

Prismaflex[®]

An integrated system for:

- CRRT (Continuous Renal Replacement Therapies)
- TPE (Therapeutic Plasma Exchange)
- HP (Hemoperfusion)

Service Manual

For use with software versions 4.XX

Service Code G5005204

Manufacturer

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- EP: 0532432, 0678301, 0611228, 0829265, 0925826, 1320394, 0643301, 0305787, 0441721, 0701830, 0706044
- EU (design): 15870
- CA: 2077848, 2303714, 2115414, 2444794, 2158245
- FR: 9111351, 9716732, 9411216, 9412252
- IT: 01320264
- JP: 3369223, 3413412, 3591864, 2823513, 3047403, 3254222, 3690846

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Chapter 1: Before You Get Started

1.1 Intended Use

Refer to Prismaflex Operator's Manual.

1.2 Contraindications

Refer to Prismaflex Operator's Manual.

1.3 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 removal and/or solute clearance.

1.3.1 Prismaflex Therapy Options

The Prismaflex system provides:

- CRRT (Continuous Renal Replacement Therapies)
 - SCUF (Slow Continuous Ultrafiltration)
 - CVVH (Continuous Veno-venous Hemofiltration)
 - CVVHD (Continuous Veno-venous Hemodialysis)
 - CVVHDF (Continuous Veno-venous Hemodiafiltration)
- CRRT Septex: (Continuous Renal Replacement Therapies with High Cut-Off membrane) - requires additional service configuration.
 - CVVHD (Continuous Veno-venous Hemodialysis)
 - CVVHD+post (Continuous Veno-venous Hemodialysis + post infusion)
- TPE (Therapeutic Plasma Exchange) - requires additional service configuration
- HP (Hemoperfusion) - requires additional service configuration

During the setup procedure the operator selects the therapy desired.

Contact your local representative for information about the additional service configuration of therapies.

1.3.2 Therapies Mechanisms

Mechanism of CRRT



WARNING

Use only prescribed dialysate solution and replacement solution/fluid with the Prismaflex system. The solution must have a density similar to that of saline solutions (close to 1) in order to avoid errors in the volumes used for fluid exchange. Use only dialysate solution and replacement solution/fluid that conform to applicable national registration, standards, or laws. If a commercially available replacement solution is used, it must be labeled as intended for Hemofiltration and Hemodialysis. For CVVH and CVVHDF it should also be labeled as intended for intravenous injection.
CVVH and CVVHDF: The solution should be labeled as intended for intravenous injection. The use of non sterile dialysate could induce risks of bacterial and pyrogenic contamination for the patient.

The mechanisms of ultrafiltration, hemofiltration and hemodialysis are used in providing the Prismaflex CRRT 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, either pre and/or post-filter.

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).

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.

Mechanism of CRRT Septex

CRRT Septex identifies CRRT therapies performed with High cut-off membranes. These membranes allow transfer of high molecular weight solutes across the membrane. Hemodialysis is the only allowed mode as to prevent excessive protein losses in effluent.

Mechanism of TPE

In therapeutic plasma exchange, plasma containing disease mediators is

pulled from the patient's blood across the filter membrane. Separation of plasma from blood is achieved by filtration: this is the plasmafiltration process. A replacement fluid is used to replace the amount of plasma removed.

Mechanism of HP

In HP, toxic substances and/or drugs are adsorbed from the plasma as the patient's blood is perfused through a charcoal cartridge. No fluid removal occurs.

1.3.3 Prismaflex Therapy Descriptions

This section describes the way the various available therapies are implemented in the Prismaflex system. Operating flow ranges for blood flow and the various solutions flows are dependent on the selected therapy and disposable set (see [Table 8.1 on page 237](#)).

CRRT (Continuous Renal Replacement Therapies)**SCUF (Slow Continuous Ultrafiltration)**

Prismaflex SCUF provides patient fluid removal and allows for PBP infusion.

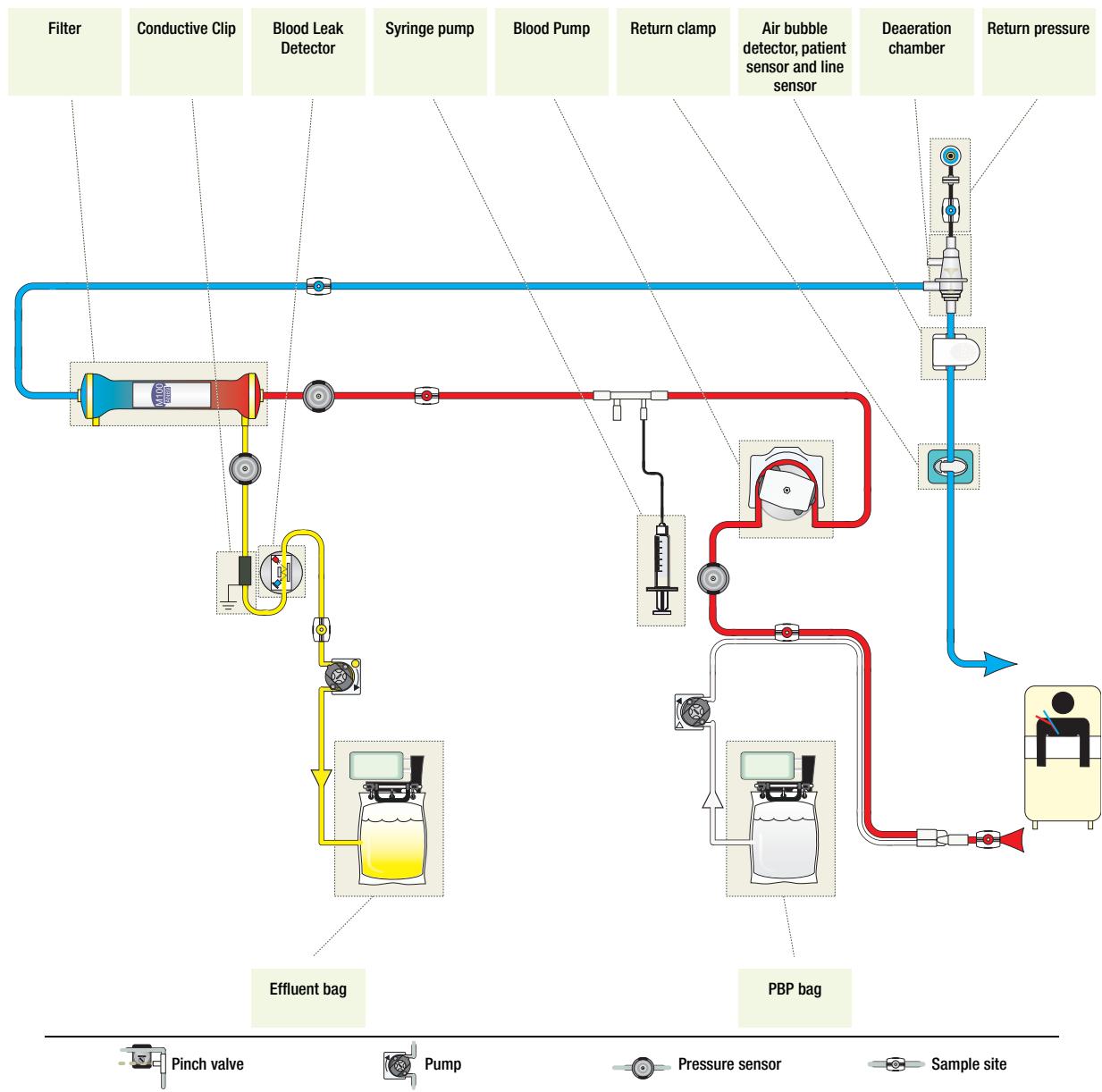


Figure 1.1 SCUF flow

CVWH pre+post filter (Continuous Veno-venous Hemofiltration)

Prismaflex CVVH provides hemofiltration with both pre and post-filter replacement infusion and allows for PBP infusion.

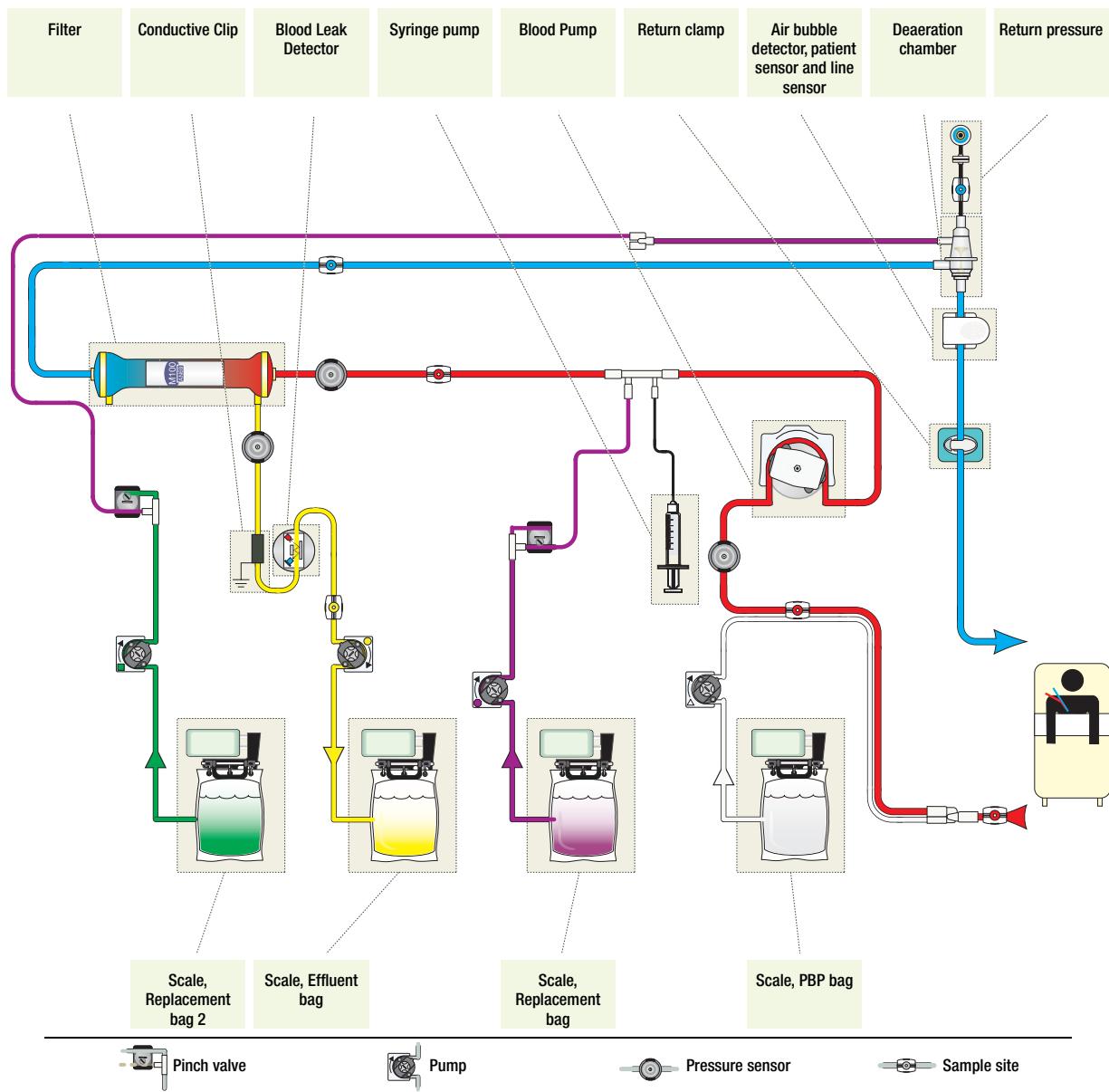


Figure 1.2 CVVH pre+post filter flow

CVVHD (Continuous Veno-venous Hemodialysis)

Prismaflex CVVHD provides hemodialysis and allows for PBP infusion.

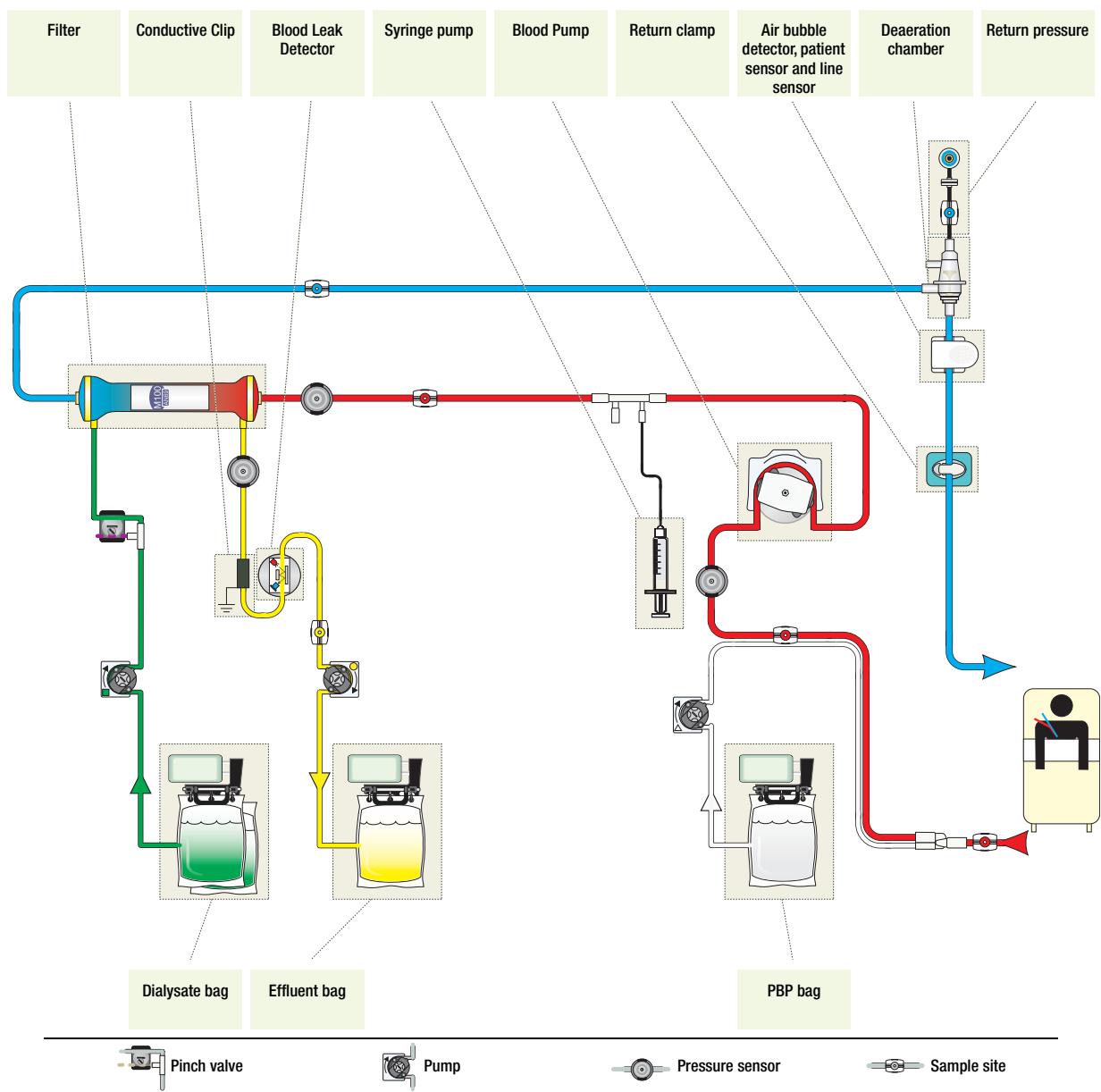


Figure 1.3 CVVHD flow

CVVHDF (Continuous Veno-venous Hemodiafiltration)

Prismaflex CVVHDF provides hemodiafiltration with either pre or post-filter replacement infusion and allows for PBP infusion.

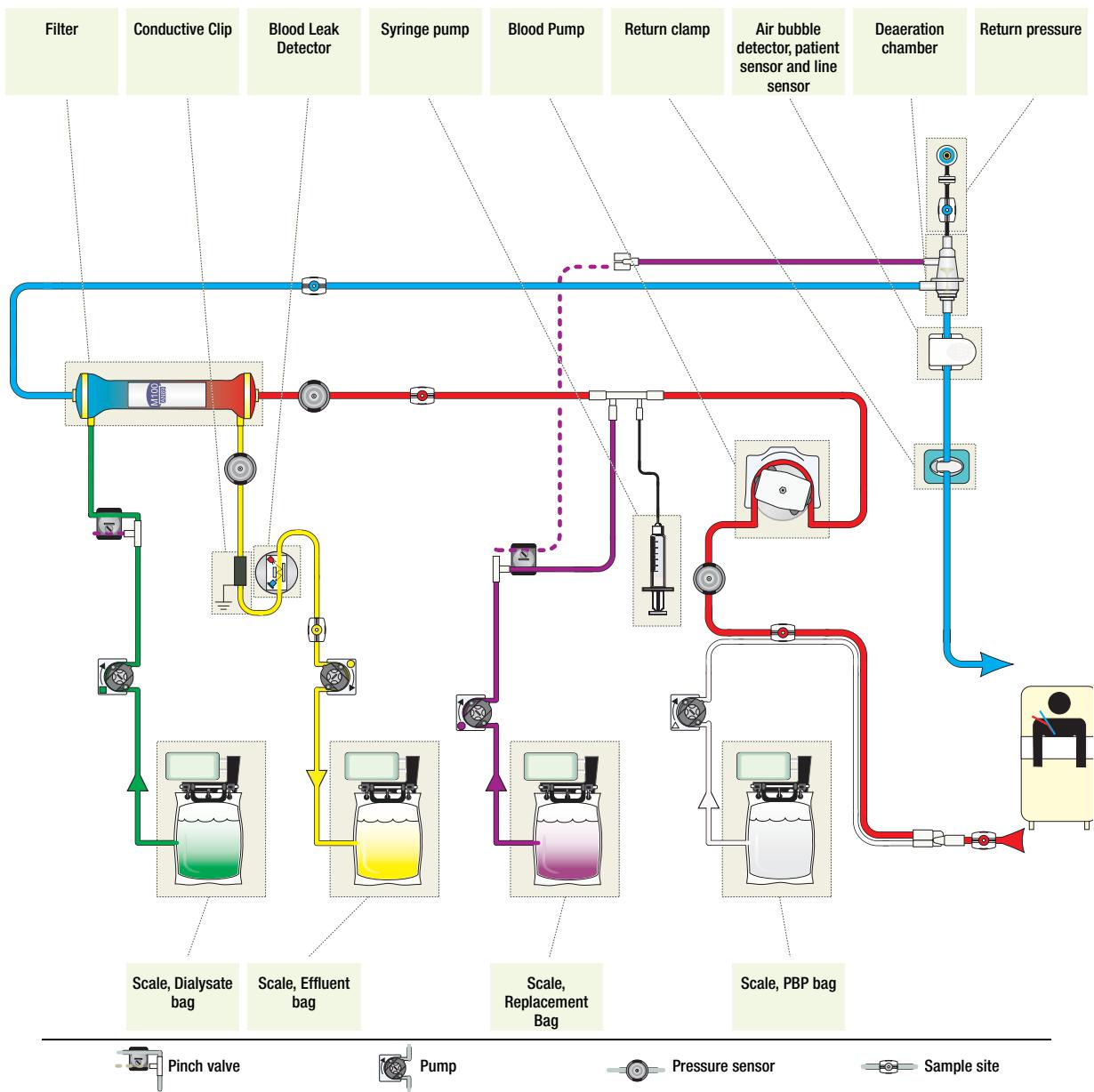


Figure 1.4 CVVHDF flow

CRRT Septex

Prismaflex CRRT Septex provides for two operating modes:

- CVVHD (Continuous Veno-venous Hemodialysis) having the same implementation as CVVHD in CRRT (see [Figure 1.3 on page 18](#))
- CVVHD+ post: having an implementation similar to CVVHDF in CRRT with post-filter replacement infusion only (see [Figure 1.4 on page 19](#))

CVVHD+post provides post-replacement infusion into the deaeration chamber; this infusion is intended to reduce the risk of clotting in the chamber that may occur in CVVHD.

Excessive protein losses during Prismaflex CRRT Septex therapies are prevented through the restrictions that apply to the convective flow rates (PBP, replacement and Patient Fluid Removal).

TPE (Therapeutic Plasma Exchange)

Prismaflex TPE provides plasmafiltration with post-filter replacement and allows for PBP infusion.

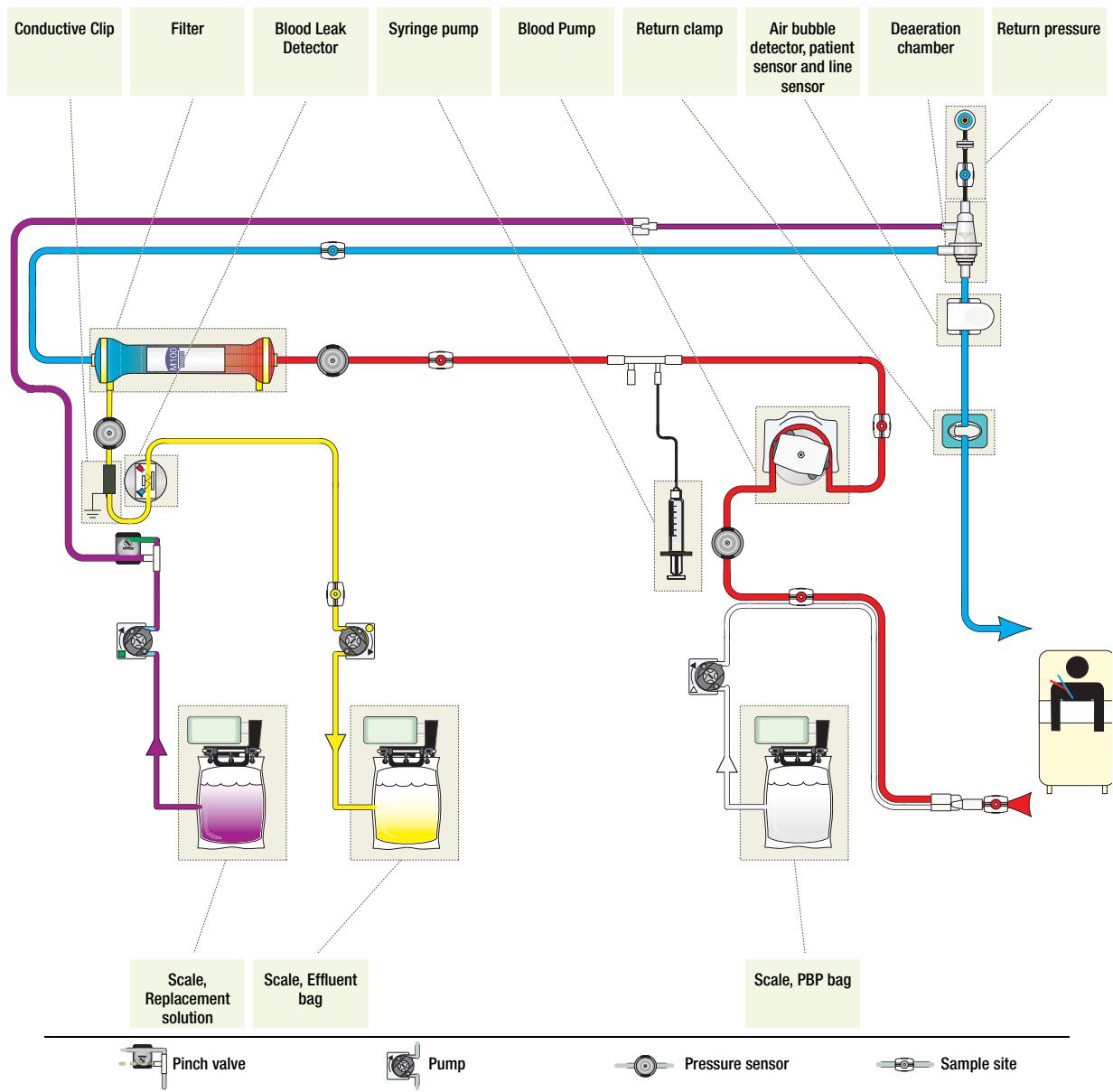


Figure 1.5 TPE flow

HP (Hemoperfusion)

Prismaflex HP provides hemoperfusion and allows for PBP infusion.

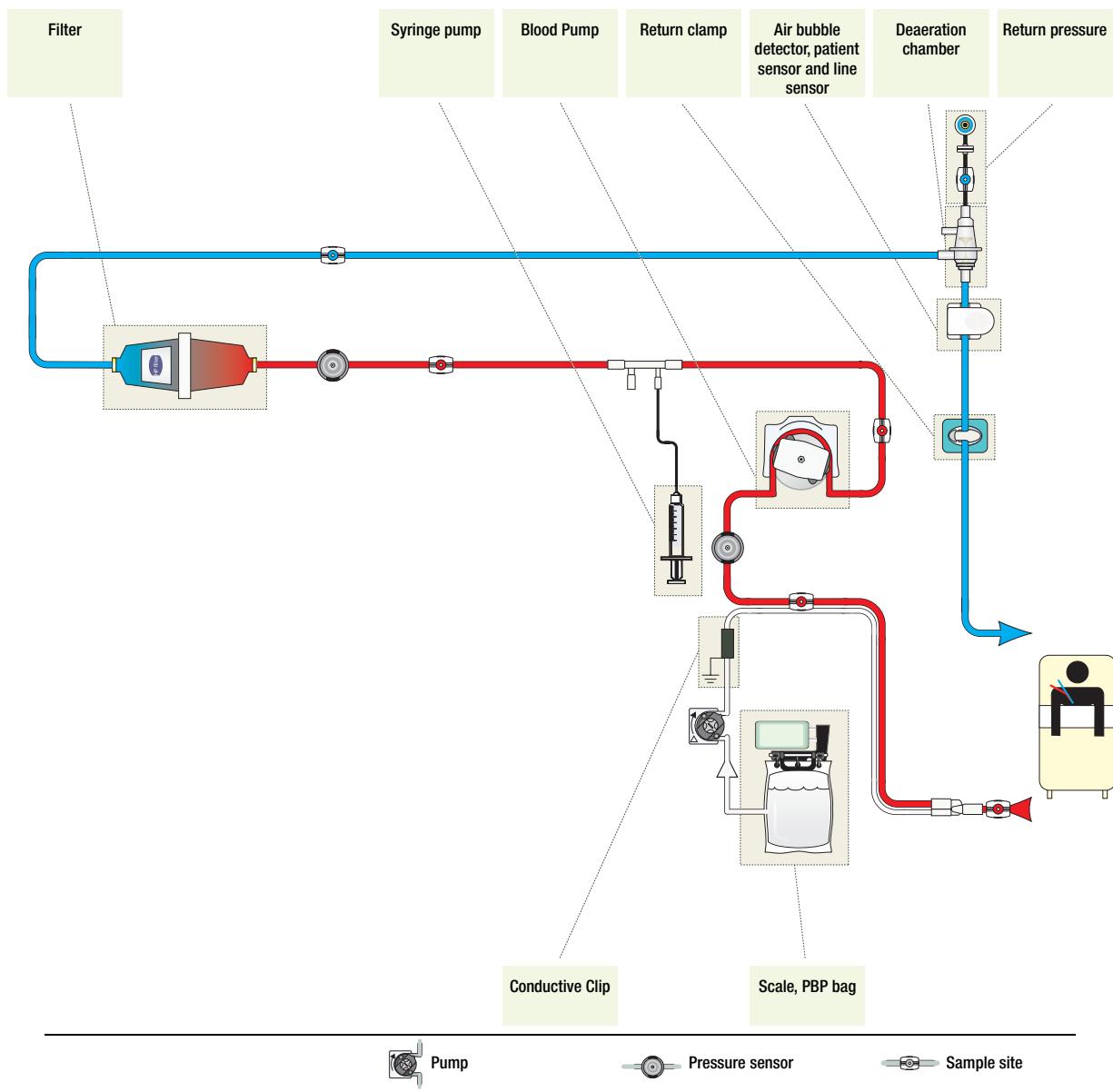


Figure 1.6 HP flow

1.3.4 Prismaflex Anticoagulation Options

The Prismaflex system provides:

- Standard Anticoagulation for treatments with anticoagulation regimen, using the Prismaflex syringe pump
- Standard No Syringe for treatments performed without anticoagulation regimen Prismaflex. Syringe pump is disabled during the entire treatment.
- Citrate Anticoagulation for treatments using Citrate anticoagulation. Requires Citrate solution on the PBP scale.

Standard No Syringe and Standard Anticoagulation methods

If no anticoagulation is required at start of the treatment, it is recommended to choose Standard anticoagulation method and to connect a syringe filled with priming solution. This ensures that the syringe line will be primed during the automatic priming cycle and be ready for anticoagulation any time during treatment through Change Syringe.

Citrate Anticoagulation method

For this anticoagulation method, a service configuration is required.

The service mode allows your facility to configure the citrate anticoagulation solution parameters to be used during treatment: identification, composition and selection of the citrate solution. Contact your local representative for additional information.



WARNING

This Anticoagulation method disables the Prismaflex syringe pump for the entire treatment. An external syringe / infusion pump must be used to ensure the Calcium supplementation to the patient.

Anticoagulation Methods and Therapies

CRRT

- Standard Anticoagulation
- Standard No Syringe
- Citrate Anticoagulation

CRRT Septex

- Standard Anticoagulation
- Standard No Syringe

TPE

- Standard Anticoagulation
- Standard No Syringe

HP

- Standard Anticoagulation
- Standard No Syringe

1.4 Where to Find Information about the Prismaflex System

1.4.1 Operator's Manual

The Operator's Manual provides installation, operating, maintenance, and troubleshooting instructions, as well as general information. Generic information about therapies is provided in "Chapter 3: General Therapy Information". This therapy-related chapter provides an overview of the system and information about operation and pressure monitoring. Specific information about TPE is provided in "Chapter 4: Therapeutic Plasma Exchange (TPE)". Specific information about HP is provided in "Chapter 5: Hemoperfusion (HP)".

1.4.2 Communication Programmer's Guide

The Programmer's Guide provides the information needed when writing a customized software program which will collect synchronous data from the Prismaflex, and store it in a personal computer (PC).

The Guide is intended for use only by trained and experienced software programmers.

1.4.3 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 that 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).

1.4.4 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.

**WARNING**

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.

1.5 Responsibility and Disclaimer

Gambro accepts responsibility for the safety, reliability, and performance of this equipment only:

- When all equipment modifications are authorized in writing by Gambro and carried out by appropriately trained and qualified people.
- When the electrical installation of the relevant room complies with all applicable local electrical codes and, if applicable, IEC requirements.
- When the equipment is used in accordance with this manual.

The service manual 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 Gambro considers to be repairable.

The service manual contains references to accessories and disposables for use with the Prismaflex system, see “[Chapter 2: Description of the Machine and its Components](#)” on page 29. The Prismaflex system has been tested and validated for use with these accessories and disposables. Gambro does not accept any responsibility or liability for use of accessories or disposables other than those specified in this manual and for use/mounting of those components not in accordance with this manual, on-line instructions and the *Instructions for Use* accompanying those components.

Since Gambro has no knowledge or control of how non Gambro service work is conducted or what effect such work will have on a machine’s operation and performance, Gambro 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.

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

Note: Check your local regulations for any restrictions on therapies, disposables etc.

1.6 General Warnings and Precautions before Use

Refer to Prismaflex Operator’s Manual.

1.7 Safety Definitions

This manual uses the following safety definitions:



WARNING

A warning means that injury or death is possible if the instructions are not obeyed.



CAUTION

A caution means that minor injury or damage to equipment is possible.

Note: Notes are added to give more information.

1.8 Symbols

Refer to Prismaflex Operator's Manual.

1.9 Certification Marks

Refer to Prismaflex Operator's Manual.

Information related to the Chinese market

Product standard: YZB/SWE 2692-2005

Registration number: SFDA(I) 20063450108

1.10 Service Information

For technical assistance, contact your local representative.

1.11 Transport



CAUTION

Be careful when you move the Prismaflex control unit, so that you don't make it overturn.

1.12 Disposal

1.12.1 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.

1.12.2 Disposal of Packaging Material

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

1.12.3 Disposal of Discarded Equipment

Discarded electromedical equipment may not be disposed of together with municipal waste but must be collected separately in order to guarantee ecologically correct disposal to prevent dispersion of potential pollutants into the environment.

Pay attention to the fact that some components of the machine (display, batteries, circuit boards, etc.) may contain toxic substances which, if released into the environment, pose a risk to the health of living organisms and the environment itself.

1.12.4 Hazardous Substances

Table 1.1 Hazardous Substances

Part	Hazardous substances					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr^{6+})	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Printed circuit board assemblies	X	0	0	0	0	0
Electromechanical components including wiring	X	0	0	0	0	0
Power supply	X	0	0	0	0	0
Batteries	X	0	0	0	0	0
Metals	0	0	0	0	0	0
Plastics	0	0	0	0	0	0
Enclosures	0	0	0	0	0	0

O: Indicates that the concentration of the hazardous substance in all homogeneous materials of the part is below the SJ/T 11363-2006 limit (Chinese regulation).

X: Indicates that the concentration of the hazardous substance in at least one homogeneous material of the part is above the SJ/T 11363-2006 limit (Chinese regulation).

Chapter 2: Description of the Machine and its Components

2.1 Introduction

2.1.1 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, 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 some situations blood return is via a single lumen venous catheter or a large peripheral vein.



WARNING

Connect the Prismaflex set to a patient via one of the following methods:

- 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);
- Arterio-venous (A-V) fistula;
- External blood access device, and single-lumen venous catheter for patient blood return.

2.1.2 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/plasma loss from the patient.
- Pumps sterile infusion solution into the blood access line for hemodilution with the pre-blood pump (PBP).
- Pumps sterile replacement solution/fluid and/or sterile dialysate. Pumps effluent.
- Monitors the system and alerts the operator to abnormal situations through alarms.

2.2 System Components

The Prismaflex system consists of the Prismaflex control unit, bags and a disposable Prismaflex set.

2.2.1 Control Unit

Each Prismaflex control unit is pre-attached to a column and a base with casters. The Prismaflex control unit comes packaged with the following items:

- Installation kit:
 - United States-style power cord, with retaining bracket (not China)
 - Continental European-style power cord, with retaining bracket (not US and China)
 - Chinese power cord, with retaining bracket (China only)
 - 4 Screws
 - 4 Scale carrying bars
- 20ml Syringe Clip
- Pump crank
- Caution Stickers
- Potential Equalization Connector
- Prismaflex Operator's Manual on CD
- Software CD
- Accompanying documents

2.3 Prismaflex Sets

Use only Prismaflex sets (manufactured by Gambro) with the Prismaflex control unit. Check with your sales representative for availability.



WARNING

- 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.
- 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.

Some sets are not available in some countries due to local regulations.

Two families of disposable sets are defined according to the size of blood pump and blood transport tubes:

- Low Flow sets (LF sets) offer the benefits of low extra corporeal blood volume; blood flow ranges and ultrafiltration capacities are limited.

- High Flow sets (HF sets) provide wide capabilities for blood flow and ultrafiltration rates.

The following Prismaflex sets are available for use with the Prismaflex control unit. CRRT sets come with an effluent bag. Additional 5000ml and 9000ml effluent bags can be purchased separately.

Table 2.1 Sets and patient weight limits

System limitations		Disposable limitation		Applicable minimum patient weight
Low Flow set	8kg	HF20 M60 ST60 TPE1000	8 kg 11 kg 11 kg 9 kg	8 kg 11 kg 11 kg 9 kg
High Flow sets	20kg	HF1000 HF14000 M100 M150 ST100 ST150 TPE2000 Septex Oxiris	30 kg 30 kg 30 kg 30 kg 30 kg 30 kg Adults 30 kg 30 kg	30 kg 30 kg 30 kg 30 kg 30 kg 30 kg Adults 30 kg 30 kg

2.3.1 Minimum Patient Weight

The minimum patient body weight allowed for a safe treatment with respect to fluid imbalance issues are defined below:

- 8 kg for Low Flow sets,
- 20 kg for High Flow sets.

These restrictions should be combined with the weight limitations of disposable sets in relation to extracorporeal blood volume. Combination of these independent limitations result in the minimum patient weight specifications described in [Table 2.1 on page 31](#).

2.3.2 CRRT Set components

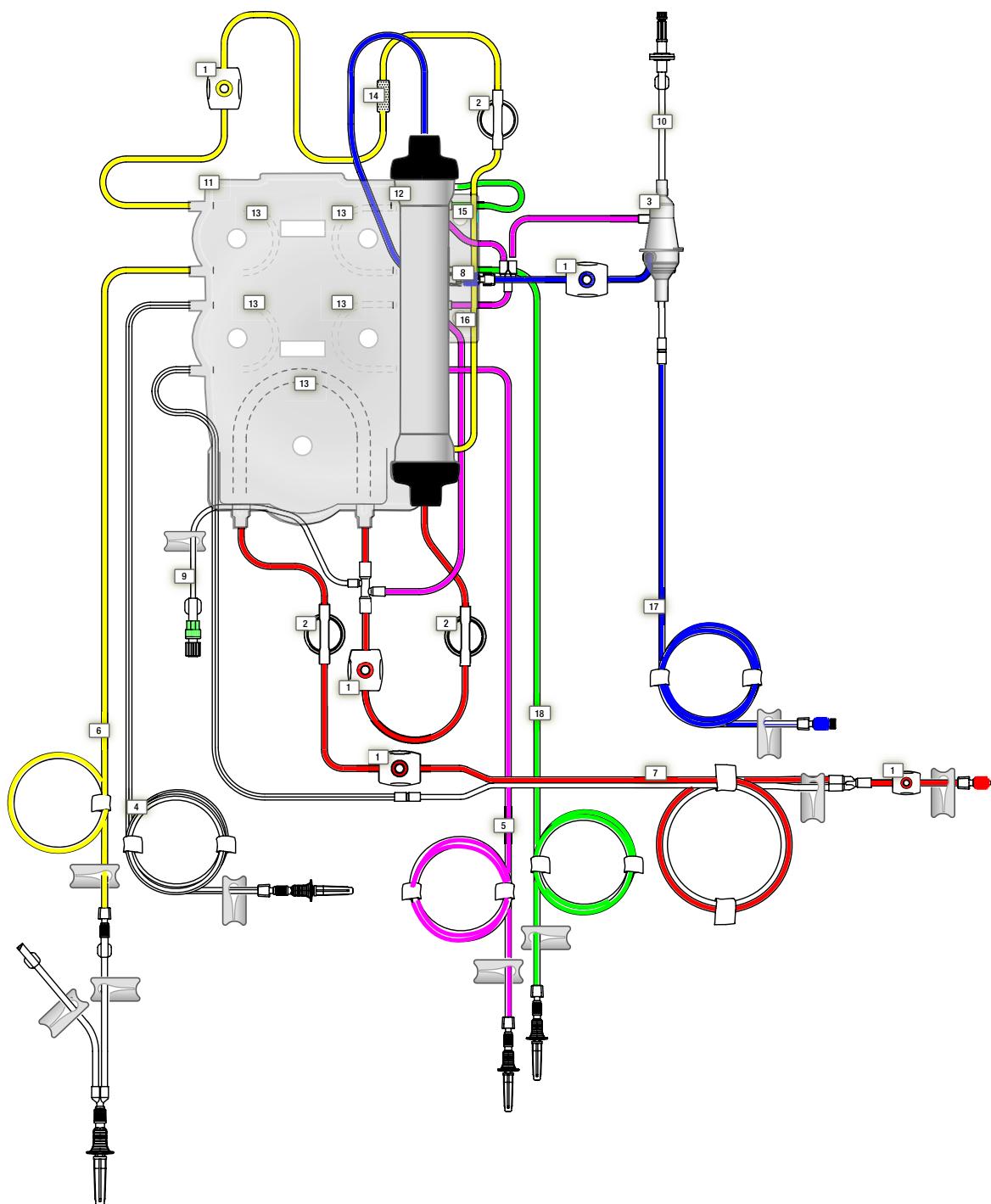


Table 2.2 CRRT Set components**1) Sample sites**

Color-coded ports with a plug that allow needle entry to the set. Used to obtain fluid or blood samples. 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), return line between filter outlet and deaeration chamber (blue), effluent line (yellow).

2) 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 before blood pump (access pod), access line after the blood pump (filter pod) and effluent line before effluent pump (effluent pod).

3) Degaeration chamber

A component on the return line that allows the Prismaflex control unit to manage air, monitor return line pressure, and add post-filter replacement solution to the return line. The blood might not appear to mix with any replacement solution the majority of the time. This is a normal operation of the device.

4) PBP (Pre-blood pump) line (white-striped)

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.

5) Replacement line (purple-striped)

Conveys replacement solution from the bag on the replacement scale (purple) to the blood flowpath.

6) Effluent line (yellow-striped)

Conveys ultrafiltrate and/or spent dialysate from the fluid compartment of the filter to the effluent bag.

7) Access line (red-striped)

Conveys blood from the patient's blood access site to the filter.

8) Warmer connection

Male-female Luer connectors allows connection of the extension line of Prismatherm II Blood Warmer. (Not available on HF 20 set)

9) Syringe line

Conveys anticoagulant from the syringe to the blood flowpath. A non-return valve is present on the syringe line.

10) Return pressure line

Connects the degeneration chamber with the return pressure port, enabling pressure monitoring and removal of air, if needed. The Prismaflex system can remove air semi-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 “[5.13 Air Removal Procedures](#)” on page 162.)

11) Cartridge

Plastic component in the center of the set that holds the filter, pump segments, and pinch valve segments. Has slots for the loader on the control unit. Allows automatic loading/unloading of the set.

12) Filter

Filter containing hollow fibers made of a semipermeable membrane. Blood flows through the hollow fibers; filtrate and/or dialysate flow counter currently in the fluid compartment.

13) Pump segments

Tubing that threads into the raceway of each peristaltic pump. Loaded automatically when the loader pulls the Prismaflex set flush with the control unit.

14) Electrostatic discharger ring

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.

15) Upper pinch valve segment (green-striped)

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.

CVHD, CVHDF: Allows dialysate hanging on the dialysate (green) scale to be conveyed to the fluid side of the filter.

CVVH: Allows solution from a second bag of replacement solution (replacement 2 hanging on the green scale) to be delivered post-filter to the degeneration chamber on the return line.

16) Lower pinch valve segment (purple-striped)

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.

CVVH, CVVHDF: 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 degeneration chamber on the return line).

17) Return line (blue-striped)

Conveys blood from the filter to the patient's blood return site.

18) Dialysate/replacement 2 line (green-striped)

Holds prescribed dialysate/replacement solution.

2.3.3 TPE Set components

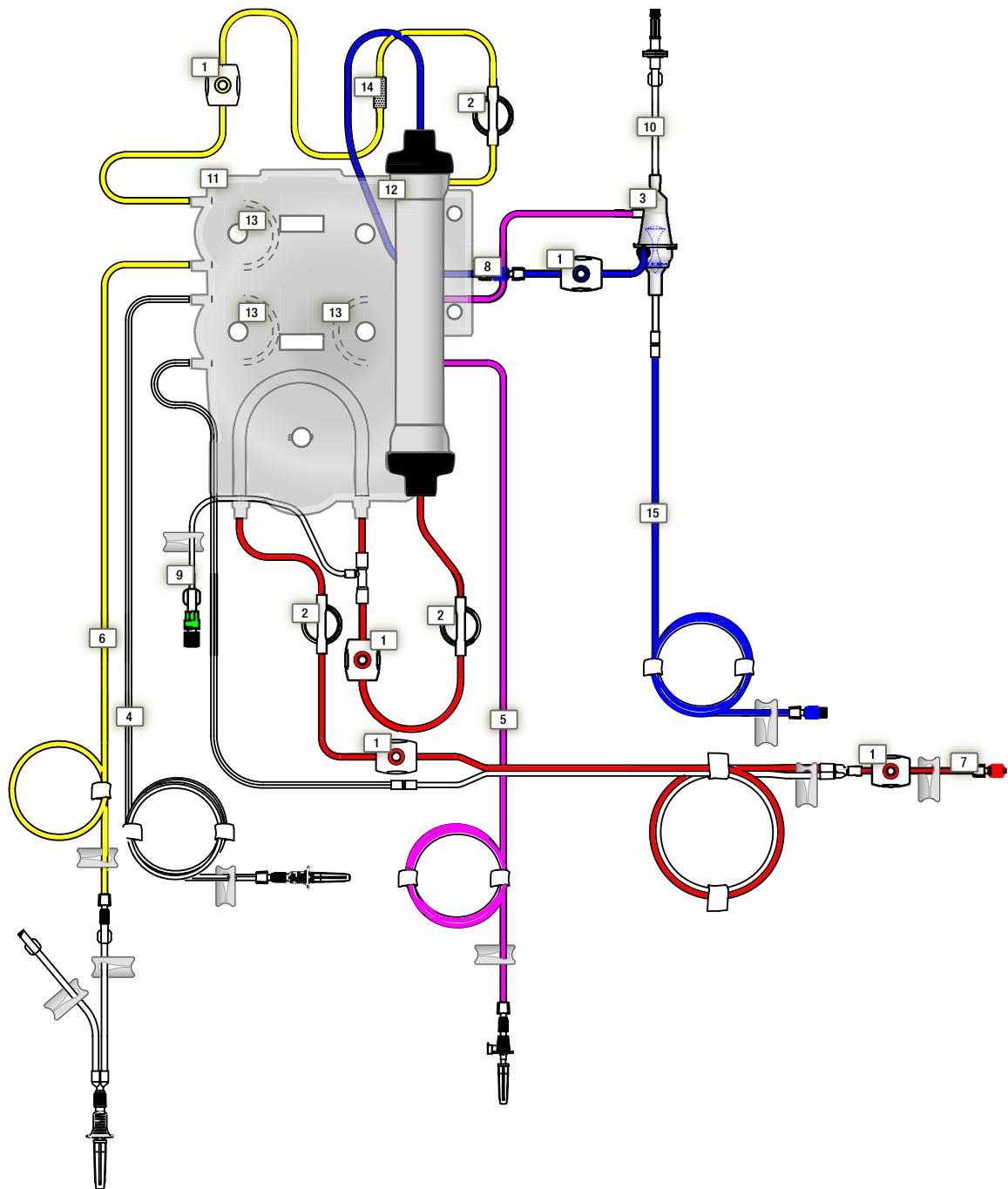


Table 2.3 TPE Set components**1) Sample sites**

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. There are three sample sites, located as follows: access line before the filter (red), return line, between filter outlet and deaeration chamber (blue); effluent line (yellow).

2) 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) enable noninvasive pressure monitoring of the access line before blood pump (access pod), access line after the blood pump (filter pod) and effluent line before effluent pump (effluent pod).

3) Deraeration chamber

A component on the return line that allows the Prismaflex control unit to manage air, monitor return line pressure, and add replacement fluid to the return line. The blood might not appear to mix with any replacement solution the majority of the time. This is a normal operation of the device.

4) PBP (Pre-blood pump) line (white-striped)

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.

5) Replacement line (purple-striped)

Conveys replacement fluid from the bag/container on the replacement scale (purple) to the blood flowpath in the return line. The fluid is delivered post-dilution (to the deaeration chamber, just beyond the filter blood outlet.)

6) Effluent line (yellow-striped)

Conveys removed plasma from the plasma/fluid compartment of the filter to the effluent bag.

7) Access line (red-striped)

Conveys blood from the patient's blood access site to the filter.

8) Warmer connection

Male-female Luer connectors allows connection of the extension line of Prismatherm II Blood Warmer.

9) Syringe line

Conveys anticoagulant from the syringe to the blood flowpath.

10) Return pressure 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 “[5.13 Air Removal Procedures](#)” on page 162.)

11) Cartridge

Plastic component in the center of the set that holds the filter and pump segments. Has slots for the loader on the control unit. Allows automatic loading of the set.

12) Filter

Filter containing hollow fibers made of a specialized membrane. Blood flows through the hollow fibers and plasma is pulled into the plasma/fluid compartment of the filter.

13) Pump segments

Tubing that threads into the raceway of each peristaltic pump. Loaded automatically when the loader pulls the Prismaflex set flush with the control unit.

14) Electrostatic discharger ring

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.

15) Return line (blue-striped)

Conveys blood from the filter to the patient's blood return site.

2.3.4 HP Kit components

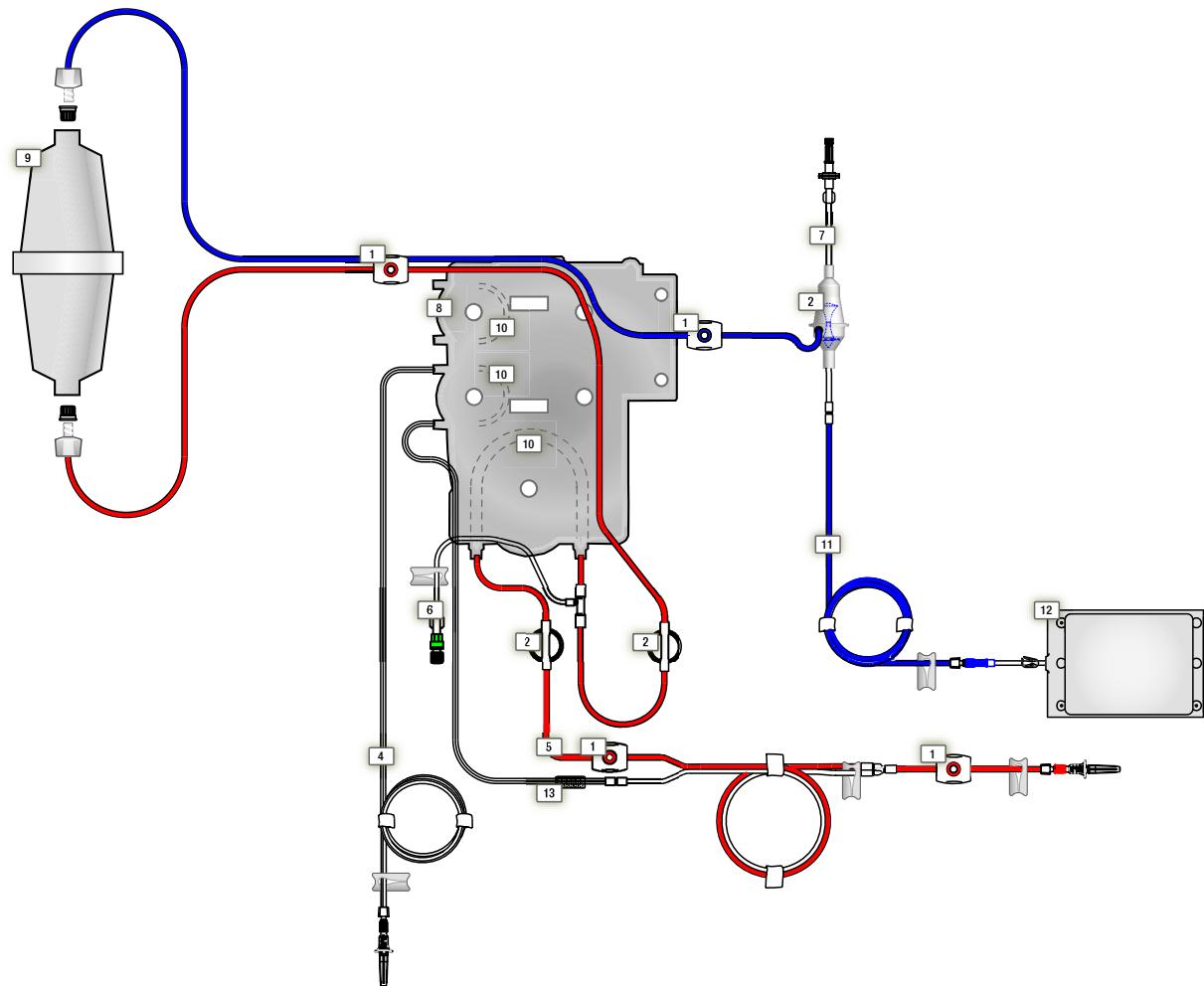


Table 2.4 HP Kit components**1) Sample sites**

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. There are three sample sites, located as follows: access line close to patient access site (red); access line before hemoperfusion cartridge (red); return line (blue).

2) Pressure pods

There are two circular “pods” in the set. Each contains a diaphragm and fits into a pressure sensor housing on the control unit. The pods and pressure sensors (inside) enable noninvasive pressure monitoring of the access line and the hemoperfusion cartridge.

3) Degaeration chamber

A compartment on the return line that allows the Prismaflex control unit to manage air and monitor return line pressure.

4) PBP (Pre-blood pump) line (white-striped)

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.

5) Access line (red-striped)

Conveys blood from the patient's blood access site to the hemoperfusion cartridge.

6) Syringe line

Conveys anticoagulant solution from the syringe to the blood flowpath.

7) Return pressure line

Connects the degeneration 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 [“5.13 Air Removal Procedures” on page 162](#).)

8) Cartridge

Plastic component in the center of the set that holds the access line, PBP line, and pump segments. Has slots for the loader on the control unit. Allows automatic loading of the set.

9) HP Cartridge

Cartridge containing activated charcoal granules that are encapsulated with a biocompatible cellulose membrane. As the patient's blood perfuses through the cartridge, toxic substances in the blood are adsorbed by the charcoal. Note: Refer to the Instructions for Use packaged with the HP kit for the specifications, physical characteristics, materials, performances, and limits of use of the hemoperfusion cartridge.

10) Pump segments

Tubing that threads into the raceway of the PBP pump and the blood pump. Loaded automatically when the loader pulls the Prismaflex set flush with the control unit.

11) Return line (blue-striped)

Conveys blood from the hemoperfusion cartridge to the patient's blood return site.

12) Priming solution collection bag

Collects the priming solution during the priming of the kit.

13) Electrostatic discharger ring

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.

2.3.5 Bags

Standard dialysate, PBP and replacement bags are 5000 ml. Standard effluent bags are 5000 ml or 9000 ml.

In the Operator's Manual, see "3.2.5 Custom Mode", "3.2.6 User-controllable Settings" and "3.2.8 Change Bags Function" for other bags.

2.4 Prismaflex Accessories

For information about accessories and spare parts, see the *Prismaflex Spare Part Catalogue* on Customer Support's Internet site.

2.4.1 Blood Warmers

In the Operator's Manual, see "Appendix E: Blood Warmers".

2.4.2 HP Cartridge Holder

See the *Prismaflex Spare Part Catalogue*.

2.4.3 UPS Requirements for Installation with Prismaflex

A UPS (uninterruptible power supply) can be used together with Prismaflex. A Spare part instruction with installation details and requirements for the UPS is available from technical support.

2.5 Prismaflex Control Unit

Note: The description below is valid for the latest version of the Prismaflex Control Unit. Older versions of the Prismaflex Control Unit might differ from these descriptions.

2.5.1 Front Panel

Following is a description of the components on the front panel of the Prismaflex control unit.

[Figure 2.1 on page 39](#) shows the pumps.

[Figure 2.2 on page 40](#) shows the pressure components.

[Figure 2.3 on page 41](#) shows sensors and clamps.

[Figure 2.4 on page 42](#) shows the scale components.

[Figure 2.5 on page 43](#) shows miscellaneous components.

Effluent pump

CRRT: Pumps ultrafiltrate/dialysate; automatically controls the ultrafiltration rate, based on the operator-set patient fluid removal rate, PBP solution rate, dialysate and replacement solution rate (if applicable).

TPE: Pumps removed plasma; automatically controls the plasmafiltration rate based only on the operator-set patient plasma loss and replacement fluid rates. PBP rate is not considered in the effluent pump rate.

The syringe pump is not included in the calculation of the effluent rate.

Syringe pump assembly

Delivers anticoagulant 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.

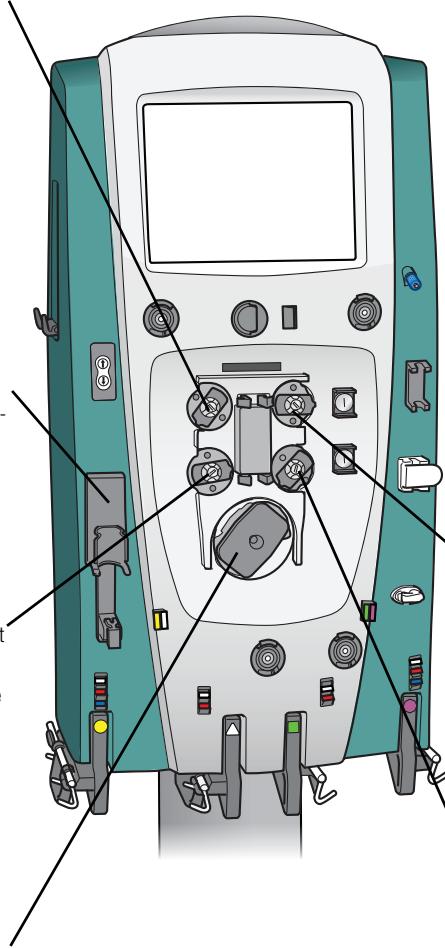
Pre-blood pump

If required, pumps a solution into the blood access line at a location immediately after patient blood enters the line and before the blood pump.

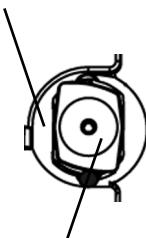
TPE: HP: Any PBP volume infused must therefore be counted as a separate fluid input when calculating the patient's input/output totals.

Blood pump

Pumps blood through the blood flowpath of the Prismaflex set.

**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.

Dialysate/Replacement 2 pump

CVHD, CVHDF: Pumps dialysate solution into the fluid compartment of the filter.

CVH: 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.

Replacement pump

Pumps replacement solution/fluid into the blood flowpath.

CRRT: Replacement solution can be delivered either pre or post-filter.

TPE: Replacement fluid is always delivered 100% post filter.

Figure 2.1 Pumps

Pressure pods

There are three circular “pods” in the set that are used. 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 before blood pump (access pod), access line after the blood pump (filter pod) and effluent line before effluent pump (effluent pod).

Pressure pod (not used, for future treatment)**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.

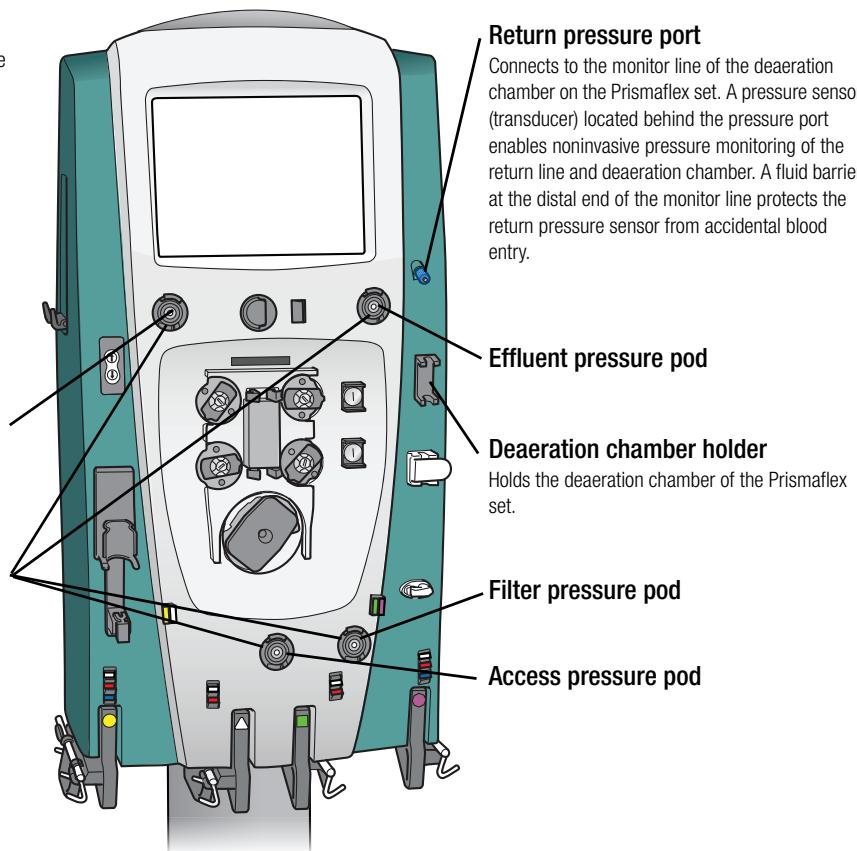


Figure 2.2 Pressure components

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 [Table 5.6 on page 152](#).

Syringe control panel

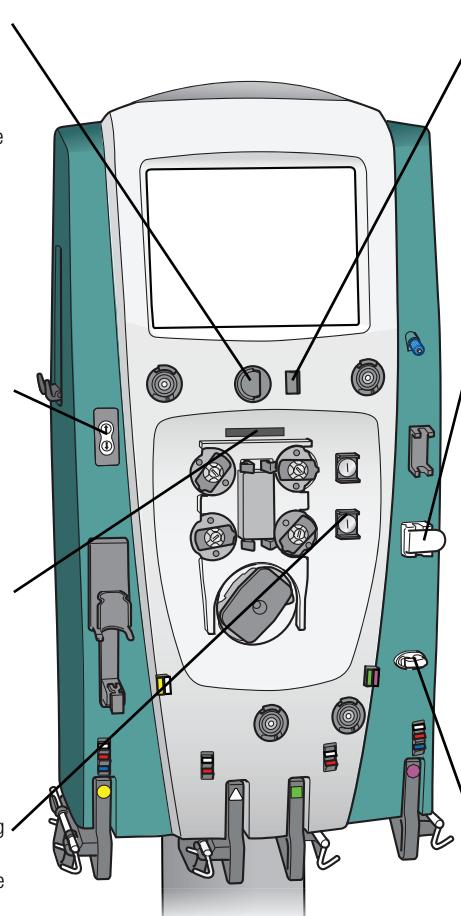
Consists of UP and DOWN buttons that allow installation and removal of the syringe. The buttons are activated/inactivated by Prismaflex software, depending upon operating conditions.

Bar code reader

Laser scanner that reads the bar code on 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.

Pinch valves (upper and lower)

CVH, CVVHDF: Upper pinch valve accepts tubing coming from the dialysate/replacement 2 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 the Operator's Manual, see "Chapter 3: General Therapy Information" for more information.

**Discharger ring guide**

Holds the electrostatic discharger ring of the Prismaflex set. Provides an electrical connection to "ground" to minimize electrical interference by Prismaflex pumps with patient electrocardiogram (ECG) recordings.

Always install the discharger ring in its guide before connecting a patient to the Prismaflex set.

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).

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 inward when tubing is correctly installed under the clamp.

Figure 2.3 Sensors and clamps

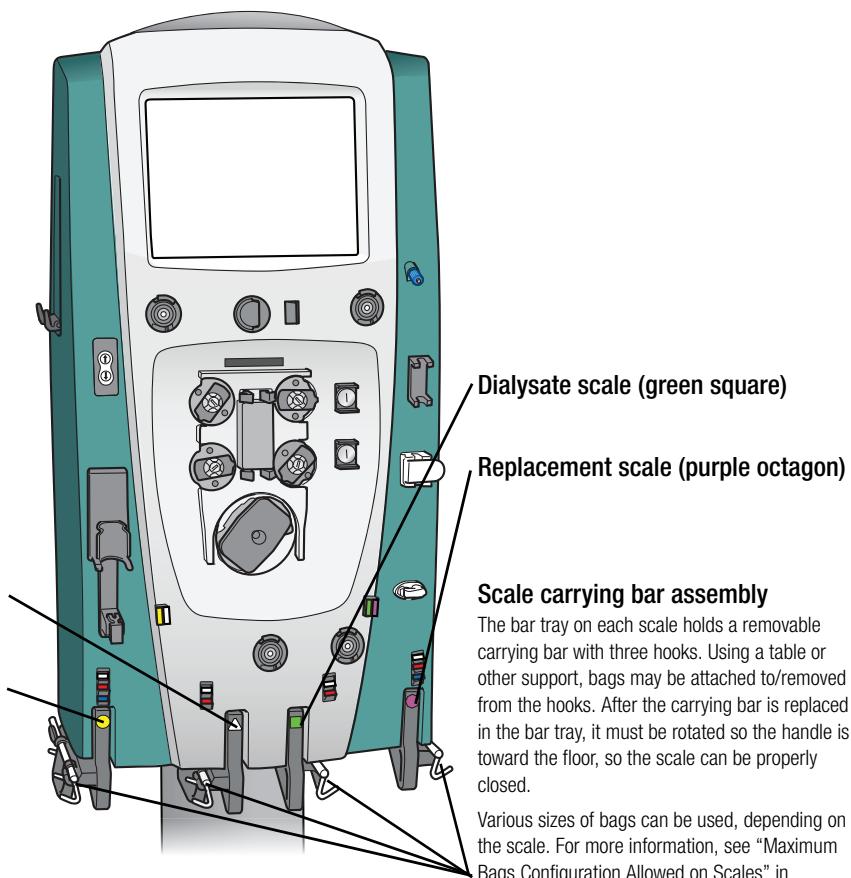
General scale Information

Independently monitor fluid bag/container weights. Weight is used by Prismaflex software to precisely control ultrafiltration/plasmafiltration and patient fluid removal/plasma loss. An alarm sounds when the PBP, dialysate and replacement solution bags/containers are nearly empty, or when the effluent bag is nearly full.

The operator pulls the bar tray of a scale out (away from) the control unit to attach or remove bags/containers. 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 requires it to be closed.

PBP scale (white triangle)

Effluent scale (yellow circle)

**Scale carrying bar assembly**

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 8: Specifications" on page 237.

Figure 2.4 Scale components

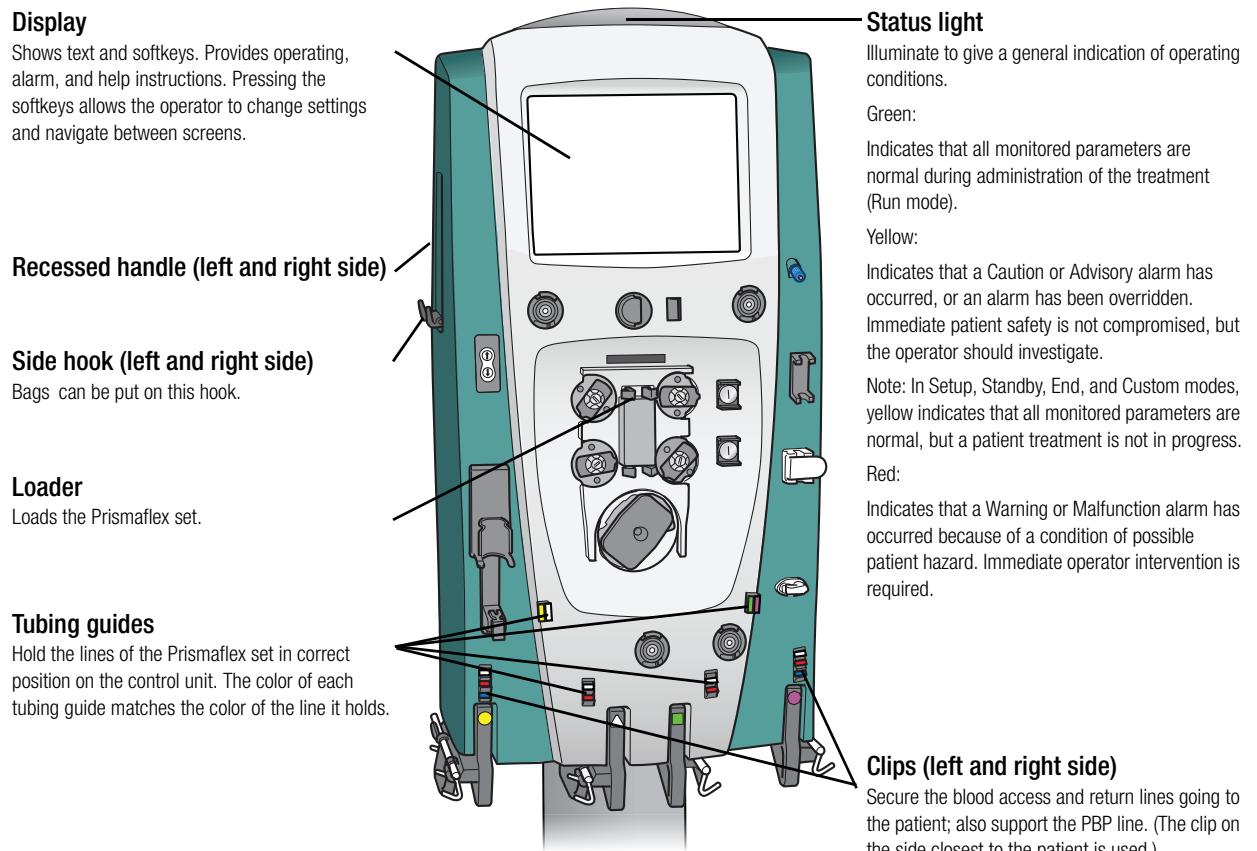


Figure 2.5 Miscellaneous components

2.5.2 Rear panel

Following is a description of the components on the rear panel of the Prismaflex control unit.

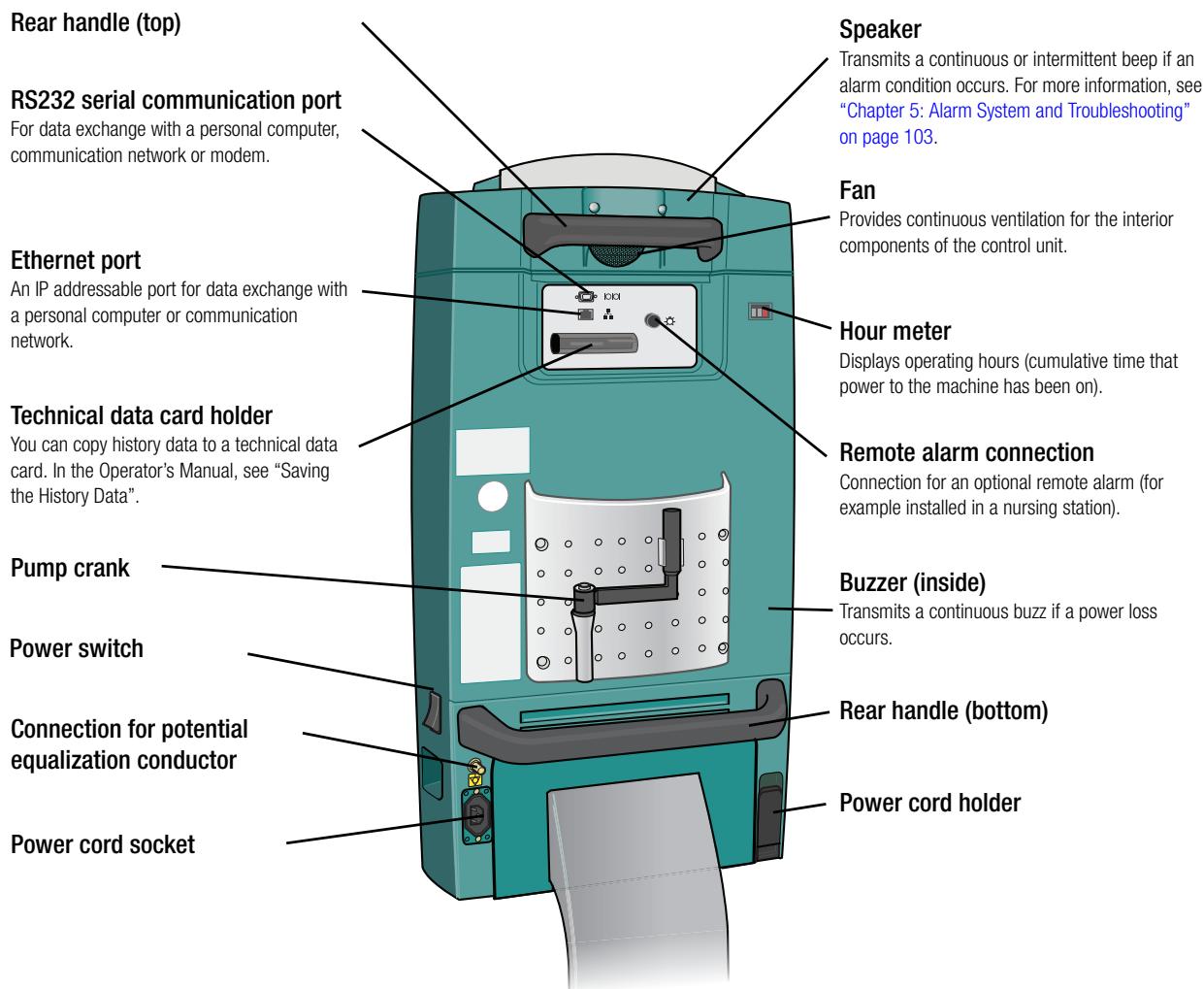


Figure 2.6 Prismaflex control unit: Rear Panel

2.5.3 Interior Components

Access to the interior of the Prismaflex control unit is gained through the rear panel. Only trained and qualified service technicians should repair the interior components. 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.

2.6 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.

2.6.1 Contents of Prismaflex Shipping Carton

Each Prismaflex control unit is pre-attached to a column and a base with casters. The Prismaflex control unit comes packaged with the following items:

- Installation kit:
 - United States-style power cord, with retaining bracket (not China)
 - Continental European-style power cord, with retaining bracket (not US and China)
 - Chinese power cord, with retaining bracket (China only)
 - 4 Screws
 - 4 Scale carrying bars
- 20 ml Syringe Clip
- Pump crank
- Caution Stickers
- Potential Equalization Connector

1. Pressure pods are a component of Prismaflex disposable sets. Descriptions of pressure pods and diaphragms are found in the Prismaflex set sections.

- Prismaflex Operator's Manual on CD
- Software CD
- Accompanying documents

2.6.2 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 socket is properly grounded and in good condition. If there is any question, have the wiring checked by a qualified electrician.

2.6.3 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 Appendix A in the Operator's Manual.

2.6.4 Space Requirements

The assembled machine requires a minimum of 63 cm × 63 cm (25 in × 25 in) of floor space. There must be enough space around the machine so that all fluid bags can hang freely from the scale carrying bars.

2.6.5 Unpacking and Assembly

Materials Needed

Torx 20 screwdriver

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

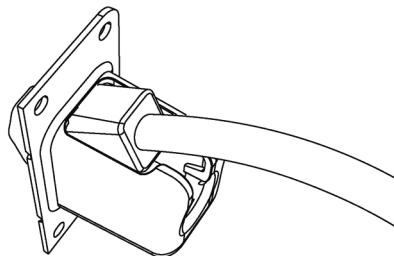
(See [Figure 2.7 on page 47](#))

1. Select the appropriate power cord and retaining bracket package.

Note: If the supplied power cord does not fit the wall socket, contact an authorized electrician that can connect the power cord to the wall socket.

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 socket on the rear panel of the control unit.
5. Using the 4 screws provided, secure the retaining bracket to the studs on either side of the power cord socket. Tighten the screws with the Torx 20 screwdriver.
6. The Prismaflex control unit has a connection on the rear panel for a Potential Equalization Conductor. If required, connect the Potential Equalization Conductor to the connector.

A Insert the power cord into the retaining bracket.



B Secure the retaining bracket to the studs on either side of the power cord socket.

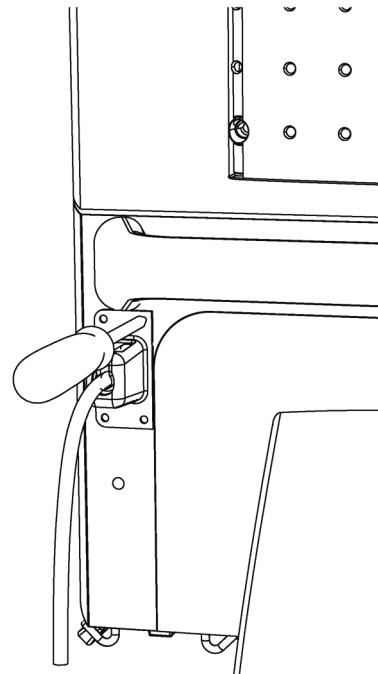


Figure 2.7 Connecting the Power Cord

Step 3: Install Scale Carrying Bars

(See [Figure 2.8 on page 48](#))

1. Working one scale at a time, install the carrying bars into the bar trays of the four scales.
 - a. Open scale, place a carrying bar on the bar tray.
 - b. 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.

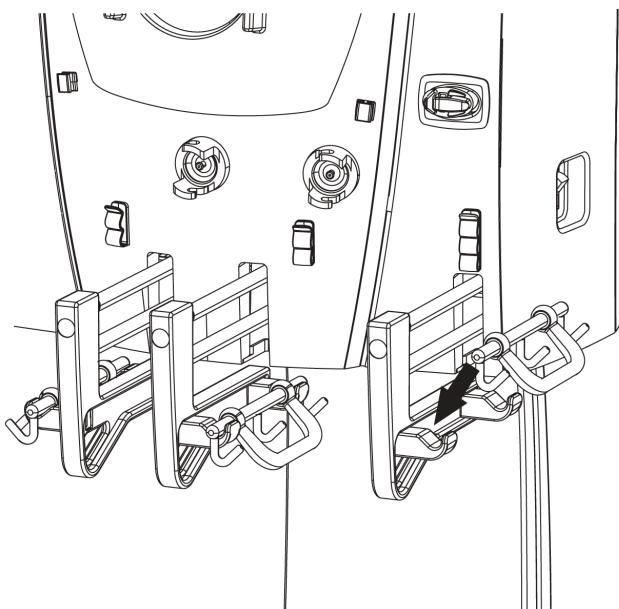


Figure 2.8 Placing the Carrying Bars on the Scales

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 technician and recorded in the *Maintenance Log* (attached to the inside wall of the rear panel). Calibration instructions are provided in "[6.3.1 Service Calibrate Screens](#)" on page 173.

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

As default the Prismaflex control unit is enabled for CRRT. Default filter set available is M60 and M100. For installation of other sets/therapies contact a trained and qualified technician and check your local restrictions and regulations.

Step 5: Installation Test

Note: Read the 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 and that the control unit beeps.
2. Choose *New Patient* when the Choose Patient screen appears and enter some patient information
3. Check that the SCUF, CVVH, CVVHD, CVVHDF softkeys are available on the Choose Therapy screen. Choose the *CVVHDF therapy*.
4. Choose *Standard - No Syringe* as Coagulation Method.
5. 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.
6. Enter the Treatment Setting Patient Fluid Loss/Gain Limit to 140ml/3h. Press CONFIRM
7. Set the following flow rates and press the CONFIRM softkey.
 - Blood: 100 ml/min
 - PBP (pre-blood pump) solution: 1000 ml/h
 - Dialysate solution: 1000 ml/h
 - Replacement solution: 1000 ml/h
 - Patient Fluid Removal: 200 ml/h
8. When the Review Prescription 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.

9. 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.
10. 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 $50 \text{ ml} \pm 5 \text{ ml}$.

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.

11. 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.
12. 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).
13. Press the STOP softkey, then press the END TREATMNT softkey and follow the instructions to unload the set.

Chapter 3: Electronic Description

3.1 Internal connections

[Figure 3.1 on page 52](#) shows the internal connections between boards. The I²C communication is displayed in [Figure 3.2 on page 53](#).

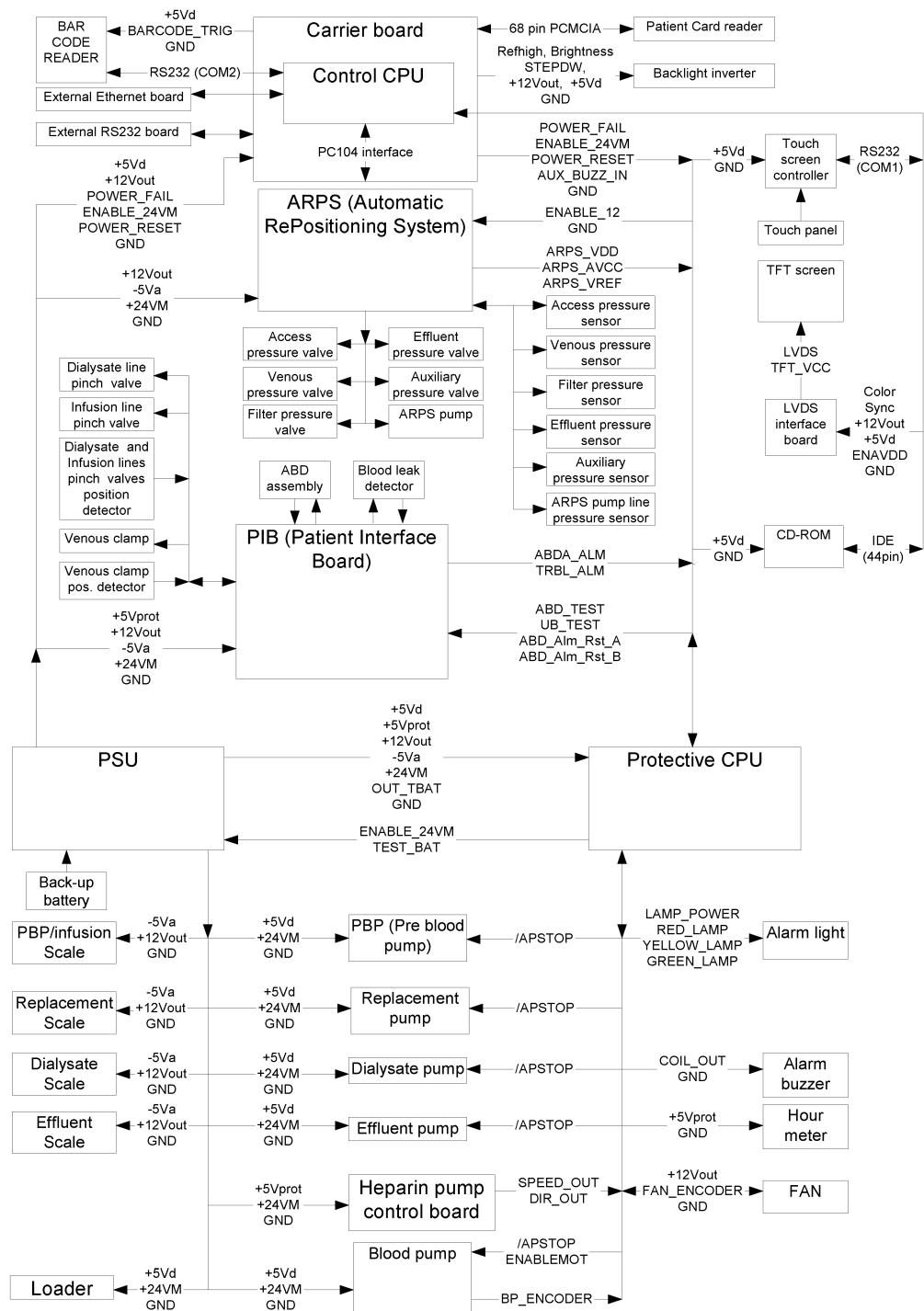


Figure 3.1 Internal connections diagram

[Figure 3.2 on page 53](#) shows the routing for the internal I²C communication. Each board except the blood pump has two I²C connectors connected in parallel. Buffering is made on each board using an I²C line driver type Philips 82B715. The I²C bus consists of 4 signals (+5V, SDA, SCL and GND). The +5V supply is connected to the Blood pump board, but it is possible (through jumpers on each board) to set a different configuration of the +5V supply.

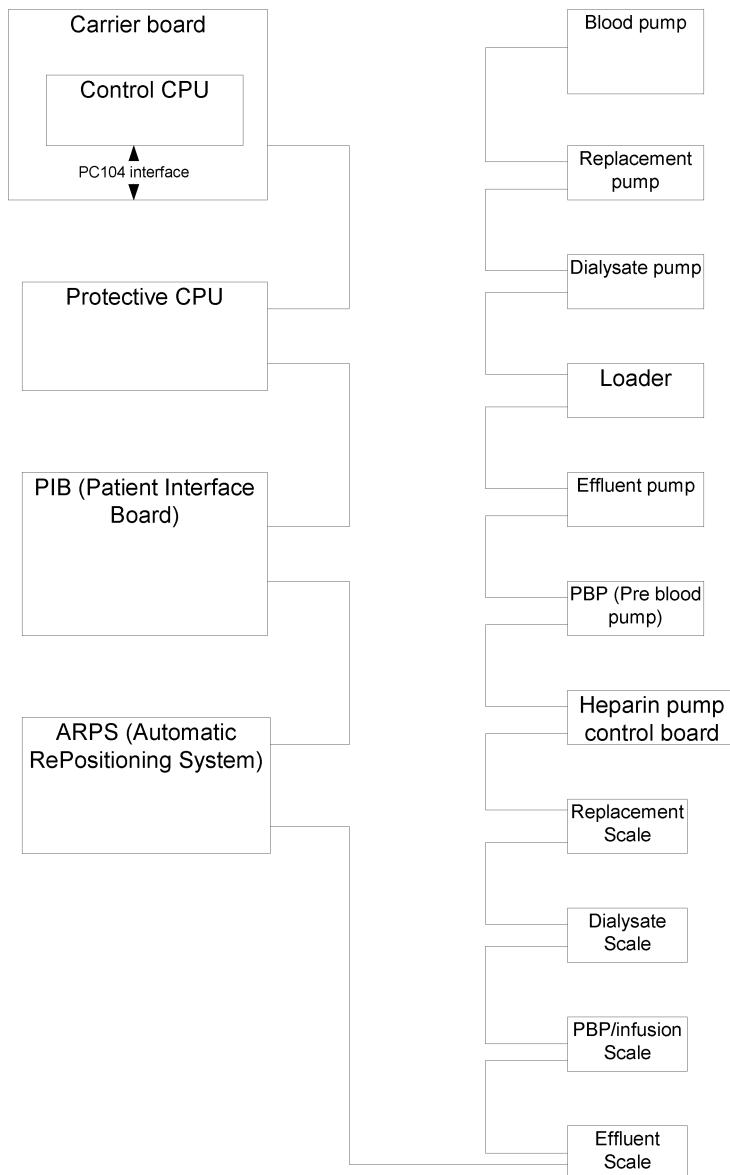


Figure 3.2 I²C Interconnection diagram

3.2 Modules

The electronic design consists in principal of the following main modules:

- Power supply unit (PSU)
- Protective CPU board
- Carrier board (working as motherboard for the Control CPU)
- Control CPU (PC-104)
- ARPS board
- PIB board

Supporting and connected modules are:

- Peristaltic fluid pumps
- Blood pump
- Syringe pump
- Loader
- Scales
- ABD assembly
- Blood leak detector
- Pinch valves
- Venous clamp
- Pressure valves
- Pressure sensors
- Bar-code reader
- Technical data card holder
- External RS232 & Ethernet boards
- LVDS interface board
- Touch screen controller
- TFT display with backlight inverter and touch screen
- Alarm light and buzzer
- Hour meter

3.3 Power Supply

The power supply provides the following DC voltages referred to a common ground:

Table 3.1 Power Supply DC Voltages

Voltage	Low limit	High limit	Nominal current	Description
+24VM	22.8V	25.2V	15A (shared with currently unused +24Vc)	Positive 24V used as supply mainly to actuators. This voltage is enabled by the signal ENABLE_24VM from the Protective CPU board
+12Vout	11.9V	12.3V	4.0A	Positive 12V used for supply of analogue parts as well as the ARPS pump
+5Vd	5.1V	5.3V	6A	Positive 5V generally used for digital circuitry
+5Vprot	5.1V	5.3V	5A	Positive 5V used for digital circuitry in the protective system and also used for miscellaneous digital circuitry
-5Va	-5.4V	-5.1V	2.0A	Negative 5V used as supply to analogue parts

The system reference ground is in the power supply unit, and all sub-system grounds originate from here to avoid ground loops as well as power noise on sensor signals.

Table 3.2 Power Supply Connections

Description	Signals	Interfacing board(s)/module(s)
Protective CPU supply & PSU voltage supervision	+5Vd, +5Vprot, +12Vout, -5Va, +24VM, GND	Protective CPU board
Enable of actuator power	ENABLE_24VM	From Protective CPU board
Carrier board (Control CPU) supply & PSU status	+5Vd, +12Vout, POWER_FAIL, POWER_RESET, ENABLE_24VM, GND	Carrier board (signals POWER_FAIL, ENABLE_24VM and POWER_RESET are passed by the Carrier board to the Protective CPU)
ARPS supply	+12Vout, -5Va, +24VM, GND	ARPS board
PIB supply	+5Vprot, +12Vout, -5Va, +24VM, GND	PIB board
Peristaltic pump & Loader supply	+5Vd, +24VM, GND	PBP/Infusion pump, Replacement pump, Dialysate pump, Effluent pump, Blood pump and Loader
Syringe pump supply	+5Vprot, +24VM, GND	Syringe pump control board
Scales supply	+12Vout, -5Va, GND	PBP/Infusion scale, Replacement scale, Dialysate scale and Effluent scale
Back-up battery test	TEST_BAT	From Protective CPU board

Table 3.2 Power Supply Connections

Battery test status	OUT_TBAT	To Protective CPU board
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3.4 Carrier board

The Carrier board has the following main functions:

- Motherboard for the Control CPU
- Backlight inverter control for user interface TFT screen
- Provides I²C communication to the PC-104 compatible Control CPU
- Contains 512kB battery backed-up memory for storage of data from therapies, events and alarms (384kB) and used for communication and for the PCMCIA controller supporting the Technical data card interface.

Table 3.3 Carrier Board Connections

Description	Signals	Interfacing board(s)/module(s)
Power input	+5Vd, +12Vout, GND	From PSU
Power status	POWER_FAIL, POWER_RESET, ENABLE_24VM and GND	From PSU To Protective CPU board
Interface to Control CPU	16-bit ISA-bus PC-104 signals	Control CPU board
External RS232	Rx, Tx, RTS, CTS, +5Vd, GND	External RS232 interface board
LCD backlight inverter power and control	+12Vout, +5Vd (NC), Brightness, Refhigh (NC), STEPDW and GND	To LCD backlight inverter (STEPDW enables inverter)
Bar-code reader power and control	+5Vd, BARCODE_TRIGGER and GND	To Bar code reader module (BARCODE_TRIGGER enables bar code reader LED)
Technical Data Card Reader	68 pin PCMCIA interface	To PCMCIA holder
Control CPU buzzer request	AUX_BUZZ_IN, GND	To Protective CPU board
I ² C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Protective CPU board

3.5 Control CPU

The Control CPU is a PC-104 compatible PC with a Pentium processor Advantec model PCM-5824. VxWorks is used as Operating System. The Control CPU has the following main functions:

- Responsibility to run the treatment (including priming and end-of-treatment etc.)
- Supervision of the behaviour of the machine

- Control of the subsystems ARPS and PIB as well as fluid pumps, blood pump, syringe pump, scales and loader (through I²C)
- Managing requests from Protective system (through I²C)
- Handling of the GUI
- Providing connection to external Ethernet interface
- Supporting the Touch screen controller through RS232 / COM1
- Supporting the Bar-code reader through RS232 / COM2
- Supporting the CD-ROM through IDE

Table 3.4 Control CPU Connections

Description	Signals	Interfacing board(s)/module(s)
Connection to motherboard	16-bit ISA-bus PC-104 signals	Carrier board
Touch screen interface	Full RS232 interface on Control CPU COM1	Touch screen controller
Bar-code reader interface	RS232 interface (Rx and Tx) on Control CPU COM2	Bar-code reader
TFT output	44-pin connector	LVDS transmitter board. Present only on older machines. (See Service Newsletter for machine numbers.)
CD-ROM interface	40 signals on 44-pin connector standard IDE-cable	CD-ROM player
External Ethernet	IRX-, IRX+ ITX- and ITX+	External Ethernet board

3.6 Protective CPU board

The Protective CPU board has the following main functions:

- Monitoring the activity of the machine and forcing the machine in a Safe State through a specific state request to the Control System in case of mismatch with the appropriate Safety Criteria
- Actuation of tests (T0 and T1) to monitor the HW integrity
- Requiring the actuation by the Control System of one or more Specific Safe State conditions (i.e. Pumps Stop, Clamps Closed)
- Forcing the power of all actuators to off (General Safe State) if previous specific safe state condition was not met or if a severe failure condition occurred
- Supervision of PWR_FAIL and PWR RESET signals
- Supervision of all supply voltages (both from PSU and from ARPS)
- Handling of air bubble alarm
- Supervision of scales (through I²C)
- Supervision (directly) of speeds for blood pump and syringe pump

- Supervision (through I²C) of speeds for Dialysate pump, Effluent pump, Infusion pump and additional PBP (Pre Blood Pump)
- Supervision (through I²C) of Access pressure, return pressure, Filter pressure, Effluent pressure, Auxiliary pressure and ARPS pump line pressure
- Activation of the alarm lights and speaker
- Activation of remote alarm
- Enabling the blood pump relay
- Enabling of +24V for pumps
- Enabling of +12V for ARPS actuators
- Back-up battery test and monitoring

Table 3.5 Protective Board Connections

Description	Signals	Interfacing board(s)/module(s)
PSU voltage supervision	+5Vd, +5Vprot, +12Vout, -5Va, +24VM, GND	From Power Supply Unit (PSU)
PSU status monitoring	POWER_FAIL, ENABLE_24VM, POWER_RESET, GND	From Carrier board
Enable of actuator power	ENABLE_24VM	To PSU
ARPS board actuator power control	ENABLE_12, GND	To ARPS board
ARPS board voltage monitoring	VDD_ARPS, AVCC_ARPS, VREF_ARPS	From ARPS board
Pump inhibition	/APSTOP	To PBP/Infusion pump, Replacement pump, Dialysate pump, Effluent pump and Blood pump
Power enable for blood pump	ENABLEMOT	To blood pump (this signal is in fact connected to the Blood Pump Relay board and disconnects the pump from the supply when e.g. manual end-of-treatment is used)
Blood pump speed supervision	BP_ENCODER	From blood pump
Syringe pump supervision	SPEED_OUT, DIR_OUT	From syringe pump
ABD (Air Bubble Detection) management	ABD_TEST, UB_TEST (not used), ABD_Alm_Rst_A, ABD_Alm_Rst_B and ABDA_ALM	PIB board
ABD trouble detection	TRBL_ALM	From PIB board
Visual Alarm	LAMP_POWER (= +5Vprot), RED_LAMP, YELLOW_LAMP, GREEN_LAMP	To Alarm light module
Audible Alarm	COIL_OUT, GND	To alarm buzzer

Table 3.5 Protective Board Connections

Description	Signals	Interfacing board(s)/module(s)
Control system alarm control – currently not used	AUX_BUZZ_IN, GND-pull-down	From Carrier board
Power supply to Touch screen controller	+5Vd, GND	To touch screen controller
Power supply to CD-ROM player	+5Vd, GND	To CD-ROM player
Power supply to hour meter	+5Vprot, GND	To hour meter
Power supply to fan	+12Vout, FAN_ENCODER, GND	To fan (3 signals; +12V, GND and FAN_ENCODER)
I ² C bus	+5Vd, I ² C_SDA, I ² C_SCL, GND	Carrier board and PIB board
Back-up battery test	TEST_BAT	To PSU
Battery test status	OUT_TBAT	From PSU

3.7 ARPS board

The ARPS (Automatic RePositioning System) board has the following main functions:

- Monitoring pressure values from Access pressure sensor, return pressure sensor, Filter pressure sensor, Effluent pressure sensor and Auxiliary pressure sensor
- Monitoring internal ARPS pump line pressure sensor
- Controlling valves between the ARPS pump and the pressure sensors for access pressure, return pressure, filter pressure, effluent pressure and auxiliary pressure
- Controlling the ARPS pump to adjust pressure sensor membrane positions and for creating pressure levels for taring and testing the pressure sensors
- Handling of increase or decrease of the fluid level in the deaeration chamber
- Providing voltage references for pressure sensor bridges and internal ADC; +10V for sensor bridges (ARPS_VDD), +5Vref for ADC and +2.5V for pressure sensor neutral position reference

Table 3.6 ARPS Board Connections

Description	Signals	Interfacing board(s)/module(s)
Access pressure sensor voltage reference and measurement signal	ARPS_VDD, AP_High_bridge, AP_Low_bridge, GND, Shield	Access pressure sensor
return pressure sensor voltage reference and measurement signal	ARPS_VDD, VP_High_bridge, VP_Low_bridge, GND, Shield	Return pressure sensor
Filter pressure sensor voltage reference and measurement signal	ARPS_VDD, FP_High_bridge, FP_Low_bridge, GND, Shield	Filter pressure sensor
Effluent pressure sensor voltage reference and measurement signal	ARPS_VDD, EP_High_bridge, EP_Low_bridge, GND, Shield	Effluent pressure sensor
Auxiliary pressure sensor voltage reference and measurement signal	ARPS_VDD, AuxP_High_bridge, AuxP_Low_bridge, GND, Shield	Auxiliary pressure sensor
ARPS pump line pressure sensor voltage reference and measurement signal	ARPS_VDD, ARPSP_High_bridge, ARPSP_Low_bridge, GND, Shield	ARPS pressure sensor
Control of Access pressure sensor valve	ARPS_VDD, AV_Open drain	To access pressure sensor valve
Control of Return pressure sensor valve	ARPS_VDD, VV_Open drain	To return pressure sensor valve
Control of Filter pressure sensor valve	ARPS_VDD, FV_Open drain	To filter pressure sensor valve
Control of Effluent pressure sensor valve	ARPS_VDD, EV_Open drain	To effluent pressure sensor valve
Control of Auxiliary pressure sensor valve	ARPS_VDD, AuxV_Open drain	To auxiliary pressure sensor valve
Control of ARPS pump	ARPS_VDD, 4 open drain H-bridge outputs for stepper motor coil	To ARPS pump
I ² C bus	+5Vd, I2C_SDA, I2C_SCL, GND	PIB board and Effluent Scale

3.8 PIB board

The PIB board has the following main functions:

- Handling of air bubble detector

- Monitoring of optical switch to detect that the blood line is present in air bubble detector
- Activation of venous clamp (through I²C)
- Monitoring venous clamp position
- Monitoring blood detector (through I²C)
- Monitoring blood leak detector (through I²C)
- Controlling and monitoring position of pinch valve for dialysate line
- Controlling and monitoring position of pinch valve for infusion line

Table 3.7 PIB Board Connections

Description	Signals	Interfacing board(s)/module(s)
Monitoring of air bubble detector	UABD_RCV, UABD_TRANSMIT, REF_BIG, REF_MICRO, GND	ABD (Air Bubble Detector) assembly
Monitoring of blood detector	PTSR_K, PTSR_A, PTST_A, PTST_K	ABD (Air Bubble Detector) assembly
Monitoring of blood line present detector	+5VP, UABD_LS, LSS2, GND	ABD (Air Bubble Detector) assembly
Monitoring of blood leak	BLDT-A, BLDT-K, BLDR-A, BLDR-K, GND	Blood leak detector board
Control of Dialysate line pinch valve	CL_MOT2_OUT1, CL_MOT2_OUT2	To dialysate line pinch valve
Control of Infusion line pinch valve	CL_MOT1_OUT1, CL_MOT1_OUT2	To infusion line pinch valve
Monitoring of Dialysate line and Infusion line pinch valves position	+5VP, PV_OPT_COM, S1_MOT1, S2_MOT1, S3_MOT1, S1_MOT2, S2_MOT2, S3_MOT2, GND	From dialysate line pinch valve and Infusion line pinch valve position detector board
Control of venous clamp	CLAMP_CMD, +24VM	To venous clamp
Monitoring of venous clamp	+5VP, VCP, LVCS, GND	Venous clamp detector board
I ² C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Protective CPU board and ARPS board

3.9 Alarm light module

The Alarm light board consists of two rows of LEDs on three different PCBs mounted in a triangle to provide 360° visibility. One of the LED rows displays red and yellow light. The other displays green light. The alarm light is controlled by the Protective CPU.

Table 3.8 Alarm Light Board Connections

Description	Signals	Interfacing board(s)/module(s)
Visual Alarm	LAMP_POWER (= +5Vprot), RED_LAMP, YELLOW_LAMP, GREEN_LAMP	To Protective CPU board

3.10 LVDS interface board

Note: LVDS transmitter board is only present on older machines. See Service Newsletter for specific machine numbers.

The LVDS interface board converts the parallel digital LCD display signals from the Control CPU into serial LVDS signals.

Table 3.9 LVDS Interface Board Connections

Description	Signals	Interfacing board(s)/module(s)
Parallel LCD interface	24 bit color, VSYNC, HSYNC, SHFCLK, DE, ENAVDD, +12Vout, +5Vd and GND	Control CPU board
LVDS to TFT screen	4 shielded TP LVDS signals, TFT_VCC, +5Vd and GND	TFT screen

3.11 External RS232 board

The external RS232 board provides an isolated serial communications port for external equipment.

Table 3.10 RS232 board Connections

Description	Signals	Interfacing board(s)/module(s)
Power and communication for external RS232 interface	Rx, Tx, RTS, CTS, +5Vd, GND	Carrier board

3.12 External Ethernet board

The external Ethernet board provides an isolated Ethernet port for external equipment.

Table 3.11 Ethernet Board Connections

Description	Signals	Interfacing board(s)/module(s)
External Ethernet interface signals	IRX-, IRX+ ITX- and ITX+	Control CPU board

3.13 Fluid pumps

The Dialysate pump, Effluent pump, Replacement pump and additional PBP (Pre Blood Pump) are all peristaltic pumps with individual electronics boards. These pumps are controlled through commands passed through the I²C communication bus. The fluid pumps are responsible to control and monitor the pump rotation direction and speed according to the commanded value.

Table 3.12 Pumps Connections

Description	Signals	Interfacing board(s)/module(s)
Power supply input	+24VM, +5Vd, GND	From PSU
Motor stop	/APSTOP	Protective CPU board
I ² C bus	+5Vd, I ² C_SDA, I ² C_SCL, GND	Dialysate pump: Loader and Replacement pump Replacement pump: Dialysate pump and Blood pump PBP/Infusion pump: Syringe pump and Effluent pump Effluent pump: PBP/Infusion pump and Loader

3.14 Blood pump

The blood pump is a peristaltic pump with an individual electronics board. The pump is controlled through commands passed through the I²C communication bus. The blood pumps is responsible to control the pump rotation direction and speed according to the commanded value.

Table 3.13 Blood Pump Board Connections

Description	Signals	Interfacing board(s)/module(s)
Power supply input	+24VM, +5Vd, GND	PSU
Motor stop and supervision	BP_ENCODER, /APSTOP, ENABLEMOT	Protective CPU board
Monitoring of speed and direction	+5Vd, Position_1, Position_2, GND	Hall sensors mounted on motor
I ² C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Replacement pump

3.15 Syringe pump

The syringe pump controls and monitors the infusion of anticoagulant to the line set by moving its actuator to push the piston of a syringe, when commanded by the Control CPU (through I²C). There are built-in detection of end-of-stroke and overload and the presence of a syringe can be detected. The movement of the actuator can also be performed manually through two hard-keys.

Table 3.14 Syringe Pump Board Connections

Description	Signals	Interfacing board(s)/module(s)
Power supply input	+24VM, +5Vprot, GND	PSU
Motor stop and supervision	SPEED_OUT, DIR_OUT	Protective CPU board
I ² C bus	+5Vd, I2C_SDA, I2C_SCL, GND	Replacement scale and PBP / Infusion pump

3.16 Loader

The Loader handles the mounting of an attached line-set by pulling it in position so that the fluid pumps and blood pump can auto route the pump segments into the peristaltic pump runways.

Table 3.15 Loader Connections

Description	Signals	Interfacing board(s)/module(s)
Power supply input	+24VM, +5Vd, GND	PSU
I ² C bus	+5Vd, I ² C_SDA, I ² C_SCL, GND	Effluent / infusion pump and Dialysate / infusion pump

3.17 Scales

The scales provide a reading of weight of the different fluid bags to two different channels for the Control and Protective systems. Also reporting to Protective that the bag holder is properly inserted into the scale. All information is passed through I²C.

Table 3.16 Scales Connections

Description	Signals	Interfacing board(s)/module(s)
Power supply input	+12Vout, -5Va and GND	PSU
I ² C bus	+5Vd, I ² C_SDA, I ² C_SCL, GND	Effluent scale: ARPS board and PBP/Infusion scale PBP/Infusion scale: Effluent scale and Dialysate scale Dialysate scale: PBP/Infusion scale and Replacement scale Replacement scale: Dialysate scale and Syringe pump

3.18 ABD assembly

The ABD has the following main function:

- detect air in the blood returned to the patient
- detect blood in the return line

3.19 Signals

This section describes the signals between the modules inside Prismaflex.

Table 3.17 Signals Description

Signal name	Description	From	To
EN_24VM	TTL square wave > 3 Hz used as watchdog to enable the +24VM voltage.	Protective	PSU
UB_TEST	Logic TTL signal, Protective activates this signal (active low) 4 times each second for a duration of 8ms to test the air bubble detector. The air bubble alarm must then be activated within 5ms.	Protective	PIB
ABDA_ALM	Logic TTL signal, PIB sends this signal to protective when a macrobubble has been detected.	PIB	Protective
TRBL_ALM	Logic TTL signal, PIB sends this signal to protective when trouble has been detected, which means that the AGC has not been able to control the amplitude of the received signal.	PIB	Protective
ABD_Alm_Rst_A	Logical TTL signal to clock the flip-flop for air bubble detector alarm. Not active status is high.	Protective	PIB
ABD_Alm_Rst_B	Logical TTL signal for clearing data of the flip-flop for air bubble detector alarm. Not active status is high.	Protective	PIB
/APSTOP	Logic TTL signal to enable the driver stage of the pumps P1, P2, P3, P4 and BLD.	Protective	P1, P2, P3, P4 and BLD
Brightness control	Analog voltage (0 – 3.75V) to control brightness of backlight to TFT.	Carrier	Inverter
Reffhigh	3.75V	Carrier	Inverter
STEPDW	Logic TTL signal to enable inverter for backlight to TFT.	Carrier	Inverter
DIR_OUT	Logic TTL signal to indicate Syringe pump direction (Low = CW, up. High = CCW, down)	Syringe pump	Protective
SPEED_OUT	TTL square wave from magnetic encoder to verify the speed of the syringe pump. 16 pulses for each mm of vertical movement.	Syringe pump	Protective

Table 3.17 Signals Description

Signal name	Description	From	To
ENABLE_12	Enable signal from protective to activate the 12V power on the ARPS board used for the ARPS pump. It is a square wave TTL level of 20 Hz frequency which stimulates the watch-dog on the ARPS board.	Protective	ARPS
ARPS_VDD	+10V reference voltage for pressure sensor bridges.	ARPS	Protective
ARPS_AVCC	+5V reference voltage for pressure sensor ADC.	ARPS	Protective
ARPS_VREF	+2.5V reference voltage for neutral position reference for pressure sensors.	ARPS	Protective
COIL_OUT	Analog sinusoidal signal 1 kHz, 1.5 kHz or 2.5 kHz sent to the alarm speaker (buzzer). The maximum amplitude can be 2Vpp with offset 0V	Protective	Speaker
AUX_BUZZ_IN	Digital square wave signal TTL level of frequency 1 kHz, 1.5 kHz or 2.5 kHz sent to the from Carrier to Protective.	Carrier	Protective
POWER_FAIL	Logic TTL signal. Low indicates that no power from the supply line has been detected.	PSU	Carrier and Protective (through Carrier)
POWER_RESET	Logic TTL signal. Low indicates the PSU is in reset condition	PSU	Carrier and Protective (through Carrier)
FAN_ENCODER	Open collector pulse signal from cooling Fan pull-up on Protective board used to read the speed of the Fan	Cooling Fan	Protective
BARCODE_TRIG	Logic signal TTL level; Low level indicates that barcode reader is active.	Carrier	Bar-code reader
TFT_VCC	A delayed +5V power to the TFT. The delay is controlled by a signal from Control CPU; ENAVDD.	LVDS_Tx board	TFT
ENAVDD	Digital signal TTL level controlling the output power to the TFT.	Control CPU	LVDS_Tx board
BP_ENCODER	Digital signal TTL level pulses indication of blood pump motor speed (gear box 30:1)	Blood pump	Protective
ENABLEMOT	Digital signal open drain to connect the blood pump motor to the driver H-bridge. Low level connects the motor to the bridge. Relay coil at motor is used as pull-up.	Protective	Blood pump

Table 3.17 Signals Description

Signal name	Description	From	To
TEST_BAT	Digital open drain signal to activate battery test by connecting a resistive load to the back-up battery and monitoring the resulting voltage across the battery. Low level activates the test.	Protective	PSU
OUT_TBAT	Digital TTL status signal for back-up battery test. Low level during the test indicates that the battery is charged. High level indicates low battery voltage.	PSU	Protective

Chapter 4: Function Check

4.1 Main-controlled Components

Touch screen
Display
CD-ROM
Bar-code reader
Technical data card (PCMCIA)
Ethernet connection
RS 232 connection
Power supply

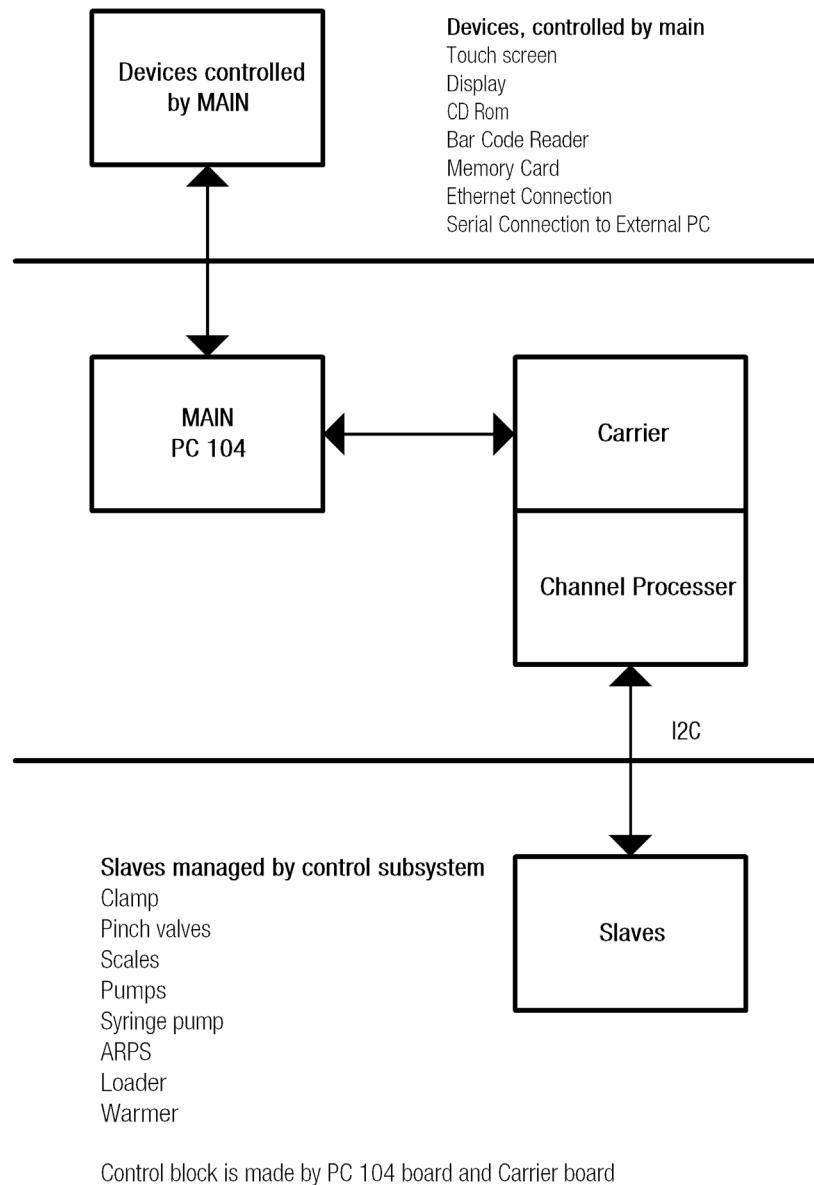


Figure 4.1 Structure of commands and communication of the Prismaflex control unit

4.2 Self-tests

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.

4.2.1 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 4.1 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	Checksum of each structure is compared to the software-calculated checksum for that structure.
(b) Range check	Structures which contain minimum and maximum setting values are range checked to ensure the range is valid.

Table 4.1 Subtests of the Initialization Self-test

Subtest	Description
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.
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?

4.2.2 Prime Self-test

The prime self-test consists of two phases of subtests: pre-prime and post-prime. The pre-prime phase starts together with the LOAD phase. The operator manually starts the post-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 4.2 on page 72](#) lists the subtests in each phase of the prime self-test, in the order they occur.

Table 4.2 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. Alarm generated is: Malfunction: Pressure zero test
Scale zero test	All the scales must read 0 ± 30 gr. Alarm generated is: Malfunction: Scale zero test
Tubing presence in air bubble detector	Occurs both before and after a set is loaded. Before loading, tubing should not be in the air bubble 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

Table 4.2 Subtests of the Prime Self-test

Subtest	Description
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 the 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.
Recognition Test	Occurs after a set is loaded. This test is performed to identify the set and verify that the set matches the selected therapy. Alarms generated are Warning: Wrong Set Loaded or Warning: Set-up error.
Syringe Pump	Occurs during the loading procedure of the syringe. Verifies direction and speed. Alarm generated is Malfunction: Prime Self-Test, with the message Syringe Pump Hardware.
Post-prime phase	All Post-prime subtests occur after the operator has pressed PRIME TEST on the “Priming X of X Cycles Complete” screen.
Blood leak detectors (CRRT, TPE)	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 time-out 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 – ARPS Pump	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 4.2 Subtests of the Prime Self-test

Subtest	Description
Pump occlusivity test	Tests whether the rollers of each peristaltic pump can completely occlude the tubing within the pump raceway and for external leakage in the disposable set (damaged component or setup error). Alarm generated is Malfunction: Prime Self-Test, with the message Pump occlusivity 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 (CRRT, TPE) Access and filter pressure pods/sensors (HP)	(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.
TMPa calibration (TPE)	Using the Automatic Reposition system, pressurizes the filter, effluent, and return pressure sensors to various pressures, determines if the sensor characteristics are within 20 percent of each other, then returns the sensors to their initial pressures. Calculates initial TMPa in less than 4 minutes. Failure of either test generates the Malfunction: Prime Self-Test, with the message TMPa calibration failed.
Remote alarm test	Occurs when the "Prime Test Passed" screen is displayed. Tests if the machine is able to send a signal to a remote alarm (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 (if a remote alarm 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 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.)

4.2.3 Periodic Self-test

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

- During a patient treatment (Run mode):

The first periodic self-test starts 10 minutes after Run mode is entered. Then a periodic self-test is conducted every two hours. Periodic self-test may be delayed 10 min by selecting the DELAY softkey. Time schedule of the periodic self-test may also be automatically modified by the system according to next intervention schedule (bag change). 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.



WARNING

The DELAY function shall not be used more than twice in a row. Failure of pressure monitoring systems may occur in case of too many consecutive uses of the DELAY function.

Periodic self-test appears as an Advisory alarm with no CONTINUE softkey. Review Prescription and History information can be read from the self-test alarm screen. A complete periodic self-test takes between 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

[Table 4.3 on page 75](#) lists the subtests done during periodic self-test, in the order they occur. Periodic self-test is interrupted by any Caution, Warning or Malfunction alarm (see exceptions in [Table 4.4 on page 76](#)).

Table 4.3 Subtests of the Periodic Self-test

Subtest	Description
Blood leak detector (CRRT, TPE)	Same as subtest (b) of Blood Leak Detector described in Table 4.2 on page 72 . 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 4.2 on page 72 . 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 (CRRT, TPE)	Same as subtest described in Table 4.2 on page 72 . Alarm generated is Malfunction: Self-Test Failure. A message identifies which pod/sensor or combination of pods/sensors have failed.
Access and filter pressure pods/sensors (HP)	

Table 4.3 Subtests of the Periodic Self-test

Subtest	Description
Return pressure sensor	Same as subtest described in Table 4.2 on page 72 . 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, depending on the subtest in progress. Of the alarms affected, some monitors operator-set limits, some monitors new, temporary limits, and others are disabled.

[Table 4.4 on page 76](#) summarizes alarm monitoring during the periodic self-test.

Table 4.4 Alarm Monitoring During the Periodic Self-test

Subtest	Alarm Name	Operator-set limit	Temporary limit	Disabled
Return pressure sensor	Return disconnection	X		
	Return extremely positive	X		
	Return pressure dropping	X		
	Return too positive	X		
Access pressure sensor	Access extremely negative (Monitored for negative pressure blood source only.)		100 mmHg below operator-set limit.	
	Access extremely positive (Monitored for positive pressure blood source only.)	X		
	Access disconnection			Disabled only during Access repositioning.
	Access pressure rising			X
	Access too negative			X

Table 4.4 Alarm Monitoring During the Periodic Self-test

Subtest	Alarm Name	Operator-set limit	Temporary limit	Disabled
Filter pressure sensor	Filter extremely positive	X		
	Set disconnection			X
	No flow in blood path			X
	Filter clotted			X
	Plasmafilter clotted (TPE)			X
	TMP excessive (CRRT)			X
Effluent pressure sensor	TMPa excessive (TPE)		100 mmHg above TMPa limit computed according to Blood Flow rate setting.	
	Filter clotted			X
	Plasmafilter clotted (TPE)			X
	TMP excessive (CRRT)			X
	TMPa excessive (TPE)		100 mmHg above TMPa limit computed according to Blood Flow rate setting.	

4.2.4 Detailed Description of Prime Self-tests

Pressure Zero Test

When the NEW PATIENT softkey is selected, all pressure pod sensors and the return pressure sensor must be 0 ± 15 mmHg.

Table 4.5 Malfunction : Pressure Zero Test

Alarm	Options
MALFUNCTION: Pressure Zero Test	DISCONNECT,RETEST

Scale Zero Test

When the NEW PATIENT softkey is selected, all scales must read 0 ± 30 gr.

Table 4.6 Malfunction : Scales Zero Test

Alarm	Options
MALFUNCTION: Scales Zero Test	DISCONNECT,RETEST

Line presence sensors of ABD and Return Line Clamp (Pre-loading)

When the NEW PATIENT softkey is selected the Protective system checks the status of the line presence switches in both the ABD and the return line clamp. The micro switches must indicate no line is present in the ABD and no line is present in the return line clamp. If a line is present an alarm message will trigger.

Note: If OVERRIDE is selected, the machine is able to continue, but will display a Caution alarm 'Yellow alarm light' throughout the treatment. An alarm message in the Examine alarms page will also be present.

Table 4.7 Malfunction: Line presence sensors

Alarm	Options
MALFUNCTION: Line in Air Detector	RETEST, OVERRIDE
MALFUNCTION: Line in Clamp	RETEST, OVERRIDE

Pinch Valves

Upper Pinch Valve: The protective system commands the upper (dialysate) pinch valve into the dialysate position, and it's position is verified by the position sensors.

The pinch valve is then commanded into the neutral position and is again verified by the position sensors.

Finally the pinch valve is commanded into the replacement 2 position and verified by the position sensors.

Lower Pinch Valve: The protective system commands the lower (pre/post) pinch valve into the pre position, and it's position is verified by the position sensors.

The pinch valve is then commanded into the neutral position and is again verified by the position sensors.

Finally the pinch valve is commanded into the post position and is verified by the position sensors.

Table 4.8 Malfunction: Pinch Valves

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	21	Upper pinch valve	DISCONNECT, RETEST, NEW SET
MALFUNCTION: Prime Self-Test	22	Lower pinch valve	DISCONNECT, RETEST, NEW SET
MALFUNCTION: Prime Self-Test	23	Upper and lower pinch valve	DISCONNECT, RETEST, NEW SET

Recognition Test

First a reference pressure is measured on the effluent, return and filter pressure sensors. Then the upper pinch valve (dialysate) is set to neutral position, which unclamps the dialysate line. At the same time the lower pinch is set to lower position (POST).

Then the protective system commands the dialysate pump to run for 4 s.

CRRT: The machine looks for a pressure change of more than 5 mmHg.

TPE: As there is no dialysate line in this therapy, the machine looks for a pressure change of less than 5 mmHg.

Table 4.9 Malfunction: Recognition Test

Alarm	Options
WARNING: Set-up error	UNLOAD, RETEST
WARNING: Wrong set loaded	UNLOAD

Syringe Pump

During the anticoagulant syringe installation procedure, the syringe pump must be commanded to run downward for a minimum of 1 sec. and then upwards for a minimum of 1 sec.; during this procedure the protective system checks that both the direction and rate is correct. The test will fail if the protective system determines that the above criteria has not been met or the test has taken longer than 30 seconds.

Note: Before the test, if the test has failed or a syringe has not been loaded, the SYRINGE DISABLE softkey can be selected. Confirming this will deactivate the Syringe Pump for the whole treatment.

Line presence sensors ABD and Return Line Clamp (Post-loading)

After the loading of the set, and the PRIME softkey is selected to initiate Priming, the Protective system checks the status of the line presence switches in both the ABD and the return line clamp. The micro switches must indicate the presence of a line in the ABD and in the return line clamp. If no line is present an alarm message will trigger.

Table 4.10 Malfunction: Line presence sensors(Post loading)

Alarm	Options
MALFUNCTION: No Line in Air Detector	DISCONNECT, RETEST, OVERRIDE
MALFUNCTION: No Line in Clamp	DISCONNECT, RETEST, OVERRIDE

Note: If OVERRIDE is selected the machine is able to continue, but will display a Caution alarm 'Yellow alarm light' throughout the treatment. An alarm message in the Examine alarms page will also be present.

BLD Normalization

Immediately after selecting the PRIME TEST softkey the Protective system requests the PIB board to normalize the BLD.

The PIB adjusts the level of the BLD's transmitter IR LED starting at a transmitter PWM (Pulse Width Modulation) level of 15% and gradually increasing until the BLD IR receiver has a value of 43000 ± 3000 .

The transmitter PWM is the signal controlling the amount of the transmitter, it is switched ON commanded by the PIB.

0% = transmitter OFF

100% = transmitter full ON

The allowed range of the transmitter PWM is between 15% and 45%.

Once the Receiver has a value of 43000 ± 3000 and the transmitter PWM is within the allowable range 15%-45% the transmitter is fixed at this PWM value and the PIB responds to the protective system the Normalization has completed. The protective system checks that the values of the receiver and the transmitter PWM are in the correct range and that the receiver value is below 3000 when the transmitter is switched OFF.

If the PIB has not responded to the protective system that the normalization has completed within 3 minutes or the values of the receiver and transmitter PWM are determined to be out of range by the protective system the test has failed. The protective system can request the PIB to perform the Normalization 3 times before issuing an alarm.

Table 4.11 Malfunction: BLD Nomalization

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	17	Blood leak detector normalization time-out. Normalization value 0.	DISCONNECT, NEW SET, REPRIME, RETEST

BLD Test

Two seconds after a successful BLD normalization the BLD test is performed. The transmitter PWM is lowered to a level simulating a blood leak. The receiver value must be reduced to a value below 15000 within 5 seconds, which is equal to the detection of a blood leak.

Table 4.12 Malfunction: BLD Test

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	18	Blood leak detector threshold error.	DISCONNECT, NEW SET, REPRIME, RETEST

+12Volt ARPS Pump

The protective system requests the control system to start turning the ARPS air pump. The protective system verifies that there is no leakage in the ARPS system by looking for pressure changes in the ARPS system. The protective system then disables the 12volt relay and checks that ARPS pump has stopped by monitoring the ARPS pressure and seeing that there is no change. Finally the protective system re-enables the 12 volt relay and checks that the ARPS pressure sensor value changes.

Table 4.13 Malfunction: +12Volt ARPS Pump

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	24	24volt/12volt	DISCONNECT, RETEST

Air/Pump security (ABD)

The protective system commands the control system to start the Blood pump and the four fluid pumps only when the blood line in the Air Bubble Detector is filled with fluid.

An ABD alarm is simulated by reducing the ABD's transmitter power to a level causing the receiver to detect an Air bubble.

The protective system must see that the:

- Air in blood hardware alarm signal is activated
- Blood pump stop HW command is activated
- All the pumps have really stopped.

The protective system then sends the commands START BP PUMP and START FLUID PUMPS to the control system; all pumps must start.

The protective system then sends the commands STOP FLUID PUMPS to the control system and checks each fluid pump remain stopped while the blood pump is running.

The protective system then sends again the commands START BP PUMP and START FLUID PUMPS to the control system and checks each pump run again.

The protective system then sends again the commands STOP BP PUMP and STOP FLUID PUMPS to the control system and checks each pump remain stopped.

The protective system clears the ABD alarm signal.

The protective system checks that the trouble signal ABD has been activated by the receiver hardware circuitry when the ABD transmitter is first switched ON.

Table 4.14 Malfunction: Air/Pump security (ABD)

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	19	Air/pumps security test	DISCONNECT, RETEST

Pump Occlusivity Test

The protective system commands the control to stop all the pumps and close the return line clamp. The protective system then commands the blood pump to start turning until the return pressure is greater than +400mmHg.

While the blood pump is turning, the protective system counts the number of rotations required to achieve this pressure using the encoder. The number of rotations must not be greater than a specific value dependent on the disposable.

The protective system reads the values of the filter, effluent and return pressure sensors.

After waiting an additional 10 seconds the protective system again reads the pressure values and compares them with the initial recorded values. Depending on which set is used the pressure change should be less than 8 to 18 mmHg.

Table 4.15 Malfunction: Pump Occlusivity Test

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	20	Pump Occlusivity Test	DISCONNECT, NEW SET, REPRIME, RETEST

Return pressure sensor

Immediately after the Occlusivity test the return pressure will normally be greater than 250 mmHg. The protective system commands the control system to run the ARPS pump until the ARPS pressure sensor is equal to that measured by return pressure sensor.

The ARPS system return valve is then opened and the pressure reading of the return and ARPS pressure sensors must be within ±20mmHg.

Table 4.16 Malfunction: Return pressure sensor

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	19	Return pressure sensor	DISCONNECT, NEW SET, REPRIME, RETEST

+24V and Return Clamp

First the protective system commands the control system to close the return clamp.

The protective system then disables the +24V relay in the Power supply and confirms that no +24V is supplied to the machine.

Next the protective system re-enables the +24V relay, confirms the +24V has been restored and checks that the return clamp has remained closed during the above operations.

The protective system finally commands the clamp to open and checks the position sensor, located in the clamp, has detected this correctly.

Table 4.17 Malfunction: +24V and Return Clamp

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	24	24 volt/12 volt	DISCONNECT, RETEST
MALFUNCTION: Prime Self-Test	25	Return clamp sensor	DISCONNECT, RETEST
MALFUNCTION: Prime Self-Test	26	24volt and Return Clamp sensor	DISCONNECT, RETEST

Access, Filter and Effluent pressure pod sensors

Repositioning using the first algorithm

During this test the pressure pods are repositioned and the sensors checked in the following sequence:

- a. Effluent pressure sensor
- b. Access pressure sensor
- c. Filter pressure sensor

Effluent pressure pod/sensor: the initial pressure of the Effluent pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial Effluent pressure value.

A verification of the Effluent pressure sensor is performed, it must be equal to the ARPS pressure sensor ± 20 mmHg for at least 2 seconds.

The ARPS pump is then commanded to run for a maximum of 3000 steps to decrease the Effluent pressure by 100 mmHg. After this the ARPS pump changes direction and re-introduces approximately 1 ml of air (about $\frac{1}{2}$ the working range of the pod).

The effluent valve is closed and the repositioning sequence of the Access pressure pod/sensor is started.

Note: If during the repositioning sequence the effluent and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped and the protective system will start the repositioning on the next pod/sensor.

Access pressure pod/sensor: the initial pressure of the Access pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial access pressure value.

A verification of the Access pressure sensor is performed it must be equal to the ARPS pressure sensor ± 20 mmHg for at least 2 seconds.

The ARPS pump is then commanded to run for a maximum of 3000 steps to decrease the Access pressure by 100 mmHg. After this the ARPS pump changes direction and re-introduces approximately 1 ml of air (about $\frac{1}{2}$ the working range of the pod).

The access valve is then closed and the repositioning sequence of the Filter pressure pod/sensor is started.

Note: If during the repositioning sequence the access and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped and the protective system will start the repositioning on the next pod/sensor.

Filter pressure pod/sensor: the initial pressure of the Filter pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial filter pressure value.

A verification of the Filter pressure sensor is performed; it must be equal to the ARPS pressure sensor ± 20 mmHg for at least 2 seconds.

The ARPS pump is then commanded to run for a maximum of 3000 steps to increase the filter pressure by 100 mmHg. After this the ARPS pump changes

direction and removes approximately 1 ml of air (about $\frac{1}{2}$ the working range of the pod).

The filter valve is then closed and the repositioning is complete.

Note: If during the repositioning sequence the filter and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped.

After the command to close the filter valve, the protective system waits 15 seconds before verifying that the effluent, access and filter pressure sensors are within ± 50 mmHg of their initial stored values.

For any pressure sensor that has failed the first repositioning sequence the protective system will command that a new repositioning sequence using the second repositioning algorithm be performed.

Repositioning using the second algorithm

The valve of the pressure sensor to be repositioned is opened.

For the negative pressure pods (Effluent and Access) the ARPS pump is commanded to run and remove air from the pod, pulling the pod membrane towards the machine until the protective system detects a pressure change greater than 10 mmHg/sec. for 3 second (it determines to be the plateau or end of travel for the pod membrane).

For the positive pod (filter) the ARPS is commanded to pump air into the pod, pushing the pod membrane away from the machine until the end of travel is detected.

The ARPS pump is then commanded by the protective system to run for a maximum of 3000 steps in the opposite direction pumping air into the pod (Effluent and Access) or removing air (Filter) while counting the number of steps of the stepper motor. When a pressure change is greater than 10 mmHg/sec., the end of travel of the pod membrane is again detected and the ARPS pump stops. The protective system then commands the ARPS pump to reverse direction again and run for half the number of steps previously counted between the pod membrane's ends of travel so placing the pod membrane in the middle of the pod before closing the valve.

Note: If during the repositioning sequence the access and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. or the repositioning time-out has been reached >2 minutes the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor has failed. The protective system will start the repositioning on the next pod/sensor.

One of the following codes will be issued if the first and second repositioning has failed on one or more of the pressure pod/sensors.

Table 4.18 Malfunction : Prime Self-Test – Pressure pod/sensor

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	1	Pressure pod/sensor – Access	DISCONNECT, NEW SET, REPRIME, RETEST
MALFUNCTION: Prime Self-Test	2	Pressure pod/sensor – Filter	DISCONNECT, NEW SET, REPRIME, RETEST

Table 4.18 Malfunction : Prime Self-Test – Pressure pod/sensor

Alarm	Code	Due to	Options
MALFUNCTION: Prime Self-Test	3	Pressure pod/sensor – Access and Filter	DISCONNECT, NEW SET, REPRIME, RETEST
MALFUNCTION: Prime Self-Tes	4	Pressure pod/sensor – Effluent	DISCONNECT, NEW SET, REPRIME, RETEST
MALFUNCTION: Prime Self-Tes	5	Pressure pod/sensor – Access and Effluent	DISCONNECT, NEW SET, REPRIME, RETEST
MALFUNCTION: Prime Self-Tes	6	Pressure pod/sensor – Filter and Effluent	DISCONNECT, NEW SET, REPRIME, RETEST
MALFUNCTION: Prime Self-Tes	7	Pressure pod/sensor – Access, Filter and Effluent	DISCONNECT, NEW SET, REPRIME, RETEST

4.2.5 Detailed Description of Periodic self-tests

Note: The Periodic self-tests occur 10 minutes after start of a treatment and then every second hour.

BLD Test

As soon at the Periodic self-test has began the Protective system commands the PIB to start the BLD test. The transmitter PWM is lower to a level simulating a blood leak. The receiver value must be reduced to a value below 15000 within 5 sec., which is equal to the detection of blood leak.

Alarm:

Table 4.19 Malfunction: Self-Test Failure BLD

Alarm	Code	Due to	Options
MALFUNCTION: Self-Test Failure	18	Blood leak detector threshold error	DISCONNECT, RETEST

+24V and Return Clamp

First the protective system commands the control system to close the clamp. The protective system then disables the +24V relay in the Power supply and confirms that no +24V is supplied to the machine.

Next the protective system re-enables the +24V relay, confirms the +24V has been restored and checks that the return clamp has remained closed during the above operations.

The protective system finally commands the clamp to open and checks the position sensor in the clamp has detected this correctly.

Table 4.20 Malfunction: Self-Test Failure +24V and Return Clamp

Alarm	Code	Due to	Options
MALFUNCTION: Self-Test Failure	24	24 volt / 12 volt	DISCONNECT, RETEST
MALFUNCTION: Self-Test Failure	25	Return clamp sensor	DISCONNECT, RETEST

Table 4.20 Malfunction: Self-Test Failure +24V and Return Clamp

Alarm	Code	Due to	Options
MALFUNCTION: Self-Test Failure	26	24 volt and Return clamp sensor	DISCONNECT, RETEST

Access, Filter and Effluent pressure pod sensors

During this test the pressure pods are repositioned and the sensors are checked in the following sequence:

- a. Effluent pressure sensor
- b. Access pressure sensor
- c. Filter pressure sensor

Effluent pressure pod/sensor: the initial pressure of the Effluent pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial effluent pressure value.

A verification of the Effluent pressure sensor is performed, it must be equal to the ARPS pressure sensor $\pm 20\text{mmHg}$ for at least 2 seconds.

The ARPS pump is then commanded to run for a maximum of 3000 steps to decrease the Effluent pressure by 100 mmHg. After this the ARPS pump changes direction and re-introduces approximately 1 ml of air (about $\frac{1}{2}$ the working range of the pod).

The effluent valve is closed and the repositioning sequence of the Access pressure pod/sensor is started.

Note: If during the repositioning sequence the effluent and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped and the protective system will start the repositioning on the next pod/sensor.

Access pressure pod/sensor: the initial pressure of the Access pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial access pressure value.

A verification of the Access pressure sensor is performed it must be equal to the ARPS pressure sensor $\pm 20\text{mmHg}$ for at least 2 seconds.

The ARPS pump is then commanded to run for a maximum of 3000 steps to decrease the access pressure by 100 mmHg. After this the ARPS pump changes direction and re-introduces approximately 1 ml of air (about $\frac{1}{2}$ the working range of the pod).

The access valve is then closed and the repositioning sequence of the Filter pressure pod/sensor is started.

Note: If during the repositioning sequence the access and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped and the protective system will start the repositioning on the next pod/sensor.

Filter pressure pod/sensor: the initial pressure of the Filter pressure sensor is measured and stored. The ARPS pump is then commanded to run until the ARPS pressure sensor is equal to the initial filter pressure value.

A verification of the Filter pressure sensor is performed; it must be equal to the ARPS pressure sensor ± 20 mmHg for at least 2 seconds.

The ARPS pump is then commanded to run for a maximum of 3000 steps to increase the filter pressure by 100 mmHg. After this the ARPS pump changes direction and removes approximately 1 ml of air (about $\frac{1}{2}$ the working range of the pod).

The Filter valve is then closed and the repositioning is complete.

Note: If during the repositioning sequence the filter and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor is skipped.

After the command to close the filter valve, the protective system waits 15 seconds before verifying that the effluent, access and filter pressure sensors are within ± 50 mmHg of their initial stored values.

For any pressure sensor that has failed the first repositioning sequence the protective system will command that a new repositioning sequence using the second repositioning algorithm be performed.

Repositioning using the Second algorithm:

The valve of the pressure sensor to be repositioned is opened.

For the negative pressure pods (Effluent and Access) the ARPS pump is commanded to run and remove air from the pod, pulling the pod membrane towards the machine until the protective system detects a pressure change greater 10 mmHg/sec for 3 seconds (it determines to be the plateau or end of travel for the pod membrane).

For the positive pod (Filter) the ARPS is commanded to pump air into the pod, pushing the pod membrane away from the machine until the end of travel is detected.

The ARPS pump is then commanded by the protective system to run for a maximum of 3000 steps in the opposite direction pumping air into the pod (Effluent and Access) or removing air (filter) while counting the number of steps of the stepper motor. When a pressure change is greater than 10 mmHg/sec, the end of travel of the pod membrane is again detected and the ARPS pump stops. The protective system then commands the ARPS pump to reverse direction again and run for half the number of steps previously counted between the pod membrane's ends of travel so placing the pod membrane in the middle of the pod before closing the valve.

Note: If during the repositioning sequence the access and ARPS pressure sensor values differ by more than 20 mmHg for longer than 5 sec. or the repositioning time-out has been reached >2 minutes the valve closes and the verification/repositioning has failed. The repositioning of this pod/sensor has failed. The protective system will start the repositioning on the next pod/sensor.

One of the following codes will be issued if the first and second repositioning has fails on one or more of the pressure pod/sensors.

Table 4.21 Malfunction: Self-Test Failure – Access, Filter and Effluent pressure pod sensors

Alarm	Code	Due to	Options
MALFUNCTION: Self-Test Failure	1	Pressure pod/sensor – Access	DISCONNECT, RETEST
MALFUNCTION: Self-Test Failure	2	Pressure pod/sensor – Filter	DISCONNECT, RETEST
MALFUNCTION: Self-Test Failure	3	Pressure pod/sensor – Access and Filter	DISCONNECT, RETEST
MALFUNCTION: Self-Test Failure	4	Pressure pod/sensor – Effluent	DISCONNECT, RETEST
MALFUNCTION: Self-Test Failure	5	Pressure pod/sensor – Access and Effluent	DISCONNECT, RETEST
MALFUNCTION: Self-Test Failure	6	Pressure pod/sensor – Filter and Effluent	DISCONNECT, RETEST
MALFUNCTION: Self-Test Failure	7	Pressure pod/sensor – Access, Filter and Effluent	DISCONNECT, RETEST

Return pressure sensor

The protective system commands the control system to run the ARPS pump until the ARPS pressure sensor is equal to that of the return pressure sensor.

The ARPS system return valve is then opened. The pressure reading of the return and ARPS pressure sensors must be within ± 20 mmHg of each other.

Table 4.22 Malfunction: Self-Test Failure – Return pressure sensor

Alarm	Code	Due to	Options
MALFUNCTION: Self-Test Failure	16	Return Pressure Sensor	DISCONNECT, NEW SET, REPRIME, RETEST

4.3 Technical Screens

The Technical Screens display technical data related to the current status of components such as pumps, scales, pressures, ABD, Patient Sensor, ARPS, Pinch Valves, Power Supply, Loader. The fourth Technical screen displays the main software version installed on the control unit and the software version of the boards.

Press the date on the top right corner of any screen to access the Technical Screens. Use the Up and Down Arrows to navigate.

4.3.1 First Technical Screen

Below is the first Technical Screen:

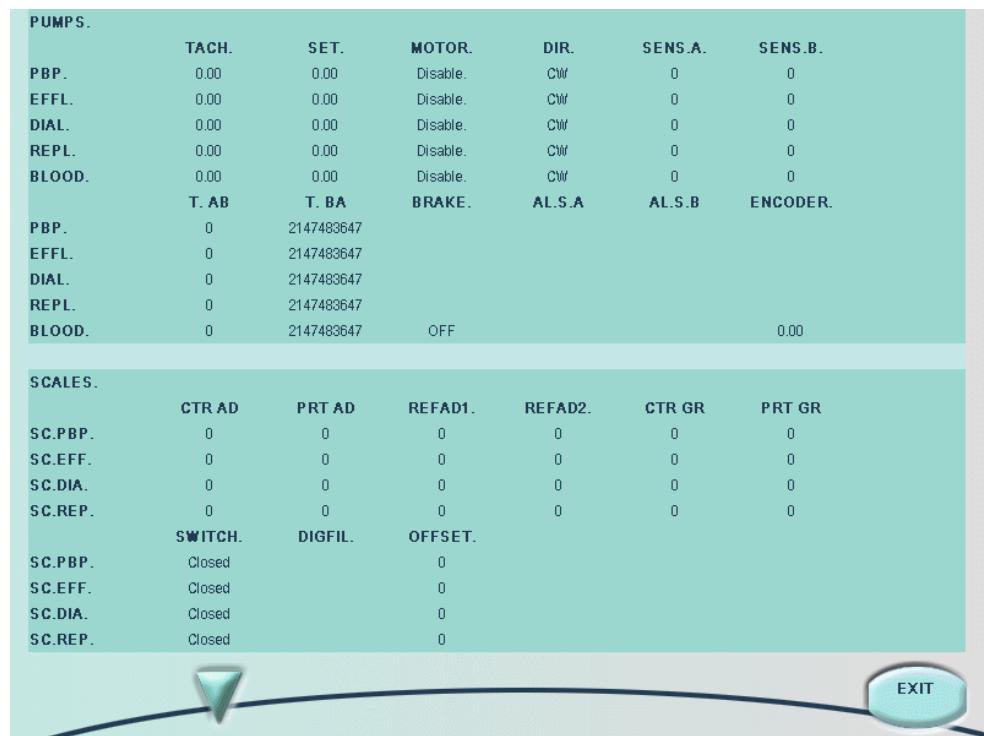


Figure 4.2 First Technical Screen

Table 4.23 Parameters Displayed in the First Technical Screen

Parameter	Description
PBP. TACH	Value, in rpm, of the PBP Pump speed read by the Protective side.
EFF. TACH	Value, in rpm, of the Effluent Pump speed read by the Protective side.
DIAL. TACH	Value, in rpm, of the Dialysate Pump speed read by the Protective side.

Table 4.23 Parameters Displayed in the First Technical Screen

Parameter	Description
REPL.TACH	Value, in rpm, of the Replacement Pump speed read by the Protective side.
BLOOD.TACH	Value, in rpm, of the Blood Pump speed read by Protective side.
PBP. SET	Value, in rpm, of the PBP Pump speed set by the Control side.
EFF. SET	Value, in rpm, of the Effluent Pump speed set by the Control side.
DIAL. SET	Value, in rpm, of the Dialysate Pump speed set by the Control side.
REPL.SET	Value, in rpm, of the Replacement Pump speed set by the Control side.
BLOOD.SET	Value, in rpm, of the Blood Pump speed set by the Control side.
PBP. MOTOR.	PBP Pump Motor status. Possible values displayed are: Enable/Disable.
EFF. MOTOR.	Effluent Pump Motor status. Possible values displayed are: Enable/Disable.
DIAL. MOTOR.	Dialysate Pump Motor status. Possible values displayed are: Enable/Disable.
REPL. MOTOR.	Replacement Pump Motor status. Possible values displayed are: Enable/Disable.
BLOOD. MOTOR.	Blood Pump Motor status. Possible values displayed are: Enable/Disable.
PBP. DIR.	PBP Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise).
EFF. DIR.	Effluent Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise).
DIAL. DIR.	Dialysate Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise).
REPL. DIR.	Replacement Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise).
BLOOD. DIR.	Blood Pump running direction. Possible values displayed are: CW (clockwise)/CCW (counterclockwise).
PBP. SENS. A.	Number of pulses accumulated for the hall sensor A of the PBP Pump.
EFF. SENS. A.	Number of pulses accumulated for the hall sensor A of the Effluent Pump.
DIAL. SENS. A.	Number of pulses accumulated for the hall sensor A of the Dialysate Pump.
REPL. SENS. A.	Number of pulses accumulated for the hall sensor A of the Replacement Pump.
BLOOD. SENS. A.	Number of pulses accumulated for the hall sensor A of the Blood Pump.
PBP. SENS. B.	Number of pulses accumulated for the hall sensor B of the PBP Pump.
EFF. SENS. B.	Number of pulses accumulated for the hall sensor B of the Effluent Pump.

Table 4.23 Parameters Displayed in the First Technical Screen

Parameter	Description
DIAL. SENS. B.	Number of pulses accumulated for the hall sensor B of the Dialysate Pump.
REPL. SENS. B.	Number of pulses accumulated for the hall sensor B of the Replacement Pump.
BLOOD. SENS. B.	Number of pulses accumulated for the hall sensor B of the Blood Pump.
PBP. T. AB.	Delay between the time in which the magnet (on the PBP Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B.
EFF. T. AB.	Delay between the time in which the magnet (on the Effluent Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B.
DIAL. T. AB.	Delay between the time in which the magnet (on the Dialysate Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B.
REPL. T. AB.	Delay between the time in which the magnet (on the Replacement Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B.
BLOOD. T. AB.	Delay between the time in which the magnet (on the Blood Pump rotor) closes the circuit of the sensor A and the time in which the magnet closes the circuit of the sensor B.
PBP. T. BA.	Delay between the time in which the magnet (on the PBP Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A.
EFF.T. BA.	Delay between the time in which the magnet (on the Effluent Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A.
DIAL. T. BA.	Delay between the time in which the magnet (on the Dialysate Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A.
REPL. T. BA.	Delay between the time in which the magnet (on the Replacement Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A.
BLOOD. T. BA.	Delay between the time in which the magnet (on the Blood Pump rotor) closes the circuit of the sensor B and the time in which the magnet closes the circuit of the sensor A.
PBP. BRAKE.	Not used.
EFF. BRAKE.	Not used.
DIAL. BRAKE.	Not used.
REPL.BRAKE.	Not used.

Table 4.23 Parameters Displayed in the First Technical Screen

Parameter	Description
BLOOD.BRAKE.	Status of the break on the Blood Pump. Possible values displayed are: Enabled/Disabled.
PBP. AL. S. A.	Not used.
EFF. AL. S. A.	Not used.
DIAL. AL. S. A.	Not used.
REPL. AL. S. A.	Not used.
BLOOD. AL. S. A.	Not currently used.
PBP. AL. S. B.	Not used.
EFF. AL. S. B.	Not used.
DIAL. AL. S. B.	Not used.
REPL. AL. S. B.	Not used.
BLOOD. AL. S. B.	Not currently used.
SC. PBP. CTR AD	PBP scale A/D value read by the Control side.
SC. EFF. CTR AD	Effluent scale A/D value read by the Control side.
SC. DIAL.CTR AD	Dialysate scale A/D value read by the Control side.
SC. REPL.CTR AD	Replacement scale A/D value read by the Control side.
SC. PBP. PRT AD	PBP scale A/D value read by the Protective side.
SC.EFF. PRT AD	Effluent scale A/D value read by the Protective side.
SC. DIAL. PRT AD	Dialysate scale A/D value read by the Protective side.
SC. REPL. PRT AD	Replacement scale A/D value read by the Protective side.
SC. PBP. REFAD1.	PBP scale A/D reference 1 value. (1st A/D channel)
SC. EFF. REFAD1.	Effluent scale A/D reference 1 value. (1st A/D channel)
SC. DIAL. REFAD1	Dialysate scale A/D reference 1 value. (1st A/D channel)
SC. REPL. REFAD1	Replacement scale A/D reference 1 value. (1st A/D channel)
SC. PBP. REFAD2.	PBP scale A/D reference 2 value. (2nd A/D channel)
SC. EFF. REFAD2.	Effluent scale A/D reference 2 value. (2nd A/D channel)
SC. DIAL. REFAD2	Dialysate scale A/D reference 2 value. (2nd A/D channel)
SC. REPL. REFAD2	Replacement scale A/D reference 2 value. (2nd A/D channel)
SC. PBP. CTR GR	Weight in grams, on the PBP scale, read by the Control side.
SC. EFF. CTR GR	Weight in grams, on the Effluent scale, read by the Control side.
SC. DIAL. CTR GR	Weight in grams, on the Dialysate scale, read by the Control side.

Table 4.23 Parameters Displayed in the First Technical Screen

Parameter	Description
SC. REPL. CTR GR	Weight in grams, on the Replacement scale, read by the Control side.
SC. PBP. PRT GR	Weight in grams, on the PBP scale, read by the Protective side.
SC. EFF. PRT GR	Weight in grams, on the Effluent scale, read by the Protective side.
SC. DIAL. PRT GR	Weight in grams, on the Dialysate scale, read by the Protective side.
SC. REPL. PRT GR	Weight in grams, on the Replacement scale, read by the Protective side.
SC. PBP. SWITCH	Status of the PBP scale switch (scale open/scale close) Possible values displayed are: Open/Close.
SC. EFF. SWITCH	Status of the Effluent scale switch (scale open/scale close) Possible values displayed are: Open/Close.
SC. DIAL. SWITCH	Status of the Dialysate scale switch (scale open/scale close) Possible values displayed are: Open/Close.
SC. REPL. SWITCH	Status of the Replacement scale switch (scale open/scale close). Possible values displayed are: Open/Close.
SC. PBP. DIGFIL	Not currently used.
SC. EFF. DIGFIL	Not currently used.
SC. DIAL. DIGFIL	Not currently used.
SC. REPL. DIGFIL	Not currently used.

4.3.2 Second Technical Screen

Below is the second Technical Screen:

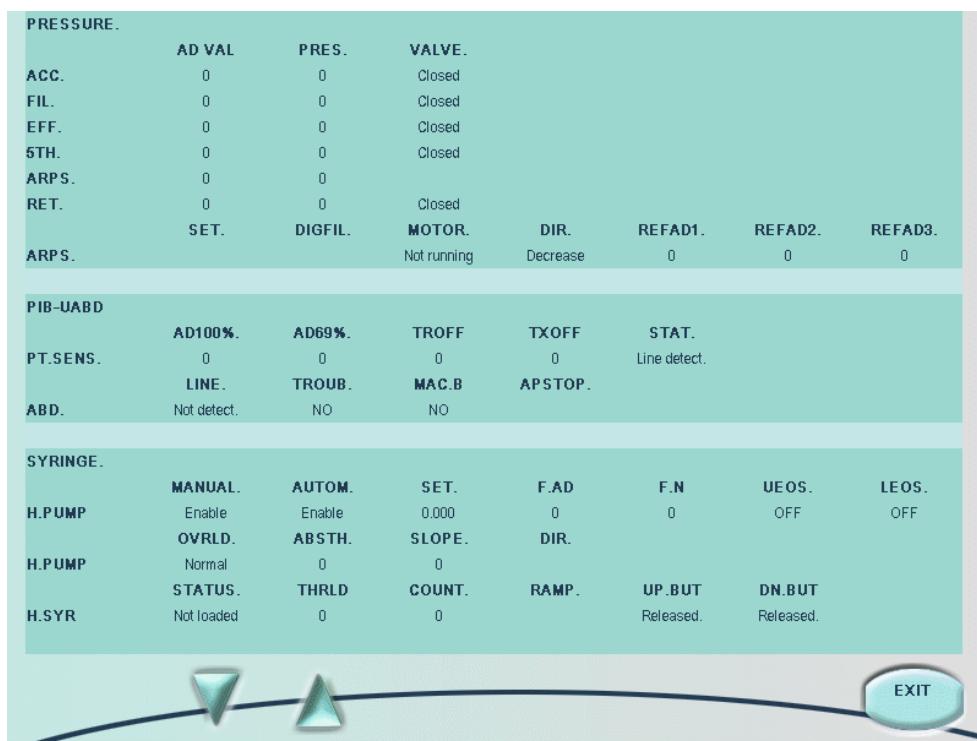


Figure 4.3 Second Technical Screen

Table 4.24 Parameters Displayed in the Second Technical Screen

Parameter	Description
ACC. AD. VAL	Access pressure A/D value acquired by the transducer.
FIL. AD. VAL	Filter pressure A/D value acquired by the transducer.
EFF. AD. VAL	Effluent pressure A/D value acquired by the transducer.
5TH. AD. VAL	5th Pod pressure A/D value acquired by the transducer.
ARPS. AD. VAL	Circuit pressure A/D value acquired by the ARPS.
RET. AD. VAL	Return pressure A/D value acquired by the transducer.
ACC. PRES	Access pressure value read by the Protective side.
FIL. PRES	Filter pressure value read by the Protective side.
EFF. PRES	Effluent pressure value read by the Protective side.
5TH. PRES	5th Pod pressure value read by the Protective side.
ARPS. PRES	ARPS circuit pressure read by the Protective side.
RET. PRES	Return pressure value read by the Protective side.

Table 4.24 Parameters Displayed in the Second Technical Screen

Parameter	Description
ACC. VALVE	Access valve status. Possible values displayed are: Open/Close.
FIL. VALVE	Filter valve status. Possible values displayed are: Open/Close.
EFF. VALVE	Effluent valve status. Possible values displayed are: Open/Close.
5TH. VALVE	5th Pod valve status. Possible values displayed are: Open/Close.
ARPS. VALVE	Not currently used.
RET. VALVE	Return valve status. Possible values displayed are: Open/Close.
ARPS. SET.	Not currently used.
ARPS. DIGFIL.	Not currently used.
ARPS. MOTOR.	ARPS Motor status. Possible values displayed are: Running, Not running.
ARPS. DIR.	ARPS Direction (Decrease = the motor runs in clockwise direction/Increase = the motor runs in counterclockwise direction) Possible values displayed are: Decrease, Increase.
ARPS. REFAD1.	ARPS A/D reference 1 value read by the Protective side.
ARPS. REFAD2.	ARPS A/D reference 2 value read by the Protective side.
ARPS.REFAD3.	ARPS A/D reference 3 value read by the Protective side.
PT. SENS. AD 100%	Patient sensor value when the transmitter power is 100%.
PT. SENS. AD 69%	Patient sensor value when the transmitter power is 69%.
PT. SENS. TROFF.	Patient sensor value when the transmitter/receiver is OFF.
PT. SENS. TXOFF.	Patient sensor value when the transmitter is OFF.
PT. SENS. STAT.	Patient sensor status. Possible values displayed are: Blood/Line Detected/Not detected.
ABD. LINE.	Presence of line in the ABD. Possible values displayed are: Line Detected/Not detected.
ABD. TROUB.	Malfunction detected in the ABD circuit. Possible values displayed are: ON/OFF
ABD. MAC.B.	Macro Bubble detected by the ABD. Possible values displayed are: ON/OFF.
ABD. APSTOP	Not currently used.
H.PUMP. MANUAL.	Activation of the Manual Mode of the Syringe Pump. Possible values displayed are: Enabled/Disabled.

Table 4.24 Parameters Displayed in the Second Technical Screen

Parameter	Description
H.PUMP. AUTOM.	Activation of the Automatic Mode of the Syringe Pump. Possible values displayed are: Enabled/Disabled.
H.PUMP. SET.	Syringe Pump rate set.
H.PUMP. F. AD.	A/D value of the load applied to the syringe plunger clamp read by the Syringe Pump.
H.PUMP. F.N.	Load applied to the syringe plunger clamp in Newtons (N).
H.PUMP. UEOS.	Upper End of stroke of the syringe plunger clamp reached. Possible values displayed are: OFF/ON.
H.PUMP. LEOS.	Lower End of stroke of the syringe plunger clamp reached. Possible values displayed are: OFF/ON.
H.PUMP. OVRLD.	Type of the overload condition of the Syringe Pump. Possible values displayed are: OFF/ON.
H.PUMP. ABSTH.	Threshold of the absolute overload of the Syringe Pump expressed in Newton.
H.PUMP. SLOPE.	Absolute slope threshold of the Syringe Pump expressed in N/mm.
H.PUMP. DIR.	Not currently used.
H. SYR. STATUS.	Status of the syringe. Possible values displayed are: Loaded/Not loaded.
H. SYR. THRLD.	Threshold for the detection of a syringe loaded.
H. SYR. COUNT.	Counter of the encoder pulses received at the selection of the Syringe control panel UP button when the Syringe Pump is in manual mode.
H. SYR. RAMP.	Not currently used.
H. SYR. UP. BUT.	Status of the UP button on the Syringe control panel. Possible values displayed are: Pressed/Released.
H. SYR. ON. BUT.	Status of the DOWN button on the Syringe control panel. Possible values displayed are: Pressed/Released.

4.3.3 Third Technical Screen

Below is the third Technical Screen:

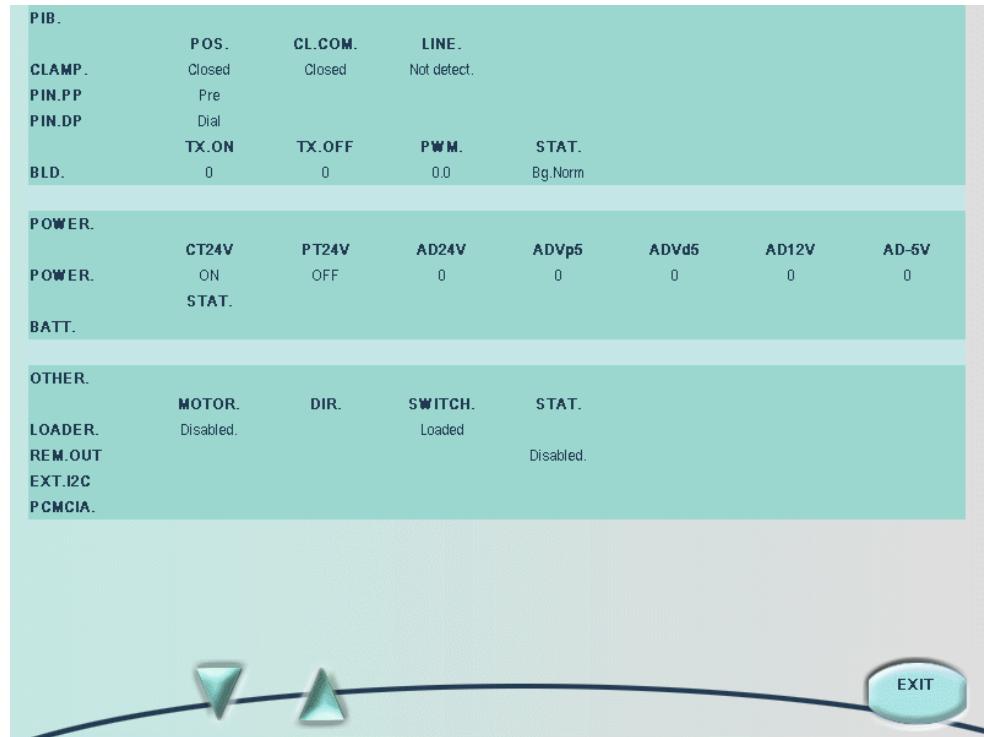


Figure 4.4 Third Technical Screen

Table 4.25 Parameters Displayed in the Third Technical Screen

Parameter	Description
CLAMP. POS	Return clamp status. Possible values displayed are: Open/Closed.
PIN. PP. POS	Lower pinch valve position. Possible values displayed are: Pre/Neutral/Post/Undefined.
PIN.DP. POS	Upper pinch valve position. Possible values displayed are: Pre/Neutral/Post/Undefined.
CLAMP. CL.COM	Comment sent by the Control side to the return clamp. Possible values displayed are: Open/Closed.
PIN. PP. CL.COM	Not used.
PIN.DP. CL.COM	Not used.
CLAMP. LINE	Line presence in the Return line clamp. Possible values displayed are: Line Detected/Not detected.
PIN. PP. LINE	Not used.
PIN.DP. LINE	Not used.
BLD. TX. ON	BLD A/D value read when the transmitter is ON.

Table 4.25 Parameters Displayed in the Third Technical Screen

Parameter	Description
BDL. TX. OFF	BLD A/D value read when the transmitter is OFF.
BDL. PWM.	PWM value.
BDL. STAT.	Status of the BLD normalization procedure. Possible values displayed are: Bg.Norm M.pwm.BLD Ms.BLD VrA.regst W.A.regDn C.pwmVal Tst.W.stop Test ok Test Fail
POWER. CT24V	Status of the +24V relay in the Power supply (Enabling/Disabling done by the Control side). Possible values displayed are: OFF/ON.
POWER. PT24V	Status of the +24V relay in the Power supply (Enabling/Disabling done by the Protective side). Possible values displayed are: OFF/ON.
POWER. AD24V	+24V A/D value.
POWER. ADVp5	5Vp A/D value.
POWER. ADVd5	5Vd A/D value.
POWER. AD12V	+12V A/D value.
POWER. AD5V	5V A/D value.
BATT. STAT.	Not currently used.
LOADER. MOTOR	Status of the motor of the Prismaflex set loader. Possible values displayed are: Enable/Disable.
REM. OUT MOTOR	Not used.
EXT.I2C MOTOR	Not used.
PCMCIA. MOTOR	Not used.
LOADER. DIR	Not used
REM. OUT DIR	Not currently used.
EXT.I2C DIR	Not currently used.
PCMCIA. DIR	Not used.
LOADER. SWITCH.	Status of the switch of the Prismaflex set loader. Possible values displayed are: Loaded / Not Loaded.
REM. OUT SWITCH.	Not used.
EXT.I2C SWITCH.	Not used.

Table 4.25 Parameters Displayed in the Third Technical Screen

Parameter	Description
PCMCIA. SWITCH.	Not used.
LOADER. STAT.	Not used.
REM. OUT STAT.	Status of the remote alarm output. Possible values displayed are: Enabled/Disabled.
EXT.I2C STAT.	Not used.
PCMCIA. STAT.	Not currently used.

4.3.4 Fourth Technical Screen

Below is the fourth Technical Screen:

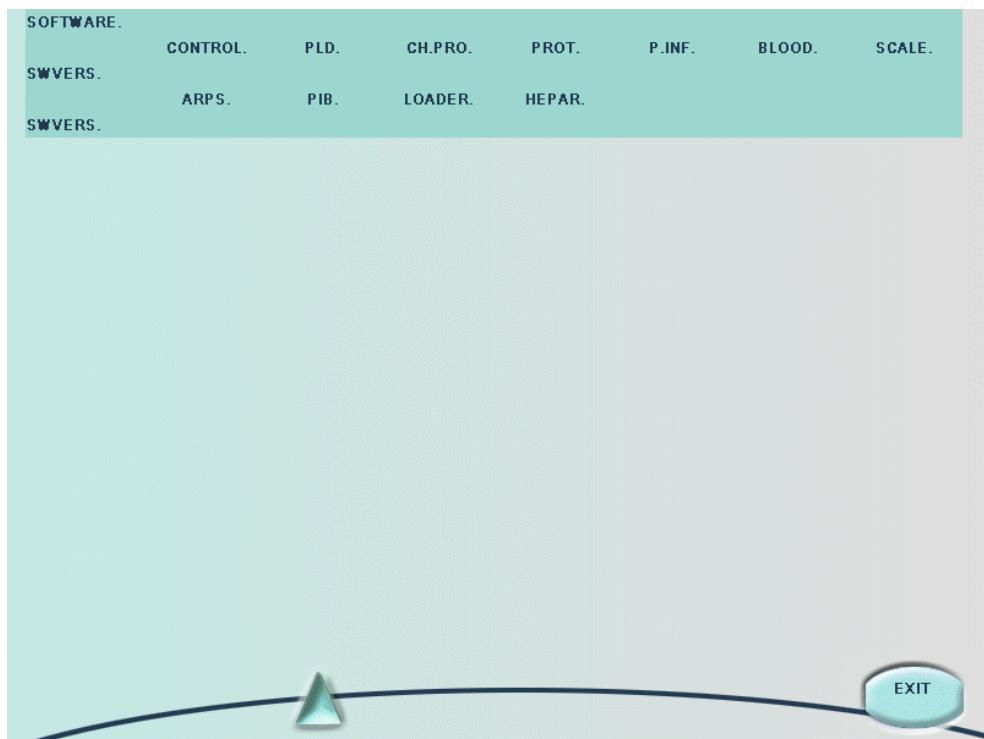


Figure 4.5 Fourth Technical Screen

Table 4.26 Parameters Displayed in the Fourth Technical Screen

Parameter	Description
SWVERS. CONTROL	Software version of the Control System. The Software version includes build information, which is not visible in every place of the application.
SWVERS.PLD.	Software version of the PLD Board.
SWVERS. CH. PRO.	Software version of the Carrier Board.
SWVERS. PROT.	Software version of the Protective Board.
SWVERS. P. INF.	Not currently used.
SWVERS. BLOOD.	Old Pump: Not currently used. New Pump: Software version of the Blood Pump.
SWVERS. SCALE.	Not currently used.
SWVERS. ARPS.	Software version of the ARPS Board.

Table 4.26 Parameters Displayed in the Fourth Technical Screen

Parameter	Description
SWVERS. PIB.	Software version of the PIB Board.
SWVERS. LOADER.	Not currently used.
SWVERS. HEPAR.	Not currently used.

Chapter 5: Alarm System and Troubleshooting

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.



WARNING

- When responding to any alarm, carefully follow the instructions on the displayed alarm screen and its associated Help screen.
- To clear some alarms, the 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 remedy the cause of failure.
- 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.
- 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.

5.1 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.

5.1.1 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.

5.1.2 Operator Response

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

When the alarm has been cleared, the following occurs:

- Warning screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

5.1.3 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:

- Warning screen leaves the display.
- Yellow light illuminates.
- EXAMINE ALARMS softkey remains displayed.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

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

5.2 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.

5.2.1 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.

5.2.2 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.

When the alarm has been cleared, the following occurs:

- Malfunction screen leaves the display.
- Green light illuminates.
- EXAMINE ALARMS softkey disappears, unless there are other active alarms.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

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 shall be terminated manually. See “[5.11 Manual Termination of Treatment](#)” on page 154.

- Turn off the power.
- Repair the control unit and clear the alarm.

5.2.3 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:

- Malfunction screen leaves the display.
- Yellow light illuminates.
- EXAMINE ALARMS softkey remains displayed.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

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

5.3 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 PBP, dialysate or replacement solution bag is empty or the effluent bag is full.

5.3.1 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.

5.3.2 Operator Response

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

When the alarm has been cleared, the following occurs:

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

5.4 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.

5.4.1 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.

5.4.2 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.

5.4.3 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 “[5.5 Alarm Priorities](#)” on page 108 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.

5.5 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.

[Table 5.1 on page 108](#) shows the priority for each alarm.

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.

Press EXAMINE ALARMS to view the list of pending alarms.

Table 5.1 Alarm Priorities

Priority	Alarm Title
Malfunctions (High Priority)	
1	General system failure
2	Communication error (Error code: XX Due to: XXXXXX) Note: Error code is 2–7. The alarm screen identifies the reason.
3	Memory error (Error code: XX Due to: XXXXXX) Note: Error code is 4, 6. The alarm screen identifies the reason.
4	Pressures Circuit Board
5	Voltage Out of Range
Warnings	
6	Air in blood
7	Return disconnection
8	Return pressure dropping
9	Set disconnection
10	Access disconnection
11	Filter clotted
12	Plasmafilter clotted
13	HP cartridge clotted
14	Blood leak detected
15	Return extremely positive
16	Access extremely negative
17	Access extremely positive
18	Filter extremely positive
19	Power failure

Table 5.1 Alarm Priorities

Priority	Alarm Title
20	Wrong set loaded (Due to: Bar code information)
21	Effluent Bag full (priming) (Effluent bag is full.)
22	Bag/container empty (priming) (XXXXXX bag is empty.) Note: The alarm screen identifies the bag.
23	Bag Volume Incorrect (priming) (Bag volume incorrect for: XXXXXX) Note: The alarm screen identifies the bag.
24	Effluent Bag Incorrect (priming) (Effluent Bag volume does not match Allowed Volume.)
25	Scale open (priming) (Scale not properly closed: XXXXXX) Note: The alarm screen identifies the scale.
26	Clamped lines (XXXXXX line is obstructed.) Note: The alarm screen identifies the line.
27	Syringe Empty-Clamped (priming)
28	Blood detected in set
29	Recirculation Time Exceeded
30	Set-up error
31	Crossed lines (Crossed lines/bags between: XXXXXX) Note: The alarm screen identifies the lines.
32	Wrong set selected
33	Wrong set loaded (Due to: Failure of recognition test)
Malfunctions	
34	Air detector
35	Clamp stuck closed
36	XXXXXX pump (Rate is incorrect.) Note: The alarm screen identifies the pump.
37	Normalization failed
38	Blood leak detector (Effluent line not properly installed in blood leak detector.)
39	Self-test failure (Code: XX Due to: XXXXXX) Note: Code is 1–7, 16, 18, 24–26. The alarm screen identifies the reason.
40	Prime self-test (Code: XX Due to: XXXXXX) Note: Code is 1–7, 16–28. The alarm screen identifies the reason.
41	Syringe pump (Rate is incorrect.)

Table 5.1 Alarm Priorities

Priority	Alarm Title
42	Scales (Scale out of calibration: XXXXX) Note: The alarm screen identifies the scale.
43	Pressure zero test
44	Scale zero test
45	Checksum interrupted (Cannot verify data in block: XX) Note: The alarm screen identifies the block.
46	Custom data (Custom mode data cannot be accessed for this treatment.)
47	Library data (Default data cannot be accessed.)
48	Cannot save custom data (New custom mode value(s) cannot be saved.)
49	Memory error (Error code: XX Due to: XXXXXX) Note: Error code is 1, 3, 5. The alarm screen identifies the reason.
50	Upper pinch valve
51	Lower pinch valve
52	Scales circuit board
53	XXXXXX scale sensor Note: The alarm screen identifies the scale sensor.
54	Syringe Not Loaded
55	Line in air detector
56	Line in clamp
57	No line in air detector
58	No line in clamp
Cautions	
59	Loss/Gain limit reached
60	Incorrect Weight Change 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 (Incorrect weight change detected for replacement bag 2 (green scale).)
66	TPE Prescription Delivered

Table 5.1 Alarm Priorities

Priority	Alarm Title
67	Effluent bag full
68	Dialysate bag empty
69	Replacement bag 2 empty
70	Replacement bag empty
71	Replacement container empty
72	PBP bag empty
73	TMP excessive (Transmembrane pressure exceeds membrane pressure limit.)
74	TMPa excessive (Access transmembrane pressure exceeds the safe limit.)
75	Bag volume incorrect (Bag volume incorrect for: XXXXX) Note: The alarm screen identifies the bag.
76	Effluent Bag Incorrect (Effluent Bag volume does not match Allowed Volume)
77	Scale open (Scale not properly closed: XXXXX) Note: The alarm screen identifies the scale.
78	No Flow in Blood Path (Filter pressure drop is minimal. Blood is not circulating through access/return lines.)
79	Patient Fluid Gain Excessive (PBP fluid input has reached the maximum allowed patient fluid gain for the therapy/set.)
Advisories	
80	Self-test in progress
81	Clamped Bag – XXXXX Note: The alarm screen identifies the bag.
82	Access pressure rising
83	Access too negative
84	Return too positive
85	Blood flow stopped (Machine has been left in the Stop screen for 60 seconds.)
86	Syringe Not Loaded
87	Fluid pumps stopped
88	Check Syringe Line
89	Syringe Empty-Clamped
90	Filter is clotting (Increasing TMP and/or pressure drop.)
91	Plasmafilter is clotting (Increasing pressure drop.)

Table 5.1 Alarm Priorities

Priority	Alarm Title
92	HP cartridge is clotting (Increasing pressure drop.)
93	TMP too high (Transmembrane pressure has reached user-set pressure limit.)
94	TMPa too high (Access transmembrane pressure has reached user-set pressure limit.)
95	Time to change set
96	Preventive maintenance due
97	Cannot detect return (Return disconnection cannot be detected. Return pressure is more negative than +10 mmHg alarm limit.)
98	Cannot detect access (negative range pressure monitoring) (Access disconnection cannot be detected. Access pressure is more positive than -10 mmHg alarm limit.)
99	Cannot detect access (positive range pressure monitoring) (Access disconnection cannot be detected. Access pressure is more negative than +10 mmHg alarm limit.)
100	Scale component missing (Carrying bar is missing from: XXXXX scale) Note: The alarm screen identifies the scale.
101	Anticoagulation check points (Citrate anticoagulation requires additional monitoring of patient's parameters.)

5.6 Warning Alarms Troubleshooting

Table 5.2 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.	Access catheter disconnected; line is clamped below the access pressure pod.	Remedy; press OVERRIDE. ^a
	Blood flow rate too low for the access device.	Increase the blood flow rate; press OVERRIDE. ^a Note: If the above Operator Responses do not clear the alarm, the set can be changed and the alarm cleared via STOP. ^b If alarm recurs with a new set, end treatment via STOP ^b ; call service.
	Access pressure pod not installed or debris in access sensor housing.	Perform Pod Adjustment procedure on access pod (see instructions at end of Troubleshooting chapter). Reprime the set by pressing STOP ^b and perform the Recirculation procedure, or, use Change Set to load/prime a new set. If alarm recurs with new set, end treatment via STOP ^b ; call service.
	Access pressure sensor failed.	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.	Patient is moving or coughing, or being moved or suctioned; access line clamped or kinked.	Remedy cause; wait 16–20 seconds for possible self-clearing. ^c If alarm does not self-clear, go to next Operator Response.
	Access catheter clotted or out of position in vein; blood flow rate too high for the access device.	If needed: (a) flush/reposition access catheter per hospital protocol; (b) Use access sample site to infuse saline and release negative pressure / lower blood flow rate. Press CONTINUE. Note: If the above Operator Responses do not clear the alarm, the set can be changed and the alarm cleared via STOP. ^b If alarm recurs with new set, end treatment via STOP ^b . Call service.
	Access pressure measurement failure (pod membrane out of position) Note: Self-test interruption as a common root cause	Perform a manual repositioning of access pod diaphragm. Press CONTINUE.
	Access pressure sensor failed.	End treatment via STOP ^b . Call service.

Table 5.2 Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Access 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.	External device (if in use) is delivering blood at a too high pressure.	Reduce the delivery pressure of the external device.
	Blood flow rate has been set too low according to the blood pressure delivered by the external device.	Increase the blood flow rate; return to alarm screen and press CONTINUE. Note: If the above Operator Responses do not clear the alarm, the set can be changed and the alarm cleared via STOP. ^b If alarm recurs with new set, end treatment via STOP. ^b Call service.
	Access pressure sensor failed.	End treatment via STOP. ^b Call service.
Air in Blood	Disconnected line; leaking connection; set not fully primed	<ul style="list-style-type: none"> • If needed, remedy possible causes. • Press Up arrow until return pressure is NEGATIVE. If unsuccessful, proceed with manual procedure (see "5.13.2 Air in Blood Alarm – Manual Air Removal" on page 162). • Press RELEASE CLAMP to remove air and draw blood from patient into the return line / deaeration chamber. • If needed, use arrows to adjust the level of fluid in the chamber. • When ready, press CONTINUE. <p>Note: If air is prevalent in entire set, press DISCONNECT and change set.</p>
	Air/foam in the tubing	In case of recurring alarm, open door of air bubble detector and look for air/foam in the tubing; inspect level of fluid in deaeration chamber. Close air bubble detector door. Press CONTINUE.
	Return line not installed in air bubble detector.	Install return line in air bubble detector. When ready, press CONTINUE.
Bag/container empty (XXXXXXXXXXXXXX is empty.) (Priming only) Depending on therapy, the following may be identified: Replacement bag Dialysate bag PBP bag Replacement bag 2 (green scale)	Identified bag is empty. ^d	Connect a new bag; press CONTINUE.
	Identified bag is partially supported (not hanging freely).	Remove partial support; press CONTINUE.

Table 5.2 Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Bag Volume Incorrect (Bag volume incorrect for: XXXXXX) Amount of fluid in bag does not match Allowed Volume.) (Priming only) (Valid only if Variable Tare is selected as Empty bag method)	Amount of fluid in the identified bag does not match the current Allowed Volume.	Choose one of the three options on the alarm screen. Warning: Carefully read 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.
The following may be identified: Replacement bag Dialysate bag PBP bag Replacement bag 2 (green scale)	No bag on scale.	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.
	Foreign object on scale.	Remove foreign object, press CONTINUE.
	Identified bag is partially supported (not hanging freely).	Remove partial support; press CONTINUE.
Blood detected in set (Pt blood sensor identifies blood in tubing.)	In Priming mode: foam in return line; return line installed in air bubble detector before expected, or is out of position in the air bubble detector.	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, check return line installation, press NO PATIENT to continue with Priming and patient connection. If alarm recurs with a new set, call service. Warning: NO PATIENT = 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.
	In Run mode: resume after switching OFF	Press CONTINUE to resume treatment
	In End treatment mode: poor blood rinseback done before Recirculation.	Verify patient is disconnected. If patient is disconnected then press NO PATIENT and continue with recirculation. If patient is connected then press DISCONNECT and change set.
	Patient sensor has failed.	Press DISCONNECT. Call service.

Table 5.2 Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Blood leak detected (CRRT, TPE)	Air bubble in effluent line at level of blood leak detector.	Press OVERRIDE ^a to dislodge bubble. In case of recurring air bubbles (effluent fluid degassing), check for kink effluent line and/or reduce uf rate.
	Effluent line not properly installed in blood leak detector.	Press line into detector from the bottom up and route securely through tubing guides. Press OVERRIDE. ^a
	Liquid or other debris in tubing path through the detector.	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
	Leak in filter membrane.	Change the set via STOP. ^b
	TPE: formed elements or lipids in plasma, discolored plasma.	Press OVERRIDE. ^a Lower replacement rate and/or patient plasma loss rate. Note: If this does not clear the alarm, the set can be changed via STOP. ^b If alarm recurs with a new set and lowered flow rates, discontinue treatment.
Clamped Lines	One of the lines is clamped.	Unclamp the line; Press REPRIME
	Occluded disposable set	Press DISCONNECT; Change set.
	One or more pressures sensors failed	Press DISCONNECT; Call service.
Crossed Lines	The lines are crossed or mingled.	Check and correct lines and bags set-up; Press REPRIME.
	Foreign object on scale	Remove the object; Press REPRIME.
	One or more scales failed	Press DISCONNECT; Turn off the machine; Call for service
Effluent bag full (Effluent bag is full.) (Priming only) (CRRT, TPE)	Effluent bag is full.	Connect a new effluent bag via instructions on the alarm screen. Press CONTINUE.
	Foreign object on effluent scale.	Remove foreign object, press CONTINUE.

Table 5.2 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) (CRRT, TPE)	A 5 liter empty bag is hanged on scale while Effluent Allowed Volume is 9000 ml.	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.
	No bag on scale	Place the appropriate bag on the scale, press CONTINUE.
	Effluent bag is partially supported (not hanging freely).	Remove partial support; press CONTINUE.
Filter clotted Filter pressure drop is \geq limit value fixed for the filter in use, or both the "Filter is Clotting" Advisory and the "TMP Excessive" Caution limits are reached. (CRRT)	Clots have formed in the filter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via STOP. ^b Test patient's clotting parameters and adjust anticoagulant delivery if needed.
	Clamped line(s) in blood flowpath.	Unclamp lines; press CONTINUE.
	Ultrafiltration rate is too high for filter in use.	Press CONTINUE and then reduce replacement solution flow rate and/or PBP solution flow rate and/or patient fluid removal rate.
	Anticoagulation delivery has failed.	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.
	Pressure measurement failure	Perform a self-test for repositioning the pressure pod membranes.

Table 5.2 Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Filter extremely positive Alarm occurs if filter pod pressure is ≥ 450 mmHg	Line between filter pressure pod and filter or line between filter and deaeration chamber is clamped or kinked.	Remedy; press CONTINUE.
	Machine is operating at high return pressure and clotting has begun in filter.	Press FLOW RATES and lower blood flow rate. Check catheter.
	Excessive pressure.	Relieve excess pressure in return line by pressing RELEASE CLAMP. If desired, lower the blood flow rate; press CONTINUE. Note 1: The RELEASE CLAMP key is available only if no other alarm requiring the clamp closed is present. ^e The filter pressure will drop as operation commences. (The appropriate Advisory or Warning alarm occurs when filter clotting becomes problematic.) Note 2: If the above Operator Responses do not clear this alarm, the set can be changed via STOP. ^b If alarm recurs with new set, end treatment via STOP. ^b Call service.
	Filter pressure sensor failed.	End treatment via STOP. ^b Call service.
HP Cartridge Clotted Filter pressure drop is \geq limit value fixed for the HP cartridge in use. (HP)	Clots have formed in the cartridge. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via STOP. ^b Test patient's clotting parameters and adjust anticoagulant delivery if needed.
	Clamped line(s) in blood flowpath.	Unclamp lines; press CONTINUE.
	Anticoagulation delivery has failed.	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.
	Pressure measurement failure	Perform a self-test for repositioning the pressure pod membranes.

Table 5.2 Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Plasmafilter Clotted Filter pressure drop is \geq limit value fixed for the plasmafilter in use, or both the "Plasmafilter is Clotting" Advisory and the "TMPa Excessive" Caution limits are reached. (TPE)	Clots have formed in the plasmafilter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via STOP ^b . Test patient's clotting parameters and adjust anticoagulant delivery if needed.
	Clamped line(s) in blood flowpath.	Unclamp lines; press CONTINUE.
	Ultrafiltration rate is too high for filter in use.	Press CONTINUE and then reduce replacement solution flow rate and/or patient plasma loss rate.
	Anticoagulation delivery has failed.	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.
	Pressure measurement failure	Perform a self-test for repositioning the pressure pod membranes.
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 ^b , then CHANGE SET, or (b) end the treatment by pressing STOP ^b , then END TREATMNT.
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.	Return catheter disconnected; return line is clamped before deaeration chamber.	Remedy; press CONTINUE.
	Blood flow rate too low for the access device or access device too large.	Increase the blood flow rate; return to alarm screen; press CONTINUE. Note: If the above Operator Responses do not clear this alarm, the set can be changed and the alarm cleared via STOP ^b . If alarm recurs with new set, end treatment via STOP ^b ; call for service.
	return pressure line not properly connected to return pressure port or fluid barrier wet.	Press STOP ^b and use Change Set to load/prime a new set. If fluid barrier wetting recurs call for service.
	Return pressure sensor failed.	End treatment via STOP ^b ; call for service.

Table 5.2 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.	Patient is moving or coughing, being moved or suctioned; return line is clamped or kinked.	Remedy cause; wait 16–20 seconds for possible self-clearing. ^c If alarm does not self-clear, go to next Operator Response.
	Return catheter is clotted or out of position in vein; blood flow rate too high.	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 1: The RELEASE CLAMP key is available only if no other alarm requiring the clamp closed is present. ^f Note 2: If the above Operator Responses do not clear this alarm, the set can be changed and the alarm cleared via STOP. ^b If alarm recurs with new set, end treatment via STOP. ^b Call service.
	Return pressure sensor failed.	End treatment via STOP. ^b 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.	Patient is moving or being moved.	Press CONTINUE. ^g
	Possible leak in return line or catheter.	Remedy; press CONTINUE. ^g Note: It's also possible to use the STOP softkey, if desired. ^b
	Return catheter disconnected.	Remedy; press CONTINUE.
Scale open (Scale not properly closed: XX) (Priming only) Scales identified: Effluent, PBP, Replacement, Dialysate, Replacement 2 (green).	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).	Inspect and remedy possible causes. Press scale toward machine until it locks into closed position. Press CONTINUE.
	Scale sensor failed.	Press DISCONNECT. Call service.

Table 5.2 Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Set disconnection Alarm occurs if filter pressure is lower than +10 mmHg and the filter pressure operating point is higher than +10 mmHg.	Filter pressure pod not installed or debris in filter sensor housing.	Perform Pod Adjustment procedure on filter pod (see instructions at end of Troubleshooting chapter). Or, use Change Set to load/prime a new set. If alarm recurs with new set, end treatment via STOP. ^b Call service.
	Line between blood pump and filter is disconnected; line between access pod and filter pod is clamped.	Remedy; press OVERRIDE. ^a
	Blood flow rate too low for the access device.	Increase the blood flow rate; return to alarm screen and press OVERRIDE. ^a Note: If the above Operator Responses do not clear this alarm, the set can be changed and the alarm cleared via STOP. ^b If alarm recurs with new set, end treatment via STOP. ^b Call service.
	Filter pressure sensor failed.	End treatment via STOP. ^b Call service.
	Return line disconnection and failure of return pressure alarm.	End treatment via STOP. ^b Call service.
Set-up error	Dialysate pump segment not loaded	Remedy, press UNLOAD and reload the set. If alarm recurs move to the next Operator Response.
	Failure of recognition test: – dialysate line clamped; – return pressure line not connected; – filter and effluent pod not set; – dialysate pump segment not loaded; – syringe line not connected.	Remedy, press Retest. If alarm recurs move to the next Operator Response.
	Return line not properly installed in return line clamp; obstruction in return line clamp.	Press RELEASE CLAMP. Remove return line; remove any obstructions; reinstall line, making sure it is completely under clamp and not kinked. Press RETEST. Press UNLOAD and load a new set if the alarm recurs.
	Deaeration return pressure line not connected to return pressure port or effluent pressure pod not correctly installed.	Secure monitor line to the luer lock of the return pressure port and attach correctly the effluent pressure pod to its housing. Press RETEST. Press UNLOAD, remedy and then reload the set if the alarm recurs.
	Pump segments improperly loaded; obstructions in pump raceways.	Press UNLOAD and then load the set again. If failure recurs for three times, retry with a new set; if failure occurs with a new set, unload set, call service and report failure code.
	Pressure sensors (internal) failed; return sensor; Dialysate pump failed.	Unload Set; call for service.
	Set disabled in Service mode.	Unload Set; call for service.

Table 5.2 Warning Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Syringe Empty-Clamped (Priming only)	Syringe line clamped.	Inspect syringe line; remove any clamps; kinks, or other obstructions; press CONTINUE
	Syringe pump is in end-of-travel position, indicating all solution in syringe has been delivered	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.
Wrong set loaded (This set cannot be used with the therapy selected.)	Loaded set does not match with selected therapy.	1. Verify physician prescription for the therapy and set. 2. Press UNLOAD to access the Load Set screen. – If needed, press CANCEL on the Load Set screen, select the prescribed therapy, then load the prescribed set. – If needed, remove the set attached to the control unit (wrong set), then load the prescribed set. Note 1: If alarm occurs repeatedly, do not use the machine until repairs are made. Note 2: If the screen Bar code reading failure appears, 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.
	Set not enable in Service; set not compatible with software version	Contact Service.
Wrong set selected	Mix up of high flow and low flow set after Bar Code Reading Failure	Press DISCONNECT, reload set.
	Foreign object on scale	Remove foreign object. Press DISCONNECT, reload set.
	Return line not connected to effluent bag or effluent bag cock opened	Press DISCONNECT, reload set.
	Scale failed	Press DISCONNECT, remove set. Call service.

a. OVERRIDE briefly overrides the alarm. Monitor closely.

b. STOP stops all pumps, clears the alarm and displays the Stop screen. The following options are available:

resume treatment, change set, end treatment and 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. This alarm occurs when the registered weight is less than the tare of the bag. 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/Replacement2, PBP and Replacement bag is set to 200 g. If Empty Bag Method is set to "Variable", the tare of the Dialysate/Replacement2, PBP and Replacement bag is automatically calculated each time a new bag is loaded.
- 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 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.
- 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 into the blue sample site (return line) to aspirate air/blood until the return pressure reaches a value lower than the alarm limit setting.
- g. CONTINUE resets all operating points and clears the alarm.

5.7 Malfunction Alarms Troubleshooting

Table 5.3 Malfunction Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Air detector	Air bubble detector failed self-tests.	Press RETEST. If alarm does not clear, end treatment via DISCONNECT or manually. ^a Call service to remedy before using machine again. Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.
Blood leak detector <i>(Effluent line not properly installed in blood leak detector.)</i> Blood leak detector failed self-tests. (CRRT, TPE)	Effluent line is not installed, is improperly installed, or is removed from detector.	Press line into detector from bottom up; route through tubing guides. Press RETEST.
	Room or sun light.	Protect BLD from light source.
	Liquid or other debris in tubing path through the detector.	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.
	Blood leak detector failed.	If alarm does not clear, end the treatment via DISCONNECT or manually. ^a Call service. Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.
Blood pump <i>(Rate is incorrect.)</i>	Momentary problem with pump roller or pump segment in raceway.	Press CONTINUE.
	Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened.	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. ^b Warning: When you manually return the blood ^a , there is no air detection. Visually check for air in the return line.
	Pump failed.	Call for service.

Table 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
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. ^b Note: Patient treatments can be conducted before problem is remedied. The last saved Custom mode values guide these treatments.
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.	End treatment via DISCONNECT or manually ^a , then start a new treatment. Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.
Clamp stuck closed	External force on return line clamp.	Remove external force; press RETEST.
	Return line clamp failed.	If alarm does not clear, end the treatment via DISCONNECT or manually. ^a Call service. Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.
Communication error Error Code: X (number 2 to 7) Due to: XXXXXXXXXXXXXXXX Code=2 No communication with the protective task Code=3 Communication link error on the protective slave Code=4 Communication link error on the control system Code=5 Missing status command from protective slave Code=6 Missing alarm command from protective slave Code=7 The protective task isn't able to send message to the slave	See "Due to" message on alarm screen.	<ul style="list-style-type: none"> • Turn machine off. • Remove return line from return line clamp. • Manually return the blood with the pump crank. • Then turn machine on. • If Query screen appears, make choice and follow instructions. • If alarm recurs, end treatment manually^a; call service before using machine again. <p>Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.</p>
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.

Table 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Dialysate pump (Rate is incorrect.) (CVVHDF, CVVHD) Dialysate pump = green pump	Momentary problem with pump roller or pump segment in raceway.	Press CONTINUE.
	Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened.	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. ^b Warning: When you manually return the blood ^a , there is no air detection. Visually check for air in the return line.
	Pump failed.	Check for clamped line. Call for service.
Dialysate scale sensor (CRRT)	The bar tray of the dialysate scale has not been pulled out and then pushed in the control unit to attach the dialysate bag.	Place the scale in open position and then in closed position. Press RETEST. If this does not clear the alarm, end treatment via DISCONNECT. Call Service.
	The scale position sensor failed.	End treatment via DISCONNECT. Call Service.
Effluent pump (Rate is incorrect.) Effluent pump = yellow pump (CRRT, TPE)	Momentary problem with pump roller or pump segment in raceway.	Press CONTINUE.
	Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened.	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. ^b Warning: When you manually return the blood ^a , there is no air detection. Visually check for air in the return line.
	Pump failed.	Check for clamped line. Call for service.
Effluent scale sensor (CRRT, TPE)	The bar tray of the effluent scale has not been pulled out and then pushed in the control unit to attach the effluent bag.	Place the scale in open position and then in closed position. Press RETEST. If this does not clear the alarm, End treatment via DISCONNECT. Call Service.
	The scale position sensor failed.	End treatment via DISCONNECT. Call Service.

Table 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
General system failure	Protective and control systems not communicating; a component of the control unit not responding.	<ul style="list-style-type: none"> • Turn machine off. • Remove return line from return line clamp. • Manually return the blood with the pump crank. • Then turn machine on. • If Query screen appears, make choice and follow instructions. • If alarm recurs, end treatment manually^a; call service before using machine again. <p>Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.</p>
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. ^b
Line in Air Detector	Return line installed in air bubble detector before loading a set.	If return line is installed in the air bubble detector, open door of air bubble detector and remove line from air bubble detector, then close door of air bubble detector. Press RETEST. If alarm doesn't clear and the line is not inserted in the air bubble detector, see next Operator Response.
	Tubing detection switch failed.	Turn off 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 bubble detector for the remainder of the treatment. Call Service.
Line in Clamp	Return line installed in Return Line Clamp before loading a set.	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 next Operator Response.
	Tubing detection switch failed.	Turn off 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 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Lower Pinch Valve	The lower pinch valve is in the wrong position for the therapy selected and the current infusion method selected (Pre/Post) due to obstructions.	Remove any obstructions and press RETEST. If this does not clear the alarm, see next Operator Response.
	The lower pinch valve failed.	End treatment via DISCONNECT. Call Service.
Memory error Error Code: XX (number 1, 3 to 6) Due to: XXXXXXXXXXXXXXXX Code=1 Memory error on Protective task. Code=3 Wrong CRC of a set value. Code=4 Set value incongruence between Protective slave and task. Code=5 Incongruence on the alarm structure of the control system. Code=6 Set value incongruence between protective and control.^c	See "Due to" message on alarm screen.	<ul style="list-style-type: none"> • Turn machine off. • Remove return line from the return line clamp. • Manually return the blood with the pump crank. • Then turn machine on. • If Query screen appears, make choice and follow instructions. • If alarm recurs, end treatment manually^a; call service before using machine again. <p>Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.</p>
No Line in Air Detector	Return line not installed or not properly installed in air bubble detector.	If return line is NOT installed in the air bubble detector, open door of air bubble detector and insert line into air bubble detector. If return line is installed in the air bubble 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 bubble detector, see next Operator Response.
	Tubing detection switch failed.	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 bubble detector for the remainder of the treatment. Call Service.
No Line in Clamp	Return line not installed or not properly installed in Return Line Clamp.	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 next Operator Response.
	Tubing detection switch failed.	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 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Normalization failed (Attempt to normalize blood leak detector has failed.) (CRRT, TPE)	Filter blood leak; defective effluent line; air bubble in effluent line at level of BLD; effluent line not correctly installed; 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).	Momentary problem with pump roller or pump segment in raceway.	Press CONTINUE.
	Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened.	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. ^b Warning: When you manually return the blood ^a , there is no air detection. Visually check for air in the return line.
	Pump failed.	Check for clamped line. Call for service.
PBP scale sensor	The bar tray of the PBP scale has not been pulled out and then pushed in the control unit to attach the PBP bag.	Place the scale in open position and then in closed position. Press RETEST. If this does not clear the alarm, end treatment via DISCONNECT. Call Service.
	The scale position sensor failed.	End treatment via DISCONNECT. Call Service.
Pressures Circuit Board	Hardware failure on pressures circuit board.	Turn machine off and end treatment manually. ^a Call Service. Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.
Pressure zero test Zero test of one or more pressure sensors failed.	One or more pressure pods are installed in pressure sensor housings, but should not be installed yet.	If pressure pods are installed in housings, remove them. Press RETEST.
	One or more pressure sensors failed.	If alarm does not clear, turn off machine. Call service. ^b
Prime self-test Code: XX (number 1 to 28) General information on Prime self-test, for more information on different alarms, see below.	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. <ul style="list-style-type: none"> • 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.

Table 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test / Self-test Code: X Due to: Pressure pod/sensor – X	Pressure pod(s) not installed; debris in sensor housing(s); leaking pod.	Do Pressure Pod Adjustment procedure on all pods reported on alarm screen. Press RETEST.
All affected pods are reported. Code=1 Access Code=2 Filter Code=3 Access and Filter Code=4 Effluent (CRRT, TPE) Code=5 Access and Effluent (CRRT, TPE) Code=6 Filter and Effluent (CRRT, TPE) Code=7 Access, Effluent and Filter (CRRT, TPE)	Clamped lines in set.	Unclamp any clamped lines; press RETEST.
	Pressure sensor(s) failed.	Unload set via DISCONNECT; call service and report failure code.
Prime self-test / Self-test Code=16 Due to: Return pressure sensor	Clamped lines in set.	Unclamp any clamped lines. Press RETEST.
	Return pressure line not securely connected to return pressure port.	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.
	Pressure sensor(s) failed.	If failure occurs again with a new set, unload set via DISCONNECT. Call service and report failure code.
Prime self-test Code=17 Due to: Blood leak detector normalization timeout (CRRT, TPE)	Effluent line not correctly installed in blood leak detector.	Reinstall effluent line (from bottom up); route through tubing guides. Press RETEST.
	Air bubble in effluent line at level of blood leak detector.	Dislodge bubble by removing line from detector / tapping on tube. Press RETEST.
	Set not fully primed.	Check for clamped lines and for connections; remedy. Press REPRIME; follow instructions. If failure recurs after the above Operator Responses, retry with a new set (Press NEW SET; follow instructions.)
	Blood leak detector failed.	If failure occurs with the new set, unload set via DISCONNECT; call service; report failure code.

Table 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test / Self-test Code=18 Due to: Blood leak detector threshold error (CRRT, TPE)	Air bubble in effluent line at level of blood leak detector.	Dislodge bubble by removing line from detector /tapping on tube. Press RETEST.
	Set not fully primed.	Check for clamped lines and for connections; remedy. Press REPRIME; follow instructions. If failure recurs after the above Operator Responses, retry with a new set (Press NEW SET; follow instructions.)
	Blood leak detector failed.	If failure occurs with the new set, unload set via DISCONNECT; call service; report failure code.
Prime self-test Code=19 Due to: Air/pumps security test	Internal malfunction.	Press RETEST. If failure recurs, unload set via DISCONNECT; call service and report failure code.
	Presence of air at ABD level.	Disconnect monitor line and refill the chamber.
Prime self-test Code=20 Due to: Pump occlusivity test	Return line not properly installed in return line clamp; obstruction in return line clamp.	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.
	Deaeration return pressure line not connected to return pressure port; errors occurred during priming cycle.	Verify the fluid barrier is not damaged and tighten fluid barrier connection to return pressure line. 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.
	Pump segments improperly loaded; obstructions in pump raceways; external leakage in set.	Check for leakages and tighten connections. If failure recurs for three times, retry with a new set (Press NEW SET and follow instructions.)
	Pump(s) failed.	If failure occurs with a new set, unload set via DISCONNECT; call service and report failure code.
Prime self-test Code=21 Due to: Upper pinch valve	Pinch valve segment not properly positioned in pinch valve.	Press RETEST. If failure recurs, retry with a new set (Press NEW SET and follow instructions.)
	Upper pinch valve failed.	If failure occurs with a new set, unload set via DISCONNECT; call service and report failure code.
Prime self-test Code=22 Due to: Lower pinch valve	Pinch valve segment not properly positioned in pinch valve.	Press RETEST. If failure recurs, retry with a new set (Press NEW SET and follow instructions.)
	Lower pinch valve failed.	If failure occurs with a new set, unload set via DISCONNECT; call service and report failure code.

Table 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Prime self-test Code=23 Due to: Upper pinch valve/ Lower pinch valve	Pinch valve segments not properly positioned in pinch valve.	Press RETEST. If failure recurs, retry with a new set (Press NEW SET and follow instructions.)
	Upper and Lower pinch valves failed.	If failure occurs with a new set, unload set via DISCONNECT; call service and report failure code.
Prime self-test / Self-test Code=24 Due to: 24 volt / 12 volt	24 volt / 12 volt test failed.	Press RETEST. If failure recurs, unload set via DISCONNECT; call service and report failure code.
Prime self-test / Self-test Code=25 Due to: Return clamp sensor	Obstruction in return line clamp.	Press and hold return clamp button; with the other hand, remove obstruction. Press RETEST.
	Return clamp sensor failed.	If alarm failure recurs, unload set via DISCONNECT; call service and report failure code.
Prime self-test / Self-test Code=26 Due to: 24 volt Return clamp sensor	24 volt and return clamp sensor tests failed.	Press RETEST. If failure recurs, unload set via DISCONNECT; call service, report failure code.
Prime self-test Code=27 Due to: TMPa (TPE)	Return line not in clamp.	Ensure return pressure line is securely connected to luer lock of the return pressure port. Press RETEST.
	Filter or effluent pressure pod not installed; debris in filter and/or effluent sensor housings.	Do Pressure Pod Adjustment procedure on any uninstalled pod (see instructions at the end of Troubleshooting chapter). Install; press RETEST. If all pods are installed, do Adjustment procedure on filter and effluent pods to remove possible debris. Install; press RETEST.
	Set not fully primed.	Press REPRIME; follow instructions. If failure recurs, retry with new set. (Press NEW SET and follow instructions.)
	Filter, effluent, or return pressure sensor failed; ARPS failed.	If alarm occurs with a new set, press unload set via DISCONNECT. Call service and report failure code.
Prime self-test Code=28 Due to: Syringe Circuit Board	Internal malfunction: syringe test not completed within 600 s.	Press RETEST to restart Syringe Test. If failure recurs, it 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.

Table 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement pump (Rate is incorrect.) Replacement pump = purple pump. (CRRT, TPE)	Momentary problem with pump roller or pump segment in raceway.	Press CONTINUE.
	Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened.	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. ^b Warning: When you manually return the blood ^a , there is no air detection. Visually check for air in the return line.
	Pump failed.	Check for clamped line. Call for service.
Replacement pump 2 (Rate is incorrect.) Replacement pump 2 = green pump.	Momentary problem with pump roller or pump segment in raceway.	Press CONTINUE.
	Impeding object or kinked line in pump raceway; thumb screw in center of rotor has loosened.	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. ^b Warning: When you manually return the blood ^a , there is no air detection. Visually check for air in the return line.
	Pump failed	Check for clamped line. Call for service.
Replacement Scale Sensor (CRRT, TPE)	The bar tray of the replacement scale has not been pulled out and then pushed in the control unit to attach the replacement bag.	Place the scale in open position and then in closed position. Press RETEST. If this does not clear the alarm, end treatment via DISCONNECT. Call Service.
	The scale position sensor failed.	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 ^d or manually. ^a Call service. ^b Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.
Scales Circuit Board	Hardware failure on scales circuit board.	End treatment via DISCONNECT. Call Service.
Scale zero test Zero test of one or more scales failed.	Unexpected presence of bag.	Remove bag from scale. Close scale and press RETEST.
	Carrying bar missing from one or more scales.	Place carrying bar back on scale. Close scale and press RETEST.
	Foreign objects are touching scales or hanging from scale carrying bars.	Make sure nothing is touching scales and no foreign objects are on scale carrying bars. Press RETEST.
	One or more scales failed.	If alarm does not clear, turn off machine. Call service. ^b

Table 5.3 Malfunction Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Syringe not loaded	The syringe is not loaded after Syringe Test has been performed.	<ul style="list-style-type: none"> – 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 via DISCONNECT. Call service to repair the syringe pump.
Syringe pump (Rate is incorrect.)	Syringe pump failed.	<ul style="list-style-type: none"> Press OVERRIDE.^e The 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/h.” Return to alarm screen and press OVERRIDE^e or end treatment manually.^a <p>Note: Always call service to repair the syringe pump and clear the alarm.</p> <p>Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.</p>
Upper Pinch Valve	The upper pinch valve is in the wrong position for the therapy selected due to obstructions.	Remove any obstructions and press RETEST. If this does not clear the alarm, see next Operator Response.
	The upper pinch valve failed.	End treatment via DISCONNECT. Call Service.
Voltage Out of Range	Internal malfunction related to the machine Power Supply or the Power supply cabling.	<ul style="list-style-type: none"> Turn machine off and end treatment manually.^a Call Service. <p>Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.</p>

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

b. This alarm must be cleared in Service mode by a trained and qualified technician.

c. Memory Error code 6 is triggered when Flow Rate Discrepancy occurs. A Flow Rate Discrepancy is when any flow rate displayed on the Status Screen differs from that displayed on the Enter Flow Settings Screen.

d. DISCONNECT key is available only if set is loaded onto control unit.

e. OVERRIDE briefly overrides the alarm. Monitor closely.

5.8 Caution Alarms Troubleshooting

Table 5.4 Caution Alarms Troubleshooting

Observation	Possible Cause(s)	Operator Response
Bag Volume Incorrect (Bag Volume incorrect for: XXXXXX) Amount of fluid in bag does not match Allowed Volume.) Depending on the therapy performed, following may be identified: Replacement bag Dialysate bag PBP bag Replacement bag 2 (green scale) (Only valid with variable Empty Bag method)	Amount of fluid in the identified bag does not match the current Allowed Volume.	Choose one of the options on the alarm screen. Warning: Carefully read 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.
	No bag on scale.	Place the appropriate bag on the scale, press CONTINUE.
	Foreign object on scale.	Remove foreign object, press CONTINUE.
	Identified bag is partially supported (not hanging freely).	Remove partial support; press CONTINUE. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
Dialysate bag empty^a (CVHD, CVHDF)	Dialysate bag is empty.	Connect a new dialysate bag. (See instructions on alarm screen.) Press CONTINUE when ready.
	Dialysate bag partially supported (not hanging freely).	Remove partial support; press CONTINUE.
	Dialysate bag has fallen down.	Connect a new dialysate bag. (See instructions on alarm screen.) Press CONTINUE when ready. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b

Table 5.4 Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Dialysate weight (Incorrect weight change detected.) (CVHD, CVHDF)	Leaking or clamped dialysate line or bag; bag is swinging on scale carrying bar.	Remedy; press CONTINUE. ^c
	Foreign object on dialysate scale; dialysate bag is partially supported (not hanging freely).	Remove object or partial support; press CONTINUE. ^c
	Incorrect puncture of dialysate bag seal.	Using aseptic technique to make sure that the dialysate bag is correctly punctured. Press CONTINUE. ^c
	Incorrect break of the frangible pin or peeling of the seal of the dialysate bag.	Break the frangible pin or peel the seal correctly. Press CONTINUE. If the problem persists, replace the dialysate bag using the CHANGE BAGS procedure.
	Missed empty bag detection / air bubbles in the dialysate fluid (2 compartment bags with incorrect break of red pin). Air bubbles in the dialysate fluid.	Check bag connections. Remedy and press CONTINUE. ^c Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
	Dialysate scale failed; internal malfunction.	Press STOP and end the treatment. Call service. Warning: After alarm clears, see History screen to verify patient fluid/plasma removal accuracy. ^c
Effluent bag full (CRRT, TPE)	Dialysate line connected to wrong bag or dialysate bag on wrong scale.	Make sure to have connected the green line to the dialysate bag on green scale. ^c
	Effluent bag is full.	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.
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) (CRRT, TPE)	Foreign object on effluent scale.	Remove foreign object, press CONTINUE. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
	A 5 liter empty bag is hanged on scale while Effluent Allowed Volume is 9000 ml.	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.
	No bag on scale.	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.
	Effluent bag is partially supported (not hanging freely).	Remove partial support; press CONTINUE.

Table 5.4 Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Effluent weight (Incorrect weight change detected for effluent bag.) (CRRT, TPE)	Leaking or clamped effluent line or bag; bag is swinging on scale carrying bar; kinking BLD tube segment	Remedy; press CONTINUE. ^c
	Foreign object on effluent scale; effluent bag is partially supported (not hanging freely).	Remove foreign object or partial support; press CONTINUE. ^c Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
	Air bubbles in the effluent fluid.	<ul style="list-style-type: none"> • If there is evidence that the filter is becoming clotted, press STOP and change the set. • If there is no clotting, lower TMP by: <ul style="list-style-type: none"> (a) decreasing the PBP, replacement and/or patient fluid removal rates; (b) increasing the blood flow rate; (c) press CONTINUE.^c • In CVHD or CVVHDF, check dialysate for air bubbles. If air bubbles are present in Dialysate verify free flow at bag connection.^c
	Effluent scale failed; internal malfunction.	Press STOP and end the treatment. Call service. Warning: After alarm clears, see History screen to verify patient fluid/plasma removal accuracy. ^c
Gain Limit Reached The Unintended Patient Fluid Gain exceeded your selected limit. A flow problem has caused Prismaflex to infuse too much fluid (GAIN) to the patient. (CRRT)	A flow problem has caused Prismaflex to infuse excess fluid to the patient.	For safety, this treatment is now permanently suspended (fluid pumps are stopped and will not re-start; blood pump continues to run). This treatment must be ended. Press STOP and change the set and continue patient treatment with a new set, or end the treatment.
Multiple incorrect weight changes alarms (PBP, dialysate, replacement, effluent).		
Flow errors due to an incorrect bag connection (e.g. incorrect break of the frangible pin or peeling of the seal).		
Flow errors due to effluent fluid degassing.		
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: XXXXXXXXXXXX (TPE) (HP)	Clearing attempts have exceeded the manufacturer-set limit of 10 tries in 3 hours.	For safety, this treatment is now permanently suspended (fluid pumps are stopped and will not re-start; blood pump continues to run). This treatment must be ended. Press STOP and change the set and continue patient treatment with a new set, or end the treatment. Use History to verify exact fluid exchange status at STOP time.

Table 5.4 Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Loss Limit Reached The Unintended Patient Fluid Loss exceeded your selected limit. A flow problem has caused Prismaflex to pull too much fluid (LOSS) from the patient. (CRRT)	A flow problem has caused Prismaflex to pull excess fluid from the patient.	For safety, this treatment is now permanently suspended (fluid pumps are stopped and will not re-start; blood pump continues to run). This treatment must be ended. Press STOP and change the set and continue patient treatment with a new set, or end the treatment.
	Multiple incorrect weight changes alarms (PBP, dialysate, replacement, effluent).	
	Flow errors due to an incorrect bag connection (e.g. incorrect break of the frangible pin or peeling of the seal).	
	Flow errors due to effluent fluid degassing.	
No Flow in Blood Path (Filter pressure drop is minimal. Blood is not circulating through access/return lines.)	Clamp or kink in access line between blood pump and filter pod or between blood pump and access pod.	If clamp/kink is located, remove it, press CONTINUE. If alarm recurs, press STOP and change the set.
	Clot in access line between access pod and filter pod.	If clot is present, press STOP and change the set.
	Blood flow rate too low.	Press CONTINUE and increase the blood flow rate.
	Wrong Filter pod pressure measurement.	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.
Patient Fluid Gain Excessive (TPE) (HP)	PBP fluid input has reached the maximum allowed Patient Fluid Gain for the therapy/set.	Stop PBP infusion and continue therapy without further patient fluid gain: Press FLOW SETTINGS, set PBP rate to zero.
		Continue therapy with further fluid gain for the patient: Press CONTINUE. Alarm will recur when Patient Fluid Gain increases 10% beyond the maximum allowed value.
		Stop therapy immediately: Press STOP. ^b
PBP bag empty^a	PBP bag is empty.	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.
	PBP bag partially supported (not hanging freely).	Remove partial support, press CONTINUE.
	PBP bag has fallen down.	Connect a new PBP bag. (See instructions on alarm screen.) Press CONTINUE when ready. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b

Table 5.4 Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
PBP weight (Incorrect weight change detected for PBP bag.)	Leaking or clamped PBP lines(2 clamps) or bag; bag is swinging on scale carrying bar; kinked line	Remedy; press CONTINUE. ^c
PBP = pre-blood pump	Foreign object on PBP scale; PBP bag is partially supported (not hanging freely).	Remove foreign object or partial support; press CONTINUE. ^c
	Seal on PBP bag is not completely broken.	Using aseptic technique, manipulate the bag seal to provide unobstructed fluid pathway. Press CONTINUE. ^c Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
	Air bubbles in the PBP fluid.	Check bag connections. Remedy and press CONTINUE. ^c
	PBP scale failed; internal malfunction.	Press STOP and end the treatment. Call service. Warning: After alarm clears, see History screen to verify patient fluid/plasma removal accuracy. ^c
	Incorrect break of the frangible pin or peeling of the seal of the PBP bag.	Break the frangible pin or peel the seal correctly. Press CONTINUE. If the problem persists, replace the PBP bag using the CHANGE BAGS procedure. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
	Non breathing spike used with a rigid container.	Replace the non breathing spike with a breathing spike; PRESS CONTINUE.
Replacement bag empty^a (CVVH, CVVHDF)	Replacement bag is empty.	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.
	Replacement bag partially supported (not hanging freely).	Remove partial support, press CONTINUE.
	Replacement bag has fallen down.	Connect a new replacement bag. (See instructions on alarm screen.) Press CONTINUE when ready. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b

Table 5.4 Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement bag 2 empty^a (on green scale) (CVVH)	Replacement bag 2 (green scale) is empty.	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.
	Replacement bag 2 is partially supported (not hanging freely).	Remove partial support, press CONTINUE.
	Replacement bag 2 has fallen down.	Connect a new replacement bag 2. (See instructions on alarm screen.) Press CONTINUE when ready. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
Replacement container empty (TPE)	Replacement container is empty.	Connect a new replacement container. Press REPLACEMENT softkey; use arrows to enter a new container volume; press CONTINUE. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
	Replacement container partially supported (not hanging freely).	Remove partial support, press CONTINUE.
	Replacement container has fallen down.	Connect a new replacement container. (See instructions on alarm screen.) Press CONTINUE when ready. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b

Table 5.4 Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement weight (Incorrect weight change detected for replacement bag.) (CRRT, TPE)	Leaking or clamped replacement line or bag; bag is swinging on scale carrying bar.	Remedy; press CONTINUE. ^c
	Foreign object on replacement scale; replacement bag partially supported (not hanging freely).	Remove object or partial support; press CONTINUE. ^c
	Seal on replacement bag not completely broken.	Using aseptic technique, manipulate the bag seal to provide unobstructed fluid pathway. Press CONTINUE. ^c Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
	Air bubbles in the replacement fluid.	Check bag connections. Remedy and press CONTINUE. ^c
	Replacement scale failed; internal malfunction.	Press STOP and end the treatment. Call service. Warning: After alarm clears, see History screen to verify patient fluid/plasma removal accuracy. ^c
	Incorrect break of the frangible pin or peeling of the seal of the replacement bag.	Break the frangible pin or peel the seal correctly. Press CONTINUE. If the problem persists, replace the replacement bag using the CHANGE BAGS procedure. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b

Table 5.4 Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Replacement 2 weight (Incorrect weight change detected for replacement bag 2 [green scale].) (CRRT, TPE)	Leaking or clamped replacement line or bag; bag is swinging on scale carrying bar.	Remedy; press CONTINUE. ^c
	Foreign object on replacement scale; replacement bag partially supported (not hanging freely).	Remove object or partial support; press CONTINUE. ^c
	Seal on replacement bag not completely broken.	Using aseptic technique, manipulate the bag seal to provide unobstructed fluid pathway. Press CONTINUE. ^c Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
	Air bubbles in the replacement fluid (replacement 2 bag).	Check bag connections. Remedy and press CONTINUE. ^c
	Green scale failed; internal malfunction.	Press STOP and end the treatment. Call service. Warning: After alarm clears, see History screen to verify patient fluid/plasma removal accuracy. ^c
	Incorrect break of the frangible pin or peeling of the seal of the replacement bag 2.	Break the frangible pin or peel the seal correctly. Press CONTINUE. If the problem persists, replace the replacement bag 2 using the CHANGE BAGS procedure. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b
Scale open (Scale not properly closed: XX) Scales identified: Effluent, PBP, Replacement, Dialysate, Replacement 2 (green).	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).	Inspect and remedy possible causes. Press scale toward machine until it locks into closed position. Press CONTINUE.
	Scale sensor failed.	Press STOP; end treatment; call for service. ^b
TMP excessive (Transmembrane pressure exceeds membrane pressure limit.) (CRRT)	Ultrafiltration rate (UFR) is too high. Too much fluid is being removed. (UFR = patient fluid removal rate + replacement solution rate + PBP rate)	– Decrease the PBP, replacement and/or patient fluid removal rates or, alternatively, increase blood flow rate. – Return to alarm screen, press CONTINUE.
	Wrong pressure information from Filter and Effluent pods or return sensor.	Clear the alarm by temporarily decreasing UFR. Perform a self-test for repositioning the pressure pod membranes. Set previous flow rates back. If alarm recurs, decrease UFR or change the set. Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b

Table 5.4 Caution Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
TMPa Excessive (Access transmembrane pressure exceeds the safe limit.) (TPE)	Effluent rate is too high. Too much plasma is being removed. (Effluent rate = patient plasma loss rate + replacement fluid rate.)	Decrease the replacement fluid or increase blood flow rate. Return to alarm screen, press CONTINUE. Note: It's also possible to use the STOP softkey, if desired. ^b
	Plasmafilter pressure drop is increasing, possibly due to insufficient anticoagulation.	Decrease blood flow rate and/or adjust anticoagulation prescription.
TPE Prescription Delivered (Prescribed Total Replacement Volume has been delivered.) (TPE)	Total Replacement Input has been achieved.	To continue treatment until remaining replacement fluid is used, press CONTINUE; when Replacement Container Empty caution occurs, press STOP and End treatment. To set new TPE Prescription Delivered alarm point, press CONTINUE, then increase the Total Replacement Input on the SET TPE Prescription screen.

a. This alarm occurs when the registered weight is less than the tare of the bag. 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 g. 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.

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

c. 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. Verify fluid removal accuracy. In case of discrepancy between the prescribed value and fluid removed, consult physician and discontinue the treatment if required.

CRRT: When the error in patient fluid balance/fluid removal exceeds the Patient Fluid Loss/Gain Limit a "Caution: Loss Limit Reached" or "Caution: Gain Limit Reached" 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.

TPE: 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.

5.9 Advisory Alarms Troubleshooting

Table 5.5 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.	Patient is moving or being moved. Possible leak in access line or catheter.	Press CONTINUE. ^a Remedy; press CONTINUE. ^a Note: It's also possible to use the STOP softkey in the above Operator Responses, 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.	Patient is coughing, moving or being moved. Catheter type not appropriate; catheter out of position in vein; catheter clotted; possible kink in access line. Blood flow rate is set too high for the access device.	Press CONTINUE. ^a Remedy; press CONTINUE. ^a Decrease blood flow rate; return to alarm screen and press CONTINUE. ^a Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b Alarm also self-clears if condition no longer exists.
Anticoagulation Check Points	Citrate anticoagulation requires additional monitoring of patient's parameters. This advisory occurs at a specific time interval when citrate is used.	Ensure proper delivery of calcium using an external syringe / infusion pump. Note: To change this interval, use SYSTEM TOOLS in 'Status' screen. Check with your physician for the occurrence of this advisory.
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.
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.	Air leak at connection to catheter/blood source (external blood access device, patient A-V fistula).	Tighten access line connections to catheter/blood source; press OVERRIDE. ^c
	Blood flow rate too high.	Decrease blood flow rate; return to alarm screen and press OVERRIDE. ^c
	Access pressure pod removed after priming.	Do Pressure Pod Adjustment procedure on access pod (see end of Troubleshooting chapter); press OVERRIDE ^c or change the set. To change set, press OVERRIDE. When Status screen appears, press STOP, then CHANGE SET.
	Wrong Access pressure range selection.	To reset Access pressure range, press OVERRIDE. When Status screen appears, press STOP, then RECIRC to perform Recirculation.

Table 5.5 Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
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.)	Blood flow rate too low for the access device / large bore catheter.	Increase blood flow rate; return to alarm screen and press OVERRIDE. ^c
	Access pressure pod removed after priming.	Do Pressure Pod Adjustment procedure on access pod (see instructions at end of Troubleshooting chapter); press OVERRIDE ^c or change the set. To change set, press OVERRIDE. When Status screen appears, press STOP, then CHANGE SET.
	Wrong Access pressure range selection.	To reset Access pressure range, press OVERRIDE. When Status screen appears, press STOP, then RECIRC to perform Recirculation.
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.	Blood flow rate too low for the access device / large bore catheter.	Increase blood flow rate; return to alarm screen and press OVERRIDE.
	Return pressure line not securely connected to return pressure port.	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.)	Clamped line(s) or bag(s).	Remedy; press CONTINUE. ^d
	Seal on a bag is not completely broken.	Press STOP. Manipulate bag seal to provide unobstructed fluid pathway. Press RESUME. ^d
	Pump segments improperly loaded; obstructions in pump raceways.	Press STOP, then CHANGE SET. ^d
	Scale failed; internal malfunction.	Press STOP and end the treatment. ^d Call service.

Table 5.5 Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Filter is clotting (Increasing TMP and/or Pressure Drop.) (CRRT)	Inadequate anticoagulation of the extra corporeal circuit.	Press STOP; change the set or test patient's clotting parameters and adjust anticoagulant delivery if needed. Note: "Filter Clotted" warning occurs when the blood in the filter is clotted.
	Ultrafiltration is too high.	Lower TMP by: (a) decreasing the PBP, replacement and/or patient fluid removal rates; (b) increasing the blood flow rate. Press OVERRIDE ^c ; continue to monitor the set.
	Kinked lines in blood flowpath.	Remedy, press OVERRIDE. ^c
	If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	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.
	Air leak between deaeration return pressure line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press OVERRIDE. If the fluid barrier is wet with blood, press STOP and change the set.
Fluid Pumps Stopped	Filter, effluent or return pressure sensor failed.	Press SYSTEM TOOLS and perform SELF-TEST. If the pod problem is not solved, press STOP and end the treatment. Turn off machine; call for service.
	Citrate anticoagulation is used and fluid pumps have stopped for more than 10 minutes.	Remedy the cause of interruption. Additional monitoring of patient's laboratory chemistry must be performed on patient: ionized calcium (Ca2+)

Table 5.5 Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
HP Cartridge is Clotting (Increasing Pressure Drop.) (HP)	Inadequate anticoagulation of the extra corporeal circuit.	Press STOP; change the set or test patient's clotting parameters and adjust if needed. Note: "HP cartridge clotted" warning occurs when the blood in the HP cartridge is clotted.
	Kinked lines in blood flowpath.	Remedy, press OVERRIDE. ^c
	If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	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.
	Air leak between deaeration return pressure line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press OVERRIDE. If the fluid barrier is wet with blood, press STOP and change the set.
	Filter or return pressure sensor failed.	Press SYSTEM TOOLS and perform SELF-TEST. If the pod problem is not solved, press STOP and end the treatment. Turn off machine; call for service.
Plasmafilter is Clotting (Increasing Pressure Drop.) (TPE)	Inadequate anticoagulation of the extra corporeal circuit.	Press STOP; change the set or test patient's clotting parameters and adjust if needed. Note: "Plasmafilter clotted" warning occurs when the blood in the Plasmafilter is clotted.
	Blood flow rate is too high or plasmafiltration rate is too high.	Decrease blood flow rate or decrease PBP and/or replacement flow rates. ^c
	Kinked lines in blood flowpath.	Remedy, press OVERRIDE. ^c
	If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	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.
	Air leak between deaeration return pressure line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press OVERRIDE. If the fluid barrier is wet with blood, press STOP and change the set.
	Filter or return pressure sensor failed.	Press SYSTEM TOOLS and perform SELF-TEST. If the pod problem is not solved, press STOP and end the treatment. Turn off machine; call for service.

Table 5.5 Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Preventive maintenance due	Time for preventive Maintenance	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.	Patient is moving or being moved.	Press CONTINUE. ^a
	Possible kink in return line; clotted catheter; catheter out of position in vein.	Remedy; press CONTINUE. ^a
	Blood flow rate is set too high for the access device.	Decrease blood flow rate; return to alarm screen and press CONTINUE. ^a Note: It's also possible to use the STOP softkey in the above Operator Responses, if desired. ^b Alarm also self-clears if condition no longer exists.
Scale component missing (Carrying bar missing from: XXXXXXX 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.
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: Following warning occurrences are delayed until the self-test process is completed: Warning: Filter Clotted (CRRT) Warning: Plasmafilter clotted (TPE) Caution: TMP Excessive (CRRT)
Syringe Empty-Clamped	Syringe line clamped.	Inspect syringe line; remove any clamps; kinks, or other obstructions; press CONTINUE.
	Syringe pump is in end-of-travel position, indicating all solution in syringe has been delivered	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/h"; return to alarm screen; (b) push plunger clamp release button to release syringe pump from end-of-travel position; (c) press CONTINUE. (Alarm clears.)

Table 5.5 Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Syringe not loaded (The syringe is not loaded)	The syringe is not loaded after Syringe Test has been performed.	<p>Press CHANGE SYRINGE; follow instructions to load the syringe and return to alarm screen.</p> <ul style="list-style-type: none"> • 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.
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.) (CRRT)	A "Time to Change" set advisory limit has been reached. Note: Liters counted for the "Time to change set" advisory occurrences are: blood, PBP solution and saline solution pumped during the Recirculation procedure.	<p>Press STOP^e and change the set or press OVERRIDE and continue to monitor the set.^f</p> <p>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 $\pm 10\%$. This percentage cannot be guaranteed, and will probably be higher, if the set is used beyond 72 hours or 780 liters.</p>
Time to Change Set (Hours of use have reached the user-set "Time to Change Set" advisory limit for this therapy/set combination.) (HP)	A "Time to Change" set advisory limit has been reached.	<p>Press STOP^e and change the set or press OVERRIDE and continue to monitor the set.^f</p> <p>Warning: Do not use the Prismaflex set beyond 6 hours. The hemoperfusion cartridge may be saturated after this operating time.</p>
Time to Change Set (Hours of use have reached the advisory limit for this therapy/ set combination.) (TPE)	A "Time to Change" set advisory limit has been reached. Note: Liters counted for the "Time to change set" advisory occurrence are: blood, PBP solution and saline solution pumped during the Recirculation procedure.	<p>Press STOP^e and change the set or press OVERRIDE and continue to monitor the set.^f</p> <p>Warning: Do not use the Prismaflex set beyond 6 hours. Doing so could result in rupture of the pump segments, causing patient injury or death. Error percentage of the blood pump is $\pm 10\%$. This percentage cannot be guaranteed, and will probably be higher, if the set is used beyond 6 hours.</p>

Table 5.5 Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
TMP too high (Transmembrane pressure has reached user-set pressure limit.) (CRRT)	Ultrafiltration rate (UFR) is too high for the present blood flow rate. (UFR = patient fluid removal rate + replacement solution rate + PBP rate)	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. ^c Note: It's also possible to use the STOP softkey in the above Operator Response, if desired. ^b
	Inadequate anticoagulation of the extra corporeal circuit.	Press STOP; change the set or test patient's clotting parameters and adjust anticoagulant delivery if needed. Note: "Filter Clotted" warning occurs when the blood in the filter is clotted.
	Kinked lines in blood flowpath.	Remedy, press OVERRIDE. ^c
	If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	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.
	Air leak between deaeration return pressure line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press OVERRIDE. If the fluid barrier is wet with blood, press STOP and change the set.
	Filter or effluent pod failure.	Press SYSTEM TOOLS and perform SELF-TEST. If the pod problem is not solved, press STOP and change the set.
	Filter, Effluent or return pressure sensor failed.	Press SYSTEM TOOLS and perform SELF-TEST. If the pressure problem is not solved, press STOP and end the treatment. Turn off machine; call for service.

Table 5.5 Advisory Alarms Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
TMPa too high (Access transmembrane pressure has reached user-set pressure limit.) (TPE)	Inadequate anticoagulation of the extra corporeal circuit.	Press STOP; change the set or test patient's clotting parameters and adjust if needed. Note: "Plasmafilter clotted" warning occurs when the blood in the Plasmafilter is clotted.
	Blood flow rate is too high or plasmafiltration rate is too high.	Decrease blood flow rate or decrease PBP and/or replacement flow rates.
	Kinked lines in blood flowpath.	Remedy, press OVERRIDE. ^c
	If syringe pump is being used for anticoagulation, syringe may be incorrectly installed or syringe pump may have failed.	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.
	Air leak between deaeration return pressure line and return pressure sensor.	If the fluid barrier is not wet with blood, secure monitor line to the luer lock of the return pressure port and press OVERRIDE. If the fluid barrier is wet with blood, press STOP and change the set.

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

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 self-clears if condition no longer exists.

d. 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.

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

5.10 Additional Troubleshooting

Table 5.6 Additional Troubleshooting

Observation	Possible Cause(s)	Operator Response
Loader is already in loaded position, so that a set cannot be loaded.	Last set was manually disconnected.	<p>Begin normal Setup procedure. When Load Set screen appears, press LOAD.</p> <ul style="list-style-type: none"> When Prepare Solutions screen appears, press UNLOAD. (It places loader 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.	<p>Turn off the machine; end treatment manually, if desired.^a Call service.</p> <p>Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.</p>
Display goes blank; status lights go off; non-mutable buzzer sounds.	Power loss; internal power supply failure.	<p>Turn off machine to stop buzzer; end treatment manually, if desired.^a Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.</p>
Effluent bag is tinged pink or red. (CRRT, TPE)	Patient's disease state may cause discoloration of the effluent.	Inspect for kinks (hemolysis). If no kinks, change set and send effluent sample to laboratory for analysis. If free of red blood cells, continue treatment. If red blood cells are present, change the set. If conditions recurs with new set, patient's disease state might be the root cause (to confirm with lab results).
	Effluent contains red blood cells, but level is below blood leak detection limit.	Send effluent sample to laboratory for analysis. If red blood cells are present, change the set.
	Hemolysis is occurring due to occlusion.	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
	Hemolysis is occurring during TPE.	Press STOP and change set.
Leakage from set connections.	Connections are loose.	Tighten the connections. If leakage continues, change the set via STOP key. ^b

Table 5.6 Additional Troubleshooting (cont.)

Observation	Possible Cause(s)	Operator Response
Softkeys won't work.	Touchscreen failed.	<p>Check if touch screen is not “occluded” with tape or something similar. Turn off machine; end treatment manually, if desired.^a</p> <p>Call service.</p> <p>Warning: When you manually return the blood, there is no air detection. Visually check for air in the return line.</p>

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

b. In the Operator's Manual, see "Change Set Procedure" in "Chapter 3: General Therapy Information".

5.11 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.

5.11.1 Manual Termination With Blood Return

(See [Figure 5.1 on page 155](#).)

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 button¹ and hold in the "In" position. With the other hand, remove the return line (blue-striped) from the return line clamp.

Note: In HP, rotate the HP cartridge in its holder so that the positions of the inlet and outlet ports are reversed.

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 return pressure line: Place a clamp on the return pressure line; disconnect the return pressure 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 ml luer-lock sterile syringe (without the needle) to the distal end of the return pressure line; aspirate air/blood until fluid level is at the correct height on the deaeration chamber.



WARNING

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

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.
5. Clamp the return line (blue-striped) and disconnect from the patient. Clamp lines to all bags.
6. Press the two clips of the loader to release the Prismaflex set. 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 Prismaflex set while turning a pump.

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

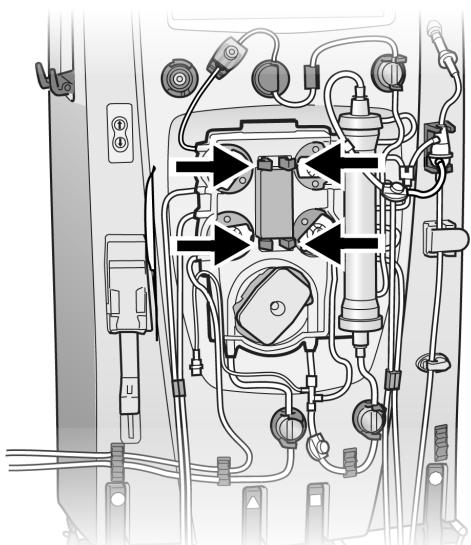
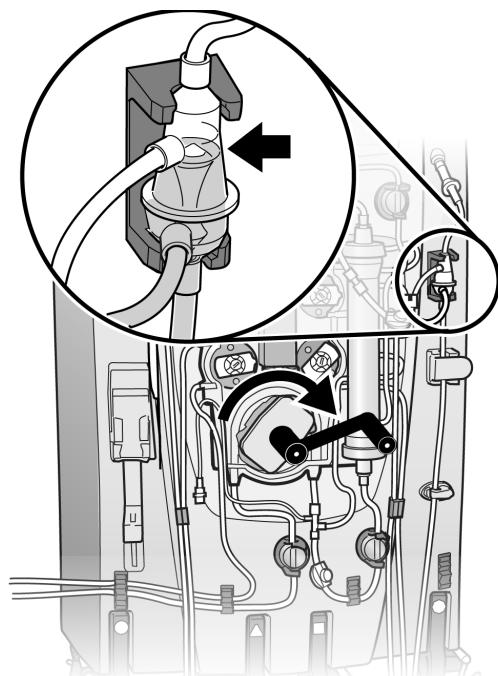
7. When the pump segments are free, use the crank to set the pinch valves in neutral position.
8. Grasp the Prismaflex set and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

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, check the fluid level in the deaeration chamber, use pump crank to turn the blood pump clockwise.

Warning: Visually check for air in the return line.



B

To manually remove the set from the control unit, press clips of loader to release the Prismaflex set. Pull Prismaflex set outward to disengage from pinch valves.

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

Figure 5.1 Manually Terminating Treatment (CRRT set shown)

5.11.2 Manual Termination Without Blood Return

Note: The patient will lose the blood contained in the blood flowpath during a manual termination without blood return. For the exact blood volume, see the Instructions for Use packaged with the 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 loader to release the Prismaflex set. 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 Prismaflex set while turning a pump.
4. When the pump segments are free, use the crank to set the pinch valves in neutral position.
5. Grasp the Prismaflex set and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

5.12 Pressure Pod Adjustment Procedure

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, press the SELF-TEST softkey from the System Tools screen to recover from the failure.

If SELF-TEST fails, the Pressure Pod Adjustment procedure can be performed. This 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.

5.12.1 Pressure Pod Adjustment (CRRT, HP)

Supplies Needed

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

Access Pod and Effluent Pod

Note: The effluent pod is not used in HP.

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. By using two clamps, isolate the pressure pod and its color-coded sample site.
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 ml saline into the \leq 5 ml syringe.
5. *Inject* a maximum of 1 ml of saline into the sample site between the clamps. (If resistance is felt, remove 1/2 ml volume.)



CAUTION

Injecting more than 1 ml 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

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. By using two clamps, isolate the pressure pod and its color-coded sample site.
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 ml fluid (if resistance is felt, reinject 1/2 ml.)



CAUTION

Removing more than 1 ml 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 is Clotted" 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 is Clotted alarm fails to occur, the pressure pod diaphragm has been adjusted incorrectly. Perform the adjustment procedure again.

5.12.2 Pressure Pod Adjustment (TPE)

Supplies Needed

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

Access Pod (TPE)

Follow the steps below to adjust the diaphragm of the access line pod (near lowest red sample site).



WARNING

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

1. Stop all pumps.

Note: Pumps might already be stopped.

2. By using two clamps, isolate the pressure pod and its color-coded sample site.
3. Twist the access 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 ml sterile saline into the ≤ 5 ml syringe.
5. Inject a maximum of 1 ml saline into the sample site between the clamps. (If resistance is felt, remove 1/2 ml.)



CAUTION

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

6. Remove the needle from the sample site. Reinstall the pressure pod in its pressure sensor housing and remove clamps from the line.
7. Resume treatment, or press the appropriate softkey on the alarm screen.
8. For access pod adjustment (TPE): 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 (upstream from the way blood/fluid is flowing) the access 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 Extremely Negative alarm fails to occur, the access pod diaphragm has been adjusted incorrectly. Perform the adjustment procedure again.

Filter and Effluent Pods (TPE)

Follow the steps below to adjust the diaphragm of the filter pod (near upper 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. By using two clamps, isolate the pressure pod and its color-coded sample site.
3. Twist the access 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 of 1 ml fluid (if resistance is felt, reinject 1/2 ml).

**CAUTION**

Removing more than 1 ml 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 the correct pressure sensor housing and remove the clamps from the line.
6. Resume treatment, or press the appropriate softkey on the alarm screen.
7. For filter pod adjustment (TPE): 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 below 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.

8. For effluent pod adjustment (TPE): 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 between the effluent pressure pod and the cartridge. The Caution: TMPa Too High alarm should occur. Unclamp the effluent line and press the CONTINUE softkey on the Caution screen. Verify that the alarm is cleared (Caution screen leaves the display, green light illuminates).

5.13 Air Removal Procedures

5.13.1 Daeaeration Chamber

The fluid level in the deaeration chamber may vary due to procedures during treatment. A small amount of air may be introduced each time (e.g. when changing bags). Frequent monitoring of the level is necessary.

If the fluid level in the deaeration chamber is not accurate (refer to the drawing displayed on the screen), the level can be adjusted while all pumps remain running. From the Status screen, press ADJUST LEVEL and use the Up or Down arrow to bring the fluid level to the correct height.

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

Maintain the fluid level of the deaeration chamber periodically:

- A too high level may put at risk the fluid barrier of the monitor line. A wet fluid barrier will lead to obstruction of the monitor line and consequently loss of return pressure monitoring.
- A too low level may trigger a premature AIR IN BLOOD alarm due to the proximity of air bubbles coming from the infusion fluids and gathering into the deaeration chamber.

Note: To reduce the risk of early clotting at the top of the chamber when operating without post-replacement infusion, it is recommended to adjust the chamber level about 1 centimeter below the usual level.

5.13.2 Air in Blood Alarm – Manual Air Removal

If unsuccessful to press Up arrow until return pressure is NEGATIVE, proceed with manual procedure:

1. Insert the 20-gauge needle with syringe into the blue sample site (return line).
2. Aspirate air/blood until the return pressure reaches a negative value (0 mmHg to -100 mmHg).
3. Remove the needle.
4. 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 return pressure 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.

5. If needed, use arrows to adjust the level of fluid in the chamber.

5.14 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.

**WARNING**

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

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.

Chapter 6: Service Maintenance

6.1 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.

6.1.1 Routine Cleaning

**CAUTION**

- Using a stronger Bleach solution than recommended can cause damage or discoloration.
- Do not clean the pump crank with sodium hypochlorite (Bleach). Sodium hypochlorite (Bleach) may damage the pump crank.

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).

6.1.2 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.

6.1.3 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.

You can clean the Touch screen with:

- 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.

6.2 Technical Preventive Maintenance

Technical preventive maintenance is by default required every 6000 hours of operation or once per year. These intervals can be changed in Service mode by trained and qualified technicians. Only trained and qualified technicians are approved to perform preventive maintenance procedures.

The Advisory: Preventive Maintenance Due alarm is a reminder. Set the correct interval in Service mode. The operator can override this alarm until it is convenient to perform the maintenance. The alarm can only be cleared in Service mode. See “[PM Timer & Date](#)” on page 225. When the alarm (Advisory: Preventive Maintenance Due) signal occurs, pressure pod sealing cones replacement is required.

Make sure to have proper electrostatic safety device (i.e. wrist grounding straps or grounding mats) in place to prevent damage to electrostatic sensitive components within the machine.

6.2.1 Tools, Supplies, and Equipment Required

A Prismaflex PM Kit (P/N G501000) consisting of:

- Pressure pod sealing cones, 4 ea
- ARPS pump segment, 1 ea
- 130 Micron air filter, 1 ea
- PM procedure
- PM checklist
- PM sticker
- Blood pump dampers

Tools and supplies needed:

- Torx T-20
- Torx T-15
- 8 mm Hex
- Prismaflex calibration weights G5000101.(Parts A+B used for scale calibrations and A+B+C+D used for calibration of the syringepump.)
- Effluent line from a Prismaflex set
- Return line from a Prismaflex set
- Digital voltmeter
- Current leakage/ground resistance tester
- 10,20, 30 and 50 ml luerlock syringe
- Pressure meter (calibrated)
- Pressure calibration tube G 5000201

- Prismaflex treatment set
- Catheter (8F) for achieving a simulated treatment with correct pressures.
- 4 fluid bags (saline or equal) of minimum 1000 ml each.
- Stopwatch
- PC with a software for reading data coming from external communications: RS232, Ethernet, PCMCIA. (Optional).
- Technical Data Card (installed before switching on the machine) (P/N G5000501)
- Inspection tool for slave pump rotor G5041701

6.2.2 Visual Inspection and Cleaning

1. Disconnect the machine's power cord from the electrical outlet.
2. Open the back door using the 8 mm Hex tool.
3. Clean any dust, debris, and/or dried fluids from the external and internal machine surfaces, including pump rotors. Clean spills from the surface of the machine using a mild detergent (detergents with germicides should NOT be used).
4. 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 70% isopropyl alcohol. Dry thoroughly when finished.
5. Verify the proper operation of all wheels and brakes.
6. Verify that there are no mechanical obstructions around the scale hooks and handles.
7. Inspect the machine for the following and replace as necessary:
 - Cracked pressure sensor housings
 - Broken tubing guides
 - Filter set holder
 - ABD incl. Door
 - Return line clamp
 - Pinch valve incl. Pinch pins
 - Damaged syringe pump components
 - Damaged power cord or plug
 - Loose internal electrical connectors

6.2.3 Verification and Cleaning Instruction to Prevent Blood Cross Contamination

In the event of a blood leakage from a pod diaphragm or if blood has reached the membrane of the return fluid barrier, perform the followings procedures:

Procedure 1: Blood leakage from the pressure pod diaphragm (Access and Filter)

1. Clean the external surface involved using a towel dipped in a disinfectant solution.
2. Replace the involved pressure transducer assembly(ies) and visually inspect for blood residuals. If blood residuals are present, replace the Pressure Pod Assembly.
3. Test the machine.

Procedure 2: Blood reached the Return fluid barrier

1. Clean the external surface involved using a towel dipped in a disinfectant solution.
2. Replace the Return Pressure Pod Assembly.
3. Test the machine.

6.2.4 Component Replacement

Pressure Pod Sealing Cones (total of 4 cones)

1. Remove the sealing cone from each transducer port (access, filter, effluent and 5th).
2. Visual inspection of all pressure transducer protectors for traces of blood
3. Install new sealing cones so that they are sealed around the tip of the transducers, with the enlarged part of the transducer port protruding through the seal. Do not use any lubricants!

Dampers in the blood pump rotor.

1. Use a T-20 to remove the Blood Pump Rotor.
2. Replace the two dampers on the Rotor and remount it on the machine.

Automatic Reposition System Filter and Pump Segment

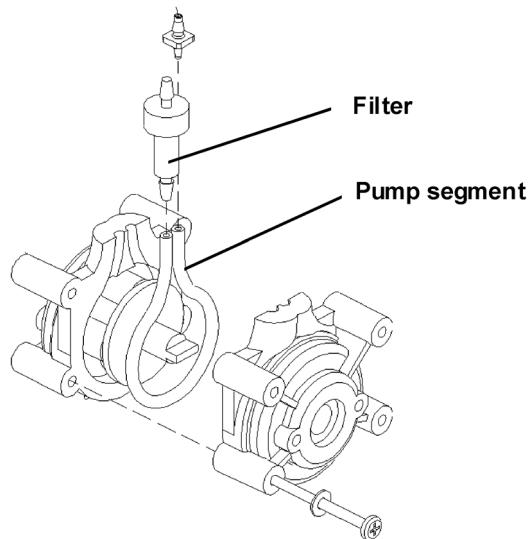


Figure 6.1 Replacing the Filter and Pump Segment

1. Loosen the four T-20 torx screws on the back of the ARPS pump housing and remove the pump assembly.
2. Separate the two halves of the pump and remove the old pump segment.
3. Remove the filter and the tubing connector from the pump segment. Save the tubing connector for use on the new pump segment. Dispose of the filter.
4. Install the new pump segment by carefully working it under each of the rollers in one-half of the housing assembly. Re-assemble the pump housing halves. The segment should be centered in the housing assembly, with equal lengths protruding from the housing on each end of the installed segment.
5. Secure the pump housing assembly to the ARPS bracket with the four screws. Make sure the coils grip before applying any force on to the screw.
6. Reconnect the tubing connector (removed in step 1) and install the new filter on the pump segment so that the filter (large end up) is on the left (next to ARPS CCA) and the tubing connector is on the right.

Rotors

Test each of the pump rotors as follows:

With the rotor installed:

1. Perform the Pump occlusivity test: this test can be done activating a priming test sequence;
2. Verify no incidental unscrewing of the clamping screw on the driving shaft (end play);
3. Verify the incidental radial play between rotor and driving shaft.

With the rotor not installed:

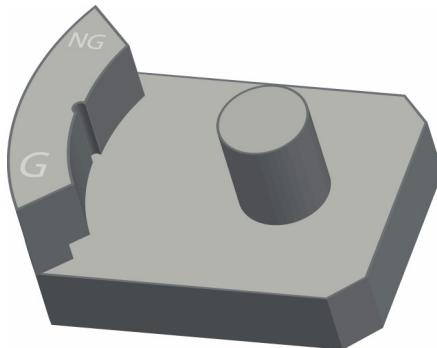


Figure 6.2 Slave pump rotor inspection tool

1. Remove the slave pump rotor from the Prismaflex machine.
2. Place the slave pump rotor in the Inspection tool.
3. Rotate the rotor clockwise in the Inspection Tool.
 - A correct rotor touches the first wider radius of the inspector tool marked G and stops at the second narrower radius marked NG.

6.2.5 Power Supply Check on Power Supply Interface CCA

1. Turn on the machine. Wait for the Query or the Setup screen and verify the following voltages:

PIB Board		
Test Point	Voltage	Tolerance
TP3	GND	
TP14 & GND	+5VD	5.1 to 5.4 V
TP15 & GND	+12V	11.2 to 12.3 V
TP13 & GND	-5V	-5.1 to -5.4 V
TP16 & GND	+24VM	22.8 to 25.2 V
Carrier Board		
TP4	GND	
TP2	+5VD	5.0 to 5.3 V

6.2.6 Service Mode Checkout

Enter Service - Diagnose mode (see “[6.3 Service Screens](#)” on page 172 for more information) and verify the proper operation and/or calibration of the components listed below:

- Pumps
- Scales

- Pressures - Pod Reposition
- Alarms Tone and Lights
- Air detector
- Syringe Pump
- Clamp and Pinch Valves
- BLD
- Internal
- Communication
- PM Timer and Date
- Clean screen
- SW configuration

If any items are out of calibration, replace and/or calibrate as needed to correct the problem.

Note: The Exit softkey appears on each Service – Diagnose screen. Any time the Exit softkey is pressed, the Prismaflex control unit returns to the Service – Diagnose screen.

6.3 Service Screens

Service screens are a series of menu- and softkey-driven screens which lead you through calibration procedures, on-line monitoring and testing of the main Prismaflex components and systems.

The main Service screen is only accessible from the start up screen by pressing the clock in the top right corner of the screen.

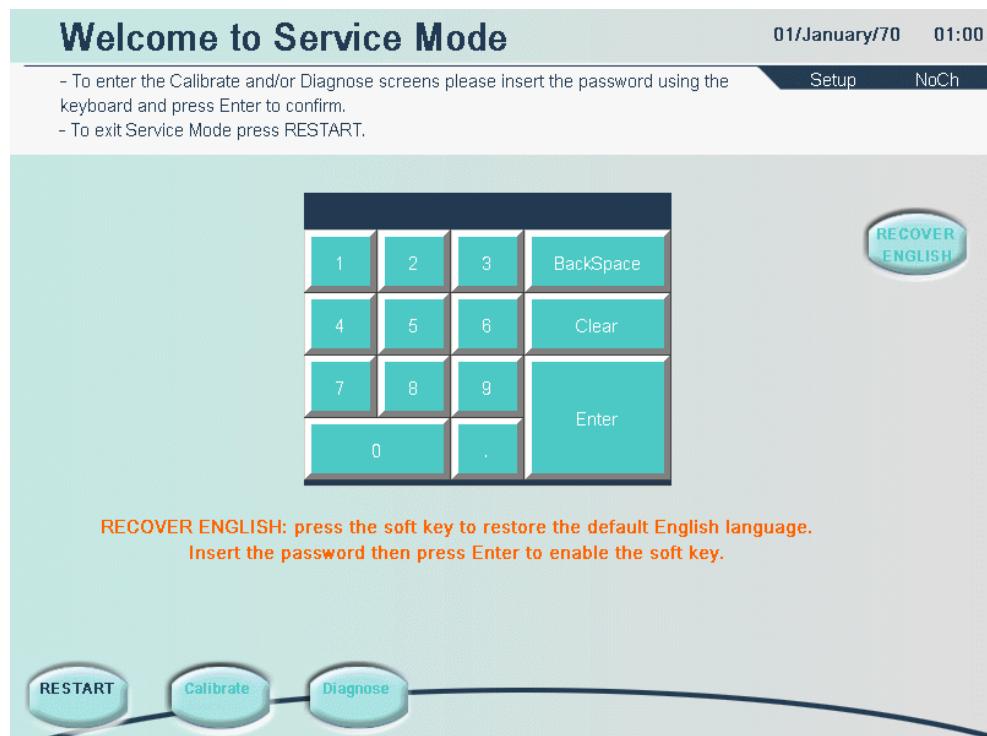


Figure 6.3 Service screens: Enter Password

[Figure 6.3 on page 172](#) shows the keypad to where to digit the password to access the Service screens:

1. Digit the password and press Enter. The “stars” in the display of letters should become white indicating a correct code.
2. With the white marking active you now can enter either Calibration or Diagnose mode. Coming back to this screen from either of the two requires a new entering of the password.

The “RECOVER ENGLISH” function is to be used when the qualified technician wants to service the machine but does not know the language installed (The Service mode is translated in the same language used for the treatment mode).

The RECOVER ENGLISH softkey is enabled only after password insertion as described above in steps 1 and 2. Pressing the RECOVER ENGLISH softkey will install the English language on the machine.

After pressing the RECOVER ENGLISH softkey, the technician must reboot the machine to allow the English language configuration file loading.

The RESTART softkey allows to go back into the treatment mode of the machine.

6.3.1 Service Calibrate Screens

By pressing the Calibrate softkey, the screen below is displayed. Use the up and down arrow keys to navigate through the three different “Calibrate” screens. Press the corresponding soft key to enter the different calibration pages.

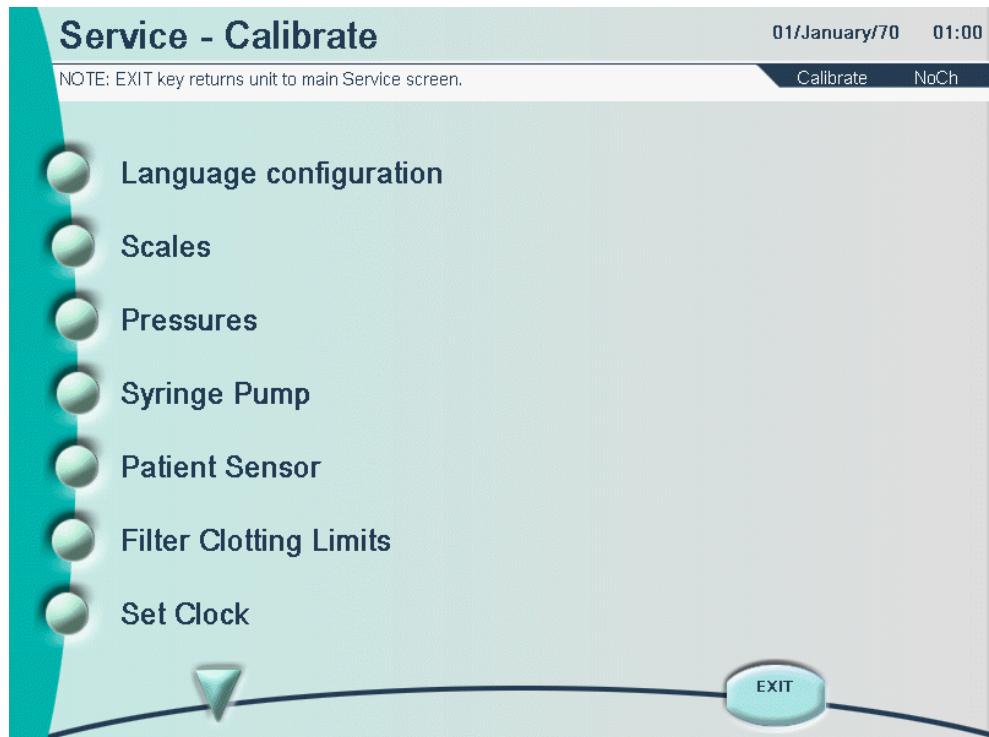


Figure 6.4 Calibrate Screen (First)

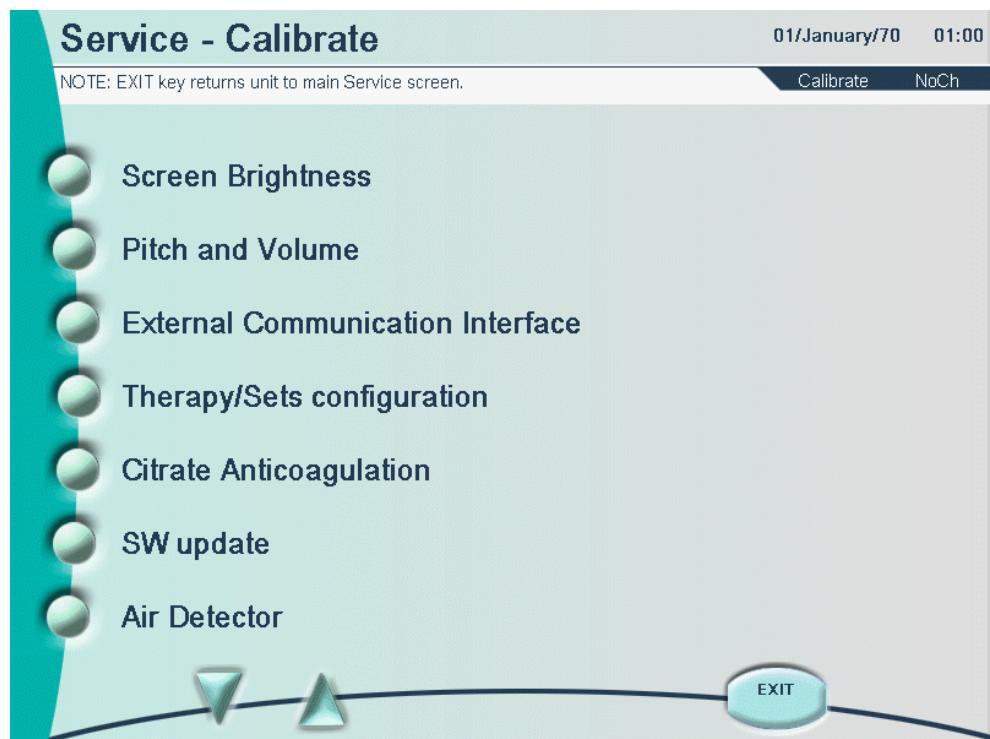


Figure 6.5 Calibrate Screen (Second)

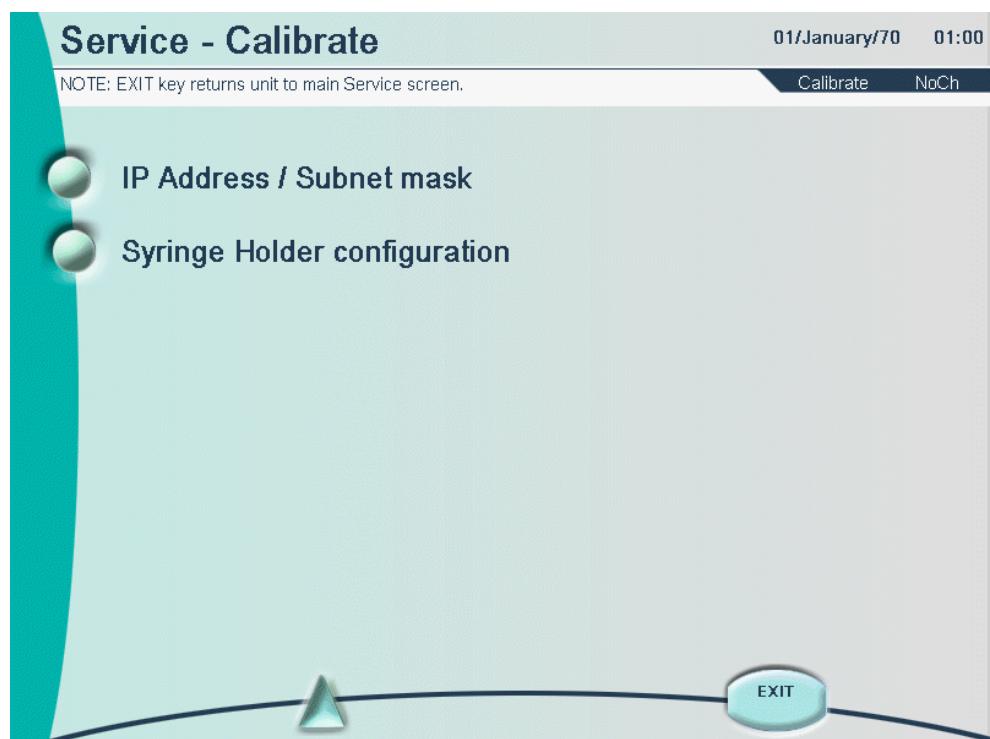


Figure 6.6 Calibrate Screen (Third)

Language configuration

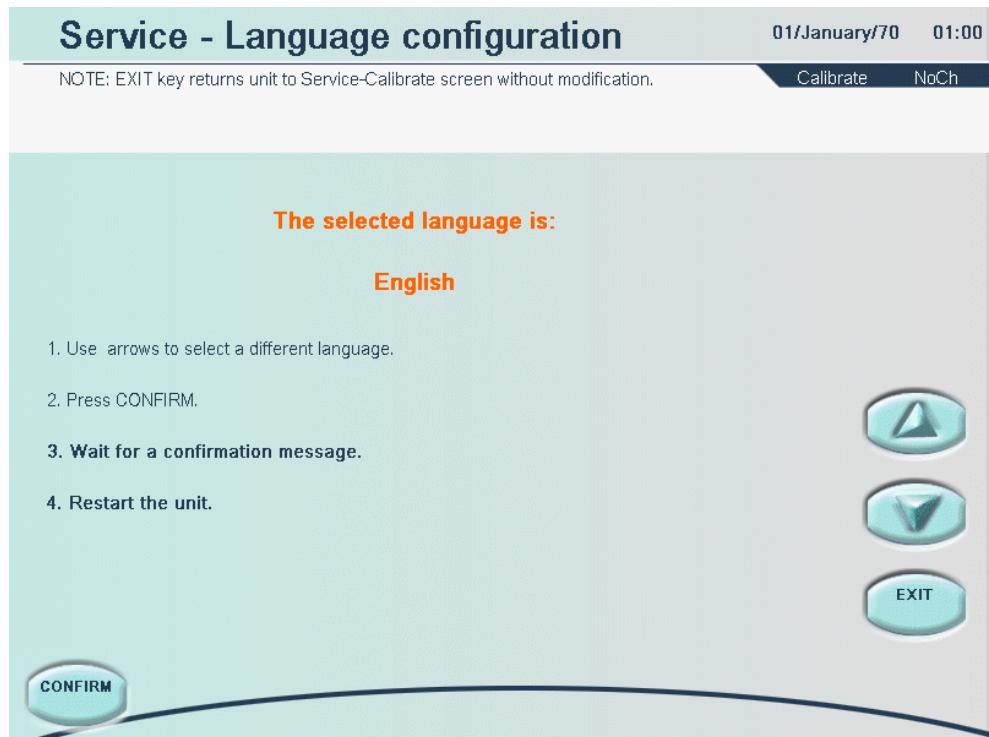


Figure 6.7 Language Configuration Screen

1. Open the back of the machine and insert the Prismaflex software CD in the CD-ROM.
2. Use the arrows to select a different language and press the CONFIRM softkey to confirm the selection.
3. Wait until a confirmation message is displayed.
4. Restart the control unit.

Scales Calibration

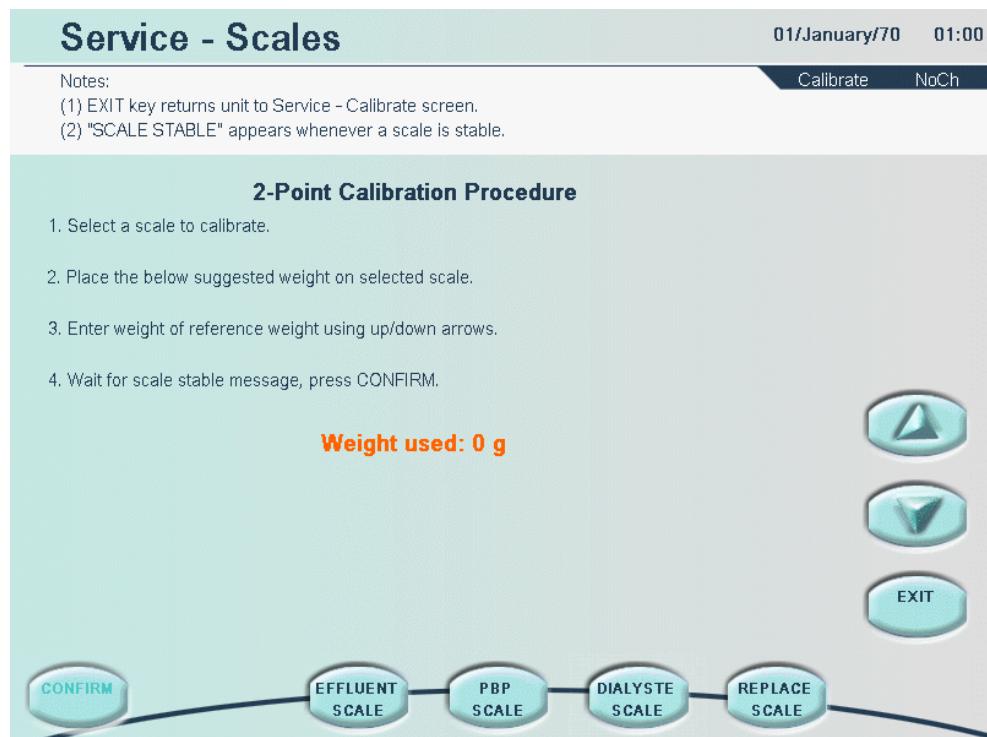


Figure 6.8 Scales Calibration Screen

From this screen it is possible to calibrate the scales.

A 2-POINT CALIBRATION PROCEDURE is used to calibrate the scales. The weights suggested are the following:

- first point 0 g
- second point 5200 g

Note: It is possible to select a different weight using the arrow buttons.

Instrument needed: a reference weight.



WARNING

Correct weights (Part A + Part B = 5200 g) must be used at the second calibration point (5200 g), when calibrating the scales. Failure to use the correct calibration weights at the second calibration point can cause serious injury or death to the patient.

Note: Be sure that the scale is closed during the calibration.

1. Select the scale to be calibrated by pressing its soft key.
2. Press "Confirm" when the message "Scale stable" appears
3. Hang the calibration weight A+B (5200 g) on the scale's middle hook.
4. Press "Confirm" when the message "Scale stable" appears.
5. Continue with the next scale until all scales have been calibrated.

If the values read from the scale at the first calibration point are outside the

valid intervals, the message “Scale out of tolerance, cannot be calibrated” appears on the screen. In this case the scale is damaged, and has to be replaced.

If the values read from the scale at the second calibration point are outside the valid interval, check that the correct weight is used. Then make sure that the correct weight value is entered and press softkey RETRY.

When a correct calibration has been performed, the message “CALIBRATION SUCCESSFUL” appears on the screen.

Verifying a scale

1. Press the date to enter technical screen.
2. Remove any weight on the scale.
3. Verify the values on the screen is within the accepted values defined in [“Table 6.1 Accepted values for scale verification” on page 202](#).
4. Place the calibration weight (part A+B) on the scale and monitor the values.
5. Gently press down the scale with your hand until the Protective Grams and Control Grams on the screen shows about 7200 g.
6. Gently release the scale.
7. Verify the values on the screen is within the accepted values defined in [“Table 6.1 Accepted values for scale verification” on page 202](#).
8. Gently lift the scale with your hand until the weight on the screen shows about 3200 g.
9. Gently release the scale.
10. Verify the values on the screen is within the accepted values defined in [“Table 6.1 Accepted values for scale verification” on page 202](#).
11. Repeat step [2–10](#) for all scales.

Pressure Sensors Calibration

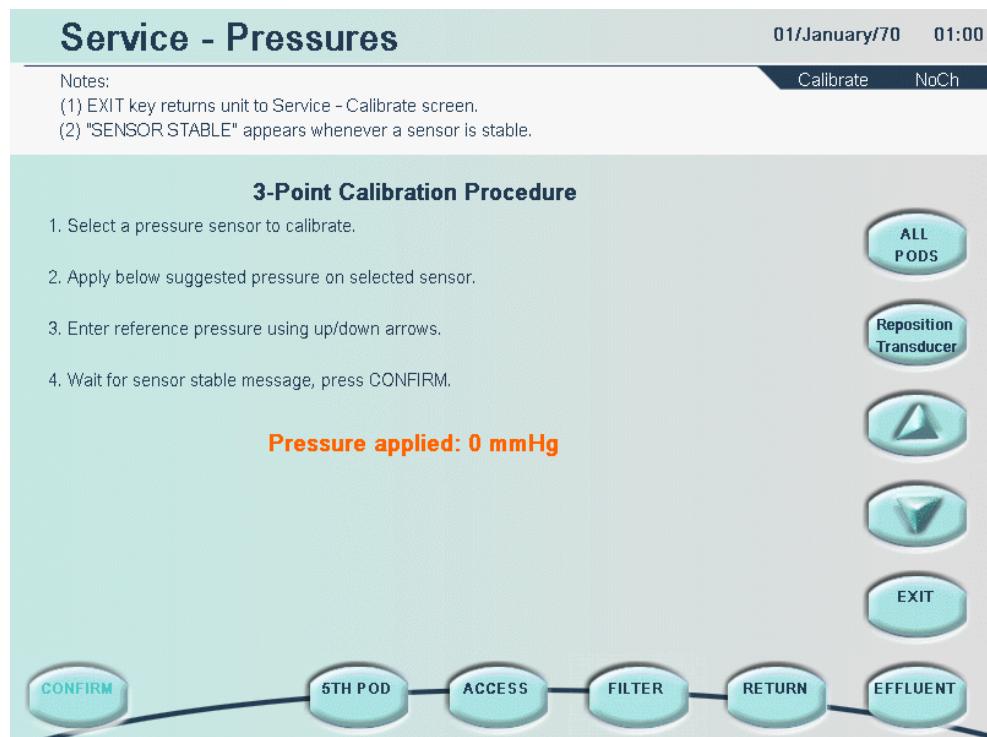


Figure 6.9 Pressure Sensors Calibration Screen

This page allows the operator to calibrate the pressure sensors following a 3-POINT CALIBRATION PROCEDURE. The pressure is displayed on the screen.

Instrument needed: 4 pressure test pods and one test connection with a luer lock, a pressure reference instrument, 3-way stop cock with luer connections.



WARNING

If calibration fails repeatedly, change the pressure sensor.

1. Select a pressure sensor to calibrate.
2. Apply the pressure suggested on the selected sensor. Wait until the "PRESSURES STABLE" message appears on the screen and then press the CONFIRM softkey.
3. Use the arrows to enter the real pressure applied and wait for sensor to stabilize, the "PRESSURE UNSTABLE" message disappears from the screen and it is replaced by "CALIBRATION SUCCESSFUL".

The pressure values suggested are the following:

- first point = 0 mmHg
- second point = 400 mmHg
- third point = -400 mmHg

Note: Use the arrows softkeys to change the pressure values (-500 to 500 mmHg).

When calibrating the Reposition Transducer the access pod position must currently be used. (The access reposition valve opens to introduce the pressure to the transducer).

Syringe Pump Calibration

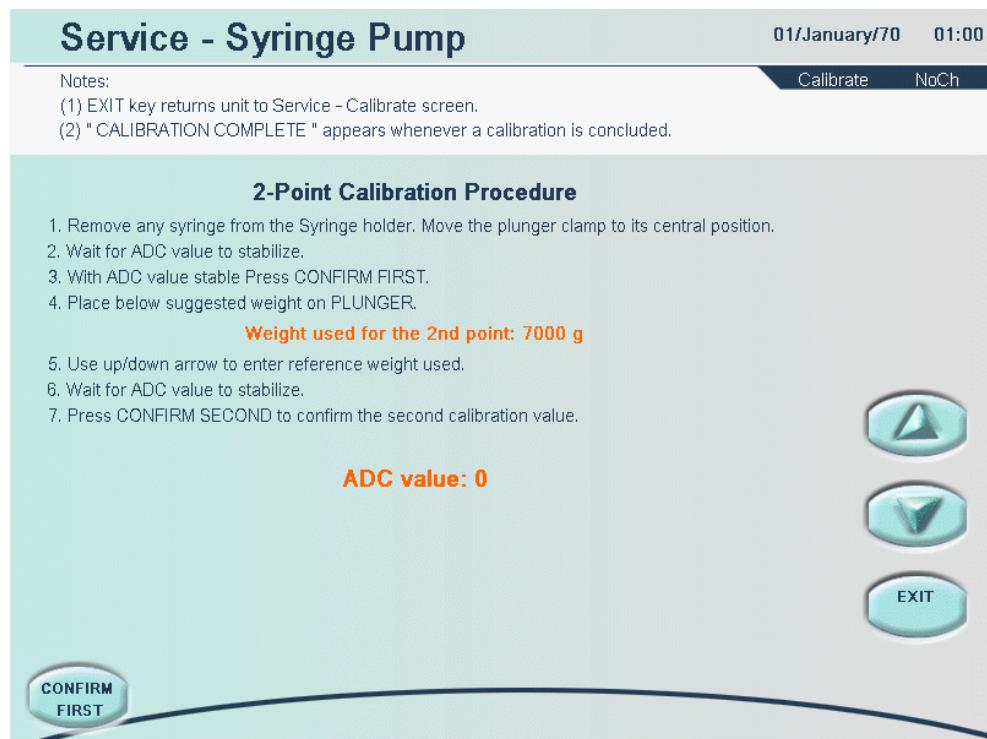
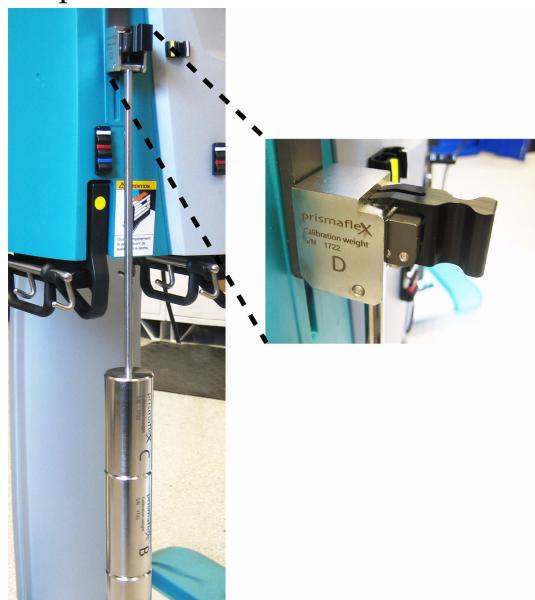


Figure 6.10 Syringe Pump Calibration Screen

1. Move the plunger to its central position with the up and down hardware keys placed above the syringe pump.
2. Press "Confirm first" when the value on the screen is stable.
3. Hang the calibration weight A+B+C+D (7000 g) on the plunger according to the picture below:



4. Press "Confirm second" when the value on the screen is stable.

5. Remove the weight from the plunger.
6. Press "Zeroing" when the value on the screen is stable.

The second point is selectable in the range between 7000 and 10000 g.

The ADC value represents the value read by the syringe pump (AD converter) when a weight is applied. The ADC value is displayed on the screen.

The syringe pump slave uses an AD converter with 10 bits so the AD value can assume values in the range between 0 and 1023.

If the value read from the pump at the first calibration point is outside the valid interval, the message "Syringe pump out of tolerance, can not be calibrated" appears on the screen. In this case the pump is damaged and has to be replaced.

If the value read from the pump at the second calibration point is outside the valid interval, most probably a wrong calibration weight is used, and both the message "Calibration failed. Check weight on plunger and retry" appears on the screen, and a new softkey RETRY becomes available. In this case, check that the correct weight is used, check that the correct weight value is selected by the arrow buttons, and then press softkey RETRY.

The calibration coefficients are calculated inside the slave with the 2 AD values read.

Instrument needed: a reference calibration weight between 7000 and 9999 g. The weight must be put on the syringe plunger clamp and must not touch the control unit.



CAUTION

Correct weights (Part A + Part B + Part C + Part D = 7000 g) must be used at the second calibration point (7000 g), when calibrating the syringe pump. Failure to use the correct calibration weights at the second calibration point will set the over-pressure alarm too low for the syringe.

Patient Sensor Calibration

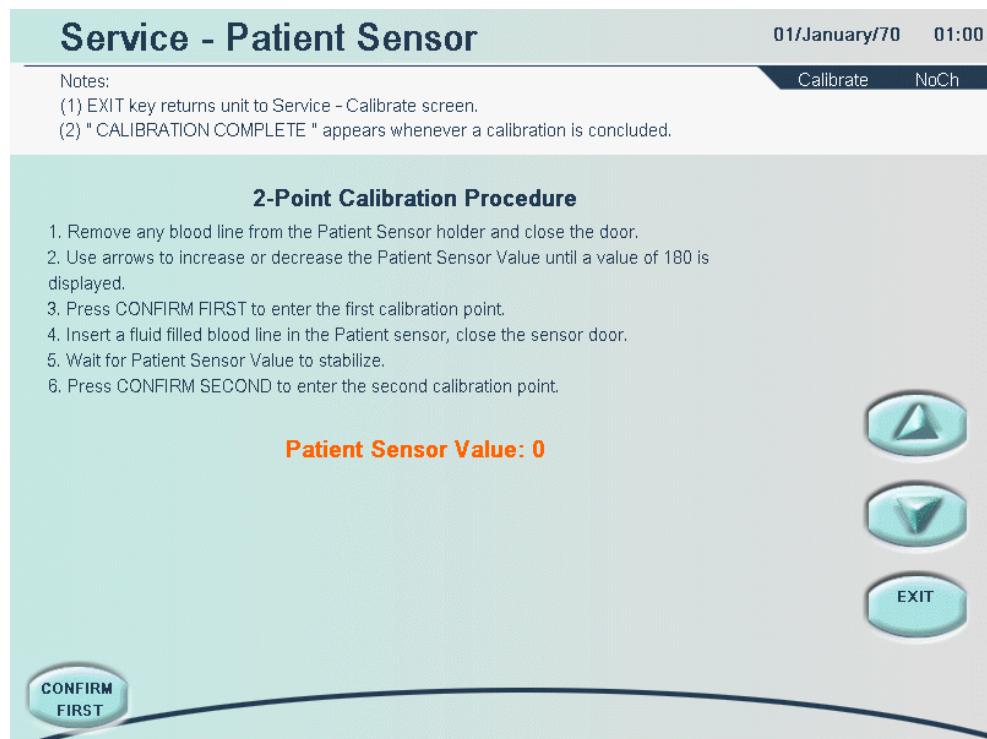


Figure 6.11 Patient Sensor Calibration Screen

Follow the 2-point calibration procedure explained in the Patient Sensor calibration page. The first calibration point for the transmitter power should be 180 ± 3 . The second calibration point should be 20-70.

The value displayed is the value calculated with the default calibration coefficients. This value is in the range 0–255. The Patient Sensor value is displayed on the screen.

Instrument needed: Prismaflex return line tube filled with clear fluid.

Filter Clotting Limits Calibration

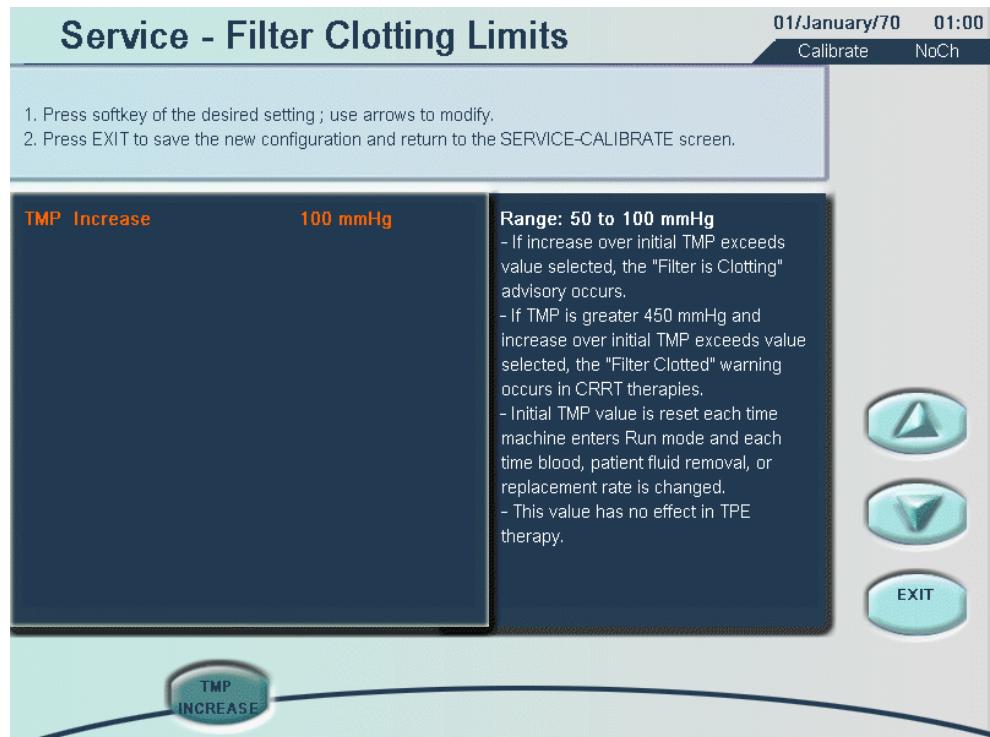


Figure 6.12 Filter Clotting Limits Calibration Screen

In this page it is possible to select the value of the increase of the TMP over which the Advisory "Filter is clotting" occurs:

$\text{TMP actual} > (\text{TMPinitial} + \text{TMPincrease})$

Press the TMP INCREASE softkey to change the value of TMP Increase in the range:

- low flow filters: 50–100 mmHg
- high flow filters: 50–80 mmHg

Set Date and Clock

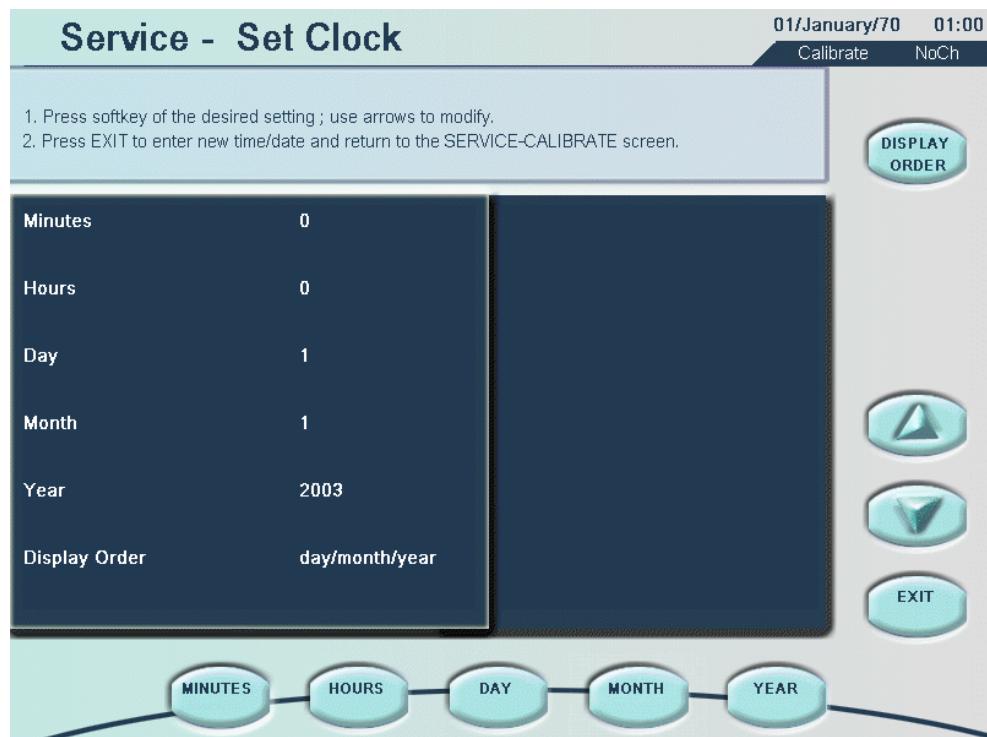


Figure 6.13 Set Date and Clock Screen

Press the softkey corresponding to the parameter to be changed. Use the arrows to adjust the displayed value.

The “Display order” parameter changes the way the current date is displayed: Day/Month/Year or Month/Day/Year

Screen brightness Calibration

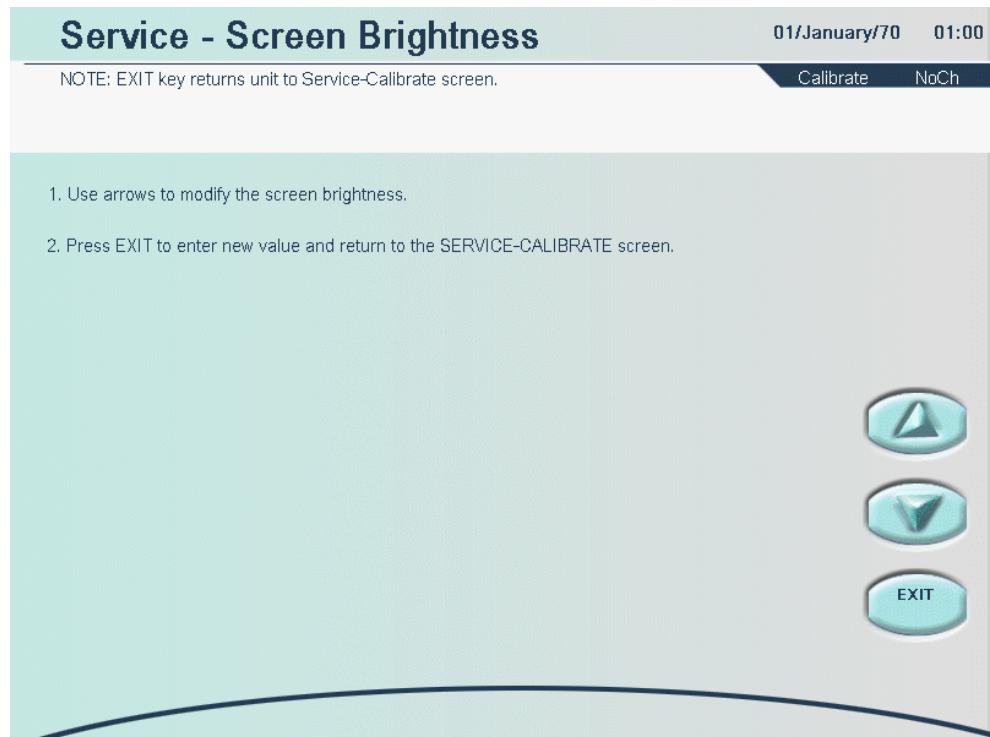


Figure 6.14 Screen brightness Calibration

Use the arrows to modify the screen brightness and press the EXIT softkey to confirm the choice.

Service Pitch and Volume

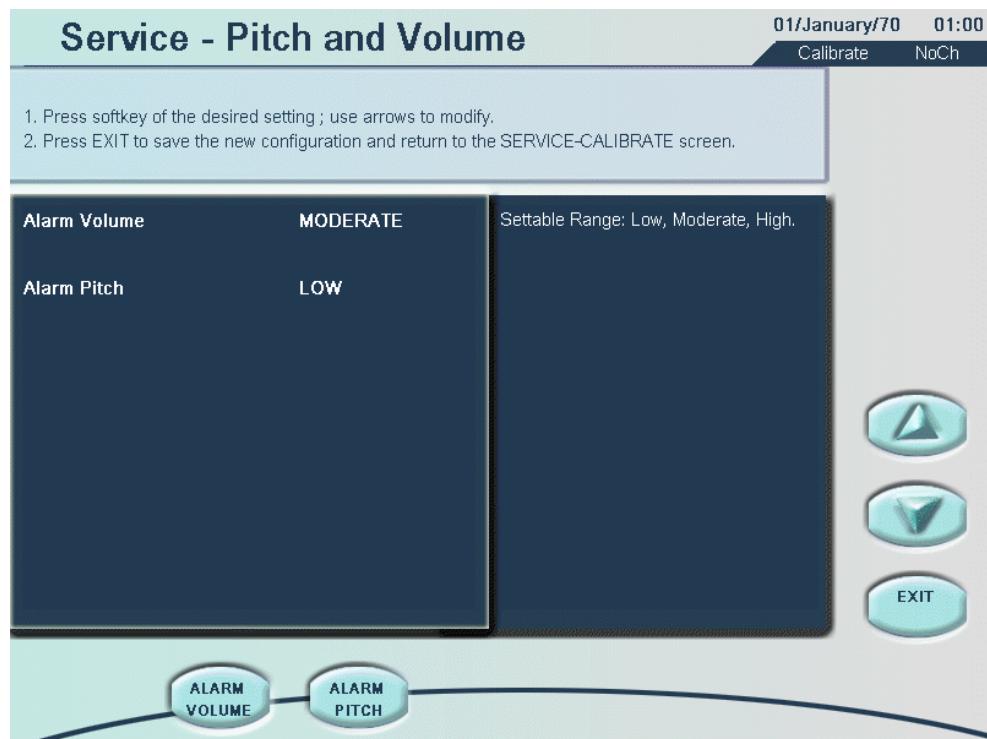


Figure 6.15 Pitch and Volume Screen

From this screen it is possible to set volume and alarm tone to one of the following values: LOW, MODERATE and HIGH.

For ALARM VOLUME the meaning of the values is the following:

- LOW is 50 dB
- MODERATE is 75 dB
- HIGH is 100 dB

For ALARM PITCH the meaning is:

- LOW is 1000 Hz
- MODERATE is 2000 Hz
- HIGH is 3000 Hz
- Default values are:
- alarm volume = MODERATE
- alarm pitch = LOW

External Communication Interface

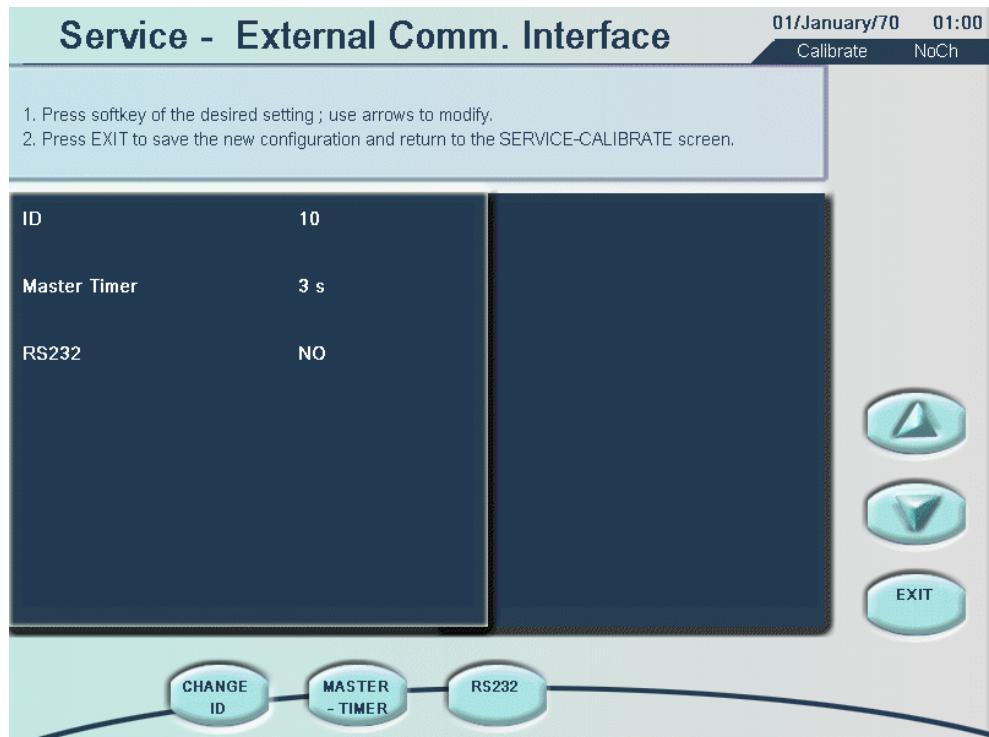


Figure 6.16 External Communication Interface Screen

This page is used to change the parameters related to the external communications.

ID: this parameter is the settable machine identity; a numerical value between 0 to 255 can be entered.

MASTER TIMER: this is the time between two subsequent transmissions in a one-way protocol. The time is selectable in the range between 1 to 10 seconds.

RS232: this parameter is used to enable or to disable the RS232 communication.

Default values are the following:

- ID = 10;
- MASTER TIMER = 3 seconds.
- RS232=disabled.

Press the softkey of the desired setting and use arrows to change the value.

Therapy/Sets Configuration

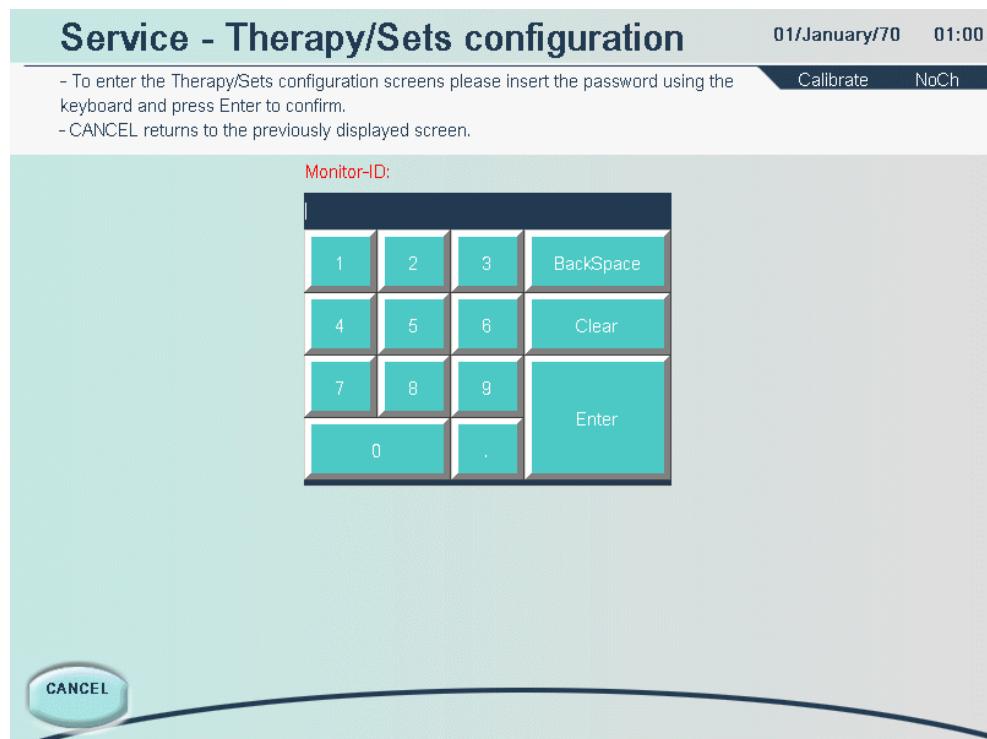


Figure 6.17 Therapy/Sets Configuration Screen (First)

To enter the Therapy/Sets configuration screen it is necessary to insert the proper password using the keyboard. Press Enter to confirm the password.

On this screen the Electronic Monitor ID can be seen. The Electronic Monitor ID needs to be provided to Gambro Customer Support in order to receive the passwords needed to unlock therapies.

There is one generic password that is used to reach the therapy/sets configuration screen. There are also therapy specific passwords that are used to unlock a particular therapy.

Unlocking a therapy does not enable it, it only means that it is possible to enable the therapy and change the sets. CRRT is unlocked by default.

Once the received password has been entered it will not be necessary to use it again, the therapy will remain unlocked (and cannot be locked).

After the received password has been entered, the following screen is displayed:

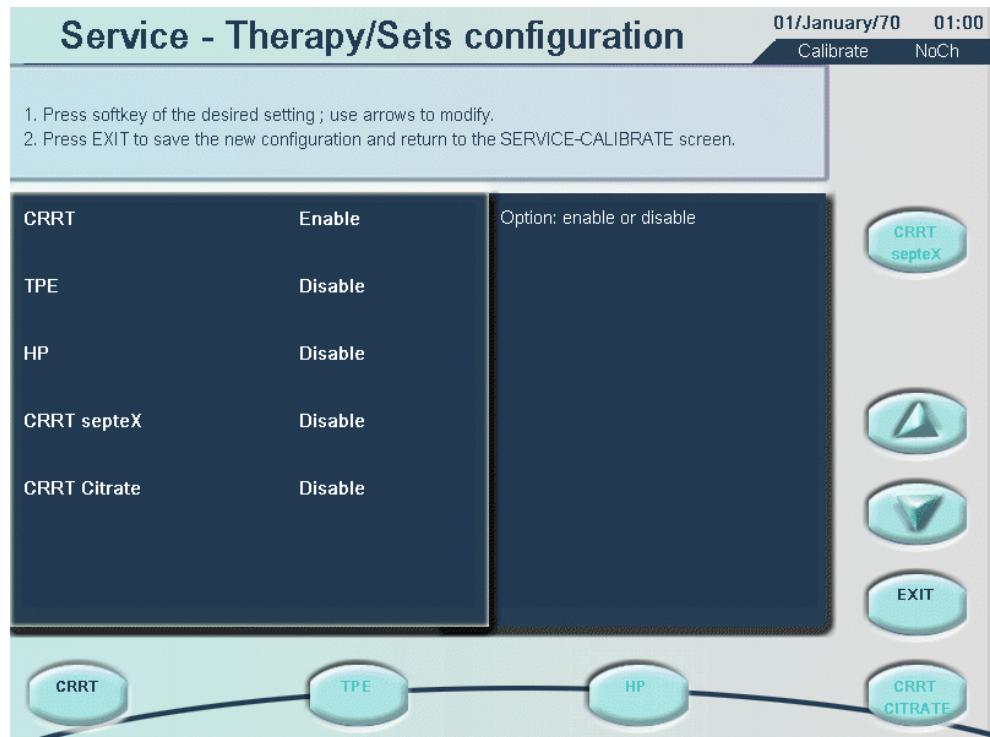


Figure 6.18 Therapy/Sets Configuration Screen (Second)

This page is used to enable or disable a therapy.

If a therapy is disabled, this therapy cannot be chosen when the operator enters the page for therapy selection: everything about this therapy is disabled.

CRRT is unlocked by default. The buttons for other therapies are disabled. Passwords received from Gambro need to be entered on the previous screen for these buttons to be unlocked.

Only when the button for the therapy is unlocked, the therapy can be enabled or the sets changed.

Press an enabled therapy button to enter the corresponding Set Configuration screen. From these screens you can enable/disable the different sets.

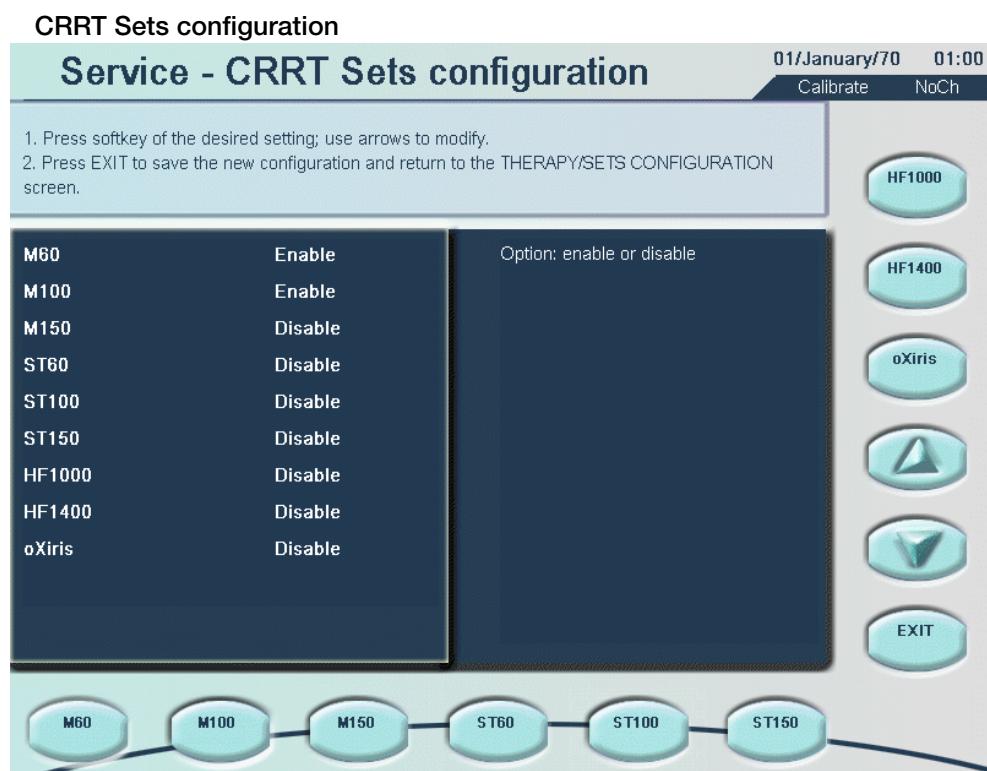


Figure 6.19 CRRT Sets Configuration Screen

Press the softkey corresponding to the set to be enabled/disabled. Use the arrows to modify. Press CONFIRM to return to the Therapy/Sets configuration screen.

Note: Before enabling a set in the Service – CRRT Sets configuration screen, verify that the selected set has been registered and can be sold in your own country.

CRRT Septex Sets configuration

The CRRT Septex Sets configuration works in the similar way as the CRRT Sets Configuration Screen (see above).

TPE Sets configuration

The TPE Sets configuration works in the similar way as the CRRT Sets Configuration Screen (see above).

HP Kit configuration

The HP Kit configuration works in the similar way as the CRRT Sets Configuration Screen (see above).

Citrate Anticoagulation CRRT

Citrate Service Mode section must be restricted to medical authorized personnel. The parameters to be customized are critical to patient safety. Check with physicians for the proper settings of the parameters.

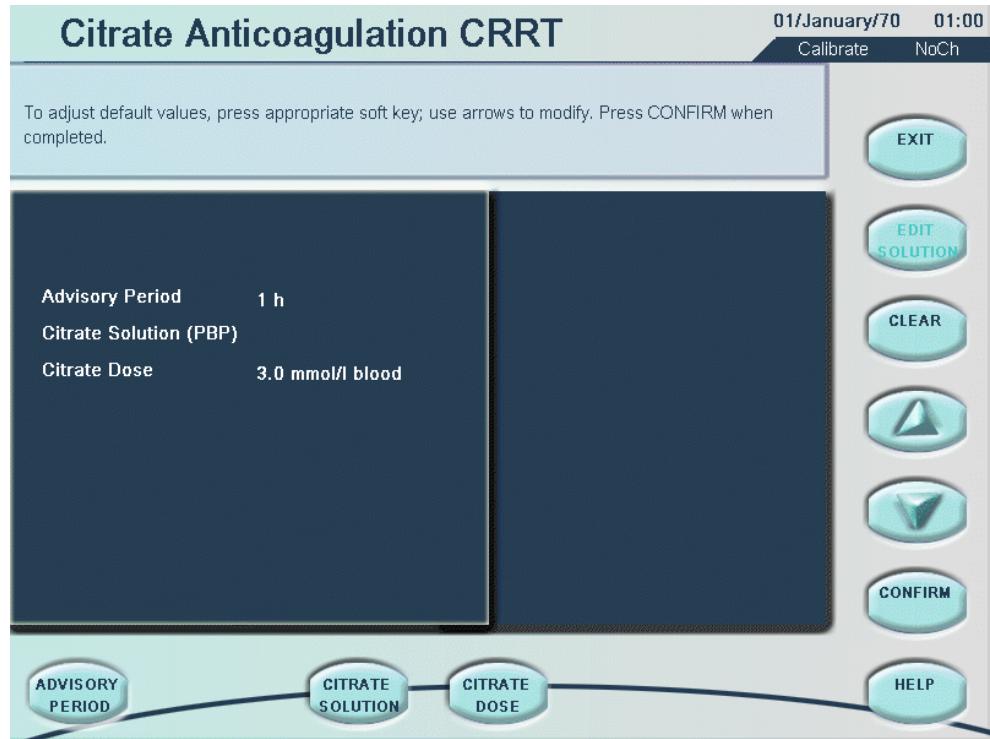


Figure 6.20 Citrate Anticoagulation CRRT Configuration Screen

The following settings can be made on this screen. Press the corresponding softbutton to change the setting.

- **Advisory Period** – Sets the time for the advisory alarm Anticoagulation Check Points. Citrate anticoagulation requires additional monitoring of patient's parameters. The advisory alarm reminds the operator of this.
- **Citrate Solution** – Sets the current citrate solution. Use the arrow keys to change solution. Press Edit Solution to view and edit the selected solution.
- **Citrate Dose** – Sets the prescribed citrate dose for the treatment. Use the arrow keys to change the dose.

Edit citrate solution

1. Press Citrate Solution on the “Citrate Anticoagulation CRRT” screen. Use the arrow keys to change to the solution you wish to change.
2. Press Edit Solution.

The following screen is shown:

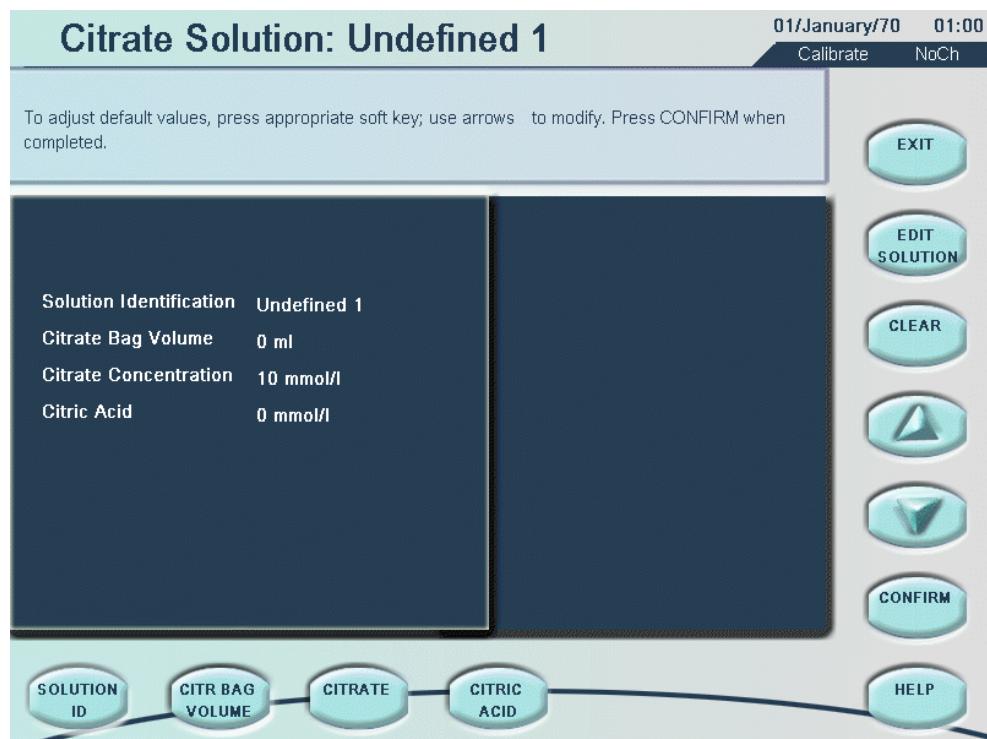


Figure 6.21 Edit Citrate Solution Screen

The following settings can be set.

- Solution ID button – Sets the name of the Solution
- Citr Bag Volume – Sets the citrate bag volume.
- Citrate – Sets the citrate concentration.
- Citrate Acid – sets the citrate acid concentration.

Service SW update

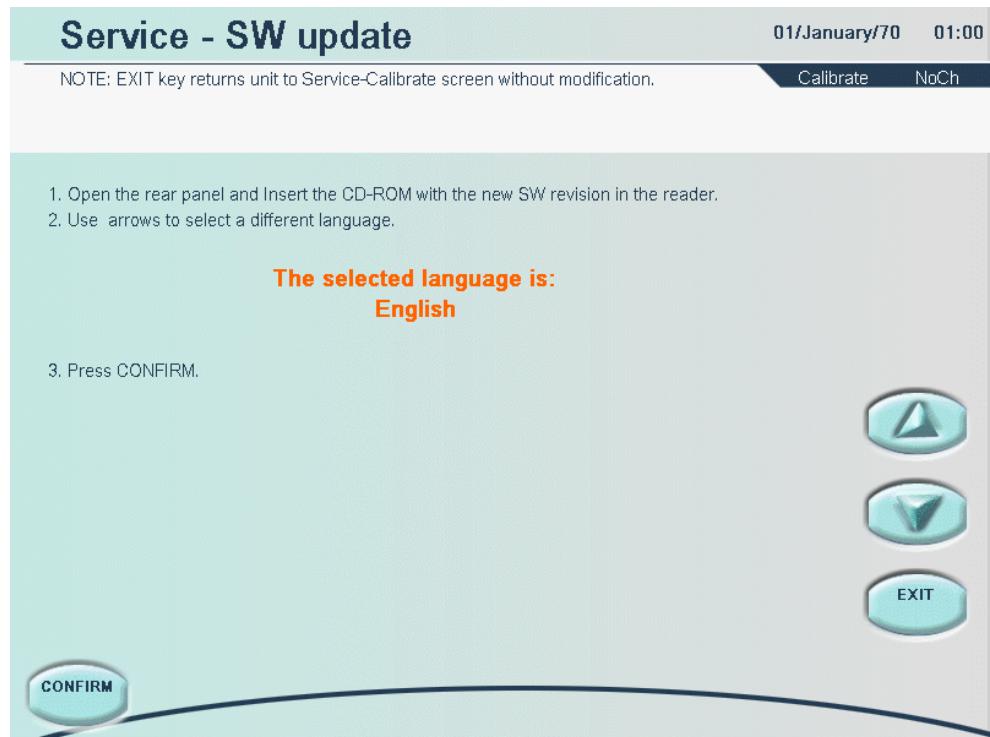


Figure 6.22 SW Update Screen (First)

This page allows the operator to install a new software release:

1. Insert the CD-ROM with the new software release in the CD-Rom reader opening the rear panel of the machine.
2. Use arrows to select the language and confirm it with the CONFIRM softkey.
3. After the confirmation message appears, restart the control unit.

By pressing the CONFIRM Softkey, the following screen is displayed:

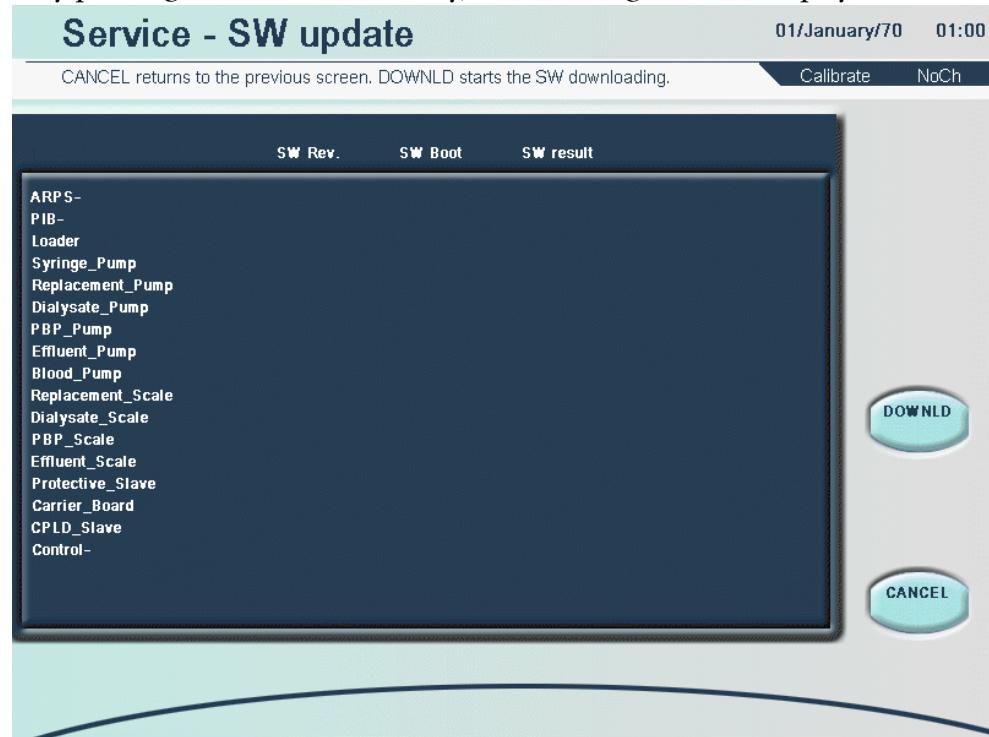


Figure 6.23 SW Update Screen (Second)

When data related to SW Rev., SW Boot and SW results appears, press the DOWNLD softkey to start the SW downloading; while the SW downloading procedure is in progress, the following message is displayed:

“SW DOWNLOADING IN PROGRESS...”

Note: Do not press the DOWNLD softkey until the CRC numbers appear in the SW Boot column (see [Figure 6.23 on page 194](#)).

Air Detector

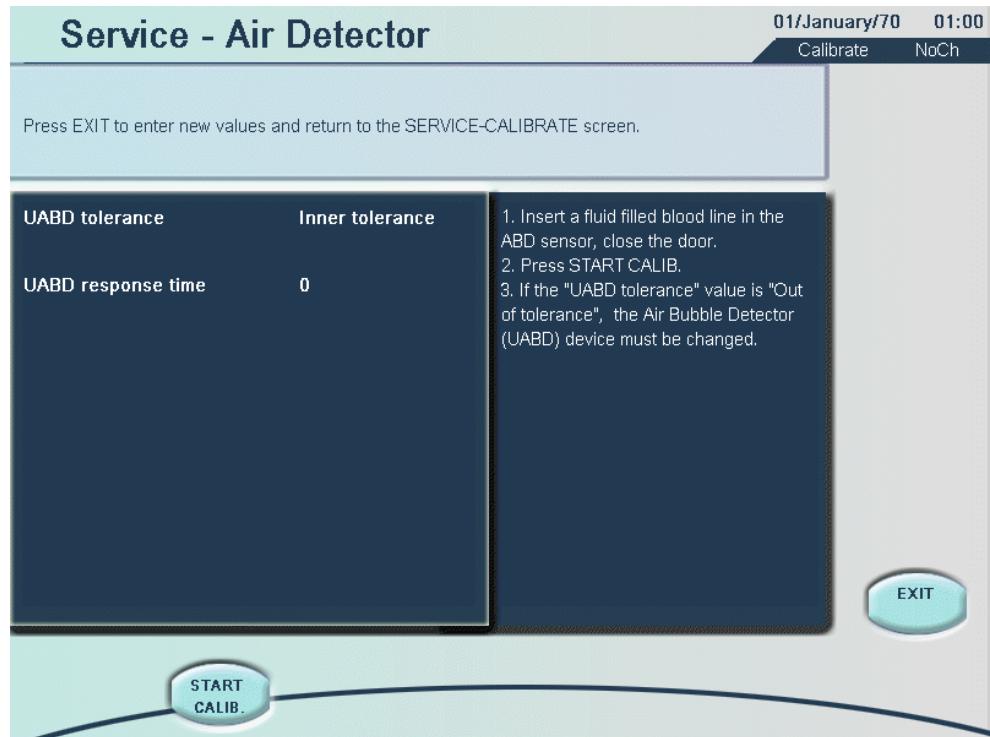


Figure 6.24 Air Detector Screen

Follow the procedure explained in the Air Detector Calibration Page.

The value displayed is the value calculated with the default calibration coefficients. This value is in the range 120-300. The Air Detector Value is displayed on the screen.

The value is out of range when is <120 or >300.

Instrument needed: Prismaflex return line tube filled with fluid.

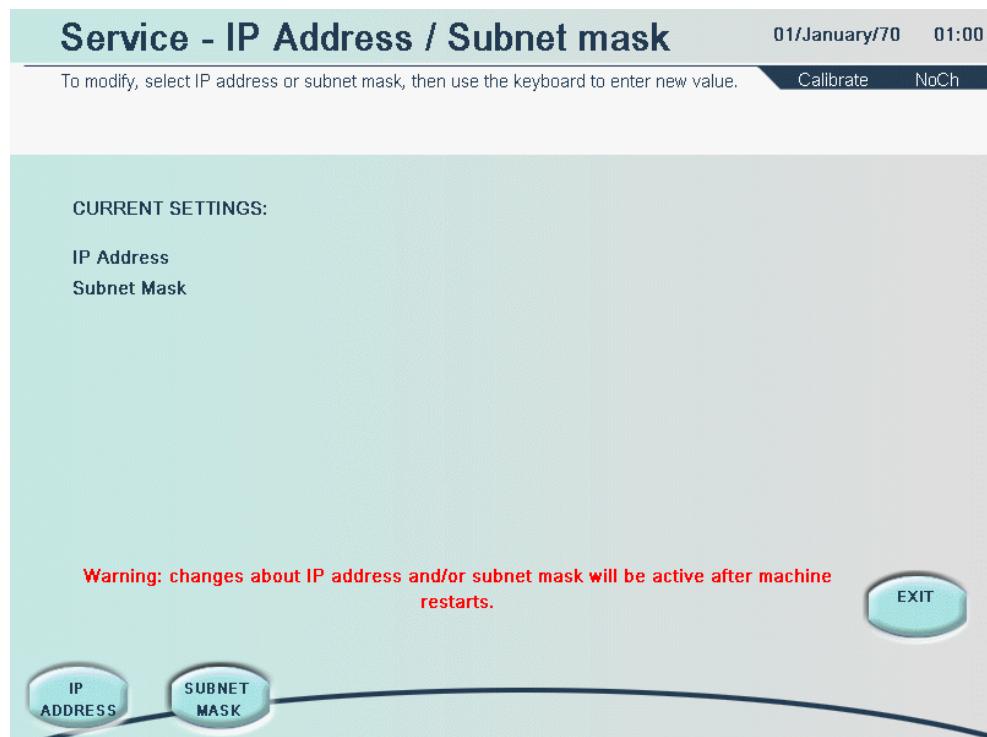
IP Address / Subnet mask

Figure 6.25 IP Address / Subnet mask Screen

Note: The new IP Address and/or Subnet mask just entered will be active after switching OFF and then ON the machine.

By pressing the IP Address / Subnet mask softkey a keypad is displayed to allow the IP Address or Subnet mask insertion.

Syringe Holder configuration

By pressing the Syringe Holder configuration softkey from the Calibrate screen, the following screen is displayed:

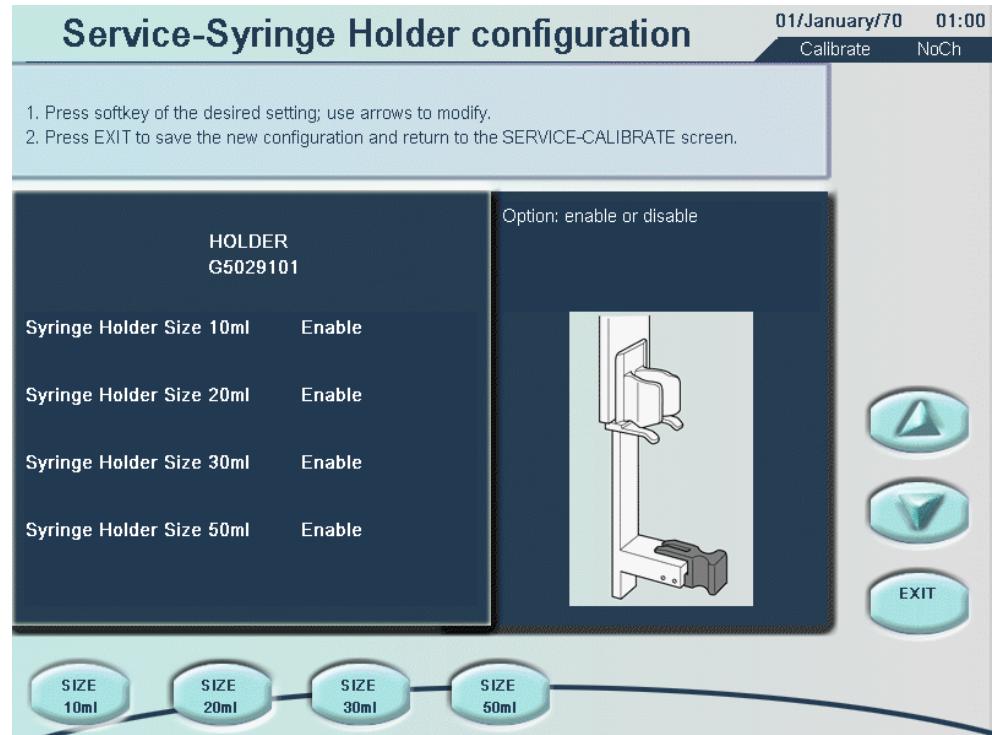


Figure 6.26 Syringe Holder Configuration Screen

Press the softkey corresponding to the syringe holder size to be set. Use the arrows to enable/disable the syringe holder size selected.

When one syringe holder size is enabled, all the others are disabled.

6.3.2 Service Diagnose Screens

By pressing the Diagnose softkey, the screen below is displayed. Use the up and down arrow keys to navigate through the two different “Diagnose” screens. Press the corresponding soft key to enter the different diagnostics pages.

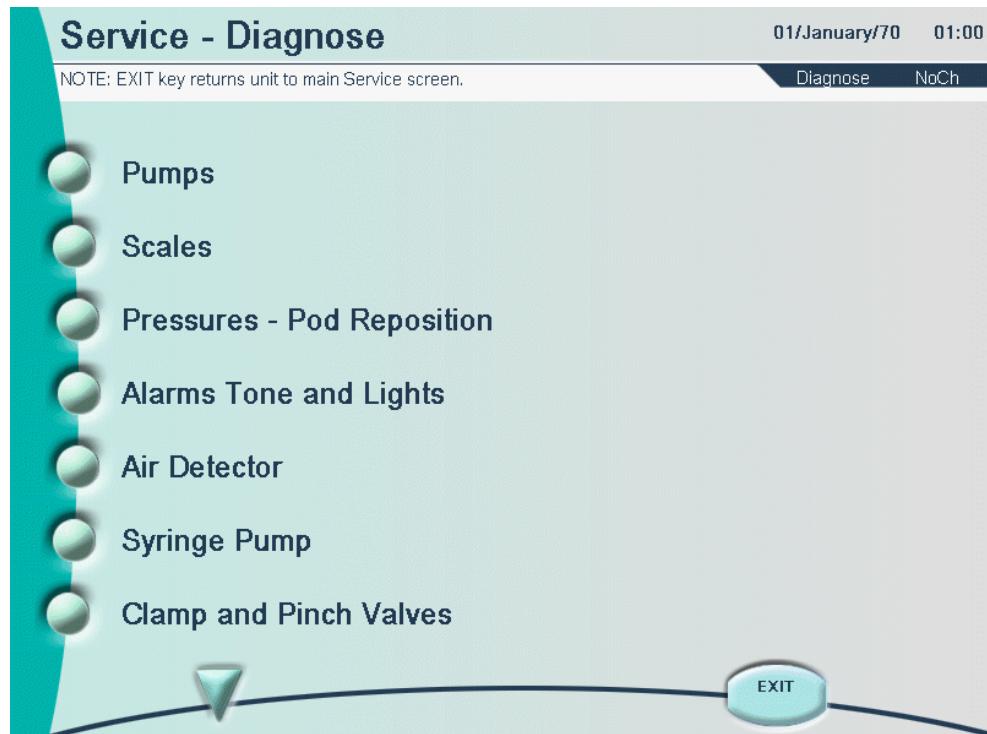


Figure 6.27 Service Diagnose Screens (First)

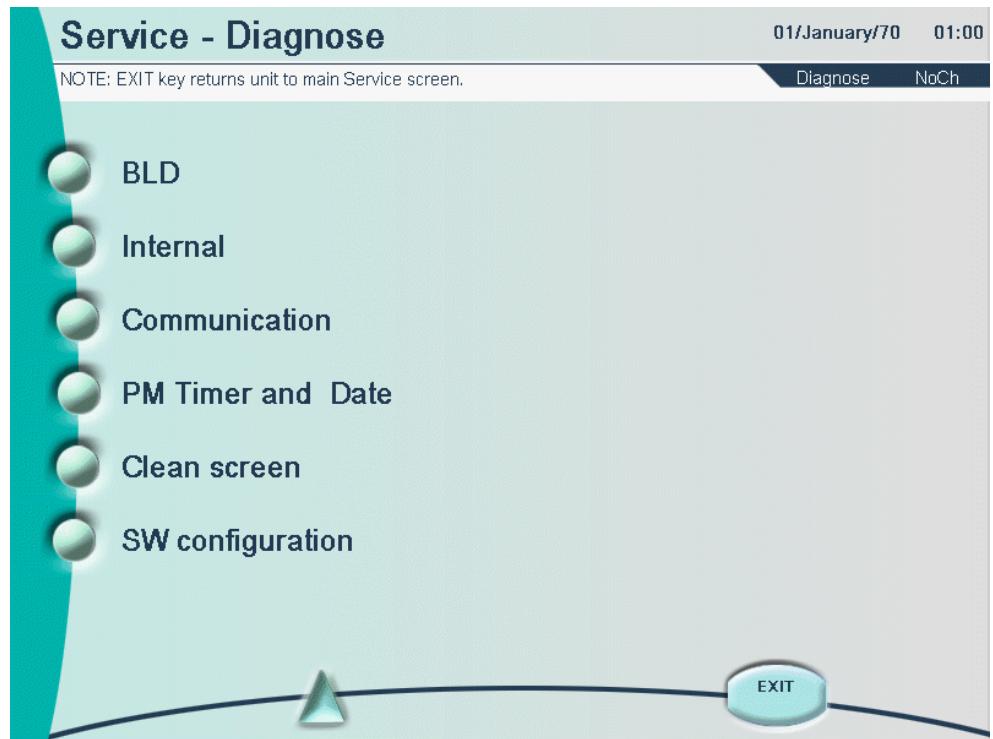


Figure 6.28 Service Diagnose Screens (Second)

Pumps Diagnose

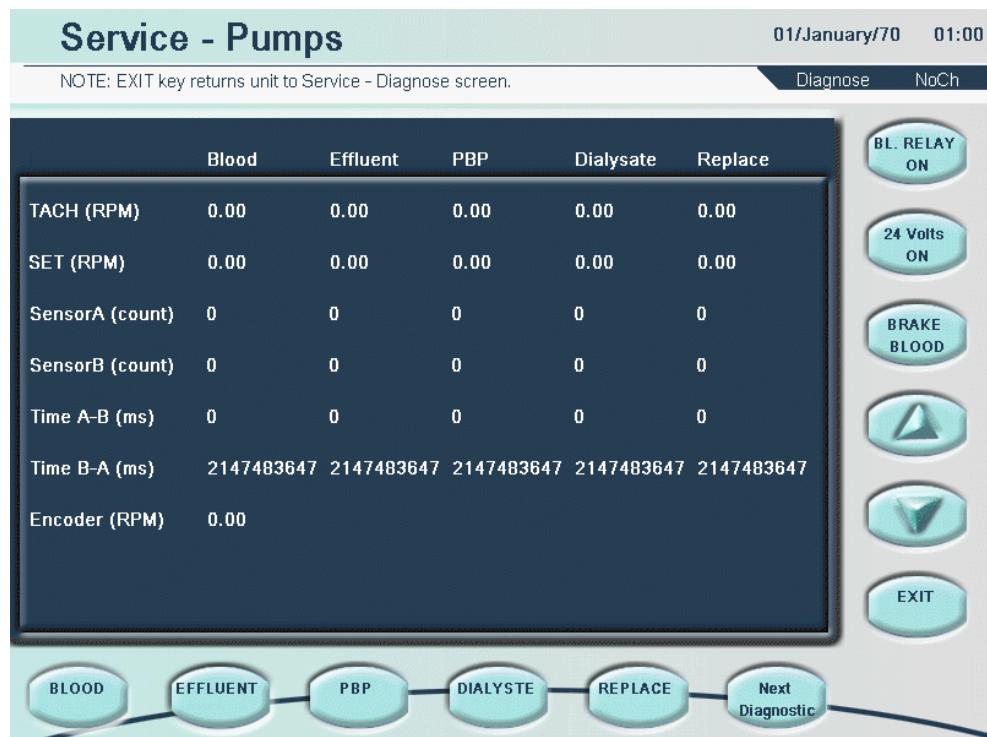


Figure 6.29 Pumps Diagnose Screen

Data displayed in the page is:

TACH: value in rpm read by the Protective side, based on hall sensors signal.

SET: rpm set by the user with the arrow softkeys

For rpm the range is:

-90 to +90 for blood pump

-250 to 250 for the other pumps (note that this is the maximum measurable range), pumps might grind if speed of 200 or more is selected and the brake is turned on/off), select a value between 180 to 200 and -180 to -200

SensorA (count): number of pulses accumulated for sensor A

SensorB (count): number of pulses accumulated for sensor B

Time A-B (ms): delay between the time in which the magnet (on the rotor) closes the circuit of the sensor A (on the stator) and the time in which the magnet closes the circuit of the sensor B (on the stator).

Time B-A (ms): time between B and A (as described above).

Encoder: value in rpm read by the Protective side, based on encoder signal.

Two or more pumps can be tested simultaneously. To test each of the pumps proceed as follows:

1. Select the pump to be tested by pressing one of the pump softkeys (Blood, Effluent, PBP, Dialysate, Replace). When you select a pump, the arrows softkeys, on the right side of the display, are enabled. Pressing the

up arrow softkey increases the pump speed and pressing the down arrow softkey decreases the speed. (The pump motor speed is indicated in rpms).

Note: NOTE: Pressing the up arrow soft key increases the pump motor speed CW and pressing the down arrow soft key decreases the motor speed. (The pump motor speed is indicated in rpm, a negative value indicates CCW direction).

2. Press the up and down arrow soft keys and release it when the desired pump speed is displayed in the Set row on the screen. The pump will start as soon as the arrow soft key is released. The TACH speed should be the same as the Set speed ($\pm 10\%$).
3. Once the pump is running, press the down soft key to decrease the set speed again. The TACH speed value should still be the same as the SET speed. ($\pm 10\%$)
4. The counter-clockwise direction is obtained selecting a negative number for rpm. Once the pump is running, press the down arrow soft key to decrease the Set motor speed until a negative value is reached. Release the arrow button. Again, the TACH speed should be the same as the Set speed ($\pm 10\%$).
5. Disabling the 24 Vdc (24 volts soft key) must stop the pumps; Turning the 24 volts ON again must restart the pumps.
6. Press the BRAKE/UNBREAK BLOOD soft key. The BRAKE BLOOD soft key must stop the blood pump, the UNBREAK Blood soft key must restart the blood pump at the same set rpm.
7. Press the BLOOD RELAY ON soft key. Turning ON the relay must stop the blood pump; turning OFF the relay must restart the blood pump.
8. Press the Next Diagnostic softkey to exit the Service - Diagnose Pumps screen and enter the Service - Diagnose Scales screen.

Scales Diagnose

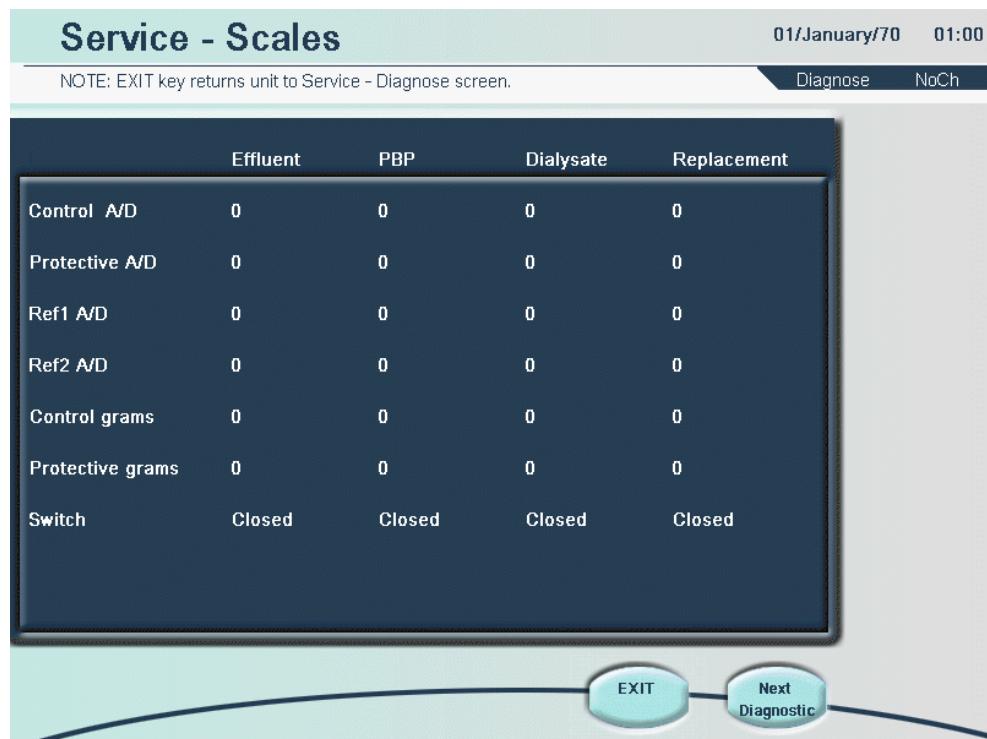


Figure 6.30 Scales Diagnose Screen

The screen displays the averaged scale readings for the control and protective Weight Transducer's, and the associated A/D values. The weight and A/D values at each Weight Transducer are continuously displayed in the row below the scale name.

- Control A/D: A/D value read by the channel used for the control side.
- Protective A/D: A/D value read by the channel used for the protective side.
- Ref1 A/D and Ref2 A/D: voltage references connected to 2 A/D channel
- Control grams/Protective grams: weight in grams read by the control/protective side with the actual calibration parameters.
- Switch: is the indication about the status of the switch (scale open / scale close)

Instruments needed: Calibration weight kit G5000101 or equivalent.

Table 6.1 Accepted values for scale verification

	No weight on scale	5.2kg calibration weight (part A+B) on scale
Control A/D	84 935 – 95 428	103 383–114 485
Protective A/D	55 312 – 65 798	36 237–47 349
Control grams	0±7g	5200 ±7g
Protective grams	0±7g	5200 ±7g

Verifying a scale

1. Remove any weight on the scale.
2. Verify the values on the screen is within the accepted values defined in "[Table 6.1 Accepted values for scale verification](#)" on page 202.
3. Place the calibration weight (part A+B) on the scale and monitor the values.
4. Gently press down the scale with your hand until the Protective Grams and Control Grams on the screen shows about 7200 g.
5. Gently release the scale.
6. Verify the values on the screen is within the accepted values defined in "[Table 6.1 Accepted values for scale verification](#)" on page 202.
7. Gently lift the scale with your hand until the weight on the screen shows about 3200 g.
8. Gently release the scale.
9. Verify the values on the screen is within the accepted values defined in "[Table 6.1 Accepted values for scale verification](#)" on page 202.
10. Repeat step 1–9 for all scales.

Pressures Diagnose – Pod Repo.

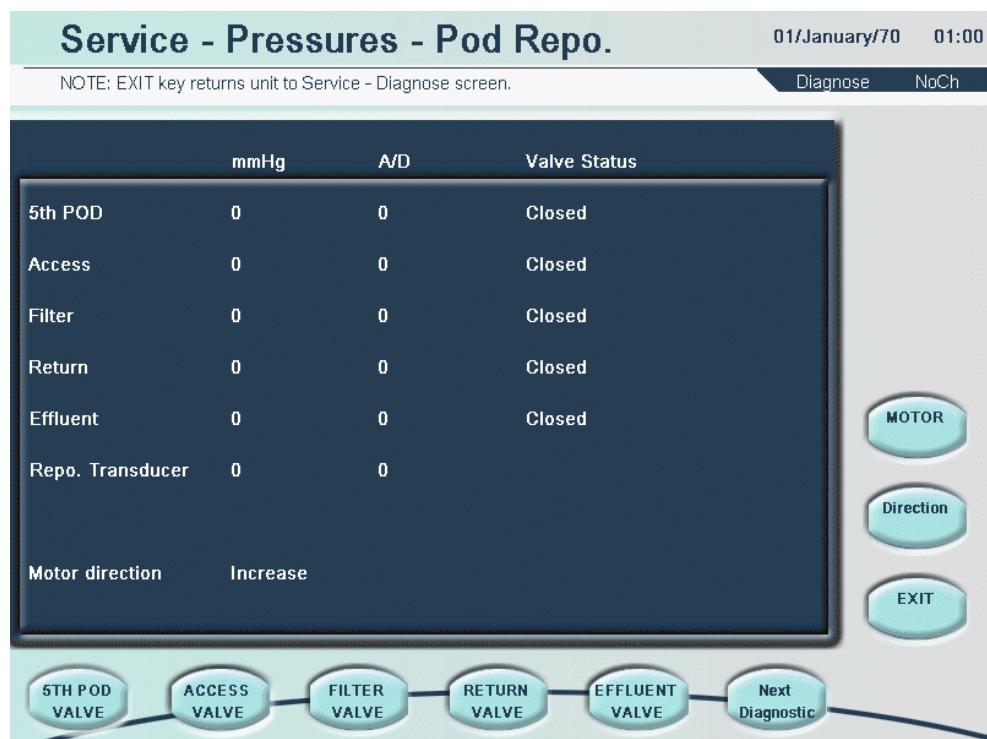


Figure 6.31 Pressures Diagnose Screen

The Service – Pressure diagnose screen displays 1 second averaged values for each of the pressure monitoring systems and the valve status in the row next to the monitor name. Data displayed in the page are:

- mmHg: pressure indication of associated valve in mmHg.
- A/D: A/D value read by the channel
- Value Status: the indication about the status of the valve (scale open / scale close)
- Repo. Transducer: ARPS pump
- Motor direction: Increase / Decrease

When applying pressure to the pressure test pods, attach an external pressure meter to the pressure test pod to verify accuracy. Pressing the buttons with valve names must open the selected valve. Releasing the buttons must close the selected valve.

Pressure tests

1. Install the pressure calibration/test tube on each of the pressure pod housings and securely onto the return.
2. Press the Access valve soft key to open the access reposition valve and allow the pressure applied at the access pressure pod to register on both the reposition and access transducers.
3. With the pressure monitors open to the ambient atmospheric pressure, the pressure must read 0 ± 4 mmHg and A/D should read 512 ± 20 .

4. Apply a pressure of -500 mmHg to all the pressure sensors. Verify that the pressure value is equal to the pressure measured by the manometer \pm 50 mmHg and verify that the A/D value is 12 ± 20 .
5. Apply a pressure of -250 mmHg to all the pressure sensors. Verify that the pressure value is equal to the pressure measured by the manometer \pm 25 mmHg and verify that the A/D value is 262 ± 20 .
6. Apply a pressure of +300 mmHg to all the pressure sensors. Verify that the pressure value is equal to the pressure measured by the manometer \pm 30 mmHg and verify that the A/D value is 812 ± 20 .
7. Apply a pressure of +350 mmHg to all the pressure sensors. Verify that the pressure value is equal to the pressure measured by the manometer \pm 35 mmHg and verify that the A/D value is 862 ± 20 .
8. Apply a pressure of +400 mmHg to all the pressure sensors. Verify that the pressure value is equal to the pressure measured by the manometer \pm 40 mmHg and verify that the A/D value is 912 ± 20 .

ARPS Repositioning proceed

Do the following procedure for all the softkeys (ACCESS VALVE, FILTER VALVE, RETURN VALVE, EFFLUENT VALVE, 5th POD VALVE [optional]).

1. Press the ASSOCIATED soft key. The soft key will illuminate and the valve for the repositioning system will open.
2. Press the Direction soft key until the "Motor Direction" row displays "Decrease", then press the MOTOR soft key to begin changing the pressure.
3. When the Valve Pressure displayed reaches approximately -250 mmHg, press the MOTOR soft key again to stop the pump. The "Reposition Press." display should decrease at the same rate as the valve pressure display, and should be approximately the same value.
4. Press the ASSOCIATED soft key again. The soft key is shaded and the valve for the repositioning system should close.

Note: Before the valve opens, the ARPS runs until the reposition transducer read a pressure equal to the pressure in the selected sensor.

At the end of the test procedures, remove the test pressure pods from all of the pressure pod housings.

Press the Next Diagnostic softkey to exit the Service - Diagnose Pressures screen and enter the Service - Diagnose Light and Tone screen.

Alarms Tone and Lights

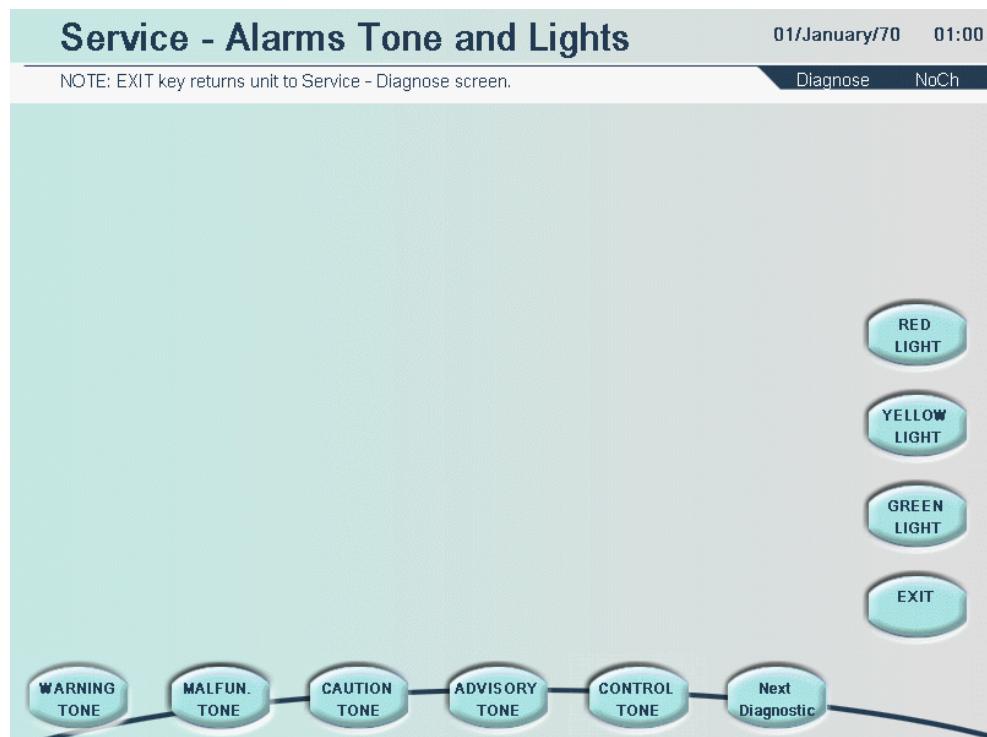


Figure 6.32 Alarms Tone and Lights Screen

1. Make sure pressing the softkey triggers the corresponding signal:

Table 6.2 Alarm tones and light signals

Softkey	Signal
WARNING TONE	Continuous beeping
MALFUN. TONE	Continuous beeping
CAUTION TONE	One beep every 5 seconds should be heard.
ADVISORY TONE	Intermittent double-beep should be heard.
CONTROL TONE	Light tone indicating touch screen response.
RED LIGHT	The Red lamp will illuminate continuously.
YELLOW LIGH	The Red lamp will illuminate continuously.
GREEN LIGHT	The Red lamp will illuminate continuously.

2. Press the Next Diagnostic softkey to exit the Service - Light and Tones screen and enter the Service - Air Detector screen.

Air Detector

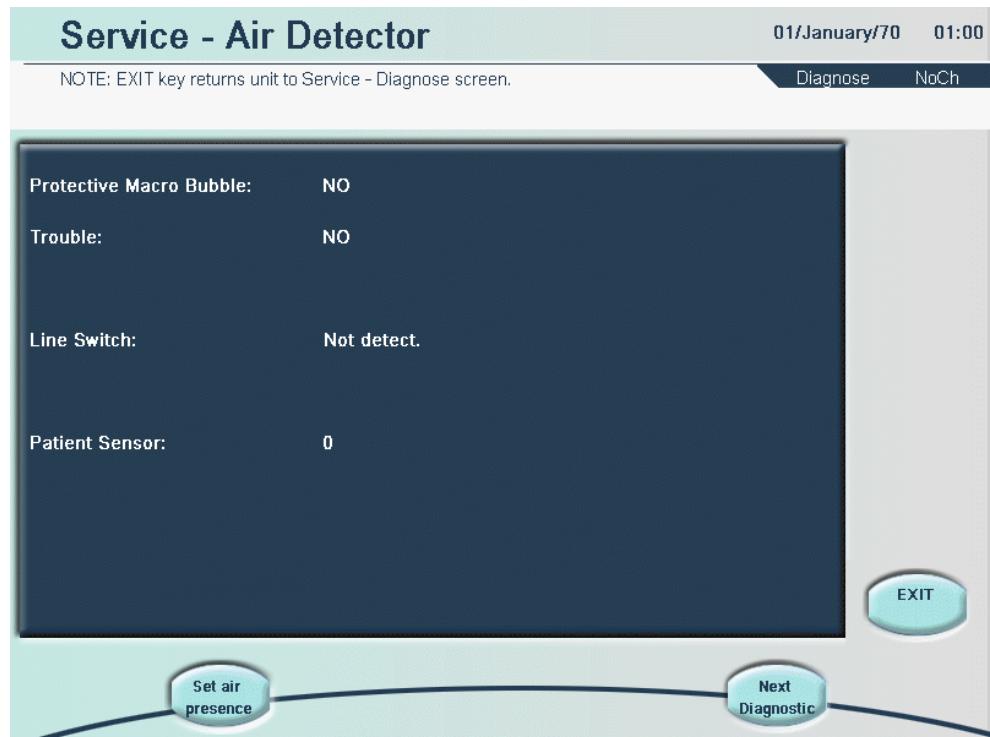


Figure 6.33 Air Detector Screen

1. The Patient Sensor row displays the value read by the Patient Sensor. Without a tube present the value should be 180 ± 3
2. Insert a fluid-filled tube into the Air Bubble Detector. Verify that "Line Switch" displays "Line Detect". Make sure that the patient sensor reading is in the range of 20–70.
3. Press the Set air presence softkey to simulate a macro bubble. Verify that "Protective Macro Bubble" displays "YES", or toggles between "YES" and "NO". Also, verify that "Trouble" displays "YES". The Line switch should show "Line Detect"
4. Press the Set air presence softkey again. Verify that "Protective Macro Bubble" displays "NO" and that "Trouble" displays "NO".
5. Press the Next Diagnostic softkey to exit the Service - Diagnose Air Detector screen and enter the Service - Diagnose Syringe Pump screen.

Syringe Pump


WARNING

The internal diameter of approved syringes has been verified at the time of printing this manual. Check that the syringe inner diameter is the same as specified in table [Table 6.3 on page 210](#) or [Table 6.4 on page 211](#). The manufacturer of the Prismaflex control unit cannot be held liable for subsequent changes that may occur to syringe dimensions.

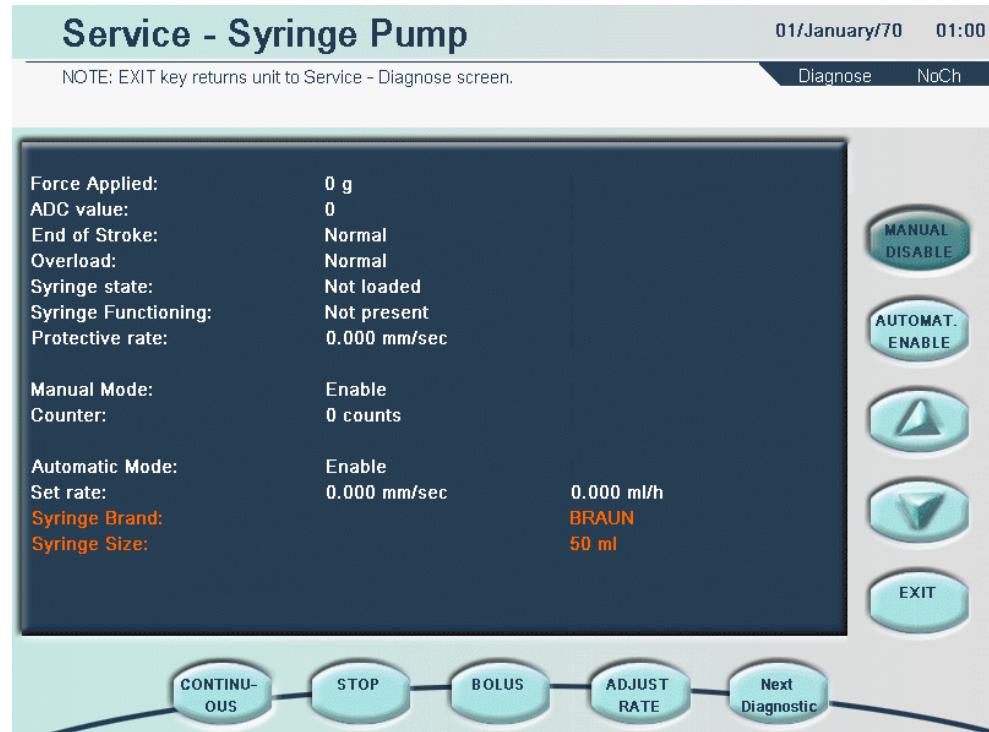


Figure 6.34 Syringe Pump Screen

Data displayed in the page are:

- Force applied (N): is the actual force applied to the syringe plunger clamp calculated by the actual calibration coefficients.
- ADC value: is the AD value read by the heparin pump.
- End of stroke:
 - Normal: no end of stroke
 - Eos UP: end of stroke up (not working for all types of clip holders)
 - Eos DOWN: end of stroke down
- Overload: this field indicates when a overload condition is reached. The overload threshold is a value syringe dependent.
- Syringe state: indicates if the syringe is loaded or not loaded.
- Syringe functioning: indicates the actual condition of the heparin pump and can assume the following values:
 - Not present. The syringe is not installed in its holder;
 - Loading. The syringe pump is loading the syringe

- Wai. Hepar. The syringe pump is waiting for automatic heparinisation
- Adaptation. The heparinisation starts
- Normal. Normal working condition
- Protective rate: mm/s read by the Protective side. In the new software version the unit is mm/s.
- Manual mode and Automatic mode: indicates if the mode is disabled or enabled reading the status of the heparin pump.
- Counter: this is the meter value of the encoder pulses received during UP manual operation. This for counting the quantity of heparin administered in manual mode.
- Set rate: is the rate set by the arrow buttons.

Syringe Pump test procedure:

Note: Carrier should be in central position.

Weight verification

1. Remove any syringe on the syringe plunger.
2. Hang the calibration weight A+B+C+D (7000g) on the plunger according to the picture below:



3. Confirm that "Force applied" on the screen is between 6800g and 7200g.
4. Remove the weight from the syringe plunger.
5. Confirm that "Force applied" on the screen is between -200g and +200g

Manual Bolus verification

1. Verify that "Manual enable" button says "Manual disable".

2. Lower the plunger by pressing the down key.
3. Place the syringe in the holder.
4. Connect the luer to a Prismaflex set or an unused effluent bag in order to get some resistance in the pump movement and adjust the plunger to 15 ml mark.
5. Press the up key to load the syringe properly and close the syringe latch. Confirm by looking at the screen that the message Syringe state "loaded" appears.
6. Make the "Manual enable" soft key show "Manual enable".

Automatic Bolus verification

1. Enable the automatic mode and press the BOLUS soft key.
2. The syringe pump should deliver a 5 ± 0.5 ml bolus in a time reported in the table below:

Table 6.3 Syringe Delivery Time

SYRINGE	VOLUME (ml)	INTERNAL DIAMETER (mm)	DELIVERY TIME (sec.)
Ecoject	50	29	15
Fresenius Injectomat	50	29	15
Terumo	50	29	15
Braun (Omnifix)	50	27.9	16
Codan Luer Lock	50	27.7	17
Kendall Monoject	50	26.6	18
BD Plastipak	50	26.4	18
ICO Gamma Plus / Monosteril	30	23.9	22
PIC 30 LL	30	23.4	23
Terumo	30	23.3	23
Braun (Omnifix)	30	22	26
BD Plastipak	30	21.7	27
Braun (Omnifix)	20	20.2	31
Kendall Monoject	20	20.1	32
Terumo	20	20	32
BD Plastipak	20	19	35
Braun (Omnifix)	10	16	50
Terumo	10	15.8	51

Table 6.3 Syringe Delivery Time

SYRINGE	VOLUME (ml)	INTERNAL DIAMETER (mm)	DELIVERY TIME (sec.)
BD Plastipak	10	14.3	62

Continuous delivery verification

1. Press the ADJUST RATE softkey. An up arrow and a down arrow appear on the right side of the screen. Set the delivery rate for the syringe pump to 0,018 mm/s. The rate is selectable in the range between 0 and 0.5 mm/s.
2. Press the Continuous softkey and start the stopwatch. Verify that in 12 minutes the syringe pump delivers the following quantity of anticoagulant:

Table 6.4 Delivery Quantity

SYRINGE	VOLUME (ml)	INTERNAL DIAMETER (mm)	DELIVERY (ml/12 min.)	ml/h
Ecoject	50	29	8.6	42.8
Fresenius Injectomat	50	29	8.6	42.8
Terumo	50	29	8.6	42.8
Braun (Omnifix)	50	27.9	7.9	39.6
Codan Luer Lock	50	27.7	7.8	39.1
Kendall Monoject	50	26.6	7.2	36.0
BD Plastipak	50	26.4	7.1	35.5
ICO Gamma Plus / Monosteril	30	23.9	5.8	29.1
PIC 30 LL	30	23.4	5.6	27.9
Terumo	30	23.3	5.5	27.6
Braun (Omnifix)	30	22	4.9	24.6
BD Plastipak	30	21.7	4.8	24.0
Braun (Omnifix)	20	20.2	4.2	20.8
Kendall Monoject	20	20.1	4.1	20.6
Terumo	20	20	4.1	20.4
BD Plastipak	20	19	3.7	18.4
Braun (Omnifix)	10	16	2.6	13.0
Terumo	10	15.8	2.5	12.7
BD Plastipak	10	14.3	2.1	10.4

3. Stop the stopwatch. When the syringe pump is operating, the “Protective rate” display value should change indicating that the monitor microprocessor is receiving the stepper motor signal increments.
4. When the delivery rate accuracy is verified, press the STOP softkey.
5. Press the Next Diagnostic softkey to exit the Service - Diagnose Syringe Pump screen and enter the Service - Diagnose Clamp and Pinch Valves screen.

Clamp and Pinch Valves

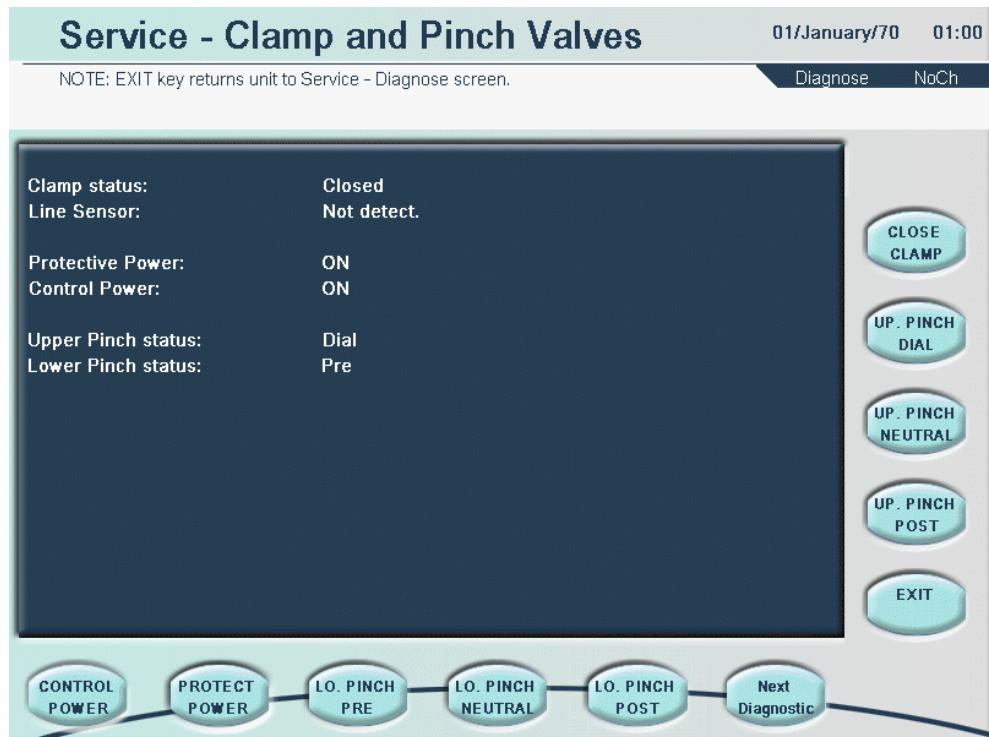


Figure 6.35 Clamp and Pinch Valves Screen

1. Press the CLOSE/OPEN CLAMP softkey to open or close the line clamp. The status of the clamp is displayed in the “Clamp status:” row.
2. Make sure that the clamp is open. Press the PROTECT POWER softkey. The clamp should close and the “Clamp status” row should indicate “Closed”.
3. To open the clamp, press the PROTECT POWER softkey again.
4. Press the CONTROL POWER softkey. The clamp should close and the “Clamp status” row should indicate “Closed”.
5. To open the clamp, press the CONTROL POWER softkey again.
6. Pressing the buttons indicating the pinch valves position, the selected pinch valve must move in the required position:
 - a. Insert a line segment in the upper pinch valve, (low position); press the UP.PINCH DIAL softkey. Verify that the upper pinch valve is in low position, the low line of the upper pinch is occluded, and the “Upper pinch status” row displays “Dial”. Remove the line segment.
 - b. Press the UP.PINCH NEUTRAL softkey. Verify that the upper pinch valve is in middle position and the “Upper pinch status” row displays “Neutral”.
 - c. Insert a line segment in the upper pinch valve, (upper position); press the UP.PINCH POST softkey. Verify that the upper pinch valve is in upper position, the upper line of the upper pinch is occluded and the “Upper pinch status” row displays “Post”. Remove the line segment.

- d. Insert a line segment in the lower pinch valve, (upper position); press the LO. PINCH PRE softkey. Verify that the lower pinch valve is in upper position, the upper line of the low pinch is occluded and the “Lower pinch status” row displays “Pre”. Remove the line segment
 - e. Press the LO. PINCH NEUTRAL softkey. Verify that the lower pinch valve is in middle position and the “Lower pinch status” row displays “Neutral”.
 - f. Insert a line segment in the lower pinch valve, (low position); press the LO. PINCH POST softkey. Verify that the lower pinch valve is in low position, the low line of the low pinch is occluded and the “Lower pinch status” row displays “Post”. Remove the line segment
7. Press the Next Diagnostic softkey so the machine will leave the Service - Diagnose Clamp and Pinch Valves screen and enter the Service - Diagnose BLD screen.

BLD – Blood Leak Detector

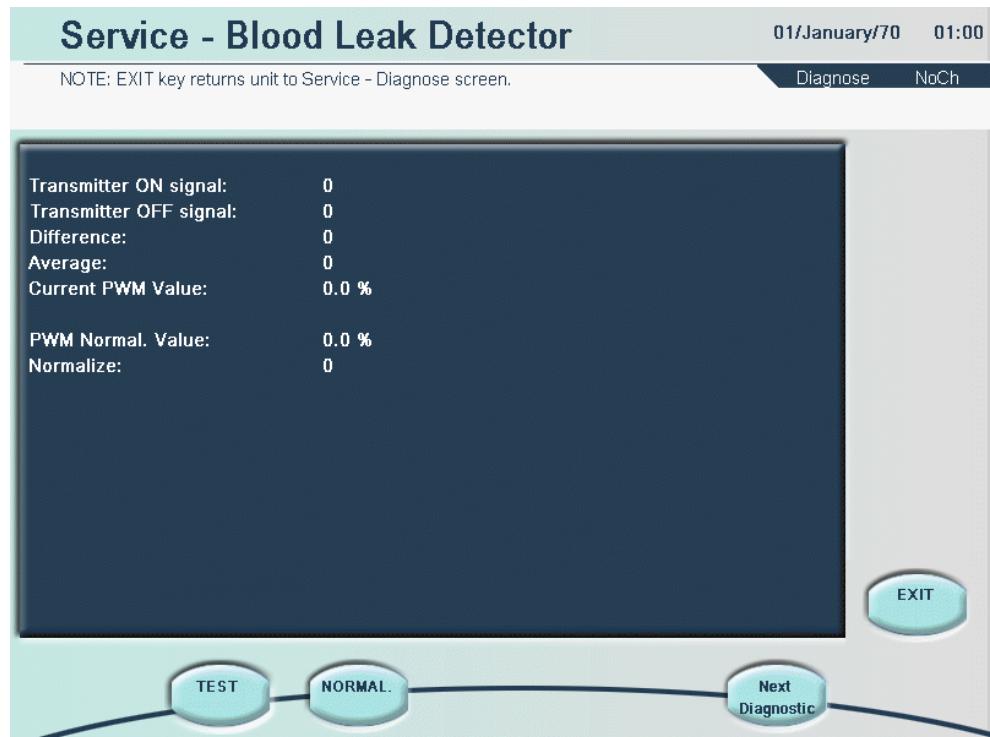
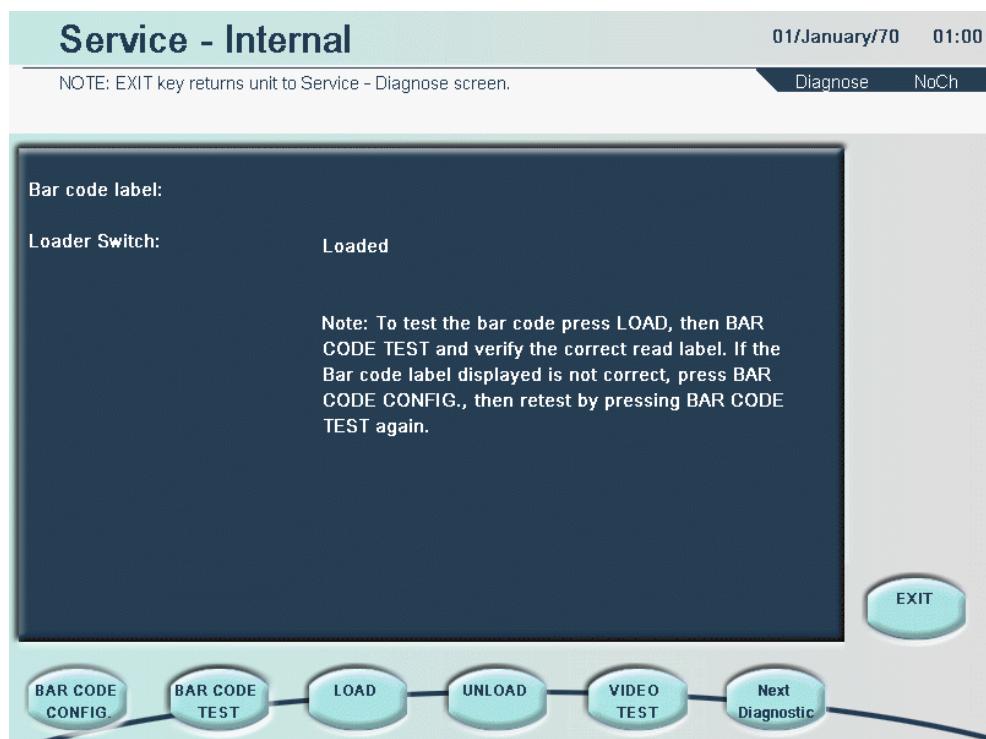


Figure 6.36 Blood Leak Detector Screen

1. Fill the effluent tubing segment from a Prismaflex set with water and install it in the blood leak detector housing.
2. Press the NORMAL. soft key.
Note: The "Normalize" value that appears after the NORMAL. soft key is pressed is stored only for use during the current Service mode. The Blood Leak Detector Normalize value is re-calibrated and stored during the Prime Self-Test.
3. Wait for BLD normalization. Verify the transmitter PWM is in the range 15%–45% and the normalization value is 43000 ± 3000 .
4. Remove the effluent tubing segment from the holder and press the NORMAL. soft key.
5. Verify the PWM Normal value is <15%.
6. Install a empty tube in the BLD holder and press the NORMAL. soft key (wait approx. 3 minutes).
7. Verify the PWM transmitter is >45%. Press the NORMAL. soft key.
8. Press and hold TEST soft key, this will generate a malfunction Prime Self Test (code 18).

Internal**Figure 6.37 Internal Screen**

1. Press the LOAD softkey. The loader should be in the 'out' position. Pressing the softkey should cause the loader to retract, and the pumps should turn in the proper direction.

Note: All the pumps runs clockwise (CW) when the LOAD or the UNLOAD soft key is pressed. If the loader is in the inner position press UNLOAD to get it back to the outer position.

2. Press the UNLOAD softkey and verify that the pumps turn in the proper direction and the loader moves in the appropriate direction.
3. Load a Prismaflex set. Pressing the BAR CODE TEST softkey the label read must appear in the "Bar code label" row.
4. If the bar code reader is not able to read the label the following appears "Bar code label: Er". Press the BAR CODE CONFIG softkey: a different bar code reader configuration is set. Retry to press the BAR CODE TEST softkey.
5. Pressing the VIDEO TEST softkey, the display turns all the pixels on for a few seconds, then off. Verify that all pixels are lighted when the display is on, and that none are lighted when the display is off. (Test not yet implemented).
6. Press the Next Diagnostic softkey to exit the Service - Diagnose Internal screen and enter the Service - Diagnose Communication screen.

Communication

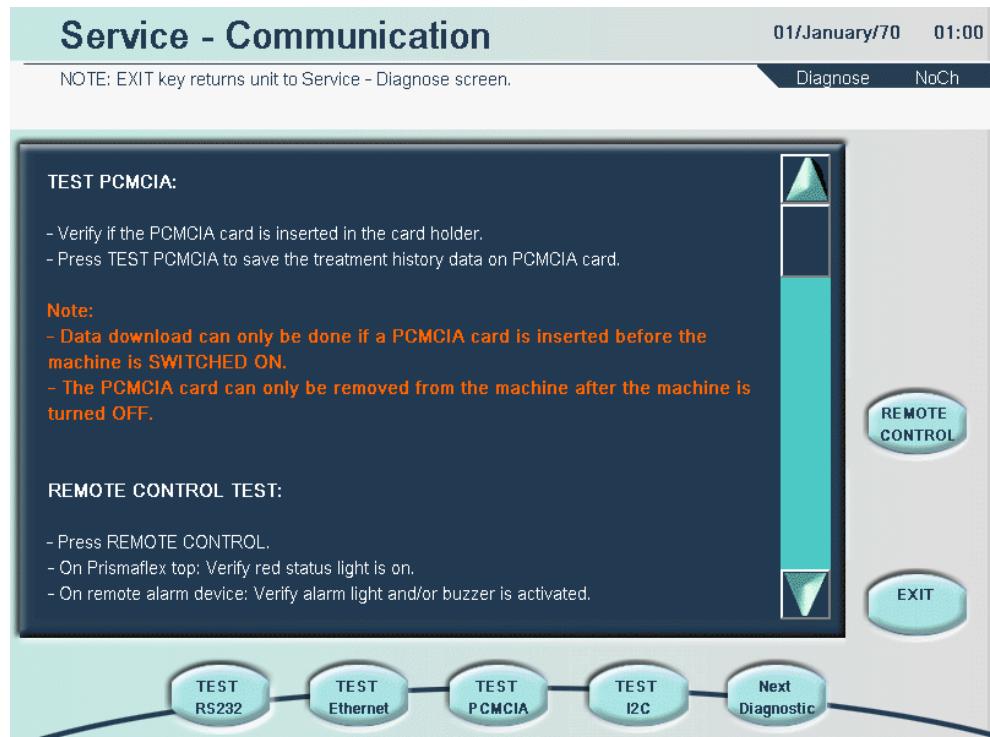


Figure 6.38 External Communication Screen (First)

Note: A PC and a software for reading data coming from RS232, Ethernet, PCMCIA, I2C are necessary to perform the following tests.

TEST RS232

Note: Optional test. Tool and procedure not yet implemented.

1. Press the TEST RS232 softkey; the following screen is displayed:

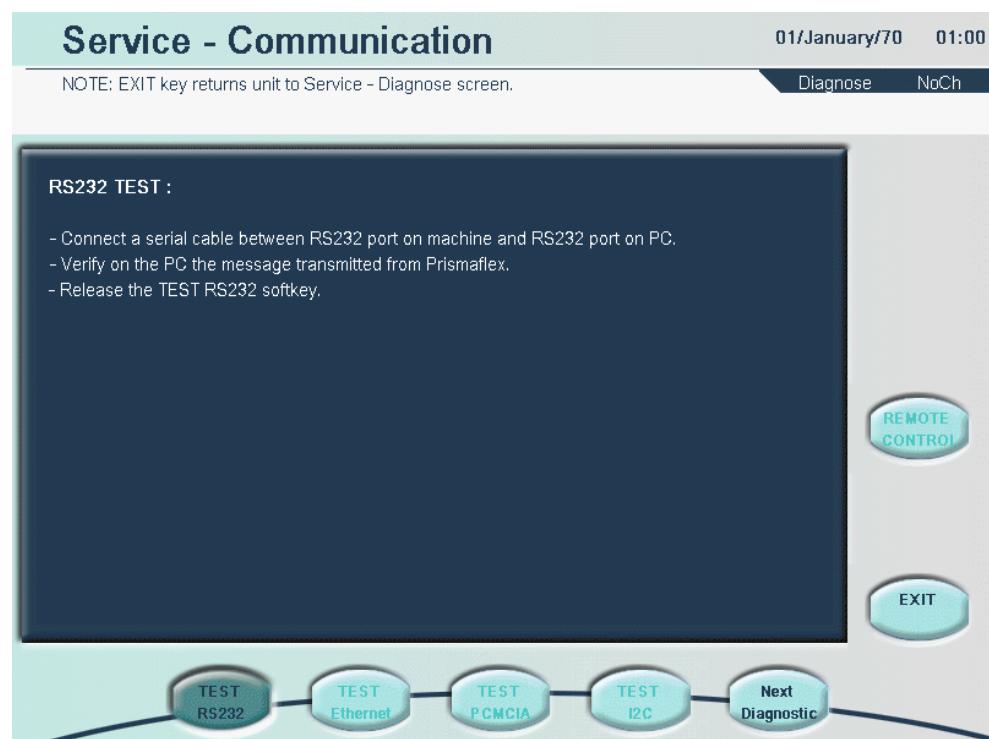


Figure 6.39 Communication Screen – Test RS232

2. Connect a serial cable between RS232 port on machine and RS232 port on PC.
3. Verify on the PC the message transmitted from the Prismaflex control unit.

Table 6.5 RS232 Test

	Field	Description
1	STX	Constant value
2	CRC	CRC of the message sent
3	Machine Identifier	Numerical value used to identify the machine by the clinical software
4	Clinical SW identifier	Not implemented
5	Message counter	Not used in a service message; this is used to combine question and its answer
6	Command code	Not implemented
7	Message information	Number of record in message body

Table 6.5 RS232 Test

	Field	Description
8	Flags	Field for Boolean values
9	Patient ID	No patient is selected in Service mode
10	SW revision	Prismaflex SW revision
11	Therapy type	In service mode no therapy is selected so the value is NOT CHOOSEN
12	Therapy status	Not therapy is selected, but user is in Service mode STATO CALIBRATION
13	Time	Current time
14	Message body length	Number of records sent

4. Release the TEST RS232 softkey.

TEST Ethernet

Note: Optional test. Tool and procedure not yet implemented.

1. Press the TEST Ethernet softkey; the following screen is displayed:

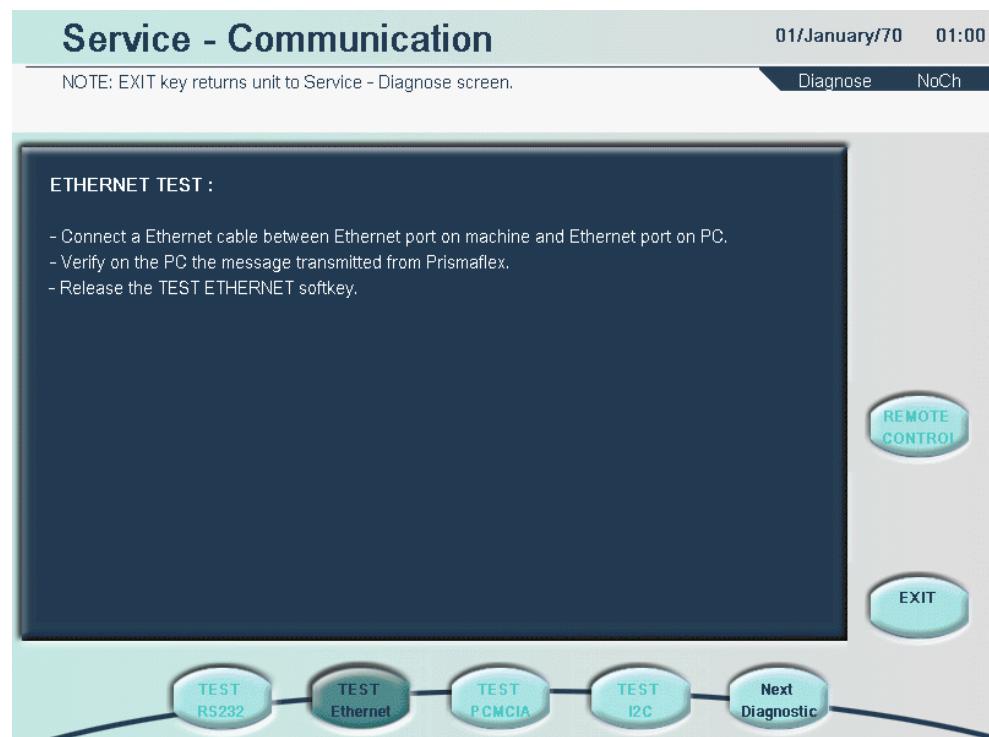


Figure 6.40 Communication screen – Test Ethernet

2. Connect a Ethernet cable between the Ethernet port on the control unit and the Ethernet port on PC.
3. Verify on PC the message transmitted from Prismaflex control unit.

Table 6.6 Ethernet Test

	Field	Description
1	STX	Constant value
2	CRC	CRC of the message sent
3	Machine Identifier	Numerical value used to identify the machine by the clinical software
4	Clinical SW identifier	Not implemented
5	Message counter	Not used in a service message; this is used to combine question and its answer
6	Command code	Not implemented
7	Message information	Number of record in message body
8	Flags	Field for Boolean values

Table 6.6 Ethernet Test

	Field	Description
9	Patient ID	No patient is selected in Service mode
10	SW revision	Prismaflex SW revision
11	Therapy type	In service mode no therapy is selected so the value is NOT CHOOSEN
12	Therapy status	Not therapy is selected, but user is in Service mode STATO CALIBRATION
13	Time	Current time
14	Message body length	Number of records sent

4. Release the TEST ETHERNET softkey.

TEST I2C

The external I2C connection and the I2C test has been removed from this machine.

TEST PCMCIA

1. Make sure that a technical data card is inserted in the card reader before the control unit boots-up. If the technical data card is not inserted, switch off the control unit, insert a technical data card and switch on again the machine. Enter the Service - Diagnose Communications page.
2. Press the TEST PCMCIA softkey; the following screen is displayed:

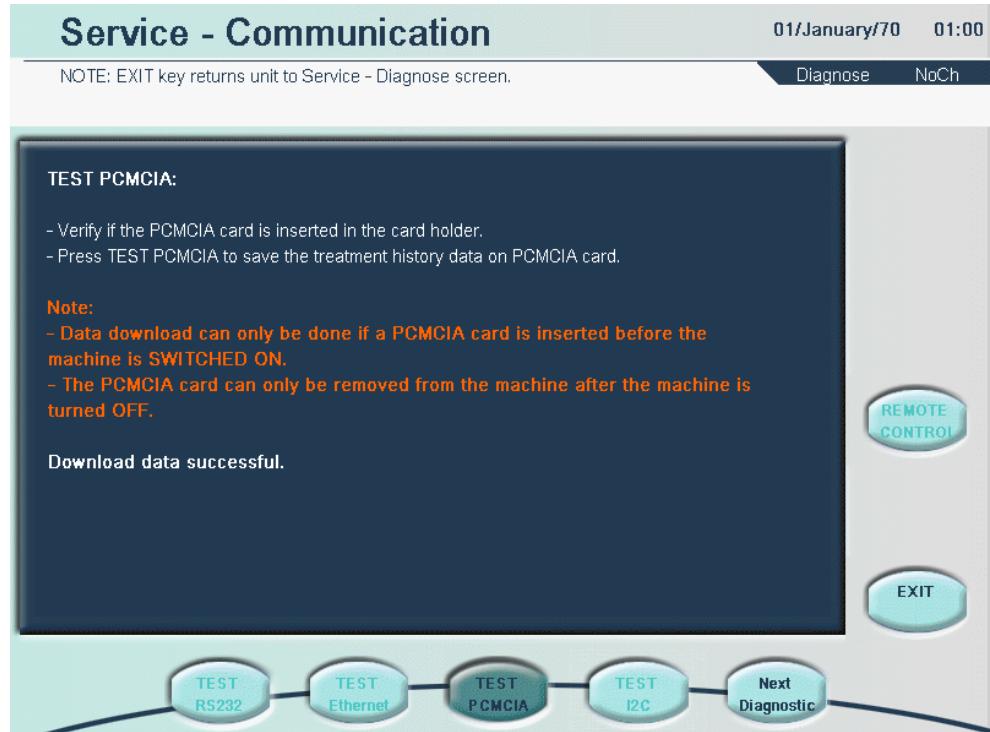


Figure 6.41 Communication Screen – Test PCMCIA

3. Wait for data download.
4. Switch off the machine and remove the technical data card from its reader.
5. Read data stored on the technical data card and verify by the PC software that the format is:

Table 6.7 Test PCMCIA: data format

For events database							
Index	Time	Class (cod)	Class	Type (cod)	Type	Sample (cod)	Sample
For scales database							
Index	Time	RUN_TIME	POST_INFUSION	PRE_INFUSION	DIALYSATE	EFFLUENT	PRE-BLOOD INF
For pressures database							
Index	Time	ACCESS_PRESSURE	FILTER_PRESSURE	EFFLUENT_PRESSURE	RETURN_PRESSURE	FIFTH_PRESSURE	/

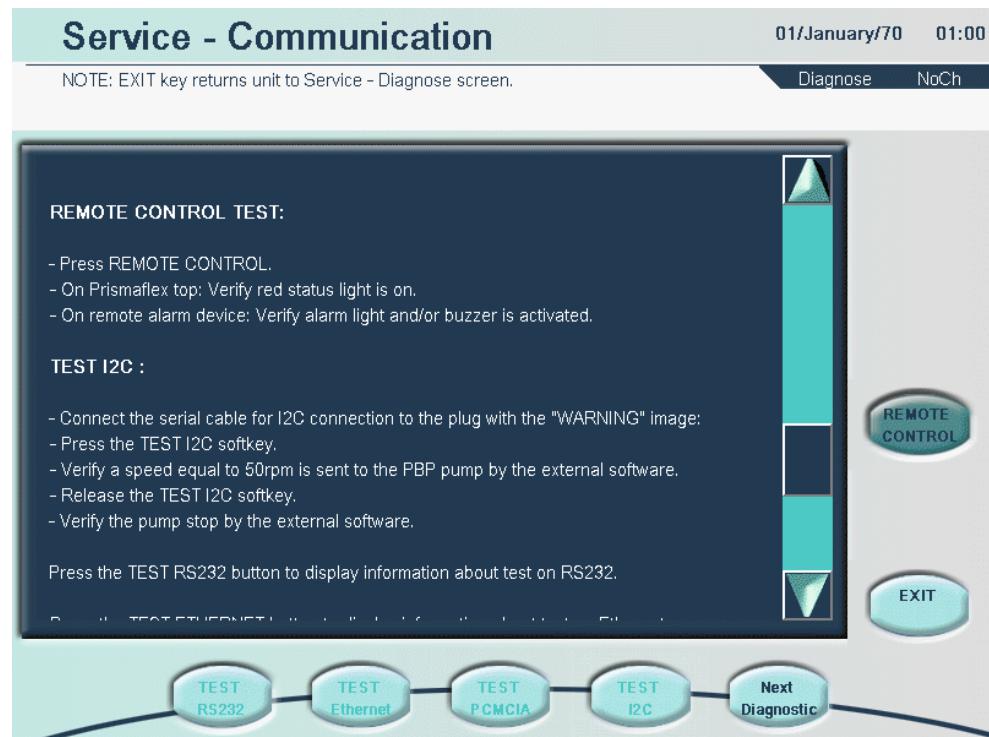
TEST Remote Alarm

Figure 6.42 Communication Screen – Test Remote Alarm

1. Verify red status light is on.
2. On the remote alarm device, verify alarm light and/or buzzer is activated.
3. Release the REMOTE CONTROL softkey.

Press the Next Diagnostic softkey to exit the Service - Diagnose Communication screen and enter the Service - Diagnose PM Timer and Date screen.

PM Timer & Date

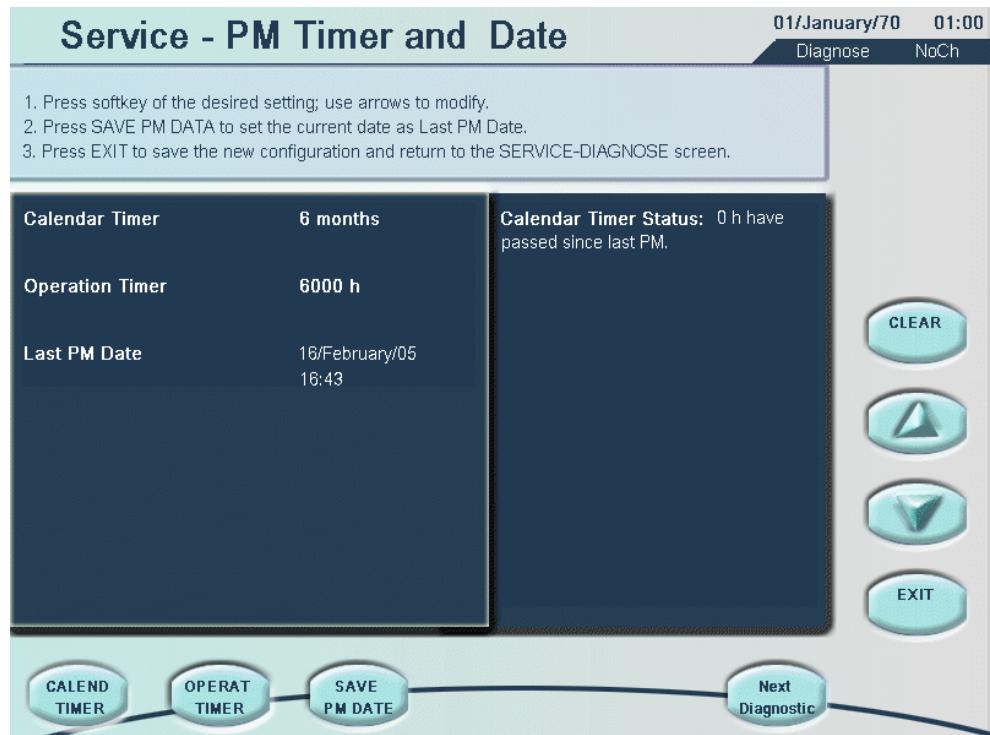


Figure 6.43 PM Timer & Date Screen

Data displayed in the page are:

Calender Timer: is the interval time based on calender time for the next occurrence of the Advisory “Preventive Maintenance Due”. This interval time is settable in the range between 1 month and 5 years with steps of 1 month, to set this value press the Calender Timer softkey and use the arrows to modify the value.

Operatation Timer: is the interval time based on run time for the next occurrence of the Advisory “Preventive Maintenance Due”. To set this value press the Opeat Timer softkey and use the arrows to modify the value.

Last PM Date: is the date of the last service intervention.

Pressing the SAVE PM DATE softkey the current date is stored as the Last PM date.

Press the Next Diagnostic softkey to exit the Service - Diagnose PM Timer and Date screen and enter the Service - Diagnose Clean screen.

Clean screen

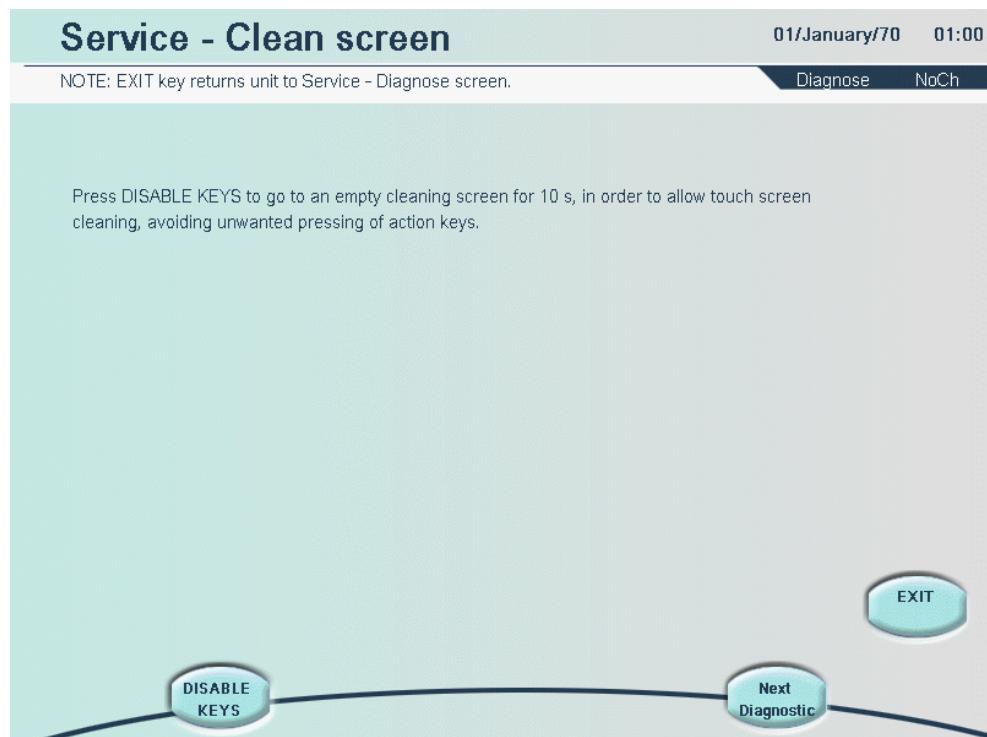


Figure 6.44 Clean Screen

Note: A stopwatch is necessary to perform the following procedure.

Press the DISABLE KEYS softkey to display a white page without any softkey. Verify the page is displayed for 10 seconds. Try to clean the screen and verify no hidden softkeys are active.

Press the Next Diagnostic softkey to exit the Service Clean Screen and enter the Service SW CONFIGURATION screen.

SW Configuration

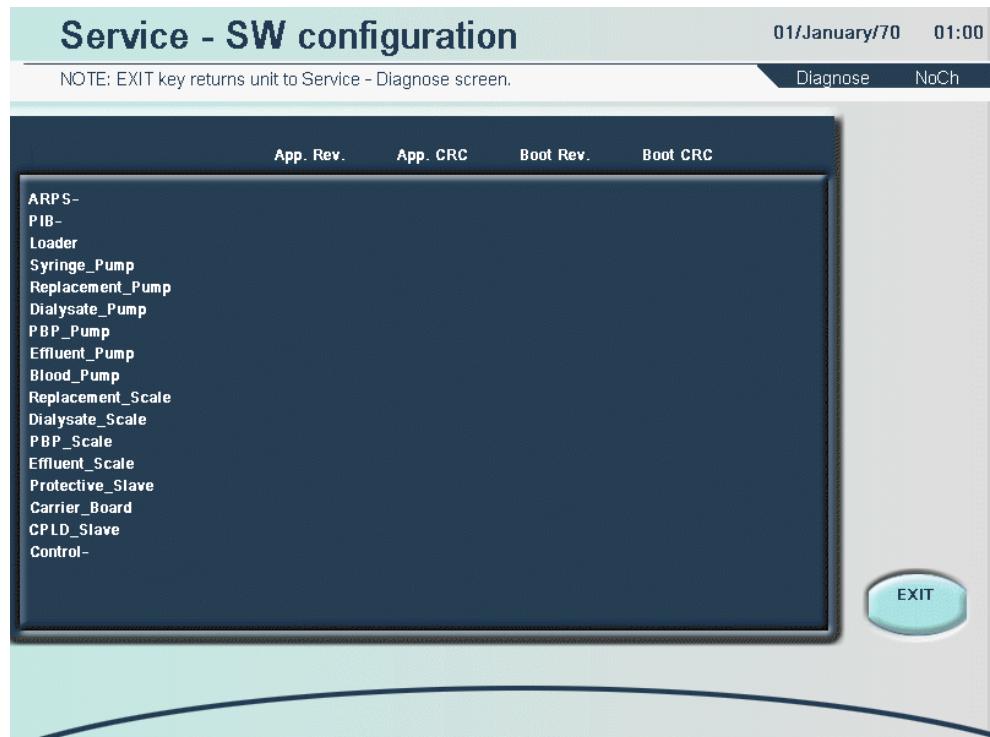


Figure 6.45 SW Configuration Screen

This screen displays, for each of the listed items, the revision level and the CRC value path, of the application and of the booter (these are not displayed on the screen above).

Press EXIT key to exit the Service SW Configuration Screen and enter the Service Diagnose page.

6.3.3 Functional Test

Before releasing the Prismaflex for use, perform the functional checkout with a Prismaflex set in place on the control unit.

The test is performed using saline solution as a substitute for priming, pre-blood, replacement and dialysate solutions, and a container of water as a substitute for the patient. Successful completion of the functional checkout indicates that the Prismaflex control unit is operating properly.



WARNING

A patient must not be connected to the Prismaflex System during the functional checkout. Be sure that the checkout is conducted using a container of water to substitute for the patient.

If a Malfunction alarm occurs during the functional checkout, the Prismaflex control unit has failed the checkout. Do not use the Prismaflex System until the problem has been corrected and the Prismaflex System has passed the checkout.

1. Turn on the Prismaflex as described under Startup in the Operation chapter of the Prismaflex Operator's Manual. The Prismaflex control unit performs an initialization test during the Startup procedure. Verify that the red, yellow, and green lights are illuminated during the initialization test.
2. Enter in Set-up page and press the Continue softkey. If the Query page is displayed instead of the Set-up page select the New Prime softkey and confirm it in the following page.
3. Select New Patient when the Choose Patient screen appears. Enter some patient information.
4. Select the CVVHDF therapy when the Choose Therapy screen appears.
5. Select *Standard - No Syringe*
6. Follow the instructions on the screen to load and prime the set. Use saline solution in place of priming and dialysate solutions. The Prismaflex control unit performs multiple self-tests during the priming cycle.
7. When priming is complete, press Continue, and the Set-Flow Rates screen appears. Set the following flow rates:
 - Blood: 180 ml/min
 - PBP: 1000 ml/h
 - Dialysate: 1000 ml/h
 - Replacement: 1500 ml/h
 - Fluid Removal Rate: 200 ml/h
8. Place the access and return lines preferably connected through an 8F catheter into the container of water; press the Enter soft key, followed by the Start soft key, to enter Run mode.

Note the hour and minute on the Status screen that the Prismaflex System enters the Run mode (this information is also on the Events Screen).

Note: Because the functional checkout is performed with water, the Advisory: Return Disconnection Cannot Be Detected alarm could occur after the Prismaflex System has entered

the Run mode. If this alarm occurs, press Override and continue with the test. The alarm will not affect the outcome of the functional checkout.

9. Let the Prismaflex System run for 15 minutes.

10. After 15 minutes, press the History softkey. When the History screen appears, set the History Start Time to the hour and minute the Prismaflex System entered the Run mode as indicated by the Prismaflex real-time clock. Set the History End Time to 15 minutes after the History Start Time. Check that the Patient Fluid Removal reads $50 \pm 5\text{ml}$.

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

11. 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 rate.

12. 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).

13. Press the Stop softkey, then press the End Treatment softkey and follow the instructions to unload the set.

6.3.4 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 “[Safety inspection](#)” on page 229.

Table 6.8 Safety inspection

Parameter	Performance	Conditions
Enclosure Leakage Current Test per IEC 60601-1 para. 19.4 (plus UL 2601-1 deviation)	Normal Condition 40 μA maximum (typically <20 μA) 60 μA maximum (typically <40 μA) Single Fault Condition 200 μA maximum (typically <100 μA) 300 μA maximum (typically < 200 μA)	Normal Condition 100–120 Vac 210–240 Vac Single Fault Condition 100–120 Vac 210–240 Vac
Earth Leakage Current Test per IEC 60601-1 para 19.4	Normal Condition 150 μA maximum (typically 90 μA) 300 μA maximum (typically 180 μA) Single Failure Condition 500 μA maximum (typically <200 μA) 1000 μA maximum (typically <500 μA)	Normal Condition 100–120 Vac 210–240 Vac Single Failure Condition 100–120 Vac 210–240 Vac

Table 6.8 Safety inspection

Discharger Ring Guide Test Measure the resistance by using a ohmmeter between the external metallic side of the conductive clip and the internal frame of the machine or the means for Potential Equalization Conductor: the resistance must be in the specified range	BF requirements: $0.9 \text{ M}\Omega \leq R \leq 1.3 \text{ M}\Omega$ CF requirements: $3.09 \text{ M}\Omega \leq R \leq 3.39 \text{ M}\Omega$	Between the conductive part of the guide and the earth ground in mains plug
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 Ω maximum 0.2 Ω maximum	Between protective conductor in appliance inlet and any accessible conductive part. Between earth ground in mains plug and any accessible conductive part.
Ground Integrity Test per IEC 60601-1, para. 18. f	0.1 Ω maximum 0.2 Ω maximum	Between protective conductor in appliance inlet and any accessible conductive part. Between earth ground in mains plug and any accessible conductive part.
General Mechanical Inspection.	All parts are in good repair and functioning properly. Exterior surfaces of machine are clean and dry.	
External Cleanliness.		

6.3.5 Log book update

Update the log book with the PM intervention.

6.3.6 Preventive Maintenance Timer Status

1. Connect the mains plug to the electrical outlet and turn the machine on.

2. Enter the Service - Diagnose mode.
3. Press the PM Timer and Date softkey.
4. Press SAVE PM DATE.

6.3.7 Preventive Maintenance Checklist

Fill in the Preventive Maintenance checklist, and give a copy of the checklist to the hospital.

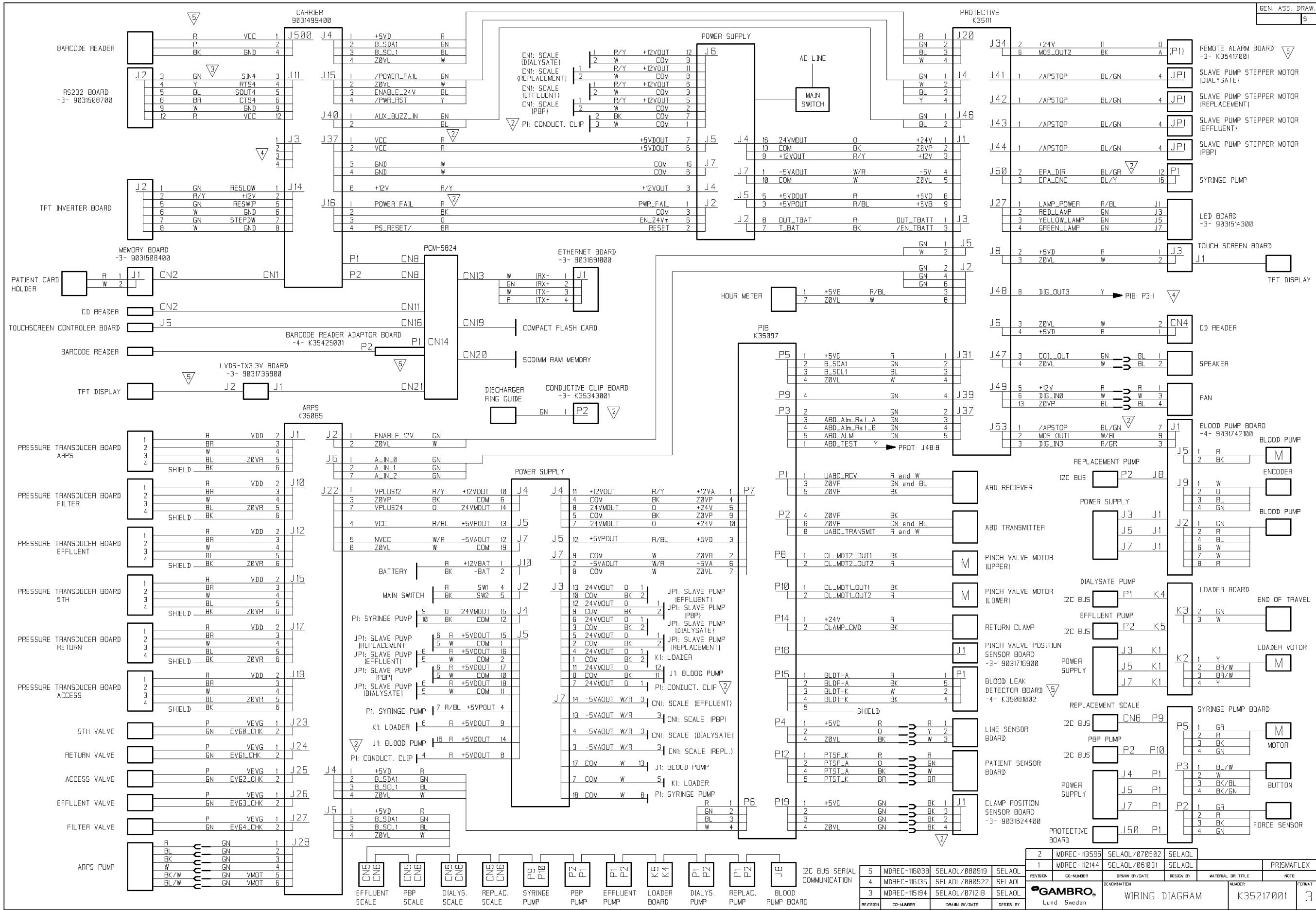
Checklist:

- Verify update of PM intervention in maintenance log book
- Verify update of PM intervention in the Service Diagnose page on the Prismaflex
- Fill in the PM sticker and apply to the machine
- Verify that the Preventive Maintenance checklist is filled in. Give a copy of the checklist to the hospital.
- Send in a service report in the Service Report system.

Chapter 7: Schematics

The following page shows a wiring diagram over the Prismaflex control unit with all internal connections between the different subunits.

K35217001, Wiring diagram



Chapter 8: Specifications

Table 8.1 Specifications

Parameter	Performance	Conditions
Environmental Requirements		
Ambient Operating Temperature	16°C to 38°C (60°F to 100°F)	
Ambient Operating Humidity	15% to 65%	Non-condensing
Ambient Operating Air Pressure	70 to 106 kPa (525 to 795 mmHg)	
Transport and Storage Temperature ^a	–18°C to +54°C (0°F to 130°F)	Prior to use, let unit rest at ambient operating temperature for 1 hour.
Transport and Storage Humidity ^a	10% to 95%	Non-condensing
Transport and Storage Air Pressure	50 to 106 kPa (375 to 795 mmHg)	
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 × 63 cm (24 in × 25 in)	
Medical Device Classification		
Classification	Class IIb per COUNCIL DIRECTIVE 93/42/EEC	
Scales Characteristics		
Scale Weight Range	Dialysate: 0 to 11 kg Replacement: 0 to 11 kg PBP: 0 to 11 kg (PBP = pre-blood pump) Effluent: 0 to 11 kg	Weight range for each scale includes the scale components (bar tray, carrying bars).

Table 8.1 Specifications

Parameter	Performance	Conditions
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	100–240 Vac	
Frequency	50/60 Hz	
Power	500–600 W	
Electrical Safety		
Classification	Mobile, Class I, applied part is Type CF, defibrillation proof per IEC 60601-1	Note! To be sure of the machines classification see type label found at the back of the machine
Classification	Mobile, Class I, applied part is Type BF, defibrillation proof per IEC 60601-1	Note! To be sure of the machines classification see type label found at the back of the machine
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
Defibrillation-proof Applied Part	Applied part is Type CF, defibrillation-proof per IEC 60601-1	Defibrillator equipment meets requirements of IEC 60601-2-4 Note! To be sure of the machines classification see type label found at the back of the machine
Defibrillation-proof Applied Part	Applied part is Type BF, defibrillation-proof per IEC 60601-1	Defibrillator equipment meets requirements of IEC 60601-2-4 Note! To be sure of the machines classification see type label found at the back of the machine
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 Prismaflex control unit has a connection for 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)

Table 8.1 Specifications

Parameter	Performance	Conditions
	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)
	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	Medical devices – Risk Managements – Part 1: Application of risk analysis to medical devices.
Syringe Settings		
Syringe Continuous Delivery Rate Range	User settable; 0, or 1.0 to 5.0 ml/h 0, or 0.5 to 5.0 ml/h 0, or 0.5 to 10.0 ml/h 0, or 2.0 to 20.0 ml/h	10 ml syringe 20 ml syringe 30 ml syringe 50 ml syringe
Increment	Increment: 0.1 ml/h	
Accuracy	± 0.6 ml/h	Pressure between 0 and +600 mmHg. Use of approved syringes

Table 8.1 Specifications

Parameter	Performance	Conditions
Syringe Bolus Delivery Volume Range	User settable; 0, or 0.5 to 5.0 ml 0, or 1.0 to 5.0 ml 0, or 2.0 to 9.9 ml	10 ml and 20 ml syringe 30 ml syringe 50 ml 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
Flow Rates and Accuracy		
Blood Flow Rate Range	User settable ^b 10 to 450 ml/min	
Increment	10 ml/min, 2ml/min for low flow sets	
Accuracy	±10% of user-set rate	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.
Return Blood Flow Rate	10 to 100 ml/min	When START RETURN softkey is pressed
Recirculation Flow Rate	0 to 150 ml/min	
Replacement Solution/Fluid Flow Rate Range	User settable ^b	
Increment	0 to 8000 ml/h 50 ml/h, 10ml/h for low flow sets	CVVH; CVVHDF
Predilution percentage Increment	0 to 100% 5%	CVVH
Predilution percentage	0 (post-dilution) or 100% (predilution)	CVVHDF
Range Increment	0 to 5000 ml/h 10 ml/h	TPE
Accuracy	± 30 ml/h	

Table 8.1 Specifications

Parameter	Performance	Conditions
Dialysate Flow Rate Range Increment Accuracy	User settable ^b 0 to 8000 ml/h 50 ml/h, 10ml/h for low flow sets $\pm 30 \text{ ml/h}$	CVVHD; CVHDF
PBP Solution Rate Range Increment Accuracy	User settable ^b 0 to 8000 ml/h 0 to 1000 ml/h $30 < Q_{pbp} < 100$ 2 ml/h $100 < Q_{pbp} < 200$ 5 ml/h $200 < Q_{pbp} < 1500$ 10 ml/h $1500 < Q_{pbp}$ 50 ml/h Q_{pbp} = PBP Solution Flow Rate ml/h $\pm 30 \text{ ml/h}$	CVVH; CVVHD; CVHDF; CRRT Septex SCUF; TPE; HP Note: Total PBP Volume is 2000 ml/treatment for TPE.
Patient Fluid Removal Performance Range Increment Accuracy	User settable 0 to 2000 ml/h 0 to 1000 ml/h for TPE 10 ml/h $\pm 30 \text{ ml/h}$ $\pm 70 \text{ ml/3 h}$ $\pm 300 \text{ ml/24 h}^c$	No occurrence of incorrect weight change alarms. Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than $\pm 3^\circ\text{C}$ (5.4°F) during treatment.
Effluent Flow Rate Range	0 to 10,000 ml/h	Depending on the therapy selected.
TPE Settings		
Pre-treatment Hematocrit Range Increment Default	10 to 60% 1% 43%	
Total Replacement Volume Range Increment Default	0 to 10,000 ml 100 ml 3000 ml	
Replacement Container Volume Range Increment	0 to 5000 ml 10 ml	
Audible Alarm		
Audible Alarm Volume (decibel level)	Low Moderate High	Meets IEC 60601-2-16
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

Table 8.1 Specifications

Parameter	Performance	Conditions
Non-mutable	Continuous for at least 2 minutes	Power loss
Access Line Pressure Sensor		
Operating Range	-250 to +300 mmHg	
Accuracy	±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.
"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	-50 to +350 mmHg	
Accuracy	±10% of reading or ±8 mmHg, whichever is greater	
"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.

Table 8.1 Specifications

Parameter	Performance	Conditions
"Return Pressure Dropping" Warning Limit	Warning alarm occurs	Pressure in the return deaeration chamber is 50 mmHg (or 70 mmHg if blood flow > 200 ml/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	-50 to +450 mmHg	
Accuracy	$\pm 10\%$ of reading or ± 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 ≥ 450 mmHg.
"Filter Is Clotting" Advisory Limits	Advisory alarm occurs	One or both limits are reached. (CRRT)
a) Filter pressure drop	a) User settable; +10 to +100 mmHg greater than initial filter pressure drop Default: +100 mmHg Increment: 10 mmHg	
b) TMP increase	b) Service settable; +50 to +100 mmHg greater than initial TMP Default: +100 mmHg Increment: 5 mmHg	
"Plasmafilter is Clotting" Advisory Limit	Advisory alarm occurs User settable; Filter pressure drop is +10 to +60 mmHg greater than initial filter pressure drop Default: +60 mmHg Increment: 10 mmHg	Limit is reached (TPE)
"HP Cartridge is Clotting" Advisory Limit	Advisory alarm occurs User settable; Filter pressure drop is +10 to +30 mmHg greater than initial filter pressure drop Default: +30 mmHg Increment: 10 mmHg	Limit is reached (HP)
"Filter Clotted" Warning Limit	Warning alarm occurs	Filter pressure drop is \geq limit value fixed for the filter in use, or both the "Filter is Clotting" Advisory and the "TMP Excessive" Caution limits are reached. (CRRT)

Table 8.1 Specifications

Parameter	Performance	Conditions
"Plasmafilter Clotted" Warning Limit	Warning alarm occurs	Filter pressure drop is \geq limit value fixed for the plasmafilter in use, or both the "Plasmafilter is Clotting" Advisory and the "TMPa Excessive" Caution limits are reached. (TPE)
"HP Cartridge Clotted" Warning Limit	Warning alarm occurs	Filter pressure drop is \geq limit value fixed for the HP cartridge in use.
"TMP Too High" Advisory Limit	Advisory alarm occurs User settable; +70 to +350 mmHg Default: +350 mmHg Increment: 10 mmHg	TMP equals user-set limit. (CRRT)
"TMPa Too High" Advisory Limit	Advisory alarm occurs User settable; 0 to +100 mmHg Default: +100 mmHg Increment: 10 mmHg	TMPa equals user-set limit. (TPE)
"TMP Excessive" Caution Limit	Caution alarm occurs	TMP $>$ limit value fixed for the filter in use (CRRT)
"TMPa Excessive" Caution Limit	Caution alarm occurs	TMPa greater than a value automatically calculated by the machine depending on the blood flow rate and the plasmafilter in use. (TPE)
Effluent Line Pressure Sensor		
Operating Range	-350 to +400 mmHg -350 to +350 mmHg	CRRT TPE
Accuracy	$\pm 10\%$ of reading or ± 8 mmHg, whichever is greater.	
Air Bubble Detector		
Macro air/foam detection	Warning alarm occurs	The transducer receives one voltage decrease of nominal signal level, which corresponds to detecting a single bubble/foam of approximately 20 μl . 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, for effluent flow rate below 5500 ml/h Leak ≥ 0.50 ml/min at 0.32 Hct, at highest effluent flow rate.

- a. For transport and storage longer than 15 weeks, use ambient operating conditions.
- b. Flow rate range depends on the Prismaflex therapy/set combination selected by the operator
- c. 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

