Cell Saver® Elite®+

User Manual

Not for use with software
prior to revision AQ

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HAEMONETICS®

Publication Information

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Chapter 1

Introduction

The Haemonetics Cell Saver Elite+ Device

What is the Purpose of This Manual?

The *Cell Saver® Elite®+ User Manual* provides users with the information needed to safely operate and maintain the Cell Saver Elite+ device and ensure optimal performance.

The manual includes:

- Detailed descriptions of the device and all components
- How to safely operate the device and troubleshoot any difficulties
- How to properly handle and maintain the device

Use this manual in conjunction with training supplied by qualified Haemonetics® personnel.

This manual applies to device list numbers CSE-EW-US and CSE-E-US and is not for use with software prior to revision AN.

What is the Cell Saver Elite+ Autotransfusion System?

The Cell Saver Elite+ Autotransfusion System provides intraoperative and postoperative blood salvage for surgical procedures with medium to high blood loss. The shed blood is collected in a reservoir, processed in a centrifuge bowl to pack red blood cells (RBCs), and then washed to remove cell stroma, platelets, activated clotting factors, extracellular potassium, free hemoglobin, anticoagulant, and cardioplegia. The washed, packed RBCs are then pumped to a reinfusion bag.

Prior to autotransfusion, the device can also sequester platelets using the autotransfusion processing set in conjunction with a Sequestration set.

The Cell Saver Elite+ system consists of the following three parts:

- **Cell Saver Elite+ device:** the electro-mechanical device and graphical user interface (GUI) touch screen.
- **Disposable components:** the single-use collection material including reservoir, aspiration and anticoagulant (A&A) line, processing set, vacuum line, and post-op lines.
- **Solutions:** anticoagulant and saline for collecting and processing salvaged blood.

Indications for Use

The Haemonetics® Cell Saver® Elite®+ Autotransfusion System and its related accessory components are intended for use to recover blood shed during or subsequent to an operation or as a result of trauma, processing the blood by a centrifugation and washing procedure, and pumping the processed red blood cells to a product bag. The intended use of the Sequestration Protocol is to collect an autologous, preoperative, platelet rich plasma product for reinfusion

to the same patient within the recommended time guidelines of the American Association of Blood Banks (AABB), 9th Edition.

Essential Performance

The essential performance of the Cell Saver Elite+ device is to collect and process red blood cells while maintaining red blood cell integrity to provide a viable Red Blood Cell product for reinfusion. See Table 6, "RBC Product Criteria", on page 16 for RBC Product Criteria.

Contraindications

Alert: The Cell Saver Elite+ device is not intended to be used for chest (pleural or mediastinal) wound drainage.

Follow the guidelines for general autotransfusion contraindications per the AABB *Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma*.

The risk/benefit ratio of blood salvage must be determined on an individual basis by the surgeons, anesthesiologists, and transfusion medicine specialists involved in the patient's care. The use of reinfused blood from the Cell Saver Elite+ system may be contraindicated, for example, in the case of sepsis or malignancy. The responsibility for the use of this device belongs solely to the physician in charge.

Features of the Cell Saver Elite+ System

The Cell Saver Elite+ system includes key enhancements to the Cell Saver line of products that increase device capabilities and ease of use. These enhancements include:

- Two suction options: on-board SmartSuction® technology and regulated on-board suction.
- The ability to retain data for up to 100 procedures and continue a procedure after being powered down during transport from the operating room to the post-anesthesia care unit (PACU).
- A built-in barcode reader to record processing set(s), solutions, and operator/patient information.
- The ability to download data using a USB flash drive.
- A touch-screen display that provides both a simple interface during operation and allows users to easily access advanced configuration options.
- A fat reduction protocol

Cell Saver Elite+ Release AQ - Key New Features

Table 1, Key New Features

Feature	Description
Manual Mode	Manual Mode enables users to operate the device manually during the Fill, Wash, Empty, Concentrate and Return phases.
Quick Transfer	When time is of the essence, Quick Transfer Mode can be used to quickly move shed blood from the reservoir to the reinfusion bag and bypass the wash phase completely.
Final Cycle	Enables users to specify the **End Procedure** behavior when air is detected during Fill.

See the *Cell Saver Elite+ Release Notes* for more information on the changes made for release AQ.

Performance Characteristics

Table 2, Vacuum Suction

Characteristic	Value
Smart Suction	
Operating vacuum	30 to 165 mmHg ±10% (4.0 to 22.0 kPa; 40.0 to 220 mbar)
Vacuum cutoff	175 mmHg (23.3 kPa; 233 mbar)
Maximum free air flow	40 L/min
Manual Mode	
Operating vacuum	50 to 250 mmHg (6.7 to 33.3 kPa; 66.7 to 333.3 mbar)
Maximum free air flow	40 L/min
Post-Op	
Operating vacuum	25 to100 (3.3 to 13.3 kPa; 33.3 to 133.3 mbar)
Maximum free air flow	40 L/min

Table 3, Cell Savage Protocol (225 mL and 125 mL Bowls)

Characteristic	Value
Centrifuge Speed (Fill)	5650 RPM ±300 RPM
Centrifuge Speed (Concentration)	3850 RPM ±300 RPM
Centrifuge Speed (Wash)	6050 RPM ±300 RPM
Pump Speed	25 mL to 1000 mL ±10%
Reservoir Level	Up to 3 kg ±25 g
Waste Bag Scale	Up to 10 L ±250 mL

Table 4, Cell Savage Protocol (70 mL Bowl)

Characteristic	Value
Centrifuge Speed (Fill, Wash)	7500 RPM ±300 RPM
Centrifuge Speed (Concentration)	5000 RPM ±300 RPM
Pump Speed	25 mL to 1000 mL ±10%
Reservoir Level	Up to 3 kg ±25 g
Waste Bag Scale	Up to 10 L ±250 mL

Table 5, Sequestration Protocol

Characteristic	Value
Centrifuge Speed (Fill)	5650 RPM ±300 RPM
Centrifuge Speed (PRP)	2450 RPM ±300 RPM
Pump Speed	10 mL to 250 mL ±10%

Blood Product Quality

Attention: *Actual performance results may vary depending on many in-use variables.*

Haemonetics recommends using the following RBC product criteria for quality control procedures. Criteria are based on Haemonetics Default and standard fat reduction protocol settings in laboratory performance with 10% hematocrit blood pools.

Table 6, RBC Product Criteria

Criteria	Product Performance
HCT	≥ 40%
RBC Recovery	≥ 80%
Free Hemoglobin Washout	≥ 95%
Heparin and Albumin Washout	≥ 95%

Laboratory testing of the 225 mL bowl using Haemonetics Default settings yielded the blood product quality results listed in the table below. Test results are based on two-cycle procedures processing 10% hematocrit test pools. Lysate and heparin were added to measure constituent washout. Results are listed below for test pools prepared both with and without lysate. Mean values are reported alongside standard error of the mean. Results may vary depending on in-use variables.

Table 7, 225 mL Bowl Test Results

Parameter	Without Lysate	With Lysate
HCT %	52 ± 0.8	58 ± 4.2
RBC Recovery %	95 ± 1.3	94 ± 1.8
WBC Removal %	40.7 ± 4.3	36.9 ± 11.3
Free Hemoglobin Washout %	-	99.0 ± 0.2
Total Protein Washout %[a]	98.5 ± 0.1	99.0 ± 0.2
Potassium Washout %	-	98.7 ± 0.2
Heparin Washout %	99.6 ± 0.1	99.7 ± 0.1
Fat Washout %[b]	99.6 ± 0.13	

a. Total protein measurement has been used as a surrogate instead of albumin only assay (albumin being a sub-category of protein).

b. Fat reduction performance is applicable for the Fat Reduction setting.

See Appendix B, “System Performance” for complete blood quality performance results for all bowl sizes and other settings, including Fat Reduction, Emergency Mode, and partial bowl and low wash.

Symbols

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 user.

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

Attention: *advises the user 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.*

Alert: advises the user against initiating an action or creating a situation which could result in serious personal injury to the patient or user.

Warning: Notifies the user of an electric shock risk.

Caution: *Notifies the user of a laser beam exposure risk.*

Symbols Found on the Device

The following symbols may appear on the device or device packaging.

General warning, caution, risk of danger

Type CF applied part

Type CF applied part provides a specific degree of protection against electric shock, particularly regarding allowable leakage current and reliability of the protective earth connection.

Electrical and electronic equipment waste (applies to EU only)

Dispose of the device using a separate collection method (according to EU and local regulation for waste electrical and electronic equipment).

IPX1

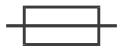
Protection against ingress of vertically dripping water

The enclosure of the device is designed to be drip-proof, providing a higher than ordinary level of protection from drips, leaks and spills.

Manufacturer

Maximum safe working load

Alternating current



Fuse

Equipotentiality

Identifies the terminals which, when connected together, bring the various parts of a system to the same potential.

EC REP

Authorized representative in the European Community (address for)

US: Rx Only

Rx only (applies to USA only)

Federal (USA) Law restricts the device to sale to or on the order of a physician.

SN

Serial number

REF

Catalog (list) number

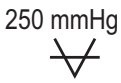
Warning; laser beam

Non-ionizing electromagnetic radiation

Used to specify RF (radio frequency) transmission for data communication.

General symbol for recovery/recyclable

To indicate that a material is part of a recovery/recycling process. (Applicable only to those products or materials for which, at the end of life, there is a well-defined collection route and recycling process, and which does not significantly impair the effectiveness of other recycling schemes.



Maximum vacuum

Storage conditions, humidity limit

Storage conditions, temperature limit

Storage conditions, keep dry

Fragile, handle with care

This end up

Refer to instruction manual/booklet

MR Unsafe

Warning: Keep away from magnetic resonance imaging (MRI) equipment.

Device Specifications

Note: The use of materials not provided or recommended by Haemonetics is the sole responsibility of the end-user, and the end-user will be responsible for any personal injury and/or property damage related to such use.

Device Classification

The Cell Saver Elite+ device is classified as a continuous operation, Class I, Type CF, IPX1 device, in accordance with IEC/EN 60529 and 60601 standards for medical electrical equipment.

Physical Specifications

The approximate dimensions and weight of the Cell Saver Elite+ device are as follows:.

Table 8, Physical Specifications

	Depth/in. (cm)	**Height/in. (cm)**	**Width/in. (cm)**
Device Alone	21.5 in. (54.6 cm)	16.5 in. (41.9 cm)	11.75 in. (29.8 cm
Device With Cart			
IV poles extended	26.5 in. (67.3 cm)	72 in. (182.9 cm)	21 in. (53.3 cm)
IV poles down	26.5 in. (67.3 cm)	48 in. (121.9 cm)	21 in. (53.3 cm)
Weight of device	56 lbs. (25 kg)		
Weight of cart	39 lbs. (18 kg)		
Safe working load of system	157 lbs. (71 kg)		

The noise level of the Cell Saver Elite+ device is < 70 dB.

Environmental Specifications

The following environmental conditions should be respected pertaining to operation and storage of the Cell Saver Elite+ device.

Alert: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Note: Store disposable components in a dry place away from solvent vapors and extremes of temperature.

Note: The device should not be used near active high-frequency surgical equipment or in the RF shielded room of MRI equipment, where the intensity of electromagnetic disturbances is high.

Table 9, Environmental Specifications

Conditions	Values
Ambient operating temperature	10 °C to 27 °C (50 °F to 80.6 °F)
Storage/transportation temperature	-20 °C to 50 °C (-4 °F to 122 °F)
Operating humidity level	8 to 80% R.H., non-condensing above 0°C
Atmospheric pressure range	≤ 2438 meters (8000 ft.)
Pollution degree	Pollution degree 2

Electrical Specifications

The electrical specifications for operating the Cell Saver Elite+ device are as follows.

Attention: *The Cell Saver Elite+ device meets the requirements of the IEC/EN 60601-1-2 Standard, Electromagnetic compatibility (EMC).*
Additional IEC/EN compliance information is available in Appendix A.

Note: The power source used must be properly grounded.

Table 10, Electrical Input Power

Rated Voltage	Rated Current	Fuse	Frequency
100–120 V	3.0 A	T3.15A 250V	50/60 Hz
200–240 V	1.5 A	T3.15A 250V	50/60 Hz

Table 11, Enclosure/Chassis Leakage Current Specifications*

Condition	Polarity	Ground	Max Value
Normal	Normal	Normal	100 µA
	Reverse	Normal	100 µA
Single Fault	Reverse	Open	500 µA
	Normal	Open	500 µA

*In accordance with IEC/EN 60601-1standard, medical electrical equipment, general requirements for safety.

Laser Specifications

The Cell Saver Elite+ device is a class 3R laser product.

The laser specifications for the Cell Saver Elite+ device are as follows.

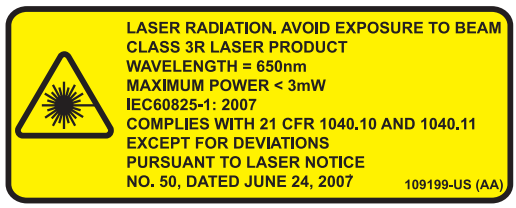
Table 12, Laser Specifications

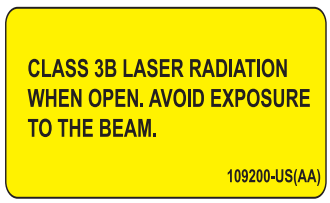
Characteristics	Values
Max radiation output	3 mW
Wavelength	650 nm
Max light output	7 mW (bowl optics) 1.7 mW +/- 0.2 mW (barcode reader)
Standards	IEC/EN 60825-1[a] 21 CFR 1040.10 and 1040.11[b]

a. The Cell Saver Elite+ device complies with IEC/EN 60825-1standard, safety of laser products, equipment classification and requirements.

b. The Cell Saver Elite+ device complies with 21CFR1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

The following labels may appear on the device:





Ordering Information

Refer to the table below for ordering information regarding disposable components.

Table 13, Disposable Components Ordering Information

Item Description	List Number	Quantity Per Case
Waste Bag, 10 L	CSE-B-1000	10
Cell Saver Elite fastpack, 225 mL, 20 µ	CSE-FP-225F	4
Cell Saver Elite fastpack, 125 mL, 150 µ	CSE-FP-125V	4
Cell Saver Elite fastpack, 225 mL, 150 µ	CSE-FP-225V	4
Cell Saver Elite processing set (70 mL)	CSE-P-70	8
Cell Saver Elite processing set (125 mL)	CSE-P-125	8
Cell Saver Elite processing set (225 mL)	CSE-P-225	8
Sequestration set	CSE-SQ-1000	8
SmartSuction filtered vacuum line, non-sterile	HAR-A-1000	10
Cell Saver collection reservoir, 3 L, 150 µ raised filter	00205-00	4
Cell Saver aspiration & anticoagulation line	00208-00	20
Cell Saver collection reservoir, 3L, 20 µ filter	00220-00	4
Cell Saver RBC bag, 1000 mL	00245-00	40

Note: Items listed may not be available in all markets. Please contact your local Haemonetics Authorized Sales Representative to discuss options and availability.

Refer to the table below for a list of user-replaceable parts.

Table 14, User-Replaceable Parts

Item Description	Part Number
Cardiotomy bracket	02116-00
Biohazard drain bag	35643-00
Wheel, 4 in., locking, antistatic	124282-01
Wheel, 4 in., locking	124282-02
Air exhaust filter cover	100875-00
Air exhaust filter	100878-00
Knob for touch screen mount and reservoir weigher	102924-00
Air intake filter	103003-00
Large cart bin	107090-00
Small cart bin	107094-00
2-hook saline bag hangers	107098-00
IV pole with 4-hook top	107099-00
70 mL centrifuge chuck adaptor	107581-00
Power cord, US	109308-00
User manual, US	130859-US

Chapter 2

Equipment Description

Overview

This chapter identifies the major components of the Cell Saver® Elite®+ system and explains their intended functions. The components are located in the following positions on the device:

- Top deck
- Front panel
- Side panel
- Rear panel
- Touch screen
- Cart

Note: Any references made to “left”, “right”, “top”, or “rear” are from the perspective of a user facing the Cell Saver Elite+ device during a procedure.

1. Device cover
2. Touch screen display
3. Effluent line sensor
4. Air detector
5. Pump cover and rotor
6. Pump platen
7. Handle
8. Reservoir weigher
9. Centrifuge system
10. Valve module
11. Cart

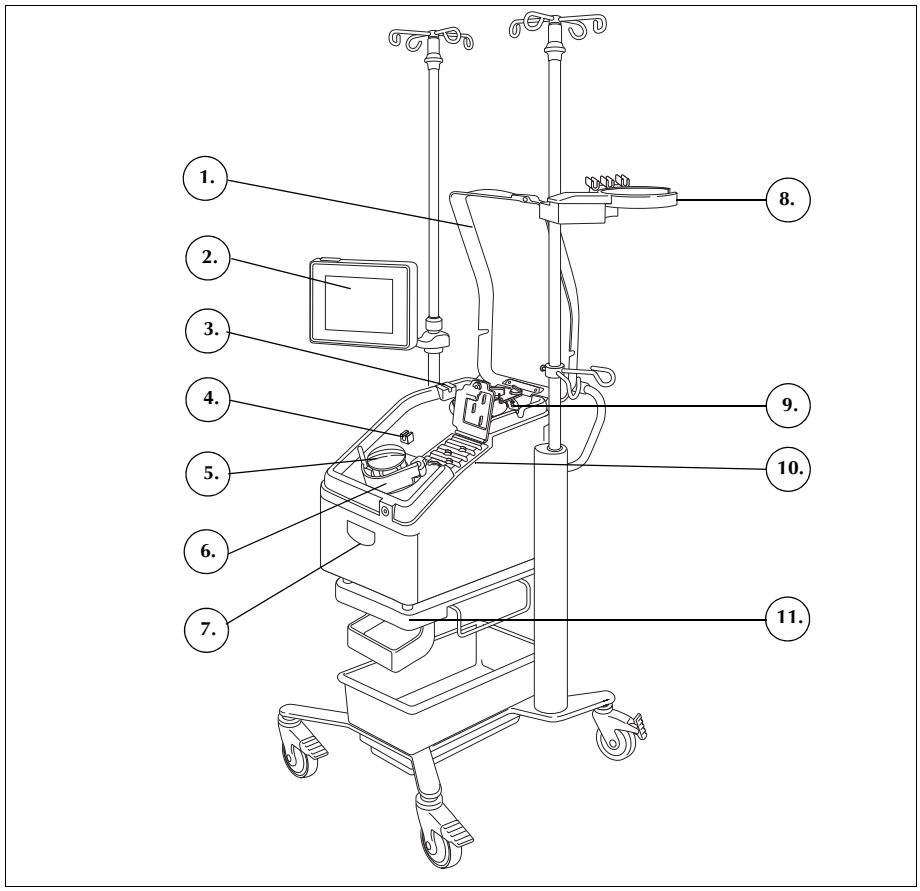


Figure 1, Cell Saver Elite+ system components

Refer to Chapter 3 for descriptions of the disposable components.

Top Deck and Front Panel Components

Device Cover

The clear plastic cover protects the top deck components and processing set while allowing the user to visually monitor both the flow of blood through the tubing, and the action of the pump and centrifuge.

The cover can be freely raised and lowered during setup and locks into place while the centrifuge and pump are rotating. The centrifuge and pump must come to a complete stop before the cover can be opened.

Effluent Line Sensor

The effluent line sensor monitors the quality of the bowl effluent, adjusts the pump speed, and advances the system to the next phase when appropriate. If the effluent line sensor is disabled, a corresponding status icon appears on the procedure diagram. (See “Status Icons” on page 42 for more information.)

Air Detector

The ultrasonic air detector monitors the fluid flow in the pump tubing.

During the Fill phase, the air detector senses air when the reservoir is empty. During the Concentrate (Conc) phase, the air detector senses when the RBC bag is empty. During the Wash phase, the air detector senses air when the saline bag is empty. If the air detector senses air during Wash and 90% or more of the necessary wash volume has been used, the device advances to the next phase.

The air detector is also used during the Empty and Return phases to determine when the centrifuge bowl is empty. This minimizes air returned to the RBC bag.

Pump

The three-roller, peristaltic pump moves fluids in and out of the centrifuge bowl. At its maximum speed it is capable of a flow of 1000 mL/min. A pump platen holds the tubing in place against the pump. The user can open and close the platen using the lever located below the platen.

Handle

There are two handles located on the front panel and the rear of the device. The handles enable easy lifting of the device when it is not attached to the cart.

Valve Module

The valve module contains a manifold pressure sensor and four channels that hold the processing set tubing in place. Three of the channels contain a pinch valve that controls the flow of fluids through the processing set during a procedure.

1. Valve module cover
2. Manifold pressure sensor
3. Latch
4. Yellow line valve
5. Red line valve
6. Blue line valve

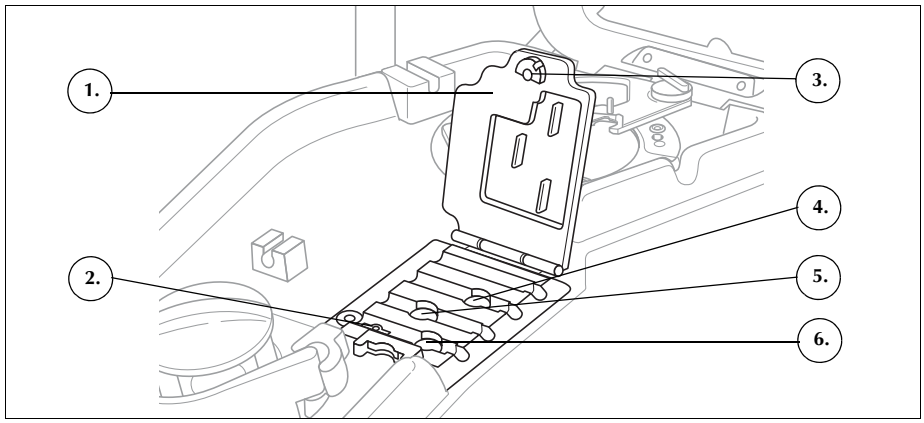


Figure 2, Valve module

Pinch Valves

The three pinch valves occlude the three color-coded lines of the harness. The function of each valve is as follows:

- **Yellow line valve**: opens the pathway to the wash solution.
- **Red line valve**: opens the pathway to the blood source.
- **Blue line valve**: opens the pathway to the RBC bag.

Manifold Pressure Sensor

The manifold pressure sensor monitors pressure levels in the blue and red lines during Empty and Return and in the yellow line during Wash. If the clamp on the RBC bag, collection bag, reservoir, or yellow line is inadvertently closed, or the saline bag empties and collapses, the manifold pressure sensor stops the pump and the device displays a message.

Valve Module Cover

The cover of the valve module secures the tubing in the channels. Push the cover down and rotate the cover latch to close the cover.

The valve module cover is open, and the valves in the module are up when loading the processing set. The cover stays locked for the duration of the procedure and unlocks automatically when the procedure is complete or if an event message requires the user to access the valve manifold.

Centrifuge System

The centrifuge system holds the processing set bowl during device operation and monitors the fluids inside the bowl.

1. Bowl optics (laser apertures)
2. Fluid detector (not shown)
3. Centrifuge chuck
4. Header arm latch
5. Header arm
6. Centrifuge drain port (under the centrifuge chuck)

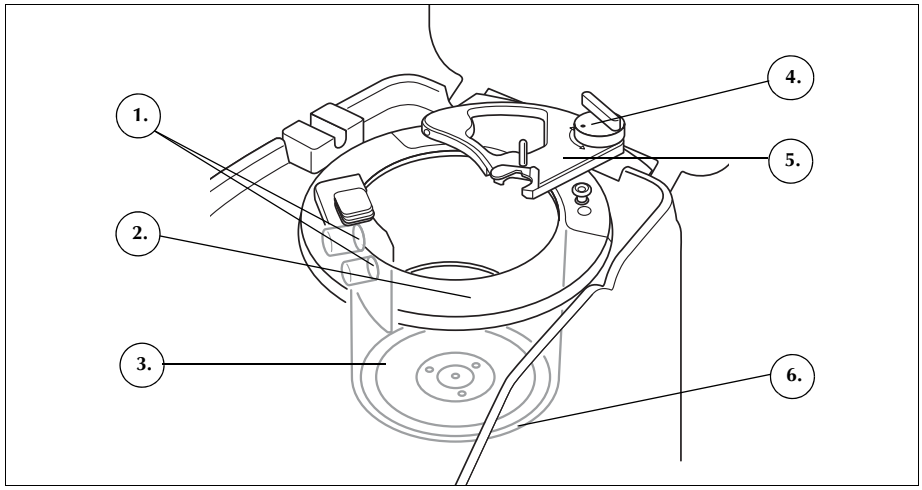


Figure 3, Centrifuge components

Bowl Optics

Caution: *The bowl optics emit laser radiation. Do not look directly into the beam.*

The bowl optics sensors mounted in the centrifuge well monitor the fluid inside the bowl and advance the device to the next phase when the RBCs reach a predetermined level within the bowl.

Example: the device automatically advances from the Fill phase to the Wash phase.

Fluid Detector

The fluid detector is an electronic fluid detection device mounted on the wall of the centrifuge well. The fluid detector detects the presence of liquid in the event of a bowl leak.

Centrifuge Chuck

Alert: The bowl base (or centrifuge chuck adaptor) must be firmly installed and evenly seated in the centrifuge chuck. If the centrifuge chuck spins with the bowl base (or adaptor) not evenly seated, as indicated by bowl wobbling or noise, bowl damage will occur and the procedure must be discontinued.

Alert: Do not grease any part of the centrifuge or centrifuge chuck adaptor. If grease has been applied to the chuck, contact the Haemonetics hotline immediately.

The centrifuge chuck holds the rotating part of the bowl during a procedure. A centrifuge drain port underneath the chuck allows blood to drain into a biohazard waste bag in the event of a bowl leak.

Header Arm

The centrifuge header arm closes around the stationary part of the bowl during a procedure. A latch secures the header arm in place.

Rear and Side Panel Components

A. Device Components
1. Waste bag weigher
2. Air intake (not shown – bottom of device)
3. Air exhaust filter (not shown – bottom of device)

B. Cables and Connections
4. Touch screen storage mount
5. Vacuum connection
6. Reservoir weigher connection
7. Equipotential ground terminal
8. Touch screen cable entry

C. Power Entry Module (PEM)
9. Power cord connection
10. ON/OFF switch
11. Main fuse holder

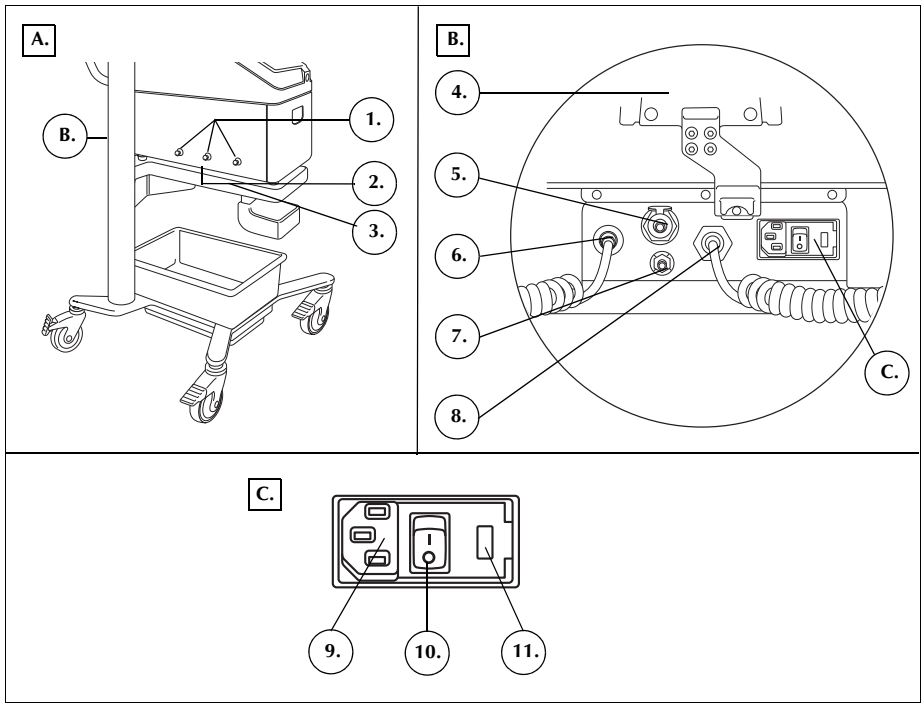


Figure 4, Rear and side panel components

Waste Bag Weigher

The waste bag weigher monitors the amount of fluid collected in the waste bag. When the weigher senses the waste bag is nearly full, the device displays a message indicating the waste bag must be emptied or replaced.

Air Intake

The air intake allows air to circulate inside the device, keeping the internal components cool. The air intake contains a removable filter that can be cleaned or replaced if necessary.

Air Exhaust Filter

The air exhaust filter is a replaceable antibacterial filter, through which externally vented exhaust from the SmartSuction® system passes.

Touch Screen Storage Mount

The touch screen storage mount holds the touch screen in place during storage and transport of the device.

Vacuum Connection

The vacuum connection allows the user to connect the filtered vacuum line that leads to the reservoir.

Touch Screen Cable Entry

The touch screen cable entry contains the cable that connects the device with the touch screen.

Equipotential Ground Terminal Connection

The equipotential ground terminal connection allows the user to connect the Cell Saver Elite+ device to other devices/equipment in the area, bringing them to the same potential.

Reservoir Weigher Connection

The reservoir weigher connection contains the cable that connects the device with the reservoir weigher.

Power Entry Module

The power entry module contains the power cord connection, ON/OFF switch, and the main fuse holder.

Power Cord

A power cord is supplied with the device. Inspect for a frayed or twisted power cord. Do not replace the power cord with a substitute. If necessary, contact the Haemonetics Customer Care Center for a replacement. Always ensure the power cord is connected to an appropriately grounded power source.

Warning: Ground continuity can only be achieved when the equipment is connected to a properly grounded outlet.

Note: The power cord can be coiled around the cart handle during transport or when the device is not connected to a power source.

Touch Screen Display

The touch screen can be positioned at a comfortable height on the cart IV pole. The user can easily rotate the display to the best viewing angle while the display is secured to the pole.

The display screen can also be mounted on a separate IV pole that is 20-25 mm in diameter.

1. Status beacon
2. Touch screen
3. Barcode reader (laser aperture)
4. STOP key
5. Touch screen mount
6. USB connection
7. Ethernet connection

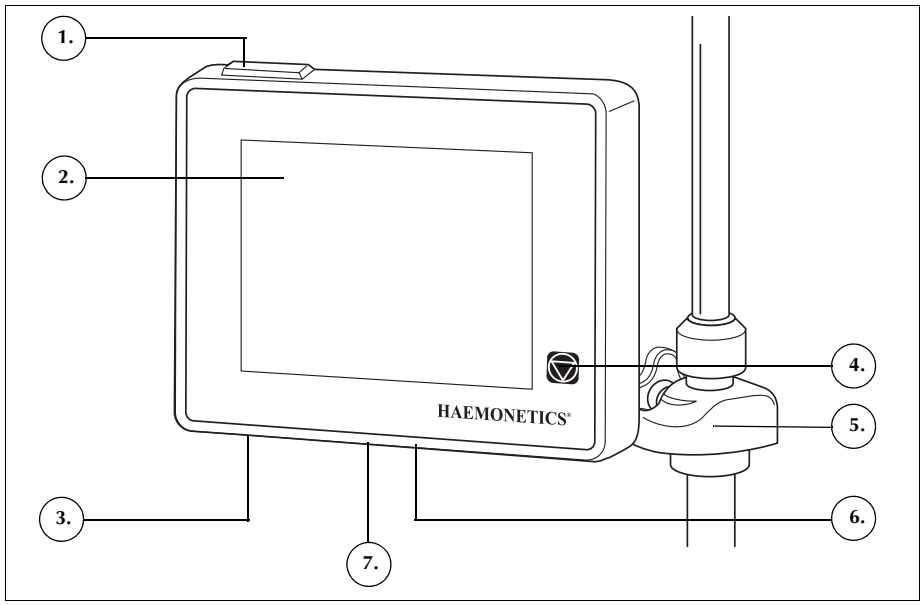


Figure 5, Parts of the device display

Status Beacon

The status beacon indicates the general status of the procedure. The beacon glows green when all operations are normal, yellow when user intervention is needed, and red when the procedure is stopped.

There are corresponding color-coded alert bars on the status indicator (page 35) and the message area (page 39).

Barcode Reader

Caution: *The class 3R barcode reader emits laser radiation. Do not look directly into the beam.*

The barcode reader scans barcode information, such as processing set list (REF) numbers, lot numbers and expiration dates, and operator and patient IDs, and stores it in the memory of the device. It is located on the bottom of the device display and is active when the *Bowl Selection* screen and *Record* or *Disposables* tabs are displayed.

Note: As a safety feature, the barcode reader emits a low-level laser until it detects a barcode. It then turns on a full-power laser to scan the barcode. The reader recognizes Codabar, Code 128, and ISBT 128 formats as valid barcode formats.

Stop Key

Pressing the (**Stop**) key stops the pump and centrifuge. The status indicator shows that the device is stopped. To restart the current phase, ensure the device cover is closed; then touch (**Play**). To start a different phase, touch the corresponding phase pad.

When the device is stopped in the Prime or Fill phase, double-pressing the **Stop** key puts the device into Standby mode.

Touch Screen Mount

The touch screen mount allows the user to move the touch screen horizontally around the IV pole and adjust the angle of the screen.

USB Connection

The USB connection is used for software upgrades and allows authorized users to download procedure and technical data to a portable USB flash drive.

***Attention:** Do not connect non-approved devices (such as cellular phones, etc.) to the USB ports. Approved devices must comply with IEC/EN 60601-1 or IEC/EN 60950-1.*

Ethernet Connection

The Ethernet connection enables the device to communicate with the designated server application (if equipped) in the absence of a wireless network connection.

Graphical User Interface

The graphical user interface (GUI) provides a simple and intuitive interface for users to use during device operation and allows easy access to advanced configuration options.

The *Processing* screen is the main procedure screen and is composed primarily of touch pads that enable you to control the procedure. If a pad is grayed out it means that particular function is not currently available.

1. Status indicator
2. Suction pad
3. Play/Pause pad
4. Active Settings pad
5. Menu
6. Fill pad
7. Wash pad
8. Empty pad
9. Volume pad
10. Message area
11. Concentrate pad
12. Return pad
13. Pump control pads
14. Emergency Mode pad
15. Procedure diagram
16. Device cover lock indicator
17. Procedure statistics

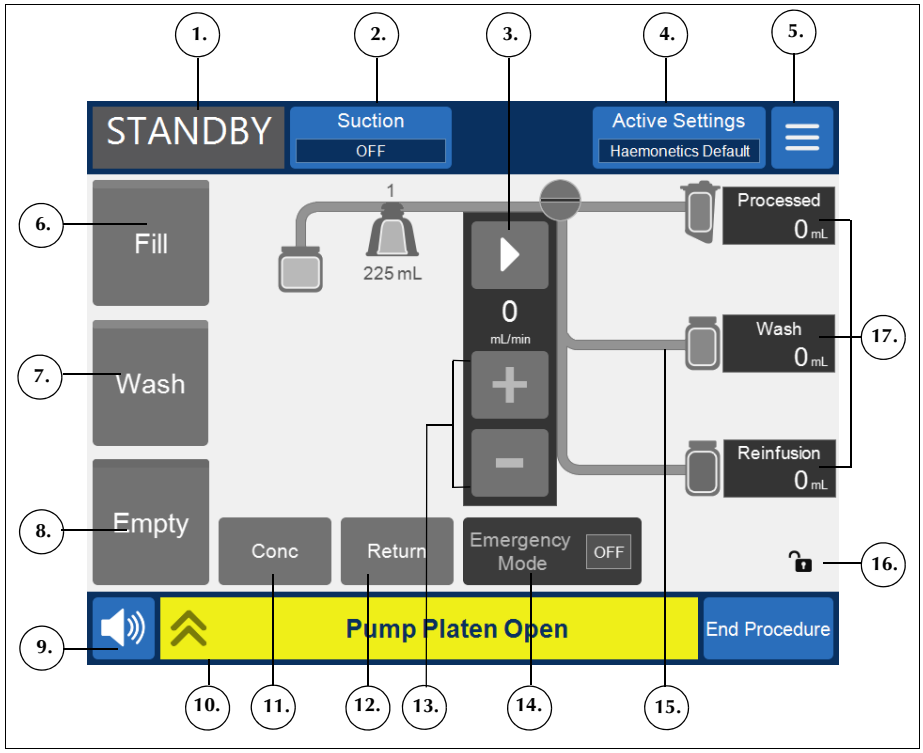


Figure 6, Parts of the Processing screen GUI

Status Indicator

The status indicator displays the current status of the device.

1. Phase/mode
2. State

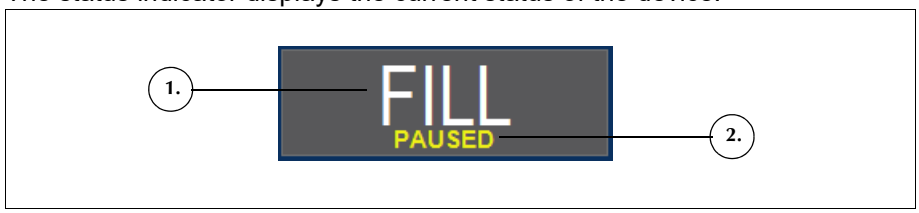


Figure 7, Example of the status indicator when the Fill phase is paused

This includes:

- **Phase/mode:** The center area shows the current phase of the device. Examples: Fill, Conc, Wash, Empty, Return, Standby.
- **State:** The area on the bottom right of the status indicator shows the current state of the device. Examples: stopped, paused.

Suction Pad

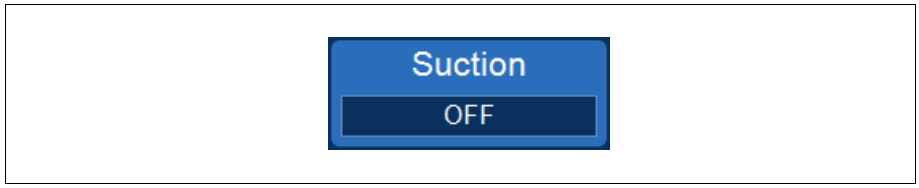


*Figure 8, Example of the **Suction** pad*

Alert: The recommended intraoperative suction setting is 200 mmHg (27 kPa; 267 mbar) or less. Maintain suction levels as low as possible to reduce RBC damage as the shed blood travels through the suction tip to the reservoir. Higher suction levels increase the amount of RBC hemolysis but may be desired in the event of excessive blood loss when the need to clear the field is greater than the need to prevent hemolysis.

The **Suction** pad allows you to choose between the following suction types:

- **SmartSuction:** Autoregulates suction levels to optimize fluid removal. The vacuum level is kept low when the device detects a high air-flow rate at the suction tip, indicating surface skimming. The vacuum level automatically increases when the device detects lower air-flow rates, indicating submergence in fluid.

Note: Efficient operation of the SmartSuction technology depends on the use of a high air-flow disposable vacuum line and aspiration and anticoagulant (A&A) line in conjunction with a reservoir that has a maximum capacity of 3 liters.
The Cell Saver Elite+ device has been calibrated to optimize SmartSuction performance with the use of Haemonetics proprietary disposable sets and recommended suction tips. Suction and fluid removal performance may decline if incorrect or non-Haemonetics disposable components are used with the system.

- **Manual:** Allows you to manually set the suction level between 50 and 250 mmHg in 10 mmHg increments.
- **Post-Op:** Provides a variable suction level with a default level of 75 mmHg. You may set the suction to 25 mmHg, 50 mmHg, 75 mmHg, 100 mmHg, or Off.

  Post-op suction utilizes periodic suction relief. Suction runs at the selected suction level for 10 minutes, turns off for 1 minute, and then returns to the selected suction level for another 10 minutes. This cycle repeats continuously throughout post-op operation.

Menu

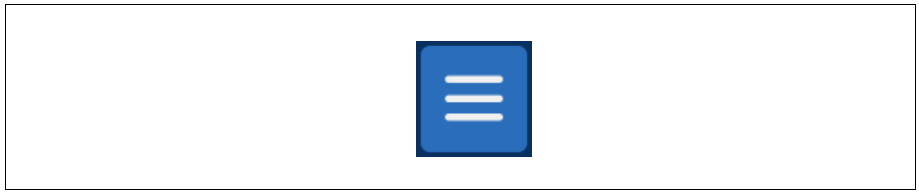


*Figure 9, Example of the **Menu** pad*

The menu allows you to access the configurable settings, the Sequestration protocol, and other options. The menu options include:

- Cell Salvage
- Sequestration (only available prior to starting the Cell Salvage protocol)
- Settings
- Records
- System
- Help

Phase Pads

Figure 10, Example of the phase pads

The phase pads include the **Fill**, **Wash**, **Empty**, **Conc**, and **Return** pads. Phase pads change color based on their status:

1. Available pad (inactive phase)
2. Active phase pad
3. Disabled pad

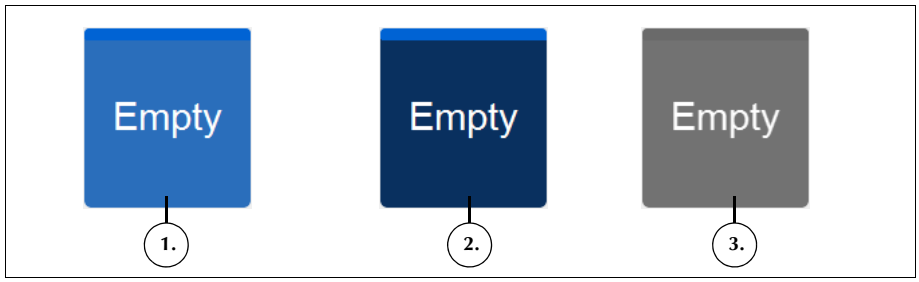


Figure 11, Example of a phase pad in different states

- **Light blue background:** The phase pad is available. The user can touch the pad to override the automatic progression of the device and manually move the device into that phase.
- **Dark blue background:** The device is already in the corresponding phase. If the device is in a paused or stopped state, you can touch the pad to resume the procedure.
- **Grayed:** The pad is disabled.

During the Wash phase, the **Wash** pad expands to show the wash volume used and the target wash volume.

1. Target wash volume
2. Wash volume used

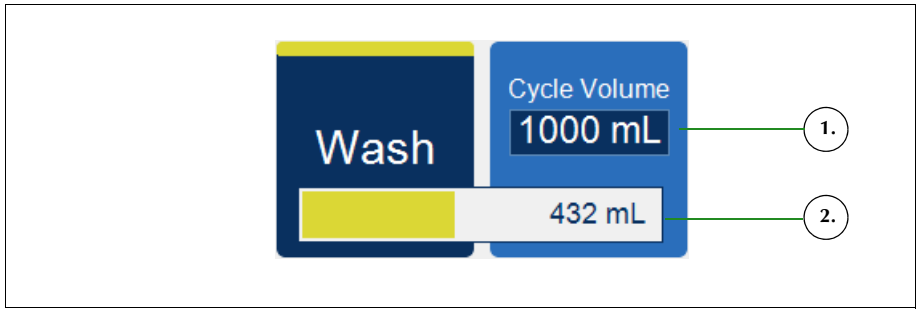


*Figure 12, Example of the **Wash** pad during the Wash phase*

To change the target wash volume for the current cycle:

1. Touch **Cycle Wash Volume**. The *Cycle Wash Volume* box appears.
2. Use the **+/-** pads to increase or decrease the target wash volume for the current wash cycle.

Note: The Cycle Wash Volume target cannot be set below the current Wash volume.

3. Touch (**Accept**) to save the change or (**Cancel**) to exit.

1. Decrease
2. Increase
3. Cancel
4. Accept

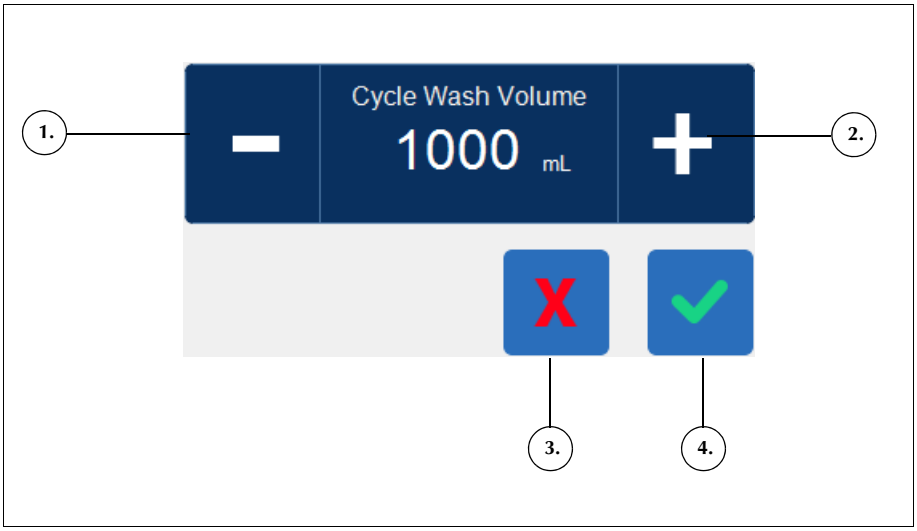


Figure 13, Example of the Cycle Wash Volume box

Message Area

Figure 14, Example of the message area

The message area at the bottom of the screen displays messages, prompts, and information for the user. Messages are color-coded to show the alert state of the device, and there is a corresponding status beacon on the top of the display screen (See page 33). Green indicates normal; yellow indicates that user intervention is needed; and red indicates that the procedure is stopped. You can touch messages to expand them to view additional information. Then touch the message bar to minimize them again. Yellow and red alerts automatically appear in full-screen view.

Pump Control Pads

1. Pause
2. Play
3. Current pump speed
4. Increase speed
5. Decrease speed

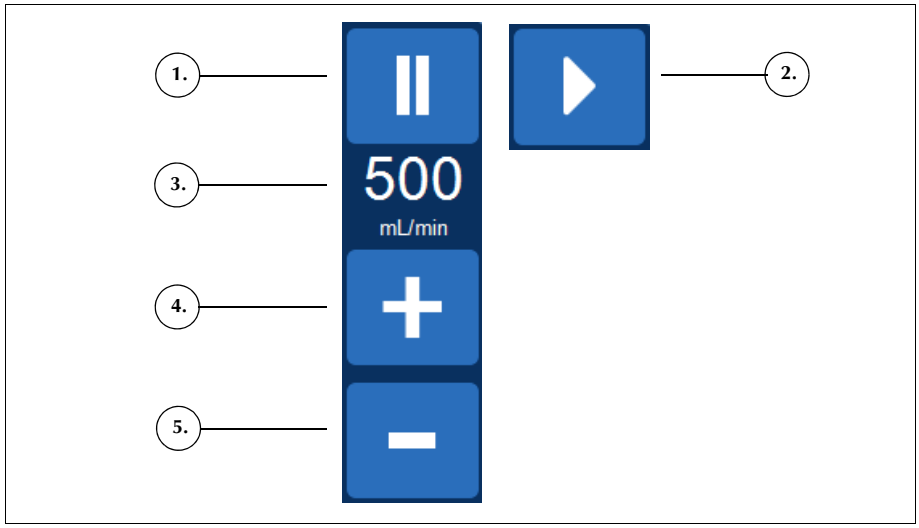


Figure 15, Example of the pump control pads

The pump control pads control the motion and speed of the pump. The device has default pump speeds that vary depending on bowl size, current phase, and mode and are set to optimize performance. The pump speed parameters can be adjusted during a procedure using the pump control pads.

To immediately stop the pumps, touch  (**Pause**). To restart the current phase, touch  (**Play**), or to start a different phase, touch the corresponding phase pad.

Procedure Diagram

The procedure diagram visually indicates the status and progress of the procedure. It shows the movement of the pump, the movement of fluid through the disposable components, if any error states occur during the procedure, and the procedure statistics.

1. Waste bag icon
2. Bowl icon (225 mL)
3. Current cycle
4. Pump icon
5. Saline bag icon
6. Reservoir icon
7. Procedure statistics
8. Example of status icon
9. RBC bag icon
10. Device cover lock indicator

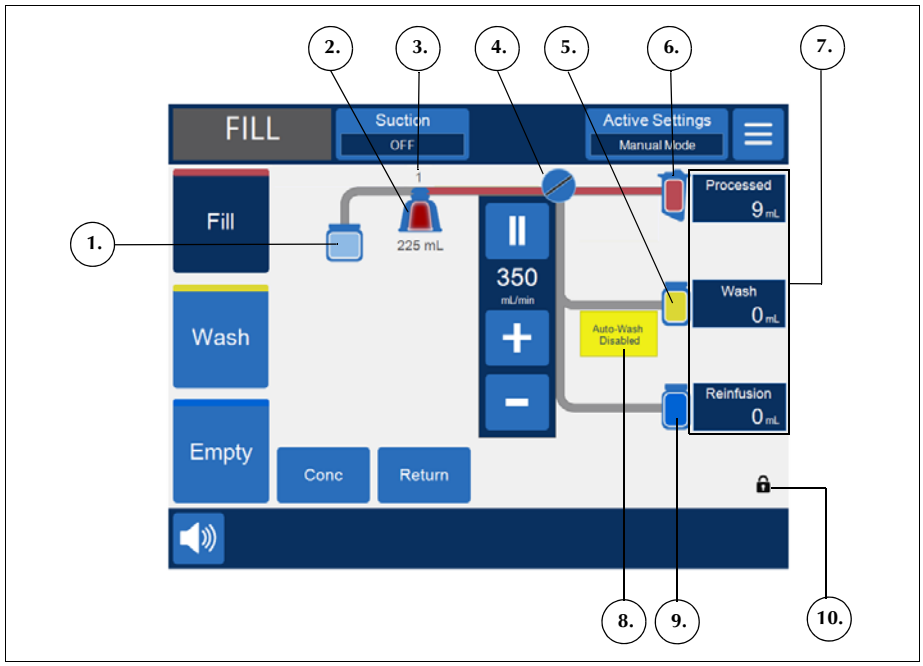


Figure 16, Example of the procedure diagram

Procedure Statistics

The procedure statistics appear at the right of the procedure diagram and indicate the volume of salvaged fluid processed, volume of saline used, and volume of RBCs added to the RBC bag.

Device Cover Lock Indicator

The device cover lock indicator appears at the lower right of the procedure diagram, and indicates if the Cell Saver Elite+ device cover is locked or unlocked .

Status Icons

The procedure diagram displays status icons when there is an event message or custom setting that affects the procedure.

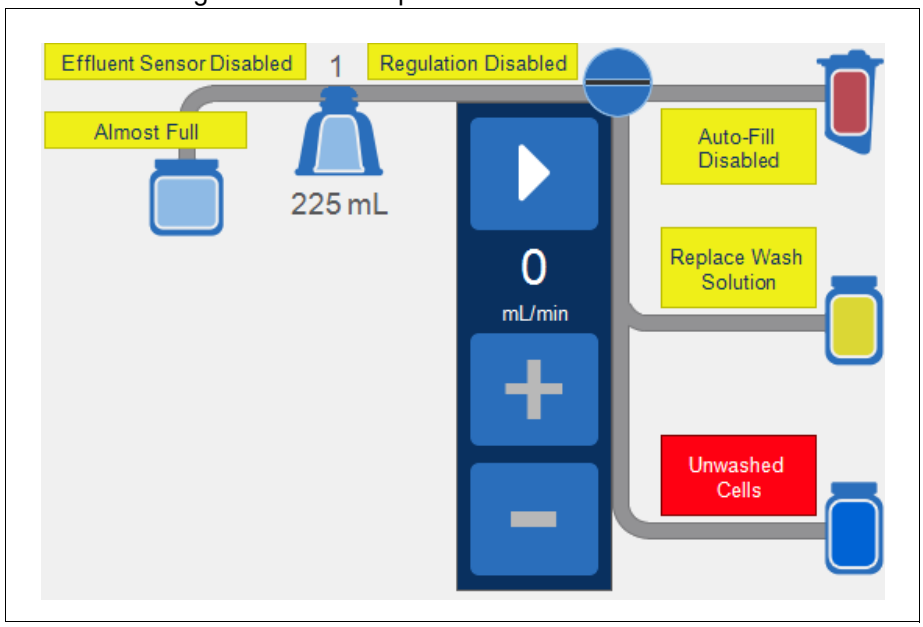


Figure 17, Example of status icons

The following is a list of possible status icons and their meanings:

- **Almost Full:** The device has detected approximately 8 liters of fluid in the waste bag. The procedure will continue but the waste bag should be emptied soon.
- **Auto-Fill Disabled:** The reservoir weigher is not active. When in Standby, you will need to touch **Fill** to enter the Fill phase.
- **Auto-Wash Disabled:** In Manual Mode, the device will remain in the Fill phase until you touch **Wash** to transition from the Fill phase to the Wash phase.
- **Effluent Sensor Disabled:** This icon appears if there has been a line sensor failure and you have chosen to continue the procedure while monitoring the quality of the effluent.

Alert: You should monitor the effluent quality during the Wash phase when the Effluent Sensor Disabled icon appears. The effluent line sensor is not active and is therefore not monitoring effluent quality.

- **Final Cycle Activated:** This icon appears when the user touches **Final Cycle**. When Final Cycle is activated, the device continues processing until air is detected in Fill, after which the device automatically completes the procedure according to the selected Final Cycle settings (see “Cell Salvage Default Settings” on page 129 for more information).

- **Full:** The device has detected approximately 8.5 liters of fluid in the waste bag. It will not process additional fluid until the waste bag is replaced or partially emptied.
- **Regulation Disabled:** The pump speed is not being regulated. This icon appears if the current settings group has pump regulation set to off or if the pump speed has been manually adjusted from the default setting and during Emergency Mode.
- **Replace Wash Solution:** The air detector has sensed air while in the Wash phase. This icon typically indicates the wash solution needs to be replaced.
- **Unwashed Cells:** This icon appears if the device enters the Empty phase without executing a Wash phase.

Alert: The cells currently moving to the RBC bag have not been washed.

- **Wash Quality Unchecked:** This icon appears after starting the Empty phase in Manual Mode.

Attention: *The cells currently moving to the RBC bag may not have been washed.*

Emergency Mode Pad

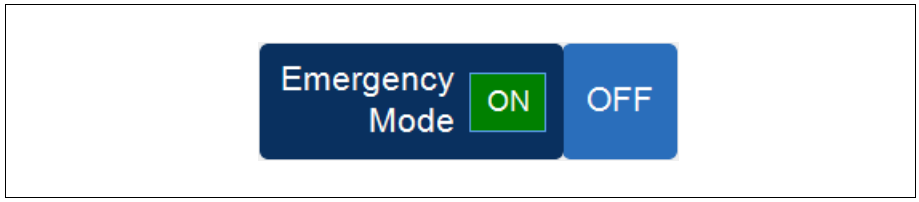


*Figure 18, Example of the **Emergency Mode** pad*

The **Emergency Mode** pad allows the user to switch the device into Emergency Mode. During Emergency Mode the device processes blood at high speeds. Emergency Mode is not available when using a 70 mL bowl processing set. See “Emergency Mode” on page 86 for more information.

Active Settings Pad

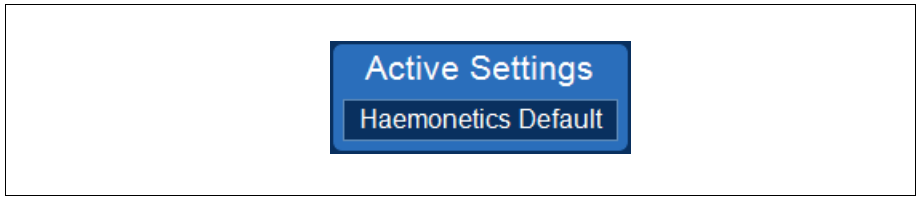


*Figure 19, Example of the **Active Settings** pad*

The **Active Settings** pad displays the current settings group selection. To change the active settings group, touch **Active Settings** and select a different settings group from the drop-down list.

*Note: If enabled, **Manual Mode** is available from the Active Settings drop-down list; and, when enabled, **Quick Transfer** is available for the 225 mL bowl, though is grayed out when the device is not in Pause or Standby. See "Making the Quick Transfer and Manual Mode Settings Available" on page 136 for more information.*

Volume Pad

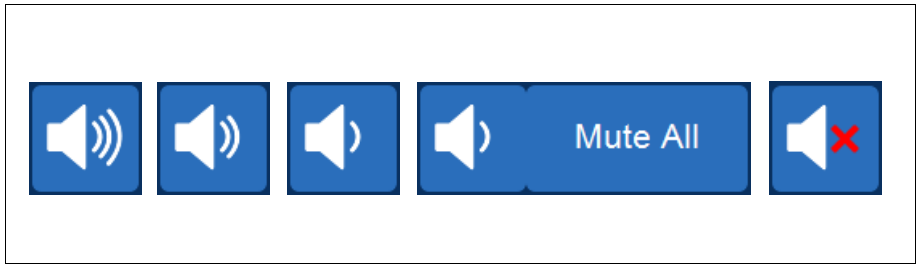


*Figure 20, Stages of the **Volume** pad*

The **Volume** pad controls the audible signal that sounds for any notices, warnings, or alerts. When a red alert occurs, an audible signal sounds continuously. You can temporarily silence the signal for that alert by touching the **Volume** pad. During normal operation when no alert is occurring, you can use the **Volume** pad to adjust the event volume or touch **Mute All** to mute the signal for all events.

Device Settings

The *System* screen provides access to the Cell Saver Elite+ device settings.

To access the *System* screen, touch (**Menu**) and select **System** from the drop-down menu.

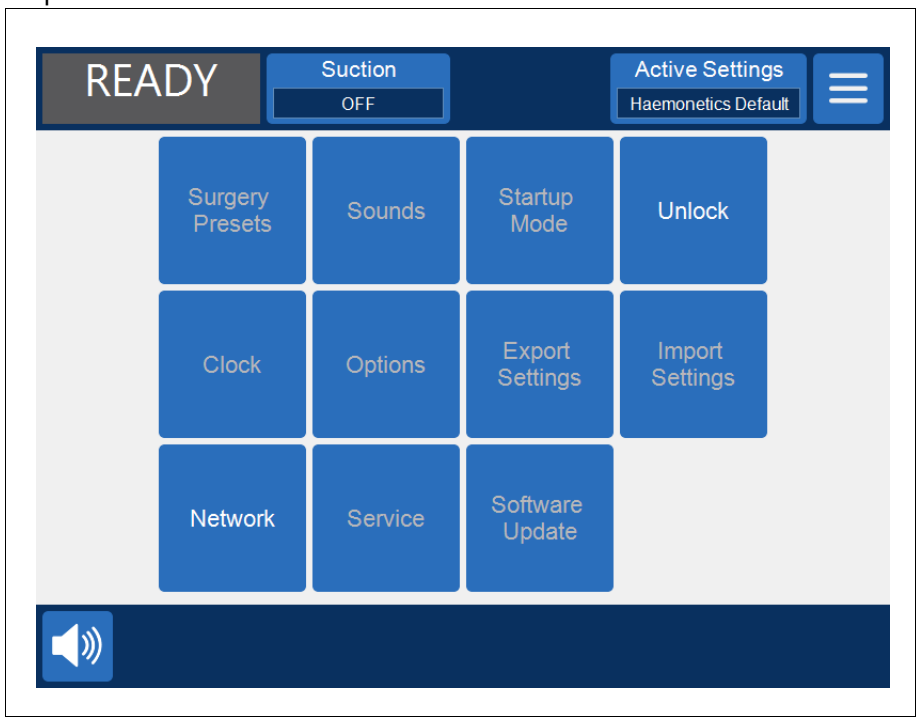


Figure 21, Example of the System screen

The device settings are password protected with three different levels of access: basic user, administrator, and Haemonetics technician. To unlock the *System* screen, touch **Unlock**, enter your password, and touch (**Accept**).

The device setting options include:

Basic User Access (Password: USER)

- **Surgery Presets:** Edit the list of surgeons, surgery types, and operators.
- **Clock:** Change the date or time.

Administrator Access

Note: Administrator Access also provides Basic User Access.

Note: Contact your local Haemonetics representative for the Administrator Access password.

- **Startup Mode:** Determine which settings group the device defaults to upon power-on.
- **Sounds:** Change the device tones and volume.
- **Options:** Change the language, region, date/time format, units of measure, and show/hide select fields.
- **Export Settings:** Export all settings to a USB flash drive.
- **Software Update:** View available software versions.
- **Import Settings:** Select settings to import from a USB flash drive.

Network Settings

For information on network settings, see the *Cell Saver Elite+ Connectivity Upgrade User Manual Addendum*.

Haemonetics Technician Access

Note: Haemonetics Technician Access also provides Basic User Access and Administrator Access.

- **Service:** Access the manufacturing screens.

Cart Components

The Cell Saver Elite+ cart has four wheels that ensure maneuverability. The unit can be tipped back on the rear wheels to pass over power cords, door sills, and other obstructions. The Cell Saver Elite+ device can be removed from the cart to allow for easy transport in cars and vans.

1. IV poles
2. Backstop
3. Device mount
4. Mounting pins
5. Wheels
6. Saline hangers
7. Handle
8. Processing set tub holder
9. Step plate
10. Antistatic wheel
11. Removable bins

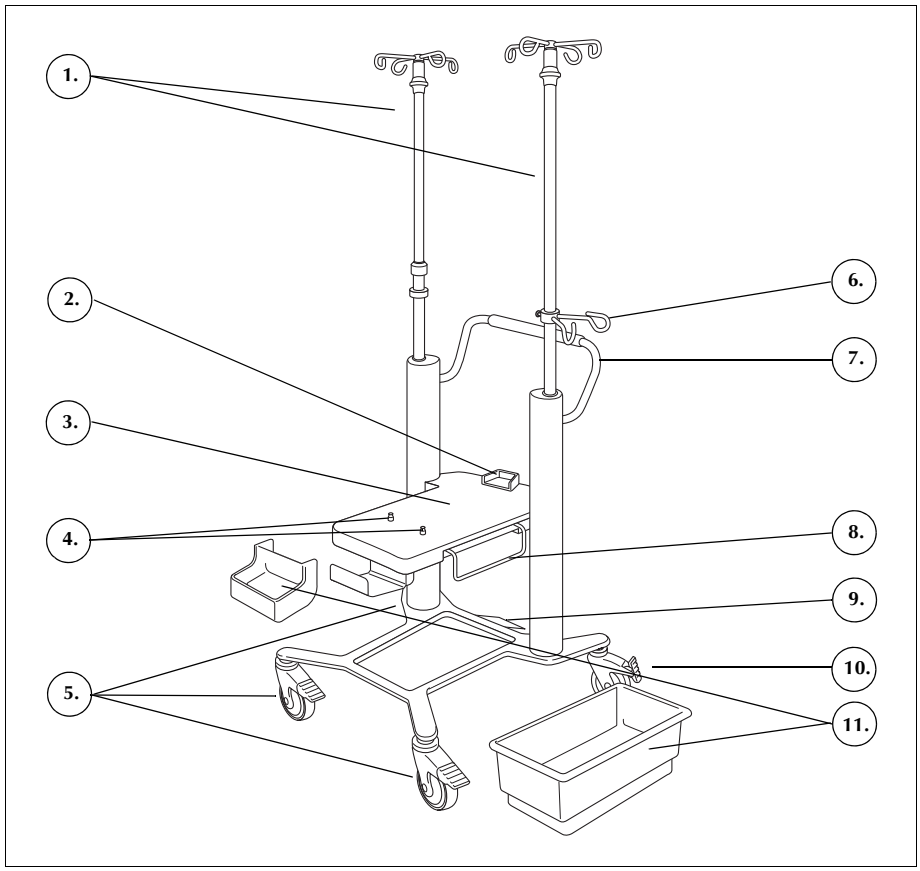


Figure 22, Cart components

IV Poles

The left IV pole contains the mount for the touch screen, and the right IV pole contains the reservoir weigher. Both poles can be easily lowered and locked in the down position for ease of transport.

Device Mount

The device mount is the flat plate that the device rests on. A backstop at the rear of the mount supports the back of the device and two locking pins near the front of the mount lock the device into place.

Wheels

The wheels can be locked to secure the cart in position. The right rear wheel provides antistatic protection.

Reservoir Weigher

The reservoir weigher holds the collection reservoir, tracks the amount of fluid in the reservoir, and communicates this information to the device. The reservoir weigher contains a tubing support that supports the tubing exiting the top of the reservoir.

For the first cycle, the device uses the preset value from calibration as a zero value. In subsequent cycles, it continues to use this value until it detects air during Fill. At that point, the system will tare the reservoir weigher, and the current weight of the reservoir and contents will be considered zero. As a result, any residual substances trapped in the filter when an air detect occurs will not count towards the volume of the reservoir.

Note: The reservoir weigher ships with the Cell Saver Elite+ device but gets mounted on the cart as shown in Figure 1 on page 26.

Saline Hangers

The saline hangers hold the saline bags during the procedure.

Handle

The handle at the back should be used when moving the cart and enables you to easily maneuver it around and over obstacles.

Processing Set Tub Holder

The processing set tub holder extends to provide support for the processing set tub during processing set installation.

Step Plate

The step plate enables the user to tilt the cart backwards slightly to pass over thresholds or small obstacles. Place one foot on the step plate and press down to tilt the cart backwards. Always hold onto the cart handle while tilting the cart to maintain stability.

Removable Bins

The removable storage bins provide convenient storage space for any items related to the device or procedure.

Chapter 3

Disposable Components Description

Overview

The Cell Saver® Elite®+ device utilizes single-use disposable components to collect blood salvaged during a procedure. Each disposable component is individually packaged in a sealed plastic tub or wrapping.

The following disposable components are available:

- Reservoir
- Aspiration and anticoagulant (A&A) line
- Vacuum line
- Processing set
- Post-op set
- Sequestration set

This chapter describes typical disposable components.

Reservoir

Reservoir

The collection reservoir holds the unprocessed salvaged blood from the field. The top of the reservoir contains a vacuum connection and three filtered inlet ports for A&A line and post-op suction set connections. The reservoir also has a drain port on the bottom and an internal filter. It connects to the processing set via the reservoir drain port.

1. Filtered inlet ports (x3)
2. Reservoir
3. Reservoir drain port
4. Vacuum line connection

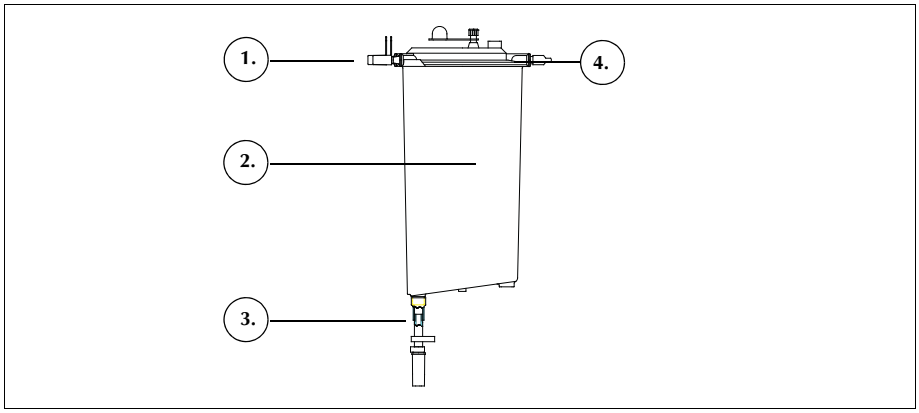


Figure 23, Example of a reservoir

The A&A Line and Post-Op Set

A&A Line

The A&A line is used to collect blood intraoperatively from the surgical field. The packaging allows it to be delivered into the sterile field.

1. Drip chamber
2. Roller clamp
3. Reservoir connection
4. Suction tip connection

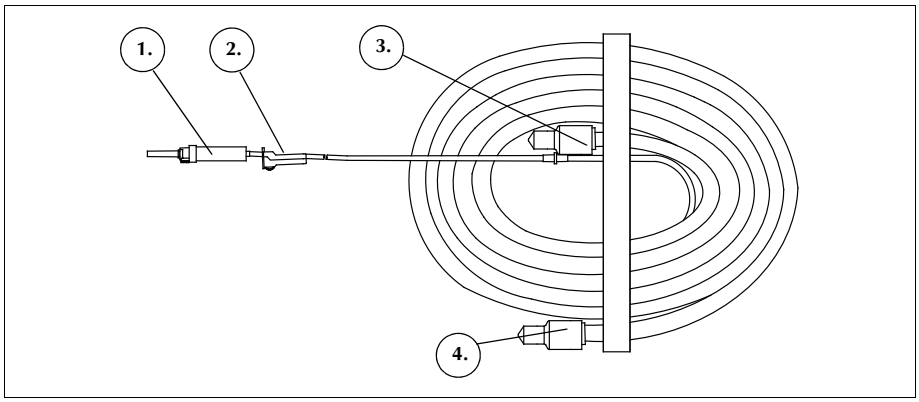


Figure 24, Example of an A&A line

Note: Efficient operation of the SmartSuction® technology depends on the use of a high air-flow disposable vacuum line and aspiration and anticoagulant (A&A) line in conjunction with a reservoir that has a maximum capacity of 3 liters.
The Cell Saver Elite+ device has been calibrated to optimize SmartSuction performance with the use of Haemonetics proprietary disposable sets and recommended suction tips. Suction and fluid removal performance may decline if incorrect or non-Haemonetics disposable components are used with the system.

Post-Op Set

The post-op set is used to collect blood postoperatively from wound drain tubing placed into the wound while the patient is in the operating room.

1. Reservoir connection
2. Wound drain connection

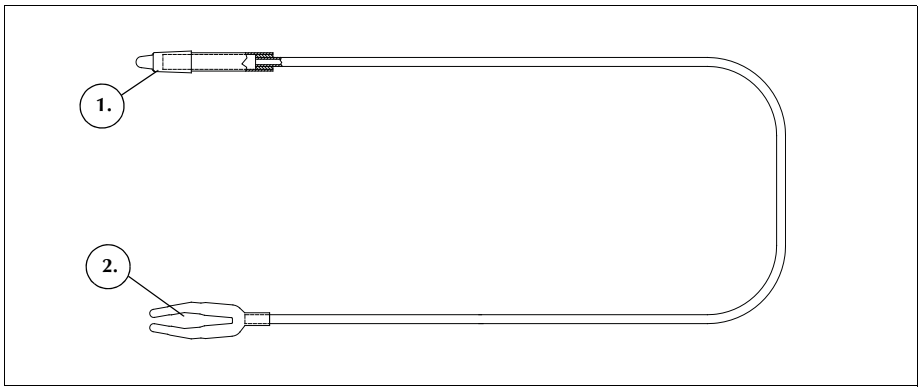


Figure 25, Example of a post-op set

Vacuum Line

Attention: *Use of an incorrect or non-Haemonetics vacuum line may affect suction performance and damage the device.*

The single-use, filtered vacuum line connects the vacuum port on the rear panel of the device to the vacuum port of the reservoir. The vacuum line contains an in-line hydrophobic filter that provides overflow protection to the device.

1. Hydrophobic filter
2. Reservoir vacuum port connection
3. Device vacuum port connection

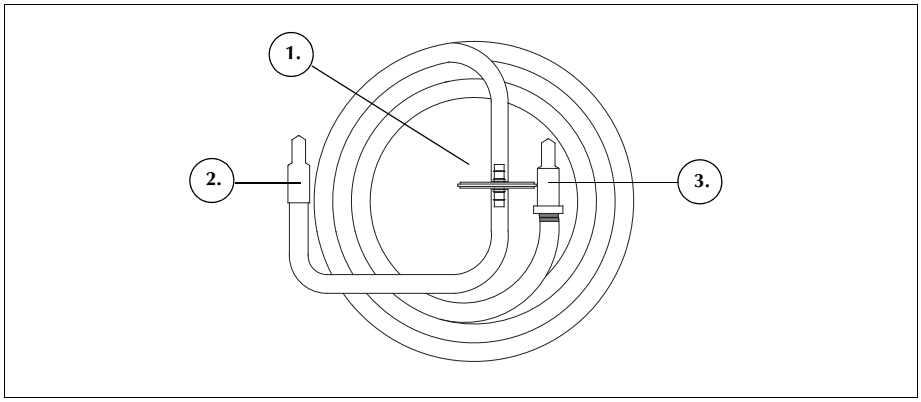


Figure 26, Example of a filtered vacuum line

Processing Set Elements

The processing set collects, washes and separates blood into RBCs and waste. The processing set includes the following parts:

- **Tubing harness:** the color-coded lines and the plastic tubing manifold.
- **Bags:** the RBC bag and waste bag.
- **Bowls:** the centrifuge bowl (70 mL, 125 mL, or 225 mL)

1. Blue line
2. Red line
3. Yellow line
4. Centrifuge bowl
5. Tubing manifold
6. Ratchet clamp
7. Cap
8. RBC bag
9. Collection reservoir connector
10. Saline bag spikes
11. Waste bag

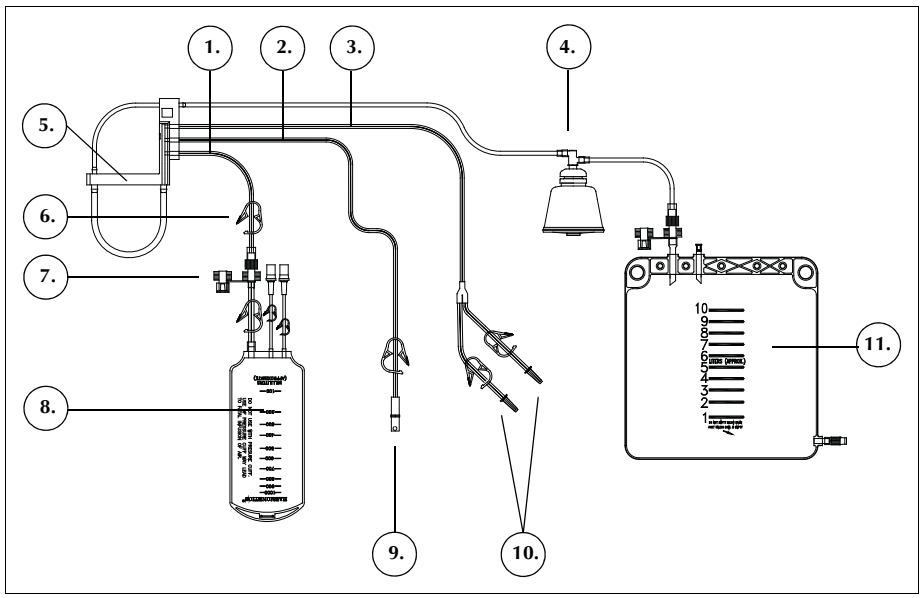


Figure 27, Example of processing set components

Tubing Harness

The processing set tubing harness contains four lines and a tubing manifold:

- The red line connects to the unprocessed blood source.
- The yellow line connects to the saline solution.
- The blue line attaches to the RBC bag.
- The tubing manifold holds the tubing in place in the pump module and holds the clear tubing going to the centrifuge.

All three color-coded lines pass through the pinch valves in the valve module. The three colored lines combine into a single clear line as they leave the valve module and enter the pump module.

The clear line passes through the pump, air detector, and valve module and enters the centrifuge well. Inside the well, the line connects to the inlet port of the bowl.

The effluent line, connected to the outlet port of the bowl, exits the centrifuge well through the effluent line sensor and connects to the waste bag.

Bags

The processing set contains the following two receptacles:

- The waste bag
- The RBC bag

Waste Bag

The 10 L waste bag holds the waste solution, including plasma, cellular components, and saline solution washed out of the red cells during processing. It contains a drain port at the bottom, for emptying the waste bag, and a vent with an antibacterial filter at the top of the bag, used to aid in venting the bag during the sterilization process.

Note: When emptying the waste bag, do not allow the fluid level in the bag to fall below the 1 liter mark. This ensures that sufficient air is retained in the system to empty the bowl.

Note: When replacing the waste bag, make sure the bowl is empty. If the bowl is not empty, return its contents to the reservoir, replace the waste bag, and process again.

RBC Bag

The 1L RBC bag holds the processed red cells for reinfusion to the patient.

Centrifuge Bowl

Centrifuge Bowl

The key component of the processing set is the centrifuge bowl. Inside the bowl the collected RBCs are separated, washed, and packed.

The bowl consists of two subassemblies: an inner assembly that remains stationary and an outer assembly that rotates. The rotating outer assembly contains the centrifugation chamber where the blood is processed. The stationary inner assembly contains the inlet and outlet ports.

The two subassemblies of the bowl are joined with a rotary seal which forms a barrier between the inside and outside of the bowl. The effectiveness of the seal may be impaired if the bowl is incorrectly seated in the chuck. Fully seating the bowl in the centrifuge chuck will ensure proper function.

1. Inlet
2. Outlet
3. Rotating outer subassembly
4. Stationary inner subassembly

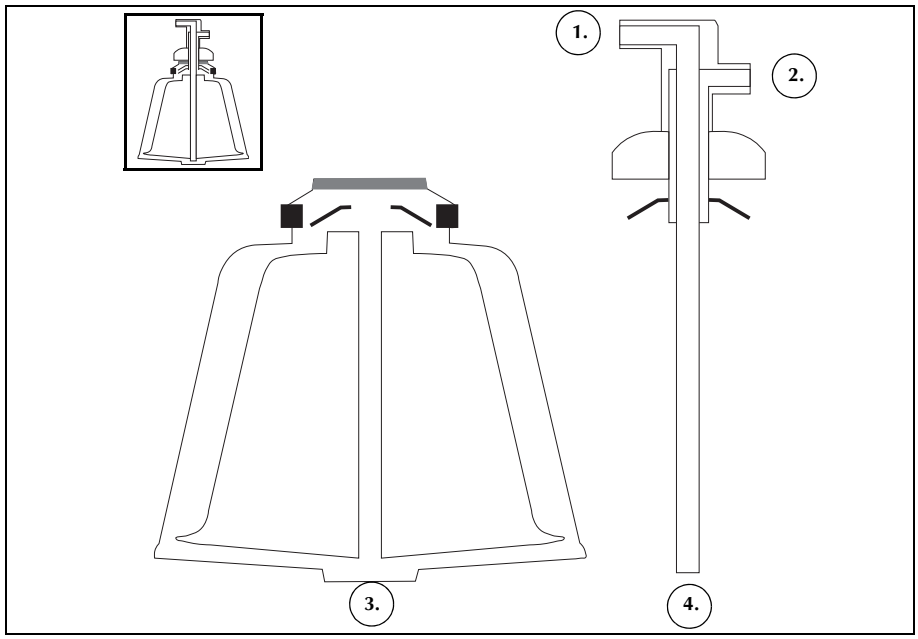


Figure 28, Example of the Latham bowl subassemblies

There are three bowl sizes: 70mL, 125mL, and 225mL. The 125mL and 225mL bowls are Latham bowls. The 70mL bowl is uniquely shaped to efficiently separate smaller volumes of fluid.

1. 70mL bowl
2. 125mL bowl
3. 225mL bowl

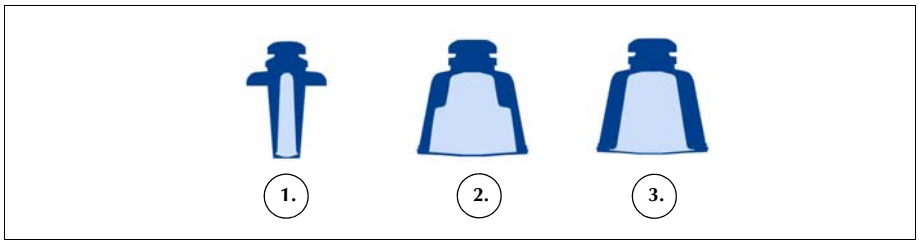


Figure 29, Example of the three bowl sizes

Centrifuge Chuck Adaptor

Alert: Do not grease any part of the centrifuge or centrifuge chuck adaptor. If grease has been applied to the chuck, contact the Haemonetics hotline immediately.

The 70mL bowl requires a centrifuge chuck adaptor to correctly load the bowl. The chuck adaptor is a white plastic cylinder that snaps into the centrifuge chuck. Install the chuck adaptor before loading the processing set.

Sequestration Set

The Sequestration set allows the sequestration of platelets before the beginning of a Cell Salvage procedure. The parts of the Sequestration set include the:

- **Blood bag adaptor harness:** the tubing that connects the blood bags to the red line of the processing set. At the end of Sequestration, the user removes the upper portion of the blood bag adaptor harness using the twist-lock connector.
- **Collection bag harness:** the collection bags and air bag

1. Blood bag line ratchet clamps
2. Blood bag spikes
3. Twist-lock connector
4. Red line connection
5. Reservoir drain port connection
6. Effluent line connection
7. Yellow, blue, and clear line ratchet clamps
8. Air bag
9. Collection bag ratchet clamps
10. Collection bags

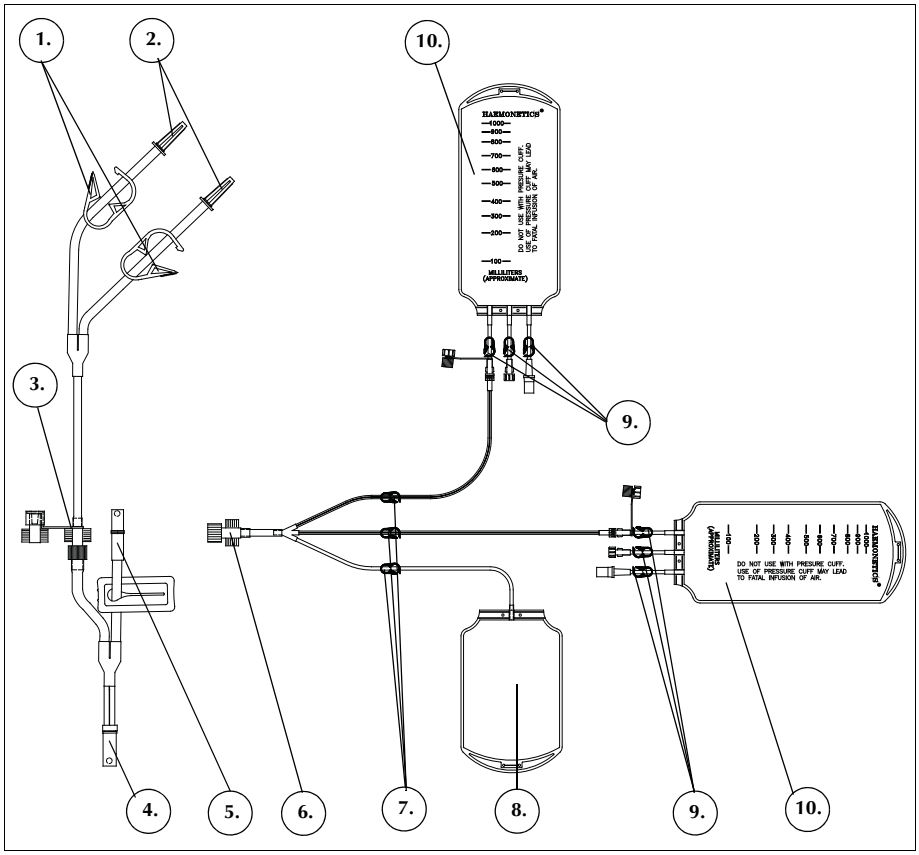


Figure 30, Example of a Sequestration set

Chapter 4

Safety and Patient Care Precautions

Storing and Handling the Device and Disposable Components

Safe and successful operation depends in part on the proper routine handling of the Cell Saver® Elite®+ device and disposable components. The user should be aware of the problems that could result if the device or disposable components are stored, installed or used incorrectly.

Storing and Handling the Device

Alert: If the Cell Saver Elite+ device is stored at a temperature outside the operating temperature range, allow sufficient time for the device to equilibrate to room temperature before use. See Table 9, "Environmental Specifications" on page 21.

Do not operate or store the Cell Saver Elite+ device in an area where flammable gases or vapors are present. The user should always handle the device with clean, dry hands or disposable gloves.

Storing and Handling the Disposable Components

Minimize the length of storage for disposable components by using products with an earlier expiration date before using those with a later expiration date. This is referred to as the first-in, first-out (FIFO) technique.

All disposable components should be stored in a dry, well-ventilated area free from exposure to chemical vapors. Many plastic components are sensitive to chemicals such as solvents, refrigerants and detergents. The mechanical properties of plastic may be seriously degraded when exposed to solvent vapors.

Avoid direct contact of plastic components with all halogenated hydrocarbon-based anesthetic agents, e.g., Isoflurane (Forane), Enflurane (Efrane or Ethrane), Halothane (Fluothane or Rhodialothan); these agents attack plastics.

The user should always handle the disposable components with clean, dry hands or disposable gloves to avoid contaminating the surface of disposable plastic components with chemicals.

Inspecting the Components

Prior to installation, the user should inspect the disposable components for twisted or flattened sections. Any product complaints or concerns should be reported to Haemonetics in a timely manner.

Note: Adhere to the expiration date printed on the product labeling.

After installing the disposable components, the user should verify the correct placement of the individual elements, prior to initiating a collection procedure. It is important that the tubing remain free of any twists or occlusions which could cause a flow obstruction.

Transporting the device

Alert: To ensure stability during transport, lower the IV poles and check that the reservoir weigher is no higher than 51 in (129 cm) from the floor.

Alert: Ensure the wheels are unlocked and swing freely before moving the cart. Failure to do so could result in injury or damage to the device. Use the wheel locks when the system is parked.

Alert: Use caution when going up or down ramps. Do not park the cart on a ramp.

Transporting a Device with Disposable Components Loaded

Before moving the device with the disposable components and solutions installed, lower the IV poles and ensure that the saline bags are on the lower right-side IV pole hooks. The reservoir weigher should be no higher than 51 in (129 cm) from the floor during transport.

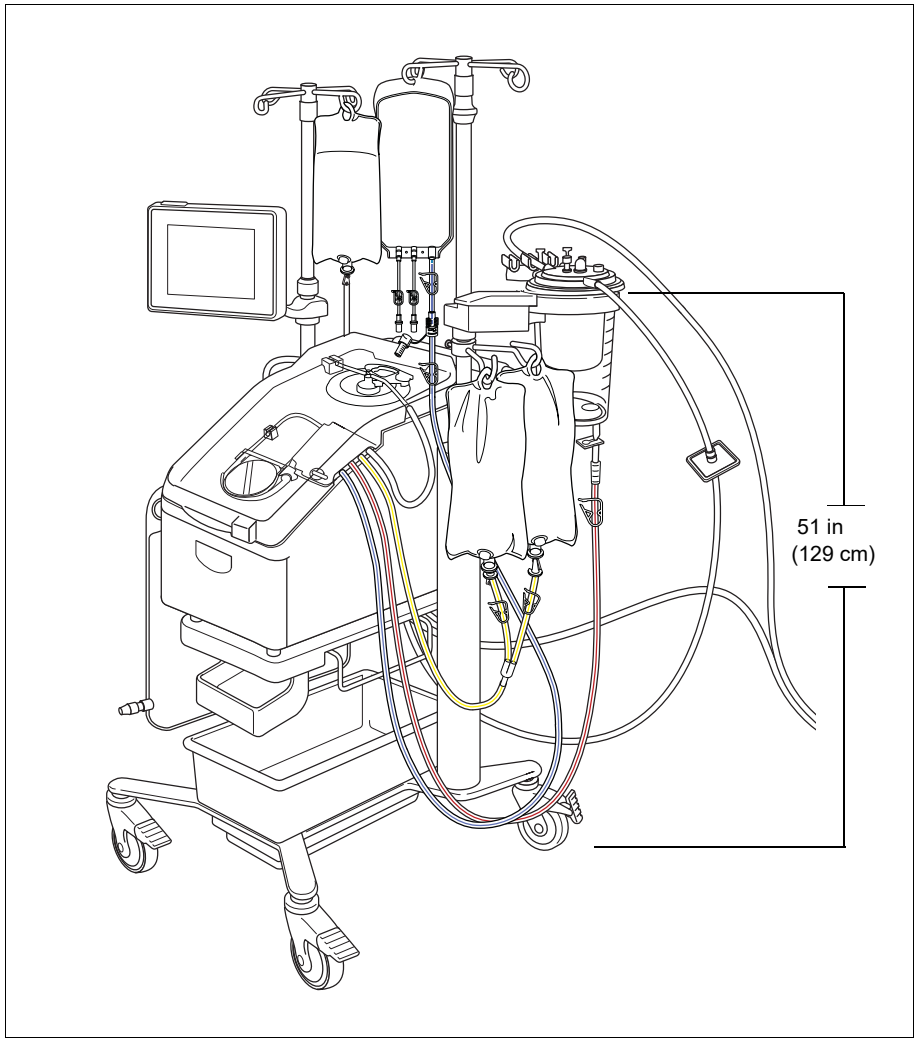


Figure 31, Example of the IV poles in the transport position

Removing the Device from the Cart

The user can remove the device from the cart to allow easy transport in cars and vans. Follow the steps below to remove the device from the cart:

1. For stability, lock at least one wheel of the cart before removing the device.
2. Remove the touch screen from the touch screen mount and place it on the touch screen storage mount.
3. Disconnect the reservoir weigher connection from the rear panel of the device.
4. Flip the quick-release levers (located on the bottom of the device mount) down to unlock the device from the cart.
5. Holding the handles on the front and rear of the device, carefully lift the device off the cart.

1. Flip the quick-release levers down
2. Lift the device off the cart

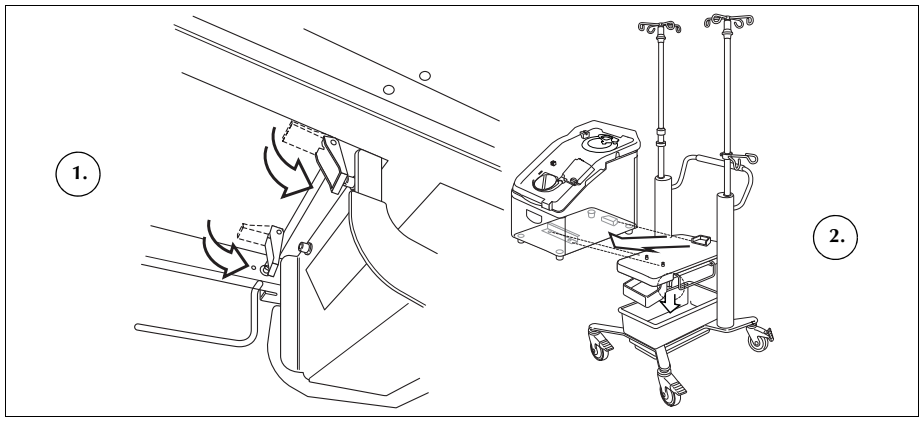


Figure 32, Removing the device from the cart

Installing the Device on the Cart

Follow the steps below to install the device on the cart:

1. Flip down the quick-release levers.
2. For stability, lock at least one wheel of the cart before installing the device.
3. Place the device on the cart, lowering the rear of the device first so that it rests securely against the backstop.
4. Lower the front of the device down onto the mounting pins.
5. Lift the quick-release levers (located on the bottom of the cart) up to lock the device into place.
6. Using the handles, gently lift up on the device to ensure it is securely fastened to the cart.
7. Remove the touch screen from the touch screen storage mount and place it on the touch screen mount.
8. Attach the reservoir weigher connection to the rear panel of the device.

Warnings for the User

Electrical Shock Hazards

Warning: Always use the device with clean dry hands, or disposable gloves. The internal parts of the device contain various electrical components. Contact with any of these components when the device is connected to an external power source could result in an electrical shock. Thus, the panels should not be removed without first powering off and unplugging the device. Access to the inner cabinet should only be performed by a Haemonetics trained technician.

Leakage Current Control

In the event of any major spill in which fluid enters the centrifuge or suction pump, a leakage current test should be performed before re-using the device. To avoid the risk of electrical shock, the test should be conducted by an on-site biomedical or clinical engineer.

The device meets the IEC/EN 60601-1 standard, medical electrical equipment, general requirements for safety (See Table 9, "Environmental Specifications" on page 21 for specifications). Each device receives a careful inspection for leakage current and ground continuity before leaving the factory.

Power Outlet Connection

A power cord is supplied with the device. Do not replace the power cord with a substitute. If necessary, contact the Haemonetics Customer Care Center for a replacement. Always ensure the power cord is connected to an appropriately grounded power source.

The Cell Saver Elite+ device must be operated in an environment compatible to the requirements of the IEC/EN 60601-1-2 Standard, Electromagnetic compatibility (EMC). Any accessories and cables not approved by Haemonetics used in conjunction with the device may increase hazards and influence compatibility with EMC requirements. Therefore, non-approved accessories and cables must not be used.

Warning: Ground continuity can only be achieved when the equipment is connected to a properly grounded outlet.

Laser Radiation Hazards

Failing to follow the procedures correctly, using controls or making adjustments not specified in the manual could result in hazardous radiation exposure.

Mechanical Hazards/ Rotating Parts

As with any equipment containing rapidly rotating parts, the potential for severe injury exists if personal contact is made, or if clothing becomes entangled with the moving parts. The device contains a safety feature designed to prevent the centrifuge from spinning if the system has not been properly secured.

However, the user should respect the usual precautions taken when working with equipment containing rotating mechanical parts.

Communicable Disease Precautions

Despite testing and screening to detect communicable diseases such as hepatitis, syphilis or HIV, the risk remains that the blood being processed may be infected. The user must take the appropriate precautions when handling blood products and disposing of blood-contaminated components to ensure personal safety as well as the safety of others who may come in contact with the blood-contaminated components.

Proper Handling of Blood-Contaminated Components

If a leak or blood-spill should occur, it should be cleaned immediately. The user should follow the local standard operating procedure outlining the steps to follow and product(s) to be used for the disinfection of components contaminated by blood.

If any blood-contaminated components must be returned to Haemonetics for further inspection, see “Product Return Guidelines” on page 162.

Proper Disposal of Biologically Contaminated Components

Any disposable components used during a procedure is considered to be biologically contaminated. It must be disposed of according to local standard operating procedures for the removal of such components and should not be mixed with non-biologically contaminated waste.

Preventing Problems During a Procedure

Understanding the Risk of Hemolysis

Alert: Forcing a pump to work against a severe flow restriction can lead to hemolysis, and thus, consequently high levels of free hemoglobin in the plasma.

Hemolysis involves the destruction of RBC membranes with the release of free hemoglobin into the plasma portion of the blood. Free hemoglobin does not have the capacity to transport oxygen and can produce serious problems. The remnants of the RBC can stimulate clot formation and damage the vascular nature of the lungs and the kidneys. This could lead to respiratory complications and/or renal failure.

Hemolysis can occur during a procedure in the rare event of a mechanically induced situation, such as overheating or excessive pressure. It can also be caused by the use of non-isotonic wash solutions.

The Cell Saver Elite+ device uses the effluent line sensor to check for the presence of excessive free hemoglobin during Wash. Wash will be extended if the free hemoglobin levels are not within an acceptable range. In some rare instances, hemolysis may occur as the bowl is emptied, after Wash and after the effluent line sensor check has been passed. Since the presence of free hemoglobin in the RBC bag may not be readily apparent, the user should monitor for other indications of abnormal operation. A restriction which causes hemolysis may also cause a reduction in flow rate and result in an abnormally long time required to empty the bowl. The device is programmed to detect abnormally long Empty and Return phases and notify the user with an alert. See “Event Troubleshooting” on page 171 for more information.

- If the user visually confirms that the bowl is still not empty, a sample should be taken from the RBC bag prior to transfusion to the patient to determine the presence of free hemoglobin.
- If the bowl is empty, this could indicate a problem with the air detector and the user should contact the Haemonetics Customer Care Center.

Avoiding Flow Restrictions

Alert: The user must avoid blocking any tubing carrying blood from the pump. A buildup of pressure in this tubing can cause the tubing to rupture and cause a large blood spill.

The user must ensure that there are no restrictions to flow in the effluent line. If the outlet port of the bowl is inadvertently clamped off, pressure builds up in the processing chamber to such an extent that the rotary seal becomes raised, like a safety valve, to release pressure. This results in the loss of the pocket of trapped sterile air. The faces of the rotary seal become wet with supernatant

and, depending upon the nature of the supernatant, the functional characteristics of the rotary seal may become altered. The increased friction and excessive heat can make the contents of the bowl unsuitable for reinfusion to the patient.

The user should also verify that the flow of sterile air to and from the waste bag is not prevented by either a flow restriction or an air leak.

Inspecting for Twists and Kinks in the Tubing

A careful inspection of the installed harness should be carried out to ensure that each section is correctly installed on the device and that all tubes are free of twists or kinks. It is particularly important that no occlusions are present in the tube between the bowl and the RBC bag when blood is being pumped out of the bowl. Forcing a pump to work against a severe flow restriction is likely to result in high levels of hemolysis with high levels of free hemoglobin.

Avoiding Overheating

Alert: The user must not use any bowl which cannot be properly seated in the centrifuge chuck. Overheating can occur, which can subsequently lead to hemolysis and make any blood being processed unsafe for reinfusion. During operation, the user should interrupt the procedure if an abnormality or noise related to the spinning bowl appears.

Alert: If during a procedure it is discovered that any portion of the equipment within proximity of the blood has been significantly overheated, the processed RBCs should be regarded as unsafe for reinfusion.

Avoiding Bowl Misalignment

An improperly installed disposable bowl can become misaligned as it spins. This can create excessive friction and noise and consequently overheat the bowl contents. The user should verify the alignment of the bowl at the time of installation.

Avoiding Continuous Aspiration

Attention: *Continuous aspiration of profuse bleeding without breaks in suction can cause electrical interference. If the device is in the Fill phase (pumps turning) and the entire tubing set is filled with fluid, there is a potential for electrical interference to be conducted through the fluid and patient to other systems, such as the ECG. If these conditions exist simultaneously, it is possible that the Cell Saver Elite+ can cause an effect on the ECG which looks like ventricular tachycardia. To eliminate the potential for this to occur, it is recommended that the user aspirate with intermittent breaks in suction.*

Avoiding Red Blood Cell Spillage

Under normal conditions the effluent line sensor ensures that there is little or no RBC spillage. However, there are four conditions that may result in RBCs spilling over into the waste bag:

1.) Overfilling of the bowl in Manual Mode.

Note: In the event of a bowl overfill, the device tries to reduce the amount of RBC spillage, which may result in an extended Wash phase and longer procedure time.

To avoid overfilling the bowl in Manual Mode:

1. Carefully watch the RBC layer as the bowl fills.
2. Touch **Wash** to manually start Wash when the RBC layer is close[1] to the bowl optics beam.

Note: The hematocrit of the product may be reduced if the Wash phase is started before the bowl is full.

Attention: *A Wash flow rate that is too low provides a poor wash of the cells due to insufficient agitation and mixing of saline solution with the RBC layer.*

2.) Excessive flow rate of saline solution due to processing parameters set by the user.

Note: Haemonetics recommends the Wash speed be at least 25 mL/min lower than the Fill speed for the 125 mL and 225 mL bowls. This ensures the cells are packed more forcefully during Wash and therefore less likely to spill.

3.) Pump regulation is disabled.

4.) The pump has paused, the RBC layer is close[1] to the bowl optics beam, and the user restarts the Fill phase or enters the Concentrate phase.

If the pump has paused and the RBC layer is close[1] to the bowl optics beam and the user restarts the Fill phase or enters the Concentrate phase, the RBCs may start to spill into the waste bag and the device will not transition into the Wash phase when expected.

When entering the Concentrate phase the centrifuge speed slows down, causing the RBC layer to expand. If the RBC layer is close[1] to the bowl optics beam, this expansion may push the RBC layer past the bowl optics beam. When entering the Concentrate phase, and when restarting the Fill phase, there is a blind[2] volume when the bowl optics and line sensor are not active. If the RBC layer passes the bowl optics trip point during this blind volume, the device does not enter the Wash phase until the line sensor detects RBCs. By the time the line sensor detects RBCs, the bowl is fully packed, and some

1. Within:
   - 6 mm (125 mL or 225 mL bowl)
   - 3 mm (70 mL bowl)

RBCs may be pushed to the waste bag when the device enters the Wash phase. In the unlikely event that the RBC layer passes the line sensor during the line sensor blind volume, the device will not enter the Wash phase.

To avoid overfilling the bowl in either scenario, follow the steps below:

1. Before restarting the Fill phase or entering the Concentrate phase, identify the location of the RBC layer.
2. If the RBC layer is close[1] to the bowl optics beam, touch **Wash** to manually enter the Wash phase. Do not restart the Fill phase or enter the Concentrate phase.

Following the above steps prevents the bowl from becoming fully packed and spilling RBCs into the waste bag.

Note: Because the device will enter the Wash phase before the optics senses the RBC layer, the hematocrit of the final RBC product may be lower than when the optics trips the device into the Wash phase.

Managing the Inventory of Air

The disposable bowl as received from the factory is full of sterile air. During each fill cycle, this sterile air is expelled into the waste bag while the bowl is filling and is returned from the waste bag while the bowl is emptying. It is important to permit the sterile air to return to the bowl from the waste bag to avoid creating a negative pressure in the bowl as it is emptying.

***Attention:** A full waste bag should be changed or emptied only when the bowl is emptied of blood (and filled with air). The waste bag may be partially emptied through the drainage port at any time as long as the fluid level in the bag does not fall below the 1L mark on the waste bag.*

2. A blind volume is a period of time when the sensor (either the bowl optics sensor or the line sensor) does not detect fluid flowing past it; the sensor does not trigger any actions during the blind volume. The purpose of the blind volume is to prevent a premature transition to the Wash phase while the RBC layer stabilizes.
   The blind volume is:
   - **125/225 mL bowl:** 25 mL (bowl optics), 25 mL (line sensor)
   - **70 mL bowl:** 35 mL (bowl optics), 35 mL (line sensor)

1. Within:
   - 6 mm (125 mL or 225 mL bowl)
   - 3 mm (70 mL bowl)

Patient Care Precautions

Reinfusing Blood

Alert: DO NOT USE A PRESSURE CUFF OR ANY OTHER MECHANICAL DEVICE WITH THE CELL SAVER ELITE+ SYSTEM. PRESSURE REINFUSION CAN RESULT IN THE FATAL INFUSION OF AIR INTO THE PATIENT.

Alert: In accordance with FDA guidelines and AABB standards, a transfusion filter designed to retain particles that are potentially harmful to the patient should be used when returning processed concentrated red cells.

Alert: The safe length of time that blood or blood products may remain in the autotransfusion disposables is dependent on collection and storage methods. Refer to the AABB standards for more information.

Gravity reinfusion of washed cells is accomplished more rapidly than infusion of the usual unit of homologous, packed cells because RBCs suspended in saline are less viscous and are already at room temperature.

The blue line is primed at the factory with sterile air. During the first empty cycle this sterile air is sent into the reinfusion bag. Therefore, the contents of the reinfusion bag should NOT be transfused under pressure.

Removing Air from the Reinfusion Bag

If it becomes necessary to remove air from the reinfusion bag:

1. Clamp the tubing between the reinfusion bag and the patient and invert the reinfusion bag.
2. Open one of the outlet ports of the RBC bag and squeeze the bag to remove the air.

Upon completing a procedure, you can touch **Remove Air** in the *Records* screen to purge any extra air from the RBC bag. See “Removing Air from the RBC Bag” on page 96 for more information.

Using a Transfer Pack

Another method of transfusing the washed autologous red cells is to transfer the blood from the reinfusion bag to a secondary transfer pack. This method of transfusing the cells is helpful if the device is located at a distance from the patient and direct reinfusion of the blood is not possible. See “General Precautions When Reinfusing Processed Blood” on page 93 for more information.

Replacing Depleted Clotting Factors

Washed, packed cells are depleted of clotting factors. The physician must monitor the quantity of washed cells returned to the patient and supplement them with fresh frozen plasma and platelets if required for hemostasis.

Contraindications for Use

Alert: The use of reinfused blood from the Cell Saver Elite+ device may be contraindicated, for example, in the case of sepsis or malignancy. The responsibility for the use of this device belongs solely to the physician in charge.

Alert: The Cell Saver Elite+ device is not intended to be used for chest (pleural or mediastinal) wound drainage.

The risk/benefit ratio of blood salvage must be determined on an individual basis by the surgeons, anesthesiologists and transfusion medicine specialists involved in the patient's care. Follow the guidelines for general autotransfusion contraindications per the AABB *Guidelines for Blood Recovery and Reinfusion in Surgery and Trauma*.

Using Anticoagulants

Anticoagulant solutions are added to salvaged blood to keep it from clotting. Different anticoagulants affect the clotting process in different ways.

- The most common anticoagulant solution is 30,000 units of heparin in 1L of normal saline. This should be delivered at a 1:7 ratio of heparinized saline to blood entering the reservoir by adjusting the roller clamp on the anticoagulant line.
- Citrate solution can also be used as an anticoagulant solution. A general guide for citrate solution delivery is a ratio between 1:5 and 1:10 anticoagulant to blood.

The rate for both anticoagulants should be set to give approximately 15 mL of anticoagulant for each 100 mL of blood collected. This equates to a drip rate of 1-2 drops per second, depending on the rate of blood collection.

Note: Recommendations for the use of anticoagulant solution presented in this manual are intended for use as guidelines only and should not substitute for the user's clinical judgment. For hypercoagulable patients, the user may find it necessary to increase the anticoagulant dosage to prevent clotting.

Factors Affecting Processing Time

Cell Salvage

The time required to process a bowl of salvaged blood depends on the following factors:

- Salvaged blood hematocrit
- Bowl volume
- Fill pump rate
- Wash volume
- Wash pump rate
- Empty pump rate

All these factors combine to determine the total processing time for any Cell Salvage system. The Cell Saver Elite+ device has been programmed to optimize this time during each procedure without compromising the final product. Any changes made to the preset processing parameters should be carefully considered prior to being executed.

Sequestration

Typical processing times for a single Sequestration cycle on the Cell Saver Elite+ device are 7-25 minutes. During this time approximately 225 to 900 mL of whole blood will be processed, resulting in the collection of 20 to 40 mL of platelet rich plasma and 50 to 600 mL of platelet poor plasma. Platelet yields are typically 3-7 times that of the incoming whole blood.

Actual time and results may vary depending on bowl size, protocol settings, hematocrit of incoming blood, and platelet pre-count of the incoming blood.

Chapter 5

General Operation: Cell Salvage

Preparing the Cell Saver Elite+ Device

Connecting to Power

Before powering on the device, make sure it is plugged into a properly grounded power outlet.

A power cord is supplied with the device. Do not replace the power cord with a substitute. If necessary, contact the Haemonetics Customer Care Center for a replacement. Always ensure the power cord is connected to an appropriately grounded power source.

Warning: Ground continuity can only be achieved when the equipment is connected to a properly grounded outlet.

Note: The Cell Saver® Elite®+ device is classified as a continuous operation, Class I, Type CF, IPX1 device, in accordance with IEC/EN 60529 and 60601 standards for medical electrical equipment.

Positioning the Device

To position the device for a procedure:

1. Extend each IV pole to the desired height.
2. Remove the touch screen display from the rear panel of the device.
3. Mount the touch screen display on the left IV pole and adjust the display to the optimal viewing angle.
4. Rotate the reservoir weigher on the right IV pole so that it faces the desired direction.

1. IV poles
2. Touch screen
3. Reservoir weigher
4. Centrifuge header arm, valve module cover, and pump platen

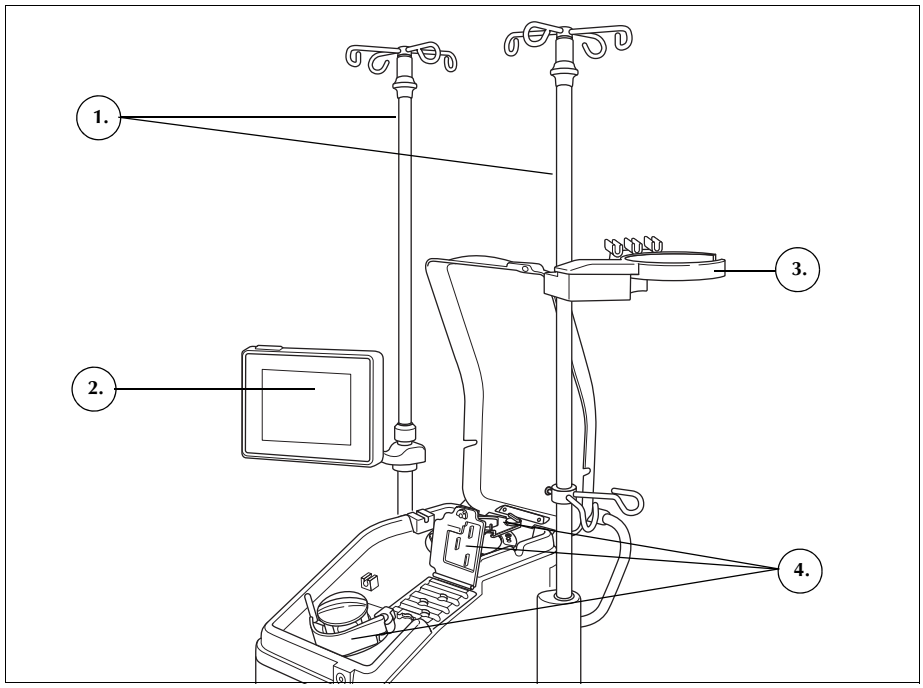


Figure 33, Device positioned for disposable components installation

Unfolding the Biohazard Waste Bag

Once the device is properly positioned, follow the steps below to set up the biohazard waste bag:

1. If the biohazard waste bag is stored in the tray on the underside of the device, remove the bag from the tray.
2. Unfold the bag and ensure that the bag is connected to the drain tube attached to the underside of the device.
3. Ensure that there are no kinks or twists in the tubing and allow the bag and its tubing to hang from the drain tube (See Figure 34).
4. Open the slide clamp and leave it open.

Attention: *The biohazard waste bag should be left hanging out of the tray at all times. In the event of a blood spill, turn off and then unplug the device from grounded AC power. Remove and replace the bag only if it is found to be contaminated with blood or fluid. See* *"Replacing the Biohazard Waste Bag" on page 159**.*

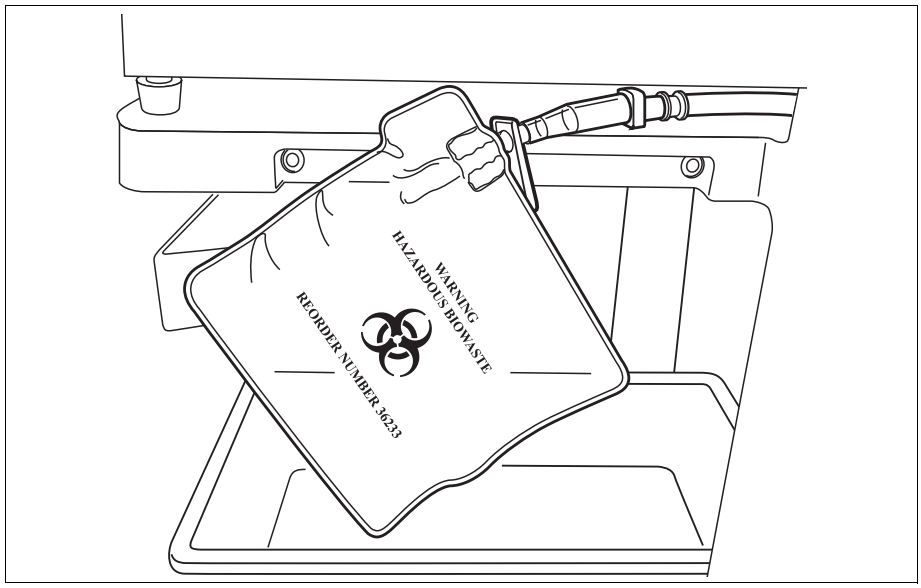


Figure 34, Allowing the biohazard waste bag to hang out of the tray

Power-on Procedure

When ready to initiate a procedure:

1. Ensure the pump platen lever is closed and the valve module cover and centrifuge header arm are closed and locked.
2. Close the device cover.
3. Press the power switch located on the rear panel of the device.
   The device goes through a series of power-on self-tests and advances to the *Bowl Selection Screen*.

Note: During the power-on self-tests (POST), the device checks the interlocks for the device and manifold covers, the centrifuge arm and the pump platen. To avoid event messages, it is recommended that these be closed during POST. If an event message instructing the user to close one of these occurs and cannot be cleared, close the specified item and restart the device.

Note: When powered on, the device defaults to the startup mode settings group as determined in the System screen (See "Device Settings" on page 45 for more information). To select a different settings group, touch ☰ *(**Menu**), select **Settings** from the drop-down menu, and choose the desired settings group.*

Installing the Cell Salvage Components

Inspecting the Disposable Components

Always inspect disposable components while removing them from the packaging.

1. Read the labeling on the processing set to ensure it is the correct set for the current procedure.
2. Check the date on the disposable components to ensure they have not expired.
3. Ensure there are no kinks or twists in the tubing that could restrict the flow of fluid.
4. Check that there are no missing caps or open connections.
5. Verify that there are no visible defects or particulate within the set.

Collect First Setup

Using a collect first setup enables you to collect fluid in the reservoir and ensure there is enough shed blood to recover before attaching a processing set. To prepare the collection reservoir and aspiration and anticoagulation (A&A) line:

Load the Reservoir and Vacuum Line

1. Place the reservoir in the reservoir weigher or cardiotomy bracket so that the three filtered inlet ports face the tubing support.

Note: The reservoir weigher should be no higher than 72 in. (183 cm) from the floor.

2. Close the slide clamp on the reservoir drain port.
3. *If using the Cell Saver Elite+ internal suction,* connect the filtered vacuum line to both the vacuum port on the back of the device and to the vacuum inlet port on the reservoir.
4. *If using external suction,* connect the external vacuum to the vacuum inlet port on the reservoir.

Attach the A&A Line and Prime the Reservoir

5. Open the A&A line packaging using aseptic technique and pass the sterile inner wrapped line into the sterile field.
6. Attach a plastic suction wand to the A&A line while inside the sterile field and pass the other end back out to the device.
7. Connect the A&A line to the reservoir and insert the A&A line into the tubing support.

8. Touch **Suction** to turn on suction. If using manual suction, set suction to a minimal acceptable level (<200 mmHg).

1. Vacuum line
2. A&A line in the tubing support

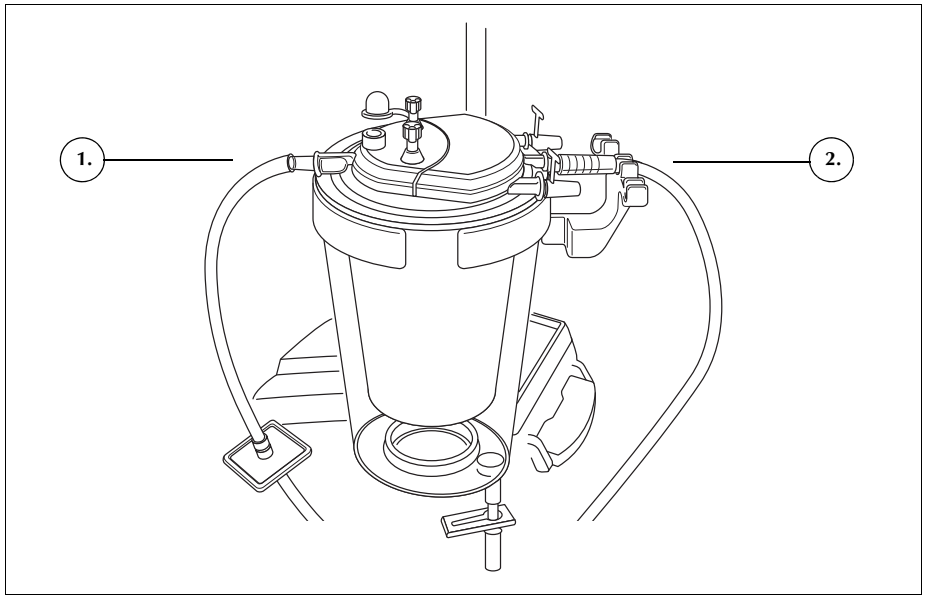


Figure 35, Reservoir vacuum line and A&A connections

9. Close the roller clamp on the A&A line.
10. Hang the anticoagulant (AC) solution bag on the IV pole.
11. Ensure that the bag is properly labeled as anticoagulant solution.

Note: The most common anticoagulant solution is 30,000 units of heparin in 1L of normal saline. This should be delivered at a 1:7 ratio of heparinized saline to blood entering the reservoir by adjusting the roller clamp on the anticoagulant line.
Citrate solution can also be used as an anticoagulant solution. A general guide for citrate solution delivery is a ratio between 1:5 and 1:10 anticoagulant to blood.
The rate for both anticoagulants should be set to give approximately 15 mL of anticoagulant for each 100 mL of blood collected. This equates to a drip rate of 1-2 drops per second, depending on the rate of blood collection.
These recommendations for the use of anticoagulant solution are intended as guidelines only and should not substitute for the user's clinical judgment.

12. Aseptically insert the spiked end of the drip chamber into the AC solution bag.
13. Squeeze the drip chamber.
14. Reopen the roller clamp on the AC drip line to allow full flow of AC solution.

15. Allow approximately 150 mL of AC solution to flow into the collection reservoir to adequately prime the filter/defoamer media.
16. Close the roller clamp until beginning the collection from the field.

Alert: Prior to pumping blood through the harness and bowl, the blood must be anticoagulated, either systemically or regionally. Non-anticoagulated blood or blood components introduced into the bowl/ harness assembly will clot. Such clotting renders the final blood product inappropriate for reinfusion.

Installing the Processing Set

When adequate shed blood recovery has occurred or is expected, prepare the processing set for installation:

Selecting the Bowl Size

1. From the *Bowl Selection* screen, scan a processing set using the barcode reader underneath the touch screen display or select the appropriate bowl size on the touch screen. The *Processing* screen appears.
2. Extend the tub holder located on the right side of the cart.
3. Place the tub in the holder so that the top of the bowl faces the back of the device.

Hanging the RBC Bag

To install the RBC bag:

1. Remove the RBC bag and tubing from the tub and hang the bag on the top hooks of the right IV pole.
2. Close the two small ratchet clamps on the reinfusion lines.
3. Ensure that the two large ratchet clamps on the blue line are open and the twist-lock connection is secure.

1. RBC bag
2. Large ratchet clamp
3. Small ratchet clamps

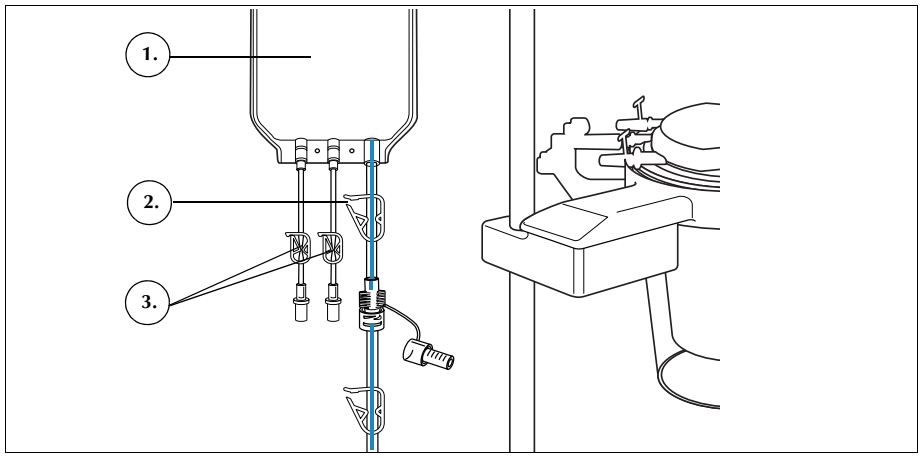


Figure 36, RBC bag

Installing the Tubing Harness

To install the processing set tubing harness:

1. Open the cover, centrifuge header arm, valve module cover, and pump platen.
2. Lift the remaining processing set components from the tub and drape them over the device with the waste bag on the left side of the device and the bowl placed loosely in the centrifuge well.
3. Thread the pump tubing around the pump.
4. Install the tubing manifold on the left side of the valve module, pressing it lightly into place.
5. Floss the tubing into the air detector.
6. Insert the clear tubing and the color-coded lines into the grooves in the valve module.
7. Close the pump platen.
8. Close and latch the valve module cover.

1. Tubing in air detector
2. Pump platen lever
3. Pump platen
4. Tubing in valve module channels

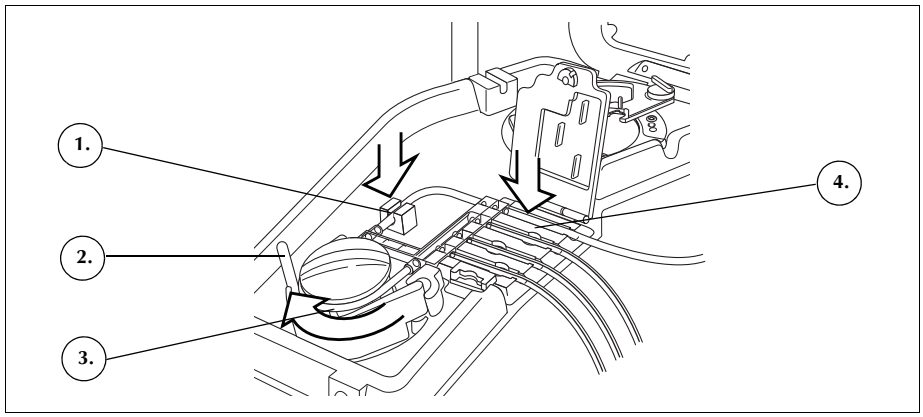


Figure 37, Tubing harness

Installing the Bowl

To install the bowl:

1. ***70 mL bowl only:*** Insert the chuck adaptor into the centrifuge well.

Note: The chuck adaptor is NOT disposable and should be saved for subsequent procedures.

2. Ensure that the lower port of the bowl faces the effluent line sensor.
3. Install the bowl in the centrifuge by carefully pressing down on the shoulders of the bowl until it is seated securely in the chuck.

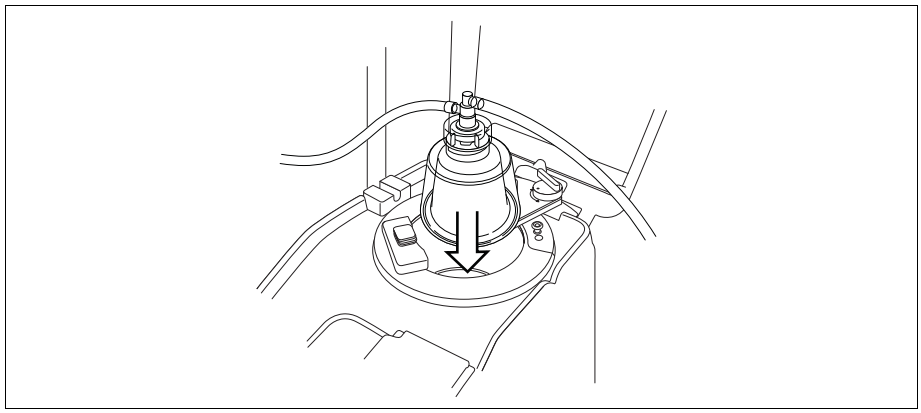


Figure 38, Inserting the bowl into the centrifuge chuck

4. ***70 mL bowl only:*** Ensure that the blue indicator lines inside the chuck adaptor are visible.
5. Position the header arm around the top of the bowl.
6. Turn the latch on the header arm clockwise until it locks into place.
7. Spin the bowl to ensure it spins freely.

1. Header arm
2. Tubing in effluent line sensor
3. Header arm latch
4. Bowl in centrifuge chuck

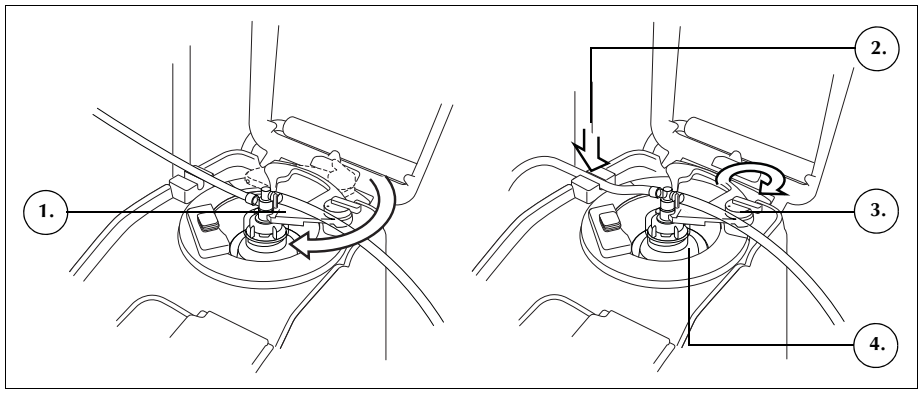


Figure 39, Closing and locking the header arm

Note: A click will be heard when the locking mechanism is completely secured.

Alert: Verify that the outlet port and effluent tubing are free of any restrictions prior to initiating a procedure. If the outlet port is inadvertently clamped off, the bowl rotary seal may become compromised. See “Avoiding Flow Restrictions” on page 65 for more information.

Installing the Effluent Line Sensor Tubing

To install the effluent line tubing:

1. Floss the effluent tubing into the effluent line sensor groove.
2. Ensure that the tubing is completely installed in the effluent line sensor.

Hanging the Waste Bag

To hang the waste bag:

1. Hang the waste bag on the pins on the left side of the device.
2. Verify that the waste bag is securely connected to the effluent line.
3. Ensure that the waste bag drain port is completely closed.

1. Waste bag pins
2. Effluent tubing connection
3. Waste bag drain port

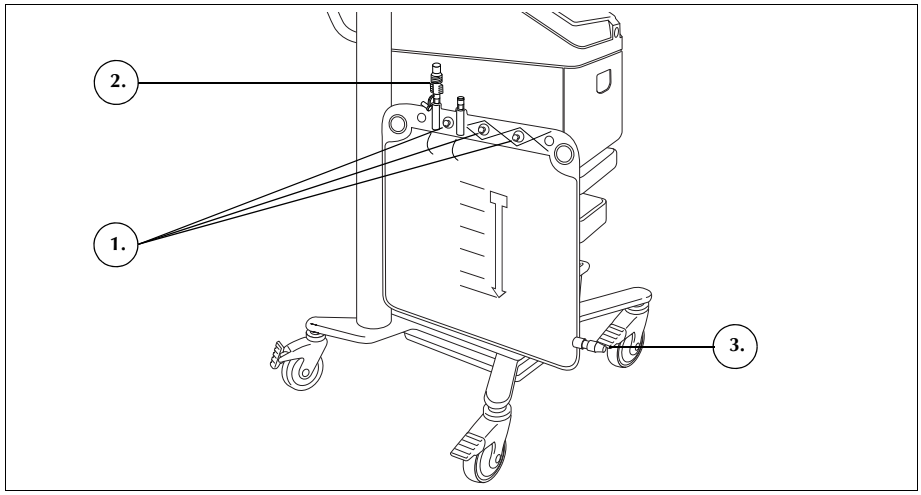


Figure 40, Hanging the waste bag

Connecting the Reservoir

1. Aseptically connect the red line to the reservoir drain port.
2. Open the reservoir drain port slide clamp.

1. Reservoir
2. Reservoir drain port slide clamp
3. Red line connection
4. Red line ratchet clamp

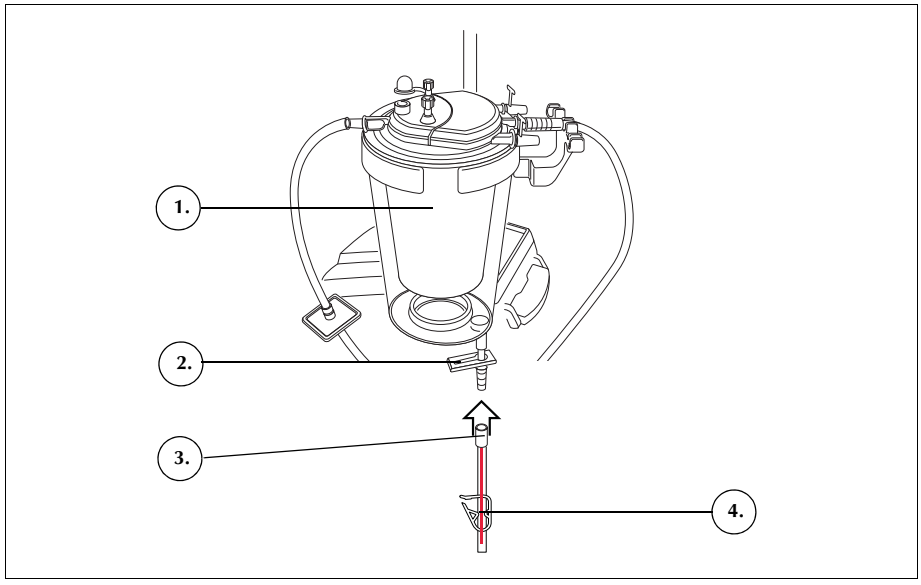


Figure 41, Red line connected to the reservoir drain port

Setting up the Saline Solution

Alert: The wash solution should be Sterile 0.9% Saline For Injection, USP. No other wash solutions should be used, as this could lead to hemolysis.

To install the saline solution:

1. Hang the saline solution bags on the lower pigtail of the right IV pole.
2. Close the ratchet clamps on the yellow lines.
3. Spike the saline solution bags and unclamp the lines.

1. Saline wash solution
2. Saline spike

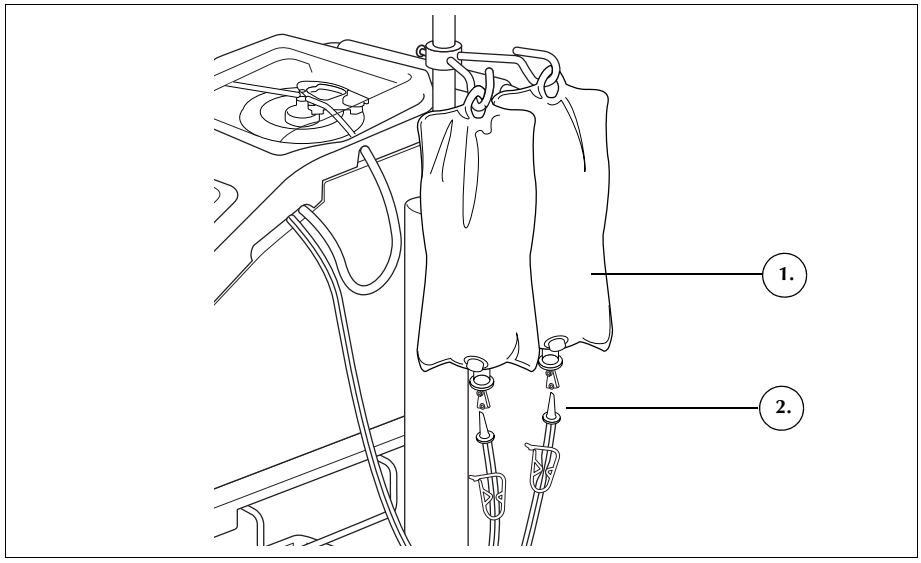


Figure 42, Spiking the saline bags

Note: Each wash cycle requires a volume of saline solution that depends on the size of the bowl in use. By default, the minimum amount of saline solution used for each bowl size is as follows (these amounts can be increased or decreased by modifying the settings as described in Chapter 7, "Protocol Settings" on page 123).

- ***225 mL bowl:*** *1000 mL saline solution.*
- ***125 mL bowl:*** *750 mL saline solution.*
- ***70 mL bowl:*** *300 mL saline solution.*

Regardless of the setting, if a Wash phase is extended, more saline is utilized.

Inspecting the Installation

Always inspect the disposable components after completing the installation.

1. Inspect all parts of the disposable components and verify that there are no twists, kinks, or flat spots.
2. Verify that all connections are secure and all appropriate clamps are closed.
3. Close the device cover, ensuring that no tubing is inadvertently clamped off.

Performing the Intraoperative Cell Salvage Procedure

The Cell Salvage procedure processes blood solution from the reservoir in a series of cycles. Each cycle consists of the Fill, Wash, and Empty phases. When the Auto-Fill parameter is enabled the procedure will start and continue automatically until the volume of fluid in the reservoir at the beginning of Fill is less than the start volume setting.

Initiating a Procedure

Once the disposable components are properly loaded onto the device, touch **Start Procedure**. The device advances to Standby.

Note: The Cell Salvage procedure can also be performed using Manual Mode, as described starting on page 88.

Procedure Overview

The device starts the **Fill phase** when the fluid in the collection reservoir reaches a preset level or when the user touches **Fill**. During the Fill phase the device pumps fluid from the reservoir into the spinning bowl.

*Note: If the reservoir contains fluid and it is desired to process that fluid but the device has not yet automatically tripped into Fill, touch **Fill** on the Cell Saver Elite+ display.*

The device starts the **Wash phase** when the bowl contains the appropriate amount of red blood cells (RBCs) or when the user touches **Wash**. During the Wash phase the device pumps saline solution into the spinning bowl. The saline solution moves through the heavy red cell layer, carrying cellular components and other waste solution out through the effluent tubing and into the waste bag. During the Wash phase, the **Wash** pad expands to show the wash volume used and the target wash volume. For information on changing the target wash volume for the current wash cycle, see “Phase Pads” on page 37.

The device starts the **Empty phase** at the completion of the Wash phase or when the user touches **Empty**. During the Empty phase the device stops the centrifuge and pumps the RBCs from the bowl to the blue line. To minimize the number of RBCs remaining in the bowl at the end of Empty, the device starts Empty at a higher speed and reduces it throughout the Empty cycle in preprogrammed increments. The default settings are specified on page 129. If the user changes the empty pump rate in the settings group, the device maintains the new speed specified in the settings group throughout the Empty cycle.

Note: If the user manually adjusts the pump speed, pump regulation is disabled. If the user then manually adjusts the pump speed back to the default value specified in the current settings group, pump regulation is enabled again.

*Note: If the device loses power during the Empty cycle, touch **Empty** after recovering the procedure to ensure the bowl empties completely.*

If there is no further blood to process, the user should end the procedure. See “Completing a Procedure” on page 95.

Cell Salvage Additional Functions

Concentrate Phase

If it becomes necessary to wash and reinfuse whatever cells are currently in the bowl and there are washed RBCs in the RBC bag, the user can initiate a **Concentration phase** by touching **Conc** on the touch screen.

During the Concentration phase the device transfers washed RBCs from the RBC bag back into the bowl. The device starts the Wash phase when the bowl contains the appropriate amount of RBCs.

If there are insufficient RBCs in the RBC bag to initiate a Wash phase, the user may wash a partial bowl.

Return Phase

If it becomes necessary to return the fluid in the bowl to the collection reservoir, the user can initiate a **Return phase** by touching **Return** on the touch screen.

During the Return phase, the device pumps fluid from the bowl through the red line and back to the collection reservoir. The volume returned to the red line is subtracted from the processed volume.

Emergency Options

In emergency situations where users are managing high blood-loss, it may be necessary to accelerate the processing time to quickly return blood to the RBC bag for reinfusion to the patient. The Cell Saver Elite+ offers two modes for this purpose:

- Emergency Mode: If time allows for washing the blood, users can initiate Emergency Mode, which accelerates the pump speed and decreases the time required to return the product to the RBC bag. This mode concentrates and washes the blood before reinfusing it back into the bag for delivery. Emergency Mode is available from the *Processing* screen (see Figure 6 on page 35) during the Fill, Wash, Empty, Concentrate, and Return phases. It is not available from a Standby or Stopped state, or when in Manual Mode or Quick Transfer Mode. For more information, see “Emergency Mode” on page 86.
- Quick Transfer Mode: When time is of the essence for returning the product to the patient due to trauma, sudden massive blood loss, thoracoabdominal aneurysm, and so on, users can initiate Quick Transfer. This mode quickly moves the shed blood from the reservoir to the reinfusion bag. The device automatically cycles through the Fill and Empty phases continuously with a non-spinning bowl until the reservoir is empty, completely bypassing the wash phase. This feature must be

enabled from the *Settings* menu prior to users being able to execute a procedure using this mode. For more information, see “Quick Transfer Mode” on page 86.

Alert: Quick Transfer Mode produces an **unwashed** final collection in which the removal of large contaminants such as skin or bone fragments is only possible through the filter reservoir. The use of a microaggregate filter is strongly recommended. Users are fully responsible for evaluating the situation and determining if the conditions justify the use of Quick Transfer Mode.

Emergency Mode

Alert: RBCs may be lost into the waste bag during Emergency Mode.

Note: The red line sensor does not monitor RBC spillage during Emergency Mode.

Note: Emergency Mode is only available with the 125 mL and 225 mL bowls. It is not available for use with the 70 mL bowl.

Note: Even if the Auto-Fill setting has been disabled, the device still processes blood continuously at high speeds through the Fill, Wash, and Empty phases.

Note: To switch to Emergency Mode when in Manual Mode, first select another settings group from the Active Settings drop-down list, and then select Emergency Mode.

*Note: To switch to Emergency Mode when in Quick Transfer, touch **End Quick Transfer**, wait until the device returns to STANDBY mode, and then select Emergency Mode.*

For more information on Manual Mode, see “Manual Mode” on page 88.

To initiate Emergency Mode:

1. Touch **Emergency Mode**.
2. Touch **On** to confirm.

During Emergency Mode the device processes blood continuously at high speeds through the Fill, Wash, and Empty phases until the air detector senses air for the first time in the Fill phase, indicating that the reservoir is empty. The device then reverts to the previous settings group and enters Standby.

Quick Transfer Mode

Alert: Quick Transfer Mode is only used to transfer unwashed shed blood into the final collection bag with no processing. The user is responsible for executing Quick Transfer Mode and determining if the product contained in the reinfusion bag is suitable for reinfusion into the patient.

Note: Quick Transfer mode is only available for use with the Cell Salvage protocol.

*Note: Quick Transfer mode is available for use with the 225 mL bowl, **NOT** the 70 mL or 125 mL bowls.*

Note: Quick Transfer mode cannot be initiated when Manual Mode is in use.

Note: Quick Transfer must be enabled in a settings group before it can be utilized. See "Making the Quick Transfer and Manual Mode Settings Available" on page 136 for more information.

Before initiating Quick Transfer Mode:

- Ensure the two large, white ratchet clamps on the blue line and the large, white ratchet clamp on the red line are open.
- Ensure the slide clamp on the outlet port of the Reservoir is open.
- Check that the vacuum applied to the reservoir is <250 mmHg (33 kPa).
- Dilution of packed red cells with saline is necessary to decrease viscosity within the Reservoir before initiating Quick Transfer.
- To avoid clotting in the Reservoir, ensure the volume of blood is properly anticoagulated before initiating Quick Transfer.

Note: If the device automatically starts the Fill phase, because the reservoir level reached the Fill start volume, then touch  (Stop).

To initiate Quick Transfer Mode:

1. Touch **Active Settings** at any time during an active cell salvage procedure.
2. Select **Quick Transfer** from the drop-down list. The *Switching to Quick Transfer* screen appears.
3. Touch **Confirm** to begin Quick Transfer.

*Note: Touch (**Pause**) to pause Quick Transfer. The  **(Play)** button pulsates when Quick Transfer is paused. Touch  **(Play)** to resume Quick Transfer.*

4. Touch **End Quick Transfer** to end Quick Transfer and return to the previously selected Active Settings in Standby. If the bowl is not empty, the contents are returned to the reservoir. When the bowl is empty, if necessary the device first purges the red line, then the blue line, and then returns to the previously selected Active Settings.

Final Cycle

Final Cycle allows the user to specify what the device does to end the procedure after air is detected in Fill. When Final Cycle is activated, the device continues processing until air is detected in Fill, after which the device automatically completes the procedure according to the selected Final Cycle settings: Last Partial Bowl Wash (Single/Double), or End Procedure. See “Cell Salvage Default Settings” on page 129 for more information.

Manual Mode

This feature enables the user to control the Cell Saver Elite+ device manually for cell salvage with minimal sensor monitoring. To control the device, the Fill, Wash, Empty, Conc, and Return phases are manually selected by the user. In Manual Mode:

- The line sensor and bowl optics are disabled.
- The air detector is used for volume accounting in the Fill, Wash, and Concentrate phases, and to determine when to end the Empty and Return phases.

Alert: When the device is in Manual Mode, sensors are disabled. As a result, the detection and determination of RBCs is the full responsibility of the operator. During Manual Mode, the operator is responsible for monitoring the Fill phase (or concentration) and manually transitioning to the Wash phase to start the next operation. If the transition is delayed, it could lead to the loss of red blood cells. If the transition is early, it could lead to low quality collection.

Alert: When the device is in Manual Mode, if the washing of the packed red blood cells is inadequate, it may lead to an excessive level of contaminants (for example, plasma free hemoglobin, anticoagulant) in the processed blood.

The following indicators are displayed in Manual Mode:

1. Effluent sensor is disabled.
2. Regulation is disabled.
3. Auto-Fill is disabled.
4. The device is in Manual Mode.
5. Automatic wash is disabled.
6. Wash quality is unchecked (this is only displayed after the Empty phase is initiated).

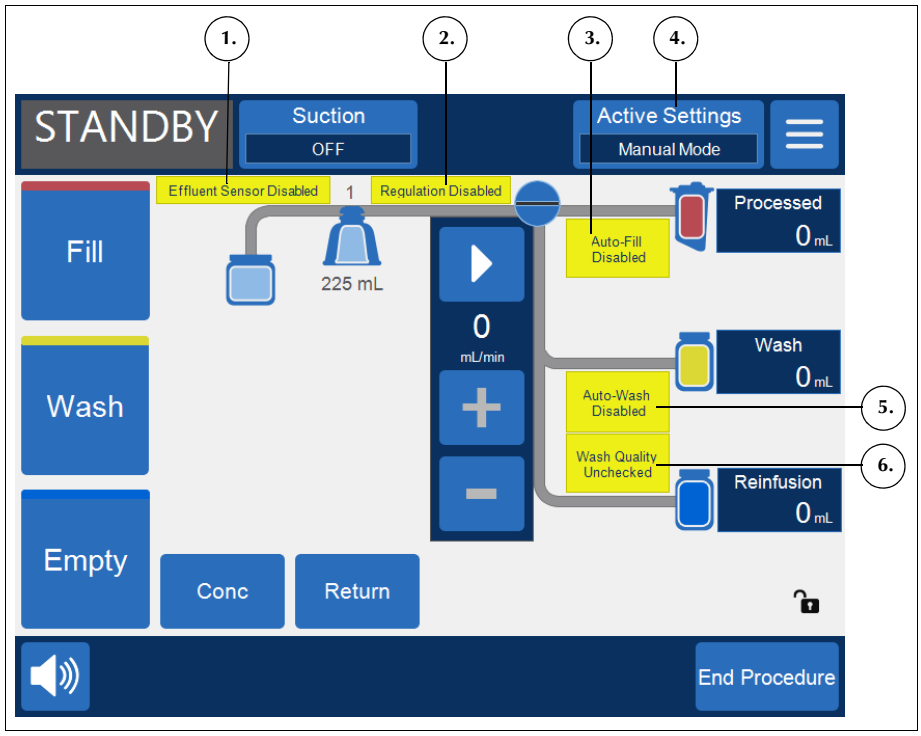


Figure 43, Example of the display in Manual Mode

Switching to Manual Mode

Note: Manual Mode must be enabled in a settings group before it can be utilized. See "Making the Quick Transfer and Manual Mode Settings Available" on page 136 for more information.

1. After starting a procedure using a settings group that has Manual Mode enabled, touch **Active Settings**.
2. Select **Manual Mode** from the drop-down list. The *Switching to Manual Mode* screen appears.
3. Touch **Confirm** to switch to Manual Mode.
   - The device remains in the same phase it was in prior to the transition to Manual Mode (for example, Fill, Wash, and so on).
   - All processing phases are now available from the touch screen.

Note: Manual Mode can be selected when in Emergency Mode.

Note: Emergency Mode and Quick Transfer cannot be directly selected when in Manual Mode. To switch to Emergency Mode or Quick Transfer Mode from Manual Mode:

*a. Touch **Active Settings** to open the drop-down list.*

b. *Either select the same settings group that was being utilized immediately prior to switching to Manual Mode or another settings group.*

c. *Select Emergency Mode or Quick Transfer.*

See "Emergency Mode" on page 86 and "Quick Transfer Mode" on page 86 for more information.

Note: To customize the Manual Mode default settings, and for a list of the factory default settings, see "Cell Salvage - Manual Mode Default Settings" on page 130 (pump rate and centrifuge speed defaults for the different phases can be modified; alert sounds can be disabled).

Collecting Fluid in the Reservoir

The AC solution flow rate should be adjusted to be consistent with the rate at which blood is collected at a 1-2 drops/second rate for heparin solution (30,000 units of heparin in 1 liter of normal saline solution).

Initiation of the Fill phase is largely dependent upon the rate of fluid collection in the reservoir. If the patient is losing blood steadily and rapidly, processing may begin as soon as a minimum of 200 mL (default of 800 mL) of fluid enters the reservoir. However, it is more typical to begin processing by initiating the Fill phase after the reservoir has accumulated 600-900 mL of volume.

Note: The reservoir volume will have a lower than normal hematrocrit due to suction hemolysis, dilution by wound irrigants, and dilution by heparinized saline.

Filling the Bowl

1. Touch **Fill** to initiate the Fill phase.

***Attention:** The Fill phase does not stop until the user presses another key, such as the Wash key.*

Using the Concentrate Option

1. Touch **Conc** to use the concentration option.

   The blue pinch valve opens and allows RBCs to be drawn from the reinfusion bag into the bowl and displaces supernatant from the bowl into the waste bag.

Washing the Cells

As the bowl is filling during either the Fill or Concentrate phase, observe when the RBC/supernatant interface reaches a point just below the neck of the bowl. When this occurs, initiate the Wash phase:

1. Touch **Wash**.

The volume of wash solution required depends upon factors such as the degree of hemodilution and amount of AC solution used. Certain minimum

volumes are required per cycle depending on the type of procedure. The user should continue washing until the effluent line is clear.

Note: If during the Wash phase, the RBC/supernatant interface disappears and RBCs begin to spill into the waste bag, touch **(Pause)** *to allow the interface to reappear, then slowly increase to a rate that just maintains this interface (usually, 200 mL/min or less).*

Emptying the Bowl

1. After the red cells have been processed, touch **Empty** to send them to the reinfusion bag.

   The message “Centrifuge Stopping” is displayed until the centrifuge bowl comes to a complete stop. The concentrated RBCs are then pumped from the bowl to the reinfusion bag.

Entering Standby Mode

The Cell Saver Elite+ device transitions to the Standby mode when it detects the bowl is empty.

Note: If the reservoir, contains more blood to be processed, touch ***Fill*** *to initiate another fill cycle.*

Note: If the amount of fluid available in the reservoir for processing is insignificant, discard the remaining fluid with the disposable set bowl according to local guidelines.

Exiting Manual Mode

1. Touch **Active Settings** to open the drop-down list.
2. Select either the same settings group that was being utilized immediately prior to switching to *Manual Mode* or a different settings group.

Note: Upon exiting Manual Mode, if the bowl is not empty and the device is in the Fill or Concentrate phase, the device returns the contents of the bowl to the reservoir; if the bowl is not empty and the device is in the Wash, Return, or Empty phase, the device continues with that phase.

Recentrifuge Delay

After the centrifuge bowl is stopped, red blood cell separation is lost. This settling of cells could lead to an RBC spillage if fluid is pumped into the bowl before the cells are allowed to separate again when the process is resumed. To prevent this, there is a recentrifuge delay which spins the centrifuge bowl for a few moments to separate the cells before pumping more fluid into the bowl when processing is resumed for a Fill, Wash or Concentration phase.

Although the delay is important to ensure proper separation, it can be overridden 15 seconds after the recentrifuge delay initiates, when the **(Play)** key begins pulsating:

1. Press **(Play)** to override the delay and resume the process.

Attention: *If the delay is overridden, be aware of the possibility of red cell spillage caused by pumping fluid into a bowl of red blood cells with poor or no separation.*

- To avoid a red cell spillage into the waste bag, either:
  - Touch **(Pause)** to stop the pump.

    or
  - Press the **+/-** pads to gradually adjust the pump to the desired speed while observing the cells for separation.

Processing a Partial Bowl

If it is necessary to process blood before a full bowl has been collected, the user can wash a partial bowl by manually starting the Wash phase.

Blood processed using a partial bowl will have a lower hematocrit than blood processed using a normal full bowl. Because the hematocrit of the bowl contents is lower, there is more supernatant in the bowl. In order to dilute the larger volume of supernatant, a partial bowl should use two times the normal saline solution.

If the user chooses to wash a partial bowl, the device either automatically doubles the wash volume, uses the default wash volume, or provides an option to double the wash volume, as determined by the Partial Bowl Wash setting. (See “Modifiable Settings” on page 129 for more information.)

Monitoring the Waste Bag

During the procedure, the device monitors the amount of fluid collected in the waste bag and alerts the user to change the bag or drain the contents of the bag when it is almost full.

When emptying the waste bag, do not allow the fluid level in the bag to fall below the 1 liter mark. This ensures that sufficient air is retained in the system to empty the bowl. Make sure that the bowl is empty before replacing the waste bag.

Emptying the Waste Bag

Attention: *Unless the bowl is completely empty, keep fluid level in the waste bag ABOVE the 1 liter mark on the waste bag. This prevents air loss.*

Drain the waste fluid into an empty container for discard.

Changing the Waste Bag

To prevent air loss, change the waste bag ONLY when the bowl is empty. Follow the steps below to change the waste bag:

1. Touch (**Pause**) to pause the procedure.
2. Remove the full waste bag.
3. Install a new waste bag.
4. Touch (**Play**) to resume the procedure.

General Precautions When Reinfusing Processed Blood

Alert: DO NOT USE A PRESSURE CUFF OR ANY OTHER MECHANICAL DEVICE. PRESSURE REINFUSION CAN RESULT IN THE FATAL INFUSION OF AIR INTO THE PATIENT.

Alert: Do not reinfuse patient blood from the RBC bag when it is connected to the Cell Saver Elite+. Reinfusion from the RBC bag if connected to the Cell Saver Elite+ could lead to an air embolism.

Alert: If reinfusing directly from the RBC bag, the bag MUST NOT become empty in between transfusions to the patient. If air enters the reinfusion line, empty the air before starting reinfusion.

Alert: Washed, packed cells are depleted of clotting factors. The physician must monitor the quantity of washed cells returned to the patient and supplement the washed, packed cells with fresh frozen plasma and platelets if required for hemostasis.

Alert: In accordance with FDA guidelines and AABB standards, a transfusion filter designed to retain particles potentially harmful to the patient should be used when returning processed concentrated RBCs.

Alert: The safe length of time that blood or blood products may remain in the autotransfusion disposables is dependent on collection and storage methods. Refer to the AABB standards for more information.

Changing Processing Sets During a Procedure

Unless otherwise required in order to resolve an event message, the valve module cover remains locked throughout the procedure to ensure it is not inadvertently opened and the fluids within the processing set are not mixed. If it becomes necessary to change the processing set during a procedure, follow the steps below:

1. Touch (**Pause**).
2. Touch **End Procedure**. A confirmation screen appears.
3. Touch **End Procedure** and wait for the device to empty the bowl (if full) and purge the blue line.

4. Once the blue line has been emptied completely, remove the current processing set from the device.
5. Install a new processing set, following the instructions beginning on page 79.
6. Once the new processing set is installed, touch **Resume Procedure**.

All procedure statistics from the procedure will be retained, and suction can remain on throughout this process.

Changing the Bowl Size During a Procedure

If the user selected the incorrect bowl size from the *Bowl Selection* screen, navigate to the *Records* screen, view the procedure record, and edit the processing set on the *Disposables* tab, following the instructions on page 143.

Completing a Procedure

When a Cell Salvage procedure is complete, you can end the procedure by touching **End Procedure**, when available. Upon confirming that you want to end the procedure, the *Records* screen displays the procedure record. If the device detects there is still fluid in the bowl, it empties the bowl before marking the procedure complete. If the fluid is clean cells, it empties the bowl to the blue line; if the fluid is unwashed cells, it returns the fluid through the red line to the reservoir. The device then pumps a small amount of air through the blue line to flush any remaining blood in the line into the RBC bag. During this Empty phase, a “Purging Blue Line” message appears in the message area. When the blue line has been fully purged, a “Procedure Complete” message appears. Remove the disposable components from the device and discard according to local standard operating procedures for biohazardous material.

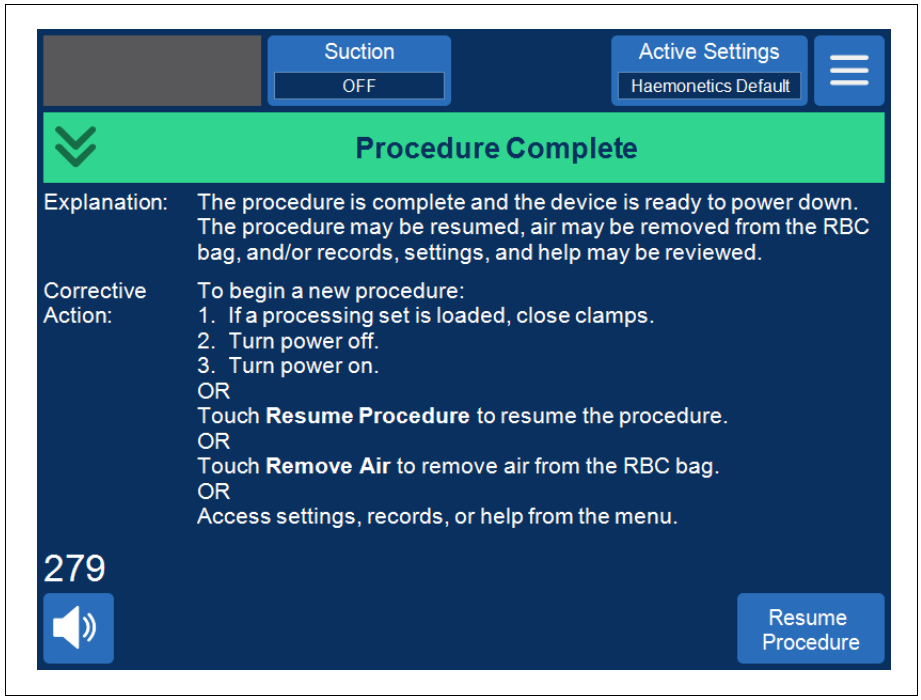


Figure 44, Expanded view of the “Procedure Complete” message

Note: To begin a new procedure, you must first power down the device and power it back on.

*Note: If you power down the device before fully purging the blue line, power the device back on, choose to resume the procedure, and touch **End Procedure**. This flushes the remaining blood in the blue line into the RBC bag.*

Note: If the device is powered off without purging the blue line and is powered on again within six hours with a processing set installed, the device prompts

you to resume the previous procedure or to save the previous procedure and start a new one. If you choose to start a new procedure, the device marks the previous procedure as complete and performs a self-test. If you instead choose to continue the previous procedure, the device instructs you to ensure all disposable components and interlocks are in place.

Additional Functions

When you end a procedure, the *Records* screen appears, displaying the procedure record for the current procedure.

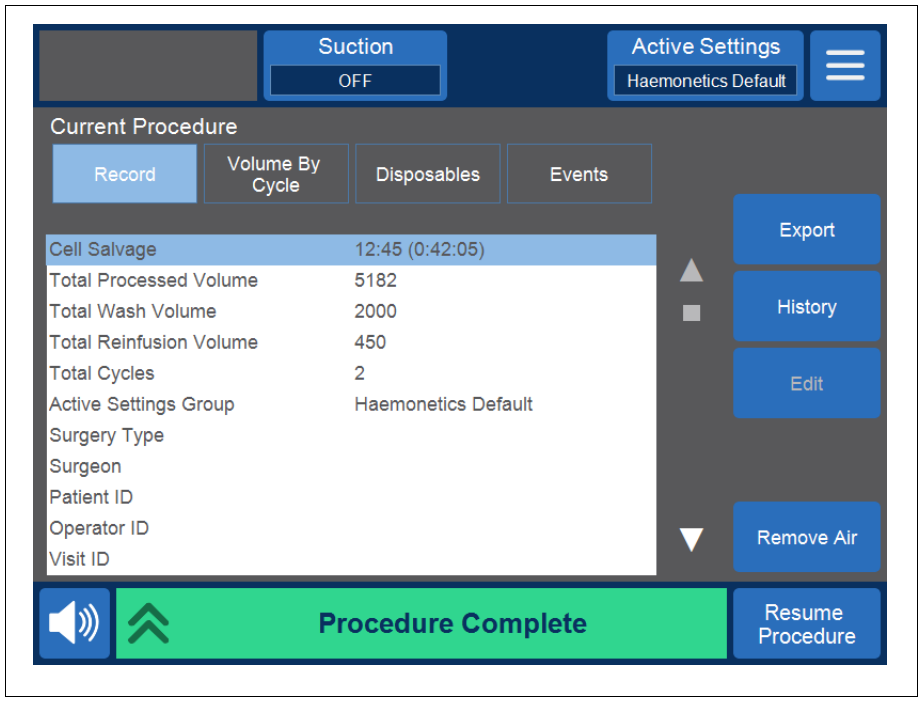


Figure 45, Example of the current procedure record

The right side of the screen provides additional actions you can take, including export the procedure record, view procedure record history for past procedures, edit the procedure record, and remove air. For more information procedure records, see Chapter 8, “Records”.

Removing Air from the RBC Bag

Alert: This process may leave residual air in the RBC bag. Do not pressure infuse. May cause fatal infusion of air.

To purge any extra air from the RBC bag, you can touch **Remove Air**. A yellow alert message appears:

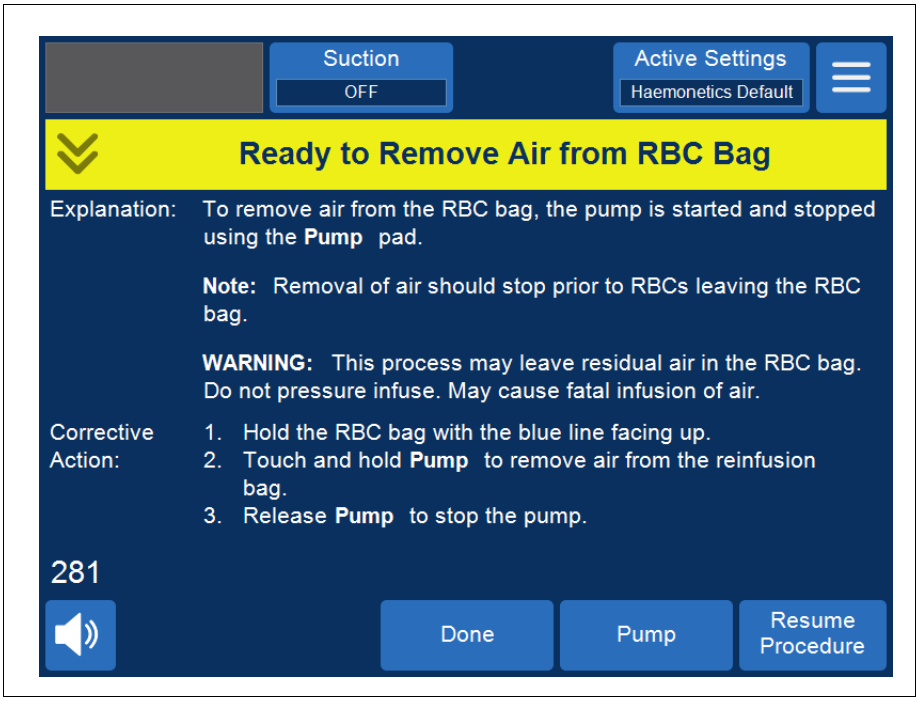


Figure 46, Example of the yellow alert message

Following the prompts on the screen,

1. Hold the RBC bag with the blue line facing up.
2. Touch and hold **Pump** to remove air from the RBC bag.The pump rotates as long you are touching **Pump**.
3. Release **Pump** to stop the pump.
4. To return to the *Records* screen, touch **Done**.

Resuming a Procedure

To resume the procedure after touching **End Procedure**, you can touch **Resume Procedure**. The touch screen returns to the *Processing* screen with the device in Standby mode. You can then choose to continue the procedure by touching one of the phase pads. To end the procedure again, touch **Procedure Complete**.

Performing the Postoperative Cell Salvage Procedure

Postoperative operation runs completely automatically. The Cell Saver Elite+ device generates the suction in the reservoir. The device begins the processing cycles when an appropriate amount of blood solution collects in the reservoir. It is usually not necessary to anticoagulate postoperative drainage blood.

Post-op suction provides a variable suction level with a default level of 75 mmHg. You may set the suction to the following levels:

- 25 mmHg
- 50 mmHg
- 75 mmHg
- 100 mmHg
- Off

Post-op suction utilizes periodic suction relief. Suction runs at the selected suction level for 10 minutes, is relieved for 1 minute, and then returns to the selected suction level for another 10 minutes. This cycle repeats continuously throughout post-op operation.

Note: Intraoperative suction levels on the Cell Saver Elite+ device are not intended to be used for postoperative wound drainage, which you should not expose to suction levels greater than 100mmHg.

Alert: Postoperative suction on the Cell Saver Elite+ device is not intended to be used for chest (pleural or mediastinal) wound drainage.

The device retains procedure data while it is powered down for transport from the operating room to the post-anesthesia care unit (PACU). When the device is powered back on, it asks you to choose to either continue the current procedure or to end the procedure and begin a new procedure.

Post-Op Set

The post-op set is used to collect blood postoperatively from wound drain tubing placed into the wound while the patient is in the operating room.

1. Reservoir connection
2. Wound drain connection

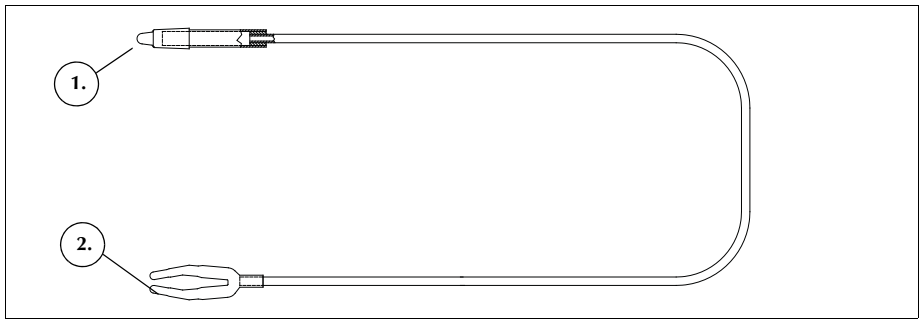


Figure 47, Example of a post-op set

Installing the Post-Op Set After Intra-Op Use

Preparing the Device and Disposable Components

Note: For post-op suction, you must use the Cell Saver Elite+ internal post-op suction levels or wall suction regulated to appropriate post-op suction levels.

Attention: *Do not activate post-op suction until the wound drain line is attached and the wound is closed. The system post-op vacuum is not sufficient to generate suction on an open line.*

1. Open the postoperative set using aseptic technique.
2. Pass the contents into the sterile field.
3. Close the clamps on the wound drain connectors of the post-op set.
4. Ensure all twist-lock connections are secure.
5. Attach the individual wound drain connectors on the post-op set to the patient wound drains.
6. Pass the capped end of the post-op set out of the sterile field to the reservoir.

Note: This connection may be made after the patient and device are present in the PACU. If using a different device in the PACU, the patient data collected in the OR will not be transferred to the second device.

7. Close the roller clamp to the anticoagulant bag on the A&A line and turn off suction to the reservoir.

Connecting to the Patient

To continue installing the post-op set without anticoagulant:

1. Disconnect the A&A line from the reservoir and discard the A&A line and the anticoagulant bag according to local standard operating procedure for biohazardous material.
2. Connect the post-op set to one of the three filtered inlet ports on the reservoir.
3. Open the wound drain clamps to the patient.

Transporting the Patient

When ready to transport the device to the post-anesthesia care unit (PACU):

1. Clamp the vacuum line between the hydrophobic filter and the device and disconnect it from the device.
2. Turn off suction on the device.
3. Power off the device and disconnect it from power.

Note: Do not touch ***End Procedure****.*

4. Lower the IV poles as far as possible.

5. Transport the device (if necessary), patient, reservoir, and tubing.

Upon Arrival

1. Raise the IV poles into operating position and ensure the reservoir is no higher than 35.5 in. (90 cm).
2. Connect the vacuum line to the device and remove the clamp.
3. Connect the device to power and power it on.
4. Touch **Continue Procedure**.
5. Touch **Suction** on the touch screen and select **Post-Op** from the drop-down list.
6. Set the appropriate suction level (The default suction level is 75 mmHg.)
7. Ensure blood is flowing towards the reservoir.

The device is ready to proceed with postoperative operation and begins the processing cycles when an appropriate amount of blood collects in the reservoir.

Installing the Postoperative Set for Post-Op Only Use

If the reservoir was not used in intra-op, follow the steps below to prime the reservoir.

1. Open the postoperative set using aseptic technique.
2. Pass the contents into the sterile field.
3. Attach the individual wound drain connectors on the post-op set to the patient wound drains.
4. Pass the capped end of the post-op set out of the sterile field to the reservoir.

Note: This connection may be made after the patient and device are present in the PACU. If using a different device in the PACU, the patient data collected in the OR will not be transferred to the second device.

5. Connect the post-op set to one of the three filtered inlet ports on the reservoir.
6. Power on the device, if it is not already on.
7. Once the wound is closed, touch **Suction** on the touch screen and select **Post-Op** from the drop-down list, or connect the reservoir to wall suction regulated to appropriate post-op suction levels.
8. Set the appropriate suction level. (The default suction level is 75 mmHg.)
9. If processing is necessary, load the processing set. (See “Installing the Processing Set” on page 79.)

Chapter 6

General Operation: Sequestration

Preparing the Cell Saver Elite+ Device

Connecting to Power

Before powering on the device, make sure it is plugged into a properly grounded power outlet.

A power cord is supplied with the device. Do not replace the power cord with a substitute. If necessary, contact the Haemonetics Customer Care Center for a replacement. Always ensure the power cord is connected to an appropriately grounded power source.

Warning: Ground continuity can only be achieved when the equipment is connected to a properly grounded outlet.

Note: The Cell Saver® Elite®+ device is classified as a continuous operation, Class I, Type CF, IPX1 device, in accordance with IEC/EN 60529 and 60601 standards for medical electrical equipment.

Positioning the Device

To position the device for a procedure:

1. Extend each IV pole to the desired height.
2. Remove the touch screen display from the rear panel of the device.
3. Mount the touch screen display on the left IV pole and adjust the display to the optimal viewing angle.
4. Rotate the reservoir weigher on the right IV pole so that it faces the desired direction.

1. IV poles
2. Touch screen
3. Reservoir weigher
4. Centrifuge header arm, valve module cover, and pump platen

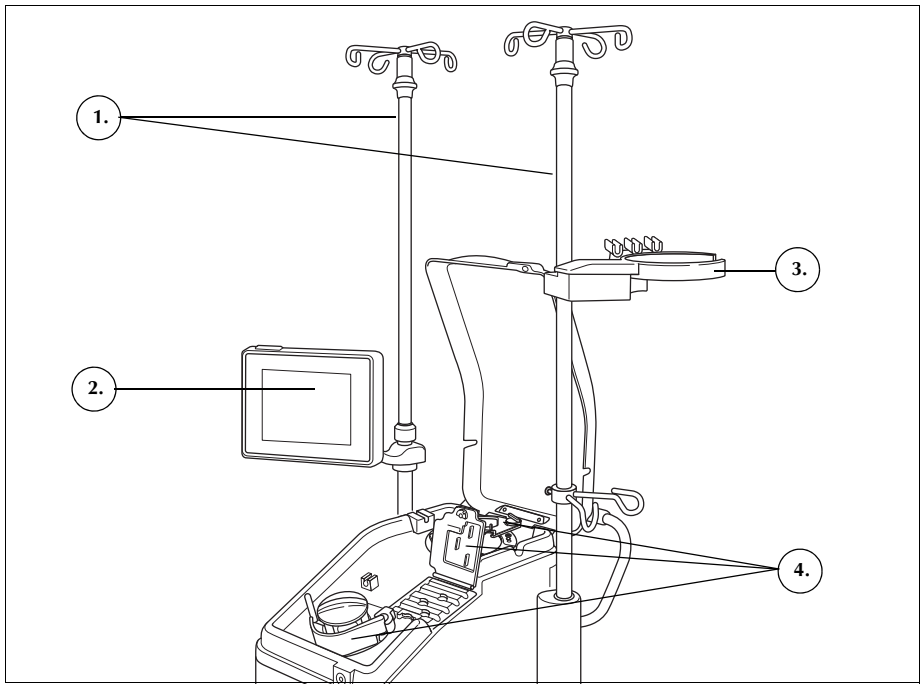


Figure 48, Device positioned for disposable components installation

Unfolding the Biohazard Waste Bag

Once the device is properly positioned, follow the steps below to set up the biohazard waste bag:

1. If the biohazard waste bag is stored in the tray on the underside of the device, remove the bag from the tray.
2. Unfold the bag and ensure that the bag is connected to the drain tube attached to the underside of the device.
3. Ensure that there are no kinks or twists in the tubing and allow the bag and its tubing to hang from the drain tube (See Figure 49).
4. Open the slide clamp and leave it open.

Attention: *The biohazard waste bag should be left hanging out of the tray at all times. In the event of a blood spill, turn off and then unplug the device from grounded AC power. Remove and replace the bag only if it is found to be contaminated with blood or fluid. See* *"Replacing the Biohazard Waste Bag" on page 159**.*

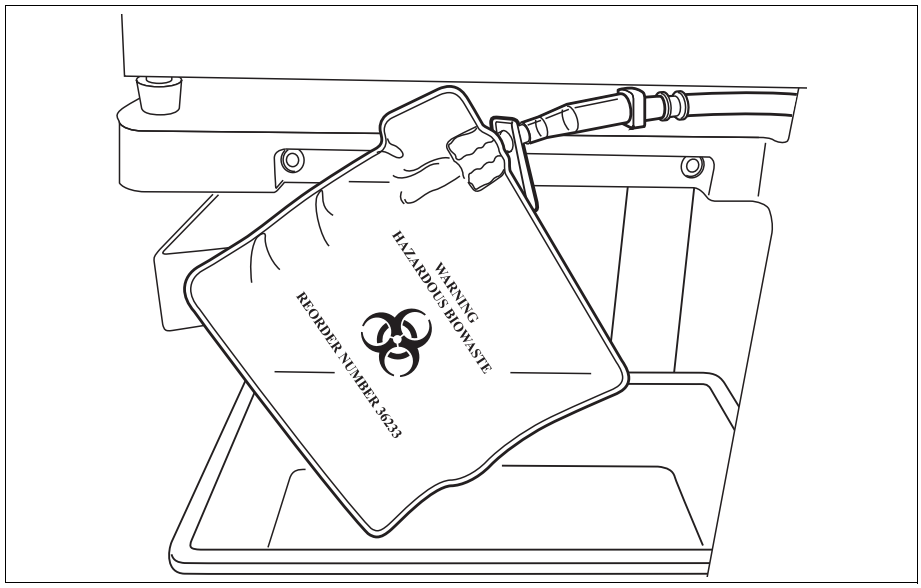


Figure 49, Allowing the biohazard waste bag to hang out of the tray

Power-on Procedure

When ready to initiate a procedure:

1. Ensure the pump platen lever is closed and the valve module cover and centrifuge header arm are closed and locked.
2. Close the device cover.
3. Press the power switch located on the rear panel of the device.
   The device goes through a series of power-on self-tests and advances to the *Bowl Selection Screen*.
4. Touch ☰ (**Menu**) and select **Sequestration** from the drop-down list to select the Sequestration protocol. The device displays the Sequestration *Bowl Selection* screen.

Note: During the power-on self-tests (POST), the device checks the interlocks for the device and manifold covers, the centrifuge arm and the pump platen. To avoid event messages, it is recommended that these be closed during POST. If an event message instructing the user to close one of these occurs and cannot be cleared, close the specified item and restart the device.

*Note: When powered on, the device defaults to the startup mode settings group as determined in the System screen (See "Device Settings" on page 45 for more information). To select a different settings group, touch ☰ (**Menu**), select **Settings** from the drop-down menu, and choose the desired settings group.*

Installing the Sequestration Disposable Components

Inspecting the Disposable Components

Always inspect disposable components while removing them from the packaging.

1. Read the labeling on the processing set to ensure it is the correct set for the current procedure.
2. Check the date on the disposable components to ensure they have not expired.
3. Ensure there are no kinks or twists in the tubing that could restrict the flow of fluid.
4. Check that there are no missing caps or open connections.
5. Verify that there are no visible defects or particulate within the set.

Loading the Reservoir and Vacuum Line

The Sequestration protocol is only available prior to starting the first Fill phase in the Cell Salvage procedure.

To prepare for the Sequestration protocol, load the reservoir and vacuum line:

1. Place the reservoir in the reservoir weigher so that the three filtered inlet ports face the tubing support.

Note: The reservoir weigher should be no higher than 72 in. (183 cm) from the floor.

2. Close the slide clamp on the reservoir drain port.
3. *If using the Cell Saver Elite+ internal suction,* connect the filtered vacuum line to both the vacuum port on the back of the device and to the vacuum inlet port on the reservoir.
4. *If using external suction,* connect the external vacuum to the vacuum inlet port on the reservoir.

Installing the Processing Set

Selecting the Bowl Size

1. If you have not already selected the Sequestration protocol, touch (**Menu**) and select **Sequestration** from the drop-down list. The device displays the Sequestration *Bowl Selection* screen.
2. From the *Bowl Selection Screen*, scan a processing set using the barcode reader underneath the touch screen display or select the appropriate bowl size on the touch screen. The *Processing* screen appears.

Note: Sequestration is not available with the 70 mL bowl set.

3. Extend the tub holder located on the right side of the cart.
4. Place the tub in the holder so that the top of the bowl faces the back of the device.

Hanging the RBC Bag

To install the RBC bag:

1. Remove the RBC bag and tubing from the tub and hang the bag on the top hooks of the right IV pole.
2. Close the two small ratchet clamps on the reinfusion lines.
3. Ensure that the two large ratchet clamps on the blue line are open and the twist-lock connection is secure.

1. RBC bag
2. Large ratchet clamp
3. Small ratchet clamps

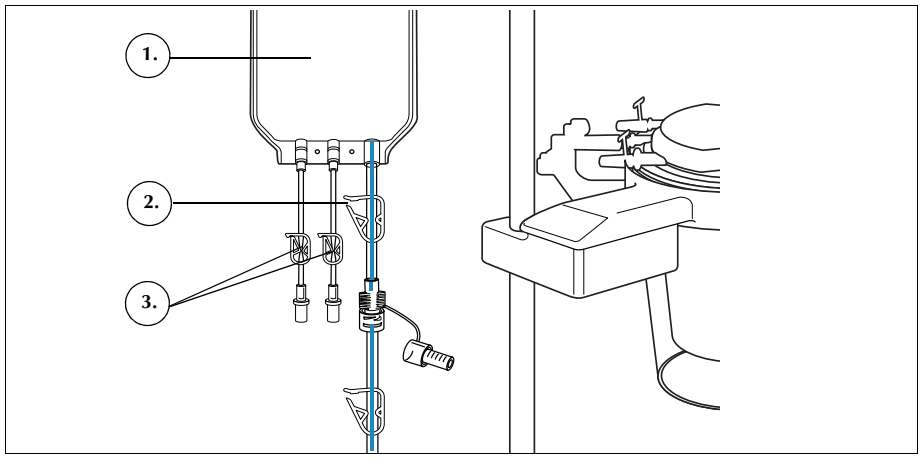


Figure 50, RBC bag

Installing the Tubing Harness

To install the processing set tubing harness:

1. Open the cover, centrifuge header arm, valve module cover, and pump platen.
2. Lift the remaining processing set components from the tub and drape them over the device with the waste bag on the left side of the device and the bowl placed loosely in the centrifuge well.
3. Thread the pump tubing around the pump.
4. Install the tubing manifold on the left side of the valve module, pressing it lightly into place.
5. Floss the tubing into the air detector.
6. Insert the clear tubing and the color-coded lines into the grooves in the valve module.
7. Close the pump platen.

8. Close and latch the valve module cover.

1. Tubing in air detector
2. Pump platen lever
3. Pump platen
4. Tubing in valve module channels

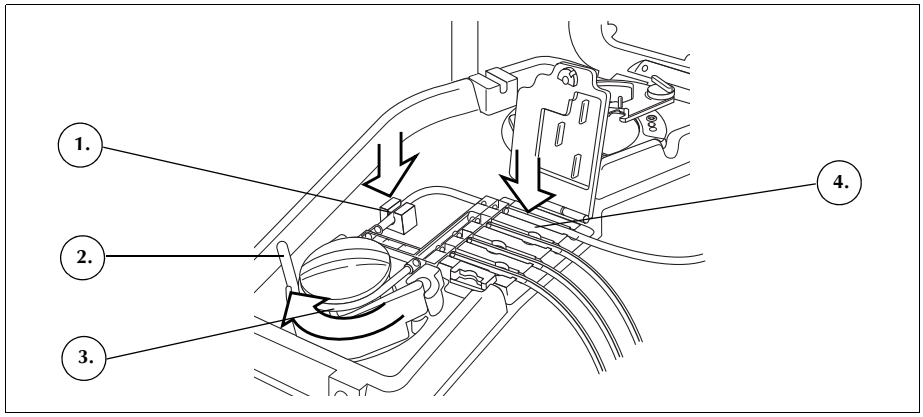


Figure 51, Tubing harness

Installing the Bowl

To install the bowl:

1. Ensure that the lower port of the bowl faces the effluent line sensor.
2. Install the bowl in the centrifuge by carefully pressing down on the shoulders of the bowl until it is seated securely in the chuck.

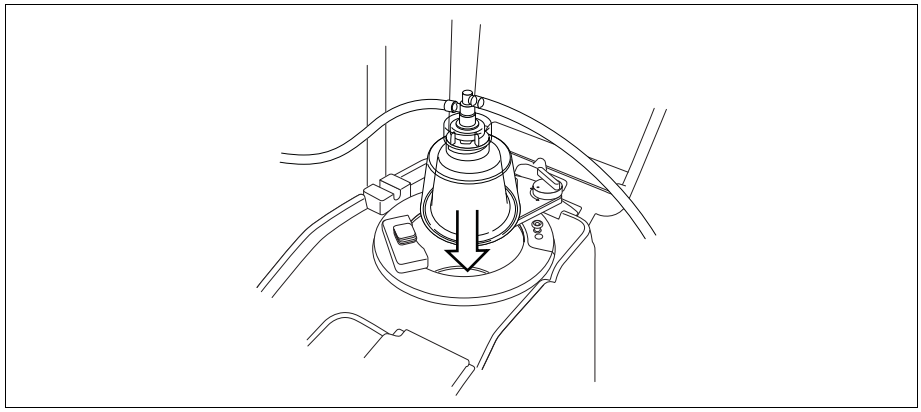


Figure 52, Inserting the bowl into the centrifuge chuck

3. Position the header arm around the top of the bowl.
4. Turn the latch on the header arm clockwise until it locks into place.
5. Spin the bowl to ensure it spins freely.

1. Header arm
2. Tubing in effluent line sensor
3. Header arm latch
4. Bowl in centrifuge chuck

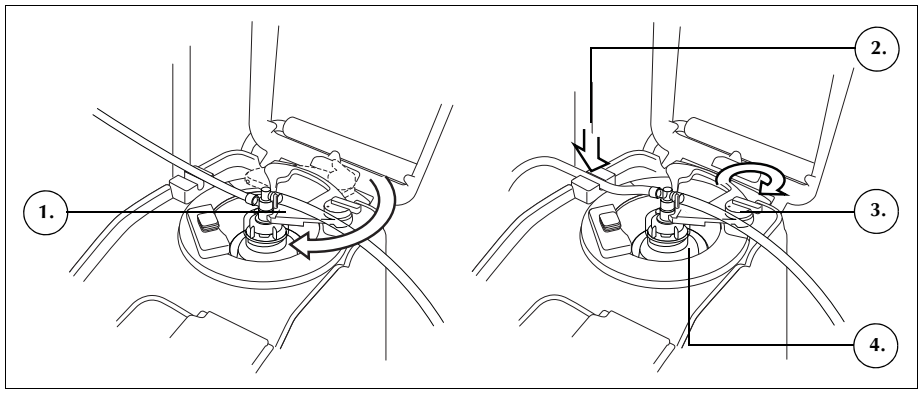


Figure 53, Closing and locking the header arm

Note: A click will be heard when the locking mechanism is completely secured.

Alert: Verify that the outlet port and effluent tubing are free of any restrictions prior to initiating a procedure. If the outlet port is inadvertently clamped off, the bowl rotary seal may become compromised. See "Avoiding Flow Restrictions" on page 65 for more information.

Installing the Effluent Line Sensor Tubing

To install the effluent line tubing:

1. Floss the effluent tubing into the effluent line sensor groove.
2. Ensure that the tubing is completely installed in the effluent line sensor.

Hanging the Waste Bag

To hang the waste bag:

1. Hang the waste bag on the pins on the left side of the device.
2. Verify that the waste bag is securely connected to the effluent line.
3. Ensure that the waste bag drain port is completely closed.

1. Waste bag pins
2. Effluent tubing connection
3. Waste bag drain port

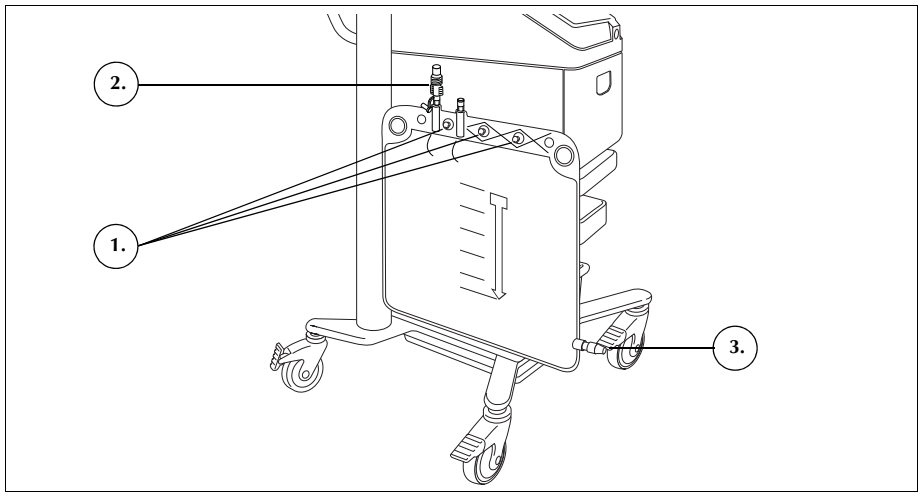


Figure 54, Hanging the waste bag

Installing the Blood Bag Adaptor Harness

Follow the steps below to install the blood bag adaptor set:

1. Close the ratchet clamps on the yellow saline lines of the processing set.
2. Connect the red line from the processing set to the red line connection on the adaptor set.
3. Connect the reservoir drain port connection on the adaptor set to the reservoir drain port.

Note: If a reservoir is not going to be used for Cell Salvage following the Sequestration procedure, the adaptor harness does not need to be connected to a reservoir. In this case, the slide clamp on the port that would connect to the adaptor harness should be closed.

1. Reservoir drain port connection
2. Red line connection
3. Line to blood bag

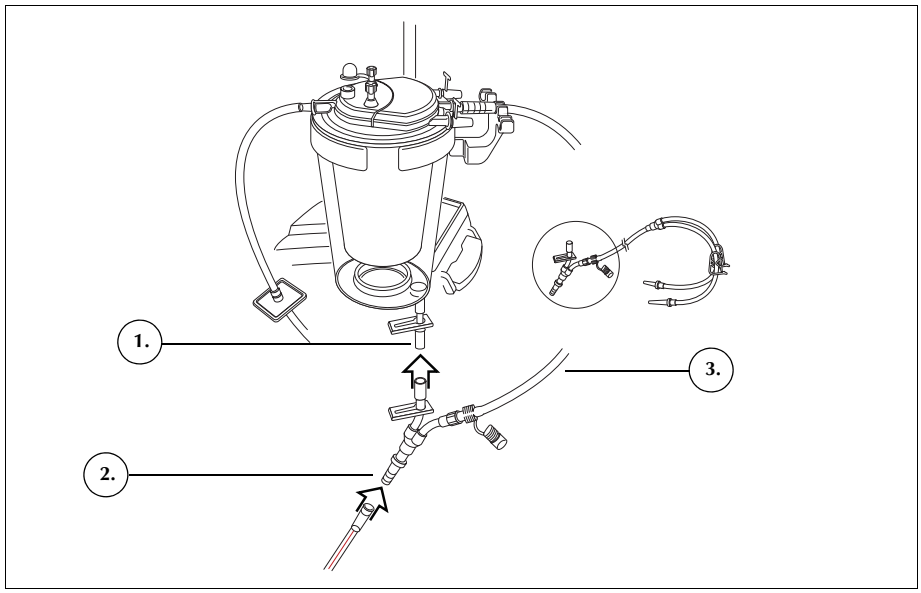


Figure 55, Blood bag adaptor harness

4. Close the clamps on both blood bag lines.
5. Hang the blood bag(s) on one of the top hooks of the right IV pole.
6. Spike the blood bag(s).
7. Open the clamp on the line leading to the blood bag(s).

Installing the Collection Bag Harness

Follow the steps below to install the collection bag harness:

1. Disconnect the effluent line tubing from the waste bag.
2. Connect the effluent line tubing to the effluent line connection on the collection bag harness.
3. Cap off the waste bag, using the cap removed from the collection bag harness.
4. Hang one collection bag on one of the waste bag pins.
5. Hang the other collection bag on a different waste bag pin.
6. Hang the air bag on the remaining waste bag pin.
7. Close the red ratchet clamps on the collection bags.
8. Ensure that the white ratchet clamps are open.

1. Effluent line connection
2. White, blue and yellow ratchet clamps
3. Green ratchet clamps
4. Collection bags
5. Air bag

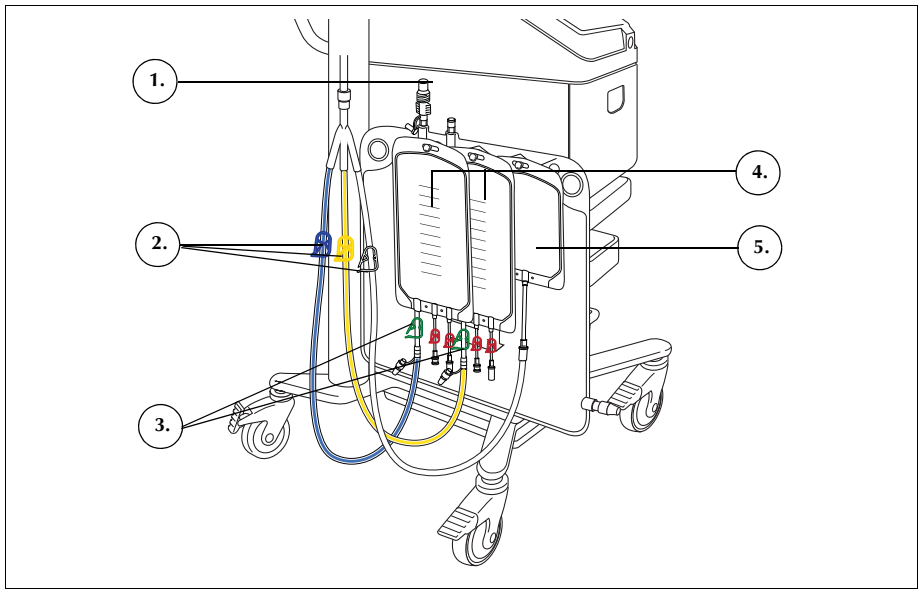


Figure 56, Blood bag adaptor harness

Inspecting the Installation

Always inspect the disposable components after completing the installation.

1. Inspect all parts of the disposable components and verify that there are no twists, kinks, or flat spots.
2. Verify that all connections are secure and all appropriate clamps are closed.
3. Close the device cover, ensuring that no tubing is inadvertently clamped off.

Performing a Sequestration Procedure

Procedure Overview

During the Sequestration procedure the device separates the blood into platelet poor plasma (PPP), platelet rich plasma (PRP), and red blood cells (RBCs).

Prior to beginning Sequestration, blood is collected into blood bags containing anticoagulant (AC) solution. During Sequestration, the device processes blood in a series of cycles. Each cycle consists of a Fill and Empty phase. During the Fill phase, the bowl fills with whole blood and then collects PPP and PRP in the collection bags. The device displays prompts throughout the procedure that instruct you to open and close clamps at the appropriate times.

The Sequestration procedure is usually performed just after the induction of anesthesia but prior to the surgical procedure and is only available when the device is first powered on and prior to starting the first Fill phase in the Cell Salvage procedure. Suction may be turned on while performing Sequestration if you want to start collecting fluid from the surgical field.

The system is first set up with a standard processing set. A Sequestration set is then attached to the processing set as described in this chapter.

Prior to running the Sequestration protocol with the Cell Saver Elite+ device, you should be familiar with the operating instructions and all associated precautions and warnings for the device, in addition to any precautions and warnings specifically related to Sequestration provided in this chapter.

Note: You may turn on the on-board suction and begin collecting fluid in the reservoir while Sequestration is being completed.

Processing from Blood Bags

Alert: Only one unit of blood should be collected and processed at a time. Unless directed by a physician, do not begin withdrawal of the second unit of blood from the patient until the first unit of concentrated autologous RBCs has been reinfused to the patient.

Prior to the Sequestration procedure, anticoagulated whole blood should be collected from the patient into a blood bag.

Initiating a Procedure

Once the disposable components are properly loaded onto the device, follow the steps below to draw blood into the bowl from the blood bag:

1. Touch **Start Procedure** to start Sequestration. The device advances to Standby.
2. Touch **Fill**.
   The device displays prompts throughout the procedure that instruct the user to open and close the white, blue, and yellow clamps on the collection bag harness at the appropriate times. What clamps to open and

close depend on whether you have chosen to collect platelet poor plasma or return it to the RBC bag in the protocol settings.

Note: The white, blue, and yellow clamps should never be closed at the same time.

Note: The prompts below correspond to the Haemonetics default settings and may appear differently if using other parameters.

3. Check that the red ratchet clamps on the collection bags are closed.
4. Following the prompts on the screen,
   a. Open the white air line clamp and close the yellow PPP line and blue PRP line clamps when prompted.
   b. Agitate the blood bag.
   c. Touch **Continue** to start the Fill phase. The pump starts drawing blood. As the bowl fills, plasma becomes visible as the first layer followed by a white band (platelets), then RBCs.

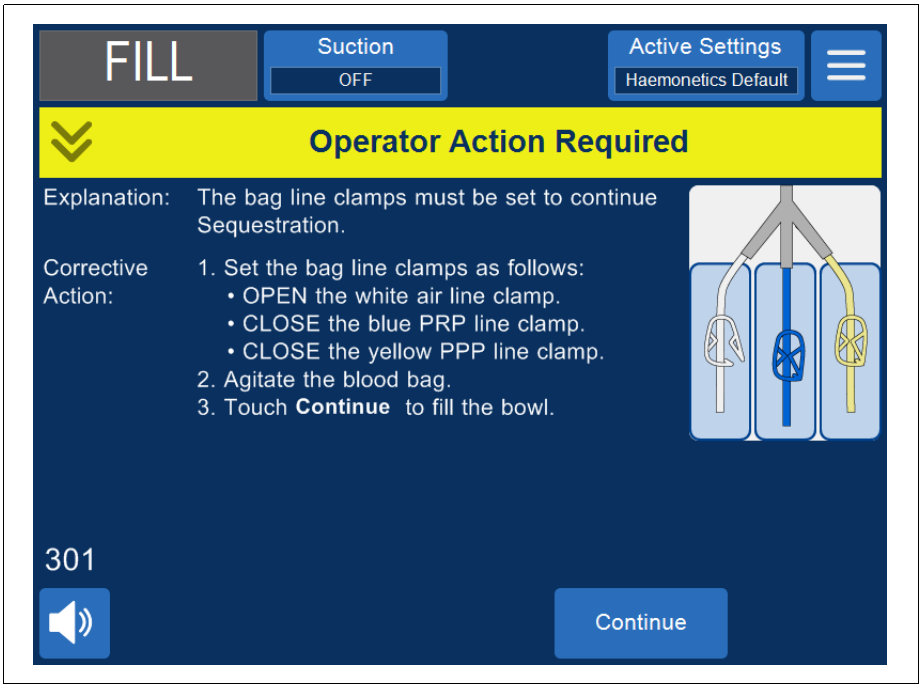


Figure 57, Example of a Sequestration process prompt

5. Observe the centrifuge bowl filling and allow air from the processing set to flow to the air bag or PPP collection bag.

Collecting PPP

The device displays another set of prompts when plasma reaches the effluent line sensor.

1. Close the white air line clamp and open the yellow PPP line clamp.
2. Touch **Continue** to begin collecting PPP.

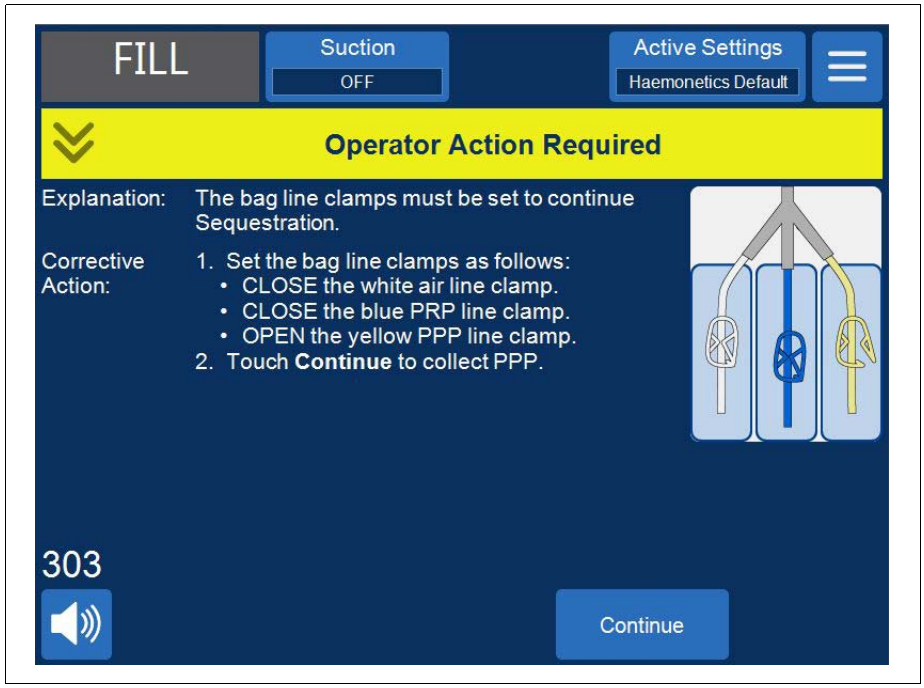


Figure 58, Example of a Sequestration process prompt

Plasma should flow into the PPP bag at a consistent flow rate until the white buffy coat band (made up of platelets and white cells), which is immediately adjacent to the top of the RBC layer, reaches the shoulder of the bowl.

Collecting PRP

The device displays another set of prompts when the buffy coat starts to exit the bowl.

1. Open the blue PRP line clamp and close the yellow PPP line clamp.
2. Touch **Continue** to begin collecting PRP.

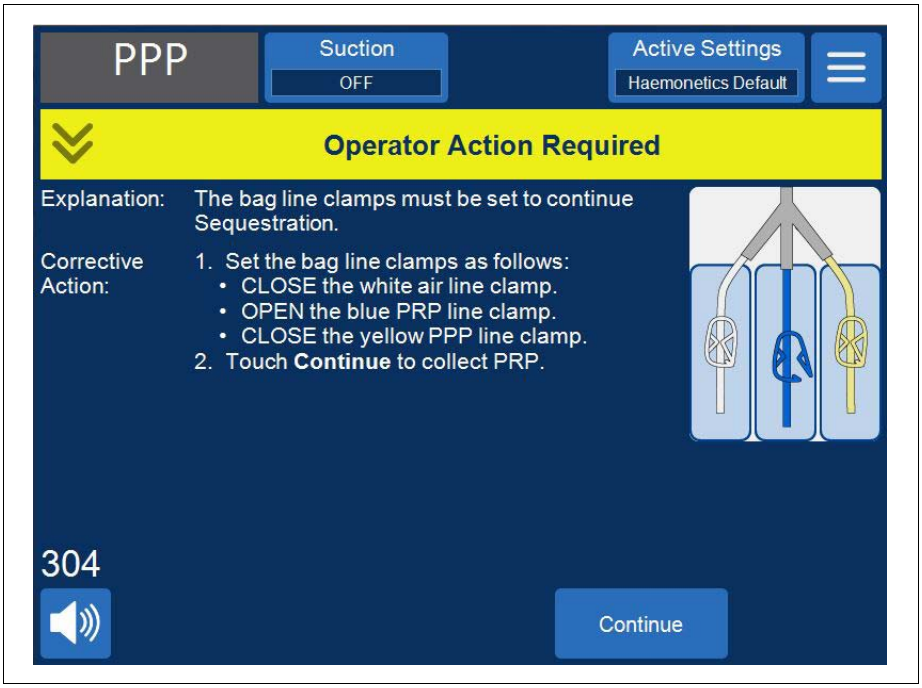


Figure 59, Example of a Sequestration process prompt

The buffy coat should flow into the PRP bag until the effluent line flow from the bowl turns medium red (indicating the presence of RBCs).

Emptying the Bowl

The device displays another set of prompts when the effluent line sensor detects the RBCs.

1. Open the white air line clamp and close the blue PRP line clamp.
2. Touch **Continue** to start the Empty phase.

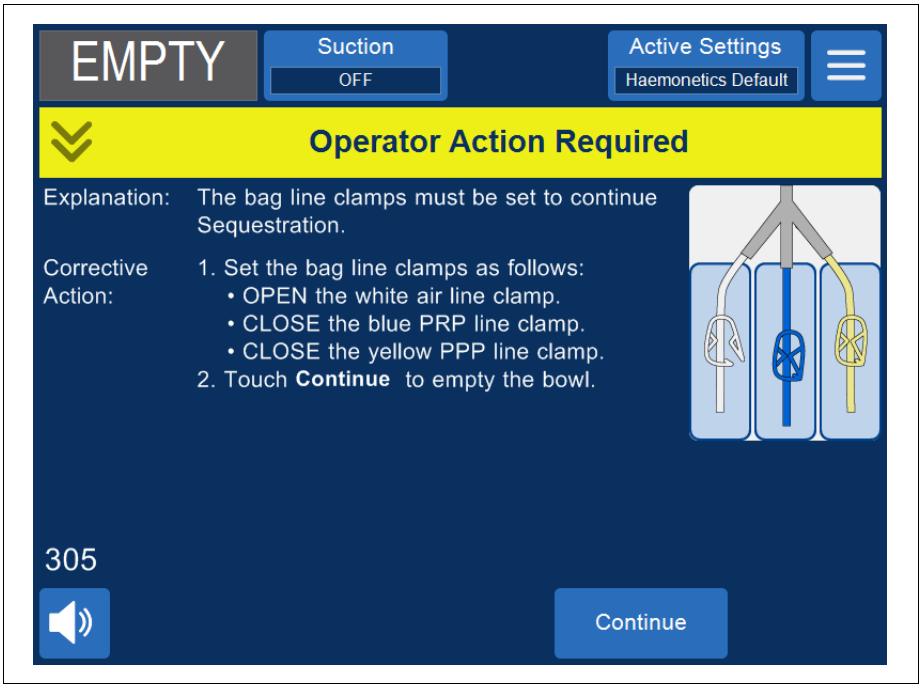


Figure 60, Example of a Sequestration process prompt

The device pumps the RBCs in the bowl into the RBC bag. Air from the air bag is drawn into the bowl to replace fluid. The pumps stop when the bowl is empty.

Note: If the device loses power during the Empty cycle, do not touch the valve cover latch while recovering the procedure. If you do open the valve cover latch, ensure it is completely closed before recovering the procedure.

Concentration During Sequestration

If, during the Fill phase, the blood bag is empty and there are RBCs from a previous cycle in the RBC bag, an event message displays the following three options:

1. Continue Using Blood Bag.
2. Continue Using RBC Bag
3. End Cycle

If you select **Continue Using RBC Bag**, the system will concentrate, or pull previously processed RBCs from the RBC bag into the bowl, to fill the bowl and push the PPP and PRP into their respective collection bags. The device will display a prompt, indicating the proper position of the clamps.

Ending the Sequestration Protocol Early

You can choose to end the Sequestration procedure early. Follow the steps below to end the procedure early:

1. Touch (**Pause**) to pause the procedure.
2. Touch **End Procedure**. A prompt appears on the screen.
3. Touch **End Procedure** to end or **Resume Procedure** to resume.

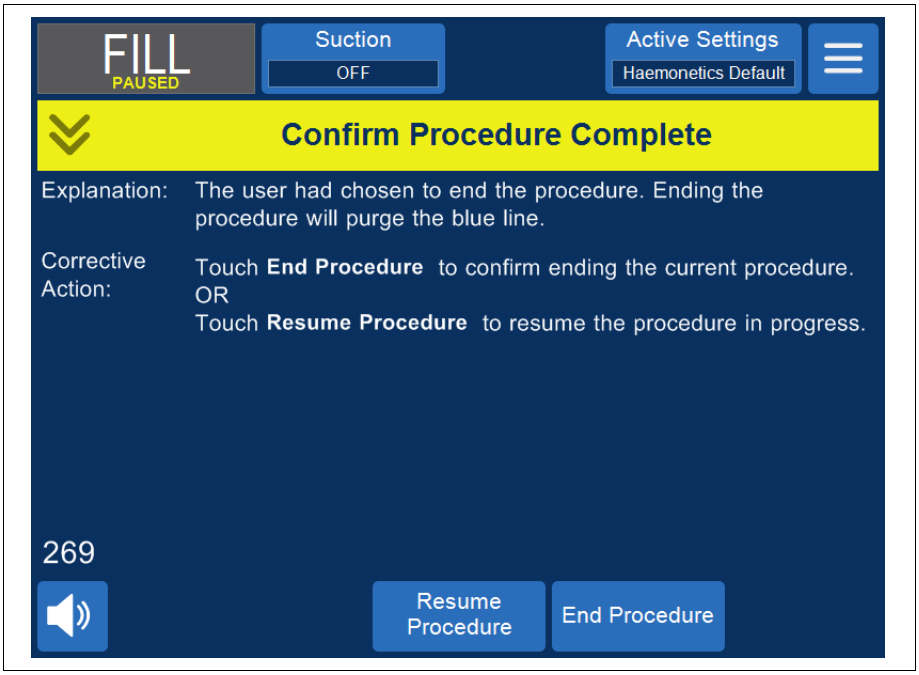


Figure 61, Ending Sequestration early

Changing to a Cell Salvage Procedure

You can also choose to end the Sequestration procedure early and change to a Cell Salvage procedure. To end Sequestration early and change to Cell Salvage:

1. Touch (**Menu**) and select **Cell Salvage** from the drop-down list. The device displays a confirmation message.
2. Touch **Continue** to continue to Cell Salvage. The device displays a prompt:

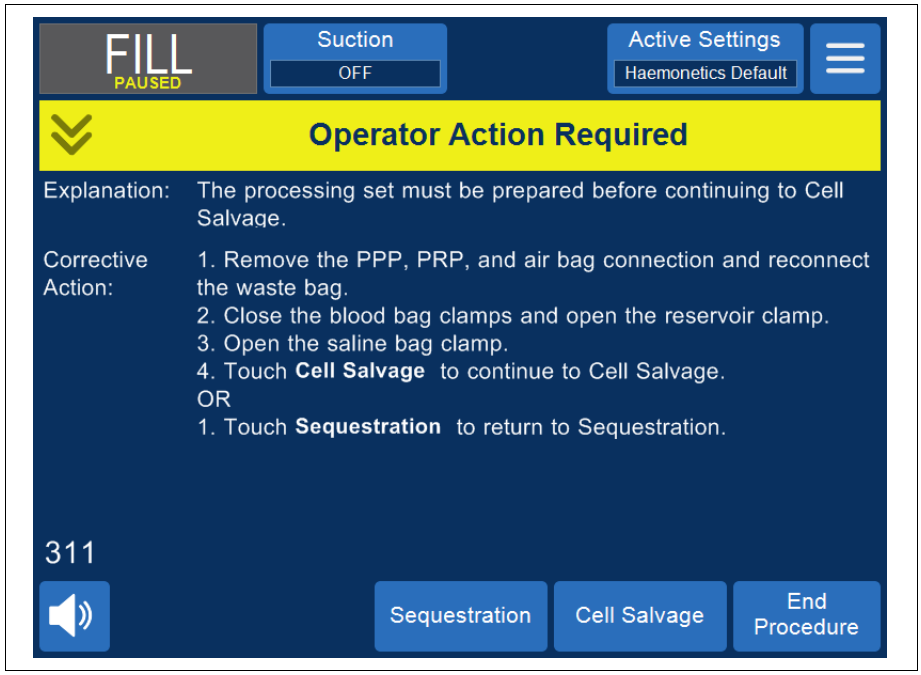


Figure 62, Changing to Cell Salvage

3. Following the instructions on the screen, change to a Cell Salvage processing set.
   a. Disconnect the collection bag harness from the effluent tubing.
   b. Cap the collection bag line to prevent drips.
   c. Connect the effluent tubing to the waste bag.
   d. Close the blood bag line clamps.
   e. Remove the upper portion of the blood bag harness, using the twist-lock connector, and cap the port using the attached caps.
   f. Open the saline bag clamp.
   g. Open the reservoir drain port clamp.
   h. Ensure that the slide clamp on the blood bag harness is open.
   i. Touch **Cell Salvage** to continue to Cell Salvage.

Completing the Sequestration Cycle

At the end of each Sequestration cycle, the device displays a prompt asking you whether to sequester another unit from the blood bag, prepare for a Cell Salvage procedure, or end the procedure.

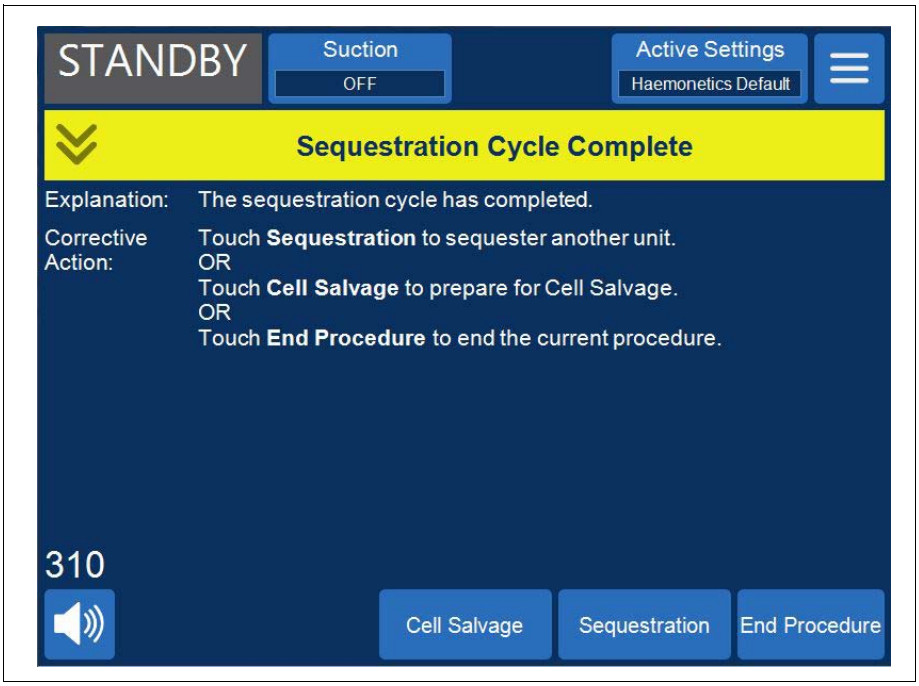


Figure 63, The Sequestration Cycle Complete message

To end the Sequestration procedure:

1. Touch **End Procedure**. A “Confirm Procedure Complete” message appears.
2. Touch **End Procedure** to confirm.

The *Records* screen displays the procedure record. If the device detects there is still fluid in the bowl, it empties the bowl to the blue line. The device then pumps a small amount of air through the blue line to flush any remaining blood in the line into the RBC bag. During this Empty phase, a “Purging Blue Line” message appears in the message area. When the blue line has been fully purged, a “Procedure Complete” message appears.

Note: Haemonetics does not recommend resuming a Sequestration procedure after marking it completed.

Note: To begin a new procedure, you must first power down the device and power it back on.

*Note: If you power down the device before fully purging the blue line, power the device back on, choose to resume the procedure, and touch **End Procedure**. This flushes the remaining blood in the blue line into the RBC bag.*

Note: If the device is powered off without purging the blue line and is powered on again within six hours with a processing set installed, the device prompts you to resume the previous procedure or to save the previous procedure and start a new one. If you choose to start a new procedure, the device marks the previous procedure as complete and performs a self-test. If you instead choose to continue the previous procedure, the device instructs you to ensure all disposable components and interlocks are in place.

General Precautions When Transferring the RBCs for Reinfusion

Alert: DO NOT USE A PRESSURE CUFF OR ANY OTHER MECHANICAL DEVICE. PRESSURE REINFUSION CAN RESULT IN THE FATAL INFUSION OF AIR INTO THE PATIENT.

Alert: The safe length of time that blood or blood products may remain in the autotransfusion disposable components is dependent on collection and storage methods. Refer to the AABB standards for more information.

Alert: In accordance with FDA guidelines and AABB standards, a transfusion filter designed to retain particles that are potentially harmful to the patient should be used when returning processed concentrated RBCs.

Attention: *Depending upon the hematocrit of the incoming whole blood, a 225 mL bowl can yield 800 mL or more of plasma and cause hypovolemia if fluid balance is not carefully maintained. Many variables influence the amount of plasma that can be sequestered, and the volume to be sequestered must be determined by an attending physician. The physician must be informed of the amount and type of anticoagulant solution used, since the plasma collected will still contain some anticoagulant solution.*

The RBCs can remain in the RBC bag or be drained to a transfer bag for reinfusion to the patient if needed. The RBCs should be treated the same as a unit of washed, packed RBCs in terms of administration to the patient and outdate of the product.

Removing the Plasma Product

After the final Sequestration pass, disconnect the plasma product as follows:

1. Remove the collection bags from the pins and invert the bags.
2. Open the white, blue and yellow clamps.
3. Tap the sides of the effluent tubing leading to the collection bags to dislodge any plasma/platelets which might have adhered to the tubing.
4. Close the green clamp on the collection bags.
5. Close the white, blue and yellow clamps.
6. Label the PPP/PRP product with the following minimum information:

- *Patient name and/or identification number*
- *Hospital identification number*
- *Date and time collected*
- *Volume collected*
- *Type and amount of AC solution used*
- *Type of product (e.g. PRP)*
- *For autologous use only*

7. Remove the collection bags from the Y-connection.

Retain the PPP/PRP product for reinfusion upon the order of a physician.

Utilize procedures consistent with those of the local blood bank for platelet product storage and handling.

It is important to remember that any autologous blood product collected has been processed from a patient who might not normally have been accepted for blood donation. Therefore, unless the blood passes current applicable or hospital donation standards, the products obtained in autotransfusion or plasma sequestration procedures must be labeled “for autologous use only”. These products should be stored separately and used solely for that purpose. If the Cell Saver Elite+ system has been set up for autotransfusion, the RBCs may be returned to the cardiotomy reservoir for later washing if desired.

Refer to the current standards for expiration date of stored blood.

Removing the Sequestration and Processing Sets

If you choose to end the procedure without performing a Cell Salvage procedure, remove the Sequestration and processing sets from the device and dispose of them according to local standard operating procedures.

Chapter 7

Protocol Settings

Overview

The Cell Saver® Elite®+ *Settings* screen provides an easy-to-use interface for changing and saving protocol settings. Using the *Settings* screen, you can pre-configure multiple settings and save them as a settings group. This enables you to quickly change settings during a procedure by touching **Active Settings** and selecting a different settings group from the drop-down list. The Cell Saver Elite+ device can store up to 30 unique settings groups.

To access the *Settings* screen:

1. Touch (**Menu**).
2. Select **Settings** from the drop-down list. The *Settings* screen appears.

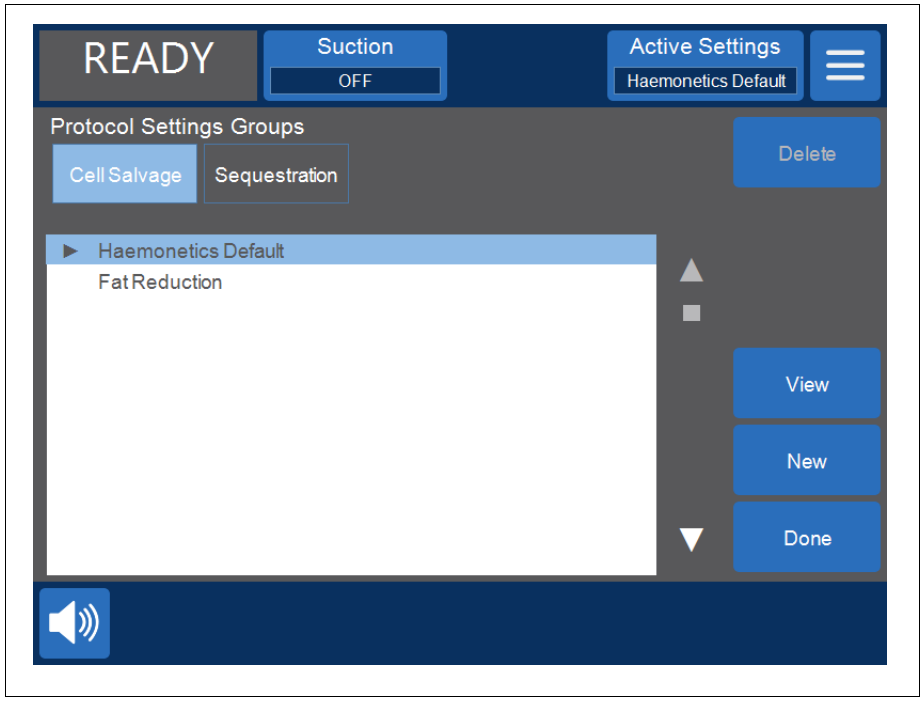


Figure 64, Example of the Settings screen

Touch **Cell Salvage** or **Sequestration** to access the settings groups for the corresponding protocol.

Working with Settings Groups

Alert: The operator is fully responsible for ensuring the safety of edited parameters.

From the *Settings* screen you can do the following:

- View the parameters for a settings group
- Create a new settings group
- Edit a settings group
- Lock a settings group
- Delete a settings group

Haemonetics configures each device with a default settings group called Haemonetics Default and a specialized settings group called Fat Reduction. These groups cannot be changed.

Creating a New Settings Group

Once you have accessed the *Settings* screen, follow the steps below to create a settings group:

1. Touch **Cell Salvage** or **Sequestration** to select a protocol.
2. Touch **New**. A keyboard appears.

3. Enter a name for the new settings group.

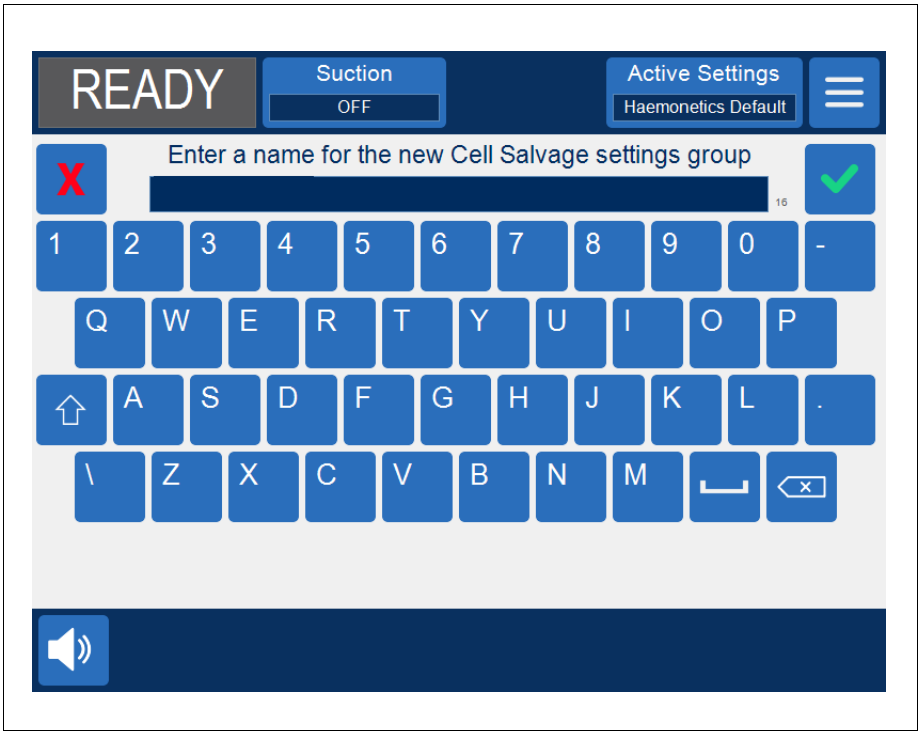


Figure 65, Creating a new settings group

4. Touch ✓ (**Accept**). The parameter list for the new settings group appears.
5. Set the parameters for the new settings group, then touch **Done**. For more information, see “Editing a Settings Group.”

Editing a Settings Group

The parameter list displays the individual settings in a settings group. Follow the steps below to edit the settings in a settings group.

1. Select a settings group to edit.
2. Touch **View**. The parameter list appears.
3. Touch a tab to select a bowl size.
4. From the list, select a setting to modify.
5. Touch ▲ (**Up**) or ▼ (**Down**) to change the value for that setting. Parameters that have been changed from the default setting will have a dot next to the value.
6. To reset a setting to its default value, select the setting and touch **Default**.

7. Touch **Done** to save the changes and return to the *Settings* screen.

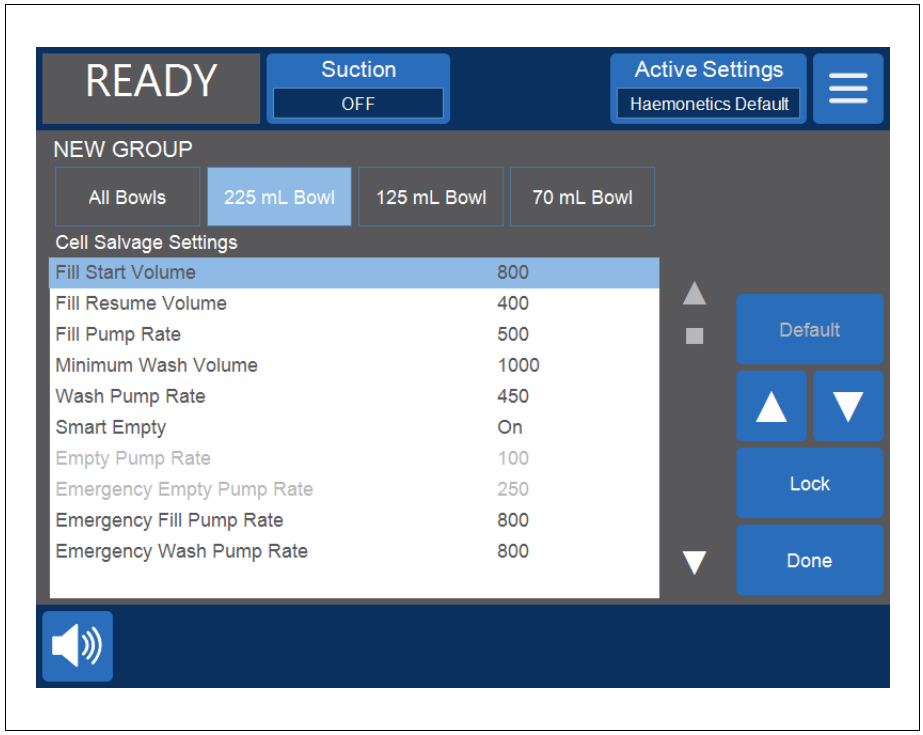


Figure 66, Example of the parameter list

*Note: If you navigate to a different screen without touching **Done**, your changes will still be saved. All changes will take place immediately, except target volume settings if the current processed volume is greater than the new target volume. In that case, the new target volume will not apply until the next cycle.*

Note: Changing the current settings group will overwrite any manual adjustments you may have made.

Locking a Settings Group

When you create or edit a settings group, you can choose to lock it so it cannot be edited without the proper password.

To lock a settings group:

1. From the parameter list, touch **Lock**. A keyboard appears.
2. Enter a password and touch (**Accept**).

To unlock a settings group:

1. From the *Settings* screen, select the settings group.
2. Touch **View**. The parameter list appears.
3. Touch **Unlock**. A keyboard appears.

4. Enter the password and touch (**Accept**).

Applying a Settings Group

You do not need to be in the *Settings* screen to change the current settings group. Follow the steps below to apply a settings group to the current procedure:

1. Touch **Active Settings**. A drop-down list appears.
2. Select a settings group. The new settings group is applied to the current procedure and appears on the **Active Settings** pad.

Note: All changes will take place immediately, except target volume settings if the current processed volume is greater than the new target volume. In that case, the new target volume will not apply until the next cycle.

Note: Changing the current settings group will overwrite any manual adjustments you may have made.

Deleting a Settings Group

Follow the steps below to delete a settings group:

1. Select the settings group to delete.
2. Touch **Delete**.
3. Touch **Confirm**.

Note: The active, Haemonetics Default, and Fat Reduction settings groups cannot be deleted.

Modifiable Settings

Default Settings

The following tables list the Haemonetics default settings for the Cell Saver Elite+ device:

Cell Salvage Default Settings

Table 15, Cell Salvage Default Settings

Parameter	Values	Default	Notes
Fat Reduction	On/Off	Off	
Auto-Fill	On/Off	On	
Partial Bowl Wash	Ask/Single/ Double	Ask	
Pump Regulation	On/Off	On	Pump regulation is not applicable for the 70 mL bowl.
Quick Transfer	On/Off	Off	This parameter is displayed only if it has been enabled in Options. See “Making the Quick Transfer and Manual Mode Settings Available” on page 136 for more information.
Manual Mode	On/Off	Off	This parameter is displayed only if it has been enabled in Options. See “Making the Quick Transfer and Manual Mode Settings Available” on page 136 for more information.
Final Cycle:	On/Off	Off	Only one of the sub-settings below can be active at a time:
• Last Partial Bowl Wash	Double/ Single/Off	Double	• This sub-setting can only be modified if Final Cycle is set to On.
• End Procedure	On/Off	Off	• This sub-setting can only be modified if Final Cycle is set to On.
Wash Line Priming	On/Off	On	
Recentrifuge Delay	On/Off	On	

Parameter	225 mL Bowl	125 mL Bowl	70 mL Bowl	Min	Max	Step
Fill Start Volume (mL)	800	800	400	200	3000	100
Fill Resume Volume (mL)	400	400	200	200	3000	100

Table 15, Cell Salvage Default Settings

Parameter	225 mL Bowl	125 mL Bowl	70 mL Bowl	Min	Max	Step
Fill Pump Rate[a] (mL/min)	500	225	100	25	1000	25
Minimum Wash Volume (mL)	1000	750	300	500[b]	5000	25[c]
Wash Pump Rate[c] (mL/min)	450	200	100	25	1000	25
Smart Empty:	On/Off	On/Off	N/A[d]	N/A	N/A	N/A
• Empty Pump Rate[e f] (mL/min)	500/400/100	300/150/100	100[d]	25	1000	25
• Emergency Empty Pump Rate[e f] (mL/min)	500/400/250	300/250/100	N/A[d]	25	1000	25
Emergency Fill Pump Rate (mL/min)	800	400	N/A	25	1000	25
Emergency Wash Pump Rate (mL/min)	800	400	N/A	25	1000	25

a. If pump regulation is on, the device optimizes the quality of the final product by adjusting the pump speed during the Fill phase from 150 - 500 mL/min (150-225 mL/min for a 125 mL bowl), during the Wash phase from 150-450 mL/min (150-200 mL/min for a 125 mL bowl), during the Concentrate phase from 125-150 mL/min (75-125 mL/min for a 125 mL bowl) and during a Wash phase after a Concentrate phase from 100-200 mL/min (75-175 mL/min for a 125 mL bowl) based upon the effluent line sensor readings.

b. Minimum wash volume for the 125 mL bowl is 375 mL; for the 70 mL bowl it is 210 mL.

c. Step is 10 mL for the 70 mL bowl.

d. For the 70 mL bowl, the Smart Empty and Emergency Empty Pump Rate settings are not available, but the Empty Pump Rate setting is always available.

e. If Smart Empty is on, the device reduces the pump speed during the Empty/Return phase in preprogrammed increments to minimize the number of RBCs remaining in the bowl at the end of the Empty/Return phase.

f. For the 225 mL and 125 mL bowls, Empty Pump Rate and Emergency Empty Pump Rate are only available for modification when Smart Empty is On, otherwise, they are grayed out.

Cell Salvage - Manual Mode Default Settings

Table 16, Cell Salvage - Manual Mode Default Settings

Parameter	Value	Default
Recentrifuge Delay	On/Off	On
Alert Sounds	On/Off	On

Table 16, Cell Salvage - Manual Mode Default Settings

Pump Rate (mL/min)	**225 mL Bowl**	**125 mL Bowl**	**70 mL Bowl**	**Min**	**Max**	**Step**
Fill Pump Rate	500	500	125	25	1000	25
Wash Pump Rate	500	500	100	25	1000	25
Empty Pump Rate	500	500	100	25	1000	25
Conc Pump Rate	150	150	75	25	1000	25
Return Pump Rate	500	500	100	25	1000	25
Centrifuge Speed (RPM)	**225 mL Bowl**	**125 mL Bowl**	**70 mL Bowl**	**Min**	**Max**	**Step**
Fill Centrifuge Speed	5650	5650	7500	2050 (2100 for the 70 mL bowl)	5650 (7500 for the 70 mL bowl)	100
Wash Centrifuge Speed	6050	6050	7500	2050 (2100 for the 70 mL bowl)	6050 (7500 for the 70 mL bowl)	100
Conc Centrifuge Speed	3850	3850	5000	2050 (2100 for the 70 mL bowl)	5650 (7500 for the 70 mL bowl)	100

Sequestration Default Settings

Table 17, Sequestration Default Settings

Parameter	**Values**	**Default**				
PPP Return Plasma	No/Yes	No				
PRP Milk	No/Yes	No				
Parameter	**225 mL Bowl**	**125 mL Bowl**	**70 mL Bowl**	**Min**	**Max**	**Step**
Fill Pump Rate (mL/min)	60	60	N/A	10	250	10
Fill Centrifuge Speed (RPM)	5650	5650	N/A	2050	5650	50
PRP Collection Pump Rate (mL/min)	20	20	N/A	10	250	10
PRP Collection Centrifuge Speed (RPM)	2450	2450	N/A	2050	5650	50
Empty Pump Rate[f] (mL/min)	500/400/100	300/150/100	N/A	25	1000	25
PRP Extend Volume (mL)	10	10	N/A	0	50	1
PRP Milk Volume (mL)	3	3	N/A	1	50	1
PRP Milk Delay (seconds)	10	10	N/A	1	30	1

Cell Salvage Settings

Alert: The operator is fully responsible for ensuring the safety of edited parameters.

Fat Reduction (On/Off)

Determines if the device uses a specialized washing sequence designed to reduce the level of fat in the final product.

- **On:** The device performs three additional steps during the Wash phase that isolate the fat and remove it from the bowl.
- **Off:** The device performs a normal Cell Salvage Wash phase.

Note: Fat Reduction is unavailable when the device is in Manual Mode.

Auto-Fill (On/Off)

Determines if the device automatically proceeds from Standby to Fill once a preset volume of fluid is collected in the reservoir or if you must touch **Fill** to start the Fill phase.

Partial Bowl Wash (Ask/Single/Double)

Determines how the device sets the wash volume when you wash a partial bowl by manually starting the Wash phase. Blood processed using a partial bowl may have a lower hematocrit than blood processed using a normal full bowl. Because the hematocrit of the bowl contents is lower, there is more supernatant in the bowl. In order to dilute the larger volume of supernatant, a partial bowl may require two times the normal saline solution.

- **Ask:** The device transitions to a Wash Paused state, displays a message indicating Wash was entered prior to filling the bowl, and prompts you to double the wash volume, continue with the normal amount of saline solution, or end the procedure. You may also continue the procedure and touch **Cycle Wash Volume** to adjust the wash volume manually.
- **Single:** The device transitions to the Wash phase using the normal wash volume.
- **Double:** The device transitions to the Wash phase and automatically doubles the wash volume.

Pump Regulation (On/Off)

Determines if the effluent line sensor is used to regulate the pump speed. Because pump regulation is used to reduce the pump speed if the effluent line sensor detects RBCs leaving the bowl, turning pump regulation off may cause cells to be lost into the waste bag.

Quick Transfer (On/Off)

Determines if Quick Transfer is available via the **Active Settings** drop-down list. For more information, see “Emergency Options” on page 85 and “Quick Transfer Mode” on page 86.

Note: Quick Transfer must be enabled in Options before it can be displayed in Settings. See "Making the Quick Transfer and Manual Mode Settings Available" on page 136 for more information.

- **On:** Allows Quick Transfer to be displayed on the **Active Settings** drop-down list.
- **Off:** Does not allow Quick Transfer to be displayed on the **Active Settings** drop-down list.

Note: Quick Transfer is unavailable when the device is in Manual Mode.

Manual Mode (On/Off)

Determines if Manual Mode is available via the **Active Settings** drop-down list. For more information, see "Manual Mode" on page 88.

Note: Manual Mode must be enabled in Options before it can be displayed in Settings. See "Making the Quick Transfer and Manual Mode Settings Available" on page 136 for more information.

- **On:** Allows Manual Mode to be displayed on the **Active Settings** drop-down list.
- **Off:** Does not allow Manual Mode to be displayed on the **Active Settings** drop-down list.

Note: Manual Mode is unavailable when the device is in Quick Transfer mode.

Final Cycle (On/Off)

Determines the **End Procedure** behavior, per the selected sub-settings below, when air is detected during Fill.

- On: The final cycle options are *Last Partial Bowl Wash* and *End Procedure*. Only one of these options can be selected to manage the last bowl.
  - **Last Partial Bowl Wash:**
    - **Double:** The device transitions to the Last Partial Bowl Wash phase and automatically doubles the wash volume.
    - **Single:** The device transitions to the Last Partial Bowl Wash phase using the normal wash volume.
    - **Off:** The device omits the Last Partial Bowl Wash.
  - **End Procedure** (On/Off)
- Off: The only option is to end the procedure immediately.

Wash Line Priming (On/Off)

Determines if the device omits the Wash Prime process at the beginning of the first Fill phase to reduce the duration of the procedure.

- **On:** The device performs the Wash Prime process at the beginning of the first Fill phase.
- **Off:** The device performs the Wash Prime process at the beginning of the first Wash phase.

Recentrifuge Delay (On/Off)

Determines if device performs the recentrifuge delay. For more information, see “Recentrifuge Delay” on page 91.

Note: This must be set separately for Cell Salvage and Manual Mode.

- **On:** The device performs the recentrifuge delay. The user can override the recentrifuge delay after 15 seconds by touching  **(Play)**.
- **Off:** The device does not perform the recentrifuge delay (the device does not wait for the centrifuge to ramp up before starting the pump).

Attention: *If the delay is turned off, be aware of the possibility of red cell spillage caused by pumping fluid into a bowl of red blood cells with poor or no separation.*

Parameters

Cell Salvage

- **Fill Start Volume:** The approximate volume of fluid in the reservoir that transitions the device from Standby to Fill when the bowl is empty.
- **Fill Resume Volume:** The approximate volume of fluid in the reservoir that transitions the device from Standby to Fill when the bowl already contains some fluid.
- **Fill Pump Rate:** The approximate rate at which the pump turns while filling the bowl with fluid.
- **Minimum Wash Volume:** The minimum volume of wash solution to be used to wash one bowl of fluid.
- **Wash Pump Rate:** The approximate rate at which wash solution enters the bowl.
- **Smart Empty:** Determines if the device slows the pump speed at a decremental rate to empty fluid from the bowl or if the pump speed remains constant. This setting is not available for the 70 mL bowl.
  - **On:** The pump empties fluid from the bowl at a preprogrammed decremental speed determined by the parameter settings.
  - **Off:** The pump empties fluid at a constant speed, which the user can adjust via the **+/-** pads from 25 mL/min to 1000 mL/min (default is 100 mL/min).

- **Empty Pump Rate:** The approximate rate at which the pump turns while emptying fluid from the bowl. For the 125 mL and 225 mL bowls, this setting is only adjustable if Smart Empty is set to “Off.” For the 70 mL bowl, this setting is always available.
- **Emergency Empty Pump Rate:** The approximate rate at which the pump turns while emptying fluid from the bowl in Emergency Mode. If Smart Empty is set to “Off”, this setting can be adjusted by the user via the **+/-** pads. This setting is not available for the 70 mL bowl.
- **Emergency Fill Pump Rate:** The approximate rate at which the pump turns while filling the bowl with fluid in Emergency Mode. This setting is not available for the 70 mL bowl.
- **Emergency Wash Pump Rate:** The approximate rate at which wash solution enters the bowl while in Emergency Mode. This setting is not available for the 70 mL bowl.

Sequestration

- **Fill Pump Rate:** The approximate rate at which the pump turns while filling the bowl with fluid and collecting PPP.
- **Fill Centrifuge Speed:** The approximate rate at which the centrifuge turns while the bowl is filling with whole blood and during the PPP collection phase.
- **PRP Collection Pump Rate:** The approximate rate at which the pump turns while collecting fluid during the PRP collection phase.
- **PRP Collection Centrifuge Speed:** The approximate rate at which the centrifuge turns during the PRP collection phase.
- **PRP Extend Volume:** The volume in milliliters to pump after the effluent line sensor detects RBCs during the PRP collection phase. Once this volume is pumped, the PRP collection is complete.
- **PRP Milk:** Determines if the process of starting and stopping the PRP collection phase is desired as determined by the programmed parameters “Milk Vol” and “Milk Delay.”
- **PRP Milk Volume:** The volume to pump during the PRP collection until the pump stops and the Milk delay time starts. This setting is only adjustable if PRP Milk is set to “Yes.”
- **PRP Milk Delay:** The time the pump will be stopped during the PRP collection phase before starting to pump the programmed Milk Vol parameter. This setting is only adjustable if PRP Milk is set to “Yes.”
- **PPP Return Plasma:** Determines which clamps to open and close at the beginning of the Empty phase and to account for volume returned. If you select “Yes,” the PPP is returned to the bowl and then to the RBC bag along with the RBCs.

Making the Quick Transfer and Manual Mode Settings Available

Two additional modes can be made available on the Cell Saver Elite+ device:

- Quick Transfer Mode enables the device to quickly move *unwashed* shed blood from the reservoir to the reinfusion bag and bypass the wash phase completely when time is of the essence.
- Manual Mode enables the device to be operated manually by the user.

Note: These modes are only available when using the Cell Salvage protocol.

Note: These modes can only be made available in a settings group. To create a new settings group, see "Creating a New Settings Group" on page 125.

Note: Contact your local Haemonetics representative for access to training and the password to make this feature available

To make the Quick Transfer or Manual Mode setting available:

1. Touch (**Menu**).
2. Select **System** from the drop-down list. The *System* screen appears.
3. Touch **Unlock**. The *Enter Access Code* screen appears.
4. Enter the access code and touch (**Accept**).
5. On the *System* screen, touch **Options**. The Option screen appears.
6. Touch either **Quick Transfer** or **Manual Mode**.
7. Touch (**Up**) or (**Down**) to change the setting to *Yes*. If desired, select the other mode and change its setting to *Yes*.
8. Touch **Done**.

The enabled functionality is now available for use in the settings group. To utilize Quick Transfer, see "Emergency Options" on page 85 and "Quick Transfer Mode" on page 86. To utilize Manual Mode, see "Manual Mode" on page 88.

Chapter 8

Records

Overview

The *Records* screen displays information about the last 100 procedures, disposable sets used, any events that may have occurred, and the device. Using the *Records* screen, you may also enter additional information and export data to a USB flash drive.

To access the *Records* screen:

1. Touch (**Menu**).
2. Select **Records** from the drop-down list. The current procedure record appears.

1. Selected procedure record
2. Touch to view record history

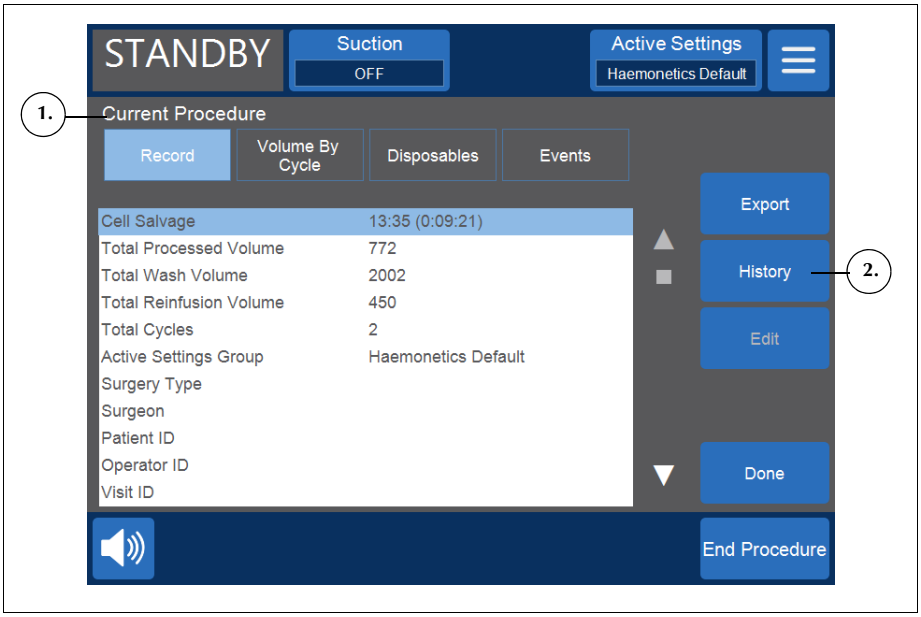


Figure 67, Example of the current procedure record

By default, when you select **Records** from the **Menu**, the device displays the procedure record for the current procedure. To access a different record, touch **History**. The *Records* screen appears.

1. Available procedure records
2. Touch to view a record

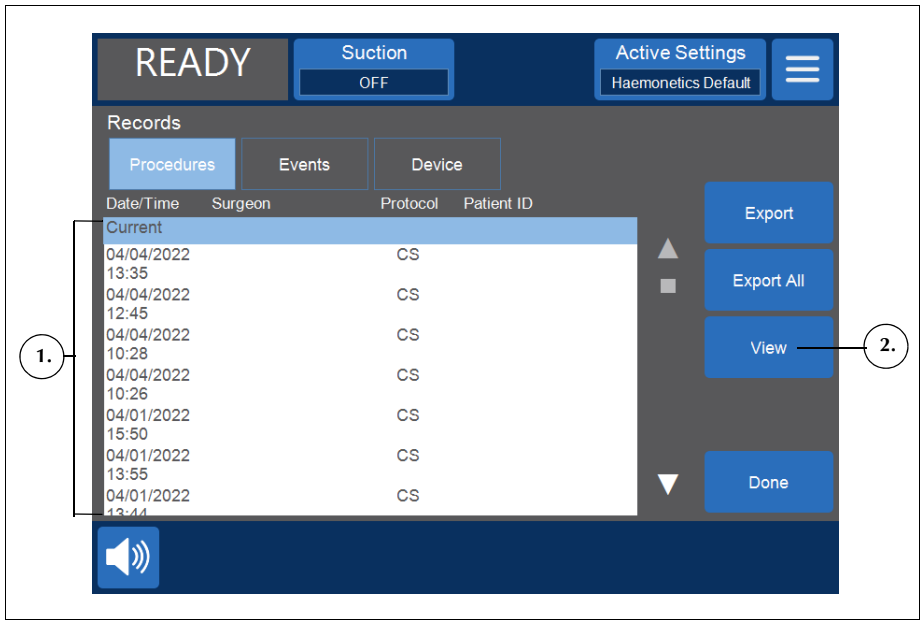


Figure 68, Example of the Records screen

From the *Records* screen, you can open a past procedure record by selecting it from the list and touching **View** (For more information on procedure records, see “Procedure Records” on page 140.); or you can touch **Events** or **Device** to view the event or device records (For more information, see “Event Records” on page 145 or “Device Records” on page 146.).

Procedure Records

Procedure records store information about specific procedures. When you first view a procedure record, the *Records* tab is selected. To access different information about the procedure, touch **Volume By Cycle**, **Disposables**, or **Events** to toggle among the different tabs.

To exit and return to the *Processing* screen, touch **Done**.

Record Tab

The *Record* tab displays general information about the procedure and can include the following:

- Cell Salvage/Sequestration start time and duration
- Suction start time
- Total processed volume
- Total wash volume
- Total reinfusion volume
- Total cycles
- Active settings group
- Surgery type*
- Surgeon*
- Patient ID*
- Operator ID*
- Visit ID*
- Exported to USB
- Comment

* If desired, the device can be configured to completely remove these fields from the procedure record or add custom fields.

The Surgery Type, Surgeon, Patient ID, Operator ID, Visit ID, and Comment fields can be edited and will remain blank unless data is entered by the user.

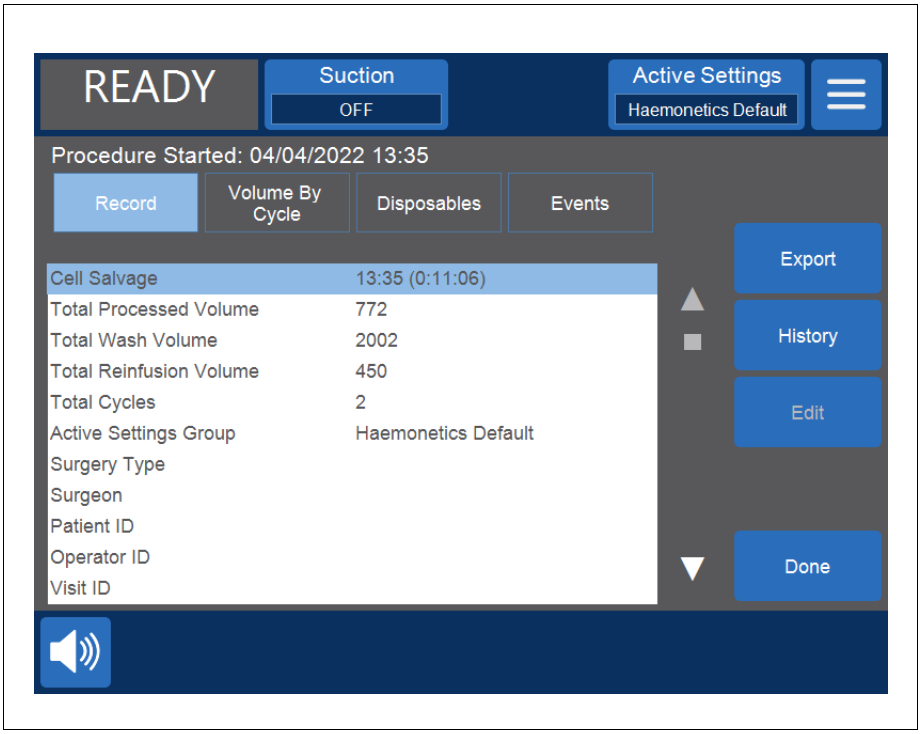


Figure 69, Example of the Record tab

Editing Procedure Details

To enter/edit procedure details:

1. Select the field and touch **Edit**.
2. Depending on the field selected, a keyboard or a list of pre-configured options appears. Either type in the information and touch (**Accept**) to save, or select an option from the list.

Note: If any IDs have barcodes, you can scan them using the barcode reader instead of manually entering the information.

Volume By Cycle Tab

The *Volume By Cycle* tab displays procedure statistics by cycle, including cycle start time, duration, processed volume, wash volume, reinfusion volume, concentrate volume, and for Sequestration PPP and PRP volume.

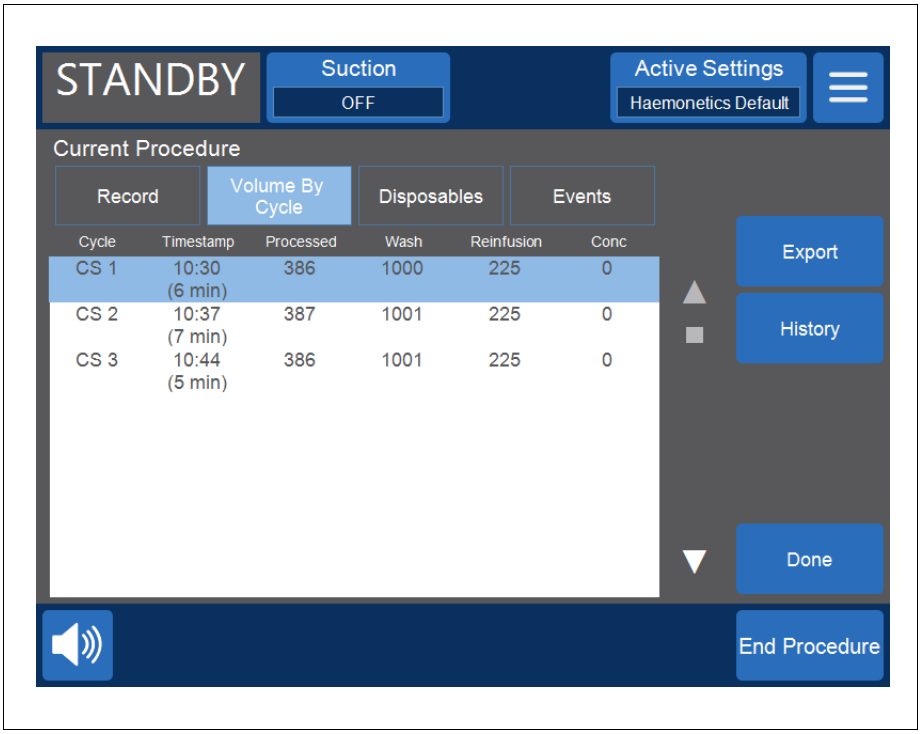


Figure 70, Example of the Volume By Cycle tab

If concentrate is used during the procedure, the volume of RBCs removed from the RBC bag during the concentrate phase will be shown next to the reinfusion volume for that cycle, as shown in Figure 70. The total reinfusion volume for the procedure is equal to the sum of the reinfusion volume of each individual cycle, minus the sum of the Conc volume for each cycle.

Disposables Tab

The *Disposables* tab displays information about the disposable sets and solutions used during a procedure. This information includes disposable type, list number (REF), lot number, and expiration date. This information can be entered using the barcode reader from the *Bowl Selection* screen when the device is first powered or from the *Disposables* tab.

1. List number
2. Expiration date

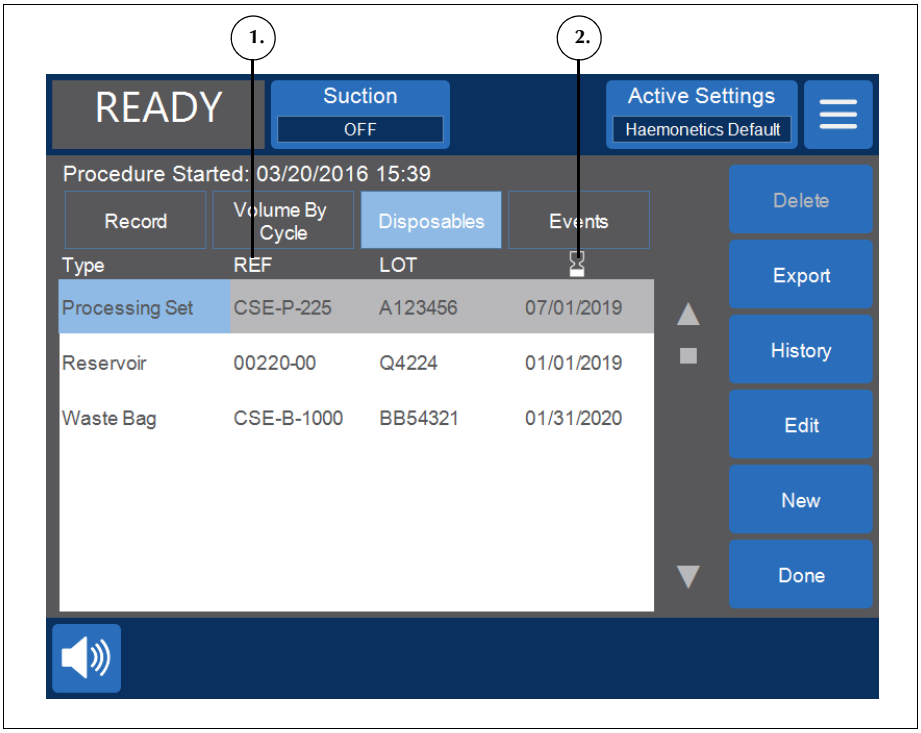


Figure 71, Example of the Disposables tab

Adding an Item to the Disposables Record

To add a new item to the disposables record, scan the barcode or follow the steps below to enter it manually.

1. Touch **New.** A new item appears with “Other” as the default type.
2. Follow the directions in “Editing an Item in the Disposables Record.”

Editing an Item in the Disposables Record

To edit an item in the disposables record:

1. Select the field of the item you want to edit.
2. Touch **Edit**.
3. Depending on the field selected, either scan the barcode of the item, select an entry from the drop-down list, or type the information using the keyboard and touch (**Accept**).

Deleting an Item from the Disposables Record

To delete an item from the disposables record:

1. Select the item you want to delete.
2. Touch **Delete**.
3. Touch **Confirm**.

Note: Processing sets cannot be deleted.

To exit and return to the *Processing* screen, touch **Done**. If you navigate to a different screen without touching **Done**, your changes will still be saved

Events Tab

The *Events* tab displays information about any event messages that may have occurred during the selected procedure. This information includes the date and time the event occurred, the event ID number, and a short description. To view the full event message, see “Event Messages” on page 166.

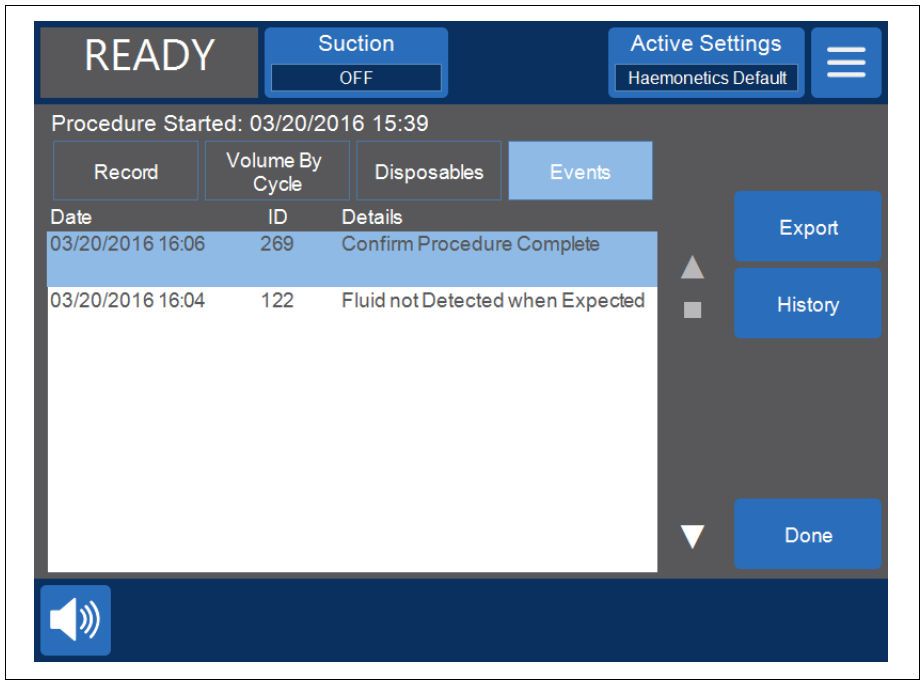


Figure 72, Example of the Events tab

Event Records

Event records store information about the last 100 event messages that have occurred on the device. This information includes the date and time the event occurred, the event ID number, and a short description. To view the full event message, see “Event Messages” on page 166.

To access the device’s event records:

1. Touch (**Menu**).
2. Select **Records** from the drop-down list.
3. Touch **History**. The *Records* screen appears.
4. Touch **Events**.

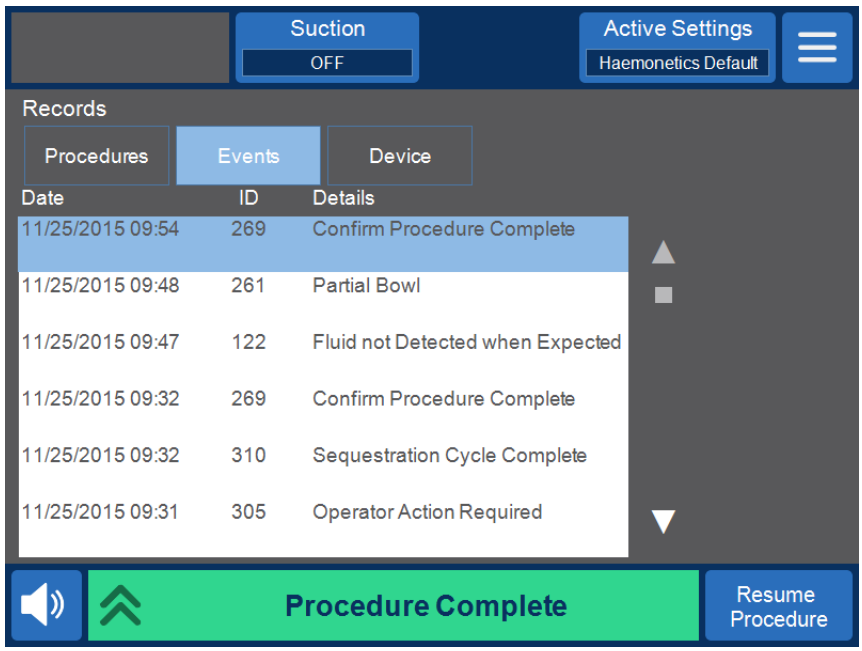


Figure 73, Example of event records

Device Records

Device records store information about the device. This information includes the following:

- Top-level software (SW) version
- Application (APP) SW version
- SmartSuction® (SS) software version
- Graphical user interface (GUI) SW version
- Date/time of last SW update
- Device serial number

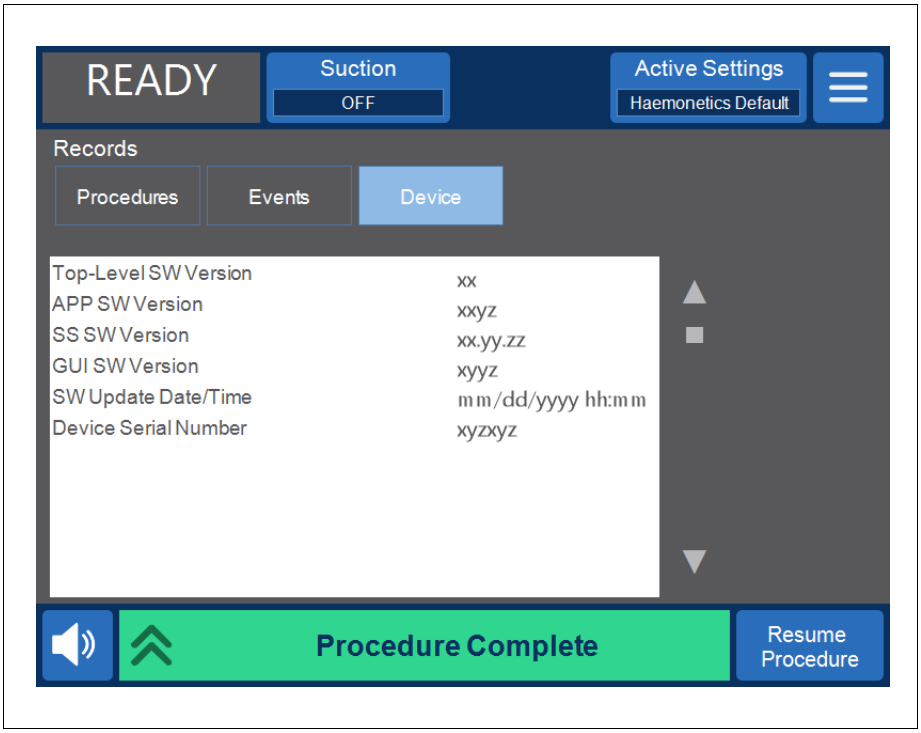


Figure 74, Example of device records

To access the device records:

1. Touch (**Menu**).
2. Select **Records** from the drop-down list.
3. Touch **History**. The *Records* screen appears.
4. Touch **Device**.

Exporting Records

The Cell Saver Elite+ device allows you to export procedure records from the last 100 procedures to a USB flash drive using the *Records* screen.

*Note: **Export**/**Export All** only appears if the USB flash drive is properly connected to the system, and the USB flash drive must be FAT-formatted.*

To export procedure records:

1. Touch (**Menu**).
2. Select **Records** from the drop-down list. The current procedure record appears.
3. Connect the USB flash drive to the device. **Export** appears.
4. Do one of the following:
   - To export the current procedure record, touch **Export**.
   - To export a different procedure record, touch **History**, select a procedure record, and touch **Export**.
   - To export all procedure records, touch **History** and touch **Export All**.

A “Data Transfer in Progress” message appears and disappears when the transfer is complete. Do not remove the USB flash drive until the data transfer is complete.

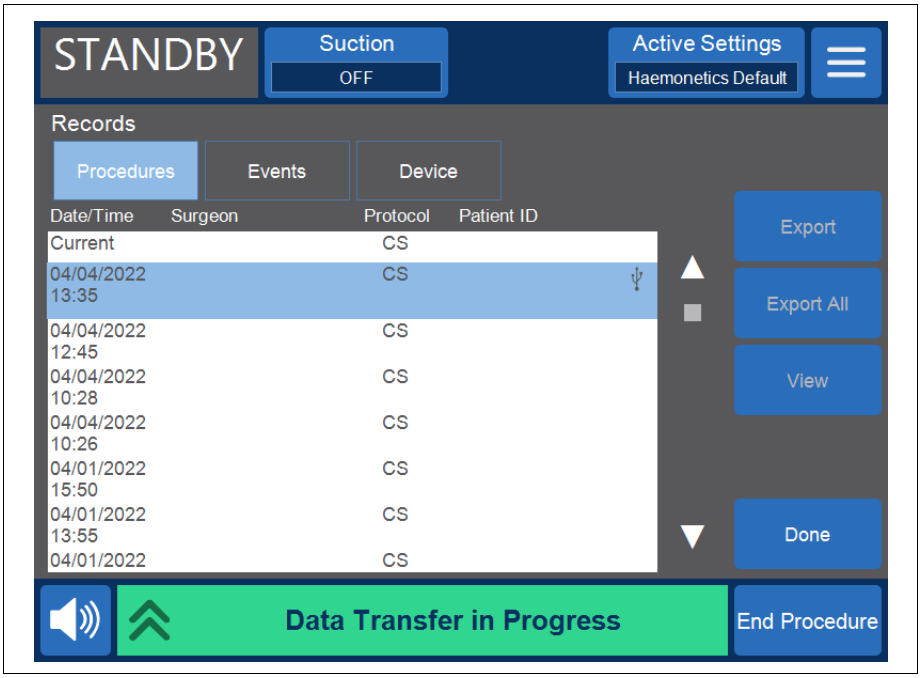


Figure 75, Exporting data

Note: The downloaded data is stored in a .CSV file and can be viewed using Microsoft® Excel®. The data for each procedure can be identified by a unique device serial number and procedure date and time.

Chapter 9

Help System

Overview

The Cell Saver® Elite®+ device is equipped with a help system that provides information on the device and protocols. The help system features a search function and includes the following help topics:

- Disposable Components Setup
- Cell Salvage
- Sequestration
- Suction
- Settings
- Records
- System
- Troubleshooting

The following chapter describes the features of this help system.

Note: The Cell Saver Elite+ help system provides useful information on the operation and use of the device. It is not meant to be a substitute for the Cell Saver Elite+ User Manual.

The Help System

Accessing the Help System

To access the help system:

1. Touch (**Menu**).
2. Select **Help** from the drop-down list. The *Help* screen appears.

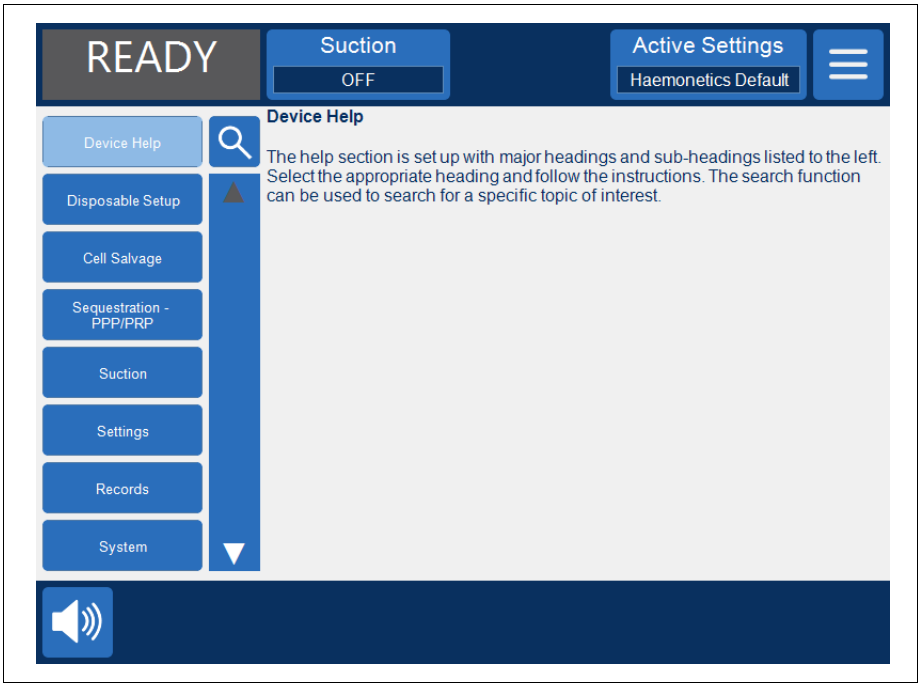


Figure 76, The Help screen

Navigating the Help Menu

The *Help* screen features a help menu on the left side of the screen with a list of topics. Use the scroll bar to view additional topics or touch (**Search**) to search for a specific keyword.

When you touch a topic, the corresponding content appears on the right side of the screen. If you select a topic that contains subtopics with additional information, the topic opens at the top of the pane with the subtopics listed below. To return to the previous list of main help topics, touch the heading at the top with the arrow to the left of it.

1. Search pad
2. Touch to return
3. Help content
4. Subtopics
5. Scroll bar

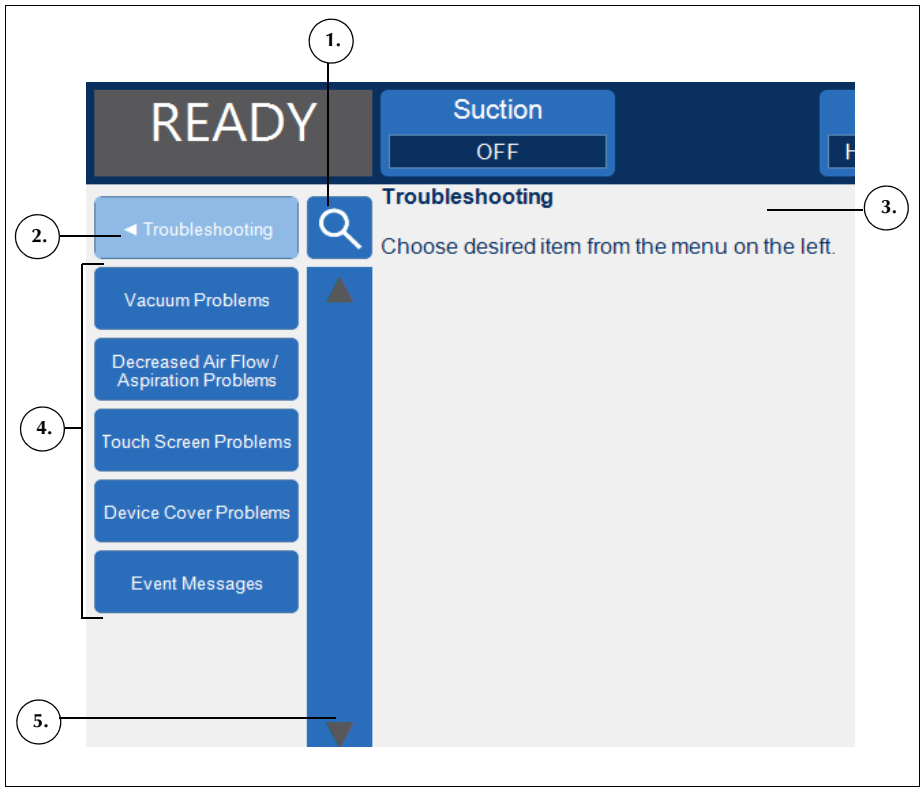


Figure 77, Example of help subtopics

Performing a Search

The Cell Saver Elite+ help system includes a search feature, which enables you to search the help content by keyword.

To perform a search:

1. Touch (**Search**). A keyboard appears.
2. Type a keyword(s) and touch (**Accept**). The search results appear on the left side of the screen.

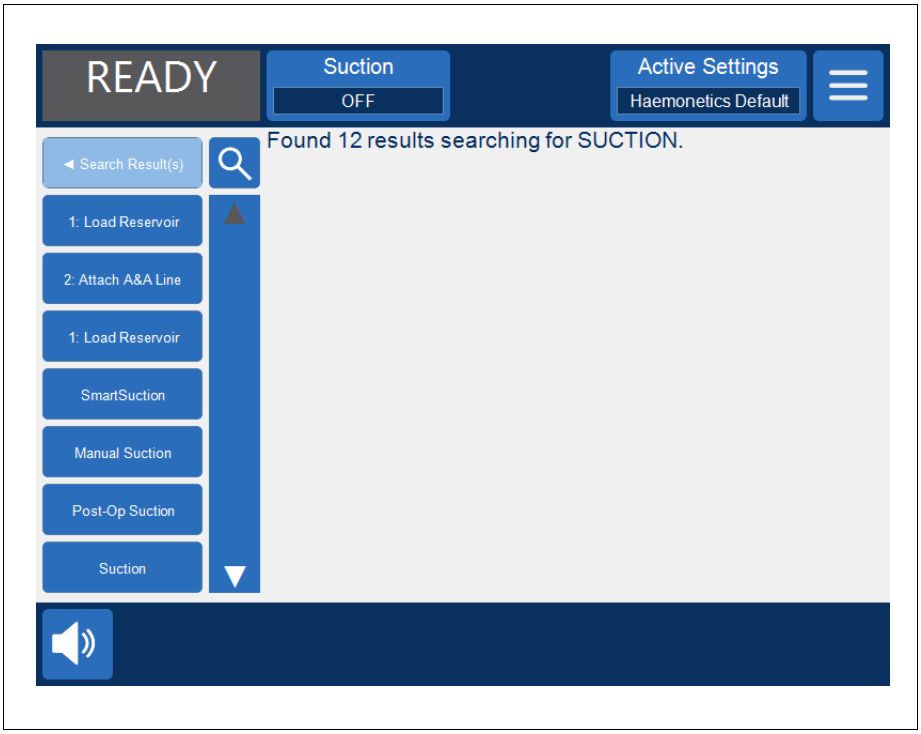


Figure 78, Example of search results

Chapter 10

Cleaning and Maintenance

Cleaning and Maintenance

Cleaning/ Maintenance Schedule

Warning: Do not service or perform any maintenance on the device while it is in use. Power off and unplug the device before cleaning to prevent the potential danger of electric shock.

Warning: No unauthorized modification of the equipment is allowed.

Alert: Special cleaning needs, such as a fluid spill, should be dealt with promptly. Follow local standard operating procedure for blood precautions when cleaning up a blood spill or dealing with blood contaminated components. Dispose of all cleaning materials as biohazardous waste.
In the event of any major spill in which fluid enters the centrifuge or suction pump, a leakage current test should be performed before re-using the device. To avoid the risk of electrical shock, the test should be conducted by an on-site biomedical or clinical engineer.

The user needs to perform routine cleaning procedures of certain key components to maintain the optimal performance of the device. Haemonetics recommends cleaning the device on an as-needed basis. Frequency of cleaning for each individual device depends on the number of procedures performed. You should inspect the device after each use and determine if more frequent cleaning is required. There is no suggested preventative maintenance schedule for the *Cell Saver® Elite®+* system due to its inherent self-evaluating structure and design. Routine cleaning should suffice.

Cleaning Supplies

Attention: *Do not immerse any part of the Cell Saver Elite+ device in liquids.*

Attention: *Do not use solvents, strong alcohol solutions, or abrasive cleaning agents. The following cleaning solutions or active ingredients have been tested for use on the Cell Saver Elite+ device:*

- *0.13% Benzalkonium Chloride solution*
- *70% Isopropyl Alcohol (Cannot be used on the cover.)*
- *Coverage Plus NPD® solution*
- *10% bleach/90% water solution (Cannot be used on the air detector.) 10% bleach/90% water solution may fade the color of the device over time with continued use.*

The following list describes the basic materials recommended for routine cleaning and maintenance:

- Cleaning solution
- Distilled/sterile, warm water
- Lint-free gauze or cloth (for cleaning and drying)
- Cotton swabs
- Personal protective equipment

If there is no established institutional policy for decontamination, Haemonetics recommends that blood spills be cleaned with a cleaning solution followed by a wipe down with distilled/sterile water. Use lint-free gauze or cloth to apply the cleaning solution and water.

Cleaning the Device

Exterior Surfaces

Clean the exterior surface of the device using a cleaning solution, water, and lint-free gauze or cloth. Any application of the cleaning solution should be followed by a wipe down with distilled/sterile water applied with lint-free gauze or cloth.

Blood Spill

Alert: Leakage of fluids into the interior of the device may create the risk of an electric spark or fire. In the event of a blood spill or leak from the bowl, immediately turn the power off and unplug the device from the grounded AC electrical outlet.

Alert: Follow universal blood precautions by wearing disposable gloves and protective eyewear when cleaning up a blood spill in the system. Dispose of all cleaning materials as biohazardous waste.

Attention: *You should never use full-strength bleach directly on the device.*

Attention: *Do not spray cleaner directly onto the device.*

In the event of a blood spill, disinfect the exterior surfaces using a cleaning solution followed by a wipe down with distilled/sterile water. Use lint-free gauze or cloth to apply the cleaning solution and water.

If blood enters the cabinet through the vacuum port remove the device from service and contact the Haemonetics Customer Care Center.

The device is equipped with a biohazard waste bag that collects fluid or blood in the event of a spill in the centrifuge well. If blood spills into the centrifuge area:

1. Turn off the power and unplug the device from the grounded AC electrical outlet.
2. Make sure the biohazard waste bag is unfolded and hanging from the device tray and that the slide clamp is open.

3. Disconnect the reservoir from the processing set and transfer to a new device, if desired.
4. Open the device cover, remove the processing set and dispose of it in an appropriate biohazard protective bag.
5. If the fluid spill was caused by a leak in the disposable set, return the disposable set to Haemonetics for evaluation (see “Product Return Guidelines” on page 162).
6. Remove all blood from the centrifuge well using absorbent cloths.
7. Use a 60 cc syringe to rinse each of the mechanical chuck clips and toggle each clip to ensure there is no residual blood around the clips.
8. Use a 60 cc syringe to irrigate the centrifuge drain holes with water. Direct the fluid into the gap between the chuck and the centrifuge wall (See Figure 79).

1. Mechanical chuck clips
2. Centrifuge drain hole
3. Centrifuge wall
4. Chuck

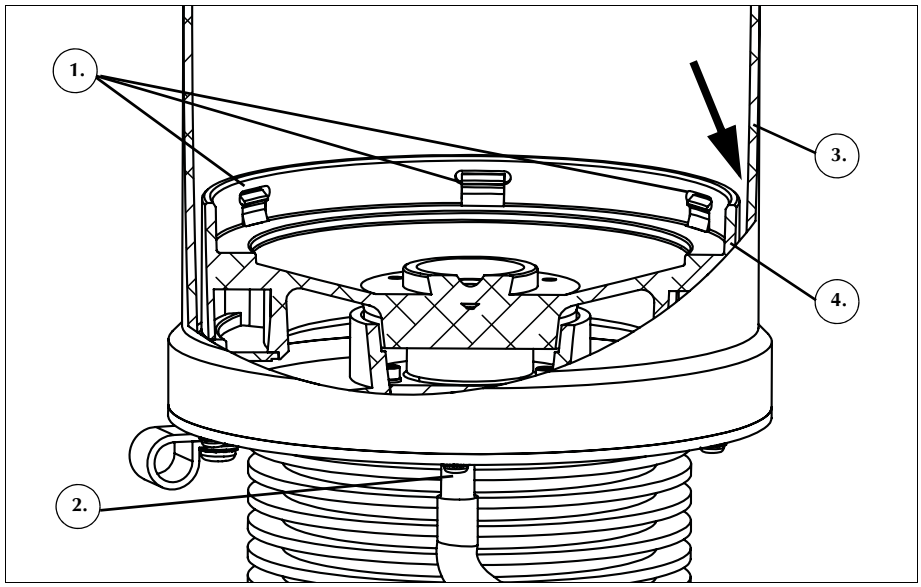


Figure 79, Irrigating the centrifuge drain holes

9. Allow the 60 cc of water to drain before adding more water.
10. Continue until the drain tube is rinsed free of spilled material.
11. Irrigate the drain holes with 60 cc of cleaning solution.
12. Rinse the drain holes with an additional 60 cc of sterile water.

Note: Make sure not to overfill the biohazard waste bag. If a new bag is needed, close the slide clamp and remove the biohazard waste bag. Empty and reconnect the bag, or replace with a new biohazard waste bag.

13. Dry the centrifuge well with lint-free gauze or cloth.

14. Decontaminate all surfaces that came in contact with the blood, using a cloth and cleaning solution.
15. After cleaning and decontamination, replace the biohazard waste bag (See “Replacing the Biohazard Waste Bag” on page 159) before returning the device to use.

Replacing the Biohazard Waste Bag

Alert: Follow universal blood precautions by wearing disposable gloves and protective eyewear when cleaning up a blood spill in the system. Dispose of all cleaning materials as biohazardous waste.

To replace the biohazard waste bag after a blood spill:

1. Close the slide clamp on the biohazard waste bag.
2. Disconnect the biohazard waste bag from the drain tube attached to the device and dispose of as biohazardous waste.
3. Attach a replacement biohazard waste bag to the drain tube connector.
4. Open the slide clamp on the replacement biohazard waste bag.

Cleaning the Optical Lenses

Caution: *The optical sensors emit laser radiation. Do not look directly into the beam.*

Attention: *The optical sensors must be clean and clear to function properly. A dirty or clouded lens could interfere with proper operation of the sensor. An optical lens should always be cleaned after a blood spill. If water alone will not clean the lenses a cleaning solution may be used, but any application of cleaning solution should be followed by a wipe down with distilled/sterile water applied with lint-free gauze or cloth to ensure no residue remains.*

The optical bowl sensors, located in the upper portion of the centrifuge well, are covered by two windows. The windows should be cleaned and dried with a soft, lint-free gauze moistened with water.

The effluent line sensor contains two optical lenses in the line sensor groove. The windows should be cleaned and dried with a soft, lint-free gauze moistened with water. Carefully pass the gauze through the effluent line sensor groove to clean and then dry the sensor.

Cleaning the Centrifuge Well

Attention: *You should never use full-strength bleach directly on the device.*

The centrifuge well should be routinely cleaned with a damp, lint-free gauze or cloth. To improve cleaning, the cloth can be dampened with cleaning solution followed by a wipe down with distilled/sterile water and dried with lint-free gauze or cloth.

The centrifuge base contains mechanical chuck clips which must be kept clean. The clips must be thoroughly cleaned after any spills (See “Blood Spill”

on page 157). A dirty or blocked clip may no longer hold the bowl correctly in place. If a clip is not functioning properly, the user must contact the Haemonetics Customer Care Center.

Cleaning the Fluid Detector

Clean the metallic surface of the fluid detector using a cotton swab moistened with water. In the event of a blood spill, clean the fluid detector using a cleaning solution followed by a wipe down with distilled/sterile water applied with lint-free gauze or cloth.

Cleaning the Pump

Attention: *Do not apply lubricant to the pump.*

The pump should be cleaned after a spill to keep the rotating parts moving freely. The pump cover and rotor may be lifted out to be cleaned as follows:

1. Open the pump platen, hold the rollers motionless while unscrewing the pump cover, and remove the pump cover and rotor.
2. Clean the area under the pump rotor and pump platen with mild soap and hot water.
3. Rinse the area with distilled/sterile water.
4. Dry the area with lint-free gauze or cloth.
5. Check that all moving parts can rotate or slide freely.
6. Ensure that the pump rotor and pump platen are completely dry before reassembling the pump.
7. Place the pump rotor and cover back into their original positions. Holding one of the rollers, tighten the pump cover.

Washing/ Replacing the Air Filters

Air Intake Filter

The bottom of the device is equipped with an air filter for filtering incoming air to the device. The filter should be washed periodically, depending upon frequency and conditions of use, to avoid malfunction resulting from an accumulation of lint and dust in air passages.

Attention: *DO NOT use soap or any cleaning agents.*

Follow the steps below to clean the air intake filter:

1. Disconnect the device from the power supply.
2. Grasp the air filter and remove it from the panel.
3. Rinse the filter under warm running water until it is clean.
4. Gently squeeze the filter to remove excess water.
5. Place on a clean cloth and allow to dry completely.

6. Reinsert the dry filter in the filter panel, ensuring that the filter completely covers the opening.
7. Record the date of maintenance.

Air Exhaust Filter

The bottom of the device is equipped with an air exhaust filter. The filter should be changed periodically, depending upon frequency and conditions of use, to avoid malfunction resulting from an accumulation of lint and dust in air passages. If the filter cover is damaged, contact the Haemonetics Customer Care Center for a replacement part.

Alert: Follow local standard operating procedure for blood precautions when dealing with blood contaminated components.

Follow the steps below to replace the air exhaust filter:

1. Disconnect the device from the power supply.
2. Unlatch the device from the cart.
3. Pull off the black plastic air exhaust filter cover. For easy removal pull from the corner of the cover.
4. Remove the filter pad and dispose of it in accordance with hospital guidelines and procedures for biohazardous waste disposal.
5. Insert a new filter pad. Ensure that the textured surface faces the device.
6. Place the black plastic cover back in position and press down on it gently until it snaps into position.
7. Record the date of maintenance.

Replacing the Fuses

The fuses are covered by a plastic fuse door, located in the power entry module at the rear of the device. At the top of the fuse door is a small indentation to allow the user to open the fuse door. The door is hinged at the bottom.

Follow the steps below to open the fuse door and replace the fuses:

1. Remove the power cord.
2. Use a small screwdriver (1/8” flathead) to open the black plastic fuse door by placing the screwdriver in the indent at the right side of the door and levering it open.
3. Using the screwdriver, gently pull out the red fuse holders by placing the screwdriver under the right side of the holder and levering out the holder.
4. Place new fuses in the fuse holders. Be sure to use appropriately rated fuses. (See Table 10, "Electrical Input Power" on page 21.)
5. Replace the fuse holders in the power entry module.
6. Close the fuse door and press gently until it snaps into place.

Inspecting the Power Cord

Inspect for a frayed or twisted power cord. To order a replacement power cord, contact the Haemonetics Customer Care Center.

Customer Service

Note: In the continental U.S., the Haemonetics Customer Care Center may be reached by calling (800) 537-2802 or by emailing productsupport@haemonetics.com. For contact information, visit www.haemonetics.com/contact-support.

Clinical Training

Your local Haemonetics representative will provide staff training upon delivery of the Cell Saver Elite+ equipment and should be contacted to organize further instruction, if needed.

Repair Service

Haemonetics maintains a worldwide network of company-trained service representatives responsible for responding to technical needs concerning equipment. If service beyond the routine maintenance and cleaning described in this manual is required, the Haemonetics Customer Care Center should be contacted to provide specific instruction.

Equipment Disposal

For details on how to properly dispose of any Cell Saver Elite+ equipment, contact your local Haemonetics office specified at the website listed above.

Product Return Guidelines

Alert: Haemonetics products must be properly cleaned and packaged prior to their return. It remains an important responsibility of the customer to reduce potential health hazards by being aware of the risks involved in the shipping, handling and testing of this material.

If, for any reason, merchandise must be returned to the company, the customer should contact the Haemonetics Customer Care Center to arrange for repairs or returns using procedures to ensure proper handling and subsequent analysis. No returns will be accepted without advanced authorization.

Units returned to Haemonetics for repair are subject to biohazard charges if any component is contaminated with blood or blood products.

Chapter 11

Troubleshooting

Troubleshooting Scenarios

Vacuum Problems

Table 18, Troubleshooting

Problem	Possible Cause	Corrective Action
The vacuum pump turns on and off intermittently.	Internal obstruction	If the problem persists, install a new vacuum line or use an alternate suction source. Contact the Haemonetics Customer Care Center.

Decreased Air Flow / Aspiration Problems

Table 19, Troubleshooting

Problem	Possible Cause	Corrective Action
Decreased air flow/ aspiration problems	Air leak	1. Ensure the vacuum line is securely connected to the device and the collection reservoir and check for leaks. 2. Check that the collection reservoir has no open tubes or ports. 3. Ensure the A&A line has been correctly connected. 4. Check the collection reservoir for leaks. 5. If the problem persists, use an alternate suction source.
	Obstruction	1. Check the vacuum tubing for obstruction or kinking. 2. Check the A&A line for obstruction or kinking. 3. Have the surgeon check the suction wand for a possible occlusion. 4. Check the junction of the A&A line and the collection reservoir for an occlusion. 5. Ensure the reservoir is not full. 6. Try briefly increasing suction to clear the line. 7. If the problem persists, use an alternate suction source.

Touch Screen Problems

Table 20, Troubleshooting

Problem	Possible Cause	Corrective Action
The touch pads are unresponsive or your touches are detected inaccurately.	The screen needs to be recalibrated.	1. While in the *Ready* screen, press the (**Stop**) key rapidly until the *Calibration* screen appears. 2. Follow the prompts to calibrate the touch screen and touch (**Accept**) when complete. 3. Restart the device.

Device Cover Problems

Table 21, Troubleshooting

Problem	Possible Cause	Corrective Action
The device cover does not unlock.	On rare occasions, the device cover does not unlock when expected after an event message appears.	1. Press the (**Stop**) key located on the device display. The device cover unlocks. 2. Resolve any issue reported by the event message.

Event Messages

The following section provides a list of event messages and corrective actions, which appear on the display screen when an action is required by the user.

Note: The "Event Message Text" in the following table is displayed in software version AQ.

Table 22, Event Messages

ID #	Event Message Text
102	**Effluent Line Sensor Failure** **Explanation:** An issue has been detected with the effluent line sensor. The procedure can be performed, but the device cannot monitor the effluent from the bowl. **Corrective Action:** To perform the procedure with the user monitoring the effluent: 1. Touch **Continue**. 2. Monitor the effluent from the bowl during processing. If red cell spillage occurs, manually decrease the pump speed. OR To end the procedure: 1. Touch **End Procedure**. 2. If in power-on self-test, power down the device. If the problem persists, service is required to resolve this issue.
103	**Manifold Pressure Sensor Failure** **Explanation:** An issue has been detected with the manifold pressure sensor. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
104	**Power Supply Failure** **Explanation:** An issue has been detected with the power supply. **Corrective Action:** Restart the device. If the problem persists, service is required.
105	**Reservoir Sensor Failure** **Explanation:** Auto-Fill is disabled. An issue has been detected with the reservoir sensor. Processing can continue, but the device cannot automatically enter the Fill phase. **Corrective Action:** Touch **Fill** to start Fill when there is adequate fluid in the reservoir. Touch **OK** to close this message. Service is required to repair the reservoir sensor.
106	**Waste Bag Sensor Failure** **Explanation:** An issue has been detected with the waste bag sensor. **Corrective Action:** Restart the device. If the problem persists, service is required.
107	**Sensor Input Failure** **Explanation:** An issue has been detected in one of the internal device components. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
108	**Air Detected in Yellow Line** **Explanation:** The air detector sensed air in the yellow line. The saline bag may be empty. **Corrective Action:** 1. Replace the saline bag if it is empty. 2. Ensure the yellow line clamp is open. 3. Check the tubing for kinks, occlusions, and proper placement in the air detector and pump. 4. Touch **Continue** to continue.
110	**Air Detected During Conc** **Explanation:** The air detector sensed air in the blue line during the Concentrate phase. The RBC bag may be empty. **Corrective Action:** 1. Ensure the blue line clamp is open. 2. Check the tubing for kinks, occlusions, and proper placement in the air detector and pump. 3. Wait for additional fluid in the reservoir. OR Touch **Wash** to wash a partial bowl.
111	**Bowl is Ready to Wash** **Explanation:** The optics have detected red cells. The bowl should be full and is ready to transition to the Wash phase. **Corrective Action:** 1. Touch **Wash** to enter the Wash phase OR 2. Touch ▶ to continue filling the bowl OR 3. Touch **Return** to return cells to the reservoir.

Table 22, Event Messages

ID #	Event Message Text
112	**Air Detected During Fill** **Explanation:** The air detector sensed air in the red line during the Fill phase. The reservoir may be empty. **Corrective Action:** 1. Ensure the red line clamp is open. 2. Check the tubing for kinks, occlusions, and correct placement in the air detector and pump. 3. Wait for additional fluid in the reservoir. OR Touch ▶ to resume filling the bowl. OR Touch **Conc** to continue filling the bowl with red cells from the RBC bag. OR Touch **Wash** to wash a partial bowl. OR Touch **Return** to return RBCs to the reservoir.
113	**Air Detected During Fill** **Explanation:** The air detector sensed air in the red line during the Fill phase. The blood bag may be empty. Sequestration has paused. **Corrective Action:** If the blood bag is not empty: 1. Ensure the red line clamp is open. 2. Check the tubing for kinks, occlusions, and correct placement. 3. Touch **Continue Using Blood Bag** to proceed. If the blood bag is empty: Touch **Continue Using RBC Bag** to proceed using the RBC bag. OR Replace the blood bag and touch **Continue Using Blood Bag** to proceed. To end the cycle: 1. Touch **End Cycle** to end the current cycle. 2. The device will empty the bowl contents to the RBC bag.

Table 22, Event Messages

ID #	Event Message Text
114	**Air Detected During Conc** **Explanation:** The air detector sensed air in the blue line during the Conc phase. The RBC bag may be empty. Sequestration has paused. **Corrective Action:** If the RBC bag is not empty: 1. Ensure the blue line clamp is open. 2. Check the tubing for kinks, occlusions, and correct placement. 3. Touch **Continue Using RBC Bag** to continue. If the RBC bag is empty: 1. Replace the blood bag. 2. Touch **Continue Using Blood Bag** to proceed. To end the cycle: 1. Touch **End Cycle** to end the current cycle. 2. The device will empty the bowl contents to the RBC bag.
115	**Air Detected Early** **Explanation:** The air detector sensed air before the expected volume was pumped from the bowl. **Corrective Action:** 1. Check the tubing for correct placement in the air detector and pump. 2. Check the tubing for kinks and occlusions. 3. Touch **Continue** to continue. **NOTE:** When in Quick Transfer mode, the following steps are also displayed: 4. Touch **New Transfer** to begin a new Fill cycle. 5. Touch **End Quick Transfer** to end Quick Transfer and return to Cell Salvage automated mode.
116	**Air Detector Failure** **Explanation:** An issue has been detected with the air detector. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
117	**Long Empty** **Explanation:** The air detector did not sense air when expected, indicating that the device may have pumped more than the expected volume of fluid from the bowl or that a tubing occlusion could be preventing fluid from emptying as expected. **Corrective Action:** 1. Ensure that fluid is not transferring from the waste bag to the bowl, which would indicate loss of sterile air. **NOTE:** If fluid is transferring from the waste bag to the bowl, waste may have reached the RBC bag. The contents of the RBC bag should be returned to the bowl to be washed again. 2. Check the tubing for correct placement in the air detector. 3. Check the effluent tubing for correct placement in the effluent line sensor. 4. Check the effluent tubing for kinks and occlusions. 5. Check the blue and red tubing for kinks and occlusions. **NOTE:** If a kink or occlusion is found in the blue tubing, it is recommended to QC the RBC product to ensure no hemolysis occurred. 6. Touch **Continue** to continue. **NOTE:** When in Quick Transfer mode, the following steps are also displayed: 7. Touch **New Transfer** to begin a new Fill cycle. 8. Touch **End Quick Transfer** to end Quick Transfer and return to Cell Salvage automated mode.
	Event Troubleshooting If the error message continues, the user should remove the bowl, tilt it upside down and visually check the base for cracks directly on or extending from the ribs: ● If no cracks are observed and the procedure is complete, proceed with using the blood in the reinfusion bag. No further action is required. If continuing with the procedure, use a new processing set. ● If cracks are confirmed, the user should assume incomplete washing of the bowl contents, and the wash cycle should be repeated on blood that is in the reinfusion bag. Take any residual RBCs in the reinfusion bag, and empty its contents into the collection reservoir to repeat the wash cycle using a new processing set. The salvaged blood may be reinfused to the patient. Cracked bowls should be reserved, reported and returned to the manufacturer.

Table 22, Event Messages

ID #	Event Message Text
118	**Barcode Reader Failure** **Explanation:** An issue has been detected with the barcode reader. Scanning has been disabled. **Corrective Action:** 1. Enter the information manually using the Records screen. 2. Touch **OK** to close this message. Service is required to repair the barcode reader.
119	**Barcode Reader Failure** **Explanation:** An issue has been detected with the barcode reader. Scanning has been disabled. **Corrective Action:** 1. Enter information manually using the Records screen. 2. Touch **OK** to close this message. Service is required to repair the barcode reader.
121	**Centrifuge Arm was Unlatched** **Explanation:** The device detected that the centrifuge header arm latch was opened. Was the bowl size or processing set changed? **Corrective Action:** If the bowl size or processing set was not changed, touch **No**. If the bowl size or processing set was changed: 1. Touch **Yes**. The device will display the Bowl Selection screen. 2. Follow the prompts on the screen.

Table 22, Event Messages

ID #	Event Message Text
122	**Fluid Not Detected When Expected** **Explanation:** The bowl optics have not detected fluid in the bowl when expected. **Corrective Action:** 1. Ensure the red line clamp is open. 2. Check the tubing for kinks and occlusions. 3. If using external vacuum, ensure the level is not greater than 250 mmHg. 4. Check for proper bowl size. 5. If the setup is correct, touch **Continue** to continue. OR 6. If the bowl size is incorrect, touch **Change Bowl Size** and then select correct bowl size from the Bowl Selection screen. **NOTE:** When using regulated external suction, ensure that the A&A line is clamped while setting the regulator vacuum level to the desired level. If the A&A line is not clamped the vacuum level may exceed the selected vacuum level and affect performance of the device.
123	**Bowl Optics Failure** **Explanation:** An issue has been detected with the bowl optics. The power-on self-test has paused. The procedure may be run, but the user must manually start the Wash phase. **Corrective Action:** To proceed manually: 1. Touch **OK** to continue with POST and run the procedure. 2. Touch **Wash** to start Wash when there is adequate fluid in the bowl. **NOTE:** The bowl is full when the red cell/supernatant interface reaches a point approximately 1/4 inch over the shoulder of the bowl. The hematocrit of the product may be reduced if the Wash phase is started before the bowl is full. OR Power down the device. Service is required to fully resolve this issue.

Table 22, Event Messages

ID #	Event Message Text
124	**Bowl Optics Failure** **Explanation:** An issue has been detected with the bowl optics. Processing has paused. Processing can continue, but the user must manually start the Wash phase. **Corrective Action:** To proceed manually: 1. Touch **Continue** to continue. 2. Touch **Wash** to start Wash when there is adequate fluid in the bowl. **NOTE:** The bowl is full when the red cell/supernatant interface reaches a point approximately 1/4 inch over the shoulder of the bowl. The hematocrit of the product may be reduced if the Wash phase is started before the bowl is full. OR To end the procedure: 1. Touch **End Procedure** Service is required to fully resolve this issue.
126	**Bowl Size Mismatch** **Explanation:** A Latham bowl was detected, but a 70 mL bowl was selected. **Corrective Action:** If a 70 mL bowl is installed: 1. Check the bowl and chuck adaptor for proper installation in the centrifuge. 2. Clean the optics. 3. Touch **Keep Bowl Size**. OR If a Latham bowl is installed: 1. Touch **Change Bowl Size**. 2. Select the new bowl size or scan the processing set barcode.

Table 22, Event Messages

ID #	Event Message Text
127	**Bowl Size Mismatch** **Explanation:** A 70 mL bowl was detected, but a Latham bowl was selected. **Corrective Action:** If a Latham bowl is installed: 1. Check the bowl and chuck adaptor for proper installation in the centrifuge. 2. Clean the optics. 3. Touch **Keep Bowl Size**. OR If a 70 mL bowl is installed: 1. Touch **Change Bowl Size**. 2. Select the new bowl size or scan the processing set barcode.
128	**Fluid Detected Early** **Explanation:** The bowl optics have detected fluid in bowl earlier than expected for the 70 mL bowl. **NOTE:** This could occur if saline was connected prior to the yellow line being installed in the valve module and saline inadvertently entered the bowl. **Corrective Action:** If a 70 mL bowl is installed: 1. Check the bowl and chuck adaptor for proper installation in the centrifuge. 2. Touch **Keep Bowl Size**. OR If a Latham bowl is installed: 1. Touch **Change Bowl Size**. 2. Select the new bowl size or scan the processing set barcode.

Table 22, Event Messages

ID #	Event Message Text
129	**Fluid Detected Early** **Explanation:** The bowl optics have detected fluid in bowl earlier than expected for the 125 mL bowl. **NOTE:** This could occur if saline was connected prior to the yellow line being installed in the valve module and saline inadvertently entered the bowl. **Corrective Action:** If a 125 mL bowl is installed: 1. Check the bowl for proper installation in the centrifuge. 2. Touch **Keep Bowl Size**. OR If a 70 mL bowl is installed: 1. Check the bowl and chuck adaptor for proper installation in the centrifuge. 2. Touch **Change Bowl Size**. 3. Select the new bowl size or scan the processing set barcode.
130	**Fluid Detected Early** **Explanation:** The bowl optics have detected fluid in bowl earlier than expected for the 225 mL bowl. **NOTE:** This could occur if saline was connected prior to the yellow line being installed in the valve module and saline inadvertently entered the bowl. **Corrective Action:** If a 225 mL bowl is installed: 1. Check the bowl for proper installation in the centrifuge. 2. Touch **Keep Bowl Size**. OR If a 70 mL or 125 mL bowl is installed: 1. Check the bowl and chuck adaptor (70 mL bowl) for proper installation in the centrifuge. 2. Touch **Change Bowl Size**. 3. Select the new bowl size or scan the processing set barcode.

Table 22, Event Messages

ID #	Event Message Text
131	**Reservoir Load Cell Calibration Failure** **Explanation:** ● The reservoir load cell calibration values are out of the acceptable range. ● Retry calibration. **Corrective Action:** See service manual for additional information.
132	**Waste Bag Load Cell Calibration Failure** **Explanation:** ● The waste bag load cell calibration values are out of the acceptable range. ● Retry calibration. **Corrective Action:** See service manual for additional information.
133	**Manifold Pressure Load Cell Calibration Failure** **Explanation:** ● The manifold pressure load cell calibration values are out of the acceptable range. ● Retry calibration. **Corrective Action:** See service manual for additional information.
135	**System Fault** **Explanation:** An issue has been detected with the system. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
137	**Centrifuge Failure** **Explanation:** An issue has been detected with the system. **Corrective Action:** Restart the device. If the problem persists, service is required.
138	**Centrifuge Slowing** **Explanation:** The procedure is waiting for the centrifuge to decelerate.
139	**Centrifuge Stopping** **Explanation:** The procedure is waiting for the centrifuge to decelerate.
141	**Recentrifuge Delay** **Explanation:** A recentrifuge delay occurred because the centrifuge and pump were stopped when there was fluid in the bowl. The centrifuge is coming up to speed and will spin for 50 seconds to re-establish separation in the bowl. The pump will start after separation is established. After 15 seconds, an override is provided to restart the centrifuge before completing the full delay. CAUTION: Overriding the delay may cause red cells to spill into the waste bag due to incomplete separation of the cells in the bowl.
142	**System Fault** **Explanation:** An issue has been detected in one of the internal device components. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
143	**Device Cover Open** **Explanation:** The device cover is open. The device cover must be closed and locked for the procedure to continue. **Corrective Action:** Close the device cover. If the problem persists, service is required.
144	**Pump Communication Failure** **Explanation:** An issue has been detected with the pump. **Corrective Action:** Restart the device. If the problem persists, service is required.
145	**Pump Failure** **Explanation:** An issue has been detected with the pump. **Corrective Action:** Restart the device. If the problem persists, service is required.
146	**Unable to Prime** **Explanation:** No fluid has been detected while attempting to prime the yellow line. **Corrective Action:** 1. Check the yellow line for kinks and occlusions. 2. Ensure the clamps on the yellow line are open and saline is connected. 3. Check the tubing placement in the air detector and pump. 4. Touch **Continue** to continue.

Table 22, Event Messages

ID #	Event Message Text
150	**Device Cover Lock Failure** **Explanation:** The device cover will not lock. The device cover must be closed and locked for the procedure to continue. **Corrective Action:** 1. Open and close the device cover. 2. Ensure that there are no obstructions to closing the cover. If the problem persists, service is required.
151	**Device Cover Open** **Explanation:** The device cover is open. The device cover must be closed and locked for the procedure to continue. **Corrective Action:** Close the device cover.
152	**Fluid Detected in Centrifuge Well** **Explanation:** The device detected fluid in the centrifuge well. There may have been a blood spill or an issue with the fluid detector. **Corrective Action:** 1. Check the effluent line for kinks and occlusions; ensure clamps are open. 2. Inspect the bowl and fluid sensor. 3. If a spill is observed, power down the device to clean the centrifuge per instructions in the manual and replace the disposable. 4. If no spill is detected, once the centrifuge well has been dried, touch **Retry**. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
153	**System Fault** **Explanation:** An issue has been detected in one of the internal device components. **Corrective Action:** Restart the device. If the problem persists, service is required.
155	**Effluent Check Required** **Explanation:** The effluent line sensor continued to detect a high level of free hemoglobin (Hgb) after two extended Wash phases. There may be an issue with tubing placement in the effluent line sensor, the effluent line sensor may be dirty, or there may be an issue with the wash solution. **Corrective Action:** If the effluent is clear: 1. Touch **Empty Bowl** to empty the bowl. 2. At the end of the Empty phase, check the tubing for correct placement in the effluent line sensor. 3. Clean the effluent line sensor with a soft, damp, lint-free gauze moistened with water only. If the effluent is not clear: 1. Ensure the correct saline solution is connected to the disposable set. 2. Touch **Extend Wash** to proceed with another extended wash. If the problem persists, service is required to resolve this issue.
157	**System Fault** **Explanation:** An issue has been detected in one of the internal device components. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
158	**System Fault** **Explanation:** An issue has been detected in one of the internal device components. **Corrective Action:** Restart the device. If the problem persists, service is required.
159	**System Fault** **Explanation:** An issue has been detected in one of the internal device components. **Corrective Action:** Restart the device. If the problem persists, service is required.
160	**Device Overheated** **Explanation:** The internal device temperature may have been high. The red cells might have been damaged if the parts of the device that contact the processing set rose above 42 °C. **Corrective Action:** 1. If the temperature of the device parts that contact the processing set cannot be verified to be below 42 °C it is recommended to either QC the product prior to reinfusion or to discard the blood in the processing set and to end the procedure. 2. Please service the device before using it again. 3. Blood remaining in the reservoir may be processed with another device and new processing set.
161	**System Fault** **Explanation:** An issue has been detected in one of the internal device components. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
162	**Valve Cover Lock Failure** **Explanation:** An issue has been detected with the valve module cover latch. **Corrective Action:** 1. Clamp the red, yellow, and blue lines. 2. Check the tubing manifold placement. 3. Check the tubing placement in the valve module. 4. Close and latch the valve module cover. 5. Unclamp the lines. 6. Close the device cover. If the problem persists, service is required.
163	**Valve Cover Not Closed** **Explanation:** The valve module cover latch is not closed. **Corrective Action:** 1. Clamp the red, yellow, and blue lines. 2. Check the tubing manifold placement. 3. Check the tubing placement in the valve module. 4. Close and latch the valve module cover. 5. Unclamp the lines. 6. Close the device cover. If the problem persists, service is required.
164	**System Fault** **Explanation:** An issue has been detected with the device memory during the power-on self-test (POST). **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
167	**Excessive Pressure in Blue Line** **Explanation:** The manifold pressure sensor detected high pressure in the blue line during the Empty phase. The centrifuge must stop before the cover will unlock and corrective action can be taken. **Corrective Action:** 1. Ensure the blue line clamp is open. 2. Check the tubing for kinks and occlusions. 3. Touch **Continue** to continue. If the problem persists, service is required.
168	**Excessive Pressure in Red line** **Explanation:** The manifold pressure sensor detected high pressure in the red line during the Return phase. The centrifuge must stop before the cover will unlock and corrective action can be taken. **Corrective Action:** 1. Ensure the red line clamp is open. 2. Check the tubing for kinks and occlusions. 3. Touch **Continue** to continue. If the problem persists, service is required.
169	**Pneumatics Failure** **Explanation:** An issue has been detected with the device's pneumatics system. It is unable to maintain adequate pressure. **Corrective Action:** Please service the device before continuing use.

Table 22, Event Messages

ID #	Event Message Text
171	**Pump Platen Open** **Explanation:** The pump platen is not fully closed. The centrifuge must stop before the cover will unlock and corrective action can be taken. **Corrective Action:** 1. Open the pump platen. 2. Ensure correct tubing placement around the pump. 3. Close the pump platen. 4. Close the device cover. If the problem persists, service is required.
172	**Pump Speed Error** **Explanation:** The pump is not operating as expected. The centrifuge must stop before the cover will unlock and corrective action can be taken. **Corrective Action:** 1. Open the pump platen. 2. Ensure tubing placement around the pump is correct. 3. Ensure the pump rollers are clean and rotate freely. 4. Close the pump platen. 5. Close the device cover. If the problem persists, service is required.
173	**Suction Failure** **Explanation:** An issue has been detected with the internal suction. All other device functions continue to operate normally. **Corrective Action:** 1. Connect an external regulated suction source to the reservoir. 2. Touch **OK** to close this message. Service is required to repair the internal suction.

Table 22, Event Messages

ID #	Event Message Text
174	**Suction Failure** **Explanation:** An issue has been detected with the internal suction. All other device functions continue to operate normally. **Corrective Action:** 1. Connect an external regulated suction source to the reservoir. 2. Touch **OK** to close this message. Service is required to repair the internal suction.
176	**Wash Must Be Confirmed** **Explanation:** The red cells in the bowl may have been washed with less than the recommended volume of saline solution. **Corrective Action:** Touch **Continue** to empty the bowl. OR Touch **Resume Wash** to enter Wash.
177	**Yellow Line Valve Position Error** **Explanation:** An issue has been detected with the yellow line valve position. The centrifuge must stop before the cover will unlock and corrective action can be taken. **Corrective Action:** 1. Clamp the red, yellow, and blue lines. 2. Open the valve module cover. 3. Check the tubing manifold placement. 4. Check the tubing placement in the valve module. 5. Close and latch the valve module cover. 6. Unclamp the lines. 7. Close the device cover. 8. Touch **Continue** to continue. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
178	**Red Line Valve Position Error** **Explanation:** An issue has been detected with the red line valve position. The centrifuge must stop before the cover will unlock and corrective action can be taken. **Corrective Action:** 1. Clamp the red, yellow, and blue lines. 2. Open the valve module cover. 3. Check the tubing manifold placement. 4. Check the tubing placement in the valve module. 5. Close and latch the valve module cover. 6. Unclamp the lines. 7. Close the device cover. 8. Touch **Continue** to continue. If the problem persists, service is required.
179	**Blue Line Valve Position Error** **Explanation:** An issue has been detected with the blue line valve position. The centrifuge must stop before the cover will unlock and corrective action can be taken. **Corrective Action:** 1. Clamp the red, yellow, and blue lines. 2. Open the valve module cover. 3. Check the tubing manifold placement. 4. Check the tubing placement in the valve module. 5. Close and latch the valve module cover. 6. Unclamp the lines. 7. Close the device cover. 8. Touch **Continue** to continue. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
181	**Waste Bag Almost Full** **Explanation:** The device has detected approximately 8 liters of fluid in the waste bag. **Corrective Action:** Empty or replace the waste bag soon. **NOTE:** When emptying the waste bag, do not allow the fluid level in the bag to fall below the 1 liter mark. This ensures that sufficient air is retained in the system to empty the bowl. **NOTE:** When replacing the waste bag, make sure the bowl is empty. If the bowl is not empty, its contents will have to be returned to the reservoir and processed again.
182	**Waste Bag Full** **Explanation:** The device has detected approximately 8.5 liters of fluid in the waste bag. **Corrective Action:** 1. Empty or replace the waste bag. 2. Touch **Continue** to continue. **NOTE:** When emptying the waste bag, do not allow the fluid level in the bag to fall below the 1 liter mark. This ensures that sufficient air is retained in the system to empty the bowl. **NOTE:** When replacing the waste bag, make sure the bowl is empty. If the bowl is not empty, its contents will have to be returned to the reservoir and processed again.

Table 22, Event Messages

ID #	Event Message Text
183	**Effluent Line Sensor Failure** **Explanation:** An issue has been detected with the effluent line sensor. The procedure can be performed, but the device cannot monitor the effluent from the bowl. **Corrective Action:** To perform the procedure with the user monitoring the effluent: 1. Touch **Continue**. 2. Monitor the effluent from the bowl during processing. If at the end of a wash phase additional washing is required: 1. Touch **Cycle Wash Volume**. 2. Increase the wash volume. OR To end the procedure: 1. Touch **End Procedure**. 2. If in the power-on self-test, power down the device. If the problem persists, service is required to resolve this issue.
184	**Air Detected During Fill** **Explanation:** The air detector sensed air in the red line during the Fill phase. The reservoir may be empty. **Corrective Action:** 1. Ensure the red line clamp is open. 2. Check the tubing for kinks, occlusions, and correct placement in the air detector and pump. 3. When additional fluid is in the reservoir, touch ▸ to resume filling the bowl. OR Touch **Conc** to continue filling the bowl with red cells from the RBC bag. OR Touch **Wash** to wash a partial bowl. OR Touch **Return** to return cells to the reservoir.

Table 22, Event Messages

ID #	Event Message Text
185	**Reservoir Load Cell Calibration Failure** **Explanation:** An issue has been detected with the reservoir sensor calibration during the power-on self-test (POST). **Corrective Action:** Please service the device before continuing use.
186	**Waste Bag Load Cell Calibration Failure** **Explanation:** An issue has been detected with the waste bag sensor calibration during the power-on self-test (POST). **Corrective Action:** Please service the device before continuing use.
187	**Manifold Pressure Sensor Calibration Failure** **Explanation:** An issue has been detected with the manifold pressure sensor calibration during the power-on self-test (POST). **Corrective Action:** Please service the device before continuing use.
189	**Header Arm is Unlatched** **Explanation:** The device detected that the header arm is unlatched. The centrifuge must stop before the cover will unlock and corrective action can be taken. **Corrective Action:** 1. Ensure that the bowl is seated properly. 2. Close and latch the centrifuge arm. 3. Close the device cover. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
190	**Software Version Error: APP** **Explanation:** An issue has been detected with the Application software version during power-up. **Corrective Action:** Please service the device before continuing use.
191	**Software Version Error: SS** **Explanation:** An issue has been detected with the SmartSuction software version during power-up. **Corrective Action:** Please service the device before continuing use.
195	**Pneumatics Failure** **Explanation:** An issue has been detected with the device's pneumatics system. It is unable to maintain adequate pressure. Processing cannot continue. **Corrective Action:** Please service the device before continuing use.

Table 22, Event Messages

ID #	Event Message Text
227	**Air Detected During Fill** **Explanation:** The air detector sensed air in the red line during the Fill phase. The blood bag may be empty. **Corrective Action:** If the blood bag is not empty: 1. Ensure the red line clamp is open. 2. Check the tubing for kinks, occlusions, and correct placement in the air detector and pump. 3. Touch **Continue Using Blood Bag** to proceed. If the blood bag is empty: 1. Replace the blood bag. 2. Touch **Continue Using Blood Bag** to proceed. OR To complete the Sequestration cycle: 1. Touch **End Cycle** to end the current cycle. 2. The device will empty the bowl contents to the RBC bag.

Table 22, Event Messages

ID #	Event Message Text
228	**Effluent Line Sensor Failure** **Explanation:** An issue has been detected with the effluent line sensor. Sequestration can continue, but the device cannot monitor the effluent from the bowl during PRP collection. **Corrective Action:** To proceed with the user monitoring the effluent: 1. Touch **Continue** to continue. 2. Monitor the effluent from the bowl. 3. When ready to end the PRP collection, touch **Empty** to empty the bowl. 4. Follow the device prompts to continue. OR To complete the Sequestration cycle: 1. Touch **End Cycle** to end the current cycle. 2. The device will empty the bowl contents to the RBC bag. If the problem persists, service is required to fully resolve this issue.
229	**Post-Op Suction Leak Detected** **Explanation:** The device has detected a leak in the suction pathway. **Corrective Action:** 1. Check for proper placement of the wound drain. 2. Ensure all connections are secure, including the wound drain, post-op line, reservoir, and vacuum line. 3. Ensure the spare reservoir ports are securely capped. 4. Check the reservoir for leaks. If the problem persists, external suction should be used and service is required to resolve this issue.

Table 22, Event Messages

ID #	Event Message Text
230	**Software Version Error: GUI** **Explanation:** An issue has been detected with the user interface software version during power-up. **Corrective Action:** Please service the device before continuing use.
231	**Software Update Complete** **Explanation:** The software has been successfully updated. The device must be restarted before continuing with normal operation. **Corrective Action:** Restart the device.
232	**Blue Line Valve Position Error** **Explanation:** An issue has been detected with the blue line valve position. This could be the result of spilled fluid or debris causing the valve to stick. **Corrective Action:** 1. Inspect the area around the blue line valve and clean if necessary. 2. Touch **Continue** to continue. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
233	**Bowl Optics Failure** **Explanation:** An issue has been detected with the bowl optics. The power-on self-test has paused. The procedure may be run, but the user must manually start the Wash phase. **Corrective Action:** To proceed manually: 1. Touch **Continue** to continue with POST and run the procedure. 2. Touch **Wash** to start Wash when there is adequate fluid in the bowl. **NOTE:** The bowl is full when the red cell/supernatant interface reaches a point approximately 1/4 inch over the shoulder of the bowl. The hematocrit of the product may be reduced if the Wash phase is started before the bowl is full. OR Power down the device. Service is required to fully resolve this issue.
234	**Centrifuge Header Arm is Unlatched** **Explanation:** The device detected that the centrifuge header arm is unlatched. **Corrective Action:** 1. Ensure the bowl is seated properly. 2. Close and latch the centrifuge arm. 3. Close the device cover. If the problem persists, service is required.
235	**Load Cell Calibration Error** **Explanation:** An issue has been detected with the calibration data for the load cells. Recalibration of the load cells is required. **Corrective Action:** Remove the device from service and recalibrate the load cells.

Table 22, Event Messages

ID #	Event Message Text
236	**Manifold Not Properly Loaded** **Explanation:** The device detected that the manifold is not properly loaded. **Corrective Action:** 1. Check the manifold positioning. 2. Close and latch the manifold cover. 3. Close the device cover. If the problem persists, service is required.
238	**Suction Calibration Error** **Explanation:** An issue has been detected with the calibration data for the device suction. Recalibration of the device suction is required. **Corrective Action:** 1. Connect an external regulated suction source to the reservoir. 2. Touch **OK** to close this message. Service is required to recalibrate the internal suction.
239	**Yellow Line Valve Position Error** **Explanation:** An issue has been detected with the yellow line valve position. This could be the result of a spilled fluid or debris causing the valve to stick. **Corrective Action:** Inspect the area around the yellow line valve and clean if necessary. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
240	**Pump Platen Open** **Explanation:** The pump platen is not fully closed. **Corrective Action:** 1. Open the pump platen. 2. Ensure correct tubing placement around the pump. 3. Close the pump platen. 4. Close the device cover. If the problem persists, service is required.
241	**Fluid Not Detected When Expected** **Explanation:** The line sensor did not sense fluid when expected. **Corrective Action:** 1. Check the effluent line for correct placement in the effluent line sensor. 2. Clean the effluent line sensor. 3. Check the line for closed clamps, kinks, or occlusions. 4. If using external vacuum, ensure the level is not greater than 250 mmHg. 5. Touch **Continue** to continue. **NOTE:** When using regulated external suction, ensure the A&A line is clamped while setting the regulator vacuum level to the desired level. If the A&A line is not clamped the vacuum level may exceed the selected vacuum level and affect performance of the device.
242	**Load Disposable** **Explanation:** A disposable must be loaded to begin a procedure. **Corrective Action:** 1. Load a disposable. 2. Touch **Start Procedure** when ready to begin a procedure.

Table 22, Event Messages

ID #	Event Message Text
244	**Remove and Reinstall Effluent Line Tubing** **Explanation:** The effluent line sensor is looking for tubing and does not detect it. This can occur due to calibration problems or if the tubing is not fully seated in the effluent line sensor. **Corrective Action:** 1. Ensure the tubing is fully seated in the effluent line sensor. 2. If the tubing is fully seated, remove it, clean the effluent line sensor, and reinstall the tubing. 3. Close the device cover.
248	**Duplicate Settings Group Name** **Explanation:** There cannot be two settings groups with the same name. **Corrective Action:** Add a group again and enter a name that does not already exist.
250	**Invalid Settings Group Name** **Explanation:** A name cannot be only spaces. Characters must be used. **Corrective Action:** Add a group again and enter a name that contains valid characters.
252	**Stop Key Failure** **Explanation:** An issue has been detected with the **Stop** key. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
253	**Load Disposable** **Explanation:** A disposable must be loaded to begin a procedure. **Corrective Action:** Load a disposable and touch **Start Procedure** when ready to begin a procedure.
254	**PRP Separation Lost** **Explanation:** A device event has caused the centrifuge to stop and the PRP separation to be lost. The RBCs in the centrifuge should be emptied to the RBC bag and the cycle started over. **Corrective Action:** 1. Touch **Empty Bowl** to empty RBCs to the RBC bag. 2. Touch **Conc** to repeat Sequestration with RBCs from the RBC bag. OR 1. Touch **Empty Bowl** to empty RBCs back to the RBC bag. 2. Touch **Fill** to repeat Sequestration with RBCs from the blood bag.
255	**Recentrifuge Delay** **Explanation:** The procedure is establishing a platelet layer. The pump will restart after a 30 second delay when separation is established. **Corrective Action:** Touch ▶ to override the delay.
256	**Data Transfer Interrupted** **Explanation:** The device was transmitting data to a storage device and the transmission was interrupted. This could occur if the storage device was removed from the USB port before completing data transfer or if the connection between the storage device and the USB port was loose. Export of the data will have to be repeated. **Corrective Action:** 1. Ensure the storage device is securely installed in the USB port. 2. Touch **Export** to begin the data transfer.

Table 22, Event Messages

ID #	Event Message Text
257	**Device Fan Failure** **Explanation:** One of the 3 fans in the device has failed during POST, Failure of this fan does not prevent operation of the device. **Corrective Action:** 1. The procedure can be continued, but it is recommended that the device be serviced prior to its next use. 2. Touch **OK** to continue.
258	**Software CRC Error** **Explanation:** An issue has been detected with the update files on the USB flash drive and the software update was not completed successfully. **Corrective Action:** Service is required to resolve this issue.
259	**Software Update Interrupted** **Explanation:** The software update process was interrupted. This may have been caused by the USB flash drive becoming partially removed from the USB port while the device was transferring data. **Corrective Action:** 1. Touch **OK** to clear the even message. 2. Ensure the USB flash drive is properly inserted into the USB port. 3. Touch **Update** to retry the update. 4. Do not remove the USB flash drive until the update is complete. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
260	**Processing Set Entry Not Recorded** **Explanation:** A processing set has already been entered in the Records screen. The device does not allow the entry of two processing sets unless the centrifuge arm has been opened and closed while replacing the first processing set. If the first set was entered incorrectly the data for that set can be edited by going to the Records screen. **Corrective Action:** 1. Go to the Records screen to edit the information for the first processing set. OR 2. Open and close the centrifuge arm to replace the first processing set. A prompt will be displayed to enter the new processing set information.
261	**Partial Bowl** **Explanation:** Blood processed using a partial bowl may have a lower hematocrit than blood processed using a normal full bowl. Because the hematocrit of the bowl contents is lower, there is more supernatant in the bowl. In order to dilute the larger volume of supernatant, a partial bowl may require two times the normal saline solution. **Corrective Action:** Select the desired response pads. To change the wash volume, touch **Cycle Wash Volume** and adjust manually.
262	**Recentrifuge Delay** **Explanation:** A recentrifuge delay occurred because the centrifuge and pump were stopped when there was fluid in the bowl. The centrifuge is coming up to speed and will spin for 50 seconds to re-establish separation in the bowl. The pump will start after separation is established. CAUTION: Overriding may cause red cells to spill into the waste bag due to incomplete separation of the cells in the bowl. **Corrective Action:** To override the delay and restart the pump now, touch ▶.

Table 22, Event Messages

ID #	Event Message Text
264	**Synchronization Error** **Explanation:** The system detected an unexpected situation. The procedure can be continued. **Corrective Action:** 1. Ensure the clamps on the red, yellow, and blue lines are properly positioned. 2. Touch ▸ to resume or an alternate phase pad as desired.
266	**Vacuum Level Out of Range** **Explanation:** The device has detected the vacuum level is outside the expected range. This can be caused if there is a kink or occlusion in the vacuum line or A&A line or if the A&A line is clamped off when the device is trying to relieve suction. All other device functions continue to operate normally. **Corrective Action:** 1. Check for kinks or obstructions in the vacuum line, A&A line, or reservoir inlet ports. 2. Ensure the A&A line is not clamped off at any point. 3. Touch **OK** to close this message. 4. Restart suction by touching **Suction**. If the problem persists, service is required.
267	**Centrifuge Reset** **Explanation:** The device had to reset the centrifuge to continue processing. The procedure can continue. **Corrective Action:** Touch **Continue** to continue.
268	**Procedure Interrupted** **Explanation:** Power was interrupted before the procedure was completed. **Corrective Action:** ● Touch **Resume Procedure** to resume the procedure in progress. ● Touch **New** to start a new procedure.

Table 22, Event Messages

ID #	Event Message Text
269	**Confirm Procedure Complete** **Explanation:** The user had chosen to end the procedure. Ending the procedure will purge the blue line. **Corrective Action:** Touch **End Procedure** to confirm ending the current procedure. OR Touch **Resume Procedure** to resume the procedure in progress,
271	**Prepare to Resume Procedure** **Explanation:** A procedure that was in progress is being resumed. To resume effectively, the bowl, centrifuge arm, pump platen, manifold valve cover, device cover, and tubing clamps must be in the correct positions. **Corrective Action:** 1. Ensure the bowl is properly placed in the centrifuge. 2. Ensure the centrifuge arm is locked. 3. Ensure the pump platen is closed. 4. Ensure the manifold valve cover is closed. 5. Ensure the device cover is closed. 6. Ensure the tubing clamps are open as required. 7. Touch **OK** to resume the previous procedure.
272	**Purging Blue Line** **Explanation:** The blue line is being purged to the reinfusion bag. Purging will complete when air is detected from the bowl. **Corrective Action:** Wait for purging to complete.

Table 22, Event Messages

ID #	Event Message Text
273	**Partial Bowl Will Be Double Washed** **Explanation:** Blood processed using a partial bowl may have a lower hematocrit than blood processed using a normal full bowl. Because the hematocrit of the bowl contents is lower, there is more supernatant in the bowl. In order to dilute the larger volume of supernatant, a partial bowl may require two times the normal saline solution. **Corrective Action:** To change the wash volume, touch **Cycle Wash Volume** and adjust manually.
274	**Partial Bowl Will Be Single Washed** **Explanation:** The user has entered Wash based on judgment that the volume of red blood cells in the bowl is sufficient to warrant a single wash volume. **Corrective Action:** To change the wash volume, touch **Cycle Wash Volume** and adjust manually.
275	**Recovered from System Fault** **Explanation:** The system has recovered from a fault. **Corrective Action:** Normal operation can continue. If the problem persists, service is required. Touch **Continue** to continue.
277	**Protocol Settings Have Been Changed** **Explanation:** The selected protocol settings group has been applied. The procedure will continue with the new settings.
278	**Records Exported to USB Flash Drive** **Explanation:** The selected procedure record(s) and data log(s) have been exported to the USB flash drive successfully. The USB device can be safely removed.

Table 22, Event Messages

ID #	Event Message Text
279	**Procedure Complete** **Explanation:** The procedure is complete and the device is ready to power down. The procedure may be resumed, air may be removed from the RBC bag, and/or records, settings, and help may be reviewed. **Corrective Action:** To begin a new procedure: 1. If a processing set is loaded, close clamps. 2. Turn power off. 3. Turn power on. OR Touch **Resume Procedure** to resume the procedure. OR Touch **Remove Air** to remove air from the RBC bag. OR Access settings, records, or help from the menu.
280	**Vacuum Detected in Yellow Line** **Explanation:** The manifold pressure sensor detected a high vacuum in the yellow line. The saline bag clamps may be closed or the saline bag may be empty. **Corrective Action:** 1. Ensure the yellow line clamp is open. 2. Check the tubing for kinks, occlusions, and proper placement in the air detector and pump. 3. Replace the saline bag if it is empty. 4. Touch **Continue** to continue.

Table 22, Event Messages

ID #	Event Message Text
281	**Ready to Remove Air from RBC Bag** **Explanation:** To remove air from the RBC bag, the pump is started and stopped using the **Pump** pad. **Note:** Removal of air should stop prior to RBCs leaving the RBC bag. **WARNING:** This process may leave residual air in the RBC bag. Do not pressure infuse. May cause fatal infusion of air. **Corrective Action:** 1. Hold the RBC bag with the blue line facing up. 2. Touch and hold **Pump** to remove air from the reinfusion bag. 3. Release **Pump** to stop the pump.
283	**USB Flash Drive Error** **Explanation:** An error occurred while transferring data with the USB flash drive. The operation did not complete successfully but can be retried. **Corrective Action:** 1. Verify the flash drive is inserted properly. 2. Touch **Continue** to continue. 3. Retry the operation. If the problem persists, a different USB flash drive or service may be required.
284	**Data Transfer in Progress** **Explanation:** The requested data transfer operation is in progress. **Corrective Action:** Wait for the operation to complete before removing the USB flash drive.

Table 22, Event Messages

ID #	Event Message Text
285	**Final Cycle** **Explanation:** The reservoir has emptied and the procedure has ended. Please select a processing behavior for the last bowl. **Corrective Action:** **Partial Bowl Wash -** The system enters the Wash phase according to the Partial Bowl Wash parameter as defined in the protocol settings. After the preset wash volume, the system empties the bowl and purges the blue line before marking the procedure complete. **Concentrate** - The system concentrates the RBCs in the bowl by transferring washed RBCs from the RBC bag until it detects a full bowl. It then executes a wash cycle, empties the bowl to the product line, and purges the blue line before marking the procedure complete. **End Procedure** - Since the fluid in the bowl is not washed, the system returns the bowl contents to the red line and purges the blue line before marking the procedure complete.
286	**Purging Red Line** **Explanation:** The device has detected the bowl is full of unwashed cells. The bowl contents are being purged to the reservoir. Purging will complete when air is detected from the bowl. **Corrective Action:** Wait for purging to complete.
301	**Operator Action Required** **Explanation:** The bag line clamps must be set to continue Sequestration. **Corrective Action:** 1. Set the bag line clamps as follows: • OPEN the white air line clamp. • CLOSE the blue PRP line clamp. • CLOSE the yellow PPP line clamp. 2. Agitate the blood bag. 3. Touch **Continue** to fill the bowl.

Table 22, Event Messages

ID #	Event Message Text
302	**Operator Action Required** **Explanation:** The bag line clamps must be set to continue Sequestration. **Corrective Action:** 1. Set the bag line clamps as follows: • CLOSE the white air line clamp. • CLOSE the blue PRP line clamp. • OPEN the yellow PPP line clamp. 2. Agitate the blood bag. 3. Touch **Continue** to fill the bowl.
303	**Operator Action Required** **Explanation:** The bag line clamps must be set to continue Sequestration. **Corrective Action:** 1. Set the bag line clamps as follows: • CLOSE the white air line clamp. • CLOSE the blue PRP line clamp. • OPEN the yellow PPP line clamp. 2. Touch **Continue** to collect PPP.
304	**Operator Action Required** **Explanation:** The bag line clamps must be set to continue Sequestration. **Corrective Action:** 1. Set the bag line clamps as follows: • CLOSE the white air line clamp. • OPEN the blue PRP line clamp. • CLOSE the yellow PPP line clamp. 2. Touch **Continue** to collect PRP.

Table 22, Event Messages

ID #	Event Message Text
305	**Operator Action Required** **Explanation:** The bag line clamps must be set to continue Sequestration. **Corrective Action:** 1. Set the bag line clamps as follows: • OPEN the white air line clamp. • CLOSE the blue PRP line clamp. • CLOSE the yellow PPP line clamp. 2. Touch **Continue** to empty the bowl.
306	**Operator Action Required** **Explanation:** The bag line clamps must be set to continue Sequestration. **Corrective Action:** 1. Set the bag line clamps as follows: • CLOSE the white air line clamp. • CLOSE the blue PRP line clamp. • OPEN the yellow PPP line clamp. 2. Touch **Continue** to empty the bowl.
307	**Operator Action Required** **Explanation:** The bag line clamps must be set to continue Sequestration. **Corrective Action:** 1. Set the bag line clamps as follows: • OPEN the white air line clamp. • CLOSE the blue PRP line clamp. • CLOSE the yellow PPP line clamp. 2. Agitate the RBC bag. 3. Touch **Continue** to concentrate.

Table 22, Event Messages

ID #	Event Message Text
308	**Operator Action Required** **Explanation:** The bag line clamps must be set to continue Sequestration. **Corrective Action:** 1. Set the bag line clamps as follows: • CLOSE the white air line clamp. • CLOSE the blue PRP line clamp. • OPEN the yellow PPP line clamp. 2. Agitate the RBC bag. 3. Touch **Continue** to concentrate.
309	**Blood Bag Is Empty** **Explanation:** Air was detected while filling the bowl. Sequestration will continue using fluid from the RBC bag. **Corrective Action:** Touch **Continue** to continue.
310	**Sequestration Cycle Complete** **Explanation:** The sequestration cycle has completed. **Corrective Action:** Touch **Sequestration** to sequester another unit. OR Touch **Cell Salvage** to prepare for Cell Salvage. OR Touch **End Procedure** to end the current procedure.

Table 22, Event Messages

ID #	Event Message Text
311	**Operator Action Required** **Explanation:** The processing set must be prepared before continuing to Cell Salvage. **Corrective Action:** 1. Remove the PPP, PRP, and air bag connection and reconnect the waste bag. 2. Close the blood bag clamps and open the reservoir clamp. 3. Open the saline bag clamp. 4. Touch **Cell Salvage** to continue to Cell Salvage. OR 1. Touch **Sequestration** to return to Sequestration.
312	**Confirmation Required** **Explanation:** The Cell Salvage menu option was selected. This will stop Sequestration. Confirmation is required to proceed. **Corrective Action:** Touch **Cancel** to continue Sequestration. OR Touch **Continue** to continue and prepare for Cell Salvage. OR Touch **End Procedure** to end the current procedure.
400	**System Fault** **Explanation:** An issue has been detected with the system. **Corrective Action:** Restart the device. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
401	**Fat Reduction Wash Cycle** **Explanation:** The fat reduction and wash phase is in process. During this phase, salvaged blood is moved into and out of the bowl in order to isolate the fat and remove it from the packed red blood cells. The normal washing step occurs in between two distinct fat reduction steps, and a secondary wash will occur at the end of the cycle. **Corrective Action:** In order to end the specialized fat reduction cycle and execute a normal wash cycle, navigate to the Protocol Settings screen and activate Haemonetics Default settings, or a custom settings group with Fat Reduction set to off. If the process has already completed the wash step using the full wash volume, touching **Empty** will empty the bowl immediately, skipping fat reduction for this cycle.
402	**Returning Cells to Bowl** **Explanation:** The user has elected to stop a fat reduction cycle during Wash. Packed red blood cells are being returned to the bowl from the reservoir tubing in order to maintain high hematocrit product. After this brief phase a normal wash cycle will begin and no further fat reduction steps will occur unless the setting is changed again.
406	**Software Update Not Completed** **Explanation:** A software update was started but did not complete. **Corrective Action:** Retry the software update. If the problem persists, service is required.

Table 22, Event Messages

ID #	Event Message Text
407	**System Fault** **Explanation:** An issue has been detected with the system. **Corrective Action:** Restart the device. If the problem persists, service is required.
408	**Software Update in Progress** **Explanation:** A software update is in progress. **Corrective Action:** Wait for all steps to complete and then restart the device.
409	**Software Update Error** **Explanation:** The software update was not completed successfully. **Corrective Action:** Retry the software update. If the problem persists, service is required.
500	**Confirmation Required** **Explanation:** The software update option was selected. This will install the selected software version and will permanently erase all user data including procedure records and settings. The software update process can take several minutes to complete and will require restarting the device when complete. Confirmation is required to proceed. **Corrective Action:** Touch **Update Software** to continue the software update process. OR Touch **Cancel** to cancel the software update process.

Table 22, Event Messages

ID #	Event Message Text
501	**Device Restart Is Required** **Explanation:** The device must be restarted before continuing with normal operation. **Corrective Action:** Restart the device.

Appendix A

IEC/EN 60601-1-2 Standard Requirements

Operation Precautions

Attention: *The Cell Saver® Elite®+ device must be operated in an environment compatible to the requirements of the IEC/EN 60601-1-2 Standard, Electromagnetic Compatibility (EMC).*

A power cord is supplied with the device. Do not replace the power cord with a substitute. If necessary, contact the Haemonetics Customer Care Center for a replacement. Always ensure the power cord is connected to an appropriately grounded power source.

Mobile radio frequency (RF) communication equipment not approved by Haemonetics and portable communication equipment can affect the system. Any accessories and cables not approved by Haemonetics, used in conjunction with the device, may increase hazards and influence compatibility with EMC requirements. Therefore, non-approved accessories and cables must not be used.

In addition, the Cell Saver Elite+ device and accessories must not be placed directly adjacent to, or on top of other equipment, unless specifically approved by Haemonetics.

Warning: Ground continuity can only be achieved when the equipment is connected to a properly grounded outlet.

Electromagnetic Compatibility

Note: There were no deviations from IEC/EN 60601-1-2 or allowances used during testing of the system.

Table 23, Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC/EN 61000-3-3	Complies	

Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 24, Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.			
Immunity Test	**IEC/EN 60601-1-2 4th Edition Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC/EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, voltage variations on power supply input lines. IEC/EN 61000-4-11	0% U_T for 0.5 cycles 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T ; 250/300 cycle	0% U_T for 0.5 cycles 0% U_T for 1 cycle 70% U_T for 25/30 cycles 0% U_T ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninteruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 25, Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The system is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.			
Immunity Test	**IEC/EN 60601-1-2 4th Edition Test Level**	**Compliance Level**	**Electromagnetic Environmental Guidance**
			Portable and mobile RF communication equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3Vrms 0.15MHz to 80MHz 6 Vrms in ISM bands 3 V/m 80 MHz to 2.7 GHz	3Vrms 0.15MHz to 80MHz 6 Vrms in ISM bands 3V/m 80 MHz to 2.7 GHz	**Recommended separation distance:** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.7 GHz Where P is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

NOTE 3: The device was subjected to immunity testing. However, during immunity testing it is not practicable to test all possible modes and operating conditions. Because of this, all critical functions of the system are designed with redundant systems to ensure ongoing safe operation of the device in all anticipated operating environments.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 26, Recommended separation distance between portable RF communications equipment and the Cell Saver Elite+ device

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **Watts (W)**	**Separation distance according to frequency of transmitter - meters (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1.0	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz, the separation for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 27, Test specifications for enclosure port immunity to RF wireless communications equipment

The system is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.						
Test Frequency (MHz)	**Band[a] (MHz)**	**Service[a]**	**Modulation[b]**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA 400	Pulse modulation[b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM[c] ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth; WLAN, 802.11 b.g.n, RFID 2450, LTE Band 7	Pulse modulation[b] 217 Hz	2	0.3	28

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used, because while it does not represent actual modulation, it would be worst case.

Table 27, Test specifications for enclosure port immunity to RF wireless communications equipment

The system is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.						
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9
5500						
5785						
NOTE: If necessary to achieve the immunity test level, the distance between the transmitting antenna and the system may be reduced to 1 m. The 1 m test distance is permitted by IEC/EN 61000-4-3.						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used, because while it does not represent actual modulation, it would be worst case.

Appendix B

System Performance

Cell Salvage

In accordance with ANSI/AAMI AT6:2005, laboratory studies were conducted to confirm the performance of the Cell Saver® Elite®+ device. The following test results are based on two-cycle procedures processing 10% hematocrit test pools. Lysate and heparin were added to measure constituent washout. Mean values are reported alongside standard error of the mean. System performance is summarized below based on bowl type and operating mode. Results may vary depending on in-use variables.

Table 28, Haemonetics Default

Parameter	225 mL Bowl	125 mL Bowl	70 mL Bowl
HCT %	58 ± 4.2	52 ± 2.4	52 ± 1.2
RBC Recovery %	94 ± 1.8	91 ± 2.9	90 ± 2.9
WBC Removal %	36.9 ± 11.3	29.4 ± 10.9	34.7 ± 10.9
Free Hemoglobin Washout %	99.0 ± 0.2	99.6 ± 0.1	99.3 ± 0.1
Total Protein Washout %[a]	99.0 ± 0.2	99.6 ± 0.1	99.4 ± 0.1
Potassium Washout %	98.7 ± 0.2	98.6 ± 0.3	98.4 ± 0.2
Heparin Washout %	99.7 ± 0.1	99.7 ± 0.0	99.7 ± 0.1

a. Total protein measurement has been used as a surrogate instead of albumin only assay (albumin being a sub-category of protein).

Table 29, Fat Reduction

Parameter	225 mL Bowl	125 mL Bowl	70 mL Bowl
HCT %	57 ± 1.2	51 ± 1.0	50 ± 0.2
RBC Recovery %	94 ± 0.5	92 ± 0.7	91 ± 0.5
WBC Removal %	51.4 ± 8.74	39.8 ± 3.29	40.7 ± 4.07
Free Hemoglobin Washout %	99.0 ± 0.28	99.5 ± 0.02	99.5 ± 0.01
Albumin Washout %	99.4 ± 0.01	99.9 ± 0.07	99.5 ± 0.10
Potassium Washout %	87.4 ± 4.56	90.4 ± 3.20	96.1 ± 0.53
Heparin Washout %	99.5 ± 0.01	99.6 ± 0.04	99.2 ± 0.45
Fat Washout %	99.6 ± 0.13	97.2 ± 0.93	93.3 ± 1.03

Table 30, Emergency Mode

Parameter	225 mL Bowl	125 mL Bowl
HCT %	53 ± 1.5	52 ± 1.6
Free Hemoglobin Washout %	98.3 ± 0.4	97.9 ± 0.2
Total Protein Washout %[a]	98.3 ± 0.5	98.4 ± 0.1
Potassium Washout %	98.7 ± 0.4	98.9 ± 0.1
Heparin Washout %	99.5 ± 0.4	99.7 ± 0.1

Table 31, Partial Bowl Double Wash

Parameter	225 mL Bowl	125 mL Bowl
Free Hemoglobin Washout %	98.9 ± 0.5	98.8 ± 0.5
Total Protein Washout %[a]	99.3 ± 0.1	99.5 ± 0.1
Potassium Washout %	95.2 ± 0.4	96.4 ± 0.1
Heparin Washout %	98.4 ± 0.1	98.6 ± 0.1

Table 32, Low Wash

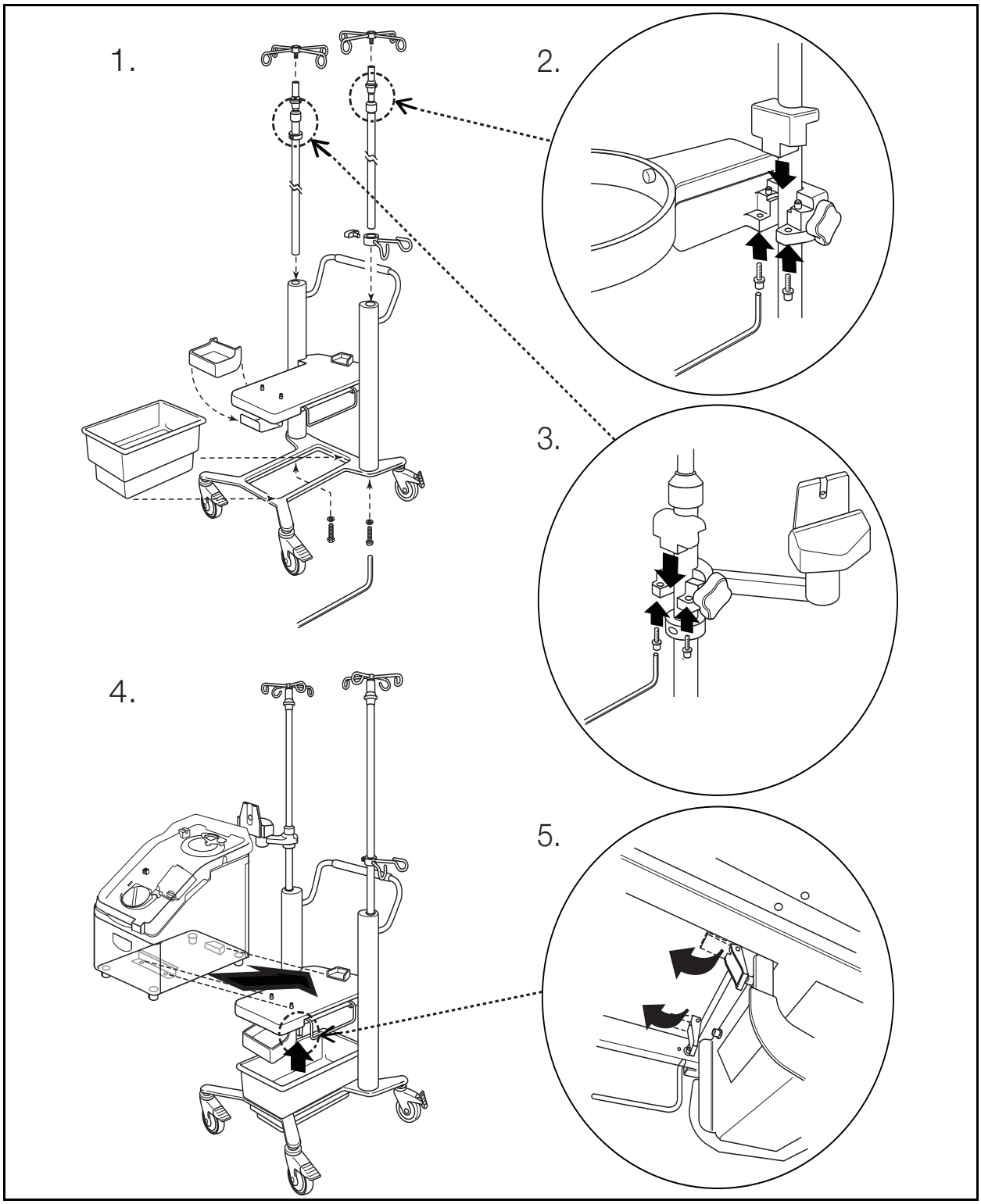
Parameter	225 mL Bowl	125 mL Bowl	70 mL Bowl
Wash volume per Cycle mL	625	375	210
HCT %	58 ± 3.0	54 ± 1.7	53 ± 1.3
RBC Recovery %	93 ± 2.8	90 ± 1.8	92 ± 3.5
WBC Removal %	28.4 ± 5.0	21.9 ± 7.1	21.6 ± 5.6
Free Hemoglobin Washout %	98.0 ± 0.3	99.2 ± 0.1	99.3 ± 0.1
Total Protein Washout %[a]	98.0 ± 0.3	99.1 ± 0.1	99.3 ± 0.1
Potassium Washout %	98.1 ± 0.1	98.5 ± 0.3	98.6 ± 0.0
Heparin Washout %	98.4 ± 0.3	99.7 ± 0.1	99.7 ± 0.0

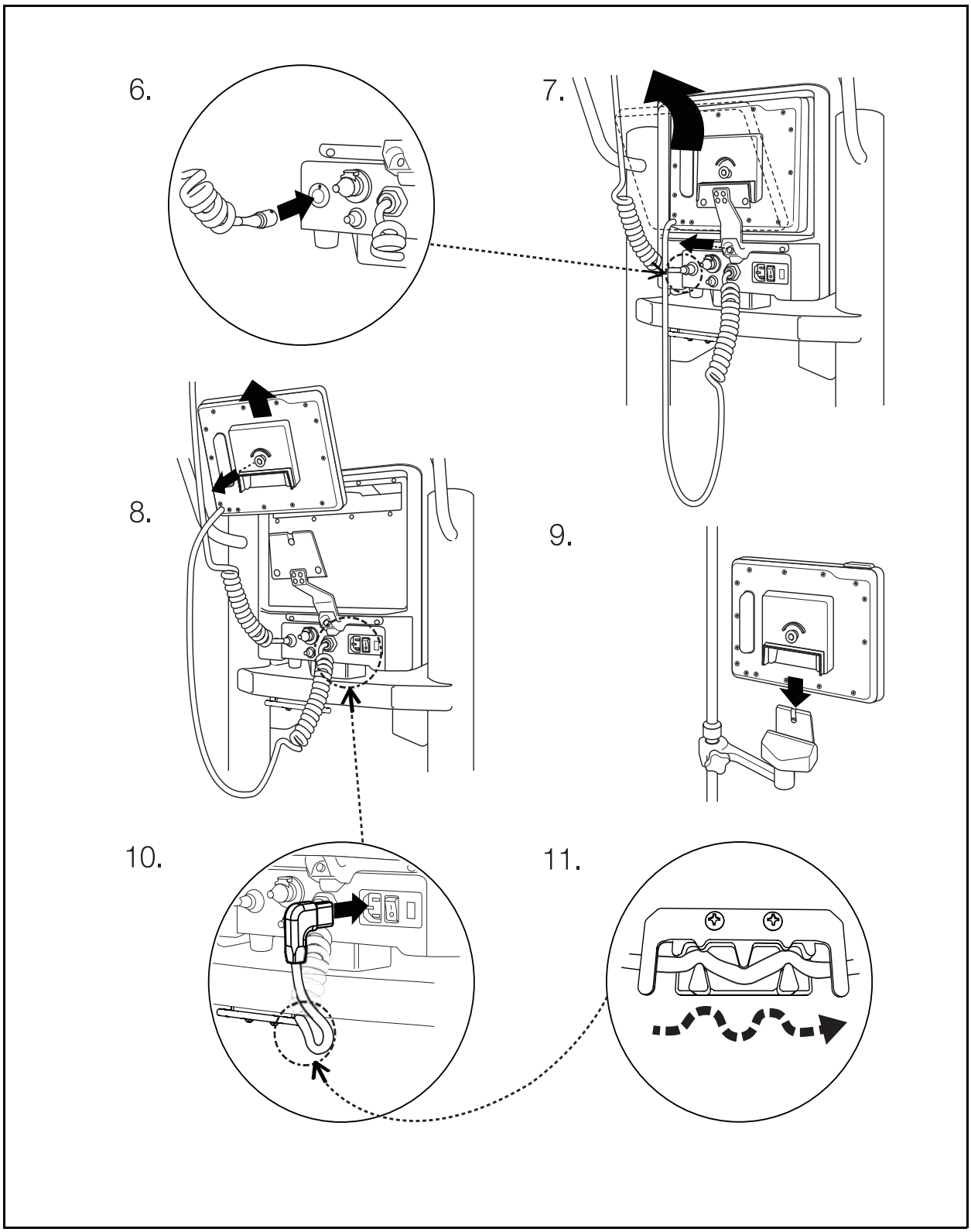
a. Total protein measurement has been used as a surrogate instead of albumin only assay (albumin being a sub-category of protein).

Appendix C

Cart Assembly Instructions

Installing the Device on the Cart

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