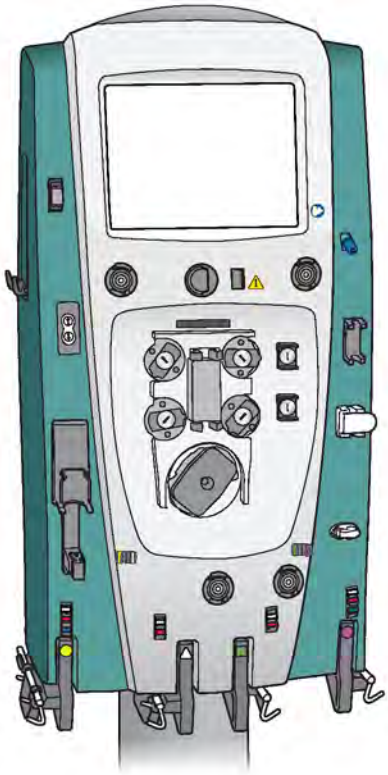
Prismaflex® Operator's Manual



Operator’s Manual

Program version 8.XX

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Trademarks

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

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1 Before you get started

1.1 General information

1.1.1 Intended use

The Prismaflex control unit is intended for:

- Continuous Renal Replacement Therapy for patients with acute renal failure and/or fluid overload.
- Therapeutic Plasma Exchange Therapy for patients with diseases where removal of plasma components is indicated.
- Hemoperfusion for patients with conditions where immediate removal of substances by adsorption is indicated.
- Hemopurification for patients with conditions where extracorporeal elimination of carbon dioxide is indicated.

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

1.1.2 Contraindications

There are no known contraindications to Continuous Renal Replacement Therapies.

There are no known contraindications to Therapeutic Plasma Exchange.

There are no known contraindications to Hemoperfusion.

There are no known contraindications to Hemopurification.

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

1.1.3 Keywords used in this manual

Applied part
Applied part is any part of the Prismaflex system that needs to physically contact the patient in normal use. Lines of the disposable set are applied parts. A general warning sign by the discharger ring guide indicates connection between the Prismaflex control unit and applied part.

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
- Hemopurification cartridge

Manual
The term Manual refers to this 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 bold letters, e.g. **NEW PATIENT** or **CHANGE BAG**.

Total weight
Total weight is weight of the Prismaflex control unit including maximum load of accessories, disposables and solutions.

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

Transport position
Transport position requires that the operator is at the rear of the Prismaflex control unit, moving the machine in a forward direction by the rear handles. See Section 4.3.1 “Moving the Prismaflex® control unit” on page 85.

1.2 Where to find information

1.2.1 Operator's manual

This manual provides operating, maintenance, and troubleshooting instructions, as well as general information. See Section 2 “Description of the Prismaflex® system” on page 35 for information about the Prismaflex control unit and system components. See Section 3 “General Prismaflex® functions” on page 59 for description of the principles of operation of the system, notably about fluid and pressure management. See Section 4 “Operating the Prismaflex® system” on page 75 for explanation of the system interface, an overview of a treatment sequence and the routine handling steps. Specific therapy information is provided for:

- CRRT in Section 5 “Continuous renal replacement therapies (CRRT)” on page 105
- TPE in Section 6 “Therapeutic plasma exchange (TPE)” on page 133
- HP in Section 7 “Hemopurification (HP)” on page 147
- Anticoagulation in Section 8 “Anticoagulation methods” on page 157

1.2.2 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).

1.2.3 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.

1.3 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 septeX – Continuous Renal Replacement Therapies with high cut-off membrane

- CVVHD – Continuous Veno-venous Hemodialysis
- CVVHD+post – Continuous Veno-venous Hemodialysis + post infusion

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

HP – Hemopurification

! **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.

1.4 Anticoagulation methods

For detailed instructions about the different anticoagulation methods, see Section 8 “Anticoagulation methods” on page 157

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

- Systemic, Prismaflex syringe pump
- No anticoagulation
- Citrate – Calcium, external pump
- Citrate – Calcium, Prismaflex syringe pump

NOTE!
All anticoagulation methods beside “No anticoagulation” require a service configuration. Contact your local representative for additional information.

1.5 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 the Service Manual and the Operator's 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.

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.

1.6 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.

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.

NOTE!
Notes are added to give more information.

1.7 General warnings and cautions

1.7.1 Warnings

General

WARNING!
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.

WARNING!
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.

WARNING!
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.

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

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

WARNING!
The combined Prismaflex and MARS system complies with the Type B applied part classification per IEC 60601-1 standard. Do not use central venous catheter in atrial location in combination with the MARS system. Failure to comply can result in arrhythmia due to leakage currents and electric shock.

WARNING!
The Prismaflex system in combination with the PrismaLung disposable kit and NovaTherm heater/cooler device complies with the Type B applied part classification per IEC 60601-1 standard. Do not use central venous catheter in atrial location in combination with the NovaTherm heater/cooler device. Failure to comply can result in arrhythmia due to leakage currents and electric shock.

Service and Repairs

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

WARNING!
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

WARNING!
All electrical installations must comply with all applicable local electrical codes and the manufacturer’s specifications.

WARNING!
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 connect to multiple socket-outlets. However, if using multiple socket-outlets, they must comply with IEC 60601-1 and must not be placed on the floor. Additional multiple socket-outlets must not be connected to the system.

WARNING!
Use only the Prismaflex hospital grade power cord to connect the Prismaflex control unit to the facility’s electrical outlet.

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

WARNING!
The protection of the Prismaflex system against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.

Environment

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

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 Section 13.5.7 “Electromagnetic emissions and immunity” on page 280 in this manual.

IT Network Connectivity

WARNING!
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 Responsible Organization should identify, analyze, evaluate and control risks due to integration of Prismaflex in an IT network. Subsequent changes to the IT network could introduce new risks and require new analysis. 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.

WARNING!
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.

WARNING!
If treatment history data is to be downloaded from the Prismaflex system, the Responsible Organization is obliged to verify its suitability for medical purposes. It is the responsibility of the physician to verify all data before prescribing any therapeutic or pharmacological action for the patient. Treatment history may be erroneous and is intended for use by Gambro authorized personnel.

WARNING!
Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1, third edition, clause 16). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local Gambro representative or the technical service department.

WARNING!
No active component is allowed to be connected to the USB port. Use only USB flash drive for data transfer.

Handling the Prismaflex Control Unit

WARNING!
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.

WARNING!
After turning ON the control unit, verify 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!
Never insert fingers in the return line clamp or in the pinch valves.

Setup and Priming

WARNING!
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.

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

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!
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 artifacts may lead to patient injury or death.

Treatment Monitoring

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

WARNING!
When responding to any alarm, carefully follow the instructions on the displayed alarm screen and its associated `Help` screen.

WARNING!
Do not override the same alarm repeatedly. End treatment and call for service.

WARNING!
Monitor patient blood chemistry to ensure electrolyte balance and normoglycemia.

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.

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 11.13 “Leakage in pressure pods or wet fluid barrier” on page 258.

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.

WARNING!
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!
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.

WARNING!
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.

WARNING!
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.

WARNING!
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.

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!
Do not touch the discharger ring during operation.

WARNING!
Do not use ultrasound gel on the air bubble detector, and ensure the inserted blood line segment is free from coaguli. Failure to comply may impair the function of the air bubble detector.

WARNING!
Blood flow and treatment efficacy may be reduced when the Access pressure is extremely negative. Refer to Section 13.1.1 “Flow rates and accuracy” on page 268 for blood flow range, accuracy and pressure ranges over which this accuracy is maintained.

Fluid Management

WARNING!
The Prismaflex control unit is intended to be used on patients weighing 8 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 2-1 “Sets and patient weight limits” on page 53.

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

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

WARNING!
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.

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

WARNING!
Do not place items in the drip tray of the Prismaflex control unit. Items placed in the drip tray, such as towels or other fluid absorbing material, may impede detection of fluid leaks and related fluid imbalance.

Solutions and Bags

WARNING!
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.

WARNING!
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.

WARNING!
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.

WARNING!
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.

WARNING!
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

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

WARNING!
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.

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

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!
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.

1.7.2 Cautions

Service and Repairs

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

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

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.

Environment

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

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

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

Handling the Prismaflex Control Unit

CAUTION!
Transport position requires that the operator is at the rear of the Prismaflex control unit, moving the machine in a forward direction by the rear handles. Do not apply force to e.g. syringe pump or scales.

CAUTION!
Before moving the Prismaflex control unit, check that all brakes are released and ensure that all of the scales are firmly closed.

Setup and Priming

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!
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.

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.

Treatment Monitoring

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

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

Hygienic Considerations

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

CAUTION!
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.

1.8 Symbols

1.8.1 About symbols

If applicable, the following symbols appear on or near the serial number label or other permanently affixed labels of this device.

See Section 13 “Specifications” on page 266 for more information.

1.8.2 Electrical safety


Equipment applied part is Type CF, defibrillation-proof per IEC 60601-1. 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.

1.8.3 Instructions and warnings


General warning sign.


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. 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.

This symbol warns of a closing motion of mechanical parts of equipment.

The weight of the Prismaflex control unit including equipment used for the treatment placed on the machine.

1.8.4 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.

1.8.5 Communication

Ethernet port.

RS232 Serial Communication port.

USB port.

Remote alarm connection.

1.8.6 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.

1.8.7 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.

1.8.8 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.

1.8.9 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.

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.

1.9 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.

CAUTION!
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.

CAUTION!
Remove the calibration weights, if equipped in the stand of the Prismaflex control unit foot, before tilting the Prismaflex control unit into horizontal position.

CAUTION!
Prior to using the Prismaflex control unit, let the unit rest at ambient operating temperature for 1 hour.

1.10 Disposal

1.10.1 Disposal of packaging material

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

1.10.2 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.

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

1.10.3 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
Electromechanical 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 GB/T 26572-2011 limit (Chinese regulation).
X: Indicates that the concentration of the hazardous substance in at least one homogeneous material of the part is above the GB/T 26572-2011 limit (Chinese regulation).

1.10.4 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 “Battery symbols” on page 32). Labelling also indicates potential presence of harmful substances (Hg = Mercury, Pb = Lead, Cd = Cadmium).

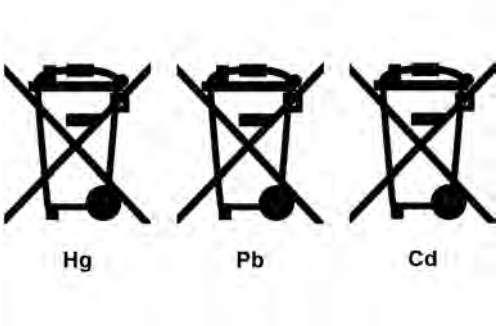

Figure 1-1. Battery symbols

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.

Table 1-1. 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

Table 1-2. Chemical Composition

Item	Active ingredients	Approx. percentage (%) of total weigh	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 -Sulphuric acid solution	60-70 20-30	-ABS resin -Glass separator	580 g
100224039	-Lead (Pb, PbO2, PbSO4) -Sulphuric acid	70 20	-ABS plastic -Fiberglass	1180 g (for one battery)

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2 Description of the Prismaflex® system

2.1 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.

2.2 Prismaflex® control unit

2.2.1 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.

2.2.2 Control unit package contents

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
- Potential equalization connector
- Prismaflex Operator’s Manual on CD

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2.2.3 Front panel components

2.2.3.1 Pumps

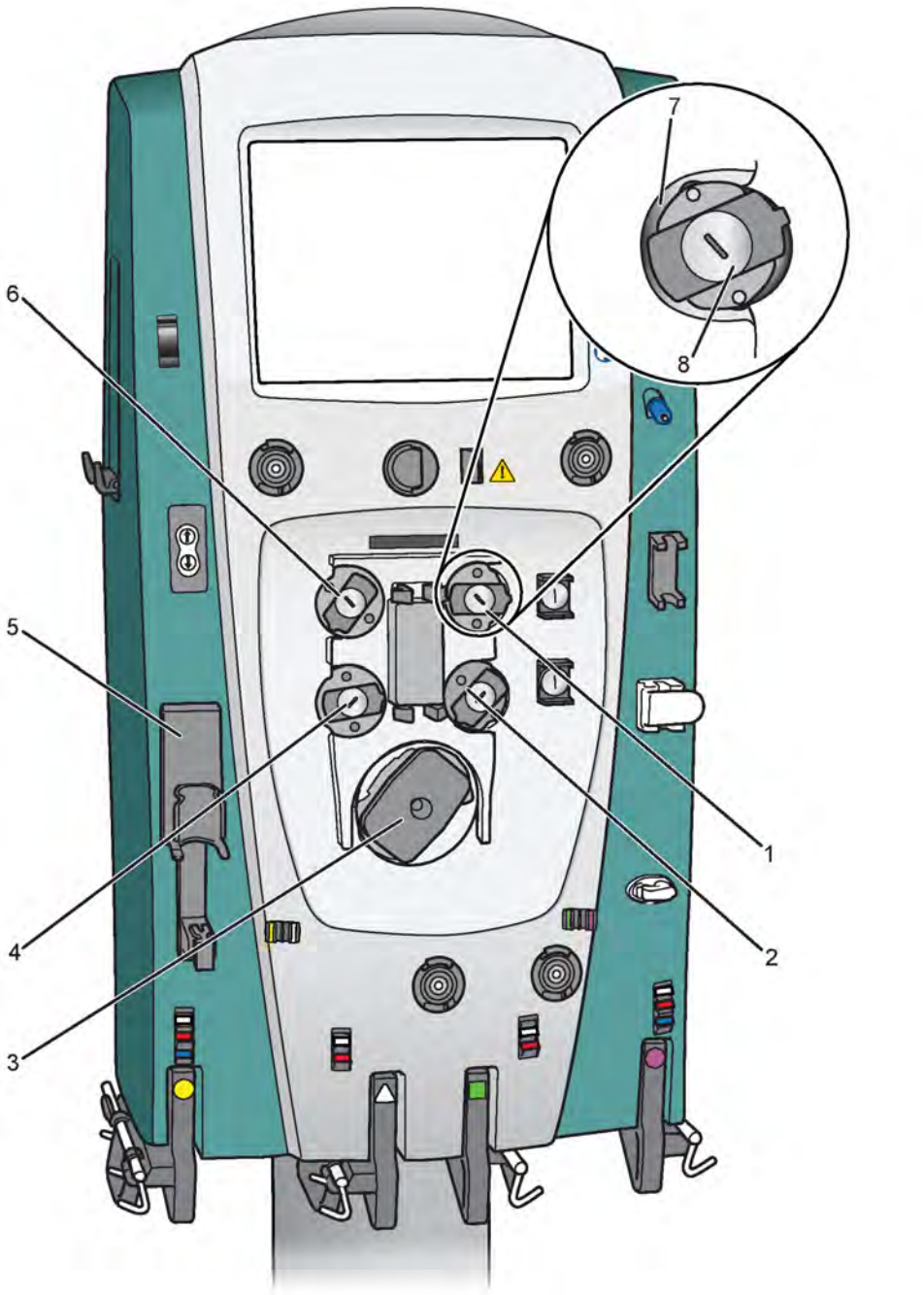

Figure 2-1. Pumps

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.

   In “Citrate – Calcium, Prismaflex syringe pump” anticoagulation the PBP is the pump infusing the citrate solution into the blood access line.

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.

   In “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method, the syringe pump delivers calcium solution into patient via a separate central venous access.

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.

2.2.3.2 Pressure components

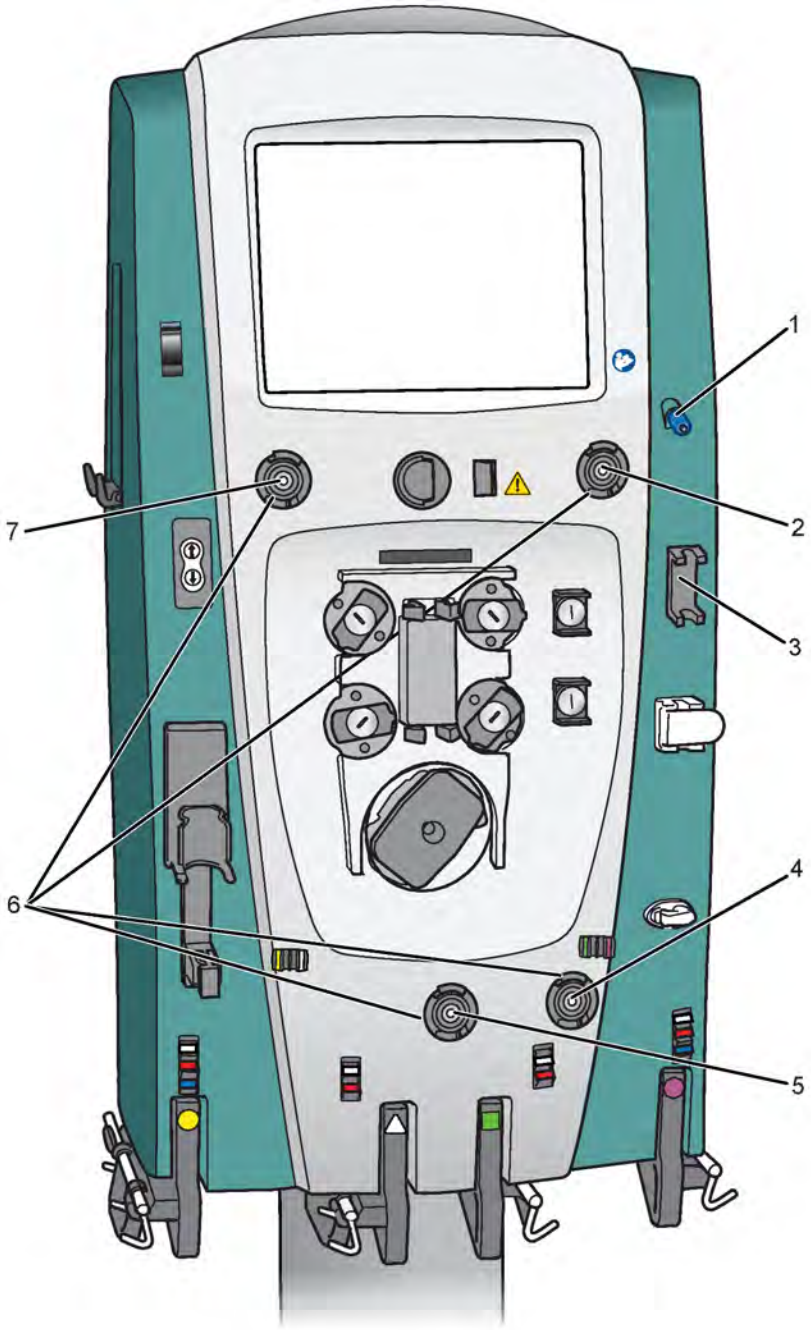

Figure 2-2. Pressure components

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)**

2.2.3.3 Sensors and clamps

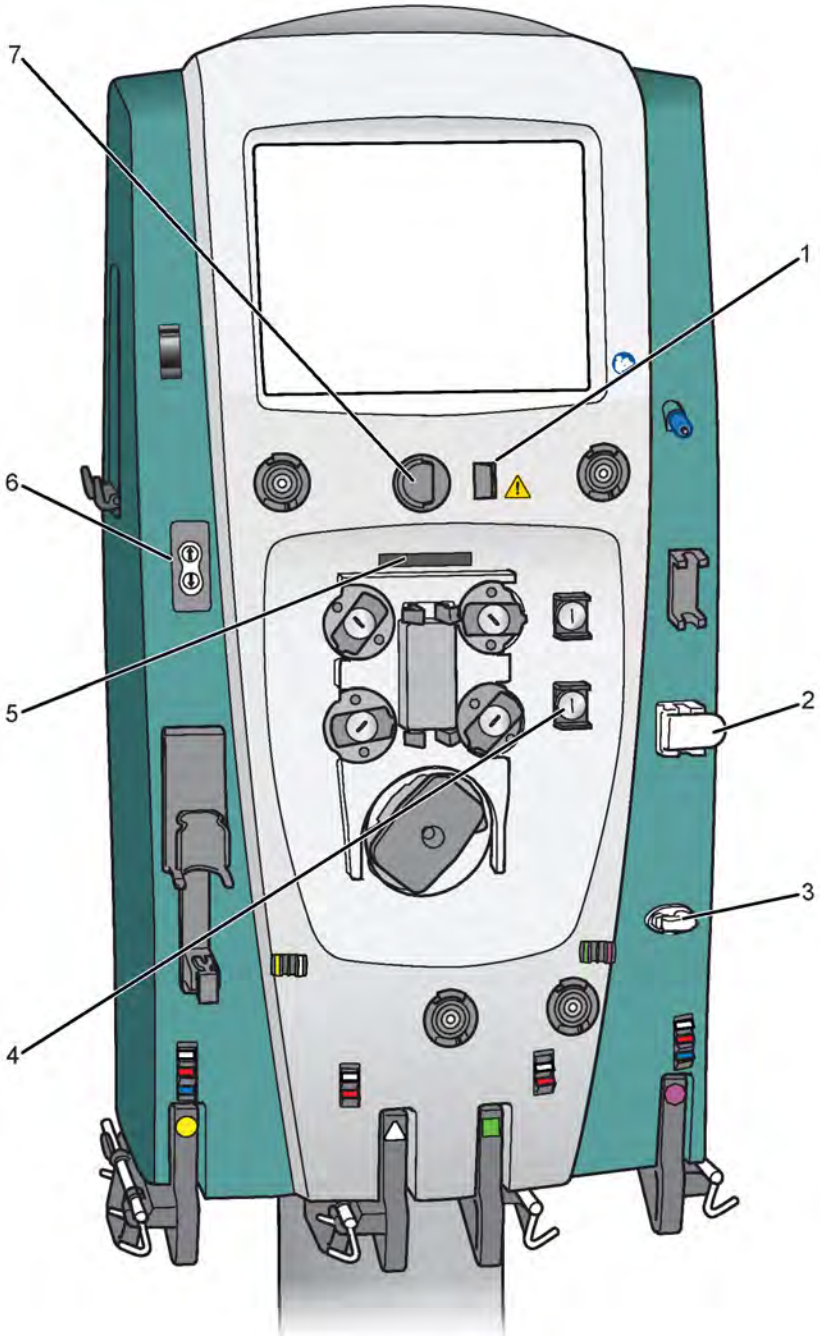

Figure 2-3. Sensors and clamps

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, artifacts 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.

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**

   Not used, not present on all models.

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.

2.2.3.4 Scale components

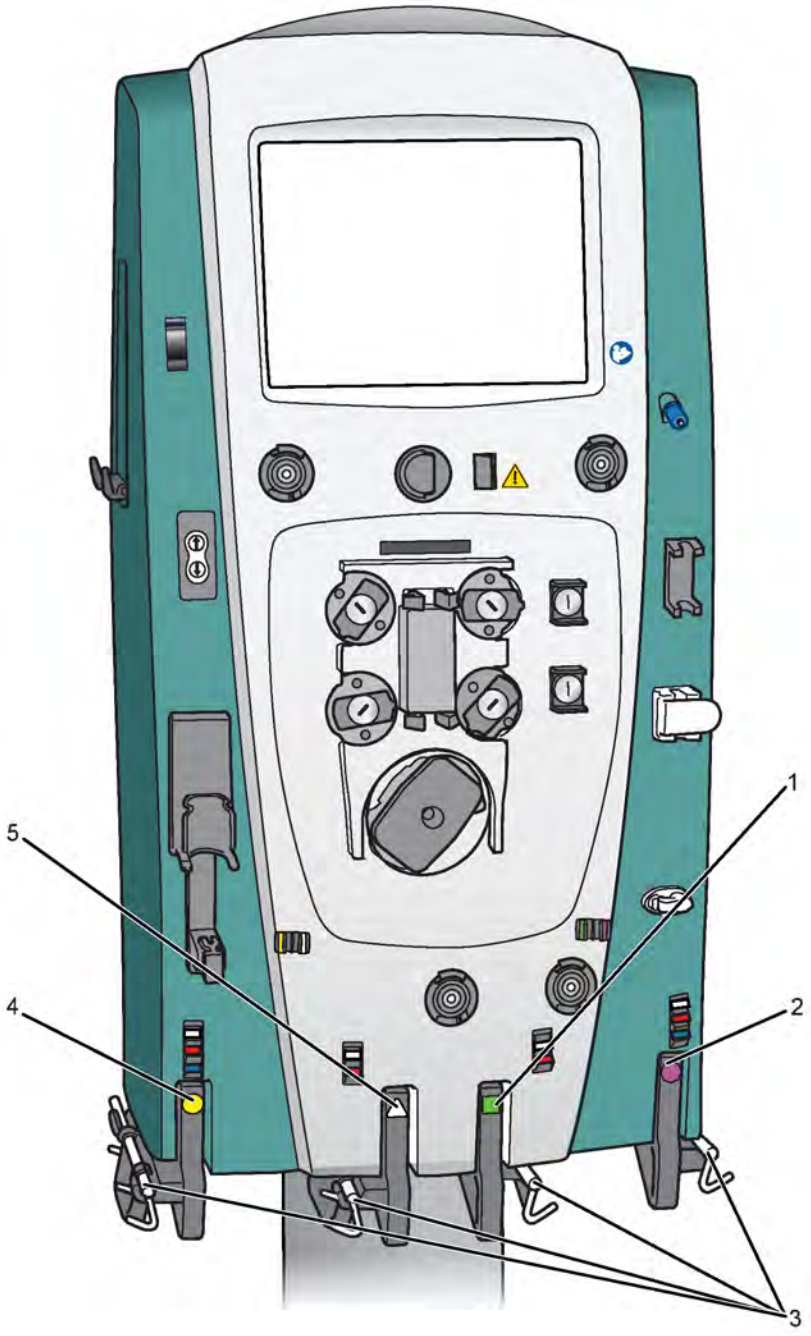

Figure 2-4. Scale components

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 Section 13.4.2 “Scales characteristics” on page 278.
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.

2.2.3.5 Miscellaneous components

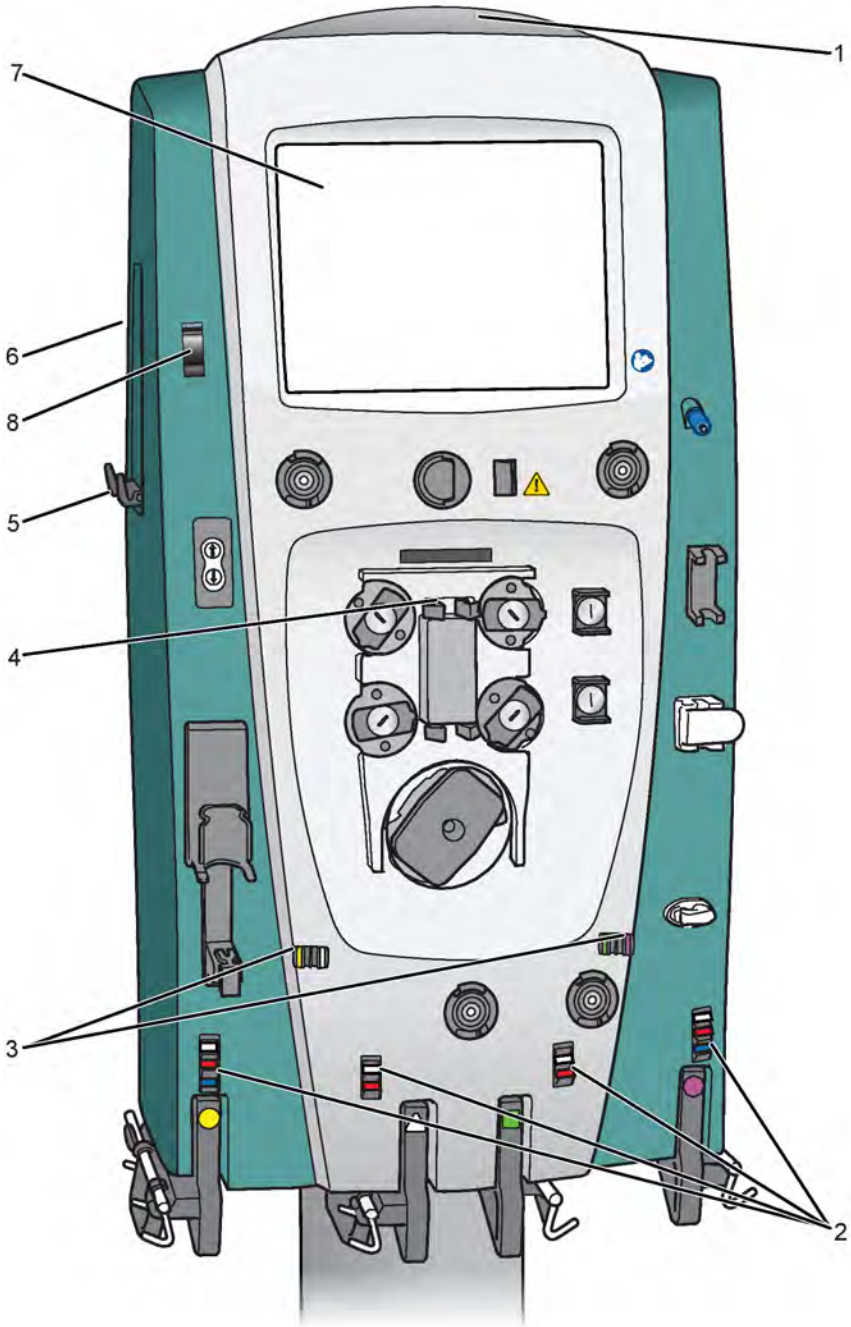

Figure 2-5. Miscellaneous components

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!**
In modes in which a 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**

   Supports the calcium infusion line when performing “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method.

   Temporarily holds the return line during setup of hemopurification sets.

2.2.4 Rear panel components

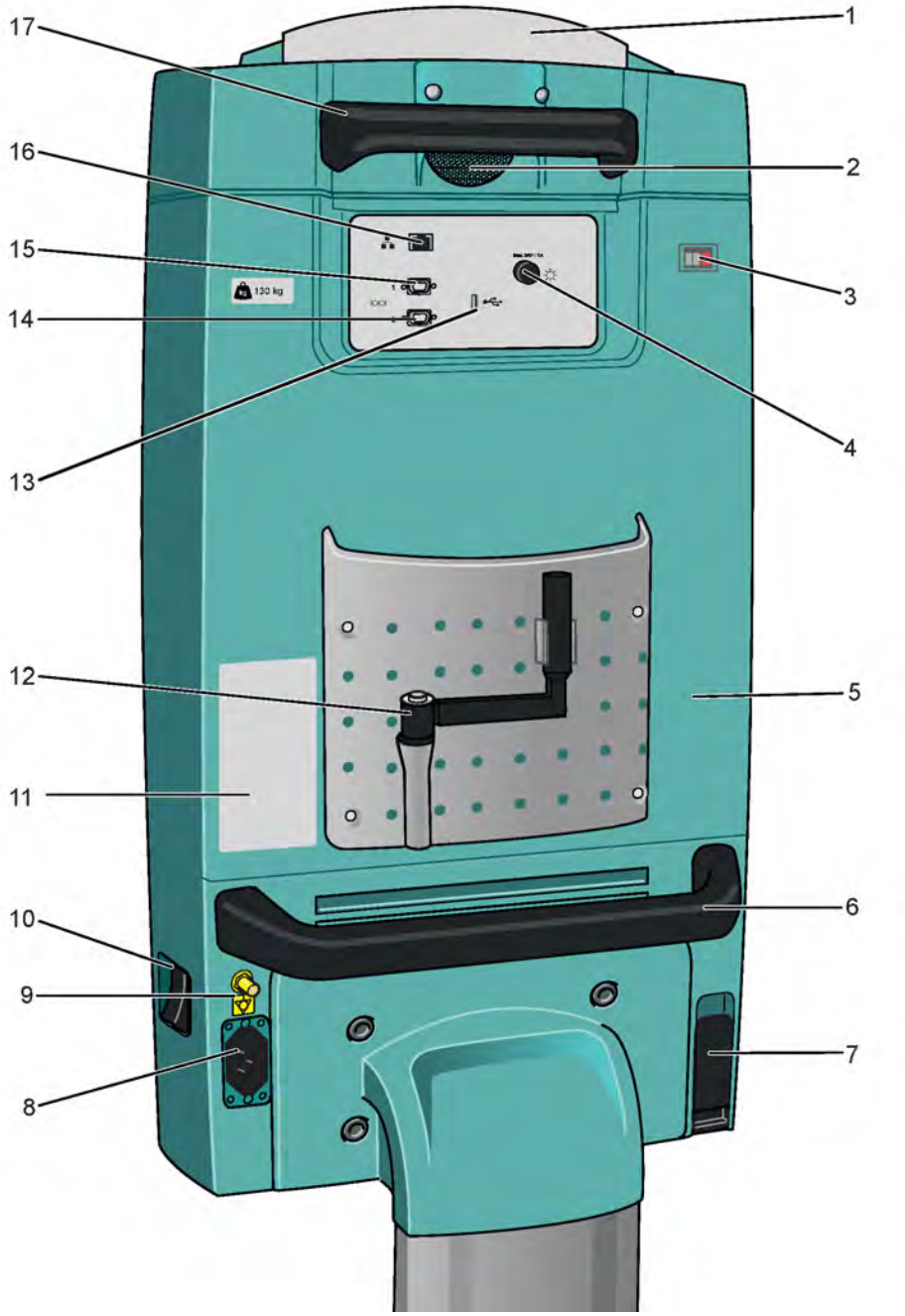

Figure 2-6. Prismaflex control unit: Rear Panel

1. **Speaker**

   Creates alarm sounds.

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. **Type label**

    Lists device specific information, including serial number (SN PAxxxxx).
12. **Pump crank**
13. **USB port**

    You can copy history data to a USB flash drive.
14. **RS232 port 1, 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. This serial port is marked 1 on the rear panel.
15. **RS232 port 2**

    The serial port that is marked 2 and covered with a cap is for future use.
16. **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.
17. **Rear handle (top)**

2.2.5 Stand with drip tray

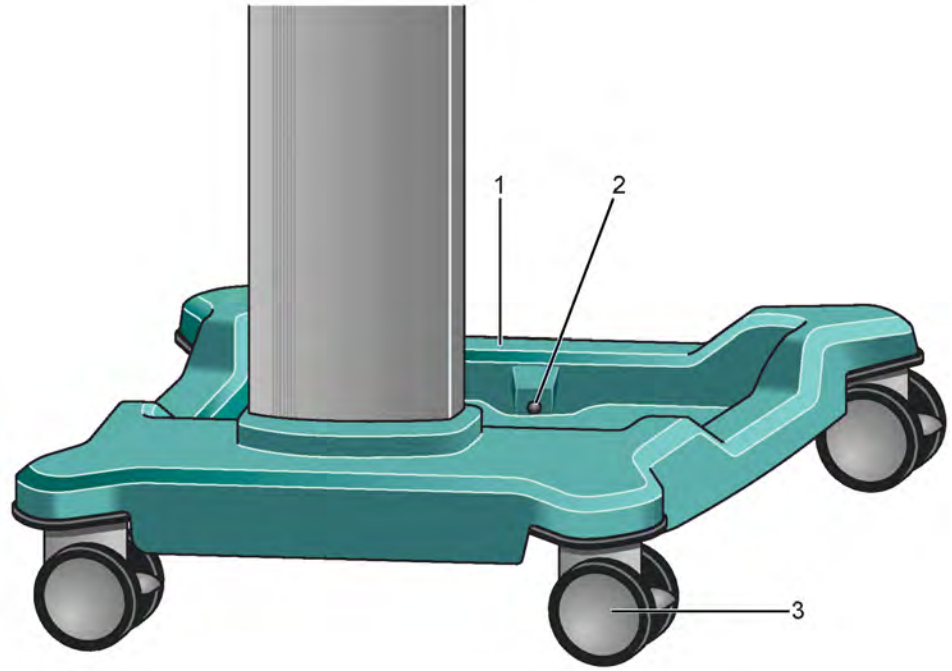

Figure 2-7. Stand – rear view

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.

2.2.6 Stand without drip tray

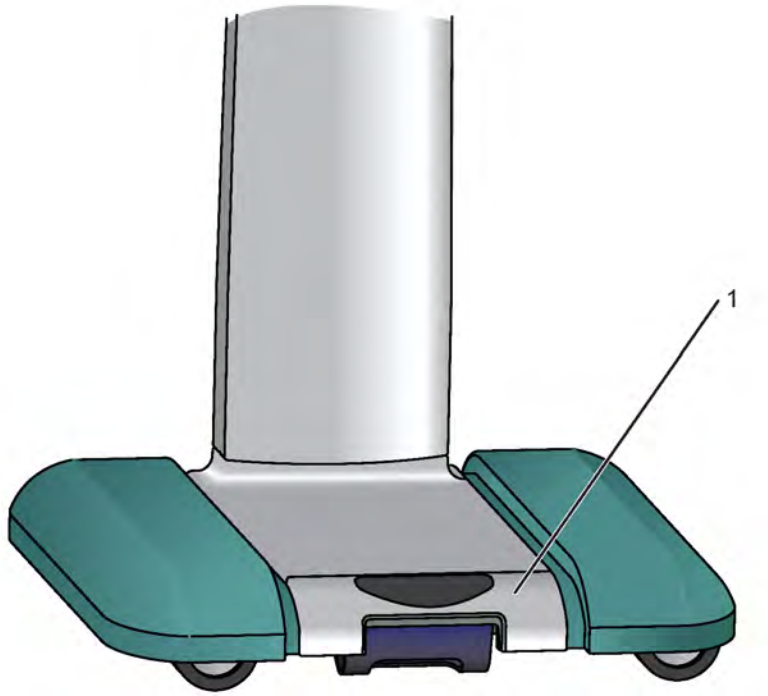

Figure 2-8. Stand – front view

1. **Brake lever**
   Push the lever to lock the casters. Lift the lever to unlock the casters.

2.2.7 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.

2.3 Disposable sets

2.3.1 About 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 5.7 “CRRT with X-MARS™ disposable set” on page 125.

NOTE!
The Adsorba kits differ from this general description, see Section 7 “Hemopurification (HP)” on page 147.

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.

WARNING!
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.

2.3.2 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 Section 14 “Prismaflex® Disposable Sets” on page 286.

2.3.3 Minimum patient weight

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

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

These restrictions should be combined with the weight limitations of disposable sets in relation to extracorporeal blood volume. Combination of these independent limitations result in the minimum patient weight specifications, described in Table 2-1 “Sets and patient weight limits” on page 53.

Table 2-1. Sets and patient weight limits

Disposable limitation		Control unit limitation	Applicable limit
HF20	8 kg	8 kg	8 kg
M60	11 kg		11 kg
ST60	11 kg		11 kg
M100	30 kg	20 kg	30 kg
ST100	30 kg		30 kg
M150	30 kg		30 kg
ST150	30 kg		30 kg
HF1000	30 kg		30 kg
HF1400	30 kg		30 kg
oXiris	30 kg		30 kg
septeX	30 kg		30 kg
X-MARS	Adults		Adults
TPE1000	9 kg	8 kg	9 kg
TPE20	9 kg		9 kg
TPE2000	Adults	20 kg	Adults
TPE60	30 kg		30 kg
Adsorba 150	30 kg	20 kg	30 kg
Adsorba 300	30 kg		30 kg
HP-X	30 kg		30 kg

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

2.3.4 Disposable set components

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

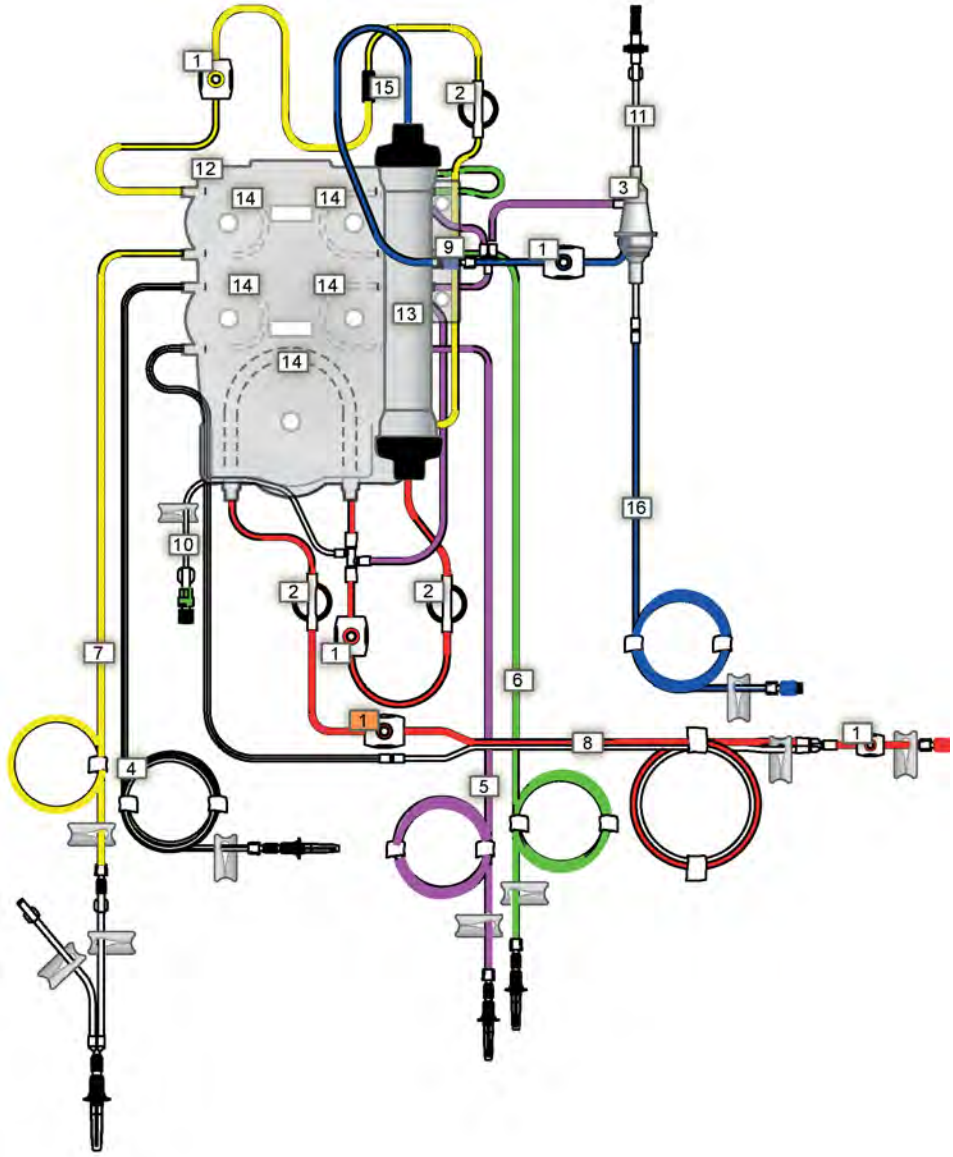

Figure 2-9. Disposable Set components

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 2-9 “Disposable Set components” on page 54 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.

   In “Citrate – Calcium, external pump” anticoagulation method the PBP line conveys the citrate solution.

   In “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method the PBP line conveys the citrate solution.

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 Section 5 “Continuous renal replacement therapies (CRRT)” on page 105.

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 Section 9 “Blood warmers” on page 171 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 11:68 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**

    In the HP-X disposable set, the discharger ring is located on the PBP line.

16. **Return line (blue-striped)**

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

2.4 Prismaflex® accessories

2.4.1 About Prismaflex® accessories

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

2.4.2 Hardware accessories

2.4.2.1 Blood warmers

See Section 9 "Blood warmers" on page 171 for further information.

2.4.2.2 HP cartridge holder

A specialized holder for HP cartridges can be mounted to the Prismaflex control unit. See the *Prismaflex Spare Part Catalog*, or contact your local Gambro representative. When using HP cartridges not produced by the Gambro group, ensure that the cartridge to be used can be mounted and secured in a safe way. See Section 7 "Hemopurification (HP)" on page 147 for further information.

2.4.3 Disposable accessories

2.4.3.1 Effluent bag

All Prismaflex disposable sets include a 5000 mL effluent bag. Additional effluent bags can be purchased separately.

Effluent bag type	Accessory Code
5L effluent bag	SP-414
5L effluent bag	A-6001
9L effluent bag	SP-418

Contact your local Gambro representative for availability.

2.4.3.2 Calcium infusion line

For the "Citrate – Calcium, Prismaflex syringe pump" anticoagulation method, the dedicated calcium infusion line (CA 250) must be used.

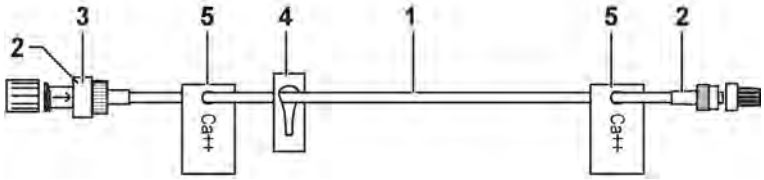

Figure 2-10. The Prismaflex CA 250 Calcium Line assembly

1. Low volume infusion tube
2. Luer lock connectors to patient vascular access and syringe
3. Check valve
4. Slide clamp
5. “Calcium” tags

2.4.3.3 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 Section 6.4.4.2 “Using multiple bags or containers in parallel” on page 144.

2.4.3.4 Prismatherm II extension line

For using the Prismatherm II blood warmer, the SP420 warmer extension line must be used and connected during setup. See Section 9 “Blood warmers” on page 171.

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3 General Prismaflex® functions

3.1 Blood flowpath management

3.1.1 Parts of the blood flowpath

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 Section 3.1.4.1 “How pressure management works” on page 62. The return line is also equipped for the collection of air and the prevention of air infusion to the patient, see Figure 2-9 “Disposable Set components” on page 54.

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.

WARNING!
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.

3.1.2 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.

3.1.3 Blood pump flow rate

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 **Q_{BP}** is blood pump flow (mL/min), **Qb** is set blood flow (mL/min) and **Q_{pbp}** is set PBP flow (mL/min).

3.1.4 Pressure management

3.1.4.1 How pressure management works

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.

3.1.4.2 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 "Pressure components" on page 40.
- 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 "Sensors and clamps" on page 42.

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.

3.1.4.3 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 “Pressure components” on page 40). 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.

3.1.4.4 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.

3.1.4.5 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. Table 3-1 “Extreme pressure default limits for CRRT” on page 64 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 Section 11 “Troubleshooting” on page 187.

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 Section 4.3.7 “Custom mode” on page 99 and Section 15 “User-controllable settings” on page 292 .

Table 3-1. Extreme pressure default limits for CRRT

mmHg		Alarm
+450	—	Warning: Filter Extremely Positive
+350	—	Warning: Return Extremely Positive
+300	—	Warning: Access Extremely Positive
+10	—	Warning: Set Disconnection; Warning: Return Disconnection
0	—	
-250	—	Warning: Access Extremely Negative

3.1.4.6 Pressure operating points

Whenever the Prismaflex control unit is operating, a reference pressure value is stored in the internal 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 Section 11 “Troubleshooting” on page 187.

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.

Table 3-2. Pressure trending limits

	mmHg		Alarm
↑	+50/+70	—	Advisory: Check Access
	0	—	Advisory: Check Return
Pressure operating Point		—	
↓	-50/-70	—	Warning: Return Pressure Dropping Advisory: Check Access
	-150	—	Warning: Access Extremely Negative

3.1.4.7 “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 Section 11 “Troubleshooting” on page 187.

3.1.4.8 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 Section 4.3.7 “Custom mode” on page 99. For more information and treatment specific details, see Section 5 “Continuous renal replacement therapies (CRRT)” on page 105, Section 6 “Therapeutic plasma exchange (TPE)” on page 133and Section 7 “Hemopurification (HP)” on page 147.

3.1.4.9 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:

Table 3-3. 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 Section 3.1.4.6 “Pressure operating points” on page 64. 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: Section 4.3.7 “Custom mode” on page 99, Section 5 “Continuous renal replacement therapies (CRRT)” on page 105, Section 6 “Therapeutic plasma exchange (TPE)” on page 133 and Section 7 “Hemopurification (HP)” on page 147.

3.2 Fluid management

3.2.1 How fluid management works

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.

3.2.2 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.

3.2.3 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 11 kg (see also Section 13 “Specifications” on page 266).

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 Section 4.3.10.4 “Changing a bag during treatment” on page 101 for further instructions.

3.2.4 Empty bag methods

3.2.4.1 Fluid bags and containers

The Prismaflex system offers two methods for the automatic detection of empty bags or containers. See also Section 4.3.10.4 “Changing a bag during treatment” on page 101 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 Section 6 “Therapeutic plasma exchange (TPE)” on page 133 .
- HP therapies. See operating instructions in Section 7 “Hemopurification (HP)” on page 147 .

Empty Bag method is user-selectable in custom mode; see Section 4.3.7 “Custom mode” on page 99. 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.

3.2.4.2 Effluent bag

The 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 Section 2.4.3.1 “Effluent bag” on page 56.

3.3 Flow problems

3.3.1 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.

3.3.2 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.

3.3.3 Resolving flow problem alarms

Instructions how to troubleshoot common flow problems are provided on the Caution: Flow Problem alarm screen and in Section 11 “Troubleshooting” on page 187 . 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. For more information and treatment specific details for this alarm, see: Section 4.3.7 “Custom mode” on page 99, Section 5 “Continuous renal replacement therapies (CRRT)” on page 105, Section 6 “Therapeutic plasma exchange (TPE)” on page 133 and Section 7 “Hemopurification (HP)” on page 147.

3.4 Air management

3.4.1 Description

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.

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

3.4.2 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 Section 4.3.13.1 “Fluid level management” on page 104.

3.4.3 Changing the fluid barrier

In case the fluid barrier has been wet, it is recommended to interrupt the therapy and change the set. Instructions are provided in Section 11.13 “Leakage in pressure pods or wet fluid barrier” on page 258.

3.5 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 syringe pump can also be used for calcium infusion during citrate treatment, if configured in service mode by an authorized service technician. Contact the local representative for further information.

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.
- **Citrate – Calcium, external pump**. For treatments using citrate anticoagulation. Requires citrate solution on the PBP scale. The Prismaflex syringe pump is disabled during the entire treatment. Calcium must be infused via an external infusion pump.
- **Citrate – Calcium, Prismaflex syringe pump**. For treatments using citrate anticoagulation. Requires citrate solution on the PBP scale. The Prismaflex syringe pump is used for calcium infusion. Requires dedicated Prismaflex calcium infusion line connected to syringe.

“Citrate - Calcium” anticoagulation methods are not available in all therapies. For detailed instructions about anticoagulation management, see Section 8 “Anticoagulation methods” on page 157.

3.6 Treatment preparation

3.6.1 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.

3.6.2 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.

NOTE!
Presence of a Citrate solution bag on PBP scale is required in the following situations:

- If the “Citrate – Calcium, external pump” anticoagulation method has been selected.
- If the “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method has been selected.

3.7 Alarm and monitoring systems

3.7.1 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 visual and audible device alarms.

Alarms are prioritized into Warning, Malfunction, Caution, and Advisory alarms. See Section 10 “Alarm system” on page 177, for more information.

3.7.2 Monitoring systems

3.7.2.1 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 Section 3.1.4.3 “Components for return pressure monitoring” on page 63.

3.7.2.2 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.

3.7.2.3 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.

3.7.2.4 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 Section 3.2 “Fluid management” on page 66, and Section 3.3 “Flow problems” on page 68.

3.7.2.5 Fluid leak detector

The Prismaflex control unit has a fluid leak detector in the drip tray of the stand. The system continually monitors the drip tray for fluids. If a fluid leak is detected, the operator is notified via alarms.

3.8 Self-tests of the Prismaflex® system

3.8.1 About 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 Section 11 “Troubleshooting” on page 187 .

3.8.2 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.

3.8.3 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.

3.8.4 Periodic self-test

3.8.4.1 Periodic self-test description

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 an alarm occurs at the scheduled start of a periodic self-test, the self-test starts after the alarm is cleared. Periodic self-test may be delayed 10 min by selecting the **DELAY TEST** softkey. When a periodic self-test has not been completed within the last 150 minutes of treatment, 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. The self-test is then resumed from the beginning of the interrupted self-test phase when the **RESUME** softkey is pressed on the `Stop` screen.
- Following an operator’s request (Run mode): A complete 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.

The following Periodic self-tests are performed:

1. Blood Leak Detector Test
2. +24 V and Return Clamp Test
3. Pressure Pod Repositioning
4. Return Pressure Sensor Test

3.8.4.2 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.

3.8.4.3 Periodic sound check

At least once every 24 hours, the system performs a sound check of the audible alarms by playing a Reminder beep and a short beep from the Power Supervision Board buzzer.

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4 Operating the Prismaflex® system

4.1 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.

4.2 System overview

4.2.1 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.

4.2.2 Definitions

4.2.2.1 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.

4.2.2.2 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.

4.2.2.3 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.

4.2.2.4 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.

4.2.3 User-controllable settings

4.2.3.1 Default values

The tables in Section 15 “User-controllable settings” on page 292 lists all user-controllable settings, their default values, setting options, and the operating mode in which they can be changed.

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 Section 4.3.7 “Custom mode” on page 99 .

4.2.3.2 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.

4.2.3.3 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.

4.2.4 Prescription settings

4.2.4.1 About 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
- the PBP flow rate when using “Citrate - Calcium” anticoagulation methods.
- the syringe flow rate when using “Citrate - Calcium, Prismaflex Syringe Pump” as a “Citrate - Calcium” method.

These flows are automatically set by software, based on all other flow rates and anticoagulation settings. See Section 5 “Continuous renal replacement therapies (CRRT)” on page 105,Section 6 “Therapeutic plasma exchange (TPE)” on page 133and Section 7 “Hemopurification (HP)” on page 147for 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 Section 8 “Anticoagulation methods” on page 157 for the description of available settings in each anticoagulation method.

4.2.4.2 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 Section 4.3.6.1 “Operating modes overview” on page 87 and Section 15 “User-controllable settings” on page 292.

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 Section 4.3.7 “Custom mode” on page 99.

4.2.4.3 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 Section 4.3.6.1 “Operating modes overview” on page 87.

4.2.5 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), pressure drop (HP).

Table 4-1. 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 SYR/LINE	Only displayed when the Citrate-Calcium anticoagulation method has been selected. Navigates the user to the `Change Syringe/Calcium Line` screen. Allows for changing of syringe and/ or calcium line.
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.

4.2.6 History data

4.2.6.1 Accessing history data

Vital machine conditions and operating data of the last treatment are automatically saved in the internal memory.

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 is automatically saved in a history data file in the internal memory for later transferral of the data to the USB flash drive. For further information, see Section 4.2.6.8 “Saving the history data” on page 85.

With the left and right arrows, the operator can scroll through four 24-hour intervals. Circles between the arrows are displayed unfilled if there is 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).

4.2.6.2 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/HP) 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 15.1 “General settings” on page 293 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.

4.2.6.3 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”).

4.2.6.4 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.

4.2.6.5 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.

4.2.6.6 History data after a completed treatment

After a treatment is concluded, the history data is stored in the internal 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.

4.2.6.7 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 internal memory.

4.2.6.8 Saving the history data

In `End mode` (when unloading the set), the history data for the current treatment is automatically saved as a file in the internal memory. The memory stores up to 100 consecutive treatment files; thereafter, the oldest data is gradually replaced with new data.

It is possible to download all history data files from the internal memory to a USB flash drive. To download the history data files:

1. Go to the `Choose Patient` screen.
2. Press the **DOWNLD DATA** soft key.
3. Follow the online instructions on the `Download` screen.

NOTE!
The naming of the folder collecting the downloaded files on the USB flash drive is based on the serial number of the Prismaflex machine.

NOTE!
The patient ID is hidden by default when using any of the external communication protocols. The Responsible Organization has the legal responsibility to comply with data security and confidentiality requirements.

4.3 Therapy operation

4.3.1 Moving the Prismaflex® control unit

The caster size of the Prismaflex control unit allows it to pass over an 10 mm step. To pass over a 2 cm step, do not push, but pull the control unit by the handles.

CAUTION!
Transport position requires that the operator is at the rear of the Prismaflex control unit, moving the machine in a forward direction by the rear handles. Do not apply force to e.g. syringe pump or scales.

4.3.2 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.

4.3.3 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. 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 Section 10 “Alarm system” on page 177). For more information, see Section 10 “Alarm system” on page 177.

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 the internal 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.

An **AUDIO PAUSED** softkey appears on certain screens. By pressing the button the operator can pause the audio for the alarm system.

4.3.4 Startup

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

Procedure

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 followed by a short PSB signal 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 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.

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 therapies and the Prismaflex disposable sets, or can proceed to the Choose Patient screen.

4.3.5 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 “Prismaflex control unit: Rear Panel” on page 48.

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 Section 11.12.1 “Reason for manual termination” on page 254.

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.

  - 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.

4.3.6 Operating modes

4.3.6.1 Operating modes overview

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.

4.3.6.2 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:

Procedure

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.
     - Choose **CUSTOM MODE** 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 Section 4.3.7 “Custom mode” on page 99.
     - Choose **LAST HISTORY** to view the history data of the last treatment.
     - Choose **DOWNLD DATA** to download all history data files from the internal memory to a USB flash drive. For more information, see Section 4.2.6.8 “Saving the history data” on page 85.
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.

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 Section 9 "Blood warmers" on page 171.

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 `Review Setup` screen, there is no possibility of returning to previous screens.

17) Adjust the deaeration chamber fluid level if needed.

18) Enter Pre-treatment settings:

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

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 4-2 “Operating Screens in Setup Mode” on page 90. 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.

4.3.6.3 Operating screens in setup mode

Table 4-2. 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`
`Choose HP Cartridge`
`Confirm Set Loaded`
`Key Reminders` (HF20, oXiris, septeX, HP with customized Cartridges)
`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, Access Line Complete` (HP)
`Verify HP Cartridge Setup` (HP)
`Priming X of Y Cycles Complete`
`Prime Test, please wait`
`Review Setup`
`Enter Treatment Settings` (CRRT)
`Enter TPE Prescription` (TPE)

Enter Flow Settings
Enter Anticoagulation Settings (depending on anticoagulation method in use)
Anticoagulation Risks (“Citrate – Calcium, external pump” and “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)
Review Prescription

4.3.6.4 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.

WARNING!
Connect patient

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

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.

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 4-3 “Operating Screens in Standby Mode” on page 91.

4.3.6.5 Operating screens in standby mode

Table 4-3. Operating Screens in Standby Mode

Connect Patient (Standby mode entered from Setup mode)
Blood Prime (available when HF20 disposable set is selected)
Verify Patient Connection
Reconnect Patient (after Recirculation procedure) (Standby mode entered from End mode)
Change Bags
Stop (Standby mode entered from Run mode)

4.3.6.6 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:

Procedure

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.
    - Change the occurrence period of the Advisory: Anticoagulation Checkpoints alarm (valid only when performing "Citrate - Calcium" anticoagulation).
    - 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.

4.3.6.7 Operating screens in run mode

Table 4-4. Operating screens in run mode

`Status`		
	`Enter Flow Settings`	
		`View Prescription Changes`
		`Enter TPE Prescription` (TPE)
		`Anticoagulation Risks` ("Citrate – Calcium, external pump" and "Citrate – Calcium, Prismaflex syringe pump" anticoagulation method)

	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
		View Anticoagulation Solution (“Citrate – Calcium, external pump” anticoagulation method)
		Anticoagulation Risks (“Citrate – Calcium, external pump” and “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)
	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 (Not valid for HP)
		Anticoagulation Check Points (“Citrate – Calcium, external pump” and “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)

4.3.6.8 End mode

4.3.6.8.1 End mode overview

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 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!
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.

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

4.3.6.8.2 Change set and end treatment procedures

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

Procedure

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.

NOTE!
Automatic blood return is disabled when:

- Cumulated Volume Returned exceeds Auto Return Volume
- The set has been blood primed
- Warning: Filter Clotted alarm has been triggered
- Warning: Plasmafilter Clotted alarm has been triggered
- Warning: HP Cartridge 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 saved in internal memory 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 **UNLOAD SYRINGE** softkey. Remove syringe from the holder.

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

4) Select the following steps depending on whether **CHANGE SET** or **END TREATMNT** is selected.

- If **CHANGE SET** has been selected:
  a) Return to the `Load Set` screen in Setup mode.
  b) 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:
  a) View history data, if desired.
  b) 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 4-5 “Change Set and End Treatment Screens in End Mode” on page 95. If a screen is accessed from a prior-appearing screen, it is indented in the table.

4.3.6.8.3 Change set and end treatment screens in end mode

Table 4-5. 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)

4.3.6.9 Recirculation in end mode

4.3.6.9.1 About 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 Section 4.3.6.9.1 “About recirculation in end mode” on page 95.

4.3.6.9.2 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.

Procedure

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
- The set has been blood primed
- Warning: Filter Clotted alarm has been triggered
- Warning: Plasmafilter Clotted alarm has been triggered
- Warning: HP Cartridge 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.

4.3.6.9.3 Saline recirculation screens from stop to patient connection

The recirculation screens available before patient connection are listed in Table 4-6 "Saline Recirculation Screens from Stop to Patient Connection" on page 97. If a screen is accessed from a prior-appearing screen, it is indented in the table.

Table 4-6. Saline Recirculation Screens from Stop to Patient Connection

`Stop`
`Stop Calcium Infusion` (applicable to "Citrate – Calcium, external pump" anticoagulation method)
`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`	
`Change Syringe and Calcium Line` (applicable to “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)	
	`Prime Calcium Line` (applicable to “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)
`Confirm Change Syringe & Ca Line` (applicable to “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)	
`Prepare to Prime`	
`Priming`	
`Priming Complete`	
`Prime Test`	
`Review Setup`	

4.3.6.9.4 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:

Procedure

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.

NOTE!
By pressing **CHANGE SYR+LINE**, the operator can change the syringe and the calcium line after recirculation for the “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method.

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 Section 4.3.6.9.5 “Blood recirculation screens in end mode” on page 99. If a screen is accessed from a prior-appearing screen, it is indented in the table.

4.3.6.9.5 Blood recirculation screens in end mode

Table 4-7. 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`		
	`Change Syringe and Calcium Line` (applicable to “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)	
		`Prime Calcium Line` (applicable to “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)
	`Confirm Change Syringe & Ca Line` (applicable to “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)	

4.3.7 Custom mode

Custom mode allows operator to change the default values of user-controllable settings. 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. The tables in Section 15 “User-controllable settings” on page 292 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:

Procedure

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.

HP, 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.

4.3.8 Screens in custom mode

Table 4-8. Screens in custom mode

Welcome to Custom Mode
Modify Defaults
Filter Settings – Menu
Filter Settings – therapy selected
Edit Priming Solution (available for user defined HP cartridges)
Configure HP Cartridge (available for user defined HP cartridges)
Priming – HP cartridge selected (available for user defined HP cartridges)
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
Citrate (available for “Citrate – Calcium, external pump” anticoagulation method)
Citrate & Calcium (available for “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)

4.3.9 User-controllable settings

User-controllable settings and the mode in which they can be altered are listed in the tables in Section 15 “User-controllable settings” on page 292 on page. 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.

4.3.10 Change bags

4.3.10.1 Change bags function overview

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.

4.3.10.2 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. [1]
- 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.

4.3.10.3 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.

4.3.10.4 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.

Procedure

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.

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

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.

NOTE!
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.

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.

4.3.11 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.

4.3.12 Change syringe procedures

4.3.12.1 Syringe usage

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

It is necessary to install and use a syringe if “Citrate – Calcium, 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.

4.3.12.2 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.

Procedure

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) Connect the filled syringe to the dedicated calcium infusion line, applicable to “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method
4) 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 4-1 “B.Braun Perfusor® syringe installation” on page 103

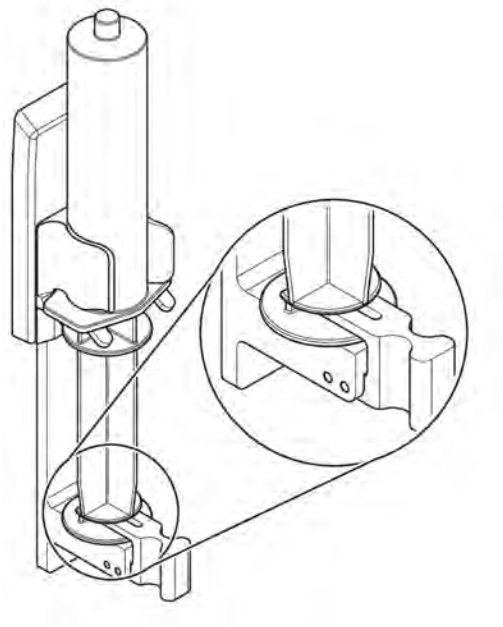


Figure 4-1. B.Braun Perfusor® syringe installation

5) Press the **AUTO UP** softkey until the **CONFIRM** softkey gets visible
6) Lock the syringe plunger

Results

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

4.3.12.3 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.

4.3.13 Deaeration chamber

4.3.13.1 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.

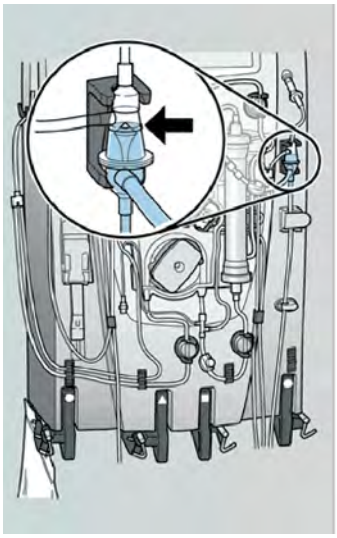


Figure 4-2. Suggested fluid level in the deaeration chamber.

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.

4.3.13.2 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.

5 Continuous renal replacement therapies (CRRT)

5.1 General warnings and cautions

5.1.1 Warnings

WARNING!
Monitor patient blood chemistry to ensure electrolyte balance and normoglycemia.

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.

WARNING!
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.

WARNING!
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.

WARNING!
As treatment proceeds, carefully monitor patient fluid balance levels in the `History` screens.

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.

WARNING!
The blood leak detector must be re-normalized if the effluent line has been removed and then reinserted into the blood leak detector during an ongoing treatment (Run Mode). See Section 11.15 "Blood leak detector normalization" on page 260

5.1.2 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.

CAUTION!
Prismaflex disposable sets require minimum blood flow rates to avoid early clotting of the extracorporeal blood circuit. Refer to Section 14 "Prismaflex® Disposable Sets" on page 286 for the specified flow rate ranges.

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

5.2 Therapy description

5.2.1 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 pass from the patient's blood across the semipermeable membrane and into dialysate flowing at counter flow through the fluid compartment of the filter. The concentration of unwanted solutes is lower in the dialysate than in the blood, causing the solutes to diffuse from an area of greater concentration (the patient's blood) to an area of lesser concentration (the dialysate solution). Solute clearance is achieved by diffusion.
Hemodiafiltration	In hemodiafiltration, both hemodialysis and hemofiltration are used. Solute removal occurs by convection and diffusion. Dialysate solution is pumped through the fluid compartment of the filter. At the same time, the effluent pump controls ultrafiltration and a replacement solution is infused into the blood flowpath.

5.2.2 CRRT modes

5.2.2.1 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.

Table 5-1. 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

Table 5-2. Available flow rate parameters depending on selected CRRT septeX Mode

CRRT mode	CVVHD	CVVHD+
Blood flow	X	X
PBP flow	X	X
Dialysate flow	X	X
Replacement flow	—	POST
Patient Fluid Removal rate	X	X

Table 5-3. 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

5.2.2.2 SCUF (slow continuous ultrafiltration)

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

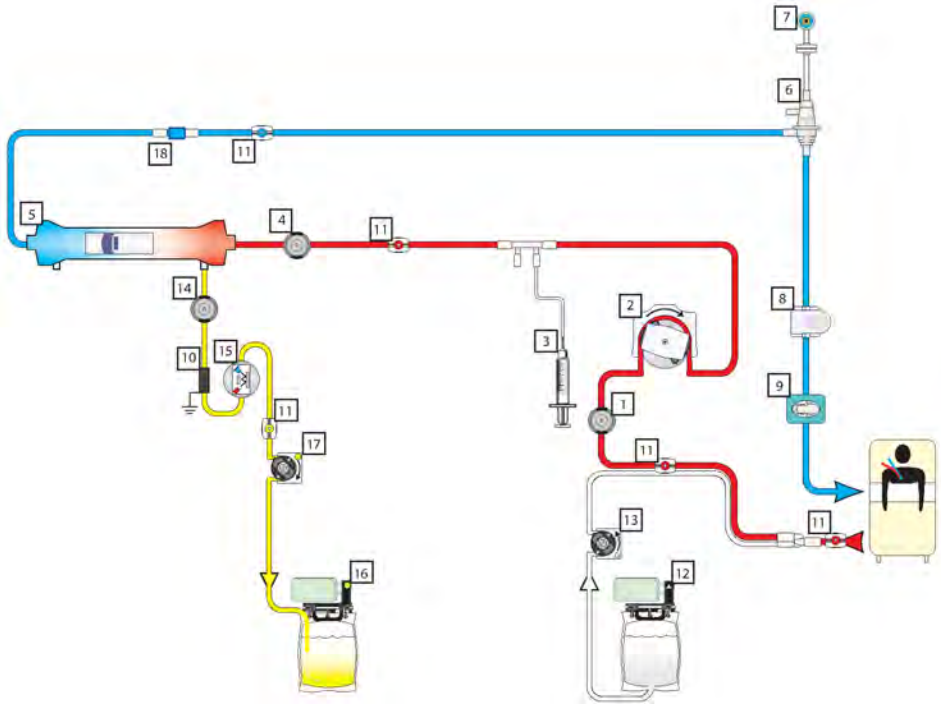


Figure 5-1. SCUF flow

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

5.2.2.3 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.

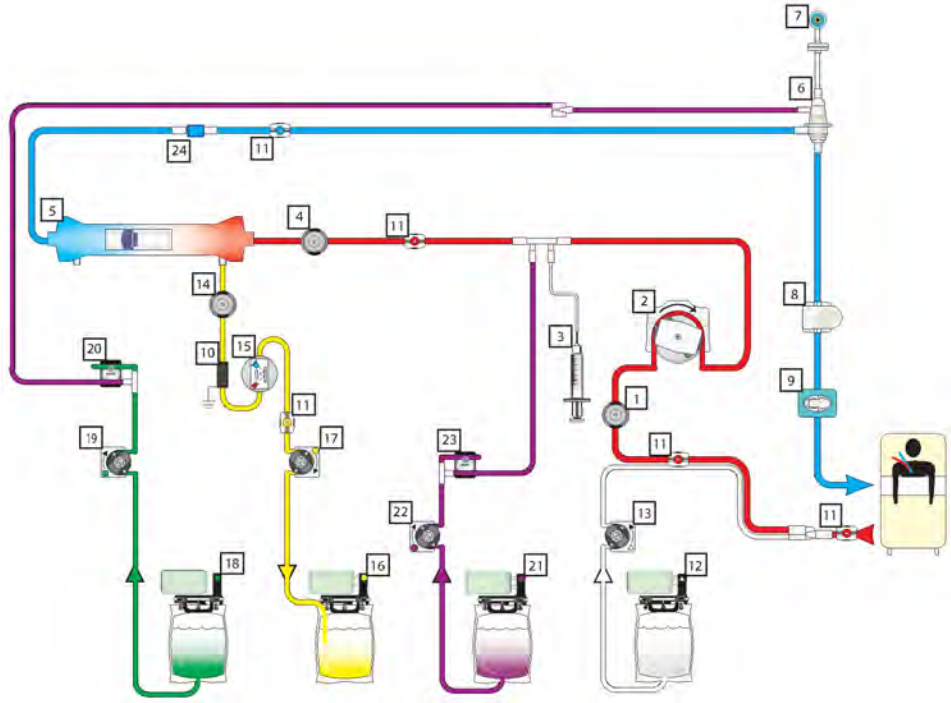


Figure 5-2. CVVH pre+post filter flow

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

5.2.2.4 CVVHD (continuous veno-venous hemodialysis)

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

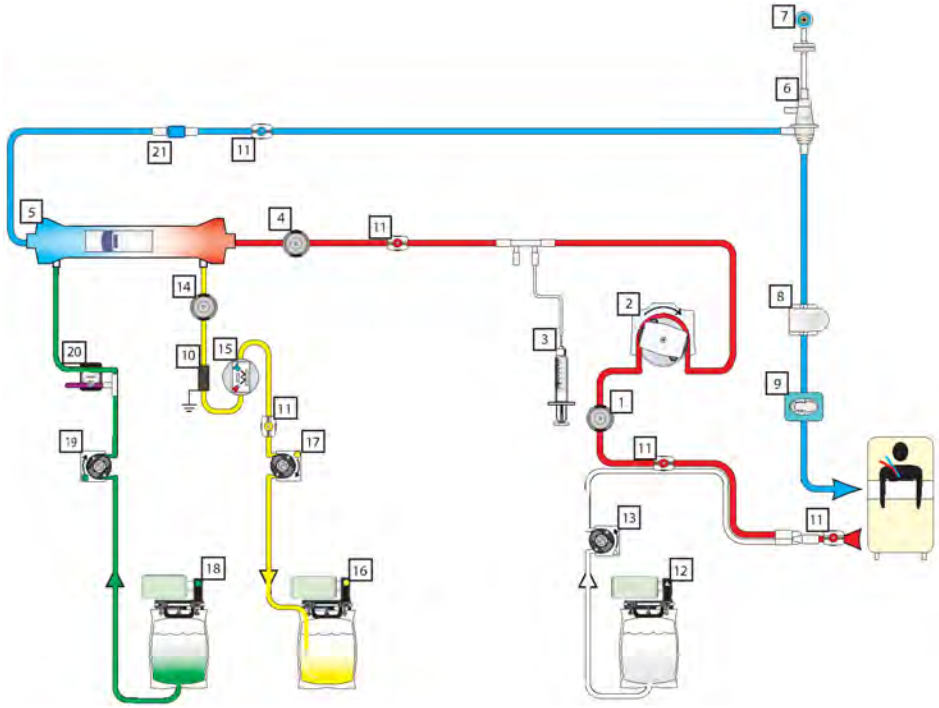


Figure 5-3. CVVHD flow

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

5.2.2.5 CVVHDF (continuous veno-venous hemodiafiltration)

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

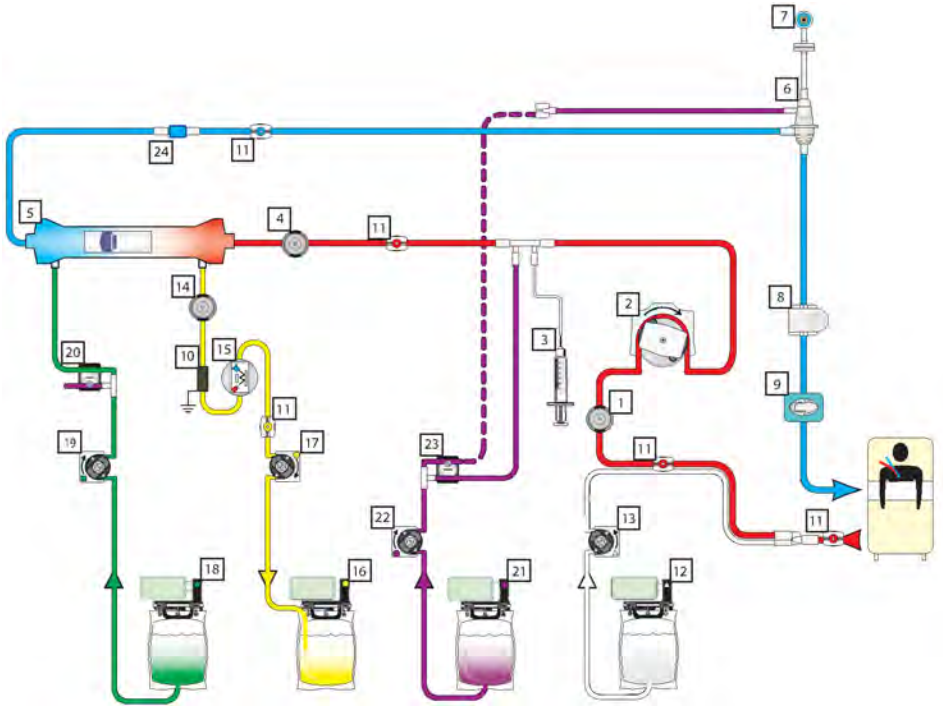


Figure 5-4. CVVHDF flow

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

5.2.3 Available anticoagulation methods in CRRT

Anticoagulation methods available in each CRRT therapy are identified in Section 8.2.3 “Therapies and anticoagulation methods” on page 159.

5.2.4 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 Section 14.2 “CRRT disposable sets” on page 287.

Table 5-4.

Low Flow sets:	HF20. Refer to Section 5.5 “CRRT with HF20 disposable set” on page 123. M60 ST60
High Flow Sets:	M100 ST100 M150 ST150 HF1000 HF1400 septeX. Refer to Section 5.6 “CRRT with septeX™ disposable set” on page 124. oXiris X-MARS. Refer to Section 5.7 “CRRT with X-MARS™ disposable set” on page 125.

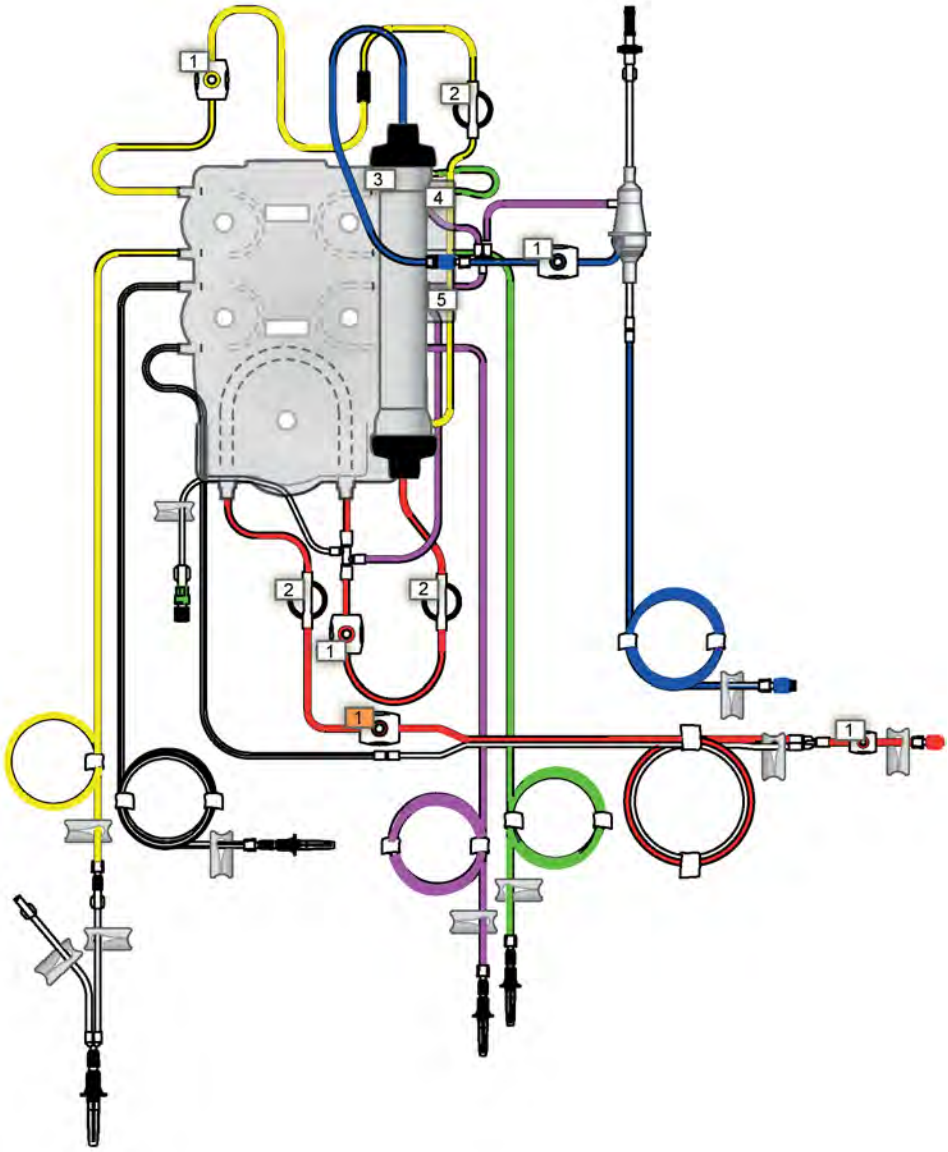


Figure 5-5. CRRT Disposable Set components

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 “CRRT Disposable Set components” on page 115 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).

5.3 Specific functions in CRRT

5.3.1 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).

5.3.2 Protecting from fluid imbalance

5.3.2.1 Unintended patient fluid loss or gain

In addition to the alarm system described in Section 3.3 “Flow problems” on page 68 to prevent flow errors, the Prismaflex system monitors the removed patient fluid to protect the patient from fluid imbalance.

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 or Gain, expressed as the accumulated fluid balance error within the last three hours.

5.3.2.2 Setting the Unintended Patient Fluid Loss/Gain Limit

The acceptable limit for the fluid balance error (Loss/Gain Limit) is patient specific. It follows from the maximum UF rate error, which is not to exceed 0.1 mL/kg/min in order to avoid complications including haemodynamic instability. Accordingly, the Loss/Gain Limit default is determined based on the cumulative UF rate error over a sliding 3 hour window. The Patient Fluid Removal accuracy of the system (±70 mL/3h) is to be considered in this interval.

The Loss/Gain Limit is calculated by the Prismaflex software as follows:

Loss/Gain Limit default = 0.1 mL/kg/min × 180 min × BW – $PFR_{accuracy}$

Where BW is Body Weight (kg) and $PFR_{accuracy}$ is Patient Fluid Removal accuracy (70 mL/3h).

The default Loss/Gain Limit is to be confirmed by the operator during the setup-phase of the treatment based on the physician's prescription. This is a mandatory action in order to be able to proceed to patient connection. The Loss/Gain Limit is settable down to a limit of 60g/3h and then active throughout the treatment.

! **NOTE!**
If the **SAME PATIENT** is chosen during the setup mode, the cumulative count for Unintended Patient Fluid Loss/Gain over the last 3 hours begins again at 0 mL.

5.3.2.3 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.

5.3.3 Pressure management

5.3.3.1 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 Section 4.3.7 “Custom mode” on page 99. TMP and Pressure drop can also be viewed in `History` screen together with the monitored pressure values. See Section 4.2.6.1 “Accessing history data” on page 81.

5.3.3.2 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 Section 3.1.4.6 “Pressure operating points” on page 64. 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 13.1.4.3 “Filter” on page 273.

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 4.3.7 “Custom mode” on page 99 and Section 4.3.9 “User-controllable settings” on page 100. If the TMP increases beyond the membrane capacity that is product dependent, the Caution: TMP Excessive alarm occurs.

5.4 Therapy operation in CRRT

5.4.1 CRRT treatment settings

The operator is required to confirm the Patient Fluid Loss/gain Limit prescription for the individual patient. See Section 5.3.2 “Protecting from fluid imbalance” on page 116.

5.4.2 Prescription settings

5.4.2.1 About prescription settings

See Table 5-1 “Available flow rate parameters depending on selected CRRT Mode” on page 109 for 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.

PBP flow rate is managed by the Prismaflex control unit when running “Citrate - Calcium” method, see Section 8 “Anticoagulation methods” on page 157.

For information about PRE/POST infusion, refer to Section 5.4.2.2 “Replacement solution delivery options ” on page 119.

For information about patient fluid removal management, refer to Section 5.4.3 “Patient fluid removal management ” on page 121.

5.4.2.2 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 5-5 “Components used with Replacement Solution Delivery Options” on page 119.

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.

See Table 5-5 “Components used with Replacement Solution Delivery Options” on page 119 for components used with each possible replacement solution delivery option in CVVH and CVVHDF.

! **NOTE!**
Not all configurations are supported in “Citrate - Calcium” anticoagulation, using the “Citrate – Calcium, Prismaflex syringe pump” method in combination with calcium containing replacement solutions. Refer to Section 8 “Anticoagulation methods” on page 157 for further information.

Table 5-5. 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)

Therapy	Delivery	Scale/Pump	Pinch Valve/ Segment
	100% Post-filter	Replacement	Lower (purple striped)
CVVHD+post	100% Post-filter	Replacement	Lower (purple striped)

5.4.2.3 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.

5.4.2.4 CRRT prescription indicators

5.4.2.4.1 About formulas

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.

Refer to applicable clinical practice guidelines for the use of these indicators (e.g. KDIGO Clinical Practice Guideline for Acute Kidney Injury[1]).

Table 5-6. Abbreviations 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_{inlet}	Filter inlet flow rate	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

[1] Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group. KDIGO Clinical Practice Guideline for Acute Kidney Injury. Kidney inter., Suppl. 2012; 2: 1–138.

Abbreviation	Explanation	Unit
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

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

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

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

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

5.4.2.4.2 Filtration fraction

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

$FF = 100 \times Q_{UFR} / Q_{inlet}$

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

5.4.2.4.3 Doses

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

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

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

5.4.3 Patient fluid removal management

5.4.3.1 Calculating the desired patient fluid removal rate

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.

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.

5.4.3.2 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 4.3.6.1 "Operating modes overview" on page 87 and Section 4.3.9 "User-controllable settings" on page 100 for more information.

If desired, the operator can change the default patient fluid removal rate in Custom mode. See Section 4.3.7 "Custom mode" on page 99.

5.4.3.3 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).

5.4.3.4 Viewing patient fluid removed

During a patient treatment (Run mode), the Patient Fluid Removed is displayed on the `History` screen. See Section 4.2.6.1 "Accessing history data" on page 81 for more information.

5.4.4 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)
  - Ultrafliltration
  - Replacement Solution Input (incl. PBP)
  - Pre-filter Input
  - Post-filter Input
  - Effluent
- Cumulated volume for:
  - Pre Blood Pump
  - Dialysate
  - Replacement
  - Syringe
  - Effluent

5.4.5 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.

5.5 CRRT with HF20 disposable set

CAUTION!
Blood priming of the extracorporeal circuit with citrated blood can result in patient reactions. Verify pH and level of ionized calcium in primed circuit prior to patient connection.

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

The HF20 disposable set is especially designed for the treatment of low body weight patients down to 8 kg. Blood flowpath consists of dedicated small transport tubes to minimize blood volume and risk of blood sedimentation at low blood flow rate.

Running of CRRT therapy and anticoagulation methods with HF20 disposable set are identical to treatment with all other CRRT disposable sets.

The `Priming Complete` screen however offers the specific **BLOOD PRIME** softkey. In case blood prime is part of physician prescription, this function offers instructions and relevant functions for the filling of the extracorporeal circuit with blood prior to patient connection.

The use of calcium solutions with a concentration lower than 300 mmol/L is recommended when running the “Citrate – Calcium, Prismaflex syringe pump”

anticoagulation method with HF20 set. See Section 8 “Anticoagulation methods” on page 157 for more information.

5.6 CRRT with septeX™ disposable set

5.6.1 Therapy information

WARNING!
Monitor patient proteinemia during therapies performed with high cut-off membranes.

WARNING!
Monitor patient blood chemistry for electrolyte balance and normoglycemia.

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

CRRT septeX provides two operating modes:

- CVVHD (Continuous Veno-venous Hemodialysis) having the same implementation as CVVHD in CRRT (see Figure 5-3 “CVVHD flow” on page 112)
- CVVHD+ post: having an implementation similar to CVVHDF in CRRT with post-filter replacement infusion only (see Figure 5-4 “CVVHDF flow” on page 113)

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

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

Anticoagulation methods available in CRRT septeX therapy are identified in Section 8.2.3 “Therapies and anticoagulation methods” on page 159.

The septeX sets are identical to the standard CRRT disposable sets, described Section 2.3.4 “Disposable set components” on page 53.

5.6.2 CRRT septeX therapy operation

Unless specified below, operation of the Prismaflex system in CRRT septeX therapy is strictly identical to its operation in standard CRRT. Pressure and fluid balance monitoring remain unchanged with respect to CRRT.

5.6.3 Flow rate settings

Flow rate prescription parameters available in CRRT septeX therapy modes are summarized in Table 5-2 “Available flow rate parameters depending on selected CRRT septeX Mode” on page 109.

5.6.4 Anticoagulation settings

Because of the restricted flow rate during CRRT septeX, “Citrate - Calcium” anticoagulation can be performed only with relatively high concentration citrate

solutions. See Section 8 “Anticoagulation methods” on page 157 for more information.

5.7 CRRT with X-MARS™ disposable set

5.7.1 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 acute or chronic liver failure. 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 5.7.3 “X-MARS™ disposable set ” on page 126
- 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

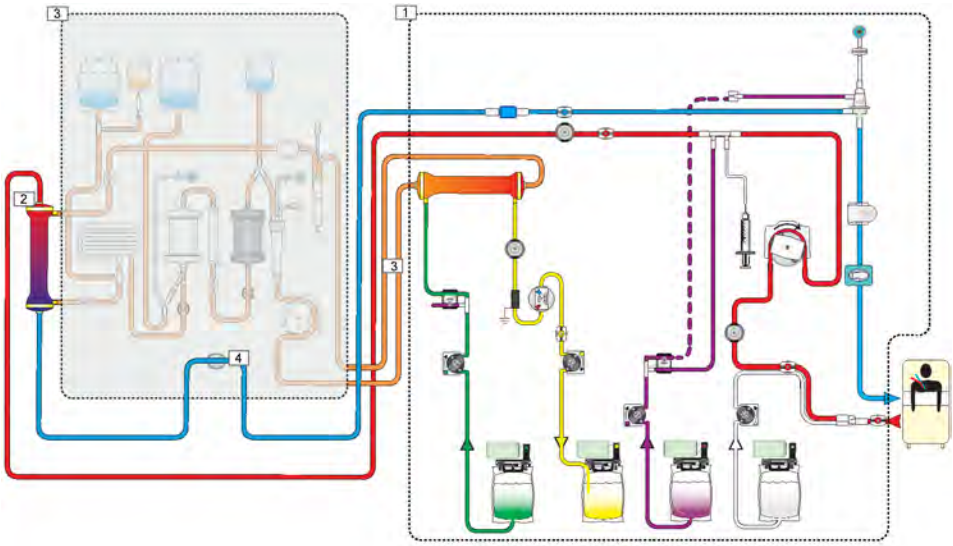
To perform a CRRT MARS treatment, first press the **CRRT MARS** softkey on the bottom of the `Choose Therapy` screen. The following modes are available:

- CVVHD
- CVVHDF

Anticoagulation methods available in the CRRT MARS therapy are identified in Section 8.2.3 “Therapies and anticoagulation methods” on page 159.

5.7.2 CRRT MARS® flowchart

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



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 filter 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**

   Return extension line of the Prismaflex system and the X-MARS disposable set is to be set in the MARS machine's clamp. In this way, the MARS system can stop the blood flow if a blood leak is detected.

5.7.3 X-MARS™ disposable set

The specially designated X-MARS disposable set must be used on 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. Beside 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* 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.

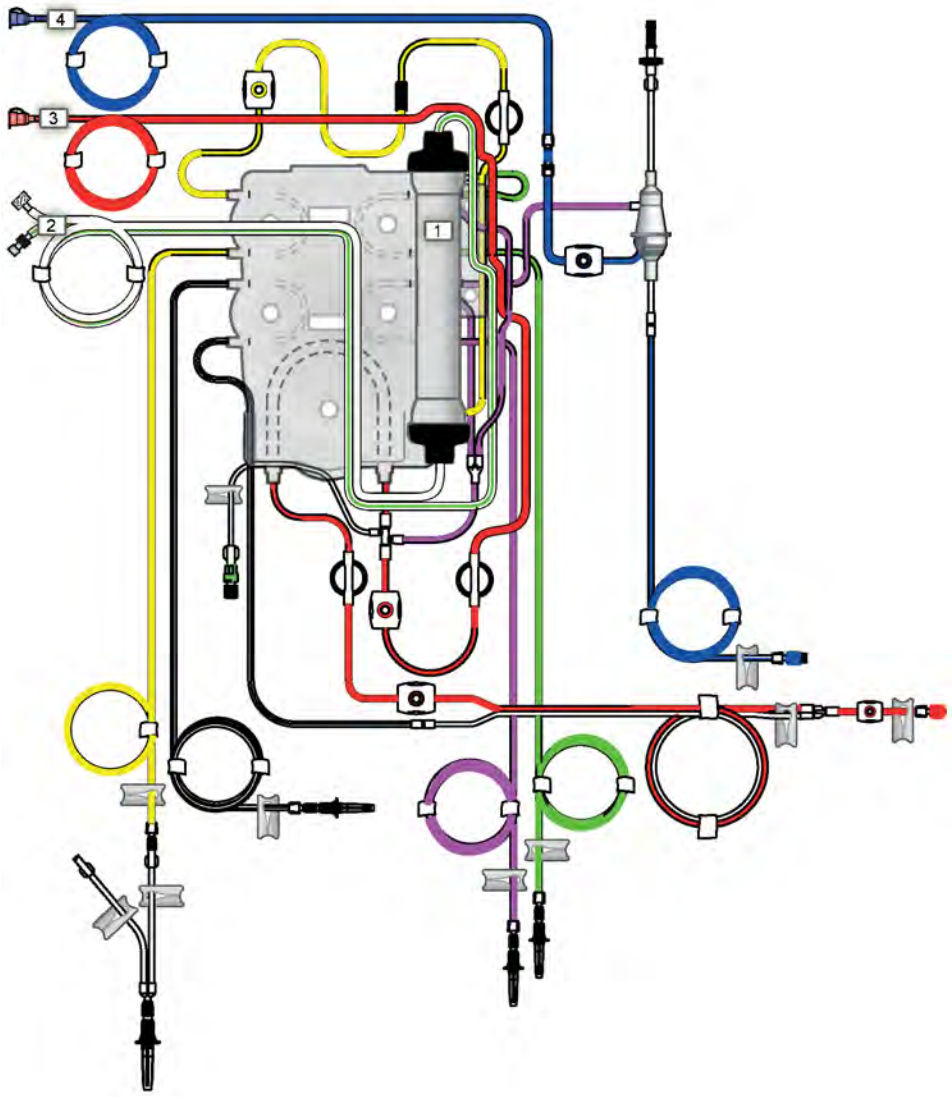


Figure 5-6. The X-MARS disposable set

1. **diaFLUX filter**

   During treatment mode, albumin solution flows inside the hollow fibres of the diaFLUX filter, while dialysate flows counter-currently 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.

5.7.4 CRRT MARS® therapy operation

5.7.4.1 About CRRT MARS® therapy operation

WARNING!
The combined Prismaflex and MARS system complies with the Type B applied part classification per IEC 60601-1 standard. Do not use central venous catheter in atrial location in combination with the MARS system. Failure to comply can result in arrhythmia due to leakage currents and electric shock.

This section contains specific information about CRRT MARS therapy.

The MARS machine must be placed on the left side of the Prismaflex control unit from user point of view. Pay attention to prevent interaction of extension lines with Prismaflex scales.

NOTE!
The specification parameters about ambient temperature, humidity and air pressure differ between the Prismaflex system and the MARS system, see Section 13 “Specifications” on page 266 for the Prismaflex control unit specifications and for technical data about the MARS system refer to the MARS Liver Support Therapy, Operating Instructions.

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.

5.7.4.2 Setup and priming

The setup and priming procedures in CRRT MARS therapy takes between one to two and a half hours to perform. 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.

Table 5-7. Operating Screens in CRRT MARS Setup Mode

Prismaflex System (Start screen)
Choose Patient
Enter Patient ID
Enter Patient Weight
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 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
Review Setup

MARS — Albumin Filling
MARS — Albumin Circulation
Enter Treatment Settings
Enter Flow Settings
Enter Anticoagulation Settings (Systemic anticoagulation method)
Review Prescription

5.7.4.3 Run mode

5.7.4.3.1 Operating screens

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 Section 4.3.6.7 “Operating screens in run mode” on page 92.

5.7.4.3.2 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.

5.7.4.3.3 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 as 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 and close the return clamp, e.g. Warning: Filter Clotted alarm, Warning: Filter Pressure Extremely Positive alarm, Warning: Return Pressure is Dropping alarm.

5.7.4.4 End mode

The X-MARS kit must be changed after 24 hours treatment at the latest.

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

5.8 CRRT with PrismaLung™ disposable kit

5.8.1 Warnings

WARNING!
Carefully read the PrismaLung disposable kit Instructions for Use before operating this device.

WARNING!
Operate the Prismaflex control unit in accordance with this manual, the Instructions for Use of the Prismaflex disposable set and solution, the Instructions for Use of the PrismaLung disposable kit, 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.

5.8.2 Cautions

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

CAUTION!
In CRRT therapy, the PrismaLung disposable kit shall not be used in combination with the Prismatherm II blood warmer due to excessive extracorporeal blood volume and pressure drop in the blood circut.

5.8.3 PrismaLung™ disposable kit

The PrismaLung disposable kit provides extracorporeal gas exchange for patients that require extracorporeal elimination of carbon dioxide. This kit is especially designed for use with the Prismaflex system.

In addition to the PrismaLung blood-gas exchanger, the PrismaLung disposable kit includes the following items that are required for use with the CRRT therapy mode:

- a gas line used to connect the flowmeter to the gas inlet port of the PrismaLung blood-gas exchanger,
- a christmas tree connector used to connect the gas line to a standard flowmeter connected to a standard hospital-wall oxygen supply line,
- two color-coded extension lines used to connect the PrismaLung blood-gas exchanger to the warmer connectors of the CRRT disposable set.

5.8.4 Setup and operation

Follow instructions on the Prismaflex control unit's screen for the setup and operation of the PrismaLung disposable kit.

Use of the PrismaLung disposable kit requires a specific holder to be mounted at the rear side of the Prismaflex control unit; contact your local Gambro representative.

Table 5-8. Operating Screens in CRRT PrismaLung Setup Mode

Prismaflex System (Start screen)
Choose Patient
Enter Patient ID
Enter Patient Weight

Enter Patient Hematocrit
Confirm Patient Information
Choose Therapy (press CRRT)
Choose Therapy Supplement (Press PrismaLung Blood-gas exchanger)
Choose Anticoagulation Method
Confirm Anticoagulation Method
Therapy and Anticoagulation Choice
Load set
Loading Pumps, please wait
Confirm Set Loaded
Key Reminders
Prepare and Connect Solutions
Connect PrismaLung Kit
Connect Oxygen Supply
Install Syringe (depending on anticoagulation method in use)
Confirm Syringe Installation (depending on anticoagulation method in use)
Verify Setup
Priming, please wait
Deaerate Blood-gas Exchanger
Priming X of Y Cycles Complete
Prime Test, please wait
Review Setup
Enter Flow Settings
Enter Anticoagulation Settings (depending on anticoagulation method in use)
Anticoagulation Risks (“Citrate – Calcium, external pump” and “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method)
Review Prescription

6 Therapeutic plasma exchange (TPE)

6.1 General warnings and cautions

6.1.1 Warnings

WARNING!
In TPE, the blood flow rate should not be set below 100 mL/min for TPE2000/TPE60 and below 50 mL/min for TPE1000/TPE20 sets due to risk of hemolysis.

WARNING!
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.

WARNING!
As treatment proceeds, carefully monitor patient plasma balance levels in the `History` screens.

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.

WARNING!
The blood leak detector must be re-normalized if the effluent line has been removed and then reinserted into the blood leak detector during an ongoing treatment (Run Mode). See Section 11.15 “Blood leak detector normalization” on page 260

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

6.1.2 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.

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

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

CAUTION!
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.

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

6.2 Therapy description

6.2.1 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.

6.2.2 TPE flowchart

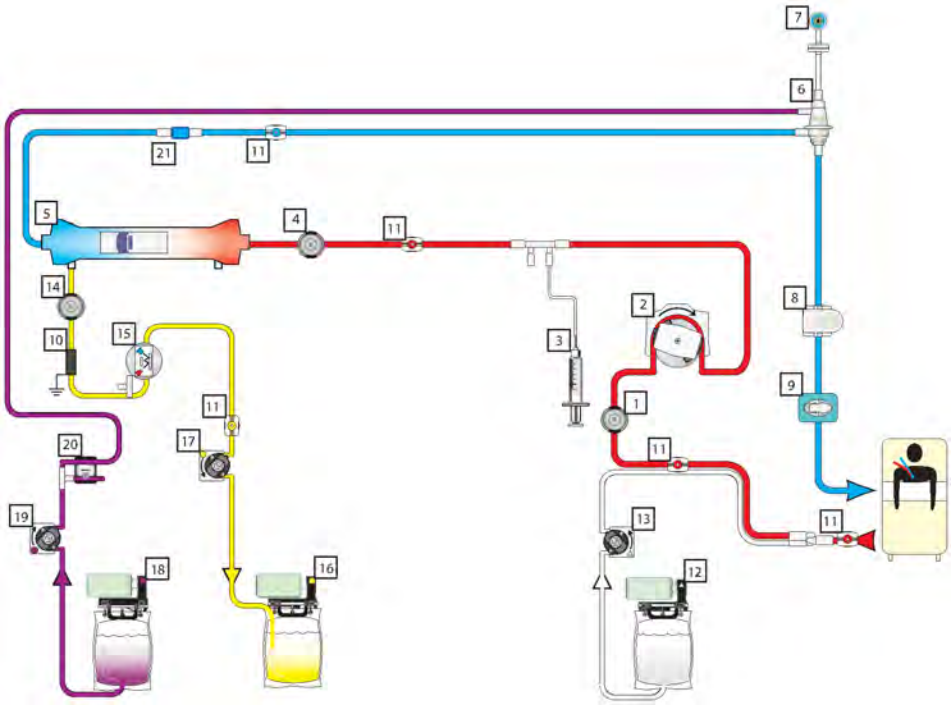


Figure 6-1. TPE flow

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

6.2.3 TPE and anticoagulation methods

Anticoagulation methods available in TPE therapy are identified in “Therapies and Anticoagulation Methods” on page Section 8.2.3 “Therapies and anticoagulation methods” on page 159.

6.2.4 TPE disposable set

Low flow sets

The available disposable sets for low flow sets are:

- TPE20
- TPE1000

Refer to the Instructions for Use enclosed with the set.

High flow sets

The available disposable sets for high flow sets are:

- TPE60
- TPE2000

Refer to the Instructions for Use enclosed with the set.

6.2.5 TPE disposable set components

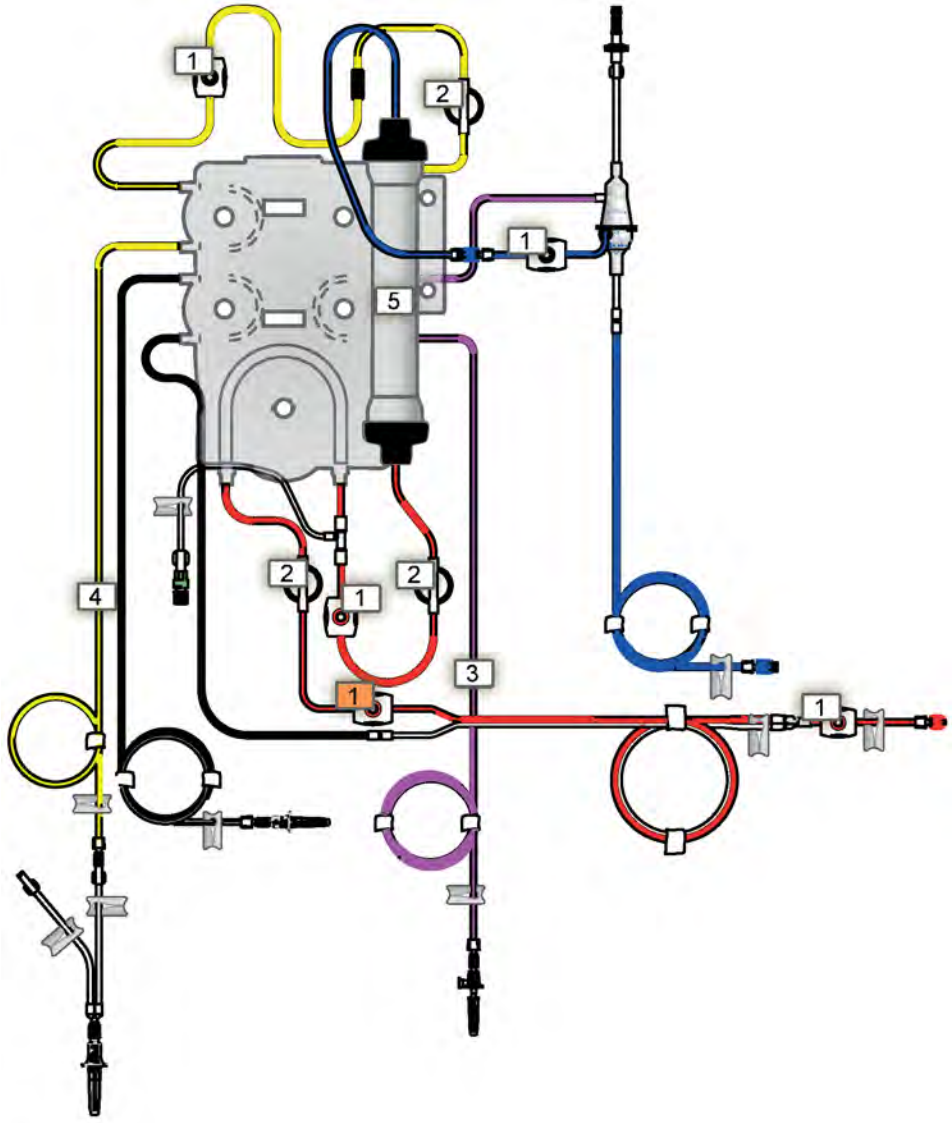


Figure 6-2. TPE disposable Set components

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 “TPE disposable Set components” on page 137 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.

6.3 Specific functions in TPE

6.3.1 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 Section 4 “Operating the Prismaflex® system” on page 75 for more information.

6.3.2 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.

6.3.3 Protecting from fluid imbalance

6.3.3.1 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 Section 3 “General Prismaflex® functions” on page 59, a third Caution: Unresolved Flow Problems alarm is active during TPE therapy. All these alarms are described in detail below.

6.3.3.2 Flow problem alarms in TPE

Each of the PBP, Replacement and Effluent flow rates are monitored according to the process described in Section 3.3.1 “Protecting from flow problems ” on page 68. 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.

6.3.3.3 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 Section 11 “Troubleshooting” on page 187 for detailed troubleshooting information.

6.3.4 Pressure management

6.3.4.1 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 Section 4.3.7 “Custom mode” on page 99.

6.3.4.2 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 4.3.7 “Custom mode” on page 99“ and Section 15.3 “TPE specific settings” on page 296.

6.3.5 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.

6.3.6 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.

6.3.7 End treatment

Per design, TPE treatments will commonly be ended on occurrence of Caution: TPE Prescription Delivered alarm. See Section 11.3 “Caution alarms” on page 207 for more information. If needed, treatment can be ended any time by pressing the **STOP** softkey present on the `Status` screen.

6.4 Therapy operation in TPE

6.4.1 TPE prescription and flow rates

6.4.1.1 About 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.

6.4.1.2 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 Section 4.3.7 “Custom mode” on page 99.

6.4.1.3 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 Section 6.4.1.4 “Patient plasma loss rate ” on page 141.

6.4.1.4 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.

6.4.1.5 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.

6.4.1.6 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.

6.4.1.7 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.

$V_{plasma} = (100 - Hct) \times 0.7 \times BW$

where $\mathbf{V_{plasma}}$ is Patient plasma volume (mL), **Hct** is Hematocrit (%), **BW** is Patient body weight (kg).

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

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

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

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

$FF = 100 \times (Q_{rep} + Q_{ppl}) / Q_{inlet}$

where **FF** is Filtration fraction (%), **Q_{ppl}** is Patient plasma loss rate (mL/h), **Q_{rep}** is Replacement flow rate (mL/h) and Q_{inlet} is filter inlet flow rate at filter inlet (mL/h).

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

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

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

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

6.4.2 Plasma balance

6.4.2.1 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.

6.4.2.2 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 **V_{ppl}** is Patient plasma loss (mL), **V_{eff}** is Effluent bag volume (mL) and **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:

1. treatment is voluntarily stopped and then later resumed; or
2. 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.

6.4.2.3 Viewing Patient Plasma Loss

During a patient treatment (Run mode), the Patient Plasma Loss is displayed on the `History` screen. See Section 4.2.6 “History data” on page 81 for more information.

6.4.3 Viewing treatment data

6.4.3.1 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

6.4.4 Replacement bag handling

6.4.4.1 Bag or container volume

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

6.4.4.2 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.

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 “Accessory SP394 with the Prismaflex system in TPE” on page 145.

1. 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.
2. The second line (with the non-vented spike) is used to connect the second container to the third one.
3. 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.

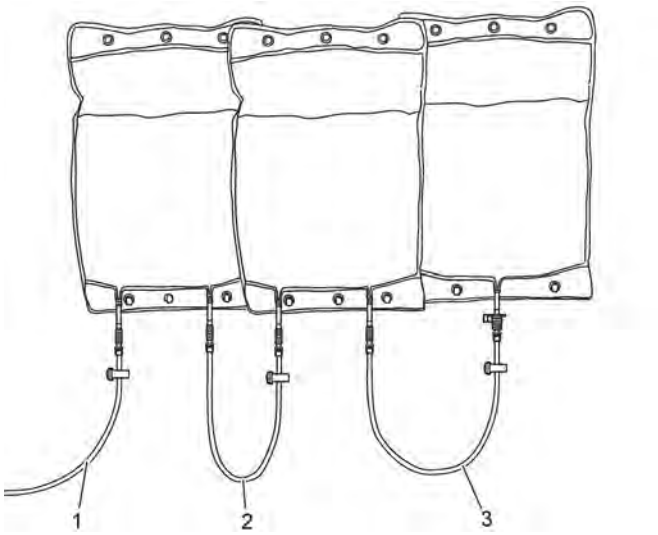


Figure 6-3. Accessory SP394 with the Prismaflex system in TPE

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)

6.4.4.3 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:

1. Change the container;
2. 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.

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7 Hemopurification (HP)

7.1 General warnings and cautions

7.1.1 Warnings

WARNING!
During HP, carefully monitor patients with severe thrombocytopenia, leukocytopenia or other coagulation disorders.

7.1.2 Cautions

CAUTION!
PBP solution is not removed in HP and accordingly, infused PBP volume is to be considered as a fluid input in the patient fluid balance.

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

7.2 Therapy description

7.2.1 Mechanism of HP

The HP treatment mode supports blood purification by means of an extracorporeal purification device. The patient's blood is directed through the Prismaflex disposable HP line set, passes the HP device, and the cleansed blood is then returned back to the patient. No fluid removal occurs.

A range of different HP devices are supported for use with the Prismaflex system. These include hemoperfusion cartridges in which toxic substances and/or drugs are adsorbed from the plasma as the patient’s blood is perfused through an adsorption column.

7.2.2 HP flowchart

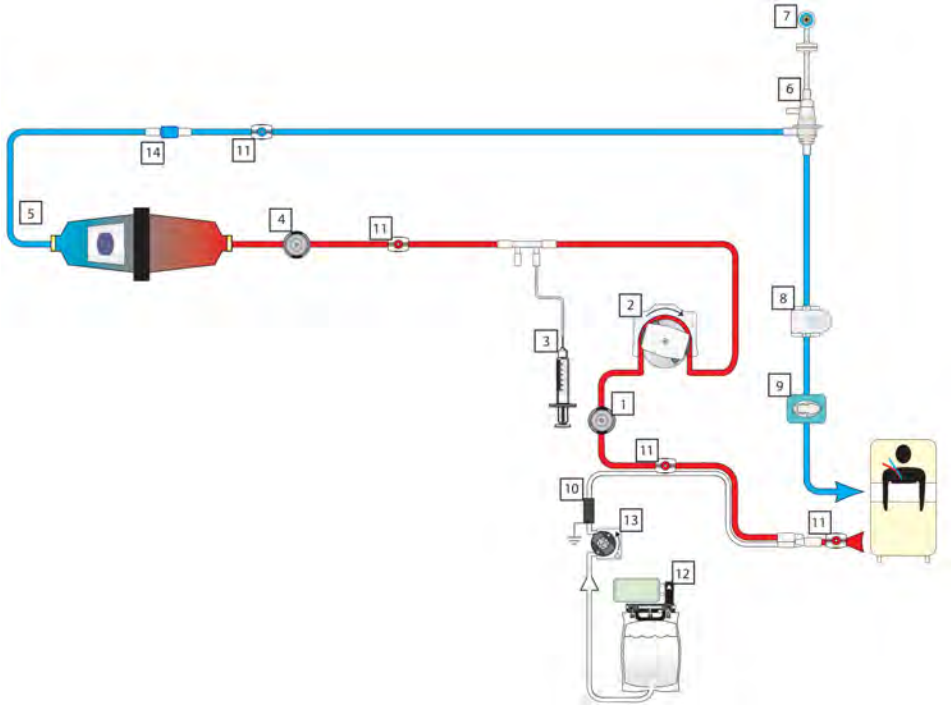

Figure 7-1. HP flow

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. Blood warmer connection

7.2.3 Available anticoagulation methods in HP

Anticoagulation methods available in HP therapies are listed in Section 8.2.3 “Therapies and anticoagulation methods” on page 159

7.2.4 HP-X hemopurification set

The HP-X disposable line set provides an extracorporeal blood circuit intended for use with hemopurification devices.

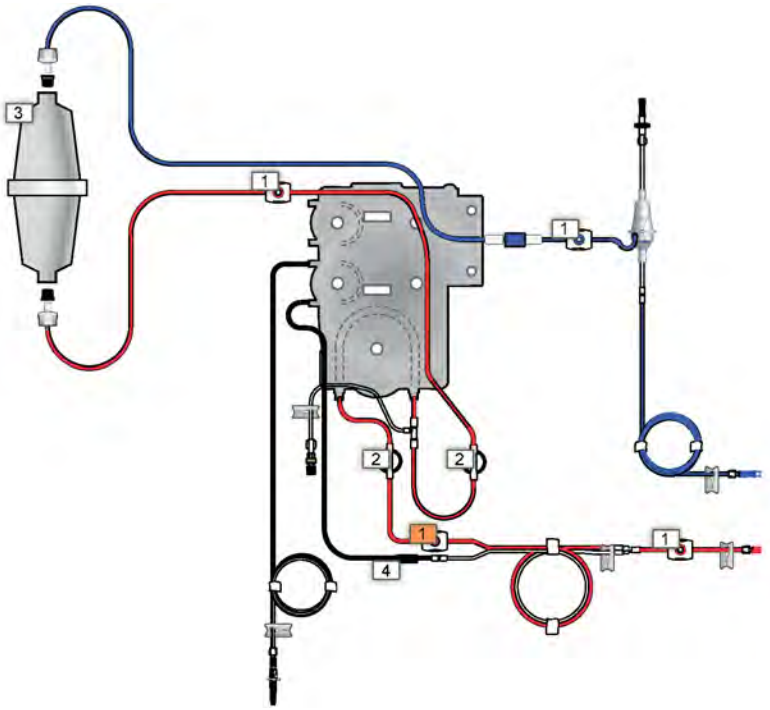

Figure 7-2. HP kit components

1. **Sample sites**

   The HP line set includes a range of sample sites, 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). The sample site marked orange in Figure 7-2 “HP kit components” on page 150 is optional.
2. **Pressure pods**

   The HP line set includes two pressure pods: at the access line before blood pump (access pod) and at the access line after blood pump (filter pod).
3. **HP device**

   The HP device, for instance a hemoperfusion cartridge, is connected using two blood connectors (ISO 8638 compliant).
4. **Electrostatic discharger ring**

   In the HP-X disposable set, the discharger ring is located on the PBP line.

NOTE!
On HP sets there is no dialysate line, replacement line or effluent line.

7.3 Specific functions in HP

7.3.1 User-controllable settings

See Section 7.3.1 “User-controllable settings” on page 150 for a lists of all user-controllable settings, their default values, setting options, and the mode in which they can be changed. For HP, default values depend on the selected HP device.

7.3.2 User-defined HP devices

User-defined HP devices, including their individual priming sequence with up to three priming solutions can be defined in Custom Mode. See Section 7.5.2 “Other cartridges” on page 153 for further instructions.

7.3.3 Bag management

The PBP scale is managed with Variable Empty Bag method in HP.

7.3.4 Fluid balance and PBP solutions

7.3.4.1 Fluid input

CAUTION!
PBP solution is not removed in HP and accordingly, infused PBP volume is to be considered as a fluid input in the patient fluid balance.

In HP therapy, there is no fluid balance system. The use of PBP solutions and anticoagulants is supported but creates a net fluid input to the patient. In this respect, HP is similar to the TPE therapy mode, although the HP configuration is much simpler. The delivery of PBP solutions is monitored by the Prismaflex software, which issues one of the following alarms in case of problems.

7.3.4.2 Flow problem alarm

Correct delivery of the prescribed PBP flow is monitored and deviations are signaled through the Caution: Flow Problem alarm. Further information on this alarm and related causes are provided in Section 11.3 “Caution alarms” on page 207.

7.3.4.3 Unresolved flow problems alarm

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.

7.3.4.4 Protecting from excessive fluid input

In HP therapy, any PBP solution infused should be counted as a separate fluid input to patient, because fluid removal is not possible. The Caution: Patient Fluid Gain Excessive alarm occurs when the PBP solution infused volume reaches a predefined threshold. To prevent unintended excessive PBP fluid input, the Caution: Patient Fluid Gain Excessive alarm temporarily suspends treatment. The operator may decide to stop or continue the treatment. See Section 11 “Troubleshooting” on page 187 for more information.

7.3.5 Pressure management

The Prismaflex software calculates the pressure drop over the HP device during therapy. This calculation is used to provide notification that clotting has begun in the HP device, or that the HP device has clotted and the set must be changed. See Section 3.1.4.9 “Filter pressure drop (pressure drop)” on page 66 for more information.

7.4 Therapy operation in HP

7.4.1 Custom mode

User-defined HP devices, including a sequence of different priming solutions can be created in Custom mode. Refer to the Instruction for Use of the individual HP device for the required data.

Approximately 250 mL in the last priming bag will be saved for the prime test. Therefore, an extra 250 mL need to be added to the priming solution that is defined last in the priming sequence, compared to the volume stated in the Instructions for Use.

7.4.2 Setup mode

In HP, the setup sequence is largely identical to the general flow as described in Section 4 “Operating the Prismaflex® system” on page 75.

Additional, HP-specific instructions detail how to:

- Choose the correct HP device during the loading sequence.
- Perform the predefined sequence of priming steps.
- Fill the access line of the blood circuit prior to its connection to the HP device.

NOTE!
Instructions on the screens remind the operator to check that the HP device is mounted and secured in the HP cartridge holder and that disposable set tubes are connected properly. These instructions apply to all HP devices. For user-defined HP devices, refer also to their Instructions for Use regarding any specific handling requirements.

7.4.3 Run mode

Run mode in HP is identical to the generic description in Section 4 “Operating the Prismaflex® system” on page 75. The processed blood volume is available on the `Status` screen as additional information.

7.4.4 End treatment

The structure of the end mode in HP is largely identical to the generic description in Section 4 “Operating the Prismaflex® system” on page 75.

The `Prepare to Return Blood` screen provides specific instructions on how to rotate the HP device for an optimized blood return process.

7.5 HP with hemoperfusion cartridges

7.5.1 Adsorba® cartridge

The Adsorba cartridge is a hemoperfusion column that contains activated charcoal granules encapsulated in a biocompatible cellulose membrane. As the patient's blood perfuses the column, toxic substances in the blood are adsorbed by the charcoal. Refer to the Instructions for Use for specifications, physical characteristics, materials, performances, and limits of use of the Adsorba cartridge.

CAUTION!
Rinsing with glucose solution is done to prevent a drop in blood glucose during the perfusion. Part of this glucose is adsorbed during the perfusion leaving a hypotonic medium which would cause hemolysis. It is always necessary to rinse with the glucose solution first, followed by the intra venous saline solution and always in that order, before connecting the cartridge to the patient.

The Adsorba cartridge is a predefined column type in the HP mode. If chosen, the operator is guided through the Adsorba specific priming sequence.

The Adsorba cartridge can be obtained either as part of a preassembled Adsorba kit, or it can be procured separately and used in combination with the HP-X line set. Please contact your Gambro representative for available options.

7.5.2 Other cartridges

Other cartridges are supported after they have been defined in Custom mode. Refer to the Instructions for Use for specifications, physical characteristics, materials, performances, and limits of use of the individual cartridge.

Ensure that the cartridge complies with the limitations outlined below.

- Physical characteristics of cartridge must be within the following ranges to ensure compatibility with the HP cartridge holder:
  - Diameter: 26 mm to 55 mm.
  - Maximum weight (fluid filled): 550 g.

NOTE!
Should any parameter fall outside these limits, consider using a specialized holder.

- Cartridge connectors must comply with ISO 8637.
- Blood flow operating range of cartridge must be within the Prismaflex control unit's range (50 to 450 mL/min).
- Priming sequence of cartridge must not necessitate a recirculation step.
- Maximum pressure drop over the cartridge should be below 300 mmHg at maximum flow rate. To avoid unjustified Warning: HP Cartridge Clotted alarms, it is recommended to have a pressure below 200 mmHg.

7.6 HP with Hemopurification Cartridges

7.6.1 PrismaLung™ disposable kit

WARNING!
Carefully read the PrismaLung disposable kit Instructions for Use before operating this device.

WARNING!
Operate the Prismaflex control unit in accordance with this manual, the Instructions for Use of the Prismaflex disposable set and solution, the Instructions for Use of the PrismaLung disposable kit, 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.

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

The PrismaLung disposable kit provides extracorporeal gas exchange for patients that require extracorporeal elimination of carbon dioxide.

In addition to the PrismaLung blood-gas exchanger, the PrismaLung disposable kit includes the following items that are required for use with the HP therapy mode:

- a gas line used to connect the flowmeter to the gas inlet port of the PrismaLung blood-gas exchanger,
- a christmas tree connector used to connect the gas line to a standard flowmeter connected to a standard hospital-wall oxygen supply line.

NOTE!
The included extension lines are not used in HP mode.

7.6.2 Setup and operation

Follow instructions on the Prismaflex control unit's screen for the setup and operation of the PrismaLung disposable kit.

Use of the PrismaLung disposable kit requires a specific holder to be mounted at the rear side of the Prismaflex control unit; contact your local Gambro representative.

Table 7-1. Operating Screens in HP-X PrismaLung Setup Mode

Prismaflex System (Start screen)
Choose Patient
Enter Patient ID
Enter Patient Weight
Enter Patient Hematocrit
Confirm Patient Information

Choose Therapy (press HP)
Choose Anticoagulation Method
Confirm Anticoagulation Method
Therapy and Anticogulation Choice
Load set
Loading Pumps, please wait
Choose HP Cartridge (Press PrismaLung)
Confirm Set Loaded
Key Reminders
Prepare and Connect Solutions
Connect PrismaLung Kit
Connect Oxygen Supply
Install Syringe (depending on anticoagulation method in use)
Confirm Syringe Installation (depending on anticoagulation method in use)
Verify Setup
Priming, please wait
Deaerate Blood-gas Exchanger
Priming X of Y Cycles Complete
Prime Test, please wait
Review Setup
Enter Flow Settings
Enter Anticoagulation Settings (depending on anticoagulation method in use)
Review Prescription

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8 Anticoagulation methods

8.1 General warnings and cautions

8.1.1 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.

WARNING!
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.

8.1.2 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 15.6 “Anticoagulation related settings” on page 299.

CAUTION!
Use only luer lock syringes with the Prismaflex control unit and monitor syringe line connection.

CAUTION!
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.

8.2 Prismaflex® anticoagulation methods

8.2.1 Anticoagulation methods overview

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.

- **Citrate – Calcium, external pump**. For treatments using citrate anticoagulation. Requires citrate solution on the PBP scale. The Prismaflex syringe pump is disabled during the entire treatment. Calcium must be infused via an external infusion pump.
- **Citrate – Calcium, Prismaflex syringe pump**. For treatments using citrate anticoagulation. Requires citrate solution on the PBP scale. The Prismaflex syringe pump is used for calcium infusion. Requires dedicated Prismaflex calcium infusion line connected to syringe.

8.2.2 Configuration of anticoagulation methods

Using the Prismaflex syringe pump requires relevant configuration of holder size in Service mode and syringe brand in Custom mode.

For the "Citrate - Calcium" methods, service and custom configurations are also required. Through the service mode, an authorized service technician can configure the citrate and/or calcium solution parameters to be used during treatment, according to the facility's demands. Contact the local representative for additional information. Through the custom mode, the operator selects which citrate or calcium solution(s) to use for the treatment. See Section 8.5 “Citrate – calcium anticoagulation” on page 161.

8.2.3 Therapies and anticoagulation methods

The anticoagulation methods available for each Prismaflex system therapy are listed below:

CRRT:

- Systemic, Prismaflex syringe pump
- No anticoagulation
- Citrate – Calcium, external pump
- Citrate – Calcium, Prismaflex syringe pump

CRRT septeX:

- Systemic, Prismaflex syringe pump
- No anticoagulation
- Citrate – Calcium, external pump
- Citrate – Calcium, Prismaflex syringe pump

CRRT MARS:

- Systemic, Prismaflex syringe pump
- No anticoagulation

TPE:

- Systemic, Prismaflex syringe pump
- No anticoagulation
- Citrate – Calcium, external pump

HP:

- Systemic, Prismaflex syringe pump
- No anticoagulation

8.3 “Systemic, Prismaflex® syringe pump” method

8.3.1 Anticoagulation settings

WARNING!
Consider syringe accuracy specifications when using highly concentrated anticoagulants. See Section 13 “Specifications” on page 266.

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 Section 13.1.2 “Syringe settings” on page 270.

Bolus:

- Bolus volume can be set within ranges depending on syringe size, defined in Section 13.1.2 “Syringe settings” on page 270.
- 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 Section 13 “Specifications” on page 266.

NOTE!
In CRRT therapies additional fluid volumes infused by the Prismaflex syringe pump are removed through the effluent, except for Immediate Boluses.

8.3.2 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 Section 4.3.7 “Custom mode” on page 99.

In Run mode, the operator can access the `Enter Anticoagulation Settings` screen and adjust the settings as needed. See Section 4.3.6.1 “Operating modes overview” on page 87 and Section 15 “User-controllable settings” on page 292.

8.3.3 Viewing the anticoagulation settings during treatment

During a patient treatment (Run mode), the current anticoagulation settings are displayed on the `Status` screen.

8.3.4 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 Section 4 “Operating the

Prismaflex® system” on page 75 on page Section 4.3.12.2 “Syringe installation” on page 102.

8.3.5 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.

8.4 “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.

8.5 Citrate – calcium anticoagulation

8.5.1 About citrate – calcium anticoagulation

Citrate binds and forms a complex with ionized calcium from the patient’s blood. This process inhibits coagulation within the set. Systemic anticoagulation does not occur. The calcium-citrate-complex is metabolized by the patient’s liver. This process converts citrate to bicarbonate and releases the ionized calcium, thus restoring patient homeostasis.

When using citrate as anticoagulation method, a certain amount of ionized (and bound) calcium will be cleared through the filter and lost in the effluent. This amount must be compensated to avoid hypocalcemia in the patient. Calcium can be infused via an external syringe/infusion pump

Magnesium also binds to citrate and may have to be compensated. The use of citrate requires additional monitoring of the patient’s parameters Ca^{2+}, Mg^{2+}, Na^{+}, HCO^{3-}, pH.

WARNING!
Using concentrated citrate solutions may cause hypernatremia. Consult physician when using concentrated citrate solutions.

WARNING!
Consult physician for use of citrate anticoagulation on patients with liver insufficiency, as this may cause metabolic acidosis and calcium imbalance.

WARNING!
Consult physician for use of citrate anticoagulation with high blood flow rates, as this may cause metabolic alkalosis.

WARNING!
During citrate anticoagulation, infuse calcium into a separate central venous line. Do not infuse calcium into a peripheral blood vessel as this may cause damage to the blood vessel and the peripheral tissue. Avoid infusing calcium into the extracorporeal circuit as this may cause clotting in the deareation chamber or the return vascular access.

WARNING!
Wait a few minutes before taking a blood sample after the PBP citrate pump has been stopped. This makes sure that the samples at the filter outlet are correct.

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.

WARNING!
The “Citrate – Calcium, external pump” anticoagulation method disables the Prismaflex syringe pump for the entire treatment. An external syringe/infusion pump must be used to ensure the calcium supplementation to the patient.

CAUTION!
During “Citrate - Calcium” anticoagulation, use calcium-free dialysate and replacement solutions to avoid clotting.

CAUTION!
With respect to the patient’s citrate load, restrict the buffer concentration (bicarbonate or lactate) of solutions to avoid metabolic alkalosis.

CAUTION!
Consult physician for use of citrate anticoagulation in SCUF therapy mode as the patient citrate load might be excessive and lead to metabolic alkalosis.

8.5.2 “Citrate – calcium” anticoagulation using the Prismaflex® system

The Prismaflex system is designed to adapt to the clinic's requirements for “Citrate - Calcium” anticoagulation. A broad range of citrate and calcium solutions can be used within the system. Allowed concentration ranges are dependent on therapy. The clinic's choice of solutions are preset in Service mode by an authorized service technician. The operator selects which solution to use for the treatment according to the prescription and changes default values for anticoagulation settings parameters in Custom mode.

8.5.3 Citrate management

8.5.3.1 Citrate solution

NOTE!
Section 8.5.3 “Citrate management” on page 163 is applicable to the following anticoagulation methods:

- “Citrate – Calcium, external pump”
- “Citrate – Calcium, Prismaflex syringe pump”

Use of “Citrate - Calcium” anticoagulation in the Prismaflex system requires a citrate solution bag on the PBP scale. This solution is infused into the access line of the set at which the anticoagulation starts.

8.5.3.2 Citrate prescription

In citrate anticoagulation, PBP flow rate is kept proportional to blood flow rate and computed by the software through the equation:

$Q_{pbp} = (Qb \times D_{cit}) / [Cit]$

Where $\mathbf{Q_{pbp}}$ is PBP flow rate (mL/h), **Qb** is Blood flow rate (mL/h), $\mathbf{D_{cit}}$ is Citrate dose expressed in millimole per liter of blood (mmol/L blood) and **[Cit]** is citrate concentration of the PBP solution (mmol/L).

Citrate dose is defined as the amount of citrate infused per liter of patient's blood treated, expressed in mmol/L blood.

Citrate dose is the user-controllable setting. Citrate concentration is the sum of citrate and citric acid concentration as defined in Service mode for the selected citrate solution.

Blood flow rate affects the PBP citrate flow rate. A change of the blood flow rate will automatically result in:

- Change of the PBP citrate flow rate.
- Change of the treatment dose (mL/kg/hr)
- Change of the estimated patient citrate load

8.5.3.3 Viewing the anticoagulation settings during treatment

During a patient treatment (Run mode), the current anticoagulation settings are displayed on the `Status` screen: citrate solution name and citrate dose. In addition, the operator can access information about the anticoagulation solution by pressing **VIEW SOLUTION** from the `Enter Anticoagulation Settings` screen.

8.5.3.4 Adjusting the citrate anticoagulation settings

`Enter Anticoagulation Settings` screen is displayed during the Setup procedure (Setup mode). The operator is prompted to assess the default blood flow rate and citrate dose for the therapy/set chosen and confirm both values prior to starting the patient treatment.

8.5.3.5 Citrate anticoagulation indicator

Estimated Citrate Load represents the amount of citrate effectively delivered to the patient. It provides an indication of potential alkalosis in the patient.

The calculation of the citrate load is based on the following two factors:

- Rate of citrate infusion, based on blood flow rate and citrate dose.
- Estimation of citrate clearance as a function of blood, PBP, replacement, dialysate and patient fluid removal rates, as well as on disposable set in use and patient hematocrit.

8.5.3.6 Recirculation procedures

In “Citrate - Calcium” anticoagulation, it is not possible to infuse citrate via PBP during a Saline or Blood Recirculation procedure. Avoid initiating a Blood Recirculation procedure from a Caution alarm, as well as from a change bag procedure, since the amount of citrate in blood can be very low in these circumstances.

8.5.3.7 Operating limits

Citrate dose ranges

The Prismaflex software restricts citrate dose to a specific range with predefined minimum and maximum values of 1.5 and 6.0 mmol/L blood respectively.

Existing limits on PBP flow rate can however further restrict this range:

- to higher minimum dose when using highly concentrated PBP citrate solution and low blood flow rate leading to very low PBP flow rate,
- to lower maximum dose when using diluted PBP citrate solution and high blood flow rate leading to very high PBP flow rate.

In these situations a change of the blood flow rate will lead to an update of the available citrate dose range.

Blood flow range

Available blood flow rate range may be reduced with respect to usual operating range of the disposable set in use. Minimum available blood flow rate can be increased in relation to the minimum allowed PBP flow rate (30 mL/h) when using concentrated citrate solutions.

Maximum blood flow rate can be decreased in relation to the maximum available PBP flow rate (set dependent) when using diluted citrate solutions.

NOTE!
Maximum available PBP flow rate is also dependent on dialysate and/or replacement flow rates when the sum of the 3 flow rates reaches up to a maximum of 8000 mL/h or less, depending on the filter in use.

Risk of patient citrate accumulation must be considered when increasing the blood flow rate.

Table 8-1. Changing Factors in Citrate Anticoagulation

	Blood flow increase	Blood flow decrease	Citrate dose increase	Citrate dose decrease
Blood flow	increase	decrease	unchanged	unchanged
Citrate dose	unchanged	unchanged	increase	decrease
PBP citrate	increase	decrease	increase	decrease
Citrate load	increase	decrease	increase	decrease

8.5.4 Calcium management in “Citrate – calcium, external pump” method

8.5.4.1 External pump

The syringe pump of the Prismaflex control unit will be disabled for the entire treatment. An external infusion pump must be used to re-infuse the lost calcium.

When using an external infusion pump for the calcium infusion, adjust or stop calcium infusion according to physician's prescription when citrate anticoagulation is stopped. Follow your facility protocol for adjustment of calcium infusion.

The Prismaflex control unit provides for reminders to start the external calcium infusion at the beginning of the treatment and to stop it when entering End mode.

WARNING!
If “Citrate – Calcium, external pump” anticoagulation method has been selected for the treatment, the external syringe/infusion pump is still running while treatment and anticoagulation have been stopped. The external calcium infusion must be stopped manually.

8.5.4.2 Calcium loss indicator

Estimated Change of Calcium Loss Rate in Effluent represents the relative variation of calcium losses in effluent due to change(s) in prescription settings.

This calculation is based on the estimation of calcium clearance as a function of blood, PBP, replacement, dialysate and patient fluid removal rates, as well as on disposable set in use.

Relative change in calcium clearance provides an estimation of the relative change in calcium loss rate in effluent. The calcium loss change is expressed as a negative percentage (less loss) or as positive percentage (more loss). This percentage can help the operator to adjust the calcium infusion to the patient, but does not release the operator from monitoring the patient's parameters Ca^{2+}, Mg^{2+}, Na^{+}, HCO^{3-}, pH. The computation of calcium loss change is based on the assumption that dialysate and replacement solutions contain no calcium.

8.5.5 Calcium management in “Citrate – calcium, Prismaflex syringe pump” method

8.5.5.1 Syringe pump

When choosing “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method, the Prismaflex syringe pump will be used for calcium infusion.

NOTE!
Only 50 mL syringes of the allowed brand can be used for the calcium solution when “Citrate – Calcium, Prismaflex syringe pump” is used as anticoagulation method.

Using the Prismaflex syringe pump for the calcium infusion will facilitate maintenance of normocalcemia in the patient. During treatment, the Prismaflex syringe pump, used for calcium infusion, is synchronized with the PBP citrate pump. Whenever the citrate infusion stops, the calcium infusion stops as well.

The Prismaflex syringe pump for calcium infusion is synchronized with the calcium loss in the effluent, and the calcium content of replacement solutions

used in post-dilution (controllable using the REPLACEMENT CA CONC setting in Custom Mode).

The corresponding calcium solution volume infused by the Prismaflex syringe pump, will be removed in the effluent.

“Citrate – Calcium, Prismaflex syringe pump” anticoagulation method requires *use of the CA 250 Calcium Line assembly*, connected to the syringe. See Figure 2-10 “The Prismaflex CA 250 Calcium Line assembly” on page 57.

WARNING!
If “Citrate – Calcium, Prismaflex syringe pump” anticoagulation has been selected, use calcium-free dialysate solutions to avoid hypercalcemia.

WARNING!
If “Citrate – Calcium, Prismaflex syringe pump” anticoagulation has been selected, make sure to match the setting REPLACEMENT CA CONC in Custom Mode with the calcium concentration of the prescribed replacement solutions to avoid hyper- or hypocalcemia.

WARNING!
If "Citrate – Calcium, Prismaflex syringe pump" anticoagulation has been selected, the Prismaflex dedicated calcium infusion line (CA 250) must be used for calcium infusion.

CAUTION!
Do not operate the control unit without the non-return valve present at the end of the calcium infusion line.

8.5.5.2 Calcium prescription

In “Citrate – Calcium, Prismaflex syringe pump” anticoagulation method, the syringe flow rate is kept proportional to the estimated calcium loss rate in effluent. It is computed by the software of the Prismaflex system through the equation:

$Q_{syr} = CaComp \times J_{Ca} / [Ca] - Q_{rep} \times [Ca_{rep}] / [Ca]$

Where **CaComp** is the calcium compensation, $\mathbf{Q_{syr}}$ is syringe flow rate (mL/h), $\mathbf{J_{Ca}}$ is estmated calcium loss rate in effluent (mmol/h), **[Ca]** is calcium concentration of the syringe solution (mmol/L), Q_{rep} is the replacement flow rate (mL/h), and $[Ca_{rep}]$ is calcium concentration of the replacement solution in post-dilution (mmol/L).

8.5.5.3 Using calcium containing replacement solutions

The Prismaflex system supports the use of calcium containing replacement solutions in CVVH and CVVHDF modes.

If informed about the calcium concentration of the prescribed replacement solution, the Prismaflex system will deliver the desired calcium compensation, adjusted for the replacement flow.

The default calcium concentration of the replacement solution is to be set according to the prescribed solution. See Section 4.3.7 “Custom mode” on page 99.

8.5.5.4 Replacement solution delivery options

The adjustment of calcium infusion incorporating calcium containing replacement solutions is limited to post dilution only. Pre-dilution with calcium containing solutions is not supported.

For CVVH, 100% post-filter delivery is set as a non-changeable default in case a non-zero calcium concentration of replacement has been selected in Custom Mode.

For CVVHDF, post-filter delivery is set as a non-changeable default in case a non-zero calcium concentration of replacement has been selected in Custom Mode.

Refer to Section 5.4.2.2 “Replacement solution delivery options ” on page 119 for details on these settings.

8.5.5.5 Viewing the calcium compensation settings during treatment

During a patient treatment (Run mode), the current anticoagulation settings are displayed on the `Status` screen: calcium solution name and calcium compensation. In addition, the operator can access information about the calcium solution by pressing **VIEW SOLUTION** from the `Enter Anticoagulation Settings` screen.

8.5.5.6 Adjusting the calcium compensation

The operator is prompted to assess the default flow rates and syringe settings, 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. To adjust calcium infusion settings, press **CALCIUM COMP** softkey and use the softkey arrows to modify the percentage value and then press **CONFIRM ALL**. The calcium compensation value is set and displayed in percentage while the corresponding infusion rate is expressed in mL/h and mmol/h.

In Custom mode the operator can change the syringe brand allowed for use. See Section 4.3.7 “Custom mode” on page 99. The default calcium compensation percentage value is also adjustable in Custom mode, together with the calcium concentration of replacement solutions used in post-dilution.

In Run mode, the operator can access the `Enter Anticoagulation Settings` screen and adjust the settings as needed.

8.5.6 Operating limits

8.5.6.1 Calcium compensation range

The Prismaflex system software restricts calcium compensation to a specific range with predefined minimum and maximum values of 5% and 200% respectively. Existing limits of syringe flow rate can, however, further restrict this range:

- The minimum available compensation will raise when using highly concentrated calcium solutions, high flows of calcium-containing replacement solutions, or low effluent flow rates.
- The maximum available compensation will decrease when using highly diluted calcium solutions, or high effluent flow rates.

In these situations a change of the citrate dose, dialysate or replacement flow rate will lead to the most significant changes of the calcium compensation range.

8.5.6.2 Flow settings and citrate dose ranges

Available range of the flow or anticoagulation settings may be reduced with respect to usual operating range of the disposable set in use. These restrictions occur in relation to the minimum and maximum allowed flow rates for the calcium syringe pump, 2 – 100 mL/h. The Prismaflex system computes and displays the available range for each prescription parameter when making settings on the `Enter Flow` or `Enter Anticoagulation Settings` screens. Selection of a parameter outside the available range is prevented by the system.

8.5.6.3 Calcium solution concentration

As shown in Section 8.5.5.2 “Calcium prescription” on page 166, the concentration of the calcium solution is one of the three main factors defining the calcium syringe flow rates:

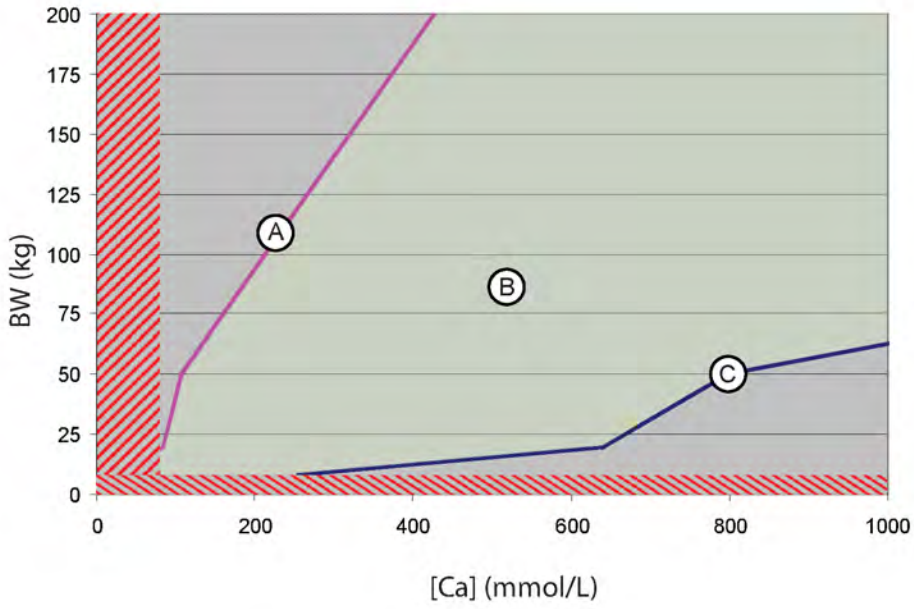
- Concentrated calcium solutions can lead to syringe flow rates in the lower range. This may significantly increase the minimum allowed settings for dialysate and/or replacement flow rates, as well as for citrate dose.
- Diluted calcium solutions can lead to syringe flow rates in the higher range and may decrease the maximum allowed settings of most prescription parameters.
- The software of the Prismaflex system restricts calcium concentration to a specific range as defined in Service mode, with predefined minimum and maximum values of 80 mmol/L and 1000 mmol/L, respectively.

Assuming calcium free replacement and dialysate solutions and a calcium loss rate in effluent as proportional (coefficient “k”) to the removal of small molecules and CRRT dose, a relation between patient body weight and calcium concentration can be established:

$Q_{syr} = [(CaComp / 100) \times k \times D_{CRRT} \times BW] / [Ca]$

Where $\mathbf{Q_{syr}}$ is Syringe flow rate (mL/h), **CaComp** is Calcium compensation (%), $\mathbf{D_{CRRT}}$ is CRRT dose (mL/kg/h), **BW** is Patient body weight (kg), **[Ca]** is Calcium concentration of the syringe solution (mmol/L) and **k** is a proportionality coefficient (mmol/L).

Above relation is used to set recommendations for the patient body weight range suitable for each calcium solution. A reminder of these recommendations is given on the `Therapy and Anticoagulation Choice` screen.



A. Represents the upper weight limit,
B. represents the recommended patient weight range,
C. represents the lower weight limit.

8.5.7 Safety system

The Prismaflex system provides additional alarms when citrate anticoagulation is performed:

Alarm specific to all "Citrate - Calcium" methods

- Advisory: Anticoagulation Checkpoints alarm reminds the additional monitoring of patient's parameter. The occurrence of the alarm can be selected in 'System Tools' as well as in Custom mode.

Alarm specific to "Citrate – Calcium, External Pump" anticoagulation method

- Advisory: Fluid Pump Stopped alarm occurs only when fluid pumps have stopped due to an alarm for more than ten minutes during treatment. Under this condition treatment and anticoagulation are interrupted while calcium delivery by the external infusion pump continues. The alarm reminds for additional monitoring of patient's parameter.

Alarms specific to "Citrate – Calcium, Prismaflex Syringe Pump" anticoagulation method

- Warning: Unsuitable Calcium Solution alarm occurs after `Confirm Loaded Set` screen if the calcium solution selected in custom mode is not suitable for use with the selected therapy or set type. (see Section 8.5.6.3 "Calcium solution concentration " on page 168)
- Warning: Ca Line Not Connected alarm is the equivalent of Advisory: Calcium Line Not Connected alarm for Setup mode; see below.

- Caution: Anticoagulation suspended alarm informs that citrate infusion is stopped since calcium infusion has been interrupted for too long. Citrate – Calcium anticoagulation is suspended. This alarms self-clears once anticoagulation is resumed.
- Advisory: Ca Line Not Connected alarm occurs when calcium infusion is not reconnected after syringe change or installation. It may also occur if connecting an infusion line other than the *CA 250 Calcium Line assembly*. See Figure 2-10 “The Prismaflex CA 250 Calcium Line assembly” on page 57.

Refer to Section 11 “Troubleshooting” on page 187 for troubleshooting instructions.

8.5.8 Factors to consider

8.5.8.1 Empty bag method

Use Variable Empty Bag method when using citrate solution bags and dialysate bags of different volumes, to prevent situations of wrong bag on wrong scale.

8.5.8.2 Calcium containing solutions

In case *non* calcium-free dialysate or replacement solutions are prescribed together with the “Citrate – Calcium, Prismaflex Syringe Pump” method in non-post delivery modes hypercalcemia may develop if operating with the default calcium compensation setting of 100%. In these conditions, the *initial* calcium compensation should be set below 100% as to take into account the amount of calcium infused through the dialysate or replacement flow. Standard patient monitoring and calcium infusion adjustment protocols shall apply after this initiation phase.

9 Blood warmers

9.1 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.

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.

CAUTION!
Use only Gambro-certified blood warmers. Refer to the Operator's Manual provided with the respective warmer for correct installation, setup, and use.

CAUTION!
Avoid moving the Prismaflex control unit when a blood warmer is installed. Adjust the warmer to resting position before moving the control unit.

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.

9.2 Blood warmers configuration

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.

9.3 Prismatherm II blood warmer

9.3.1 Description

CAUTION!
In CRRT therapy, the PrismaLung disposable kit shall not be used in combination with the Prismatherm II blood warmer due to excessive extracorporeal blood volume and pressure drop in the blood circut.

NOTE!
The Prismatherm II blood warmer must only be used with the PrismaLung disposable kit in combination with the HP-X set.

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.

9.3.2 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 9-1 “Maximum blood flow rate (Qbmax) compatible with the use of Prismatherm II blood warmer” on page 173.

9.3.3 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.

Table 9-1. Maximum blood flow rate (Qbmax) compatible with the use of Prismatherm II blood warmer

Prismaflex disposable set	Qbmax mL/min	Preturn mmHg
M60, ST60	180	80
M100, ST100	300/320	130
M150, ST150, oXiris	350/370	160
HF 1000, septeX	330/350	150
HF 1400	350/360	150
TPE20, TPE1000	180	90
TPE60, TPE2000	350	150

NOTE!
The above values are determined to provide an operating Filter pressure below +400 mmHg. For TPE1000, the “Plasmafilter is Clotted” alarm defines the threshold.

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.

9.4 Sleeve blood warmers

9.4.1 Description

WARNING!
Highest set point (43 °C) of the Prismacomfort warmer and the Prismaflo II 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.

WARNING!
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.

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 two sleeve warmer accessories having similar characteristics and performance:

- Prismacomfort
- Prismaflo II

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 Prismacomfort Operator Manual or the Prismaflo II Operator Manual for more information.

For information about availability of sleeve warmers and sleeve size, refer to the local Gambro representative.

9.5 NovaTherm™ heater/cooler device

WARNING!
The Prismaflex system in combination with the PrismaLung disposable kit and NovaTherm heater/cooler device complies with the Type B applied part classification per IEC 60601-1 standard. Do not use central venous catheter in atrial location in combination with the NovaTherm heater/cooler device. Failure to comply can result in arrhythmia due to leakage currents and electric shock.

CAUTION!
Avoid moving the Prismaflex control unit when a blood warmer is installed.

The NovaTherm heater/cooler device circulates temperature-controlled water through the heat exchanger of the PrismaLung blood-gas exchanger in order to adjust patient temperature.

The NovaTherm heater/cooler is designed to work together with the heat exchanger of the PrismaLung blood-gas exchanger. No other use is supported.

Refer to NovaTherm Operator Manual for more information.

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10 Alarm system

10.1 General warnings and cautions

WARNING!
When responding to any alarm, carefully follow the instructions on the displayed alarm screen and its associated `Help` screen.

WARNING!
Do not override the same alarm repeatedly. End treatment and call for service.

10.2 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. See also Section 11 "Troubleshooting" on page 187, where all alarms are described with information about how to troubleshoot each alarm.

10.3 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 **AUDIO PAUSED** softkey to temporarily silence the audible alarm (for 2 minutes, or until a higher priority alarm occurs).

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.

10.4 Warning alarms

10.4.1 Occurrence of 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.

10.4.2 Control unit actions during warning alarms

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.

10.4.3 Operator response to warning alarms

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.

10.4.4 Overriding 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.

10.5 Malfunction alarms

10.5.1 Occurrence of 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.

10.5.2 Control unit actions during malfunction alarms

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.

10.5.3 Operator response to malfunction alarms

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. This included:

- 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 Section 11.12 "Manual termination of treatment" on page 254.

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

10.5.4 Overriding 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.

10.6 Caution alarms

10.6.1 Occurrence of 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.

10.6.2 Control unit actions during caution alarms

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.

10.6.3 Operator response to caution alarms

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.

10.7 Advisory alarms

10.7.1 Occurrence of 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.

10.7.2 Control unit actions during advisory alarms

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.

10.7.3 Operator response to advisory alarms

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.

10.7.4 Overriding 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 Section 10.8.1 “About alarm priorities” on page 182.

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.

10.8 Alarm priorities

10.8.1 About 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 Runmode.

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

10.8.2 Alarm priority list

Table 10-1. Alarm Priority list: Malfunctions (High Priority) and Warnings

Priority	Alarm Title
Malfunctions (High Priority)	
1	General System Failure
2	Communication Error
3	Memory Error

Priority	Alarm Title
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	HP Cartridge Clotted
13	Blood Leak Detected
14	Access Extremely Negative
15	Return Extremely Positive
16	Access Extremely Positive
17	Filter Extremely Positive
18	Power Failure
19	Wrong Set Loaded
20	Effluent Bag Full
21	Bag/Container Empty
22	Bag Volume Incorrect
23	Effluent Bag Incorrect
24	Scale Open
25	Clamped Lines
26	Syringe Plunger Not Secured
27	Syringe Line Clamped
28	Syringe Empty
29	Calcium Line Clamped
30	Ca Line Not Connected
31	Calcium Syringe Empty
32	Recirculation Time Exceeded
33	Effluent Bag Full
34	Set-up Error
35	Wrong Set Selected
36	Crossed Lines
37	Clamped
38	Wrong Set Loaded
39	Loading Error
40	Battery Low
41	Unsuitable Ca Solution
42	Effluent Line Not in BLD
43	Fluid Leak Detected
44	Lines Not Clamped

Table 10-2. Alarm Priority list: Malfunctions

Priority	Alarm Title
Malfunctions	
45	Air Detector
46	Clamp Stuck Closed
47	Blood Pump
48	Effluent Pump
49	Replacement Pump
50	Dialysate Pump
51	Replacement 2 Pump
52	PBP Pump
53	Normalization Failed
54	Blood Leak Detector
55	Self-Test Failure
56	Prime Self-Test
57	Syringe Pump
58	Scales
59	Pressure Zero Test
60	Scale Zero Test
61	Custom Data
62	Library Data
63	Cannot Save Custom Data
64	Memory Error
65	Upper Pinch Valve
66	Lower Pinch Valve
67	Scales Circuit Board
68	Effluent Scale Sensor
69	Replacement Scale Sensor
70	Dialysate Scale Sensor
71	PBP Scale Sensor
72	Syringe Not Loaded / Ca Syringe Not Loaded
73	Line in Air Detector
74	Line in Clamp
75	No Line in Air Detector
76	No Line in Clamp
77	Memory Error, code 7
78	Auto Blood Return
79	Sound Check

Table 10-3. Alarm priority list: Cautions

Priority	Alarm Title
Cautions	
80	Loss Limit Reached/Gain Limit Reached
81	Unresolved Flow Problems
82	Flow Problem

Priority	Alarm Title
83	TPE Prescription Delivered
84	Effluent Bag Full
85	Bag Empty
86	TMP Excessive
87	TMPa Excessive
88	Bag Volume Incorrect
89	Effluent Bag Incorrect
90	Scale Open
91	Patient Fluid Gain Excessive
92	Anticoagulation Suspended
93	Fluid Leak Detected

Table 10-4. Alarm priority list: Advisory

Priority	Alarm Title
Advisory	
94	Check Access
95	Check Return
96	Blood Flow Stopped
97	Calcium Line Clamped
98	Ca Line Not Connected
99	Syringe not loaded / Ca Syringe Not Loaded
100	Fluid Pumps Stopped
101	Check Syringe Line
102	Syringe Empty
103	Syringe Line Clamped
104	Calcium Syringe Empty
105	Syringe Almost Empty / Ca Syringe Almost Empty
106	Filter is Clotting
107	Plasmafilter is Clotting
108	HP Cartridge is Clotting
109	TMP Too High
110	TMPa Too High
111	Time to Change Set
112	Cannot Detect Return
113	Download Interrupted
114	Anticoagulation Checkpoints
115	Self-Test Overdue
116	Memory Backup
117	MARS Treatment
118	Battery Exhausted
119	Main Power Lost
120	Incomplete Bolus
121	Check Oxygen Supply

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11 Troubleshooting

11.1 Warning alarms

Access Extremely Negative

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.

Cause	Operator action
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**/**DISCONNECT**[h]. If alarm recurs with a new set, end treatment via **STOP**/**DISCONNECT**[h]. Call service.

Access Extremely Positive

Alarm occurs if the access pressure is more positive than the user-controllable “Access Extremely Positive” Warning Limit.

Cause	Operator action
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**/**DISCONNECT**h. If alarm recurs with a new set, end treatment via **STOP**/**DISCONNECT**h. 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**/**DISCONNECT**h. If alarm recurs with new set, end treatment via **STOP**/**DISCONNECT**h. Call service.

Air in Blood

Cause	Operator action
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. Note: If air is present in entire set, press **DISCONNECT** to load and prime a new set. Remedy possible causes. Press Up arrow until return pressure is NEGATIVE. If unsuccessful, proceed with manual procedure. 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**.
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 Volume Incorrect

Valid only if Variable Empty Bag method is selected.

This alarm appears during priming only.

Cause	Operator action
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**. Note: If hanging multiple bags on the scale, the total fluid capacity of all bags on the scale must not exceed the allowed volume for that scale.
Foreign object on scale.	Remove foreign object. Press **CONTINUE**.
Identified solution bag is partially supported (not hanging freely).	Remove partial support. Press **CONTINUE**.

Bag/Container Empty

This alarm appears during priming only.

Cause	Operator action
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**.

Battery Low

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 Section 11.11 “Power failure” on page 253

Cause	Operator action
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

The alarm has an Alarm Condition Delay of up to 20 seconds.

Cause	Operator action
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 has been removed and then reinserted into the blood leak detector during an ongoing treatment (Run Mode).
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 has been removed and then reinserted into the blood leak detector during an ongoing treatment (Run Mode).
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.

Ca Line Not Connected

Cause	Operator action
The calcium infusion line is not connected to the syringe.	Connect a dedicated calcium infusion line to the syringe. Press **CONTINUE**.
Wrong line connected.	Use only a dedicated infusion line for the calcium infusion when the “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen.
The unused and stowed syringe line on the disposable set is connected to the calcium syringe.	Clamp the unused line on the disposable set and leave it unused during entire treatment when “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen. Press **CHANGE SYR/LINE** softkey and follow the instructions on the screen to connect a dedicated calcium infusion line to the syringe.
A syringe of the wrong size is installed.	Use only a 50 mL syringe of the allowed brand when the “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen.
Air in syringe.	Press **CHANGE SYR/LINE**. Follow instructions to install a full syringe and return to *alarm* screen. Press **CONTINUE**.

Calcium Line Clamped

Cause	Operator action
The calcium infusion line is clamped.	Unclamp the calcium infusion line. Press **CONTINUE**.
Incorrect installation of calcium infusion line.	Inspect calcium infusion line, remove any clamps, kinks or other obstructions. Use the clip above the syringe pump for the calcium infusion line to avoid kinks. Press **CONTINUE**.Note: In case of recurring alarm, press **CHANGE SYR/LINE** softkey to change both the syringe and the calcium infusion line.

Calcium Syringe Empty

This alarm appears during priming only.

Cause	Operator action
Calcium syringe is empty.	Press **CHANGE SYR/LINE** softkey and follow the instructions on the screen to install a full syringe and return to *alarm* screen. Press **CONTINUE**.

Clamped Lines

Cause	Operator action
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

Cause	Operator action
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

This alarm appears during priming only.

Cause	Operator action
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

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.

Cause	Operator action
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

Cause	Operator action
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 service.
Blood leak detector failed.	Press **DISCONNECT**, remove set. Call service.

Filter Clotted

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.

MARS Note: TMP value in the MARSFLUX filter is not considered for this alarm during CRRT MARS therapy; see section “Pressure management” in Prismaflex Operator´s Manual.

Cause	Operator action
Clots have formed in the filter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via **STOP**/**DISCONNECT**h. 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**/**DISCONNECT**h 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 "Citrate - Calcium" anticoagulation: Citrate delivery has failed.	Press **STOP**/**DISCONNECT**h and change the set. Ensure that PBP pump works properly. If PBP pump has failed, call service.
During CRRT MARS treatment: The MARS monitor has detected a blood leak.	If blood leak confirmed, press **STOP**/**DISCONNECT**h and change the set. If not, troubleshoot the MARS monitor and press **CONTINUE**.

Filter Extremely Positive

Alarm occurs if filter pod pressure is ≥450 mmHg.

Cause	Operator action
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**/**DISCONNECT**[h]. If alarm recurs with new set, end treatment via **STOP**/**DISCONNECT**[h]. Call service.
Filter pressure sensor failed.	End treatment via **STOP**/**DISCONNECT**[h]. Call service.
During CRRT MARS treatment: The MARS monitor has detected a blood leak.	If blood leak confirmed, press **STOP**/**DISCONNECT**[h] and change the set. If not, troubleshoot the MARS monitor and press **CONTINUE**.

Fluid Leak Detected

The fluid leak detector has detected a leak.

Cause	Operator action
A leak has been detected in the drip tray.	Check and ensure that: ● All connections are tight and leak-free. ● All bags are leak-free. ● All lines are connected and leak-free. ● There is no fluid in the drip tray. Dry the drip tray and wipe off the sensor. Press **REPRIME**/ **CONTINUE** to resume the treatment.

Other possible causes: Wet area at the Fluid Leak Detector.	If problem recurs, make sure that the sensor is dry and not contaminated by e.g. fluid residues. If the alarm still does not clear, press **DISCONNECT** and call for Service.

HP Cartridge Clotted

Filter pressure drop exceeds limit for the HP cartridge in use.

Cause	Operator action
Clots have formed in the HP cartridge. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via **STOP**/**DISCONNECT**[h]. Test patient's clotting parameters and adjust anticoagulant delivery if needed.
Clamped line(s) in blood flowpath.	Unclamp lines. Press **CONTINUE**.
During "Systemic, Prismaflex syringe pump" anticoagulation: Anticoagulation delivery has failed.	Press **STOP**/**DISCONNECT**[h] and change the set. Ensure that syringe is properly installed in syringe pump and plunger is moving upward during treatment. If plunger is not moving, syringe pump has failed. If desired, connect syringe line to a medically acceptable alternate anticoagulant delivery system. Call service to repair pump.
Pressure measurement failure.	Perform a self-test to reposition the pressure pod membranes.

Lines Not Clamped

Cause	Operator action
Access and/or Return line not clamped.	Clamp Access and Return lines and disconnect patient.
Other possible causes: Air in blood, External leakage in set, Internal Malfunction, Pressure pod not connected, monitor line not connected to return pressure port.	Press **OVERRIDE** followed by **CONFIRM** to resume the unload process. Check that Access and Return lines are clamped and press **UNLOAD** when the softkey is active.

Loading Error

Not possible to load/unload the set.

Cause	Operator action
Pinch valves position not correct.	Press **RETEST** to reposition the pinch valves and clear the alarm.

Plasmafilter Clotted

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.

Cause	Operator action
Clots have formed in the plasmafilter. Note: Clotting is usually due to inadequate anticoagulation of the blood flowpath.	Change the set via **STOP**/**DISCONNECT**[h]. 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**/**DISCONNECT**[h] 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 "Citrate - Calcium" anticoagulation: Citrate delivery has failed.	Press **STOP**/**DISCONNECT**[h] and change the set. Ensure that PBP pump works properly. If PBP pump has failed, call service.

Power Failure

Power lost for more than 15 seconds after machine entered Run mode.

Cause	Operator action
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

Cause	Operator action
Recirculation Time has exceeded the manufacturer-set limit.	Press **STOP RECIRC.** and resume the treatment.

Return Disconnection

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.

Cause	Operator action
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

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.

Cause	Operator action
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** / **DISCONNECT**[h]. If alarms recur with a new set, end treatment via **STOP**/**DISCONNECT**[h]. Call service.

Return Pressure Dropping

This alarm occurs if return pressure is 50 mmHg or 70 mmHg (with blood flow >200 mL/min) below its operating point.

Cause	Operator action
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

This alarm appears during priming only.

Cause	Operator action
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

Alarm occurs if filter pressure is lower than +10 mmHg and the filter pressure operating point is higher than +10 mmHg.

Cause	Operator action
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

Alarm occurs if pre-prime self-test fails.

Cause	Operator action
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

Cause	Operator action
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

Cause	Operator action
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**.

Syringe Plunger Not Secured

Cause	Operator action
The syringe plunger clamp latch is not closed.	Close the syringe plunger clamp latch. Press **CONTINUE**.

Unsuitable Ca solution

Alarm occurs after `Confirm Loaded Set` screen if no valid set of initial flow settings with reasonable operating ranges is available when using the selected calcium solution. See the chapter about anticoagulation in Operator's Manual. *Alarm* screen indicates if selected calcium solution is too diluted or too concentrated.

Cause	Operator action
The calcium solution selected in custom mode is not suitable for use with the selected therapy or set type.	Press **MODIFY SOLUTION**. Use arrows to select another calcium solution. Press **CONTINUE**. The CONTINUE button will only be available if suitable calcium solution is selected.
Alarm is recurring; no suitable calcium solution is available.	Press **UNLOAD** to load a different set type. Consult physician.

Wrong Set Loaded

This set cannot be used with the therapy selected.

Cause	Operator action
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

Cause	Operator action
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.

11.2 Warning alarm 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.

h. In run mode: **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.

Outside run mode: **DISCONNECT** stops all pumps, clears the alarm and displays the Confirm Disconnection screen. The following options are available: Cancel and Disconnect.

11.3 Caution alarms

Anticoagulation Suspended

Citrate infusion is stopped because calcium infusion has been interrupted for too long. Citrate – Calcium anticoagulation is suspended. This alarms self-clears once anticoagulation is resumed.

Cause	Operator action
Calcium syringe empty or not loaded, Calcium line clamped or not connected, fluid pumps stopped.	Press **OVERRIDE** and remedy underlying cause to prevent clotting in the set. Note: Calcium infusion requires additional monitoring of patient's parameters. Check prescription.

Bag Empty

Cause	Operator action
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

Variable Empty Bag method is selected, and amount of fluid in bag does not match Allowed Volume.

Cause	Operator action
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

Cause	Operator action
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

Effluent Bag volume does not match expected volume.

Cause	Operator action
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

Flow problem detected with fluid indicated on screen[c].

Cause	Operator action
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.

Fluid Leak Detected

The fluid leak detector has detected a leak.

Cause	Operator action
A connector is loose or not connected. A line is broken. **Other possible causes:** Wet area at the Fluid Leak Detector.	Check and ensure that: ● All connections are tight and leak-free. ● All bags are leak-free. ● All lines are connected and leak-free. ● There is no fluid in the drip tray. Dry the drip tray and wipe off the sensor. When the Fluid Leak Detector stops detecting fluid, the **CONTINUE** button is enabled. If the **CONTINUE** button does not get enabled, make sure that the sensor is dry and not contaminated by e.g., fluid residues. If the **CONTINUE** button is still not enabled, press **STOP** and end the treatment. Call service if problem recurs.

Gain Limit Reached

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.

Cause	Operator action
A flow problem has caused the Prismaflex control unit to infuse excess fluid to the patient: Repeated flow obstructions due to	Press **STOP** and end the treatment. If indicated, restart treatment with a new set.

closed clamps or kinked lines; Flow errors due to incorrect use of the acccess port on the effluent bag.	Use **HISTORY** to verify exact fluid exchange status at **STOP** time.

Loss Limit Reached

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.

Cause	Operator action
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

Cause	Operator action
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

Cause	Operator action
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

Scale not properly closed.

Cause	Operator action
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**[b] and end treatment. Call service.

TMP Excessive

Transmembrane pressure exceeds membrane pressure limit.

Cause	Operator action
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**/**DISCONNECT**[d] 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**.

TMPa Excessive

Access transmembrane pressure exceeds the safe limit.

Cause	Operator action
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.

TPE Prescription Delivered

Prescribed Total Replacement Volume has been delivered.

Cause	Operator action
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

Too many attempts to remedy Caution: Flow Problem alarms. Accuracy of patient fluid removal may be compromised.

Cause	Operator action
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.

11.4 Caution alarm 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.

d. In run mode: **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.

Outside run mode: **DISCONNECT** stops all pumps, clears the alarm and displays the Confirm Disconnection screen. The following options are available: Cancel and Disconnect.

11.5 Advisory alarms

Anticoagulation Check Points

Cause	Operator action
Reminder to monitor patient parameters.	"Citrate-Calcium" anticoagulation methods requires additional monitoring of patient parameters. This advisory occurs at a specific time interval when citrate is used. If "Citrate – Calcium, External Pump" anticoagulation method is selected, ensure proper delivery of calcium using an external syringe / infusion pump. Note: To change this checkpoint interval, use **SYSTEM TOOLS** in *Status* screen. Check with your physician for the occurrence of this advisory.

Battery Exhausted

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.

Cause	Operator action
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 " Section 11.11 "Power failure" on page 253" 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

Machine has been left in the Stop screen for 60 seconds.

Cause	Operator action
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.

Ca Line Not Connected

Cause	Operator action
Calcium line is not connected to the syringe.	Connect a dedicated calcium infusion line to the syringe. Press **CONTINUE**.
Wrong line connected.	Use only a dedicated infusion line for the calcium infusion when the “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen.
The unused syringe line on the disposable set is connected to the calcium syringe.	Clamp the unused syringe line on the disposable set and left unused during entire treatment when “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen. Press **CHANGE SYR/LINE** softkey and follow the instructions on the screen to connect a dedicated calcium infusion line to the syringe.
A syringe of the wrong size is installed.	Use only a 50 mL syringe of the allowed brand when the “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen.
Air in syringe.	Press **CHANGE SYR/LINE**. Follow instructions to install a full syringe and return to *alarm* screen. Press **CONTINUE**.
Missing non-return valve on calcium infusion line.	Press **CHANGE SYR/LINE**. Follow instructions to install a new calcium infusion line with a non-return valve and return to *alarm* screen. Press **CONTINUE**.

Ca Syringe Almost Empty

Cause	Operator action
Calcium syringe will be empty in 5 minutes.	To install a full syringe when this advisory appears, press **CHANGE SYR/LINE** and follow instructions on the screen. Then return to *alarm* screen and press **CONTINUE**.

Ca Syringe Not Loaded

Cause	Operator action
The calcium syringe is not loaded.	Press the **CHANGE SYR/LINE** softkey to load a calcium syringe. Then press **RETEST**

to restart Syringe Test. If failure recurs, end treatment via **DISCONNECT**. Call service.

Calcium Line Clamped

Cause	Operator action
Calcium line is clamped.	Unclamp the calcium infusion line. Press **CONTINUE**.
The central venous access on the patient is clamped.	Unclamp the central venous access on the patient.
The central venous access on the patient is obstructed by clots or sticks fast to the intima of the vein.	Check patient access patency for potential obstructions. Consult a physician for assessment of the central venous catheter.
Incorrect installation of syringe line.	Inspect calcium infusion line, remove any clamps, kinks or other obstructions. Use the clip above the syringe pump for the calcium infusion line to avoid kinks. Press **CONTINUE**. Note: In case of recurring alarm, press **CHANGE SYR/LINE** softkey to change both the syringe and the calcium line.

Calcium Syringe Empty

Cause	Operator action
Calcium syringe is empty.	Press **CHANGE SYR/LINE** softkey and follow the instructions on the screen to install a full syringe. Then return to *alarm* screen and press **CONTINUE**. Note: Use only a 50 mL syringe of the allowed brand when the “Citrate – Calcium, Prismaflex Syringe Pump” method is chosen.

Cannot Detect Return

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.

Cause	Operator action
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

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).

Cause	Operator action
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 Oxygen Supply

Cause	Operator action
The blood circuit is stable and the sweep gas flow shall be switched on.	Check that the gas outlet of the PrismaLung blood-gas exchanger is unobstructed. Also, check that the oxygen supply line (green) is connected to the sweep gas inlet of the PrismaLung blood gas exchanger. Switch on the sweep gas flow and adjust it according to prescription. Press **CONTINUE** when ready.

Check Return

This alarm occurs if return pressure is 50 mmHg or 70 mmHg (if blood flow >200 mL/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).

Cause	Operator action
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

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

Cannot save treatment data.

Cause	Operator action
Internal memory malfunction.	Insert an empty USB flash drive into the port on the rear panel. Press **DOWNLD DATA** to save the treatment data. Press **CONTINUE** to proceed with the treatment. If the alarm continues to occur with subsequent treatments, call service for repairs.

Filter is Clotting

Increasing TMP and/or Pressure Drop.

Note: TMP value in the MARSFLUX filter is not considered for this alarm during CRRT MARS therapy.

Cause	Operator action
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.

Fluid Pumps Stopped

Cause	Operator action
Citrate anticoagulation is used and fluid pumps have stopped for more than 10 minutes. Not applicable to "Citrate – Calcium, Prismaflex Syringe Pump" anticoagulation method.	Remedy the cause of interruption. Additional monitoring of patient's laboratory chemistry must be performed on patient: ionized calcium (Ca^{2+})

HP Cartridge is Clotting

Increasing Pressure Drop.

Cause	Operator action
Inadequate anticoagulation of the extra corporeal circuit.	Press **STOP**, change the set or test patient's clotting parameters and adjust if needed.
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 service. Or operator's action directs wrong measurement.
Wrong measurement of Filter pressure.	End treatment by pressing **STOP**. Call service.

Incomplete Bolus

Appears when a bolus is interrupted. The blood pump has been stopped, either by the operator or another alarm.

Cause	Operator action
An anticoagulation bolus could not be completed.	Check patient´s anticoagulation status. If indicated, administer not delivered volume.

Main Power Lost

Main power is lost and system operates on battery backup.

Cause	Operator action
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

Cause	Operator action
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

Applicable when machine configuration does not include the back-up battery (check with the local representative for more information).

Cause	Operator action
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

Increasing Pressure Drop.

Cause	Operator action
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.
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 service.
Wrong measurement of filter or effluent pressure.	End treatment by pressing **STOP**. Call service.

Self-Test Overdue

No periodic self-test has been completed within the last 150 minutes of treatment.

Cause	Operator action
Test was interrupted by secondary alarms.	Press **OVERRIDE**; remedy root cause of secondary alarms (e.g. access problems). Self-test will resume automatically from the beginning of the interrupted self-test phase.
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 resume automatically from the beginning of the interrupted self-test phase.
Test was repeatedly overridden by operator.	Press **OVERRIDE**; self-test will resume automatically from the beginning of the interrupted self-test phase.

Syringe Almost Empty

Cause	Operator action
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

Cause	Operator action
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: 1. Press **ANTICOAG SETTINGS**, change to "`Continuous, 0 mL/h`"; return to *alarm* screen. 2. Push plunger clamp release button to release syringe pump from end-of-travel position. 3. Press **CONTINUE** and alarm clears.

Syringe Line Clamped

Cause	Operator action
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

Cause	Operator action
The syringe is not loaded after Syringe Test has been performed.	1. Press **CHANGE SYRINGE**, follow instructions to load the syringe and return to *alarm* screen. 2. Press **RETEST** to restart Syringe Test. 3. If failure recurs, press **DISCONNECT**, call service and report failure.

Time to Change Set

Hours of use have reached the operator-set “Time to Change Set” limit for this therapy/set combination.

Cause	Operator action
A “Time to Change Set” advisory limit has been reached.	Press **STOP**/**DISCONNECT**[h] 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**/**DISCONNECT**[h] 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.

TMP Too High

Transmembrane pressure has reached user-set pressure limit.

Cause	Operator action
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**/**DISCONNECT**[h], 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**/**DISCONNECT**[h] 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**/**DISCONNECT**[h] 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**/**DISCONNECT**[h] and end the treatment. Turn off machine. Call service.
Wrong measurement of filter or effluent pressure.	End treatment by pressing **STOP**/**DISCONNECT**[h]. 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.

TMPa Too High

Access transmembrane pressure has reached user-set pressure limit.

Cause	Operator action
Inadequate anticoagulation of the extra corporeal circuit.	Press **STOP**/**DISCONNECT**[h], 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**/**DISCONNECT**[h] and end the treatment. Turn off machine. Call service. Or operator's action directs wrong measurement.

11.6 Advisory alarm 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.

h. In run mode: **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.

Outside run mode: **DISCONNECT** stops all pumps, clears the alarm and displays the Confirm Disconnection screen. The following options are available: Cancel and Disconnect.

11.7 Malfunction alarms

Air Detector

Cause	Operator action
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

Cause	Operator action
Blood return volume incongruence.	End treatment via **DISCONNECT**. If alarm recurs, call service.

Blood Leak Detector

Effluent line not properly installed in blood leak detector. Blood leak detector failed self-tests.

Cause	Operator action
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 has been removed and then reinserted into the blood leak detector during an ongoing treatment (Run Mode).
Blood leak detector failed.	If alarm does not clear, change set via **CHANGE SET** or end treatment via **DISCONNECT**[a]. Call service.

Blood Pump

Rate of Blood pump is incorrect.

Cause	Operator action
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: 1. Press **CONTINUE**. When `Status` screen appears, immediately press **STOP**. 2. On `Stop` screen, choose **END TREATMENT** and follow the instructions to disconnect patient and unload set. 3. Call service to remedy/clear alarm[b].
Pump failed.	Call service.

Ca Syringe Not Loaded

This alarm appears during priming only.

Cause	Operator action
The calcium syringe is not loaded.	Press the **CHANGE SYR/LINE** to load a calcium syringe. Then press **RETEST** to restart the Syringe Test. If failure recurs, end treatment via **DISCONNECT**. Call service.

Cannot Save Custom Data

Cause	Operator action
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.

Clamp Stuck Closed

Cause	Operator action
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

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

Cause	Operator action
See "Due to" message on `alarm` screen.	1. Turn machine off, remove return line from return line clamp, and return blood (when applicable). Note: Treatment can not resume using the loaded set once blood has been returned. 2. Restart machine. Once `Query` screen appears, make choice and carefully follow instructions. 3. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

Custom Data

Cause	Operator action
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

Rate of dialysate (green) pump is incorrect.

Cause	Operator action
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: 1. Press **CONTINUE**. When `Status` screen appears, immediately press **STOP**. 2. On `Stop` screen, choose **END TREATMENT** and follow the instructions to disconnect patient and unload set. 3. Call service to remedy/clear alarm[b].
Clamped line.	Check for clamped line. Press **CONTINUE**
Pump failed.	Call service.

Dialysate Scale Sensor

This alarm appears during priming only.

Cause	Operator action
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

Rate of effluent (yellow) pump is incorrect.

Cause	Operator action
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: 1. Press **CONTINUE**. When `Status` screen appears, immediately press **STOP**.

	2. On `Stop` screen, choose **END TREATMENT** and follow the instructions to disconnect patient and unload set. 3. Call service to remedy/clear alarm[b].
Pump failed.	Call service.

Effluent Scale Sensor

This alarm appears during priming only.

Cause	Operator action
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

Error Code: 1 to 7

Cause	Operator action
Turning Fluid pumps or Blood pump when machine in Safe state; Clamp forced to wrong position when machine in Safe state; Unanticipated actuator movement.	1. Turn machine off, remove return line from return line clamp, and return blood (when applicable). Note: Treatment can not resume using the loaded set once blood has been returned. 2. Restart machine. Once `Query` screen appears, make choice and carefully follow instructions. 3. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

Library Data

Cause	Operator action
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

Cause	Operator action
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

Cause	Operator action
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

Cause	Operator action
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

Cause	Operator action
See "Due to" message on *alarm* screen.	1. Turn machine off, remove return line from return line clamp, and return blood (when applicable).Note: Treatment can not resume using the loaded set once blood has been returned. 2. Restart machine. Once `Query` screen appears, make choice and carefully follow instructions. 3. If alarm recurs, end treatment manually (see above). Call service and report failure code before using machine again.

No Line in Air Detector

Cause	Operator action
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

Cause	Operator action
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

Attempt to normalize blood leak detector has failed.

Cause	Operator action
Filter blood leak; defective effluent line; air bubble in effluent line at level of BLD; effluent line not correctly installed; blood leak detector failed. Note: The Malfunction: Normalization failed alarm is displayed when the blood leak detector normalization has failed 3 times in a row.	Press **CHANGE SET** and follow the instructions to load a new set. If alarm recurs with new set, detector has failed. Press **DISCONNECT** to end treatment. Call service.

PBP Pump

Rate of pre-blood (white) pump is incorrect.

Cause	Operator action
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: 1. Press **CONTINUE**. When `Status` screen appears, immediately press **STOP**. 2. On `Stop` screen, choose **END TREATMENT** and follow the instructions to disconnect patient and unload set. 3. Call service to remedy/clear alarm[b].
Pump failed.	Call service.

PBP Scale Sensor

This alarm appears during priming only.

Cause	Operator action
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.

Pressure Zero Test

Zero test of one or more pressure sensors failed.

Cause	Operator action
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.

Pressures Circuit Board

Cause	Operator action
Hardware failure on pressures circuit board.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). Call service.

Prime Self-Test

Code: 1 to 28.

Detailed information on different alarm codes follows below.

Cause	Operator action
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. 1. **DISCONNECT** provides instructions to unload/remove set. 2. **NEW SET** gives instructions to unload set, load a new set, and start a new priming cycle. 3. **REPRIME** provides instructions to reprime the set. 4. **RETEST** restarts the prime test.

Prime Self-Test

Code: 1–7.

Due to: Pressure pod/sensor. All affected pods are reported.

1. Code=1 Access
2. Code=2 Filter
3. Code=3 Access and Filter
4. Code=4 Effluent (CRRT, TPE)
5. Code=5 Access and Effluent (CRRT, TPE)
6. Code=6 Filter and Effluent (CRRT, TPE)
7. Code=7 Access, Effluent and Filter (CRRT, TPE)

Cause	Operator action
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

Code=16

Due to: Return pressure sensor.

Cause	Operator action
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

Code=17 and 18

Due to: Blood leak detector normalization timeout or Blood leak detector threshold error.

Cause	Operator action
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

Code=19

Due to: Air/pumps safety test.

Cause	Operator action
Internal malfunction.	Press **RETEST**. If failure recurs, unload set via **DISCONNECT**. Call service and report failure code.
Presence of air at ABD level.	Disconnect monitor line and refill the chamber.

Prime Self-Test

Code=20

Due to: Pump occlusivity test.

Cause	Operator action
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

Code=21 – 23

Due to: Pinch valve(s).

Cause	Operator action
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

Code=24

Due to: 24 volt / 12 volt.

Cause	Operator action
24 volt / 12 volt test failed.	Press **RETEST**. If failure recurs, unload set via **DISCONNECT**. Call service and report failure code.

Prime Self-Test

Code=25

Due to: Return clamp sensor.

Cause	Operator action
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

Code=26

Due to: 24 volt Return clamp sensor.

Cause	Operator action
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

Code=28

Due to: Syringe Pump HW.

Cause	Operator action
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

Rate of replacement (purple) pump is incorrect.

Cause	Operator action
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: 1. Press **CONTINUE**. When `Status` screen appears, immediately press **STOP**. 2. On `Stop` screen, choose **END TREATMENT** and follow the instructions to disconnect patient and unload set.

	3. Call service to remedy/clear alarm[b].
Pump failed.	Call service.

Replacement Pump 2

Rate of replacement 2 (green) pump is incorrect.

Cause	Operator action
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: 1. Press **CONTINUE**. When `Status` screen appears, immediately press **STOP**. 2. On `Stop` screen, choose **END TREATMENT** and follow the instructions to disconnect patient and unload set. 3. Call service to remedy/clear alarm[b].
Pump failed.	Call service.

Replacement Scale Sensor

This alarm appears during priming only.

Cause	Operator action
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.

Scale Zero Test

Zero test of one or more scales failed.

Cause	Operator action
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.

Scales

The alarm has an Alarm Condition Delay of up to 20 seconds.

Scale in question is specified on the `alarm` screen.

Cause	Operator action
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 Section 11.12 “Manual termination of treatment” on page 254. Call service.

Scales Circuit Board

Cause	Operator action
Hardware failure on scales circuit board.	End treatment via **DISCONNECT**. Call service.

Self-Test Failure

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

Code=30, Sound check

WARNING!
The blood leak detector must be re-normalized if the effluent line has been removed and then reinserted into the blood leak detector during an ongoing treatment (Run Mode).

Sound Check

Cause	Operator action
The Start-up sounds were not detected successfully by the Prismaflex control unit.	Press **RETEST** to perform the sound check again. If the alarm does not clear: ● if a patient is connected: end the treatment by pressing the **DISCONNECT** button. If doing manual termination with blood return: air detection is not provided. Check the return line for air. ● if the monitor was not in treatment mode: turn the machine OFF and then turn it back ON. If the alarm recurs, call service to fix the issue before using the machine again.
The Start-up sounds were not detected due to too much surrounding noise.	Press **RETEST** at a later time, with less surrounding noise.

Syringe Not Loaded

Cause	Operator action
The syringe is not loaded after Syringe Test has been performed.	1. Press **CHANGE SYRINGE**, follow instructions to load the syringe and return to `alarm` screen. 2. Press **RETEST** to restart Syringe Test. 3. If failure recurs, press **DISCONNECT**, call service and report failure.

Syringe Pump

Code: 1–9.

Code = 1 Working mode incongruence between Syringe pump and set mode. The alarm has an Alarm Condition Delay of up to 15 seconds.

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.

Cause	Operator action
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). Call service. For “Citrate – Calcium, Prismaflex syringe pump” method: if alarm recurs, it is not possible to proceed. Press **END TREATMENT** and follow the instructions on the screen. **! NOTE!** Always call service to repair the syringe pump and clear the alarm.

Upper Pinch Valve

Cause	Operator action
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

Cause	Operator action
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 Section 11.12 “Manual termination of treatment” on page 254.Call service.

11.8 Malfunction alarm footnotes

a. Manual termination instructions are provided at the end of the Troubleshooting chapter in the Operator's Manual for Prismaflex.

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.

11.9 Miscellaneous

Display Error

Display goes blank, status lights go off, non-mutable buzzer sounds.

Cause	Operator action
Power loss, internal power supply failure.	Turn off machine to stop buzzer, end treatment manually, if desired[a].

Display Error

Display goes blank momentarily, then screen reappears.

Cause	Operator action
Power was lost and restored within 15 seconds.	None required.

Display Error

Display goes blank or logo screen fails to leave display, status lights may still be on, no buzzer.

Cause	Operator action
Internal power supply failure; internal malfunction.	Turn machine off, remove return line from return line clamp, and return blood (when applicable).See Section 11.12 “Manual termination of treatment” on page 254. Call service.

Display Error

Display “floats around”

Cause	Operator action
Display failure.	Turn machine off, remove return line from return line clamp, and return blood (when applicable).See Section 11.12 “Manual termination of treatment” on page 254. Call service.

Loader

Loader is already in loaded position, so that a set cannot be loaded.

Cause	Operator action
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.

Mis-colored Effluent bag

Effluent bag is tinged pink or red.

Cause	Operator action
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 **STOP**[b].
Hemolysis is occurring during TPE therapy.	Press **STOP** and change set.

Set Connections

Leakage from set connections.

Cause	Operator action
Connections are loose.	Tighten the connections. If leakage continues, change the set via **STOP**[b].

Softkeys

Softkeys won’t work.

Cause	Operator action
Touchscreen failed.	Turn machine off, remove return line from return line clamp, and return blood (when applicable). See Section 11.12 “Manual termination of treatment” on page 254. Call service.

11.10 Miscellaneous footnotes

a. Manual termination instructions are provided in Section 11.12 “Manual termination of treatment” on page 254.

b. See “Change Set and End Treatment Procedures” in “End Mode” in the Operator’s Manual.

11.11 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.

Once line power is reinstated, treatment and alarm settings are automatically restored to their previously set values.

See also Advisory: Battery Exhausted and Advisory: Memory Back-up for more information.

11.12 Manual termination of treatment

11.12.1 Reason for manual termination

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.

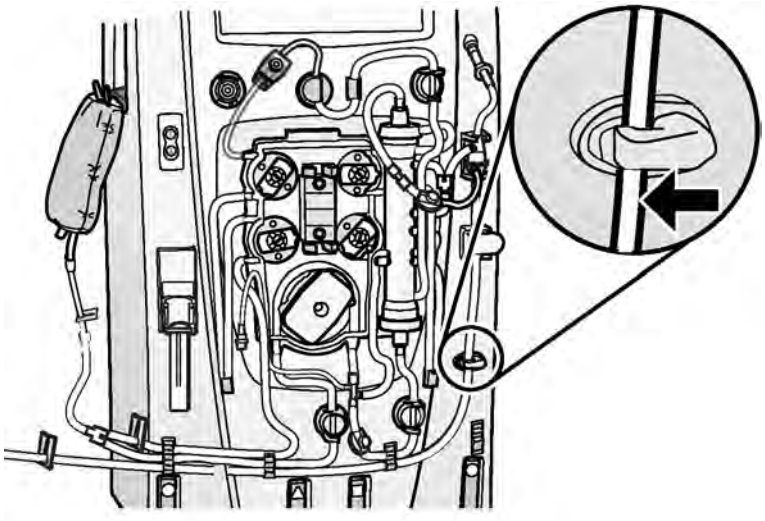
11.12.2 Manual termination with blood return

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.

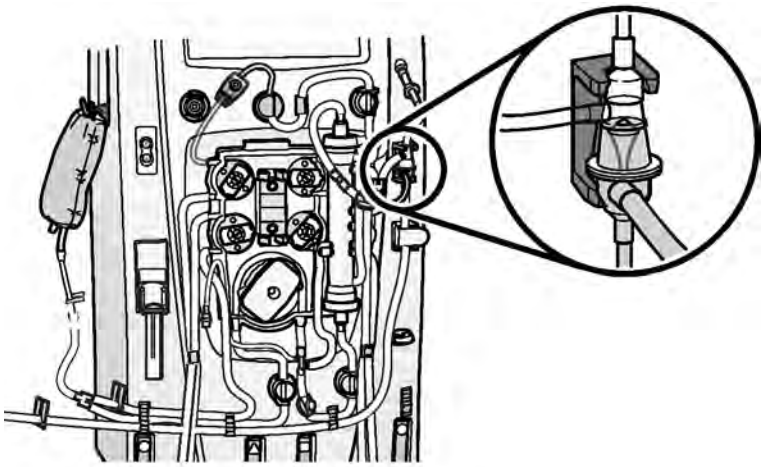
Procedure

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.



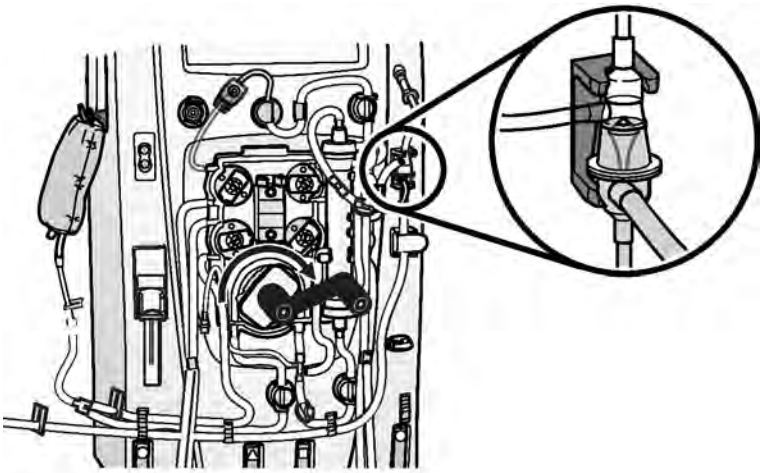
7) Visually check the fluid level in the deaeration chamber. If the level is too low, remove excess air as follows:

- 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.

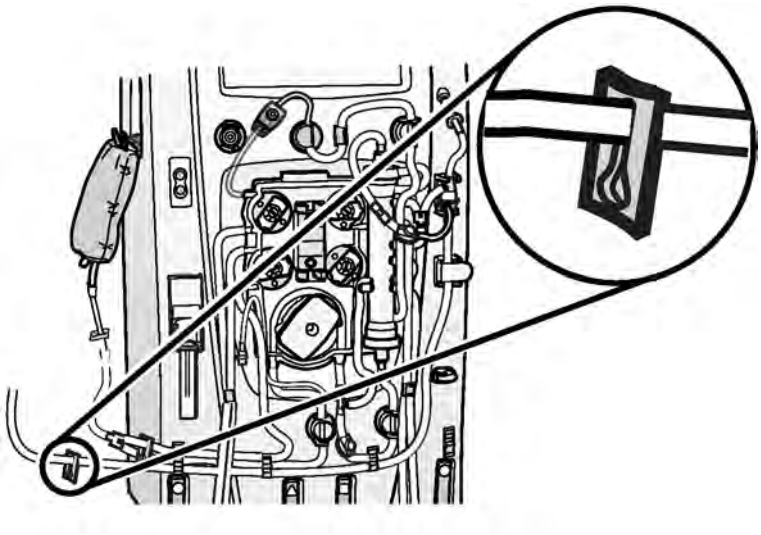


WARNING!
When blood is returned manually, there is no air detection. Visually check for air in the return line until patient is disconnected.

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.

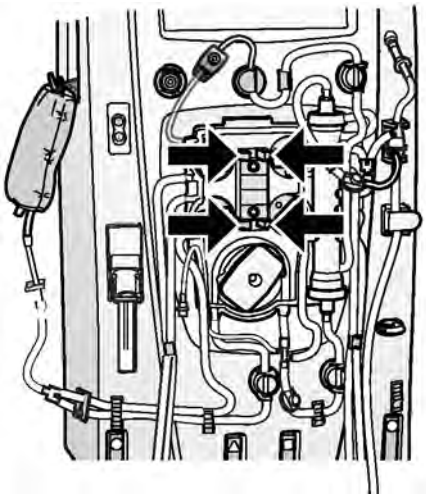


9) Clamp the return line (blue-striped) and disconnect from the patient. Clamp lines to all bags.



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.

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.

11.12.3 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.

Procedure

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.

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.

11.13 Leakage in pressure pods or wet 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.

CAUTION!
Do not operate the machine without a fluid barrier present at the end of monitor line.

Blood/fluid reached the fluid barrier

When blood or fluid has reached the fluid barrier at the distal end of the monitor line it will impair the pressure monitoring. Set needs to be changed before continuing the treatment.

Blood/fluid passed the fluid barrier or Leakage in pressure pods

If blood or fluid has passed the fluid barrier, 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.

11.14 Air removal procedures

11.14.1 Deaeration chamber

Frequent monitoring of the level is necessary. See Section 3.4 “Air management” on page 69.

11.14.2 Air in blood alarm – manual air removal

Before you begin

If pressing the Up arrow until return pressure is NEGATIVE is unsuccessful, proceed with manual procedure:

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.

11.15 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 Tools` screen.

Procedure

1) Press **Normalize BLD** from the `System Tools` screen.
2) Draw a sample from effluent line and test for blood. If blood present, discontinue the treatment and change the set. If no blood is present, proceed with the following step.

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

3) Verify the signal value displayed in the screen is 38000 or greater. If necessary, move effluent line slightly up or down in the blood leak detector to raise the signal value.

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

4) Press **START NORM**. The infrared LED drive signal is still adjusted so the received A/D signal range is between 42000 and 45000.
5) When normalization finishes, control unit automatically returns to the `Status` screen.

11.16 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.

12 Maintenance

12.1 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.

12.2 Hygiene and maintenance

12.2.1 Routine cleaning

CAUTION!
Using a stronger sodium hypochlorite (Bleach) solution than recommended can cause damage or discoloration.

CAUTION!
Do not clean the pump crank with sodium hypochlorite (Bleach). Sodium hypochlorite (Bleach) may damage the pump crank.

CAUTION!
Do not use other cleaning solutions than those recommended as the touch screen may be damaged.

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 with:
    - Ethyl alcohol (90%)
    - Isopropyl alcohol (70%);
    - Sodium hypochlorite (Bleach) 0.1%;
    - Citric acid (0.6%);
    - Sodium hypochlorite (1.5%);

12.2.2 Cleaning the blood leak detector

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

12.2.3 Cleaning the touch screen

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

You can clean the Touch screen with:

- Isopropyl alcohol (70%);
- Citric acid (0.6%);
- Sodium hypochlorite solution (active chlorine from 50,000 to 60,000 ppm) / Bleach diluted with water at a ratio of 1:50.

12.3 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)
- (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

12.4 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.

13 Specifications

13.1 Performance

13.1.1 Flow rates and accuracy

13.1.1.1 Therapy/set combination

Flow rate ranges and increment depend on the Prismaflex therapy/set combination selected by the operator. See Section 14 “Prismaflex® Disposable Sets” on page 286.

13.1.1.2 Blood flow rate

Range	10 to 450 mL/min
Increment	2 to 10 mL/min
Accuracy	Accuracy ±10% of user-set rate (at nominal blood flow of 450 mL/min or the highest achievable disposable blood flow, having 37 °C, at an access pressure of -200 mmHg and without any PBP flow)
Return Blood Flow Rate	6 to 100 mL/min When **START RETURN** softkey is pressed
Recirculation Flow Rate	20 to 100 mL/min

13.1.1.3 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%

13.1.1.4 Replacement solution/fluid flow rate

Table 13-1. CVVH; CVVHDF

Range	0 to 8000 mL/h
Increment	20 to 50 mL/h
Accuracy	± 30 mL/h

Table 13-2. CVVH

Predilution percentage	0 to 100%
Increment	5%

Table 13-3. CVVHDF

Predilution percentage	0 (postdilution) or 100% (predilution)
Accuracy	± 30 mL/h

Table 13-4. TPE

Range	0 to 5000 mL/h
Increment	10 mL/h
Accuracy	± 30 mL/h

13.1.1.5 Dialysate flow rate

Table 13-5. CVVHD; CVVHDF

Range	0 to 8000 mL/h
Increment	50 mL/h
Accuracy	± 30 mL/h

13.1.1.6 PBP solution rate

Table 13-6. 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

Table 13-7. TPE; HP

Range	0 to 1000 mL/h Note: Total PBP Volume is 2000 mL/treatment for TPE and HP.
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

13.1.1.7 Patient fluid removal performance / patient plasma loss performance

Table 13-8. 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.

Table 13-9. 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.

13.1.1.8 Effluent flow rate

Range	0 to 10,000 mL/h Depending on the therapy selected.

13.1.2 Syringe settings

13.1.2.1 Systemic, Prismaflex syringe pump anticoagulation method

Table 13-10. 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

Table 13-11. 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)

Table 13-12. 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

13.1.2.2 Citrate – calcium, Prismaflex syringe pump anticoagulation method Syringe Continuous Delivery Rate

Range	0, or 2.0 to 100 mL/h (50 mL syringe)
Increment	Not applicable
Accuracy	7%

13.1.2.3 Supported syringe sizes and types

Volume	Brand	Type
20 mL (Holder 20)	BD	PLASTIPAK
	TERUMO	
	Covidien / Kendall	Monoject
	B. Braun	Omnifix
	Others	
30 mL (Holder 30)	BD	PLASTIPAK
	TERUMO	
	B. Braun	Omnifix
	Others	

Volume	Brand	Type
50 mL (Holder 50)	BD	PLASTIPAK
	TERUMO	
	Codan	Luer lock
	Fresenius	Injectomat
	Covidien / Kendall	Monoject
	B. Braun	Omnifix
	Others	
50 mL (Holder 50B)	B. Braun	Perfusor

13.1.3 TPE settings

Table 13-13. Patient Hematocrit

Range	10 to 60%
Increment	1%
Default	30%

Table 13-14. Total Replacement Volume

Range	0 to 10,000 mL
Increment	100 mL
Default	3000 mL

Table 13-15. Replacement Container Volume

Range	0 to 5,000 mL
Increment	10 mL

13.1.4 Pressure sensor range, accuracy and alarm limits

13.1.4.1 Access

Operating Range	–250 to +450 mmHg
Accurancy	±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.

13.1.4.2 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.

13.1.4.3 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	Advisory alarm occurs Pressure in filter pod (immediately before the filter) is ≥450 mmHg.
a)Filter pressure drop	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
“HP Cartridge is Clotting” Advisory Limit	Advisory alarm occurs User controllable: Filter pressure drop is +10 to +30 mmHg (or one third of Max Pressure Drop for user defined HP cartridges) greater than initial filter pressure drop. Default: +30 mmHg (or one third of Max Pressure Drop for user defined HP cartridges) Increment: 10 mmHg Limit is reached (HP)
“Filter Clotted” Warning Limit	“Filter Clotted” Warning Limit 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)

“HP Cartridge Clotted” Warning Limit	Warning alarm occurs Filter pressure drop is ≥ limit value fixed for the HP cartridge in use
“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)

13.1.4.4 Trans Membrane Pressure (TMP/ TMPa)

Accuracy	±20 mmHg (CRRT) ±22 mmHg (TPE)
“TMP Too High” Advisory Limit	Advisory alarm occurs TMP equals user-set limit (CRRT) User controllable: +70 to +300 mmHg Default: +300 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)

13.1.4.5 Effluent

Operating Range	–350 to +400 mmHg (CRRT) –350 to +400 mmHg (TPE)
Accuracy	±15 mmHg

13.1.5 Patient safety

13.1.5.1 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.

13.1.5.2 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.

13.1.5.3 Fluid leak detector

Fluid leak detection	Caution alarm occurs. A fluid detector in the drip tray of the stand continually monitors the drip tray for fluids. A Caution alarm is issued once fluid has accumulated in excess of 50 mL.

13.2 Alarm signals

13.2.1 Standard

The audible and visual alarm indicators meet IEC 60601-2-16.

13.2.2 Audible

13.2.2.1 Sound pressure levels

The default setting for the Alarm sound is High volume, High pitch. Contact your local representative when alarm volume or pitch level should be adjusted. The minimum sound pressure level is 53 dB(A) Advisory alarms, Low volume, Low pitch.

WARNING!
The Responsible Organization shall compare and evaluate the sound pressure level of the Prismaflex control unit with the surrounding sound levels in the facility, and when different alarm presets are used for different Prismaflex control units in any single area. The Responsible Organization has to ensure that the control unit's alarm sound can be recognized when an alarm is present.

Malfunction alarms	81 dB(A)
Warning alarms	71 dB(A)
Caution alarms	68 dB(A)
Advisory alarms	68 dB(A)

13.2.2.2 Characteristics

Alarms can be silenced for 2 minutes, after which the audible alarm resumes if the alarm condition has not been remedied.

Recurring high sound	Warning and Malfunction alarms
Recurring medium sound	Caution alarms
Recurring low sound	Advisory alarms
Continuous for at least 2 minutes (alarm cannot be silenced)	Power loss

13.2.3 Visual

Red flashing	Warning and Malfunction alarms
Yellow flashing	Caution alarms
Yellow constantly lit	Advisory alarms

13.3 Information signals

13.3.1 Standards

Information signals meet IEC 60601-1-8.

13.3.2 Characteristics

3 sound pulses repeated 2 times at startup	Startup signal
3 sound pulses repeated 2 times during treatment	Chart reminder signal

13.4 Physical data

13.4.1 Weight and dimensions

	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)

	Stand without drip tray	Stand with drip tray
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)

13.4.2 Scales characteristics

13.4.2.1 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

13.4.2.2 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.

13.4.3 Power

13.4.3.1 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)

13.4.3.2 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.

13.4.4 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
USB Interface	USB 2.0 compatible

13.5 Environmental data

13.5.1 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 °C to 38 °C the upper limit is reduced by 2% per degree and at maximum ambient temperature (38 °C) the maximum operating relative humidity is consequently 65% (non-condensing).
Ambient Operating Air Pressure:	70 to 106 kPa (525 to 795 mmHg)

13.5.2 Transportation and storage

Transport and Storage Temperature:	–18 °C to +54 °C (0 °F to 130 °F)
Transport and Storage Humidity:	10% to 95% (non-condensing)
Never store unit in an environment where condensation may form.	
Prior to use, let unit adjust to ambient operating condition for at least 1 hour.	

13.5.3 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.

13.5.4 Vibration levels

Vibrations during operation	Acceleration Spectral Density (ASD), isotropic, 2-200 Hz ASD ≤ 5×10^{-8} g^2/Hz

13.5.5 Fluid spillage

Fluid Spillage:	IPX1 (Protection against vertically falling water drops) As specified in IEC 60529

13.5.6 Cleanability

Cleanability:	Not damaged by mild detergent; citric acid (0.6%); liquid soap; ethyl alcohol (90%); isopropyl alcohol (70%); sodium hypochlorite (0.1% to 1.5%). Pump rotors are removable.

13.5.7 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.

Guidance and manufacturer's declaration – Electromagnetic Immunity			
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	Compliance Level	Electromagnetic Environment – Guidance

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Prismaflex system is used exceeds the applicable RF compliance level above, the Prismaflex system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Prismaflex system.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Guidance and manufacturer's declaration – Electromagnetic Immunity			
			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 √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 √P 80 MHz to 800 MHz d = 2.3 √P 800 MHz to 2.5 GHz where “P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Prismaflex system is used exceeds the applicable RF compliance level above, the Prismaflex system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Prismaflex system.

[b] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Prismaflex system			
The Prismaflex system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Prismaflex system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prismaflex system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distances according to frequency of transmitter (m)**		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.			

13.6 Electrical safety

13.6.1 Classification

WARNING!
The protection of the Prismaflex system against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.

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.

Classification:	Mobile, Class I, applied part is Type CF, defibrillation proof as per IEC 60601-1
	Mobile, Class I, applied part is Type B, as per IEC 60601-1 when using the Prismaflex system in combination with the MARS system.
	Mobile, Class I, applied part is Type B, as per IEC 60601-1 when using the Prismaflex system in combination with the PrismaLung disposable kit and a NovaTherm heater/cooler device.

13.6.2 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

13.6.3 Defibrillation-proof applied part

Applied part is Type CF, defibrillationproof per IEC 60601-1

Defibrillator equipment meets requirements of IEC 60601-2-4

13.6.4 Radio frequency interference

Meets European Standard EN 55011, limit B

Meets IEC 60601-1-2

13.6.5 Electromagnetic compatibility

Meets IEC 60601-1-2

13.6.6 Potential equalization

Meets IEC 60601-1

The Prismaflex control unit has a connection for a Potential Equalization Conductor.

See Section 2.2.4 “Rear panel components” on page 48.

13.6.7 Continuous operation

The Prismaflex system is intended for continuous operation.

13.7 Conformity to international rules

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-16	Medical electrical equipment - Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
CAN/CSA No.601.1-M90 incl. S1-94 CAN/CSA No. 601.1B-90	Medical Electrical Equipment - Part 1: General requirements for safety
UL 60601-1	Medical electrical equipment - Part 1: General requirements for safety

13.8 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

14 Prismaflex® Disposable Sets

14.1 Minimum and maximum flow rates

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.

14.2 CRRT disposable sets

14.2.1 Low flow sets

14.2.1.1 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
ST60	1	1000	50 to 180	5	93
HF20	1	500	20 to 100	2	58

14.2.1.2 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
ST60	60 to 200	0 to 2000	5
HF20	60 to 150	0 to 500	5

14.2.1.3 Solution flow rates

Set	Replacement flow range predilution	Replacement flow range postdilution	Replacement flow increment	Dialysate flow range	PBP flow range
M60	0 to 4000	0 to 3000	50	0 to 4000	0 to 2000
ST60	0 to 4000	0 to 3000	50	0 to 4000	0 to 2000
HF20	0 to 2500	0 to 2000	20	0 to 2500	0 to 1000

14.2.1.4 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
ST60	10 to 100	40	5	30 to 100	5
HF20	6 to 50	20	2	20 to 50	2

14.2.2 High flow sets

14.2.2.1 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
ST100	1	1000	80 to 400	10	152
M150	2	2000	100 to 450	10	189
ST150	2	2000	100 to 450	10	189
HF1000	1	1000	80 to 400	10	165
HF1400	2	2000	100 to 450	10	186
oXiris	2	2000	100 to 450	10	189

14.2.2.2 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
ST100	100 to 400	0 to 2000	10
M150	100 to 400	0 to 2000	10
ST150	100 to 400	0 to 2000	10
HF1000	100 to 400	0 to 2000	10
HF1400	100 to 400	0 to 2000	10
oXiris	100 to 400	0 to 2000	10

14.2.2.3 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
ST100	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
ST150	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
oXiris	0 to 8000	0 to 8000	50	0 to 8000	0 to 4000

14.2.2.4 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
ST100	10 to 100	70	5	50 to 100	5

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)
M150	10 to 100	70	5	50 to 100	5
ST150	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
oXiris	10 to 100	70	5	50 to 100	5

14.2.3 Other sets

14.2.3.1 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)
septeX	1	1000	80 to 400	10	164
X-MARS[a]	1	2000	130 to 450	10	279

[a] 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.

14.2.3.2 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)
septeX	100 to 400	0 to 1000	10
X-MARS	100 to 400	0 to 1000	10

14.2.3.3 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)
septeX	0	0 to 500	50	0 to 8000	0 to 500
X-MARS	0 to 4000	0 to 4000	50	0 to 8000	0 to 4000

14.2.3.4 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)
septeX	10 to 100	70	5	50 to 100	5
X-MARS	10 to 100	70	5	50 to 100	5

14.3 TPE disposable sets

14.3.1 Low flow sets

14.3.1.1 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)
TPE1000	2	2000	50 to 180	5	71
TPE20	1	1000	50 to 180	5	65

14.3.1.2 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)
TPE1000	10 to 100	40	5	30-100	5
TPE20	10 to 100	40	5	30-100	5

14.3.2 High flow sets

14.3.2.1 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 250/400[a]	5	125
TPE60	1	1000	100 to 400	5	146

[a] Depending on machine default set up

14.3.2.2 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
TPE60	10 to 100	70	5	50 to 100	5

14.4 HP kits

14.4.1 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)
Adsorba 150	3	2500	50 to 250	10	247
Adsorba 300	3	2500	100 to 350	10	367
HP-X	User defined[a]	1000 to 15000	50 to 450	10	108[b]
HP-X Prismalung	1	1000	10 to 450	10	173

[a] Defined by dividing priming volume and bag volume for user defined cartridge in Custom mode. See Section 15.4 "HP specific settings" on page 297.
[b] Only for the line set. Blood volume for user defined cartridge shall be added for total blood volume.

14.4.2 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)
Adsorba 150	10 to 100	70	5	30 to 100	5
Adsorba 300	10 to 100	70	5	50 to 100	5
HP-X	10 to 100	50	5	50 to 100	5
HP-X Prismalung	10 to 100	50	5	100	5

15 User-controllable settings

15.1 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/Year	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[a]			
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	0:00 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

[a] See Section 13 “Specifications” on page 266

15.2 CRRT specific settings

Setting	Default	Options	Change Default	Change Present Treatment	
			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.	HF20: 60 - 150 mL M60, ST60: 60 - 200 mL M60, ST60: 60 - 200 mL M60, ST60: 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[a]	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 30 mL/h)[b]	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[c] Increment: 20 mL/h for HF20.	X	X	X

[a] See Section 13 “Specifications” on page 266
[b] See Section 13 “Specifications” on page 266
[c] See Section 13 “Specifications” on page 266
[d] See Section 13 “Specifications” on page 266
[e] See Section 13 “Specifications” on page 266
[f] See Section 13 “Specifications” on page 266

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
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[d]	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[e]	X	X	X
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[f]	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		

[a] See Section 13 “Specifications” on page 266
[b] See Section 13 “Specifications” on page 266
[c] See Section 13 “Specifications” on page 266
[d] See Section 13 “Specifications” on page 266
[e] See Section 13 “Specifications” on page 266
[f] See Section 13 “Specifications” on page 266

15.3 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 [a]	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) [b]	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[c]	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		

[a] See Section 13 “Specifications” on page 266
[b] See Section 13 “Specifications” on page 266
[c] See Section 13 “Specifications” on page 266

15.4 HP specific settings

Setting	Default	Options	Change Default	Change Present Treatment	
			Custom	Setup	Run
“HP Cartridge is Clotting” Advisory Limit	Filter pressure drop is +30 mmHg (or one third of Max Pressure Drop for user defined HP cartridges) greater than initial filter pressure drop	+10 to +30 mmHg (or one third of Max Pressure Drop for user defined HP cartridges) 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[a]	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)[b]	X	X	X
Time to Change Set	6 hours	1 to 72 hours Increment 1 hour	X	X	X
Empty Bag Method	Variable	Variable	X		
Allowed Bag Volume — PBP Bag	5000 m	250 to 5000 mL Increment: 50 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		

[a] See Section 13 “Specifications” on page 266
[b] See Section 13 “Specifications” on page 266

15.5 User defined HP cartridges

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
HP Cartridge ID	Undefined	Use keyboard to enter HP Cartridge ID	X		
HP Cartridge Volume	0 mL	0 to 400 mL Increment: 5 mL	X		
Max Blood Flow	0 mL/min	0, 50 to 450 mL/min Increment: 10 mL/min	X		
Max Pressure Drop (”HP Cartridge Clotted” Warning Limit)	150 mmHg	50 to 300 mmHg Increment: 50 mmHg	X		
Solution ID	Undefined	Use keyboard to enter Solution ID	X		
Priming Volume	0 mL	0 to 5000 mL Increment: 250 mL	X		
Bag Volume (priming)	0 mL	0 to 5000 mL Increment: 250 mL	X		
Flow Rate (priming)	0 mL/min	0 to 300 mL/min Increment: 10 mL/min	X		

15.6 Anticoagulation related settings

15.6.1 Systemic anticoagulation method

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
Syringe Brand[a]	TERUMO 50	20 mL (Holder 20): BD PLASTIPAK TERUMO Covidien / 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 Covidien / 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

[a] Syringe holder size is configurable in service mode.

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
Syringe Bolus Delivery Interval	Once every 6 hours.	Once every 1 to 24 hours Increment: 1 hour Note: Immediate option also available in Run mode		X	X
Syringe “Immediate” Bolus Volume Note: End mode, Recirculation only	0 mL (no delivery)	0 mL, or 0.5 to 5.0 mL Increment: 0.1 mL			

[a] Syringe holder size is configurable in service mode.

15.6.2 Citrate – calcium method

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
Syringe Brand[a]	TERUMO 50	50 mL (Holder 50): BD PLASTIPAK TERUMO Codan Luer lock Fresenius Injectomat Covidien / Kendall Monoject B. Braun (Omnifix) 50 mL (Holder 50B): B. Braun (Perfusor)	X		
Calcium solution	Defined in Service mode, then solution selectable in Custom mode	Calcium concentration: 80 to 1000 mmol/L Increment: 1 mmol/L	X		
Citrate solution[b]	Defined in Service mode, then solution selectable in Custom mode	Citrate concentration: 10 to 600 mmol/L (CRRT) 75 to 600 mmol/L (CRRT septeX) 50 to 300 mmol/L (TPE) Citrate acid concentration: 0 to 100 mmol/L (CRRT, CRRT septeX) 0 to 50 mmol/L (TPE) Increment: 1 mmol/L	X		

[a] Syringe holder size is configurable in service mode.
[b] The sum of the citrate and citric acid concentrations is not allowed to exceed the maximum citrate concentration applicable to the selected therapy.

Setting	Default	Options	Change Default	Change Present Value	
			Custom	Setup	Run
Calcium compensation	100%	5 to 200%	X	X	X
Citrate Dose	3.0 mmol/L of blood	0, 1.5 to 6.0 mmol/L of blood Increment: 0.1 mmol/L of blood	X	X	X
Replacement Calcium Concentration	0.00 mmol/L	Calcium concentration: 0.00 to 1.75 mmol/L Increment: 0.05 mmol/L	X		

[a] Syringe holder size is configurable in service mode.
[b] The sum of the citrate and citric acid concentrations is not allowed to exceed the maximum citrate concentration applicable to the selected therapy.

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