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MCS®+ 9000

Haemonetics® MCS®+ UPP™ (Universal Platelet Protocol) - Operation Manual -

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CONSUMER INFORMATION

Proprietary rights

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Disclaimer

This manual is intended as a guide to provide the operator with necessary instructions on the proper use and maintenance of certain Haemonetics Corporation products. This manual should be used in conjunction with instruction and training supplied by qualified Haemonetics personnel.

Any failure to following the instructions as described could result in impaired product function, injury to the operator or others, or void applicable product warranties. Haemonetics accepts no responsibility for liability resulting from improper use or maintenance of its products.

Utilization of Haemonetics products may require the operator to handle and dispose of blood-contaminated material. An operator must fully understand and implement all regulations governing the safe handling of blood products and waste, including the policies and procedures of their facility.

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Symbols found in this document

The terms *Note, Caution* and *Warning* are used in this manual with the following symbols to emphasize certain details for the operator.

Note: Provides useful information regarding a procedure or operating technique when using Haemonetics material.

Caution: *Advises the operator against initiating an action or creating a situation which could result in damage to equipment, or impair the quality of the blood products; personal injury is unlikely.*

Warning: Advises the operator against initiating an action or creating a situation which could result in serious personal injury to either the donor or the operator.

- Text preceded by this bullet indicates an item on a list of information for the operator.

➔ Text preceded by this bullet indicates an action for the operator.

Manufacturer information

Device and device software

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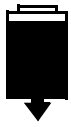
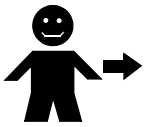
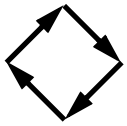
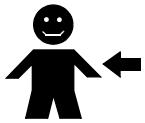
Explaining the display screen icons

These symbols, located on the left side of the center screen area, provide a pictorial representation of the MCS+ mode in progress.

Screen icons

Screen icons	Explanation	State
	Displayed during solution priming sequences.	PRIME
	Displayed prior to initiating a cycle.	READY
	Displayed as donor/patient blood is being drawn into the centrifuge bowl.	DRAW
	Displayed as collected plasma is being recirculated through the disposable set.	DWELL/ SURGE (sub states)
	Displayed as blood components/fluids are being returned to the donor/patient.	RETURN
	Displayed on all operator warning screens.	NOTICE

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Chapter 1

Introduction

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THE MCS+ UNIVERSAL PLATELET PROTOCOL

What are the features of the MCS+ universal platelet protocol procedure?

The universal platelet protocol (UPP) collects the following platelet products:

- Concentrated, leuko-reduced platelets suspended in additive solution
- Leuko-reduced platelets suspended in anticoagulated plasma

Depending on the options selected by the operator, and the disposable set used in the procedure, the platelets can be collected with:

- A configurable volume of unfiltered plasma
- A unit of leuko-reduced RBCs suspended in preservative solution
- A unit of unfiltered plasma and a unit of leuko-reduced RBCs suspended in preservative solution

*Table 2-1*lists the various product collection options available.

The UPP protocol provides all the features of the existing platelet protocols, including donor comfort features such as citrate control and adjustable pump speed.

Extracorporeal volume management

One of the enhanced features of the UPP protocol is the **extracorporeal volume (ECV) management**.

During each Draw mode, the system calculates whether the next Draw mode will exceed the maximum allowable ECV (configured as a percentage of the donor total blood volume). If the allowable ECV will be exceeded, the system modifies the next Draw mode as follows:

- ➔ Calculates how much plasma will be collected during this Draw mode.
- ➔ Fills the bowl until half of the estimated plasma is collected.
- ➔ Stops Draw and enters Return, returning the plasma to the donor (this is also called anticipated plasma return).
- ➔ Stops Return and re-enters Draw, completing the bowl filling process.

The rest of the cycle proceeds normally. The system continues to estimate maximum allowable ECV and modify the Draw modes, if necessary, until the last cycle.[1]

Super surge Draw mode

Another enhanced feature of the UPP protocol is the **super surge Draw mode** that takes place during the last cycle.

---

1. Anticoagulant and saline solution are considered as volume compensation solutions.

During every cycle but the last cycle, the UPP protocol collects platelets into the Air-Intermediate platelet bag. In the last cycle, the collected platelets are recirculated back into the bowl. This creates a larger platelet layer than in previous cycles. The system then collects this platelet layer in a small volume of plasma to create the concentrated platelet product.

Plasma return during Dwell, Surge, and Centrifuge Braking

Another enhanced feature of the UPP protocol is the ability to initiate the plasma return sequence in parallel with the platelet collection sequence (Dwell and Surge), to spread the return of plasma over a longer time period.

At the end of the Draw mode, the device calculates if the amount of plasma collected will exceed the minimum amount required to both constitute the plasma product and to perform bowl rinse and mixed return (plasma and red blood cells) at the end of the Return phase. If the device calculates that there will be excess plasma, the device can return the excess plasma to the donor during platelet collection and centrifuge stopping.

This features enables the device to return plasma to the donor as soon as possible, and also ensures that the amount of anticoagulated fluid returned to the donor is spread out optimally over the return time.

Platelet Post-Count

Another enhanced feature of the UPP protocol is the **platelet post-count estimate**.

The device uses the donor parameters and the product and procedure targets to estimate the concentration of platelets remaining in the donor's blood after the collection procedure is complete.

The device prevents the post-count from decreasing below a programmed limit by restricting the maximum allowable product and procedure target values. If the operator attempts to set a procedure target that would cause the post-count to decrease below the programmed limit, the device displays an error message and automatically restricts the procedure target.

What materials are required to perform a universal platelet protocol?

The following material is required to perform a UPP collection procedure:

- A disposable set.
- The Haemonetics UPP protocol card.
- Venipuncture material and extra clamps.
- An adequate quantity of an anticoagulant solution.
- Platelet additive solution (when collecting concentrated platelets)
- Red cell additive solution (when collecting concurrent red cells).
- Saline solution (optional)

THE UPP COLLECTION SETS

Figure 1-1, depicts the elements of the UPP disposable set (LN 999F-E).

1. Donor line sample pouch
2. Donor/needle line
3. Single pump manifold
4. AC solution line
5. Blood filter chamber
6. Donor pressure monitor (DPM)
7. Dual pump manifold
8. Latham bowl
9. Plasma bag
10. System pressure monitor (SPM)
11. Air-platelet bag
12. Additive solution line
13. Platelet filter
14. Air removal pouch
15. Platelet storage bags and sampling bulbs
16. Air-Intermediate platelet bag

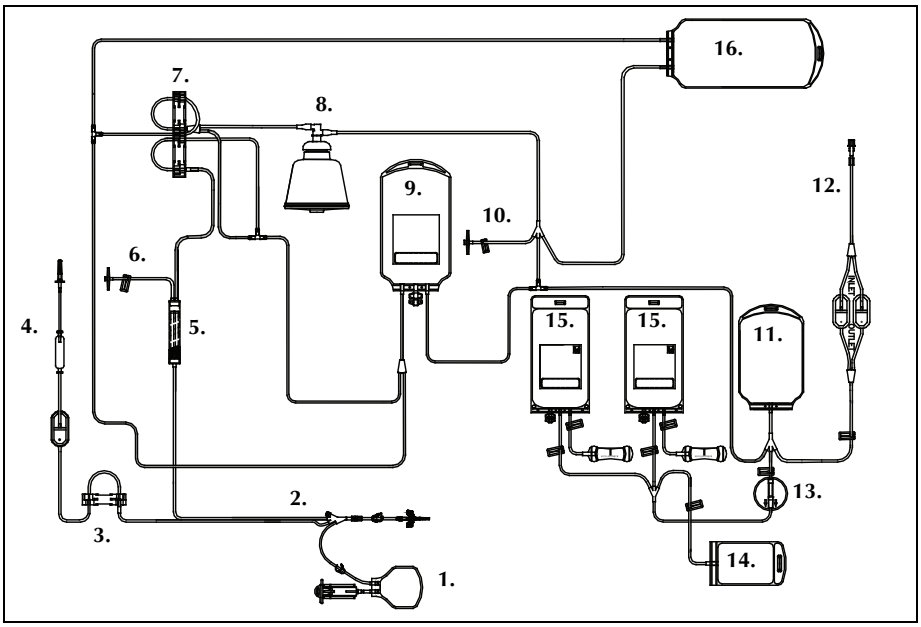

Figure 1-1, Example of an MCS+ UPP *disposable set*

Figure 1-2, depicts the elements of the UPP disposable set (LN 949FF-E).

1. Donor line sample pouch
2. Donor/needle line
3. Single pump manifold
4. AC solution line
5. Blood filter chamber
6. Donor pressure monitor (DPM)
7. Dual pump manifold
8. Latham bowl
9. Plasma bag
10. System pressure monitor (SPM)
11. Air-platelet bag
12. Additive solution line
13. Platelet filter
14. Air removal pouch
15. Platelet storage bags (with sampling bulbs on LN949FF-E)
16. Air-Intermediate platelet/ RBC bag
17. RBC additive solution line
18. Leukoreduction filter
19. Filtered RBC bag
20. RBC sample bag

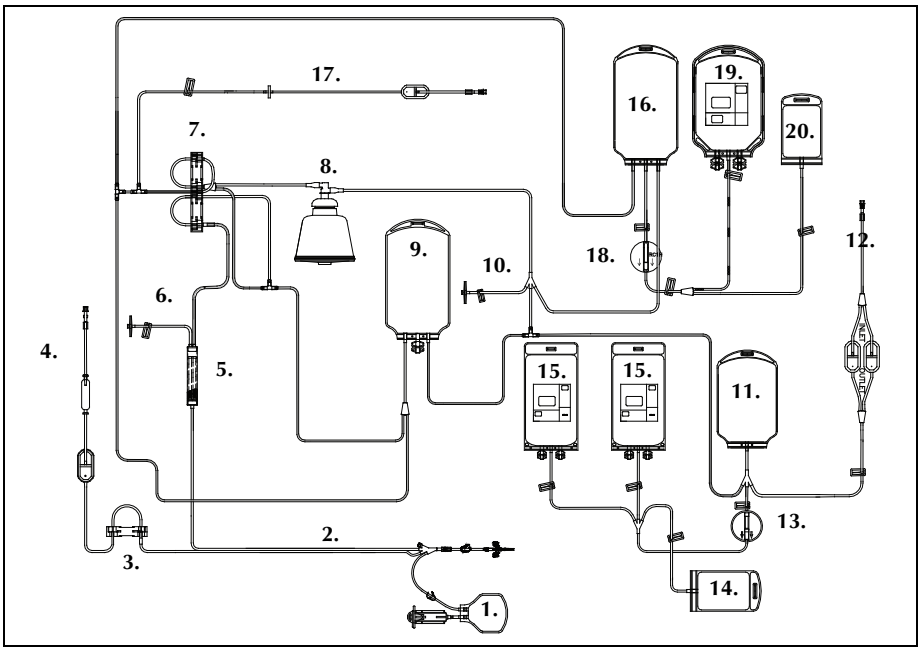

Figure 1-2, Example of an MCS+ UPP *disposable set*

Figure 1-3, depicts the elements of the UPP disposable set (LN 997CF-E).

1. Donor line sample pouch
2. Donor/needle line
3. Single pump manifold
4. AC solution line
5. Blood filter chamber
6. Donor pressure monitor (DPM)
7. Dual pump manifold
8. Latham bowl
9. Plasma bag
10. System pressure monitor (SPM)
11. Platelet reservoir bag
12. Saline solution line
13. Platelet filter
14. Air removal pouch
15. Platelet storage bags and sampling bulbs
16. Air bag

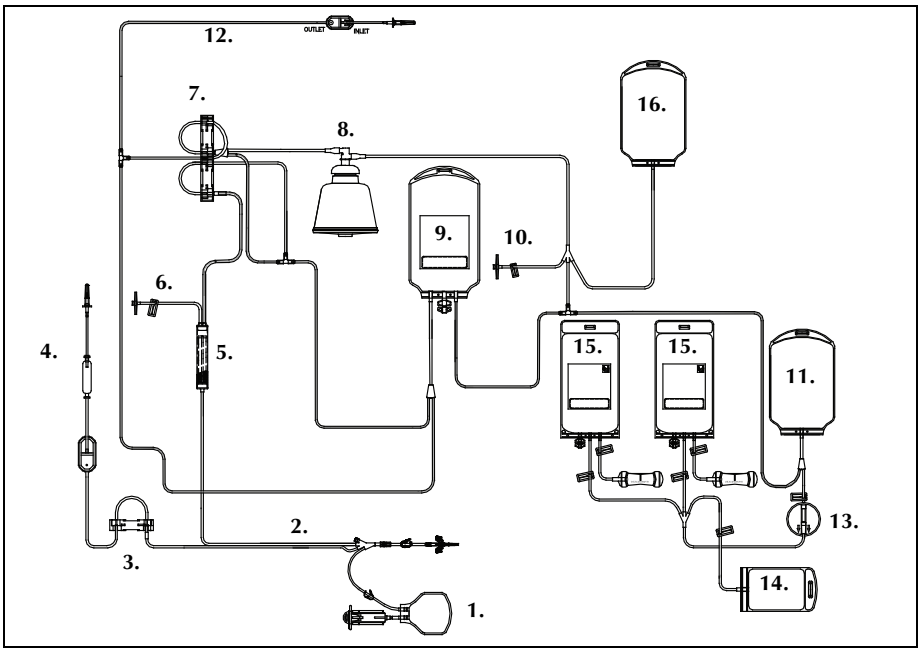

Figure 1-3, Example of an MCS+ UPP *disposable set*

Chapter 2

Setting up the device and disposable set

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PREPARING THE MCS+ DEVICE

Setting up the device

Use the following steps to setup the MCS+ device:

- ➔ Place the device on a flat, stable surface.
- ➔ Open the cover.
- ➔ Extend the middle section of both solution poles, ensuring that all hooks are raised.
- ➔ Extend the weigher arm to a 90 degree angle from the top deck to ensure maximum accuracy.
- ➔ Insert the UPP protocol card into the open card port (right side panel) until the release tab pops out (see *Figure 2-1*).
- ➔ Close the card port door securely.
- ➔ Power-on the MCS+ device.

Note: The card port cannot be properly closed unless the protocol card has been fully inserted. To remove a protocol card, press the release tab.

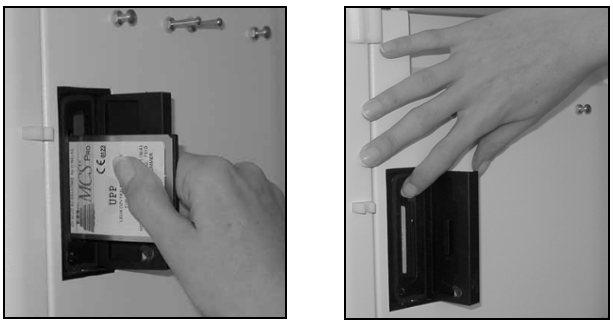

Figure 2-1, MCS+ protocol insertion and removal

System testing

The MCS+ device performs a series of internal self-diagnostic tests prior to each collection procedure. During the internal tests the following screen appears:

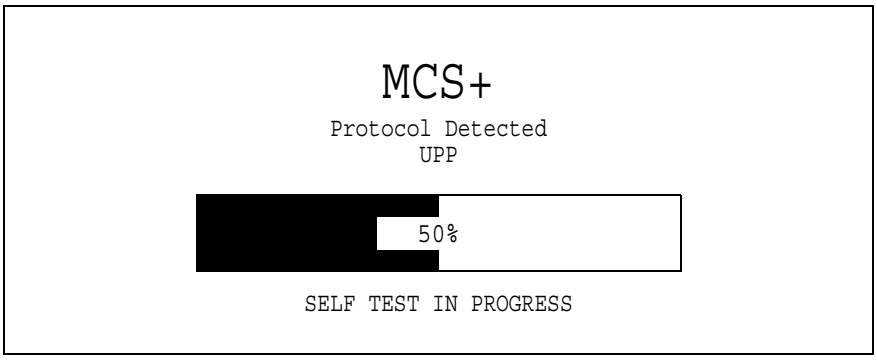

Figure 2-2, MCS+ self test screen

Verify the centrifuge lock

The following message prompts the operator to verify the centrifuge locking mechanism:

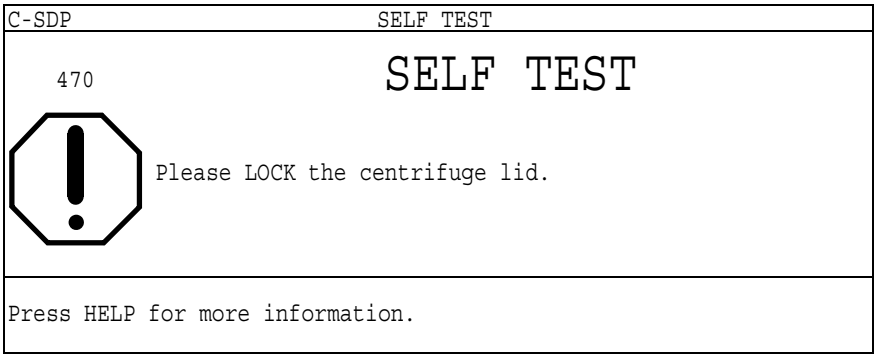

Figure 2-3, Centrifuge lock test screen message

➔ Lock, unlock and re-lock the centrifuge lid to confirm that the centrifuge can be properly isolated from the operator and donor/patient.

Selecting protocol options

The following screen prompts the operator to choose a protocol option:

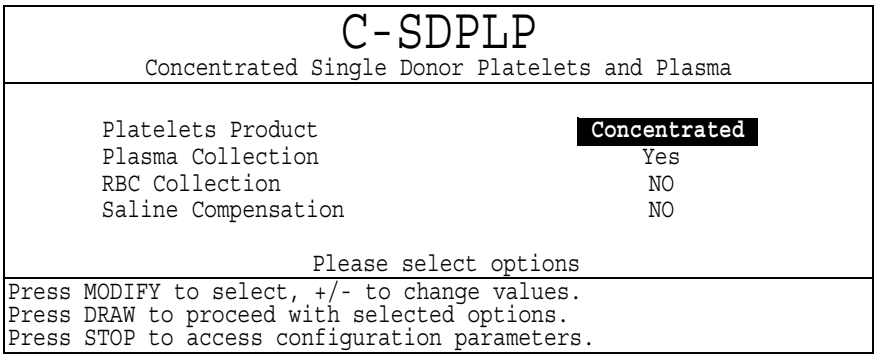

Figure 2-4, Protocol option selection menu

Use the following steps to select protocol options:

- ➔ Press the Modify key to access an option; the selected option is highlighted on the screen.
- ➔ Press the Yes/No key to select the option. The acronym and description at the top of the screen will change depending on the options selected.

Table 2-1, UPP protocol options

Protocol	Disposable set	Description	Option			
			Platelet product	Plasma collection	RBC collection	Saline comp.
C-SDP	999F-E 999FF-P-SL	Concentrated single donor platelets	Concentrated	NO	NO	NO
C-SDPRBC	949FF-E 949FF-P-SL	Concentrated single donor platelets and RBC	Concentrated	NO	YES	NO
C-SDPLP	999F-E 999FF-P-SL	Concentrated single donor platelets and plasma	Concentrated	YES	NO	NO
C-SDPLPRBC	949FF-E 949FF-P-SL	Concentrated single donor platelets, plasma and RBC	Concentrated	YES	YES	NO
SDP	997CF-E 999F-E 999FF-P-SL	Single donor platelets	In plasma	NO	NO	NO
SDPS	997CF-E	Single donor platelets with saline compensation	In plasma	NO	NO	YES

Table 2-1, UPP protocol options

Protocol	Disposable set	Description	Option			
			Platelet product	**Plasma collection**	**RBC collection**	**Saline comp.**
SDPRBC	949FF-E 949FF-P-SL	Single donor platelets and RBC	In plasma	NO	YES	NO
SDPLP	997CF-E 999F-E 999FF-P-SL	Single donor platelets and plasma	In plasma	YES	NO	NO
SDPLPS	997CF-E	Single donor platelets and plasma with saline compensation	In plasma	YES	NO	YES
SDPLPRBC	949FF-E 949FF-P-SL	Single donor platelets, plasma and RBC	In plasma	YES	YES	NO

Operator configuration feature

➔ Press the STOP key to access the initial Operator Configuration menu from the protocol selection menu.

The Operator Configuration feature provides access to parameters related to nominal dose volume and modifiable procedure parameter defaults. Modification of these parameters permit the operator to adjust the UPP procedure according to specific collection requirements.

Caution: *Adjust these parameters according to local standard operating procedure. Modifications will influence the results of the UPP collection procedure.*

The Operator Configuration feature also provides an weigher check which validates the calibration of the MCS+ weigher arm.
See *Appendix B* for further details concerning the specific Operator Configuration parameter menus and the weigher check.

Installing the disposable set

Use the following steps to install the disposable set:

➔ Press the Draw key to confirm the protocol option selection.

The system displays the initial disposable set installation screen.

```
UPP                                                        Installation

            Please perform the following:

            Insert the bowl securely
            Lock the centrifuge lid
            Secure the dual pump manifold
            Install the line sensor tubing
            Plasma bag with ports down on the weigher arm
            Connect the system pressure monitor (SPM)
            Connect the donor pressure monitor (DPM)

Press HELP for more information.
Press STOP to return to protocol selection.
```

Figure 2-5, Initial installation screen display

Note: As the operator installs each element, the corresponding text disappears from the screen.

After installing the disposable set, the operator receives a verification message prior to initiating the pump autoload sequence. At this time the operator can return to the protocol selection menu if necessary. Once the priming sequence is initiated, the protocol selection menu and the operator configuration parameters are no longer accessible for modification.

Inspecting the disposable material

The operator should inspect the disposable material prior to, as well as during, installation on the MCS+ device, using the following guidelines:

- ➔ Verify that the disposable set corresponds with the UPP protocol.
- ➔ Verify that neither the packaging tub nor cover has been damaged.
- ➔ Inspect all tubing sections during installation and ensure that no occlusions are present which could obstruct the flow through the disposable set.

Caution: *A disposable set should not be used if the packaging has been damaged during shipping or storage. This could compromise the sterility of the collected blood products.*

Any action that compromises the sterile fluid pathway before the products are hermetically sealed affects the storage of the products. If the sterile fluid pathway has been compromised, the product shelf life should be reduced to 24 hours.

Chapter 3

Installing the 999F-E disposable set

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- Install the centrifuge bowl 3-6
- Load all valves and SPM 3-7
- Install the donor and AC lines 3-8
- Install the BLAD, blood filter chamber, DLADs, and DPM 3-9
- Clamp the lines 3-9
- Verify installation 3-10
- Initiate pump autoload 3-12

INSTALLING THE DISPOSABLE SET

The disposable elements are packaged so that the operator may remove each section individually from the tub. With some brief initial preparation, the UPP disposable sets elements can be efficiently installed in the following general order:

- Platelet harness (platelet storage bags and sampling bulbs, pre-filter platelet bag, and air removal pouch)
- Plasma bag
- Air-Intermediate platelet bag
- Centrifuge bowl and dual pump manifold
- AC, additive solution, and donor lines
- Blood filter chamber

Preparing to install the disposable set

➔ Inspect the disposable set following the instructions in “Inspecting the disposable material” on page 2-6.

➔ Completely remove the cover from the disposable tub and place the open tub on the top deck of device with the bowl on the right side, near the line sensor and clear valve.

➔ Remove all cold-seal tape from the set as it is installed.

The following keys will be active during installation:

- Press the **Help** key for assistance concerning the installation of each listed element.
- Press the **STOP** key to return to the protocol selection menu, if necessary.

Figure 3-1, Placing the tub on the top deck

Install the bags

➔ Remove the platelet harness from the tub and hang, ports down, on the pins on the right-side of the front panel. The platelet harness is composed of a pre-filter bag, two platelet storage bags with sampling bulbs, a sample pouch, a platelet filter, and the platelet additive solution (PAS) line that ends in a luer lock connection.

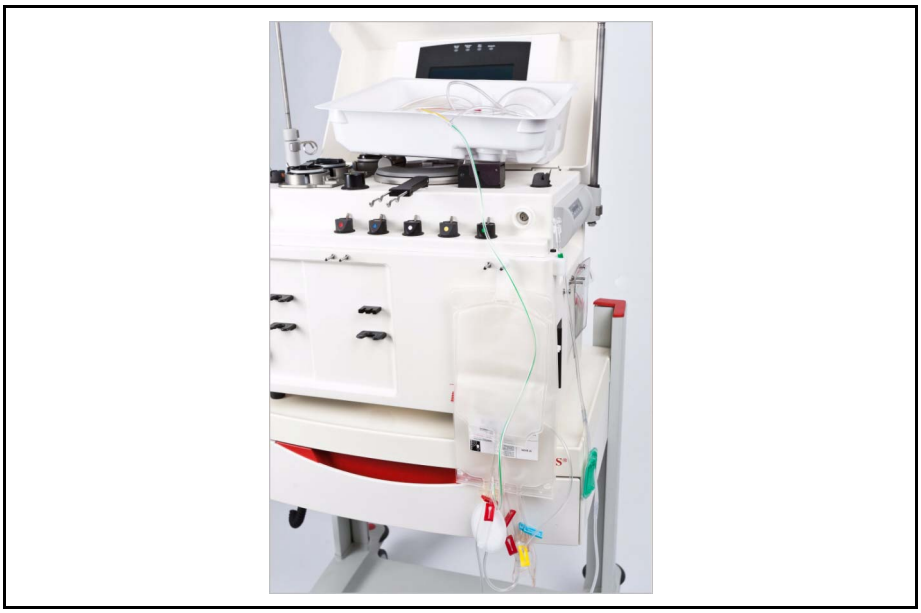

Figure 3-2, Installing the platelet harness

➔ Place the line between the bowl and the platelet filter to the right side of the device, so that it can be easily installed into the green valve later in the installation sequence.

➔ Insert the platelet additive solution (PAS) line into the tubing holder at the top of the right side panel. Ensure that the luer lock connector located on the PAS line rests on the top of the tubing holder.

➔ Remove the plasma bag and hang it on the weigher.

Figure 3-3, Installing the plasma bag or plasma harness

➔ Ensure that the yellow tubing line is on the right side of the weigher arm.

➔ Ensure that the orange and white tubing lines are on the left side of the weigher arm.

➔ Loop the purple line behind the disposable tub so that it is between the tub and the membrane panel.

➔ Hang the Air-Intermediate platelet bag on the middle hook of the right-side solution pole with ports facing down. Ensure that the ports are at the level of the top deck.

Figure 3-4, Installing the Air-intermediate platelet bag

➔ Once all bags have been removed from the tub, place the open tub against the control panel with the centrifuge bowl in the upper right section.

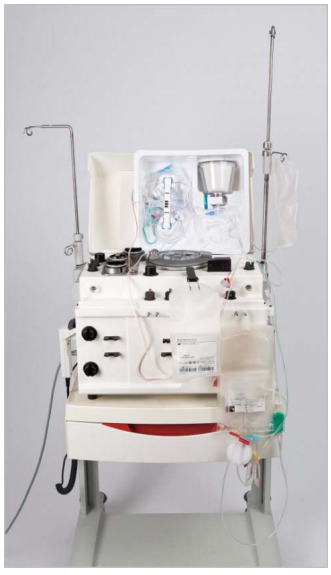

Figure 3-5, Placing the tub in the device cover

Note: The operator is not required to access the keypad during the initial disposable set installation screen display. When the operator has completed an action on this screen, the corresponding text will disappear.

Install the centrifuge bowl

- ➔ Unlock and open the centrifuge lid.
- ➔ To remove the bowl and dual pump manifold from the tub:
  - ➔ *Remove the bowl by gently pulling the header of the bowl forward and flipping the base of the bowl back and down.*
  - ➔ *Remove the dual-pump manifold by gently pulling the top of the manifold forward and down.*

Caution: *Flipping the bowl and the dual-pump manifold in opposite directions prevents the bowl inlet tubing from twisting. Check the bowl inlet tubing to make sure that it is not twisted before proceeding.*

- ➔ Place the bowl in the centrifuge well with the inlet port facing left. Press down firmly on the head of the bowl to fully seat it in the centrifuge chuck.

Warning: The text "Insert the bowl securely" disappears from the screen once the bowl is placed in the centrifuge chuck. However, the operator must ensure that bowl is securely seated in the chuck.

- ➔ Loop the dual pump tubing around the Blood (red) and Transfer (white) pumps in preparation for the pump autoload sequence.
- ➔ Snap the dual pump manifold securely into place above the dual pump housing identification window.

➔ Close and lock the centrifuge lid.

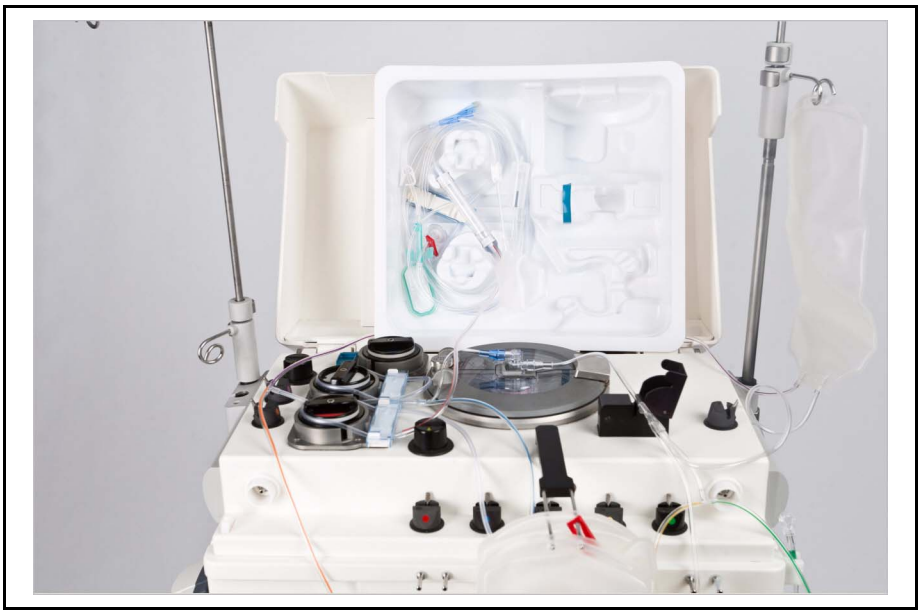

Figure 3-6, Installing the centrifuge bowl

Load all valves and SPM

MCS+ color-coded valves [1. - 8.]

1. Purple
2. Orange
3. Red
4. Blue
5. White
6. Yellow
7. Green
8. Clear

9. AC pump
10. Transfer pump
11. Blood pump
12. Optical line sensor
13. Weigher
14. DPM
15. SPM
16. ACAD
17. BLAD
18. Dual pump ID window

➔ Install the tubing exiting the bowl into the line sensor.

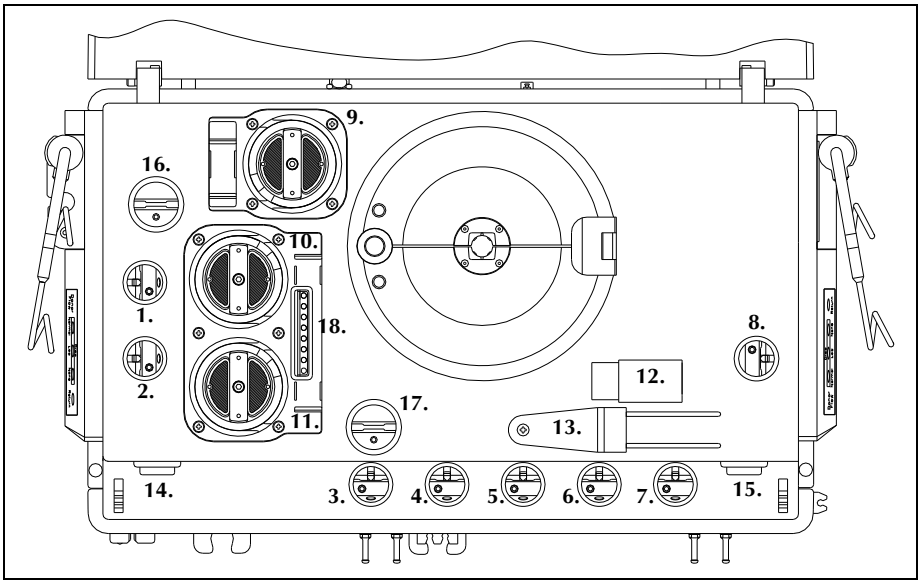

Figure 3-7, MCS+ top deck with color-coded valves

Figure 3-8, Installing the tubing

- ➔ Load the yellow-coded tubing into the yellow valve.
- ➔ Load the green-coded tubing into the green valve.
- ➔ Load the blue-coded tubing into the blue valve.
- ➔ Load the white-coded tubing into the white valve.
- ➔ Load the red-coded tubing exiting the BLAD into the red valve (donor valve).
- ➔ Load the orange-coded tubing into the orange valve.
- ➔ Load the purple-coded tubing into the purple valve.
- ➔ Load the clear tubing leading to the Air-Intermediate platelet bag into the clear valve.
- ➔ Install the SPM. Give the filter a quarter turn to secure the luer connection and tug lightly to verify proper installation.

Warning: Failure to correctly install the filter may result in fluid contacting the filter membrane. Once the filter membrane becomes wet, the pressure monitor can no longer provide an accurate reading. The sterile pathway should be considered compromised, and the product life should be reduced to 24 hours.

Install the donor and AC lines

- ➔ Remove the donor and AC lines from the tub.
- ➔ Snap the single pump manifold into place and loop the AC tubing around the AC pump.

- ➔ Install the AC solution line tubing exiting the single pump manifold into the ACAD.
- ➔ Remove the paper tab from the donor needle tubing section and unroll the tubing.
- ➔ Clamp the donor line sample pouch and the donor needle tubing.
- ➔ Remove the empty disposable tub from the MCS+ cover and recycle or discard according to standard operating procedure.

Install the BLAD, blood filter chamber, DLADs, and DPM

- ➔ Install the red-coded tubing into the BLAD.
- ➔ Install the blood filter chamber in the filter holders on the front panel.
- ➔ Install the colorless tubing exiting the blood filter chamber into the two DLADs by passing the tubing first through the DLAD2 (bottom) and then through the DLAD1 (top).
- ➔ Install the tubing exiting the DLAD1 into the tubing guide.
- ➔ Install the DPM. Give the filter a quarter turn to secure the luer connection and tug lightly to verify proper installation.

Warning: Failure to correctly install the filter may result in fluid contacting the filter membrane. Once the filter membrane becomes wet, the pressure monitor can no longer provide an accurate reading.

Clamp the lines

Platelet harness

Depending on the platelet filtration method, two options exist for clamping the lines on the platelet harness:

- **For platelets in plasma, or immediate filtration of concentrated platelets:** close all clamps on the platelet harness, except for the clamp on the Air-platelet bag and the clamp on one of the platelet storage bags.
- **For concentrated platelets suspended in additive solution prior to leuko-reduction:** close all clamps on the platelet harness.

Haemonetics recommends verifying that the platelet yield is above $5x10^{11}$ before dividing the platelets into two bags.

Haemonetics recommends opening the clamps on both platelet storage bags if a platelet yield of $6x10^{11}$ or above is targeted.

Donor line

- ➔ Close the clamp on the needle line.
- ➔ Close the clamp on the donor line sample pouch.

Verify installation

Once all of the listed elements are installed, a version of the following message appears:

```
C-SDP                                                    Installation

           Please verify the following:
           Valves are loaded
           Pump tubing is looped
           PRP/Air/RBC bag with ports down is on the right
           pole at mid height
           Plasma bag ports down is on the front weigher
           Platelet bags ports down are on the front pin
           Platelets additive line is clamped*
           Needle line tubing is clamped

Press DRAW to load the pumps.
Press STOP to return to protocol selection.
```

Figure 3-9, Loading confirmation screen

*Only appears for C-SDP or RBC procedures

➔ Visually inspect all of the listed elements and ensure that all actions are complete, prior to proceeding with the pump autoload sequence.

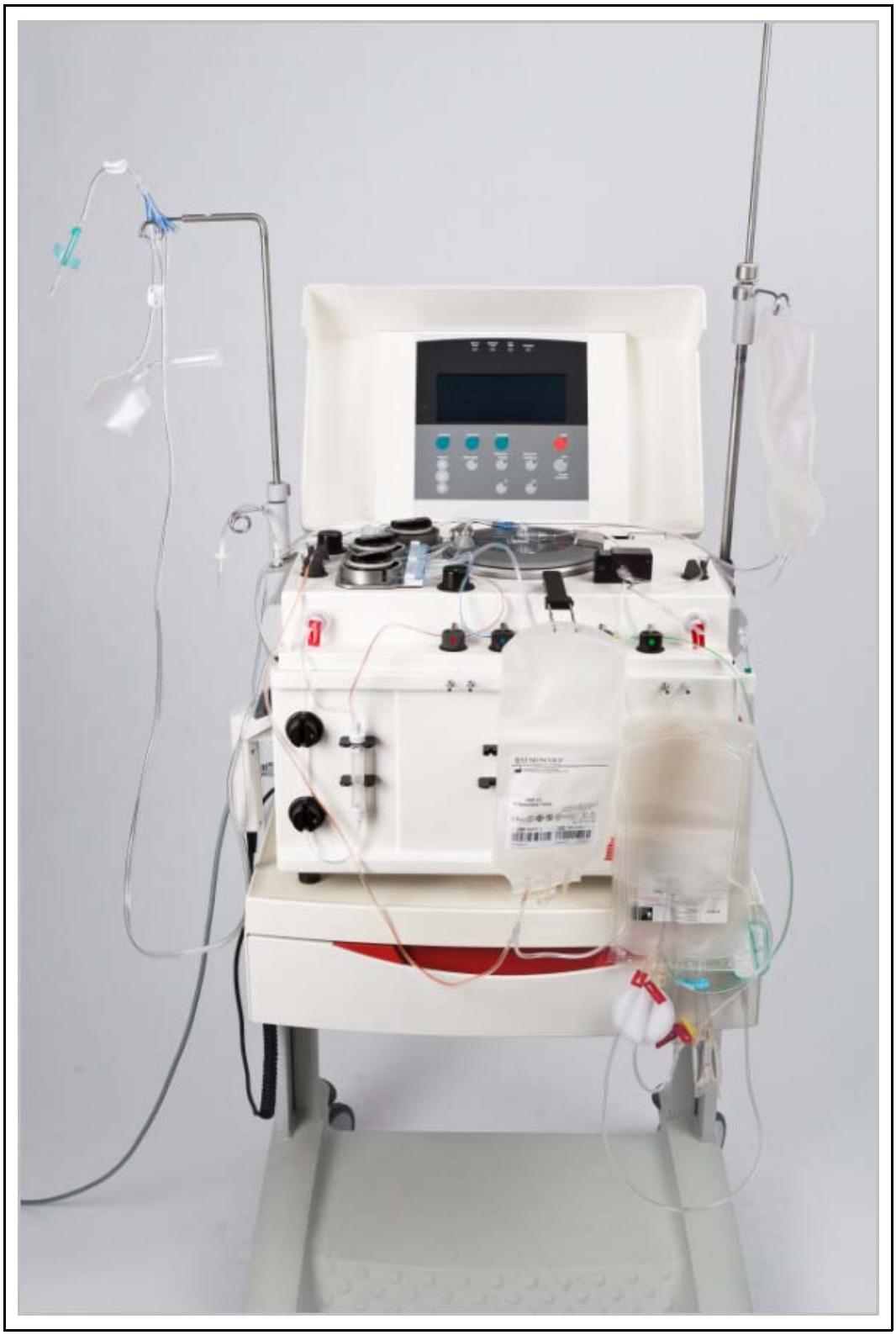

Figure 3-10, 999F-E disposable set, fully installed

Initiate pump autoload

The MCS+ features an automatic pump loading function. Use the following steps to autoload the pumps:

➔ Verify that the pump tubing is properly looped around the pump rotors and passes through the autoload guides of the AC, Transfer and Blood pumps.

Figure 3-11, Preparation for MCS+ pump tubing autoload

➔ Ensure that the clamps on the needle line tubing and donor line sample pouch are closed.

➔ Ensure that the clamp on the DPM line is open.

➔ Press the Draw key to initiate pump tubing autoload.

Once the Draw key has been pressed, the following message appears:

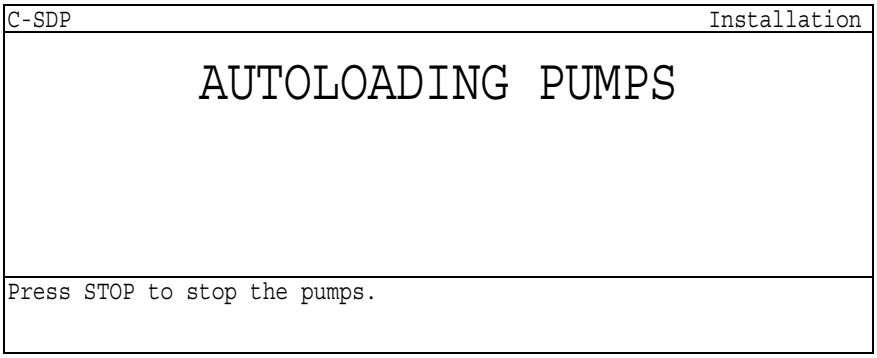

Figure 3-12, Pump autoload screen display

At this point, the pumps rotate to autoload the pump tubing. The recirculation pump rotates until all air is removed from the platelet harness. The centrifuge

bowl spins briefly to test the installation of the disposable bowl.
The STOP key and the Draw key are active.

If the pump tubing has not been satisfactorily loaded:

- ➔ Check that the tubing is correctly installed in the pump and re-install if necessary.
- ➔ Ensure that the clamps on the needle line tubing and donor line sample pouch are closed.
- ➔ Ensure that the clamp on the DPM line is open.
- ➔ Press the Draw key to repeat the autoload sequence.

Caution: *If any abnormality or noise appears during the pump autoload sequence related to the spinning bowl, the operator should:*

- ➔ *Press the STOP key to interrupt the procedure.*
- ➔ *Remove the disposable set entirely and dispose of appropriately.*
- ➔ *Power-off, then power-on the device to initiate a new procedure, using a new disposable set.*

Warning: Do not use any bowl which cannot be properly seated in the centrifuge chuck. Overheating can result and potentially lead to hemolysis.

Chapter 4

Installing the 949FF-E disposable set

INSTALLING THE DISPOSABLE SET 4-2
- Preparing to install the disposable set. 4-2
- Install the bags 4-3
- Install the centrifuge bowl 4-6
- Load all valves and SPM 4-7
- Install the donor and AC lines 4-8
- Install the BLAD, blood filter chamber, DLADs, and DPM 4-9
- Clamp the lines 4-9
- Verify installation 4-10
- Initiate pump autoload 4-12

INSTALLING THE DISPOSABLE SET

The disposable elements are packaged so that the operator may remove each section individually from the tub. With some brief initial preparation, the UPP disposable sets elements can be efficiently installed in the following general order:

- Platelet harness (platelet storage bags and sampling bulbs, pre-filter platelet bag, and air removal pouch)
- Plasma bag
- Air-Intermediate platelet bag
- RBC bags (post-filter RBC bag and RBC sample bag)
- Centrifuge bowl and dual pump manifold
- AC, additive solution, and donor lines
- Blood filter chamber

Preparing to install the disposable set

➔ Inspect the disposable set following the instructions in “Inspecting the disposable material” on page 2-6.

➔ Completely remove the cover from the disposable tub and place the open tub on the top deck of device with the bowl on the right side, near the line sensor and clear valve.

➔ Remove all cold-seal tape from the set as it is installed.

The following keys will be active during installation:

- Press the **Help** key for assistance concerning the installation of each listed element.
- Press the **STOP** key to return to the protocol selection menu, if necessary.

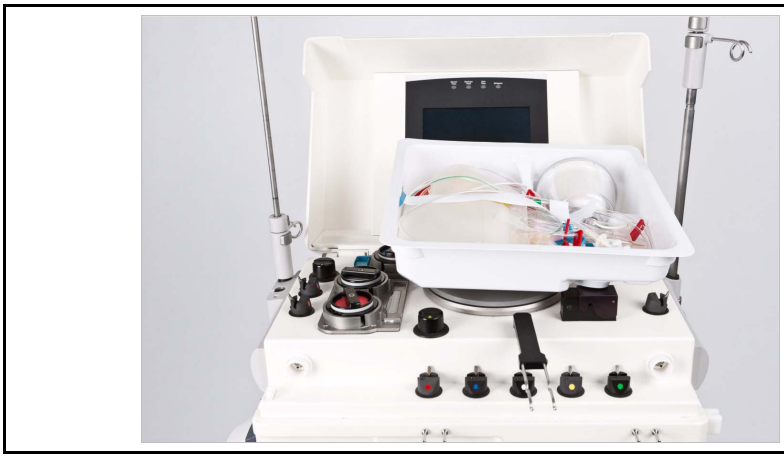

Figure 4-1, Placing the tub on the top deck

Install the bags

➔ Remove the platelet harness from the tub and hang, ports down, on the pins on the right-side of the front panel. The platelet harness is composed of a pre-filter bag, two platelet storage bags with sampling bulbs, a sample pouch, a platelet filter, and the platelet additive solution (PAS) line that ends in a luer lock connection.

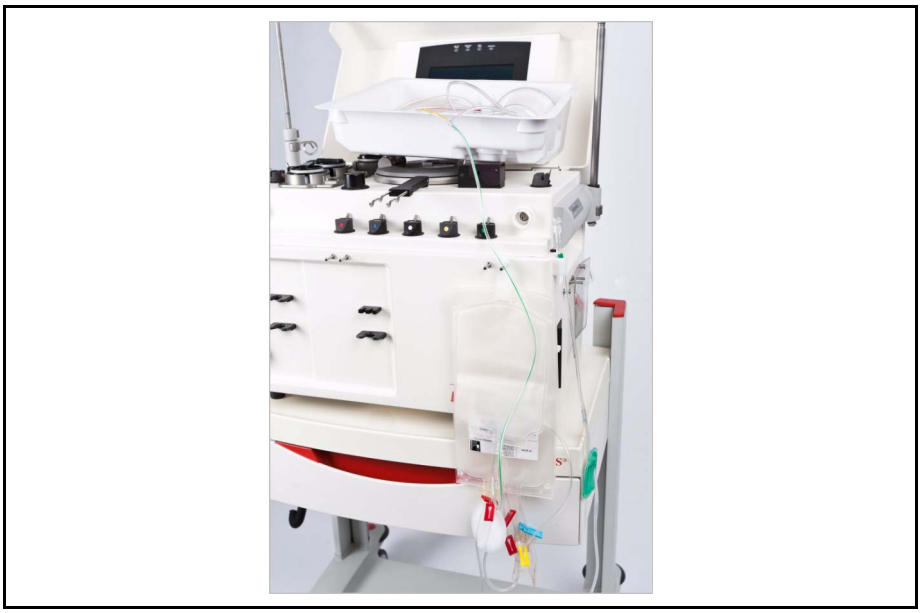

Figure 4-2, Installing the platelet harness

➔ Place the line between the bowl and the platelet filter to the right side of the device, so that it can be easily installed into the green valve later in the installation sequence.

➔ Insert the platelet additive solution (PAS) line into the tubing holder at the top of the right side panel. Ensure that the luer lock connector located on the PAS line rests on the top of the tubing holder.

➔ Remove the plasma bag and hang it on the weigher.

Figure 4-3, Installing the plasma bag or plasma harness

➔ Ensure that the yellow tubing line is on the right side of the weigher arm.

➔ Ensure that the orange and white tubing lines are on the left side of the weigher arm.

➔ Loop the purple line behind the disposable tub so that it is between the tub and the membrane panel.

➔ Hang the Air-Intermediate platelet bag on the middle hook of the right-side solution pole with ports facing down. Ensure that the ports are at the level of the top deck.

Figure 4-4, Installing the Air-Intermediate platelet bag, post-filter RBC bag, and RBC sample bag

➔ Hang the post-filter RBC bag and RBC sample bag on the upper hook of the right-side IV pole with ports facing down.

➔ Once all bags have been removed from the tub, place the open tub against the control panel with the centrifuge bowl in the upper right section.

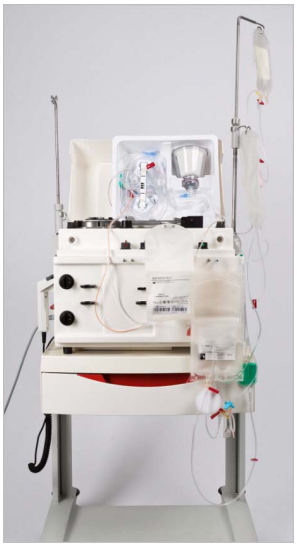

Figure 4-5, Placing the tub in the device cover

Note: The operator is not required to access the keypad during the initial disposable set installation screen display. When the operator has completed an action on this screen, the corresponding text will disappear.

Install the centrifuge bowl

➔ Unlock and open the centrifuge lid.

➔ To remove the bowl and dual pump manifold from the tub:

  ➔ *Remove the bowl by gently pulling the header of the bowl forward and flipping the base of the bowl back and down.*

  ➔ *Remove the dual-pump manifold by gently pulling the top of the manifold forward and down.*

Caution: *Flipping the bowl and the dual-pump manifold in opposite directions prevents the bowl inlet tubing from twisting. Check the bowl inlet tubing to make sure that it is not twisted before proceeding.*

➔ Place the bowl in the centrifuge well with the inlet port facing left. Press down firmly on the head of the bowl to fully seat it in the centrifuge chuck.

Warning: The text "Insert the bowl securely" disappears from the screen once the bowl is placed in the centrifuge chuck. However, the operator must ensure that bowl is securely seated in the chuck.

➔ Loop the dual pump tubing around the Blood (red) and Transfer (white) pumps in preparation for the pump autoload sequence.

➔ Snap the dual pump manifold securely into place above the dual pump housing identification window.

➔ Close and lock the centrifuge lid.

Figure 4-6, Installing the centrifuge bowl

Load all valves and SPM

MCS+ color-coded valves [1. - 8.]

1. Purple
2. Orange
3. Red
4. Blue
5. White
6. Yellow
7. Green
8. Clear

9. AC pump
10. Transfer pump
11. Blood pump
12. Optical line sensor
13. Weigher
14. DPM
15. SPM
16. ACAD
17. BLAD
18. Dual pump ID window

➔ Install the tubing exiting the bowl into the line sensor.

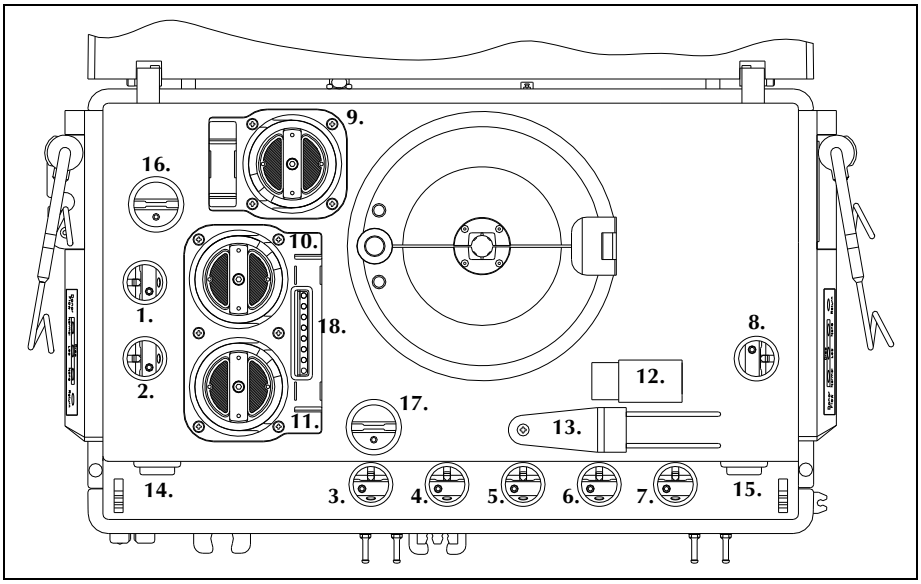

Figure 4-7, MCS+ top deck with color-coded valves

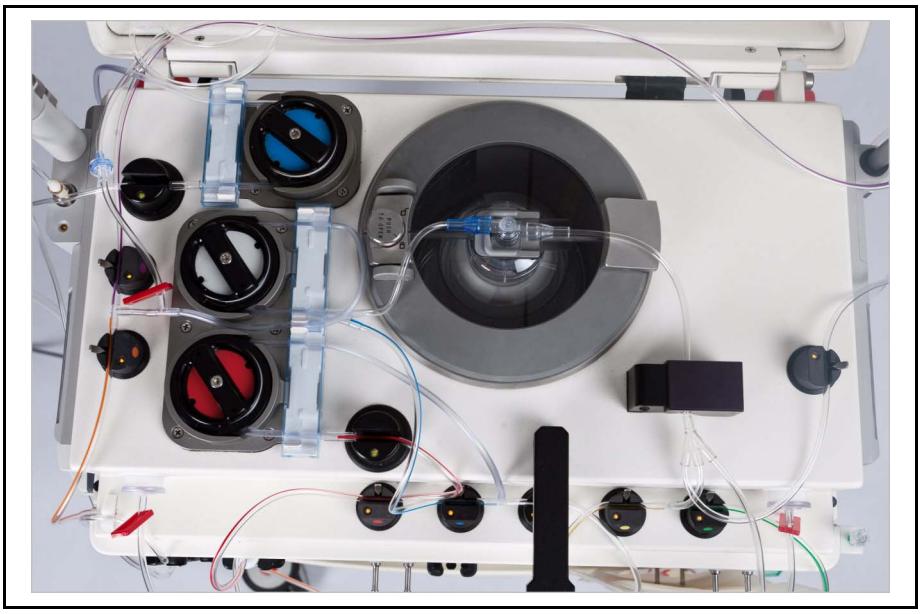

Figure 4-8, Installing the tubing

- ➔ Load the yellow-coded tubing into the yellow valve.
- ➔ Load the green-coded tubing into the green valve.
- ➔ Load the blue-coded tubing into the blue valve.
- ➔ Load the white-coded tubing into the white valve.
- ➔ Load the red-coded tubing exiting the BLAD into the red valve (donor valve).
- ➔ Load the orange-coded tubing into the orange valve.
- ➔ Load the purple-coded tubing into the purple valve.
- ➔ Load the clear tubing leading to the Air-Intermediate platelet bag into the clear valve.
- ➔ Install the SPM. Give the filter a quarter turn to secure the luer connection and tug lightly to verify proper installation.

Warning: Failure to correctly install the filter may result in fluid contacting the filter membrane. Once the filter membrane becomes wet, the pressure monitor can no longer provide an accurate reading. The sterile pathway should be considered compromised, and the product life should be reduced to 24 hours.

Install the donor and AC lines

- ➔ Remove the donor and AC lines from the tub.
- ➔ Snap the single pump manifold into place and loop the AC tubing around the AC pump.

- ➔ Install the AC solution line tubing exiting the single pump manifold into the ACAD.
- ➔ Remove the paper tab from the donor needle tubing section and unroll the tubing.
- ➔ Clamp the donor line sample pouch and the donor needle tubing.
- ➔ Remove the empty disposable tub from the MCS+ cover and recycle or discard according to standard operating procedure.

Install the BLAD, blood filter chamber, DLADs, and DPM

- ➔ Install the red-coded tubing into the BLAD.
- ➔ Install the blood filter chamber in the filter holders on the front panel.
- ➔ Install the colorless tubing exiting the blood filter chamber into the two DLADs by passing the tubing first through the DLAD2 (bottom) and then through the DLAD1 (top).
- ➔ Install the tubing exiting the DLAD1 into the tubing guide.
- ➔ Install the DPM. Give the filter a quarter turn to secure the luer connection and tug lightly to verify proper installation.

Warning: Failure to correctly install the filter may result in fluid contacting the filter membrane. Once the filter membrane becomes wet, the pressure monitor can no longer provide an accurate reading.

Clamp the lines

Platelet harness

Depending on the platelet filtration method, two options exist for clamping the lines on the platelet harness:

- **For platelets in plasma, or immediate filtration of concentrated platelets:** close all clamps on the platelet harness, except for the clamp on the Air-platelet bag and the clamp on one of the platelet storage bags.
- **For concentrated platelets suspended in additive solution prior to leuko-reduction:** close all clamps on the platelet harness.

Haemonetics recommends verifying that the platelet yield is above $5x10^{11}$ before dividing the platelets into two bags.

Haemonetics recommends opening the clamps on both platelet storage bags if a platelet yield of $6x10^{11}$ or above is targeted.

RBC harness

- ➔ Close all clamps on the RBC harness.
- ➔ Close the clamp on the RBC sample bag. Ensure the clamp is closed as close to theY-connector as possible.

➔ Close the clamp between the Air-Intermediate platelet and RBC bag and the RBC filter as close to the bag as possible.

Donor line

➔ Close the clamp on the needle line.

➔ Close the clamp on the donor line sample pouch.

Verify installation

Once all of the listed elements are installed, a version of the following message appears:

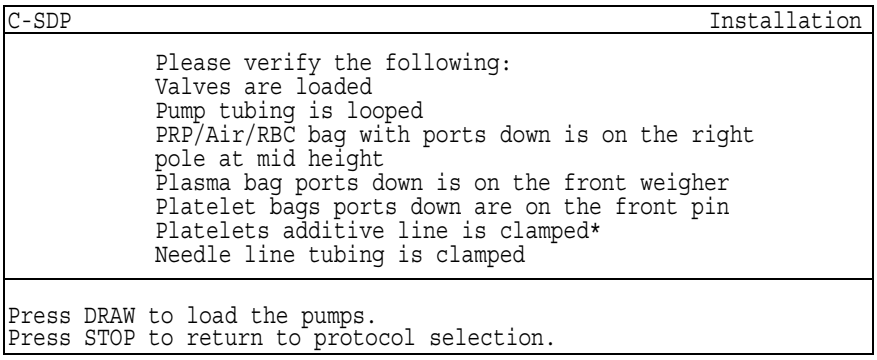

Figure 4-9, Loading confirmation screen

*Only appears for C-SDP or RBC procedures

➔ Visually inspect all of the listed elements and ensure that all actions are complete, prior to proceeding with the pump autoload sequence.

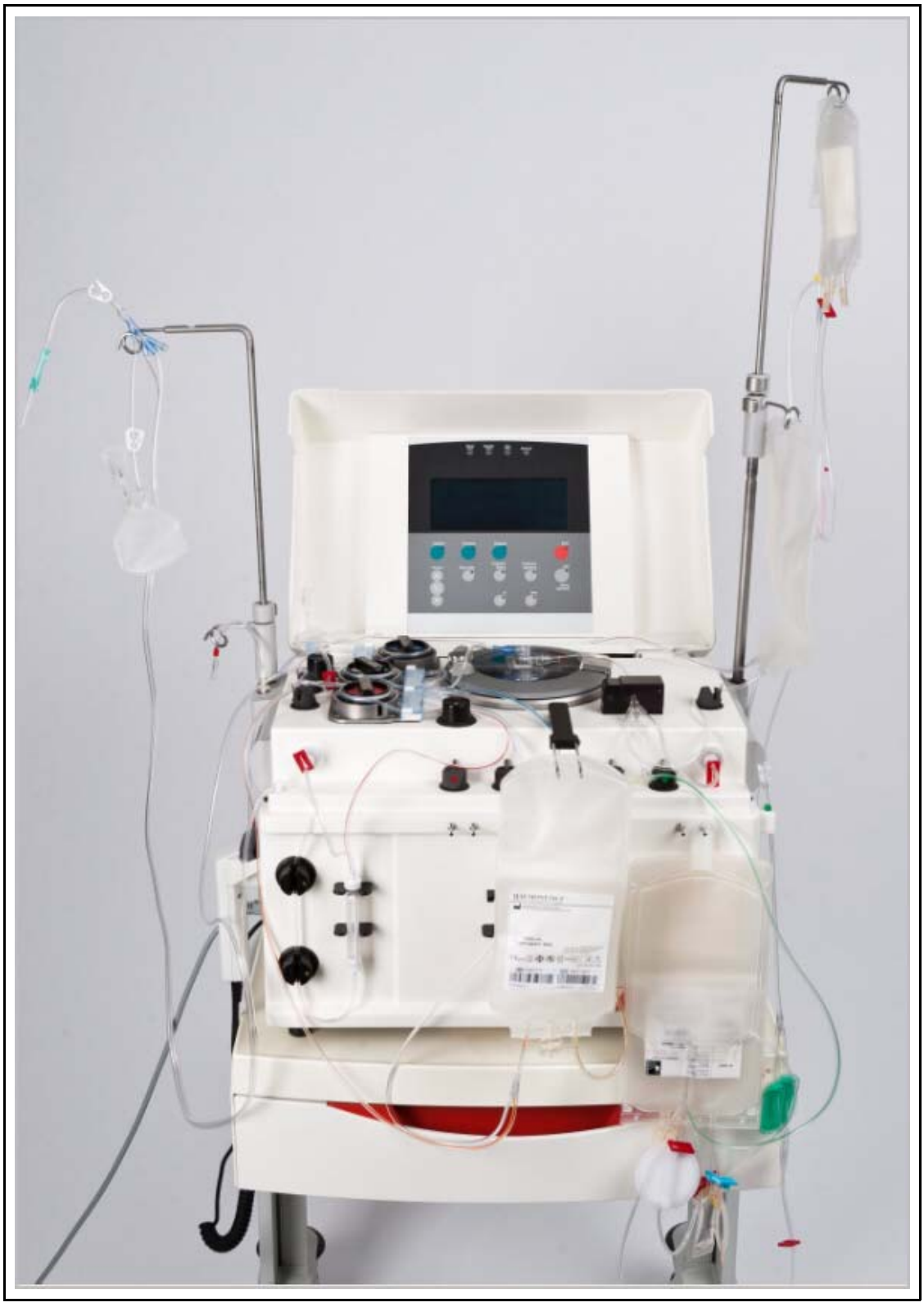

Figure 4-10, 949FF-E disposable set, fully installed

Initiate pump autoload

The MCS+ features an automatic pump loading function. Use the following steps to autoload the pumps:

➔ Verify that the pump tubing is properly looped around the pump rotors and passes through the autoload guides of the AC, Transfer and Blood pumps.

Figure 4-11, Preparation for MCS+ pump tubing autoload

➔ Ensure that the clamps on the needle line tubing and donor line sample pouch are closed.

➔ Ensure that the clamp on the DPM line is open.

➔ Press the Draw key to initiate pump tubing autoload.

Once the Draw key has been pressed, the following message appears:

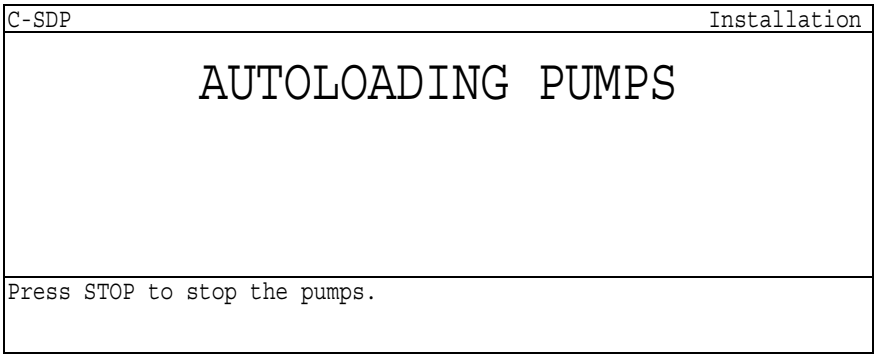

Figure 4-12, Pump autoload screen display

At this point, the pumps rotate to autoload the pump tubing. The recirculation pump rotates until all air is removed from the platelet harness. The centrifuge

bowl spins briefly to test the installation of the disposable bowl.
The STOP key and the Draw key are active.

If the pump tubing has not been satisfactorily loaded:

- ➔ Check that the tubing is correctly installed in the pump and re-install if necessary.
- ➔ Ensure that the clamps on the needle line tubing and donor line sample pouch are closed.
- ➔ Ensure that the clamp on the DPM line is open.
- ➔ Press the Draw key to repeat the autoload sequence.

Caution: *If any abnormality or noise appears during the pump autoload sequence related to the spinning bowl, the operator should:*

- ➔ *Press the STOP key to interrupt the procedure.*
- ➔ *Remove the disposable set entirely and dispose of appropriately.*
- ➔ *Power-off, then power-on the device to initiate a new procedure, using a new disposable set.*

Warning: Do not use any bowl which cannot be properly seated in the centrifuge chuck. Overheating can result and potentially lead to hemolysis.

Chapter 5

Installing the 997CF-E disposable set

INSTALLING THE DISPOSABLE SET 5-2
- Preparing to install the disposable set. 5-2
- Install the bags 5-3
- Install the centrifuge bowl 5-5
- Load all valves and SPM 5-6
- Install the donor and AC lines 5-7
- Install the BLAD, blood filter chamber, DLADs, and DPM 5-8
- Clamp the lines 5-8
- Verify installation 5-9
- Initiate pump autoload 5-11

INSTALLING THE DISPOSABLE SET

The disposable elements are packaged so that the operator may remove each section individually from the tub. With some brief initial preparation, the UPP disposable sets elements can be efficiently installed in the following general order:

- Platelet harness (platelet storage bags and sampling bulbs, platelet reservoir bag, and air removal pouch)
- Plasma bag
- Air bag
- Centrifuge bowl and dual pump manifold
- AC, saline, and donor lines
- Blood filter chamber

Preparing to install the disposable set

➔ Inspect the disposable set following the instructions in "Inspecting the disposable material" on page 2-6.

➔ Completely remove the cover from the disposable tub and place the open tub on the top deck of device with the bowl on the right side, near the line sensor and clear valve.

➔ Remove all cold-seal tape from the set as it is installed.

The following keys will be active during installation:

- Press the **Help** key for assistance concerning the installation of each listed element.
- Press the **STOP** key to return to the protocol selection menu, if necessary.

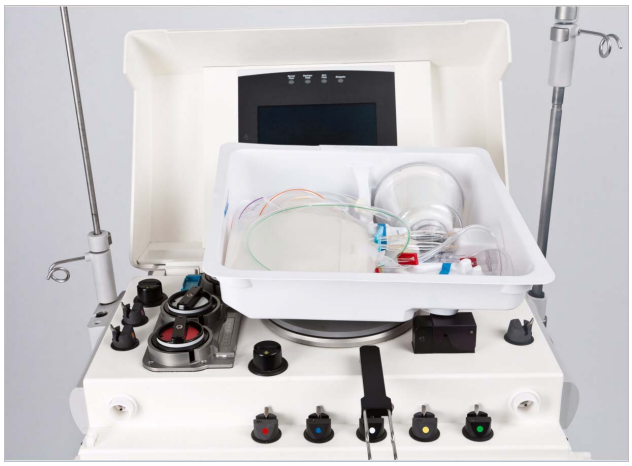

Figure 5-1, Placing the tub on the top deck

Install the bags

➔ Remove the platelet harness from the tub and hang, ports down, on the pins on the right-side of the front panel. The platelet harness is composed of a platelet reservoir bag, two platelet storage bags with sampling bulbs, an air removal pouch, and a platelet filter.

Figure 5-2, Installing the platelet harness

➔ Place the line between the bowl and the platelet filter to the right side of the device, so that it can be easily installed into the green valve later in the installation sequence.

➔ Hang the air bag on the middle hook of the right side solution pole with ports facing down. Ensure that the ports are at the level of the top deck.

➔ Remove the plasma bag and hang it on the weigher.

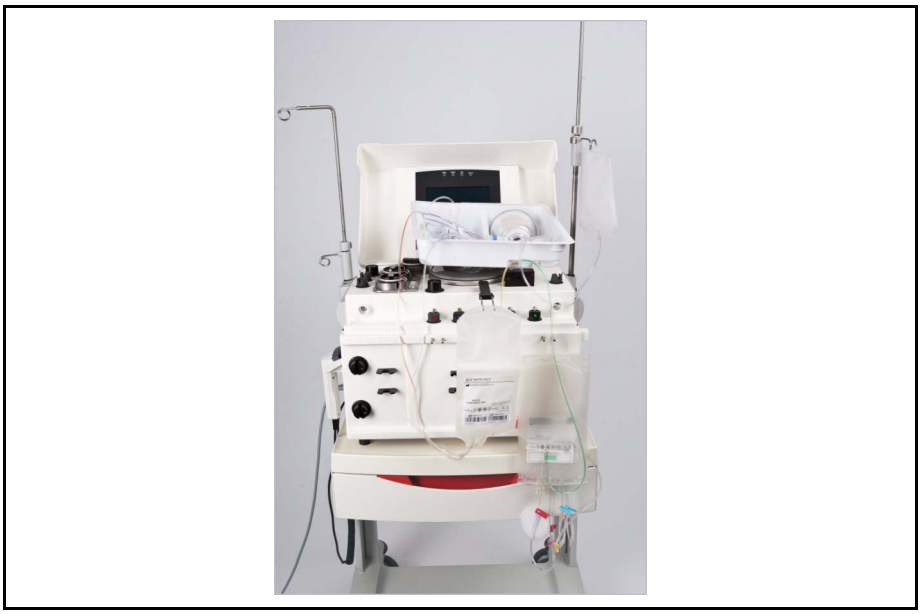

Figure 5-3, Installing the plasma bag or plasma harness

➔ Ensure that the yellow tubing line is on the right side of the weigher arm.

➔ Ensure that the orange and white tubing lines are on the left side of the weigher arm.

➔ Once all bags have been removed from the tub, place the open tub against the control panel with the centrifuge bowl in the upper right section.

Figure 5-4, Placing the tub in the device cover

➔ Remove the purple saline line from the tub and temporarily place it on the left-side IV pole.

Note: The operator is not required to access the keypad during the initial disposable set installation screen display. When the operator has completed an action on this screen, the corresponding text will disappear.

Install the centrifuge bowl

➔ Unlock and open the centrifuge lid.

➔ To remove the bowl and dual pump manifold from the tub:

- ➔ *Remove the bowl by gently pulling the header of the bowl forward and flipping the base of the bowl back and down.*
- ➔ *Remove the dual-pump manifold by gently pulling the top of the manifold forward and down.*

Caution: *Flipping the bowl and the dual-pump manifold in opposite directions prevents the bowl inlet tubing from twisting. Check the bowl inlet tubing to make sure that it is not twisted before proceeding.*

➔ Place the bowl in the centrifuge well with the inlet port facing left. Press down firmly on the head of the bowl to fully seat it in the centrifuge chuck.

Warning: The text "Insert the bowl securely" disappears from the screen once the bowl is placed in the centrifuge chuck. However, the operator must ensure that bowl is securely seated in the chuck.

➔ Loop the dual pump tubing around the Blood (red) and Transfer (white) pumps in preparation for the pump autoload sequence.

➔ Snap the dual pump manifold securely into place above the dual pump housing identification window.

➔ Close and lock the centrifuge lid.

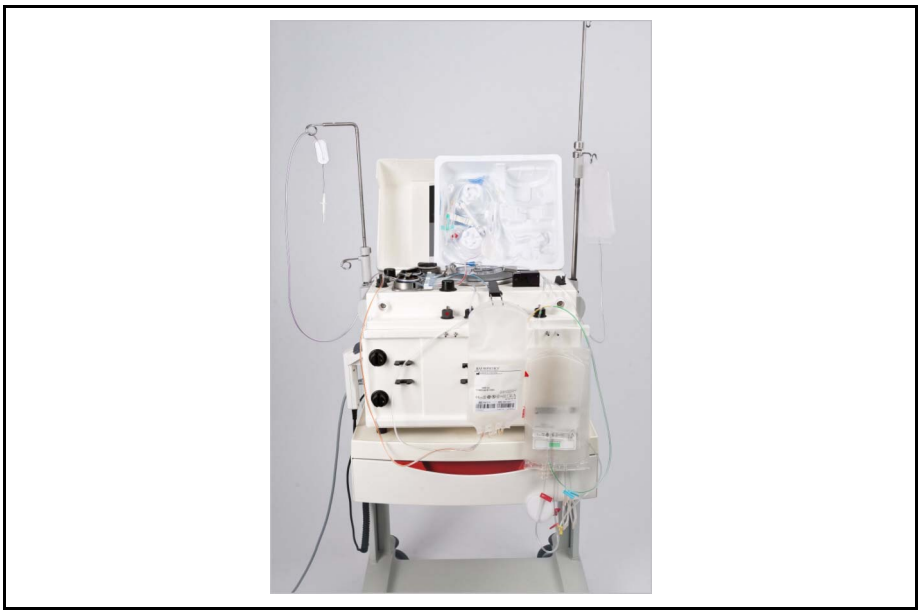

Figure 5-5, Installing the centrifuge bowl

Load all valves and SPM

MCS+ color-coded valves [1. - 8.]

1. Purple
2. Orange
3. Red
4. Blue
5. White
6. Yellow
7. Green
8. Clear

9. AC pump
10. Transfer pump
11. Blood pump
12. Optical line sensor
13. Weigher
14. DPM
15. SPM
16. ACAD
17. BLAD
18. Dual pump ID window

➔ Install the tubing exiting the bowl into the line sensor.

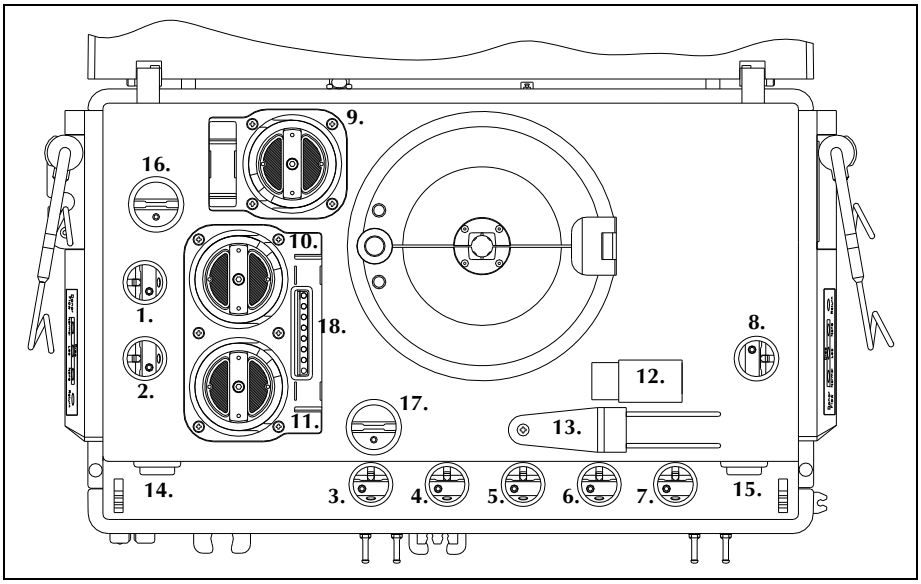

Figure 5-6, MCS+ top deck with color-coded valves

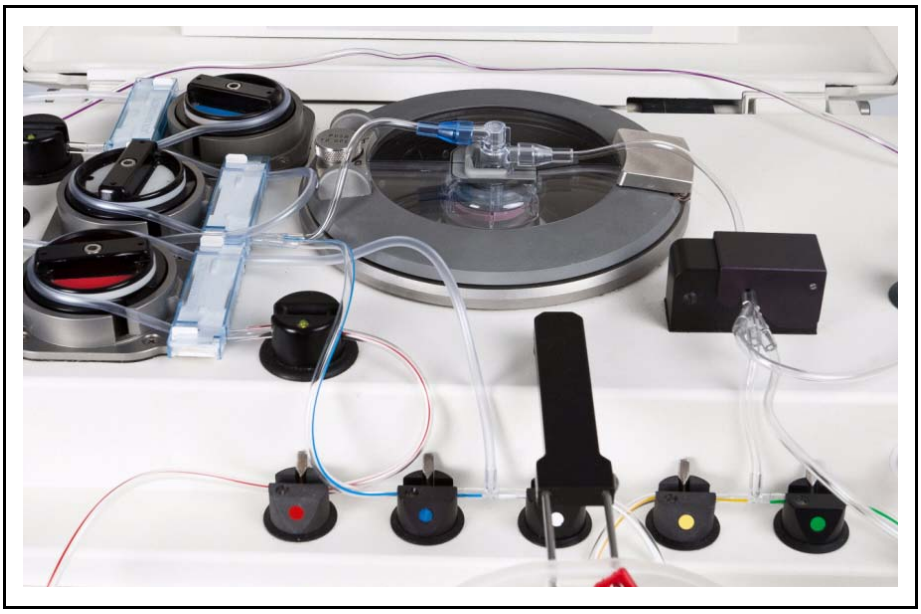

Figure 5-7, Installing the tubing

- ➔ Load the yellow-coded tubing into the yellow valve.
- ➔ Load the green-coded tubing into the green valve.
- ➔ Load the blue-coded tubing into the blue valve.
- ➔ Load the white-coded tubing into the white valve.
- ➔ Load the red-coded tubing exiting the BLAD into the red valve (donor valve).
- ➔ Load the orange-coded tubing into the orange valve.
- ➔ Load the purple-coded tubing into the purple valve.
- ➔ Load the clear tubing leading to the air bag into the clear valve.
- ➔ Install the SPM. Give the filter a quarter turn to secure the luer connection and tug lightly to verify proper installation.

Warning: Failure to correctly install the filter may result in fluid contacting the filter membrane. Once the filter membrane becomes wet, the pressure monitor can no longer provide an accurate reading. The sterile pathway should be considered compromised, and the product life should be reduced to 24 hours.

Install the donor and AC lines

- ➔ Remove the donor and AC lines from the tub.
- ➔ Snap the single pump manifold into place and loop the AC tubing around the AC pump.

- ➔ Install the AC solution line tubing exiting the single pump manifold into the ACAD.
- ➔ Remove the paper tab from the donor needle tubing section and unroll the tubing.
- ➔ Hang the donor needle tubing section over the left IV pole.
- ➔ Clamp the donor line sample pouch and the donor needle tubing.
- ➔ Remove the empty disposable tub from the MCS+ cover and recycle or discard according to standard operating procedure.
- ➔ Move the purple saline line to the right IV pole.

Install the BLAD, blood filter chamber, DLADs, and DPM

- ➔ Install the red-coded tubing into the BLAD.
- ➔ Install the blood filter chamber in the filter holders on the front panel.
- ➔ Install the colorless tubing exiting the blood filter chamber into the two DLADs by passing the tubing first through the DLAD2 (bottom) and then through the DLAD1 (top).
- ➔ Install the tubing exiting the DLAD1 into the tubing guide.
- ➔ Install the DPM. Give the filter a quarter turn to secure the luer connection and tug lightly to verify proper installation.

Warning: Failure to correctly install the filter may result in fluid contacting the filter membrane. Once the filter membrane becomes wet, the pressure monitor can no longer provide an accurate reading.

Clamp the lines

Platelet harness

- ➔ Close the slide clamps to the platelet sampling bulbs.
- ➔ Close the slide clamp to the air removal pouch.

Haemonetics recommends verifying that the platelet yield is above $5x10^{11}$ before dividing the platelets into two bags.

Haemonetics recommends opening the clamps on both platelet storage bags if a platelet yield of $6x10^{11}$ or above is targeted.

Donor line

- ➔ Close the clamp on the needle line.
- ➔ Close the clamp on the donor line sample pouch.

Verify installation

Once all of the listed elements are installed, a version of the following message appears:

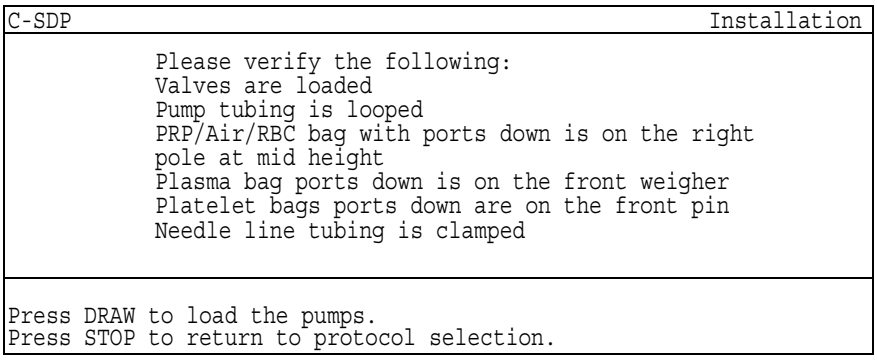

Figure 5-8, Loading confirmation screen

➔ Visually inspect all of the listed elements and ensure that all actions are complete, prior to proceeding with the pump autoload sequence.

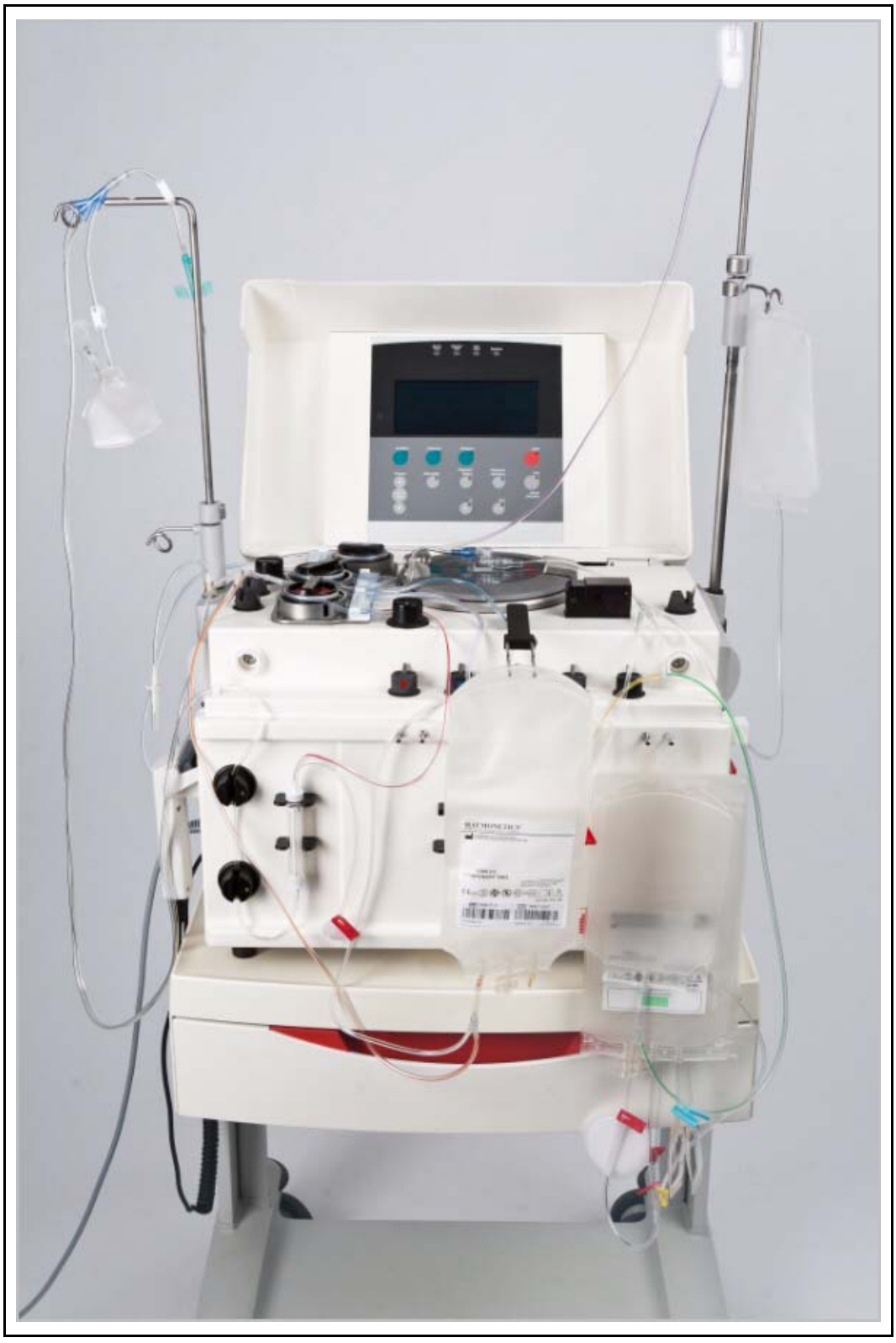

Figure 5-9, 997CF-E disposable set, fully installed

Initiate pump autoload

The MCS+ features an automatic pump loading function. Use the following steps to autoload the pumps:

➔ Verify that the pump tubing is properly looped around the pump rotors and passes through the autoload guides of the AC, Transfer and Blood pumps.

Figure 5-10, Preparation for MCS+ pump tubing autoload

➔ Ensure that the clamps on the needle line tubing and donor line sample pouch are closed.

➔ Ensure that the clamp on the DPM line is open.

➔ Press the Draw key to initiate pump tubing autoload.

Once the Draw key has been pressed, the following message appears:

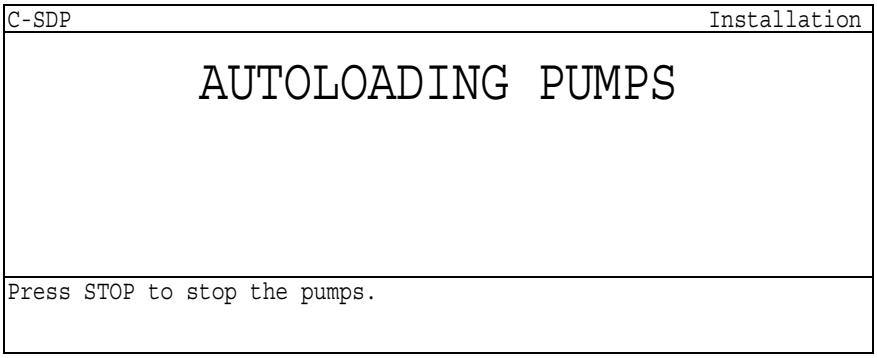

Figure 5-11, Pump autoload screen display

At this point, the pumps rotate to autoload the pump tubing. The recirculation pump rotates until all air is removed from the platelet harness. The centrifuge

bowl spins briefly to test the installation of the disposable bowl.
The STOP key and the Draw key are active.

If the pump tubing has not been satisfactorily loaded:

- ➔ Check that the tubing is correctly installed in the pump and re-install if necessary.
- ➔ Ensure that the clamps on the needle line tubing and donor line sample pouch are closed.
- ➔ Ensure that the clamp on the DPM line is open.
- ➔ Press the Draw key to repeat the autoload sequence.

Caution: *If any abnormality or noise appears during the pump autoload sequence related to the spinning bowl, the operator should:*

- ➔ *Press the STOP key to interrupt the procedure.*
- ➔ *Remove the disposable set entirely and dispose of appropriately.*
- ➔ *Power-off, then power-on the device to initiate a new procedure, using a new disposable set.*

Warning: Do not use any bowl which cannot be properly seated in the centrifuge chuck. Overheating can result and potentially lead to hemolysis.

Chapter 6

Priming the disposable set

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Preparing the AC solution line 6-3
Preparing the saline solution line 6-3
Initiating the priming sequence 6-4
The READY state 6-5

PRIMING THE DISPOSABLE SET

Once the pumps are loaded, the following screen appears:

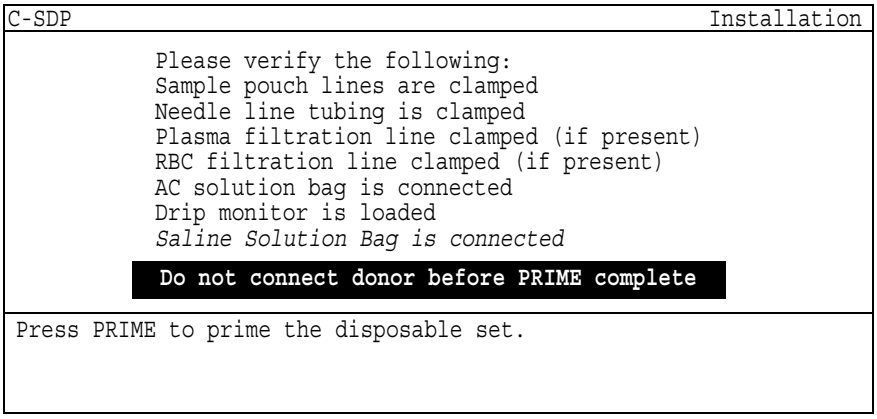

Figure 6-1, Example of a pre-priming installation screen display

The last line only appears if the operator selects saline as an option.

To complete the installation of the disposable set, set up the saline and AC solution bags and initiate prime. The MCS+ device features an automatic disposable set priming sequence.

Warning: Haemonetics advises priming the disposable set immediately prior to performing the donor venipuncture. The Venipuncture MUST not be performed before the AC priming is complete.

Caution: *The operator must ensure that the platelet sample pouch and donor sample pouch lines have been clamped before continuing. Failure to clamp the platelet sample pouch line introduces the risk that any air displaced from the reservoir bag could block the platelet filter and inhibit complete filtration of the final platelet product.*

Preparing the solution bags

The UPP protocol requires the following solution bags:

- One 500 ml or 750 ml ACDA bag
- *If concentrated platelets are collected:* one 500 ml bag of platelet additive solution (PAS).
- *If a RBC unit is collected:* one 140 ml bag of SAGM solution

The donor's blood is anticoagulated with ACDA in a 1:9 ratio of anticoagulant to whole blood. In concentrated platelet procedures, a small amount of ACDA (approximately 6% of the pre-concentration platelet volume) is added to the platelets in the Air-Intermediate platelet bag prior to concentration.

The bag of SAGM and bag of PAS are not connected to the set until the end of the collection procedure, as part of the automated procedure for completing platelet and RBC products (leuko-reduction and suspension in storage solution).

Preparing the AC solution line

Use the following steps to prepare the AC solution lines:

- ➔ Hang the ACDA solution bag on the upper hook of the **left** solution pole.
- ➔ Adjust the height of the left pole according to the size of ACDA solution bag used. *The larger the volume of ACDA solution used, the higher the pole should be raised.*
- ➔ Connect the ACDA solution bag to the anticoagulant line connector.
- ➔ Verify correct installation of the set in the AC pump.
- ➔ If present, break the frangible seal in the ACDA solution bag.
- ➔ Draw fluid into the AC drip chamber by squeezing it until it is partially filled.
  The level of ACDA solution in the drip chamber should not exceed 5 mm.

Caution: *If the drip chamber is overfilled, this could affect the readings of the optical sensor in the AC drip monitor. The operator should remove the ACDA bag from the solution pole, invert the bag and squeeze the drip chamber, directing some of the ACDA solution into the ACDA solution bag.*

- ➔ Install the AC drip chamber by sliding it through the top of the AC drip monitor housing until it is completely seated and resting on the base of the housing.

Preparing the saline solution line

When performing a collection procedure using a saline compensation solution, the saline line priming sequence occurs prior to the AC solution line priming sequence.

Note: If it becomes necessary to manually enable saline compensation during a procedure, saline solution will be pumped into the bowl at the beginning of the subsequent Return cycle.

Use the following steps to prepare the saline compensation line:

- ➔ Spike the saline solution bag onto the compensation line using local standard operating procedures.
- ➔ Hang the saline solution bag on the upper hook of the **right** solution pole.

Caution: *Ensure that the purple compensation line was used to spike the saline solution bag by visually following the saline tubing from the bag to the dual pump manifold.*

Initiating the priming sequence

➔ Press the Prime key to initiate the automatic priming sequence once the correct installation of all of the listed items is verified.

The Prime sequence automatically prepares the disposable set with AC solution.

Note: The operator may press the STOP key to stop the pumps from rotating and interrupt the priming sequence if necessary.

Simultaneous rotations of the Blood and AC pumps prime the AC line, the donor line, and the line between the dual-pump manifold and one of the following bags:

- Air-Intermediate platelet bag (LN 999FF-E, or 999FF-P)
- Air-Intermediate platelet and RBC bag (LN 949FF-E or 949FF-P)

In C-SDP procedures the device continues to pump AC solution until the bag is primed with enough AC for the default number of cycles (usually five cycles).

After the device transfers enough AC solution into the Air bag, the display screen displays the HaemoCalculator screen.

➔ Use the Haemo Calculator menu to provide the donor characteristics, product targets and other current procedure information.

See *Chapter 7, Protocol Parameters* for information on the Haemo Calculator, Haemo Update and Modify Parameters settings.

Note: When using an MCS+ device equipped with a bar-code reader, the operator can use the reader to enter certain information at this point. Descriptions of the data acquisition features and information sequence are available in the MCS+ device Operation Manual.

➔ Press the PRIME key to complete the priming sequence.

Based on the donor characteristics and procedure information provided, the device estimates the number of cycles necessary to complete the procedure.

If the number of cycles required for the procedure remains at the default number, the system proceeds to the READY state.

If the procedure requires more than the default number of cycles, the device will transfer additional AC solution to the Air-Intermediate platelet (Air-Intermediate platelet and RBC) bag to provide enough AC solution for the entire procedure. When the device finishes transferring the AC solution the system proceeds to the READY state.

The READY state

After the operator enters the Haemo Calculator parameters, the system enters the Ready state.

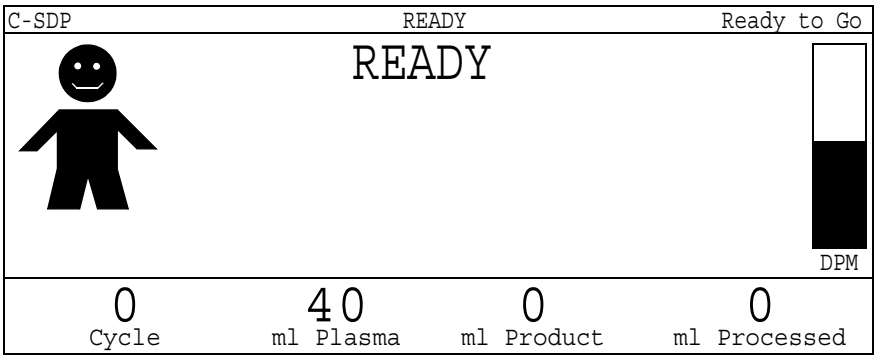

Figure 6-2, Example of the READY mode screen display

The READY screen display indicates that the first Draw cycle can be initiated.

The operator can choose among the following options:

- ➔ Press the Draw key to initiate the first collection cycle.
- ➔ Press the Modify key to access the Modify Parameters menu and adjust additional procedure parameters. See *Chapter 7, The Modify Parameters menu* section for further information.

Chapter 7

Protocol Parameters

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THE HAEMO CALCULATOR MENU

The Haemo Calculator menu automatically appears at the end of PRIME. The Haemo Calculator menu may also be accessed by pressing the Help key when viewing the Haemo Update display.

Note: The HaemoCalculator is not accessible during certain phases of DRAW, Dwell, Surge, and RETURN.

```
C-SDP                                  STOP
Cycle 0                  0 Product Volume              0 ml Processed

                    HAEMO CALCULATOR

Sex                              M      Target Plasma Vol        0 ml
Height                         170 cm   Target RBC Volume        0
Weight                          65 kg   *Target Yield          4.0 10e11
Blood Volume                  4550 ml   Target Cycles            8
HCT                             40 %    Target Duration        115 min
Plt Pre-Count                  250 10e3 Expected Plt Vol       325 ml
Plt Post-Count                 250 10e3 Expected Doses           1

        Estimated Platelet Yield is outside configured range
Press MODIFY to select, +/- to change values.
Press SAVE to save right column values.
Press HELP to return to main display.
```

Figure 7-1, Example of the Haemo Calculator menu

Modify the Haemo Calculator settings based on specific donor characteristics and collection needs. Once the individual donor parameters are entered, the Haemo Calculator estimates the total blood volume to be processed for the specified donor. All measurements of volume are expressed in milliliters (ml).

The donor hematocrit should be entered according to pre-donation blood sampling results. The Haemo Calculator uses the donor hematocrit to predict the number of cycles required to attain the procedure targets, until the MCS+ device can determine the hematocrit of the anticoagulated whole blood entering the bowl. In addition, the device uses this determined value to maintain the critical flow (optimal conditions for the separation of the blood components in the bowl during the DRAW mode).

A warning appears if the estimated yield or estimated product volume is outside a configured range. The operator should change the Target yield or Target doses to resolve the warning. If it is not possible to change the Target yield or doses then the donor does not qualify for the procedure.

The minimum and maximum for product volume and yield are determined by configuration parameters. Contact your Haemonetics representative if you wish to make changes to these limits. The initial DRAW sequence cannot be initiated if a warnings for either of these parameters is displayed.

Donor parameters

Enter the individual donor parameters to customize the UPP procedure for each donor.

- **Sex** is the gender of the donor expressed as (F) female or (M) male.
- **Height** is the height of the donor expressed in centimeters (cm).
- **Weight** is the weight of the donor expressed in kilograms (kg).
- **Blood Volume** is the estimated total blood volume of the donor. This volume is automatically calculated by the Haemo Calculator, based on the donor characteristics, as entered by the operator.

Note: The calculation is made according to the equations provided in the AABB Technical Manual (13th edition, page 757).

- **HCT** is the hematocrit of the donor as determined by a pre-procedure blood sample, expressed as a percentage.
- **Platelet Pre-Count** is the amount of platelets contained in a specific quantity of donor whole blood, as determined by a pre-donation sample. The Haemo Calculator uses this measurement to determine the total volume of anticoagulated whole blood necessary to process in order to collect the programmed target yield of platelets.

Caution: *If a current donor platelet pre-count is not available, a previously recorded value may be used, although it will affect the reliability of the Haemo Calculator estimation. The pre-count may be changed at any point during the procedure.*

- **Platelet Post-Count** is an estimate of the concentration of platelets remaining in the donor's blood after the collection procedure is complete. The device calculates this value using the donor parameters and the product and procedure targets.

  The device prevents the post-count from decreasing below a programmed limit by restricting the maximum allowable product and procedure target values. If the operator attempts to set a procedure target that would cause the post-count to decrease below the programmed limit, the device displays an error message and automatically restricts the procedure target.

Product and procedure targets

The Haemo Calculator screen displays collection product and procedure duration values. The default settings can be modified by the operator for each procedure to reflect individual donor characteristics and collection needs.

Note: The MCS+ device automatically converts the plasma weight to volume using the accepted conversion factor of 1.026 g/ml.

- **Target Plasma Volume** is the quantity of anticoagulated plasma to be collected with the platelet concentrate, expressed in ml. The setting is 0 if concurrent plasma collection has not been selected. The MCS+ device will not collect more than the maximum allowable volume of combined plasma and platelets.
- **Target RBC Volume** is the post-filtration quantity of red cell concentrate (including residual plasma) to be collected concurrent with the platelet concentrate, expressed in ml. The setting is 0 if RBC collection has not been selected. The MCS+ device will not collect more than the maximum allowable volume of combined RBCs and platelets.
- **Expected Doses** indicates the number of platelet doses to be collected. The device automatically calculates this value using the donor parameters and the product and procedure targets. 1 = single dose; 2 = double dose.
- **Expected Platelet Volume** is the estimated total product volume (platelets in plasma + additive solution) collected at the end of a procedure. The estimated product volume for procedures without additive solution is equal to the platelet volume.

The operator can modify one of the following parameters to specify the platelet target. The system estimates the other two parameters and updates them if any relevant parameters change during the procedure.

- **Target Yield** is the quantity of platelets to be collected during the procedure.
- **Target Cycles** is the number of cycles calculated as necessary to complete the collection procedure, based on the donor parameters and procedure information entered into the Haemo Calculator.
- **Target Duration** is the approximate time required to complete the current procedure, expressed in minutes. The time depends on the donor hematocrit and donor blood flow rates. The operator can also define a limit to the duration of the procedure by entering a maximum accepted time. The Haemo Calculator then provides a prediction of the Target Yield possible within this time span.

Note: The maximum combined product volume that can be collected in a procedure is limited by the maximum total product volume calculated by the device, which depends on specific donor profiles.This limitation affects the estimated platelets product volume and yield displayed in the Haemo Calculator screen, as well as in the controlled RBC and plasma targets displayed in the Haemo Update screen.

The maximum volume of plasma that can be collected concurrently with the platelets may also be limited by the ECV limit configured in the device. When it is necessary to sequester plasma prior to the last cycle in order to meet the targeted plasma volume, the UPP software prevents this from happening if the estimated donor ECV would exceed the maximum allowed ECV configured in the device. Consequently, the plasma target might not be reached in such cases.

Adjusting the Haemo Calculator values

Use the following steps to enter the donor and procedure parameters for the current collection procedure:

- ➔ Press the Modify key to scroll through the parameter list.
- ➔ Press the + and – keys to increase (+) or decrease (–) the value highlighted on the screen.
- ➔ Press the Save key to retain the modified values in the right column in the MCS+ memory. Use the Operator Configuration parameters Donor menu (*Appendix B*) to save all parameters listed in the left column.

Table 7-1, Configurable settings for the Haemo Calculator menu

Parameter	Unit of measure	Default value	Range of values	Increment of change
Sex	*Values listed in "Parameter reference information" on page 7-10*			
Height				
Weight				
HCT				
Plt Pre-Count				
Target Plasma Vol	ml	0 or 225	0-999	5
Target RBC Vol	ml	0 or 180	0 or 160-223[1]	5
Expected Doses	–	1	1 or 2	1
Target Yield	10e11	3.0	0.5-9.9	0.1
Target Cycles	–	calculated	1-15	1
Target Duration	min	calculated	10-180	5

[1]The maximum value depends on the programmed loss in filtration.

End of procedure criteria

When the operator modifies either the Target Yield, Target Cycles or Target Duration, an asterisk (*) appears on screen to indicate that this is the selected target. The MCS+ device uses this value to determine the end of the collection procedure.

The system checks the selected target at the start of each Return cycle to determine if it is the final cycle.

Table 7-2, Summary of end of procedure criteria for an C-SDP protocol

Selected target parameter	Last cycle if:
Target Yield	The estimated platelet yield equals or surpasses the target yield.
Target Cycles	The current cycle equals the Target Cycle value.
Target Duration	The time remaining before passing the target is less than half of the time needed for a full cycle.

THE HAEMO UPDATE MENU

The Haemo Update screen display lists the most recently calculated values of the current collection procedure.

```
C-SDP                                STOP
Cycle 0                  0 Product Volume          0 ml Processed

                        HAEMO UPDATE

Ctrl Tgt Plasma          0 ml      Plasma Volume          0 ml
Ctrl Tgt RBC Vol         0 ml      Platelets Volume       0 ml
AC Volume Used          28 ml      Plt Additive Vol       0 ml
DURATION                 0 min     Plt Prod Volume        0 ml
NaCl Volume Used         0 ml      Estimated Yield      0.0 10e11
AC in Plasma             0 ml      Est Final Yield      0.0 10e11
AC in Platelets          0 ml      Target Yield         4.4 10e11

Press HELP for the Haemo Calculator display.

Press STOP to return to main display.
```

Figure 7-2, Example of the Haemo Update screen display

The left column of the Haemo Update screen display lists the most current procedure information. The right column lists collection product information. The top section provides an ongoing update of certain procedure statistics.

- **Ctrl Tgt Plasma (Controlled plasma target)** is the maximum Plasma target that the device can collect, calculated as part of the maximum combined product volume for the programmed donor profile.
- **Ctrl Tgt RBC Vol (Controlled RBC target)** is the maximum RBC target that the device can collect, calculated as part of the maximum combined product volume for the programmed donor profile.
- **AC Volume Used** is the quantity of AC solution used during the procedure, including the volume used during the priming sequence.
- **Collection Time:** the number of minutes elapsed since initiating the procedure by pressing the draw key.
- **NaCl Volume Used** is the quantity of saline solution used for the procedure, including the volume used during the priming sequence.
- AC in Plasma is the quantity of AC solution in the plasma product.
- AC in Platelets is the quantity of AC solution in the platelet product.
- **Plasma Volume** is the current volume of anticoagulated plasma contained in the plasma bag; measured by the MCS+ weigher in grams and converted by the Haemo Calculator into a measurement in milliliters (1.026 g/ml).
- **Platelets Volume** is the estimated volume of platelets and plasma collected in the platelet harness.
- **Platelet Additive Volume** is the estimated volume of additive transferred to the platelet harness.

- **Platelet Product Volume** is the overall platelet product volume, which is the sum of the additive solution volume and the platelets-in-plasma volumes.
- **Estimated Yield** is the estimated number of platelets collected.
- **Est Final Yield (Estimated Final Yield)** is the estimated number of platelets collected at the end of the procedure.
- **Target Yield** is the targeted number of platelets to be collected.

Controlled plasma target and platelet post-count

At the end of each Draw mode the device recalculates whether the platelet post-count limit will be reached during the next cycle. If the post-count limit will be reached, the device ends the procedure at the end of the next Return phase.

Note: For super surge procedures, the device performs the super surge and then ends the procedure.

Since the device calculates the amount of plasma to collect each cycle based on the number of target cycles in the procedure, the device might not be able to collect enough plasma to reach the plasma target if the procedure is ended early.

Note: The HaemoCalculator is not accessible during certain phases of DRAW, Dwell, Surge, and RETURN.

THE MODIFY PARAMETERS MENU

The Modify Parameters screen lists a number of less frequently used parameters which the operator can modify for each procedure. The screen can be accessed from the main screen display by pressing the Modify key. The top section of the screen displays an update of current procedure statistics.

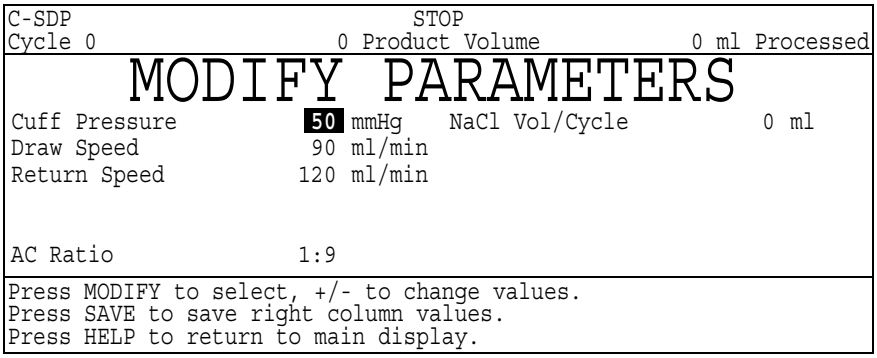

Figure 7-3, Example of the Modify Parameters menu

- **Cuff Pressure** adjusts the automatic inflation and deflation of the pressure cuff during the procedure.
- **Draw Speed** is the targeted maximum donor flow rate used during the DRAW mode of the procedure. The MCS+ device continuously regulates the Draw pump speed so that the pressure measured by the DPM in the donor line does not exceed safety limits.
- **Return Speed** is the targeted maximum pump rate applied during the RETURN mode of the procedure. The MCS+ device continuously regulates the Return pump speed so that the pressure measured by the DPM in the donor line does not exceed safety limits.
- **AC Ratio** is the ratio of anticoagulant to donor whole blood. This parameter is for information only and can not be modified.
- The donor's blood is anticoagulated with ACDA in a 1:9 ratio of anticoagulant to whole blood.
- **NaCl Volume/Cycle** is the volume of saline compensation solution returned to the donor with red cells and plasma, to ensure isovolemia. The default volume is 0 when no saline compensation is selected. The operator may change the volume/cycle during the procedure if it becomes necessary to begin saline compensation. The new volume/cycle value cannot be saved and returns to 0 for the subsequent procedure.

Warning: If saline compensation is chosen during (rather than at the beginning of) the procedure, the operator must connect the saline bag before continuing the procedure.

Adjusting the Modify Parameters values

The Modify Parameters values can be adjusted as follows:

- ➔ Press the Modify key to scroll through the parameter list.
- ➔ Press the + and – keys to increase (+) or decrease (–) the value listed on the screen.
- ➔ Press the Save key to retain the modified values in the MCS+ memory.

Note: Each protocol option independently saves the parameters listed in the right column. General procedure parameters listed in the left column can be directly saved for all options by using the operator configuration parameters, Procedure menu (Appendix B*).*

Table 7-3, Default settings for the Modify Parameters menu

Parameter	Unit of measure	Default value	Range of values	Increment of change
Cuff Pressure	*Values listed in "Parameter reference information" on page 7-10*			
Draw Speed				
Return Speed				
NaCl Vol/Cycle	ml	0 (C-SDP / C-PLP) 40 (SDPS / SDPLPS)	0-100	5

Parameter reference information

Table 7-4, Procedure parameter menu information

Parameter	Unit of measure	Default value	Range of values	Increment of change
Cuff Pressure	mmHg	50	0-100	5
Draw Speed	ml/min	85	20-100	5
Return Speed	ml/min	140	20-140	5
AC bag volume	ml	500	0-1000	50
NaCl bag volume	ml	500	0-1000	50
Final beeps	–	1	1-10	1

Chapter 8

The Collection Procedure

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PERFORMING THE COLLECTION PROCEDURE

Preparing the donor

Once the parameters have been adjusted on the Haemo Calculator screen and the READY mode is displayed, the operator should prepare the donor for the venipuncture, handling all biologically contaminated materials according to standard operating procedures.

After performing the venipuncture, a donor blood sample can be drawn using the attached donor sample pouch, following local standard operating procedures for sampling blood.

An example of the sample collection method is as follows:

- ➔ Inflate the pressure cuff.
- ➔ Clean the venipuncture site using aseptic technique.
- ➔ Ensure that the donor line as well as the donor sample pouch tubing are clamped.
- ➔ Perform the venipuncture respecting aseptic technique.
- ➔ Unclamp the donor sample pouch line and allow a sufficient sample of blood to flow into the pouch, then re-clamp the line.
- ➔ Seal the sample pouch tubing between the Y-connector and the sample pouch.
- ➔ Fill the necessary donor blood sample containers with the contents of the sample pouch according to local standard operating procedures.

Warning: The injection port on the 4-way connector of the donor needle tubing must not be used for any reason, and the needle itself should not be changed prior to hermetically sealing the collection products. Use of this port compromises the sterile fluid pathway and the system should be considered as "open". The sterile pathway should be considered compromised, and the product life should be reduced to 24 hours.

Initiating component collection

- ➔ Press the Draw key to initiate the first collection cycle.

The pressure cuff automatically inflates, the pumps and centrifuge begin to spin, and all monitoring components used during the DRAW mode are activated. During the first Draw cycle the weigher is automatically tared to 0 to account for the initial weight of the bags.

The operating modes

An MCS+ collection protocol is the repetition of one basic cycle of operating states, or operating modes. The cycle is repeated until either the end procedure criteria are automatically reached, or the operator manually intervenes to terminate the procedure.

UPP collection procedure with basic DRAW mode

A basic UPP collection procedure cycle consists of specific phases during each operating mode, occurring according to the following general sequence. The cycle repeats until the procedure is complete.

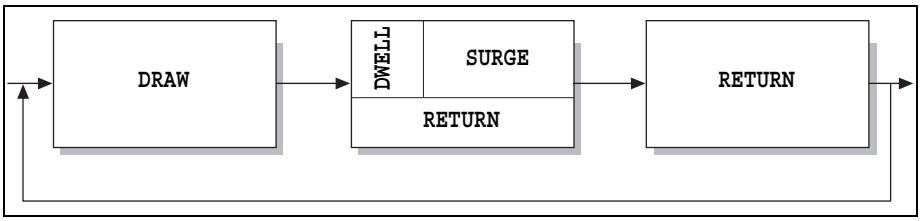


Figure 8-1, Sequence of a basic cycle

UPP collection procedure with modified DRAW mode:

If the system calculates that the next Draw mode will exceed the maximum allowable extracorporeal volume (ECV), the system modifies the next Draw mode as follows:

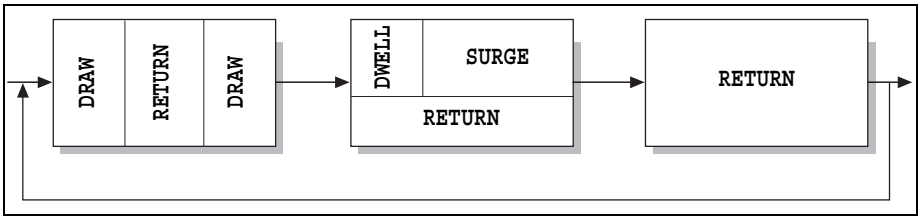


Figure 8-2, Sequence of a cycle modified for ECV control

UPP collection procedure with super surge DRAW mode

During the last cycle Draw mode of the procedure **only**, the device pulls the platelet rich plasma (PRP) from the Air-Intermediate platelet bag into the bowl to be reprocessed. During the PRP recirculation, the device can continue to draw from the donor or return plasma.

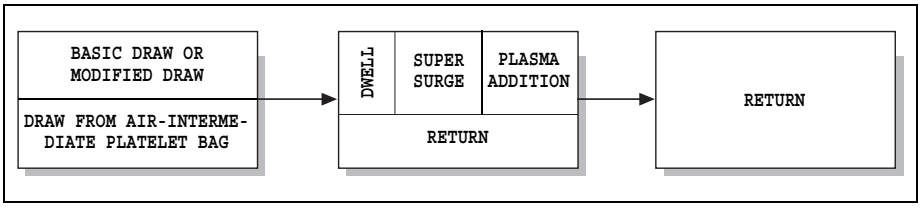


Figure 8-3, Sequence of a super surge cycle

MCS+ main display screen

The MCS+ main display screen is composed of three sections and continually updates information for the operator throughout the collection procedure.

- The upper screen area identifies the selected UPP protocol options as well as indicates changes in the operating mode and current phase.
- The center screen area contains an icon to represent the donor and the current mode, the DPM bar graph, and the current pump speed(s).
- The lower screen area communicates data to the operator concerning the cycle in progress, plasma volume, platelet volume and anticoagulated blood volume processed.

Main display information
1. Current mode and phase
2. Current pump speeds
3. DPM bar graph
4. Current cycle
5. Plasma volume
6. PRP or platelets volume
7. Volume processed
8. Indication that the AC drip monitor is disabled
9. Indication appearing during final RETURN mode

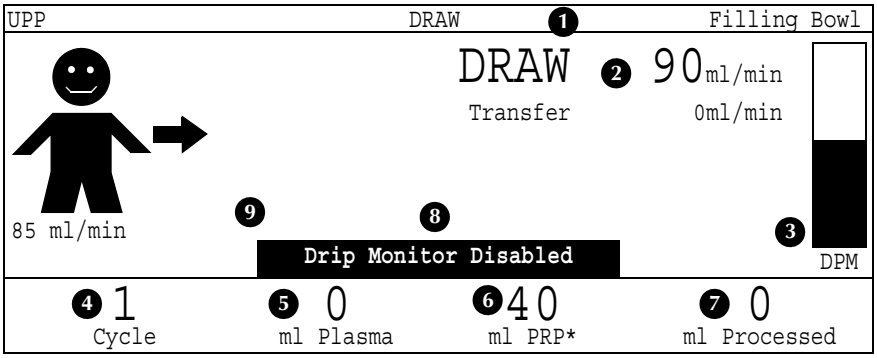


Figure 8-4, Example of an C-SDP main screen display
**PRP displayed for super surge procedures, platelets displayed for non super surge procedures*

The DRAW mode

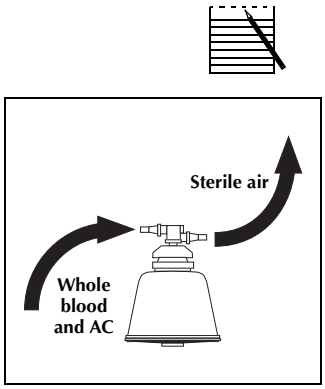
The UPP protocol has two types of DRAW mode.

- **Basic DRAW mode:** the device uses basic DRAW mode when there is no possibility of exceeding the maximum allowable ECV. See "UPP collection procedure with basic DRAW mode" on page 8-3.
- **Modified DRAW mode**: the device uses a modified DRAW mode if the device calculates that the maximum allowable ECV will be exceeded. See "UPP collection procedure with modified DRAW mode:" on page 8-3.

The DRAW mode contains the following phases:

Filling the bowl

Anticoagulated whole blood from the donor is drawn into the bowl and displaces sterile air in the bowl into the Air bag as the bowl is fills.



Note: Air management may differ depending on the type of disposable set used. and procedure status.

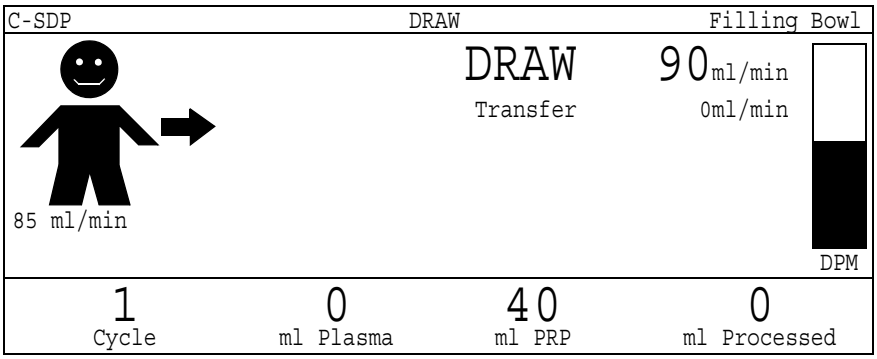


Figure 8-5, Example of Filling Bowl screen display

Air/Plasma interface

When the optical bowl sensor has detected the air/plasma interface, the following screen appears:

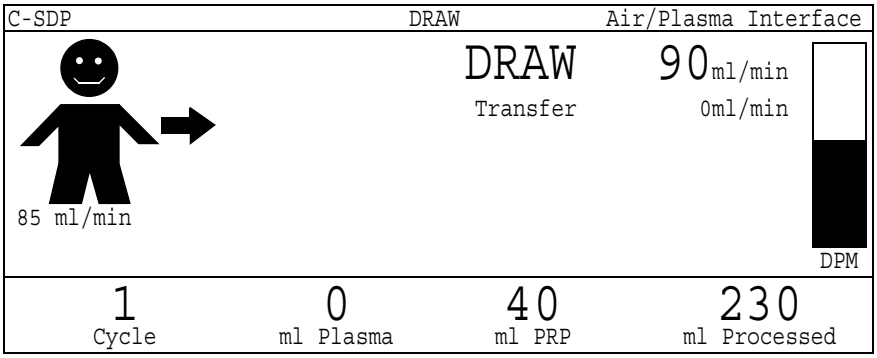


Figure 8-6, Example of Air/Plasma Interface screen display

The first few mls of plasma enter one of the following bags, depending on the protocol:

- Air-Intermediate platelet bag (LN 999FF-E, or 999FF-P)
- Air-Intermediate platelet and RBC bag (LN 949FF-E or 949FF-P)
- Air bag (LN 997CF-E)
- PRP bag (super surge cycle)

C-SDP (super surge) - last Draw cycle only

During the last cycle Draw mode of the procedure **only**, the device pulls the platelet rich plasma from the Air-Intermediate platelet bag into the bowl to be reprocessed.

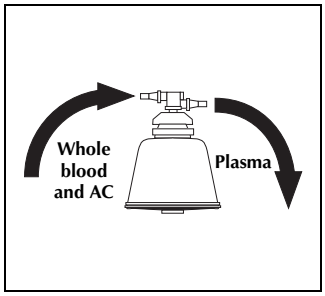
During the PRP recirculation, the device can continue to draw from the donor or return plasma. Plasma is returned to the donor at a calculated rate by the citrate control feature.

Return speed can be reduced using the slew keys, Blood pump can be paused using the PUMP START/STOP key.

Warning: If the procedure was stopped using the STOP key during the last Draw mode, the device will not collect platelets during this cycle.

Collecting plasma

The yellow-coded valve opens to allow the plasma exiting the bowl to be collected in the plasma bag on the weigher, as indicated by the following display.



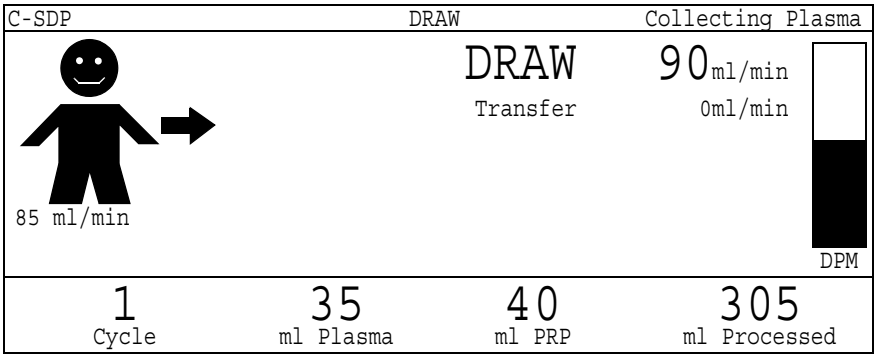


Figure 8-7, Example of Collecting Plasma screen display

Transferring plasma

When a sufficient quantity of plasma is available in the plasma bag, the Transfer pump rotates to draw plasma from the plasma collection bag into the centrifuge bowl in order to maintain the *critical flow*.

Note: Critical Flow refers to a constant rate of plasma flowing into the bowl. The critical flow process is used by the MCS+ device to reduce the HCT and optimize the separation of blood cell layers within the centrifuge bowl, ultimately maximizing the platelet collection. The MCS+ device adapts the speed of the Transfer pump depending on the value of the donor hematocrit and donor flow during the DRAW mode. From the second cycle on, a minimum of plasma is kept to perform critical flow during the filling of the bowl

Returning plasma (modified DRAW mode only)

If necessary to maintain the ECV below the programmed limit, the device estimates how much plasma will be collected during that cycle. When half the estimated volume of plasma is collected, the device pauses DRAW and starts returning this plasma to the donor. The centrifuge continues to spin to maintain critical flow and separation in the bowl.

The following screen appears:

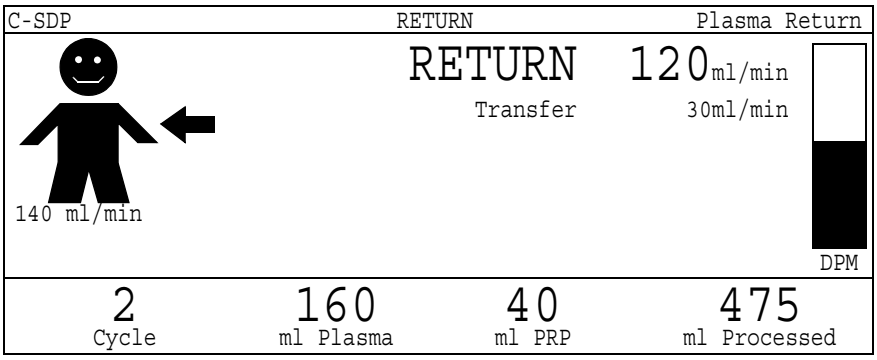
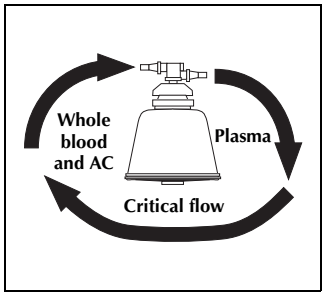


Figure 8-8, Example of Plasma Return screen display

When the appropriate amount of plasma has been returned to the donor, the device stops RETURN and resumes DRAW.

Bowl optics reference

After a certain time (approximately one minute), the optical bowl sensor measures the optical density of the donor plasma. The MCS+ device uses this "bowl optics reference" to determine when to initiate the Dwell/Surge phase. The following screen appears:



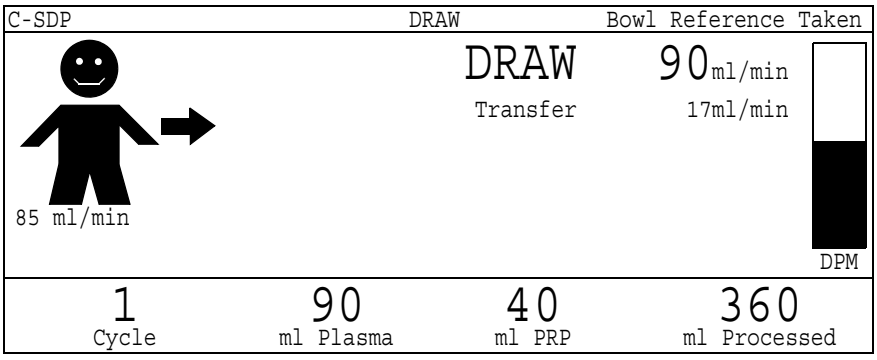


Figure 8-9, Example of Bowl Reference screen display

Note: The protocol contains a feature which enhances the "bowl optics" reference algorithm to avoid RBC spillage in the case of lipidic plasma from the donor.

Line sensor reference

Once the optical bowl sensor detects the plasma/buffy coat interface, it records an optical reference for the line sensor and the following screen appears:

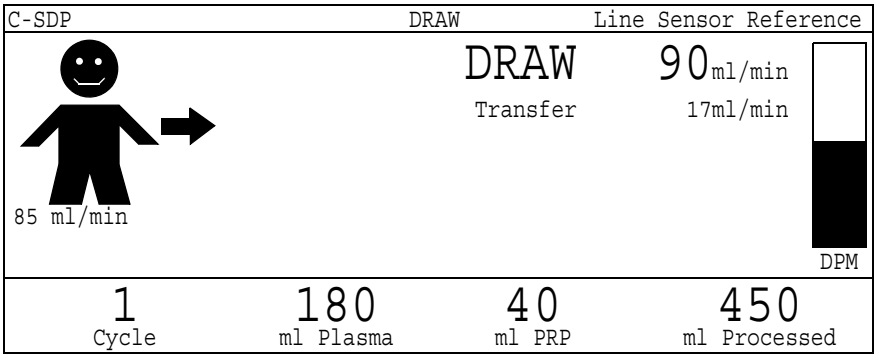


Figure 8-10, Example of Line Sensor Reference screen display

Optics volume

The DRAW mode continues until the buffy coat layer reaches the ideal position for platelet collection. The following screen appears:

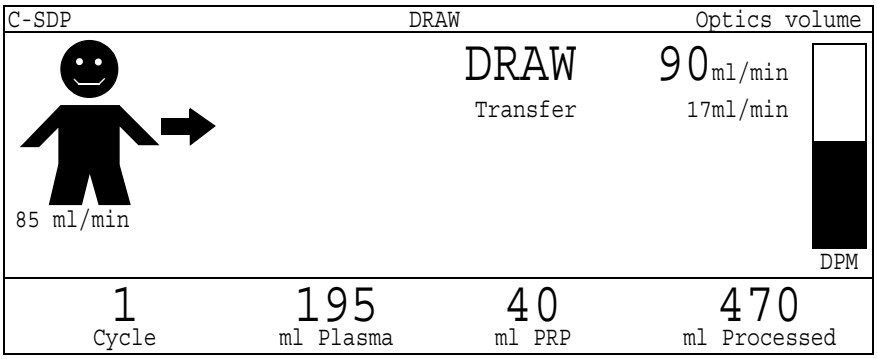


Figure 8-11, Example of Optics Volume screen display

The Blood pump stops drawing blood from the donor and the Dwell phase initiates.

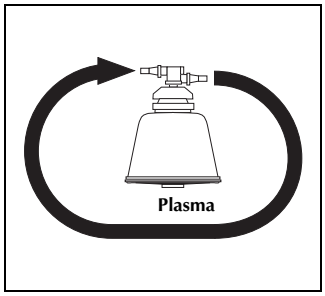
The Dwell and Surge phases

Platelet collection occurs during the Dwell and Surge phases of the DRAW mode. The UPP protocol allows the device to return fluid to the donor during the Dwell, Surge phases and while the centrifuge is stopping.

At the end of the Draw mode, the device calculates if the amount of plasma collected will exceed the minimum amount required to both constitute the plasma product and to perform bowl rinse and mixed return (plasma and red blood cells) at the end of the Return phase. If the device calculates that there will be excess plasma, the device can return the excess plasma to the donor during platelet collection and centrifuge stopping.

Dwell

The Transfer pump rotates to circulate plasma from the plasma bag through the bowl at a constant flow rate. This clears the bowl feed tube of residual whole blood and stabilizes the separation between the blood cell layers within the bowl.



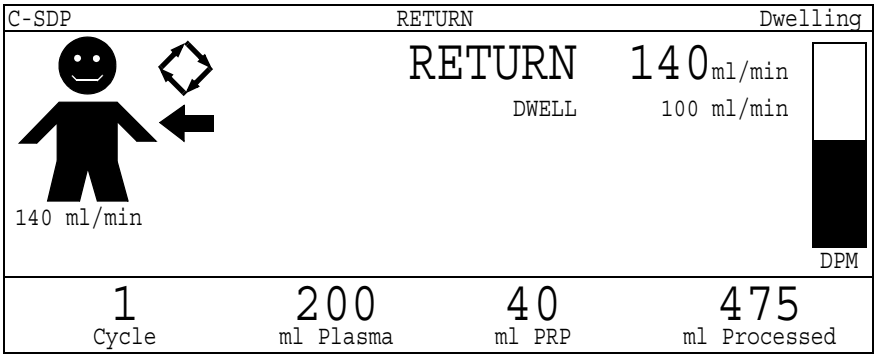


Figure 8-12, Example of Dwelling screen display

Surge

Once the Dwell phase is complete, plasma circulates at an increasing flow rate from the plasma bag into the bowl. This increasing flow rate elutriates the platelets out of the bowl. Optimal separation of blood cell layers contributes to obtaining high platelet recovery rates.

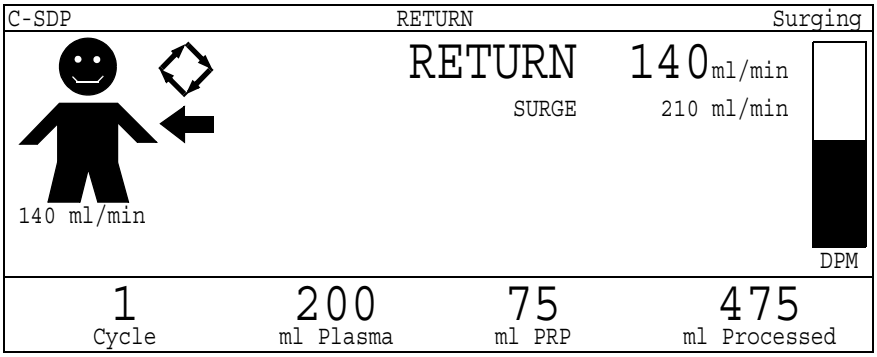


Figure 8-13, Example of Surging screen display

Collecting platelets

C-SDP procedure

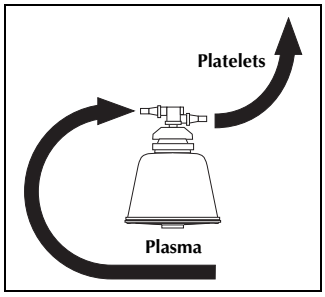
All cycles except the last cycle: once the line sensor detects the presence of platelets in the effluent tubing, the platelet peak is collected into the Air-Intermediate platelet bag.

Last cycle: during the final surge (Super surge), the platelets are collected in the air-platelet bag.

SDP procedure

All cycles: once the line sensor detects the presence of platelets in the effluent tubing, the platelet peak is collected into the air-platelet bag.

The screen displays the following information:



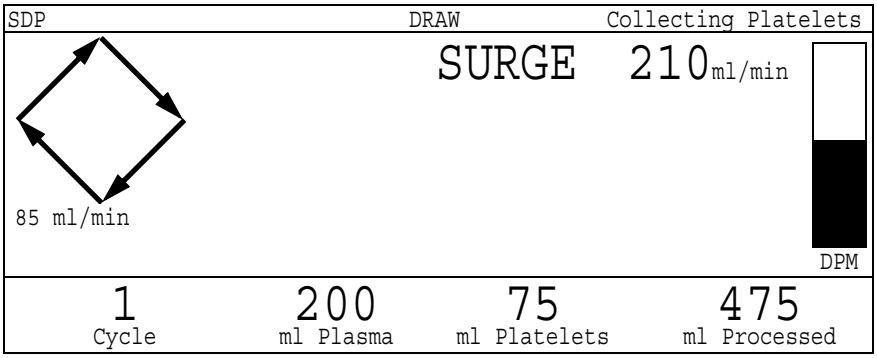


Figure 8-14, Example of Collecting Platelets screen display

Platelet volume

The system estimates the volume of PRP or Platelets collected, based on the volume of plasma that is pumped into the bowl during the collection period. Approximately 1 ml of plasma is transferred by each pump revolution.

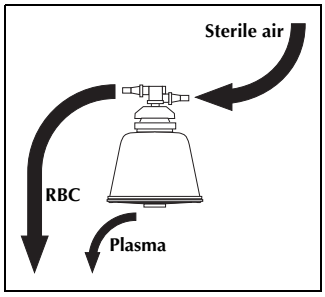
The RETURN mode

Once the centrifuge stops, the RETURN mode begins automatically.

Caution: *Do not remove the pressure cuff from the donor before the Return mode is complete.*

Returning cells

To ensure that blood components mix effectively prior to infusion to the donor, collected plasma from the plasma bag is simultaneously returned to the donor with red cells.



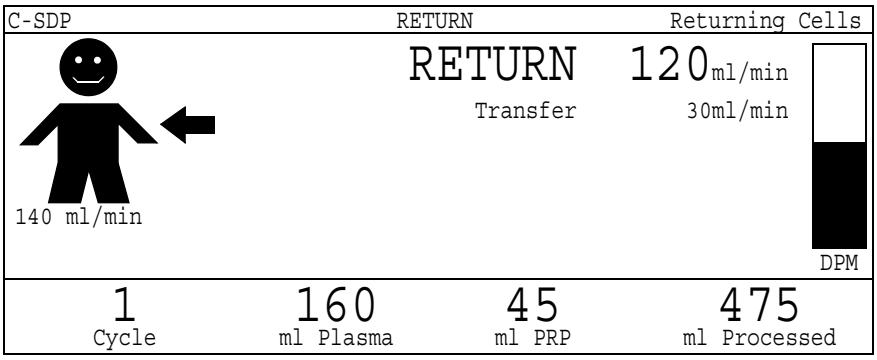
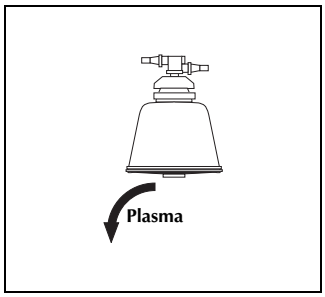


Figure 8-15, Example of Returning Cells screen display

Ending return

Once most of contents of the bowl have been returned to the donor, the Transfer pump sends some plasma into the spinning bowl to remove remaining cells. When the BLAD detects air, this signals the end of the RETURN mode. Some plasma transfers from the plasma bag into the donor line using the orange-coded valve. This rinses the blood filter and ensures that most of the red blood cells have been returned to the donor. The following message appears:



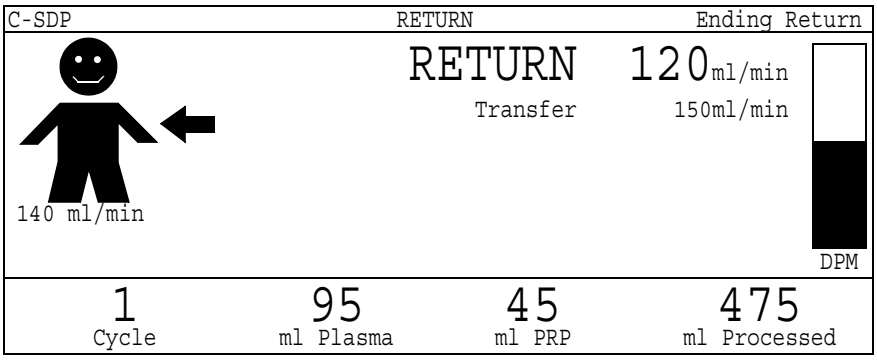


Figure 8-16, Example of Ending Return screen display

Brief Draw at the end of the last Return:

In the rare event that the blood filter empties too quickly during the last Return mode, the device re-primes the blood filter by drawing anticoagulated whole blood from the donor. Once sufficient volume has been drawn from the donor to re-prime the blood filter, the Return mode resumes the phase that was interrupted when the device detected air. For example, if the device detects air during the bowl remix phase (non-RBC procedures), the bowl remix phase resumes after the blood filter has been re-primed.

Plasma volume accounting

The MCS+ programming retains a calculated volume of plasma in the plasma bag after each cycle in order to do the following:

- Ensure plasma circulation (critical flow) during the subsequent cycle, except for the final cycle.
- Plasma required for platelets and possibly plasma product

The maximum plasma product volume is limited according to a pre-set total product volume limit (combined platelet and plasma product volumes). The plasma product is collected as late as possible during the procedure in order to minimize the donor ECV.

FINALIZING THE PLATELET, RBC, AND PLASMA PRODUCTS

After the final Return cycle is complete the device either displays the Procedure Complete screen or continues to post-procedure processing, depending on the protocol selected.

- **Procedure Complete screen:** SDP procedures without concurrent RBC collection
- **Post-procedure processing:** C-SDP procedures and any procedures with concurrent RBC collection

Platelet leukoreduction options

There are three ways to complete platelet leukoreduction, depending on the protocol selected:

- **SDP procedure** with filtration of platelets at every cycle as they leave the bowl; therefore only the last cycle of platelets collected have to transit through filter while last return is being performed.
- **C-SDP procedure with filtration of concentrated platelets immediately after super surge**, followed by a filter rinse with the entire volume of platelet additive solution needed for suspension of platelets (pre-filter clamp was left open at set installation).

  Once collection is complete, the leukoreduction method requires the platelet harness to be suspended by the tether on the weigher arm, and the platelet additive solution line to be loaded in the clear valve instead of the PRP line. See “Post-procedure processing” on page 8-14 for more information.
- **C-SDP procedure with suspension of concentrated platelets in platelet additive solution prior to leukoreduction** (pre-filter clamp was closed at set installation).

  This leukoreduction method requires the platelet harness to be suspended by the tether on the weigher arm, and the platelet additive solution line to be loaded in the clear valve instead of the PRP line. See “Post-procedure processing” on page 8-14 for more information.

Post-procedure processing

After the final Return cycle is complete, the device displays the following screen:

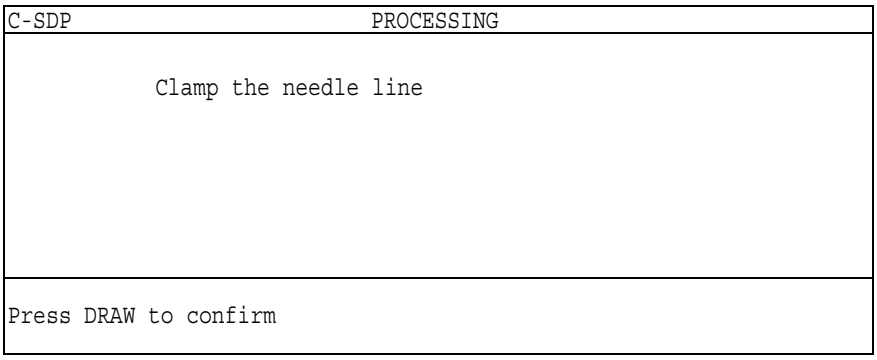


Figure 8-17, Processing screen display

➔ Clamp the donor/needle line.

Note: The donor can be disconnected from the disposable set at any time during post-procedure processing. See "Disconnecting the donor from the disposable set" on page 8-19.

➔ Press DRAW to continue.

The device displays a prompt to move the product bags.

➔ Unload the tubing from the clear valve.

➔ *If collecting concentrated platelets (C-SDP),* move the platelet harness from the right pins to the weigher arm with ports facing down.

➔ *If collecting RBCs,* move the Air-Intermediate platelet and RBC bag from the right pole to the weigher arm with ports facing up.

➔ *If collecting concentrated platelets,* load the platelet additive line into the clear valve.

➔ Press DRAW to continue.

After the operator presses DRAW, the device verifies that weigher detects the presence of the product bags. If the device detects the proper weight change it displays a prompt to install the additive solution(s).

➔ If collecting concentrated platelets:

  ➔ *Hang the platelet additive solution bag on the top right pole hook.*

  ➔ *Connect the platelet additive solution to the platelet additive solution line.*

  ➔ *Break frangible seal on the additive solution bag.*

  ➔ *Verify that additive solution is flowing towards the bacteriostatic filter.*

  ➔ *Open the platelet additive solution line clamp located between the air-platelet bag and the bacteriostatic filters.*

- ➔ If collecting RBCs:
  - ➔ *Hang the RBC additive solution bag on the weigher.*
  - ➔ *Connect the RBC additive solution to the RBC additive solution line.*
  - ➔ *Break frangible seal on the additive solution bag.*
  - ➔ *Verify that additive solution is flowing towards the bacteriostatic filter.*
  - ➔ *Open the additive solution line clamp located between the T-connector and the bacteriostatic filter.*
- ➔ Press YES to initiate processing.

After the operator presses YES, the device begins transfer of the RBC storage solution (if using an RBC protocol) and the platelet additive solution. Once transfer is complete, the device displays the Procedure Complete screen.

Warning: Do not touch the weigher until the device displays the Procedure Complete screen.

Automatic procedure ending

Once the selected end of procedure criteria have been met, the following screen appears and a "beep" sounds.

UPP			PROCEDURE COMPLETE
Volume Processed	4100 ml	RBC Volume	0 ml
AC Volume Used	481 ml	RBC Additive Vol	0 ml
DURATION	100 min	RBC Product Vol	0 ml
Number of Cycles	8	Platelet Volume	150 ml
NaCl Volume Used	0 ml	Plt Additive Vol	140 ml
PRP Volume	0 ml	Plt Product Volume	290 ml
AC in Plasma	0 ml	Estimated Yield	4.8 10e11
AC in Platelets	0 ml	Target Yield	4.4 10e11
AC in RBC	0 ml	Plt Pre-Count	*** 10e3
Plasma Volume	15 ml	Plt Post-Count	*** 10e3

CHECK PLATELET PRODUCT
Procedure target limited by est. donor plt post-count
Estimated Platelet Yield is outside configured range

Figure 8-18, Example of Procedure Complete screen display

This message remains on-screen until the disposable set has been removed from the MCS+ device.

The following warnings may appear at the bottom of the screen:

- **CHECK PLATELET PRODUCT:** appears if the operator manually stopped the platelet additive transfer during processing.
- **CHECK RBC PRODUCT:** appears if the operator manually stopped the RBC additive transfer during processing.
- **Procedure target limited by est. donor plt post-count:** appears if the device automatically restricted the procedure targets to prevent the

platelet post-count from decreasing below the programmed limit. (The procedure statistic **Plt Post-Count** is the estimated amount of platelets remaining in the donor after the collection procedure is complete.)

- **Estimated platelet yield/Estimated Product Volume is outside configured range**: appears if the platelet yield or volume is outside the configured range.

Note: If the bar-code reader is enabled and the donation number or donor number was not entered at the beginning of the procedure, the MCS+ prompts the operator again to enter the donation/donor number before displaying the Procedure Complete screen message.

Note: The AC Volume Used statistic which appears on the Procedure Complete screen display includes the volume of AC solution used during the autopriming sequence in addition to the AC solution used to anticoagulate the donor whole blood during each cycle.

Manually ending a procedure

Certain situations may arise in which the operator may need to interrupt a procedure rather than allow it to end automatically. In these situations it is possible for a collection procedure to be terminated by manual operator intervention rather than by an MCS+ automatic procedure ending. The following two sections describe the possible interventions.

Interrupting a Draw cycle with the Return key

If the Return key is pressed during a Draw cycle, the following message appears:

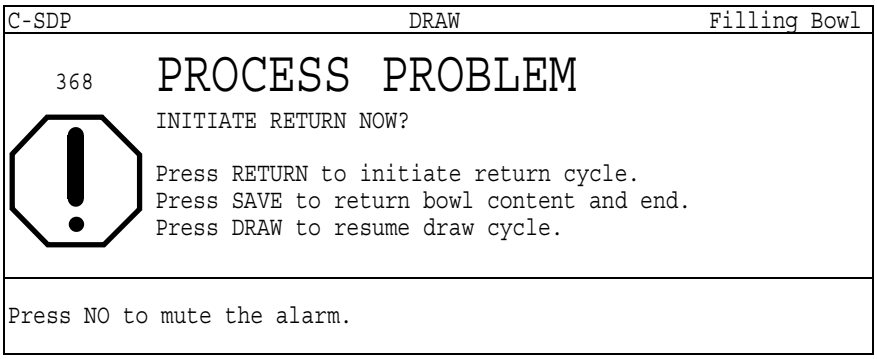


Figure 8-19, Process Problem screen display (368)

The operator can choose among the following actions depending on why the Return key was pressed at this point in the procedure:

➔ Press the Return key to interrupt the Draw cycle in progress and proceed directly to the subsequent Return cycle.

➔ Press the Save key to interrupt the Draw cycle in progress, initiate a Return cycle and terminate the procedure.

Note: If collecting concentrated platelets, the device performs one more cycle to complete the super surge and collect platelets.

➔ Press the Draw key to continue the Draw cycle in progress.

Interrupting the procedure with the STOP key

If necessary, the operator can press the STOP key from a Draw or Return cycle to discontinue the procedure.

A sequence of messages will appear in which the STOP message appears, followed by the READY mode screen display:

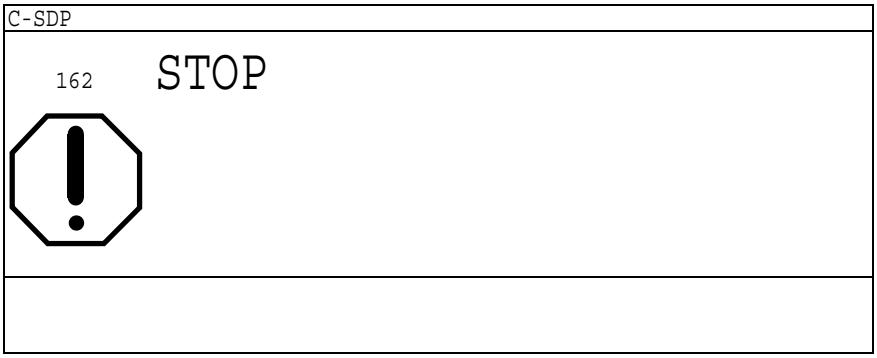


Figure 8-20, Example of the STOP screen display

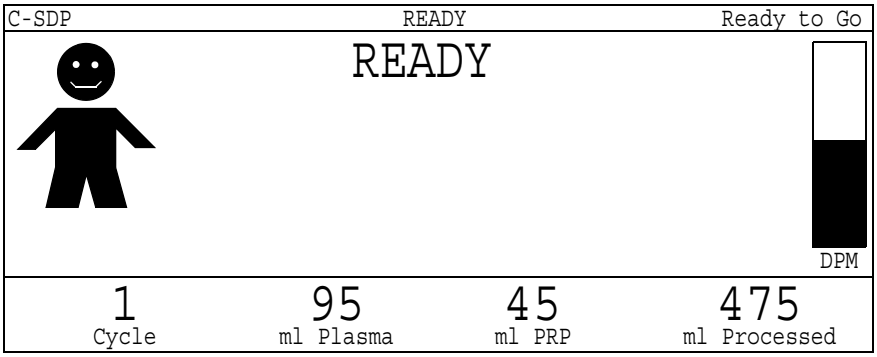


Figure 8-21, Example of the READY mode screen display

When the READY mode screen display appears, press the STOP key again. The following message appears:

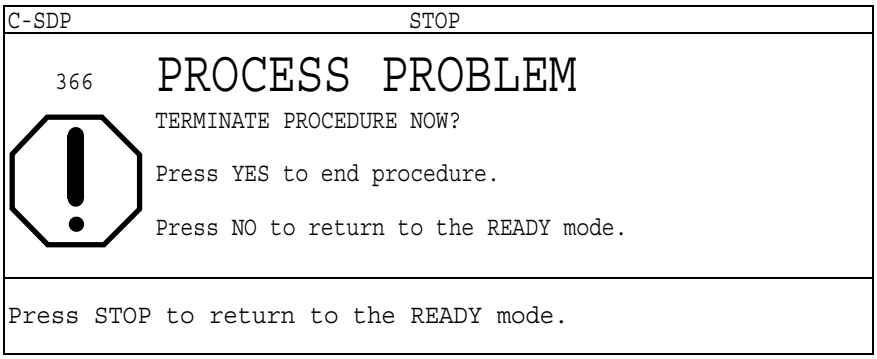


Figure 8-22, Process Problem screen display (366)

The operator then has the following choices:

➔ Press the STOP key or the No key to return to the READY mode.

- *From the READY mode, Haemonetics recommends that the operator initiate a Return cycle.*

➔ Press the Yes key to remain in the procedure termination sequence.

If the Yes key is pressed, the following message appears:

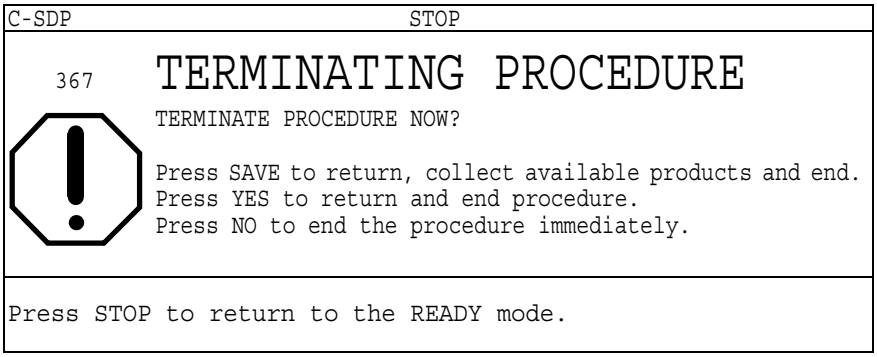


Figure 8-23, Process Problem screen display (367)

At this point, the operator must confirm that the procedure should be discontinued by one of the following actions:

➔ Press the Save key to return the contents of the bowl to the donor and collect the available products before ending the procedure.

Note: If collecting concentrated platelets, the device performs one more cycle to complete the super surge and collect platelets.

➔ Press the Yes key to return the contents of the bowl to the donor and before ending the procedure.

➔ Press the No key to immediately terminate the procedure.
The contents of the bowl will not be returned to the donor.

However, the operator could decide to continue the procedure as follows:

➔ Press the STOP key to cancel the termination sequence and return to the READY mode.

Note: The procedure data is automatically sent to HaemoNet or to the printer if data acquisition features are applicable.

The operator should disconnect the donor from the disposable set according to standard operating procedure in this type of situation.

Disconnecting the donor from the disposable set

When the collection procedure has been completed, the operator can disconnect the donor from the disposable set as follows:

➔ Clamp the AC line and blood line tubing.

➔ Draw a post-procedure donor sample if necessary.

➔ Remove the venipuncture needle from the arm of the donor.

➔ Apply a pressure dressing and discharge the donor according to the local standard operating procedures.

Collecting a post-procedure donor sample

The post-procedure donor blood sample should be collected using a method that ensures that the sample reflects donor whole blood, and is not a mixture of donor blood and blood solution returned to the donor during the procedure.

This section describes two possible methods of collecting a donor whole blood sample.

Method 1

➔ Select a donor vein that is different from the vein that was used for collection.

➔ Perform venipuncture five minutes after the end of last procedure return

Note: Five minutes is compromise between waiting long enough to ensure post-procedure donor blood has become homogeneous, and not retaining the donor too long after the procedure.

➔ Draw the required sample(s) according to local standard operating procedure.

➔ Remove the needle and dispose of appropriately.

Method 2

➔ Clamp the needle line and donor/blood line tubing.

➔ Disconnect the donor/blood line tubing from the needle tubing.

Note: The first 10-15 mls of blood drawn should be discarded, as it will not be representative of donor whole blood.

➔ Draw the required sample(s) according to local standard operating procedure.

➔ Remove the needle and dispose of appropriately.

Warning: The injection port on the 4-way connector of the donor needle tubing must not be used for any reason and the needle itself should not be changed prior to hermetically sealing the collection products. Use of this port compromises the sterile fluid pathway and the system should be considered as "open". The sterile pathway should be considered compromised, and the product life should be reduced to 24 hours.

Initiating platelet leukoreduction

For C-SDP procedures that use the method of suspending the concentrated platelets in platelet additive solution prior to leukoreduction, filtration can take place up to four hours after the platelets are suspended in platelet additive solution and kept at room temperature

To initiate platelet leukoreduction:

➔ Open the clamp above the leukoreduction filter to start filtration.

➔ Ensure the level of fluid is balanced between the air-platelet bag and the platelet storage bags before finalizing the platelet product.

Finalizing the platelet product

Caution: *Pressure must not be applied to any part of the filter or bag assembly during the filtration process. The operator should also carefully follow local standard operating procedure for all of these situations.*

Follow the instructions in this section for all three types of leuko-reduction (see "Platelet leukoreduction options" on page 8-13).

Once free level of fluid is balanced between pre- and post-filter bags:

➔ Remove the platelet harness from the pins (SDP) or weigher arm (C-SDP).

➔ Cut the tether on the platelet harness.

➔ Slowly hang the platelet storage bags from the filter and air-platelet bag so that the remaining platelet product transfers through the filter and into the storage bags.

➔ Once all the platelet product has transferred to the storage bags, heat-seal the filter outlet tubing and remove the storage bags.

Note: Further specific advice may be obtained from your local Haemonetics representative concerning post-collection handling of collected products.

Caution: *The recommended storage technique is using a horizontal agitator at 70 cycles per minute. The platelets should be maintained at room temperature (20° C - 24° C) up to a maximum of five days. The agitator should be located in a well-ventilated area away from exposure to direct sunlight or direct UV irradiation. Platelet storage should be conducted according to the local standard operating procedures.*
The platelets may be stored for up to seven days when the collection procedure is coupled with 100% screening for bacterial contamination with a device cleared for that purpose with its recommended method prior to transfusion.

Warning: Pressure reinfusion of a plasma product containing air to a patient can lead to an air embolism, and result in severe injury or death.

Finalizing the RBC product

Filtration can be performed cold, after cooling the collected RBC to 4° C, for up to 48 hours. Once the RBC collection procedure is complete, the following actions are necessary to retrieve the RBC product:

- ➔ Detach the Air-Intermediate platelet and RBC bag from the disposable.
- ➔ Mix product before filtration.
- ➔ Hang the Air-Intermediate platelet and RBC bag so the height between the Air-Intermediate platelet and RBC bag and filtered RBC bag is 1.6 meters.
- ➔ Open the clamp located below the Air-Intermediate platelet and RBC bag to start filtration.
- ➔ Once Air-Intermediate platelet and RBC bag is empty, close the clamp located at the filter outlet.
- ➔ Press on the filtered RBC bag to direct all the air into the RBC sample pouch.
- ➔ Close the clamp on the RBC sample pouch.
- ➔ Open the clamp at the filter outlet and let the filtration continue until the filter inlet is empty.
- ➔ Hermetically seal the tubing between the leukoreduction filter and the 2-way connector, then remove the filtered RBC and RBC sample bags from the set.

Finalizing the plasma product (non-filtered)

To remove the residual air from the plasma product:

- ➔ Remove the plasma bag from the weigher and rehang the bag with ports facing up.

➔ Remove the yellow line from the yellow valve.

➔ Press on the plasma bag to push the air back into the bowl.

➔ Seal the line between the plasma bag and the bowl.

Warning: Pressure reinfusing plasma to a patient can lead to an embolism, and result in severe injury or death.

Weighing and sampling products

Platelet product

The platelet product samples should be collected according to local standard operating procedure. To ensure sample accuracy, Haemonetics recommends one of the following method for sampling the platelet product when using a disposable set with platelet sampling bulbs:

For sets with sampling bulbs:

➔ Allow the product to rest for one hour.

➔ Gently agitate the product to resuspend the platelets before taking the product sample.

➔ Hold the product bag ports facing down and open the slide clamp between the product bag and the sampling bulb.

➔ Draw a platelet product sample by gently squeezing and releasing the sample bulb.

➔ Close the blue slide clamp in between the sample bulb and the platelet bag and heat seal and remove the sample bulb.

➔ Open the slide clamp in between the three-way connector and the air removal pouch and displace any residual air from the platelet storage bag into the air removal pouch by gently pressing the platelet storage bags, ports facing up.

➔ Once all air has been displaced into the air removal pouch, close the slide clamp and heat seal and disconnect the air removal pouch.

➔ Handle and store the platelet concentrate according to the local standard operating procedures.

For sets with an air removal pouch:

➔ Allow the product to rest for one hour.

➔ Gently agitate the product to resuspend the platelets before taking the product sample.

➔ Hold the product bag ports facing down and open the slide clamp between the product bag and the air removal pouch.

➔ Allow the platelet product to flow into the air removal pouch and completely fill the air removal pouch.

- ➔ Raise the air removal pouch and allow the product in the air removal pouch to drain back into the platelet bag.
- ➔ Repeat this “priming” action (at least three times), retaining only the volume necessary for a sample in the pouch and close the clamp.

Note: Haemonetics recommends priming the sample pouch in this manner to ensure sample accuracy before removing the necessary volume.

Note: If any air remains in the final platelet bag, it can be expressed into the sample pouch; however, do not apply pressure to the pouch.

RBC

- ➔ Gently agitate the RBC product bag to homogenize the RBC product.
- ➔ Fill the RBC sample bag with homogeneous RBC product and then transfer a portion of the RBCs back to the RBC bag, until only the appropriate sample volume is in the air bag.
- ➔ Heat-seal and remove the air bag.
- ➔ Handle and store the RBC unit according to the local standard operating procedures.

Plasma

- ➔ Hold the plasma bag ports facing down, seal the plasma bag tubing with a hemostat, and disconnect the plasma bag from the set.
- ➔ Controlling plasma transfer with the hemostat, collect sample in a sample tube. Day 0 plasma is collected for the objective of counting residual cells.
- ➔ When plasma sample is collected tubing is heat sealed between the hemostat and the bag.

Appendix A

Troubleshooting

NOTICE MESSAGES A-2
Monitoring the solution bags A-2
Platelet peak too small A-3
Drip monitor disabled A-4
Protocol-specific error messages A-4

NOTICE MESSAGES

The MCS+ device is designed with sophisticated software capable of detecting irregularities during a collection procedure. During a UPP procedure, NOTICE messages may appear if the software error detection system detects irregularities.

Monitoring the solution bags

The platelet protocol allows the operator to enter the volume of the solution bags in the Procedure Parameters menu of the Operator Configuration feature. Further information about this menu is provided in *Appendix B*.

The MCS+ device monitors the amounts of solution(s) used during each cycle and displays the volumes on the Haemo Update menu during the procedure. A Notice message relative to the type of solution being monitored appears in the following situations:

- The quantity of AC solution remaining in the bag may not be adequate to complete the subsequent Draw cycle.
- The quantity of saline solution remaining in the bag may not be adequate to complete the Return cycle in progress.

Both solution monitoring Notice messages and related Help messages will provide the operator with the same general information, as well as the same choice of actions. The only variation is the type of solution being monitored, designated as either “AC bag” or “Saline bag”.

Note: A solution bag Notice message will not appear if the relevant bag volume is set to zero on the Operator Configuration Procedure Parameters menu.

The following screen display illustrates a solution bag monitoring message:

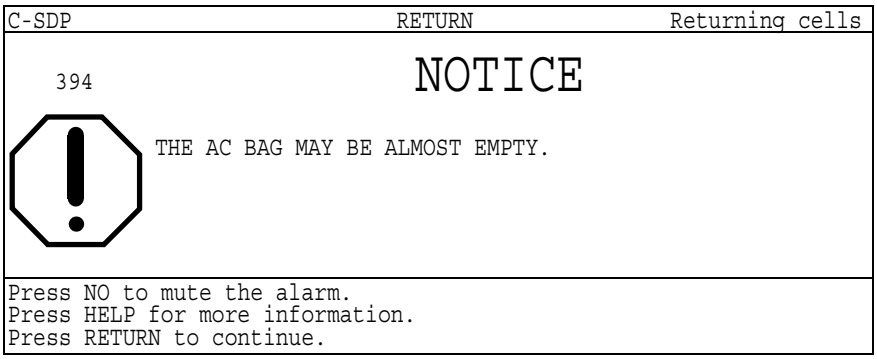


Figure A-1, AC solution bag Notice message

The operator should choose the appropriate action for the current procedure:

➔ Press the Return key and continue with the solution remaining in the bag.

➔ Press the HELP key and access the Haemo Update statistics.

- *From the Haemo Update statistics, the operator can verify the volume of solution used and decide if it is necessary to change the bag.*

Note: The operator can press the No key to mute the alarm while changing the solution bag.

Platelet peak too small

During platelet collection, the MCS+ line sensor is measuring the optical density of the platelet component passing into the platelet reservoir bag. The *platelet peak* is a graphical representation of the line sensor reading as the platelet content increases, reaches its *peak* and then declines. If the line sensor does not detect the expected platelet peak value, the operator will be notified that the "platelet peak is too small". The following Notice message will be displayed:

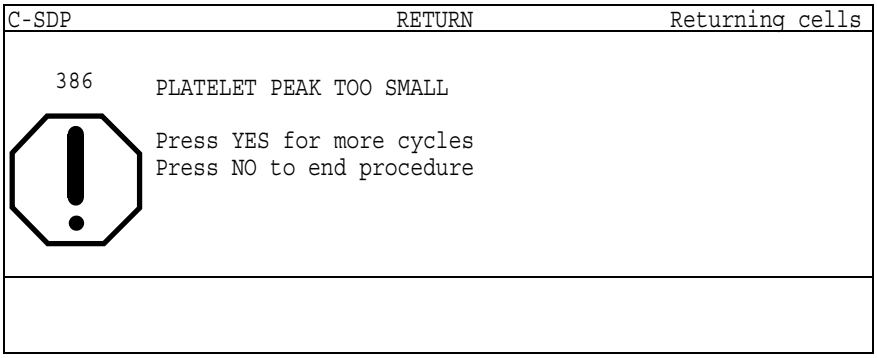


Figure A-2, Platelet Peak Too Small Notice message

If this NOTICE message is displayed, it could indicate a low concentration of platelets in the donor blood being collected (i.e. platelet pre-count of <180 x 10e3/µl). The operator will need to verify the platelet pre-count of the donor.

If the donor platelet pre-count is less than 180 x 10e3/µl, continuing the collection may reduce the donor post-collection platelet count to an inappropriately low level. A decision on whether to continue or terminate the collection procedure should be made by the person responsible for donor safety. The applicable standard operating procedures for acceptable levels of post-collection platelet counts should be followed. The target platelet yield and the donor circulating platelet count should be taken into account.

If the donor platelet pre-count is greater than 180 x 10e3/µl, this error message may indicate that the platelets are not being separated effectively at the buffy coat layer. This could in turn create the difficulty in collecting the platelets during Surge.

➔ Press the Yes key to proceed with another collection cycle.

or

➔ If the error message is repeated during the next cycle, press the No key to terminate the procedure at the end of the current Return cycle.

Note: If collecting concentrated platelets, the device performs one more cycle to complete the super surge and collect platelets.

Drip monitor disabled

The message "Drip monitor disabled" indicates that the operator has deactivated the monitoring of the AC solution line by the AC drip monitor. This message remains displayed throughout the collection procedure on the lower section of the main screen display.

Caution: *Inadequate anticoagulation could potentially have an adverse effect on platelet collection efficiency and platelet quality, which could interfere with the action and efficiency of the leukoreduction filter.*

Warning: If the AC drip monitor is disabled, it is the responsibility of the operator to ensure that the correct amount of anticoagulant solution is being delivered to the donor whole blood.

Haemonetics recommends that the drip monitor **not** be disabled. If a drip monitor error message is displayed, the instructions on the HELP screen should be followed. The procedure should only be continued if:

- The problem is corrected by the operator.

or

- The operator can visually verify that the AC solution is being appropriately delivered by the MCS+ device.

Protocol-specific error messages

The following table contains additional notice messages that may appear during a UPP procedure.

#	NOTICE message	HELP message
268	**PRIMING PROBLEM** PRIMING TIME LIMIT WILL BE EXCEEDED IN 15 MINUTES	The message "Priming time limit will be exceeded in 15 minutes" appears if the device remains idle for too long after the priming sequence was initiated. If the time limit is reached the device automatically transitions to Procedure Complete. To prevent the priming sequence from exceeding the time limit: ➔ Complete the priming sequence ➔ Perform the venipuncture ➔ Start the first draw mode before the time limit is exceeded.
269	**NOTICE** Some config. changes have not been saved. If you press DRAW these changes will be lost.	There is no Help screen associated with this message.

#	NOTICE message	HELP message
270	**ABORT AUTOMATIC TRANSFER?** *RBC message:* You are about to abort the automatic transfer of RBC additive solution to the [DESTINATION*]. Press NO to return to Automatic Transfer. Press YES to abort Automatic Transfer. *Where DESTINATION = bowl or RBC product. *Platelet message* You are about to abort the automatic transfer of additive solution to the platelet product. Press NO to return to Automatic Transfer. Press YES to abort Automatic Transfer.	There is no Help screen associated with this message.
290	**INSTALLATION PROBLEM** THE CLEAR VALVE IS NOT CORRECTLY LOADED Press DRAW to load the pumps and repeat valve check.	The message "The clear valve is not correctly loaded" appears if the clear valve loading test fails. Verify the following: ● The CLEAR valve is correctly loaded with the CLEAR PRP tubing. ● CLEAR tubing is not occluded. ● The SPM is correctly loaded and the slide clamp on the SPM is open. After resolving the error state, press the Prime key exit the autoload sequence or press "Draw" to repeat the autoload sequence, including the valve check.
291 and 292	**INSTALLATION PROBLEM** THE [COLOR*] VALVE IS NOT CORRECTLY LOADED Press DRAW to load the pumps and repeat valve check. *Where COLOR = green or yellow	The message "The [COLOR*] valve is not correctly loaded" appears if the [COLOR] valve loading test fails. Verify the following: ● The [COLOR] valve is correctly loaded with the [COLOR]-striped Platelet/Plasma bag tubing. ● [COLOR]-striped tubing is not occluded. ● Tubing is loaded into each pump. ● The SPM is correctly loaded and the slide clamp on the SPM is open. After resolving the error state, press the Prime key exit the autoload sequence or press "Draw" to repeat the autoload sequence, including the valve check. *Where COLOR = green or yellow

#	NOTICE message	HELP message
293 and 294	**INSTALLATION PROBLEM** THE [COLOR*] VALVE IS NOT CORRECTLY LOADED Press DRAW to load the pumps and repeat valve check. *Where COLOR = blue or white	The message "The [COLOR*] valve is not correctly loaded" appears if the [COLOR] valve loading test fails. Verify the following: ● The [COLOR] valve is correctly loaded with the [COLOR]-striped tubing. ● All outlet valves are correctly loaded with tubing of the same color ● The SPM is correctly loaded and the slide clamp on the SPM is open. ● The orange-striped tubing and the purple-striped tubing are not occluded. After resolving the error state, press the Prime key exit the autoload sequence or press "Draw" to repeat the autoload sequence, including the valve check. *Where COLOR = blue or white
295	**INSTALLATION PROBLEM** THE PURPLE AND ORANGE VALVES NOT CORRECTLY LOADED Press DRAW to load the pumps and repeat valve check.	The message "The purple and orange valves not correctly loaded" appears if the purple and orange valve loading tests fails. Verify the following: ● The PURPLE and ORANGE valves are correctly loaded with the PURPLE and ORANGE tubing. ● All valves are correctly loaded with tubing of the same color. ● The SPM is correctly loaded and the slide clamp on the SPM is open. ● Tubing is loaded in each pump. After resolving the error state, press the Prime key exit the autoload sequence or press "Draw" to repeat the autoload sequence, including the valve check.
296	**INSTALLATION PROBLEM** BOWL OUTLET VALVES ARE NOT CORRECTLY LOADED Press DRAW to load the pumps and repeat valve check.	The message "The bowl outlet valves are not correctly loaded" appears if the bowl outlet valves (yellow, green, and clear) loading tests fails. Verify the following: ● The YELLOW, GREEN and CLEAR valves are loaded with tubing of the same color. ● The SPM is correctly loaded and the slide clamp on the SPM is open. ● Tubing is loaded in each pump. ● ORANGE/PURPLE tubings are not occluded. After resolving the error state, press the Prime key exit the autoload sequence or press "Draw" to repeat the autoload sequence, including the valve check.

#	NOTICE message	HELP message
297	**INSTALLATION PROBLEM** PLATELET BAG AIR REMOVAL FAILED Press DRAW to load the pumps and repeat air removal.	The message "Platelet bag air removal failed" appears if the bowl outlet valves (yellow, green, and clear) loading tests fails. Verify the following: ● Slide clamp on platelet harness additive solution line is closed. ● All valves are correctly loaded with tubing of the same color. ● The SPM is correctly loaded and the slide clamp on the SPM is open. ● Tubing is loaded in each pump. After resolving the error state, press the Prime key exit the autoload sequence or press "Draw" to repeat the autoload sequence, including the valve check.
298	**INSTALLATION PROBLEM** TUBINGS IN VALVES ARE INVERTED Press DRAW to load the pumps and repeat valve check.	The message "Tubings in valves are inverted" appears when the Purple and Orange valve inversion test fails. Verify the following: ● The YELLOW, GREEN, PURPLE and ORANGE valves are correctly loaded with tubing of the same color. ● All outlet valves are correctly loaded with tubing of the same color. ● The SPM is correctly loaded and the slide clamp on the SPM is open. ● Tubing is loaded in each pump. After resolving the error state, press the Prime key exit the autoload sequence or press "Draw" to repeat the autoload sequence, including the valve check.
290	**INSTALLATION PROBLEM** THE RED VALVE IS NOT CORRECTLY LOADED Press DRAW to load the pumps and repeat valve check.	The message "The red valve is not correctly loaded" appears when the red valve loading test fails. Verify the following: ● The RED valve is correctly loaded with red-striped tubing. ● There are no kinks on the AC, donor, and red-striped tubing. ● The DPM is correctly loaded and the slide clamp on the DPM is open. ● Tubing is loaded in each pump. After resolving the error state, press the Prime key exit the autoload sequence or press "Draw" to repeat the autoload sequence, including the valve check.
386	**PLATELET PEAK TOO SMALL** Press YES for more cycles Press NO to end procedure.	See "Platelet peak too small" on page A-3 for further troubleshooting information.

#	NOTICE message	HELP message
387	**SUSPECTED RED CELL SPILLAGE** Inspect product. If spill confirmed, clamp off collected product and perform full QC. Press YES for more cycles Press NO to end procedure	The MCS+ software detects an unexpected rapid drop in the optical line sensor reading. Discontinue the collection if necessary and perform a full quality control check for yield and leukocyte content. Use the following steps if the operator inspects the platelet reservoir bag and line and confirms a red cell spillage: ➔ Press the No key to end the procedure. If collecting concentrated platelets, the device performs one more cycle to complete the super surge and collect platelets. ➔ Immediately clamp off the collected platelet product from the reservoir bag. This action prevents additional red blood cells from entering the final product. A full quality control check should be performed to verify platelet yield and white blood cell count. ➔ Press the Yes key to perform more cycles if the operator inspects the platelet product and decides to continue the procedure.
388	**PROCESS PROBLEM** ADDITIVE FLOW RATE IS OUT OF RANGE	The clear valve closes and this message appears if the required volume of additive solution was not added to the platelet bag within a configured amount of time. Verify the following: ● Additive solution bag is on pole upper hook. ● Additive transfer bag is on front weigher. ● Solution and transfer bags are connected. ● Solution bag seal is broken. ● Solution is visible in transfer bag. After resolving the error state, press the Prime key to resume the transfer sequence. Monitoring of flow rate will **not** resume If the error cannot be resolved: ➔ Press STOP to abort the automatic transfer of additive solution. When the secondary help screen appears: ➔ Press YES to abort automatic transfer. OR ➔ Press NO to return to the automatic transfer.

#	NOTICE message	HELP message
389	**PROCESSING PROBLEM** DISPLACEMENT OF BAGS NOT DETECTED	The message "Displacement of bags not detected" appears when the operator has pressed "DRAW/YES" to indicate that the product harnesses have been moved, but the device has not detected the appropriate weight change on the weigher. ➔ Verify that the product harnesses have been moved to the front weigher. ➔ Verify that the additive solution transfer bag was moved from the front weigher and that it contains at least 100 ml of additive solution. **WARNING: Discard the disposable set if additive solution has reached the leukoreduction filter.** ➔ After resolving the error state, and if no fluid has reached the leukoreduction filter, press the Prime key to resume the priming sequence.
390	**PROCEDURE TARGET LIMITED AUTOMATICALLY** PROCEDURE TARGET HAD TO BE AUTOMATICALLY LIMITED TO AVOID LOWERING THE ESTIMATED DONOR PLATELET POST-COUNT	The message **Procedure target limited automatically** indicates that the device has automatically limited a procedure target after the operator has attempted to set a target amount that would cause the donor platelet post-count to decrease below the programmed limit. The device calculates the amount of plasma to collect each cycle based on the number of target cycles in the procedure. If the device automatically limits the number of cycles in the procedure, or ends the procedure early, the device might not be able to collect enough plasma to reach the plasma target. Press YES to continue.
391	**INSTALLATION PROBLEM** LINE SENSOR HAS DETECTED ADDITIVE SOLUTION **If fluid has reached leukoreduction filter, power off and restart with new disposable set.**	The message "Line sensor has detected additive solution" appears when the line sensor detects additive solution during the valve-loading check. Verify the following: ● Clear tubing is in the clear valve. ● Yellow-striped tubing is in the yellow valve. ● White-striped tubing is in the white valve. **WARNING: Discard the disposable set if additive solution has reached the leukoreduction filter.** After resolving the error state, press the Prime key to move to the next step of the autoload sequence.

#	NOTICE message	HELP message
392	**PROCESS PROBLEM** INITIATION OF ADDITIVE TRANSFER HAS FAILED	Before opening the clear valve to begin transferring additive solution, the device briefly monitors the weigher. This message appears if the device detects a weight change on the weigher during the monitoring period. ➔ Check for kinks in the additive transfer line. ➔ Ensure the platelet bags hang freely on weigher. **DO NOT TOUCH THE WEIGHER** ➔ Once the issue is resolved, press PRIME to resume the procedure. The device monitors the weigher again, and if no excessive weight change is detected the clear valve opens and the additive priming sequence resumes.
393	**PROCESS PROBLEM** PRP RECIRCULATION END DETECTED TOO EARLY	If message "PRP recirculation end detected too early" appears, verify the following: ➔ The PRP/Air/RBC bag is on the right IV pole at mid height with ports facing down. ➔ All valves are correctly loaded. After resolving the error state, press the Draw key to continue the procedure.

Appendix B

Operator Configuration Parameters

OPERATOR CONFIGURATION PARAMETERS B-2
- Accessing the operator configuration feature B-2
- Performing the weigher check B-3
- Modifying the parameter settings B-4
- Saving any modified values B-5
- Exiting the configuration feature. B-5
- The parameter menu groups. B-6
- Parameter reference information B-7
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OPERATOR CONFIGURATION PARAMETERS

Certain parameters are located in the operator configuration feature of the protocol software. These parameters can affect the characteristics of the collected product. Any modifications to the default settings provided by Haemonetics should be made according to local standard operating procedure.

The operator configuration feature also contains a weigher test which validates the calibration of the MCS+ weigher arm. This item appears as the first item on the list and is highlighted on the display screen when the initial menu is first accessed.

Accessing the operator configuration feature

The operator can access the operator configuration feature from the protocol option selection menu. The protocol selection menu remains accessible during installation of the disposable set elements at any point prior to initiating the pump autoload sequence.

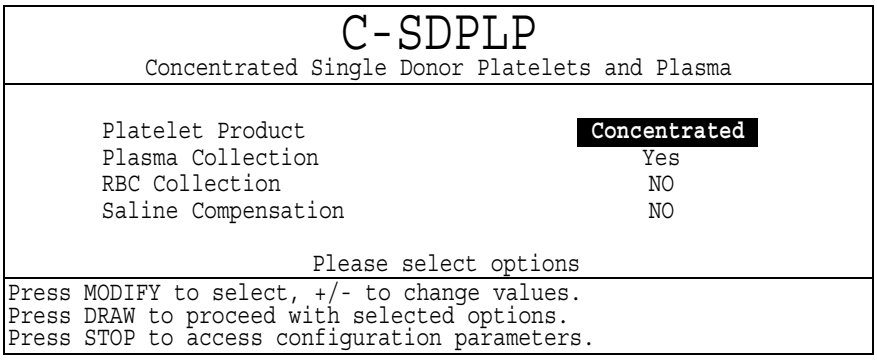

Figure B-1, Example of a protocol option selection menu

➔ Press the STOP key to access the initial operator configuration menu.

The following screen appears:

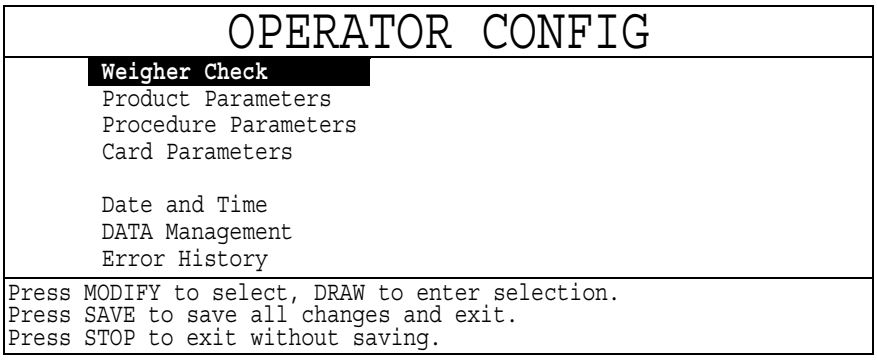

Figure B-2, Initial Operator Configuration menu

Performing the weigher check

➔ When the weigher check item appears highlighted on the display screen, press the Draw key to enter the selection.

The following screen appears:

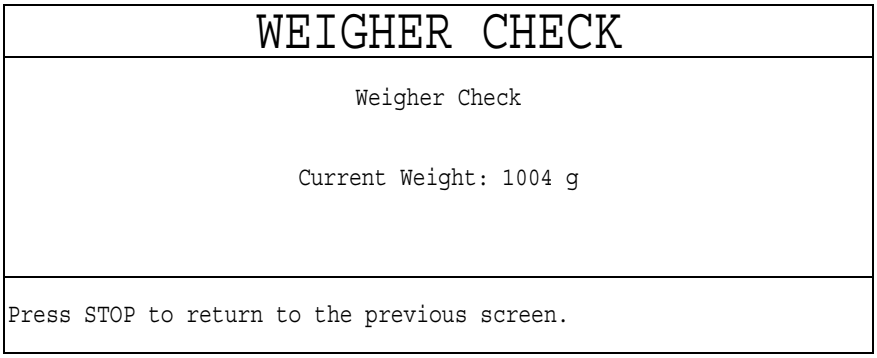

Figure B-3, MCS+ Weigher Check screen

The operator should perform the check with a certified weight and place it on a **fully extended** weigher arm to achieve proper results.

Note: The weight should not exceed 1300 grams.

The measurement of the weight displayed in grams on the screen display should be within 1% of the certified weight, for example:

- When using a certified weight of 500 grams, the readout should be between 495 and 505 grams.
- When using a certified weight of 1000 grams, the readout should be between 990 and 1010 grams.

If the reading is not within 1% of the certified weight, the operator should first power-off, then power-on the device and repeat the weigher check. If the reading remains greater than 1% out of range, the operator should power-off the device and contact an authorized Haemonetics representative.

Note: To ensure maximum accuracy during the weigher check, the weigher arm should be positioned at a 90° angle to the top deck prior to powering-on the device.

➔ Once the weigher check has been performed, press the STOP key to return to the initial Operator Configuration menu.

Modifying the parameter settings

This initial Operator Configuration menu lists particular parameters by groups. To adjust individual settings, the operator first needs to access each listed parameter group as follows:

- ➔ Press the Modify key to scroll the parameter menu; the selected group of parameters appears highlighted on the screen.
- ➔ Press the Draw key to access the selected parameter group.

Each group of parameters displays a specific menu from which the operator can adjust individual parameter settings. The settings displayed provide the Haemonetics default values until other values are entered and saved by the operator.

The following screen display provides an example of a specific parameter group menu.

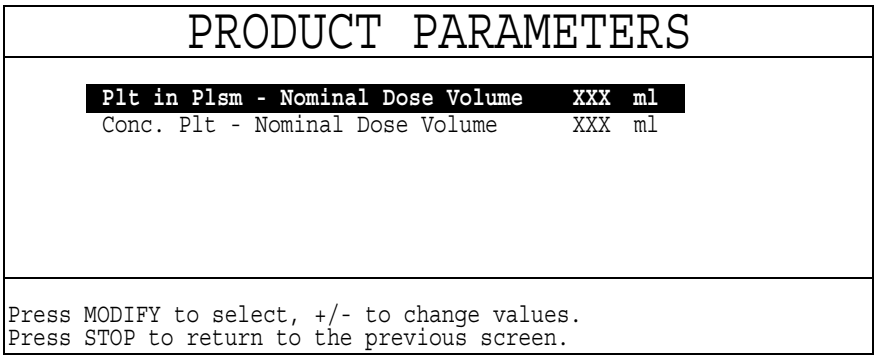

Figure B-4, Product parameter menu

Once each specific group of parameters is displayed, the operator can consult the current values and return to the previous screen (the initial operator configuration menu), without modifying the settings as follows:

- ➔ Press the STOP key to return to the initial menu.

The operator can then change the value for any of the listed parameter settings as follows:

- ➔ Press the Modify key to scroll the list of parameters; the selected parameter will appear highlighted on the screen.
- ➔ Press the + and – keys to increase (+) or decrease (–) the value listed on the screen.

Saving any modified values

Once modifications have been made within a specific group of parameters, the operator needs to return to the initial menu, prior to any further action. From the initial menu, the operator can continue to view and/or modify other parameter settings by consulting each specific parameter group. Once all desired changes have been made within each group, the operator should proceed as follows to retain the new values:

➔ Press the STOP key to return to the initial menu.

➔ Press the Save key to retain all modified values as the current settings.

Once the Save key is pressed, all changes are retained in the MCS+ memory and the device automatically exits the configuration menu and changes the screen display.

One exception exists concerning the use of the Save key. The DATE and TIME menu requires the operator to use the Save key directly within the specific menu to retain any modifications. This menu appears as follows:

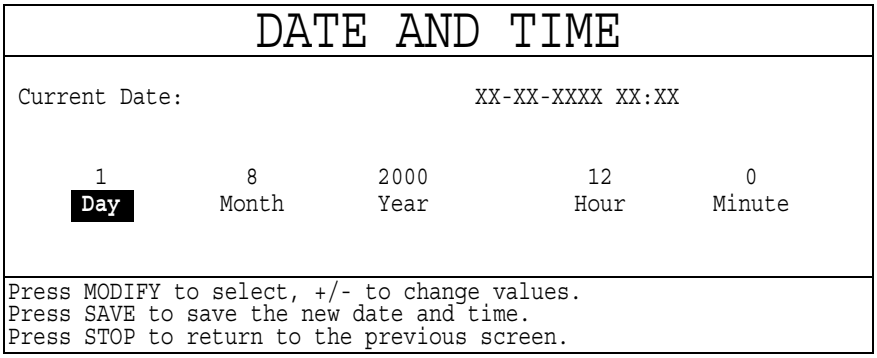

Figure B-5, Date & Time parameter menu

Exiting the configuration feature

The operator can exit the operator configuration feature from the initial menu after either only consulting the settings, or after having modified certain values, according to the following actions:

➔ Press the Save key to retain all modified values within each parameter group and exit the initial menu.

or

➔ Press the STOP key to exit the initial menu; no modification will be made to any of the current values.

If the operator presses STOP, a notice message appears prompting the operator to confirm whether to exit without saving the changes. The following actions are available:

➔ Press STOP to return to the configuration screen.

➔ Press SAVE to save all changes and exit.

➔ Press DRAW to confirm exit without saving.

The parameter menu groups

Product parameters

The **Product** parameter menu lists the nominal dose volume for either a single donor platelet product (Plt in Plsm) or a concentrated platelet product (conc. Plt).

Procedure parameters

The **Procedure** parameter menu permits the operator to adjust the default settings for certain parameters which appear on the MODIFY PARAMETERS menu. The operator can also change the number of “beeps” heard at the end of a procedure from this menu.

Card parameters

The **Card** parameter menu identifies the program and permits the operator to reinstate Haemonetics default values to all operator configuration parameters by selecting “YES.” The default setting is “NO”.

Date and Time

The **Date and Time** menu permits the operator to adjust the current day, month, year and time of day, using a twenty-four hour clock for the hour and minutes.

Data Management

The **DATA Management** menu lists stored data for the last ten procedures.The operator can download the data to different devices, depending on the selected technical configuration. Further explanation and details related to this menu and the treatment of stored data can be found in the MCS+ device Operation Manual.

Error History

The **Error History** menu lists the last ten collection procedures which required the operator to perform a Recovery Procedure. Specific information can be retrieved about each situation from the sub-menus of each listed error.

Parameter reference information

The tables in this section list the operator configuration parameters according to how they are displayed on the specific parameter group menus. Modifications to any setting on these menus changes the default value displayed for each relevant parameter for **all** of the options.

Table B-1, Product parameter menu information

Parameter	Unit of measure	Default value	Range of values	Increment of change
Plt in Plsm – Nominal Dose Volume	ml	100	50–800	1/10
Conc. Plt – Nominal Dose Volume	ml	305	*	1/10

**** Note: TC Min/Maximum = Technician Configuration Minimum. To change these limits, the operator should contact a Haemonetics representative.***

Table B-2, Procedure parameter menu information

Parameter	Unit of measure	Default value	Range of values	Increment of change
Cuff Pressure	mmHg	50	0-100	5/10
Draw Speed	ml/min	85	20-100	5/10
Return Speed	ml/min	140	20-140	5/10
AC bag volume	ml	500	0-1000	25/50
NaCl bag volume	ml	500	0-1000	25/50
Final beeps	–	1	1-10	1

Printing procedure data

When the MCS+ device is configured to send a record of the completed procedure statistics to a printer and an automatic print-out is not generated for any reason, the operator can use the DATA Management menu to download the procedure statistics and generate a printed record. The following is an example of a print-out.

```
PROCEDURE RECORD
DONATION #          E55555555555555             DONOR #          222222222222222
Date:               14-09-2004
MACHINE TYPE:       MCS+                        Protocol:        C-SDPLPRBC
SERIAL NB.:         02E107                      VERSION:         MCS+2-UPP-X.X-LL.X

DISPOSABLE
               LIST #                  LOT #
                      HEabc0123               ABCDE01234


ANTICOAGULANT
               LIST #                  LOT #
                      HEabc0123               abcABC0123
                      HEabc0123               abcABC0123

SOLUTIONS
               LIST #                  LOT #
                      HEabc0123               abcABC0123
                      HEabc0123               abcABC0123

HAEMOCALCULATOR DATA
                        Sex    x              Target Plasma Vol      x  ml
                     Height    x  cm          Target RBC Volume      x  ml
                     Weight    x  kg            Est Final Yield      x| 10ell
                Blood Volume   x  ml               Target Yield      x  10e11
                        HCT    x  %              Target Cycles      x
              Plt Pre-Count    x  10e3           Target Duration      x  min
             Plt Post-Count    x  10e3            Expected Doses      x
             Donor Post-ECV    x  ml            Expected Plt Vol      x  ml

PROCEDURE DATA
           Volume Processed    x  ml            Number of Cycles      x
             Procedure Time    x  min              Plasma Volume      x  ml
              Donation Time    x  min                 RBC Volume      x  ml
            Collection Time    x  min           RBC Additive Vol      x  ml
             Prime Duration    x  min         RBC Product Volume      x  ml
         Idle B4 Processing    x  min            Platelet Volume      x  ml
            Processing Time    x  min        Plt Additive Volume      x  ml
             AC Volume Used    x  ml             Plt Product Vol      x  ml
           AC used in Prime    x  ml        Plsm Addition to Plt      x  ml
           NaCl Volume Used    x  ml             Estimated Yield      x  10e11
               AC in Plasma    x  ml                Target Yield      x  10e11
            AC in Platelets    x  ml                   AC in RBC      x  ml
                               Estimated Platelet Yield is outside configured range
PROCEDURE RESULTS
  PLATELETS _____________________  10E11        LEUKOCYTES _____________________  10E6

COMMENTS
_____________________________________________________________________________
_____________________________________________________________________________
```

```
INSTALLATION OPERATOR #          XXXXXXXXXXX
VERIFICATION OPERATOR #          XXXXXXXXXXX
VENIPUNCTURE OPERATOR #          XXXXXXXXXXX

    PHYSICIAN_____________________  (if required by local rules)
                Date / Signature
```