

**Baxter**



# **PRISMAFLEX System**

## **M60/M100/M150**

Hemofilter Sets

Making possible personal.

# PRISMAFLEX System M60/M100/M150 Sets

## Preconnected Hemofilter Sets with the AN 69 Dialyzer Membrane for CRRT

The PRISMAFLEX Set is indicated for use only with the PRISMAFLEX Control Unit in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both.

This set is intended for use in the following veno-venous therapies: SCUF; CVVH; CVVHD; CVVHDF.

All treatments administered via the PRISMAFLEX Set must be prescribed by a physician. The size, weight, state of uremia, cardiac status, and general physical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.

The PRISMAFLEX M100 & M150 Sets should be restricted to patients with a body weight greater than 30 kg (66 lb). The pediatric use of the PRISMAFLEX M60 Set should be restricted to children with a body weight greater than 11 kg (24 lb) with respect to extracorporeal blood volume.

The M150, M100 and M60 hemofilter sets are designed for prescription flexibility on the PRISMAFLEX System. Both set configurations are created with the AN 69 Dialyzer Membrane and can be used to perform all CRRT therapies (SCUF, CVVH, CVVHD and CVVHDF).

### General data

	PRISMAFLEX M60 Set	PRISMAFLEX M100 Set	PRISMAFLEX M150 Set
Weight	780 g	800 g	860 g
Overall dimensions	27 x 22 x 9 cm	27 x 22 x 9 cm	27 x 22 x 9 cm
Blood volume in set ± 10 %	93 ml	152 ml	189 ml
Minimal patient weight	11 Kg	30 Kg	30 Kg

### Materials

- AN 69 HF hollow fiber: Acrylonitrile and sodium methallyl sulfonate copolymer
- Filter housing and headers: Polycarbonate
- Filter potting compound: Polyurethane
- Tubing material: plasticized polyvinyl chloride (PVC)
- Cartridge: PETG
- Sterilization mode: EtO (ethylene oxide)
- Not made with natural rubber latex
- Contains DEHP, which may pose risks to infant development

### Filter operating specifications

- Maximum TMP\* (mmHg/kPa): 450/60
- Maximum blood pressure (mmHg/kPa): 500/66.6
- Minimum blood flow rate:  
PRISMAFLEX M60 Set: 50 ml/min  
PRISMAFLEX M100 Set: 75 ml/min  
PRISMAFLEX M150 Set: 100 ml/min

### Filter data

- Nominal physical characteristics
  - Effective surface area:  
PRISMAFLEX M60 Set: 0.6 m<sup>2</sup>  
PRISMAFLEX M100 Set: 0.9 m<sup>2</sup>  
PRISMAFLEX M150 Set: 1.5 m<sup>2</sup>
  - Fiber internal diameter (wet): 240 µm
  - Fiber wall thickness: 50 µm

### Sieving coefficient

- (bovine plasma, Pc 60 g/l, T = 37°C)  
Urea = 1, Creatinine = 1, Vitamin B12 = 1,  
Inulin = 0.95, Myoglobin = 0.55, Albumin <0.01

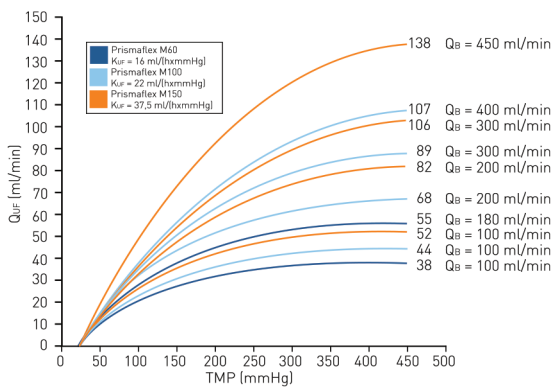
### In vitro performances

- Blood priming volume in filter  $\pm 10\%$ :  
 PRISMAFLEX M60 Set: 42 ml  
 PRISMAFLEX M100 Set: 66 ml  
 PRISMAFLEX M150 Set: 105 ml
- Blood pressure drop (in post dilution mode)  
 (bovine blood, Hematocrit 32%,  $P_c^{***} = 60$  g/l,  $T = 37^\circ\text{C}$ )

	PRISMAFLEX M60 Set	PRISMAFLEX M100 Set	PRISMAFLEX M150 Set
$Q_B^{**} = 100$ ml/min - $Q_{UF}^{****} = 1$ l/h	47 mmHg	31 mmHg	20 mmHg
$Q_B^{**} = 180$ ml/min - $Q_{UF}^{****} = 2$ l/h	91 mmHg	60 mmHg	—
$Q_B^{**} = 300$ ml/min - $Q_{UF}^{****} = 2$ l/h	—	73 mmHg	51 mmHg
$Q_B^{**} = 400$ ml/min - $Q_{UF}^{****} = 2$ l/h	—	105 mmHg	64 mmHg
$Q_B^{**} = 450$ ml/min - $Q_{UF}^{****} = 2$ l/h	—	—	70 mmHg

### CVWH Performances

- “In vitro” ultrafiltration with blood (in post-dilution)  
 (values  $\pm 15\%$ ) (Continuous venovenous hemofiltration)  
 (Bovine blood at  $37^\circ\text{C}$ , Hematocrit 32%,  $P_c^{***} = 60$  g/l).



### CVWD Clearances

- Clearances versus inlet dialysate flow rate  
 (Continuous venovenous hemodialysis) (Saline,  $T = 37^\circ\text{C}$ ).

	PRISMAFLEX M60 Set $Q_B^{**} = 100$ ml/min $Q_{UF}^{****} = 0$ ml/min			PRISMAFLEX M100 Set $Q_B^{**} = 150$ ml/min $Q_{UF}^{****} = 0$ ml/min				PRISMAFLEX M150 Set $Q_B^{**} = 200$ ml/min $Q_{UF}^{****} = 0$ ml/min			
	1	2.5	4	1	2.5	4	8	1	2.5	4	8
QD l/h ml/min	17	42	67	17	42	67	133	17	42	67	133
Urea ( $\pm 10\%$ )	17	39	54	17	41	63	95	17	42	66	117
Vitamin B12 ( $\pm 20\%$ )	14	23	28	16	30	37	45	17	37	49	64
Inulin ( $\pm 20\%$ )	12	17	19	14	23	26	30	16	31	37	45

\*Transmembrane pressure.

\*\*Access blood flow rate.

\*\*\*Protein concentration.

\*\*\*\*Ultrafiltration flow rate (1).

(1)The ultrafiltration flow rate is the “patient fluid removal flow rate + replacement flow rate + pre-blood-pump flow rate.”

## Ordering information

	Factory ID	Code No.	No. Units/Box
PRISMAFLEX M60 Set	8353510	106696	4
PRISMAFLEX M100 Set	8353520	106697	4
PRISMAFLEX M150 Set	8353584	109990	4
SP414 - 5-liter bag	6032957	106690	50
SP418 - 9-liter bag	6033765	107650	30

**Contact your local Baxter sales representative to learn more about the product.**  
**For Customer Support, call 800-525-2623.**

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

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