Prismaflex®

Addendum to Operator's Manual
Contents of this Addendum are applicable to:

- Prismaflex Operator's Manual SW version 7.XX

Chapter 2 Description of the Prismaflex System
Following information shall be added after Rear Panel Components:

> **NOTE!**
> The leakage detector is not enabled in SW 7.xx.

Stand with drip tray

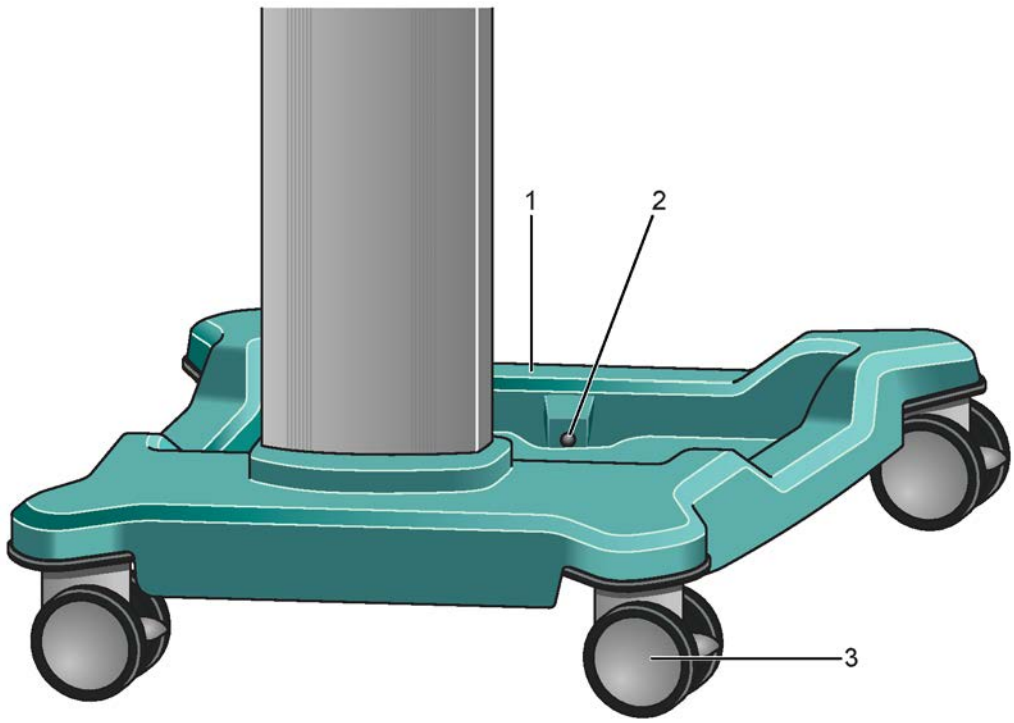


Figure 1-1. Stand - rear view

1. **Drip tray**
   Collects leaking fluid from the disposable set or bags.
2. **Leakage detector**
   Detects fluid in the drip tray.
3. **Caster**
   Push the lever to lock the caster. Locking prevents rotation and rolling of the caster. Lift the lever to unlock the caster.

Stand without drip tray

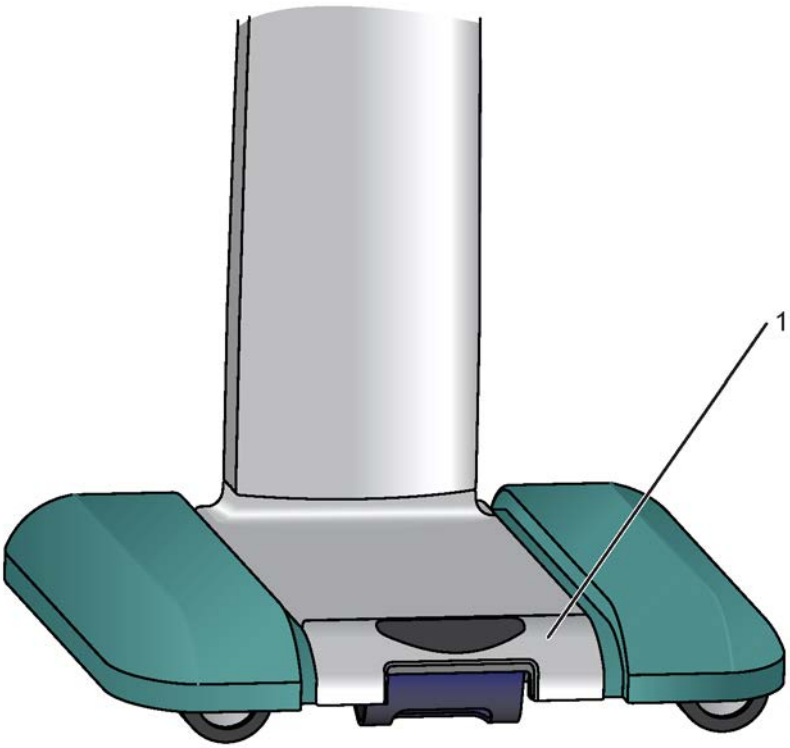


Figure 1-2. Stand - front view

1. **Brake lever**

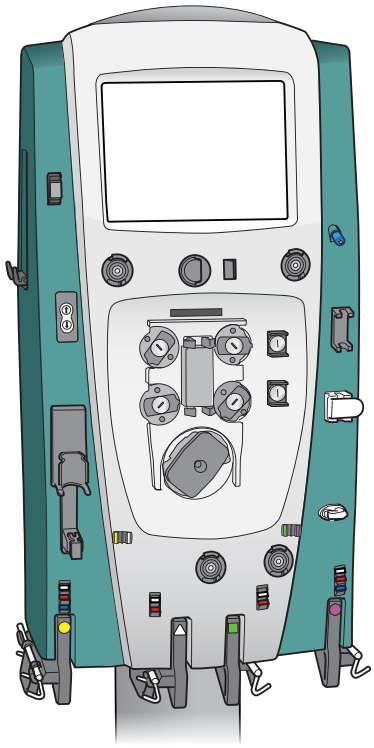
   Push the lever to lock the casters. Lift the lever to unlock the casters.

Chapter 13 Specifications

Weight, height, width and base specification shall be replaced with below information:

	Stand without drip tray	**Stand with drip tray**
Weight	Approximately 78 kg (172 lb) without fluid bags and Prismaflex disposable set	
Height	Approx. 163 cm (64 in)	Approx. 163 cm (64 in)
Width	Approximately 49 cm (19 in)	
Base	Approximately 60 cm × 63 cm (24 in × 25 in)	Approximately 70 cm × 70 cm (28 in × 28 in)

Prismaflex®



Operator's Manual

For use with software versions 7.xx

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

Order number:

G5039912

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Prismaflex®

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2. Description of the Prismaflex® System
3. General Prismaflex® Functions
4. Operating the Prismaflex® System
5. Continuous Renal Replacement Therapies (CRRT)
6. Therapeutic Plasma Exchange (TPE)
7. Anticoagulation Methods
8. Blood Warmers
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10. Troubleshooting
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Chapter 1

Before You Get Started

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General Information

Intended Use

The Prismaflex control unit is intended for:

- Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.
- Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.
- Continuous Renal Replacement Therapy (CRRT) in conjunction with the MARS system to conduct MARS treatments for patients weighing 20 kilograms or more.

All treatments administered via the Prismaflex control unit must be prescribed by a physician.

Contraindications

For contraindications that may apply to the disposable set selected for the therapy, refer to the Instructions For Use of the disposable set.

Keywords Used in this Manual

Authorized service technicians
This term refers to Gambro trained and certified service technicians.

Filter
Depending on the therapy in use, Filter stands for either:

- Hemofilter/Dialyzer
- Plasmafilter

Manual
The term Manual refers to this Operator's Manual unless specified differently.

Operator
In this manual, Operator designates appropriately trained and qualified clinical staff who is in charge of the Prismaflex control unit. The operator sets the prescribed values in accordance with the prescribed treatment, responds to alarms, troubleshoots the Prismaflex control unit, handles the bags, etc. Once the training material is read through and understood, the operator is approved to operate the Prismaflex control unit. The operator works within one meter from the front of the Prismaflex control unit.

Responsible Organization
In this manual, Responsible Organization means a function or a person who can identify, analyze, and control potential risks that could occur, for example, when connecting the Prismaflex control unit to other equipment or when making changes to the equipment connected to the Prismaflex control unit.

Screens
The Prismaflex control unit displays different screens during operation. Whenever a screen is referred to in this manual, it is identified by its title, e.g. *Enter Flow Settings* screen or *Status* screen.

Softkeys
Whenever a Softkey on the Prismaflex screen is referred to in this manual, it is written in capital italic letters, e.g. *NEW PATIENT* or *CHANGE BAG*.

Training Material
This operator's manual is the primary training material for staff who is to operate the Prismaflex system.

Where to Find Information

Operator's Manual

This manual provides operating, maintenance, and troubleshooting instructions, as well as general information. Chapter 2: "Description of the Prismaflex® System" provides information about the Prismaflex control unit and system components. Chapter 3: "General Prismaflex® Functions" describes the principles of operation of the system, notably about fluid and pressure management. Chapter 4: "Operating the Prismaflex® System" explains the system interface, gives an overview of a treatment sequence and describes the routine handling steps. Specific therapy information is provided for:

- CRRT in chapter 5: "Continuous Renal Replacement Therapies (CRRT)"
- TPE in chapter 6: "Therapeutic Plasma Exchange (TPE)"
- Anticoagulation in chapter 7: "Anticoagulation Methods"

Online Instructions

Detailed operating instructions are incorporated in the software of the Prismaflex control unit. The instructions are available *online*, 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 treatment, verifying settings, and ending patient treatments).
- Alarm screens (instructions when an alarm situation occurs).
- Help screens (additional information about an operating or alarm screen).

Instructions for Use of Prismaflex® Disposable Sets

Instructions for use are provided with Prismaflex disposable sets, and provide operating flow rates, filter pressures, priming requirements, performance data, and other information for use of the set with the Prismaflex system.

Therapies

The Prismaflex control unit pumps blood from the patient, through the filter in a Prismaflex disposable set, and back to the patient's venous circulation. As the blood passes through the filter, the desired treatment processes take place. Depending on the therapy in use, these processes can include fluid removal and/or solute clearance. For instructions about the different therapies, see each respective therapy chapter.

During the setup procedure, the operator selects the therapy desired. 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 MARS®– Continuous Renal Replacement Therapies supporting Molecular Adsorbents Recirculation System

- CVVHD – Continuous Veno-venous Hemodialysis
- CVVHDF – Continuous Veno-venous Hemodiafiltration

TPE – Therapeutic Plasma Exchange

Note: All therapies beside CRRT require a service configuration. Contact your local representative for additional information.

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

Anticoagulation Methods

For detailed instructions about the different anticoagulation methods, see chapter 7: "Anticoagulation Methods."

During the setup procedure, the operator selects the desired anticoagulation method. The Prismaflex system includes:

- Systemic, Prismaflex syringe pump
- No anticoagulation

Note: All anticoagulation methods beside "No anticoagulation" require a service configuration. Contact your local representative for additional information.

Responsibility and Disclaimer

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

- If any modifications to the equipment have been authorized in writing by Gambro and carried out by an authorized service technician.
- If the electrical installation for powering the equipment complies with all applicable local electrical codes and requirements including, if applicable, IEC requirements.
- If the equipment is used in accordance with this manual.

Gambro will provide, on request, a service manual which contains all necessary circuit diagrams, calibration instructions, and service information to enable authorized service technicians to repair those parts of this equipment which Gambro considers to be repairable.

This manual contains references to accessories and disposables for use with the Prismaflex system, see chapter 2: “Description of the Prismaflex® System” on page 2:1. 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 or if any specified accessory or disposable is not used in accordance with this manual, online instructions and the *Instructions for Use* accompanying those accessories and disposables.

Since Gambro has no control over service work which is not performed by authorized service technicians, 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 repair has been performed by any person other than an authorized service technician of Gambro.

Under no circumstances will Gambro be liable for any indirect, incidental, special 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, solutions, etc. that may apply.

Safety Definitions

This manual uses the following safety definitions:

WARNING

⚠ A warning alerts the reader about a situation which, if not avoided, could result in an adverse reaction, injury or death.

WARNING

CAUTION

! A caution alerts the reader about a situation which, if not avoided, could result in minor or moderate injury to the user or patient or damage to the equipment or other property.

CAUTION

Note: Notes are added to give more information.

General Warnings and Cautions

Warnings

WARNING

General

⚠ Carefully read this Prismaflex Operator's Manual and the Prismaflex disposable set and solution bag Instructions for Use before operating this device. Note: Deviation in the classification of a warning and a caution between the manual and disposable IFU may occur. If found, refer to the manual. Before first use, ensure that the installation test has been successfully performed.

⚠ Operate the Prismaflex control unit in accordance with this manual, the Instructions for Use of the Prismaflex disposable set and solutions, and the online instructions. The use of operating or maintenance procedures other than those published by the manufacturer, or the use of accessory devices not recommended by the manufacturer, can result in patient injury or death.

⚠ The manufacturer will not be responsible for patient safety if the procedures to operate, maintain, and calibrate the Prismaflex system are other than those specified in this manual, the Service Manual, the Instructions for Use of the Prismaflex disposable set and solutions, and the online instructions.

⚠ Procedures using the Prismaflex system must be performed under the responsibility of a physician.

⚠ Procedures using the Prismaflex system must be performed by trained and qualified clinical staff.

Service and Repairs

⚠ Service and repairs are only allowed to be performed by an authorized service technician.

⚠ Ensure that scales and pressure sensors of the Prismaflex control unit are accurately calibrated. Calibrations must be performed by an authorized service technician.

Electrical Safety

⚠ All electrical installations must comply with all applicable local electrical codes and the manufacturer's specifications.

⚠ The correct installation of a medical electrical system requires that each system component be individually connected to the main power. It is strongly recommended not to use multiple portable socket-outlets. However, if using multiple portable socket-outlets, they must comply with IEC 60601-1-1 and must not be placed on the floor. Additional multiple portable socket-outlets must not be connected to the system.

⚠ Use only the Prismaflex hospital grade power cord to connect the Prismaflex control unit to the facility's electrical outlet.

⚠ To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective ground.

Environment

⚠ Do not use the Prismaflex control unit near flammable gas or a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

WARNING → → →

→ → → WARNING

⚠ Do not use cellular phones or other radiofrequency emitting equipment within a short distance from the Prismaflex control unit since disturbance may occur. Refer to “Guidance and Manufacturer’s Declaration — Electromagnetic Emissions and Immunity” on page 12:11 in this manual.

Patient Data Management Systems and Remote Alarms

⚠ If a Patient Data Management System (PDMS) is to be used with the Prismaflex system, the Responsible Organization is obliged to verify compatibility between the two systems. The use of a PDMS not compatible with the Prismaflex system can result in presentation of erroneous data. It is the responsibility of the physician to verify all data before prescribing any therapeutic or pharmacological action for the patient.

⚠ If a remote alarm is to be used with the Prismaflex system, the Responsible Organization is obliged to verify its function. Even if a remote alarm is used, the operator is obliged to periodically monitor the patient in person.

Handling the Prismaflex Control Unit

⚠ Lock brakes on the wheels to limit movement of the control unit that might pull on tubing connected to the patient or significantly alter fluid balance.

⚠ After turning ON the Prismaflex control unit, verify the audible alarm and that the green, yellow, and red status lights are lit alternately during the Prismaflex startup sequence. In case of malfunction, switch OFF the Prismaflex control unit and call for service.

⚠ Never insert fingers in the return line clamp or in the pinch valves.

Setup and Priming

⚠ During priming and operation, observe the system closely for leakage at joints and connections within the set. Leakage can cause blood loss or air embolism. If leakage cannot be stopped by tightening the connections, replace the set.

⚠ Clamp unused lines after priming is complete and before starting a patient treatment according to therapy configuration.

⚠ Before connecting the blood return line to the patient, make sure the blood line segment from the air bubble detector to the patient is free of air.

⚠ Install the discharger ring on the Prismaflex disposable set in its guide before connecting a patient to the Prismaflex system in order to minimize cardiac monitor disturbance. Misinterpretation of ECG readings due to artefacts may lead to patient injury or death.

Treatment Monitoring

⚠ Carefully observe the Prismaflex treatment system, including the disposable set, during a patient treatment.

⚠ Monitor patient blood chemistry to ensure electrolyte balance and normoglycemia.

⚠ Monitor patient temperature to avoid hypo- or hyperthermia. Pay special attention when using high fluid exchange rates, when using a high capacity blood warmer, or when treating low body weight patients.

WARNING → → →

→ → → WARNING

⚠ Blood or fluid leakage from a pod diaphragm or wetting of the fluid barrier at the distal end of the monitor line will impair pressure monitoring in the Prismaflex system and requires immediate troubleshooting. Follow the instructions in section “Leakage in Pressure Pods or Blood Reaching Fluid Barrier” on page 10:61.

⚠ Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring. Their use can impede the detection of return disconnections, potentially resulting in severe blood loss.

⚠ The Prismaflex control unit may not be able to detect disconnections of the set from the blood access device, which can result in severe blood loss. Ensure that the patient's blood access and return connections are firmly secured; pay special attention in case a warmer sleeve is in use.

⚠ The Prismaflex control unit may not be able to detect all situations that can result in hemolysis, including kinks in a blood line or cannula that are too thin. Observe the effluent bag for pink or red tinge as an indicator of hemolysis.

⚠ Air may enter into the extracorporeal circuit at connection points downstream of the air detector if pressures are negative. Ensure that the patient's blood return connection is firmly secured. Do not connect additional devices between the return line and the blood access device.

⚠ Collecting blood samples from improper sample sites in the set can lead to incorrect blood chemistry results. The dilution effect of infusions must be considered according to the flow settings and sample sites, for example PBP infusion rate on an access site blood sample. After pumps have (re)started, wait for some minutes before taking a blood sample to obtain stabilized conditions.

⚠ Always inspect the blood flowpath for signs of clotting before returning the blood in the disposable set to the patient. If clotting is suspected, do not return the blood to the patient.

Fluid Management

⚠ The Prismaflex control unit is intended to be used on patients weighing 20 kg or more. A higher minimum patient weight limit may apply for the disposable set selected for the therapy. Refer to the Instructions For Use of the disposable set and Table “Sets and patient weight limits” on page 2:17.

⚠ Fluid balance deviations, even if within the specified Prismaflex control unit accuracy, can exceed a level that can be tolerated by low-weight patients.

⚠ The overall patient fluid balance is subject to fluid losses or gains outside the control of the Prismaflex treatment system. The overall fluid balance must therefore be periodically verified by weighing the patient.

⚠ Ignoring and/or indiscriminately pressing the *CONTINUE* softkey as a response to Caution: Flow Problem alarms may lead to incorrect patient weight loss or gain. Always identify and solve the originating cause of alarms before pressing the *CONTINUE* softkey.

⚠ Do not hang anything except fluid bags on the scales of the Prismaflex control unit. Foreign objects on the scales can significantly alter fluid balance.

⚠ Leakages from the fluid bags can significantly alter fluid balance. Carefully observe fluid bags and connectors during treatment.

WARNING → → →

→ → → WARNING

Solutions and Bags

⚠ Ensure that dialysate solution and infusion solutions (PBP and replacement) are of appropriate composition and at appropriate temperature, as prescribed by a physician. Before using a solution/fluid, make sure it is free of precipitates and other particulate matter. The use of incorrect solution/fluid can result in patient injury or death.

⚠ The Prismaflex system is unable to detect all situations in which a fluid bag has been attached to the wrong line or has been hung on an incorrect scale. It is the sole responsibility of the operator to verify that bags are properly connected and hung on the correct scale, as indicated by the Prismaflex graphical user interface.

⚠ When connecting solution bags, follow the instructions in the package insert of the solution for correct use of the access ports. Incorrect use of the access port or other restrictions to fluid flow might lead to incorrect patient weight loss and may result in machine alarms. Continuing treatment without resolving the originating cause may result in patient injury or death.

⚠ When hanging a fluid bag, evenly distribute its weight among the three hooks of the scale carrying bar. If only one hook is needed, use the center hook. Failure to comply can significantly alter fluid balance.

Hygienic Considerations

⚠ Use aseptic technique when handling the blood and fluid lines in the disposable set.

⚠ Do not use the Prismaflex disposable set if the package is damaged, if the sterilization caps are missing or loose, or if the blood lines are kinked.

⚠ Destroy the Prismaflex disposable set after a single use, using appropriate procedures for potentially contaminated material. Do not resterilize.

⚠ Do not use the Prismaflex control unit after blood leakage from a pod diaphragm or after blood having passed the fluid barrier at the distal end of the monitor line. Place the control unit into quarantine to avoid risk of infection and have it inspected by an authorized service technician.

⚠ Use a 21-gauge (or smaller) needle to obtain blood or fluid samples. Use of larger needles can cause leaks in the sample sites, resulting in blood loss or air embolism. Use aseptic technique whenever inserting needles into sample sites.

WARNING

Cautions

CAUTION

General

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

Service and Repairs

! Do not open the Prismaflex control unit. There are no operator-serviceable parts inside the device.

! Only authorized service technicians may access Service mode. If Service mode is inadvertently entered, restart the control unit to return to Operating mode.

CAUTION → → →

→ → → CAUTION

Electrical Safety

- Although all Prismaflex systems comply with IEC 60601-1 requirements for hemodialysis machines (Type BF applied part), it is recommended that a Prismaflex control unit Type CF applied part is used when the blood access is from a central dialysis catheter. The type label at the back of the control unit indicates the classification. Note: The combined Prismaflex and MARS system complies with the Type B applied part classification per IEC 60601-1 standard.

- Devices connected to the RS232 serial communication port or the Ethernet port must comply with IEC 60950. Connected cables must have a Kitagawa RFC-10 ferrite or equivalent to fulfill EMC requirements.

Environment

- Refer to the Prismaflex disposable set Instructions for Use and the solution/fluid package insert for environmental requirements, including storage conditions.

- Variations in room temperature of ±3 °C (5.4 °F) or more can cause the scales to become inaccurate.

Handling the Prismaflex Control Unit

- Before moving the Prismaflex control unit, check that the brake is released and ensure that all of the scales are firmly closed.

Setup and Priming

- Pay particular attention to the extracorporeal blood volume. For patients with a high ratio of extracorporeal volume to patient blood volume, the physician may decide to prime the extracorporeal circuit with adequate volume substitution before patient connection.

- Do not allow air to enter the blood compartment of the disposable set after priming has started. If a large amount of air enters, the set must be replaced.

- If a patient is not connected to the Prismaflex disposable set shortly after priming is complete, flush the set with at least 500 ml priming solution (saline with heparin added) before connecting a patient. This may require the use of a new bag of priming solution and a new (empty) collection bag. Consult the Instructions for Use packaged with the set for details about priming volumes.

Treatment Monitoring

- Pay careful attention to the possible medical hazards associated with coagulation in the blood flowpath.

- Blood return from a blood primed extracorporeal circuit can result in hypervolemia. Consult physician's prescription.

Hygienic Considerations

- To prevent contamination, the Prismaflex disposable set must be used as soon as its package and sterilization caps are removed.

- Chemicals other than those recommended in this manual for cleaning and disinfection could damage the Prismaflex control unit and Prismaflex disposable sets. Obtain permission from the manufacturer before using a non-recommended chemical on the Prismaflex system. Do not use halogenated aromatic and aliphatic solvents or ketonic solvents.

CAUTION

Symbols

If applicable, the following symbols appear on or near the serial number label or other permanently affixed labels of this device. For more information, see chapter 12: “Specifications” on page 12:1.

Electrical Safety

Equipment applied part is Type BF, defibrillation - proof per IEC 60601-1.
Note: To be sure of the Prismaflex control unit’s classification see type label found at the back of the Prismaflex control unit.

Equipment applied part is Type CF, defibrillation-proof per IEC 60601-1.
Note: To be sure of the Prismaflex control unit’s classification see type label found at the back of the Prismaflex control unit.

IPX1 Device meets the “drip proof” classification requirements.

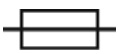
Device requires an alternating supply current.

Nearby high-voltage conductors could be hazardous if contacted.

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

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

This symbol identifies the point of connection of a potential equalization conductor. The terminal is connected to the chassis and should be connected to corresponding terminals on other equipment in order to eliminate potential differences.



Fuse.

Certain components within this equipment are sensitive to electrostatic discharge.

Instructions and Warnings

Attention, consult accompanying documents.

Read instructions before use.

This symbol warns against an incline of the Prismaflex control unit of more than 5° from the floor.
Note: This warning label must be applied on the warmer holder before use. It should be mounted on deliverance. The background color is yellow.

Pull out scale completely before hanging bag.

Pull out scale completely before hanging bag.

Risk of tipping the Prismaflex control unit from pushing, leaning, resting, etc.
The colors are red, white, and black.

This symbol is applied on the stand if the Prismaflex calibration weight kit is stored inside. Calibration weights are to be removed before tilting the Prismaflex control unit into horizontal position.
The color is black on a yellow background.

Information

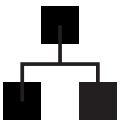
Date of manufacture with year as four digits.

Manufacturer. The year of manufacture may be included in the symbol expressed as four digits.

Catalog number.

Serial number.

Communication



Ethernet port.

RS232 Serial Communication port.

Remote alarm connection.

Environmental

This symbol indicates that:
– since the equipment contains dangerous substances, it must be recycled rather than disposed together with other municipal waste;
– the equipment was placed on the market after 13 August 2005.

The device contains toxic or hazardous substances or elements.

Recycle the cardboard.

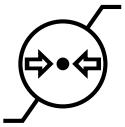
Transportation and Storage

Fragile – handle with care.

Keep dry.

The maximum stacking load permitted on the transport package is 100 kg.

This end up.

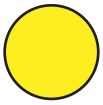


Atmospheric pressure limitation. Upper and lower limits are expressed with numeric values in kPa.

Humidity limitation. Upper and lower limits are expressed with numeric values in %.

Temperature limitation. Upper and lower limits are expressed with numeric values in degrees Celsius or Fahrenheit.

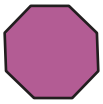
Solutions



Circle sign; placed as colored symbol on effluent scale and in the graphical user interface in screens related to effluent. On the disposable set the symbol is a relief shape in the plastic cover indicating the effluent pump.

Triangle sign; placed as colored symbol on PBP scale and in the graphical user interface in screens related to PBP. On the disposable set the symbol is a relief shape in the plastic cover indicating the PBP pump.

Square sign; placed as colored symbol on dialysate scale and in the graphical user interface in screens related to dialysate. On the disposable set the symbol is a relief shape in the plastic cover indicating the dialysate pump.



Octagon sign; placed as colored symbol on replacement scale and in the graphical user interface in screens related to replacement. On the disposable set the symbol is a relief shape in the plastic cover indicating the replacement pump.

Certification Marks

The CE-conformity mark indicates that the Prismaflex control unit conforms to the requirements in the EC Council Directive 93/42/EEC of 14 June, 1993 concerning medical devices. It also indicates that the notified body British Standards Institution (BSI, No. 0086) has approved the Quality Management System. The CE conformity mark is only valid for the Prismaflex control unit. Disposables and any accessories specified for use with the Prismaflex control unit are marked with CE conformity marks in their own right. (See “ Prismaflex® Disposable Sets” on page 2:16.)

The CSA (C-US) mark indicates that the Prismaflex control unit conforms to the requirements related to safety of medical devices for the US and Canada. The “C” and the “US” adjacent to the CSA mark indicate that the Prismaflex control unit has been evaluated to the applicable ANSI/UL and CSA standards for use in the US and Canada.

The CCC mark indicates that the Prismaflex control unit conforms to the safety requirements for China Compulsory Certification (CCC) as described by the competent authority Certification and Accreditation Administration of People's Republic of China (CNCA). The “S” adjacent to the CCC mark indicates that safety requirements are met.

Installation, Service and Transport

Please note that Prismaflex control unit has to be installed by an authorized service technician. For installation information, see the Prismaflex Service Manual.

For technical assistance, contact your local Gambro representative.

CAUTION

- 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.
- The Prismaflex control unit weighs approximately 78 kg (172 lb). Use at least two people to lift it out of the shipping carton. Handle the control unit carefully.
- Remove the calibration weights, if equipped in the stand of the Prismaflex control unit foot, before tilting the Prismaflex control unit into horizontal position.
- Prior to using the Prismaflex control unit, let the unit rest at ambient operating temperature for 1 hour.

CAUTION

Disposal

Disposal of Packaging Material

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

Disposal of Discarded Equipment

Discarded electromedical equipment must not be disposed 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 Prismaflex control unit (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.

Hazardous Substances

Hazardous Substances

Part	Hazardous substances					
	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	Hexavalent chromium (Cr6+)	Polybrominated biphenyls (PBB)	Polybrominated diphenyl ethers (PBDE)
Printed circuit board assemblies	X	O	O	O	O	O
Electro-mechanical components including wiring	X	O	O	O	O	O
Power supply	X	O	O	O	O	O
Batteries	X	O	O	O	O	O
Metals	O	O	O	O	O	O
Plastics	O	O	O	O	O	O
Enclosures	O	O	O	O	O	O
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).						

Disposal of Waste Batteries and Accumulators

According to Directive 2006/66/EC and RAEE Directive concerning batteries the manufacturer shall provide instructions how to replace/remove batteries in a safely and environmentally friendly manner. By following this directive we are helping man and nature from being exposed to harmful substances.

The labelling with a crossed-over waste bin indicates that the batteries shall not be discarded in normal waste (see figure 1:1). Labelling also indicates potential presence of harmful substances (Hg = Mercury, Pb = Lead, Cd = Cadmium).

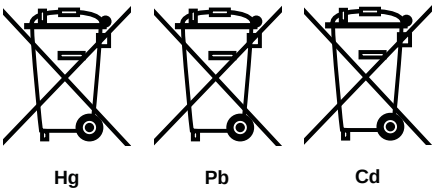


Figure 1:1 Battery symbols

Batteries must not be discarded in normal waste; instead separate and proper collection systems should be used. Always check local regulations for correct environmental disposal.

The table below describes where the batteries are located, the type of battery, and chemical composition for correct disposal.

Batteries found in Prismaflex control unit

Item	Description	Type	Location
7319090001 VL2330	Memory back-up	Vanadium rechargeable lithium battery 3V	Carrier board
BR1632	Battery to real-time clock and BIOS	Lithium battery 3V	PC-104 board
7319260003	Battery back-up during power failure	One 12V rechargeable lead battery	Bottom inside of the Prismaflex control unit
100224039	Battery back-up during power failure	Two 12V rechargeable lead battery	Bottom inside of the Prismaflex control unit

Chemical Composition

Item	Active ingredients	Approx. percentage (%) of total weight	Main passive materials	Weight
7319090001 VL2330	-Vanadium pentoxide -Lithium alloy -Organic electrolyte	5–21 0.2–2 5–15	Steel	3.5 g
BR1632	-Polycarbon-monofluoride -Lithium metal -Organic electrolyte	5–15 0.9–4 6–16	Steel	1.5 g
7319260003	-Metallic lead and lead compounds -Sulphuric acid solution	60–70 20–30	-ABS resin -Glass separator	580 g
100224039	-Lead (Pb, PbO_2, $PbSO_4$) -Sulphuric acid	70 20	-ABS plastic -Fiberglass	1180 g (for one battery)

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Chapter 2

Description of the Prismaflex® System

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System Components

The Prismaflex system consists of the Prismaflex control unit, a Prismaflex disposable set, disposable solutions and optional accessories. Prismaflex disposable sets, disposable solutions and accessories are purchased separately.

Prismaflex® Control Unit

Control Unit Functions

The Prismaflex control unit is a software-controlled device that performs the following functions:

- Loads and primes the Prismaflex disposable set automatically.
- Pumps blood through the blood flowpath of the Prismaflex disposable set.
- Delivers anticoagulant solution into the blood flowpath.
- Pumps sterile infusion solutions into the blood flowpath of the Prismaflex disposable set, according to therapy in use.
- Pumps sterile dialysate into the fluid compartment of the filter in CRRT therapies.
- Controls the patient fluid removal or plasma loss, according to the therapy in use.
- Monitors the system and alerts the operator to abnormal situations through alarms.

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
  - Continental European-style power cord, with retaining bracket
  - 4 screws
  - 4 scale carrying bars
- 20 ml syringe clip
- Pump crank
- Caution stickers
- Potential equalization connector
- Prismaflex Operator’s Manual on CD

Front Panel Components

The front panel components of the Prismaflex control unit are illustrated and described in the following figures.

- Figure 2:1 on page 2:4 shows the pumps.
- Figure 2:2 on page 2:6 shows the pressure components.
- Figure 2:3 on page 2:8 shows sensors and clamps.
- Figure 2:4 on page 2:10 shows the scale components.
- Figure 2:5 on page 2:12 shows miscellaneous components.

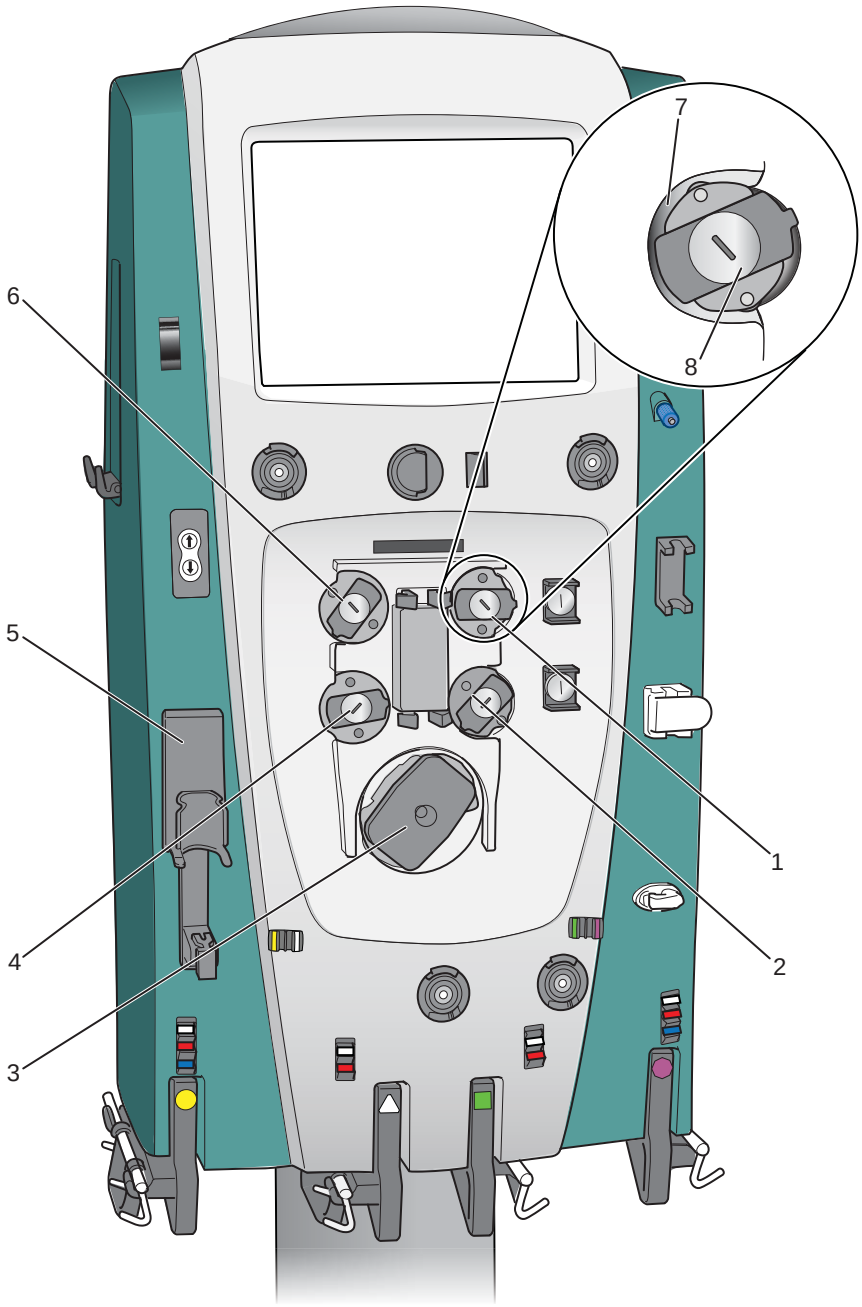

Figure 2:1 Pumps

1. Dialysate/replacement 2 pump

CVVHD, CVVHDF: Pumps dialysate solution into the fluid compartment of the filter.

CVVH: 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.

2. 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.

3. Blood pump

Pumps blood through the blood flowpath of the Prismaflex disposable set.

4. Pre-blood pump (PBP)

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.

5. Syringe pump assembly

The pump assembly holds the solution-filled syringe and controls the rate of delivery. Delivery can be continuous or in boluses.

In “Systemic, Prismaflex syringe pump” anticoagulation method, the syringe pump delivers anticoagulant into the blood flowpath.

6. Effluent pump

CRRT: Pumps ultrafiltrate/dialysate; automatically controls the ultrafiltration rate, based on the operator-set patient fluid removal rate, PBP, dialysate, replacement, and syringe flow rates (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 and syringe flow rates are not considered in the effluent pump rate.

7. Pump raceway

Tubing pathway within each peristaltic pump. The raceways accept the pump segments of the Prismaflex disposable set.

8. 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.

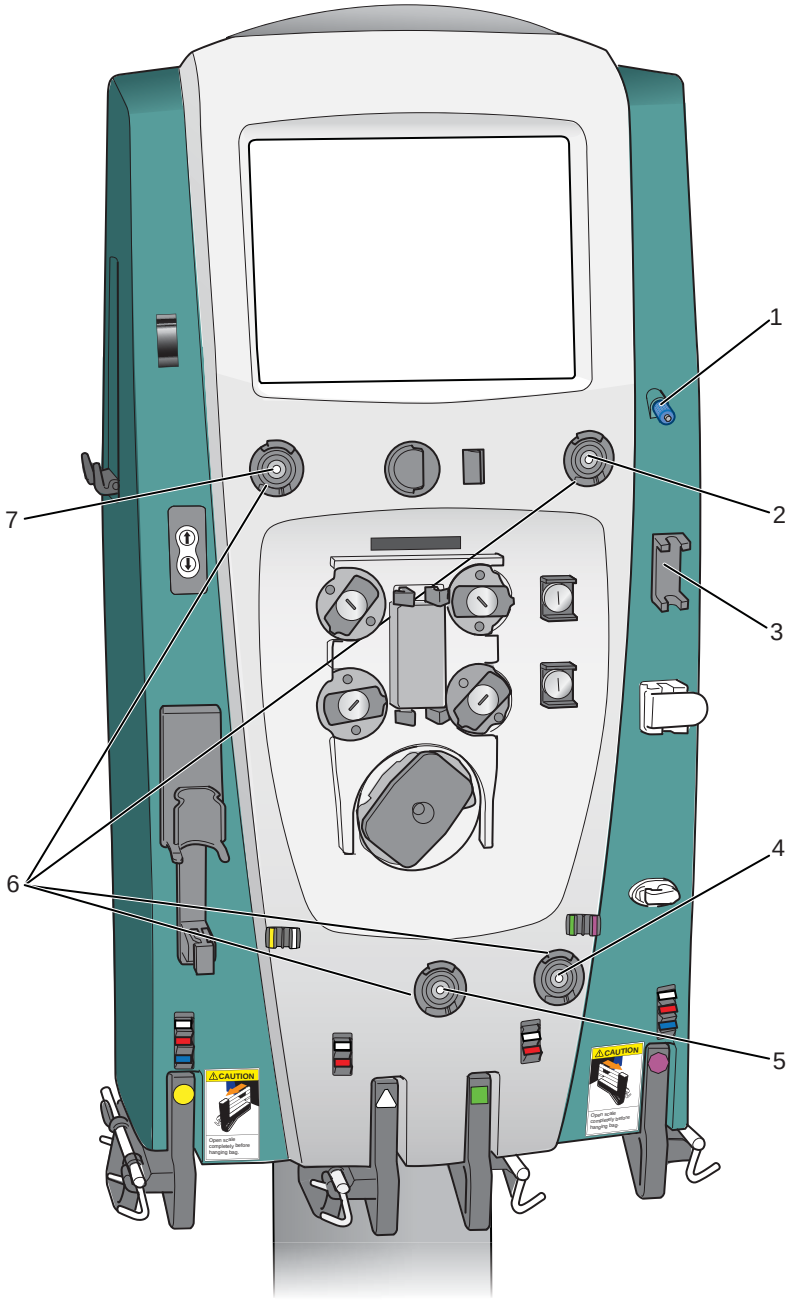

Figure 2:2 Pressure components

1. **Return pressure port**
   Connects to the monitor line of the deaeration chamber on the Prismaflex disposable set. A pressure sensor (transducer) located behind the pressure port enables noninvasive pressure monitoring of the return line and deaeration chamber. A fluid barrier at the distal end of the monitor line protects the return pressure sensor from accidental blood entry.

2. **Effluent pressure pod**

3. **Deaeration chamber holder**
   Holds the deaeration chamber of the Prismaflex disposable set.

4. **Filter pressure pod**

5. **Access pressure pod**

6. **Pressure sensor housings**
   Housings that hold the pressure pods of the Prismaflex disposable set. A pressure sensor (transducer) is located behind each housing. The sensors and pressure pods enable noninvasive pressure monitoring of the access, filter, and effluent lines. There are no air-blood interfaces.

7. **Pressure pod (not used, for future therapy)**

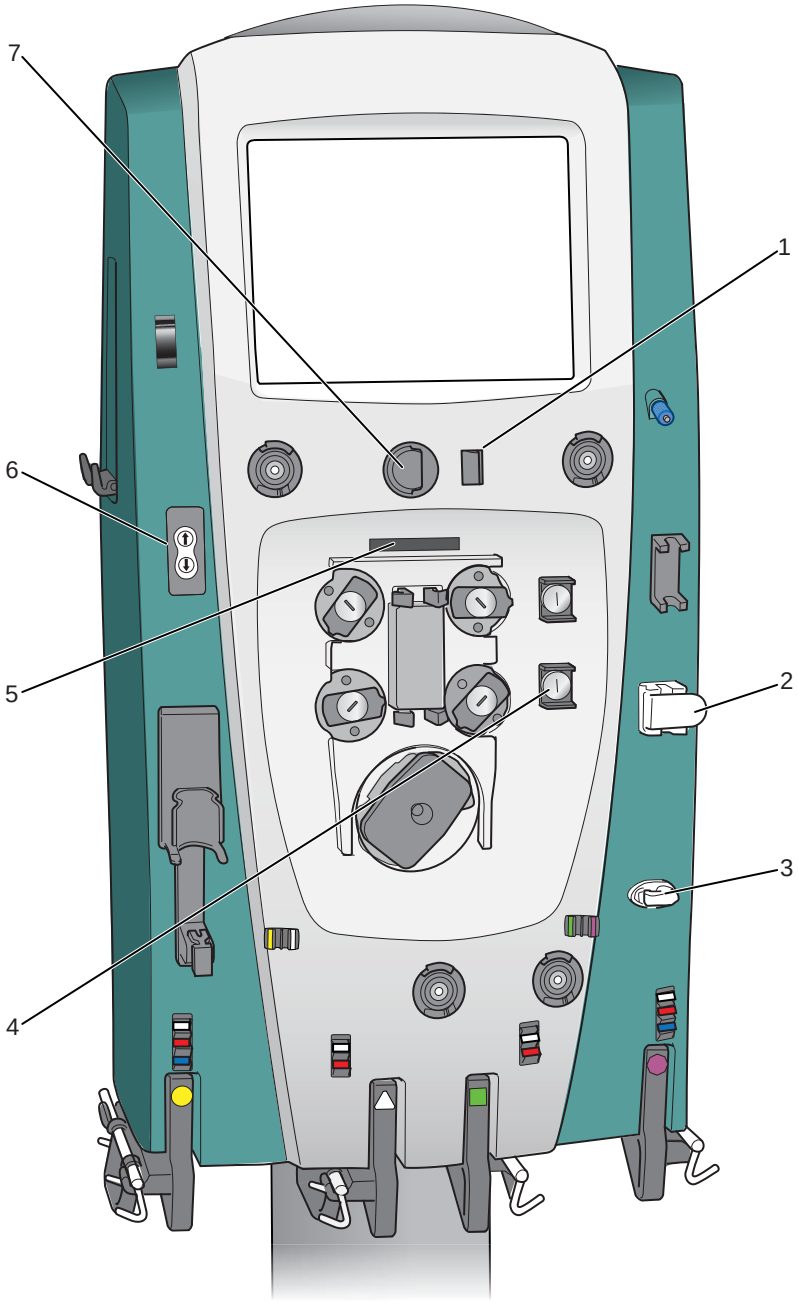

Figure 2:3 Sensors and clamps

1. Discharger ring guide

Holds the electrostatic discharger ring of the Prismaflex disposable set. The main function of the discharger ring is to lower the voltage potential in the blood/fluid path. As a result, artefacts on cardiac monitors will be minimized.
Always install the discharger ring in its guide before connecting a patient to the Prismaflex disposable set.

2. Air bubble detector (housing also includes a tubing detection switch)

Ultrasonic transmission/detection device that continuously monitors the return line for air bubbles. A Warning alarm occurs if air is detected.

3. Return line clamp (assembly also includes 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.

4. Pinch valves (upper and lower)

CVVH, 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. For more information, see chapter 4: “Therapy Operation” on page 4:11.

5. Bar code reader

The bar code reader that decodes the bar code on the Prismaflex disposable set during the set loading procedure. With this information, Prismaflex software accesses the default alarm limits, flow rate ranges, and priming sequence for the set that is loaded.

6. 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 on operating conditions.

7. 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. For more information, see section “Miscellaneous” on page 10:54.

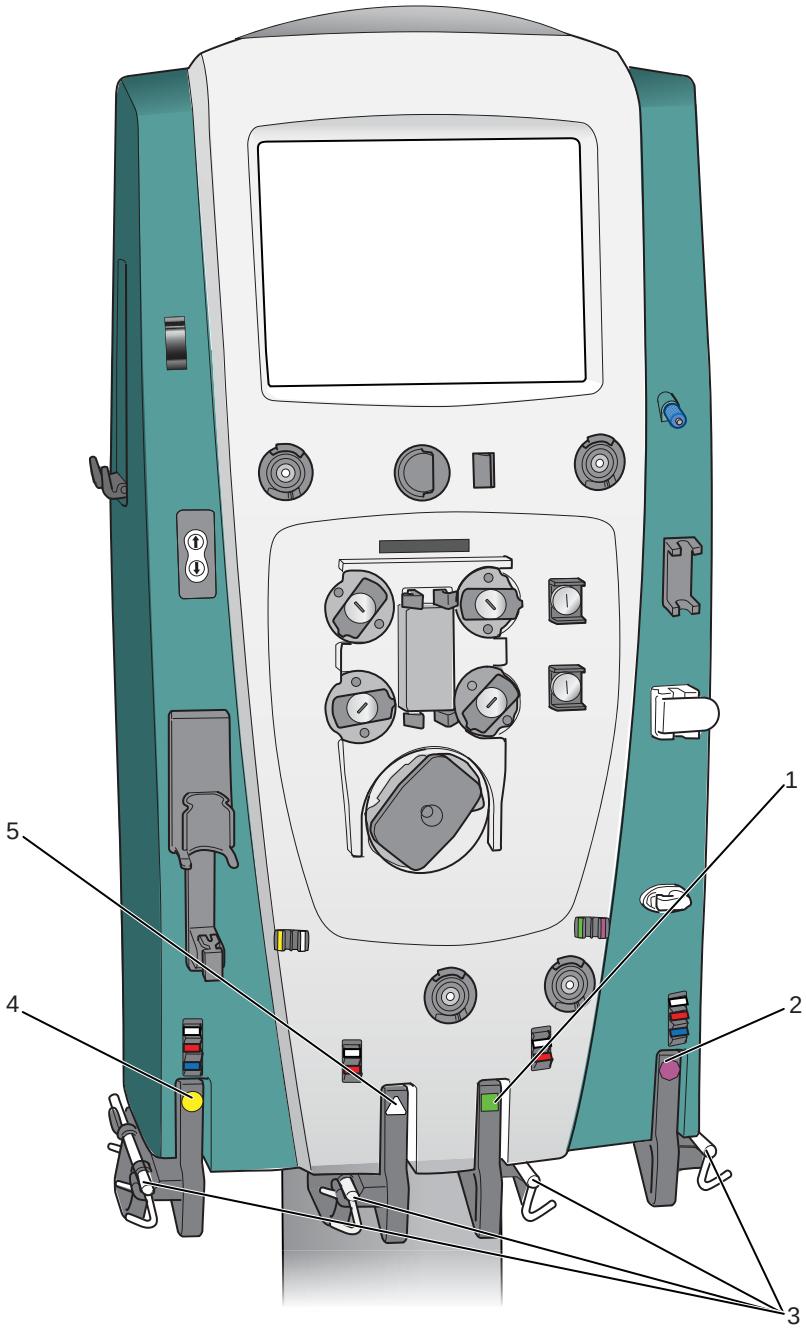

Figure 2:4 Scale components

1. **Dialysate scale (green square)**

2. **Replacement scale (purple octagon)**

3. **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 "Scale Characteristics" in chapter 12: "Specifications" on page 12:1.

4. **Effluent scale (yellow circle)**

5. **PBP scale (white triangle)**

6. **General scale Information**
   Independently monitor fluid bag/container weights. Weight is used by Prismaflex software to precisely control solution flow rates 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 require it to be closed.

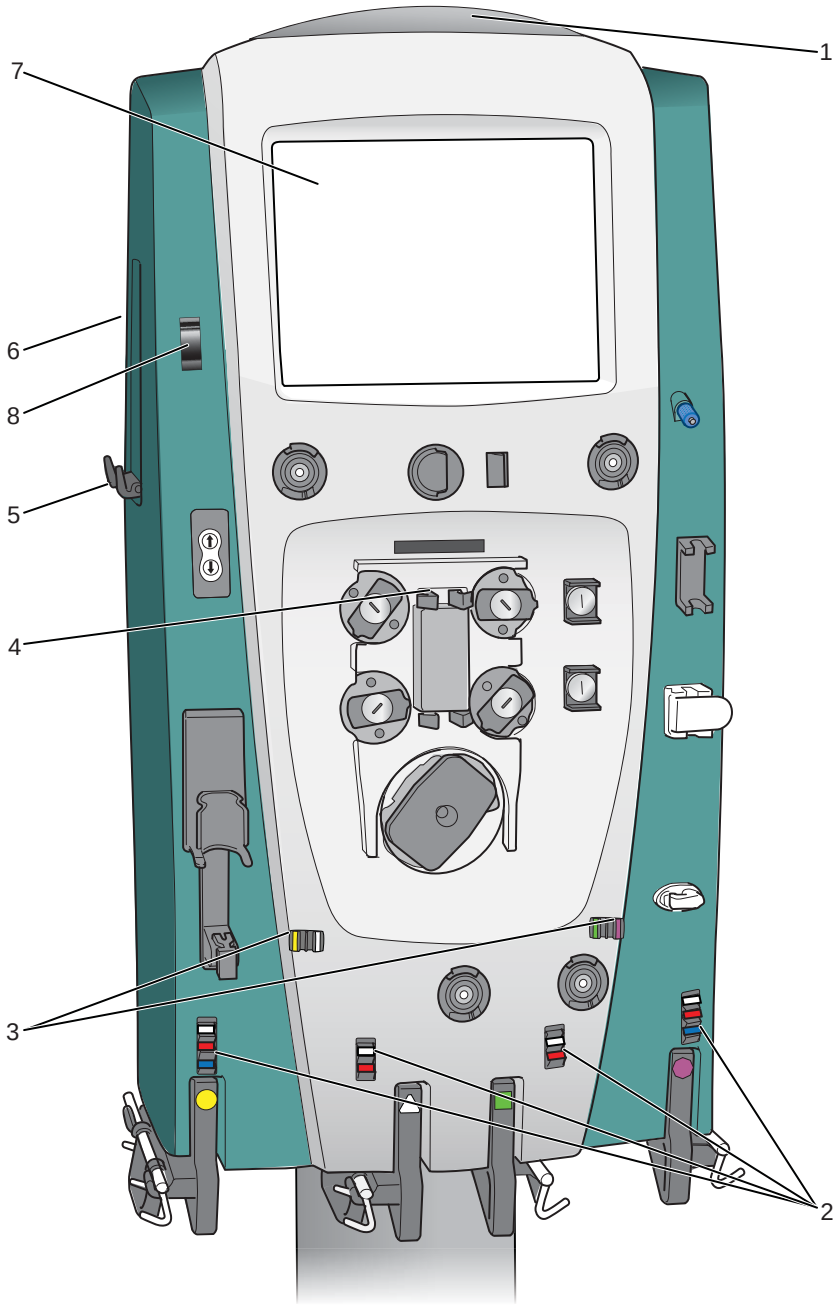

Figure 2:5 Miscellaneous components

1. Status light

Lights up to give a general indication of operating conditions.

Green constant light: Indicates that all monitored parameters are normal during administration of the treatment (Run mode).

Yellow constant light: Indicates that an Advisory alarm has occurred, or an alarm has been overridden. Immediate patient safety is not compromised, but the operator should investigate (Run mode).
Note: During modes in which a patient treatment is not in progress (Setup, Standby, End, and Custom mode), yellow indicates that monitoring is active, and that all monitored parameters are normal.

Yellow flashing light: Indicates that a Caution alarm has occurred. Immediate patient safety is not compromised, but the operator should investigate (Run mode).

Red flashing light: Indicates that a Warning or Malfunction alarm has occurred because of a condition of possible patient hazard. Immediate operator intervention is required (Run mode).

2. Tubing clips

Secure the blood lines going to the patient, including the PBP line. Route tubing through clips closest to patient, according to color coding.

3. Tubing guides

Hold the lines of the Prismaflex disposable set in correct position on the control unit. The color of each tubing guide matches the color of the line it holds.

4. Loader

Loads the Prismaflex disposable set.

5. Side hooks (left and right side)

Bags can be put on this hook.

6. Recessed handles (left and right side)

7. Display

Shows text and softkeys. Provides operating, alarm, and help instructions. Pressing the softkeys allows the operator to change settings, start and stop functions, and navigate between screens.

8. Upper clip

Rear Panel Components

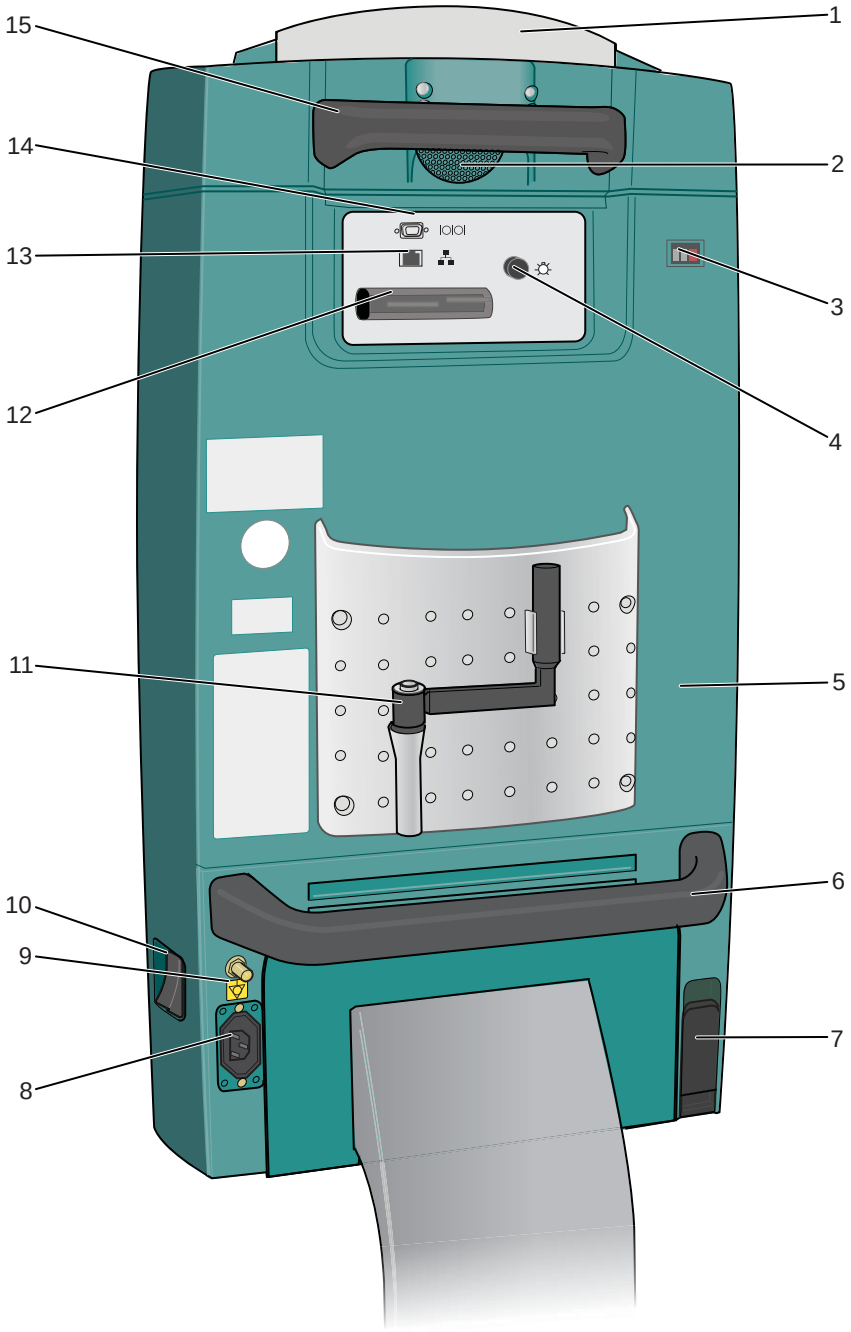

Figure 2:6 Prismaflex control unit: Rear Panel

1. Speaker
Creates alarm sounds. For more information, see chapter 9: “Alarm System” on page 9:1.

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

3. Hour meter
Displays operating hours (cumulative time that power to the Prismaflex control unit has been on).

4. Remote alarm connection
Connection for an optional remote alarm (for example installed in a nursing station).

5. Buzzer (inside)
Transmits a continuous buzz if a power loss occurs.

6. Rear handle (bottom)

7. Power cord holder

8. Power cord socket

9. Connection for potential equalization conductor
Potential equalization terminal is connected to the monitor chassis. It can be connected to corresponding terminals on other equipment to eliminate potential differences. Do not use it for additional protective grounding.

10. Power switch

11. Pump crank

12. Technical data card holder
You can copy history data to a technical data card. See “Saving the History Data” on page 4:10.

13. Ethernet port
An IP addressable port for data exchange with a personal computer or communication network. Network communication ability is only intended for sending out data and will not receive data that changes the settings in the Prismaflex control unit.

14. RS232 serial communication port
For data exchange with a personal computer, communication network or modem. Network communication ability is only intended for sending out data and will not receive data that changes the settings in the Prismaflex control unit.

15. Rear handle (top)

Interior Components

Access to the interior of the Prismaflex control unit is gained through the rear panel. Only authorized service technicians should repair the interior components. Complete descriptions of these components are provided in the Prismaflex Service Manual.

Prismaflex® Disposable Sets

The Prismaflex disposable sets are single-use disposable devices intended for use with the Prismaflex control unit. Each set consists of:

- A cartridge holding the lines, the pump segment tubes, and the filter which provides the interface to the loader of the Prismaflex control unit.
- A preconnected blood flowpath.
- Preconnected flowpaths for PBP, dialysate, replacement and effluent as applicable.

Each set is identified by a bar code label allowing the Prismaflex control unit to automatically identify the set that is loaded.

Note: The X-MARS kit differs from this general description, see section “CRRT with X-MARS™ Disposable Set” on page 5:18.

WARNING

⚠ Use only the Prismaflex disposable sets listed in this manual with the Prismaflex control unit. The use of Prismaflex disposable sets other than those listed in this manual may result in patient injury or death.

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

WARNING

Low and High Flow Sets

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 extracorporeal blood volume; blood flow ranges and ultrafiltration capacities are limited.
- High Flow sets (HF sets) provide broad capabilities for blood flow and ultrafiltration rates.

Prismaflex disposable sets available for use with the Prismaflex control unit are listed in chapter 13.

Minimum Patient Weight

Alarm limits set the minimum patient body weight allowing for a safe treatment with respect to fluid imbalance issues, namely:

- 20 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 “Sets and patient weight limits” on page 2:17.

Sets and patient weight limits

Control unit limitations		Disposable limitation		Applicable minimum patient weight
Low Flow set	20 kg	M60	11 kg	20 kg
High Flow sets	20 kg	HF1000 HF1400 M100 M150 TPE2000 X-MARS	30 kg 30 kg 30 kg 30 kg Adults Adults	30 kg 30 kg 30 kg 30 kg Adults Adults

Some sets are not available in some countries due to local regulations. Check with your Gambro representative for availability.

Disposable Set Components

The disposable set components are illustrated and described in the figure below.

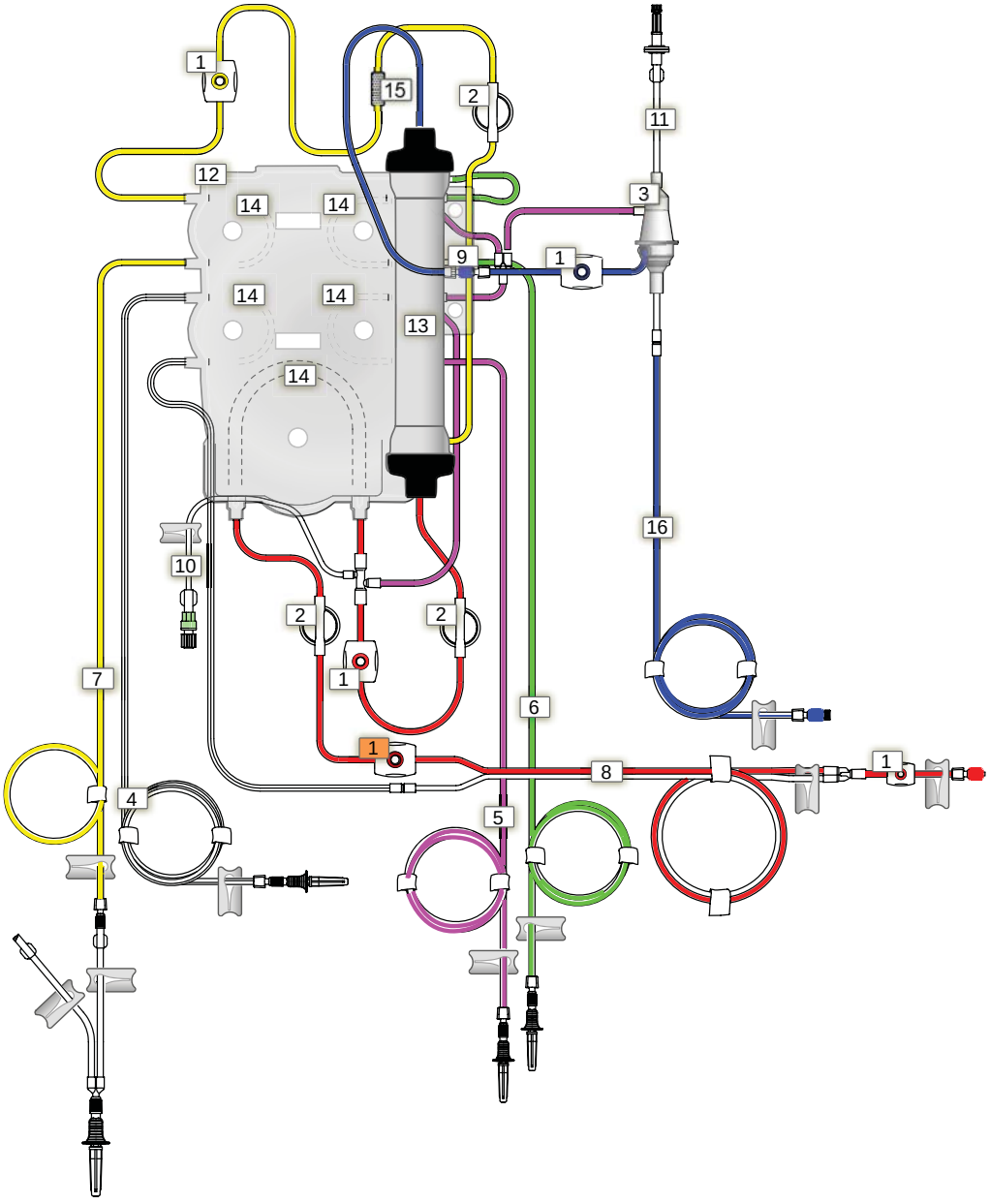

Figure 2:7 Disposable Set components

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. The sample site marked orange in figure 2:7 is optional.

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.

3. Deaeration 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.

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, not available in all therapies.

6. Dialysate/replacement 2 line (green-striped)

Conveys solution from the green-coded scale to the fluid compartment of the filter (dialysate) or to blood flowpath (replacement 2). Available in CRRT disposable sets only. See chapter 5, “Continuous Renal Replacement Therapies (CRRT).”

7. Effluent line (yellow-striped)

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

8. Access line (red-striped)

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

9. Warmer connection

Male-female luer connectors allow connection of blood warmer circuits, see chapter 8: “Blood Warmers” on page 8:1 for more information.

10. Syringe line

In the systemic Prismaflex syringe pump anticoagulation method, the syringe line on the disposable set conveys anticoagulant from the syringe to the blood flowpath. A non-return valve is present on the syringe line. The syringe line is pre-clipped to the cartridge and should remain so if not using the Systemic anticoagulation method.

11. Chamber monitor line

Connects the deaeration chamber with the return pressure port, enabling pressure monitoring and removal of air, if needed. The Prismaflex system can remove air semiautomatically by drawing it out through the return pressure port. A fluid barrier at the distal end of the line protects the return pressure port from accidental blood/fluid entry. See “Air Removal Procedures” on page 10:61 for more information.

12. Cartridge

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

13. Filter

Filter characteristics are dependant on the chosen Prismaflex disposable set. Refer to therapy sections for more information.

14. Pump segments

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

15. Electrostatic discharger ring

16. Return line (blue-striped)

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

Prismaflex® Accessories

For information about accessories and spare parts, see the *Prismaflex Spare Part Catalog* provided by your local representative.

Hardware Accessories

Blood Warmers

See chapter 8: "Blood Warmers" on page 8:1 for further information.

UPS Requirements for Installation with Prismaflex® Control Unit

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

Disposable Accessories

For information and supply of all listed disposable accessories, contact your local Gambro representative.

Effluent Bag

All Prismaflex disposable sets include a 5000 ml effluent bag. Additional effluent bags can be purchased separately. Contact your local Gambro representative.

SP-394 Accessory for TPE

The SP-394 accessory is designed for connecting several replacement containers at a time during TPE therapy. The SP-394 accessory for TPE is illustrated in the TPE chapter on page 6:14.

Prismatherm II Extension Line

For using the Prismatherm II blood warmer, the SP420 warmer extension line must be used and connected during setup. See chapter 8: "Blood Warmers" on page 8:1 .

Chapter 3

General Prismaflex® Functions

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About the Chapter

This chapter describes the Prismaflex control unit functions.

Blood Flowpath Management

Blood flowpath consists of:

- Access line connecting the patient to the blood pump.
- Peristaltic blood pump.
- Filter line connecting the blood pump outlet to the filter inlet.
- Blood compartment of the filter.
- Return line connecting filter outlet to the patient.

Each segment of the blood flowpath is equipped for pressure monitoring, see “Pressure Management” on page 3:3. The return line is also equipped for the collection of air and the prevention of air infusion to the patient, see Figure 2:7 on page 2:18.

WARNING

⚠ Always connect the return line directly to the blood access device. Do not connect additional devices between the return line and the blood access device. The use of additional devices, such as three-way valves, stopcocks, or extension lines, may impair return pressure monitoring. Their use can impede the detection of return disconnections, potentially resulting in severe blood loss.

⚠ The Prismaflex control unit may not be able to detect disconnections of the set from the blood access device, which can result in severe blood loss. Ensure that the patient's blood access and return connections are firmly secured; pay special attention in case a warmer sleeve is in use.

WARNING

Blood Access Monitoring

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 Prismaflex disposable set. In some situations, blood return is via a single lumen venous catheter or a large peripheral vein.

The size of the catheter should be adapted to patient and blood flow rate prescription for the extracorporeal therapy. An inadequate catheter-blood flow combination may lead to very negative access pressure and/or very positive return pressure with a possible high occurrence rate of the Warning: Access Pressure Extremely Negative alarm or the Warning: Return Extremely Positive alarm. Reduction of the blood flow rate or change of vascular access to a larger catheter shall then be considered. On the other hand, inadequate catheter-blood flow combination can result in access or return pressure close to zero and prevent the system from detecting disconnection at the vascular access. Increase of blood flow rate or change of vascular access to a smaller catheter should then be considered.

Blood Pump and Pre Blood Pump

The PBP solution is added to the access line immediately after the patient's blood enters from the access site, and before the access line reaches the blood pump. Because of this, the amount of blood actually pumped with each revolution of the blood pump is reduced. To maintain the set blood flow, the Prismaflex software increases the blood pump flow:

$Q_{BP} = Qb + Q_{pbp}$

Where $\mathbf{Q_{BP}}$ is blood pump flow (ml/min), **Qb** is set blood flow (ml/min) and $\mathbf{Q_{pbp}}$ is set PBP flow (ml/min).

Pressure Management

The Prismaflex control unit features an integral pressure monitoring system which allows for the noninvasive assessment of the access, filter, return, and effluent pressures.

Monitoring provides notification to the operator in case of abnormal pressure conditions, for instance in the return or access line. Additional data is gathered by the Prismaflex software and is used to calculate important treatment-related pressures, including pressure drop in the filter. These calculations are used to provide notification that clotting has begun in the filter or that the filter has clotted and the set must be changed.

Components for Access, Filter, and Effluent Monitoring

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

- Pressure pods. Prismaflex disposable sets have a pressure pod in these locations: access line (access pod), filter inlet (filter pod) and effluent line (effluent pod). See Figure 2:2 on page 2:6.

- Pressure sensor housings. The front panel of the control unit has three sensor housings that accept the pressure pods described above. The housings provide connections between the pods and the pressure sensors inside the control unit. The locations of the sensor housings are shown in Figure 2:3 on page 2:8.

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

- Pressure sensors. A pressure sensor (transducer) is located inside the control unit, behind each pressure sensor housing.

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

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

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

Components for Return Pressure Monitoring

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

- Deaeration chamber, located on the return line of the set.
- Chamber monitor line. An integral part of the deaeration chamber, this line provides a connection between the top portion of the deaeration chamber and the return pressure port on the control unit.
- Return pressure port. The front panel of the control unit has a luer-lock port located on the upper right (see Figure 2:2 on page 2:6). The port connects with the chamber monitor line.
- Pressure sensor. The return pressure sensor is located inside the control unit, behind the return pressure port.

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

The topmost portion of the deaeration chamber is air filled and connected to a pressure sensor inside the control unit via the chamber monitor line. Fluctuations in the chamber pressure are monitored by this sensor. Proper operation of the return pressure sensor is tested by the automatic reposition system (ARPS) every two hours.

Pressures During Operation

Pressures vary within the set depending on individual patient characteristics (blood pressure and blood viscosity) as well as size of the patient catheter, flow rates, and therapy being delivered. The actual pressures at all monitoring sites can be viewed on the *Status* screen during a patient treatment.

The following pressure ranges are typical during use of the Prismaflex system:

Access pod pressure	Can be negative or positive, depending on the blood source to which the access line is connected.
Return pressure	Always positive.
Filter pod pressure	Always positive and higher than return pressure. The filter pod is located immediately before the filter and measures the area of most positive (highest) pressure in the set.
Effluent pod pressure	Can be positive or negative, depending on the ultrafiltration rate and therapy chosen.

Extreme Pressure Limits

Pressure limits are enforced by Prismaflex software to ensure patient safety. If a monitored pressure goes outside the manufacturer-established *extreme* limits, a Warning alarm occurs. Warning alarms stop all pumps and close the return line clamp. Extreme pressure default limits for CRRT on page 3:5 shows the manufacturer-established extreme pressure limits.

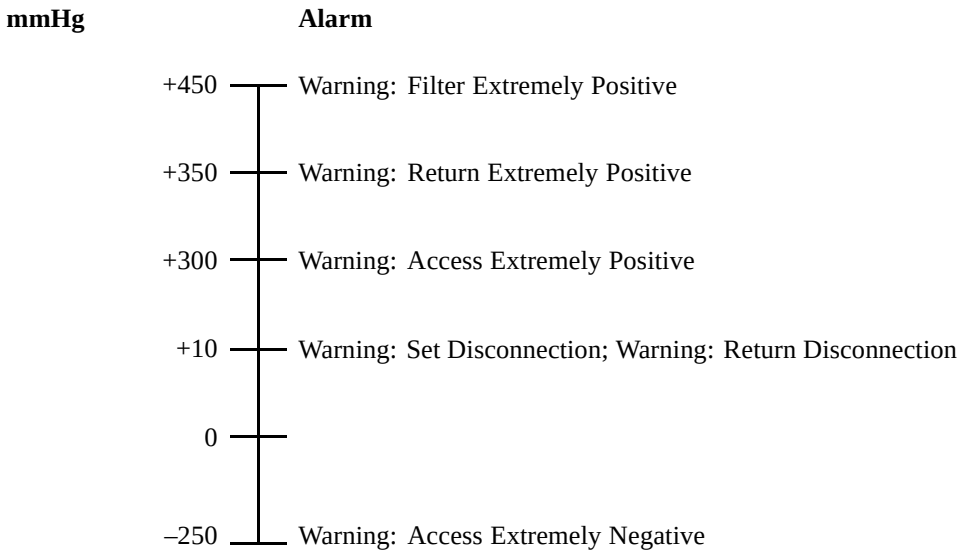
Access and Return “Extreme” Warning alarms feature a self-clearing functionality. If the monitored pressure returns to normal values within a 15 second period and no

other self-clear attempt was performed with the previous 2 minutes, the alarm will clear automatically. During the self-clear time the monitor will not give an audible alarm.

Detailed information on the individual alarms is also available in the "Troubleshooting" chapter starting on page 10:1.

Three of the extreme pressure alarm limits, Warning: Access Extremely Negative alarm, Warning: Access Extremely Positive alarm, and Warning: Return Extremely Positive alarm are operator-controllable in Custom mode. If desired, the operator can modify these limits, so that an alarm will occur prior to reaching the manufacturer-established extreme limit. For more information, see “Custom Mode” on page 4:25 and “User-controllable Settings” on page 14:1.

Extreme pressure default limits for CRRT



Pressure Operating Points

Whenever the Prismaflex control unit is operating, a reference pressure value is stored in software memory for each pressure pod and the return line sensor. This value is called the pressure operating point. Software continually compares the current pressure at each monitoring site with the pressure operating point. In this way, the control unit can detect changing pressure conditions in the set and notify the operator with an Advisory or Warning alarm. During calculations of pressure operating point some pressure alarms are not active. It is important to manually monitor the blood pathways closely when the calculations are in progress.

Initial Values

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

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

Subsequent Values

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

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

- After the blood pump changes speed during Run mode (due to operator changing the flow rate).
- After the blood pump restarts (following an alarm or after pressing *RESUME* from the *Stop* screen).
- After the operator presses the *CONTINUE* softkey from a Caution alarm screen.
- After the operator presses the *CONTINUE* softkey from an Advisory: Check Access or an Advisory: Check Return alarm screen.
- After the operator changes position of the replacement pre/post pinch valve.
- The pressure operating points are also updated after periodic self-test.

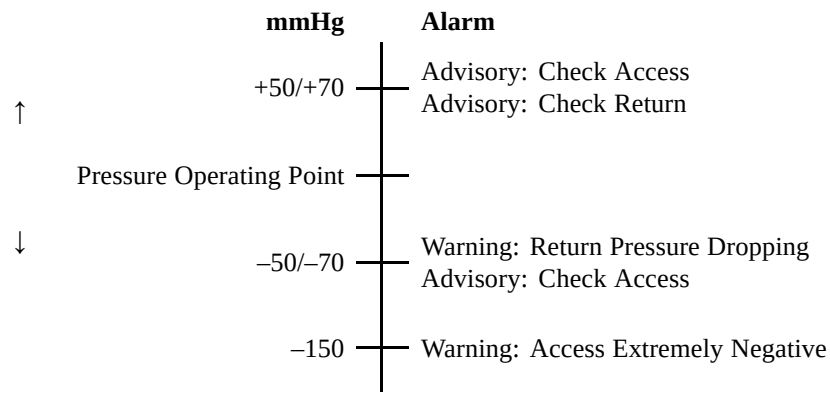
Note: If the return pressure operating point is above +10 mmHg, it is not reset after a periodic self-test, Caution alarm or Advisory: Check Access alarm.

Pressure Trending Limits

If the access or return pressure changes 50 mmHg (or 70 mmHg if blood flow >200 ml/min) negative or positive from its established pressure operating point, the control unit notifies the operator by issuing an Advisory alarm or a Warning alarm. Detailed information on the individual alarms is available in the Troubleshooting chapter starting on page 10:1.

Alarms can be cleared by pressing *CONTINUE* on the alarm screen. This resets the pressure operating points to the current pressures at each monitoring site.

Pressure trending limits



"Cannot Detect Disconnection" Limits

The detection of return disconnections requires a large pressure drop on the return line. If pressure and/or flow conditions on the blood return result in an operating point that is below +10 mmHg, the Prismaflex control unit cannot enable disconnection monitoring.

The control unit then issues an Advisory: Cannot Detect Return alarm in order to notify the operator and to give instructions how to remedy the situation.

Detailed information on the individual alarms is also available in the Troubleshooting chapter starting on page 10:1.

Software-calculated Pressures

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

These additional pressure data are displayed and updated on the *Status* screen during a patient treatment. In addition, a Status Graph (line graph) showing the trends of these pressures over an operator-controllable period of 1 to 3 hours can be displayed, see “Custom Mode” on page 4:25. For more information and treatment specific details, see chapter 5: “Continuous Renal Replacement Therapies (CRRT)”, chapter 6: “Therapeutic Plasma Exchange (TPE)” .

Filter Pressure Drop (Pressure Drop)

Filter pressure drop is a calculated value used to determine pressure conditions in the blood compartment of the filter. Filter pressure drop is calculated by Prismaflex software as follows:

$\Delta P_{fil} = P_{fil} - P_{ret}$

Where $\mathbf{\Delta P_{fil}}$ is Filter pressure drop (mmHg), $\mathbf{P_{fil}}$ is Filter pod pressure (mmHg) and $\mathbf{P_{ret}}$ is Return sensor pressure (mmHg)

Filter pressure and Return pressure readings are automatically corrected for hydrostatic pressure biases (–25 mmHg).

During patient treatment, clotting can occur in the blood compartment of the filter. Clotting adds resistance to the blood flow through the filter and causes the filter pressure drop to increase. In case of severe clotting, the set needs to be exchanged.

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

Increase of Filter Pressure Drop with Filter Use

	Start time	During use
Filter pod pressure	150 mmHg	300 mmHg
– Return sensor pressure	90 mmHg	180 mmHg
= Filter pressure drop	60 mmHg	120 mmHg
= Displayed Filter pressure drop	**35 mmHg**	**95 mmHg**

In the above example, filter pressure drop increased by 60 mmHg.

During operation, software sets the initial value for filter pressure drop at the same time as the initial operating points are established, see “Pressure Operating Points” on page 3:5. The amount of increase above the initial filter pressure drop contributes to the Advisory: Filter Is Clotting alarm. The limit for triggering this alarm can be set by the operator. For more information and treatment specific details for this alarm, see “Custom Mode” on

page 4:25, chapter 5: “Continuous Renal Replacement Therapies (CRRT)”, chapter 6: “Therapeutic Plasma Exchange (TPE)” .

Fluid Management

Fluid management by the Prismaflex system is achieved through interaction between pumps and scales in order to control the prescribed fluid flows from bags and containers. Additional monitoring protects the patient from fluid imbalance.

Pumps and Scales

The Prismaflex control unit has four occlusive, peristaltic pumps and four scales. The number of pumps and scales used and their function depends on the selected therapy. Color coding of the scales matches the color coding of disposable lines and clamps. Matching color coding is also present in online instructions and alarms.

The Prismaflex system maintains set flow rates of individual solutions on the base of pump and scale pairs. Software within the control unit controls the speed of the peristaltic pumps based on the changing weight of the fluid bags/containers as measured by the related scales.

Flow rates are either directly set by the operator (for instance for dialysate or replacement), or computed by the software based on the operator-set flow and anticoagulation settings (for instance effluent and PBP).

During a patient treatment (Run mode), all the peristaltic pumps turn clockwise and if the blood pump stops for any reason, all other pumps also stop. When the blood pump resumes, the other pumps also resume after a short delay.

Solution Bags and Containers

The Prismaflex system is validated to operate with Gambro bags. Standard dialysate, PBP and replacement solution bags are 5000 ml. Standard effluent bags are 5000 ml. Prismaflex scales can accept bags/containers with a total weight of up to 11kg (see also chapter 12: “Specifications”).

Before using any bag that is not a Gambro bag on the Prismaflex system, the operator must verify that:

- the bag or container does not interfere with the Prismaflex control unit cabinet or base
- the bag or container does not interfere with bags hung on adjacent scales
- Prismaflex disposable set lines are not kinked or interfering with other bags or the base when connected to the bag/container
- bag perforations match the hooks on the scale carrying bar
- the bag is compatible with the selected Empty Bag method, see next section.

See “Changing a Bag During Treatment” on page 4:27 for further instructions.

Empty Bag Methods

Fluid Bags and Containers

The Prismaflex system offers two methods for the automatic detection of empty bags or containers. See also “Changing a Bag During Treatment” on page 4:27 for further instructions.

- Fixed Empty Bag: triggered once the bag weight reaches the predefined lower limit (default: 230 g)
- Variable Empty Bag: triggered once the specified volume has been pumped from the bag or container

When an empty bag is detected, the control unit stops and informs operator via the Caution: Bag Empty alarm.

Fixed Empty Bag method is the default method in CRRT therapy and is validated for bags supplied from Gambro. If using any bag that is not supplied from Gambro, the operator must verify if they are compatible with the Fixed Empty Bag method.

Variable Empty Bag method is especially designed for the use of containers like bottles. It is the only available mode in:

- TPE therapies. See operating instructions in chapter 6.

Empty Bag method is user-selectable in custom mode; see “Custom Mode” on page 4:25. Incorrect selection of the Empty Bag method or of the bag/container volume may result in failure of the Empty Bag alarm, leading to air intake in the blood flowpath.

Effluent Bag

Prismaflex system manages the effluent bag by controlling the amount of fluid pumped into the effluent bag. This volume can be adjusted according to the size of effluent bag in use; see accessories description “Effluent Bag” on page 2:20.

Protecting from Flow Problems

Flow problems in the fluid lines, bag connectors or pump segments can affect fluid transport within the system. If not properly addressed, such problems can negatively affect the patient’s fluid balance.

The Prismaflex system is designed to detect and mitigate such situations and to assist the operator in the required troubleshooting procedures. The Prismaflex system thereby provides for safe fluid balance management.

Detection of Flow Problems

During operation, the Prismaflex control unit continuously monitors the weight of the solution bags and the effluent bag. Should the actual weight of a bag vary more than 20 g from its expected value, this indicates problems with fluid flow. In addition, the control unit monitors the speed of the fluid pumps. Should any of the pumps constantly operate with either minimum or maximum allowed speed, this also indicates issues with fluid flow in the system.

Once a flow problem is suspected, the control unit will stop all fluid pumps in order to mitigate the underlying problem and to protect the patient's fluid balance. The blood pump continues to run and circulates the blood through the blood flowpath. The operator is notified through a Caution: Flow Problem alarm.

Resolving Flow Problem Alarms

Instructions how to troubleshoot common flow problems are provided on the Caution: Flow Problem alarm screen and in chapter 10: "Troubleshooting". The operator should thoroughly investigate and remedy all problems before pressing the *CONTINUE* softkey, which restarts the fluid pumps. Once the underlying problems are resolved, the Prismaflex control unit will temporarily adjust the fluid flow on the affected bag in order to compensate for the occurred flow deviation.

If the underlying problem persists, subsequent Caution: Flow Problem alarms will occur. Episodes of unresolved alarms can result in substantial fluid loss or gain in the patient. These are additionally monitored by the Prismaflex system and if indicated, additional alarms are issued. See chapter 5: "Continuous Renal Replacement Therapies (CRRT)", and chapter 6: "Therapeutic Plasma Exchange (TPE)" for treatment specific details on these alarms.

Air Management

WARNING

⚠ Before connecting the blood return line to the patient, make sure the blood line segment from the air bubble detector to the patient is free of air.

WARNING

Description

Prismaflex blood flowpath is designed to minimize trapping of air bubbles and to collect all air in the deaeration chamber. To this end upward blood flow is managed in the filter and in the pods. The specific design of the deaeration chamber provides for:

- a stable layer of infusion fluid at the top of the chamber when using post-replacement infusion, thus preventing air-blood interface and minimizing clotting
- a circular blood flow pattern in the chamber allowing for efficient removal of air bubbles within a limited blood volume

Deaeration Chamber Monitoring

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. See "Deaeration Chamber" on page 4:30.

Anticoagulation Methods

The Prismaflex control unit has a syringe pump that delivers anticoagulant to the blood flow, if desired. Various syringe sizes and brands can be used.

The following anticoagulation methods are selectable on the *Choose Anticoagulation Method* screen:

- **Systemic, Prismaflex syringe pump**. For treatments with anticoagulation regime, using the Prismaflex syringe pump.
- **No anticoagulation**. For treatments performed without anticoagulation regimen. The Prismaflex syringe pump is disabled during the entire treatment.

Treatment Preparation

Set Loading and Identification

Loading sequence automatically installs all the pump segments of the Prismaflex disposable set in the pump raceways. It identifies the set by reading its bar code. This identification allows the system for selecting the relevant operating flow and pressure ranges, as well as the specific priming sequence.

Set Priming

Set priming is structured in one or more priming cycles. The operator initiates each priming cycle which usually requires 1000 ml of priming fluid. During priming, the Prismaflex system checks for common handling errors, e.g. clamped or tangled lines, and gives troubleshooting instructions when necessary. The operator must connect one or more solution bags to the blood flowpath to prime, according to instructions given on the screen. Solution bags/containers will be required on the scales according to the selected therapy.

Note: Presence of a PBP solution bag is not required if not part of the prescription, or if the default PBP flow rate is zero. Presence of a PBP solution bag is required in the following situations:

- After a Change Set sequence where PBP was prescribed.

Alarm and Monitoring Systems

Alarm System

The Prismaflex control unit continually monitors itself and the Prismaflex disposable set for abnormal conditions. Depending on the circumstance, the operator is alerted by the following:

- Red flashing status light alerting for Warning or Malfunction alarms
- Yellow flashing status light alerting for Caution alarms
- Yellow constant status light alerting for Advisory alarms
- Audible alarm with a sound pattern referring to the type of alarm
- Alarm screen on the display, giving instructions for responding to the abnormal condition

Alarms are prioritized into Warning, Malfunction, Caution, and Advisory alarms. See chapter 9: “Alarm System” on page 9:1, for more information.

Monitoring Systems

Pressure

The Prismaflex control unit has an integral pressure monitoring system. The system alerts the operator (via alarms) to abnormal pressure conditions, such as clotting or extreme positive pressure in the return line. For more information, see “Components for Return Pressure Monitoring” on page 3:4.

Blood Leak

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

Air Bubble

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

Flow Rates and Volumes

The Prismaflex control unit has scales that continually monitor pumped volumes and flow rates of the PBP, dialysate, replacement and effluent pumps. For more information refer to page 3:8 of this chapter.

Self-tests of the Prismaflex® System

The Prismaflex software continually monitors the operation of the control unit and the Prismaflex disposable set. As part of this regular monitoring, three different types of self-tests are performed.

Note: Complete descriptions of these self-tests and all other monitoring routines of the Prismaflex control unit are provided in the Prismaflex Service Manual. For Prime Self-test and Periodic Self-test, see also chapter 10: “Troubleshooting”.

Initialization Test

The initialization test ensures that the control and protective subsystems are operating properly. The initialization test begins after the operator turns the power switch to the “On” position. The *Logo* screen appears on the machine display, the buzzer sounds (and cannot be turned off) and some status lights are lit during the test. After the initialization test completes, the control unit enters Setup mode.

Prime Self-test

The prime self-test is started when the device is in Setup mode. 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 post-prime phase starts when the Prime test is entered from the *Priming X of Y Cycles Complete* screen.

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

Periodic Self-test

A periodic self-test is conducted by the control unit during Run mode. A test is initiated at the following times:

- During patient treatment (Run mode): A periodic self-test is conducted every two hours. The first periodic self-test starts 10 minutes after Run mode is entered. If another alarm occurs at the scheduled start of a periodic self-test, the self-test may be delayed up to 15 seconds. Periodic self-test may be delayed 10 min by selecting the *DELAY TEST* softkey. When the user has initiated three delays of a due self-test the Advisory: Self-Test Overdue alarm occurs. Time schedule of the periodic self-test may also be automatically modified by the system according to next intervention schedule (bag change or syringe empty).

- If needed, an ongoing self-test can be interrupted by pressing the *STOP* softkey. Self-test is then restarted when pressing the *RESUME* softkey in the *Stop* screen.

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

A complete periodic self-test takes approximately 1 to 6 minutes. Once started, its progress is signalled to the operator through messages on the *Status* screen. Certain functions, including adjustments to treatment parameters, are unavailable during an ongoing test and the related softkeys are gray. Any treatment interruptions via the *STOP* softkey should be avoided during an ongoing test in order to allow for its swift and successful completion.

Note: The information icon "i" on the *Status* screen is lit with an orange color during self-test.

If any of the subtests fail, the ongoing run of the periodic self-test is terminated and a Malfunction: Self-test Failure alarm occurs. The alarm screen identifies the failed subtest and provides instructions for the operator.

Alarm Monitoring During the Periodic Self-test

Pressure management is affected by an ongoing periodic self-test. Dependent on the various sub-tests in progress, pressure limits are either replaced by temporary limits, or are temporarily disabled. Occurrences of related alarms may be postponed until after completion of the test.

Note: Return pressure monitoring and related alarms remain active during periodic self-tests.

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Chapter 4

Operating the Prismaflex® System

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About the Chapter

This chapter contains information about the user interface, definitions, access to treatment history and general handling of the machine during start up, treatment and termination of treatment.

System Overview

Interactive Display

The Prismaflex control unit has a color touch screen display. The touch screen allows the operator to interact with the control unit by pressing various softkeys.

During operation, different screens appear on the display, showing information about the treatment, giving steps the operator should take, and alerting the operator to any abnormal conditions. Specific display contents depend on the software mode and operating conditions at the moment. Some types of operating data, such as history data, are only displayed when requested by the operator. The display is also a vehicle for servicing the system.

Softkeys are located along the bottom of each screen and may also appear on the sides and/or in the middle of the screen. Softkeys allow the operator to give commands to the control unit and navigate between screens. The operator presses the desired softkey to initiate the function described by its name. The name and function of many of the softkeys change, depending on operating conditions. In this way, the operator is led through operating and alarm response situations.

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

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

Definitions

Treatment

A treatment is initiated by pressing the *NEW PATIENT* softkey in the *Choose Patient* screen. A CRRT treatment commonly spans over a sequence of disposable sets, which can be exchanged through the Change Set procedure. A treatment can also be resumed through the *SAME PATIENT* softkey in the *Choose Patient* screen.

A treatment is discontinued once:

- Ten filter sets have been used.
- Custom mode is entered.
- Service mode is entered.

- The treatment remained interrupted for more than 24 h.

Treatment Time

Treatment time starts running once the treatment is started on the first disposable set in the treatment sequence.

The Treatment time continues running during interruptions, including recirculation phases and downtimes of the control unit of up to 24 hours.

Filter Time

Filter time is the treatment time elapsed on the current disposable set. For the first set in the treatment sequence, Filter time equals Treatment time.

Number of Used Sets

A treatment is limited to ten sets. After the 10th set has been unloaded, the treatment ends.

Note: Sets that are replaced during Setup mode are not considered for the set count.

User-controllable Settings

The tables in chapter 14: “User-controllable Settings” lists all user-controllable settings, their default values, setting options, and the operating mode in which they can be changed.

Default Values

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

- Each possible therapy/set combination has its own default values, including values for flow rates, bag volumes, and alarm limits.
- There are additional default values for settings that apply to all therapy/set combinations, for example, the level of the audible alarm beep, brand of the syringe allowed for use, and initial settings for *History* and *Status* screen.
- All settings revert to their default values whenever a New Patient procedure is chosen.
- The operator can change the default values of the user-controllable settings. This can only be done in Custom mode. For more information, see “Custom Mode” on page 4:25.

Current Values

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

When the operator chooses a particular therapy/set combination during the Setup procedure, the control unit uses the default values assigned to that combination. The operator can modify some of these values during the Setup procedure (Setup mode) or while the patient treatment is underway (Run mode). Any changes made in Setup or Run modes apply only to that treatment and do not affect the default values.

Safety Relevant Settings

Some user-controllable settings are critical to patient safety. These include flow rate and anticoagulation settings. These settings are modifiable via the *Enter Treatment Settings*, *Enter Flow Settings*, and *Enter Anticoagulation Settings* screens.

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

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

Prescription Settings

Prescription settings include both Flow Rates and Anticoagulation Settings.

Flow rates are the settings that control the rate of blood flow, PBP and replacement infusion, dialysate and/or other flows depending on the therapy in use. Flow rates are directly user-controllable except:

- the effluent flow rate in CRRT
- the effluent flow rate in TPE

These flows are automatically set by software, based on all other flow rates and anticoagulation settings. See chapter 5, 6 for the description of available flow rate settings in each therapy.

Anticoagulation settings are the settings that control the intensity of the anticoagulation; setting parameters are dependent on the anticoagulation method in use. All anticoagulation settings are directly user-controllable. See chapter 7 for the description of available settings in each anticoagulation method.

Adjusting the Prescription Settings

During the Setup procedure (Setup mode), the *Enter Flow Settings* and *Enter Anticoagulation Settings* screens are displayed. The operator is prompted to assess the default flow rates for the therapy/set chosen, make any changes desired for the current treatment, and confirm all values shown on the *Review Prescription* screen prior to starting the patient treatment.

In Run mode, the operator can access the *Enter Flow Settings* and *Enter Anticoagulation Settings* screens for adjusting the prescription parameters as needed. See “Operating Modes” on page 4:13 and chapter 14: “User-controllable Settings”.

The *VIEW CHANGES* softkey (only available in Run mode) is lit when a change in the settings has been made. By pressing this button you can see the previously entered values and the new values.

In Custom mode, if desired, the operator can change the default flow rates. See “Custom Mode” on page 4:25.

Viewing the Prescription Settings during Treatment

During a patient treatment (Run mode), the current prescription settings are displayed on the *Status* screen. For more information, see “Operating Modes” on page 4:13.

Status Screen

The *Status* screen is the main operating screen while a treatment is ongoing. It displays the pressure conditions in the set, the flow rates, the anticoagulation settings, and the calculated prescription parameters. The operator is also notified when the next intervention is required, e.g. changing a bag or syringe empty. If abnormal situations occur, an alarm screen will appear that provides information about action that needs to be taken.

The *Status* screen contains the following icons:

Patient ID

Patient weight

Filter time, time elapsed on current disposable set

Treatment time, total treatment time for patient

Current clock time

Currently delivered therapy, based on UFR dose

Prescribed therapy

The control unit is running on battery

Information, lit orange when updated information is displayed

The *Status* screen contains four tabs and by pressing a tab, the contents will become visible.

Prescription	Displays information about prescription settings and prescription indicators. Press the *ADJUST* softkey in the lower right corner to change settings.
Anticoagulation	Displays information about Anticoagulation settings. Press the *ADJUST* softkey in the lower right corner to change settings.
Info	Displays information about next intervention, self-test in progress, pressure operating point calculations in progress and waiting for stabilization of scales.
TMP	Displays a pressure graph; TMP and pressure drop (CRRT), TMPa and pressure drop (TPE) .

Status screen softkeys

STOP	Stops all pumps and navigates to the *Stop* screen. Allows for *RESUME, CHANGE SET, RECIRCULATE* or *END TREATMENT*.
CHANGE BAGS	Navigates user to the *Change Bags* screen. Allows for changing of bags and/or adjustment of allowed bag volume.
CHANGE SYRINGE	Only displayed when the systemic method has been selected. Navigates user to the *Change Syringe* screen. Allows for changing of syringe.
ADJUST CHAMBER	Navigates user to the *Adjust Deaeration Chamber* screen. Allows for correction of fluid level in the chamber.
SYSTEM TOOLS	Navigates user to the *System Tools* screen.
HISTORY	Navigates user to the *History* screen, which allows viewing of treatment history information.
HELP	Navigates user to the *Help* screens.
ADJUST	Allows for modifications of settings. Navigates user to either the *Enter Flow Settings* or to the *Enter Anticoagulation Settings* screen, depending on whether the prescription tab or the anticoagulation tab is selected. This softkey is not displayed in the anticoagulation tab when “No anticoagulation” has been selected.
DELAY TEST	This softkey is only available during the self-test. It stops and postpones the self-test. Note that the effective interruption of the self-test may take up to 1 minute.

History Data

Vital machine conditions and operating data are stored and updated minute-by-minute in software memory. The memory stores up to 96 hours of treatment data; thereafter, the oldest data are gradually replaced with new data.

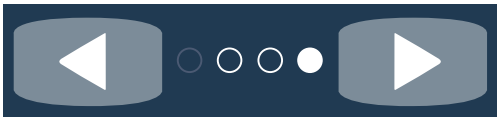
History data include:

- Patient Fluid Removal/Patient Plasma Loss including Unintended Patient Fluid Loss/Gain volume
- Doses and Solutions
- Pressures
- Events

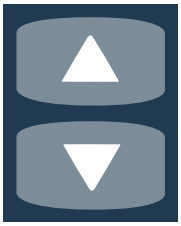
When entering *History* screen, each category of data can be accessed by pressing corresponding softkey. The *History* screen can be accessed from the *Status* screen during a treatment (Run mode) and from the *Treatment Complete* screen when ending a treatment (End mode). History data for the last performed treatment can be accessed from the *Choose Patient* screen (Setup mode).

Note: Displayed values are not updated continuously.

History data are automatically saved on the removable technical data card when ending a treatment. Data can also be saved in setup mode when entering *Choose Patient* screen. See section “Saving the History Data” on page 4:10.



With the left and right arrows the operator can scroll among four 24–hour intervals. Circles between the arrows are displayed unfilled if there are data available for that specific period and a filled circle indicates the selected 24–hour period. The circle to the right indicates the current day.



With the up and down arrows the operator can scroll within the selected 24–hour interval (not available for pressures).

Patient Fluid Removal / Patient Plasma Loss

To facilitate periodic and total patient fluid removal volumes during a treatment, all fluids controlled by the Prismaflex system are updated minute-by-minute. This process begins when treatment (Run mode) starts. These periodic and cumulative totals are reported in the *Patient Fluid Removal* (CRRT) or *Patient Plasma Loss* (TPE) screen. This screen is the pre-selected screen when accessing *History* screen.

Information is structured to make it easy for charting. Starting time for the chart (i.e. when a new shift begins) and chart time interval can be configured in the Custom mode. A chart reminder beep can be configured in the Run mode. See section “General Settings” on page 14:2 for details.

The Patient Fluid Removal / Patient Plasma Loss values are displayed in a scrollable table where values are viewed one 24-hour period at a time, starting from the configured begin time for the chart or the start time of the treatment, whichever occurs later. With arrows to the right, the operator can scroll among the displayed values for the current period.

The Patient Fluid Removal / Patient Plasma Loss table has three columns:

Time	This column shows chart time intervals. The date is displayed next to the time when a new calendar day has begun.
Periodic	This column presents the accumulated volume for the chart time interval.
Total	This column shows the accumulated value since the start of the selected 24–hour period.

The footer in the table displays current values including time, current periodic volume, and current accumulated volume for the treatment.

In CRRT, this screen displays values for unintended patient fluid loss or gain volume and the limit selected in Setup mode.

Doses and Solutions

The *Doses and Solutions* screen displays information about delivered doses and the amount of used solutions. Begin time for the 24–hour period can be configured in Custom mode.

Information has been divided in two subcategories and by pressing the softkey on the right side of the table, information will be displayed for each category.

DOSES	Displays average doses and their respective cumulated volumes for the selected time period.
SOLUTIONS	Displays cumulated solution volumes for the selected time period.

Cumulated volumes is a running value for the selected time period and doses are averages of the corresponding cumulated volumes per patient weight of the selected time period.

Note: Time span of the selected time period is not subtracted with any treatment downtime.

At the bottom of the table three different time periods can be selected:

DAILY VALUES	Displays values per 24–hour period with begin time defined in Custom mode. By pressing the arrows to the left, different 24–hour periods can be viewed.
TOTAL VALUES	Displays values for the whole treatment.
LATEST 24h	Displays values of a moving period of the last 24 hours.

The time span of the displayed doses and cumulated volumes is displayed in the header of the table. Depending on the selected time period, the time span is either start and stop time (“XX:YY–XX:YY”) for the period or the resulting time span (“Xh Ymin”).

Pressures

The pressure graph displays history information for the measured and computed pressures depending on the therapy in use. By using the softkeys provided, the operator can view all the pressures, a combination of pressures, or just one pressure at a time.

Information related to operating pressures is available when pressing *PRESSURES* softkey. The operator selects the desired 24–hour period by pressing the arrows in the lower left corner. By pressing the *ZOOM IN* softkey, the 24–hour window will be split and by pressing the left/right arrows, the operator can navigate between 6–hour windows through the whole treatment. Pressing *ZOOM OUT* softkey will zoom out to 24–hour window and by pressing the left/right arrows the operator can navigate among the different 24–hour periods.

Note: The zoom in window always starts at 00:00 even if treatment started later in the day.

Events

Certain events that may occur during setup and delivery of a treatment are stored and displayed on the three *Events* screens. The control unit stores the date, hour and minute that events occur, as well as the description of the event. Up to 2500 events can be stored.

Pressing *the EVENTS* softkey on the *History* screens displays the *Events* screen and the events are displayed in chronological order, starting with the most recent. Arrow keys to the right on the *Events* screen allow the operator to scroll up or down in the chronological list. When the operator presses the *ALL EVENTS* softkey, all events are displayed. If desired, the operator can then view only alarm-related events by pressing the *ALARM EVENTS* softkey or treatment-related settings by pressing the *SETTING EVENTS* softkey.

An event is recorded when any of the following occurs:

- Patient ID, weight and hematocrit are entered.
- Therapy and anticoagulation method are initially selected (Setup mode).
- A Prismaflex disposable set is loaded and automatically identified by the bar code reader or manually identified by the operator.
- A bar code reading failure has occurred.
- Flow rates and anticoagulation settings are initially set (Setup mode).
- TPE Prescription setting are initially set (Setup mode).
- A syringe is installed/removed from the syringe pump.
- An anticoagulation bolus dose has been infused from the Prismaflex syringe pump.
- Prime test is passed.
- Treatment is started (Run mode).
- A flow rate or anticoagulation setting has changed during treatment.
- The level of the deaeration chamber has been adjusted
- TPE prescription setting has changed during treatment.
- The allowed volume of a bag or container has changed.

- The System Tools function “Blood Leak Detector normalization” is used.
- An alarm occurs.
- An alarm screen is cleared from the display.
- Any of these softkeys were pressed: *LOAD*, *PRIME*, *PRIME+TEST*, *PRIME TEST*, *STATUS* (when pressed on the *Change Bags* screen), *CHANGE BAGS*, *RESUME*, *STOP*, *START RECIRC*, *STOP RECIRC*, *RESUME RECIRC*, *START RETURN*, *END TREATMENT*, *CHANGE SET*, or *UNLOAD*.
- TPE is continued after the physician prescription is delivered.
- A manual or automatic blood return procedure has been used. Information related to start, stop, and adjustment of settings are recorded.
- A blood warmer is selected.
- When the counter for number of used disposable sets is updated.

History Data After a Completed Treatment

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

The last history data will be deleted if one of following conditions occurs:

- *NEW PATIENT* softkey is pressed.
- Custom mode is entered.
- Service mode is entered.

History Data During a Power Loss

If the machine is powered down (switched off) or a total power loss occurs during treatment, history data are retained in the Prismaflex software memory.

Saving the History Data

In End mode (when unloading the set), the History data for the current treatment are downloaded automatically to a removable technical data card. The technical data card is placed in the holder on the rear of the Prismaflex control unit.

Note: In case automatic download has failed previously, the History data for the last treatment can be downloaded in Setup mode from the *Choose Patient* screen. Press the *DOWNLOAD DATA* softkey and follow online instructions. See section “History Data After a Completed Treatment” on page 4:10 for limitations.

Therapy Operation

Moving the Prismaflex® Control Unit

The wheel size of the Prismaflex control unit allows it to pass over an 8 mm step. To pass over a 2 cm step, do not push, but pull the control unit by the handles.

CAUTION

! When moving the Prismaflex control unit, grab the recessed handles at left and right hand side. Do not apply force to e.g. syringe pump or scales.

CAUTION

Control and Navigation

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

Screen Layout

Screens (text and softkeys) displayed by the Prismaflex control unit have the following landmarks:

- The top of the screen shows the screen title.
- For all operating modes except run mode upper right corner shows date, clock time, current operating mode and therapy selected by the operator.
- In run mode upper right corner shows filter time, treatment time, clock time, currently delivered therapy and therapy selected by the operator.
- The bottom right softkey of most operating and alarm screens has a *HELP* key. Pressing this key provides more details about the displayed screen and softkey functions.
- The bottom right softkey of *Help* screens is labeled *EXIT HELP*. Pressing this key allows the operator to return to the screen that was displayed when *HELP* was pressed.
- An *EXAMINE ALARMS* key appears above the *HELP* key whenever an alarm occurs, whenever the operator overrides an alarm, or whenever one or more lower-priority alarms are pending during an alarm.[1] For more information, see chapter 9: “Alarm System”.

[1] The *EXAMINE ALARMS* key does not appear on the *Enter Flow Settings* screen, the *Enter Anticoagulation Settings* screen, the *Status* screen, the *History* screen or any other screen accessed via these screens. (See chapter 9: “Alarm System” on page 9:1.)

- A drawing may appear on certain screens, such as the *Load Set* screen. The drawing provides an easy visual reference for the operator in performing the actions described on the screen. A drawing for a certain action is activated by pressing the radio button in front of the action.

- The *CONFIRM ALL* softkey appears on *Flow Rates* and *Alarm Limits* (Custom mode), *Enter Flow Settings* and *Enter Anticoagulation Settings* screens. *CONFIRM ALL* places all operator choices into software memory and exits the currently displayed screen.

- Arrows appear on certain screens. These enable the operator to adjust settings. For example, arrows are used to set the flow rates or view a certain time period within the history data. By pressing and holding the arrows, the operator can scroll through the available options. By pressing and releasing the arrows, the operator can make fine adjustments. The arrows also allow the operator to increase/decrease fluid level in the deaeration chamber of the set.

- A mute button appears on certain screens. By pressing the button the operator can pause the audio for the alarm system.

Startup

Startup of the Prismaflex control unit consists of the following steps:

1. Connect the power cord to the wall socket.

2. Operator turns the power switch to the “On” position. The control unit performs an initialization test to check the system electronics, startup signal sounds twice and status lights (green, red and yellow) are lit during the test. The progress of the startup phase is displayed on the screen.

WARNING

⚠ After turning ON the control unit, verify the audible alarm (two start up signals) and that the green, yellow and red status lights are lit alternately during the start up sequence. In case of malfunction, switch OFF the control unit and call for service.

WARNING

3. When the initialization test is successfully completed, the Prismaflex control unit is in the Setup mode and is ready for operation. If desired, the operator can look at therapy information screens for an overview of the Prismaflex system therapies and the Prismaflex disposable sets, or can proceed to the *Choose Patient* screen.

Restart and Query screen

Troubleshooting may require the operator to switch off the machine via the main power switch, located at the bottom of the right side of the machine see figure 2:6 on page 2:14.

As the machine is turned on again, the *Query* screen will be displayed.

From the *Query* screen, the operator can choose one of two actions:

- Begin on the same operating screen as when the unit was turned off by pressing the *CONTINUE* key.

- Stop treatment and start over in Setup mode by pressing the *NEW PRIME* key. Starting over in Setup mode requires priming a new set. The operator is prompted to confirm this choice by pressing the *NEW PRIME* softkey and follow online instructions given in *Disconnect* screen to terminate treatment

  If the patient is connected when the *Query* screen is displayed consider the following:

  - if Manual Termination procedure has not been performed while the machine was shut down, press *CONTINUE* and follow the online instructions to resume operation at the point where the system was shut off. Define appropriate operator response to the specific alarm or condition that lead to switching off the machine. Operator response may require to disconnect, return blood (when applicable) and/or end treatment. See “Manual Termination of Treatment“ on page 10:57.

CAUTION

! In case the machine has been switched off while the patient was connected, it is important to assess blood clotting in the circuit before resuming the treatment.

CAUTION

  - if Manual Termination procedure has been performed while the machine was shut down and no set loaded on the machine, press *NEW PRIME* to initiate a new treatment.

Operating Modes

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

Additional and specific instructions and descriptions are available in the separate therapy and anticoagulation methods chapters.

Setup Mode

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

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

1. In the Prismaflex *System* screen, choose *THERAPY INFO* or *CONTINUE*.

   - If *THERAPY INFO* is chosen, the control unit advances to the *Therapy Info* screen and an overview of the available Prismaflex therapies and Prismaflex disposable sets are presented.

   - If *CONTINUE* is chosen, the control unit advances to *Choose patient* screen where for example Custom mode and view/download history data of the last treatment are available. In Custom mode it is possible to alter default settings of one or more Prismaflex system therapies. If time, date, chart time or other settings have been changed in Custom, *LAST HISTORY* and *SAME PATIENT* are disabled. For more information, see “Custom Mode” on page 4:25.

2. Choose *NEW PATIENT* or *SAME PATIENT*.

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

   - If *SAME PATIENT* is chosen, the control unit retains the history data of the last treatment, retains the last therapy and anticoagulation choices and advances to the *Load Set* screen (move to Step 7 below).

   - If *SAME PATIENT* is chosen, PBP, dialysate and/or replacement solution bags in use can remain in use until empty.

3. Enter an identification for the patient (optional).

4. Enter the patient's current weight, then enter the patient's current hematocrit.

5. Press *CONFIRM* softkey to continue, or press the appropriate softkey to correct patient information.

6. Choose therapy.

7. Choose anticoagulation method and confirm selection.

8. Positioning of the desired set onto the control unit may vary depending on the therapy and set chosen. See information on control unit's display. Make sure the lines move freely in their guides and are not pinched.

WARNING

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

WARNING

9. Automatically load the set by pressing the *LOAD* softkey. When *LOAD* is pressed, the following occurs: (a) the peristaltic pumps begin turning; (b) the Prismaflex disposable set is pushed outwards and then drawn inward; (c) the pump segments are threaded into the pump raceways; (d) the pinch valve segments are threaded into the pinch valves; (e) the bar code reader scans the bar code label on the Prismaflex disposable set.

Note: When the *LOAD* softkey is pressed, the control unit automatically performs a test. If the test fails, the Warning: Set-up Error alarm or the Warning: Wrong Set Loaded alarm is generated.

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

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

11. Prepare and connect solutions using the step-by-step instructions. Pressing the radio button in front of the instruction will display a drawing corresponding to the instruction.

12. Install blood warmer and confirm the installation, if applicable. See chapter 8: "Blood Warmers" on page 8:1.

13. Install a syringe and confirm the syringe installation, if applicable.

14. Verify the setup. Make sure that all used lines are unclamped. Verify that all connections are correct and secure.

15. Automatically prime the set by pressing the *PRIME* or *PRIME + TEST* softkey. Priming period and sequence depends on therapy/set selected.

Note: After priming is complete, do not remove the pressure pods from their pressure sensor housings and do not disconnect the deaeration chamber monitor line from the return pressure port. If one or more pods are removed, the set must be changed. If the monitor line is disconnected, the set must be reprimed and the fluid level in the deaeration chamber adjusted.

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

Note: When *PRIME + TEST* is pressed the Prime test in next step will continue automatically after the finished Priming sequence.

16. Perform the prime test by pressing the *PRIME TEST* softkey. The control unit performs multiple self-tests lasting between 5 and 10 minutes depending on the therapy selected. Refer to the Prismaflex Service Manual for a list of the prime self-tests.

Note: After pressing the *CONTINUE* softkey on the *Prime test passed* screen there is no possibility of returning to previous screens.

17. Adjust the deaeration chamber fluid level if needed.

18. Enter Pre-treatment settings:

    18.a. Set Patient Fluid Loss/Gain LIMIT in Enter Treatment Settings (only CRRT)

    18.b. Enter TPE prescription settings (only TPE)

19. Adjust flow rates and anticoagulation settings if an anticoagulation method is used.

20. Review the prescription settings and confirm by pressing *CONTINUE*. The system will now proceed to Standby mode.

The operating screens that appear in Setup mode are listed by title in Table “Operating Screens in Setup Mode” on page 4:16. Screens are listed in the order in which they appear during the Setup procedeure.

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

Operating Screens in Setup Mode

Prismaflex System (Start screen)
Choose Patient
Enter Patient ID (optional)
Enter Patient Weight
Enter Patient Hematocrit
Confirm Patient Information
Choose Therapy
Choose Anticoagulation Method
Confirm Anticoagulation Method
Therapy and Anticogulation Choice
Load Set
Loading Pumps, please wait
Confirm Set Loaded
Prepare and Connect Solutions
Connect Blood Warmer (Prismatherm II)
Install Syringe (depending on anticoagulation method in use)
Confirm Syringe Installation (depending on anticoagulation method in use)
Verify Setup
Priming, please wait
Priming X of Y Cycles Complete
Prime Test, please wait
Prime Test Passed
Enter Treatment Settings (CRRT)
Enter TPE Prescription (TPE)
Enter Flow Settings
Enter Anticoagulation Settings (depending on anticoagulation method in use)
Review Prescription

Standby Mode

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

If necessary, the *Enter Flow Settings* and *Enter Anticoagulation Settings* screens can be re-accessed for further adjustments before starting the treatment.

WARNING

Connect patient

⚠ Before connecting the blood return line to the patient, make sure the blood line segment from the air bubble detector to the patient is free of air.

⚠ Clamp unused lines after priming is complete and before starting a patient treatment according to therapy configuration.

WARNING

CAUTION

! If a patient is not connected to the Prismaflex disposable set shortly after priming is complete, flush the set with at least 500 ml priming solution (saline with heparin added) before connecting a patient. This may require the use of a new bag of priming solution and a new (empty) collection bag. Consult the Instructions for Use packaged with the set for details about priming volumes.

CAUTION

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

During Standby mode all pumps are stopped, appropriate alarms are enabled, and the yellow status light is lit. The screens that appear in Standby mode are listed in table “Operating Screens in Standby Mode” on page 4:17.

Operating Screens in Standby Mode

Connect Patient (Standby mode entered from Setup mode)
Verify Patient Connection
Reconnect Patient (after Recirculation procedure) (Standby mode entered from End mode)
Change Bags
Stop (Standby mode entered from Run mode)

Run Mode

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

During Run mode, all appropriate alarms are enabled and the green status light is lit, unless an alarm occurs or the *CHANGE BAG* softkey is selected.

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

1. Administer the treatment to the patient. The fluid pumps operate according to settings validated by the operator. Bag weights are monitored and history data is accumulated and stored.

2. Adjust flow rates and anticoagulation settings as needed. This includes changing the syringe if needed.

3. Change fluid bags at any time through the Change Bags/Containers function. Modify the Allowed Volume for any bag if Variable Empty Bag method is active and if necessary.

4. Adjust the Deaeration Chamber.

5. View history data.

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

7. From the *System Tools* screen, do any of the following:

- Adjust the following settings: Status Graph Period, Chart Reminder, audible alarm volume, value for Patient Weight and the value for Patient Hematocrit.

- View list of pending alarms.

- Clean the touch screen (an empty screen is displayed to avoid an unwanted selection of softkeys).

- Perform an immediate self test sequence.

- Retest (re-normalize) the sensitivity of the blood leak detector.

Here are the operating screens in Run Mode listed. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Operating Screens in Run Mode

Status

- *Enter Flow Settings*
  - *View Prescription Changes*
  - *Enter TPE Prescription* (TPE)
- *Enter Anticoagulation Settings* (not available for "No anticoagulation" anticoagulation method)
  - *Change Syringe* (depending on anticoagulation method in use)
  - *Confirm Change Syringe* (depending on anticoagulation method in use)
  - *View Prescription Changes*
- *History*
  - *Patient Fluid Removal / Patient Plasma Loss*
  - *Doses and Solutions*
  - *Pressures*
  - *Events*
- *Change Bags/Containers*
- *Adjust Deaeration Chamber*
- *System Tools*
  - *Modify Settings*
  - *Clean Screen*
  - *Initiate Self Test*
  - *Normalize Blood Leak Detector*

End Mode

The control unit enters End mode when the operator presses *STOP*, then presses the *CHANGE SET*, *END TREATMNT*, or *RECIRC* softkey. Appropriate alarms are enabled and the yellow status light is lit.

End mode allows the operator to perform the following procedures:

- Change Set – Remove the present set, with or without returning blood to the patient and load a new set.
- End Treatment – Terminate the present treatment, with or without returning blood to the patient; view/download history data if desired.
- Recirculate – Temporarily disconnect patient and recirculate saline or blood through the blood lines. Reconnect patient and resume treatment when ready.

WARNING

⚠ Always inspect the blood flowpath for signs of clotting before returning the blood in the set to the patient. If clotting is suspected, *do not* return the blood to the patient.

WARNING

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

Change Set and End Treatment Procedures

After pressing *CHANGE SET* or *END TREATMNT*, the operator follows the instructions displayed to perform the following actions:

1. Return blood to the patient if desired. This is done by pressing the *RETURN BLOOD* softkey, if necessary changing the blood return settings and following the instructions on the *Return Blood* screen.

CAUTION

Blood return from a blood primed extracorporeal circuit can result in Hypervolemia. Consult physician´s prescription.

CAUTION

Note: Automatic blood return is disabled when:

- Cumulated Volume Returned exceeds Auto Return Volume
- Warning: Filter Clotted alarm has been triggered
- Warning: Plasmafilter Clotted alarm has been triggered

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

2. Disconnect the patient from the set, clamp all lines and unload the set by pressing the *UNLOAD* softkey. The machine automatically advances to the *Treatment Complete* screen.

Note: History data is automatically downloaded to the Technical Data Card when set is unloaded.

3. Remove the set, syringe (if empty or unwanted), and fluid bags (if empty or unwanted).

Note: To remove syringe, open plunger clamp latch. Press and hold “Down button” on Syringe control panel until arm reaches lowest position.

WARNING

⚠ Destroy the Prismaflex disposable set after a single use, using appropriate procedures for potentially contaminated material. Do not resterilize.

WARNING

If *CHANGE SET* has been selected:

4. Return to the *Load Set* screen in Setup mode.
5. Place a new set on the control unit and load it by pressing the *LOAD* softkey. Treatment continues once the control unit reaches Run mode.

If *END TREATMNT* has been selected:

4. View history data, if desired.

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

The *Change Set* and *End Treatment* screens available in End mode are listed in Table “Change Set and End Treatment Screens in End Mode” on page 4:21. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Change Set and End Treatment Screens in End Mode

End Treatment
Prepare to Return Blood (optional)
Return Blood (optional)
Enter Blood Return Settings (optional)
Disconnect Patient
Confirm Unload
Unloading pumps, please wait
Remove set (for Change Set procedure)
Treatment Complete (for End Treatment procedure)
History (for End Treatment procedure)

Recirculation in End Mode

Recirculation may be necessary if the patient needs to be temporarily disconnected from the set. Two recirculation procedures are available from *Choose Recirculation Mode* screen:

- Saline recirculation which recirculates saline solution in the blood lines after blood return. This procedure will require a priming before patient reconnection

- Blood recirculation which recirculates the blood in the blood lines after the patient has been disconnected

Saline recirculation can be performed for maximum 120 minutes. Blood recirculation can be performed for maximum 60 minutes. See Warning: Recirculation Time Exceeded alarm in chapter 10: “Troubleshooting”.

Saline Recirculation Procedure

To perform a Saline recirculation procedure following is needed:

- Saline bag to return blood to patient and to perform the recirculation

- Priming solution to prime the set after the recirculation and before reconnecting to patient

- A Y−line connector to joint the access and return lines during the recirculation

Press *SALINE RECIRC* softkey on the *Choose Recirculation mode* screen and follow the operating steps according to instructions on the screen:

1. Hang a bag of sterile saline on priming hook and connect a Y-line to the saline bag. Prime the Y-line with priming solution.

2. Disconnect the access line from the patient and connect it to the bag of sterile saline using the Y-line, then enter the desired blood return settings.

3. Return blood to the patient by pressing the *AUTO RETURN* softkey or by pressing and holding the *MANUAL RETURN* softkey to pump saline through the access line.

Note: Automatic blood return is disabled when:

- Cumulated Volume Returned exceeds Auto Return Volume
- Warning: Filter Clotted alarm has been triggered
- Warning: Plasmafilter Clotted alarm has been triggered

Note: If the set has significant clotting, the operator can choose to automatically unload it and cycle into the Change Set procedure. This can be done by pressing *DISCONNECT* without returning the patient's blood.

4. Enter the desired Recirculation Rate.

Note: The Recirculation Rate can be changed at any time while Recirculation is in progress.

5. Set the syringe pump to deliver an Immediate Bolus to the access line if "Systemic, Prismaflex syringe pump" anticoagulation method is active and as needed.

Note: The only syringe pump delivery available in the Recirculation procedure is Immediate Bolus. Whenever the operator sets the Immediate Bolus Volume to a value greater than zero, a bolus is administered on exiting the *Enter Recirc Flow Rates* screen. If needed, a new (full) syringe can be installed during Recirculation.

6. Disconnect the patient from the return line, connect the return line to the saline bag using the second Y-line extension and begin Recirculation.

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

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

   Note: The set must be replaced if the maximum saline recirculation time is exceeded or in case of poor blood return.

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

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

Note: If needed, prescription parameters can be reached and modified by pressing *REVIEW PRESCR* in *Reconnect Patient* screen.

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

The recirculation screens available before patient connection are listed in “Saline Recirculation Screens from Stop to Patient Connection” on page 4:23. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Saline Recirculation Screens from Stop to Patient Connection

Stop
Choose Recirculation mode
Prepare to Return Blood
Return Blood
Enter Blood Return Settings
Initiate Saline Recirculation
Recirculation in Progress
Adjust Chamber
Enter Recirculation Flow Rate
Change Syringe (applicable to “Systemic, Prismaflex syringe pump” anticoagulation method)
Confirm Change Syringe
Saline Recirculation Stopped
Prepare to Prime
Priming
Priming Complete
Prime Test
Prime Test Passed

Blood Recirculation Procedure

To perform a Blood Recirculation procedure the following is needed:

- A Y−line connector to joint the access and return lines during the recirculation
- A small volume saline bag to perform the recirculation

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

1. Hang a bag of sterile saline, 100 ml or less, on priming hook and connect a Y-line to the saline bag. Prime the Y-line with priming solution.
2. Disconnect the access line from the patient and connect it to the bag of sterile saline using the Y-line.
3. Disconnect the patient from the return line, connect the return line to the saline bag using the second Y-line extension.
4. Unclamp any clamp line: saline bag, Y line and set lines
5. Press *START RECIRC* to begin Recirculation. The blood recirculates within a closed loop.

   Note: If the set has significant clotting, the operator can choose to automatically unload it and cycle into the Change Set procedure. This can be done by pressing *DISCONNECT* without returning the patient's blood. The control unit automatically advances to the *Disconnect Patient* screen where instructions are provided.

   Note: The *Recirculation in Progress* screen offers the same information as in Saline Recirculation. The same functions are also available to change Recirculation Rate, deliver an Immediate syringe bolus or stop the Recirculation.

   Note: The set must be replaced if the maximum recirculation time is exceeded.

6. When ready, stop recirculation.
7. Follow the steps to reconnect the patient. Resume treatment by pressing the *START* softkey on the *Verify Patient Connection* screen.

The recirculation screens available in End mode are listed in Table “Blood Recirculation Screens in End Mode” on page 4:25. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Blood Recirculation Screens in End Mode

Recirculate
Prepare Blood Recirculation
Initiate Blood Recirculation
Recirculation in Progress
Adjust Chamber
Enter Recirculation Flow Rate
Change Syringe (Systemic Anticoagulation method only)
Confirm Change Syringe
Blood Recirculation Stopped

Custom Mode

Custom mode allows operator to change the default values of user-controllable settings[2]. The tables in chapter 14: "User-controllable Settings" provides a list of the user-controllable settings and the mode(s) in which they can be altered.

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

1. Enter Custom mode by pressing *CUSTOM MODE* on the *Choose Patient* screen.

2. When the *Modify Defaults* screen in Custom mode appears, select the default setting(s) to customize. Specify the new default value(s) on the appropriate Custom mode sub-screen.

   To modify default flow rates and alarm limits, the operator first chooses the desired therapy/set combination in Filter settings, then chooses Flow Rates or Alarm Limits and sets the desired default value(s).

   CRRT: To modify the Empty Bag Method and the Allowed Volume for dialysate, PBP and replacement bags, the operator first selects the type of therapy (CRRT) in Bag volume, then selects the Empty Bag Method. If Variable Empty Bag method is selected, the operator selects the bag (Dialysate, PBP or Replacement) and sets the desired default value for Allowed volume.

   TPE: To modify Allowed Volume, the operator first selects the type of therapy, then selects the bag and sets the desired default value.

   The new default values are saved in memory each time the operator presses the *MODIFY DEFAULTS* softkey and whenever the *EXIT CUSTOM* softkey is pressed from any screen.

The screens available in Custom mode are listed in Table "Screens in Custom Mode" on page 4:26.

[2] Only the default values of enabled Prismaflex therapies and filters can be customized. Prismaflex therapies can be enabled/ disabled only in Service mode, by authorized service technicians. The enabled Prismaflex therapies are identified on the *Welcome to Custom Mode* screen.

Screens in Custom Mode

Welcome to Custom Mode
Modify Defaults
Filter Settings – Menu
Filter Settings – therapy selected
Alarms & Flows – therapy/set selected
Flow Rates – therapy/set selected
Alarm Limits – therapy/set selected
Syringe Brand
Bag Volume – Menu
Bag Volume – therapy selected
Other Settings
Time & Date

User-controllable Settings

User-controllable settings and the mode in which they can be altered are listed in the tables in chapter 14 “User-controllable Settings” on page 14:1. Each setting has a default value and a range of setting options.

Most of the user-controllable settings can be adjusted in more than one mode. Settings that affect the safety system, such as alarm limits, can only be adjusted in Custom mode.

Change Bags Function

Any of the bags in use can be changed at any time during a patient treatment (Run mode) or when in Connect Patient in Standby Mode. This is done by using the Change Bags function available on the Status screen and on the Connect Patient screen.

Prismaflex® Control Unit Actions

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

- Blood pump continues to operate; all other pumps stop[3] .
- Yellow status light lights up as a reminder that therapy is not being delivered.
- After two minutes the audible alarm sounds as a reminder that therapy is not being delivered.
- *Change Bags/Containers* screen appears and provides online instructions.

[3] Anticoagulant syringe does not stop and continues to operate when “Systemic, Prismaflex syringe pump” anticoagulation method is selected.

Modifying the Allowed Bag Volume During Treatment in Variable Empty Bag mode

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

When the *MODIFY BAG* softkey is pressed, a list of bags in use appears, along with softkeys for selecting the bags. The operator presses the softkey for the bag volume to be modified, then uses the Arrow keys to choose a new Allowed Volume. An alarm occurs when resuming the treatment if there is a discrepancy between the Allowed Volume of a bag and the actual volume sensed by the scale on which the bag is hanging. *MODIFY BAG* softkey is available only when Variable Empty Bag method has been selected from CUSTOM mode. Effluent bag always provides for *MODIFY EFFLUENT* softkey.

Changing a Bag During Treatment

Change fluid bags when the appropriate Caution alarm occurs (PBP Bag Empty, Replacement Bag Empty, Dialysate Bag Empty or Effluent Bag Full). Changing a bag before the alarm occurs may only be done by using the Change Bags function and following the instructions on the *Change Bags/Containers* screen.

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

1. Press *CHANGE BAGS* on the *Status* screen to access the *Change Bags/Containers* screen.
2. Open the scale of the bag to be changed. The *Changing Bag* screen is displayed.
3. Move the scale carrying bar to the side hook.
4. Clamp the bag and the line of the set connected to it. Disconnect the bag from the line.
5. Hang a new bag on the scale carrying bar and connect it to the line.
6. Unclamp the new bag and line.
7. Hang the scale carrying bar with bag on the scale; close the scale.
8. If changing to a larger/smaller bag when using the Variable Empty Bag method, press *MODIFY BAG* or *MODIFY EFFLUENT* and use the arrows to select the total volume capacity of the new bag[4] .
9. Verify that lines to bags in use are unclamped and unused lines are clamped.
10. Press *CONTINUE* to return to the *Status* screen and resume the patient treatment.

[4] With Fixed Empty Bag method, no action is required when changing to a larger/smaller bag. For the effluent bag, it is possible to change only the total volume capacity by pressing *MODIFY EFFLUENT* in the *Change Bags* screen.

Initiation of PBP Flow

In case no PBP bag was present during priming, it remains possible to initiate PBP solution flow when the treatment is running.

The operator must perform the following sequential actions:

- Press *CHANGE BAG* and hang a PBP bag on the scale
- Set the desired PBP flow rate in the *Enter Flow Settings* screen
- Monitor fluid level in the deaeration chamber for the next five minutes as some air might flow through the blood flowpath.

Change Syringe Procedures

It is necessary to install and use a syringe if “Systemic, Prismaflex syringe pump” anticoagulation method is selected during setup.

Installing a syringe in the Prismaflex syringe holder requires that the appropriate syringe size and brand are used. Syringe size is predefined in Service mode by an authorized service technician and syringe brand is selected by the operator in Custom mode. Selected syringe size shall correspond to the numerical label on the mounted syringe holder. For the B.Braun Perfusor® syringe a separate holder (50B) can be ordered. Contact your local representative for additional information.

Syringe Installation

A luer lock syringe of the allowed brand and size should be filled and installed in the syringe pump during Setup mode. This is done while the *Install Syringe* screen is displayed. Detailed instructions with drawings are available on the Prismaflex control unit screens. Main installation steps are:

1. Open the syringe plunger clamp latch and press the *AUTO DOWN* softkey so that the syringe arm reaches its lowest position
2. Connect the filled syringe to the syringe line, applicable to “Systemic, Prismaflex syringe pump” anticoagulation method
3. Set the syringe in its holder
   when installing the B.Braun Perfusor® syringe − push the plunger clamp latch correctly on to the syringe plunger, as illustrated in figure 4:2

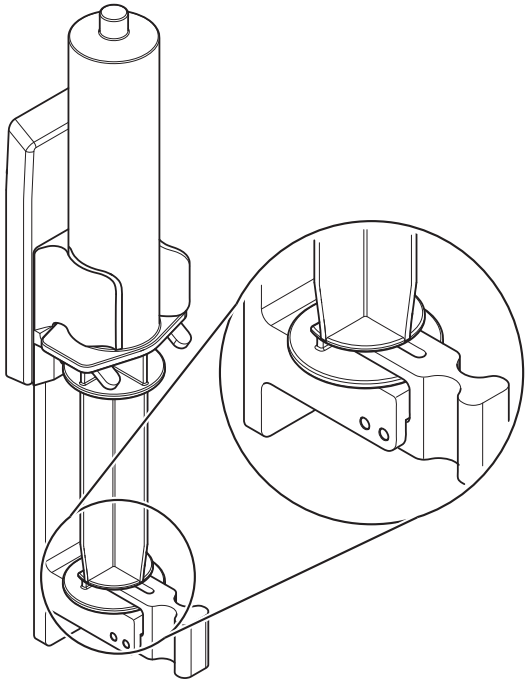


Figure 4:2 B.Braun Perfusor® syringe installation

4. Press the *AUTO UP* softkey until the *CONFIRM* softkey gets visible

5. Lock the syringe plunger

The line connected to the syringe is primed during the automatic priming cycle.

Note: As an alternative to the *AUTO DOWN* and *AUTO UP* softkeys, syringe control panel buttons can be used to move the syringe arm. In this case, keep the button pressed until the syringe arm is moved to its lowest position or until the *CONFIRM* key appears. These buttons are disabled outside the syringe installation or change procedures.

Syringe Change

The syringe must be changed after the Advisory: Syringe Empty alarm, and can also be changed at any time during treatment from the *Enter Anticoagulation Settings* screen. Change syringe steps are similar to the ones for installation, after the syringe infusion line has been clamped and the empty syringe unlocked.

Deaeration Chamber

Fluid level management

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.

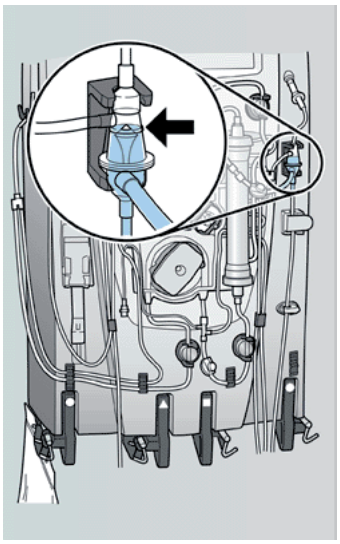


Figure 4:15 Suggested fluid level in the deaeration chamber.

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* softkey and use the Up or Down arrows 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 passed out through the return line pressure port. Maintain the fluid level of the deaeration chamber periodically:

- A too high level increases the risk of wetting 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. In case the fluid barrier has been wet, it is recommended to interrupt the therapy and change the set.
- 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 accumulating 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 to about 1 centimeter below the usual level; refer to the drawing displayed on the screen.

Foam management

In some circumstances, a significant amount of foam may develop at the top of the deaeration chamber. In this situation some foam may reach the fluid barrier in case of sudden return access obstruction and pressure increase. Experience shows that increase of the post-replacement infusion rate reduces the amount of foam.

Chapter 5

Continuous Renal Replacement Therapies (CRRT)

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General Warnings and Cautions

Warnings

WARNING

⚠ Monitor patient blood chemistry to ensure electrolyte balance and normoglycemia.

⚠ The Prismaflex disposable set must be changed after 72 hours of use. Continued use beyond this limit could result in rupture of the pump segments.

Note: To ensure adequate filter performance, it is recommended that CRRT disposable sets are changed every 24 hours of use.

⚠ Renal replacement therapy with high-permeability hemofilters may reduce the concentration of therapeutic drugs in the patient. The prescribing physician should consult the literature of the drug manufacturer for further information and consider the need to monitor the concentration of the drug in order to ensure an appropriate therapeutic dosage.

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

⚠ Use only dialysate solution and replacement solution/fluid that conform to applicable national registration, standards, or laws. For CVVH and CVVHDF it should also be labeled as intended for intravenous injection. The use of non sterile dialysate could induce risks of bacterial and pyrogenic contamination for the patient.

⚠ As treatment proceeds, carefully monitor patient fluid balance levels in the *History* screens.

⚠ Monitor patient temperature to avoid hypo- or hyperthermia. Pay special attention when using high fluid exchange rates, when using a high capacity blood warmer, or when treating low body weight patients.

⚠ The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started. See Troubleshooting chapter on page 10:62.

WARNING

Cautions

CAUTION

- Observe the effluent bag for pink or red tinge as an indicator of undetected micro blood leaks or hemolysis. Discoloration of effluent due to the patient's disease process (rhabdomyolysis for example) should also be considered as a root cause.
- Prismaflex disposable sets require minimum blood flow rates to avoid early clotting of the extracorporeal blood circuit. Refer to chapter 13: " Prismaflex® Disposable Sets" for the specified flow rate ranges.
- Use saline or alkaline solution (pH ≥ 7.3) with heparin added to prime the set.

CAUTION

About the Chapter

This chapter completes and deepens the information given in chapter 2, 3 and 4 when operating in CRRT. This chapter provides information about specific functions in CRRT and general operating instructions in CRRT as a complement to chapter 4.

At the end of this chapter there are detailed information given for following CRRT modalities:

- CRRT with X-MARS disposable set

Therapy Description

Mechanisms of CRRT

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

Ultrafiltration — In ultrafiltration, plasma water with solutes is drawn 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 drawn 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 required solutes. Unwanted solutes are not replaced, so their concentration decreases in the patient's blood. Solute removal is achieved by convection (solvent drag across the membrane).

Hemodialysis — In hemodialysis, unwanted solutes and toxins pass from the patient's blood across the semipermeable membrane and into dialysate flowing at counter flow through the fluid compartment of the filter. Solute clearance is achieved by diffusion.

For certain indications, substances such as drugs or poisons may be preferentially removed from the blood into the dialysate, while other substances such as calcium and alkali may be transferred into the blood from the dialysate.

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.

Available CRRT Modes

The following section outlines the various therapy configurations that are available in the Prismaflex system. Operating flow ranges for blood flow and the various solutions flows further depend on the selected therapy and disposable set, see tables below.

Available flow rate parameters depending on selected CRRT Mode

CRRT mode	SCUF	CVVH	CVVHD	CVVHDF
Blood flow	X	X	X	X
PBP flow	X	X	X	X
Dialysate flow	—	—	X	X
Replacement flow	—	X	—	X
PRE-POST infusion	—	PRE%	—	PRE/POST
Patient Fluid Removal rate	X	X	X	X

Available flow rate parameters depending on selected CRRT MARS Mode

CRRT mode	CVVHD	CVVHDF
Blood flow	X	X
PBP flow	X	X
Dialysate flow	X	X
Replacement flow	—	X
PRE-POST infusion	—	PRE/POST
Patient Fluid Removal rate	X	X

SCUF (Slow Continuous Ultrafiltration)

The CRRT mode SCUF provides patient fluid removal and allows for PBP infusion.

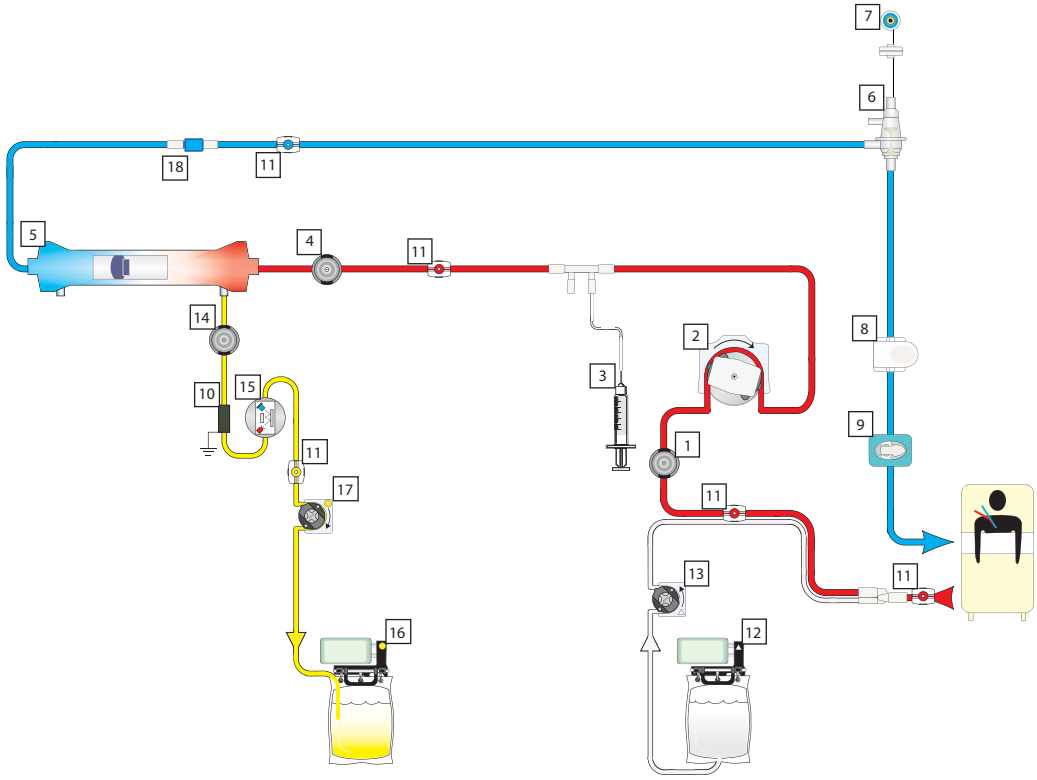

Figure 5:1 SCUF flow

1. Access pressure sensor
2. Blood pump
3. Syringe pump
4. Filter pressure sensor
5. Filter
6. Deaeration chamber
7. Return pressure sensor
8. Air bubble detector and line sensor
9. Return clamp and line sensor
10. Discharger ring guide
11. Sample site
12. Scale, PBP bag
13. PBP pump
14. Effluent pressure sensor
15. Blood leak detector
16. Scale, effluent bag
17. Effluent pump
18. Blood warmer connection

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

The CRRT mode CVVH provides hemofiltration with both pre and post-filter replacement infusion and allows for PBP infusion

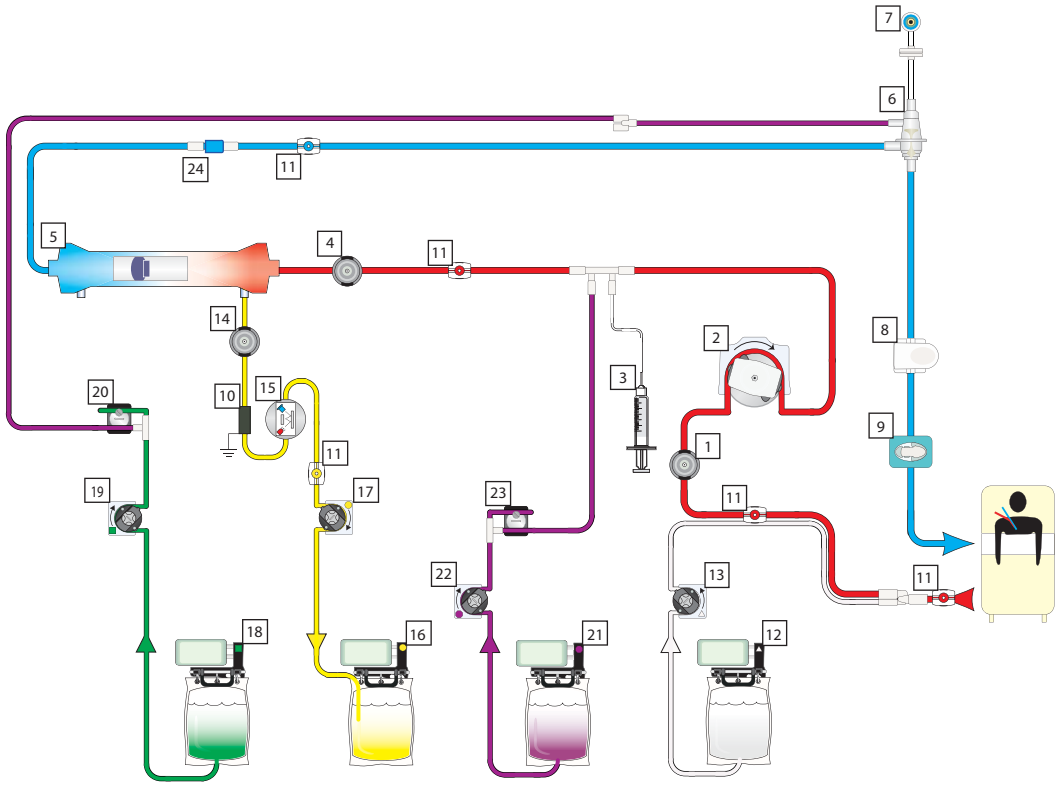

Figure 5:2 CVVH pre+post filter flow

1. Access pressure sensor
2. Blood pump
3. Syringe pump
4. Filter pressure sensor
5. Filter
6. Deaeration chamber
7. Return pressure sensor
8. Air bubble detector and line sensor
9. Return clamp and line sensor
10. Discharger ring guide
11. Sample site
12. Scale, PBP bag
13. PBP pump
14. Effluent pressure sensor
15. Blood leak detector
16. Scale, effluent bag
17. Effluent pump
18. Scale, replacement 2 bag
19. Replacement 2 pump
20. Upper pinch valve
21. Scale, replacement bag
22. Replacement pump
23. Lower pinch valve
24. Blood warmer connection

CVVHD (Continuous Veno-venous Hemodialysis)

The CRRT mode CVVHD provides hemodialysis and allows for PBP infusion.

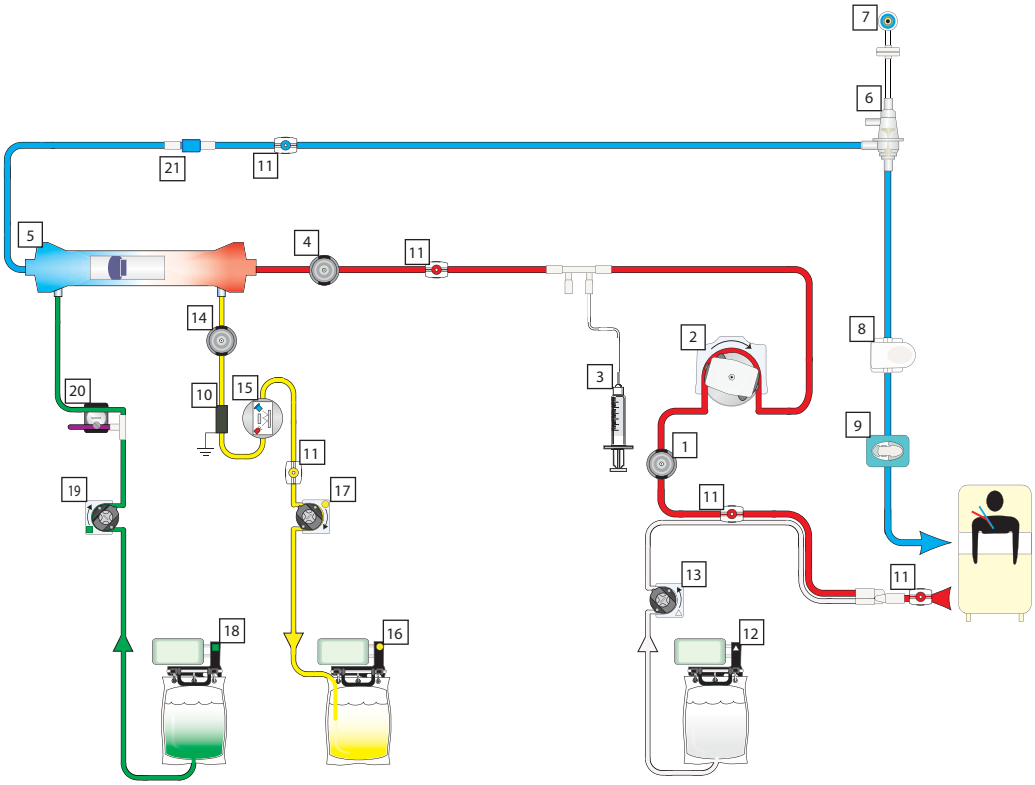

Figure 5:3 CVVHD flow

1. Access pressure sensor
2. Blood pump
3. Syringe pump
4. Filter pressure sensor
5. Filter
6. Deaeration chamber
7. Return pressure sensor
8. Air bubble detector and line sensor
9. Return clamp and line sensor
10. Discharger ring guide
11. Sample site
12. Scale, PBP bag
13. PBP pump
14. Effluent pressure sensor
15. Blood leak detector
16. Scale, effluent bag
17. Effluent pump
18. Scale, dialysate bag
19. Dialysate pump
20. Upper pinch valve
21. Blood warmer connection

CVVHDF (Continuous Veno-venous Hemodiafiltration)

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

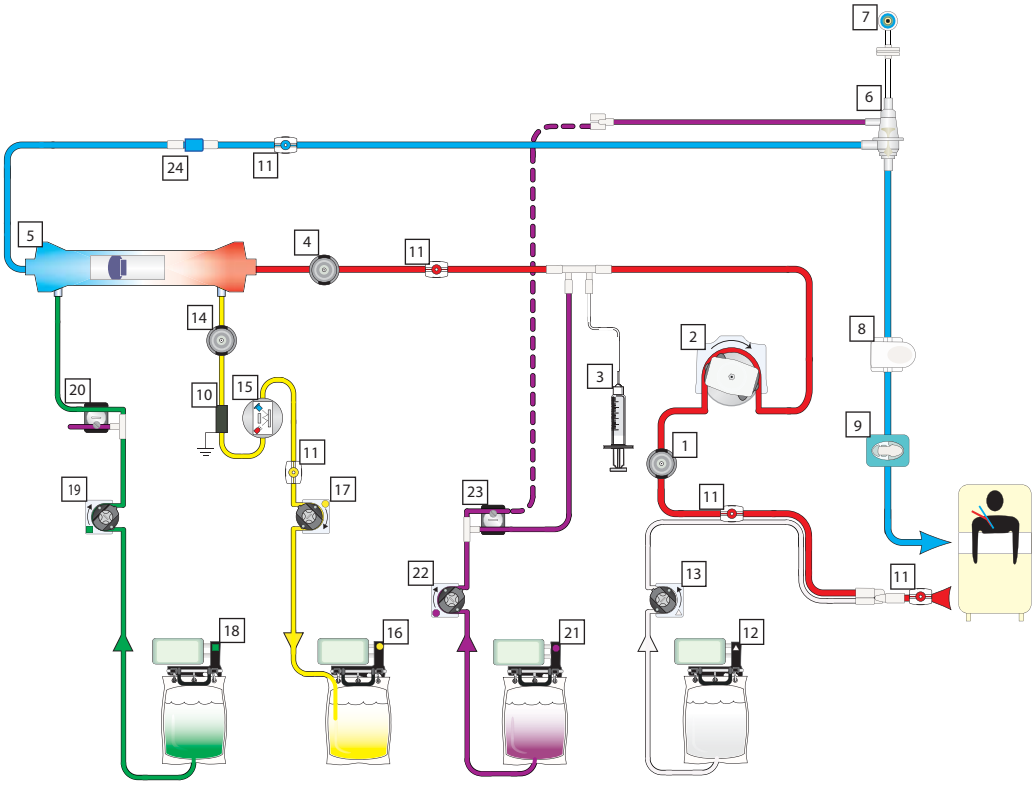

Figure 5:4 CVVHDF flow

1. Access pressure sensor
2. Blood pump
3. Syringe pump
4. Filter pressure sensor
5. Filter
6. Deaeration chamber
7. Return pressure sensor
8. Air bubble detector and line sensor
9. Return clamp and line sensor
10. Discharger ring guide
11. Sample site
12. Scale, PBP bag
13. PBP pump
14. Effluent pressure sensor
15. Blood leak detector
16. Scale, effluent bag
17. Effluent pump
18. Scale, dialysate bag
19. Dialysate pump
20. Upper pinch valve
21. Scale, replacement bag
22. Replacement pump
23. Lower pinch valve
24. Blood warmer connection

Available Anticoagulation Methods in CRRT

Anticoagulation methods available in each CRRT therapy are identified in “Therapies and Anticoagulation Methods” on page 7:3.

CRRT Disposable Set

The full range of Prismaflex disposable sets available for CRRT is described below. Further information about characteristics and operating ranges can be found in the Instructions for Use that comes enclosed with the disposable set and in “CRRT Disposable Sets” on page 13:2.

Low Flow sets:	M60
High Flow Sets:	M100
	M150
	HF1000 HF1400
	X-MARS[1]

[1] Refer to section “CRRT with X-MARS™ Disposable Set” on page 5:18.

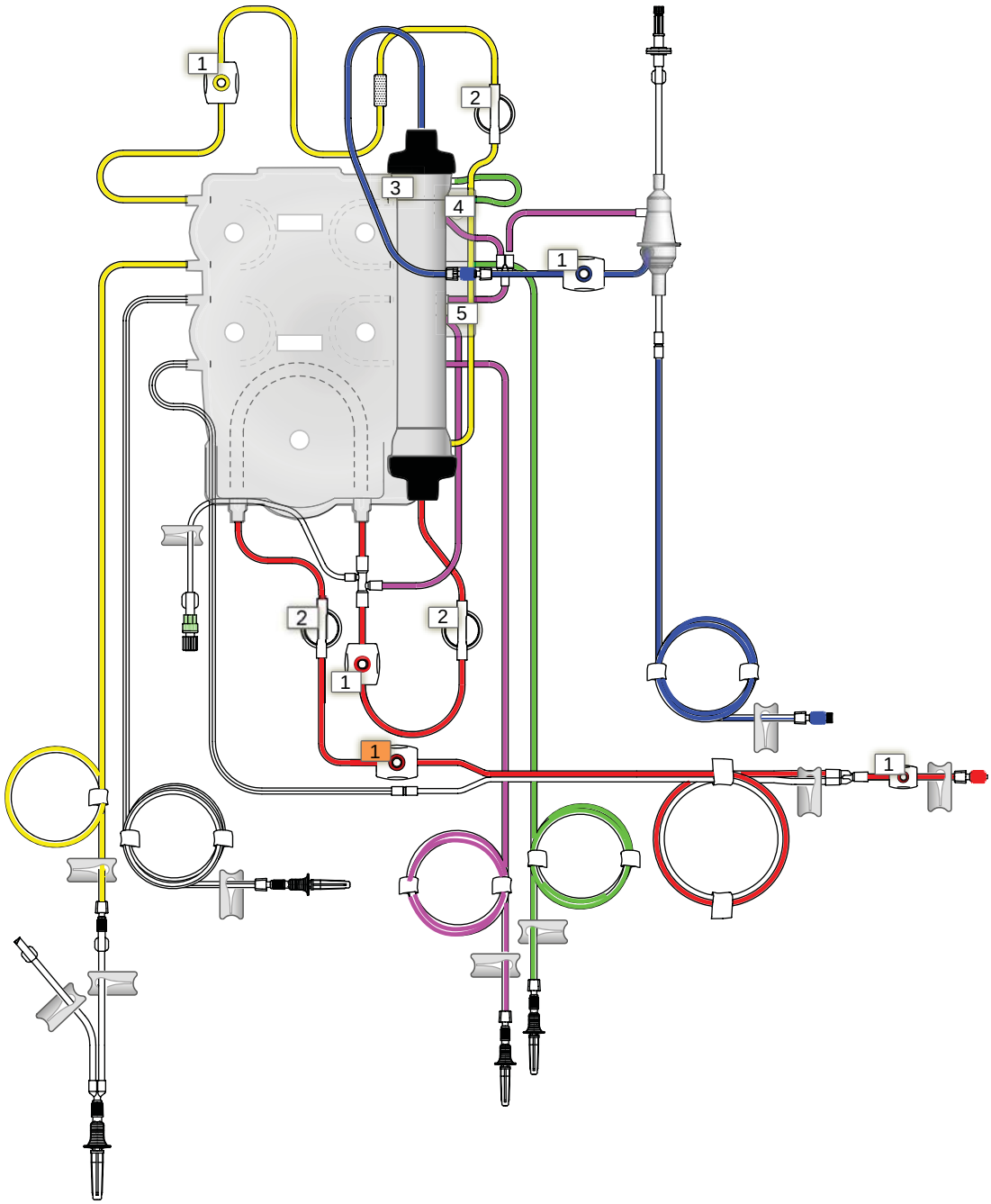

Figure 5:5 CRRT Disposable Set components

1. Sample sites

In the CRRT disposable sets, sample sites are located as follows: access line before the junction with PBP infusion line (red), access line before the blood pump (red), filter line (red), return line between filter outlet and deaeration chamber (blue), effluent line (yellow). The sample site marked orange in figure 5:5 is optional.

2. Pressure pods

In the CRRT sets, pods are located as follows: access line before blood pump (access pod), access line after blood pump (filter pod) and effluent line before effluent pump (effluent pod).

3. 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.

4. **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 solutions delivery.
   CVVHD, CVVHDF: 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 deaeration chamber on the return line.

5. **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 deaeration chamber on the return line).

Specific Functions in CRRT

Machine Control of Patient Fluid Removal Rate

The Prismaflex software automatically calculates the effluent flow rate needed to achieve the patient fluid removal rate. Any PBP, dialysate, replacement and syringe solution infused by the Prismaflex control unit is automatically accounted for, as shown below.

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

The formula which governs the effluent pump rate for CRRT:

$Q_{eff} = Q_{pfr} + Q_{pbp} + Q_{rep} + Q_{dial} + Q_{syr}$

Where $\mathbf{Q_{eff}}$ is Effluent rate (ml/h), $\mathbf{Q_{pfr}}$ is Patient fluid removal rate (ml/h), $\mathbf{Q_{pbp}}$ is PBP flow rate (ml/h), $\mathbf{Q_{rep}}$ is Replacement solution rate (ml/h), $\mathbf{Q_{dial}}$ is Dialysate solution rate (ml/h) and $\mathbf{Q_{syr}}$ is Syringe flow rate (ml/h)

Protecting From Fluid Imbalance

In addition to the alarm system functions described in chapter 3 to prevent flow errors, the Prismaflex system also monitors the Patient Fluid Removed in order to protect from fluid imbalance.

Unintended Patient Fluid Loss or Gain

In CRRT, additional information is reported on the *History* screen to help the operator understand the larger picture related to the patient's fluid balance. This information includes the Unintended Patient Fluid Loss/Gain, that is the amount of fluid removal variance that occurred within the last three hours.

Note: If *SAME PATIENT* is chosen during Setup mode, the value for Unintended Patient Fluid Loss/Gain is reset and begins again at 0 ml.

Loss or Gain Limit Reached Alarm

The Caution: Loss/Gain Limit Reached alarm occurs whenever the operator-set limit for Unintended Patient Fluid Loss or Gain is reached. Occurrence of this alarm indicates that there are unresolved flow problems in the system.

To prevent serious, unintended patient fluid loss or gain, the Caution: Loss/Gain Limit Reached alarm permanently suspends treatment (fluid pumps will not re-start). This alarm requires the operator to end the treatment.

The alarm screen reports the amount of unintended patient fluid loss or gain that has accumulated and shows the operator that this amount now matches the allowed limit. For patient charting, the operator should make a written note of the ml of Unintended Patient Fluid Loss or Gain reported.

The *STOP* softkey is provided on the alarm screen and accesses the *Stop treatment* screen. When ready to end the treatment, the operator should press this key and follow the online instructions. The Return Blood option will be available.

Patient Fluid Loss or Gain Limit

The Patient Fluid Loss/Gain Limit controls the onset of the Caution: Loss/Gain Limit Reached alarm. It thereby determines the amount of unintended patient fluid loss or gain that is allowed within the last three hours.

To correlate the Patient Fluid Loss/Gain Limit to the individual patient, the operator is prompted to enter the prescribed limit during the Setup procedure. The prescribed limit should be based on the patient's ability to tolerate potential fluid imbalance. The range of settable values is further dependent on the type of disposable set in use.

During treatment, the selected value of the Patient Fluid Loss/Gain Limit is shown in the Patient Fluid Removal section of the *History* screen.

Pressure Management

Software-calculated Pressures

During CRRT, Prismaflex software uses monitored pressure values to calculate transmembrane pressure (TMP) in addition to the filter pressure drop (Pressure Drop). Both computed pressures are used to provide notification that clotting or membrane pore plugging (clogging) is beginning in the filter, or that the filter has clotted or membrane pores have plugged (clogged) and the set must be changed.

The TMP and Pressure Drop are displayed and updated on the *Status* screen during a patient treatment. In addition, a Status graph (line graph) showing the trends of these two pressures over an operator-controllable period of one to three hours, can be displayed. See Custom Mode on page 4:25. TMP and Pressure drop can also be viewed in *History* screen together with the monitored pressure values. See section “History Data” on page 4:7.

Transmembrane Pressure (TMP)

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

The TMP is calculated by Prismaflex software as follows:

$TMP = [(P_{fil} + P_{ret}) / 2] - P_{eff}$

Where **TMP** is Transmembrane pressure (mmHg), $\mathbf{P_{fil}}$ is Filter pressure (mmHg), $\mathbf{P_{ret}}$ is Return pressure (mmHg) and $\mathbf{P_{eff}}$ is Effluent pressure (mmHg)

Filter pressure and effluent pressure readings are automatically corrected by software for hydrostatic pressure biases to compute and display TMP data (–18 mmHg correction).

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

During operation, software sets the initial TMP value at the same time as the initial pressure operating points are established (shortly after entering Run mode), see “Pressure Operating Points” on page 3:5. Thereafter, the initial TMP value is reset each time the blood flow, patient fluid removal or replacement solution rates are changed and also after self-test.

The *amount of increase* above the initial TMP value contributes to the Advisory: Filter Is Clotting alarm. This TMP parameter can be set only in Service mode by an authorized service technician. For more information, see “Filter Is Clotting” Advisory Limits in section “Filter” on page 12:6.

If the TMP rises above +300 mmHg, the Advisory: TMP Too High alarm occurs. If desired, the operator can lower this Advisory alarm limit, so that the advisory occurs prior to reaching +300 mmHg. For more information, see section “Custom Mode” on page 4:25 and chapter 14: “User-controllable Settings” on page 14:1. If the TMP increases beyond the membrane capacity that is product dependent, the Caution: TMP Excessive alarm occurs.

Therapy Operation in CRRT

CRRT Treatment Settings

The operator is required to confirm the Patient Fluid Loss/gain Limit prescription for the individual patient. See section “Protecting From Fluid Imbalance” on page 5:11.

Prescription Settings

The table Available flow rate parameters depending on selected CRRT Mode on page 5:4 shows the flow rate settings possibilities for each mode when running CRRT. The operator can set the flow rates on the *Enter Flow Settings* screen, during Setup or Run modes.

For information about PRE/POST infusion, refer to Replacement Solution Delivery Options section on page 5:13.

For information about Patient Fluid Removal Management section, refer to page 5:16.

Replacement Solution Delivery Options

The desired replacement solution delivery is selected on the *Enter Flow Settings* screen after the set has been primed. There are various delivery options, depending on the CRRT therapy and anticoagulation method selected.

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

CVVH requires that two bags of replacement solution always be hung, so that the set can be primed appropriately. One bag is placed on the replacement scale (purple) and the second bag is placed on the replacement 2 scale (green). The way these 2 bags are used is described in Table “Components used with Replacement Solution Delivery Options” on page 5:14.

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

Table “Components used with Replacement Solution Delivery Options” on page 5:14 shows the components used with each possible replacement solution delivery option in CVVH and CVVHDF.

Components used with Replacement Solution Delivery Options

Therapy	Delivery	Scale/Pump	Pinch Valve/ Segment
CVVH	100% Prefilter	Replacement Green: no delivery	Lower (purple-striped)
	Pre/Post	Replacement (delivers prefilter portion)	Lower (purple-striped)
		Green (delivers post-filter portion)	Upper (green-striped)
	100% Post-filter	Replacement (delivers 1/2 of the selected flow rate)	Lower (purple-striped)
		Green (delivers 1/2 of the selected flow rate)	Upper (green-striped)
CVVHDF	100% Pre-filter	Replacement	Lower (purple-striped)
	100% Post-filter	Replacement	Lower (purple-striped)
CVVHD+post	100% Post-filter	Replacement	Lower (purple-striped)

Total Predilution

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

$PRE\%_{tot} = (Q_{pbp} + Q_{rep(pre)}) / (Q_{pbp} + Q_{rep})$

Where **$PRE\%_{tot}$** is Total predilution (%), **Q_{pbp}** is PBP flow rate (ml/h), **Q_{rep}** pre is Pre-filter replacement flow rate (ml/h), **Q_{rep}** is Replacement flow rate (ml/h)

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

CRRT Prescription Indicators

Three prescription indicators are computed as a function of flow rate settings, patient body weight and hematocrit value:

- Filtration Fraction represents the level of internal filtration over the filter membrane within the disposable set.
- Effluent Dose represents the effluent flow rate normalized to patient body weight.
- Ultrafiltration Dose represents the fluid amounts contributed by PBP, replacement and patient fluid removal rates, normalized to patient body weight.

Following abbreviations are used in the equations for each prescription indicator:

Abbreviation	Explanation	Unit
$D_{CRRT-eff}$	Effluent dose	ml/kg/h
Q_{eff}	Effluent flow rate	ml/h
BW	Patient body weight	kg
$D_{CRRT-UFR}$	Ultrafiltration dose	ml/kg/h
Q_{plasma}	Plasma water flow rate (at patient access)	ml/h
Q_{pre}	Pre-infusion flow rate	ml/h
Q_{UFR}	Ultrafiltration rate	ml/h
Q_{pbp}	PBP flow rate	ml/h
Q_{dial}	Dialysate flow rate	ml/h
Q_{rep}	Replacement flow rate	ml/h
Q_{pfr}	Patient fluid removal flow rate	ml/h
QP_{pfl}	Prescribed patient fluid loss	ml/h
Qb	Blood flow rate	ml/h
PRE%	Predilution	%
Hct	Hematocrit (default value 30%)	%
FF	Filtration fraction	%

With

$Q_{eff} = Q_{pbp} + Q_{dial} + Q_{rep} + Q_{pfr}$

$Q_{plasma} = (1 – (Hct / 100)) \times Qb$

$Q_{pre} = Q_{pbp} + (PRE\% / 100) \times Q_{rep}$

$Q_{UFR} = Q_{pbp} + Q_{rep} + Q_{pfr}$

Filtration Fraction

Filtration fraction (FF) is calculated according to the formula below:

$FF = 100 \times (Q_{UFR}) / (Q_{plasma} \times 0.95 + Q_{pre})$

The filtration fraction value is displayed in following screens: *Enter Flow Settings*, *Review prescription*, *View Prescription Changes*, and *Status* screen.

Doses

Effluent dose ($D_{CRRT\text{-}eff}$) and the Ultrafiltration dose ($D_{CRRT\text{-}UFR}$) are calculated according to the formula below:

$D_{CRRT\text{-}eff} = Q_{eff} / BW$

$D_{CRRT\text{-}UFR} = [Q_{plasma} / (Q_{plasma} + Q_{pre})] \times (Q_{UFR} / BW)$

Patient Fluid Removal Management

WARNING

⚠ The overall patient fluid balance is subject to fluid losses or gains outside the control of the Prismaflex treatment system. The overall fluid balance must therefore be periodically verified by weighing the patient.

WARNING

Calculating the Desired Patient Fluid Removal Rate

The patient fluid removal rate is the *net amount of fluid* the Prismaflex control unit removes from the patient each hour (after accounting for any PBP and replacement volumes as well as syringe infusion volumes being used). *Net fluid removal* occurs whenever the operator sets the patient fluid removal rate to a value above zero.

The Prismaflex software *does not* measure or account for sources not supported by the Prismaflex system of patient fluid intake (such as hyperalimentation, blood, or drug infusion) or fluid output (such as urine and wound drainage). The operator must account for these other sources when calculating the patient fluid removal rate, as well as when calculating the patient's input/ output totals.

The patient fluid removal rate must be adjusted if the weight loss prescribed by the physician is changed or if the patient's fluid inputs or outputs, not supported by the Prismaflex system, change.

Adjusting the Patient Fluid Removal Rate

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

During the patient's treatment (Run mode), the operator can access the *Enter Flow Settings* screen and adjust the patient fluid removal rate as needed. See section "Operating Modes" on page 4:13 and chapter 14: "User-controllable Settings" on page 14:1 for more information.

If desired, the operator can change the default patient fluid removal rate in Custom mode. See "Custom Mode" on page 4:25.

Measuring Patient Fluid Removed

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

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

$V_{pfr} = V_{eff} - V_{pbp} - V_{dial} - V_{rep} - V_{syr}$

Where $\mathbf{V_{pfr}}$ is Patient fluid removed (ml), $\mathbf{V_{eff}}$ is Effluent bag volume (ml), $\mathbf{V_{pbp}}$ is PBP pumped (ml), $\mathbf{V_{dial}}$ is Dialysate pumped (ml), $\mathbf{V_{rep}}$ is Replacement solution pumped (ml) and $\mathbf{V_{syr}}$ is Syringe solution pumped (ml).

Viewing Patient Fluid Removed

During a patient treatment (Run mode), the Patient Fluid Removed is displayed on the *History* screen. See "History Data" on page 4:7 for more information.

Viewing Treatment Data

In History screen, treatment data includes following information for CRRT treatments:

- Patient Fluid Removed
- Current Unintended Patient Fluid Loss/Gain
- Patient Fluid Loss/Gain Limit set during set-up
- Doses (cumulated volume and average dose)
  - Ultraflitration
  - Replacement Solution Input (incl. PBP)
  - Pre-filter Input
  - Post-filter Input
  - Effluent
- Cumulated volume for:
  - Pre Blood Pump
  - Dialysate
  - Replacement
  - Syringe
  - Effluent

Time to Change Set

CRRT sets should be changed after a use time of 24 hours in order to achieve optimal treatment performance and stability. Set performance (e.g. clearance) is maximal within this period, and can be expected to deteriorate in case of treatment time exceeding a 24 hour interval. Treatment stability can be impaired by pressure alarms, which often result from excessive clotting in the filter. Clotting is more likely to occur in case of prolonged set use.

In CRRT, the Advisory: Time to Change Set alarm notifies the operator when a set change is due. Activation of the advisory depends on the time spent in treatment, including recirculation, with the current disposable set. This time is controllable to 24, 48 or 72 hours in CUSTOM mode.

It is possible to override the Advisory: Time to Change Set alarm. It is the responsibility of the operator to restrict the set usage time to appropriate limits.

CRRT with X-MARS™ Disposable Set

Description of CRRT MARS® Therapy

CRRT MARS therapy is specifically designed for the combination of the MARS system and Prismaflex system.

The MARS liver support system is designed to remove protein-bound and water-soluble toxins from the blood in cases of drug overdose and poisonings. The MARS system needs to be combined with a dialysis system. For instructions and information about the MARS machine and treatment, see the separate manual “MARS Liver Support Therapy, Operating Instructions” and “Instructions for Use MARS Treatment kit”. Contact your local representative for more information and supply.

The CRRT MARS therapy is optimized for the delivery of continuous renal replacement therapy in combination with MARS system by:

- using a specially designed disposable set, see section “X-MARS™ Disposable Set” on page 5:20
- providing setup instructions on the Prismaflex control unit screen for both the Prismaflex system and MARS system
- adapting pressure monitoring to the specific combination of the two machines

To perform a CRRT MARS treatment, first press the *CRRT MARS* softkey. On the bottom of the *Choose Therapy* screen, the following modes are available:

- CVVHD
- CVVHDF

Anticoagulation methods available in the CRRT MARS therapy are identified in “Therapies and Anticoagulation Methods” on page 7:3.

CRRT MARS® Flowchart

The CRRT MARS flowchart shows the overall organisation of the Prismaflex system and MARS system during treatment mode. The interfaces between the two systems are described below.

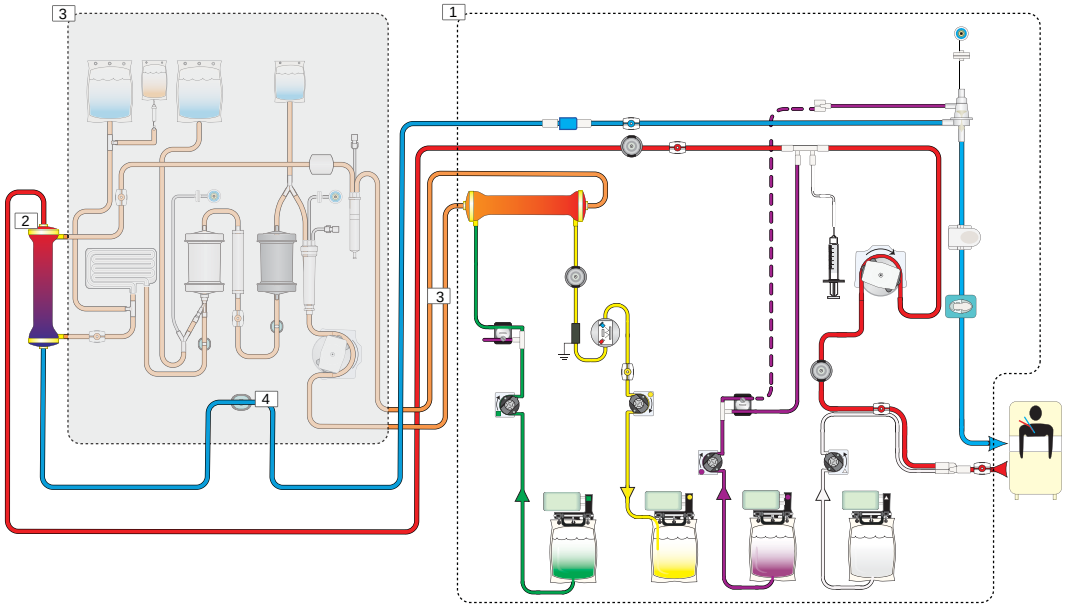

Figure 5:6 CRRT MARS Flowchart

1. X-MARS disposable set

Contains the diaFLUX filter, blood circuit and fluid lines.

2. MARSFLUX filter

MARSFLUX filter is a component of the "MARS® Treatment Kit Type 1116/1 – X-MARS." It is to be connected to the access and return line extensions of the X-MARS disposable set to close the blood flowpath. The fluid compartment of the MARSFLUX filter is connected to the albumin circuit of the MARS system.

3. diaFLUX extension lines and albumin circuit

The diaFLUX extension lines are to be connected to the albumin circuit of the MARS system.

4. Prismaflex return extension line and MARS venous clamp

The Prismaflex return extension line of the X-MARS disposable set is to be set in the MARS machine's venous clamp. In this way, the MARS system can stop the blood flow in case of a critical malfunction or alarm, such as blood leak detected.

X-MARS™ Disposable Set

The specially designed X-MARS disposable set must be used on the Prismaflex control unit to perform the CRRT MARS therapy.

The X-MARS disposable set is supplied within the MARS Treatment Kit Type 1116/1 – X-MARS. Besides the X-MARS disposable set, the kit also contains all other setup components necessary for the CRRT MARS treatment, notably the MARSFLUX filter. For information about the specific kit, refer to the Instructions for Use for the MARS Treatment Kit Type 1116/1 – X-MARS US that comes enclosed in the kit carton.

CAUTION

! Pay particular attention to the extracorporeal blood volume. For patients with a high ratio of extracorporeal volume to patient blood volume, the physician may decide to prime the extracorporeal circuit with adequate volume substitution before patient connection.

CAUTION

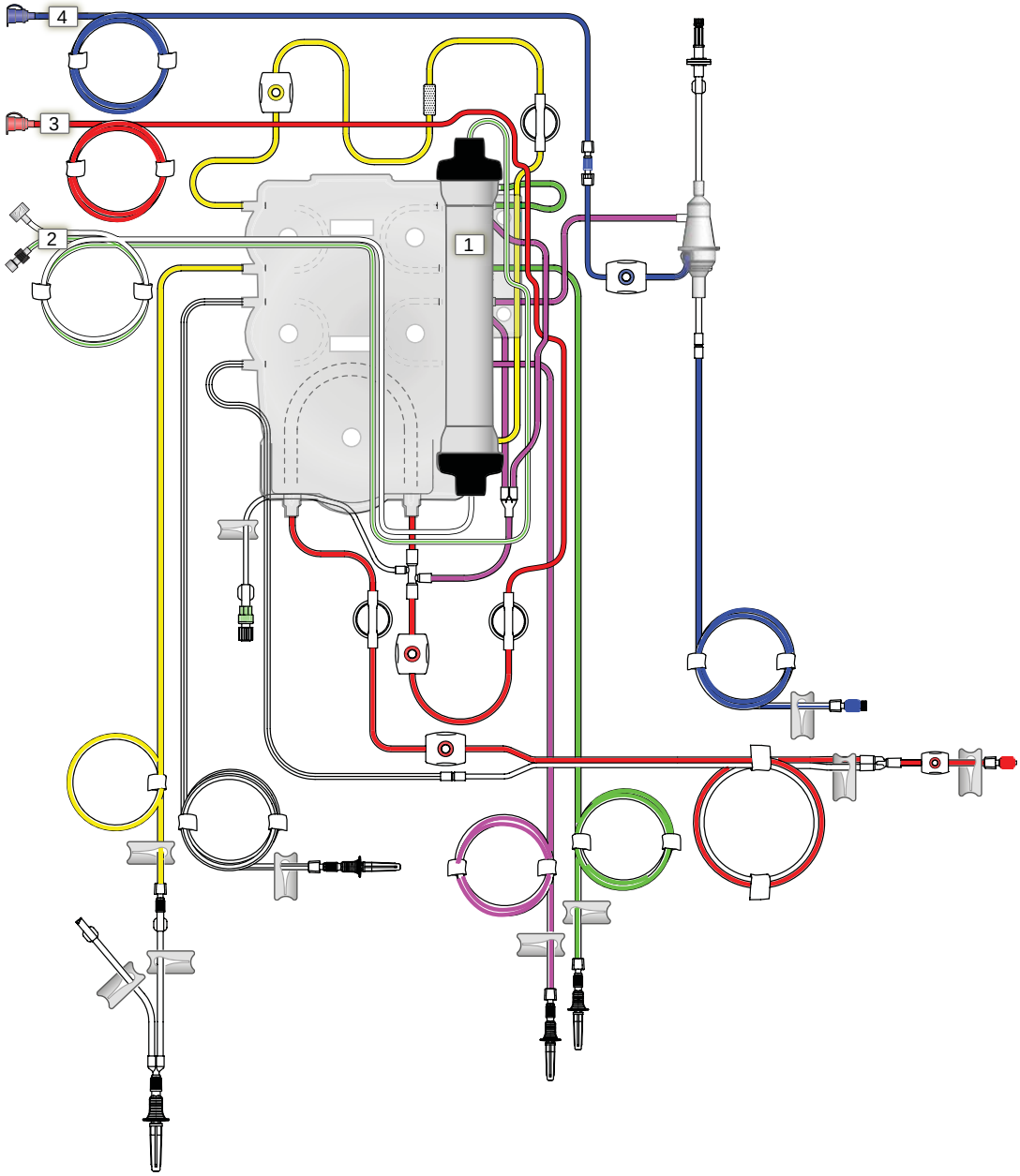

Figure 5:7 The X-MARS disposable set

1. **diaFLUX filter**
   During treatment mode, albumin solution flows inside the hollow fibres of the diaFLUX filter, while dialysate flows in the fluid compartment. The diaFLUX filter is preconnected to dialysate and effluent lines.

2. **diaFLUX extension lines**
   These lines allow for connecting the albumin circuit of the MARS system to the diaFLUX filter.

3. **Prismaflex access line extension**
   This line connects the free end of the Prismaflex access line (red) to the top inlet of the MARSFLUX filter.

4. **Prismaflex return line extension**
   This line connects the free end of the Prismaflex return line (blue) to the bottom outlet of the MARSFLUX filter. This line is also to be set in the venous clamp of the MARS machine.

Operating during CRRT MARS® Therapy

This section contains specific information about how to run the CRRT MARS therapy.

The MARS machine must be placed on the left side of the Prismaflex control unit (from user point of view), and on a secure surface that keeps the MARSFlux and diaFlux filter at equal levels/height. Pay attention to prevent interaction of extension lines with Prismaflex scales. See the Instructions for Use or Operating Instructions for more information on machine placement.

Note: The specification parameters about ambient temperature, humidity and air pressure differ between the Prismaflex system and the MARS system, see chapter 12: “Specifications” on page 12:1 for the Prismaflex control unit specifications and for technical data about the MARS system refer to the MARS Liver Support Therapy, Operating Instructions.

Setup and Priming

The setup and priming procedures in CRRT MARS therapy takes approximately 60 to 90 minutes, depending on user experience. For the setup a MARS Treatment Kit Type 1116/1 – X-MARS is needed, which contains all necessary components for the setup. Follow instructions on the Prismaflex screen to do the setup and priming. These instructions specify whether the instructions on the MARS system are to be followed or disregarded.

If single-liter priming solution bags are used, the operator will be required to pause the prime and change to a second single-liter bag of priming solution to avoid air-entry into the blood circuit. An alternative option is to use a double-spiked “Y” connector to combine two single-liter priming solution bags for each priming cycle. Contact your local representative for more information and to order this priming accessory.

Note: Heparinised priming solution is recommended for the blood circuit. Do not use heparinised priming solution for the albumin circuit since the heparin will be trapped in the adsorption cartridges, and thus may reduce effectiveness of the MARS treatment.

Due to the standby time during the filling and recirculation of the MARS albumin circuit, it is strongly recommended to flush the blood flowpath with at least 500 ml priming

solution before connecting the patient. This is done by using the *MANUAL PRIME* softkey on the *Connect Patient* screen.

Operating Screens in CRRT MARS Setup Mode

Prismaflex System (Start screen)

Choose Patient

Enter Patient ID

Enter Patient Weight

Enter Patient Hematocrit

Confirm Patient Information

Choose Therapy (press CRRT MARS)

Choose Therapy (CVVHD and CVVHDF are selectable)

Choose Anticoagulation Method ("Systemic, Prismaflex syringe pump" or "No anticoagulation")

Confirm Anticoagulation Method

Therapy and Anticogulation Choice

MARS – General Information

MARS – Preparation

MARS – Install Heater

MARS – Install Dialyzer & Adsorbers

MARS – Install Unit 1

MARS – Install Unit 2

MARS – Install Unit 3

MARS – Install Unit 4

MARS – Complete Heater Installation

Install Prismaflex set

Connect Prismaflex & MARS

Loading Pumps, please wait

Confirm Set Loaded

Prepare and Connect Solutions

Install Syringe (Systemic anticoagulation method)

Confirm Syringe Installation (Systemic anticoagulation method)

Verify Setup

Priming, please wait

Prismaflex Priming Complete

MARS – Prepare to Prime

MARS – Priming, 1st Cycle

MARS – Priming, 2nd Cycle

MARS — Priming, 3rd Cycle

Priming complete

Prime Test, please wait

Prime Test Passed

MARS – Albumin Filling

MARS – Albumin Circulation

Enter Treatment Settings

Enter Flow Settings

Enter Anticoagulation Settings (Systemic anticoagulation method)

Review Prescription

Connect Patient

Verify Patient Connection

Start Treatment

Run Mode

During run mode the *Status* screen will display the same parameters as during ordinary CRRT. The operating screens in CRRT MARS therapy do not differ from the operating screens in ordinary CRRT treatment. See “Operating Screens in Run Mode” on page 4:19.

Pressure Management

During CRRT MARS therapy, the Prismaflex software uses monitored pressure values to calculate transmembrane pressure (TMP) in the same way as in ‘standard’ CRRT. However, because of the specific therapy configuration, the measured value matches with the sum of MARSFLUX filter and diaFLUX filter transmembrane pressures. Due to this, the filter pressure drop is the only value used to provide notification about clotting in the MARSFLUX filter. During CRRT MARS therapy, displayed TMP values and TMP related alarms are no suitable indicators for clotting in the MARSFLUX filter.

Blood Leak Monitoring

During CRRT MARS therapy, the MARS machine monitors the albumin circuit for blood. If blood is detected because of a leakage at the MARSFLUX filter, the MARS machine notifies the operator via an alarm and closes its return clamp to stop the blood flow. Closure of the MARS return clamp triggers one or several pressure alarms in the Prismaflex system that will stop the blood pump.

End Mode

MARS therapy is recommended for 6 to 8 hours. The maximum treatment time allowed for the X-Mars kit is 24 hours, after which the treatment must be stopped and the kit discarded per routine.

When ending treatment, press *STOP* on the Prismaflex control unit and follow instructions on the screen.

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Chapter 6

Therapeutic Plasma Exchange (TPE)

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General Warnings and Cautions

Warnings

WARNING

⚠ In TPE, the blood flow rate should not be set below 100 ml/min for TPE2000 sets due to risk of hemolysis.

⚠ It is recommended to obtain a detailed drug history before each TPE procedure. For drugs potentially affected by TPE, the physician should either adjust the doses or give the medications immediately after the procedure, since drugs will pass through the membrane of the filter.

⚠ As treatment proceeds, carefully monitor patient plasma balance levels in the *History* screens.

⚠ Monitor patient temperature to avoid hypo- or hyperthermia. Pay special attention when using high fluid exchange rates, when using a high capacity blood warmer, or when treating low body weight patients.

⚠ The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started. See Troubleshooting chapter on page 10:62.

⚠ TPE in conjunction with citrate containing replacement solutions may require calcium substitution in order to avoid hypocalcaemia.

WARNING

Cautions

CAUTION

PBP solution delivery is not removed in TPE. Therefore this fluid volume is considered as a fluid input in the patient fluid balance.

TPE requires use of replacement fluid with adequate protein content in order to avoid hypoproteinemia.

Observe the effluent bag for pink or red tinge as an indicator of undetected micro blood leaks or hemolysis.

When changing bags/ containers during TPE, it is important to enter the new replacement container volume on the *Change Bags/Containers* screen. If the volume for the replacement container is wrong, air could be introduced into the set.

Use saline or alkaline solution (pH ≥ 7.3) with heparin added to prime the set.

CAUTION

About the Chapter

This chapter completes and deepens the information given in chapter 2, 3 and 4 when operating in TPE. This chapter provides information about specific functions in TPE and general operating instructions in TPE as a complement to chapter 4.

Therapy Description

Mechanism of TPE

In Therapeutic Plasma Exchange (TPE), blood plasma and therein contained disease mediators are removed from the patient's blood through filtration over a filter membrane. A replacement fluid is administered in order to compensate for the plasma volume that is removed through this plasmafiltration process.

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

TPE Flowchart

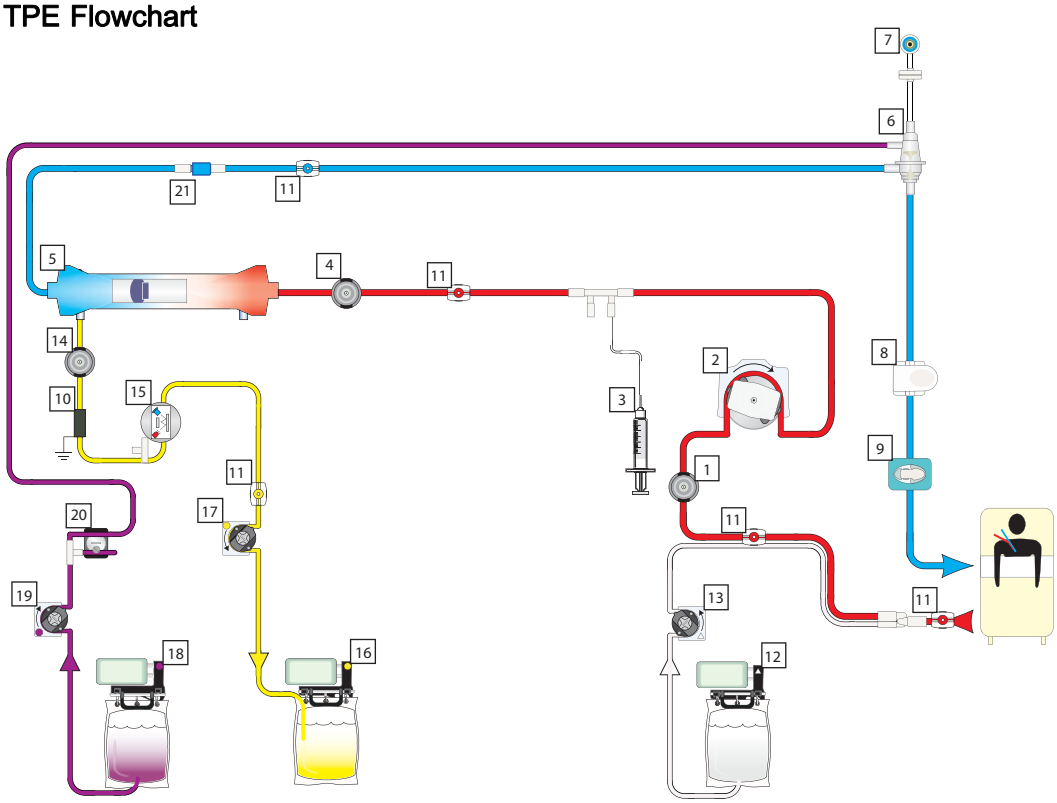

Figure 6:1 TPE flow

1. Access pressure sensor
2. Blood pump
3. Syringe pump
4. Filter pressure sensor
5. Filter
6. Deaeration chamber
7. Return pressure sensor
8. Air bubble detector and line sensor
9. Return clamp and line sensor
10. Discharger ring guide
11. Sample site
12. Scale, PBP bag
13. PBP pump
14. Effluent pressure sensor
15. Blood leak detector
16. Scale, effluent bag
17. Effluent pump
18. Scale, replacement bag
19. Replacement pump
20. Upper pinch valve
21. Blood warmer connection

TPE and Anticoagulation Methods

Anticoagulation methods available in TPE therapy are identified in “Therapies and Anticoagulation Methods” on page 7:3.

TPE Disposable Set

High Flow Sets

The available disposable sets for high flow sets are:

- TPE2000

Refer to the Instructions for Use enclosed with the set.

TPE Disposable Set Components

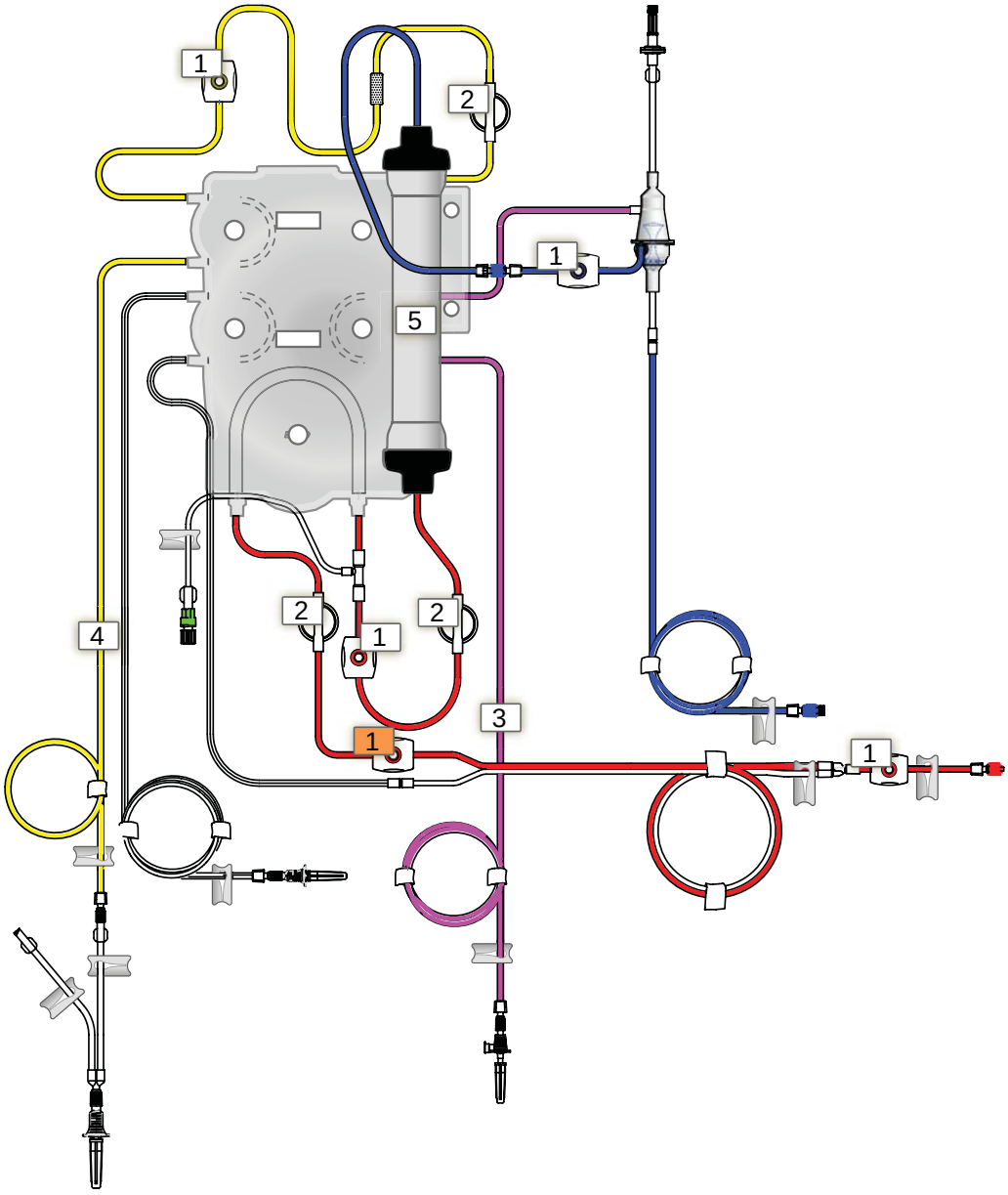

Figure 6:2 TPE disposable Set components

1. Sample sites

In the TPE disposable sets there are five sample sites, located as follows: patient end of access line (red), access line before the blood pump (red), filter line (red), return line, between filter outlet and deaeration chamber (blue); effluent line (yellow). The sample site marked orange in figure 6:2 is optional.

2. Pressure pods

In TPE disposable sets, there are three pods, located as follows: access line before the blood pump (access pod), access line after the blood pump (filter pod) and effluent line before the effluent pump (effluent pod).

3. 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 postdilution (to the deaeration chamber, just beyond the filter blood outlet).

4. **Effluent line (yellow-striped)**
   Conveys removed plasma from the plasma/fluid compartment of the filter to the effluent bag.

5. **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.

Specific Functions in TPE

Bag Management

TPE replacement solutions are being administered from containers having various weights and sizes. Accordingly, the replacement and PBP scales in TPE are per default managed with the Variable Empty Bag method. To facilitate the use of small size TPE replacement containers, volumes can be adjusted down to a minimum of 10 ml, in steps of 10 ml. See chapter 4 for more information.

Machine Control of Patient Plasma Loss

The Prismaflex software automatically calculates the effluent flow rate needed to achieve the patient plasma loss rate. Any replacement solution infused by the Prismaflex control unit is automatically accounted for, as shown below:

$Q_{eff} = Q_{ppl} + Q_{rep}$

Where $\mathbf{Q_{eff}}$ is Effluent rate (ml/h), $\mathbf{Q_{ppl}}$ is Patient plasma loss rate (ml/h) and $\mathbf{Q_{rep}}$ is Replacement fluid rate (ml/h)

During operation, software controls the effluent pump speed to maintain the required effluent rate. PBP solution and syringe infused volumes are not accounted for when defining the TPE effluent flow rate; these infused volumes are net fluid inputs for the patient.

Protecting from Fluid Imbalance

Protecting the Patient from Plasma Imbalance

The Prismaflex system is designed to provide solute removal from the patient's blood, net fluid removal from the patient's blood, or both. If net plasma loss is not desired, the Prismaflex system is designed to operate to maintain a zero plasma balance in the patient's blood (no net plasma loss or gain).

Flow problems in the fluid lines, bags, or pump segments can change the flow rate within the fluid lines and the filter and cause errors in the amount of patient plasma loss. The Prismaflex Safety System protects from these situations via alarms that suspend the treatment and alert the operator. In addition to the alarm system described in chapter 3, a third Caution: Unresolved Flow Problems alarm is active during TPE therapy. All these alarms are described in detail below.

Flow Problem Alarms in TPE

Each of the PBP, Replacement and Effluent flow rates are monitored according to the process described in section “Protecting from Flow Problems” on page 3:9. Whenever a Caution: Flow Problem alarm is triggered on replacement or effluent scales, the Actual Patient Plasma Loss is higher or lower than the target value set by the Patient Plasma Loss. When the alarm is triggered on PBP scale, the PBP input is higher or lower than the target value set by the PBP input flow rate and Patient Plasma loss remains unaffected.

The Caution: Unresolved Flow Problems alarm occurs when the limit of the Flow Problem alarms have occurred within the last three hours of treatment. Occurrence of this alarm indicates that there are ongoing problems with unresolved alarms.

To prevent serious, unintended patient fluid removal loss or gain, this alarm permanently suspends treatment (fluid pumps will not re-start). This alarm requires the operator to end the treatment.

The *STOP* softkey is provided on the alarm screen and accesses the *Stop* screen. When ready to end the treatment, the operator should press this key and follow the online instructions. The return blood option will be available.

Note: *STOP* softkey should be pressed only when ready to proceed with the end treatment sequence.

Protecting from Excessive Fluid Input

As the effluent pump does not account for PBP solution, any PBP solution constitutes an additional fluid input to the patient. To prevent unintended fluid input, the Caution: Patient Fluid Gain Excessive alarm occurs once the volume of infused PBP solution reaches the predefined threshold and suspends the treatment. The operator can then decide to either stop or to continue the treatment. See chapter 10 for detailed troubleshooting information.

Pressure Management

Software-calculated Pressures

During TPE therapy, Prismaflex software uses monitored pressure values to calculate Access Transmembrane pressure (TMPa) in addition to the filter pressure drop (Pressure Drop). Both computed pressures are used to provide notification that clotting or membrane pore plugging (clogging) is beginning in the filter, or that the filter has clotted or membrane pores have plugged (clogged) and the set must be changed. The TMPa and Pressure Drop are displayed and updated on the *Status* screen during a patient treatment. In addition, a Status Graph (line graph) showing the trends of these two pressures over an operator-controllable period of one to three hours can be displayed. See Custom Mode on page 4:25.

Access Transmembrane Pressure (TMPa)

Access transmembrane pressure is the pressure difference between the blood and fluid compartments at the inlet side of the filter.

The TMPa is calculated by Prismaflex software as follows:

$TMPa = P_{fil} - P_{eff}$

Where **TMPa** is Access transmembrane pressure (mmHg), $\mathbf{P_{fil}}$ is Filter pressure (mmHg) and $\mathbf{P_{eff}}$ is Effluent pressure (mmHg)

Filter pressure and effluent pressure readings are automatically corrected by software for hydrostatic pressure biases to compute and display TMPa data (–30 mmHg correction).

During a patient treatment, permeability of the membrane decreases due to protein coating on the blood side of the membrane. This causes the TMPa to increase. In order to help prevent hemolysis, the pressure gradient between blood inlet and the effluent outlet of the filter should be strictly controlled and the blood flow rate should not fall below minimum recommended flow rate of the selected Prismaflex system TPE disposable set.

There are two alarms specific to TMPa: the Caution: TMPa Excessive alarm and the Advisory: TMPa Too High alarm. If desired, the operator can lower the alarm limit of the Advisory alarm so that it occurs prior to reaching the manufacturer-established limit of +100 mmHg. For more information, see section “Custom Mode” on page 4:25 and section “TPE Specific Settings” on page 14:5.

Start-up Phase

To promote blood safety, the start-up of replacement and effluent pumps is delayed (from entering Run mode) by a few minutes. This allows blood to initially contact the filter without the influence of ultrafiltration pressures. This TPE start-up phase also allows the operator to change bags/containers as wished, before the actual treatment commences.

TPE Prescription Delivered

Unlike CRRT, a TPE therapy is not a continuous treatment. For the Prismaflex system the duration of a TPE treatment is defined in respect to a target replacement volume that is to be exchanged (Total Replacement Volume). Once this prescribed volume has been delivered the Prismaflex control unit notifies the operator through a Caution: TPE Prescription Delivered alarm. The operator can then choose either to stop the treatment, to continue the treatment until the replacement bag is empty, or to set a new replacement volume target.

End Treatment

Per design, TPE treatments will commonly be ended on occurrence of Caution: TPE Prescription Delivered alarm. See section “Caution Alarms” on page 10:17 for more information. If needed, treatment can be ended any time by pressing the *STOP* softkey present on the *Status* screen.

Therapy Operation in TPE

TPE Prescription and Flow Rates

The TPE Prescription consists of three settings: Patient Hematocrit; Total Replacement Volume (total amount of replacement fluid to infuse over the entire treatment); and Replacement Container Volume (volume of replacement fluid in the bag/ container hanging on the scale).

Flow rates are the settings that control the rate of blood flow, patient plasma loss, PBP and replacement fluid infusion, and effluent flow during a patient treatment. All flow rates except effluent are user-controllable.

Adjusting the TPE Prescription and Flow Rates

During the Setup procedure (Setup mode), the *Enter TPE Prescription* screen is displayed first and the *Enter Flow Settings* screen is displayed next. The operator is prompted to assess the default TPE Prescription settings and flow rates, make any changes desired for the current treatment, and confirm all values prior to starting the patient treatment. During treatment (Run mode), press the *TPE PRESCR* softkey on the *Enter Flow Settings* screen to reach the *Enter TPE Prescription* screen

Note: There is no default value for the Replacement Container Volume. The volume of fluid in the replacement container must be entered for each treatment.

In Custom mode, if desired, the operator can change the default flow rates. See “Custom Mode” on page 4:25.

Considerations When Using PBP Solution

When using PBP solution during TPE, be aware of the considerations below:

- The effluent pump rate does not account for PBP solution. Any PBP solution infused must be counted as a *separate fluid input* when calculating patient Input/Output totals.
- The software-calculated Target Patient Plasma Loss does not account for PBP solution. (See “Patient Plasma Loss Rate” on page 6:10.)

Patient Plasma Loss Rate

The patient plasma loss rate is the *net amount of plasma* the Prismaflex system removes from the patient each hour after accounting for any replacement fluid being used.

If the patient plasma loss rate is set above zero, a *net plasma loss occurs*, resulting in a negative plasma balance in the patient.

In TPE, the physician usually prescribes a zero net plasma loss; therefore, in most cases the patient plasma loss rate is set to 0 ml/h.

Software Calculations of Target Patient Plasma Loss

Prismaflex software calculates a Target Patient Plasma Loss based on settings entered by the operator. This calculated value is displayed on the *Enter TPE Prescription* and *Enter Flow Settings* screens.

Software calculates the Target Patient Plasma Loss by first determining the treatment time according to the formula below.

$T = V_{rep(tot)} / Q_{rep}$

Where **T** is Treatment time (h), $\mathbf{V_{rep(tot)}}$ is Volume to replace (Total Replacement Volume (ml)) and $\mathbf{Q_{rep}}$ is Replacement fluid rate (ml/h)

Target Patient Plasma Loss is then calculated as follows:

$V_{ppl(tgt)} = Q_{ppl} \times T$

Where $\mathbf{V_{ppl(tgt)}}$ is Target patient plasma loss (ml), $\mathbf{Q_{ppl}}$ is Patient plasma loss rate (ml/h) and **T** is Treatment time (h)

If the total replacement volume, replacement fluid rate, or patient plasma loss rate is changed during a treatment, the Target Patient Plasma Loss also changes.

Note: The Target Patient Plasma Loss for the treatment must be the same number as the net plasma loss prescribed by the physician, whether this is zero or a number above zero.

Setting the Pt Plasma Loss Rate to Achieve Prescribed Target Loss

If the prescribed net plasma loss is above zero, the operator must indirectly enter this volume as the Target Patient Plasma Loss value. This is done during the Setup procedure by performing the steps below (in the order listed).

1. On the *Enter TPE Prescription* screen, enter the prescribed Total Replacement Volume. Press *CONFIRM* to proceed to the *Enter Flow Settings* screen.

2. On the *Enter Flow Settings* screen, enter the prescribed replacement fluid rate. When the calculated Target Patient Plasma Loss appears, adjust the patient plasma loss rate (up or down) until the calculated loss equals the physician-prescribed net plasma loss.

Note: The software-calculated Target Patient Plasma Loss does not account for PBP solution. To remove the PBP volume infused as treatment is progressing, the patient plasma loss rate can be set to equal the PBP solution rate. If this is done, be aware that plasma is being removed while non-plasma (PBP solution) is being added.

Formulas Used in TPE

Below is a summary of the formulas used by Prismaflex software in managing TPE. Software calculations are based on the operator-set TPE Prescription and flow rate values. The results of software calculations are displayed on the *Enter TPE Prescription* and/or *Flow Rates* screens.

$$Vplasma = (100 - Hct) \times 0.7 \times BW$$

where **Vplasma** is Patient plasma volume (ml), **Hct** is Hematocrit (%), **BW** is Patient body weight (kg)

$$R_{exch} = V_{rep(tot)} / Vplasma$$

where $\mathbf{R_{exch}}$ is Plasma volume exchange (dimensionless), $\mathbf{V_{rep(tot)}}$ is Total Replacement Volume (ml) and **Vplasma** is Patient plasma volume (ml)

$$Hct_{post} = [(Qb / (Qb - Q_{eff})] \times Hct$$

where $\mathbf{Hct_{post}}$ is Post-filter Hematocrit (%), **Qb** is Operator set blood flow rate (ml/h), **Hct** is Hematocrit (%) and $\mathbf{Q_{eff}}$ is Effluent flow rate (ml/h)

$$FF = 100 \times (Q_{rep} + Q_{ppl}) / (Q_{plasma} \times 0.95 + Q_{pbp})$$

$$Q_{plasma} = (1 - (Hct / 100)) \times Qb$$

where **FF** is Filtration Fraction (%), $\mathbf{Q_{ppl}}$ is Patient plasma loss rate (ml/h), $\mathbf{Q_{rep}}$ is Replacement flow rate (ml/h), **Qb** is Operator set blood flow rate (ml/h), **Hct** is Hematocrit (%), Q_{pbp} is PBP flow rate (ml/h) and $\mathbf{Q_{plasma}}$ is plasma flow rate (ml/h)

$$V_{eff(tgt)} = Q_{eff} \times T$$

where $\mathbf{V_{eff(tgt)}}$ is Target effluent (ml), $\mathbf{Q_{eff}}$ is Effluent rate (ml/h) and **T** is Treatment time (h)

$V_{ppl(tgt)} = Q_{ppl} \times T$

where $\mathbf{V_{ppl(tgt)}}$ is Target patient plasma loss (ml), $\mathbf{Q_{ppl}}$ is Patient plasma loss rate (ml/h) and **T** is Treatment time (h)

Plasma Balance

Patient Plasma Loss

Patient Plasma Loss is the *net amount of plasma* removed from the patient by the Prismaflex system during a specified time period. In TPE, the physician usually prescribes a zero net plasma loss for the patient.

Measuring Patient Plasma Loss

The replacement scale and effluent scale mounted on the bottom of the Prismaflex control unit support the replacement fluid bag/container and effluent bag and constantly measure their weights. The change in combined weight of the fluid bags/containers in use indicates how much plasma has been removed from the patient by the control unit.

When fluid bags/containers are replaced, the software automatically accounts for their new weights. The following formula applies:

$V_{ppl} = V_{eff} - V_{rep}$

Where $\mathbf{V_{ppl}}$ is Patient plasma loss (ml), $\mathbf{V_{eff}}$ is Effluent bag volume (ml) and $\mathbf{V_{rep}}$ is Replacement solution volume (ml)

The Displayed Actual Patient Plasma Lost will be less than the one calculated from the "operator-set" Patient Plasma Loss rate and the Elapsed time shown in the *Status* screen (this applies also in the *History* screen) if:

a. treatment is voluntarily stopped and then later resumed; or

b. an alarm occurs that stops the fluid pumps.

"Operator-set" Patient Plasma Loss shall be calculated multiplying Run Time in *History* screen by Patient Plasma Loss rate.

Viewing Patient Plasma Loss

During a patient treatment (Run mode), the Patient Plasma Loss is displayed on the *History* screen. See section "History Data" on page 4:7 for more information.

Viewing Treatment Data

Information Included in Treatment Data

In *History* screen, treatment data includes following information for TPE treatments:

- Patient Plasma Loss (*net* plasma volume removed)
- Doses (cumulated volume and average dose)
  - Ultrafliltration
  - Replacement Solution Input (incl. PBP)

- Pre-filter Input (PBP input, not included in effluent)
- Post-filter Input (actual volume delivered, replacement fluid pumped)
- Effluent (*total* plasma volume removed)

• Cumulated volume for:

- Pre Blood Pump
- Dialysate (always zero)
- Replacement (actual replacement volume delivered)
- Syringe
- Effluent

Replacement Bag Handling

Replacement fluid for TPE may be stored in small volumes bags or containers that require multiple changes during the treatment.

Using Multiple Bags or Containers in Parallel

WARNING

⚠ When hanging a fluid bag, evenly distribute its weight amongst the three hooks of the scale carrying bar. If only one hook is needed, use the center hook. Failure to comply can significantly alter fluid balance.

WARNING

Using the accessory SP394 with the Prismaflex system in TPE requires a special procedure. The device can be used to connect together several containers (bags or bottles) of replacement fluid. See Figure 6:3 on page 6:14.

a. The end of the line equipped with the vented spike (accessory with blue cap) must be connected to the first container. The other end of this line is then connected to the second container.

b. The second line (with the non-vented spike) is used to connect the second container to the third one.

c. The third container is then connected to the replacement line of the Prismaflex system TPE disposable set.

When bottles are used, the vented cap (blue) of the spike attached to the first bottle must be open.

When bags are used, the vented cap (blue) of the spike can remain closed.

Note: After one of the lines is connected to a container, it is recommended to prime the line by gravity and clamp it before attaching the other end of the line to another container.

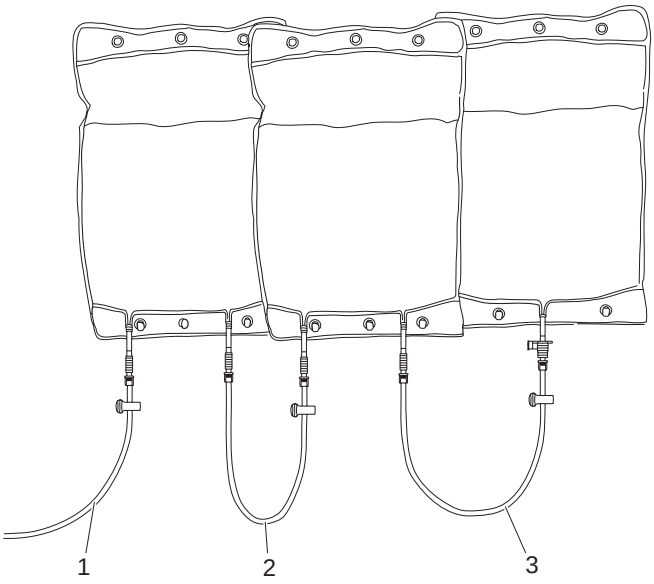

Figure 6:3 Accessory SP394 with the Prismaflex system in TPE

1. Replacement fluid line of TPE set
2. Second line equipped with the non-vented spike
3. First line equipped with the vented spike (blue cap)

Handling Empty Bag/Container Alarm

The Advisory: Replacement Container Empty alarm appears when the machine has consumed the set volume for the replacement container. The operator then has two options:

a. Change the container;

b. Decide to use a residual volume in the container already hanging on the scale. In this case an opening/closing sequence (without changing container) must be performed on the scale, and the residual volume to consume must be set.

Chapter 7

Anticoagulation Methods

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General Warnings and Cautions

Warnings

WARNING

⚠ To assure proper flow control of syringe solution, use only the syringes approved for use with the Prismaflex system. The internal diameter of approved syringes has been verified at the time of printing this manual. The manufacturer of the Prismaflex system cannot be held liable for subsequent changes that may occur to syringe dimensions.

⚠ Closely monitor the patient's clotting parameters, especially when increasing and/or decreasing the amount of anticoagulant delivered or after changing the prescribed therapy setting or after changing the syringe.

WARNING

Cautions

CAUTION

! When setting up a patient treatment, install only the allowed syringe. The allowed syringe is the syringe brand that has been selected in Custom mode from among the approved syringes. See section "Anticoagulation Related Settings" on page 14:6.

! Use only luer lock syringes with the Prismaflex control unit and monitor syringe line connection.

! Keep the syringe line clamped and stowed along the left side of the set during the entire treatment when not running the "Systemic, Prismaflex syringe pump" method.

CAUTION

About the Chapter

This chapter contains information about available anticoagulation methods for each therapy and how these are handled by the machine.

Prismaflex® Anticoagulation Methods

Exposing a patient's blood to an extracorporeal circuit as done during the Prismaflex control unit treatments initiates coagulation. Effective anticoagulation is essential to optimize fluid and/or solute removal and filter longevity. Little or no anticoagulation may be needed for patients with coagulopathies, trombocytopenia or liver failure. Anticoagulation is administered during the treatments in accordance with physician prescription.

The following anticoagulation methods are selectable on the *Choose Anticoagulation Method* screen:

- **Systemic, Prismaflex syringe pump**. For treatments with anticoagulation regimen, using the Prismaflex syringe pump.
- **No anticoagulation**. For treatments performed without anticoagulation regimen. The Prismaflex syringe pump is disabled during the entire treatment.

Configuration of Anticoagulation Methods

Using the Prismaflex syringe pump requires relevant configuration of holder size in Service mode and syringe brand in Custom mode.

Therapies and Anticoagulation Methods

The anticoagulation methods available for each Prismaflex system therapy are listed below:

CRRT:

- Systemic, Prismaflex syringe pump
- No anticoagulation

CRRT MARS:

- Systemic, Prismaflex syringe pump
- No anticoagulation

TPE:

- Systemic, Prismaflex syringe pump
- No anticoagulation

“Systemic, Prismaflex® Syringe Pump” Method

WARNING

⚠ Consider syringe accuracy specifications when using highly concentrated anticoagulants. See Table “Specifications” on page 12:1.

WARNING

The anticoagulation settings control delivery of anticoagulant solution from the Prismaflex system syringe to the blood flow. The settings are user-controllable and include the following delivery methods:

Continuous:

- The rate can be set within different ranges depending on syringe size. See specifications data for syringe settings in Specifications chapter on page 12:1.

Bolus:

- Bolus volume can be set within ranges depending on syringe size, defined in Syringe settings section in chapter Specifications on page 12:1.
- Delivery interval can be set as “immediate” in Run and Recirculation modes
- Delivery interval can be set to once every hour to 24 hours

See the bolus volume range in Specifications chapter on page 12:1.

Note: In CRRT therapies additional fluid volumes infused by the Prismaflex syringe pump are removed through the effluent, except for Immediate Boluses.

Adjusting the Anticoagulation Settings

Enter Anticoagulation Settings screen is displayed during the Setup procedure. The operator is prompted to assess the default flow rates and syringe settings for the therapy/set chosen, make any changes desired for the current treatment, and confirm all values shown on the *Enter Anticoagulation Settings* screen prior to starting the patient treatment.

In Custom mode, the operator can change the syringe brand allowed for use. See “Custom Mode” on page 4:25.

In Run mode, the operator can access the *Enter Anticoagulation Settings* screen and adjust the settings as needed. See section “Operating Modes” on page 4:13 and chapter 14: “User-controllable Settings” on page 14:1.

Viewing the Anticoagulation Settings during Treatment

During a patient treatment (Run mode), the current anticoagulation settings are displayed on the *Status* screen.

Changing the Syringe

In Systemic, Prismaflex syringe pump anticoagulation method, the syringe must be connected to the syringe line on the disposable set to infuse anticoagulant between blood pump and filter. The syring line on the disposable set is initially stowed along the left

side of the set cartridge. Follow instructions and drawings on the screen for the correct connection of the syringe. Instructions on how to install and change syringes are also described in chapter 4 on page 4:28.

Recirculation Procedures

In Systemic, Prismaflex syringe pump anticoagulation method, anticoagulant boluses can be delivered during the Saline or Blood Recirculation procedures. Press *RECIRC RATES* softkey on the *Recirculation in progress* screen if this is desired.

“No anticoagulation” Method

The selection of “No anticoagulation” disables the Prismaflex syringe pump until a new treatment is started.

Note: Even if no anticoagulation is required at start of the treatment, it is recommended to choose “Systemic, Prismaflex syringe pump” anticoagulation method and to connect a syringe filled with sterile saline solution. This ensures that the syringe line will be primed during the automatic priming cycle and is ready for anticoagulation any time during treatment through *CHANGE SYRINGE* softkey.

Note: If starting up the anticoaglulation therapy via the Prismaflex syringe pump and setting the infusion flow rate to a minimum, it will take time before the anticoagulation solution reaches the set and is effective. Therefore, consider filling a syringe with anticoagulation solution from the start. This ensures that the syringe line will be primed during the automatic priming cycle and is ready for effective anticoagulation any time during treatment.

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Chapter 8

Blood Warmers

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Description 8:4

General Warnings and Cautions

WARNING

⚠ Monitor patient temperature to avoid hypo- or hyperthermia. Pay special attention when using high fluid exchange rates, when using a high capacity blood warmer, or when treating low body weight patients.

⚠ Do not attach/connect the extension line of a blood warmer to the return line downstream of the air detector. The Prismaflex system can not detect air introduced in the line downstream the air detector.

WARNING

CAUTION

! Use only Gambro-certified blood warmers. Refer to the Operator's Manual provided with the respective warmer for correct installation, setup, and use.

! Avoid moving the Prismaflex control unit when a blood warmer is installed. Adjust the warmer to resting position before moving the control unit.

CAUTION

CRRT may induce significant hypothermia. TPE may also induce significant hypothermia. The cooling power depends primarily on the fluid exchange rate and the temperature of the fluid bags. The Prismaflex control unit allows for several blood warmer accessories to compensate for heat losses.

About the Chapter

This chapter provides information when handling Blood warmers. Each warmer, that can be used with the Prismaflex system, is described in a dedicated section with details about how to operate the warmer unit during setup, treatment and end of treatment.

All warmers can be configured in service mode by an authorized service technician. If required by the enabled warmer model, a dedicated *Connect Blood Warmer* screen is displayed with instructions on how to connect the warmer to the disposable set. When a sleeve warmer is enabled no specific setup screen will be displayed.

Prismatherm II Blood Warmer

Description

Prismatherm II blood warmer consists of a heated aluminium cylinder and an extension line coiled into the cylinder groove. The Prismatherm II extension line connects at the Prismaflex disposable set warmer connection, between the filter outlet and the deaeration chamber. The extension line of a blood warmer must be placed upstream of the air bubble detector. The Prismaflex system cannot detect air introduced in the line, for instance due to a blood warmer, downstream of the air bubble detector.

WARNING

⚠ Do not attach/connect the extension line of a blood warmer to the return line downstream of the air detector. The Prismaflex system can not detect air introduced in the line downstream the air detector.

WARNING

Prismatherm II Operating Temperature

Operating temperature of the heating cylinder is user selectable and matched with the maximum temperature of the cylinder, not the blood outlet temperature.

Connection of Prismatherm II extension line SP420 to the Prismaflex system circuit significantly increases the volume to the extra corporeal blood circuit. This added volume requires attention during prescription, especially with low body weight patients (see also Prismaflex sets IFU).

Post-replacement infusion solution flows into the deaeration chamber downstream of the warmer connection. Efficiency of the Prismatherm II blood warmer is thus reduced when high rates of post-dilution replacement are prescribed.

Prismatherm II blood warmer is only compatible with the sets specified in table “Maximum blood flow rate (Qbmax) compatible with the use of Prismatherm II blood warmer” on page 8:3.

Prismatherm II Pressure Drop

The use of Prismatherm II extension line causes pressure drop between filter outlet and deaeration chamber. This pressure drop is basically proportional to blood flow rate but also dependent on blood hemoconcentration at filter outlet.

Therefore the utilization of Prismatherm II blood warmer biases to some extent Filter Pressure Drop and TMP measurements (see Prismatherm II Operator Manual “Pressure Effects” section).

The Warning: Filter Extremely Positive alarm and the Warning: Filter Clotted alarm may be triggered when using Prismatherm II blood warmer at high blood flow rate. The table below gives indications about the maximum blood flow rates that are compatible with the various Prismaflex system sets when using Prismatherm II blood warmer. The table shows maximum blood flow rate (Qbmax) compatible with the use of Prismatherm II blood warmer, as determined from in vitro experiments using bovine blood (hematocrit 32%, protein content 60g/L) and a 13F catheter.

Maximum blood flow rate (Qbmax) compatible with the use of Prismatherm II blood warmer

Prismaflex disposable set	Qb_{max} ml/min	P_{return} mmHg
M60	180	80
M100	300/320	130
M150	350/370	160
HF1000	330/350	150
HF1400	350/360	150
TPE2000	250	150

Note: The above values are determined to provide an operating Filter pressure below +400 mmHg.

In the clinical setting, the above flow rate values may need to be significantly decreased in case of high blood viscosity (high hematocrit or other causes).

Refer to Prismatherm II Operator Manual for more information.

Sleeve Blood Warmers

WARNING

⚠ Highest set point (43°C) of the Prismacomfort warmer and the Prismaflo II / IIS warmer must be used with care when operating the Prismaflex system at low effluent flow rates (below 500 ml/h) with patients below 30 kg. Global positive heat balance and net patient warming may be present in such circumstances.

⚠ The Prismaflex control unit may not be able to detect disconnections of the set from the blood access device, which can result in severe blood loss. Ensure that the patient's blood access and return connections are firmly secured; pay special attention in case a warmer sleeve is in use.

WARNING

Description

Sleeve blood warmers consist of a control unit and a silicone sleeve to be set around the return line of the Prismaflex disposable set, downstream of the return clamp. This sleeve is warmed with electrical wire resistors.

The Prismaflex system offers the following sleeve warmer accessories having similar characteristics and performance:

- Prismacomfort
- Prismaflo II
- Prismaflo IIS

Efficiency of the sleeve blood warmers is independent of the therapy configuration and on the infusion of replacement solution in pre or post dilution.

Two sizes of sleeves are available to fit the full range of the Prismaflex disposable sets and the tubing diameter of return line. Sleeve size must match tubing size for efficient warming.

Refer to the Operator Manual of the respective warmer for more information.

For information about availability of sleeve warmers and sleeve size, refer to your local Gambro representative.

Chapter 9

Alarm System

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General Warnings and Cautions

Warnings

WARNING

⚠ When responding to any alarm, carefully follow the instructions on the displayed alarm screen and its associated *Help* screen.

⚠ Do not override the same alarm repeatedly. End treatment and call for service.

WARNING

About the Chapter

This chapter gives an overview of the alarm system and describes the different levels of signals given by the Prismaflex control unit. In chapter 11, all alarms are described with information about how to troubleshoot each alarm.

Alarm Management System

The Prismaflex control unit continually monitors itself and the Prismaflex disposable 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 provides instructions on how to respond to the alarm. Press the *MUTE* softkey to temporarily silence the audible alarm (for 2 minutes).

When applicable, a *Help* screen is available to provide additional information.

Some of the alarms are possible to override. Press *EXAMINE ALARMS* to see the complete list.

Note: *EXAMINE ALARMS* softkey is placed in the *Modify Settings* screen in Run mode.

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.

Prismaflex® 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 flashing light.
- Recurring high sound, 10 sound pulses repeated approx. every 8 seconds until muted.
- Warning screen appears on the display.

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 is lit.
- *EXAMINE ALARMS* softkey disappears, unless there are other active alarms.
- Blood pump restarts and return line clamp opens. Seven seconds later, other pumps restart.

Overridden Warning Alarms

To clear some Warning alarms, the Prismaflex control unit must override the alarm for a short period of time. After completing the response instructions given on the Warning screen, the operator presses the *OVERRIDE* softkey. During the override period, the following occurs:

- Warning screen leaves the display.
- Yellow constant light.
- *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.

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.

Prismaflex® 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 flashing light.
- Recurring high sound, 10 sound pulses repeated approx. every 8 seconds until muted.
- Malfunction screen appears on the display.

Operator Response

Some malfunctions can be cleared by the operator; others require service by an authorized service 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 is lit.
- *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 an authorized service 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 should be terminated manually. See “Manual Termination of Treatment” on page 10:57.

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

Overridden Malfunction Alarms

To clear some Malfunction alarms, the Prismaflex control unit must override the alarm for a brief time. After completing the response instructions given on the Malfunction screen, the operator presses the *OVERRIDE* softkey. During the override period, the following occurs:

- Malfunction screen leaves the display.
- Yellow constant light.
- *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.

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.

Prismaflex® 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 flashing light.
- Recurring medium sound, 3 sound pulses repeated approx. every 11 seconds until muted.
- Caution screen appears on the display.

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 is lit.
- *EXAMINE ALARMS* softkey disappears, unless there are other active alarms.
- PBP, replacement, dialysate, and effluent pumps restart within a few seconds.

Advisory Alarms

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

Prismaflex® Control Unit Actions

The following actions occur during an Advisory alarm:

- No pumps stop; treatment continues.
- Yellow constant light.
- Recurring low sound, 2 sound pulses repeated approx. every 21 seconds until muted.
- Advisory screen appears on the display.

Operator Response

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 occurs:

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

Overridden Advisory Alarms

Many Advisory alarms can be overridden by the operator. If an Advisory alarm is overridden, it remains overridden indefinitely. If the overridden alarm is a self-clearing alarm, it clears when the condition no longer exists. If the overridden alarm is not selfclearing, it remains in a list of pending alarms. Pending alarms can be viewed by pressing the *EXAMINE ALARMS* softkey. See "Alarm Priorities" on page 9:8 for more information.

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

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

Alarm Priorities

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

The priority for each alarm is shown in the Alarm Priority List.

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.

Note: *EXAMINE ALARMS* softkey is placed in the *Modify Settings* screen in Run mode.

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

Alarm Priority List

Priority	**Alarm Title**
Malfunctions (High Priority)	
1	General System Failure
2	Communication Error
3	Memory Error
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	Filter Clotted
11	Plasmafilter Clotted
12	Blood Leak Detected
13	Access Extremely Negative
14	Return Extremely Positive

Priority	Alarm Title
Warnings	
15	Access Extremely Positive
16	Filter Extremely Positive
17	Power Failure
18	Wrong Set Loaded
19	Effluent Bag Full
20	Bag/Container Empty
21	Bag Volume Incorrect
22	Effluent Bag Incorrect
23	Scale Open
24	Clamped Lines
25	Syringe Line Clamped
26	Syringe Empty
27	Recirculation Time Exceeded
28	Set-up Error
29	Wrong Set Selected
30	Crossed Lines
31	Loading Error
32	Battery Low
33	Effluent Line Not in BLD

Priority	Alarm Title
Malfunctions	
34	Air Detector
35	Clamp Stuck Closed
36	Blood Pump
37	Effluent Pump
38	Replacement Pump
39	Dialysate Pump
40	Replacement 2 Pump
41	PBP Pump
42	Normalization Failed
43	Blood Leak Detector
44	Self-Test Failure
45	Prime Self-Test
46	Syringe Pump
47	Scales
48	Pressure Zero Test
49	Scale Zero Test
50	Checksum Interrupted
51	Custom Data
52	Library Data
53	Cannot Save Custom Data
54	Upper Pinch Valve
55	Lower Pinch Valve
56	Scales Circuit Board
57	Effluent Scale Sensor
58	Replacement Scale Sensor
59	Dialysate Scale Sensor
60	PBP Scale Sensor
61	Syringe Not Loaded
62	Line in Air Detector
63	Line in Clamp
64	No Line in Air Detector
65	No Line in Clamp
66	Auto Blood Return

Priority	Alarm Title
Caution	
67	Loss Limit Reached/Gain Limit Reached
68	Unresolved Flow Problems
69	Flow Problem
70	TPE Prescription Delivered
71	Effluent Bag Full
72	Bag Empty
73	Replacement container empty
74	TMP Excessive
75	TMPa Excessive
76	Bag Volume Incorrect
77	Effluent Bag Incorrect
78	Scale Open
79	Patient Fluid Gain Excessive

Priority	Alarm Title
Advisory	
80	Check Access
81	Check Return
82	Blood Flow Stopped
83	Syringe not loaded
84	Check Syringe Line
85	Syringe Empty
86	Syringe Line Clamped
87	Syringe Almost Empty
88	Filter is Clotting
89	Plasmafilter is Clotting
90	TMP Too High
91	TMPa Too High
92	Time to Change Set
93	Cannot Detect Return
94	Download Interrupted
95	Self-Test Overdue
96	Memory Backup
97	MARS Treatment
98	Battery Exhausted
99	Main Power Lost
100	Incomplete Bolus

Chapter 10

Troubleshooting

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General Warnings and Cautions

Warnings

WARNING

⚠ When blood is returned manually, there is no air detection. Visually check for air in the return line until patient is disconnected.

WARNING

About the Chapter

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

The Prismaflex system alarms are listed in the following categories:

- Warning Alarms starting on page 10:3
- Malfunction Alarms starting on page 10:35
- Caution Alarms starting on page10:17
- Advisory Alarms starting on page 10:24
- Miscellaneous starting on page 10:54, provides instructions for handling other abnormal situations that can occur.

Possible causes for each alarm and appropriate operator actions are given.

Note: The alarms are listed in alphabetical order within each category.

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

Warning Alarms

Access Extremely Negative

Observation:
Alarm occurs if the access pressure is more negative than the user-controllable "Access Extremely Negative" Warning Limit. or if access pressure is 150 mmHg or more below its operating point.

Note: An operating point is the pressure value when the pressure is considered stable after an event such as an alarm, change of blood flow, etc.

This alarm self-clears if pressure goes back to normal limits within 15 seconds[c]. During the self-clear time the monitor will not give an audible alarm.

Possible cause(s):	**Operator action(s):**
Patient is moving, coughing, or being suctioned.	Wait 15 seconds for self-clearing[c] attempt. Note: If a self-clear attempt fails wait until the pressure is back to normal in the non self-clearing screen, then press *CONTINUE* [g].
Access line clamped, kinked or partially blocked.	Note: If a self-clear attempt fails, wait until the pressure is back to normal in the non self-clearing screen, then press *CONTINUE* [g].
Access catheter clotted or out of position in vein, or blood flow rate too high for the access device.	Flush/reposition access catheter per hospital protocol. Use access sample site to infuse saline to release negative pressure and/or lower blood flow rate. Press *CONTINUE* [g].
Access pressure sensor failed.	End treatment, call service. 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 Extremely Positive

Observation:
Alarm occurs if the access pressure is more positive than the user-controllable "Access Extremely Positive" Warning Limit.

Possible cause(s):	**Operator action(s):**
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 blood flow rate. Return to *alarm* screen and press *CONTINUE*.
Access pressure sensor failed.	End treatment. Call service.

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 measurement failure.	Perform a self-test to reposition the pressure pod membranes. Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the problem persists, change set via *STOP* [b]. If alarm recurs with new set, end treatment via *STOP*. Call service.

Air in Blood

Possible cause(s):	**Operator action(s):**
Disconnected line, leaking connection, set not fully primed, return line not installed in air detector.	Check blood access and set for possible leakage or disconnection. Remedy possible causes. Press Up arrow until return pressure is NEGATIVE. If unsuccessful, proceed with manual procedure (see "Air in Blood Alarm – Manual Air Removal" on page 10:61). 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*. Note: If air is present in entire set, press *DISCONNECT* to load and prime a new set.
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*.

Bag/Container Empty

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
Identified solution bag is empty[d].	Connect a new bag. Press *CONTINUE*.
Identified solution bag is partially supported (not hanging freely).	Remove partial support. Press *CONTINUE*.

Bag Volume Incorrect

Observation:
Valid only if Variable Empty Bag method is selected.

This alarm appears during priming only.

Possible cause(s):	Operator action(s):
Amount of fluid in the identified solution bag does not match the current Allowed Volume.	Choose one of the three options on the *alarm* screen. **Caution:** 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 solution bag is partially supported (not hanging freely).	Remove partial support. 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.

Battery Low

Observation:
Main power is still out and batteries are out of energy.
Applicable when machine configuration includes the back-up battery (check with the local representative for more information). See Power Failure on page 10:57

Possible cause(s):	Operator action(s):
Main power has been lost and battery is out of energy.	If patient is in treatment, press *STOP* softkey to end treatment. If a patient is connected in SETUP mode, press *DISCONNECT* softkey to disconnect the patient. Switch off the machine. If a patient is connected in END mode, press *OVERRIDE* softkey to end the treatment. Switch off the machine.
Machine is unplugged and battery is out of energy.	Connect power cord. Press *STOP* and select *RESUME* to restart the treatment.

Blood Leak Detected

Possible cause(s):	Operator action(s):
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 in effluent line and/or reduce ultrafiltration 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]. After alarm clears, press *Normalize BLD* in System Tools screen and follow instructions. ⚠ **Warning:** The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started. See Troubleshooting chapter on page 10:62.
Liquid or 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]. After alarm clears, press *Normalize BLD* in System Tools screen and follow instructions. ⚠ **Warning:** The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started. See Troubleshooting chapter on page 10:62.

Leak in filter membrane.	Change the set via *STOP* [b]. Send sample of the effluent to blood lab for a cell count.
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

Possible cause(s):	**Operator action(s):**
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

Possible cause(s):	**Operator action(s):**
The lines are crossed or tangled.	Check and correct lines and bags setup. Press *REPRIME*.
Foreign object on scale.	Remove the object. Press *REPRIME*.
One or more scales failed.	Press *DISCONNECT*, turn off the machine. Call service.

Effluent Bag Full

Observation:
This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
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*.

Effluent Bag Incorrect

Observation:
Effluent Bag volume does not match Allowed Volume.
Cause: a 5000 ml empty bag is hung on scale while Effluent Allowed Volume is 9000 ml.

This alarm appears during priming only.

Possible cause(s):	Operator action(s):
A 5000 ml empty bag is hung on the scale while Effluent Allowed Volume is 9000 ml.	Replace the 5000 ml bag hung on the scale with a 9000 ml 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*.

Effluent Line Not in BLD

Possible cause(s):	Operator action(s):
Effluent line of new set is not installed in blood leak detector.	Remedy and press *RETEST*. If alarm recurs, press *DISCONNECT* and load a new set. If alarm recurs with a new set, call for service.
Blood leak detector failed.	Press *DISCONNECT*, remove set. Call service.

Filter Clotted

Observation:
Filter pressure drop exceeds limit for the filter in use, or both the “Filter is Clotting” Advisory and the “TMP Excessive” Caution limits are reached.
Note: TMP value in the MARSFLUX filter is not considered for this alarm during CRRT MARS therapy; see section “Pressure management” on page 5:23 .

Possible cause(s):	Operator action(s):
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.
Pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes.
During "Systemic, Prismaflex syringe pump" anticoagulation: 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.
During CRRT MARS treatment: The MARS monitor has detected a blood leak.	If blood leak confirmed, press *STOP* and change the set. If not, troubleshoot the MARS monitor and press *CONTINUE*.

Filter Extremely Positive

Observation:
Alarm occurs if filter pod pressure is ≥450 mmHg.

Possible cause(s):	**Operator action(s):**
Line between filter pressure pod and filter or line between filter and deaeration chamber is clamped or kinked.	Remedy and press *CONTINUE*.
Machine is operating at high return pressure and clotting has begun in filter.	Press *FLOW SETTINGS* 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.

During CRRT MARS treatment: The MARS monitor has detected a blood leak.	If blood leak confirmed, press *STOP* and change the set. If not, troubleshoot the MARS monitor and press *CONTINUE*.

Loading Error

Observation:
Not possible to load/unload the set.

Possible cause(s):	Operator action(s):
Pinch valves position not correct.	Press *RETEST* to reposition the pinch valves and clear the alarm.

Plasmafilter Clotted

Observation:
Filter pressure drop exceeds limit for the plasmafilter in use, or both the "Plasmafilter is Clotting" Advisory and the "TMPa Excessive" Caution limits are reached.

Possible cause(s):	Operator action(s):
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.
Pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes.
During "Systemic, Prismaflex syringe pump" anticoagulation: 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.

Power Failure

Observation:
Power lost for more than 15 seconds after machine entered Run mode.

Possible cause(s):	Operator action(s):
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: continue treatment with a new set by pressing *STOP* [b], then *CHANGE SET*, or end the treatment by pressing *STOP* [b], then *END TREATMENT*.

Recirculation Time Exceeded

Possible cause(s):	Operator action(s):
Recirculation Time has exceeded the manufacturer-set limit.	Press *STOP RECIRC.* and resume the treatment.

Return Disconnection

Observation:
Alarm occurs if return pressure is lower than +10 mmHg and the return pressure operating point is higher than +10 mmHg. The alarm reoccurs if the following return pressure operating point is lower than +10 mmHg.

Alarm also occurs once if the operating point is lower than +10 mmHg after an operator induced (re)start of the blood pump. Should this pressure condition persist, it will be indicated by subsequent Advisory Cannot Detect Return alarms.

Note: An operating point is the pressure value when the pressure is considered stable after an event such as an alarm, change of blood flow, etc.

Possible cause(s):	Operator action(s):
Return line or catheter is disconnected.	Make sure return catheter is securely connected to both the return line and the patient. To resume treatment, press *CONTINUE* [g].

Chamber monitor 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 service.
Blood flowpath obstructed before deaeration chamber.	Remedy, if possible. Press *CONTINUE*. If not possible, press *STOP* [b] and use *CHANGE SET* to load/prime a new set.
Return pressure sensor failed.	End treatment via *STOP* [b]. Call service.

Return Extremely Positive

Observation:
Alarm occurs if return pressure is more positive than the user-controllable “Return Extremely Positive” Warning Limit.

This alarm self-clears if pressure goes back to normal limits within the self-clear time and the monitor will not give an audible alarm.

Possible cause(s):	**Operator action(s):**
Patient is moving, coughing, or being suctioned.	Wait 15 seconds for self-clearing[c] attempt. Note: If a self-clear attempt fails wait until the pressure is back to normal in the non self-clearing screen, then press *CONTINUE* [g].
Return line clamped or kinked.	Remedy, and wait for self-clearing attempt Note: If a self-clear attempt fails, wait until the pressure is back to normal in the non self-clearing screen, then press *RELEASE CLAMP* and then *CONTINUE* [g].
Return catheter clotted or out of position in vein, or blood flow rate too high.	Flush/reposition return catheter per hospital protocol and/or lower the blood flow rate. Relieve excess pressure in return line by pressing *RELEASE CLAMP*. Press *CONTINUE*. Note: The *RELEASE CLAMP* is only available if there is no other alarm requiring clamp closed.
Return pressure sensor failed.	End treatment, call service. If the above operations do not clear the alarm, the set can be changed and the alarm cleared via *STOP* [b]. If alarms recur with a new set, end treatment via *STOP* [b]. Call service.

Return Pressure Dropping

Observation:
This alarm occurs if return pressure is 50 mmHg or 70 mmHg (with blood flow>200ml/min) below its operating point.

Possible cause(s):	Operator action(s):
Possible leakage or disconnection of return line or catheter.	Make sure return catheter is securely connected to both the return line and the patient. To resume treatment, press *CONTINUE* g
Patient is moving or being moved.	Press *CONTINUE* g.
Blood flowpath obstructed or leaking before deaeration chamber.	Remedy, if possible. Press *CONTINUE*. If not possible, press *STOP* b and use *CHANGE SET* to load/prime a new set.
The hydrophobic membrane is wet, and/or service line is disconnected.	Press *STOP* b and use *CHANGE SET* to load/prime a new set. If fluid barrier gets wet again with a new set, call service.
Return pressure sensor failed.	End treatment via *STOP* b. Call service.
During CRRT MARS treatment: The MARS monitor has detected a blood leak.	If blood leak confirmed, press *STOP* and change the set. If blood leak not confirmed, troubleshoot the MARS monitor and press *CONTINUE*.

Scale Open

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
Impeding object blocking scale from fully closing, bag improperly positioned on hooks, carrying bar not centred 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.

Set Disconnection

Observation:
Alarm occurs if filter pressure is lower than +10 mmHg and the filter pressure operating point is higher than +10 mmHg.

Possible cause(s):	Operator action(s):
Filter pressure pod not installed or debris in sensor housing.	Clean pod from debris and reinstall pod as applicable. Press *OVERRIDE* to clear alarm and perform self-test through *SYSTEM TOOLS* as to reposition pod membrane. If the pod problem recurs, press *STOP* to change the set. If alarm recurs with new set, end treatment and call service.
Line between blood pump and filter is disconnected.	Make sure the line is securely connected. To resume treatment, press *OVERRIDE* [a].
Blood flowpath is obstructed before filter pressure pod.	Remedy, if possible. Press *OVERRIDE* [a] If not possible, press *STOP* [b] and press*CHANGE SET* to load/prime a new set.
Blood flow rate too low for the access device.	Increase the blood flow rate and press *OVERRIDE* [a].
Filter pressure sensor failed.	End treatment via *STOP* [b]. Call service.
Return line disconnection and failure of return pressure alarm.	Check return line and catheter; remedy as applicable. If fluid barrier wet, press *STOP* and press *CHANGE SET* to load/prime a new set. If fluid barrier is not wet, press *OVERRIDE* [a] to clear alarm and to reach *Status* screen. Press *SYSTEM TOOLS* and perform self-test in order to check return pressure sensor.
Pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes. Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the problem persists, change set via *STOP* [b]. If alarm recurs with new set, end treatment via *STOP*. Call service.

Set-up Error

Observation:
Alarm occurs if pre-prime self-test fails.

Possible cause(s):	Operator action(s):
Set-up is incorrect.	Check Return line in clamp. Press *RELEASE CLAMP* to reposition. Reinstall the return line in clamp. Check chamber monitor line installation, Filter and Effluent pods installation, clamp on dialysate line. Check that the pressure sensors has not failed. Check that the dialysate pump segment is loaded. Check that the syringe line and/or one-way valve are connected. Check that the syringe line is clamped.

Check that the right set is loaded. (see HELP)
Remedy and press *RETEST*.
If alarm still recurs, press *UNLOAD* and load a new set.
If alarm recurs with a new set, call service.

Syringe Empty

Possible cause(s):	Operator action(s):
Syringe is empty.	Press *CHANGE SYRINGE*, follow instructions to install a full syringe and return to *alarm* screen. Press *CONTINUE*. Note: A full syringe is required during priming. If anticoagulation of blood flowpath is not desired, syringe should be filled with sterile saline solution.

Syringe Line Clamped

Possible cause(s):	Operator action(s):
Syringe line clamped, kinked or obstructed.	Inspect syringe line; remove any clamps, kinks or other obstruction. Press *CONTINUE* g.
Incorrect installation of syringe line	Reinstall syringe line. Press *CONTINUE* g.
Alam is recurring.	Press *CHANGE SYRINGE*; follow instructions to change the syringe and return to alarm screen. Then press *CONTINUE*.

Wrong Set Loaded

Observation:
This set cannot be used with the therapy selected.

Possible cause(s):	Operator action(s):
Failure of recognition test.	Check that the set matches the selected therapy. Verify physician prescription for the therapy and set. 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: If alarm occurs repeatedly, do not use the machine until repairs are made.

Wrong Set Selected

Possible cause(s):	Operator action(s):
Mix up of high flow and low flow set after Bar Code Reading Failure. At the end of the first priming cycle in case of “Bar code reading failure”, the operator has to verify that the loaded set and the prescribed set are the same, by pressing *CONFIRM*.	If loaded set does match set identified on screen, press *CONFIRM*. Otherwise, press *DISCONNECT* and reload set.
Foreign object on scale.	If loaded set does match set identified on screen, press *CONFIRM*. Otherwise, press *DISCONNECT* and reload set.
Return line not connected to effluent bag or effluent bag cock opened.	If loaded set does match set identified on screen, press *CONFIRM*. Otherwise, press *DISCONNECT* and reload set.
Scale failed.	Press *DISCONNECT*, remove set. Call service.

Footnotes

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 if the pressure has returned to normal limits within 15 seconds and there are no other active Warning or Malfunction alarms. If self-clear is unsuccessful, return line clamp closes and blood pump stops. In that case the alarm must be manually cleared by the operator. During the self-clearing period there will be no audible signal. 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 2 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 a fixed value (default: 230 g). If Variable Empty Bag method is selected, 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 a risk, open the return line clamp using the *STOP* and *RESUME* softkeys. If opening of the return clamp is considered a risk, insert a 21-gauge needle with syringe into 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 a risk, open the return line clamp using the *STOP* and *RESUME* softkeys. If opening of the return clamp is considered a 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.

Caution Alarms

Bag Empty

Possible cause(s):	Operator action(s):
Bag as indicated on screen is empty.	Connect a new bag (see instructions on *alarm* screen). If Variable Empty Bag method is set in Custom mode, 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.
Bag partially supported (not hanging freely).	Remove partial support, press *CONTINUE*.
Bag has fallen down.	Connect a new bag (follow on-screen instructions). Press *CONTINUE* when ready.

Bag Volume Incorrect

Observation:
Variable Empty Bag method is selected, and amount of fluid in bag does not match Allowed Volume.

Possible cause(s):	Operator action(s):
Amount of fluid in the identified solution bag does not match the current Allowed Volume.	Choose one of the options on the *alarm* screen.

Caution:

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 solution bag is partially supported (not hanging freely).	Remove partial support. Press *CONTINUE*.

Effluent Bag Full

Possible cause(s):	Operator action(s):
Effluent bag is full.	Connect a new effluent bag (see instructions on *alarm* screen). If changing to a larger/smaller bag, press *MODIFY BAG* and use arrows to set a new Allowed Volume. Press *CONTINUE*.
Foreign object on effluent scale.	Remove foreign object. Press *CONTINUE*.

Effluent Bag Incorrect

Observation:
Effluent Bag volume does not match expected volume.

Possible cause(s):	Operator action(s):
A 5000 ml empty bag is hung on the scale while Effluent Allowed Volume is 9000 ml.	Replace the 5000 ml bag hung on the scale with a 9000 ml 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*.

Flow Problem

Observation:
Flow problem detected with fluid indicated on screen[c].

Possible cause(s):	Operator action(s):
Closed clamp or major leak on line or bag, bag is swinging, kinked line.	Remedy and press *CONTINUE*.
Effluent drain port not fully closed.	Remedy and press *CONTINUE*.
Bag connector not firmly tightened, if bag connected through Luer.	Make sure the Luer connector is firmely tightened.

Foreign object on scale, bag is partially supported (not hanging freely).	Remove object or partial support. Press *CONTINUE*.
Incorrect puncture of the bag, if bag connected through spike.	Using aseptic technique to make sure that the solution bag is correctly punctured.
Incorrect use of the frangible pin, if required for the particular bag.	Break the frangible pin correctly. Press *CONTINUE*. If the problem persists, replace the solution bag using the *CHANGE BAGS* procedure.
Second compartment of bag not opened, if double compartment bag in use.	Press *CONTINUE* and immediately replace the bag using the *CHANGE BAGS* procedure. Closely monitor the deaeration chamber level since residual air from the fluid line might reach the blood flowpath.
Air bubbles in the solution bag or line.	Check bag connections. Remedy and press *CONTINUE*.
Air bubbles in the effluent fluid.	Check effluent line for kink between pod and pump. Remedy and press *CONTINUE*.
Non breathing spike used with a rigid container.	Replace the non breathing spike with a breathing spike. Press *CONTINUE*.
Line connected to wrong bag or bag on wrong scale.	Make sure that the line is connected to the correct bag. Color-coding of line must match color of used scale.
Non-occlusive pump or scale failure.	Press *STOP* and end the treatment. Call service.
Environment with vibrations.	If the source of vibrations cannot be stopped, press *STOP* and end the treatment. Call service.

Gain Limit Reached

Observation:
The Unintended Patient Fluid Gain exceeded the selected limit and the treatment was therefore permanently suspended for safety reasons. Fluid pumps are stopped and will not re-start; the blood pump continues to run.

Possible cause(s):	Operator action(s):
A flow problem has caused the Prismaflex control unit to infuse excess fluid to the patient: Repeated flow obstructions due to closed clamps or kinked lines; Flow errors due to incorrect use of the acccess port on the effluent bag.	Press *STOP* and end the treatment. If indicated, restart treatment with a new set. Use *HISTORY* to verify exact fluid exchange status at *STOP* time.

Loss Limit Reached

Observation:
The Unintended Patient Fluid Loss exceeded the selected limit and the treatment was therefore permanently suspended for safety reasons. Fluid pumps are stopped and will not re-start; the blood pump continues to run.

Possible cause(s):	Operator action(s):
A flow problem has caused the Prismaflex control unit to pull excess fluid from the patient: Repeated flow obstructions due to closed clamps or kinked lines; Flow errors due to incorrect use of the access port on a solution bag (PBP, dialysate, replacement); Flow errors due to effluent fluid degassing.	Press *STOP* and end the treatment. If indicated, restart treatment with a new set. Use *HISTORY* to verify exact fluid exchange status at *STOP* time.

Patient Fluid Gain Excessive

Possible cause(s):	Operator action(s):
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. End treatment: Press *STOP* [b].

Replacement Container Empty

Possible cause(s):	Operator action(s):
Replacement container is empty.	Connect a new replacement container. Press *REPLACEMENT* softkey, use arrows to enter a new container volume. Press *CONTINUE*.
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.

Scale Open

Observation:
Scale not properly closed.

Possible cause(s):	Operator action(s):
Impeding object blocking scale from fully closing, bag improperly positioned on hooks, carrying bar not centred 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*and end treatment. Call service[b].

TMPa Excessive

Observation:
Access transmembrane pressure exceeds the safe limit.

Possible cause(s):	Operator action(s):
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*.
Plasmafilter pressure drop is increasing, possibly due to insufficient anticoagulation.	Decrease blood flow rate and/or adjust anticoagulation prescription.

TMP Excessive

Observation:
Transmembrane pressure exceeds membrane pressure limit.

Possible cause(s):	Operator action(s):
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 measurement of filter and effluent pressure.	Clear the alarm by temporarily decreasing UFR. Press *SYSTEM TOOLS* from *Status* screen and perform a self-test. Set previous flow rates back. If alarm recurs decrease UFR or change the set.
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP* and 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.
During CRRT MARS treatment: MARSFLUX filter and diaFLUX filter combined transmembrane pressure exceeds membrane pressure limit.	Decrease replacement and/or patient fluid removal and/or PBP rates. Press *CONTINUE*.

TPE Prescription Delivered

Observation:
Prescribed Total Replacement Volume has been delivered.

Possible cause(s):	Operator action(s):
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 *FLOW SETTINGS*, then increase the Total Replacement Input on the *Enter TPE Prescription* screen.

Unresolved Flow Problems

Observation:
Too many attempts to remedy Caution: Flow Problem alarms. Accuracy of patient fluid removal may be compromised.

Possible cause(s):	**Operator action(s):**
Clearing attempts have exceeded the manufacturer-set limit of 10 tries in 3 hours.	Press *STOP* and end the treatment. If indicated, restart treatment with a new set. Use *HISTORY* to verify exact fluid exchange status at *STOP* time.

Footnotes

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 a fixed value (default: 230 g). If Variable Empty Bag method is selected, 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 alarm or Caution: Gain Limit Reached alarm will occur requiring therapy to be discontinued or the set to be changed. TPE: After 10 unsuccessful attempts to clear this alarm in less than 3 hours, a Caution: Unresolved Flow Problems alarm will occur requiring therapy to be discontinued or the set to be changed.

Advisory Alarms

Battery Exhausted

Observation:
Applicable when machine configuration includes the back-up battery (check with the local representative for more information).
Appears when the power level of the back-up battery is too low.

Possible cause(s):	Operator action(s):
Back-up battery is depleted.	Press *OVERRIDE* and continue with setup. Machine needs to remain on for charging the battery at least 4 hours. Note: In case of main power failure before the battery back-up is fully charged again, the machine will operate as if no battery back-up was installed. See "Power Failure" on page 10:57 for more information.
Alarm recurs due to old battery or broken internal wiring.	Leave the machine on or operate for more than 24 hours. If the alarm does not self-clear within 24 hours, call service.

Blood Flow Stopped

Observation:
Machine has been left in the Stop screen for 60 seconds.

Possible cause(s):	Operator action(s):
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 Return

Observation:
This alarm occurs when the return pressure operating point is more negative than +10 mmHg. Machine is unable to detect return line and catheter disconnections.

Possible cause(s):	**Operator action(s):**
Return line or catheter is disconnected.	Make sure return catheter is securely connected to both the return line and the patient. To override this alarm, press *OVERRIDE*.
Catheter size too large or blood flow too low.	If catheter size is too large for the prescribed blood flow rate, consider to change to a smaller catheter. If compatible with prescription, press *FLOW SETTINGS* and increase the blood flow rate. When back in the alarm screen, press *OVERRIDE*.
Chamber monitor 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 *STOP*, then *CHANGE SET*.)
Return pressure sensor failed.	End treatment via *STOP* [b]. Call service.

Check Access

Observation:
When running with an operating point below –10 mmHg, this alarm occurs if access pressure is 50 mmHg or 70 mmHg (if blood flow>200 ml/min) above or below its operating point, or if the pressure rises above 0 mmHg.

When running with an operating point in the range between –10 mmHg and +20 mmHg, this alarm occurs if the access pressure is 50 mmHg or 70 mmHg (if blood flow>200 ml/min) below its operating point, or if the access pressure is 10 mmHg or more above its operating point.

When running with an operating point above +20 mmHg, this alarm occurs if the access pressure drops below +10 mmHg.

NOTE: An operating point is the pressure value when the pressure is considered stable after an event (alarm, change of blood flow, etc).

Possible cause(s):	**Operator action(s):**
Possible leakage or disconnection of access line or catheter.	Make sure access line is securely connected to catheter/blood source. Remedy, press *CONTINUE* [a].
Possible kink or obstruction in access line or catheter.	Remedy, press *CONTINUE* [a].

Patient is coughing or being moved.	Press *CONTINUE* [a].
Catheter is clotted or out of position.	Check the position of the catheter in the vein.
Blood flow rate is too high.	Decrease blood flow rate, return to alarm screen and press *CONTINUE* [a].
Blood flowpath is obstructed after access pressure pod.	Remedy, if possible. Press *CONTINUE* [a]. If not possible, press *STOP* [b] and use *CHANGE SET* to load/prime a new set.

Check Return

Observation:
This alarm occurs if return pressure is 50 mmHg or 70 mmHg (if blood flow>200ml/min) above its operating point.

NOTE: An operating point is the pressure value when the pressure is considered stable after an event (alarm, change of blood flow, etc).

Possible cause(s):	**Operator action(s):**
Possible kink or obstruction in return line or catheter.	Remedy, press *CONTINUE* [g].
Patient is moving.	Press *CONTINUE* [g].
Catheter is clotted or out of position in vein.	Remedy, press *CONTINUE* [g].
Blood flow rate is too high.	Decrease blood flow rate, return to alarm screen and press *CONTINUE*. This alarm self-clears once condition no longer exists.

Check Syringe Line

Observation:
Alarm occurs when pressure exerted by syringe pump indicates syringe line may be clamped. All pumps are stopped while confirmation of clamping is in progress.
This alarm self-clears when condition no longer exists.

Note: If this alarm is not cleared within 8 seconds the Advisory: Syringe Line Clamped alarm occurs.

Download Interrupted

Observation:
Download of history data to the technical data card has failed.

Possible cause(s):	Operator action(s):
The technical data card is full.	Insert an empty technical data card into the technical data card holder. Press *DOWNLD DATA* to retry downloading the history data.
There is no technical data card in the technical data card holder or the technical data card in the holder is damaged.	Insert a new technical data card into the technical data card holder. Press *DOWNLD DATA* to retry downloading the history data.
Internal malfunction related to the technical data card holder/reader.	Press *CONTINUE* to clear the alarm and proceed without downloading history data. If alarm recurs during subsequent treatments, call service.

Filter is Clotting

Observation:
Increasing TMP and/or Pressure Drop.

Note: TMP value in the MARSFLUX filter is not considered for this alarm during CRRT MARS therapy; see section “Pressure management” on page 5:23.

Possible cause(s):	Operator action(s):
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP*, change the set or test patient’s clotting parameters and adjust anticoagulant delivery if needed. The Warning: Filter Clotted alarm 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 and 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 chamber monitor 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.
Wrong measurement of filter or effluent pressure.	Press OVERRIDE to reach *Status* screen. Press SYSTEM TOOLS and perform a self-test.
Filter, effluent or return pressure sensor failed.	Press *OVERRIDE* to reach *Status* screen. Press *SYSTEM TOOLS* and perform a self-test. If pressure sensor failure is confirmed, end the treatment and call service.

Incomplete Bolus

Observation:
Appears when a bolus is interrupted. The blood pump has been stopped, either by the operator or another alarm.

Possible cause(s):	**Operator action(s):**
An anticoagulation bolus could not be completed.	Check patient´s anticoagulation status. If indicated, administer not delivered volume.

Main Power Lost

Observation:
Main power is lost and system operates on battery backup.

Possible cause(s):	**Operator action(s):**
Power Cord is not connected.	Reconnect the power cord. Press *OVERRIDE* to continue treatment until the Warning: Battery Low alarm occurs. This alarm self-clears when condition no longer exists.

MARS Treatment

Possible cause(s):	**Operator action(s):**
CRRT MARS treatment ongoing for more than 1 minute.	Set the MARS pump to the prescribed flow rate and press the *START* softkey on the MARS monitor. Press *CONTINUE* on the Prismaflex screen to return to *Status* screen. Make sure that all blue clamps are open.

Memory Back-Up

Observation:
Applicable when machine configuration does not include the back-up battery (check with the local representative for more information).

Possible cause(s):	**Operator action(s):**
Memory back-up battery is depleted.	Press *OVERRIDE* [c] and continue with setup. Machine needs to remain on for charging the battery at least 4 hours. Note: In case of main power lost before the battery is charged again, the machine will stop. When resuming power, machine will start up with *Query screen*. Select *NEW PRIME* or *CONTINUE* and follow the instructions on the screen.
Alarm recurs due to old battery or broken internal wiring.	Leave the machine on or operate for more than 24 hours. If the alarm does not self-clear within 24 hours, call service.

Plasmafilter is Clotting

Observation:
Increasing Pressure Drop.

Possible cause(s):	**Operator action(s):**
Inadequate anticoagulation of the extra corporeal circuit. Note: The Warning: Plasmafilter clotted alarm occurs when the blood in the Plasmafilter is clotted.	Press *STOP*, change the set or test patient's clotting parameters and adjust if needed.
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 and 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 chamber monitor 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.	Clear the alarm to reach *Status* screen. 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.
Wrong measurement of filter or effluent pressure.	End treatment by pressing *STOP*. Call service.

Self-Test Overdue

Observation:
Periodic self-test failed completion within the last 150 minutes of treatment.

Possible cause(s):	**Operator action(s):**
Test was interrupted by secondary alarms.	Press *OVERRIDE*; remedy root cause of secondary alarms (e.g. access problems). Self-test will start automatically.
Test was interrupted by operator interventions (including update of prescription settings, and bag or syringe changes)	Press *OVERRIDE*; postpone operator interventions and return to *Status* screen, if possible. Self-test will start automatically.
Test was repeatedly overridden by operator.	Press *OVERRIDE*; self-test will start automatically.

Syringe Almost Empty

Possible cause(s):	**Operator action(s):**
Syringe will be empty in 5 min.	To install a full syringe when this advisory appears, press *CHANGE SYRINGE* and follow instructions on screen. Then return to *alarm* screen and press *CONTINUE*.

Syringe Empty

Possible cause(s):	Operator action(s):
Syringe pump is in end-of-travel position, indicating that syringe is empty.	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: Press *ANTICOAG SETTINGS*, change to "*Continuous, 0 ml/h*"; return to *alarm* screen. Push plunger clamp release button to release syringe pump from end-of-travel position. Press *CONTINUE* and alarm clears.

Syringe Line Clamped

Possible cause(s):	Operator action(s):
Syringe line on the disposable set is clamped, kinked or obstructed in another way.	Inspect syringe line; remove any clamps; kinks, or other obstructions. Press *CONTINUE*.
Incorrect installation of syringe line.	Reinstall syringe line. Press *CONTINUE*.
Alarm is recurring.	Press *CHANGE SYRINGE*; follow instruction to change the syringe and return to alarm screen. Then Press *CONTINUE*.

Syringe Not Loaded

Possible cause(s):	Operator action(s):
The syringe is not loaded after Syringe Test has been performed.	Press *CHANGE SYRINGE*, follow instructions to load the syringe and return to *alarm* screen. Press *RETEST* to restart Syringe Test. If failure recurs, press *DISCONNECT*, call service and report failure.

Time to Change Set

Observation:
Hours of use have reached the operator-set “Time to Change Set” limit for this therapy/set combination.

Possible cause(s):	**Operator action(s):**
A “Time to Change Set” advisory limit has been reached.	Press *STOP* [e] and change the set or press *OVERRIDE* and continue to monitor the set[f].

⚠ **Warning:**

The Prismaflex disposable set must be changed after 72 hours of use. Continued use beyond this limit could result in rupture of the pump segments.

Note: To ensure adequate filter performance, it is recommended that CRRT disposable sets are changed every 24 hours of use.

During CRRT MARS treatment: A “Time to Change Set” advisory limit has been reached.	Press *STOP* [e] and change the disposable sets on both the Prismaflex control unit and the MARS monitor or press *OVERRIDE* and continue to monitor the set[f].

Note: Do not use the X-MARS kit beyond 24 hours. The adsorption columns (diaMARS IE 250 and diaMARS AC 250) are likely to be saturated after this operating time.

TMPa Too High

Observation:
Access transmembrane pressure has reached user-set pressure limit.

Possible cause(s):	**Operator action(s):**
Inadequate anticoagulation of the extra corporeal circuit.	Press *STOP*, change the set or test patient’s clotting parameters and adjust if needed.

Note: The Warning: Plasmafilter clotted alarm 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 and 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.
Filter or effluent pressure sensor failed.	Clear the alarm to reach *Status* screen. 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. Or operator's action directs wrong measurement.

TMP Too High

Observation:
Transmembrane pressure has reached user-set pressure limit.

Possible cause(s):	**Operator action(s):**
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].
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: The Warning: Filter Clotted alarm occurs when the blood in the filter is clotted.
Kinked lines in blood flowpath.	Remedy and 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 chamber monitor 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.	Clear the alarm to reach *Status* screen. Press *SYSTEM TOOLS* and perform *SELF-TEST*. If the pod problem is not solved, press *STOP* and change the set.

Filter or effluent pressure sensor failed.	Clear the alarm to reach *Status* screen. 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.
Wrong measurement of filter or effluent pressure.	End treatment by pressing *STOP*. Call service.
During CRRT MARS treatment: MARSFLUX filter and diaFLUX filter transmembrane pressure has reached user-set pressure limit.	Decrease the replacement and/or patient fluid removal and/or PBP rates.

Footnotes

a. *CONTINUE* clears the alarm and resets all operating points except for the return pressure operating point if it is above +10 mmHg.
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 when 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.
g. *CONTINUE* clears the alarm and resets all operating points.

Malfunction Alarms

Air Detector

Possible cause(s):	Operator action(s):
Air bubble detector failed self-tests.	Press *RETEST*. If alarm does not clear, end treatment via *DISCONNECT* or manually[a]. Call service. Do not use device until serviced.
Return line not installed or improperly installed in air bubble detector.	Install return line in air bubble detector. When ready, press *CONTINUE*.

Auto Blood Return

Possible cause(s):	Operator action(s):
Blood return volume incongruence.	End treatment via *DISCONNECT*. If alarm recurs, call service.

Blood Leak Detector

Observation:
Effluent line not properly installed in blood leak detector. Blood leak detector failed self-tests.

Possible cause(s):	Operator action(s):
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 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:** The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started. See Troubleshooting chapter on page 10:62.

Blood leak detector failed.	If alarm does not clear, change set via *CHANGE SET* or end treatment via *DISCONNECT* [a]. Call service.

Blood Pump

Observation:
Rate of Blood pump is incorrect.

Possible cause(s):	**Operator action(s):**
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When *Status* screen appears, immediately press *STOP*. On *Stop* screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

Cannot Save Custom Data

Possible cause(s):	**Operator action(s):**
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[b].

Note: Patient treatments can be conducted before problem is remedied. The last saved Custom mode values will be used for these treatments.

Checksum Interrupted

Possible cause(s):	**Operator action(s):**
Power loss occurred while internal "checksum" information update was in progress. Some settings might have been lost. Data block in question is identified on the alarm screen.	End treatment via *DISCONNECT* or manually[a], then start a new treatment.

Clamp Stuck Closed

Possible cause(s):	Operator action(s):
External force on return line clamp.	Check return line clamp. Press *RETEST*.
Return line clamp failed.	If alarm does not clear, change set via *CHANGE SET* or end treatment via *DISCONNECT* [a]. Call service.

Communication Error

Observation:
Error Code: 2 to 7
Due to:
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

Possible cause(s):	Operator action(s):
See "Due to" message on *alarm* screen.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See section "Manual Termination of Treatment" on page 10:57. Note: Treatment can not resume using the loaded set once blood has been returned. Restart machine. Once *Query* screen appears, make choice and carefully follow instructions. See section "Restart and Query screen" on page 4:12. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

Custom Data

Possible cause(s):	Operator action(s):
Not able to access Custom mode values for selected therapy/set.	Discontinue use. If applicable, use *DISCONNECT* to unload/remove set. Turn machine off and call service to remedy and clear the alarm.[b]

Dialysate Pump

Observation:
Rate of dialysate (green) pump is incorrect.

Possible cause(s):	Operator action(s):
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When *Status* screen appears, immediately press *STOP*. On *Stop* screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Clamped line.	Check for clamped line. Press *CONTINUE*
Pump failed.	Call for service.

Dialysate Scale Sensor

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
The bar tray of the dialysate scale has not been pulled out and then pushed into 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

Observation:
Rate of effluent (yellow) pump is incorrect.

Possible cause(s):	Operator action(s):
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.

Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When *Status* screen appears, immediately press *STOP*. On *Stop* screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

Effluent Scale Sensor

Observation:
This alarm appears during priming only.

Possible cause(s):	**Operator action(s):**
The bar tray of the effluent scale has not been pulled out and then pushed into 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.

General System Failure

Observation:
Error Code: 1 to 6

Possible cause(s):	**Operator action(s):**
Turning Fluid pumps or Blood pump when machine in Safe state; Clamp forced to wrong position when machine in Safe state; No communication.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See section “Manual Termination of Treatment” on page 10:57. Note: Treatment can not resume using the loaded set once blood has been returned. Restart machine. Once *Query* screen appears, make choice and carefully follow instructions. See section “Restart and Query screen” on page 4:12. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

Library Data

Possible cause(s):	Operator action(s):
Cannot access manufacturer-set default values.	Discontinue use. If applicable, use *DISCONNECT* to unload/remove set. Turn machine off and call service to remedy and clear the alarm.[b]

Line in Air Detector

Possible cause(s):	Operator action(s):
Return line installed in air bubble detector before loading a set.	Remove line from air bubble detector, then close door of air bubble detector. Press *RETEST*. If alarm doesn't clear, turn machine off. Call service.
Tubing detection switch failed.	Turn machine off. Call service.

Line in Clamp

Possible cause(s):	Operator action(s):
Return line installed in Return Line Clamp before loading a set.	Remove line from Return Line Clamp. Press *RETEST*. If alarm doesn't clear, turn machine off. Call service.
Tubing detection switch failed.	Turn machine off. Call service

Lower Pinch Valve

Possible cause(s):	Operator action(s):
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, end treatment via DISCONNECT. Call service.
The lower pinch valve failed.	End treatment via *DISCONNECT*. Call service.

Memory Error

Observation:
Error Code: number 1, 3 – 7
Due to:
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]
Code=7 Backup memory

Possible cause(s):	**Operator action(s):**
See “Due to” message on *alarm* screen.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See section “Manual Termination of Treatment” on page 10:57. Note: Treatment can not resume using the loaded set once blood has been returned. Restart machine. Once *Query* screen appears, make choice and carefully follow instructions. See section “Restart and Query screen” on page 4:12. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

No Line in Air Detector

Possible cause(s):	**Operator action(s):**
Return line not installed or not properly installed in 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, end treatment via *DISCONNECT*. Call service.
Tubing detection switch failed.	End treatment via *DISCONNECT*. Call service.

No Line in Clamp

Possible cause(s):	Operator action(s):
Return line not installed or not properly installed in Return Line Clamp.	Insert line into the clamp. Press *RETEST*. If alarm doesn't clear, end treatment via *DISCONNECT*. Call service.
Tubing detection switch failed.	End treatment via *DISCONNECT*. Call service.

Normalization Failed

Observation:
Attempt to normalize blood leak detector has failed.

Possible cause(s):	Operator action(s):
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

Observation:
Rate of pre-blood (white) pump is incorrect.

Possible cause(s):	Operator action(s):
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When *Status* screen appears, immediately press *STOP*. On *Stop* screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

PBP Scale Sensor

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
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

Possible cause(s):	Operator action(s):
Hardware failure on pressures circuit board.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See Manual Termination of Treatment on page10:57. Call service.

Pressure Zero Test

Observation:
Zero test of one or more pressure sensors failed.

Possible cause(s):	Operator action(s):
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 or are incorrectly calibrated.	If alarm does not clear, turn off machine. Call service.

Prime Self-Test

Observation:
Code: 1–7.
Due to: Pressure pod/sensor. 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)

Possible cause(s):	**Operator action(s):**
Pressure pod(s) not installed; debris in sensor housing(s); leaking pod.	Install/check that all reported pressure pod(s) on the alarm screen are installed correctly. Press *RETEST*.
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

Observation:
Code: 1 to 28.

Detailed information on different alarm codes follows below.

Possible cause(s):	**Operator action(s):**
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. *DISCONNECT* provides instructions to unload/remove set. *NEW SET* gives instructions to unload set, load a new set, and start a new priming cycle. *REPRIME* provides instructions to reprime the set. *RETEST* restarts the prime test.

Prime Self-Test

Observation:
Code=16
Due to: Return pressure sensor.

Possible cause(s):	**Operator action(s):**
Clamped lines in set.	Unclamp any clamped lines. Press *RETEST*.
Chamber monitor 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 the same set again. 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.
Air in set and bad priming quality.	Press *REPRIME* to prime the set again.

Prime Self-Test

Observation:
Code=17 and 18
Due to: Blood leak detector normalization timeout or Blood leak detector threshold error.

Possible cause(s):	**Operator action(s):**
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* and follow instructions. If failure recurs after the above Operator Responses, retry with a new set (Press *NEW SET* and follow instructions.)
Blood leak detector failed.	If failure occurs with the new set, unload set via *DISCONNECT*. Call service and report failure code.
Liquid or 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].

Prime Self-Test

Observation:
Code=19
Due to: Air/pumps safety test.

Possible cause(s):	Operator action(s):
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

Observation:
Code=20
Due to: Pump occlusivity test.

Possible cause(s):	Operator action(s):
Return line not properly installed in return line clamp; obstruction in return line clamp.	Press *REPRIME*. Install return line in the released return line clamp and prime the same set again. If failure occurs again, press *DISCONNECT* and use *CHANGE SET* to load/prime a new set.
Deaeration chamber monitor 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 chamber monitor 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

Observation:
Code=21 – 23
Due to: Pinch valve(s).

Possible cause(s):	Operator action(s):
Pinch valve(s) segment(s) not properly positioned in pinch valve(s).	Press *RETEST*. If failure recurs, retry with a new set (Press *NEW SET* and follow instructions.)
Pinch valve(s) failed.	If failure occurs with a new set, unload set via *DISCONNECT*. Call service and report failure code.

Prime Self-Test

Observation:
Code=24
Due to: 24 volt / 12 volt.

Possible cause(s):	Operator action(s):
24 volt / 12 volt test failed.	Press *RETEST*. If failure recurs, unload set via *DISCONNECT*. Call service and report failure code.

Prime Self-Test

Observation:
Code=25
Due to: Return clamp sensor.

Possible cause(s):	Operator action(s):
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

Observation:
Code=26
Due to: 24 volt Return clamp sensor.

Possible cause(s):	Operator action(s):
24 volt and return clamp sensor tests failed.	Press *RETEST*. If failure recurs, unload set via *DISCONNECT*. Call service and report failure code.

Prime Self-Test

Observation:
Code=27
Due to: TMPa.

Possible cause(s):	**Operator action(s):**
Return line not in clamp.	Ensure chamber monitor 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.	Install/check that all reported pressure pod(s) on the alarm screen are installed correctly. 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

Observation:
Code=28
Due to: Syringe Pump HW.

Possible cause(s):	**Operator action(s):**
Internal malfunction: syringe test not completed within 600 s.	Press *RETEST* to restart Syringe Test. . If failure recurs, press *DISCONNECT*, call service and report failure code number.

Replacement Pump

Observation:
Rate of replacement (purple) pump is incorrect.

Possible cause(s):	**Operator action(s):**
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When *Status* screen appears, immediately press *STOP*. On *Stop* screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

Replacement Pump 2

Observation:
Rate of replacement 2 (green) pump is incorrect.

Possible cause(s):	**Operator action(s):**
Momentary problem with pump roller or pump segment in raceway.	Press *CONTINUE*.
Impeding object, clamped line or kinked line in pump raceway; thumb screw in center of rotor has loosened.	If alarm recurs, end treatment: Press *CONTINUE*. When *Status* screen appears, immediately press *STOP*. On *Stop* screen, choose *END TREATMENT* and follow the instructions to disconnect patient and unload set. Call service to remedy/clear alarm[b].
Pump failed.	Call for service.

Replacement Scale Sensor

Observation:
This alarm appears during priming only.

Possible cause(s):	Operator action(s):
The bar tray of the replacement scale has not been pulled out and then pushed into 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

Observation:
Scale in question is specified on the *alarm* screen.

Possible cause(s):	Operator action(s):
Specified scale is out of calibration.	Press *RETEST*. If alarm does not clear, end treatment via *DISCONNECT* [d]. Turn machine off, remove return line from return line clamp, and return blood (when applicable). See Manual Termination of Treatment on page10:57. Call service.

Scales Circuit Board

Possible cause(s):	Operator action(s):
Hardware failure on scales circuit board.	End treatment via *DISCONNECT*. Call service.

Scale Zero Test

Observation:
Zero test of one or more scales failed.

Possible cause(s):	**Operator action(s):**
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.

Self-Test Failure

Observation:
For **Possible cause(s)** and **Operators action(s)**,
see correspondent code for Prime Self-Test Alarm.
Code=1–7, Pressure pod/sensor
Code=16, Return pressure sensor
Code=18, Blood leak detector threshold error
Code=24, 24 volt / 12 volt
Code=25, Return clamp sensor
Code=26, 24 volt Return clamp sensor

WARNING

⚠ The blood leak detector must be re-normalized if the effluent line is removed and then reinserted into the blood leak detector after treatment (Run mode) has started. See Blood Leak Detector Normalization on page 10:62.

WARNING

Syringe Not Loaded

Possible cause(s):	Operator action(s):
The syringe is not loaded after Syringe Test has been performed.	- Press *CHANGE SYRINGE*, follow instructions to load the syringe and return to *alarm* screen. - Press *RETEST* to restart Syringe Test. - If failure recurs, press *DISCONNECT*, call service and report failure.

Syringe Pump

Observation:
Code: 1–9.
Code = 1 Working mode incongruence between Syringe pump and set mode.
Code = 2 Rate is incorrect.
Code = 3 Syringe pump is moving in the wrong direction.
Code = 4 Configuration incongruence between Syringe pump and the system / wrong version of firmware.
Code = 5 Lower sensor out of order.
Code = 6 Maximum of load sensor / unable to read force (short circuit).
Code = 7 Minimum of load sensor / unable to read force (grounded).
Code = 8 Working mode incongruence between Syringe pump and Control unit.
Code = 9 Encoder signal error / engine mechanically blocked.

Possible cause(s):	Operator action(s):
Syringe pump failed.	Press *OVERRIDE* [e]. The syringe pump test will restart after 60 seconds. For "Systemic, Prismaflex syringe pump" method: if alarm recurs, it is possible to continue without using the syringe pump, if desired. To do this, press *ANTICOAG SETTINGS* and set the syringe pump delivery to "Continuous, 0 ml/h." Return to *alarm* screen and press *OVERRIDE* [e] or turn machine off, remove return line from return line clamp, and return blood (when applicable). See Manual Termination of Treatment on page 10:57. Call service.

Note: Always call service to repair the syringe pump and clear the alarm.

Upper Pinch Valve

Possible cause(s):	Operator action(s):
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, end treatment via DISCONNECT. Call service.
Pinch valve(s) failed.	End treatment via *DISCONNECT*. Call service.

Voltage Out of Range

Possible cause(s):	Operator action(s):
Internal malfunction related to the machine Power Supply or the Power supply cabling.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See Manual Termination of Treatment on page10:57. Call service.

Footnotes

a. Manual termination instructions are provided at the end of the Troubleshooting chapter.
b. This alarm must be cleared in Service mode by an authorized service 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.

Miscellaneous

Display Error

Observation:
Display goes blank, status lights go off, non-mutable buzzer sounds.

Possible cause(s):	Operator action(s):
Power loss, internal power supply failure.	Turn off machine to stop buzzer, end treatment manually, if desired[a].

Display Error

Observation:
Display goes blank momentarily, then screen reappears.

Possible cause(s):	Operator action(s):
Power was lost and restored within 15 seconds.	None required.

Display Error

Observation:
Display goes blank or logo screen fails to leave display, status lights may still be on, no buzzer.

Possible cause(s):	Operator action(s):
Internal power supply failure; internal malfunction.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See Manual Termination of Treatment on page10:57. Call service.

Display Error

Observation:
Display “floats around”

Possible cause(s):	Operator action(s):
Display failure.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See Manual Termination of Treatment on page10:57. Call service.

Loader

Observation:
Loader is already in loaded position, so that a set cannot be loaded.

Possible cause(s):	Operator action(s):
Last set was manually disconnected.	Begin normal Setup procedure. When *Load Set* screen appears, press *LOAD*. Press *STOP* in *Loading pumps, please wait* screen, then press *UNLOAD*. When *Load set* screen reappears after *Unloading pumps, please wait* screen, follow online instructions to load the set.

Miss-colored Effluent bag

Observation:
Effluent bag is tinged pink or red.

Possible cause(s):	Operator action(s):
Patient's disease state.	Discoloration may indicate removed free hemoglobin, rather than a blood leak in the filter membrane. Press *OVERRIDE* and send effluent sample to blood lab for a cell count. If the result confirms blood cell presence, change the set via *STOP* [b].
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 via *STOP* [b].
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 there are no kinks in the access and return lines. If hemolysis continues, change the set via the STOP key[b].
Hemolysis is occurring during TPE therapy.	Press *STOP* and change set.

Set Connections

Observation:
Leakage from set connections.

Possible cause(s):	Operator action(s):
Connections are loose.	Tighten the connections. If leakage continues, change the set via STOP key[b].

Softkeys

Observation:
Softkeys won't work.

Possible cause(s):	Operator action(s):
Touchscreen failed.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See Manual Termination of Treatment on page 10:57. Call service.

Footnotes

a. Manual termination instructions are provided at the end of the Troubleshooting chapter.
b. See "Change Set and End Treatment Procedures" in chapter 4: "End Mode" on page 4:19.

Power Failure

The Prismaflex control unit is designed to support the operator during loss of line power or in case the power cord needs to be temporarily unplugged during operation. The way the control unit handles such situations depends on the availability of an additional back-up battery in the control unit, which is available as an accessory.

Note: Line power is required to start the Prismaflex control unit, even if equipped with a back-up battery.

- If a back-up battery is installed, the treatment will proceed during a power failure. The Advisory: Main Power Lost alarm will appear and a battery icon will be visible at the top of the *Status* screen. Once the battery is nearly depleted, the Warning: Battery Low alarm indicates that the treatment must be ended. Instructions how to do so are provided on the alarm screen.

- If a back-up battery is not installed, the treatment will be suspended once line power is lost. Should power be restored within 15 seconds, the treatment will resume. Otherwise, the Warning: Power Failure alarm will appear on the screen and provide recovery instructions.

See also Advisory: Battery Exhausted and Advisory: Memory Back-up for more information.

Manual Termination of Treatment

An ongoing treatment can be terminated manually at any time. Manual termination may be required due to an unresolvable alarm, power failure or other emergencies.

Manual Termination With Blood Return

Note: A sterile spike connector may be required.

Note: The following procedure might trigger alarms on the control unit. These can be safely ignored in this context.

1. Turn off the control unit using the power switch. Ignore the resulting auditory alarm, if any.

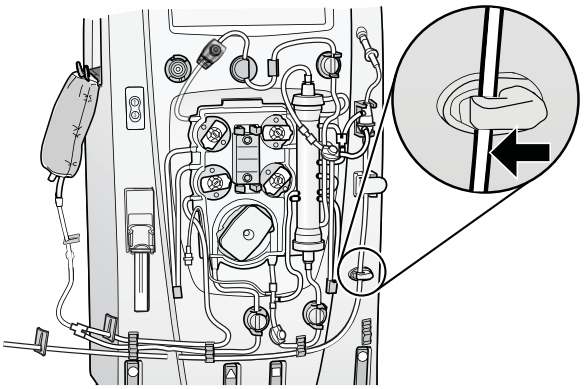
2. If line power is available, wait for 10 seconds and then switch on the control unit to silence the alarm.

3. Clamp the access line (red-striped) and disconnect from the patient.

4. Attach the access line to a 1 liter bag of sterile saline. Use a spike connector, if needed.

5. Unclamp the access line.

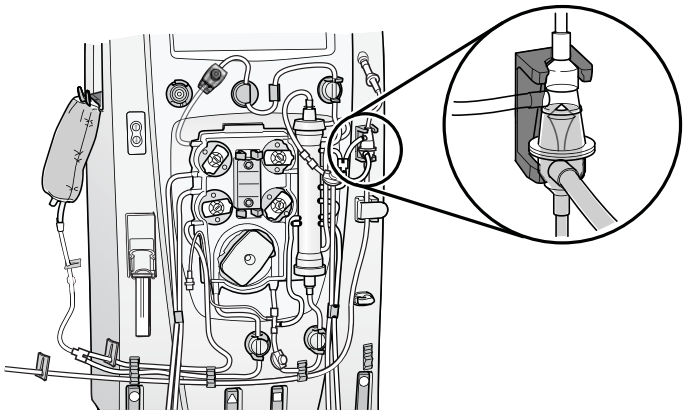
6. Press the return clamp button located on the left side of the return line clamp assembly and hold in the “In” position. With the other hand, remove the return line (blue-striped) from the return line clamp.



7. Visually check the fluid level in the deaeration chamber. If the level is too low, remove excess air as follows:

   - Place a clamp on the chamber monitor line and disconnect the chamber monitor line from the return pressure port. By opening/closing the clamp, let blood fill the deaeration chamber to the correct level.

   - In case of insufficient blood flow into the chamber, attach a luer-lock sterile syringe (without the needle) to the distal end of the chamber monitor line; aspirate air/blood until fluid level in the chamber is correct.

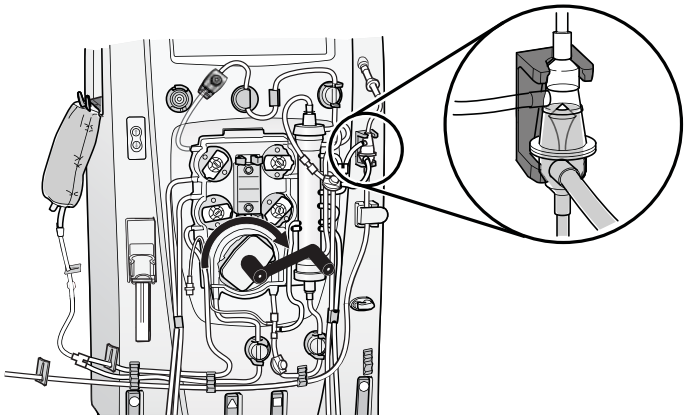


WARNING

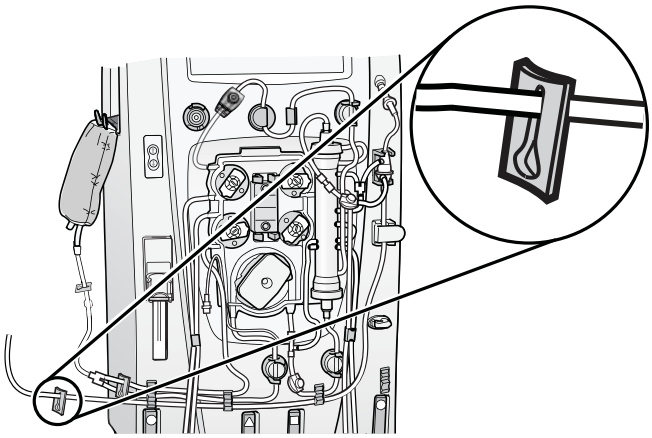
⚠ When blood is returned manually, there is no air detection. Visually check for air in the return line until patient is disconnected.

WARNING

8. 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 volume is returned to the patient.



9. Clamp the return line (blue-striped) and disconnect from the patient. Clamp lines to all bags.

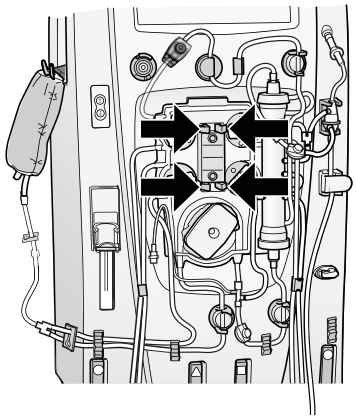


WARNING

⚠ Unloading or removing the disposable set with the patient still connected will result in severe blood loss. Always ensure patient is disconnected from the disposable set before unloading or removing set from the control unit.

WARNING

10. Press the two clips of the loader to release the Prismaflex disposable set. Pull out the regressed “screw driver” from the pump crank. Starting with any of the fluid pumps, insert the screw driver into the pump rotor and turn 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 disposable set while turning the pump.



11. When the pump segments are free, use the “screw driver” tool in the crank to set the pinch valves in neutral position.

12. Grasp the Prismaflex disposable set and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

Manual Termination Without Blood Return

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

WARNING

⚠ Unloading or removing the disposable set with the patient still connected will result in severe blood loss. Always ensure patient is disconnected from the disposable set before unloading or removing set from the control unit.

WARNING

3. Press the two clips of the loader to release the Prismaflex disposable set. Pull out the regressed “screw driver” from the pump crank. Starting with any of the fluid pumps, insert the screw driver into the pump rotor and turn 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 disposable set while turning the pump.

4. When the pump segments are free, use the “screw driver” tool in the crank to set the pinch valves in neutral position.

5. Grasp the Prismaflex disposable set and pull out to disengage the lines from the pinch valves. Take the set off the control unit and discard as usual.

Leakage in Pressure Pods or Blood Reaching Fluid Barrier

WARNING

⚠ Do not use the Prismaflex control unit after blood leakage from a pod diaphragm or after blood having passed the fluid barrier at the distal end of the monitor line. Place the control unit into quarantine to avoid risk of infection and have it inspected by an authorized service technician.

WARNING

CAUTION

! Do not operate the machine without a fluid barrier present at the end of monitor line.

CAUTION

Under normal conditions, the Prismaflex pressure transducers have proven to be safe and effective in measuring during treatment. However, in the unlikely event of a blood/infusion solution leakage from a pod diaphragm or if blood has reached the fluid barrier of the monitor line, immediate troubleshooting is required.

Blood/infusion fluid reached the fluid barrier (Return)
Wetting of the fluid barrier at the distal end of the monitor line will impair pressure monitoring in the Prismaflex system. The sets needs to be changed immediately.

Blood/infusion solution has passed through the fluid barrier and reached the return pressure port, or leakage from a pod diaphragm. Treatment shall be stopped immediately and the machine must be put into quarantine and tagged as “DO NOT USE“. Additional verification is required either by the facility’s biomedical and/or authorized service technician.

Air Removal Procedures

Deaeration Chamber

Frequent monitoring of the level is necessary. See section “Air Management” on page 3:10.

Air in Blood Alarm – Manual Air Removal

If pressing the Up arrow until return pressure is NEGATIVE is unsuccessful, 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 chamber monitor line and automatically eliminated from the set through the return pressure port. Blood is also drawn from the patient into the return line and deaeration chamber.

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

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 at the beginning of the prime test sequence, when the effluent line is full of priming solution. The infrared transmitter/ detector is adjusted to receive a signal range between 42000 and 45000. 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 *Normalize 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.

WARNING

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 between 42000 and 45000.

5. When normalization finishes, control unit automatically returns to the *Status* screen.

Cardiac Monitor Procedures

Electrically isolated peristaltic pumps such as those on the Prismaflex control unit can produce electrostatic charges in the disposable set. While these electrostatic charges are not hazardous to the patient, they may appear as an artefact on cardiac monitors.

To minimize this electrical interference:

- always install the discharger ring in its guide before connecting a patient to the Prismaflex disposable set
- follow the ECG supplier's instructions for chronic patient monitoring carefully regarding:
  - use of specific electrodes with low contact impedance,
  - correct application of the electrodes, including appropriate placement of the N electrode

CAUTION

! When starting a treatment with the Prismaflex system, observe the cardiac monitor before and after starting the blood pump to verify that the artefact is not present. If a cardiac dysrhythmia is exhibited, stop the blood pump and reassess the cardiac rhythm before resuming treatment and/or treating the patient.

CAUTION

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Chapter 11

Maintenance

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Cleaning the Touch screen 11:2
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Service

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 an authorized service technician.

For service or to order parts, contact your Gambro representative.

Hygiene and Maintenance

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.
- Do not use other cleaning solutions than those recommended as the touch screen may be damaged.

CAUTION

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).

Cleaning the Blood Leak Detector

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

Cleaning the Touch screen

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

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.

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 authorized service technicians. Upcoming as well as overdue maintenance procedures are signalled to the operator through a reminder screen at the startup of the control unit. Only authorized service technicians are approved to perform preventive maintenance procedures.

During preventive maintenance the following components should be replaced:

- Pressure pod sealing cones; (6000 h or 12 months)
- Automatic Reposition System (ARPS) filter and pump segment; (6000 h or 12 months)
- Blood Pump Rotor (only after 20000 hours of operation have elapsed).

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

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

During preventive maintenance the authorized service technician should also perform the following tests, verifications, operations:

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

- Verify the presence and the integrity of the conductivity gaskets of the scales
- Apply the proper quantity of grease on the scale bearings

Periodic Safety Inspection

A safety inspection of the Prismaflex control unit is required every 12 months, or as stipulated by local requirements. Only authorized service technicians are approved to perform the safety inspection procedures.

Chapter 12

Specifications

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Performance

Flow Rates and Accuracy

Flow rate ranges and increment depend on the Prismaflex therapy/set combination selected by the operator. See chapter 13: " Prismaflex® Disposable Sets" on page 13:1.

Blood Flow Rate

Range	10 to 450 ml/min
Increment	2 to 10 ml/min
Accuracy	±10 % of user-set rate at nominal blood flow of 450 ml/min or the highest achievable disposable blood flow, having 37 ºC, at an access pressure of -200 mmHg and without any PBP flow.
Return Blood Flow Rate	6 to 100 ml/min
Recirculation Flow Rate	20 to 100 ml/min

Automatic Blood Return Volume

Range	50 to 150% of the disposable set volume (rounded to closest 5 ml in End mode)
Increment	5% (5 ml in End mode)
Accuracy	±15%

Replacement Solution/Fluid Flow Rate

CVVH; CVVHDF	
Range	0 to 8000 ml/h
Increment	20 to 50 ml/h
Accuracy	± 30 ml/h
CVVH	
Predilution percentage	0 to 100%
Increment	5%
Accuracy	± 30 ml/h
CVVHDF	
Predilution percentage	0 (postdilution) or 100% (predilution)
Accuracy	± 30 ml/h
TPE	
Range	0 to 5000 ml/h
Increment	10 ml/h
Accuracy	± 30 ml/h

Dialysate Flow Rate

CVVHD; CVVHDF	
Range	0 to 8000 ml/h
Increment	50 ml/h
Accuracy	± 30 ml/h

PBP Solution Rate

CRRT	
Range	0 to 4000 ml/h
Increment	30 ml/h < Q_{pbp} < 100 ml/h: 2 ml/h 100 ml/h < Q_{pbp} < 200 ml/h: 5 ml/h 200 ml/h < Q_{pbp} < 1500 ml/h: 10 ml/h Q_{pbp} > 1500 ml/h: 50 ml/h Q_{pbp} = PBP Solution Flow Rate
Accuracy	± 30 ml/h
TPE	
Range	0 to 1000 ml/h Note: Total PBP Volume is 2000 ml/treatment for TPE .
Increment	30 ml/h < Q_{pbp} < 100 ml/h: 2 ml/h 100 ml/h < Q_{pbp} < 200 ml/h: 5 ml/h 200 ml/h < Q_{pbp} < 1500 ml/h: 10 ml/h Q_{pbp} > 1500 ml/h: 50 ml/h Q_{pbp} = PBP Solution Flow Rate
Accuracy	± 30 ml/h

Patient Fluid Removal Performance / Patient Plasma Loss Performance

CRRT	
Range	0 to 2000 ml/h
Increment	5 to 10 ml/h
Accuracy	±30 ml/h ±70 ml/3 hr ±300 ml/24 hr Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ±3 °C (5.4 °F) during treatment.
TPE	
Range	0 to 1000 ml/h
Increment	10 ml/h
Accuracy	±30 ml/h ±70 ml/3 hr ±300 ml/24 hr Scales calibrated at ambient temperature at which they will be used. Ambient temperature change less than ±3 °C (5.4 °F) during treatment.

Effluent Flow Rate

Range	0 to 10,000 ml/h Depending on the therapy selected.

Syringe Settings

Systemic, Prismaflex Syringe Pump Anticoagulation Method

Syringe Continuous Delivery Rate

Range	User controllable; 0, or 0.5 to 5.0 ml/h (20 ml syringe) 0, or 0.5 to 10.0 ml/h (30 ml syringe) 0, or 2.0 to 20.0 ml/h (50 ml syringe)
Increment	0.1 ml/h
Accuracy	±15 % < 2 ml/h, ±5 % ≥ 2 ml/h (20 ml syringe) ±10 % < 2 ml/h, ±5 % ≥ 2 ml/h (30 ml syringe) ±10 % < 3 ml/h, ±5 % ≥ 3 ml/h (50 ml syringe) Pressure between 0 and +600 mmHg. Use of approved syringes

Syringe Bolus Delivery Volume

Range	User controllable; 0, or 0.5 to 5.0 ml (20 ml syringe) 0, or 1.0 to 5.0 ml (30 ml syringe) 0, or 2.0 to 9.9 ml (50 ml syringe) 0, or 0.5 to 5.0 ml (all syringe sizes, recirculation mode)
Increment	0.1 ml
Accuracy	±15 % < 2 ml, ±5 % ≥ 2 ml (20 ml syringe) ±10 % < 2 ml, ±5 % ≥ 2 ml (30 ml syringe) ±10 % < 3 ml, ±5 % ≥ 3 ml (50 ml syringe)

Syringe Bolus Delivery Interval

Range	User controllable; 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

TPE Settings

Patient Hematocrit

Range	10 to 60%
Increment	1%
Default	30%

Total Replacement Volume

Range	0 to 10,000 ml
Increment	100 ml
Default	3000 ml

Replacement Container Volume

Range	0 to 5000 ml
Increment	10 ml

Pressure Sensor Range, Accuracy and Alarm Limits

Access

Operating Range	–250 to +450 mmHg
Accuracy	±15 mmHg
“Access Extremely Negative” Warning Limit	Warning alarm occurs Pressure in access pod equals warning limit. User controllable: –10 to –250 mmHg Default: –250 mmHg 150 mmHg below operating point Increment: 5 mmHg
“Access Extremely Positive” Warning Limit	Warning alarm occurs Pressure in access pod equals warning limit. User controllable: +10 to +450 mmHg Default: +300 mmHg Increment: 5 mmHg
“Check Access” Advisory Limit	Advisory alarm occurs When running with an operating point below –10 mmHg, this alarm occurs if access pressure is 50 mmHg or 70 mmHg (if blood flow>200 ml/min) above or below its operating point, or if the pressure rises above 0 mmHg. When running with an operating point in the range between –10 mmHg and +20 mmHg, this alarm occurs if the access pressure is 50 mmHg or 70 mmHg (if blood flow>200 ml/min) below its operating point, or if the access pressure is 10 mmHg above its operating point. When running with an operating point above +20 mmHg, this alarm occurs if the access pressure drops below +10 mmHg.

Return

Operating Range	–50 to +350 mmHg
Accuracy	±5 mmHg
"Return Extremely Positive" Warning Limit	Warning alarm occurs Pressure in return deaeration chamber equals warning limit. User controllable: +15 to +350 mmHg Default: +350 mmHg Increment: 5 mmHg
"Check Return" Advisory Limit	Advisory alarm occurs This alarm occurs if return pressure is 50 mmHg (or 70 mmHg if blood flow >200 ml/min) above its operating point.
"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

Operating Range	–50 to +450 mmHg
Accuracy	±15 mmHg
"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 a) Filter pressure drop	Advisory alarm occurs One or both limits are reached (CRRT) a) User controllable: +10 to +100 mmHg greater than initial filter pressure drop Default: +100 mmHg Increment: 10 mmHg
b) TMP increase	b) Service controllable: +50 to +100 mmHg greater than initial TMP Default: +100 mmHg Increment: 5 mmHg
"Plasmafilter is Clotting" Advisory Limit	Advisory alarm occurs Limit is reached (TPE) User controllable: Filter pressure drop is +10 to +60 mmHg greater than initial filter pressure drop Default: +60 mmHg Increment: 10 mmHg

“Filter Clotted” Warning Limit	Warning alarm occurs Filter pressure drop is ≥ limit value fixed for the filter in use, or both the “Filter is Clotting” Advisory and the “TMP Excessive” Caution limits are reached (CRRT)
“Plasmafilter Clotted” Warning Limit	Warning alarm occurs Filter pressure drop is ≥ limit value fixed for the plasmafilter in use, or both the “Plasmafilter is Clotting” Advisory and the “TMPa Excessive” Caution limits are reached (TPE)
“TMP Too High” Advisory Limit	Advisory alarm occurs TMP equals user-set limit (CRRT) User controllable: +70 to +350 mmHg Default: +350 mmHg Increment: 10 mmHg
“TMPa Too High” Advisory Limit	Advisory alarm occurs TMPa equals user-set limit (TPE) User controllable: 0 to +100 mmHg Default: +100 mmHg Increment: 10 mmHg
“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

Operating Range	–350 to +400 mmHg (CRRT) –350 to +400 mmHg (TPE)
Accuracy	±15 mmHg

Patient Safety

Air Bubble Detector

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 20 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.

Alarm Signals

The audible and visual alarm indicators meet IEC 60601-2-16.

Audible

Sound Pressure Levels

Default	High volume, high pitch
Malfunction alarms	76 dB(A)
Warning alarms	67 dB(A)
Caution alarms	67 dB(A)
Advisory alarms	66 dB(A)

Characteristics

Alarms can be silenced for 2 minutes, after which audible alarm resumes if alarm condition has not been remedied.

Fast beep	Warning and Malfunction alarms
Moderate beep	Caution alarms
Slow beep	Advisory alarms
Continuous for at least 2 minutes (alarm unable to silence)	Power loss

Visual

Red flashing	Warning and Malfunction alarms
Yellow flashing	Caution alarms
Yellow constantly lit	Advisory alarms

Physical Data

Weight and Dimensions

Weight:	Approximately 78 kg (172 lb) Without fluid bags and Prismaflex disposable set
Height:	Approximately 163 cm (64 in)
Width:	Approximately 49 cm (19 in)
Base:	Approximately 60 cm × 63 cm (24 in × 25 in)

Scale Characteristics

Scale Weight Range

Weight range for each scale includes the scale components (bar tray, carrying bars).

Dialysate:	0 to 11 Kg
Replacement:	0 to 11 Kg
PBP:	0 to 11 Kg
Effluent:	0 to 11 Kg

Scale Accuracy

≤7 g error for a mass from 0 to 5200 g,
≤14 g error for a mass from 5201 g to 11,000 g.

Power

Line Power

Line Voltage:	100 – 240 VAC
Line Current:	5 – 2.5 A (5 A maximum RMS at 100 VAC, 2.5 A maximum RMS at 240 VAC)
Frequency:	50/60 Hz
Power:	500 – 600 W
Average Energy Consumption:	<150 W (CVVHDF treatment)

Battery Backup

Memory Backup	12 V / 1.2 Ah
Battery Backup	24 V / 2.9 Ah

The Prismaflex system will operate on battery backup for at least 10 minutes with healthy, fully charged batteries.

External Communication

Remote Alarm	Max voltage: 24 VAC Max Current: 1 A AMP CPC (Circular Plastic Connector), 4 pin, female connector
RS232	DB9–type, female connector
Ethernet	10base-T compatible 8 pin RJ45 female connector
Technical data card	PCMCIA compatible memory card

Environmental Data

Operation

Ambient Operating Temperature:	16 °C to 38 °C (60 °F to 100 °F)
Ambient Operating Humidity (for control units with serial number up to PA5409):	15% to 65% (Non-condensing)
Ambient Operating Humidity (for control units with serial number from PA5410 and on):	**Lower ambient operating humidity limit:** 15% (Non-condensing) in the temperature interval 16 °C to 38 °C. **Upper ambient operating humidity limit:** 85% (Non-condensing) in the temperature interval 16 °C to 28 °C. In the temperature interval 28 ºC to 38 ºC the upper limit is reduced by 2% per degree and at maximum ambient temperature (38 ºC) the maximum operating relative humidity is consequently 65% (Non-condensing).
Ambient Operating Air Pressure:	70 to 106 kPa (525 to 795 mmHg)

Transportation and Storage

Transport and Storage Temperature:	–18 °C to +54 °C (0 °F to 130 °F) Prior to use, let unit rest at ambient operating temperature for 1 hour.
Transport and Storage Humidity:	10% to 95% (Non-condensing)
Transport and Storage Air Pressure:	50 to 106 kPa (375 to 795 mmHg)

Noise Level

Noise level	< 65 dB(A) over a 24 h period, measured at a distance of 0.5 m from the Prismaflex control unit, during normal operation and without any alarm condition.

Vibration Levels

Vibrations during operation	Acceleration Spectral Density (ASD), isotropic, 2-200 Hz ASD $\leq 5\times10^{-8}$ g^2/Hz

Fluid Spillage

Fluid Spillage:	IPX1 (Protection against vertically falling water drops) As specified in IEC 60529

Cleanability

Cleanability:	Not damaged by mild detergent; liquid soap; ethyl alcohol (90%); isopropyl alcohol (70%); sodium hypochlorite (0.1%). Pump rotors are removable.

Electromagnetic Emissions and Immunity

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

Guidance and manufacturer's declaration – Electromagnetic Immunity			
The Prismaflex system is intended for use in the electromagnetic environment specified below. The customer or the user of the Prismaflex system should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 KV contact ±8 KV air	±6 KV contact ±8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC/EN 61000-4-4	±2 KV for power supply lines ±1 KV for input/output lines	±2 KV for power supply lines ±1 KV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 KV differential mode ±2 KV common mode	±1 KV differential mode ±2 KV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T(60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Prismaflex system requires continued operation during power mains interruptions, it is recommended that the Prismaflex system be powered from an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC / EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – Electromagnetic Immunity			
The Prismaflex system is intended for use in the electromagnetic environment specified below. The customer or the user of the Prismaflex system should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Com-pliance Level**	**Electromagnetic Environment – Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Prismaflex system including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter. Recommended separation distance
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1] , should be less than the compliance level in each frequency range[2] . Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Prismaflex system is used exceeds the applicable RF compliance level above, the Prismaflex system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Prismaflex system.

[2] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Prismaflex system			
The Prismaflex system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Prismaflex system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prismaflex system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distances according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 KHz to 800 MHz $d = 1.2 \sqrt{P}$	800 KHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at maximum output power not listed above, the recommended separation distance d in meter (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Electrical Safety

CAUTION

Devices connected to the RS232 serial communication port or the Ethernet port must comply with IEC 60950. Connected cables must have a Kitagawa RFC-10 ferrite or equivalent to fulfill EMC requirements.

CAUTION

Note! To be sure of the machine's classification see type label found at the back of the Prismaflex control unit.

Classification:	Mobile, Class I, applied part is Type CF, defibrillation proof per IEC 60601-1
	Mobile, Class I, applied part is Type BF, defibrillation proof per IEC 60601-1
	Mobile, Class I, applied part is Type B, per IEC 60601-1 when using the Prismaflex system in combination with the MARS system.

AC Leakage Current

	Protective ground open
300 μA maximum rms	100/115 VAC, 50/60 Hz
500 μA maximum rms	220/240 VAC, 50/60 Hz

Defibrillation-proof Applied Part

Applied part is Type CF, defibrillationproof per IEC 60601-1

Applied part is Type BF, defibrillationproof per IEC 60601-1

Defibrillator equipment meets requirements of IEC 60601-2-4

Radio Frequency Interference

Meets European Standard EN 55011, limit B
Meets IEC 60601-1-2

Electromagnetic Compatibility

Meets IEC 60601-1-2

Potential Equalization

Meets IEC 60601-1

The Prismaflex control unit has a connection for a Potential Equalization Conductor.
See Rear Panel Components on page 2:14.

Continuous Operation

The Prismaflex system is intended for continuous operation.

Conformity to International Rules

IEC 60601-1:1988	Medical electrical equipment - Part 1: General requirements for safety; incl. A1:1991, A2:1995
IEC 60601-1-1:2000	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2:2001	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-4:2000	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
IEC 60601-2-16:1998	Medical Electrical Equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment
CAN/CSA No.601.1-M90 incl. S1-94 (R1999)	
CAN/CSA No. 601.1B-90 (R2002)	Medical Electrical Equipment - Part 1: General requirements for safety
UL 60601-1	Medical electrical equipment - Part 1: General requirements for safety

Medical Device Classification

Classification, EU	Class II b per COUNCIL DIRECTIVE 93/ 42/EEC
Classification, USA	Class II per FDA 21 CFR 876
Classification, Canada	Class III per SOR/98-282
Classification, Australia	Class II b per Therapeutic Goods Act 1989, Bill 2002

Chapter 13

Prismaflex® Disposable Sets

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Minimum blood flow range allowed by the monitor is 10 ml/min during Run mode for all sets and therapies. Reported low blood flow range limit refers to the minimum blood flow rate recommended for each set.

Maximum allowed flow rate values reported in this chapter are absolute maximum possible settings for each individual flow. Available maximum flow rate will be lowered in some therapy modes (i.e. pre- or post-replacement infusion, SCUF) and with respect to the current value of the other flow or anticoagulation settings.

CRRT Disposable Sets

Low Flow Sets

Priming Parameters and Blood Flow Rates

Set	Number of priming cycles	Total priming volume (ml)	Blood flow range (ml/min)	Blood flow increment (ml/min)	Blood volume (ml)
M60	1	1000	50 to 180	5	93

Patient Fluid Removal and Patient Fluid Loss/Gain Limit

Set	Unintended Fluid Loss or Gain limit (ml/3 h)	Patient fluid removal range (ml/h)	Patient fluid removal increment (ml/h)
M60	60 to 200	0 to 2000	5

Solution Flow Rates

Set	Replacement flow range predilution (ml/h)	Replacement flow range postdilution (ml/h)	Replacement flow increment (ml/h)	Dialysate flow range (ml/h)	PBP flow range (ml/h)
M60	0 to 4000	0 to 3000	50	0 to 4000	0 to 2000

Return Blood and Recirculation Flow Rates

Set	Return Blood flow range (ml/min)	Default set value for Return Blood (ml/min)	Return Blood increment (ml/min)	Recirculation flow rate range (ml/min)	Recirculation flow rate increment (ml/min)
M60	10 to 100	40	5	30 to 100	5

High Flow Sets

Priming Parameters and Blood Flow Rates

Set	Number of priming cycles	Total priming volume (ml)	Blood flow range (ml/min)	Blood flow increment (ml/min)	Blood volume (ml)
M100	1	1000	80 to 400	10	152
M150	2	2000	100 to 450	10	189
HF1000	1	1000	80 to 400	10	165
HF1400	2	2000	100 to 450	10	186
X-MARS*	1	2000	130 to 450	10	279

*The X-MARS kit on the Prismaflex control unit requires one single priming cycle. Full priming of the X-MARS kit requires further priming cycles from the MARS monitor. Refer to MARS® Liver Support Therapy Operating Instructions and follow instructions on the Prismaflex screen.

Patient Fluid Removal and Patient Fluid Loss/Gain Limit

Set	Unintended Fluid Loss or Gain limit (ml/3 h)	Patient fluid removal range (ml/h)	Patient fluid removal increment (ml/h)
M100	100 to 400	0 to 2000	10
M150	100 to 400	0 to 2000	10
HF1000	100 to 400	0 to 2000	10
HF1400	100 to 400	0 to 2000	10
X-MARS	100 to 400	0 to 1000	10

Solution Flow Rates

Set	Replacement flow range predilution (ml/h)	Replacement flow range postdilution (ml/h)	Replacement flow increment (ml/h)	Dialysate flow range (ml/h)	PBP flow range (ml/h)
M100	0 to 8000	0 to 6000	50	0 to 8000	0 to 4000
M150	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000
HF1000	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000
HF1400	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000
X-MARS	0 to 4000	0 to 4000	50	0 to 8000	0 to 4000

Return Blood and Recirculation Flow Rates

Set	Return Blood flow range (ml/min)	Default set value for Return Blood (ml/min)	Return Blood increment (ml/min)	Recirculation flow rate range (ml/min)	Recirculation flow rate increment (ml/min)
M100	10 to 100	70	5	50 to 100	5
M150	10 to 100	70	5	50 to 100	5
HF1000	10 to 100	70	5	50 to 100	5
HF1400	10 to 100	70	5	50 to 100	5
X-MARS	10 to 100	70	5	50 to 100	5

TPE Disposable Sets

High Flow Sets

Priming Parameters and Blood Flow Rates

Set	Number of priming cycles	Total priming volume (ml)	Blood flow range (ml/min)	Blood flow increment (ml/min)	Blood volume (ml)
TPE2000	3	3000	100 to 250	5	125

Return Blood and Recirculation Flow Rates

Set	Return Blood flow range (ml/min)	Default set value for Return Blood (ml/min)	Return Blood increment (ml/min)	Recirculation flow rate range (ml/min)	Recirculation flow rate increment (ml/min)
TPE2000	10 to 100	70	5	50 to 100	5

Chapter 14

User-controllable Settings

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About the Chapter

User-controllable settings and the mode in which they can be altered are listed in the tables below. Each setting has a default value and a range of setting options. Some settings, such as alarm limits, can only be adjusted in Custom mode. Most of the user-controllable settings can be adjusted in more than one mode.

General Settings

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
Time	Time set by the manufacturer	Should always be set to current hour and minute (24-hour clock)	X		
Date	Date set by the manufacturer	Should always be set to current year, month, and day	X		
Date Display	Day/Month/Y-ear	Day/Month/Year, or Month/ Day/Year	X		
Patient Body Weight	Mandatory input during setup	1–999 kg		X	X
Patient Hematocrit	30%	10 to 60% Increment: 1%		X	X
Return Blood Flow Rate Note: End Mode only	Specific to therapy / set	10 to 100 ml/min Increment: 10 ml/min			
Auto Blood Return Volume Note: In End mode the setting is rounded to closest 5 ml	75% of the disposable set volume	50 to 150% of the disposable set volume	X		
Recirculation Rate Note: End mode, Recirculation only	Specific to set	10 to 150 ml/min Increment: 10 ml/min			
Status Graph Display (line graph of TMP and Pressure Drop trends)	On	On, Off	X		
Status Graph Period	Last 3 hours	Last 1, 2, or 3 hours	X		X
Chart Reminder	Off	On, Off			X
Chart begin time	00:00	00:00 to 23:00	X		
Doses begin time	00:00	00:00 to 23:00	X		
Chart intervall	1 h	1, 2, 3, 4, 6, 8, 12 or 24 hours	X		
Audible alarm volume	High	Low, Moderate, High			X

CRRT Specific Settings

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
"Time to Change Set" Advisory Limit	After 72 hours of use	After 24 to 72 hours of use. Increment: 24 hours	X		
"TMP Too High" Advisory Limit	+300 mmHg	+70 to +300 mmHg Increment: 10 mmHg	X		
"Filter is Clotting" Advisory Limit	Filter pressure drop is +100 mmHg greater than initial filter pressure drop	+10 to +100 mmHg greater than initial filter pressure drop Increment: 10 mmHg	X		
"Loss Or Gain Limit Reached" Caution Limit	(Body Weight * 18 - 70) ml. The value is rounded to closest 10 ml. If the value exceeds the limit for the set, the maximum value for the set will be used.	M60: 60 - 200 ml Other sets: 100 - 400 ml Increment: 10 ml		X	
Blood Flow Rate	Specific to therapy / set	Specific to therapy/set Maximum Range: 10 to 450 ml/min Increment: Specific to set / therapy	X	X	X
PBP Flow Rate	0 ml/h	Specific to therapy/set Maximum Range: 0, 10 to 4000 ml/h Increment: flow rate dependent (min 30ml/h)	X	X	X
Replacement Flow Rate	0 ml/h	Specific to therapy/set Maximum Range: 0, 50 to 8000 ml/h Increment: 50 ml/h	X	X	X
Replacement Solution Delivery Method	CVVH: 100% Pre-filter CVVHDF: Pre-filter	CVVH: 0 to 100% Pre-filter Using Replacement PRE%: increment 5% CVVHDF: Pre-filter or Postfilter	X	X	X
Dialysate Flow Rate	0 ml/h	Specific to therapy/set Maximum Range: 0, 50 to 8000 ml/h Increment: 50 ml/h	X	X	X
Patient Fluid Removal Rate	0 ml/h	Specific to therapy/set Maximum Range: 0, 10 to 2000 ml/h Increment: 10 ml/h	X	X	X

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
Empty Bag Method	Fixed	Fixed or Variable	X		
Allowed Bag Volume — PBP Bag	5000 ml	250 to 5000 ml Increment: 50 ml	X		X
Allowed Bag Volume — Replacement Bag	5000 ml	500 to 5000 ml Increment: 100 ml	X		X
Allowed Bag Volume — Dialysate Bag	5000 ml	500 to 5000 ml Increment: 100 ml	X		X
Allowed Bag Volume — Effluent Bag	5000 ml	5000 or 9000 ml	X		X
“Access Extremely Negative” Warning Limit	–250 mmHg	–10 to –250 mmHg Increment: 5 mmHg	X		
“Access Extremely Positive” Warning Limit	+300 mmHg	+10 to +450 mmHg Increment: 5 mmHg	X		
“Return Extremely Positive” Warning Limit	+350 mmHg	+15 to +350 mmHg Increment: 5 mmHg	X		

TPE Specific Settings

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
"TMPa Too High" Advisory Limit	+100 mmHg	0 to +100 mmHg Increment: 10 mmHg	X		
"Plasmafilter is Clotting" Advisory Limit	Filter pressure drop is +60 mmHg greater than initial filter pressure drop.	+10 to +60 mmHg greater than initial filter pressure drop. Increment: 10 mmHg	X		
Blood Flow Rate	Specific to therapy / set	Specific to therapy/set Maximum Range: 10 to 450 ml/min Increment: Specific to set / therapy	X	X	X
PBP Flow Rate	0 ml/h	Specific to therapy/set Maximum Range: 0, 10 to 1000 ml/h Increment: flow rate dependent (min 30ml/h)	X	X	X
Replacement Fluid Flow Rate	0 ml/h	0, 50 to 5000 ml/h Increment: 10 ml/h	X	X	X
Patient Plasma Loss Rate	0 ml/h	0, 10 to 1000 ml/h Increment: 10 ml/h	X	X	X
Empty Bag Method	Variable	Variable	X		
Total Replacement Volume	3000 ml	0 to 10,000 ml Increment: 100 ml		X	X
Replacement Container Volume	N/A	0 to 5000 ml Increment: 10 ml		X	X
Allowed Bag Volume — PBP Bag	5000 ml	250 to 5000 ml Increment: 50 ml	X		X
Allowed Bag Volume — Effluent Bag	5000 ml	5000 or 9000 ml	X		X
"Access Extremely Negative" Warning Limit	–250 mmHg	–10 to –250 mmHg Increment: 5 mmHg	X		
"Access Extremely Positive" Warning Limit	+300 mmHg	+10 to +450 mmHg Increment: 5 mmHg	X		
"Return Extremely Positive" Warning Limit	+350 mmHg	+15 to +350 mmHg Increment: 5 mmHg	X		

Anticoagulation Related Settings

Systemic Anticoagulation Method

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
Syringe Brand	TERUMO 50	20 ml (Holder 20): BD PLASTIPAK TERUMO Kendall Monoject B. Braun (Omnifix) Others 30 ml (Holder 30): BD PLASTIPAK TERUMO B. Braun (Omnifix) Others 50 ml (Holder 50): BD PLASTIPAK TERUMO Codan Luer lock Fresenius Injectomat Kendall Monoject B. Braun (Omnifix) Others 50 ml (Holder 50B): B. Braun (Perfusor) Others	X		
Syringe Delivery Method	Continuous	Continuous or Bolus		X	X
Syringe Continuous Delivery Rate	0 ml/h	0, 0.5 to 5.0 ml/h for 20 ml syringe; 0, 0.5 to 10.0 ml/h for 30 ml syringe. 0, 2.0 to 20.0 ml/h for 50 ml syringe Increment: 0.1 ml/h		X	X
Syringe Bolus Delivery Volume	0 ml	0, 0.5 to 5.0 ml for 20 ml syringe; 0, 1.0 to 5.0 ml for 30 ml syringe; 0, 2.0 to 9.9 ml for 50 ml syringe Increment: 0.1 ml		X	X
Syringe Bolus Delivery Interval	Once every 6 hours.	Once every 1 to 24 hours Increment: 1 hour Note: Immediate option also available in Run mode		X	X
Syringe “Immediate” Bolus Volume Note: End mode, Recirculation only	0 ml (no delivery)	0 ml, or 0.5 to 5.0 ml Increment: 0.1 ml			

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