Spectra Optia® Apheresis System

Operator's Manual

TERUMOBCT

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Contents

1

Preface

About This Operator's Manual

This manual contains information and instructions on how to safely operate, transport, troubleshoot, and maintain the Spectra Optia® Apheresis system. **You should read and understand the information in this manual before using the system**.

Conventions Used in this Manual

This manual uses certain conventions to help you identify the tasks that you must perform. The conventions are described below.

Numbered Steps

All step-by-step instructions are numbered and the numbers appear in bold, as shown in the following example:

1 Unpack the system from the shipping container.

When steps are numbered, the sequence in which they are performed is important. Always perform the steps in the order presented.

Touch screen buttons

Many of the steps instruct you to touch a button on the screen. The text on the button appears in bold, as shown in the following example:

1 Touch **Confirm**.

Bullets

Bullets (•) are used to indicate items in a list.

Warnings, Cautions, and Notes

The following examples show how warnings, cautions, and notes appear in this document:

Warning: Warnings alert the operator of serious hazards, consequences, or conditions that are likely to result in a harmful reaction, trauma, or death to the patient or operator.

Caution: Cautions alert the operator to the possibility of a problem with the device associated with its use or misuse. This includes device malfunction, failure, and damage to the device or other property.

Note: Notes emphasize important details.

Spectra Optia Apheresis System

Intended Use

The Spectra Optia Apheresis System, a blood component separator, may be used to perform the following therapeutic apheresis, cell collection, and cell processing procedures*:

- Therapeutic plasma exchange
- Therapeutic plasma exchange with a secondary plasma device
- Red blood cell exchange, depletion, and depletion/exchange
- Mononuclear cell collection from the peripheral blood
- Granulocyte collection from the peripheral blood
- White blood cell depletion
- Platelet depletion
- Processing of harvested bone marrow

*Procedure availability varies by country.

Contraindications for Use

Leukocytapheresis is contraindicated in AML FAB M3 (APL) because of the accompanying disseminated intravascular coagulation. (Vahdat L, et al., “Early mortality and the retinoic acid syndrome in acute promyelocytic leukemia: impact of leukocytosis, low-dose chemotherapy, PMN/RAR-alpha isoform and CD13 expression in patients treated with all-trans retinoic acid.” Blood 1994; 84: 3843-3849. Daver, et al., “Clinical characteristics and outcomes in patients with acute promyelocytic leukaemia and hyperleucocytosis.” British Journal of Haematology 2015, 168, 646-653.)

Other contraindications for the use of the Spectra Optia system are limited to those associated with the infusion of solutions and replacement fluids as required by the apheresis procedure, and those associated with all types of automated apheresis systems.

Warnings and Cautions for Use

Below is a complete listing of warnings and cautions that apply to the use of the Spectra Optia system and the Seal Safe system. Although the information may also appear in other sections of this manual, the operator should read and understand the information in these lists before using the system.

Some of the warnings or cautions may instruct you to contact Terumo BCT. Customers in the U.S. should contact Terumo BCT Customer Support. Customers outside the U.S. should contact their local Terumo BCT representative.

Warnings for Use

System warnings

1. DANGER: Do not use the Spectra Optia system in an explosive atmosphere.
2. To avoid possible patient injury or loss of life, use only operating procedures published by Terumo BCT.
3. Terumo BCT will not be responsible for patient safety if the procedures to operate the Spectra Optia system are other than those specified by Terumo BCT. Individuals performing the procedures must be appropriately trained and qualified.

4 Use only the filler and the tubing sets that Terumo BCT manufactures for the Spectra Optia system.

5 The manufacturer, assembler, installer, or importer regards itself as responsible for effects on the safety, reliability, and performance of the device, only if the device is employed in accordance with the instructions for use.

6 The Spectra Optia system can interfere with EKG monitoring when a patient is simultaneously undergoing apheresis and EKG monitoring.

7 The Spectra Optia system alarms are inactive when the system is turned off.

Service warnings

8 To avoid possible patient injury or loss of life, use only maintenance procedures published by Terumo BCT.

9 Terumo BCT will not be responsible for patient safety if the procedures to maintain and calibrate the Spectra Optia system are other than those specified by Terumo BCT. Individuals performing the procedures must be appropriately trained and qualified.

10 Only a qualified service representative should perform equipment modifications. Any modifications must be approved in writing by Terumo BCT.

11 Turn off the system before cleaning or disinfecting to prevent possible electrical shock or damage to the equipment.

12 The power cord should be unplugged from the wall to isolate the device from the power supply before servicing. Do not position the device to make it difficult to unplug the power cord.

13 Only a qualified service representative should service or repair the Spectra Optia system.

14 When cleaning and disinfecting equipment surfaces that might have been exposed to blood, take adequate precautions to prevent possible exposure to and transmission of infectious diseases.

Electrical warnings

15 All electrical installations must comply with all applicable local electrical codes and Terumo BCT's specifications.

16 To avoid the risk of electric shock, plug the system into a properly installed, three-wire, grounded electrical receptacle that is protected by an approved branch circuit overcurrent protection and disconnection device. The branch circuit protection and disconnection device must be located away from, but close enough to, the system so that the system can be easily disconnected from the main power supply if the centrifuge malfunctions.

17 Non-medical electrical equipment connected to the Ethernet connection should not be located within the patient environment. The definition of "patient environment" can be found in the IEC standard 60601-1 Edition 3.1, definition 3.79.

18 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). The installer of accessory equipment is responsible for the integrated medical system compliance with requirements of IEC 60601-1 Edition 3.1. If you are in doubt, contact your Terumo BCT service representative.

General procedural warnings

19 Do not connect the patient before the system instructs you to do so.

20 Rigorous attention should be paid to proper venipuncture site selection and decontamination.

21 It is advisable to obtain the patient's detailed drug history before each apheresis procedure. For those drugs potentially affected by apheresis procedures, the physician should either adjust the doses or give the medications immediately after the procedure.

22 To avoid potential side effects and complications during apheresis, patients taking angiotensin-converting enzyme (ACE) inhibitors should discontinue these medications before the procedure. The patient's attending physician should prescribe and supervise this and any medication change before apheresis.

23 The operator must verify the correct input of information relevant to the safety of each apheresis procedure.

24 When preparing to perform a procedure, ensure that the lines are connected to the correct fluids, and that fluid is flowing into the drip chambers:

- AC line (orange) to the anticoagulant container
- Saline line (green) to the saline (0.9%) container

25 Check that the tubing is correctly loaded in all pumps before starting a procedure. Visually inspect each pump to ensure that tubing does not protrude.

26 Before starting a procedure, inspect all lines, especially those in the centrifuge and on the front panel, to ensure that they are not obstructed. Tubing that is occluded or mechanically constrained can lead to malfunction or fluid imbalance. Inlet and return lines perform without difficulty as long as the interior diameter of the tubing is larger than the interior diameter of the patient's inlet and return access.

27 Residual ethylene oxide (EO) found within a Spectra Optia system tubing set may cause allergic, including anaphylactoid and anaphylactic, reactions. The Spectra Optia system allows you to rinse the tubing set with saline solution when you are concerned about hypersensitivity reactions associated with the residual EO, which is a result of sterilization. This option is available to select before you connect the patient. Refer to "Selecting and Performing a Custom Prime" on page 79 for instructions on performing a saline rinse.

28 Only blood or blood products should be processed in the centrifuge.

29 If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

30 When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

31 Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

32 Monitor the return line for air. If you see air in the line, go to the operation status screen, touch **Remove Air From Return Line**, and follow the instructions on the screen.

33 Before connecting the patient, ensure that the AC line contains anticoagulant at the inlet manifold.

34 The inlet and return pressure sensors are not intended to detect infiltrations of the vein. Monitor the patient for infiltrations.

35 Tubing sets may occasionally fail, which could result in the loss of blood, blood products, or the introduction of air into the tubing set. It is very important that the operator watch for leaks in the cassette, all tubing and welds, and in the channel while the set is in use. Operators should take adequate precautions in handling blood and blood products in accordance with their facility's standard operating procedures.

36 When handling extracorporeal blood circuits, take adequate precautions to prevent the possible exposure to and transmission of infectious diseases.

37 You must completely close the inlet saline line when the system instructs you to do so. If the line is left open, the additional saline will dilute the blood in the channel, which could result in an ineffective procedure.

38 The following can cause fluid imbalance:

- Administration of replacement fluid that is not at room temperature during a procedure
- Use of improperly vented fluid containers
- Equipment malfunction
- Improperly clamped or closed lines, or improperly loaded valves
- Use of inadequately primed or clotted filters on the replace line of the Exchange Set
- Tubing that is incorrectly loaded in the pumps

39 The alarm system is inactive during a manual rinseback. If you must perform a manual rinseback, watch for air in the return line. If you see air, immediately discontinue the rinseback.

40 Do not apply excess pressure to the vent bag when pushing fluid from the reservoir to the patient during a manual rinseback or you could damage the red blood cells that you are returning to the patient.

41 Do not continue to squeeze the vent bag after the fluid in the reservoir reaches the level of the reservoir filter during a manual rinseback. If you continue to squeeze the bag, you could deliver air to the patient.

42 Do not touch **Unload** to unload the tubing from the pumps or remove the tubing set when a patient is connected to the Spectra Optia system, or the patient may receive surplus fluids through the inlet and return lines.

43 All used disposable materials should be considered hazardous, and should be handled and disposed of at the end of the procedure in accordance with all applicable regulations.

44 Turn off the system before cleaning to prevent possible electrical shock or damage to the equipment.

Exchange procedure warnings

45 Platelets are removed with red blood cells during a red blood cell exchange (RBCX) procedure. The approximate percentage of platelets removed depends on the number of total blood volumes (TBV) processed, as shown in the table below. It is the physician's responsibility to determine the appropriate treatment for the patient.

TBV Processed	Percentage Platelets Removed (Approximate)
0.5	39
1.0	63
1.5	78
2.0	86

46 Terumo BCT does not recommend performing rinseback during RBCX procedures. The data that the system uses to predict the run targets does not include rinseback volume. If rinseback is performed, the run targets may not be accurate.

47 Before performing a therapeutic plasma exchange procedure with a secondary plasma device (TPE-SPD procedure), carefully review the instructions for use provided by the manufacturer of the secondary plasma device.

48 Some secondary plasma devices can leach small amounts of potentially toxic substances to patients and must be flushed before use. Flush the device according to the manufacturer's instructions to ensure patient safety.

49 Some secondary plasma devices can remove significant quantities of plasma-circulating proteins, including important clotting factors and albumin. The attending physician should evaluate each patient and prescribe replacement proteins, if appropriate.

50 If a TPE-SPD procedure is being performed on a patient who has a TBV of 1 liter or less, Terumo BCT recommends that the treated plasma bag and the AC container be weighed throughout the TPE-SPD procedure to assess and manage the fluid balance.

Collection and depletion procedure warnings

51 Platelets are collected with target cells during continuous mononuclear cell collection (CMNC) procedures, granulocyte (PMN) collection procedures, and white blood cell depletion (WBCD) procedures. If the initial platelet count is low and the patient is not properly managed, excessive platelet depletion can occur.

52 Red blood cells (RBC) are collected with target cells during granulocyte (PMN) collection procedures, white blood cell depletion (WBCD) procedures, and platelet depletion (PLTD) procedures. If the procedure is not properly monitored, excessive RBC depletion may occur. To monitor excessive RBC depletion, consider testing the patient's hematocrit throughout the run.

53 Do not use a blood warmer on the replace line during a white blood cell depletion (WBCD) procedure or a platelet depletion (PLTD) procedure. Using a blood warmer on the replace line slows the flow of replacement fluid into the reservoir, affecting the system's management of the fluid balance.

54 During collection and depletion procedures, the operator must monitor the plasma line for hemolysis. The RBC detector is not used to monitor the plasma line during these procedures. If hemolysis occurs that is not related to the patient's condition, the operator should consider consulting the physician to determine whether or not to continue the procedure and perform rinseback.

55 Before using a granulocyte-colony stimulating factor (G-CSF) or other agents to prepare the patient for a procedure performed on the Spectra Optia system, consult the manufacturer's package insert for potential contraindications and adverse events.

General tubing set warnings

56 **Do Not Reuse/Not for Reuse**: Terumo BCT, Inc.(Terumo BCT Ltd) products bearing the "Do Not Reuse" symbol are intended for single use only and are not intended to be reused or re-sterilized in any manner. Terumo BCT cannot ensure the functionality or sterility of the product if it is reused or re-sterilized.

Reuse of a single-use product could result in:

- Product performance issues due to a loss of product integrity, including but not limited to the following:
  - Fluid leaks
  - Parts that are warped or deformed
  - Plastics that are brittle and discolored
  - Filters that have reduced filtration capabilities
- Exposure to excessive ethylene oxide (EO) residuals
- Viral infections such as hepatitis or human immunodeficiency virus (HIV)
- Bacterial infections
- Cross-contamination

Any of these risks could result in serious injury or death. These risks are shared by product users, donors, patients, and recipients of end products of the device.

57 Terumo BCT, Inc. (Terumo BCT Ltd.) products bearing the DEHP symbol contain phthalates (DEHP). Whole blood donors are not exposed to DEHP; the potential health risk to apheresis donors is low, because the time-averaged DEHP dose exposure is very low. Patient groups that include pregnant or nursing women and children are considered to be the most at risk to potential harmful effects of exposure to DEHP. However, regulatory bodies have noted that the benefit of doing a needed procedure is far greater than the risk associated with exposure to DEHP. It is the responsibility of the treating physician to balance this risk for the patient.

Accessory set warnings

58 Use only the Spectra Optia BMP Accessory Set when performing a BMP procedure on the Spectra Optia system. The system's performance has not been validated using other accessories.

Fluid warnings

59 When using biologically-derived replacement fluids, closely monitor the patient for reactions.

60 Use only the fluids specified in this manual when performing procedures on the Spectra Optia system. Using a fluid with a different composition or concentration could cause hemolysis.

61 Before using hydroxyethyl starch (HES) for a procedure performed on the Spectra Optia system, consult the manufacturer's package insert for potential contraindications and adverse events.

Seal Safe system warnings

62 Use only the sealer head and radio frequency (RF) cable provided by Terumo BCT with the Seal Safe system. The Seal Safe system does not function correctly with components from other tubing sealers.

63 Do not seal the tubing within 8 cm (3 in) of the needle, or you may cause a burn at the needle entry point.

64 Do not place your fingers within 2.5 cm (1 in) of the Seal Safe system's sealing jaw, or you may receive a radio frequency (RF) burn.

65 Do not release the lever of the sealer head until after the indication light goes out. Releasing the lever sooner could result in an inadequate seal.

66 Ensure that the sealer head and the tubing are free of moisture and debris before using the Seal Safe system.

67 Moisture on the surface of the tubing or the sealer head may cause an electrical arc to occur between the jaws when the power is applied, terminating the sealing process. If an arc occurs, carefully inspect the seal to ensure it is satisfactory.

68 Ensure that there is no tension on the tubing when operating the Seal Safe system. Stretching the hot tubing could cause a leak.

69 Do not submerge the Seal Safe system in liquid or you may receive an electric shock.

70 Disconnect the sealer head from the RF cable before cleaning to avoid receiving a serious radio frequency (RF) burn during the cleaning process.

71 The jaw on the sealer head contains an indentation where the spring rests. If you do not properly seat the spring in the indentation after cleaning, you may damage the spring, which could cause inadequate tubing seals.

72 Do not open the sealer head to service the device or you may receive an electric shock. Contact a qualified service representative to service the device.

Cautions for Use

System cautions

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

2 Each operator should be thoroughly familiar with the Spectra Optia system's operating instructions before using the system. All procedures should be performed by qualified medical personnel under the supervision of a physician.

3 The Spectra Optia system and the Seal Safe system comply with all relevant international standards concerning electromagnetic emissions and compatibility. Before undergoing apheresis, patients with active implantable medical devices should review the implant manufacturer's instructions for any cautions or contraindications concerning the use of and/or proximity to devices that emit electromagnetic energy. Examples of active implantable devices include cardiac pacemakers and cardioverter defibrillators, cochlear implants, vagus nerve stimulators, and devices that stimulate the peripheral or central nervous systems. This caution also extends to other devices that may be connected to the patient such as ECG equipment and infusion systems. Care should be taken to prevent the Seal Safe system from touching the patient or any cables of the devices that may be connected to the patient.

4 Do not use the Spectra Optia system under any of the following conditions:

- Power cords, plugs, or receptacles are damaged or worn.
- Switches are loose.
- System has received a physical shock, or liquid has spilled on the electronics housed under the cover.
- Anyone has received an electrical shock while using the system.
- System appears to be overheating.

5 Keep hair, fingers, clothing, and other articles away from pumps and valves to avoid entanglement.

6 Do not put open containers containing fluid on the device. Fluid spills can contribute to electrical and mechanical hazards.

7 To avoid damage to the Spectra Optia system, do not operate the centrifuge without a filler installed or before loading the channel.

8 Before installing a filler or loading a tubing set, inspect the filler and visible interior of the centrifuge chamber for fluid spills or structural damage. Ensure the metal band around the perimeter of the filler is centered and secure.

9 To avoid damage to the centrifuge and the filler, do not operate the centrifuge if the filler latch is not lowered and locked in place. Ensure that the filler cannot be pulled off the gear train without unlocking and raising the filler latch.

10 To avoid personal injury or damage to the system, use proper lifting techniques when lifting the Spectra Optia system.

11 Ensure that the wheel pedal is pressed to the right side (locked position) and the rear wheel brake levers are locked during procedures, so that the Spectra Optia system does not move.

12 When the wheel pedal is not in the locked position (pressed to the right side) and the rear wheel brake levers are released, ensure at least one person is in continuous contact with and controls the movement of the Spectra Optia system.

13 Only perform procedures when the system is on a smooth, dry, level surface.

14 Do not leave the device unattended in a traffic area.

15 In the event of a prolonged power interruption, the use of an uninterruptible power supply (UPS) may allow the operator to discontinue the procedure and perform rinseback. However, a UPS does not ensure that the operator can complete the procedure as intended.

16 When using the Spectra Optia system with another device, consult the device manufacturer's instructions for use for any precautions or contraindications for using the device in proximity to equipment that emits electromagnetic energy.

17 The use of cables other than those specified by Terumo BCT could result in improper function of the Spectra Optia system.

18 Portable RF communications equipment including peripherals, such as antenna cables and external antennas, should be located no closer than 30 cm (12 in) from any part of the Spectra Optia system including cords, or the system may not perform properly.

Service cautions

19 Clean the Spectra Optia system using a mild, non-abrasive cleaning solution or a mild detergent. Industry standard practice defines mild cleaning solution and mild detergent as a solution or detergent that is safe on skin and on washable surfaces, such as dishwashing liquid. Use of a solution that is not compatible with the materials on the system may damage the material or operating characteristics of the system.

20 Disinfect the Spectra Optia system using a disinfecting solution that is compatible for use on the system. Use of a disinfecting solution that is not compatible could damage the material or operating characteristics of the system.

21 Use only a gauze pad, a lint-free cloth, or a wipe when cleaning or disinfecting the touch screen, the covers on the AIM system lights in the centrifuge, and the aperture plate on the filler. Use of an abrasive brush, scrub material, or a sharp object can damage the surface of the components.

22 To avoid damaging the touch screen, do not douse the touch screen with fluid or leave fluid on the screen after cleaning or disinfecting the screen. Always dry the screen with a gauze pad or a clean cloth after exposing it to fluid.

23 Terumo BCT has validated the methods described in this manual for cleaning and decontaminating the Spectra Optia system. Before using an alternative method, verify that it will not damage the system.

24 Do not lubricate pumps or pump rotors for any reason.

General procedural cautions

25 The Spectra Optia system has many safety features. However, a patient reaction can occur rapidly. Therefore, it is imperative that the operator monitor the patient and the system throughout the procedure.

26 The physiological condition of patients may affect the outcomes of procedures performed on the Spectra Optia system.

27 Patients with impaired or abnormal citrate metabolism (for example, if the patient has liver or renal disease) may present an increased risk of citrate sensitivity. Attending physicians should assess the appropriateness of such patients for apheresis procedures and prescribe how they should be monitored during procedures.

28 Use aseptic technique throughout all procedures to ensure patient safety or product quality.

29 Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit.

30 The higher the inlet:AC ratio used during the procedure, the greater the risk is for platelet aggregates and clots to form in the tubing set.

31 For patient comfort and optimal system operation, ensure that the fluids used during the procedure are at room temperature before connecting them to the tubing set.

32 Before loading the tubing set, confirm that the filler that is installed is the correct filler for the procedure. Using the incorrect filler will compromise the performance of the system and the outcome of the procedure.

33 Do not connect the fluids to the tubing set before the system instructs you to do so.

34 To avoid a failed test of the tubing set, do not raise and lower the cassette after there is fluid in the set.

35 Handling and transfusion of blood products should be conducted in accordance with applicable standards and regulations, and performed under the direction of a licensed physician.

36 If you leave the roller clamp on the saline line completely open when the patient is connected, you will quickly infuse a large volume of saline to the patient.

37 Before using the injection port on the inlet line to infuse medication to the patient during a procedure, you must pause the system or the medication will be pumped into the extracorporeal circuit instead of to the patient.

38 If you use the injection port on the return line to infuse fluid or medication, monitor the patient for hypervolemia. The Spectra Optia system cannot account for the additional volume of fluid infused through the injection port.

Collection and depletion procedure cautions

39 When transferring plasma from the plasma bag to the collection bag during an MNC collection procedure, you must put the collection bag lower than the plasma bag as indicated in the instructions on the screen. Otherwise, cells in the collection bag can flow into the plasma bag.

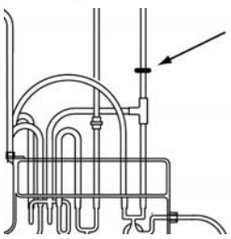
40 Confirm that the bone marrow has been filtered to remove clots, bone chips, and debris before transferring it into the BMP bag of the BMP Accessory Set. The bone marrow must be adequately filtered before processing to reduce the risk of obstructing the tubing set.

41 Ensure that the bone marrow is adequately anticoagulated before processing. Inadequate anticoagulation causes clumping and can result in decreased cell recovery.

42 Ensure that the bone marrow is at room temperature before processing. If the bone marrow is cold, it will not adequately separate in the tubing set channel, and the system performance may be compromised.

43 If you leave the roller clamp on the saline line completely open when the BMP bag is connected, you will quickly infuse a large volume of saline into the bag.

44 When performing a collection procedure using the Collection Set or the IDL Set, seal the collect line above the T-shaped connector to the plasma line as shown in the illustration below. If you seal the collect line below the connector, the cells in the collection bag could flow back into the tubing set when the system raises the cassette.



45 When using hydroxyethyl starch (HES) during a procedure, you must add 46.7% trisodium citrate solution to the HES for anticoagulation. Failure to use the correct solution can result in inadequate anticoagulation of the extracorporeal circuit, ineffective sedimentation and collection of cells, and adverse patient reactions.

46 If hydroxyethyl starch (HES) is not used during a PMN collection procedure, the collection efficiency will be lower.

47 If you use a low inlet pump flow rate during a CMNC procedure, it will take the system longer to process the required volume to establish the interface and to collect the target cells. Be aware of how this is relevant to a patient with a small total blood volume. Also, try to avoid conditions that will cause a delay in establishing the interface, such as pump pauses.

General tubing set cautions

48 The blood and fluid pathways of the tubing set are sterilized with ethylene oxide and are nonpyrogenic. Do not use the set if any of the following conditions are true:

- Severe kinks in the tubing are apparent, such that the interior diameter of the tubing is smaller than the interior diameter of the patient's inlet or return access.
- Tubing set appears to be incorrectly assembled.
- Tubing set is damaged.
- Any clamps are closed on the lines.
- End caps on the lines of the tubing set are missing when you open the package.

49 You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.

50 Do not stretch the tubing when folding the channel to install it in the centrifuge to avoid damaging the tubing set.

51 Use only your fingers to load the channel into the filler. To avoid puncturing the channel, never use a sharp object.

52 Do not seal the inlet line of the four-lumen tubing. Sealing the line could cause the tubing set to fail when you raise the cassette to unload the set.

53 Ensure all luer connections are secure.

54 To prevent port damage, do not use a needle or a blunt cannula to access the needleless injection port.

55 Use only standard luer connection devices to access the needleless injection ports; non-standard syringes or connectors can damage the needleless injection port. A standard luer connector must conform to the harmonized standards ISO 594-1 or ISO 594-2. Syringes and male luer connectors have a large variety of configurations and can vary significantly in design and dimensions.

56 To prevent damage to the needleless injection port housing, do not overtighten the connector. Do not use any instruments to tighten the connection.

Exchange Set cautions

57 Do not remove the cap on the unused luer on the second remove line on the remove bag to prevent fluid leakage. Ensure the cap fits tightly.

Collection Set cautions

58 The Collection Set is no longer considered functionally closed if any of the following conditions are true:

- Inlet needle is not connected.
- First attempt to insert the inlet needle fails (unless you attach a new needle using a connection device that maintains the sterility of the tubing set).
- Inlet needle is disconnected during the procedure.
- If using the diversion bag to collect a blood sample, the sample is taken before the line to the bag is sealed.
- Injection port on the inlet line is accessed.
- Product bag or the diversion bag is disconnected before the line to the bag is sealed.
- Product sample is removed from the sample bulb before you permanently seal the line.
- Sterile barrier filters are damaged.
- Integrity of the tubing set is compromised for any reason.

59 To correctly lock the needle protector over the inlet needle, you must hold it in place while you pull the tubing to remove the needle. It will not lock if you use the wings of the needle or the body of the needle protector to remove the needle. After use, visually confirm that the needle protector is locked over the needle and that the wings are secured behind the locked prongs.

IDL Set cautions

60 The IDL Set is no longer considered functionally closed if any of the following conditions are true:

- Inlet needle is not connected.
- First attempt to insert the inlet needle fails (unless you attach a new needle using a connection device that maintains the sterility of the tubing set).
- Inlet needle is disconnected during the procedure.
- If using the diversion bag to collect a blood sample, the sample is taken before the line to the bag is sealed.
- Injection port on the inlet line is accessed.
- Frangible connector on the replace line is broken for any reason.
- Product bag or the diversion bag is disconnected before the line to the bag is sealed.
- Product sample is removed from the sample bulb before you permanently seal the line.
- Sterile barrier filters are damaged.
- Integrity of the tubing set is compromised for any reason.

61 To correctly lock the needle protector over the inlet needle, you must hold it in place while you pull the tubing to remove the needle. The needle protector will not lock if you use the wings of the needle or the body of the needle protector to remove the needle. After use, visually confirm that the needle protector is locked over the needle and that the wings are secured behind the locked prongs.

Fluid cautions

62 Hydroxyethyl starch (HES) is not approved or available for use in some countries for apheresis procedures. Check your country regulations before you consider using HES for a procedure on the Spectra Optia system.

Seal Safe system cautions

63 The Spectra Optia system and the Seal Safe system comply with all relevant international standards concerning electromagnetic emissions and compatibility. Before undergoing apheresis, patients with active implantable medical devices should review the implant manufacturer's instructions for any cautions or contraindications concerning the use of and/or proximity to devices that emit electromagnetic energy. Examples of active implantable devices include cardiac pacemakers and cardioverter defibrillators, cochlear implants, vagus nerve stimulators, and devices that stimulate the peripheral or central nervous systems. This caution also extends to other devices that may be connected to the patient such as ECG equipment and infusion systems. Care should be taken to prevent the Seal Safe system from touching the patient or any cables of the devices that may be connected to the patient.

64 Use the Seal Safe system only on tubing distributed by Terumo BCT. The Seal Safe system may not perform as expected on other tubing.

65 To avoid possible damage to the Seal Safe system, always disconnect the sealer head and the RF cable before transporting the Spectra Optia system.

Service Information

Terumo BCT or its subsidiaries will not be responsible for the safety, reliability, or performance of this equipment unless:

- Operational procedures, calibration, and repairs are carried out by appropriately qualified persons.
- All equipment modifications are authorized in writing by Terumo BCT and performed by appropriately qualified persons.
- The electrical installation of the relevant room complies with all applicable local electrical codes and IEC requirements.
- The equipment is used in accordance with the published instructions for use.

Detailed service information for this equipment, including schematic diagrams and recommended service procedures, is available from your Terumo BCT representative.

Special Use of Additional Equipment and Devices During Apheresis Procedures

You may require one or more of the following items to complete an apheresis procedure using the Spectra Optia system:

- Blood/fluid warmer (used for patient comfort but has no impact on the performance of the device)
- Fluids such as saline solution, anticoagulant solution, and replacement fluid

For instructions on how to safely use the additional items with the Spectra Optia system, refer to the guidelines provided by the device or fluid manufacturer.

Fluids Administered During Apheresis Procedures

This section includes descriptions of fluids that may be used during apheresis procedures on the Spectra Optia system. Before use, verify that the fluid has not expired by checking the expiration date printed on the package. Do not use the item if the current date is past the expiration date.

Saline Solution

Use sterile 0.9% sodium chloride injection to prime the tubing set and to perform the procedure.

Anticoagulant

ACD-A

Each 100 mL of ACD-A contains 2.2 g sodium citrate hydrous, 730 mg citric acid anhydrous, and 2.45 g dextrose hydrous.

Citrate toxicity

ACD-A can cause citrate toxicity in certain patients. 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. Terumo BCT recommends that you frequently assess the condition of the patient throughout the apheresis procedure.

Hydroxyethyl Starch (HES)

HES is a sedimenting agent that causes RBC to separate more efficiently from granulocytes during a collection procedure. When using HES, you must add trisodium citrate to the HES for anticoagulation.

Replacement Fluids

Careful selection and use of appropriate replacement fluids contributes to the maintenance of the patient's plasma oncotic pressure and blood pressure. During TPE and depletion procedures, the patient response to decreasing blood viscosity and plasma protein levels may vary and be difficult to predict. In addition, non-target cells may be depleted and may require replacement. Therefore, the physician should prescribe the type and volume of replacement fluid used. The prescription should consider the patient's fluid status, protein balance, and other pertinent factors that the physician believes could affect the patient's condition.

Adverse Events of Apheresis Procedures

Be aware of possible patient reactions to apheresis procedures, and be prepared to take appropriate action should any reactions occur. Some previously reported reactions are:

- Anxiety
- Headache
- Light-headedness
- Digital and/or facial paresthesia
- Fever
- Chills
- Hematoma
- Hyperventilation
- Nausea and vomiting
- Syncope (fainting)
- Urticaria
- Hypotension
- Allergic reactions
- Infection
- Hemolysis
- Thrombosis in patient and device
- Hypocalcemia
- Hypokalemia
- Thrombocytopenia
- Hypoalbuminemia
- Anemia
- Coagulopathy
- Fatigue
- Hypomagnesemia
- Hypogammaglobulinemia
- Adverse tissue reaction
- Device failure/disposable failure
- Air embolism
- Blood loss/anemia
- Electrical shock hazard
- Fluid imbalance
- Inadequate separation of blood components

Reactions to Blood Products Transfused During Procedures

Reactions to transfused blood products can include fever, circulatory overload, shock, allergic reactions, alloimmunization, transfusion-related acute lung injury (TRALI), and graft-versus-host disease (GVHD), as well as transmission of infectious diseases and bacteria. (Sources: *Circular of Information for the Use of Human Blood and Blood Components*, AABB, et al, ed., April, 2006; *Guide to the preparation, use and quality assurance of blood components*, 10th Edition, Council of Europe Publishing; Blood. Toy P et al., "Transfusion-Related Acute Lung Injury: Incidence and Risk Factors." *Blood*, 2012; 119: 1757-1767.)

Disposal of Infectious and Non-Infectious Waste

Follow your local regulations for disposing of material that may be contaminated with biohazardous products.

Return of Used Product

If for any reason this product must be returned to Terumo BCT, Inc., a returned goods authorization (an RGA number) is required from Terumo BCT prior to shipping.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number, may be obtained from the Terumo BCT Quality Assurance Department.

IT IS THE RESPONSIBILITY OF THE HEALTH CARE INSTITUTION TO ADEQUATELY PREPARE AND IDENTIFY THE PRODUCT FOR RETURN SHIPMENT.

Please contact your local representative for information regarding returned goods and product complaints.

2

Introduction

Spectra Optia System Description

The Spectra Optia Apheresis System is a transportable, automatic blood component separator that uses centrifugation and optical detection (Automated Interface Management system or AIM system) to perform therapeutic apheresis and cell collection procedures.

The Spectra Optia system's touch screen interface enables the operator to communicate with the system. The operator follows the instructions on the screen to enter patient data and procedure data, load and prime the tubing set, and perform and troubleshoot procedures. The system displays detailed information about the procedure, so that the operator can adjust the run values to achieve a specific outcome or troubleshoot a condition. After the procedure is complete, the system provides a report of procedure data for the patient record.

Table 2-1 lists the procedures that are available on the system and the procedure abbreviations that appear on the bottom of the screens. The abbreviation appears after you select the procedure.

Table 2-1: Spectra Optia system procedures and procedure abbreviations

Procedure	Procedure Abbreviation
Therapeutic plasma exchange	TPE
Therapeutic plasma exchange with a secondary plasma device	SPD
Red blood cell exchange	RBCX
Mononuclear cell collection	MNC
Continuous mononuclear cell collection	CMNC
Granulocyte collection	PMN
White blood cell depletion	WBCD
Platelet depletion	PLTD
Bone marrow processing	BMP

Spectra Optia System Components

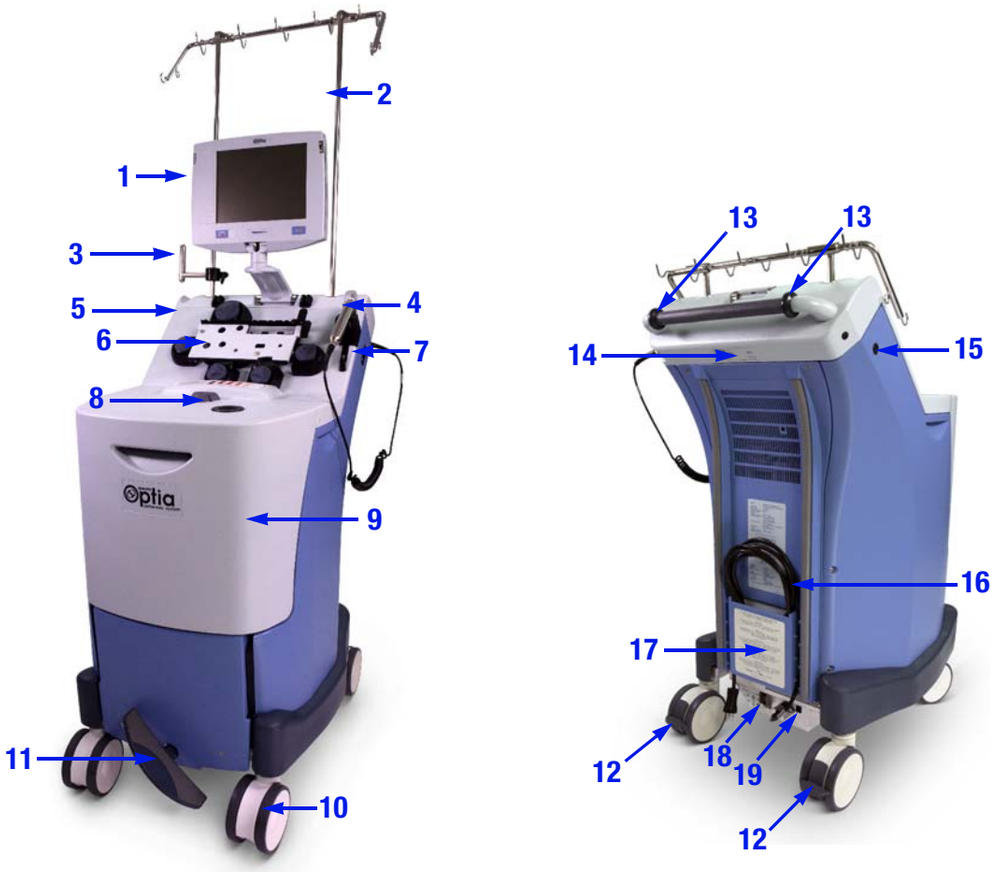


Figure 2-1: Spectra Optia Apheresis System front and back views

Table 2-2: Spectra Optia system components

	Component	Function
1	Monitor with touch screen	Allows you to communicate with the system.
2	Dual IV pole	Has hooks for hanging bags and containers. You can adjust the height of the pole for transporting the device, or to hang and remove bags.
3	Accessory bracket	Can be used to hold an additional device used during an apheresis procedure, such as a blood warmer or an infusion pump.
4	Seal Safe system	Used to seal the lines of the tubing set. The system generates a radio frequency (RF) electromagnetic field between the jaws of the sealer head to seal the tubing.
5	Front panel	Holds the pumps, valves, sensors, and detectors.
6	Cassette tray	Holds the tubing set cassette in place.
7	Power switch	Allows you to turn power to the system on and off.
8	View port	Allows you to look through the centrifuge door to see the interface in the channel.
9	Centrifuge door	Allows access to the centrifuge chamber.

Table 2-2: Spectra Optia system components (continued)

	Component	Function
10	Wheels	Allow you to move and transport the system.
11	Wheel pedal	Allows you to secure the front wheels in a forward position to facilitate control when moving the device. Also allows you to lock the wheels in place so that the system does not roll.
12	Rear wheel brake levers	Allow you to lock the rear wheels in place to prevent the machine from moving.
13	Handle wheels	Help to move the system when it is in a horizontal position.
14	System serial number	Unique number used to identify the system.
15	IV pole release button	Allows you to raise and lower the IV pole by pressing the button.
16	Power cord	Connects the system to a power source.
17	Power cord holder	Secures the power cord during transport and storage.
18	Circuit breaker	Protects the device from electrical damage by monitoring the current and shutting of the flow of power if the current gets too high.
19	Ethernet port	Allows you to connect the system to an external device to export data or to print a procedure report.

Note: Spectra Optia system operators are allowed to remove the system components listed below. All other components must be removed by a qualified service representative.

- Pump rotors
- Tubing set
- Filler
- Seal Safe system sealer head and RF cable
- Accessory bracket
- Power cord and power cord clamp
- Ethernet cable, if used

Front Panel

The front panel of the Spectra Optia system holds the pumps, sensors, and valves that are used to perform an apheresis procedure. The components of the front panel are shown in Figure 2-2, and are described in Tables 2-3 through 2-5.

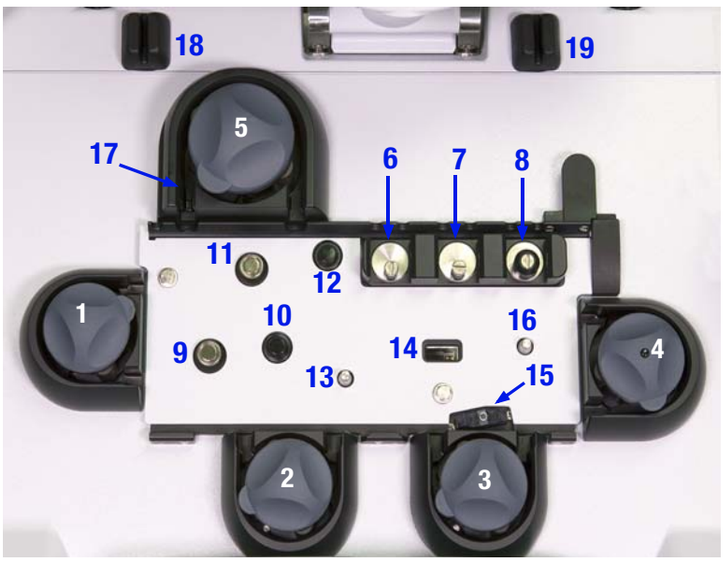


Figure 2-2: Front panel components (cassette tray shown in the lowered position)

Pumps

Table 2-3: Pumps

	Pump	Function
1	AC (anticoagulant) pump	Pumps anticoagulant from the AC container into the inlet line.
2	Inlet pump	Pumps anticoagulated blood from the patient into the channel.
3	Plasma pump	Pumps plasma out of the channel.
4	• Replace pump (exchange) • Collect pump (collection, depletion) (Pump has a black dot on the pump rotor.)	• Exchange procedures: Pumps replacement fluid out of the fluid container and into the reservoir. • Collection and depletion procedures: Pumps the targeted component out of the channel or the chamber and into the collection bag or the reservoir.
5	Return pump	Pumps the contents of the reservoir to the patient.

Valves

Table 2-4: Valves

	Valve	Function
6	RBC valve	Directs the flow of red blood cells from the channel.
7	Plasma valve	Directs the flow of plasma from the channel.
8	• Remove valve (exchange) • Collect valve (collection, depletion)	Directs the flow of the separated blood components pumped from the channel.

Sensors and detectors

Table 2-5: Sensors and detectors

	Sensor/Detector	Function
9	Inlet pressure sensor	Monitors negative pressure in the inlet line to ensure that adequate inlet pressure is maintained.
10	Low-level reservoir sensor	Monitors the volume of fluid in the reservoir, and ensures that air does not enter the return line.
11	Return pressure sensor	Monitors positive pressure in the return line to ensure that the correct level of return pressure is not exceeded.
12	High-level reservoir sensor	Monitors the volume of fluid in the reservoir to help control the volume of fluid in the tubing set.
13	Centrifuge pressure sensor	Monitors pressure in the channel and lines in the centrifuge to ensure that the correct level of pressure is not exceeded.
14	Barcode reader	Reads the tubing set identification number on the cassette to ensure that the correct tubing set is loaded for the procedure selected.
15	RBC detector	• Exchange procedures: Detects red blood cells in the plasma line. • MNC collection procedures: Detects red blood cells in the collect line.
16	• Plasma pressure sensor (exchange) • Collect pressure sensor (collection, depletion)	• TPE with a secondary plasma device (SPD) procedures: Monitors pressure in the plasma line. • Collection and depletion procedures: Monitors pressure in the collect line.
17	Return line air detector (Detector is a component of the return pump.)	Monitors air in the return line. Signals the system if the patient has excess air in circulation.
18	AC fluid detector	Detects fluid in the anticoagulant (AC) line. Signals the system if the line contains air instead of fluid.
19	Replacement fluid detector	Exchange and depletion procedures: Detects fluid in the replace line. Signals the system if the line contains air instead of fluid.

Return line air detector

The return line air detector is an ultrasonic detector located in the return pump that detects air in the return line. If the volume of air detected exceeds what is safe for the patient to have in circulation, the return line air detector

signals the system and an alarm occurs. Follow the instructions on the alarm screens to perform an air removal to remove the air from the line.

During an air removal the system pumps 18 mL of saline into the return line to flush the fluid in the line into the reservoir and the air into the vent bag. The total volume of saline delivered to the patient for the air removals performed is displayed on the operation status screen during the run and on the procedure summary screen after the procedure has been completed.

Warning: Monitor the return line for air. If you see air in the line, go to the operation status screen, touch Remove Air From Return Line, and follow the instructions on the screen.

Centrifuge Chamber

The Spectra Optia system centrifuge spins to create a centrifugal force that separates the blood into cellular components. The centrifuge chamber houses the centrifuge and the system components, as shown in Figures 2-3 and 2-4, and described in Table 2-6.

Figure 2-3: Centrifuge chamber components

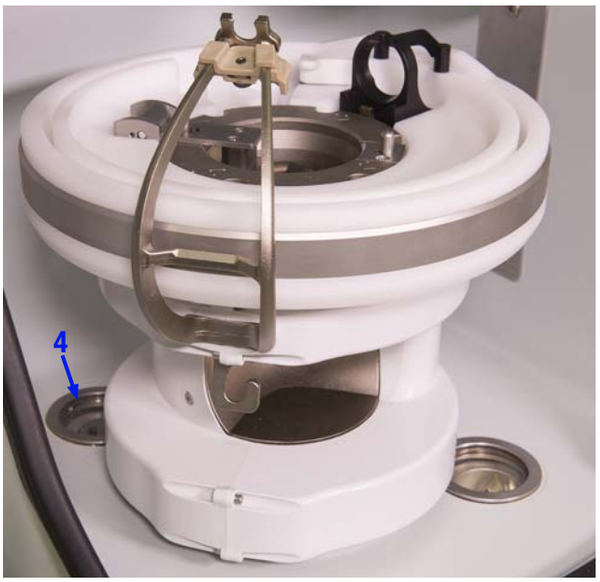


Figure 2-4: AIM system light behind the gear shroud

Table 2-6: Centrifuge chamber components

	Component	Function
1	Upper collar holder	Secures the upper collar at the entrance to the centrifuge chamber.
2	Centrifuge arm	Holds the upper bearing holder. Lowers the filler latch if the latch is left in the raised position when the centrifuge spins.
3	Upper bearing holder	Secures the upper bearing to the tip of the centrifuge arm.
4	AIM system lights (2) One light is located on the ceiling of the centrifuge chamber, and one light is located on the floor of the chamber behind the gear shroud (Figure 2-4).	Illuminate the filler and the connector to allow the AIM system to determine the position of the interface. Each light is protected by a clear plastic cover.
5	Strobe lights (2)	Provide illumination for viewing different areas of the channel through the view port.
6	Fluid leak detector	Detects moisture in the centrifuge chamber.
7	Filler (standard filler is shown)	Secures the tubing set channel, the connector, and the lines that are attached to the connector to the centrifuge.
8	Lower bearing holder	Secures the lower bearing at the entrance to the loading port.
9	Gear shroud	Covers the centrifuge gear train.
10	Loading port	Allows access to the filler for loading the tubing set.

Filler

The filler secures the tubing set channel, the connector, and the lines that are attached to the connector to the centrifuge. The Spectra Optia system has two fillers: the standard filler and the IDL filler. Confirm that you are using the correct filler for the procedure before you load the tubing set. See Table 5-1 on page 62 for instructions on the correct filler to use for each procedure.

The fillers and components are shown in Figures 2-5 and 2-6. The components are described in Table 2-7.

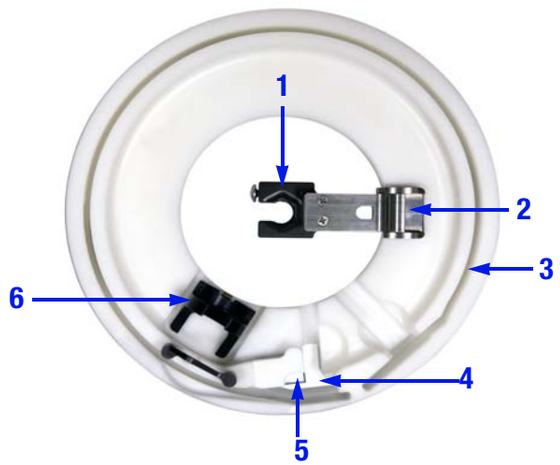


Figure 2-5: Standard filler

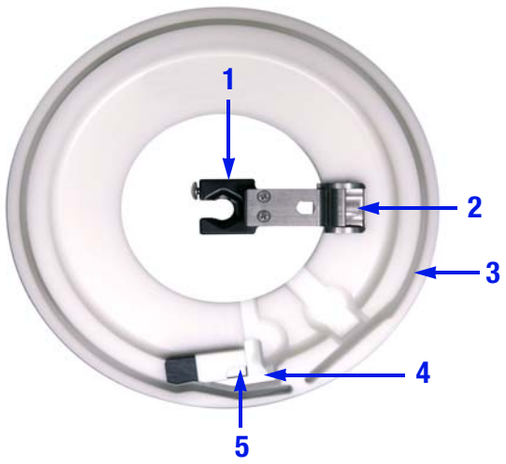


Figure 2-6: IDL filler

Table 2-7: Filler components

	Component	Function
1	Centrifuge collar holder	Secures the lower collar of the tubing set at the opening to the centrifuge loading port.
2	Filler latch	Locks the filler onto the centrifuge.
3	Groove	Secures the channel and the connector in the filler.
4	Aperture plate	Plastic component that is attached to the underside of the filler directly beneath the opening for the connector (Figure 2-7). Ensures uniform lighting to the appropriate areas of the connector. Helps the AIM system control the concentration of cells that flow through the collect port during a collection or depletion procedure.
5	Optical reference	Black corner piece that provides a reference point for the AIM system to use to determine the position of the interface during a procedure (Figures 2-8 and 2-9).
6	Chamber bracket (standard filler only)	Secures the chamber onto the standard filler if a Collection Set is used.

Figure 2-7: Aperture plate

Figure 2-8: Optical reference

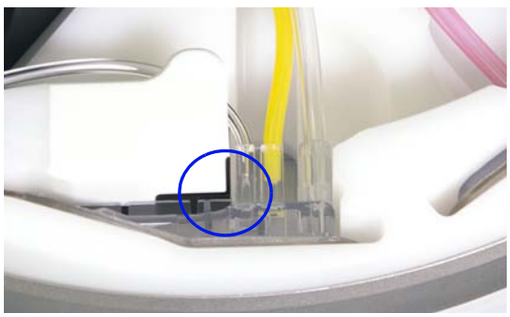


Figure 2-9: Optical reference (shown with the connector loaded)

AIM System

The AIM system is an optical detection system that is composed of hardware and software, and that interprets the interface position in the tubing set connector during procedures on the Spectra Optia system. To accurately interpret the interface position, the AIM system focuses on the optical reference on the filler, which is illuminated by the AIM system lights in the centrifuge chamber.

The AIM system has three main functions:

- Monitor the interface position.
- Interpret the interface position and measure the intensity of the light passing through the connector.
- Adjust the plasma pump flow rate to maintain the optimal interface position so that the target blood components can be collected or removed.

For additional information about how the AIM system functions during each procedure, see the procedure functional descriptions in Chapters 7 through 14.

Operating Modes

The Spectra Optia system has two modes of operation: Automatic mode and Semi-Automatic mode. Below are descriptions of the two modes.

Automatic Mode

During Automatic mode, the system uses the configuration parameters and the procedure data entered to determine and control the pump flow rates, centrifuge speed, packing factor, run targets, and to establish the interface position. The AIM system monitors the interface position, so that the desired blood components can be collected or removed, and the fluid remaining in the channel can be returned to the patient.

Semi-Automatic Mode

During Semi-Automatic mode, the AIM system does not control the position of the interface. The software controls the interface position using the entered hematocrit and other procedure values during TPE procedures. During collection procedures, the operator can use the up and down arrows on the collection status screen to adjust the interface position. For information about the reasons for entering Semi-Automatic mode and instructions for using Semi-Automatic mode, see “Using Semi-Automatic Mode” on page 219.

Procedure States

Table 2-8 describes the Spectra Optia system's procedure states. Both Automatic mode and Semi-Automatic mode include these states.

Table 2-8: Procedure states

State	Description
Load	Operator selects the procedure and loads the appropriate tubing set.
Tubing set test	System verifies that the correct tubing set is loaded, and confirms the function of the pumps, valves, and sensors.
Prime	System primes the tubing set to remove air from the set, to perform volumetric tests, and to balance the pumps prior to the start of the run. The system also verifies that the correct filler is installed.
Run	Operator connects the patient and the system performs apheresis according to the selected procedure.
Rinseback	System returns the blood remaining in the tubing set to the patient after the run is complete to reduce the patient's RBC loss. The operator may choose to perform or skip rinseback.
Disconnect test	System verifies that the lines to the patient are clamped. During a collection procedure, the system also verifies that the collect line to the collection bag is sealed.
Unload	System raises the cassette and unloads the tubing from the pumps.
Procedure summary	System displays the final procedure values.
Next procedure	System prepares for the next procedure.

Packing Factor

The packing factor represents the relationship between the inlet pump flow rate and the centrifuge speed during the run. It indicates how tightly the cells are packed in the channel. When the inlet pump flow rate is increased or decreased, the centrifuge speed increases or decreases accordingly. The packing factor is displayed on the main run screen.

Using the optimal (default) packing factor ensures that more of the target cells or components are collected or removed and that more of the non-target cells or components are returned to the patient. See Chapters 7 through 14 for the default packing factor for each procedure. If the inlet pump flow rate used is high or very low, it may not be possible for the system to achieve the optimal packing factor because the centrifuge has already reached its maximum or minimum speed. The centrifuge cannot spin any faster or slower to accommodate the change to the inlet pump flow rate.

If you are performing a CMNC, a PMN collection, or a WBCD procedure and conditions require that you use a packing factor that is not the default, be aware that an excess number of platelets could be collected. The system displays a warning screen with instructions for monitoring the patient for platelet depletion and for resuming the procedure in Caution status.

Operation Status Screen

The operation status screen allows you to monitor and respond to certain conditions that could occur during the run. Table 2-9 describes the messages and parameters that can appear on the operation status screen during a procedure.

Table 2-9: Operation status screen

Message or Parameter	Procedures	Description
• AIM system: enabled • AIM system: disabled	All procedures	Indicates whether the AIM system was disabled in response to an alarm condition or is currently operational.
• Proceed to Semi-Automatic mode • Proceed to Automatic mode	• TPE • SPD • MNC • CMNC • PMN • WBCD • PLTD • BMP	Allows you to change the mode of operation in response to an alarm condition or to troubleshoot certain procedure conditions.
• Disable RBC detector • Enable RBC detector	• TPE • SPD • RBCX • MNC	Allows you to disable or enable the RBC detector in response to an alarm condition or to troubleshoot certain procedure conditions. • MNC collection procedures: If the RBC detector is disabled, the collection phase control automatically changes to Operator.
• Disable RBC too soon alarm • Enable RBC too soon alarm	MNC	Allows you to change the frequency of the alarm that occurs when RBC are detected in the collect line before the chamber is full. To prevent the alarm from occurring each time cells are detected, disable the alarm. If you decide you want the alarm to continue to recur, you can re-enable it.
Remove air from return line	All procedures	Allows you to initiate an air removal if you see air in the return line and an alarm has not occurred.
Total saline to patient: *volume* mL	All procedures	Displays the total volume of saline that was delivered to the patient as a result of the air removals performed during the current procedure.
Caution status: *Reason for Caution status*	All procedures	Explains the reason for Caution status. See “Caution Status” on page 32 for details about conditions that cause the system to enter Caution status.

Caution Status

Caution status alerts you that the system is operating outside of certain established limits. When the system is operating in Caution status, a yellow line appears on the bottom of the screen. The yellow line disappears if the system operation changes and Caution status no longer applies. To view the reason why the system is operating in Caution status, touch the **Operation Status** tab. The reason is shown in yellow text on the operation status screen.

Certain conditions that cause the system to enter Caution status are procedure-specific. Table 2-10 describes the conditions that cause the system to enter Caution status during each procedure.

Table 2-10: Conditions for Caution status

Procedure	Condition
All procedures	Target or actual AC infusion rate exceeds 1.2 mL/min/L of the patient's TBV.
TPE	Patient data or procedure data that was entered caused the predicted fluid balance to be less than 90% or greater than 110% of the patient's TBV.
SPD	Patient data or procedure data that was entered caused the target or actual fluid balance to be less than 85% or greater than 140% of the patient's TBV.
RBCX	Patient data or procedure data that was entered caused the predicted fluid balance to be less than 95% or greater than 105% of the patient's TBV.
MNC	• Patient data or procedure data that was entered caused the target or actual fluid balance to be less than 85% or greater than 140% of the patient's TBV. • Control selected for the collection phase is Operator.
CMNC	• Patient data or procedure data that was entered caused the target or actual fluid balance to be less than 85% or greater than 140% of the patient's TBV. • Return to Patient button on the collection status screen was touched. Cells are not being collected. • Packing factor that was entered exceeds the default. An excess number of platelets may be collected. • Procedure data that was entered caused the packing factor to exceed the default. An excess number of platelets may be collected.
PMN	• Patient data or procedure data that was entered caused the target or actual fluid balance to be less than 85% or greater than 115% of the patient's TBV. • Return to Patient button on the collection status screen was touched. Cells are not being collected. • Packing factor that was entered exceeds the default. An excess number of platelets may be collected. • Procedure data that was entered caused the packing factor to exceed the default. An excess number of platelets may be collected. • Target or actual collect volume exceeds 15% of the patient's TBV. An excess number of RBC may be collected.
WBCD	• Patient data or procedure data that was entered caused the target or actual fluid balance to be less than 85% or greater than 115% of the patient's TBV. • Return to Patient button on the collection status screen was touched. Cells are not being collected. • Packing factor entered exceeds the default. An excess number of platelets may be collected. • Procedure data that was entered caused the packing factor to exceed the default. An excess number of platelets may be collected.
PLTD	• Patient data or procedure data that was entered caused the target or actual fluid balance to be less than 85% or greater than 115% of the patient's TBV. • Return to Patient button on the collection status screen was touched. Cells are not being collected.
BMP	Return to BMP Bag button on the collection status screen was touched. Cells are not being collected.

Fluid Balance Limits

Table 2-11 shows the hypovolemia and hypervolemia limits the system enforces for each patient procedure. The limits are a percentage of the patient's TBV.

Table 2-11: Fluid balance limits

Procedure	Fluid Balance Limits (% TBV)	
	Hypovolemia	Hypervolemia
TPE	75	125
SPD	75	220
RBCX	75	125
MNC	75	N/A
CMNC	75	N/A
PMN	75	125
WBCD	70	125
PLTD	70	125

Spectra Optia System Touch Screen

Navigating the Procedure Screens

The Spectra Optia system's touch screen allows you to perform, adjust, and monitor procedures. A procedure screen is divided into several areas, as shown in Figure 2-10 and described in Table 2-12.

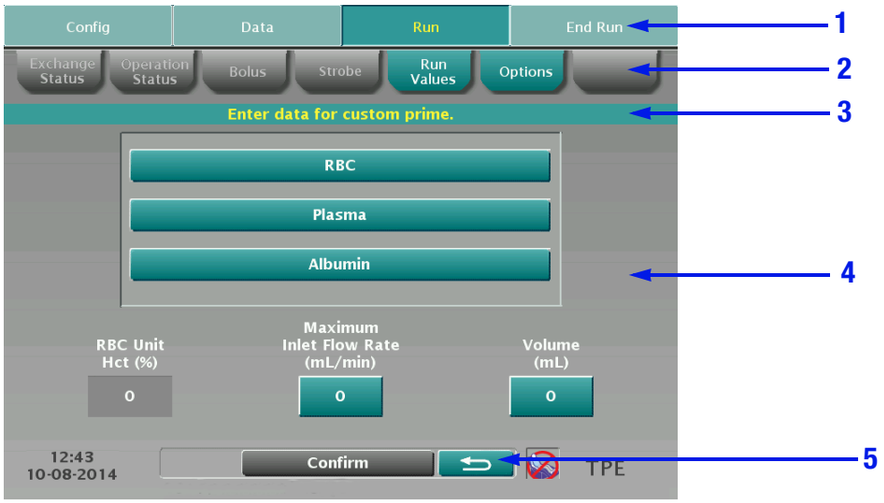


Figure 2-10: Example of a Spectra Optia system screen

Table 2-12: Description of a procedure screen

	Area	Description
1	Menu bar	Contains menu buttons that you touch to show or hide menu tabs.
2	Menu tabs	• Associated with a specific menu button. • Appear when the menu button is touched. • Provide access to screens that allow you to view information or modify the procedure.
3	Message bar	Displays information about the status of the procedure or instructions to enter data.
4	Activity area	Displays tasks to complete and buttons that allow you to do the following: • Navigate to another screen. • Change the operating mode. • Change values or information about the procedure.
5	Action bar	Contains buttons that you touch to perform the action stated on the button or to navigate to a different screen.

Entering and changing numerical data using the data entry pad

To enter numerical data or to change a numerical value for certain operating parameters during the procedure, touch the button for the parameter and use the data entry pad that the system displays on the screen. See Chapters 7 through 14 for more information about entering and changing data during the run.

Screen Colors

The Spectra Optia system uses a color scheme to indicate the different procedure states, allowing you to quickly determine the progress of the procedure. Table 2-13 describes the color that corresponds to each procedure state.

Table 2-13: Color schemes for procedure states

Procedure State	Color
Load, prepare procedure, tubing set test, prime (patient is not connected)	Teal
Run, rinseback, disconnect test (patient is connected)	Blue
Unload, procedure summary, next procedure (patient has been disconnected)	Burgundy

Screen Buttons

The screen displays active and inactive buttons, as shown in the following examples:

- Active button: 

  Active buttons are colored according to the procedure state and appear as if they are raised. Touch an active button to enter, change, or save data, or to proceed to the next activity or action.

- Inactive button: 

  Inactive buttons are gray. They indicate that the action or the information is not available.

Buttons, Icons, and Images

The buttons, icons, and images described in Table 2-14 can appear on the monitor or on the screens. They allow you to operate and adjust the Spectra Optia system during a procedure, or they communicate important information about the procedure.

Table 2-14: Buttons, icons, and images

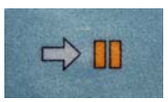
Graphic	Description	Location	Function
	Go back button	• Bottom right side of screens • Top left side of the report summary screen and the report detail screen	Returns you to a previous screen or to the main run screen. The button is active only when it is safe to return to a previous screen. On some screens you must confirm any data you change before you touch the go back button, or the data will not be saved.
  (muted)   (muted)	Alarm mute button (Icon on the button depends on the software version in use.)	Bottom left side of alarm screens	Allows you to mute the alarm tone during an alarm condition. The tone is automatically restored if another alarm occurs.
	Stop button	Bottom left corner of the monitor	Stops the centrifuge and pauses the pumps.
	Pause button	Bottom right corner of the monitor	Pauses the pumps.
	Active alarm button	Bottom left side of the screen during an alarm condition	Indicates an active alarm. Takes you to an active alarm screen or to a list of active alarms, if more than one alarm is active.
	Clock button	• Run time graph on the main run screen • Exchange procedures: Run time graph on the exchange status screen	Allows you to view clock time or elapsed time for the run.
	Up and down scroll buttons	• Active alarm screens • Alarm history screen • Procedure selection screen	Allows you to view additional information on the screen.

Table 2-14: Buttons, icons, and images (continued)

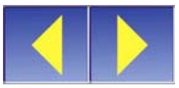
Graphic	Description	Location	Function
	Left and right arrow buttons	Strobe screen	• Allows you to adjust the timing of the strobe. • Allows you to view different areas of the channel.
	Left and right scroll buttons	• Alarm action screens • Report summary screen • Report detail screen	• Allows you to scroll through alarm action screens. • Allows you to scroll through pages of the report summary screen and the report detail screen.
	Check mark icon	• Procedure preparation screen • Patient data screen	Appears on buttons. Indicates that the required task is complete or the selection is confirmed.
	Do not connect patient icon	Bottom right side of the screens before the patient is connected	Safety feature that reminds you that the patient should not be connected during the current operating state.
	Semi-Automatic mode icon	Bottom right side of the run screens	Indicates that the system is operating in Semi-Automatic mode.
	Interface graphic	TPE procedures: Main run screen	Displays a representation of the current interface and the thickness of the buffy coat in the connector.
	Collect port image	Collection and depletion procedures: Main run screen, collection status screen	Shows a real-time image of cells flowing through the collect port.
	Algorithm control icon	TPE procedures: Main run screen	Indicates that the AIM system is not controlling the interface position. The system is using certain procedure data to control the position instead.
	Blood drop icon	RBCX procedures: • Run values screen • Run targets screen Appears on a button on the data entry pad. Touch **FCR** to toggle to  .	Allows you to enter the values for defective RBC instead of the fraction of cells remaining (FCR) for an exchange or a depletion/exchange procedure.
	Single-needle icon	TPE procedures: Main run screen	Indicates that the single-needle option was selected and confirmed.

Table 2-14: Buttons, icons, and images (continued)

Graphic	Description	Location	Function
	Blood warmer icon	TPE procedures: Screens that instruct the user to prime the blood warmer tubing and connect it to the single-needle connector.	Shows the blood warmer on the return line and connection of the blood warmer tubing to the single-needle connector.
#	Hash mark icon	• Run values screen • Run targets screen Appears on a button on the data entry pad. Touch **mL** to toggle to **#**.	Allows you to enter the number of collection phases instead of the target collect volume.
	Test tube icon	MNC collection procedures: Collection status screen	Graph on the collection status screen only. Indicates that the control selected for the collection phase is Inlet.
	Inlet volume processed icon	MNC collection procedures: • Main run screen • Collection status screen • Run targets screen	• Indicates the inlet volume processed (mL) during the current accumulation phase. • Indicates the inlet volume processed (mL) during the current and previous accumulation phases.
	RBC detected icon	MNC collection procedures: Collection status screen	Graph on the collection status screen. Indicates the inlet volume that was processed before the RBC detector detected cells in the collect line.
	Operator override icon	• TBV (total blood volume) button on the patient data screen	• Indicates that the operator entered the patient's TBV instead of using the volume the system calculated.
		• MNC collection procedures: Collection status screen	• Indicates that the control selected for the collection phase is Operator.
≠	Not equal icon	MNC collection procedures: • Run values screen • Run targets screen • Procedure summary screen	Indicates that the current volume in the bag may be different from the displayed volume because plasma was transferred from the plasma bag into the collection bag.
	Up and down arrow buttons	TPE-SPD procedures: Data entry pad that appears if you touch **Replace** on the main run screen	Allows you to adjust the volume in the treated plasma bag.

Table 2-14: Buttons, icons, and images (continued)

Graphic	Description	Location	Function
	Up and down arrow buttons	Collection and depletion procedures: Collection status screen	• Automatic mode: Used to increase or decrease the collection preference. • Semi-Automatic mode: Used to increase or decrease the concentration of cells flowing through the collect port.
	Collection preference graphic	Collection and depletion procedures: Collection status screen	Represents a buffy coat.

3

Installing and Transporting the Spectra Optia System

Installing the Spectra Optia System

Installation information is included in the shipping container of each Spectra Optia system. An authorized service representative uses this information to install the system in your facility. The service representative also tests the system to confirm it is functioning properly before you begin using it.

Setting Up the Spectra Optia System

Perform the following steps to set up the Spectra Optia system:

1. Unpack the system from the shipping container.
2. Put the system in the desired location and press the wheel pedal to the right side and press the rear wheel brake levers to lock the system in place.
3. Establish a safety boundary of at least 30 cm (11.8 in) around the perimeter of the system from all points within which hazardous material is not permitted. When the centrifuge is spinning, limit access inside the boundary to necessary individuals.
4. Raise the monitor until it is fully upright.
5. Press the IV pole release button located on the left side of the front panel and raise the IV pole.
6. Attach one end of the RF cable of the Seal Safe system to the connector on the Spectra Optia system, and the other end of the cable to the connector on the sealer head. Turn the ends of the cable clockwise on the connectors to lock them in place.
7. Put the sealer head into the holder.
8. Plug the system into a properly installed, three-wire, grounded electrical receptacle that is protected by an approved branch circuit overcurrent protection and disconnection device. The branch circuit protection and disconnection device must be located away from but close enough to the system so that the system can be easily disconnected from the main power supply if the centrifuge malfunctions.

Turning the Spectra Optia System On and Off

1 Confirm that the proper power cord is attached to the system and plugged into an appropriate electrical receptacle.

2 Press the power switch on the upper-right side of the system to the ON position. The system performs a series of self-diagnostic tests to validate the functionality of the hardware and software before you begin the procedure. Once the tests are complete, the buttons on the screen become active and you may begin the procedure.

3 To turn off the system, press the power switch to the OFF position.

Caution: When the wheel pedal is not in the locked position (pressed to the right side) and the rear wheel brake levers are released, ensure at least one person is in continuous contact with and controls the movement of the Spectra Optia system.

Caution: Ensure that the wheel pedal is pressed to the right side (locked position) and the rear wheel brake levers are locked during procedures, so that the Spectra Optia system does not move.

Caution: Only perform procedures when the system is on a smooth, dry, level surface.

Caution: Do not leave the device unattended in a traffic area.

Transporting the Spectra Optia System

The Spectra Optia system can be transported manually or in a vehicle. It is not necessary to recalibrate the system after transport; the system is ready for use.

Preparing the Spectra Optia System for Transport

1. Unplug the Spectra Optia system and secure the power cord in the power cord holder.
2. Press the IV pole release button located on the left side of the front panel and lower the IV pole.
3. Lower the monitor and lay it over the front panel (Figure 3-1).

Figure 3-1: Monitor lowered over the front panel

4. Open the centrifuge door and confirm that the filler latch on the filler is lowered and locked. Close the centrifuge door.
5. Remove the following components and transport them separately to avoid damage to the system and the components:
   - Blood warmer and accessory bracket, if used.
   - Seal Safe system sealer head and cable.

Caution: To avoid possible damage to the Seal Safe system, always disconnect the sealer head and the RF cable before transporting the Spectra Optia system.

6. If you are transporting the system in a vehicle, cover the system with a heavy-duty cover or a shipping blanket to protect the system.

7 Press the wheel pedal to the appropriate position:

- To lock the front wheels in a forward position for moving in corridors, press the wheel pedal to the left side.
- To allow free movement of all wheels, press the wheel pedal to the horizontal position.
- To lock the front wheels in position, press the wheel pedal to the right side (Figure 3-2).

Figure 3-2: Front wheels in the locked position

8 To lock the rear wheels in place, press down on each of the rear wheel brake levers (Figure 3-3).

Figure 3-3: Rear wheel brake levers in the locked position

Transporting the Spectra Optia System in a Vehicle

Perform steps 1 through 6 of “Preparing the Spectra Optia System for Transport” on page 44. Then follow the instructions in this section to load the system into the vehicle and secure the system for transport.

Loading the system into the vehicle

1 If the vehicle has a liftgate, perform steps a. through e. to load the system in a vertical position into the vehicle. If the vehicle does not have a liftgate, proceed to step 2.

a. Completely lower the liftgate of the vehicle.

b. Roll the system onto the liftgate with the handle facing the vehicle.

c. Press the wheel pedal to the right to lock the front wheels.

d. Raise the liftgate. To prevent the system from falling, use one hand to steady the system while the liftgate is in operation.

e. Press the wheel pedal to the horizontal position to unlock the front wheels, and then roll the system into the vehicle.

2 If the vehicle does not have a liftgate, perform steps a. through c. to load the system in a horizontal position into the vehicle.

Note: Before transporting the system in a horizontal position, consider removing the filler from the centrifuge chamber and transporting it separately. This helps to minimize wear on the centrifuge and reduce the risk of damage to components inside the centrifuge chamber.

a. Tip the system backward so that the front wheels are off the ground.

b. Use the specially-designed lift handles, if installed, or the metal frame of the device to lift the system into the vehicle. Do not use the bumpers or the blue side panels for lifting, or you may damage the system. Always use proper lifting technique when lifting the system.

c. Lay the system in the vehicle so that it rests on the rear wheels and the two wheels on the handle of the system.

Securing the system inside the vehicle

1 Use a cargo strap to secure the system inside the vehicle so that the system remains stable during transport. Do not put any weight or objects on the monitor or on the centrifuge cover during transport.

2 Ensure that any other equipment in the vehicle is secured to prevent damage to the system.

Storing the Spectra Optia System

Cover the Spectra Optia system and store it in a clean environment, according to the specifications stated in Table 18-2 on page 242.

4

Configuring the Spectra Optia System

Configuring the Spectra Optia System

The Spectra Optia system allows you to configure procedure-independent and procedure-specific operating parameters to meet your facility's requirements. Configuration settings for the procedure-independent parameters apply to all procedures. Configuration settings for procedure-specific parameters apply to only the specified procedure. Several parameters have a default setting. The system uses the default setting unless you enter a different setting. You must touch **Confirm** after you finish configuring the parameters to save the settings.

You can configure most procedure-independent operating parameters after you turn on the system and before you connect the patient except for the language setting, and the inlet pressure and return pressure alarm limits, which are described in Table 4-2.

You can configure procedure-specific operating parameters after you select the procedure and before you enter and confirm the patient data.

To configure the parameters, perform the following steps:

1. Touch the **Config** menu button. The configuration tabs appear.
2. Touch the tab for the parameters that you want to configure. The corresponding configuration screen appears.
3. Touch the button for the parameter that you want to configure:
   - For parameters with only two settings, toggle between the settings until the setting that you prefer appears on the button.
   - For parameters with more than two settings, a list appears to enable you to select a setting.
   - For parameters that require a numeric setting, a data entry pad appears to enable you to enter a number. The range of acceptable values appears on the data entry pad.
4. Repeat step 3 until you finish configuring the parameters.
5. Touch **Confirm**.

Configuring Procedure-Independent Operating Parameters

Tables 4-1 through 4-3 show the configuration parameters and setting options for the operating parameters that apply to all procedures.

System

Table 4-1 shows the operating parameters to configure for the system.

Table 4-1: System configuration parameters and setting options

Tab	Parameter	Description	Setting Options
System	Language	Language that appears on the screen. A language must be configured before a procedure can be selected. The language cannot be changed after the procedure is selected.	Multiple languages available
	Time format	Format used to display the time.	• hh:mm (24-hour) • hh:mm (12-hour, a.m./p.m.)
	Decimal	Punctuation used to represent a decimal point.	• 0,00 (comma) • 0.00 (point)
	Current time	Current time.	• hh:mm (24-hour) • hh:mm (12-hour, a.m./p.m.)
	Alarm volume	Audible volume of the alarm tone.	• Low • High
	Date format	Format used to display the date.	• mm-dd-yyyy • dd-mm-yyyy
	Software	Software version and verification value for each type of procedure. This information is used to confirm that the system software version and the verification value for a particular procedure type have not changed after software for a new procedure type was installed.	Not configurable
	Current date	Current date.	• mm-dd-yyyy • dd-mm-yyyy

Procedure

Table 4-2 shows the operating parameters to configure for procedures.

Table 4-2: Procedure configuration parameters and setting options

Tab	Parameter	Description	Setting Options
Procedure	Height units	Unit of measure for the patient's height.	• ft, in (feet, inches) • cm (centimeters)
	Weight units	Unit of measure for the patient's weight.	• lb (pounds) • kg (kilograms)
	Pressure alarm limit: Inlet (mmHg)	Limit at which an inlet pressure alarm occurs.	–250 to –100 (Default: –250)
	Pressure alarm limit: Return (mmHg)	Limit at which a return pressure alarm occurs.	200 to 400 Default: 400
	Custom prime recommendation (% TBV)	Percentage of the patient's total blood volume (TBV) or RBC volume in the tubing set at which the system displays a screen recommending a custom prime.	• 10 • 15 Default: 10
	AC container: Notification	Indication of whether the system will display a notification when the AC container is nearly empty.	• Yes • No Default: Yes
	AC container: Volume (mL)	Volume of AC in the AC container used during the procedure.	250 to 1000 Default: 1000

Report

Table 4-3 shows the operating parameters to configure for the report.

Table 4-3: Report configuration parameters and setting options

Tab	Parameter	Description	Setting Options
Report	Device	Device that is used to deliver a copy of the report. If you select "Printer," you must also select a paper size.	• No Device • Printer • Computer Default: No Device
	Paper	Size of paper that is used to print the report if "Printer" is the device selected.	• Letter • A4 Default: Letter
	IP address	IP address for the device that is used to print the report. The format for the address is XXX.XX.XXX.XXX. The first five digits must be 172.21 to match the system's address.	Device-specific
	Port	Port number for the device that is used to print the report. The format for the number is XXXX. It is recommended that you use the default number.	100 to 9999 Default: 9100
	Connection	Test that is used to verify that a device for printing a report is connected to the system. Touch **Test** to verify the connection. If the system can verify the connection, "Passed" appears on the button. If the system cannot verify the connection, "Failed" appears.	Not configurable
	Report	Type of procedure report that you want to view or print. There are two types of reports: • Summary: Single-page report including the system serial number, the date of the procedure, the patient data, the fluid balance, and the initial and final run values) • Detail: Summary report plus additional procedure details, which are reported according to time configured for the report update interval.	• Summary • Detail Default: Summary
	Report update interval (min)	Interval at which procedure information appears on the report.	10 to 60 Default: 15

Configuring Procedure-Specific Operating Parameters

Tables 4-4 through 4-15 show the configuration parameters and setting options for the operating parameters that apply to specific procedures.

Therapeutic Plasma Exchange (TPE)

Table 4-4 shows the operating parameters to configure for a TPE procedure.

Table 4-4: Parameters and setting options to configure for a TPE procedure

Tab	Parameter	Description	Setting Options
TPE	AC infusion rate (mL/min/L TBV)	Rate at which anticoagulant (AC) is infused to the patient. The configured rate represents the maximum rate at the start of the run.	0.8 to 1.2 Default: 0.8
	Inlet:AC ratio (__:1)	Ratio of the inlet pump flow rate to the AC pump flow rate. The configured ratio represents the ratio at the start of the run.	6 to 15 Default:10
	Plasma volumes exchanged	Run target. Number of the patient's plasma volumes to be exchanged, accounting for the amount of AC in the plasma removed. The configured number represents the number the system uses to calculate the initial run values.	0.5 to 4 Default: 1
	Custom replacement fluid (%)	Percentage of citrate in the custom replacement fluid.	0 to 25 Default: 0

Therapeutic Plasma Exchange With A Secondary Plasma Device (TPE-SPD)

Tables 4-5 and 4-6 show the operating parameters to configure for a TPE-SPD procedure.

Table 4-5: Parameters and setting options to configure for a TPE-SPD procedure

Tab	Parameter	Description	Setting Options
SPD	AC infusion rate (mL/min/L TBV)	Rate at which anticoagulant (AC) is infused to the patient. The rate configured represents the maximum rate at the start of the run.	0.8 to 1.2 Default: 0.8
	Inlet:AC ratio (__:1)	Ratio of the inlet pump flow rate to the AC pump flow rate. The ratio configured represents the ratio at the start of the run.	6 to 15 Default:10
	Plasma volumes treated	Run target. Number of the patient's plasma volumes to be treated, accounting for the amount of AC in the plasma removed. The number configured represents the number the system uses to calculate the initial run values.	0.5 to 4 Default: 1

Table 4-6: Parameters and setting options to configure for a secondary plasma device

Tab	Parameter	Description	Setting Options
Plasma Device	Prime divert volume (mL)	Volume of plasma pumped into the plasma device to displace the fluid that was used to prime the plasma device into the waste bag. This is typically the volume of the plasma device.	0 to 500 Default: 0
	Saline prime	Indication that a saline prime of the plasma device will be performed.	• Yes • No Default: No
	Replace pump balance (%)	Percentage change in the replace pump flow rate that is required to balance the flow rates of the replace pump and the plasma pump so that the desired volume of treated plasma is maintained in the treated plasma bag.	50 to 150 Default: 100
	Maximum plasma flow rate (mL/min)	Maximum flow rate of the plasma pump during the run.	2 to 142 Default: 100
	Plasma pressure alarm limit: Notification (mmHg)	Limit at which the operator is notified of elevated pressure in the plasma line.	50 to configured alarm limit for maximum plasma pressure Default: 200
	Plasma pressure alarm limit: Maximum (mmHg)	Limit at which the operator is notified that the pressure in the plasma line is too high.	50 to 1350 Default: 250

Red Blood Cell Exchange (RBCX)

Table 4-7 shows the operating parameters to configure for an RBCX procedure.

Table 4-7: Parameters and setting options to configure for an RBCX procedure

Tab	Parameter	Description	Setting Options
RBCX	AC infusion rate (mL/min/L TBV)	Rate at which anticoagulant (AC) is infused to the patient. The configured rate represents the maximum rate at the start of the run.	0.8 to 1.2 Default: 0.8
	Inlet:AC ratio (__:1)	Ratio of the inlet pump flow rate to the AC pump flow rate. The configured ratio represents the ratio at the start of the run.	6 to 15 Default: 13
	Custom replacement fluid (%)	Percentage of citrate in the custom replacement fluid.	0 to 25 Default: 0

Mononuclear Cell (MNC) Collection

Tables 4-8 and 4-9 show the operating parameters to configure for an MNC collection procedure.

Table 4-8: Parameters and setting options to configure for an MNC collection procedure

Tab	Parameter	Description	Setting Options
MNC	Run target: Whole blood processed (mL)	Amount of the patient's blood to be processed. Does not include AC. If you enter a value for this parameter, the system automatically sets the targets for the run time and the TBV processed to zero.	100 to 50000 Default: 0
	Run target: Run time (min)	Time required to complete the run. The run starts when the patient is connected and ends when the run targets have been attained. When you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the TBV processed to zero.	40 to 480 Default: 0
	Run target: TBV processed	Number of the patient's total blood volumes to be processed. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the run time to zero.	1 to 10 Default: 2
	Plasma: Plasma bag (mL)	Volume of plasma to be collected into the plasma bag.	0 to 500 Default: 0
	Plasma: Collection bag (mL)	Volume of plasma to be collected into the collection bag.	0 to 500 Default: 0
	Chamber flush (mL)	Volume of plasma the system uses to flush cells from the chamber into the collection bag during the collection phase.	6 to 100 Default: 16
	Chamber chase (mL)	Volume of plasma the system uses to rinse any cells remaining in the collect line between the chamber and the collect valve into the collection bag. The chamber chase occurs after the chamber flush and before the collect valve moves into the return position.	0 to 100 Default: 2

Table 4-9: Parameters and setting options to configure for the use of AC during an MNC collection procedure

Tab	Parameter	Description	Setting Options
AC	AC infusion rate (mL/min/L TBV)	Rate at which AC is infused to the patient. The configured rate represents the maximum rate at the start of the run.	0.8 to 1.2 Default: 0.9
	Inlet:AC ratio (__:1)	Ratio of the inlet pump flow rate to the AC pump flow rate. The configured ratio represents either the target ratio if inlet:AC ratio ramping is indicated, or the ratio at the start of the run.	6 to 15 Default: 12
	Inlet:AC ratio ramping	Indication that the system will ramp the inlet:AC ratio at the start of the run. The system processes the first 100 mL of inlet volume at a ratio of 8.0:1. While processing the next 100 mL, the system ramps the ratio to the target ratio. Ramping is automatically disabled if you choose to perform a custom prime.	• Yes • No Default: Yes

Continuous Mononuclear Cell Collection (CMNC)

Tables 4-10 and 4-11 show the operating parameters to configure for a CMNC collection procedure.

Table 4-10: Parameters and setting options to configure for a CMNC collection procedure

Tab	Parameter	Description	Setting Options
CMNC	Run target: Whole blood processed (mL)	Amount of the patient's blood to be processed. Does not include AC. If you enter a value for this parameter, the system automatically sets the targets for the run time and the TBV processed to zero.	100 to 50000 Default: 0
	Run target: Run time (min)	Time required to complete the run. The run starts when the patient is connected and ends when the run targets have been attained. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the TBV processed to zero.	40 to 480 Default: 0
	Run target: TBV processed	Number of the patient's total blood volumes to be processed. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the run time to zero.	1 to 10 Default: 2
	Plasma collection: Plasma bag (mL)	Volume of plasma to be collected into the plasma bag.	0 to 500 Default: 0
	Plasma collection: Collection bag (mL)	Volume of plasma to be collected into the collection bag.	0 to 500 Default: 0
	Plasma collection	Timing of the plasma collection.	• Beginning of Run • End of Run Default: End of Run

Table 4-11: Parameters and setting options to configure for the use of AC during a CMNC procedure

Tab	Parameter	Description	Setting Options
AC	AC infusion rate (mL/min/L TBV)	Rate at which AC is infused to the patient. The configured rate represents the maximum rate at the start of the run.	0.8 to 1.2 Default: 0.8
	Inlet:AC ratio (__:1)	Ratio of the inlet pump flow rate to the AC pump flow rate. The configured ratio represents the ratio at the start of the run.	6 to 15 Default: 12

Granulocyte (PMN) Collection

Table 4-12 shows the operating parameters to configure for a PMN collection procedure.

Table 4-12: Parameters and setting options to configure for an PMN collection procedure

Tab	Parameter	Description	Setting Options
PMN	Run target: Whole blood processed (mL)	Amount of the patient's blood to be processed. Does not include AC. If you enter a value for this parameter, the system automatically sets the targets for the run time and the TBV processed to zero.	100 to 50000 Default: 6000
	Run target: Run time (min)	Time required to complete the run. The run starts when the patient is connected and ends when the run targets have been attained. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the TBV processed to zero.	40 to 480 Default: 0
	Run target: TBV processed	Number of the patient's total blood volumes to be processed. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the run time to zero.	0.5 to 5 Default: 0
	AC infusion rate (mL/min/L TBV)	Rate at which AC is infused to the patient. The configured rate represents the maximum rate at the start of the run.	0.8 to 1.2 Default: 0.8
	Inlet:AC ratio (__:1)	Ratio of the inlet pump flow rate to the AC pump flow rate. The ratio configured represents the ratio at the start of the run.	6 to 15 Default:13
	Plasma (mL)	Volume of plasma to be collected into the plasma bag.	0 to 500 Default: 0
	HES	Indication that hydroxyethyl starch (HES) will be used for the procedure. The selection determines the default packing factor: • Yes: Default packing factor is 1.6 • No: Default packing factor is 4.5 The selection also appears on the top left side of the main run screen.	• Yes • No Default: Yes

White Blood Cell Depletion (WBCD)

Table 4-13 shows the operating parameters to configure for WBCD procedure.

Table 4-13: Parameters and setting options to configure for a WBCD procedure

Tab	Parameter	Description	Setting Options
WBCD	Run target: Whole blood processed (mL)	Amount of the patient's blood to be processed. Does not include AC. If you enter a value for this parameter, the system automatically sets the targets for the run time and the TBV processed to zero.	100 to 50000 Default: 0
	Run target: Run time (min)	Time required to complete the run. The run starts when the patient is connected and ends when the run targets have been attained. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the TBV processed to zero.	40 to 480 Default: 0
	Run target: TBV processed	Number of the patient's total blood volumes to be processed. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the run time to zero.	0.5 to 5 Default: 2
	AC infusion rate (mL/min/L TBV)	Rate at which AC is infused to the patient. The configured rate represents the maximum rate at the start of the run.	0.8 to 1.2 Default: 0.8
	Inlet:AC ratio (__:1)	Ratio of the inlet pump flow rate to the AC pump flow rate. The ratio configured represents the ratio at the start of the run.	6 to 15 Default: 12
	Custom replacement fluid (%)	Percentage of citrate in the custom replacement fluid.	0 to 25 Default: 0
	HES	Indication that hydroxyethyl starch (HES) will be used for the procedure. The selection determines the default packing factor: • Yes: Default packing factor is 1.6 • No: Default packing factor is 4.5 The selection also appears on the top left side of the main run screen.	• Yes • No Default: No

Platelet Depletion (PLTD)

Table 4-14 shows the operating parameters to configure for PLTD procedure.

Table 4-14: Parameters and setting options to configure for a PLTD procedure

Tab	Parameter	Description	Setting Options
PLTD	Run target: Whole blood processed (mL)	Amount of the patient's blood to be processed. Does not include AC. If you enter a value for this parameter, the system automatically sets the targets for the run time and the TBV processed to zero.	100 to 50000 Default: 0
	Run target: Run time (min)	Time required to complete the run. The run starts when the patient is connected and ends when the run targets have been attained. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the TBV processed to zero.	40 to 480 Default: 0
	Run target: TBV processed	Number of the patient's total blood volumes to be processed. If you enter a value for this parameter, the system automatically sets the targets for the whole blood processed and the run time to zero.	0.5 to 5 Default: 1.5
	AC infusion rate (mL/min/L TBV)	Rate at which AC is infused to the patient. The configured rate represents the maximum rate at the start of the run.	0.8 to 1.2 Default: 0.8
	Inlet:AC ratio (__:1)	Ratio of the inlet pump flow rate to the AC pump flow rate. The ratio configured represents the ratio at the start of the run.	6 to 15 Default: 10
	Custom replacement fluid (%)	Percentage of citrate in the custom replacement fluid.	0 to 25 Default: 0

Bone Marrow Processing (BMP)

Table 4-15 shows the operating parameters to configure for a BMP procedure.

Table 4-15: Parameters and setting options to configure for BMP procedure

Tab	Parameter	Description	Setting Options
BMP	Inlet flow rate (mL/min)	Maximum flow rate at which the inlet pump pumps bone marrow from the BMP bag into the tubing set during the run.	20 to 142 Default:120
	Collect plasma	Indication that plasma will be collected.	• Yes • No Default: No

Configuring the Use of a Blood Warmer

This section contains information about configuring operating parameters for the use of a blood warmer. Parameters for configuring the use of a blood warmer can vary according to the procedure you are performing. Table 4-16 shows all available parameters and setting options.

Table 4-16: Parameters and setting options to configure for using a blood warmer

Tab	Parameter	Description	Setting Options
Blood Warmer	Return line	Indication that a blood warmer will be connected to the return line. You must prime the blood warmer tubing set before you connect the patient.	• Yes • No Default: No
	Replace line	Indication that a blood warmer will be connected to the replace line during a procedure using an Exchange Set.	• Yes • No Default: No
	Tubing set (mL)	Volume of the blood warmer tubing set on the return line. The system uses this information to adjust the calculation for the extracorporeal volume, the minimum volume required for a custom prime, and the volume of saline required for rinseback.	1 to 100 Default: 40

5

Preparing to Perform a Procedure

Supplies Required to Perform a Procedure

Assemble the supplies listed below before you begin a procedure. See the procedure-specific chapters of this manual for the additional supplies required for each procedure.

- Spectra Optia Apheresis System
- Spectra Optia tubing set

  Table 5-1 shows the tubing set required for each procedure.
- Standard or IDL filler

  Table 5-1 shows the filler required for each procedure. See page 27 for more information about the fillers.
- 0.9% sodium chloride injection USP
- One of the following anticoagulant solutions:
  - ACD-A (Anticoagulant Citrate Dextrose Solution A)
  - Option for PMN and WBCD procedures: Solution of hydroxyethyl starch (HES) and 46.7% trisodium citrate

    For instructions on preparing the solution, see “Preparing an anticoagulant solution containing HES and trisodium citrate” on page 162 or on page 178.
- If using peripheral access:
  - Needle for the return site that is of sufficient gauge to accommodate the procedure pump flow rate
  - Supplies for preparing the venipuncture site
  - Blood pressure cuff
- If using a vascular access device:
  - Supplies to disinfect, aspirate from, and connect to the device according to your standard operating procedures

Optional supplies:

- Blood warmer and blood warmer tubing set, if using a blood warmer
- Spectra Optia® Apheresis System Collection Preference Tool
- Hemostats for clamping lines
- Supplies for collecting blood samples
- Apheresis procedure record

Table 5-1: Tubing set and filler required

Procedure	Tubing Set	Filler
TPE	Exchange Set	Standard
SPD	Exchange Set	Standard
RBCX	Exchange Set	Standard
MNC	Collection Set	Standard
CMNC	IDL Set	IDL

Table 5-1: Tubing set and filler required (continued)

Procedure	Tubing Set	Filler
PMN	IDL Set	IDL
WBCD	IDL Set	IDL
PLTD	IDL Set	IDL
BMP	IDL Set	Standard

Selecting the Procedure

You must select the type of procedure you want to perform before you load the tubing set. Perform the following steps to select a procedure:

1 Touch **Select Procedure**. The procedure selection screen appears.

2 Select the procedure you want to perform.

3 Touch **Confirm**. Once the system finishes loading the procedure software. a screen appears that displays the filler and the tubing set required for the procedure.

Installing the Filler

Before you load the tubing set, verify that the correct filler is installed in the centrifuge. To remove and install a filler, perform the following steps:

Removing the Filler

1 Open the centrifuge door.

2 Push the filler latch pin (Figure 5-1, number 1) toward the center of the centrifuge and raise the filler latch.

3 Push the filler locking pin (Figure 5-1, number 2) toward the center of the centrifuge. With the pin pushed in, grasp the edge of the filler and lift up to raise the filler off the centrifuge.

Figure 5-1: Location of the filler latch pin (1) and the filler locking pin (2)

Re-Installing the Filler

1 Align the two notches on the bottom of the filler with the two metal pins on the centrifuge as shown in Figure 5-2, and firmly press the filler down until the filler locking pin is securely in place. You should hear a click when the pin is in the correct position.

Figure 5-2: Notches on the filler aligned with the pins on the centrifuge

2 Verify that the filler is secure by pulling it upwards. If the filler is properly locked, it should remain firmly in place.

3 Lower the filler latch.

Loading the Tubing Set

Follow the instructions below to unpack the tubing set, load the set on the system, and test the set. After you load the set, the system performs a test to ensure that you have loaded the correct set for the procedure.

Caution: Before loading the tubing set, confirm that the filler that is installed is the correct filler for the procedure. Using the incorrect filler will compromise the performance of the system and the outcome of the procedure.

Caution: You may load the tubing set up to 24 hours before the procedure as long as you do not lower the cassette or prime the set. Once you lower the cassette or prime the set, you must use the set during the same work shift.

Note: Single-use tubing sets for the Spectra Optia system are considered applied parts because they make contact with the patient. The tubing sets comply with the Class II Type BF electrical safety requirements of IEC 60601-1.

1 Verify that the tubing set has not expired by checking the expiration date on the cover of the package.

2 Document the lot number of the tubing set to use for future reference.

3 Touch **Prepare Tubing Set**. The screen appears instructing you to prepare the set.

Unpacking the Lines and the Bags

Put the tubing set package on top of the centrifuge cover with the package label upright and facing you, and remove the cover from the package. Follow the instructions below according to the type of tubing set you are using.

Exchange Set

1. Take the line holder out of the package. The line holder holds the replace line (white clamps), the AC line (orange), the saline line (green), and the extra remove line (yellow clamp). The remove bag with the attached remove line is located inside the line holder.
2. Take out the remove bag and the extra remove line. Put the remove bag with attached lines on the right side of the centrifuge cover.
3. Take out the replace line and put the line over the right side of the front panel.
4. Take out the AC line (orange) and the saline line (green) and hang the lines over the left side of the front panel. Set the empty line holder aside.
5. Take the vent bag out of the package and hang the bag on the left side of the IV pole.
6. Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).
7. Hang the remove bag on the IV pole.

Collection Set

1. Take the product bags and the vent bag out of the package and hang the bags from left to right on the IV pole in the following order: vent bag, plasma bag, collection bag.
2. Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).
3. Take out the AC line (orange) and the saline line (green) and hang the lines over the left side of the front panel.

IDL Set

1. Take the product bags and the vent bag out of the package and hang the bags from left to right on the IV pole in the following order: vent bag, plasma bag, collection bag.
2. Take out the replace line and put the line over the right side of the front panel between the two sides of the IV pole.
3. Take out the coiled inlet line (red clamps) and remove the paper tape from the coil. Hang the inlet connection on the left end of the IV pole. Repeat this step with the return line (blue clamps).
4. Take out the AC line (orange) and the saline line (green) and hang the lines over the left side of the front panel.

Snapping the Cassette into the Cassette Tray

1 Take the cassette out of the package and put the bottom of the cassette into the bottom edge of the cassette tray (Figure 5-3).

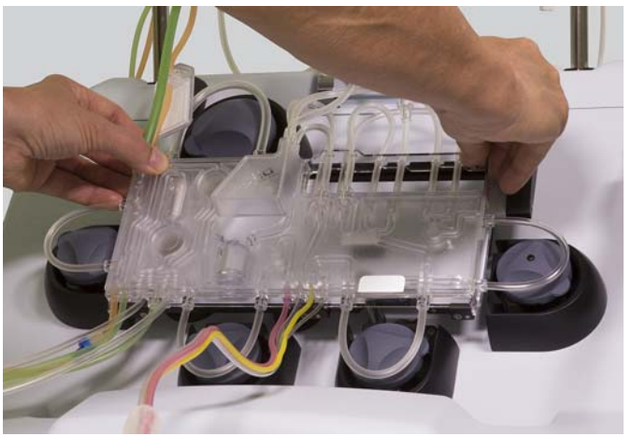


Figure 5-3: Cassette snapped into the cassette tray

2 Ensure that there is nothing lodged behind the cassette or the tray that could interfere with the loading.

3 Press on the top corners of the cassette to snap the cassette into the tray.

Loading the Channel into the Centrifuge

1 Take the channel out of the package and put it on top of the centrifuge cover. Set the empty package aside.

2 Open the centrifuge door.

3 Locate the pin on the filler latch. Raise the latch by pushing the pin toward the center of the filler while pulling the latch up.

4 Turn the centrifuge so that the loading port faces you.

5 Extend the lines between the cassette and the channel, and ensure that they are not twisted.

6 Pull the channel up through the loading port and then through the opening in the center of the filler. To avoid damaging the chamber and the collect line when using a Collection Set, guide the chamber through the loading port with one hand as you pull the channel through the loading port with the other hand (Figure 5-4). Lower the filler latch and lock it in place.

Figure 5-4: Channel pulled through the loading port (Collection Set shown here)

7 Position the lower collar in the collar holder on the filler latch so that the inlet line (pink line) is not obstructed by the other lines. Ensure that either the base of the pink line aligns with the space between the two screws (Figure 5-5, number 1) or is adjacent to the indentation on the filler latch.

8 Grasp the centrifuge loop below the lower collar and gently pull the collar down until you hear the “click” of the locking pin as it pops out and locks the collar in the collar holder. Ensure that the notch at the base of the locking pin (Figure 5-5, number 2) is visible. If the collar is locked, you can see the notch.

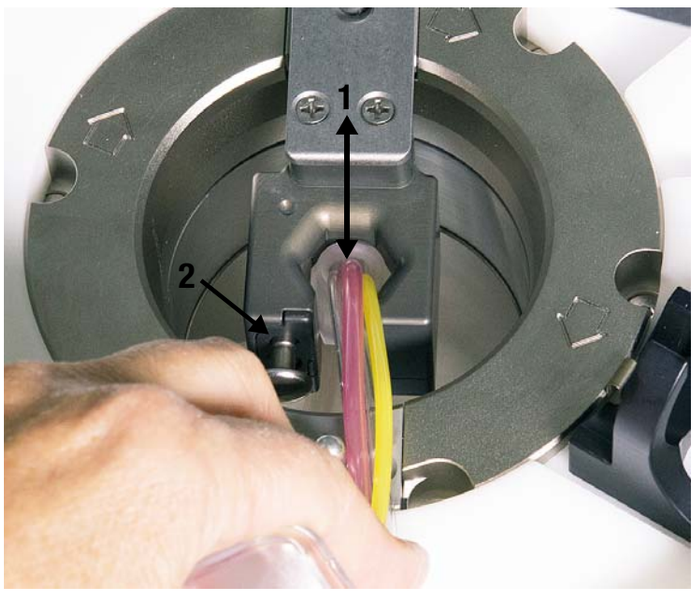


Figure 5-5: Lower collar correctly positioned and locked with the notch on the locking pin visible

9 Starting with the connector (Figure 5-6, number 1), insert the channel into the groove in the filler, finishing with the inlet port (Figure 5-6, number 2). Run your finger over the groove and push down any section of the channel that is not completely inserted in the groove. The channel must sit flush with the groove.

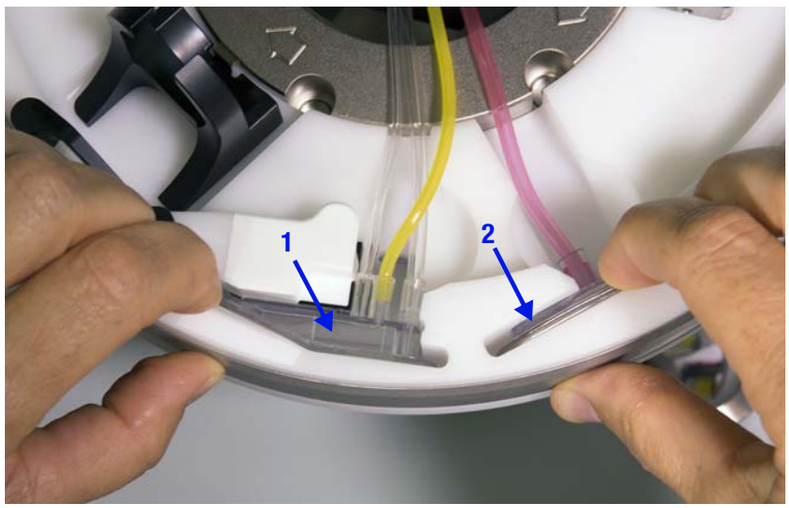


Figure 5-6: Channel pressed into the groove (Exchange Set shown here)

10 If you are using a Collection Set, put the chamber (Figure 5-7, number 3) into the chamber bracket. Ensure that the chamber sits behind the clip at the opening of the bracket, so that the clip retains the chamber in the bracket. Put the collect line to the chamber behind the lip of the optical reference (Figure 5-7, number 4), so that the line does not block the optical reference.

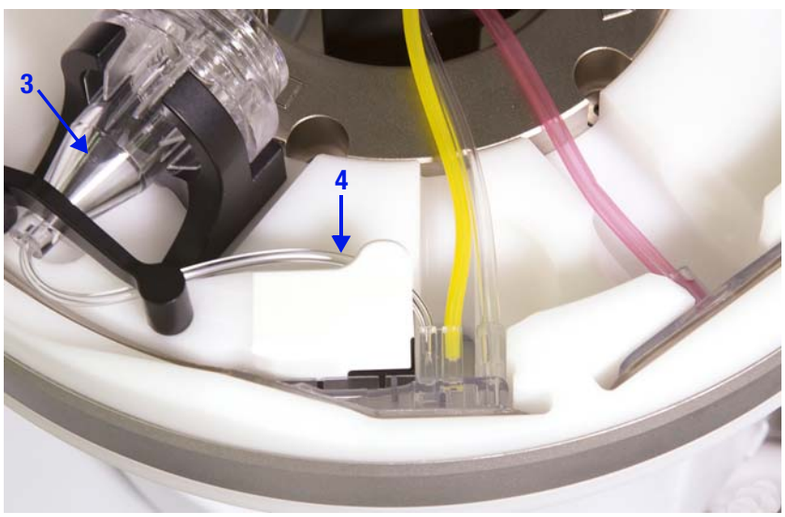


Figure 5-7: Collect line correctly positioned behind the lip of the optical reference

Loading the Lower and Upper Bearings and the Upper Collar

1 Insert the narrow part of the lower bearing into the lower bearing holder (Figure 5-8) and the narrow part of the upper bearing into the upper bearing holder (Figure 5-9). Ensure that the braided section of the loop is not twisted.

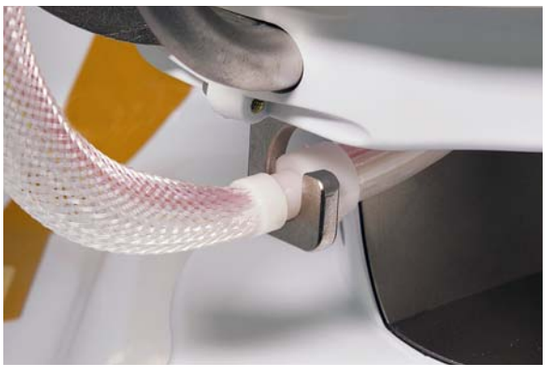


Figure 5-8: Lower bearing inserted in the lower bearing holder

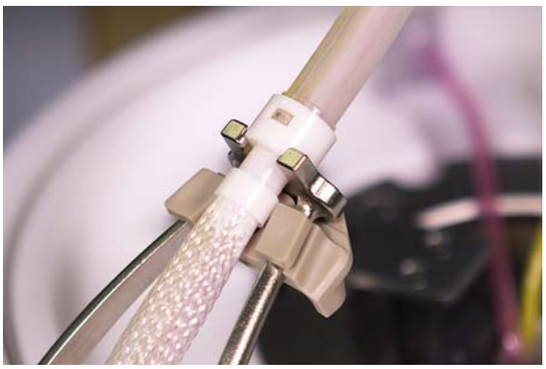


Figure 5-9: Upper bearing inserted in the upper bearing holder

2 Position the upper collar below the upper collar holder and insert the line into the holder (Figure 5-10). Pull the line up to secure the upper collar in the holder (Figure 5-11).

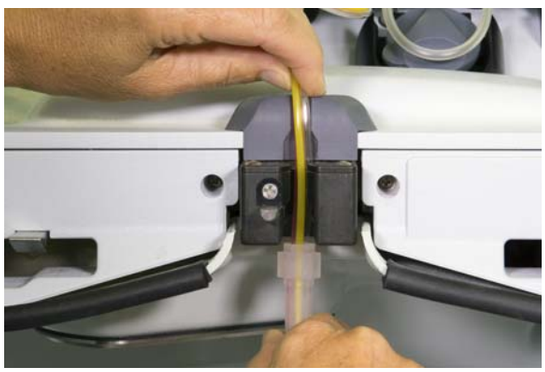


Figure 5-10: Line inserted in the upper collar holder

Figure 5-11: Upper collar secured in the upper collar holder

3 Spin the centrifuge clockwise to ensure that it rotates freely.

4 Close the centrifuge door.

5 Touch **Load**. The system lowers the cassette and performs several tests to verify that the tubing set and the system components function properly.

6 Discard the empty tubing set package, according to your standard operating procedures.

Priming the Tubing Set

Follow the instructions on the screen to prime the tubing set. The progress of the prime is displayed on the screen. After the AC line is primed, the system sounds a tone to notify you to open the inlet saline line and the return saline line in order for the prime to continue. Before the system primes the channel, it performs a test to verify that the correct filler is installed.

The Exchange Set and the Collection Set are primed in 3 to 4 minutes. The IDL Set is primed in approximately 9 minutes. When the system finishes priming the set, it sounds a tone. The patient data screen appears.

Note: The AC line is not used during a BMP procedure.

Note: The menu buttons at the top of the screen are active so that you may enter or change the patient data or the procedure data during the prime.

6

Selecting Procedure Options

Selecting Procedure Options

Procedure options are optional steps that you may choose to perform during a procedure. To select the options you must first select a procedure. The available options vary by procedure and apply to the current procedure only. The options are summarized in Table 6-1.

To select the procedure options, do the following:

1 Touch the **Run** menu button. The run tabs appear.

2 Touch the **Options** tab. The options screen appears.

3 Follow the instructions below to select the procedure options.

4 When you are finished selecting the options, touch **Confirm**.

5 Follow the instructions on the screen to resume the procedure.

Table 6-1: Procedure options

Procedure Option	Procedure	Description
Rinseback • Yes • No	All procedures	Allows you to specify whether the system should perform or skip rinseback at the end of the run. During rinseback, the system pumps saline through the tubing set and evacuates the fluid in the channel to return the remaining blood components to the patient. If you perform a custom prime, the system will automatically skip rinseback unless you specify otherwise. The default setting for performing rinseback is Yes for most procedures. If you are performing a red blood cell exchange procedure, or if you selected to perform a custom prime, the default setting is No.
Custom prime • Yes • No	• TPE • SPD • RBCX • MNC • CMNC • PMN • WBCD • PLTD	Allows you to fill the tubing set with specified fluid (RBC, plasma, or albumin) after you prime the set with saline and before you connect the patient. Performing a custom prime helps to maintain isovolemia when the patient has a low RBC volume or a low total blood volume, such as a pediatric patient. After the custom prime is complete and the run is started, the fluid used is pumped from the channel to the patient before the system establishes the interface.The default setting for performing a custom prime is No.
HES • Yes • No	• PMN • WBCD	Allows you to indicate the use of hydroxyethyl starch (HES) during a procedure. The default setting is the configured setting.
Saline rinse • Yes • No	All procedures	Allows you to rinse the tubing set with saline solution when you are concerned about hypersensitivity reactions associated with residual ethylene oxide in the tubing set, which is a result of sterilization. This option is available to select before you connect the patient. The default setting for performing a saline rinse is No.
Single Needle • Yes • No	TPE	Allows you to indicate the use of a single access to perform a procedure. The default setting for the single-needle option is No.
Collect plasma • Yes • No	BMP	Allows you to specify whether the system should collect plasma at the end of the run. The system uses procedure data to determine the optimal plasma volume to collect, but you may change the volume during the run. The default setting to collect plasma is the configured setting.

Table 6-1: Procedure options (continued)

Procedure Option	Procedure	Description
Blood warmer • Return line • Tubing set (mL)	• TPE • SPD • RBCX • MNC • CMNC • PMN • WBCD	Allows you to indicate the use of a blood warmer on the return line without having to change the configured setting. You must also enter the volume of the blood warmer tubing set so that the system can adjust the volume of saline required to perform rinseback. The default setting for using a blood warmer is the configured setting.
Blood warmer • Replace line	• TPE • SPD • RBCX	Allows you to indicate the use of a blood warmer on the replace line without having to change the configured setting. The default setting for using a blood warmer is the configured setting.

Plasma collection
• Before the run starts:
  • Beginning of run
  • End of run
• After the run starts:
  • Now
  • End of run
	CMNC	Allows you to indicate when the configured volume of plasma should be collected during the run. The selections change depending on whether the run has started. The default setting for plasma collection is End of Run.

Selecting Rinseback

Warning: Terumo BCT does not recommend performing rinseback during RBCX procedures. The data that the system uses to predict the run targets does not include rinseback volume. If rinseback is performed, the run targets may not be accurate.

The system considers the patient's TBV and the fluid balance safety limit when determining the volume of fluid that can be used to perform rinseback. There are four stages of rinseback. If the patient's fluid balance has reached the maximum limit for the procedure, the system might not complete all four stages. The stages are as follows:

- Stage 1: The system pumps the blood out of the channel for return to the patient. If you are using an Exchange Set or a Collection Set, the system returns approximately 50 mL of volume to the patient. If you are using an IDL Set, approximately 115 mL of volume is returned.
- Stages 2 through 4. During each stage, the system performs the following steps:
  a. Pumps 20 mL of saline into the channel.
  b. Restarts the centrifuge, spins the centrifuge to rinse the channel, and then stops the centrifuge.
  c. Pumps the contents out of the channel for return to the patient.

If you intend to perform rinseback, confirm that the selection for rinseback is Yes. The system prompts you to perform rinseback at the end of the run. If you do not want to perform rinseback, change your selection to No. If you selected a custom prime, the default setting for rinseback is No. If you select No and decide later to perform rinseback, perform the following steps:

1 When the run targets screen appears, touch the **End Run** menu button. The end run tabs appear.

2 Touch the **Rinseback** tab.

3 Follow the instructions on the screen to proceed with rinseback.

Selecting and Performing a Custom Prime

The system prompts you to enter data for the custom prime after it primes the tubing set and before you connect the patient. Two methods are available for selecting a custom prime:

- Select the custom prime option on the options screen. The custom prime option is available to select before you connect the patient.
- Accept the system's recommendation to perform a custom prime. The system makes the recommendation based on the custom prime recommendation limit that was configured. If you change the patient data so that the recommendation limit is no longer exceeded, the system will display an alert that a custom prime may no longer be necessary.

If you perform a custom prime, you need the following supplies:

- Fluid for the custom prime
- Empty bag
- Filter or blood administration set (optional)
- Appropriate connectors to connect the inlet and return lines to the fluid and the empty bag

Note: If you perform a custom prime, the system does not perform the step to divert the saline used to prime the tubing set. The saline is removed from the set during the custom prime.

Selecting the custom prime option

To select the custom prime option, touch the custom prime button until **Yes** appears on the button.

Accepting a custom prime recommendation

After you enter the patient data, the system displays a screen recommending that you consider performing a custom prime. Perform the following steps:

1. Review the information on the screen, and confirm that it is correct. The screen also shows the recommended fluid to use, the patient's TBV and RBC volume that is in the tubing set, and what the system predicts the patient's Hct to be if a custom prime is not performed.
2. To accept the recommendation, touch **Yes**. To decline the recommendation, touch **No**.

Entering data for the custom prime

If you select the custom prime option or accept a custom prime recommendation, the system prompts you to enter data for the custom prime. Perform the following steps:

1. Choose one of the following fluid types to use for the custom prime by touching the corresponding button on the screen:
   - RBC
   - Plasma
   - Albumin

2 Enter the fluid data by touching the corresponding buttons on the screen:

- RBC unit Hct (%)
  - This entry is available if you select RBC as the fluid type.
- Maximum inlet pump flow rate (mL/min)
  - If you are using a filter, determine if the filter has a flow rate limit before you enter a maximum inlet pump flow rate.
  - Ensure that the access on the return line can accommodate the flow rate you entered.
- Volume (mL) of the custom prime fluid
  - The patient will not receive the full benefit of the custom prime if the volume entered is less than 200 mL (Exchange Set or Collection Set) or 300 mL (IDL Set), plus the volume of any blood warmer tubing on the return line.

3 Touch **Confirm**.

Starting the custom prime

1 Perform the steps that appear on the screen:

a. Connect the inlet line to the container of fluid to use for the custom prime. Connect a filter, if indicated.

b. Connect the return line to the empty bag.

c. Unclamp the inlet line and the return line.

2 Touch **Start Custom Prime**. The status of the custom prime appears on the screen.

Note: Monitor the progress of the custom prime. If the actual volume in the container of custom prime fluid is less than the volume you entered on the screen, you may need to stop the custom prime before it is complete to avoid drawing air into the tubing set.

3 When the custom prime is complete, the screen appears instructing you to connect the patient lines.

Ending the custom prime before it is complete

1 Touch **End Custom Prime**. A screen appears on which you must confirm your decision to end the custom prime.

Note: If you end the custom prime before the system has processed the recommended volume, an alarm occurs reminding you that the patient will not receive the full benefit of the custom prime. Follow the instructions on the screen to either resume or end the custom prime.

2 Touch **End Custom Prime**, and then touch **Confirm**.

Extending the custom prime

You can extend the custom prime by increasing the volume entered for the fluid to use for the custom prime. To extend the custom prime, perform the following steps:

1 When the screen appears instructing you to connect the patient lines, touch the go back button. The screen appears that instructs you to prime the inlet and return lines. **Do not** perform the instructions on the screen.

2 Touch **Confirm**. The screen appears that prompts you to enter the fluid data.

- If you decide not to extend the custom prime when you reach this screen, touch the **Options** tab. The options screen appears. Change the custom prime button to **No**, and touch **Confirm**.

3 Touch the volume button and enter the sum of the original fluid volume plus the volume of the additional fluid.

For example, if the volume that you first entered for the custom prime was 250 mL and you decide to extend the custom prime by 30 mL, enter 280 mL.

4 Touch **Confirm**.

5 Touch **Start Custom Prime**.

Indicating the Use of HES

Touch the button for HES until the desired selection appears on the button. The change applies to the current procedure only. To change the default setting, you must change the configured setting.

The selection determines the default packing factor for the procedure. If you select Yes, the default packing factor is 1.6. If you select No, the default packing factor is 4.5.

Selecting and Performing a Saline Rinse

The system prompts you to perform the saline rinse after it primes the tubing set and before you connect the patient. If you perform a saline rinse, you need the following supplies:

- New container of saline that contains at least 250 mL.

Note: The system uses 250 mL of saline for a saline rinse. If you intend to perform a saline rinse more than once, you need additional saline.

- Empty bag of sufficient volume to hold the saline that is used for the saline rinse.
- Appropriate connector to connect the return line to the empty bag.

The inlet pump flow rate during a saline rinse depends on the tubing set you use. Ensure that the access to the bag on the return line can accommodate the flow rate. The inlet pump flow rates for the tubing sets are as follows:

- Exchange Set: 120 mL/min
- Collection Set: 90 mL/min
- IDL Set: 90 mL/min

Selecting the saline rinse option

To select the saline rinse option, touch the saline rinse button until **Yes** appears on the button. Resume the procedure.

Starting the saline rinse

1. When the screen appears with the message “Prepare for saline rinse,” perform the steps that appear on the screen:
   a. Spike the new container of saline, and squeeze the drip chamber to ensure that saline drips into the chamber.
   b. Connect the empty bag to the return line.
2. Touch **Continue**.
3. Perform the steps that appear on the screen:
   a. Wait 15 minutes to allow any residual ethylene oxide in the tubing set to diffuse into the saline.
   b. Open the inlet saline line and the return saline line.
   c. Unclamp the return line and flush the line to the access site with at least 50 mL of saline.
   d. Close the return saline line.
4. Touch **Start Saline Rinse**. The status of the saline rinse appears on the screen.
5. To stop the saline rinse before it is complete, touch **Cancel Saline Rinse**. A screen appears on which you must confirm your decision to cancel the saline rinse. Touch **End Saline Rinse**, and then touch **Confirm**.

6 After the saline rinse is complete, perform the steps that appear on the screen:

- Close the inlet saline line.
- Clamp the return line.

7 Touch **Continue**. The screen instructing you to connect the patient lines appears.

8 If you intend to perform more than one saline rinse, proceed to the next section, "Repeating a saline rinse." **Do not** touch **Confirm**.

Repeating a saline rinse

You can perform a saline rinse as many times as necessary. To repeat a saline rinse, perform the following steps:

1 On the screen instructing you to connect the patient lines touch the go back button.

2 When the screen appears instructing you to clear the saline from the saline drip chamber and rehang the container, touch **Confirm**.

3 Repeat the steps under "Starting the saline rinse" above.

Selecting and Confirming the Single-Needle Option

To use a single needle for a TPE procedure, you must first select and confirm the single-needle option. See "Converting the Access to a Single Needle" on page 91 for instructions. You may change your selection for the single-needle option before you prime the inlet line, the return line, and the single-needle connector. If you selected to perform a saline rinse or a custom prime, you will be instructed to perform these steps before connecting the single-needle connector.

Indicating Plasma Collection (BMP)

Touch the collect plasma button on the BMP options screen until the desired selection appears on the button. The change applies to the current procedure only. To change the default setting, you must change the configured setting.

Indicating the Use of a Blood Warmer

Follow the instructions below to indicate the use of a blood warmer during the procedure. You must prime the blood warmer tubing set before you connect the patient. If you are using a blood warmer on the replace line, refer to "Exchange Procedures: Using a Blood Warmer on the Replace Line" on page 267.

Exchange procedures

1 Select the line on the tubing set to which you want to connect the blood warmer. To use more than one blood warmer, select both the return line and the replace line:

- To indicate a blood warmer on the return line, touch the return line button until **Yes** appears on the button.
- To indicate a blood warmer on the replace line, touch the replace line button until **Yes** appears on the button. Ensure that you connect the blood warmer to the replace line before you spike the replacement fluid.

2 If you indicated a blood warmer on the return line, enter the volume of the blood warmer tubing set:

a. Touch the tubing set volume button. A data entry pad appears.

b. Enter the volume of the tubing set. The volume you entered appears on the button.

Collection and depletion procedures

1 Touch the return line button until **Yes** appears on the button.

2 Touch the tubing set volume button. A data entry pad appears.

3 Enter the volume of the blood warmer tubing set. The volume you entered appears on the button.

Indicating the Timing of Plasma Collection (CMNC)

Indicate your selection for when the system should collect plasma during a CMNC procedure by touching the button for the desired option. The change applies to the current procedure only.

7

Therapeutic Plasma Exchange (TPE) Procedures

Functional Description of a Therapeutic Plasma Exchange (TPE) Procedure

During a TPE procedure, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor of 20. The AIM system monitors the interface position and adjusts the flow rate of the plasma pump to maintain the optimal interface position to remove the plasma. When the AIM system determines that the buffy coat has reached a specific thickness in the connector, or when an inlet volume equal to 0.25 of the patient's TBV has been processed, the system slows the plasma pump and flushes the buffy coat through the RBC port and into the reservoir. The replace pump pumps replacement fluid into the reservoir, where it combines with the RBC and the other cellular components for return to the patient. The system manages the volume of plasma that is removed and fluid that is replaced according to the fluid balance the operator selects.

TPE Procedures Using a Single Needle

During a TPE procedure using a single needle, the system performs therapeutic plasma exchange using a single patient access. The run consists of two phases. During the first phase, the system pumps the patient's blood into the tubing set, separates and removes the plasma, and pumps replacement fluid and the RBC and the other cellular components from the channel into the reservoir. When the high-level reservoir sensor detects fluid, indicating that the reservoir is full, the first phase stops and the second phase begins. During the second phase, the system returns the contents of the reservoir to the patient. When the low-level reservoir sensor no longer detects fluid, indicating the reservoir is empty, the second phase stops and the first phase restarts. The system repeats this cycle until the run ends.

Preparing to Perform a Procedure

Supplies

Assemble the supplies listed on page 62 before you begin a procedure. You will also need the following additional supplies:

- Replacement fluid prescribed by the patient's physician
- Spectra Optia® Single-Needle Connector, if performing a TPE procedure using a single needle

Optional supplies:

- Filters for the replacement fluid

Selecting the Procedure and Loading the Tubing Set

Follow the instructions starting on page 64 to select the procedure and load the tubing set. Before you load the tubing set, verify that the set and the solutions you are using have not expired by checking the expiration date printed on the packaging. Do not use an item if the current date is past the expiration date.

Navigating the TPE Procedure Screens

Menu Buttons and Tabs

Table 7-1 shows the menu buttons and tabs to use to navigate the screens during a TPE procedure. Menu buttons and tabs are active depending on the current operating state. Touch a menu button to display the corresponding tabs.

Table 7-1: Menu buttons and tabs on TPE procedure screens

Config	Data	Run	End Run
System	Patient data	Exchange Status	Rinseback
Report	Fluid	Operation status	Disconnect
Procedure	Alarm history	Bolus	Run targets
TPE	Report	Strobe	
Blood warmer		Run values	
		Options	

Descriptions of Buttons, Icons, and Images

See Table 2-14 on page 36 for descriptions of the buttons, icons, and images that can appear on the screen during a TPE procedure.

Entering and Changing Data During the Run

The Spectra Optia system requires that you enter specific data, such as patient data, to perform a TPE procedure. The system also allows you to change numerical values for certain operating parameters during the run. Table 7-2 shows data entry ranges for the operating parameters according to the screen on which each data entry button appears. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad displays either the established range for the parameter or the calculated range, if the range changes based on related data. Also, the range for Caution status is displayed in yellow, if the data you enter could cause the system to operate in Caution status.

Table 7-2: Data entry ranges for TPE procedure parameters

Screen	Parameter	Range
Patient data	Sex	• Male • Female
	Height: • ft • in • cm	 • 1 to 8 • 0 to 11 • 30 to 244
	Weight: • lb • kg	 • 5 to 500 • 2 to 227
	Hct (%)	10 to 70
	TBV (mL)	300 to 15000
Fluid data	Replacement fluid	• Plasma • Saline/Albumin • Custom
	Fluid balance (mL or %)	± 25% of the patient's TBV (Caution status applies if the entry exceeds ± 10% of the patient's TBV.)
Options	Rinseback	• Yes • No Default: • Yes if a custom prime is not selected • No if a custom prime is selected
	Custom prime	• Yes • No Default: No
	Saline rinse	• Yes • No Default: No
	Single needle	• Yes • No Default: No

Table 7-2: Data entry ranges for TPE procedure parameters (continued)

Screen	Parameter	Range
	Blood warmer: • Return line • Replace line	• Yes • No
	Blood warmer: Tubing set volume (mL)	1 to 100
Custom prime	Fluid type	• RBC • Plasma • Albumin
	RBC unit Hct (%)	25 to 80
	Inlet flow rate (mL/min)	5 to 120
	Volume (mL)	100 to 400 (Volume should be at least 200 mL for the patient to receive the full benefit.)
Run values	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
	Plasma removed (mL)	Depends on the patient's plasma volume
	Run time (min)	40 to 480
	Plasma volumes exchanged	0.5 to 4
	Inlet flow rate (mL/min)	5 to 142
	Replace volume: Target (mL)	Depends on the patient's plasma volume
Main run	Packing factor	4 to 20 Default: 20 (Packing factor can be changed only during Semi-Automatic mode.)
	Inlet flow rate (mL/min)	5 to 142
	Replace volume (mL)	Depends on the patient's plasma volume
	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if entered ratio is not within the recommended range of 6:1 to 15:1.)

Table 7-2: Data entry ranges for TPE procedure parameters (continued)

Screen	Parameter	Range
Exchange status	Replacement fluid	• Plasma • Saline/Albumin • Custom
Bolus	Volume (mL)	10 to a volume that equals +25% of the patient's TBV
	Flow rate (mL/min)	10 to 120
Run targets	Plasma volumes exchanged	0.5 to 4
	Run time (min)	40 to 480
	Plasma removed (mL)	Depends on the patient's plasma volume
	Replacement fluid used (mL)	Depends on the patient's plasma volume
Rinseback	Return flow rate (mL/min)	2 to 100 Default: inlet flow rate that was in use when the run ended or 100 mL/min, whichever is slower

Entering and Confirming Patient and Procedure Data

This section contains instructions for entering patient data, entering fluid data, and reviewing and confirming run values. You can enter the data after you select the procedure and before you connect the patient. It is important that the data you enter be as accurate and as current as possible.

Note: When you are required to enter numerical data, the system displays a data entry pad for entering the data. The acceptable numerical range appears on the data entry pad.

Entering Patient Data

1 Touch the buttons on the screen to enter the following information:

- Sex
- Height
- Weight
- Hematocrit (Hct)

The Spectra Optia system uses the sex, height, and weight to calculate the patient's TBV. See page 266 for the formula the system uses to calculate this value. If you prefer not to use the TBV that the system calculated, touch **TBV** and enter a different volume. The operator override icon ( ) will appear on the button.

Note: If the patient weighs less than 25 kg (approximately 55 lb), the system does not calculate a TBV. You must calculate and enter the appropriate TBV for the patient.

2 Touch **Confirm**. The fluid data screen appears.

Entering Fluid Data

Perform the steps below to select the type of replacement fluid you are using and to enter the fluid balance.

Selecting the type of replacement fluid

1 Touch **Fluid Type**. A list of replacement fluid types appears.

2 Select one of the following replacement fluid types by touching the corresponding button on the screen:

- Plasma
  - The system assumes that the plasma contains 15% citrate.
- Saline/Albumin
  - The system assumes that the saline/albumin contains 4% citrate.
- Custom
  - The system uses the citrate content that was entered on the TPE configuration screen. A data entry pad appears to allow you to change the citrate content (%) of the fluid for the current procedure only.

Entering the fluid balance

Note: The fluid balance includes fluid that was administered and removed during the run and rinseback but does not include fluid bolus volume.

1 To enter the fluid balance, choose one of the following options:

- To enter the fluid balance in mL, touch **Volume** and use the data entry pad to enter a negative or positive volume. The system calculates and displays the corresponding percentage.
- To enter the fluid balance as a percentage, touch **Percent** and use the data entry pad to enter a percentage. The system calculates and displays the corresponding volume.

2 Touch **Confirm** to save the fluid data. The run values screen appears.

Reviewing and Confirming the Run Values

1 Review the run values that appear on the screen and confirm that they are correct. The run targets for a TPE procedure are listed below. A black frame appears around the button of the primary run target.

- Plasma volumes exchanged (mL)
- Run time (min)
- Plasma removed (mL)
- Replace volume: Target (mL)

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed revert to white.

2 When you are finished reviewing the run values, touch **Confirm**.

Converting the Access to a Single Needle

You may select the single-needle option and convert the access to a single needle before or after you start the run.

Selecting and Confirming the Single-Needle Option

To use a single needle for the procedure, you must first select and confirm the single-needle option. Perform the following steps to select and confirm the single-needle option:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Options** tab. The options screen appears.
3. Touch the button for the single-needle option until **Yes** appears on the button. A screen appears asking you to confirm the conversion to a single-needle access.
4. Touch **Convert Access to Single Needle**.
5. Touch **Confirm**. The options screen reappears.
6. Review or select additional procedure options and then touch **Confirm**.

Note: If you select and confirm the single-needle option before you start the run, you may change your selection before you prime the inlet line, the return line, and the single-needle connector. If you select and confirm the single-needle option during the run, you cannot change your selection. You must complete the run using a single needle.

Connecting the Single-Needle Connector

Perform the following steps to connect the single-needle connector to the tubing set. Do not connect the single-needle connector until you are instructed to do so.

Note: If you selected to perform a saline rinse or a custom prime, you will be instructed to perform these steps before you connect the single-needle connector.

1. Select and confirm the single-needle option according to the instructions under “Selecting and Confirming the Single-Needle Option” above. The single-needle icon ( ) appears on the main run screen and on the exchange status screen to indicate that you have confirmed the option.
2. Follow the instructions on the screen to connect and prime the single-needle connector.

Priming the Inlet Line, the Return Line, and the Replace Line

Warning: When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

1 Follow the instructions on the screen to prime the inlet line and the return line. If you are using a blood warmer on the replace line, follow the instructions under "Exchange Procedures: Using a Blood Warmer on the Replace Line" on page 267 to connect and prime the blood warmer tubing set and to prime the replace line. If you are not using a blood warmer or you are using a blood warmer on the return line, follow the instructions on the screen.

2 Touch **Confirm**.

3 Follow the instructions on the screen to spike the replacement fluid container, to prime the replace line, and to put the replace line into the replacement fluid detector.

4 Touch **Continue**. The screen appears with instructions for connecting the patient.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions on the screen to connect the patient and start the run.

2 Touch **Start Run**. The system begins drawing the patient's blood into the tubing set. The main run screen appears, and the system diverts approximately 40 mL of saline that was used to prime the tubing set into the remove bag.

Note: If you performed a custom prime, the system does not perform the step to divert the saline. The saline was removed from the set during the custom prime.

Monitoring the Run

The system displays information on the screens to help you monitor the progress of the run. To access the screens, touch the **Run** menu button and then the tab for the screen you want to view. Be sure to verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and in the bags.
See “Glossary of Terms” on page 278 for descriptions of the buttons on the screens.

Main Run Screen

The main run screen is the default run screen and displays or provides access to the information you most likely need to monitor the run. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen. There is no tab for the main run screen.

Algorithm control

The plasma of certain patients can cause extreme turbulence or platelet swirling to occur in the connector. If this condition persists, the AIM system cannot effectively control the position of the interface. The system begins using the entered hematocrit to calculate the plasma pump flow rate, and the algorithm control icon appears on the screen in place of the interface image. After the interface position is stable for at least one minute, the AIM system resumes control.

Exchange Status Screen

To access the exchange status screen, touch the **Exchange Status** tab. Use this screen to view information about the current status of the run, including the patient’s fluid balance, the fluid administered, and the volumes that have been exchanged and replaced during the run.

Replacement fluid

The type of replacement fluid currently in use appears on the button on this screen. Touch this button to change the type of replacement fluid and then follow the instructions on the screens.

Monitoring the Patient

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the pumps. An alarm occurs indicating that the procedure was paused and the pumps were stopped.
2. Notify the attending physician of the patient's condition according to your facility's standard operating procedures.
3. Touch the go back button to go to the run values screen, and decrease the AC infusion rate as desired.
4. Touch the active alarm button to return to the alarm screen, and then touch **Continue**. The run values screen appears.
5. Review the run values and confirm that they are correct.
6. Touch **Confirm** to resume the procedure.
7. If decreasing the AC infusion rate does not alleviate the symptoms, touch the pause button to pause the pumps again, and notify the attending physician.

Giving a Fluid Bolus

Perform the following steps to use the system to give the patient a fluid bolus:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Bolus** tab. The fluid bolus screen appears.
3. Follow the instructions on the screen to spike the saline container on the replace line. Confirm that the replace line is not clamped.
4. Touch **Volume** and enter the volume (mL) of the bolus.
5. Touch **Flow Rate** and enter the flow rate (mL/min) for the bolus.

Note: If the fluid you use for the bolus is not saline, enter a flow rate that takes into account the percentage of citrate in the fluid and that is in accordance with your local transfusion practices.

6. To begin the bolus, touch **Start Bolus**. The system delivers the bolus.

   The screen displays the progress of the bolus. To cancel the bolus before delivery is complete, touch **Cancel Bolus**.
7. When the bolus is complete, the system pauses. Touch **Continue** to resume the procedure.

Bolus volume and reported fluid balance

Be aware that the patient's fluid balance displayed on the exchange status screen and on the procedure summary screen does not include the volume of any bolus that was given to the patient during the procedure. The system reports the total bolus volume in separate fields on the screens.

Optimizing the Run

Prediction for Removing a Substance From the Patient's Plasma

Table 7-3 shows how the number of plasma volumes exchanged correlates to the removal of a hypothetical substance from the patient's plasma. The percentage that is removed is based on the assumption that there is no equilibration with the extravascular compartment and that the patient's plasma volume remains constant during the procedure. Consider using this guideline to help you determine your procedure goals.

Table 7-3: Plasma exchange efficiency of a TPE procedure

Plasma Volumes Exchanged	Percentage Removed
0.5	39
1.0	63
1.5	78
2.0	86
2.5	92
3.0	95

Source:

George W. Buffaloe, et al., "Technical Considerations," *Therapeutic Plasma Exchange Disease Compendium*, 1983, Dau P (ed.).

Handling Turbulence or Platelet Swirling in the Connector

If extreme turbulence or platelet swirling persists for more than 10 seconds, the system begins using the entered hematocrit to calculate the plasma pump flow rate, and the algorithm control icon (▒) appears on the main run screen in place of the interface image. Consider the following options when this condition occurs:

- Take no action. The AIM system automatically resumes control of the interface position after the position stabilizes.
- Decrease the inlet pump flow rate to help reduce the turbulence. It could be necessary to decrease the flow rate to 62 mL/min or less to achieve the optimal packing factor of 20.0.

Decreasing the Run Time After Converting the Access to a Single Needle

Converting the access to a single needle during the run causes an increase in the predicted run time for the procedure. Consider the following alternatives for decreasing the predicted run time if a shorter run is necessary:

- Increase the inlet pump flow rate or increase the AC infusion rate.

  Increasing these rates allows the system to process more blood in less time. Be aware that either option results in a greater volume of AC delivered to the patient and increases the potential for the patient to experience a citrate reaction.

- Increase the inlet:AC ratio.

  This causes the inlet pump flow rate to increase. However, it decreases the system's ability to manage anticoagulation of the extracorporeal circuit and can result in clumping in the circuit. Monitor the run carefully as you increase the inlet:AC ratio.

The increase in the run time can be more significant if you changed the inlet pump flow rate that the system had established at the start of the run. After the conversion, the system resumes the run using the rate you entered rather than using a rate that is optimal for a single access.

8

Therapeutic Plasma Exchange with a Secondary Plasma Device (TPE-SPD) Procedures

Functional Description of a Therapeutic Plasma Exchange With a Secondary Plasma Device (TPE-SPD) Procedure

During a TPE-SPD procedure, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor of 20. The AIM system monitors the interface position and adjusts the flow rate of the plasma pump to maintain the optimal interface position for removing the plasma. When the AIM system determines that the buffy coat has reached a specific thickness in the connector, or when an inlet volume equal to 0.25 of the patient's TBV has been processed, the system slows the plasma pump and flushes the buffy coat through the RBC port and into the reservoir.

The plasma pump pumps the plasma to the secondary plasma device. The treated plasma is then pumped into the treated plasma bag. The replace pump pumps the contents of the treated plasma bag into the reservoir, where it combines with the RBC and the cellular components from the channel for return to the patient. The system uses the replace pump balance to manage the volume of plasma removed and the volume of plasma returned.

Preparing to Perform a Procedure

Supplies

Assemble the supplies listed on page 62 before you begin a procedure. You will also need the following additional supplies:

- Secondary plasma device (plasma device), as prescribed

Warning: Before performing a therapeutic plasma exchange procedure with a secondary plasma device (TPE-SPD procedure), carefully review the instructions for use provided by the manufacturer of the secondary plasma device.

- Hemostats
- Extension tubing set to use to connect the plasma device to the Exchange Set
- Bag with a needle adapter to hold the treated plasma (treated plasma bag) and to attach to the outlet end of the plasma device

Optional supplies:

- Bag to use for fluid waste diverted from the plasma device
- Connectors for connecting the treated plasma bag, the waste bag, or the tubing set to the plasma device. For example:
  - Two 3-way stopcocks or two Y-shaped connectors
  - Male-to-male luer connector (optional)

Selecting the Procedure and Loading the Tubing Set

Follow the instructions starting on page 64 to select the procedure and load the tubing set. Before you load the tubing set, verify that the set and the solutions you are using have not expired by checking the expiration date printed on the packaging. Do not use an item if the current date is past the expiration date.

Navigating the TPE-SPD Procedure Screens

Menu Buttons and Tabs

Table 8-1 shows the menu buttons and tabs to use to navigate the screens during a TPE-SPD procedure. Menu buttons and tabs are active depending on the current operating state. Touch a menu button to display the corresponding tabs.

Table 8-1: Menu buttons and tabs on TPE-SPD procedure screens

Config	Data	Run	End Run
System	Patient data	Treatment status	Rinseback
Procedure	Plasma device	Operation status	Disconnect
Report	Alarm history	Bolus	Run targets
SPD	Report	Strobe	Treated plasma
Blood warmer		Run values	
Plasma device		Options	

Descriptions of Buttons, Icons, and Images

See Table 2-14 on page 36 for descriptions of the buttons, icons, and images that can appear on the screen during a TPE-SPD procedure.

Entering and Changing Data During the Run

The Spectra Optia system requires that you enter specific data, such as patient data, to perform a TPE-SPD procedure. The system also allows you to change numerical values for certain operating parameters during the run. Table 8-2 shows data entry ranges for the operating parameters according to the screen on which each data entry button appears. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad displays either the established range for the parameter or the calculated range, if the range changes based on related data. Also, the range for Caution status is displayed in yellow, if the data you enter could cause the system to operate in Caution status.

Table 8-2: Data entry ranges for TPE-SPD procedure parameters

Screen	Parameter	Range
Patient data	Sex	• Male • Female
	Height: • ft • in • cm	 • 1 to 8 • 0 to 11 • 30 to 244
	Weight: • lb • kg	 • 5 to 500 • 2 to 227
	Hct (%)	10 to 70
	TBV (mL)	300 to 15000
Plasma device	Prime divert volume (mL)	0 to 500 (Volume cannot exceed 15% of the patient's TBV.)
	Replace pump balance (%)	50 to 150
	Saline prime	• Yes • No
	Plasma flow rate (mL/min)	2 to 142
Options	Rinseback	• Yes • No Default: • Yes if a custom prime is not selected • No if a custom prime is selected
	Custom prime	• Yes • No Default: No
	Saline rinse	• Yes • No Default: No
	Blood warmer • Return line • Replace line	• Yes • No

Table 8-2: Data entry ranges for TPE-SPD procedure parameters (continued)

Screen	Parameter	Range
	Blood warmer tubing set volume (mL)	1 to 100
Custom prime	Fluid type	• RBC • Plasma • Albumin
	RBC unit Hct (%)	25 to 80
	Inlet flow rate (mL/min)	5 to 120
	Volume (mL)	100 to 400 (Volume should be at least 200 mL for the patient to receive the full benefit.)
Saline prime	Volume (mL)	5 to 2000
	Flow rate (mL/min)	1 to 100
Run values	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if entered ratio is not within the recommended range of 6:1 to 15:1.)
	Plasma treated (mL)	Depends on the patient's plasma volume.
	Run time (min)	40 to 480
	Plasma volumes treated	0.5 to 4
	Inlet flow rate (mL/min)	5 to 142
	Plasma flow rate (mL/min)	2 to 142
Main run	Packing factor	4 to 20 Default: 20 (Packing factor can be changed only during Semi-Automatic mode.)
	Inlet flow rate (mL/min)	5 to 142
	Plasma flow rate (mL/min)	2 to 142
	Replace pump balance (%)	50 to 150
	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)

Table 8-2: Data entry ranges for TPE-SPD procedure parameters (continued)

Screen	Parameter	Range
Bolus	Volume (mL)	10 to a volume that equals +25% of the patient's TBV
	Flow rate (mL/min)	10 to 120
Run targets	Plasma volumes treated	0.5 to 4
	Run time (min)	40 to 480
	Plasma treated (mL)	Depends on the patient's plasma volume.
Treated plasma	Volume (mL)	5 to 2000
	Return flow rate (mL/min)	2 to 100
Plasma device rinse	Volume (mL)	5 to 2000
	Flow rate (mL/min)	1 to 100
Rinseback	Return flow rate (mL/min)	2 to 100 Default: inlet flow rate that was in use when the run ended or 100 mL/min, whichever is slower

Entering and Confirming Patient and Procedure Data

This section contains instructions for entering patient data, entering fluid data, and reviewing and confirming run values. You can enter the data after you select the procedure and before you connect the patient. It is important that the data you enter be as accurate and as current as possible.

Note: When you are required to enter numerical data, the system displays a data entry pad for entering the data. The acceptable numerical range appears on the data entry pad.

Entering Patient Data

1 Touch the buttons on the screen to enter the following information:

- Sex
- Height
- Weight
- Hematocrit (Hct)

The Spectra Optia system uses the sex, height, and weight to calculate the patient's TBV. See page 266 for the formula the system uses to calculate this value. If you prefer to override the TBV the system calculated, touch **TBV** and enter a different volume. The operator override icon ( ) will appear on the button.

Note: If the patient weighs less than 25 kg (approximately 55 lb), the system does not calculate a TBV. You must calculate and enter the appropriate TBV for the patient.

2 Touch **Confirm**. The data screen for the plasma device appears.

Reviewing and Confirming the Plasma Device Data

The default values that appear on the screen correspond to the values that were configured on the plasma device configuration screen.

1 Review the values on the screen. Change them if needed so that they are correct for the current procedure.

2 Touch **Confirm**. The run values screen appears.

Reviewing and Confirming the Run Values

1 Review the run values that appear on the screen and confirm that they are correct. The run targets for a TPE-SPD procedure are listed below. A black frame appears around the button of the primary run target.

- Plasma volumes treated
- Run time
- Plasma treated (mL)

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed revert to white.

2 When you are finished reviewing the run values, touch **Confirm**.

Connecting the Plasma Device Using an Extension Tubing Set

Follow the instructions in this section to use an extension tubing set to connect the plasma device to the Exchange Set.

Setting Up and Priming the Extension Tubing Set

1. Follow the instructions on the screen to empty the saline drip chamber on the saline line.
2. Touch **Confirm**.
3. Follow the instructions on the screen to connect and prime the extension tubing set and to connect the extension tubing set to the inlet end of the plasma device.
4. Touch **Confirm**.

Connecting the Treated Plasma Bag

If you intend to use the system to prime the plasma device with saline, follow the instructions under "Saline prime: Yes." If not, follow the instructions under "Saline prime: No."

If you are performing a prime divert or you are using a blood warmer on the replace line, perform the following steps before you connect the treated plasma bag:

- To perform a prime divert to remove any fluid in the plasma device, you must have entered a value for the prime divert volume on the plasma device configuration screen or on the plasma device data screen. You must also ensure that a waste bag or other appropriate container is connected to the outlet end of the plasma device to hold the diverted fluid. After the prime divert is complete, the system pumps a volume into the treated plasma bag that is equal to 50 mL or 5% of the patient's TBV, whichever is less.
- If you are using a blood warmer on the replace line, follow the instructions "Exchange Procedures: Using a Blood Warmer on the Replace Line" on page 267 before you connect the treated plasma bag. If you are not using a blood warmer or are using a blood warmer on the return line, follow the instructions on the screen to connect and prime the blood warmer tubing after you connect the treated plasma bag.

Saline prime: Yes

To use the Spectra Optia system to prime the plasma device, you must select **Yes** for a saline prime on the plasma device configuration screen or on the plasma device data screen. You may prime the plasma device as many times as necessary. If you ultimately decide not to perform the prime, touch **Skip Prime**.

Note: Monitor the volume in the saline container on the saline line. Saline from this container is also used for priming the plasma device. If the container empties, air could be drawn into the tubing set.

1. Follow the instructions on the screen to connect a waste bag to the outlet end of the plasma device.
2. Touch **Confirm**.
3. Follow the instructions on the screen to spike the replace line into the saline container.
4. Touch **Confirm**. The screen appears instructing you to enter the data required for the prime and to prime the plasma device.
5. Enter the volume of saline and the flow rate required for the prime.

6 Touch **Start Prime**. The system starts priming the plasma device.

- To pause the prime, touch **Pause Prime**.
- To restart the prime, touch **Start Prime**.

The screen displays the progress of the prime.

- Current Prime indicates the volume of saline that has been processed for the current prime.
- Total Prime indicates the total volume of saline that was processed for priming the plasma device during the current procedure.

7 After the volume for the prime has been processed, perform one of the following steps:

- To process additional volume, repeat steps 5 and 6.
- If you are finished priming the plasma device, touch **Prime Complete**.

8 Follow the instructions on the screen to clamp the replace line, spike the second replace line into the treated plasma bag, unclamp the second replace line, and connect the treated plasma bag to the outlet end of the plasma device.

9 Touch **Confirm**.

Saline prime: No

1 If you intend to perform a prime divert, follow the instructions on the screen to connect a waste bag to the outlet end of the plasma device.

2 Touch **Confirm**.

3 Follow the instructions on the screen to spike the second replace line into the treated plasma bag, and to connect the treated plasma bag to the outlet end of the plasma device.

4 Touch **Confirm**.

Priming the Inlet Line and the Return Line

Warning: When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

1 Follow the instructions on the screen to prime the inlet line, the return line, and the blood warmer tubing set, if used.

2 Touch **Confirm**. The screen appears with instructions for connecting the patient and starting the run.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions on the screen to connect the patient.

2 Touch **Start Run**. The system begins drawing the patient's blood into the tubing set. The main run screen appears, and the system diverts approximately 40 mL of saline that was used to prime the tubing set into the plasma device. If you are performing a prime divert, the system begins pumping plasma into the plasma device to divert the fluid that is in the plasma device into the waste bag.

Note: If you performed a custom prime, the system does not perform the step to divert the saline. The saline was removed from the set during the custom prime.

Filling the Treated Plasma Bag

1 When the system is ready to fill the treated plasma bag with the initial volume of treated plasma, a tone sounds. Follow the instructions on the screen to confirm that the treated plasma bag is empty and to ensure that the appropriate lines are unclamped so that plasma will flow into the treated plasma bag.

2 Touch **Confirm**. The main run screen reappears. The system begins pumping treated plasma from the plasma device into the treated plasma bag. The volume pumped into the bag is 50 mL or 5% of the patient's TBV, whichever is less. Once the volume has been pumped into the bag, the replace pump starts, and the system begins returning treated plasma to the patient.

3 If you did not use the system to prime the plasma device, follow the instructions on the screen to perform the following steps:

a. Squeeze the drip chamber on the line to the treated plasma bag to fill the chamber with treated plasma.

b. Touch **Confirm**. The main run screen reappears.

Monitoring the Run

The system displays information on the screens to help you monitor the progress of the run. To access the screens, touch the **Run** menu button and then the tab for the screen you want to view. See “Glossary of Terms” on page 278 for descriptions of the buttons on the screens.

Main Run Screen

The main run screen is the default run screen and displays or provides access to the information you most likely need to monitor the run. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen. There is no tab for the main run screen.

Treatment Status Screen

To access the treatment status screen, touch the **Treatment Status** tab. Use this screen to view information about the current status of the run, including the patient’s fluid balance, the cumulative volume of fluid boluses delivered, the total volume of plasma treated (mL), and the plasma volumes treated.

Monitoring the Patient

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the pumps. An alarm occurs indicating that the procedure was paused and the pumps were stopped.
2. Notify the attending physician of the patient's condition according to your facility's standard operating procedures.
3. Touch the go back button to go to the run values screen, and decrease the AC infusion rate as desired.
4. Touch the active alarm button to return to the alarm screen, and then touch **Continue**. The run values screen appears.
5. Review the run values and confirm that they are correct.
6. Touch **Confirm** to resume the procedure.
7. If decreasing the AC infusion rate does not alleviate the symptoms, touch the pause button to pause the pumps again, and notify the attending physician.

Giving a Fluid Bolus

Perform the following steps to give the patient a fluid bolus:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Bolus** tab. The fluid bolus screen appears.
3. Follow the instructions on the screen to spike the saline container on the replace line. Confirm that the replace line is not clamped.
4. Touch **Volume** and enter the volume (mL) of the bolus.
5. Touch **Flow Rate** and enter the flow rate (mL/min) for the bolus.

Note: If the fluid you use for the bolus is not saline, enter a flow rate that takes into account the percentage of citrate in the fluid and that is in accordance with your local transfusion practices.

6. To begin the bolus, touch **Start Bolus**. The system delivers the bolus.

   The screen displays the progress of the bolus. To cancel the bolus before delivery is complete, touch **Cancel Bolus**.
7. When the bolus is complete, the system pauses. Touch **Continue** to resume the procedure.

Bolus volume and reported fluid balance

Be aware that the patient's fluid balance displayed on the treatment status screen and on the procedure summary screen does not include the volume of any bolus that was given to the patient during the procedure. The system reports the total bolus volume in separate fields on the screens.

Optimizing the Run

Adjusting the Volume of Treated Plasma in the Treated Plasma Bag

Periodically monitor the volume in the treated plasma bag to ensure that an adequate volume is maintained during the run. To increase or decrease the volume in the treated plasma bag, perform the following steps:

1 Go to the main run screen.

2 Ensure that the target flow rates and volumes are displayed. If they are not displayed, touch **Current** to toggle to the target values.

3 Touch the button for the replace flow rate. A data entry pad appears allowing you to adjust the volume currently in the bag or the volume maintained in the bag.

Adjusting the volume currently in the treated plasma bag

1 To adjust the volume currently in the treated plasma bag, perform one of the following steps:

- To add treated plasma to the bag, touch **Fill**. The replace pump pauses.
- To remove treated plasma from the bag, touch **Drain**. The AC, inlet, and plasma pumps pause.

Each time **Fill** or **Drain** is touched, the volume pumped into or out of the treated plasma bag is the lesser of 25 mL or 2.5% of the patient's TBV.

To cancel the filling or the draining before the system pumps the entire volume, touch **End**.

2 When you finish adjusting the volume, touch **Cancel** to close the data entry pad.

Adjusting the volume maintained in the treated plasma bag

1 To adjust the volume maintained in the treated plasma bag, you must change the replace pump balance. Do one of the following:

- To increase the volume maintained in the bag, touch the up arrow button until the desired replace pump balance is displayed.
- To decrease the volume of treated plasma maintained in the bag, touch the down arrow button until the desired replace pump balance is displayed.

Note: The replace pump balance decreases when you increase the volume to be maintained in the bag and increases when you decrease the volume to be maintained in the bag.

2 When you finish adjusting the replace pump balance, touch **Confirm**.

Managing a Positive Fluid Balance

The total volume of the AC used during a TPE-SPD procedure is returned to the patient with the treated plasma. As a result, the patient's fluid balance is always positive at the end of the run. Consider the following guidelines to help decrease the volume if the additional volume is an issue for the patient:

- Increase the inlet:AC ratio to 15.0. Be aware that if the extracorporeal circuit is not adequately anticoagulated, platelet clumping could occur. For more information about anticoagulation and addressing clumps or clots in the circuit, see "Managing Anticoagulation of the Extracorporeal Circuit" on page 221.
- Do not rinse the contents remaining in the plasma device into the treated plasma bag at the end of the run.
- Do not return the contents of the treated plasma bag to the patient at the end of the run. Keep in mind that doing this leaves the patient in a plasma-negative condition.

Returning the Contents of the Treated Plasma Bag to the Patient

Perform the following steps to return the contents of the treated plasma bag to the patient before rinseback. You may only return the contents before rinseback if a run target was attained.

1. Ensure that the run targets screen is displayed. If the tabs are not displayed, touch the **End Run** menu button to display the tabs.
2. Touch the **Treated Plasma** tab. The screen appears instructing you to return the treated plasma.
3. Follow the instructions on the screens. When the return is complete, the run targets screen re-appears. Perform rinseback or disconnect the patient to complete the procedure.

Note: If you decide not to return the contents in the treated plasma bag to the patient, touch **Skip Return** to decline the return.

Rinsing the Plasma Device and Performing Rinseback

The Spectra Optia system gives you the option to rinse the plasma in the plasma device into the treated plasma bag before you perform rinseback. You may rinse the plasma device as many times as necessary. To rinse the plasma device or to perform rinseback, touch **Rinseback** and follow the instructions on the screens.

Rinsing the plasma in the plasma device into the treated plasma bag

Before you begin the rinse, check the volume in the saline container on the saline line and confirm that it contains enough volume to complete the rinse. Spike a new container, if necessary. Follow the instructions on the screen to complete the rinse.

Note: If you decide not to rinse the plasma in the plasma device into the treated plasma bag, touch **Skip Rinse** to decline the rinse.

Performing rinseback

When you are finished rinsing the plasma device, the screen that shows the status of rinseback appears, and rinseback begins. To return the contents of the treated plasma bag to the patient during or after rinseback, follow the instructions in "Returning the Contents of the Treated Plasma Bag to the Patient" on page 111.

Managing a Prime Divert When the Patient Has a Low TBV

For patient safety, the Spectra Optia system does not allow you to enter a prime divert volume greater than 15% of the patient's TBV. Therefore, if the volume for the plasma device you are using exceeds the 15% limit, the system will not divert the entire volume of fluid in the plasma device. Consider either manually priming the plasma device with albumin or performing a manual prime divert.

Manually Priming the Plasma Device with Albumin

1. Before you connect the plasma device to the Exchange Set, use gravity to manually prime the plasma device with albumin.
2. Touch the **Data** menu button. The data menu tabs appear.
3. Touch the **Plasma Device** tab. The plasma device screen appears.
4. On the plasma device screen, enter a value of 0.0 mL for the prime divert volume, and select **No** for a saline prime.
5. Follow the instructions starting on page 105 to connect the plasma device to the Exchange Set, to prime the inlet line and the return line, and to connect the patient and start the run. Since you are not priming the plasma device with saline, be sure to follow the instructions under "Saline prime: No."
6. After you touch **Start Run**, ensure that the albumin in the plasma device is flowing into the treated plasma bag.

Performing a Manual Prime Divert

1. Connect the plasma device to the Exchange Set according to the instructions starting on page 105. If you did not use the system to prime the plasma device, connect a waste bag to the outlet end of the plasma device.
2. Touch the **Data** menu button. The data menu tabs appear.
3. Touch the **Plasma Device** tab. The plasma device screen appears.
4. On the plasma device screen, enter a value of 0.0 mL for the prime divert volume.
5. When the screen appears with the instructions for spiking the second replace line into the treated plasma bag, perform the following steps:
   a. Spike the second replace line into the treated plasma bag.
   b. Spike the replace line into a container of albumin. If you used the system to prime the plasma device, remove the spike from the saline container and spike the line into the albumin container.
   c. Unclamp the replace line and use the albumin to prime the line and the drip chamber on the second replace line.
   d. Clamp the second replace line before albumin flows into the treated plasma bag.
   e. Clamp the line from the plasma device to the treated plasma bag.
   f. Confirm that the line from the plasma device to the waste bag is unclamped.
   g. Put the replace line into the replacement fluid detector.
   h. Touch **Confirm**.
6. Follow the instructions starting on page 106 to prime the inlet line and the return line and to connect the patient and start the run.
7. Once a volume of plasma that equals the volume of the plasma device has been processed, perform the following steps:

a. Touch the pause button to pause the pumps. An alarm screen appears.

b. Clamp the line to the waste bag and unclamp the line to the treated plasma bag to allow the system to begin filling the treated plasma bag.

c. Touch **Continue** to restart the pumps.

d. Once the system processes an addition 50 mL of plasma, clamp the replace line to the albumin container and unclamp the second replace line to the treated plasma bag. The system begins returning the treated plasma to the patient.

9

Red Blood Cell Exchange (RBCX) Procedures

RBCX Procedure Types

The Spectra Optia system can be used to perform the following types of red blood cell exchange (RBCX) procedures:

- Exchange
- Depletion/Exchange
- Depletion

During an exchange procedure, the system removes defective RBC from the patient and replaces them with healthy donor RBC. During a depletion procedure, the system removes excess or defective RBC from the patient and replaces them with desired replacement fluid. A depletion/exchange procedure consists of a depletion procedure followed by an exchange procedure.

Functional Description of a Red Blood Cell Exchange (RBCX) Procedure

During an RBCX procedure, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor of 20. The plasma pump pumps the plasma into the reservoir, while the RBC are passively pushed out of the connector and into the remove bag. The AIM system monitors the intensity of the light near the top and bottom of the connector to detect any RBC spillover; however, it does not monitor or control the interface position during an RBCX procedure. The replace pump pumps replacement fluid into the reservoir where it combines with the plasma for return to the patient.

During an exchange procedure, RBC are removed from the channel until the target fraction of cells remaining (FCR) or the target for replaced volume has been attained. During a depletion procedure, RBC are removed from the channel until the target Hct (if performing a depletion procedure) or minimum Hct (if performing a depletion/exchange procedure) has been attained.

The hematocrit of the blood in the RBC line exiting the centrifuge varies depending on the procedure type, the run targets, and the hematocrit of the replacement RBC if an exchange procedure is performed.

Preparing to Perform a Procedure

Supplies

Assemble the supplies listed on page 62 before you begin a procedure. You will also need the following additional supplies:

- Replacement fluid prescribed by the patient's physician

Optional supplies:

- Filters for the replacement fluid

Selecting the Procedure and Loading the Tubing Set

Follow the instructions starting on page 64 to select the procedure and load the tubing set. Before you load the tubing set, verify that the set and the solutions you are using have not expired by checking the expiration date printed on the packaging. Do not use an item if the current date is past the expiration date.

Navigating the RBCX Procedure Screens

Menu Buttons and Tabs

Table 9-1 shows the menu buttons and tabs to use to navigate the screens during an RBCX procedure. Menu buttons and tabs are active depending on the current operating state. Touch a menu button to display the corresponding tabs.

Table 9-1: Menu buttons and tabs on RBCX procedure screens

Config	Data	Run	End Run
System	Patient data	Exchange status	Rinseback
Report	Fluid	Operation status	Disconnect
Procedure	Alarm history	Bolus	Run targets
RBCX	Report	Strobe	
Blood warmer		Run values	
		Options	

Descriptions of Buttons, Icons, and Images

See Table 2-14 on page 36 for descriptions of the buttons, icons, and images that can appear on the screen during an RBCX procedure.

Entering and Changing Data During the Run

The Spectra Optia system requires that you enter specific data, such as patient data, to perform an RBCX procedure. The system also allows you to change numerical values for certain operating parameters during the run. Table 9-2 shows data entry ranges for the operating parameters, according to the screen on which each data entry button appears. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad displays either the established range for the parameter or the calculated range, if the range changes based on related data. Also, the range for Caution status is displayed in yellow, if the data you enter could cause the system to operate in Caution status.

Table 9-2: Data entry ranges for RBCX procedure parameters

Screen	Parameter	Range
Patient data	Sex	• Male • Female
	Height: • ft • in • cm	 • 1 to 8 • 0 to 11 • 30 to 244
	Weight: • lb • kg	 • 5 to 500 • 2 to 227
	Hct (%)	10 to 80
	TBV (mL)	300 to 15000
Fluid data	Exchange type	• Exchange • Depletion/Exchange • Depletion Default: Exchange
	Depletion: Fluid type	• Plasma • Saline/Albumin • Custom
	Exchange: Fluid Hct (%)	10 to 80
	Fluid balance (mL or %)	± 25% of the patient's TBV (Caution status applies if the entry exceeds ± 5% of the patient's TBV.)
Options	Rinseback	• Yes • No Default: No
	Custom prime	• Yes • No Default: No
	Saline rinse	• Yes • No Default: No

Table 9-2: Data entry ranges for RBCX procedure parameters (continued)

Screen	Parameter	Range
	Blood warmer • Return line • Replace line	• Yes • No
	Blood warmer: Tubing set volume (mL)	1 to 100
Custom prime	Fluid type	• RBC • Plasma • Albumin
	RBC unit Hct (%)	25 to 80
	Inlet flow rate (mL/min)	5 to 120
	Volume (mL)	100 to 400
Run values	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
	FCR (%) • Starting defective RBC (%) • Target defective RBC (%)	1 to 99 • 10 to 100 • 1 to 99 (Depends on the starting defective RBC entered.)
	Minimum Hct (%)	20 to current patient Hct (Maximum Hct could be lower than the current patient Hct if the patient has a low TBV.)
	Target Hct (%)	20 to 60 or current patient Hct (Maximum Hct could be lower than the current patient Hct if patient has a low TBV.)
	Replaced (mL): Exchange	10 to 10000
	Inlet flow rate (mL/min)	5 to 142
Main run	Inlet flow rate (mL/min)	5 to 142
	Replace volume (mL)	10 to 10000
	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
Exchange status	Current patient Hct (%)	10 to 80

Table 9-2: Data entry ranges for RBCX procedure parameters (continued)

Screen	Parameter	Range
Bolus	Volume (mL)	10 to a volume that equals +25% of the patient's TBV
	Flow rate (mL/min)	10 to 120
Run targets	Target Hct (%)	20 to 60 or current patient Hct (Maximum Hct could be lower than the current patient Hct if the patient has a low TBV.)
	FCR (%)	1 to 99
	Replaced (mL): Exchange	10 to 10000
Rinseback	Return flow rate (mL/min)	2 to 100 Default: inlet flow rate that was in use when the run ended or 100 mL/min, whichever is slower

Entering and Confirming Patient and Procedure Data

This section contains instructions for entering patient data, entering fluid data, and reviewing and confirming run values. You can enter the data after you select the procedure and before you connect the patient. It is important that the data you enter be as accurate and as current as possible.

Note: When you are required to enter numerical data, the system displays a data entry pad for entering the data. The acceptable numerical range appears on the data entry pad.

Entering Patient Data

1 Touch the buttons on the screen to enter the following information:

- Sex
- Height
- Weight
- Hematocrit (Hct)

The Spectra Optia system uses the sex, height, and weight to calculate the patient's TBV. See page 266 for the formula the system uses to calculate this value. If you prefer not to use the TBV that the system calculated, touch **TBV** and enter a different volume. The operator override icon ( ) will appear on the button.

Note: If the patient weighs less than 25 kg (approximately 55 lb), the system does not calculate a TBV. You must calculate and enter the appropriate TBV for the patient.

2 Touch **Confirm**. The fluid data screen appears.

Selecting the Exchange Type and Entering the Fluid Data

The fluid data buttons are active or inactive according to the exchange type you select. Perform the steps below to select the exchange type, to enter the replacement fluid data, and to enter the fluid balance desired for the patient at the end of the procedure.

Selecting the exchange type

The default exchange type is Exchange and appears on the button for the exchange type when the screen appears. To select a different exchange type, perform the following steps:

1 Touch **Exchange**. The following list of exchange types appears:

- Exchange
- Depletion/Exchange
- Depletion

2 Select the exchange type by touching the corresponding button on the screen.

Entering the replacement fluid data

Depletion:

1 Touch **Fluid Type**. A list of replacement fluid types appears.

2 Select one of the following replacement fluid types by touching the corresponding button on the screen:

- Plasma
  - The system assumes that the plasma contains 15% citrate.
- Saline/Albumin
  - The system assumes that the saline/albumin contains 4% citrate.
- Custom
  - The system uses the citrate content entered on the RBCX configuration screen. A data entry pad appears to allow you to change the citrate content (%) of the fluid for the current procedure only.

Exchange:

1 Touch **Fluid Hct**. The data entry pad appears.

2 Enter the average Hct (%) of the replacement fluid for the exchange.

- The system assumes that the portion of the replacement fluid that is not RBC contains 19% citrate.

Note: The system uses data you enter, including the Hct of the replacement fluid, to determine when the target Hct has been attained. It is important that you enter an accurate Hct for the replacement fluid.

Entering the fluid balance

Note: The fluid balance includes fluid that was administered and removed during the run and rinseback but does not include fluid bolus volume.

1 To enter the fluid balance, choose one of the following options:

- To enter the fluid balance in mL, touch **Volume** and use the data entry pad to enter a negative or positive volume. The system calculates and displays the corresponding percentage.
- To enter the fluid balance as a percentage, touch **Percent** and use the data entry pad to enter a percentage. The system calculates and displays the corresponding volume.

2 Touch **Confirm** to save the fluid data. The run values screen appears.

Entering and Confirming Run Values

Enter the run targets listed below, according to the type of RBCX procedure you selected. Table 9-3 contains descriptions of the run targets that appear on the run values screens. Then review the run values and make any changes necessary to achieve your run targets. A black frame appears around the button of the primary run target.

Exchange procedures

- Target Hct (%)
- One of the following targets:
  - Replaced: Exchange (mL)
  - FCR (%)

Depletion/Exchange procedures

- Minimum Hct (%)
- Target Hct (%)
- One of the following targets:
  - Replaced: Exchange (mL)
  - FCR (%)

Depletion procedures

- Target Hct (%)

Table 9-3: Descriptions of run targets for RBCX procedures

Run Target	Description
FCR (%)	Fraction of cells remaining. Target percentage of starting defective RBC that will remain in the patient's blood at the end of the procedure. (Target defective RBC (%)/starting defective RBC (%) = FCR.) After you enter an FCR for an exchange procedure, the system calculates and displays the volume of replacement fluid that is required to complete the procedure. **Note:** You may enter the starting and target defective RBC instead of the FCR, and the system will calculate and display the FCR. To do this, touch the button for FCR on the screen and then touch **FCR** on the data entry pad. The blood drop icon (♦) appears on the data entry pad to allow you to enter the values for defective RBC.
• Starting defective RBC (%)	Percentage of defective RBC in the patient's blood at the start of the procedure
• Target defective RBC (%)	Percentage of defective RBC in the patient's blood at the end of the procedure
Minimum Hct (%)	Lowest patient Hct during the procedure
Target Hct (%)	Desired patient Hct at the end of the procedure
Replaced (mL): Exchange	Volume of replacement fluid that is required to complete the exchange procedure. If you enter a volume here, the system calculates and displays the FCR.

Perform the following steps to enter and confirm the run targets and run values:

1 Touch the button on the screen that corresponds to the target value you want to enter. The data entry pad appears.

2 Enter the target value.

3 Review the run values that appear on the screen and confirm that they are correct. A black frame appears around the button of the primary run target.

Note: During depletion/exchange procedures, the system displays the run time for the depletion in parentheses above the total run time for the depletion/exchange.

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed revert to white.

4 When you are finished entering and confirming the run targets and the run values, touch **Confirm**.

Priming the Inlet Line, the Return Line, and the Replace Line

Warning: When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

1 Follow the instructions on the screen to prime the inlet line and the return line. If you are using a blood warmer on the replace line, follow the instructions under "Exchange Procedures: Using a Blood Warmer on the Replace Line" on page 267 to connect and prime the blood warmer tubing set and to prime the replace line. If you are not using a blood warmer or you are using a blood warmer on the return line, follow the instructions on the screen.

2 Touch **Confirm**.

3 Follow the instructions on the screen to spike the replacement fluid container, to prime the replace line, and to put the replace line into the replacement fluid detector.

4 Touch **Continue**. The screen appears with instructions for connecting the patient.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions on the screen to connect the patient and start the run.

2 Touch **Start Run**. The system begins drawing the patient's blood into the tubing set. The main run screen appears, and the system diverts approximately 40 mL of saline that was used to prime the tubing set into the remove bag.

Note: If you performed a custom prime, the system does not perform the step to divert the saline. The saline was removed from the set during the custom prime.

Monitoring the Run

The system displays information on the screens to help you monitor the progress of the run. To access the screens, touch the **Run** menu button and then the tab for the screen you want to view. Be sure to verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and in the bags.
See “Glossary of Terms” on page 278 for descriptions of the buttons on the screens.

Main Run Screen

The main run screen is the default run screen and displays or provides access to the information you most likely need to monitor the run. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen. There is no tab for the main run screen.

Exchange Status Screen

To access the exchange status screen, touch the **Exchange Status** tab. Use this screen to view information about the current status of the run, including the patient’s fluid balance, the fluids administered, the patient Hct, and the volumes exchanged and replaced during the run.

If you are performing a depletion/exchange procedure, a yellow tick mark appears on the run time graph to indicate when the depletion procedure will end and the exchange procedure will begin.

Replacement fluid

The type of replacement fluid currently in use appears on the button on this screen. Touch this button to change the type of replacement fluid and then follow the instructions on the screens.

Patient Hct

The system uses the patient Hct and the replacement fluid Hct that was entered before the start of the run to predict the current patient Hct displayed on the screen. The system does not take into account RBC that were released from the spleen when predicting this value.

Monitoring the Patient

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the pumps. An alarm occurs indicating that the procedure was paused and the pumps were stopped.
2. Notify the attending physician of the patient's condition according to your facility's standard operating procedures.
3. Touch the go back button to go to the run values screen, and decrease the AC infusion rate as desired.
4. Touch the active alarm button to return to the alarm screen, and then touch **Continue**. The run values screen appears.
5. Review the run values and confirm that they are correct.
6. Touch **Confirm** to resume the procedure.
7. If decreasing the AC infusion rate does not alleviate the symptoms, touch the pause button to pause the pumps again, and notify the attending physician.

Giving a Fluid Bolus

Perform the following steps to give the patient a fluid bolus:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Bolus** tab. The fluid bolus screen appears.
3. Follow the instructions on the screen to spike the saline container on the replace line. Confirm that the replace line is not clamped.
4. Touch **Volume** and enter the volume (mL) of the bolus.
5. Touch **Flow Rate** and enter the flow rate (mL/min) for the bolus.

Note: If the fluid you use for the bolus is not saline, enter a flow rate that takes into account the percentage of citrate in the fluid and that is in accordance with your local transfusion practices.

6. To begin the bolus, touch **Start Bolus**. The system delivers the bolus.

   The screen displays the progress of the bolus. To cancel the bolus before delivery is complete, touch **Cancel Bolus**.
7. When the bolus is complete, the system pauses. Touch **Continue** to resume the procedure.

Bolus volume and reported fluid balance

Be aware that the patient's fluid balance displayed on the exchange status screen and on the procedure summary screen does not include the volume of any bolus that was given to the patient during the procedure. The system reports the total bolus volume in separate fields on the screens.

Optimizing the Run

Impact of Patient Data and Procedure Data on the Procedure Outcome

It is essential to enter accurate data when performing an RBCX procedure. Small errors in the data entered can result in large deviations in the expected outcome. The following patient data and procedure data can affect the procedure outcome:

- Patient Hct
- Patient TBV
- Percentage of starting defective RBC
- Replacement fluid Hct
- Replacement fluid volume
- Patient fluid balance

If the patient's laboratory values are not within the expected range after the procedure is completed, review the data that was entered and verify that it was accurate. To review the data on the report screen, perform the following steps:

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Report** tab. The screen appears with a list of reports. The reports are identified by the procedure date, start time, procedure type, and the patient's TBV. The report for a procedure that was just completed is labeled **Current**.
3. Touch the button that corresponds to the report you want to view. The report appears on the screen. For instructions on printing a copy of the report, see "Printing Procedure Data Reports" on page 274.

Updating the Entered Patient Hct

Updating the entered hematocrit could be necessary under the following circumstances:

- The patient's condition indicates a need to draw a blood sample and compare the laboratory value to what was entered before the run was started.
- The AIM system detects that the RBC interface is too close to the top of the channel, and an alarm occurs.

If you need to update the entered Hct during the run, perform the following steps:

1. If the pumps are not paused, touch the pause button to pause the pumps. An alarm occurs because the procedure was paused.
2. Measure the patient's Hct according to your standard operating procedures.
3. Touch the **Run** menu button. The run tabs appear.
4. Touch the **Exchange Status** tab. The exchange status screen appears.
5. Touch the button for the patient Hct. The data entry pad appears.

6 Enter the current patient Hct. A screen appears to confirm the change to the Hct.

7 Follow the instructions on the screen to verify and confirm the change. The run values screen appears.

8 Review the run values.

9 Touch **Confirm**.

10 Return to the alarm screen and touch **Continue** to restart the pumps and resume the procedure.

10

Mononuclear Cell (MNC) Collection Procedures

Functional Description of a Mononuclear Cell (MNC) Collection Procedure

The Spectra Optia system cycles through a number of accumulation and collection phases during an MNC collection procedure. The number of phases depends on the patient's WBC count and the goals of the procedure.

Accumulation phase

During the accumulation phase, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor of 20. The AIM system adjusts the plasma pump flow rate to control the concentration of cells that flow through the collect port (based on the collection preference), and the collect pump pumps the MNC and platelets from the connector into the chamber. The chamber fills with MNC and the platelets flow through the chamber and are returned to the patient.

The plasma pump also pumps plasma out of the channel and either into the reservoir, or into the plasma bag or the collection bag if plasma collection is targeted. The red blood cells (RBC) are pushed out of the channel and into the reservoir, where they combine with the plasma for return to the patient.

Collection phase

A collection phase occurs at the beginning of the second and all subsequent accumulation phases. The collection phase begins once the system predicts that the chamber is at least 50% full of MNC, and the RBC detector detects RBC in the collect line. When the phase begins, the system stops the plasma pump to lower the interface, stops the collect pump, and decreases the centrifuge speed. It then restarts the collect pump and moves the collect valve into the collect position. The collect pump pumps plasma through the chamber to flush the chamber contents into the collection bag.

After the system flushes the chamber, it stops the collect pump and increases the centrifuge speed. It then restarts the plasma pump and the collect pump to start the chase. During the chase, the system displaces the cells remaining in the collect line between the chamber and the collect valve into the collection bag before it moves the collect valve into the return position to end the collection phase.

Preparing to Perform a Procedure

Supplies

Assemble the supplies listed on page 62 before you begin a procedure.

Selecting the Procedure and Loading the Tubing Set

Follow the instructions starting on page 64 to select the procedure and load the tubing set. Before you load the tubing set, verify that the set and the solutions you are using have not expired by checking the expiration date printed on the packaging. Do not use an item if the current date is past the expiration date.

Navigating the MNC Collection Procedure Screens

Menu Buttons and Tabs

Table 10-1 shows the menu buttons and tabs to use to navigate the screens during an MNC collection procedure. Menu buttons and tabs are active depending on the current operating state. Touch a menu button to display the corresponding tabs.

Table 10-1: Menu buttons and tabs on MNC collection procedure screens

Config	Data	Run	End Run
System	Patient data	Fluid balance	Rinseback
Procedure	Alarm history	Operation status	Disconnect
Report	Report	Collection status	Run targets
MNC		Strobe	Plasma
Blood warmer		Run values	
AC		Options	
		Advanced control	

Descriptions of Buttons, Icons, and Images

See Table 2-14 on page 36 for descriptions of the buttons, icons, and images that can appear on the screen during an MNC collection procedure.

Entering and Changing Data During the Run

The Spectra Optia system requires that you enter specific data, such as patient data, to perform an MNC collection procedure. The system also allows you to change numerical values for certain operating parameters during the run. Table 10-2 shows data entry ranges for the operating parameters according to the screen on which the data entry button appears. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad displays either the established range for the parameter or the calculated range, if the range changes based on related data. Also, the range for Caution status is displayed in yellow, if the data you enter could cause the system to operate in Caution status.

Table 10-2: Data entry ranges for MNC collection procedure parameters

Screen	Parameter	Range
Patient data	Sex	• Male • Female
	Height • ft • in • cm	 • 1 to 8 • 0 to 11 • 30 to 244
	Weight • lb • kg	 • 5 to 500 • 2 to 227
	TBV (mL)	300 to 15000
	Hct (%)	10 to 70
	WBC (E3/µL)	1 to 200
	Plt (E3/µL)	10 to 500
Options	Rinseback	• Yes • No Default: • Yes if a custom prime is not selected • No if a custom prime is selected
	Custom prime	• Yes • No Default: No
	Saline rinse	• Yes • No Default: No
	Blood warmer: Return line	• Yes • No
	Blood warmer: Tubing set volume (mL)	1 to 100
Custom prime	Fluid type	• RBC • Plasma • Albumin
	RBC unit Hct (%)	25 to 80

Table 10-2: Data entry ranges for MNC collection procedure parameters (continued)

Screen	Parameter	Range
	Inlet flow rate (mL/min)	5 to 120
	Volume (mL)	100 to 400 (Volume should be at least 200 mL for the patient to receive the full benefit.)
Run values	AC infusion rate (mL/min/L TBV)	0.2 to 2.5. (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
	Whole blood processed (mL)	Patient's TBV multiplied by 1 to 10
	Run time (min)	40 to 480
	TBV processed	1 to 10
	Inlet flow rate (mL/min)	10 to 125
	Plasma volume: Target (mL):	Depends on the volume of plasma collected into the collection bag. (Total volume of plasma collected cannot exceed 100% of the patient's total plasma volume, and cannot cause the target or actual fluid balance to be less than 75% of the patient's TBV.)
	Collect flow rate (mL/min)	0.5 to 10 (Flow rate can be changed only when the system is operating in Semi-Automatic mode.)
	Collect volume: Target (mL) • Volume (mL) • Number of collection phases (#)	Depends on the total volume of plasma that was collected. (Sum of the total plasma volume and the collect volume cannot exceed 100% of the patient's total plasma volume, and the collect volume must be less than or equal to the volume of 50 collection phases.
	Plasma volume in collection bag: Target (mL)	Depends on the volume of plasma to be collected into the plasma bag. (Total volume of plasma collected cannot exceed 100% of the patient's total plasma volume, and cannot cause the target or actual fluid balance to be less than 75% of the patient's TBV.)

Table 10-2: Data entry ranges for MNC collection procedure parameters (continued)

Screen	Parameter	Range
Main run	Inlet flow rate (mL/min)	10 to 125
	Collect flow rate (mL/min)	0.5 to 10 (Flow rate can be changed only when operating in Semi-Automatic mode.)
	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
Collection status	Collection preference	20 to 80 Default: Depends on the patient's WBC and platelet counts that were entered
Advanced control	Control • System (Default) • Inlet volume (mL) • Operator • RBC Detector	 • N/A • 250 to 5000. Default: 1000 • N/A • N/A
	Chamber flush (mL)	6 to 100
	Chamber chase (mL)	0 to 100
Run targets	Plasma bag (mL): Target	Depends on the volume of plasma to be collected into the collection bag. (Total volume of plasma collected cannot exceed 100% of the patient's total plasma volume, and cannot cause the target or actual fluid balance to be less than 75% of the patient's TBV.)
	Run time (min)	40 to 480
	Whole blood processed (mL)	Patient's TBV multiplied by 1 to 10
	TBV processed	1 to 10
	Collection bag: Plasma (mL)	Depends on the volume of plasma to be collected into the plasma bag. (Total volume of plasma collected cannot exceed 100% of the patient's total plasma volume, and cannot cause the target or actual fluid balance to be less than 75% of the patient's TBV.)

Table 10-2: Data entry ranges for MNC collection procedure parameters (continued)

Screen	Parameter	Range
	Collection bag: Collect • Volume (mL) • Number of collection phases (#)	Depends on the total volume of plasma to be collected. (Sum of the total plasma volume and the collect volume cannot exceed 100% of the patient's total plasma volume, and the collect volume must be less than or equal to the volume of 50 collection phases.
Rinseback	Return flow rate (mL/min)	2 to 100 Default: inlet flow rate that was in use when the run ended or 100 mL/min, whichever is slower

Entering and Confirming Patient and Procedure Data

This section contains instructions for entering patient data, and reviewing and confirming run values. You can enter the data after you select the procedure and before you connect the patient. It is important that the data you enter be as accurate and as current as possible.

Note: When you are required to enter numerical data, the system displays a data entry pad for entering the data. The acceptable numerical range appears on the data entry pad.

Entering Patient Data

1 Touch the buttons on the screen to enter the following information:

- Sex
- Height
- Weight
- Hematocrit (Hct)
- White blood cell (WBC) count
- Platelet count

The Spectra Optia system uses the sex, height, and weight to calculate the patient's TBV. See page 266 for the formula the system uses to calculate this value. If you prefer not to use the TBV that the system calculated, touch **TBV** and enter a different volume. The operator override icon ( ) will appear on the button.

Note: If the patient weighs less than 25 kg (approximately 55 lb), the system does not calculate a TBV. You must calculate and enter the appropriate TBV for the patient.

2 Touch **Confirm**. The run values screen appears.

Reviewing and Confirming Run Values

1 Review the run values that appear on the screen and confirm that they are correct. The run targets for an MNC collection procedure are listed below. A black frame appears around the button of the primary run target.

- Whole blood processed (mL)
- TBV processed
- Run time (min)
- Collect volume: Target (mL)

The configured volumes for plasma collection into the plasma bag and plasma collection into the collection bag appear on the buttons. The system attempts to collect the plasma during the early part of the run. It collects the plasma volume into the plasma bag before it collects the plasma volume into the collection bag.

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed revert to white.

2 When you are finished reviewing the run values, touch **Confirm**.

Priming the Inlet Line and the Return Line

Warning: When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

1 Follow the instructions on the screen to prime the inlet line and the return line. If you are using a blood warmer on the return line, follow the instructions on the screen to connect and prime the blood warmer tubing set.

2 Touch **Confirm**. The screen appears with instructions for connecting the patient and starting the run.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions below and on the screen to connect the patient.

- If you are performing a peripheral venipuncture, see “Collection Set and IDL Set: Additional Instructions for Use” on page 269 for instructions on using the needle protector.
- If you are performing a peripheral venipuncture and want to use the diversion bag on the inlet line, see “Using the Diversion Bag to Collect a Sample From a Venipuncture” on page 269 for instructions.

2 Touch **Start Run**. The system begins drawing the patient’s blood into the tubing set. The main run screen appears, and the system diverts approximately 40 mL of saline that was used to prime the tubing set into the saline container.

Note: If you performed a custom prime, the system does not perform the step to divert the saline. The saline was removed from the set during the custom prime.

Monitoring the Run

The system displays information on the screens to help you monitor the progress of the run. To access the screens, touch the **Run** menu button and then the tab for the screen you want to view. Be sure to verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and in the bags.
See "Glossary of Terms" on page 278 for descriptions of buttons that appear on the screens.

Main Run Screen

The main run screen is the default run screen and displays or provides access to the information you most likely need to monitor the run. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen. There is no tab for the main run screen.

Collection Status Screen

To access the collection status screen, touch the **Collection Status** tab. Use this screen to monitor the progress of the accumulation phase and to adjust the collection preference, if necessary. You can also find information about the current and previous collection and accumulation phases on this screen.

Collection preference

The collection preference is a reference number that the AIM system uses to determine the concentration of cells that should flow through the collect port. The collection preference can affect the type of cells that fill the chamber and how quickly the chamber fills.

AIM system and the concentration of cells flowing through the collect port

The AIM system cannot identify the type of cells that flow through the collect port; it can only control the concentration of cells. It determines the concentration by evaluating how much light penetrates the contents in the collect port as follows:

- High collection preference: More light can penetrate the contents. The concentration is low and the color in the collect port looks light.
- Low collection preference: Less light can penetrate the contents. The concentration is high and the color in the collect port looks dark.

The system then uses this information to adjust the plasma pump flow rate and achieve the specified collection preference.

Collection preference and cell counts

The system uses the WBC count and the platelet count that you entered on the patient data screen to calculate the collection preference for the run as follows:

- The higher the cell counts, the lower the collection preference.
- The lower the cell counts, the higher the collection preference

For information about optimizing the collection preference during the run, see "Optimizing the Collection Preference" on page 144.

Trend graph

The trend graph shows the status of the current accumulation phase. It represents an area of the buffy coat that is in the connector. The horizontal black line on the graph indicates the current collection preference. The green diamonds indicate the concentration of cells flowing into the chamber as compared to the collection preference.

If the system is unable to collect cells at the target collection preference, the green diamonds could appear above or below the black line. As long as the diamonds appear in a controlled path within 20 units either above or below the line, the run is progressing as intended.

Graph of inlet volume processed

The graph in the bottom right corner of the screen shows the inlet volume (mL) processed for the current and previous six accumulation phases. The inlet volume processed icon ( ) appears to the left of the graph as an indication. The row of numbers below the graph indicates the length of time in minutes of each accumulation phase.

There are two rows of numbers above the graph:

- The top row displays the volume that was processed when the RBC detector detected cells in the collect line. The RBC detected icon ( ) appears to the right of the row as an indication.
- The bottom row displays the volume that was processed before a collection phase was initiated.

Advanced Control Screen

To access the advanced control screen, touch the **Advanced Control** tab. Use this screen to make adjustments to the run.

Flush chamber

To immediately change the position of the collect valve and flush the chamber, perform one of the following steps:

- To return the contents of the chamber to the patient, touch the button for return to patient and then touch **Apply**. The collect pump pumps a volume of plasma equal to 1.5 multiplied by the flush volume through the chamber to flush the contents of the chamber to the patient. If you return the contents of the chamber to the patient, the system does not display the inlet volume that was processed before you initiated the return on the graph on the collection status screen.
- To initiate a collection phase and flush the contents of the chamber into the collection bag, touch the button for collect into bag and then touch **Apply**.

Clumping in connector

To address clumping in the connector, touch **Decrease Inlet:AC Ratio**. The system decreases the inlet:AC ratio to 8:1. After 100 mL of inlet volume has been processed, a screen appears with instructions for ensuring that the clumping is resolved and for resuming the procedure. For additional information about anticoagulation in the tubing set, see “Managing Anticoagulation of the Extracorporeal Circuit” on page 221.

Collection phase control

The collection phase control allows you to specify how collection phases are initiated. The selected control also appears on the collection status screen. The following collection phase controls are available:

- **System** (default control): The system initiates a collection phase when the RBC detector detects RBC in the collect line and the system predicts that the chamber is at least 50% full of target cells. The system uses an algorithm to predict the number of target cells in the chamber.
- **Inlet**: The system initiates a collection phase after a specified inlet volume (mL) has been processed. When you select this control, a data entry pad appears for you to enter the desired volume to be processed. The volume that you enter appears on the button. When the Inlet control is selected, the test tube icon ( ) appears on the graph of the inlet volume processed on the collection status screen.
- **Operator**: This control allows the operator to initiate a collection phase when desired. To initiate a collection phase, you must go to the advanced control screen and touch the collect into bag button. The system enters Caution status when this control is selected. When the Operator control is selected, the operator override icon ( ) appears on the graph of the inlet volume processed on the collection status screen.
- **RBC Detector**: The system initiates a collection phase when the RBC detector detects RBC in the collect line and the system predicts that the chamber is at least 25% full of target cells. The system uses an algorithm to predict the number of target cells in the chamber.

Chamber

The configured volumes for the chamber flush and the chamber chase appear on the buttons. You can adjust the volumes at any time during the run. Any changes to the volumes take immediate effect and apply to the current procedure only.

Monitoring the Patient

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the pumps. An alarm occurs indicating that the procedure was paused and the pumps were stopped.
2. Notify the attending physician of the patient's condition according to your facility's standard operating procedures.
3. Touch the go back button and go to the run values screen and decrease the AC infusion rate as desired.
4. Touch the active alarm button to return to the alarm screen, and then touch **Continue**. The run values screen appears.
5. Review the run values and confirm that they are correct.
6. Touch **Confirm** to resume the procedure.
7. If decreasing the AC infusion rate does not alleviate the symptoms, touch the pause button to pause the pumps again, and notify the attending physician.

Optimizing the Run

Optimizing the Collection Preference

The collection preference controls the concentration of cells that flow through the collect port. The system uses the WBC count and the platelet count that you entered on the patient data screen to calculate the collection preference. You can use the up and down arrows on the screen to increase or decrease the collection preference during the run to accommodate the patient's condition and to achieve your procedure goals. Consider the following guidelines when adjusting the collection preference, keeping in mind that the patient's WBC and platelet counts affect the contents of the collection:

- Use a low collection preference to increase the concentration of cells in the collect port. The system adjusts the plasma pump flow rate so that it collects more deeply in the buffy coat. This maximizes the yield of target cells but could increase RBC contamination of the collected product.
- Use a high collection preference to decrease the concentration of cells in the collect port. The system adjusts the plasma pump flow rate so that it collects more shallowly in the buffy coat. This helps to minimize RBC contamination of the collected product but could result in a lower yield of target cells.

Minimizing Buffy Coat Accumulation

A buffy coat can accumulate in the connector for several reasons. To minimize accumulation of a buffy coat, consider performing the following steps:

- Avoid pausing the pumps and conditions that cause the pumps to pause, such as alarm conditions. After the pumps restart, it takes time for the collect pump to reach the target flow rate, which slows the collection of cells from the connector.
- Decrease the collection preference. The interface might not be high enough to allow the system to collect the buffy coat.
- Decrease the inlet pump flow rate until the buffy coat stops accumulating. If the inlet pump flow rate is too fast, cells enter the channel faster than the collect pump can remove them, causing the accumulation. The maximum flow rate for the collect pump during the accumulation phase is 3 mL/min.
- Confirm that the platelet count that was entered on the patient data screen is correct. If decreasing the collection preference and the inlet pump flow rate did not reduce the accumulation and the collect pump flow rate is less than 3 mL/min, increase the entered platelet count by 50. Do this only if you considered all other options and you were still unable to reduce the buffy coat.

Decreasing the Run Time

Consider the following alternatives to decrease the predicted run time if a shorter run is necessary:

- Avoid pausing the pumps and conditions that cause the pumps to pause, such as alarm conditions. After the pumps restart, it takes time for the pumps to reach the target flow rates again, which adds time to the run.
- Increase the inlet pump flow rate, or increase the AC infusion rate. Increasing these rates allows the system to process more blood in less time. Be aware that either option results in faster delivery of AC to the patient, which increases the potential for the patient to experience a citrate reaction.

- Increase the inlet:AC ratio. This causes the inlet pump flow rate to increase. However, it decreases the system's ability to manage anticoagulation of the extracorporeal circuit and can result in clumping in the circuit. Monitor the run carefully as you increase the inlet:AC ratio.
- Decrease the target run time. Make the run time the run target by entering the desired time on the run values or run targets screen. This ensures that the run ends when required.

Transferring Plasma from the Plasma Bag into the Collection Bag

Caution: When transferring plasma from the plasma bag to the collection bag during an MNC collection procedure, you must put the collection bag lower than the plasma bag as indicated in the instructions on the screen. Otherwise, cells in the collection bag can flow into the plasma bag.

The system allows you to transfer plasma from the plasma bag into the collection bag during the run except during a collection phase. To transfer plasma during the run, perform the following steps:

1. Touch the **End Run** menu button. The end run tabs appear.
2. Touch the **Plasma** tab.
3. Follow the instructions on the screen to put the collection bag lower than the plasma bag.
4. Touch **Start Transfer**. The plasma valve moves into the neutral position and the RBC valve moves into the collect position.
5. Allow the plasma to flow from the plasma bag into the collection bag.
6. When the transfer is complete, touch **Resume Run**, or if the run targets have been attained and you want to end the run, touch **End Transfer**. The plasma and RBC valves move back to the return position. The not equal icon (≠) appears next to the plasma bag volume and the collection bag volume on the screens indicating that the current volumes may be different from the displayed volumes.

Note: If you obtained a product sample before you transferred plasma into the collection bag, consider taking a new sample. The additional volume you added to the collection bag could affect the cell concentration.

Transferring plasma when a collection phase is ready to start

If the chamber is full and a collection phase is ready to start, the system pauses the pumps and delays the collection phase. To complete the transfer, follow the instructions under "Transferring Plasma from the Plasma Bag into the Collection Bag" above, beginning with step 4. To cancel the transfer and allow the collection phase to occur, touch the go back button.

Handling the Contents of a Partially Full Chamber

This section contains instructions for collecting or recovering the contents of a partially full chamber.

Resuming the Current Accumulation Phase

Unless the collect volume is the run target, the chamber could be partially full when a run target is attained. If the chamber contains cells, the inlet volume that was processed for the current accumulation phase appears on the screen. If you want to collect the contents in the chamber before you end the run, resume the current accumulation phase to fill the chamber.

To resume the current accumulation phase, increase the collect volume to make it the run target. When the chamber is full, the system initiates a collection phase. When the collection phase is complete, the run targets screen reappears.

Collecting the Contents During Rinseback

If you need to end the run prematurely and want to collect the contents of the chamber during rinseback, perform the following steps:

1. Touch the **End Run** menu button to display the menu tabs.
2. Touch the **Rinseback** tab. The screen with instructions to confirm your selection to perform rinseback appears.
3. Touch **Yes** for collect into bag.
4. Touch **Proceed to Rinseback** and follow the instructions on the screens. The system initiates a collection phase and then performs rinseback.

Recovering the Contents in the Chamber After Disconnecting the Patient

Consider the following options for recovering the contents in the chamber if you need to prematurely end the run and disconnect the patient:

Recovering the contents in the chamber during rinseback.

1. Touch the **End Run** menu button to display the menu tabs.
2. Touch the **Rinseback** tab. The screen with instructions to confirm your selection to perform rinseback appears.
3. Touch **Yes** for collect into bag.
4. Connect a bag to the return line.
5. Touch **Proceed to Rinseback** and follow the instructions on the screens. The system initiates a collection phase and then performs rinseback.

Removing the chamber

If performing rinseback is not an option, you can still recover the cells by removing the chamber. To remove the chamber, first clamp both lines to the chamber with a hemostat to ensure it does not leak. Then detach the chamber from the set.

11

Continuous Mononuclear Cell Collection (CMNC) Procedures

Functional Description of a Continuous Mononuclear Cell Collection (CMNC) Procedure

During a CMNC procedure, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor of 4.5. The AIM system adjusts the flow rate of the plasma pump to control the concentration of cells that flow through the collect port (based on the collection preference). When the AIM system detects cells in the collect port, the system sounds a tone, the collect valve moves into the collect position, and the collect pump pumps the mononuclear cells (MNC) into the collection bag. The plasma pump pumps plasma out of the channel and either into the reservoir or into the plasma bag or the collection bag, if plasma collection is targeted. The system always prioritizes collecting the MNC over collecting the plasma. The red blood cells (RBC) are pushed out of the channel and into the reservoir, where they are combined with the plasma for return to the patient.

Preparing to Perform a Procedure

Supplies

Assemble the supplies listed on page 62 before you begin a procedure.

Selecting the Procedure and Loading the Tubing Set

Follow the instructions starting on page 64 to select the procedure and load the tubing set. Before you load the tubing set, verify that the set and the solutions you are using have not expired by checking the expiration date printed on the packaging. Do not use an item if the current date is past the expiration date.

Navigating the CMNC Procedure Screens

Menu Buttons and Tabs

Table 11-1 shows the menu buttons and tabs to use to navigate the screens during a CMNC procedure. Menu buttons and tabs are active depending on the current operating state. Touch a menu button to display the corresponding tabs.

Table 11-1: Menu buttons and tabs on CMNC procedure screens

Config	Data	Run	End Run
System	Patient data	Fluid balance	Rinseback
Procedure	Alarm history	Operation status	Disconnect
Report	Report	Collection status	Run targets
CMNC		Strobe	
Blood warmer		Run values	
AC		Options	

Descriptions of Buttons, Icons, and Images

See Table 2-14 on page 36 for descriptions of the buttons, icons, and images that can appear on the screen during a CMNC procedure.

Entering and Changing Data During the Run

The Spectra Optia system requires that you enter specific data, such as patient data, to perform a CMNC procedure. The system also allows you to change numerical values for certain operating parameters during the run. Table 11-2 shows data entry ranges for the operating parameters according to the screen on which each data entry button appears. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad displays either the established range for the parameter or the calculated range, if the range changes based on related data. Also, the range for Caution status is displayed in yellow, if the data you enter could cause the system to operate in Caution status.

Table 11-2: Data entry ranges for CMNC procedure parameters

Screen	Parameter	Range
Patient data	Sex	• Male • Female
	Height: • ft • in • cm	 • 1 to 8 • 0 to 11 • 30 to 244
	Weight: • lb • kg	 • 5 to 500 • 2 to 227
	TBV (mL)	300 to 15000
	Hct (%)	10 to 70
Options	Rinseback	• Yes • No Default: • Yes if a custom prime is not selected • No if a custom prime is selected
	Custom prime	• Yes • No Default: No
	Saline rinse	• Yes • No Default: No
	Blood warmer: Return line	• Yes • No
	Blood warmer: Tubing set volume (mL)	1 to 100
	Plasma collection	• Now • End of Run
Custom prime	Fluid type	• RBC • Plasma • Albumin
	RBC unit Hct (%)	25 to 80
	Inlet flow rate (mL/min)	5 to 70

Table 11-2: Data entry ranges for CMNC procedure parameters (continued)

Screen	Parameter	Range
	Volume (mL)	100 to 400 (Volume should be at least 300 mL for the patient to receive the full benefit.)
Run values	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
	Whole blood processed (mL)	Patient's TBV multiplied by 1 to 10
	Run time (min)	40 to 480
	TBV processed	1 to 10
	Inlet flow rate (mL/min)	5 to 142
	Plasma volume: Target (mL) in plasma bag	0 to the patient's plasma volume minus the current collect volume and the current volume of plasma in the collection bag (Sum of the total plasma volume and the collect volume cannot exceed 100% of the patient's total plasma volume.)
	Collect flow rate (mL/min)	0.5 to 10 Default: • 1.0 if the inlet flow rate is equal to or greater than 20 • Inlet flow rate multiplied by 0.05 if the inlet flow rate is less than 20
	Collect volume: Target (mL)	5 to the patient's plasma volume minus the current volume of plasma in the plasma bag and in the collection bag
	Plasma in collection bag: Target (mL)	0 to the patient's plasma volume minus the current collect volume and the current volume of plasma in the plasma bag (Sum of the total plasma volume and the collect volume cannot exceed 100% of the patient's total plasma volume.)
Main run	Packing factor	1 to 20 Default: 4.5
	Inlet flow rate (mL/min)	5 to 142

Table 11-2: Data entry ranges for CMNC procedure parameters (continued)

Screen	Parameter	Range
	Collect flow rate (mL/min)	0.5 to 10
	Collect volume (mL)	5 to the patient's plasma volume minus the current volume of plasma in the plasma bag and in the collection bag.
	AC infusion rate (mL/min/L TBV)	0.2 to 2.5. (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
Collection status	Collection preference	10 to 90 Default: 50 after the interface is established
Run targets	Plasma bag (mL)	0 to the patient's plasma volume minus the current collect volume and the current volume of plasma in the collection bag (Sum of the total plasma volume and the collect volume cannot exceed 100% of the patient's total plasma volume.)
	Run time (min)	40 to 480
	Whole blood processed (mL)	Patient's TBV multiplied by 1 to 10
	TBV processed	1 to 10
	Collection bag: Plasma (mL)	0 to the patient's plasma volume minus the current collect volume and the current volume of plasma in the plasma bag (Sum of the total plasma volume and the collect volume cannot exceed 100% of the patient's total plasma volume.)
	Collection bag: Collect (mL)	5 to patient's plasma volume minus the current volume of plasma in the plasma bag and in the collection bag.
Rinseback	Return flow rate (mL/min)	2 to 100 Default: inlet flow rate that was in use when the run ended or 100 mL/min, whichever is slower

Entering and Confirming Patient and Procedure Data

This section contains instructions for entering patient data and reviewing and confirming run values. You can enter the data after you select the procedure and before you connect the patient. It is important that the data you enter be as accurate and as current as possible.

Note: When you are required to enter numerical data, the system displays a data entry pad for entering the data. The acceptable numerical range appears on the data entry pad.

Entering Patient Data

1 Touch the buttons on the screen to enter the following information:

- Sex
- Height
- Weight
- Hematocrit (Hct)

The Spectra Optia system uses the sex, height, and weight to calculate the patient's TBV. See page 266 for the formula the system uses to calculate this value. If you prefer not to use the TBV that the system calculated, touch **TBV** and enter a different volume. The operator override icon ( ) will appear on the button.

Note: If the patient weighs less than 25 kg (approximately 55 lb), the system does not calculate a TBV. You must calculate and enter the appropriate TBV for the patient.

2 Touch **Confirm**. The run values screen appears.

Reviewing and Confirming the Run Values

1 Review the run values that appear on the screen and confirm that they are correct. The run targets for a CMNC procedure are listed below. A black frame appears around the button of the primary run target.

- Whole blood processed (mL)
- TBV processed
- Run time (min)
- Collect volume: Target (mL)

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed revert to white.

2 When you are finished reviewing the run values, touch **Confirm**.

Collecting plasma

To collect the plasma, the system stops the collect pump, increases the centrifuge speed and decreases the inlet pump flow rate to 60 mL/min, if necessary, to increase the packing factor to at least 14 and to reduce the number of platelets flowing through the plasma port. Once the target packing factor is achieved, the system decreases the plasma pump flow rate, which lowers the interface position. The system then increases the plasma pump flow rate and once any remaining platelets have been cleared from the plasma line, the system moves the plasma valve into the collect position and begins collecting plasma.

If you configured the procedure to collect plasma at the beginning of the run and you increase the target plasma volume during the run, a screen appears with instructions for indicating whether the additional volume should be collected immediately (now) or at the end of the run. Follow the instructions on the screen to indicate your preference and resume the run.

Priority of collect volume and plasma volume

The system always prioritizes collection of the target collect volume over the target plasma volume when the plasma collection is selected to occur at the end of the run. If you decrease a run target, make sure you thoroughly review the values that have changed on the run values screen before you touch **Confirm**. If the decrease in the run target is significant, the target plasma volume could be reduced to zero, and the collect volume could also decrease.

Priming the Inlet Line and the Return Line

Warning: When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

1 Follow the instructions on the screen to prime the inlet line and the return line. If you are using a blood warmer on the return line, follow the instructions on the screen to connect and prime the blood warmer tubing set.

2 Touch **Confirm**. The screen appears with instructions for connecting the patient and starting the run.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions below and on the screen to connect the patient.

- If you are performing a peripheral venipuncture, see “Collection Set and IDL Set: Additional Instructions for Use” on page 269 for instructions on using the needle protector.
- If you are performing a peripheral venipuncture and want to use the diversion bag on the inlet line, see “Using the Diversion Bag to Collect a Sample From a Venipuncture” on page 269 for instructions.

2 Touch **Start Run**. The system begins drawing the patient’s blood into the tubing set. The main run screen appears, and the system diverts approximately 40 mL of saline that was used to prime the tubing set into the saline container.

Note: If you performed a custom prime, the system does not perform the step to divert the saline. The saline was removed from the set during the custom prime.

Monitoring the Run

The system displays information on the screens to help you monitor the progress of the run. To access the screens, touch the **Run** menu button and then the tab for the screen you want to view. Be sure to verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and in the bags.
See “Glossary of Terms” on page 278 for descriptions of the buttons on the screens.

Main Run Screen

The main run screen is the default run screen and displays or provides access to the information you most likely need to monitor the run. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen. There is no tab for the main run screen.

Collection Status Screen

To access the collection status screen, touch the **Collection Status** tab. Use this screen to monitor the progress of the run and to adjust the collection preference. You can also use this screen to change the position of the collect valve to immediately direct the flow of cells from the collect line into the reservoir for return to the patient, if necessary.

Collection preference

The collection preference is a reference number that the system uses to adjust the plasma pump flow rate, which affects the concentration of cells that flow through the collect port. You can use the up and down arrows to change the collection preference during the run to accommodate the conditions of the patient’s blood and achieve the desired outcome of the procedure.

The default collection preference for a CMNC procedure is 50. While establishing the initial interface or while re-establishing the interface after a pump pause or a centrifuge stop, the system targets a higher preference to avoid collecting non-target cells before the interface is stable. The collection preference that the system targets depends on whether or not you change the preference before the interface is established.

- If you do not change the collection preference, the system targets a collection preference of 60.
- If you change the collection preference, the system targets a collection preference that is about 10 points higher than the number that you selected, but is not less than a preference of 20.

Once the interface is established, the system gradually decreases the collection preference either to the default or to the number that you selected. For more information about optimizing the collection preference during the run, see “Optimizing the Collection Preference” on page 158.

Trend graph

The trend graph represents an area of the buffy coat that is in the connector. The horizontal black line on the graph indicates the current collection preference. The green diamonds indicate the concentration of cells flowing through the collect port as compared to the collection preference.

If the system is unable to collect cells at the target collection preference, the green diamonds could appear above or below the black line. As long as the diamonds appear in a controlled path within 20 units either above or below the line, the run is progressing as intended.

Return to patient and collect into bag buttons

The position of the collect valve determines whether the system is directing the flow of cells in the collect line back to the patient or into the collection bag. The system indicates the current position of the collect valve by showing the corresponding button on this screen in a touched (lowered) position. You can manually change the position of the collect valve at any time during the run.

- To direct the flow of cells from the collect line back to the patient, touch the return to patient button and then touch **Apply**. The collect valve moves into the return position and the system begins pumping the cells into the reservoir for return to the patient.

Note: If you touch the return to patient button, the system operates in Caution status because cells are not being collected. The collect valve stays in the return position until you touch the collect into bag button.

- To direct the flow of cells in the collect line into the collection bag, touch the collect into bag button and then touch **Apply**. The collect valve moves into the collect position, and the system begins pumping the cells into the collection bag.

Monitoring the Patient

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the pumps. An alarm occurs indicating that the procedure was paused and the pumps were stopped.
2. Notify the attending physician of the patient's condition according to your facility's standard operating procedures.
3. Touch the go back button to go to the run values screen, and decrease the AC infusion rate as desired.
4. Touch the active alarm button to return to the alarm screen, and then touch **Continue**. The run values screen appears.
5. Review the run values and confirm that they are correct.
6. Touch **Confirm** to resume the procedure.
7. If decreasing the AC infusion rate does not alleviate the symptoms, touch the pause button to pause the pumps again, and notify the attending physician.

Optimizing the Run

Optimizing the Collection Preference

The collection preference controls the concentration of cells that flow through the collect port. You can use the up and down arrows on the screen to increase or decrease the collection preference during the run to accommodate the patient's condition and to achieve your procedure goals. Consider the following guidelines when adjusting the collection preference, keeping in mind that the patient's WBC and platelet counts affect the contents of the collection:

- Use a low collection preference to increase the concentration of cells in the collect port. The system adjusts the plasma pump flow rate so that it collects more deeply in the buffy coat. This maximizes the yield of target cells but could increase RBC contamination of the collected product.
- Use a high collection preference to decrease the concentration of cells in the collect port. The system adjusts the plasma pump flow rate so that it collects more shallowly in the buffy coat. This helps to minimize RBC contamination of the collected product, but could result in a lower yield of target cells.

Monitoring the contents in the collect line and adjusting the color

Monitor the collect line where it exits the centrifuge below the cassette, and use the collection preference to adjust the color of the contents in the line. To accurately evaluate the color, you should allow the collect pump to process 1 mL to 2 mL of volume before making an additional adjustment.

The Collection Preference Tool can help you evaluate which color is appropriate for the procedure. If the contents in the line look either too light or too dark, consider making adjustments to the run according to the following guidelines:

- Color is too light:
  - Decrease the collection preference. This increases the concentration of cells that flow through the collect port.
  - Reset the collect pump flow rate to the default flow rate. When the collect pump flow rate is too slow, cells can accumulate in the connector, making it difficult to collect cells that are deeper in the buffy coat.
- Color is too dark:
  - Increase the collection preference. This decreases the concentration of cells that flow through the collect port.

Minimizing Buffy Coat Accumulation

A buffy coat can accumulate in the connector for several reasons. To minimize accumulation of a buffy coat, consider performing one of the following steps:

- Avoid pausing the pumps and conditions that cause the pumps to pause, such as alarm conditions. After the pumps restart, it takes time for the collect pump flow rate to reach the target speed, which slows the collection of cells from the connector.
- Increase the collect pump flow rate, especially if it is currently slower than the default flow rate established by the system. Increase the flow rate in increments of 0.1 mL/min until the buffy coat stops accumulating.

Note: If the patient has a high WBC count, consider using a collect pump flow rate of 1.0 mL/min to 1.5 mL/min, especially if you are using a high inlet flow rate.

- Decrease the collection preference. The interface may not be high enough to allow the system to collect the buffy coat.

Collecting a Target Volume

If the procedure goal is a specific volume in the collection bag, consider changing the collect volume. This causes the collect volume to become the run target. This target only includes the volume pumped by the collect pump. The volume of any plasma collected is not included.

Decreasing the Run Time

Consider the following alternatives for decreasing the predicted run time if a shorter run is necessary:

- Avoid pausing the pumps and conditions that cause the pumps to pause, such as alarm conditions. After the pumps restart, it takes time for the pumps to reach the target flow rates again, which adds time to the run.
- Increase the inlet pump flow rate or increase the AC infusion rate. Increasing these rates allows the system to process more blood in less time. Be aware that either option results in a greater volume of AC delivered to the patient and increases the potential for the patient to experience a citrate reaction.
- Increase the inlet:AC ratio. This causes the inlet pump flow rate to increase. However, it decreases the system's ability to manage anticoagulation of the extracorporeal circuit and can result in clumping in the circuit. Monitor the run carefully as you increase the inlet:AC ratio.
- Decrease the target run time. Make the run time the run target by entering the desired time on the run values or run targets screen. This ensures that the run ends when required.

  If you decrease the run time and intend to collect plasma at the end of the run, make sure you review the target plasma volume on the run values screen and confirm that it is still appropriate. The system prioritizes collection of the target collect volume over the target plasma volume. This means that if you decrease the run time, the system will decrease the target plasma volume. You can increase the target plasma volume if it is too low, but be aware that the collect volume will decrease as a result.

Addressing Clumping in the Connector

Clumping can affect collection efficiency by interfering with the separation in the connector. The potential for platelet clumping is difficult to predict since it does not always correlate with the patient's platelet count. If you see platelet clumping in the connector, perform the following steps:

1. Decrease the inlet:AC ratio to 8:1 until the clump disappears and until the system has processed at least 100 mL of inlet volume.
2. Check the connector for clumping and then perform one of the following steps:
   - If the clumping is resolved, consider increasing the inlet:AC ratio to 10:1. Allow the system to process 500 mL to 1,000 mL of inlet volume before you consider increasing the ratio again. Do not increase the ratio by more than 2.0 for every 500 mL to 1,000 mL of inlet volume processed.
   - If the clumping persists, leave the inlet:AC ratio at 8:1 until the clumping disappears or for the remainder of the run. Some clumps may become clots that are difficult to eliminate. Maintaining the ratio at 8:1 will help minimize the impact on the collection efficiency.

For additional information about anticoagulation in the tubing set, see "Managing Anticoagulation of the Extracorporeal Circuit" on page 221.

12

Granulocyte (PMN) Collection Procedures

Functional Description of a Granulocyte (PMN) Collection Procedure

During a PMN collection procedure, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor: 1.6, when HES is used, or 4.5, when ACD-A is used. The AIM system adjusts the flow rate of the plasma pump to control the concentration of cells that flow through the collect port (based on the collection preference). When the AIM system detects cells in the collect port, the system sounds a tone, the collect valve moves into the collect position, and the collect pump pumps granulocytes into the collection bag. The plasma pump pumps plasma out of the channel and either into the reservoir or into the plasma bag, if plasma collection is targeted. The system always prioritizes collecting the PMN over collecting the plasma. The red blood cells (RBC) are pushed out of the channel and into the reservoir, where they combine with the plasma for return to the patient.

Preparing to Perform a Procedure

Supplies

Assemble the supplies listed on page 62 before you begin a procedure.

Anticoagulant Solutions for PMN Collection Procedures

You can use a solution that contains hydroxyethyl starch (HES) or ACD-A to perform a PMN collection procedure on the Spectra Optia system.

Caution: If hydroxyethyl starch (HES) is not used during a PMN collection procedure, the collection efficiency will be lower.

Using HES

HES is a sedimenting agent that causes RBC to separate more efficiently from granulocytes during a PMN collection procedure. If you choose to use HES, you must select **Yes** for HES on the PMN configuration screen or on the options screen. "HES: Yes" appears on the main run screen as a reminder of your selection. When using HES, you must add trisodium citrate to the HES for use as the anticoagulant. The default packing factor when HES is used is 1.6.

Preparing an anticoagulant solution containing HES and trisodium citrate

To prepare the correct anticoagulant solution, add 30 mL to 40 mL of 46.7% trisodium citrate solution to 500 mL of HES. To prepare an anticoagulant solution with the same concentration as ACD-A, add 38 mL of trisodium citrate solution to the HES.

Using ACD-A

If you choose to use ACD-A, you must select **No** for HES on the PMN configuration screen or on the options screen. "HES: No" appears on the main run screen as a reminder of your selection. Also refer to "Optimizing a PMN Collection Procedure When Using ACD-A" on page 173 for information about adjustments you can make to optimize the run. The default packing factor when ACD-A is used is 4.5.

Selecting the Procedure and Loading the Tubing Set

Follow the instructions starting on page 64 to select the procedure and load the tubing set. Before you load the tubing set, verify that the set and the solutions you are using have not expired by checking the expiration date printed on the packaging. Do not use an item if the current date is past the expiration date.

Navigating the PMN Collection Procedure Screens

Menu Buttons and Tabs

Table 12-1 shows the menu buttons and tabs to use to navigate the screens during a PMN collection procedure. Menu buttons and tabs are active depending on the current operating state. Touch a menu button to display the corresponding tabs.

Table 12-1: Menu buttons and tabs on PMN collection procedure screens

Config	Data	Run	End Run
System	Patient data	Fluid balance	Rinseback
Procedure	Alarm history	Operation status	Disconnect
Report	Report	Collection status	Run targets
PMN		Strobe	
Blood warmer		Run values	
		Options	

Descriptions of Buttons, Icons, and Images

See Table 2-14 on page 36 for descriptions of the buttons, icons, and images that can appear on the screen during a PMN collection procedure.

Entering and Changing Data During the Run

The Spectra Optia system requires that you enter specific data, such as patient data, to perform a PMN collection procedure. The system also allows you to change numerical values for certain operating parameters during the run. Table 12-2 shows data entry ranges for the operating parameters according to the screen on which each data entry button appears. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad displays either the established range for the parameter or the calculated range, if the range changes based on related data. Also, the range for Caution status is displayed in yellow, if the data you enter could cause the system to operate in Caution status.

Table 12-2: Data entry ranges for PMN collection procedures

Screen	Parameter	Range
Patient data	Sex	• Male • Female
	Height: • ft • in • cm	 • 1 to 8 • 0 to 11 • 30 to 244
	Weight: • lb • kg	 • 5 to 500 • 2 to 227
	TBV (mL)	300 to 15000
	Hct (%)	10 to 70
Options	Rinseback	• Yes • No Default: • Yes if a custom prime is not selected • No if a custom prime is selected
	Custom prime	• Yes • No Default: No
	HES Selection determines the default packing factor. • Yes: Default packing factor is 1.6 • No: Default packing factor is 4.5	• Yes • No
	Saline rinse	• Yes • No Default: No
	Blood warmer: Return line	• Yes • No
	Blood warmer: Tubing set volume (mL)	1 to 100
Custom prime	Fluid type	• RBC • Plasma • Albumin

Table 12-2: Data entry ranges for PMN collection procedures (continued)

Screen	Parameter	Range
	RBC unit Hct (%)	25 to 80
	Inlet flow rate (mL/min)	5 to 70
	Volume (mL)	100 to 400 (Volume should be at least 300 mL for the patient to receive the full benefit.)
Run values	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
	Whole blood processed (mL)	Patient's TBV multiplied by 0.5 to 5
	Run time (min)	40 to 480
	TBV processed	0.5 to 5
	Inlet flow rate (mL/min)	5 to 142
	Plasma volume: Target (mL) in plasma bag	0 to the patient's plasma volume minus the current collect volume and the current volume of plasma in the collection bag (Sum of the total plasma volume and the collect volume cannot exceed 100% of the patient's total plasma volume.)
	Collect flow rate (mL/min)	0.5 to 25 Default: inlet flow rate multiplied by 0.075
	Collect volume: Target (mL)	5 to the patient's plasma volume minus the current volume of plasma in the plasma bag and in the collection bag
Main run	Packing factor • HES: Yes • HES: No	1 to 20 • Default: 1.6 • Default: 4.5
	Inlet flow rate (mL/min)	5 to 142
	Collect flow rate (mL/min)	0.5 to 25
	Collect volume (mL)	5 to the patient's plasma volume minus the current volume of plasma in the plasma bag and in the collection bag

Table 12-2: Data entry ranges for PMN collection procedures (continued)

Screen	Parameter	Range
	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
Collection status	Collection preference	10 to 90 Default: 60 after the interface is established
Run targets	Run time (min)	40 to 480
	Whole blood processed (mL)	Patient's TBV multiplied by 0.5 to 5
	TBV processed	0.5 to 5
	Plasma bag (mL)	0 to the patient's plasma volume minus the current collect volume and the current volume of plasma in the collection bag (Sum of the total plasma volume and the collect volume cannot exceed 100% of the patient's total plasma volume.)
	Collection bag (mL)	5 to the patient's plasma volume minus the current volume of plasma in the plasma bag and in the collection bag
Rinseback	Return flow rate (mL/min)	2 to 100 Default: inlet flow rate that was in use when the run ended or 100 mL/min, whichever is slower

Entering and Confirming Patient and Procedure Data

This section contains instructions for entering patient data and reviewing and confirming run values. You can enter the data after you select the procedure and before you connect the patient. It is important that the data you enter be as accurate and as current as possible.

Note: When you are required to enter numerical data, the system displays a data entry pad for entering the data. The acceptable numerical range appears on the data entry pad.

Entering Patient Data

1 Touch the buttons on the screen to enter the following information:

- Sex
- Height
- Weight
- Hematocrit (Hct)

The Spectra Optia system uses the sex, height, and weight to calculate the patient's TBV. See page 266 for the formula the system uses to calculate this value. If you prefer not to use the TBV that the system calculated, touch **TBV** and enter a different volume. The operator override icon ( ) will appear on the button.

Note: If the patient weighs less than 25 kg (approximately 55 lb), the system does not calculate a TBV. You must calculate and enter the appropriate TBV for the patient.

2 Touch **Confirm**. The run values screen appears.

Reviewing and Confirming the Run Values

1 Review the run values that appear on the screen and confirm that they are correct. The run targets for a PMN procedure are listed below. A black frame appears around the button of the primary run target.

- Whole blood processed (mL)
- TBV processed
- Run time (min)
- Collect volume: Target (mL)

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed revert to white.

2 When you are finished reviewing the run values, touch **Confirm**.

Collecting plasma

To collect the plasma, the system stops the collect pump, increases the centrifuge speed and decreases the inlet pump flow rate to 60 mL/min, if necessary, to increase the packing factor to at least 14.0 and to reduce the number of platelets flowing through the plasma port. Once the target packing factor is achieved, the system decreases the plasma pump flow rate, which lowers the interface position. The system then increases the plasma pump flow rate and once any remaining platelets have been cleared from the plasma line, the system moves the plasma valve into the collect position and begins collecting plasma.

Priority of collect volume and plasma volume

The system always prioritizes collection of the target collect volume over the target plasma volume. If you decrease a run target, make sure you thoroughly review the values that have changed on the run values screen before you touch **Confirm**. If the decrease in the run target is significant, the target plasma volume could be reduced to zero, and the collect volume could also decrease.

Priming the Inlet Line and the Return Line

Warning: When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

1 Follow the instructions on the screen to prime the inlet line and the return line. If you are using a blood warmer on the return line, follow the instructions on the screen to connect and prime the blood warmer tubing set.

2 Touch **Confirm**. The screen appears with instructions for connecting the patient and starting the run.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions below and on the screen to connect the patient.

- If you are performing a peripheral venipuncture, see “Collection Set and IDL Set: Additional Instructions for Use” on page 269 for instructions on using the needle protector.
- If you are performing a peripheral venipuncture and want to use the diversion bag on the inlet line, see “Using the Diversion Bag to Collect a Sample From a Venipuncture” on page 269 for instructions.

2 Touch **Start Run**. The system begins drawing the patient’s blood into the tubing set. The main run screen appears, and the system diverts approximately 40 mL of saline that was used to prime the tubing set into the saline container.

Note: If you performed a custom prime, the system does not perform the step to divert the saline. The saline was removed from the set during the custom prime.

Monitoring the Run

The system displays information on the screens to help you monitor the progress of the run. To access the screens, touch the **Run** menu button and then the tab for the screen you want to view. Be sure to verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and in the bags.
See “Glossary of Terms” on page 278 for descriptions of the buttons on the screens.

Main Run Screen

The main run screen is the default run screen and displays or provides access to the information you most likely need to monitor the run. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen. There is no tab for the main run screen.

Collection Status Screen

To access the collection status screen, touch the **Collection Status** tab. Use this screen to monitor the progress of the run and to adjust the collection preference. You can also use this screen to change the position of the collect valve to immediately direct the flow of cells in the collect line into the reservoir for return to the patient, if necessary.

Collection preference

The collection preference is a reference number that the system uses to adjust the plasma pump flow rate, which affects the concentration of cells that flow through the collect port. You can use the up and down arrows to change the collection preference during the run to accommodate the conditions of the patient’s blood and achieve the desired outcome of the procedure.

The default collection preference for a PMN collection procedure is 60. While establishing the initial interface or while re-establishing the interface after a pump pause or a centrifuge stop, the system targets a higher preference to avoid collecting non-target cells before the interface is stable. The collection preference that the system targets depends on whether or not you change the preference before the interface is established.

- If you do not change the collection preference, the system targets a collection preference of 70.
- If you change the collection preference, the system targets a collection preference that is about 10 points higher than the number that you selected, but is not less than a preference of 65.

Once the interface is established, the system gradually decreases the collection preference either to the default or to the number that you selected. For more information about optimizing the collection preference during the run, see “Optimizing the Collection Preference” on page 173.

Trend graph

The trend graph shows the status of the collection. It represents an area of the buffy coat that is in the connector. The horizontal black line on the graph indicates the current collection preference. The green diamonds indicate the concentration of cells flowing through the collect port as compared to the collection preference.

If the system is unable to collect cells at the target collection preference, the green diamonds could appear above or below the black line. As long as the diamonds appear in a controlled path within 20 units either above or below the line, the run is progressing as intended.

Return to patient and collect into bag buttons

The position of the collect valve determines whether the system is directing the flow of cells in the collect line back to the patient or into the collection bag. The system indicates the current position of the collect valve by showing the corresponding button on this screen in a touched (lowered) position. You may manually change the position of the collect valve at any time during the run.

- To direct the flow of cells from the collect line back to the patient, touch the return to patient button and then touch **Apply**. The collect valve moves into the return position and the system begins pumping the cells into the reservoir for return to the patient.

Note: If you touch the Return to Patient button, the system operates in Caution status because cells are not being collected. The collect valve stays in the return position until you touch the Collect into Bag button.

- To direct the flow of cells in the collect line into the collection bag, touch the collect into bag button and then touch **Apply**. The collect valve moves into the collect position and the system begins pumping the cells into the collection bag.

Monitoring the Patient

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the pumps. An alarm occurs indicating that the procedure was paused and the pumps were stopped.
2. Notify the attending physician of the patient's condition according to your facility's standard operating procedures.
3. Touch the go back button to go to the run values screen, and decrease the AC infusion rate as desired.
4. Touch the active alarm button to return to the alarm screen, and then touch **Continue**. The run values screen appears.
5. Review the run values and confirm that they are correct.
6. Touch **Confirm** to resume the procedure.
7. If decreasing the AC infusion rate does not alleviate the symptoms, touch the pause button to pause the pumps again, and notify the attending physician.

Optimizing the Run

Optimizing a PMN Collection Procedure When Using ACD-A

Caution: If hydroxyethyl starch (HES) is not used during a PMN collection procedure, the collection efficiency will be lower.

If you choose to use ACD-A instead of HES during the procedure, confirm that **No** for HES is selected on the PMN configuration screen or on the options screen. To optimize the collection when using ACD-A, consider making one or more of the following adjustments to the run:

- Process more whole blood than the default of 6,000 mL. Be aware that doing this increases the run time and the collect volume.
- Decrease the collection preference to collect more cells closer to the RBC interface. The color of the contents in the collect line should appear slightly darker than the darkest color on the Collection Preference Tool.
- Increase the packing factor above the default of 4.5. Be aware that using a packing factor higher than the default could result in an excess number of platelets collected. The system displays a warning screen with instructions for monitoring the patient for platelet depletion and for resuming the procedure in Caution status.
- Increase the collect pump flow rate above the default flow rate. This results in more cells collected and a larger collect volume.

Optimizing the Collection Preference

The collection preference controls the concentration of cells that flow through the collect port. You can use the up and down arrows on the screen to increase or decrease the collection preference during the run to accommodate the patient's condition and to achieve your procedure goals. Consider the following guidelines when adjusting the collection preference, keeping in mind that the patient's cell counts affect the contents of the collection:

- Use a low collection preference to increase the concentration of cells in the collect port. The system adjusts the plasma pump flow rate so that it collects more deeply in the buffy coat. This maximizes the yield of target cells but could increase RBC contamination of the collected product.
- Use a high collection preference to decrease the concentration of cells in the collect port. The system adjusts the plasma pump flow rate so that it collects more shallowly in the buffy coat. This helps to minimize RBC contamination of the collected product but could result in a lower yield of target cells.

Monitoring the contents in the collect line and adjusting the color

Monitor the collect line where it exits the centrifuge below the cassette, and use the collection preference to adjust the color of the contents in the line. To accurately evaluate the color, you should allow the collect pump to process 1 mL to 2 mL of volume before making an additional adjustment.

The Collection Preference Tool can help you evaluate which color is appropriate for the procedure. If the contents in the line look either too light or too dark, consider making adjustments to the run according to the following guidelines:

- Color is too light:
  - Decrease the collection preference. This increases the concentration of cells that flow through the collect port.
  - Reset the collect pump flow rate to the default flow rate. When the collect pump flow rate is too slow, cells can accumulate in the connector, making it difficult to collect cells that are deeper in the buffy coat.
- Color is too dark:
  - Increase the collection preference. This decreases the concentration of cells that flow through the collect port.

Minimizing Buffy Coat Accumulation

A buffy coat can accumulate in the connector for several reasons. To minimize accumulation of a buffy coat, consider performing one of the following steps:

- Avoid pausing the pumps and conditions that cause the pumps to pause, such as alarm conditions. After the pumps restart, it takes time for the collect pump flow rate to reach the target speed, which slows the collection of cells from the connector.
- Increase the collect pump flow rate, especially if it is currently slower than the default flow rate established by the system. Increase the flow rate in increments of 0.1 mL/min until the buffy coat stops accumulating.
- Decrease the collection preference. The interface may not be high enough to allow the system to collect the buffy coat.

Targeting a Lower Collect Volume

If the predicted collect volume is more than desired or the procedure goal is a specific volume in the collection bag, consider performing one of the following steps, keeping in mind that either step will decrease the collection efficiency:

- Decrease the collect pump flow rate. This decreases the collect volume without affecting the inlet volume processed. This also increases the concentration of cells in the connector, so you should monitor the connector for buffy coat accumulation.
- Enter a target collect volume. The collect volume becomes the run target. The system processes less inlet volume and therefore the run is shorter.

Decreasing the Run Time

Consider the following alternatives for decreasing the predicted run time if a shorter run is necessary:

- Avoid pausing the pumps and conditions that cause the pumps to pause, such as alarm conditions. After the pumps restart, it takes time for the pumps to reach the target flow rates again, which adds time to the run.
- Increase the inlet pump flow rate or increase the AC infusion rate. Increasing these rates allows the system to process more blood in less time. Be aware that either option results in a greater volume of AC delivered to the patient and increases the potential for the patient to experience a citrate reaction.
- Increase the inlet:AC ratio. This causes the inlet pump flow rate to increase. However, it decreases how well the system manages anticoagulation of the extracorporeal circuit and can result in clumping in the circuit. Monitor the run carefully as you increase the inlet:AC ratio.
- Decrease the target run time. Make the run time the run target by entering the desired time on the run values or run targets screen. This ensures that the run ends when required.

If you decrease the run time and intend to collect plasma at the end of the run, make sure you review the target plasma volume on the run values screen and confirm that it is still appropriate. The system prioritizes collection of the target collect volume over the target plasma volume. This means that if you decrease the run time, the system will decrease the target plasma volume. You can increase the target plasma volume if it is too low, but be aware that the collect volume will decrease as a result.

Addressing Clumping in the Connector

Clumping can affect collection efficiency by interfering with the separation in the connector. The potential for platelet clumping is difficult to predict since it does not always correlate with the patient's platelet count. If you see platelet clumping in the connector, perform the following steps:

1. Decrease the inlet:AC ratio to 8:1 until the clump disappears and until the system has processed at least 100 mL of inlet volume.
2. Check the connector for clumping and then perform one of the following steps:
   - If the clumping is resolved, consider increasing the inlet:AC ratio to 10:1. Allow the system to process 500 mL to 1,000 mL of inlet volume before you consider increasing the ratio again. Do not increase the ratio by more than 2.0 for every 500 mL to 1,000 mL of inlet volume processed.
   - If the clumping persists, leave the inlet:AC ratio at 8:1 until the clumping disappears or for the remainder of the run. Some clumps may become clots that are difficult to eliminate. Maintaining the ratio at 8:1 will help minimize the impact on the collection efficiency.

For additional information about anticoagulation in the tubing set, see "Managing Anticoagulation of the Extracorporeal Circuit" on page 221.

13

White Blood Cell Depletion (WBCD) and Platelet Depletion (PLTD) Procedures

Functional Description of a White Blood Cell Depletion (WBCD) or a Platelet Depletion (PLTD) Procedure

During a WBCD or a PLTD procedure, the system pumps the patient's blood into the tubing set and spins the centrifuge at the speed required to target the optimal (default) packing factor: 4.5 for a WBCD procedure using ACD-A, and 20 for a PLTD procedure. The AIM system adjusts the flow rate of the plasma pump to control the concentration of cells that flow through the collect port (based on the collection preference). When the AIM system detects cells in the collect port, the system sounds a tone, the collect valve moves into the collect position, and the collect pump pumps the cells into the collection bag. The plasma pump pumps plasma out of the channel and into the reservoir. The red blood cells (RBC) are pushed out of the channel and into the reservoir, where they combine with the plasma for return to the patient.

If the operator chooses to give replacement fluid during the run, the plasma valve periodically moves to the return position to allow small volumes of replacement fluid to flow by gravity into the reservoir. In the reservoir, the replacement fluid combines with the RBC and the plasma from the channel. The system manages the volume of cells collected and fluid replaced according to the fluid balance the operator selects.

Preparing to Perform a Procedure

Supplies

Assemble the supplies listed on page 62 before you begin a procedure. You will also need the following additional supplies:

- Replacement fluid prescribed by the patient's physician

Note: Using a filter for the replacement fluid during a WBCD or a PLTD procedure is not recommended. A filter can slow the flow of the replacement fluid into the reservoir and ultimately to the patient.

Anticoagulant Solutions for WBCD Procedures

You can use ACD-A or a solution that contains hydroxyethyl starch (HES) to perform a WBCD procedure on the Spectra Optia system.

Using ACD-A

To indicate the use of ACD-A, you must select **No** for HES on the WBCD configuration screen or on the options screen. "HES: No" appears on the main run screen as a reminder of your selection. The default packing factor when ACD-A is used is 4.5.

Using HES

To indicate the use of HES, you must select **Yes** for HES on the WBCD configuration screen or on the options screen. "HES: Yes" appears on the main run screen as a reminder of your selection.When using HES, you must add trisodium citrate to the HES for use as the anticoagulant. The default packing factor when HES is used is 1.6.

Preparing an anticoagulant solution containing HES and trisodium citrate

To prepare the correct anticoagulant solution, add 30 mL to 40 mL of 46.7% trisodium citrate solution to 500 mL of HES. To prepare an anticoagulant solution with the same concentration as ACD-A, add 38 mL of trisodium citrate solution to the HES.

Selecting the Procedure and Loading the Tubing Set

Follow the instructions starting on page 64 to select the procedure and load the tubing set. Before you load the tubing set, verify that the set and the solutions you are using have not expired by checking the expiration date printed on the packaging. Do not use an item if the current date is past the expiration date.

Navigating the WBCD and PLTD Procedure Screens

Menu Buttons and Tabs

Table 13-1 shows the menu buttons and tabs to use to navigate the screens during a WBCD or a PLTD procedure. Menu buttons and tabs are active depending on the current operating state. Touch a menu button to display the corresponding tabs.

Table 13-1: Menu buttons and tabs on WBCD and PLTD procedure screens

Config	Data	Run	End Run
System	Patient data	Fluid balance	Rinseback
Procedure	Alarm history	Operation status	Disconnect
Report	Report	Collection status	Run targets
WBCD or PLTD		Strobe	
Blood warmer		Run values	
		Options	

Descriptions of Buttons, Icons, and Images

See Table 2-14 on page 36 for descriptions of the buttons, icons, and images that can appear on the screen during a WBCD or a PLTD procedure.

Entering and Changing Data During the Run

The Spectra Optia system requires that you enter specific data, such as patient data, to perform a WBCD or a PLTD procedure. The system also allows you to change numerical values for certain operating parameters during the run. Table 13-2 shows data entry ranges for the operating parameters according to the screen on which each data entry button appears. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad displays either the established range for the parameter or the calculated range, if the range changes based on related data. Also, the range for Caution status is displayed in yellow, if the data you enter could cause the system to operate in Caution status.

Table 13-2: Data entry ranges for WBCD and PLTD procedures

Screen	Parameter	Range
Patient data	Sex	• Male • Female
	Height: • ft • in • cm	 • 1 to 8 • 0 to 11 • 30 to 244
	Weight: • lb • kg	 • 5 to 500 • 2 to 227
	TBV (mL)	300 to 15000
	Hct (%)	10 to 70
	WBCD procedures: WBC (E3/µL)	1 to 1000
	PLTD procedures: Plt (E3/µL)	10 to 7000
Options	Rinseback	• Yes • No • Yes if a custom prime is not selected • No if a custom prime is selected
	Custom prime	• Yes • No Default: No
	HES Selection determines the default packing factor. • Yes: Default packing factor is 1.6 • No: Default packing factor is 4.5	• Yes • No
	Saline rinse	• Yes • No Default: No
	Blood warmer: Return line	• Yes • No
	Blood warmer: Tubing set volume (mL)	1 to 100

Table 13-2: Data entry ranges for WBCD and PLTD procedures (continued)

Screen	Parameter	Range
Custom prime	Fluid type	• RBC • Plasma • Albumin
	RBC unit Hct (%)	25 to 80
	Inlet flow rate (mL/min)	5 to 70
	Volume (mL)	100 to 400 (Volume should be at least 300 mL for the patient to receive the full benefit.)
Run values	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
	Whole blood processed (mL)	Patient's TBV multiplied by 0.5 to 5
	Run time (min)	40 to 480
	TBV processed	0.5 to 5
	Target fluid balance (mL or %)	70% to 125% of the patient's TBV (Caution status applies if the entry exceeds ± 15% of the patient's TBV.)
	Replacement fluid: • Fluid type	• No fluid • Plasma • Saline/Albumin • RBC • Custom
	• Average Hct of RBC (%) • Citrate content (%) of custom fluid	• 10 to 80 • 0 to 25
	• Volume (mL)	10 to patient's TBV
	Inlet flow rate (mL/min)	5 to 142
	Collect flow rate (mL/min)	0.5 to 25 Default: • WBCD: depends on the patient's WBC count • PLTD: depends on the patient's platelet count
	Collect volume: Target (mL)	5 to the patient's plasma volume

Table 13-2: Data entry ranges for WBCD and PLTD procedures (continued)

Screen	Parameter	Range
Main run	Packing factor: WBCD procedures • HES: Yes • HES: No	1 to 20 • Default: 1.6 • Default: 4.5
	Packing factor: PLTD procedures	1 to 20 Default: 20
	Inlet flow rate (mL/min)	5 to 142
	Collect flow rate (mL/min)	0.5 to 25
	Collect volume (mL)	5 to the patient's plasma volume
	AC infusion rate (mL/min/L TBV)	0.2 to 2.5 (Caution status applies if the entry exceeds 1.2.)
	Inlet:AC ratio (__:1)	2 to 50 (Warning appears if the entered ratio is not within the recommended range of 6:1 to 15:1.)
Collection status	Collection preference	10 to 90 Default: 75 after the interface is established
Run targets	Run time (min)	40 to 480
	Whole blood processed (mL)	Patient's TBV multiplied by 0.5 to 5
	TBV processed	0.5 to 5
	Collection bag (mL)	5 to the patient's plasma volume
Rinseback	Return flow rate (mL/min)	2 to 100 Default: inlet flow rate that was in use when the run ended or 100 mL/min, whichever is slower

Entering and Confirming Patient and Procedure Data

This section contains instructions for entering patient data and reviewing and confirming run values. You can enter the data after you select the procedure and before you connect the patient. It is important that the data you enter be as accurate and as current as possible.

Note: When you are required to enter numerical data, the system displays a data entry pad for entering the data. The acceptable numerical range appears on the data entry pad.

Entering Patient Data

1 Touch the buttons on the screen to enter the following information:

- Sex
- Height
- Weight
- Hematocrit (Hct)
- WBCD procedures: WBC count
- PLTD procedures: Platelet count

The Spectra Optia system uses the sex, height, and weight to calculate the patient's TBV. See page 266 for the formula the system uses to calculate this value. If you prefer not to use the TBV that the system calculated, touch **TBV** and enter a different volume. The operator override icon ( ) will appear on the button.

Note: If the patient weighs less than 25 kg (approximately 55 lb), the system does not calculate a TBV. You must calculate and enter the appropriate TBV for the patient.

2 Touch **Confirm**. The run values screen appears.

Reviewing and Confirming the Run Values and the Fluid Data

1 Review the run values that appear on the screen and confirm that they are correct. The run targets for a WBCD procedure or a PLTD procedure are listed below. A black frame appears around the button of the primary run target.

- Whole blood processed (mL)
- TBV processed
- Run time (min)
- Collect volume: Target (mL)

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed revert to white.

2 Review the target fluid balance and the replacement fluid data. To select replacement fluid to use during the run and to change the target fluid balance, proceed to "Entering and changing the fluid data" below.

Note: You must use replacement fluid if the data you entered results in a target fluid balance of less than 70% of the patient's TBV.

3 When you are finished reviewing the run values and the fluid data, touch **Confirm.**

Entering and changing the fluid data

Follow the instructions below to select the replacement fluid, to enter the replacement fluid volume, and to change the target fluid balance.

Entering the replacement fluid data

If you choose to give replacement fluid to the patient during the run, perform the following steps to select the type of replacement fluid and to enter the volume:

1 Touch the button for the replacement fluid. A list of replacement fluid types appears.

2 Select one of the replacement fluid types listed below by touching the corresponding button on the screen. The replacement fluid type you select and the applicable citrate content (%) or average hematocrit (%) appear on the button:

- No Fluid (default)
- Plasma
  - The system assumes that the plasma contains 15% citrate.
- Saline/Albumin
  - The system assumes that the saline/albumin contains 4% citrate.
- RBC
  - A data entry pad appears for you to enter the average hematocrit (%) of the fluid.
  - The system assumes that the portion of the replacement fluid that is not RBC contains 19% citrate.
- Custom
  - The system uses the citrate content that was entered on the WBCD or PLTD configuration screen. A data entry pad appears to allow you to change the citrate content (%) of the fluid for the current procedure only.

3 Touch the volume button. A data entry pad appears.

4 Enter the volume of the replacement fluid. The system calculates and displays the target fluid balance.

Changing the target fluid balance

The system uses configuration settings and the patient data you entered to calculate the target fluid balance for the patient at the end of the procedure. To change the target fluid balance, you must first select the type of replacement fluid to use during the run. Perform the following steps to change the target fluid balance:

1. To enter the target fluid balance as a percentage, touch the percent (%) button. To enter it as a volume, touch the volume (mL) button. A data entry pad appears.
2. Enter the new target fluid balance. The value you enter appears on the button. The system calculates and displays the volume of replacement fluid required to achieve the target fluid balance.

Note: If you enter the target fluid balance as a percentage, the system calculates and displays the corresponding volume on the volume button. The reverse applies if you enter the target fluid balance as a volume.

Priming the Inlet Line and the Return Line

Warning: When connecting a blood warmer tubing set to the return line, ensure that the tubing connection is tight. Put the luer connection no higher than 20 in (50 cm) above the return access to prevent the possibility of air entering the tubing.

Warning: If you are using a blood warmer on the return line, ensure that you completely prime the blood warmer tubing set to remove all the air in the set before you connect the patient.

1 Follow the instructions on the screen to prime the inlet line and the return line. If you are using a blood warmer on the return line, follow the instructions on the screen to connect and prime the blood warmer tubing set.

2 Touch **Confirm**. The screen appears with instructions for connecting the patient and starting the run.

Positioning the IV Pole and the Replacement Fluid Container

If you are using replacement fluid during the run, confirm that the IV pole is raised to the highest level and hang the replacement fluid container as high as possible on the pole, so that the fluid flows freely through the replace line and into the reservoir.

Connecting the Patient and Starting the Run

Warning: Before connecting the patient, check the inlet and return lines for air. If air is present in the lines, remove the air before connecting the patient.

1 Follow the instructions below and on the screen to connect the patient.

- If you are performing a peripheral venipuncture, see “Collection Set and IDL Set: Additional Instructions for Use” on page 269 for instructions on using the needle protector.
- If you are performing a peripheral venipuncture and want to use the diversion bag on the inlet line, see “Using the Diversion Bag to Collect a Sample From a Venipuncture” on page 269 for instructions.

2 Touch **Start Run**. The system begins drawing the patient’s blood into the tubing set. The main run screen appears and the system diverts approximately 40 mL of saline that was used to prime the tubing set into the saline container.

Note: If you performed a custom prime, the system does not perform the step to divert the saline. The saline was removed from the set during the custom prime.

Monitoring the Run

The system displays information on the screens to help you monitor the progress of the run. To access the screens, touch the **Run** menu button and then the tab for the screen you want to view. Be sure to verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and in the bags.
See “Glossary of Terms” on page 278 for descriptions of the buttons on the screens.

Main Run Screen

The main run screen is the default run screen and displays or provides access to the information you most likely need to monitor the run. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen. There is no tab for the main run screen.

Collection Status Screen

To access the collection status screen, touch the **Collection Status** tab. Use this screen to monitor the progress of the run and to adjust the collection preference. You can also use this screen to change the position of the collect valve to immediately direct the flow of cells in the collect line into the reservoir for return to the patient, if necessary.

Collection preference

The collection preference is a reference number that the system uses to adjust the plasma pump flow rate, which affects the concentration of cells that flow through the collect port. You can use the up and down arrows to change the collection preference during the run to accommodate the conditions of the patient’s blood and achieve the desired outcome of the procedure.

The default collection preference for WBCD and PLTD procedures is 75. While establishing the initial interface or while re-establishing the interface after a pump pause or a centrifuge stop, the system targets a higher preference to avoid collecting non-target cells before the interface is stable. The collection preference that the system targets depends on whether or not you change the preference before the interface is established.

- If you do not change the collection preference, the system targets a collection preference of 85.
- If you change the collection preference, the system targets a collection preference that is about 10 points higher than the number that you selected, but is not less than a preference of 65.

Once the interface is established, the system gradually decreases the collection preference either to the default or to the number that you selected. For more information about optimizing the collection preference during the run, see “Optimizing the Collection Preference” on page 190.

Trend graph

The trend graph represents an area of the buffy coat that is in the connector. The horizontal black line on the graph indicates the current collection preference. The green diamonds indicate the concentration of cells flowing through the collect port as compared to the collection preference.

If the system is unable to collect cells at the target collection preference, the green diamonds could appear above or below the black line. As long as the diamonds appear in a controlled path within 20 units either above or below the line, the run is progressing as intended.

Return to patient and collect into bag buttons

The position of the collect valve determines whether the system is directing the flow of cells from the collect line back to the patient or into the collection bag. The system indicates the current position of the collect valve by showing the corresponding button on this screen in a touched (lowered) position. You may manually change the position of the collect valve at any time during the run.

- To direct the flow of cells from the collect line back to the patient, touch the return to patient button and then touch **Apply**. The collect valve moves into the return position, and the system begins pumping the cells into the reservoir for return to the patient.

Note: If you touch the return to patient button, the system operates in Caution status because cells are not being collected. The collect valve stays in the return position until you touch the collect into bag button.

- To direct the flow of cells in the collect line into the collection bag, touch the collect into bag button and then touch **Apply**. The collect valve moves into the collect position and the system begins pumping the cells into the collection bag.

Monitoring the Patient

Managing Citrate Toxicity

If the patient experiences citrate toxicity, perform the following steps:

1. Touch the pause button to pause the pumps. An alarm occurs indicating that the procedure was paused and the pumps were stopped.
2. Notify the attending physician of the patient's condition according to your facility's standard operating procedures.
3. Touch the go back button to go to the main run screen, and decrease the AC infusion rate as desired.
4. Touch the active alarm button to return to the alarm screen, and then touch **Continue**. The run values screen appears.
5. Review the run values and confirm that they are correct.
6. Touch **Confirm** to resume the procedure.
7. If decreasing the AC infusion rate does not alleviate the symptoms, touch the pause button to pause the pumps again, and notify the attending physician.

Optimizing the Run

Facilitating the Flow of Replacement Fluid

During WBCD and PLTD procedures, replacement fluid is delivered by gravity. The system does not pump the fluid into the reservoir. To facilitate the flow of the replacement fluid, perform the following steps:

- Make sure that the IV pole from which the replacement fluid hangs is fully extended to maximize the effect of gravity.
- Confirm that the frangible connector on the replace line is completely broken so that it does not obstruct the fluid flow.
- Fill the drip chamber on the replace line so that it is nearly full to prevent the formation of bubbles in the line.
- Remove any air bubbles you see in the replace line.

Improving the flow of replacement fluid contained in bottles

Fluid contained in bottles might not flow as well by gravity as fluid contained in bags because bottles are not vented. If the replacement fluid you are using is contained in a bottle, perform the following steps when spiking the bottle to help improve the flow:

1. Squeeze and hold the drip chamber on the spike on the replace line.
2. Continue squeezing the drip chamber as you spike the bottle. Do not stop squeezing the drip chamber until you invert the bottle and see that the spike is immersed in fluid.
3. Release the drip chamber. It should fill with fluid.

Optimizing the Collection Preference

The collection preference controls the concentration of cells that flow through the collect port. You can use the up and down arrows on the screen to increase or decrease the collection preference during the run to accommodate the patient's condition and to achieve your procedure goals. Consider the following guidelines when adjusting the collection preference, keeping in mind that the patient's cell counts affect the contents of the collection:

- Use a low collection preference to increase the concentration of cells in the collect port. The system adjusts the plasma pump flow rate so that it collects more deeply in the buffy coat. This maximizes the yield of target cells but could increase RBC contamination of the collected product.
- Use a high collection preference to decrease the concentration of cells in the collect port. The system adjusts the plasma pump flow rate so that it collects more shallowly in the buffy coat. This helps to minimize RBC contamination of the collected product but could result in a lower yield of target cells.

Monitoring the contents in the collect line and adjusting the color

Monitor the collect line where it exits the centrifuge below the cassette, and use the collection preference to adjust the color of the contents in the line. To accurately evaluate the color, you should allow the collect pump to process 1 mL to 2 mL of volume before making an additional adjustment.

The Collection Preference Tool can help you evaluate which color is appropriate for the procedure. If the contents in the line look either too light or too dark, consider making adjustments to the run according to the following guidelines:

- Color is too light:
  - Decrease the collection preference. This increases the concentration of cells that flow through the collect port.
  - Verify that you have entered an accurate WBC count or platelet count.
  - Reset the collect pump flow rate to the default flow rate. When the collect pump flow rate is too slow, cells can accumulate in the connector, making it difficult to collect cells that are deeper in the buffy coat.
- Color is too dark:
  - Increase the collection preference. This decreases the concentration of cells that flow through the collect port.

Minimizing Buffy Coat Accumulation

A buffy coat can accumulate in the connector for several reasons. To minimize accumulation of a buffy coat, consider performing one of the following steps:

- Avoid pausing the pumps and conditions that cause the pumps to pause, such as alarm conditions. After the pumps restart, it takes time for the collect pump flow rate to reach the target speed, which slows the collection of cells from the connector.
- Increase the collect pump flow rate, especially if it is currently slower than the default flow rate established by the system. Increase the flow rate in increments of 0.1 mL/min until the buffy coat stops accumulating.
- Decrease the collection preference. The interface may not be high enough to allow the system to collect the buffy coat.

Targeting a Lower Collect Volume

If the predicted collect volume is higher than desired or the procedure goal is a specific volume in the collection bag, consider performing one of the following steps, keeping in mind that either step will decrease the collection efficiency:

- Decrease the collect pump flow rate. This decreases the collect volume without affecting the inlet volume processed. It also decreases the need for replacement fluid.

  As a result, the concentration of cells in the connector could increase, so you should monitor the connector for buffy coat accumulation. Consider waiting to decrease the collect pump flow rate until after one TBV has been processed and the patient's cell count could be lower.
- Enter a target collect volume. The collect volume becomes the run target. The system processes less inlet volume and therefore the run is shorter.

Addressing Clumping in the Connector

Clumping can affect collection efficiency by interfering with the separation in the connector. The potential for platelet clumping is difficult to predict, since it does not always correlate with the patient's platelet count. If you see platelet clumping in the connector, perform the following steps:

1 Decrease the inlet:AC ratio to 8:1 until the clump disappears and until the system has processed at least 100 mL of inlet volume.

2 Check the connector for clumping and then perform one of the following steps:

- If the clumping is resolved, consider increasing the inlet:AC ratio to 10:1. Allow the system to process 500 mL to 1000 mL of inlet volume before you consider increasing the ratio again. Do not increase the ratio by more than 2.0 for every 500 mL to 1,000 mL of inlet volume processed.
- If the clumping persists, leave the inlet:AC ratio at 8:1 until the clumping disappears or for the remainder of the run. Some clumps may become clots that are difficult to eliminate. Maintaining the ratio at 8:1 will help minimize the impact on the collection efficiency.

For additional information about anticoagulation in the tubing set, see "Managing Anticoagulation of the Extracorporeal Circuit" on page 221.

14

Bone Marrow Processing (BMP) Procedures

Functional Description of a Bone Marrow Processing (BMP) Procedure

The BMP procedure is intended for bone marrow processing for the purpose of hematopoietic reconstitution. During a BMP procedure, the system pumps bone marrow from the bone marrow processing (BMP) bag into the tubing set channel and spins the centrifuge at the speed required to target the optimal (default) packing factor of 20. The AIM system adjusts the flow rate of the plasma pump to control the concentration of cells that flow through the collect port (based on the collection preference). The BMP bag must contain at least 125 mL of RBC for the system to establish an interface that is high enough to collect cells. When the AIM system detects cells in the collect port, the system sounds a tone, the collect valve moves into the collect position, and the collect pump pumps the cells into the collection bag. The plasma pump pumps plasma out of the channel and either into the reservoir or into the plasma bag, if plasma collection is targeted. The red blood cells (RBC) are pushed out of the channel and into the reservoir where they combine with the plasma for return to the BMP bag for additional processing.

Preparing to Perform a Procedure

Supplies

Assemble the supplies listed on page 62 before you begin a procedure. You will also need the following additional supplies:

- Spectra Optia® BMP Accessory Set

Optional supplies:

- Blood administration set with a male luer connector and the appropriate size filter for filtering clots, bone chips, and debris from the bone marrow
- Sterile tubing welder with the appropriate replacement wafers

Filtering the Bone Marrow

Filter the bone marrow according to your facility's standard operating procedure. The bone marrow must be filtered to remove fat, bone particles, and cellular debris before it is processed. The 200-micron filter on the administration line in the BMP Accessory Set may be used for additional filtration, if desired.

Adding ACD-A to the Bone Marrow

The bone marrow must be adequately anticoagulated before processing to prevent clumping in the tubing set. The recommended ratio of bone marrow to ACD-A is 10:1. Perform the following steps to calculate the necessary volume of ACD-A and to add it to the bone marrow:

1. Determine the tare weight of the bag containing the bone marrow.
2. Weigh the bag of bone marrow (BM bag).
3. Calculate the bone marrow (BM) volume:

$$\frac{\text{BM bag weight} - \text{bag tare weight}}{1.058} = \text{BM volume (mL)}$$

4 Calculate the volume of ACD-A to add to the BM bag:

$$\frac{\text{BM volume (mL)}}{10} = \text{ACD-A (mL)}$$

5 Add the ACD-A volume from step 4 to the BM bag and mix the contents of the bag thoroughly.

6 Calculate the total BM volume (BMV) to enter on the BM data screen during the procedure:

BM volume (mL) + ACD-A (mL) = BMV (mL)

7 Measure the hematocrit (Hct) of the bone marrow in the BM bag. This is the Hct you enter on the BM data screen during the procedure.

Transferring the Bone Marrow Into the BMP Accessory Set

Perform the following steps to transfer the bone marrow from the BM bag into the BMP Accessory Set:

1 Verify that the accessory set has not expired by checking the expiration date on the cover of the package.

2 Open the package containing the accessory set and unpack the contents.

3 Unfold the BMP bag and lay it on a flat surface.

4 Clamp the following lines of the accessory set:

- Inlet line (red clamp)
- Sample bulb assembly (white clamp)
- Lines to both spikes (white clamps) on the administration line
- Both lines (white clamps) of the luer connector assembly
- Return line (blue clamp)

5 Connect the BM bag to the administration line using one of the following two methods:

- Spike the BM bag using one of the spikes on the administration line. The 200–micron filter on the line to the spike provides additional filtration.
- Connect the BM bag to the luer connector assembly on the administration line. If the bone marrow requires filtration, use a blood administration set with the appropriate size filter to connect the bag to the luer connector.

6 Unclamp the line to the spike or on the line of the luer connector assembly on the administration line.

7 Hang or hold the BM bag above the BMP bag and transfer the bone marrow.

8 Seal the administration line below the luer connector on the inlet line (Figure 14-1). You must seal the line below the connector, or you will not be able to connect the BMP bag to the inlet line of the tubing set.

9 Remove the administration line and the BM bag. Discard the line and the bag according to your facility's standard operating procedure.

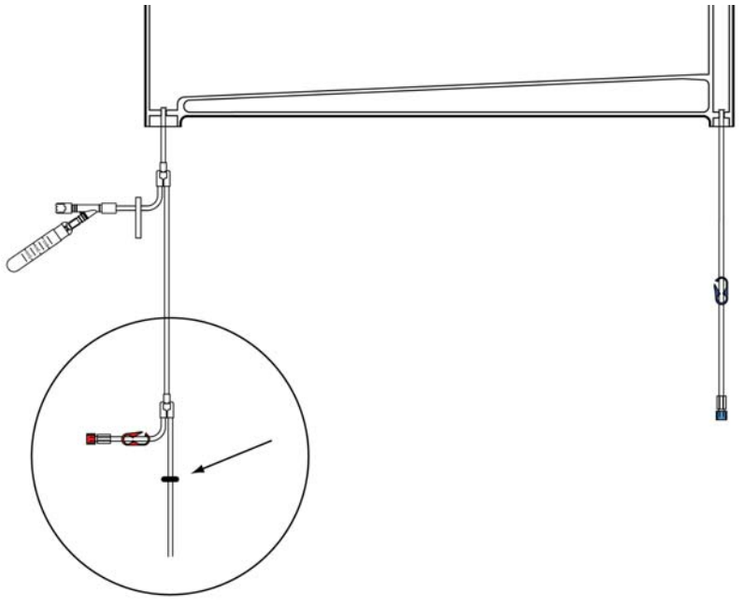


Figure 14-1: Correct location to seal the administration line on the BMP Accessory Set

Selecting the Procedure

Follow the instructions on page 64 to select the procedure.

Preparing the Tubing Set for Plasma Collection When Using an IDL Set With Catalog Number 10300

If you configured the system to collect plasma and you are using an IDL Set with the catalog number 10300, a screen appears before you load the tubing set instructing you to prepare the tubing set for plasma collection. Unpack the tubing set, and then either spike the plasma bag on the replace line of the tubing set or use a sterile tubing welder to connect the plasma bag to the replace line. Using a sterile tubing welder to connect the plasma bag helps to maintain a functionally closed system.

Spiking the plasma bag on the replace line

Seal or clamp the plasma bag line, and then follow the instructions on the screen.

Using a sterile tubing welder to connect the plasma bag to the replace line

Connect the plasma bag line to the replace line between the frangible connector and the cassette of the tubing set. Follow the manufacturer's instructions for using the sterile tubing welder.

Loading and Priming the Tubing Set

Verify that the tubing set and the saline solution you are using have not expired by checking the expiration date printed on the packaging. Do not use an item if the current date is past the expiration date. Then follow the instructions starting on page 65 to load and prime the tubing set.

The AC line is not used during a BMP procedure. After you load the tubing set, follow the instructions on the screen to seal the AC line. This AC line should be sealed to prevent air from entering the set.

Navigating the BMP Procedure Screens

Menu Buttons and Tabs

Table 14-1 shows the menu buttons and tabs to use to navigate the screens during a BMP procedure. Menu buttons and tabs are active depending on the current operating state. Touch a menu button to display the corresponding tabs.

Table 14-1: Menu buttons and tabs on BMP procedure screens

Config	Data	Run	End Run
System	BM data	Operation status	Rinseback
Procedure	Alarm history	Collection status	Disconnect
Report	Report	Strobe	Run targets
BMP		Run values	
		Options	

Descriptions of Buttons, Icons, and Images

See Table 2-14 on page 36 for descriptions of the buttons, icons, and images that can appear on the screen during a BMP procedure.

Entering and Changing Data During the Run

The Spectra Optia system requires that you enter specific data, such as BM data, to perform a BMP procedure. The system also allows you to change numerical values for certain operating parameters during the run. Table 14-2 shows data entry ranges for the operating parameters according to the screen on which each data entry button appears. To change or enter data, touch the button for the parameter that you want to change. A data entry pad appears to enable you to enter a number. The data entry pad displays either the established range for the parameter or the calculated range, if the range changes based on related data. Also, the range for Caution status is displayed in yellow, if the data you enter could cause the system to operate in Caution status.

Table 14-2: Data entry ranges for BMP procedures

Screen	Parameter	Range
BM data	BMV (mL)	300 to 3000
	Hct (%)	10 to 50
Options	Rinseback	• Yes • No Default: Yes
	Saline rinse	• Yes • No Default: No
	Collect plasma	• Yes • No
Run values	BM processed (mL)	BMV multiplied by 4 to 10 Default: BMV multiplied by the number of BM cycles. (Minimum volume depends on the volume of RBC in the BMP bag.)
	BM cycles	4 to 10 (Minimum number of cycles depends on the volume of RBC in the BMP bag.)
	Inlet flow rate (mL/min)	20 to 142
	Plasma volume (mL): Target	0 to 500
	Collect flow rate (mL/min)	1 to 5 Default: inlet pump flow rate multiplied by 0.0167
	Collect volume (mL): Target	Up to 500
Main run	Packing factor	1 to 20 Default: 20
	Inlet flow rate (mL/min)	20 to 142
Collection status	Collection preference	10 to 90 Default: 50 after the interface is established

Table 14-2: Data entry ranges for BMP procedures (continued)

Screen	Parameter	Range
Run targets	BM processed (mL)	BMV multiplied by 4 to 10 (Minimum volume depends on the volume of RBC in the BMP bag. Default is the BMV multiplied by the number of BM cycles.)
	BM cycles	4 to 10 (Minimum number of cycles depends on the volume of RBC in the BMP bag.)
	Collection bag (mL)	Up to 500
	Plasma bag (mL)	0 to 500
Rinseback	Return flow rate (mL/min)	2 to 100 Default: inlet flow rate that was in use when the run ended or 100 mL/min, whichever is slower

Entering and Confirming Bone Marrow (BM) and Procedure Data

This section contains instructions for entering the BM data and reviewing and confirming the run values. You can enter the data after you select the procedure and before you connect the BMP bag. It is important that the data you enter be as accurate as possible.

Note: When you are required to enter numerical data, the system displays a data entry pad for entering the data. The acceptable numerical range appears on the data entry pad.

Entering BM Data

1 Touch the buttons on the screen to enter the following information:

- BMV (mL)
- Hematocrit (Hct)

The BMP bag must contain at least 125 mL of RBC. The tubing set channel must contain enough RBC for the system to establish an interface that is high enough for cells to be pumped into the collect line. If the bag contains less than 125 mL, the system displays instructions for either increasing the RBC volume or discontinuing the procedure.

2 Touch **Confirm**. The run values screen appears.

Reviewing and Confirming the Run Values

1 Review the run values that appear on the screen and confirm that they are correct. The run targets for a BMP procedure are listed below. A black frame appears around the button of the primary run target.

- BM processed (mL)
- BM cycles
- Collect volume: Target (mL)

If you configured the system to collect plasma, the default volume of plasma appears on the button for the target volume. The default target volume is equal to the collect volume.

If you change a value, the color of the value on the button changes from white to yellow. Values that were affected by a change appear with a yellow arrow. The arrow points up or down to indicate an increase or decrease in the value as a result of the change.

Note: Only the color of the last value you changed remains yellow. The values you previously changed revert to white.

2 When you are finished reviewing the run values, touch **Confirm**.

Preparing to Start the Run

Follow the instructions below and on the screens to connect the BMP bag to the tubing set and to prime the inlet line.

Connecting the BMP Bag to the Tubing Set

1 Lay the BMP bag lower than the saline container.

2 Connect the inlet and return lines on the BMP bag to the inlet and return lines on the tubing set using one of the following two methods:

- Use the luer connectors on the inlet and return lines to connect the BMP bag to the tubing set. Verify that the luer connections are secure and that the connections do not leak.
- Use a sterile tubing welder to connect the BMP bag to the tubing set. Follow the manufacturer's instructions for using the sterile tubing welder. Using a sterile tubing welder to connect the BMP bag helps to maintain a functionally closed system.

3 Touch **Confirm.**

Priming the Inlet Line

1 Unclamp the inlet line and prime the line. Be sure to prime the inlet line through the port on the BMP bag. Be careful not to add more saline than is necessary to the BMP bag to prime the inlet line.

2 Close the inlet saline line only.

3 Touch **Confirm.**

Starting the Run

1 Follow the instructions on the screen to hang the BMP bag and ensure that it is not creased. Be sure to hang the BMP bag on the back hooks of the IV pole, and use each eyelet on the bag and one eyelet per hook. Remove any creases in the BMP bag so that the cells can circulate freely in the bag.

Note: You must hang the BMP bag on the back hooks of the IV pole. The front hooks cannot properly accommodate the bag.

2 Touch **Start Run**. The system begins drawing the bone marrow into the tubing set. The main run screen appears, and the system diverts approximately 40 mL of saline used to prime the tubing set into the saline container.

Mixing the Contents of the BMP Bag During the Run

Mixing the contents of the BMP bag helps incorporate the saline coming into the bag from the return line and prevents the cellular components from settling in areas of the bag. Gently mix the contents several times during each BM cycle. When mixing, leave the bag hanging on the IV pole and avoid drawing air into the inlet line.

Monitoring the Run

The system displays information on the screens to help you monitor the progress of the run. To access the screens, touch the **Run** menu button and then the tab for the screen you want to view. Be sure to verify that the volumes displayed on the screens are consistent with the actual volumes in the fluid containers and in the bags.
See “Glossary of Terms” on page 278 for descriptions of the buttons on the screens.

Main Run Screen

The main run screen is the default run screen and displays or provides access to the information you most likely need to monitor the run. If you want to return to the main run screen after viewing a different screen, touch the go back button, the active menu button, or the tab for the current screen. There is no tab for the main run screen.

Collection Status Screen

To access the collection status screen, touch the **Collection Status** tab. Use this screen to monitor the progress of the run and to adjust the collection preference. You can also use this screen to change the position of the collect valve to immediately direct the flow of cells in the collect line into the reservoir for return to the BMP bag, if necessary.

Collection preference

The collection preference is a reference number that the system uses to adjust the plasma pump flow rate, which affects the concentration of cells that flow through the collect port. You can use the up and down arrows to change the collection preference during the run to accommodate the conditions of the bone marrow and achieve the desired outcome of the procedure.

The default collection preference for a BMP procedure is 50. While establishing the initial interface or while re-establishing the interface after a pump pause or a centrifuge stop, the system targets a higher preference to avoid collecting non-target cells before the interface is stable. The collection preference that the system targets depends on whether or not you change the preference before the interface is established.

- If you do not change the collection preference, the system targets a collection preference of 70.
- If you change the collection preference, the system targets a collection preference that is about 10 points higher than the number that you selected, but is not less than a preference of 70.

Once the interface is established, the system gradually decreases the collection preference either to the default or to the number that you selected. For more information about optimizing the collection preference during the run, see “Optimizing the Collection Preference” on page 204.

Trend graph

The trend graph represents an area of the buffy coat that is in the connector. The horizontal black line on the graph indicates the current collection preference. The green diamonds indicate the concentration of cells flowing through the collect port as compared to the collection preference.

If the system is unable to collect cells at the target collection preference, the green diamonds could appear above or below the black line. As long as the diamonds appear in a controlled path within 20 units either above or below the line, the run is progressing as intended.

Return to BMP bag and collect into bag buttons

The position of the collect valve determines whether the system is directing the flow of cells in the collect line back to the BMP bag or into the collection bag. The system indicates the current position of the collect valve by showing the corresponding button on this screen in a touched (lowered) position. You may manually change the position of the collect valve at any time during the run.

- To direct the flow of cells in the collect line back to the BMP bag, touch the return to BMP bag button and then touch **Apply**. The collect valve moves into the return position, and the system begins pumping the cells into the reservoir for return to the BMP bag.

Note: If you touch the return to BMP bag button, the system operates in Caution status because cells are not being collected. The collect valve stays in the return position until you touch the collect into bag button.

- To direct the flow of cells in the collect line into the collection bag, touch the collect into bag button and then touch **Apply**. The collect valve moves into the collect position and the system begins pumping the cells into the collection bag.

Optimizing the Run

Optimizing the Collection Preference

The collection preference controls the concentration of cells that flow through the collect port. You can increase or decrease the collection preference during the run to accommodate the condition of the bone marrow and to achieve your procedure goals. Consider the following guidelines when changing the collection preference:

- Decrease the collection preference to collect as many target cells as possible. This may result in greater RBC contamination of the collected product.
- Increase the collection preference to minimize RBC contamination of the collected product. This may result in a lower yield of target cells.

Monitoring the contents in the collect line and adjusting the color

Monitor the collect line where it exits the centrifuge below the cassette, and use the collection preference to adjust the color of the contents in the line.

The Collection Preference Tool can help you evaluate which color is appropriate for the procedure. If the contents in the line look either too light or too dark, consider changing the collection preference according to the following guidelines:

- If the color is too light, decrease the collection preference. This increases the concentration of cells that flow through the collect port.
- If the color is too dark, increase the collection preference. This decreases the concentration of cells that flow through the collect port.

Addressing Clumping in the Connector

Clumping can affect collection efficiency by interfering with the separation in the connector. Clumping and the formation of clots can occur during a BMP procedure if the bone marrow was not adequately anticoagulated using ACD-A. If you see clumping in the connector, verify that the appropriate amount of ACD-A was added to the BM bag. If the clumping persists, consider adding ACD-A to the BMP bag.

Reducing the Concentration of Platelets in the Collection Bag

Decreasing the packing factor reduces the volume of platelets flowing into the collection bag. If the concentration of platelets in the collection bag is higher than desired, consider decreasing the packing factor to 4.5 to help reduce the concentration.

Changing the Target Plasma Volume

The system collects the target plasma volume after the other run targets have been attained. The plasma valve moves into the collect position, and the system pumps plasma into the plasma bag. A message appears on the message bar indicating that the plasma collection is in process. When the plasma collection is complete, the plasma valve moves into the return position.

If you decide to collect plasma and you did not previously configure the procedure for plasma collection or select the option to collect plasma, perform the following steps:

1. Touch the target button for the plasma bag, and enter the desired volume. The screen appears instructing you to prepare the tubing set for plasma collection.
2. If you are using an IDL Set with catalog number 10300, spike the plasma bag to the tubing set, or connect the plasma bag according to the instructions under “Using a sterile tubing welder to connect the plasma bag to the replace line” on page 196. The run values screen appears.
3. Touch **Confirm**. The run targets screen appears and the system collects that target plasma volume.

Concentrating the RBC in the BMP Bag

To concentrate the RBC in the BMP bag, remove as much plasma as possible from the BMP bag. Follow the instructions under “Changing the Target Plasma Volume” above and enter the maximum volume of plasma available to collect. The maximum volume is displayed in the volume range on the data entry pad. This volume is based on the volume of plasma required to maintain a maximum Hct of 65% in the BMP bag.

15

Ending the Run and Completing the Procedure

Ending the Run Before a Run Target is Attained

Warning: Terumo BCT does not recommend performing rinseback during RBCX procedures. The data that the system uses to predict the run targets does not include rinseback volume. If rinseback is performed, the run targets may not be accurate.

If you decide to end the run before a run target is attained, perform the following steps:

1 Touch the **End Run** menu button.

2 Choose one of the following options:

- To perform rinseback, touch the **Rinseback** tab.
- To skip rinseback, touch the **Disconnect** tab.

3 Follow the instructions on the screens to complete the procedure and disconnect the patient.

Ending the Run After a Run Target is Attained

The run targets screen appears and the system sounds a tone when one or more run targets have been attained. The screen displays the target and current values of the run targets. The volume of AC in the product bags is also displayed on the screens of the collection procedures. A yellow frame around a current value indicates that the run target was attained. Review the run targets and decide to end or extend the run.

Ending the Run

Perform the following steps to end the run:

1 Touch **Rinseback** and follow the instructions on the screen to confirm your selection.

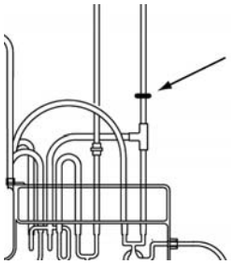
- If you are not performing rinseback, touch **Disconnect** and follow the instructions on the screen to confirm your selection.
- If you decide not to perform rinseback, follow the instructions to skip rinseback under “Ending the Run Before a Run Target is Attained” above.

2 Follow the instructions on the screen to clamp the inlet line.

3 Touch **Continue**. The system tests the pressure in the inlet line.

4 Follow the instructions on the screen to open the inlet saline line and to clamp and then seal the lines to the product bags. See “Sealing the lines using the Seal Safe System” on page 210 for instructions on using the Seal Safe system.

Caution: When performing a collection procedure using the Collection Set or the IDL Set, seal the collect line above the T-shaped connector to the plasma line as shown in the illustration below. If you seal the collect line below the connector, the cells in the collection bag could flow back into the tubing set when the system raises the cassette.



5 Touch **Continue**. The screen that shows the status of rinseback appears.

6 When rinseback is complete, follow the instructions under “Completing the Procedure” to disconnect the patient and complete the procedure.

Extending the Run

Perform the following steps to extend the run:

1 Touch the button for the run target that you want to increase, and enter a new value for the target on the data entry pad. The run values screen appears.

2 Review the run values.

3 Touch **Confirm**. The system resumes the run. When the new run target is attained, the run targets screen reappears.

4 Follow the instructions on the screens to disconnect the patient and complete the procedure.

Completing the Procedure

Disconnecting the Patient and Sealing the Lines

Follow the instructions on the screen to disconnect the patient or the BMP bag, seal the lines to the fluid containers and the bags, and raise the cassette. See "Sealing the lines using the Seal Safe System" below for instructions on using the Seal Safe system. The system confirms that the saline lines are closed and the inlet and return lines are clamped. The system then raises the cassette. The procedure summary screen appears.

Sealing the lines using the Seal Safe System

Warning: Ensure that the sealer head and the tubing are free of moisture and debris before using the Seal Safe system.

Warning: Do not seal the tubing within 8 cm (3 in) of the needle, or you may cause a burn at the needle entry point.

Warning: Do not place your fingers within 2.5 cm (1 in) of the Seal Safe system's sealing jaw, or you may receive a radio frequency (RF) burn.

Caution: Use the Seal Safe system only on tubing distributed by Terumo BCT. The Seal Safe system may not perform as expected on other tubing.

Perform the following steps to seal the lines to the fluid containers and the bags using the Seal Safe system:

1 Hold the sealer head in the palm of your hand with your fingers on the plastic cover of the lever, so that the jaws open facing upward and you can see the indicator light on the head (Figure 15-1).

Figure 15-1: Hold the sealer head with jaws open facing upward

2 Place the tubing into the jaw of the head and squeeze the lever until the jaw is completely closed and the indicator light illuminates (Figure 15-2).

Figure 15-2: Hold the jaw closed until the indicator light illuminates

3 After the indicator light goes off, hold the jaw closed for one second, and then release the lever.

4 Remove the tubing and inspect the integrity of the seal.

5 Put the sealer head back into the holder on the Spectra Optia system.

Reviewing the Data on the Procedure Summary Screens

The procedure summary contains important data about the procedure. The screens appear at the end of the procedure after you raise the cassette. The data displayed varies by procedure. Table 15-1 contains descriptions of the data that may appear on the screens.

Table 15-1: Data on the procedure summary screens

Data	Description
AC in collection bag	Total volume (mL) of AC from the AC container that is in the collection bag
AC in plasma bag	Total volume (mL) of AC from the AC container that is in the plasma bag
AC in remove bag	Total volume (mL) of AC from the AC container that is in the remove bag
AC to patient	Total volume (mL) of AC from the AC container that the patient received
AC used	Total volume (mL) of AC that was used during the run
AC used for prime	Total volume (mL) of AC from the AC container that was used for priming the tubing set
Bolus	Total volume (mL) of fluid that was delivered to the patient for a bolus
Blood removed	Total volume (mL) of blood that is in the remove bag
BM cycles	Total number of times that the system processed the bone marrow volume (BMV)
BM processed	Total volume (mL) of bone marrow that the inlet pump processed during the run
Collect	Total volume (mL) of cells and AC that the collect pump processed into the collection bag
Collection bag	Combined volume (mL) of cells, AC, and plasma that are in the collection bag
Custom prime	Total volume (mL) of fluid that was used for the custom prime
End time	Time the system completed the run or rinseback, if rinseback was performed
FCR	Percentage (%) of starting defective cells remaining in the patient's blood at the end of the run
Fluid balance	Patient fluid balance (mL or %) at the end of the run. This does not include any bolus volume.
Inlet processed	Total volume (mL) of fluid, including whole blood and AC, that the inlet pump processed
Plasma bag	The total volume (mL) of plasma that is in the plasma bag. This includes AC.
Plasma in collection bag	Total volume (mL) of plasma that the plasma pump processed into the collection bag. This includes AC.
Plasma removed	Total volume (mL) of plasma that is in the remove bag
Plasma treated	Total volume (mL) of the patient's plasma that was treated
Plasma volumes exchanged	Total number of the patient's plasma volumes that were exchanged
Plasma volumes treated	Total number of the patient's plasma volumes that were treated
Remove bag	Total volume (mL) of saline, AC, and blood in the remove bag
Replaced:Depletion	Total volume (mL) of replacement fluid used during the depletion
Replaced:Exchange	Total volume (mL) of replacement fluid used during the exchange
Replacement used	Total volume (mL) of fluid that the replace pump processed. This does not include any bolus volume.

Table 15-1: Data on the procedure summary screens (continued)

Data	Description
Rinseback	Total volume (mL) of fluid that the return pump processed during rinseback. This does not include any bolus volume delivered during rinseback.
Run time	Total time (min) that was taken to process inlet volume before the run targets were attained. This does not include the time to complete rinseback or the time when the inlet pump was paused.
Saline diverted	Total volume (mL) of saline used to prime the tubing set that was diverted to the saline container after the run started
Saline rinse	Total volume (mL) of saline that was used for the saline rinse
Saline to patient due to air removal	Total volume (mL) of saline delivered to the patient due to the system removing air from the return line
Start time	Time when the operator touched **Start Run**
Target Hct	Target Hct (%) for the patient at the end of the run
TBV processed	Total number of patient TBV that were processed
Tubing set	Difference between the volume (mL) of fluid in the tubing set at the start of the run and the volume in the set at the start of rinseback, or at the end of the run if rinseback is not performed. A negative value indicates that there is fluid volume in the set.
Volume removed	Total volume (mL) of fluid that the plasma pump processed
Volume replaced	Total volume (mL) of fluid that the replace pump processed. This does not include any bolus volume or the volume of a saline prime
Whole blood processed	Total volume (mL) of the patient's blood that the inlet pump processed during the run.

Starting a New Procedure

Touch **New Procedure** on page 2 of the procedure summary. The system resets so that you can select your next procedure.

Removing the Tubing Set

Note: If you do not perform rinseback, the channel of the tubing set will be full of fluid when you unload the set. After you raise the cassette, empty the channel by putting the cassette and the bags at a level below the channel, allowing the fluid in the channel to drain into the vent bag.

Once you finish the procedure and raise the cassette, perform the following steps to remove the tubing set:

1. Open the centrifuge door.
2. Remove the upper collar from the collar holder by grasping the lines above and below the collar and pulling the lines downward.
3. Remove the upper and lower bearings from the bearing holders.
4. If you are using a Collection Set, remove the chamber from the bracket.
5. Gently pull the channel from the filler.
6. Push in the locking pin on the centrifuge collar holder, and remove the collar from the holder by grasping the tubes above the collar and pulling upward.
7. Push the filler latch pin toward the center of the centrifuge, and raise the filler latch.
8. Fold the channel in half, and pull the channel through the loading port and out of the centrifuge chamber.
9. Lower the filler latch.
10. Close the centrifuge door.
11. Remove the lines from the fluid detectors.
12. Remove any bags from the IV pole.
13. Press the latch on the upper right corner of the cassette tray, and lift the cassette from the tray.
14. Discard the tubing set, according to your standard operating procedures.

16

Troubleshooting

Troubleshooting Alarms

The Spectra Optia system has independent control and safety systems that constantly monitor the performance of the system. If either system detects an operation error or a potentially unsafe operating condition, the system sounds an alarm and illuminates the warning lights on the monitor. The warning lights remain constant if the control system detected the error, and flash if the safety system detected the error.

The operator plays an essential role in the safe operation of the system. If an alarm occurs, it is crucial for the operator to consider all possible causes for the alarm and thoroughly read the instructions that appear on the screen to resolve the alarm. It is the operator's responsibility to determine if it is safe to continue the procedure, and to follow the appropriate instructions.

Navigating the Alarm Screens

The system displays information about the alarm and troubleshooting instructions on the screen. Figure 16-1 shows an example of an active alarm screen, which appears if an alarm occurs. Figure 16-2 shows an example of an alarm action screen, which shows the steps to perform to resolve the condition causing the alarm. Tables 16-1 and 16-2 contain descriptions of the different areas of the screens.

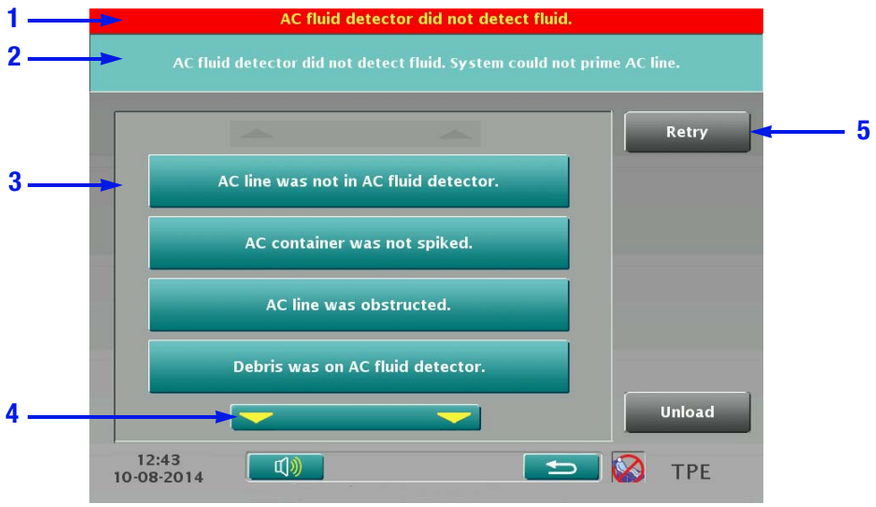


Figure 16-1: Example of an active alarm screen

Table 16-1: Description of an active alarm screen

	Area	Description
1	Alarm name	States the name of the alarm that occurred.
2	Alarm explanation	Provides a brief explanation of the condition that caused the alarm.
3	Possible causes	Lists the possible causes of the alarm in order of most likely (top) to least likely (bottom). Each possible cause is an active button that you can touch to display the action steps you should perform to resolve the condition causing the alarm.
4	Scroll button	Indicates that additional possible causes for the alarm condition exist. Touch the button to view the additional causes.
5	Action buttons	Displays buttons of available actions that you can touch to help resolve the condition. For details, read the action steps for the possible cause before you touch an action button.

Figure 16-2: Example of an alarm action screen

Table 16-2: Description of an alarm action screen

	Area	Description
1	Alarm name	States the name of the alarm that occurred.
2	Alarm explanation	Provides a brief explanation of the condition that caused the alarm.
3	Possible cause	Shows the possible cause of the alarm, which was selected from the list on an active alarm screen.
4	Action steps	Shows the action steps to perform to resolve the condition causing the alarm.

If an alarm occurs, perform the following steps:

Note: If you want to temporarily silence the alarm tone, touch the mute button at the bottom of the screen.

1 Read the alarm name and the alarm explanation.

2 Read the list of possible causes for the alarm, and identify the most probable cause for the alarm.

3 Touch the button for the cause that you identified. The alarm action screen appears.

4 Follow the steps on the screen to resolve the condition causing the alarm.

5 If the actions for the cause you identified do not resolve the condition, repeat steps 2 through 4 until you resolve the condition. To view previous or subsequent alarm action screens, touch the scroll buttons. To return to the active alarm screen, touch the go back button.

Note: Most alarm conditions can be resolved by reading the possible causes for the alarm and following the instructions on the alarm actions screens. It is not necessary to contact a service representative unless instructed.

Troubleshooting Multiple Alarms

To view a list of active alarms, do the following:

1. Touch the active alarm button at the bottom of the screen. The screen of active alarms appears with a list of active alarms.
2. Touch the button of the alarm that you want to troubleshoot.
3. To exit the screen, touch the go back button.

Note: You must resolve all conditions causing alarms before you can resume the procedure. The active alarm button appears at the bottom of the screen if there are additional conditions to resolve. Some conditions may resolve themselves when you troubleshoot other conditions, and as a result will disappear from the list of active alarms.

Viewing Alarm History

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Alarm History** tab. The alarm history screen appears with a list of alarms that have occurred, including the time the alarm occurred.
3. To exit the screen, touch the go back button.

Muting the Alarm Tone

You may silence the alarm tone for 2 minutes by touching the mute button on the lower left corner of the screen. The system sounds a reminder tone every minute thereafter to remind you that there is an active alarm. If a new alarm occurs, the system restores the alarm tone.

Using Semi-Automatic Mode

Note: Semi-Automatic mode is not available during an RBCX procedure.

When the system is operating in Semi-Automatic mode, the AIM system does not control the position of the interface. The system controls the interface position using the entered hematocrit and other procedure values. There are two reasons to enter Semi-Automatic mode:

- You may choose to enter Semi-Automatic mode with the AIM system enabled if certain procedure conditions occur.
- You may be required to disable the AIM system and enter Semi-Automatic mode to resume the procedure if certain alarm conditions occur.

Entering Semi-Automatic Mode With the AIM System Enabled

- Exchange procedures: You may choose to enter Semi-Automatic mode because the AIM system did not correctly identify the position of the interface due to a patient condition. The AIM system continues to monitor the interface position although it does not control it. Since the AIM system remains enabled, you may return to Automatic mode at any time.
- Collection and depletion procedures: You may choose to enter Semi-Automatic mode to control the concentration of cells that flow through the collect port. The AIM system monitors the interface position but it does not control the position. The system displays the image of the collect port on the main run screen and the collection status screen. It also displays the status of the collection on the trend graph on the collection status screen, but does not display the collection preference. Since the AIM system remains enabled, you may return to Automatic mode at any time.

Perform the following steps to enter Semi-Automatic mode with the AIM system enabled:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Operation Status** tab. The operation status screen appears.
3. Touch **Proceed to Semi-Automatic Mode**.
4. Touch **Confirm**.

To return to Automatic mode, perform the following steps:

1. Touch the **Run** menu button. The run tabs appear.
2. Touch the **Operation Status** tab. The operation status screen appears.
3. Touch **Proceed to Automatic Mode**.
4. Touch **Confirm**.
5. If you are performing an exchange procedure, continue to monitor the interface position to ensure that it does not drift from the intended position.

Entering Semi-Automatic Mode With the AIM System Disabled

When the AIM system is disabled, it does not monitor or control the interface position. During collection and depletion procedures, the system does not display the image of the collect port on the main run screen or on the collection status screen. It also does not display the collection preference on the trend graph on the collection status screen. A button to disable the AIM system appears on the alarm screen. Once you disable the AIM system, you must complete the procedure in Semi-Automatic mode.

Resuming the Procedure in Semi-Automatic Mode

Once you have entered Semi-Automatic mode, follow the instructions below to resume the procedure.

Exchange procedures

1. Look through the viewport to view the interface position. The interface position should appear low and the RBC layer should be thin.

   To adjust the interface position, go to the patient data screen and change the entered Hct. If the position seems too high, increase the Hct by 3 percentage points. You may do this up to three times for a total increase of 9 percentage points.

2. Monitor the interface position and adjust the position again, if necessary.

MNC collection procedures

1. Go to the collection status screen.
2. Look through the view port to view the concentration of cells flowing through the collect port. Once the interface is in the correct position, you should see swirls of cells flowing through the collect port. If the AIM system is enabled, the image of the collect port on the screen should also show the swirls.
3. Ensure the concentration of cells flowing through the collect port is correct. To adjust the concentration of cells, touch the up or down arrow button one time to adjust the plasma pump flow rate:
   - To decrease the concentration of cells, touch the up arrow button.
   - To increase the concentration of cells, touch the down arrow button.
4. View the collect port again and re-evaluate the concentration of the cells. If the concentration needs further adjustment, touch the up or down arrow button again.
5. If the collection phase control is System, allow the system to initiate a collection phase when the RBC detector detects target cells in the collect line.
6. Continue to monitor the concentration of cells flowing through the collect port, and adjust the concentration again, if necessary.

CMNC, PMN collection, and depletion procedures

1. Go to the collection status screen.
2. Look through the view port to view the concentration of cells flowing through the collect port. Once the interface is in the correct position, you should see swirls of cells flowing through the collect port. If the AIM system is enabled, the image of the collect port on the screen should also show the swirls.
3. Examine the collect line where it exits the centrifuge to ensure the color in the line is correct. To adjust the color, touch the up or down arrow button one time to adjust the plasma pump flow rate:
   - If the color is too light, decrease the collection preference by touching the down arrow button. This increases the concentration of cells that flow through the collect port.
   - If the color is too dark, increase the collection preference by touching the up arrow button. This decreases the concentration of cells that flow through the collect port.
4. Examine the collect line again and re-evaluate the color. If the color needs further adjustment, touch the up or down arrow button again.
5. Continue to monitor the collect line and adjust the color again, if necessary.

Managing Anticoagulation of the Extracorporeal Circuit

Caution: Terumo BCT has validated the system's performance when the extracorporeal circuit is properly anticoagulated using ACD-A, and recommends using ACD-A to anticoagulate the circuit.

Proper anticoagulation of the system's extracorporeal circuit ensures that the flow of blood and fluid through the circuit is not obstructed during the procedure. Terumo BCT recommends that you use an inlet:AC ratio up to 15:1 when using ACD-A. The system's default inlet:AC ratio depends on the procedure selected. You may need to use a different ratio, however, for a patient with a unique hematologic condition. If the circuit is not adequately anticoagulated, platelet aggregates or clots may form, and eventually cause an obstruction in one or more of the following areas:

- Filter at the bottom of the reservoir
- Collect port (Collection Set, IDL Set)
- Tubing set connector, which can result in an unstable interface

To eliminate the aggregates or clots, decrease the inlet:AC ratio. If an alarm occurs indicating a possible obstruction, follow the instructions on the alarm action screen, and monitor the system for the rest of the procedure. If you do not eliminate the obstruction, the system may require that you discontinue the procedure.

Handling Fluid Leaks

The fluid leak detector is a strip of moisture-sensitive material running down the back wall and floor of the centrifuge chamber. If it detects moisture inside the centrifuge chamber, or if it is not functioning correctly, an alarm occurs.

1. If you do not see signs of blood or moisture, wipe the surface and along the ridges of the detector with an alcohol wipe, using a gentle, side-to-side motion.
2. Dry the detector using a gauze pad or a soft, lint-free cloth.
3. If you see a fine spray of blood or moisture on the inside walls of the centrifuge chamber, a small leak exists. Do one of the following to discontinue the procedure:
   - If the patient is not connected and the cassette is lowered, touch **Unload** and unload the tubing set.
   - If the patient is connected and the procedure is in progress, go to the main run screen and touch the **End Run** menu button to display the menu tabs. Then choose one of the following options:
     – If rinseback is an option, consider completing stage 1 of rinseback. Touch the **Rinseback** tab and follow the instructions on the screen to perform rinseback. During stage 1, the centrifuge does not spin. After the system starts pumping saline into the tubing set and spinning the centrifuge to complete stages 2 through 4, the alarm could recur. If the alarm recurs, touch the **Disconnect** tab and follow the instructions on the screen to disconnect the patient and end the procedure.
     – If rinseback is not an option, touch the **Disconnect** tab, and follow the instructions on the screen to disconnect the patient and end the procedure.
4. Follow the instructions in Chapter 17, "Maintaining the Spectra Optia System," to disinfect the centrifuge chamber. If you are unable to adequately perform the disinfection, contact your Terumo BCT representative for assistance.

Resuming a Procedure After a System Reset

The system resets itself under the following conditions:

- Power to the system fails and is then restored.
- You touch **Reset**, according to instructions on an alarm screen.
- An alarm condition causes the system to reset itself.
- You turn the system off and then on again.

After the reset, the system performs a series of tests to ensure that it is safe to resume the procedure. A screen appears with instructions for how to proceed after the reset. Do the following:

1. Follow the instructions on the screen to resume the procedure at the point before the reset occurred. You may also choose to discontinue the procedure.
   - If the reset occurred during a run and you chose to continue the procedure, a screen appears asking you to ensure that both saline lines are closed. Follow the instructions on the screen to confirm that the lines are closed.
   - If an alarm was active when the reset occurred, the action buttons that appear on the screen will be the same as the buttons that were available on the alarm screen. If the alarm condition still exists after you complete the instructions on the screen, the alarm will recur.
2. Verify that the system restored the patient and procedure data you entered before the reset occurred. The system restores the data only if the tubing set cassette was in the lowered position when the reset occurred.
   - If the reset occurred before you started a custom prime, the system does not restore the custom prime data. Go to the screen that instructs you to enter the custom prime data and re-enter the data.
3. Verify that you completed the task that appeared on the screen before the reset occurred. Depending on when the reset occurred, you may need to repeat a sequence of steps.
   - If the reset occurred during administration of a fluid bolus, the system discontinued the bolus. Go to the exchange status screen to view the volume that the system administered.

Note: If power to the device has been off for more than 8 hours, the system might not allow you to resume the procedure.

Performing a Manual Rinseback

Important: You should read and understand these instructions before you attempt to perform a manual rinseback.

If you are not able to complete a procedure due to an alarm condition, a power interruption, or a system malfunction, you may choose to perform a manual rinseback. Perform the following steps to complete a manual rinseback.

Clamping and Sealing the Lines

1. Clamp the inlet and return lines.
2. Close the saline lines.
3. Disconnect the inlet line from the patient.
4. Seal the AC line.
5. Seal the following lines according to the type of tubing set you are using:
   - Exchange Set: remove line, replace line
   - Collection Set: collect line to the collection bag, plasma line to the plasma bag
   - IDL Set: collect line to the collection bag, plasma line to the plasma bag, replace line

Note: Ensure that you do not seal the line to the vent bag. If you seal the line, you will not be able to resume the manual rinseback.

6. Turn off the Spectra Optia system.

Draining the Channel

1. Open the centrifuge door. If the door does not open, follow the instructions on page 226 to manually open the door.
2. Remove the channel from the filler and hang it on the IV pole with the inlet line at the highest point, so that the fluid in the channel drains into the cassette reservoir.
3. If you are using an Exchange Set, ensure that the RBC valve is in the return position (Figure 16-3), or the fluid will not drain.

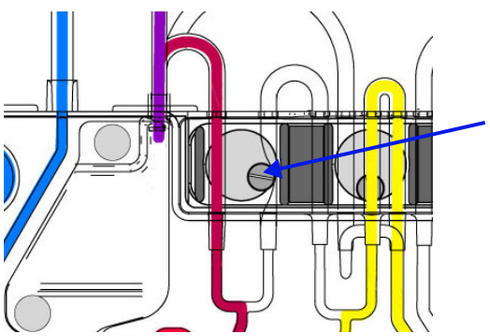


Figure 16-3: RBC valve in the return position (Exchange Set shown here)

Returning the Fluid to the Patient

1 Remove the rotor from the return pump:

a. Push in the rotor and turn it to the left to unlock.

b. Pull the rotor off the pump.

2 Use a hemostat to clamp the RBC line directly below the cassette (Figure 16-4).

Note: Do not seal the RBC line instead of clamping it. If you seal the line, the tubing set could leak when you raise the cassette to unload the set.

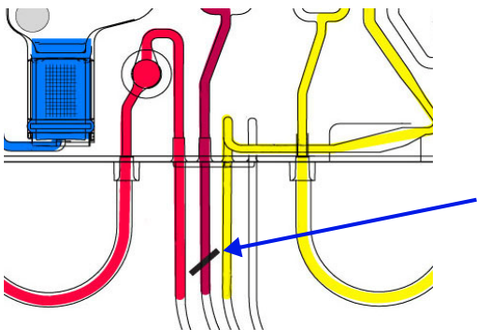


Figure 16-4: Where to clamp the RBC line (Exchange Set shown here)

3 Unclamp the return line (Figure 16-5).

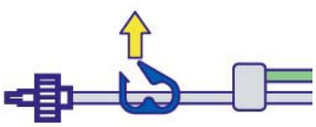


Figure 16-5: Return line unclamped

4 Gently squeeze the vent bag to push the fluid from the reservoir to the patient. This should take several minutes to complete. Do not try to expedite this process by applying more pressure to the bag.

Warning: Do not apply excess pressure to the vent bag when pushing fluid from the reservoir to the patient during a manual rinseback or you could damage the red blood cells that you are returning to the patient.

5 When the level of fluid in the reservoir drops to the level of the reservoir filter (Figure 16-6), clamp the return line and stop squeezing the vent bag.

Warning: Do not continue to squeeze the vent bag after the fluid in the reservoir reaches the level of the reservoir filter during a manual rinseback. If you continue to squeeze the bag, you could deliver air to the patient.

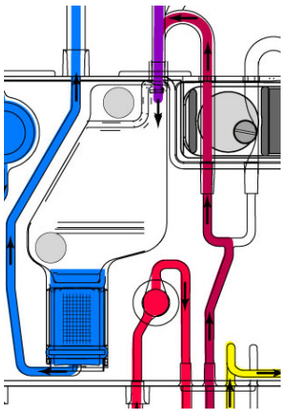


Figure 16-6: Level of fluid in the reservoir at the level of the reservoir filter (Exchange Set shown here)

6 Disconnect the patient.

7 Remove the hemostat from the RBC line. Ensure that you do this before you raise the cassette in step 9, or the return pressure sensor will leak.

8 Replace the rotor on the return pump:

   a. Pull the tubing out of the pump housing and down toward the cassette.

   b. While holding the return pump tubing in the position described in step a., push the rotor back in the housing.

9 If the system functions, perform the following steps:

   a. Turn on the system.

   b. Touch **Disconnect** to discontinue the procedure.

   c. Touch **Unload** to raise the cassette.

   d. Unload the tubing set.

10 If the system does not function, manually raise the cassette according to the instructions on page 226, and then unload the tubing set.

Manual Method for Opening the Centrifuge Door and Raising the Cassette

If the power to the system is interrupted when the centrifuge is spinning, or the system does not function correctly, the pumps stop and the centrifuge door may not open. To unload the tubing set, you need to manually open the centrifuge door and raise the cassette.

Manually Opening the Centrifuge Door

1 Confirm that the system is turned off. Unplug the system from the power source.

2 Remove the cap from the centrifuge door lock-release hole, which is located near the top-right corner of the centrifuge door.

3 Insert the centrifuge door key or a long, thin, metal rod into the lock-release hole (Figure 16-7). Push in the key until you hear a click.

Note: Do not use a cotton swab, stick, or other breakable object to manually open the centrifuge door, as it may break and jam the door.

Figure 16-7: Centrifuge door key in the lock-release hole

4 Remove the key.

5 Squeeze the centrifuge door handle and gently lower the door. Replace the cap into the lock-release hole.

Manually Raising the Cassette

If a system malfunction occurs and you must turn off the Spectra Optia system, you can manually raise the cassette to remove the tubing set. To raise the cassette and open the valves, perform the following steps:

Warning: Do not touch Unload to unload the tubing from the pumps or remove the tubing set when a patient is connected to the Spectra Optia system, or the patient may receive surplus fluids through the inlet and return lines.

1 Confirm that the patient is disconnected.

2 Seal or clamp the lines to the fluid containers.

3 Unplug the system from the power source.

4 Turn each valve to the neutral position using a flat-blade screwdriver (Figure 16-8).

Figure 16-8: Valves turned to the neutral position

5 Remove each pump rotor from the pumps:

a. Push in the rotor and turn it to the left.

b. Pull the rotor off the pump.

6 Insert the screwdriver into the small hole in the vent on the back of the system (Figure 16-9) until you engage the slotted end of the pin attached to the back of the cassette tray. You may need to angle the screwdriver to locate the pin.

Figure 16-9: Screwdriver inserted in the hole in the back of the system

7 Turn the screwdriver counterclockwise until it no longer turns, and the cassette tray is in the fully raised position.

8 Follow the instructions on page 214 to remove the tubing set from the system.

17

Maintaining the Spectra Optia System

Cleaning and Disinfecting the Spectra Optia System

This section contains instructions for cleaning and disinfecting the Spectra Optia system. Follow the instructions for cleaning the system to remove dirt and other substances that could impair the function of the system. Follow the instructions for disinfecting the system to eliminate potentially infectious substances. Always confirm that the system is clean and undamaged before use.

Warning: Turn off the system before cleaning or disinfecting to prevent possible electrical shock or damage to the equipment.

Warning: When cleaning and disinfecting equipment surfaces that might have been exposed to blood, take adequate precautions to prevent possible exposure to and transmission of infectious diseases.

Compatible Cleaning Solutions

Caution: Clean the Spectra Optia system using a mild, non-abrasive cleaning solution or a mild detergent. Industry standard practice defines mild cleaning solution and mild detergent as a solution or detergent that is safe on skin and on washable surfaces, such as dishwashing liquid. Use of a solution that is not compatible with the materials on the system may damage the material or operating characteristics of the system.

The cleaning solutions listed below are compatible for use on the Spectra Optia system. Use the solution specified in the instructions when cleaning.

- Mild detergent
- 70% isopropyl alcohol
- Water

Compatible Disinfecting Solutions

Caution: Disinfect the Spectra Optia system using a disinfecting solution that is compatible for use on the system. Use of a disinfecting solution that is not compatible could damage the material or operating characteristics of the system.

The disinfecting solutions listed below are compatible for use on the Spectra Optia system.

- 0.63% sodium hypochlorite
- 70% isopropyl alcohol
- 0.50% ammonium chloride

If the disinfecting solution used by your facility contains an active ingredient that is not on this list, test the solution before use by applying it to an inconspicuous area on the system to confirm that is does not damage or discolor the system.

Application of Cleaning and Disinfecting Solutions

Caution: Use only a gauze pad, a lint-free cloth, or a wipe when cleaning or disinfecting the touch screen, the covers on the AIM system lights in the centrifuge, and the aperture plate on the filler. Use of an abrasive brush, scrub material, or a sharp object can damage the surface of the components.

The materials listed below are recommended for use alone or in conjunction with a compatible cleaning or disinfecting solution. Avoid using abrasive material, which could damage the function of the components and the appearance of the system.

- Gauze pad
- Soft lint-free cloth
- Cotton swab
- Commercial or industrial wipe that is pre-moistened with a compatible solution from the lists above.

Frequency of Cleaning and Disinfecting

Some of the system components require more frequent cleaning than other components. See “Cleaning Schedule for the Spectra Optia System”on page 239 for the recommended frequency of cleaning. Disinfect the system when it is exposed to an infectious substance or according to your standard operating procedures.

Cleaning and Disinfecting the System Components

This section contains instructions for cleaning and disinfecting the components that can come in contact with dirt and infectious material. Use the solutions and materials described under “Cleaning and Disinfecting the Spectra Optia System” when performing these activities. The operator is responsible for cleaning and disinfecting these components.

Surface of the System

Exterior surfaces

Wipe the exterior surfaces of the Spectra Optia system using a mild detergent or a disinfecting solution.

Touch screen

Caution: To avoid damaging the touch screen, do not douse the touch screen with fluid or leave fluid on the screen after cleaning or disinfecting the screen. Always dry the screen with a gauze pad or a clean cloth after exposing it to fluid.

1. Wipe the touch screen, using a mild detergent or a disinfecting solution.
2. Dry the touch screen, using a gauze pad or a soft, lint-free cloth.

Components on the Front Panel

Fluid spilled on the components on the front panel could interfere with the system operation even if it is not visible. For the location of the components, see “Front Panel” on page 23.

Sensors and detectors

1. The sensors are easier to access if the cassette tray is in the lowered position. Perform the following steps to lower the cassette tray:
   a. Turn on the system.
   b. Touch **Select Procedure**. The procedure selection screen appears.
   c. Select any procedure and touch **Confirm**.
   d. When the screen that instructs you to load a tubing set appears, do not load a tubing set.
   e. Touch **Load**. The system lowers the cassette tray.
   f. Turn off the system.
2. Wipe the sensors and the detectors, using water or a disinfecting solution.
3. After disinfecting, wipe the sensors and the detectors again, using water to remove any residue left by the disinfecting solution.

Valves

Wipe the surfaces of the valves, using mild detergent or a disinfecting solution.

Pump housings and pump rotors

1 Remove each pump rotor from the housing as follows:

   a. Push in the rotor and turn it to the left (Figure 17-1).

   b. Pull the rotor out of the housing.

Figure 17-1: Removing the rotor from the pump housing

2 Wipe the housing and the rotor, using mild detergent or a disinfecting solution.

Note: If necessary, you can rinse the pump rotors with water or mild detergent before disinfection to loosen any residue left by a spill.

3 Wipe the rotor again using water to remove any residue left by the detergent or solution.

4 Allow the rotor to air-dry before replacing it in the housing.

5 Align the rotor with the housing. Ensure that the metal bar in the housing aligns with the corresponding slot in the rotor. Push in the rotor and turn it to the right to lock the rotor in place. If you do not properly install the rotor, an alarm will occur the next time you load a tubing set.

Note: Ensure that you install the rotor with the black dot in the housing for the replace/collect pump.

Components in the Centrifuge Chamber

Dirt or residue on the components in the centrifuge chamber can affect the performance of the components or the performance of the AIM system. For the location of the fluid leak detector and the AIM system lights, see “Centrifuge Chamber” on page 26. For the location of the aperture plate and the optical reference, see “Filler” on page 27.

Fluid leak detector

1 Wipe the surface and along the ridges of the detector, using a mild detergent or disinfecting solution and a gentle, side-to-side motion. Be careful not to damage the ridges of the detector.

2 Wipe the detector again using water to remove any residue left by the solution.

3 Dry the detector, using a gauze pad or a soft, lint-free cloth.

Covers on the AIM system lights

Caution: Use only a gauze pad, a lint-free cloth, or a wipe when cleaning or disinfecting the touch screen, the covers on the AIM system lights in the centrifuge, and the aperture plate on the filler. Use of an abrasive brush, scrub material, or a sharp object can damage the surface of the components.

1 Wipe the covers, using water or a disinfecting solution.

2 After disinfecting, wipe the covers again using water to remove any residue that was left by the disinfecting solution.

3 Dry the covers, using a gauze pad or a soft, lint-free cloth.

Filler

1 Follow the instructions on page 64 to remove the filler from the centrifuge.

2 Wipe the filler, using a mild detergent or a disinfecting solution. Use a cotton swab to clean the groove of the filler and a dry cotton swab or alcohol pad to remove excess fluid.

Note: If necessary, you can rinse the filler with water or mild detergent before disinfection to loosen any residue left by a spill.

3 Wipe the surfaces of the aperture plate, using water to remove any residue that was left by the cleaning solution or disinfecting solution.

4 Dry the aperture plate, using a gauze pad or a soft, lint-free cloth.

5 Allow the remaining surfaces of the filler to air-dry completely.

6 Follow the instructions on page 65 to re-install the filler on the centrifuge.

Seal Safe System: Jaw Cavity

Examine the sealer head after each procedure. If you see dirt or fluid in the jaw cavity, follow the instructions below to remove the residue. It is important that the jaw cavity be kept clean. Residue left in the cavity can impair the performance of the device.

Warning: Disconnect the sealer head from the RF cable before cleaning to avoid receiving a serious radio frequency (RF) burn during the cleaning process.

1 Disconnect the sealer head from the RF cable.

2 Remove and discard the splash guard, if used.

3 Clean the jaw cavity, using a cotton swab dampened with alcohol. Do not use other cleaning or disinfecting solutions to clean the cavity (Figure 17-2).

Figure 17-2: Cleaning the jaw cavity with a cotton swab

4 Clean all areas outside the jaw cavity. Squeeze the lever to expose areas outside of the cavity, and clean those areas.

5 Dry all parts of the jaw and jaw cavity, using a cotton swab.

Seal Safe System: Sealer Head

Follow the instructions below to clean the sealer head and to replace the splash guard. You must disassemble the sealer head to clean it.

Disassembling of the sealer head

1 Disconnect the sealer head from the RF cable.

2 Remove and discard the splash guard, if used.

3 Hold the sealer head in a vertical position with the jaw end pointing upward, and use your thumb to depress the jaw to the closed position. Do not squeeze the lever. For additional leverage, place the bottom of the sealer head on a padded surface (Figure 17-3).

Figure 17-3: Depressing the jaw to the closed position

4 Remove the lever by slightly releasing the jaw and pulling the lever down and back (Figure 17-4).

Figure 17-4: Removing the lever

5 Remove the jaw by pulling it up and sideways (Figure 17-5).

Figure 17-5: Removing the jaw

Cleaning the sealer head

1 Wipe the components with alcohol applied to a cotton swab. Do not use other cleaning or disinfecting solutions to clean the components.

2 Dry the components using a cotton swab, a gauze pad, or a soft, lint-free cloth.

Reassembling the sealer head

1 Ensure that the spring is in place in the head.

2 Locate the grooves on both sides of the head. Align the jaw with the grooves and slide it down the sealer head until it touches the spring (Figure 17-6). Ensure that the spring fits into the indentation in the jaw.

Figure 17-6: Aligning the jaw with the grooves

3 Use your thumb to slightly depress the jaw. Ensure that the spring stays in place.

4 Replace the lever by tipping it at a 45° angle and positioning the lever pivots behind and below the pivot slots (Figure 17-7).

Figure 17-7: Replacing the lever

5 Push down the lever to engage the lever pivots while simultaneously depressing the jaw with your thumb.

6 Release your thumb. The lever should fully engage and secure the jaw on the sealer head.

7 Squeeze the lever to ensure that the head mechanically functions. If the jaw does not completely close, check the position of the spring.

8 Attach a new splash guard, if required, according to the instructions “Attaching a new splash guard” below.

9 Reconnect the RF cable to the sealer head and put the sealer head back into the holder.

Attaching a new splash guard

Perform the following steps to attach a new splash guard after cleaning the sealer head or as necessary:

1 Disconnect the RF cable from the sealer head if it is still connected.

2 Prepare a new splash guard:

a. Remove the perforated inset from one side of the splash guard (Figure 17-8).

b. Fold the other inset inward at a 90° angle to form a clip (Figure 17-8).

Figure 17-8: Inset folded to form a clip

c. Fold the sides of the splash guard inward at the perforations (Figure 17-9).

Figure 17-9: Splash guard folded at the perforations

3 Align the splash guard with the lever assembly on the sealer head.

4 Attach the splash guard and use the clip to lock it in place (Figure 17-10).

Figure 17-10: Attaching the splash guard and locking it in place

5 Reconnect the RF cable to the sealer head and put the sealer head back into the holder.

Cleaning Schedule for the Spectra Optia System

Table 17-1 shows the summarized instructions and suggested frequency for cleaning the Spectra Optia system. The schedule can change, depending on how often the system is used. Use this schedule in conjunction with the detailed instructions in this chapter to clean the system.

Table 17-1: Suggested cleaning schedule for the Spectra Optia system

Component	Frequency		
	After Each Procedure	**Weekly**	**Monthly**
System surface	• Use mild detergent. • Allow to air-dry.		
Touch screen	• Use mild detergent. • Dry with a gauze pad.		
Front panel: sensors		• Use water only. • Allow to air-dry.	
Front panel: detectors		• Use water only. • Allow to air-dry.	
Front panel: valves		• Use mild detergent. • Allow to air-dry.	
Front panel: pumps			• Use mild detergent. • Allow to air-dry.
Centrifuge chamber: filler surface			• Use mild detergent. • Allow to air-dry.
Centrifuge chamber: filler aperture plate and optical reference			• Use water only. • Allow to air-dry.
Centrifuge chamber: fluid leak detector			• Use mild detergent. • Dry with a gauze pad.
Centrifuge chamber: covers on AIM system lights			• Use water only. • Dry with a gauze pad.
Seal Safe system: jaw cavity	As needed: • Use 70% isopropyl alcohol. • Dry with a cotton swab.		
Seal Safe system: sealer head			• Use 70% isopropyl alcohol. • Dry with a cotton swab. • Replace the splash guard.

Performing Preventive Maintenance

To prolong equipment life and to ensure maximum performance of the Spectra Optia system, a qualified service technician should calibrate the system and perform preventive maintenance every 6 months, with a compliance window of ± 30 days from the scheduled date of the maintenance. Contact your Terumo BCT representative for more information.

18

Spectra Optia System Specifications

Spectra Optia System Specifications

General System Specifications

Electrical

Table 18-1: Electrical power and safety

Characteristics	Performance	Conditions
Electrical power rating	100 V AC to 240 V AC 50/60 Hz, 1050 VA	Where a circuit breaker provides excess current protection
Ethernet port	Port is electrically isolated.	• Location where a device can be connected to the system to print reports or to collect and transmit data to Terumo BCT • Location where service personnel can connect to the system to download procedure information to a computer when a patient is not connected
Safety certifications	Meets the requirements of EN 60601-1 and EN 61010-2-20	CE Marking
	Device is certified by CSA International in accordance with applicable U.S. and Canadian standards. For applicable standards for the product, see Table 18-36 on page 261.	CSA Certification to applicable U.S. and Canadian standards
	Meets the requirements of category IP21 of IEC 60529	

Environmental

Table 18-2: Environmental: Spectra Optia device

Characteristics	Performance	Conditions
Ambient operating temperature	15.5 °C to 27.7 °C (60 °F to 82 °F)	
Ambient operating humidity	8% to 80%	Relative humidity (RH), non-condensing
Cleaning	• Surface of the device can be cleaned and disinfected • Pump rotors can be removed for cleaning and disinfection • Channel leaks are contained within the centrifuge chamber • Centrifuge chamber can be cleaned and disinfected	Device is not damaged by cleaning and disinfecting with the compatible cleaning solutions and disinfecting solutions, according to the instructions described in Chapter 17 of this manual.
Access by foreign material	Device is protected against access by foreign objects and falling water.	

Table 18-2: Environmental: Spectra Optia device (continued)

Characteristics	Performance	Conditions
Restrictions	Device is not for use in an explosive atmosphere.	
Shipping temperature	–29 °C to 60 °C (–20 °F to 140 °F)	
Shipping humidity	8% to 90%	Relative humidity (RH), non-condensing
Storage temperature	0 °C to 60 °C (32 °F to 140 °F)	
Storage humidity	8% to 80%	Relative humidity (RH), non-condensing

Table 18-3: Environmental: Seal Safe system

Characteristics	Performance	Conditions
Ambient operating temperature (sealer head with RF cable)	15.5 °C to 27.7 °C (60 °F to 82 °F)	
Ambient operating humidity	8% to 80%	Relative humidity (RH), non-condensing
Cleaning	Components can be cleaned and disinfected.	Device is not damaged by cleaning and disinfecting with the compatible cleaning solutions and disinfecting solutions, according to the instructions described in Chapter 17 of this manual.
Fluid spillage	The unit is safe to use if fluid is spilled on the sealer head or on the RF cable.	

Table 18-4: Environmental: Tubing sets

Characteristics	Performance	Conditions

Storage temperature	• Long term storage range: 0 °C to 35 °C (32 °F to 95 °F)
	• Permitted excursions:
	  • –29 °C to 0 °C (–20 °F to 32 °F) for up to 72 hours
	  • 35 °C to 50 °C (95 °F to 122 °F) for up to 6 weeks	

Storage humidity	• 0% to 75% • Permitted excursions: Up to 85% RH ± 5% for up to 72 hours	Relative humidity (RH), non-condensing

Physical

Table 18-5: Physical: Spectra Optia system

Characteristics	Performance	Conditions
Floor space required	0.43 m^2 (4.6 ft^2)	Applies to a floor slope of less than 5°
Minimum clearance	30 cm (11.8 in) around the perimeter of the device	

Table 18-5: Physical: Spectra Optia system (continued)

Characteristics	Performance	Conditions
Height	• 106.4 cm (41.9 in) (without the IV pole) • 162.1 cm (63.8 in) (with the IV pole)	
Width	52.7 cm (20.75 in)	
Depth	81.3 cm (32.0 in)	
Weight	Up to 97 kg (213 lb) without accessories	
System weight plus Safe Working Load	102 kg (225 lb)	Safe Working Load is the maximum external load that includes tubing set, accessories, and solutions.

Table 18-6: Physical: Seal Safe system

Characteristics	Performance	Conditions
Physical dimensions (sealer head with RF cable)	Diameter: 2.5 cm (1 in) Relaxed length: Approximately 1.1 m (3.7 ft)	
Weight	External parts: 0.4 kg (0.9 lb)	

Sound pressure level

Table 18-7: Sound pressure level during system operation

Characteristics	Performance	Conditions
Average sound pressure level during the run state	68 dB(A) SPL to 70 dB(A) SPL	Normal operating conditions

Table 18-8: Sound pressure level of alarm tone

Characteristics	Performance	Conditions
Sound pressure level	• Low setting: 62 dB(A) SPL • High setting: 75 dB(A) SPL	

System Components

Centrifuge

Table 18-9: Centrifuge speed and g-force

Characteristics	Performance	Conditions
Centrifuge speed	• Standard filler: up to 3,000 rpm • IDL filler: 550 to 2,500 rpm	
Maximum g-force in the channel	1,200 g	Device is operating at maximum speed.

Pumps

Table 18-10: Pump flow rates

Characteristics	Performance	Conditions
AC pump	Up to 12 mL/min	When a patient is connected
Inlet pump	• MNC collection procedures: Up to 125 mL/min • All other procedures: Up to 142 mL/min	
Plasma pump	• MNC collection procedures: Up to 125 mL/min • All other procedures: Up to 142 mL/min	Operator can enter a pump flow rate from within this range during the procedure.

Collect pump	• MNC collection procedures: 0.5 mL/min to 10 mL/min
	  • During accumulation phase: Up to 3 mL/min
	  • During collection phase: Up to 7 mL/min
	• CMNC procedures: 0.5 mL/min to 10 mL/min
	• PMN collection, WBCD, PLTD procedures: 0.5 mL/min to 25 mL/min
	• BMP procedures: 1 mL/min to 5 mL/min
		Operator can enter a pump flow rate from within this range during the procedure.

Replace pump	• TPE, TPE-SPD, RBCX procedures: Up to 150 mL/min • During administration of a bolus: 10 to 120 mL/min	• Normal operating conditions • Operator can enter a pump flow rate from within this range for the administration of a bolus.
Return pump	• All procedures: Up to 295 mL/min • During rinseback: 2 mL/min to 100 mL/min	• Normal operating conditions • Operator can enter a pump flow rate from within this range for rinseback.

Table 18-11: Pump volume accuracy

Characteristics	Performance	Conditions
Fluid balance accuracy	• TPE, TPE-SPD, RBCX procedures: ± 8% of commanded balance • MNC collection, CMNC, PMN collection, WBCD, PLTD procedures: ± 8% up to 2 TBV processed	• Normal operating conditions • No line restrictions • Pump accuracy can be affected by the temperature and viscosity of the fluids.
Fluid replaced accuracy	WBCD, PLTD procedures: ± 10% or 100 mL up to 2 TBV processed	• Applies if replacement fluid is administered during the procedure • Normal operating conditions • No line restrictions • Volume accuracy can be affected by the temperature and viscosity of the fluids.
Volume accuracy of all pumps	± 6% or 20 mL of displayed value, whichever is greater	• Normal operating conditions • No line restrictions • Pump accuracy can be affected by the temperature and viscosity of the fluids.

Sensors and detectors

Table 18-12: AC and replacement fluid detectors

Characteristics	Performance	Conditions
Time to alarm	Alarm is generated less than 2 seconds either after the detector senses the absence of fluid or when the line is removed from the detector after fluid is sensed.	

Table 18-13: Centrifuge pressure sensor

Characteristics	Performance	Conditions
Operating range	400 mmHg to 2,000 mmHg	
Alarm point	1,350 mmHg	Accuracy ± 10%

Table 18-14: Fluid leak detector

Characteristics	Performance	Conditions
Detection sensitivity	• Fluid leaks are detected when moisture reaches the wall or bottom of the chamber. • Detector is capable of detecting a drop of 0.5 mL of fluid in the centrifuge.	Normal operating conditions

Table 18-15: Inlet and return pressure sensors

Characteristics	Performance	Conditions
Operating range	–300 mmHg to +500 mmHg	

Table 18-15: Inlet and return pressure sensors (continued)

Characteristics	Performance	Conditions
Default alarm point	• Inlet pressure sensor: –250 mmHg ± 30 mmHg • Return pressure sensor: +400 mmHg ± 37 mmHg	
Pressure accuracy	± 6% of the sensor reading or ± 20 mmHg, whichever is greater	

Table 18-16: RBC detector

Characteristics	Performance	Conditions
RBC detection level	> 1.5% hematocrit	• TPE procedures: System automatically diverts fluid away from the remove bag when it detects RBC. • MNC collection procedures: System initiates a collection phase when it detects RBC exiting the chamber.

Table 18-17: Low-level and high-level reservoir sensors

Characteristics	Performance	Conditions
Pump stroke volume between sensors	• 49 mL ± 9 mL • Sensors detect foam as air.	Level sensor requires a load force of > 5 lb (2.3 kg) each (> 10 lb [4.5 kg] total).
Alarm occurrence	When fluid is not detected at the low-level sensor, the system stops the pumps before air enters the line.	System performs a duplicate (redundant) safety check. If condition is not resolved after a specific number of tries, operator must disconnect patient.

Table 18-18: Return line air detector

Characteristics	Performance	Conditions
Alarm occurrence	Alarm is generated if the system calculates that the patient might have more than 1 mL of air in circulation.	Normal operating conditions

Monitor and touch screen

Table 18-19: Monitor and touch screen

Characteristics	Performance	Conditions
Monitor with graphical user interface (GUI) touch screen	• Monitor holds a touch screen that provides a tactile operator interface. • Monitor has a speaker for sounding procedure and alarm tones, alarm lights, and two external dedicated buttons with icons (stop button and pause button).	Screen is touched to cause a change in resistance.
Size	Measures 26.7 cm (10.5 in) diagonally	

Table 18-19: Monitor and touch screen (continued)

Characteristics	Performance	Conditions
Screen type	• Color, liquid crystal display (LCD) • Monitor holds backlight bulbs, which a service representative can replace when necessary.	

System Software

Safety system

Table 18-20: Safety system

Characteristics	Performance	Conditions
Alarms	Audible alarm (mutable), steady red lights, flashing red lights, and an alarm screen.	• Lights flash if a safety system alarm occurs. • Lights are constant if a control system alarm occurs.
Safety	No single point of failure causes injury to the patient or the operator.	

Alarms

Table 18-21: Basic safety and performance requirements

Characteristics	Performance	Conditions
Priority assignment	Conditions causing alarms are considered low priority according to guidance provided by IEC 60601-1-8, which indicates that the operator must be made aware of the condition causing the alarm so that appropriate action can be taken.	

Table 18-22: AC infusion rate alarm

Characteristics	Performance	Conditions
Detection method	Detection cycle: 1. The return pump stops. The cycle starts. The system pumps a small amount of air into the reservoir. 2. The return pumps starts. The low-level reservoir sensor detects air. 3. The return pump stops. The cycle ends and the next cycle starts.	AC infusion rate is too high.

Table 18-23: AC pump flow rate alarms

Characteristics	Performance	Conditions
Detection method	• AC pump speed is too fast.	• AC pump speed is greater than 120 rpm. The pump stopped within two revolutions.
	• AC is flowing directly to the patient.	• AC pump flow rate is greater than the inlet pump flow rate for more than 0.4 mL net AC pumped to the patient.
	• Inlet:AC ratio is too low.	• System calculated an inlet:AC ratio that is greater than 20% below the operator-specified value for 2 mL of inlet volume.
	• Inlet:AC ratio is too high.	• System calculated inlet:AC ratio that is 20% above the operator-specified value for 10 mL of inlet volume.
Delay time	Less than 5 cycles of occlusion	

Table 18-24: Inlet:AC ratio alarms

Characteristics	Performance	Conditions
Detection method	• AC ratio is greater than 20% below the configured value.	• AC ratio is too low.
	• AC ratio is greater than 20% above the configured value.	• AC ratio is too high.
Delay time	Alarm occurs when either of the above conditions is met during the run until rinseback starts.	

Extracorporeal Volume (ECV)

Note: Under normal operating conditions, the ECV does not exceed the typical ECV shown in Table 18-25. Under certain infrequent alarm conditions, the ECV may momentarily increase to the maximum ECV unless the patient's TBV is less than 750 mL. If the patient's TBV is less than 750 mL, the ECV does not exceed the typical ECV under any condition.

Table 18-25: ECV by procedure

Procedure	Tubing Set	Filler	Typical ECV (mL)	Maximum ECV (mL)
TPE: • Dual-needle access • Single-needle access	 • Exchange • Exchange	 • Standard • Standard	 • 141 • 185	 • 185 • 185
RBCX	Exchange	Standard	141	185
TPE-SPD	Exchange	Standard	141*	185*
MNC collection	Collection	Standard	147	191
CMNC	IDL	IDL	253	297
PMN collection	IDL	IDL	253	297
WBCD	IDL	IDL	253	297
PLTD	IDL	IDL	253	297

*ECV shown does not include the volume of the secondary plasma device used during the procedure.

Tubing Set and Accessory Set Components

Note: Single-use tubing sets for the Spectra Optia system are considered applied parts because they make contact with the patient. The tubing sets comply with the Class II Type BF electrical safety requirements of IEC 60601-1.

Table 18-26: Tubing set and accessory set components

Characteristics	Performance	Conditions
Remove bag volume	6 L	Bag is a component of the Exchange Set.
Collection bag volume	940 mL	Bag is a component of the Collection Set and the IDL Set.
Plasma bag volume	• Liquid: 1,000 mL • Frozen: 600 mL	• Bag is a component of the Collection Set, the IDL Set, and the BMP Accessory Set. • Volume shown is the maximum target volume.
BMP bag volume	3 L	Bag is a component of the BMP Accessory Set.

Table 18-26: Tubing set and accessory set components (continued)

Characteristics	Performance	Conditions
Reservoir volume	• Between the high- and low-level sensors: 49 mL • Entire reservoir: 56 mL	Reservoir prevents more than 0.5 mL of air from entering the return line.
Sterile barrier filter	Collection Set and IDL Set: • 0.2 microns. • Helps to maintain a functionally closed system.	Filter is on the AC line and on the saline line.
Reservoir filter	Prevents particles (200 microns or larger) from entering the return line exiting the reservoir.	
Inlet line trap	Traps large particles.	
AC check valve	Prevents the free flow of AC through the tubing set.	
Administration line filter on BMP Accessory Set	200 microns. Can be used for additional filtration of bone marrow.	Filter is used for additional filtration of bone marrow, if desired.

RBC residual volume	• When rinseback is performed (average volume):
	  • Exchange Set: 10 mL
	  • Collection Set: 10 mL
	  • IDL Set: 17 mL
	• When rinseback is not performed: Equal to the ECV of the tubing set multiplied by the patient's Hct
		Normal operating conditions

Channel life	• Exchange Set: 6 hours • Collection Set: 8 hours • IDL Set: 8 hours	Normal operating conditions

Electromagnetic Compatibility (EMC)

The Spectra Optia system complies with either the 60601-1-2 (4th Ed.) emission limits described in Tables 18-27 through 18-29, or the 60601-1-2 (3rd Ed.) emission limits described in the Tables 18-30 through 18-35. Operators should ensure that the system is used in an environment that complies with these specifications. If you are unsure which set of EMC information applies to your Spectra Optia system, contact your Terumo BCT representative.

60601-1-2 (4th Ed.) EMC information

Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 18-27: Emissions tests 60601-1-2 (4th Ed.)

Emissions Test	Compliance	Electromagnetic Environment–Guidance
Conducted and radiated radio frequency (RF) emissions CISPR 11	Group 1	The system uses high frequencies only for internal function (e.g., computer timing signals and internal communication). The RF emissions meet the requirements of standard CISPR 11. Therefore, RF emissions are very low and are not likely to interfere with nearby electronic equipment.
Conducted and radiated RF emissions CISPR 11	Group 2 Class A	The Spectra Optia system emits RF for the Seal Safe system, so the Seal Safe can perform its intended function. The RF is only emitted when sealing tubing. Nearby electronic equipment may be affected.
Harmonic distortion IEC 61000-3-2	Class A	Not applicable
Voltage fluctuations and flicker emissions IEC 61000-3-3	Complies	

Table 18-28: Immunity tests and test levels 60601-1-2 (4th Ed.)

Immunity Test	Test Level IEC 60601
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air
Radiated RF EM fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
For proximity fields from RF wireless communications equipment IEC 61000-4-3	See immunity test levels and test frequencies in Table 18-29
Electrical fast transients/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines 100 kHz repetition frequency

Table 18-28: Immunity tests and test levels 60601-1-2 (4th Ed.) (continued)

Immunity Test	Test Level IEC 60601
Surges IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Power frequency magnetic fields IEC 61000-4-8	30 A/m
Voltage dips IEC 61000-4-11	0% U45; 0.5 cycle At phase angles 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° UT 100 V and 230 V
	0% UT; 1 cycle 70% UT; 25 cycles Single phase: at 0° UT 100 V and 230 V
Voltage interruptions IEC 61000-4-11	0% UT; 250 cycles UT 100 V and 230 V

Note: UT is the voltage of the main alternating-current power supply before use of the test level.
Electromagnetic environment–guidance for IEC 61000-4-11
If the user of the Spectra Optia system is aware of frequent power interruptions at his or her facility and requires continued operation during mains power interruptions, it is recommended that the Spectra Optia system be powered from a suitably rated uninterruptible power supply.

Table 18-29: Test specification for ENCLOSURE PORT IMMUNITY to RF wireless comm. equip. 60601-1-2 (4th Ed.)

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
870						
930						

Table 18-29: Test specification for ENCLOSURE PORT IMMUNITY to RF wireless comm. equip. 60601-1-2 (4th Ed.) (continued)

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
1.720	1.700 to 1.990	GSM 1800 CDMA 1900 GSM 1900 DECT; LTE Band 1, 2, 3, 25; UMTS	Pulse modulation b) 217 Hz	2	0.3	28
1.845						
1.970						
2.450	2.500 to 2.570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation b) 217 Hz	2	0.3	28
5.240	5.100 to 5.800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0.2	0.3	9
5.500						
5.785						

60601-1-2 (3rd Ed.) EMC information

Emissions guidance

Note: The term “emissions” refers to the effects that the system can have on other devices in its vicinity.

Table 18-30: EMC emissions guidance 60601-1-2 (3rd Ed.)

Emission Test	Compliance	Electromagnetic Environment
Radio frequency (RF) emissions CISPR 11	Group 1	System uses high frequencies only for internal function (e.g., computer timing signals and internal communication). Device meets RF emissions requirements of standard CISPR 11. Therefore, RF emissions are very low and are not likely to interfere with nearby electronic equipment.
RF emissions CISPR 11	Group 2	Seal Safe system emits RF when sealing tubing. Nearby electronic equipment not compliant with standard IEC 60601-1-2 or standard CISPR 24 may be affected.
RF emissions CISPR 11	Class A	System is suitable for use in all establishments other than residential and establishments directly connected to the public low-voltage power supply network that supplies power to buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

Note: The term “immunity” refers to the system’s ability to operate correctly in the presence of electromagnetic disturbances.

Table 18-31: Electromagnetic immunity 60601-1-2 (3rd Ed.)

Immunity Test	Test Level IEC 60601	Compliance Level	Electromagnetic Environment
Electrostatic discharge IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input and output lines	± 2 kV for power supply lines ± 1 kV for input and output lines	Quality of the main power supply should be that of a typical blood center or a hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to earth	± 1 kV line to line ± 2 kV line to earth	Quality of the main power supply should be that of a typical blood center or a hospital environment.

Table 18-31: Electromagnetic immunity 60601-1-2 (3rd Ed.) (continued)

Immunity Test	Test Level IEC 60601	Compliance Level	Electromagnetic Environment
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11		Class A	Refer to Table 18-32.
Power frequency (50/60 hertz (Hz)) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields of power frequency should be at levels characteristic of a typical location in a typical blood center or hospital environment.

Table 18-32: Voltage variations 60601-1-2 (3rd Ed.)

Immunity Test	Test Level IEC 60601-1-2	Compliance Levels		Electromagnetic Environment
		100 V	230 V	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycles < 40% UT (> 60% dip in UT) for 5 cycles < 70% UT (> 30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	< 5% UT (> 95% dip in UT) for 0.5 cycles < 70% UT (> 30% dip in UT) for 2 cycles < 85% UT (> 15% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	< 5% UT (> 95% dip in UT) for 0.5 cycles < 40% UT (> 60% dip in UT) for 5 cycles < 70% UT (> 30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 seconds	• Quality of the main power supply should be that of a typical blood center or a hospital environment. • Interruptions of the main power supply at voltages of 100 or less will cause the system to restart and the procedure to resume as permitted by IEC 61000-4-11. • If power interruptions are frequent, the use of a suitably rated uninterruptible power supply is recommended.

Note: UT is the voltage of the main alternating-current power supply before use of the test level.

Guidance and manufacturer's declaration

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 18-33: Electromagnetic immunity (table 1 of 2) 60601-1-2 (3rd Ed.)

Immunity Test	Test Level IEC 60601-1-2	Compliance Level	Electromagnetic Environment: Recommended Separation Distance
			Portable and mobile RF communications equipment should be used no closer to any part of the system, including cords, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$ For calculations based on this equation, see Table 18-35.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz For calculations based on this equation, see Table 18-35.
Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			

Table 18-34: Electromagnetic immunity (table 2 of 2) 60601-1-2 (3rd Ed.)

Immunity Test	Test Level IEC 60601-1-2	Compliance Level	Electromagnetic Environment: Recommended Separation Distance
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts, according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). For calculations based on this equation, see Table 18-35. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

[a] Field strengths from fixed transmitters—such as base stations for radio telephones (cellular and cordless) and land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts—cannot be theoretically predicted with accuracy. To assess the impact of fixed RF transmitters on the electromagnetic environment, consider performing an electromagnetic site survey. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level, the system should be observed to confirm normal operation. If abnormal performance is observed, it may be necessary to reorient or relocate the system.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The Spectra Optia system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. According to immunity test data, it is unlikely that commonly used communication devices such as cell phones or other wireless-equipped devices meeting 802.11g/n standards will adversely affect the Spectra Optia system. However, if electromagnetic interference is noticed, or higher-powered devices such as two-way radios are to be used in the vicinity of the Spectra Optia system, the user can help prevent interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Spectra Optia system. Refer to Table 18-35 for recommended separation distances according to the frequency and maximum output power specified by the manufacturer of the communications device.

Table 18-35: Recommended separation distances between portable and mobile RF communications devices and the Spectra Optia system 60601-1-2 (3rd Ed.)

Maximum Output Power Rating (W) of Transmitter	**Separation Distance (m) According to Frequency of Transmitter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Note: For transmitters rated at a maximum output power not listed in the table, the recommended separation distance d in meters can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts, according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Symbols and Certifications

The symbols shown in Table 18-36 can appear on the Spectra Optia system, as applicable.

Table 18-36: Spectra Optia system symbols and certifications

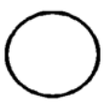
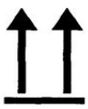
Symbol	Definition
CE 0086	Indicates that the product was manufactured in accordance with Annex II of the European Council Directive 93/42/EEC, as amended.
C SP® US	Indicates that the device is certified by CSA International in accordance with applicable U.S. and Canadian standards for conformance with the requirements of CAN/CSA-C22.2 No. 601-1-M90, CAN/CSA-C22.2 No. 1010.2.20-94, and UL 60601-1, as well as the applicable respective amendments to these standards.
	Indicates that the device is classified as Type BF per safety standard EN 60601-1. This classification is based on the degree of protection against electrical shock, as defined in that standard.
IP21	Indicates that the device is protected against access by solid objects and falling water, as defined in standard IEC 60529.
	Indicates that the device requires an alternating supply current.
	Indicates a protective conductor terminal. The symbol is located near the chassis' grounding locations.
	Indicates a protective earth ground. The symbol is located near the chassis' main grounding location and at other protective ground points.
	Indicates that the main power is turned on.
	Indicates that the main power is turned off.
	Indicates that the equipment is subject to directive 2012/19/EU concerning waste electrical and electronic equipment (WEEE) and must be disposed of accordingly.
	Indicates a non-pyrogenic fluid pathway.

Table 18-36: Spectra Optia system symbols and certifications (continued)

Symbol	Definition
	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	Indicates the medical device manufacturer.
	Indicates the date when the medical device was manufactured (or sterilization date, if the product is sterile).
	Indicates the Authorized representative in the European Community.
	Indicates the product quantity when the quantity is placed in the square.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date after which the medical device is not to be used.
	Indicates the presence of a sterile fluid path. The method of sterilization is ethylene oxide (EO).
Rx Only	Indicates that the use of the product is by prescription only.
	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Indicates that the user should consult the instructions for use.
	Indicates a medical device that needs protection from light sources.

Table 18-36: Spectra Optia system symbols and certifications (continued)

Symbol	Definition
	Indicates a medical device that needs to be protected from moisture.
	Indicates that the product packaging complies with European Directive 94/62/EC for packaging and packaging waste.
	Indicates that the product is made from high-density polyethylene.
	Indicates that the product contains phthalates, specifically Di(2-ethylhexyl) phthalate (DEHP).
	Indicates a medical device that is not to be resterilized.
	Indicates the range of temperatures to which the device can be safely exposed.
	Indicates the range of humidity to which the device can be safely exposed.
	Indicates the correct upright position of the transport package.
	Indicates that the contents of the transport package are fragile; therefore, it shall be handled with care.
	Indicates that stacking of the transport package is not allowed and no load should be placed on the transport package.

A

Supplementary Information

Formula for Calculating Total Blood Volume (TBV)

Table A-1: Formula for calculating TBV (mL) using data in metric and English units

Metric		
	Female	183 + [356 × height^3 (meters)] + [33.1 × weight (kg)]
	Male	604 + [367 × height^3 (meters)] + [32.2 × weight (kg)]
English		
	Female	183 + [0.005835 × height^3 (inches)] + [15 × weight (lb)]
	Male	604 + [0.006012 × height^3 (inches)] + [14.6 × weight (lb)]

Sources:

Allen TH, et. al., "Prediction of Blood Volume and Adiposity in Man From Body Weight and Cube of Height." *Metabolism*, 1956; 5, no. 3: 328-345.

Nadler SB, et al., "Prediction of Blood Volume in Normal Human Adults." *Surgery,* 1962; 52, no. 2: 224-232.

TPE Procedures: Plasma and Platelet Removal Efficiency

Table A-2: Plasma and platelet removal efficiency for TPE procedures using the Spectra Optia system

Measure	Result (%)
Plasma removal efficiency	87.0 (mean)
Platelet removal efficiency	1.0 (median)

Source:

Tormey CA, et al., "Improved Plasma Removal Efficiency for Therapeutic Plasma Exchange Using a New Apheresis Platform." *Transfusion,* 2010; 50: 471-477.

Exchange Procedures: Using a Blood Warmer on the Replace Line

Note: If you are performing a TPE-SPD procedure and used the system to prime the plasma device, the saline container on the replace line must contain a volume equal to or greater than the volume of the blood warmer tubing set in order to completely prime the tubing set.

1. Load the blood warmer tubing set onto the blood warmer. Be sure to leave enough tubing on each end of the set to allow connection to the replace line.
2. Clamp one end of the blood warmer tubing set.
3. Clamp both replace lines.
4. Unscrew the luer connector on the replace line.
5. Connect the female end of the luer connector on the blood warmer tubing set to the male end of the luer connector on the replace line.
6. Spike the replacement fluid container with the replace line and squeeze the drip chamber.
7. Unclamp both replace lines to prime the lines and fill the drip chamber on the second replace line.
8. Reclamp the second replace line.
9. Unclamp the blood warmer tubing set and prime the tubing set.
10. Reclamp the blood warmer tubing set.
11. Connect the male end of the luer connector on the blood warmer tubing set to the female end of the luer connector on the replace line.
12. Put the replace line into the replacement fluid detector so that the luer connector is below the fluid detector and the manifold is above the fluid detector. The luer connector must be positioned below the replacement fluid detector.

    Note: Ensure that you put the luer connector below the replacement fluid detector. If the blood warmer tubing set is not positioned below the fluid detector and the tubing fills with air during the procedure, you must disconnect the blood warmer tubing set at the luer connector and manually reprime the set. If you do not reprime the set, the vent bag could overfill with air.

13. Unclamp the blood warmer tubing set.
14. Touch **Continue**.

A

Tubing Sets: Using the Needleless Injection Ports

The needleless injection ports on the Spectra Optia system tubing sets are intended to allow you to infuse fluid or medication or to draw samples without the use of a needle. Use a syringe or extension tubing set that has a male luer connector to connect to the port.

To use the needleless injection port, perform the following steps:

1 Swab the surface of the needleless injection port according to your standard operating procedure (SOP). Let the port air-dry.

Note: Testing on the needleless injection port included swabbing the surface of the port with 70% isopropyl alcohol for 25 to 30 seconds and allowing it to air-dry for 1 minute.

2 Using aseptic technique, carefully connect the syringe or the extension tubing set to the port by pushing the syringe or other luer connector straight into the port using a clockwise, twisting motion. Do not try to connect to the port at an angle or to pry open the slit in the port. Once the connection is made, ensure that it is secure.

3 To disconnect from the port, twist the syringe or connector counterclockwise. The port completely closes after each use and therefore does not require a separate injection port cap.

4 Flush the port after each use according to your SOP.

Collection Set and IDL Set: Additional Instructions for Use

Using the Needle Protector on the Inlet Needle of the Collection Set and the IDL Set

The inlet needle on the Collection Set and the IDL Set has a needle protector to protect you from accidental injury when you remove the needle. Follow the instructions below to correctly insert and remove the inlet needle.

Inserting the inlet needle

1. Prepare the venipuncture site according to your standard operating procedure.
2. Position the needle protector away from the wings of the needle so it does not interfere with the venipuncture.
3. Grasp the wings, remove the tip protector from the needle, and perform the venipuncture.
4. Secure the needle tubing, according to your standard operating procedure.

Removing the inlet needle

1. Release the needle tubing, according to your standard operating procedure.
2. Prepare the dressing and place it over the venipuncture site, according to your standard operating procedure.
3. Ensure that the finger hook on the needle protector points up. Slide the needle protector forward into position under the wings of the needle.
4. Place the index finger of one hand inside the finger hook. While maintaining appropriate pressure on the venipuncture site, pull the tubing with the other hand so that the needle slides into the needle protector.
5. Continue pulling the tubing until you hear a “click,” indicating that the needle protector is locked in place. Once the needle is locked in the needle protector, release the finger hook while maintaining pressure on the venipuncture site.
6. Dispose of the needle, according to your standard operating procedure.

Using the Diversion Bag to Collect a Sample From a Venipuncture

To use the diversion bag on the inlet line, perform the following steps:

1. Perform the venipuncture with the inlet needle.
2. Unclamp the inlet line.
3. Unclamp the line to the diversion bag.
4. Allow the desired volume of blood to flow into the diversion bag.
5. Clamp and then seal the line to the diversion bag. You may also remove the bag.

Adding Anticoagulant to the Collection Bag

Perform the following steps to add the appropriate anticoagulant to the collection bag:

1. Clamp the line above the tubing containing the frangible connector on the accessory line of the collection bag.
2. Completely break the frangible connector by bending the tubing back and forth.
3. Using aseptic technique, remove the cap from the luer connector below the sterile barrier filter, and attach a syringe containing the desired amount of anticoagulant to the connector.
4. Unclamp the line above the frangible connector.
5. Slowly inject the anticoagulant through the sterile barrier filter into the collection bag.
6. Clamp the line above the frangible connector.
7. Remove the syringe from the luer connector.

Note: To prevent fluid from flowing from the collection bag towards the luer connector, do not remove the syringe from the luer connector before you clamp the line above the frangible connector.

8. To ensure that you delivered all of the anticoagulant in the syringe into the collection bag, perform the following steps:
   a. Attach a syringe containing at least 2.3 mL of saline to the luer connector. (The volume of the accessory line and sterile barrier filter is approximately 2.3 mL.)
   b. Unclamp the line above the frangible connector.
   c. Slowly inject the saline through the sterile barrier filter to flush the anticoagulant from the filter into the collection bag.
   d. Clamp the line above the frangible connector.
   e. Remove the syringe from the luer connector.

Using the Sample Bulbs to Obtain a Product Sample

This section contains instructions for using a sample bulb on the collection bag to obtain a product sample, and options for removing a sample from a bulb.

Obtaining a Product Sample

To obtain a product sample using the sample bulbs on the collection bag, perform the following steps:

1. Ensure that the line between the collection bag and the manifold on the sample bulb assembly is clamped.
2. Clamp one of the lines between the manifold and the sample bulb.
3. Gently mix the product in the bag to ensure that you obtain a representative sample.
4. Unclamp the line between the collection bag and the manifold on the sample bulb assembly.
5. Gently squeeze the sample bulb attached to the line that is not clamped to withdraw the desired amount of the sample.
6. To express any excess sample back into the collection bag, perform the following steps:
   a. Invert the sample bulb, and hold it above the fluid level of the collection bag.
   b. Gently squeeze the sample bulb to express the excess sample into the bag.
7. To use the residual air in the sample bulb to clear the fluid from the line between the collection bag and the sample bulb, perform the following steps:
   a. Hold the sample bulb upright and below the collection bag.
   b. Gently squeeze the sample bulb. The residual air in the bulb pushes the product from the line into the collection bag.
   c. While maintaining pressure on the sample bulb, clamp the line between the manifold and the sample bulb.
8. Before you remove the sample bulb containing the product sample, permanently seal the line between the clamp below the manifold and the sample bulb.
9. Disconnect the sample bulb at the seal on the line.

Removing a Product Sample From the Sample Bulb

Below are three options for removing a sample from a sample bulb. Select one of these options or follow your own process or standard operating procedure to remove the sample.

Option 1: Convert the sample bulb to a test tube to remove the sample

To convert the sample bulb to a test tube to remove the sample, cut off the top of the sample bulb at the dotted line on the bulb. The bulb accommodates stoppers suitable for use with 12 mm × 75 mm test tubes.

Option 2: Pour the product sample into a test tube or other container

To pour the sample into a test tube or other container, cut the line below the seal, and gently squeeze the sample bulb to express the sample into the container.

Option 3: Aspirate the sample from the sample bulb using a needle or a needleless adapter with an attached syringe

To aspirate the sample from the bulb, perform the following steps:

1. Insert a needle or a needleless adapter with an attached syringe into the sampling port.
2. Invert the sample bulb.
3. Slowly aspirate the product sample into the syringe. A small amount of product may remain in the sampling port.

4 Remove the needle or the needleless adapter from the sampling port.

5 Transfer the sample to a test tube or other container.

6 Discard the sample bulb.

Calculating the Volume of the Collected Product

To calculate the volume of the collected product after a collection procedure, divide the weight of the collected product by the specific gravity of the cells. Follow the steps below to determine the weight of the collected product and perform the calculation.

Determining the Weight of the Collected Product

Note: The scales used to weigh the collected product should be routinely calibrated before use. Tare weight should be re-established following any manufacturing change to the bag or internal procedure revision.

To determine the weight of the collected product, you must subtract the weight of the tare bag from the weight of the collection bag after the procedure is completed.

Preparing a tare bag and establishing a tare weight

1. Seal an empty collection bag at the tubing location stated in your facility's standard operating procedure (SOP). Ensure that the bag contains any tubing, label, clamp, or other component that is on the bag when a collected product is weighed at your facility.
2. Weigh the tare bag and record the weight. Ensure that all tubing, labels, clamps, and other components are on the scale when you weigh the bag.
3. Mark the tare bag with the tare weight, the date used to establish the weight, and the product for which it can be used. Retain this bag for your reference to verify that the tare weight you are using represents the current bag configuration.

Determining the weight of the collected product

Determine the weight of the collected product using one of the following methods:

Method 1:

1. Put the tare bag on the scale. Ensure that all tubing, labels and other components are also on the scale.
2. Set the weight on the scale to zero.
3. Remove the tare bag from the scale.
4. Put the collection bag containing the collected product on the scale, and weigh the bag according to your facility's SOP. The weight shown on the scale is the weight of the collected product.

Method 2:

1. Weigh the collection bag containing the collected product according to your facility's SOP.
2. Subtract the tare weight you recorded for the tare bag from the weight of the collection bag. The result is the weight of the collected product.

Calculating the Volume of the Collected Product

Terumo BCT uses 1.03 as the specific gravity for calculating the volume. To determine the volume, use the following formula:

Weight of collected product ÷ 1.03 = Volume of collected product

Printing Procedure Data Reports

The Spectra Optia system stores procedure data reports for up to one hundred procedures. Perform the steps below to connect a printer or a computer to the Spectra Optia system and to print a copy of a report.

Connecting a Printer to the Spectra Optia System

Ensure that the printer meets the following requirements before connecting it to the system:

- Printer must be network compatible. The system cannot communicate with Universal Serial Bus (USB) or parallel printers.
- Printer must be compatible with Adobe® PostScript® 3™ page description language. The system does not communicate properly with printers that are only compatible with earlier versions of the language.
- Printer must have a configurable Internet Protocol (IP) address. The address you assign to the printer must begin with 172.21 to correspond with the system's address.
- Printer must be able to use transmission control protocol (TCP) port number 9100 for Local Area Network (LAN) printing.
- Ethernet cable used to connect the printer to the system must be a crossover cable.

Note: If you are connecting the system to the printer via a network device, such as a router or a switch, use a standard Ethernet cable.

Perform the following steps to connect your Spectra Optia system to a printer:

1. Connect one end of the crossover cable to the printer and the other end of the cable to the Ethernet port on the Spectra Optia system. The Ethernet port is located on the bottom right side of the back of the system next to the connection for the power cord.
2. Configure the parameters and options on the report configuration screen to use a printer to print a copy of the report. See Table 4-3 on page 51 for descriptions of the parameters and options.
3. Touch **Test** on the connection button to verify the connection between the system and the printer.

For additional information about connecting a printer to the Spectra Optia system, contact your Terumo BCT service representative.

Connecting a Computer to the System

Ensure that the computer meets the following requirements before connecting it to the system:

- Computer must have the following applications installed:
  - File Transfer Protocol (FTP) server software
  - Software used to convert PostScript files to Portable Document Format (PDF) files
- Ethernet cable used to connect the computer to the system must be a crossover cable.

Note: If you are connecting the system to the printer via a network device, such as a router or a switch, use a standard Ethernet cable.

Perform the following steps to connect your Spectra Optia system to a computer:

1. Connect one end of the cross-over cable to the computer, and the other end of the cable to the Ethernet port on the Spectra Optia system. The Ethernet port is located on the bottom right side of the back of the system next to the connection for the power cord.
2. Configure the parameters and options on the report configuration screen to use a computer to print a copy of the report. See Table 4-3 on page 51 for descriptions of the parameters and options.
3. Touch **Test** on the connection button to verify the connection between the system and the computer.

For additional information about connecting a computer to the Spectra Optia system, contact your local Terumo BCT service representative.

Printing a Report

Perform the following steps to deliver the report to either a printer or a computer for printing:

1. Touch the **Data** menu button. The data tabs appear.
2. Touch the **Report** tab. The screen appears with a list of reports in order of the most recent procedure to the least recent procedure. The reports are identified by the procedure date, start time, procedure type, and patient's TBV. To view additional reports, touch the scroll bar.

Note: The button on the screen for the report for a procedure that was just completed is labeled **Current**.

3. Touch the button that corresponds to the report that you want to print. The report appears on the screen.
4. Touch the button at the top left side of the report to deliver a copy of the report to the device specified on the report configuration screen as follows:
   - If you selected a printer, **Print** appears on the button.
   - If you selected a computer, **Print to File** appears on the button.
   - If you did not select a device and intend only to view the report, **No Device** appears on the button.

B

Glossary of Terms

Glossary of Terms

A	Abbreviation for ampere.
AC	Abbreviation for anticoagulant.
AC infusion rate	Rate in mL/min/L TBV at which anticoagulant is infused to the patient during the run.
ACD-A	Anticoagulant used during apheresis procedures. ACD-A stands for Anticoagulant Citrate Dextrose Solution A.
Administration line	Component of the BMP Accessory Set used to transfer bone marrow from the transfer bag (BM bag) into the accessory set.
AIM	Abbreviation for automated interface management.
AIM system	Optical detection system used by the Spectra Optia system to monitor and control the position of the interface in the channel.
Albumin	Plasma protein that helps to maintain fluid balance and to control the viscosity of plasma.
Allogeneic	Describes a blood transfusion or transplantation in which the donor and the recipient are different but of the same species.
Alloimmunization	Transfusion complication whereby a recipient develops antibodies toward antigens from a donated blood product.
A/m	Abbreviation for ampere per meter.
Anticoagulant	Agent used to prevent the formation of blood clots.
Antigen	Foreign substance capable of stimulating an immune response when introduced into the body.
Apheresis	Blood component separation procedure in which whole blood is drawn from a patient or donor, and passed through a device that separates the blood into components. Particular components are either removed or collected, and the remaining components are returned.
Autologous	Describes a blood transfusion or transplantation in which the donor and the recipient are the same.
Bearing	Hard plastic component of the centrifuge loop of the tubing set that connects the loop to the centrifuge arm and to the entrance of the centrifuge loading port.
Blood component	In apheresis, the RBC, WBC, platelets, and plasma.
Blood warmer	Device used to increase the temperature of fluid or blood delivered or returned to a patient.
BM	Abbreviation for bone marrow.
BM bag	Bag containing source bone marrow before the bone marrow is transferred into the BMP bag to perform a BMP procedure.

BMP bag	Component of the BMP Accessory Set that holds the bone marrow during a BMP procedure.
BMP procedure	Apheresis procedure used to collect MNC from source bone marrow.
Bolus	Dose of fluid given to a patient intended to mitigate hypovolemia.
Bone marrow	Spongy tissue inside some bones that contains stem cells.
Buffy coat	Fraction of blood after centrifugation that contains most of the white blood cells and platelets.
Cassette	Component of the tubing set that snaps onto the front panel of the system and directs the flow of fluid through the set.
Catheter	Tube that can be inserted into a vessel to allow the flow of blood or injection of fluid.
Centrifugation	Process that uses centrifugal force to separate a mixture.
Centrifuge loop	Component of the tubing set. The group of lines that are loaded into the centrifuge.
Channel	Component of the tubing set used to separate a patient's blood into cellular components.
Chamber (Collection Set)	Component of the Collection Set used for the secondary separation of platelets and target cells.
Circulatory overload	Elevation in blood pressure caused by an increase in blood volume.
CISPR	Abbreviation for International Special Committee on Radio Interference, a subcommittee of the IEC.
Citrate	Salt or ester of citric acid that is used as an anticoagulant because it binds calcium ion.
Citrate toxicity	Condition that could occur in certain patients as a result of infusion of ACD-A during an apheresis procedure. 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.
Clotting	Result of activated platelets releasing chemicals that stimulate clotting factors, causing the blood to coagulate.
Clumping	Result of activated platelets sticking together during an apheresis procedure.
CMNC	Abbreviation for continuous mononuclear cell collection.
CMNC procedure	Apheresis procedure used to collect MNC from a patient.
Collar	Six-sided plastic component of the centrifuge loop of the tubing set that secures the end of the loop in the centrifuge.
Collect line	Component of the Collection Set and the IDL Set used to carry collected blood components to the collection bag.

Collection bag	Component of the Collection Set and the IDL Set used to hold collected blood components for collection or depletion purposes.
Connector	Component of the tubing set that secures the lines where the separated components exit the channel. It may also facilitate separation.
Custom prime	Process of filling the tubing set with specified fluid after priming the set with saline and before starting the run. Useful when treating a patient with a low RBC volume or low TBV to maintain isovolemia.
dB	Abbreviation for decibel.
Default	Setting or value that is preset by the manufacturer and used by the system in the absence of a selection made by the operator.
Diversion bag	Component of the Collection Set and the IDL Set used to capture a skin plug after performing a peripheral venipuncture or to collect a blood sample.
ECV	Abbreviation for extracorporeal volume.
Electrolyte	Mineral in blood and body fluids essential to the function of muscle action and other body processes.
Electromagnetic compatibility	Branch of electrical sciences that studies the unintentional generation, propagation, and reception of electromagnetic energy with reference to electromagnetic interference (EMI) that such energy may induce. Electromagnetic compatibility ensures that, when used as intended, electronic and electrical equipment works correctly when subjected to certain amounts of EMI and does not emit EMI that could interfere with other equipment.
EMC	Abbreviation for electromagnetic compatibility.
Erythrocyte	Term for a red blood cell.
Erythrocytapheresis	Apheresis procedure used to separate RBC from a patient's blood.
Ethylene oxide	Chemical compound that is used to sterilize medical products and devices.
EO	Abbreviation for ethylene oxide.
Extracorporeal circuit	Tubing that carries the blood when the blood is outside of the patient's body. This includes the Spectra Optia system tubing set and the tubing set of any other device connected to the set.
Extracorporeal volume	Volume of the patient's blood that is outside of the body during an apheresis procedure.
FCR	Abbreviation for fraction of cells remaining.
Four-lumen tubing	Lines that comprise the centrifuge loop of the tubing set.
Fluid shift	Change in the patient's intravascular volume during an apheresis procedure as blood is drawn, one or more components are retained, and the remaining components are returned, with or without replacement fluid.

Fraction of cells remaining	Desired percentage of starting defective RBC remaining in the patient's blood at the end of a RBC exchange procedure.
Functionally closed system	Blood collection system that uses sterile barrier filters to prevent bacteria from entering the system.
G-CSF	Abbreviation for granulocyte-colony stimulating factor.
Gear train	Component of the centrifuge chamber that consists of a series of rotating gears that keep the filler and the centrifuge arm spinning at the proper speed.
GHz	Abbreviation for gigahertz.
Graft-versus-host disease	Condition that occurs when cells from a transplanted organ or tissue attack the cells or tissue of the transplant recipient.
Granulocyte	Type of WBC.
Granulocyte-colony stimulating factor	Protein that can be given to a patient to stimulate the bone marrow to produce WBC.
GVHD	Abbreviation for graft-versus-host disease.
Hct	Abbreviation for hematocrit.
Hematoma	Localized collection of blood in an organ, space, or tissue due to a break in the wall of a blood vessel.
Hgb	Abbreviation for hemoglobin.
Hemolysis	Disruption of the RBC membrane, causing the release of hemoglobin.
Hemostat	Instrument used to compress a bleeding vessel or to stop the flow of fluid through a tube.
HES	Abbreviation for hydroxyethyl starch.
Hydroxyethyl starch	Volume expander that can be used during PMN collection procedures and WBCD procedures and that causes the RBC to form rouleaux, facilitating collection of WBC.
Hz	Abbreviation for hertz.
Inlet:AC ratio	Ratio of the inlet pump flow rate to the AC pump flow rate, expressed as parts of inlet volume to one part of anticoagulant.
Inlet access	Refers to the patient access from which whole blood is drawn.
Inlet flow rate	Speed at which blood is drawn from the patient.
Inlet line	Line on the tubing set used to carry anticoagulated blood from the patient to the channel.
Inlet pressure	Force per unit of area on the blood flow as it is drawn from the patient.
Interface	Area where the cellular components of blood meet the plasma in the connector.

IEC	Abbreviation for International Electrotechnical Commission, an international standards organization for electrical, electronic, and related technologies.
IP (Internet Protocol) address	Numerical identifier for a computer or a device on a network that enables communication among the devices on the network.
IV	Abbreviation for intravenous.
kV	Abbreviation for kilovolt.
Leukapheresis	Apheresis procedure used to separate WBC from a patient's blood.
Leukemia	Cancer of the blood-forming cells in the bone marrow.
Lymphocyte	Type of WBC.
Malaria	Disease caused by a parasite and usually transmitted through a mosquito bite, which infects the RBC.
Manifold	Component of the tubing set. A connector with multiple ports used to join a line with one or more other lines. It may also include an injection port.
Manual rinseback	Process whereby the operator, not the system, performs rinseback, in case of a power or system failure.
MHz	Abbreviation for megahertz.
mmHg	Abbreviation for millimeters of mercury.
MNC	Abbreviation for mononuclear cell or mononuclear cells.
MNC collection procedure	Apheresis procedure used to collect MNC from a patient.
Mononuclear cell	Type of WBC.
Obstruction	Object or a condition that restricts the flow of fluid through the tubing set.
Packed RBC	Preparation of RBC with most of the plasma removed.
Packing factor	Relationship between the inlet flow rate and the centrifuge speed that indicates the degree of separation of the blood components during an apheresis procedure.
Paresthesia	Tingling sensation around the mouth that is a symptom of citrate toxicity or hypocalcemia.
Patient access	Refers to the device used to gain entry to a patient's venous system.
Peripheral blood	Blood in a vein or artery.
Peripheral blood stem cell	Stem cell that circulates in the peripheral blood.
Plasma	Fluid portion of the blood that transports proteins and enzymes through the body.
Plasma bag	Bag on the tubing set that holds collected plasma. This bag is on the Collection Set and in the BMP Accessory Set.

Plasma device	Short form for secondary plasma device.
Plasma line	Line on the tubing set used to carry concurrently collected plasma to the plasma bag. This line is on the Collection Set and on the IDL Set.
Plasmapheresis	Apheresis procedure used to separate plasma from a patient's blood.
Platelet	Small cell fragment that aids in blood coagulation by helping to repair damage to walls of blood vessels.
PLTD procedure	Apheresis procedure used to collect excess platelets from a patient.
PLTD	Abbreviation for platelet depletion.
PMN	Abbreviation for granulocyte or granulocytes.
PMN collection procedure	Apheresis procedure used to collect granulocytes from a donor.
Port number	Numerical identifier used for the transmission of data between devices in a network.
Primary run target	Specific value that has been configured or entered on the run values screen and that when attained, causes the system to end the run. A black frame appears around the button of the primary run target to distinguish it from other run targets.
Prime	Process of pumping saline through the tubing set to prepare the set for the run.
Procedure	Series of steps performed to accomplish apheresis on the Spectra Optia system. A procedure starts when the procedure is selected and ends when the patient is disconnected.
Radio frequency	Frequency in which radio waves are transmitted.
RBC	Abbreviation for red blood cell or red blood cells.
RBCX	Abbreviation for red blood cell exchange.
Red blood cell	Formed element of the blood responsible for delivering oxygen from the lungs to the tissues and helping to return carbon dioxide from the tissues to the lungs.
Red blood cell depletion procedure	Type of red blood cell exchange procedure in which excess or defective RBC are removed from a patient and replaced with desired replacement fluid.
Red blood cell depletion/exchange procedure	Type of red blood cell exchange procedure that consists of a depletion procedure followed by an exchange procedure.
Red blood cell exchange procedure	Apheresis procedure used to remove defective RBC from a patient and replace them with healthy donor RBC.
Remove bag	Bag on the tubing set that holds the removed blood components. This bag is only on the Exchange Set.
Remove line	Line on the Exchange Set used to carry removed blood components from the channel to the remove bag.

Replace line	Line on the tubing set used to carry replacement fluid from the replacement fluid container to the reservoir. This line is on the Exchange Set and on the IDL Set.
Replacement fluid	Fluid given to the patient during an exchange procedure to replace the blood components removed.
Reservoir	Component of the tubing set cassette that contains the fluid to be returned to the patient.
Reservoir filter	200-micron filter located at the exit of the reservoir used to filter the fluid returned to the patient.
Return access	Refers to the patient access through which blood components and fluids are returned.
Return flow rate	Speed at which blood is returned to the patient.
Return line	Line that carries fluid from the reservoir to the patient.
Return pressure	Force per unit of area on the blood flow as it is returned to the patient.
RF	Abbreviation for radio frequency.
Rinseback	Process that clears the channel of remaining cells and returns them to the patient after the run.
rpm	Abbreviation for revolutions per minute.
Run	State during a procedure when apheresis is performed. The run starts when the patient is connected and ends when a run target is attained.
Run target	One or more values that appear on the run values screen and on the run targets screen that should be attained when the run ends. The system predicts these values based on the primary run target.
Saline	Sterile 0.9% sodium chloride and water solution used to prime the tubing set and to perform an apheresis procedure.
Saline rinse	Process that rinses the tubing set with saline before the run to clear the set of any residual ethylene oxide, a by-product of sterilization.
Secondary plasma device	Device used to treat the separated plasma before it is returned to the patient.
Sickle cell disease	Inherited blood disorder that affects the hemoglobin in RBC.
Single-needle access	Single patient access for both the inlet access and the return access.
Spillover	Condition when some RBC from the channel have entered the plasma line.
SPD	Abbreviation for the procedure on the Spectra Optia system that is performed with a secondary plasma device.
SPL	Abbreviation for sound pressure level.
Stem cell	Non-specialized cell capable of renewing itself through cell division or of being induced to become a tissue-specific or organ-specific cell.

System reset	Process that occurs when the system restarts itself after a power interruption or under certain alarm conditions.
TBV	Abbreviation for total blood volume.
Therapeutic apheresis	Apheresis procedure used to remove a pathological blood component in order to treat a patient.
TPE	Abbreviation for therapeutic plasma exchange.
TPE procedure	Apheresis procedure used to remove plasma from a patient and replace it with new plasma or a compatible replacement fluid.
Total blood volume	Entire volume of the patient's circulating blood, including the plasma and the cellular components.
Treated plasma bag	Bag that holds the treated plasma before it is returned to the patient during a TPE procedure using an SPD.
Uticaria	Temporary skin condition caused by allergic reaction and characterized by a rash and severe itching.
V	Abbreviation for volt.
V AC	Abbreviation for volts of alternating current.
Vascular access device	Type of catheter used to access to the central venous system of a patient.
Vent bag	Bag on the tubing set that holds air that has been displaced from the system.
V/m	Abbreviation for volts per meter.
W	Abbreviation for watt.
WBC	Abbreviation for white blood cell or white blood cells.
White blood cell	Cellular component of the immune system that protects all cells and tissues against foreign organisms and matter.
WBCD	Abbreviation for white blood cell depletion.
WBCD procedure	Apheresis procedure used to collect excess white blood cells from a patient.

Index

C

D

E

F

N

O

P

R

S

T

U

V

W

Y