SECTION 1 – INTRODUCTION

INTRODUCTION

The *COBE Spectra Apheresis System Operator's Manual* is intended for the person who will be operating the COBE Spectra™ Apheresis System. The recommended procedures in this *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 *Manual* before attempting to use the Spectra system.

SYSTEM DESCRIPTION

The Spectra Apheresis System is intended to separate and collect blood components from both donors and patients. From donors, blood products are collected for transfusion to patients. If desired, plasma can be collected concurrently with platelets. The plasma thus collected is available for use as plasma or fresh frozen plasma. Alternatively, it may be used as source plasma for further processing into Factor VIII and Factor IX concentrates.

The Spectra system with Version 5.1 LRS™ (LeukoReduction System) software 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 sufficient total blood volumes. This provides the additional advantage of keeping some HLA-matched donors, such as family members of cancer patients, from having to undergo as many apheresis procedures.

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, and 6.0) can be used to perform therapeutic plasma exchange on patients with autoimmune diseases or for patients about to undergo a transplant operation. It can be used to perform red blood cell exchange on patients with hematological disorders such as sickle cell anemia and thalassemia, for which packed red blood cells would typically be used as the replacement fluid, and on patients with polycythemia or hemochromatosis, for which normal saline or albumin would typically be used as the replacement fluid. The system can also be used to perform therapeutic platelet depletions from patients with thrombocytosis.

The Spectra system (Version 6.0) can be used to harvest peripheral blood stem cells (PBSC) contained in the mononuclear cell layer after mobilization of stem cells into the peripheral circulation of autologous patients and allogeneic donors. The Spectra system offers an automated PBSC collection cycle and low volume PBSC collections. Plasma can be collected concurrently with PBSCs for use in cell cryopreservation.

The Spectra system (Versions 4.7, 5.1, and 6.0) can also be used for mononuclear and granulocyte (polymorphonuclear) white cell harvests from individuals and bone marrow.

Spectra platelet collection and plasma exchange procedures can be performed in either the Dual-Needle mode (one access needle and one return needle) or Single-Needle mode (one access/return needle). Because of the design of the Single-Needle procedures, both the extracorporeal volume and 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 consists of disposables (preconnected separation channel and blood tubing) and the Spectra Apheresis System. The system components include the following:

- Spectra Disposables – Each consists of a separation channel that spins in the centrifuge to separate blood into its components and blood tubing that routes blood and replacement fluids through the system.

- The Spectra Apheresis System – is an automated centrifuge-based blood cell separator that provides the functions necessary to control and monitor the extracorporeal circuit during apheresis procedures.

The system's automated procedures set and maintain the red blood cell/plasma interface for you by defining the pump flow rates, run time, and centrifuge speed. This automation is enhanced by the user-friendly communications display and associated keyboard. The display and keyboard allow two-way communication between you and the system. This ensures complete donor/patient safety and still allows you freedom to control the procedure. Other Spectra ease-of-use features include the following: rapid tubing installation, automatic prime, predictable collection and exchange results, clear alarm information, and automatic rinseback.

Figure 1-1 is an overall exterior view of the Spectra Apheresis System without the disposables or flow path overlay.

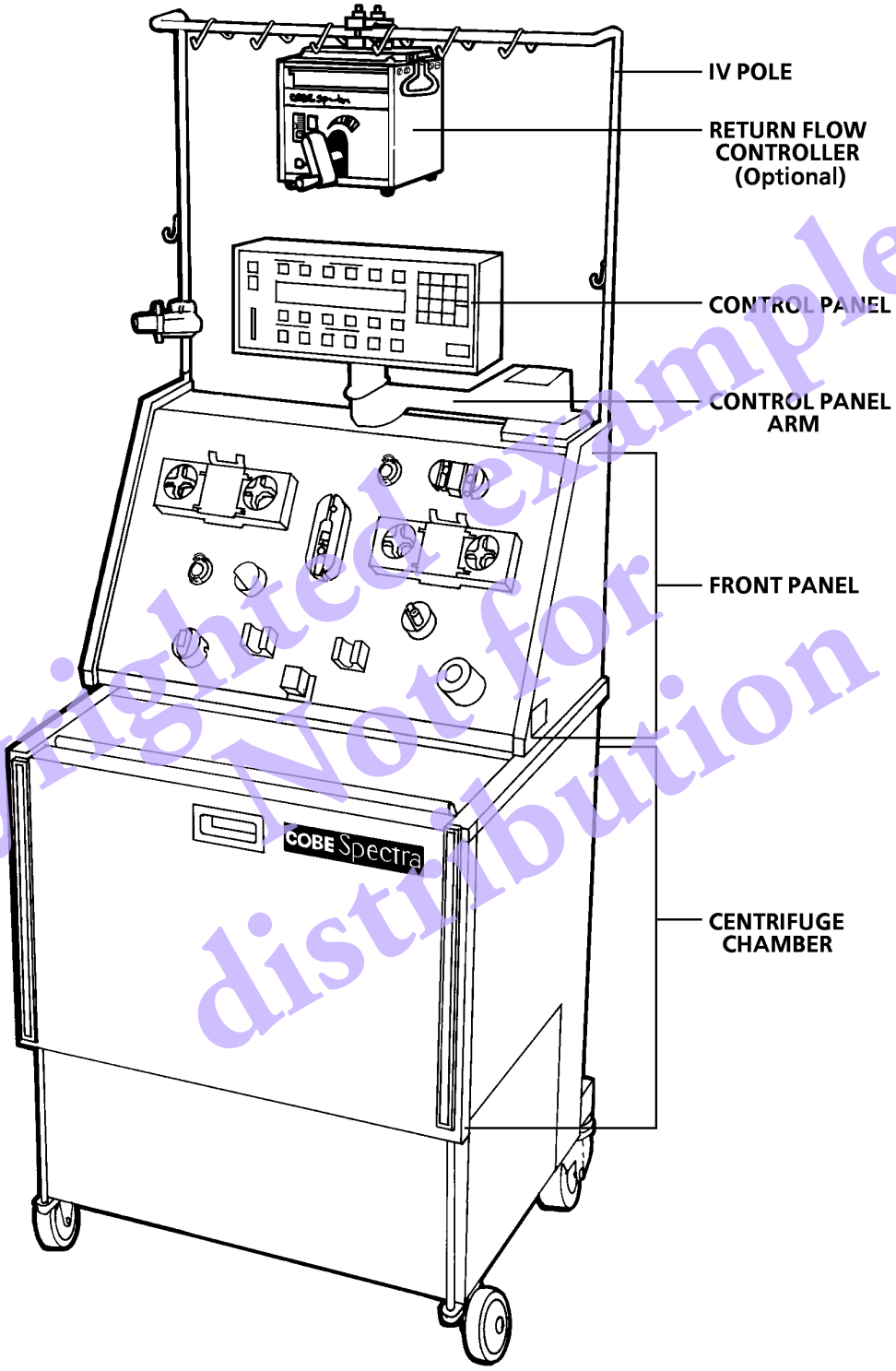

Figure 1-1. Spectra Apheresis System Without Disposables or Flow Path Overlay Attached

DISPOSABLES AND ACCESSORY SETS

Each Spectra disposable is composed of the separation channel and blood tubing that are preconnected for easy installation. Each disposable separates whole blood into its major components: erythrocytes (red cells), leukocytes (white cells), thrombocytes (platelets), and plasma. However, each disposable carries out a different separation function, as follows:

5 **Dual-Needle Extended Life Platelet Set (ELP™ Set)** – is a functionally closed set used either to collect donor platelets for storage up to 5 days or for therapeutic platelet depletions. If desired, it can also be used to collect plasma concurrently with platelets. This set consists of a dual-stage platelet channel and extended life platelet blood tubing and is for use with Dual-Needle procedures.

- **Dual-Stage Platelet Channel** – collects platelets and, if desired, plasma with low cellular contamination. This is done in two stages: first, it separates platelets and plasma from red and white cells; second, it concentrates platelets by reducing plasma volume.

- **Extended Life Platelet Tubing** – collects platelets for extended storage and, if desired, plasma through a functionally closed circuit consisting of tubing, access needle, return needle, platelet collect bags, plasma collect bag, and filters (sterile barriers used on incoming fluid lines). This disposable is for Dual-Needle operations: one donor/patient access point and one donor/patient return connection.

6 **Single-Needle Extended Life Platelet Set (ELP™ Single-Needle Set) –** is a functionally closed set used to collect platelets for storage up to 5 days. If desired, it can also be used to collect plasma concurrently with platelets. This set consists of a dual-stage platelet channel and extended life platelet blood tubing and is for use with Single-Needle procedures.

- **Dual-Stage Platelet Channel** – collects platelets and, if desired, plasma with low cellular contamination. This is done in two stages: first, it separates platelets and plasma from red cells and white cells; then it concentrates platelets by reducing plasma volume.

- **Extended-Life Platelet Tubing** – collects platelets for extended storage and, if desired, plasma through a functionally closed circuit consisting of tubing, access/return needle, platelet collect bags, plasma collect bag, and filters (sterile barriers used on incoming fluid lines.) This disposable is for Single-Needle operations: one access/return donor/patient connection.

7 **Dual-Needle Extended Life Platelet Set with LRS™ Chamber (LRS™ Set)** – is a functionally closed set used either to collect single donor platelets for storage up to 5 days or for therapeutic platelet depletions. If desired, it can also be used to collect plasma concurrently with platelets. This set consists of a dual-stage platelet channel, LRS Chamber, and extended life platelet blood tubing. This set is for use with Dual-Needle LRS procedures.

- **Dual-Stage Platelet Channel** – collects platelets and, if desired, plasma with low cellular contamination. This is done in two stages: first, it separates platelets and plasma from red and white cells; second, it concentrates platelets by reducing plasma volume.

- **LRS™ Chamber** – performs the final separation of leukocytes from platelets prior to transport of the platelet component from the LRS Chamber into the collect storage bag.

- **Extended Life Platelet Tubing** – collects platelets for extended storage and, if desired, plasma through a functionally closed circuit consisting of tubing, access needle, return needle, platelet collect bags, plasma collect bag, and filters (sterile barriers used on incoming fluid lines). This disposable is for Dual-Needle operations: one donor/patient access point and one donor/patient return connection.

8 **Automated Peripheral Blood Stem Cell Set (AutoPBSC Set) –** is used to harvest the mononuclear cell layer which contains peripheral blood stem cells and also harvest plasma from individuals. This set consists of a dual-stage channel and AutoPBSC blood tubing.

- **Dual-Stage Channel –** separates mononuclear cell populations from red cells, platelets, and plasma.

- **AutoPBSC Tubing –** collects the mononuclear cells and returns the rest of the blood back to the donor/patient. The AutoPBSC tubing set collects mononuclear cells through a functionally closed circuit consisting of tubing, access needle, return needle, mononuclear cell collect bag, plasma collect bag, and filters (sterile barriers used on incoming fluid lines).

9 **Single-Needle Extended Life Platelet Set with LRS™ Chamber (LRS™ Single-Needle Set) –** is a functionally closed set used to collect single donor platelets for storage up to 5 days. If desired, it can also be used to collect plasma concurrently with platelets. This set consists of a dual-stage platelet channel and extended life platelet blood tubing and is for use with Single-Needle procedures.

- **Dual-Stage Platelet Channel** – collects platelets and, if desired, plasma with low cellular contamination. This is done in two stages: first, it separates platelets and plasma from red cells and white cells; then it concentrates platelets by reducing plasma volume.

- **LRS™ Chamber** – performs the final separation of leukocytes from platelets prior to transport of the platelet component from the LRS Chamber into the collect storage bag.

- **Extended-Life Platelet Tubing** – collects platelets for extended storage and, if desired, plasma through a functionally closed circuit consisting of tubing, access/return needle, platelet collect bags, plasma collect bag, and filters (sterile barriers used on incoming fluid lines.) This disposable is for Single-Needle operations: one access/return donor/patient connection.

10 **Therapeutic Plasma Exchange Set (TPE Set)** – is used to remove plasma from patients requiring therapeutic plasma exchange. This set consists of a single-stage TPE channel and TPE blood tubing. It can be used for either Dual-Needle or, when used with the Single-Needle Set (see No. 6 below), Single-Needle procedures.

- **Single-Stage TPE Channel** – separates plasma from the cellular components.

- **TPE Tubing** – transports blood for therapeutic plasma exchange procedures.

11 **Red Blood Cell Exchange Set (RBCX Set)** – is used to remove red blood cells from patients requiring red blood cell exchange or erythrocytopheresis. This set consists of a single-stage RBCX channel and RBCX blood tubing.

- **Single-Stage RBCX Channel** – separates cellular components from plasma.

- **RBCX Tubing** – transports blood for red blood cell exchange procedures.

12 **White Blood Cell Set (WBC Set) –** is used to remove selected populations of white cells from individuals or from bone marrow and is also used to perform lymphoplasma exchange procedures. This set consists of a single-stage WBC channel and WBC blood tubing.

- **Single-Stage WBC Channel** – separates mononuclear or polymorphonuclear granulocyte white cell populations from red cells, platelets, and plasma.

- **WBC Tubing –** transports blood to remove white cells.

13 **Single-Needle Set (Single-Needle Set) –** is used to convert TPE disposables to Single-Needle operation.

- **Single-Needle Bag –** during draw phase of Single-Needle procedures, holds blood components to be returned to donor/patient during return phase. The bag is placed in the Single-Needle Return Flow Controller. (See Figure 1-21.)

- **"Y" Connector –** used to connect access and return lines of a TPE disposable to one donor/patient access/return needle so the set can be used for Single-Needle procedures.

14 **Bone Marrow Processing Set (BMP Set) –** is used in conjunction with the COBE Spectra WBC Set to remove selected populations (mononuclear cells) of white blood cells from harvested bone marrow product. The set consists of two bags from which to draw and return the bone marrow during each processing cycle. There is an access and return line on the set to attach to the access and return line of the COBE Spectra WBC Set.

15 **Accessory Platelet Storage Bag –** is a functionally closed accessory bag used to store platelets for up to 5 days. The product consists of a platelet storage bag identical to those found on Spectra ELP sets, 46 centimeters of tubing (18 inches) and a capped male luer for venting during sterilization.

16 **Two Bag Platelet Storage Set –** is intended for use with the COBE Spectra ELP, ELP with LRS Chamber, SN ELP, and SN ELP with LRS Chamber sets to aliquot and store collected platelets for up to 5 days. The product consists of two platelet storage bags identical to those found on Spectra ELP sets, 45.7 centimeters (18 inches) of tubing and a capped male luer for venting during sterilization.

The components of these eight Spectra disposables, the Single-Needle Set, the Bone Marrow Processing Set, the Accessory Platelet Storage Bag, and the Two Bag Platelet Storage Set are described in greater detail on the following pages.

DUAL-STAGE PLATELET/AutoPBSC CHANNEL (See Figure 1-2)

The dual-stage platelet/AutoPBSC channel is used for platelet collections and depletions or peripheral blood stem cell collections, and if desired, concurrent plasma collection. Anticoagulated whole blood enters the first stage of the channel through the inlet tube. In the first stage, the red blood cells (RBC) and white blood cells (WBC) are separated from the platelet-rich plasma.

In a platelet procedure, the red cells and white cells exit the channel through the RBC tube (connected upstream to the control tube). Platelet-rich plasma flows over the dam into the second stage. The platelets are concentrated in the plasma in the second stage and exit through the collect tube. The remaining plasma flows around the channel to the plasma tube.

In an AutoPBSC procedure, white blood cells accumulate above the layer of red blood cells. Periodically, the software causes a harvest, forcing the mononuclear cells over the dam into the second stage. These cells exit through the collect tube and are routed to the PBSC collect bag.

If a specific volume of plasma is to be concurrently collected, that volume is routed to the plasma collect bag. A small volume of plasma and red cells flows to the control tube to provide the interface control mechanism. Control is maintained by balancing the pressure drops between the RBC and control tubes in conjunction with the density and viscosity of packed red cells and plasma.

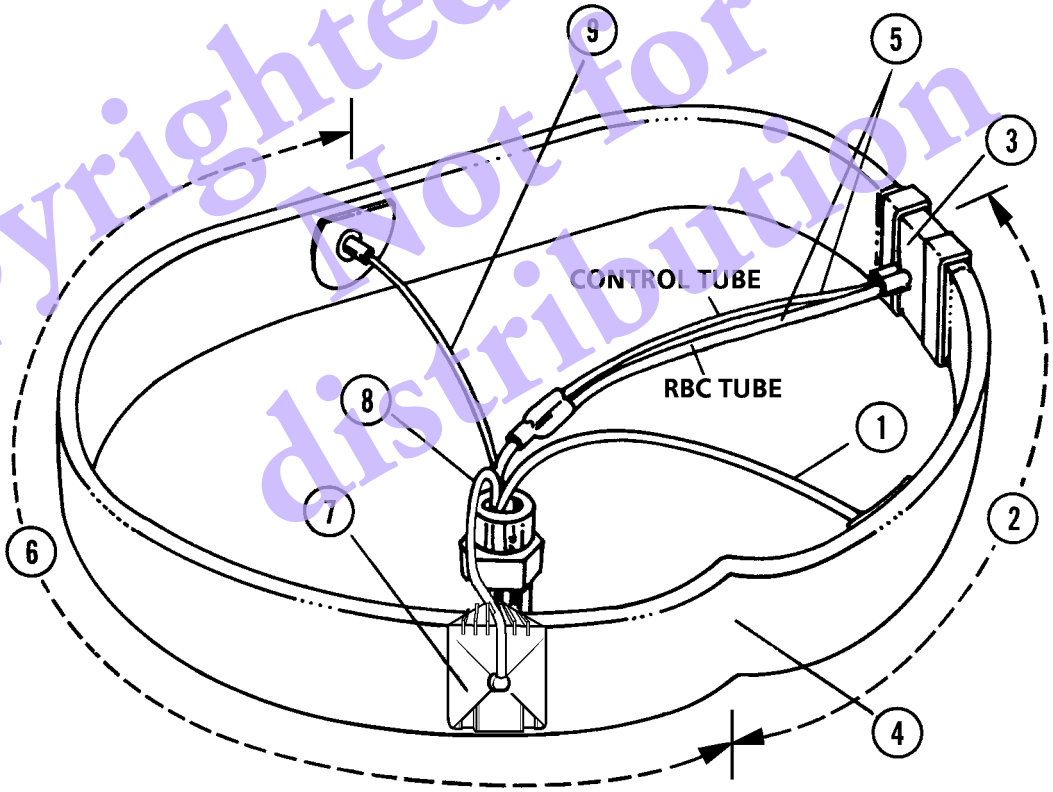

Figure 1-2. Dual-Stage Platelet Channels

1 **Inlet Tube (red plastic)** – where anticoagulated whole blood enters the channel.

2 **First Stage** – red cells and white cells are separated from platelet-rich plasma in this area of the channel between the control chamber (**3**) and the second stage (**6**).

3 **Control Chamber** – maintains the interface between the first and second stages.

4 **Dam** – separation point between the first (**2**) and second (**6**) stages. During an AutoPBSC procedure, mononuclear cells separate from red blood cells and form a layer of cells just beneath the dam in the first stage (**2**) of the channel.

5 **Two Exit Tubes** – are joined into one tube near the centrifuge collar (see Centrifuge Loop in the **Blood Tubing** description):

   a. Red blood cell tube (clear plastic) – with the larger diameter, where red cells (and white cells during an ELP procedure) exit the channel for return to donor/patient.

   b. Control tube – with the smaller diameter, controls the position of the interface.

6 **Second Stage** – increased centrifugal forces in this area of the channel cause platelets to separate from plasma during an ELP procedure. During an AutoPBSC Harvest Phase, accumulated mononuclear cells are forced over the dam (4) into this stage where they can be harvested.

7 **Platelet Collection Chamber** – where platelets are concentrated before exiting the channel during an ELP procedure.

8 **Collect Tube (clear plastic)** – where platelet concentrate exits the channel for the collect bags. In AutoPBSC procedures, where accumulated mononuclear cells exit the channel during a Harvest Phase.

9 **Plasma Tube (yellow plastic)** – where plasma exits the channel for the plasma bag or to be mixed with red blood cells prior to return to the donor/patient.

DUAL-STAGE PLATELET FILLER WITH LRS CHAMBER BRACKET (See Figure 1-3)

The dual-stage channel with LRS Chamber is used for platelet collections to obtain leukocyte (white blood cell) contamination levels below 1 x 10^6 without post-collection leukoreduction, and if desired, concurrent plasma collection. Anticoagulated whole blood enters the first stage of the channel through the inlet tube. In the first stage, the red blood cells (RBC) and white blood cells (WBC) are separated from the platelet-rich plasma. The red cells and white cells exit the channel through the RBC tube (connected upstream to the control tube). Platelet-rich plasma and a few remaining leukocytes flow over the dam into the second stage. The platelets and the remaining leukocytes are concentrated in the plasma in the second stage. They are then directed into the LRS Chamber where final leukocyte removal takes place. The leukoreduced platelets then exit through the collect tube. The remaining plasma flows around the channel to the plasma tube. If a specific volume of plasma is to be concurrently collected, that volume is routed to the plasma collect bag. A small volume of plasma and red cells flows to the control tube to provide the interface control mechanism. Control is maintained by balancing the pressure drops between the RBC and control tubes in conjunction with the density and viscosity of packed red cells and plasma.

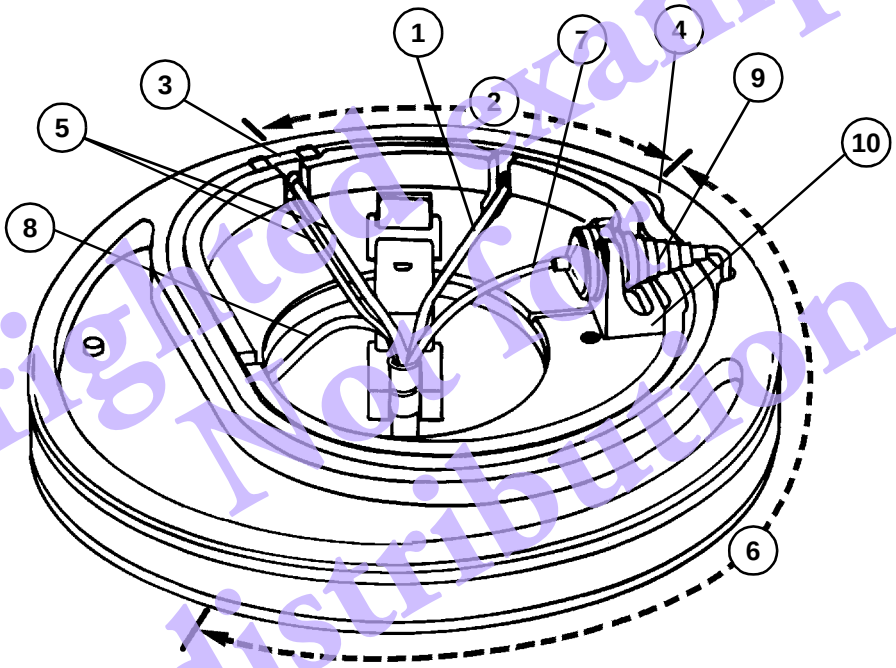

Figure 1-3. Dual-Stage Platelet Filler with LRS Chamber Bracket

1 **Inlet Tube (red plastic)** – where anticoagulated whole blood enters the channel.

2 **First Stage** – red cells and white cells are separated from platelet-rich plasma in this area of the channel between the control chamber (**3**) and the second stage (**6**).

3 **Control Chamber** – maintains the interface between the first and second stages.

4 **Dam** – separation point between the first (**2**) and second (**6**) stages.

5 **Two Exit Tubes** – are joined into one tube near the centrifuge collar (see Centrifuge Loop in the **Blood Tubing** description):

   a. Red blood cell tube (clear plastic) – with the larger diameter, where red cells and white cells exit the channel for return to donor/patient.

   b. Control tube – with the smaller diameter, controls the position of the interface.

6 **Second Stage** – increased centrifugal forces in this area of the channel cause platelets to separate from plasma.

7 **Collect Tube (clear plastic)** – where platelet concentrate exits the channel for the collect bags.

8 **Plasma Tube (yellow plastic)** – where plasma exits the channel for the plasma bag or to be mixed with red blood cells prior to return to the donor/patient.

9 **LRS Chamber** – where white blood cells are separated from platelet-rich plasma.

10 **LRS Chamber Bracket** – holds LRS Chamber.

SINGLE-STAGE TPE CHANNEL (See Figure 1-4)

The single-stage TPE channel is used for therapeutic plasma exchange procedures. Anticoagulated whole blood enters the inlet chamber through the inlet tube. As it flows through the channel, all the cellular components settle to the outside with the plasma on the inside. Most of the plasma is withdrawn through the plasma out tube, and all the cellular components exit through the RBC return tube. The red cell/plasma interface is maintained in this channel by withdrawing a slightly smaller amount of plasma through the plasma out tube than the total plasma volume (within the anticoagulated whole blood) entering the channel. The extra plasma then holds the red cell interface out at the RBC return port.

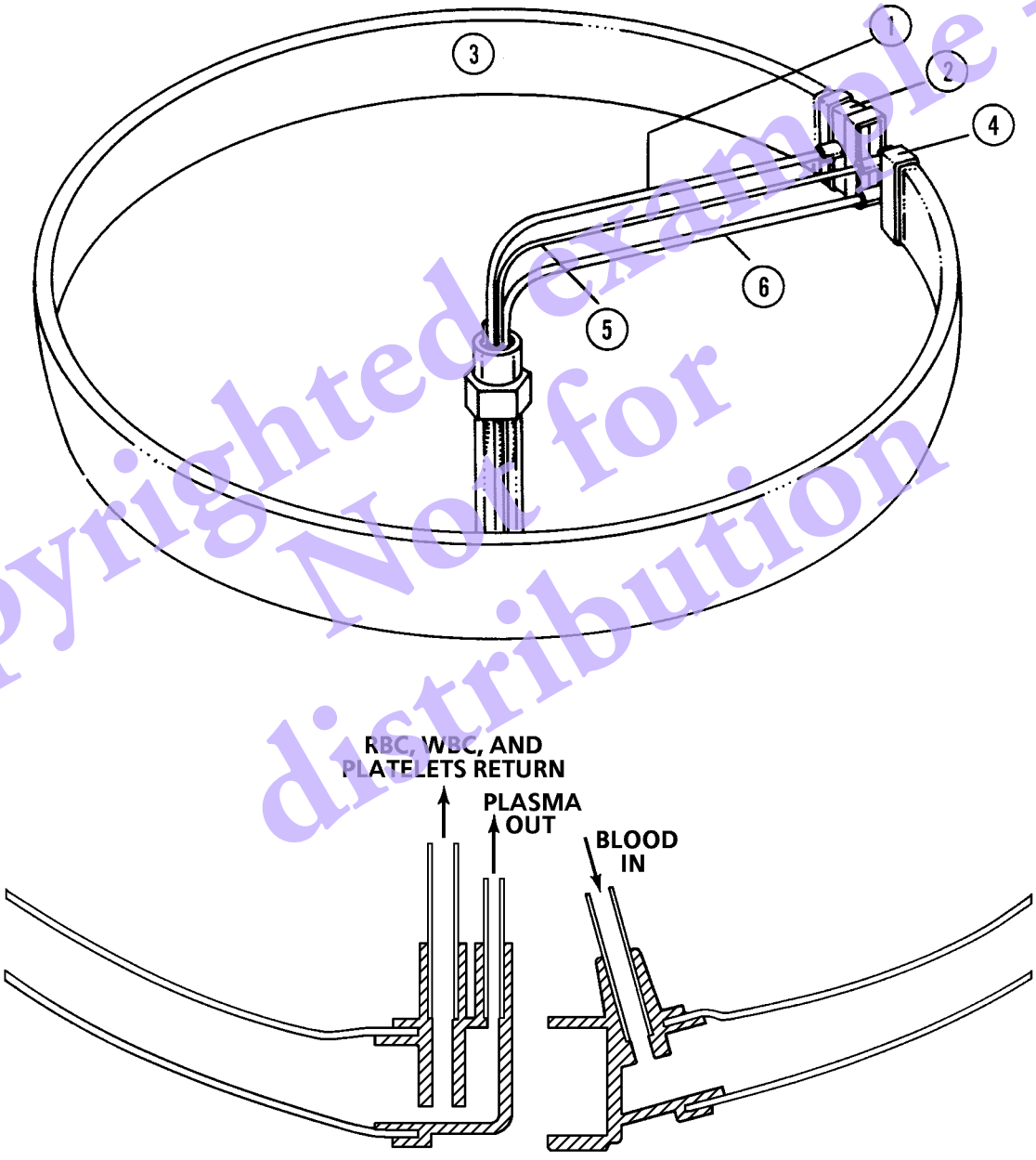

Figure 1-4. Single-Stage TPE Channel

1 **Inlet Tube (red plastic)** – where anticoagulated whole blood enters the inlet chamber (**2**).

2 **Inlet Chamber** – where anticoagulated whole blood enters the channel (**3**).

3 **Channel** – where centrifugal force and the differences among the specific gravities of the blood components cause plasma to separate from whole blood.

4 **Collection Chamber** – contains the exit tubes (**5** and **6**).

5 **Plasma Out Tube (yellow plastic)** – where plasma exits the channel for the plasma waste bag.

6 **RBC Return Tube (clear plastic)** – where cellular components (red cells, white cells, and platelets) exit the channel for return to the patient.

SINGLE-STAGE RBCX CHANNEL (See Figure 1-5)

The single-stage RBCX channel is used for therapeutic red blood cell exchange procedures. Anticoagulated whole blood enters the inlet chamber through the inlet tube. As it flows through the channel, all the cellular components settle to the outside with the plasma on the inside. The red blood cells are withdrawn through the red blood cell out tube, and plasma exits through the plasma return tube. The red cell/plasma interface is maintained in this channel by withdrawing a slightly smaller amount of plasma through the plasma return tube than the total plasma volume (within the anticoagulated whole blood) entering the channel. The extra plasma then holds the red cell interface out at the red blood cell out port.

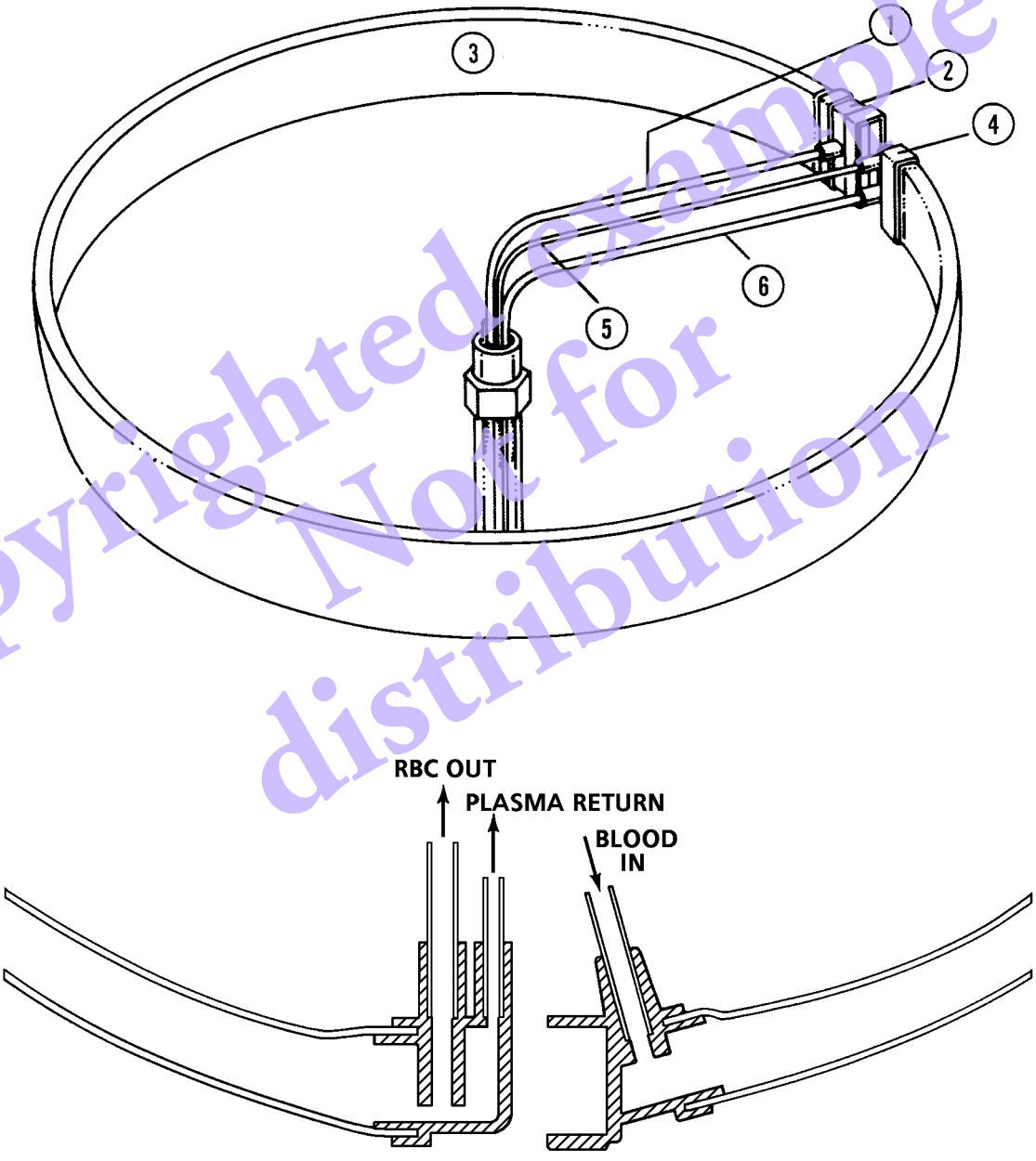

Figure 1-5. Single-Stage RBCX Channel

1 **Inlet Tube (red plastic) –** where anticoagulated whole blood enters the inlet chamber (**2**).

2 **Inlet Chamber –** where anticoagulated whole blood enters the channel (**3**).

3 **Channel –** where centrifugal force and the differences among the specific gravities of the blood components cause plasma to separate from whole blood.

4 **Collection Chamber –** contains the exit tubes (**5** and **6**).

5 **Plasma Return Tube (yellow plastic) –** where plasma exits the channel for return to the patient.

6 **RBC Out Tube (clear plastic) –** where red blood cells exit the channel for the red blood cell waste bag.

SINGLE-STAGE WBC CHANNEL (See Figure 1-6)

The single-stage WBC channel is used to collect either mononuclear cells (MNC) or granulocytes [polymorphonuclear cells (PMN)]. Anticoagulated whole blood enters the inlet chamber through the inlet tube. As it flows through the channel, it is separated into three layers: the red cells are on the outside, the buffy coat containing the selected white cells is in the center, and the platelet-rich plasma is on the inside. The red cell/plasma interface is held in a constant position by balancing the pressure drops in conjunction with the density and viscosity of the red cells and plasma flowing through the RBC and control tubes. The white cells are drawn from the channel through the WBC collect tube, while the platelet-rich plasma exits through the plasma tube. This set is also used for bone marrow processing and lymphoplasma exchange.

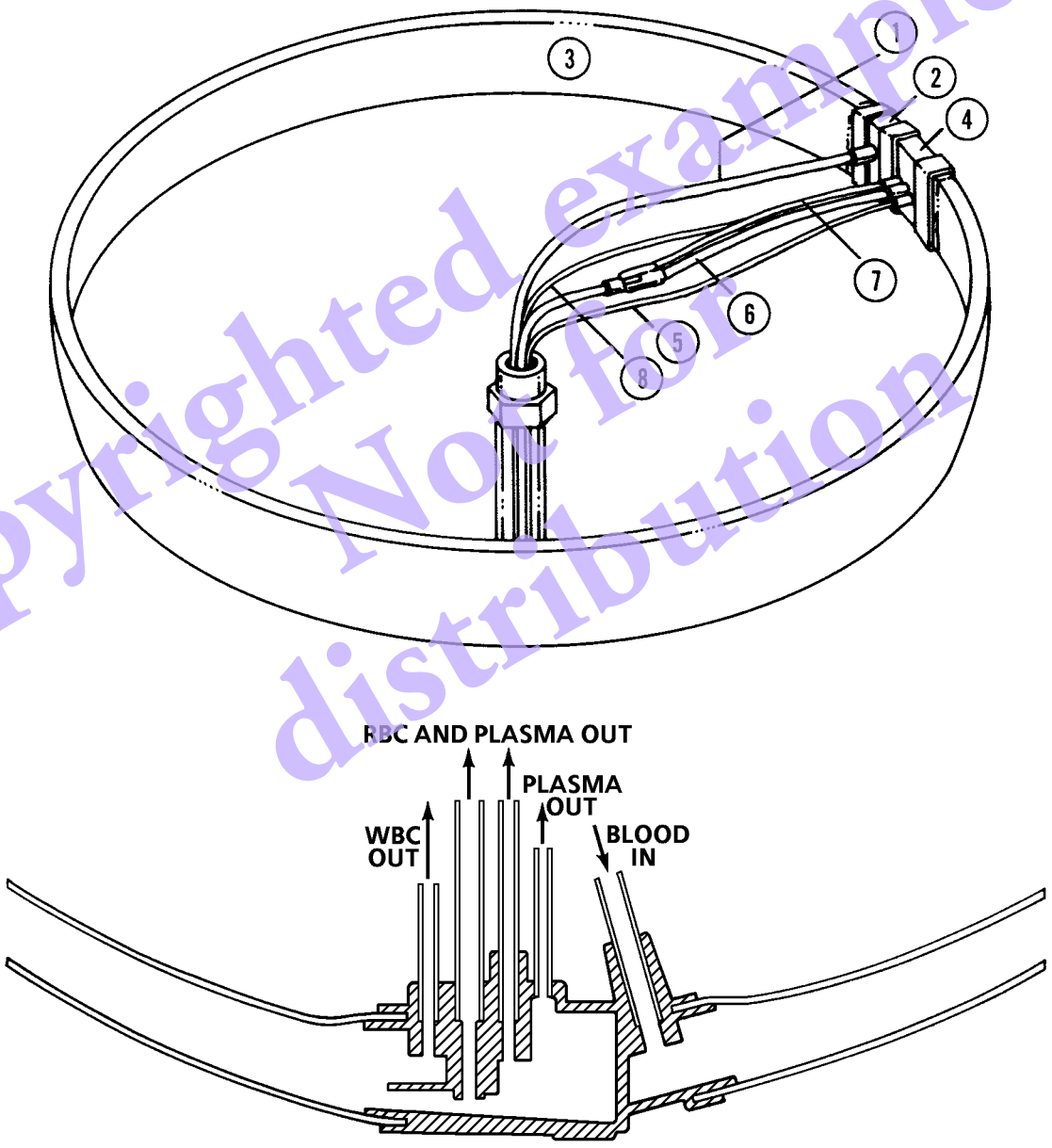

Figure 1-6. Single-Stage WBC Channel

1 **Inlet Tube (red plastic)** – where anticoagulated whole blood enters the inlet chamber (**2**).

2 **Inlet Chamber** – where anticoagulated whole blood enters the channel (**3**).

3 **Channel** – where centrifugal force and the differences among the specific gravities of the blood components cause whole blood to separate into selected components.

4 **Collection Chamber** – contains the exit tubes (**5, 6, 7,** and **8**).

5 **WBC Collect Tube –** where white cells exit the channel for the collect bag.

6 **RBC Tube (clear plastic, larger diameter) –** where red cells exit the channel for return to the donor or patient.

7 **Control Tube (clear plastic, smaller diameter) –** maintains the interface in the channel. The RBC and control tubes are joined into one tube near the centrifuge collar (see Centrifuge Loop in the **Blood Tubing** description).

8 **Plasma Tube (yellow plastic) –** where platelet-rich plasma exits the channel and is mixed with red blood cells prior to return to the donor or patient.

BLOOD TUBING (See Figures 1-7 through 1-14)

1 Donor/Patient Access

- Access Needle (ELP, AutoPBSC, and LRS) – 17 gauge needle with backeye for donor access.
- Needle Clamp (ELP and LRS) – opens and closes the donor access.
- Access Luer – connects to the donor/patient access needle for Dual-Needle procedures and to access/return needle for Single-Needle ELP, LRS, and TPE procedures.
- Access Line Clamp – opens and closes the access line.

2 Access Manifold – consists of the access injection site and connections for the access saline line (**3**), anticoagulant line (**4**), and inlet line (**6**). For identification purposes, the three lines are taped together with red tape until they reach the front panel.

3 Access Saline Line (green-striped) – carries saline used for priming the extracorporeal circuit and maintaining the donor/patient access when the pumps are turned off.

- Access Saline Filter (ELP and LRS) – provides a sterile barrier (**5**).
- Access Saline Clamp – a roller clamp that opens, closes, or allows a saline drip into the access saline line.
- Access Saline Spike/Drip Chamber – connects to the saline container.

4 Anticoagulant (AC) Line with an Orange Spike – carries anticoagulant.

- AC Filter (ELP, AutoPBSC, and LRS) – provides a sterile barrier (**5**).
- Orange AC Spike/Drip Chamber – connects to the anticoagulant container.

5 Sterile Barrier Filters (ELP, AutoPBSC, and LRS) – 0.2-micron filters prevent bacteria from entering the system, thereby maintaining a closed, bacteria-free environment for the collection of extended life platelets.

6 Inlet Line (red-striped) – carries anticoagulated whole blood to the centrifuge.

7 Access Pressure Sensor – attaches to the access pressure sensor housing on the front panel to monitor the donor/patient access blood pressure.

8 Access Pump Cartridge – holds and organizes the AC and inlet pump tubing.

9 Inlet Air Chamber – provides an inlet filter (200 micron) and air detection chamber.

10 Centrifuge Loop – consists of the following:

a. Four-Lumen (ELP, AutoPBSC, LRS, WBC) or Three-Lumen (TPE, RBCX) Tubing – carries fluid in and out of the channel.

b. Sleeves – reinforce the tubing at flex points.

c. Collars – fix the two ends of the loop in the centrifuge.

d. Bearings – are contact points between the centrifuge arm and the loop.

11 **Four-Lumen Connector** – provides a tubing-size transition between the centrifuge loop (**10**) and the front panel lines for ELP, AutoPBSC, LRS, and WBC sets. This connector is red on the AutoPBSC set.

Three-Lumen TPE/RBCX Connector – provides a tubing-size transition between the centrifuge loop (**10**) and the front panel lines for the TPE and RCBX sets.

12 **Collect Concentration Monitor Cuvette (ELP, AutoPBSC, LRS, and TPE)** – fits into the collect concentration monitor to measure the concentration of platelets (ELP and LRS), to detect the presence of PBSC during the Harvest Phase of an AutoPBSC procedure, and to detect red cell contamination (over 3**%** hematocrit) in the collect line [ELP, AutoPBSC, and LRS (**13**) and TPE (**15**)]. This cuvette slides along the collect line on the AutoPBSC set.

13 **Collect/Replace Line** – carries the collected component to the collect bag (ELP, AutoPBSC, LRS, and WBC) or replace solution (TPE and RBCX) to the return line (**23**) at the return air chamber (**20**).

- On the AutoPBSC set, the collect line has a smaller diameter between the four-lumen connector (**11**) and the Y-connector located above the return pump cartridge (**18**) than is standard on Spectra disposables. This enables low volume PBSC collections.
- Replace Solution Spikes (TPE and RBCX) – two spikes to connect to the replace solution containers.
- Collect Bag Clamps (Four for ELP and LRS; two for WBC) – close off the collect bags.

14 **Collect Bag(s)** (1-Liter Bag: two for ELP and LRS; one for AutoPBSC and WBC) – where the collected component is stored. The bag is made from citricized PVC.

15 **Plasma/RBC Line** – carries plasma for ELP, LRS, TPE, AutoPBSC, and WBC procedures and removed red cells for RBCX procedures.

- Auxiliary Bag Connector (TPE, RBCX, and WBC) – a luer to attach to a plasma bag, if desired, during TPE or WBC procedures or a red blood cell bag, if desired, during RBCX procedures.
- Plasma/RBC Line Clamp – closes off the plasma/RBC line to plasma/RBC collection bag and auxiliary bag connector.

16 **Plasma/RBC Bag (ELP, AutoPBSC, LRS, TPE, and RBCX)** – for ELP, AutoPBSC, and LRS, a 600 ml bag to hold concurrently collected plasma; for TPE, a 4-liter waste bag to hold removed plasma; for RBCX, a 4-liter waste bag to hold removed red cells.

17 **RBC/Plasma Line** – carries separated blood components from the channel for return to the donor/patient as follows:

- ELP and LRS – carries red cells and white cells.
- AutoPBSC – carries red cells to/from the RBC Reservoir (**32**).
- TPE – carries red cells, white cells, and platelets.
- RBCX – carries plasma.
- WBC – carries red cells.

18 **Return Pump Cartridge** – organizes tubing as follows:

- ELP, AutoPBSC, LRS, and WBC – holds and organizes the plasma and collect pump tubing
- TPE – holds and organizes the plasma and replace pump tubing
- RBCX – holds and organizes the red blood cell and replace pump tubing

19 **Return Pressure Sensor** – attaches to the return pressure sensor housing on the front panel to monitor the donor/patient return blood pressure.

20 **Return Air Chamber** – provides a return filter (200 micron) and air detection chamber.

21 **Waste Divert Lines** – carry saline and purged air to the waste bag.

22 **Prime Solution Waste Bag** – used at the following times:

- During prime.
- When diverting excess saline during the first portion of a procedure.
- When purging air from the air chambers (**9**) and (**20**).

23 **Return Line** (blue-striped) – carries blood components returned to the donor/patient.

24 **Return Saline Manifold** – connects the return saline line (**25**) to the return line (**23**). For identification purposes, these two lines are taped together with blue tape until they reach the front panel.

25 **Return Saline Line** – carries saline used during prime and to maintain the donor/patient return when the pumps are turned off.

- Return Saline Clamp – a roller clamp that opens, closes, or allows a saline drip into the return saline line.
- Return Saline Spike/Drip Chamber – connects to the saline container.

26 **Donor/Patient Return**

- Return Injection Site – used if an injection is required for the donor/patient.
- Return Clamp – closes off the return to the donor/patient.
- Return Luer – for Dual-Needle ELP, AutoPBSC, LRS, TPE, RBCX, and WBC, connects to the donor/patient return needle. For Single-Needle ELP and LRS, connects to the Single-Needle “Y” manifold **(28)**.

27 **Single-Needle Bag –** holds blood components withdrawn from donor/patient during a draw phase of a Single-Needle ELP and LRS procedure until they are returned to the donor/patient during a return phase.

28 **Single-Needle “Y” Manifold –** connects inlet and return lines on a Single-Needle ELP and LRS disposable to a single access/return needle.

29 **Male/Female Luer Lock Connector –** for Dual-Needle TPE procedures, the male luer lock is connected to the female luer lock. For Single-Needle TPE procedures, it is connected to the two lines of the Single-Needle bag (Figure 1-15), converting the TPE disposable from a Dual-Needle set to a Single-Needle set.

30 Replacement Fluid Port (Included on all WBC Sets; used for Lymphoplasma Exchange Only) – connects to the plasma line (**15**) above the four-lumen connector (**11**) to allow replacement fluid containers to be attached to the WBC set during lymphoplasma exchange.

31 Blood Sampling Bag – used to collect blood from a donor during Single-Needle ELP and Single-Needle LRS procedures for sampling purposes.

32 RBC Reservoir (AutoPBSC) – used to accumulate red blood cells to be used during Harvest Phase.

33 LRS Chamber on the Dual Needle ELP with LRS Chamber and Single-Needle ELP with LRS Chamber Sets – used to produce single-donor platelet components with leukocyte contamination levels below 1×10^6.

The blue sleeves on the disposables are for use with the COBE Seal Safe System™.

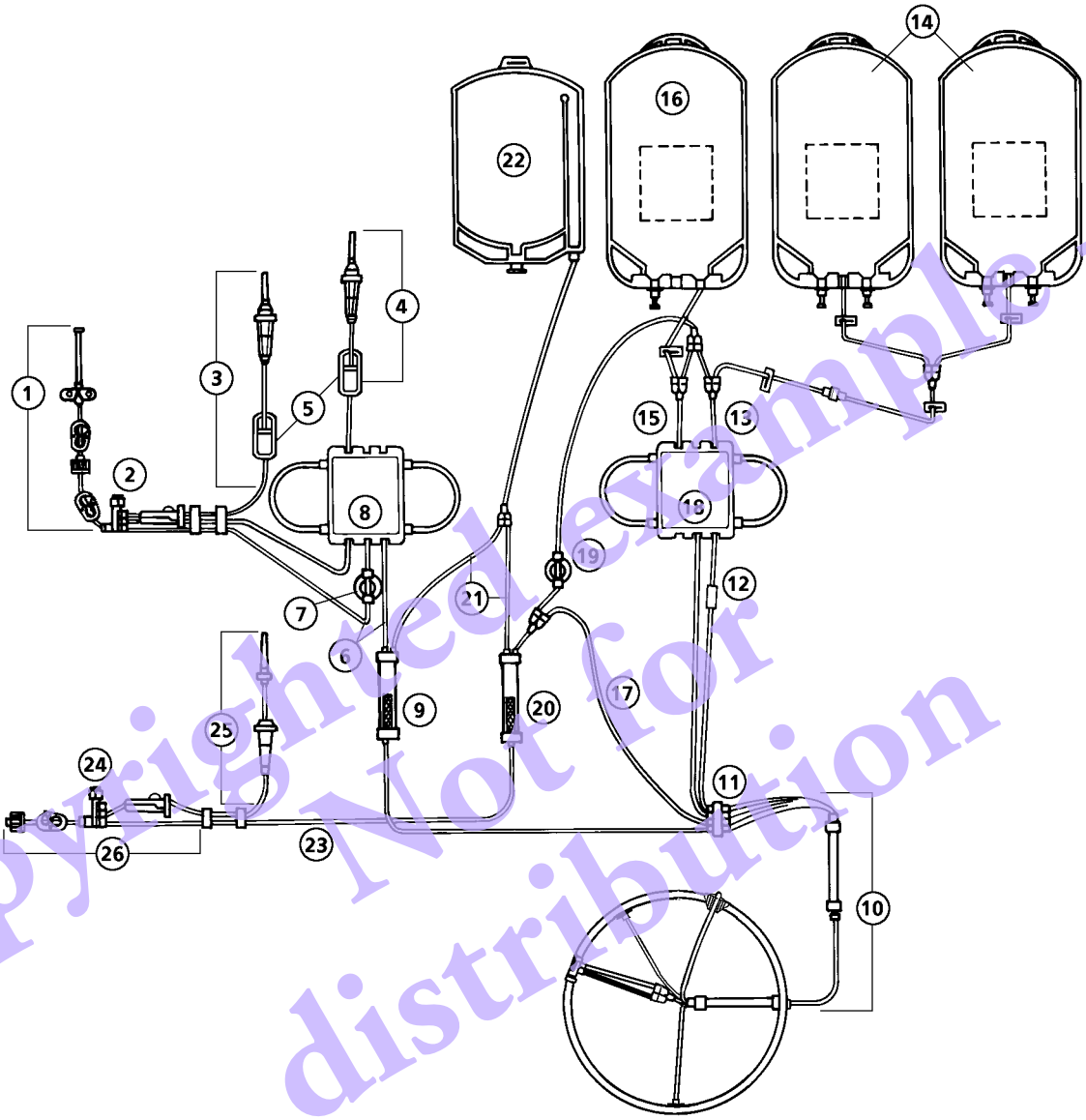

Figure 1-7. Dual-Needle ELP Blood Tubing

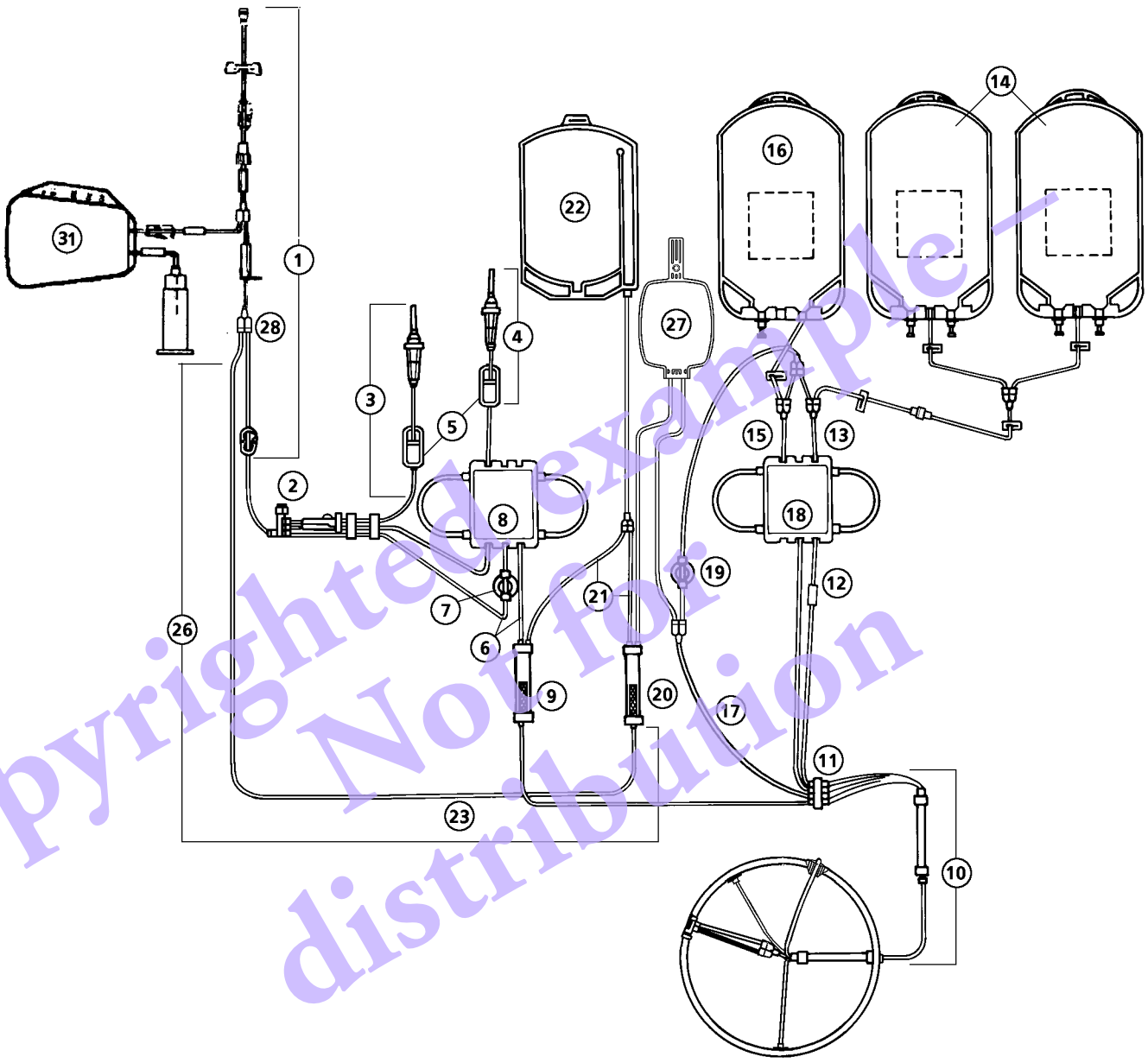

Figure 1-8. Single-Needle ELP Blood Tubing

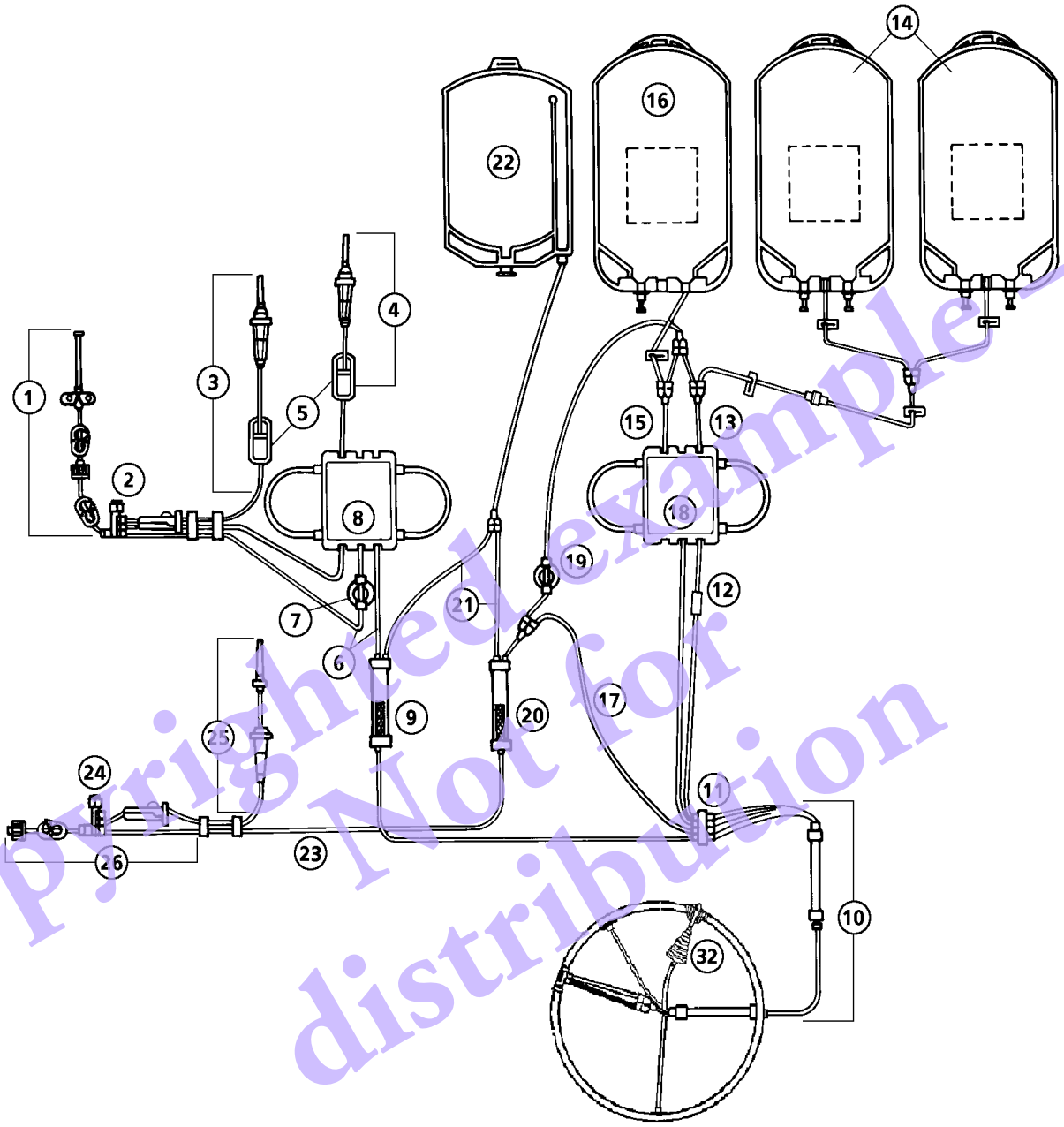

Figure 1-9. Dual-Needle Extended Life Platelet Set with LRS Chamber
For Use With Version 5.1 Software Only

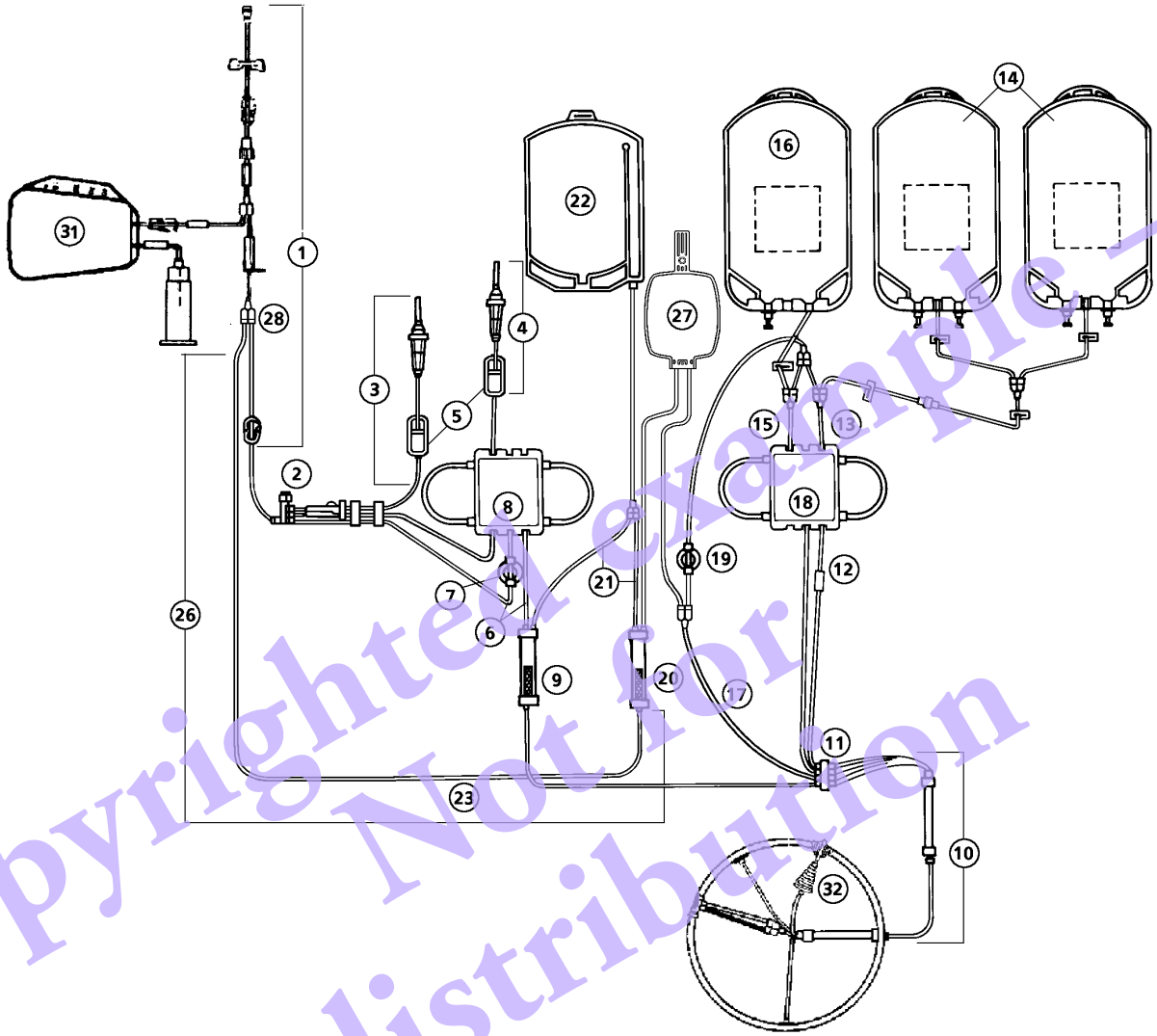

Figure 1-10. Single-Needle Extended Life Platelet Set with LRS Chamber
For Use With Version 5.1 Software Only

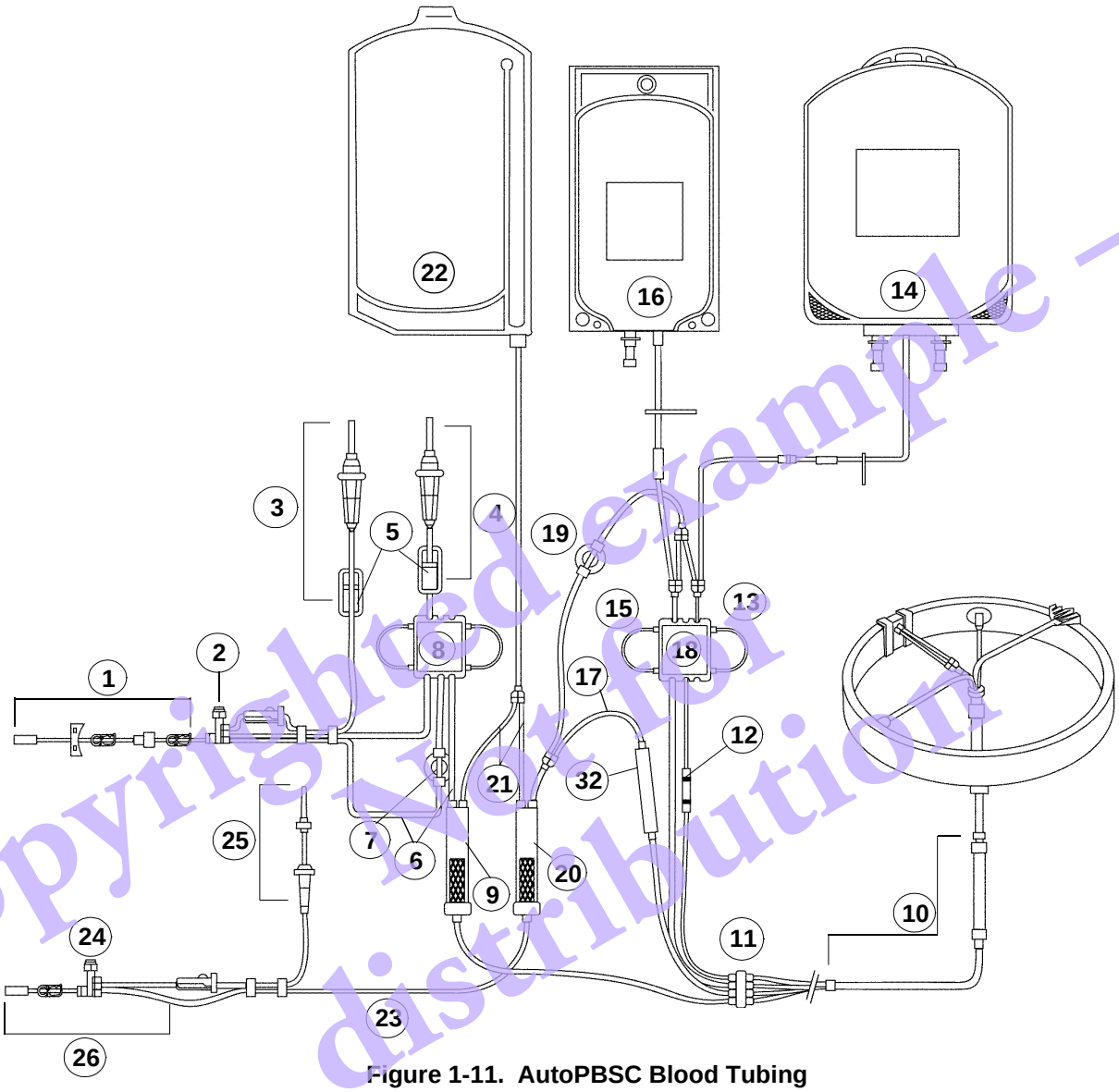

Figure 1-11. AutoPBSC Blood Tubing
For Use With Version 6.0 Software Only

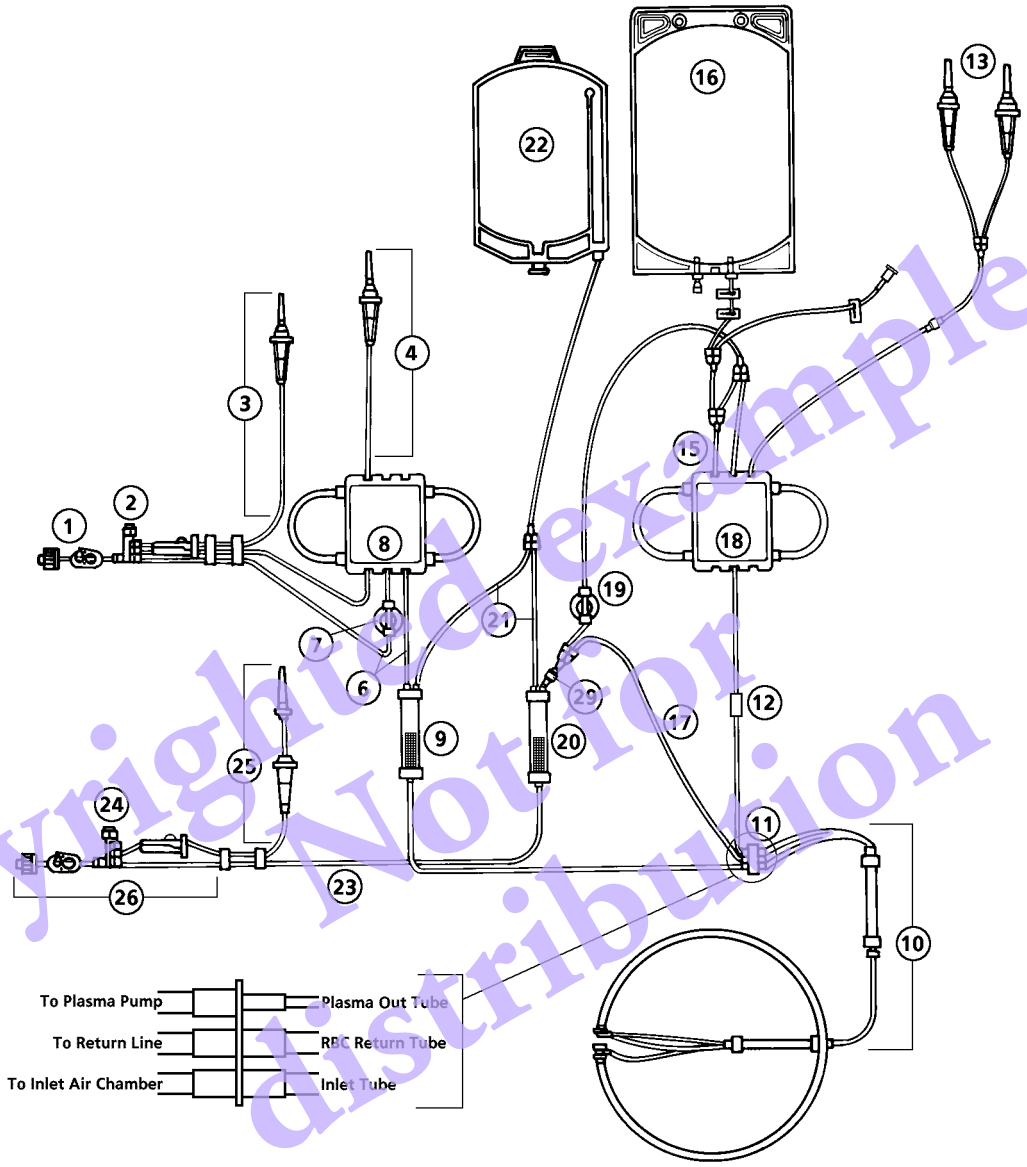

Figure 1-12. TPE Blood Tubing

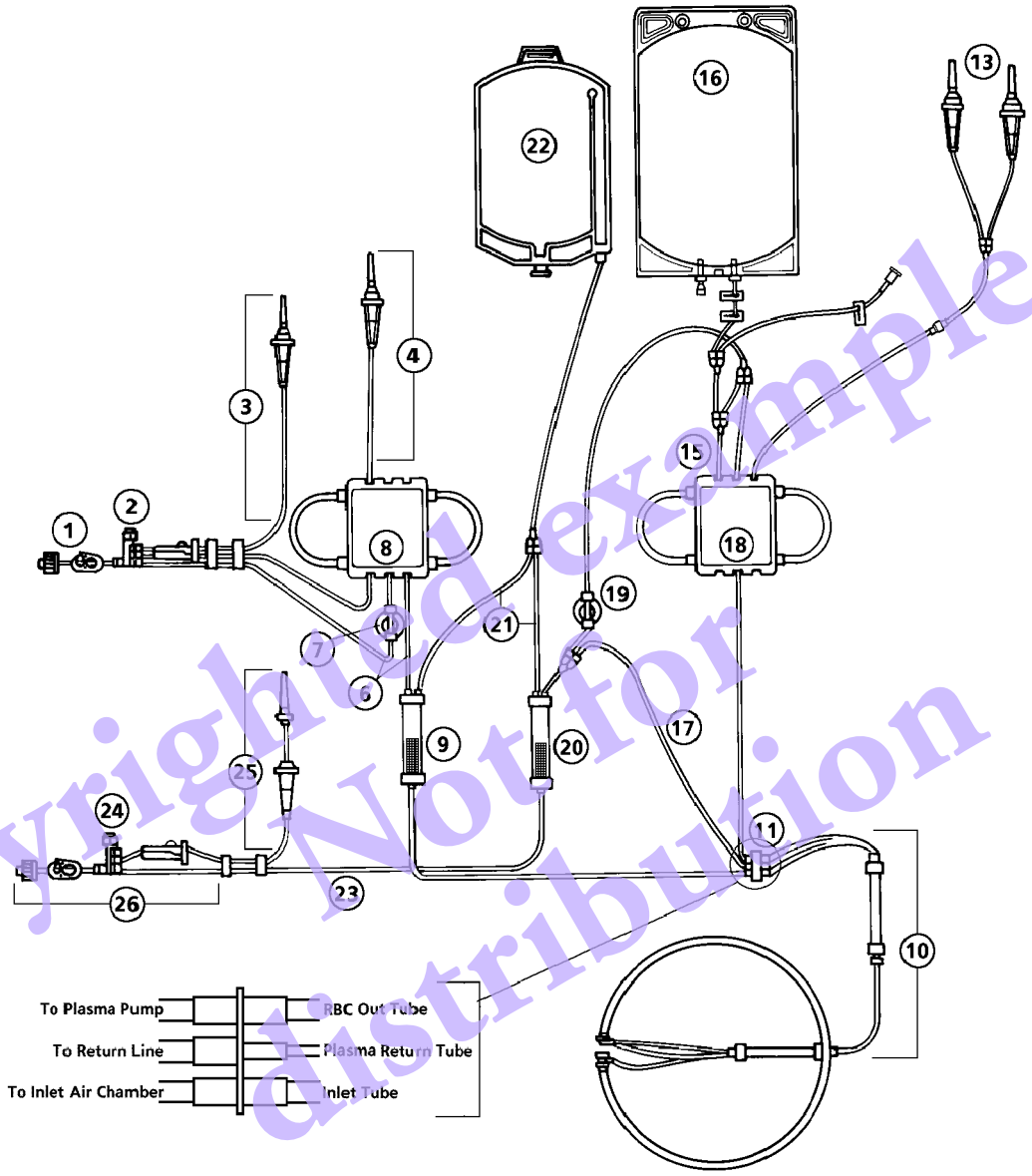

Figure 1-13. RBCX Blood Tubing

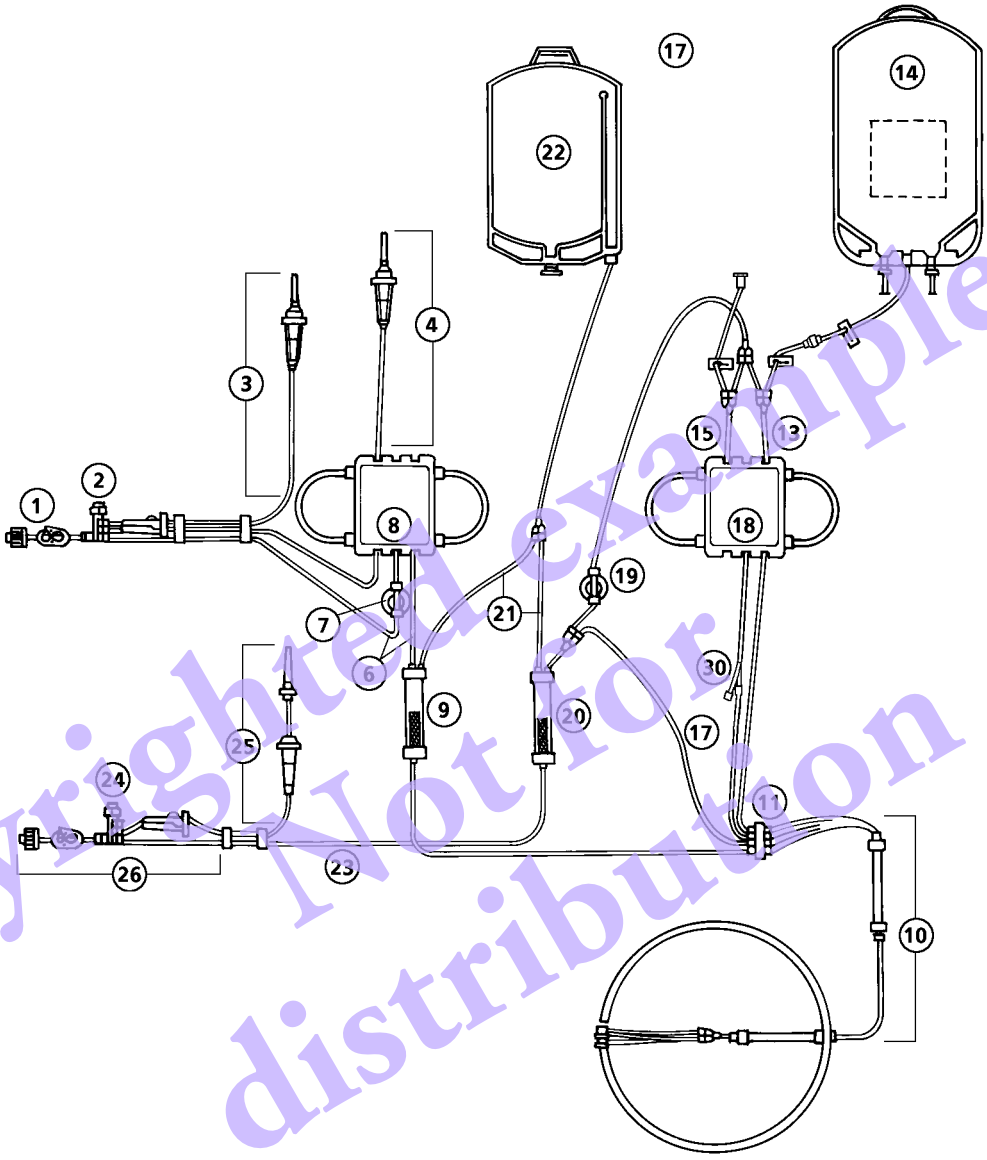

Figure 1-14. WBC Blood Tubing

SINGLE-NEEDLE SET: SINGLE-NEEDLE BAG AND "Y" CONNECTOR (See Figure 1-15)

The Single-Needle bag and "Y" connector illustrated in Figure 1-15 are used to convert the Dual-Needle TPE disposables to Single-Needle operation. The steps for providing this conversion are provided in SECTION 12 – RECOVERY PROCEDURES.

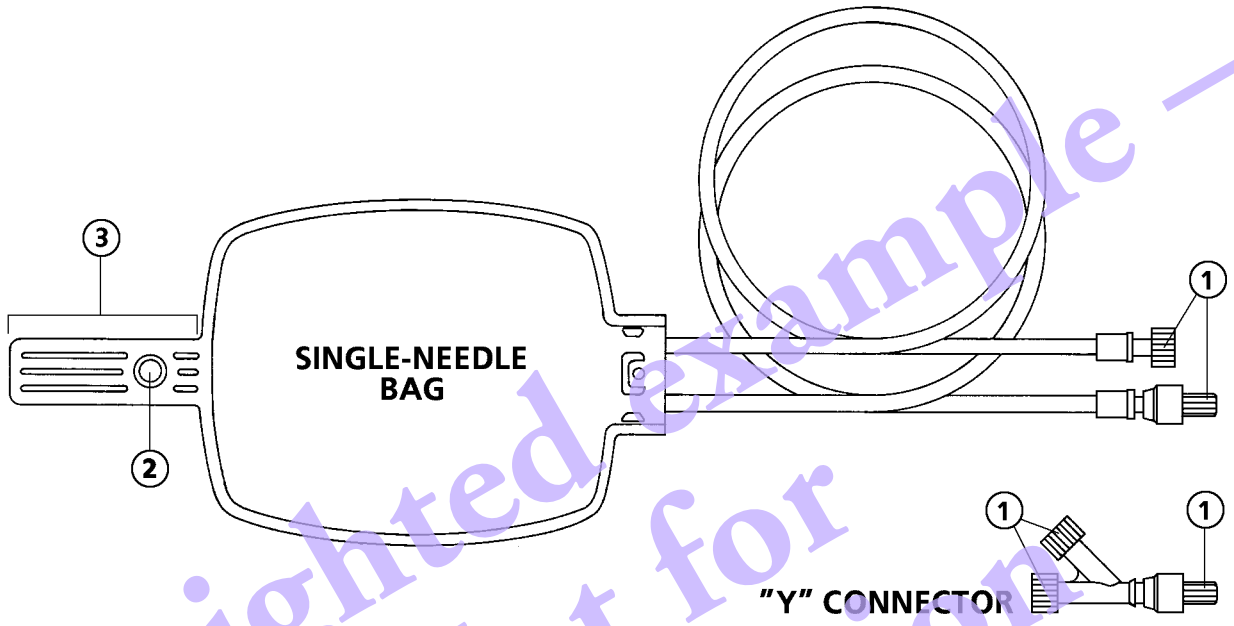

Figure 1-15. Single-Needle Set

1 **Protective Caps**

2 **Locator Hole** on Single-Needle bag

3 **Load Tab** on Single-Needle bag

BONE MARROW PROCESSING (BMP) SET (See Figure 1-16)

The BMP set illustrated in Figure 1-16 is used with the WBC set to conduct bone marrow processing procedures.

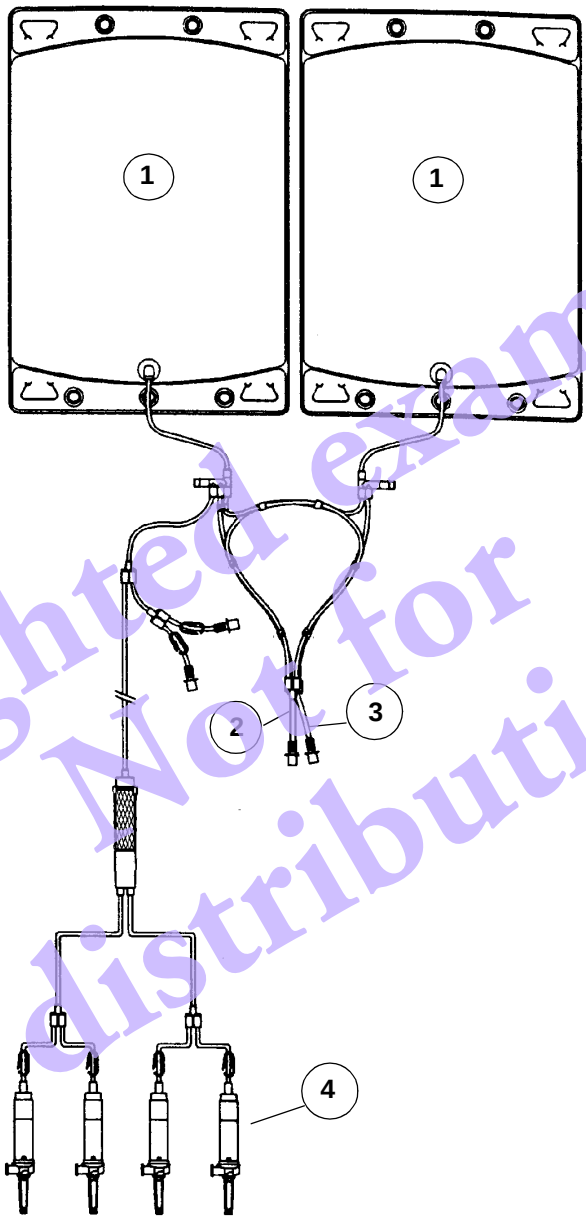

Figure 1-16. BMP Blood Tubing

1 Bag

2 Access Line

3 Return Line

4 Drip Chambers

ACCESSORY PLATELET STORAGE BAG (See Figure 1-17)

The Accessory Platelet Storage Bag is illustrated in Figure 1-17. It is intended for use with the COBE Spectra ELP Set, the COBE Spectra Single-Needle ELP Set, COBE Spectra Dual-Needle Extended-Life Platelet Set with LRS Chamber, the COBE Spectra Single-Needle Extended-Life Platelet Set with LRS Chamber, and the COBE Spectra Apheresis system to store collected platelets.

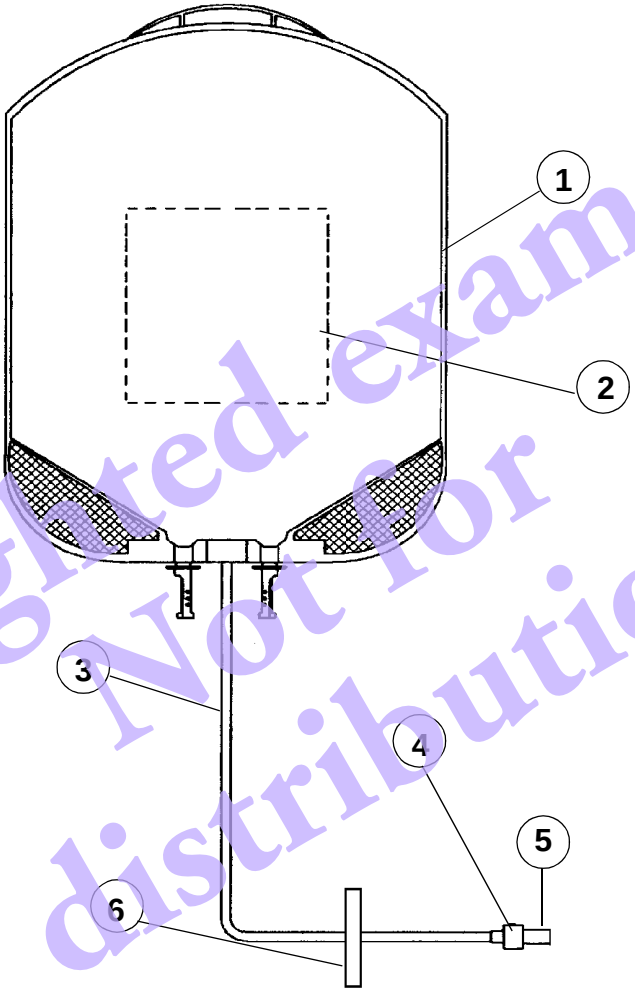

Figure 1-17. Accessory Platelet Storage Bag

1 Citrate Plasticized Bag

2 Volunteer Donor Label

3 Sterile Dockable Tubing, 18" long

4 Male Locking Luer

5 Luer Cap (breathable to allow for sterilization)

6 Slide Clamp

SYSTEM COMPONENTS

The Spectra Apheresis System (Figure 1-1) 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 system. A swivel arm on top of the Spectra system holds the control panel that includes the keyboard and display screen.

CENTRIFUGE CHAMBER (See Figure 1-18)

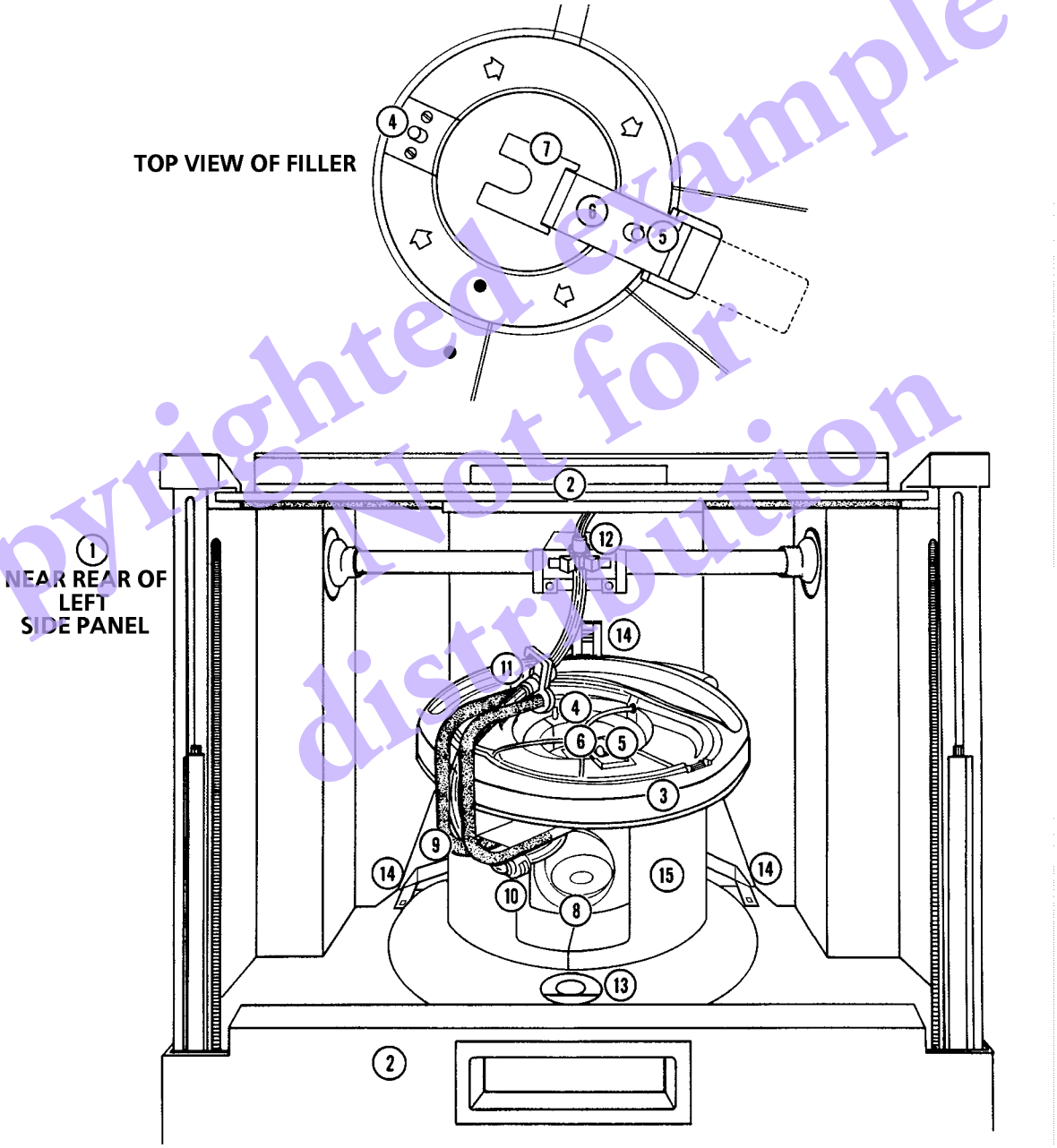

Figure 1-18. Centrifuge Chamber

1 **Power Switch** – turns the power on and off to the Spectra system.

2 **Centrifuge Cover and Door** – allow access to the centrifuge. To protect against excessive light from the strobe (**13**), the cover is opaque. The view port in the cover is transparent so that you can use the strobe to monitor the separation in the channel. The cover and door are interlocking. To open, turn the power on and press the UNLOCK COVER key 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.

3 **Filler** – holds the separation channel. There are three configurations: one for a dual-stage platelet/ AutoPBSC channel, one for a dual-stage platelet channel with LRS Chamber, and one for single-stage channels (TPE, RBCX, and WBC).

4 **Filler Locking Pin** – located on the centrifuge opposite the filler latching pin (**5**) and filler latch (**6**), the filler locking pin locks the filler onto the centrifuge.

5 **Filler Latching Pin** – locks the filler latch (**6**) and, together with the filler locking pin (4), locks the filler (**3**) onto the centrifuge.

6 **Filler Latch** – locks the filler onto the centrifuge. To remove the filler, push the filler latching pin (**5**) toward the center of the centrifuge and raise the filler latch (**6**). Then push the filler locking pin (**4**) toward the center of the centrifuge and raise the filler.

7 **Centrifuge Collar Holder** – located on the end of the filler latch (**6**), the centrifuge collar holder has a hinged cover to hold one of the nonrotating ends of the centrifuge loop.

8 **Centrifuge Loading Port** – is an opening in the centrifuge housing to enable loading the channel.

9 **Centrifuge Arm** – holds the centrifuge loop in place as the centrifuge spins.

10 **Lower Bearing Holder** – secures the centrifuge loop in place on the centrifuge arm (**9**).

11 **Upper Bearing Holder** – secures the centrifuge loop in place on the centrifuge arm (**9**).

12 **Upper Collar Holder** – attaches the upper end of the blood tubing centrifuge loop to the horizontal arm above the centrifuge.

13 **Strobe** – can be turned on to monitor separation in the channel through the centrifuge cover view port (**2**). Pressing the increase key on the keyboard moves the strobe clockwise, which makes the section of the channel being viewed in the view port appear to move to the right. Pressing the decrease key moves the strobe in the opposite direction.

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

15 **Gear Shroud** – protects you from pinch points in the gear train.

FRONT PANEL (See Figure 1-19)

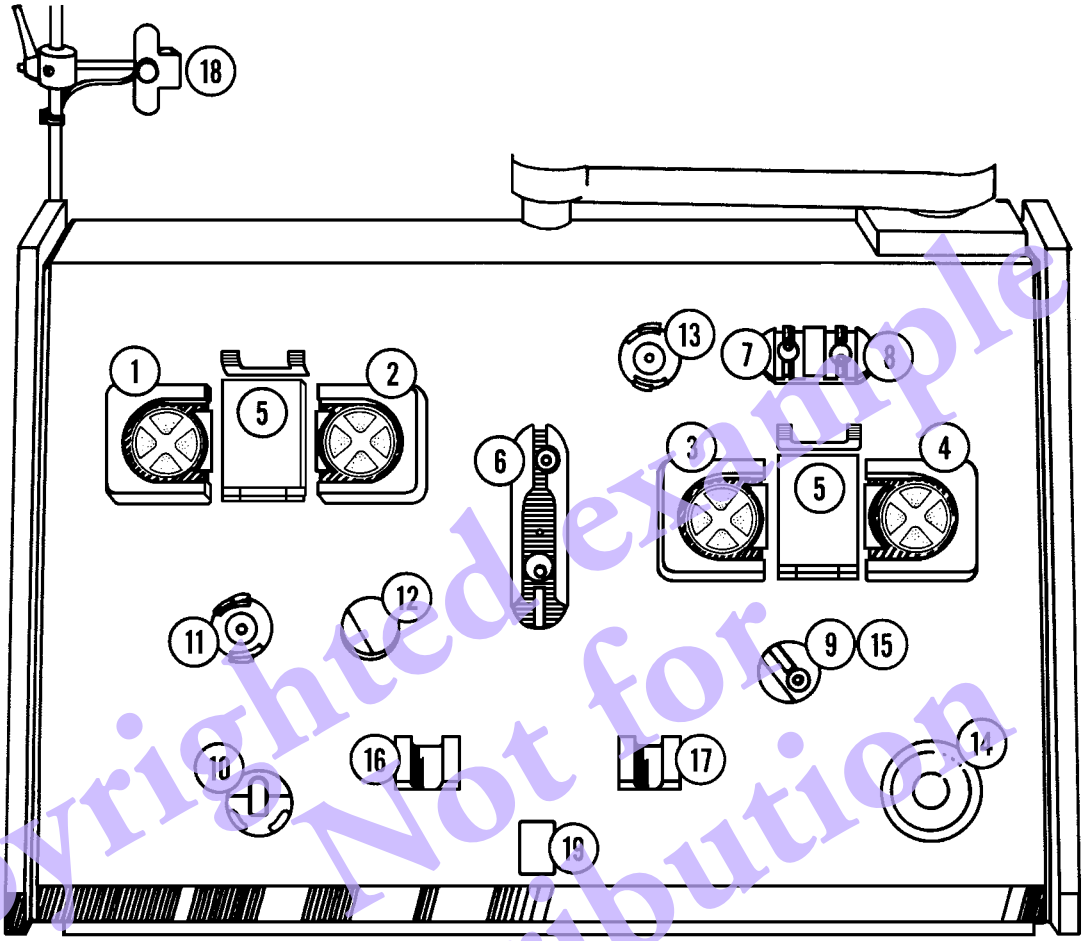

Figure 1-19. Front Panel

Four Pumps – are peristaltic-type 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.

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

2 **Inlet Pump** – pumps anticoagulated whole blood from the donor/patient access to the centrifuge.

3 **Plasma/Red Blood Cell Pump** – for ELP, AutoPBSC, LRS, TPE, and WBC procedures, pumps plasma from the centrifuge to a collect bag or to recombine with cellular components for return to the donor or patient. For AutoPBSC procedures, it is used during the Harvest Phase. For the red blood cell exchange procedure, pumps red blood cells from the centrifuge to the red blood cell collect bag(s).

4 **Collect/Replace Pump** – pumps cells for collection from the centrifuge to the collect bag; or pumps replace solution or red blood cells from the container to recombine with cellular components for return to the patient. In AutoPBSC Procedures, it is used during the Harvest and Chase Phases to recirculate fluids through the RBC Reservoir.

5 **Cartridge Clamps** – retract to facilitate loading of the pumps. After the pumps are loaded, the clamps hold the pump cartridges in place. To unload the cartridges, unload the pumps and then depress the clamps to release the pump cartridges, which can then be removed and discarded.

Five Valves – four of the five valves are pinch-type where a post rotates onto the tubing to close it and rotates off the tubing to open it. The fifth valve is the return line valve, which is a solenoid, fail-safe clamp that clamps the return line during loss-of-power conditions.

6 **Waste Divert Valve** – consists of one 2-way valve (upper) and one 3-way valve (lower) that operate in conjunction with each other. The valve assembly opens to allow saline to be removed from the centrifuge to the waste bag when a donor/patient procedure begins. It also opens to remove air from the inlet and return air chambers to the waste bag. In addition, the valve is used during the recirculation step of the Rinseback mode. A final position allows tubing to be loaded or unloaded.

7 **Plasma/RBC Valve** – For ELP, AutoPBSC, LRS, TPE, and WBC procedures, a 3-way valve that directs plasma flow to a plasma bag or to recombine with cellular components for return to the donor or patient. A third position allows tubing to be loaded or unloaded. For ELP, LRS, and WBC procedures, the valve can be moved only during Manual operation. Changing from Manual to Automatic operation during WBC procedures moves the valve back to the Return position, allowing plasma to be returned to the donor or patient. For RBCX procedures, the valve directs red blood cell flow to a red blood cell collect bag.

8 **Collect/Replace Valve** – a 3-way valve that directs flow to the collect bag or, during a red cell spillover, directs flow back to the donor (to protect the platelet product). In a plasma exchange procedure, it allows replacement solution to be pumped from the container to recombine with formed elements for return to the patient. In an RBCX procedure, it allows the replacement red blood cells to be pumped from the container to recombine with plasma for return to the patient. A third position allows tubing to be loaded or unloaded. In an AutoPBSC procedure, it allows platelets to be returned to the patient/donor and directs flow to the collect bag only during a Harvest Phase.

9 **Red Blood Cell/Plasma Line Valve** – a 2-way valve that is in the same housing as the RBC detector (**15**). This valve closes during the Prime mode to allow air to be pulled out of the channel before it is primed. Also, this valve closes during the Rinseback mode to collapse the channel.

10 **Return Line Valve** – a 2-way valve that closes during a loss of power or some alarm conditions, such as 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.

Three Pressure Sensors

11 **Access Pressure Sensor** – a diaphragm-type sensor with a transducer that monitors negative pressure from the donor/patient access site to the inlet pump. This sensor checks for access blood pressure that is too low.

12 **Centrifuge Pressure Sensor** – a strain gauge sensor that measures a force change just following the inlet pump. This sensor checks for centrifuge over pressure (air block or occluded tubing).

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

Two Concentration Sensors – are optical sensors.

14 **Collect Concentration Monitor** – checks the platelet, PBSC, or RBC concentration in the collect line for the following purposes:

During ELP and LRS procedures only:

- Project the platelet concentration in the collect bag at the end of the procedure. (The Predicted CCM Concentration function is not active during LRS procedures.)
- Estimate the current platelet yield at any time during the procedure.
- Project the platelet yield for the end of the procedure except for LRS procedures. (The CCM predict function is not active during LRS procedures.)
- Detect red cell spillovers greater than 3% hematocrit, and protect the platelet concentration in the collect bag by diverting the red cells back to the donor.
- Monitor collect line for excessive leukocyte contamination in LRS procedures only.

NOTE

The collect concentration monitor (CCM) is not accurate during platelet depletion procedures.

During AutoPBSC procedures:

- Detect PBSC harvests.
- Detect red cell spillovers greater than 3% hematocrit.

During TPE procedures:

- Detect red cell spillovers greater than 3% hematocrit in the collect line and divert the red cells back to the patient.

15 **RBC Detector** – located in the same housing as the RBC/Plasma line valve (9). The sensor detects when red blood cells reach this point (at the beginning of a donor/patient procedure), then closes the waste divert valve and opens the return line valve. The default amounts of inlet volume that will be processed if no red blood cells are detected are based on the inlet volume and disposable as follows: ELP and LRS sets=120 ml; AutoPBSC, TPE, and WBC sets=150 ml.

Three Air Sensors – are ultrasonic sensors.

16 **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.

17 **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.

18 **Anticoagulant (AC) Level Detector** – detects when the anticoagulant container is empty. For WBC PMN (granulocyte) removal procedures, detects when the prescribed hydroxyethyl starch (HES)/ sodium citrate concentrate container is empty.

19 **Packaging Hook** – holds the package containing the disposable in place on the centrifuge cover for convenient installation of the tubing on the front panel.

Flow Path Overlays – three overlays that name each device on the front panel, helping to ensure correct installation of tubing when setting up disposables.

- Collect Flow Path Overlay – used for collection and depletion procedures.
- TPE Flow Path Overlay – used for therapeutic plasma exchange procedures.
- RBCX flow path overlay – used for therapeutic red blood cell exchange procedures.

CONTROL PANEL (See Figure 1-20)

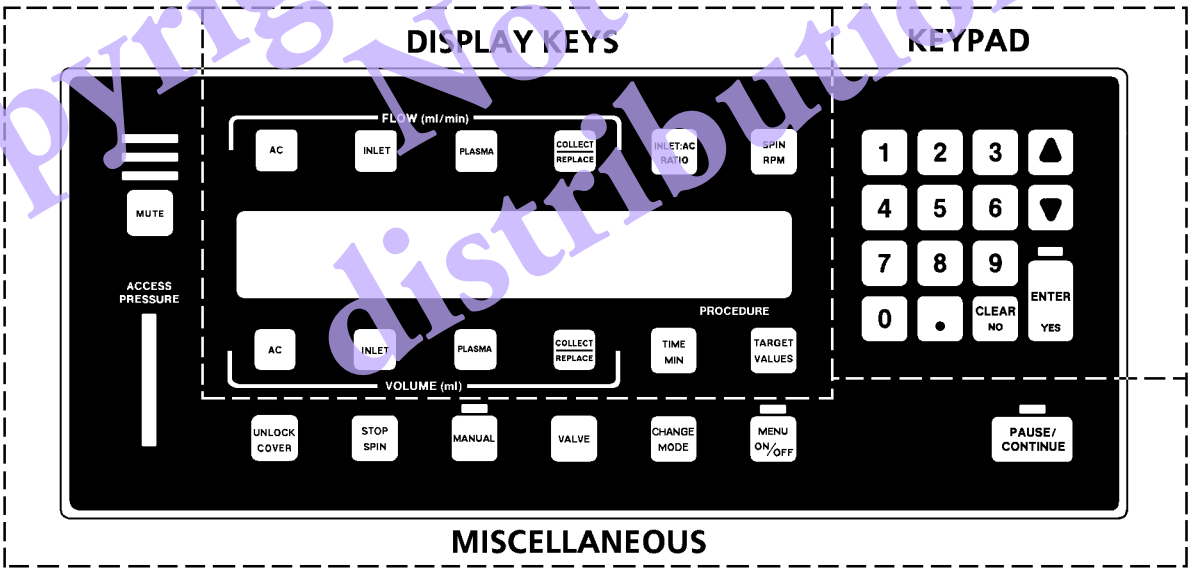

Figure 1-20. Control Panel

NOTE

The keyboard can be rotated downward 90 degrees to lower the height of the Spectra for moving.

Keyboard – keys are grouped into three major functional areas. The numeric keypad is located in the upper right-hand corner. The display keys are the 12 that surround the display screen (6 keys above and 6 keys below). The miscellaneous keys are located on the bottom row and left-hand side. When any key is pressed, it causes a beeping sound. For detailed information on the use of the keyboard, see APPENDIX A – KEYBOARD SELECTIONS.

Keypad

Digit Keys – 0 through 9 are used for entering numeric information and making menu selections.

Increase/Decrease Keys – are multifunctional as described below:

- Upward- and downward-pointing arrows are used to make incremental changes to the numeric value displayed. When an arrow key is pressed and released quickly (within 3/4 second), the numeric value changes a relatively small amount (1-10 units). When an arrow key is held down, after 3/4 second the numeric value starts changing by 10 to 100 units every 1/2 second until the key is released.

- When the keypad is not being used for a numeric entry, the up and down arrows may be used to move the location of the strobe flash on the separation channel. Pressing the up arrow moves the area of the channel displayed by the strobe to the right. Pressing the down arrow moves the area being displayed to the left.

Decimal Point Key – after pressing this key, fraction digits may be entered for a displayed value already showing a decimal point.

CLEAR/NO Key – is multifunctional as described below:

- Numeric Entry – when using the digit keys, the CLEAR/NO key clears the entered digits, restores the displayed value present before the first digit key was pressed, and allows the increase/decrease keys to be used. When using the increase/decrease keys, the CLEAR/NO key stops or cancels numeric entry.

- YES/NO Questions – when answering YES/NO questions, the CLEAR/NO key indicates a NO answer. This usually causes a screen to be displayed that allows modification of the information that is unacceptable.

- Menu Selection – the CLEAR/NO key is used to back up through menu and patient data screens. If the first level message screen is displayed, the CLEAR/NO key removes the message display and exits the menu system.

- Message Display – The CLEAR/NO key displays the screen messages that are ranked below the current highest-priority screen message.

ENTER LED – is a green LED located over the ENTER/YES key that flashes when you are expected to enter a number, answer a YES/NO question, or make a menu selection (when the ENTER key is a valid choice).

ENTER/YES Key – is multifunctional as described below:

- Numeric Entry – the ENTER/YES key accepts the modified number and completes numeric entry.

- YES/NO Questions – when answering YES/NO questions, the ENTER/YES key indicates a YES answer.

- Menu Selection – the ENTER/YES key makes an explicit menu choice, selects a default choice, leaves the previously selected choice unchanged, or may not be a valid choice.

- Restores Screen Messages – the ENTER/YES key restores the display of higher-priority alarm messages or overridden warnings that have been removed by the CLEAR/NO key.

Display Keys

NOTE

Any action which places Spectra in the Manual Mode during an LRS procedure will require lab measurement of the WBC contamination and platelet content of the collected product.

AC FLOW Key – when pump flow rates are shown on the top line of the display screen, the AC FLOW key allows the AC pump flow rate (in ml per minute) to be changed (in Manual operation only).

INLET FLOW Key – when pump flow rates are shown on the top line of the display screen, the INLET FLOW key allows the inlet pump flow rate (in ml per minute) to be changed.

PLASMA FLOW Key – when pump flow rates are shown on the top line of the display screen, the PLASMA FLOW key allows the plasma pump flow rate (in ml per minute) to be changed (in Manual operation only for ELP, AutoPBSC, LRS, RBCX, and TPE procedures and in Manual and Automatic operation for WBC procedures). For RBCX procedures, pressing the PLASMA FLOW key changes the red blood cell flow instead of the plasma flow.

COLLECT/REPLACE FLOW Key – when pump flow rates are shown on the top line of the display screen, the COLLECT/REPLACE key allows the displayed flow rate (in ml per minute) to be changed (in Manual operation only for ELP, AutoPBSC, LRS, RBCX, and TPE procedures and in Manual and Automatic operation for WBC procedures).

INLET/AC RATIO Key – when pump flow rates are shown on the top line of the display screen, the INLET/AC RATIO key allows the ratio of the inlet flow rate to AC flow rate to be changed.

SPIN RPM Key – when pump flow rates are shown on the top line of the display screen, the SPIN RPM key allows the centrifuge speed (in revolutions per minute) to be changed (in Manual operation only for ELP, AutoPBSC, LRS, and RBCX; in Manual and Automatic operation for TPE).

AC VOLUME Key – the AC VOLUME key serves as a label as follows:

- During Run Mode – AC VOLUME represents the current actual accumulated volume of anticoagulant (in ml) used at any time during the Run portion of the procedure.

- When TARGET VALUES ("Target") Are Displayed – AC VOLUME represents the expected total amount of anticoagulant (in ml) to be used for the procedure.

INLET VOLUME Key – since inlet volume is used as a limiting factor for ELP, AutoPBSC, LRS, TPE, and WBC procedures, the INLET VOLUME key allows the value to be changed as follows:

- During Run Mode – INLET VOLUME represents the current actual accumulated volumes of whole blood and anticoagulant (in ml) that have been processed at any time during the Run portion of the procedure.

- When TARGET VALUES ("Target") Are Displayed – the end-of-run target value is shown and the INLET VOLUME key allows the inlet volume target value (in ml) to be changed.

PLASMA VOLUME Key – since plasma volume is used as a limiting factor for therapeutic plasma exchange procedures, the PLASMA VOLUME key allows the value to be changed as follows:

- During Run Mode – PLASMA VOLUME represents (at any time during the Run portion of the procedure) the current actual accumulated volume of plasma and anticoagulant (in ml) collected for either an optional concurrent plasma collection or a therapeutic plasma exchange.

- When TARGET VALUES ("Target") Are Displayed – for therapeutic plasma exchange procedures, the end-of-run target value is shown and the PLASMA VOLUME key allows the plasma volume target value (in ml) to be changed. For optional concurrent plasma collections, PLASMA VOLUME represents the expected total amount of plasma and anticoagulant to be collected.

COLLECT/REPLACE VOLUME Key – since collect volume is used as a limiting factor for ELP, AutoPBSC, LRS, and WBC procedures, and replace volume is used as a limiting factor for therapeutic plasma exchange and red blood cell exchange procedures, the COLLECT/REPLACE VOLUME key allows these values to be changed as follows:

- During Run Mode – COLLECT/REPLACE VOLUME represents (at any time during the Run portion of the procedure) the current actual accumulated volume for one of the following:

  – Amount collected (in ml) for a donor collection or patient depletion.

  – Amount of replace solution (in ml) used during a therapeutic plasma exchange or red blood cell exchange.

- When TARGET VALUES ("Target") Are Displayed – for ELP, AutoPBSC, LRS, and WBC procedures, the end-of-run target value is shown and the COLLECT/REPLACE key allows the collect volume target value (in ml) to be changed. For therapeutic plasma exchange and red blood cell exchange procedures, the end-of-run target value is shown and the COLLECT/REPLACE key allows the exchange volume target value (in ml) to be changed.

TIME MIN Key – since run time is used as a limiting factor for a procedure, the TIME MIN key allows the value to be changed as follows:

- During Run Mode – TIME MIN represents the elapsed time of the procedure in minutes.

- When TARGET VALUES ("Target") Are Displayed – the end-of-run time is shown and the TIME MIN key allows the run-time target value to be changed.

  For RBCX procedures, you cannot use the TIME MIN key to change the target value. To change the target time, change the collect/replace volume using the COLLECT/REPLACE VOLUME key.

TARGET VALUES Key – changes back and forth between showing target values and current actual values on the bottom line of the display screen. When showing target values, "Target" is displayed in the bottom right corner. With the exception of the AC volume, the end-of-run target values can be changed by pressing the TARGET VALUES key, selecting the end point to be changed by pressing the appropriate VOLUME key, and entering the new target value. When showing current actual values, one of the following is displayed in the bottom right corner:

- PLTC – Dual-Needle ELP Collection (Dual-Needle ELP Set)

- SNPLTC – Single-Needle ELP Collection (Single-Needle ELP Set)

- AuPBSC – Automatic PBSC Procedure (AutoPBSC Set)

- PBSC – Assisted PBSC Procedure (AutoPBSC Set)

- Numeric Value – In AutoPBSC Procedures, the next inlet volume at which a harvest event is due (AutoPBSC Set)
- LRS – Dual-Needle LRS Collection (Dual-Needle LRS Set)
- SNLRS – Single-Needle LRS Collection (Single-Needle LRS Set)
- PLTD – Platelet Depletion (Dual-Needle ELP Set)
- TPE – Dual-Needle Plasma Exchange (TPE Set)
- SNTPE – Single-Needle Plasma Exchange (TPE Set)
- RBCX – Red Cell Exchange (RBCX Set)
- MNC – Mononuclear Cell Removal (WBC Set)
- PMN – Polymorphonuclear Cell or Granulocyte Removal (WBC Set)
- BMP – Bone Marrow Processing Procedure (WBC and BMP Sets)

Miscellaneous Keys

Status Lights (Located Directly Above MUTE Key)

- Safe LED – is a steady green LED that lights to indicate no alarm or warning conditions are present and all alarms are enabled. (All safety systems are activated.) A steady green LED only occurs in Run mode.
- Warning LED – is a yellow LED that flashes to indicate warning conditions or to alert the user of the start of a Harvest Phase during AutoPBSC procedures. It is a steady light if the warning condition is temporarily overridden or the Spectra system is not in Run mode (some alarms are disabled in Prime and Rinseback modes).
- Alarm LED – is a red LED that flashes to indicate alarm conditions. It is a steady light if the alarm condition is temporarily overridden.

MUTE Key – temporarily silences the error and warning audio alarms. They will stay silent for 2 minutes or until a new, higher-priority alarm occurs.

ACCESS PRESSURE Bar Graph – is a LED bar graph that displays access pressure. There are 18 bars, at 25 mmHg per bar, ranging from 25 mmHg (at the top) to –400 mmHg. The first yellow bar corresponds to the default warning limit (–200 mmHg).

UNLOCK COVER Key – allows the centrifuge cover and door to be opened when the centrifuge is completely stopped. The latches will remain open for 20 seconds – until the centrifuge cover is opened.

STOP SPIN Key – turns off the centrifuge, stops the pumps (puts the Spectra system in Pause with the PAUSE LED flashing), and closes the return line valve once the centrifuge has stopped. Pressing the PAUSE/CONTINUE key restarts the centrifuge and pumps and opens the return line valve. You need to press the PAUSE/CONTINUE key a second time (after seeing the “Centrifuge up to speed. CONTINUE” message) to start the pumps.

> **Note:** If the STOP SPIN key is pressed during a harvest event in AutoPBSC Procedures, it immediately terminates the harvest.

MANUAL LED – is a red LED that lights when the Spectra system is performing a procedure in "Manual," overriding the automatic flow rate settings.

MANUAL Key – is only active in the Run mode or after Prime when donor/patient data entry is complete. Pressing the MANUAL key while the MANUAL LED is off puts the system in Manual operation, allowing you to control the pump flow rates, centrifuge speed, and valve positions (also lights the MANUAL LED). Pressing the MANUAL key while the MANUAL LED is on returns the system to Automatic operation, letting the algorithms control the pump and centrifuge speeds. (For more details, refer to Appendix C.)

NOTE

Any action which places Spectra in the Manual Mode during an LRS procedure will require lab measurement of the WBC contamination and platelet content of the collected product.

VALVE Key – causes a menu to be displayed, allowing the selection of a particular valve to be moved. The menu will continue to be displayed after a selection has been made so that more valves may be moved. The menu will be displayed for 30 seconds or until the valve key is pressed again or the MENU ON/OFF, CHANGE MODE, ENTER/YES, or CLEAR/NO key is pressed. (For more details, refer to Appendix A.)

CHANGE MODE Key – causes a menu to be displayed, allowing you to choose a different mode of operation. The choices include Load Set, Prime, Run, Rinseback, Unload Set, and Diagnostics. After pressing a valid digit key, the menu is removed and the Spectra system starts the selected mode of operation. If no selection is made, the menu will be removed after 30 seconds. Also, the menu can be removed by pressing the MENU ON/OFF, VALVE, or CLEAR/NO key. (For more details, refer to Appendix A.)

MENU LED – is a green LED located over the MENU ON/OFF key that lights when the menu system is being used.

MENU ON/OFF Key – starts the menu system when the MENU LED is not lit by displaying the first set of choices and lighting the MENU LED. More choices can be viewed by pressing the ENTER/YES key. When a selection is made, the current display is removed (possibly replaced by the next set of choices). If no selection is made, the display will be removed after 30 seconds. Or you can exit the menu system at any point by pressing the MENU ON/OFF key when the MENU LED is lit. The CLEAR/NO key can be used to back out of the menu system one step at a time. The VALVE or CHANGE MODE keys will replace any display with their respective menus. (For more details, refer to Appendix A.)

PAUSE LED – is a green LED located over the PAUSE/CONTINUE key that lights to indicate that the Spectra system is in a Pause condition (the pumps are stopped). A flashing LED indicates that the pumps can be restarted by pressing the PAUSE/CONTINUE key. A steady LED indicates that an alarm condition must be removed before the pumps can be restarted.

PAUSE/CONTINUE Key – is used in conjunction with the PAUSE LED as follows:

- When the PAUSE LED is off, pressing the PAUSE/CONTINUE key pauses the Spectra system (stopping the pumps and lighting the PAUSE LED). 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 centrifuge loop.

- When the PAUSE LED is on and flashing, pressing the PAUSE/CONTINUE key will restart the pumps and turn off the 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 put itself into Pause. You are prompted to clear the alarm (the PAUSE LED will be on steady, not flashing) before pressing the PAUSE/CONTINUE key.

Display Screen – shows a 2 line by 40 character display. Information displayed on the screen can be grouped into six general categories: 1) state message displays, 2) alarm message displays, 3) operator information displays, 4) VALVE key displays, 5) CHANGE MODE key displays, and 6) MENU ON/OFF key displays.

State Message Displays – show the current state of the Spectra system. (A state is defined as one of possibly many individual steps that the system takes to complete each mode of operation.) The current step the system is performing determines the pump flow rates, centrifuge speed, valve positions, enabled alarms, and display message. The display message either explains what action the 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 an abbreviation of the current procedure appears in the lower right-hand corner. A list of these abbreviations follows the TARGET VALVES key discussion earlier in this section.

Alarm Message Displays – 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 message will be displayed first with an asterisk (*) indicator in the lower right-hand corner. This indicates there are more alarms than the one currently being shown. Press the CLEAR/NO key to temporarily view the lower-priority alarm(s). The display of the highest-priority alarm will resume after 30 seconds or if the ENTER/YES key is pressed. For additional information on Spectra alarms and the actions to take in response to those alarms, see SECTION 11 – TROUBLESHOOTING.

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

- __ __ key is invalid! – the key selection is not allowed at that particular time (e.g., TARGET VALUES, MANUAL, etc.)

- __ __key – first use MANUAL! – the key selection is allowed only during Manual operation (e.g., AC FLOW, PLASMA FLOW, etc.)

- __ __key – first use TARGET! – the key selection is allowed only when TARGET VALUES are displayed (e.g., INLET VOLUME, TIME MIN, etc.)

VALVE Key Displays – are menus that allow you to move individual valves. The first level menu lets you select the valve to move. The second level menu lets you choose a position to which the valve is to be moved. (See APPENDIX A – KEYBOARD SELECTION for more details.)

CHANGE MODE Key Displays – allow you to put the system in a different mode of operation. (See APPENDIX A – KEYBOARD SELECTIONS for more details.) The modes of operation that can be selected are as follows:

- Load Set
- Prime
- Run
- Rinseback
- Unload Set
- Diagnostics

MENU ON/OFF Key Displays – are menus that allow you to select a number of options. When you make a selection, the display is either removed or replaced by another set of choices. These displays also include donor/patient data questions that determine parameters for donor/patient procedures.

RETURN FLOW CONTROLLER (See Figure 1-21)

The COBE Spectra™ Single-Needle Return Flow Controller – is a Spectra option used only during Single-Needle ELP and LRS 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 phases of a Single-Needle procedure for return to the donor/patient during the return phases of a Single-Needle procedure.
- To provide controlled pressure on the Single-Needle bag to produce the desired return flow during the return phases of a Single-Needle procedure.

To interpret the meaning of the symbols on the Return Flow Controller's front cover, see Figure 1-22, which is a copy of the permanent label on the Return Flow Controller's back cover. That label provides translations of the meaning of these symbols.

The explanation of the number labels in Figure 1-21 follows:

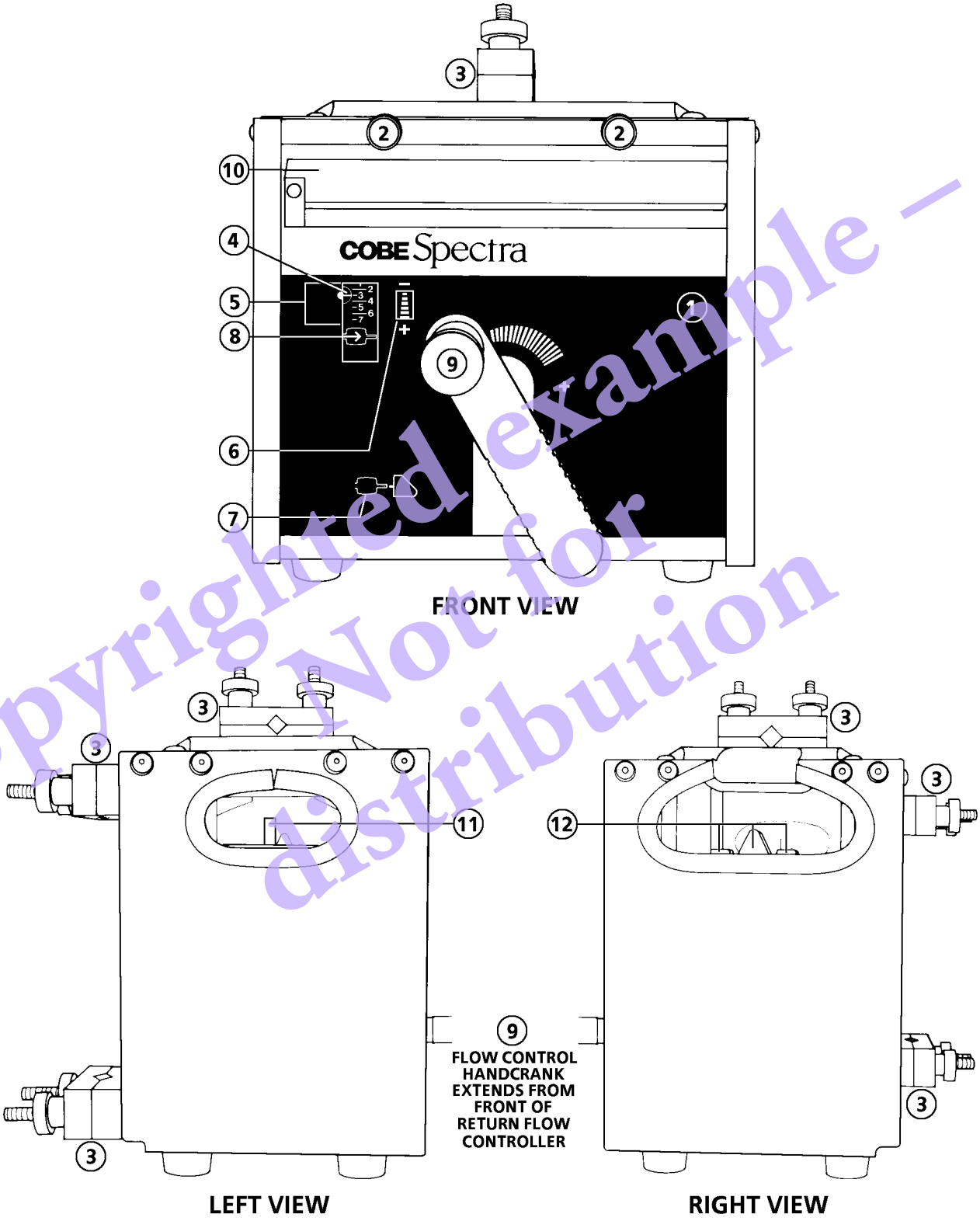

Figure 1-21. Return Flow Controller

1 **Front Cover** – used to keep the Return Flow Controller's internal mechanism clean and to graphically illustrate operating modes.

2 **Front Cover Thumb Nuts** – used to remove front cover so the inside of the Return Flow Controller can be cleaned. See **OPERATOR MAINTENANCE OF RETURN FLOW CONTROLLER** section of SECTION 13 – MAINTENANCE for instructions on how to do this.

3 **IV Pole Mounting Clamps** – used to attach the Return Flow Controller to the horizontal or vertical segments of the IV pole. (See Figures 2-3 and 2-4 in SECTION 2 – INSTALLATION.) For instructions on how to install the Return Flow Controller on the IV pole, see **INSTALLATION OF RETURN FLOW CONTROLLER** section of SECTION 2 – INSTALLATION.

4 **Return Flow Indicator** – used to indicate the current return flow position on the return flow scale **(5)**.

5 **Return Flow Scale** – a numerical scale between 0 and 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 flow rate. A display screen message displays the appropriate starting position to which to set the scale. See Figure 1-23 for a detailed view of the return flow scale set to 3.

6 **Return Flow Guide** – helps determine the direction in which to turn the flow controller hand crank **(9)**. As the crank is turned clockwise to increase the return flow rate, the red triangle in the left return flow guide window widens. As the crank is turned counterclockwise to decrease the return flow rate, the red triangle narrows.

7 **Bag Load Indicator** – when the flow control handcrank **(9)** is at the counterclockwise stop, a red arrow appears in the graphic's clear window, indicating that the Return Flow Controller is in the Bag Load position. (See Figure 1-23.)

8 **Prime Mode Position Indicator** – when the flow control handcrank **(9)** is at the clockwise stop, this graphic aligns with the return flow indicator, indicating that the Return Flow Controller is in Prime Mode position. (See Figure 1-23.)

9 **Flow Control Handcrank** – used to place the Return Flow Controller in the Bag Load and Prime Mode positions and to set the return flow rate. (See Figure 1-23.)

10 **Bag Mounting Plate** – plate in top section of Return Flow Controller on which the Single-Needle bag lies after it is inserted into the Return Flow Controller.

11 **Bag Locator Pin** – pin on bag mounting plate **(10)** over which the locator hole in the Single-Needle bag (Figure 1-15) is placed.

12 **Bag Alignment Block** – the two Single-Needle bag (Figure 1-15) 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 Single-Needle Return Flow Controller is required to run Single-Needle procedures. Do not attempt to install (activate) and run a Single-Needle procedure without a Return Flow Controller and the appropriate disposables.

Figure 1-22. Return Flow Controller Symbol Translation

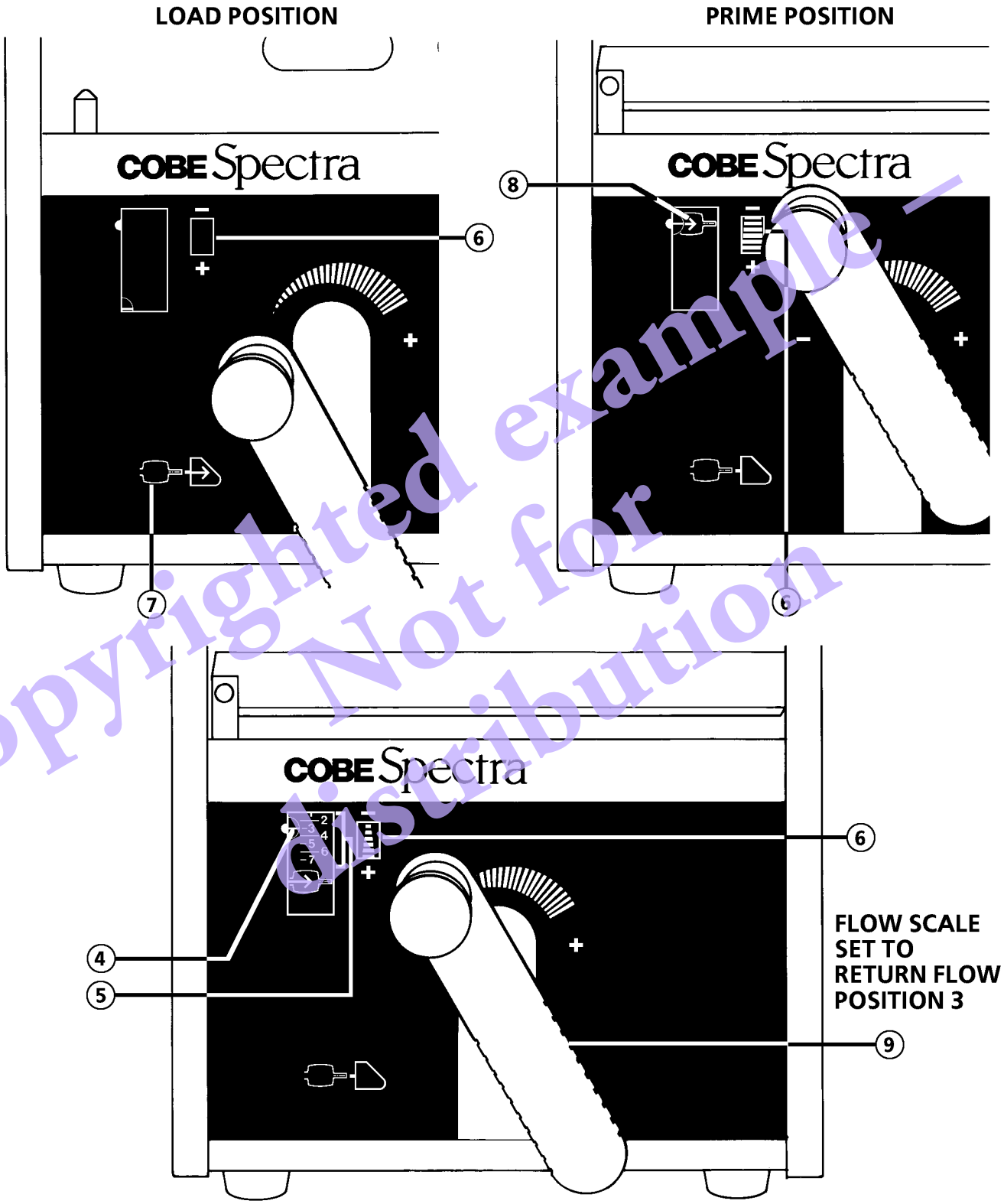

Figure 1-23. Control Indicators on Return Flow Controller

FUNCTIONAL DESCRIPTION

SEPARATION

The Spectra Apheresis System uses a centrifugal method to separate whole blood into its major components: erythrocytes (red cells), leukocytes (white cells including PBSC), 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. For therapeutic plasma and red blood cell exchange procedures, appropriate replacement fluid is combined with the returned components.

Anticoagulated whole blood is pumped into the channel while the channel is rotating clockwise in the centrifuge. This causes the component of highest density (red 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, depending on the procedure performed.

The inlet and collection chambers are separated in the channel. There is one inlet tube that delivers anticoagulated whole blood into the channel. In the TPE and red blood cell exchange (RBCX) channels, there are two tubes for removing components. The tube for removing cellular components extends to the outer wall and the tube for removing plasma is located at the inner wall. However, in a platelet/AutoPBSC or WBC channel, there are four tubes extending into appropriate areas of the channel. The red cell tube reaches to the outermost wall of the channel, the plasma tube is located at the innermost wall, and the collect and interface control tubes are placed in between where the red cell/plasma interface is located. The interface refers to the thin line (where the separated white cells or platelets are located) between the separated packed red cells and the plasma.

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

SATURATED FLUIDIZED PARTICLE BED SEPARATION

The collect pump directs platelet-rich plasma and the few remaining white cells from the second stage of the channel into the LRS Chamber. White cells are separated from platelets based on the fluid dynamics of the conical separation chamber, the sedimentation velocity of the platelet and white cell components, and the plasma flow rate through the separation chamber. These dynamics result in an advancing platelet bed, that upon saturation traps white cells in lower levels of the LRS Chamber. Platelets exit to the collect storage bags.

FLUID FLOWS

Fluid flows are controlled by the four variable-speed peristaltic pumps on the front panel (Figure 1-19):

- The AC pump controls the flow of anticoagulant from the AC container to the inlet line. For WBC granulocyte (PMN) removal procedures, it pumps a prescribed hydroxyethyl starch/sodium citrate solution to the inlet line.

- The INLET pump controls the flow of whole blood plus anticoagulant from the donor/patient access into the centrifuge.

- The function performed by the PLASMA/RED BLOOD CELL pump depends upon the apheresis procedure in process:

  – For ELP, AutoPBSC, LRS, TPE, and WBC procedures, it recombines the plasma separated by the centrifuge with cellular components for return to the donor or patient. (When concurrently collecting plasma, it pumps plasma to the collect bag.) For AutoPBSC procedures, it is used during the Harvest Phase.

  – For TPE procedures and ELP, AutoPBSC, or LRS procedures involving concurrent plasma collection, it directs the plasma separated by the centrifuge to a plasma collect bag(s).

  – For RBCX procedures, it controls the flow of separated red blood cells, directing them from the centrifuge to a collect bag(s).

- The COLLECT/REPLACE pump controls the flow of components being removed or replaced.

  – For ELP, AutoPBSC, LRS, and WBC procedures, it directs the platelets or PBSC being collected and WBCs being removed to a collect bag(s). In AutoPBSC procedures, it is used during the Harvest and Chase Phases to recirculate fluids through the RBC Reservoir.

  – For TPE and RBCX procedures, it delivers the appropriate replacement fluid.

For Dual-Needle procedures, when you use the Spectra keyboard to enter a pump flow rate, you are entering the actual flow rate for that pump for the current procedure. An exception occurs during Dual-Needle procedures when the high flow configuration is set to "on." During the portion of such Dual-Needle high-flow procedures when the red blood cell/plasma interface is being established, the inlet flow rate is limited to 45 ml/min. Also, for 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 Spectra establishes a stable interface. For more information on the high blood flow configuration, see **High Flow Configuration** subsection of the **SETTING CONFIGURATION VALUES** section of this INTRODUCTION.

Note: For AutoPBSC procedures, only the inlet flow rate can be changed.

On the other hand, for Single-Needle procedures, when you enter a pump flow rate, you are entering the average flow rate for that pump for the current procedure. At any specific instant during a procedure, the instantaneous flow rate for a specific pump can be faster or slower than the average flow rate. The average flow rate is the average of the pump speeds of the draw and return phases.

When you enter a pump flow rate for a Single-Needle procedure, you may occasionally find that the Spectra system tells you that the flow rate you entered was too high. The system does this by either providing an alarm or lowering the flow rate that you entered. It will not always be obvious why the entered 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 may be due to a variety of factors:

- The system limits average inlet flow rates to 65 ml/min for Single-Needle ELP and Single-Needle LRS procedures and to 60 ml/min for Single-Needle TPE procedures.

- The Return Flow Controller's maximum return pressure of 450 mmHg for Single-Needle ELP and Single-Needle LRS and 400 mmHg for Single-Needle TPE procedures limits the return flow rate during Single-Needle procedures.

- The Single-Needle draw phase's instantaneous inlet flow rate is limited to 100 ml/min for Single-Needle ELP and Single-Needle LRS and 150 ml/min for Single-Needle TPE procedures.

For more information on Single-Needle flow control, see the **SINGLE-NEEDLE FLOW CONTROL** section in APPENDIX C – MANUAL AND AUTOMATIC OPERATION.

The upper limits on the average inlet flow rate of 65 ml/min for Single-Needle ELP and LRS procedures and of 60 ml/min for Single-Needle TPE procedures mean that, under certain circumstances, Single-Needle procedures can take longer than comparable Dual-Needle procedures to process the same amount of blood. However, as Dual-Needle inlet flow rates increase 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 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:

$$80/65 = 1.23$$

SYSTEM COMPONENTS

Blood tubing and separation channels form the extracorporeal circuit to and from the donor/patient. The tubing configuration minimizes extracorporeal blood volume. Each disposable and its accompanying channel holds less than 280 milliliters of whole blood equivalent. The AutoPBSC disposable has been designed to hold a minimal extracorporeal volume of less than 165 ml for use with pediatric patients. During Single-Needle procedures, the draw cycle can add up to 100 milliliter maximum to the extracorporeal volume. The blood tubing is arranged on the front panel of the Spectra Apheresis System. The channels are placed in the centrifuge chamber. The Spectra system is designed to perform various procedures by utilizing different disposables.

In addition to housing the four pumps, which control fluid flow, the front panel also contains valves and sensors. (See Figure 1-19.) There are five valves:

- The WASTE DIVERT valve is a pinch-type valve that

  – Passes air from the air chambers into the waste bag.

  – Allows the air chambers to be automatically primed.

  – Diverts prime saline to the waste bag at the beginning of a procedure.

- The PLASMA/RBC valve is a pinch-type valve.

  – For ELP, AutoPBSC, LRS, and WBC procedures, its Return position recombines the plasma flow with cellular components for return to the donor or patient.

  - For TPE procedures and ELP, AutoPBSC, or LRS procedures involving concurrent plasma collection, its Collect position directs the plasma flow to a plasma collect bag(s).

  - For RBCX procedures, its Collect position directs the red blood cell flow to a red blood cell collect bag(s).

- The COLLECT/REPLACE valve is a pinch-type valve.

  - Its Collect position is used for cell collection during ELP, AutoPBSC, LRS, and WBC procedures.

  - Its Return position is used to return red blood cells back to the donor when a red cell spillover occurs during an ELP, AutoPBSC, or LRS procedure, which protects the platelet or PBSC product from red blood cell contamination. During an AutoPBSC procedure, the Return position sends platelets back to the patient/donor.

  - Its Open/Load position allows the Spectra system to deliver appropriate replacement fluid during TPE and RBCX procedures.

- The RBC/PLASMA LINE valve is a pinch-type valve in the same housing as the RBC detector. It closes during Prime to allow air to be pulled out of the channel and closes during the Rinseback mode to collapse the channel.

- The RETURN LINE valve is a solenoid, fail-safe clamp that

  - Closes if air is detected in the return air chamber.

  - Closes during power interruptions and some other alarm conditions.

  - Closes during the draw phase and opens during the return phase of each Single-Needle cycle.

  - Closes during the Harvest Phase in an AutoPBSC procedure.

The Spectra system has six safety sensors on its front panel:

- The ACCESS and RETURN PRESSURE sensors are diaphragm-type sensors that monitor pressure and turn off the pumps if the pressure exceeds safety limits. During Single-Needle procedures, the RETURN PRESSURE sensor also measures the pressure in the Single-Needle bag.

- The INLET and RETURN AIR detectors stop the pumps and close the RETURN LINE valve when they detect air in the inlet or return air chamber.

- The RBC detector is located in the same housing as the RBC/PLASMA LINE valve. It determines when blood has replaced saline at the beginning of a procedure and stops the diversion of inlet flow to the waste bag so that blood components are not lost. If more than 120 milliliters of inlet volume for ELP and LRS procedures or more than 150 milliliters of inlet volume for all other procedures have been processed, the RBC detector will be overridden. Then the WASTE DIVERT valve will automatically close and the RETURN LINE valve will automatically open. The RBC detector is inactive during RBCX procedures.

- The AC LEVEL detector is located on the left vertical segment of the IV pole. It triggers an operator warning when the anticoagulant container becomes empty.

A control panel (Figure 1-20) is attached to an arm that extends from the top of the Spectra front panel. (See Figure 1-1.) It consists of a keyboard and display screen, which are an integral part of the Spectra alarm system. The following alarm indicators, located on the control panel, alert you when an alarm condition occurs:

- Red alarm or yellow warning LED flashes.
- Audio alarm sounds.
- Alarm message displays on the screen.

When an alarm condition occurs, the system automatically stops its pumps (Pauses the system) and, if necessary, stops the centrifuge or closes the RETURN LINE valve. Less severe conditions (warnings) do not cause the system to shut down. For additional information on the Spectra alarms and warnings, the conditions that may have caused them, and how to troubleshoot/remove those conditions, see SECTION 11 – TROUBLESHOOTING.

In addition to giving alarm information, the screen displays messages that prompt you to input donor/patient data. The microprocessor utilizes this input to calculate the flow and speed parameters that will automatically control separation. Information on flow rates, centrifuge speed, volumes processed, and procedure time appears on the display screen. The display keys and miscellaneous keys are used to adjust parameters and define steps in the procedure for Manual operation. See APPENDIX A – KEYBOARD SELECTIONS and APPENDIX B – DATA INPUT LIMITS for additional information.

AUTOMATIC AND MANUAL OPERATION

The Spectra Apheresis System is capable of operating under Automatic or Manual control. Typical operation is in the Automatic mode where initial values of pump and centrifuge speed are defined automatically to separate components. In this mode, you have the opportunity to adjust the inlet pump flow rate while automatically maintaining the dilution ratio (whole blood plus anticoagulant to anticoagulant); proper plasma, collect, and replace flow rates; and correct centrifuge speed. It is always possible to override the Automatic control. Under the Manual mode, all flow rates and speeds (including anticoagulant and centrifuge) are adjustable. For additional information on the Automatic and Manual modes of operation, see APPENDIX C – MANUAL AND AUTOMATIC OPERATION.

If Manual mode is entered during an LRS procedure, white cell and platelet levels of the product should be verified by appropriate measurement techniques.

ANTICOAGULATION

BACKGROUND

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, and LRS procedures.

ACD-A is the approved anticoagulant for the COBE Spectra Apheresis System for ELP and LRS procedures and the preferred anticoagulant for therapeutic plasma exchange, red blood cell exchange, and WBC removal procedures. A suggested procedure when heparin must be used in anticoagulation for therapeutic plasma exchange is provided in SECTION 10 – HELPFUL HINTS. For granulocyte (PMN) removal, hydroxyethyl starch/sodium citrate concentrate should be used as the anticoagulant.

The Spectra system controls the AC pump flow rate in order to establish the rate at which anticoagulant returns to the donor or patient. The incidence of symptomatic hypocalcemia is related to the flow rate of ACD-A as well as the donor's or patient's "size" or, more correctly, total blood volume. Therefore, the Spectra system asks for information about the donor's or patient's sex, height, and weight to determine the total blood volume, which is the unit of measure used by the Spectra system for the donor's/patient's "size". Using the configured rate of ACD-A infusion (ml of AC/min/liter of total blood volume) to the donor or patient, the Spectra system then calculates the amount of anticoagulant removed with the plasma and sets the ACD-A pump flow rate appropriately for the size of the donor or patient.

SYSTEM OPERATION

The AC infusion rate is based upon the concept that a donor's or patient's ability to metabolize ACD-A is directly related to that individual's total blood volume. Therefore, the COBE Spectra Apheresis System maintains a constant infusion rate of anticoagulant per minute per liter of total blood volume. Refer to Figure 1-24 to see the relationships between donor/patient variables and other variables such as AC pump flow rate, AC infusion rate, AC infusion rate configuration, inlet/AC ratio, and inlet flow rate.

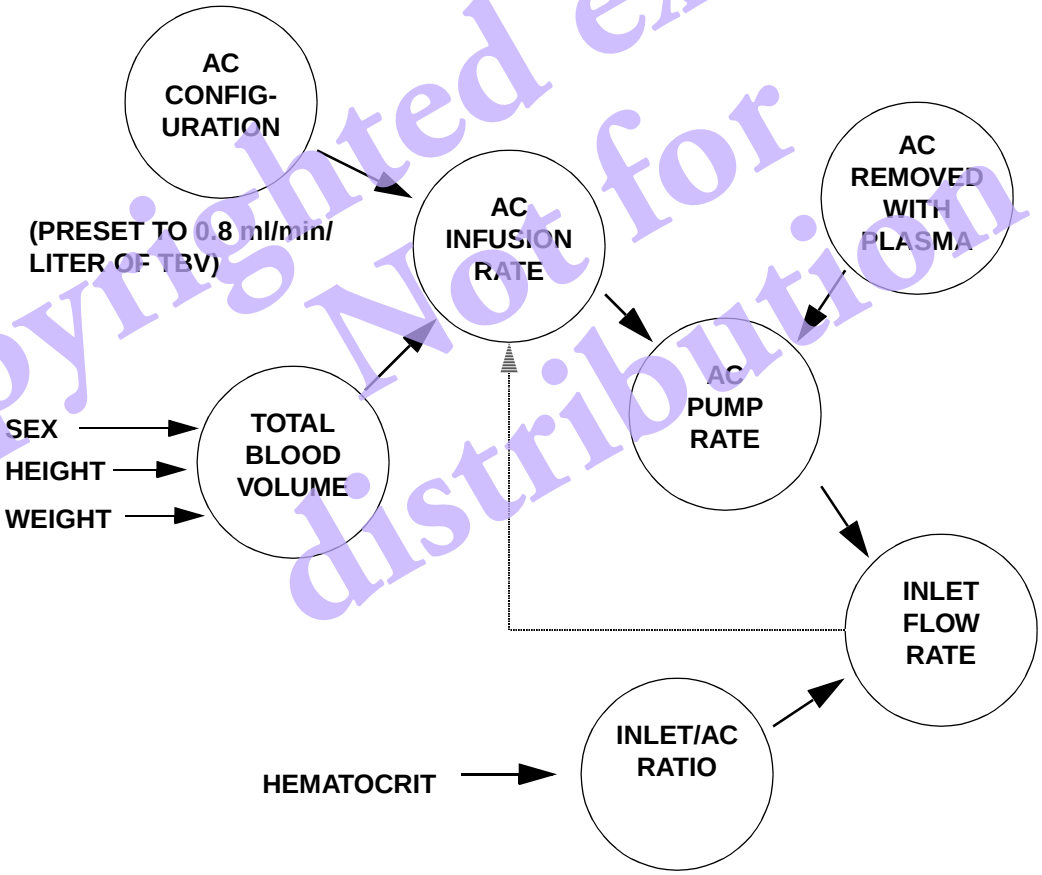

Figure 1-24. Donor/Patient Data Calculations

As indicated in Figure 1-24, the Spectra system first calculates the total blood volume based upon the sex, height, and weight entered as donor or patient data. The AC infusion rate to the donor or patient is then calculated using the total blood volume and the AC infusion rate configuration value that has been programmed into the system. The default value for the AC infusion rate configuration is 0.8 ml/min/liter of TBV. At the direction of the medical director, the AC infusion rate configuration can be changed to a value between 0.8 and 1.2 ml/min/liter of TBV. For additional information on the AC infusion rate configuration, see the **Configuration of AC Infusion Rate** subsection of the **SETTING CONFIGURATION VALUES** section later in this INTRODUCTION.

For example:

Total Blood Volume X AC Configuration = AC Infusion Rate

5 liters X 0.8 ml/min/liter TBV = 4.0 ml/min

NOTE

The Nadler and Allen formula (shown here in metric and English units) for total blood volume is as follows:

Females: 183 + [356 x Height^3 (meters)] + [33.1x weight (kg)] = TBV in mls
Males: 604 + [367 x Height^3 (meters)] + [32.2 x weight (kg)] = TBV in mls

Females: 183 + [0.005835 x Height^3 (inches)] + [15 x weight (lbs)] = TBV in mls
Males: 604 + [0.006012 x Height^3 (inches)] + [14.6 x weight (lbs)] = TBV in mls

Any direct changes you make to the inlet flow rate change the AC infusion rate. By increasing the inlet flow rate, you can increase the AC infusion rate to 1.2 ml/min/liter of TBV for all procedures except RBCX procedures and to 1.4 ml/min/liter of TBV for RBCX procedures. If you increase the inlet flow rate to the point that the AC infusion rate would exceeds 1.2 or 1.4 ml/min/liter of TBV, the “AC infusion rate exceeds allowable limits” alarm occurs. For TPE procedures, you may continue to run in a “yellow” warning state at an AC infusion rate greater than 1.2 ml/min to accommodate certain medical situations, such as infusion of calcium gluconate. See SECTION 11 – TROUBLESHOOTING for details on the “AC infusion rate exceeds allowable limits” alarm.

To deliver anticoagulant at the rate initially prescribed, as in the example above, the Spectra system calculates the amount of anticoagulant removed with the plasma in the collection bags. The AC pump flow rate is set so that the amount of anticoagulant removed to the collection bags subtracted from the AC pump flow rate is the AC infusion rate to the donor or patient.

In ELP and LRS procedures, the Spectra system then calculates an inlet/AC ratio to

- Keep the blood from clotting during separation and collection
- Establish a pH and ionized calcium environment that keeps the platelets from clumping
- Establish the initial pH necessary for appropriate extended life storage of platelets

In ELP and LRS procedures, the donor’s hematocrit is used to calculate the inlet/AC ratio, which is the ratio between inlet flow rate and AC flow rate. (If custom ratio is utilized, the inlet/AC ratio is determined by the custom settings.) The inlet/AC ratio varies with the hematocrit because the pH buffering capabilities of the blood in an extracorporeal circuit is directly related to the blood’s hematocrit.

NOTE

The inlet/AC ratio configuration can be changed at the request of the medical director. Refer to the **Configuration of Inlet/AC Ratio** subsection of the **SETTING CONFIGURATION VALUES** section later in this INTRODUCTION. All other Spectra procedures have a default inlet/AC ratio that remains the same for each procedure.

A combination of the AC pump rate and inlet/AC ratio is then used to calculate the inlet flow rate. Therefore, the inlet flow rate will be different for each individual donor or patient. See the following example:

AC Pump Rate X (Inlet/AC Ratio) = Inlet Flow Rate

Example: *5 ml/min X 9/1 = 45 ml/min*

When plasma is collected concurrently with platelets during ELP and LRS procedures, more blood can be processed, which increases the platelet yield by 5% to 20%. The amount of blood processed is increased because some of the ACD-A added to the donor's inlet flow is removed to the plasma collect bag, and, as discussed above, the Spectra system calculates the amount of ACD-A in the plasma collect bag. Because some of the ACD-A is removed, the donor's inlet flow rate and, consequently, the total amount of blood processed can be increased without an equivalent increase in the rate of ACD-A flow back to the donor. When you select to collect plasma concurrently with platelets, the Spectra system automatically increases the inlet flow rate based on both the donor data you have entered and the amount of ACD-A removed to the plasma collect bag.

ANTICOAGULATION MANAGEMENT

The use of ACD-A as an anticoagulant in apheresis can cause symptomatic hypocalcemia in certain patients or donors. Mild forms of this condition are generally recognized by peripheral paresthesia, tingling sensations in the extremities, and/or restlessness. Severe forms of this condition can result in significant cardiac dysfunction. Because of these possibilities, COBE BCT recommends that the condition of the donor or patient be assessed frequently throughout the apheresis procedure.

When symptomatic hypocalcemia occurs, pause the machine and notify the physician. The inlet flow rate should be decreased if the run is continued. In this case, the inlet/AC ratio will be maintained and the AC flow rate will decrease. This will effectively lower the infusion rate of anticoagulant to the individual and, thus, should alleviate the symptoms. If decreasing the inlet flow rate does not alleviate hypocalcemic symptoms, the procedure should be stopped and appropriate medical treatment should be prescribed.

CAUTION

Patients or donors with impaired or abnormal citrate and/or calcium metabolism (e.g., liver and renal diseases) may present an increased risk of citrate sensitivity. For this reason, the attending physician should assess appropriateness of such patients or donors for apheresis and prescribe how they should be monitored.

Occasionally, during donor platelet collection, patient platelet depletion, and WBC removal procedures, you may observe clumping in the collect line. This may be alleviated by decreasing the inlet/AC ratio slightly, for example, from 9:1 down to 8.5:1. The Spectra system will respond by decreasing the inlet flow rate, thus providing more citrate per volume of extracorporeal blood while maintaining the rate at which the anticoagulant is returned to the donor/patient. There is no increased risk of hypocalcemia because of this change, but by providing more citrate to the circuit per volume of blood, the pH and ionized calcium environment will be modified, helping to alleviate clumping. See APPENDIX C – MANUAL AND AUTOMATIC OPERATION for information on changing the inlet/AC ratio. Platelet clumping in the collect line caused by a high concentration of platelets may also be alleviated by increasing the collect pump flow rate from, for example, 1.0 ml/min to 2.0 ml/min.

SETTING CONFIGURATION VALUES

The following 13 parameters may be set by pressing the MENU ON/OFF key and choosing Configuration (which is Selection 6). These 13 parameters are independent of one another. Changes to the parameters always affect the current procedure immediately except configuration of procedure end points, which will affect the next run only. See the sections of APPENDIX A – KEYBOARD SELECTIONS that discuss the Configuration Selection Messages for information on how to set these configurable parameters.

CONFIGURATION OF HEIGHT/WEIGHT UNIT

A configuration selection is provided to allow the medical staff using the Spectra system to use either English or metric (centimeters, kilograms) values when entering donor and patient height and weight.

CONFIGURATION OF DECIMAL POINT/THOUSANDS SEPARATOR

A configuration selection is also provided to allow the medical staff to choose between using the period as the decimal point and comma as the thousands separator or using the comma as the decimal point and period as the thousands separator when entering values via the Spectra keypad.

CONFIGURATION OF AC INFUSION RATE

The AC infusion rate is the amount of anticoagulant delivered to the donor/patient based on total blood volume. During manufacturing, the AC infusion rate for ELP, AutoPBSC, and LRS procedures is set to a default value of 0.80 ml/minute/liter of TBV. This rate was chosen to reduce the risk of hypocalcemic reactions resulting from a drop in the donor's/patient's plasma ionized calcium. The AC infusion rate can be increased from the default value of 0.80 ml/min/liter of TBV up to a maximum of 1.10 ml/min/liter of TBV.

Increasing the AC infusion rate will increase the amount of blood processed and, therefore, increase the platelet yield during platelet collection procedures for an equivalent process time. However, this may increase the hypocalcemic symptoms in the donor. Medical directors need to set this value based upon their own requirements for managing donor reactions and platelet yields.

CONFIGURATION OF TOTAL PLASMA REMOVED DURING PLATELET COLLECTIONS

The total volume of plasma removed is the number of milliliters of plasma that the Spectra system is allowed to remove from a donor during a platelet or PBSC collection procedure. The system provides configuration selections to control either:

- The maximum total volume of plasma removed (collected plasma and plasma in cell collect bags combined) OR
- The volume of plasma removed as a percentage of the donor's total blood volume. The default percentage is 12% of total blood volume. You can enter a value between 1% and 15%.

The volume of plasma removed is set initially at a maximum of 600 ml for donors who weigh more than 175 pounds (or 80 kg) and at a maximum of 500 milliliters for donors who weigh less than 175 pounds (or 80 kg). The Spectra system provides configuration selections to change the maximum number of milliliters to values between 10 and 1500 ml. The donor weight that will trigger a warning when the maximum number of milliliters of plasma is reached may also be changed. The allowable donor weight range is 0 to 500 pounds (0 to 230 kg).

When setting new parameters for plasma collect, the Spectra system will automatically prompt you for all three of the following values:

- First bracket: The upper limit of plasma collected for donors who weigh more than the donor weight indicated on this message.
- Second bracket: The amount of plasma permissible if the donor weighs less than the weight set on this message.
- Third bracket: The donor weight that determines which plasma volume to collect.

Pressing the ENTER key saves the values in the brackets. You can only move forward from this set of three messages by pressing ENTER after the third (donor weight cutoff) message. When you press ENTER at this point, you will be returned to the message you were at originally.

For normal donor collections, the maximum volume of plasma removed must be set in compliance with local regulations and applicable standards. It is the responsibility of the physician in charge to prescribe the plasma collection configuration.

NOTE

The Spectra system calculates the amount of anticoagulant removed with the plasma so that maximum volume of plasma collected represents actual plasma volume without anticoagulant.

CONFIGURATION OF PROCEDURE END POINTS

Configuration Selection Messages in APPENDIX A allow you to set end points for Spectra ELP, LRS, TPE, and MNC apheresis procedures.

For ELP and LRS Procedures

Spectra systems are shipped with a default end point of 100-minute target time for ELP and LRS procedures. For LRS procedures, the actual run time may be up to 4 minutes less depending on collect pump flow rates, which are automatically managed by the system throughout the procedure. A Configuration Selection Message allows you to change this default target time to a value between 10 and 999 minutes.

For AutoPBSC Procedures

Spectra systems are shipped with a default end point of 2.0 X TBV for AutoPBSC procedures. A Configuration Selection Message allows you set a default end point for AutoPBSC procedures based on run time, inlet volume, or number of total blood volumes to be processed.

For TPE Procedures

The total number of plasma volumes to exchange during a therapeutic plasma exchange procedure should be prescribed by the physician in charge.

The Spectra system is programmed during manufacture to allow 1.0 plasma volume to be exchanged. This value can be modified to a value between 0.2 and 5.0 plasma volumes in the Configuration Selection Messages.

A Configuration Selection Message allows you to set a default end point for TPE procedures based on the number of total plasma volumes to be exchanged when the procedure ends. (Total plasma volume) = (Total Blood Volume) x (1 – Hct).

For MNC Procedures

Spectra systems are shipped with a default end point of 2.0 X TBV for MNC procedures. A Configuration Selection Message allows you to set a default end point for MNC procedures based on run time, inlet volume, or number of total blood volumes to be processed.

For RBCX, PMN, and BMP Procedures

Configuration cannot be changed for these procedures.

CONFIGURATION OF INLET/AC RATIO

ELP and LRS Procedures

The COBE Spectra Apheresis System provides the physician with three range options for automatic setting of the inlet/AC ratios (inlet flow rate/AC flow rate) during ELP and LRS procedures and a custom option. All three range options are based on the donor's hematocrit, as shown in the following table:

INLET/AC RATIO AS A FUNCTION OF HEMATOCRIT AT SPECIFIC INLET/AC RATIO CONFIGURATION SELECTIONS

Hematocrit	Low Inlet/AC Ratio	Medium Inlet/AC Ratio (1.33 X "Low")	High Inlet/AC Ratio (1.67 X "Low")
35	8.2	10.9	13.7

INLET/AC RATIO AS A FUNCTION OF HEMATOCRIT AT SPECIFIC INLET/AC RATIO CONFIGURATION SELECTIONS

40	7.3	9.7	12.2
45	6.6	8.8	11.0
50	6.0	7.9	10.0

Higher ratios allow either *more blood to be processed* per unit of time for a constant AC infusion rate or *less AC infusion to the donor* per unit of time for a constant volume of blood processed.

You can also define a custom inlet/AC ratio. The “Custom” option allows you to set the default inlet/AC ratio from 2:1 to 50:1 and to specify as many as three ratio changes to occur at pre-determined transition times during a procedure. You can divide the ELP and LRS procedures into a maximum of four time segments and specify an inlet/AC ratio for each segment. For example:

time:	0	+ 10	+ 30	+ 40 . . . end
ratio:	6.5	8.0	10.0	13.0

The above settings tell the Spectra system to use a ratio of 6.5 for the first 10 minutes (first transition time), a ratio of 8.0 for the next 30 minutes (second transition time), a ratio of 10.0 for the following 40 minutes (third transition time), and a ratio of 13.0 for the remainder of the procedure.

If you enter a 0 for any transition time, the Spectra system assigns a 0 to any remaining transition times and uses the last-assigned inlet/AC ratio during all remaining time. To prevent incorrect time entries, you cannot edit any time segments that follow a 0 time entry.

During the procedure, the ratio automatically changes to the new value at the preset transition time. The Spectra system reports the new ratio on the Run screen. The inlet flow rate increases or decreases with a higher or lower ratio; the AC infusion rate remains constant.

During a procedure, you can modify the inlet/AC ratio by using the INLET/AC RATIO key. The modified value replaces the Custom default value for the current time segment.

When it is necessary to modify a configuration value, it should be done between procedures. The inlet pump flow rate should be decreased to manage the AC flow rate in response to an anticoagulant reaction during a procedure. The inlet/AC ratio should be reduced directly in response to platelet clumping during a procedure.

For ELP and LRS procedures, the default inlet/AC ratio set by COBE BCT during manufacturing is the medium inlet/AC ratio in the table above. This ratio can be altered by selecting the low, high, or custom inlet/AC ratio using the Configuration Selection Messages in APPENDIX A.

NOTE

For Platelet depletion procedures, the default inlet/AC ratio is 6:1.

For TPE Procedures

The default factory-set inlet/AC ratio for TPE procedures is 10:1. This default ratio can be altered to a value between 2:1 and 50:1 by using the Configuration Selection Messages in APPENDIX A.

For AutoPBSC Procedures

The default factory-set inlet/AC ratio for AutoPBSC procedures is 12:1. This default ratio can be altered to a value between 2:1 and 50:1 by using the Configuration Selection Messages in APPENDIX A.

For MNC Procedures

The default factory-set inlet/AC ratio for MNC procedures is 12:1. This default ratio can be altered to a value between 2:1 and 50:1 by using the Configuration Selection Messages in APPENDIX A.

For PMN Procedures

The default factory-set inlet/AC ratio for PMN procedures is 13:1. This default ratio can be altered to a value between 2:1 and 50:1 by using the Configuration Selection Messages in APPENDIX A.

During any of the above procedures, you may select an inlet/AC ratio other than the configured or default ratio by pressing the INLET/AC RATIO key and entering an inlet/AC ratio between 2:1 and 50:1. Under most circumstances, changes you make to the inlet/AC ratio will change the inlet pump flow rate only; the AC pump flow rate will remain the same. If the change to the inlet/AC ratio is large enough, the AC pump flow rate will change to maintain a constant AC infusion rate. If the inlet flow is maximized (that is, set at 65 ml/min for Single-Needle platelet procedures) and the inlet/AC ratio is increased, the AC pump flow rate will decrease to maintain the requested inlet/AC ratio. **The decision to change the default ratios should be made by the medical staff based on their requirements for the apheresis procedures and products.**

CONFIGURATION OF HARVEST VOLUME (AutoPBSC PROCEDURES ONLY)

A configuration selection is provided to allow the operator to set the amount of cellular volume that is collected each harvest. The range is 1-5 mL. Decreasing this setting will decrease RBC contamination of the product but may reduce the amount of MNCs and PBSCs collected as well. The total collect volume for each cycle is equivalent to Harvest Volume plus Chase Volume.

CONFIGURATION OF CHASE VOLUME (AutoPBSC PROCEDURES ONLY)

A configuration selection is provided to allow the operator to set the default plasma volume used each cycle to chase harvested cells into the collect bag. The range is 2-20 mL. In order to ensure the maximum amount of cells reach the collect bag, the minimum Chase Volume setting is 2 mL. The lower this setting, the lower the total collect volume. The total collect volume for each cycle is equivalent to Harvest Volume plus Chase Volume.

CONFIGURATION OF HIGH FLOW

During high inlet flow (over 45 ml/min) Dual-Needle ELP procedures, setting the high flow configuration to “on” guards against red cell spillover into the platelet collection chamber while the red blood cell/plasma interface is being established. It does this by employing an algorithm to allow the interface to stabilize before running over 45 ml/min. The high flow configuration is factory set to “on.” The high flow option is automatically disabled during LRS procedures.

CONFIGURATION OF CENTRIFUGE STEP DOWN

During Dual-Needle ELP procedures, use of centrifuge step down will decrease the centrifuge speed in stages as the run time increases for procedures with inlet flow rates less than 40 ml/min. At these lower flow rates, centrifuge step down improves platelet yields. Centrifuge step down is disabled automatically at inlet flow rates above 40 ml/min and during LRS procedures. See the table in **Centrifuge Step Down Selection Message** subsection of the **Option 6 – First Configuration Selection Message** section of APPENDIX A – KEYBOARD SELECTIONS for the specific centrifuge step down speeds. Spectras are shipped from the factory with step down enabled. The step down option is disabled during an LRS procedure.

CONFIGURATION OF SINGLE-NEEDLE OPTION

Spectra systems that are shipped with the Single-Needle Option come with the Single-Needle software present but not activated. The Single-Needle Option Configuration allows you to activate the Option when you are ready to begin running Single-Needle ELP and LRS procedures and TPE procedures. It remains activated until you use the Single-Needle Option Configuration to deactivate it.

CONFIGURATION OF LRS (LEUKOREDUCTION SYSTEM) ENABLING SCREEN

NOTE

The LRS Enabling Screen is unique to Version 5.1 Software for the COBE Spectra Apheresis System and is not available in Software Versions 4.0 – 4.9 and lower for the COBE Spectra Apheresis System.

Press “MENU, 6, ENTER, ENTER” to arrive at the LRS Enabling Screen. If yield calibration is enabled, the following message is displayed:

```
Configuration:  1=high flow, 2=step down
3=Single Needle, 4=LRS, 5=yield cal.
```

If yield calibration is not enabled, the following message is displayed:

```
Configuration:  1=high flow, 2=step down
3=Single Needle, 4=LRS
```

The LRS Enabling Screen will always be shown as selection four in the configuration section. Select “LRS” (Option 4 in the previous screens). When “LRS” is selected, one of the following messages is displayed:

```
Enable LRS                  1=YES,  2= NO
(currently NOT enabled)
```

or

```
Enable LRS                  1=YES,  2= NO
(currently enabled)
```

This screen displays a variable message with a default of NOT enabled. If the operator selects “1” for yes, then the message, “currently enabled”, is displayed and the LRS selection will appear in the ELP section of the set selection screens. If the operator selects “2” for no, then the message, “currently NOT enabled”, is displayed and the LRS selection will not appear on the ELP set selection screens and therefore LRS procedures are NOT enabled.

CONFIGURATION OF YIELD CALIBRATION

Yield configuration allows you to enter Yield Scaling Factors (YSFs) for platelet yield and CCM yield predictions to bring the Spectra yield values closer to actual laboratory counts. This adjustment is made for each individual Spectra system. To determine YSFs, you must use the formulas given in the COBE Spectra Yield Scaling Factor (YSF) Worksheet, available from COBE BCT. The YSF for both platelet yield prediction and CCM prediction is factory set to 1.00.