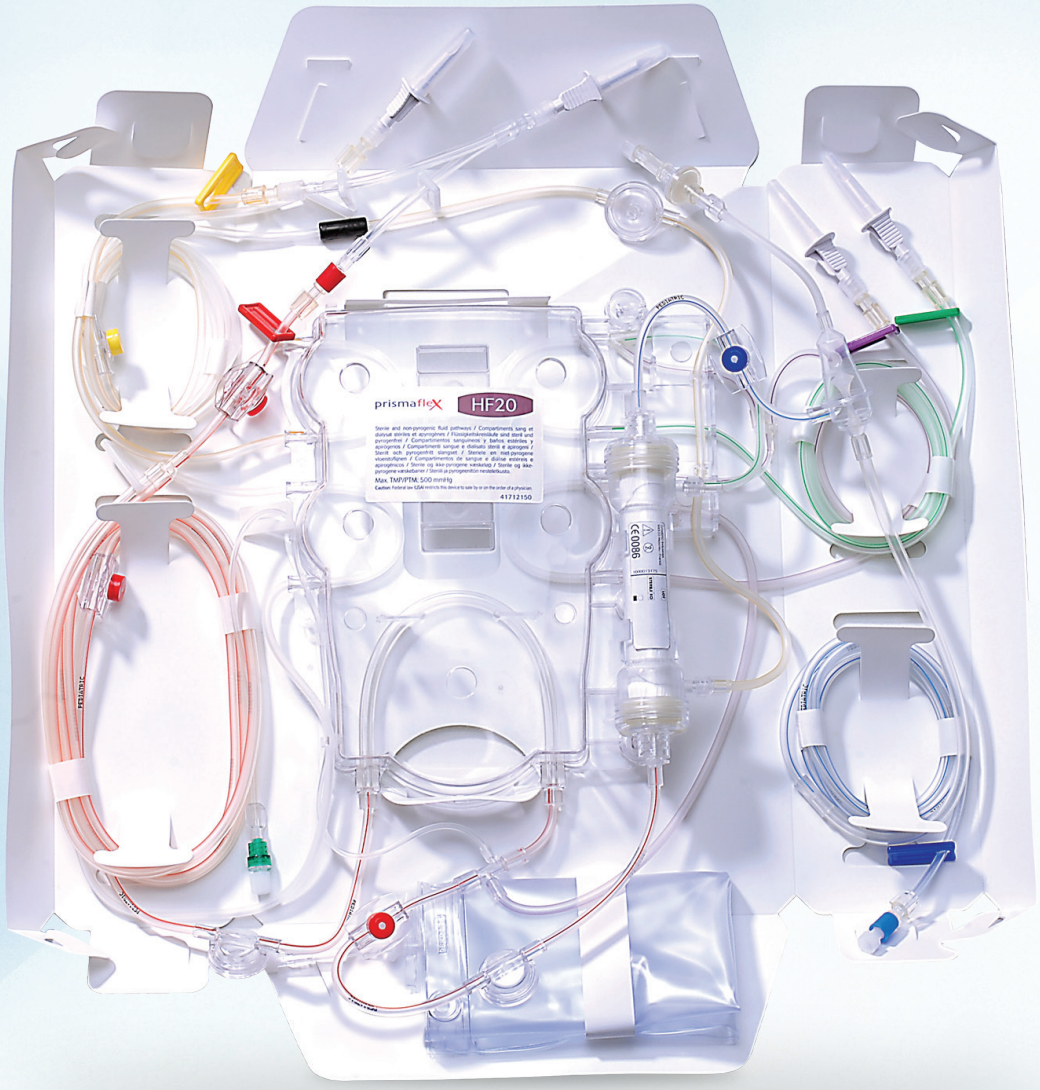
Baxter



HF20 SET FOR CRRT
FOR LOW BODY WEIGHT PATIENTS

Membrane for CRRT Powered By

PrisMax and **Prismaflex**

The **Prismaflex** HF20 Set is Authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the **Prismaflex** HF20 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.

HF20 SET

The **Prismaflex** HF20 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 with low weight (8-20 kg) and low blood volume or who cannot tolerate a larger extracorporeal circuit volume who have acute renal failure, fluid overload, or both.

PHYSICAL CHARACTERISTICS [1]

	HF20 set
Membrane effective surface area	0.2 m^2
Fiber internal diameter (wet)	215 µm
Fiber wall thickness	50 µm
Blood volume in set	58 mL
Overall dimensions	27 x 22 x 9 cm
Weight	677 g
Minimal patient weight	8 kg

MATERIALS

PAES hollow fiber: Polyarylethersulfone

Housing and headers: Polycarbonate

Potting compound: Polyurethane

Tubing material: Plasticized polyvinyl chloride (PVC)

Cartridge: PETG

OPERATING PARAMETERS

Maximum TMP (mmHg/kPa)	500/66.6
Maximum blood pressure (mmHg/kPa)	500/66.6
Minimum blood flow rate	20 mL/min
Maximum blood flow rate	100 mL/min

PERFORMANCE SPECIFICATIONS [2]

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

QB (mL/min)	20	50	100
Max.QUF (± 20%)	9	17	24

Sieving coefficient
(bovine plasma, Cp 60 g/L, 37°C)
QB = 50 mL/min, QUF = 10 mL/min

• Urea	1.00
• Vitamin B_{12}	1.00
• Inulin	0.92
• Albumin	<0.01

(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).

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

CLEARANCES

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

Parameters QB/QS QUF	20 mL/min 0 mL/min					50 mL/min 0 mL/min					100 mL/min 0 mL/min				
QD-L/h	0.5	1	1.5	2	2.5	0.5	1	1.5	2	2.5	0.5	1	1.5	2	2.5
QD-mL/min	8	17	25	33	42	8	17	25	33	42	8	17	25	33	42
Urea (±10%)	8	12.5	14.5	15.7	16.5	8.3	15.5	20.9	25.1	28.7	8.3	16.4	23.6	30.1	36.3
Creatinin (±10%)	7.8	11.7	13.6	14.7	15.6	8.3	15.0	19.7	23.1	26.0	8.3	16.2	22.9	28.5	33.5
Vitamin B12 (±20%)	6.5	8.6	9.5	10.0	10.3	7.6	11.7	13.9	15.4	16.5	8.1	13.9	17.6	20.3	22.5
Inulin (±20%)	5.6	7.0	7.5	7.8	7.9	6.9	9.8	11.2	12.1	12.7	7.9	12.6	15.2	16.9	18.1

ORDERING INFORMATION

	Code N°	N° units/box
HF20 set	109841	4

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

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Deerfield, IL 60015

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USMP/MG120/20-0005 09/20

HF20 SET

Emergency Use Authorization for the United States
The **Prismaflex** HF20 Set has been Authorized by the FDA to provide continuous renal replacement therapy (CRRT) to treat low weight (8-20 kg) and low blood volume patients or patients who have acute renal failure, fluid overload, or both, and who cannot tolerate a larger extracorporeal circuit volume in an acute care environment during the Coronavirus Disease 2019 (COVID-19) pandemic.

The **Prismaflex** HF20 Set has neither been cleared or approved to provide CRRT in an acute care environment.

The **Prismaflex** HF20 Set has been authorized by FDA under EUA201769.

The **Prismaflex** HF20 Set is Authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the **Prismaflex** HF20 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
The **Prismaflex** HF20 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 with low weight (8-20 kg) and low blood volume or who cannot tolerate a larger extracorporeal circuit volume 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** HF20 Sets include:

- The inability to establish vascular access
- Severe hemodynamic instability
- Known hypersensitivity to any component of the **Prismaflex** HF20 Set

This set is intended for use in the following veno-venous therapies: Slow Continuous Ultrafiltration (SCUF); Continuous Veno-Venous Hemofiltration (CVVH); Continuous Veno-Venous Hemodialysis (CVVHD); Continuous Veno-Venous Hemodiafiltration (CVVHDF).

All treatments administered with the **Prismaflex** HF20 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.

Additional Product Information for the United States
To access COVID-19 Resources, product details, product use information, and the comprehensive **Prismaflex** Control Unit Operator's Manual and **PrisMax** Control Unit Operator's Manual, please visit https://usrenalacute.baxter.com.