Baxter

The PRISMAFLEX System

Therapeutic Plasma Exchange

Making possible personal.

One Platform. Multiple Therapies.

Therapeutic Plasma Exchange on the PRISMAFLEX System.

The PRISMAFLEX Control Unit is intended for:

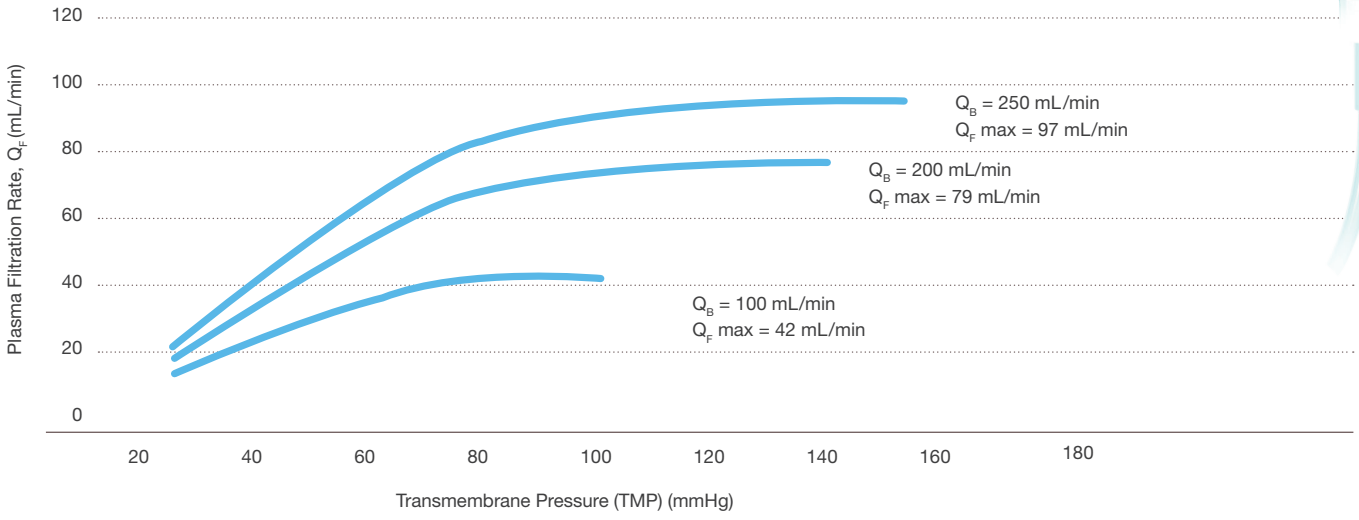
- Continuous Renal Replacement Therapy (CRRT) for patients weighing 20 kilograms or more with acute renal failure and/or fluid overload.
- Therapeutic Plasma Exchange (TPE) therapy for patients weighing 20 kilograms or more with diseases where removal of plasma components is indicated.

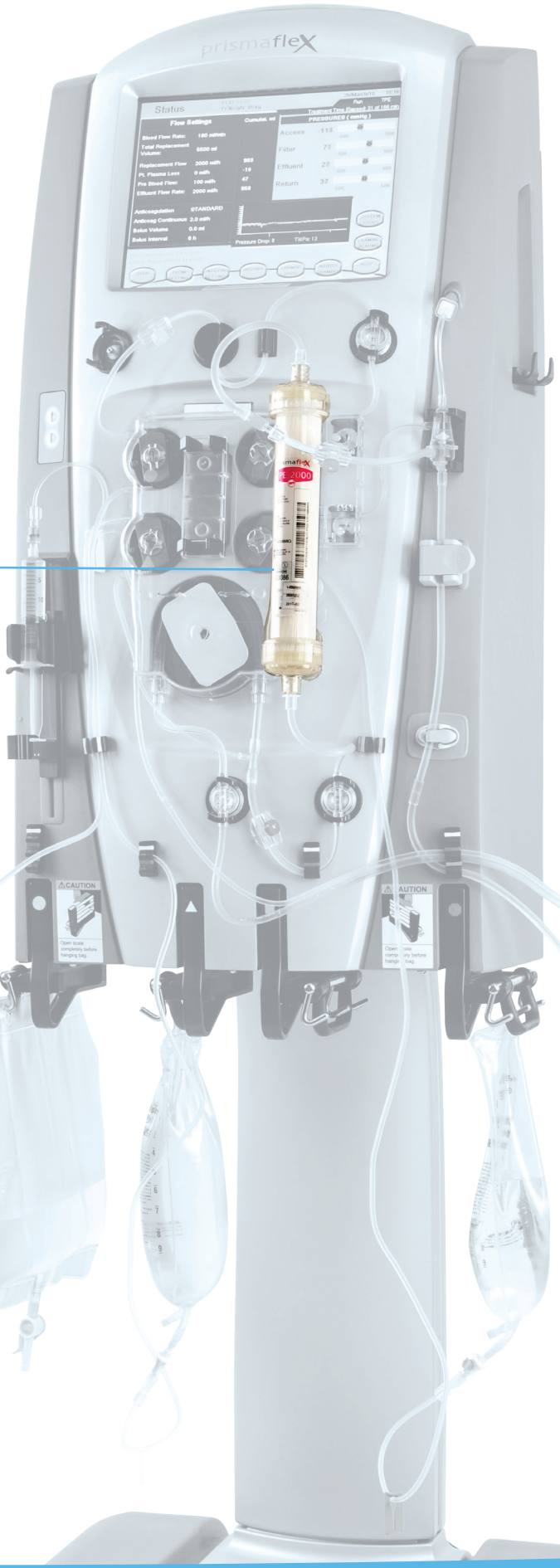
A Solution for Multiple Therapies

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

Plasma Filtration Rate (Q_F) Capability with Increased Blood Flow Rate (Q_B)

Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions.





Filtering Out Disease Mediators

Plasma exchange on the PRISMAFLEX System is achieved by plasma filtration with simultaneous infusion of a replacement solution. During Therapeutic Plasma Exchange (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 post-plasma filter to replace the removed plasma.

During TPE, PRISMAFLEX Software uses monitored pressure values to calculate Access Transmembrane Pressure (TMPa), in addition to the filter pressure drop.

The PRISMAFLEX TPE 2000 Set	
Effective surface area	0.35m^2
Blood volume in plasmafilter	41 mL*
Blood volume in set	125 mL*
Fiber membrane material	Polypropylene
Minimum blood flow rate	100 mL/min
Maximum blood flow rate	250 mL/min
Sieving Coefficient (in vivo data - 19 treatments)	
albumin	0.97
IgG	1.00
Apolipoprotein B	0.95
IgM	0.92
TMPa Maximum (mmHg or kPa)**	
Qb = 100 mL/min	120 mmHg (16 kPa)
Qb = 200 mL/min	171 mmHg (22.8 kPa)
Qb = 250 mL/min	193 mmHg (25.7 kPa)
Catalog number	114093

*±10% **TMPa = Access Transmembrane Pressure = Filter pressure (Pfil) - Effluent pressure (Peff)

TPE on the PRISMAFLEX System

The ability to run TPE on the PRISMAFLEX System offers clinicians notable features, including the flexibility and ease of use to meet the needs of your patients.

Flexibility to Meet Diverse Patient Needs

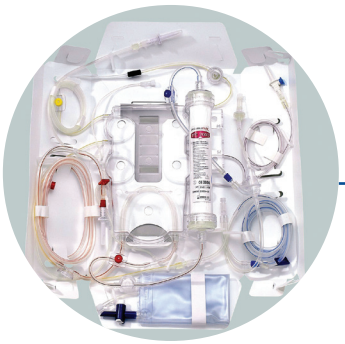
- Built-in prescription assistance
- Pre-connected TPE set with auto-recognition feature

Ease of Use from Start to Finish

- Integrated anticoagulant and infusion pre-blood pump (PBP)
- Replacement volume capability to support treatment protocols

Confidence in Safety Features

- Ability to pre-fill the TPE circuit with blood before initiating treatment
- Self-regulating pressure system to automatically accommodate blood flow rate adjustments
- Flow rate capabilities to allow adjustment for lower blood volume patients



Disposable PRISMAFLEX TPE 2000 Set

Intuitive user interface design

Deaeration chamber for return line monitoring

Polypropylene hollow fiber prismafilter

Delivering Value to Your Organization

The PRISMAFLEX System is a platform that is flexible enough to meet the diverse needs of your patients.

Manage Equipment

- Hospitals that already own a PRISMAFLEX System can run TPE without purchasing an additional machine.
- The PRISMAFLEX System is compatible with a wide selection of membranes for individual patient requirements.
    - The PRISMAFLEX HF1000/HF1400 Sets should be restricted to patients with a body weight greater than 30 kg (66 lb).

Decrease Maintenance

- Using the PRISMAFLEX System for TPE and CRRT means one machine for multiple therapies, potentially decreasing maintenance costs.

Streamline Training

- Setting up and executing a TPE procedure on the PRISMAFLEX System is similar to setting up a Continuous Renal Replacement Therapy (CRRT) procedure.
- Nurses that use the PRISMAFLEX System for Continuous Renal Replacement Therapy may find that the training for TPE is also similar.

Simplify Ordering

- Hospitals that are already placing orders through Baxter Healthcare Corporation can add PRISMAFLEX System TPE Sets to their existing orders.
- The only extra part needed from Baxter to run TPE on the PRISMAFLEX System is the TPE 2000 Disposable Set.

Expand Your Options with a Leader in Membrane-Based TPE

- With 24/7 clinical support and a large, experienced support team to help train your staff, Baxter provides all the resources you need to confidently offer patients the latest innovations in membrane-based TPE technology.
- With the acquisition of Gambro in 2013, Baxter further enhanced its global renal leadership with a comprehensive product and therapies portfolio to meet the needs of patients in the large and growing dialysis market.
- The combination of these two respected renal leaders — Baxter and Gambro — enables Baxter to better serve healthcare providers and patients through a collective offering of innovative renal products and therapies.


prismaflex
WARNING
Only intended for patients
weighing 20 kilograms or more.

The PRISMAFLEX TPE 2000 Set is indicated for use only with the PRISMAFLEX Control Unit, after having selected TPE therapy (therapeutic plasma exchange).
The PRISMAFLEX TPE 2000 Set is intended for use in therapeutic plasma exchange, thus in diseases where removal of plasma components in indicated. The use of the PRISMAFLEX TPE 2000 Set should be restricted to adults. The size, weight, state of uremia, cardiac status and general physical condition of the patient must be evaluated by the prescribing physician before each treatment.
The device should be used only on the direction of a physician who has evaluated all of the pertinent features of this device in relation to the individual patient. Patients with bleeding tendencies must be closely supervised during the treatment. Treatment should be discontinued if acute hemorrhage that can not be corrected (hematemesis, hemoptysis and melena) occurs during TPE.

Contact your local Baxter sales representative to learn more about CRRT and TPE on the PRISMAFLEX System.

For Customer Support call 800-525-2623.

Rx Only. For safe and proper use of the devices mentioned herein, refer to the *Instructions for Use.*

References:
1. PRISMAFLEX System Operator's Manual, version 5.10, US Lundia AB Sweden.
2. PRISMAFLEX TPE 2000 Plasmafilter, 2010 Instructions for Use.
3. PRISMAFLEX HF1000/HF1400 Instructions for Use.
4. PRISMAFLEX M60/M100/M150 Instructions for Use.

www.baxter.com

USMP/MG120/14-0123(1) 500 10/15

Baxter