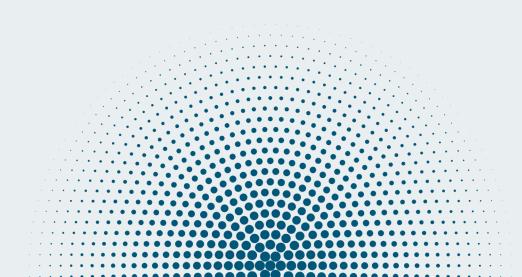
Small patients. Small solutions. Big results.

Carpediem[™] cardio-renal pediatric dialysis emergency machine





The Carpediem[™] system

Improved clinical outcomes for your smallest patients

97%

Neonate survival rate upon discontinuation of treatment.^{1*}

Acute kidney disease in neonates is common

40% AKI incidence rates

in the ICU.²

78% Of acute kidney

injuries (AKI) are caused by sepsis.³ 60%

Mortality rates among neonates with AKI.⁴

And deadly

65%

AKI mortality rate among neonates supported with ECMO.³



Innovations in pediatric CRRT

For the first time, pediatric patients with acute kidney injury (AKI) and fluid overload (FO) can be treated with a dialysis system designed specifically for them.⁵

The first of its kind, the Carpediem[™] system provides CRRT treatment for pediatric patients by:

- Reducing damage to blood vessel access location, while providing necessary and adequate diffusive clearances⁶
- Enabling CVVH, CVVHD, and SCUF treatments.⁷ Pediatric patients suffer high morbidity and mortality rates from AKI and FO, when treated with retrofitted CRRT machines designed for adult patients.⁵
- Delivering treatment with tailored performance and precise control:
 - High-precision scales monitor fluid balance.⁷
 - Heparin pump can deliver continuous or bolus therapy.⁷
 - Blood leak sensor will stop treatment if alarm threshold is detected: .15ml of blood in 10ml of ultrafiltrate (hematocrit: 25%) with an effluent flow of 10ml/min.⁷
 - Air sensor stops treatment upon detection of air bubble >10 $\mu L.^7$

The right therapy for the right patient

Designed on a miniaturized platform, the Carpediem[™] system delivers continuous renal replacement therapy (CRRT) for pediatric patients weighing 2.5–10 kgs.⁷

Three-rollers peristaltic pumps

Miniaturized pumps support reduced priming volume and pressure shock.^{6,8}

Pediatric access

Small catheter use reduces risk of potential damage to small pediatric vessels.⁶

Precise

Monitors fluid output with a +/- 30 g range over 24 hours. System scales have sensitivity of +/- 1 g.⁷



Hemodynamic advantage

Blood pump flow rate⁷:

2–50 mL/min Increments: 1 mL/min



Infusion/dialysis pump flow rate⁷:

Up to 10 mL/min (Depending on selected modality)



Effluent pump flow rate⁷:



Up to 15 mL/min (Depending on selected modality)

Peristaltic pumps^{5,6,8,9}

with cradle movements, instead of rotors, support small circuit lines.

Carpediem[™] System components are designed to:

- Reduce priming volume
- Reduce circuit pressure peaks
- Minimize blood hemolysis and enable the use of smaller catheter sizes





Reinvented

Clinical decisions can now be determined without the increased risks and complexities which have traditionally plagued pCRRT treatments. For the first time, there's no need to adapt adult machines.⁹

Dedicated

CRRT can be a rigorous process for small patients. The Carpediem[™] system is better suited to clinically address AKI and FO for these fragile patients.⁵

Focused

The simple design of the Carpediem[™] system enables staff to focus on what is important.

Life saving

Clinical data from the Carpediem[™] EU Registry demonstrates a 97% survival rate (upon discontinuation of treatment).^{1*}

Purposeful design to give every baby a chance

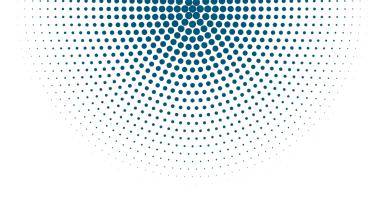


Capital

CFN CODE	Description	Name	UOM
M410000B006	CARPEDIEM [™] device	CARPEDIEM™	1 EA
IB7000020	Warmer	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
IB0580807	Pre-assembled blood-set included in the Complete kit model 015	BL 250 PREASSEMBLED DEVICE FOR HEMOFILTRATION/ HEMODIALYSIS 015 FOR CARPEDIEM™	4/CT
IB0580808	Pre-assembled blood-set included in the Complete kit model 025	BL 250 PREASSEMBLED DEVICE FOR HEMOFILTRATION/ HEMODIALYSIS 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
LB10B2685	Warmer tubing set	Extension Set 46000	20 / CT



References

- *53% Carpediem[™] system patients survived to ICU discharge. Mortality after pCRRT discontinuation due to critical illness with underlying pathologies many not amenable to treatment. Refer to the operator's manual for details.
- 1. Based on internal report CARPEDIEM System DEN180055. CARPEDIEM System De Novo Application Clinical Data Section. 2020.
- 2. Sutherland S, et al. AKI in Hospitalized Children Comparing the pRIFLE, AKIN, and KDIGO Definitions. *CJASN*. 2015; 10(4)554-61.
- 3. Selewski D., Charlton J., Jetton J., et al. Neonatal acute kidney injury. *Pediatrics.* 2015; 136(2): e463–473.
- Zappitelli M., Ambalavanan N., Askenazi D. et al. Developing a neonatal acute kidney injury research definition: a report from the NIDDK neonatal AKI workshop. *Pediatric Res.* 2017; 82(4):569–573.
- Ronco C, Garzotto F, Ricci Z. CA.R.PE.DI.E.M. (Cardio-Renal Pediatric Dialysis Emergency Machine): evolution of continuous renal replacement therapies in infants. A personal journey. *Pediatr Nephrol.* 2012;27(8):1203–1211.
- 6. Vidal E, Cocchi E, Paglialonga F, et al. Continuous veno-venous hemodialysis using the Cardio-Renal Pediatric Dialysis Emergency Machine[™]: first clinical experiences. *Blood Purif.* 2018;31:1–7.
- 7. Carpediem[™] dialysis system [Operator's Manual]. Minneapolis, MN: Medtronic; 2020.
- Garzotto, F, Zaccaria M, et al. Choice of Catheter size for infants in Continuous Renal Replacement Therapy: Bigger Is Not Always Better. *Pediatric Critical Care Medicine*. 2019; 20(3): 170-179.
- Ronco C, Garzotto F, Brendolan A, et al. Continuous renal replacement therapy in neonates and small infants: development and first-in-human use of a miniaturised machine (CARPEDIEM). *Lancet.* 2014;383:1807–1813.

Indications for Use: The CARPEDIEM System is indicated for use in acute kidney injury or fluid overloaded patients requiring hemodialysis or hemofiltration therapy. It is intended to provide continuous renal replacement therapy (CRRT) to patients weighing between 2.5 and 10 kilograms.

Limitations for Use: Do not use CARPEDIEM if patient treatment requires performance outside its operating and accuracy range as well as the operating limits specified in the CARPEDIEM System Operator's Manual. The CARPEDIEM system allows anticoagulation method with heparin only. Contraindications: Patients with a history of allergic reactions to polyethersulfone should not be treated using the Carpediem system. The choice to perform CRRT must consider the balance between risk and benefit for patients that have general contraindications to using an extracorporeal therapy. These factors include: hemodynamic instability, contraindication to suitable anticoagulation, low platelet count, lack of suitable placement for vascular access.

Warnings: Replacement fluid for hemofiltration should be prescribed by a physician and should be commercially available or prepared in the hospital pharmacy, labeled sterile and for intravenous injection. The device is intended to be used by trained clinicians who are experienced in administrating and managing continuous renal replacement therapy (CRRT) in in critically ill pediatric patients .

Cautions: Read all Instructions for Use carefully prior to use. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with the system and its components, refer to the Carpediem System Operator's Manual and the respective system component's Instructions for Use. Rx Only.

710 Medtronic Parkway Minneapolis, MN 55432



© 2023 Mozarc Medical Holding LLC. Mozarc, Mozarc Medical, the Mozarc Medical logos, and Empowering Patients. Enriching Lives. are trademarks of Mozarc Medical. Covidien and Medtronic are trademarks of Medtronic used under license. ^{TM*} Third-party brands are trademarks of their respective owners. 05/2023 – US-RC-2300032 – WF#9429507