#### Baxter



### The PRISMAFLEX System

## One platform. Multiple therapies.

The PRISMAFLEX System is a flexible, filter-based solution that meets the demands of multiple therapies with a versatile platform that can be customized to specific patient needs.

#### The PRISMAFLEX Control Unit is intended for:

Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal



The PRISMAFLEX System pumps blood from the patient through a filter and back into the patient's circulatory system. As the blood passes through the filter, the desired treatment processes take place. Depending on the therapy, the processes can include fluid removal, hemofiltration or plasma exchange.



#### Confidence

This complete system is designed to closely mimic the body's kidney function. It features state-of-the-art technology that helps to support critically ill patients. When considering patients' diverse therapy needs, you can have confidence in the PRISMAFLEX System.

#### **Versatility**

No two patients are the same. The diversity of critically ill patients requires individualized care. Unlike intermittent hemodialysis (IHD) or slow low efficiency dialysis (SLED), the PRISMAFLEX System delivers slow, continuous 24-hour treatment for:

- Metabolic control
- Fluid removal
- Acid/base control
- Electrolyte balance

The PRISMAFLEX System delivers all modes of continuous renal replacement therapy (CRRT) and therapeutic plasma exchange (TPE) without additional equipment. The PRISMAFLEX System can be used for:

CVVHDF - Continuous Veno-Venous Hemodiafiltration

CVVHD - Continuous Veno-Venous Hemodialysis

CVVH - Continuous Veno-Venous Hemofiltration

SCUF - Slow Continuous Ultrafiltration

TPE - Therapeutic Plasma Exchange



#### **CRRT** on the **PRISMAFLEX** System

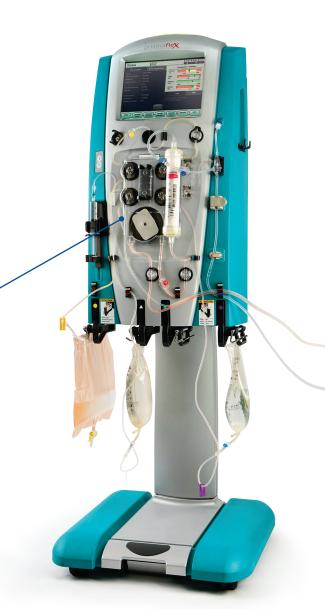
CRRT is a dialysis modality used to treat critically ill, hospitalized patients in the intensive care unit who develop acute kidney injury (AKI). Unlike chronic kidney disease, which occurs slowly over time, AKI often occurs in hospitalized patients treated in an intensive care environment, and it typically occurs over a few hours to a few days.

The innovative PRISMAFLEX System is designed specifically to support critically ill AKI patients. The physiologic therapy enables slow and continuous fluid removal and supports patient recovery.

#### **TPE on the PRISMAFLEX System**

TPE is a procedure that separates plasma that may contain disease mediators from the patient's blood. Plasma exchange on the PRISMAFLEX System is achieved by plasma filtration with simultaneous infusion of a replacement solution.

During TPE, plasma is removed and pumped through the large-pore membrane of the plasma filter, while a colloid solution, such as albumin and/or plasma, or a combination of crystalloid/colloid solution is infused postplasma filter to replace the removed plasma.



## Treating patients with the PRISMAFLEX System

Baxter is a true leader in the industry, advancing filter-based blood purification therapies for patients with a steadfast focus on safety. We are committed to making ongoing improvements to the PRISMAFLEX System and software. Our attention to continuous advancements ensures we always deliver systems and software that meet and exceed your needs.

The PRISMAFLEX System is designed for the critically ill patient. Its fluid algorithms help balance patient chemistry with fluid removal for optimal therapy delivery. Clinicians can monitor how much therapy the patient is receiving within 7 mL of fluid accuracy, at any given time.

For nurses and clinicians, time is precious. The PRISMAFLEX System may help save time by providing automatic adjustments and immediate visual feedback of the system's condition. With this system, you can spend your time serving, observing and caring for patients – not managing machines.

The PRISMAFLEX System features the latest 7.11 software with updated, user-friendly design enhancements and streamlined alarm management – helping make the system intuitive and easy to use from start to finish.

#### 7.11 software features include:

Design improvements

- · Improved, logic-based screens and displays.
- A more robust history screen with up to 96 hours of treatment data.
- · Easier dose tracking.

Streamlined alarm management

- · Minimized multiple-alarms.
- Consolidation of access and return pressure alarms.
- Updated color-coded alarm icons and notifications.

#### Overall ease of use

- Easy-to-understand prescription assistance and delivery choices.
- Updated images to more clearly explain the steps to mix and connect solution bags and change the effluent bags.
- · One-click auto blood return.

Safety-focused features

#### Integrated anticoagulation

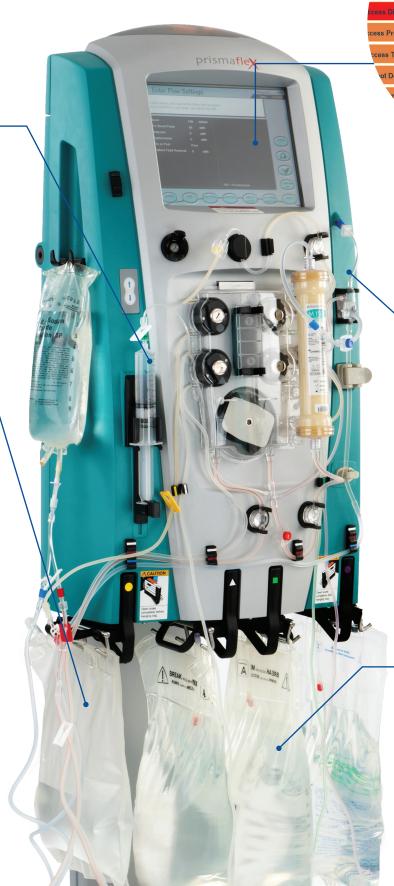
Therapies such as CRRT require carefully balanced anticoagulation, which is administered during therapy in accordance with a physician's order. The PRISMAFLEX System:

- Provides automated and integrated anticoagulation options through the fifth fluid pump (pre-blood pump) and syringe pump.
- Eliminates the need for manual dose programming of ancillary pumps outside the system.

#### **Accurate fluid management**

We encourage you to compare our accuracy specifications to other systems. The PRISMAFLEX System:

- Features a highly accurate, scale-based fluid management system (+/- 300 mL/24 hrs).
- Provides fluid removal accuracy through algorithms and self-calibrating fluid scales.
- Monitors accumulated fluid balance/imbalance and adjusts accordingly to help reduce risk of patient injury.
- · Allows for easier dose tracking.

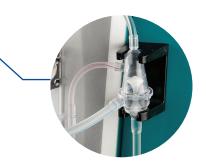




#### Streamlined alarm management

The PRISMAFLEX System features streamlined alarm management to minimize multiple-alarm situations. The updated alerts and alarms comply with new 2016 international standards.

- Consolidated access and return pressure alarms minimize end user interventions and alarm fatigue.
- The preventive maintenance reminder screen, as well as color-coded alarm icons and notifications, make the system easy to use and manage.
- Alarms for blood leak detection and incomplete dosage or bolus keep clinicians informed of the status during all treatments.



#### **Patented deaeration chamber**

Automatic air removal via the patented deaeration chamber is a key safety feature on the PRISMAFLEX System. The fluid level in the chamber may vary due to procedures during treatment. Small amounts of air may be introduced each time a bag is changed; therefore, frequent monitoring of the levels is important. The deaertion chamber:

- Automatically removes air during therapy.
- · Monitors return line pressure.
- Adds post-filter replacement solution to the return line.
- Includes a fluid barrier that protects the return pressure sensor from accidental blood entry.



#### Innovative sterile solutions

With market-leading sterile dialysate and FDA-approved replacement fluids, Baxter is your source for sterile solutions designed for therapy flexibility. Our multiple sterile solution formulations:

- Allow for prescription flexibility and acid-base balance using a wide range of bicarbonate buffered solutions with various ionic formulations.
- May help reduce preparation time, waste and potential for medication errors associated with manually mixed products.
- Are packaged in two-compartment bags to ensure solution stability.

# Time-management benefits

#### Optimized touch screens \_\_\_

The logic-based design of the PRISMAFLEX System's status and notification touch screens allows for easy use from start to finish. The design features include:

- · Logic-based screens and displays.
- · Intuitive symbols and large, easy-to-use buttons.
- · Color-coded, large and easy-to-read pressure bar displays.

#### **Integrated EMR connectivity**

The EMR connectivity of the PRISMAFLEX System promotes improved clinician workflow by helping to reduce manual documentation. The PRISMAFLEX System:

- Integrates conveniently with most hospital EMR systems, either directly or through a third party.
- · Eliminates manual recording and transfer of treatment data.
- Enables treatment data download.

#### State-of-the-art features and benefits

The PRISMAFLEX System's state-of-the-art 7.11 software offers the following benefits:

- Easy-to-understand prescription delivery choices.
- Clear, image-based explanations of the steps to mix and connect solution bags and change the effluent bags.
- One-click auto blood return.
- A robust history screen with up to 96 hours of treatment data.
- Easier dose tracking.



#### Automated pressure monitoring and calibration

The PRISMAFLEX System provides automatic, real time tracking of all relevant pressures including filter pressure and transmembrane pressure (TMP). Benefits include:

- Self-checks every two hours to eliminate manual monitoring and calibration of pressure sensors.
- · Automatic detection of system leaks.
- Possible reduction of nurse intervention due to the automated system checks.

#### Proven hemofilter sets

By providing a wide range of molecular clearances, Baxter hemofilter sets are designed to maximize therapy delivery for critically-ill patients and help reduce complexity for clinicians. Hemofilter sets designed for the PRISMAFLEX System:

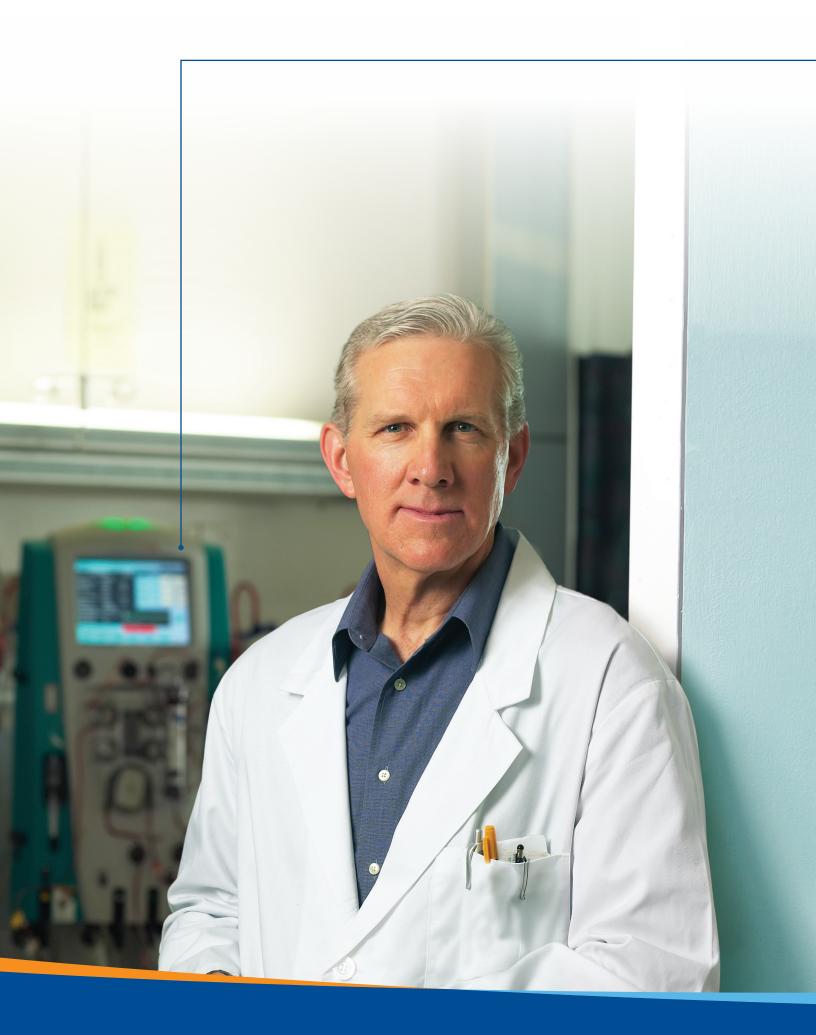
- Offer proven performance. AN 69 hemofilters were used exclusively in the 2009 RENAL study, featured in the New England Journal of Medicine.
- · Provide middle/large molecule clearance.
- Offer both low to high flow to help meet your patients' needs.
- Eliminates the requirement for periodic filter flushings.



# Complete system from start to finish

The PRISMAFLEX System can help you meet the demands of multiple therapies with a complete and versatile platform that can be customized to specific patient needs.

- All sets automatically load and self-prime.
- Tubing on hemofilter sets are preconnected and color coded for easy visual setup.
- System disposables and effluent never need to touch the floor.
- Back-up battery enables 10+ minutes of uninterrupted therapy delivery upon temporary power disconnect.
- · Intuitive on-screen troubleshooting visuals are accessible during setup and therapy delivery.
- Does not require confirmation that therapy bags are draining equally.
- · Scale-based systems allow for real time automated measuring of fluid loss/gain.



# Expand your treatment options with an industry leader

With 24/7 clinical support and a large, experienced support team to help train your staff on the new PRISMAFLEX System 7.11 software, Baxter provides all the resources you need to confidently offer patients the latest innovations in filter-based blood purification therapies.

With the 2013 acquisition of Gambro, Baxter further enhanced its global renal leadership by expanding its product and therapies portfolio. The combined experience of these two respected renal leaders enables Baxter to better serve health care providers and patients through a collective offering of innovative renal products and therapies.

To learn more about the PRISMAFLEX System and the latest 7.11 software, please call 800-4Baxter.

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- Prismaflex System Operator's Manual, version 7.11.
   Prismaflex System Service Manual SW 7.XX
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