2 Introduction

The COBE Spectra Essentials is written for the person who will be operating the COBE Spectra Apheresis System. The instructions recommended throughout this book and the entire Operator's Manual have been developed and tested to provide safe, reliable, and efficient operation of the Spectra system. It is important that you, the operator, read and thoroughly understand the information in this book before using the Spectra system.

This chapter describes the physical components of the Spectra system, including the centrifuge chamber, front panel, control panel, and Return Flow Controller. It also provides information on

- *How the Spectra system separates blood into its components*
- *How the Spectra system's pumps and valves control anticoagulant and inlet flow, blood components being collected or removed, and fluids being returned to the donor or patient*
- *How the Spectra system's safety sensors and alarms/warnings help ensure its safe operation*

Spectra System Description

The Spectra system is designed to separate and collect/remove blood components from human donors and patients. From donors, blood products are collected for transfusion to patients. Plasma also can be collected concurrently with platelets. The plasma thus collected is available for use as plasma or fresh frozen plasma. It also can be used as source plasma for further processing into Factor VIII and Factor IX concentrates.

The Spectra version 5.1 LRS (LeukoReduction System) or Spectra version 7.0 LRS Turbo can be used to collect leukocyte-reduced, extended life platelets for transfusion to appropriate thrombocytopenic patients.

Because of the Spectra system's ability to estimate platelet yields before a platelet collection procedure starts, donor pools can be optimized by collecting double-platelet products from donors with sufficiently high platelet counts and total blood volumes. This reduces the number of apheresis procedures necessary for some HLA-matched donors, such as family members of cancer patients.

For patients undergoing therapeutic procedures, the Spectra system can be used to exchange or deplete blood components. In addition, it can be used for autologous collections of platelets and plasma from patients who will later require transfusion of those blood products.

The Spectra system (versions 4.7, 5.1, 6.1, and 7.0) can be used to perform therapeutic plasma exchange procedures on patients with autoimmune diseases or on patients about to undergo a transplant operation. It can be used to perform red blood cell exchange procedures on patients with hematological disorders such as sickle cell anemia and thalassemia and to perform RBC depletions on patients with polycythemia or hemochromatosis. During red blood cell exchange procedures, packed RBCs are typically be used as the replacement fluid for patients with hematological disorders; during RBC depletions, normal saline or albumin is typically used. The Spectra system also can be used to perform therapeutic platelet depletions from patients with thrombocytosis.

The Spectra version 6.1 offers an automated PBSC collection procedure, used to harvest peripheral blood stem cells contained in the mononuclear cell layer after mobilization of stem cells into the peripheral circulation of autologous patients and allogeneic donors. The Spectra system also offers low volume PBSC collections. Plasma can be collected concurrently with PBSCs for use in cell cryopreservation.

The Spectra system (versions 4.7, 5.1, 6.1, and 7.0) can be used for mononuclear and granulocyte (polymorphonuclear) white blood cell harvests from individuals, for bone marrow processing, and for WBC depletions.

Platelet collection and plasma exchange procedures can be performed with either a Dual-Needle (one access needle and one return needle) or Single-Needle (one access/return needle) disposable tubing set. Because of the design of the Single-Needle procedures, both the extracorporeal volume and the process time remain low. In addition, the donor or patient benefits from a single access/return needle site and the apheresis staff benefits from having to perform and manage only one venipuncture.

The Spectra system components include the following:

- A disposable tubing set consists of a separation channel that spins in the centrifuge to separate blood into its components and tubing that routes blood and replacement fluids through the Spectra system. See *Disposable Tubing Sets* on page 2-23 for more information.
- The COBE Spectra Apheresis System, an automated centrifuge-based blood cell separator. The Spectra system's software uses pumps, valves and sensors to control and monitor the extracorporeal circuit during apheresis procedures.

  The Spectra system's software establishes and maintains the red blood cell/plasma interface by controlling the pump flow rates and centrifuge speed. This automation is enhanced by the control panel, with its user-friendly display and keyboard, which allow two-way communication between you and the Spectra system. This ensures donor/patient safety and still allows you freedom to control the procedure. Other ease-of-use features include the following: rapid tubing installation, automatic prime, predictable collection and exchange results, clear alarm information, and automatic Rinseback.

  Figure 2-1 shows an exterior view of the COBE Spectra Apheresis System without a disposable tubing set or flow path overlay.

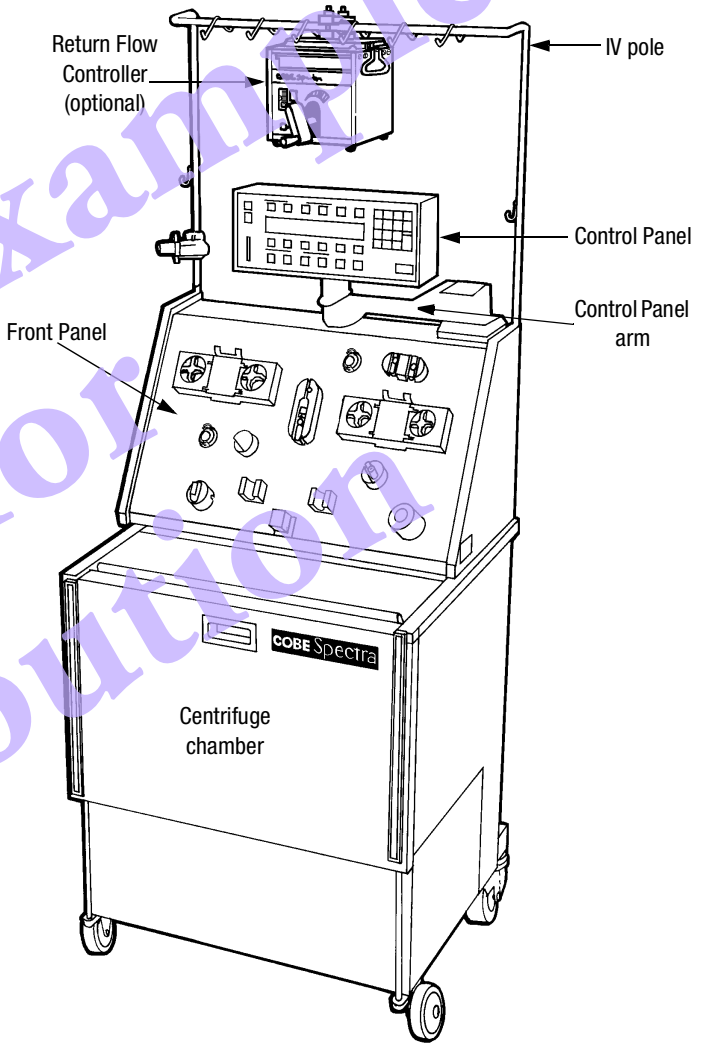

Figure 2-1: COBE Spectra Apheresis System

Spectra System Components

The COBE Spectra Apheresis System (Figure 2-1) can be divided into three sections: centrifuge chamber, front panel, and control panel. The front of the Spectra system opens to provide access to the centrifuge chamber. Above the centrifuge chamber is the sloping front panel containing the pumps, valves, and sensors used by the Spectra system. A swivel arm on top of the Spectra system holds the control panel that includes the keyboard and display.

Centrifuge Chamber

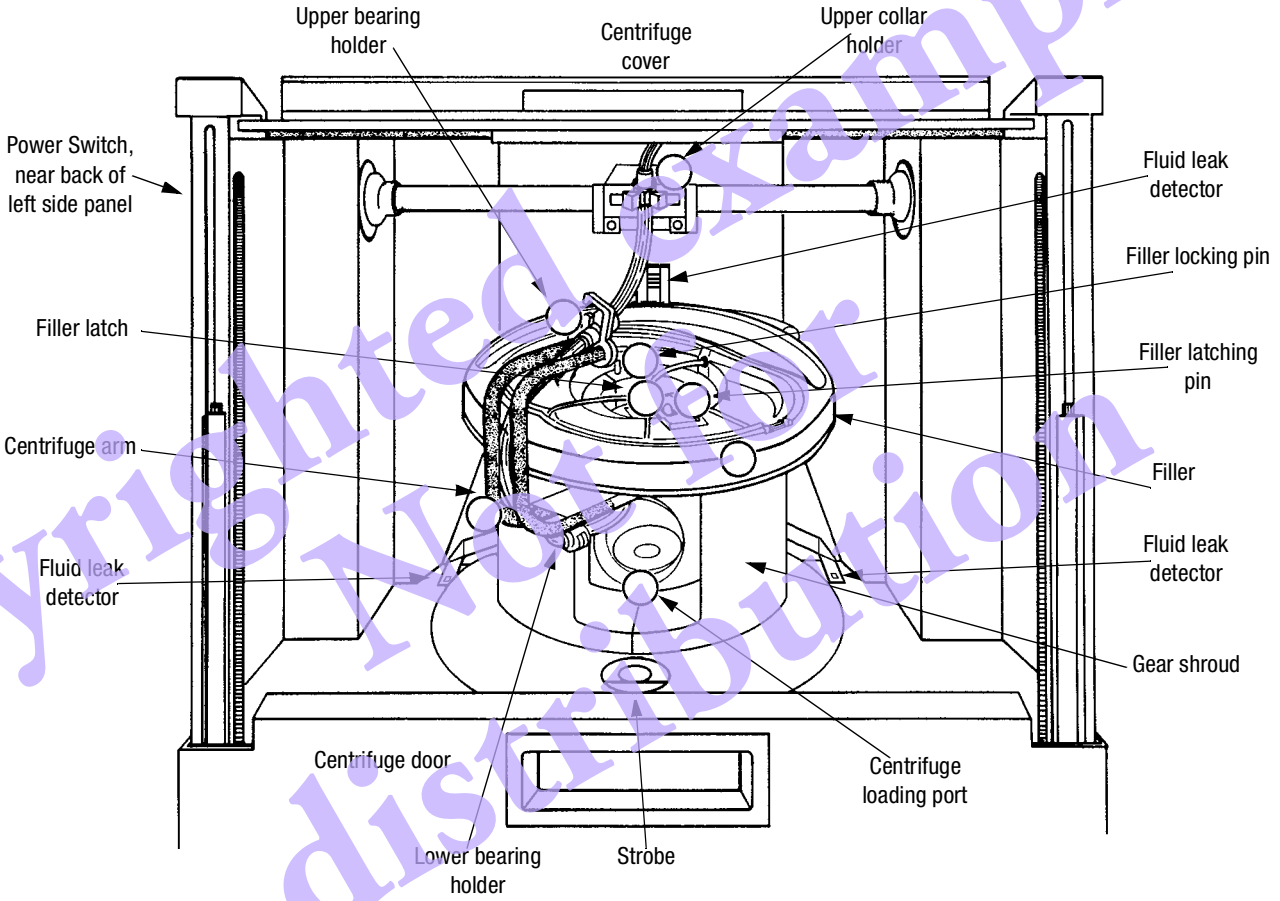

Figure 2-2: Centrifuge chamber

Power Switch – Turns the Spectra system power on and off.

Centrifuge Cover and Door – Allow access to the centrifuge. To protect you from excessive light from the strobe, the cover is opaque. The view port in the cover is transparent so you can watch the strobe to monitor the separation in the channel. The cover and door are interlocking. To open, turn the power on and press **UNLOCK COVER** on the control panel. Slide the cover back and lower the door. Reverse the order to close and lock the door and cover. To ensure safety, the cover and door will not open when the centrifuge is spinning.

Filler – Holds the separation channel. For more information, see *Fillers* on page 2-7.

Filler Locking Pin – Located on the centrifuge opposite the filler latching pin and filler latch, the filler locking pin locks the filler onto the centrifuge.

Filler Latching Pin – Locks the filler latch and, together with the filter locking pin, locks the filler onto the centrifuge.

Filler Latch – locks the filler onto the centrifuge.

Centrifuge Collar Holder – Located on the end of the filler latch, the centrifuge collar holder has a hinged cover to hold one of the nonrotating ends of the channel's multi-lumen tubing.

Centrifuge Loading Port – An opening in the centrifuge housing to enable channel loading.

Centrifuge Arm – Holds the channel's multi-lumen tubing in place as the centrifuge spins.

Lower Bearing Holder – Secures the channel's multi-lumen tubing on the centrifuge arm.

Upper Bearing Holder – Secures the channel's multi-lumen tubing on the centrifuge arm.

Upper Collar Holder – Attaches the upper end of the channel's multi-lumen tubing to the horizontal arm above the centrifuge.

Strobe – Can be turned on to monitor separation in the channel through the centrifuge cover view port. Press the up-arrow key on the keyboard to move the strobe clockwise, which makes the section of the channel being viewed in the view port appear to move to the right. Press the down-arrow key to move the strobe counterclockwise.

Fluid Leak Detector – Detects a blood or fluid leak from the channel when the centrifuge is spinning.

Gear Shroud – Protects you from pinch points in the gear train.

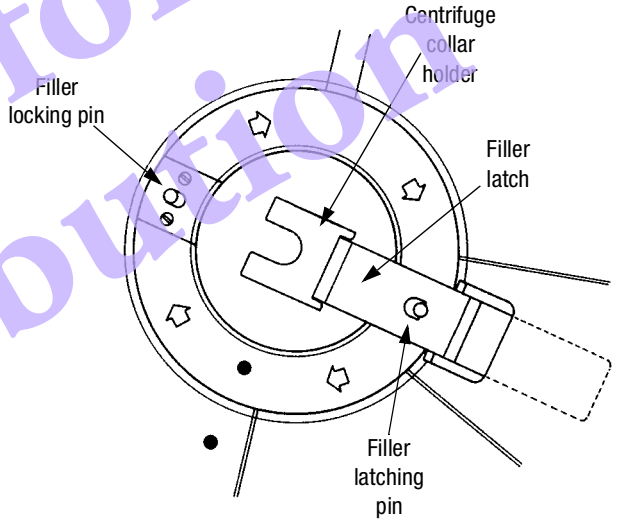

Figure 2-3: Top view of centrifuge

Fillers

There are four fillers for use with the Spectra system.

Figure 2-4: Fillers from left to right: single-stage, dual-stage platelet/AutoPBSC, dual-stage platelet with LRS bracket, and dual-stage LRS Turbo.

Each procedure requires a specific filler. The following table lists each procedure and the filler used in that procedure. See the individual procedure for illustration of the correct filler.

Procedure	Filler
BMP MNC & PMN Collection RBCX TPE WBC Depletion, & LPE	Single-Stage
AutoPBSC Platelet Depletion ELP	Dual-Stage Platelet/AutoPBSC
LRS	Dual-Stage Platelet with LRS Bracket
LRST	Dual-Stage LRS Turbo

Front Panel

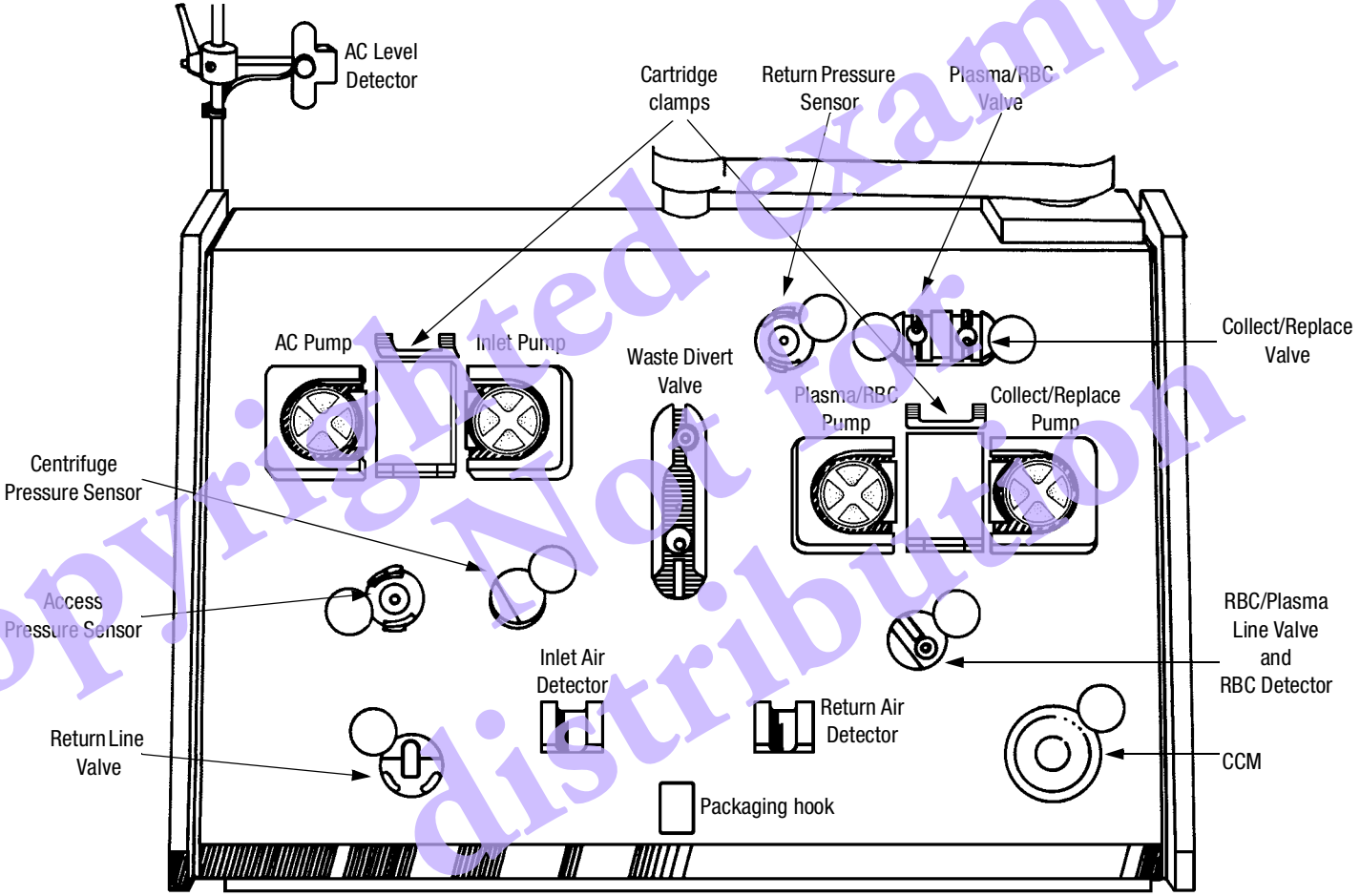

Figure 2-5: Front panel

Pumps

The Spectra system has four peristaltic-type pumps with removable rotors for easy cleaning. The pumps are automatically loaded as the pump cartridges are pulled onto the pumps. The action is reversed for automatic unloading.

Anticoagulant (AC) Pump – Pumps anticoagulant from the AC container to the inlet line. During a WBC granulocyte (PMN) removal procedure, pumps a prescribed hydroxyethyl starch/sodium citrate solution to the inlet line.

Inlet Pump – Pumps anticoagulated whole blood from the donor/patient access to the centrifuge.

Plasma/RBC Pump – During ELP, AutoPBSC, LRS, LRST, TPE, and WBC procedures, it pumps plasma from the centrifuge to a collection bag or to recombine with cellular components for return to the donor or patient. During an RBCX procedure, it pumps RBCs from the centrifuge to the RBC collection bag(s).

Collect/Replace Pump – Pumps cells for collection from the centrifuge to the collection bag, or pumps replacement solution or RBCs from the replament fluid container for return to the patient.

Cartridge Clamps – Retract to facilitate loading of the pumps. After the pumps are loaded, the clamps hold the pump cartridges in place.

Valves

The Spectra system has five valves. Four are pinch-type valves where a post rotates onto the tubing to close it and rotates off the tubing to open it. The fifth valve—the return line valve—is a solenoid, fail-safe clamp that clamps the return line during power loss or certain alarm conditions.

All five valves have an “open” or “load” position to let you load or unload the disposable tubing set.

Waste Divert Valve – Consists of a 2-way valve (upper) and a 3-way valve (lower) that operate in conjunction with each other. The valve assembly opens to allow saline to be removed from the centrifuge (and directed to the waste bag) at the beginning of a procedure. It also opens to remove air from the inlet and return air chambers, and is used during the recirculation step of Rinseback.

Plasma/RBC Valve – During ELP, AutoPBSC, LRS, LRST, TPE, and WBC procedures, this 3-way valve directs plasma to a plasma bag or to recombine with cellular components for return to the donor or patient. During ELP, LRS, LRST, and WBC procedures, the valve can be moved only in Manual mode. Re-entering Automatic mode during a WBC procedure moves the valve back to the Return position, allowing plasma to be returned to the donor or patient. During RBCX procedures, the valve directs RBCs to a RBC collection bag.

Collect/Replace Valve – A 3-way valve that directs flow to the collection bag or, during a red blood cell spillover, back to the donor (to protect the platelet product). During a plasma exchange procedure, it allows replacement solution to be pumped from the container to the patient. During an RBCX procedure, it allows the replacement RBCs to be pumped from the container to recombine with plasma for return to the patient. During an

AutoPBSC procedure, it allows platelets to be returned to the donor/patient and MNCs and plasma to the collection bag only during a Harvest Phase.

RBC/Plasma Line Valve – A 2-way valve in the same housing as the RBC detector. This valve closes during Prime to allow air to be pulled out of the channel before it is primed and during Rinseback to collapse the channel.

Return Line Valve – A 2-way valve that closes during a power loss and some alarm conditions (certain system, air, and pressure alarms and any alarm that stops the centrifuge). During Single-Needle procedures, it also moves to allow for the Draw and Return phases of each Single-Needle cycle.

Pressure Sensors

The Spectra system has three pressure sensors:

Access Pressure Sensor – A diaphragm-type sensor with a transducer that monitors negative pressure from the donor/patient access site. This sensor checks for low access pressure.

Centrifuge Pressure Sensor – A strain gauge sensor that measures pressure just beyond the inlet pump. This sensor monitors for high centrifuge pressure (caused by an air block or occluded tubing).

Return Pressure Sensor – A diaphragm-type sensor with a transducer that monitors positive pressure above the return air chamber. This sensor checks for high return pressure. During Single-Needle procedures, this sensor monitors the pressure in the Single-Needle bag.

Sensors

The Spectra system has two optical sensors:

- **Collect Concentration Monitor** – monitors the density in the collect line

  During ELP, LRS, and LRST procedures, the CCM helps the software

  – Estimate the current platelet yield at any time during the procedure

  – Calculate the platelet concentration in the collection bag at the end of the procedure (during ELP procedures only)

  – Predict the platelet yield for the end of the procedure (during ELP procedures only)

  – Detect red blood cell spillovers greater than 3% hematocrit and protect the platelet concentration in the collection bag by diverting the red blood cells to the donor

  – Monitor the collect line for events which can cause cellular contamination (during LRS and LRST procedures only)

Note: The CCM is not accurate during platelet depletion procedures.

During an AutoPBSC procedure, the CCM detects AutoPBSC harvests and red blood cell spillovers.

During a TPE procedure, the CCM detects red blood cell spillovers.

- **RBC Detector** – Located in the same housing as the RBC/Plasma line valve. At the beginning of the procedure, the sensor monitors the line in the RBC/Plasma line valve for RBCs. When it sees RBCs in the line, it closes the waste divert valve and opens the return line valve.

  If no RBCs are detected by the time the default inlet volume is reached, the Spectra system displays the "NO RBCs DETECTED" alarm (see page 12-41 for more information). The following table shows the default inlet volume for the different procedures:

Disposable Tubing Set	Default Inlet Volume
ELP, LRS, LRST	120 mL
TPE, AutoPBSC, WBC	150 mL

Air Sensors

The Spectra system has three ultrasonic sensors:

Inlet Air Detector – Detects air in the inlet air chamber, stops the pumps to prevent air from entering the centrifuge, and closes the return line valve to prevent air from being returned to the donor/patient.

Return Air Detector – Detects air in the return air chamber, stops the pumps, and closes the return line valve to prevent air from being returned to the donor/patient.

Anticoagulant (AC) Level Detector – Detects for air in the fluid in the AC line.

Flow Path Overlays

The Spectra system comes with three flow path overlays that name each component on the front panel. These help you correctly install the disposable tubing sets.

Collect Flow Path Overlay – Used for collection and depletion procedures.

TPE Flow Path Overlay – Used for TPE procedures.

RBCX flow path overlay – Used for RBCX procedures.

Miscellaneous

Packaging Hook – Holds the disposable tubing set package in place on the centrifuge cover for convenient installation of the tubing on the front panel.

Control Panel

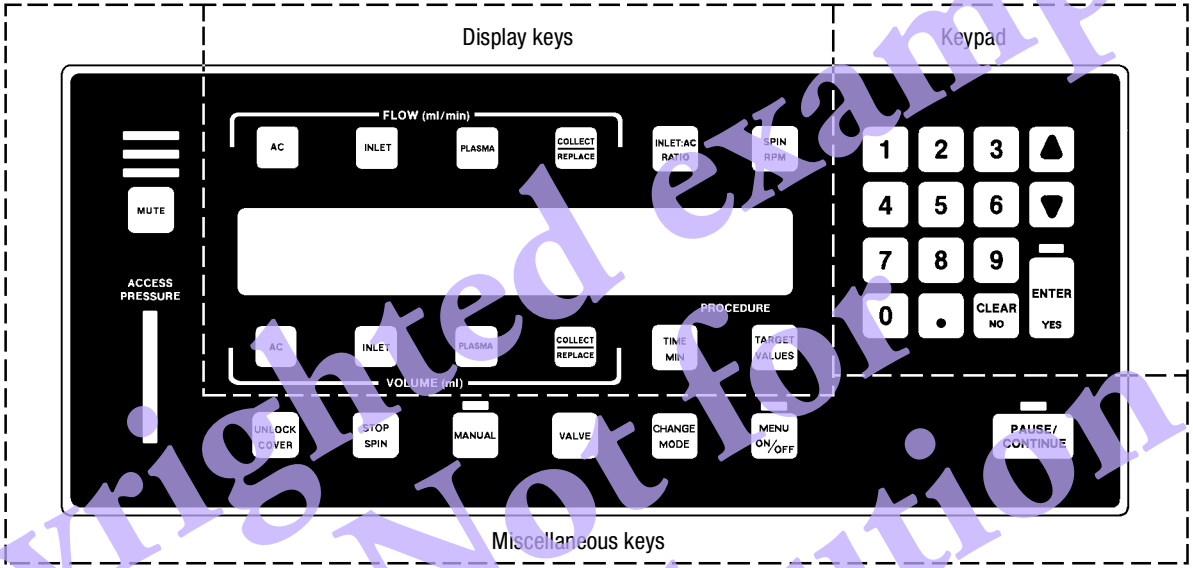

Figure 2-6: Control panel

Note: The control panel can be rotated downward 90 degrees to lower the height of the Spectra system for moving.

The contol panel has both a keyboard and a display. On the keyboard, the keys are grouped into three major functional areas:

- The numeric keypad, located in the upper right-hand corner
- The 12 display keys that surround the display (6 keys above the display and 6 keys below)
- The miscellaneous keys located on the bottom row and left-hand side

When you press a key, the Spectra system beeps. For detailed information on using the keyboard, see Chapter 5, *Software Options and Configuration*.

Keypad

Numerical Keys – Use the keys numbered 0 through 9 for entering numeric information and making menu selections.

Up-Arrow/Down-Arrow Keys

- Use the up- and down-arrow keys to make incremental changes to the numeric value displayed. When you press and release an arrow key quickly (within 3/4 second), the numeric value changes a relatively small amount (1–10 units). When you press and hold down an arrow key, after 3/4 second the numeric value starts changing by 10–100 units every 1/2 second until you release the key.
- You can also use the up- and down-arrow keys to move the location of the strobe flash on the separation channel. Press the up arrow to move the area of the channel displayed by the strobe to the right. Press the down arrow to move the area being displayed to the left.

Decimal Point Key – Press the decimal point key to enter a decimal point.

CLEAR NO Key

The **CLEAR NO** key is almost always referred to as either **CLEAR** or **NO** in the text, depending on the context or the message on the display.

- **Numeric Entry** – When you use the numerical keys, pressing **CLEAR NO** clears the entered numbers, restores the original displayed value, and lets you use the up-arrow/down-arrow keys. When you use the up-arrow/down-arrow keys, you can press **CLEAR NO** to stop or cancel the numeric entry.
- **YES/NO Questions** – Press **CLEAR NO** to indicate a No answer. A screen usually appears that lets you modify the unacceptable information.
- **Menu Selection** – Press **CLEAR NO** to go back through the menu and patient data screens. If the first level screen is displayed, you can press **CLEAR NO** to remove the screen and exit the menu system.
- **Screen Display** – Press **CLEAR NO** to display the screens ranked below the current highest-priority screen.

Enter LED – A green LED above the ENTER/YES key that flashes when you are expected to enter a number, answer a Yes/No question, or make a menu selection. The Enter LED flashes whenever you can press **ENTER** in response to a screen on the display.

ENTER YES Key

The **ENTER YES** is almost always referred to as either **ENTER** or **YES** in the text, depending on the context or the message on the display.

- **Numeric Entry** – Press **ENTER YES** to accept a modified entry or to complete a numeric entry.
- **Yes/No Questions** – Press **ENTER YES** to indicate a Yes answer.
- **Menu Selection** – Press **ENTER/YES** to make an explicit menu choice, select a default choice, or leave the previously selected choice unchanged.
- **Restores Screens** – Press **ENTER YES** to restore the display of higher-priority alarm messages or overridden warnings that have been removed by pressing **CLEAR NO**.

Display Keys

The "Flow" keys above the display let you change pump flow rates (when the Spectra system allows you to do so).

"Flow" key	Function
AC	Functions only in Manual mode. When pump flow rates are displayed on the top line of the display, press **AC** to change the AC pump flow rate (in mL per min).
INLET	When pump flow rates are displayed on the top line of the display, press **INLET** to change the inlet pump flow rate (in mL per min).
PLASMA	When pump flow rates are displayed on the top line of the display, press **PLASMA** to change the plasma pump flow rate (in mL/min). Functions only in Manual mode during ELP, AutoPBSC, LRS, LRST, RBCX, and TPE procedures. During RBCX procedures, press **PLASMA** to change the RBC pump flow rate instead of the plasma pump flow rate.
COLLECT/REPLACE	When pump flow rates are displayed on the top line of the display, press **COLLECT/REPLACE** to change the displayed pump flow rate (in mL per min). Functions only in Manual mode during ELP, AutoPBSC, LRS, LRST, RBCX, and TPE procedures.
INLET/AC RATIO	When pump flow rates are displayed on the top line of the display, press **INLET:AC RATIO** to change the ratio of the inlet pump flow rate to the AC pump flow rate (the Inlet:AC ratio).
SPIN RPM	When pump flow rates are displayed on the top line of the display, press **SPIN RPM** to change the centrifuge speed (in revolutions per min). Functions only in Manual mode during ELP, AutoPBSC, LRS, LRST, and RBCX.

The "Volume" keys below the display label the information displayed on the bottom line. If you press **TARGET VALUES** and then press one of the "Volume" keys, you can change the target value associated with that key.

"Volume" key	Function
AC	• During the Run, the current actual accumulated volume of anticoagulant (in mL) used is shown above the AC key. • When the target end results are displayed, press **AC** to display the expected total amount of anticoagulant (in mL) to be used in the procedure.
INLET	Inlet volume is used as a limiting factor for ELP, AutoPBSC, LRS, LRST, TPE, and WBC procedures. • During the Run, the current actual accumulated volumes of whole blood and anticoagulant (in mL) that have been processed are shown above the INLET key. • When the target end results are displayed, press **INLET** to change the target inlet volume (in mL).
PLASMA	Plasma volume is used as a limiting factor for TPE procedures. Plasma can be collected concurrently with platelets and WBCs. • During the Run, the current actual accumulated volume of plasma and anticoagulant (in mL) collected is shown above the PLASMA key. • When the target end results are displayed, press **PLASMA** to change the target plasma volume (in mL). • Press **PLASMA** during the Run to display the current actual accumulated volume of plasma and AC collected. When the target end results are displayed, press **PLASMA** to display the expected total amount of plasma and anticoagulant to be collected.

"Volume" key	Function
COLLECT/REPLACE	Collect volume is used as a limiting factor for ELP, AutoPBSC, LRS, LRST, and WBC procedures. Replace volume is a limiting factor for TPE and RBCX procedures. • During the Run, the current actual accumulated volume is shown above the COLLECT/REPLACE key. This volume represents either: – Amount collected (in mL) for a donor collection or patient depletion procedure. – Amount of replace solution (in mL) used during a TPE or RBCX procedure. • When the target end results are displayed in ELP, AutoPBSC, LRS, and WBC procedures, press **COLLECT/REPLACE** to change the target collect volume (in mL). In TPE and RBCX procedures, press **COLLECT/REPLACE** to change the target replace volume (in mL).
TIME MIN	Run time is used as a limiting factor for procedures. • During the Run, the elapsed procedure time (in minutes) is shown above the TIME MIN key. • When the target end results are displayed, press **TIME MIN** to change the target run time. This key does not function during RBCX procedures.
TARGET VALUES	Press **TARGET VALUES** to toggle back and forth between the target end results and the current actual values on the bottom line of the display. When target end results are shown, "Target" is displayed in the bottom right corner. With the exception of the AC volume, the target end results can be changed by pressing **TARGET VALUES**, pressing the appropriate "Volume" key above the display, then entering the new target value. When the current actual values are displayed, either a numerical value or a procedure abbreviations is shown in the bottom right corner. The numerical value represents the next inlet volume at which a harvest event is due during AutoPBSC procedure. See the list following this table for the procedure abbreviations.

Procedure Abbreviations

- **AuPBSC** – AutoPBSC Procedure
- **BMP** – Bone Marrow Processing Procedure
- **LRS** – Dual-Needle LeukoReduction System Collection Procedure
- **LRST** – Dual-Needle LRS Turbo Collection Procedure
- **MNC** – Mononuclear Cell Collection, MNC Depletion, or MNC Lymphoplasma Exchange Procedures
- **PLTC** – Dual-Needle Extended Life Platelet Collection Procedure
- **PLTD** – Platelet Depletion Procedure
- **PMN** – Polymorphonuclear Cell (Granulocyte) Collection or Depletion Procedure

- **RBCX** – Red Blood Cell Exchange or Deplection Procedure
- **SNLRS** – Single-Needle LeukoReduction System Collection Procedure
- **SNLRST** – Single-Needle LRS Turbo Collection Procedure
- **SNPLTC** – Single-Needle Extended Life Platelet Collection Procedure
- **SNTPE** – Single-Needle Therapeutic Plasma Exchange Procedure
- **TPE** – Dual-Needle Therapeutic Plasma Exchange Procedure

Miscellaneous Keys

Status Lights (located directly above the MUTE key):

- **Green LED** – A steady green LED indicates no alarm or warning conditions are present, all alarms are enabled, and all safety systems are activated. A steady Green LED only occurs during the Run.
- **Warning LED** – A flashing yellow LED indicates warning conditions or signals the start of a Harvest during an AutoPBSC procedure. A steady yellow Warning LED indicates a warning condition has been temporarily overridden or the Spectra system is not in the Run. Some alarms are disabled during Prime and Rinseback.
- **Alarm LED** – A flashing red LED indicates alarm conditions. A steady red Alarm LED light indicates the alarm condition has been temporarily overridden.

MUTE Key – Press to temporarily silence the error and warning alarms. The alarms will stay silent for 2 minutes or until a new, higher-priority alarm occurs.

ACCESS PRESSURE Bar Graph – An LED bar graph that displays access pressure. There are 18 bars, at 25 mm Hg intervals. The top bar represents 25 mm Hg; the bottom bar represents –400 mm Hg. The first yellow bar corresponds to the default warning limit (–200 mm Hg).

UNLOCK COVER Key – Press to unlock the centrifuge cover and door when the centrifuge is completely stopped. The latches will remain open for 20 seconds or until you open the centrifuge cover.

STOP SPIN Key – Press to stop the centrifuge, stop the pumps, put the Spectra system in Pause with the Pause LED flashing, and close the return line valve once the centrifuge has stopped. Press **PAUSE/CONTINUE** to restart the centrifuge and pumps and open the return line valve. When the centrifuge is up to speed, the Spectra system displays the "Centrifuge up to speed. CONTINUE" screen. Press **PAUSE/CONTINUE** again.

Note: If you press **STOP SPIN** during an AutoPBSC Harvest, the Harvest is immediately terminated.

Manual LED – A red LED that lights when the Spectra system is in Manual mode.

MANUAL Key – The Manual key works only during the Run or after Prime when donor/patient data entry is complete. Press **MANUAL** to put the Spectra system in Manual mode, which lets you control the pump flow rates, centrifuge speed, and valve positions. This also lights the Manual LED. Press **MANUAL**

while the Manual LED is on to return the Spectra system to Automatic mode, letting the software control the pump and centrifuge speeds. For more information, see Chapter 6, *Automatic and Manual Mode*.

Note: Any action which places Spectra system in the Manual mode during an LRS or LRST procedure will require lab measurement of the platelet and WBC content of the collected product.

VALVE Key – Lets you move valves independent of the software. See *The VALVE Key* on page 5-16 for more information.

CHANGE MODE Key – Lets you change the Spectra system's mode of operation. The choices include Load Set, Prime, Run, Rinseback, Unload Set, and Diagnostics. See *The CHANGE MODE Key* on page 5-20 for more information.

Menu LED – A green LED above the MENU ON/OFF key that lights when you are using the menu system.

MENU ON/OFF Key – Press this key to enter the menu system. The first set of choices will be displayed and the Menu LED will light. More choices can be viewed by pressing **ENTER**. If no selection is made, the screen will be removed after 30 seconds. You can exit the menu system at any point by pressing **MENU ON/OFF** when the Menu LED is lit. Press **CLEAR** to back out of the menu system one step at a time. For more information, see *The MENU ON/OFF Key* on page 5-10.

Pause LED – A green LED above the PAUSE/CONTINUE key that lights to indicate that the Spectra system is paused and the pumps are stopped. A flashing Pause LED indicates that the pumps can be restarted by pressing **PAUSE/CONTINUE**. A steady Pause LED indicates that an alarm condition must be removed before the pumps can be restarted.

PAUSE/CONTINUE Key – Used in conjunction with the Pause LED as follows:

- Press **PAUSE/CONTINUE** to pause the Spectra system and stop the pumps. The Pause LED lights. If the pumps are stopped for more than 60 seconds, the centrifuge speed will be limited to 1800 rpm to reduce temperature rise in the channel's multi-lumen tubing.
- When the Pause LED is flashing, press **PAUSE/CONTINUE** to restart the pumps and turn off the Pause LED. The centrifuge speed will be increased automatically if it has been reduced to 1800 rpm.
- Certain alarm conditions will cause the Spectra system to Pause itself. You are prompted to clear the alarm (the Pause LED will be on steadily, not flashing) before pressing **PAUSE/CONTINUE**.

Display

The control panel includes a 2-line by 40-character display. Information displayed can be grouped into six general categories:

- State screens,
- Alarm screens,
- Operator information screens,
- VALVE key displays,
- CHANGE MODE key displays, and
- MENU ON/OFF key displays.

State Screens – Indicate the current state of the Spectra system. (A state is defined as one of possibly many individual steps that the Spectra system takes to complete each mode of operation.) The

step the Spectra system is currently performing determines the pump flow rates, centrifuge speed, valve positions, alarms enabled, and screen displayed. The screen either explains what action the Spectra system is performing at that time or prompts you to take a specific action or make a selection from a menu. The current mode of operation or a procedure abbreviation appears in the lower right-hand corner. A list of these abbreviations follows the TARGET VALVES key discussion on page 2-15.

Alarm Screens – identify the source of an alarm and prompt you as to what action to take to clear the alarm condition. When there is more than one alarm, the highest priority alarm screen will be displayed first with an asterisk (*) in the lower right-hand corner. This indicates there are more alarms than the one currently displayed. Press **CLEAR** to temporarily view the lower-priority alarm(s). The highest-priority alarm will reappear after 30 seconds or if you press **ENTER**. For additional information on Spectra alarms and the actions to take in response to those alarms, see Chapter 12, *General Alarms and Troubleshooting* or the alarms and troubleshooting sections of the individual procedures.

Operator Information Screens – provide you information and prompts for conditions that do not involve donor/patient safety. Three of the more common information displays (accompanied by a long beep) relate to making an inappropriate key selection as follows:

- __ __ key is invalid! – The key you pressed will not work at that particular time (e.g., **TARGET VALUES**, **MANUAL**, etc.).
- __ __key – first use MANUAL! – The key you pressed works only during Manual mode (e.g., **AC**, **PLASMA**, etc.).
- __ __key – first use TARGET! – The key you pressed works only when the target end results are displayed (e.g., **INLET**, **TIME MIN**, etc.).

VALVE Key Displays – See *The VALVE Key* on page 5-16.

CHANGE MODE Key Displays – See Chapter 5, *Software Options and Configuration*.

MENU ON/OFF Key Displays – See *The MENU ON/OFF Key* on page 5-10.

Return Flow Controller

The COBE Spectra Return Flow Controller is used only during Single-Needle ELP, LRS, LRST collections and Single-Needle TPE procedures. It has two purposes:

- To hold the Single-Needle bag, which, in turn, holds blood components removed from the donor/patient during the Draw phase of a Single-Needle procedure for return to the donor/patient during the Return phase
- To provide controlled pressure on the Single-Needle bag to produce the desired return flow during the Return phase of a Single-Needle procedure

The meaning of the symbols on the Return Flow Controller's front cover are shown in Figure 2-8 on page 2-21, which is a copy of the permanent label on the Return Flow Controller's back cover.

The explanation of the labels in Figure 2-7 follows:

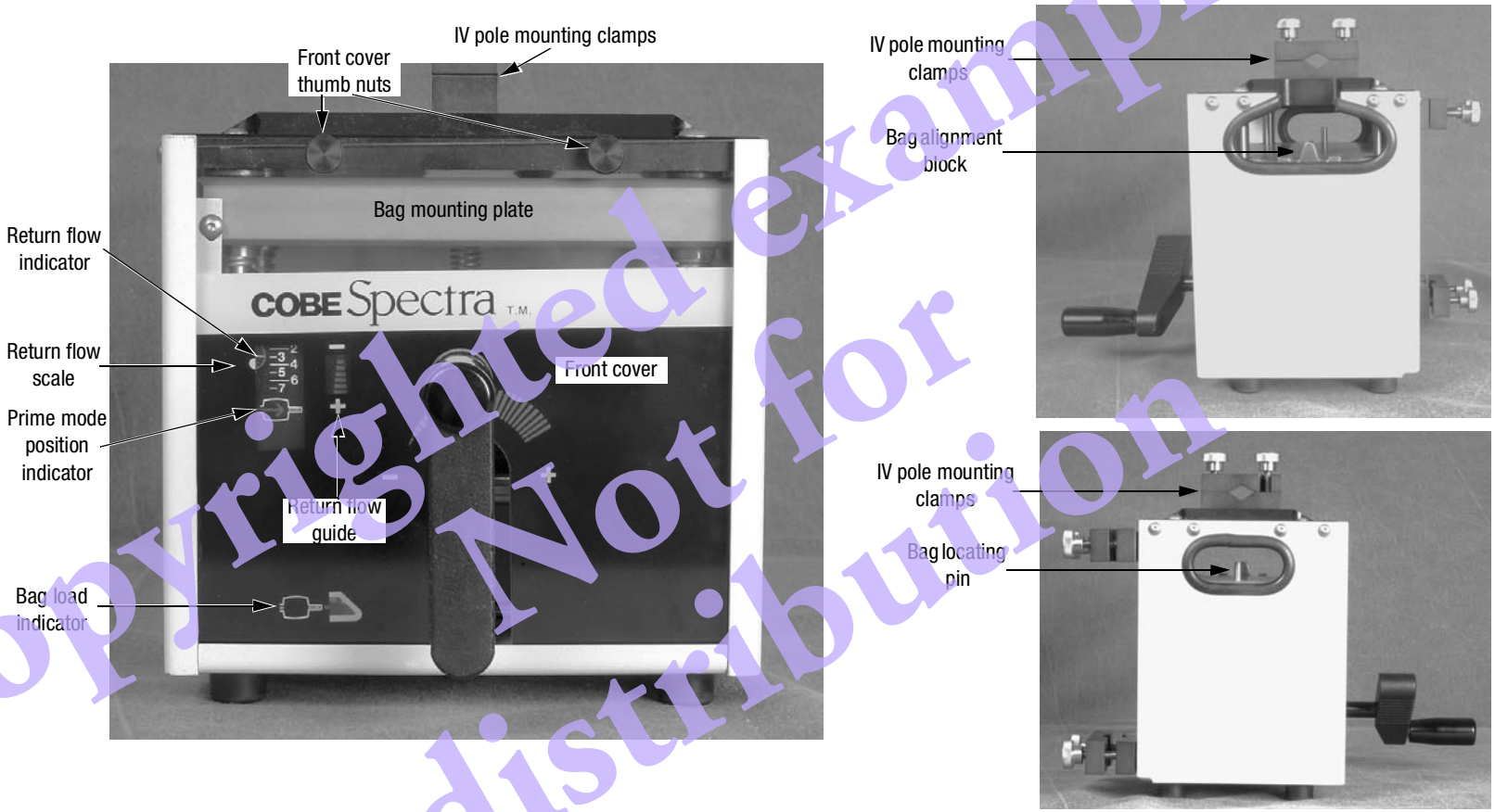

Figure 2-7: Return Flow Controller, front, left and right views

Front Cover – Keep the Return Flow Controller's internal mechanism clean and graphically illustrates operating modes.

Front Cover Thumb Nuts – Used to remove the front cover so the inside of the Return Flow Controller can be cleaned. See *Operator Maintenance of Return Flow Controller* on page 10-1 for instructions on how to do this.

IV Pole Mounting Clamps – Used to attach the Return Flow Controller to the horizontal or vertical segments of the IV pole. (See Figures 3-1 and 3-2 in Chapter 3, *Installing, Moving, and Returning the Spectra System*.) For instructions on how to install the Return Flow Controller on the IV pole, see *Installing the Return Flow Controller* on page 3-3.

Return Flow Indicator – Indicates the current return flow position on the return flow scale.

Return Flow Scale – A numerical scale from 0 to 7 used to set the Return Flow Controller to the appropriate pressure for returning the blood components (withdrawn during a Single-Needle Draw phase) to the donor/patient. On the scale, 0 (zero) is the "low flow" position and 7 is the maximum flow setting. The correct setting is determined by the inlet pump flow rate. A screen shows the appropriate starting position to which to set the scale. See Figure 2-11 for a detailed view of the return flow scale set to 3.

Return Flow Guide – Helps you determine the direction in which to turn the flow controller hand crank. As you turn the crank clockwise to increase the return flow rate, the red triangle in the left return flow guide window widens. As you turn the crank counterclockwise to decrease the return flow rate, the red triangle narrows.

Bag Load Indicator – When the flow control handcrank is at the counterclockwise stop, a red arrow appears in the clear window, indicating that the Return Flow Controller is in the Bag Load position (see Figure 2-9).

Prime Mode Position Indicator – When the flow control handcrank is at the clockwise stop, the red arrow is at the top of the window, indicating that the Return Flow Controller is in Prime position (see Figure 2-10).

Flow Control Handcrank – Turn this to place the Return Flow Controller in the Bag Load and Prime Mode positions and to set the return flow rate (see Figure 2-7).

Bag Mounting Plate – The plate in the top section of Return Flow Controller on which the Single-Needle bag lies after you insert it into the Return Flow Controller.

Bag Locator Pin – The pin on the bag mounting plate over which you place the locator hole in the Single-Needle bag.

Bag Alignment Block – The two Single-Needle bag lines are placed on either side of the center brass triangle. The Single-Needle bag is inserted from this side of the Return Flow Controller.

Caution: The Return Flow Controller is required for Single-Needle procedures. Do not attempt to install (activate) and perform a Single-Needle procedure without a Return Flow Controller and the appropriate disposable tubing set.

Figure 2–8: Return Flow Controller symbols

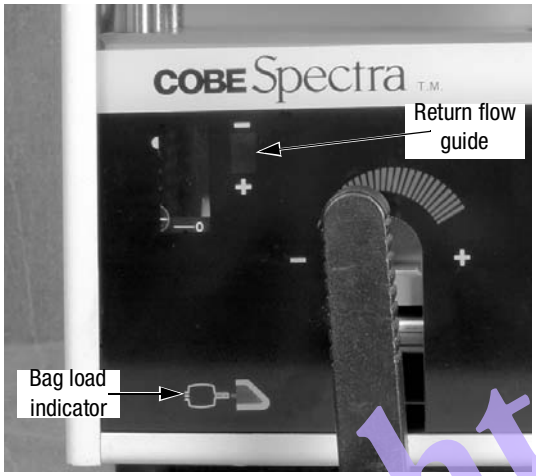

Figure 2-9: Return Flow Controller in Load position

Figure 2-10: Return Flow Controller in Prime position

Figure 2-11: Return Flow Controller set to 3

Disposable Tubing Sets

Each Spectra disposable tubing set includes the separation channel and tubing preconnected for easy installation. The disposable tubing set helps the Spectra system separate whole blood into its major components: erythrocytes (red blood cells), leukocytes (white blood cells), thrombocytes (platelets), and plasma. Each disposable tubing set performs a different separation function; see the individual procedure for more information about the separation processes and disposable tubing set functions. (For more information about and illustrations of each disposable tubing set, go to the Gambro BCT website (**www.gambrobct.com**) or contact a Gambro BCT representative.)

Dual-Needle Extended Life Platelet (ELP™) Disposable Tubing Set – A functionally closed disposable tubing set used either to collect donor platelets for extended storage or for therapeutic platelet depletions. It can also be used to collect plasma concurrently with platelets. This disposable tubing set consists of a dual-stage platelet channel and extended life platelet tubing and is used in Dual-Needle ELP procedures.

Single-Needle Extended Life Platelet (ELP™) Disposable Tubing Set – A functionally closed disposable tubing set used to collect platelets for extended storage. It can also be used to collect plasma concurrently with platelets. This disposable tubing set consists of a dual-stage platelet channel and extended life platelet tubing and is used in Single-Needle ELP procedures.

Dual-Needle Extended Life Platelet Disposable Tubing Set with LRS™ Chamber – A functionally closed disposable tubing set used either to collect leukoreduced single-donor platelets for extended storage or for therapeutic platelet depletions. It can also be used to collect plasma concurrently with platelets. This disposable tubing set consists of a dual-stage platelet channel, LRS chamber, and extended life platelet tubing and is used in Dual-Needle LRS and LRS Turbo procedures.

Single-Needle Extended Life Platelet Disposable Tubing Set with LRS™ Chamber – A functionally closed disposable tubing set used to collect leukoreduced single-donor platelets for extended storage. It can also be used to collect plasma concurrently with platelets. This disposable tubing set consists of a dual-stage platelet channel, LRS chamber, and extended life platelet tubing and is used in Single-Needle LRS and LRS Turbo procedures.

AutoPBSC Disposable Tubing Set – A functionally closed disposable tubing set used to harvest mononuclear cells, which includes peripheral blood stem cells, and also harvest plasma from individuals. This disposable tubing set consists of a dual-stage AutoPBSC channel and AutoPBSC tubing and is used in AutoPBSC procedures.

Therapeutic Plasma Exchange (TPE) Disposable Tubing Set – used to remove plasma from patients requiring therapeutic plasma exchange. This disposable tubing set consists of a single-stage TPE channel and TPE tubing, and can be used for either Dual-Needle TPE procedures or, when used with the Single-Needle Set (see below), Single-Needle TPE procedures.

Single-Needle Set – Used to convert a TPE disposable tubing set for a Single-Needle TPE procedure.

Red Blood Cell Exchange (RBCX) Disposable Tubing Set – Used to remove RBCs from patients requiring red blood cell exchange or erythrocytopheresis. This disposable tubing set consists of a single-stage RBCX channel and tubing and is used in RBCX procedures.

White Blood Cell (WBC) Disposable Tubing Set – Used to remove selected white blood cells from individuals or from bone marrow and to perform lymphoplasma exchange procedures. This disposable tubing set consists of a single-stage WBC channel and tubing and is used in MNC, PMN, BMP, WBC Depletion and LPE procedures.

Bone Marrow Processing (BMP) Set – Used with the WBC disposable tubing set to remove mononuclear cells from a harvested bone marrow product. The set consists of two bags from which to draw and return the bone marrow during each processing cycle, and an access and return line to attach to the access and return line of the WBC disposable tubing set.

Accessory Platelet Storage Bag – A functionally closed accessory bag used to store platelets. The bag consists of a platelet storage bag identical to those found on ELP disposable tubing sets, 46 cm (18 inches) of tubing, and a capped male luer for venting during sterilization.

Functional Description

Separation

The Spectra system uses a centrifugal method to separate whole blood into its major components: erythrocytes (red blood cells), leukocytes (white blood cells, including peripheral blood stem cells), thrombocytes (platelets), and plasma. Whole blood is drawn from a donor or patient, anticoagulated, pumped into the centrifuge, and separated into components. The component removed is collected and the other components are returned to the donor/patient. In TPE and RBCX procedures, appropriate replacement fluid is combined with the returned components.

During the procedure, anticoagulated whole blood is pumped into the channel while the channel (in the filler) is rotating clockwise in the centrifuge. This causes the highest density component (red blood cells) to go to the outer wall of the channel, with layers of components progressing toward the inner wall where the lowest density component (plasma) gravitates. Several outlet tubes are located in the channel. Flow from these tubes collects or returns various components to the donor/patient, depending on the procedure performed.

The inlet and collection chambers are separate in the channel. The inlet tube delivers anticoagulated whole blood to the channel. In the TPE and RBCX channels, there are two tubes for removing components. The tube for removing cellular components extends (inside the channel) to the outer wall of the channel, and the tube for removing plasma extends to the inner wall.

In a platelet/AutoPBSC or WBC channel, there are four tubes connected to appropriate areas of the channel. The red blood cell tube extends to the outer wall of the channel, the plasma tube extends only to the inner wall, and the collect and interface control tubes extend to the red blood cell/plasma interface. The interface is the line (where the separated white blood cells or platelets are located) between the separated packed red blood cells and the plasma.

The control tube, along with the relationship between RBC pump and plasma pump flow rates, establishes and maintains the level of the RBC/plasma interface so that platelets or white blood cells can be collected at the interface. The relationship between the centrifuge speed and specific gravity of platelets and white blood cells determines which cells will collect on the interface. Red blood cells and plasma are collected directly from their respective tubes.

Saturated Fluidized Particle Bed Separation in LRS/LRS Turbo Procedures

The collect pump directs platelet-rich plasma and the few remaining white blood cells from the second stage of the channel into the LRS chamber. White blood cells are separated from platelets based on the fluid dynamics of the conical separation chamber, the sedimentation velocity of the platelets and white blood cells, and the flow rate through the separation chamber.

These dynamics result in an advancing platelet bed, which, upon saturation, traps white blood cells in lower levels of the LRS chamber. Platelets exit to the collect storage bags.

Fluid Flows (General)

Fluid flows are controlled by the four variable-speed peristaltic pumps on the front panel (Figure 2-5).

- The AC pump controls the flow of anticoagulant from the AC container to the inlet line.
- The inlet pump controls the flow of whole blood plus anticoagulant from the donor/patient access into the centrifuge.
- The Plasma/RBC pump function depends upon the apheresis procedure:
  - During ELP, AutoPBSC, LRS, LRST, and WBC procedures, it either recombines the plasma separated by the centrifuge with cellular components for return to the donor or patient or pumps plasma to the collection bag.
  - During ELP, AutoPBSC, LRS, LRST, and WBC procedures involving concurrent plasma collection, it directs the plasma separated by the centrifuge to a plasma collection bag(s).
  - During TPE procedures, it controls the flow of separated plasma from the centrifuge to the plasma bag.
  - During RBCX procedures, it controls the flow of separated RBCs from the centrifuge to the RBC bag.
- The collect/replace pump controls the flow of components being removed or replaced.
  - During ELP, AutoPBSC, LRS, and WBC procedures, it pumps the platelets or peripheral blood stem cells being collected and WBCs being removed to a collection bag(s).
  - During TPE and RBCX procedures, it pumps the appropriate replacement fluid.

During Dual-Needle procedures, when you use the Spectra keyboard to change a pump flow rate, you are entering the actual pump flow rate for that pump for the current procedure. An exception occurs during platelet collection procedures when the high flow configuration is set to "On." During the portion of such high-flow procedures when the RBC/plasma interface is being established, the inlet pump flow rate is limited to 45 mL/min. During all AutoPBSC procedures, regardless of the High Flow Configuration, the inlet flow is limited to 45 and then 65 mL/min during the first portion of the procedure while the Spectra system establishes a stable interface. For more information on the high blood flow configuration, see *Configuring the High Flow (ELP Procedures)* on page 5-6.

Note: During ELP, LRS, LRST, TPE, and AutoPBSC procedures, only the inlet pump flow rate can be changed.

During Single-Needle procedures, when you change a pump flow rate, you are entering the average pump flow rate for that pump for the current procedure. At any time during a procedure, the instantaneous pump flow rate for a specific pump can be faster or

slower than the average pump flow rate. The average pump flow rate is the average of the pump flow rates during the Draw and Return phases.

When you change a pump flow rate during a Single-Needle procedure, the Spectra system occassionally may alert you that the the pump flow rate you entered was too high. The Spectra system does this by either displaying an alarm or lowering the pump flow rate you entered. It will not always be obvious why the entered pump flow rate was too high because the limitations placed on Single-Needle pump flow rates are more complex than those placed on Dual-Needle pump flow rates.

For example, for Dual-Needle procedures, pump flow rates are limited only by the AC infusion rate and donor access characteristics, such as their venous blood flow. For Single-Needle procedures, the upper limit on pump flow rates can depend on a variety of factors:

- The Spectra system limits average inlet pump flow rates to 65 mL/min for Single-Needle ELP and LRS procedures and to 60 mL/min for Single-Needle TPE procedures. The limit for LRST procedures in 70 mL/min.
- The Return Flow Controller's maximum return pressure of 450 mm Hg for Single-Needle ELP, LRS and LRST and 400 mm Hg for Single-Needle TPE procedures limits the return flow rate during Single-Needle procedures.
- The Single-Needle Draw phase's instantaneous inlet pump flow rate is limited to 100 mL/min for Single-Needle ELP and LRS and 150 mL/min for Single-Needle TPE procedures.

For more information on Single-Needle flow control, see *Single-Needle Flow Control* on page 6-6.

The upper limits on the average inlet pump flow rate of 65 mL/min for Single-Needle ELP and LRS procedures, 60 mL/min for Single-Needle TPE procedures, and 70 mL/min for LRST procedures mean that, under certain circumstances, Single-Needle procedures can take longer than comparable Dual-Needle procedures to process the same amount of blood. As Dual-Needle inlet pump flow rates increase, however, to above the upper limits for Single-Needle procedures, the comparable Single-Needle process time will increase additionally based on the following ratio:

$$Q_{in}\ (\text{Dual-Needle})/Q_{in\_avg}\ (\text{Single-Needle maximum})$$

For example, if a Dual-Needle ELP or LRS collection procedure were run at an inlet pump flow rate of 80 mL/min, a comparable Single-Needle ELP or LRS collection procedure would take an additional 20% longer to process the same amount of blood:

$$80/65 = 1.23$$

Modes of Operation

During each procedure, the Spectra system cycles through five distinct modes of operation. These modes are, in order: Load set, Prime, Run, Rinseback, Unload Set. A sixth mode, Diagnostics, usually occurs at the end of Prime, but you can also select it at other times. See *The CHANGE MODE Key* on page 5-20 for more information about modes, states (steps within modes), and how you can change the mode if necessary.

Load Set

During Load Set, the pump cartridges are retracted and the tubing is loaded into the pumps.

Prime

During Prime, the AC line fills with anticoagulant and the disposable tubing set fills with saline as air is removed from the set. Pumps turn and valves open and close to test the function and integrity of the system.

Run

During the Run, the system automatically operates the pumps and centrifuge at appropriate speeds and controls valve positions to perform the procedure you selected according to configured parameters. The system monitors itself during the procedures and, if necessary, generates alarms which pause the system and alert you as to what may be wrong (see Chapter 12, *General Alarms and Troubleshooting*, for more information).

Rinseback

Once the procedure has reached the chosen endpoint, the system prompts you to disconnect the access line and open the access saline line. The disposable tubing set is flushed with saline to return red blood cells to the donor/patient.

Unload Set

Once rinseback is complete and the donor/patient is disconnected, the final Run values are displayed and you are prompted to unload the pumps. The inlet pump turns to verify that the donor/patient is disconnected. After successful completion of the donor disconnect test, the pumps are unloaded.

Note: Once the pumps are unloaded, data from the procedure is no longer available.

Diagnostics

After a disposable set is loaded and primed, the operator is given an option to complete alarm tests. Press **CHANGE MODE**, then press 6 to select "Diagnosics," to perform the alarm test again (see Chapter 7, *Alarm Tests*, for more information).

Anticoagulation

Anticoagulation is necessary to prevent coagulation in the extracorporeal circuit. It also establishes a pH and ionized calcium environment that prevents cell clumping during ELP, AutoPBSC, LRS, and LRST procedures. See Chapter 8, *Anticoagulation*, for a thorough discussion of anticoagulation during Spectra system procedures.

Automatic and Manual Mode

The Spectra system can operate in Automatic or Manual mode. The system normally operates in Automatic mode, but you can put it in Manual mode for more control. For additional information on the Automatic and Manual modes of operation, see Chapter 6, *Automatic and Manual Mode*.