Cell Saver®5+
Autologous Blood Recovery System
- Operator's Manual -

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Scope

This manual is intended for users of the Haemonetics® Cell Saver® 5+ Autologous Blood Recovery System.

The contents of this Operator's Manual explain the operation and basic maintenance for the Cell Saver 5+ System. Diagnostics and subsequent repairs to this system should only be attempted by a qualified technician.

Symbols found in this document

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

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

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

Warning: advises the operator against initiating an action or creating a situation which could result in serious personal injury to the donor, the operator, or the blood product recipient.

Buyer's Use of Product

Warning: Haemonetics Corporation warrants only the Haemonetics Cell Saver 5+ system (CS5+) as supplied by it. When properly assembled, maintained and operated by a qualified operator, the CS5+ has the capability of safely and adequately performing Cell salvage and sequestering procedures.

Warning: Bodily injury may result from the use of disposable sets manufactured by others with this system. Please contact Haemonetics Corporation to determine the safety of using disposables other than those supplied by Haemonetics.

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician.*

Warning: This manual provides certain basic information concerning the maintenance and operation of the Haemonetics Cell Saver 5+ System and is intended to be used in conjunction with and as a supplement to the training supplied by a Haemonetics Clinical Specialist or other qualified personnel. Departures or deviations from the procedures contained in this manual should not be made except in conformity with official changes made to the manual by Haemonetics Corporation. Other departures or deviations are at the operator's own risk.

Safe and effective use of Haemonetics products requires application of proper techniques of setup and operation, and accordingly, should be undertaken only by trained personnel.

Any Buyer that intends to use Haemonetics products should:

- Read carefully the instructions supplied herewith.
- Secure training in the procedures to be used.

Information with respect to the availability of such training can be obtained by writing Haemonetics Corporation, Attention: Patient Division.

The uses to which the Haemonetics products may be applied, and the results obtained therefrom, shall be the sole responsibility of the Buyer. Haemonetics expressly disclaims responsibility for the use of the products by the Buyer.

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All Haemonetics products are manufactured in accordance with ISO 9000 standards.

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Chapter 1

Introduction

INTRODUCING THE CELL SAVER 5+ SYSTEM

Haemonetics introduced the first successful autologous blood collection system, the original Cell Saver 1 System.

The Haemonetics Cell Saver 5+ Autologous Blood Recovery System, shown in Figure 1-1, represents the fifth generation of autologous blood recovery systems. Using the latest microprocessor technology, the Cell Saver 5+ System (CS5+) delivers a new level of automation in the processing of autologous blood.

Operator interaction and surveillance are minimized by the use of a sensor which automatically senses the fluid level in the reservoir and initiates the machine's operation. Processing time has also been reduced while maintaining a high quality end product.

Cell Saver Systems salvage blood shed during or after a surgical procedure or as the result of trauma. The shed blood, which is collected in a sterile reservoir, is processed by the Cell Saver System in a centrifuge bowl. The red blood cells (RBCs) are concentrated and washed to remove cell stroma, platelets, activated clotting factors, extracellular potassium, free hemoglobin, anticoagulant, and cardioplegia. The washed, concentrated RBCs may then be returned to the patient.

Use of the CS5+ should be considered when the anticipated blood loss from a clean wound can be retrieved at a rate permitting aspiration without undue hemolysis. The presence of any of the following criteria may be an indication for blood salvage: the anticipated blood loss is 20% or more of the patient's estimated blood volume; blood would ordinarily be crossmatched for the procedure; more than 10% of the patients undergoing the procedure require transfusion; the mean transfusion for the procedure exceeds one unit. Specific types of surgery where cell salvage is especially useful include open heart and vascular surgery, total joint replacement and spine surgery, liver transplantation, ruptured ectopic pregnancy, and selected neurosurgical procedures. Postoperative salvage is employed most often following cardiac and certain types of orthopedic procedures.[1]

Figure 1-1: The Haemonetics Cell Saver 5+ Autologous Blood Recovery System

Indications for Use

The Haemonetics Cell Saver 5+ System and its related accessory components are intended to be used for the recovery and processing of blood shed during or subsequent to an operation or as a result of trauma. The recovered blood is processed by a centrifugation and washing procedure before pumping the red cell product to either a bag for gravity reinfusion into the patient or an extracorporeal circuit. The Haemonetics Cell Saver 5+ System may also be used for preoperative platelet and plasma sequestration.

Contraindications for Use

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. Refer to Appendix A for a chart of contraindicated substances, the effects of their use, and the recommended corrective actions to perform.

Warning: The use of reinfused blood from the Cell Saver 5+ 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.

AUTOLOGOUS BLOOD TRANSFUSION

Autologous blood is now widely accepted as the first choice for reinfusion.

The term, autologous blood, refers to blood derived from the same individual. An autologous blood transfusion therefore, is one in which a patient receives his or her own blood. The blood may have been donated earlier or salvaged from shed blood during surgery or postoperatively. Allogeneic blood, on the other hand, is donor blood from sources other than the patient who is receiving it.

Autologous vs. Allogeneic Transfusion

The advantages of autologous transfusion are well documented. The major advantages are as follows:

- No disease transmission risk
- Reduced risk of transfusion reactions
- Minimal compatibility testing
- Reduced demand on blood bank inventory

Cell Saver Systems and Autologous Transfusion

In addition to the general benefits of autologous transfusion, Cell Saver Systems provide the following benefits:

- Portability
- Rapid setup
- Rapid return of patient's own cells
- Reduction of net blood loss
- Removal of red cell stroma
- Removal of plasma-free hemoglobin
- Removal of anticoagulant
- Removal of activated clotting factors
- Removal of extracellular potassium
- Cost-effectiveness
- General acceptance by Jehovah's Witnesses

Historical Overview

The following paragraphs are a brief summary of the history of transfusion methods.

Early Experiments with Transfusion

Some of the earliest recorded attempts at transfusion were undertaken by a French physician, Jean Denys, who in the 1660's performed transfusions between animals and humans with predictably disastrous results.[2]

Quite reasonably, the French government stepped in and forbade the transfusion of blood except with the permission of a member of the Faculty of Medicine of Paris (which was strongly opposed to the practice). Rumors of Denys' experiments and his results were circulated throughout Europe, and fear of such practices spread to other countries.

In 1818 an English surgeon, James Blundell, reported on a human-to-human transfusion that he had performed (though unsuccessfully). Blundell later did perform successful transfusions, and his are the first recorded successes.[3]

More importantly, Blundell's attempts were relatively scientific and he recorded much useful information on transfusion. He also noted that the donation of a small quantity of blood produced no harmful effects on the donor.[4]

First Recorded Uses of Autologous Transfusion

In the late 1800's James Highmore, an English surgeon, proposed the use of autotransfusion (as autologous transfusion is also known), and suggested that a patient's shed blood was an overlooked source that could be used to great advantage. His article, appearing in The Lancet in 1874, advocated intraoperative autotransfusion, specifically in the case of post-partum hemorrhage.[5] Highmore later recorded his successful use of autotransfusion in a variety of cases.[6]

The Use and Acceptance of Allogeneic Blood

In the early 1900's techniques for typing and matching blood were developed. Gradually, allogeneic transfusions became accepted, though the general method was to transfuse blood directly from donor to recipient rather than to use banked blood.

The first blood bank was established at Cook County Hospital, Chicago on March 15, 1937, but the real rise of allogeneic transfusions came during World War II.[7] The need for blood during the war was large, as would be expected, and the donor pool in the United States grew enormously to meet this need. Using banked blood was, quite simply, the easiest alternative, and allogeneic transfusions became the norm.

Naturally, doctors returning from the war continued to rely on donor blood though several factors were developing which would make this less and less practical. The Korean and later the Vietnam wars followed World War II placing the usual high demands on the donor pool. Concurrently, other large demands

were being placed on the donor pools with the development and refinement of sophisticated surgical procedures such as open heart surgery.

The shortages of donor blood during the Vietnam War revived interest in autotransfusion. In Vietnam, an American military surgeon named Klebanoff began using the open heart pump to capture, anticoagulate, filter, and reinfuse the blood lost in surgery.[8]

Klebanoff's machine was introduced in the 1970's by Bentley Laboratories in a commercial version. Klebanoff's machine was effective though unsophisticated. Blood was simply anticoagulated, filtered, and reinfused. The Bentley machine was the first attempt to modernize autologous blood recovery in decades.

Haemonetics Cell Saver Systems

Haemonetics Cell Saver Systems are aptly named. Their primary purpose is the recovery of red blood cells (RBCs). The RBCs are recovered from the shed blood that has, in the past, simply been discarded after an operation. Cell Saver Systems collect, concentrate, and wash the RBCs, removing unwanted components, and then return them to the reinfusion bag or a extracorporeal circuit for reinfusion.

The first Haemonetics Cell Saver System was released in 1975. With each generation of Cell Saver System, Haemonetics has improved performance and increased automation. Today, Haemonetics Cell Saver Systems are used in a wide range of surgical procedures.

SPECIAL FEATURES OF THE CS5+

The CS5+ improves upon the design and performance of its predecessors. The CS5+ processes shed blood faster without compromising the quality of the end product (concentrated RBCs). Haemonetics has improved and streamlined the features and functions of earlier units and introduced the latest microprocessor and sensor technologies to produce a significant advance in autologous blood recovery systems, one which meets the demands and needs of the modern operating room.

Automated Operation

An onboard computer (microprocessor) uses data from a variety of sensors to control the processing of blood, allowing an unprecedented level of automation.

The bowl optics sensor in the centrifuge well, an ultrasonic air detector on the tubing line and an optical effluent line sensor provide information to the CS5+ microprocessor. The processor determines the optimal processing parameters for each individual cycles of the machine.

These parameters have been thoroughly tested and carefully calculated to produce consistently optimal results under most operating conditions. Although it is possible to reprogram the parameters, changes should be carefully considered.

The *ultrasonic air detector* monitors the fluid flow in the tubing. When air in the pump tubing is detected, the pump is stopped, the appropriate tubing is clamped and a message is sent to the display.

The *bowl optics sensor* monitors the red blood cell level in the bowl. This sensor initiates tripping to the WASH mode when the RBC level reaches the sensor trip point.

Note: Bowl optics sensor is disabled when processing the 70mL bowl.

The *effluent line sensor* monitors the quality of the effluent as it leaves the bowl. Among the actions the system might initiate are determining when the RBCs are adequately washed or slowing the pump rate in WASH or FILL mode if RBC spillage is detected. Additionally, with the 70mL bowl algorithm, the effluent line sensor monitors the red blood cell level to initiate tripping to WASH mode.

Computer Guided Setup

The on-board microprocessor guides the operator through system setup by displaying instructions on the display panel. For help in setting up the CS5+, press the HELP key on the control panel. Figure 1-2 illustrates typical setup instructions.

HELP
1. Prepare the collection (reservoir and suction). 2. Ready the machine and bowl disposable. 3. Install the bowl. 4. Hang the bags. 5. Install the tubing harness. 6. Set up the saline. 7. Inspect and finish.
Press START to resume

Figure 1-2: HELP display

Operators with multiple responsibilities involving frequent interruptions find the setup instructions useful as a checklist. When called away from setup to attend to another duty, the operator leaves the setup instruction as a reminder. When returning to complete the setup, the operator checks the instruction and continues from that point.

Caution: *The instructions provided by the display panel are not intended to replace formal training by Haemonetics in the operation of the Cell Saver 5+ System, nor do they relieve the operator of the obligation to read this manual.*

Performance Readouts

The right hand side of the display panel provides information relative to the operation of the system. Pump rate, wash volume, processed volume, number of bowls processed, and product volume as well as current mode of operation are constantly updated and displayed. The status of the CS5+ is available at a glance.

SPECIFICATIONS

Dimensions and Weight

Table 1-1: Dimensions and weight*

	Depth/in. (cm)	Height/in. (cm)	Width/in. (cm)
Machine alone			
IV Pole extended	14.5 (37)	74.5 (189)	16 (41)
IV Pole down	14.5 (37)	37 (94)	16 (41)
Machine with Cart			
IV Pole extended	23 (58)	88.5 (225)	19 (48)
IV Pole down	23 (58)	54.5 (138)	19 (48)
Weight of Machine	71 lb (32.2 Kg)		
Weight of Cart	35 lb (15.9 Kg)		

* *All dimensions nominal*

Maneuverability and Portability

The CS5+ is provided with a cart that has four caster wheels that ensure maneuverability. The unit may be tipped back on the rear wheels to get over power cords, door sills, and other obstructions. The front two casters may be locked to secure the CS5+ cart in position. The CS5+ can be removed from the cart to allow for easy transport in cars and vans.

There are two different types of carts supplied with the CS5+ system.

Machine Removal

There is a locking mechanism on the back of the cart. Depress the release button on the right of the latch. A handle will pivot outward from the left side of the latch. Pull on the handle to ensure the lock is completely disengaged. To remove the machine from the cart, lift the machine.

Machine Installation

There is a visible locking mechanism on the back of the cart, depress the release button on the right of the latch. A handle will pivot outward from the left side of the latch. If necessary, pull on this handle until it is in the fully open position. Set the machine on the cart and push the latch handle inward until it locks into place.

Fluid Management Systems

The CS5+ is equipped with a pole for hanging saline solution, the anticoagulant solution, the reservoir, reinfusion bag, and transfer packs. The IV pole has a handgrip at the base of the IV pole and contains pigtails for hanging bags. The lower half of the IV pole may be raised and lowered by turning the handgrip at the base of the IV pole counterclockwise, adjusting the IV pole to the proper height, and turning the handgrip clockwise to tighten. To adjust the upper half of the IV pole, turn the small handgrip above the reservoir ring counterclockwise, raise or lower the pole as needed, and turn the handgrip clockwise to tighten.

Hooks and a waste bag weigher are provided on the front of the unit for hanging and monitoring the level in the waste bag.

Processing Speed

Typical processing time is 3 to 5 minutes.

a. **Centrifuge Speed:** 5650 rpm, programmable from 2050 to 5650 rpm in 100 rpm increments. 7000 rpm when utilizing the 70ml bowl.
b. **Pump Speed:** Programmable from 25 to 1000 ml/min in 25 ml/min increments; may be temporarily reset with PUMP SPEED arrow keys from 0 to 1000 ml/min in MANUAL mode and from 200 to 600 ml/min in the AUTOMATIC mode. Maximum speed for 70ml bowl is 300ml/min.
c. The following table shows the factory default settings.

Processing Speeds (in ml/min)

	Automatic	Emergency	Manual
225 ml bowl			
Fill	600[a]	800	500
Wash	500[a]	800	500
Empty/Return[b]	500/300/250	500/300/250	500
Concentrate	450	450	350
125 ml bowl			
Fill	300[a]	400	500
Wash	300[a]	400	500
Empty/Return[b]	400/250/200	400/250/200	500
Concentrate	250	450	350
70 ml bowl			
Fill	125		125
Wash (from FILL)	100		100
Wash (from CONC)	75		75
Empty/Return	100		100
Concentrate	75		75
Sequester (125 ml or 225 ml bowl)			
Draw			60
Empty[b]			400/250/200

[a.] The machine will adjust the pump speed during the automatic FILL mode between 300-600 ml/min (200-300 ml/min for a 125 ml bowl) and during the automatic WASH mode between 250-500 ml/min (200-300 ml/min for a 125 ml bowl) based upon the effluent line sensor readings to optimize the quality of the final product. Pump speed will not adjust with the 70 ml bowl.

[b.] The machine will adjust the pump speed during the automatic EMPTY/RETURN mode in preprogrammed increments to assure optimal performance.

Construction

a. **Cabinet and Cart Materials:** Fabricated sheet metal and cast aluminum.

b. **Control Panel:** Membrane switch technology, environmentally sealed with backlit option keys.

Note: Only Haemonetics disposable sets may be used with the Cell Saver 5+ System; the system will not function properly with other sets.

Machine Symbol Chart

(as per IEC 601–1:88)

Type BF
Class 1 equipment with isolated (floating) applied part providing adequate protection against electrical shock, particularly regarding allowable leakage currents and reliability of the protective earth connection.

Alternating Current

IPX1 **Protection against Dripping Water**

Power Off

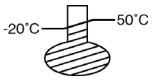
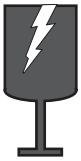
Power On

Protective Earth

Attention (consult accompanying documents)

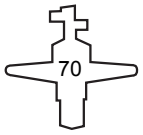
Fuse Symbol

Disposable Packaging Symbol Chart

REF	**Catalog number**
	**Expiration date**
LOT	**Lot number**
STERILE EO	**Contents sterile by exposure to ethylene oxide**
STERILE EO	**Fluid path sterile by exposure to ethylene oxide**
	**Do not reuse**
	**Caution: consult operator manual for instructions**
	**Storage conditions, humidity level**
	**Storage conditions, temperature level**
	**Fragile, handle with care**

Bowl symbol chart

During a procedure, the bowl icon on screen reflects the bowl size currently in use. See below for bowl sizes and corresponding icons.



70 mL bowl

125 mL bowl

225 mL bowl

Primary Power

a. **Electrical Voltage:** 110/220 VAC (±15%), switch-selectable.
b. **Operating Frequency:** 47 – 63 Hz.
c. **Operating Current:**
   - At 110 Vac 2.6 amp, steady state; 4 amp, surge,
   - At 220 Vac 1.3 amp, steady state; 2 amp, surge.
d. **Power Cord:** Detachable 16-foot (4.9m) E-183553/C, #18 low-leakage SJT P-350, <HAR>, VDE tested.
e. The Cell Saver 5+ has UL approval.
f. **Input Fuse Rating:** M2.5 Amperes @ 250 VAC

Environmental Conditions

a. **Operating Temperature:** 10° to 27° Celsius (50° to 80° F).
b. **Humidity:** 95% maximum, noncondensing.
c. **Possible Explosion Hazard** if used in the presence of flammable anesthetics

Storage and Transport Conditions

a. **Relative humidity:** 8% – 80% rh
b. **Temperature:** –20°C to + 50°C

ORDERING INFORMATION

The following is a summary of the List Numbers associated with the Cell Saver 5+ System.

Note: There is no latex present in the fluid pathways of the Haemonetics disposable components in the following list.

List No.	Description
200	Collection Reservoir, 3L, 150 micron filter. Sterile, disposable, for single patient use.
205	Collection Reservoir, 3L, 150 micron filter. Sterile, disposable, for single patient use.
208	Basic Aspiration and Anticoagulation Assembly. Includes double-lumen suction tubing with step-down adapter and tubing stubs. Sterile, disposable, for single patient use.
220	Collection Reservoir, 3L, 20 micron filter. Sterile, disposable, for single patient use.
244	Sequestering Kit. Sterile, disposable, for single patient use.
245	High Speed Reinfusion Bag, 1-liter capacity. Sterile, disposable, for single patient use.
246	High Speed Waste Bag, 10-liter capacity. Sterile, disposable, for single patient use.
260	CS5+ Fast Pack Includes LN 263 Basic Cell Saver 5+ Bowl set, LN 205 Blood Collection Reservoir, LN 208 Basic Aspiration and Anticoagulation Assembly.
260F	CS5+ Fast Pack with Filtered Reservoir Includes LN 263 Basic Cell Saver 5+ Bowl Set, LN 220 Blood Collection Reservoir, LN 208 Basic Aspiration and Anticoagulation Assembly.
261	Basic Low Volume (125 ml) Cell Saver 5+ Bowl Set. Includes tubing harness, reinfusion bag, waste bag, 125 ml centrifuge bowl. Sterile fluid path, disposable, for single patient use.
263	Basic High Speed Cell Saver 5+ Bowl Set. Includes high speed tubing harness, reinfusion bag, waste bag, and 225 ml centrifuge bowl. Sterile fluid path, disposable, for single patient use.

List No.	Description
265	CS5+ Low Volume Fast Pack Includes LN 261 Basic Cell Saver 5+ Bowl Set, LN 205 Blood Collection Reservoir, LN 208 Basic Aspiration and Anticoagulation Assembly.
265F	CS5+ Low Volume Fast Pack with Filtered Reservoir Includes LN 261 Basic Cell Saver 5+ Bowl Set, LN 220 Blood Collection Reservoir, LN 208 Basic Aspiration and Anticoagulation Assembly.
291A	Basic Mini Volume (70 ml) Cell Saver 5+ Bowl Set, Includes tubing harness, reinfusion bag, waste bag, and 70 ml centrifuge bowl. Sterile fluid path, disposable, for single patient use.
2005 110 EP	Haemonetics Cell Saver 5+ System for 110 Vac English Language.

REFERENCES

[1]"Guidelines for Blood Salvage and Reinfusion in Surgery and Trauma," *American Association of Blood Banks, 1993*.

[2]Geoffrey Keynes, ed., *Blood Transfusion. Bristol: John Wright & Sons Ltd., 1949, pp. 15-16*.

[3]Keynes., p. 22.

[4]Blundell, James, "Experiments on the Transfusion of Blood by the Syringe," *Medico-chirurgical Trans 9:56-92, Feb. 3, 1818*.

[5]Highmore, William, "Overlooked Source of Blood-Supply for Transfusion in Post-Partum Hemorrhage," *Lancet, Jan. 17, 1874, p. 89*.

[6]Brzica, S.M. Jr., Pineda A.A., Taswell H.F., "Autologous Blood Transfusion," *Mayo Clinic Proceedings, Vol. 51 (1976), p. 728*.

[7]Telischi, M., "Evolution of Cook County Hospital Blood Bank," *Transfusion, Nov.- Dec. 1974, p. 623*.

[8]Solot, Jerald, A. "Autotransfusion: An Update," *Journal of AOA, Vol. 81, No. 9, (May 1982), p. 618/93*.

Chapter 2

Equipment and Disposable Description

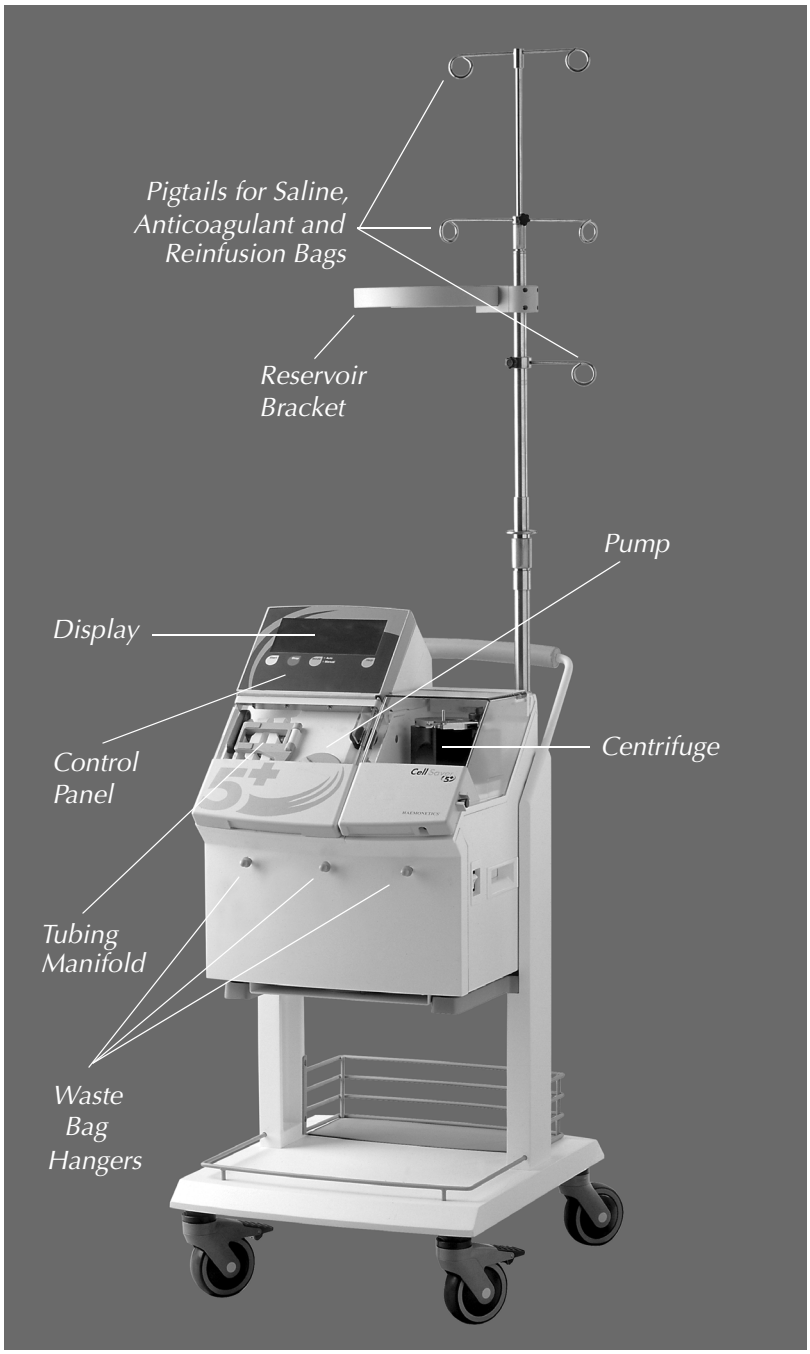


Figure 2-1: Cell Saver 5+ components

GENERAL

This chapter identifies the major components of the Cell Saver 5+ System (CS5+), and explains their intended uses. A general description of the operation of the system is also provided. For detailed setup and operating instructions for the various protocols performed by the CS5+, please refer to Chapters 3 through 6.

The controls and indicators for the CS5+ have been greatly simplified over the previous Cell Saver Systems. This is a reflection of simplified operating procedures and improved automation.

CONTROLS AND INDICATORS

Figure 2-1 shows the CS5+. The control panel consists of a plastic covered key pad section, a backlit key pad section, and the display screen. Only the necessary readouts are illuminated, thus helping the operator to focus on information needed. All control panel components are covered to protect the system from spills and to allow easy cleaning. The control panel is shown in Figure 2-2.

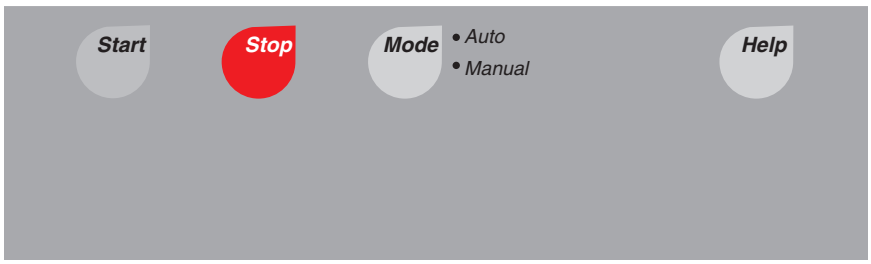


Figure 2-2: Control panel

ON/OFF Power Switch and Fusing

The ON/OFF power switch is located on the right side of the system. This machine is a two-fuse system. The primary fuse is located in the power entry module in the back of the machine. The secondary fuse is internal on the power supply and should only be replaced by trained service personnel.

Display Panel

The display panel of the CS5+ provides important information regarding the functioning of the system. As statistics change, they are updated on the display. For example, should the pump reduce speed from 1000 ml/min to 750 ml/min the readout on the display will change from 1000 to 750.

During normal operation the display is segmented so that the same type data will be displayed in the same area for all protocols. The display is segmented into three main areas: 1. The left section provides general information regarding the state of the system. 2. The right section provides procedure data, mode of operation, and information regarding the programmable parameters. 3. The bottom area of the display is used to provide user prompts. Figure 2-3 shows a typical display.

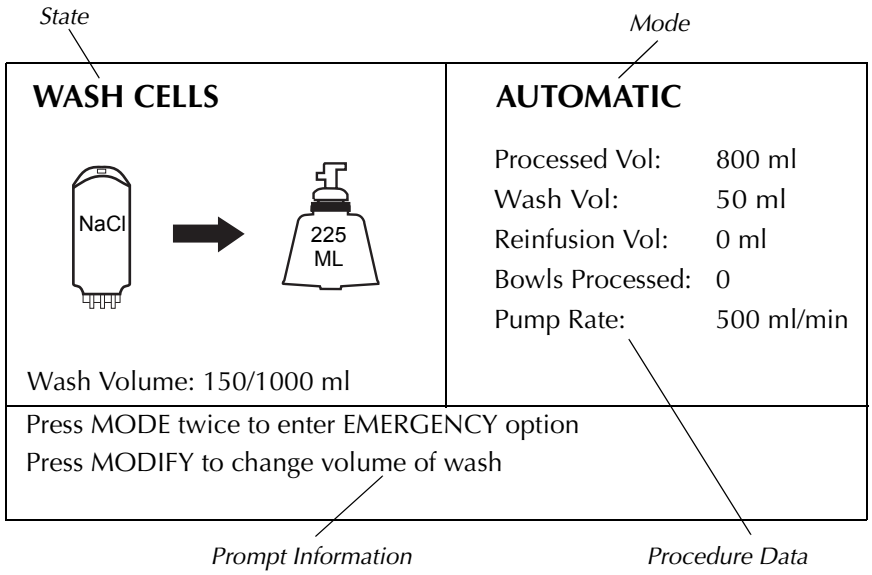


Figure 2-3: Typical display with descriptions

Control Panel

The control panel is divided into two main sections: the Automatic Control Panel and the Manual Control Panel. Only Start, Stop, Mode, and Help are permanently visible as shown in Figure 2-4.

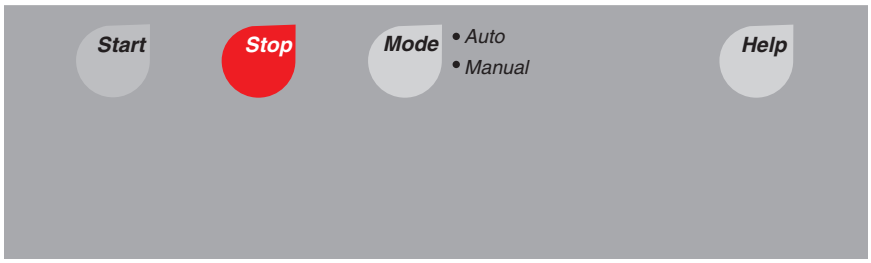


Figure 2-4: Control panel: automatic

The other control keys are backlit when moving into Manual operation or when modifying the preset parameters as shown in Figure 2-5. Following is a summary of the functions of the controls on this panel.

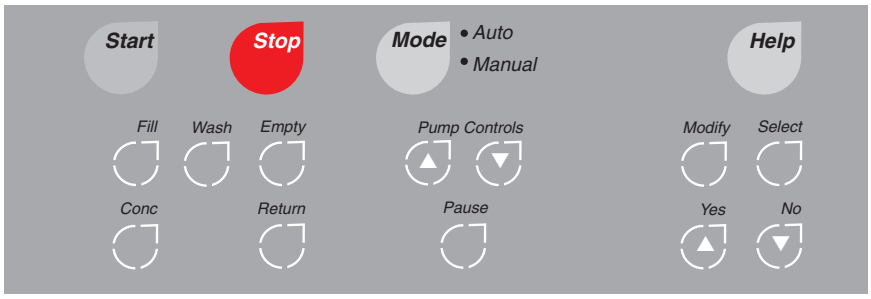


Figure 2-5: Control panel: manual operation

The switches of the control panel are covered with a plastic membrane which can be wiped down for cleaning and disinfecting. Because the switches are sealed, spills have no effect on their operation.

As previously discussed, during automatic operation the control panel only has the four control keys (and appropriate keys lit, that allow the cycle to be advanced). To manually operate the system, the MODE key can be pressed and the additional control keys will illuminate as shown in Figure 2-5.

Definition of Key Purpose and Usage:

The following keys are constantly active; they can be used in either Manual or Auto modes of operation:

START Initiates or resumes processing after the process is stopped or paused. Can be used in either Auto or Manual mode of operation.

STOP Stops the process by stopping the pump and centrifuge and closing all valves.

MODE Switches between Auto and Manual operation and the Emergency Option.

HELP Displays troubleshooting directions and is available to assist the operator through special situations such as error messages. On power-up, HELP provides an abbreviated set-up checklist.

MODIFY Activates/deactivates “modify action” keys.

The following keys are the process state keys:

FILL *Cell Saver:* Pumps fluid into spinning bowl from reservoir or extracorporeal circuit.

Sequester: Pumps whole blood into spinning bowl from a blood source.

CONC *Cell Saver:* Pumps fluid into spinning bowl from product bag. (Supplements Fill—usually selected when bowl is partially full and reservoir is empty.)

Sequester: Pumps fluid into spinning bowl from product bag.

WASH *Cell Saver:* Pumps saline into spinning bowl from saline bag.

Sequester: Not used.

EMPTY *Cell Saver:* Pumps fluid from stationary bowl into product bag or reservoir.

Sequester: Pumps fluid from stationary bowl into product bag or reservoir.

RETURN *Cell Saver:* Pumps fluid from stationary bowl back into reservoir or into extracorporeal circuit. [Alternative to Empty where contents of bowl are pumped back (returned) through "Fill" line (red) instead of (emptied) to product bag.]

Sequester: Not used.

The following keys control the pump:

▲ *Cell Saver:* Raises the pump speed in increments of 25 ml/min to a maximum of 1000 ml/min (maximum of 600 ml/min in Automatic).

Sequester: Raises the pump speed in increments of 10 ml/min to a maximum of 250 ml/min in FILL and CONC and in increments of 25 ml/min to a maximum of 1000 ml/min for EMPTY.

▼ *Cell Saver:* Lowers the pump speed in increments of 25 ml/min to a minimum of 25 (minimum of 200 ml/min in Automatic).

Sequester: Lowers the pump speed in increments of 10 ml/min to a minimum of 10 ml/min in FILL and CONC and in increments of 25 ml/min to a minimum of 25 ml/min in EMPTY.

PAUSE *Pause:* Stops the pump. Does not stop the centrifuge.

The following keys are "modify action" keys:

MODIFY Allows operator to access the modifiable parameters.

▲/Yes Either increases a numerical value, answers "yes" to a yes-no question, or toggles between multiple options.

▼/No Either decreases a numerical value, answers "no" to a yes-no question, or toggles between multiple options.

SELECT Moves down a list of parameters/questions.

Automatic Controls (See Figure 2-4.)

Located directly below the display, the Automatic controls regulate the automatic functioning of the CS5+. The Automatic Controls are as follows:

a. START, as its name suggests, is used to initiate the first cycle of a set of cycles. Also, if the system is in STANDBY, pressing START resumes the process where it was stopped.

b. STOP simply stops the pump and centrifuge and closes all valves. The machine "remembers" which action it was performing when STOP was pressed. Pressing STOP twice enters STANDBY. Pressing START will cause the CS5+ to resume processing in automatic or manual.

c. MODE (Auto/Manual) Pressing this key once while in Automatic operation will move the system into Manual control. The LED will illuminate next to the word MANUAL or AUTO to indicate the mode that the system is in. Also, the available function keys will be backlit and made available for the operator to press. The operator can easily revert to Automatic control by pressing the MODE key to switch back to AUTO processing.
Pressing this key twice within two seconds while in Automatic operation or once when in Manual operation allows the operator to enter an emergency option. A message requesting confirmation to enter the emergency option will be displayed on the screen. If, within five seconds, the operator does not press YES to confirm the emergency option, the CS5+ will revert to the AUTOMATIC mode.

d. HELP assists the user with helpful information as previously discussed.

Manual Controls (See Figure 2-5)

Located below the Automatic Controls on the left, these keys allow the operator to manually run the machine once MANUAL operation is selected by pressing the MODE key. These keys may also be accessed during the AUTOMATIC mode.

Modify Controls (See Figure 2-5)

Located below the Automatic Controls on the far right, these keys allow the operator to modify the set parameters for the given process or permanently. The Modify keys become active during protocol selection, Protocol Setup, or various points during both Automatic and Manual operation.

MAJOR COMPONENTS

The CS5+ consists of two groups of components: the machine and the disposable. The machine controls the fluid pathway provided by the disposable. The machine includes a centrifuge, peristaltic fluid pump, pinch valves, and various sensors. A cart is provided with the system for added maneuverability and for setting the system at the proper working height.

Hardware

A description of each major component follows:

The CS5+ tubing manifold is keyed to fit onto the deck in only one way. It cannot be loaded incorrectly.

Valves

There are three valves which occlude the three color-coded lines of the harness. In the Automatic mode, the CS5+ controls the opening and closing of the valves. The function of each valve is as follows:

a. RED Line Valve: Opens the pathway to the blood source, usually a reservoir or extracorporeal circuit.
b. YELLOW Line Valve: Opens the pathway to the wash solution.
c. BLUE Line Valve: Opens the pathway to the reinfusion bag.

Pump

Fluids are moved in and out of the centrifuge bowl by a 3-roller, occlusive pump. At its maximum speed it is capable of a flow of 1000 ml/min.

Air Detector

This device ultrasonically detects air in the pump tubing leading to the centrifuge bowl. During the FILL or CONCENTRATE (CONC) modes, air bubbles are detected when the source of blood to be processed is exhausted. If, during WASH, 90% or more of the necessary wash volume has been pumped, air bubbles caused by emptying the wash solution container will advance the CS5+ to the next mode, usually EMPTY.

If the air detector senses air in the line, prior to at least 90% completion of the programmed wash volume, the display panel will print “SALINE BAG EMPTY, REPLACE SALINE BAG,” for the operator’s information.

The air detector is also used during the EMPTY and RETURN modes to determine when the centrifuge bowl is empty.

Note: The air detector is disabled in the manual mode for the FILL, CONCENTRATE, and WASH modes, but not for EMPTY or RETURN.

Centrifuge Well (See Figure 2-6.)

The centrifuge that is installed in your CS5+ System utilizes six mechanical clips on the centrifuge chuck which secure the bowl base as the bowl is snapped into place. No tools are necessary to load the bowl.

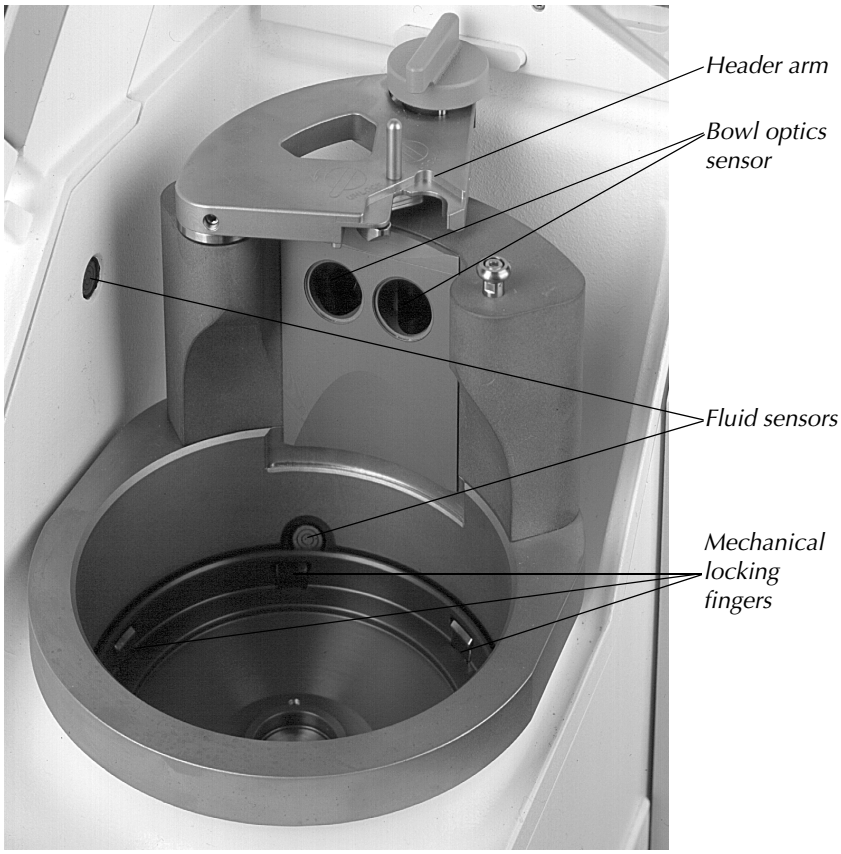


Figure 2-6: Centrifuge well with bowl optics sensor(s) and header arm

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

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

Bowl Optics Sensors

Photoelectric bowl optics sensors mounted in the centrifuge well advance the machine from FILL to WASH (or CONC to WASH) when the RBCs reach a predetermined level within the bowl.

Note: The Bowl Optics sensors ARE disabled in the manual mode and when using the 70 mL bowl.

Fluid Sensors (See Figure 2-6)

The fluid leak sensors are mounted in the centrifuge well. These sensors stop the pump and the centrifuge if fluid comes in contact with the fluid sensor surface in the unlikely event of a bowl leak. One sensor is located on the side of the centrifuge well at the level of the bowl seal and the other is located below the bowl optics sensor, near the base of the centrifuge well.

Waste Bag Weigher (See Figure 2-7)

The waste bag weigher checks the weight of the fluid in the waste bag, alerting the operator when it is almost full and also when it is full. In the Automatic mode, the message "EMPTY WASTE BAG" is displayed when approximately eight liters of fluid are in the bag. In both the Automatic or Manual modes, the message "WASTE BAG FULL" is displayed when approximately nine liters of fluid are in the bag. In the Manual mode the waste bag weigher can be turned off by pressing the MODIFY key and going into the setup screen.

Clamped Line Sensor

Figure 2-7: Clamped line sensor

The clamped line sensor monitors pressure levels in the blue and red lines during EMPTY and RETURN. If the clamp on the bag or reservoir is inadvertently closed, the clamped line sensor will cause the pump to stop and the following message will be displayed.

CLAMPED LINE DETECTED
Check for kinks or occlusions in tubing.
Ensure clamp on reinfusion bag and reservoir are open.

Effluent Line Sensor

The effluent line sensor monitors the quality of the bowl effluent. During FILL and WASH it adjusts pump speed to reduce red cell spillage. It also trips the system to EMPTY once the proper effluent quality has been reached after a "minimum" wash volume has been introduced. The effluent line sensor is disabled during the Manual mode and the EMERGENCY option.

During 70mL bowl operation, the effluent line sensor detects the RBCs and advances the machine from FILL to WASH modes appropriately, in addition to monitoring effluent line quality during WASH (as described above).

The operator has the option of disabling the pump regulation function of the effluent line sensor when using the 125ml or 225ml bowls. This is accomplished by pressing the MODIFY key and going into the setup screen and selecting OFF for the Pump Regulation option. When this option is selected, the message, "PUMP REGULATION OFF" will flash on the screen and the effluent line sensor will not adjust the pump speeds. However, when Pump Regulation OFF mode is selected, the effluent line sensor will still monitor effluent line quality in WASH mode and extend washes appropriately (as described above). This option is available on a per procedure basis only.

Warning: Red cells may be lost into the waste bag as a result of choosing the pump regulation off option.

Reservoir Level Sensor

The Reservoir Level Sensor monitors the weight of the reservoir throughout the procedure to estimate the volume of fluid in the reservoir.

The CS5+ is equipped with a reservoir level sensor that, in the Automatic mode, is designed to trip the system into the FILL mode when a predetermined amount of solution has been suctioned from the field. The reservoir level sensor does not function in the Manual mode. The preset trip point is approximately 800 ml of fluid in the reservoir (400ml when using the 70 ml bowl) for initial fill of the bowl and approximately 400 ml (200ml for 70 ml bowl) to restart a fill of the bowl. The operator can modify the trip points to accommodate for different situations or turn the reservoir level sensor on or off by pressing the MODIFY key and going into the setup screen while in the Automatic mode.

Disposables

A variety of disposables are available for use with the CS5+. Chapter 4 explains the available disposables in detail. The purpose of this section is to give a general understanding of the uses and operating characteristics of the disposables rather than to provide specifications:

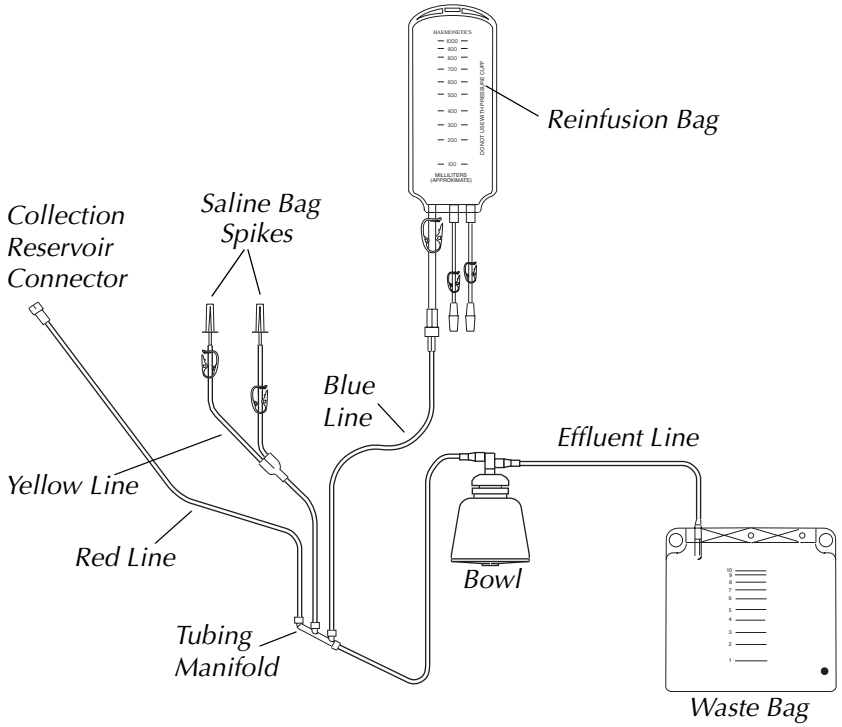


Figure 2-8: Cell Saver 5+ disposable harness with Latham bowl

Harness

Figure 2-8 illustrates the harness used with the CS5+. The harness consists of three lines:

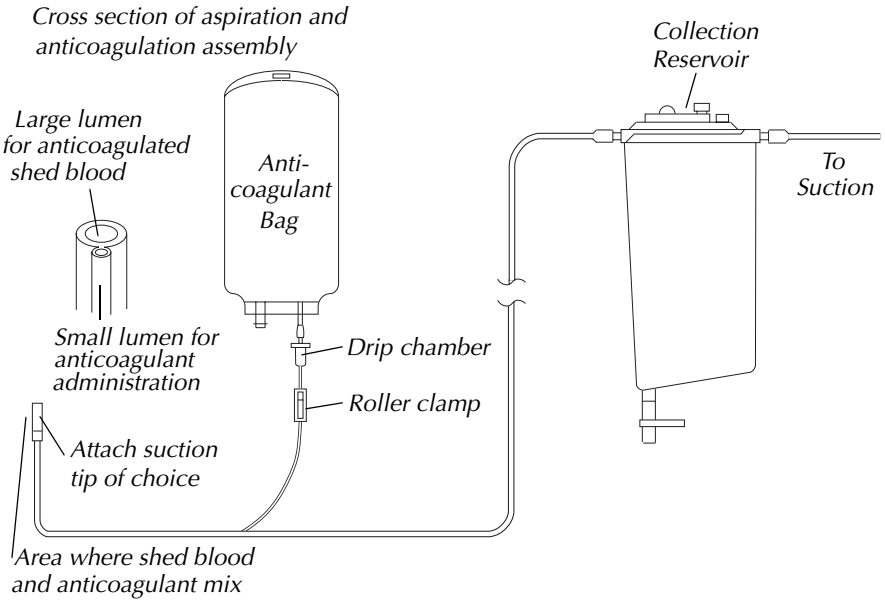
1. the yellow line from the wash solution,
2. the red line from the unprocessed blood source,
3. the blue line to the reinfusion bag.

All three lines pass through valves on the CS5+. The three lines are joined at a tubing manifold (see Figure 2-8). A clamped line sensor is located under the blue line to warn of occluded lines during EMPTY and RETURN. After the junction, the single line passes through the pump and then the air detector. After passing through the air detector, the single line enters the centrifuge well through a slot in the rim where it is held down by the cover. Once inside the well, the line is attached to the inlet port of the bowl.

The effluent line is attached to the outlet port of the bowl and exits the centrifuge through the effluent line sensor and is then connected to the waste bag.

Receptacles

Every CS5+ disposable setup must be equipped with a waste bag and a reinfusion bag. There must also be a source of unprocessed blood which may be either a collection reservoir or an extracorporeal circuit. Figure 2-8 identifies the receptacles used in a typical set up.



Anticoagulant and collected blood are mixed in a small chamber at the end of the A&A Assembly where it connects to the suction tip.

Figure 2-9: Reservoir and A&A line setup

Collection Disposables

An Aspiration and Anticoagulation (A&A) Assembly provides the two-lumen tubing and a small mixing chamber which is attached to any suction tip. Anticoagulant is drawn into the mixing chamber by suction. Blood and anticoagulant are combined in the chamber and then pass up the tubing to a collection reservoir such as the LN 205 Collection Reservoir in Figure 2-9.

See page 1-16 for a list of disposable accessory devices that may be used with the Cell Saver 5+ System.

Centrifuge Bowl

The central part of the disposable is the centrifuge bowl. It is in this bowl that the RBCs are separated, concentrated, and washed. As indicated in Figure 2-11, the bowl consists of two subassemblies: an inner one which remains stationary and an outer one which rotates. The outer subassembly rotates primarily at 5650 rpm (7000 rpm for 70 ml bowl), and provides the chamber in which centrifugal processing is accomplished. The inner subassembly provides inlet and outlet ports. Although the shape of the various bowls may differ, the fluid pathway is identical.

The two subassemblies are joined with a rotary seal which forms a barrier between the inside and outside of the bowl. The seal's effectiveness may be lost if the bowl is incorrectly mounted in the chuck. Fully seating the bowl in the chuck will assure proper alignment.

Warning: It is important to make certain that the outlet passage system is free of any restrictions to flow Prior to initiating flow in the bowl. If the clamp on the outlet port is inadvertently closed, the blood being processed may be compromised by friction or heat, rendering it inappropriate for reinfusion. (See Chapter 3 for more information.)

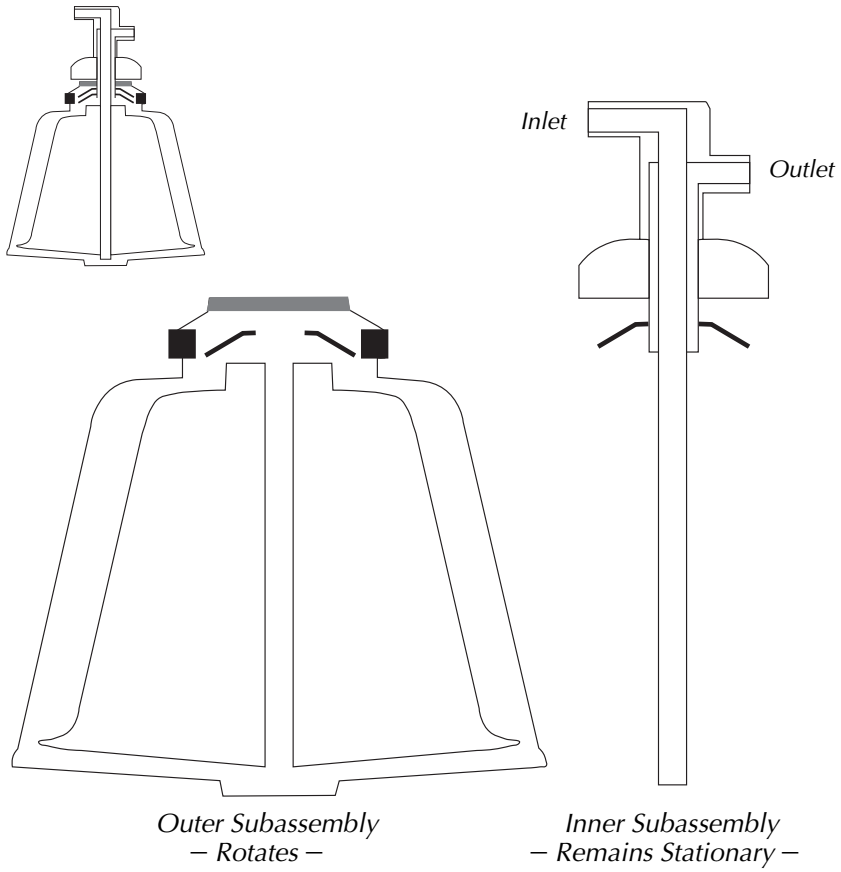
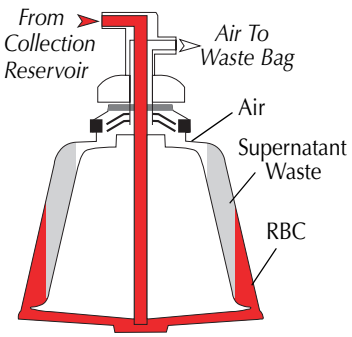


Figure 2-10: The centrifuge bowl and subassemblies

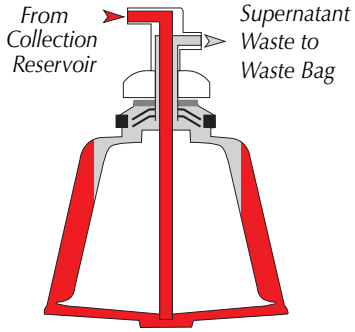
How the Bowl Works

Figure 2-11 illustrates the operation of the bowl through the FILL-WASH-EMPTY modes. Operation is identical for the 125 ml, 225 ml and 70 ml bowls. When blood solution is pumped into the spinning bowl through the inlet port, the red cells are centrifuged outward toward the bowl's perimeter. The lighter, lower density supernatant moves towards the bowl's core. When the bowl overflows,

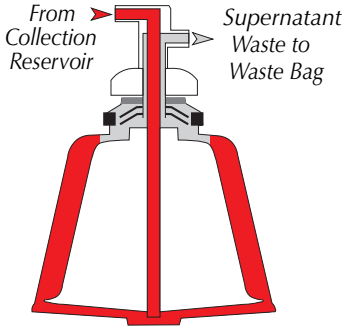
supernatant is forced through the outlet port. The hematocrit of blood in the bowl increases as more blood solution is pumped in and the supernatant is forced out.



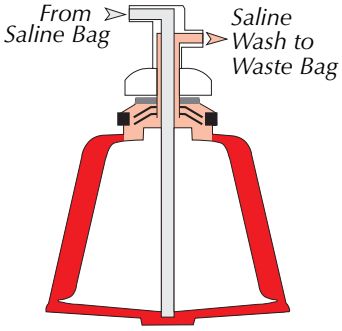
1. In FILL, Blood is pumped in; separation begins as the bowl spins.



2. The supernatant wastes overflow; RBCs stay in the bowl.

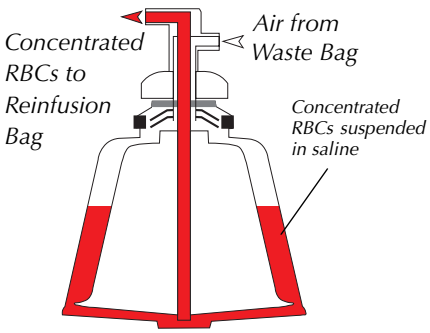


3. As overflow continues, the Hct in the bowl increases to approximately 50%.



4. In WASH, saline circulates through the RBC layer and displaces the waste.

5. The overflow runs clear. Free hemoglobin and anticoagulant are in the waste bag.



6. In EMPTY, the bowl stops spinning. Washed, concentrated RBCs are pumped to the reinfusion bag.

Figure 2-11: How the bowl works

Warning: Prior to pumping blood through the CS5+ 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.

Anticoagulant recommendations presented in this manual are intended as guidelines only (refer to Chapter 3 for recommendations). For hypercoagulable patients, the operator may find it necessary to increase the anticoagulant dosage to prevent clotting.

When the bowl is used for cell washing, the volume of red cells gives a cell/ supernatant interface as shown in Figure 2-12. Filling the bowl to the appropriate level as shown will give an hematocrit of approximately 50% for the washed cells.

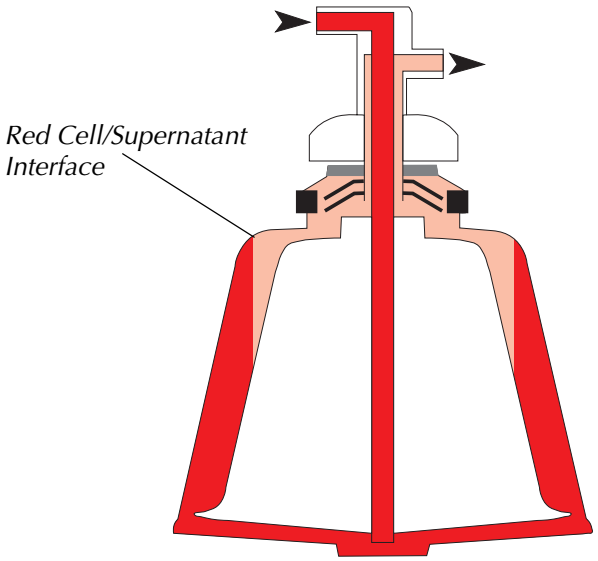


Figure 2-12: Red cell / interface

The hematocrit may be increased by filling the bowl until the red cell interface is closer to the center of the bowl, although manually regulating the interface is not advised. Conversely, a lower hematocrit will result if filling is terminated before the red cell interface reaches the level shown in Figure 2-12. Under Automatic control, the interface is controlled by the bowl optics sensor to produce consistently good results.

In general, filling the bowl to a lower hematocrit will necessitate a higher volume of wash solution (two times the standard wash volume) to dilute the supernatant and achieve an adequate wash out.

Emptying red cells from the bowl is accomplished by bringing the centrifuge to a complete stop, and then reversing the flow in the pump tubing. The centrifuge may briefly rotate in both directions to facilitate the removal of the red cells from the bowl.

GENERAL OPERATION

This section provides a general overview of how the CS5+ works. For detailed instructions for each protocol performed by the CS5+, consult Chapters 5 – 7.

Note: Note that the Cell Saver 5+ System is programmed to produce consistently good results in most procedures. Carefully consider this prior to making any changes to the original program or running the system in manual.

Cell Saver 5+ operation is simple. The level sensor on the reservoir bracket will automatically initiate a FILL mode when the predetermined levels are detected.

Physical setup involves installing the harness (which consists of the tubing through which the fluids will be collected, and later enter and exit the Cell Saver System), hanging the appropriate solutions for washing and anticoagulating the blood, and installing the bowl in the centrifuge well.

In the MODIFY mode the operator can modify some operational parameters during Protocol Setup and during various stages of processing. But if no alterations are made, the CS5+ automatically detects what size bowl is being used during either the loading sequence or the first FILL mode.

Blood Collection

The collection of blood is the simplest of the Cell Saver System's tasks. The blood is collected into a collection reservoir (such as the LN 205) through an Aspiration and Anticoagulation (A&A) Assembly (such as the LN 208). See page 1-16 for a list of the disposable accessory devices that may be used with the device.

The A&A Assembly described earlier is attached to a suction tip. Mixing of anticoagulant and blood is accomplished in the small mixing chamber of the tubing connector. This mixing chamber is located behind the handle of the suction tip, which is used to remove blood and fluids from the wound. Using the A&A Assembly, the operator should aspirate with intermittent breaks in suction. The blood and fluids are collected in the collection reservoir

Warning: Anticoagulant must be added to normal saline solution, not sterile water or other irrigating solution.

It is important that shed blood suctioned from a patient be collected in a sterile container such as the LN 205 Collection Reservoir, even if there is some doubt that the amount collected will be sufficient to warrant processing by the Cell Saver System. Once the blood is collected in the reservoir, it may be processed if desired, or it may simply be discarded. Using the reservoir leaves open the option to process.

Filling the Centrifuge Bowl

Once the disposable has been loaded the CS5+ displays a current setting screen. The operator may choose to restore default settings and then enter STANDBY mode. The CS5+ then automatically starts a FILL cycle when the predetermined level of fluid has been collected into the reservoir (the default level is 800 ml; the operator can press START a second time to initiate a FILL cycle before this level is reached). At that point the centrifuge bowl begins spinning, and the red line valve opens. The pump begins to FILL the bowl by transferring fluid from the reservoir while keeping track of how much fluid it is pumping. Note that on the first cycle (only) of a procedure, the saline line will automatically be primed before the red line valve opens.

Cell Separation and Concentration in the Bowl

The spinning of the centrifuge traps the heavier and denser red blood cells and causes them to move toward the outer walls of the centrifuge; red blood cells form the outer layer while the supernatant floats inward toward the core of the bowl. The lighter fraction is forced out the effluent (exit) tubing from the bowl and into the waste bag.

Red Cell Washing

After the process described above has been completed, the optical RBC sensor located in the centrifuge well will detect that the RBC content of the bowl is sufficient (approximately 50% hematocrit) to warrant washing. When utilizing the 70 ml bowl, the effluent line sensor detects the full bowl.

The optical RBC sensor (or effluent line sensor for the 70 ml bowl) will cause the red fill line to be closed, and the yellow wash line to be opened, allowing wash solution to enter the bowl and wash the RBCs. Washing the RBCs further removes unwanted components such as cell stroma, free hemoglobin, activated clotting factors, platelets, and anticoagulant.

Warning: Normal saline is the recommended wash solution for use with the Haemonetics Cell Saver 5+.

At the start and finish of the WASH mode there is a brief “switching” of the valves that the operator may notice. At the start of the WASH mode, the blue line valve opens for one pump revolution so that the few milliliters of fluid that may have entered this line during the FILL mode will be drawn out (and not sent to the reinfusion bag).

At the end of the WASH mode, just before the system enters the EMPTY or RETURN mode, the red valve opens for two pump revolutions, and then closes while the blue valve opens. The two pump revolutions force any wash solution left in the line into the red FILL line where it will be returned to the bowl and eventually sent to the waste bag during the next FILL mode. If this wash solution was left in the line it would be sent to the reinfusion bag where it would dilute the end product.

In the Automatic mode the wash volume is programmable from 750 - 3000 ml (500 - 3000 ml for a 125 ml bowl, 300 - 3000 ml for a 70 ml bowl). The recommended wash volume for a 225 ml bowl is 1000 ml(750ml for a 125 ml bowl and 300ml for a 70 ml bowl).

Washing Partial Bowls

In general, filling the bowl to a lower hematocrit will necessitate a higher volume of wash solution to achieve adequate washout. 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, two times the normal wash solution (usually 2 x 1000 ml) is needed.

Emptying the Bowl

After the minimum volume of wash solution has been introduced and when the effluent line sensor detects adequate washing, the wash line is closed and the reinfusion line is opened. The pump then reverses direction and pumps concentrated RBCs suspended in wash solution from the bowl to the reinfusion bag.

The above cycle, FILL-WASH-EMPTY, is repeated as often as blood loss requires. The Reservoir Level Sensor will initiate additional cycles as blood begins to be collect again reaching the predetermined levels.

Chapter 3

Safety and Patient Care Precautions

GENERAL

Chapter 3 provides general information on Safety and Patient Care Precautions for the Cell Saver 5+ System (CS5+), and discusses parameters that affect processing times.

SAFETY AND PATIENT CARE PRECAUTIONS

The following paragraphs outline precautions that must be taken to ensure safe operation of the CS5+.

Storage and Handling of Disposables

Many plastics are sensitive to chemicals such as solvents, refrigerants, and detergents. Under particularly adverse conditions of exposure to solvent vapors, the mechanical properties of plastics may be seriously degraded.

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

In managing the inventory of stored disposables, apply the first-in, first-out (FIFO) technique to minimize the length of storage for any unit.

Warning: Store all disposables in a dry, well-ventilated area free from exposure to chemical vapors. Avoid contaminating the surface of disposable plastic components with chemicals by making sure that hands or gloves contacting the plastic surface are clean and dry.

Flammable Locations

The CS5+ is intended to be used in locations which are free of flammable gases and vapors.

Warning: The Cell Saver 5+ System should never be used in the presence of flammable agents.

Note: Oxygen is nonflammable. Refer to NFPA No. 56A, pages 14 and 76.

Electrical Shock Hazards

Inside the cabinet of the CS5+ there are various electrical terminal strips and other components. Personal contact with any of these components while the power is connected could result in electrical shock. Thus, the panels should not be removed without first turning off and unplugging the machine.

Warning: Have leakage current tested routinely.

Leakage current is a primary indicator of electrical shock hazard due to personnel making contact with any exposed portion of the equipment. Each instrument is carefully checked during final inspection to verify that leakage current is less than 300 microamperes @ 120V and 500 microamperes @ 240V.

The owner should have a leakage current test performed routinely to ensure that the machine continues to qualify under the 300 microampere standard. Particular attention should be given to leakage current after an event such as a saline spill or a major voltage surge in the house electrical system.

In view of the high conductivity of electrolytes, always avoid touching any portion of the system with wet hands. Always work with clean, dry hands.

Rotating Machinery

It must be recognized that even small, rapidly rotating parts have enough dynamic energy to cause severe injury if any part of the person or clothing gets caught in them. As a safety feature, the CS5+ is equipped with a trip mechanism that stops the centrifuge if the cover is open.

Warning: Persons operating this equipment or working nearby should take the standard precautions applicable to all rotating machinery.

Communicable Disease

Despite the application of all available tests to screen for communicable disease such as hepatitis, HIV, or syphilis, there is always the risk that the blood being processed is infected.

All blood spills should be cleaned immediately pursuant to those policies and procedures dictated by the medical facility's Infection Control Plan, as legally required by the OSHA Blood Borne Pathogen Standard.

When any Haemonetics product (equipment or disposables) which has been used during a procedure is returned to Haemonetics for any reason, the customer must decontaminate and repackage the product in compliance with the medical facility's Infection Control Plan and U.S. Department of Transportation regulations for interstate shipping of blood contaminated products.

Restrictions to Flow

Warning: No restriction to flow can be permitted in the effluent line.

If the clamp on the outlet port is inadvertently closed, pressure will build up in the processing chamber to such an extent that the rotary seal will be raised like a safety valve to release pressure. This will result in the loss of the pocket of trapped air and wetting of the rotary seal faces with supernatant. Depending upon the nature of the supernatant, the functional characteristics of the rotary seal may become altered. Heating and wear effects may become quite noticeable, and under this circumstance, the contents of the bowl cannot be considered appropriate for reinfusion

Warning: Avoid blocking any tubing carrying blood from the pump. A buildup of pressure in this tubing can result in the wide dispersal of blood.

Observe the waste bag to verify that the accumulation of air in the air/waste bag is not being prevented by either a flow restriction or an air leak.

Twists and Kinks in Tubing

A careful recheck of the mounted harness should be carried out to make certain that each section is in the correct position on the machine, and that all tubes are free of twists or kinks that would prohibit fluid flow. It is particularly important that no occlusion remain in the tube between the bowl and the reinfusion bag when blood is being pumped out of the bowl. Working the pump against a severe flow restriction results in high levels of hemolysis with high levels of plasma hemoglobin. (See the warning on plasma hemoglobin which follows.)

Plasma Hemoglobin

Working the blood pump against a severe flow restriction may cause hemolysis. Since the presence of free hemoglobin in the reinfusion bag is not readily apparent, one should watch for some other indication of abnormal operation. A restriction that will cause hemolysis may also cause a reduction in flow rate, which in turn, could result in an abnormally long time to empty the bowl.

The CS5+ is programmed to detect abnormally long EMPTY and RETURN modes, and to notify the operator by displaying a warning. See See “Appendix C: Machine messages/troubleshooting” on page APP-8.

Continuous Aspiration

Continuous aspiration of profuse bleeding without breaks in suction can cause electrical interference. If the Cell Saver 5+ is in FILL mode (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 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 operator aspirate with intermittent breaks in suction.

Overheating

Overheating of the centrifuge, which might be injurious to red cells in the nearby passageways, can occur as a consequence of defective bearings. It is recommended that the operator feel the centrifuge well with his/her hand to detect any evidence of overheating each time a bowl is removed at the end of a procedure. If any portion of the upper surface of the chuck is found to be above 37°C (98.6°F), the machine should be serviced before further use.

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

Red Cell Spillage

Under normal conditions there should be little or no red cell spillage. The effluent line sensor should mitigate any spillage. During the WASH mode, two conditions may especially result in red cells spilling over into the waste bag:

1. Overfilling of the bowl during manual processing.
2. Excessive flow rate of saline solution due to operator reprogramming of parameters.

Warning: Too low a flow rate will give a poor wash due to insufficient turbulence and mixing in the RBC layer.

Managing the Inventory of Air

The disposable bowl, as received from the factory, is full of sterile air. During each recovery mode, air is passed over into the waste bag while the bowl is filling, and is returned from the waste bag during the emptying of the bowl. It is important to permit this air to return to the bowl from the waste bag to avoid a negative pressure in the bowl during emptying.

Note: If the waste bag fills and must be either changed or emptied, this must be carried out while the bowl is empty (and filled with air). The waste bag may be partially emptied at any time as long as the fluid level in the bag is not below the waste bag drain port.

Pressure Reinfusion

Warning: Do not use a pressure cuff or any other mechanical device with the Cell Saver 5+ System. Pressure reinfusion can result in the fatal infusion of air into the patient.

The user will find that gravity reinfusion of washed cells is accomplished more rapidly than infusion of the usual unit of allogeneic, concentrated cells. This is because red cells suspended in saline are of lower viscosity, and because washed cells are at room temperature.

The blue reinfusion line comes primed with 40 ml of sterile air from the factory. At the first EMPTY mode this air is sent into the reinfusion bag; therefore, DO NOT PRESSURE REINFUSE.

Should it become necessary to remove air from the reinfusion bag, this may be accomplished by closing the clamp on the line between the reinfusion bag and the patient, inverting the reinfusion bag, and opening one of the transfusion line clamps on the bag and squeezing the bag to remove its air.

Another method of transfusing the washed autologous red cells is by transferring the blood from the reinfusion bag to a secondary transfer pack. The air is burped from the secondary transfer pack into the reinfusion bag. The transfer pack is sealed and given to the anesthesiologist for infusion to the patient. This method of infusing the washed autologous red cells is helpful if the machine is located at a distance from the patient and direct reinfusion of the blood is not possible.

Depletion of Clotting Factors

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

Contraindications for Use

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. Refer to Appendix A for a chart of substances, effects, and recommended actions.

Warning: The use of reinfused blood from the Cell Saver 5+ 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.

Anticoagulant Use

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. A drip rate of one drop per second is generally adequate.

FACTORS AFFECTING PROCESSING TIME

Cell Salvage

The time required to process a centrifuge bowl of salvaged blood is dependent upon the following factors:

- Salvaged blood hematocrit
- Bowl volume
- Bowl filling rate
- Wash volume
- Wash flow rate
- Empty flow rate

All these factors combine to determine the total processing time for any cell salvage system. The CS5+ 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.

Sequestering

Typical processing times for performing the sequestering procedure on the CS5+ is 25 – 40 minutes. Actual time and results may vary depending on individual variability in vascular access, and the patient's tolerance to the sequester procedure, surgical condition, height, weight, hematocrit and platelet pre-count.

Chapter 4

Setup Procedures for Cell Salvage

GENERAL OPERATION

Chapter 4 provides detailed setup procedures for the Cell Saver 5+ System (CS5+) and required disposable components. The following sections describe the basic setup regardless of how the system will be operated for a Cell Saver procedure.

Note: Machine should be powered on and given an opportunity to complete the self-test prior to loading disposable. The LOAD DISPOSABLE screen appears after the SELF-TEST is complete.

SETUP

Power On Procedure

When ready to begin processing, or to install disposables using the HELP function, press the POWER ON switch located on the right side of the CS5+.

If the machine has been restarted within the past two hours, the CS5+ gives you the option of saving information, as shown on the following screen:

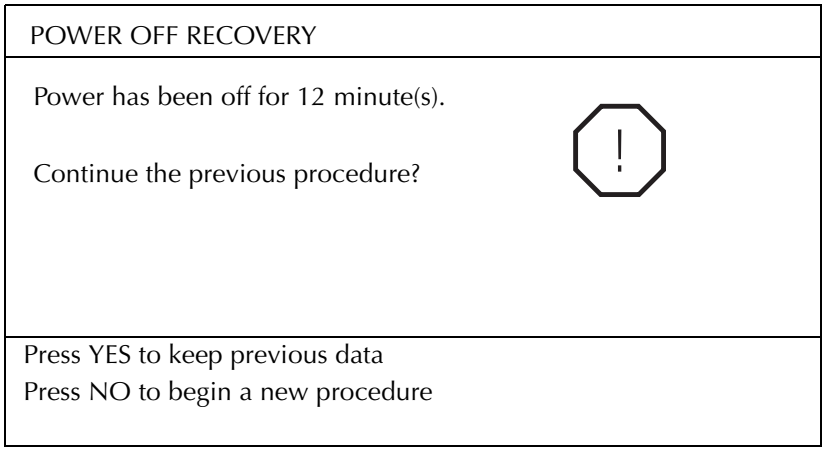


Figure 4-1: Power OFF recovery

Press YES if you would like to retain the data from before the unit was turned off. Press NO to start a new procedure.

The unit then goes into self-test to insure that all the functions are operating before the unit is allowed to be used in a procedure. A SELF-TEST screen will be displayed indicating the stage of self-test completion:

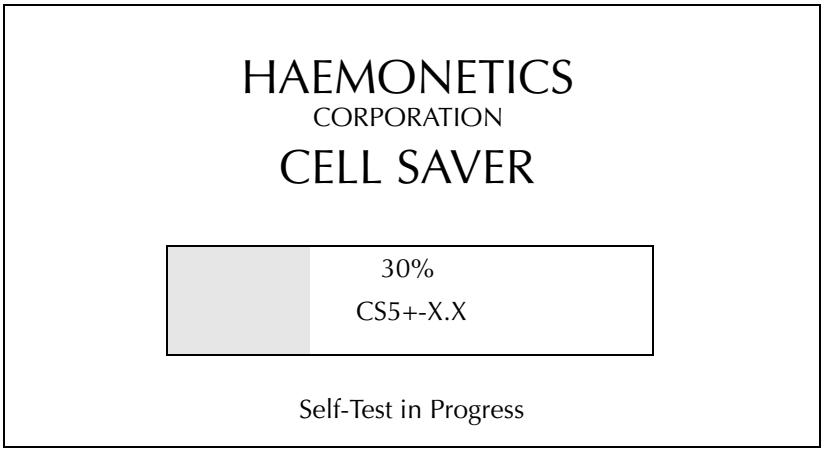


Figure 4-2: Self-Test Display

X.X indicates the current revision of software installed on the machine.

If a fault is found an appropriate message with actions will be displayed:

SELF TEST	**NOTICE**
UNEXPECTED SENSOR READING Waste bag weigher	
To retry the test, press YES To proceed in MANUAL mode, press MODE	

Figure 4-3: Self-Test Failure Screen

Note: Do not load disposables until the self-test is complete.

After the system self-test the display will change to the following message:

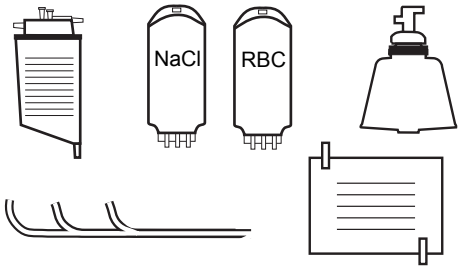
LOAD	**DISPOSABLE**
	
When disposable is loaded, press START.	

Figure 4-4: Installing the Cell Saver Disposables

Installing the Cell Saver Disposables

Pressing the HELP key provides abbreviated setup instructions. The following paragraphs elaborate on these instructions.

Note: The setup instructions provided by the HELP key are merely reminders and are not intended to serve as a substitute for formal Haemonetics training on the use of the CS5+.

1. Prepare the Collection — "Standby"
   - Install a collection reservoir and close the reservoir drain clamp.
   - Open the Aspiration and Anticoagulation set using aseptic technique. Pass the sterile inner wrapped line to the sterile field. In the sterile field, attach a plastic suction wand.

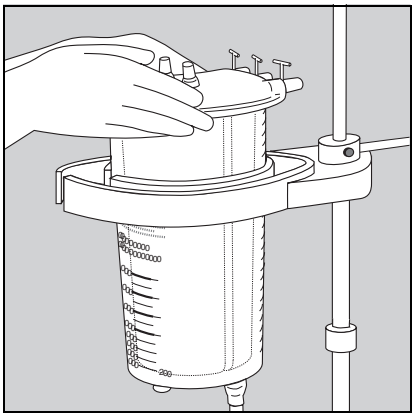


Figure 4-5: Install Collection Reservoir

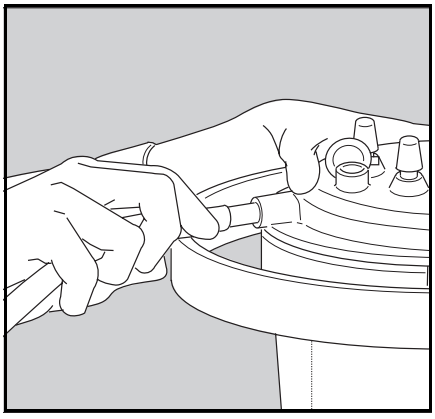


Figure 4-6: Connect anticoagulation and aspiration set to reservoir

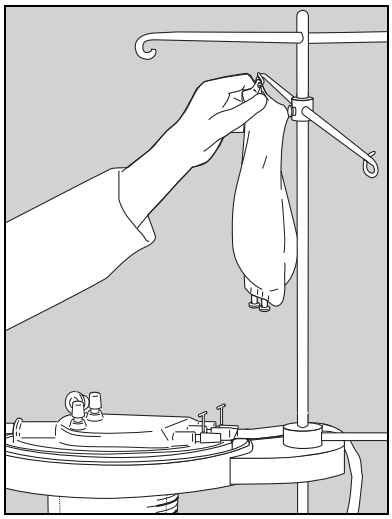


Figure 4-7: Hang the anticoagulant solution from the IV pole

- Connect the Aspiration and Anticoagulation set to the reservoir. Attach suction source to reservoir and **set suction at a minimal acceptable flow rate (under 200 mmHg).** Close the clamp on the anticoagulant IV drip line.

Warning: When using a vacuum source, vacuum greater than 200 mmHg may cause hemolysis.

- Hang the anticoagulant solution from the IV pole and then aseptically insert the spiked end of the drip chamber into the anticoagulant solution. Be sure the bag is properly labeled as anticoagulant.

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 for anticoagulant to blood entering the reservoir by adjusting the roller clamp on the anticoagulant line to approximately 1 drop per second.

Note: 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. A drip rate of one drop per second is generally adequate.

- Reopen the clamp on the anticoagulant drip line to allow full flow of anticoagulant solution. Allow approximately 100 ml of anticoagulant to flow into the collection reservoir to adequately prime the filter/defoamer media, and adjust to desired drip rate. (Open clamp on the reservoir drain only after the entire CS5+ disposable set has been installed and you are ready to process blood in the CS5+.)

2. Ready the Machine and Bowl Disposable.
   - Open the fluid deck cover, pump lever, and manifold door. Open the centrifuge cover by pulling the grey/blue knob on the right side of the cover and opening the header arm.
   - Peel back the protective lid on the tub.
3. Install the Bowl
   - Lift the bowl out of the tub, center and place it firmly into the centrifuge well or into the white centrifuge adapter ensuring the red indicator lines are visible (70m ml bowl). Push the bowl (or adapter) down and snap into place. Ensure that the lower bowl port points to the right of the machine.

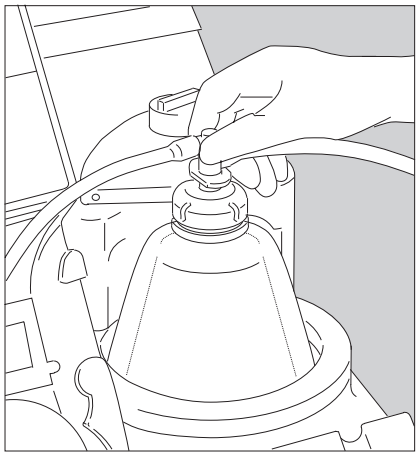


Figure 4-8: Install Bowl

   - Swing the bowl arm clockwise into place, and secure the bowl header by turning the locking knob from 8 o'clock to 12 o'clock.
   - Manually spin the bowl to ensure proper seating and level rotation.

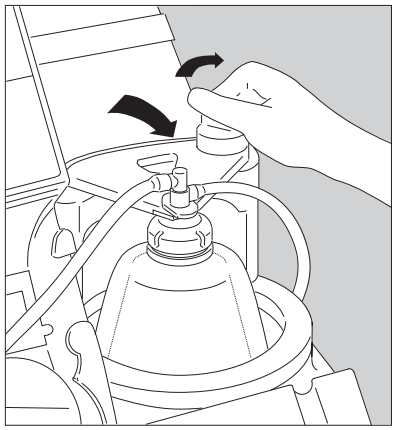


Figure 4-9: Secure Header Arm

- Thread the effluent tubing through the effluent line sensor. Be sure that the tubing is threaded deep into the effluent line sensor notch.

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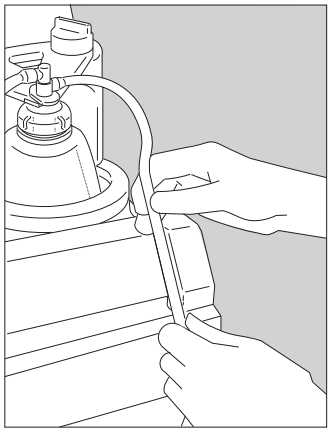


Figure 4-10: Thread Tubing through Line Sensor

4. Hang the Bags
   - Hang the reinfusion bag on the IV pole. Close the two small clamps on the bag. Ensure that the large clamp is open and the bag is securely connected to the blue line.

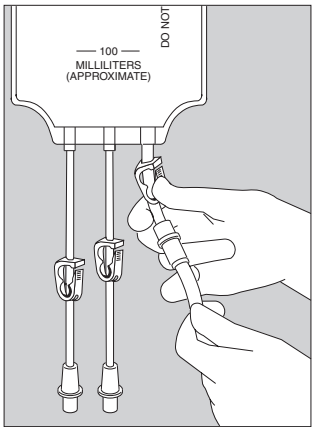


Figure 4-11: Hang Reinfusion Bag; Check Connection to Blue Line

- Hang the waste bag on the pins on the front of the machine. Ensure that the waste bag is securely connected to the effluent line and the drain port is completely closed.

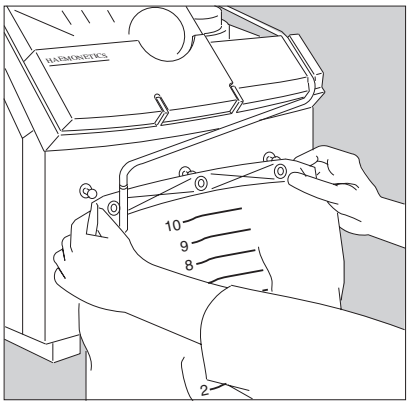


Figure 4-12: Hang Waste Bag and Check Connection to Effluent Line

5. Install the tubing harness.
   - Floss the tubing through the air detector.
   - Thread the pump tubing around the pump.
   - Place the tubing manifold in the slots.

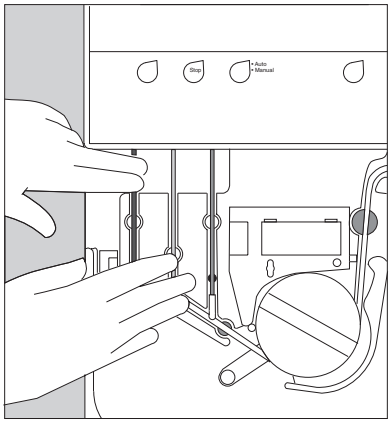


Figure 4-13: Install Tubing Manifold

   - Engage the manifold door and close the pump lever.
   - Close the centrifuge cover. An audible click will be heard, indicating that the cover is locked in the closed position.
   - Close the fluid deck cover.
   - Aseptically attach the red line to the bottom reservoir port and ensure reservoir slide clamp is open.

6. Set up the saline. (Each cycle requires approximately 750 to 1000 ml.)
   - Hang the saline wash containers on the IV pole.
   - Close the clamps on both of the yellow wash lines before spiking the saline bags.
   - Spike the containers of normal saline, and open the clamps on the lines

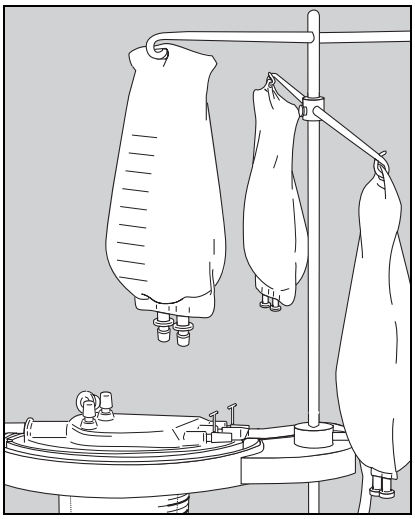


Figure 4-14: Hang the saline wash containers on the IV pole

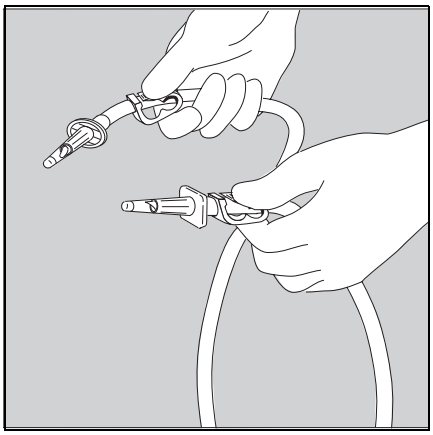


Figure 4-15: Close the ratchet clamps on both spikes before spiking saline

7. Inspect & Finish
   - Inspect all parts of the disposable set to be sure that there are no twists, kinks, or flat spots that would prohibit fluid flow, and that all connections are secure and all appropriate clamps and covers are closed.

Warning: The bowl base (or adapter) must be firmly installed and evenly seated in the centrifuge chuck. If the centrifuge chuck spins with the bowl base (or adapter) not evenly seated, as indicated by bowl wobbling or noise, bowl damage will occur and the bowl and harness set must be replaced.

Once the disposable is properly loaded, press START. A screen similar to the following will appear.

CURRENT SETTINGS	
AUTOMATIC Min Wash Vol. - 225: 1000 ml -125: 750 ml Reservoir Level: 800 ml Resume at Level: 400 ml Reservoir Level Sensor: ON Pump Regulation: ON Empty RBCs to: Blue Line	NO WASH Option: OFF Protocol: Cell Saver
Press START to begin procedure Press MODIFY to change settings Press YES to restore default settings	

Note: Press YES to restore default settings.

This screen notifies the user of the current settings of the modifiable parameters. These parameters may be changed by pressing the MODIFY key.

CELL SAVER SETUP	
AUTOMATIC Min Wash Vol. - 225: 1000 ml -125: 750 ml Reservoir Level: 800 ml Resume at Level: 400 ml Reservoir Level Sensor: ON Pump Regulation: ON Empty RBCs to: Blue Line	NO WASH Option: OFF Protocol: Cell Saver
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished	

Similar screens appear when using the 70 ml bowl.

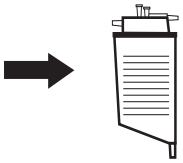
Note: Changes made at this point will become permanent until changed by the user. The no wash option, pump regulation off option, and min wash volumes below 1000 ml for a 225 ml bowl, 750 ml for a 125 ml bowl are retained on a per procedure basis only.

The selection of the sequestering protocol should be made at this point. The sequestering protocol is not available for use with the 70ml bowl.

If sequestering is chosen, the following screen will appear. If no changes are to be made, press START. For further information about the sequestering protocol refer to Chapter 7.

CURRENT SETTINGS			
MANUAL	Assisted Sequester Mode	OFF	
	Fill Bowl DRAW Rate:	60	ml/min
	Fill Bowl Centrifuge Speed:	4750	rpm
	Return Plasma?	NO	
Press START to begin procedure Press MODIFY to change settings Press YES to restore default settings			

If the Cell Saver protocol is chosen, after all modifications have been completed, press the MODIFY key to return to the current settings screen. Then press START to proceed to STANDBY. The following screen will be displayed.

STANDBY	**AUTOMATIC**
 Need 800 ml in reservoir to FILL automatically	Processed Vol: 0 ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Press START to FILL bowl or CONC to concentrate Press MODIFY to change parameters	

Press START to FILL bowl, CONC to concentrate, or wait for the reservoir level sensor to sense approximately 800 ml in the reservoir.

Chapter 5

Automatic Operation: Cell Salvage

GENERAL

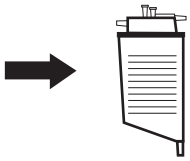
This section explains how to operate the Cell Saver 5+ (CS5+) Autologous Blood Recovery System in the AUTOMATIC mode.

PROCESSING IN THE AUTOMATIC MODE

Before any blood can be processed, the disposables must be loaded correctly. Follow the directions in the previous chapter.

Note: Anticoagulant, as prepared in Chapter 4, is not controlled by the CS5+. This should be done manually in a 1:7 ratio (for heparin solution) of anticoagulant rate to the rate of blood entering the reservoir.

1. After the system has been turned on, completed the self-test segment, shown the current settings screen, and the disposables are properly loaded, the following message is displayed:

STANDBY	**AUTOMATIC**
 Need 800 ml in reservoir to FILL automatically	Processed Vol: 0 ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Press START to FILL bowl or CONC to concentrate Press MODIFY to change parameters	

The system is ready to begin processing when the fluid level in the collection reservoir reaches the preset level.

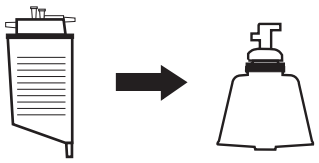
Note: At any time during STANDBY the operator can initiate a FILL MODE by pressing start or the backlit fill key when it is illuminated.

Note: The preset parameters can also be modified at this time, including adjusting the preset level of the Reservoir level sensor, by pressing the MODIFY key.

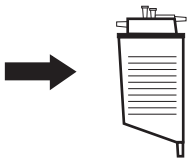
Warning: Once the disposable is loaded and fluids connected, the operator should not open the manifold over the clamps. This may result in a mixing of fluids.

2. When the preset level is reached, the machine automatically enters the FILL mode and the unprocessed blood will be pumped into the spinning centrifuge bowl. On the first cycle (only) of a procedure, the saline line will automatically be primed before the unprocessed blood is pumped into the spinning centrifuge bowl.

The following screen will be displayed:

FILL BOWL	**AUTOMATIC**
	Processed Vol: xx ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0 Pump Rate: 600 ml/min
Press MODE twice to enter EMERGENCY option	

3. The CS5+ optics and effluent line sensor will monitor the processing of the cells in the bowl and the quality of the effluent solution. From this information the CS5+ will automatically determine what the quality of the incoming blood is and control the processing parameters to optimize the procedure. In the AUTOMATIC FILL mode, the CS5+ will optimize the processing by operating at the optimum pump speed between 300 ml/min and 600 ml/min (or 200 - 300 ml/min if the 125 ml bowl is being used). Therefore, the pump speed may vary as the bowl is being filled. The CS5+ will operate at default settings when using the 70 ml bowl. Pump speeds will not vary with the 70 ml bowl.
4. If the reservoir empties before the bowl is full the system reverts to STANDBY and the display provides this information in the following screen.

STANDBY	**AUTOMATIC**
 Need 400 ml in reservoir to FILL automatically	Processed Vol: 695 ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0 Reservoir was emptied
Press START to FILL bowl or CONC to concentrate Press RETURN to empty bowl into reservoir Press WASH to wash partial bowl	

Note: The system will resume filling once the preset level has been reached in the reservoir.

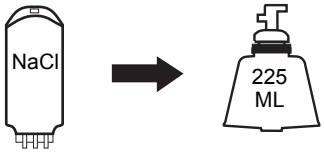
The operator can begin a FILL mode at anytime during Standby by pressing the START key. But at this point, the operator has other options, depending upon which keys are lit. The operator can:

a. Press the backlit WASH key to advance to the wash mode and wash a partially filled bowl (see previous discussion in Chapter 2; twice the standard wash volume should be used).
b. Press the backlit RETURN key to move the contents of the bowl back into the reservoir for future processing.

Note: When the bowl size is detected, the bowl size appears inside the bowl icon on the screen.

5. When the optical sensor detects the bowl is full of cells, or when the operator presses the backlit WASH key, the system will enter the wash mode and bring saline solution into the bowl. The saline is pumped into the bowl and flows through the red blood cells, washing debris, free HgB, heparin or other anticoagulant, activated clotting factors, etc., into the waste bag.

The following display will be shown while the system is in the WASH mode:

WASH CELLS	**AUTOMATIC**
	Processed Vol: 800 ml Wash Vol: 150 ml Reinfusion Vol: 0 ml Bowls Processed: 0 Pump Rate: 500 ml/min
Wash Volume: 150/1000 ml	
Press MODE twice to enter EMERGENCY option Press MODIFY to change minimum wash volume Press YES to double the programmed wash volume	

Pressing YES will double the program wash volume for this wash cycle only. This prompt will be available for the entire wash sequence until the minimum wash volume is reached. When the double wash volume WASH mode is complete, the machine will revert back to the original programmed wash volume.

If minimum wash volume is manually modified by the operator, the volume selected will be used throughout the procedure instead of the preprogrammed value. If the wash volume is 1000 ml or greater for a 225 ml bowl (750 ml or greater for a 125 ml bowl or 300 ml or greater for the 70 ml bowl), this modification will be permanent until changed by the operator.

In this AUTOMATIC WASH mode, the CS5+ will optimize the processing by operating at the optimum pump speed between 250 ml/min and 500 ml/min (or 200–300 ml/min if the 125 ml bowl is being used or 100-300 ml/min for the 70 ml bowl). Therefore, the pump speed may vary as the contents of the bowl are being washed. In the AUTOMATIC mode, if an RBC spill occurs, the pump rate will drop to 50 ml/min and then adjust itself upward when RBCs are no longer being spilled. The CS5+ will operate at default settings when using the 70 ml bowl. Pump speeds will not vary with the 70 ml bowl. Also in the AUTOMATIC mode, the system will automatically extend the wash in 250 ml increments (or 75 ml increments for the 70 ml bowl) until the effluent line is clear.

Pump speed may be adjusted in AUTOMATIC by utilizing the UP and DOWN arrow keys. If the pump speed is increased and an RBC spill occurs, reengage the effluent line sensor.

Warning: The pump regulation function of the effluent line sensor is disabled with any pump speed adjustment by the operator.

In order to reengage the Effluent Line Sensor:

a. Use the UP and DOWN arrow keys to adjust the speed to the original setting prior to manipulation. When this speed is reached, the “Pump Regulation Off” message will be removed from the screen and fully automatic operation will continue.

OR

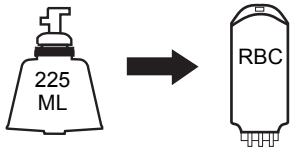
b. Press the PUMP PAUSE key twice, once to pause the pump and a second time to resume at the default speed.

If air is detected prior to the completion of the wash cycle, an alarm will sound and the following message will be displayed:

Saline bag empty
Replace saline bag

The operator should check saline bags and proceed.

When the appropriate volume of saline has entered the bowl, the system will automatically stop the pump, the centrifuge will stop spinning, and the red blood cells suspended in saline will be pumped out of the centrifuge bowl and into the reinfusion bag. The centrifuge may briefly rotate in both directions to facilitate the removal of the red cells from the bowl. The following screen will be displayed while the RBCs are being emptied into the reinfusion bag:

EMPTY BOWL	**AUTOMATIC**
	Processed Vol: 800 ml Wash Vol: 1000 ml Reinfusion Vol: 100 ml Bowls Processed: 0 Pump Rate: 500 ml/min
Press MODE twice to enter EMERGENCY option	

6. After processing one bowl, the system will start processing again when the preset reservoir level is detected. If no more blood will be processed, turn the power off and remove the disposable set.
7. During the procedure the system will monitor the amount of fluid collected in the waste bag. When the amount is close to 9 liters (or 4.5 liters when using the 70 ml bowl) the system will alert the operator to change or drain the contents of the waste bag. The system will sound an audible signal and the system will move into a PAUSE state and indicate the waste bag is full. Once corrective action is taken press START to resume processing.

Note: If the waste bag is full and must be changed, this must be carried out while the bowl is empty (and filled with air). The waste bag may be partially emptied through the drain spout at any time as long as the fluid level in the bag is not below the long green line indicated on the bag. Complete emptying or changing of the bag must be accomplished while the bowl is empty of blood.

8. Reinfusion to the patient can begin as soon as there are RBCs in the reinfusion bag. Collection of shed blood into the reservoir, filling the bowl, and reinfusion to the patient can occur simultaneously throughout the procedure.

Warning: DO NOT allow the reinfusion bag to become empty between reinfusions to the patient. If air does enter the reinfusion line, it must be purged before starting reinfusion.

Warning: Close the clamp between the reinfusion bag and the patient between reinfusions. Do not close the white clamp on the blue line between the reinfusion bag and the CS5+.

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

Warning: DO NOT use a pressure cuff or any other mechanical device with the CS5+. Pressure reinfusion can result in the fatal infusion of air into the patient.

A transfer pack can be used to transfer the contents from the reinfusion bag to a second bag that can be handed off to anesthesia. Attach a transfer bag to one of the small ports on the reinfusion bag and open the small clamp. When the cells have been transferred to the transfer bag, express any air back to the reinfusion bag, close the clamps and seal and detach the bag. These red blood cells are now ready for transfusion following standard transfusion protocols.

Warning: In accordance with FDA guidelines and AABB standards, a transfusion filter capable of retaining particles potentially harmful to the recipient should be used when returning processed concentrated red cells.

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

9. Whenever the air sensor detects air in the tubing in EMPTY, the system assumes all the RBCs have been transferred to the product bag from the bowl and it stops the pump. When air is sensed in FILL, the system assumes the reservoir is empty and stops the pump and centrifuge, moves into the STANDBY state and displays a message similar to:

Need 400 ml in reservoir to FILL automatically

The system will resume processing when the reservoir level sensor senses the reservoir has once again filled with fluid to the proper trip point.

A separation delay will occur when the system resumes processing. This delay is designed to promote proper separation of the cells presently in the bowl prior to the addition of new cells.

The operator can initiate a FILL mode by pressing the FILL key when it is backlit.

When air is sensed in the WASH mode and less than 90% of the wash volume has been processed, the pump stops, an audible chime is sounded and the display reads:

Saline bag empty
Replace saline bag

The operator should replace the saline bags and then press START to resume processing.

If 90% or more of the wash volume has been pumped, then the system advances to EMPTY.

Warning: At anytime during the Automatic operation the operator can advance the system to MANUAL operation by pressing the MODE key.

Because of the controls and “intelligence” built into the machine, automatic processing will produce consistently good results

Warning: Results are dependent upon the correct setup of solutions and disposables.

MODIFYING THE PRESET PARAMETERS

The CS5+ is programmed with preset processing parameters that can be modified by the operator while in AUTOMATIC operation. These parameters can all be modified from the STANDBY state or some parameters can be changed at various points in the processing cycle.

To modify the preset parameters the operator should:

1. Press the MODIFY key and a screen similar to the following will be displayed:

CELL SAVER SETUP			
AUTOMATIC			
Min Wash Vol. - 225:	1000 ml	NO WASH Option:	OFF
-125:	750 ml	Protocol:	Cell Saver
Reservoir Level:	800 ml		
Resume at Level:	400 ml		
Reservoir Level Sensor:	ON		
Pump Regulation:	ON		
Empty RBCs to:	Blue Line		
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished			

2. Use the SELECT key to move from parameter to parameter. Use the UP/DOWN arrows to adjust the values up or down or to toggle between choices.
3. After changing the parameters, press MODIFY to return to STANDBY.

Note: All modifications to the preset parameters will be retained from procedure to procedure until reprogrammed by the operator with the following exceptions:

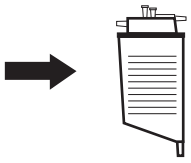
1. *A minimum wash volume below 1000 ml for a 225 ml bowl, 750 ml for a 125 ml bowL will only be saved for the current procedure.*
2. *The NO wash option will only be saved for the current procedure.*
3. *The pump regulation off option (when available) will only be saved for the current procedure.*
4. *The Protocol Parameter is not available if the 70 mL bowl adaptor has been detected or the Cell Saver protocol has been entered.*

ADDITIONAL FUNCTIONS IN AUTOMATIC

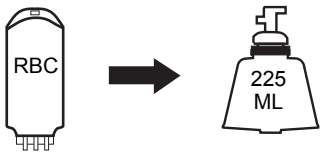
CONC (Concentrate) Option

The concentrate option is used when the volume of red cells in the bowl is low, and it is necessary to wash and return whatever cells there are. (This is sometimes at the end of a procedure when the bowl is less than full, and no more blood loss is expected.) In the Concentrate option the blue line valve opens, and the washed, concentrated red cells are returned from the reinfusion bag to the bowl to increase the RBC volume in the bowl and maintain a high hematocrit product. (Washing a partially filled bowl would produce a low hematocrit end product.)

The operator can access the CONC option in AUTO mode when, during a FILL mode, the system senses an empty reservoir and the system goes into STANDBY. At this point the following is displayed:

STANDBY	**AUTOMATIC**
 Need 400 ml in reservoir to FILL automatically	Processed Vol: 2525 ml Wash Vol: 2000 ml Reinfusion Vol: 400 ml Bowls Processed: 2 Reservoir was emptied
Press START to FILL bowl or CONC to concentrate Press RETURN to empty bowl into reservoir Press MODIFY to change parameters	

When the operator presses the CONC key the system pulls RBCs from the reinfusion bag and continues to fill the bowl. The following screen is displayed:

CONC	**AUTOMATIC**
	Processed Vol: 2525 ml Wash Vol: 2000 ml Reinfusion Vol: 400 ml Bowls Processed: 2 Pump Rate: 450 ml/min
Press MODE twice to enter EMERGENCY option	

When the RBCs reach the trip point, the WASH mode is initiated. To prevent overfilling of the bowl with red cells before the WASH mode begins, the blue line valve closes, the red line valve opens, and the pump reverses to withdraw blood from the tubing to the bowl header into the red line.

PUMP REGULATION Option

In cases where the operator wants the machine to process the blood quickly, the operator has the option of disabling the pump regulation function of the effluent line sensor.

Warning: Red cells may be lost into the waste bag as a result of choosing the pump regulation off option

Note: The pump regulation off option is retained on a per procedure basis only.

The Pump Regulation function of the effluent line sensor can be disabled by entering the MODIFY section at any time during operation. Once the MODIFY key is pressed, a screen similar to the following is displayed:

CELL SAVER SETUP			
AUTOMATIC			
Min Wash Vol. - 225:	1000 ml	NO WASH Option:	OFF
-125:	750 ml		
Reservoir Level:	800 ml		
Resume at Level:	400 ml		
Reservoir Level Sensor:	ON		
Pump Regulation:	ON		
Empty RBCs to:	Blue Line		
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished			

1. To turn off the Pump Regulation option, use the SELECT key to highlight the "Pump Regulation" option, and then press the down arrow to indicate OFF.
2. Press MODIFY to return to the original operating mode.

Selection of the Pump Regulation OFF option will cause a "Pump Regulation OFF" message to appear on the screen during the FILL and WASH modes.

The effluent line sensor will still extend the wash volume with the Pump Regulation OFF option selected until the proper effluent quality has been reached. In this case, the system will automatically extend the wash in 250 ml increments (or 75 ml increments for the 70 ml bowl) until the effluent is clear.

EMPTY RBCs TO BLUE/RED LINE (RETURN Option)

"Empty RBCs to Blue Line" directs the CS5+ to send a bowl of washed RBCs to the blue line and the reinfusion bag after a wash cycle has been completed. This is the default value. If "Empty RBCs to Red Line" is chosen, the CS5+ will send a full bowl of washed RBCs to the red line. An additional parameter choice will be displayed if the red line is chosen.

VOLUME TO RESERVOIR/ CIRCUIT

This selection notifies the volume accounting algorithm of the Cell Saver 5+ to increase or decrease the Volume Processed and Reinfusion Volume appropriately.

For example:

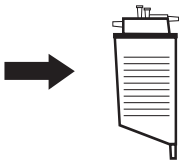
If Volume to Reservoir is chosen, the processed volume will decrease as the blood is returned to the reservoir for reprocessing.

If Volume to Circuit is chosen, the Processed Volume and Reinfusion Volume will increase as the blood is returned directly to the patient via the extracorporeal circuit.

In MODIFY, the destination of the returned cells may be adjusted. The default value in the CS5+ is to pump the volume to the reservoir.

Warning: A safety/warning device should be used for the detection and elimination of gaseous bubbles when returning cells to the patient via the extracorporeal circuit.

To enable the "Empty RBCs to Red Line" option for automatic processing the operator must enter the MODIFY section when the system is in STANDBY. The following screen is displayed in STANDBY:

STANDBY	**AUTOMATIC**
	Processed Vol: 0 ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Need 800 ml in reservoir to FILL automatically	
Press START to FILL bowl or CONC to concentrate Press MODIFY to change parameters	

Once the MODIFY key is pressed a screen similar to the following is displayed:

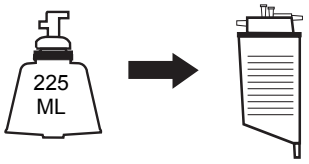
CELL SAVER SETUP			
AUTOMATIC			
Min Wash Vol. - 225:	1000 ml	NO WASH Option:	OFF
-125:	750 ml		
Reservoir Level:	800 ml		
Resume at Level:	400 ml		
Reservoir Level Sensor:	ON		
Pump Regulation:	ON		
Empty RBCs to:	Blue Line		
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished			

1. To enable the Empty RBCs to Red Line option press the SELECT key until the "Empty RBCs to" Option is highlighted and then press the up arrow to indicate the Red Line.
   At this point a screen similar to the following will appear:

CELL SAVER SETUP			
AUTOMATIC			
Min Wash Vol. - 225:	1000 ml	Volume to:	Reservoir
-125:	750 ml	NO WASH Option:	OFF
Reservoir Level:	800 ml		
Resume at Level:	400 ml		
Reservoir Level Sensor:	ON		
Pump Regulation:	ON		
Empty RBCs to:	Red Line		
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished			

2. It is necessary to designate where the volume of washed RBCs will be pumped after the red line — to the reservoir or to the circuit. This information will allow the CS5+ to accurately account for the volume processed and reinfused to the patient.
3. Press MODIFY to return to the STANDBY screen.

An example of the display that will appear when the system trips into RETURN is:

RETURN	AUTOMATIC
	Processed Vol: 2525 ml Wash Vol: 2000 ml Reinfusion Vol: 400 ml Bowls Processed: 2 Pump Rate: 250 ml/min
Press MODE twice to enter EMERGENCY option	

4. After the bowl empties, the system either initiates another FILL mode if the level in the reservoir is above the preset level or the system returns to the STANDBY mode.

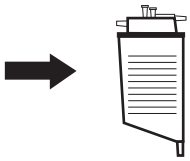
NO WASH Option

If minimum turn-around time on concentrated cells is a higher priority than washing the cells, such as in an emergency, or the cells are being hemoconcentrated for return to the extracorporeal circuit, the physician may request that the operator omit the WASH mode, thus reducing the processing time to the length of the FILL-EMPTY modes.

Warning: The no wash option should only be selected after the physician has performed a careful assessment of the risk/benefit ratio of washing cells versus not washing cells, and has determined, based on his/her own medical judgement, that return of the cells without processing through the wash mode is in the best interest of the patient.

Note: The NO wash option is retained on a per procedure basis only.

The WASH mode may be bypassed by entering the MODIFY section when the system is in STANDBY. The following screen is displayed in STANDBY:

STANDBY	**AUTOMATIC**
 Need 800 ml in reservoir to FILL automatically	Processed Vol: 0 ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Press START to FILL bowl or CONC to concentrate Press MODIFY to change parameters	

Once the MODIFY key is pressed a screen similar to the following is displayed:

CELL SAVER SETUP	
AUTOMATIC Min Wash Vol. - 225: 1000 ml -125: 750 ml Reservoir Level: 800 ml Resume at Level: 400 ml Reservoir Level Sensor: ON Pump Regulation: ON Empty RBCs to: Blue Line	NO WASH Option: OFF
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished	

1. To turn on the NO WASH option use the SELECT key to highlight the “NO WASH Option” and then press the up arrow to indicate ON.
2. Press MODIFY to return to the STANDBY screen.

Selection of the NO WASH option will cause a “Unit Not Washed” message to appear on the screen during FILL.

Alternatively, you can move from FILL to EMPTY by just pressing the EMPTY key once the machine trips into WASH.

Note: The operator must be aware that the processed blood will still contain anticoagulant, increased free hemoglobin, and other cellular debris normally removed by the washing process. The surgeon/anesthesiologist should be advised of this deviation in processing and the reason for the variance documented.

EMERGENCY Option

The emergency option is available for those situations in which the speed at which blood is available for return to the patient is the most important factor. The emergency option is accessible from the AUTOMATIC mode when the machine is in the FILL,WASH, EMPTY, CONC, and RETURN functions. This option cannot be entered from the STANDBY or stop state.

Note: The EMERGENCY option is not available for use with the 70 mL bowl

The emergency option will process blood continuously through the FILL, WASH, and EMPTY cycles until the air detector sees air for the first time in the FILL sequence, meaning the reservoir is empty. Upon seeing an air detected message in the FILL sequence, the CS5+ will switch back to the AUTOMATIC mode and the machine will enter STANDBY. The operator may also choose to CONCentrate or RETURN cells to the reservoir while in the emergency option.

Parameters in EMERGENCY Option

The preset parameters in the EMERGENCY mode are:

	225 ml bowl	125 ml bowl
FILL	800 ml/min*	400 ml/min
WASH	800 ml/min	400 ml/min
EMPTY	500/300/250 ml/min	500/300/250 ml/min
CONC	450 ml/min	450 ml/min
WASH VOL	1000 ml	750 ml

*If the air/plasma interface has not yet been detected by the optics, the fill rate will remain at 400 ml/min until this event occurs, at which time it will increase to 800 ml/min.

Note: The line sensor will not be active during the emergency option.

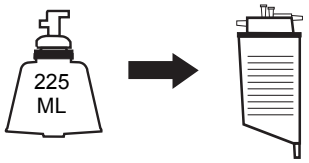
Warning: Red cells may be lost into the waste bag as a result of choosing the emergency option.

Entering the EMERGENCY Option

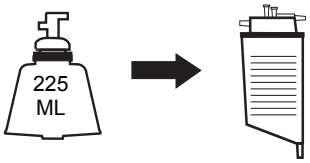
To enter the EMERGENCY Option from the AUTOMATIC mode, press the MODE key twice within 2 seconds. The operator will then be prompted to confirm this choice by pressing the YES key within 5 seconds. If the YES key is not pressed within 5 seconds, or the NO key is pressed, the CS5+ will revert back to the AUTOMATIC mode. While waiting for confirmation, the pump speed will slow to 25 ml/minute.

EMPTY BLUE LINE Option

At the completion of the procedure, approximately 40 mL (13 mL for the 70 mL bowl) of RBCs remain in the blue line that should be emptied to the reinfusion bag. When the EMPTY mode is complete and prior to entering STANDBY a message will flash for 10 seconds: "Is Case Completed? Y/N."

RETURN	AUTOMATIC
	Processed Vol: 1250 ml Wash Vol: 1000 ml Reinfusion Vol: 75 ml Bowls Processed: 0 500 ml/min Is Case Completed? Y/N
Press MODE twice to enter EMERGENCY option	

If the NO key is pressed or no action is taken within 10 seconds, the machine will enter STANDBY. If the YES key is pressed within 10 seconds, the following message will flash: "Empty Blue Line? Y/N."

RETURN	AUTOMATIC
	Processed Vol: 1250 ml Wash Vol: 1000 ml Reinfusion Vol: 75 ml Bowls Processed: 0 500 ml/min Empty Blue Line? Y/N
Press MODE twice to enter EMERGENCY option	

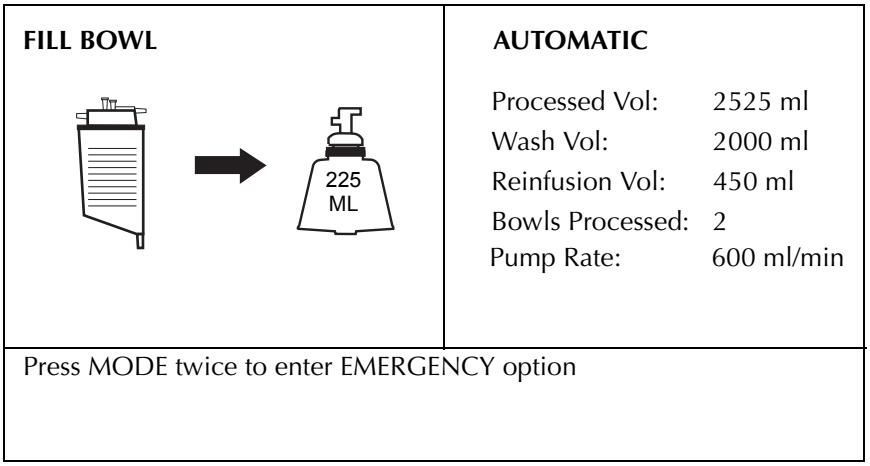
If the YES key is pressed, the machine will empty the line at 100 mL/min and then enter STANDBY. If the NO key is pressed, the machine will enter STANDBY without emptying the line.

Warning: Do not empty the blue line during the procedure or the bowl displacement air will be lost adversely affecting subsequent EMPTY modes. Only empty the blue line at the completion of the procedure.

SYSTEM STATUS

The next section briefly discusses some information regarding the display and how current procedure statistics are displayed.

The current system status is displayed as shown in the following example:



The top left section displays the current operating status of the machine. In this case, the CS5+ is in the FILL mode and fluid is being pumped from the reservoir into the bowl.

The right shows the current procedure statistics and parameters. In this case, the CS5+ is under AUTO control, the pump is filling at 600 ml/min, 2 bowls have been processed, 2000 ml of saline solution have been used, a total of 2525 ml of volume has been processed from the reservoir and 450 ml of concentrated RBCs have been sent to the reinfusion bag.

To increase the pump speed *temporarily,* press the UP (+) slew key. This allows the operator to make minor adjustments to speed without reprogramming the system. These temporary changes are valid only for the present mode (e.g., FILL) and as the system enters the next mode, the programmed values take over again. The temporary pump speeds may be increased to 600 ml/min (300 ml/min for the 70 ml bowl) or decreased to 200 ml/min.

Warning: The effluent line sensor is disabled with any pump speed adjustment by the operator.

To return to full automatic operation (enabling the effluent line sensor):

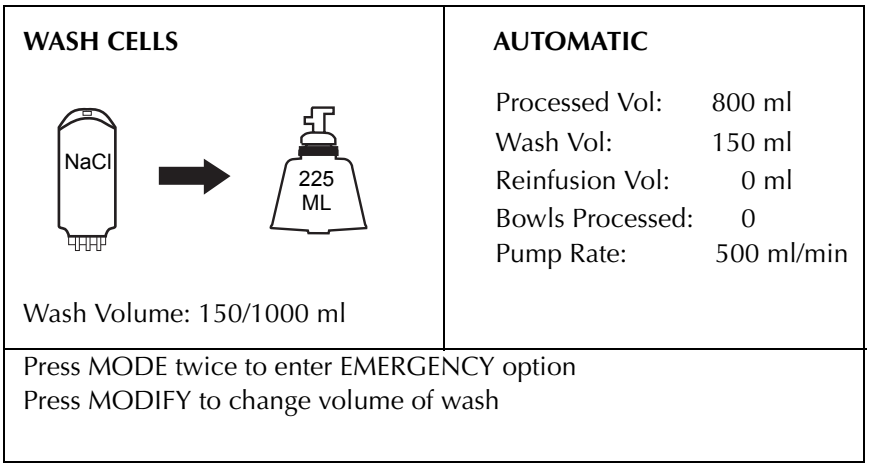
1. Press the UP (▲) or DOWN (▼) key until the "Pump Regulation Off" message disappears from the screen. This will occur when the pump is returned to its original speed.

OR

2. Press the PUMP/PAUSE key twice, once to pause the pump and a second time to resume at the default speed.

Wash Volume Monitor

During any automatic WASH mode, the display panel displays a running, cumulative total of wash solution used on the current WASH mode on the left hand side of the display, as shown in the following figure. This counting function returns to zero each time the WASH mode is entered, and terminates when the machine advances to EMPTY. An indication of the Total Wash volume used is shown in the procedure statistics area on the right side of the display as indicated in the following figure.



Volume Accounting Function

The Volume Accounting Function of the CS5+ allows the operator to monitor the approximate fluid volume processed and the approximate fluid volume returned to the patient by the CS5+. This information is constantly displayed during each mode, and is being constantly updated.

Note: Volumes displayed are approximate. The volumes are calculated by mL per pump revolution.

To ensure the accuracy of the Volume Accounting Function it is important to observe the following guidelines:

1. Do not allow the O.R. suction to be regulated too high. Vacuum settings in excess of 200 mmHg could compromise the efficiency of the CS5+ occlusive roller pump. This would compromise the accuracy of the Volume Accounting Function which assumes a certain volume of fluid per pump revolution.
2. Subsequent to RESERVOIR EMPTY displays, do not press the START key until at least 400 ml of fluid accumulate in the reservoir. Processing smaller volumes may cause the Volume Accounting Function to overestimate the PROCESSED VOLUME. Because the red reservoir line contains no fluid whenever the reservoir is drained, the air in the length of tubing from the pump to the reservoir is pumped into the bowl before fluid may be pumped. Frequently RESUMING for small amounts of fluid will cause a disproportionate ratio of air to fluid. (Remember that the CS5+ can usually process 500 ml (or 125ml for the 70 ml bowl) of fluid in approximately one minute.

Note: The reinfusion VOLUME display will read approximately 40 ml too high because of the 40 ml of fluid trapped in the blue line until the end of the procedure. WHEN USING THE 70 ML BOWL, 20 ML OF FLUID WILL BE IN THE BLUE LINE. (An example illustrating this relationship is shown in the following paragraph.) Remember to subtract this 40 ml from the readout until the blue line is drained at the end of the procedure and the 40 ml (OR 20 ML) are recovered.

REINFUSION VOLUME	Display	Actual Volume Returned to Reinfusion Bag
	200	160
	400	360
	600	560

Note: Accurate volume accounting and WASH monitor functions require that all clamps are open and that no kinks, twists, or flat spots which prohibit fluid flow are present in the tubing.

TROUBLESHOOTING

Sometimes situations arise during the operation of the Cell Saver 5+ where no matter what you do, something goes wrong. Generally, the operator can manage a large portion of these problems by pressing HELP on the Cell Saver 5+ for troubleshooting assistance. The Machine Messages chart in Appendix C describes some situations that may happen and the actions that may be taken to correct the situation.

If you are not comfortable troubleshooting problems with your equipment or disposables, Haemonetics has a **24 hour Hotline (800) 433-3431** that you may call for assistance.

Chapter 6

Manual Operation

GENERAL

This chapter explains how to operate the Cell Saver (CS5+) System in the MANUAL mode.

Though not recommended, it is possible to process blood manually in the CS5+. Given the processing capabilities of the CS5+, manual processing is unnecessary. The steps involved in manual processing during autotransfusion are outlined below.

In order to place the system into the MANUAL mode of operation, press the MODE key on the control panel

Note: When in the manual mode, it is the responsibility of the operator to advance the system from one function to the next. The air detector is enabled in MANUAL EMPTY AND MANUAL RETURN and THE WASTE BAG WEIGHER IS ENABLED IN MANUAL FILL, MANUAL WASH AND MANUAL CONC, but otherwise, all sensing devices are disabled in the manual mode (including BOWL OPTICS sensor and the effluent line sensor).

Once the machine has advanced into the FILL mode, it will remain there indefinitely until the operator initiates a change. The MANUAL mode allows the operator to reverse the process cycle, or skip entire functions. Examples of such maneuvers would be as follows: 1) to go from WASH to FILL; 2) to go directly from FILL to EMPTY.

After the centrifuge bowl has been stopped, the red cell separation is lost. This settling of cells could lead to a red cell spillage if, when restarting, fluid is pumped into the bowl before the cells are allowed to separate once again.

When processing is RESUMED in the AUTOMATIC mode, there is a “recentrifuge delay” which allows the centrifuge a few moments to attain separation before starting to pump more fluid into the bowl. The recentrifugation delay can be overridden in the MANUAL mode by pressing the START key a second time after the recentrifuge delay has been on for 15 seconds. If the operator chooses to override the delay, the operator must be aware of the possibility of cell spillage caused by pumping fluid into a bowl with poor or no separation.

To avoid a cell spillage, the operator must press the PUMP PAUSE control. Pressing PUMP PAUSE again will cause the pump to resume at the previous rate. Or to adjust pump speeds, use the PUMP SLEW keys to gradually change the pump speed until the desired speed is reached while observing that the cells have time to separate.

Warning: In the manual mode all mode changes and advances must be initiated by the operator.

Unlike the sensing devices, all cumulative Volume Accounting Functions (Volume Processed, Volume Returned, and Wash Monitor) are operative during manual operation.

CONTROLS AND INDICATORS

By pressing the MODE key once the machine switches from Automatic operation to Manual operation. Once MANUAL operation is selected the backlit control panel lights up and additional control keys become functional as shown in Figure 6-1.

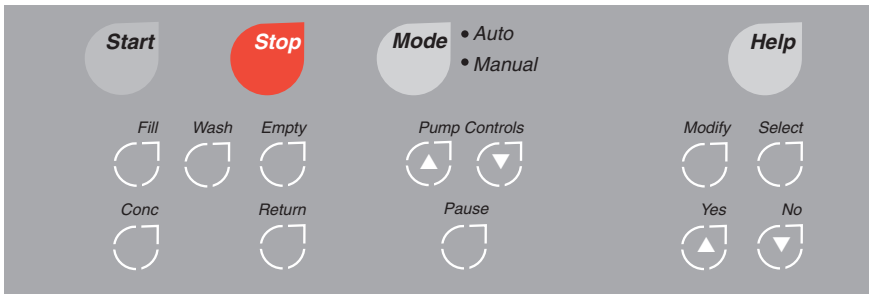
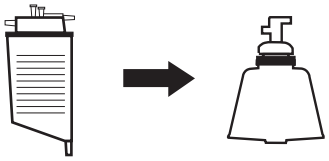


Figure 6-1: Control panel: MANUAL STANDBY

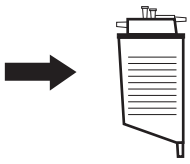
The display panel will also give you indication of which mode you are in as shown in the following figure.

FILL BOWL	**MANUAL**
	Processed Vol: 2525 ml Wash Vol: 2000 ml Reinfusion Vol: 450 ml Bowls Processed: 2
Pump Rate: 500 ml/min	
Press MODE key for AUTOMATIC Press ARROW keys to change values	

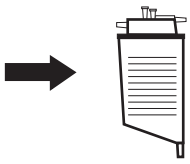
The operator can easily move back to AUTO operation by pressing the MODE key once.

MANUAL OPERATION

1. Set up the system and disposables as described in Chapter 4. Choose the Cell Saver Protocol as described in the section, *Processing In Automatic Mode* in Chapter 5+, at which time the following display will be shown:

STANDBY	**AUTOMATIC**
	Processed Vol: 0 ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Need 800 ml in reservoir to FILL automatically	
Press START to FILL bowl or CONC to concentrate Press MODIFY to change parameters	

2. When you are ready to start processing, press the MODE key to move into Manual operation and the following screen will be displayed:

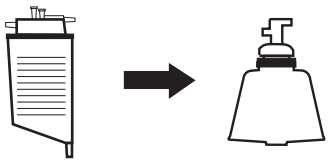
STANDBY	**MANUAL**
	Processed Vol: 0 ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Press MODE key for AUTOMATIC Press START to fill bowl or CONC to concentrate Press MODIFY to change parameters	

Note: The preset program parameters are still in effect in the manual mode. It is possible to reprogram parameters such as pump speed for the manual mode; the reprogramming process is the same for both automatic and manual modes (by pressing the MODIFY key).

3. Initiation of the FILL mode is largely dependent upon the rate of fluid collection in the reservoir. If the patient's rate of blood loss is steady and rapid, processing may begin as soon as 100 ml of fluid enter the reservoir. Typically, however, the processing mode (FILL) can be initiated after the reservoir has accumulated 600–900 ml of volume or 200-600 ml when using the 70 ml bowl

Note: While in the Manual Mode, all modifications to the preset parameters will be retained from procedure to procedure until reprogrammed by the operator.

4. Press the START or FILL key to initiate the FILL mode. The following screen will be displayed:
   :

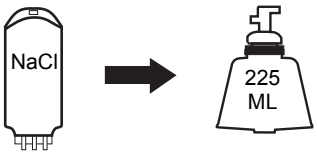
FILL BOWL	**MANUAL**
	Processed Vol: 2525 ml Wash Vol: 2000 ml Reinfusion Vol: 450 ml Bowls Processed: 2
Pump Rate: 500 ml/min	
Press MODE key for AUTOMATIC Press ARROW keys to change values	

The recommended maximum FILL speed is 600 ml/minute for the 225 ml bowl, 300ml/min for the 125 ml bowl and 125ml/min for the 70 ml bowl.

To manually concentrate on the last bowl filling, press the CONC key. This will cause the blue valve to open bringing blood down from the reinfusion bag into the bowl. These red cells will displace the supernatant, forcing the supernatant into the waste bag.

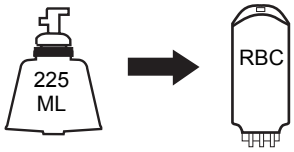
5. When the red cell/supernatant interface reaches a point approximately 1/4 inch over the shoulder of the bowl, press the WASH key (the recommended maximum WASH speed is 500 ml/minute for the 225 ml bowl and 300 ml/min for the 125 ml bowl and 100ml/min for the 70 ml bowl). The volume of wash solution required will depend upon such factors as hemodilution and amount of anticoagulant used. Wash the red cells with a minimum of 1000 ml of saline when performing a standard procedure and 1500 ml of saline when performing an Orthopedic procedure. Wash with a minimum of 300 ml of saline when using a 70 ml bowl. Continue washing until the effluent line is clear.

During the WASH mode the following display will be shown:

WASH CELLS	**MANUAL**
	Processed Vol: 800 ml Wash Vol: 150 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Pump Rate: 500 ml/min Wash Volume: 150 ml	
Press MODE key for AUTOMATIC Press ARROW keys to change values	

Note: If during the WASH mode the red cell/supernatant interface disappears and red cells begin to spill into the waste bag, reduce the pump speed to zero or press pump pause and allow this interface to reappear. Slowly increase the pump speed to a rate that just maintains this interface (usually 200 ml/minute wash or greater).

6. Press the EMPTY key (the recommended maximum EMPTY speed is 500 ml/min for the 225 and 125 ml bowls and 100 ml/min for the 70ml bowl). During EMPTY the display will read:

EMPTY BOWL	**MANUAL**
	Processed Vol: 1250 ml Wash Vol: 1000 ml Reinfusion Vol: 75 ml Bowls Processed: 0
Pump Rate: 500 ml/min	
Press MODE key for AUTOMATIC Press ARROW keys to change values	

A “Centrifuge Stopping” message will blink on the screen until the centrifuge comes to a complete stop. The concentrated red cells are pumped from the bowl to the reinfusion bag. Under certain conditions the centrifuge will briefly rotate in both directions to expedite the removal of the red cells from the bowl.

7. Reinfusion to the patient can begin as soon as there is a safe level of blood in the reinfusion bag (2–3 inches). Collection of the shed blood into the collection reservoir, filling the bowl, and reinfusion to the patient can occur simultaneously after the first processed blood is pumped to the reinfusion bag.

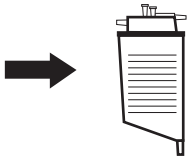
Warning: Do not allow the reinfusion bag to become empty between reinfusions to the patient. If air does enter the reinfusion line, it must be purged prior to restarting reinfusion.

Warning: DO NOT PRESSURE REINFUSE. Pressure reinfusion can lead to the fatal infusion of air into the patient.

The Haemonetics Cell Saver 5+ System's disposables are not intended to be used with a pressure reinfusion cuff. For information on removing air from the reinfusion bag see the section, *Pressure Reinfusion* in Chapter 3.

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

8. Once the system has sensed that the bowl is empty the system will revert to a STANDBY state and the following will be displayed.

STANDBY	**MANUAL**
	Processed Vol: 1250 ml Wash Vol: 1000 ml Reinfusion Vol: 200 ml Bowls Processed: 1
Press MODE key for AUTOMATIC Press START to fill bowl or CONC to concentrate Press MODIFY to change parameters	

If there is more blood to be processed in the reservoir, press START to begin the FILL mode as previously discussed in steps 5 and 6.

If the amount available for processing is insignificant, simply discard the remaining fluid with the bowl.

Warning: Close the clamp between the reinfusion bag and the patient between reinfusions.

EMERGENCY Option

An emergency option is available from the MANUAL mode. This option is described in detail in Chapter 5. The EMERGENCY option is not available for use with the 70 ml bowl. To enter the EMERGENCY option from the MANUAL mode, press the MODE key twice. The operator will then be prompted to confirm this choice by pressing the YES key within 5 seconds. If the YES key is not pressed within 5 seconds, or the NO key is pressed, the CS5+ will revert to the AUTOMATIC mode.

The CS5+ is programmed with preset processing parameters that can be modified by the operator while in MANUAL operation. These parameters can all be modified from the STANDBY state or some parameters can be changed at various points in the processing cycle.

To modify the preset parameters the operator should:

1. Press the MODIFY key and the following will be displayed:

CELL SAVER		**SETUP**
MANUAL	FILL rate	500 ml/min
	WASH rate:	500 ml/min
	EMPTY rate:	500 ml/min
	Centrifuge Speed:	5650 rpm
	Waste Bag Weigher:	ON
	ALARM Sound:	ON
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished		

2. Use the SELECT key to move from parameter to parameter. Use the UP/DOWN arrows to adjust the values up or down or to toggle between selections.
3. Once done with changing the parameters press MODIFY to return to STANDBY.

Note: WHILE IN MANUAL MODE, ALL modifications to the preset parameters will be retained from procedure to procedure until reprogrammed by the operator.

Chapter 7

Sequestering on the Cell Saver 5+ System

GENERAL

This section explains how to perform sequestering on the Cell Saver 5+ (CS5+) Autologous Blood Recovery System. This protocol allows for the separation of platelet-rich plasma (PRP) and platelet-poor plasma (PPP) from RBCs.

OVERVIEW OF THE SEQUESTERING PROTOCOL

The Sequestering Protocol is usually performed before the Cell Saver Protocol. After the power on and self-tests complete, the system is set up with the standard bowl processing set. The Sequestering Kit (List No. 244) is attached to the standard bowl processing set as described in this chapter for the sequestration of platelet-rich plasma (PRP) and/or platelet-poor-plasma (PPP).

Note: The sequestering protocol is not available for use with the 70 mL bowl.

Two methods exist for performing sequestering: Manual Sequester Mode and Assisted Sequester Mode. For both methods, blood is collected into blood bags containing anticoagulant. The blood is separated into PRP, PPP, and red blood cells (RBCs). Typical processing time is 25 to 40 minutes.

The sequestering process is identical for both methods. The Assisted Sequester Mode provides preprogrammed processing parameters for optimal performance along with prompts to assist the operator with steps of the process. The Manual Sequester Mode allows the operator to select desired processing parameters and provides no operator prompts.

Loading the Disposable Set

After the system has been turned on and the machine self-test has been completed, the operator will be prompted to load the disposable. Install the List No. 244 Sequestering Kit as described below.

Before any blood can be processed, the Cell Saver disposable must be loaded correctly. Follow the directions for loading the standard processing kit as described in Chapter 4.

Step 1: Open the centrifuge cover.

Step 2: Open the LN 244 Disposable Kit. Locate the poly bag containing the removal tool and open by tearing the perforated strip.

Step 3: Use the removal tool to pry off the effluent line from the outlet port of the Cell Saver 5+ bowl.

Note: Save the removal tool for later use.

Step 4: Remove the cap from the bowl connector of the LN 244 sequestering harness.

Step 5: Place the bowl connector cap on the waste bag effluent line.

Step 6: Install the bowl connector of the LN 244 sequestering harness to the outlet port of the centrifuge bowl.

Step 7: Install the large bore tubing on the sequestering harness into the effluent line sensor by grasping the distal (towards the bags) connection tubing stop and using a "flossing" motion, pull the tuning down through the sensor until the bowl end connection tubing stop reaches the upper end of the effluent line. Ensure that this large-bore tubing is fully seated in the line sensor groove along its entire length.

Step 8: Close the centrifuge cover.

Step 9: Hang the collection bag with yellow-striped tubing onto one of the waste bag posts on the Cell Saver 5+. Hang the collection bag with blue-striped tubing onto another waste bag post. Hang the air bag on the remaining post.

Step 10: Close the red clamps on the product bags and ensure that the tubing and cap connections to the product bags are secure.

Step 11: Ensure that the white product bag clamps are open.

Setting the Parameters

Note: The sequester protocol is only available when the unit is first powered ON.

Warning: prior to undertaking sequestration on the CS5+, the operator should be familiar with the operating instructions for the CS5+ and any associated precautions and warnings in addition to any precautions and warnings included in this chapter specific to the sequester procedure.

1. Press START and the current settings screen will appear:

CURRENT SETTINGS			
AUTOMATIC			
Min Wash Vol. - 225:	1000 ml	NO WASH Option:	OFF
-125:	750 ml	Protocol:	Cell Saver
Reservoir Level:	800 ml		
Resume at Level:	400 ml		
Reservoir Level Sensor:	ON		
Pump Regulation:	ON		
Empty RBCs to:	Blue Line		
Press START to begin procedure Press MODIFY to change settings Press YES to restore default settings			

2. Press MODIFY to see the SETUP screen.

CELL SAVER SETUP			
AUTOMATIC			
Min Wash Vol. - 225:	1000 ml	NO WASH Option:	OFF
-125:	750 ml	Protocol:	Cell Saver
Reservoir Level:	800 ml		
Resume at Level:	400 ml		
Reservoir Level Sensor:	ON		
Pump Regulation:	ON		
Empty RBCs to:	Blue Line		
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished			

Use the SELECT key to highlight parameters and use the ARROW keys to change values.

3. Press MODIFY to see the SEQUESTER SETUP screen.

SEQUESTER SETUP			
MANUAL	Assisted Sequester Mode:	OFF	
	Fill Bowl DRAW Rate:	60	rpm
	Fill Bowl Centrifuge Speed:	4750	rpm
	Return Plasma?	NO	
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished			

Use the SELECT key to highlight parameters and use the ARROW keys to change values.

The preset default parameters for the manual sequester mode are as follows:	
Assisted Sequester Mode:	OFF
Fill Bowl DRAW Rate:	60 ml/min
Fill Bowl Centrifuge Speed:	4750 rpm
Return Plasma?	NO

4. Press MODIFY to save changes and return to the current settings screen.
5. Press START to enter the STANDBY screen.

STANDBY	**SEQUESTER** Processed Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Press START to FILL bowl or CONC to concentrate Press MODIFY to change parameters Press YES to select Cell Saver protocol	

Note: Performing Sequestering is a MANUAL operation requiring operator intervention to move from one stage to another. The process should be understood completely before pursuing.

Note: Before starting the sequestering process, check to make sure that the AIR bag clamp is open and the collection bag clamps are closed, unless using the PPP bag for air management. Ensure that while the bowl is filling, the air in the disposable system is entering the AIR bag. The air will be emptied out of the AIR bag during the empty mode.

Note: If pump pause is selected during processing, the pump will stop and the centrifuge speed will be maintained for five minutes. After five minutes, the speed will be reduced and after six minutes in pause the centrifuge will stop.

METHOD 1 — MANUAL SEQUESTRATION

1. Collect whole blood from the patient via short intravenous or arterial cannula into anticoagulated blood bag(s).

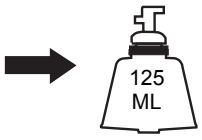
Warning: Only one unit of blood should be collected and processed at a time. Unless directed by a physician, do not begin withdrawal of the second unit of blood from the patient until the first unit of concentrated red autologous blood cells has been returned.

2. Spike the blood collection bag with either of the wash line bag spikes on the Basic CS5+ Bowl Set. Close the clamp on the unused wash line spike. On the product bags, ensure that the RED bag clamps are closed and the white bag clamps are open. On the harness, ensure the BLUE (PRP) bag clamp and YELLOW (PPP) bag clamp are closed. Open the air bag clamp.

Note: If the PPP collection bag will be used for system air management, ensure that the yellow bag clamp is open and the sir bag clamp is closed before starting the procedure.

3a. Press START key to initiate filling the bowl from the blood bag. The pump will start drawing at 60 ml/min.

b. As the bowl fills, plasma will be seen on the top followed by a white band (platelets), and then red cells. The following screen will be shown:

FILL BOWL	**SEQUESTER**
	Processed Vol: 300 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Pump Rate: 60 ml/min Centrifuge: 4750 rpm	
Press SELECT to advance highlight Press ARROW keys to change values Press MODIFY to change parameters	

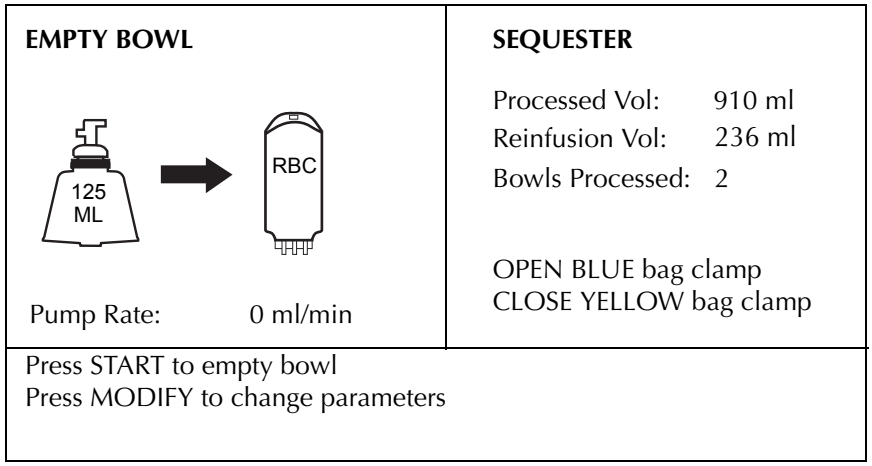
4a. Observe the centrifuge bowl filling and allow air from the circuit and the bowl to flow to the air bag (or PPP collection bag if used for air management).

b. When plasma reaches the effluent line, open the yellow clamp to the PPP bag and close the air bag clamp.

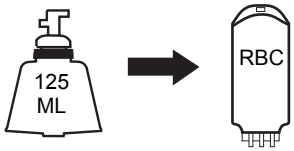
Caution: *Never close the yellow (PPP), Blue (PRP), and white (air) bag clamps at the same time.*

5. Continue to observe the centrifuge bowl. Allow plasma to run into the PPP bag at the same flow rate. The white buffy coat band (made up of platelets and white cells) which is immediately adjacent to the top of the red cell level will be seen coming up over the shoulder of the bowl and starting to express into the PPP bag. At this time, OPEN the BLUE collection bag clamp and then CLOSE the YELLOW collection bag clamp to allow platelet-rich plasma to enter the PRP bag. When the effluent line from the bowl turns medium red (indicating the presence of red cells), allow the machine to continue processing for approximately 30 ml and then press the EMPTY key to stop both the centrifuge and pump.
6. When the centrifuge comes to a complete stop, the screen display will prompt the operator to close the PRP collection bag clamp and open the bag clamp that has the system air. Once this is completed the START key must be pressed to empty the contents of the bowl.

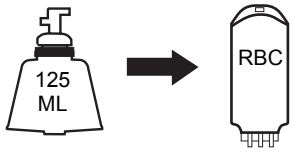
If the “Return Plasma?” parameter in the Sequester Setup is set to “NO” the following screen is displayed:



If the "Return Plasma?" parameter in the Sequester Setup is set to "YES" the following screen is displayed:

EMPTY BOWL	**SEQUESTER**
	Processed Vol: 910 ml Reinfusion Vol: 236 ml Bowls Processed: 2
Pump Rate: 0 ml/min	OPEN PPP bag clamp CLOSE PRP bag clamp
Press START to empty bowl Press MODIFY to change parameters	

7. When the START key is pressed, the pump will speed up to 400 ml/min to pump the RBCs from the bowl to the reinfusion bag. Under certain conditions the centrifuge will briefly rotate in both directions to expedite the removal of the red cells from the bowl. The following display will be shown:

EMPTY BOWL	**SEQUESTER**
	Processed Vol: 910 ml Reinfusion Vol: 236 ml Bowls Processed: 2
Pump Rate: 0 ml/min	
Press ARROW keys to change values Press MODIFY to change parameters	

8. When the bowl completely empties, the pump will stop and the following display will be shown:

STANDBY	**SEQUESTER** Processed Vol: 510 ml Reinfusion Vol: 125 ml Bowls Processed: 1
Press START to fill bowl or CONC to concentrate Press MODIFY to change parameters Press YES to select Cell Saver protocol	

9. The RBCs are reinfused to the patient as deemed necessary by anethesia. Refer to AABB standards for expiration time of RBCs.

Warning: In accordance with FDA guidelines and AABB standards a transfusion filter capable of retaining particles potentially harmful to the recipient should be used when returning processed concentrated red cells.

10. If another pass is desired, the entire procedure may be repeated using Steps 1 through 7, until the desired volume of PPP/PRP has been collected.

Note: The concentrate mode can be used if it is necessary to pull additional blood into the bowl for the final cycle. Just press the concentrate key if you run out of whole blood when filling the bowl. This allows the operator to push out the remaining PRP from the bowl.

System Breakdown

1. After the final pass, remove the collection bag(s) from the pin(s) and invert it (them). Tap the sides of the tubing going from the bowl to the collection bag to dislodge any plasma/platelets that might have adhered to the tubing wall.
2. Close the product bag(s) clamp(s) and remove the collection bag(s) from the "3-way split" connection. Label the product(s) with the following minimum information:
   - Patient's name and/or identification number
   - Hospital identification number
   - Date and time collected
   - Amount collected
   - Type and amount of anticoagulant used
   - Type of product
   - Technician's name

Note: Remember that any autologous blood product collected has been processed from a patient who might not normally been accepted for blood donation. Therefore, unless the blood passes AABB or hospital donation standards, the products obtained in autotransfusion or plasma sequestration procedures must be labeled "for autologous use only." They should be kept segragrated and used solely for that purpose.

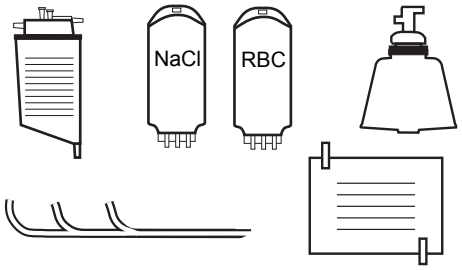
Note: If the system has been set up for autotransfusion, the red cells may be returned to the collection reservoir for later washing if desired.

Warning: Refer to the current AABB standards for expiration date for stored blood.

3. Retain the product(s) for reinfusion upon a physician's order. Use procedures consistent with your blood bank protocol for platelet product storage and handling.
4. Using the removal tool provided in the LN 244 Disposable Kit, remove the harness from the outlet port of the bowl. Connect the effluent line tubing between the outlet port of the bowl and the waste bag.
5. Disconnect the blood collection bag from the wash line spike and spike a bag of wash solution if cell salvage will be performed.

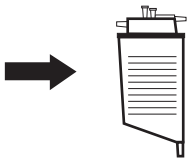
6. To perform a cell salvage procedure once the sequestering procedure is complete, press the YES key while the system is in STANDBY to return the CS5+ to the Cell Saver Protocol.

LOAD DISPOSABLE



When disposable is loaded, press START

7. Ensure proper setup for Cell Saver procedure.
8. The current settings screen will appear. Press START.

STANDBY	**AUTOMATIC**
	Processed Vol: 0 ml Wash Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0
Need 800 ml in reservoir to FILL automatically	
Press START to FILL bowl or CONC to concentrate Press MODIFY to change parameters	

9. The CS5+ is now set up for normal Cell Saver procedure. Ensure that the reservoir is properly set up with its clamp open and press START to begin the cell salvage procedure in Automatic or press the MODE key to proceed with Manual operation, if desired.

METHOD 2 — ASSISTED SEQUESTER MODE

1. Collect whole blood from the patient via short intravenous or arterial cannula into anticoagulated blood bag(s).

Note: 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 red autologous blood cells has been returned.

Power on the machine and select the Sequester protocol at the Cell Saver SETUP screen. If the Assisted Sequester Mode parameter is set to OFF, use the SELECT key to highlight it and the ARROW keys to select Assisted Sequester Mode to YES. The following SEQUESTER SETUP screen is displayed:

SEQUESTER SETUP			
ASSISTED	Assisted Sequester Mode:	ON	
	Fill Bowl DRAW Rate:	60	ml/min
	Fill Bowl Centrifuge Speed:	4750	rpm
	PRP Collection DRAW Rate:	60	ml/min
	PRP Collect Centrifuge Speed:	4750	rpm
	PRP Extend Collection Volume:	30	ml
	Return Plasma?	NO	
	Milk PRP Collection Layer?	YES	
	Milk Vol: 3 ml Milk Delay:	10	sec
Press ARROW keys to change values Press SELECT to advance highlight Press MODIFY when finished			

The following table indicates the modifiable parameters in the Sequester mode of those machines equipped with Assisted Sequester. The table indicates the default setting of each parameter, the maximum and minimum values attainable, and the incremental value when it is changed by pressing the up or down arrow key.

Note: The "milk delay" parameters will only be displayed if the "milk PRP collection layer?" parameter is set to YES. "Milking" Enables an automatic pump start/stop/restart sequence during collection.

SEQUESTER SETUP - ASSISTED SEQUESTER

PARAMETER	Default	Max	Min	↑↓
Assisted Sequester Mode:	OFF	ON	OFF	Toggle
Fill Bowl DRAW Rate:	60	250	10	10
Fill Bowl Centrifuge Speed:	4750	5650	2050	100
PRP Collection DRAW Rate:	60	250	10	10
PRP Collect Centrifuge Speed:	4750	5650	2050	10
PRP Extend Collection Volume:	30	300	0	5
Return Plasma?	NO	YES	NO	Toggle
Milk PRP Collection Layer?	NO	YES	NO	Toggle
Milk Vol:	3	25	1	1
Milk Delay:	10	30	1	1

Sequester Setup Terminology

Fill Bowl DRAW Rate: The programmed pump speed in milliliters per minute the pump runs while the bowl is filling with whole blood and during the PPP collection phase.

Fill Bowl Centrifuge Speed: The programmed centrifuge speed in revolutions per minute the centrifuge turns while the bowl is filling with whole blood and during the PPP collection phase.

PRP Collection DRAW Rate: The programmed pump speed in milliliters per minute the pump runs during the PRP collection phase.

PRP Collect Centrifuge Speed: The programmed centrifuge speed in revolutions per minute the centrifuge turns during the PRP collection phase.

PRP Extend Collection Volume: The volume in milliliters to pump after the line sensor detects RBCs during the PRP collection phase. Once this volume is pumped, the PRP collection is considered complete.

Return Plasma? This question is asked to determine which clamps to prompt the operator to open and close at the beginning of the EMPTY phase and to account for volume returned. If the operator selects YES, the PPP is returned to the bowl and then to the reinfusion bag along with the RBCs.

Milk PRP Collection Layer? This question is asked to determine if the process of starting and stopping the PRP collection phase is desired as determined by the programmed parameters “Milk Vol” and “Milk Delay.”

Milk Vol: The volume to pump in milliliters during the PRP collection until the pump stops and the Milk Delay time starts.

Milk Delay: The time in seconds the pump will be stopped during the PRP collection phase before starting to pump the programmed Milk Vol parameter.

2. Once the Assisted Sequester Setup parameters have been set and the START key is pressed to begin a new procedure, the screen display changes to the STANDBY screen and further information is requested before processing can begin. The machine needs to know which bag to manage the system air in. The display is as follows:

STANDBY	**SEQUESTER** Processed Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 0/ 0 ml PRP Volume: 0/ 0 ml Use PPP bag for Air? Y/N
Press YES to use the PPP collection bag for air Press NO to use the air bag for air	

Selecting the YES key uses the PPP collection bag to manage the air, while pressing the NO key selects the air bag.

3. Once a selection is made for system air management, the display changes to the following to assist the operator in final setup confirmation of the disposable set.

If the PPP collection bag was selected to manage the system air:

STANDBY CLOSE RED bag clamps CLOSE AIR bag clamp OPEN YELLOW bag clamp CLOSE BLUE bag clamp **AGITATE BLOOD BAG**	**SEQUESTER** Processed Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 0/ 0 ml PRP Volume: 0/ 0 ml
Press START to fill bowl or CONC to concentrate Press MODIFY to change parameters Press YES to select Cell Saver protocol	

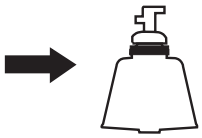
If the AIR bag was selected to manage the system air:

STANDBY	**SEQUESTER**
	Processed Vol: 0 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 0/ 0 ml PRP Volume: 0/ 0 ml
CLOSE RED bag clamps OPEN AIR bag clamp CLOSE YELLOW bag clamp CLOSE BLUE bag clamp **AGITATE BLOOD BAG**	
Press START to fill bowl or CONC to concentrate Press MODIFY to change parameters Press YES to select Cell Saver protocol	

4. Spike the blood collection bag with either of the wash line bag spikes on the Basic CS5+ Bowl Set. Close the clamp on the unused wash line spike.

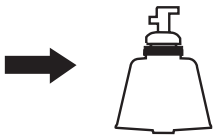
5a. Press the START key to initiate filling the bowl from the blood bag. The pump will start drawing at 60 ml/min.

b. As the bowl fills, plasma will be seen on the top followed by a white band (platelets), and then red cells. The following screen will be shown:

FILL BOWL	**SEQUESTER**
	Processed Vol: 90 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 0/ 0 ml PRP Volume: 0/ 0 ml
Pump Rate: 60 ml/min Centrifuge: 4750 rpm	
Press SELECT to advance highlight Press ARROW keys to change values Press MODIFY to change parameters	

6a. Observe the centrifuge bowl filling and allow air from the circuit and the bowl to flow to the air bag or PPP collection bag.

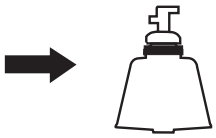
b. When plasma reaches the effluent line, the machine will decide if the process should pause as determined by the selection that was made for air management.
If the selection to manage the system air was in the AIR bag, the process stops the pump and prompts the operator to open the YELLOW (PPP) bag clamp and close the air bag clamp. Once this is completed the machine waits for the START key to be pressed to continue processing as shown in the following screen display:

PAUSE	**SEQUESTER**
	Processed Vol: 139 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 0/ 0 ml PRP Volume: 0/ 0 ml
Pump Rate: 60 ml/min Centrifuge: 4750 rpm	OPEN YELLOW bag clamp CLOSE AIR bag clamp
Press START to resume collection of PPP Press MODIFY to change parameters	

Caution: *Never close the yellow (PPP), blue (PRP), and white (air) bag clamps at the same time.*

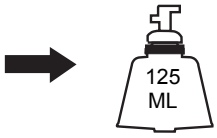
If the PPP collection bag was chosen to manage the system air, the machine continues processing.

On the first cycle the bowl size is determined by the machine. The high volume bowl (225 ml) and low volume bowl (125 ml) can both be used for sequestering. By default the machine expects to detect a low volume bowl (125 ml). If on the first cycle, the machine detects a high volume bowl just prior to collecting PPP, the pump is paused and the display prompts the operator to confirm that a high volume bowl is being used. The following display is shown:

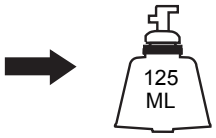
PAUSE	**SEQUESTER**
	Processed Vol: 215 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 0/ 0 ml PRP Volume: 0/ 0 ml
Pump Rate: 0 ml/min Centrifuge: 4750 rpm	HIGH Volume Bowl sensed *Is this correct? Y/N?
Press YES to select HIGH volume bowl Press NO to select LOW volume bowl	

The machine expects a response from the operator within 15 seconds. If a low volume bowl is being used, the operator can override the machine detector and select a low volume bowl by pressing the NO key. If a high volume bowl is being used the operator can press the YES key or nothing. Once a key is pressed or 15 seconds has elapsed the pump restarts and the machine continues processing.

7. Plasma is being collected in the PPP bag. The display is incrementing the PPP volume along with the Processed Volume and displays PPP Collection phase as shown below:

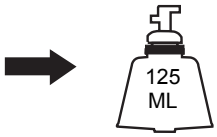
PPP COLLECTION	**SEQUESTER**
	Processed Vol: 166 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 27/ 27 ml PRP Volume: 0/ 0 ml
Pump Rate: 60 ml/min Centrifuge: 4750 rpm	
Press SELECT to advance highlight Press ARROW keys to change values Press MODIFY to change parameters	

8. The white buffy coat band (made up of platelets and white cells), which is immediately adjacent to the top of the red cell level, will be seen coming up over the shoulder of the bowl. The machine bowl optics determines the optimum time for collection of PRP. When this is determined the pump pauses and the operator is prompted to open the BLUE (PRP) bag clamp and close the YELLOW (PPP) bag clamp. Once this is completed the machine waits for the START key to be pressed to continue processing as shown in the following screen display:

PAUSE	**SEQUESTER**
	Processed Vol: 239 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 100/ 100 ml PRP Volume: 0/ 0 ml
Pump Rate: 60 ml/min Centrifuge: 4750 rpm	OPEN BLUE bag clamp CLOSE YELLOW bag clamp
Press START to resume collection of PRP Press MODIFY to change parameters	

Caution: *Never close the yellow (PPP), blue (PRP), and white (air) bag clamps at the same time.*

9. Once the START key is pressed the machine first looks at the centrifuge speed for PRP collection that was programmed in Sequester Setup. If the programmed PRP collection centrifuge speed is equal to or greater than the programmed Fill Bowl centrifuge speed, the pump is started and PRP collection is resumed. If the programmed PRP collection centrifuge speed is less than the programmed Fill Bowl centrifuge speed, there will be a 30 second delay to allow the centrifuge to reduce its speed to reach its new programmed speed at which time the pump will restart and PRP collection will resume as shown in the following display:

PRP COLLECTION	**SEQUESTER**
	Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 100/ 100 ml PRP Volume: 0/ 0 ml
Pump Rate: 0 ml/min Centrifuge: 2400 rpm	PUMP RESTART IN XX SEC Press START to override
Press SELECT to advance highlight Press ARROW keys to change values Press MODIFY to change parameters	

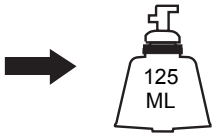
10. Once the PRP collection process resumes, PRP is being collected into the PRP collection bag and the PRP Volume on the display is incrementing along with the Processed Volume.

PRP COLLECTION	**SEQUESTER**
	Processed Vol: 248 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 100/ 100 ml PRP Volume: 9/ 9 ml
Pump Rate: 60 ml/min Centrifuge: 4750 rpm	
Press SELECT to advance highlight Press ARROW keys to change values Press MODIFY to change parameters	

If the “Milk PRP Collection Layer?” parameter in the Sequester Setup is set to YES, the pump will process the “Milk Vol” parameter setting and then the pump will stop and pause for the “Milk Delay” parameter setting. Once the Milk Delay time

has been reached the pump restarts and the process repeats. This process of stopping and starting will continue until the PRP collection is completed.

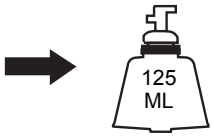
11. After 10 ml of PRP have been collected the effluent line sensor starts looking for RBCs spilling into the PRP collection bag. Once RBCs have been detected the machine alerts the operator that the PRP Extended Collection has started. The PRP Extended Collection Volume is programmed by the operator in the Sequester Setup.

PRP COLLECTION	**SEQUESTER**
	Processed Vol: 269 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 100/ 100 ml PRP Volume: 30/ 30 ml
Pump Rate: 60 ml/min Centrifuge: 4750 rpm	Extending PRP Collection
Press SELECT to advance highlight Press ARROW keys to change values Press MODIFY to change parameters	

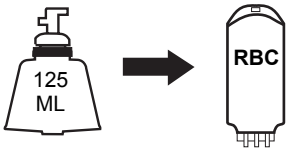
Note: If the sensor tubing is not properly installed in the line sensor, the CS5+ will not detect the red blood cells spilling into the PRP collection bag and the CS5+ will not stop at the desired end collection point.

If the line sensor does not sense the red blood cells spilling into the PRP collection bag the operator can press the stop or empty key to end the PRP collection.

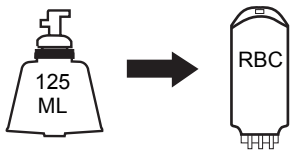
12. Once the pump has pumped the programmed PRP Extended Collection Volume, the pump is stopped and the PRP collection is complete and the display adds COMPLETE to the screen as follows:

PRP COLLECTION COMPLETE	**SEQUESTER**
	Processed Vol: 299 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 100/ 100 ml PRP Volume: 60/ 60 ml
Pump Rate: 0 ml/min Centrifuge: 4750 rpm	
Press START to continue collection into PRP layer Press EMPTY to end collection of PRP Press MODIFY to change parameters	

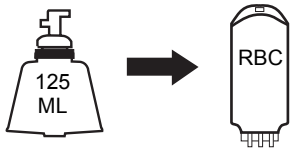
13. Press the EMPTY key to stop the centrifuge. When the centrifuge comes to a complete stop, the screen display will prompt the operator to close the blue (PRP) collection bag clamp and open the bag clamp that has the system air. Once this is completed the START key must be pressed to empty the contents of the bowl.
    If the "Return Plasma?" parameter in the Sequester Setup is set to "NO" the following screen is displayed:

EMPTY BOWL	**SEQUESTER**
	Processed Vol: 299 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 100/ 100 ml PRP Volume: 60/ 60 ml OPEN AIR bag clamp CLOSE BLUE bag clamp
Pump Rate: 0 ml/min	
Press START to empty bowl Press MODIFY to change parameters	

If the “Return Plasma?” parameter in the Sequester Setup is set to “YES” the following screen is displayed:

EMPTY BOWL	**SEQUESTER**
	Processed Vol: 299 ml Reinfusion Vol: 0 ml Bowls Processed: 0 PPP Volume: 100/ 100 ml PRP Volume: 60/ 60 ml OPEN YELLOW bag clamp CLOSE BLUE bag clamp
Pump Rate: 0 ml/min	
Press START to empty bowl Press MODIFY to change parameters	

14. When the START key is pressed, the pump will speed up to 400 ml/min, RBCs from the bowl will mix with plasma and be pumped to the reinfusion bag. Under certain conditions the centrifuge will briefly rotate in both directions to expedite the removal of the red cells from the bowl. The following display will be shown:

EMPTY BOWL	**SEQUESTER**
	Processed Vol: 299 ml Reinfusion Vol: 50 ml Bowls Processed: 0 PPP Volume: 100/ 100 ml PRP Volume: 60/ 60 ml
Pump Rate: 400 ml/min	
Press ARROW keys to change values Press MODIFY to change parameters	

15. When the bowl completely empties, the pump stops and the following display is shown:

STANDBY	**SEQUESTER**	
	Processed Vol:	299 ml
	Reinfusion Vol:	199 ml
	Bowls Processed:	1
	PPP Volume: 0/	40 ml
	PRP Volume: 0/	60 ml
Press START to fill bowl or CONC to concentrate Press MODIFY to change parameters Press YES to select Cell Saver protocol		

16. The RBCs should be treated the same as a unit of washed, concentrated RBCs in terms of administration to the patient and outdate of the product.

Warning: In accordance with FDA guidelines and AABB standards, a transfusion filter capable of retaining particles potentially harmful to the recipient should be used when returning processed concentrated red cells.

17. If another pass is desired, the entire procedure may be repeated using Steps 5 through 14, until the desired volume of PPP/PRP has been collected.

Note: The concentrate mode can be used if it is necessary to pull additional blood into the bowl for the final cycle. Press the CONC key if you run out of whole blood when filling the bowl. This allows the operator to push out the remaining PRP from the bowl.

System Breakdown

1. After the final pass, remove the collection bag(s) from the pin(s) and invert it (them). Tap the sides of the tubing going from the bowl to the collection bag to dislodge any plasma/platelets that might have adhered to the tubing wall.
2. Close the product(s) bag clamp(s) and remove the collection bag(s) from the "3-way split" connection. Label the product(s) with the following minimum information:
   - Patient's name and/or identification number
   - Hospital identification number
   - Date and time collected
   - Amount collected
   - Type and amount of anticoagulant used
   - Type of product
   - Technician's name
   - Technician's name

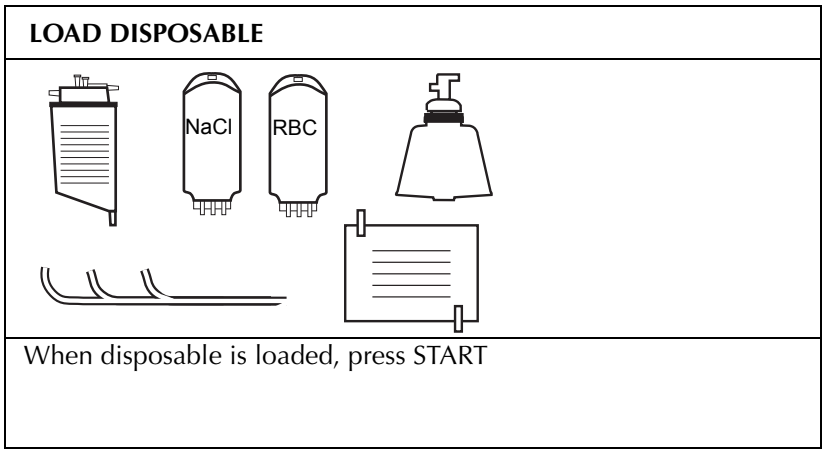
Note: Remember that any autologous blood product collected has been processed from a patient who might not normally been accepted for blood donation. Therefore, unless the blood passes AABB or hospital donation standards, the products obtained in autotransfusion or plasma sequestration procedures must be labeled "for autologous use only." They should be kept segragrated and used solely for that purpose.

Note: If the system has been set up for autotransfusion, the red cells may be returned to the collection reservoir for later washing if desired.

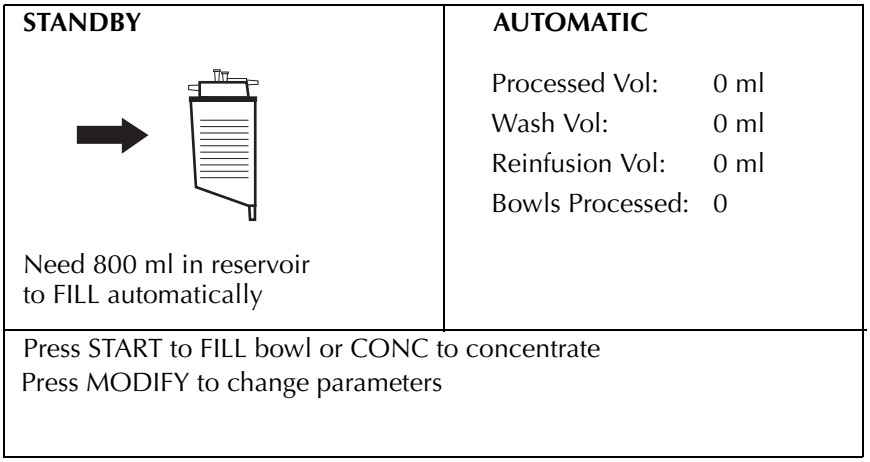
Warning: Refer to the current AABB standards for expiration date for stored blood.

3. Retain the product(s) for reinfusion upon a physician's order. Use procedures consistent with your blood bank protocol for platelet product storage and handling.
4. Using the removal tool provided in the LN 244 Disposable Kit, remove the harness from the outlet port of the bowl. Connect the effluent line tubing between the outlet port of the bowl and the waste bag.
5. Disconnect the blood collection bag from the wash line spike and spike a bag of wash solution if cell salvage is to be performed.

6. To perform a cell salvage procedure once the sequestering procedure is complete, press the YES key while the system is in STANDBY to return the CS5+ to the Cell Saver Protocol.



7. Ensure proper setup for Cell Saver procedure.
8. The current settings screen will appear. Press START.



9. The CS5+ is now set up for normal Cell Saver procedure. Ensure that the reservoir is properly set up, with its clamp open and press START to begin the cell salvage procedure in Automatic or press the MODE key to proceed with Manual operation, if desired.

Chapter 8

Maintenance

GENERAL

The Cell Saver 5+ System (CS5+CS5+) has been designed to require minimal maintenance. Most maintenance will consist of cleaning the system, and assuring that the pump rollers are clean and free-rolling. The date and type of maintenance performed should be recorded regularly.

Warning: Do not grease any part of the mechanical centrifuge. If grease has been applied to the mechanical centrifuge, contact Haemonetics hotline immediately.

MAINTENANCE AND CLEANING

Normal maintenance of the CS5+ System consists of keeping the machine clean. Clean the CS5+ with a damp cloth using a facility approved cleaning solution, unless otherwise specified.

All blood spills should be cleaned immediately pursuant to those policies and procedures dictated by the medical facility's Infection Control Plan, as legally required by the OSHA Blood Borne Pathogen Standard.

When any Haemonetics product (equipment or disposables) which has been used during a procedure is returned to Haemonetics for any reason, the customer must decontaminate and repackage the product in compliance with the medical facility's Infection Control Plan and U.S. Department of Transportation regulations for interstate shipping of blood contaminated products.

Warning: Disconnect electrical power from the CS5+ before servicing the system.

Cleaning the Centrifuge Well

The centrifuge well should be routinely cleaned with a damp, lint-free towel. The towel can be dampened with a mild detergent spray to improve cleaning. Do not use 100% bleach directly on the machine; a bleach/water solution or some other disinfectant may be indicated.

Follow by drying with a lint-free cloth. A drain port connected to a biohazard waste container bag will catch fluids if a spill occurs. Remove and replace the bag should this occur.

Warning: Do not grease any part of the mechanical centrifuge. If grease has been applied to the mechanical centrifuge, contact Haemonetics hotline immediately.

Note: If the mechanical chuck becomes contaminated with blood, call Haemonetics Hotline at (800) 433-3431. If blood has entered the mechanical locking fingers, the mechanical chuck must be cleaned by a trained biomed or a haemonetics field service engineer.

Optics Lens Cleaning

The window(s) of the optical level sensor(s) located inside the centrifuge may be cleaned with a soft, damp, lint-free cloth (moistened with water only). Buff dry to assure that there are no spots left on the window.

Warning: In order to function properly, the optical sensor lens(es) must be clean and clear. A dirty or clouded lens could interfere with proper operation of the sensor. Always clean the optical lens(es) after a blood spill.

Cleaning the Effluent Line Sensor

The effluent line sensor should be cleaned by flossing with a water dampened lint-free cloth followed by flossing with a dry lint-free cloth.

Air Detector Cleaning

The air detector should be cleaned by flossing with a water dampened cloth followed by a dry lint-free cloth.

Cleaning the Tubing Valves

The tubing valves and clamped line sensor may be cleaned by wiping with a mild detergent-dampened lint-free cloth.

Blood Pump Cleaning

The blood pump should be cleaned after a spill to keep the rotating parts moving freely. The pump rotor may be lifted out by holding the rotor stationary and unscrewing the cover. Clean the area under the pump rotor and pump arm until all moving parts can rotate or slide freely. Secure the pump rotor back into its original position. Wipe inside the pump assembly with mild detergent-dampened cloth. Rinse the pump under the faucet with warm water. If required, pump rotor can be cleaned in an ultrasonic cleaner. Dry thoroughly.

Cleaning After a Spill

The exterior of the CS5+, including the control panel, should be cleaned with a mild detergent or disinfectant at regular intervals as well as any time a spill has occurred. Do not use 100% bleach directly on the machine; a bleach/water solution or some other disinfectant may be indicated. The air filter should also be cleaned as described in the next section.

Note: If the mechanical chuck becomes contaminated with blood, call Haemonetics hotline at (800) 433-3431 for further assistance. If blood has entered the finger-locking mechanism, the mechanical chuck must be cleaned by a trained biomed or a haemonetics field service engineer.

Cleaning the Air Filter

The CS5+ is equipped with a rear panel air filter for incoming cooling air. Correct filter maintenance will avoid malfunction resulting from an accumulation of lint and dust in air passages. The filter should be washed periodically, depending upon frequency and conditions of use.

Supplies Needed

The only supply needed is warm running water.

Filter Cleaning Procedure

Cleaning the air filter is simple and easy. The following steps outline the correct procedure.

1. Unplug the CS5+.
2. If there is a louvered panel covering the filter, remove the four screws which hold it in place, and set the panel and screws aside.
3. Grasp the filter and pull it out.
4. Rinse the filter under warm running water until it is clean. Do not use soap or any cleaning solution.
5. Squeeze out excess water, place on a clean cloth, and allow to dry completely.
6. Ensure the filter is 100% dry. Reinsert the filter into the panel, making sure the filter completely covers the opening. Replace the louvered panel, if so equipped, with the openings facing down.
7. Record the date of maintenance.

Note: A quick reference guide for cleaning the Cell Saver 5+ is found in Appendix B.

FIELD SERVICE

Throughout the United States and in many locations worldwide, Haemonetics maintains a network of factory-trained field service engineers. If a problem should arise, one of these equipment specialists can usually be on-site within twenty-four hours to diagnose and correct any malfunction. Your field service engineer also can answer any questions about or be called to perform routine maintenance. Maintenance contracts are available to ensure that your Haemonetics instrument continues to function well.

TECHNICAL SERVICES

Installation and Training

Haemonetics has a large network of clinical specialists proficient in both the medical and technical aspects of all Haemonetics equipment. They are experienced trainers who can listen and respond to your questions and concerns. Upon delivery of your Haemonetics instrument, thorough on-site training of personnel will be arranged at your convenience. Should the application or staff change as the program grows, additional training is available at nominal cost.

Hotline

Haemonetics has a convenient twenty-four hour, toll-free hotline. A technical and clinical specialist is always available to answer questions about operation and use of Haemonetics equipment. The Hotline number is (800) 433-3431 within the continental United States.

RETURNED GOODS AUTHORIZATION (RGA) SYSTEM

The Returned Goods Authorization (RGA) system outlines the procedures to be followed when returning goods. The system assures that returned goods are properly handled and analyzed. Because of the potential health hazard inherent in the shipment, handling, and defect analysis of biologically contaminated products, it is important that these procedures be carefully followed.

RGA Procedure

The steps that should be followed in returning any equipment are outlined below. All devices to be returned to Haemonetics for product performance or quality problems should be handled according to the Product Complaint Coordinator's instructions ([800] 433-3431). Merchandise received by a customer which was shipped in error by Haemonetics will be handled by the Customer Services Department (800) 225-5297.

1. Call the Product Complaint Coordinator at (800) 433-3431 for return of any product felt to be unacceptable for patient use (damaged packaging, broken component, etc.).
2. The Product Complaint Coordinator will request the following information:
   - Customer name and address
   - Contact name, title, and phone number
   - Product List Number
   - Product Lot Number
   - Number of damaged devices to be returned
   - Detailed description of the problem or defect
   - Number of cartons to be returned.
3. The Product Complaint Coordinator will provide additional steps that need to be taken at this point.
4. If the disposables have been exposed to blood, a detailed description of the problem experienced must be provided to the Product Complaint Coordinator (i.e. how was the product being used when the incident occurred, for how long had the product been used, was the disposable attached to Haemonetics equipment, etc.). Supply the same information as outlined in item 2 (i.e., product list number, lot number, etc.). In many situations, you will be asked to dispose of some goods after reporting the defect.

5. Should Haemonetics request the return of contaminated disposables, or equipment, the disposables or equipment must be decontaminated prior to shipment pursuant to those policies and procedures dictated by the medical facility's Infection Control Plan, as required by OSHA Blood Borne Pathogen Standard. Repackaging of equipment or disposables for return to Haemonetics must comply with U.S. Department of Transportation regulations for interstate shipment of blood contaminated products.

Warning: Bloody materials, if returned unwashed, cannot be analyzed and pose a potentially serious health hazard to individuals involved in shipping, handling, and testing.

Appendices

APPENDIX A: COMPLICATIONS AND CONTRAINDICATIONS

Complications of and contraindications to perioperative blood recovery[1]
(Per 1997 AABB Guidelines for blood recovery and reinfusion in surgery and trauma pg 19-22)

Substance	Effects	Recommended Action
Pharmacologic Agents		
A. Clotting Agents		
1. Microfibrillar Products Examples: Avitene®, Helitene®, Oxycel®, Gelfoam® Powder, Instat® MCH	May cause platelet aggregation and clot formation. Reported to pass through a microaggregate filter into the blood stream causing emboli.	Avoid aspiration when product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
2. Sponge/Fabric Materials Examples: Surgicel™, Surgicel™ Nu-Knit®, Gelfoam® Sponge, Helistat®, Instat™, Hemopad®, Super Stat®, HemoFoam®	Activates clotting sequence by acting as a contact agent. May clot off system.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
3. Topical Liquids Examples: Thrombin-JMI™, Thrombostat®, Thrombogen®	Creates a fibrin clot by direct action on fibrinogen. May clot off system.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
B. Irrigating Solutions		
1. Alcohol	Causes red cell lysis.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
2. Antibiotics Examples: Bacitracin, Neomycin, Polymyxin	Can result in renal and neuro toxicity if blood is not washed.	Increase amount of wash volume by 500 ml.
3. Betadine	Causes red cell lysis.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.

Complications of and contraindications to perioperative blood recovery[1]
(Per 1997 AABB Guidelines for blood recovery and reinfusion in surgery and trauma pg 19-22)

Substance	Effects	Recommended Action
4. Chloropactin (Bleach)	Causes red cell lysis.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
5. Hydrogen Peroxide	Causes red cell lysis.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
6. Hypertonic Solution Examples: 3% NaCl, 7% NaCl, Dextrose solutions	Causes red cell crenation.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
7. Hypotonic Solution Examples: Sterile Water, Glycine	Causes red cell lysis.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
8. Lactated Ringers (in presence of citrate anticoagulant)	Calcium present may bind with citrate activating coagulation sequence.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
C. Methylmethacrylate		
1. Liquid or powder form	May cause circulatory collapse.	Avoid aspiration in area where product is being used. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
2. Hardened Form	May cause clogging of the system.	Avoid aspiration in area where product is being used. Flush suction line occasionally with anticoagulant or normal saline to keep clear.

Complications of and contraindications to perioperative blood recovery[1]
(Per 1997 AABB Guidelines for blood recovery and reinfusion in surgery and trauma pg 19-22)

Substance	Effects	Recommended Action
Contaminants		
A. Amniotic Fluid	Contains proteolytic enzymes which may activate clotting.	Cell salvage is an option after delivery of the fetus, removal of the amniotic fluid, and copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
B. Bone Chips/Bone Grafting Materials	May cause clogging of the system.	Flush suction line occasionally with anticoagulant solution or normal saline to keep clear.
C. Bowel Contents	Potential for bacteremia.	Do not aspirate into system. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
D. Fat	May not wash out completely.	Retain visible fat layer in reservoir and reinfusion bag. Increase wash volume to 2000 ml. If visible fat layer exists in reinfusion bag, piggyback two microaggregate filters between reinfusion bag and transfer pack or infusion set.
E. Gastric and Pancreatic Fluid	Proteolytic enzyme may cause red cell lysis.	Do not aspirate into system. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
F. Infection at Site of Aspiration	Potential for bacteremia	Avoid aspiration in the presence of purulent material.
G. Skin Lesions (Infectious)	Incising a lesion may introduce organisms.	Cell salvage may be used if incision is not through a lesion.
H. Urine	Potential for bacteremia if urinary tract infection present.	Avoid aspiration into system in the presence of a urinary tract infection.
I. Mucous Membrane Procedures Examples: Oral, Nasal, Vaginal	Potential for bacteremia due to normal resident bacteria.	Medical risks and benefits should be discussed between the surgeon and the medical director of the surgical services program.

Complications of and contraindications to perioperative blood recovery[1]
(Per 1997 AABB Guidelines for blood recovery and reinfusion in surgery and trauma pg 19-22)

Substance	Effects	Recommended Action
Malignancy		
A. Primary at Operative Site	Cell salvage is widely used in surgical excision of malignant tumors. The available data would tend to indicate that the procedure is safe and does not increase the incidence of metastatic disease. However, since a control trial has not been performed (and it is questionable whether it will ever be performed), the decision to use cell salvage in malignancies must be left to the discretion of the surgeon.	Avoid cell salvaging at tumor site. Medical risks and benefits should be discussed between the surgeon and the medical director of the surgical services program. Consider the use of a leukoreduction filter.
B. Metastatic at Operative Site	Potential for further spread of disease.	Disease already systemic. Use at discretion of surgeon.
C. Pheochromocytoma	Potential for marked hypertension due to high concentrations of catecholamines.	Avoid aspirating at the tumor site. Resumption is an option after copious irrigation with 0.9% sodium chloride solution to an alternate suction source.
D. Ascites	Tumor cells may be present.	Avoid aspirating into the system if the surgical procedure is for ovarian malignancy.
Hematologic Disorders		
A. Sickle Cell Trait	Wash procedure produces potential sickling of salvaged cells.	Alert staff of potential for red cell sickling.
B. Confirmed Sickle Cell Anemia	Wash procedure produces potential sickling of salvaged cells.	Medical risks and benefits should be discussed between the surgeon and the medical director of the surgical services program.

Complications of and contraindications to perioperative blood recovery[1]
(Per 1997 AABB Guidelines for blood recovery and reinfusion in surgery and trauma pg 19-22)

Substance	Effects	Recommended Action
C. Cold Agglutinin Antibody	Agglutination of red cells may occur at temperatures lower than 37°C. Cold agglutinins are in plasma and will be washed off.	If cold agglutinins show significant activity at room temperature recommend transfusion of blood through a blood warmer.
Miscellaneous		
A. Titanium Alloy Prosthesis	Effect of darkened tissue or clots (blue/green/black) surrounding prosthesis unknown to systemic circulation.	Discontinue cell salvage until the prosthesis and all darkened tissue has been removed. Resume after the wound has been irrigated with 0.9% sodium chloride solution to an alternative suction source.
B. Liposuction	Fat concentration in salvaged blood may be too high to remove by washing.	Avoid cell salvage.

References

[1]"Guidelines for Blood Salvage and Reinfusion in Surgery and Trauma," American Association of Blood Banks, 1997.

APPENDIX B: CLEANING PROCEDURES

Cleaning Procedures for Cell Saver 5+ Parts (detailed instructions in chapter 8)

Part	Procedure
Air Detector	1. Floss with lint-free cloth dampened with clear water. 2. Floss again using a dry lint-free cloth.
Air Filter	1. Remove the four screws on the louvered panel covering the air filter. Lay the panel door and screws aside. 2. Pull out filter and rinse with warm water until clean. Do not use soap or cleaning solutions. 3. Let the filter dry over night. Replace the filter and panel door.
Centrifuge Spills:	1. Wipe clean the centrifuge chuck and centrifuge well with a damp cloth using a mild detergent spray. 2. Ensure mechanical locking fingers are thoroughly cleaned. 3. Dry all areas with a lint-free cloth. 4. Remove and replace the biohazard waste bag, if necessary.
Control Panel	1. Wipe the control panel with a mild detergent-dampened cloth. 2. Wipe with a lint-free cloth dampened with clear water, 3. Dry with a lint-free cloth.
Effluent Line Sensor	1. Floss with a lint-free cloth dampened with clear water. 2. Floss again using a dry lint-free cloth.
Bowl Optics Sensors	1. Clean daily and when soiled to ensure adequate detection of and Fluid Leak Sensors reflective light. 2. Wipe the sensor with a lint-free cloth dampened with clear water. 3. Dry completely using a lint-free cloth.
Pump	1. Unscrew the pump cover and remove the pump rotor. 2. Wipe inside of the pump rotor assembly with a mild detergent-dampened cloth. 3. Rinse the pump under a faucet with warm water. If necessary, pump rotor can be placed in an ultrasonic cleaner. 4. Dry thoroughly using a lint-free cloth and replace the pump rotor.
Tubing Clamps and Clamped Line Sensor	1. Wipe with a lint-free cloth dampened with mild detergent. 2. Wipe with a lint-free cloth dampened with clear water. 3. Dry with a lint-free cloth.

APPENDIX C: MACHINE MESSAGES/TROUBLESHOOTING

Machine Messages/Troubleshooting

Condition/Reason	Mode	Action
"AIR DETECTED EARLY" Air detected before bowl has been emptied.	EMPTY/RETURN	1. Check tubing placement. 2. Check for occlusions in effluent tubing. 3. Check for bowl displacement air in waste bag.
"AIR DETECTED IN FILL CYCLE"	FILL	1. Check tubing in air detector. 2. Check for occlusions in harness and bowl. 3. Open clamp on stepdown connector to red line. 4. Check suction: less than 200 mmHg. 5. Check tubing in valves for correct placement.
"BOWL TYPE CONFIRMATION" The white, 70 ml bowl adapter has been detected in the centrifuge well.	FILL/LOAD DISPOSABLE	1. Press YES if using the white bowl adapter. 2. Press NO if NOT using the bowl adapter.
"CENTRIFUGE COVER NOT CLOSED" Centrifuge does not operate unless cover is closed.	FILL/WASH	1. Open and close centrifuge cover. 2. Ensure inlet and outlet tubing is placed correctly.
"CENTRIFUGE ERROR" Overspeed detected. Unable to reach or maintain rate. Failed to stop. CENTRIFUGE STALLED	FILL/WASH	Check bowl for proper seating.
"CENTRIFUGE STOPPING" Delay while centrifuge gradually slows to a stop.	STOP/EMPTY	System ignores any input from the control panel.
"CENTRIFUGE WARNING" Fluid detected in centrifuge well.	ANY	1. Inspect disposable inside centrifuge well for leakage. 2. Check effluent tubing for occlusion. 3. Check if waste bag is too full to permit more fluid. 4. Clean centrifuge well as necessary.

Machine Messages/Troubleshooting

Condition/Reason	Mode	Action
"CENTRIFUGE WARNING" Fluid detected at base of bowl.		1. Power OFF. 2. Clean centrifuge. 3. Restart machine.
"CLAMPED LINE DETECTED" Pressure sensed in fluid lines.	ANY	1. Check for occlusions or kinks in tubing. 2. Ensure clamps on reinfusion bag and reservoir are open.
DISPLAY INOPERATIVE	ANY	Contact Haemonetics Hotline.
"LONG EMPTY (or RETURN) CYCLE" Air should be detected by 300ml.	EMPTY/RETURN	1. Check tubing placement. 2. Check for occlusions in effluent, blue and red tubing. 3. Check for bowl displacement air in waste bag. 4. Verify bowl size recognition.
"PLEASE BE SURE PUMP PLATEN AND VALVE DOOR ARE CLOSED"	ANY	Inspect closure of pump and valve door.
"PRODUCT BAG WAS EMPTIED" Air is detected.	CONC	1. If bag is empty, press STOP to wait for more salvaged blood or press WASH to complete cycle. 2. If bag is not empty: • Check tubing in air detector. • Check tubing in valves for correct placement.
"PUMP ERROR" Pump is not turning. Incorrect pump rate is detected.	ANY	1. Check pump platen. • Open pump platen. • Check for proper tubing placement. • Close pump platen. 2. Clean pump rotor. (Refer to Appendix B in the Operator's Manual.)
"PUMP RESTART IN XX SECONDS" Centrifuge regains rate before starting pump to prevent RBC spillage.	FILL/WASH	No action required. May override after 15 seconds, IF RBCs have reconcentrated, by pressing START.
"SALINE BAG EMPTY Air is detected during the WASH mode.	WASH	1. If bag is empty, add more wash solution. 2. If bag is not empty: • Check spike in bag. • Open clamp to bag. • Close clamp to unused spike. • Check tubing in air detector. • Check tubing in clamps for correct placement.

Machine Messages/Troubleshooting

Condition/Reason	Mode	Action
"SENSOR ERROR"	ANY	Proceed in MANUAL mode.
"SYSTEM FAULT"	ANY	Power OFF and ON machine. If failure continues, call Hotline.
"UNEXPECTED SENSOR READING" 1. Precision sensor input test. 2. Waste bag weigher sensor. 3. Reservoir level sensor. 4. Clamped line sensor. 5. Free hemoglobin sensor. 6. Red blood cell line sensor. 7. Bowl optics sensor	ANY	1. Restart machine. If failure continues, call Hotline. 2. Check waste bag and weigher. 3. Check reservoir placement and reservoir tubings placement. 4. Ensure red and blue line clamps are open and no kinks or occlusions are in tubing. 5. Clean sensor and tubing. 6. Clean red cell line sensor and inspect shoulder of bowl for blemishes. 7. Clean bowl optics sensor.
"UNIT NOT WASHED" When system leaves FILL or CONC without entering or completing WASH.	EMPTY/RETURN	Confirm that operator does not wish to wash blood.
"VALVE ERROR"	ANY	1. Check reservoir line (RED), saline line (YELLOW), or product line (BLUE). 2. Close clamps on red, blue, and yellow lines, remove tubing from manifold and inspect area around valve and manifold.
"WASTE BAG FULL" Greater than 9 L in waste bag.	ANY	Empty or change waste bag. Ensure bowl is empty.

If you are not comfortable troubleshooting problems with your equipment or disposables, Haemonetics has a 24 hour Hotline (800) 433-3431 that you may call for assistance.

APPENDIX D: IEC 60601-1 STANDARD REQUIREMENTS

Caution: *The Cell Saver device must be operated in an environment compatible to the requirements of the IEC 60601-1-2 Standard, Electromagnetic compatibility.*

Operation precautions

To comply with the IEC 60601-1-2 Standard for Medical Electrical Equipment, general requirements for safety, it is not permitted to power the Cell Saver device using a power cord not supplied by Haemonetics, a multiple portable socket outlet or an extension cord.

Mobile 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 device and accessories must not be placed directly adjacent to, or top of other equipment, unless specifically approved by Haemonetics.

Electromagnetic immunity

The Cell Saver system is intended for use in the electromagnetic environment specified in the following tables and the operator must ensure that each system is used in such an environment..

IEC 60601-1-2: 2001, Table 201: Guidance and manufacturer's declaration - electromagnetic emissions

The Cell Saver system is intended for use in the electromagnetic environment specified below. The customer or the user of the Cell Saver system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment guidance**
RF emissions CSIPR 11	Group 1	The Cell Saver 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 CSIPR 11	Class A	The Cell Saver system is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

IEC 60601-1-2: 2001, Table 202: Guidance and manufacturer's declaration - electromagnetic immunity

The Cell Saver system is intended for use in the electromagnetic environment specified below. The customer or the user of the Cell Saver system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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 IIEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±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 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the Cell Saver system requires continued operation during power mains interruptions, it is recommended that the Cell Saver system be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 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.			

IEC 60601-1-2: 2001, Table 204: Guidance and manufacturer's declaration - electromagnetic immunity

The Cell Saver system is intended for use in the electromagnetic environment specified below. The customer or the user of the Cell Saver system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the Cell Saver system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: (To be calculated)
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1=3 Vrms	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	E1=3 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,5 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.

[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 Cell Saver system is used exceeds the applicable RF compliance level above, the Cell Saver system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Cell Saver system.

[b] Over the frequency range 150 kHz to (0 MHz, field strengths should be less than $[V_1]$V/m.

IEC 60601-1-2: 2001, Table 206: Recommended separation distance between portable RF communications equipment and the Cell Saver device

The Cell Saver system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cell Saver system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cell Saver system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter 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	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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.

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