

Technical Data Sheet

Carpediem™ machine

Carpediem™ (cardio renal pediatric dialysis emergency machine) is a miniaturized platform designed for continuous renal replacement therapy in pediatric patients.

The Carpediem™ system is indicated to deliver:

- Slow continuous ultrafiltration (SCUF)
- Continuous veno-venous hemofiltration (CVVH)
- Continuous veno-venous hemodialysis (CVVHD)

The system is designed to minimize the extracorporeal circuit volume, ensure accurate weight balance, and maintain blood flow rates with small-dimension catheters.^{1,2}

Key features include:

- Three-3 roller peristaltic pumps
- A weighing system composed of two pairs of load cells to control fluid balance
- Three pressure transducers measuring:
 - Arterial pressure
 - Pre-filter pressure
 - Venous pressure
- Air sensor coupled with an electroclamp that prevents air being delivered to the patient
- Blood leakage detector is intended to detect blood leakage from the filter to the effluent line
- Syringe pump for heparin administration



Figure 1. Carpediem™ machine

Codes available

CFN Code	Model
IB7010200	Carpediem™ model 220-240 V~, 50 / 60 Hz
IB7010250	Carpediem™ model 110-240 V~, 50 / 60 Hz

Power supply

220-240 V ~ (+ / - 10%), 0.5 A, 50 / 60 Hz

110-120 V ~ (+ / - 10%), 1 A, 50 / 60 Hz

Power absorbed

75 VA in normal conditions of use

135 VA for a second after opening the electroclamp on the return line

Operating conditions

Temperature between 20° C and 30° C

Max. relative humidity 80% non-condensing

Do not expose to direct sunlight and artificial light

Atmospheric pressure between 70 and 106 kPa

Transport conditions

Temperature between -29° C and +60 °C

Relative humidity between 10 and 96% non-condensing

Atmospheric pressure between 70 and 106 kPa

If the transport or storage period is more than 15 weeks, refer to the ambient operating conditions (see above).

Machine body material

Baydur 67 (PU) outer shell

Outside machine dimensions

- Height: 450 mm
- Width: 500 mm
- Depth: 220 mm
- Machine weight: 45 kg (body + trolley + preassembled device with syringe and installed bags)

Trolley

- Load-bearing structure in painted steel
- Base cover in painted ABS
- Machine support base in anodised aluminum
- IV pole in steel with maximum applicable load of 1 kg
- Max. IV pole height: 2000 mm

Arterial pressure

- -400 mmHg to +100 mmHg (operating range)
- Resolution: 5 mmHg

Arterial pressure alarm

Visual and acoustic when exceeding the following limits:

- Priming limits: maximum +100 mmHg, minimum -200 mmHg
- Treatment limits: maximum -10 mmHg, minimum threshold settable -50 to -250 mmHg

Venous pressure

- -100 mmHg to +400 mmHg (operating range)
- Resolution: 5 mmHg

Venous pressure alarm

Visual and acoustic when exceeding the following limits:

- Priming limits: maximum + 400 mmHg, minimum – 100 mmHg
- Patient connection limits: maximum + 250 mmHg, minimum – 40 mmHg
- Treatment limits: Blood pump active
 - absolute maximum + 250 mmHg,
 - absolute minimum + 5 mmHg
 - Relative range adjustable from ± 20 to ± 100 mmHg, with respect to the instantaneous pressure
- Return limits: maximum + 350 mmHg, minimum – 40 mmHg

Drop pressure

- Drop pressure operating range -100 mmHg + 400 mmHg

Drop pressure alarm

Visual and acoustic when exceeding the following limits:

- Priming limit: maximum + 250 mmHg,
- Treatment limits: maximum + 250 mmHg, minimum – 10 mmHg
- Return limits: maximum + 250 mmHg, minimum – 100 mmHg

Pre-filter pressure

- -100 mmHg to +400 mmHg (operating range)
- Resolution 5 mmHg

Pre-filter pressure alarm

Visual and acoustic when exceeding the thresholds listed below:

- Priming limit: maximum +400 mmHg
- Treatment limits: maximum +350 mmHg, minimum +5 mmHg
- Return limits: maximum +400 mmHg, minimum -100 mmHg

Blood pump flow

- Programmable from 2 mL / min to 50 mL / min
- Resolution: 1 mL / min
- Acoustic and visual alarm activation for pump stop of more than 2 minutes

Infusion / dialysis fluid pump flow

Programmable in CVVH:

- From 0 to 150 mL / h for HCD 0075 filter*
- From 0 to 240 mL / h for HCD 015 filter
- From 0 to 600 mL / h for HCD 025 filter

Programmable in CVVHD:

- From 0 to 600 mL / h for HCD 015 filter
- From 0 to 600 mL / h for HCD 025 filter

*not available in the US

Effluent pump flow

Programmable in CVVH:

- From 0 to 150 mL / h for HCD 0075 filter*
- From 0 to 240 mL / h for HCD 015 filter
- From 0 to 600 mL / h for HCD 025 filter

The effluent pump flow is limited to maximum 20% of the blood flow (in CVVH).

Programmable in CVVHD:

- From 0 to 840 mL / h for HCD 015 filter
- From 0 to 900 mL / h for HCD 025 filter

*not available in the US

Maximum weight loss programmable

2000 g

Weight loss accuracy:

±30 g in 24 h

Accuracy is ensured when the equipment operates in an environment where the temperature varies within the range of $\pm 3^{\circ}\text{C}$.

Heparin pump

Programmable:

- Continuous mode: heparin flow from 0.4 to 20 mL / h with resolution of 0.1 mL / h
- Bolus mode: Bolus volume from 0.1 to 3 mL with resolution of 0.1 mL
- Accuracy: 2% with pressure from 0 to 600 mmHg

Load cells

- Two load cells on each scale to measure infusion / dialysis and effluent bags weight
- Maximum load applicable on each scale: 2.4 kg
- Load cells resolution: 1 g

Display

- 4.7" backlit color display

Air sensor

- Ultrasound
- Alarm threshold at the typical flow rates (less than 35 mL / min) of the blood pump: air bubble >10 μL . Detection of air bubbles larger than 15 μL is in any case assured in all operating conditions.

Blood leakage detector

- Optical
- Alarm threshold for 0.15 mL of blood in 10 mL of ultrafiltrate (hematocrit: 25%) with an effluent flow of 10 mL / min
- Accuracy: 0.2%
- Alarm override time: 30 sec

Maximum circuit pressure

- 500 mmHg (measured before the filter)

References:

1. Ronco C, Ricci Z, Goldstein SL. (R)evolution in the Management of Acute Kidney Injury in Newborns. *Am J Kidney Dis.* 2015;66(2):206-11.
2. Garzotto F, Zanella M, Ronco C. The evolution of pediatric continuous renal replacement therapy. *Nephron Clin Pract.* 2014;127(1-4):172-5.

NOTE: For complete system details, including product and important safety information such as indications, contraindications, warnings and precautions associated with the system and its components, refer to the Carpediem operators manual and the respective system component's Instructions for Use.

Carpediem™ is an active, non-invasive, class IIb medical device CE0123 manufactured by Bellco S.r.l.

Not for use in the U.S.

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