Baxter

M60/M100/M150 AND ST60/ST100/ST150 SETS WITH AN 69

Membrane for CRRT Powered By

PrisMax and **Prismaflex**

The Prismaflex ST Set is Authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the Prismaflex ST Set under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1).

M60/M100/M150 AND **ST60/ST100/ST150** SETS

The **Prismaflex** set is indicated for use only with the **Prismaflex** control unit or with the **PrisMax** control unit (in countries where **PrisMax** is cleared or registered) in providing continuous fluid management and renal replacement therapies. The system is intended for patients who have acute renal failure, fluid overload, or both. These sets are intended for use in the following veno-venous therapies: SCUF, CVVH, CVVHD, CVVHDF.

PHYSICAL CHARACTERISTICS [1]

	M60 set	M100 set	M150 set	ST60 set	ST100 set	ST150 set
Membrane effective surface area	0.6 m^2	0.9 m^2	1.5 m^2	0.6 m^2	1 m^2	1.5 m^2
Fiber internal diameter (wet)	240 µm			240 µm		
Fiber wall thickness	50 µm			50 µm		
Blood volume in set	97 mL	155 mL	193 mL	97 mL	155 mL	193 mL
Overall dimensions	27 x 22 x 9 cm			27 x 22 x 9 cm		
Weight	758 g	814 g	874 g	772 g	828 g	894 g
Minimal patient weight	11 kg	30 kg	30 kg	11 kg	30 kg	30 kg

OPERATING PARAMETERS

	M60 set	M100 set	M150 set	ST60 set	ST100 set	ST150 set
Maximum TMP (mmHg/kPa)	450/60			450/60		
Maximum blood pressure (mmHg/kPa)	500/66.6			500/66.6		
Minimum blood flow rate	50 mL/min	75 mL/min	100 mL/min	50 mL/min	75 mL/min	100 mL/min
Maximum blood flow rate	180 mL/min	400 mL/min	450 mL/min	180 mL/min	400 mL/min	450 mL/min

MATERIALS

	M60 set	M100 set	M150 set	ST60 set	ST100 set	ST150 set
Hollow fiber	**AN 69** HF hollow fiber: Acrylonitrile and sodium methallyl sulfonate copolymer			**AN 69** ST hollow fiber: Acrylonitrile and sodium methallyl sulfonate copolymer Surface treatment agent: Polyethylene imine		
Filter housing and headers	Polycarbonate			Polycarbonate		
Filter potting compound	Polyurethane			Polyurethane		
Tubing material	Plasticized polyvinyl chloride (PVC)			Plasticized polyvinyl chloride (PVC)		
Cartridge	PETG			PETG		
Sterilization mode	EtO (ethylene oxide)			EtO (ethylene oxide)		

ORDERING INFORMATION

	Code N°	N° units/box
M60 set	106696	4
M100 set	106697	4
M150 set	109990	4
ST60 set	107643	4
ST100 set	107636	4
ST150 set	107640	4
5-liter effluent bag	114423 (A6001)	50 (A6001)
9-liter effluent bag	107650 (SP418)	30

PERFORMANCE SPECIFICATIONS [2]

Maximum ultrafiltration rate (mL/min) [3] (bovine blood; Hct 32%; Cp 60 g/L, 37°C)

	M60 set		M100 set				M150 set				ST60 set		ST100 set				ST150 set			
QB (mL/min)	100	180	100	200	300	400	100	200	300	450	100	180	100	200	300	400	100	200	300	450
Max.QUF (± 15%)	38	55	44	68	89	107	52	82	106	138	39	56	45	70	91	109	52	82	106	136
Sieving coefficient (bovine plasma, Cp 60 g/L, 37°C); QB = 100 mL/min; QUF = 20 mL/min																				
Urea	1										1									
Creatinine	1										None									
Vitamin B_{12}	1										1									
Inulin	0.95										0.96									
Sieving coefficient (human plasma, Cp 60 g/L, 37°C); QB = 100 mL/min; QUF = 20 mL/min																				
Myoglobin	0.70										0.70									
Albumin	<0.0045										<0.0045									

ACRONYMS

TMP: Transmembrane pressure
QB/QS: Arterial blood flow rate
QUF: Ultrafiltration flow rate (fluid removal + replacement flow rate + pre blood pump flow rate)
QD: Dialysate flow rate
Hct: Hematocrit
Cp: Protein concentration

Rx Only. For the safe and proper use of the devices mentioned herein, please refer to the Instructions for Use. or Operator's Manual.

CLEARANCE (mL/min) (saline solution; 37°C)

Parameters:	M60 set			M100 set				M150 set				ST60 set			ST100 set				ST150 set			
QB/QS QUF	100 mL/min 0 mL/min			150 mL/min 0 mL/min				200 mL/min 0 mL/min				100 mL/min 0 mL/min			150 mL/min 0 mL/min				200 mL/min 0 mL/min			
QD L/h QD mL/min	1 17	2.5 42	4 67	1 17	2.5 42	4 67	8 133	1 17	2.5 42	4 67	8 133	1 17	2.5 42	4 67	1 17	2.5 42	4 67	8 133	1 17	2.5 42	4 67	8 133
Urea (±10%)	17	39	54	17	41	63	95	17	42	66	117	17	40	56	17	41	63	97	17	42	66	117
Vitamin B_{12} (±20%)	14	23	28	16	30	37	45	17	37	49	64	15	26	30	16	32	41	50	17	38	51	68
Inulin (±20%)	12	17	19	14	23	26	30	16	31	37	45	13	19	22	15	26	30	35	16	33	40	49

(1) Nominal values – given for indication (2) Typical mean values obtained from laboratory testing of post-sterilization sample lots. Results may vary depending on patient and clinical conditions. (3) Ultrafiltration is controlled by the control unit and is independent of the ultrafiltration coefficient (KUF).

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PRISMAFLEX ST SET

Emergency Use Authorization for the United States

The **Prismaflex** ST Set has been Authorized by the FDA to provide continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the Coronavirus Disease 2019 (COVID-19) pandemic.

The **Prismaflex** ST Set has neither been cleared or approved to provide CRRT in an acute care environment.

The **Prismaflex** ST Set has been authorized by FDA under EUA200704.

The **Prismaflex** ST Set is Authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the **Prismaflex** ST Set under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Intended Use for Patients with COVID-19

The **Prismaflex** ST Set is indicated for use only with the **Prismaflex** control unit or with the **PrisMax** control unit in providing continuous fluid management and renal replacement therapies in an acute care environment during the Coronavirus Disease 2019 (COVID-19) pandemic. The system is intended for patients who have acute renal failure, fluid overload, or both.

Relative contraindications (individual risk/benefit to be determined by treating physician) for the use of **Prismaflex** ST Sets include:

- The inability to establish vascular access
- Severe hemodynamic instability
- Known hypersensitivity to any component of the Prismaflex ST

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

All treatments administered with the **Prismaflex** ST Set must be prescribed by a physician. The size, weight, metabolic and fluid balance, cardiac status, and general clinical condition of the patient must be carefully evaluated by the prescribing physician before each treatment.