TERUMO BLOOD AND CELL TECHNOLOGIES

Bone Marrow Processing (BMP) Procedure Training Version 12

Spectra Optia® Apheresis System

TS-OPTI-01023

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
  - Red blood cell exchange, depletion and depletion/exchange for the transfusion management of sickle cell disease in adults and children (USA)
- 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
  - Processing of harvest bone marrow for the purpose of facilitating hematopoietic reconstitution (USA)

*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. *Br J Haematol*. 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 BMP procedure using the Spectra Optia system:

- Discuss the principles of the procedure.
- State preparation requirements for the bone marrow.
- Describe and be able to enter the data needed to perform the procedure.
- Discuss how the data you entered affects the procedure and the run targets.
- View and change the data on the run values screen.
- Make changes to data on the data, run, and end run menu screens.
- Troubleshoot issues that may arise.

Note: Not all protocols are commercially available in all world areas. Contact your local Terumo Blood and Cell Technologies representative for additional information regarding regulatory status and local availability.

Presentation Overview

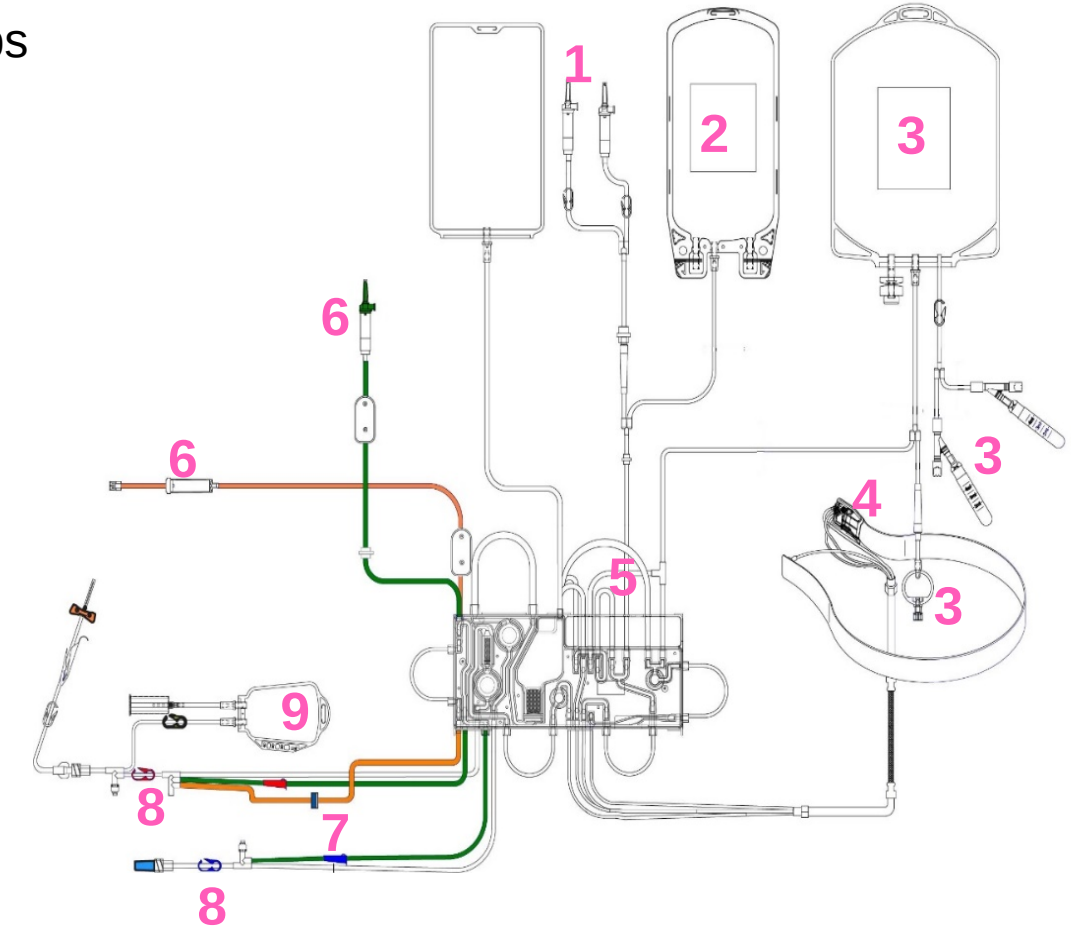
- Introduction
- Preparing to Perform the Procedure
- Monitoring the Run
- Completing the Run
- Making Changes
- Troubleshooting

Introduction

- IDL Set
- Basic Principles of the Procedure
- AIM System Control of Collection
- Collection Preference
- BMP Accessory Set

IDL Set

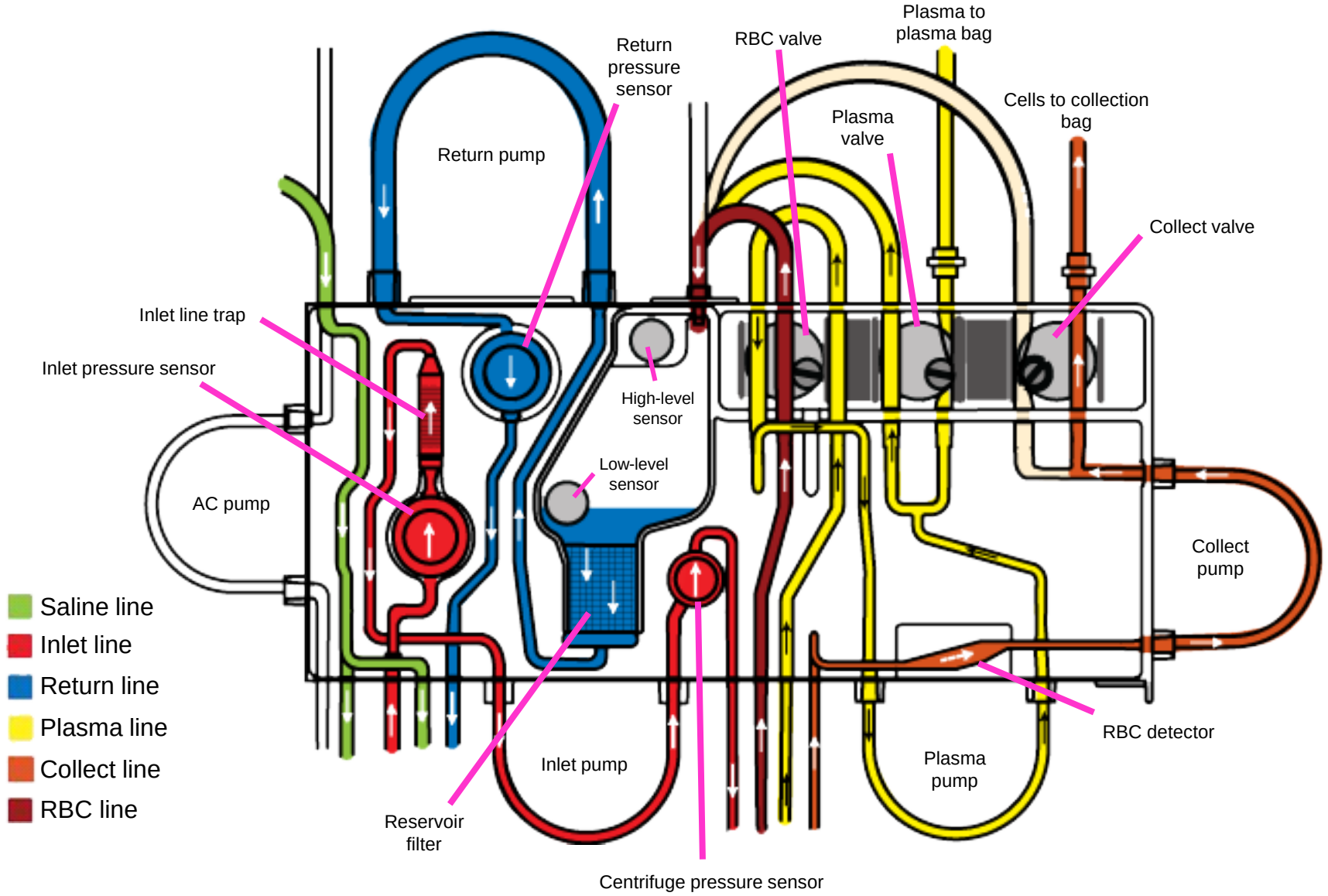
- Replace line
  - Frangible connector
- Plasma bag
- Collection bag
  - Spike port
  - Sample bulbs
  - Sterile barrier filter
- Connector
- Cassette
- AC and saline tubing
  - AC Correct Connect luer*
  - Saline spike
  - Sterile barrier filters
- AC check valve
- Colored clamps
- Diversion bag



*Correct Connect availability is dependent upon regulatory approval.

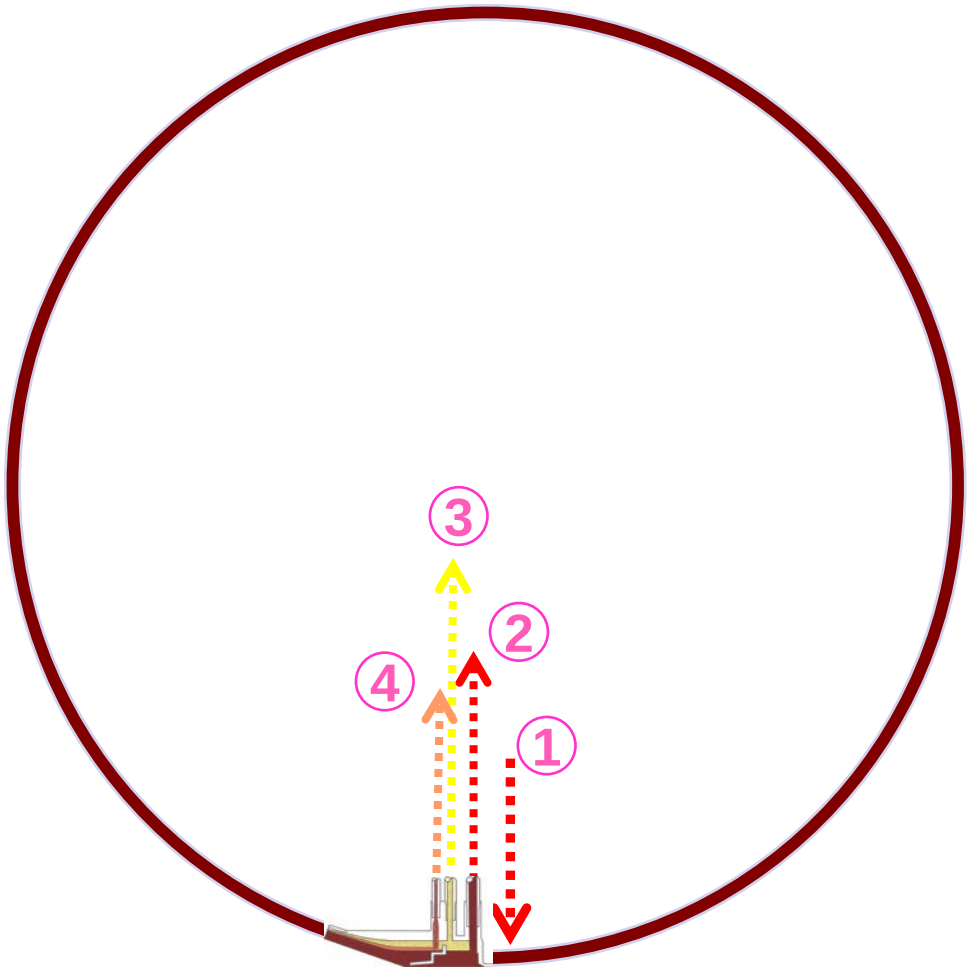
Basic Principles of the Procedure

Introduction



Basic Principles of the Procedure (continued)

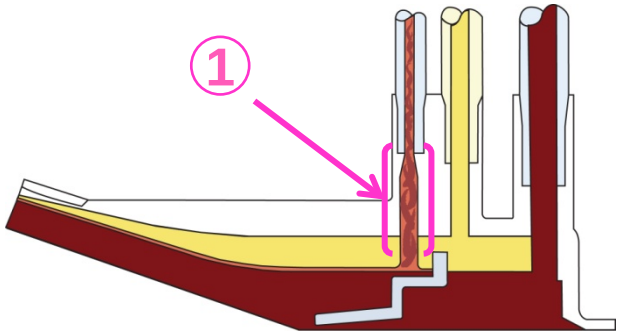
Introduction

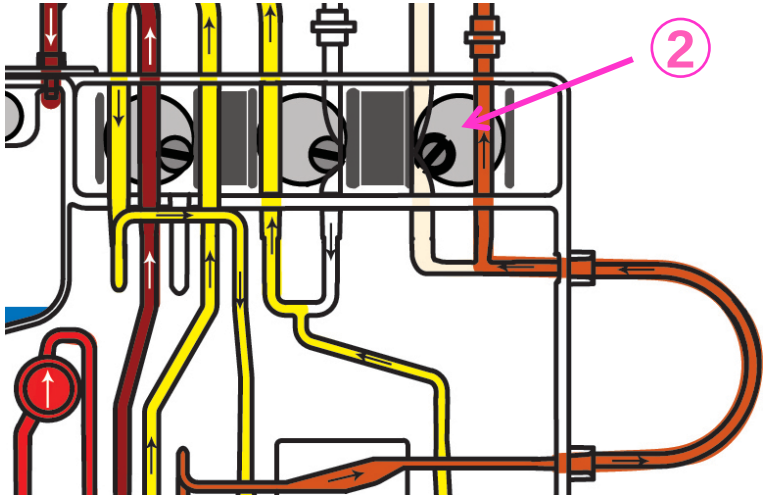


- Bone marrow enters the channel.
- Red blood cells (RBC) flow to the reservoir.
- Plasma is pumped to the reservoir.
- Cells are continuously pumped into the collection bag.

AIM System Control of Collection

Introduction



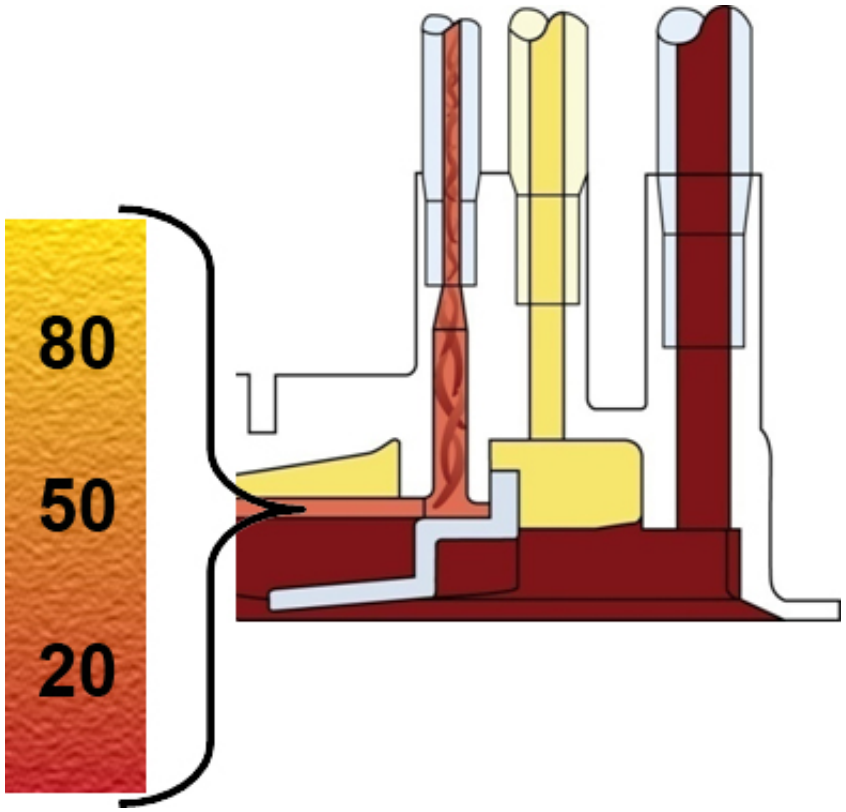


- The AIM system controls the concentration of cells in the collect port.
- When cells are detected in the collect port, the collect valve moves to the collect position.
  - The cells are continuously collected into the collection bag.

Collection Preference

Introduction

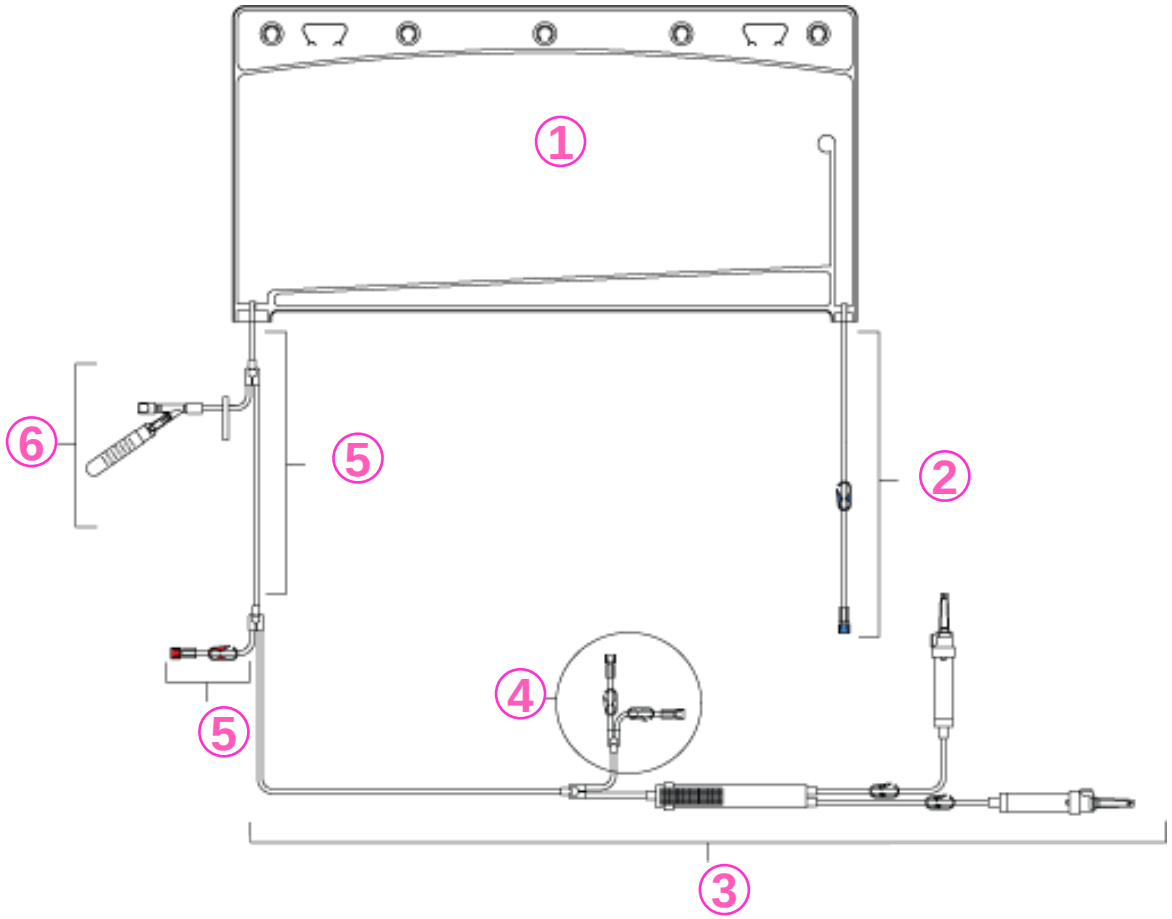
- A fine control of the depth at which cells are collected from within the buffy coat layer.
- Affects the concentration of cells that flow into the collection bag.



BMP Accessory Set

Introduction

- BMP bag
- Return line
- Administration line
- Luer connector assembly
- Inlet line
- Sample bulb assembly



Questions?

Preparing to Perform the Procedure

- Preparing the Bone Marrow for Processing
- Transferring Bone Marrow to the BMP Bag
- Configuration – BMP Procedure
- Preparing the Tubing Set
- Loading the Channel (Very Important)
- Sealing the AC Line
- Entering Bone Marrow Data
- Run Values
- Connecting the BMP Bag and Priming the Line
- Hanging the BMP Bag

Preparing the Bone Marrow for Processing

Preparing the Procedure

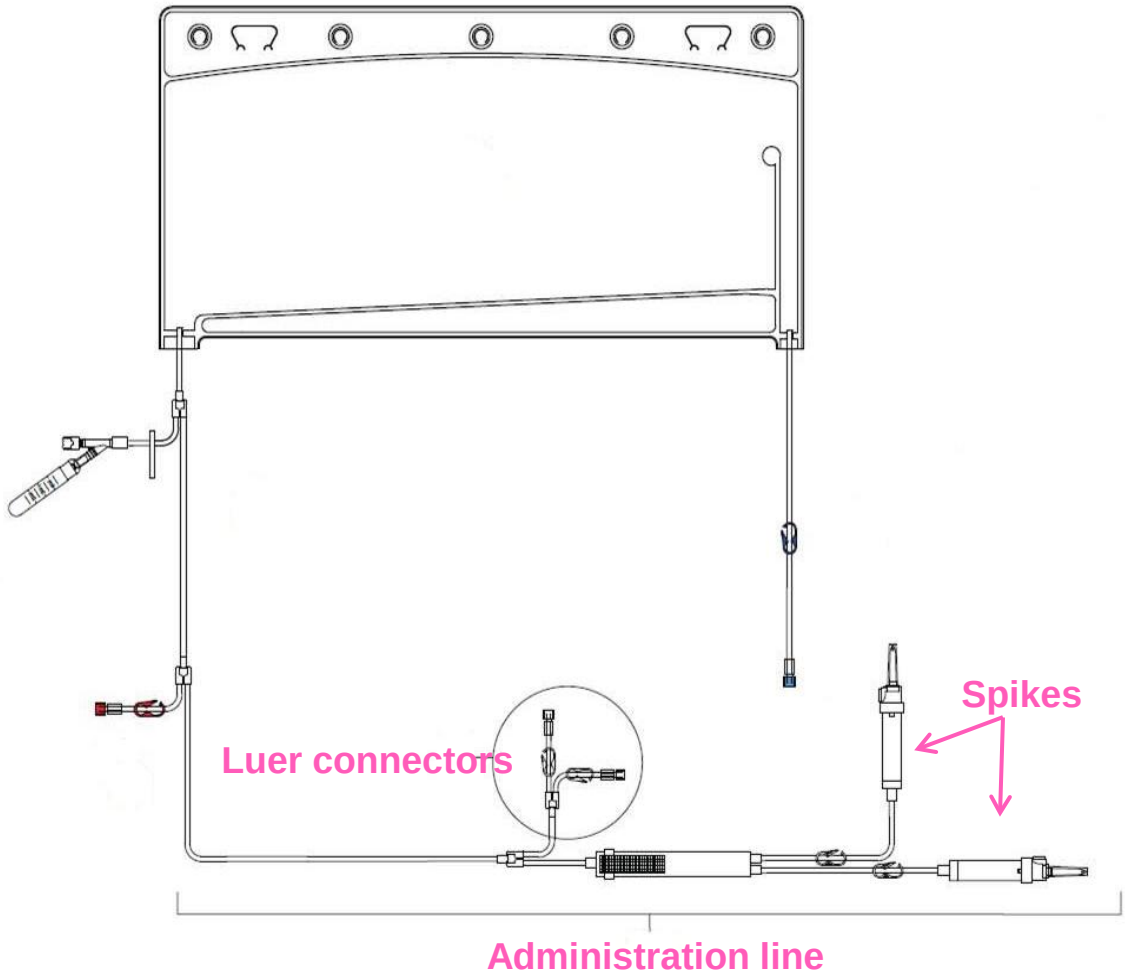
- Filtering the bone marrow
- Adding anticoagulant (ACD-A)
  - Anticoagulant (ACD-A) must be added to the bone marrow prior to processing
  - AC is not connected to the Spectra Optia system during a BMP procedure
- Transferring bone marrow to the BMP Accessory Set:
  - Spikes
  - Luer connectors

Transferring Bone Marrow to the BMP Bag

Preparing the Procedure

Steps:

1. Lay the BMP bag flat.
2. Close **all** clamps.
3. Connect bone marrow using spikes or luers.
4. Open the clamp on the appropriate administration line.
5. Hang the bone marrow bag(s), then transfer bone marrow to the BMP bag.
6. Seal and remove the administration line.



Note: Determine the volume and hematocrit of the bone marrow.

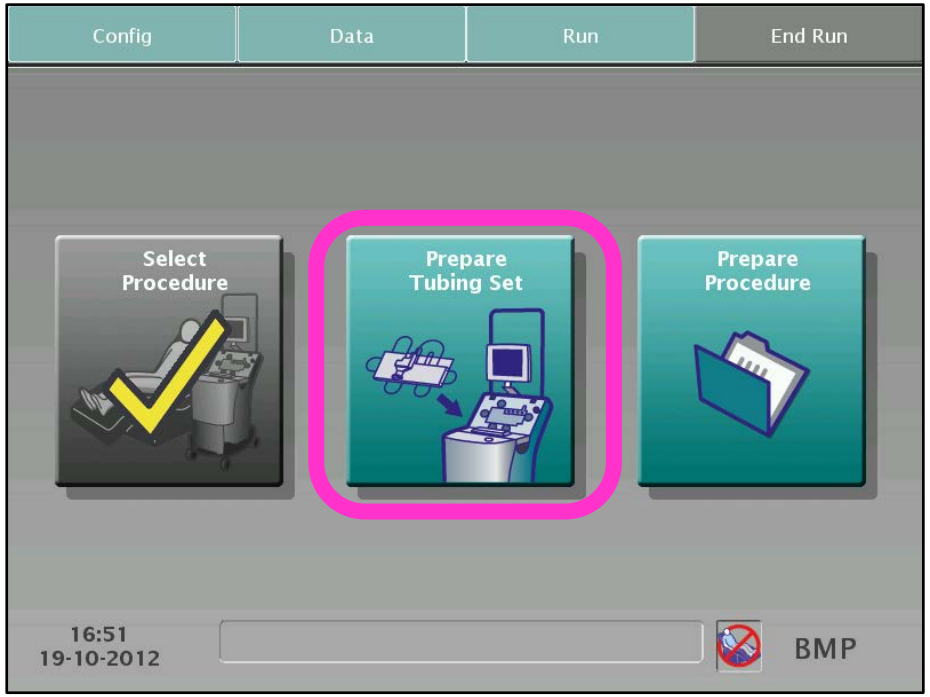
Configuration – BMP Procedure

Preparing the Procedure

Preparing the Tubing Set

Preparing the Procedure

1



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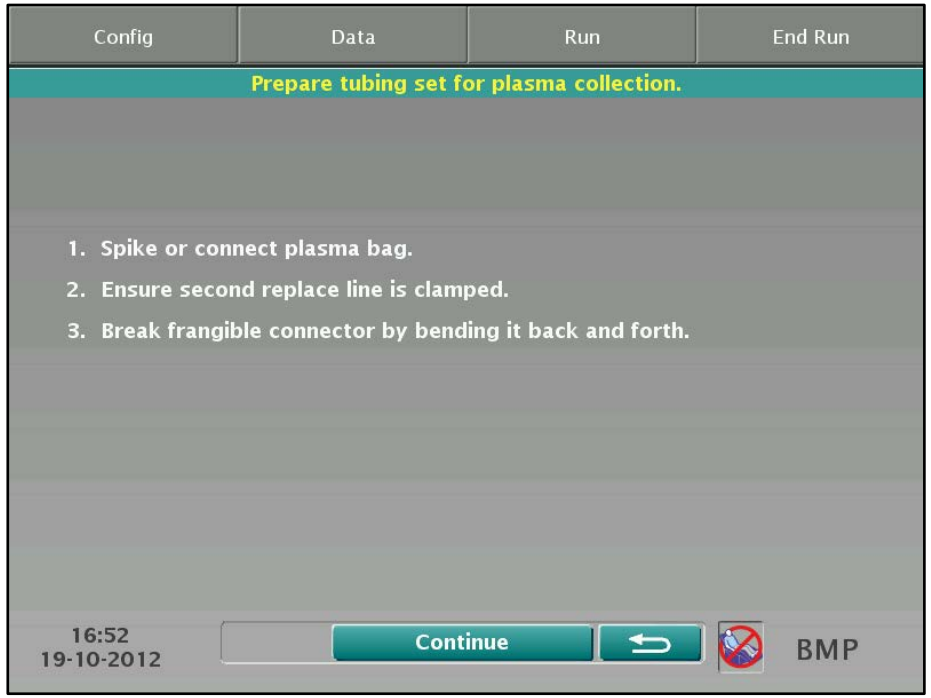
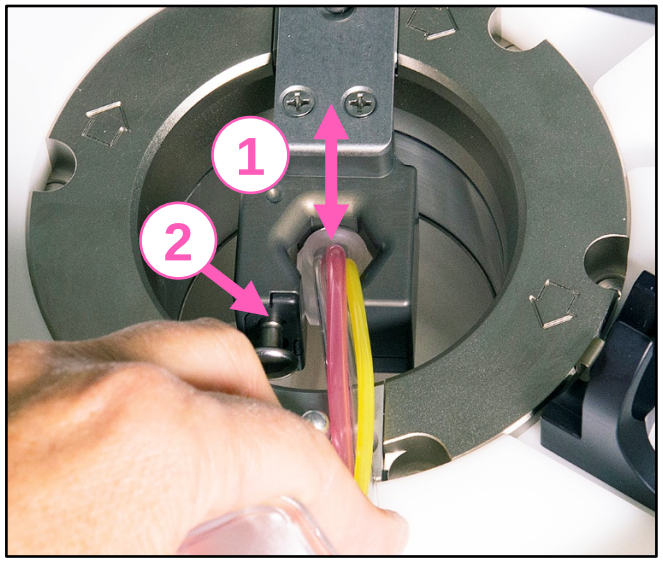


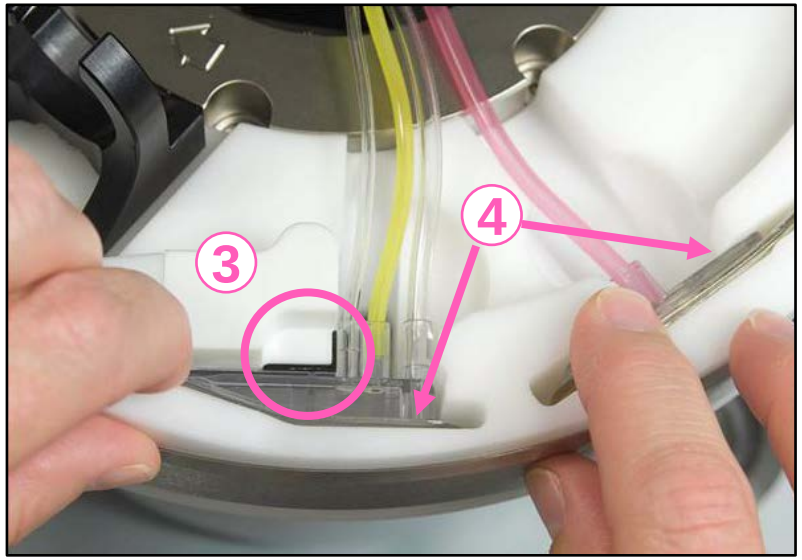
Loading the Channel (Very Important)

Preparing the Procedure

Use the standard filler

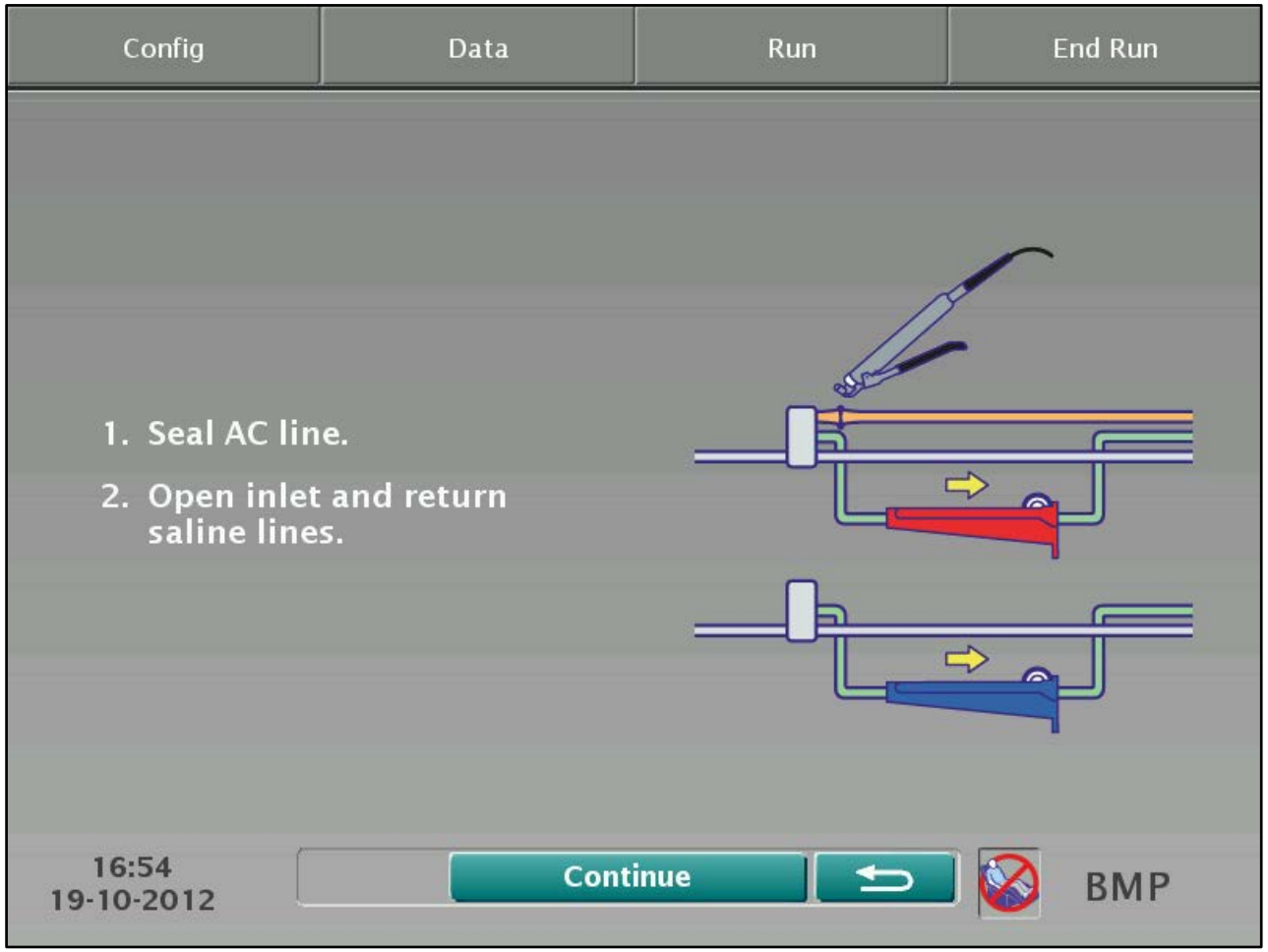
1. Centrifuge collar is in the correct position.
2. Notch on the locking pin is visible.
3. Optical reference is visible.
4. Channel sits flush with the groove.





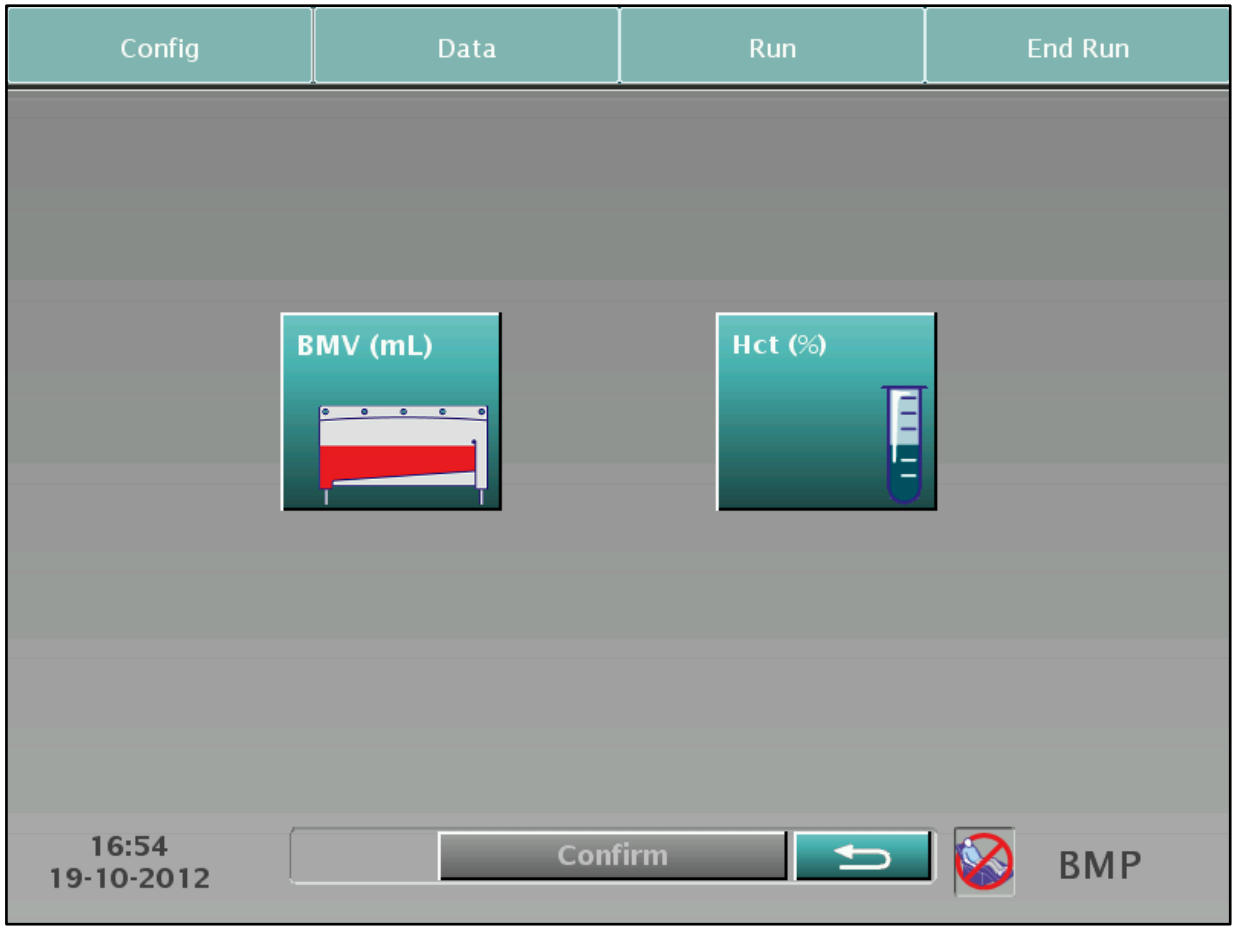
Sealing the AC Line

Preparing the Procedure



Entering the Bone Marrow Data

Preparing the Procedure



Run Values

Preparing the Procedure

Connecting the BMP Bag and Priming the Line

Preparing the Procedure

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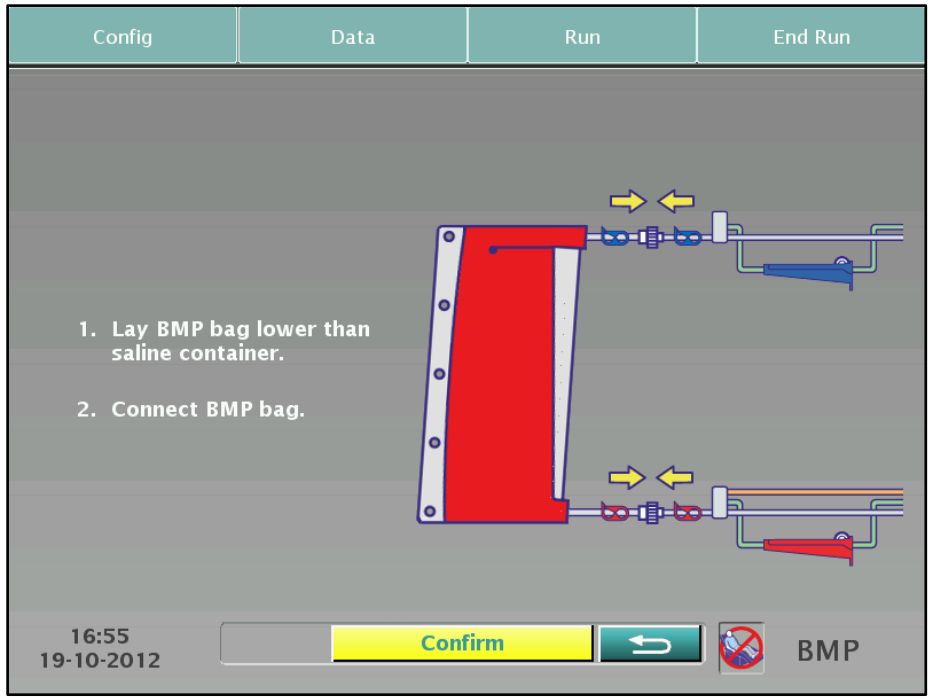

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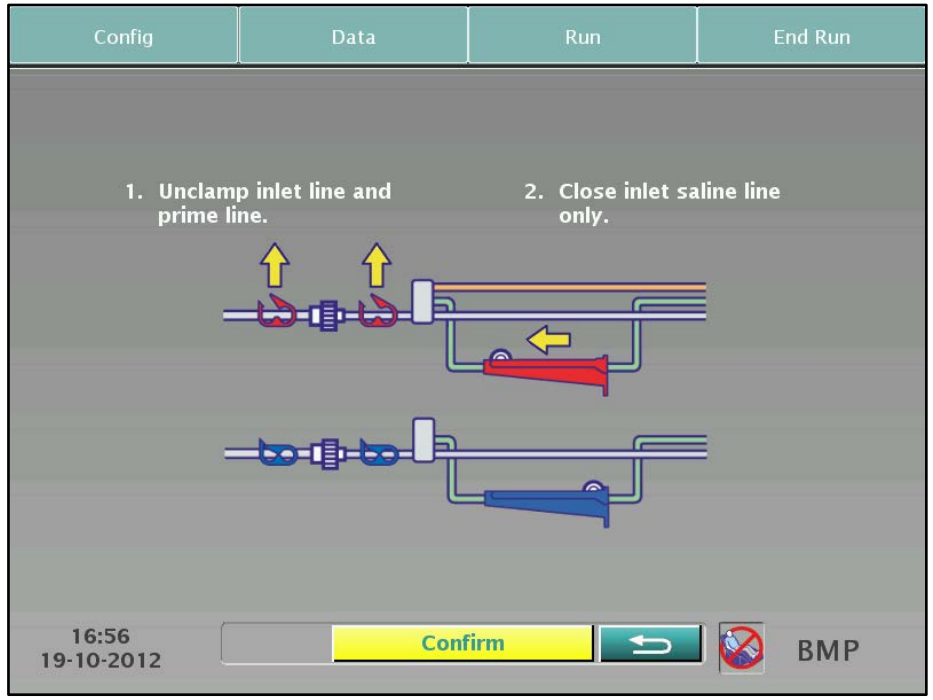
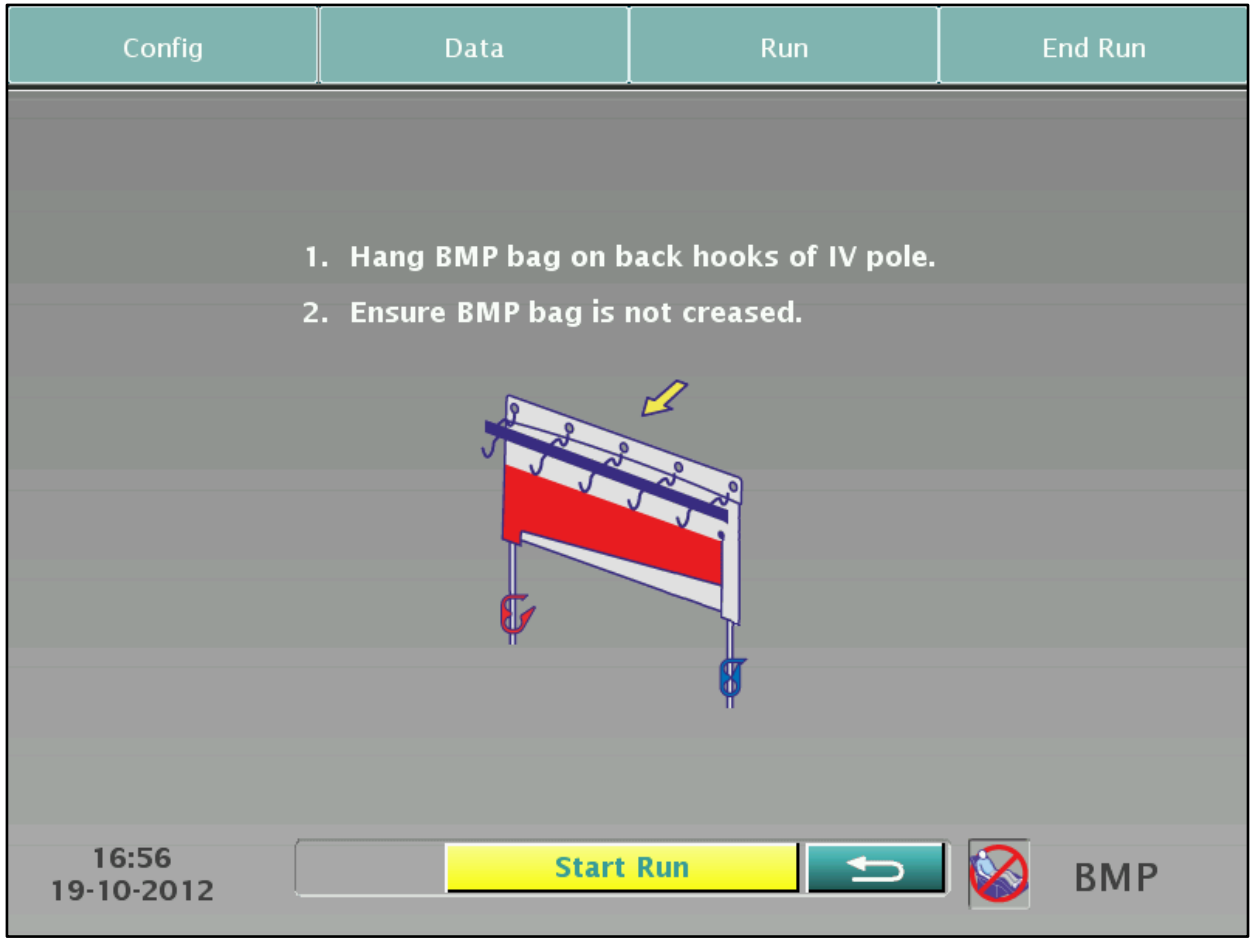


Hanging the BMP Bag

Preparing the Procedure



Use all five hooks on the IV pole to hang the BMP bag.

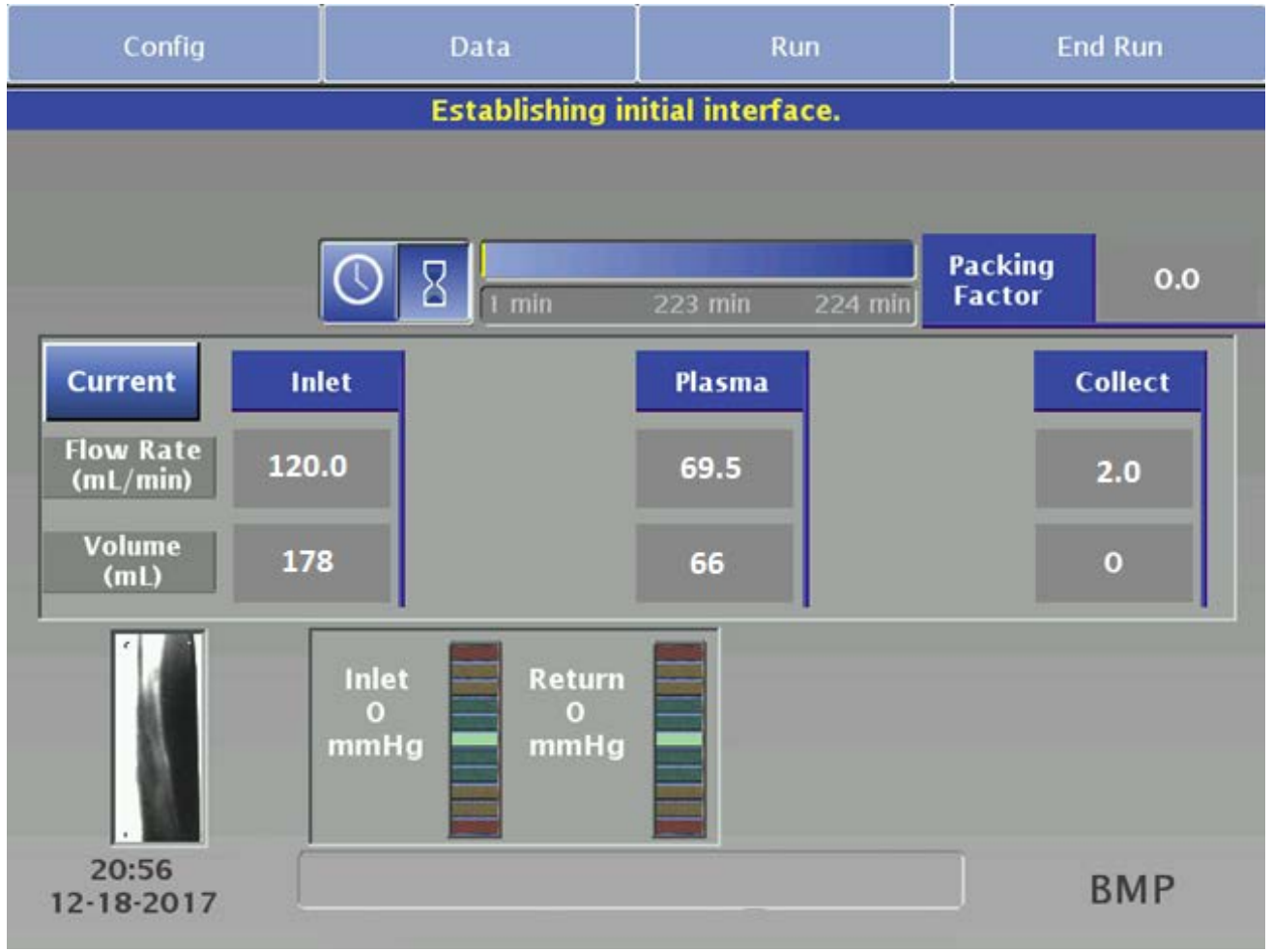
Questions?

Monitoring the Run

- Main Run Screen
- Mixing the Contents of the BMP Bag During the Run
- Collection Status
- Monitoring the Collect Line From the Centrifuge

Main Run Screen

Establishing the Interface



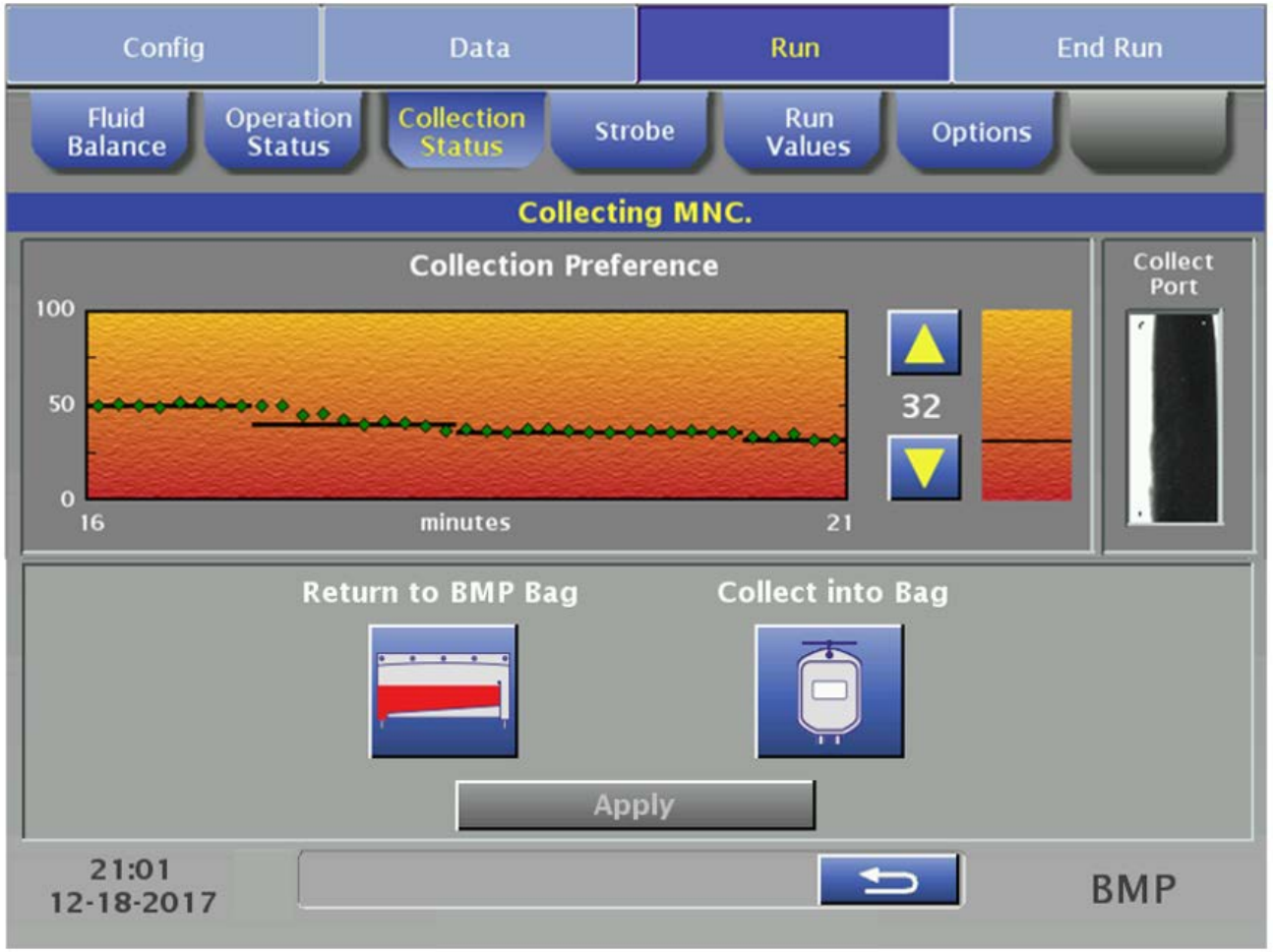
Mix the Contents of the BMP Bag During the Run

Monitoring the Run

- Mix the contents of the BMP bag several times during each BM cycle.
- Mixing the bone marrow:
  - Incorporates the initial saline from the return line into the bone marrow.
  - Prevents cellular components from settling.

Collection Status

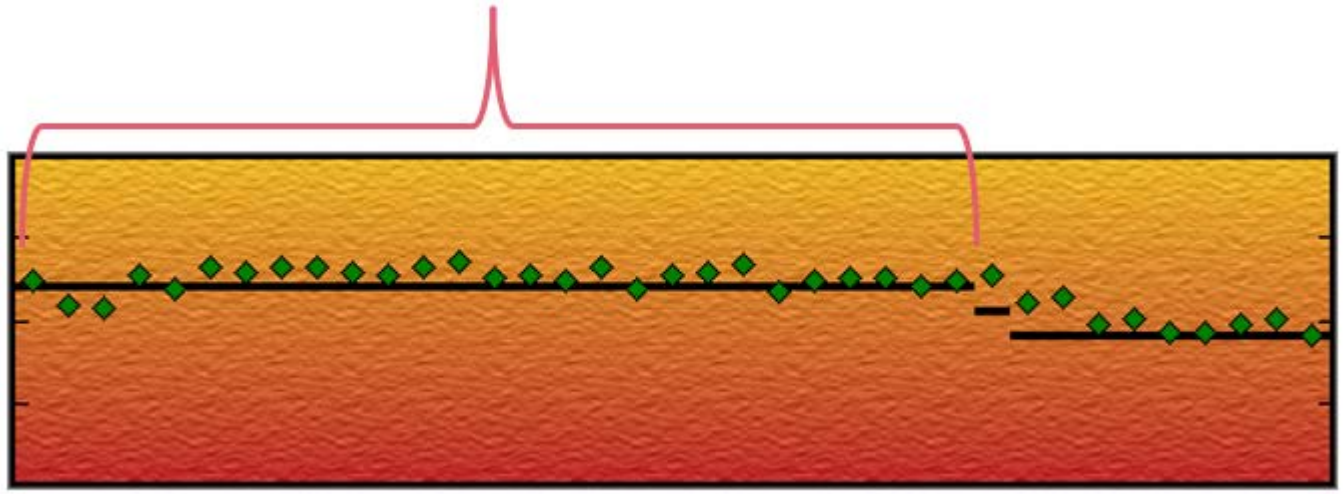
Monitoring the Run



Collection Status (continued)

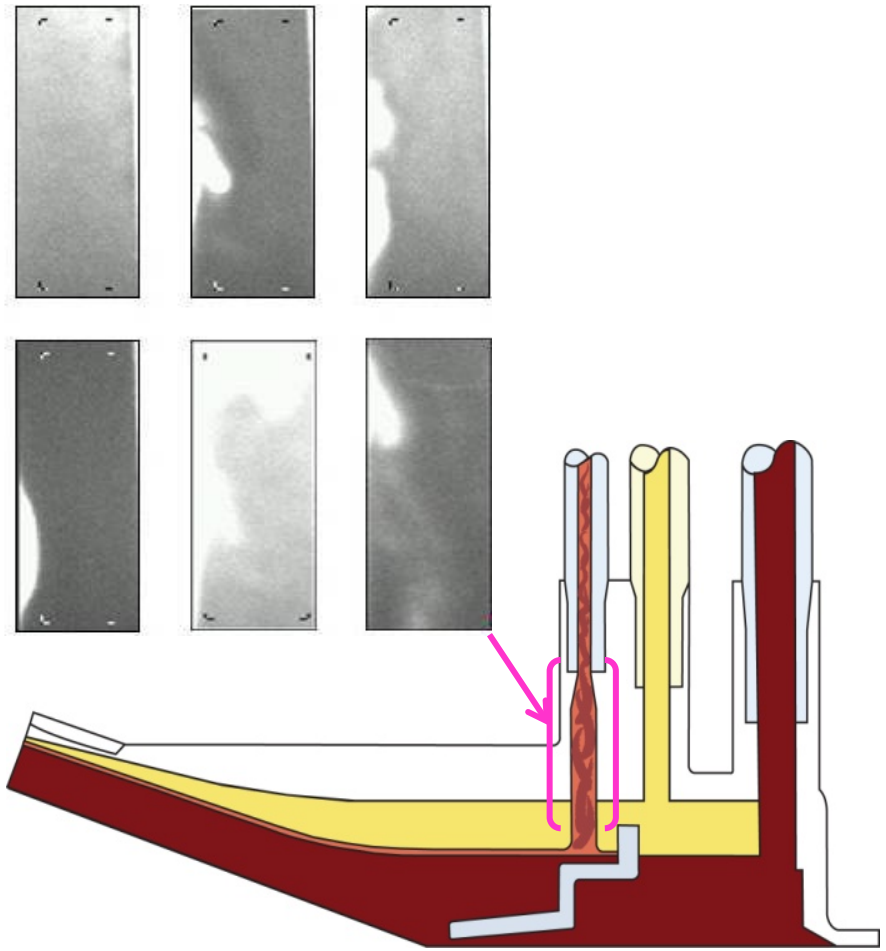
Monitoring the Run

- Collection preference trend graph
  - Black line indicates the targeted collection preference.
  - Green diamonds indicate the concentration of cells at the collect port.



Collection Status (continued)

Monitoring the Run

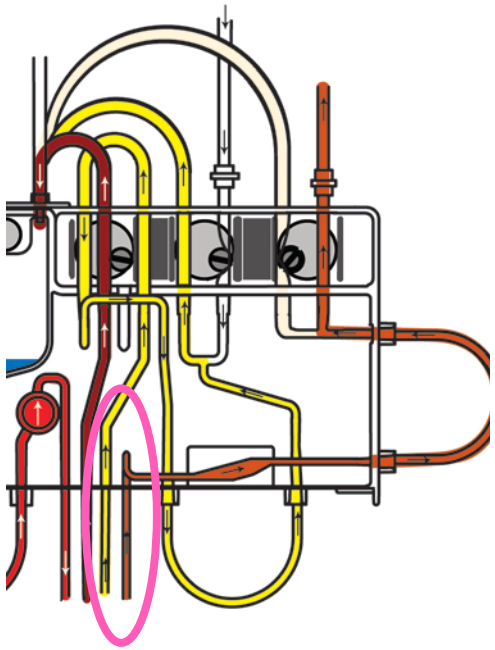


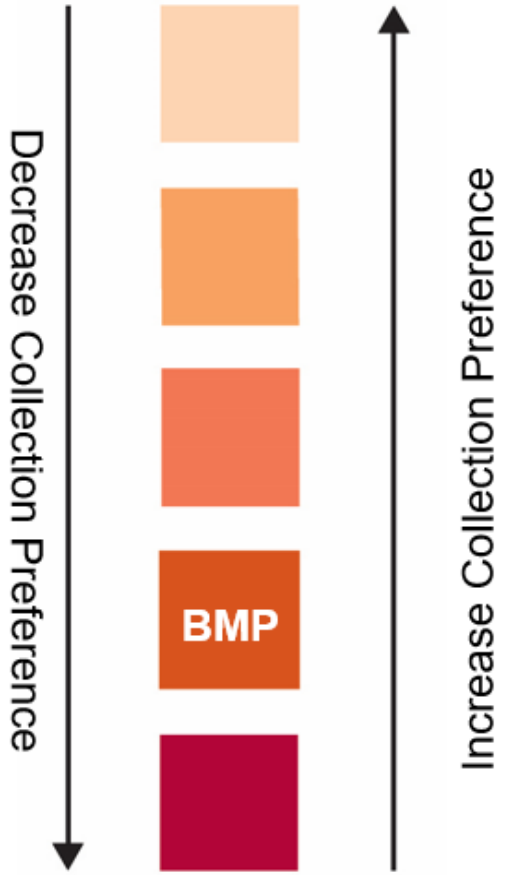
- Collect port image
  - The AIM system captures images of the collect port.
  - The images show the variation of the concentration of cells in the collect port.

Monitor the Collect Line From the Centrifuge

Monitoring the Run

- Monitor the color in the collect line.





Questions?

Completing the Run

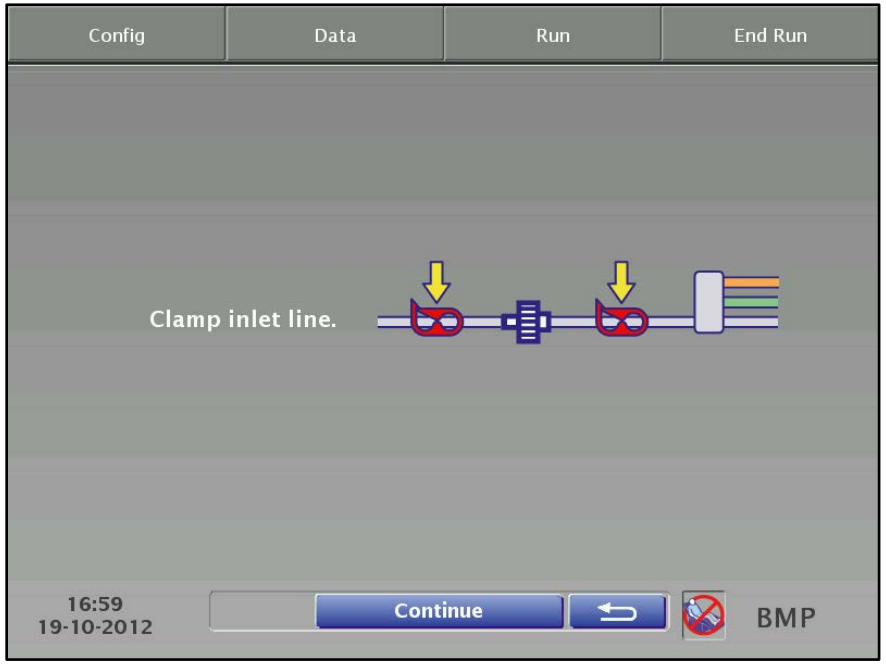
- Run Targets Attained
- Rinseback
- Rinseback in Progress
- Procedure Summary

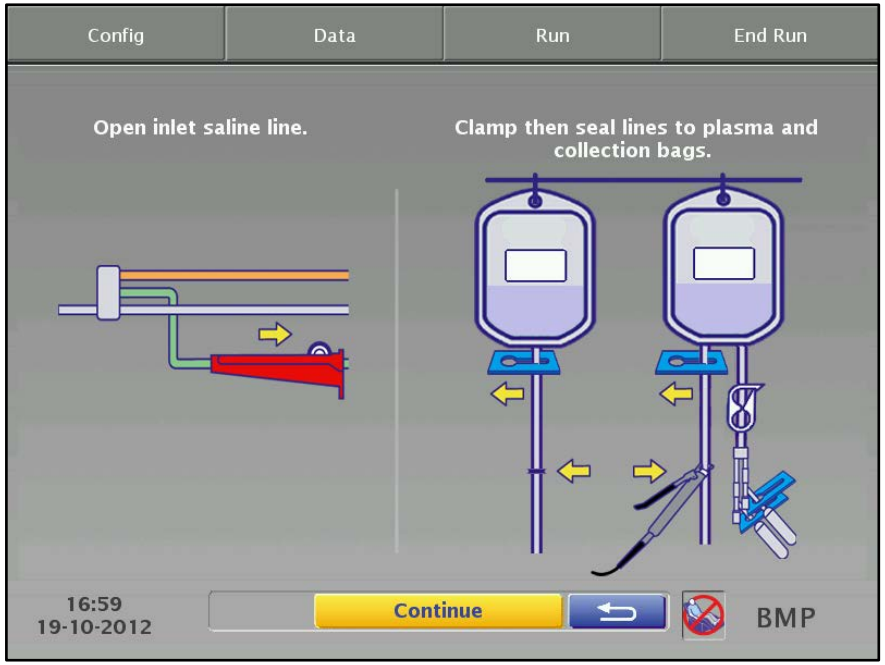
Run Targets Attained

Completing the Run

Rinseback

Completing the Run





Rinseback in Progress

Completing the Run

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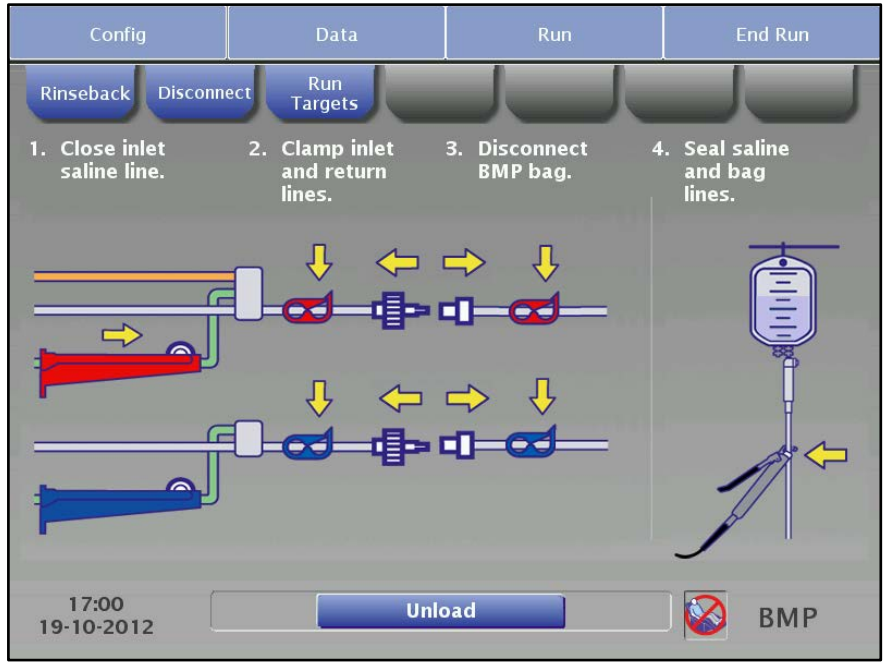


Procedure Summary

Completing the Run

Questions?

Making Changes

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

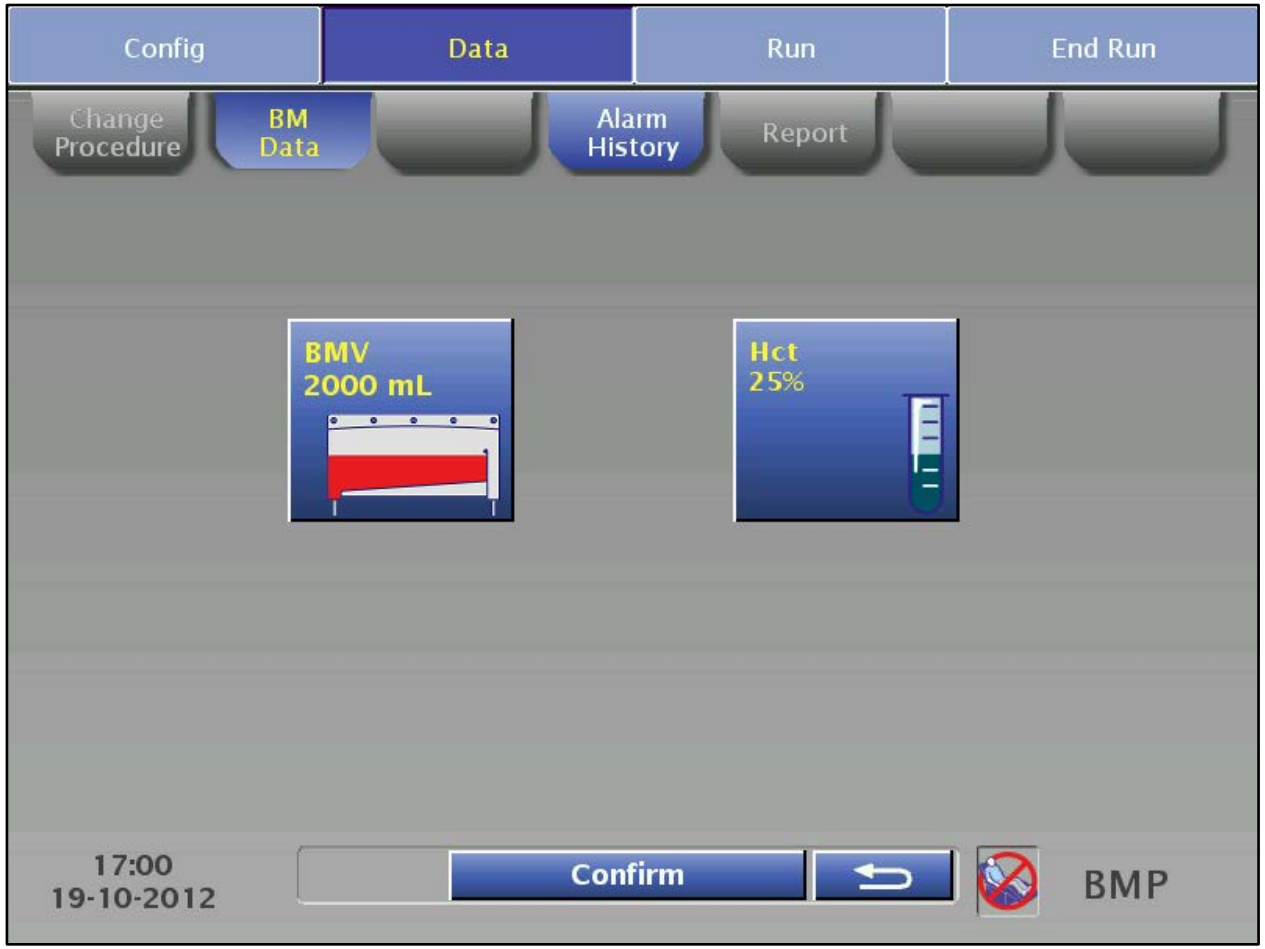
Data Menu

Making Changes – Data Menu

- Change Procedure
- BM Data
- Alarm History
- Report

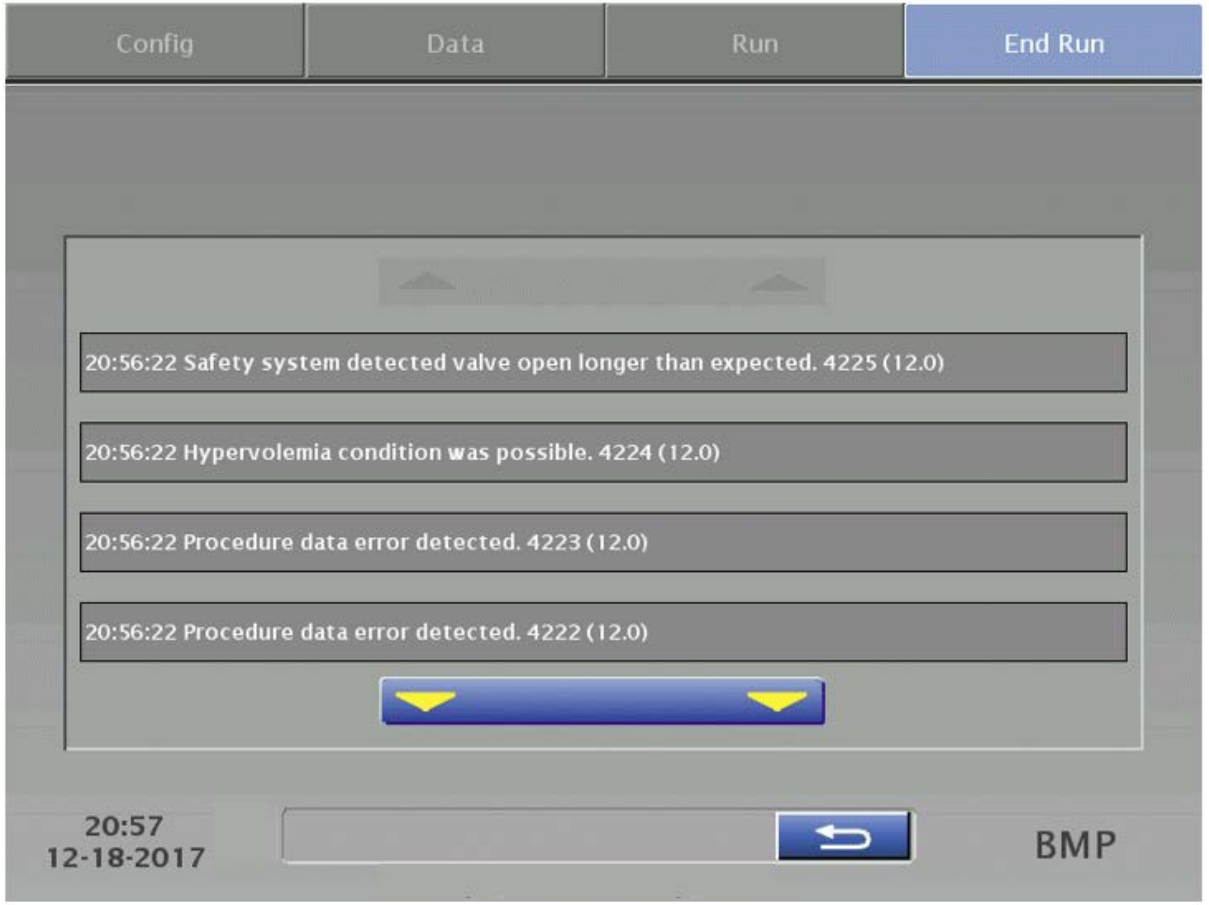
BM Data

Making Changes – Data Menu



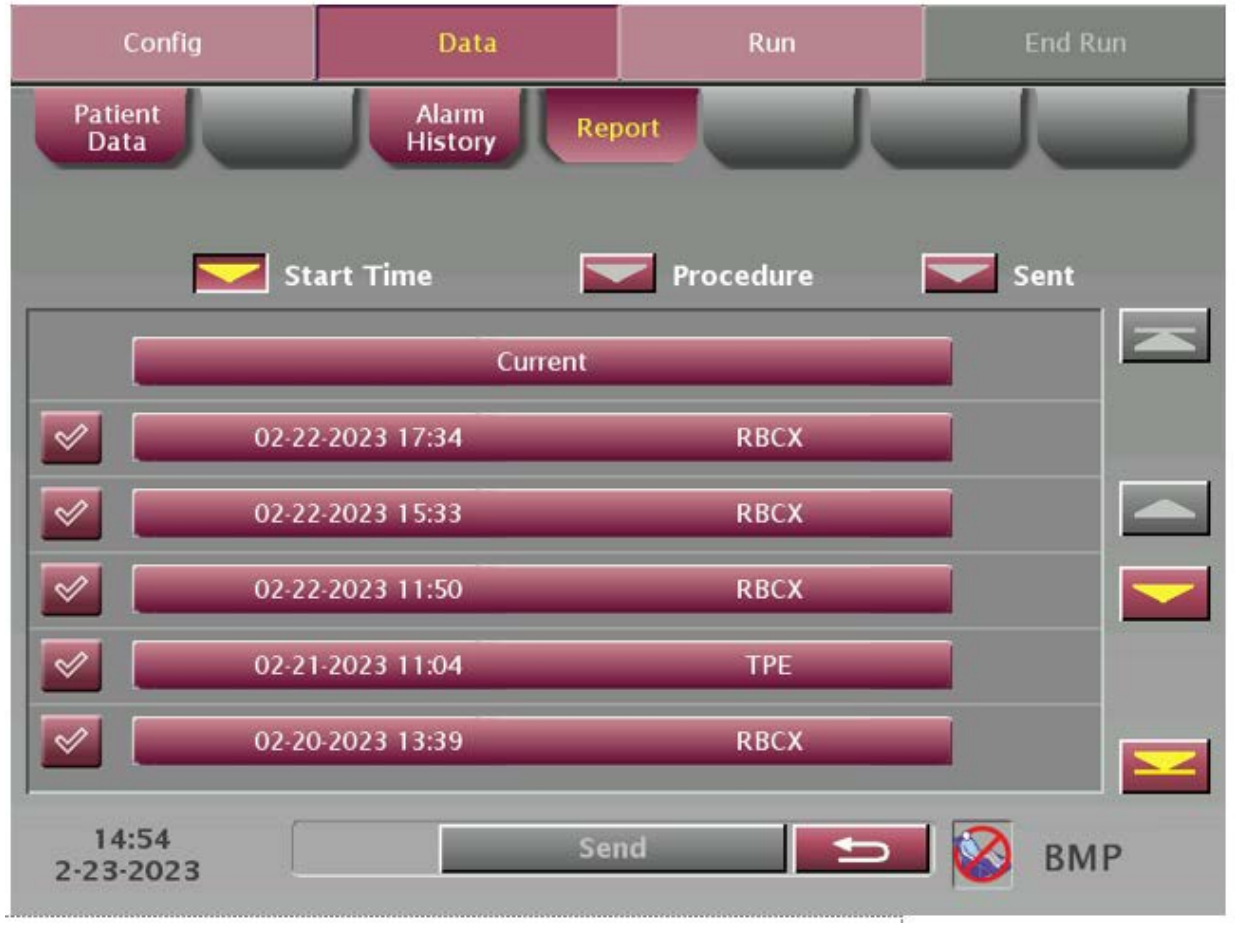
Alarm History

Making Changes – Data Menu



Report

Making Changes – Data Menu



Run Menu

Making Changes – Run Menu

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

Operation Status

Making Changes – Run Menu

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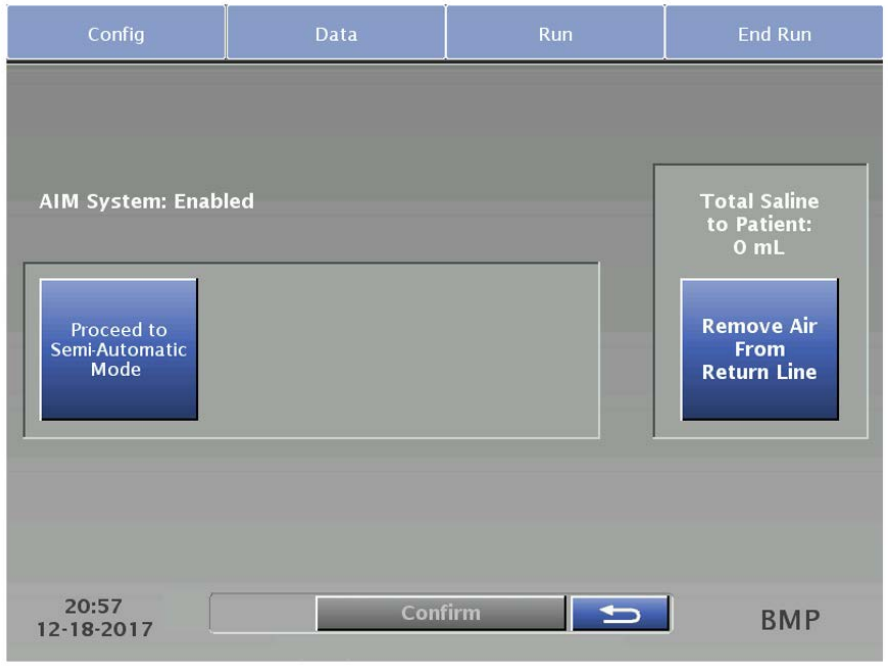

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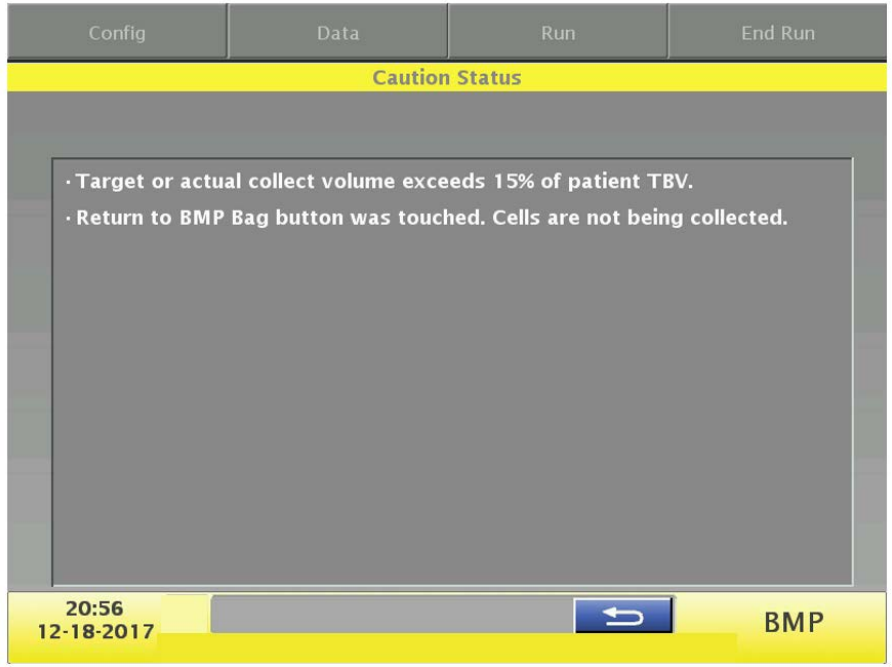
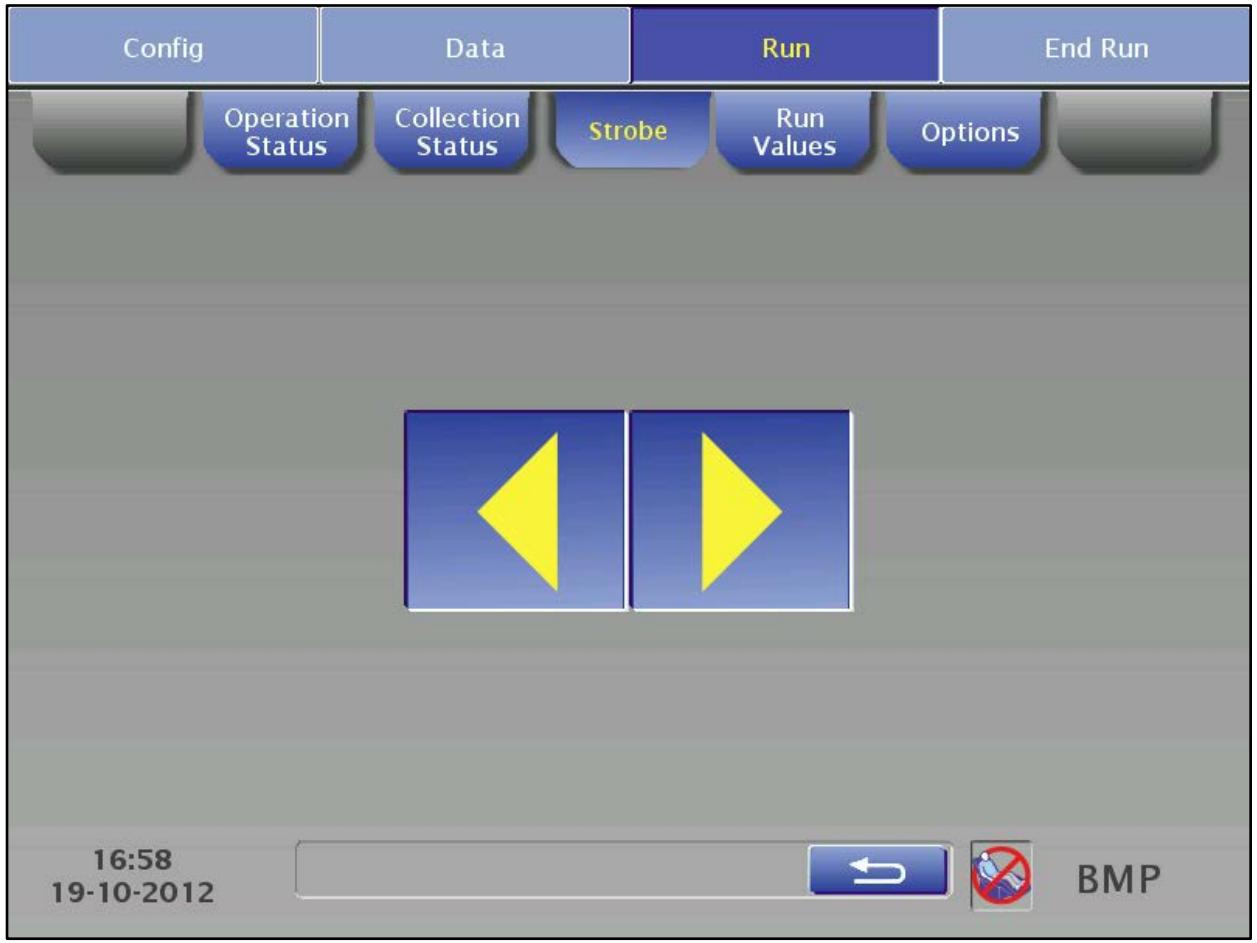


Collection Status

Making Changes – Run Menu

Strobe

Making Changes – Run Menu

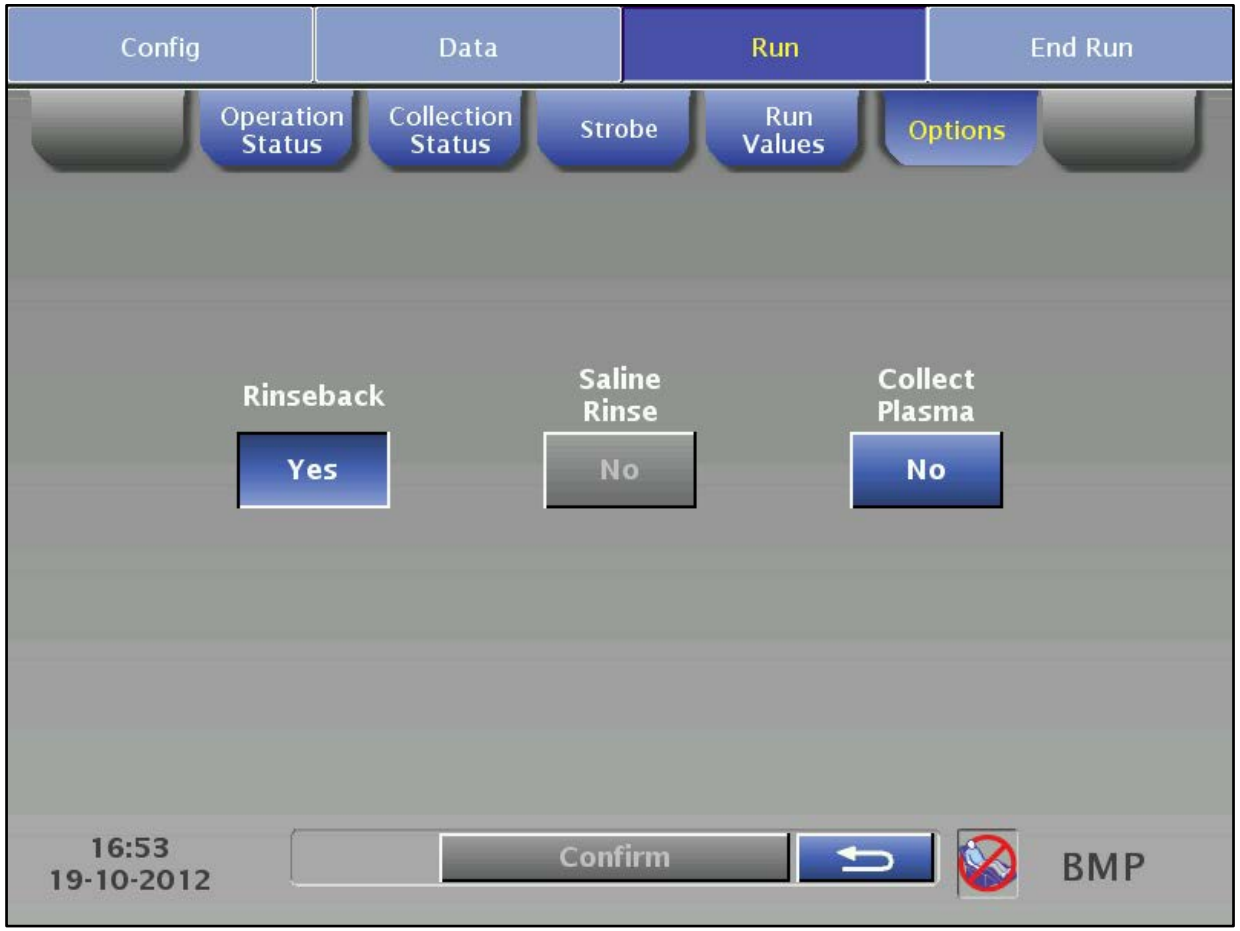


Run Values

Making Changes – Run Menu

Options

Making Changes – Run Menu



End Run Menu

Making Changes – End Run Menu

- Rinseback, Disconnect, Run Targets

Rinseback, Disconnect, Run Targets

Making Changes – End Run Menu

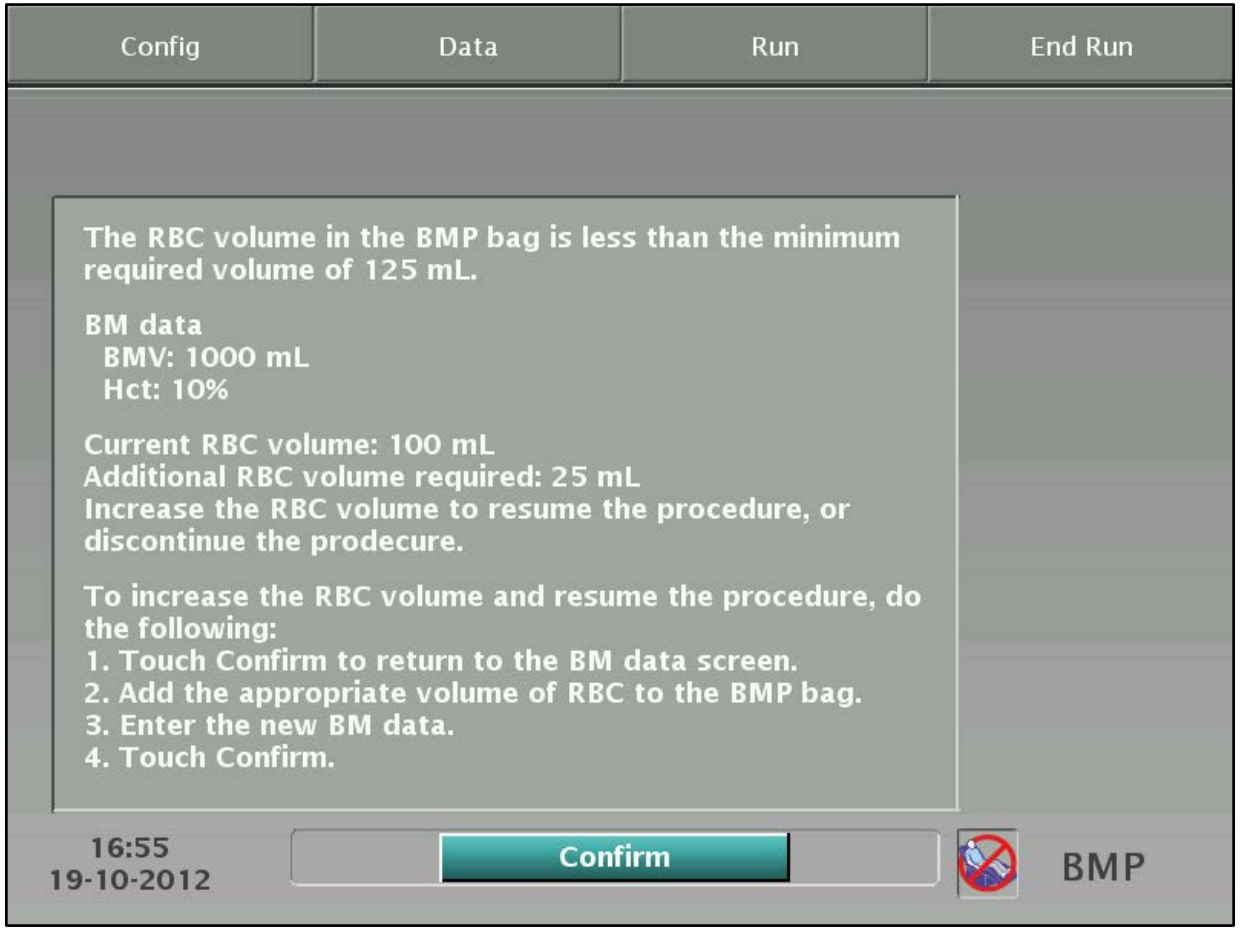
Questions?

Troubleshooting

- Low RBC Volume Bone Marrow
- Contents in Collect Line Look Too Light
- Contents in Collect Line Look Too Dark
- Interpreting the Trend Graph
- Clumping in the Collect Port
- Platelet Concentration Too High in Collection Bag
- Possible Alarms During a BMP Procedure

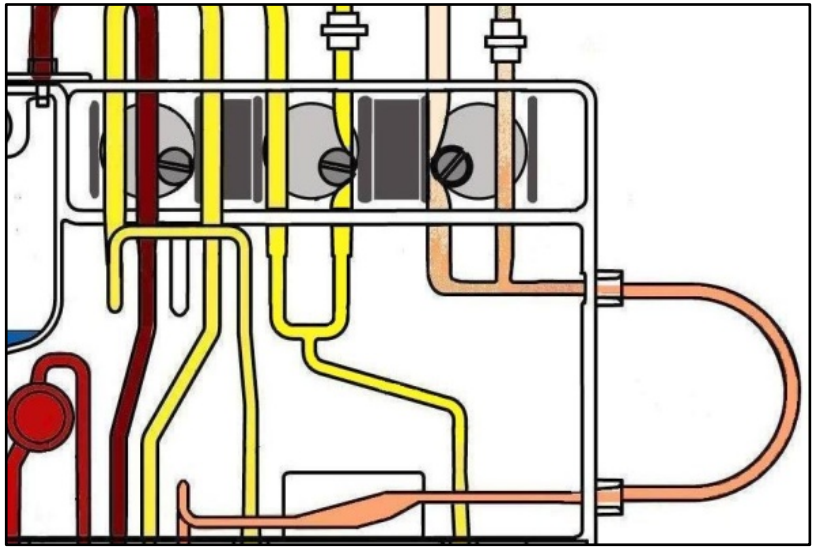
Low RBC Volume Bone Marrow

Troubleshooting



Contents in Collect Line Look Too Light

Troubleshooting

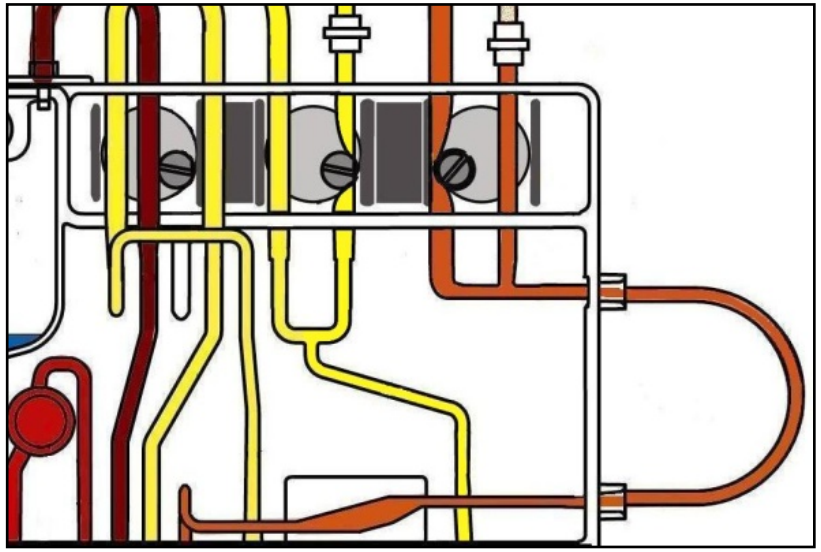


Collection preference is too high

Decrease the collection preference to darken the contents

Contents in Collect Line Look Too Dark

Troubleshooting



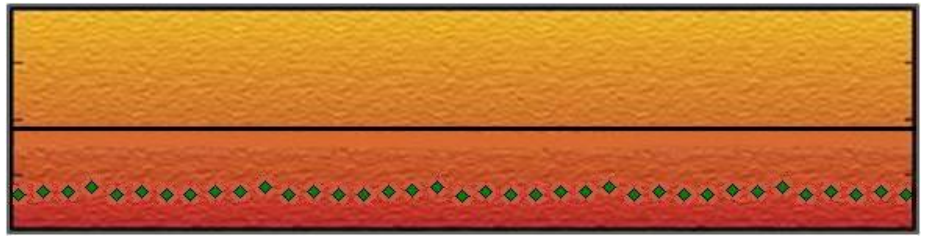
Collection preference is low

→

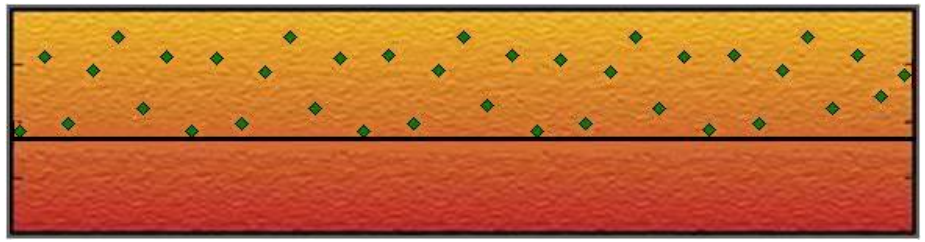
Increase the collection preference to lighten the contents

Interpreting the Trend Graph

Troubleshooting



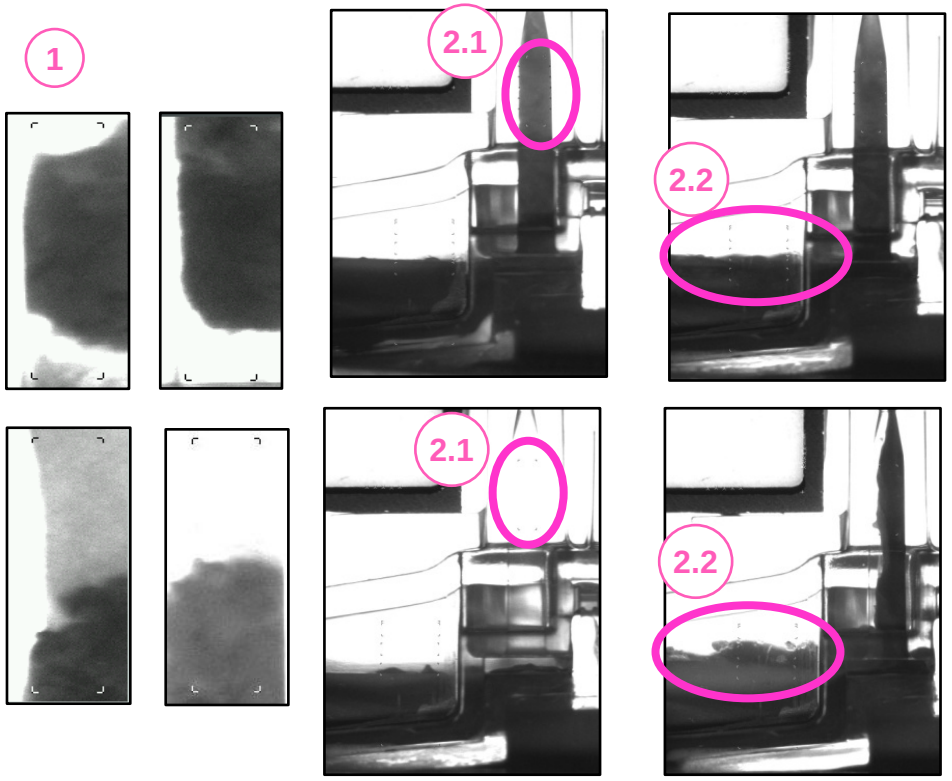
Tracking below the collection preference → Do nothing, or increase the collection preference



Erratic behavior → Do nothing, or decrease the collection preference

Clumping in the Collect Port

Troubleshooting



1. Collect port image alternates between dark and light
2. Viewport
   (2.1) Collect port
   (2.2) Interface

Inadequate anticoagulation → Add more ACD-A to BMP bag

Platelet Concentration Too High in BMP Collection Bag

Troubleshooting

- If the platelet concentration in the collection bag is too high, the packing factor can be reduced.
- The default inlet flow rate is 120 mL/min
  - Resulting in a default packing factor = 10.1

Excessive platelet contamination at packing factor 10.1

→

Decrease packing factor to 4.5

Possible Alarms During a BMP Procedure

Troubleshooting

- “Centrifuge pressure exceeded limit”
  - BMP bag inlet line not completely primed – air in centrifuge
- “Return pressure was too high”
  - Bone marrow volume > 3.0 L
- “AIM system did not detect interface”
  - Saline left open – excess saline in BMP bag

Questions?


TERUMO