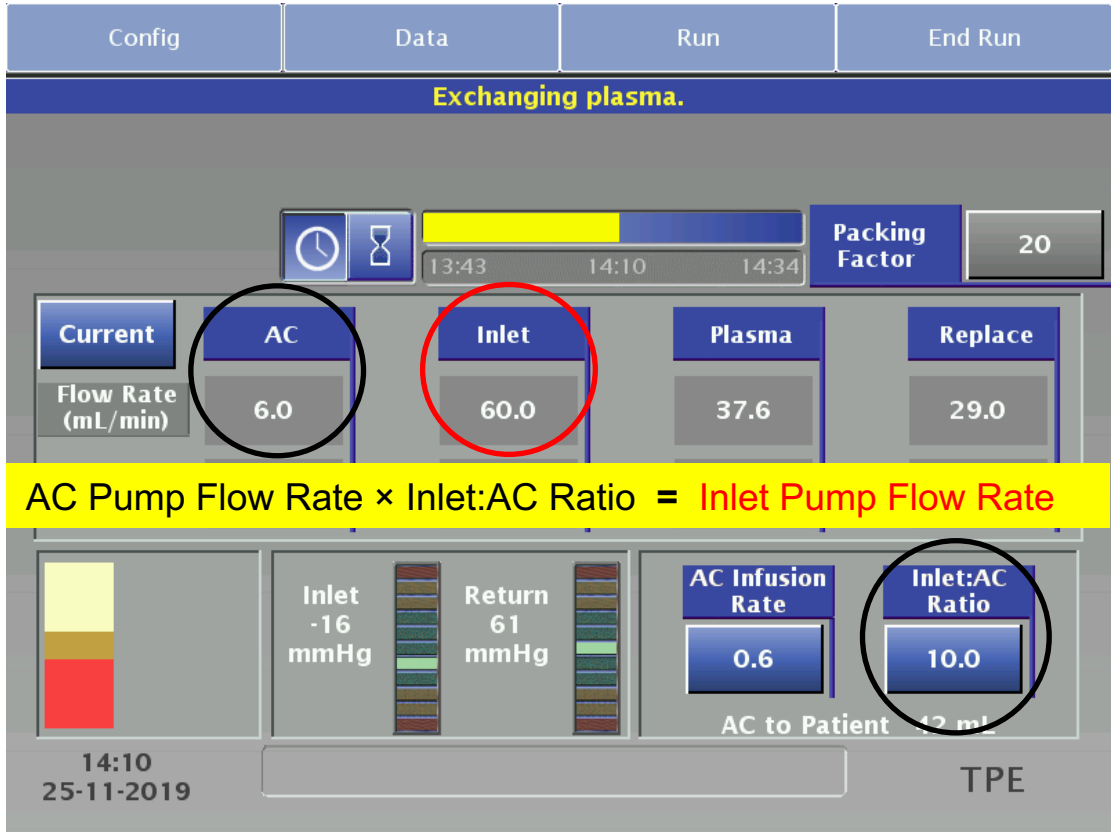


Inlet Pump Flow Rate

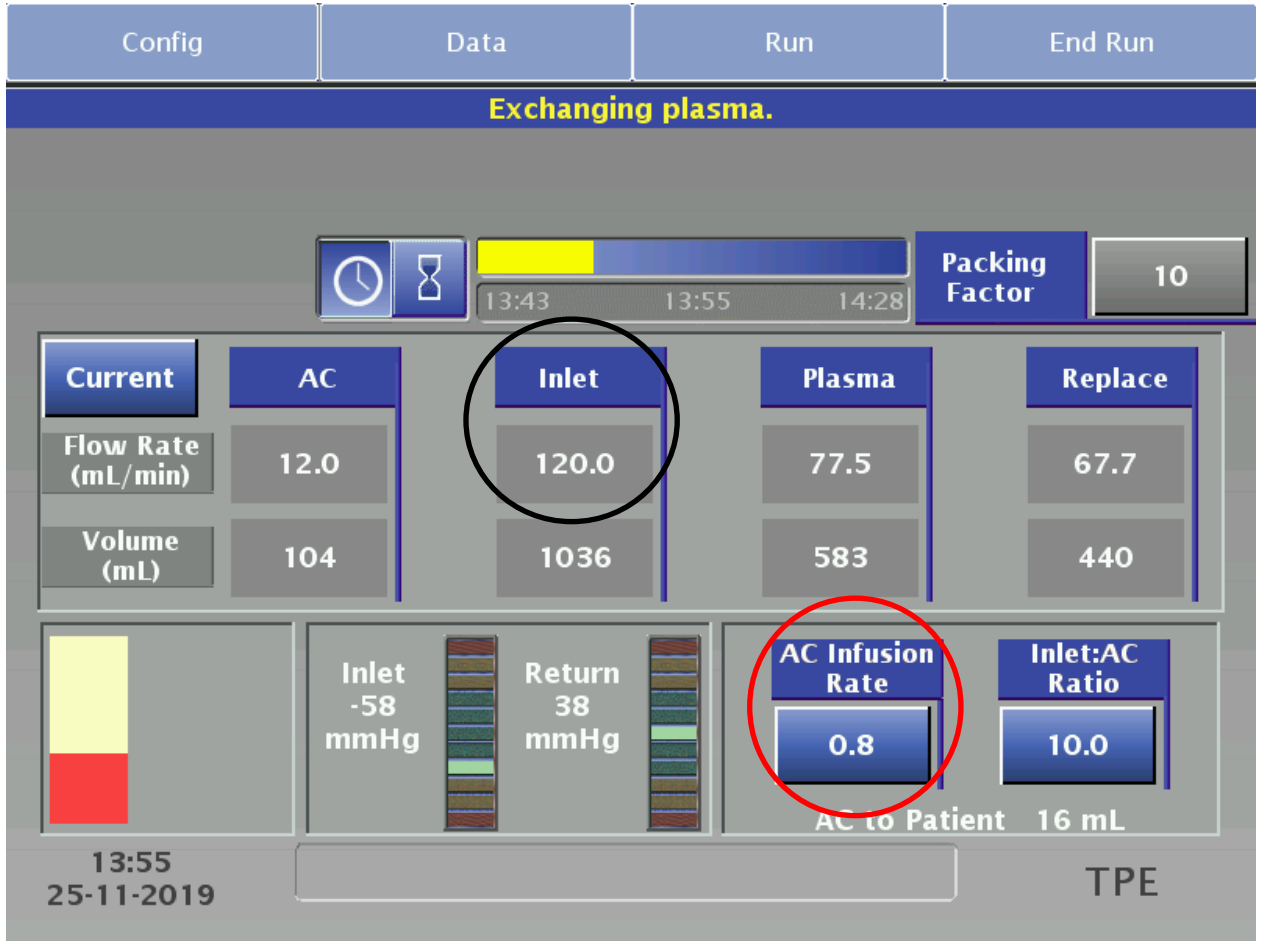
The rate at which anticoagulated whole blood (WB) is drawn into the system by the inlet pump



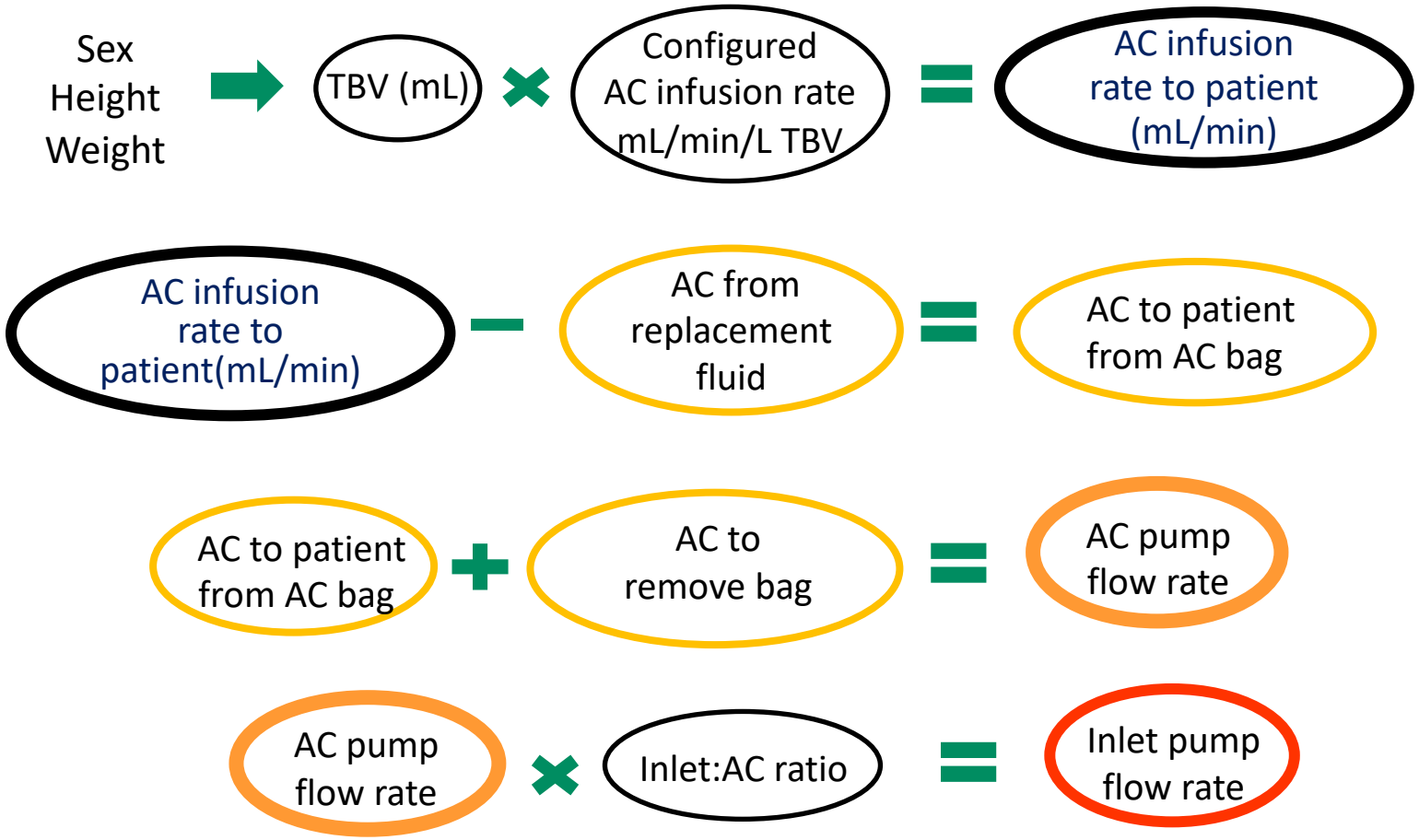
Inlet Pump Flow Rate



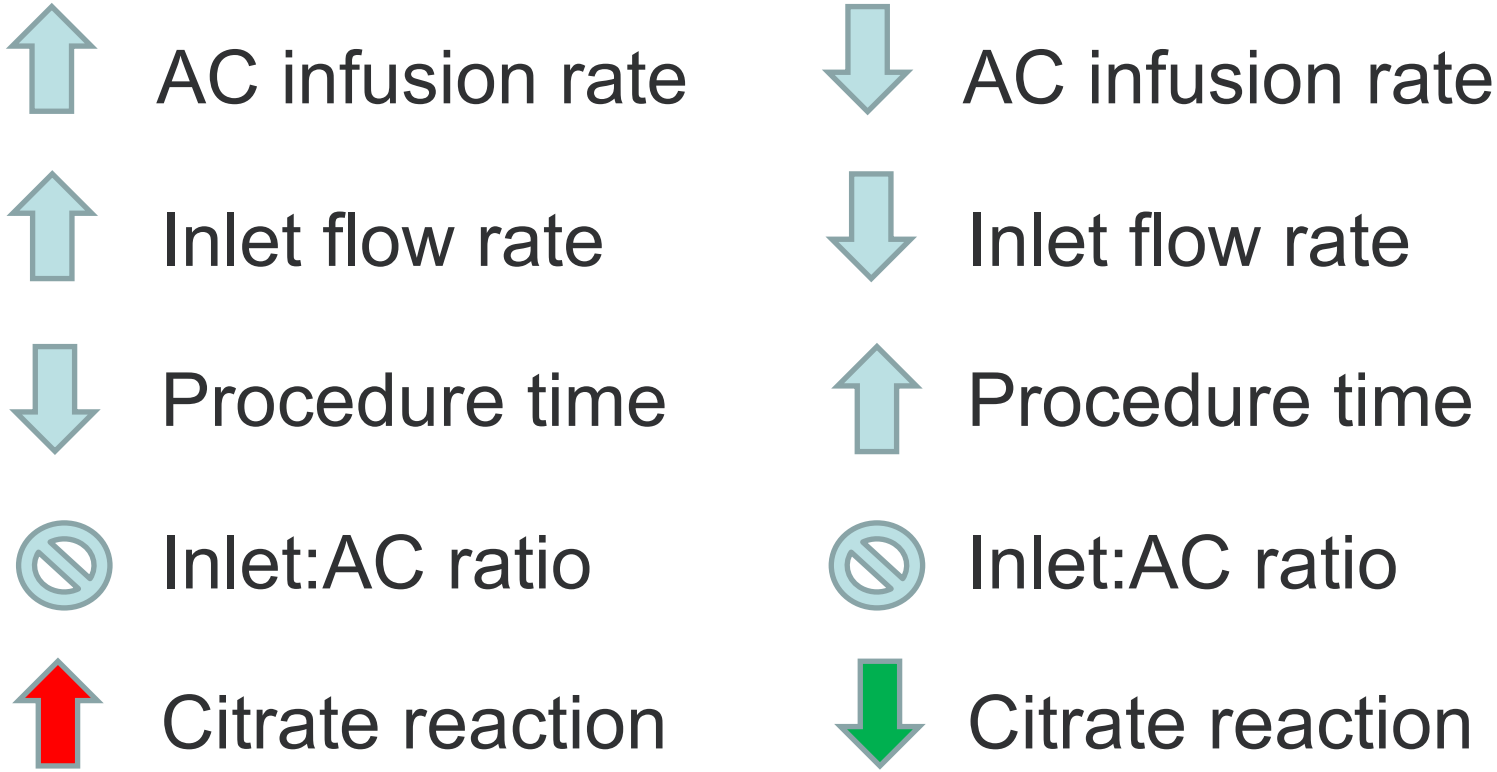
Inlet Pump Flow Rate



Summary: AC Management Concepts

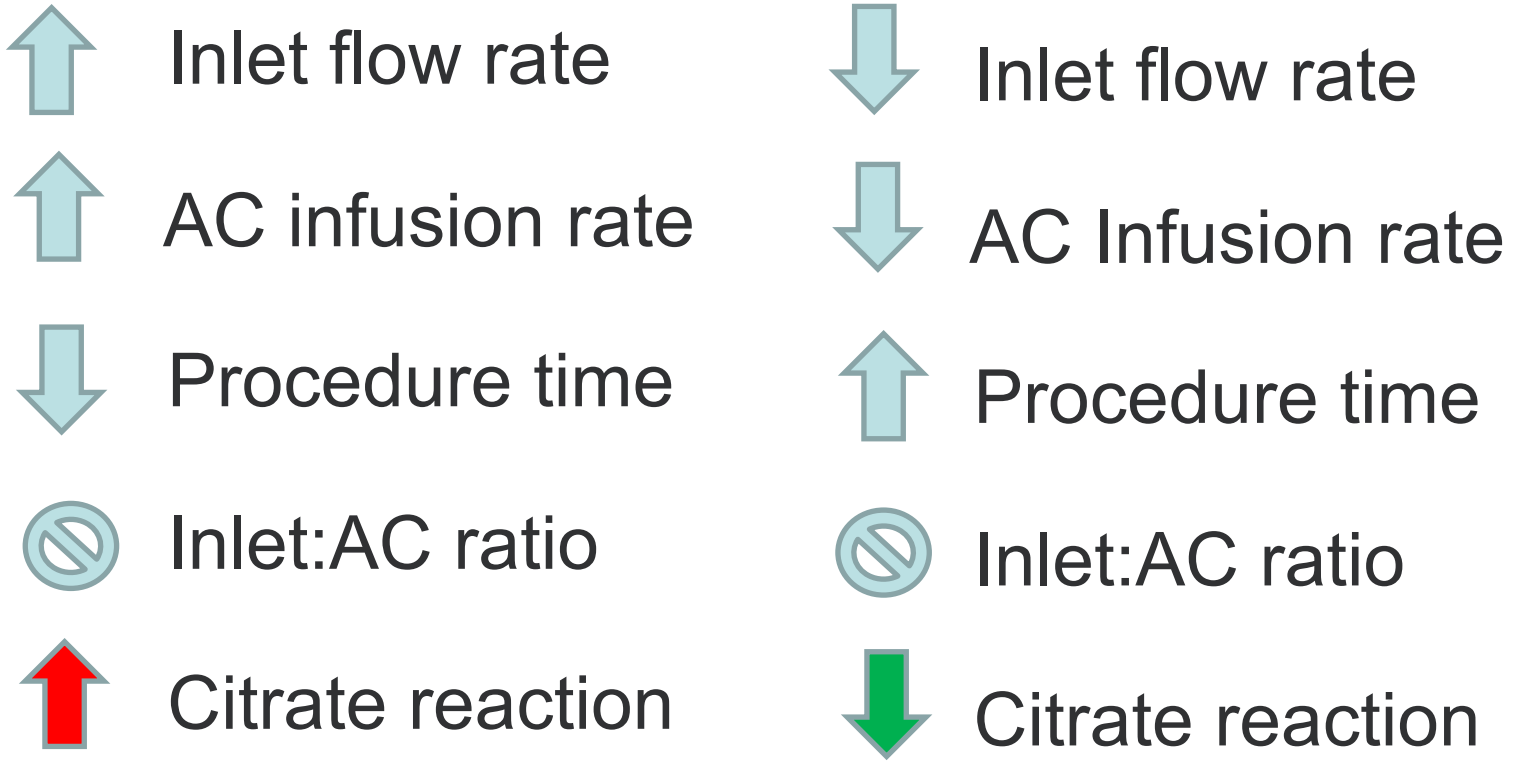


Consequences of Changing the AC Infusion Rate



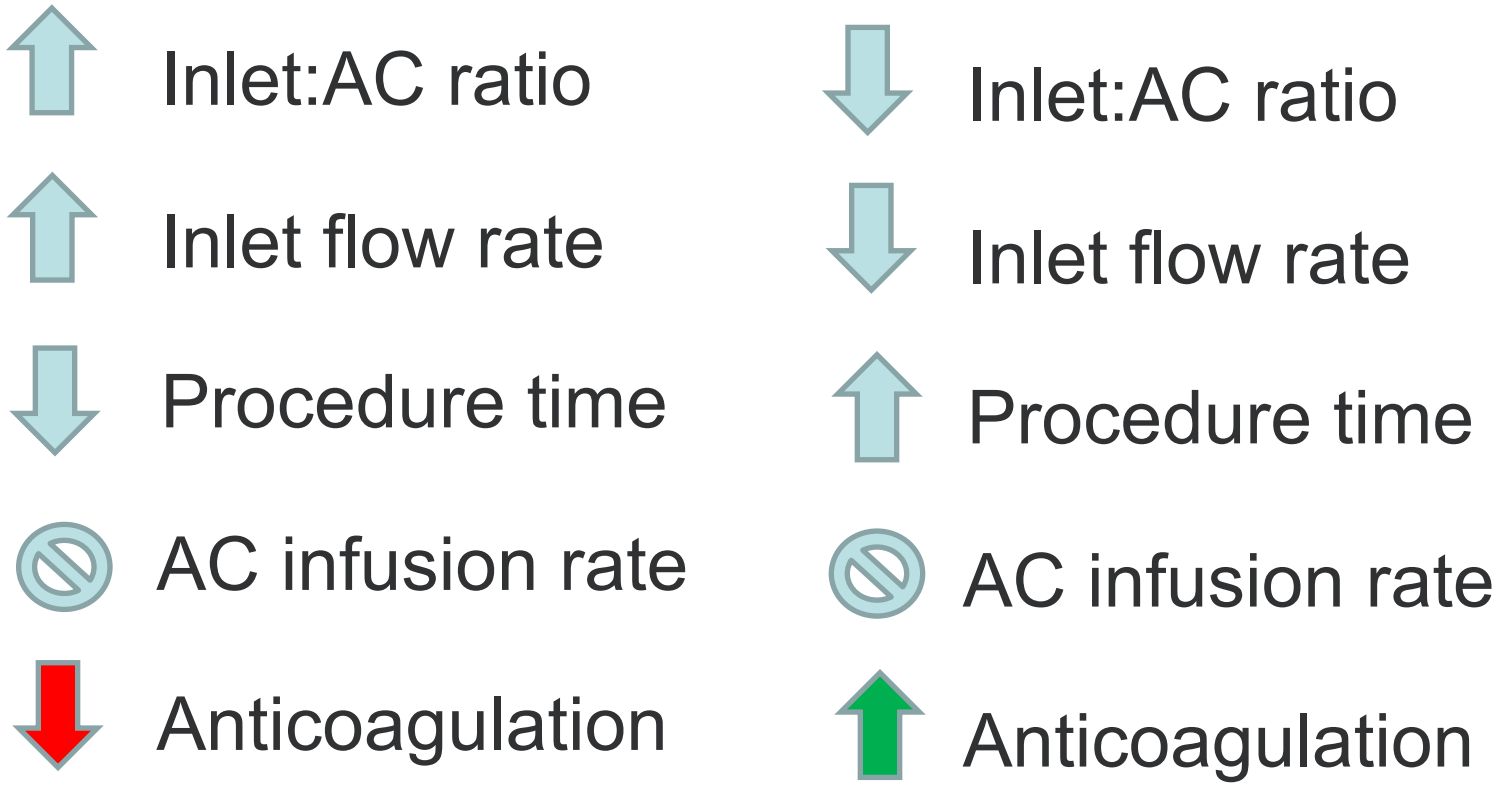
Note: If the recommended maximum AC infusion rate limit of 1.2 mL/min/L TBV is exceeded, the system operates in caution status.

Consequences of Changing the Inlet Flow Rate



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



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

Questions?

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