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Before You Get Started

Indications

The PRISMA® System is indicated for continuous solute and/or fluid removal in patients with acute renal failure or fluid overload. All treatments administered via the PRISMA System must be prescribed by a physician.

Contraindications

There are no known contraindications to continuous renal replacement therapy.

System Components

The PRISMA System consists of the PRISMA® Control Unit and a disposable PRISMA® Set. (PRISMA Sets are purchased separately.)

Control Unit

Each PRISMA Control Unit is packaged with the following items:

- Column (hollow pole with flat plate attached to one end)
- Base with casters
- Installation kit
- Calibration weights (2)
- PRISMA System Operator's Manual

Set

Use only PRISMA Sets (manufactured by HOSPAL) with the PRISMA Control Unit. Two types of disposable sets may be used (check with your sales representative for availability).

- Post-dilution set (provides for addition of replacement solution after blood leaves the filter).
- Pre-dilution set (provides for addition of replacement solution before blood enters the filter).

PRISMA Sets come with an effluent bag, which may be preconnected. To facilitate priming, a prime collection bag is preconnected to each set. Additional PRISMA Effluent Bags can be purchased separately.

Where to Find Information About the PRISMA System

Operator's Manual

This manual provides installation, operating, maintenance, and troubleshooting instructions, as well as general information. See the Contents section for a complete list of topics.

On-line Instructions

Detailed operating instructions are incorporated in the software of the PRISMA Control Unit. The instructions are available *on-line,* through the interactive display. Instructions include the following screens:

- Operating screens (step-by-step instructions the operator follows *each time* in setting up, administering, and ending patient treatments).
- Alarm screens (instructions if an alarm situation occurs).
- Help screens (additional information about an Operating or Alarm screen).

PRISMA Set Instructions for Use

Instructions for use are provided with PRISMA Sets.

Warnings

1. Carefully read this *PRISMA System Operator's Manual* and the PRISMA Set *Instructions for Use* before operating this device. Before first use, ensure that the installation test has been successfully performed. See the Installation chapter for instructions on performing the installation test.
2. Operate this device only in accordance with the procedures contained in this *PRISMA System Operator's Manual*, the PRISMA Set *Instructions for Use*, and the on-line instructions. The use of operating or maintenance procedures other than those published by the manufacturer, or the use of accessory devices not recommended by the manufacturer, can result in patient injury or death.
3. The manufacturer will not be responsible for patient safety if the procedures to operate, maintain, and calibrate the PRISMA System are other than those specified in this *PRISMA System Operator's Manual*, the *PRISMA System Service Manual*, the PRISMA Set *Instructions for Use*, and the on-line instructions. Anyone who performs the procedures must be appropriately trained and qualified.
4. All electrical installations must comply with all applicable local electrical codes and the manufacturer's specifications.
5. The PRISMA Control Unit weighs approximately 23 kg (50 lb). Use at least two people to lift it out of the shipping carton. Handle the control unit carefully.
6. Use only PRISMA Sets manufactured by HOSPAL with the PRISMA Control Unit. **The use of non-PRISMA sets can result in patient injury or death.**
7. Do not connect a patient to the PRISMA System during the installation test. Be sure that the test is conducted using a container of water to substitute for the patient.
8. If a Malfunction alarm occurs during the installation test, the PRISMA Control Unit has failed the test. Do not use the control unit. Call a trained and qualified technician for service.
9. Use only prescribed dialysate and replacement solutions with the PRISMA System. In the United States, dialysate should conform to AAMI Standard RD5. If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.

10. In the United States, commercial replacement solution is available only in bags of 3 liters or less. In accordance with guidelines from the United States Food and Drug Administration, the PRISMA System has been programmed to accept only bags of 3 liter volume or less on the replacement scale. If a larger-volume bag is placed on the replacement scale, the Caution: Replacement Solution Volume alarm occurs.
11. Ensure that dialysate and replacement solutions are of appropriate composition and at appropriate temperature, as prescribed by a physician. Before using solutions, make sure they are free of precipitates and other particulate matter. **The use of incorrect solutions can result in patient injury or death.**
12. To assure proper anticoagulant flow control, **use only 20-cc BD, Braun, Monoject, or Terumo luer lock syringes.** The internal diameter of these syringes has been verified at the time of printing this manual. The manufacturer of the PRISMA System cannot be held liable for subsequent changes that may occur to syringe dimensions. See *Anticoagulant Settings* in the Specifications chapter for verified internal diameters.
13. Use only luer lock syringes with the PRISMA System. **Use of non-luer lock syringes can result in patient blood loss** if the anticoagulant line becomes dislodged from the syringe. See #12 (above) for the list of approved syringes.
14. Do not hang anything except soft plastic fluid bags from the scale hooks on the bottom of the PRISMA Control Unit. Foreign objects on the scale hooks can significantly alter fluid balance, resulting in patient injury or death.
15. Do not support the fluid bags by any means other than the provided scale hooks. Fluid balance can be significantly altered, resulting in patient injury or death. When hanging a fluid bag, always center it on the 3-hook assembly, so that its weight is evenly distributed.
16. Lock brakes on casters to limit movement of the control unit that might pull on tubing connected to the patient.
17. All blood and fluid flowpaths of the set are sterile and nonpyrogenic. Use aseptic technique when handling the blood and fluid lines in the set.

18. During priming and operation, observe closely for leakage at joints and connections within the set. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.
19. Do not allow air to enter the blood compartment of the filter after priming has started. If a large amount of air enters, the set must be replaced.
20. Do not connect a blood heater to the return line below the air bubble detector. The PRISMA System cannot detect air introduced in the line below the air detector.
21. If a patient is not connected to the PRISMA Set shortly after priming is complete, flush the set with at least 500 ml priming solution (saline with heparin added) before connecting a patient. This requires use of a new bag of priming solution and a new (empty) collection bag.
22. Ensure proper functioning of the display and software by confirming the correct sequence of the numbers on the Priming Complete screen. If the numbers displayed are not in sequential order, manually unload the set and call for service—*do not* connect a patient.
23. All lines in the PRISMA Set have a preattached slide clamp. **Clamp the following lines after priming is complete and before starting a patient treatment** (Run mode). For SCUF and CVVHD, clamp the replacement line; for SCUF and CVVH, clamp the dialysate line; for all therapies, clamp the anticoagulant line (if not in use).
24. Connect the PRISMA Set to a patient via venous blood access and return devices. A dual-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used.
25. During a patient treatment, ensure the display is operating correctly by checking the following functions:
    a. Numbers on the Set Flow Rates and Modify Anticoag screens should scroll in correct increments and in sequential order when the arrow keys are pressed. (If the increment or sequence is incorrect, terminate the treatment and call for service. See the Specifications chapter for a list of the correct increments.)
    b. A short beeping sound should be generated each time a softkey is pressed. (If a beep is not generated, terminate the treatment and call for service.)

25. Due to the nature of use of the PRISMA Set (low blood flow rate, extended treatment time, and other special factors), the possibility for coagulation within the blood flowpath is substantially enhanced. Give careful attention to the possible medical hazards associated with coagulation of the blood flowpath.
26. Closely monitor the patient's clotting parameters, especially when increasing the amount of anticoagulant delivered or after changing the anticoagulant syringe.
27. Weigh the patient daily, or as appropriate, to assure proper fluid balance. Monitor the patient's blood chemistry as often as necessary.
28. Collecting blood samples from improper sample sites in the set can lead to incorrect blood chemistry results.
29. When responding to any alarm, carefully follow the instructions on the displayed Alarm screen and its associated Help screen.
30. The blood leak detector must be re-normalized if the effluent line is repositioned or removed and then reinserted into the blood leak detector after treatment (Run mode) has started. This is done by pressing the NORMALIZE BLD softkey on the Status screen. The detector must be re-normalized before continuing a patient treatment.
31. To clear some alarms, the PRISMA Control Unit must *override* the alarm for 60 seconds. The Alarm screen on the display notifies the operator that the alarm will be overridden if the OVERRIDE softkey is pressed. A new alarm for the same condition cannot occur during the override period; therefore, *carefully observe the set and all operation during the override period.* If the alarm condition is still present after the override period, the control unit issues a new alarm.
32. The control unit may not be able to detect disconnections of the set from the patient's catheter. Carefully observe the set and all operation while using the PRISMA System for a patient treatment.
33. The PRISMA Set must be changed after 72 hours of use. Continued use beyond 72 hours could result in rupture of the pump segments, with patient injury or death.

    Note: To assure adequate filter performance, it is recommended that the PRISMA Set be changed after 24 hours of use. An Advisory alarm occurs if the set is not changed after 48 hours. The operator can reset this advisory to occur between 24 and 72 hours of operation.

34. Always inspect the blood flowpath for signs of clotting before returning the blood in the set to the patient (via the automatic RETURN BLOOD option, or the Manual Termination With Blood Return procedure). If clotting is suspected, *do not* return the blood to the patient.
35. If power is lost to the PRISMA Control Unit, the patient can be manually disconnected from the set. If performing a Manual Termination With Blood Return, visually check for air in the blood return line until the patient is disconnected.
36. If the display goes blank while power is on, immediately terminate the treatment and call for service.
37. Continuous renal replacement therapy with high-permeability hemofilters may reduce the concentration of therapeutic drugs in the patient. The prescribing physician should consult the literature of the drug manufacturer for further information and consider the need to monitor the concentration of the drug in order to assure an appropriate therapeutic dosage.
38. Use only the PRISMA RS232 Cable Kit for communicating with external equipment. All external equipment must be IEC 60950 compliant.
39. Use only GAMBRO RENAL CARE PRODUCTS or HOSPAL approved accessories.
40. Electrically isolated peristaltic pumps such as those on the PRISMA System can produce electrostatic charges in the disposable set. While these electrostatic charges are not hazardous to the patient, they may appear as an artifact on cardiac monitors. When starting a treatment with the PRISMA System, observe the cardiac monitor before and after starting the blood pump to verify that the artifact is not present.

Precautions

1. Procedures using the PRISMA System must be performed under the responsibility of a physician.
2. Federal law (USA) restricts this device to sale by or on the order of a physician.
3. If for any reason this product must be returned to the manufacturer, it is the responsibility of the health care institution to adequately prepare and identify the product for return shipment.

4. There are no operator-serviceable parts inside this device. Repairs must be performed by a trained and qualified technician.
5. Store the PRISMA Set in a dry place, between 0 °C (32 °F) and 30 °C (86 °F).
6. Prior to using the PRISMA Control Unit, let the unit rest at ambient operating temperature for 1 hour.
7. The rear handle of the PRISMA Control Unit is intended only for pushing the unit on its casters; the handle is not intended for lifting the unit.
8. The accuracy of the PRISMA Control Unit depends on accurate scale and pressure calibration. Ensure that scales and pressure sensors are accurately calibrated. Calibrations must be performed by a trained and qualified person. Calibration instructions are provided in the *PRISMA System Service Manual.*
9. Some solvents and chemicals, if used in contact with the filter, could damage the PRISMA Set. No chemical of this type should be used without permission of the manufacturer. The following are especially forbidden: (a) halogenated aromatic and aliphatic solvents; (b) ketonic solvents.
10. To prevent contamination, the PRISMA Set must be used as soon as its package and sterilization caps are removed.
11. Do not use the PRISMA Set if the package is damaged, if the sterilization caps are missing or loose, or if the blood lines are kinked.
12. Destroy the PRISMA Set after a single use, using appropriate procedures for potentially contaminated material. Do not resterilize.
13. When handling PRISMA Sets, hospital personnel should take adequate precautions at all times to prevent exposure to or transmission of HIV, hepatitis virus, or other infectious agents.
14. The PRISMA System is not designed for a heater to be connected to the replacement solution line. A heater generates air bubbles which collect in the return line pressure pod. Therefore, it is recommended **not** to use a heater on the replacement solution line.
15. If a heater is connected to the dialysate line, the PRISMA System does not automatically prime the additional tubing needed for the heater. Separate priming of this tubing is required.

16. Do not use any type of lubricant on the internal or external components of the PRISMA Control Unit or PRISMA Set. Use of lubricant can adversely affect performance of the control unit.

17. If anticoagulation of the blood flowpath is *not* desired, fill a 20-cc BD, Braun, Monoject, or Terumo luer lock syringe with *priming solution* and load it into the syringe pump during Setup mode, while the Prepare Solutions screen is on the display. This assures the anticoagulant line will be primed during the automatic priming cycle.

18. After priming is complete, *do not* remove the pressure pods from the pressure sensor housings. Pressure sensing becomes inaccurate if pods are removed, or if they are removed and then reinserted in the sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure must be performed.

19. Press only one softkey at a time. Pressing two or more softkeys simultaneously causes the PRISMA Control Unit to ignore all except the first keypress.

20. **Change fluid bags only when the appropriate Caution alarm occurs** (Replacement Bag Empty, Dialysate Bag Empty, Effluent Bag Full). Changing a bag before the alarm occurs can cause inaccurate information in treatment history.

21. During the initialization test, when the PRISMA Control Unit is first turned on, Service mode can be accessed by pressing certain softkeys simultaneously. Only trained and qualified technicians should access Service mode. If Service mode is inadvertently entered, turn the unit off, then on to return to Operating mode.

22. Use a 20-gauge (or smaller diameter) needle to obtain blood or fluid samples, to remove trapped air from the PRISMA Set, or to reposition pod diaphragms. Use of larger needles can cause holes in the sample sites, resulting in blood loss or air embolism. Use aseptic technique whenever inserting needles into sample sites.

23. When repositioning pod diaphragms, injecting or removing more than 1 cc of fluid may move the diaphragm beyond the center point of the pod. See "Diaphragm Reposition Procedure" in the Troubleshooting chapter for more information.

24. When operating the PRISMA System, avoid bumping the cartridge of the PRISMA Set. Bumping may cause the pump segments to become dislodged in the raceways of the pumps and result in loss of pump

effectiveness. If this happens, a variety of alarms will occur to alert you. These include the Caution: Effluent Weight, Caution: Replacement Weight, Caution: Dialysate Weight, Advisory: Return Pressure, and Advisory: Access Pressure alarms.

25. Hemofiltration (CVVH) with high replacement solution flow rates can result in transmembrane pressures (TMP) which may be sufficiently high to cause one of the following alarms: Warning: Filter is Clotted; Caution: TMP Excessive; Advisory: Filter is Clotting; Advisory: TMP Too High. If these alarms occur, reduce the replacement solution flow rate until the alarm no longer appears. Use of predilution sets with the largest surface area filter available will minimize occurrence of these alarms.

Symbols and Certification

If applicable, the following symbols appear on or near the serial number label or other permanently affixed labels of this device. See the Specifications chapter for more information.

1. This symbol indicates that the equipment applied part is Type BF, defibrillation-proof complying with IEC 601.1.

2. This symbol indicates that consultation of the accompanying documents prior to equipment operation is critical to the safe operation of the device.

IPX1

3. This symbol indicates that the device meets the "drip proof" classification requirements of IEC 601.1 under the applicable conditions.

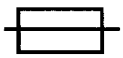
4. This symbol indicates that the device requires an alternating supply current.

5. This symbol indicates that conductors carrying high voltage are nearby and that these could be hazardous if contacted.

6. This symbol is located near functional ground locations on this device.

7. This symbol is located near protective ground locations on this device.

8. This symbol identifies the point of connection of a potential equalization conductor.



9. This symbol indicates a fuse.

10. This symbol indicates that certain components within this equipment are sensitive to electrostatic discharge.

CE
0086

11. This symbol indicates that the equipment conforms to Council Directive 93/42/EEC, of 14 June, 1993 relating to Medical Devices. Also indicates that the notified body which has approved the manufacturer's quality system is the British Standards Institution (BSI). The CE Mark affixed to the PRISMA Control Unit covers only the PRISMA Control Unit. Disposables specified for use with the PRISMA Control Unit have separate CE Marks. See Warning number 6.

Disclaimer

The manufacturer (and/or subsidiaries) accepts responsibility for the safety, reliability, and performance of this equipment only if all operational procedures, calibrations, and repairs are carried out by appropriately trained and qualified people; if all equipment modifications are authorized in writing by the manufacturer and carried out by appropriately trained and qualified people; if the electrical installation of the relevant room complies with all applicable local electrical codes and, if applicable, IEC requirements; and if the equipment is used in accordance with the published instructions for use (this document).

The manufacturer (and/or subsidiaries) will provide on request, at nominal cost, a service manual which contains all necessary circuit diagrams, component parts lists, calibration instructions, and service information to enable appropriately trained and qualified technical personnel to repair those parts of this equipment which the manufacturer considers to be repairable.

Service Information

For technical assistance, contact the appropriate address below.

United States, Central America, South America Customers

GAMBRO Technical Services, Inc.
1185 Oak Street
Lakewood, Colorado 80215-4498 USA
Phone: 800-525-2623
Phone: 303-232-6800

Mexico Customers

COBE de Mexico
Moctezuma No. 26
Col. Jose Toriello Guerra
C.P. 14050 Mexico, D.F.
Phone: 52-5-528-2595
Fax: 52-5-528-2959

Returning Used Product

If for any reason this product must be returned to the manufacturer, a returned goods authorization (RGA) number may be required from the manufacturer before shipping.

If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. (See "Routine Cleaning" in the Maintenance chapter.) It should be shipped in the original carton, or an equivalent carton, to prevent damage during shipment. The product should be properly labeled with an RGA number, if required.

Further instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number, may be obtained by contacting the manufacturer at the address below.

WARNING

It is the responsibility of the health care institution to adequately prepare and identify the product for return shipment.

The shipping address for returned goods is:

GAMBRO RENAL CARE PRODUCTS
Returned Goods Coordinator
Quality Assurance Department
1185 Oak Street
Lakewood, Colorado 80215-4498 USA
Phone: 800-525-2623
Phone: 303-232-6800

Chapter 1: Product Description

Introduction

The PRISMA System provides continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

Blood Access

All PRISMA therapies use venous blood access and return. A dual-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used.

PRISMA Control Unit Functions

The PRISMA Control Unit performs the following functions:

- Loads and primes the PRISMA Set automatically.
- Pumps blood through the blood flowpath of the set.
- Delivers anticoagulant solution into the blood flowpath.
- Controls fluid removal from the patient.
- Pumps sterile replacement solution and/or dialysate. Pumps effluent.
- Monitors the system and alerts the operator to abnormal situations through alarms.

PRISMA Therapy Options

The PRISMA Control Unit pumps venous blood from the patient, through the filter in a disposable PRISMA Set, and back to the patient's venous circulation. As the blood passes through the filter, fluid removal and/or solute clearance can take place.

Four different renal replacement and fluid management therapies are available with the PRISMA System. During the Setup procedure, the operator selects the therapy desired.

SCUF (Slow Continuous Ultrafiltration)

Objective

The sole objective of SCUF therapy is to provide fluid balance in the patient by removing plasma water (Paganini, 1986). The patient fluid removal rate may be set to balance the effects of infusions to the patient, such as parenteral nutrition or drug administration, or to correct a fluid overload condition. The patient fluid removal rate is the *net* amount of fluid that the PRISMA System removes from the patient each hour.

Fluid Removal

In SCUF, the blood pump moves the patient's blood through the PRISMA Set, from the access connection, through the filter, and back to the patient through the return connection. As the blood passes through the filter, the effluent pump operates to provide ultrafiltration, pulling plasma water from the blood and pumping it into the effluent bag.

Flow Rates

The blood pump and patient fluid removal rates are operator-settable, within the flow rate limits listed in the Specifications chapter. The effluent pump rate is controlled by PRISMA software. The software uses the operator-set flow rates to calculate the required ultrafiltration rate (UFR). The effluent pump always runs at a rate sufficient to achieve the required UFR. In SCUF therapy, the effluent pump runs at the same rate as the patient fluid removal rate.

Note: The replacement pump and the dialysate pump are *not used* for SCUF therapy and no fluid bags are used. SCUF *does not* provide control over metabolic waste products, electrolytes, or buffer in the patient's blood, other than to remove the solutes contained in the removed plasma water.

CVVH (Continuous Veno-venous Hemofiltration)

Objective

The objective of CVVH therapy is to provide fluid balance as well as to control azotemia and electrolyte balance through convection. In CVVH therapy, plasma water is removed from the patient's blood by ultrafiltration, while a sterile replacement solution is simultaneously infused into the blood flowpath to maintain intravascular fluid volume.

Because unwanted solutes are removed by taking off plasma water, increased clearances are achieved by using higher ultrafiltration rates to remove more plasma water. Compared to CVVHD therapy (hemodialysis), CVVH therapy provides less efficient removal of solutes of small molecular weight (<350 daltons), but more efficient removal of solutes of larger molecular weight (Bellomo, 1996).

Pumps

In CVVH therapy, the blood pump moves the patient's blood through the PRISMA Set, from the access connection, through the filter, and back to the patient through the return connection. As the blood passes through the filter, the effluent pump operates to provide ultrafiltration, pulling plasma water from the blood and pumping it into the effluent bag. The replacement pump operates to move replacement solution from the replacement solution bag and into the PRISMA Set. The replacement solution can be infused into the set before the blood passes through the filter (pre-dilution PRISMA Set) or after the blood leaves the filter (post-dilution PRISMA Set).

Fluid Removal

As with SCUF therapy, the operator can control the patient's fluid balance by setting the patient fluid removal rate. The patient fluid removal rate is the *net* amount of fluid that the PRISMA System removes from the patient each hour.

Flow Rates

The blood, replacement, and patient fluid removal rates are operator-settable within the limits listed in the Specifications chapter. PRISMA software calculates the required UFR and controls the effluent pump rate to achieve it.

In CVVH therapy, the required UFR is equal to the sum of the patient fluid removal rate and the replacement pump rate. Solute clearance is increased by increasing the replacement solution rate.

Note: The dialysate pump is *not* used for CVVH therapy.

Replacement Solution Composition

The composition of sterile replacement solution must be individualized for each patient by prescription of the physician, to provide correction of electrolyte and acid-base disturbances (Palevsky, 1996). Important considerations include concentrations of sodium, potassium, and cations, plus concentration and type of buffer.

The composition of the replacement solution is always tailored to the individual patient's requirements. Replacement solution is made either by the hospital pharmacy or by adding salts and buffer to a base solution of sterile saline or Ringer's solution. (When adding salts or buffer, follow the instructions given on the label of the base solution.) If a commercially prepared solution is used as a base, it must be labeled "for intravenous injection." Peritoneal dialysis solution or other commercial solutions which are not labeled for intravenous injection *must not* be used.

CVVHD (Continuous Veno-venous Hemodialysis)

Objective

The objective of this therapy is to provide fluid balance as well as to control azotemia and electrolyte balance through diffusion. Plasma water is removed from the patient's blood by ultrafiltration only to the degree required to maintain fluid balance. A dialysate solution is continuously pumped through the fluid side of the filter and the concentration gradient between the filter's blood and fluid sides causes unwanted blood solutes to diffuse into the dialysate, where they can be removed.

Pumps

In CVVHD therapy, the blood pump moves the patient's blood through the PRISMA Set, from the access connection, through the filter, and back to the patient through the return connection. The dialysate pump operates to pump fresh dialysate from the dialysate bag and into the fluid side of the filter. The effluent pump operates to pump the spent dialysate into the effluent bag and to remove plasma water from the patient's blood (if patient fluid removal is desired).

Fluid Removal

As with SCUF therapy, the operator can control the patient's fluid balance by setting the patient fluid removal rate. The patient fluid removal rate is the *net* amount of fluid that the PRISMA System removes from the patient each hour.

Flow Rates

The blood, dialysate, and patient fluid removal rates are operator-settable within the limits listed in the Specifications chapter. PRISMA software calculates the required UFR, based on the operator-set patient fluid removal rate (if any). The software controls the effluent pump rate to achieve the required UFR, as well as to pump spent dialysate.

Note: The replacement pump is *not* used for CVVHD therapy.

Dialysate Solution Composition

Dialysate solution used in CVVHD therapy must conform to the requirements of AAMI standard RD5 and its composition must be prescribed by the physician. It should have an electrolyte composition that approximates normal plasma water, as individualized to achieve the therapy goals for the patient. The dialysate solution should also have an appropriate level of buffer, such as bicarbonate or lactate, and may contain some glucose to prevent reduction of the patient's serum glucose level. Commercial dialysate preparations are available which are labeled for this application.

CVVHDF (Continuous Veno-venous Hemodiafiltration)

Objective

The objective of this therapy is to provide fluid and electrolyte balance, as well as to control azotemia through both convection *and* diffusion. This is accomplished by running CVVH therapy and CVVHD therapy concurrently. (See explanations of CVVH and CVVHD therapies in this chapter.)

Pumps

In CVVHDF therapy, the blood pump moves the patient's blood through the PRISMA Set, from the access connection, through the filter, and back to the patient through the return connection. As the blood passes through the filter, the effluent pump operates to provide ultrafiltration, pulling plasma water from the blood, as well as to pump ultrafiltrate and spent dialysate out of the fluid side of the filter and into the effluent bag. The replacement pump

operates to move replacement solution from the replacement solution bag and into the PRISMA Set. The dialysate pump operates to continuously pump fresh dialysate from the dialysate bag and into the fluid side of the filter.

Fluid Removal

As with SCUF therapy, the operator can control the patient's fluid balance by setting the patient fluid removal rate. The patient fluid removal rate is the *net* amount of fluid that the PRISMA System removes from the patient each hour.

Flow Rates

The blood, replacement, dialysate, and patient fluid removal rates are operator-settable within the limits listed in the Specifications chapter. PRISMA software calculates the required UFR and controls the effluent pump rate to achieve it.

In CVVHDF therapy, the required UFR is equal to the sum of the patient fluid removal rate, the replacement pump rate, and the dialysate pump rate. Solute clearance by convection is increased by increasing the replacement solution rate.

Replacement Solution Composition

The composition of sterile replacement solution must be individualized for each patient by prescription of the physician, to provide correction of electrolyte and acid-base disturbances (Palevsky, 1996). Important considerations include concentrations of sodium, potassium, and cations, plus concentration and type of buffer.

The composition of the replacement solution is always tailored to the individual patient's requirements. Replacement solution is made either by the hospital pharmacy or by adding salts and buffer to a base solution of sterile saline or Ringer's solution. (When adding salts or buffer, follow the instructions given on the label of the base solution.) If a commercially prepared solution is used as a base, it must be labeled "for intravenous injection." Peritoneal dialysis solution or other commercial solutions which are not labeled for intravenous injection *must not* be used.

Dialysate Solution Composition

Dialysate solution must conform to the requirements of AAMI standard RD5 and its composition must be prescribed by the physician. It should have an electrolyte composition that approximates normal plasma water, as

individualized to achieve the therapy goals for the patient. The dialysate solution should also have an appropriate level of buffer, such as bicarbonate or lactate, and may contain some glucose to prevent reduction of the patient's serum glucose level. Commercial dialysate preparations are available which are labeled for this application.

WARNING

Use only prescribed dialysate and replacement solutions with the PRISMA System. In the United States, dialysate should conform to AAMI Standard RD5. If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.

Therapy References:

Paganini E. Continuous Replacement Modalities in Acute Renal Dysfunction. *Acute Continuous Renal Replacement Therapy.* Martinus Nijhoff Publishing, 1986.

Bellomo R. Choosing a Therapeutic Modality: Hemofiltration vs. Hemodialysis vs. Hemodiafiltration. *Seminars in Dialysis* 1996; 9(2) (Mar-Apr):88-92.

Palevsky P. Continuous Renal Replacement Therapy Component Selection: Replacement Fluid and Dialysis Solutions. *Seminars in Dialysis* 1996; 9(2) (Mar-Apr):107-11.

PRISMA Control Unit

Figure 1 shows the PRISMA Control Unit. Following is a description of the components on the panels.

Front Panel

Status Lights — Illuminate to give general indication of operating conditions.

Green — Indicates all monitored parameters are normal during administration of the treatment (Run mode).

Yellow — Indicates a Caution or Advisory alarm has occurred, or an alarm has been overridden. Immediate patient safety is not compromised, but the operator should investigate. **Note:** Yellow light also illuminates when the control unit is in Setup, Standby, End, and Custom modes. In these cases, it indicates that all monitored parameters are normal, but a patient treatment is not in progress.

Red — Indicates a Warning or Malfunction alarm has occurred because of a condition of possible patient hazard. Immediate operator intervention is required.

Display — Shows text and softkeys. Provides operating, alarm, and help instructions. A touchscreen overlay provides "active" areas for softkeys. Pressing the softkeys allows the operator to change settings and navigate between screens.

Pressure Sensor Housings — Housings that hold the four pressure pods of the PRISMA Set. A pressure sensor is located behind each housing. The sensors and pressure pods enable noninvasive pressure monitoring of the access line, filter, return line, and effluent line. There are no air-blood interfaces.

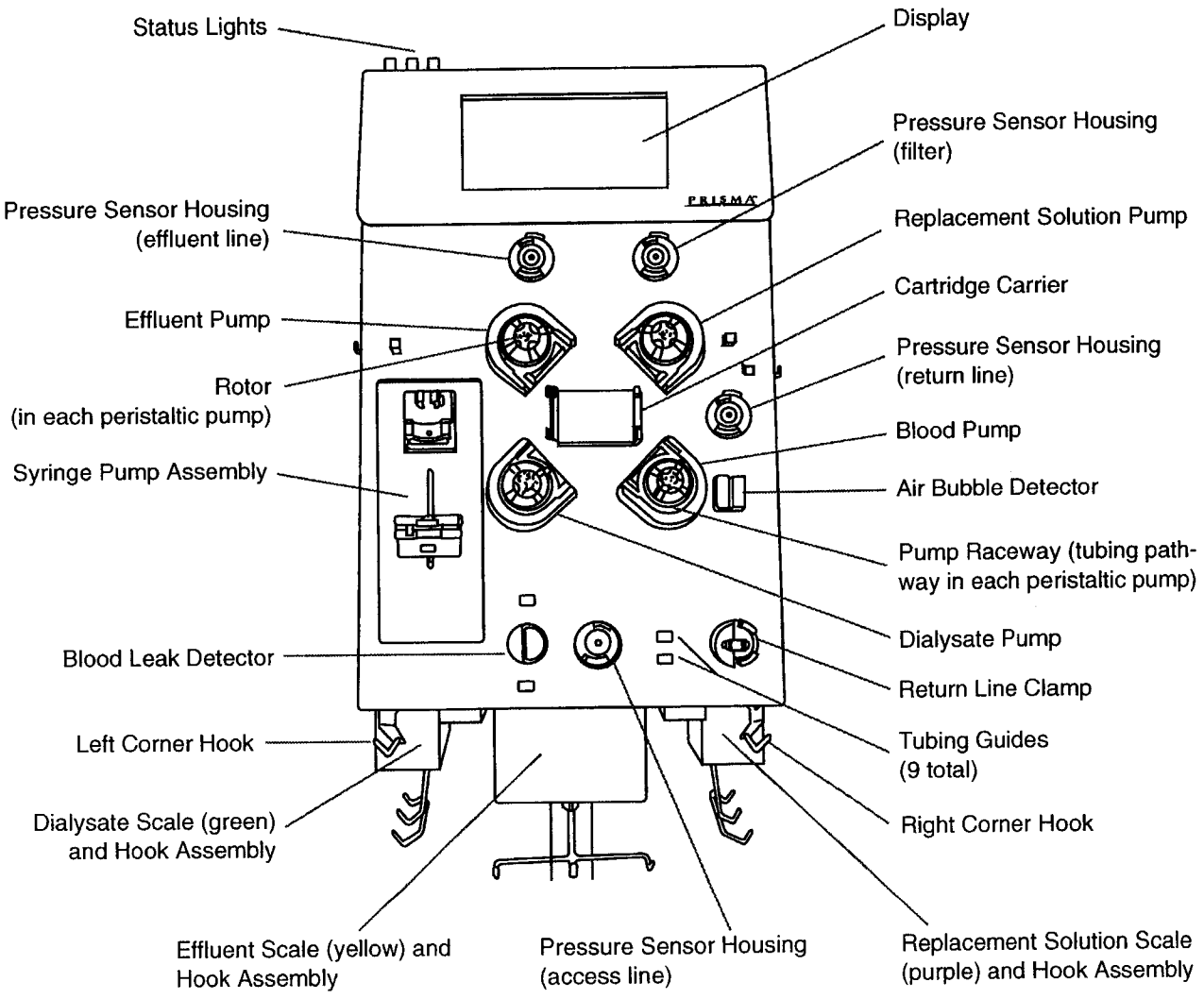


Figure 1. PRISMA Control Unit

Replacement Solution Pump	Pumps replacement solution into the blood flowpath. Depending on the set used, replacement is delivered pre-dilution (before blood enters the filter) or post-dilution (after blood leaves the filter). This pump is an occlusive, peristaltic pump.
Cartridge Carrier	Accepts the cartridge of the PRISMA Set; enables automatic loading of the set.
Blood Pump	Pumps blood through the blood flowpath of the set. This pump is an occlusive, peristaltic pump.
Air Bubble Detector	Continuously monitors the return line for air bubbles. A Warning alarm occurs if a macro bubble is detected, or if the number of micro bubbles exceeds the warning limit.
Pump Raceway	Tubing pathway within each peristaltic pump. The raceways accept the pump segments of the PRISMA Set.
Dialysate Pump	Pumps fresh dialysate solution into the fluid compartment of the filter. This pump is an occlusive, peristaltic pump.
Return Line Clamp	Occlusive clamp that closes during all Warning and Malfunction alarms, when power is off, and during some self-tests. Prevents blood and/or air from passing to the patient.
Tubing Guides	Hold the lines of the PRISMA Set in correct position on the control unit.
Corner Hooks	*Right hook* holds the priming solution bag during priming. *Left hook* holds the prime collection bag during priming and holds the sterile saline bag during blood return.
Blood Leak Detector	Continuously monitors the effluent line for the presence of red blood cells, indicating a leak in the filter membrane. A Warning alarm occurs if red blood cells are detected.

Syringe Pump Assembly Holds the anticoagulant syringe and controls the rate of anticoagulant delivery into the blood flowpath. Anticoagulant can be delivered continuously or in boluses.

Rotor Center component of each peristaltic pump that rotates during pump operation. Holds two rollers that occlude the pump segment in the raceway. Occlusion moves the fluid in the pump segment forward in discrete amounts and prevents backflow.

Effluent Pump Pumps ultrafiltrate and/or dialysate from the fluid compartment of the filter into the effluent bag. Automatically controls the ultrafiltration rate based on the operator-set patient fluid removal rate and replacement solution rate (if applicable). This pump is an occlusive, peristaltic pump.

Bottom Panel

Scales Independently monitor fluid bag weights. Weight information is used by PRISMA software to precisely control ultrafiltration and patient fluid removal. A Caution alarm sounds when the dialysate and replacement solution bags are nearly empty, or when the effluent bag is nearly full. The scales are color-coded: dialysate is green; replacement is purple; effluent is yellow.

Scale Hook Assemblies Three hooks on each scale that hold needed fluid bags. The following bag volumes are allowed: dialysate and effluent scales, up to 5-L; replacement scale, up to 3-L.

Right Side Panel

Power Switch Turns power on and off to the machine. The label "I" means ON and the label "O" means OFF.

Left Side Panel

Fan — Provides continuous ventilation for the interior components of the control unit.

Rear Panel

A serial communication port (P1) and an hour meter are located on the rear panel. Access to the interior of the control unit is gained through the rear panel. Inside the control unit are circuit card assemblies (CCAs) and other electronic and mechanical components. Only trained and qualified service technicians should repair the interior components. To open the rear panel, loosen the two screws located along the right-rear side of the PRISMA Control Unit.

Figure 2 shows the interior components of the PRISMA Control Unit. For complete descriptions of the electronic components, see the *PRISMA Service Manual.*

Controller CCA — The Controller CCA receives input signals from the display/touchscreen, the scales, and the Monitor CCA. See "Controller CCA" on page 19.

Monitor CCA — See "Monitor CCA" on page 18.

Detector CCA — Signals from the air bubble and blood leak detection systems are sent to the Detector CCA. See "Detector CCA" on page 19.

Hour Meter — Located on the outside of the rear panel, the electronic hour meter displays the time that the machine's power has been on.

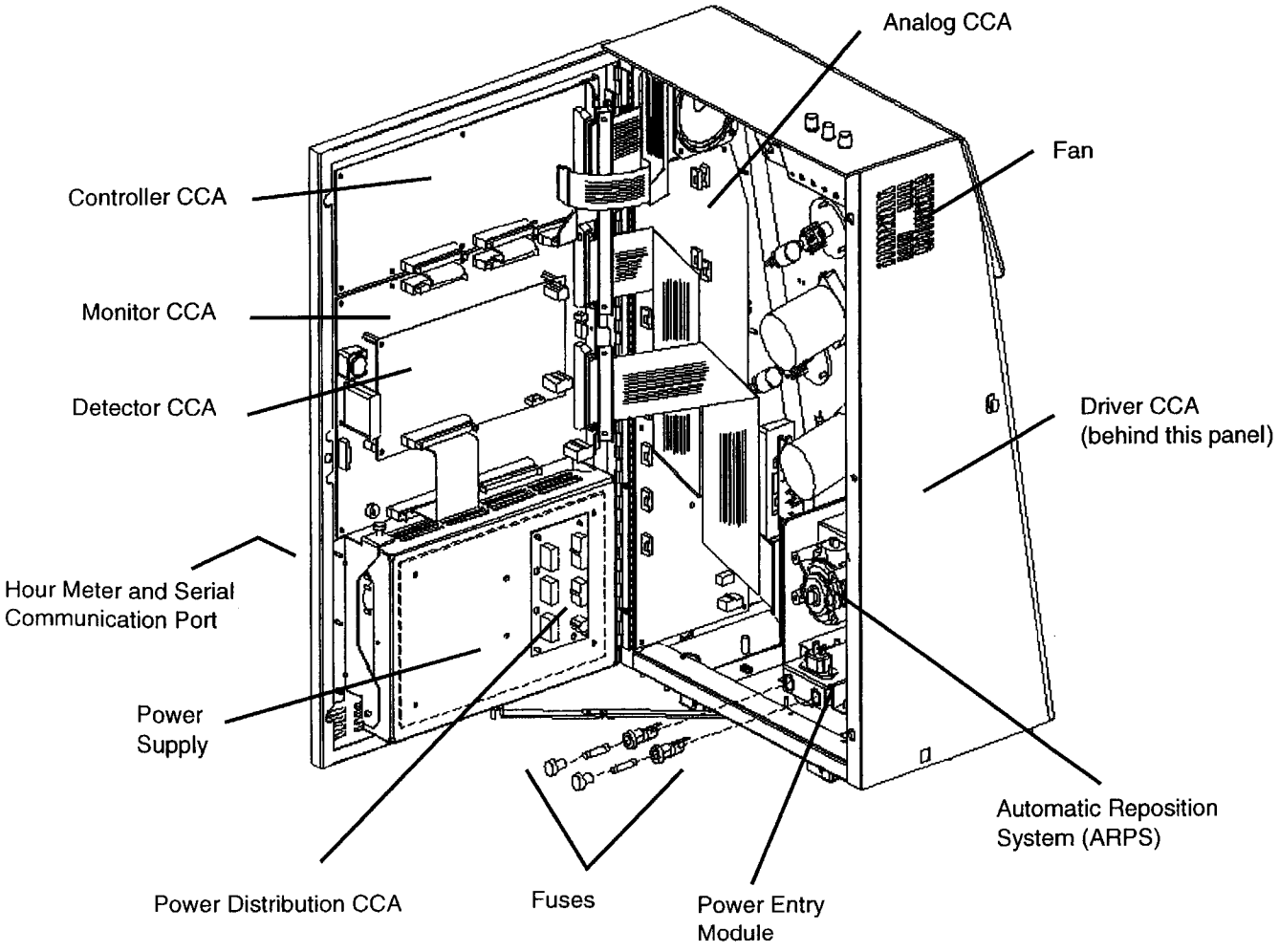


Figure 2. PRISMA Rear Panel View

Serial Communication Port	The serial communication port is located on the outside of the rear panel. This port is used as an RS232 link between the PRISMA System and equipment that conforms with IEC 60950.
Power Supply	DC power for the PRISMA Control Unit is generated in the universal input power supply. The power supply accepts standard line voltages of 110, 220, and 240 Vac without special wiring or hardware configurations.
Power Distribution CCA	The Power Distribution CCA is the central point for power cables that distribute power to PRISMA CCAs. See "Power System" on page 17.
Fuses	Standard AGC fuses provide electrical protection for the PRISMA Control Unit in the event of excessive current drain.
Power Entry Module	The power entry module connects the electrical power cord to the PRISMA Control Unit power supply.
Automatic Reposition System (ARPS)	The automatic reposition system is used to ensure proper pressure monitoring. See "Automatic Reposition System (ARPS)" on page 21.
Driver CCA	The Driver CCA contains circuitry to decode signals and power the pump motors, the return line clamp solenoid, and the alarm lamp drivers. See "Driver CCA" on page 23.
Analog CCA	Analog signals from the scales and the pressure monitors are received by the Analog CCA. The CCA converts the analog signals to digital signals and sends the digital information to the various CCAs in the PRISMA Control Unit. (See "Analog CCA" on page 23.)

Electronic Description

Figure 3 shows the block diagram of the PRISMA Control Unit. The control unit contains seven circuit card assemblies (CCAs), a power supply, display and touchscreen, pump motors, return line clamp, pressure sensors, an automatic pressure diaphragm repositioning system (ARPS), weight scale assemblies, an air bubble detector (UABD), and a blood leak detector (BLD). The seven CCAs that provide a path for these functions are the Power Distribution CCA, Monitor CCA, Controller CCA, Detector CCA, Automatic Reposition CCA (ARPS), Driver CCA, and the Analog CCA. A detailed description of the electronic system is given in the *PRISMA Service Manual*

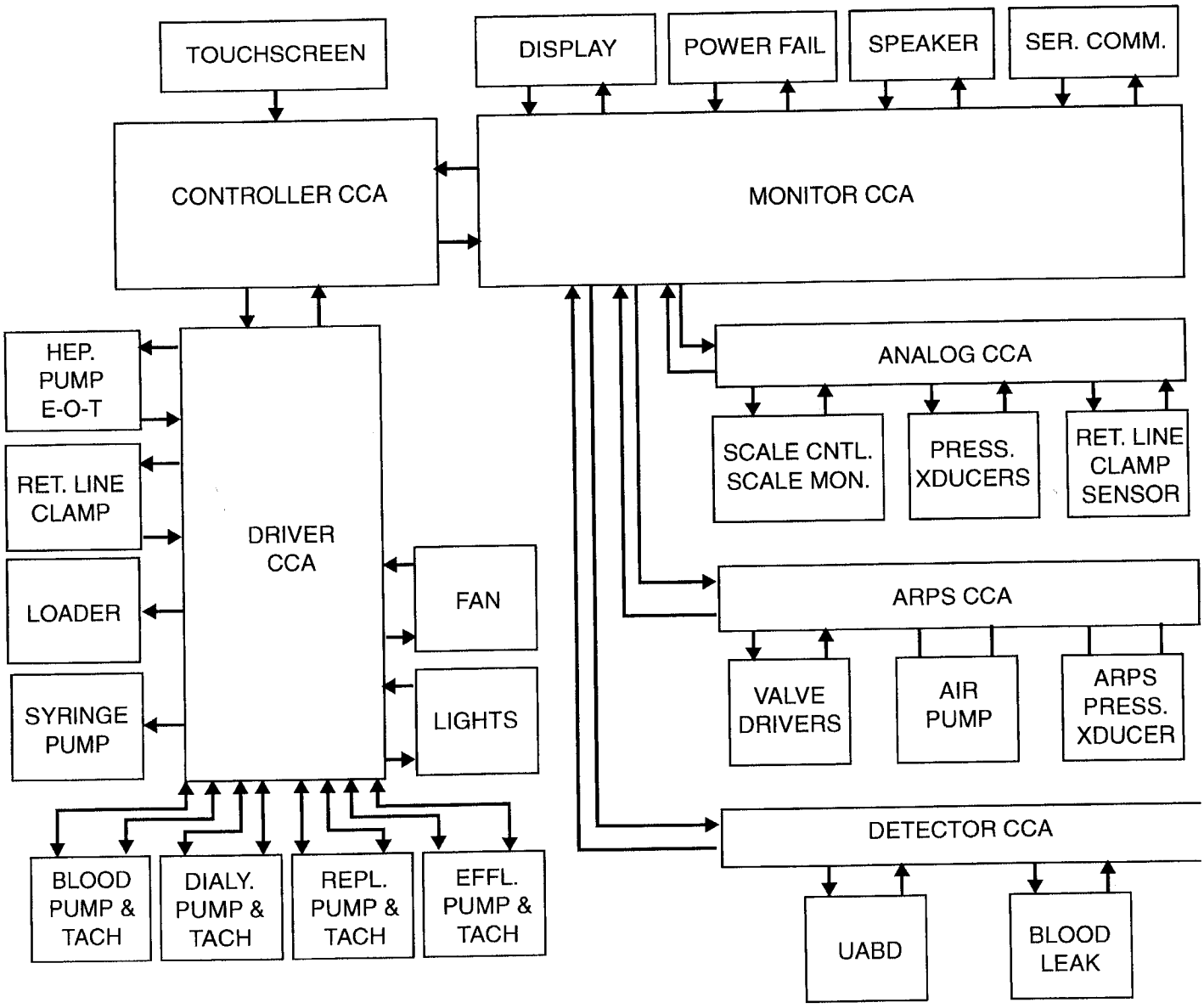


Figure 3. PRISMA Block Diagram

Power System

Figure 4 shows the block diagram of the PRISMA power system. The control unit contains a universal-input switching power supply which allows any standard ac line voltage (115 Vac, 220 Vac, 240 Vac) to be directly connected without special wiring or hardware configurations. The power supply uses pulse-width modulation to control the amount of power provided from the primary side of the input transformer. Both ac voltage input lines are equipped with replaceable 5 amp fuses which are located in the power entry module, before the power switch.

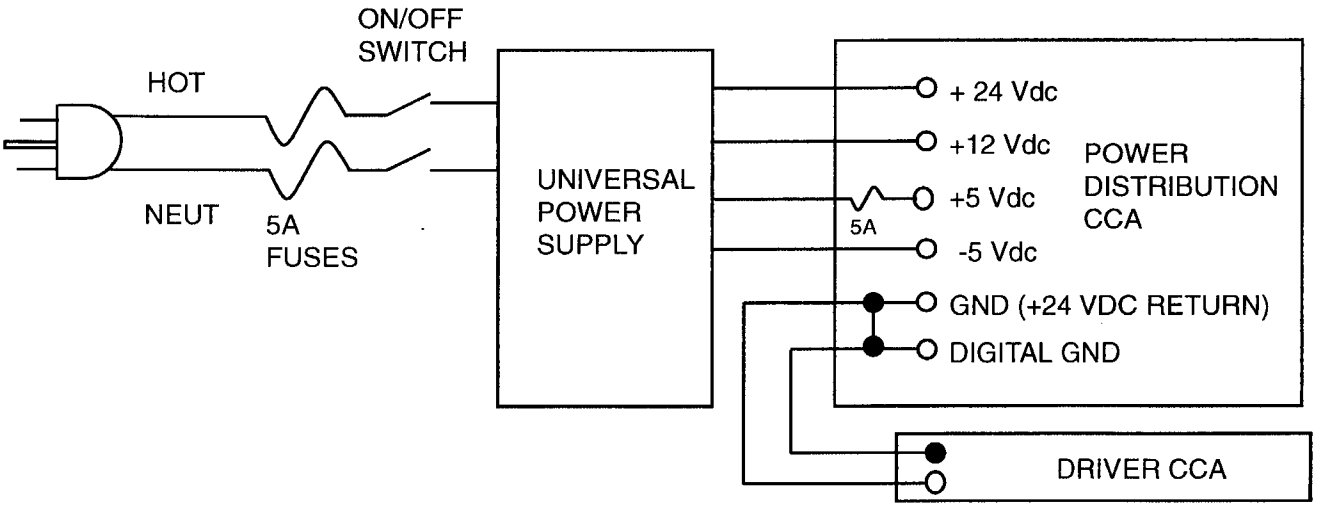


Figure 4. PRISMA Power System Block Diagram

The power supply provides regulated outputs of +24, +12, + 5 and -5 Vdc, with test points (on the Power Distribution CCA) for measuring each voltage. A secondary fuse for the +5 Vdc is located on the Power Distribution CCA. Two separate lines supply ground references for the digital and +24 Vdc sources. Note that both grounds are connected together on the Power Distribution CCA.

Table 1. Power Supply Voltages

Voltage	Tolerance	Where Used
+24 Vdc	±0.96 Vdc	Pump motors, return line clamp, display, status lights
+5 Vdc	±0.15 Vdc	Digital logic, operational amplifiers
+12 Vdc, -5 Vdc	±0.48 Vdc	Op amps, A/D converters, air bubble detector (UABD), scales, pressures, cooling fan (the fan uses +12 Vdc only)

Monitor CCA

The Monitor CCA contains:

- The display driver and audible alarm
- An RS232 serial port
- A watch dog monitoring circuit
- A power-fail circuit
- The language EPROMs or FLASH devices

The Monitor CCA also:

- Monitors the status of most systems and CCAs
- Disables certain features during alarm conditions

Display

The PRISMA front panel has a 512 x 256 pixel electroluminescent display. The display uses two voltages; +5 Vdc for the display driver logic circuits and +24 Vdc to power the display itself. The display uses software-driven video commands from the Monitor CCA to create screen images.

Speaker

The speaker produces a high-frequency tone when a touchscreen key is pressed or a low-frequency tone when an alarm condition is indicated.

Serial Port (RS232)

An optically isolated RS232 serial port is provided to interface with equipment that conforms with IEC 60950 (processing equipment standard).

Controller CCA

The Controller CCA contains:

- Dual-ported RAM for communications with the Monitor microprocessor
- Softkey input circuitry
- A watch dog circuit for the controller microprocessor

The Controller CCA also:

- Sends the proper control signals to the Driver CCA to control the pumps, loader, syringe pump, and return line clamp.
- Works with the Monitor CCA to maintain the system status.
- Generates signals for the audible and visual alarms.
- Uses feedback from the scales for pump speed control during the different therapies and flow rates.

Detector CCA

The Detector CCA contains circuitry for:

- The ultrasonic air bubble detector
- The blood leak detector

Ultrasonic Air Bubble Detector (UABD)

The PRISMA System uses an ultrasonic air bubble detector to monitor for air bubbles in the return line during a patient treatment. The detector assembly consists of two piezoelectric ultrasonic transducers (a transmitter and a receiver) which surround a portion of the return line when the PRISMA Set is placed in the machine. When an air bubble passes through the detection area, some of the ultrasound is absorbed by the air bubble which causes a reduction in the level of sound detected by the receiver. If a large bubble passes through the detector, or, if a sufficient number of micro bubbles pass through the detector during a specified time, the Air in Blood alarm occurs which shuts down the blood pump and closes the return line clamp.

Under normal circumstances (no bubbles present) the comparators all receive the same 2.5 Vdc signal. However, when a bubble passes through the detector, the voltage drops below 2.5 Vdc. Bubbles with a diameter of about 0.58 mm cause the voltage to drop to about 2.2 Vdc for a designated time period and create a Micro Air in Blood alarm. Bubbles larger than 3 mm cause the voltage to drop below 1.5 Vdc and create an Air in Blood alarm.

To ensure safety, two separate but identical comparator sections are used. One section sends signals to the Monitor microprocessor and the other sends signals to the controller microprocessor. Should a component failure occur in one (monitor or controller) section, the other (monitor or control) section will still operate properly. However since both sections operate in an identical manner, any disagreement between the two sections is detected by both microprocessors and an Air in Blood alarm would occur.

Blood Leak Detector (BLD)

The non-invasive blood leak detector (BLD) monitors the effluent line for blood passing through the blood filter. Unlike chronic dialysis machines where the effluent goes down the drain, the PRISMA System collects the effluent in the effluent bag. Low concentrations of blood in the effluent bag may cause the contents of the bag to appear red or pink, even though the leak may not be enough to activate the alarm.

Figure 5 shows the components that make up the BLD. The BLD consists of a detector housing, an infrared LED, a phototransistor and two mirrors. The LED and phototransistor are held in the housing at an angle such that the light beam passes through the tubing four times before being detected by the phototransistor.

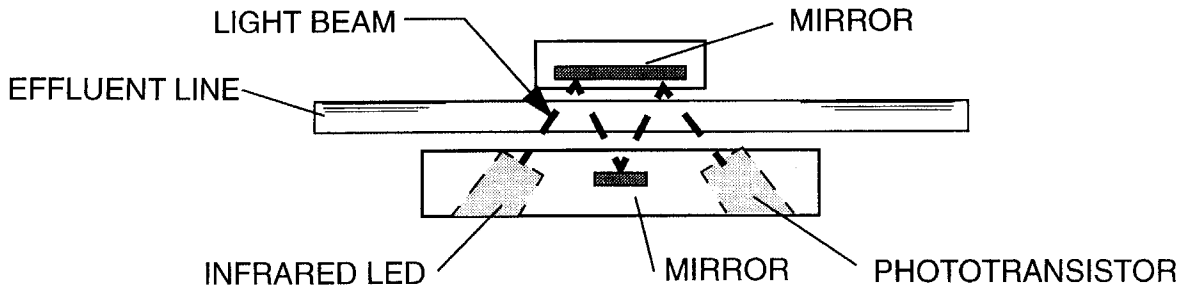


Figure 5. Blood Leak Detector Assembly

Normalization

The blood leak detector is automatically calibrated by the PRISMA Control Unit near the end of the priming sequence when the effluent line is full of saline. The infrared LED drive signal is adjusted so the received A/D signal range is 167 to 184. From this point the upper and lower limit range can detect when blood is present or when the tubing is not installed.

Automatic Reposition System (ARPS)

The automatic repositioning system (ARPS) is used to ensure proper pressure monitoring. During each periodic self-test and prime self-test, the pressure pod diaphragms in the blood circuit are automatically repositioned using the ARPS system. Figure 6 gives the functional block diagram of the ARPS.

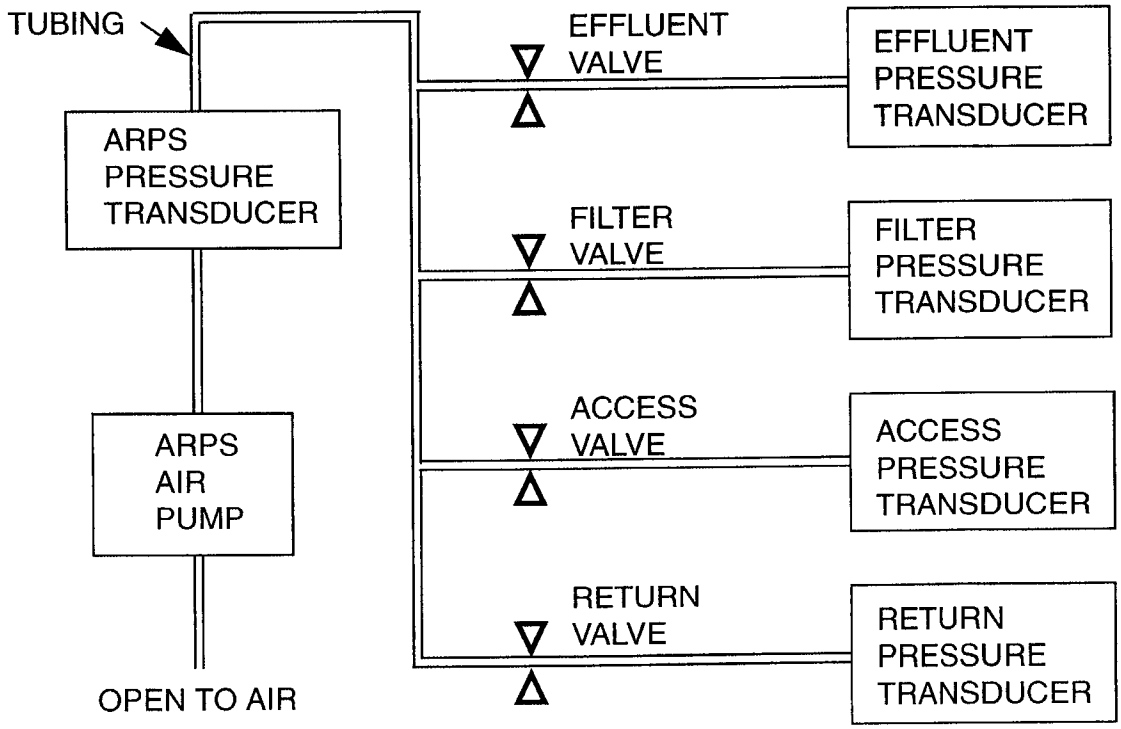


Figure 6. ARPS Functional Block Diagram

Components

The ARPS system contains the following components:

- The ARPS CCA, with air pump motor drivers, A/D converter, PAL decoders, and valve drivers
- The air pump motor
- The ARPS pressure sensor
- Four valves

Note: There are no alarms generated that specify a failure in the ARPS. If a failure occurs, it is detected during one of the self-tests, and a Self-test malfunction alarm occurs.

Reposition Sequence

The ARPS system sequentially repositions each diaphragm in the following order: effluent, return, filter, access. The ARPS air pump pressurizes the tubing on the air pump-side of each valve until the pressure is equal on both sides of the valve. For example, if the pressure at the return valve is 200 mmHg, the air pump pressurizes the other side of the return valve to 200 mmHg. Once pressurized, the valve opens and the air pump then injects additional air until the pressure at the sensor rises by 50 mmHg and remains above that level for 2 seconds, indicating the end of the pressure diaphragm travel. When the end of the diaphragm travel is determined, the air pump removes approximately 1 cc of air and at that point, the diaphragm will be in its neutral position. The system then automatically performs a pressure verification to ensure that the post-reposition pressure is within 50 mmHg of the pre-reposition pressure. If the pressure is outside of this range a Malfunction: Self-test Failure alarm is generated. The sequence is different for pressure pods that normally read negative pressure than for the pods that normally read positive pressures.

Note: Only one pressure pod is tested at a time. When one of the pods has been repositioned, the system test proceeds to the next pressure pod. This cycle continues until all pods have been repositioned.

Driver CCA

The Driver CCA contains circuits for:

- Peristaltic pumps
- Return line clamp
- Syringe pump
- Cartridge loader
- Lights and fan

Peristaltic Pumps

The four peristaltic pumps in the PRISMA Control Unit are driven by step-type dc motors that are capable of continuous operation between 0 and 220 rpm.

The motor speed is determined by the square wave CLK signal frequency which is generated by the Controller CCA, which is sent to the motor through the Driver CCA. The greater the frequency of the CLK signal, the greater the pump motor rpm.

A Hall effect sensor mounted on the pump generates one pulse for each revolution of the pump. The signal passes through a ribbon cable to the Driver CCA where it is conditioned with a Schmidt trigger and capacitor. The conditioned Hall effect signal is then sent to the Monitor CCA through a 50-pin ribbon cable.

Return Line Clamp

The return line clamp is used to isolate the patient from the blood circuit in the event of certain alarm conditions. The line clamping piston is spring loaded so that it is normally closed and the line clamp solenoid must be energized for the clamping piston to be in the open position. The clamp solenoid is controlled by cycling the input to the FET.

Analog CCA

The Analog CCA contains circuitry for:

- Pressure monitoring
- Scales
- Biasing circuitry for the return line clamp position sensor

Pressure Sensors

The PRISMA System uses COBE CDX III pressure sensors to monitor:

- Filter pressure (–50 to +500 mmHg)
- Access pressure (+50 to –250 mmHg)
- Return pressure (–50 to +350 mmHg)
- Effluent pressure (–350 to +50 mmHg)
- Reposition pressure: (–250 to +250 mmHg)

Note: The reposition pressure sensor circuitry is in the ARPS CCA.

The Analog CCA uses four identical circuits to drive and condition the four separate pressure sensor signals. The CDX III pressure sensor transducer is a semiconductor strain gauge bridge that responds to pressure changes. As the pressure applied to the pressure sensor changes, the bridge becomes unbalanced and produces a voltage difference between the output terminals.

Scale Assemblies

Each of the PRISMA scale assemblies consists of six linear springs and two LVDT (linear variable differential transformer) sensors to convert weight into an electrical signal. In each scale assembly, one LVDT provides input for the control functions and another LVDT provides input for the monitor functions. Scales are necessary to measure dialysate and replacement solutions and effluent fluids.5

Return Line Clamp Position Sensor

The return clamp position sensor is located on the return line clamp. An LED transmitter and a phototransistor receiver are used to monitor the position of the clamp.

Software Description

The PRISMA software revision R02.13 routines described in this chapter are Power Up, Periodic Self-test, Prime and Prime Self-test, Fluid Balance Calculations, Alarms, and Service Mode, which consists of the Calibrate and Diagnose modes.

Power Up

To ensure that the basic functions of the microprocessors and memory are operating properly, the PRISMA Control Unit performs the following checks when the power is turned on.

- Processor Flag Check. The processor verifies that all condition flags can be set. If this test fails, the watch dog expires and the machine will reset.
- Calculation of CRCs (Cyclical Redundancy Check). The calculations must match the CRCs stored in ROM. If the calculations are correct, the ROM is not corrupted. If this test fails, the watch dog expires and the machine will reset.
- Write-to and read-from RAM. Whatever is read from the RAM must match what is written. If this test fails a Malfunction: RAM R/W alarm occurs.
- Check Battery-Backed RAM checksums. Generate a Malfunction: BB Memory Failure alarm if any of the following three conditions occur: three consecutive checksums or range check test failures occur for a specific structure; the calibration value and the shadow calibration structure and range check test fails; two or more structures fail on the first, second, or third attempts.
- Verify communication between microprocessors. Both control and monitor microprocessors write-to and read-from the dual-ported RAM. If no errors occur, the microprocessors are considered operational else the machine will reset.
- Access a decision tree to determine where to start, i.e., how was the machine turned off; does the Query screen need to be displayed; was this a power failure and what was the duration; does an alarm screen need to be displayed?
- Parity Test. The parity interrupt vector is modified to point to the test conclusion location. The parity error test signal is activated and a RAM location is accessed. An interrupt will result in successful completion of the test, while no interrupt will result in a watch dog expiration (i.e., the machine resets and a Malfunction: Parity Error alarm occurs).

Periodic Self-test

After the START softkey has been pressed and a treatment has started, a periodic self-test starts every two hours. The test checks the operation of the air bubble detector and the integrity of the blood circuit. The self-test begins 10 minutes[1] after the treatment starts and then occurs every two hours afterwards. If any test failure occurs during the self-test, the Malfunction: Self Test Failure alarm occurs.

The Controller portion of the self-test checks the air bubble detector at the start of the self-test and then sends the proper state variable to the Monitor processor (via dual-ported RAM) to initiate the Monitor portion of the self-test. These tests include the air bubble detector tests, bubble fault test, 24 volt test, microbubble test, blood leak detector test, and the pressure sensor test.

Monitor Tests

Bubble Detector Test
The return line clamp closes and the macro bubble test signal runs for 600 msec (by the controller processor). A macro bubble signal must be received by both processors. The return line clamp opens after the macro bubble test signal is cleared.

Bubble Fault Test
When the macro bubble test signal stops, the fault line should start momentarily and be detected by the system.

24 Volt Test
The Monitor initiates the 24 volt switch for 500 milliseconds. A 24 volt feedback signal (indicating initiation of the switch) must be received to complete the self-test.

Microbubble Test
The monitor processor starts the microbubble with 16 500-millisecond pulses. The microbubble detection routine must detect a sufficient number of bubbles to successfully pass the test.

1. If another alarm occurs at the scheduled start of a self-test, the self-test may be delayed up to 5 minutes.

Blood Leak Detector Test
The BLD test signal is sent for 500 milliseconds and the BLD interrupt service routine must detect a blood leak.

Pressure Sensor Test
The return and filter pressure sensors are pressurized from behind the diaphragm until a 50 mmHg increase is detected, then the diaphragm is repositioned to a neutral position. In a similar manner, the access and effluent pressure sensors are depressurized from behind the diaphragm until a decrease of 50 mmHg is detected. The diaphragm is then repositioned to a neutral position. A maximum of 45 seconds is allowed for each sensor test.

Controller Test

Bubble Detector Test
During the air bubble test the controller processor must detect a macro bubble signal during the macro bubble portion of the periodic self-test. A failure results in a malfunction alarm.

Note: During the self-test the pressure extreme alarms for the return and filter are set to monitor at their maximum limits, and the filter clotting and TMP are also monitored at *their* maximum limits. The response to the air bubble alarms is inhibited only while the return line clamp is closed. The entire self-test takes approximately 2.5 minutes.

Self-test Failure Malfunction Alarms

If a machine failure occurs during the self-test, a Malfunction: Self-test Failure alarm occurs. If a failure occurs during the self-test portion of the prime test, both Malfunction: Self-test Failure and Malfunction: Prime Self-test alarms occur.

In addition to the alarm message, a hexadecimal failure code appears on the screen. The series of the numbers displayed tells you what component or components failed during the Self-test. See Appendix A for more information.

Prime

The PRISMA Control Unit utilizes a reverse prime, which means that the flow of saline is from the return line to the access line. The priming sequence used to prime the blood circuit is dependent upon which therapy is to be run.

Prime Test

The prime test is performed in the following sequence:

1. Normalize the blood leak detector.
2. Test the blood leak detector.
3. Initiate a periodic self-test.
4. PRISMA Set recognition test.

During the normalization and blood leak detector test, all pumps are stopped with the line clamp open. After the blood leak detector test passes, the blood pump is commanded to run at approximately 10 ml/min (clockwise) with the return line clamp open. A periodic self-test is then initiated after the blood leak detector test passes the prime test.

Note the following conditions regarding the periodic self-test and the prime test:

- The Periodic Self-test in Progress Advisory screen is not displayed when the periodic self-test is initiated during the prime test.
- All tests of the periodic self-test are performed during the prime test except for the micro air in blood and blood leak detector tests.
- If a periodic self-test failure occurs during the prime test, the Malfunction: Self-test Failure and Malfunction: Prime Self-test alarms are generated.
- If a periodic self-test failure occurs during the prime test, these screen messages appear: "Failure Due To: (4-digit hexadecimal number)" and "Possible Causes: Periodic self-test failed during prime-self test sequence." See Appendix A for troubleshooting information.

If the periodic self-test passes during the prime test, the following machine actions occur:

- The blood pump stops
- The return line clamp closes
- The current effluent pressure value is stored
- A 3 second timer starts

- The dialysate pump runs at approximately 40 ml/min (clockwise for SCUF and CVVH therapies, counterclockwise for CVVHD and CVVHDF therapies)
- The PRISMA Set recognition test starts

The PRISMA Set recognition test monitors the effluent pressure to verify that a CRRT-type set has been loaded when a CRRT-type therapy has been selected. Therefore, if the effluent pressure does not drop by more than 25 mmHg from the initial recorded pressure for the SCUF or CVVH therapies, or does not increase by more than 25 mmHg from the initial recorded effluent pressure for CVVHD or CVVHDF therapies within a 3 second time period, a Malfunction: Prime Self-test alarm is generated. Pressing RETEST will restart the entire test.

SCUF Priming Sequence

Priming Complete In:	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7 minutes	93 cw	0	0	0	0.5 ml bolus
6 minutes	93 cw	4080 ccw	0	0	0
5 minutes	93 cw	4080 ccw	0	0	0
4 minutes	93 cw	2040 ccw	0	0	0
3 minutes	93 cw	2040 ccw	300 cw	300 cw	0
2 minutes	93 cw	2040 ccw	0	0	0
1 minute	93 cw	0	0	0	0
0 minutes	0	0	0	0	0
Prime Self-Test					

Priming Complete In: 7
The blood lines and blood side of the filter are filled and the anticoagulant line is primed.

Priming Complete In: 6
Saline is still pumped by the blood pump and the effluent pump now pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 5
Saline is still pumped by the blood pump and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 4
Saline is still pumped by the blood pump and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 3
Saline is still pumped by the blood pump and the effluent pump continues to pulls saline across the filter to fill the effluent side of the filter. The dialysate and replacement lines are now partially primed by pulling saline from the effluent side of the filter for the dialysate line and the return line for the replacement line. This removes the potential for an air-blood interface since these lines are not used in the therapy.

Priming Complete In: 2
The blood pump and effluent pump continue to pump fluid at the same rate as the previous minute.

Priming Complete In: 1
The blood pump continues to pump fluid at the same rate as the previous minute.

Priming Complete In: 0
All pumps are off for approximately 0.5 minutes.

Prime Self-Test
A prime self-test runs as described earlier in this chapter for approximately 1.5 minutes.

CVVH Priming Sequence

Priming Complete In:	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7 minutes	93 cw	0	0	1,020 ccw	0.5 ml bolus
6 minutes	93 cw	4080 ccw	0	0	0
5 minutes	93 cw	4080 ccw	0	0	0
4 minutes	93 cw	2040 ccw	0	0	0
3 minutes	93 cw	2040 ccw	300 cw	0	0
2 minutes	93 cw	2040 ccw	0	0	0
1 minute	93 cw	0	0	0	0
0 minutes	0	0	0	0	0
Prime Self-Test					

Priming Complete In: 7
Blood lines and blood side of the filter are filled and the anticoagulant line is primed. The replacement line is primed from the replacement solution bag.

Priming Complete In: 6
Saline is still pumped by the blood pump and the effluent pump now pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 5
Saline is still pumped by the blood pump and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 4
Saline is still pumped by the blood pump and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 3
Saline is still pumped by the blood pump and the effluent pump continues to pull saline across the filter to fill the effluent side of the filter. The dialysate line is now partially primed by pulling saline from the effluent side of the filter. This removes the potential for an air-blood interface since these lines are not used in the therapy.

Priming Complete In: 2
The blood pump and effluent pump continue to pump fluid at the same rate as the previous minute.

Priming Complete In: 1
The blood pump continues to pump fluid at the same rate as the previous minute.

Priming Complete In: 0
All pumps are off for approximately 0.5 minutes.

Prime Self-Test
A prime self-test runs as described earlier in this chapter for approximately 1.5 minutes.

CVVHD Priming Sequence

Priming Complete In:	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7 minutes	93 cw	1020 ccw	1,020 ccw	0	0.5 ml bolus
6 minutes	93 cw	4080 ccw	0	0	0
5 minutes	93 cw	4080 ccw	0	0	0
4 minutes	93 cw	2040 ccw	0	0	0
3 minutes	93 cw	2040 ccw	0	300 cw	0
2 minutes	93 cw	2040 ccw	0	0	0
1 minute	93 cw	0	0	0	0
0 minutes	0	0	0	0	0
Prime Self-Test					

Priming Complete In: 7
The blood lines and blood side of the filter are filled, the anticoagulant line is primed, and the dialysate line is primed from the dialysate bag.

Priming Complete In: 6
Saline is still pumped by the blood pump and the effluent pump now pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 5
Saline is still pumped by the blood pump and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 4
Saline is still pumped by the blood pump and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 3
Saline is still pumped by the blood pump and the effluent pump continues to pulls saline across the filter to fill the effluent side of the filter. The replacement line is now partially primed by pulling saline from the return line. This removes the potential for an air-blood interface since these lines are not used in the therapy.

Priming Complete In: 2
The blood pump and effluent pump continue to pump fluid at the same rate as the previous minute.

Priming Complete In: 1
The blood pump continues to pump fluid at the same rate as the previous minute.

Priming Complete In: 0
All pumps are off for approximately 0.5 minutes.

Prime Self-Test
A prime self-test runs as described earlier in this chapter for approximately 1.5 minutes.

CVVHDF Priming Sequence

Priming Complete In:	Blood (ml/min, dir)	Effluent (ml/hr, dir)	Dialysate (ml/hr, dir)	Replacement (ml/hr, dir)	Anticoagulant (ml/hr)
7 minutes	93 cw	1020 ccw	1,020 ccw	1,020 ccw	0.5 ml bolus
6 minutes	93 cw	4080 ccw	0	0	0
5 minutes	93 cw	4080 ccw	0	0	0
4 minutes	93 cw	2040 ccw	0	0	0
3 minutes	93 cw	2040 ccw	0	0	0
2 minutes	93 cw	2040 ccw	0	0	0
1 minute	93 cw	0	0	0	0
0 minutes	0	0	0	0	0
Prime Self-Test					

Priming Complete In: 7
Blood lines and blood side of the filter are filled, the anticoagulant line is primed, and the dialysate line is primed from the dialysate bag and the replacement line is primed from the replacement bag.

Priming Complete In: 6
Saline is still pumped by the blood pump and the effluent pump now pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 5
Saline is still pumped by the blood pump and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 4
The blood pump continues to pump fluid and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete in: 3
The blood pump continues to pump fluid and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 2
The blood pump continues to pump fluid and the effluent pump pulls saline across the filter to fill the effluent side of the filter.

Priming Complete In: 1
The blood pump continues to pump fluid at the same rate as the previous minute.

Priming Complete In: 0
All pumps are off for approximately 0.5 minutes.

Prime Self-Test
A prime self-test runs as described earlier in this chapter for approximately 1.5 minutes.

Service Mode

Service Mode consists of two functions, Calibrate and Diagnose. While in Service Mode, all alarms are disabled. For detailed information, see the *PRISMA Service Manual.*

Calibration

Only two components on the PRISMA Control Unit require calibration; the scales and the pressure sensors. The pumps do not require calibration since they use stepper motors.

The PRISMA Control Unit will not allow you to calibrate either the scales or the pressure sensors if the same values are entered for at least two of the calibration points. For example, 0 mmHg is used for both the 0 and the -250 mmHg points while calibrating the access pressure sensor.

Scales
The scales utilize a 3-point calibration; 0 g, 2600 g, and 5200 g. The three points are used to form two lines which more accurately represent the performance of the scales as demonstrated in the graph below. Two 2600 g weights have been provided with each machine, and should be used while doing the calibrations.

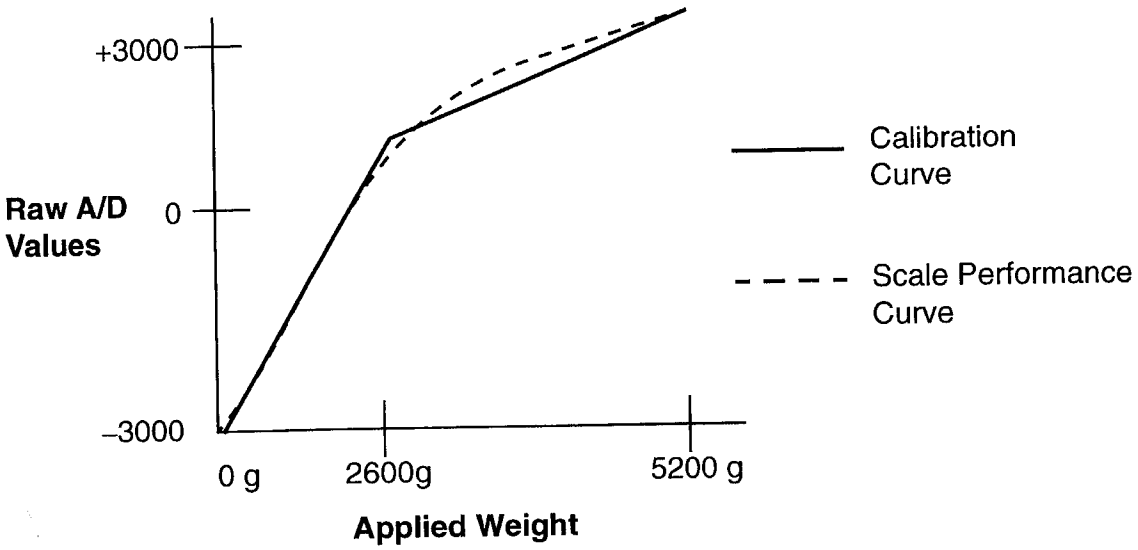


Figure 7. Scales Calibration Curve

Pressures

All pressure sensors require a two point calibration. Each pressure sensor is calibrated within the following ranges:

Access: –250 to +50, mmHg

Effluent: –350 to +50 mmHg

Filter: –50 to +500 mmHg

Return: –50 to +350 mmHg

Reposition: +250 to –250 mmHg

Diagnose

The Diagnose mode is used to aid in troubleshooting the major subsystems on the PRISMA Control Unit. This mode allows the service technician to isolate each subsystem for testing purposes. The subsystems available in this mode include the following:

Pumps
From this screen it is possible to run each pump individually and verify the correct direction and speed by observing the commanded speed versus the tachometer display. Using the 24 VOLTS softkey, you can test the control and monitor 24 Vdc switch. If the 24 VOLTS softkey is pressed, all pumps should stop.

Scales
Using the Scales screen, you can monitor the A/D values as well as the calibrated weight in grams for control and monitor of each individual scale. This screen is useful in verifying scale calibration.

Pressures
From this screen it is possible to monitor the millivolt readings as well as the calibrated pressure for each individual pressure sensor. This screen is useful in verifying the pressure sensor calibration.

Lights and Tones
This screen allows you to turn on each individual alarm lamp as well as listen to each alarm tone.

Air Detector
The air detector screen provides test functions for the macro and micro bubble detector functions.

Syringe Pump
The syringe pump can be tested in continuous delivery mode or in bolus delivery mode when using this screen. There is an indication of end of travel status and a hex counter to verify the pulses to the syringe pump motor.

Clamp
This screen allows you to operate the return line clamp. The status of the clamp is indicated by an independent optical switch. Like the pumps, both the control and monitor 24 Vdc switch can be controlled from here. If either softkey is pressed and the clamp is open, the clamp should close.

Blood Leak Detector
The blood leak detector service screen can be used to test the Normalization and self-test functions of the detector system.

Load/Unload
Pressing Load from the Diagnose main menu will cause the linear actuator to be retracted (towards the rear of the machine) and the pumps to operate in a similar manner to the loading of a blood circuit in normal run mode. Once Load has been pressed, the UNLOAD softkey is displayed in the same

softkey location. The LOAD softkey is always displayed when first entering Diagnose mode even if the linear actuator is in the loaded position. The only way to access the UNLOAD softkey is to first press LOAD. The time required for load/unload is approximately 7 seconds.

Automatic Reposition System
Pressing the REPO softkey allows you to test the automatic reposition system components. By pressing the Effluent, Access, Filter, and Return valve keys on the Service-Pod Reposition screen it is possible to observe the corresponding transducer readings, as well as the ARPS transducer. Pressures can be increased or decreased by pressing ARPS MOTOR and changing directions of the pump rotation with the DIRECTION softkey.

Internal

Test Softkeys
This screen is accessed from the Service-Internal screen and allows you to verify that each of the softkeys is functioning properly. When a numbered softkey is pressed it becomes highlighted and is working normally.

a. Test Video

The Video screen is also accessed from the Service-Internal screen. The video test illuminates all pixels for 5 seconds, then turns the pixels off for 5 seconds, then displays the Service-Internal screen again. This test allows you to determine if a pixel is burned out, or if a burned in or latent image exists

Test Watchdog
Pressing either the controller or the monitor watchdog test keys will inhibit the kick signal to the watchdog causing the timer to expire and reset the machine.

Set PM Timer Status
The PRISMA Control Unit records the length of time since the last preventive maintenance procedure has occurred. Once the timer has reached 6500 hours an advisory alarm occurs that indicates a preventive maintenance is needed. The advisory alarm remains active until you press the SET PM TIMER softkey, then the down arrow softkey until the PM status displays zero.

For a more detailed description of the screens and their functionality, see the *PRISMA Service Manual*

PRISMA Set

Figure 8 shows the assembled PRISMA Control Unit with a PRISMA Set, anticoagulant syringe, and fluid bags in place. The figure portrays CVVHD therapy, which uses only dialysate solution. Following is a description of the components of the PRISMA Set and the fluid bags.

Sample Sites Ports with a plug that allow needle entry to the access, effluent, and return lines. Used to obtain fluid or blood samples or to remove trapped air. Access is gained via a 20-gauge (or smaller diameter) needle, attached to a syringe. There are six sample sites in the PRISMA Set. They are color coded as follows: red on access line, yellow on effluent line, blue on return line.

Pressure Pods There are four circular "pods" in the set. Each contains a diaphragm and fits into a pressure sensor housing on the control unit. The pods and pressure sensors (inside) enable noninvasive pressure monitoring of the access line, return line, effluent line, and the filter.

Cartridge Flat, plastic component in the center of the PRISMA Set that holds the filter and pump segments. Has slots that accept the tabs of the cartridge carrier on the control unit. Allows automatic loading of the set.

Filter Hemofilter/dialyzer containing hollow fibers made of a semipermeable membrane. Blood flows through the hollow fibers; ultrafiltrate and/or dialysate are contained in the fluid compartment.

Pump Segments Tubing that threads into the raceway of each peristaltic pump. Loaded automatically when the cartridge carrier pulls the cartridge flush with the control unit.

Return Line (blue-striped) Conveys blood from the filter to the patient's blood return site.

Access Line (red-striped) Conveys blood from the patient's blood access site to the filter.

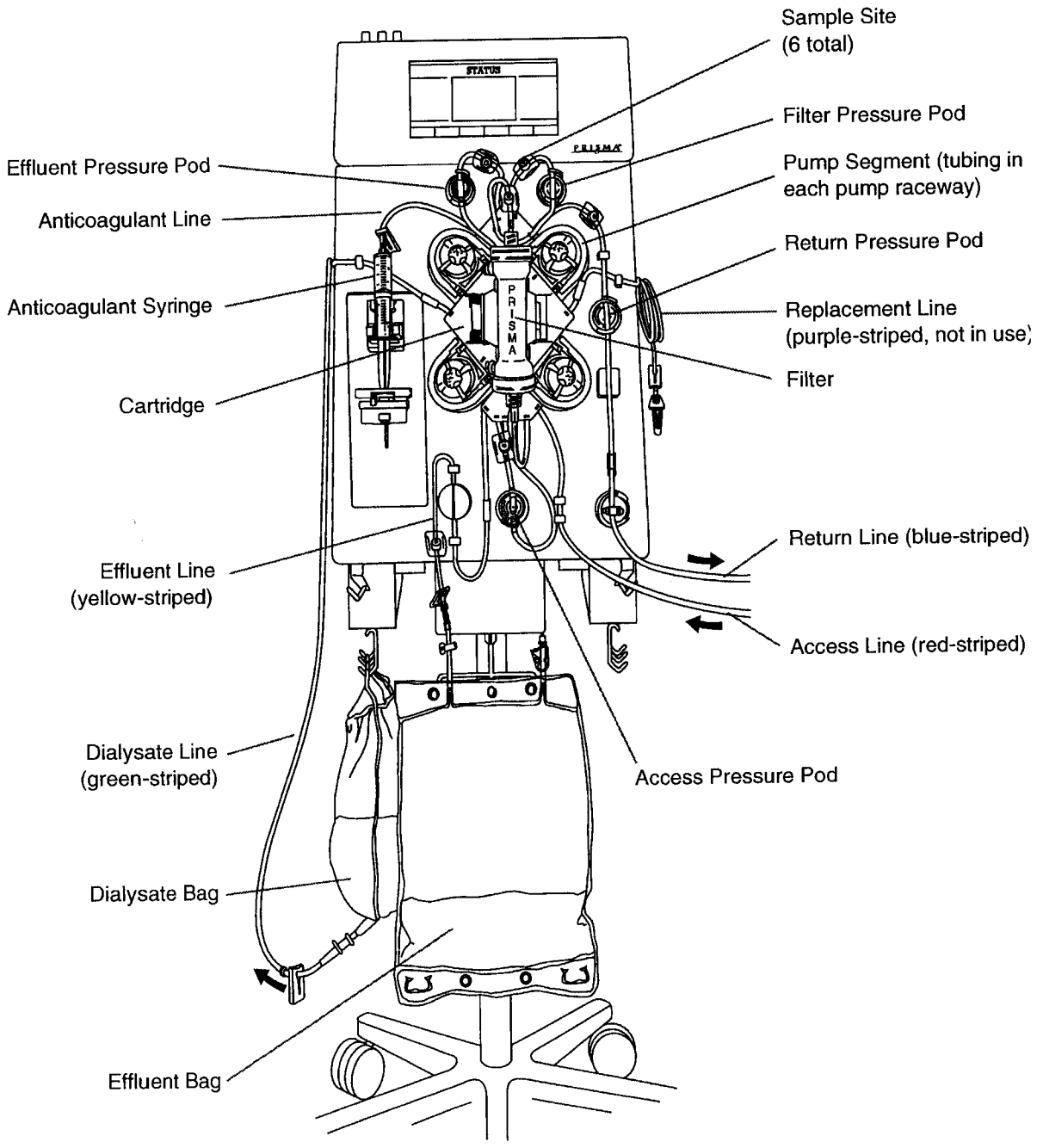


Figure 8. PRISMA Set in Place on the Control Unit (CVVHD Therapy)

Replacement Solution Bag	Holds prescribed replacement solution. Used in CVVH and CVVHDF therapies.
Replacement Line (purple-striped)	Conveys replacement solution from the replacement solution bag to the blood flowpath. In the post-dilution set, connects to the return line, just beyond the filter blood outlet. In the pre-dilution set, connects to the access line just before the filter blood inlet.
Effluent Bag	Collects ultrafiltrate and/or spent dialysate. One effluent bag is supplied with each set. Used in all therapies.
Dialysate Bag	Holds prescribed dialysate solution. Used in CVVHD and CVVHDF therapies.
Dialysate Line (green-striped)	Conveys fresh dialysate solution to the fluid side of the filter.
Effluent Line (yellow-striped)	Conveys ultrafiltrate and/or spent dialysate from the fluid compartment of the filter to the effluent bag.
Anticoagulant Line	Conveys anticoagulant solution from the anticoagulant syringe to the blood flowpath.

System Overview

Communicating With the PRISMA Control Unit

The front panel of the PRISMA Control Unit has an electroluminescent display overlaid with a touchscreen. The display shows screens of written information. The touchscreen allows the operator to interact with the control unit by pressing various *softkeys.*

Interactive Display

During operation, different screens appear on the display, showing information about the treatment, giving steps the operator should take, and alerting the operator to any abnormal conditions. Specific display contents depend on the software mode and operating conditions at the moment.

Some types of operating data, such as treatment history data, are only displayed when requested by the operator. The display is also a vehicle for servicing the system.

Softkeys are located along the sides and bottom of each screen. These allow the operator to give commands to the control unit and navigate between screens. The operator presses the desired softkey to initiate the function described by the softkey name.

The name and function of many of the softkeys change, depending on operating conditions. In this way, the operator is led through operating and alarm response situations.

User-controllable Settings

In order to administer the specific patient treatment prescribed by the physician, the operator controls many of the control unit's settings. For example, pump flow rates, the patient fluid removal rate, and anticoagulant settings. (Other settings are controlled only by the manufacturer or by trained and qualified service technicians.)

Table 9 in the Operation chapter lists all user-controllable settings, their default values, setting options, and the mode in which they can be changed.

Default Values

There are default values for each setting. These are initially set by the manufacturer. The following information pertains to default values:

- The default value controls operation, unless the operator sets a new value during setup or administration of a treatment.
- All settings revert to their default values whenever a New Patient procedure is chosen.
- If desired, the operator can change the default values for the PRISMA therapies. This can only be done in Custom mode. For more information, see "Custom Mode" in the Operation chapter.

Current Values

Current values are those that control operation during a patient treatment.

When the operator chooses a particular therapy during the Setup procedure, the control unit uses the default values assigned to that therapy. If desired, the operator can reset some of these values during the Setup procedure (Setup mode) or while the patient treatment is underway (Run mode).

Any changes made in Setup or Run modes apply only to that treatment and do not affect the default values.[2]

Pumps

The control unit has four occlusive, peristaltic pumps. These include the blood, replacement solution, dialysate, and effluent pumps. The control unit has one syringe pump that delivers anticoagulant solution to the blood flow, if desired.

During a patient treatment (Run mode), the peristaltic pumps turn counterclockwise. During priming of the PRISMA Set (Setup mode), some of the pumps turn clockwise. If the blood pump stops for any reason during treatment, all other pumps also stop.

The PRISMA software controls the speeds of the peristaltic pumps. The blood pump speed is based solely on the operator-set blood flow rate. The dialysate, replacement, and effluent pump speeds are based on all operator-set flow rates, as well as on the changing weights of fluid bags in use. In this way, desired flow rates are constantly maintained.

Flow Rates and Anticoagulant Settings

Flow rates are the settings that control the rate of blood flow, patient fluid removal, replacement solution infusion, dialysate flow, and effluent flow during a patient treatment. All flow rates are directly user-settable except the effluent flow rate. The effluent flow rate is automatically controlled by the PRISMA software, based on all other flow rates.

Anticoagulant settings are those that control delivery of anticoagulant solution to the blood flow, if anticoagulation is desired. These settings include the Delivery Method (Continuous or Bolus), Delivery Rate (applicable only for Continuous delivery), Bolus Volume and Bolus Interval (applicable only for Bolus delivery).

2. An exception is the setting "Language." Changing the language in Run mode also changes the default language.

Adjusting the Flow Rates and Anticoagulant Settings

During the Setup procedure (Setup mode), the Set Flow Rates screen is displayed. The operator is asked to review the default flow rates and anticoagulant settings, then make any changes desired for the *current treatment.* During the patient's treatment (Run mode), the operator can access the Set Flow Rates screen and adjust the flow rates and anticoagulant settings as needed. See "Operating Modes" and "User-controllable Settings" in the Operation chapter for more information.

If desired, the operator can change the default flow rates and anticoagulant settings in Custom mode. See "Custom Mode" in the Operation chapter.

Patient Fluid Removal Rate

The patient fluid removal rate is the *net amount of fluid* the PRISMA System removes from the patient each hour (after accounting for any replacement solution being used). *Net fluid removal* occurs whenever the operator sets the patient fluid removal rate to a value above zero.

Calculating the Desired Patient Fluid Removal Rate

The PRISMA Control Unit software *does not* measure or account for non-PRISMA sources of patient fluid intake (such as hyperalimentation, blood, or drug infusion) or fluid output (such as urine and wound drainage). It also does not account for anticoagulant solution infused via the PRISMA anticoagulant syringe pump. The operator must account for these other sources when calculating the patient fluid removal rate, as well as when calculating the patient's input/output totals.

The following formula may be useful:

Prescribed patient weight loss (ml/hr)
\+ Non-PRISMA fluid inputs (ml/hr)
\- Non-PRISMA fluid outputs (ml/hr)
= Patient fluid removal rate to be set on the PRISMA Control Unit (ml/hr)

The patient fluid removal rate must be adjusted if the weight loss prescribed by the physician is changed or if the patient's non-PRISMA fluid inputs or outputs change.

Adjusting the Patient Fluid Removal Rate

During the Setup procedure (Setup mode), the Set Flow Rates screen is displayed. The operator is asked to review the default patient fluid removal rate, then make any changes desired for the *current treatment.*

During the patient's treatment (Run mode), the operator can access the Set Flow Rates screen and adjust the patient fluid removal rate as needed. See "Operating Modes" and "User-controllable Settings" in the Operation chapter for more information.

If desired, the operator can change the default patient fluid removal rate in Custom mode. See "Custom Mode" in the Operation chapter.

Machine Control of Patient Fluid Removal Rate

The PRISMA software automatically calculates the ultrafiltration rate needed to achieve the patient fluid removal rate. Any PRISMA replacement solution additions are automatically accounted for, as shown below:

Patient fluid removal rate (ml//hr)
+ Replacement solution rate, if any (ml/hr)
= Required ultrafiltration rate (ml/hr)

During operation, software controls the effluent pump speed to maintain the required ultrafiltration rate.

Fluid Balance

Actual Patient Fluid Removed

Actual Patient Fluid Removed is the *net amount of fluid* removed from the patient by the PRISMA System during a specified time period. It is the patient's "PRISMA System output" for use in periodic totalling of patient I/O (input and output) volumes.

Measuring Actual Patient Fluid Removed

The three precision scales mounted on the bottom of the PRISMA Control Unit support the dialysate, replacement solution, and effluent bags and constantly measure the weight of the bags. The change in combined weight of the fluid bags in use indicates how much fluid has been removed from the patient by the control unit. When fluid bags are replaced, the software automatically accounts for the new bag weights.

The total Actual Patient Fluid Removed should equate with the operator-set patient fluid removal rate.[3] For example, if the patient fluid removal rate is 100 ml/hr and 90 minutes of treatment has elapsed, the Actual Patient Fluid Removed will be 150 ml.

Viewing Actual Patient Fluid Removed

During a patient treatment (Run mode), the Actual Patient Fluid Removed during the current *I/O Period* (see description of I/O Period below) is displayed and continuously updated on the Status screen. It is also displayed on the Treatment History screen. The Treatment History screen is available for viewing during a treatment (Run mode) and when ending a treatment (End mode).

On the Treatment History screen, the operator can view the amount of Actual Patient Fluid Removed for the last full I/O Period, or for a specified period of time during the last 24 hours of treatment. See "I/O Data" and "Treatment History Data" in this chapter for more information.

I/O Data

To facilitate periodic totalling of patient I/O (input and output) volumes during a treatment, the control unit displays cumulative totals of all *PRISMA-controlled* fluids.

This *I/O Data* is continually updated and displayed on the Status screen during a treatment (Run mode). Data accumulates for the length of time stipulated by the *I/O Period*, a user-controllable setting of 60, 30, or 15 minutes. At the end of the I/O Period, data accrual starts over at zero. If desired, the operator can set a reminder beep to signal the end of the I/O Period.

In addition to being displayed on the Status screen during a treatment, I/O Data is also accumulated and stored minute-by-minute in the treatment history memory. See "Treatment History Data" in this chapter for more information.

Depending on the therapy in use, I/O Data displayed on the Status screen includes the following:

- Time Elapsed (during the I/O Period)
- Replacement Solution Input
- Dialysate Used

3. Actual Patient Fluid Removed will differ from the operator-set patient fluid removal rate if: (a) treatment is stopped, then later resumed; (b) an alarm occurs that stops the replacement, dialysate, and effluent pumps.

- Effluent Volume (ultrafiltrate; spent dialysate)
- Actual Patient Fluid Removed

The I/O Period default is 60 minutes; the I/O Reminder Beep default is "On." If desired, the operator can change these default settings before beginning the Setup procedure. During a treatment (Run mode), the operator can also adjust the I/O Period and reminder beep settings. See "User-controllable Settings" in the Operation chapter for more information.

Treatment History Data

Vital machine conditions and operating data are stored and updated minute-by-minute in software memory. The memory stores up to 24 hours of treatment data; thereafter, the old data are deleted and the new data are added minute-by-minute. The history data can be viewed on the Treatment History screen and on the Events screen. These screens are available during a treatment (Run mode) and when ending a treatment (End mode). History data for the last treatment can be viewed from the Choose Patient screen (Setup mode).

I/O History

Cumulative totals for the I/O Data displayed on the Status screen are stored and displayed on the Treatment History screen. Data for the *last full I/O Period* are displayed when the operator first brings the Treatment History screen to the display.

The operator can change the time period on the Treatment History screen by using the arrow keys. In this way, the operator can view fluid totals for all or a portion of the last 24 hours of treatment.

Events History

Certain *events* that may occur during setup and delivery of a treatment are stored and displayed on the Events screen.

The control unit stores the hour and minute that events occur, as well as the name of the event. Up to 100 events can be stored.

An event is recorded when any of the following occur:

- Therapy, flow rates, and anticoagulant settings are initially selected (Setup mode).
- Treatment is started (Run mode).

- A flow rate or anticoagulant setting is changed during treatment.
- The sensitivity of the blood leak detector is set (normalized).
- An alarm occurs.
- An alarm screen is cleared from the display.
- Any of these softkeys are pressed: LOAD, PRIME, RESUME, STOP, UNLOAD.

History Data After a Treatment

After a treatment is concluded, the treatment history data is stored in memory. It can be viewed from the Choose Patient screen (Setup mode) by pressing the LAST TREATMENT HISTORY softkey. **The Last Treatment History data is deleted when the NEW PATIENT softkey is pressed as well as any time the date or time is changed in Custom mode.**

History Data During a Power Loss

If a power loss occurs during a treatment, the treatment history data is retained in memory.

Alarm Safety System

The PRISMA Control Unit continually monitors itself and the PRISMA Set for abnormal conditions. Depending on the circumstance, the operator is alerted by the following:

- Red or yellow status light
- Audible alarm
- Alarm screen on the display, giving instructions for responding to the abnormal condition

Alarms are prioritized into Warning, Malfunction, Caution, and Advisory alarms. See the Alarm System chapter for more information.

Pressure Monitoring System

The PRISMA Control Unit has an integral pressure monitoring system. The system alerts the operator (via alarms) to abnormal pressure conditions, such as extreme positive pressure in the return line or clotting in the filter. See the Pressure Monitoring chapter for more information.

Chapter 2: Installation

WARNING

- **Read these installation instructions before starting installation of the PRISMA Control Unit. Read the *PRISMA System Operator's Manual* and perform the installation test before first use.**
- **All electrical installations must comply with all applicable local electrical codes and manufacturer specifications.**
- **The PRISMA Control Unit weighs approximately 23 kg (50 lb). Use at least two people to lift it out of the shipping carton. Handle the control unit carefully.**

Contents of PRISMA Shipping Carton

- PRISMA Control Unit
- Column (hollow pole with flat plate attached to one end)
- Base with casters
- Installation kit containing the following:
  - United States-style power cord, with retaining bracket
  - Self-locking #10 nuts (4)
  - Self-locking #6 nuts (2)
  - Flat washers (4)
  - Silicone tubing retainer pieces (3)
  - Scale hook assemblies (3)
  - Rotor wrench
- Calibration weights (2)
- PRISMA System Operator's Manual

Electrical Requirements

The control unit operates satisfactorily from an electrical power source that delivers the following:

- 85 to 135 Vac, 47 to 63 Hz
- 180 to 260 Vac, 47 to 63 Hz

It is essential that the power receptacle be properly grounded and in good condition. If there is any question, have the wiring checked by a qualified electrician.

Space Requirements

The assembled machine requires a minimum of 80 cm x 80 cm (30 in x 30 in) of floor space. There must be enough space around the machine so that all fluid bags can hang freely from the scale hooks.

Unpacking and Assembly

Materials Needed

- Table (can use shipping carton with flaps folded down)
- Straight-blade screwdriver
- 3/8-inch wrench
- 5/16-inch wrench

Step 1: Attach Base

(See Figure 9)

1. Open the shipping carton and remove upper section containing the column and base. Stand the column upright, with the flat plate on the floor.
2. Invert the base and place it on the column, fitting the locator screw (center of the base) into the slot in the column. Tap sharply on the base with the palm of your hand to ensure it is fitted securely on the column.

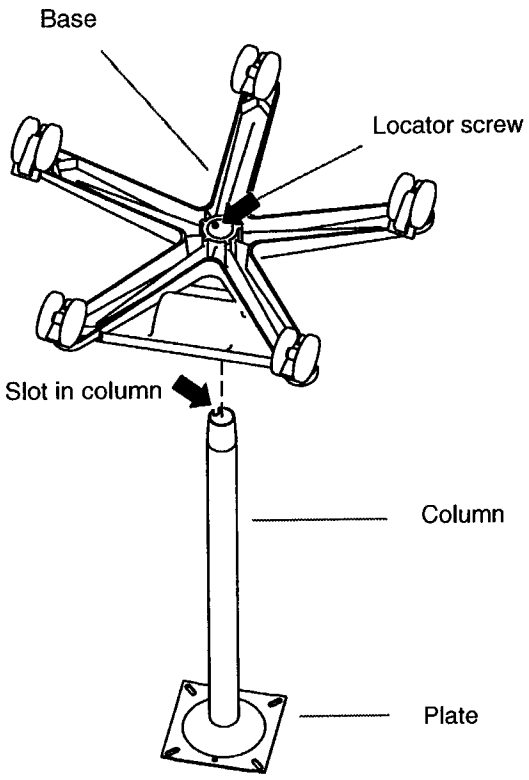


Figure 9. Fitting Column Into the Base

Step 2: Connect Power Cord

(See Figure 10)

1. Place the control unit on a table on its rear panel, keeping foam packing in place. Inspect all components on the front panel. If any damage has occurred, immediately contact your local sales or service representative.
2. Select the appropriate power cord and retaining bracket package. With the column/base assembly standing upright, start at the bottom and thread the female connector end of the power cord up through the column. Allow 1/2 to 1 m (2 to 3 ft) of power cord to extend out the top of the column.

3. Move the column/base with the power cord close enough to the control unit to permit attaching the power cord to the bottom of the control unit. Pass the female connector end of the power cord through the hole in the center of the control unit and plug it into the receptacle inside.

4. Place the retaining bracket around the power cord. Secure the bracket to the studs on the bottom of the control unit with the #6 self-locking nuts provided. Tighten the nuts using a 5/16-inch wrench.

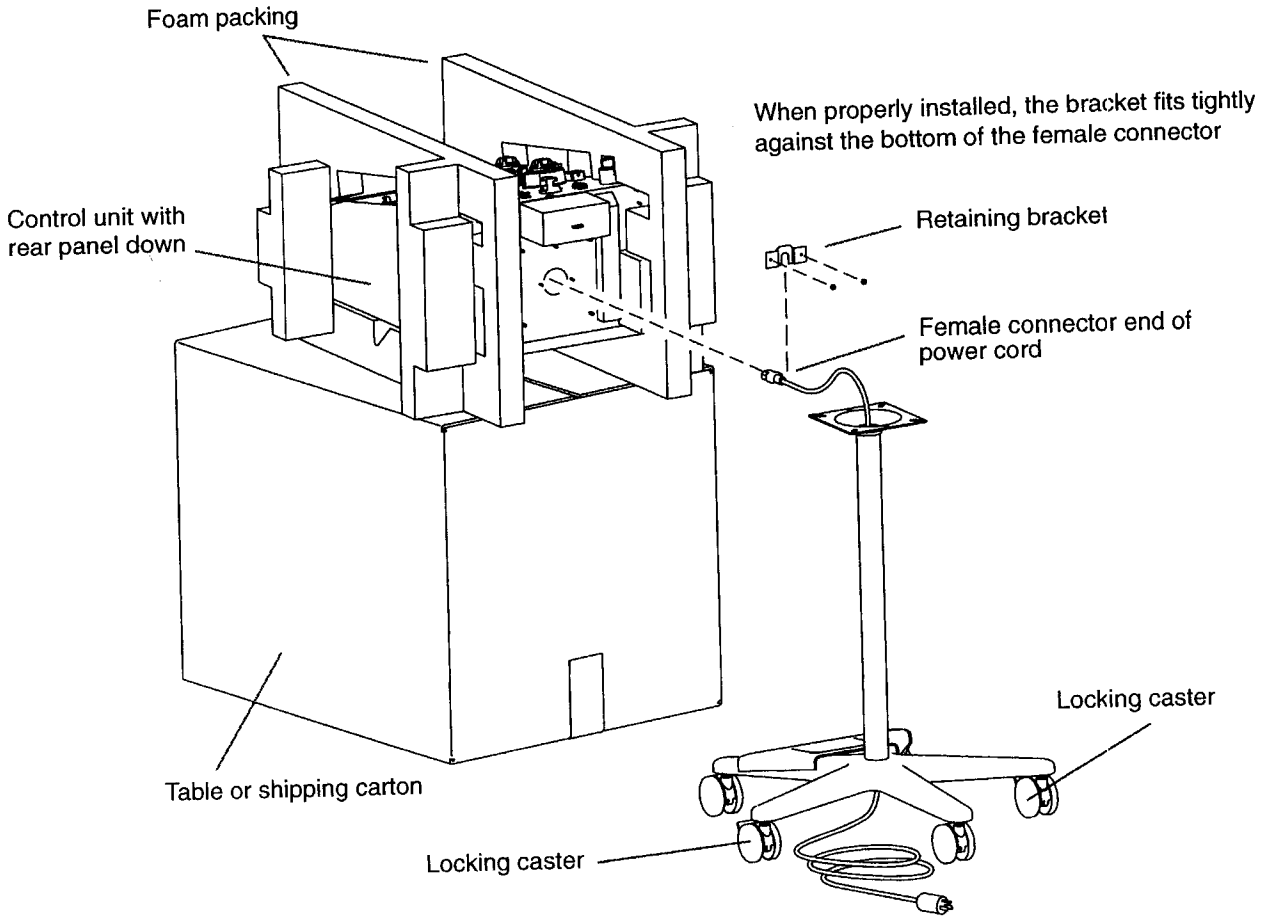


Figure 10. Connecting Power Cord to the PRISMA Control Unit

Step 3: Attach Column/Base to Control Unit

(See Figure 11)

1. Lift the column/base assembly, slide it over the power cord, and place the plate over the four large studs on the bottom of the control unit. Note the orientation of the base with respect to the control unit.
2. Secure the base to the control unit with a flat washer and a #10 self-locking nut at each corner of the plate. Tighten the nuts using a 3/8-inch wrench.
3. Secure the power cord to the retainer located on the edge of the storage tray for the calibration weights. To secure, twist the tabs on the retainer and slide the cord between the tabs.

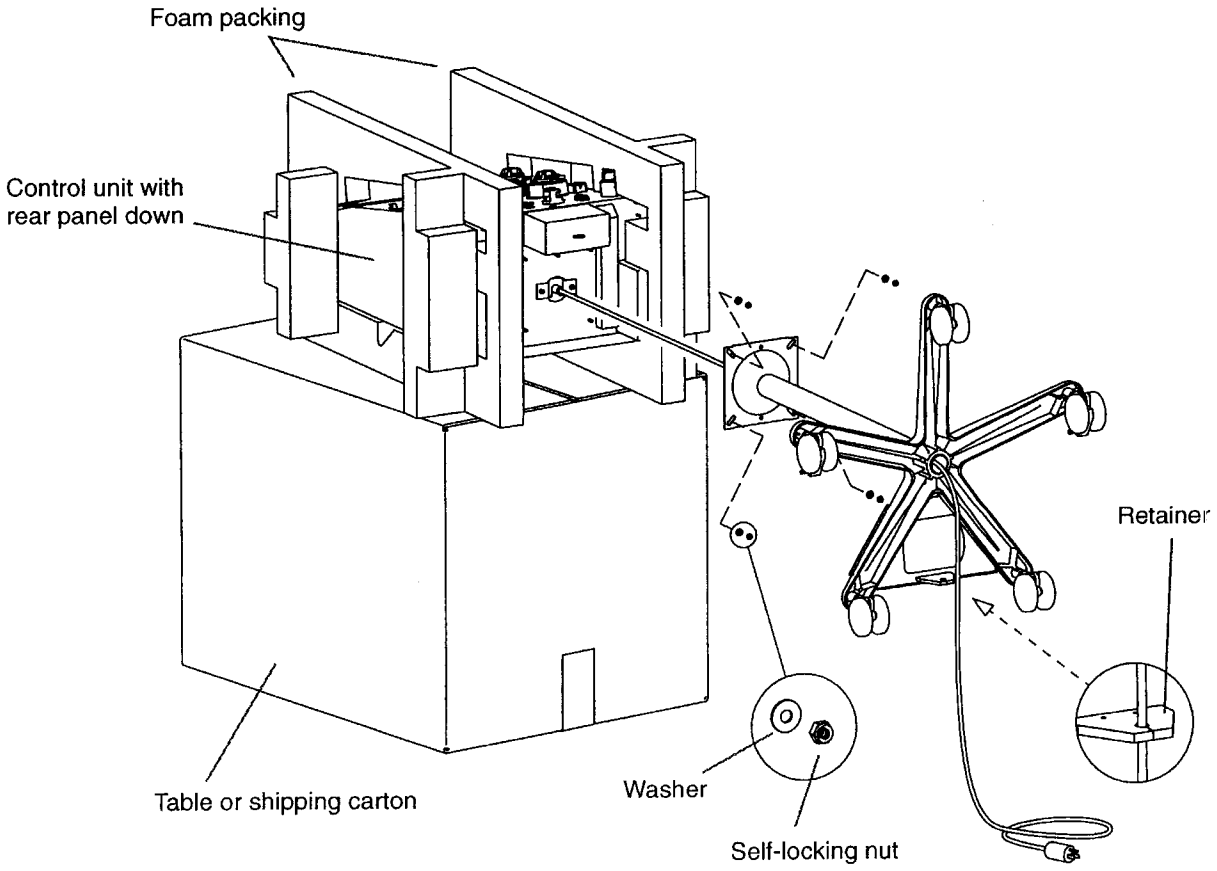


Figure 11. Attaching Column/Base to the PRISMA Control Unit

Step 4: Attach Scale Hook Assemblies

(See Figure 12)

1. Place the assembled machine in the upright position and remove the foam packing material.
2. Hang a scale hook assembly from the pierced metal tab under each scale. Slide a silicone tubing retainer over the end of the hook in the metal tab.
3. Place the calibration weights in the storage tray.

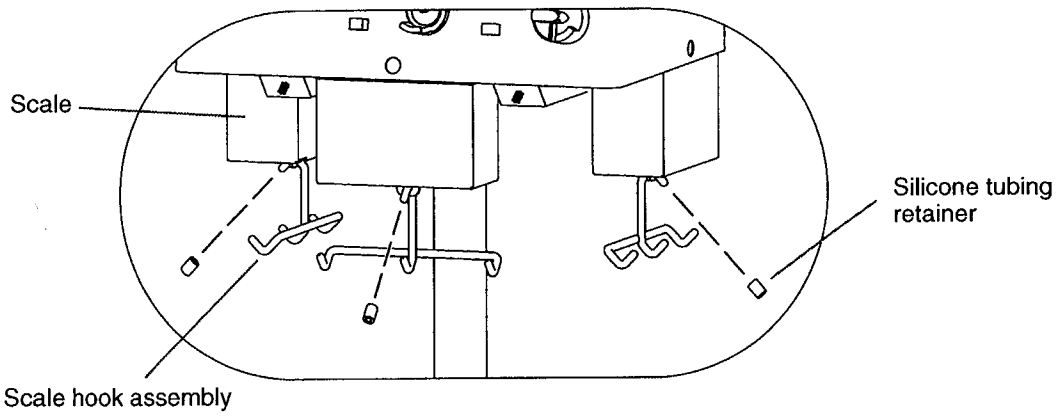


Figure 12. Hanging Hooks on the Scales

Step 5: Machine Calibrations

Before first use of the PRISMA Control Unit, the operations below must be performed in Service mode by a trained and qualified person, and recorded in the *Maintenance Log* (attached to the inside wall of the rear panel). Calibration instructions are provided in the *PRISMA System Service Manual.*

1. Calibrate all scales.
2. Check all pressure sensors; calibrate if necessary.

Step 6: Installation Test

Note: Read this Operator's Manual before performing the installation test. If desired, install the PRISMA Overlay on the front panel of the control unit. (PRISMA Overlays can be purchased separately. Contact your sales representative for the overlay part number.)

Before the first use of the PRISMA Control Unit on a patient, the installation test must be performed with a PRISMA Set in place on the control unit.

The installation test verifies that the control unit is properly installed. The test is performed using saline solution as a substitute for priming and dialysate solutions and a container of water as a substitute for the patient. Successful completion of the installation test indicates that the PRISMA Control Unit is functioning properly.

WARNING

- ***Do not* connect a patient to the PRISMA System during the installation test. Be sure that the test is conducted using a container of water to substitute for the patient.**
- **If a *Malfunction* alarm occurs during the installation test, the PRISMA Control Unit has failed the test. Do not use the control unit. Call a trained and qualified technician for service.**

Supplies Needed

- PRISMA Set
- Two 1-L bags of saline solution
- 1-L fluid container, filled with 500 ml tap water

Procedure

To perform the installation test, follow the steps below.

1. Turn on the control unit as described under "Startup" in the Operation chapter. The control unit performs an initialization test during the Startup procedure. Verify that the red, yellow, and green lights are illuminated.
2. Choose *New Patient* when the Choose Patient screen appears; confirm *New Patient* choice by pressing CONTINUE on the Confirm Patient screen. Choose the *CVVHDF* therapy when the Choose Therapy screen appears.
3. Follow the instructions on the display to load and prime the set. (Use saline solution in place of priming and dialysate solutions.) The control unit performs multiple self-tests during the priming cycle.
4. When priming is complete, the Set Flow Rates screen appears. Set the following flow rates:
   - Blood: 100 ml/min
   - Replacement Solution: 1000 ml/hr
   - Dialysate: 1000 ml/hr
   - Patient Fluid Removal Rate: 200 ml/hr
   - Anticoagulant: Continuous Delivery at 0 ml/hr
5. Place the access and return lines into the container of water; press the CONTINUE softkey to enter Run mode. Note the hour and minute the control unit enters Run mode.

   Note: Because the installation test is performed with water, the *Advisory: Return Disconnection Cannot Be Detected* alarm could occur after the control unit has entered Run mode. If this alarm occurs, press OVERRIDE and continue with the test. The alarm will not affect the outcome of the installation test.
6. Let the control unit run for 15 minutes. Note that the fluid totals in the I/O Data Box (center of Status screen) are updated as operation proceeds.
7. After 15 minutes, press the TREATMENT HISTORY softkey. When the Treatment History screen appears, set the History Start Time to the hour and minute the control unit entered Run mode. Set the History End Time to 15 minutes after the History Start Time. Check that the Actual Patient Fluid Removed reads 50 ml, ± 5 ml.

Note: If an alarm has occurred that stopped a peristaltic pump, the Actual Patient Fluid Removed will not read 50 ml. Remedy the problem that caused the alarm and perform the installation test again.

8. Place a clamp on the access line (red) below the cartridge. The *Warning: Access Pressure Extremely Negative* alarm should occur. Verify that the red light illuminates continuously and the audible alarm sounds at a fast beep.
9. Unclamp the access line and press the CONTINUE softkey on the Warning screen. Verify that the alarm is cleared (Warning screen leaves display, green light illuminates).
10. Press the STOP softkey, then press the END TREATMENT softkey and follow the instructions to unload the set.

Chapter 3: Operation

Startup

Startup of the PRISMA Control Unit consists of the following steps:

1. Operator turns the power switch to the "on" position.
2. The control unit performs an initialization test to check the system electronics. The Logo screen is displayed and all status lights are illuminated during the test.
3. When the initialization test is successfully completed, the Choose Patient screen appears on the display and the yellow status light illuminates. This indicates the PRISMA Control Unit is in the Setup mode and is ready for operation.

Note: The above actions occur when a new PRISMA Control Unit is initially turned on. These actions also occur whenever the unit is turned on after being turned off in the Treatment Complete screen. If the control unit was last turned off in a screen other than Treatment Complete, a Query screen appears after the initialization test is completed. From the Query screen, the operator can choose one of two actions:

- Begin on the same operating screen as when the unit was turned off (by pressing the CONTINUE key).
- Start over at the Choose Patient screen (by pressing the RESTART key).

Control and Navigation

The PRISMA Control Unit is operated by means of the interactive display on the upper front panel. The screens displayed lead the operator through the operating procedures. Help screens provide additional information, if needed. The softkeys that appear on each screen enable the operator to give commands to the control unit and navigate between screens.

WARNING

If the display goes blank while power is on, immediately terminate the treatment and call for service.

Screen Layout

Screens (text and softkeys) displayed by the PRISMA Control Unit have the following landmarks:

- The upper left corner shows the operating modes of the PRISMA Control Unit, with the current mode highlighted.
- The upper right corner shows the PRISMA therapies with the current therapy highlighted.
- The far right softkey of Operating and Alarm screens is labeled HELP. Pressing this key provides more detail about the displayed screen.
- The far right softkey of Help screens is labeled EXIT HELP. Pressing this key allows the operator to return to the screen that was displayed when HELP was pressed.
- An EXAMINE ALARMS key appears above the HELP key whenever an alarm occurs, whenever the operator overrides an alarm, or whenever one or more lower-priority alarms are pending during an alarm. For more information, see the Alarm System chapter.
- Arrows appear on certain screens. These enable the operator to adjust settings. For example, arrows are used to set the flow rates or view a certain time period within the treatment history data. By pressing and holding the arrows, the operator can scroll through the available options. By pressing and releasing the arrows, the operator can make fine adjustments.

Operating Modes

In the course of performing a treatment, the control unit passes through four normal Operating modes: Setup, Standby, Run, and End. Following is a description of each of the Operating modes.

Setup Mode

The control unit automatically goes into Setup mode after successful completion of the initialization test. Setup mode enables the operator to load the PRISMA Set onto the control unit, prepare and connect needed solutions, and prime the set.

While the control unit is in Setup mode, appropriate alarms are enabled and the yellow status light is illuminated.

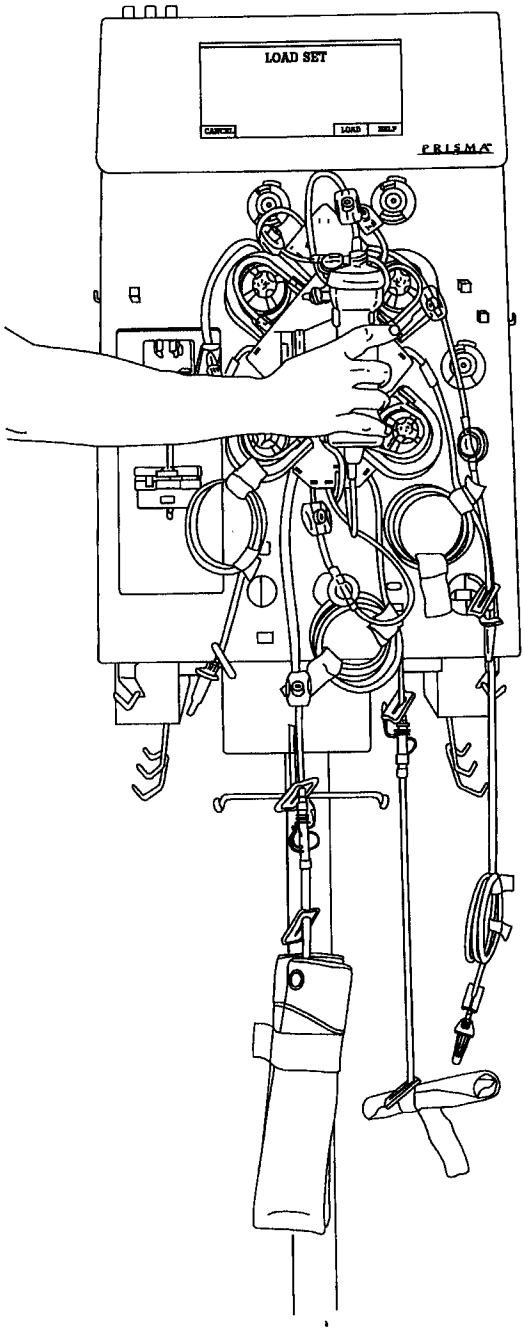
The operator follows the instructions on the display to perform the following sequential actions:

1. Enter Custom mode, if desired, to alter default settings of one or more PRISMA therapies. See "Custom Mode" in this chapter for more information.
2. View treatment history data of the last treatment.
3. Choose New Patient or Same Patient.

   If *New Patient* is chosen, the control unit deletes the treatment history data of the last treatment and advances to the Choose Therapy screen.

   If *Same Patient* is chosen, the control unit retains the treatment history data of the last treatment, retains the last chosen therapy and all its setting values, and advances to the Load Set screen (described in Step 5 below). The therapy can be changed, if desired, by pressing the CANCEL softkey when the Load Set screen appears. Dialysate and/or replacement solution bags in use can remain in use until empty when *Same Patient* is chosen.
4. Choose the therapy desired. The control unit accesses the default settings and screens for the therapy chosen.
5. Position the PRISMA Set onto the control unit. This includes (a) placing the cartridge of the set in the cartridge carrier, (b) routing lines of the set through tubing guides, air detector, and blood leak detector, (c) hanging the effluent bag on the effluent scale hook and (d) attaching the pressure pods to the pressure sensor housings. See Figure 13.

A Snap cartridge into cartridge carrier by tilting slot over the tabs on control unit.



B Press each pressure pod into the corresponding pressure sensor housing, using a twisting motion.

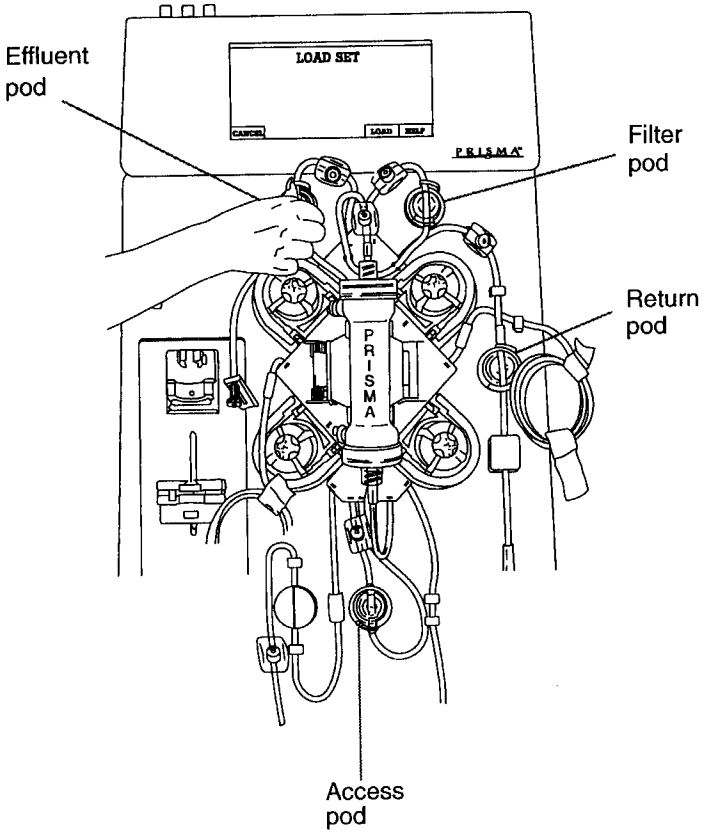


Figure 13. Positioning PRISMA Set on the Control Unit

6. Automatically load the set by pressing the LOAD softkey. When LOAD is pressed, the pumps begin turning, the set is drawn inward, and the pump segments of the set are threaded into the pump raceways.
7. Prepare solutions; connect fluid bags, priming solution, and anticoagulant syringe to the set; automatically prime the set by pressing the PRIME softkey. Priming takes approximately 7 minutes.

   Note: When PRIME is pressed, the pumps run at internally set speeds and some pumps turn clockwise. After the set is primed, the control unit performs multiple self-tests, lasting approximately 1.5 minutes. The following are tested: type of set loaded, all four pressure sensors and pods, return line clamp, blood pump, blood leak detector, air bubble detector, and 24-volt switch.
8. Review/adjust flow rates and anticoagulant settings. Set the patient fluid removal rate, if desired.

The Operating screens that appear in Setup mode are listed, by title, in Table 2. Screens are listed in the order in which they automatically appear during the Setup procedure.

Note: The written information on the screens varies, depending on the therapy chosen. In this way, the instructions pertinent to each therapy are displayed for the operator.

Table 2. Operating Screens in Setup Mode

Choose Patient
Treatment History
Events
Confirm New Patient
Choose Therapy
Load Set
Loading pumps, please wait
Unloading pumps, please wait (for use if loading was unsuccessful)
Prepare Solutions
Connect Lines to Solutions
Priming, please wait

Table 2. Operating Screens in Setup Mode (cont.)

Priming Complete
Set Flow Rates
Modify Anticoag

Standby Mode

The control unit automatically goes into Standby mode after the operator completes all Setup procedures and presses the CONTINUE softkey on the Set Flow Rates screen. The Connect Patient screen appears. The operator can connect the patient to the primed set at this time.

WARNING

- **If a patient is not connected to the PRISMA Set shortly after priming is complete, flush the set with at least 500 ml priming solution (saline with heparin added) before connecting a patient. This requires use of a new bag of priming solution and a new (empty) collection bag.**
- **All lines in the PRISMA Set have a preattached slide clamp. Clamp the following lines after priming is complete and before starting a patient treatment (Run mode). For SCUF and CVVHD, clamp the replacement line; for SCUF and CVVH, clamp the dialysate line; for all therapies, clamp the anticoagulant line (if not in use).**

The control unit also enters Standby mode any time the STOP softkey is pressed during Run mode. The Stop screen appears and provides options to re-enter Run mode by pressing RESUME, or proceed to End mode by pressing CHANGE SET, END TREATMENT, or TEMP DISCON.

During Standby mode, *all pumps are stopped*, appropriate alarms are enabled, and the yellow status light is illuminated. The screens that appear in Standby mode are listed in Table 3.

Table 3. Operating Screens in Standby Mode

Connect Patient
Stop

Run Mode

The control unit enters Run mode after the operator connects the patient to the primed set and presses the START softkey from the Connect Patient screen.

During Run mode, all appropriate alarms are enabled and the green status light is illuminated, unless an alarm occurs.

The Status screen is the first Run mode screen and is normally displayed during the entire patient treatment. From the Status screen, the operator can access all the other Run mode screens. Run mode allows the operator to perform the following actions:

1. Administer the treatment to the patient. The fluid pumps operate according to default settings or those entered by the operator. Bag weights are monitored and treatment data is accumulated and stored.
2. Adjust any flow rates, anticoagulant settings, and the patient fluid removal rate, as needed.
3. Adjust Status screen settings, which include the Pressure Display, Flow Rate Display, I/O Interval, I/O Reminder, and Language.
4. View treatment history data.
5. Reset (re-normalize) the sensitivity of the blood leak detector, if needed.

WARNING

The blood leak detector must be re-normalized if the effluent line is repositioned or removed and then reinserted into the blood leak detector after treatment (Run mode) has started. This is done by pressing the NORMALIZE BLD softkey on the Status screen. The detector must be re-normalized before continuing a patient treatment.

6. Temporarily stop the patient's treatment by pressing the STOP softkey.

The Operating screens available in Run mode are listed in Table 4.

Table 4. Operating Screens in Run Mode

Status
Set Flow Rates
Modify Anticoag
Treatment History
Events
Test Effluent Line for Blood
Normalize Blood Leak Detector
Modify Settings

End Mode

The control unit enters End mode when the operator presses STOP, then presses the CHANGE SET, END TREATMENT, or TEMP DISCON softkey. Appropriate alarms are enabled and the yellow status light is illuminated.

End mode allows the operator to perform the following procedures:

1. Change Set (remove the present PRISMA Set, with or without returning blood to the patient, and load a new set).
2. End Treatment (terminate the present treatment, with or without returning blood to the patient, and view treatment history data before turning off the machine).
3. Temporary Disconnection (temporarily disconnect the patient from the set).

Following is a description of the operator and machine actions that occur in each End mode procedure.

Change Set Procedure

After pressing CHANGE SET, the operator follows the instructions displayed to perform the following actions:

1. Return blood to the patient, if desired, pressing the RETURN BLOOD softkey or by returning blood manually.

   Note: The blood pump automatically runs at 110 ml/min when the RETURN BLOOD softkey is pressed. **If a slower blood return rate is desired, the operator must return blood manually** (by turning the blood pump counterclockwise, rather than pressing RETURN BLOOD).

In either case, the operator should follow the instructions provided on the Return Blood screen.

2. Disconnect the patient from the set and unload the pump segments by pressing the UNLOAD softkey. Remove the set and return to the Load Set screen in Setup mode.
3. Place a new PRISMA Set on the control unit and load the set by pressing the LOAD softkey. Treatment continues once the control unit reaches Run mode.

The "Change Set" screens available in End mode are listed in Table 5.

Table 5. "Change Set" Screens in End Mode

Change Set
Return Blood (optional)
Disconnect Patient
Unloading pumps, please wait
Remove Set

End Treatment Procedure

After pressing END TREATMENT, the operator follows the instructions displayed to perform the following actions:

1. Return blood to the patient, if desired, by pressing the RETURN BLOOD softkey or by returning blood manually.

   Note: The blood pump automatically runs at 110 ml/min when the RETURN BLOOD softkey is pressed. **If a slower blood return rate is desired, the operator must return blood manually** (by turning the blood pump counterclockwise, rather than pressing RETURN BLOOD). In either case, the operator should follow the instructions provided on the Return Blood screen.

2. Disconnect the patient from the set and unload the pump segments by pressing the UNLOAD softkey. (The control unit automatically advances to the Treatment Complete screen.)
3. Remove the set; view treatment history, if desired.
4. Turn off the control unit.

The "End Treatment" screens available in End mode are listed in Table 6.

Table 6. "End Treatment" Screens in End Mode

End Treatment
Return Blood (optional)
Disconnect Patient
Unloading pumps, please wait
Treatment Complete
Treatment History
Events

Temporary Disconnection Procedure

After pressing TEMP DISCON, the operator follows the instructions displayed to perform the following actions:

1. Disconnect the access line from the patient and connect it to a bag of sterile saline.
2. Return blood to the patient using the START RETURN softkey to pump saline through the access line.

   Note: If the set has significant clotting, the operator can choose to automatically unload it and cycle into the Change Set procedure. This can be done by pressing CONTINUE without returning the patient's blood, then pressing UNLOAD when the "TEMP DISCON – Prepare to Prime" screen (Step 3 below) appears.
3. Disconnect the return line from the patient and connect it to a bag of priming solution. Disconnect the access line from the saline bag and connect it to an empty collection bag.
4. Pump priming solution into the blood lines. (The control unit automatically returns to the Priming, Please Wait screen in Setup mode.)

5. Resume treatment by reconnecting the patient to the set and pressing the START softkey.

WARNING

If a patient is not connected to the PRISMA Set shortly after priming is complete, flush the set with at least 500 ml priming solution (saline with heparin added) before connecting a patient. This requires use of a new bag of priming solution and a new (empty) collection bag.

The "Temporary Disconnection" screens available in End mode are listed in Table 7.

Table 7. "Temporary Disconnection" Screens in End Mode

Temporary Disconnection
TEMP DISCON - Return Blood
TEMP DISCON - Prepare to Prime (first screen of instructions)
TEMP DISCON - Prepare to Prime (second screen of instructions)
Unloading pumps, please wait (optional, if set has significant clotting)

Custom Mode

Custom mode allows the operator to change the *default settings* of the PRISMA therapies. To change a default setting, the operator follows the instructions on the display to perform the following steps:

1. Enter Custom mode by pressing CUSTOM on the Choose Patient screen.
2. Choose the PRISMA therapy to be altered.
3. Review all user-controllable settings for the chosen therapy and change the default values, as desired.

   Note: The new default values are stored in memory when the EXIT CUSTOM key is pressed from any screen.

The screens available in Custom mode are listed in Table 8.

Table 8. Screens in Custom Mode

Welcome to Custom Mode
Choose Therapy to Customize
Modify Defaults
Clock
Modify Alarm Limits
Set Default Flow Rates
Modify Anticoag Defaults
Modify Settings

User-controllable Settings

User-controllable settings and the mode in which they can be altered are listed in Table 9. Each setting has a default value and a range of setting options.

Some user-controllable settings, such as alarm limits, can only be adjusted in Custom mode. These settings are listed first in the table, followed by the settings that can be adjusted in Custom, Setup, and Run modes. The settings adjustable only in Custom and Run modes are listed last.

Table 9. User-controllable Settings

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Clock	A time set by the manufacturer.	Should always be set to current year, month, day, hour.	X		
"Time to Change Set" Advisory Limit	After 72 hours of use.	After 24 to 72 hours of use. Increment: 24 hours	X		
"Access Pressure Extremely Negative" Warning Limit	- 250 mmHg	- 15 to - 250 mmHg Increment: 5 mmHg	X		
"Return Pressure Extremely Positive" Warning Limit	+350 mmHg	+15 to +350 mmHg Increment: 5 mmHg	X		
"TMP Too High" Advisory Limit	+350 mmHg	+70 to +350 mmHg Increment: 10 mmHg	X		
"Filter is Clotting" Advisory Limit	Filter pressure drop is 100 mmHg greater than initial filter pressure drop.	10 to 100 mmHg greater than initial filter pressure drop. Increment: 10 mmHg	X		
Anticoagulant Delivery Method	Continuous	Continuous or Bolus	X	X	X
Anticoagulant Continuous Delivery Rate	0 ml/hr	0, 0.5 to 5.0 ml/hr Increment: 0.1 ml/hr	X	X	X
Anticoagulant Bolus Delivery Volume	0 ml	0, 0.5 to 5.0 ml Increment: 0.1 ml	X	X	X

Table 9. User-controllable Settings (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Anticoagulant Bolus Delivery Interval	Once every 6 hours.	Once every 1 to 24 hours. Increment: 1 hour **Note:** *Immediate* option also available in Run mode only.	X	X	X
Blood Flow Rate	10 ml/min	10 to 180 ml/min Increment: 5 ml/min	X	X	X
Replacement Solution Flow Rate	0 ml/hr	CVVH: 0, 100 to 4500 ml/hr Increment: 10 ml/hr	X (2000 ml/hr maximum)	X	X
		SCUF, CVVHD, CVVHDF: 0, 100 to 2000 ml/hr Increment: 10 ml/hr	X	X	X
Dialysate Flow Rate	0 ml/hr	0 to 2500 ml/hr Increment: 50 ml/hr	X	X	X
Patient Fluid Removal Rate	0 ml/hr	SCUF: 0, 10 to 2000 ml/hr; CVVH, CVVHD, CVVHDF: 0, 10 to 1000 ml/hr Increment: 10 ml/hr	X	X	X
Pressures Display on Status screen	On	Off, On	X		X
Flow Rates Display on Status screen	On	Off, On	X		X
I/O Period on Status screen	60 minutes	60 minutes, 30 minutes, 15 minutes	X		X
I/O Reminder Beep	On	Off, On	X		X

Table 9. User-controllable Settings (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Language	R02.13.A: English	R02.13.A: English, French, German, Dutch, Italian, Spanish, Swedish	X		X[a]
	R02.13.A1: English	R02.13.A1: English, French, German, Italian	X		X[a]
	R02.13.A2: English	R02.13.A2: English, German, Spanish, Swedish	X		X[a]
	R02.13.A3: English	R02.13.A3: English, French, German, Dutch	X		X[a]

a. Changing the language in Run mode also changes the default language.

Anticoagulant Syringe Installation Procedure

A 20-cc syringe should be filled and installed in the syringe pump during Setup mode, while the Prepare Solutions screen is on the display.

- If anticoagulation of the blood flowpath is desired, the syringe should be filled with anticoagulant solution.
- If anticoagulation is not desired, the syringe should be filled with priming solution. This assures the anticoagulant line will be primed during the automatic priming cycle.

During treatment, an Advisory alarm occurs whenever the anticoagulant syringe is empty. The empty syringe can be removed and a full one installed with no interruption in treatment.

WARNING

- **To assure proper anticoagulant flow control, use only 20-cc BD, Braun, Monoject, or Terumo luer lock syringes. The internal diameter of these syringes has been verified at the time of printing this manual. The manufacturer of the PRISMA System cannot be held liable for subsequent changes that may occur to syringe dimensions. See *Anticoagulant Settings* in the Specification chapter for verified internal diameters.**
- **Use only luer lock syringes with the PRISMA System. Use of non-luer lock syringes can result in patient blood loss if the anticoagulant line becomes dislodged from the syringe. See above for the list of approved syringes.**

Initial Syringe Installation

(See Figure 14)

To install the syringe into the syringe pump, perform the following steps.

1. Fill the syringe with 20 cc of anticoagulant solution (or priming solution if anticoagulation is not desired). Push the plunger of the syringe to expel all air.
2. Open the plunger clamp by moving the slide all the way to the right.
3. Push the plunger clamp release button while moving the plunger clamp down as far as possible.
4. Attach the luer lock connector of the anticoagulant line to the anticoagulant syringe.
5. Place the wing of the syringe into the syringe holder between the metal clip and plastic housing. Snap the barrel of the syringe between the barrel clips.
6. While pushing the plunger clamp release button, move the clamp up to the bottom of the plunger. Release the button.
7. Move the slide to the left, ensuring that the plunger is securely clamped.

Changing the Syringe During Treatment

To remove an empty anticoagulant syringe and replace it with a full one during treatment, perform the following steps:

1. Clamp the anticoagulant line and disconnect it from the empty syringe.
2. Move slide to the right; press the clamp release button and move the clamp down as far as possible. Pull the empty syringe out of the syringe holder and barrel clips. Discard the syringe.
3. Fill a new syringe with 20 cc of anticoagulant solution. Push the plunger to expel all air; connect the anticoagulant line to the full syringe.
4. Install the full syringe, following Steps 5 through 7 under "Initial Syringe Installation." See Figure 8.

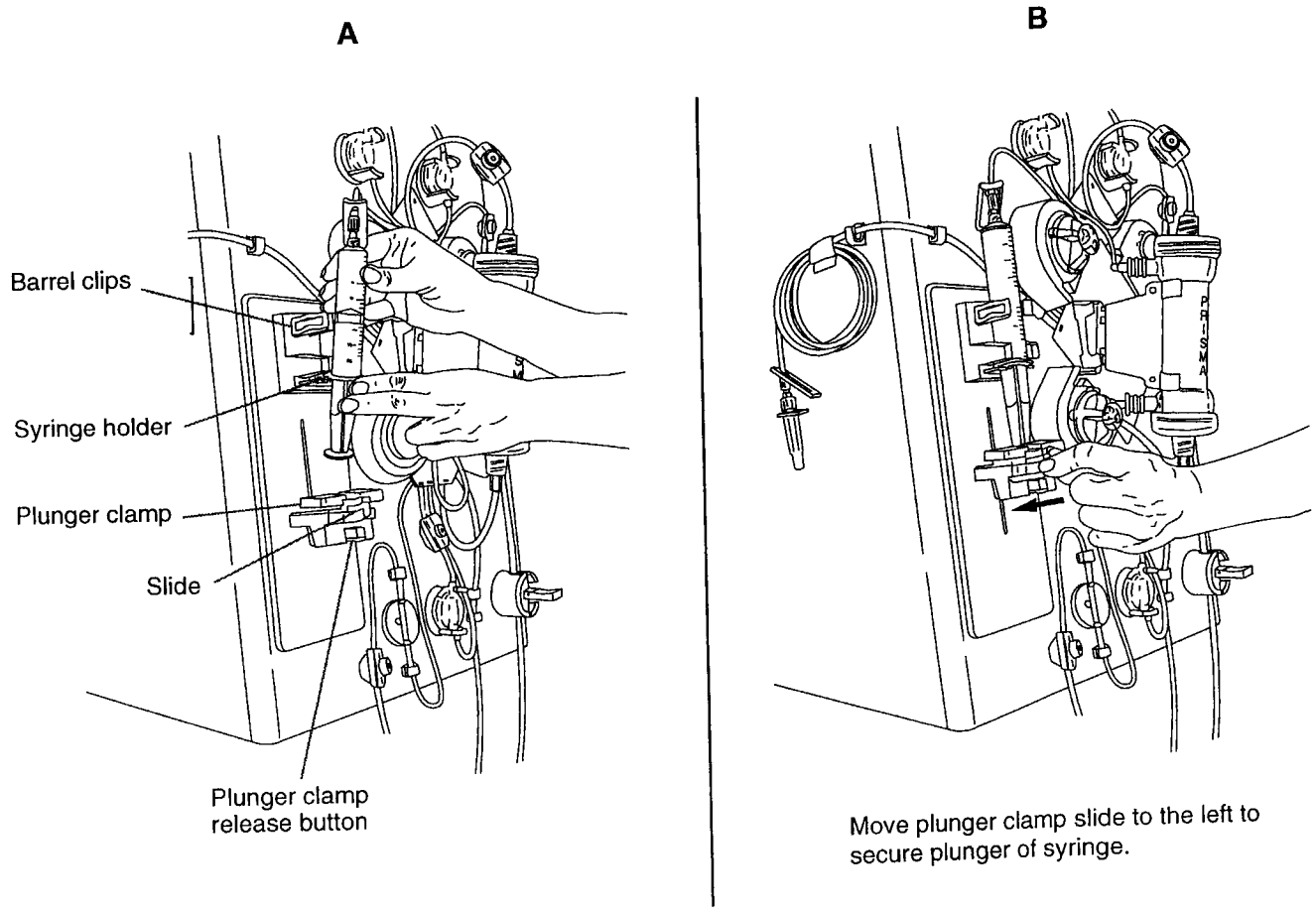


Figure 14. Installing Anticoagulant Syringe in the Syringe Pump

Warning Alarms

Warning alarms occur if conditions of possible patient hazard exist that require prompt operator intervention; for example, air bubbles in the return line or extreme positive pressure in the return line.

Control Unit Actions

The following actions occur during a Warning alarm:

- The PRISMA Control Unit enters a "safe state" by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient's blood does not circulate through the blood flowpath.
- Red light illuminates.
- Audible alarm sounds.
- Warning screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

The Warning screen gives the operator instructions for responding to the Warning alarm. Appropriate responses are different for each warning.

The alarm has been cleared when the following occur:

- Pumps restart and return line clamp opens.
- Warning screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

Chapter 4: Alarm System

The PRISMA Control Unit continually monitors itself and the PRISMA Set for proper functioning during operation. If an abnormal situation occurs, the control unit signals a Warning, Malfunction, Caution, or Advisory alarm.

The operator is notified of an alarm condition via a red or yellow status light, an audible alarm, and an Alarm screen on the display. Each Alarm screen has instructions for how to respond to the alarm and provides a MUTE key, which allows the operator to temporarily silence the alarm (for 2 minutes). When applicable, a Help screen is available to provide additional information.

WARNING

- **When responding to any alarm, carefully follow the instructions on the displayed Alarm screen and its associated Help screen.**
- **To clear some alarms, the PRISMA Control Unit must *override* the alarm for a brief time (60 seconds). The Alarm screen notifies the operator that the alarm will be overridden if the OVERRIDE softkey is pressed. A new alarm for the same condition cannot occur during the override period. Therefore, *carefully observe the set and all operation during the override period.* If the alarm condition is still present after the override period, the control unit issues a new alarm.**
- **If power is lost to the PRISMA Control Unit, the patient can be manually disconnected from the set. If performing a Manual Termination With Blood Return, visually check for air in the blood return line until the patient is disconnected.**
- **The control unit may not be able to detect disconnections of the set from the patient's catheter. Carefully observe the set and all operation while using the PRISMA System.**

Warning Alarms

Warning alarms occur if conditions of possible patient hazard exist that require prompt operator intervention; for example, air bubbles in the return line or extreme positive pressure in the return line.

Control Unit Actions

The following actions occur during a Warning alarm:

- The PRISMA Control Unit enters a "safe state" by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient's blood does not circulate through the blood flowpath.
- Red light illuminates.
- Audible alarm sounds.
- Warning screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

The Warning screen gives the operator instructions for responding to the Warning alarm. Appropriate responses are different for each warning.

The alarm has been cleared when the following occur:

- Pumps restart and return line clamp opens.
- Warning screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

Overridden Warning Alarms

To clear some Warning alarms, the PRISMA Control Unit must override the alarm for a brief time. After completing the response instructions given on the Warning screen, the operator presses the OVERRIDE softkey. During the override period, the following occur:

- Pumps restart and return line clamp opens.
- Warning screen leaves the display.
- Yellow light illuminates.
- EXAMINE ALARMS softkey remains displayed.

When the override period is complete, the alarm either clears or recurs.

Malfunction Alarms

Malfunction alarms occur if patient safety cannot be monitored due to a failure of the system; for example, failure during self-tests, errors in the software, or hardware failure.

Control Unit Actions

The following actions occur during a Malfunction alarm:

- The PRISMA Control Unit enters a "safe state" by stopping all pumps and closing the return line clamp. Treatment is suspended. The patient's blood does not circulate through the blood flowpath.
- Red light illuminates.
- Audible alarm sounds.
- Malfunction screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

Some malfunctions can be cleared by the operator; others require service by a trained and qualified technician. The Malfunction screen gives instructions for responding to the Malfunction alarm. Appropriate responses are different for each malfunction.

The alarm has been cleared when the following occur:

- Pumps restart and return line clamp opens.
- Malfunction screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

If the operator cannot clear a particular Malfunction alarm, it must be cleared in Service mode by a trained and qualified technician. The Malfunction screen gives appropriate instructions, which include the following:

- End the patient's treatment (with or without returning blood).

  Note: If the DISCONNECT key is not available, the treatment can be terminated manually. Instructions for manual termination are given in the Troubleshooting chapter.

- Turn off the power.
- Call for service to repair the control unit and clear the alarm.

Overridden Malfunction Alarms

To clear some Malfunction alarms, the PRISMA Control Unit must override the alarm for a brief time. After completing the response instructions given on the Malfunction screen, the operator presses the OVERRIDE softkey. During the override period, the following occur:

- Pumps restart and return line clamp opens.
- Malfunction screen leaves the display.
- Yellow light illuminates.
- EXAMINE ALARMS softkey remains displayed.

When the override period is complete, the alarm either clears or recurs.

Caution Alarms

Caution alarms occur if a condition exists for which the proper action is to suspend treatment, but it is safe to continue blood and anticoagulant flow; for example, the dialysate or replacement solution bag is empty, or the effluent bag is full.

Control Unit Actions

The following actions occur during a Caution alarm:

- Replacement solution, dialysate, and effluent pumps stop.
- Blood and anticoagulant pumps continue to operate and the return line clamp remains open.[3] The patient's blood continues to circulate through the blood flowpath, but treatment is suspended.
- Yellow light illuminates.
- Audible alarm sounds.
- Caution screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

The Caution screen gives the operator instructions for responding to the Caution alarm. Appropriate responses are different for each caution.

The alarm has been cleared when the following occur:

- Replacement, dialysate, and effluent pumps restart.
- Caution screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

3. If a Caution alarm occurs during the automatic priming sequence in Setup mode, the blood and anticoagulant pumps stop. The return clamp remains open.

Advisory Alarms

Advisory alarms occur if a condition exists of which the operator should be aware, but the patient is not at immediate risk; for example, when preventive maintenance is due. The patient's treatment continues during an Advisory alarm.

Control Unit Actions

The following actions occur during an Advisory alarm:

- No pumps stop; treatment continues.
- Yellow light illuminates.
- Audible alarm sounds.
- Advisory screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

The "Time for Preventive Maintenance" Advisory alarm can only be cleared by a service technician; the other advisories can either be cleared *or overridden* by the operator; some advisories are also *self-clearing.*

The Advisory screen gives the operator instructions for responding to the Advisory alarm; appropriate responses are different for each advisory.

When an advisory has been cleared (self-cleared or cleared by the operator), the following occur:

- Advisory screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.

Overridden Advisory Alarms

Many Advisory alarms can be overridden by the operator. If an Advisory alarm is overridden, it remains overridden indefinitely. If the overridden alarm is a self-clearing alarm, it clears when the condition no longer exists. If the overridden alarm is not self-clearing, it remains in a list of pending alarms. Pending alarms can be viewed by pressing the EXAMINE ALARMS softkey. See the "Alarm Priorities" section in this chapter for more information.

If the operator overrides an Advisory alarm, the following control unit actions occur:

- Advisory screen leaves the display.
- Yellow light remains illuminated.
- EXAMINE ALARMS softkey remains displayed.

Alarm Priorities

All alarms are prioritized. This means that if multiple problems exist, only the highest-priority Alarm screen is displayed. Clearing the highest-priority alarm causes the next-highest-priority Alarm screen to be displayed, and so on. As each alarm appears on the display, the operator follows the instructions on the screen in order to respond to the alarm.

The priority for each alarm is shown in Table 9.

Whenever an alarm occurs, the EXAMINE ALARMS softkey appears and the name of the alarm is stored in a *pending (active) alarms* list. Until the alarm is cleared, the EXAMINE ALARMS softkey remains displayed and the alarm name remains in the pending alarms list. Overridden alarms are considered active alarms.

The operator can press EXAMINE ALARMS to view the list of pending alarms.

Table 9. Priority of PRISMA System Alarms

Priority Number	Alarm Title
1	Parity error (Memory malfunction.) **Note:** This Malfunction alarm takes precedence over all other alarms.
Warnings	
2	Air in blood
3	Micro air in blood
4	Return disconnection
5	Set disconnection
6	Access disconnection
7	Filter is clotted
8	Blood leak detected
9	Return pressure (Return pressure extremely positive.)
10	Access pressure (Access pressure extremely negative.)
11	Filter pressure (Filter pressure extremely positive.)
12	Power failure
Malfunctions	
13	Air detector
14	Clamp stuck open
15	Blood pump (Rate is incorrect.)
16	Effluent pump (Rate is incorrect.)

Table 9. Priority of PRISMA System Alarms (cont.)

Priority Number	Alarm Title
Malfunctions (cont.)	
17	Replacement pump (Rate is incorrect.)
18	Dialysate pump (Rate is incorrect.)
19	Normalize BLD failed
20	Self-test failure (Periodic self-test failed at test: XXXXX) **Note:** Test in question is identified on the Alarm screen.
21	Syringe pump (Rate is incorrect.)
22	Blood leak detector (Effluent line not properly installed in blood leak detector.)
23	Clamp stuck closed
24	Scales (Scale out of calibration: XXXXX) **Note:** Scale in question is identified on the Alarm screen.
25	Stuck key
26	Command path (Internal malfunction.)
27	BB memory failure (Initialization test failed.)
28	DPRAM failure (Internal malfunction.)
29	RAM R/W failure (Initialization test failed.)

Table 9. Priority of PRISMA System Alarms (cont.)

Priority Number	Alarm Title
Malfunctions (cont.)	
30	Prime self-test
31	Pressure zero test
32	Scale zero test
33	Checksum interrupted
Cautions	
34	Effluent weight (Incorrect weight change detected.)
35	Replacement weight (Incorrect weight change detected.)
36	Dialysate weight (Incorrect weight change detected.)
37	Effluent bag full
38	Dialysate bag empty
39	Replacement bag empty
40	Anticoag syringe empty **Note:** This Caution is enabled only during priming (Setup mode). During a patient treatment (Run mode), the Advisory: Anticoag syringe empty alarm is enabled.
41	TMP excessive (Transmembrane pressure exceeds membrane pressure limit.)

Table 9. Priority of PRISMA System Alarms (cont.)

Priority Number	Alarm Title
Advisories	
42	Periodic self-test in progress (Test complete in approximately 2 minutes.)
43	Return pressure (Return pressure is dropping.)
44	Access pressure (Access pressure is rising.)
45	Access too negative
46	Return too positive
47	Blood flow stopped (Machine has been left in the Stop screen for 60 seconds.)
48	Anticoag syringe empty
49	Bag placement (Effluent scale indicates an incorrect bag placement.)
50	Bag placement (Replacement scale indicates an incorrect bag placement.)
51	Bag placement (Dialysate scale indicates an incorrect bag placement.)
52	Filter is clotting (Filter is beginning to clot.)
53	TMP too high (Transmembrane pressure has reached user-set pressure limit.)
54	Time to change set
55	Time for preventive maintenance
56	Return disconnection cannot be detected
57	Access disconnection cannot be detected

Chapter 5: Pressure Monitoring

The PRISMA Control Unit has an integral pressure monitoring system providing noninvasive assessment of the access, return, and effluent lines, and the filter.

Monitoring provides notification to the operator of abnormal pressure conditions, such as extreme positive pressure in the return line.

Monitoring also provides data needed by PRISMA software to calculate other vital pressure conditions, such as *transmembrane pressure* (TMP) and *filter pressure drop*. These calculations are used to provide notification that clotting has begun in the filter or that the filter has clotted and the PRISMA Set must be changed.

CAUTION

After priming is complete, *do not* remove the pressure pods from the pressure sensor housings. Pressure sensing becomes inaccurate if pods are removed, or if they are removed and then reinserted in the sensor housings. If pods are removed, the set must be changed or the Diaphragm Reposition procedure must be performed.

Pressure Monitoring Components

Components of the pressure monitoring system include:

- Pressure pods. The PRISMA Set has a pressure pod in each of these locations: access line (access pod), return line (return pod), blood line immediately before the filter (filter pod), effluent line (effluent pod).
- Pressure sensor housings. The front panel of the control unit has four sensor housings. Their locations are shown in Figure 1, "PRISMA Control Unit" in the Product Description chapter. The housings receive the pressure pods of the PRISMA Set and provide connection between the pods and the pressure sensors inside the control unit.
- Pressure sensors. A pressure sensor (transducer) is located inside the control unit, behind each pressure sensor housing.

Each pressure pod has a fluid compartment (top side) and an air compartment (bottom side). The compartments are separated by a flexible diaphragm. During a patient treatment, the fluid compartment is filled with the fluid flowing through the line to which the pod is attached.

Fluctuations in fluid pressure cause the diaphragm of the pod to move, compressing or expanding the air column on the other side of the diaphragm. The pressure sensor receives these fluctuations and converts them to electrical signals that are sent to PRISMA software and interpreted as a pressure value.

Pressures During Operation

Pressures vary within the PRISMA Set, depending on individual patient characteristics (blood pressure, size, general condition, hematocrit), as well as size of the patient catheter, flow rates, and therapy being delivered. Current pressure at each pressure pod can be viewed on the Status screen during a patient treatment.

The following information is general and intended only to acquaint the operator with broad pressure ranges that can be expected with use of the PRISMA System.

Access pod pressure	Always negative Typical: -50 to -150 mmHg
Return pod pressure	Always positive Typical: +50 to +150 mmHg
Filter pod pressure	Always positive The filter pod is located immediately before the filter and measures the area of most positive (highest) pressure in the PRISMA Set. Typical: +100 to +250 mmHg
Effluent pod pressure	Can be positive or negative, depending on the ultrafiltration rate and therapy chosen. Typical: >+50 to -150 mmHg

Extreme Pressure Limits

Pressure limits are enforced by PRISMA software to ensure patient safety. If a monitored pressure goes outside the manufacturer-established *extreme* limits, a Warning alarm occurs. Warning alarms stop all pumps and close the return line clamp. Figure 15 shows the manufacturer-established extreme pressure limits.

Two of the extreme pressure limits (Warning: Access Pressure Extremely Negative and Warning: Return Pressure Extremely Positive) are operator-settable in Custom mode. If desired, the operator can modify these limits, so that a Warning alarm will occur prior to reaching the manufacturer-established extreme limit. For more information, see "Custom Mode" and "User-controllable Settings" in the Operation chapter.

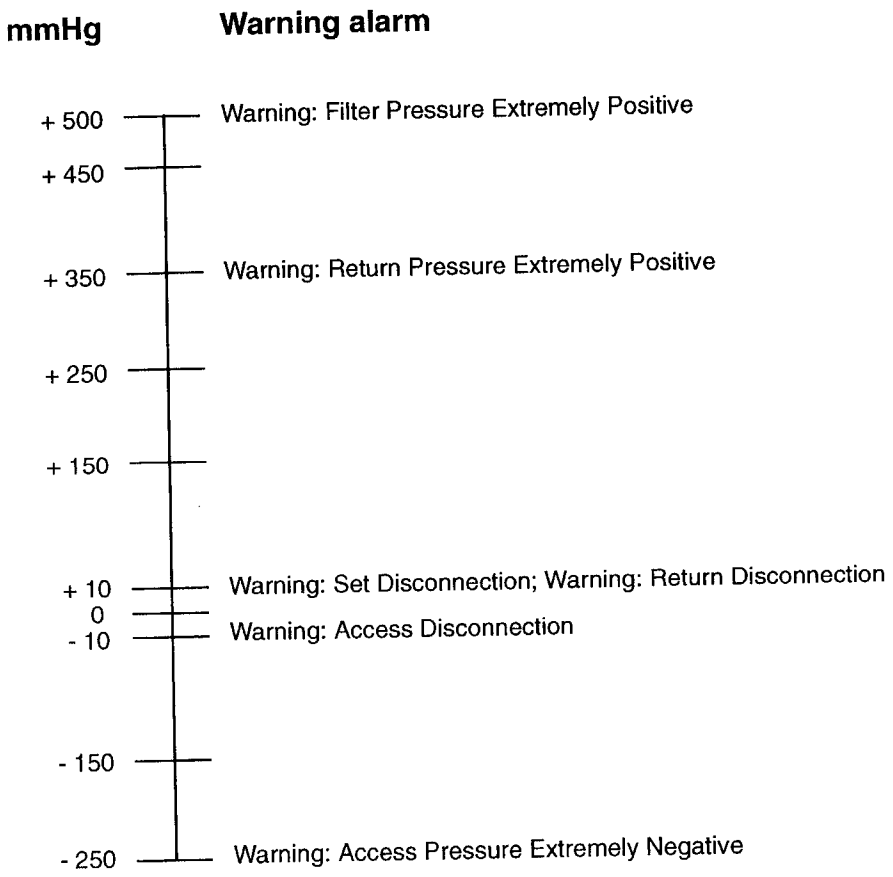


Figure 15. Extreme Pressure Limits

Pressure Operating Points

Whenever the PRISMA Control Unit is operating, a *reference* pressure value is stored in software memory for each pressure pod. This value is called the *pressure operating point.* Software continually compares the current pressure at each pod with the pressure operating point. In this way, the control unit can detect changing pressure conditions in the PRISMA Set and notify the operator with an Advisory alarm.

Initial Values

Operating points are initially established a short time after the control unit enters Run mode, when pumps have attained the proper speed and blood flow through the set is stabilized. The amount of time that elapses before all operating points are established depends on the operator-set blood flow rate, as shown below.

Blood flow rate	Time to establish operating point
0 to 50 ml/min	4 minutes
55 to 100 ml/min	2 minutes
105 to 180 ml/min	90 seconds

The operating points are established by recording the current pressure at each pressure pod at the end of the time periods shown above. The machine cannot issue pressure Advisory alarms until the operating points are established.

Subsequent Values

During operation, operating points are reset whenever one or more of the following occurs.

1. After the blood pump changes speed during Run mode (due to operator changing the flow rate).
2. After the blood pump restarts (following an alarm or after pressing RESUME from the Stop screen).
3. After the operator presses the CONTINUE softkey from a pressure trending Advisory alarm screen.

Operating points are reset within 30 seconds. During this time, the Advisory alarms pertinent to pressure fluctuations cannot be issued.

Pressure Trending Limits

If the access or return pressure changes 50 mmHg negative or positive from its pressure operating point, the control unit notifies the operator by issuing an Advisory alarm, as shown in Figure 16. These alarms can be cleared by pressing the CONTINUE key on the alarm screen. This resets the pressure operating points to the current pressures in each pod.

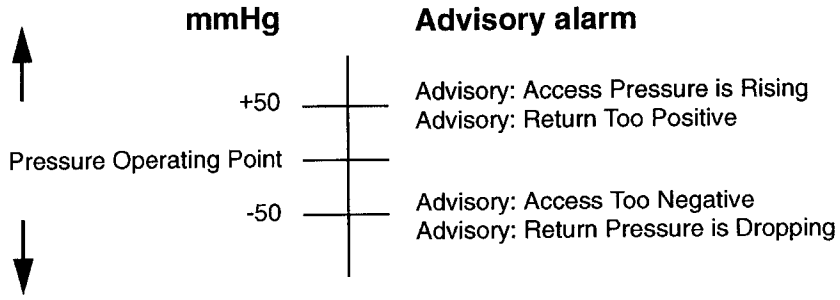


Figure 16. Pressure Trending Limits

"Cannot Detect Disconnection" Limits

If the access pod operating point is set more positive than -10 mmHg, or if the return pod operating point is set below +10 mmHg, a "Cannot Detect Disconnection" Advisory alarm occurs, as shown in Figure 17. The operator is notified that the pressure is too close to zero for disconnection monitoring to be enabled.

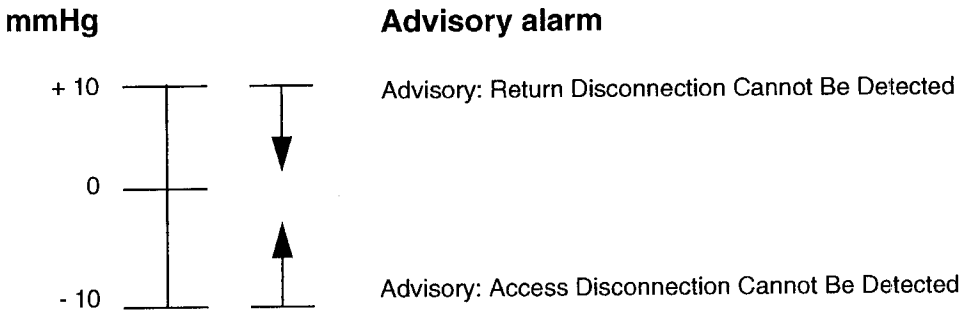


Figure 17. "Cannot Detect Disconnection" Pressure Limits

Software-calculated Pressures

PRISMA software uses monitored pressure values to calculate other vital pressure conditions, including *transmembrane pressure* (TMP) and *filter pressure drop*. These pressures indicate conditions within the filter. They are used to provide notification that clotting or membrane pore plugging (clogging) is beginning in the filter—or that the filter has clotted or membrane pores have plugged (clogged) and the PRISMA Set must be changed.

Transmembrane Pressure (TMP)

Transmembrane pressure is the pressure exerted on the filter membrane during operation of the PRISMA System. It reflects the pressure difference between the fluid and blood compartments of the filter.

The TMP is calculated by PRISMA software as follows:

$$TMP = \frac{\text{Filter Pressure} + \text{Return Pressure}}{2} - \text{Effluent Pressure}$$

During a patient treatment, permeability of the membrane decreases due to protein coating on the blood side of the membrane. This causes the TMP to increase.

During operation, software sets the initial TMP value at the same time as the initial pressure operating points are established (shortly after entering Run mode). Thereafter, the initial TMP value is reset each time the blood flow, patient fluid removal, or replacement solution rates are changed.

The *amount of increase* above the initial TMP value contributes to the Advisory: Filter Is Clotting alarm. This TMP parameter is settable only in Service mode by a trained and qualified person. For more information, see "Filter Pressure—Filter Is Clotting Advisory Limits" in the Specifications chapter. Additional information is available in the *PRISMA System Service Manual*.

If the TMP rises above +350 mmHg, the Advisory: TMP Too High alarm occurs. If desired, the operator can lower this Advisory alarm limit, so that the advisory occurs prior to reaching +350 mmHg. For more information, see "Custom Mode" and "User-controllable Settings" in the Operation chapter. If the TMP increases beyond the membrane capacity of +450 mmHg, the Caution: TMP Excessive alarm occurs.

Filter Pressure Drop

Filter pressure drop is a calculated value used to determine pressure conditions in the hollow fibers of the filter. Filter pressure drop is calculated by PRISMA software as follows:

Filter pod pressure
- Return pod pressure
= Filter pressure drop

During a patient treatment, microclotting can occur in the hollow fibers of the filter, eventually leading to gross clotting and the need to change to a new PRISMA Set. Clotting creates resistance as blood flows through the filter fibers and causes the filter pressure drop to increase.

The following example shows how filter pressure drop increases with filter use:

	Begin Time	After Filter Has Been in Use
Filter pod pressure	100 mmHg	200 mmHg
- Return pod pressure	90 mmHg	110 mmHg
= Filter pressure drop	10 mmHg	90 mmHg

In the above example, filter pressure drop increased by 80 mmHg.

During operation, software sets the initial value for filter pressure drop at the same time the initial operating points are established (shortly after entering Run mode). This initial value is reset each time the blood flow rate is changed. The *amount of increase* above the initial filter pressure drop contributes to the Advisory: Filter Is Clotting alarm. The operator can set the amount of increase that will trigger the alarm. For more information, see "Custom Mode" and "User-controllable Settings" in the Operation chapter and "Filter Pressure—Filter Is Clotting Advisory Limits" in the Specifications chapter. Additional information is available in the *PRISMA System Service Manual*.

Chapter 6: Troubleshooting

The alarm screens give on-line instructions for responding to most alarm situations. Under certain circumstances, however, the alarm system cannot give the necessary detailed instructions. This chapter of the manual provides the additional information that may be needed.

Tables 10, 11, 12, and 13 list the PRISMA System alarms by *category*, as follows: Table 10: Warnings, Table 11: Malfunctions, Table 12: Cautions, Table 13: Advisories. Possible causes for each alarm, and appropriate operator actions are also given. Within each category, the alarms are listed in alphabetical order. Table 14 provides instructions for handling other abnormal situations that could occur.

This chapter also contains instructions for Manual Termination of Treatment procedures (with and without returning blood to the patient), Pod Diaphragm Reposition procedures, and Air Removal procedures.

Table 10. Warning Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Access disconnection Alarm occurs if access pressure is more positive than -10 mmHg *and* the access pressure operating point is more negative than -10 mmHg.	1. Access catheter disconnected; line is clamped below the access pressure pod. 2. Access pressure pod not installed or debris in access sensor housing. 3. Blood flow rate too low for the access device. 4. Access pressure sensor failed.	1. Remedy; press OVERRIDE.[a] 2. Perform Pod Diaphragm Reposition procedure on access pod (see instructions at end of Troubleshooting chapter); press OVERRIDE.[a] 3. Increase the blood flow rate; return to Alarm screen and press OVERRIDE.[a] Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via the STOP key.[b] If alarm recurs with new set, see Step 4. 4. End treatment via STOP. Call for service.
Access pressure (Access pressure extremely negative.) Alarm occurs if access pressure is more negative than the user-settable "Access Pressure Extremely Negative" Warning Limit.	1. Access line clamped or kinked. 2. Access catheter clotted or out of position in vein. 3. Patient is moving or being moved. 4. Blood flow rate too high for the access device. 5. Access pressure sensor failed.	1. Remedy; press CONTINUE. 2. Flush or reposition per hospital protocol; press CONTINUE. 3. Press CONTINUE. 4. Lower the blood flow rate; return to Alarm screen and press CONTINUE. Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with new set, see Step 5. 5. End treatment via STOP. Call for service.

Table 10. Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Air in blood	1. Return line not installed in air detector. 2. Air bubble in line due to disconnected line, leaking connection, or incompletely primed set.	1. Press return line into air detector; press CONTINUE. 2. Remove air via instructions on Alarm screen. (Instructions also given under "Air Removal Procedures" at the end of the Troubleshooting chapter.) Identify and remedy cause; press CONTINUE. Note: If air is prevalent in entire set, change the set via the DISCONNECT key.
Blood leak detected	1. Air bubble in effluent line at level of blood leak detector. 2. Effluent line not properly installed in blood leak detector. 3. Liquid or other debris in tubing path through the detector. 4. Leak in filter membrane.	1. Dislodge bubble by giving the effluent pump a quick half-turn counterclockwise. Press OVERRIDE.[a] 2. Press line into detector from the bottom up and route securely through tubing guides. Press OVERRIDE.[a] 3. Remove line from detector. Using a "flossing" action, clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly. Clean effluent line with water and dry thoroughly. Reinsert line into detector and tubing guides. Press OVERRIDE.[a] **Warning:** If the effluent line is repositioned or removed/ reinserted in detector, the detector must be reset by pressing NORMALIZE BLD on the Status screen after the alarm clears. This must be done before continuing patient treatment. 4. Change the set via STOP.[b]

Table 10. Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Filter is clotted Alarm occurs if filter pressure minus return pressure is ≥250 mmHg or if one or both of the "Filter Is Clotting" Advisory Limits is reached and TMP is ≥450 mmHg.	1. Clamped line(s) in blood flowpath. 2. Replacement solution flow rate is too high for filter in use. 3. Clots have formed in the filter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath. 4. Anticoagulant syringe incorrectly installed or syringe pump failed.	1. Unclamp lines; press CONTINUE. 2. Reduce replacement solution flow rate. 3. Change the set via STOP.[b] Test patient's clotting parameters and adjust anticoagulant delivery if needed. 4. Press STOP and change the set. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect anticoagulant line to a medically acceptable alternate anticoagulant delivery system. Call for service to repair pump.
Filter pressure **(Filter pressure extremely positive.)**	1. Line between filter pressure pod and filter is clamped or kinked. 2. Machine is operating at high return pressure and clotting has begun in filter. 3. Filter pressure sensor failed.	1. Remedy; press CONTINUE. 2. Lower the blood flow rate, return to Alarm screen and press CONTINUE. The filter pressure will drop as operation commences. (The appropriate Advisory or Warning alarm occurs when filter clotting becomes problematic.) Note: If Steps 1 and 2 do not clear this alarm, the set can be changed via STOP.[b] If alarm recurs with new set, see Step 3. 3. End treatment via STOP. Call for service.

Table 10. Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Micro air in blood	Leaking connection; set not fully primed.	Remove micro air via instructions on Alarm screen. (Instructions also given under "Air Removal Procedures" at the end of the Troubleshooting chapter.) Identify and remedy cause; press OVERRIDE.[a] Note: If air is prevalent in entire set, change the set via the DISCONNECT key.
Power failure (Power lost for more than 15 seconds after machine entered Run mode.)	Main power failure; machine suddenly unplugged; power switch turned off.	- Inspect blood flowpath for signs of clotting. If clotted, change the set via STOP.[b] - If flowpath is not clotted, press CONTINUE. (Clears alarm and restarts treatment at same place as when power was lost.) Note: If set was manually unloaded during power loss, you can do one of the following: (a) continue treatment with a new set by pressing STOP, then CHANGE SET, (b) end the treatment by pressing STOP, then END TREATMENT.[b]

Table 10. Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Return disconnection Alarm occurs if return pressure is lower than +10 mmHg *and* the return pressure operating point is higher than +10 mmHg.	1. Return catheter is disconnected; line is clamped above the return pressure pod. 2. Return pressure pod not installed or debris in return sensor housing. 3. Blood flow rate too low for the access device. 4. Return pressure sensor failed.	1. Remedy; press OVERRIDE.[a] 2. Perform Pod Diaphragm Reposition procedure on return pod (see instructions at end of Troubleshooting chapter); press OVERRIDE.[a] 3. Increase the blood flow rate; return to Alarm screen; press OVERRIDE.[a] Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with new set, see Step 4. 4. End treatment via STOP. Call for service.
Return pressure (Return pressure extremely positive.) Alarm occurs if return pressure is more positive than the user-settable "Return Pressure Extremely Positive" Warning Limit.	1. Return line clamped or kinked. 2. Return catheter is clotted or out of position in vein. 3. Blood flow rate too high. 4. Return pressure sensor failed.	1. Remedy; relieve excess pressure in return line by (a) manually turning effluent pump counterclockwise, or (b) pulling out on the return line clamp. Press CONTINUE. 2. Flush or reposition per hospital protocol; relieve excess pressure as described in Step 1; press CONTINUE. 3. Lower the blood flow rate; return to Alarm screen; relieve excess pressure as described in Step 1. Press CONTINUE. Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with new set, see Step 4. 4. End treatment via STOP. Call for service.

Table 10. Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Set disconnection Alarm occurs if filter pressure is lower than +10 mmHg *and* the filter pressure operating point is higher than +10 mmHg.	1. Line between blood pump and filter is disconnected; line between blood pump and filter pod is clamped.	1. Remedy; press OVERRIDE.[a]
	2. Filter pressure pod not installed or debris in filter sensor housing.	2. Perform Pod Diaphragm Reposition procedure on filter pod (see instructions at end of Troubleshooting chapter); press OVERRIDE.[a]
	3. Blood flow rate too low for the access device.	3. Increase the blood flow rate; return to Alarm screen and press OVERRIDE.[a] Note: If Steps 1, 2, and 3 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with new set, see Step 4.
	4. Filter pressure sensor failed.	4. End treatment via STOP. Call for service.

a. OVERRIDE briefly overrides the alarm. Monitor closely.
b. STOP stops all pumps, clears the alarm, and displays the Stop screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient from set.
c. Manual termination instructions are provided at the end of the Troubleshooting chapter.

Table 11. Malfunction Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Air detector Air detector failed self-tests.	Air detector failed self-tests.	- Press RETEST. - If alarm does not clear, end treatment via DISCONNECT [c] or manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
BB memory failure (Initialization test failed.)	Initialization test failed.	Turn off machine. End treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Blood leak detector (Effluent line not properly installed in blood leak detector.) Blood leak detector failed self-tests. *(continued on next page)*	1. Effluent line is not installed, is improperly installed, or is removed from blood leak detector. 2. Liquid or other debris in tubing path through the detector. *(continued on next page)*	1. Press line into detector from bottom up and route securely through tubing guides. Press RETEST. 2. Remove line from detector. Using a "flossing" action, clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly. Clean effluent line with water and dry thoroughly. Reinsert line into detector and tubing guides. Press OVERRIDE. **Warning:** If the effluent line is repositioned or removed/ reinserted in detector, the detector must be reset by pressing NORMALIZE BLD on the Status screen after the alarm clears. This must be done before continuing patient treatment. *(continued on next page)*

Table 11. Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Blood leak detector *(continued)*	*(continued)* 3. Blood leak detector failed.	*(continued)* 3. If alarm does not clear, end the treatment via DISCONNECT [c] or manually.[d] Call for service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Blood pump **(Rate is incorrect.)**	1. Pump has been manually turned. 2. Impeding object in pump raceway. 3. Thumb screw in center of rotor has loosened. 4. Pump failed.	1. Press CONTINUE. 2. Remove object; press CONTINUE. 3. Tighten thumb screw; press CONTINUE. 4. If alarm does not clear, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Checksum interrupted **(Cannot verify data in block: XX)** Data block in question is identified on the Alarm screen.	Power loss occurred while internal "checksum" information update was in progress. Some settings may have been lost.	Review the current alarm limits displayed on the Alarm screen. - If limits are incorrect, end treatment via DISCONNECT [c] or manually.[d] Reset limits in Custom mode, then restart treatment. - If limits are correct, press SET FLOW RATES and review current flow rates. Reset rates, if necessary. Press CONTINUE. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 11. Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Clamp stuck closed	1. External force on return line clamp. 2. Return line clamp failed.	1. Remove external force; press RETEST. 2. If alarm does not clear, end the treatment via DISCONNECT [c] or manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Clamp stuck open	1. Foreign object under the return line clamp. 2. Return line clamp failed.	1. Pull clamp open and remove object. Let clamp snap shut. Press RETEST. 2. If alarm does not clear, end treatment via DISCONNECT [c] or manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Command path (Internal malfunction.)	Internal malfunction.	Turn off machine. End treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Dialysate pump (Rate is incorrect.)	1. Pump has been manually turned. 2. Impeding object in pump raceway. 3. Thumb screw in center of rotor has loosened. 4. Pump failed.	1. Press CONTINUE. 2. Remove object; press CONTINUE. 3. Tighten thumb screw; press CONTINUE. 4. If alarm does not clear, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 11. Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
DPRAM failure (Internal malfunction.)	Internal malfunction.	Turn off machine. End treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Effluent pump (Rate is incorrect.)	1. Pump has been manually turned. 2. Impeding object in pump raceway. 3. Thumb screw in center of rotor has loosened. 4. Pump failed.	1. Press CONTINUE. 2. Remove object; press CONTINUE. 3. Tighten thumb screw; press CONTINUE. 4. If alarm does not clear, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Normalize BLD failed (Filter blood leak; defective effluent line; detector failed.)	Filter blood leak; defective effluent line; blood leak detector failed.	- Press CHANGE SET and follow the instructions to load a new set. - If alarm recurs with new set, detector has failed. Press DISCONNECT to end the treatment. Call for service.
Parity error (Memory malfunction.)	Memory malfunction.	- To reload memory and clear the alarm, turn machine off, then on. - If alarm recurs, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 11. Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Pressure zero test Zero test of one or more pressure sensors failed.	1. One or more pressure pods are installed in pressure sensor housings, but should not be installed yet. 2. One or more pressure sensors failed.	1. If pressure pods are installed in housings, remove them. Press RETEST. 2. If alarm does not clear, turn off machine. Call for service.[a]
Prime self-test **(Failure Due To: XXXX)** XXXX = 4-digit code identifying one or more of the tests that make up the periodic self-test. (The periodic self-test is run as part of the prime self-test sequence.)	Periodic self-test failed.	- Use Appendix A to locate the test failure number(s) for each digit in the 4-digit code. Follow the remedy instructions provided.
(Failure Due To: Blood Leak Detector Normalization OR **Blood Leak Detector Threshold)**	1. Effluent line not correctly installed in blood leak detector. 2. Air bubble in effluent line at level of blood leak detector. 3. Set not fully primed. 4. Blood leak detector failed.	1. Remove effluent line from detector and reinstall. Press RETEST. 2. Dislodge bubble by giving the effluent pump a quick half-turn counterclockwise. Press RETEST. 3. Hang new 1-L bag of priming solution and connect return line to it. Connect access line to an empty collection bag. Press REPRIME. Note: If Steps1, 2, and 3 do not clear the alarm, the set can be unloaded and alarm cleared via UNLOAD. If alarm recurs with same "Failure Due To: Blood Leak Detector Normalization or Threshold" message, see Step 4. 4. Unload set; call for service.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 11. Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test *(continued)* **(Failure Due To: PRISMA Set Recognition Test Failed)**	*(continued)* 1. PRISMA TPE Set is loaded, but a CRRT therapy is chosen.	*(continued)* 1. Unload set and clear alarm via UNLOAD. (Control Unit proceeds to Disconnect Patient, then Treatment Complete.) Obtain a PRISMA Set for CRRT and start over.
	2. Dialysate line is clamped.	2. Unclamp dialysate line, identify problem and remedy; press RETEST.
	3. Effluent pressure pod or dialysate pump segment not installed.	3. Identify problem and remedy; press RETEST. Note: To install the dialysate pump segment, manually turn pump until segment works itself into raceway.
	4. Effluent pressure pod failed due to kinked line(s) in the set.	4. Ensure there are no kinks or occlusions in the lines of the set; press RETEST. Note: If alarm recurs due to this cause, it may be necessary to do the Diaphragm Reposition procedure on the effluent pod before pressing RETEST. (See instructions at end of Troubleshooting chapter.)
	5. Priming solution bag empty	5. Hang new 1-L bag of priming solution and connect return line to it. Connect access line to an empty collection bag, if necessary. Press REPRIME. Note: If alarm recurs after doing Steps 1 through 5, see Step 6.
	6. Filter port(s) leaking. Note: There are two filter ports which connect the fluid compartment of the filter to the dialysate and effluent lines of the set.	6. Tighten luer connections. Press RETEST. If leaking does not stop, follow directions in Step 1 to unload set and start again with new set.
	7. Effluent pressure sensor (internal) failed; dialysate pump failed.	7. Unload set; call for service.

Table 11. Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
RAM R/W failure (Initialization test failed.) All lights are illuminated with this alarm.	Initialization test failed.	- To reload memory and clear the alarm, turn machine off, then on. - If alarm recurs, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Replacement pump (Rate is incorrect.)	1. Pump has been manually turned. 2. Impeding object in pump raceway. 3. Thumb screw in center of rotor has loosened. 4. Pump failed.	1. Press CONTINUE. 2. Remove object; press CONTINUE. 3. Tighten thumb screw; press CONTINUE. 4. If alarm does not clear, end treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Scales (Scale out of calibration: XXXX) Scale in question is specified on the Alarm screen.	1. Specified scale is out of calibration. 2. Room temperature variations are greater than ±3 °C (5.4 °F) from the temperature at which the scales were calibrated.	1. Press RETEST. If alarm does not clear, end treatment via DISCONNECT [c] or manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air. 2. Call for service.

Table 11. Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Scale zero test Zero test of one or more scales failed.	1. Foreign objects are touching scales or hanging from scale hooks. 2. Room temperature variations are greater than ±3 °C (5.4 °F) from the temperature at which the scales were calibrated. 3. One or more scales failed.	1. Make sure nothing is touching scales and no foreign objects are on scale hooks. Press RETEST. 2. Call for service. 3. If alarm does not clear, turn off machine. Call for service.[a]
Self-test failure (Failure Due To: XXXX) XXXX= 4-digit code identifying the test(s) that failed.	One or more of the tests conducted during the periodic self-test have failed.	- Use Appendix A to locate the test failure number(s) for each digit in the 4-digit code. Follow the remedy instructions provided.
Stuck key	1. External force on one or more softkeys for more than 5 minutes. 2. Touchscreen malfunction.	1. Remove external force. (Alarm clears.) 2. If alarm does not clear, turn off machine. End treatment manually.[d] Call for service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 11. Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Syringe pump (Rate is incorrect.)	Syringe pump failed.	- Press OVERRIDE to retest the pump.[b] - If alarm recurs, continue without anticoagulant, if desired. To do this, set Anticoagulant to "Continuous, 0 ml/hr," return to Alarm screen and press OVERRIDE.[b] **OR** End treatment manually.[d] Note: Always call service to repair the syringe pump and clear the alarm. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

a. This alarm must be cleared in Service mode by a trained and qualified technician.
b. OVERRIDE briefly overrides the alarm. Monitor closely.
c. DISCONNECT key is available only if set is loaded onto control unit.
d. Manual termination instructions are provided at the end of the Troubleshooting chapter.

Table 12. Caution Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Anticoag syringe empty This Caution is enabled only during priming (Setup mode). During a patient treatment (Run mode), the Advisory: Anticoag syringe empty alarm is enabled.	1. Anticoagulant syringe pump is in end-of-travel position during priming of the set. 2. Anticoagulant line is clamped.	1. Install full syringe so that anticoagulant line will be primed. (See "Anticoagulant Syringe Installation Procedure" in the Operation chapter.) Press CONTINUE. 2. Unclamp line; press CONTINUE.
Dialysate bag empty	1. Dialysate bag is empty. 2. Dialysate bag partially supported (not hanging freely).	1. Connect a new dialysate bag; press CONTINUE. 2. Remove partial support; press CONTINUE. Note: STOP softkey is also available for use if desired.[a, b]
Dialysate weight (Incorrect weight change detected.)	1. Leaking or clamped dialysate line or bag; bag is swinging on scale hook. 2. Room temperature variations are greater than ±3 °C (5.4 °F) from the temperature at which the scales were calibrated. 3. Foreign object on dialysate scale. 4. Dialysate bag partially supported (not hanging freely). 5. Seal on dialysate bag not completely broken. 6. Cartridge of the PRISMA Set is dislodged from cartridge carrier. 7. Dialysate scale failed; internal malfunction.	1. Remedy; press CONTINUE. 2. Call for service. 3. Remove object; press CONTINUE. 4. Remove partial support; press CONTINUE. 5. Using aseptic technique, manipulate bag seal to provide unobstructed fluid pathway. 6. Press cartridge into cartridge carrier; press CONTINUE. Note: STOP softkey is available for use in above steps, if desired.[a] 7. Press STOP and end the treatment. Call for service.

Table 12. Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent bag full	1. Effluent bag is full.	1. Connect a new effluent bag. (See instructions on the Help screen available from the Alarm screen.) Press CONTINUE.
	2. Foreign object on effluent scale.	2. Remove foreign object, press CONTINUE. Note: STOP softkey is available for use if desired.[a, b]
Effluent weight (Incorrect weight change detected.)	1. Leaking or clamped effluent line or bag; bag is swinging on scale hook.	1. Remedy; press CONTINUE.
	2. Foreign object on effluent scale.	2. Remove object; press CONTINUE.
	3. Effluent bag partially supported (not hanging freely).	3. Remove partial support; press CONTINUE.
	4. Cartridge of the PRISMA Set is dislodged from cartridge carrier.	4. Press cartridge into cartridge carrier; press CONTINUE. Note: STOP softkey is also available for use in above steps, if desired.[a]
	5. Room temperature variations are greater than ±3 °C (5.4 °F) from the temperature at which the scales were calibrated.	5. Call for service.
	6. Effluent scale failed; internal malfunction.	6. Press STOP and end the treatment. Call for service.
Replacement bag empty	1. Replacement bag is empty.	1. Connect a new replacement bag; press CONTINUE.
	2. Replacement bag partially supported (not hanging freely).	2. Remove partial support, press CONTINUE. Note: STOP softkey is available for use if desired.[a, b]

Table 12. Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement weight (Incorrect weight change detected.)	1. Leaking or clamped replacement line or bag; bag is swinging on scale hook.	1. Remedy; press CONTINUE.
	2. Foreign object on replacement scale.	2. Remove object; press CONTINUE.
	3. Replacement bag partially supported (not hanging freely).	3. Remove partial support; press CONTINUE.
	4. Seal on replacement bag not completely broken.	4. Using aseptic technique, manipulate bag seal to provide unobstructed fluid pathway.
	5. Cartridge of the PRISMA Set is dislodged from cartridge carrier.	5. Press cartridge into cartridge carrier; press CONTINUE. Note: STOP softkey is available for use in above steps, if desired.[a]
	6. Room temperature variations are greater than ±3 °C (5.4 °F) from the temperature at which the scales were calibrated.	6. Call for service.
	7. Replacement scale failed; internal malfunction.	7. Press STOP and end the treatment. Call for service.
TMP excessive (Transmembrane pressure exceeds membrane pressure limit.)	Ultrafiltration rate (UFR) is too high. Too much fluid is being removed. (UFR = patient fluid removal rate + replacement solution rate.)	- Decrease the replacement solution and/or patient fluid removal flow rates. - Return to Alarm screen, press CONTINUE. Note: STOP softkey is available for use if desired.[a]

a. Pressing STOP stops all pumps, clears the alarm, and displays the Stop screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient from set.

b. STOP is not available if this alarm occurs while the control unit is priming the set.

Table 13. Advisory Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Access disconnection cannot be detected Access pressure must be more negative than -10 mmHg for disconnection monitoring to be enabled. This alarm occurs if, during treatment, the access pressure operating point is set to a pressure more positive than -10 mmHg.	1. Blood flow rate too low for the access device. 2. Access pressure pod removed after priming.	1. Increase blood flow rate; return to Alarm screen and press OVERRIDE.[a] 2. Do Pod Diaphragm Reposition procedure on access pod (see instructions at end of Troubleshooting chapter); press OVERRIDE. **OR** Change the set. To change set, press OVERRIDE. When Status screen appears, press STOP, then CHANGE SET.
Access pressure (Access pressure is rising.) Alarm occurs if access pressure is 50 mmHg above its operating point.	1. Patient is moving or being moved. 2. Possible leak in access line or catheter.	1. Press CONTINUE.[d] 2. Remedy; press CONTINUE.[d] Note: STOP softkey is available for use if desired.[b] Alarm also self-clears if condition no longer exists.
Access too negative Alarm occurs if access pressure is 50 mmHg below its operating point.	1. Patient is moving or being moved. 2. Possible kink in access line; clotted catheter; catheter out of position in vein. 3. Blood flow rate is set too high for the access device.	1. Press CONTINUE.[d] 2. Remedy; press CONTINUE.[d] 3. Decrease blood flow rate; return to Alarm screen and press CONTINUE.[d] Note: STOP softkey is available for use if desired.[b] Alarm also self-clears if condition no longer exists.

Table 13. Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Anticoag syringe empty	1. Syringe pump is in end-of-travel position, indicating all anticoagulant solution in syringe has been delivered.	1. Install a full syringe (see "Anticoagulant Syringe Installation Procedure" in Operation chapter); press CONTINUE. **OR** Continue without anticoagulant delivery. To do this: (a) change to "Continuous, 0 ml/hr"; return to Alarm screen; (b) push plunger clamp release button to release syringe pump from end-of-travel position; (c) press CONTINUE. (Alarm clears.)
	2. Anticoagulant line is clamped.	2. Unclamp line; press CONTINUE.
Bag placement (Dialysate scale indicates an incorrect bag placement.)	1. Effluent bag incorrectly placed on dialysate scale. 2. Dialysate bag not on dialysate scale.	1. Hang effluent bag on yellow scale; press CONTINUE. 2. Hang dialysate bag on green scale; press CONTINUE.
Bag placement (Effluent scale indicates an incorrect bag placement.)	1. Replacement or dialysate bag incorrectly placed on effluent scale.	1. Hang effluent bag on yellow scale; replacement bag on purple scale; dialysate bag on green scale; press CONTINUE.
	2. Foreign object on effluent scale.	2. Remove foreign object; hang effluent bag on yellow scale; press CONTINUE.
	3. Multiple effluent bags on effluent scale.	3. Hang one effluent bag on yellow scale; press CONTINUE.
Bag placement (Replacement scale indicates an incorrect bag placement.)	1. Effluent bag incorrectly placed on replacement scale. 2. Replacement bag not on replacement scale.	1. Hang effluent bag on yellow scale; press CONTINUE. 2. Hang replacement bag on purple scale; press CONTINUE.

Table 13. Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Blood flow stopped (Machine has been left in the Stop screen for 60 seconds.)	Machine left in the Stop screen for more than 60 seconds (all pumps stopped).	- Inspect blood flowpath for signs of clotting. If clotted, change the set. (Press CONTINUE to clear alarm and return to the Stop screen, then choose CHANGE SET.) - If flowpath not clotted, press CONTINUE to clear alarm and return to the Stop screen.
Filter is clotting (Filter is beginning to clot.) Alarm occurs when one or both of the Filter is Clotting limits is reached. For more information, see "Filter Pressure—Filter Is Clotting Advisory Limit" in the Specifications chapter.	1. Filter is beginning to clot and/ or TMP is rising. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath. 2. Replacement solution flow too high for filter in use. *(continued)*	1. Press STOP; change the set **OR** lower TMP by (a) decreasing the replacement and/or patient fluid removal rates, (b) increasing the blood flow rate. Press OVERRIDE[a]; continue to monitor the set. Test patient's clotting parameters and adjust anticoagulant delivery if needed. Note: Filter Clotted warning occurs when the blood in the filter is clotted. 2. Press STOP; change the set **OR** lower TMP by (a) decreasing the replacement and/or patient fluid removal rates, (b) increasing the blood flow rate. Press OVERRIDE[a]; continue to monitor the set. Test patient's clotting parameters and adjust anticoagulant delivery if needed. Note: Filter Clotted warning occurs when the blood in the filter is clotted. *(continued)*

Table 13. Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
(Continued) **Filter is clotting** **(Filter is beginning to clot.)**	3. Kinked lines in blood flowpath. 4. Air leak between return pod and return sensor housing. 5. Anticoagulant syringe incorrectly installed or syringe pump failed. 6. Filter or return pressure sensor failed.	3. Remedy, press OVERRIDE. 4. Do Pod Diaphragm Reposition procedure on return pod (see instructions at end of the Troubleshooting chapter); press OVERRIDE. 5. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect anticoagulant line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump. 6. Press STOP and end the treatment. Turn off machine; call for service.
Periodic self-test in progress **(Test complete in approximately 2 minutes.)**	Periodic self-test is underway. Test occurs every 2 hours to ensure proper functioning of safety systems. The return line clamp is closed, then opened during the test.	None required. Self-clears when complete. **Warning:** Micro Air in Blood alarm is overridden for 1 minute during this test. Monitor closely. (Air in Blood [macro air] alarm remains enabled during the test.)
Return disconnection cannot be detected Return pressure must be higher than +10 mmHg for disconnection monitoring to be enabled. This alarm occurs if, during treatment, the return pressure operating point is set to a pressure below +10 mmHg.	1. Blood flow rate too low for the access device. 2. Return pressure pod removed after priming.	1. Increase blood flow rate; return to Alarm screen and press OVERRIDE.[a] 2. Do Pod Diaphragm Reposition procedure on return pod (see instructions at end of Troubleshooting chapter); press OVERRIDE. **OR** Change the set. To change set, press OVERRIDE. When Status screen appears, press STOP, then CHANGE SET.

Table 13. Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Return pressure (Return pressure is dropping.) Alarm occurs if return pressure is 50 mmHg below its operating point.	1. Patient is moving or being moved. 2. Possible leak in return line or catheter.	1. Press CONTINUE.[d] 2. Remedy; press CONTINUE.[d] Note: STOP softkey is available for use if desired.[b] Alarm also self-clears if condition no longer exists.
Return too positive Alarm occurs if return pressure is 50 mmHg above its operating point.	1. Patient is moving or being moved. 2. Possible kink in return line; clotted catheter; catheter out of position in vein. 3. Blood flow rate is set too high for the access device.	1. Press CONTINUE.[d] 2. Remedy; press CONTINUE.[d] 3. Decrease blood flow rate; return to Alarm screen and press CONTINUE. Note: STOP softkey is available for use if desired.[b] Alarm also self-clears if condition no longer exists.
Time for preventive maintenance	6500 hours of operation have elapsed.	Press OVERRIDE; schedule preventive maintenance at earliest convenience. Note: This alarm must be cleared in Service mode by a trained and qualified technician.
Time to change set (Hours of use have reached the user-settable "Time to Change Set" advisory limit.)	Set has been used too long.	Press STOP[e] and change the set. **OR** Press OVERRIDE and continue to monitor the set.[c] **Warning:** Do not use the PRISMA Set beyond 72 hours. Doing so could result in rupture of the pump segments, causing patient injury or death.

Table 13. Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
TMP too high (Transmembrane pressure has reached user-set pressure limit.)	1. Ultrafiltration rate (UFR) is too high for the present blood flow rate. (UFR = patient fluid removal rate + replacement solution rate) 2. Replacement solution flow rate too high for filter in use.	1. Decrease the replacement and/or patient fluid removal flow rates. **OR** Increase the blood flow rate. Return to Alarm screen and press OVERRIDE.[a] Note: STOP softkey is available for use if desired.[b] 2. Decrease the replacement and/or patient fluid removal flow rates. **OR** Increase the blood flow rate. Return to Alarm screen and press OVERRIDE.[a] Note: STOP softkey is available for use if desired.[b]

a. Alarm can also be overridden if operator decides action is not necessary at this time. Alarm self-clears if condition no longer exists.

b. Pressing STOP stops all pumps, clears the alarm, and displays the Stop screen. The following options are available: resume treatment, change set, end treatment, or temporarily disconnect patient from set.

c. Alarm can also be overridden if operator decides action is not necessary at this time. Alarm clears when set is unloaded.

d. CONTINUE resets all operating points and clears the alarm.

e. Pressing STOP stops all pumps and displays the Stop screen. The set can be changed by pressing CHANGE SET on the Stop screen. Alarm clears when set is unloaded.

Table 14. Additional Troubleshooting

Observation	Possible Cause(s)	Operator Response
Cartridge carrier is flush with front panel of machine, so that a set cannot be loaded.	Last set was manually disconnected.	- Begin normal Setup procedure. When Load Set screen appears, press LOAD. - When Prepare Solutions screen appears, press UNLOAD. (Places cartridge carrier in correct position.) - When Load Set screen reappears, follow on-line instructions to load the set.
Display goes blank momentarily, then screen reappears.	Power was lost and restored within 15 seconds.	None required.
Display goes blank or logo screen fails to leave display; status lights may still be on; no buzzer.	Internal power supply failure; internal malfunction.	- Turn off the machine; end treatment manually, if desired.[a] - Call for service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Display goes blank; status lights go off; non-mutable buzzer sounds.	Power loss; internal power supply failure.	Turn off machine to stop buzzer; end treatment manually, if desired.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Effluent bag is tinged pink or red.	1. Patient's disease state may cause discoloration of the ultrafiltrate. 2. Ultrafiltrate contains red blood cells, but level is below blood leak detection limit.	1. Send ultrafiltrate sample to laboratory for analysis. If free of red blood cells, continue treatment. If red blood cells are present, change the set. 2. Send ultrafiltrate sample to laboratory for analysis. If red blood cells are present, change the set.

Table 14. Additional Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Leakage from set connections.	Connections are loose.	- Tighten the connections. - If leakage continues, change the set via STOP key. See "Change Set Procedure" in the Operation chapter.
Softkeys won't work.	Touchscreen failed.	- Turn off machine; end treatment manually, if desired.[a] - Call for service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

a. Manual termination instructions are provided at the end of the Troubleshooting chapter.

Manual Termination of Treatment

(See Figure 18)

The patient's treatment can be terminated manually at any time. Manual termination may be required due to an alarm, power failure, or other emergency.

Manual Termination With Blood Return

Note: A sterile spike connector may be required.

1. Turn off the power. Clamp the access line (red-striped) and disconnect from the patient. Attach the access line to a 1-L bag of sterile saline. (Use spike connector, if needed.) Unclamp the access line.
2. Remove the return line (blue-striped) from the return line clamp.
3. Manually turn the blood pump *counterclockwise* until sufficient blood is returned to the patient.

WARNING

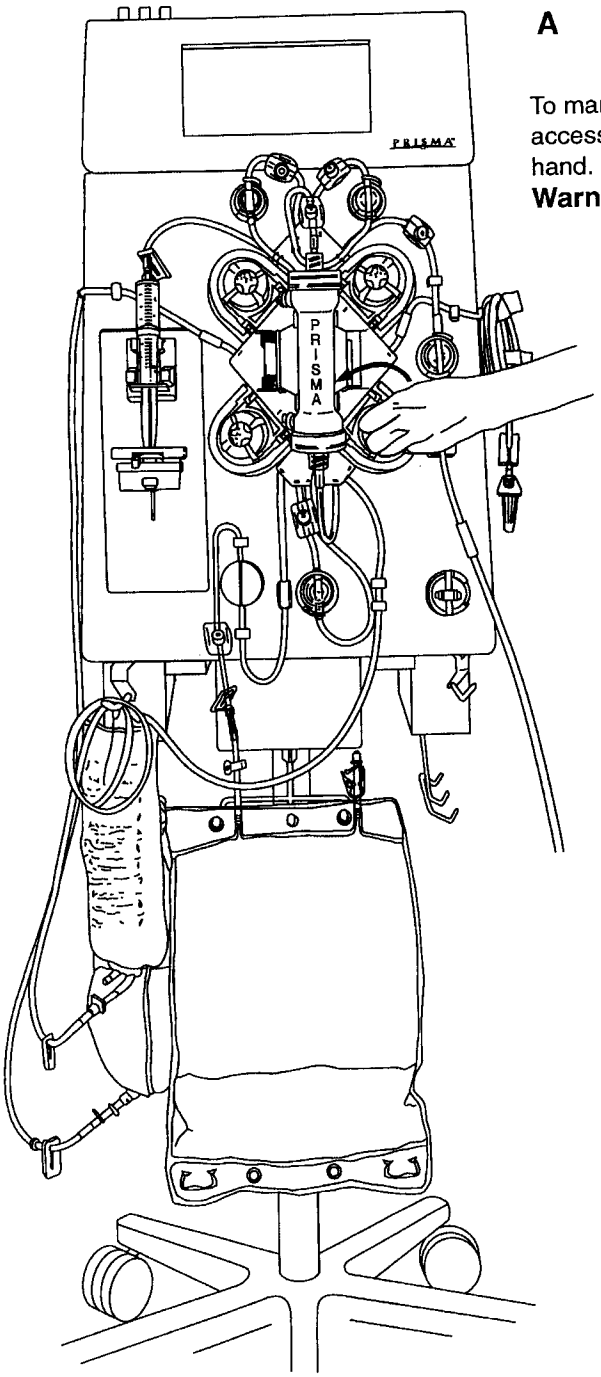
The alarm system is disabled. Visually check for air in the blood return line until the patient is disconnected.

4. Clamp the return line (blue-striped) and disconnect from the patient. Clamp lines to all bags.
5. Press the clip of the cartridge carrier (left side) to release the cartridge. Starting with any peristaltic pump, manually turn each pump *counterclockwise.* (The pump segment will work itself out of the pump raceway in a few turns of the rotor. To assist, gently tug on the cartridge assembly while turning a pump.)
6. When the pump segments are free, remove the set and discard as usual.

Manual Termination Without Blood Return

Note: The patient will lose the blood contained in the blood flowpath during a manual termination without blood return. For the exact blood volume, see the *Instructions for Use* packaged with the PRISMA Set.

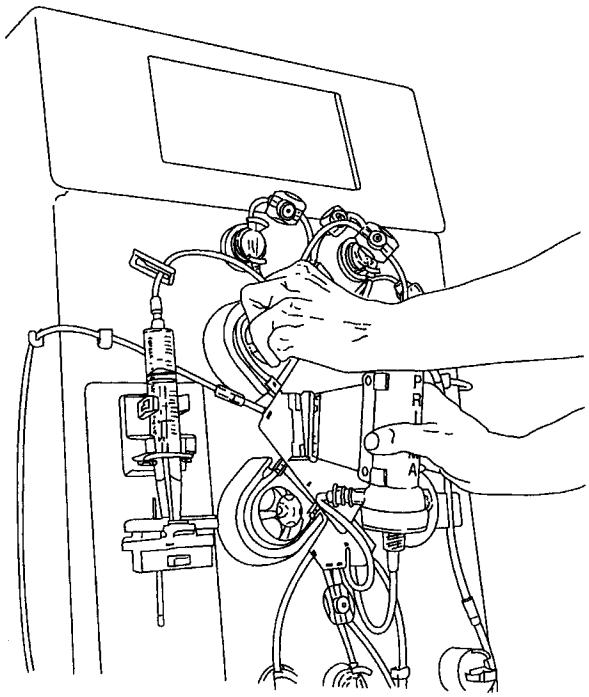
1. Turn off the power. Clamp the access line (red-striped) and return line (blue-striped) and disconnect from the patient.
2. Clamp lines to all bags.
3. Press the clip of the cartridge carrier (left side) to release the cartridge. Starting with any peristaltic pump, manually turn each pump *counterclockwise*. (The pump segment will work itself out of the pump raceway in a few turns of the rotor. To assist, gently tug on the cartridge assembly while turning a pump.)
4. When the pump segments are free, remove the set and discard as usual.



A

To manually return the patient's blood, connect saline to access line, then turn the blood pump counterclockwise by hand.

Warning: Watch return line for air.



B

To manually remove the set from the control unit, press clip of cartridge carrier to release the cartridge. Turn each pump counterclockwise.

Warning: Ensure patient is disconnected from set before removing set from control unit.

Figure 18. Manually Terminating Treatment

Diaphragm Reposition Procedure

The Diaphragm Reposition procedure can be performed if a pressure pod is accidentally removed after priming is complete, or if an Alarm screen identifies one or more pods as a possible cause of the alarm. The procedure is done separately for each affected pod.

The Reposition Procedure moves the pod diaphragm back to the center of the pod, so that pressure monitoring can again occur. The procedure also clears the pressure sensor housing of any debris that may be preventing a tight seal between the pod and the sensor housing.

Supplies Needed

- Isopropyl alcohol and lint-free cloth
- 20-gauge (or smaller diameter) needle attached to a ≤ 5-cc syringe
- Sterile saline (needed only for access and effluent pods)

Reposition for Access and Effluent Pods

(See Figure 19)

Follow the steps below to reposition the diaphragm of the *access line pod* (near lowest red sample site) or the *effluent line pod* (near upper yellow sample site).

1. Stop all pumps, then clamp the line below the affected pod and above the sample site of the pod.

   Note: Pumps might already be stopped.

2. Remove the affected pod from its pressure sensor housing.

   Note: Pod might already be removed.

3. Use a lint-free cloth and alcohol to clean the sealing cone inside the sensor housing.

4. Use the needle and syringe to reposition the diaphragm of the affected pod. When the procedure has been completed, resume treatment, or press the appropriate softkey on the Alarm screen.

CAUTION

Use aseptic technique when repositioning with needle and syringe.

a. Draw 3 cc saline into the ≤ 5-cc syringe.

b. *Inject* a maximum of 1 cc of saline into the color-coded sample site between the clamps. (If resistance is felt, remove 1/2 cc volume.)

CAUTION

Injecting more than 1 cc of saline may move the diaphragm beyond the center point of the pod.

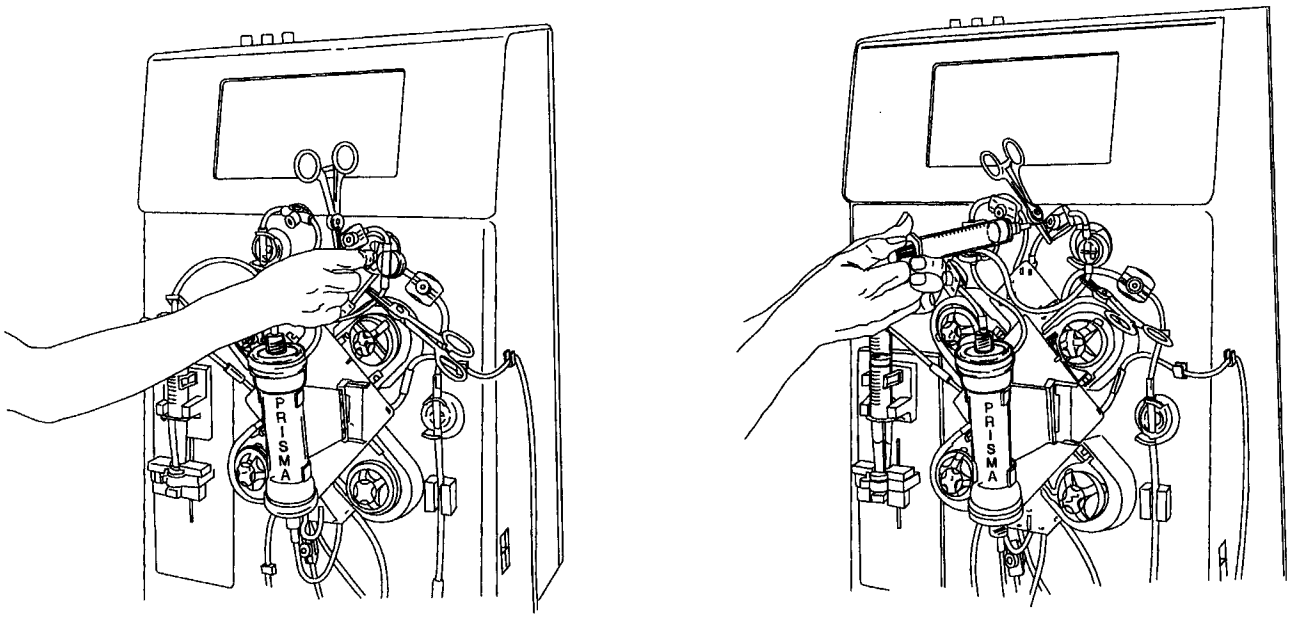
c. Remove the needle from the sample site. Reinstall the pressure pod in the correct pressure sensor housing and remove the clamps from the line.

d. Resume the treatment.

e. *For access pod reposition only:* Perform the following test to ensure proper functioning of the access pod. When the control unit is in Run mode, place a clamp on the access line between the access pressure pod and the cartridge. The Warning: Access Pressure Extremely Negative alarm should occur. Unclamp the access line and press the CONTINUE softkey on the Warning screen. Verify that the alarm is cleared (Warning screen leaves the display, green light illuminates).

WARNING

If the Warning: Access Pressure Extremely Negative alarm fails to occur, the access pod diaphragm has been repositioned incorrectly. Perform the reposition procedure again.



A

Clean the sealing cone inside the pressure sensor housing.

B

Inject or remove fluid via the appropriate sample site (depending on which pod is being repositioned).

Figure 19. Repositioning a Pressure Pod

Reposition for Filter and Return Pods

(See Figure 19)

Follow the steps below to reposition the diaphragm of the *filter pod* (near upper red sample site) or the *return line pod* (near blue sample site).

1. Stop all pumps, then clamp the line below the affected pod and above the sample site of the pod.

   Note: Pumps might already be stopped.

2. Remove the affected pod from its pressure sensor housing.

   Note: Pod might already be removed.

3. Use a lint-free cloth and alcohol to clean the sealing cone inside the sensor housing.
4. Use the needle and syringe to reposition the diaphragm of the affected pod. When the procedure has been completed, resume treatment, or press the appropriate softkey on the Alarm screen.

CAUTION

Use aseptic technique when repositioning with needle and syringe.

a. Insert the needle with empty syringe into the color-coded sample site between the clamps.
b. *Remove* a maximum of 1 cc of fluid (if resistance is felt, reinject 1/2 cc).

CAUTION

Removing more than 1 cc of fluid may move the diaphragm beyond the center point of the pod.

c. Remove the needle from the sample site. Reinstall the pressure pod in the correct pressure sensor housing and remove the clamps from the line.
d. Resume the treatment.
e. Perform the following test to ensure proper functioning of the pressure pod. When the control unit is in Run mode, place a clamp on the line below the affected pressure pod. An "Extremely Positive" Warning alarm should occur. Unclamp the line and press the CONTINUE softkey on the Warning screen. Verify that the alarm is cleared (Warning screen leaves the display, green light illuminates).

WARNING

If the "Extremely Positive" alarm fails to occur, the pressure pod diaphragm has been repositioned incorrectly. Perform the reposition procedure again.

Air Removal Procedures

Air is normally removed from the set during the automatic priming cycle; however, small bubbles may become trapped in the filter header or pressure pods. These can be removed via the sample sites in the set lines.

Note: If air occurs in the return line during treatment, a Warning alarm occurs. Air removal instructions are provided on the Warning screen, as well as here under "Return Line During Air in Blood Alarm."

Supplies Needed

20-gauge (or smaller diameter) needle attached to a ≤ 5-cc syringe

Access Pressure Pod

1. Ensure that all peristaltic pumps are stopped. Clamp the access line (red-striped) at cartridge.
2. Insert the 20-gauge needle with syringe into the *lower* red sample site and aspirate air/blood until the air is removed or resistance is felt.
3. Remove the needle; unclamp the access line.

Return Pressure Pod

1. Ensure that all peristaltic pumps are stopped. Clamp the return line (blue-striped) at cartridge.
2. Insert the 20-gauge needle with syringe into the blue sample site and aspirate air/blood until the air is removed or resistance is felt.
3. Remove the needle; unclamp the return line.

Effluent Pressure Pod

1. Ensure that all peristaltic pumps are stopped.
2. Insert the 20-gauge needle with syringe into the *upper* yellow sample site and aspirate air/ultrafiltrate until the air is removed or resistance is felt. Remove the needle.

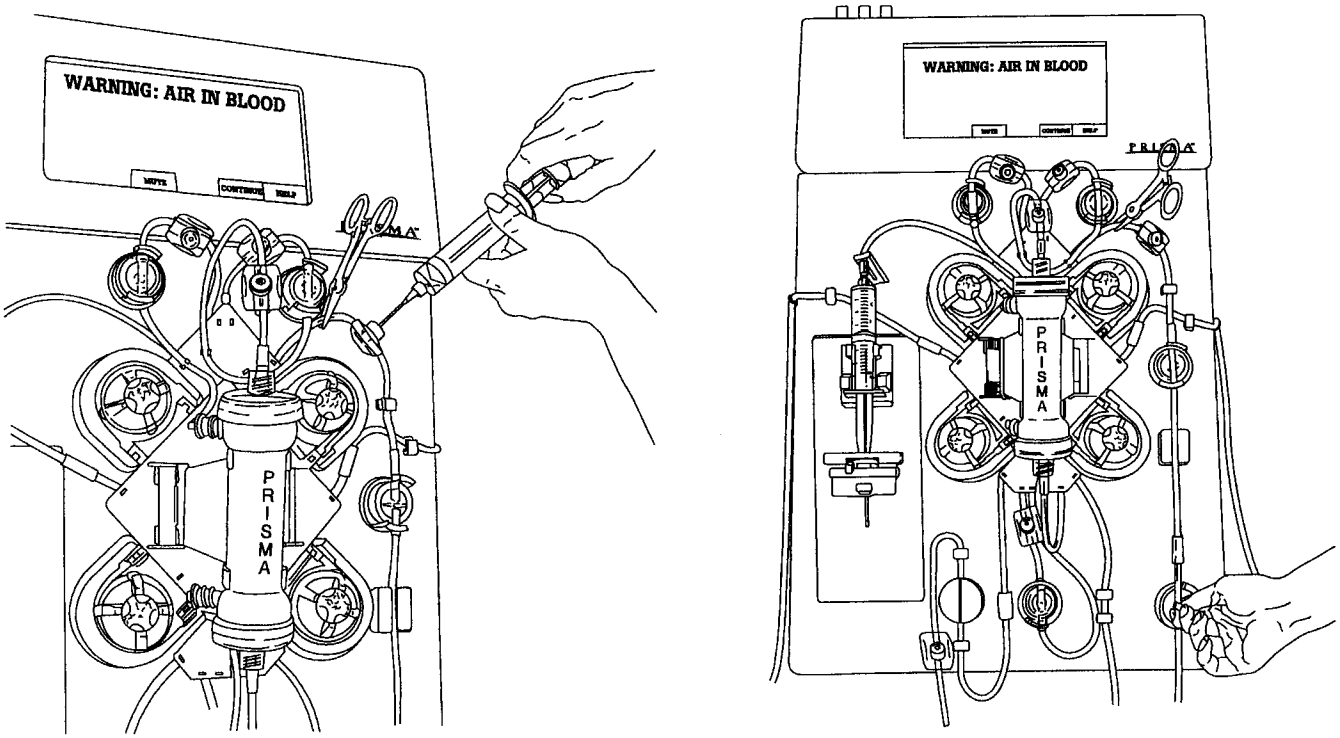
Filter Pressure Pod/Filter Header

1. Ensure that all peristaltic pumps are stopped.
2. Insert the 20-gauge needle with syringe into the *upper* red sample site *closest to the filter pod* (to remove air from pod) or into the upper red sample site *nearest the filter header* (to remove air from header). Aspirate air/blood until the air is removed or resistance is felt. Remove the needle.

Return Line During Air in Blood Alarm

(See Figure 20)

1. Clamp the return line (blue-striped) at the cartridge.
2. Insert the 20-gauge needle with syringe into the blue sample site and aspirate air/blood until the return pressure displays a negative number on the Warning screen.
3. Remove the needle; pull the return clamp open.
4. Repeat until all air is removed, then unclamp the return line and press CONTINUE from the Alarm screen.



A Aspirate air/blood via blue sample site.

B Pull return clamp open.

Figure 20. Removing Air From the Return Line