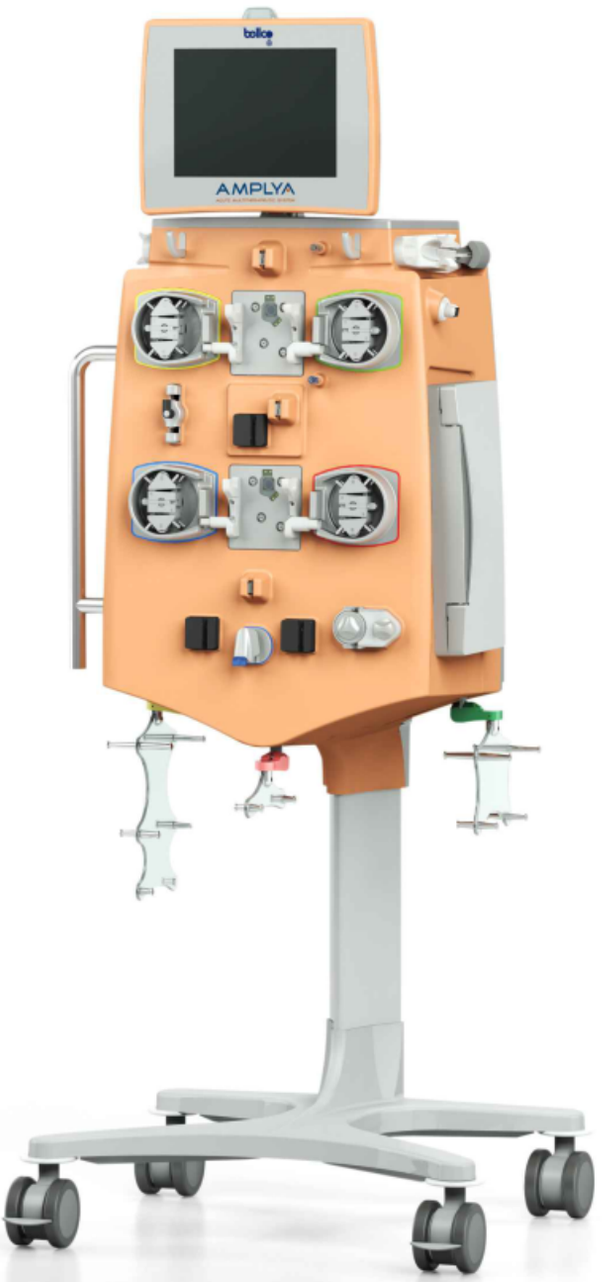
# AMPLYA™

ACUTE MULTITHERAPEUTIC SYSTEM




# *TECHNICAL REPORT*

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# DESCRIPTION

**AMPLYA™** is Bellco's multi-therapeutic and technological response to the treatment of multiple organ failure of acute critical patients. The system allows various types of extracorporeal blood clearance in critical care through a novel personalised and integrated therapeutic approach using a single platform for multiple options.

**AMPLYA™** is equipped with five peristaltic pumps and three scales and is equipped with advanced sensors (hematocrit meter, level sensors, sensors to detect blood in the filtrates, pressure sensors, air sensor) whose functions are to monitor the patient and prevent complications.

**AMPLYA™** has been designed ergonomically to give an immediate, practical and intuitive approach. All internal access and operating parts of **AMPLYA™** have been arranged to improve the quality and safety of the operators' work as well as to make the system easy to use.

**AMPLYA™** is intended for hospital use for haemofiltration, haemodiafiltration, haemodialysis, ultrafiltration, plasma adsorption (CPFA®), plasma exchange (therapeutic TPE), hemoperfusion and $CO_2$ removal (Abylcap) treatments for the purpose of blood clearance in acute patients, as well as in clinical conditions of possible acute or chronic renal failure and water overload.

The system enables the following treatments to be performed:

- **Continuous RRT treatments**:
  SCUF – Slow Continuous Ultrafiltration
  CVVH – Continuous Veno-Venous Haemofiltration
  CVVHD – Continuous Veno-Venous Haemodialysis
  CVVHDF – Continuous Veno-Venous Haemodiafiltration

- **Intermittent RRT treatments:**
  IHF-HVHF – Intermittent Haemofiltration - High Volume Haemofiltration
  IHD-SLED – Intermittent Haemodialysis - Slow Low Efficiency Dialysis
  IHDF - Intermittent Haemodiafiltration

- **Standard extra-renal treatments:**
  PEX - Therapeutic plasma exchange
  HP - Haemoperfusion

- **Extra-renal treatments**:
  **ABYLCAP** ($CO_2$ Removal) is an extracorporeal treatment for patients with ARDS (Acute Respiratory Distress Syndrome), implemented using an ECMO technology oxygenator. The oxygenator removes $CO_2$ and enables partial oxygenation of the blood, though it remains secondary to mechanical ventilation.

- **Exclusive**:
  **CPFA®** (Coupled Plasma Filtration Adsorption) is an extracorporeal treatment for patients with multi-organ failure (MOF) or sepsis, implemented using a dedicated sorbent cartridge. The cartridge contains a resin developed for this specific indication and makes it possible to adsorb the main inflammatory mediators involved.

## LIMITATIONS OF USE

**AMPLYA™** is not designed, marketed or intended for use other than as specified. It must not be used outside the specifications, operating values, and instructions for use indicated by the manufacturer.

**AMPLYA™** must not be used in the following cases:

- Patients weighing less than 15 kg
- All situations described in medical literature as constituting a potential or real risk to the patient and which might be related to devices containing an extracorporeal blood clearance circuit and/or any of the intended uses of **AMPLYA™**.

## MAIN ARCHITECTURE CHARACTERISTICS

**AMPLYA™**'s electronic architecture is composed of a control microprocessor and a protection microprocessor which control all the actuators/detectors/transducers, and a personal computer which supervises all the operating functions and facilitates operator/machine interaction making the treatment management approach immediate and safe. The **AMPLYA™** multiprocessor architecture makes the system:

- *Customisable*: The various functions and the operating parameter settings can be configured according to the centre's customs
- *Flexible*: Various treatment modes can be carried out with the same machine, using the same disposable
- *Updatable*: New software versions can be installed quickly and easily

**AMPLYA™'s** multiprocessor architecture enables the use of high-level software so that the operator can interact with **AMPLYA™** with flexibility and ease of use, guaranteeing patient safety even in a single-failure condition. The self-diagnostic tests run automatically at power up, during both priming/rinsing and before the start of a treatment, making it possible to check that the components are working properly. Help messages shown on the display making all the operating functions easy to understand. Relevant treatment data is displayed on a single screen on the operator interface, both numerically and using ideograms for easier reading.

# OPERATOR INTERFACE

**AMPLYA™**'s user interface incorporates a highly intuitive touch-screen that makes it possible to interact with the machine clearly, quickly and directly through a 12" adjustable screen.

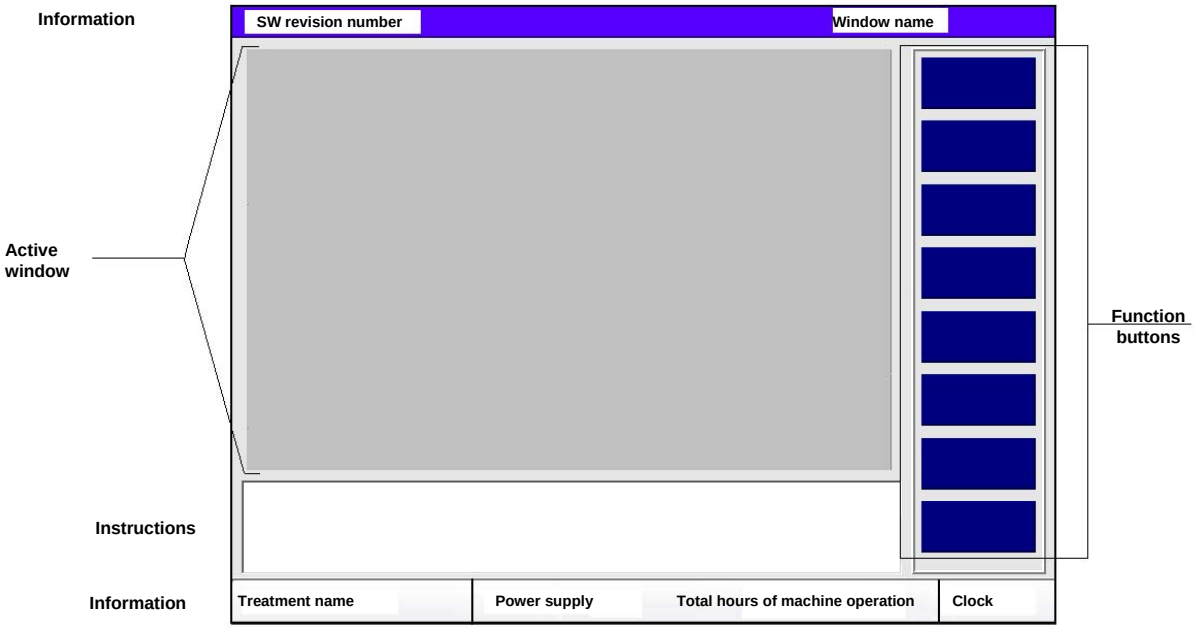
The interface displays the data and enables the operator to change the treatment parameters. The screen is divided into 5 areas in which information messages may be shown.

**Information:** this area consists of a top section that indicates the software revision number and the title of the active window, and a bottom section that shows the treatment name, the power supply status (mains or battery), the total hours of machine operation and the current time.

**Active window:** this main area displays information and allows the operator to modify the parameters and read the data.

**Function buttons:** this area displays buttons that allow activation of the various functions identified by the names on the buttons.

**Instructions:** this area displays messages that explain to the operator the operations that can be performed in each of the windows.

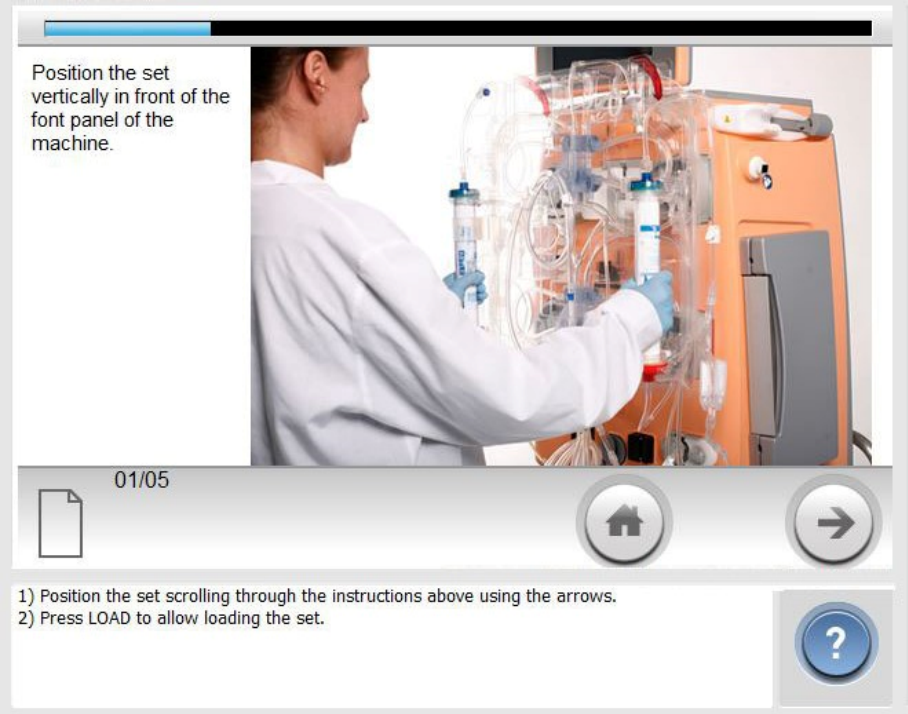


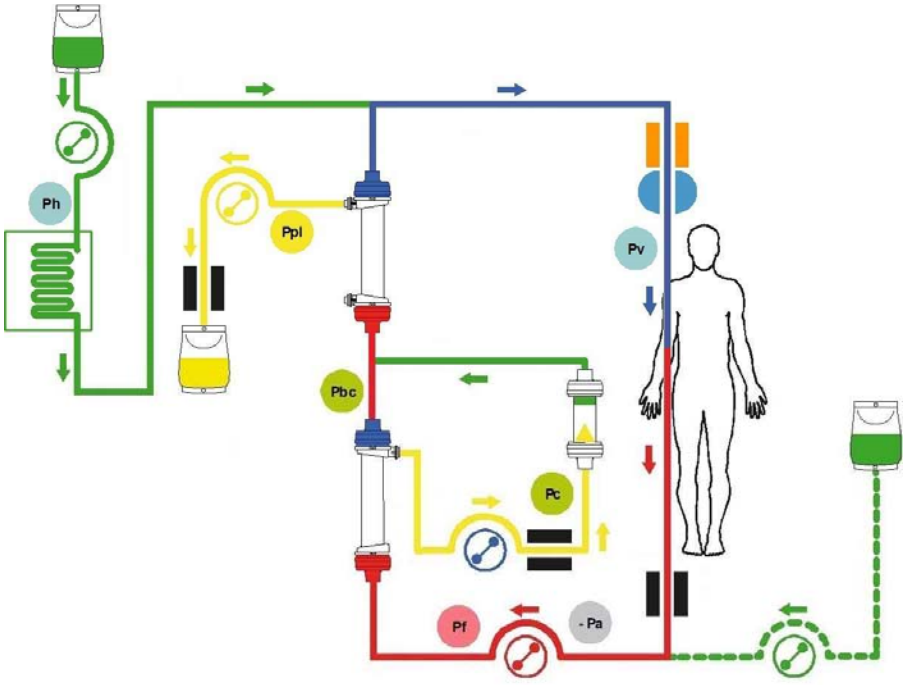

Boxes with priority information that may appear in the active window:

1. Alarm windows when an alarm is detected.
2. Error windows when the operator confirms a value beyond the permitted limits.
3. Numerical and alphanumerical keypads for parameter modification.

The machine is also equipped with simple and immediate online help to support the operator through messages and graphic images during the various treatment phases and during preparation.

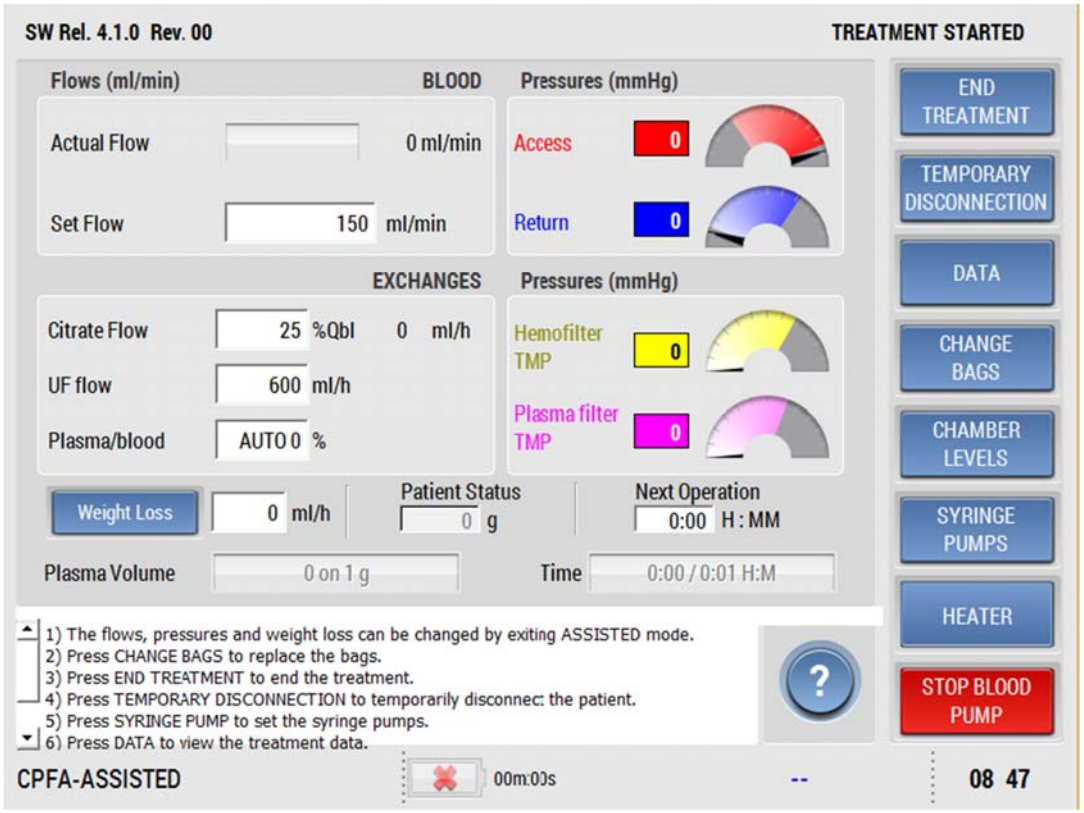
Installation of the preassembled cassette (composed of bloodlines and a filter or filters), is very simple as the online instructions are accompanied, step by step, with pictures that highlight the parts of the circuit referred to.



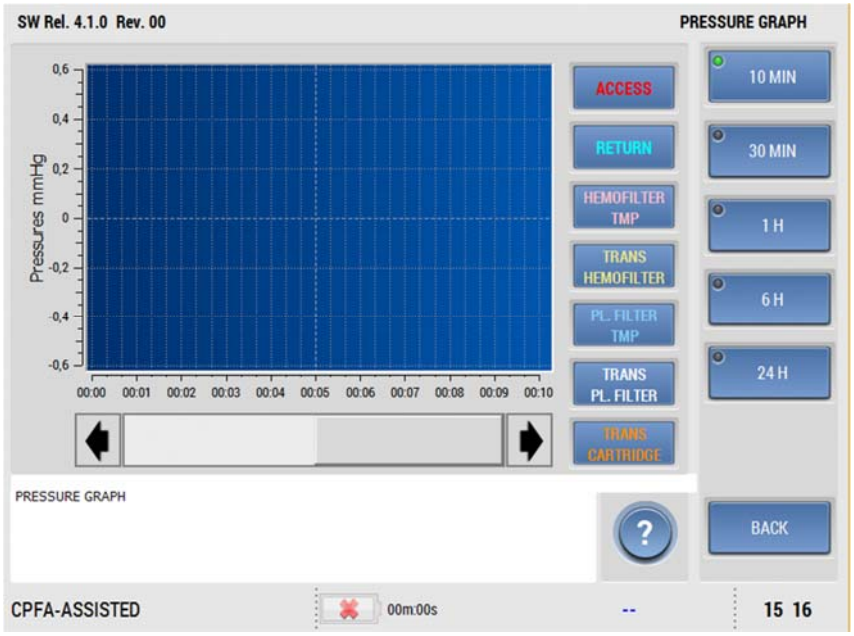




Help messages shown on the display make all the operating functions easy for the operator to understand.
The relevant data for conducting the dialysis session is shown on the operator interface.

The operator interface is structured in such a way that the operator has to confirm any commands twice thus ensuring that the actual intended action is carried out. Data can be viewed in graph form during the treatment, such as pressures, infusion volumes or haematocrit.




The operator interface makes it possible to view data in



- Display of absolute values of the following parameters that vary according to the treatment:
  - Blood return pressure: alarm from -30 to +300 mmHg with 1 mmHg resolution
  - Blood access pressure: alarm from -300 to +30 mmHg with 1 mmHg resolution
  - Hemofilter inlet pressure: alarm from +30 to +600 mmHg with 1 mmHg resolution
  - Plasma filter inlet pressure: alarm from 30 to +600 mmHg with 1 mmHg resolution
  - Oxygenator inlet pressure: alarm from 30 to 300 mmHg with 1 mmHg resolution
  - Ultrafiltrate pressure: alarm at +150 mmHg with 1 mmHg resolution
  - UF pre-pump pressure: operation from -400 to +100 mmHg with 1 mmHg resolution
  - Cartridge inlet pressure (CPFA®): alarm at +500 mmHg with 1 mmHg resolution
  - Cartridge outlet pressure (CPFA®): alarm at +600 mmHg with 1 mmHg resolution
  - Plasma pre-pump pressure (CPFA®): operation from 0 to +800 mmHg with 1 mmHg resolution
  - Replacement fluid access pressure: alarm at -150 mmHg with 1 mmHg resolution
  - Hemofilter TMP: alarm at 400 mmHg with 1 mmHg resolution
  - Plasma filter TMP: alarm at 80 mmHg with 1 mmHg resolution
  - Trans-hemofilter: alarm at 650 mmHg with 1 mmHg resolution
  - Trans-plasma filter: alarm at 250 mmHg with 1 mmHg resolution
  - Trans-cartridge (CPFA®): alarm at 600 mmHg with 1 mmHg resolution
  - Trans-cartridge (HP): alarm at 400 mmHg with 1 mmHg resolution
  - Trans-oxygenator: alarm at 200 mmHg with 1 mmHg resolution
  - Patient weight loss
  - Volume infused in pre-dilution (5$^{th}$ pump)
  - Volume infused in pre-infusion
  - Volume infused in post-infusion
  - Dialysate volume
  - Filtrate volume (UF)
  - Hematocrit
  - Oxygen saturation
  - Filtration fraction
  - Volume of treated blood
  - Volume of treated plasma (CPFA® and plasma therapies)
  - Patient variation
  - Replaced plasma
  - Blood flow
  - Syringe pump speed 1 and syringe pump speed 2
  - Anticoagulant residual or calcium residual (if in citrate modality)
  - Infused fluid temperature
  - Volume infused from the fifth pump
  - Treatment time
  - Intervention time at bag change, at syringe change and at ionized calcium check (if in citrate modality)
- Display in graphic form of the following parameters:
  - Arterial access pressure
  - Venous return pressure
  - Hemofilter transmembrane pressure
  - Trans-hemofilter pressure
  - Trans-oxygenator
  - Trans-plasma filter pressure (CPFA®)
  - Plasma filter transmembrane pressure (CPFA®)
  - Cartridge fall pressure change (CPFA®)
  - Patient weight loss
  - Total volume of infused fluid
  - Filtrate volume (UF)
  - Pre-dilution volume
  - Hematocrit
  - Oxygen saturation
  - Volume infused from syringe pump 1 and from syringe pump 2
  - Temperature of infusion fluid and dialysate

**AMPLYA™** is equipped with systems that control the measurements from the scales and the pump speeds in order to monitor and control, in real time and throughout the treatment time, the following parameters:

- Fluid balance
- Partial and total ultrafiltration volume
- Infusion rate of the replacement solution
- Dialysis fluid flow
- Patient weight loss.

These parameters can be called up by the user and displayed during the treatment.

## ALARM MANAGEMENT

**AMPLYA™** immediately notifies any alarm condition to the operator visually, optically and acoustically:

- Visually: messages and/or windows on the display
- Optically: flashing light located at the top of the screen
- Acoustically: buzzer with different frequency according to a scale of priorities.

**AMPLYA™** is equipped with an alarm management system which the machine detects and controls malfunctions and errors, establishing the presence of potential or actual risks.

In the event of alarms, the following safety actions occur:

- the exchange pumps and the syringe pump are stopped
- if necessary, the blood pump is stopped
- the heater is turned off
- a short, clear message is shown on the screen
- an acoustic signal sounds and a warning light flashes to notify the operator that an abnormal condition has occurred.

**If several alarms occur simultaneously, the system independently establishes and displays the order of priority of the existing alarms.**
The visual alarm signal can be clearly seen by an operator when standing in front of the machine. The warning light on the monitor flashes for the entire duration of the alarm with variable frequency and colour according to an alarm priority scale. The acoustic warning differs in intensity and frequency according to an alarm priority scale.

The alarms are classified based on a priority indicating the importance of a particular alarm and the urgency with which it needs to be resolved:

- High priority alarm
- Low priority alarm

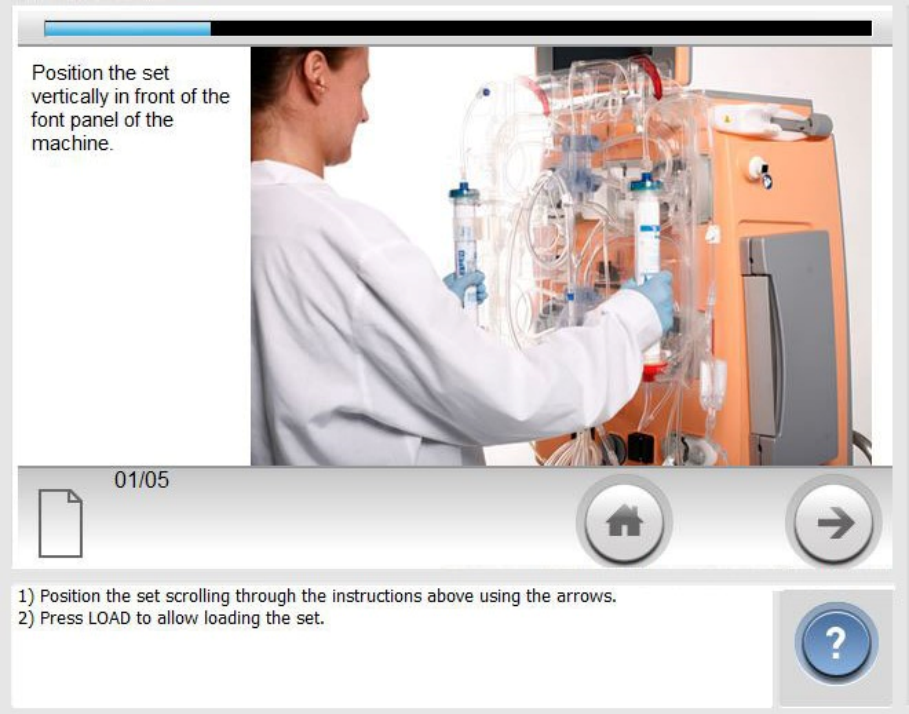
**The background colour of the alarm window and the colour of the warning light when activated** vary depending on the alarm.
**In the case of high priority alarms that cause a stop or slow down of the blood pump, the alarm window background and the warning light are displayed in red** to more effectively draw the attention of the operator. In this case, the operator needs to intervene quickly in order to correct the problem that triggered the event and prevent the blood from coagulating in the extracorporeal circuit.
**In the case of low priority alarms whose only function is to warn the operator, the alarm window background and the warning light are yellow** to indicate that the blood is continuing to circulate.
In the case of **system alarms the alarm window background is purple**.

# MACHINE CHARACTERISTICS

## CASSETTES AND CAMERA SYSTEM

**AMPLYA™** enables flexibility and safety in the sequence of operations because of a double-cassette system for all treatments.

**AMPLYA™** makes it possible to load pre-assembled single-use cassettes automatically, reducing staff interventions to a minimum due to a panel on which the lines and filters required for the specific treatment are pre-assembled and to a plug & play double cassette system with automatic insertion of 8 (4+4) pressure transducers and 4 pump segments (2+2)




When the cassette loading procedure is complete, press the **LOAD** button to enable the machine to load the set.
When the button is pressed, a loading confirmation window appears.
After confirming the LOAD, wait until loading of the CASSETTE is complete before proceeding.

This system is equipped with dual cameras reader to adjust the fluid level inside the cassette.

During treatment, there is no need to adjust the fluid levels in the top cassette as the **cameras carry out a control action activating pumps inside the machine to adjust these levels,** ensuring a high level of safety for patients undergoing treatment.

## PRIMING MANAGEMENT

**AMPLYA™** enables automatic priming for all options of therapies without intervention from nursing staff.
**AMPLYA™ primes and rinses the entire cassette using the infusion solution, so there is no need for a bag change between the priming phase and the start of treatment.**

This makes it possible to:

- Avoid the use of saline solution bags
- Not disconnect the access and return line, but to leave them linked, maintaining the sterility of the entire kit intact during priming.
- Prepare the machine not only for priming, but also for treatment.

## SCALES

**AMPLYA™** is equipped with a high level of exchange autonomy controlled by the 3 scales, thereby saving time and reducing the possibility of error: **2 independent scales for the replacement fluids (23 and 12 kg to enable the use of 4 and 2 fluid bags) and one for the effluent fluids (UF at 26 kg which enables the use of 5 discharge bags)** have been implemented to ensure accuracy and at the same time designed to ensure stability and **insensitivity to movements**.
The **AMPLYA™** flow control principle is based on automatic evaluation of the fluid exchanged using the weights measured on the scales.
During the priming and rinsing phases, some tests are run automatically (pressures, integrity of the lines, functioning of the scales and sensors).
The exchange volumes protection system is based on three scales: infusion/dialysate, pre-dilution and UF.
During treatment, the system checks that:

- the weight reductions, calculated based on initial time (treatment start or bag change), weight/volume of the bags on the infusion and pre-dilution scales are consistent with the expected values calculated based on the values set by the operator
- the weight variations, calculated with respect to an initial time (treatment start or bag change), weight/volume of the bags on the UF scale are consistent with the expected values calculated based on the values set by the operator
- the infusion, pre-dilution and UF pump speeds are consistent with the expected values calculated based on the values set by the operator.

## FLUID HEATER

The fluid heater heats the replacement fluid that circulates in the bag which is in contact with the ceramic heating plate.

During treatment, the heater temperature can be set to six levels. The machine displays the temperature of the infusion liquid and/or the dialysate outgoing from the heater.

The heater can be set to obtain a temperature controlled at the outlet even at high flows. The temperature of the outgoing replacement fluid depends on the flow and temperature of the incoming replacement fluid and the temperature level selected. The temperature is adjusted by comparing the temperature the system has to reach, based on what the operator has selected, with the actual temperature measured by the ceramic plate by means of a sensor.
System safety is ensured by the fluid and plate overheating alarms, and by the test on the temperature sensors.
The system provides alarms when the heater door is open, when there is no bag in the heater and when there is fluid leakage from the bag.
The thermoregulation system is equipped with 4 temperature sensors (part of the protection system):

- 2 measure the plate temperature
- 1, in contact with the bag inlet line, measures the temperature of the fluid coming into the heater
- 1, in contact with the bag outlet line, measures the temperature of the fluid going out of the heater.

## FIFTH PUMP AND CENTRAL SCALE

The fifth pump draws replacement fluid from a bag hung on the central scale.

**AMPLYA™** is equipped with a peristaltic fifth pump that is opened manually, with scales to manage high flow haemo-dilution infusions.
During treatment, the fifth pump is activated and coupled to the blood pump (the flow is set in relation to the blood flow rate) in order to pre-dilute the blood, infusing replacement fluid before the blood pump.

The fifth pump flow is calculated by the system using the third scale and the control systems for the scales load cells.

During treatment, the fifth pump operates only when the ultrafiltration pump operates.
The above picture shows the fifth pump. The system is capable of detecting (by means of a magnetic sensor), during both priming and treatment, and opening of the fifth pump cover, if the treatment requires pre-dilution of the blood with replacement fluid.

## LOCAL REGIONAL ANTICOAGULATION AND ASSISTED CITRATE-CALCIUM

**AMPLYA™** is equipped with a system for managing the local regional anticoagulation using citrate-calcium. The machine, taking into account the ideal patient weight calculated by the machine itself through a dedicated setting window, automatically calculates the rate to set for the citrate infusion using the 5$^{th}$ pump in pre-infusion. The calcium is administered through the syringe pump integrated in the machine and its infusion rate and infusion/dialysis fluid flows are adjusted automatically. Citrate anticoagulation is available in CVVH, CVVHDF and CPFA® treatments. The machine periodically notifies the nurses to do an arterial blood gas (ABG) analysis to check the level of ionized calcium in the patient. The ionized calcium value is to be entered into the **AMPLYA™** anticoagulation dedicated setting window which will instruct the nurse to change the calcium or citrate infusion rate.
**AMPLYA™** provides indications on the type of solutions/drugs to use in relation to the selected treatment. Both 10% chloride calcium and 10% glucose calcium can be used. The function is activated before starting the priming phase and at any time the operator decides to quit the assisted citrate and switch to the citrate free function.

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## SYRINGE PUMP

**AMPLYA™** is equipped with 2 syringe pumps for anticoagulation.
Pump 1 is **intended for administration of anticoagulant or calcium (if using citrate) in bolus or continuous infusion mode**

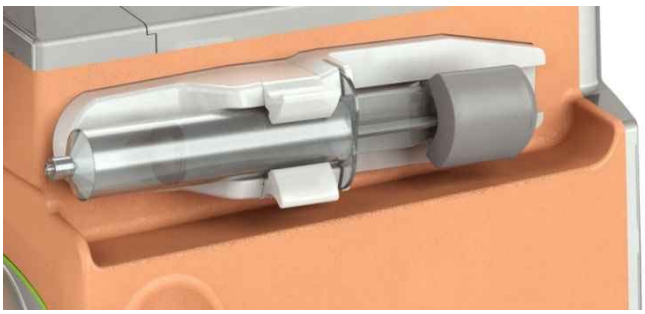
- Continuous flow: variable from 0.1 to 30 ml/h with steps of 0.1 ml/h.
- Bolus flow: variable from 0.1 to 20 ml/h with steps of 0.1 ml.

Pump 2 is **intended for administration in continuous infusion mode**

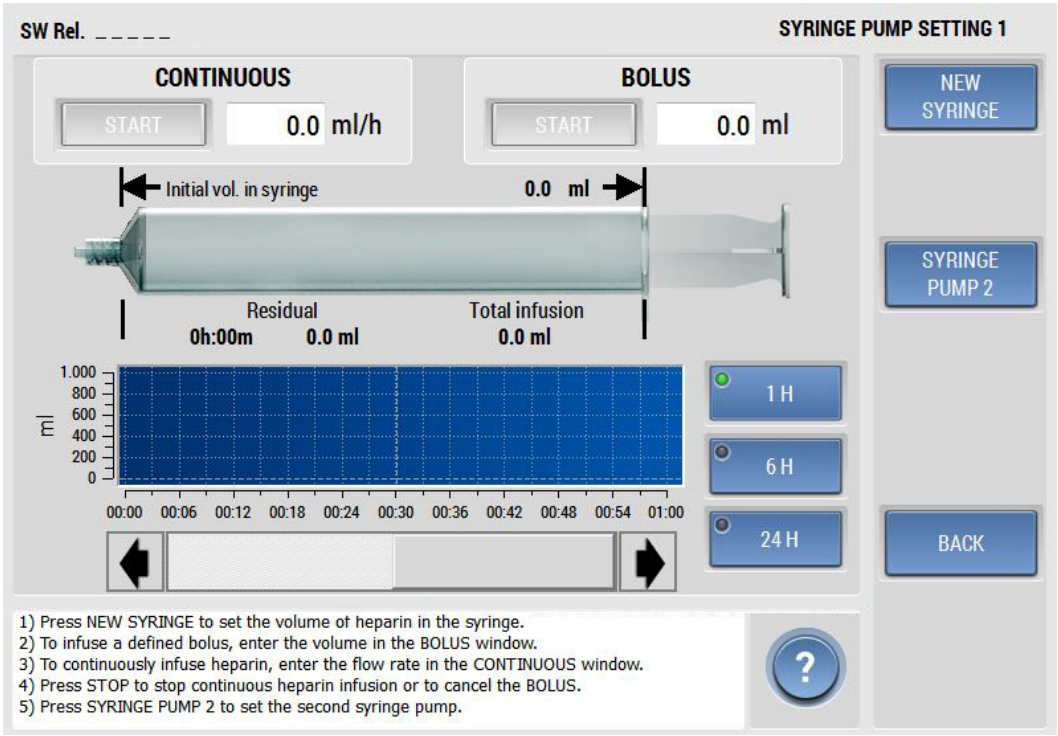
- Continuous flow: variable from 0.1 to 30 ml/h with steps of 0.1 ml/h.

Compatible syringe specifications:

1. Standard type
2. With Luer-lock connector
3. With rubber seals
4. Size: 30 and 50 ml.



A graph displays the administration in real time.



## HEMATOCRIT AND OXYGEN SATURATION MEASURING SYSTEM

**AMPLYA™** comes equipped with a sensor with the capability of continuously supplying **the absolute hematocrit and oxygen saturation measurement**. The sensor interfaces with the single-use cuvette inserted in the blood access line and is capable of continuously providing the absolute values of these parameters.

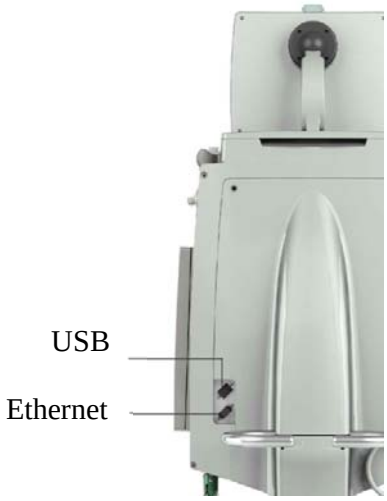
The hematocrit and oxygen saturation measuring system uses a reader that takes optical absorbance measurements at different wavelengths.
The advantages of the system are: non-invasive measurement, sterility maintenance and the ease of use for the operator. In addition, the hematocrit and oxygen saturation measurements do not affect the machine's operation.
The operator interface enables the data to be viewed in graph format during the treatment.
The measurements made by the device help the operator understand the haemodynamic state of the patient, the blood volume refilling capacity and if there is a need to modify the treatment fluid parameters, which, together with filtration modulation, can improve the haemodynamic state of the patient.

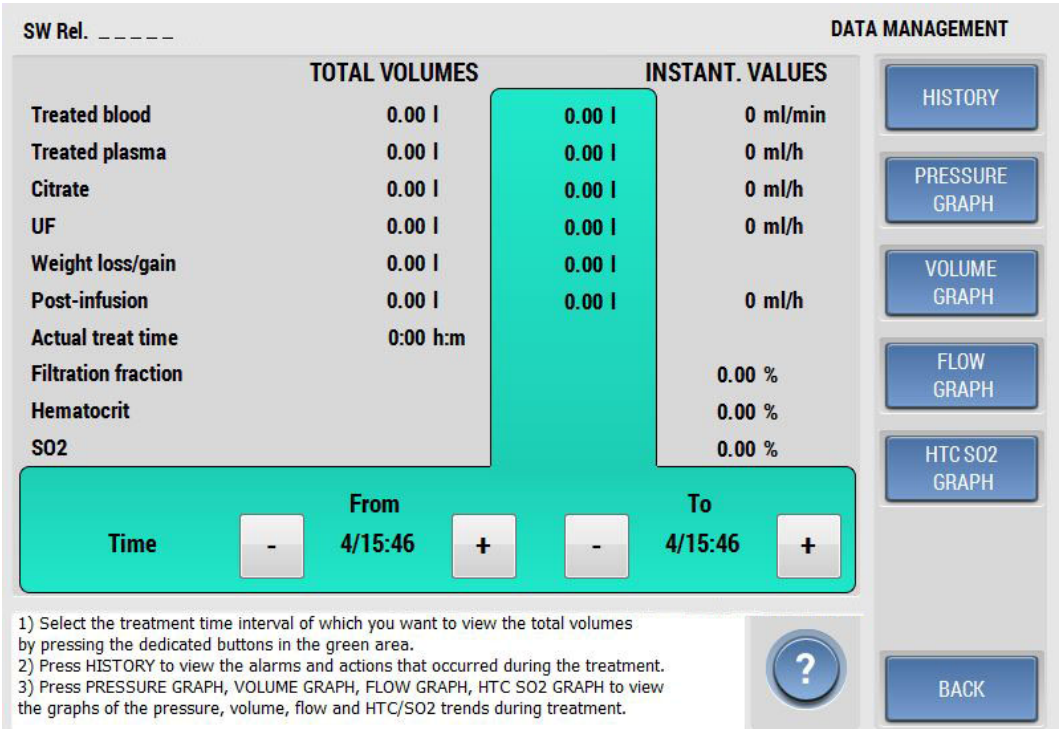
## COMMUNICATION PORTS

**AMPLYA™** is equipped with a USB communication port so that data can be downloaded on a key. It is also equipped with an Ethernet port. There is a dedicated interface which makes it possible to connect to **AMPLYA™** and download system data. The connection takes place through a dedicated protocol for **AMPLYA™.**

**AMPLYA™** has a historical archive with over **300 hours of capacity** with the option of accessing the most important information regarding the treatments performed, the clinical parameter settings, and the pressure and infused fluid volume graphs.

The treatment data can be extracted through either the **Ethernet port or the USB port** when the machine is disconnected from the patient.



# SAFETY

## ➢ INITIAL CALIBRATIONS

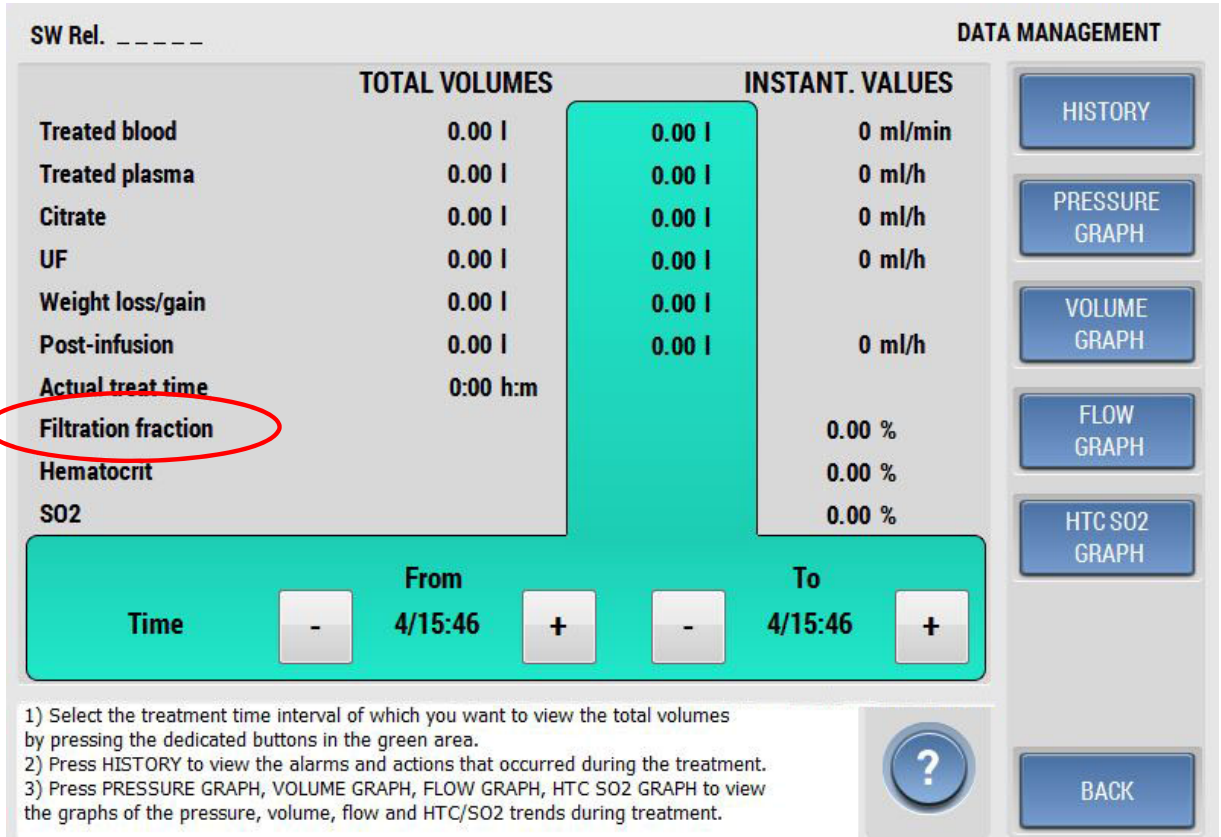
**AMPLYA™** continuously runs tests to check data consistency between the processors and the PC and continuously verifies that the machine components (i.e. motors, scales and sensors) are functioning properly.

## ➢ PRESSURE TRANSDUCERS

**AMPLYA™** is equipped with non-invasive measurement transducers without stasis points and are not subject to contamination.

## ➢ FILTRATION FRACTION AND FLUID CONTROL

During treatment, **AMPLYA™** is capable of displaying all fluids administered and patient weight lossand calculating and controlling the filtration fraction (maximum limit permitted 30%). In order to prevent hemoconcentrations in the hemofilter and the consequent coagulation risks, the system does not allow setting **a UF flow incompatible with the blood flow**. This data must be set by the operator so that it matches the physical reality of the patient and thus enables **AMPLYA™** to calculate the fluid balance and manage it automatically.



## ➢ AIR DETECTOR

**AMPLYA™**is equipped with an ultrasound air bubble detector intended to monitor the blood in the venous return line for the presence of air bubbles. This detector generates an alarm which interrupts the venous return and operation of all the peristaltic pumps when an air volume of more than 40 µl is detected. The safety electroclamp also closes with activation of this alarm.

## ➢ BLOOD LEAK DETECTORS

There are 2 optical blood detectors on the filtrate and plasma line (CPFA® and PEX), capable of detecting blood leaks of more than 0.35 ml/min compared to the maximum flow.

## ➢ EMERGENCY BATTERIES

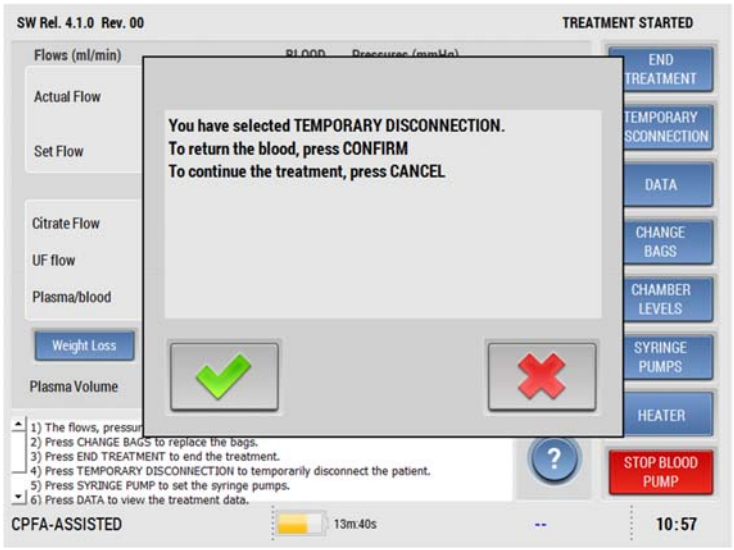
**AMPLYA™** is equipped with two 12 V lead batteries that ensure that, in the event of power supply loss, the pumps can operate for at least 20 minutes and the treatment data is retained in the memory (this is considering that allowing the battery to be fully charged). The data retention capacity allows all treatment settings entered before the power loss to be saved, ensuring data consistency (flows, minimum and maximum pressures permitted by the system, etc.). During these 20 minutes, the operator can monitor the remaining time (via the battery icon) before machine shutdown at the bottom of the screen.

- After 20 minutes of battery-powered operation, the machine considers the battery fully discharged and turns off. In this situation, the operator can choose to continue with manual blood return to the patient.

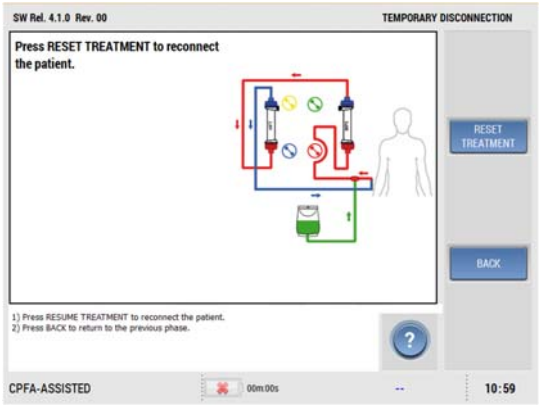
If the power is restored before the 20 minutes have elapsed, the system continues operating as it was during battery powered operation, activating the heater if required.

## ➢ TEMPORARY PATIENT DISCONNECTION

The system allows for automatic, temporary patient disconnection during treatment ensuring patient and operator safety.



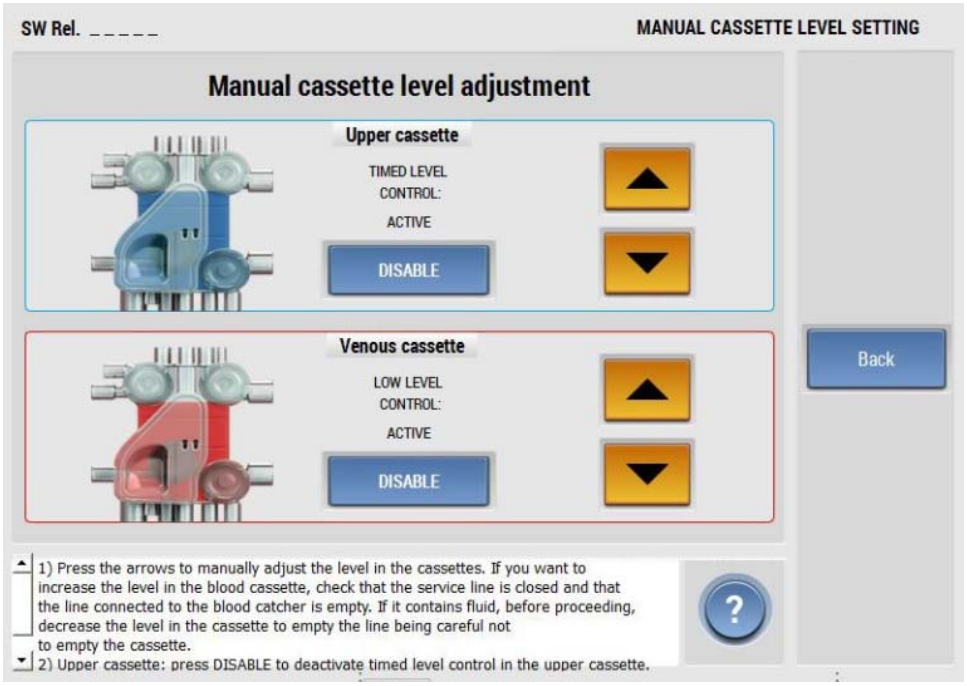

In this case **AMPLYA™** retains all the treatment data in memory and is capable of restarting without needing to reset the parameters.




In addition, during the pause, the pressure alarms and the alarms relating to the flow and weight recorded by the scales intervene less frequently than during treatment in order to allow staff to attend to the patient, maintaining the safety of the treatment to be restored.

## ➢ CHAMBER LEVELS

Pressing the **CHAMBER LEVELS** button, a page can be accessed that allows the user to manually adjust the levels in the venous cassette and the level in the upper cassette. The machine periodically carries out an automated procedure that adjust the level in the upper cassette , preventing air getting into the circuit and maintaining a high level of safety for the patient. From this page you can also disable the level control of each cassette by pressing the appropriate button.




## ➢ ELECTROMAGNETIC INTERFERENCE

**AMPLYA™** complies with standards for electromagnetic compatibility, so it does not cause interference with other medical devices compliant to the same standards (IEC standard 60601-1-2).

## ➢ DIMENSIONS AND TRANSPORTABILITY

The system has the following dimensions:

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

The 87 kg-weight is supported by 4 double, revolving wheels equipped with a braking system, ensuring that the machine is very easy to manoeuver, move and position from one location to another.

# COMPLIANCE WITH STANDARDS

**AMPLYA™** has been designed and constructed in compliance with international standards relating to the safety of medical electrical equipment:

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

**AMPLYA™** bears CE marking in accordance with European Directive 93/42/EEC of 14 June 1993 on Medical Devices.
Notifying Body: TÜV SÜD Product Service - Munich (Germany), number 0123.

In addition, BELLCO is a company that operates within a global quality system, certified by the German TÜV for compliance to EN ISO 13485 and UNI EN ISO 9001.

# TREATMENTS

RRT
RENAL REPLACEMENT THERAPY

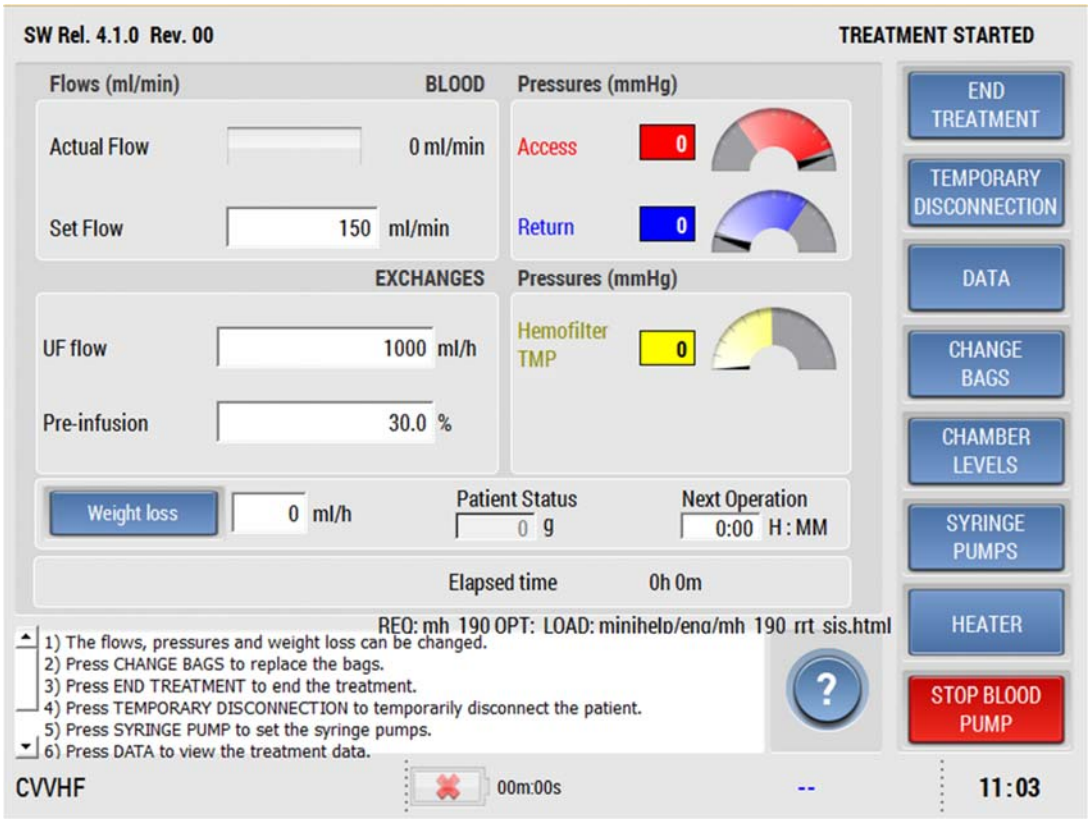
A **single pre-assembled set of lines coupled with a hemofilter** (with 6 different measurements possible) to control low or high flow treatments: in **RRT the treatment can be changed without changing the circuit due to the double clamp which makes it possible to switch from CVVHDF to CVVHD or to CVVH and vice versa.** With 6 hemofilters from 0.3 $m^2$ to 2.2 $m^2$ , all patients with body weight of more than 15 kg can be treated. The single-use extracorporeal circuit includes only one filter (hemofilter/hemodiafilter) for plasma water removal.

The infusion system can be programmed for pre-dilution, post-dilution or pre- and post-dilution at the same time, with adjustable flows by percentage setting. In CVVHDF a pre and post infusion can be performed at the same time, thanks to the pre-dilution pump located upstream of the blood pump.

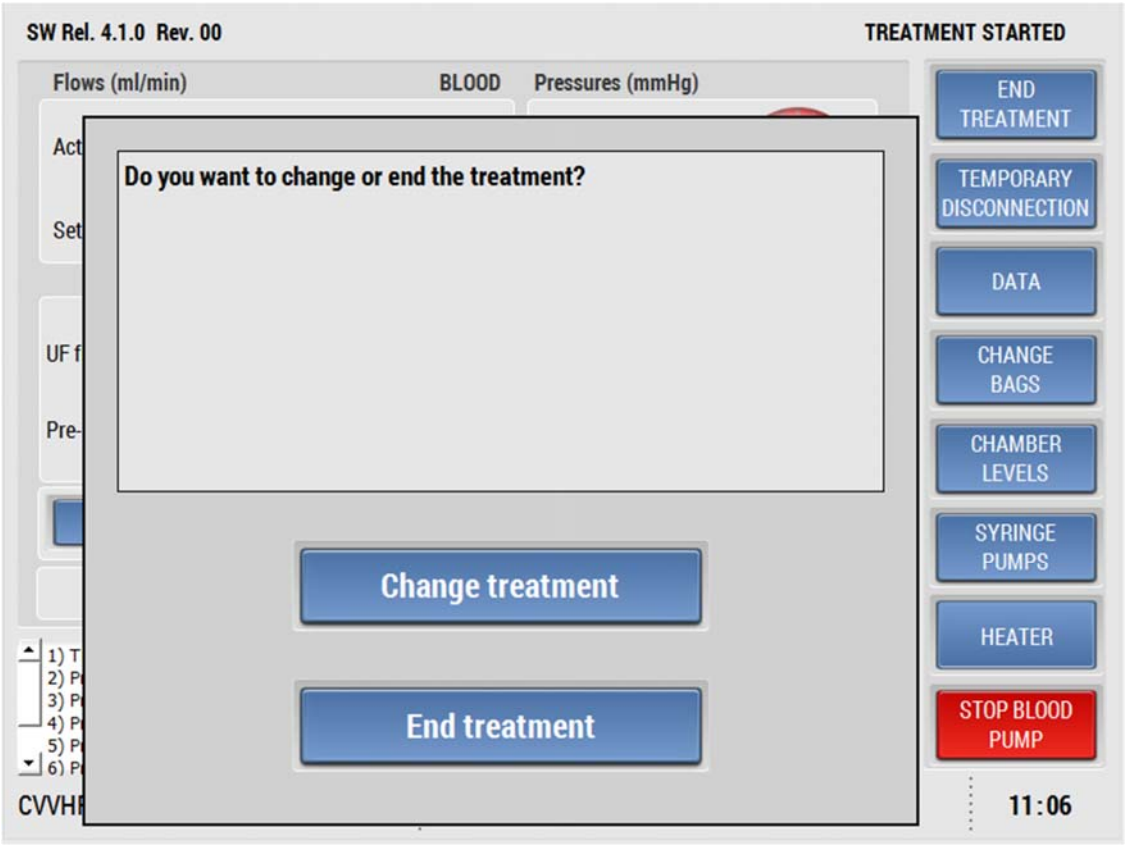
The types of RRT treatment are:
- Haemodiafiltration
- Haemodialysis
- Haemofiltration
- Ultrafiltration.

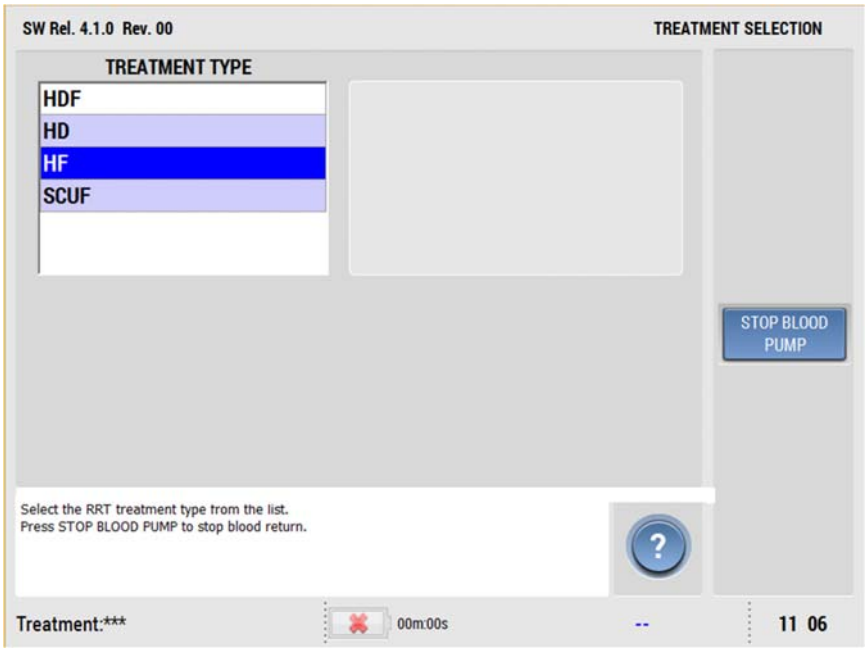
The RRT treatments share the same priming/rinsing procedure.

**AMPLYA™** displays the data required to manage treatment on the main screen. For example, the screen for managing haemofiltration (CVVHF) looks like this:



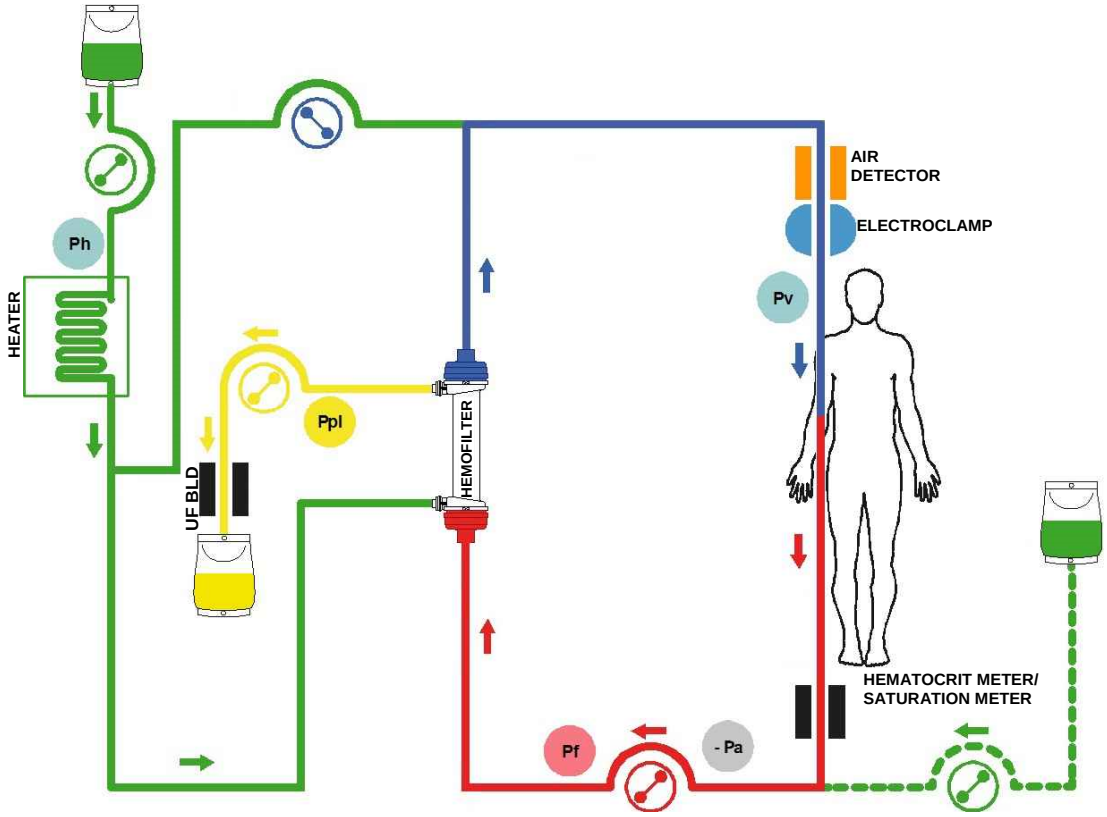
To change therapy during treatment, the machine prompts for a confirmation on the selection screen, thereby keeping the blood pump moving and avoiding any coagulation in the circuit.



## ➢ HAEMODIAFILTRATION

Haemodiafiltration (HDF) is an RRT treatment and can be continuous (CVVHDF) or intermittent (IHDF).
Bellco provides circuits with hemofilters in different sizes. The **hemofilter** sizes vary from 0.3 $m^2$ to 1.7 $m^2$ for increasing flow values.
The single-use circuit includes a line for fluid infusion into the dialysate compartment of the filter, a line for replacement fluid infusion at the hemofilter outlet (post-infusion), and a line for extraction of the waste fluid (ultrafiltrate).

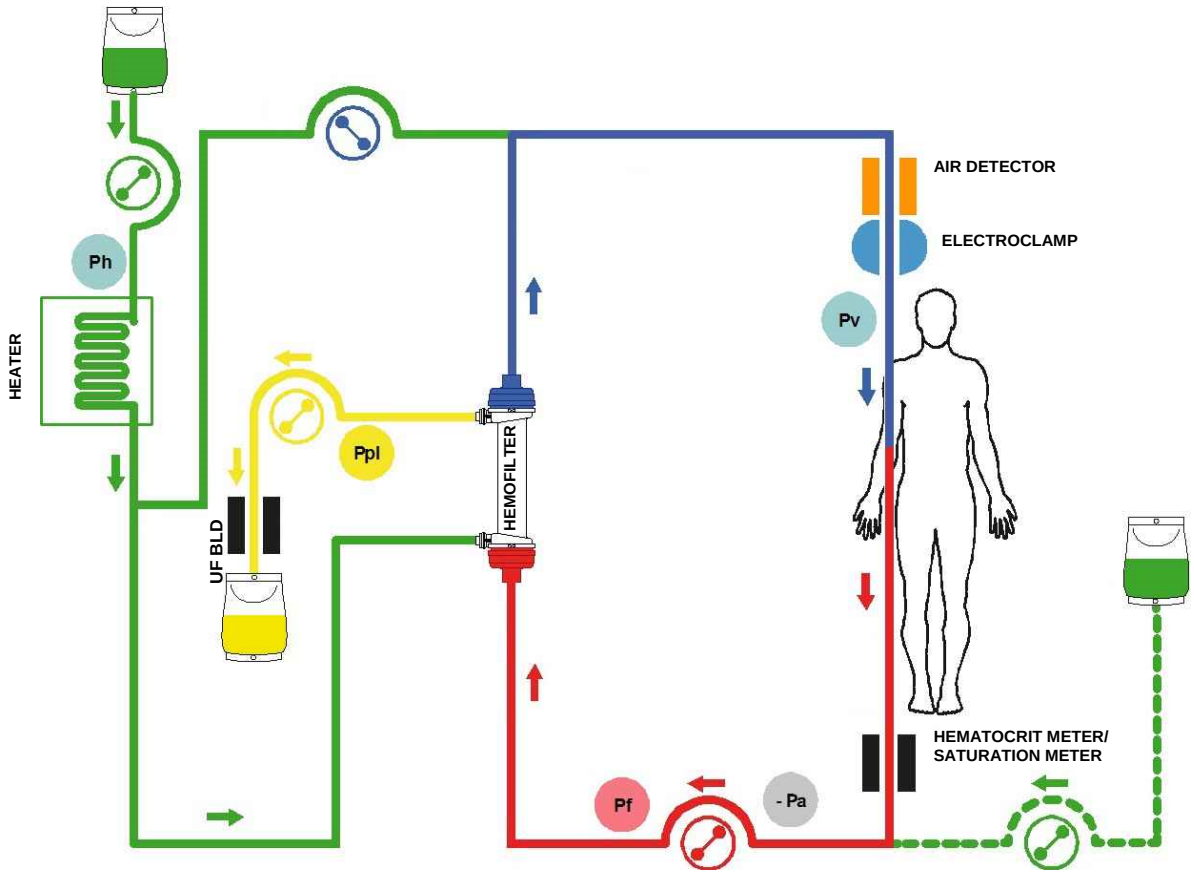



Below are the treatment specifications for HDF:

- Blood flow ($Q_b$): 30  450 ml/min
- Patient weight loss/gain: 0  2 l/h
- Pre-dilution pump flow (5th pump): 0  4 l/h
- Dialysate flow: 0 or 0.5  12 l/h
- UF flow: 0 or 0.1  12 l/h
- Maximum UF pump flow rate: 16 l/h
- Maximum intermittent treatment time: 24 h
- Maximum continuous treatment time: 72 h

## ➢ HAEMODIALYSIS

Haemodialysis is an RRT treatment and may be continuous (CVVHD) or intermittent (IHD-SLED). Bellco provides circuits with hemofilters in different sizes. The **hemofilter** sizes vary from 0.3 $m^2$ to 1.7 $m^2$ for increasing flow values.
The single-use circuit includes a line for fluid infusion into the dialysate compartment of the filter and a line for extraction of the waste fluid (ultrafiltrate).

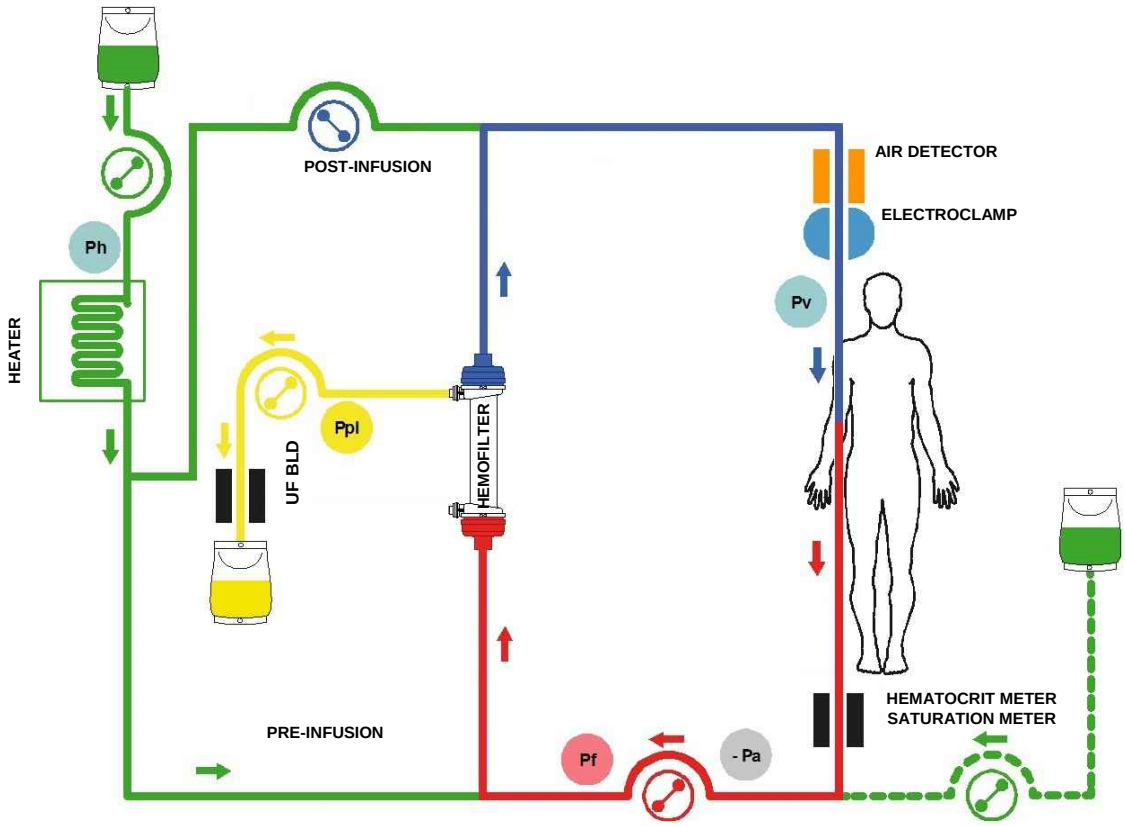



Below are the treatment specifications:

- Blood flow ($Q_b$): 30 ÷ 450 ml/min
- Patient weight loss/gain: 0 ÷ 2 l/h
- Pre-dilution pump flow (5th pump): 0 ÷ 4 l/h
- Dialysate flow: 0 or 0.5 ÷ 12 l/h
- Maximum UF pump flow rate: 16 l/h
- Maximum intermittent treatment time: 24 h
- Maximum continuous treatment time: 72 h

## ➢ HAEMOFILTRATION

Haemofiltration is an RRT treatment and may be continuous (CVVH) or intermittent (IHF-HVHF).
Bellco provides circuits with hemofilters in different sizes. The **hemofilter** sizes vary from 0.3 $m^2$ to 2.2 $m^2$, for increasing flow values.
The single-use circuit includes a line for replacement fluid infusion at the hemofilter inlet (pre-infusion), a line for replacement fluid infusion at the hemofilter outlet (post-infusion), and a line for extraction of the waste fluid (ultrafiltrate).

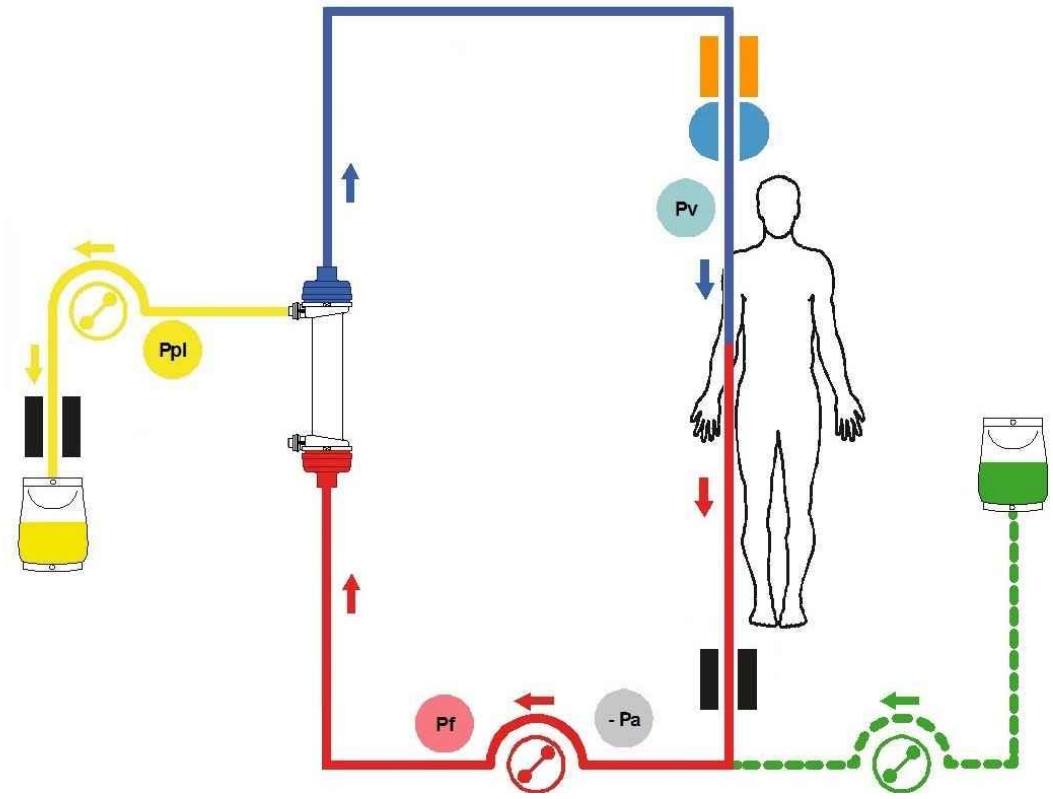



Below are the treatment specifications:

- Blood flow ($Q_b$): 30 ÷ 450 ml/min
- Patient weight loss/gain: 0 ÷ 2 l/h
- Pre-dilution pump flow (5$^{th}$ pump): 0 ÷ 4 l/h
- UF flow: 0.5 ÷ 12 l/h
- Maximum UF pump flow rate: 16 l/h
- Pre-infusion flow: 0 or 30% ÷ 100% of the infusion flow
- Maximum intermittent treatment time: 24 h
- Maximum continuous treatment time: 72 h

## ➢ ULTRAFILTRATION

Ultrafiltration or SCUF is a continuous RRT treatment of maximum 72 h.
Bellco provides circuits with hemofilters in different sizes. The hemofilter sizes vary from 0.3 $m^2$ to 1.7 $m^2$, for increasing flow values.
The single-use circuit includes a line for extraction of the waste fluid (ultrafiltrate).




Below are the treatment specifications:

- Blood flow ($Q_b$): 0; 30 ÷ 450 ml/min
- Patient weight loss: 0 ÷ 2 l/h
- Pre-dilution pump flow (5th pump): 0 ÷ 4 l/h
- Maximum UF pump flow rate: 6 l/h

CPFA®
COUPLED PLASMA FILTRATION ADSORPTION

Sepsis is one of the main causes of mortality in the treatment of acute patients. Uncontrolled inflammation leads to the production of pro- and anti-inflammatory cytokines. During sepsis, there is often a dynamic state oscillating between immune-paralysis and exaggerated inflammatory response. Initial therapeutic attempts to block triggering of the inflammatory cascade have demonstrated several challenges:

- It is difficult to quickly identify the infective agent responsible. This is why some therapeutic agents against specific bacteria (lipopolysaccharides) may not be effective if used against inappropriate micro-organisms

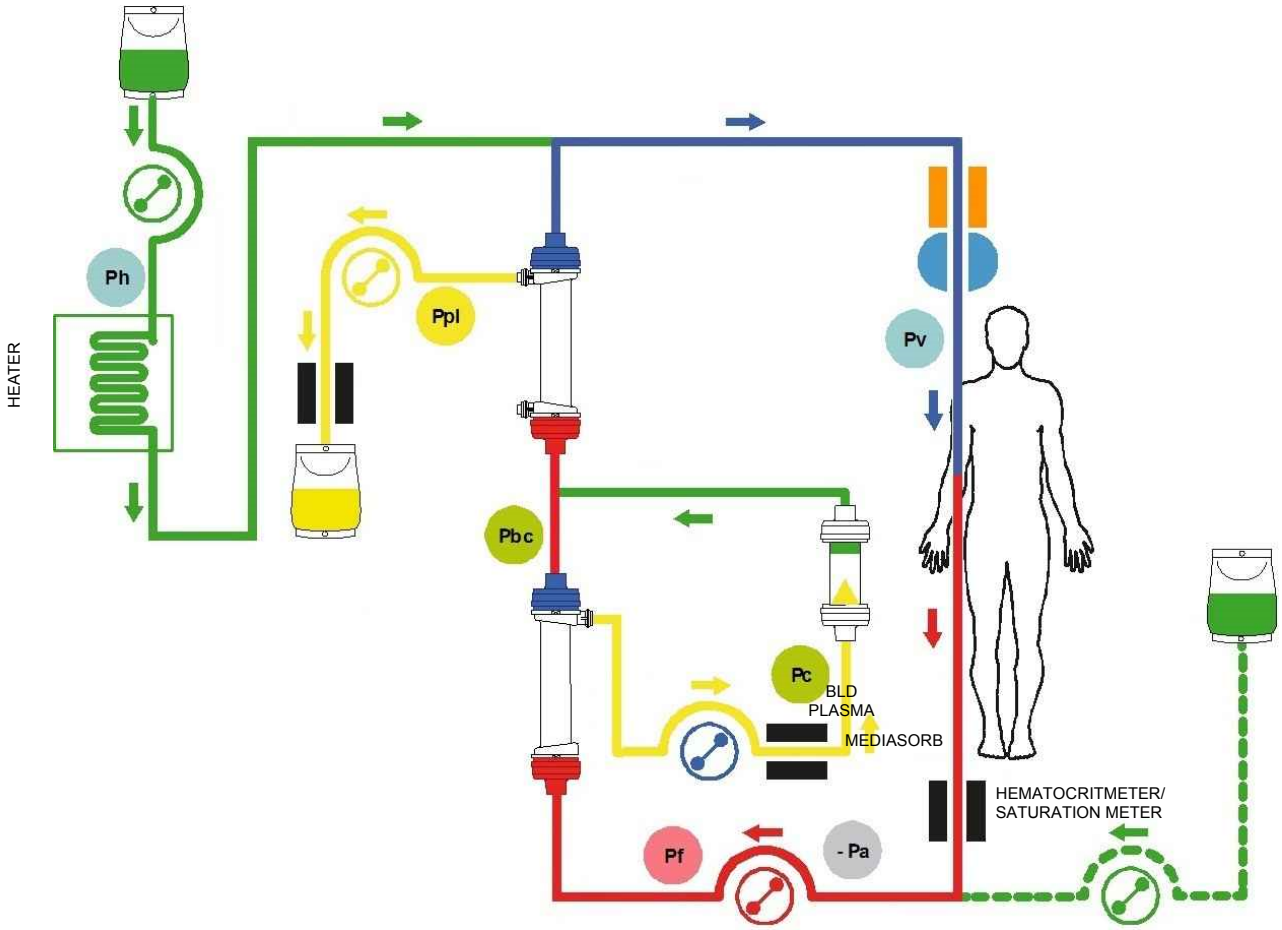
- Therapeutic agents used against the initial mediators of the inflammatory cascade (such as TNF-α) are effective only if employed early.

Initially sorbents, carbons and resins were used to remove toxic substances from the blood by haemoperfusion, even if the initial therapeutic promise was counterbalanced by problems with the release of metals, small particles, poor uniformity of action and bio-incompatibility.
The aim of CPFA® is extensive removal of inflammatory mediators, with good adsorption kinetics.
Coupled plasma filtration adsorption (CPFA®) is an extracorporeal treatment for patients with multi-organ failure (MOF) or sepsis, implemented using a dedicated sorbent cartridge. The resin developed for this specific indication makes it possible to adsorb the main inflammatory mediators involved.
The technique, using a plasma filter, separates the plasma from the blood, through a cartridge capable of adsorbing a wide range of pro- and anti-inflammatory mediators. The plasma thus cleared is returned to the patient. This first stage is followed, serially, by a hemofilter that performs clearance by convection.

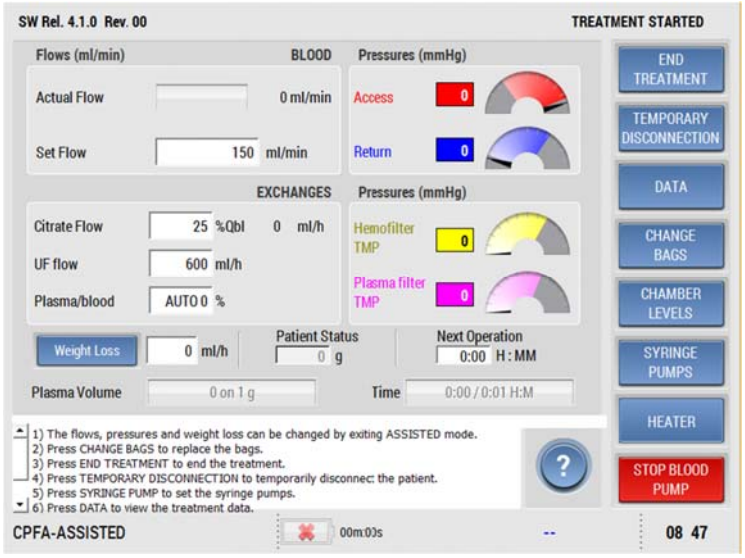
Bellco provides a single circuit for CPFA® with a 1.4 $m^2$ hemofilter and a 0.5 $m^2$ plasmafilter.
The single-use extracorporeal circuit includes a line for replacement fluid infusion at the hemofilter outlet (post-infusion), a line for extraction of the waste fluid (ultrafiltrate), and lines for connection to the Mediasorb cartridge for plasma treatment and return of the treated plasma.

The function of the **MEDIASORB** adsorbent cartridge is to clear the plasma which, once treated, is reinfused into the blood before the hemofilter inlet.

Below are the treatment specifications:
- Blood flow ($Q_b$): 30 ÷ 250 ml/min
- Patient weight loss/gain: 0 ÷ 2 l/h
- Pre-dilution pump flow (5th pump): 0 ÷ 4 l/h
- UF flow: 0 ÷ 4.5 l/h
- Maximum UF pump flow rate: 8.5 l/h
- Plasma flow set manually: 5-20% of the blood flow
- Plasma flow set automatically: from 13 to 20% of the blood flow in the first two hours, then always 20%
- Target volume of plasma: 250 ml of plasma per kg of patient weight




The treatment management screen is as follows:

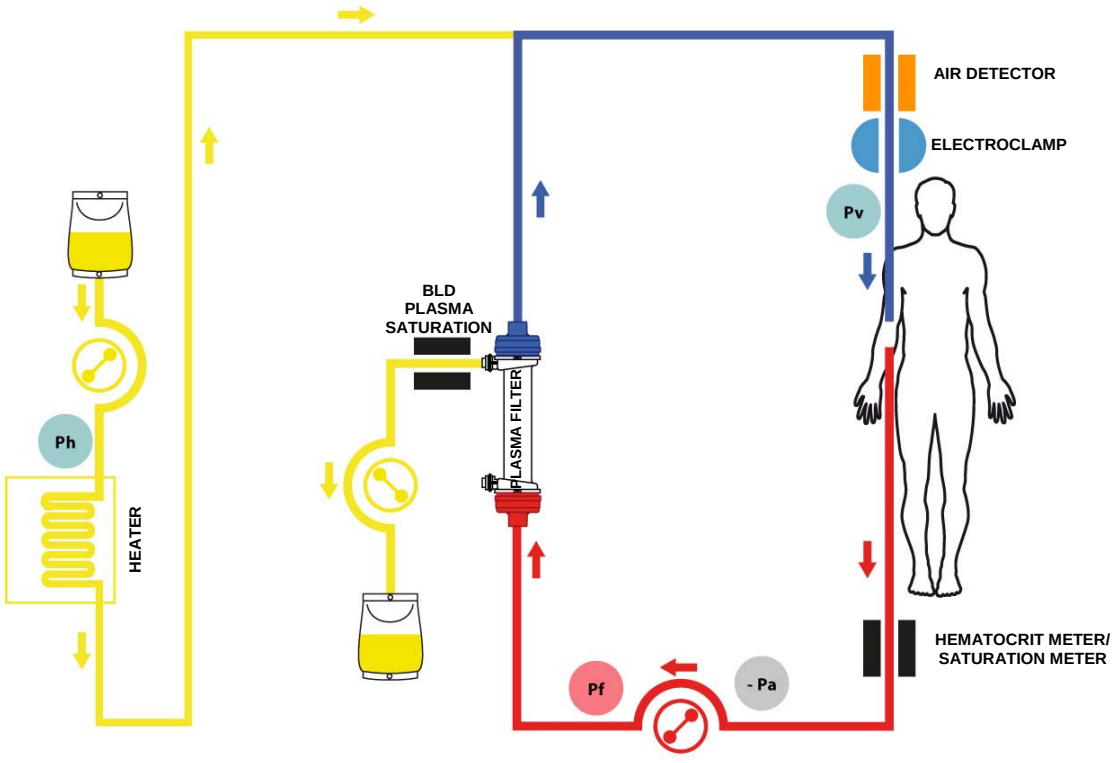



The machine is equipped with default settings to reach the plasma clearance rate necessary for adequate treatment efficiency based on the setting of the ideal patient weight.

# PEX – Plasma Exchange

Therapeutic treatment aimed at separating whole blood and subsequent removal of the plasma fraction through a plasma filter, and compensating for this plasma fraction volume with fluids produced for this purpose or donor plasma.
Plasma exchange (PEX) separates and removes the plasma from the blood through a plasma filter and replaces the removed plasma with a replacement fluid. Replacement fluids are colloidal pharmaceutical solutions (e.g. HES, albumin solution) or fresh frozen plasma (from a donor).
Bellco provides a circuit that includes a plasma filter with a 0.5 $m^2$ membrane.
The single-use circuit includes a line for replacement fluid infusion at the plasma filter outlet (post-infusion) and a line for extraction of the plasma from the patient's blood (ultrafiltrate). The treatment is always performed only post-dilution.

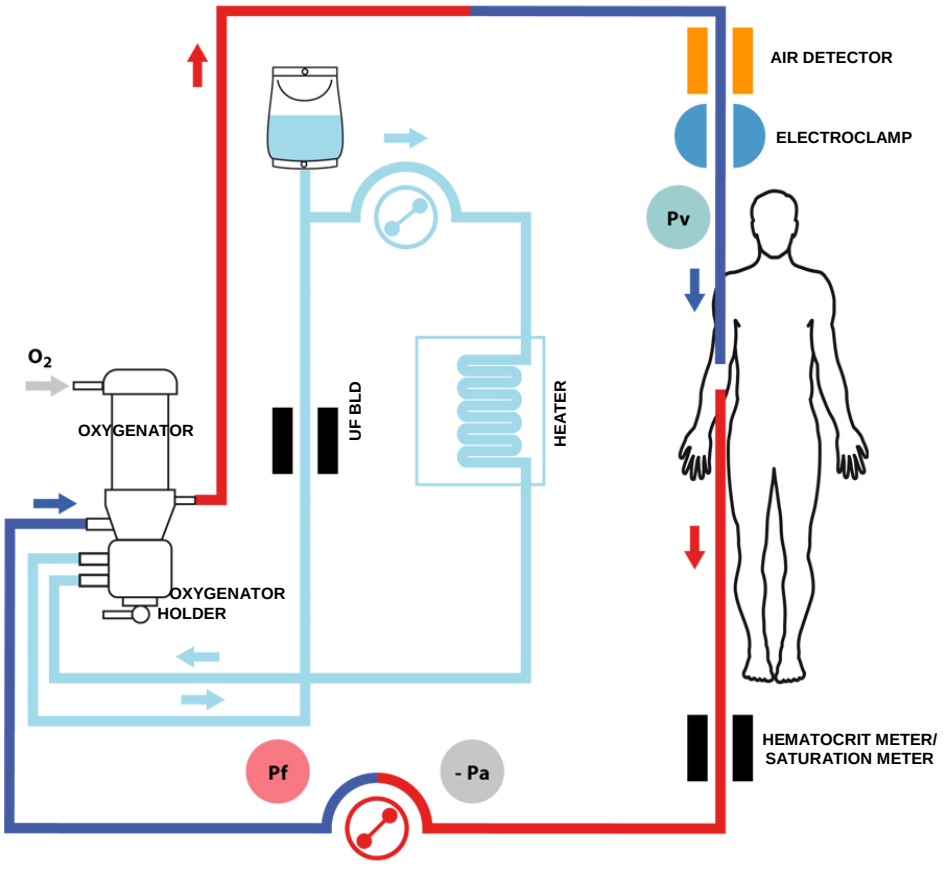
Below are the treatment specifications:
- Blood flow ($Q_b$): 30 ÷ 250 ml/min
- Plasma removal flow: 5-20% of the blood flow
- Maximum infusion flow 3 l/h
- Target volume of plasma: 0 ÷ 30 l



The **AMPLYA™** flow control principle is based on blood circulation and the removal of $CO_2$. The quantity of $CO_2$ removed is related to the $CO_2$ pressure gradient.
The single-use extracorporeal circuit is made up of two units: the extracorporeal circulation circuit and the heating circuit. The blood is taken from the patient and, through the extracorporeal circulation circuit, circulates inside the oxygenator before being re-infused to the patient. The water for injectable preparations, through the heating circuit, is heated by the **AMPLYA™** heater plate and is then recirculated in the dedicated oxygenator holder. When the oxygenator is placed in its holder, it is a heat exchanger for the blood.

Below are the treatment specifications:

- Blood flow ($Q_b$): 30 ÷ 550 ml/min
- Infusion pump flow (for recirculation of heating fluid): 200 ml/min.

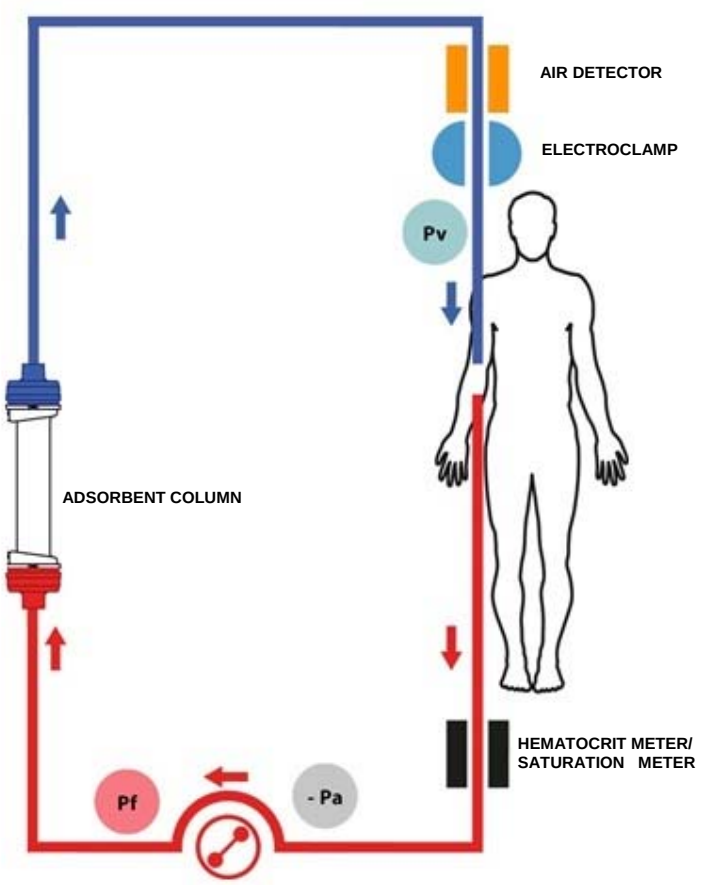


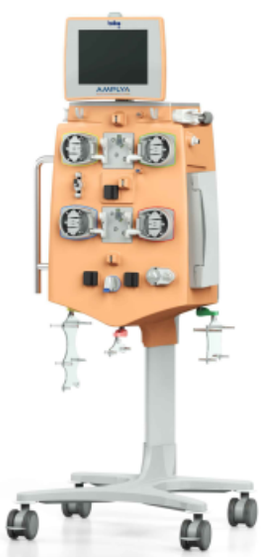
# HP – Haemoperfusion

Therapeutic treatment aimed at blood depuration through adsorption of toxic substances during the extracorporeal circulation when the blood of the patient passes through an adsorbent column.

Below are the treatment specifications:

- Blood flow ($Q_b$): 30 ÷ 450 ml/min





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