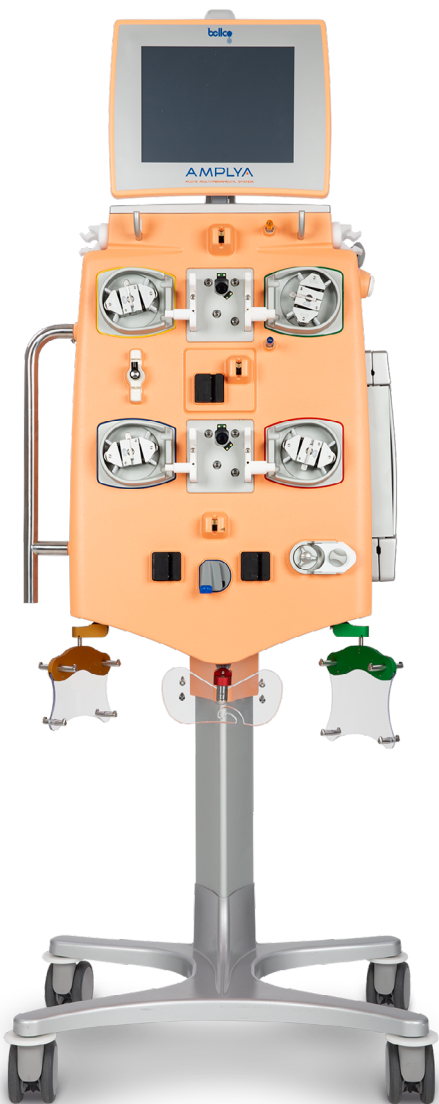


A single platform for multiple options



**AMPLYA Acute
Multitherapeutic system™**

The therapeutic choice

AMPLYA Acute Multitherapeutic system™ is indicated for use in critically ill patients who may be treated with extracorporeal blood purification.^{1,2}

The AMPLYA system™ is able to perform a broad range of extracorporeal blood treatment therapies.

Continuous Renal Replacement Therapies:

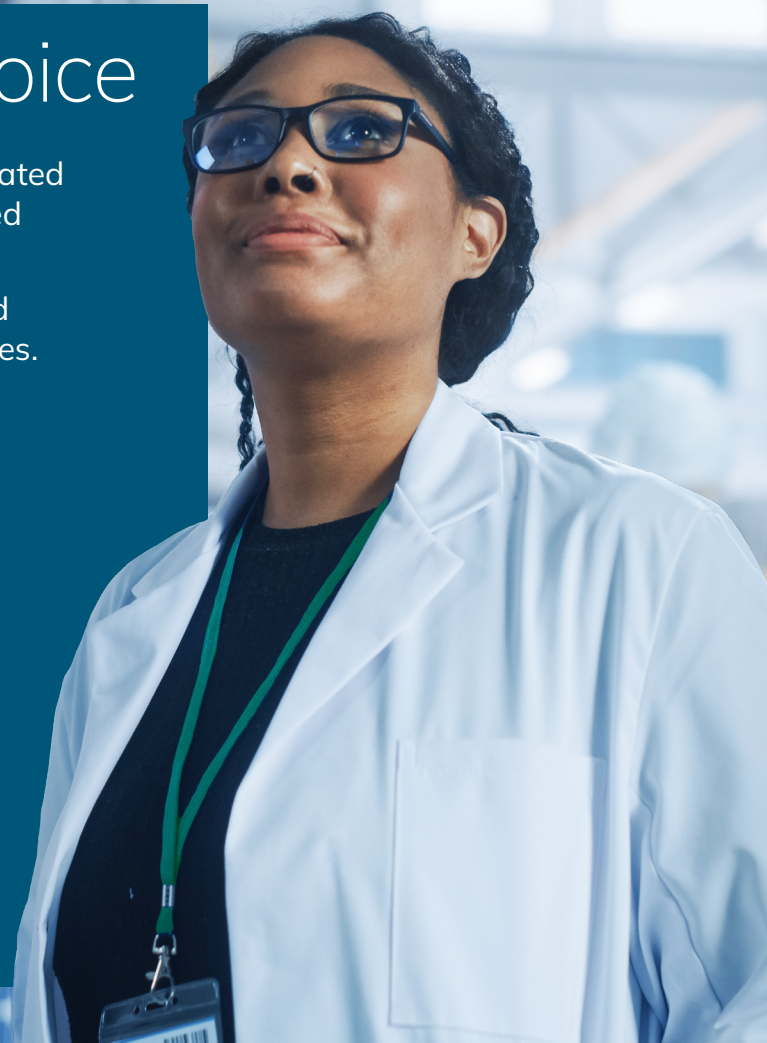
- CVVH
- CVVHDF
- CVVHD
- SCUF

Intermittent Renal Replacement Therapies:

- IHF
- IHDF
- IHD

The AMPLYA system™ performs:

- CPFA (Coupled Plasma Filtration Adsorption)
- PEX (Plasma Exchange)
- HP (Hemoperfusion)



The added value of Amplya

Completeness

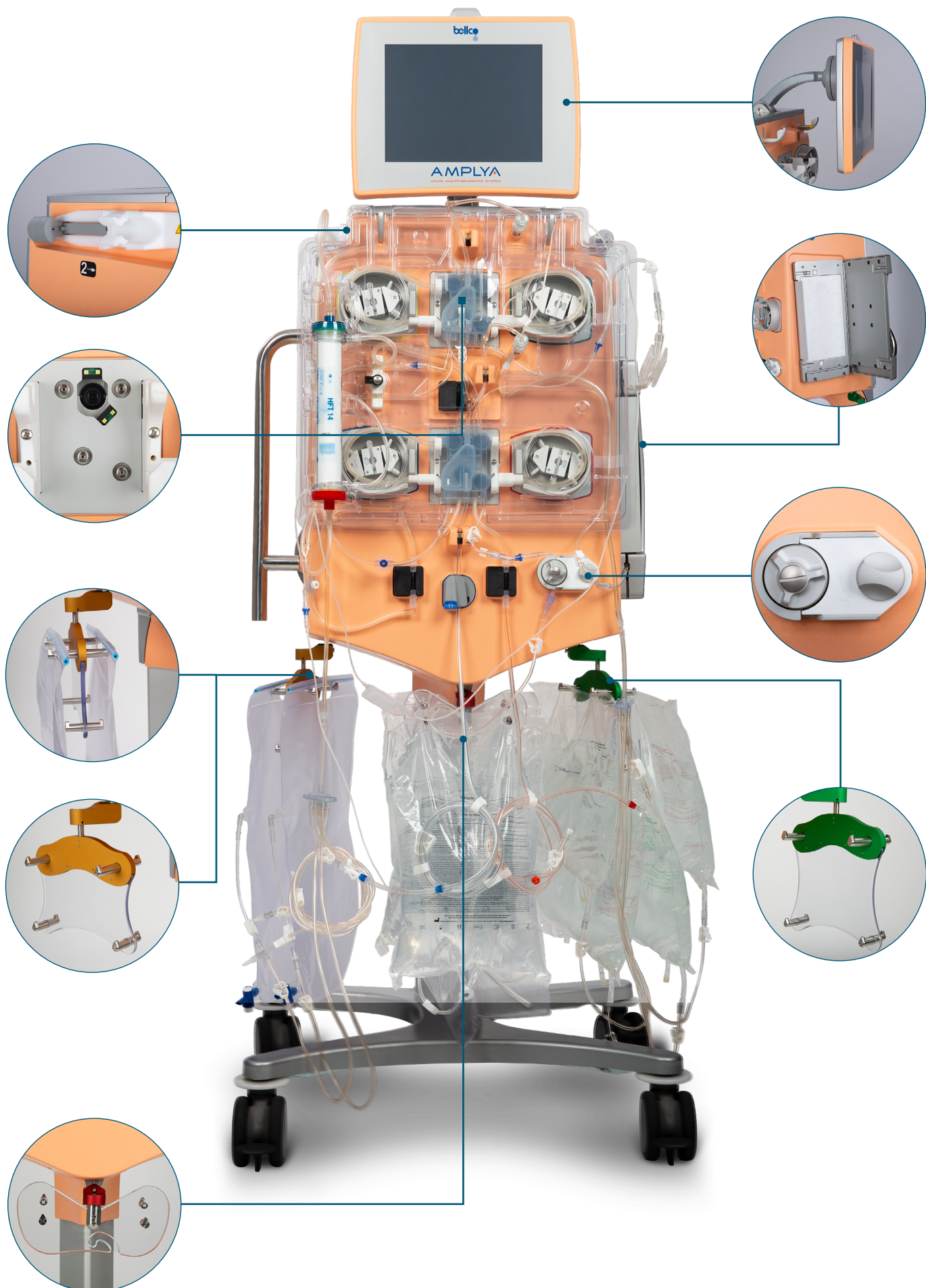
- Continuous and intermittent renal replacement therapies.
- Systemic or locoregional anticoagulation systems.
- Preassembled RRT device with pre-connected hemofilter (six hemofilter surface areas are available).
- 23 kg infusion/replacement fluid scale capacity.
- 26 kg ultrafiltrate scale capacity.
- 12 kg central scale fluid capacity.
- Integrated heater.
- Dedicated optical sensor that can read hematocrit and oxygen saturation levels.
- Double syringe pump.

Automation

- Fast disposable installation due to the plug & play preassembled device.
- Automatic priming can be performed in all modalities.
- Automated level control.
- 300 hours of stored data.
- No need to stop treatment during bag change.
- Treatment information is displayed with descriptions and graphics on a 12.1" touch screen.
- Assisted citrate locoregional anticoagulation.

Intuitiveness

- Colour touch screen.
- Intuitive and user-friendly user interface.
- The AMPLYA system™ alerts users to information and timing about the next intervention.
- Step by step instructions in each phase of preparation.
- Online guide that supports users with messages and diagrams during preparation and treatment.



Completeness Automation Intuitiveness



Completeness

The AMPLYA system™ can perform both systemic and locoregional anticoagulation.¹

Systemic anticoagulation

- The AMPLYA system™ has a double syringe pump and accepts standard syringe sizes (30 and 50 mL).
- Complete anticoagulation system due to the simultaneous operation of the double syringe pump.

Locoregional anticoagulation

- The AMPLYA system™ can perform assisted and unassisted citrate locoregional anticoagulation.

Locoregional anticoagulation in the following modalities:

- ASSISTED CITRATE 10/2
- ASSISTED CITRATE 18/0
- ASSISTED CITRATE 20/4

The AMPLYA system™ enables implementation of unassisted citrate protocol, in which all parameters are set by the operator.

Hematocrit and oxygen saturation reading

The AMPLYA system™ has a dedicated optical sensor that can read hematocrit and oxygen saturation levels. The system's operator interface can provide numerical and graphical data views.

CPFA with dedicated sorbent for cytokine removal through plasma adsorption.^{3,4}

In CPFA, the automated AMPLYA system™ guides the operator to achieve the minimum plasma dose.



Automation

Double cassette plug & play system allows:

- Broad range of extracorporeal blood treatment therapies.
- High level of automation.
- Fast disposable-installation.

High treatment autonomy thanks to scales fluid capacity

Two independent scales for the replacement fluids (23 and 12 kg scale capacity) together with the ultrafiltrate scale (26 kg) have been designed to guarantee accuracy and at the same time stability reducing false positive alarms.

300 hours of stored data

The AMPLYA system™ has an internal database that can store 300 hours of treatment data. Data can be downloaded online via Ethernet port or offline to USB key.

Fully automated preparation and treatment

Automatic priming can be performed in all modalities with the AMPLYA system™. The AMPLYA system™ rinses the pre-assembled device using the infusion solution.

Automatic level control

The AMPLYA system™ has two cameras that control fluid levels in the chambers within the blood and infusion circuits. The camera provides feedback and automatically adjusts the fluid levels in the chambers.

Intuitiveness

User-friendly interface and 12.1" touch screen monitor

The AMPLYA system™ user interface is intuitive and user-friendly. Treatment information is displayed with descriptions and graphics on a 12.1" touch screen.



Ordering information

Capital

CFN code	Description	UOM
IBAXXX700	AMPLYA machine	1 EA

Disposable

CFN code	Description	Details	UOM
IB0600000	KABL14P05 KIT CPFA X AMPLYA	Procedure pack including lines, hemofilter 1.4 m ² , plasmafilter 0.5 m ² , Mediasorb cartridge and 5 x 5L waste bags	1/CT
IB0590040	KABLP05 KIT PEX X AMPLYA	Procedure pack including lines, plasmafilter 0.5 m ² and 5 x 5L waste bags	1/CT
IB0580790	ABLE Pre-assembled device for HP for Amplya	-	1/CT
IB0580903	ABLD03 Pre-assembled device for RRT for Amplya	Pre-assembled device for RRT with hemofilter 0.3 m ²	2/CT
IB0580905	ABLD05 Pre-assembled device for RRT for Amplya	Pre-assembled device for RRT with hemofilter 0.5 m ²	2/CT
IB0580908	ABLD08 Pre-assembled device for RRT for Amplya	Pre-assembled device for RRT with hemofilter 0.8 m ²	2/CT
IB0580914	ABLD14 Pre-assembled device for RRT for Amplya	Pre-assembled device for RRT with hemofilter 1.4 m ²	2/CT
IB0580917	ABLD17 Pre-assembled device for RRT for Amplya	Pre-assembled device for RRT with hemofilter 1.7 m ²	2/CT
IB0580922	ABLD22 Pre-assembled device for RRT for Amplya	Pre-assembled device for RRT with hemofilter 2.2 m ²	2/CT
IB0507006	5 liters waste bag	2 pcs per primary packaging	15/CT
IB0507008	13 liters waste bag	2 pcs per primary packaging	20/CT
IB0514110	BL031 5-litre drainage bag	5 pcs per primary packaging	20/CT
IB0513210/F	BL131 Infusion set for 5 th pump Amplya	-	20/CT
IB0549800	BL370 Infusion set for syringe pump	-	20/CT



IB0580903
IB0580905
IB0580908
IB0580914
IB0580917
IB0580922



IB0580790



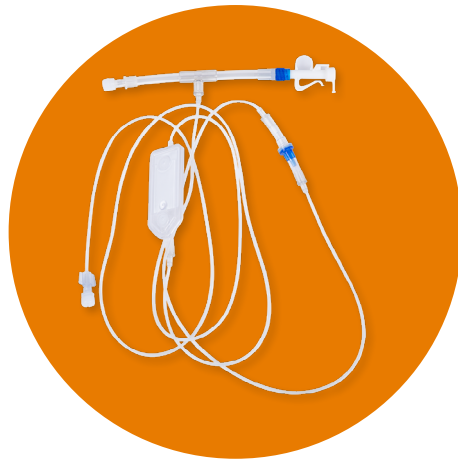
IB0600000



IB0590040



IB0507006
IB0514110



IB0549800



IB0507008



IB0513210/F



References

1. Mariano F, Hollo' Z, Depetris N, et al. Coupled-plasma filtration and adsorption for severe burn patients with septic shock and acute kidney injury treated with renal replacement therapy. *Burns*. 2020; 46(1):190-198.
2. Donati G, Capelli I, Croci Chiocchini AL, Natali N, Scrivo A, La Manna G. Coupled Plasma Filtration Adsorption Application for Liver and Thyroid Toxins. *Contrib Nephrol*. 2017;190:31-42.
3. Netti GS, Sangregorio F, Spadaccino F, et al. LPS removal reduces CD80-mediated albuminuria in critically ill patients with Gram-negative sepsis. *Am J Physiol Renal Physiol*. 2019; 316(4):F723-F731.
4. Tetta C, Cavaillon JM, Schulze M, R, et al. Removal of cytokines and activated complement components in an experimental model of continuous plasma filtration coupled with sorbent adsorption. *Nephrol Dial Transplant*. 1998; 13(6):1458-64.

The AMPLYA system™ is an active, non-invasive, class IIb medical device CE0123 manufactured by Bellico S.r.l.

The pre-assembled devices for RRT and CPFA for Amplya are non-active, non-invasive class IIb medical devices CE0123 manufactured by Bellico S.r.l.

The Mediasorb Cartridge is a non-active, non-invasive class IIb medical device CE0123 manufactured by Bellico S.r.l.

The pre-assembled device for CPFA for Amplya and the Mediasorb Cartridge are included in KABL14P05 – KIT CPFA X AMPLYA procedure pack.

The pre-assembled device for PEX for Amplya is a non-active, non-invasive, class IIb medical device CE0123 manufactured by Bellico S.r.l.

The pre-assembled device for PEX for Amplya and the 5-litre drainage bag are included in KABL P05 – KIT PEX X AMPLYA procedure pack.

The pre-assembled device for HP for Amplya is a non-active, non-invasive, class IIa medical device CE0123 manufactured by Bellico S.r.l.

The 5-litre drainage bag (IB0514110) and infusion set for 5th pump on Amplya are non-active, non-invasive, class Is medical device CE0123 manufactured by Bellico S.r.l.

The infusion set for syringe pump is a non-active, non-invasive, class IIa medical device CE0123 manufactured by Bellico S.r.l.

The 5-litre (IB0507006) and 13-litre (IB0507008) waste bags are non-active, non-invasive, class Ins CE medical devices manufactured by Bellico S.r.l.

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