Prismaflex™

An integrated system for continuous fluid management and Renal Replacement Therapies.

Operator's Manual

For use with software versions 1.07

0086

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Questions or comments about this publication can be directed to your local representative or to manufacturer.

The Prismaflex™ machine is protected by one or more of the following patents/patent applications:

- U.S. patents: 4861242, 5441636, 5644402, 5722399, 5679245, 5776345, 5910252, 5762805, 5578223, 5725775, 5698090, 5211849;
- European patents/patent applications: 0611227, 0611228, 0678301, 0701830, 0829265, 0706044, 0607301;
- GB patents: 2208897;
- Canadian patents/patent applications: 1284598, 2115414, 2115415, 2158245, 2444794, 2303714, 2119375;
- Japanese patents/patent applications: 1772297, 117332/96, 3469287, 315530/94, 3413412, 3140781;
- German patents: P-3828123.6;
- French patents: 8811046;
- Italian patents/patent applications: MI2002A001390, MI2002A001389, MI2003A000214, MI2003A000212, MI2003A000213, MI2003A000216, MO2003A000165, MI2003A000211, MO2003A000259, MO2003A000293, 1223781;
- International patent applications: PCT/IB03/02281, PCT/IB2004/000055, PCT/IB2004/000062, PCT/IB2004/000105, PCT/IB2004/000061, PCT/IB2004/000104.

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Before You Get Started

Indications

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

Contraindications

There are no known contraindications to Continuous Renal Replacement Therapy (CRRT).

System Components

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

Control Unit

Each *Prismaflex* Control Unit is pre-attached to a column and a base. The *Prismaflex* Control Unit comes packaged with the following items:

- Installation kit:
  - United States-style power cord, with retaining bracket
  - Continental European-style power cord, with retaining bracket
  - Self-locking #4 nuts (2)
  - Scale carrying bars (4)
- Hexagonal wrench (for opening rear panel)
- Pump crank
- *Prismaflex Operator's Manua*l

Set

Use only *Prismaflex* Sets (manufactured by HOSPAL) with the *Prismaflex* Control Unit. Check with your sales representative for availability.

Prismaflex CRRT Sets

The following *Prismaflex* Sets are available for use with CRRT (Continuous Renal Replacement Therapies), which include SCUF, CVVH, CVVHD, CVVHDF.

- M 60 Set
- M 100 Set
- HF 1000 Set
- HF 1400 Set
- ST 60 Set *(Not currently available in US)*
- ST 100 Set *(Not currently available in US)*
- ST 150 Set *(Not currently available in US)*

All the above *Prismaflex* Sets may be available in two versions: a version with the blue sample site on the monitor line of the deaeration chamber and a version without the blue sample site on the monitor line of the deaeration chamber. Drawings in this manual show the version provided with the blue sample site on the monitor line of the deaeration chamber.

All *Prismaflex* Sets come with an effluent bag. To facilitate priming, a prime collection bag is preconnected to each set. Additional *Prismaflex* Effluent Bags can be purchased separately in standard 5-liter and 9-liter sizes.

Prismaflex Device Accessories

The following optional *Prismaflex* blood warmers can be installed to the *Prismaflex* Control Unit:

- HOSPAL Prismaflo™
- HOSPAL Prismatherm II™

Maximum Allowed Bag Sizes and Configurations

The scales of the *Prismaflex* Control Unit accept only the following maximum bags configuration:

- 4 standard 5000-ml fluid bags
- 1 standard 9000-ml fluid bag, plus 3 standard 5000-ml fluid bags

Only standard 5-liter fluid bags and standard 9-liter fluid bags can be placed on the scales. For more information, see “Maximum Bags Configuration Allowed on Scales” in Chapter 7: Specifications.

Where to Find Information About the *Prismaflex* System

Operator’s Manual

This manual provides installation, operating, maintenance, and troubleshooting instructions, as well as general information. Chapter 1 provides information about the *Prismaflex* therapy and the *Prismaflex* Control Unit. Specific information about CRRT therapy is provided in Chapter 3. The therapy-related chapter provides a description of the *Prismaflex* Set, an overview of the system, and information about operation and pressure monitoring. See the Contents section for a complete list of topics.

On-line Instructions

Detailed operating instructions are incorporated in the software of the *Prismaflex* 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).

Instructions for Use of *Prismaflex* Sets

Instructions for use are provided with *Prismaflex* Sets, and provide maximum flow rates and filter pressures, priming requirements, and other information for use of the set with the *Prismaflex* System.

Warnings

1. Carefully read this *Prismaflex Operator’s Manual* and the *Prismaflex* 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 *Prismaflex Operator's Manual*, the *Prismaflex* 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 *Prismaflex* System are other than those specified in this *Prismaflex Operator's Manual*, the *Prismaflex Service Manual*, the *Prismaflex* Set *Instructions for Use*, and the on-line instructions. Anyone who performs the procedures must be appropriately trained and qualified.
4. **Ensure the proper *Prismaflex* Set has been loaded for the selected therapy. Using the wrong set for the therapy can cause patient injury or death.**
5. All electrical installations must comply with all applicable local electrical codes and the manufacturer's specifications.
6. Use only the *Prismaflex* hospital grade power cord to plug the *Prismaflex* Control Unit to the facility electrical outlet.
7. *Prismaflex* Sets come equipped with an electrostatic discharger ring on the effluent line. When installed in its guide on the *Prismaflex* Control Unit, the discharger ring provides an electrical connection to ground. This minimizes electrical interference by the *Prismaflex* pumps with patient electrocardiogram (ECG) recordings. **Always install the discharger ring in its guide before connecting a patient to the *Prismaflex* Set**.
8. The *Prismaflex* Control Unit weighs approximately 60 kg (132 lb). Use at least two people to lift it out of the shipping carton. Handle the control unit carefully.
9. Use only the *Prismaflex* Sets listed in this manual with the *Prismaflex* Control Unit. **The use of *Prismaflex* Sets other than those listed in this manual may result in patient injury or death.**
10. Do not connect a patient to the *Prismaflex* System during the installation test. Be sure that the test is conducted using a container of water to substitute for the patient.

11. If a Malfunction alarm occurs during the installation test, the *Prismaflex* Control Unit has failed the test. Do not use the control unit. Call a trained and qualified technician for service.
12. Use only prescribed dialysate solution and replacement solution/fluid with the *Prismaflex* System. Use only dialysate solution and replacement solution/fluid which conform with applicable national registration, standards, or laws and the Council Directive 65/65/EEC. If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.
13. Ensure that dialysate solution and replacement solution/fluid are of appropriate composition and at appropriate temperature, as prescribed by a physician. Before using a solution/fluid, make sure it is free of precipitates and other particulate matter. **The use of incorrect solution/ fluid can result in patient injury or death.**
14. To assure proper flow control of syringe solution, **use only the syringes approved for use with the *Prismaflex* System. When setting up a patient treatment, install only the "allowed syringe."** (The allowed syringe is the syringe size/brand that has been selected in Custom mode from among the approved syringes). The internal diameter of approved syringes has been verified at the time of printing this manual. The manufacturer of the *Prismaflex* System cannot be held liable for subsequent changes that may occur to syringe dimensions. See *Syringe Pump Settings* in the Specifications chapter for a list of approved syringes.
15. Use only luer lock syringes with the *Prismaflex* System. **Use of non-luer lock syringes can result in patient blood loss** if the syringe line becomes dislodged from the syringe. See *Syringe Pump Settings* in the Specifications chapter for a list of approved syringes.
16. Do not hang anything except fluid bags from the scales on the bottom of the *Prismaflex* Control Unit. Foreign objects on the scales can significantly alter fluid balance, resulting in patient injury or death.
17. 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.
18. Lock brakes on the wheels to limit movement of the control unit that might pull on tubing connected to the patient.

19. 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.
20. 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.
21. 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.
22. *(This warning has been intentionally deleted).*
23. Use only the blood warmers listed in this manual. Install and operate them following the Operator's Manual provided with the selected blood warmer.
24. If a patient is not connected to the *Prismaflex* 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 may require use of a new bag of priming solution and a new (empty) collection bag. (Consult the *Instructions for Use* packaged with the set for details.)
25. All lines in the *Prismaflex* 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 PBP line and the syringe line (if not in use).
26. Connect the *Prismaflex* Set to a patient via one of the following methods: (a) Central 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);
(b) Arterio-venous (A-V) fistula; (c) External blood access device, and single-lumen venous catheter for patient blood return.
27. During a patient treatment, ensure the display is operating correctly by checking the following functions:
    a. Numbers on the Enter Flow Rates and Enter Syringe Settings 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.)

28. Due to the nature of use of the *Prismaflex* 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.
29. Closely monitor the patient's clotting parameters, especially when increasing and/or decreasing the amount of anticoagulant delivered or after changing the prescribed therapy setting or after changing the syringe.
30. Weigh the patient daily, or as appropriate, to assure proper fluid balance. Monitor the patient's blood chemistry as often as necessary.
31. Collecting blood samples from improper sample sites in the set can lead to incorrect blood chemistry results.
32. When responding to any alarm, carefully follow the instructions on the displayed Alarm screen and its associated Help screen.
33. The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started. This is done by pressing the NORM BLD softkey on the System Tools screen. The detector must be re-normalized before continuing a patient treatment.
34. To clear some alarms, the *Prismaflex* 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.
35. The control unit may not be able to detect disconnections of the set from the blood access and return connections, which can result in blood loss. **Ensure that the patient's blood access and return connections are firmly secured.** Carefully observe the set and all operation while using the *Prismaflex* System for a patient treatment.

36. *Prismaflex* Sets must be changed after 72 hours of use or after 780 liters have been processed through the filter. Continued use beyond these limits could result in rupture of the pump segments, with patient injury or death.

    Note: To assure adequate filter performance, it is recommended that the *Prismaflex* Set be changed after 24 hours of use. An Advisory alarm occurs if the set is not changed after 72 hours or 780 liters have been processed. The operator can reset this advisory to occur between 24 and 72 hours of operation.

37. 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.

38. If power is lost to the *Prismaflex* 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.

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

40. 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.

41. The *Prismaflex* Control Unit is provided with a RS232 Serial Communication port and an Ethernet port, for exchanging data between the control unit and an external personal computer or a communication network. All external equipment connected to the *Prismaflex* Control Unit must be compliant with IEC 60950.

42. The *Prismaflex C*ontrol Unit makes available the treatment related data through connection to external devices (personal computer or communication network) for storage and display. The intended use of this information is to support the physicians, but it cannot be considered as the sole data to prescribe any therapeutic or pharmacological action for the patient. It is the responsibility of the physician to verify all data.

43. Use only the *Prismaflex* Remote Alarm Kit for connecting the *Prismaflex* Control Unit to a remote alarm device.
44. Use only GAMBRO DASCO-approved accessories.
45. Electrically isolated peristaltic pumps such as those on the *Prismaflex* Control Unit 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. To minimize this electrical interference:
    - **always install the discharger ring on the effluent line in its guide before connecting a patient to the *Prismaflex* Set**
    - **follow the ECG supplier's instructions for chronic patient monitoring carefully regarding (1) use of specific electrodes with low contact impedance, and (2) correct application of the electrodes, including appropriate placement of the N electrode**.

    When starting a treatment with the *Prismaflex* System, observe the cardiac monitor before and after starting the blood pump to verify that the artifact is not present. If a cardiac dysrhythmia is exhibited, stop the blood pump and reassess the cardiac rhythm before resuming treatment and/or treating the patient.
46. Never insert fingers in the return line clamp and in the pinch valves.
47. The *Prismaflex* System conforms to IEC 60601-1-2 Standard on Electromagnetic Compatibility, thus it has an adequate degree of protection against electromagnetic disturbances. However, to prevent any problems, it is not recommended to use cellular phones (hand-held) in the therapy room or, at least, to keep a minimum distance of 10 m (33 ft.) from the *Prismaflex* System. Refer to, and be compliant with, local standards and guidelines. (For additional information about special precaution regarding EMC, refer to Appendix A in this manual).
48. Do not use the *Prismaflex* Control Unit near flammable gas, or near flammable anaesthetic mixtures with air, with oxygen or with nitrous oxide.
49. The correct installation of a MEDICAL ELECTRICAL SYSTEM requires that each SYSTEM component be individually connected to the main power. It is strongly recommended: NOT TO USE MULTIPLE

PORTABLE SOCKET-OUTLETS. However, if using multiple portable socket-outlets, they must comply with IEC 60601-1-1 Standard and MUST NOT BE PLACED ON THE FLOOR.

50. It is the responsibility of the user to properly connect the *Prismaflex* Control Unit to a remote alarm device. Verify the proper functioning of this remote system after connecting the control unit.

51. When using a remote alarm device connected to the *Prismaflex* Control Unit, periodically check on the patient in person.

    a. After turning ON the control unit, ensure it is operating correctly by checking the following functions:the green, yellow and red status lights should be illuminated alternately;

    b. The non-mutable buzzer should sound while the status lights are illuminated.

    In case of malfunction, switch OFF the control unit and call for Service.

52. The *Prismaflex* Sets are equipped with pressure sensors protectors; if an external pressure sensor becomes wetted, to avoid bad pressure readings causing pressure alarms replace it immediately and inspect it. If fluid is visible on the side of the transducer protector that faces the machine, call for Service to open the machine and check for contamination after the treatment is completed. If contamination has occurred, the involved part must be replaced disinfected before using the *Prismaflex* System for patient treatment.

53. Changing of the therapy settings that implies the use of lines containing non-circulating fluid (for example, changing the pre- and post-filter options for delivery of the replacement solution or starting using the PBP Pump) during the treatment may increase the risk of clot release to the patient. It is the operator's responsibility to verify that no cloths are present in the line before using it.

54. The *Prismaflex* Control Unit may not be able to detect leakages of the fluid bags. Leakages of the fluid bags can significantly alter fluid balance, resulting in patient injury or death. Carefully observe the fluid bags and all operation while using the *Prismaflex* System for a patient treatment.

Precautions

1. Procedures using the *Prismaflex* System must be performed under the responsibility of a physician.
2. There are no operator-serviceable parts inside this device. Repairs must be performed by a trained and qualified technician.
3. Relating to the *Prismaflex* Set storage conditions and temperature, refer to the *Prismaflex* Set Instruction for Use.
4. Prior to using the *Prismaflex* Control Unit, let the unit rest at ambient operating temperature for 1 hour.
5. The accuracy of the *Prismaflex* 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 *Prismaflex Service Manual*.
6. Chemicals other than those recommended in this manual for cleaning and disinfection could damage the *Prismaflex* Control Unit and *Prismaflex* Sets. Obtain permission from the manufacturer before using a non-recommended chemical on the *Prismaflex* System. The following are especially forbidden: (a) halogenated aromatic and aliphatic solvents; (b) ketonic solvents.
7. To prevent contamination, the *Prismaflex* Set must be used as soon as its package and sterilization caps are removed.
8. Do not use the *Prismaflex* Set if the package is damaged, if the sterilization caps are missing or loose, or if the blood lines are kinked.
9. Destroy the *Prismaflex* Set after a single use, using appropriate procedures for potentially contaminated material. Do not resterilize.
10. When handling *Prismaflex* Sets, hospital personnel should take adequate precautions at all times to prevent exposure to or transmission of HIV, hepatitis virus, or other infectious agents.
11. The *Prismaflex* System is not designed for a heater to be connected to the replacement solution line. A heater generates air bubbles which collect in the deaeration chamber. Therefore, it is recommended **not** to use a heater on the replacement solution line.

12. If a heater is connected to the dialysate line, the *Prismaflex* System does not automatically prime the additional tubing needed for the heater. Separate priming of this tubing is required.
13. Do not use any type of lubricant on the internal or external components of the *Prismaflex* Control Unit or *Prismaflex* Set. Only authorized service technicians can apply lubricants to machine components. Improper use of lubricant can adversely affect performance of the control unit.
14. If anticoagulation of the blood flowpath via the syringe pump is *not* desired, fill the allowed syringe (specified in Custom mode) with *priming solution* and install it in the syringe pump during Setup mode, while the Prepare Solutions screen is on the display. This assures the syringe line will be primed during the automatic priming cycle.
15. After priming is complete, do not remove the pressure pods from their pressure sensor housings and do not disconnect the deaeration chamber monitor line from the return pressure port. If one or more pods are removed, the Diaphragm Reposition Procedure must be performed on the affected pod(s) and the set must be reprimed. If the Diaphragm Reposition Procedure fails, the set must be changed. If the monitor line is disconnected, the set must be reprimed and the fluid level in the deaeration chamber adjusted.
16. Press only one softkey at a time. Pressing two or more softkeys simultaneously causes the *Prismaflex* Control Unit to ignore all except the *first* keypress.
17. Change fluid bags when the appropriate Caution alarm occurs (Replacement Bag Empty, Dialysate Bag Empty, Effluent Bag Full). Changing a bag before the alarm occurs may only be done by using the Change Bags function and following the instructions on the Change Bags/Containers screen.
18. Only trained and qualified technicians can access Service mode. If Service mode is inadvertently entered, turn the unit off, then on to return to Operating mode.
19. Use a 21-gauge (or smaller diameter) needle to obtain blood or fluid samples, to remove trapped air from the *Prismaflex* 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.

20. When adjusting pod diaphragms, injecting or removing more than 1 cc of fluid may move the diaphragm beyond the center point of the pod. See “Pressure Pod Adjustment Procedure” in the Troubleshooting chapter for more information.
21. 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.
22. The wheel size of the *Prismaflex* Control Unit allow it to pass over an 8 mm step. To pass over a 2 cm step, do not push, but pull the control unit.
23. Wait at least 5 seconds after switching the machine off before turning it on again.
24. Before moving the machine, check that the brake is released and ensure that all the scales are firmly closed.
25. Avoid moving the machine when a blood warmer is installed. Remove the warmer before moving the machine.
26. Do not use sodium hypochlorite (Bleach®) to clean the the pump crank. Use of sodium hypochlorite (Bleach®) on this component may damage it.
27. For the Touchscreen cleaning use the following disinfectants:
    - Isopropyl alcohol (70°);
    - Sodium hypochlorite solution (active chlorine from 50,000 to 60,000 ppm)/Bleach diluted with water at a ratio of 1:50.
28. The PRISMAFLEX System is unable to detect all of the situations where a bag has been attached to the wrong line or has been hung on the incorrect scale. The use of colour coded lines, colour coded clamps as well as the specific label on the PBP line are intended to prevent such errors.
29. The default setting for the Empty Bag Method parameter is "Fixed". If you are using bottles, tanks or non standard bags, change the Empty Bag Method setting to "Variable" in the Custom Mode before starting a new treatment. This ensures the correct tare is used to detect an empty container.

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 per IEC 60601.1.

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 60601.1 under the applicable conditions.

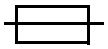
4. This symbol indicates that the device requires an alternating supply current.

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.

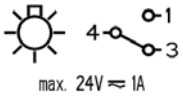
11. This symbol indicates that the equipment conforms to Council Directive 93/42/EEC, of 14 June, 1993 relating to Medical Devices. Also indicates that the notified body which has approved the manufacturer's quality system is the British Standards Institution (BSI). The CE Mark affixed to the *Prismaflex* Control Unit covers only the *Prismaflex* Control Unit. Disposables specified for use with the *Prismaflex* Control Unit have separate CE Marks. (See Warning number 9.)

12. This symbol Indicates that the equipment conforms to the rules related to the Safety of Medical Electrical Equipment for U.S. and Canada.The "C" and "US" indicator adjacent to the CSA mark signifies that the product has been evaluated to the applicable ANSI/UL and CSA Standards, for use in the U.S. and Canada.

13. This symbol indicates the date of manufacture. It is accompanied by the year expressed as four digits.

14. This symbol indicates the presence of an Ethernet port.

15. This symbol indicates the presence of an RS232 Serial Communication port.



16. This symbol indicates the presence of a remote alarm connector.

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 your representative at the applicable address below.

AUSTRALIA	GAMBRO PTY Ltd. 11-13 King Street Oakleight AU-VICTORIA 3166 Tel. 61-395 633400 Fax 61-395 630344
AUSTRIA	GAMBRO HOSPAL Gmbh Ricoweg 30 A AT-2351 Wr. NEUDORF Tel. 43/2.23.664.666 Fax 43/2.23.664.666-55 E-mail office.wneudorf@gambro.com Web www.gambro.at
BELGIUM	GAMBRO NV/SA 15, Groenveldstraat BE-3001 HEVERLEE BELGIUM Tel. 32-16298750 Fax 32-16226521
CANADA	GAMBRO Inc 9157, du Champ d´Eau CDN St. Leonard, QUEBEC H1P 3M3 Tel. 1 - 514 327 16 35 Fax 1 - 514 327 08 22
DENMARK	GAMBRO A/S Jydekrogen 8 2625 VALLENSBAEK Tel. 45/43 62 05 00 Fax 45/43 62 07 49

ESTONIA	GAMBRO ESTONIA Raudtee 10-1 11614 TALLINN Tel. 372/672 3160 Fax 372/672 3161
FINLAND	OY GAMBRO Sahaajankatu 24 FIN - 00810 HELSINKI Tel. 358/9 759 41 20 Fax 358/9 78 11 46
FRANCE	HOSPAL S.A 61 av. Tony Garnier F - 69007 Lyon Tel. 33 / 04 37 28 11 11 Fax 33 / 04 37 28 11 44
GERMANY	Gambro Hospal GmbH Lochhamer Str. 15 D - 82152 Planegg-Martinsried Tel. 49 /89. 89 933-0 Fax 49 /89. 89 933-2999
HONG KONG	GAMBRO CHINA Ltd Room 3206-8,32/F New York Life Tower Windsor House 311 Gloucester Road , Causeway Bay HONG KONG Tel. 852/2576 2688 Fax 852/2687 1255
HUNGARY	GAMBRO Kft Diosarok ut 5 1125 BUDAPEST Tel. 36/1 202 64 11 Fax 36/1 355 29 89
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Disposal of Batteries

The *Prismaflex* Control Unit contains a lithium energy cell and a lead-acid battery. The lithium energy cell is embedded in a semiconductor on the monitor circuit card assembly. When replacing these components, follow local regulations for proper disposal.

Disposal of Packaging Material

The *Prismaflex* Control Unit shipping carton, foam packing, and other packaging material should be disposed of according to local regulations.

Warranty

Since GAMBRO DASCO has no knowledge or control of how non-GAMBRO DASCO service work is conducted or what effect such work will have on a machine's operation and performance, GAMBRO DASCO will in no way be responsible or liable for any damages resulting from the operation or performance of any device, or any injury caused thereby, after repairs have been attempted by anyone other than a factory representative of GAMBRO DASCO.

Under no circumstances will GAMBRO DASCO be liable for indirect or consequential damages of any kind, its liability being hereby limited solely to repair or replacement.

This warranty is in lieu of any other expressed or implied warranties, including any implied warranty of salability or fitness for use and of any other obligation on the part of GAMBRO DASCO.

This manual contains references to disposables, accessories and spare parts for use with the *Prismaflex* System. The *Prismaflex* System has been tested and validated for use with disposables, accessories and spare parts listed in this manual. The manufacturer does not accept responsibility or liability for use of disposables or accessories other than those specified in this manual, for use of not genuine spare parts and for use/mounting of those components not in accordance with the *Instructions for Use* accompanying those components. Depending on the circumstances, use of disposables or accessories other than those specified in this manual, use of not genuine spare parts and use/mounting of those components not in accordance with the above mentioned Instruction for Use may reduce the manufacturer's warranties for the *Prismaflex* System.

Chapter 1: Product Description

Introduction

The *Prismaflex* System provides continuous fluid management and renal replacement therapies . The system is intended for patients who have acute renal failure and/or fluid overload .

Blood Access

The most commonly used blood access method for *Prismaflex* therapies is central venous access and return. A dual-lumen venous catheter is the recommended blood access device; however, two single-lumen venous catheters can also be used.

In certain circumstances, such as pediatric treatments, arterial blood access via arterio-venous (A-V) fistula may be desirable. Blood access may also be via an external blood access device connected to the disposable *Prismaflex* Set. In these situations, blood return is via a single lumen venous catheter.

Prismaflex Control Unit Functions

The *Prismaflex* Control Unit is a software controlled device that performs the following functions:

- Loads and primes the *Prismaflex* Set automatically.
- Pumps blood through the blood flowpath of the *Prismaflex* Set.
- Delivers anticoagulant solution into the blood flowpath.
- Controls fluid removal from the patient.
- Pumps sterile, pre-blood pump (PBP) infusion solution into the blood access line.
- Pumps sterile replacement solution/fluid and/or sterile dialysate. Pumps effluent.
- Monitors the system and alerts the operator to abnormal situations through alarms.

Therapy Overview

The *Prismaflex* Control Unit pumps blood from the patient, through the filter in a disposable *Prismaflex* Set, and back to the patient's venous circulation. As the blood passes through the filter, the desired treatment processes take place. Depending upon the therapy in use, these processes can include fluid removaland/or solute clearance.

Prismaflex Therapy Options

The *Prismaflex* System provides four renal replacement therapies and continuous fluid management for CRRT . During the Setup procedure, the operator selects the therapy desired.

CRRT (Continuous Renal Replacement Therapies)

SCUF (Slow Continuous Ultrafiltration)
Provides patient fluid removal by ultrafiltration.

CVVH (Continuous Veno-venous Hemofiltration)
Provides solute removal by convection. Can provide patient fluid removal, if desired.

CVVHD (Continuous Veno-venous Hemodialysis)
Provides solute clearance by diffusion. Can provide patient fluid removal, if desired.

CVVHDF (Continuous Veno-venous Hemodiafiltration)
Provides solute removal by both convection and diffusion. Can provide patient fluid removal, if desired.

Mechanisms of Therapy

The mechanisms of ultrafiltration, hemofiltration and hemodialysis are used in providing the *Prismaflex* therapy options.

Ultrafiltration

In ultrafiltration, plasma water with solutes is pulled from the patient's blood across the semipermeable membrane in the filter. The effluent pump automatically controls the ultrafiltration rate.

Hemofiltration

In hemofiltration, plasma water with solutes is pulled from the patient's blood across the semipermeable membrane by means of ultrafiltration. *A replacement solution is simultaneously infused* into the blood flowpath.

The replacement solution adds back some or all of the water removed, as well as the wanted solutes. Unwanted solutes are not replaced, thus their concentration decreases in the patient's blood. Solute removal is achieved by *convection* (solvent drag across the membrane).

WARNING

Use only prescribed dialysate solution and replacement solution/fluid with the *Prismaflex* System. Use only dialysate solution and replacement solution/fluid which conform with applicable national registration, standards, or laws and the Council Directive 65/65/EEC. If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.

Hemodialysis

In hemodialysis, unwanted solutes pass from the patient's blood across the semipermeable membrane and into dialysate flowing at counter flow through the fluid compartment of the filter.

The concentration of unwanted solutes is lower in the dialysate than in the blood, causing the solutes to diffuse from an area of greater concentration (the patient's blood) to an area of lesser concentration (the dialysate solution). Solute clearance is achieved by *diffusion*.

Hemodiafiltration

In hemodiafiltration, both hemodialysis and hemofiltration are used. Solute removal occurs by *convection and diffusion.*

Dialysate solution is pumped through the fluid compartment of the filter. At the same time, the effluent pump controls ultrafiltration and a replacement solution is infused into the blood flowpath.

WARNING

Use only prescribed dialysate solution and replacement solution/fluid with the *Prismaflex* System. Use only dialysate solution and replacement solution/fluid which conform with applicable national registration, standards, or laws and the Council Directive 65/65/EEC. If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.

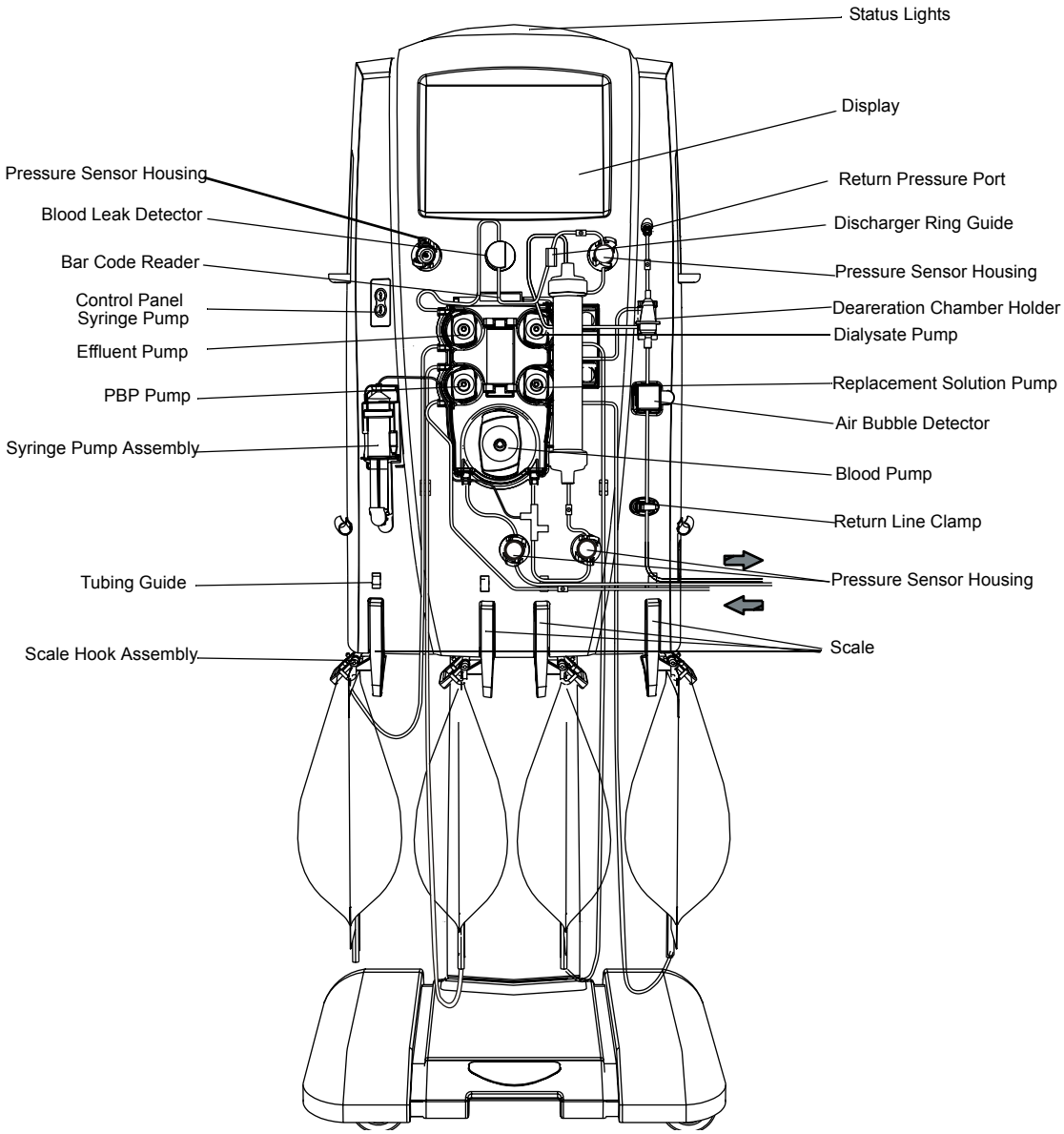


Figure 1. *Prismaflex* Control Unit: Front Panel

Prismaflex Control Unit

Figure 1 shows the front panel of the *Prismaflex* Control Unit.

Figure 2 shows the rear panel of the *Prismaflex* Control Unit.

Following is a description of the components on the control unit.

Front Panel

Status Lights	Illuminate to give a general indication of operating conditions. The three groups of lights are arranged in a triangle to be easily visible from every direction.
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.
Cartridge Carrier	Accepts the cartridge of *Prismaflex* Sets; enables automatic loading of the *Prismaflex* Set.

Bar Code Reader	Laser scanner that reads the bar code on the cartridge of the *Prismaflex* Set during the Setup procedure. With this information, *Prismaflex* software accesses the correct alarm limits and flow rate ranges for the set that is loaded.
Return Pressure Port	Connects to the monitor line of the deaeration chamber on the *Prismaflex* Set. A pressure sensor (transducer) located behind the pressure port enables noninvasive pressure monitoring of the return line and deaeration chamber. A fluid barrier at the distal end of the monitor line protects the return pressure sensor from accidental blood entry.
Deaeration Chamber Holder	Accepts the deaeration chamber of the *Prismaflex* Set.
Pressure Sensor Housings	Housings that hold the pressure pods of the *Prismaflex* Set. A pressure sensor (transducer) is located behind each housing. The sensors and pressure pods enable noninvasive pressure monitoring of the access line, filter, and effluent line. There are no air-blood interfaces. **Note:** The upper left pressure sensor housing is for use with future *Prismaflex* therapies.
Pinch Valves (upper and lower)	Upper pinch valve accepts tubing coming from the dialysate pump; lower pinch valve accepts tubing coming from the replacement pump. The valves open/close automatically to allow pre- and post-filter options for delivery of replacement solution in CVVH and CVVHDF therapies. For more information, see Chapter 3: Continuous Renal Replacement Therapies (CRRT).

Dialysate Pump	**For CVVHD and CVVHDF therapies:** Pumps fresh dialysate solution into the fluid compartment of the filter. **For CVVH therapy:** If post-filter replacement delivery has been chosen and replacement solution has been placed on the green scale, this pump delivers replacement solution into the post-filter blood flowpath. For more information, see Chapter 3: Continuous Renal Replacement Therapies (CRRT). This pump is an occlusive, peristaltic pump.
Air Bubble Detector *(housing also has a tubing detection switch and a patient blood sensor)*	Ultrasonic transmission/detection device that continuously monitors the return line for air bubbles. A Warning alarm occurs if a bubble is detected. The below two sensors are also located in the air bubble detector housing. • Tubing detection switch (physically moves down when tubing is installed). • Patient blood sensor (infrared sensor that detects if blood is in the tubing).
Replacement Solution/Fluid Pump	Pumps replacement solution/fluid into the blood flowpath. **For CVVH therapy:** Replacement solution can be delivered 100% pre-filter, 100% post-filter, or in percentages of pre- and post-filter. **For CVVHDF therapy:** Replacement solution can be delivered 100% pre-filter or 100% post-filter. This pump is an occlusive, peristaltic pump.
Return Line Clamp *(assembly also has a tubing detection switch)*	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. For patient safety, a tubing detection switch is also located in the return clamp assembly. The switch physically moves down when tubing is correctly installed under the clamp.

Clips *(left and right)*	Secure the blood access and return lines going to the patient; also support the PBP line. (The clip on the side closest to the patient is used; the lines are secured in the clip after the patient is connected to the *Prismaflex* Set.)
Tubing Guides	Hold the lines of the *Prismaflex* Set in correct position on the control unit. The color of each tubing guide matches the color of the line it holds.
Blood Pump	Pumps blood through the blood flowpath of the *Prismaflex* Set. This pump is an occlusive, peristaltic pump.
Pump Raceway	Tubing pathway within each peristaltic pump. The raceways accept the pump segments of the *Prismaflex* Set.
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. If needed, the operator can insert a pump crank into the rotor and manually turn the pump.
Syringe Pump Assembly	Delivers anticoagulant, or other solution into the blood flowpath via a syringe. The pump assembly holds the solution-filled syringe and controls the rate of delivery. Delivery can be continuous or in boluses.
Syringe Pump Control Panel	Consists of UP and DOWN buttons that allow installation and removal of the syringe. The buttons are activated/ inactivated by *Prismaflex* software, depending upon operating conditions.
Pre-blood Pump (PBP)	If required, pumps a sterile infusion solution into the blood access line at a location immediately after patient blood enters the line and *before* the blood pump. This pump is an occlusive, peristaltic pump.

Effluent Pump	Pumps ultrafiltrate/dialysate; automatically controls the ultrafiltration rate, based on the operator-set patient fluid removal rate, PBP solution rate, dialysate rate (if applicable) and replacement solution rate (if applicable).
Discharger Ring Guide	Holds the electrostatic discharger ring on the effluent line of the *Prismaflex* Set. Provides an electrical connection to "ground" to minimize electrical interference by *Prismaflex* pumps with patient electrocardiogram (ECG) recordings.
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. **Note:** The blood leak detector does not detect the presence of hemolyzed blood; however, a pink or red tinge in the effluent bag may indicate hemolysis. For more information, see the "Additional Troubleshooting" table in the Troubleshooting Chapter.
Priming Hook (left recessed handle)	Holds the priming solution bag during priming; holds the sterile saline bag during blood return.
Recessed Handles *(left and right)*	Provide hand holds for easily moving the control unit.

Bottom Panel

Scales

Independently monitor fluid bag/container weights. Weight is used by *Prismaflex* software to precisely control ultrafiltration and patient fluid removal. An alarm sounds when the PBP, dialysate, and replacement solution bags are nearly empty, or when the effluent bag is nearly full. A color-coded shape identifies each scale, as follows: Dialysate = green shape; Replacement = purple shape; PBP = white shape; Effluent = yellow shape.
The operator pulls the bar tray of a scale out (away from) the control unit to attach or remove bags. When the tray is pulled out, the scale is in “open” position; when the tray is completely pushed in, the scale is in “closed” position. An alarm sounds if the scale is open when operating conditions require that it be closed.

Scale Hook Assemblies

The bar tray on each scale holds a removable carrying bar with three hooks. Using a table or other support, bags may be attached to/removed from the hooks. After the carrying bar is replaced in the bar tray, it must be rotated so the handle is toward the floor, so the scale can be properly closed.
Various sizes of bags can be used, depending on the scale. For more information, see “Maximum Bags Configuration Allowed on Scales” in Chapter 7: Specifications.

Right Side Panel

Power Switch

Turns power on and off to the machine. The label “I” means ON and the label “O” means OFF.

Rear Panel

Hour Meter

Displays the cumulative hours of machine operation (total time that power to the machine has been on).

Fan

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

Speaker	Transmits a continuous or intermittent beep if an alarm condition occurs. For more information, see Chapter 4: Alarm System.
Buzzer	Transmits a continuous buzz if a power loss occurs.
Gambro Serial Communication Port	Connects devices that use a FCC68 plug to the *Prismaflex* Control Unit.
RS232 Serial Communication Port	Connects devices that conform with IEC 60950 (processing equipment standard) to the *Prismaflex* Control Unit. May be used for exchanging data between the control unit an external personal computer, or communication network.
Ethernet Port	Provides a connection for exchanging data between the *Prismaflex* Control Unit and an external personal computer or communication network. This port is IP addressable.
Patient Card Holder	A PC Card slot that accepts a patient information card (PC Card). Allows transfer of history data from the *Prismaflex* Control Unit to the PC Card. The data is transferred in a text format (.txt) that can be imported into commonly used software programs.
Remote Alarm Connector	Connects the *Prismaflex* Control Unit to an optional remote alarm device installed in a separate location, such as a nursing station.
Rear Handles *(top and bottom)*	Provide a means to easily move the control unit.

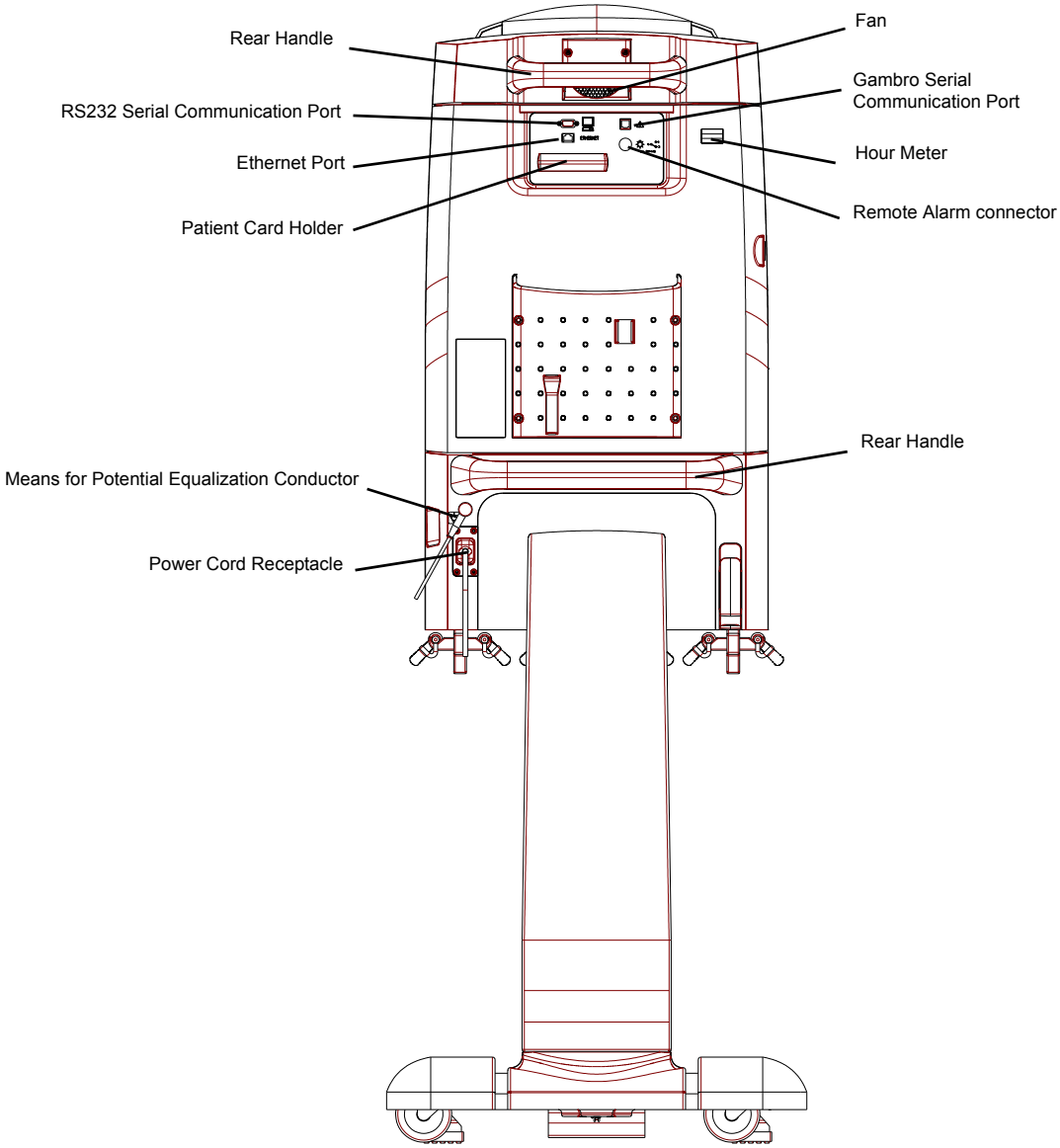


Figure 2. *Prismaflex* Control Unit: Rear Panel

Interior Components

Access to the interior of the *Prismaflex* Control Unit is gained through the rear panel. Inside the control unit are 12 circuit card assemblies (CCAs). The Control CCA and microprocessor, together with the Protective CCA and microprocessor, manage the other CCAs. An internal Automatic Reposition system (ARPS) can pump air into or remove air from the pressure sensors and their attached pressure pods.[1] Using the ARPS, the machine can automatically place pressure pod diaphragms into “neutral” position and test the accuracy of the pressure sensors. There are many other electronic and mechanical components inside the control unit. Only trained and qualified service technicians should repair the interior components. Complete descriptions of these components are provided in the *Prismaflex Service Manual*.

Self-Tests of the *Prismaflex* System

The *Prismaflex* software continually monitors the operation of the control unit and the *Prismaflex* Set. As part of this regular monitoring, three *self-tests* are performed. Each self-test consists of a series of *subtests* done in a sequential order.

The first self-test is the *initialization test*. This test series is done after the operator turns the power switch to “On.” The initialization test ensures that the Control and Protective microprocessors and memory are operating properly. When the initialization test is successfully completed, the control unit enters Setup mode.

The second self-test is the *prime self-test*. This occurs when the device is in Setup mode, while the operator is selecting the physician-ordered therapy, and is loading, priming, and inspecting the *Prismaflex* Set. The third test series is the *periodic self-test*, which is conducted every two hours during Run mode while the patient treatment is underway. Following is a summary of the three self-tests.

Note: Complete descriptions of these self-tests and all other monitoring routines of the *Prismaflex* Control Unit are provided in the *Prismaflex Service Manual*.

1. Pressure pods are a component of *Prismaflex* disposable Sets. Descriptions of pressure pods and diaphragms are found in the *Prismaflex* Set sections of Chapters 3, 4, and 5.

Initialization Test

The initialization test begins after the operator turns the power switch to the “On” position. The Logo screen appears on the machine display, the non-mutable buzzer sounds, and some status lights are illuminated during the test. After the initialization test completes, the control unit enters Setup mode.

The initialization test consists of the following subtests:

Table 1. Subtests of the Initialization Self-Test

Subtest	Description
Processor flag check	The processor verifies that all condition flags can be set.
Calculation of cyclical redundancy check (CRCs)	The calculations must match the CRCs stored in ROM. If the calculations are correct, the ROM is not corrupted.
Write-to and read-from RAM	Whatever is read from the RAM must match what is written.
Information structures stored in Main Compact Flash and Protective CPU Eprom (a)Checksum comparison (b) Range check	Checksum of each structure is compared to the software-calculated checksum for that structure. Structures which contain minimum and maximum setting values are range checked to ensure the range is valid.
Note: A congruency check on the system database is performed before the priming phase of the Prime Self-Test.	
Communication between microprocessors	Both Control and Protective microprocessors must write and read through the I2C bus.

Table 1. Subtests of the Initialization Self-Test

Subtest	Description
Startup condition	Software accesses a decision tree to determine where to start, that is, How was the control unit turned off? Does the Query screen need to be displayed? Was this a power failure? Does an alarm screen need to be displayed?

Prime Self-Test

The prime self-test consists of two phases of subtests: pre-prime and post-prime. The pre-prime phase starts when the NEW PATIENT softkey is selected. The operator manually starts the prime phase of testing by pressing the PRIME TEST softkey on the “Priming X of X Cycles Complete” instruction screen. It includes all the subtests done during the periodic self-test of Run mode, as well as additional subtests.

During the testing process, if any subtest fails, an alarm occurs informing the operator about the specific failure and providing instructions.

Table 2 provides a list of the subtests in each phase of the prime self-test. The subtests are presented in the order in which they occur.

Table 2. Subtests of the Prime Self-Test

Subtest	Description
Pre-prime phase	
Pressure zero test	All the pressure pod sensors and the return pressure sensor must be 0±15 mmHg. Alarms generated is: Malfunction: Pressure zero test
Scale zero test	All the scales must read 0±30 gr. Alarm generated is: Malfunction: Scale zero test

Table 2. Subtests of the Prime Self-Test

Subtest	Description
Tubing presence in air detector	Occurs both before and after a set is loaded. Before loading, tubing should **not** be in the air detector. After loading, the return line should be present in the detector. Alarms generated are: Malfunction: Line in Air Detector Malfunction: No Line in Air Detector
Tubing presence in return clamp	Occurs both before and after a set is loaded. Before loading, tubing should **not** be in the clamp. After loading, the return line should be present in the clamp. Alarms generated are: Malfunction: Line in Clamp Malfunction: No Line in Clamp
Position of pinch valves	Occurs after a set is loaded. Tests whether an optical sensor in each pinch valve can properly detect various positions of the pinch valves. Alarm generated is Malfunction: Prime Self-Test, with the message *Upper Pinch Valve* or *Lower Pinch Valve*.
Syringe Hw Test	Occurs during the loading procedure of the syringe after selecting the INSTALL SYRINGE softkey. Alarm generated is Malfunction: Prime Self-Test, with the message *Syringe Pump HW*.

Table 2. Subtests of the Prime Self-Test

Subtest	Description
Post-Prime phase	**All the Post-Prime subtests occur after the operator has pressed PRIME TEST on "Priming X of X Cycles Complete" screen.**
Blood leak detector	a. "Normalizes" the infrared blood leak detector to establish a calibrated monitoring range. Alarm generated is Malfunction: Prime Self-Test, with the message *Blood leak detector normalization timeout failure*. b. After normalization is complete, the blood leak detector is tested to determine if it can detect a simulated blood leak. Alarm generated is Malfunction: Prime Self-Test, with the message *Blood leak detector threshold error.*
+12-volt	The Protective CCA disables the 12-volt relay that powers the Automatic Reposition system motor. Protective CCA then checks to see if the relay is disabled, and finally, re-enables the relay. Alarm generated is Malfunction: Prime Self-Test, with the message *24 volt / 12 volt.*
Air/pump security	Tests whether all pumps stop when a simulated air bubble is detected. Also verifies that the Control CCA can activate a "safe state" wherein all pumps are stopped and the return clamp is closed. Alarm generated is Malfunction: Prime Self-Test, with the message *Air/pumps security test*.

Table 2. Subtests of the Prime Self-Test

Subtest	Description
Pump occlusion	Tests whether the rollers of each peristaltic pump can completely occlude the tubing within the pump raceway. Alarm generated is Malfunction: Prime Self-Test, with the message *Pump occlusion test.*
Return pressure sensor	Using the Automatic Reposition system inside the machine, tests the return pressure sensor for accuracy. A maximum of 45 seconds is allowed for the test. Alarm generated is Malfunction: Prime Self-Test, with the message *Return pressure sensor*.
24-volt and return clamp	Tests the functioning of the 24-volt relay, in conjunction with the return clamp sensor, and the Control and Protective microprocessors. The clamp is closed, the 24-volt relay is turned off, then on; and the return clamp is re-opened. Alarm generated is Malfunction: Prime Self-Test. There are three possible failure messages: *24-volt*; *24-volt and return clamp sensor; return clamp sensor*.
Access, filter, and effluent pressure pods/sensors	(Done individually for each pod/sensor.) Using the Automatic Reposition system, tests the sensor for accuracy, then moves the pod diaphragm to neutral position. A maximum of 120 seconds is allowed for each pod/sensor. Alarm generated is Malfunction: Prime Self-Test. A message identifies which pod/sensor or combination of pods/sensors have failed.

Table 2. Subtests of the Prime Self-Test

Subtest	Description
Post-prime phase	
Remote alarm test	Occurs when the “Prime Test Complete” screen is displayed. Tests if the machine is able to send a signal to a remote alarm device (by simulating an alarm in the *Prismaflex* System). The red status light should illuminate on the *Prismaflex* Control Unit and the light or buzzer should activate on the remote alarm device (if a remote device is connected). Note: The test is done regardless of whether a remote alarm device is connected. **If this test fails, no alarm is generated. When a remote alarm device is connected, the operator is responsible for verifying that the simulated alarm is recognized by both the *Prismaflex* System and the remote alarm device.** (Instructions are provided on the Prime Test Passed screen.)

Periodic Self-Test

A periodic self-test is conducted by the control unit at the following times:

- During the prime phase of the prime self-test (Setup mode). For more information, refer to the “Prime Self-Test” section in this chapter.
- During a patient treatment (Run mode). A periodic self-test is conducted every two hours. The first periodic self-test starts 10 minutes[2] after Run mode is entered.

2. If another alarm occurs at the scheduled start of a periodic self-test, the self-test may be delayed up to 15 seconds.

- Following an operator's request (Run mode). A periodic self-test is conducted by pressing the SELF-TEST softkey from the System Tools screen.

A complete periodic self-test takes approximately 1 to 6 minutes. During the testing process, if any subtest fails, the entire periodic self-test fails and the Malfunction: Self-Test Failure alarm occurs. The alarm screen identifies the subtest that failed and provides instructions for the operator.

Subtests

The subtests done during periodic self-test are listed in "Table Subtests of the Periodic Self-Test", in the order in which they are done.

Table 3. Subtests of the Periodic Self-Test

Subtest	Description
Blood leak detector	Same as subtest (b) described in Table 2. Alarm generated is Malfunction: Self-Test Failure, with the message *Blood leak detector threshold error.*
24 volt and return clamp	Same as subtest described in Table 2. Alarm generated is Malfunction: Self-Test Failure. There are three possible failure messages: *24-volt*; *24-volt and return clamp sensor; return clamp sensor*.
Access, filter, and effluent pressure pods/sensors	Same as subtest described in Table 2. Alarm generated is Malfunction: Self-Test Failure. A message identifies which pod/ sensor or combination of pods/sensors have failed.
Return pressure sensor	Same as subtest described in Table 2. Alarm generated is Malfunction: Self-Test Failure, with the message *Return pressure sensor*.

Alarm Monitoring During the Periodic Self-Test

Some alarms are managed differently during the periodic self-test, according to the subtest in progress. Of the alarms affected, some are monitored at their operator-set limits, some are monitored at new, temporary limits, and

others are disabled. Table summarizes alarm monitoring during the periodic self-test.

Table 4. Alarm Monitoring During the Periodic Self-Test

Subtest	Alarm Name	Operator-set limit	Temporary limit	Disabled
All	Return disconnection Return extremely positive Return pressure dropping Return too positive	**X**		
Access pressure sensor	Access extremely negative (Monitored for negative pressure blood source only.) Access extremely positive (Monitored for positive pressure blood source only.)		50 mmHg *below* operator-set limit 50 mmHg *above* operator-set limit	
	Access disconnection Access pressure rising Access too negative			**X**
Filter pressure sensor	Filter extremely positive	**X**		
	Set disconnection No blood in filter Filter is clotted TMP excessive Filter is clotting TMP too high			**X**

Table 4. Alarm Monitoring During the Periodic Self-Test

Subtest	Alarm Name	Operator-set limit	Temporary limit	Disabled
Effluent pressure sensor	Filter is clotted TMP excessive Filter is clotting TMP too high			**X**

Chapter 2: Installation

WARNING

- **Read these installation instructions before starting installation. Read the *Prismaflex 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 assembled *Prismaflex* machine weighs approximately 60 kg (132 lb). Use at least two people to lift it out of the shipping carton. Handle the control unit carefully.**

Contents of *Prismaflex* Shipping Carton

- *Prismaflex* Control Unit, pre-attached to column and base with casters
- Installation kit containing the following:
  - United States-style power cord, with retaining bracket
  - Continental European-style power cord, with retaining bracket
  - Self-locking #4 nuts (2)
  - Scale carrying bars (4)
- Pump crank
- *Prismaflex Operator's Manua*l
- Software Upgrading Cd-Rom

Electrical Requirements

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

- from 100 (-10%) Vac to 240 (+10%) Vac; from 45 Hz to 65 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.

Electromagnetic Environment Requirements

The *Prismaflex* Control Unit needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Appendix A, in this manual.

Space Requirements

The assembled machine requires a minimum of 63 cm x 63 cm (25 in x 25 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

One 5/16-inch wrench

Step 1: Unpacking

1. Open the shipping carton. Carefully lift the machine out of the carton and place it upright. Remove carefully the foam packing paying attention not to damaging the machine components. Dispose of the shipping carton, foam packing, and other packaging material according to local regulations.
2. Inspect all components, paying particular attention to the front panel of the control unit. If any damage has occurred, immediately contact your local sales or service representative.

Step 2: Connect Power Cord

(See Figure 3)

1. Select the appropriate power cord and retaining bracket package.
2. Insert the power cord into the retaining bracket guide, so that the retaining bracket fits tightly against the female connector of the power cord.

3. Turn the retaining bracket by an half turn so that the retaining bracket guide is downward.
4. Plug the power cord into the power cord receptacle on the rear panel of the control unit.
5. Using the #4 self-locking nuts provided, secure the retaining bracket to the studs on either side of the power cord receptacle. Tighten the nuts with the 5/16-inch wrench.
6. The *Prismaflex* Control Unit has a means on the rear panel for the connection of a POTENTIAL EQUALIZATION CONDUCTOR. If required connect the POTENTIAL EQUALIZATION CONDUCTOR to the means.

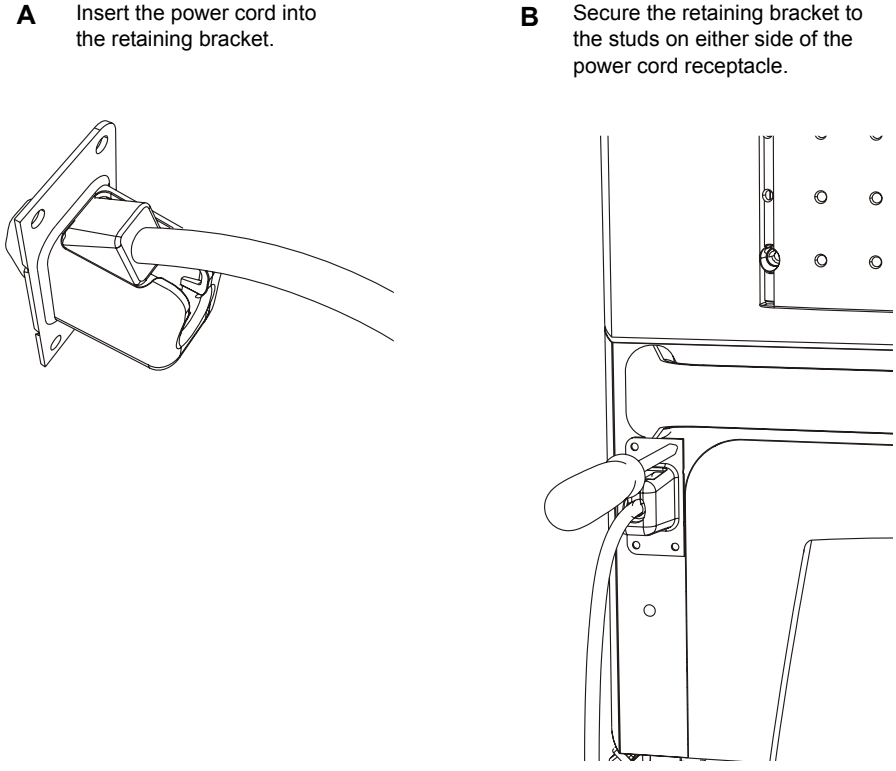


Figure 3. Connecting the Power Cord

Step 3: Install Scale Carrying Bars

(See Figure 4)

1. Working one scale at a time, install the carrying bars into the bar trays of the four scales.

   b. Open scale, place a carrying bar on the bar tray.

   c. Rotate the carrying bar so that the handle is toward the floor; close the scale.

   Note: Scale will not close properly unless the handle of the carrying bar is rotated toward the floor.

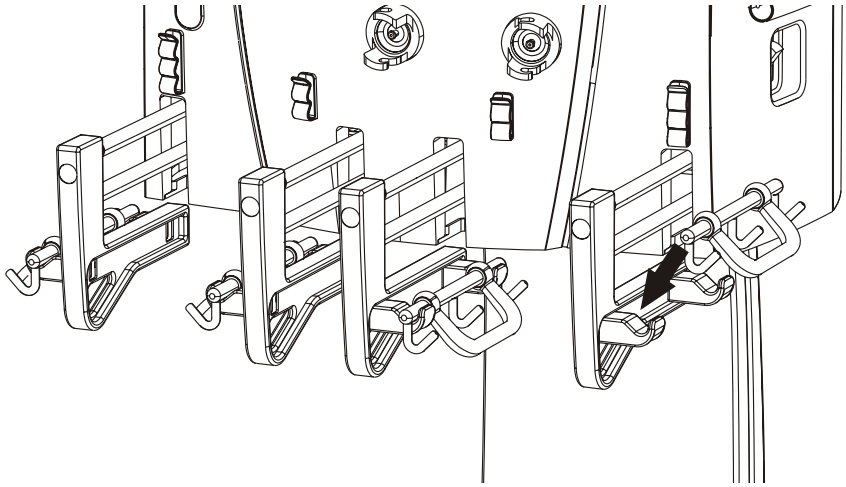


Figure 4. Placing the Carrying Bars on the Scales

Step 4: Machine Calibrations

Before first use of the *Prismaflex* 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 *Prismaflex Service Manual*.

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

Step 5: Installation Test

Note: Read this Operator's Manual before performing the installation test.

Before the first use of the *Prismaflex* Control Unit on a patient, the installation test must be performed with a *Prismaflex* CRRT 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 solution and fluid bags, and a container of water as a substitute for the patient. Successful completion of the installation test indicates that the *Prismaflex* Control Unit is functioning properly.

WARNING

- ***Do not* connect a patient to the *Prismaflex* 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 *Prismaflex* Control Unit has failed the test. Do not use the control unit. Call a trained and qualified technician for service.**

Supplies Needed

- A *Prismaflex* CRRT Set
- Four 1-liter bags of saline solution
- One 1-liter fluid container, filled with 500 ml tap water

Procedure

To perform the installation test, follow the steps below.

1. Plug the power cord into the wall outlet and turn on the control unit, as described under "Startup" in the CRRT 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 Enter Patient Information screen. Check that the SCUF, CVVH, CVVHD, CVVHDF softkeys are available on the Choose Therapy screen. Choose the *CVVHDF therapy*.
3. Follow the instructions on the display to load and prime the set. (Use saline solution in place of priming, dialysate, PBP, and replacement solutions.) The control unit performs multiple self-tests during the priming cycle.
4. Set the following flow rates and press the ENTER softkey.
   - Blood: 100 ml/min
   - PBP (pre-blood pump) solution: 1000 ml/hr
   - Dialysate solution: 1000 ml/hr
   - Replacement solution: 1000 ml/hr
   - Patient Fluid Removal: 200 ml/hr
   - Syringe: Continuous Delivery at 0 ml/hr
5. When the Review Flow Rates screen appears, verify the above flow rates, then press CONTINUE. When the Connect Patient screen appears, place the access and return lines into the container of water; press the START 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. During this time, press the HISTORY softkey from the Status screen. The main History screen appears, displaying the View Period titled “Last I/O Period.” Note that the fluid totals are continually updated as operation proceeds.
7. After 15 minutes, access the main History screen again. When it appears, press CHANGE PERIOD to see the “History Time Period” view. Using the arrow softkeys, 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 Patient Fluid Removed reads 50 ml ± 5 ml.

Note: If an alarm has occurred that stopped a peristaltic pump, the 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 TREATMNT softkey and follow the instructions to unload the set.

Chapter 3: Continuous Renal Replacement Therapies (CRRT)

Prismaflex CRRT Set

Figure 5 shows the assembled *Prismaflex* Control Unit with a *Prismaflex* CRRT Set, syringe, and fluid bags in place. The figure portrays CVVHDF therapy, which uses both dialysate, PBP and replacement solution. (See the foldout sheet at the back of the manual for an illustration of the other CRRT therapies). Following is a description of the components of the set and the fluid bags.

Sample Sites Color-coded ports with a plug that allow needle entry to the set. Used to obtain fluid or blood samples or to remove trapped air. Access is gained via a 21-gauge (or smaller diameter) needle attached to a syringe. In the CRRT Sets sample sites are located as follows: access line before blood pump (red), access line after blood pump (red), monitor line of deaeration chamber (blue), return line (blue), effluent line (yellow).
Note: Depending on the *Prismaflex* Set version, the blue sample site in the monitor line of the deaeration chamber may not be available. (See "*Prismaflex* CRRT Sets" in the Before You Get Started section of this manual.)

Pressure Pods There are three 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 the control unit) enable noninvasive pressure monitoring of the access line, filter, and effluent line.

Deaeration Chamber	A compartment on the return line that allows the *Prismaflex* Control Unit to manage air, monitor return line pressure, and add post-filter replacement solution (if any) to the return line.
Chamber Monitor Line	Connects the deaeration chamber with the return pressure port, enabling pressure monitoring and removal of air, if needed. The *Prismaflex* System can remove air automatically by drawing it out through the return pressure port. A fluid barrier at the distal end of the line protects the return pressure port from accidental blood/fluid entry. (See “Air Removal Procedures” in Chapter 5: Troubleshooting.)
Cartridge	Plastic component in the center of the set that holds the filter, pump segments, and pinch valve segments. Has slots that accept the tabs of the cartridge carrier on the control unit. Allows automatic loading of the set.
Filter	Filter containing hollow fibers made of a semipermeable membrane. Blood flows through the hollow fibers; filtrate 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.
Pinch Valve Segments	Tubing that threads automatically through the upper and lower pinch valves when the set is loaded. Can be occluded or opened by the pinch valves, depending on operator selections for therapy and replacement solution delivery.
Upper Pinch Valve Segment *(green-striped)*	**CVVHD and CVVHDF therapies:** Allows fresh dialysate hanging on the dialysate (green) scale to be conveyed to the fluid side of the filter. **CVVH therapy:** If desired, allows solution from a second bag of replacement solution (hanging on the green scale) to be delivered post-filter to the deaeration chamber on the return line.

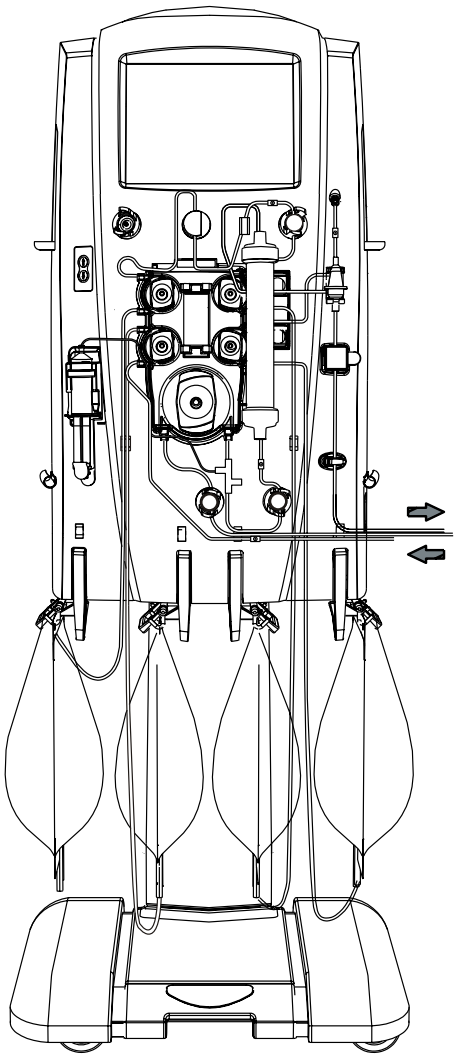


Figure 5. A *Prismaflex* CRRT Set in Place on the Control Unit

Lower Pinch Valve Segment *(purple-striped)*	**CVVH and CVVDHF therapies:** Allows replacement solution hanging on the replacement scale (purple) to be delivered either: (a) pre-filter (to the access line just before the filter); or (b) post-filter (to the deaeration chamber on the return line).
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.
PBP Line *(white-)striped)* PBP = Pre-blood pump	If required, conveys a prescribed infusion solution from the bag on the PBP scale (white) to the blood access line. The PBP solution enters the access line at a location immediately after patient blood enters and before the blood pump.
Replacement Line *(purple-striped*)	Conveys replacement solution from the bag on the replacement scale (purple) to the blood flowpath. The lower pinch valve segment is an integral part of this line.
Dialysate Line *(green-striped)*	**CVVHD and CVVHDF therapies:** Conveys dialysate from the dialysate bag on the dialysate scale (green) to the fluid side of the filter. **CVVH therapy:** If desired, conveys solution from a second replacement bag (on green scale), to the deaeration chamber on the return line. The upper pinch valve segment is an integral part of this line.
Effluent Line *(yellow-striped)*	Conveys ultrafiltrate and/or spent dialysate from the fluid compartment of the filter to the effluent bag.
Effluent Bag	Collects ultrafiltrate and/or spent dialysate. One effluent bag is supplied with each set. Used in all CRRT therapies.
PBP Bag PBP = Pre-blood pump	Holds prescribed infusion solution. May be used in all CRRT therapies.

Dialysate Bag	Holds prescribed dialysate solution. **Used in CVVHD and CVVHDF therapies**.
Replacement Solution Bag	Holds prescribed replacement solution. Used in CVVH and CVVHDF therapies.
Effluent Line *(yellow-striped)*	Conveys ultrafiltrate and/or spent dialysate from the fluid compartment of the filter to the effluent bag.
Electrostatic Discharger Ring *(on effluent line)*	When installed in the ring guide on the *Prismaflex* Control Unit, provides an electrical connection to "ground," to minimize electrical interference by *Prismaflex* pumps with patient electrocardiogram (ECG) recordings.
Syringe Line	Conveys anticoagulant or other solution from the syringe to the blood flowpath.

System Overview

Communicating with the *Prismaflex* Control Unit

The front panel of the *Prismaflex* Control Unit has a color touchscreen display. 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 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 bottom of each screen and may also appear on the sides. Softkeys 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 its 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.

In most cases, when the operator presses a softkey, a new screen appears immediately. In other cases, the same screen remains on the display and the color of the pressed softkey changes to indicate that it is *selected*. The selected softkey may need to be pressed again to *deselect* it before the action requested can occur. Instructions on the screen guide the operator if this is required.

Softkeys may appear on certain screens, but be inactive until the operator makes a certain choice or performs a required action. When a softkey is not available for use, its name or symbol is gray. When the softkey becomes available, its name or symbol assumes its normal color.

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. Other settings are controlled only by the manufacturer or by trained and qualified service technicians.

Table 13 in this chapter lists all user-controllable settings, their default values, setting options, and the operating mode in which they can be changed.

Default Values

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

- Each possible CRRT therapy/set combination has its own default values, including values for flow rates, bag volumes, and alarm limits.
- There are additional default values for settings that apply to all therapy/set combinations, for example, the decibel level of the audible alarm beep, and the size and brand of the syringe allowed for use.
- The default value of a setting controls operation, unless the operator selects a new value for that setting 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 of the user-controllable settings. This can only be done in Custom mode. For more information, see "Custom Mode" in this chapter.

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

When the operator chooses a particular CRRT therapy/set combination during the Setup procedure, the control unit uses the default values assigned to that combination. If desired, the operator can modify 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.

Safety Relevant Settings
Some user-controllable settings are critical to patient safety. These include all flow rates, syringe pump settings, and the PBP solution delivery method. These settings are modifiable via the Enter Flow Rates screen.

Whenever the operator modifies a safety relevant setting, the new value is shown *twice* for operator confirmation. The modified value is shown on the Enter Flow Rates screen, then again on a separate screen. In Setup mode, the separate screen is the Review Flow Rates screen; in Run mode, it is the Status screen.

The operator must assure that the values of safety relevant settings are the same in the Enter Flow Rates screen and the confirmation screen. If the screens display different values for the same setting, a data corruption has occurred. In this event, use of the *Prismaflex* Control Unit must be discontinued until service has made repairs.

Pumps

The control unit has five occlusive, peristaltic pumps:

- Blood pump
- PBP solution pump
- Replacement solution pump
- Dialysate solution pump
- Effluent pump

In addition, the control unit has one syringe pump that delivers anticoagulant or other solution to the blood flow, if desired.

During priming of the set (Setup mode), the blood pump turns clockwise and performs *forward priming* of the blood lines and filter. During a patient treatment (Run mode), all the peristaltic pumps turn clockwise and if the

blood pump stops for any reason, all other pumps also stop. When the blood pump resumes, the other pumps also resume after a short delay.

The *Prismaflex* software controls the speeds of the peristaltic pumps to constantly maintain the operator-set flow rates. The blood pump speed is managed so that the operator-set blood flow rate is maintained *at the blood access site*. The PBP, replacement, dialysate, and effluent pump speeds are based on all operator-set flow rates, as well as on the changing weights of the fluid bags in use.

Flow Rates and Syringe Pump Settings

Flow rates are the settings that control the rate of blood flow, patient fluid removal, PBP and replacement solution infusion, dialysate flow, and effluent flow during a patient treatment. All flow rates are directly user-controllable except the effluent flow rate, which is automatically set by software, based on all other flow rates. Below is the formula which governs the effluent pump rate.

Patient fluid removal rate (ml/hr)
+ PBP solution rate (ml/hr)
+ Replacement solution rate (ml/hr)
+ Dialysate solution rate (ml/hr)

= Effluent rate (ml/hr) set by *Prismaflex* software

Syringe pump settings control delivery of anticoagulant solution from a syringe to the blood flow. These settings are user-controllable and include the Delivery Method (Continuous or Bolus), Delivery Rate (applicable only for Continuous delivery), Bolus Volume and Bolus Interval (applicable only for Bolus delivery).

Adjusting the Flow Rates and Syringe Pump Settings

During the Setup procedure (Setup mode), the Enter Flow Rates screen is displayed. The operator is asked to assess the default flow rates and syringe pump settings for the therapy/set chosen, make any changes desired for the *current treatment,* and confirm all values shown on the Review Flow Rates screen prior to starting the patient treatment.

During the patient's treatment (Run mode), the operator can access the Enter Flow Rates screen and adjust the flow rates and syringe pump settings as needed. (See "Operating Modes" and "User-controllable Settings" in this chapter.) In Custom mode, if desired, the operator can change the default

flow rates and the syringe size/brand allowed for use. (See “Custom Mode” in this chapter.)

Viewing the Flow Rate Settings During Treatment

During a patient treatment (Run mode) the current flow rate settings, syringe pump settings, and other vital information are displayed on the Status screen. If desired, the operator can enter the patient’s *current weight* into software memory both during the Setup procedure and during Run mode. If the patient’s weight has been entered, the Status screen also displays the flow rates per patient kilogram (ml/hr/kg). (See “Operating Modes” in this chapter.)

PBP Rate and Blood Pump Speed

Use of PBP solution is typically done to accomplish pre-filter blood dilution. The PBP volume is added to the access line immediately *after* the patient’s blood enters from the access site, and *before* the access line reaches the blood pump. Because of this, the amount of blood actually pumped with each revolution of the blood pump is reduced. To maintain the operator-set blood flow rate at the blood access site, *Prismaflex* software increases the blood pump speed, according to the calculation below:

Operator-set BFR + Operator-set PBP rate per minute = Blood pump speed

Ratio of PBP to Blood in the Access Line

Whenever the PBP rate is greater than zero, software calculates the *dilution ratio*, which is the portion of PBP flow as compared to the portion of blood flow in the access line. The ratio is displayed on the Enter Flow Rates screen during the time the operator is adjusting the PBP rate or the blood flow rate.

The first number in the PBP:Blood ratio is always “1” and indicates the part of access line flow contributed by PBP solution. The second number indicates the part of flow contributed by blood. Ratio is calculated according to the formula below:

1:(Operator-set BFR / Operator-set PBP rate per minute)

The PBP rate must be lower than the blood flow rate so that (Operator-set BFR / Operator-set PBP rate per minute) is always greater than or equal to 1.

Replacement Solution Delivery Options

WARNING

Use only prescribed dialysate solution and replacement solution/fluid with the *Prismaflex* System. Use only dialysate solution and replacement solution/fluid which conform with applicable national registration, standards, or laws and the Council Directive 65/65/EEC. If a commercially available replacement solution is used, it must be labeled as intended for intravenous injection.

The desired replacement solution delivery is selected on the Enter Flow Rates screen after the set has been primed. The pinch valves (on the control unit) and pinch valve segments (on the set) enable various delivery options, depending upon the CRRT therapy selected.

For CVVH therapy: Replacement solution can be delivered 100% pre-filter; 100% post-filter; or in a combination of pre- and post-filter (pre/post), for example: 50% pre-filter and 50% post-filter.

Depending on operator selections, delivery of the replacement solution may use only the replacement scale and pump (purple), or it may also use the green scale and pump.

CVVH therapy requires that *two bags* of replacement solution always be hung, so that the set can be primed appropriately. One bag is placed on the replacement scale (purple) and the second bag is placed on the green scale.

For CVVHDF therapy: Replacement solution can be delivered either 100% pre-filter or 100% post-filter. The replacement solution is always delivered through the replacement scale and pump (purple). One bag of replacement solution is hung on the replacement scale.

Table 5 shows the components used with each possible replacement solution delivery option of CVVH and CVVHDF therapies.

Table 5: Components used with Replacement Solution Delivery Options

Therapy	Delivery	Scale/Pump	Pinch Valve/Segment
CVVH	100% Pre-filter	Replacement	Lower (purple-striped)
	Pre/Post	Replacement *(delivers pre-filter portion)*	Lower (purple-striped)
		Green *(delivers post-filter portion)*	Upper (green-striped)
	100% Post-filter	Replacement *(delivers 1/2 of the selected flow rate)*	Lower (purple-striped)
		Green *(delivers 1/2 of the selected flow rate)*	Upper (green-striped)
CVVHDF	100% Pre-filter	Replacement	Lower (purple-striped)
	100% Post-filter	Replacement	Lower (purple-striped)

Total predilution

The *Prismaflex* software calculates the *total predilution* value, which is the ratio of pre-filter blood dilution to the total blood dilution. *Total predilution* is calculated according to the formula below:

$$\textit{Total predilution (\%)} = \frac{\text{PBP solution rate + Pre-filter Replacement solution}}{\text{PBP solution rate + Replacement solution}}$$

The *total predilution* value is displayed in the Enter Flow Rates screen.

Patient Fluid Removal Rate

The patient fluid removal rate is the *net amount of fluid* the *Prismaflex* Control Unit removes from the patient each hour (after accounting for any PBP solution and 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 *Prismaflex* software *does not* measure or account for non-*Prismaflex* 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 solution infused via the *Prismaflex* 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 fluid loss (ml/hr)
\+ Non-*Prismaflex* fluid inputs (ml/hr)
\- Non-*Prismaflex* fluid outputs (ml/hr)
= Patient fluid removal rate (ml/hr) to be set on *Prismaflex* Control Unit

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

Adjusting the Patient Fluid Removal Rate

During the Setup procedure (Setup mode), the Enter Flow Rates screen is displayed. The operator is asked to assess the default patient fluid removal rate, make any change desired for the *current treatment,* and confirm the patient fluid removal rate on the Review Flow Rates screen prior to starting the patient treatment.

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

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

Machine Control of Patient Fluid Removal Rate

The *Prismaflex* software automatically calculates the ultrafiltration rate needed to achieve the patient fluid removal rate. Any PBP solution and replacement solution infused by the *Prismaflex* Control Unit is automatically accounted for, as shown below.

Patient fluid removal rate (ml//hr)
+ PBP solution rate, if any (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

Patient Fluid Removed

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

Measuring Patient Fluid Removed

The four precision scales mounted on the bottom of the *Prismaflex* Control Unit support the PBP, replacement solution, dialysate, 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 Patient Fluid Removed should equate with the operator-set patient fluid removal rate.[1] For example, if the patient fluid removal rate is 100 ml/hr and 90 minutes of treatment has elapsed, the Patient Fluid Removed will be 150 ml.

Viewing Patient Fluid Removed

During a patient treatment (Run mode), the Patient Fluid Removed is displayed on the History screen. The operator can view the amount of Patient Fluid Removed for the last full I/O Period or for a time period stipulated by the operator. See "History Data" in this chapter for more information.

1. 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.

History Data

Vital machine conditions and operating data are stored and updated minute-by-minute in software memory. The memory stores up to 90 hours of treatment data; thereafter, the old data are deleted and the new data are added minute-by-minute.

History data includes I/O Data, Events, and Graphs. Each category of data may be viewed on a history screen specific to it. I/O Data are displayed on the main History screen; Events data are displayed on the Events screens, and graphical data related to fluid flows and pressures are displayed on Graph screens. The Events and Graph screens are available from the main History screen.

The History screen can be accessed from the Status screen during a treatment (Run mode) and from the Treatment Complete screen when ending a treatment (End mode). History data for the last treatment performed can be accessed from the Choose Patient screen (Setup mode). History data can also be saved onto a patient information card, if desired. (See"Saving the History Data" in this chapter.)

I/O Data

To facilitate periodic totalling of patient I/O (input and output) volumes during a treatment, the *cumulative totals* of all *Prismaflex*-controlled fluids are computed and updated minute-by-minute. This process begins when treatment (Run mode) starts. These cumulative totals, called *I/O Data*, are reported on the main History screen.

View Periods for I/O Data

Depending on the default View Period stipulated in Custom mode, the *initial* view on the History screen is either the default *I/O Period* or the default *History Time Period*. I/O Period is an operator-controllable setting of either 60, 30, or 15 minutes, whereas the *History Time Period* is an operator-defined period of time which can span the entire treatment (up to 90 hours).

Before beginning the Setup procedure, the operator can use Custom mode to change the default values for View Period, I/O Period, and the number of hours for the History Time Period.[2] These settings can also be changed during treatment, using the softkeys on the main History screen. I/O Period is

2. In Custom mode, the default History Time Period is indirectly set by selecting the default Cumulative Hours value.

also modifiable from the Modify Settings screen, accessible via the Status screen.

Note: During treatment, the History Time Period displayed can be changed by pressing the START TIME and END TIME keys. The period of time selectable is: from the last minute of treatment to the last 90 hours of treatment with increments of 1 minute.

Information Included in I/O Data
I/O Data include the information below. Only the data appropriate to the selected therapy are displayed.

Note: All I/O Data, *except* Blood Volume Processed, are totals covering only the operator-selected View Period.

- Blood/Fluid Volume Processed (**total liters pumped through the current filter since start of treatment**, including any fluid pumped during Recirculation procedure).
- Run Time (time blood was treated during the selected View Period)
- Cumulative Hours reported (does not display when I/O Period is the selected view)
- PBP Solution Input
- Replacement Solution Input
  - Pre-filter Input
  - Post-filter Input
- Dialysate Used
- Effluent Volume (ultrafiltrate; spent dialysate)
- Patient Fluid Removed

Events

Certain events that may occur during setup and delivery of a treatment are stored and displayed on the three Events screens. The control unit stores the date, hour and minute that events occur, as well a description of the event. Up to five thousand events can be stored.

Events are displayed in chronological order, starting with the most recent. Arrow keys on the Events screens allow the operator to scroll up or down the chronological list. When the operator presses the EVENTS softkey from the History screen, all events are displayed. If desired, the operator can then

view only the alarm-related events or only the events related to flow rates and syringe pump settings.

An event is recorded when any of the following occur:

- Patient ID is entered/not entered.
- Patient weight is entered.
- Therapy is initially selected (Setup mode).
- A *Prismaflex* Set is loaded and automatically identified by the bar code reader or manually identified by the operator.
- Flow rates and syringe pump settings are initially selected (Setup mode).
- A syringe is installed/removed from the syringe pump.
- Prime test is passed.
- Treatment is started (Run mode).
- TMP value is reset.
- A flow rate or syringe pump setting is changed during treatment.
- The Allowed Volume of a bag or container is changed.
- The sensitivity of the blood leak detector is normalized.
- An alarm occurs.
- An alarm screen is cleared from the display.
- Any of these softkeys are pressed: LOAD, PRIME, PRIME TEST, STATUS (when pressed on the Change Bags screen), CHANGE BAGS, RESUME, STOP, START RECIRC, STOP RECIRC, RESUME RECIRC, START RETURN, UNLOAD.

Graphs

History information related to fluid flows and operating pressures is available on Graph screens, allowing easy visualization of trends over time. Graphs are accessed from the main History screen.

The operator selects the desired amount of time to view, using the START/END TIME and arrow softkeys, and the graphs automatically adjust to the selected time period.[3] For time periods of 12 or fewer hours, the time increment on the graphs is one hour. For time periods greater than 12 hours,

the time increment is divided evenly over the requested time span. The graphs information displays from less recent data (left) to more recent data (right). In addition to a graph, the Graph screens also display the Cumulative Hours and Run Time pertinent to the selected time period.

Fluid Graphs
The Fluid Graphs include the Pt Fluid Balance Graph (bar graph), the Dose Graph (line graph), and the Cumulative Volumes Graph (line graph).

The Pt Fluid Balance Graph displays the Patient Fluid Removed during each time increment of the graph. On the right side of the screen, the total Patient Fluid Removed over the requested time period is reported.

If the patient weight has been entered, the Dose Graph displays the ml/hr/kg flow that was occurring at each time point on the graph. There is a separate line for each fluid in use. The following are reported: PBP solution, Replacement solution, Dialysate, and Effluent. On the right side of the screen, the total volume pumped over the requested time period is reported for each fluid.

For each fluid in use, the Cumulative Volumes Graph reports the total volume pumped during each time increment of the graph. There is a separate line for each fluid in use. The following are reported: PBP solution, Replacement solution, Dialysate, Effluent. On the right side of the screen, the total volume pumped over the requested time period is reported for each fluid.

Pressure Graph
The Pressure Graph displays history information for the following pressures: access line, filter line, effluent line, return line/deaeration chamber, TMP (transmembrane pressure), and Pressure Drop (filter pressure drop). By using the softkeys provided, the operator can view all the pressures, a combination of pressures, or just one pressure at a time.

History Data After a Treatment

After a treatment is concluded, the history data is stored in *Prismaflex* software memory. It can be viewed from the Choose Patient screen (Setup mode) by pressing the LAST HISTORY softkey. **The last 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.**

3. The START/END TIME and arrow softkeys must be deselected before the graph updates to the requested time period.

History Data During a Power Loss

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

Saving the History Data

If desired, the history data can be copied electronically to a removable patient information card (PC Card). The card is placed in the patient card holder on the rear of the *Prismaflex* Control Unit and the data is copied using the DOWNLOAD DATA softkey on the History screen. The data is transferred in a .txt format, which can be imported into commonly used software programs. Each time the DOWNLOAD DATA softkey is pressed, all of the information in all of the History screens is copied.

The card has to be placed in the patient card holder to copy data and has to be removed from the patient card holder after data is saved only when the *Prismaflex* Control Unit is switched off. It is recommended to use a separate patient card for each patient whose record is being saved.

History data can be downloaded at any time during a treatment (Run mode) and when ending a treatment (End mode). In addition, the history data for the last treatment performed can be downloaded in Setup mode while the Choose Patient screen is displayed.
Note: The history data for the last treatment must be downloaded *before* choosing the patient. This is done by pressing LAST HISTORY, then pressing DOWNLOAD DATA when the History screen appears.

Alarm Safety System

The *Prismaflex* Control Unit continually monitors itself and the *Prismaflex* 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 Chapter 4: Alarm System for more information.

Monitoring Systems for CRRT Therapies

Pressure

The *Prismaflex* 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” section of this chapter for more information.

Blood Leak

The *Prismaflex* Control Unit has an infrared blood leak detector that monitors the effluent line for blood. If blood is detected, the operator is notified via a Warning alarm which stops the blood pump and closes the return line clamp.

Air Bubble

The *Prismaflex* Control Unit has an ultrasonic air bubble detector that continually monitors the return line for the presence of air. The detector consists of two ultrasonic transducers (transmitter and receiver). If air is detected, the operator is notified via a Warning alarm that stops the blood pump and closes the return line clamp.

Patient Connection

The *Prismaflex* Control Unit has additional sensors within the housing of the air bubble detector, including a tubing detection switch and a patient blood sensor. These sensors can detect the presence/absence of the return line and whether blood is in the line. (The presence of blood in the return line at this location on the machine is interpreted by *Prismaflex* software as an indication that a patient is connected to a loaded *Prismaflex* Set.)

A Warning alarm occurs if the operating mode of the machine indicates that a return line should NOT be installed and/or that blood should NOT be in the return line. The operator is required to verify whether a patient is connected and take appropriate action. Depending upon operator response, patient safety alarms may be enabled immediately or may be disabled until start of treatment. (See “Warning: Blood Detected in Set” alarm in Chapter 5: Troubleshooting.)

Operation

Startup

Startup of the *Prismaflex* 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, the non-mutable buzzer sounds, and some status lights are illuminated during the test.
3. When the initialization test is successfully completed, the yellow status light illuminates. This indicates the *Prismaflex* Control Unit is in the Setup mode and is ready for operation. If desired, the operator can look at therapy information screens for an overview of the *Prismaflex* therapies and *Prismaflex* Sets, or can proceed to the Choose Patient screen.

Note: The above actions occur when a new *Prismaflex* 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).
- Stop treatment and start over in Setup mode (by pressing the NEW PRIME key). **Starting over in Setup mode requires priming a new *Prismaflex* CRRT Set. The operator is asked to confirm this choice by pressing the CONTINUE softkey.**

Control and Navigation

The *Prismaflex* 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.

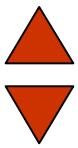
Screen Layout

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

- The top of the screen shows the screen title.
- The upper right corner shows the date, time, current operating mode, and the therapy selected by the operator.
- The bottom right softkey of most Operating and Alarm screens has a HELP key. Pressing this key provides more detail about the displayed screen.
- The bottom 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.[4] For more information, see the Alarm System chapter.

4. EXAMINE ALARMS does not appear on the Enter Flow Rates screen and the screens accessed via Enter Flow Rates, such as Enter Syringe Settings. (See Chapter 4: Alarm System.)

- A drawing may appear on certain screens, such as the Load Set screen. The drawing provides an easy visual reference for the operator in performing the actions described on the screen.



- 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 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. The arrows also allow the operator to increase/decrease fluid level in the deaeration chamber of the set.

- The ENTER softkey appears on Enter Flow Rates and Enter Syringe Settings screens. ENTER places one or more operator choices into software memory and exits the currently displayed screen.

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 these 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 *Prismaflex* CRRT 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. Perform preliminary procedures, if desired.
    - Enter Custom mode to alter default settings of one or more *Prismaflex* therapies. See “Custom Mode” in this chapter for more information.
    - Enter Therapy Information screens to read an overview of the *Prismaflex* therapies and *Prismaflex* Sets.
    - View/download history data of the last treatment.

2. Choose New Patient or Same Patient.

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

   If *Same Patient* is chosen, the control unit retains the 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 among the four Continuous Renal Replacement therapies, if desired, by pressing the CANCEL softkey when the Load Set screen appears.

3. If desired, enter an identification for the patient (up to 20 characters and/or numbers) into software memory. If desired, enter the patient's current weight.

4. Choose the therapy desired.

5. Position the desired set onto the control unit. This includes (a) placing the cartridge in the cartridge carrier; (b) routing PBP, replacement, and dialysate lines through tubing guides; (c) attaching the pressure pods to the pressure sensor housings; (d) routing effluent line through the blood leak detector; (e) inserting the electrostatic discharger ring on the effluent line into its guide; (f) installing the deaeration chamber in its holder and attaching the chamber monitor line to the return pressure port; (g) routing the return line through the air detector and return line clamp and then close the door of air detector; and, (h) hanging the effluent bag on the effluent scale. See Figure 6.

WARNING

Ensure that the proper *Prismaflex* Set has been chosen for the selected therapy. Using the wrong set for the therapy can cause patient injury or death.

6. Automatically load the set by pressing the LOAD softkey. When LOAD is pressed, the following occur: (a) the peristaltic pumps begin turning; (b) the cartridge is drawn inward; (c) the pump segments are threaded into the pump raceways; (d) the pinch valve segments are threaded into the pinch valves and the pinch valves rotate in the correct position for the therapy selected; (e) the bar code reader scans the bar code label on the filter.

7. Confirm the identity of the set that has been loaded.

   Note: If the bar code reader cannot read the bar code, the operator must manually enter the set's identity and confirm it. Once the set's identity is confirmed, the control unit accesses the default settings and screens for the therapy/set selected.

8. Prepare solutions; connect fluid bags and priming solution bag.
9. If the syringe is used install the syringe following the instructions displayed on the screen; if the syringe is not used, press NO SYRINGE. The selection of NO SYRINGE will not allow to use the syringe until a new set is loaded.
10. Automatically prime the set by pressing the PRIME softkey. Priming takes between 6 and 11 minutes, depending on the therapy/set selected.

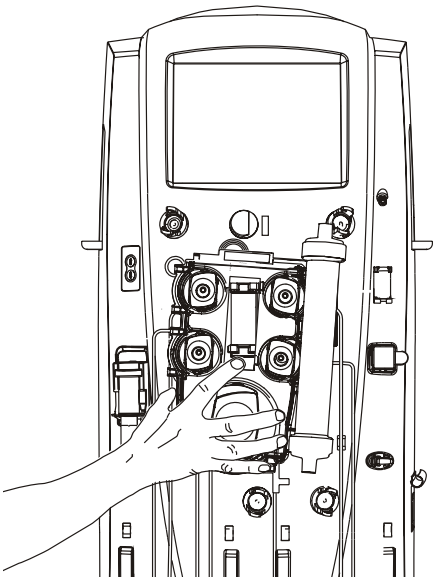
    Note: When PRIME is pressed, a priming sequence specific to the chosen therapy is conducted. During this sequence, the pumps run at internally set speeds. The blood pump turns clockwise (except for a few seconds in counterclockwise) and *forward primes* the blood lines and filter.

11. Perform the prime test by pressing the PRIME TEST softkey. The control unit performs multiple self-tests lasting between 1 minute and and 6 minutes (depending on the therapy selected). During the prime test, the following are tested: blood leak detector, all three pressure sensors and pods, return pressure port/sensor; return line clamp, pumps, both pinch valves, air bubble detector, and 24-volt switch. Pumps automatically turn on and off to perform these tests. (See Table 2, "Subtests of the Prime Self-Test" in Chapter 1: Product Description for a list of the prime self-tests.)
12. If needed, adjust flow rates and syringe pump settings. Set the patient fluid removal rate, if desired.
13. Review current flow rates and syringe pump settings on a separate screen; confirm by pressing CONTINUE.

The Operating screens that appear in Setup mode are listed, by title, in Table 6. Screens are listed in the order in which they automatically appear during the Setup procedure. If a screen is accessed from a prior-appearing screen, it is indented in the table.

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

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.

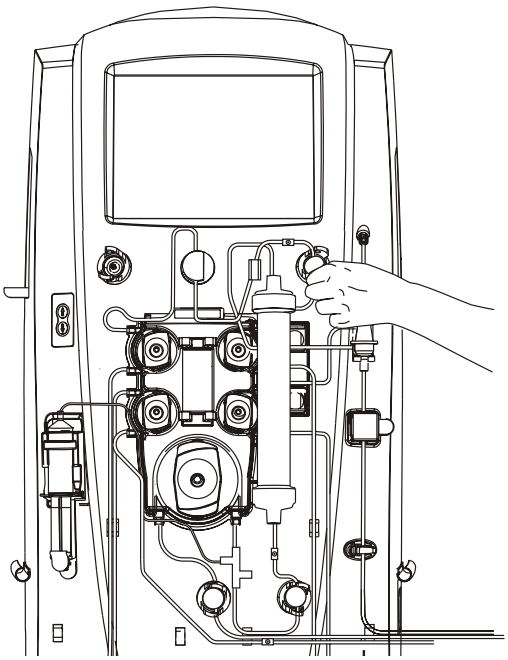


Figure 6. Positioning a *Prismaflex* CRRT Set on the Control Unit

Table 6: CRRT Operating Screens in Setup Mode

Logo Screen
Choose Patient
History

Table 6: CRRT Operating Screens in Setup Mode (cont.)

Events screens
Graph screens (Fluid and Pressure)
Enter Patient Information (optional)
Use keyboard to enter Patient ID *(optional)*
Use keyboard to enter Patient Weight *(optional)*
Choose Therapy
Load Set
Loading pumps, please wait
Unloading pumps, please wait *(for use if loading was unsuccessful)*
Confirm Set Loaded: Unknown *(appears if set cannot be identified by bar code reader)*
Confirm Set Loaded
Prepare and Connect Solutions
Install Syringe/No Syringe
Priming, please wait
Disconnect Set *(for use if needed)*
Remove Set *(for use if needed)*
Priming X of X Cycles Complete
Prime Test, please wait
Prime Test Passed
Prepare to Reprime *(for use if needed)*
Adjust Deaeration Chamber *(for use if needed)*
Enter Flow Rates
Enter Syringe Pump Settings
Change Syringe
Review Flow Rates

Standby Mode

The control unit automatically goes into Standby mode after the operator completes all Setup procedures and presses the CONTINUE softkey on the

Review Flow Rates screen. The Connect Patient screen appears. The operator can connect the patient to the primed set at this time. If necessary, the Enter Flow Rates screen can be re-accessed for further adjustments before starting the treatment.

WARNING

- **If a patient is not connected to the *Prismaflex* 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 a new bag of priming solution and may require a new (empty) collection bag.**
- **All lines in the set have a pre-attached slide clamp. After priming is complete and before starting a patient treatment (Run mode), clamp lines as follows. SCUF and CVVHD: replacement line; SCUF: dialysate line; All therapies: syringe line (if not in use) and PBP 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 TREATMNT, or RECIRC.

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 7.

Table 7: CRRT Operating Screens in Standby Mode

Connect Patient *(Standby mode entered from Setup mode)*
Reconnect Patient (after Recirculation procedure) *(Standby mode entered from Setup mode)*
Stop *(Standby mode entered from Run mode)*

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 or Reconnect Patient screen.

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

The Status screen is the main 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 history data is accumulated and stored.
2. Adjust flow rates, syringe pump settings, and the patient fluid removal rate, as needed.

   Note: To initiate PBP solution flow, when the treatment is running, the operator must perform the following sequential actions: press CHANGE BAG and hang a PBP bag on the scale; set the desired PBP flow rate in the Enter Flow Rates screen; monitor fluid level in the deaeration chamber and, if needed, remove the excess air intake from the PBP line.
3. Change the syringe as needed. **Note:** The CHANGE SYRINGE softkey activates the Syringe Control Panel, located on the front panel of the control unit.
4. Change fluid bags at any time through the Change Bags/Containers function. Modify the Allowed Volume for any bag, if desired.
5. From the System Tools screen, do any of the following:
   - View instruction screens for performing the Pressure Pod Adjustment Procedure. Instructions specific to each pod are available.
   - Automatically adjust the fluid level in the deaeration chamber.
   - Adjust the following settings: Status Graph Period, I/O Period, I/O Reminder (On/Off), and the audible alarm volume.
   - Clean the touchscreen (an empty screen is displayed to avoid an unwanted selection of softkeys)
   - Perform an immediate self test sequence
   - Enter or modify the value for Patient Weight
   - Reset (re-normalize) the sensitivity of the blood leak detector.

WARNING

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

6. View/download history data.
7. Temporarily stop the patient's treatment by pressing the STOP softkey.

The Operating screens available in Run mode are listed in Table 8. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Table 8: CRRT Operating Screens in Run Mode

Status
Enter Flow Rates
Enter Syringe Pump Settings
Change Syringe
Change Bags/Containers
History
Events screens
Graph screens (Fluid and Pressure)
Change Period
System Tools
Pressure Pod Adjustment Procedure
Adjust Deaeration Chamber
Modify Settings
Clean Screen
Initiate Self Test
Normalize Blood Leak Detector

End Mode

The control unit enters End mode when the operator presses STOP, then presses the CHANGE SET, END TREATMNT, or RECIRC 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 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; view/download history data if desired.
3. *Recirculate* - Return blood to the patient; temporarily disconnect patient and recirculate saline through the blood lines. When ready, reprime the set; reconnect patient and resume treatment.

   Note: When a total volume of 780 liters has been processed through the filter, the Advisory: Time to Change Set alarm occurs. The volume of saline pumped during the Recirculation procedure adds to the total liters processed; for example, recirculating at 100 ml/min for two hours would add 12 liters to the total volume processed.

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—by pressing the RETURN BLOOD softkey, selecting the desired blood return rate, and following the instructions on the Return Blood screen—or by returning blood manually.

   Note: The blood pump runs at the operator-selected Blood Return Rate when the START RETURN softkey is pressed and held.

   Note: Returning blood manually involves turning the machine off and cranking the blood pump clockwise. Step-by-step instructions are provided in “Manual Termination of Treatment” in Chapter 5: Troubleshooting.

2. Disconnect the patient from the set and unload the pump segments and pinch valve segments by pressing the UNLOAD softkey. Remove the set, the syringe (if empty or unwanted), and any empty or unwanted fluid bags; return to the Load Set screen in Setup mode.

WARNING

Follow facility procedures for the proper disposal of the used *Prismaflex* Set and fluid bags, in conformance with local regulations.

3. Place a new set on the control unit and load it by pressing the LOAD softkey. Treatment continues once the control unit reaches Run mode.

WARNING

Ensure that the proper *Prismaflex* Set has been loaded for the selected therapy. Using the wrong set for the therapy can cause patient injury or death.

The “Change Set” screens available in End mode are listed in Table 9.

Table 9: CRRT “Change Set” Screens in End Mode

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

End Treatment Procedure

After pressing END TREATMNT, 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, selecting the desired blood return rate, and following the instructions on the Return Blood screen—or by returning blood manually.

Note: The blood pump runs at the operator-selected blood return rate when the START RETURN softkey is pressed and held.

Note: Returning blood manually involves turning the machine off and cranking the blood pump clockwise. Step-by-step instructions are provided in “Manual Termination of Treatment” in Chapter 5: Troubleshooting.

2. Disconnect the patient from the set and unload the pump segments and pinch valves by pressing the UNLOAD softkey and then confirming set unloading. (The control unit automatically advances to the Treatment Complete screen.)
3. Remove the set, syringe, and all bags. View/download history data, if desired.

WARNING

Follow facility procedures for the proper disposal of the used *Prismaflex* Set and fluid bags, in conformance with local regulations.

4. Turn off the control unit if no more patient treatments are desired or press the NEW TREAT softkey to start a new patient treatment and load a new set.

The “End Treatment” screens available in End mode are listed in Table 10. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Table 10: CRRT “End Treatment” Screens in End Mode

End Treatment
Enter Blood Return Rate (optional)
Return Blood (optional)
Disconnect Patient
Confirm Patient Disconnected
Unloading pumps, please wait
Treatment Complete
History
Events screens

Table 10: CRRT "End Treatment" Screens in End Mode (cont.)

Graph screens

Recirculation Procedure

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

1. Hang a bag of sterile saline on priming hook and connect a Y-line to the saline bag. Prime the Y-line with priming solution.
2. Enter the desired Blood Return rate, then disconnect the access line from the patient and connect it to the bag of sterile saline using the Y-line.
3. Return blood to the patient by pressing and holding 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 DISCONNECT without returning the patient's blood. (The control unit automatically advances to the Disconnect Patient screen and instructions are provided.)
4. Enter the desired Recirculation Rate.

   Note: The Recirculation Rate can be changed at any time while Recirculation is in progress.
5. Set the syringe pump to deliver an "Immediate" bolus to the access line, as needed.

   Note: The only syringe pump delivery available in the Recirculation procedure is "Immediate" Bolus. Whenever the operator sets the "Immediate" Bolus Volume to a value greater than zero, a bolus is administered upon exiting the Enter Recirc Flow Rates screen. If needed a new (full) syringe can be installed during Recirculation.
6. Disconnect the patient from the return line, connect the return line to the saline bag using the second Y-line extension and begin Recirculation.

   Note: The Recirculation in Progress screen reports the following information: Recirculation Time, Recirculation Rate, Status of the Set (milliliters of patient blood and/or saline that have been processed through the filter). Most alarms are disabled during Recirculation.

Note: If necessary, Recirculation can be stopped and the treatment ended. This requires unloading the set, automatically advancing to the Treatment Complete screen, and following the instructions to remove the set, syringe, and bags. If desired, the patient's treatment can be restarted by selecting "Same Patient" when the machine is again in Setup mode.

7. When ready, stop recirculating and prepare to reprime the set. The set is prepared by: (a) disconnecting access and return line from each other, (b) connecting access line to a bag of priming solution, (c) connecting return line to a new (empty) prime collection bag.

   Note: When PRIME is pressed, the control unit leaves End mode and enters Setup mode.

8. Prime the set. When the prime test is successfully completed, reconnect the patient; resume treatment by pressing the START softkey on the Reconnect Patient screen.

   Note: Abbreviated priming and prime test sequences are conducted when a *Prismaflex* Set is primed following the Recirculation procedure.

WARNING

If a patient is not connected to the *Prismaflex* 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 may require a new (empty) collection bag.

The "Recirculation" screens available in End mode are listed in Table 11. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Table 11: CRRT "Recirculation" Screens in End Mode

Recirculate
Enter Blood Return Rate *(required)*
Return Blood *(required)*
Disconnect Patient (optional, if set has significant clotting. Cycles to *Change Set* procedure)
Unloading, please wait (optional, part of *Change Set* procedure)

Table 11: CRRT "Recirculation" Screens in End Mode (cont.)

Remove Set (optional, part of *Change Set* procedure)
Enter Recirc Flow Rates *(required)*
Change Syringe
Connect Blood Lines
Recirculation in progress
Recirculation Stopped
Unload Set *(optional, if set becomes unusable. Cycles to End Treatment procedure)*
Unloading pumps, please wait *(optional, part of End Treatment procedure)*
Treatment Complete *(optional, part of End Treatment procedure)*
Prepare to Prime

Custom Mode

Custom mode allows authorized personnel to change the *default values* of user-controllable settings.[5] Table 13 provides a list of the user-controllable settings and the mode(s) in which they can be altered.

To change a default value, the operator follows the instructions on the display to perform the following steps:

1. Enter Custom mode by pressing CUSTOM MODE on the Choose Patient screen.
2. When the main Custom mode screen (Modify Defaults) appears, select the default setting(s) to customize. Specify the new default value(s) on the appropriate Custom mode sub-screen.

5. Only the default values of *enabled Prismaflex* therapies can be customized. *Prismaflex* therapies can be enabled/disabled only in Service mode, by trained and qualified *Prismaflex* Service Technicians. The enabled *Prismaflex* therapies are identified on the Welcome to Custom Mode screen.

Notes:

- To modify default flow rates and alarm limits, the operator first chooses the desired therapy/set combination, then chooses “Flow Rates” or “Alarm Limits” and sets the desired default value(s).
- To modify the Empty Bag Method and the Allowed Bag Volume for Dialysate, PBP and Replacement bags, the operator first selects the type of therapy (CRRT), then selects the Empty Bag Method. If the Empty Bag Method selected is “Variable”, the operator selects the bag (Dialysate, PBP or Replacement) and sets the desired default value.
- To modify Allowed Bag Volume for the Effluent bag, the operator first selects the type of therapy (CRRT), then selects the Effluent bag and sets the desired default value.
- The new default values are saved in memory each time the operator presses the MODIFY DEFAULTS softkey (to return to the Custom: Modify Defaults menu screen) and whenever the EXIT CUSTOM softkey is pressed from any screen.

The screens available in Custom mode are listed in Table 12. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Table 12: CRRT Screens in Custom Mode

Welcome to Custom Mode
Modify Defaults
Alarms & Flows - Menu
Alarms & Flows - *therapy selected* (*CRRT, TPE, or HP)*
Alarms & Flows - *therapy/set selected*
Flow Rates - *therapy/set selected*
Alarm Limits - *therapy/set selected*
Syringe Size and Brand
Other Settings
Bag Volume - Menu
Bag Volume - *therapy selected (CRRT)*
Time/Date

User-controllable Settings

User-controllable settings and the mode in which they can be altered are listed in Table 13. Each setting has a default value and a range of setting options.

Most of the user-controllable settings can be adjusted in more than one mode. Some settings, such as alarm limits, can only be adjusted in Custom mode, and some settings, such as I/O Reminder Beep can only be adjusted in Run mode.

Table 13: User-controllable Settings in CRRT Therapies

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Time	A time set by the manufacturer	Should always be set to current hour and minute (24-hour clock) Increments: 1 hour; 1 minute	X		
Date	A date set by the manufacturer	Should always be set to current year, month, and day Increments: 1 year; 1 month; 1 day	X		
Date Display	Day/Month/Year	Day/Month/Year, or Month/Day/Year	X		
“Time to Change Set” Advisory Limit	After 72 hours of use	After 24 to 72 hours of use. Increment: 24 hours	X		
“Access Extremely Negative” Warning Limit	-250 mmHg	-10 to -250 mmHg Increment: 5 mmHg	X		
“Access Extremely Positive” Warning Limit	+300 mmHg	+10 to +300 mmHg Increment: 5 mmHg	X		

Table 13: User-controllable Settings in CRRT Therapies (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
"Return Extremely Positive" Warning Limit	+350 mmHg	+15 to +350 mmHg Increment: 5 mmHg	X		
"TMP Too High" Advisory Limit	+300 mmHg	+70 to +300 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		
Blood Flow Rate	10 ml/min	Specific to therapy/set Maximum Range: 10 to 450 ml/min Increment: 10 ml/min (See Specifications chapter.)	X	X	X
Return Blood Flow Rate **Note:** End Mode only	10 ml/min	10 to 100 ml/min Increment: 10 ml/min (see Specifications chapter)	N/A	N/A	N/A
Recirculation Rate **Note:** End mode, Recirculation only	10 ml/min	10 to 150 ml/min Increment: 10 ml/min	N/A	N/A	N/A
PBP Solution Flow Rate PBP = pre-blood pump	0 ml/hr	Specific to therapy/set Maximum Range: 0, 10 to 8000 ml/hr Increment: 10 ml/hr (see Specifications chapter) *(see Warning (a))*	X	X	X

Table 13: User-controllable Settings in CRRT Therapies (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Replacement Solution Flow Rate	0 ml/hr	Specific to therapy/set Maximum Range: 0, 50 to 8000 ml/hr Increment: 50 ml/hr or 5% depending on the therapy/set (see Specifications chapter)	X	X	X
Replacement Solution Delivery Method	CVVH: 100% Pre-filter CVVHDF: Pre-filter	CVVH: 0 to 100% Pre-filter CVVHDF: Pre-filter or Post-filter *(see Warning (a))*	X	X	X
Dialysate Flow Rate	0 ml/hr	Specific to therapy/set Maximum Range: 0, 50 to 8000 ml/hr Increment: 50 ml/hr (see Specifications chapter)	X	X	X
Patient Fluid Removal Rate	0 ml/hr	Specific to therapy/set Maximum Range: 0, 10 to 2000 ml/hr Increment: 10 ml/hr (see Specifications chapter)	X	X	X
Syringe Size	20-cc	10-, 20-, 30-cc	X		

Table 13: User-controllable Settings in CRRT Therapies (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Syringe Brand	BD 20	**10-cc brands:** BD 10 PLASTIPAK, TERUMO 10, Others. **20-cc brands:** PIC 20 LL, TERUMO 20, ICO STERIL, BD 20 PLASTIPAK, ICO GAMMA PLUS, Others. **30-cc brands:** TERUMO, BD 30 PLASTIPAK, PIC 30 LL, ICO GAMMA PLUS, ICO STERIL, Others.	X		
Syringe Delivery Method	Continuous	Continuous or Bolus		X	X
Syringe Continuous Delivery Rate	0 ml/hr	0, 1.0 to 5.0 ml/hr for 10-cc syringe; 0, 0.5 to 5.0 ml/hr for 20-cc syringe; 0, 0.5 to 10.0 ml/hr for 30-cc syringe. Increment: 0.1 ml/hr		X	X
Syringe Bolus Delivery Volume	0 ml	0, 0.5 to 5.0 ml for 10-cc and 20-cc syringe; 0, 1.0 to 5.0 ml for 30-cc syringe. Increment: 0.1 ml		X	X

Table 13: User-controllable Settings in CRRT Therapies (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Syringe Bolus Delivery Interval	Once every 6 hours.	Once every 1 to 24 hours Increment: 1 hour **Note:** *Immediate* option also available in Run mode		X	X
Syringe “Immediate” Bolus Volume **Note:** End mode, Recirculation only	0 ml (no delivery)	0 ml, or 0.5 to 5.0 ml Increment: 0.1 ml	N/A	N/A	N/A
Empty Bag Method	Fixed	Fixed or Variable	X		
Allowed Bag Volume					
PBP Bag	5000 ml	250 to 5000 ml Increment: 250 ml	X		X
Replacement Bag	5000 ml	500 to 5000 ml Increment: 250 ml	X		X
Dialysate Bag	5000 ml	500 to 5000 ml Increment: 250 ml	X		X
Effluent Bag	5000 ml	5000 or 9000 ml (see Specifications chapter)	X		X
Initial View Period, History screen	I/O Period	I/O Period or History Time Period	X		
I/O Period, History screen	60 minutes	15, 30, or 60 minutes	X		X
Cumulative Hours, History screen	Last 12 hours **Note:** This value is also the default History Time Period	Last 1 to 90 hours Increment: 1 hour	X		

Table 13: User-controllable Settings in CRRT Therapies (cont.)

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
Status Graph Display (line graph of TMP and Pressure Drop trends)	On	On, Off	X		
Status Graph Period	Last 3 hours	Last 1, 2, or 3 hours	X		X
I/O Reminder Beep *(This feature is not currently available)*	On	On, Off			X
Audible alarm volume	Moderate	Low, Moderate, High			X

WARNING (a)

Changing of the therapy settings that implies the use of lines containing non-circulating fluid (for example, changing the pre- and post-filter options for delivery of the replacement solution or starting using the PBP Pump) during the treatment may increase the risk of clot release to the patient. It is the operator's responsibility to verify that no cloths are present in the line before using it.

Syringe Installation Procedure

A luer lock syringe of the allowed brand and size should be filled and installed in the syringe pump during Setup mode. This is done while the Prepare and Connect Solutions screen is on the display.

- **If anticoagulation of the blood flowpath will be provided via the syringe pump,** the syringe should be filled with anticoagulant solution.
- **If anticoagulation will not be provided via the syringe pump,** the syringe should be filled with priming solution. This assures that the syringe line will be primed during the automatic priming cycle.

During priming (Setup mode), treatment (Run mode) and the Recirculation procedure (End mode), an Advisory alarm occurs to notify the operator that the syringe is empty. The alarm screen provides access to the Change Syringe instruction screen. If desired, the operator can also change the syringe before it is empty, by using the CHANGE SYRINGE softkey, which is available on the Enter Syringe Pump Settings and Enter Recirc Flow Rates screens. The syringe can be removed and a full one installed with no interruption in treatment or recirculation.

WARNING

- **To assure proper syringe flow control, install only the "allowed syringe" selected in Custom mode. (See Table 12 and "Syringe Pump Settings" in the Specifications chapter for a list of approved syringes from which to choose.)**
- **The internal diameter of approved syringes have been verified at the time of printing this manual. The manufacturer of the *Prismaflex* Control Unit cannot be held liable for subsequent changes that may occur to syringe dimensions.**
- **Use only luer lock syringes with the *Prismaflex* Control Unit. Use of non-luer lock syringes can result in patient blood loss if the syringe line becomes dislodged from the syringe.**

Syringe Control Panel

Syringes are installed/removed from the syringe pump by using the Syringe Control Panel ("Up" and "Down" buttons) on the *Prismaflex* Control Unit. The Syringe Control Panel is automatically activated/deactivated by *Prismaflex* software, according to machine operating conditions.

The Syringe Control Panel is active in the following situations:

- During Setup mode, until the PRIME softkey is pressed.
- During Run mode, when the operator presses CHANGE SYRINGE from the Enter Syringe Pump Settings screen.
- During the Advisory: Syringe Empty alarm, when the operator presses CHANGE SYRINGE from the alarm screen.

- During End mode Recirculation procedure, when the operator presses CHANGE SYRINGE from the Enter Recirc Flow Rates screen.
- During End mode Change Set and End Treatment procedures, when the operator presses UNLOAD from the Disconnect Patient screen.

Initial Syringe Installation

(See Figure 7)

Note: The instructions below are also available on the *Prismaflex* display, by pressing the HELP softkey on the Prepare and Connect Solutions screen in Setup mode.

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

1. Fill syringe with proper solution; push plunger to expel all air. Attach syringe line to syringe.
2. Pull plunger clamp latch to open position. Press and hold “Down” button on Syringe Control Panel to move the plunger clamp to its lowest position.
3. Open the barrel guard. Insert wings of syringe into the slot on syringe holder. Slide barrel guard to the left to secure syringe.
4. With Up/Down buttons, adjust position of plunger clamp so that the platform fits against the syringe plunger.
5. Press plunger clamp latch toward the control unit to lock the syringe plunger in place.

Changing the Syringe During Treatment or Recirculation

Note: The instructions below are provided on the *Prismaflex* display when the operator presses CHANGE SYRINGE from the Enter Syringe Pump Settings or Enter Recirc Flow Rates screens.

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

1. Access the Enter Syringe Pump Settings screen; press CHANGE SYRINGE to activate the Syringe Control Panel on the control unit. Clamp syringe line and disconnect it from syringe.
2. Pull plunger clamp latch away from the control unit to release the syringe plunger. Slide barrel guard to the right; pull syringe out of holder and discard.

3. Fill a new syringe with proper solution; push plunger to expel all air. Connect syringe line to new syringe.
4. Press and hold “Down” button on Syringe Control Panel to move the plunger clamp to its lowest position.
5. Insert wings of syringe into the slot on syringe holder. Slide barrel guard to the left to secure syringe.
6. With Up/Down buttons, adjust position of plunger clamp so that the platform fits against the syringe plunger. Press plunger clamp latch toward the control unit to lock the syringe plunger in place.
7. Unclamp syringe line; press the CONFIRM softkey on the Change Syringe screen.

A Insert wings of syringe into the slot on syringe holder.

B Slide barrel guard to the left to secure the syringe.

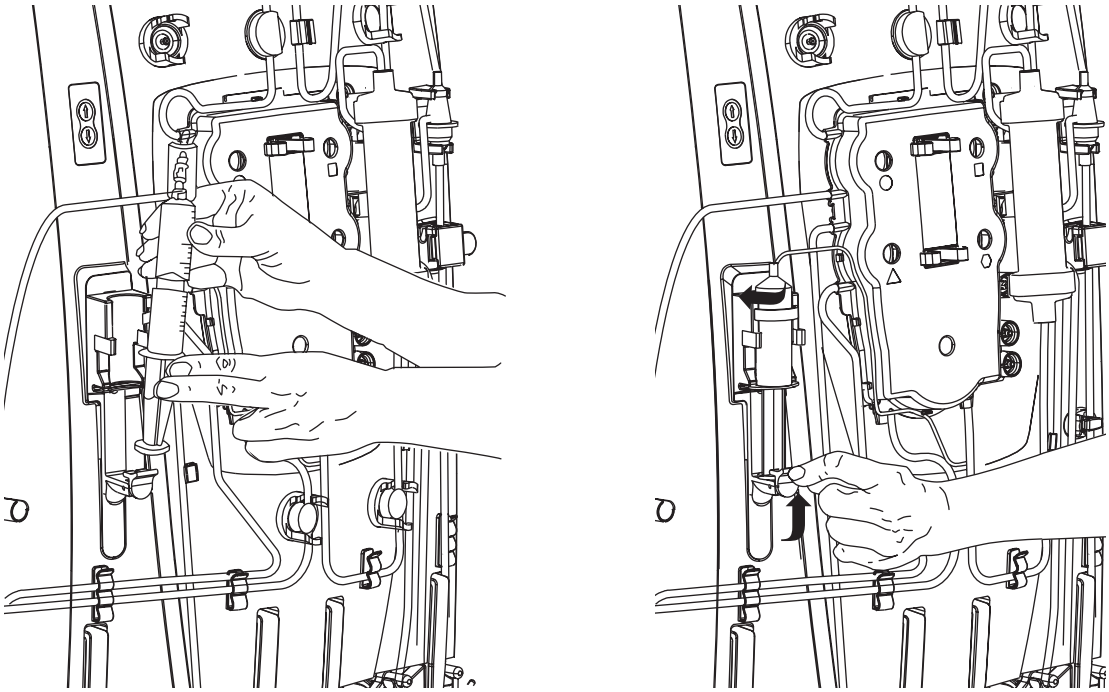


Figure 7. Installing the Syringe with a *Prismaflex* CRRT Set

Change Bags Function

Any of the bags in use can be changed at any time during a patient treatment (Run mode), not just when a Bag Empty/Bag Full alarm occurs. This is done by using the Change Bags function available on the Status screen.

Prismaflex Control Unit Actions

When CHANGE BAGS on the Status screen is pressed, the following control unit actions occur:

- Blood and syringe pumps continue to operate; all other pumps stop.
- Yellow status light illuminates as a reminder that therapy is not being delivered.
- Audible alarm sounds as a reminder that therapy is not being delivered.
- Change Bags/Containers screen appears and provides on-line instructions.

Modifying the Allowed Bag Volume During Treatment

While changing any bag, the operator can also change to using a different *size* of bag, if desired. For example, the operator can change from using an effluent bag of 5000 ml total capacity to using an effluent bag of 9000 ml total capacity. This is done by using the Modify Bag function on the Change Bags/ Containers screen.

When the MODIFY BAG softkey is pressed, a list of bags in use appears, along with softkeys for selecting the bags. The operator presses the softkey for the bag volume to be modified, then uses the Arrow keys to choose a new Allowed Volume. An alarm occurs if there is a discrepancy between the Allowed Volume of a bag and the actual volume sensed by the scale on which the bag is hanging.

Changing a Bag During Treatment

Note: Instructions for changing a bag/container are also provided on the *Prismaflex* display when the operator presses CHANGE BAGS from the Status screen.

To change a bag during treatment, perform the following steps.

1. Press CHANGE BAGS on the Status screen to access the Change Bags/ Containers screen.
2. Press the MUTE key to silence the audible alarm.
3. Open the scale of the bag to be changed. Clamp the bag and the line of the set connected to it. Disconnect the bag from the line.
4. Hang a new bag on the scale and connect it to the line.
5. Unclamp the new bag and line; close the scale.

6. If changing to a larger/smaller bag, press MODIFY BAG and use the arrows to select the total volume capacity of the new bag.[6]
7. Verify that all lines to bags in use are unclamped and that all unused lines remain clamped.
8. Press CONTINUE to return to the Status screen and resume the patient treatment.

6. If a Fixed Empty Bag Method is used to monitor the bag volume, it is possible to change only the total volume capacity of the effluent bag by pressing MODIFY EFFLUENT in the Change Bags screen.

Pressure Monitoring

The *Prismaflex* 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 *Prismaflex* software to calculate other vital pressure conditions, such as *transmembrane pressure* (TMP) and *filter pressure drop* (Pressure Drop). These calculations are used to provide notification that clotting has begun in the filter or that the filter has clotted and the set must be changed.

CAUTION

After priming is complete, *do not* remove the pressure pods from their pressure sensor housings and do not disconnect the deaeration chamber monitor line from the return pressure port. If one or more pods are removed, the Diaphragm Reposition Procedure must be performed on the affected pod(s) and the set must be reprimed. If the Diaphragm Reposition Procedure fails, the set must be changed. If the monitor line is disconnected, the set must be reprimed and the fluid level in the deaeration chamber adjusted.

Components for Access, Filter, and Effluent Monitoring

Components for monitoring the pressures in the access line, filter, and effluent line include the following:

- Pressure pods. *Prismaflex* CRRT Sets have a pressure pod in these locations: access line (access pod), blood line immediately before the filter (filter pod), effluent line (effluent pod).
- Pressure sensor housings. The front panel of the control unit has three sensor housings that accept the pressure pods described above. The housings provide connection between the pods and the pressure sensors inside the control unit. The locations of the sensor housings are shown in Figure 5 in Chapter 1: Product Description.

  Note: A fourth pressure sensor housing (upper left of control unit), is for use with future therapies and not applicable to CRRT therapies.

- 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, which normally rests in the middle of the pod, at the *pressure neutral position*. During a patient treatment, the fluid compartment of the pod 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 *Prismaflex* software and interpreted as a pressure value.

During operation, the pressure diaphragms can move slightly out of neutral position. The *Prismaflex* Control Unit has an automatic reposition system (ARPS), located internally. To ensure proper pressure monitoring, every two hours the ARPS moves all diaphragms back to neutral position and tests the pressure sensors for correct functioning.

Components for Return Pressure Monitoring

Components for monitoring the pressure in the return line include the following:

- Deaeration chamber, located on the return line of the set.
- Chamber monitor line. An integral part of the deaeration chamber, this line provides a connection between the top portion of the deaeration chamber and the return pressure port on the control unit.
- Return pressure port. The front panel of the control unit has a luer-lock port located on the upper right (see Figure in Chapter 1: Product Description). The port connects with the chamber monitor line.
- Pressure sensor. The return pressure sensor is located inside the control unit, behind the return pressure port.

During a patient treatment, blood flows out of the outlet port of the filter, into a short portion of the return line, then into the deaeration chamber on the return line. The chamber also receives any *post-filter* replacement solution that is in use. The fluid in the chamber then flows into the final portion of return line leading to the patient.

The topmost portion of the deaeration chamber and the chamber monitor line are filled with a few millimeters of air. Fluctuations in the pressure exerted by this column of air are received by the pressure sensor located behind the return pressure port. The sensor converts the pressure to an electrical signal that is sent to *Prismaflex* software. To ensure proper pressure monitoring, every two hours the automatic reposition system (ARPS) tests the return pressure sensor for correct functioning.

Pressures During Operation

Pressures vary within the 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. The actual pressures at all monitoring sites 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 *Prismaflex* System.

Access pod pressure	Can be negative or positive, depending on the blood source to which the access line is connected.
Return pressure	Always positive
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 set.
Effluent pod pressure	Can be positive or negative, depending on the ultrafiltration rate and therapy chosen.

Access Pressure Monitoring Ranges

To issue the proper access pressure alarms for a patient treatment, *Prismaflex* software must receive operator confirmation of the monitoring range to use. A few minutes after a patient treatment starts (or restarts after completing a Recirculation procedure), an Advisory alarm occurs requesting the operator to confirm a “Positive” or a “Negative” monitoring range. The blood source that the access line is connected to determines the range which should be selected, as shown below.

Note: The monitoring range **cannot** be changed once the operator selects it.

Access Line Connected To:	Proper Monitoring Range
Patient central venous catheter	Negative
External blood access device	Positive
Patient arterio-venous fistula	Positive

Extreme Pressure Limits

Pressure limits are enforced by *Prismaflex* 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 8 shows the manufacturer-established extreme pressure limits.

Three of the extreme pressure limits (Warning: Access Extremely Negative, Warning: Access Extremely Positive, and Warning: Return 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 this chapter.

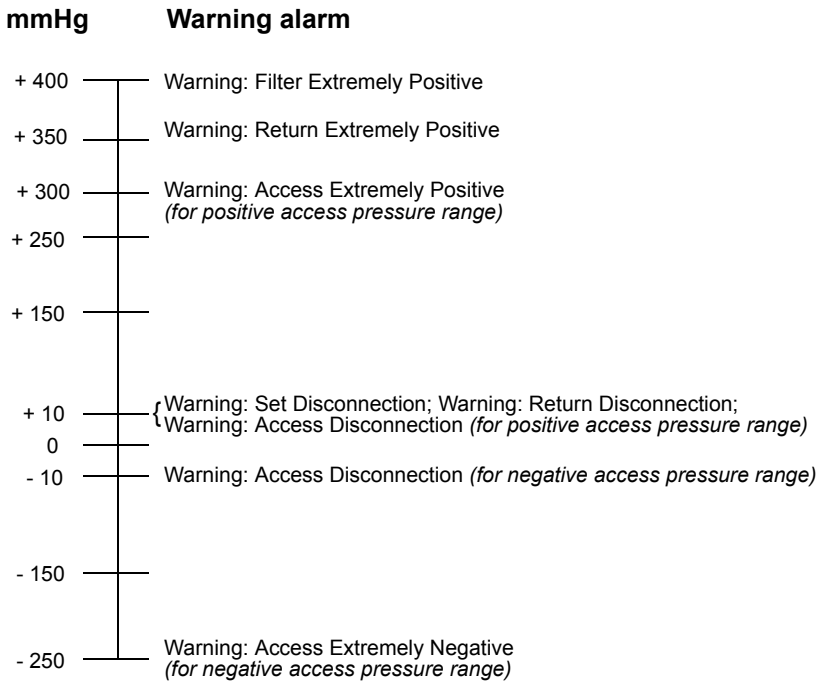


Figure 8. Extreme Pressure Limits, CRRT Therapies

Pressure Operating Points

Whenever the *Prismaflex* Control Unit is operating, a *reference* pressure value is stored in software memory for each pressure pod and the return line sensor. This value is called the *pressure operating point*. Software continually compares the current pressure at each monitoring site with the pressure operating point. In this way, the control unit can detect changing pressure conditions in the 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 initial operating points are established depends on the operator-set blood flow rate and the filter blood volume.

The initial operating points are established by recording the current pressure at each pressure pod at the end of the time periods shown above.

Note: The control unit cannot issue pressure Advisory alarms until the operating points are established.

Subsequent Values

During operation, certain events cause the control unit to reset (re-establish) all pressure operating points by again recording the current pressure at each monitoring site and storing the value in memory. This ensures that pressure monitoring remains accurate during the patient treatment.

Note: Operating points are re-established within 30 seconds. During this brief time, the control unit cannot issue pressure Advisory alarms.

Operating points are re-established whenever one or more of the following occurs:

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

Pressure Trending Limits

If the access or return pressure changes 50 mmHg (or 70 mmHg if blood flow>200ml/min) negative or positive from its established pressure operating point, the control unit notifies the operator by issuing an Advisory alarm or a Warning alarm, as shown in Figure 9. These alarms can be cleared by pressing the CONTINUE key on the alarm screen. This resets the pressure operating points to the current pressures at each monitoring site.

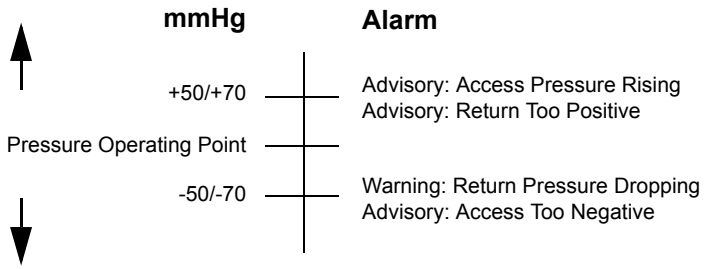


Figure 9. Pressure Trending Limits, CRRT Therapies

"Cannot Detect Disconnection" Limits

If an access or return pressure operating point is set too close to zero, the *Prismaflex* Control Unit cannot enable disconnection monitoring. The control unit issues a "Cannot Detect Disconnection" Advisory alarm to notify the operator and give instructions for remedying the situation. The pressures at which these Advisory alarms occur are shown in Figure 10.

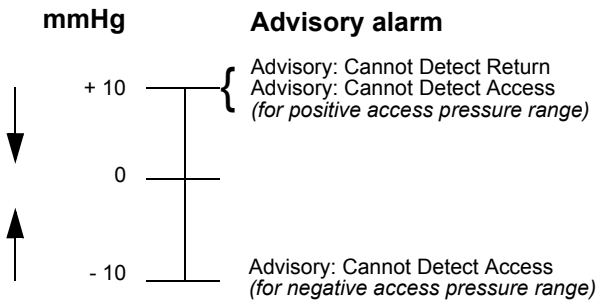


Figure 10. "Cannot Detect Disconnection" Pressure Limits, CRRT Therapies

Software-calculated Pressures

Prismaflex software uses monitored pressure values to calculate other vital pressure conditions, including *transmembrane pressure* (TMP) and *filter pressure drop* (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 set must be changed.

The TMP and Pressure Drop are displayed and updated on the Status screen during a patient treatment. In addition, a Status Graph (line graph) showing the trends of these two pressures over an operator-settable period of 1 to 3 hours can be displayed, if desired.

Transmembrane Pressure (TMP)

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

The TMP is calculated by *Prismaflex* software as follows:

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

Filter pressure and Effluent pressure readings are automatically corrected by software for hydrostatic pressure biases to compute and display TMP data.

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.

If the TMP rises above +300 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 +300 mmHg. For more information, see “Custom Mode” and “User-controllable Settings” in this chapter. If the TMP increases beyond the membrane capacity of +450 mmHg, the Caution: TMP Excessive alarm occurs.

Filter Pressure Drop (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 *Prismaflex* software as follows:

Filter pod pressure
- Return sensor pressure
= Filter pressure drop

Filter pressure and Effluent pressure readings are automatically corrected by software for hydrostatic pressure biases to compute and display Pressure Drop data.

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 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 sensor 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 this chapter and “Filter Pressure—Filter Is Clotting Advisory Limits” in the Specifications chapter.

Chapter 4: Alarm System

The *Prismaflex* Control Unit continually monitors itself and the *Prismaflex* 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.

WARNINGS

- **When responding to any alarm, carefully follow the instructions on the displayed alarm screen and its associated Help screen.**
- **To clear some alarms, the *Prismaflex* 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.**
- **Do not override the same alarm repeatedly. End treatment and call for service.**
- **If power is lost to the *Prismaflex* 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.**

WARNINGS (cont.)

- **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 *Prismaflex* 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 *Prismaflex* 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 with a fast beeping tone.
- 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:

- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.
- 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 *Prismaflex* 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:

- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.
- 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 *Prismaflex* 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 with a fast beeping tone.
- 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:

- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.
- 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 *Prismaflex* 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:

- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.
- 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 syringe pump 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:

- PBP, replacement, dialysate, and effluent pumps stop.
- Blood and syringe pumps continue to operate and the return line clamp remains open. The patient's blood continues to circulate through the blood flowpath, but treatment is suspended.
- Yellow light illuminates.
- Audible alarm sounds with a moderate beeping tone.
- 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:

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

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 with a slow beeping tone.
- Advisory screen appears on the display.
- EXAMINE ALARMS softkey appears.

Operator Response

The “Preventive Maintenance Due” 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 14.

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 14. Priority of *Prismaflex* System Alarms

Priority Number	Alarm Title
Malfunctions (High Priority)	
1	General system failure
2	Communication error (Error code: XX.) **Note:** Code number is identified on the alarm screen.
3	Memory error (Error code: 04.)
4	Pressures Circuit Board
5	Voltage Out of Range
Warnings	
6	Air in blood
7	Return disconnection
8	Return pressure dropping

Table 14. Priority of *Prismaflex* System Alarms

Priority Number	Alarm Title
Warnings (cont.)	
9	Set disconnection
10	Access disconnection
11	Filter clotted
12	Blood leak detected
13	Return extremely positive
14	Access extremely negative
15	Access extremely positive
16	Filter extremely positive
17	Power failure
18	Wrong set loaded
19	Effluent Bag full *(all therapies, during priming)* (Effluent bag is full.)
20	Bag/container empty *(all therapies, during priming)* (XXXXXX bag is empty.) **Note:** Bag in question is identified on the alarm screen.
21	Bag Volume Incorrect *(all therapies, during priming)* (Bag volume incorrect for: XXXXXX.) **Note:** Bag in question is identified on the alarm screen.
22	Effluent Bag Incorrect *(priming only)* (Effluent Bag volume does not match Allowed Volume)
23	Scale open *(all therapies, during priming)* (Scale not properly closed: XXXXXX) **Note:** Scale in question is identified on the alarm screen
24	Syringe Empty-Clamped *(priming only)*
25	Blood detected in set
26	Recirculation Time Exceeded

Table 14. Priority of *Prismaflex* System Alarms

Priority Number	Alarm Title
Malfunctions	
27	Air detector
28	Clamp stuck closed
29	Blood pump (Rate is incorrect.)
30	Effluent pump (Rate is incorrect.)
31	Replacement pump (Rate is incorrect.)
32	Replacement 2 pump *(CVVH only)* (Rate is incorrect.)
33	Dialysate pump (Rate is incorrect.)
34	PBP pump (Rate is incorrect.)
35	Normalization failed
36	Blood leak detector (Effluent line not properly installed in blood leak detector.)
37	Self-test failure (Code: *1 to 26*) Due to: (*Reason identified on alarm screen*.)
38	Prime self-test (Code: *1 to 28*) Due to: (*Reason identified on alarm screen*.)
39	Syringe pump (Rate is incorrect.)
40	Scales (Scale out of calibration: XXXXXX.) **Note:** Scale in question is identified on the alarm screen.
41	Pressure zero test
42	Scale zero test

Table 14. Priority of *Prismaflex* System Alarms

Priority Number	Alarm Title
Malfunctions (cont.)	
43	Checksum interrupted (Cannot verify data in block XX.) **Note:** Block in question is identified on the alarm screen.
44	Custom data (Custom mode data cannot be accessed for this treatment.)
45	Library data (Default data cannot be accessed.)
46	Cannot save custom data (New custom mode values cannot be saved.)
47	Memory error (Error code: XX.) **Note:** Code number is other than 04.
48	Upper pinch valve
49	Lower pinch valve
50	Scales circuit board
51	Effluent scale sensor
52	Replacement scale sensor
53	Dialysate scale sensor
54	PBP scale sensor
55	Syringe Not Loaded
56	Line in air detector
57	Line in clamp
58	No line in air detector
59	No line in clamp

Table 14. Priority of *Prismaflex* System Alarms

Priority Number	Alarm Title
Cautions	
60	Weight alarm not cleared (Too many attempts to remedy below alarm. Accuracy of patient fluid removal may be compromised.)
61	Effluent weight (Incorrect weight change detected for effluent bag.)
62	Replacement weight (Incorrect weight change detected for replacement bag/container.)
63	PBP weight (Incorrect weight change detected for PBP bag.)
64	Dialysate weight (Incorrect weight change detected for dialysate bag.)
65	Replacement 2 weight *(CVVH only)* (Incorrect weight change detected for replacement bag 2.)
66	Effluent bag full
67	Dialysate bag empty
68	Replacement bag 2 empty *(CVVH only)*
69	Replacement bag empty
70	PBP bag empty
71	TMP excessive (Transmembrane pressure exceeds membrane pressure limit.)
72	Bag volume incorrect (Bag volume incorrect for: XXXXXX) **Note:** Bag in question is identified on the alarm screen.
73	Effluent Bag Incorrect (Effluent Bag volume does not match Allowed Volume)
74	Scale open (Scale not properly closed: XXXXXX) **Note:** Scale in question is identified on the alarm screen. If more than one scale is open, notification priority is as follows (highest to lowest): Effluent, Replacement, Replacement 2, Dialysate, PBP.

Table 14. Priority of *Prismaflex* System Alarms

Priority Number	Alarm Title
75	No blood in filter (Filter pressure in minimal. Blood flow is minimized through filter.)
Advisories	
76	Self-test in progress (Test complete in approximately 1 to 6 minutes.)
77	Clamped Bag
78	Access pressure rising
79	Access too negative
80	Return too positive
81	Blood flow stopped (Machine has been left in the Stop screen for 60 seconds.)
82	Syringe Not Loaded
83	Check Syringe Line
84	Syringe Empty-Clamped
85	Filter is clotting (Increasing TMP and/or pressure drop.)
86	TMP too high (Transmembrane pressure has reached user-set pressure limit.)
87	Time to change set
88	Preventive maintenance due
89	Cannot detect return Return disconnection cannot be detected. Return pressure is more negative than +10 mmHg alarm limit.)
90	Cannot detect access *(negative range pressure monitoring)* (Access disconnection cannot be detected. Access pressure more positive than -10 mmHg alarm limit.)
91	Cannot detect access *(positive range pressure monitoring)* (Access disconnection cannot be detected. Access pressure more negative than +10 mmHg alarm limit.)

Table 14. Priority of *Prismaflex* System Alarms

Priority Number	Alarm Title
Advisories (cont.)	
92	Confirm Positive Access Pressure
93	Identify access range (Monitoring range for access pressure cannot be determined. Access line pressure is between -10 mmHg and +10 mmHg.)
94	Confirm access range (XXXXXX access pressure range: XXXX mmHg to XXXX mmHg) **Note:** Alarm screen identifies “positive” or “negative” and its associated pressure range.
95	Bar code reader error (Bar code reader is out of service.)
96	Download interrupted (Patient information card is full.)
97	Download interrupted (Patient information card not inserted.)
98	Download interrupted (Cannot write to patient information card.)
99	Effluent bag volume (Effluent bag volume has reached 5 liters.)
100	Scale component missing (Carrying bar is missing from: XXXXXX scale.) **Note:** Scale in question is identified on the alarm screen.

Chapter 5: Troubleshooting

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

Tables 15 through 18 list the *Prismaflex* System alarms by *category*, as follows: Table 15: Warnings, Table 16: Malfunctions, Table 17: Cautions, Table 18: Advisories. Possible causes for each alarm, and appropriate operator actions are also given. Within each category, the alarms are listed in alphabetical order. Table 19 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), Pressure Pod Adjustment procedures, and Air Removal procedures.

Table 15: Warning Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Access disconnection For negative access pressure monitoring: This alarm occurs if access pressure is more positive than -10 mmHg *and* the access pressure operating point is more negative than -10 mmHg. For positive access pressure monitoring: This alarm occurs if access pressure is more negative than +10 mmHg and the access pressure operating point is more positive than +10 mmHg.	1. Access catheter disconnected; line is clamped below the access pressure pod. 2. Blood flow rate too low for the access device. 3. Access pressure pod not installed or debris in access sensor housing. 4. Access pressure sensor failed.	1. Remedy; press OVERRIDE.[a] 2. Increase the blood flow rate; press OVERRIDE.[a] Note: If Steps 1 and 2 do not clear the alarm, the set can be changed and the alarm cleared via STOP.[b] If alarm recurs with a new set, see Step 4. 3. Perform Pod Adjustment procedure on filter pod (see instructions at end of Troubleshooting chapter). Reprime the set by pressing STOP[b] and performing the Recirculation procedure. Or, use Change Set to load/prime a new set. If alarm recurs with new set, see Step 4. 4. End treatment via STOP[b]; call service.
Access extremely negative This alarm self-clears if pressure goes back to normal limits within 16 seconds.[c] Alarm occurs if access pressure monitoring is in the *negative range* and the access pressure is more negative than the user-settable “Access Extremely Negative” Warning Limit.	1. Patient is moving or coughing, or being moved or suctioned; access line clamped or kinked. 2. Access catheter clotted or out of position in vein; blood flow rate too high for the access device. 3. Access pressure sensor failed.	1. Remedy cause; wait 16-20 seconds for possible self-clearing.[c] **If alarm does not self-clear, go to Step 2.** 2. If needed: (a) flush/reposition access catheter per hospital protocol, (b) lower the blood flow rate. **Press CONTINUE.** Note: If Steps 1and 2 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 3. 3. End treatment via STOP. Call service.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Access pressure extremely positive Alarm occurs if access pressure monitoring is in the *positive range,* and the access pressure more positive than the user-settable "Access Extremely Positive" Warning Limit.	1. Access line connection to blood source is obstructed; access line clamped/kinked between access pod and *Prismaflex* blood pump. 2. External device (if in use) is delivering blood at a too-high pressure. 3. Blood flow rate too low for the access device. 4. Access pressure sensor failed.	1. Remedy; press CONTINUE. 2. Reduce the delivery pressure of the external device. 3. Increase the blood flow rate; return to alarm screen and press CONTINUE. Note: If Steps 1 through 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[b]. Call service.
Air in blood	Return line not installed in air detector; disconnected line; leaking connection; incompletely primed set.	- Open door of air detector. Look for air/foam or abnormal level of fluid in the deaeration chamber. - If needed, remedy possible causes. Remove air/adjust deaeration chamber, using instructions on alarm screen. (Instructions also given under "Air Removal Procedures" at the end of the Troubleshooting chapter.) - When ready, close detector door; press CONTINUE. Note: If air is prevalent in entire set, change the set via the DISCONNECT key.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Bag/container empty (XXXXXXXXXXXXX is empty.) (Priming only) Depending on therapy, the following may be identified: Replacement bag Dialysate bag PBP bag Replacement bag 2 (green scale)	1. Identified bag is empty.[g] 2. Identified bag is partially supported (not hanging freely).	1. Connect a new bag; press CONTINUE. 2. Remove partial support; press CONTINUE.
Bag Volume Incorrect (Bag volume incorrect for: XXXXXX Amount of fluid in bag does not match Allowed Volume.) (Priming only) The following may be identified: Replacement bag Dialysate bag PBP bag Replacement bag 2 (green scale)	1. Amount of fluid in the identified bag does not match the current Allowed Volume. 2. No bag on scale. 3. Foreign object on scale. 4. Identified bag is partially supported (not hanging freely).	1. Choose one of the three options on the alarm screen. **Warning:** Carefully read the the alarm Help screen *before* making a choice. Choose Keep Bag *only* to use a partially full bag that is of the *same* total volume capacity as the current Allowed Volume. 2. Place the appropriate bag on the scale, press CONTINUE. Note: If hanging multiple bags on the scale, the total fluid capacity of all bags on the scale must not exceed the allowed volume for that scale. 3. Remove foreign object, press CONTINUE. 4. Remove partial support; press CONTINUE.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Blood detected in set (Pt blood sensor identifies blood in tubing.)	1. Poor blood rinseback done before Recirculation; end Treatment procedure done incorrectly; return line installed in air detector before expected, or is out of position in the air detector.	1. Use decision process below to determine appropriate action 1. **System is resuming after switch off:** press CONTINUE to resume treatment. 2. **System is in Recirculation:** verify the proper set-up of the set and in particular of the recirculation circuit. **If NO problem is found with the set**, press NO BLOOD to continue with Recirculation. **If a problem is found with the set**, press DISCONNECT to change the set. 3. **System is in Priming:** verify if blood is present in the set. **If blood IS present in the set**, press DISCONNECT to change the set. **If blood IS NOT present in the set**, press NO BLOOD to continue with Priming and patient connection. If alarm recurs with a new set, call service. **Warning:** NO BLOOD = Patient sensor disabled until next switch OFF and ON of the control unit and patient safety alarms are disabled until start of treatment (Run mode). CONTINUE = All patient safety alarms, including “Air in Blood” are enabled immediately.
	2. Patient sensor has failed.	2. Press DISCONNECT. Call service.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
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. Press OVERRIDE[a] to dislodge bubble. 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 removed/reinserted in detector, the detector must be reset by pressing NORM BLD on the System Tools screen after the alarm clears. This must be done before continuing patient treatment. BLD signal value must be ≥38.000 for normalization to be allowed. 4. Change the set via STOP.[b]
Effluent Bag full **(Effluent bag is full.)** (Priming only)	1. Effluent bag is full. 2. Foreign object on effluent scale.	1. Connect a new effluent bag via instructions on the alarm screen. Press CONTINUE. 2. Remove foreign object, press CONTINUE.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent Bag Incorrect (Effluent Bag volume does not match Allowed Volume. Cause: a 5 liter empty bag is hanged on scale while Effluent Allowed Volume is 9000 ml) (Priming only)	1. A 5 liter empty bag is hanged on scale while Effluent Allowed Volume is 9000 ml. 2. No bag on scale. 3. Effluent bag is partially supported (not hanging freely).	1. Replace the 5 liter bag hanged on scale by a 9 liter bag or change the Effluent Allowed Volume by pressing MODIFY BAG. Press CONTINUE. 2. Place the appropriate bag on the scale, press CONTINUE. Note: If hanging multiple bags on the scale, the total fluid capacity of all bags on the scale must not exceed the allowed volume for that scale. 3. Remove partial support; press CONTINUE.
Filter clotted Alarm occurs if filter pressure minus return pressure is ≥200 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, PBP solution flow rate or patient fluid removal 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. Syringe incorrectly installed or syringe pump failed.	1. Unclamp lines; press CONTINUE. 2. Press CONTINUE and then reduce replacement solution flow rate and/or PBP solution flow rate and/or patient fluid removal rate. 3. Change the set via STOP.[b] Test patient’s clotting parameters and adjust anticoagulant delivery if needed. 4. Press STOP[b] 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 syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Filter extremely positive Alarm occurs if filter pod pressure is ≥450 mmHg	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. Relieve excess pressure in return line by pressing RELEASE CLAMP. If desired, lower the blood flow rate; press CONTINUE. Note: The RELEASE CLAMP key is available only if no other alarm requiring the clamp closed is present.[f] 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.[b] Call service.
Power failure **(Power lost for more than 15 seconds after machine entered Run mode.)**	Main power failure; machine suddenly unplugged.	- Inspect blood flowpath. 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, either: (a) continue treatment with a new set by pressing STOP, then CHANGE SET, or (b) end the treatment by pressing STOP, then END TREATMNT.[b]

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Recirculation Time Exceeded	Recirculation Time has exceeded the manufacturer-set limit of 2 hours.	Press STOP RECIRC. and resume the treatment, after repriming the set or end treatment.
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 disconnected; return line is clamped before deaeration chamber. 2. Blood flow rate too low for the access device. 3. Chamber monitor line not connected to return pressure port. 4. Return pressure sensor failed.	1. Remedy; press CONTINUE. 2. Increase the blood flow rate; return to alarm screen; press CONTINUE. Note: If Steps 1 and 2 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. 3. Verify the fluid barrier is not damaged. If not damaged, secure monitor line to the luer lock of the return pressure port, press CONTINUE and, if necessary, adjust the fluid level in the deaeration chamber. If the fluid barrier is damaged, press STOP and use Change Set to load/prime a new set. 4. End treatment via STOP; call for service.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Return extremely positive This alarm self-clears if pressure goes back to normal limits within 16 seconds.[c] Alarm occurs if return pressure is more positive than the user-settable “Return Extremely Positive” Warning Limit.	1. Patient is moving or coughing, being moved or suctioned; return line is clamped or kinked. 2. Return catheter is clotted or out of position in vein; blood flow rate too high. 3. Return pressure sensor failed.	1. Remedy cause; wait 16-20 seconds for possible self-clearing.[c] If alarm does not self-clear, go to Step 2 2. If needed: (a) flush/reposition return catheter per hospital protocol, (b) lower the blood flow rate. Relieve excess pressure in return line by pressing RELEASE CLAMP. When return pressure falls below the user-set value (+350 mmHg is the default value), press CONTINUE. Note: The RELEASE CLAMP key is available only if no other alarm requiring the clamp closed is present.[e] Note: If Steps 1 and 2 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 3. 3. End treatment via STOP. Call service.
Return pressure dropping Alarm occurs if return pressure is 50 mmHg or 70 mmHg (with blood flow>200ml/min) 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]

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Scale open **(Scale not properly closed: XX)** (Priming only) Scales identified: Effluent, PBP, Replacement, Dialysate, Replacement 2 (green).	1. Impeding object blocking scale from fully closing; bag improperly positioned on hooks; carrying bar not centered on bar tray or handle not rotated down (toward floor). 2. Scale sensor failed.	1. Inspect and remedy possible causes. Press scale toward machine until it locks into closed position. Press CONTINUE. 2. Press DISCONNECT. Call service.
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. 2. Blood flow rate too low for the access device. 3. Filter pressure pod not installed or debris in filter sensor housing. 4. Filter pressure sensor failed.	1. Remedy; press OVERRIDE.[a] 2. Increase the blood flow rate; return to alarm screen and press OVERRIDE.[a] Note: If Steps 1 and 2 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. 3. Perform Pod Adjustment procedure on filter pod (see instructions at end of Troubleshooting chapter). Reprime the set by pressing STOP and performing the Recirculation procedure. Or, use Change Set to load/prime a new set. If alarm recurs with new set, see Step 4. 4. End treatment via STOP. Call service.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Syringe Empty-Clamped (Priming only)	1. Syringe line clamped. 2. Syringe pump is in end-of-travel position, indicating all solution in syringe has been delivered	1. Inspect syringe line; remove any clamps; kinks, or other obstructions; press CONTINUE 2. Press CHANGE SYRINGE; follow instructions to install a full syringe and return to alarm screen. Press CONTINUE. Note: Install only the allowed syringe (size/brand specified in Custom mode). Note: **A full syringe is required during priming**. If anticoagulation of blood flowpath is not desired, syringe should be filled with priming solution.

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Wrong set loaded (This set cannot be used with the therapy selected.)	1. Wrong therapy has been chosen and/or wrong set has been loaded.	1. **Verify physician prescription** for therapy and *Prismaflex* Set to use. **Press UNLOAD.** - If needed, press CANCEL on the Load Set screen and select the prescribed therapy on the Choose Therapy screen. - If remove the set attached to the control unit, then load the prescribed set. Note: If alarm occurs repeatedly, proceed to Step 2.
	2. Bar code reader failed. Note: Failure can result in *Unknown* identity reported on the Confirm Set Loaded screen, or in an ***erroneous*** set identity being reported.	2. If the word *Unknown* appears on the Confirm Set Loaded screen, manually identify the loaded set by using the softkeys provided. If the *Prismaflex* Set reported on the Confirm Set Loaded screen is ***erroneous***, unload the set, turn off control unit, call service to repair bar code reader. **Do not use machine until repairs are made.**

Table 15: Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response

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 recirculate.

c. A self-clearing attempt is started 8 seconds after this alarm occurs, ***if*** the pressure has returned to normal limits and there are no other active Warning or Malfunction alarms. Self-clear is accomplished within 8 seconds. If self-clear is unsuccessful, return line clamp closes, blood pump stops, and the alarm must be manually cleared by the operator. Both for Access and for Return pressure alarms, self-clearing can start only if another self-clearing procedure has not been performed in the last 10 minutes.

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

e. If the RELEASE CLAMP softkey is not available and opening of the return clamp is not considered at risk, open the return line clamp using the STOP and RESUME softkeys. If opening of the return clamp is considered at risk, insert a 21-gauge needle with syringe into the blue sample site (return line) to aspirate air/blood until the return pressure reaches a value lower than the alarm limit setting.

f. If the RELEASE CLAMP softkey is not available and opening of the return clamp is not considered at risk, open the return line clamp using the STOP and RESUME softkeys. If opening of the return clamp is considered at risk, insert a 21-gauge needle with syringe the upper red sample site closest to the filter pod to aspirate air/blood until the filter pressure reaches a value lower than 450 mmHg.

g. This alarm occurs when the Control Unit detects that the weight of the identified bag is lower than the tare of the bag itself. The tare of each bag is automatically calculated by the Control Unit depending on the Empty Bag Method setting in Custom mode. If Empty Bag Method is set to "Fixed", the tare of the Dialysate, PBP, Replacement, Replacement2 bag is set to 200 gr. If Empty Bag Method is set to "Variable", the tare of the Dialysate, PBP, Replacement, Replacement2 bag is automatically calculated each time a new bag is loaded.

Table 16: Malfunction Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Air detector	Air detector failed self-tests.	- Press RETEST. - If alarm does not clear, end treatment via DISCONNECT or manually.[d] Call service to remedy before using machine again. **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.	1. Effluent line is not installed, is improperly installed, or is removed from detector. 2. Liquid or other debris in tubing path through the detector. 3. Blood leak detector failed.	1. Press line into detector from bottom up; route 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 RETEST. **Warning:** If effluent line is removed/reinserted in detector, the detector must be reset (normalized) by pressing NORM BLD on System Tools screen. This **must** be done before continuing patient treatment. A reminder appears in “Next Intervention” line of Status screen for 60 seconds after alarm clears. 3. If alarm does not clear, end the treatment via DISCONNECT or manually.[d] Call service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Blood pump (Rate is incorrect.)	1. Momentary problem with pump roller or pump segment in raceway. 2. Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened; pump failed.	1. Press CONTINUE. 2. If alarm recurs, end treatment: (a) Press CONTINUE, when Status screen appears, immediately press STOP; (b) On Stop screen, choose END TREATMNT; follow the instructions to disconnect patient and unload set; (c) Call service to remedy/clear alarm.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Cannot Save Custom Data	Error in saving newly customized values.	Press EXIT CUSTOM. If desired, return to Custom mode, and try again to customize. If alarm recurs, call service to remedy/clear alarm.[a] Note: Patient treatments can be conducted before problem is remedied. The last-saved Custom mode values guide these treatments.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
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 or manually.[d] Reset limits in Custom mode, then restart treatment. - If limits are correct, press FLOW RATES and review current flow rates. Re-enter rates, if necessary. Press CONTINUE. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
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 or manually.[d] Call service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Communication error **Error Code: X** (number 1 to 7) **Due To: XXXXXXXXXXXXXXX**	See "Due To" message on alarm screen.	Turn machine off; wait 5 seconds, then turn machine on. - If Query screen appears, make choice and follow instructions. - If alarm recurs, end treatment manually; call service and report error code. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Custom data	Not able to access Custom mode values for selected therapy/set.	Treatment will be done using manufacturer-set default values for this therapy/set. Flow rates and syringe settings can be modified before starting treatment. Press CONTINUE to proceed. **Note**: After treatment is over, enter Custom mode and re-specify desired defaults for this therapy/set.
Dialysate pump (Rate is incorrect.) (CVVHDF and CVVHD only) Dialysate pump = green pump	1. Momentary problem with pump roller or pump segment in raceway. 2. Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened; pump failed.	1. Press CONTINUE. 2. If alarm recurs, end treatment: (a) Press CONTINUE, when Status screen appears, immediately press STOP (b) On Stop screen, choose END TREATMNT; follow the instructions to disconnect patient and unload set; (c) Call service to remedy/clear alarm.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Dialysate scale sensor	1. The bar tray of the dialysate scale has not been pulled out and then pushed in the control unit to attach the dialysate bag. 2. The scale position sensor failed.	1. Place the scale in open position and then in closed position. Press RETEST. If this does not clear the alarm, see step 2. 2. End treatment via DISCONNECT. Call Service.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent pump **(Rate is incorrect.)** Effuent pump = yellow pump	1. Momentary problem with pump roller or pump segment in raceway. 2. Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened; pump failed.	1. Press CONTINUE. 2. If alarm recurs, end treatment: (a) Press CONTINUE, when Status screen appears, immediately press STOP; (b) On Stop screen, choose END TREATMNT; follow the instructions to disconnect patient and unload set; (c) Call service to remedy/clear alarm.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Effluent scale sensor	1. The bar tray of the effluent scale has not been pulled out and then pushed in the control unit to attach the effluent bag. 2. The scale position sensor failed.	1. Place the scale in open position and then in closed position. Press RETEST. If this does not clear the alarm, see step 2. 2. End treatment via DISCONNECT. Call Service.
General system failure	Protective and control systems not communicating; a component of the control unit not responding.	Turn machine off; wait 5 seconds, then turn machine on. - If Query screen appears, make choice and follow instructions. - If alarm recurs, end treatment manually; call service and report error code. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Library data	Cannot access manufacturer-set default values.	Discontinue use. If applicable, use DISCONNECT to unload/remove set. Turn machine off;call service to remedy and clear the alarm.[a]

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Line in Air Detector	1. Return line installed in air detector before loading a set.	1. If return line is installed in the air detector, open door of air detector and remove line from air detector, then close door of air detector. Press RETEST. If alarm doesn't clear and the line is not inserted in the air detector, see step 2.
	2. Tubing detection switch failed.	2. Turn off the machine or continue the treatment by pressing OVERRIDE. In this case it is the operator's responsibility to visually monitor the set and check the correct placement of return line in the air detector for the remainder of the treatment. Call Service
Line in Clamp	1. Return line installed in Return Line Clamp before loading a set.	1. If return line is installed in the Return Line Clamp, remove line from Return Line Clamp. Press RETEST. If alarm doesn't clear and the line is not inserted in the Return Line Clamp, see step 2.
	2. Tubing detection switch failed.	2. Turn off the machine or continue the treatment by pressing OVERRIDE. In this case it is the operator's responsibility to visually monitor the set and check the correct placement of return line in the clamp for the remainder of the treatment. Call Service

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Lower Pinch Valve	1. The lower pinch valve is in the wrong position for the therapy selected and the current infusion method selected (Pre/ Post) due to obstructions. 2. The lower pinch valve failed.	1. Remove any obstructions and press RETEST. If this does not clear the alarm, see step 2. 2. End treatment via DISCONNECT. Call Service.
Memory error **Error Code: XX** (number 1 to 5) **Due To: XXXXXXXXXXXXXXX**	See “Due To” message on alarm screen.	Turn machine off; wait 5 seconds, then turn machine on. - If Query screen appears, make choice and follow instructions. - If alarm recurs, end treatment manually; call service and report error code. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
No Line in Air Detector	1. Return line not installed or not properly installed in air detector.	1. If return line is NOT installed in the air detector, open door of air detector and insert line into air detector. If return line is installed in the air detector, press line into detector from bottom up and route securely through tubing guides. Press RETEST. If alarm doesn't clear and the line is correctly inserted in the air detector, see step 2.
	2. Tubing detection switch failed.	2. End treatment via DISCONNECT or continue the treatment by pressing OVERRIDE. In this case it is the operator's responsibility to visually monitor the set and check the correct placement of return line in the air detector for the remainder of the treatment. Call Service
No Line in Clamp	1. Return line not installed or not properly installed in Return Line Clamp.	1. If return line is NOT installed in the clamp, insert line into the clamp. If return line is installed in the clamp, press line into the clamp. Press RETEST. If alarm doesn't clear and the line is correctly inserted in the clamp, see step 2.
	2. Tubing detection switch failed.	2. End treatment via DISCONNECT or continue the treatment by pressing OVERRIDE. In this case it is the operator's responsibility to visually monitor the set and check the correct placement of return line in the clamp for the remainder of the treatment. Call Service.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Normalization failed (Attempt to normalize blood leak detector has failed.)	Filter blood leak; defective effluent line; blood leak detector failed. Note: The "Malfunction: Normalization failed" alarm is displayed when the blood leak detector normalization has failed 3 times in a row.	- 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 treatment. Call service.
PBP pump (Rate is incorrect.) PBP pump = Pre-blood pump (white).	1. Momentary problem with pump roller or pump segment in raceway. 2. Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened; pump failed.	1. Press CONTINUE. 2. If alarm recurs, end treatment: (a) Press CONTINUE, when Status screen appears, immediately press STOP; (b) On Stop screen, choose END TREATMNT; follow the instructions to disconnect patient and unload set; (c) Call service to remedy/clear alarm.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
PBP scale sensor	1. The bar tray of the PBP scale has not been pulled out and then pushed in the control unit to attach the PBP bag. 2. The scale position sensor failed.	1. Place the scale in open position and then in closed position. Press RETEST. If this does not clear the alarm, see step 2. 2. End treatment via DISCONNECT. Call Service.
Pressures Circuit Board	Hardware failure on pressures circuit board.	Turn machine off and end treatment manually. Call Service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 16: 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 service.[a]
Prime self-test **Code: XX** (number 1 to 28) **Due To: XXXXXXXXXXXXXXX**	One or more of the tests conducted during prime self-test failed.	Softkeys on alarm screen vary, depending upon failure reason. All softkeys clear the alarm. **NEW SET** gives instructions to unload set, load a new set, and start a new priming cycle. **RETEST** restarts the prime test. **REPRIME** provides instructions to reprime the set. **DISCONNECT** provides instructions to unload/remove set.
Due to: 24 volt / 12 volt **Code=24**	24 volt / 12 volt test failed.	Press RETEST. If failure recurs, unload set via DISCONNECT; call service and report failure code.
Due to: 24 volt **Return clamp sensor** **Code=26**	24 volt and return clamp sensor tests failed.	Press RETEST. If failure recurs, unload set via DISCONNECT; call service, report failure code.
Due to: Air/pumps security test **Code=19**	Internal malfunction.	Press RETEST. If failure recurs, unload set via DISCONNECT; call service and report failure code.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test *(continued)* **Due To: Blood leak detector normalization timeout** **Code=17**	*(continued)* 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.	*(continued)* 1. Reinstall effluent line (from bottom up); route through tubing guides. Press RETEST. 2. Dislodge bubble by inserting pump crank into rotor of the effluent pump and giving a quick half-turn counterclockwise. Press RETEST. 3. Press REPRIME; follow instructions. If failure recurs, retry with a new set (Press NEW SET; follow instructions.) 4. If failure occurs with a new set, unload set via DISCONNECT; call service; report failure code.
Due To: Blood leak detector threshold error **Code=18**	1. Air bubble in effluent line at level of blood leak detector. 2. Set not fully primed. 3. Blood leak detector failed.	1. Dislodge bubble by inserting pump crank into rotor of the effluent pump and giving a quick half-turn counterclockwise. Press RETEST. 2. Press REPRIME; follow instructions. If failure recurs, retry with a new set (Press NEW SET; follow instructions.) 3. If failure occurs with a new set, unload set via DISCONNECT; call service; report failure code.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test *(continued)* **Due To: Syringe Pump Hw Code=28**	*(continued)* Internal malfunction.	*(continued)* Press RETEST to restart Syringe Test. If failure recurs will not be possible to use the syringe for the treatment. Choose one of the actions: (a) Unload set via DISCONNECT; (b) Proceed the treatment without using the syringe by pressing SYRINGE DISABLE and then CONFIRM DISABLE.
Due to: Pump occlusivity test Code=20	1. Return line not properly installed in return line clamp; obstruction in return line clamp.	1. Press and hold return clamp button; remove return line; remove any obstructions; reinstall line, making sure it is completely under clamp and not kinked. Press RETEST. Note: Pressing RETEST more than twice requires the connection of a new priming bag.
	2. Deaeration chamber monitor line not connected to return pressure port; errors occurred during priming cycle.	2. Verify the fluid barrier is not damaged. If not damaged, secure monitor line to the luer lock of the return pressure port and press REPRIME to prime again the same set. If the fluid barrier is damaged, press DISCONNECT and use Change Set to load/prime a new set.
	3. Pump segments improperly loaded; obstructions in pump raceways.	3. If failure recurs for three times, retry with a new set (Press NEW SET and follow instructions.)
	4. Pump(s) failed.	4. If failure occurs with a new set, unload set via DISCONNECT; call service and report failure code.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test *(continued)* **Due to: Lower pinch valve** **Code=22**	*(continued)* 1. Pinch valve segment not properly positioned in pinch valve. 2. Lower pinch valve failed.	*(continued)* 1. Press RETEST. If failure recurs, retry with a new set (Press NEW SET and follow instructions.) 2. If failure occurs with a new set, unload set via DISCONNECT; call service and report failure code.
Due to: Pressure pod/sensor - All affected pods are reported. **Code=1 Access** **Code=2 Filter** **Code=3 Access and Filter** **Code=4 Effluent** **Code=5 Access and Effluent** **Code=6 Filter and Effluent** **Code=7 Access, Effluent and Filter**	1. Clamped lines in set. 2. Pressure pod(s) not installed or debris in sensor housing(s). 3. Set not fully primed. 4. Pressure sensor(s) failed.	1. Unclamp any clamped lines; press RETEST. 2. Do Pressure Pod Adjustment procedure on all pods reported on alarm screen. Press RETEST. 3. Press REPRIME; follow instructions. If failure recurs, retry with a new set (Press NEW SET and follow instructions.) 4. Unload set via DISCONNECT; call service and report failure code.
Due to: Return clamp sensor Return clamp sensor test failed. **Code=25**	1. Obstruction in return line clamp. 2. Return clamp sensor failed.	1. Press and hold return clamp button; with the other hand, remove obstruction. Press RETEST. 2. If alarm failure recurs, unload set via DISCONNECT; call service and report failure code.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test *(continued)* **Due to: Return pressure sensor** **Code=16**	*(continued)* 1. Clamped lines in set. 2. Chamber monitor line not securely connected to return pressure port. 3. Set not fully primed. 4. Pressure sensor(s) failed.	*(continued)* 1. Unclamp any clamped lines. Press RETEST. 2. Verify the fluid barrier is not wet/damaged. If not wet/damaged, secure monitor line to the luer lock of the return pressure port and press REPRIME to prime again the same set. If the fluid barrier is wet/damaged, press DISCONNECT and use Change Set to load/prime a new set. 3. Press REPRIME; follow instructions. If failure recurs, retry with a new set (Press NEW SET and follow instructions.) 4. If failure occurs again with a new set, unload set via DISCONNECT. Call service and report failure code.
Due to: Upper pinch valve **Code=21**	1. Pinch valve segment not properly positioned in pinch valve. 2. Upper pinch valve failed.	1. Press RETEST. If failure recurs, retry with a new set (Press NEW SET and follow instructions.) 2. If failure occurs with a new set, unload set via DISCONNECT; call service and report failure code.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test *(continued)* **Due to: Upper pinch valve/ Lower pinch valve** **Code=23**	*(continued)* 1. Pinch valve segments not properly positioned in pinch valve. 2. Upper and Lower pinch valves failed.	*(continued)* 1. Press RETEST. If failure recurs, retry with a new set (Press NEW SET and follow instructions.) 2. If failure occurs with a new set, unload set via DISCONNECT; call service and report failure code.
Replacement pump (Rate is incorrect.) Replacement pump = purple pump.	1. Momentary problem with pump roller or pump segment in raceway. 2. Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened; pump failed.	1. Press CONTINUE. 2. If alarm recurs, end treatment: (a) Press CONTINUE, when Status screen appears, immediately press STOP (b) On Stop screen, choose END TREATMNT; follow the instructions to disconnect patient and unload set; (c) Call service to remedy/clear alarm.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement pump 2 **(Rate is incorrect.)** Replacement pump 2 = green pump.	1. Momentary problem with pump roller or pump segment in raceway. 2. Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened; pump failed	1. Press CONTINUE. 2. If alarm recurs, end treatment: (a) Press CONTINUE, when Status screen appears, immediately press STOP (b) On Stop screen, choose END TREATMNT; follow the instructions to disconnect patient and unload set; (c) Call service to remedy/clear alarm.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Replacement Scale Sensor	1. The bar tray of the replacement scale has not been pulled out and then pushed in the control unit to attach the replacement bag. 2. The scale position sensor failed.	1. Place the scale in open position and then in closed position. Press RETEST. If this does not clear the alarm, see step 2. 2. End treatment via DISCONNECT. Call Service.
Scales **(Scale out of calibration: XXXX)** Scale in question is specified on the alarm screen.	Specified scale is out of calibration.	Press RETEST. If alarm does not clear, end treatment via DISCONNECT [c] or manually.[d] Call service.[a] **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.
Scales Circuit Board	Hardware failure on scales circuit board.	End treatment via DISCONNECT. Call Service.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Scale zero test Zero test of one or more scales failed.	1. Carrying bar missing from one or more scales. 2. Foreign objects are touching scales or hanging from scale hooks. 3. One or more scales failed.	1. Place carrying bar back on scale. Close scale and press RETEST. 2. Make sure nothing is touching scales and no foreign objects are on scale hooks. Press RETEST. 3. If alarm does not clear, turn off machine. Call service.[a]
Self-test failure **Code XX** (number 1 to 20)	One or more tests done during the periodic self-test have failed. See reasons listed in “Prime Self-Test” in this table.	See instructions in “Malfunction: Prime Self-Test” in this table. **Note:** Softkeys perform slightly different actions than they do in Prime Self-Test alarm. RETEST retests circuitry, clears alarm if retest sequence passes. DISCONNECT provides instructions for ending the treatment and discarding set.
Due To: 24 volt / 12 volt **Code=24**	24 volt/12 volt test failed.	Press RETEST. If failure recurs, end treatment via DISCONNECT; call service and report failure code.
Due To: 24 volt and Return clamp sensor **Code=26**	24 volt and return clamp sensor tests failed.	- Remove any obstruction in the return line clamp and press RETEST. - If alarm does not clear, end treatment via DISCONNECT; call service and report failure code.
(continued on next page)	*(continued on next page)*	*(continued on next page)*

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Self-test failure*(continued)* **Due To: Return clamp sensor** **Code=25**	*(continued)* Return clamp sensor test failed.	*(continued)* - Remove any obstruction in the return line clamp and press RETEST. - If alarm does not clear, end treatment via DISCONNECT; call service and report failure code.
Due to: Blood leak detector threshold error **Code=18**	Blood leak detector failed.	- Press RETEST. - If alarm does not clear, end treatment via DISCONNECT; call service and report failure code.
Due to: Pressure pod/sensor - **Code=1 Access** **Code=2 Filter** **Code=3 Access and Filter** **Code=4 Effluent** **Code=5 Access and Effluent** **Code=6 Filter and Effluent** **Code=7 Access, Effluent and Filter**	1. Pressure pod(s) not installed or debris in sensor housing(s). 2. Pressure sensor(s) failed.	1. Do Pressure Pod Adjustment procedure on all pods reported. Press RETEST. 2. If alarm does not clear, end treatment via DISCONNECT; call service and report failure code.
Due to: Return pressure sensor **Code=16**	1. Chamber monitor line not connected to return pressure port. 2. Pressure sensor(s) failed.	1. Verify the fluid barrier is not damaged. If not damaged, secure monitor line to the luer lock of the return pressure port and press RETEST. If the fluid barrier is damaged, load a new set. 2. If alarm does not clear, end treatment via DISCONNECT; call service and report failure code.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Syringe pump (Rate is incorrect.)	Syringe pump failed.	- Press OVERRIDE.[b] PressThe syringe pump test will restart after 60 seconds. - If alarm recurs, continue without using the syringe pump, if desired. To do this, press FLOW RATES and set the syringe pump delivery 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.
Syringe not loaded	The syringe is not loaded after SyringeTest has been performed.	- Press CHANGE SYRINGE; follow instructions to load the syringe and return to alarm screen. Press RETEST to restart Syringe Test. - If alarm recurs, continue without using the syringe pump, if desired. To do this, press SYRINGE DISABLE and then CONFIRM DISABLE **OR** End treatment DISCONNECT. Call service to repair the syringe pump.
Upper Pinch Valve	1. The upper pinch valve is in the wrong position for the therapy selected due to obstructions. 2. The upper pinch valve failed.	1. Remove any obstructions and press RETEST. If this does not clear the alarm, see step 2. 2. End treatment via DISCONNECT. Call Service.

Table 16: Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Voltage Out of Range	Internal malfunction related to the machine Power Supply or the Power supply cabling.	Turn machine off and end treatment manually. Call Service. **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 17: Caution Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Dialysate bag empty (CVVHD, CVVHDF only)	1. Dialysate bag is empty.[c]	1. Connect a new dialysate bag. (See instructions on alarm screen.) If the Empty Bag Method set in Custom mode is "Variable", it is possible to change to a larger/smaller bag, by pressing MODIFY BAG and using arrows to set a new Allowed Volume. Press CONTINUE when ready.
	2. Dialysate bag partially supported (not hanging freely).	2. Remove partial support; press CONTINUE. Note: STOP softkey is also available for use in above steps, if desired.[a]
Dialysate weight (Incorrect weight change detected.) (CVVHD, CVVHDF only)	1. Leaking or clamped dialysate line or bag; bag is swinging on scale hook.	1. Remedy; press CONTINUE.[b]
	2. Foreign object on dialysate scale; dialysate bag is partially supported (not hanging freely).	2. Remove object or partial support; press CONTINUE.[b]
	3. Seal on dialysate bag not completely broken.	3. Using aseptic technique, manipulate bag seal to provide unobstructed fluid pathway. Press CONTINUE. Note: STOP softkey is available for use in above steps, if desired.[a]
	4. Air bubbles in the dialysate fluid.	4. Check bag connections. Remedy and press CONTINUE[b] **or** if there is evidence that the filter is becoming clotted, press STOP and change the set.
	5. Dialysate scale failed; internal malfunction.	5. Press STOP and end the treatment. Call service. **Warning:** After alarm clears, see History screen to verify patient fluid/plasma removal accuracy.[b]

Table 17: 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 alarm screen.) If changing to a larger/ smaller bag, press MODIFY BAG; use arrows to set a new Allowed Volume. Press CONTINUE.
	2. Foreign object on effluent scale.	2. Remove foreign object, press CONTINUE. Note: STOP softkey is also available for use in above steps, if desired.[a]
Effluent Bag Incorrect (Effluent Bag volume does not match Allowed Volume. Cause: a 5 liter empty bag is hanged on scale while Effluent Allowed Volume is 9000 ml)	1. A 5 liter empty bag is hanged on scale while Effluent Allowed Volume is 9000 ml.	1. Replace the 5 liter bag hanged on scale by a 9 liter bag or change the Effluent Allowed Volume by pressing MODIFY BAG. Press CONTINUE.
	2. No bag on scale.	2. Place the appropriate bag on the scale, press CONTINUE. Note: If hanging multiple bags on the scale, the total fluid capacity of all bags on the scale must not exceed the allowed volume for that scale.
	3. Effluent bag is partially supported (not hanging freely).	3. Remove partial support; press CONTINUE.

Table 17: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent weight (Incorrect weight change detected for effluent bag.)	1. Leaking or clamped effluent line or bag; bag is swinging on scale hook.	1. Remedy; press CONTINUE.[b]
	2. Foreign object on effluent scale; effluent bag is partially supported (not hanging freely).	2. Remove foreign object or partial support; press CONTINUE.[b] Note: STOP softkey is also available for use in above steps, if desired.[a]
	3. Air bubbles in the effluent fluid.	3. If there is evidence that the filter is becoming clotted, press STOP and change the set. If there is no clotting, lower TMP by (a) decreasing the replacement and/or patient fluid removal rates, (b) increasing the blood flow rate; then press CONTINUE.[b]
	4. A 5000 ml bag is used with a 9000 ml allowed volume setting.	4. Press CONTINUE.[b] Remedy by pressing the CHANGE BAGS softkey from the STATUS screen.
	5. Effluent scale failed; internal malfunction.	5. Press STOP and end the treatment. Call service. **Warning:** After alarm clears, see History screen to verify patient fluid/plasma removal accuracy.[b]

Table 17: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Incorrect Bag Volume **(Bag Volume incorrect for: XXXXXX** **Amount of fluid in bag does not match Allowed Volume.)** The following may be identified: Replacement bag Dialysate bag PBP bag Replacement bag 2 (green scale)	1. Amount of fluid in the identified bag does not match the current Allowed Volume. 2. No bag on scale. 3. Foreign object on scale. 4. Identified bag is partially supported (not hanging freely).	1. Choose one of the options on the alarm screen. **Warning:** Carefully read the the alarm Help screen *before* making a choice. Choose KEEP BAG *only* to use a partially full bag that is of the *same* total volume capacity as the current Allowed Volume. 2. Place the appropriate bag on the scale, press CONTINUE. 3. Remove foreign object, press CONTINUE. 4. Remove partial support; press CONTINUE.
No blood in filter **(Filter pressure drop is mininal. Blood is not circulating through filter.)**	1. Clamp or kink in access line between blood pump and filter pod or between blood pump and access pod. 2. Clot in access line between blood pump and filter pod or between access pod and filter pod. 3. Blood flow rate too low. 4. Wrong Filter pod pressure measurement.	1. If clamp/kink is located, remove it, press CONTINUE. If alarm recurs, press STOP and change the set. 2. If clot is present, press STOP and change the set. 3. Press CONTINUE and increase the blood flow rate. 4. Press CONTINUE and start a self-test by pressing the SELF-TEST softkey from the System Tools screen. If alarm recurs, press STOP and change the set.

Table 17: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
PBP bag empty	1. PBP bag is empty.[c]	1. Connect a new PBP bag. If the Empty Bag Method set in Custom mode is “Variable”, it is possible to change to a larger/ smaller bag, by pressing MODIFY BAG and using arrows to set a new Allowed Volume. Press CONTINUE when ready.
	2. PBP bag partially supported (not hanging freely).	2. Remove partial support, press CONTINUE. Note: STOP softkey is also available for use in above steps, if desired.[a]
PBP weight (Incorrect weight change detected for PBP bag.) PBP = pre-blood pump	1. Leaking or clamped PBP line or bag; bag is swinging on scale hook.	1. Remedy; press CONTINUE.[b]
	2. Foreign object on PBP scale; PBP bag is partially supported (not hanging freely).	2. Remove foreign object or partial support; press CONTINUE.[b]
	3. Seal on PBP bag is not completely broken.	3. Using aseptic technique, manipulate the bag seal to provide unobstructed fluid pathway. Press CONTINUE.[b] Note: STOP softkey is also available for use in above steps, if desired.[a]
	4. Air bubbles in the PBP fluid.	4. Check bag connections. Remedy and press CONTINUE[b].
	5. PBP scale failed; internal malfunction.	5. Press STOP and end the treatment. Call service. **Warning:** After alarm clears, see History screen to verify patient fluid/plasma removal accuracy.[b]

Table 17: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement bag empty (CVVH, CVVHDF only)	1. Replacement bag is empty.[c] 2. Replacement bag partially supported (not hanging freely).	1. Connect a new replacement bag. If the Empty Bag Method set in Custom mode is "Variable", it is possible to change to a larger/smaller bag, by pressing MODIFY BAG and using arrows to set a new Allowed Volume. Press CONTINUE when ready. 2. Remove partial support, press CONTINUE. Note: STOP softkey is also available for use in above steps, if desired.[a]
Replacement bag 2 empty (on green scale; CVVH only)	1. Replacement bag 2 (green scale) is empty.[c] 2. Replacement bag 2 is partially supported (not hanging freely).	1. Connect a new replacement bag 2. If the Empty Bag Method set in Custom mode is "Variable", it is possible to change to a larger/smaller bag, by pressing MODIFY BAG and using arrows to set a new Allowed Volume. Press CONTINUE when ready. 2. Remove partial support, press CONTINUE. Note: STOP softkey is also available for use in above steps, if desired.[a]

Table 17: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement weight (Incorrect weight change detected for replacement bag.)	1. Leaking or clamped replacement line or bag; bag is swinging on scale hooks. 2. Foreign object on replacement scale; replacement bag partially supported (not hanging freely). 3. Seal on replacement bag not completely broken. 4. Air bubbles in the replacement fluid. 5. Replacement scale failed; internal malfunction.	1. Remedy; press CONTINUE.[b] 2. Remove object or partial support; press CONTINUE.[b] 3. Using aseptic technique, manipulate the bag seal to provide unobstructed fluid pathway. Press CONTINUE.[b] Note: STOP softkey is available for use in above steps, if desired.[a] 4. Check bag connections. Remedy and press CONTINUE[b]. 5. Press STOP and end the treatment. Call service. **Warning:** After alarm clears, see History screen to verify patient fluid/plasma removal accuracy.[b]
Replacement 2 weight (Incorrect weight change detected for replacement bag 2 [green scale].)	1. Leaking or clamped replacement line or bag; bag is swinging on scale hooks. 2. Foreign object on replacement scale; replacement bag partially supported (not hanging freely). 3. Seal on replacement bag not completely broken. 4. Air bubbles in the replacement fluid (replacement 2 bag). 5. Green scale failed; internal malfunction.	1. Remedy; press CONTINUE.[b] 2. Remove object or partial support; press CONTINUE.[b] 3. Using aseptic technique, manipulate the bag seal to provide unobstructed fluid pathway. Press CONTINUE.[b] Note: STOP softkey is available for use in above steps, if desired.[a] 4. Check bag connections. Remedy and press CONTINUE[b]. 5. Press STOP and end the treatment. Call service. **Warning:** After alarm clears, see History screen to verify patient fluid/plasma removal accuracy.[b]

Table 17: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Scale open **(Scale not properly closed: XX)** Scales identified: Effluent, PBP, Replacement, Dialysate, Replacement 2 (green).	1. Impeding object blocking scale from fully closing; bag improperly positioned on hooks; carrying bar not centered on bar tray or handle not rotated down (toward floor). 2. Scale sensor failed.	1. Inspect and remedy possible causes. Press scale toward machine until it locks into closed position. Press CONTINUE. 2. Press STOP; end treatment; call for service.[a]
TMP excessive **(Transmembrane pressure exceeds membrane pressure limit.)** (CRRT only)	Ultrafiltration rate (UFR) is too high. Too much fluid is being removed. (UFR = patient fluid removal rate + replacement solution rate + PBP rate)	- Decrease the replacement and/or patient fluid removal rates. - Return to alarm screen, press CONTINUE. Note: To achieve same UFR as before, increase blood flow rate a few minutes after treatment resumes. Note: STOP softkey is available for use if desired.[a]
Incorrect Weight Change Alarm Not Cleared **Too many attempts to remedy below alarm. Accuracy of patient fluid removal may be compromised.** **Incorrect weight change detected for: XXXXXXXXXXX**	Clearing attempts have exceeded the manufacturer-set limit of 10 tries in 3 hours.	Press STOP and change the set and continue patient treatment with a new set, or end the treatment.

Table 17: Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response

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. Too many unsuccessful attempts to clear this alarm could lead to error in patient fluid balance/fluid removal that could result in patient injury or death. Press HISTORY and verify fluid removal accuracy. In case of discrepancy between the prescribed value and fluid removed, consult physician and discontinue the treatment if required. After 10 unsuccessful attempts to clear this alarm in less than 3 hours, a "Caution Weight Alarm Not Cleared" will occur requiring therapy to be discontinued or the set to be changed.The number of unsuccessful attempts to clear the alarm is displayed on the screen.

c. This alarm occurs when the Control Unit detects that the weight of the identified bag is lower than the tare of the bag itself. The tare of each bag is automatically calculated by the Control Unit depending on the Empty Bag Method setting in Custom mode. If Empty Bag Method is set to "Fixed", the tare of the Dialysate, PBP, Replacement, Replacement2 bag is set to 200 gr. If Empty Bag Method is set to "Variable", the tare of the Dialysate, PBP, Replacement, Replacement2 bag is automatically calculated each time a new bag is loaded.

Table 18: Advisory Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Access pressure rising Alarm occurs if access pressure is 50 mmHg or 70 mmHg (if blood flow>200ml/min) 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 or 70 mmHg (if blood flow>200ml/min) below its operating point.	1. Patient is coughing, moving or being moved. 2. Catheter type not appropriate; catheter out of position in vein; catheter clotted; possible kink in access line. 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.
Bar code reader error **(Bar code reader is out of service.)**	Bar code reader out of service.	Press RETRY. If alarm recurs, press OVERRIDE to continue with Setup procedures. Note: When treatment is finished, call service to repair bar code reader and clear the alarm.
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.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Cannot detect access (Access disconnection cannot be detected. Access pressure is more NEGATIVE than +10 mmHg.) Disconnection monitoring is not enabled. This alarm occurs when a *positive* access pressure range is in effect and the access pressure operating point is more negative than +10 mmHg.	1. Air leak at connection to catheter/blood source (external blood access device, patient A-V fistula). 2. Blood flow rate too high. 3. Access pressure pod removed after priming.	1. Tighten access line connections to catheter/blood source; press OVERRIDE.[a] 2. Decrease blood flow rate; return to alarm screen and press OVERRIDE.[a] 3. Do Pressure Pod Adjustment procedure on access pod (see end of Troubleshooting chapter); press OVERRIDE.[a] **OR** Change the set. To change set, press OVERRIDE. When Status screen appears, press STOP, then CHANGE SET.
Cannot detect access (Access disconnection cannot be detected. Access pressure is more POSITIVE than -10 mmHg.) Disconnection monitoring is not enabled. This alarm occurs when a *negative* access pressure range is in effect and the access pressure operating point is more positive than -10 mmHg.	1. Blood flow rate too low for the access device. 2. Access pressure pod removed after priming. 3. Wrong Access pressure range selection.	1. Increase blood flow rate; return to alarm screen and press OVERRIDE.[a] 2. Do Pressure Pod Adjustment procedure on access pod (see instructions at end of Troubleshooting chapter); press OVERRIDE[a] **OR** Change the set. To change set, press OVERRIDE. When Status screen appears, press STOP, then CHANGE SET. 3. To reset Access pressure range, press OVERRIDE. When Status screen appears, press STOP, then RECIRC to perform Recirculation.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Cannot detect return (Return disconnection cannot be detected. Return pressure is more negative than +10 mmHg alarm limit.) Disconnection monitoring is not enabled. This alarm occurs when the return pressure operating point is more negative than +10 mmHg.	1. Blood flow rate too low for the access device. 2. Chamber monitor line not securely connected to return pressure port.	1. Increase blood flow rate; return to alarm screen and press OVERRIDE. 2. If the fluid barrier is not damaged, secure monitor line to the luer lock of the return pressure port and press OVERRIDE. If the fluid barrier is damaged, change the set (press OVERRIDE, when Status screen appears, press STOP, then CHANGE SET.)
Check Syringe Line	Pressure exerted by syringe pump indicates syringe line may be clamped. All pumps are stopped while confirmation of clamping is in progress (maximum time of 8 seconds). Note: The audible alarm (slow beeping tone) is disabled for this Advisory alarm.	Inspect syringe line; remove any clamps; kinks, or other obstructions. This alarm self-clears if condition no longer exists. Note: If this alarm is not cleared within 8 seconds, “Syringe Empty-Clamped” advisory occurs.
Clamped Bag (No flow from bag detected since last CONTINUE action.)	1. Clamped line(s) or bag(s). 2. Seal on a bag is not completely broken. 3. Pump segments improperly loaded; obstructions in pump raceways. 4. Scale failed; internal malfunction.	1. Remedy; press CONTINUE[f]. 2. Press STOP[f]. Using aseptic technique, manipulate bag seal to provide unobstructed fluid pathway. Press RESUME. 3. Press STOP, then CHANGE SET[f]. 4. Press STOP and end the treatment[f]. Call service.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Confirm access range (POSITIVE access range xxxx mmHg to xxxx mmHg.)	**Negative Range:** Patient central venous catheter; patient A-V fistula **Positive Range:** External blood access device, patient A-V fistula 1. Access pod removed after priming. 2. Access pressure sensor failed.	- If positive pressure monitoring range reported is correct for catheter/blood source; press CONFIRM to clear alarm and proceed. - If the access monitoring range is not correct, remedy other possible causes, as follows: 1. Do Pressure Pod Adjustment procedure on access pod (see instructions at end of Trouble-shooting chapter); press RETEST. If reported monitoring range is now accurate, press CONFIRM to proceed. 2. If range is still incorrect, press CHANGE SET, unload this set and try with new set.
Confirm Positive Access Pressure (A POSITIVE Access Pressure range has been selected)	A POSITIVE Access Pressure range has been selected. **Positive Range:** External blood access device, patient A-V fistula, patient arterial catheter.	- If the access monitoring range selected is correct for the blood source; press CONFIRM to clear alarm and run the treatment with a positive access pressure range. - If the access monitoring range is not correct, press CANCEL. **Warning:** Positive access range cannot be cancelled after it is confirmed. If range is wrong, control unit cannot issue proper safety alarms during the patient treatment.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Download Interrupted (Patient information card is full.)	1. Patient information card is full. 2. Internal malfunction.	1. Remove patient information card and insert a new (empty) card; press DOWNLOAD DATA. If alarm recurs, press CONTINUE to clear alarm and proceed with treatment. 2. If alarm continues to occur with subsequent treatments, call service for repairs.
Download Interrupted (Patient information card not inserted.)	1. Patient information card not inserted. 2. Internal malfunction.	1. Insert the patient information card fully into the card holder; press DOWNLOAD DATA. If alarm recurs, press CONTINUE to clear alarm and proceed with treatment . 2. If alarm continues to occur with subsequent treatments, call service for repairs.
Download Interrupted (Cannot write to patient information card.)	1. Cannot write to patient information card. 2. Internal malfunction.	1. Verify patient information card is undamaged. Insert a new card, if necessary; press DOWNLOAD DATA. If alarm recurs, press CONTINUE to clear alarm and proceed with treatment . 2. If alarm continues to occur with subsequent treatments, call service for repairs.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent bag volume (Effluent bag volume has reached 5 liters, while Allowed volume is 9 liters)	Five liters has collected in the presently hanging, nine liter effluent bag.	Verify the size of the effluent bag in use. - If a 9 liters bag is hanging on the scale, press CONTINUE to clear alarm and proceed with treatment. Note: A Caution alarm occurs when effluent bag has reached its maximum 9 liter volume and must be changed. - If a 5 liters bag is hanging on the scale, change the bag by pressing first CONTINUE and then CHANGE BAGS in the Status screen.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Filter is clotting (Increasing TMP and/or Pressure Drop.) 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.	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. Replacement solution flow too high for filter in use.	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 on next page)	*(continued on next page)*	*(continued on next page)*

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Filter is clotting *(continued)* **(Increasing TMP and/or Pressure Drop.)**	*(continued)* 3. Kinked lines in blood flowpath. 4. If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed. 5. Air leak between deaeration chamber monitor line and return pressure sensor. 6. Filter or return pressure sensor failed.	*(continued)* 3. Remedy, press OVERRIDE.[a] 4. Ensure syringe is properly installed in syringe pump holder and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump. 5. If the fluid barrier is not damaged, secure monitor line to the luer lock of the return pressure port and press OVERRIDE. If the fluid barrier is damaged, press STOP and change the set. 6. Press STOP and end the treatment. Turn off machine; call for service.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Identify access range (Monitoring range for access pressure cannot be determined. Access line pressure is between -10 mmHg and +10 mmHg.)	For access line monitoring range to be automatically established, pressure sensors must register an access pressure outside the -10 to +10 mmHg span. Operator must identify proper range to be used.	- Verify access line is securely connected to catheter/blood source. - Identify the correct pressure range for catheter/blood source. **Negative Range:** Patient central venous catheter, pt. A-V fistula. **Positive Range**: External blood access device, pt. A-V fistula, patient arterial catheter. - If the chosen pressure range is correct, press CONFIRM to clear alarm and proceed; if range is wrong, press CANCEL to change the range. **Warning:** Negative Access range cannot be cancelled after it is selected. If range is wrong, control unit cannot issue proper safety alarms during the patient treatment.
Preventive maintenance due	3000 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.
Return too positive Alarm occurs if return pressure is 50 mmHg or 70 mmHg (if blood flow>200ml/min)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.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Self-test in progress (Test complete in: min. 1 minute, max. 6 minutes.)	Self-test is underway. Test occurs every 2 hours to ensure proper functioning of safety systems; if the self-test is interrupted due to a Warning or a Caution alarm, it will restart in the next 10 minutes. The return line clamp is closed and then opened during the test. Pressures display is not available during repositioning of Pod diaphragms.	None required. Self-clears when complete. While Self-Test is underway, monitor periodically the patient. Note: DELAY TEST softkey is available for use if it is necessary to stop and postpone self-test; FLOW RATE and HISTORY softkey are available for use if it is necessary to view flow settings and history data before the self-test process completion. Note: In case of abnormal pressure during self-test execution, it is recommended to re-launch a self-test by pressing the SELF-TEST softkey from the System Tools screen. **Warning:** “Filter Clotted“ warning occurence is delayed until the self-test process completion.
Scale component missing (Carrying bar missing from: XXXXXXXX scale.)	Carrying bar (with hooks) is not on the bar tray of the identified scale.	Return the carrying bar to the bar tray; close scale. If condition cannot be resolved, press OVERRIDE and turn machine off.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Syringe Empty-Clamped	1. Syringe line clamped. 2. Syringe pump is in end-of-travel position, indicating all solution in syringe has been delivered	1. Inspect syringe line; remove any clamps; kinks, or other obstructions; press CONTINUE. 2. Press CHANGE SYRINGE; follow instructions to install a full syringe; press CONTINUE. Note: Install only the allowed syringe (size/brand specified in Custom mode). **If desired,** continue without syringe delivery. To do this: (a) Press FLOW RATES; 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.)
Syringe not loaded **(The syringe is not loaded)**	The syringe is not loaded after SyringeTest has been performed.	- Press CHANGE SYRINGE; follow instructions to load the syringe and return to alarm screen. Press RETEST to restart Syringe Test. - If alarm recurs, continue without using the syringe pump, if desired. To do this, press SYRINGE DISABLE and then CONFIRM DISABLE **OR** End treatment DISCONNECT. Call service to repair the syringe pump.

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Time to change set **(Hours of use have reached the operator-set "Time to Change Set" limit for this therapy/set combination.)** OR **(780 liters have been processed.)**	A "Time to Change" set advisory limit has been reached. Note: Liters counted for the "Time to change set" advisory occurence are: blood, PBP solution and saline solution pumped during the Recirculation procedure.	Press STOP[e] and change the set. **OR** Press OVERRIDE and continue to monitor the set.[c] **Warning:** Do not use the *Prismaflex* Set beyond 72 hours or 780 liters processed. Doing so could result in rupture of the pump segments, causing patient injury or death. Error percentage of the blood pump is +/- 10%. This percentage cannot be guaranteed, and will probably be higher, if the set is used beyond 72 hours or 780 liters.
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+ PBP rate) 2. Replacement solution flow rate and/or PBP rate too high for filter in use.	1. Decrease the replacement and/or patient fluid removal flow rates and/or PBP. **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 and/or PBP. **OR** Increase the blood flow rate. Return to alarm screen and press OVERRIDE.[a] Note: STOP softkey is available for use if desired.[b]

Table 18: Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response

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 and recirculate sterile saline though 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.

f. Too many unsuccessful attempts to clear this alarm could lead to error in patient fluid balance/fluid removal that could result in patient injury or death. If alarm reoccurs, press HISTORY and verify fluid removal accuracy. In case of discrepancy between the prescribed value and fluid removed, consult physician and discontinue the treatment if required.

Table 19: 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 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.

Table 19: Additional Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent bag is tinged pink or red.	1. Patient's disease state may cause discoloration of the effluent. 2. Effluent contains red blood cells, but level is below blood leak detection limit. 3. Hemolysis is occurring due to occlusion.	1. Send effluent sample to laboratory for analysis. If free of red blood cells, continue treatment. If red blood cells are present, change the set. 2. Send effluent sample to laboratory for analysis. If red blood cells are present, change the set. 3. Verify that the correct clamps are open for the therapy in use, especially for the access line (red) and return line (blue). Verify no kinks in the access and return lines. If hemolysis continues, change the set via the STOP key.[b]
Leakage from set connections.	Connections are loose.	- Tighten the connections. - If leakage continues, change the set via STOP key.[b]
Softkeys won't work.	Touchscreen failed.	- Turn off machine; end treatment manually, if desired.[a] - Call service. **Warning:** If doing Manual Termination With Blood Return, air detection is not provided. Watch return line for air.

Table 19: Additional Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Unable to Normalize BLD	1. Blood in effluent line.	1. Wait for blood to clear and BLD signal value to be ≥38000 before normalizing OR change the set.
	2. Air bubble in effluent line at level of blood leak detector.	2. Dislodge bubble by giving the effluent pump a quick half-turn counterclockwise.
	3. Effluent line not properly installed in blood leak detector.	3. Press line into detector from the bottom up and route securely through tubing guides.
	4. Liquid or other debris in tubing path through the detector.	4. 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. **Warning:** If the effluent line is removed/reinserted in detector, the detector must be reset by pressing NORMALIZE BLD. This must be done before continuing patient treatment. BLD signal value must be ≥38000 for normalization to be allowed.
	5. Leak in filter membrane.	5. Change the set via the STOP key.[b]

a. Manual termination instructions are provided at the end of the Troubleshooting chapter.
b. See "Change Set Procedure" in the Operation section of the appropriate chapter (3 or 4).

Manual Termination of Treatment

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, or when the blood return rate needs to be less than 10 ml/min.

Manual Termination With Blood Return

(See Figure 11)

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-liter bag of sterile saline. (Use spike connector, if needed.) Unclamp the access line.
2. Press the return clamp button[1] and hold in the "In" position. With the other hand, remove the return line (blue-striped) from the return line clamp.
3. Visually check the fluid level in the deaeration chamber. If the level is too low, remove excess air as follows (depending on the *Prismaflex* Set version):
   - Air removal through the sample site on the chamber monitor line[2]: Insert a sterile, 21-gauge needle attached to a < 5-cc syringe into the sample site on the chamber monitor line; aspirate air/blood until fluid level is at the correct height on the deaeration chamber.
   - Air removal through the chamber monitor line: Place a clamp on the chamber monitor line; disconnect the chamber monitor line from the return pressure port; by opening/closing the clamp, let blood fill the deaeration chamber until fluid level is at the correct height.

     Note: In case no blood pressure is available, attach a 30-cc luer-lock sterile syringe (without the needle) to the distal end of the chamber monitor line; aspirate air/blood until fluid level is at the correct height on the deaeration chamber.

1. Return clamp button is located on the left side of the return line clamp assembly.

2. Chamber monitor line connects the deaeration chamber with the return pressure port on the control unit.

4. Remove the pump crank from its holder on the rear panel. Insert crank into the rotor of the blood pump and turn *clockwise* until sufficient blood is returned to the patient.

WARNING

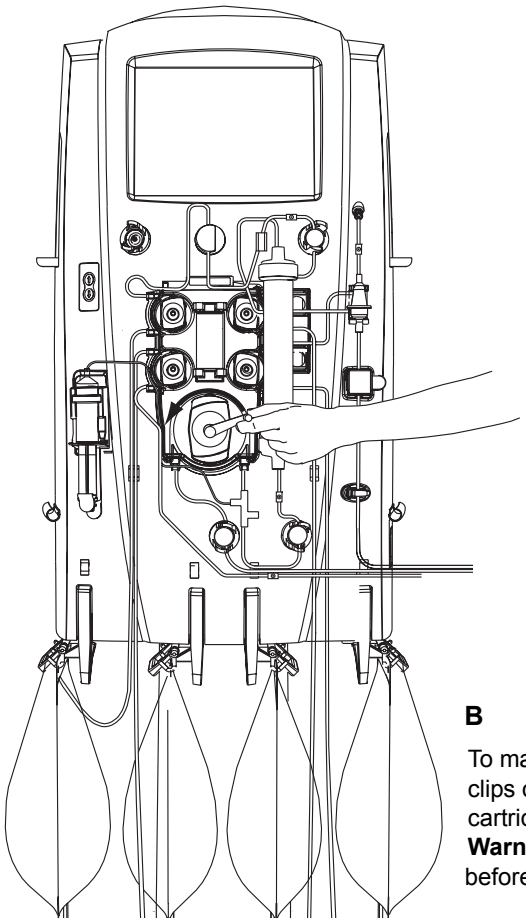
The alarm system is disabled. Visually check for air in the blood return line until the patient is disconnected.

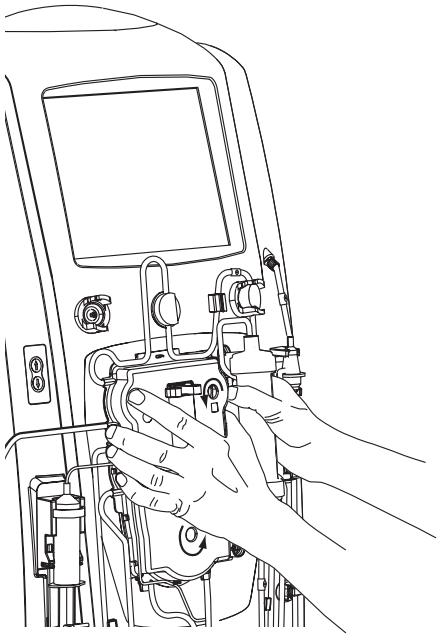
5. Clamp the return line (blue-striped) and disconnect from the patient. Clamp lines to all bags.
6. Press the two clips of the cartridge carrier to release the cartridge. Starting with any peristaltic pump, insert the pump crank into the rotor and turn each pump *counterclockwise*. (The pump segment 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.
7. When the pump segments are free, grasp the cartridge and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

   Note: Remaining solutions may be used with a new set, if desired.

A

To manually return the patient's blood, connect saline to access line, use pump crank to turn the blood pump *clockwise*.
Warning: Watch return line for air.





B

To manually remove the set from the control unit, press clips of cartridge carrier to release the cartridge. Pull cartridge outward to disengage from pinch valves.
Warning: Ensure patient is disconnected from set before removing set from control unit.

Figure 11. Manually Terminating Treatment (CRRT Set shown)

Manual Termination Without Blood Return

(See Figure 11)

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 *Prismaflex* 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 two clips of the cartridge carrier to release the cartridge. Starting with any peristaltic pump, insert the pump crank into the rotor and 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, grasp the cartridge and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

Pressure Pod Adjustment Procedure

The Pressure Pod Adjustment 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 adjustment 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.

The steps of the Pressure Pod Adjustment procedure vary, depending on the following factors:

- Type of *Prismaflex* Set in use
- Exact pressure pod(s) affected

Instructions for performing the proper Reposition procedure for the situation at hand are provided below.

Pressure Pod Adjustment

Supplies Needed

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

Access Pod

Effluent Pod (See Figure 12)

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

CAUTION

Use aseptic technique with syringe, needle and sample site.

1. Stop all pumps.

   Note: Pumps might already be stopped.

2. To reposition the diaphragm of the effluent line pod: clamp the line below the effluent line pod (upstream from the way blood/fluid is flowing) and between cartridge and its color-coded sample site (downstream from the way blood/fluid is flowing).

   To reposition the diaphragm of the access line pod: clamp the line above access line pod (downstream from the way blood/fluid is flowing) and between patient end and its sample site (upstream from the way blood/fluid is flowing).

3. Twist the affected pod slightly to release/remove it from its pressure sensor housing.

   Note: Pod might already be removed.

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

4. Draw 3 cc saline into the ≤ 5-cc syringe.
5. *Inject* a maximum of 1 cc of saline into the 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.

6. Remove needle from sample site. Reinstall the pressure pod in the correct pressure sensor housing and remove the clamps from the line.
7. Resume treatment, or press the appropriate softkey on the alarm screen.
8. **For access pod :** 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 *below* the access pressure pod. 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 adjusted incorrectly. Perform the adjustment procedure again.

9. **For effluent pod :** Perform the following test to ensure proper functioning of the effluent pod. When the control unit is in Run mode, place a clamp on the effluent line below the effluent pressure pod. Verify that effluent pressure decreases. Unclamp the effluent line and verify that effluent pressure increases.

WARNING

If the effluent pressure fails to respond properly, diaphragm has been adjusted incorrectly. Do adjustment procedure again.

Filter Pod

(See Figure 12)

Follow the steps below to adjust the diaphragm of the *filter pod* (near upper red sample site).

CAUTION

Use aseptic technique with syringe, needle, and sample site.

1. Stop all pumps.

   Note: Pumps might already be stopped.

2. Clamp the line above the filter pod (downstream from the way blood/fluid is flowing) and above its color-coded sample site (upstream from the way blood/fluid is flowing).

3. Twist the filter pod slightly to release/remove it from its pressure sensor housing.

   Note: Pod might already be removed.

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

4. Insert the needle with empty syringe into the sample site between the clamps. *Remove* a maximum 1 cc 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.

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

6. When the procedure has been completed, resume treatment, or press the appropriate softkey on the alarm screen.

7. Perform the following test to ensure proper functioning of the filter pressure pod. When the control unit is in Run mode, place a clamp on the line *above* the filter pressure pod. The Warning: “Filter Extremely Positive” 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 Warning: Filter Extremely Positive alarm fails to occur, the pressure pod diaphragm has been adjusted incorrectly. Perform the adjustment 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. Air may also accumulate in the deaeration chamber. This air can be removed by following the procedures below.

Note: Air removal procedures are the same, regardless of which type of *Prismaflex* Set is in use. The instructions below apply to all the types of *Prismaflex* Sets.

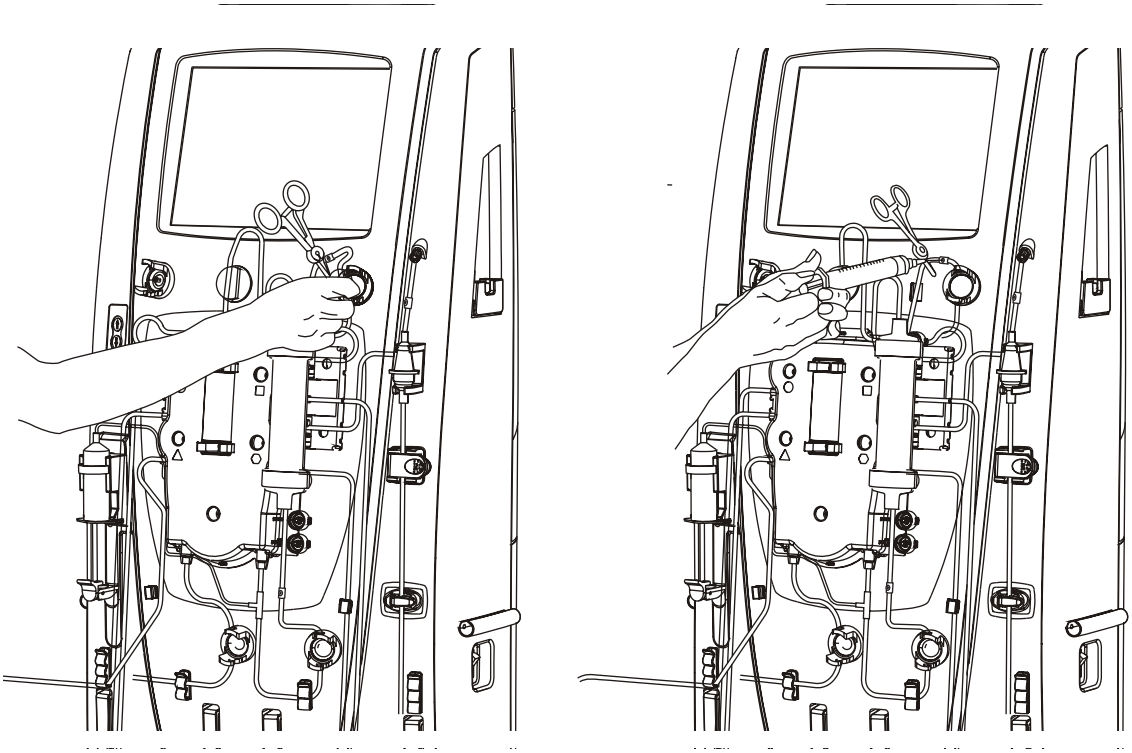
Note: If air occurs in the return line during treatment, a Warning alarm occurs. Air removal instructions are provided on the Warning screen, as well as here under “Return Line During Air in Blood Alarm.”

Supplies Needed

- 21-gauge (or smaller diameter) needle attached to a ≤ 5-cc syringe
- Tubing clamp

Access Pressure Pod

1. Ensure that all peristaltic pumps are stopped. Clamp the access line (red-striped) below the *lower* red sample site.
2. Insert the 21-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.



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 adjusted).

Figure 12. Adjusting a Pressure Pod

Effluent Pressure Pod

1. Ensure that all peristaltic pumps are stopped.
2. Insert the 21-gauge needle with syringe into the yellow sample site and aspirate air/effluent 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. Clamp the line above the filter pod and above its color-coded sample site (to remove air from pod) or clamp the line above the blue sample site on the return line (to remove air from header).
3. Insert the 21-gauge needle with syringe into the *upper* red sample site *closest to the filter pod* (to remove air from pod) or into the blue sample site on the return line (to remove air from header). Aspirate air/blood until the air is removed or resistance is felt. Remove the needle.

Deaeration Chamber

If the fluid level in the deaeration chamber is too low (refer to the drawing displayed on the screen), the excess air in the chamber can be removed automatically while all pumps remain running. From the Status screen, access the System Tools screen, then press ADJUST LEVEL and use the Up arrow to bring the fluid level to the correct height.

Note: When the Up arrow is pressed, the excess air is drawn into the chamber monitor line and eliminated through the return pressure port.

Return Line During Air in Blood Alarm

Open the door of the air detetector and look for air/foam in the tubing; inspect the level of fluid in the deaeration chamber.

Use the alarm screen to perform the steps below:

1. Press the Up arrow until the return pressure reported is negative (0 mmHg to -100 mmHg). If unsuccessful, proceed with the following manual procedure:
   - Insert the 21-gauge needle with syringe into the blue sample site (return line).
   - Aspirate air/blood until the return pressure reaches a negative value.
   - Remove the needle
2. Press RELEASE CLAMP to remove air and draw blood from patient into the return line/deaeration chamber.

   Note: When the return line clamp releases, air in the blood is drawn into the chamber monitor line and automatically eliminated from the set through the return pressure port. Blood is also drawn from the patient into the return line and deaeration chamber.

3. If needed, press ADJUST CHAMBER and use the arrows to adjust the level of fluid in the chamber. (Fluid should be at the level of the horizontal line on the chamber.)
4. Close air detector door; press CONTINUE.

Blood Leak Detector Normalization

The Blood Leak Detector is an infrared transmission/detection device that continuously monitors the effluent line for blood that may have passed through the filter.

The Blood Leak Detector is automatically normalized after the end of the priming sequence, when the effluent line is full of priming solution. The infrared transmitter/detector is adjusted to receive a signal range between 40000 and 46000. If the received signal goes above or below the alarm limits, the Blood Leak Detected warning alarm is triggered.

If the effluent line has been removed/reinserted in the detector, the Blood Leak Detector has to be normalized also in Run mode, from the System Tool screen.

To normalize the Blood Leak Detector during treatment, perform the following steps:

1. Press NORM BLD from the System Tool screen.
2. Draw a sample from effluent line and test for blood. If blood present, discontinue the treatment and change the set. If no blood is present, proceed with the following step.
3. Verify the signal value displayed in the screen is 38000 or greater. If necessary, move effluent line slightly up or down in the blood leak detector to raise the signal value.

   Note: If the received signal value goes below 38000 as displayed on the Normalize BLD screen, the blood leak detector cannot be re-normalized and the set has to be changed. This prevents normalization when a blood leak is occurring.

4. Press START NORM. The infrared LED drive signal is still adjusted so the received A/D signal range is 40000 to 46000.
5. When normalization finishes, control unit automatically returns to the Status screen.

WARNING

Before normalizing the Blood Leak Detector, fluid in effluent line must be tested and verified to be free of blood.

Chapter 6: Maintenance

Service

For service or to order parts, contact your representative. See “Service Information” in the Before You Get Started section of this manual.

Operator Maintenance

There are no user-serviceable parts inside the *Prismaflex* Control Unit. Do not attempt any internal or external maintenance or repair, other than the routine cleaning described below. All other maintenance and repairs must be done by a trained and qualified technician.

Routine Cleaning

The following cleaning procedures should be done after completion of each patient treatment with the *Prismaflex* Control Unit, or as required during treatment:

1. Clean spills from the surface of the machine using a mild detergent.
2. Disinfect the surfaces of the machine using a solution of 90% ethyl alcohol; 70% isopropyl alcohol, or 0.1% sodium hypochlorite (Bleach®).

Note: Using a stronger Bleach® solution than recommended can cause damage or discoloration.

Do not use sodium hypochlorite (Bleach®) to clean the pump crank. Use of sodium hypochlorite (Bleach®) on this component may damage it.

Cleaning the Blood Leak Detector

The tubing path through the blood leak detector should be cleaned as required to remove liquid or other debris. Using a “flossing action,” clean inside the detector with a lint-free cloth and isopropyl alcohol. Dry thoroughly when finished.

Cleaning the Touch screen

The Touch screen may be cleaned also when the *Prismaflex* Control Unit is performing a treatment. To clean the Touch screen press the CLEAN SCREEN softkey from the System Tools screen: for 10 seconds an empty screen is displayed to allow cleaning without unwanted pressing of softkeys.

For the Touchscreen cleaning use the following disinfectants:

- **Isopropyl alcohol (70°);**
- **Sodium hypochlorite solution (active chlorine from 50,000 to 60,000 ppm)/Bleach diluted with water at a ratio of 1:50.**

Technician Maintenance

Technical Preventive Maintenance

Technical preventive maintenance is required every 3000 hours of operation or once every 6 months. Only trained and qualified technicians are approved to perform preventive maintenance procedures. These procedures are performed in Service mode.

When 3000 hours of operation have elapsed, the Advisory: Preventive Maintenance Due alarm occurs. The operator can override this alarm until it is convenient to perform the maintenance. This advisory can only be cleared when the control unit is placed in Service mode.

For a complete description of all technical preventive maintenance procedures, please refer to the *Prismaflex Service Manual.*

During preventive maintenance the following components should be replaced:

- Pressure pod sealing cones;
- Automatic Reposition System (ARPS) filter and pump segment;
- Blood Pump Rotor (only after 20000 hours of operation have elapsed).

During preventive maintenance the technician should verify the proper operation and/or calibration of the following items in Service mode:

- Pumps;
- Scales;
- Reposition pressure;
- Return pressure sensor;
- Light and alarm tones;
- Air Detector;
- Syringe pump;
- Return line clamp;
- Blood Leak Detector;
- Pod reposition;
- Internal system;
- Load/unload functions;
- Communication system.

During preventive maintenance the technician should also perform the following test, verifications, operations:

- Clean any dust, debris and/or dried fluids from the external and internal machine surfaces, including pump rotors;
- Perform the rotor occlusion test for all the pumps;
- Verify the proper functioning and integrity of the Blood Pump rotor;
- Verify the presence and the integrity of the conductivity gaskets of the

scales;

- Apply the proper quantity of graese on the scale bearings.

Periodic Safety Inspection

A safety inspection of the *Prismaflex* Control Unit is required every 12 months, or as stipulated by local requirements. Only trained and qualified technicians are approved to perform the safety inspection procedures. The inspection consists of the tests listed in Table 20.

Table 20: Periodic Safety Inspection Tests

Parameter	Performance	Conditions
Enclosure Leakage Current Test per IEC 60601.1. para. 19.4 (plus UL 2601-1 deviation)	50 mA maximum (typically < 20 mA) 300 mA maximum (typically < 100 mA) 300 mA maximum (typically < 200 mA)	Protective ground intact. Protective ground open. 100 - 120Vac 210 - 240 Vac
Earth Leakage Current Test per IEC 60601.1 para 19.4	500 mA maximum (typically < 200 mA) 1000 mA maximum (typically < 500 mA)	Normal Condition Single Failure Condition
Note: Before performing the remaining tests, turn off the power switch and disconnect the mains plug from the electrical outlet.		
Ground Integrity Test per IEC 60601.1, para. 18. f	0.1 ohm maximum 0.2 ohm maximum	Between protective conductor in appliance inlet and any accessible conductive part. Between earth ground in mains plug and any accessible conductive part.
Discharger Ring Guide Test (using a digital multi meter, ohm function)	0.9 MΩ ≤ R < 1.3 MΩ	Between the conductive part of the guide and the earth ground in mains plug
General Mechanical Inspection	All parts are in good repair and functioning properly.	
External Cleanliness	Exterior surfaces of machine are clean and dry.	

Chapter 7: Specifications

Parameter	Performance	Conditions
Environmental Requirements		
Ambient Operating Temperature	16 °C to 38 °C (60 °F to 100 °F)	
Ambient Operating Humidity	0% to 90%	Non-condensing
Maximum Operating Altitude	3048 m (10,000 ft) above sea level	
Storage Temperature	-18 °C to +54 °C (0 °F to 130 °F)	Prior to use, let unit rest at ambient operating temperature for 1 hour.
Fluid Spillage	IPX1 (Protection against vertically falling water drops)	As specified in IEC 60529
Cleanability	Not damaged by mild detergent; liquid soap; ethyl alcohol (90%); isopropyl alcohol (70%); sodium hypochlorite (0.1%). Pump rotors are removable.	
Physical Characteristics of *Prismaflex* Control Unit		
Weight	Approximately 60 kg (132 lb)	Without fluid bags, and *Prismaflex* Set
Height	Approximately 162 cm (64 in)	
Width	Approximately 49 cm (19 in)	
Base	Approximately 60 cm x 63 cm (24 in x 25 in)	

Parameter	Performance	Conditions
Medical Device Classification		
Classification	Class IIb per COUNCIL DIRECTIVE 93/42 EEC	
Scales Characteristics		
Scale Weight Range	Dialysate: 0 to 15 Kg (33 lb) Replacement: 0 to 15 Kg (33 lb) PBP: 0 to 15 Kg (33 lb) *(PBP = pre-blood pump)* Effluent: 0 to 15 Kg (33 lb)	Weight range for each scale includes the scale components (bar tray, carrying bars).
Maximum Bags Configuration Allowed on Scales	Four scales, each holding a standard 5000 ml fluid bag. Three scales (PBP, dialysate replacement), each holding a standard 5000 ml fluid bag; one scale (effluent) holding a standard 9000 ml fluid bag.	
AC Power		
Line Voltage Input Line Current	100–240 Vac, 50/60 Hz 5–2.5 A (5 A maximum rms at 100 Vac; 2.5 A maximum rms at 240 Vac)	
Electrical Safety		
Classification	Mobile, Class I, applied part is Type BF, defibrillation proof per IEC 60601-1	
AC Leakage Current	 300 μA maximum rms 500 μA maximum rms	Protective ground open 100/115 Vac, 50/60 Hz 220/240 Vac, 50/60 Hz

Parameter	Performance	Conditions
Electrical Safety (cont.)		
Defibrillation-proof Applied Part	Applied part is Type BF, defibrillation-proof per IEC 60601-1	Defibrillator meets requirements of IEC 60601-2-4
Radio Frequency Interference	Meets European Standard EN 55011, limit B	Meets IEC 60601-1-2
Electromagnetic Compatibility	Meets IEC 60601-1-2	
Potential Equalization	Meets IEC 60601-1	The Equipment is provided with a means for the connection of a POTENTIAL EQUALIZATION CONDUCTOR.
Conformity to International Rules		
	IEC 60601-1 VDE 0750-1 CEI 62/5 BS 5724-1 UL 2601-1	MEDICAL ELECTRICAL EQUIPMENT Part 1. General Requirements for Safety (Equivalent to EN 60601-1)
	EN 60601-2-16 VDE 0750-206 CEI 62/98 BS 5724-2-16	MEDICAL ELECTRICAL EQUIPMENT Part 2-16. Particular Requirements for Safety of Hemodialysis, Hemodiafiltration and Hemofiltration Equipment (Equivalent to EN 60601-2-16)
	EN 60601-1-2	MEDICAL ELECTRICAL EQUIPMENT Part 1. General Requirements for Safety 2. Collateral standard: Electromagnetic compatibility - Requirements and Tests (Equivalent to EN 60601-1-2)

Parameter	Performance	Conditions
Conformity to International Rules (cont.)		
	EN 60601-1-1	MEDICAL ELECTRICAL EQUIPMENT Part 1-1. General Requirements for Safety. 1. Collateral standard: Safety Requirements for Medical Electrical System (Equivalent to EN 60601-1-1)
	EN 60601-1-4	MEDICAL ELECTRICAL EQUIPMENT Part 1-4. General Requirements for Safety. 1. Collateral standard: Programmable electrical medical systems (Equivalent to EN 60601-1-4)
	CAN/CSA C22-2 N° 601-1-M90	MEDICAL ELECTRICAL EQUIPMENT Part 1. General Requirements for Safety
	CAN/CSA C22-2 N° 601-2-16-92	MEDICAL ELECTRICAL EQUIPMENT Part 2. Particular Requirements for Safety of Hemodialysis Equipment
	UL 2601-1	Standard for MEDICAL ELECTRICAL EQUIPMENT Part 1. General Requirements for Safety
	ISO 14971-1 (2000)	Medical devices - Risk Managements - Part 1: Application of risk analysis to medical devices.

Parameter	Performance	Conditions
Syringe Settings		
Syringe Continuous Delivery Rate Range	User settable; 0, or 1.0 to 5.0 ml/hr 0, or 0.5 to 5.0 ml/hr 0, or 0.5 to 10.0 ml/hr	 10-cc syringe 20-cc syringe 30-cc syringe
Increment	Increment: 0.1 ml/hr	
Accuracy	0.1 ml/hr ± 0.6 ml/hr	Pressure between 0 and +600 mmHg. Use of approved syringes[a]
Syringe Bolus Delivery Volume Range	User settable; 0, or 0.5 to 5.0 ml 0, or 1.0 to 5.0 ml	 10-cc and 20-cc syringe 30-cc syringe
Increment	0.1 ml	
Accuracy	±0.5 ml	
Syringe Bolus Delivery Interval Range	User settable; Once every 1 to 24 hours Note: *Immediate* option also available in Run mode and Recirculation mode.	
Increment	1 hour	
Syringe Bolus Delivery Rate	1 ml/≤20 sec	Use of approved syringes[a]

Parameter	Performance	Conditions
Flow Rates and Accuracy		
Blood Flow Rate Range Increment Accuracy Return Blood Flow Rate	User settable[b] 10 to 450 ml/min 10 ml/min ±10% of user-set rate 10 to 100 ml/min	 The accuracy of blood flow is maintained if: - the inlet pressure is higher (less negative) than -250 mmHg; - the outlet pressure is lower than +350 mmHg. When START RETURN softkey is pressed
Replacement Solution/Fluid Flow Rate Range Increment Range Increment Accuracy	User settable[b] 0 to 4000 ml/hr 0 to 8000 ml/hr 50 ml/hr 0 , or 1% to 100% of 8000 ml/hr 5% ±10% of user-set rate	 CVVH 100% Post CVVHDF CVVH 100% Pre; CVVH Pre/Post

Parameter	Performance	Conditions
Flow Rates and Accuracy (cont.)		
Dialysate Flow Rate	User settable[b]	
Range Increment	0 to 4000 ml/hr 50 ml/hr	CVVH 100% Post
Range Increment	Post- filter% of 8000 ml/hr *(assigned by software)*[c] 1%	CVVH Pre/Post
Range Increment	0 to 8000 ml/hr 50 ml/hr	CVVHD; CVVHDF
Accuracy	±10% of user-set rate	
PBP Solution Rate Range Increment	User settable[b]; 0 to 1000 ml/hr 10 ml/hr	SCUF
Range Increment	0 to 8000 ml/hr 10 ml/hr	CVVH; CVVHD; CVVHDF
Accuracy	±10% of user-set rate	
Patient Fluid Removal Rate Range Increment Accuracy	User settable[b]; 0 to 2000 ml/hr 10 ml/hr ±30 ml/hr, ±600 ml/24 hr[d]	Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ±3 °C (5.4 °F) during treatment.
Effluent Flow Rate Range	0 to 10,000 ml/hr	Depending on the therapy selected.
Audible Alarm		
Audible Alarm Volume (decibel level)	Low Moderate High	Meets IEC 60601-2-16

Parameter	Performance	Conditions
Audible Alarm (cont.)		
Can be muted for 2 minutes, after which audible resumes if alarm condition has not been remedied.	Fast beep Moderate beep Slow beep	Warning and Malfunction alarms Caution alarms Advisory alarms
Non-mutable	Continuous for at least 2 minutes	Power loss
Access Line Pressure Sensor		
Operating Range Accuracy	-250 to +300 mmHg ±10% of reading or ±8 mmHg, whichever is greater	
“Access Extremely Negative” Warning Limit	Warning alarm occurs User settable; -10 to -250 mmHg Default: -250 mmHg Increment: 5 mmHg	Pressure in access pod equals warning limit.

Parameter	Performance	Conditions
Access Line Pressure Sensor (cont.)		
"Access Extremely Positive" Warning Limit	Warning alarm occurs User settable; +10 to +300 mmHg Default: +300 mmHg Increment: 5 mmHg	Pressure in access pod equals warning limit.
"Access Too Negative" Advisory Limit	Advisory alarm occurs	Pressure in access pod is 50 mmHg (or 70 mmHg if blood flow>200ml/min) more negative than the established operating point.
"Access Pressure Rising" Advisory Limit	Advisory alarm occurs	Pressure in access pod is 50 mmHg (or 70 mmHg if blood flow>200ml/min) more positive than the established operating point.
"Access Disconnection" Warning Limit	Warning alarm occurs	Pressure in the access pod is more positive than -10 mmHg and the established operating point is more negative than -10 mmHg (negative working range). Pressure in the access pod is more negative than 10 mmHg and the established operating point is more positive than 10 mmHg (positive working range).
Return Line Pressure Sensor		
Operating Range Accuracy	-50 to +350 mmHg ±10% of reading or ±8 mmHg, whichever is greater	

Parameter	Performance	Conditions
Return Line Pressure Sensor (cont.)		
“Return Extremely Positive” Warning Limit	Warning alarm occurs User settable; +15 to +350 mmHg Default: +350 mmHg Increment: 5 mmHg	Pressure in return deaeration chamber equals warning limit.
“Return Too Positive” Advisory Limit	Advisory alarm occurs	Pressure in the return deaeration chamber is 50 mmHg (or 70 mmHg if blood flow>200ml/min) more positive than the established operating point.
“Return Pressure Dropping” Advisory Limit	Warning alarm occurs	Pressure in the return deaeration chamber is 50 mmHg (or 70 mmHg if blood flow>200ml/min) more negative than the established operating point.
“Return Disconnection” Warning Limit	Warning alarm occurs	Pressure in the return deaeration chamber is lower than +10 mmHg and the established operating point is higher than +10 mmHg.
Filter Pressure Sensor		
Operating Range Accuracy	-50 to +500 mmHg $\pm$10% of reading or $\pm$8 mmHg, whichever is greater	
“Set Disconnection” Warning Limit	Warning alarm occurs	Pressure in filter pod (immediately before the filter) is lower than +10 mmHg.
“Filter Extremely Positive” Warning Limit	Warning alarm occurs	Pressure in filter pod (immediately before the filter) is $\geq$450 mmHg.

Parameter	Performance	Conditions
Filter Pressure		
"Filter Is Clotting" Advisory Limits a) Filter pressure drop b)TMP increase	Advisory alarm occurs a) User settable; +10 to +100 mmHg greater than initial filter pressure drop Default: +100 mmHg Increment: 10 mmHg b) Service settable; +50 to +200 mmHg greater than initial TMP Default: +100 mmHg Increment: 5 mmHg	One or both limits are reached. CRRT therapy
"Filter Clotted" Warning Limit	Warning alarm occurs	Filter pressure minus return pressure is ≥200 mmHg **OR** both the "Filter is Clotting" Advisory Limit is reached *and* TMP is ≥450 mmHg.
"TMP Too High" Advisory Limit	Advisory alarm occurs User settable; +70 to +300 mmHg Default: +300 mmHg Increment: 10 mmHg	TMP equals user-set limit.
"TMP Excessive" Caution Limit	Caution alarm occurs	TMP ≥450 mmHg
Effluent Line Pressure Sensor		
Operating Range Accuracy	-350 to +50 mmHg ±10% of reading or ±8 mmHg, whichever is greater	

Parameter	Performance	Conditions
Air Bubble Detector		
Macro air/foam detection	Warning alarm occurs	One voltage decrease of nominal signal level is received from the transducer such that a single bubble/foam approximately 20 μl is detected. Foam sensitivity was tested using bovine blood. Air was injected into the pre-filter blood line at a rate of 1 ml/min creating foam in the post-filter blood circuit.
Blood Leak Detector		
Minimum blood leak detection	Warning alarm occurs within 7 seconds of detection.	Leak ≥0.35 ml/min at 0.25 Hct, at highest effluent flow rate.

a. 10-cc luer lock syringes of the following types are approved for use with the *Prismaflex* Control Unit: BD 10 PLASTIPAK, TERUMO 10. To attain the published delivery rate accuracy, the internal diameter of the syringe must be between 14.4 and 15.8 mm.

   20-cc luer lock syringes of the following types are approved for use with the *Prismaflex* Control Unit: PIC 20 LL, TERUMO 20, ICO STERIL, BD 20 PLASTIPAK, ICO GAMMA PLUS. To attain the published delivery rate accuracy, the internal diameter of the syringe must be between 19 and 20 mm.

   30-cc luer lock syringes of the following types are approved for use with the *Prismaflex* Control Unit: TERUMO, PIC 30 LL, ICO GAMMA PLUS, ICO STERIL. To attain the published delivery rate accuracy, the internal diameter of the syringe must be between 21.7 and 24.3 mm.

b. Flow rate range depends on the *Prismaflex* therapy/set combination selected by the operator.

c. Post-filter percentage of 8000 ml/hr is automatically assigned by software after operator selects desired Pre-filter percentage. The post-filter portion of replacement solution is pumped by the green scale from replacement bag 2.

d. Patient Fluid Removed is calculated via this formula:

   Change in effluent bag weight

   - Change in replacement bag weight (if applicable)
   - Change in dialysate bag weight (if applicable)
   - Change in PBP bag weight (if applicable)

   = Patient Fluid Removed

Appendix A: Guidelines and Manufacturer's Declaration - Electromagnetic Emissions and Immunity

Guidance and manufacturer's declaration - Electromagnetic Emissions		
The *Prismaflex* System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Prismaflex* System should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emission CISPR 11 / EN 55011	Group 1	The *Prismaflex* System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11 / EN 55011	Class B	The *Prismaflex* System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC / EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC / EN 61000-3-3	Complies	

Guidance and manufacturer's declaration - Electromagnetic Immunity			
The *Prismaflex* System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Prismaflex* System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 KV contact ±8 KV air	±6 KV contact ±8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC/EN 61000-4-4	±2 KV for power supply lines ±1 KV for input/output lines	±2 KV for power supply lines ±1 KV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 KV differential mode ±2 KV common mode	±1 KV differential mode ±2 KV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input linesIEC / EN 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec.	<5 % U_T (>95 % dip in U_T) for 0.5 cycles 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *Prismaflex* System requires continued operation during power mains interruptions, it is recommended that the *Prismaflex* System be powered from an uninterruptible power supply or a battery.

Guidance and manufacturer's declaration - Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Power frequency (50/60 Hz) magnetic field IEC / EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - Electromagnetic Immunity			
The *Prismaflex* System is intended for use in the electromagnetic environment specified below. The customer or the user of the *Prismaflex* System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the *Prismaflex* System including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms	d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz d = 1.2 $\sqrt{P}$ 800 MHz to 2.5 GHz where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and manufacturer's declaration - Electromagnetic Immunity
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Prismaflex* System is used exceeds the applicable RF compliance level above, the *Prismaflex* System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Prismaflex* System. [b] Over the frequency range 150 KHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the *Prismaflex* System

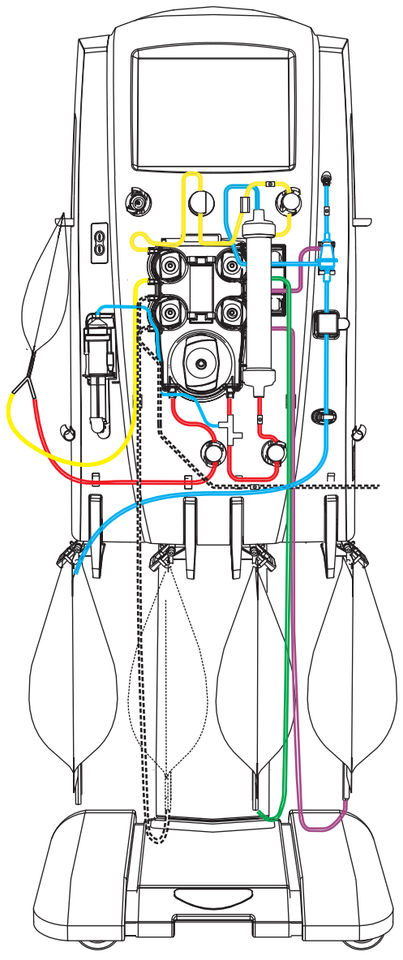
The *Prismaflex* System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Prismaflex* System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications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

Rated maximum output power of transmitter (W)	**Separation distances according to frequency of transmitter** (m)		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 KHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 KHz to 2.5 GHz** $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

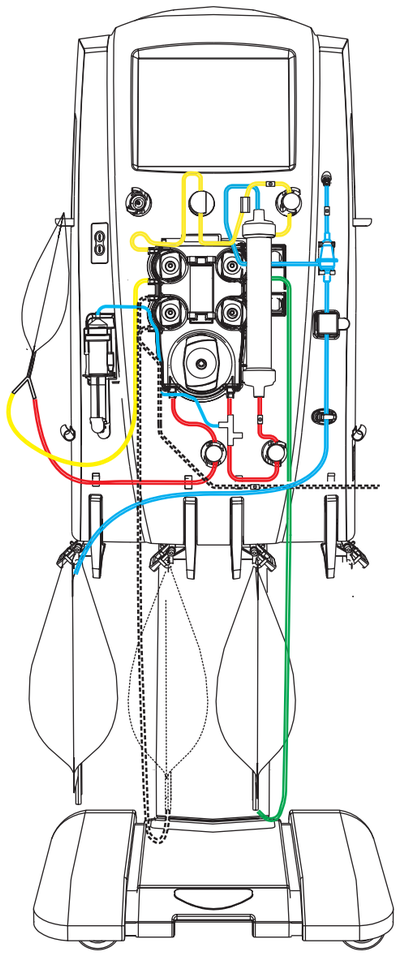
For transmitters rated at maximum output power not listed above, the recommended separation distance d in meter (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, object and people.

Prismaflex System During Priming (Setup mode)



CVVHDF



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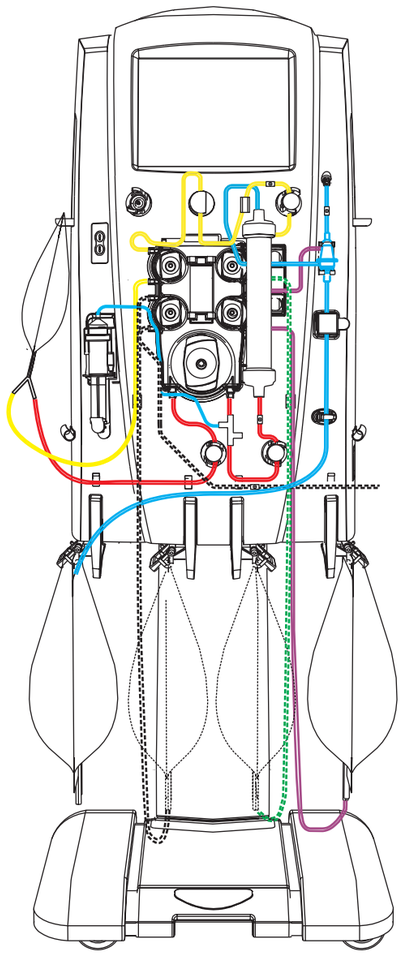
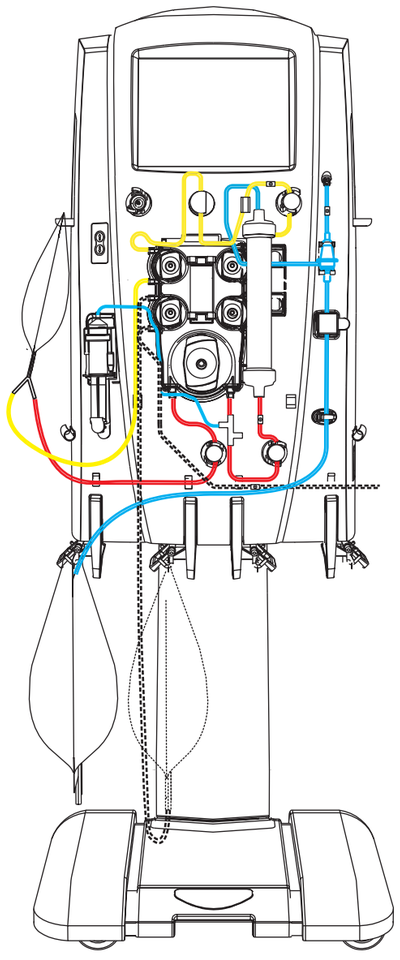
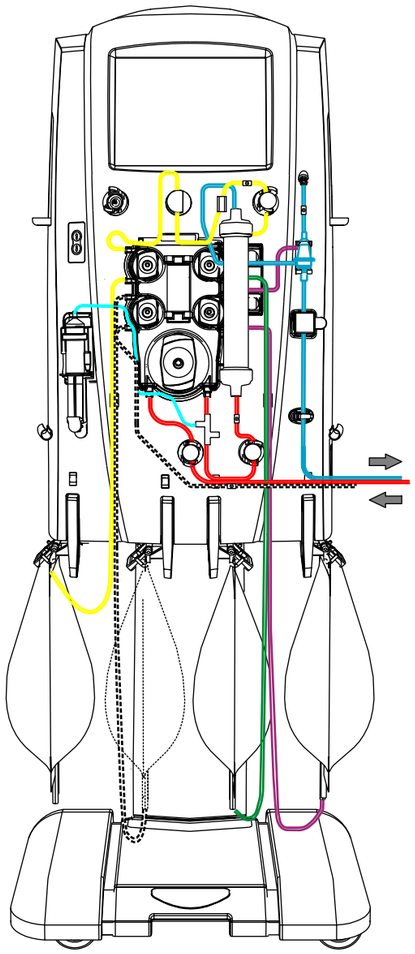


CVVH



SCUF

Prismaflex System During Patient Treatment (Run mode)



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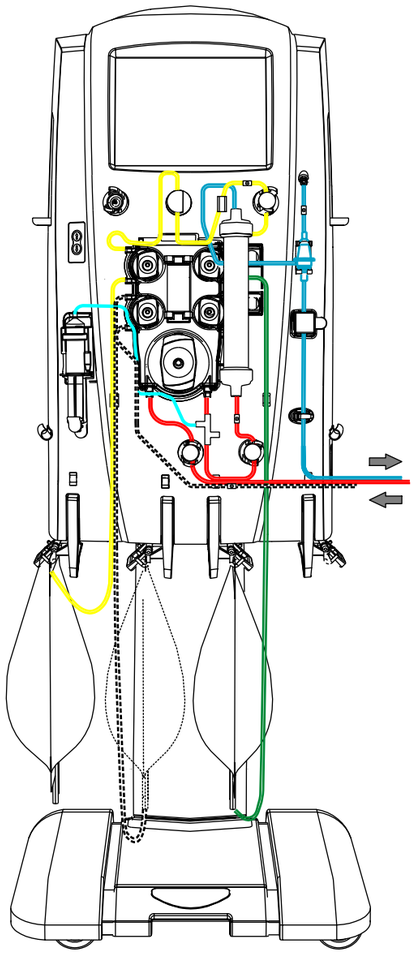

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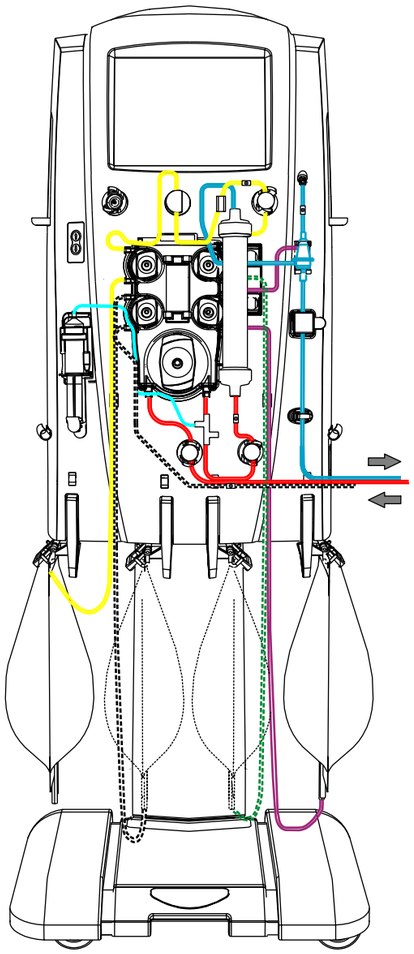
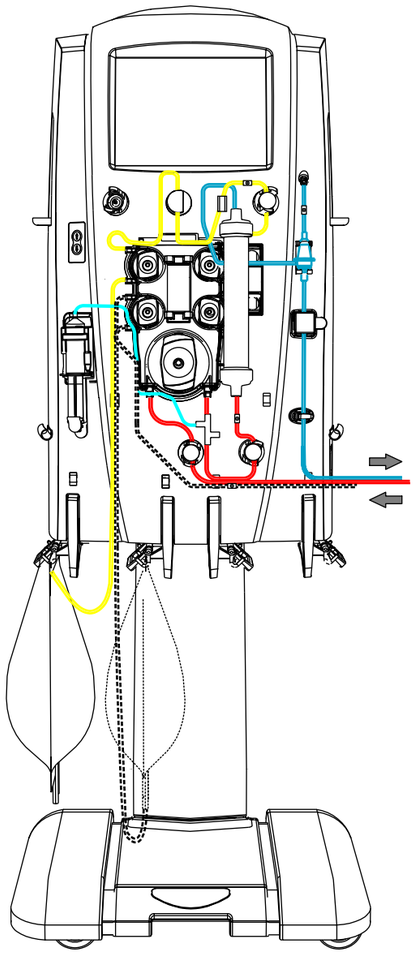


CVVH



SCUF