Cell Saver® 5+

Working with the Haemonetics® Cell Saver®5+

Autologous Blood Recovery System

– Operation Manual –

CE 0123

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IMPORTANT INFORMATION FOR THE CUSTOMER

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Understanding the purpose of this manual

This manual is intended for use as a guide, uniquely for material as supplied by the Haemonetics Corporation. It provides the operator with necessary information to safely carry out specific procedures and satisfactorily maintain Haemonetics produced equipment. The manual is to be used in conjunction with instruction and training as supplied by qualified Haemonetics personnel.

Haemonetics guarantees its products when correctly used by a properly trained operator. Any failure to respect the procedures as described could result in impaired function of the equipment, as well as in injury to the operator and/or patient. When properly assembled, maintained and operated properly, the Cell Saver systems can safely and adequately perform various cell salvaging procedures.

Haemonetics accepts no responsibility for problems resulting from failure to comply with prescriptions as outlined by the company. Any modifications estimated as necessary by the customer should be evaluated by a Haemonetics Clinical Specialist.

Safe utilization of Haemonetics material and equipment requires the operator to correctly handle and dispose of blood-contaminated material. The operator of any Haemonetics equipment must fully understand and implement the local prevailing policies and procedures of each facility in which Haemonetics products are used, concerning blood-contaminated material as well as blood products.

It remains solely the responsibility of the customer to fully assess and ensure the safety of any products obtained from Haemonetics prescribed procedures, prior to further application or use. Haemonetics declines any responsibility for choices made by the consumer concerning the utilization of these products and by-products.

USA Federal Law restricts this device to sale by or on the order of a physician.

Contacting Haemonetics worldwide

The operator should consult the following alphabetical list containing all international branch addresses when contacting the appropriate Haemonetics representative for each locality.

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UNDERSTANDING THE USE OF SYMBOLS

Symbols found in this document

The terms *Note, Caution* and *Warning* are used in this manual with the following symbols to emphasize certain details for the 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 by-products; personal injury is unlikely.*

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

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

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

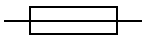
Symbols found on the device

- IEC 60601-1 Standard, Medical Electrical Equipment, Part 1: General requirements for safety.
- IEC 60417-1 Standard, Graphical symbols for use on equipment, Part 1: Overview and application.

Type BF applied part
This symbol indicates that the applied portion (i.e. the part which comes in contact with the patient) of the device is electrically isolated. The device has an internal electrical power source providing adequate protection against electrical shock, in particular pertaining to acceptable leakage current and the reliability of the protective earth connection.

Protective earth [ground]
Used to identify any terminal intended for connection to an external conductor, for protection against electrical shock in case of a fault.

~ **Alternating current**
Used to indicate on the rating plate that the device is suitable for alternating current only.



Fuse symbol
Used to identify fuse boxes or the location of a fuse box.

Power OFF
Position of the main power switch indicating disconnection from the mains.

Power ON
Position of the main power switch indicating connection to the mains.

IPX1 **Protection against ingress of liquid**
Indicates that the enclosure of the device is designed to provide a specified degree of protection against harmful ingress of water or liquid into the equipment (under applicable conditions).

Attention (Consult accompanying documents)

Non-ionizing electromagnetic radiation
Used to specify RF transmission for data communication.

Symbol found on the chuck adapter

DO NOT DISCARD

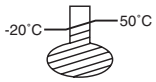
The following symbols have been designed for devices manufactured by Haemonetics

Bar-code reader connection

RS232 connection with power to one pin

Symbols found on disposable packaging

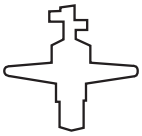
The following symbols are used by Haemonetics on disposable set packaging.

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**
STERILE R	**Contents sterile by exposure to gamma irradiation**
STERILE R	**Fluid path sterile by exposure to gamma irradiation**
	**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

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Chapter Six Cell Saving using Manual Operation

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Chapter One

Presenting the Cell Saver 5+ System

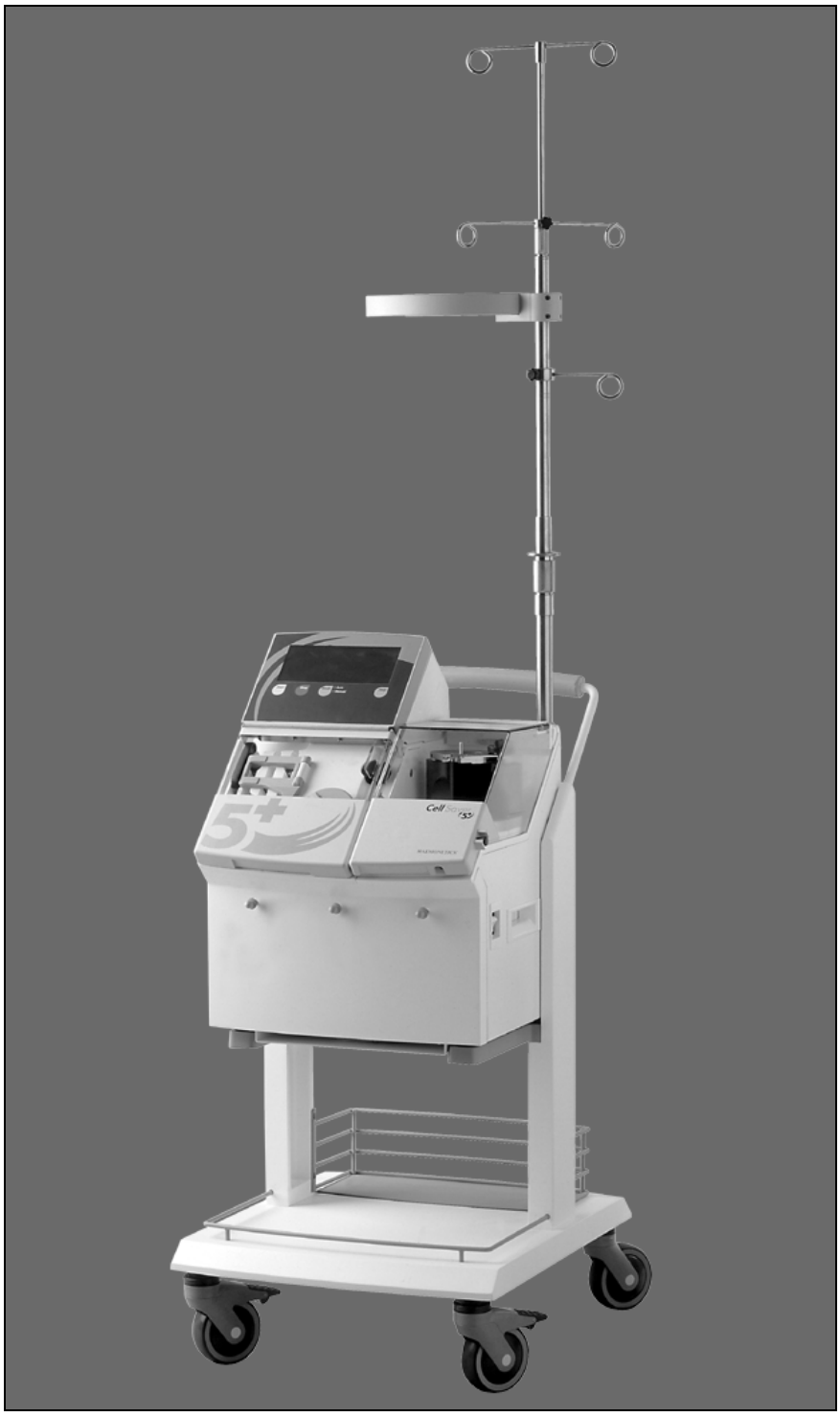

Figure 1-1, The Haemonetics Cell Saver 5+

INTRODUCING THE CELL SAVER 5+ SYSTEM

The Haemonetics Cell Saver 5+ Autologous Blood Recovery System (CS5+) represents the fifth generation since the introduction of the first successful autologous blood collection system, the original Cell Saver 1 System.

Using the latest microprocessor technology, the Cell Saver 5+ system delivers a high level of automation in the processing of autologous blood. Operator interaction and surveillance are minimized by the use of a sensor which automatically detects the level of fluid in the reservoir and initiates device operation. Processing time has also been reduced while maintaining the highest quality end product.

The Haemonetics Cell Saver 5+ system and its related accessory devices are intended to be used for the recovery of blood shed during or after an operation, or as the result of trauma. The shed blood is collected in a sterile reservoir, then processed by the Cell Saver system in a centrifuge bowl to pack red blood cells (RBCs), then washed to remove cell stroma, platelets, activated clotting factors, extracellular potassium, free hemoglobin, anticoagulant, and cardioplegia.

The washed, packed RBCs may then be pumped to a bag for gravity reinfusion to the patient, or, to the arterial line of an extracorporeal circuit for reinfusion to the patient

Indications for use

The CS5+ system should be considered for a procedure when it is anticipated that blood will be shed from a clean wound and retrieved at a rate permitting aspiration without undue hemolysis. The presence of any of the following criteria may be an indication for blood salvage:

- Anticipated blood loss is 15% or more of the patient's estimated blood volume.
- Blood would ordinarily be crossmatched.
- More than 10% of the patients undergoing the type of procedure require transfusion.
- The mean transfusion rate for the type procedure exceeds one unit.

Specific types of surgery for which the technique is especially useful include:

- Open heart and vascular surgery.
- Total joint replacements and spinal surgery.
- Liver transplantation.
- Ruptured ectopic pregnancy.
- Selected neurosurgical procedures.

Post-operative salvage is employed most often following cardiac and certain types of orthopedic procedures [1].

A disposable bowl called the *70mL Bowl* has been designed specifically for low volume peri-operative cell salvage. This new step in cell saving is very well adapted for every type of low volume blood loss situation, including peri-operative pediatric cell salvage and post-operative orthopedic cell salvage. Use of this bowl will allow blood to be available earlier for reinfusion to the patient.

The Haemonetics Cell Saver 5+ system may also be used for pre-operative plasma sequestration.

Contraindications for use

The risk/benefit ratio of blood salvage must be determined on an individual basis by the surgeons, anaesthetists and transfusion medicine specialists involved in the patient care. The *Appendix A* provides a list of recommended contraindications.

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.

EXPLAINING AUTOLOGOUS BLOOD TRANSFUSION

Autologous blood is now widely accepted as the first choice for transfusion, whenever possible. The term **autologous blood** refers to blood which is derived from one individual. An autologous blood transfusion can be defined as a procedure in which a patient receives his or her own blood. The blood may have been collected earlier or salvaged from shed blood intra-operatively or postoperatively.

Homologous blood is blood of the same type, donated or derived from sources other than the patient who is receiving the transfusion.

Autologous versus homologous transfusion

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

- No risk of disease transmission.
- No transfusion reactions.
- Requires minimal compatibility testing.
- Reduces demand on blood bank inventory.

Cell Saver systems and autologous transfusion

In addition to the general benefits of autologous transfusion, the 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 solution.
- Removal of activated clotting factors.
- Removal of extracellular potassium.
- Cost-effectiveness.
- General acceptance by Jehovah's witnesses.

Historical overview

The following paragraphs summarize 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 which 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 a great deal of 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, an English surgeon named James Highmore proposed the use of autotransfusion (another term used for *autologous transfusion*) and suggested that a patient's own shed blood was an overlooked source which could be used to great advantage. His article which appeared in *The Lancet* in 1874, advocated intra-operative 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 homologous blood

In the early 1900's, techniques for typing and matching blood were developed. Homologous transfusions gradually became accepted, though the general method remained the transfusion of blood directly from donor to recipient, rather than the use banked blood.

The first blood bank was established at Cook County Hospital, Chicago on March 15, 1937. However, the real rise of homologous transfusions came during World War II [7]. There was a great need for blood during the war, 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 homologous transfusions became the norm.

Naturally, doctors returning from the war continued to rely on donor blood, although several factors were developing which would make this less and less practical. The Korean and Vietnam wars which followed World War II placed the usual high demands on the donor pool. Concurrently, other large demands were being placed on the donor pools by 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 device was introduced commercially in the 1970's by Bentley Laboratories. The device was effective though unsophisticated, as blood was simply anticoagulated, filtered, and reinfused. The Bentley device was the first attempt to modernize autologous blood recovery in decades.

Haemonetics Cell Saver systems

Haemonetics Cell Saver systems are aptly named since the primary purpose is the recovery of red blood cells (RBCs). The RBCs are recovered shed blood which in the past was simply discarded after an operation. Cell Saver systems trap and wash the RBCs, removing unwanted components, then pack the RBCs and return them to a transfer container for reinfusion.

The first Haemonetics Cell Saver system was released in 1975. With each generation of the Cell Saver systems, Haemonetics has improved performance and increased automation. Haemonetics offers a variety of Cell Saver systems to be used for a wide range of surgical procedures.

PRESENTING SPECIAL CELL SAVER 5+ FEATURES

The CS5+ model improves upon the design and performance of its predecessors by processing shed blood faster without compromising the quality of the end product (packed RBCs). Haemonetics has improved and streamlined the features and functions of earlier units to meet the demands and needs of the modern operating room. An onboard computer (microprocessor) uses data from a variety of sensors to control the processing of blood, allowing an unprecedented level of automation.

Automated operation

Through the use of an **effluent line sensor**, the CS5+ device determines the optimal processing parameters by procedure. 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.

An optical RBC 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 which then regulates the cycles of the device based on this information.

The **ultrasonic air detector** monitors the 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 **centrifuge well optical sensor** monitors the red blood cell level in the bowl. This sensor initiates tripping to the WASH state when the RBC level indicates a high hematocrit. The **effluent line sensor** monitors the quality of the effluent blood as it leaves the bowl. As a result of these readings, the system could initiate one of the following actions:

- Determining when the RBCs are adequately washed.
- Slowing the pump rate in the WASH state if RBC spillage is detected.

Computer guided setup

The on-board microprocessor guides the operator in setting up the system through a list of installation instructions. For assistance in setting up the CS5+ system, the operator can use the Help key on the control panel (as described in *Chapter Four*) to receive a list of instructions as follows:

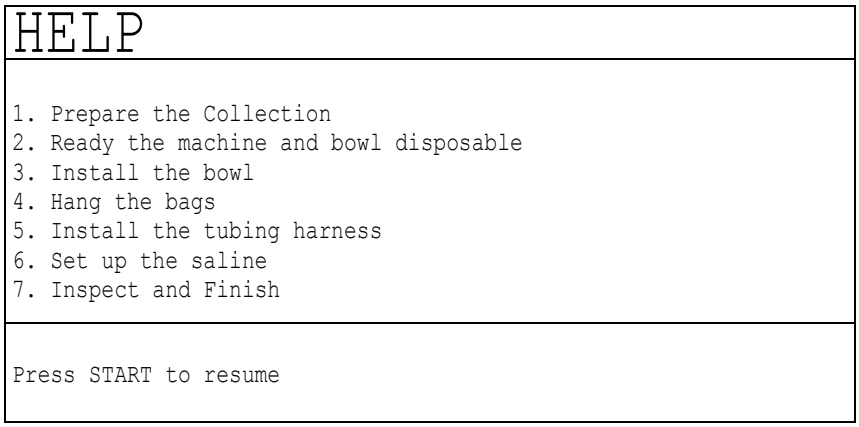

Figure 1-2, Help display installation instructions

Operators with multiple responsibilities involving frequent interruptions find the setup instructions useful as a checklist. If called away to attend to another duty, the operator can leave the setup instructions as a reminder, then return to the instruction list and continue from that point.

Final blood product quality

The final blood product of the CS5+ standard volume (225 ml) bowl consists of red blood cells suspended in saline with a hematocrit of at least 50%.

Performance readouts

The right side of the display panel provides information relative to CS5+ operation which is constantly updated. System status is available at a glance.

Data acquisition tools

The CS5+ device provides helpful data acquisition tools designed to provide efficient support for quality assurance in anesthesiology.

Emergency mode

The CS5+ device provides easy and quick access to an emergency protocol to allow high speed blood processing (800 ml/min) while continuing with automatic operation in high blood loss procedures.

LISTING THE CELL SAVER 5+ SPECIFICATIONS

The CS5+ device is destined for continuous operation.

Caution: *The CS5+ equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with nitrous oxide.*

The dimensions and weight of the CS5+ device are as follows:

Characteristics	Depth (cm)	Height (cm)	Width (cm)
Device alone			
Pole extended	37	189	41
Pole retracted	37	86	41
Device with cart			
Pole extended	58.5	230	48
Pole retracted	58.5	127	48
Weight of the device: 34.0 kg *Weight of the cart: 20.4 kg*			

The following environmental conditions should be respected pertaining to operation, transport and storage of the CS5+ device:

Conditions	Values
Ambient operating temperature	10° C to 27° C (50° F to 80° F)
Storage temperature	–20° C to 50° C
Storage humidity level	Maximum relative humidity rate of 90%, non-condensing

The electrical specifications for operating the CS5+ device are as follows:

Characteristics	Values (relative to input voltage)	
Input voltage	230 VAC ± 10%	110 VAC ± 10%
Operating current	~1.9 A	~ 2.6 A
Fuse rating	F2.5 A @ 250 V	F5.0 A @ 250 V
Operating frequency range	50 - 60 Hz	50 - 60 Hz
Maximum leakage current	500 µA	100 µA

Note: Haemonetics will regulate the proper voltage setting upon installation. The power source used must be properly grounded.

Caution: *The Cell Saver 5+ device must be operated in an environment compatible to the requirements of the IEC 60601-1-2:2001 Standard, Electromagnetic compatibility.*

Mobile RF communication equipment not approved by Haemonetics and portable communication equipment can affect the Cell Saver 5+ device. 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 5+ device and accessories must not be placed directly adjacent to, or top of other equipment, unless specifically approved by Haemonetics.

Fluid management systems

The device is equipped with a pole for hanging the saline solution, reservoir, reinfusion bag, anticoagulant solution and transfer packs. The pole may be raised and lowered by loosening the lower knob. The top portion can be extended by releasing the upper knob. The movable pole hooks are used for hanging the saline and reinfusion bags.

The waste bag weigher provides three hooks on the front of the device for hanging and monitoring the level in the waste bag.

Processing speeds

- Typical processing time: 5 minutes.
- Centrifuge speed:
  - *For the Latham bowls:* 5650 rpm, programmable from 2050 rpm to 5650 rpm in 100 rpm increments.
  - *For the 70mL Bowl:* 7000 rpm, programmable from 2050 rpm to 7000 rpm in 100 rpm increments.
- Pump speed:
  - *For the Latham bowls:* programmable from 25 to 1000 ml/min in 25 ml/min increments.
  - *For the 70mL Bowl:* programmable from 25 to 300 ml/min in 25 ml/min increments.
  - May be temporarily reset with Pump Control arrow keys.

Maneuverability and portability

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

Note: The following description is for an operator facing the rear of the cart.

- To remove the device from the cart, depress the release button located to the right of the latch, as illustrated in *Figure 1-3*. A handle will pivot outward from the left side of the latch. Pull on the handle to ensure that the lock is completely disengaged. Lift the device off of the cart.
- To replace the device on the cart, depress the release button located to the right of the latch. If necessary, pull on this handle until it is in the fully open position. Replace the device on the cart and push the latch handle toward the device until it locks into place.

Figure 1-3, The Cell Saver 5+ cart

Construction

- Cabinet and cart materials: fabricated sheet metal and cast aluminum.
- Control panel: membrane switch technology, environmentally sealed with backlit option keys.

ORDERING CELL SAVER 5+ DISPOSABLE SETS

The following disposable material can be ordered to use with the Cell Saver 5+ system:

LN200, 205	Collection reservoir, 150 micron filter, 3000 ml. Sterile, disposable, single use only.
LN220	Filtered collection reservoir, 20 micron filter, 3000 ml. Sterile, disposable, single use only.
LN208	Aspiration and Anticoagulation assembly. Includes double-lumen suction tubing with step-down adapter and tubing stubs. Sterile, disposable, single use only.
LN245	Reinfusion bag, 1-liter capacity. Sterile, disposable, single use only.
LN246	Waste bag, 10-liter capacity. Sterile, disposable, single use only.
LN261, 261E	Cell Saver 5/5+ Bowl Set (125mL Bowl). Includes tubing harness, reinfusion bag, waste bag, 125 ml centrifuge bowl. Sterile fluid path, disposable, single use only.
LN263, 263E	Cell Saver 5/5+ Bowl Set (225mL Bowl). Includes tubing harness, reinfusion bag, waste bag, and 225 ml centrifuge bowl. Sterile fluid path, disposable, single use only.
LN291E	Cell Saver 5/5+ Bowl Set (70mL Bowl), single use only.
LN02005-110EP	Haemonetics Cell Saver 5+ system for 110 VAC.
LN02005-220EP	Haemonetics Cell Saver 5+ system for 220-240 VAC.

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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 Two

Describing the Cell Saver 5+ System Components

1. Centrifuge cover
2. Centrifuge
3. Effluent line sensor
4. Power switch
5. Waste bag weigher
6. Valve and pump section
7. Keypad
8. Display screen

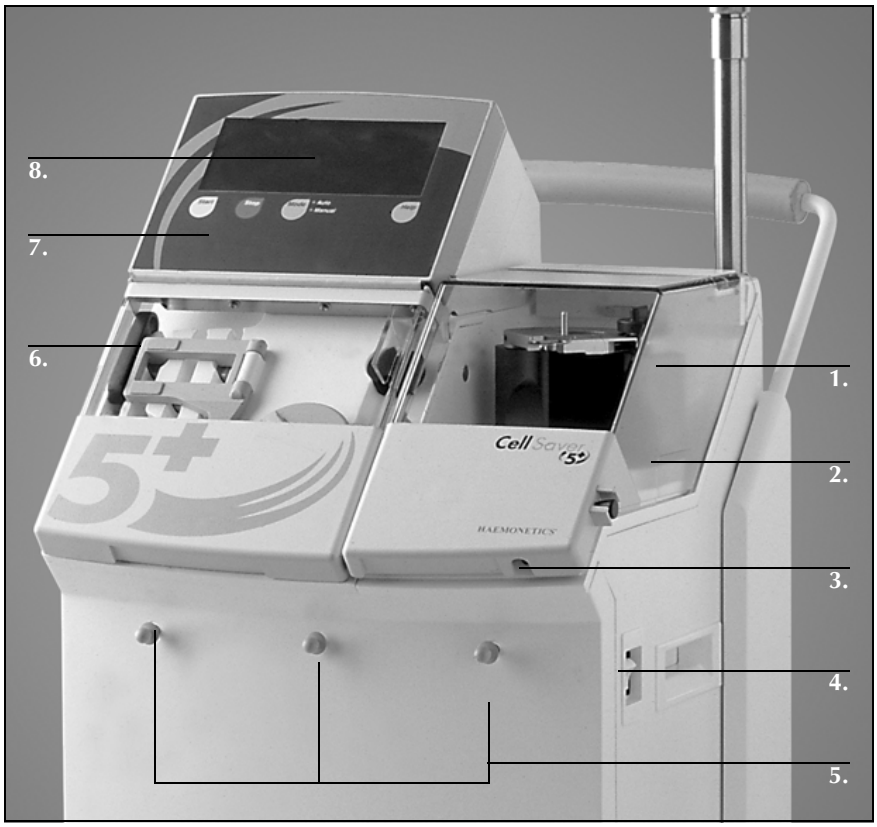

Figure 2-1, The Cell Saver 5+ components

PRESENTING THE CELL SAVER 5+ SYSTEM COMPONENTS

This chapter identifies the major components of the Cell Saver 5+ system and explains their intended utilization. Detailed installation and operating instructions for the various protocols performed by the CS5+ device will be provided in subsequent chapters.

The CS5+ system consists of two groups of components: the device components and the disposable set elements. The device controls the fluid pathway provided by the disposable set. The device components include the control panel elements and the hardware elements. A cart is provided with the system for added maneuvrability and for adjusting the system to a proper working height.

The controls and indicators for the CS5+ system have been streamlined since earlier models, reflecting simplified operating procedures and increased automation.

Power switch and power entry module

The ON/OFF power switch is located on the right side of the device.
The CS5+ device is a two-fuse system. The primary fuse is located in the power entry module on the rear of the device. The secondary fuse is located internally on the power supply and should only be replaced by trained service personnel.

Figure 2-2, CS5+ power switch (A)
and power entry module (B)

DESCRIBING THE CELL SAVER 5+ CONTROL PANEL

The control panel consists of a display screen and a keypad. Only the necessary readouts will be visible, thus helping the operator to focus on pertinent information. All control panel components are sealed and covered with a plastic membrane to protect the system from spills and allow for easy cleaning and disinfecting.

Display screen

The CS5+ display screen provides important information about the functioning of the system. As procedure statistics change, the readout is updated. For example, if the pump speed decreases from 600 ml/min to 500 ml/min, the readout on the display screen will change from 600 to 500.

During normal operation, the display screen is segmented into three main areas; data and information will be displayed in the same area for all protocols.

- The left section provides general information regarding the state of the system.
- The right section provides procedure data, mode of operation, and information regarding the programmable parameters.
- The lower section provides the actions available to operator at that specific point in the procedure.

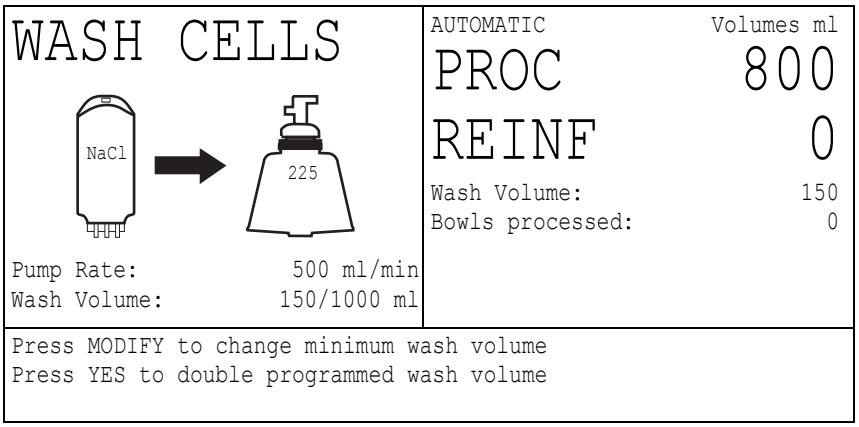

Figure 2-3, Example of the Cell Saver 5+ screen display

Keypad

The CS5+ keypad is divided into two main sections:

- the Automatic control section of permanently visible keys.
- the Semi-automatic/Manual control section of backlit keys.

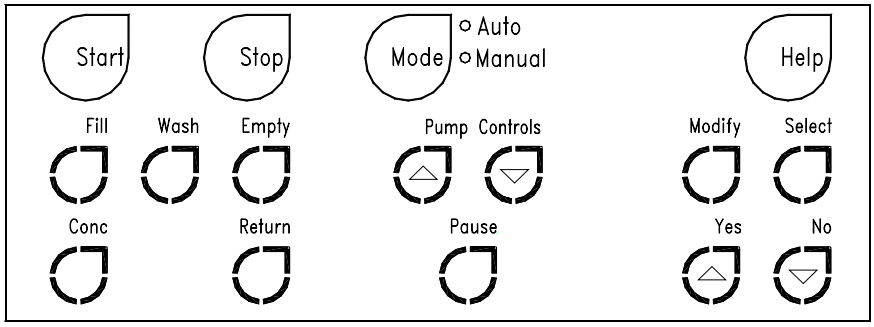

Figure 2-4, The Cell Saver 5+ keypad

The top four keys, *Start*, *Stop*, *Mode* and *Help* will be visible at all times during any type of CS5+ procedure. They are referred to as the Automatic control keys.

When the CS5+ device is operating in the automatic mode, other keys will be backlit at the appropriate times during each cycle, to allow the operator to advance through the cycle or modify preset parameters.

Located below the Automatic control key section are the Semi-automatic/ Manual control keys, consisting of the Modify control keys, the Process state keys and the Pump control keys.

When the CS5+ device is operating in the manual mode, these keys will be continuously backlit. They will be active at different points in the procedure depending on the current process state, or during modification of the preset parameters.

Automatic control keys

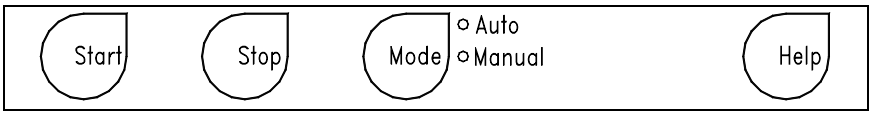

Figure 2-5, Automatic key section

These four keys are "mode-insensitive" and will regulate the automatically controlled functioning of the CS5+ device in either the manual or automatic mode, as described in the following table.

Key	Purpose
Start	Used to initiate the first cycle of a set of cycles. Used to resume operation (from STANDBY) at the point in which the process was stopped.
Stop	Used to interrupt the process by stopping the pump and centrifuge and closing all clamp-valves.
Mode	Used to change between the AUTO and MANUAL modes of operation. Can be used to switch modes during the course of any procedure. When pressed, the LED will illuminate next to the selected mode.
Help	Used to assist the operator with the disposable set installation procedure. Used to display context-specific information and assist the operator through special situations when the "help" information is available.

Modify control keys

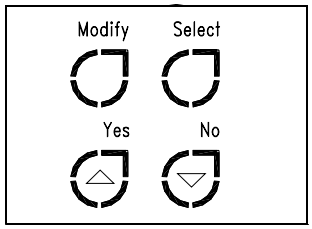

Figure 2-6, Modify control key section

These keys are also "mode-insensitive" and will allow the operator to change certain procedure parameters for a given CS5+ procedure and /or subsequent procedures. The keys become active during protocol selection, protocol setup and other various points during both automatic and manual operation.

Key	**Purpose**
Modify	Used to activate or deactivate the other modify "action" keys. When active, the operator can enter the modify loop and the other keys will be backlit.
△/Yes	Used to increase a numerical value by a specific increment. Used to respond "yes" to a Yes/No question.
▽/No	Used to decrease a numerical value by a specific increment. Used to respond "no" to a Yes/No question.
Select	Used to scroll a list of parameters or questions.

Process state keys

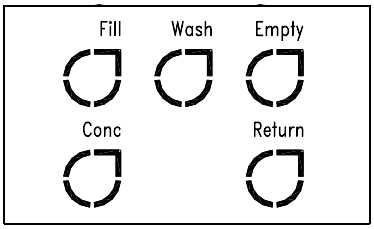

Figure 2-7, Process state key section

These keys can be used when backlit at specific points during the automatic mode; they will be permanently lit for use during the manual mode. Use will vary according to the selected CS5+ protocol as described in the following table:

Key	Purpose
Fill	*Cell Saver:* Used to pump fluid from the reservoir into a spinning bowl. *Sequester:* Used to pump whole blood from a blood source into a spinning bowl.
Conc	*Cell Saver / Sequester:* Used to pump fluid from the product bag into a spinning bowl. Supplements "Fill" and is usually selected when the bowl is partially full and the reservoir is empty.
Wash	*Cell Saver:* Used to pump saline into a spinning bowl from the saline solution bag. *Sequester:* Not used.
Empty	*Cell Saver / Sequester:* Used to pump fluid from a stationary bowl into a product bag.
Return	*Cell Saver:* Used to pump fluid from a stationary bowl back into the reservoir or into a bypass circuit. Can be used as an alternative to the *Empty* key where the contents of the bowl are pumped back (returned) through the "Fill" line instead of being sent (emptied) to the product bag. *Sequester:* Not used.

Pump control keys

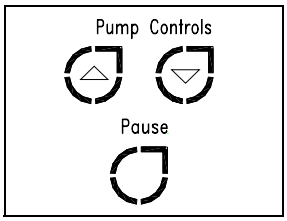

Figure 2-8, Pump control key section

These keys can be used to regulate the pump speed during any CS5+ procedure, however the increments of change will vary between the Cell Saving and Sequestering protocols, as described in the following table:

Key	Purpose
△	*Cell Saver:* Used to increase the pump speed by increments of 25 ml/min up to a maximum of 1000 ml/min. *Sequester:* Used to increase the pump speed. *Fill:* increments of 10 ml/min up to a maximum of 250. *Empty, Conc:* increments of 25 ml/min to a max of 1000.
▽	*Cell Saver:* Used to decrease the pump speed by increments of 25 ml/min to a minimum of 0. *Sequester:* Used to decrease the pump speed. *Fill:* increments of 10 ml/min to a minimum of 0. *Empty, Conc:* increments of 25 ml/min to a minimum of 0.
Pause	*Cell Saver / Sequester:* Used to stop only the pump (not the centrifuge).

DESCRIBING THE CELL SAVER 5+ HARDWARE ELEMENTS

The primary hardware elements of the CS5+ device consist of the centrifuge, a peristaltic blood pump, pinch valves and various sensors.

Valves

There are three pinch valves (also referred to as *clamps*) which occlude the three color-coded lines of the disposable set harness. The three color-coded lines are attached to a tubing manifold which is inserted below the valve slots. The manifold is held in place by a locking manifold latch.

In the automatic mode, the CS5+ device controls the opening and closing of the valves. The function of each valve is as follows:

- Red line valve: opens the pathway to the blood source, usually a reservoir or extracorporeal circuit.
- Yellow line valve: opens the pathway to the wash solution.
- Blue line valve: opens the pathway to the reinfusion bag.

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

1. Red line valve
2. Blue line valve
3. Yellow line valve
4. Manifold lock
5. Clamped line sensor
6. Pump lever
7. Pump
8. Manifold latch
9. Air detector

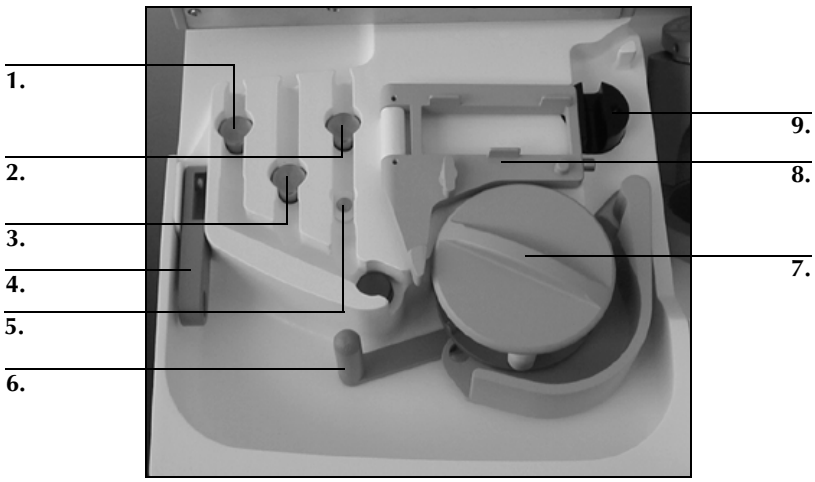

Figure 2-9, CS5+ valve and pump section

Pump

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

Air detector

This element uses ultrasound to detect air in the pump tubing leading to the centrifuge bowl. During the FILL or CONCENTRATE (CONC) process states, air bubbles are detected when the source of blood to be processed is exhausted.
The CS5+ device will revert to the STANDBY state and will display one of the following messages depending on the process state in progress:

```
Reservoir was emptied
```

or

```
Product bag was emptied
```

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 device to the next state, usually EMPTY. If the air detector senses air in the line prior to at least 90% completion of the programmed wash volume, the following information will be displayed for the operator:

```
Saline bag empty!
Replace saline bag
```

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

Clamped line sensor (blue line sensor)

The clamped line sensor monitors pressure levels in the blue line to the reinfusion bag. If the bag is inadvertently clamped, the clamped line sensor will cause the pump to stop and the following message will be displayed:

```
Clamped Line Detected
Please open fluid lines
```

Centrifuge well

The centrifuge well contains a chuck to secure the bowl in place. There are no screws to tighten. The operator should place the bowl on the centrifuge chuck, close the centrifuge arm around the top of the bowl and lock the centrifuge knob. Further details will be provided in the subsequent chapters concerning disposable set installation.

1. Centrifuge knob
2. Centrifuge arm
3. Mechanical chuck clip (6x)
4. Centrifuge chuck
5. Fluid detectors
6. Optical bowl sensor

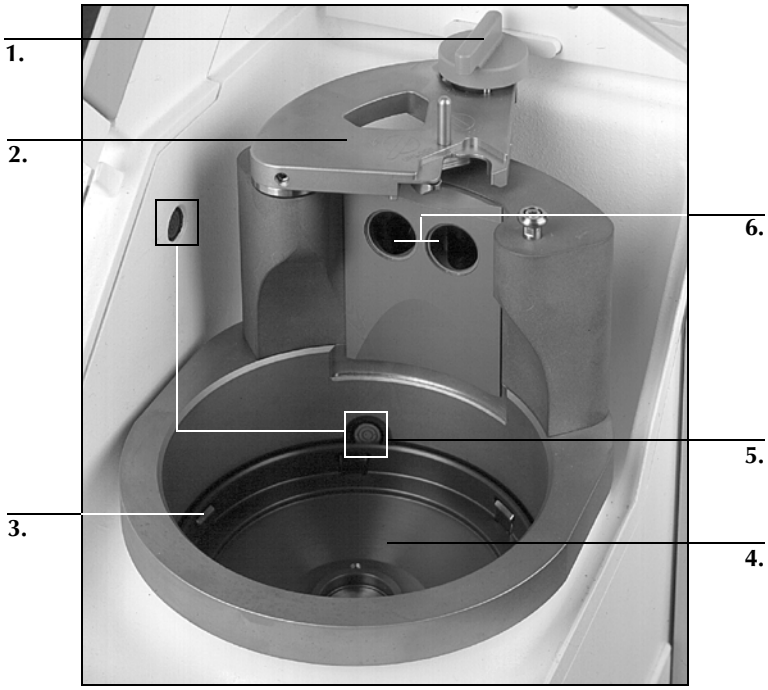

Figure 2-10, CS5+ centrifuge well components

Fluid detectors

The CS5+ system is equipped with an electronic fluid detection system designed to detect the presence of liquid. The CS5+ safety system will automatically stop the centrifuge and pump if there is contact between liquid of any sort and the fluid detector(s) located inside the centrifuge well and to the left of the bowl.

Optical bowl sensor

A photoelectric sensor mounted in the centrifuge will detect when the RBCs reach a predetermined level within the bowl and will advance the process states from FILL to WASH (or CONC to WASH) in the AUTOMATIC mode.

Warning: The optical bowl sensor is disabled in the manual mode.

Effluent line sensor

The device is equipped with an effluent line sensor which monitors the quality of the bowl effluent (fluid to waste). The line sensor groove contains two optical sensors which are used to:

- Provide information regarding the wash status and advance the system to the EMPTY state once the proper effluent quality has been reached after a "minimum" wash volume has been introduced.
- Regulate the pump speed in the FILL and WASH states to ensure optimal efficiency with the cell saving process.

Waste bag weigher

The waste bag weigher determines the weight of the fluid in the waste bag and alerts the operator first when it is almost full, then when it is full.
In the AUTOMATIC mode, the message "**Please empty waste bag**" is displayed when approximately 8 liters of fluid are in the bag for the Latham bowl sets and approximately 4.5 liters for the 70mL Bowl set. In both the AUTOMATIC and MANUAL modes, the following message will be displayed when 9 liters or more of fluid are in the waste bag for the Latham bowl sets and 4.5 liters or more for the 70mL Bowl set.

```
Waste Bag Full
Please empty waste bag
```

Reservoir level sensor

The device is equipped with a reservoir level sensor which monitors the weight of the reservoir throughout the procedure to estimate the volume of fluid it contains. This sensor is designed to trip the system into the FILL mode when an appropriate amount of solution has been aspirated from the operating field. The preset trip point will depend on the size of the bowl. The operator can modify the trip points to adjust to varying situations (example: 800 ml for a standard bowl set LN263).

PRESENTING THE DISPOSABLE SET ELEMENTS

A variety of disposable sets are available for use with the CS5+ device. This section provides a general understanding of the various elements, uses and operating characteristics. Detailed installation instructions and further specifications will be provided in subsequent chapters. The following figure illustrates a typical disposable set designed for a CS5+ procedure:

1. Centrifuge bowl
2. Tubing manifold
3. Red line
4. Collection reservoir connector
5. Yellow line
6. Saline bag spikes
7. Blue line
8. Reinfusion bag
9. Effluent line
10. Waste bag

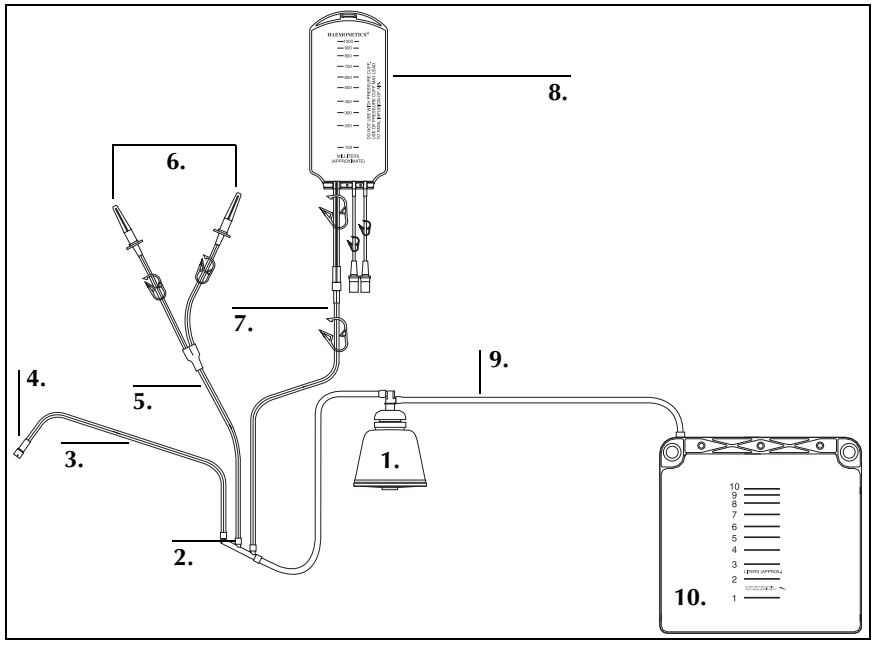

Figure 2-11, Example of a Cell Saver 5+ disposable set

Harness tubing

The harness consists of three lines:

- The yellow-coded tubing connected to the saline solution.
- The red-coded tubing connected to the unprocessed blood source.
- The blue-coded tubing connected to the reinfusion bag.

All three color-coded lines pass through the pinch valves on the device and are joined at a tubing manifold. A clamped line sensor is located under the blue line to warn of an occluded line to the reinfusion bag.
After the junction, the single tubing line passes first through the pump, 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, attached to the outlet port of the bowl, exits the centrifuge through the effluent line sensor and is then connected to the waste bag.

Receptacles and collection containers

Every CS5+ disposable setup must be equipped with the following receptacles: a waste bag, a reinfusion bag and a source of unprocessed blood which may be either a collection reservoir or an extracorporeal circuit. A typical disposable set will have saline tubing and spikes to connect to a saline solution source. An aspiration and anticoagulation (A&A) assembly is also required. The A&A assembly contains a double lumen tubing which can be attached to a suction tip for aspiration from the field. Blood and AC solution are drawn into the tubing by wall suction, mixed and then passed through the tubing into a collection reservoir. The roller clamp regulates the AC solution flow.

Aspiration and Anticoagulation Assembly

1. Suction line connector
2. Cross section of A&A tubing
   a. large lumen for anticoagulated shed blood
   b. small lumen for solution administration
3. Saline and AC solution bag
4. Drip chamber
5. Roller clamp
6. Collection reservoir
7. Line to vacuum source
8. Reservoir drain

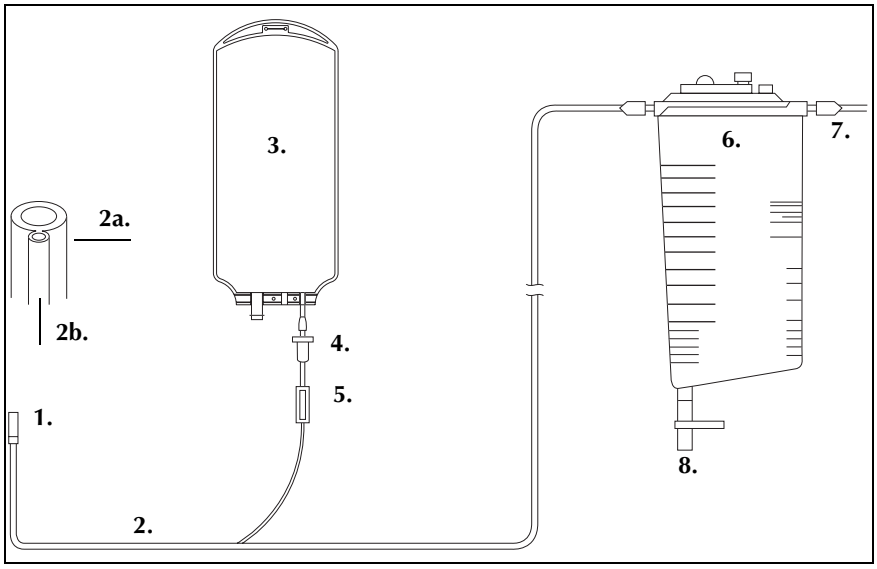

Figure 2-12, The Aspiration & Anticoagulation assembly

Centrifuge bowl

The key component of the disposable set is the centrifuge bowl, where the RBCs are separated, washed, and packed. Both models of centrifuge bowls, the Latham bowl and the 70mL Bowl, consist of two subassemblies: an inner assembly which remains stationary and an outer assembly which rotates. The outer assembly rotates with the centrifugation chamber where the blood is processed. The stationary inner assembly contains the inlet and outlet ports.

1. Inlet
2. Outlet
3. Outer subassembly - Rotates -
4. Inner subassembly - Remains stationary -

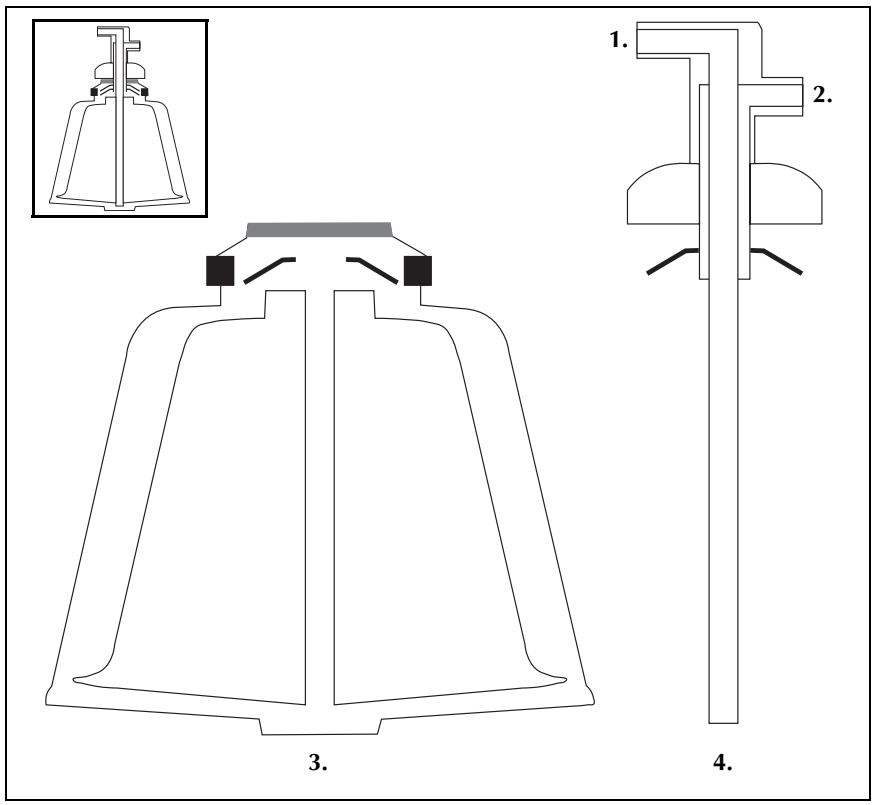

Figure 2-13, The Latham bowl and subassemblies

Warning: It is important to verify that the outlet port and effluent tubing are free of any restrictions to flow, prior to initiating flow in the bowl. If the outlet port is inadvertently clamped off, the blood being processed may be compromised by friction or heat, rendering it inappropriate for reinfusion. *Chapter Three* will provide further information about this type of situation.

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

The 70mL Bowl will require the use of a centrifuge chuck adapter to correctly load the bowl.

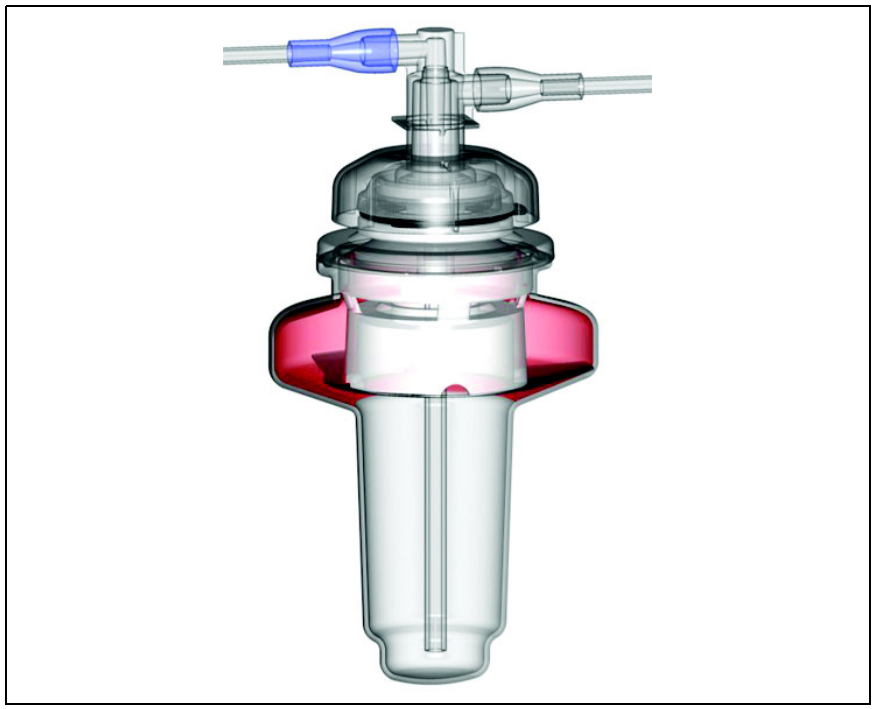

Figure 2-14, The 70mL Bowl

Describing the operation of the bowl

When blood is pumped into the spinning bowl through the inlet port, the red blood cells are centrifuged outward toward the perimeter of the bowl. The lighter, lower density supernatant is "floated" inward, toward the core of the bowl. When the bowl overflows, supernatant is forced through the outlet port. The hematocrit of blood in the bowl increases as blood is pumped in and the supernatant is forced out.

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.

The following series of drawings illustrate the operation of the bowl through the FILL-WASH-EMPTY states.

Filling the bowl to the appropriate level as shown will give a hematocrit of at least 50% for the washed cells. The hematocrit may be increased by filling the bowl until the red cell interface is closer to the center of the bowl, however manually regulating the interface in this manner is not advised. Conversely, a lower hematocrit will result if filling is terminated before the red cell interface reaches the level shown. Under automatic control, the interface is controlled by the optical bowl sensor to produce consistently good results.

In general, filling the bowl to a lower hematocrit will necessitate a higher volume of wash solution to achieve a given result. Because the hematocrit is lower, there is more supernatant in the bowl. In order to dilute the larger volume of supernatant, more wash solution is needed.

Emptying red blood cells from the bowl is accomplished by braking the centrifuge to a complete stop, then reversing the flow in the pump tubing.

Note: Recommendations for the use of anticoagulant solution presented in this manual are intended for use as guidelines only. For hypercoagulable patients, the operator may find it necessary to increase the anticoagulant dosage to prevent clotting.

1. 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 at least 50%.
4. Normal 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. The bowl stops spinning. Washed, packed RBCs are pumped to the reinfusion bag.

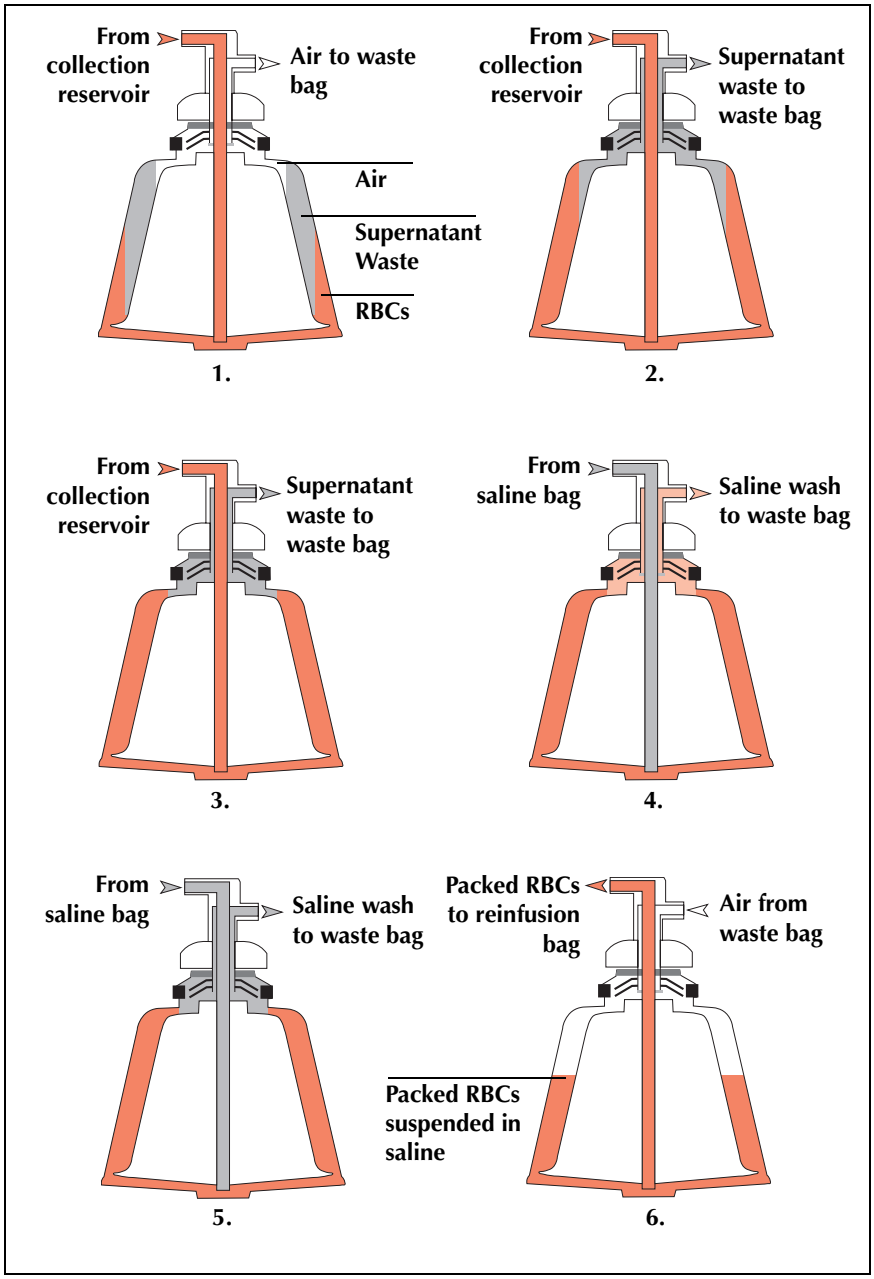

Figure 2-15, Operation of the bowl

Chapter Three

Ensuring Safe Operation and Patient Care

UNDERSTANDING SAFE OPERATING PRACTICES

This chapter provides general information about:

- Safe operating practices for the CS5+ system.
- Precautions to take when providing patient care.
- Explanation about procedure parameters and processing times.

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

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

Correctly storing and handling disposable material

In managing the inventory of stored disposables sets, sets with an earlier expiration date should be used prior to those with a later expiration date to minimize the length of storage for any particular packaged set. This is referred to as the first-in, first-out (FIFO) technique.

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

Caution: *Direct contact of the disposable plastic materials with all halogenated hydrocarbon-based anaesthetic agents, e.g., Isoflurane (Forane), Enflurane (Efrane or Ethrane), Halothane (Fluothane or Rhodialothan) must be avoided as these agents attack plastics.*

Avoiding electrical shock hazards

Inside the CS5+ cabinet are various electrical terminal strips and components. Personal contact with any of these electrical elements while the device is connected to the power source could result in electrical shock. The CS5+ cabinet panels should not be removed without first powering off and disconnecting the device from the power source.

Leakage current is a primary source 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 100 microamperes @110 V and 500 microamperes @230 V.

Warning: A leakage current test should performed routinely to ensure that the device continues to qualify under the specific leakage current limit. Particular attention should be given to leakage current after an event such as a saline spill or a major voltage surge in the electrical system of the building.

Electrolytic solutions are highly conductive; therefore the operator must avoid touching any portion of the CS5+ system with wet hands and should always work with clean, dry hands.

Working with rotating machinery

As with any equipment continuing rapidly rotating parts, the potential for severe injury exists if personal contact is made or if clothing becomes entangled with the moving parts. The CS5+ device is equipped with a safety feature which will stop the centrifuge from spinning if the cover is opened.

Warning: Operators or personnel working in proximity of this equipment should respect the standard precautions applicable to all rotating machinery.

Power outlet connection

To comply with the IEC 60601-1-2:2001 Standard for Medical Electrical Equipment, general requirements for safety, it is not permitted to power the Cell Saver 5+ device using a power cord not supplied by Haemonetics, a multiple portable socket outlet or an extension cord.

Warning about communicable diseases

Despite the application of all 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 by following policies and procedures as outlined by each medical facility for infection control.

All disposable material should be eliminated according to the local standard operating procedure concerning biologically contaminated material and biohazard waste. It should not be mixed with non-biologically contaminated waste.

PREVENTING PROBLEMS DURING A CELL SAVER 5+ PROCEDURE

Avoiding the consequences of flow restriction

The operator must ensure that there are no restrictions to flow in the effluent line. If the outlet port of the bowl is inadvertently clamped off, pressure 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 sterile air. The faces of the rotary seal faces will be wet with supernatant and depending upon the nature of the supernatant, the functional characteristics of the rotary seal may become altered. The increased friction and excessive heat can make the contents of the bowl unsuitable for reinfusion to the patient.

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

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

Understanding the risk of hemolysis

Hemolysis involves the destruction of red blood cell membranes with the release of free hemoglobin into the plasma portion of the blood. Working the blood pump against a severe flow restriction may cause hemolysis. Since the presence of free hemoglobin in the reinfusion bag may not be readily apparent, the operator should monitor for other indications of abnormal operation. A restriction which will cause hemolysis may also cause a reduction in flow rate, which in turn could result in an abnormally long time required to empty the bowl.

The CS5+ device is programmed to detect abnormally long EMPTY and RETURN states and notify the operator with an alarm while displaying the following message:

```
LONG EMPTY CYCLE.
```

Warning: If the operator visually confirms that the bowl is still not empty, a sample should be taken from the reinfusion bag prior to transfusion to the patient to determine the presence of plasma hemoglobin. If the bowl is empty, this could indicate a problem with the air detector and the operator should contact the local Haemonetics technical representative.

Inspecting for twists and kinks in the tubing

A careful inspection of the installed harness should be carried out to ensure that each section is correct installed on the CS5+ device and that all tubes are free of twists or kinks. It is particularly important that no occlusions are present in the tube between the bowl and the reinfusion bag when blood is being pumped out of the bowl. Working the pump against a severe flow restriction is likely to result in high levels of hemolysis with high levels of plasma hemoglobin.

Avoiding bowl misalignment

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

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

Controlling for overheating

Overheating of the centrifuge can occur as a result of a mechanical or maintenance related problem such as defective bearings and might cause damage to the red blood cells. It is recommended that the operator touch the centrifuge well 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 centrifuge chuck is found to be above 37° C (98.6° F), the CS5+ device 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 blood cells should be regarded as unsafe for reinfusion.

Avoiding red blood cell spillage

Under normal conditions there should be little or no red blood cell spillage and the effluent line sensor will reduce the occurrence of spillage. During the WASH state, two conditions may especially result in red blood cells spilling over into the waste bag:

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

To avoid a red cell spillage due to overfilling, the operator can press the Pause key and stop the pump, then use the pump slew keys to gradually adjust the pump speed to the desired speed while observing the cells for separation. Pressing the pump Pause key again will cause the pump to resume at the previous rate.

Caution: *A wash flow rate which is too low will provide a poor wash of the cell since there will be insufficient agitation and mixing of saline solution with the RBC layer.*

Managing the inventory of air

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

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

PROVIDING SAFE PATIENT CARE

Reinfusing blood

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

The blue-coded harness line is primed at the factory with 20 ml of sterile air. During the first empty cycle this sterile air is sent into the reinfusion bag. Therefore, the contents of the reinfusion bag should NOT be transfused under pressure.

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.

Should it become necessary to remove air from the reinfusion bag:

- ➔ Clamp the tubing between the reinfusion bag and the patient and invert the reinfusion bag.
- ➔ Unclamp one of the red clamps on the tubing to the reinfusion bag and squeeze the bag to remove the air.

Replacing depleted clotting factors

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

Contraindications for use

The risk/benefit ratio of blood salvage must be determined on an individual basis by the surgeons, anaesthetists and transfusion medicine specialists involved in the patient care. The *Appendix A* provides a list of recommended contraindications.

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.

FACTORS AFFECTING PROCESSING TIME

Cell Saving

The time required to process a centrifuge bowl of salvaged blood depends on 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+ device has been programmed to optimize this time during each procedure without compromising the final product. Any changes made to the preset processing parameters should be carefully considered prior to being executed.

Sequestering

Typical processing times for performing the sequestering procedure with the CS5+ device are from 25 to 40 minutes. During this time approximately 1200 to 2500 ml of whole blood will be processed, resulting in the collection of 1.5 to 3.0 x 10e11 platelets in 500 to 1600 ml of plasma. Actual time and results may vary depending on individual variability in vascular access, patient tolerance to the sequestering procedure, surgical condition, height, weight, hematocrit and platelet pre-count.

Chapter Four

Preparing for a Cell Saver 5+ Procedure

UNDERSTANDING GENERAL SYSTEM OPERATION

This chapter provides a general overview of how the Cell Saver 5+ system works. Detailed instructions for each protocol performed by the CS5+ system are provided in *Chapters Five, Six and Seven*.

Collecting blood

The collection of blood is the simplest of the Cell Saver system tasks. The blood is drawn into a collection reservoir (such as the LN205) through an aspiration and anticoagulation (A&A) assembly (such as the LN208).
The A&A assembly described in *Chapter Two* is attached to a suction tip. Mixing of AC solution and blood occurs in the small mixing chamber of the tubing connector. This mixing chamber is located after the suction tip which is used to remove blood and fluids from the wound. The blood and fluids are then collected in the collection reservoir.

Warning: AC solution must be added to a saline solution suitable for intravenous use. Sterile water or other irrigating solution must not be used.

It is important that shed blood suctioned from a patient be collected in a sterile container such as the LN205 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 discarded. Using the reservoir leaves open the option of processing the blood.

Filling the centrifuge bowl

Once the disposable set has been loaded, the operator should press the Start key on the front panel. The CS5+ device will automatically initiate a fill cycle when the appropriate level of fluid has been collected into the reservoir.

Note: The default level is 800 ml for the Latham bowls and 400 ml for the 70mL Bowl, however, the operator can press the Start key a second time to initiate a fill cycle before this level is reached.

At this point the centrifuge bowl begins to spin and the red line valve opens. The bowl begins to fill as the pump transfers fluid from the reservoir while monitoring the volume of fluid being pumped.

Separating and packing the cells in the bowl

The spinning of the centrifuge traps the heavier red blood cells and causes them to be driven toward the outer walls of the centrifuge. Red blood cells form the outer layer while the supernatant plasma floats inward toward the core of the bowl. The lighter fraction is forced out the effluent tubing from the bowl and into the waste bag.

Washing the red blood cells

After the process described above has been completed, the optical sensors will detect that the RBC content of the bowl is sufficient to warrant washing (at least 50% hematocrit).

The optical RBC sensor will initiate clamping the red-coded fill line and opening the yellow-coded wash line. This causes saline solution to enter the bowl and wash the red blood cells. Washing the RBCs removes unwanted components such as cell stroma, free hemoglobin, activated clotting factors, platelets, and AC solution.

Warning: Saline solution designated for intravenous use is the most suitable solution for use with Cell Saver equipment.

At the end of the WASH state, just before the system enters the EMPTY or RETURN state, the red valve will open for two pump revolutions, then close while the blue valve opens. The two pump revolutions will force any saline remaining in the line into the red-coded fill line, where it will be returned to the bowl and eventually sent to the waste bag during the next fill cycle. If this saline was left in the line, it would be sent to the reinfusion bag where it would dilute the end product.

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

Once the minimum wash volume of saline has been introduced and the effluent line sensor has detected adequate washing, the wash line will be clamped and the reinfusion line will be opened. The pump then reverses direction, sending packed RBCs suspended in saline solution from the bowl to the reinfusion bag.

The above cycle of FILL-WASH-EMPTY will be repeated as often as blood loss requires. The reservoir level sensor will initiate additional cycles as blood begins to be collected again and reaches the appropriate level to initiate a fill cycle.

INITIATING A CELL SAVER 5+ PROCEDURE

This section provides general details about initiating a procedure and installing a CS5+ system disposable set, regardless of how the system will be operated for a Cell Saver procedure.

Variations will exist at certain points depending on whether the set contains a Latham bowl or a 70mL Bowl. These differences which concern primarily the installation of the centrifuge bowl and the line sensor tubing will be clearly indicated in the text.

Note: The 70mL Bowl is mainly intended for pediatric use or to improve blood availability in the case of low bleeding.

Cell Saver 5+ operation is simple. Physical setup involves:

- ➔ Installing the bowl in the centrifuge well.
- ➔ Installing the tubing harness for the passage of fluids in and out of the system.
- ➔ Hanging the appropriate solutions for washing and anticoagulating the blood.

The level sensor on the reservoir bracket will automatically initiate the fill cycle when the appropriate fluid level has been detected. In the MODIFY state, the operator can change some operational parameters during Protocol Setup and during various stages of processing.

Caution: *The Cell Saver 5+ system is programmed to produce consistently good results during most procedures. The operator should carefully consider this prior to making any changes to the original program or operating the system in the manual mode.*

If no modifications are made, the CS5+ device automatically adjusts to the appropriate bowl size in use during the first fill cycle.

Explaining the power on procedure

When ready to initiate processing, the operator should:

➔ Press the power on switch located on the right side of the CS5+ device.

If the device has been powered off for less than six hours, the CS5+ system will provide the option of saving information as depicted in the following message:

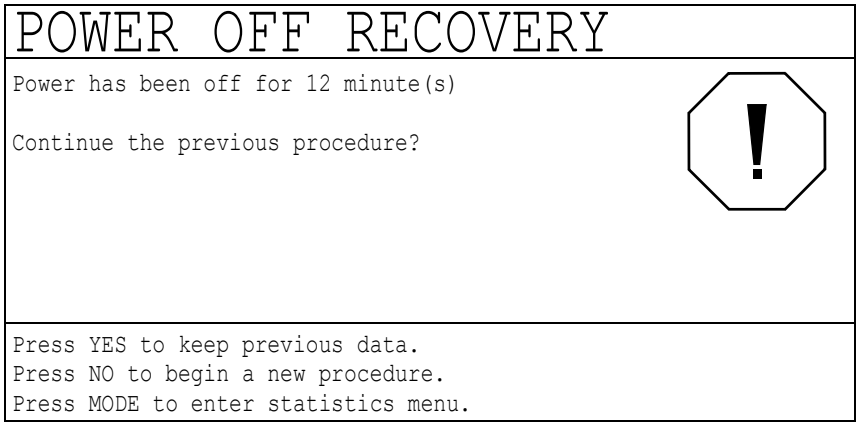

Figure 4-1, Example of a Power off recovery message

➔ Press the Yes key to retain data collected prior to powering off the device.

➔ Press the No key to initiate a new procedure.

At this point, or if the device has been powered off for more than six hours, the Self Test screen display will appear as depicted. The CS5+ system will perform a series of internal diagnostic tests to ensure that all functions are operating prior to each CS5+ procedure.

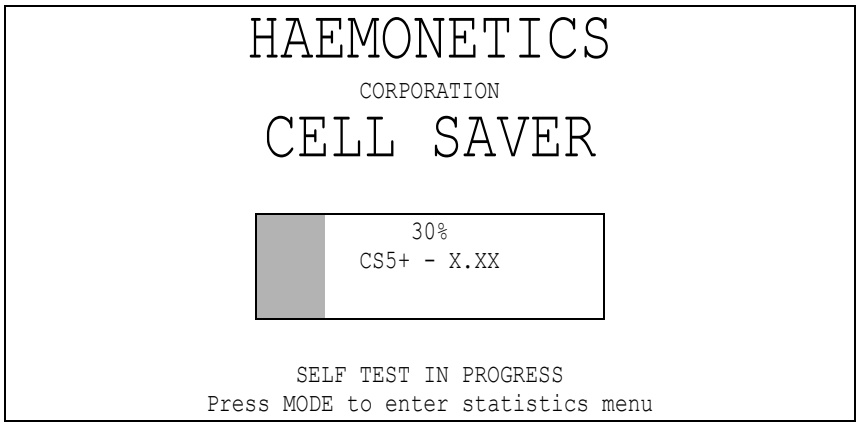

Figure 4-2, Example of a Self Test screen display

The Self Test screen display will indicate the stage of self test completion and the current version of software installed in the device (CS5+-X.XX).
If a fault is detected by the safety system, a Notice message with appropriate operator actions will be displayed as illustrated in the following example:

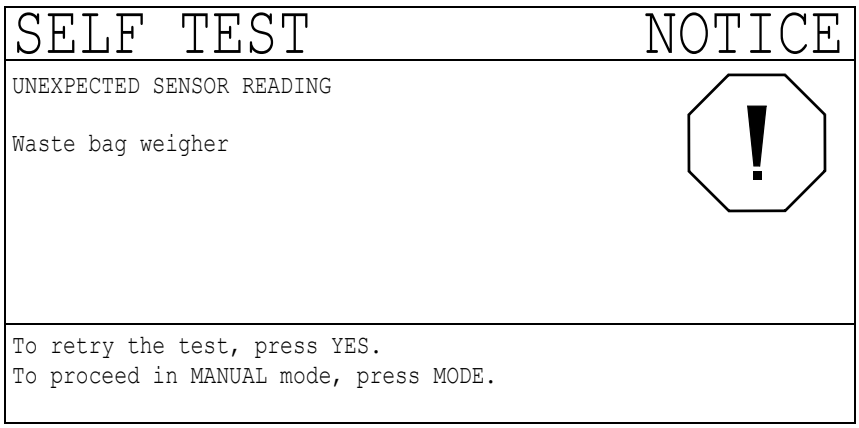

Figure 4-3, Example of a Self Test Notice message

Once the CS5+ system self test has been successfully completed, the following information will be displayed:

Figure 4-4, Load Disposable screen message

At this point the operator can follow the instructions for loading the disposable set as described in the section *Installing a Cell Saver disposable set.*
The operator can also press the Help key and consult the installation list as illustrated in *Chapter One, Figure 1-2*.

Explaining the bowl type confirmation message

Once the disposable set has been loaded on the CS5+ device, the system will automatically detect the size of the bowl and adjust the processing parameters accordingly.

If for any reason the system cannot detect the type of bowl which has been installed, the following message will be displayed:

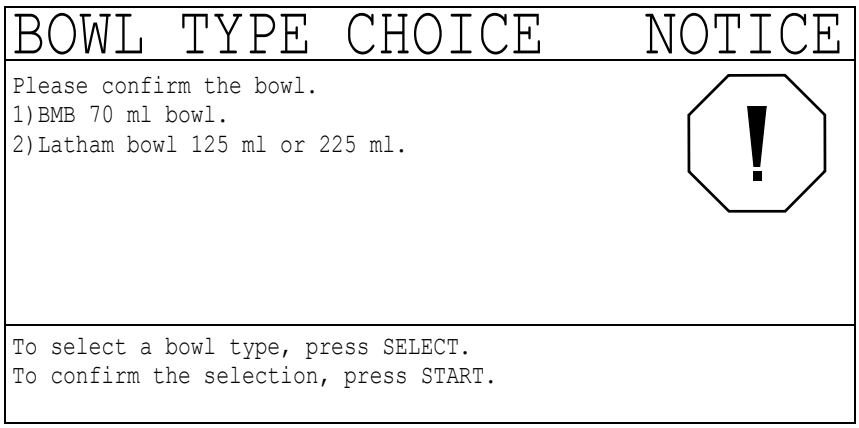

Figure 4-5, Bowl type confirmation message

If this message should appear, the operator should:

- ➔ Press the Select key to select and highlight the correct bowl type.
- ➔ Press the Start key to confirm the selection.

Once the type of disposable bowl in use has been confirmed for the CS5+ system, the message will not appear again. This message could be displayed during the procedure up to and including the first fill cycle.

INSTALLING A CELL SAVER DISPOSABLE SET

At this point the operator can press the Help key for abbreviated installation instructions, as illustrated in *Chapter One, Figure 1-2*. The following paragraphs provide further details related to the HELP installation list.

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+ device.

Preparing the collection system

- ➔ Install a collection reservoir on the IV pole and clamp the reservoir drain.
- ➔ Open the Aspiration and Anticoagulation set using aseptic technique.
- ➔ Pass the sterile inner wrapped line onto the sterile field and in the sterile field, attach a plastic suction wand.
- ➔ Connect the Aspiration and Anticoagulation set to the reservoir. Attach wall suction to reservoir and **set suction at a minimal acceptable level (recommended –80 to –150 mmHg)**. Close the roller clamp on the anticoagulant line.

1. Connector to vacuum source (yellow cap)
2. Reservoir
3. Connector to aspiration line (blue cap)

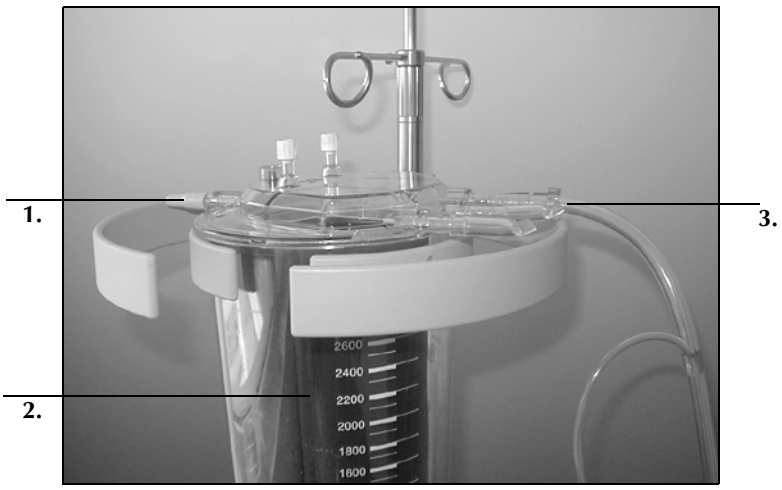

Figure 4-6, Connecting the A&A assembly to the reservoir

Warning: When using a vacuum source, the operator should be aware that vacuum force greater than –200 mmHg may cause hemolysis.

- ➔ Hang the AC solution bag on the IV pole, then aseptically insert the spiked end of the drip chamber into the AC solution bag.
- ➔ Ensure that the bag is properly labelled as anticoagulant solution.

Caution: *The recommended AC solution is 30,000 units of heparin in 1 liter of normal saline solution. The drip rate should be set during the procedure at 1-2 drops per second depending on the rate of blood flow being processed.*
Citrate (ACD-A 3% to 4% sodium citrate) can also be used as an AC solution. The ratio of citrate solution volume to blood volume should range between 1:5 to 1:10 or approximately 70 ml of citrate per 500 ml of recovered blood.

- ➔ Reopen the roller clamp on the AC drip line to allow full flow of AC solution, allowing approximately 150 ml of AC solution to flow into the collection reservoir to adequately prime the filter/defoamer media.
- ➔ Close the roller clamp until beginning the collection from the field.
- ➔ Open the clamp below the reservoir drain once the entire disposable set has been installed and the CS5+ device is ready to process blood.

Preparing the device and disposable set

- ➔ Power on the CS5+ device and wait for the self-test to be completed (if not already performed).
- ➔ Open the centrifuge cover, fluid deck cover, bowl arm, pump lever and tubing manifold latch.
- ➔ Peel back the protective lid on the disposable tub.

Installing the bowl

For the 70mL Bowl

➔ First insert the chuck adapter into the centrifuge well.

The chuck adapter is NOT designed for single use and should be saved subsequent procedures.

Symbol:
DO NOT DISCARD

Figure 4-7, Inserting the chuck adapter (for use with the 70mL Bowl)

For all sets

➔ Lift the bowl out of the tub and place it in the centrifuge well.

➔ **Ensure that the red indicator lines inside the chuck adapter are visible.**

➔ Ensure that the lower port of the bowl faces the right side of the device (*step A*).

➔ Position the bowl arm above the bowl by moving it clockwise.

➔ Turn the locking knob on the bowl arm clockwise from the 8 o'clock to 12 o'clock position (*step B*).

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

Figure 4-8, Securing the centrifuge bowl (steps A and B)

Installing the tubing harness

➔ Place the valve tubing manifold in the tubing slots and thread the pump tubing around the pump.

➔ Insert the tubing into the air detector.

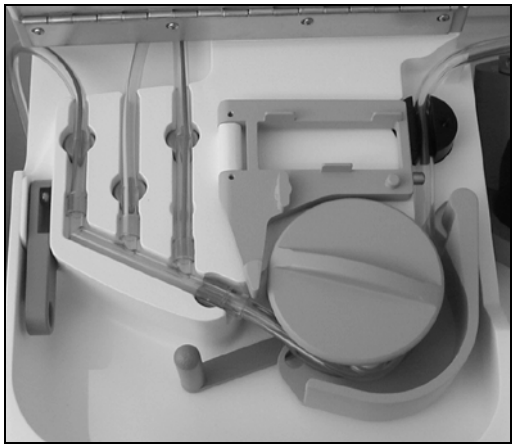

Figure 4-9, Installing the tubing harness

➔ Close and lock the manifold latch and lock the pump lever.

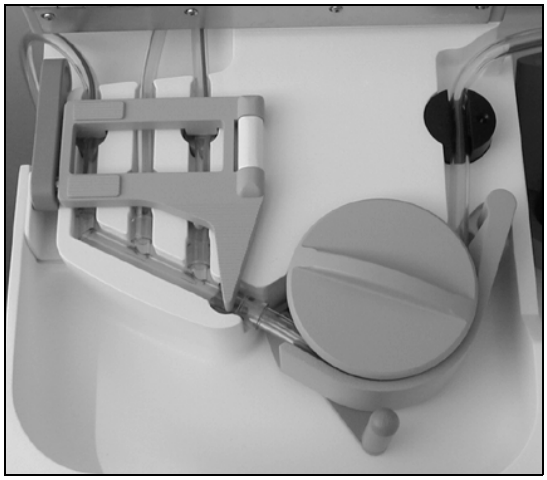

Figure 4-10, Securing the tubing harness

➔ Close the fluid deck cover.

Installing the line sensor tubing

For the Latham bowl sets

➔ Thread the effluent tubing through the effluent line sensor groove.

➔ Ensure that the tubing is deeply inserted as depicted.

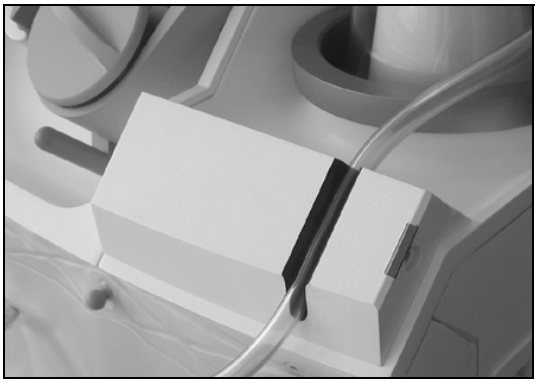

Figure 4-11, Installing the line sensor tubing: Latham bowl sets

For the 70mL Bowl set

➔ Locate the line sensor tubing section on the effluent tubing.

➔ Thread the line sensor section through the effluent line sensor groove.

➔ Ensure that the tubing is deeply inserted as depicted.

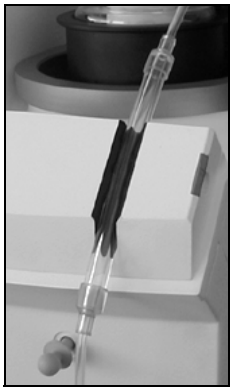

Figure 4-12, Installing the line sensor tubing: 70mL Bowl set

For all sets

➔ Close the centrifuge cover.

Hanging the bags

➔ Hang the reinfusion bag on the IV pole as depicted.

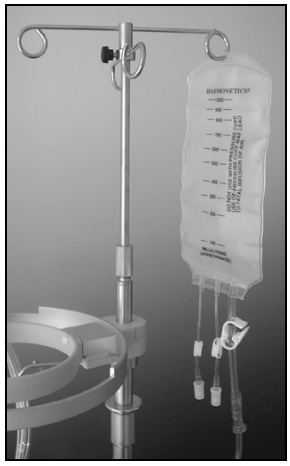

Figure 4-13, Hanging the reinfusion bag

➔ Close the two small clamps on the each reinfusion line to the patient.

➔ Verify that the bag is securely connected to the blue-coded line.

➔ Ensure that the large clamp on the blue-coded line is open.

➔ Hang the waste bag on the pins on the front of the device as depicted.

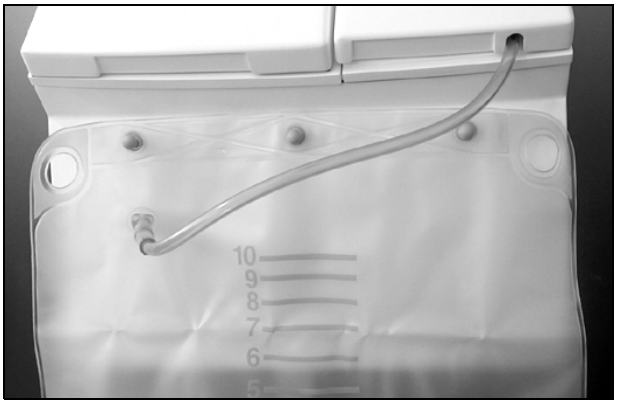

Figure 4-14, Hanging the waste bag

➔ Verify that the waste bag is securely connected to the effluent line.

➔ Ensure that the drain port is completely closed.

Connecting the reservoir

➔ Aseptically connect the red-coded line to the drain tube on the bottom of the reservoir.

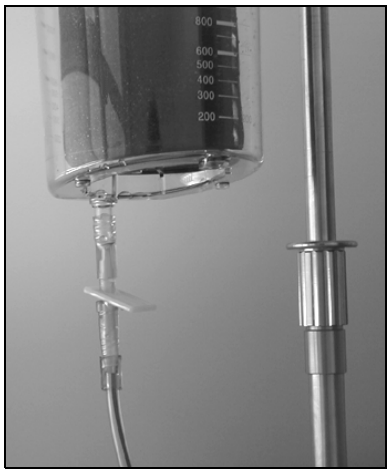

Figure 4-15, Connecting the red line to the reservoir

Setting up the saline solution

➔ Hang the saline wash solution bags on the lower pigtail of the IV pole so that they hang in a cascading manner.

➔ Close the clamps on both of the yellow-coded wash lines.

➔ Spike the saline bags and unclamp the lines.

Note: Each wash cycle requires a volume of saline solution which will depend on the size of the bowl in use.

- Latham bowl 225 ml: 1000 ml saline solution.
- Latham bowl 125 ml: 750 ml saline solution.
- 70mL Bowl: 300 ml saline solution.

Inspecting the installation

➔ Inspect all parts of the disposable set and verify that there are no twists, kinks or flat spots.

➔ Verify that all connections are secure and all appropriate clamps and covers are closed.

Entering the STANDBY state

Once the disposable set has been properly loaded, the operator can prepare the system for processing as follows:

Figure 4-16, Load disposable screen message

➔ Press the Start key to enter the STANDBY state.

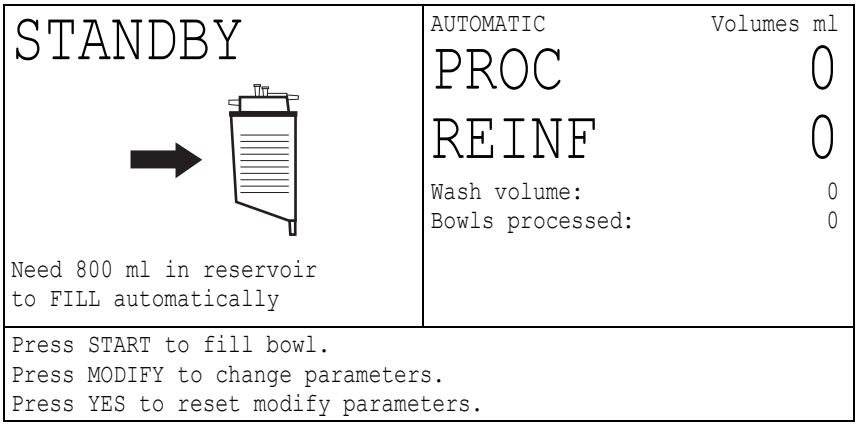

Figure 4-17, Example of a STANDBY state screen display (initial)

The CS5+ system will be ready to proceed with collection. The operator should refer to the appropriate chapter for specific instructions about protocol function:

- *Chapter Five* for the Cell Saver protocol, Automatic operation.
- *Chapter Six* for the Cell Saver protocol, Manual operation.
- *Chapter Seven* for the Sequester protocol.

Chapter Five

Cell Saving using Automatic Operation

PERFORMING A PROCEDURE IN THE AUTOMATIC MODE

This chapter will explain how to operate the CS5+ device in the AUTOMATIC mode to perform cell salvage. The descriptions are applicable to all of the bowl types – the Latham bowls (225 ml and 125 ml) as well as the 70mL Bowl, unless specifically indicated otherwise in the text.

Examples of the screen displays which the operator will encounter during operation will use default settings and values possible with the Latham 225 ml bowl. Reference tables which list the default settings according to the different types of bowls are provided in the section *Summarizing setting variations*.

Prior to processing any blood, the disposable set must installed as explained in *Chapter Four*. Because of the controls and "intelligence" built into the CS5+ device, automatic processing will produce consistently good results when the solutions have been properly prepared and the disposable set has been correctly installed.

Note: Anticoagulant solution administration is not regulated by the CS5+ device and should be done manually or by another device. The recommended AC solution is 30,000 units of heparin in 1 liter of normal saline solution. The drip rate should be set during the procedure at 1-2 drops per second depending on the rate of blood flow being processed.

Explaining the STANDBY state

Once the CS5+ device has been powered on and the system self-test has been successfully completed, the following information will be displayed:

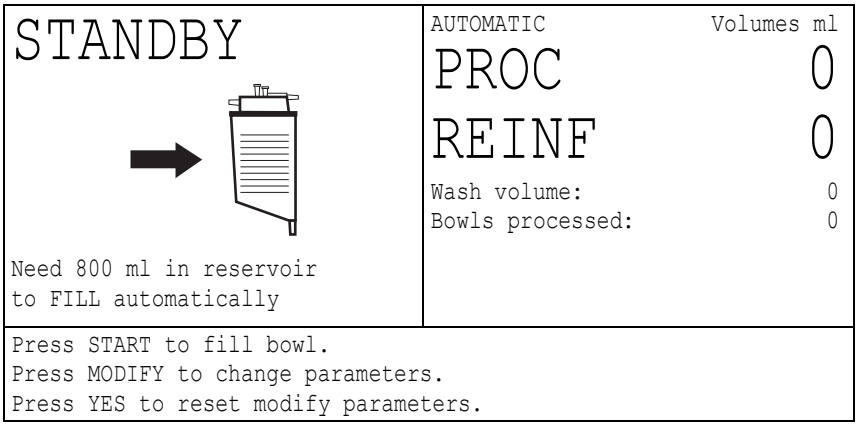

Figure 5-1, Example of a STANDBY state screen display (initial)

This information indicates that the CS5+ system in the initial STANDBY state and processing will begin once the fluid in the collection reservoir reaches the preset level. At any time during the STANDBY state, the operator can initiate the FILL state by either of the following actions:

- Pressing the Start key.
- Pressing the Fill key when it is backlit.

The operator can also adjust the settings of preset processing parameters at this time, including the volume of the reservoir level sensor (*Reservoir level parameter*) by pressing the Modify key. Further information about these parameters is provided in the section *Modifying certain processing parameters*.

Filling the bowl

Once the preset reservoir level has been reached, the CS5+ device will automatically enter the FILL state and the unprocessed blood will be pumped into the spinning centrifuge bowl. During the first cycle *only*, the saline line will automatically be primed before the unprocessed blood is pumped into the spinning bowl. The following information will be displayed as the bowl is being filled:

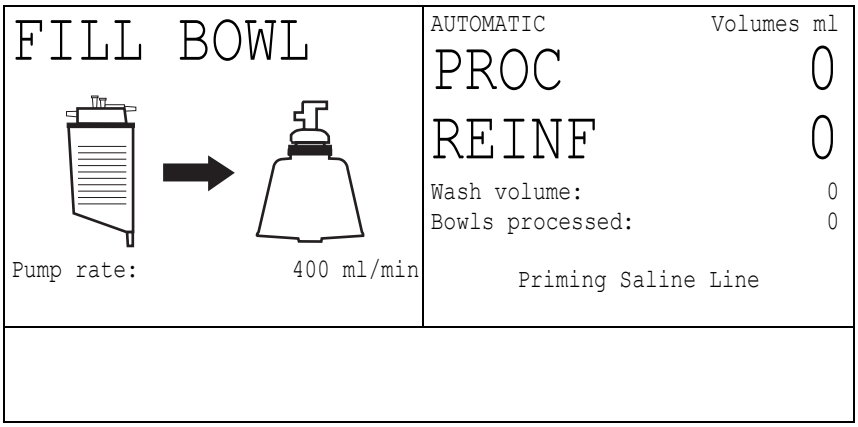

Figure 5-2, Example of a FILL state screen display

Note: If at any point up to and including the first fill cycle the CS5+ system cannot detect the type of bowl installed, the bowl-type confirmation message will be displayed as illustrated in Chapter Four, Figure 4-5*. The operator should reconfirm which type of bowl is installed and continue the procedure. Once the message has appeared it will not be displayed again during the procedure.*

The CS5+ optical bowl sensor 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+ system will automatically determine the quality of the incoming blood and control the processing parameters to optimize the procedure.

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

Note: For the Latham bowl sets, the pump speed may vary as the bowl is being filled; for the 70mL Bowl set, the pump speed will remain constant.

If the reservoir becomes empty before the bowl is full, the CS5+ system will revert to the STANDBY state and provide the following information:

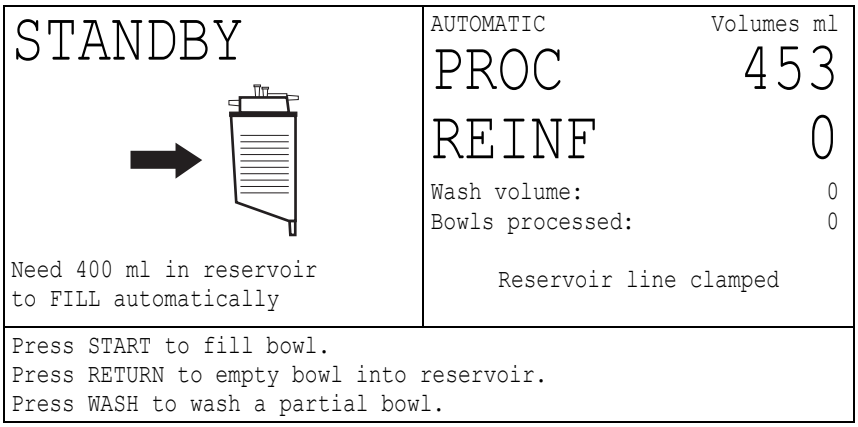

Figure 5-3, Example of a STANDBY state screen display (resume)

The CS5+ system will resume filling the bowl once the preset level (*Resume at Level parameter*) has been detected in the reservoir.

Besides initiating the FILL state at anytime from the STANDBY state, the operator has other options available, when other keys are backlit.

The operator can:

- ➔ Press the backlit Return key to send the contents of the bowl into the reservoir for future processing.
- ➔ Press the backlit Wash key to advance to the WASH state and wash a partially filled bowl.

Caution: *Washing partial bowls will produce a lower hematocrit end product.*

Washing the cells

When the CS5+ system detects that the bowl contains the appropriate quantity of red blood cells, the device will automatically enter the WASH state and provide the following information:

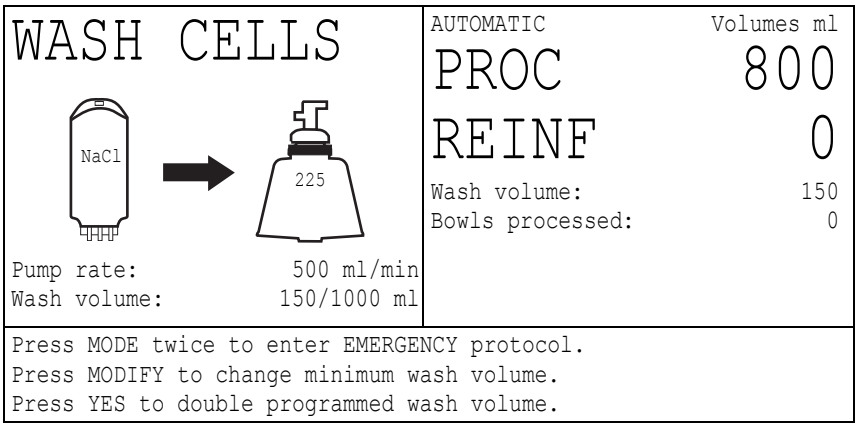

Figure 5-4, Example of a double WASH state screen display

Pressing the Yes key 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 state is complete, the machine will revert back to the original programmed wash volume.

The minimum wash volume parameter can be modified by the operator as described in the section *Describing additional auto mode functions*.

During the automatic WASH state, the CS5+ system will optimize the process by operating at pump rates within the following ranges:

- Latham 225 ml bowl: 200 to 500 ml/min.
- Latham 125 ml bowl: 200 to 300 ml/min.
- 70mL Bowl: 100 ml/min and after 5/6 of the wash volume 75 ml/min.

If an RBC spill occurs into the waste bag during automatic operation when using a Latham bowl, the pump rate will decrease then automatically increase when the system detects that RBCs are no longer being spilled.

For all bowl types, the system will automatically extend the wash (up to two times) in preset increments according to bowl size, until the effluent line is clear.

Emptying the bowl

When the appropriate volume of saline has entered the bowl, the CS5+ system will automatically stop the pump. The centrifuge will stop spinning and the red blood cells suspended in saline solution will be pumped from the bowl into the reinfusion bag. The following information will be displayed during the EMPTY state:

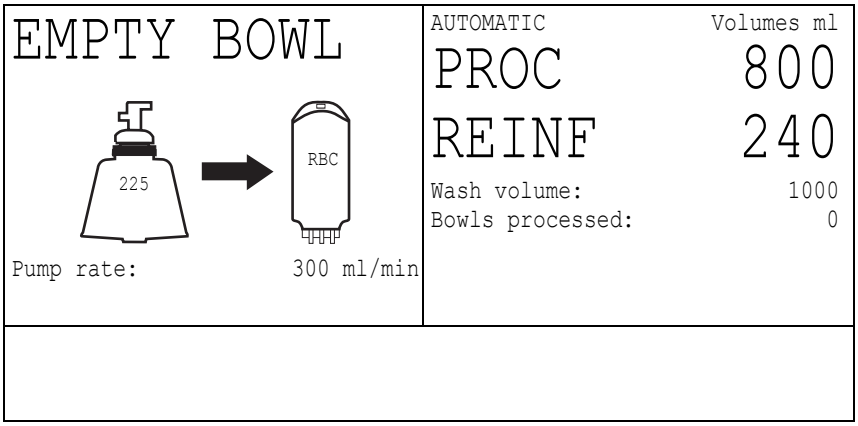

Figure 5-5, Example of an EMPTY state screen display

After one bowl has been processed, the system will start processing again when the preset reservoir level is detected. If there is no further blood to process, the operator should power off the device and remove the disposable set.

Monitoring the waste bag

During the procedure, the CS5+ system will monitor the amount of fluid collected in the waste bag and alert the operator to change or drain the contents of the waste bag when it is almost full. If the waste bag does become full, the CS5+ system will produce an audible alarm, move into a PAUSE state and indicate that the waste bag is full. Once corrective action is taken, the operator should:

➔ Press the Start key to resume processing.

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

Reinfusing processed blood

Reinfusion of the processed blood to the patient can begin as soon as there are red blood cells in the reinfusion bag. Collection of shed blood in the reservoir, filling the bowl, and reinfusing processed blood to the patient can occur simultaneously throughout the procedure.

A transfer pack can be used to transfer the contents from the reinfusion bag to a second bag as follows:

- ➔ Attach a transfer bag to one of the small ports on the reinfusion bag.
- ➔ Open the slide clamp and allow all of the cells to flow into the transfer bag.
- ➔ Close the slide clamp on both bags and remove the transfer bag.

At this point, the red blood cells will be ready for reinfusion following standard transfusion protocols.

Important Warnings about reinfusing processed blood

Warning: The reinfusion bag MUST NOT become empty in between transfusions to the patient. If air does enter the reinfusion line, it must be removed before starting reinfusion.

The slide clamp between the reinfusion bag and the patient MUST be closed between reinfusions. The white slide clamp on the blue line between the reinfusion bag and the CS5+ device MUST NOT be closed.

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

A PRESSURE CUFF OR ANY OTHER MECHANICAL DEVICE MUST NOT BE USED WITH THE CS5+ DEVICE. PRESSURE REINFUSION CAN RESULT IN THE FATAL INFUSION OF AIR INTO THE PATIENT.

Warning: In accordance with the applicable current guidelines and standards, it is recommended that a transfusion filter capable of retaining particles potentially harmful to the recipient be used when returning processed packed red blood cells.

The operator should refer to the current standards for expiration date of stored blood.

Explaining the air sensor detection messages

Whenever the air sensor detects air in the disposable tubing during the EMPTY state, the CS5+ system assumes that all RBCs have been transferred to the product bag from the bowl and the pump will stop. When air is detected during the FILL state, the system assumes that the reservoir is empty. The pump and centrifuge will stop and the device will move into the STANDBY state, displaying the following information:

```
Need 400 ml in reservoir to FILL automatically
```

The CS5+ system will resume processing when the reservoir level sensor detects that the reservoir contains the appropriate amount of fluid to begin filling the bowl. The operator can also initiate the FILL state by pressing the Fill key when it is backlit.

If the air sensor detects air in the WASH state when less than 90% of the wash solution volume has been processed, the pump will stop and a beep will be heard. The following message will be displayed:

```
Saline bag empty!
Replace saline bag.
```

The operator should replace the saline bag and then press the Start key to resume processing. If 90% or more of the wash solution volume has been pumped, the CS5+ system will advance to the EMPTY state.

Explaining the recentrifugation delay

Once the centrifuge bowl has been stopped, red blood cell separation is lost. This settling of cells could lead to an RBC spillage if fluid is pumped into the bowl before the cells are allowed to separate again when the process is resumed. To prevent this, there is a “recentrifuge delay” which will spin the centrifuge bowl for a few moments to separate the cells before pumping more fluid into the bowl when processing is resumed for a FILL, WASH or CONCENTRATION state.

The delay is important to ensure proper separation, however it can be overridden as follows:

➔ Press the Start key *once* upon resuming the process.

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

To avoid a red cell spillage into the waste bag, the operator can:

➔ Press the Pause key and stop the pump.
The word "Pause" will flash on the screen display.

➔ Press the Pump slew keys to gradually adjust the pump speed.

The operator can adjust the pump to the desired speed while observing the cells for separation.

To resume the process at the previous pump rate:

➔ Press the Pause key again.

DESCRIBING ADDITIONAL AUTO MODE FUNCTIONS

At any time during automatic operation, the operator can advance the system to manual operation by pressing the Mode key once. The operator can also use the Mode key to access an EMERGENCY mode, which may be used during a procedure to manage high blood loss situations.
In certain situations, the operator will be able to select the concentration option, used to maintain a high hematocrit end product. Other options exist in which the operator can modify certain processing parameters, accessible by pressing the Modify key and entering the Cell Saver setup screen display. These options will be presented in further detail in the following sections.

Using the EMERGENCY mode

In the EMERGENCY mode, the CS5+ device will process blood at high speeds while in automatic operation: 800 ml/min during the FILL state, 800 ml/min during the WASH state and 300 ml/min during the EMPTY state. The pump speed regulation using the effluent line sensor is inactive in the EMERGENCY mode.
The EMERGENCY mode is not available when using a 70mL Bowl disposable set.
To enter the EMERGENCY mode when using a Latham bowl disposable set:

- ➔ Press the Mode key *twice*.
- ➔ Confirm the selection by pressing the Yes key **within 10 seconds**.

The following screen will be displayed:

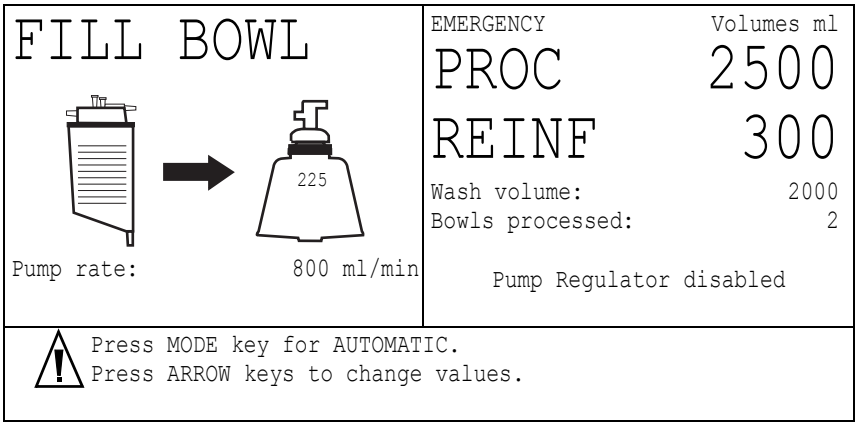

Figure 5-6, Example of a EMERGENCY mode screen display

If the operator presses the Modify key during the EMERGENCY mode to access the processing parameters, the following information will be displayed:

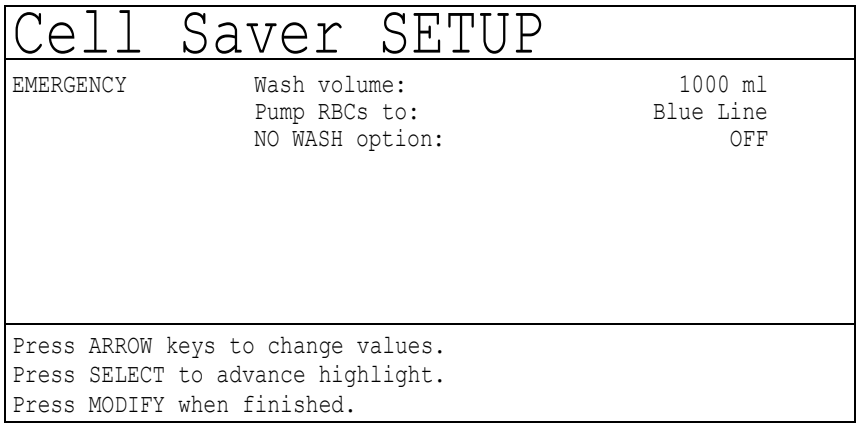

Figure 5-7, Example of the EMERGENCY mode setup screen display

The *Wash Volume, Pump RBCs to (RETURN)* and *No WASH options* are the only processing parameters which can be adjusted in the EMERGENCY mode.
The EMERGENCY mode will be stopped automatically once the air detector has sensed air in the tubing. The screen display will change to the AUTOMATIC mode STANDBY state screen display.

Explaining the CONCENTRATE state option

The concentration option is used when the volume of red blood cells in the bowl is low and it becomes necessary to wash and return whatever cells are present. This is sometimes the case at the end of a procedure when the bowl is not completely full and yet no more blood loss is expected.
During the CONCENTRATE state, the blue line valve opens and the washed, packed red blood cells are sent from the reinfusion bag to the bowl to increase the RBC volume in the bowl and thus maintain a high hematocrit product. Washing a partially filled bowl would produce a low hematocrit end product.
The operator can access the CONCENTRATE state during automatic operation if the CS5+ system detects an empty reservoir during a a FILL state and moves into the STANDBY state. At this point, the Conc key will be backlit on the keypad.

Note: The Conc key will only be available in the STANDBY state if the reinfusion volume displayed on the right side of the display screen is greater than 0.

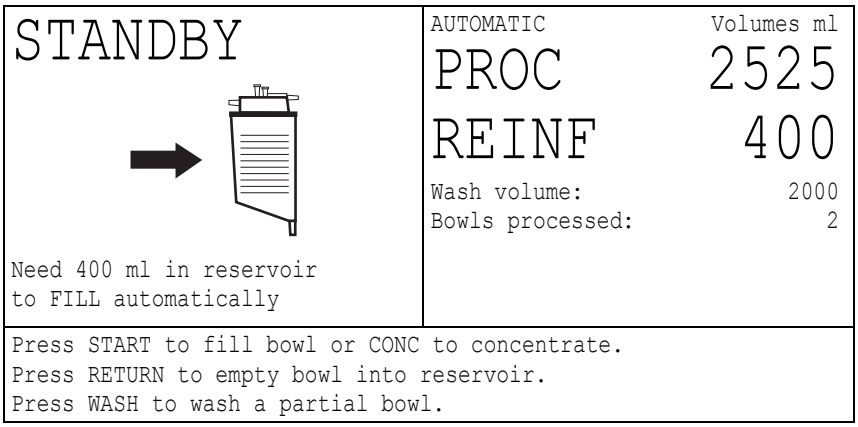

Figure 5-8, Example of a STANDBY screen display

➔ Press the backlit Conc key to draw red blood cells from the reinfusion bag into the bowl and receive the following information:

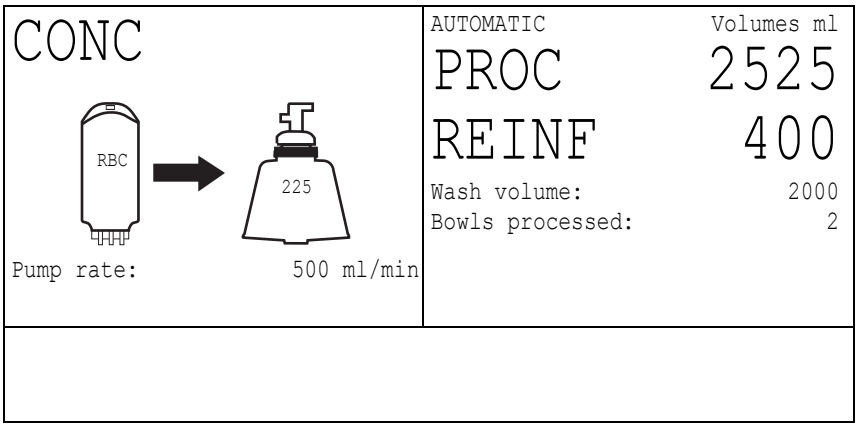

Figure 5-9, Example of a CONCENTRATION state screen display

For the Latham bowl sets, the pump speed may vary as the bowl is being filled; for the 70mL Bowl set, the pump speed will remain constant.

When the appropriate quantity of RBCs are detected in the bowl, the CS5+ system will automatically enter the WASH state.

Modifying certain processing parameters

During automatic operation, the operator can access certain processing parameters at different points in the procedure and adjust the settings to correspond with specific needs.

The values listed on any of the display screen examples in this section will be relevant for a Latham 225 ml bowl. Other settings are provided in the reference tables at the end of this chapter.

To modify the settings of the available processing parameters:

➔ Press the Modify key to access the automatic operation setup screen display as follows:

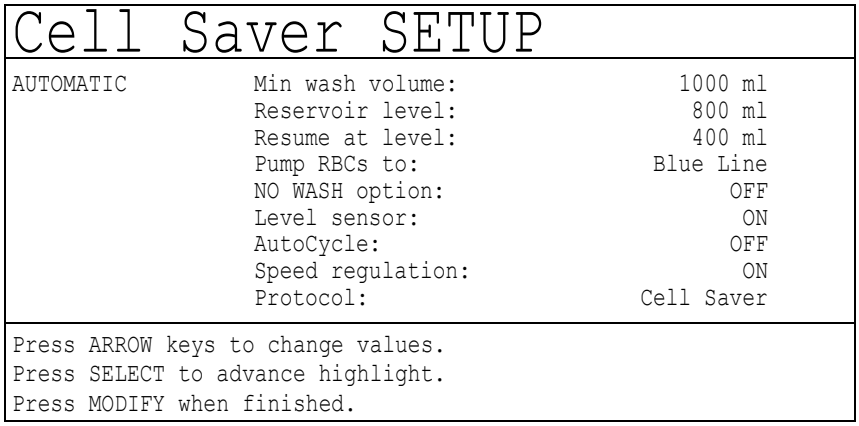

Figure 5-10, Example of the Cell Saver Setup screen display

➔ Press the Select key to scroll the list and highlight the parameter to modify.

➔ Press the Arrow keys [↑↓] to adjust the value displayed on the screen.

➔ Press the Modify key to return to the STANDBY state screen display.

Automatic saving of modified parameters

All parameters described in this section are automatically stored from procedure to procedure by the CS5+ device. This allows customized operation based on the working environment.

At the beginning of every procedure, the CS5+ device allows the operator to reset the modified parameters to the default settings from the initial STANDBY state screen display as follows:

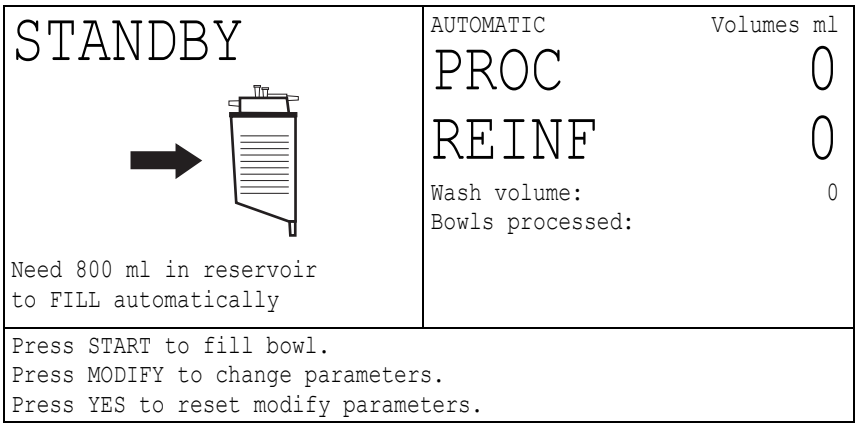

Figure 5-11, Example of the initial STANDBY state screen display

➔ Press the Yes key to reset the modified parameter to the default settings.

Pump RBCs to (RETURN) option

By default, the *Pump RBCs to* option is set at *Blue Line*, meaning that the packed red blood cells will automatically be sent through the blue-coded tubing to the reinfusion bag.

This setting can be changed to send the contents of the packed red cells through the *Red Line* (red-coded tubing) for two different applications.

- During a cell saving procedure: to send the contents of a partially filled bowl to the collection reservoir until more shed blood is collected which will permit a full bowl to be processed.
- During open-heart surgical procedures: to concentrate and wash the volume removed from the extracorporeal circuit. The RETURN option sends the washed red blood cells through the red line (the FILL line) into the cardiotomy reservoir, rather than through the blue line to the reinfusion bag. A Y-connector in the tubing is used to divert the flow of fluid.

When the Return key is lit and the *Red Line* option is enabled, the operator can press this key to empty the contents of the bowl content through the red line 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 *Red Line* RETURN option for automatic processing the operator should:

➔ Press the Modify key to access the Cell Saver setup display.

➔ Press the Select key until *Pump RBCs to* is highlighted.

➔ Press the arrow to indicate *Red Line* as the option.

➔ Press the Modify key to return to the STANDBY state screen display.

When the system is in the RETURN state, the following information will be displayed.

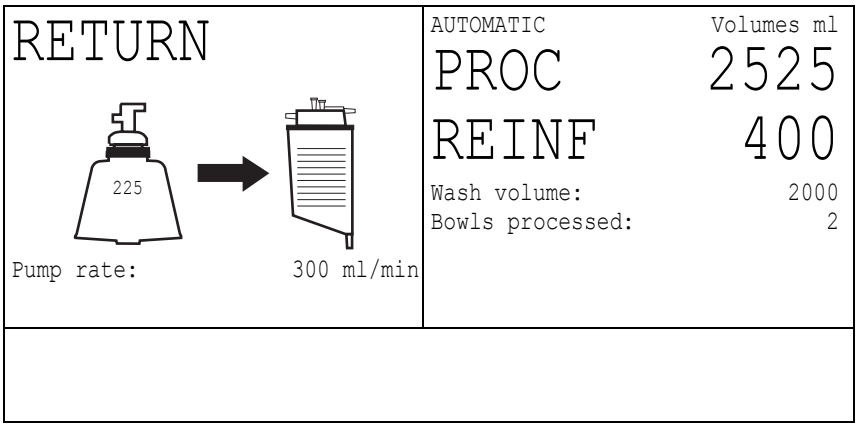

Figure 5-12, Example of the RETURN state screen display

Once the bowl is empty, the CS5+ system will either initiate another FILL state if the level in the reservoir is above the preset level, or return to the STANDBY state.

When the *Pump RBCs to* option is set by default at *Blue Line* and the packed red cells are sent to the reinfusion bag, volume accounting is performed as follows:

- During the EMPTY state: according to the reinfusion volume increments.
- During the RETURN state: according to the processed volume decrements; the reinfusion volume remains unchanged.

When the *Pump RBCs to* option is set at *Red Line,* the bowl will automatically be emptied through the red line towards the bypass circuit. In this case, volume accounting is performed as follows:

- During the EMPTY state: according to the reinfusion volume increments.
- During the RETURN state: according to the reinfusion volume increments; the processed volume remains unchanged.

Minimum Wash Volume option

The *Min Wash Vol* will not be accessible to the operator until the CS5+ system has determined the type of the bowl installed in the centrifuge.

The recommended minimum wash volumes vary depending on the type of centrifuge bowl being used:

- 1000 ml for the Latham 225 ml bowl.
- 750 ml for the Latham 125 ml bowl.
- 300 ml for the 70mL Bowl.

When performing a new prodedure, using the same type of bowl as the previous procedure, the CS5+ system will check that the minimum wash volume is not lower than the recommended one.
If lower, the device will reset the minimum wash volume to the recommended one, otherwise the CS5+ system will keep the previous minimum wash volume.

When performing a new procedure, not using the same type of bowl, the CS5+ system will reset automatically the appropriate recommended minimum wash volume.

The operator may decide to increase or decrease the minimum wash volume depending on the quality of the incoming shed blood as follows:

- ➔ Press the Modify key to access the Cell Saver setup display.
- ➔ Press the Select key until *Min Wash Vol* is highlighted.
- ➔ Use the Arrow keys to modify the minimum wash volume.

NO WASH option

If minimum turn-around time on packed cells is a higher priority than washing the cells, as in case of an emergency situation, or if the cells are being hemoconcentrated for return to the bypass circuit, the physician may request that the operator omit the WASH state. This will reduce the processing time to the length of the FILL-EMPTY cycles. To enable the *NO WASH* option the operator should:

- ➔ Press the Modify key to access the Cell Saver setup display.
- ➔ Press the Select key until the *NO WASH* option is highlighted.
- ➔ Use the arrow keys to select *ON*.
- ➔ Press the Modify key to return to the STANDBY screen.

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 state is in the best interests of the patient.

Alternatively, if the *NO WASH* option has not been selected, the operator can manually move from FILL to EMPTY by pressing the Empty key once the system has moved into the WASH state.
When the operator chooses to no wash the RBCs, the following message will flash on the screen display:

```
Unit Not Washed
```

Note: The **NO WASH** *option may be permanently hidden from the Cell Saver SETUP screen by Haemonetics field service if the physician wants to prevent erroneous use of this option by the Cell Saver 5+ operator.*

Reservoir Level and Resume at Level options

These options allow the operator to customize the thresholds used by the reservoir level sensor to initiate or resume the FILL state from the STANDBY state:

- *Reservoir level* (initial): target volume in the reservoir required to automatically initiate a fill cycle when the bowl is empty.
- *Resume at level* (resume): target volume in the reservoir to required to automatically resume a fill cycle when the bowl is partially filled.

To customize the settings for the reservoir sensor level:

➔ Press the Modify key to access the Cell Saver setup display.

➔ Press the Select key until either *Reservoir level* or *Resume at Level* is highlighted.

➔ Press the Arrow keys to modify the values.

➔ Press the Modify key to return to the STANDBY screen display.

Level Sensor option

To disable the reservoir level sensor function in the STANDBY state, the operator can set the *Level Sensor* option to OFF. By doing this, only pressing the Start key will initiate the FILL state from the STANDBY state.

This function can be modified as follows:

➔ Press the Modify key to access the Cell Saver setup display.

➔ Press the Select key until *Level Sensor* is highlighted.

➔ Use the Arrow keys to select OFF.

AutoCycle option

This option allows the operator to start a new FILL cycle automatically, immediately after completing an EMPTY cycle, without the level sensor and when the collection device is mechanically not compatible with the level sensor. To enable this feature, the operator should set the *AutoCycle* option to ON.

Note: The ability to use this option must be enabled by Haemonetics field service.

- When this parameter is set at OFF, the FILL cycle can be started through level sensor detection or by pressing the Start key.
- When this parameter is set at ON, after an EMPTY cycle, the FILL cycle will start automatically from the STANDBY state after 3 seconds of pause time. The whole procedure cycle: FILL, WASH, EMPTY, STANDBY, FILL, ... will continue to be performed, as long as trip to WASH is automatic, and there is blood in the collection container.

Speed regulation option

As previously discussed, the pump speed in the FILL, CONC and WASH states is optimized according to the blood quality determined by the effluent line sensor. To disable this feature, the operator should set the *Speed regulation* option to OFF.

When this parameter is set at OFF, the pump speed selected by the operator during the FILL, WASH and CONC states will be used systematically for all subsequent cycles unless another bowl type is detected.

One application for use is during emergency procedures where processing speed is more critical than optimized quality.

When pump speed regulation is disabled, the following message will be displayed during the FILL and WASH states to remind the operator that the line sensor control of the pump speed is not active:

```
Bowl optic and line sensor disabled
```

VIEWING THE CELL SAVER 5+ SYSTEM STATUS

The following section provides information about the how procedure statistics are presented on the CS5+ display screen.

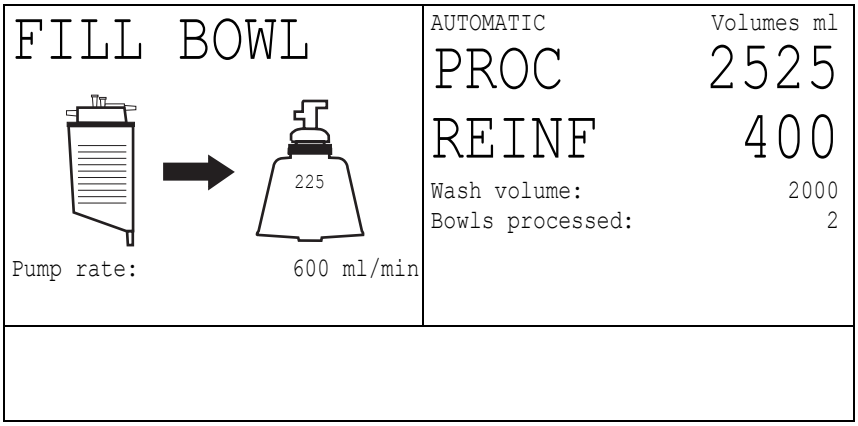

Figure 5-13, Example of a FILL state screen display

The upper left section displays the current operating status of the device. In this example, the CS5+ device is in the FILL state and fluid is being pumped from the reservoir into the bowl at 600 ml/min.
The right section provides the current procedure statistics for this example as follows:

- The CS5+ device is under automatic control.
- Two bowls have been processed.
- 2000 ml of saline solution has been used during the wash cycles.
- A total volume of 2525 ml of fluid has been processed from the reservoir.
- 400 ml of packed RBCs have been sent to the reinfusion bag.

The operator can make minor adjustments to increase or decrease pump speed without reprogramming the system by using the slew keys of the pump control keypad section. These temporary changes are valid only for the present operating state (e.g.FILL). As the system enters the next state, the programmed values are reinstated. The temporary pump speeds may range from 0 to 1000 ml/min adjusted by 25 ml/min increments.
The Pause key can be pressed to stop the pump.

Wash volume monitoring

During an automatic WASH state, an ongoing volume of wash solution used during the current wash cycle is displayed on the left side of the display screen, as visible in the following figure.

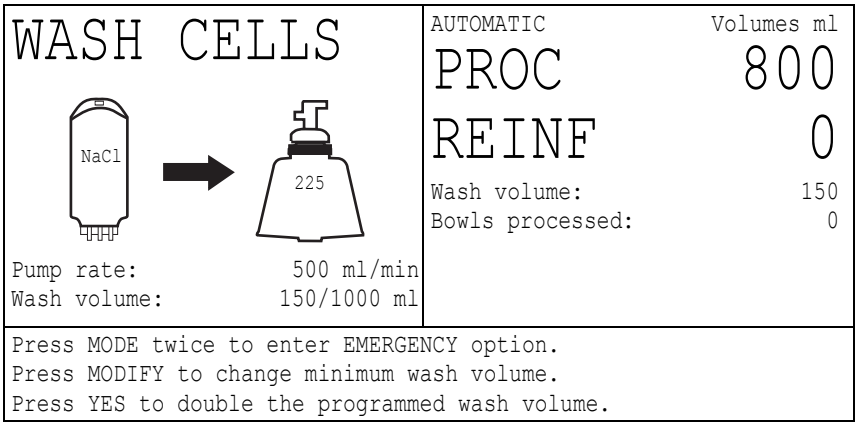

Figure 5-14, Example of a WASH state screen display

This *Wash volume* accounting function returns to zero each time the WASH state is entered and terminates when the CS5+ system advances to the EMPTY state. The cumulative total of wash solution volume used for all of the wash cycles performed during the procedure is listed in the procedure statistics area on the right side of the display screen as *Wash vol*.

Volume accounting function

The volume accounting function (VAF) of the CS5+ device allows the operator to monitor the approximate volume of fluid processed and the approximate fluid volume of fluid returned to the patient by the CS5+. This information is constantly displayed and updated during each operating state.
To ensure the accuracy of the volume accounting function, it is important to remember the following guidelines:

- The operating room suction must not be regulated at too high of a pressure setting. Vacuum settings in excess of –200 mmHg could compromise the efficiency of the CS5+ occlusive roller pump. This would in turn would compromise the accuracy of the volume accounting function which assumes a certain volume of fluid per pump revolution.
- Subsequent to an empty reservoir message, the operator should not press the Start key to fill the bowl until at least 500 ml of fluid have are present in the reservoir. Processing smaller volumes may cause the volume accounting functions 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 the FILL state for small amounts of fluid will cause a disproportionate ratio of air to fluid.

Note: The CS5+ device can usually process 500 ml of fluid in approximately one minute.

- The product volume displayed to the operator will list approximately 20 ml more than what is contained in the reservoir because 20 ml of fluid remain trapped in the blue line until the end of the procedure. The operator should remember to subtract this 20 ml volume from the display readout until the blue line is drained at the end of the procedure and the 20 ml are recovered.
  For example, if 400 ml of product volume is listed on the display screen, there will actually be 380 ml in the reinfusion bag until the 20 ml are emptied from the blue line at the end of the procedure.

Warning: Accurate volume accounting and WASH monitoring functions require that all slide clamps be open and that no kinks, twists or flat spots are present in the tubing.

SUMMARIZING SETTING VARIATIONS

The following tables summarize the different values for default settings used throughout the various states of the Cell Saving protocol, depending on the type of centrifuge bowl in operation.

Table 5-1, pump rate range

State	70mL Bowl	Latham 125	Latham 225
FILL	125 ml/min	300 ml/min	600 ml/min
WASH	100-75 ml/min	300 ml/min	500 ml/min
EMPTY	100 ml/min	100-75 ml/min	300-250 ml/min

Table 5-2, Wash volume per cycle

State	70mL Bowl	Latham 125	Latham 225
WASH	300 ml	750 ml	1000 ml

Table 5-3, Maximum centrifuge speed

State	70mL Bowl	Latham 125	Latham 225
FILL	7000 rpm	5650 rpm	5650 rpm
WASH	7000 rpm	5650 rpm	5650 rpm

Table 5-4, Reservoir sensor level

State	70mL Bowl	Latham 125	Latham 225
STANDBY Initial cycle	400 ml	800 ml	800 ml
STANDBY Subsequent cycles	200 ml	600 ml	600 ml
STANDBY Resume	200 ml	400 ml	400 ml

Chapter Six

Cell Saving using Manual Operation

PERFORMING A PROCEDURE IN THE MANUAL MODE

This chapter explains how to operate the CS5+ system in the MANUAL mode to perform cell salvage. The descriptions are applicable to all of the bowl types - the Latham bowls (225 ml and 125 ml) as well as the 70mL Bowl, unless specifically indicated otherwise in the text.

It is possible to process blood manually, however given the automatic processing capabilities of the CS5+ device, manual processing is generally unnecessary and is not recommended. In the MANUAL mode, the operator is responsible for advancing the CS5+ system from one processing state to the next. Once the system is advanced into the FILL state, it will remain there until the operator initiates a change.

Warning: In the MANUAL mode of operation, the operator must initiate all changes and advance to each operating state using the manual control keys.

The optical RBC bowl sensor and the effluent line sensor are disabled during manual operation and the CS5+ device will flash the following messages:

- During the FILL state:

```
Bowl optic and line sensor disabled
```

- During the WASH state:

```
Pump Regulator disabled
```

Unlike the optical sensors, all volume accounting functions (volume processed, volume returned, and wash monitor) remain operative during manual operation.

Note: If at any point during the procedure up to and including the first fill cycle the CS5+ system cannot detect the type of bowl installed, the bowl-type confirmation message will be displayed as illustrated in Chapter Four, Figure 4-5. *The operator should reconfirm which type of bowl is installed and continue the procedure. Once the message has appeared it will not be displayed again during the procedure.*

Explaining the manual control keys

The CS5+ device switches from automatic operation to manual operation when the Mode key is pressed. Once manual operation is selected, all backlit manual control keys will be continuously lit and become functional at different points in the procedure, depending on the current process state.

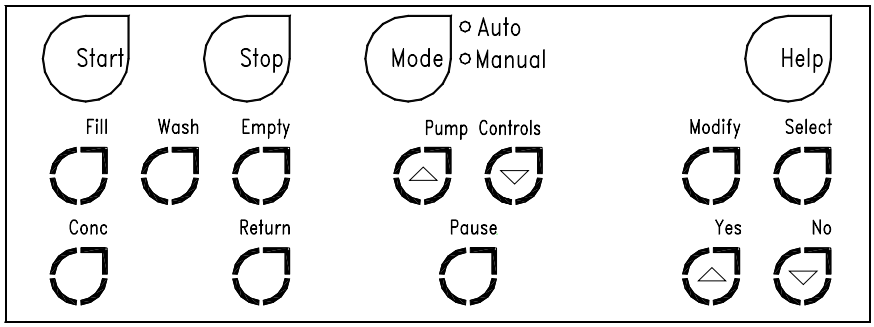

Figure 6-1, CS5+ keypad: Manual operation

The operator will be able to press the Mode key at any time to return to automatic operation. The present mode of operation will be visible in the upper right side of the screen display as depicted:

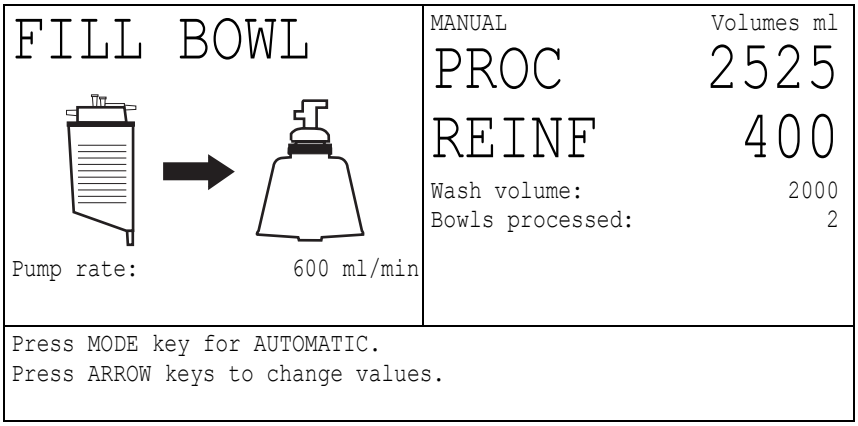

Figure 6-2, Example of a FILL state screen display (manual)

Selecting manual operation

Prior to processing any blood, the disposable set must be installed as explained in *Chapter Four*. Once the CS5+ device has been powered on and the system self-test has been successfully completed, the initial STANDBY state message will appear.

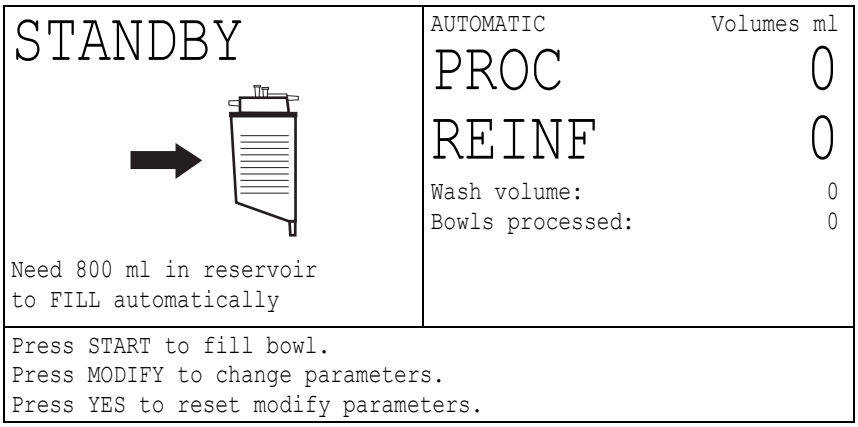

Figure 6-3, Example of the initial STANDBY state screen display

To switch to manual operation at this point, the operator can:

➔ Press the Mode key *once*.

The following screen display will appear.

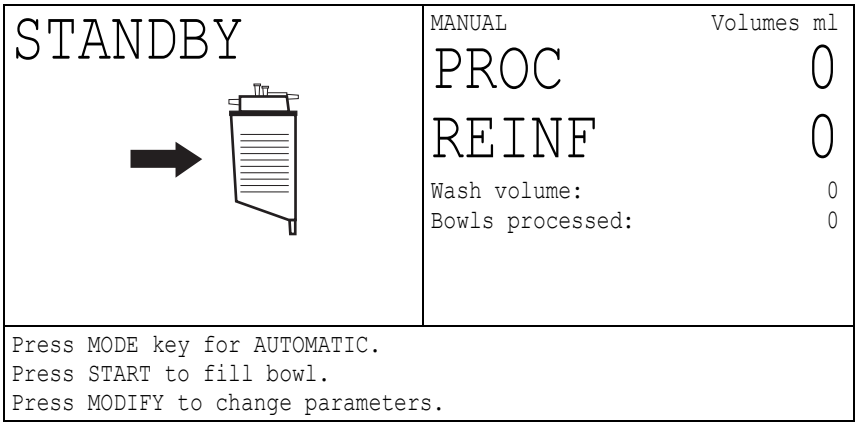

Figure 6-4, Example of the STANDBY state screen display (manual)

Modifying preset processing parameters

The CS5+ system preset processing parameters are programmed with the same default settings in the MANUAL mode as in the AUTOMATIC mode. As during automatic operation, it is possible to access and adjust certain settings during manual operation, available on the MANUAL mode setup screen display such as pump speed (FILL/WASH/EMPTY rates).

To modify the parameter settings:

➔ Press the Modify key to access the manual setup menu:

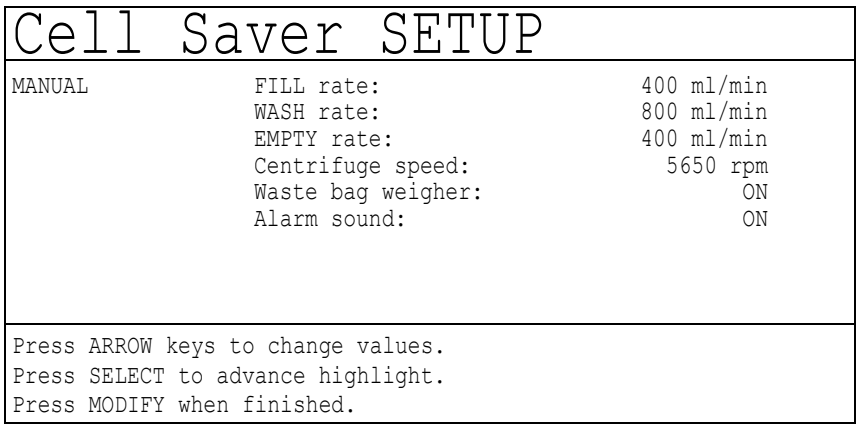

Figure 6-5, Example of the MANUAL mode setup menu

➔ Press the Select key to scroll the list and highlight the selected parameter.

➔ Press the Arrow keys to adjust the value displayed.

➔ Press the Modify key to return to the STANDBY state screen display.

In the MANUAL mode the operator has the possibility of disabling the waste bag weigher by setting the parameter to OFF, in which case the notice messages will not appear when the waste bag is almost full and then completely full. The customary *beep* which is heard when an error condition is detected can also be set to OFF.

All modifications to the preset parameters will be retained from procedure to procedure until modified again or reset to the default values by the operator.

Explaining the recentrifugation delay

Once the centrifuge bowl has been stopped, red blood cell separation is lost. This settling of cells could lead to an RBC spillage if fluid is pumped into the bowl before the cells are allowed to separate again when the process is resumed. To prevent this, there is a "recentrifuge delay" which will spin the centrifuge bowl for a few moments to separate the cells before pumping more fluid into the bowl when processing is resumed for a FILL, WASH or CONCENTRATION state.

The delay is important to ensure proper separation, however it can be overridden as follows:

➔ Press the Start key *twice* upon resuming the process.

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

To avoid a red cell spillage into the waste bag, the operator can:

➔ Press the Pause key and stop the pump.
The word "PAUSE" will flash on the screen display.

➔ Press the Pump slew keys to gradually adjust the pump speed.

The operator can adjust the pump to the desired speed while observing the cells for separation.

To resume the process at the previous pump rate:

➔ Press the Pause key again.

Collecting fluid in the reservoir

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

Initiation of the FILL state is largely dependent upon the rate of fluid collection in the reservoir. If the patient is losing blood steadily and rapidly, processing may begin as soon as 100 ml of fluid enter the reservoir. However, it is more typical to begin processing by initiating the FILL state after the reservoir has accumulated 600-900 ml of volume.

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

Filling the bowl

To initiate the FILL state, the operator can either:

➔ Press the Start key.

or

➔ Press the backlit Fill key.

The following information will be displayed:

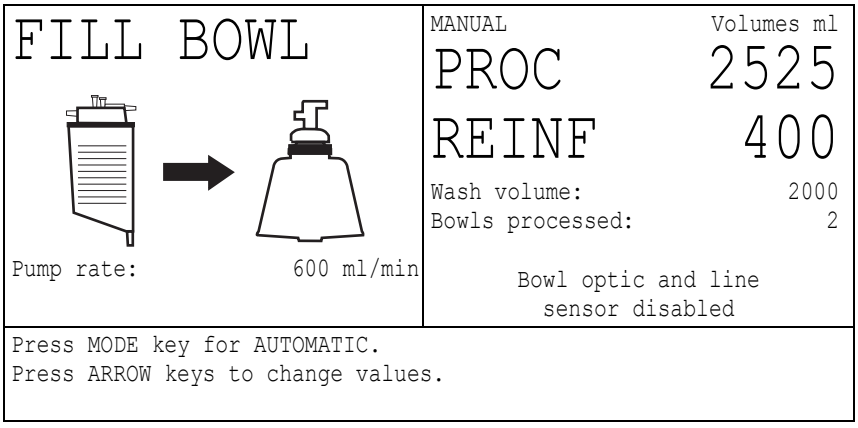

Figure 6-6, Example of the FILL state screen display (manual)

The initial fill speed will be 400 ml/min until the bowl type is determined and the preset parameters will be in effect. The recommended maximum fill speeds are listed at the end of this chapter in *Table 6-1, Pump rate range*.

Using the CONCENTRATE state

To manually use the concentration option during the final fill cycle:

➔ Press the backlit Conc key.

The blue pinch valve will open and allow RBCs to be drawn from the reinfusion bag into the bowl and displace supernatant from the bowl into the waste bag.

Washing the cells

As the bowl is filling during either the FILL or CONCENTRATE state, the operator should observe when the RBC/supernatant interface reaches a point just below the neck of the bowl. At this point the operator can initiate a wash cycle as follows:

➔ Press the Wash key to receive the following information:

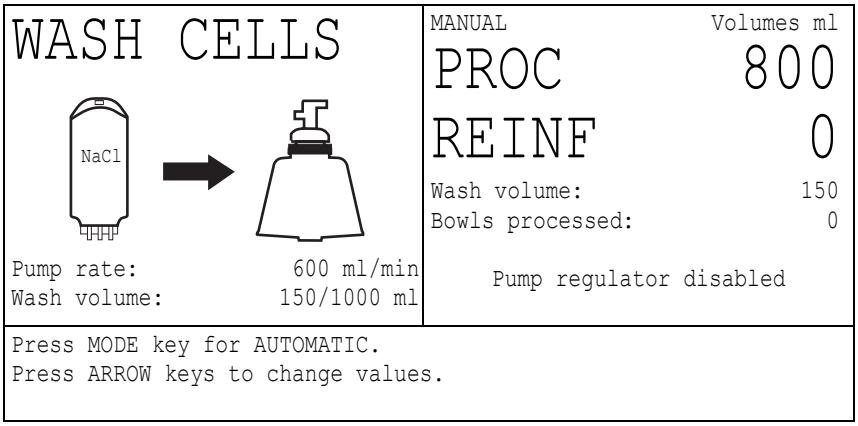

Figure 6-7, Example of the WASH state screen display (manual)

The volume of wash solution required will depend upon factors such as the degree of hemodilution and amount of AC solution used. Certain minimum volumes will be required per cycle depending on the type of procedure. The operator should continue washing until the effluent line is clear. The recommended maximum wash speed and wash solutions volumes are listed for all bowl types in the section at the end of this chapter, *Summarizing parameter variations*.

Note: If during the WASH state the RBC/supernatant interface disappears and RBCs begin to spill into the waste bag, the pump speed can be reduced to zero to allow the interface to reappear, then slowly increased to a rate that just maintains this interface (usually 200 ml/min of wash solution or greater).

Emptying the bowl

Once the red cells have been processed, the operator can send them to the reinfusion bag as follows:

➔ Press the Empty key.

When the system is advanced to the EMPTY state, the following information will be displayed:

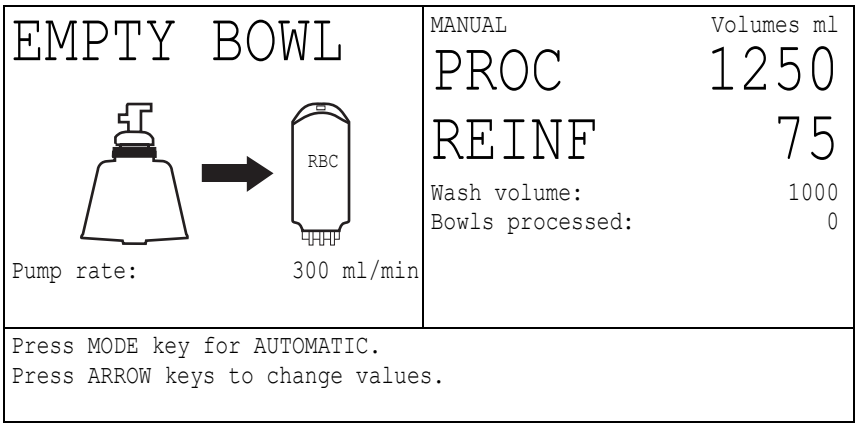

Figure 6-8, Example of the EMPTY state screen display (manual)

The message *Centrifuge stopping* will flash on the right side of the screen until the centrifuge bowl comes to a complete stop. The concentrated RBCs will then be pumped from the bowl to the reinfusion bag.

Reinfusing processed blood

Reinfusion of the processed blood to the patient can begin as soon as there is an appropriate and safe level of blood in the reinfusion bag. Collection of shed blood in the reservoir, filling the bowl, and reinfusion to the patient can occur simultaneously throughout the procedure once the first cycle of processed blood has been pumped to the reinfusion bag.

Important Warnings about reinfusing processed blood

Warning: The reinfusion bag MUST NOT become empty in between transfusions to the patient. If air does enter the reinfusion line, it must be removed before starting reinfusion.

The slide clamp between the reinfusion bag and the patient MUST be closed between reinfusions. The white slide clamp on the blue line between the reinfusion bag and the CS5+ device MUST NOT be closed.

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

A PRESSURE CUFF OR ANY OTHER MECHANICAL DEVICE MUST NOT BE USED WITH THE CS5+ DEVICE. PRESSURE REINFUSION CAN RESULT IN THE FATAL INFUSION OF AIR INTO THE PATIENT.

Reentering the STANDBY state

The CS5+ system will revert to the STANDBY state when it has detected that the bowl is empty. The following information will be displayed:

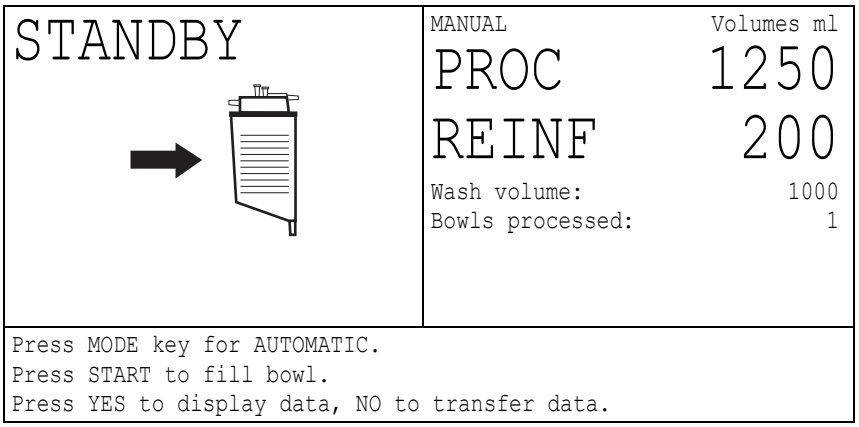

Figure 6-9, Example of a STANDBY state screen display (manual)

If the reservoir, contains more blood to be processed:

➔ Press the Start key to initiate another fill cycle.

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

SUMMARIZING PARAMETER VARIATIONS

The following table summarize the different values for default settings used throughout the various states of the cell saving protocol and which are recommended for use during manual operation.

Table 6-1, Pump rate range

State	70mL Bowl	Latham 125	Latham 225
FILL	125 ml/min	300 ml/min	600 ml/min
WASH	100 ml/min	300 ml/min	500 ml/min
EMPTY	100 ml/min	100 ml/min	300 ml/min

Table 6-2, Wash volume per cycle

Procedure type	70mL Bowl	Latham 125	Latham 225
Standard	300 ml	750 ml	1000 ml
Orthopedic	400 ml	1000 ml	1500 ml

Table 6-3, Maximum centrifuge speed

State	70mL Bowl	Latham 125	Latham 225
FILL	7000 rpm	5650 rpm	5650 rpm
WASH	7000 rpm	5650 rpm	5650 rpm

Chapter Seven

Sequestering using the Cell Saver 5+ System

PRESENTING THE CELL SAVER 5+ SEQUESTERING PROTOCOL

This chapter explains how to perform the sequestering protocol using the CS5+ system. This protocol provides the possibility to collect *Platelet Rich Plasma* (PRP) just after the induction of anesthesia but prior to the surgical procedure.
The sequestering protocol is usually performed before the cell saving protocol and is only available when the device is first powered on.
The CS5+ system should first be prepared with the standard processing set (Latham bowl 225 or 125 ml).
Sequestering is not available with the 70mL Bowl set.
If sequestering of Platelet Rich Plasma is desired, the sequestering set LN244 should be attached to the standard bowl processing set as described in this chapter or in the Directions For Use (DFU) provided with the set.

Describing method of sequestering

During the sequestering, the blood is collected into blood packs containing AC solution. The blood is separated into platelet poor plasma (PPP), platelet rich plasma (PRP) and red blood cells (RBCs). Typical processing time using this method is 25 to 40 minutes. During this time approximately 1200 to 2500 ml of whole blood is processed resulting in the collection of 1.5 to 3.0 x 10e11 platelets in 500 to 1600 ml of plasma. *
Typically the pH is 7.02 at 6 hours and 7.01 at 24 hours post-collection when stored in accordance with the current applicable standards.

* *Data on file at Haemonetics Corporation. Actual results may vary depending on patient platelet pre-count, hematocrit, height, weight, physical condition, etc.*

INITIATING A SEQUESTERING PROCEDURE

Prior to processing any blood, the disposable set must be correctly installed on the CS5+ device according to installation instructions for the standard processing set described in *Chapter Four* and the Directions for Use (DFU) provided with the sequestering set.

Caution: *Prior to the sequestering protocol with the CS5+ system, the operator should be familiar with the operating instructions and all associated precautions and warnings for the CS5+ device, in addition to any precautions and warnings specifically related to sequestering as provided in this chapter.*

Selecting the sequestering protocol

Once the disposable material has been properly installed and the CS5+ device has competed the system self-test, the STANDBY state information will be displayed.The operator can select the sequestering protocol by entering the Cell Saver setup menu as follows:

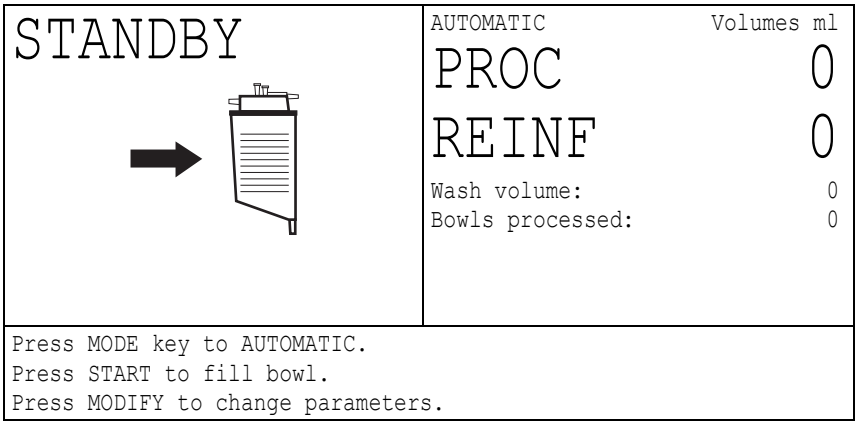

Figure 7-1, Example of a STANBY state screen display (automatic)

Note: The sequestering protocol is only available from the initial STANDBY state screen display of the AUTOMATIC mode when the device is first powered on.

➔ Press the Modify key to display the processing parameters menu.

The following information will be displayed and the operator should proceed as follows:

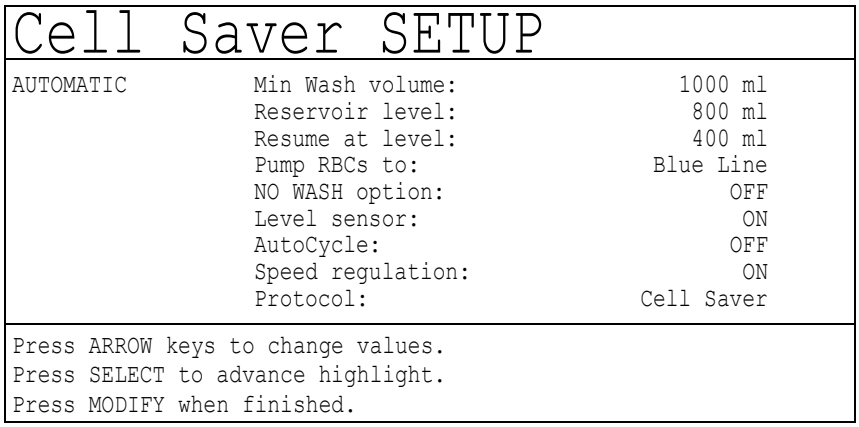

Figure 7-2, Example of the Cell Saver setup menu

- ➔ Press the Select key until *Protocol* is highlighted.
- ➔ Press the Arrow keys [↑↓] to change the selection to *Sequester*.
- ➔ Press the Modify key to return to the STANDBY state screen.

The screen display will now indicate *Sequester* on the right side as follows:

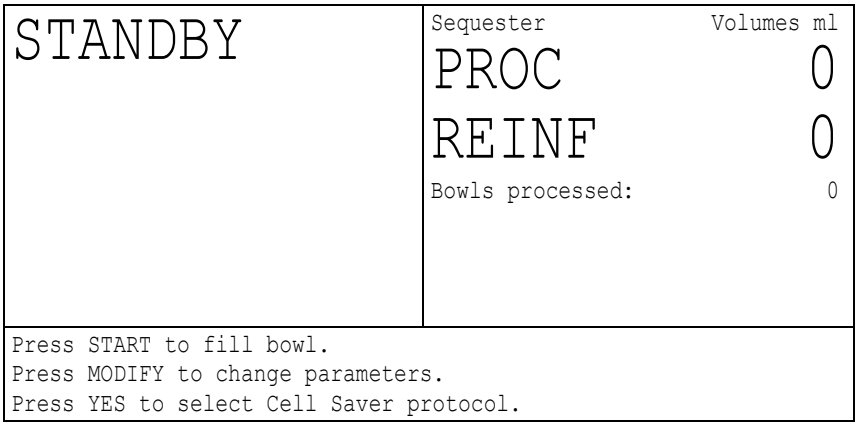

Figure 7-3, Example of the STANDBY state screen display (Sequester)

Setting the processing parameters

Performing sequestering is a **MANUAL** operation requiring operator intervention to move from one stage to another. The process should be completely understood before the sequestering protocol is used.

The preset parameters for both sequestering methods are set at:

- Pump draw rate: 60 ml/min.
- Centrifuge speed: 4750 rpm.
- Empty rate: 200 ml/min.

To change the settings the operator will need to enter the sequester setup menu from the STANDBY state screen display.

➔ Press the Modify key to receive the following information:

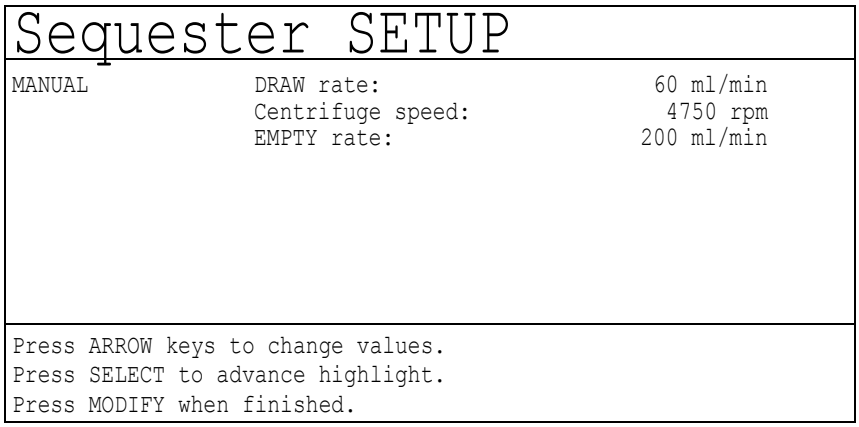

Figure 7-4, Example of the Sequester setup menu

➔ Press the Select key to scroll the list and highlight the parameter.

➔ Press the Arrow keys [↑↓] to adjust the value displayed on the screen.

➔ Press the Modify key to return to the STANDBY state screen display.

Before starting the sequestering process, the operator should verify that the waste bag clamp is open and the collection bag clamps are closed. While the bowl is filling, the operator should ensure that the air in the disposable system is entering the waste bag. The air will be removed from waste bag during the EMPTY state.

Warning: Only one (1) unit of blood should be collected and processed at a time. Unless directed by a physician, the second unit of blood should not be drawn from the patient until the first unit of packed autologous red blood cells has been returned.

PROCESSING FROM BLOOD BAGS

Using this method to sequester plasma, the operator will first need to collect whole blood from the patient via a short intravenous or arterial cannula into blood bag(s) containing anticoagulant solution.

Warning: Only one (1) unit of blood should be collected and processed at a time. Unless directed by a physician, the second unit of blood should not be drawn from the patient until the first unit of packed autologous red blood cells has been returned.

Then operator should continue as follows:

- ➔ Spike the blood collection bag with the yellow-coded wash line bag spike on the standard CS5+ disposable set.
- ➔ Clamp the unused wash line spike section.

Filling the bowl

The operator can now begin to draw blood into the bowl from the blood bag.

- ➔ Press the Start key to initiate filling the bowl.

The pump will start drawing blood at 60 ml/min. As the bowl fills, plasma will be visible as the first layer followed by a white band (platelets), then red blood cells. The following information will be displayed:

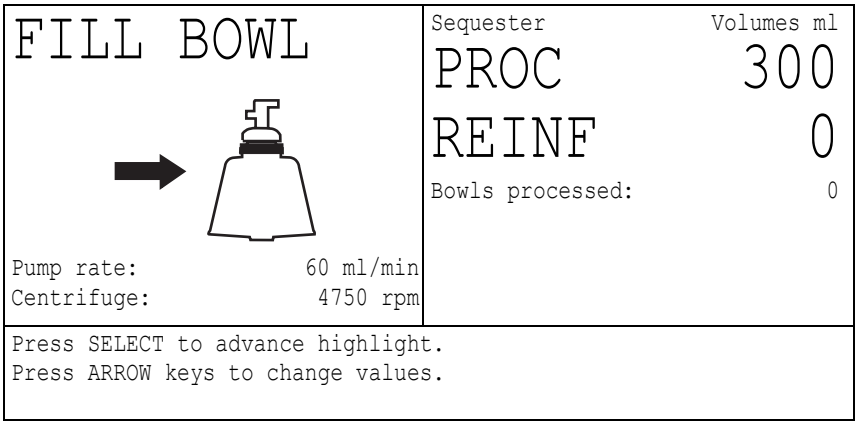

Figure 7-5, Example of the FILL state screen display

The operator should observe the centrifuge bowl as it fills and allow air to flow from the circuit to the waste bag.

When plasma reaches the effluent line:

- ➔ Unclamp the clear line to the plasma collection bag.
- ➔ Clamp the line to the waste bag.

Caution: *Both clamps should never be closed at the same time.*

➔ Continue to observe the centrifuge bowl as it fills.

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

➔ Unclamp the blue-coded line to the PRP bag.

➔ Clamp the clear line to the PPP bag.

When the effluent line flow from the bowl turns medium red (indicating the presence of red blood cells):

➔ Press the Empty key to stop both the centrifuge and the pump.

Emptying the bowl

At this point the operator can proceed to empty the bowl as follows:

➔ Open the clamp on the waste bag line.

➔ Close the clamp on the blue-coded line to the PRP bag.

Once the centrifuge has completely stopped, the pump will transfer the RBCs to the reinfusion bag up to 200 ml/min and display the following information:

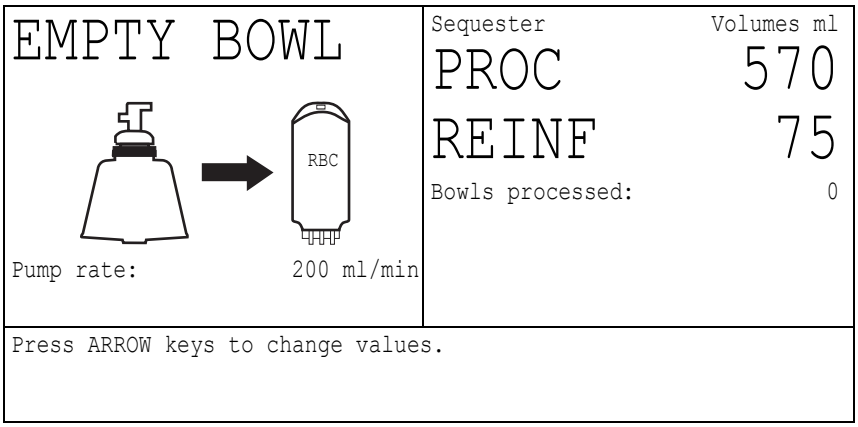

Figure 7-6, Example of the EMPTY state screen display

When the bowl is completely empty, the pump will stop and the following information will be displayed:

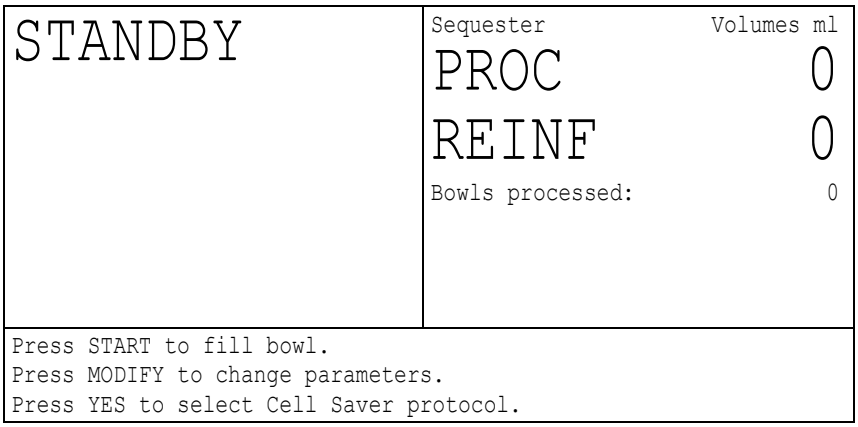

Figure 7-7, Example of the STANDBY state screen display

Transferring the RBCs for reinfusion

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

Warning: In accordance with the applicable current guidelines and standards, it is recommended that a transfusion filter capable of retaining particles potentially harmful to the recipient be used when returning processed red cells.

Warning: The operator should refer to the current standards for expiration date of stored blood.

A PRESSURE CUFF OR ANY OTHER MECHANICAL DEVICE SHOULD NOT BE USED WITH THE CS5+ SYSTEM. PRESSURE REINFUSION CAN RESULT IN THE FATAL INFUSION OF AIR INTO THE PATIENT.

If another sequestering pass is desired, the entire procedure may be repeated following the previous bulleted steps until the desired volumes of PRP and PPP have been collected.

Warning: Care must be exercised when sequestering plasma. A 225 ml bowl can yield 800 ml or more of plasma and cause hypovolemia if fluid balance is not carefully maintained. Many variables influence the amount of plasma which can be sequestered and the volume to be sequestered must be determined by an attending physician. The physician must be informed of the amount and type of anticoagulant solution used, since the plasma collected will still contain some AC solution.

Note: The CONCENTRATE state can be used if necessary to draw additional blood into the bowl for the final cycle. The operator should press the Conc key if the whole blood supply is depleted when filling the bowl. This allows the operator to push the remaining PRP out of the bowl.

COMPLETING THE SEQUESTERING PROCEDURE

Removing the plasma product

After the final sequestering pass, the operator should disconnect the plasma product as follows:

- ➔ Remove the collection bags from the pins and invert the bags.
- ➔ Tap the sides of the effluent tubing leading to the collection bags to dislodge any plasma/platelets which might have adhered to the tubing.
- ➔ Remove the collection bags from the Y-connection.
- ➔ Label the PRP product with the following minimum information:
  - Patient name and/or identification number.
  - Hospital identification number.
  - Date and time collected.
  - Volume collected.
  - Type and amount of AC solution used.
  - Type of product (e.g. *PRP*).
- ➔ Retain the PRP product for reinfusion upon the order of a physician.
- ➔ Utilize procedures consistent with those of the local blood bank for platelet product storage and handling.

It is important to remember that any autologous blood product collected has been processed from a patient who might not normally have been accepted for blood donation. Therefore, unless the blood passes current applicable or hospital donation standards, the products obtained in autotransfusion or plasma sequestration procedures must be labeled "*for autologous use only*". These products should be stored separately and used solely for that purpose. If the CS5+ system has been set up for autotransfusion, the red blood cells may be returned to the cardiotomy reservoir for later washing if desired.

Warning: The operator should refer to the current standards for expiration date of stored blood.

Removing the sequestering disposable set

- ➔ Remove the Y-connector from the effluent line on the standard Cell Saver collection set.
- ➔ Connect the effluent line from the bowl directly to the waste bag.
- ➔ Disconnect the blood collection bag from the wash line spike.
- ➔ Spike a bag of normal saline solution with the wash line spike.

Selecting the cell saving protocol

The STANDBY state screen display will be visible at this time.

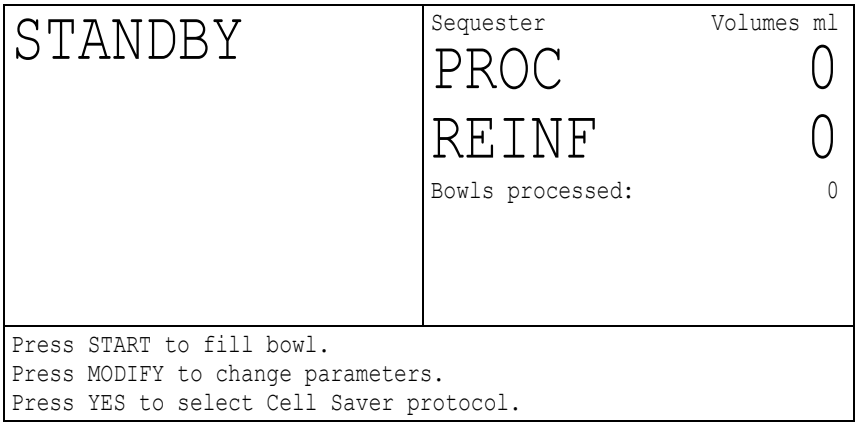

Figure 7-8, Example of the STANDBY screen display (sequester)

To perform a cell salvage procedure once the plasma sequestering procedure is complete, the operator should:

➔ Press the Yes key to select the Cell Saver protocol.

When the Yes key is pressed form the STANDBY state screen display, the following information will appear:

Figure 7-9, Load disposable screen display

This screen display indicates that the CS5+ system is ready to perform a cell saving procedure. At this point the operator can:

➔ Press the Start key to initiate a Cell Saver protocol.

Chapter Eight

Using Data Acquisition Features

PROVIDING AN OVERVIEW OF THE FEATURES

Virtually every medical organization uses standard forms to document the anaesthesia process and these forms are included in the patient file. As a part of the anaesthesia process, the results of intra- and post-operative autotransfusion are generally recorded in these forms as well. Recent quality assurance requirements tend to increase the number of parameters which need to be recorded. In some sites, all information is later introduced in a computerized patient file system.

A comprehensive solution is to provide simple and efficient tools to relieve medical staff from time consuming tasks such as:

- Copying information displayed by the CS5+ device during operation.
- Introducing this information on a computer terminal.

To implement this, Haemonetics has introduced on the CS5+ device a choice of data acquisition tools including:

- The automatic recording of the parameters describing the autotransfusion process.
- The ability to retrieve the recorded information on a choice of external devices (printer, computer system).

These data acquisition tools can be separated in two categories:

- On-line data acquisition features: accessible during the autotransfusion process. These tools allow the visualization or transfer of information concerning the current procedure.
- Off-line data acquisition features: permit management of the information recorded during the previous procedures. These tools are not available during processing.

Listing the recorded parameters

The following parameters are automatically stored during each procedure. This information is retained in the CS5+ memory for the last 10 procedures.

- Date, day, month and year.
- Type of surgery.
- Disposable installation time: the time at which the disposable was installed on the CS5+ device.
- Procedure start time: the time at which the first fill cycle was initiated.
- Bowl size: the type of the bowl used in the disposable set (70mL Bowl or Latham bowl 125 ml/225 ml).
- Vacuum in the reservoir: the vacuum force applied to the collection reservoir during the procedure in mmHg.
- Mode of operation (AUTOMATIC for automatic operation, MANUAL for manual operation, MIXED if both modes were used during the procedure).

- Patient ID: a 10 digit number identifying the patient (social security number, hospital file number, etc.).
- Volume accounting functions: the total processed volume, the total reinfused volume, the total washed volume and the number of bowls processed.
- Procedure duration and procedure number.
- Number of concentrate cycles performed during the procedure.
- Volume status cycle by cycle: the processed, washed and reinfused volume at the end of each complete cycle.
- Error codes recorded during the procedure.
- Estimated Blood Loss (EBL) for the patient.
- Estimated Plasma Loss (EPL) for the patient.

These two last parameters will be displayed and calculated only if the related option has been set in the utility mode.

Explaining the output devices

One of the goals of data acquisition is to avoid paperwork by providing the recorded information in the form and on the media which responds best to the requirements of the physician. To implement this, various output devices can be connected to the CS5+ system such as a non-thermal printer, a compatible PC.
Further information is provided in the section *Listing data output devices*.

EXPLAINING ON-LINE DATA ACQUISITION FEATURES

On-line data acquisition features are tools which the operator can access during the current CS5+ procedure. The following features are available during the course of each procedure:

- Viewing the current procedure statistics.
- Transferring the current recorded values to an output device.
- Entering a patient identification number, hematocrit value and type of surgical procedure.

Viewing the current procedure data

Whenever the CS5+ system is in the STANDBY state, the following information will be displayed:

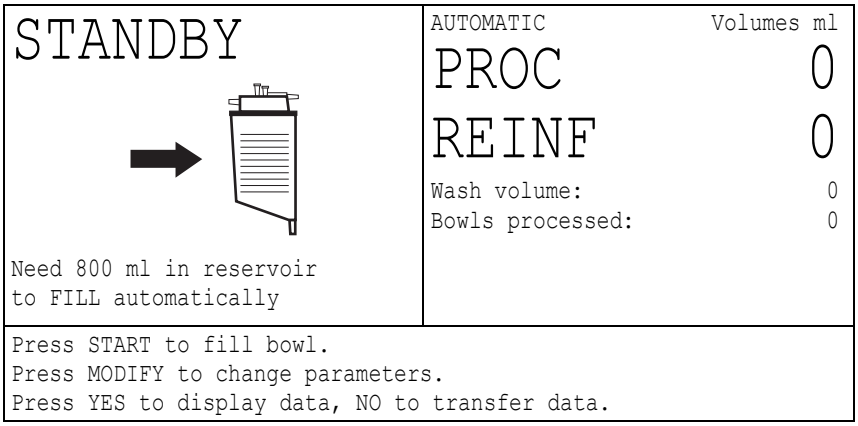

Figure 8-1, Example of the STANDBY state screen display

From the STANDBY state screen display, the operator can choose to view the current statistics on the View Data screen display or send the information directly to a connected output device.

To access the View Data screen display:

➔ Press the Yes key to display the following information.

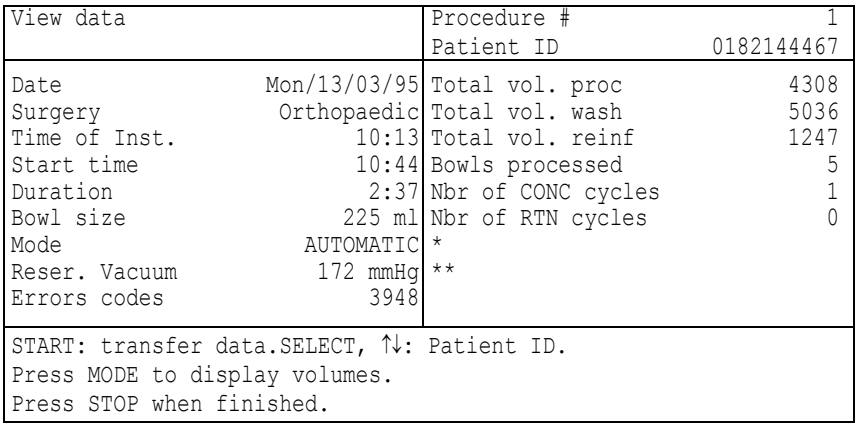

Figure 8-2, Example of the View Data screen display

The current values of the recorded parameters will be displayed.

*Note: The following information will also be displayed if the option was set in the utilities menu: *EBL Patient (35%), **EPL Patient.*

At this point the operator can choose among the following actions:

- ➔ Press the Stop key to return to STANDBY mode.
- ➔ Enter a patient ID number as follows:
  - Use the Select key to highlight the patient ID option and move through the 10 digits of the patient ID.
  - Use the Arrow keys [↑↓] to select each digit from 0 to 9.
- ➔ Press the Start key to transfer the data to the output device connected to the CS5+ device.
- ➔ Press the Mode key to display the volume status after each cycle.

The following information will be displayed when the Mode key is pressed:

Procedure volumes — Procedure # 1
Patient ID 0182144467

	1	2	3	4	5
Proc	1265	1893	2433	3098	4308
Wash volume	1512	2263	3018	3772	5036
Reinf	492	622	756	890	1247
Duration	91	106	112	121	157

Press STOP when finished.

Figure 8-3, Example of the Procedure Volumes screen display

The *Proc* (Processed), *Wash* and *Reinf* (Reinfusion) are the volumes calculated at the end of each cycle. *Duration* is the time in minutes since the start of the first cycle, updated at the end of each subsequent cycle.

Transferring procedure data

When the device is in the STANDBY state, the operator may also directly transfer the recorded data to the configured output device as follows:

- ➔ Press the No key.

Optionally entering certain data

By default, the patient ID and the surgery type should be entered in the upper right section of the View Data screen display. However, if the technician has set the option in the utilities menu, the patient ID number and surgery type may also be entered in a dedicated screen display. This dedicated screen display will appear once the disposable set installation has been completed but prior to initiating the procedure.

The operator can do this as follows:

➔ Press the Start key when the LOAD DISPOSABLE screen display appears.

This action will display the following information:

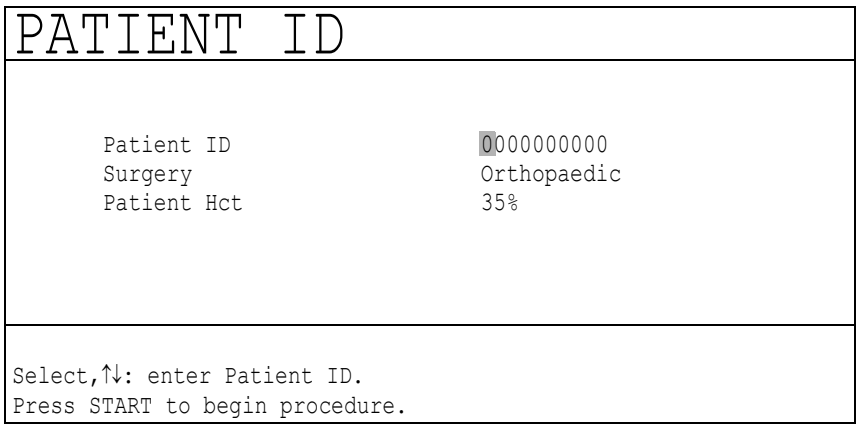

Figure 8-4, Example of the Patient ID screen display

At this point the operator has the possibility to:

➔ Enter a patient ID number as follows:

- Use the Select key to highlight the patient ID option and scroll through the 10 digits of the patient ID.
- Use the Arrow keys [↑↓] to select each digit from 0 to 9.

➔ Press the Select key to choose a surgery type.

➔ Enter a patient hematocrit (if the option was set in the utilities menu as for a patient ID number).

➔ Press the Start key to enter the STANDBY state.

EXPLAINING OFF-LINE DATA ACQUISITION FEATURES

Off-line data acquisition features are tools designed for the management of information recorded during a previous autotransfusion procedure and are not accessible during the cell saving process for safety reasons. During each procedure parameters are automatically stored in the CS5+ memory. The information concerning the last 10 procedures are retained in a FIFO (First In, First Out) manner which means that a new procedure will erase the oldest procedure.
The management of off-line information can be separated into in four categories:

- **Transfer data** function: allows procedure data to be transferred to the output device.
- **View data** function: allows the information recorded for a selected procedure to be displayed on the screen.
- **Set time** function: allows the CS5+ clock to be set to the current date and time.
- **Clear data** function: allows the memory to be cleared of all data recorded.

Accessing off-line data acquisition

These functions are available from the off-line data acquisition menu which can be accessed during the powered on procedure.
If the CS5+ device has been powered off for more than 6 hours, the following information will appear during the power on procedure.

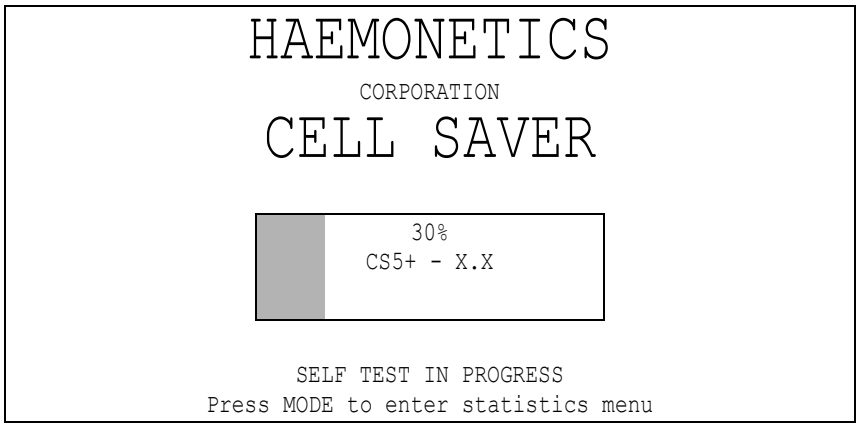

Figure 8-5, Example of the Self test screen display

If the CS5+ device has been powered off for less than 6 hours, the following information will appear:

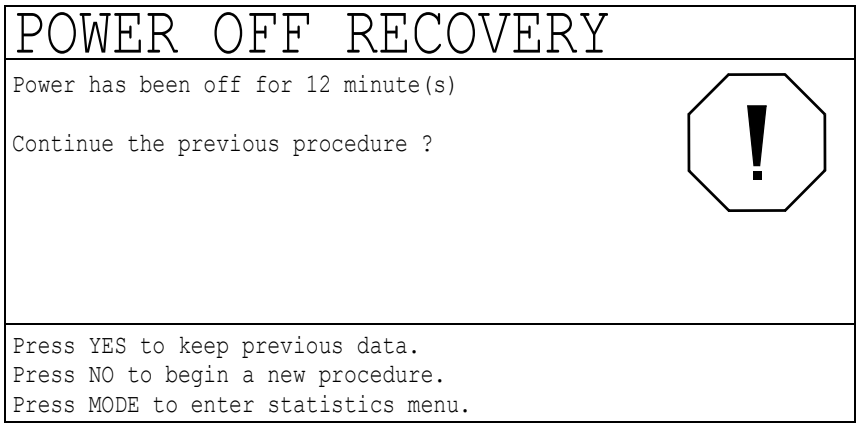

Figure 8-6, Example of the Power off recovery message

In either case, the operator can access the off-line data acquisition menu and select an off-line data acquisition function as follows:

➔ Press the Mode key to receive the following screen display:

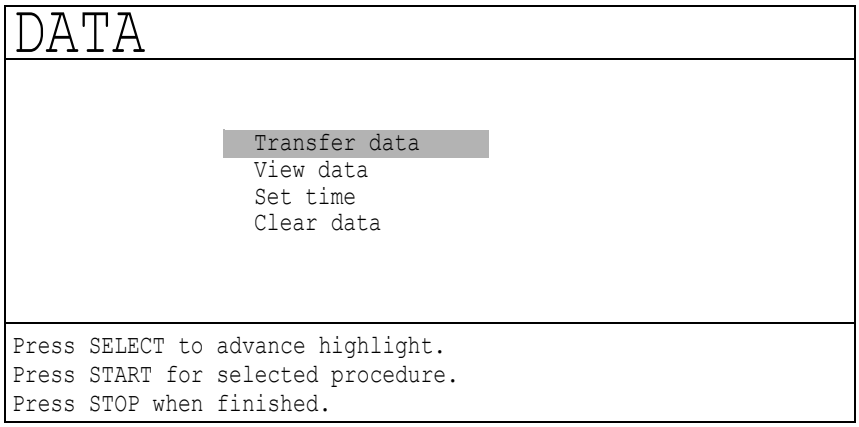

Figure 8-7, Off-line data acquisition menu

➔ Press the Select key to scroll the list and highlight a selection.

➔ Press the Start key to confirm the selection.

Working with the Transfer Data function

The Transfer Data screen display will allows the operator to transfer the recorded information for a selected procedure to an output device connected to the CS5+ device. When it is selected from the off-line data acquisition menu, the following information will be displayed:

```
Transfer data
Procedure #                    1 Device:                    PC19200
1. 1821444671          Mon/       13/03/1995          10:44
2. 1831451134          Mon/        3/03/1995          17:13
3. 1831450511          Wed/        5/03/1995          23:05
4.                     Thu/        6/03/1995           9:19
5. 1891000142          Fri/        7/03/1995           7:32
6. 1082239875          Sun/       19/13/1995          21:01
7. 0188258119          Mon/       20/03/1995           8:14
8.                     Tue/       21/03/1995          10:49
9.                     Wed/       22/03/1995           9:34
10.                    Wed/       22/03/1995          13:47
Press ARROW keys to change values.
Press START to transfer data to remote device.
```

Figure 8-8, Example of the Transfer Data screen display

The procedures available in the CS5+ memory which have been referenced by patient ID (if entered), date and start time will be listed. If no patient was ID was entered, the corresponding area will remain blank.

The upper portion of the screen display lists two options:

- **Procedure #:** this selection allows the operator to determine which procedure information to send to the output device.
- **Device:** this selection will format the data according to the requirements of the connected output device.

The operator can work with the displayed information as follows:

➔ Press the Select key to switch between *Procedure #* or *Device*.

➔ Use the Arrow keys to highlight one or all of the available procedures.

➔ Press the Start key to initiate the transfer of data.

The following message will be displayed during the transfer of data to the output device:

Transfer in progress

The following message will be displayed once the transfer has been completed:

Transfer complete

The operator should remember that the CS5+ device does not control the data transfer and therefore should verify the following points:

- The output device has been properly connected.
- The output device has actually received the information sent.
- The entire data transfer is correct.

Warning: The physician must consider the information provided by the CS5+ device as indicative. This information must not be used as the only indication for medical treatment.

When the Transfer Data information is displayed, the following keys are available to the operator:

- Start key: initiates the transfer of the selected information to the selected output device type.
- Stop key: returns the screen display to the data acquisition menu.
- Select key: toggles between the *Procedure #* and the *Device* options.
- Arrow keys: used to select a procedure(s) or change settings of the *Procedure #* and *Device* options.

Working with the View Data function

The View Data function allows the operator to visualize information recorded during previous procedures. When it is selected from the off-line data acquisition menu, the following information will be displayed:

View data		Procedure #	1
		Patient ID	0182144467
Date	Mon/13/03/95	Total vol. proc	4308
Surgery	Orthopaedic	Total vol. wash	5036
Time of Inst.	10:13	Total vol. reinf	1247
Start time	10:44	Bowls processed	5
Duration	2:37	Nbr of CONC cycles	1
Bowl size	225 ml	Nbr of RTN cycles	0
Mode	AUTOMATIC	*	
Reser. Vacuum	172 mmHg	**	
Errors codes	3948		
START: transfer ↑↓:display next procedure's data. Press MODE to display volumes. Press STOP when finished.			

Figure 8-9, Example of the View Data screen display

*Note: The following information will also be displayed if the option was set in the utilities menu: *EBL Patient (35%), **EPL Patient.*

When the View Data information is displayed, the following keys will be available to the operator:

- Arrow keys: allows the operator to display all of the procedures available. When selected, the View Data screen display will list the first procedure stored in memory (Procedure #1). Pressing the arrow key will display the following procedure (Procedure #2), etc.
- Mode key: provides access to the volume status cycle by cycle for the selected procedure.

If the operator presses the Mode from the View Data menu, the following information will be displayed:

Procedure volumes — Procedure # 1
Patient ID 0182144467

	1	2	3	4	5
Proc	1265	1893	2433	3098	4308
Wash volume	1512	2263	3018	3772	5036
Reinf	492	622	756	890	1247
Duration	91	106	112	121	157

Press STOP when finished.

Figure 8-10, Example of the Procedure Volumes screen display

Working with the Set Time function

The device has an internal clock responsible for recording the time and date. This clock is precise and does not need to be set regularly. However, for countries where the summer/winter time (daylight saving time) pattern is applied, the clock will need to be set twice a year.
When the Set Time function is selected from the off-line data acquisition menu, the following information will be displayed:

SET TIME

Current time: 10:45
Current date: Mon/13/03/1995

Press SELECT to advance highlight.
Press ARROW keys to change values.
Press STOP when finished.

Figure 8-11, Example of the Set Time screen display

The information will be presented as follows:

- Current time: listed by hour and minutes.
- Current date: listed by day of the week, date, month and year.

To modify the time and date:

➔ Press the Select key to scroll the list and highlight an item.

➔ Use the arrow keys to modify the value displayed.

Once the correct time and date have been entered:

➔ Press the Stop key to save the changes and exit.

Note: The setting of the clock will take effect only after the Stop key has been pressed. The time and date are not updated simply because the screen display in the Set Time menu has been changed.

Working with the Clear Data function

The Clear Data function is used to erase all data stored in the CS5+ memory. When it is selected from the off-line data acquisition menu, the following information will be displayed:

```
CLEAR DATA

                Ready to clear data...

Press START to clear all recorded data.
Press STOP when finished.
```

Figure 8-12, Example of the Clear Data screen display

To use this function:

➔ Press the Start key to erase all of the recorded procedure data.

➔ Press the Stop key to return to the main menu.

Note: Clearing the data is not functionally necessary. As previously mentioned, the memory of the CS5+ device is managed in a way that earlier recorded procedures are erased by new procedures. The Clear Data feature is provided to allow the operator to clarify data management by erasing information that has been retrieved.

LISTING DATA OUTPUT DEVICES

The following options are available for use with the CS5+ system:

Printer1 Transmission at 9600 bauds, data alignment using TAB (09h) control character, suitable for printers with 80 or more characters per line.

Printer2 Transmission at 9600 bauds, data alignment using spaces (for printers not accepting the TAB character), suitable for printers with 40 or more characters per line.

PC9600 Transmission at 9600 bauds in a spreadsheet-compatible format.

PC19200 Transmission at 19200 bauds in a spreadsheet-compatible format.

In all cases, transmission is performed according to the EIA RS232C protocol with the corresponding settings:

- 8 data bits.
- 1 stop bit.
- No parity check.
- No handshaking (neither hardware nor software).

Further information on printer compatible with the CS5+ are provided in the *Appendix A, Presenting the CS5+ compatible printer*.

Chapter Nine

Maintaining the Cell Saver 5+ Device

PROVIDING AN OVERVIEW OF NORMAL MAINTENANCE

The Cell Saver 5+ device is easy to use and has been designed to require minimal maintenance. Normal maintenance will consist of:

- Cleaning the system and any spilled blood.
- Ensuring that the pump rollers are clean and free-rolling.

A record should be kept regularly of the date and type of maintenance performed.

Haemonetics recommends a maintenance visit once or twice a year by an authorized Haemonetics technician who will perform a series of maintenance controls and fine-tune the device for maximum performance. The local Haemonetics representative can be contacted for details of a Preventive Maintenance Plan (PMP) for the CS5+ equipment.

Warning: To eliminate the potential danger of electrical shock, the CS5+ device must be disconnected from any power supply prior to servicing or cleaning the system.

The following list described the basic material required for routine cleaning and maintenance:

- Disinfectant cleaning solution compatible for use with the CS5+ material, specific for blood-born pathogens.
- Warm water.
- 70% Isopropyl alcohol.
- Lint-free gauze or cloth (for cleaning and drying).
- Cotton swabs.
- Protective gloves.
- Philips-head screw driver.

If there is no established institutional policy for decontamination, Haemonetics recommends that blood spills be cleaned with a 10% bleach solution applied with lint-free gauze.
If there is any question about the compatibility of a cleaning solution with the CS5+ material, the operator should contact Haemonetics.

DESCRIBING SPECIFIC CLEANING PROCEDURES

Cleaning the optical lenses

The optical bowl sensor, located in the upper portion of the centrifuge well, contains a window which covers the two lenses. The window should be cleaned with a soft, damp, lint-free gauze moistened with water *only*.

The effluent line sensor contains two optical lenses in the line sensor groove. The operator should carefully pass the gauze through this groove to clean and then dry the sensor.

Caution: *The optical sensors must be clean and clear to function properly. A dirty or clouded lens could interfere with proper operation of the sensor. An optical lens should always be cleaned after a blood spill.*

Cleaning the centrifuge well

The centrifuge well should be routinely cleaned with a damp, lint-free cloth (or gauze). The towel can be dampened with a mild detergent spray to improve cleaning.

Caution: *The operator should never use full-strength bleach directly on the device; a bleach/water solution or some other disinfectant may be indicated.*

The centrifuge base contains mechanical chuck clips which must be kept clean. The clips must be thoroughly cleaned after any spills. A dirty or blocked clip may no longer hold the bowl correctly in place. If a clip is not functioning properly, the operator must contact an authorized Haemonetics representative.

Cleaning the fluid detectors

The CS5+ device contains two fluid detectors: one inside of the centrifuge well above the chuck, one exterior to the bowl on the panel to the left of the bowl. The metallic surface of the detector should be cleaned using a cotton swab moistened with 70% alcohol.

Cleaning the blood pump

The blood pump should be cleaned after a spill to keep the rotating parts moving freely. The roller portion of the pump may be lifted out to be cleaned as follows:

- ➔ Hold the rollers motionless while unscrewing the pump cover.
- ➔ Clean the area under the roller portion and pump arm until all moving parts can rotate or slide freely.
- ➔ Secure the roller head back into its original position.

Cleaning after a spill

The exterior surfaces of the CS5+ device including the control panel, should be cleaned with a mild detergent or disinfectant solution at regular intervals, as well as following any spill.

Caution: *The operator should never use full-strength bleach directly on the device; a bleach/water solution or some other disinfectant may be indicated.*

The CS5+ device is equipped with a biohazard waste bag which will collect fluid or blood in the event of a spill in the centrifuge well. To completely evacuate a larger spill from the centrifuge well, the operator should:

- ➔ Irrigate the centrifuge drain holes with cleaning solution until the tube is rinsed clean of the spilled material.
- ➔ Remove the bag and replace it with a new bag.
- ➔ Dispose of the used waste bag according to the local established policies for biohazard waste.

Washing the air filter

The CS5+ rear panel is equipped with an air filter for cooling incoming air to the device. The filter should be washed periodically, depending upon frequency and conditions of use to avoid malfunction resulting from an accumulation of lint and dust in air passages. The filter should only be washed with warm running water.
Cleaning the air filter is simple and easy as described in the following steps:

- ➔ Disconnect the CS5+ from the power supply.
- ➔ Remove the retainer plate using a Philips-head screw driver.
- ➔ Grasp the air filter and remove it from the panel.
- ➔ Rinse the filter under warm running water until it is clean.
  DO NOT use soap or any cleaning agents.
- ➔ Gently squeeze the screen to remove excess water.
- ➔ Place on a clean cloth and allow to dry completely.
- ➔ Reinsert the filter in the filter panel, ensuring that the filter completely covers the opening.
- ➔ Replace the retainer plates and tighten the screws.
- ➔ Record the date of maintenance.

PROVIDING CUSTOMER SERVICE

Field service

Haemonetics maintains a world wide network of company trained service representatives. These technical specialists are available to diagnose and repair any malfunctions with the blood processing equipment and will be on site as soon as possible. The authorized Haemonetics technician can answer any questions about routine maintenance and quality control as well as provide routine annual or semi-annual maintenance, such as leakage current tests. Maintenance contracts are available to ensure that Haemonetics equipment continues to function properly.

Installation and clinical training

Haemonetics has a large network of specialists proficient in both the medical and technical aspects of all Haemonetics equipment. These experienced trainers can listen to and respond to questions and concerns. A thorough, on-site training in the operation of the CS5+ device will be provided for the personnel by the Clinical Specialists upon delivery of the equipment at a conveniently arranged time.

Returned goods authorization system

Haemonetics seeks to provide the customer with equipment and material which respects the highest established standards of quality in design and manufacturing. If for any reason the merchandise must be returned to the company, the customer should refer to the Haemonetics Returned Goods Authorization (RGA) system to ensure proper handling and subsequent analysis of the material.

First, the customer should contact the local Haemonetics Representative (or Haemonetics Customer Service Department) and provide the following information:

- Product list number, lot number and manufacture date.
- Number of articles to be returned.
- Description of defect.
- Number of parcels being shipped.

The Haemonetics representative may ask for additional details, depending on the nature of the problem. The customer should be prepared to provide a thorough description of the problem encountered as well as the product information listed above.

If a contaminated disposable set must be returned by courier services, the Haemonetics representative may provide specific instructions concerning preparation for shipping blood-contaminated products. In addition to the Haemonetics guidelines, the consumer should strictly follow the local standard operating procedure related to the shipment of blood-contaminated materials and thus minimize any potential health hazards involved.

In some cases, it may be necessary to dispose of the contaminated goods after reporting the problem to the Haemonetics representative. This should be done according to the locally established guidelines pertaining to the disposal of biologically contaminated material.

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

Appendix A

Providing Reference Information

COMPLICATIONS OF AND CONTRAINDICATIONS TO PERIOPERATIVE BLOOD RECOVERY

Table A-1, Complications of and contraindications to perioperative blood recovery*

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.

Table A-1, Complications of and contraindications to perioperative blood recovery*

Substance	Effects	Recommended Action
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.
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.

Table A-1, Complications of and contraindications to perioperative blood recovery*

Substance	Effects	Recommended Action
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.
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.

Table A-1, Complications of and contraindications to perioperative blood recovery*

Substance	Effects	Recommended Action
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.
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.

Table A-1, Complications of and contraindications to perioperative blood recovery*

Substance	Effects	Recommended Action
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.
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.

* *per AABB Guidelines for Blood Salvage and Reinfusion in Surgery and Trauma, 1997.*
The physician should apply any existing local regulation or recommendation related to complications or contraindications.

DESCRIBING CELL SAVER 5+ ERROR CODES

The CS5+ data acquisition will automaticaly store all critical errors occurring during a procedure using codes.
The following table lists these error codes with a brief description:

Code	Error message on the screen	Description
1	System error. Software timing error.	**Software timing error.**
2	Clamp error. Check reservoir (red) line. Remove tubing and inspect area around clamp.	**RED clamp position error.** Occurs whenever the clamp should be open/closed but is not detected as open/closed.
3	Clamp error. Saline (yellow) line. Remove tubing and inspect area around clamp.	**YELLOW clamp position error.** Occurs whenever the clamp should be open/closed but is not detected as open/closed.
4	Clamp error. Product (blue) line. Remove tubing and inspect area around clamp.	**BLUE clamp position error.** Occurs whenever the clamp should be open/closed but is not detected as open/closed.
5	System error. Pump driver error.	**Pump error.** Software initialization error.
6	Centrifuge error. Centrifuge unable to maintain requested speed. Check bowl for proper seating.	**Illegal centrifuge speed.** Centrifuge speed request is above specified limit.
7	System error. Keypad error.	**Keypad error.**
9	System error. Processor error.	**System fault, processor error.**
*10	Reservoir level. Check reservoir level sensor and disposable. Check tubing placement. Check for occlusions in harness and bowl.	**Air detected too early in FILL mode.** Occurs whenever air is detected in FILL mode before at least 50 ml have been processed. Probable cause: level sensor initiated a fill cycle without fluid in the reservoir (accuracy problem).
11	System error. Software stack error.	**Stack empty error, software state management error.**
13	Solenoid error.	**Solenoid task error.**

Code	Error message on the screen	Description
14	System error. Software definition error.	**Software definition error.**
15	System error. Software read error.	**Software read error.**
16	System error. Software queue error.	**Software queue error.**
17	System error. Software write error.	**Software write error.**
18	Centrifuge error. Centrifuge stalled. Check bowl for proper setting.	**Centrifuge stall error.**
19	Centrifuge error. Overspeed detected. Check bowl for proper seating.	**Centrifuge overspeed error.**
21	Centrifuge error. Fluid detected in centrifuge well. Inspect disposable inside centrifuge well.	**Fluid detection in the centrifuge area.** One or both of the fluid detectors sensed fluid.
22	Unexpected sensor reading. Bowl optics sensor. Clean bowl optics sensor and disposable.	**Optics algorithm error.** Software was unable to initialize the optics algorithm task properly.
23	Air sensor error.	**Air sensor error.**
24	Air detected early. Check tubing placement. Check for occlusions in harness and bowl.	**Early air detection in empty.** Air was detected before 75% of the nominal bowl volume was pumped.
25	Centrifuge error. Device failed to stop.	**Centrifuge does not stop.**
*26	Centrifuge cover not closed! Close centrifuge cover.	**Centrifuge cover is open.**
27	Long empty cycle. Check tubing placement. Check for occlusions on the effluent side. Check for transfer of air from waste bag to bowl.	**Empty/Return cycle too long.** Empty/Return cycle did not complete after the nominal bowl size +50 ml were pumped out of the bowl.
28	Centrifuge error. Centrifuge unable to reach proper speed. Check bowl for proper seating.	**Centrifuge is unable to stabilize speed.**

Code	Error message on the screen	Description
29	Sensor error. Proceed in MANUAL mode.	**Analog-to-digital conversion timeout error.**
30	System error. Software signal error.	**Analog-to-digital conversion queue full error.**
31	System error. Internal aknowledgment error.	**State acknowledgment error.**
32	Unexpected sensor reading. Waste bag weigher sensor. Check waste bag and disposable.	**Waste bag weigher analog-to-digital conversion error.**
33	Unexpected line sensor reading. Please check product quality.	**Yellow/Green line sensor error.** Sensor output is out of specification.
34	Unexpected sensor reading. Clean red cell line sensor and disposable.	**Effluent line sensor error.** Sensor output is out of specification.
35	Unexpected sensor reading. Precisionsensor input test. Restart machine. If failure continues, call Haemonetics hot-line.	**Analog-to-digital converter error.**
37	System error. Air detector.	**Air detector error.**
*38	Waste bag full. Please empty waste bag.	**Waste bag full error.** Occurs at the moment that the waste bag volume reaches its capacity.
*39	Clamped line detected. Please open fluid lines.	**Clamped line detected.** In empty/return, too much pressure was sensed in the manifold due to a clamped line.
40	Unexpected sensor reading. Reservoir level. Check reservoir level sensor and dispos-able.	**Level sensor analog-to-digital conversion error.**
41	Unexpected sensor reading. Clamped line sensor. Check valve door and disposable.	**Clamped line sensor analog-to-digital conversion error.**
42	Pump error. Incorrect pump direction detected.	**Incorrect pump direction detected.** Pump was detected as turning in the wrong direction.

Code	Error message on the screen	Description
43	Pump error. Clean pump rotor. Check tubing positioning.	**Pump stalled error.** Pump rotation is blocked.
44	Pump error. Incorrect pump speed detected.	**Incorrect pump speed.** Pump speed target could not be reached.
*45	Please be sure pump platen and valve door are closed.	**Pump lever or manifold latch error.** The pump lever or manifold latch is/are not locked.
46	Sensor is not calibrated. Reservoir level.	**Level sensor calibration error.** Level sensor calibration is out of the operating range.
47	Sensor is not calibrated. Waste bag weigher.	**Waste bag weigher calibration error.** Waste bag weigher calibration is out of the operating range.
*49	Unexpected sensor reading. Line sensor out of range. Clean line sensor and check disposable insertion.	**Line sensor tubing installation error.** Line sensor signal with tubing installed is below specification.
Note: The asterisk (*) signifies that the specified error code is not recorded.		

PRESENTING THE CS5+ COMPATIBLE PRINTER

The Cell Saver 5+ can be connected to a non-thermal printer, presented below.

Note: To ensure long life of the printer and compliance with warrantly requirements, it is recommended to use the paper and ribbon reference on page A-12 *of this manual.*

Non-thermal printer overview

1. Power indicator lights [red and green]
2. Ribbon
3. Printer lid and its guideline
4. Feed button
5. Paper roll in the paper chamber

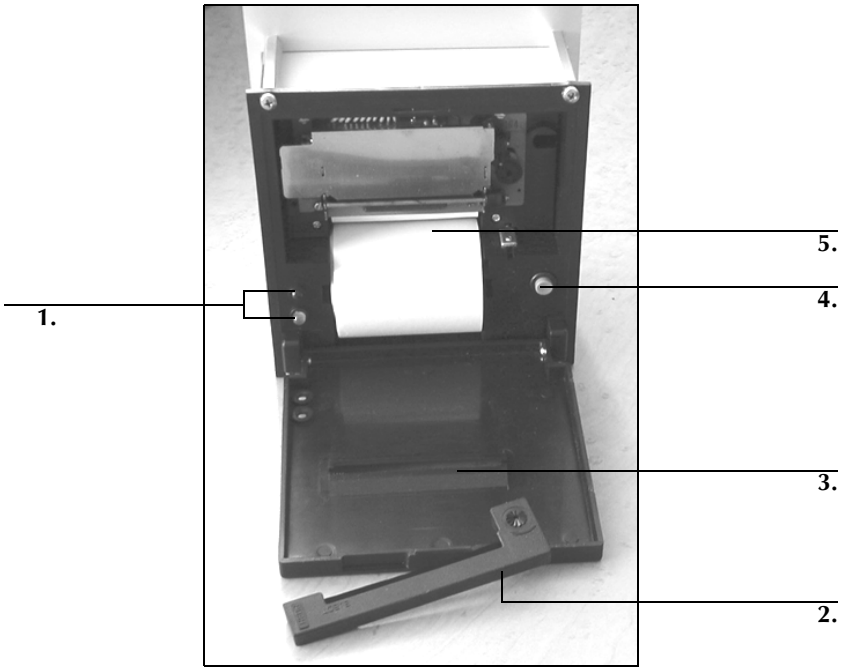

Figure A-1, Printer open with ribbon removed

Changing the paper roll during a printing procedure

To change the paper during a printing procedure, the operator should:

➔ Open the printer lid.

➔ Remove the old paper roll.

Note: Do not place the new roll in the paper chamber now.

➔ Introduce the edge of paper into the printer.

➔ Push the Feed button until the paper appears on the output of the printing head.

➔ Place the paper roll in the paper chamber.

➔ Push the Feed button to continue printing.

➔ Close the lid, ensuring the paper pass through the guideline lid.

Ribbon installation

If the printout is no longer readable, the operator should verify the ribbon state.
If the ribbon is not finished, the operator shoud proceed as follows:

➔ Open the printer lid.

➔ Turn the wheel marked with an arrow until only the unused section of the ribbon is exposed.

To install a new ribbon:

1. Ribbon
2. Wheel and arrow to move the ribbon
3. PUSH / EJECT text

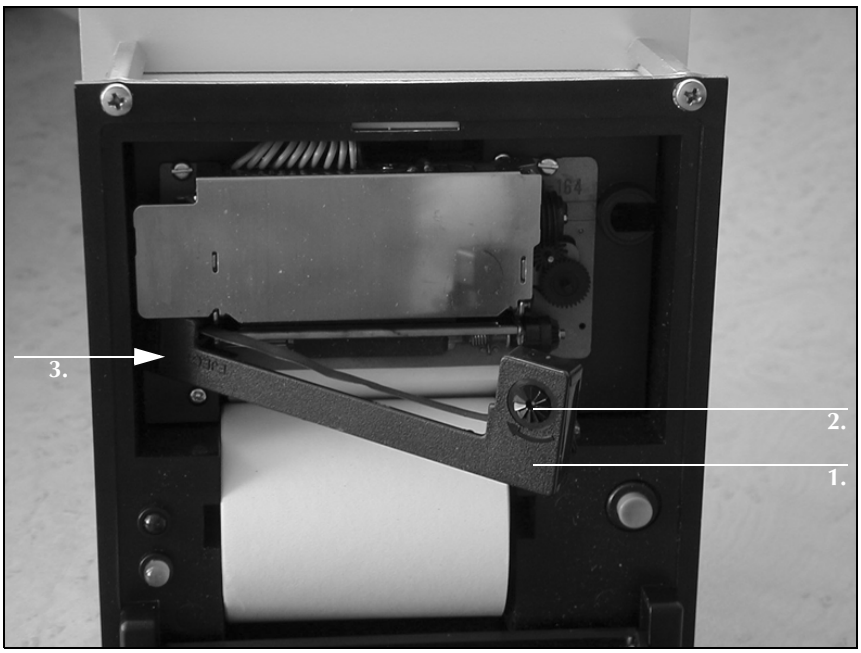

Figure A-2, Removal of the ribbon by pressing on the PUSH / EJECT text

➔ Open the printer lid.

➔ Press on the ribbon as indicated by the PUSH / EJECT text.

➔ Place the new ribbon.

➔ Close the printer lid.

Ordering references

- P/N 52276-00 Non-thermal printer kit.
- P/N 52273-00 Non-thermal printer.
- P/N 52274-00 Non-thermal paper.
- P/N 52308-00 Typewriter ribbon.

EXPLAINING IEC 60601-1-2:2001 STANDARD REQUIREMENTS

Electromagnetic immunity

The Cell Saver 5+ 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 immunity

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CSIPR 11	Group 1	The CS5+ 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 CS5+ system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 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

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 IEC 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 IEC 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 CS5+ system requires continued operation during power mains interruptions, it is recommended that the CS5+ 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

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 CS5+ system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
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 CS5+ system is used exceeds the applicable RF compliance level above, the CS5+ system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CS5+ system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

The CS5+ system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CS5+ system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CS5+ system as recommended below, according to the maximum output power of the communications equipment.

IEC 60601-1-2:2001, Table 206: Recommended separation distance between portable RF communications equipment and the CS5+ device

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.