

AMPLYA™

ACUTE MULTITHERAPEUTIC SYSTEM



The right therapy way

AMPLYA™ is Bellco's multitherapeutic and biotechnological response to treatment of multiple organ failure of acute critical patients. The system performs various types of extracorporeal blood clearance in critical care through a novel personalised and integrated therapeutic approach: a single platform with a myriad of options.

CHARACTERISTICS

- AMPLYA™ is equipped with 5 peristaltic pumps and 3 scales
- High-volume exchange capacity controlled by the 3 scales (up to 25 litres)
- Historical database with a 300-hour plus capacity
- External connection via Ethernet* or USB port
- Adjustable 12" colour touch screen
- Absolute hematocrit and oxygen saturation measurement
- Single-use, plug & play disposable system consisting of two cassettes linked to 6 hemofilters for quick and safe installation
- Heater with ceramic plate for the infusion fluids
- Dual camera system to measure the levels in the two cassettes
- Four pivoting wheels (the front two are lockable) and three handles ensure easy maneuverability
- Backup battery ensures treatment data is maintained in the event of a power interruption

Treatment modes:

Renal treatments		Special treatments	Extra-renal treatments
Continuous	Intermittent		
SLED	IHF-HVHF		HP*
SCUF	IHD	CPFA®	PEX
CVVH	IHDF		CASCADE FILTRATION*
CVVHD			ABYLCAP
CVVHDF			ABYLCAP HD*

Glossary:

SLED - slow extended dialysis
 SCUF - slow continuous ultrafiltration
 CVVH - continuous veno-venous haemofiltration
 CVVHD - continuous veno-venous haemodialysis
 CVVHDF - continuous veno-venous haemodiafiltration
 IHF-HVHF - intermittent haemofiltration - high volume haemofiltration
 IHD - intermittent haemodialysis
 IHDF - intermittent haemodiafiltration
 CPFA® - coupled plasma filtration adsorption
 HP - haemoperfusion*
 PEX - plasma exchange
 CASCADE FILTRATION - *
 ABYLCAP - CO₂ removal
 ABYLCAP HD - CO₂ removal with haemodialysis*

TREATMENT TECHNICAL DATA

Flows**:

Treatments: IHF-HVHF, CVVH

Blood flow: 30-450 ml/min
 Infusion flow: 0-12 l/h
 Ultrafiltration flow: 0.5-12 l/h
 Patient weight loss/gain: 0 - ±2 l/h
 Maximum UF pump flow rate: 16 l/h

Treatments: SCUF

Blood flow: 30-450 ml/min
 Maximum UF pump flow rate: 0-6 l/h
 Patient weight loss: 0-2 l/h

Treatments: IHD, SLED, CVVHD

Blood flow: 30-450 ml/min
 Dialysate flow: 0-0.5-12 l/h
 Ultrafiltration flow: 0-12 l/h
 Patient weight loss/gain: 0 - ±2 l/h
 Maximum UF pump flow rate: 16 l/h

5th pump pre-dilution: 0-4 l/h

Treatments: IHDF, CVVHDF

Blood flow: 30-450 ml/min
 Infusion flow: 0-12 l/h
 Dialysate flow: 0-0.5-12 l/h
 Ultrafiltration flow: 0-0.1-12 l/h
 Patient weight loss/gain: 0 - ±2 l/h
 Maximum UF pump flow rate: 16 l/h

Treatments: CPFA®

Blood flow: 30-250 ml/min
 Plasma flow: 5-20% of the blood flow (maximum value 50 ml/min or 64ml/min in pre-dilution)
 Infusion flow: 0-4.5 l/h
 Ultrafiltration flow: 0-4.5 l/h
 Patient weight loss/gain: 0 - ±2 l/h
 Maximum UF pump flow rate: 8.5 l/h

Treatments: HP*

Blood flow: 30-450 ml/min

Treatments: PEX

Blood flow: 30-250 ml/min
 Plasma flow: 5-20 % of the blood flow (maximum value 50 ml/min)
 Infusion flow: 0.1-3 l/h

Treatments: CASCADE FILTRATION*

Blood flow: 30-250 ml/min
 Plasma flow: 5-25 % of the blood flow (maximum value 62.5 ml/min)
 Infusion flow: 0.1-15 l/h

Treatments: ABYLCAP

Blood flow: 30-550 ml/min

Treatments: ABYLCAP HD*

Blood flow: 30-550 ml/min
 Dialysate flow: 0-0.5-12 l/h
 Ultrafiltration flow: 0-12 l/h
 Maximum UF pump flow rate: 0-16 l/h
 Patient weight loss/gain: 0 - ±2 l/h

Pressures**:

Number of pressure transducers: 10 (4 sensors per cassette and 2 external sensors)
 Blood return pressure: -30 to +300 mmHg with 1 mmHg resolution
 Blood access pressure: -300 to +30 mmHg with 1 mmHg resolution
 Hemofilter inlet pressure: +30 to +600 mmHg with 1 mmHg resolution
 Plasma filter inlet pressure: 30 to +600 mmHg with 1 mmHg resolution
 Oxygenator inlet pressure: 30 to +300 mmHg with 1 mmHg resolution
 Ultrafiltrate pressure: +150 mmHg with 1 mmHg resolution
 UF pre-pump pressure: -400 to +100 mmHg with 1 mmHg resolution
 Cartridge inlet pressure (CPFA®): +500 mmHg with 1 mmHg resolution
 Cartridge outlet pressure (CPFA®): +600 mmHg with 1 mmHg resolution
 Plasma pre-pump pressure (CPFA®): 0 to +800 mmHg with 1 mmHg resolution
 Replacement fluid access pressure: -150 mmHg with 1 mmHg resolution

Calculated pressures**:

Hemofilter TMP: 400 mmHg with 1 mmHg resolution
 Plasma filter TMP: 160 mmHg with 1 mmHg resolution
 Trans-hemofilter: 650 mmHg with 1 mmHg resolution
 Trans-plasma filter: 160 mmHg with 1 mmHg resolution
 Trans-cartridge: 600 mmHg with 1 mmHg resolution
 Trans-oxygenator: 200 mmHg with 1 mmHg resolution

Fluid control:

Number of scales: 3
 Measuring system: load cells
 Maximum infusion scale capacity: 23 kg ± 10 g
 Maximum ultrafiltrate scale capacity: 28 kg ± 10 g
 Maximum 3rd scale capacity: 12 kg ± 10 g

Heater:

Operating range: 30 to 40°C
 Maximum power: 400 W
 Maximum heated flow: 12 l/h

Syringe pump:

Compatible syringes: 30cc - 50cc
 Bolus mode: 0.1 to 20 ml (at maximum speed) in steps of 0.1 ml
 Continuous mode: 0.1 to 20 ml/h in steps of 0.1 ml/h
 Accuracy: depends on the inside diameter tolerances of the syringes

Alarms:

White, red and yellow warning lights on the machine
 Acoustic warning (can be silenced for 2 minutes)
 Message on the screen indicating the problem and the action to take to solve it

Blood leak detectors:

Number of sensors: 2
 Detection system: optical
 Plasma BLD accuracy: 0.35 ml/min of blood (Hct 0.32) at a maximum plasma flow of 64 ml/min
 UF BLD accuracy: 0.35 ml/min of blood (Hct 0.32) at a maximum plasma water flow of 16 l/h

Air detector:

Number of sensors: 1
 Detection system: ultrasound
 Notes: detects air or bubbles greater than 40 µl

Hematocrit meter:

Reading 25-50% with 0.1% resolution

Saturation meter:

Reading 40-100% with 0.1% resolution

MACHINE TECHNICAL DATA

Device classification:

EN 60601-1: Class I-Type CF
 93/42/EEC: Class II B

Dimensions and weight

Machine body structure: BAYDUR 110
 Weight: 87 kg
 with monitor fully extended:
 • Height: 1760 mm
 • Depth: 600 mm
 • Width: 700 mm

with monitor not extended:

- Height: 1470 mm
- Depth: 600 mm
- Width: 700 mm

Power supply:

Voltage: 220V - 240V ± 10%
 Frequency: 50-60 Hz
 Average power absorbed: 400 W
 Max. absorption: 2.5 A (220V - 240V-)

Battery power:

Two 12V 3.4Ah lead batteries
 One 7.2V 1.300 mA NiMH battery

External connections:

- Ethernet port *
- USB port

Ambient operating conditions:

Temperature between +20°C and 30°C
 Relative humidity: 30-75% non-condensing
 Pressure: 700 - 1060 hPa

Transport and storage conditions:

Temperature between -19°C and 70°C
 Relative humidity: 10-95% non-condensing
 Pressure: 700 - 1060 hPa

Safety standards:

IEC 60601-1
 IEC 60601-1-2
 IEC 60601-1-6
 IEC 60601-1-8
 IEC 60601-2-16
 IEC 62304
 ISO 14971

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

* forthcoming introduction

** they may change in relation to the hemofilters used



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AMPLYA™ is manufactured in compliance with European Directive 93/42 of 14 June 1993 relative to medical devices.
 Notifying body: TÜV SÜD Product Service (No. 0123)

Company with Quality Management System certified according to EN ISO 13485:2003/AC2007 and UNI EN ISO 9001:2008