Technical data sheet

BL 250 complete kit for hemofiltration/ hemodialysis 015 and 025 with the Carpediem™ cardio-renal pediatric dialysis emergency machine

Product description

The BL250 complete kit for hemofiltration and hemodialysis is packaged as a single-use kit for CVVH, CVVHD or SCUF modalities. This hemofiltration/hemodialysis kit is indicated for use with the Carpediem™ system in acute kidney injury or fluid overloaded patients requiring continuous renal replacement therapy (CRRT) and weighing between 2.5 and 10 kilograms.

Preassembled Blood-Set

Within the complete kit, the preassembled blood-set is comprised of a filter with preconnected tubing lines and attachments. The filter offers high permeability, polyethersulfone (PES) hollow fibers.

Preassembled Blood-Set Sizing

All preassembled blood-set options have similar tubing volume, but different filter surface areas:

- HCD 015 model – 0.16 m^2 filter surface area with 32 mL total priming volume
- HCD 025 model – 0.29 m^2 filter surface area with 41 mL total priming volume

The preassembled blood-set components are listed in Figure 1:

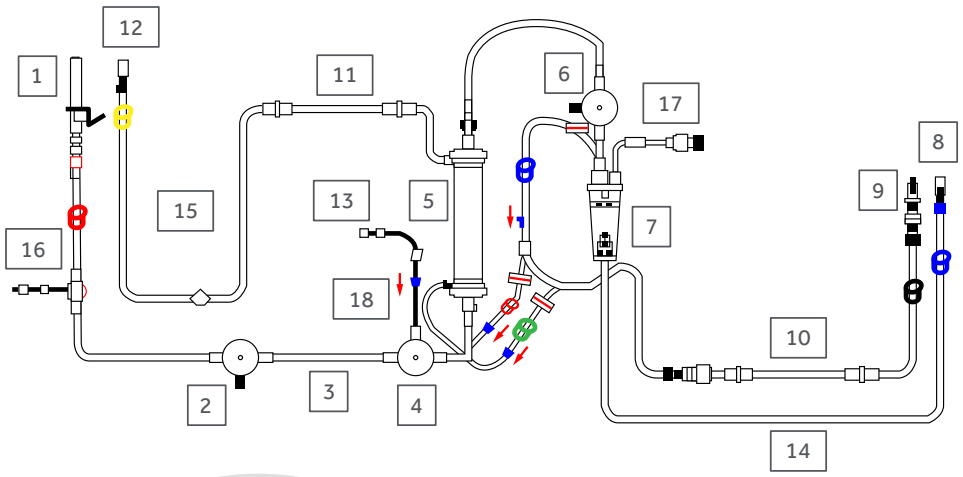

Figure 1 – legend:

1. Access line Luer lock
2. Access pressure dome
3. Blood pump segment
4. Pre-filter pressure transducer
5. Filter
6. Return pressure dome
7. Return chamber
8. Return line Luer lock
9. Infusion/dialysis line Luer lock
10. Infusion/dialysis pump segment
11. Effluent pump segment
12. Effluent line Luer lock
13. Heparin pump line Luer lock
14. Return return line
15. Effluent line
16. Access service line
17. Air chamber service line
18. Heparin line

The complete kit includes:

- 1 preassembled blood-set
- 3 waste fluid bags
- 1 syringe (10 mL)
- 1 preassembled blood-set IFU
- 1 complete kit IFU

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Preassembled blood-set intended use

The preassembled blood-set is intended to be used with the Carpediem™ system only for continuous renal replacement therapy (CRRT) for pediatric patients weighing between 2.5 and 10 kilograms.

Preassembled blood-set sterilization and shelf life

Sterile and non-pyrogenic

Sterilizing method: Ethylene oxide (EO)

Shelf life: 3 years

Do not re-sterilize

Technical characteristics

Filter	
Components	**Materials**
Membrane	Polyethersulfone (PES)
Housing	Copolyester
Header	Copolyester
Potting	Polyurethane
O-ring	Silicone rubber

3-liter waste bag	
Components	**Materials**
Film	Polyvinyl chloride (PVC) DOP free
Tube	Polyvinyl chloride (PVC) DOP free
Joint female luer lock	Polyvinyl chloride (PVC)
Vented male cone cap	Polypropylene (PP)
Clamp	Polypropylene (PP)

Tubing Sets	
Components	**Materials**
Tubing lines	Polyvinyl chloride (PVC)
Blood pump segment	Polyvinyl chloride (PVC)
Infusion pump segment	Polyvinyl chloride (PVC)
Heparin line	Polyvinyl chloride (PVC)
Pressure transducer membrane	Silicon rubber
Tube adapter	Polyvinyl chloride (PVC)
Line connector	Polyvinyl chloride (PVC) – Acrylonitrile butadiene styrene (ABS)
Pressure transducer holder	Polyvinyl chloride (PVC)
Air chamber	Polyvinyl chloride (PVC)
Air chamber filter	Polyethylene (PE)
Filter connector	Polyvinyl chloride (PVC)
Access port	Polyvinyl chloride (PVC) – isoprene – Polypropylene (PP)
Clamps	Polypropylene (PP)
INF/UF luer connector ring	Polycarbonate (PC)
Air drip chamber service line cap	Polyethylene (PE)
INF Y-connector	Polyvinyl chloride (PVC)
One-way valve	Silicon rubber - Acrylonitrile butadiene styrene (ABS)
Port caps	Polypropylene (PP)
Vented spike	Acrylonitrile butadiene styrene (ABS) – low density polyethylene (LDPE)
Unvented spike	Acrylonitrile butadiene styrene (ABS) – low density polyethylene (LDPE)
INF/UF luer connector	Polyvinyl chloride (PVC)

Filter technical characteristics									
Model	Total priming volume (mL)[1]	Surface area (m^2)	Fiber wall thickness (µm)	Fiber internal diameter (µm)	Priming volume blood compartment (mL)	Blood compartment pressure drop (mmHg)		Dialysate compartment pressure drop (mmHg)	Total length (mm)
						Q_B 10 mL/min	Q_B 50 mL/min	Q_D 10 mL/min	
HCD 015	32	0.16	30	200	11	19	32	10	128
HCD 025	41	0.29	30	200	20	22	35	17	140

1 Feature/characteristic specific to the entire preassembled blood-set

Performance

Filter model (clearances mL/min)[1]	HCD 015				HCD 025			
Blood flow (QB)	5	10	20	50	5	10	20	50
Urea	2.8	4.2	5.6	7.8	2.6	4.0	5.4	7.2
Creatinine	2.9	4.3	5.7	7.8	2.8	4.2	5.8	7.5
Phosphate	3.0	4.4	5.5	7.7	2.8	4.3	5.8	7.2
Vitamin B_{12}	3.0	4.3	5.0	6.5	2.9	4.3	5.5	6.7

1 In vitro clearance: Q_D = 10 mL/min, Q_F = 0 mL/min; saline solution: NaCl = 0.9%

Dialyzer model (clearance at max QF and QD mL/min)[1]	HCD 015[2]	HCD 025[3]
Urea	10.6	10.9
Creatinine	10.7	11.1
Phosphate	10.6	11.1
Vitamin B_{12}	9.2	10.5

1 Saline solution: NaCl 0.9%, Q_D = 10 mL/min
2 Q_F = 14 mL/min, Q_B = 50 mL/min, Q_D = 10 mL/min
3 Q_F = 15 mL/min, Q_B = 50 mL/min, Q_D = 10 mL/min

	Ultrafiltration coefficient[1]			
	Dialyzer model			
	HCD 015		HCD 025	
K_{uf} (mL/h*mmHg)	Q_B 10 mL/min	Q_B 50 mL/min	Q_B 10 mL/min	Q_B 50 mL/min
	4.8	9.8	9.0	22.1

1 Bovine blood Hct = 32%, protein = 60g/L

Sieving coefficient	
Marker	HCD 015 / HCD 025
Inulin	0.8
Myoglobin	0.34
Albumin	0.002

Storage and disposal conditions

Store at temperatures between 5° – 30° C (41° – 86° F)

Disposal: Dispose of the device after treatment in accordance with applicable government and health center protocols.

Quick reference guide and ordering information

Capital			
CFN Code	**Description**	**Name**	**UOM**
M410000B006	Carpediem™ machine (110-120 V)	Carpediem™ cardio-renal pediatric dialysis emergency machine	1 EA
LB10B2685	Warmer BW685 (110-120 V)	BW685	1 EA

Disposables/Consumables			
IB0595570	Complete kit model 015	BL 250 hemofiltration/hemodialysis kit 015 for Carpediem™	4 / CT
IB0595580	Complete kit model 025	BL 250 hemofiltration/hemodialysis kit 025 for Carpediem™	4 / CT
MD042	Dialysate Bag/Fluid Bag	HMB32 - ml 500 + 1500	4 / CT
IB0507009	Non-sterile waste bag	3L Non-sterile waste bag	20 / CT
4100-X00V0	Syringe	10 ml (12 ml) Henke-Ject™ Luer Lock	100 / CT
FP4600203	Warmer tubing set	Extension Set 46000	20 / CT

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